TITLE PAGE

Division: Worldwide Development

Information Type: Worldwide Epidemiology Final Study Report

Title:	Belimumab (BENLYSTA) Pregnancy Registry (BEL114256) Final Analysis Report
Compound Number:	GSK1550188
Phase:	IV
Effective Date:	26 June 2023
Description:	A Post-Authorization Safety Study Conducted by GSK The purpose of the Belimumab Pregnancy Registry (BPR) was to evaluate pregnancy and infant outcomes for pregnancies in women with systemic lupus erythematosus (SLE) exposed to commercially supplied belimumab within the 4 months preconception and/or during pregnancy. In addition, the BPR protocol planned to collect pregnancy and infant outcomes for pregnancies in women with SLE from the SABLE (Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus) protocol who were not exposed to belimumab and enrolled in the BPR
Subject:	Pregnancy Registry
Author(s):	**GSK:** Juliao, Patricia, Epidemiology Lead, Director, Epidemiology; Curtis, Paula, Statistic lead, Principal Statistician, Clinical Statistics; Demetriou, Lydia, Study Delivery Lead, Value Evidence and Outcomes Study Delivery; Marino, Rebecca, Safety & Medical Governance Lead, Director, Pharma Safety **PPD:** Chan, Ronna L., Research Scientist, Epidemiology and Scientific Affairs, PPD, part of Thermo Fisher Scientific
Indication Studied:	Systemic Lupus Erythematosus

PASS INFORMATION

Title	Belimumab (BENLYSTA) Pregnancy Registry (BEL114256)
Version identifier of the final study report	Version 1.0
Date of last version of the final study report	26 June 2023
EU PAS register number	EUPAS6577
Active substance	L04AA26, Belimumab
Medicinal product	BENLYSTA 120mg and 400mg powder for concentrate for solution for infusion (EU/1/11/700/001-002) BENLYSTA 200 mg solution for injection (EU/1/11/700/003-007)
Product reference	EU/1/11/700/006 EU/1/11/700/007
Procedure number	EMEA/H/C/2015/MEA/013
Marketing authorization holder(s)	GSK (Ireland) Limited 12 Riverwalk Citywest Business Campus Dublin 24 Ireland
Joint PASS	No
Research question and objectives	The purpose of the Belimumab Pregnancy Registry (BPR) was to evaluate pregnancy and infant outcomes for pregnancies in women with systemic lupus erythematosus (SLE) exposed to commercially supplied belimumab within the 4 months preconception and/or during pregnancy. The primary endpoint was birth defect, and secondary endpoints included spontaneous miscarriage (also referred to as spontaneous abortion), live birth [including full-term birth, preterm birth, small-for-gestational-age (SGA), stillbirth, neonatal death], elective termination, stillbirth, and serious infections and/or non-serious infection/fevers (clinically significant as per protocol) in infants through one year of age. In addition, the BPR protocol planned to collect pregnancy and infant outcomes for pregnancies in women with SLE from the SABLE

	(Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus; BEL116543) registry who were not exposed to belimumab and enrolled in the BPR.
Countries of study	US, Canada, Germany, Slovakia, Belgium, Austria, Spain, Sweden, France, Portugal, Israel, Italy, Switzerland
Author	Ronna L. Chan, Ph.D., M.P.H. Research Scientist Epidemiology and Scientific Affairs PPD, part of Thermo Fisher Scientific ronna.chan@evidera.com

MARKETING AUTHORIZATION HOLDER(S)

Marketing authorization holder(s)	GSK (Ireland) Limited 12 Riverwalk Citywest Business Campus Dublin 24 Ireland
Marketing authorization holder contact person	Mr. Paul Clifford, Senior Director, Global Regulatory Affairs GSK House 980 Great West Road Brentford, Middlesex, TW8 9GS, United Kingdom Email: paul.x.clifford@gsk.com Tel: +44 20 8990 2458

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LIST OF ABBREVIATIONS

Abbreviation	Definition
ACOG	American Congress of Obstetricians and Gynecologists
ACR	American College of Rheumatology
AE	Adverse event
BDE	Birth defect evaluator
BLyS	B lymphocyte stimulator
BPR	Belimumab Pregnancy Registry
CDC	Centers for Disease Control and Prevention
cEDD	Corrected estimated date of delivery
CI	Confidence interval
CIOMS	Council for International Organizations of Medical Sciences
CMG	Case Management Group
CNS	Central nervous system
COVID-19	Coronavirus disease 2019
CRF	Case report form
DoC	Date of conception
dsDNA	Double-stranded deoxyribonucleic acid
EC	Ethics Committee
ED	Exclusionary defect
EDC	Electronic data capturing
EMA	European Medicines Agency
EU	European Union
EUROCAT	European Surveillance of Congenital Anomalies
GA	Gestational age
GCSP	Global Clinical Safety and Pharmacovigilance
HCP	Healthcare provider
INTERGROWTH-21st	International Fetal and Newborn Growth Consortium for the 21st Century
IRB	Institutional review board
IV	Intravenous
LMP	Last menstrual period
LTFU	Lost to follow-up
MACDP	Metropolitan Atlanta Congenital Defects Program
mEDD	Most accurate estimated due date
MMF	Mycophenolate mofetil

Abbreviation	Definition
MTX	Methotrexate
N/A	Not available
NSAID	Non-steroidal anti-inflammatory drug
OB	Obstetrical
OTIS	Organization of Teratology Information of Specialists
PAS	Post Authorization Study
PASS	Post-authorization safety study
PGA	Physician Global Assessment
POAP	GSK Internal Pregnancy Outcome Advisory Panel
RAP	Reporting and Analysis Plan
SAB	Spontaneous abortion
SABLE	Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus
SAC	Scientific Advisory Committee
SAE	Serious Adverse Event
SD	Standard deviation
SDI	SLICC/ACR Damage Index
SGA	Small-for-gestational-age
SLE	Systemic lupus erythematosus
SLICC	Systemic Lupus Erythematosus International Collaborating Clinic
US	United States
WHO	World Health Organization

TRADEMARK INFORMATION

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None

1. RESPONSIBLE PARTIES

BPR Project Team (GSK and PPD core members)

Name	Title and Affiliation
GSK	
Lydia Demetriou, MSc	Study Delivery Lead, Value Evidence and Outcomes Study Delivery
Paula Curtis, PhD	Statistic Lead, Principal Statistician, , Clinical Statistics
Patricia Juliao, PhD	Epidemiology Lead, Director, Epidemiology
Rebecca Marino, PharmD	Safety Evaluation & Risk Management Product Specialist, Scientific Director, Pharma Safety
PPD	
Ronna Chan, PhD, MPH	Research Scientist, Epidemiology and Scientific Affairs
Paige Churchill, BA	Senior Director, Medical Affairs Research Operations
Tammy Moore, BS	Director of Project Management

A Scientific Advisory Committee (SAC) of external clinical researchers was established to provide expert review of the data, increase awareness and enrollment in the Belimumab Pregnancy Registry (BPR), and disseminate information about the BPR. The SAC meets on an annual basis to review the data; reviews the interim summary report, which is made available to healthcare providers (HCPs); and discusses the general conduct of the BPR. Members of the BPR Steering Committee provide oversight of the conduct of the BPR. The Steering Committee is composed of SAC along with representatives from the sponsor company, GSK, and the company managing the BPR, PPD.

BPR Scientific Advisory Committee

Name	Title and Affiliation
Michelle Petri, MD Committee Chair	Professor, Department of Medicine, Director, Lupus Center, Division of Rheumatology, John Hopkins University, Baltimore, MD
Helain Landy, MD	Professor and Chair, Department of Obstetrics and Gynecology, MedStar Georgetown University Hospital, Department of Obstetrics & Gynecology, Washington, DC
Carl Laskin, MD	Associate Professor, Department of Medicine and Obstetrics & Gynecology, Director TRIO Fertility, University of Toronto, ON
Richard Miller, PhD	Professor, University of Rochester, School of Medicine & Dentistry, Department of Obstetrics/Gynecology, NY
M. Anthony Moody, MD	Associate Professor of Pediatrics, Duke Human Vaccine Institute, Duke University School of Medicine, Durham, NC
Hugh Tilson, MD	Adjunct Professor, Public Health Leadership, The University of North Carolina at Chapel Hill, Gillings School of Global Public Health, Chapel Hill, NC

Investigators

Name	Institution (Country)
Nancy Agmon-Levin, MD	Allergy and Immunology, Chaim Sheba Medical Center (Israel)
Zahir Amoura, MD	Internal Medicine, Groupe Hospitalier Pitié Salpétrière (France)
Ronna Chan, PhD, MPH	Epidemiology and Scientific Affairs, PPD (USA and Canada)
Rebecca Fischer-Betz, MD	Internal Medicine, Universitatsklinikum Dusseldorf (Germany)
Frauke Förger, MD	Internal Medicine, Inselspital Bern (Switzerland)
Iva Gunnarsson, MD	Internal Medicine, Karolinska Universitetssjukhuset Solna (Sweden)
Jozef Lukac, MD	Internal Medicine, Narodny ustav reumatickych chorob (Slovakia)
Michel Malaise, MD	Internal Medicine, CHU de Liège (Belgium)
Marta Mosca, MD	Allergy & Immunology, Azienda Ospedaliero Universitaria Pisana (Italy)
Esther Ruiz Lucea, MD	Internal Medicine, Hospital Universitario Basurto (Spain)
Maria Jose Santos, MD	Internal Medicine, Hospital Garcia de Orta (Portugal)
Michael Schirmer, MD	Internal Medicine, Medizinische Universitat Innsbruck (Austria)

2. ABSTRACT

Title

Belimumab (BENLYSTA) Pregnancy Registry (BEL114256) Final Analysis Report

Keywords

Belimumab, pregnancy exposure registry, pregnancy outcomes, birth defects

Rationale and background

Systemic lupus erythematosus (SLE) is a disabling and life-threatening chronic autoimmune condition that can impact any organ system. To date, there is no cure for SLE, and people with SLE may experience a heavy clinical burden of poor or untimely diagnosis, use of multiple toxic medications, and significant impacts on quality of life and activities of daily living.

Belimumab is a recombinant, human, immunoglobulin G1λ monoclonal antibody that binds soluble B lymphocyte stimulator (BLyS) with high affinity and inhibits its biological activity. Following in vitro and animal model studies, belimumab was identified as a potential therapeutic agent for autoimmune diseases in which BLyS may play a role in disease pathogenesis. Belimumab was the first biologic agent approved for the treatment of SLE; however, data from human subjects who received substantial exposure to belimumab during pregnancy are lacking.

Research questions and objectives

The purpose of the Belimumab Pregnancy Registry (BPR) was to evaluate pregnancy and infant outcomes for pregnancies in women with SLE exposed to commercially supplied belimumab within the four months' preconception and/or during pregnancy and outcomes for pregnancies in women with SLE who were not exposed to belimumab and were enrolled through the Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus (SABLE) registry. The primary endpoint was birth defect, defined as any major structural or chromosomal defect or combination of two or more conditional defects in live-born infants, stillbirths, or fetal losses (spontaneous miscarriage, stillbirth, ectopic pregnancy, and molar pregnancy) of any gestational age (including outcomes prior to $20^{0/7}$ weeks' gestational age or weighing <500 g). This definition was consistent with, but not restricted to, the Centers for Disease Control and Prevention (CDC) Metropolitan Atlanta Congenital Defects Program (MACDP) definition. Secondary endpoints included spontaneous miscarriage, live birth (including full-term birth, preterm birth, small-for-gestational-age [SGA], neonatal death), elective termination, stillbirth, and serious infections and/or non-serious infection/fevers (clinically significant as per protocol) and developmental milestones met in infants through one year of age.

The overall goal of the BPR was to collect data on real-word reproductive experience with belimumab to complement reproductive data from animal toxicology studies.

Study design

The BPR was a global, prospective cohort study with voluntary participant registration following informed consent by the pregnant woman for her participation and assent for participation of her infant. Between 16 July 2012 and 28 October 2022, the BPR recruited and enrolled women with SLE exposed to commercially supplied belimumab within the four months' preconception and/or during pregnancy; the protocol planned to collect outcome information for pregnancies in women with SLE who were not exposed to belimumab while participating in the SABLE protocol and enrolled in the BPR. Data were collected at the time of enrollment, at the end of the second trimester (at approximately 26 weeks' gestation), and at pregnancy outcome. For pregnancies that resulted in live births, infant outcomes at the time of birth were reported. Infant follow-up information was collected at 4 and 12 months of age. Retrospective reports of pregnancy were those in which the pregnancy outcome occurred before enrollment into the BPR or at the time of first contact with the BPR. Data collected for the retrospective cases were entered into the electronic data capturing (EDC) system using the same procedure as the prospective cases but were summarized separately.

Setting

The registry was strictly observational; the schedule of office visits and all treatment regimens was determined by the treating healthcare provider (HCP). The registry collected data that were routinely documented in the participant's medical record during usual clinical care.

Participants and study size

A total of 87 pregnant individuals with SLE who were exposed to commercially supplied belimumab within four months' preconception and/or during pregnancy consented and enrolled into the BPR. Of the 87 pregnant individuals, two had previously enrolled in a belimumab clinical trial and five previously enrolled in the BPR. Among the 87 pregnant individuals, 72 (82.8%) were considered evaluable with confirmed outcomes and 15 were considered unevaluable, which included 10 participants who were deemed invalid or ineligible, five participants who were considered lost-to-follow-up prior to pregnancy outcome, and none with unconfirmed pregnancy or exposure. Among the 72 evaluable pregnant individuals with confirmed pregnancy outcomes, 61 (84.7%) individuals were pregnant at the time of enrollment and were prospectively enrolled into the main study cohort to assess the key outcomes of the study. The remaining 11 (15.3%) of 72 individuals were included as retrospective reports as they had completed pregnancies (such as live birth or spontaneous miscarriage) prior to enrollment and were summarized separately) No unexposed pregnant individuals with SLE from SABLE enrolled into the BPR.

Variables and data sources

Registry enrollment was voluntary and could be initiated by pregnant women or their HCPs, who acted as data reporters to the registry. After informed consent was obtained from eligible women, the participant and/or her HCPs completed the ***Registration Form*** and the initial HCP data collection forms and submit them to the registry.

Following registry enrollment of participants, confirmation of commercially supplied belimumab exposure was obtained from the HCP (primarily from the belimumab prescriber or the infusion center, but confirmation was accepted from alternate HCPs). Confirmation of pregnancy was obtained from any HCP. Data were collected at three timepoints: at enrollment (maternal demographics, exposure information, disease severity, medical and pregnancy history, concurrent medical conditions, concomitant medications, and maternal adverse events [AEs]); at the end of the second trimester of pregnancy (approximately 26 weeks' gestational age) for which data collected at enrollment were updated and pregnancy/outcome status was assessed; and at pregnancy outcome (outcome of the pregnancy, characteristics of live-born infants, birth defects, and maternal AEs). For live births, infant data (anthropometrics, infections, developmental milestones, birth defects, and AEs) were collected at pregnancy outcome, at 4 months of age, and at 12 months of age. A hierarchy for source data was established to maximize the collection of key data points. For example, data on SLE disease severity were sought from the belimumab prescriber or other HCP; data regarding the pregnancy and pregnancy outcome were sought primarily from the obstetric HCP and secondarily from alternate HCPs (SLE prescriber or pediatric HCP), and data on live-born infants were sought primarily from the pediatric HCP and alternatively from the obstetrical (OB) HCP or SLE prescriber.

Results

Between 16 July 2012 and 28 October 2022, a total of 61 evaluable pregnant individuals with confirmed pregnancy outcomes in the prospective cohort were enrolled in the BPR of which half (n=32, 52%) were enrolled in the first trimester of pregnancy and 44 (72.1%) had prenatal testing prior to enrollment. The majority (n=49, 80.3%) of the prospective cohort were participants from the US, nearly three-quarters (n=45, 73.8%) were White or Caucasian and the mean maternal age (SD) was 31.9 (4.60) years.

Among the 61 pregnant individuals in the prospective cohort, the earliest period of exposure to belimumab was within the four months' preconception for almost all individuals (n=57, 93.4%). For four individuals, the earliest period of exposure to belimumab was the first (n=2) or the second (n=2) trimester. Last belimumab exposure occurred in the first trimester for nine (14.8%) individuals, in the second trimester for 32 (52.5%) individuals, in the third trimester for one (1.6%) individual, and in the post-pregnancy period for 19 (31.1%) individuals.

There were 61 pregnancies, of which one was a stillbirth and three were spontaneous miscarriages (one twin pregnancy resulted in one spontaneous miscarriage and one live birth). Of the 58 pregnancies with a live birth, there were 61 live birth infants (54 singleton pregnancies and seven live birth infants from four twin pregnancies).

Of the 61 live birth infants, 42 (68.9%) were full-term and 19 (31.1%) were preterm. Among the 54 singleton pregnancies that resulted in live birth infants, 14 (25.9%) were preterm (defined as infant born at $<37^{0/7}$ weeks); in addition, five of seven live birth infants (71.4%) from twin pregnancies were preterm infants.

Among the 61 live birth pregnancies in the prospective cohort enrolled prior to 20 weeks' gestation, four live birth pregnancies resulted in infants that were considered as SGA

based on the International Fetal and Newborn Growth Consortium for the 21st Century (INTERGROWTH-21st) standards (6.6%; 95% confidence interval [CI]: 0.3% – 12.8%), and 12 live birth pregnancies resulted in infants that were considered SGA based on Alexander criteria (19.7%; 95% CI: 9.7% – 29.6%).

Among the 61 live birth infants from 58 prospective live birth pregnancies, 11 resulted in a major birth defect (using MACDP definition) as confirmed by the BDE (birth defect evaluator) (11/61, 18.0%; 95% CI: 8.4% – 27.7 %) while 12 resulted in a major birth defection when using either MADCP or European Surveillance of Congenital Anomalies (EUROCAT) (12/61, 19.7%; 95% CI: 9.7% to 29.6%). There was no indication or pattern of birth defects associated with belimumab.

There were 17 defect events among the 12 infants (five infants had two defects), using either/or MACDP/ EUROCAT. Five infants had defect events considered to be defects of known cause or no temporal association, and two infants had defect events with insufficient data on defect and/or belimumab exposure window for proper assessment.

Of the 12 live birth pregnancies with major birth defects, the earliest belimumab exposure occurred pre-conceptionally in 11 (91.7%) individuals and the mean (SD) cumulative belimumab exposure was 223.3 (79.03) days. Eleven (91.7%) had prenatal testing prior to enrollment of which one had an abnormal result (infant with atrial septal defect) and one where results were not available (Arnold Chiari type II malformation). Six (50.0%) were of advanced maternal age (35 to 39 years), one (8.3%) with a multiple gestation, and one (8.3%) reported an elective termination in a previous pregnancy.

Seven (58.3%) of the 12 live birth pregnancies with major birth defects had the presence of one or more comorbidity and/or pregnancy complication. Five (41.7%) infants from the 12 live birth pregnancies with a preterm birth and two were SGA. Exposure to concomitant medications of interest during pregnancy in the 12 live birth pregnancies included antimalarials (n=10, 83.3%), corticosteroids (n=6, 50.0%), aspirin (n=4, 33.3%), azathioprine (n=2, 16.7%), heparin (n=2, 16.7%), antiepileptics (n=2, 16.7%), cyclosporin (n=1, 8.3%); exposure of these drugs occurred in all three trimesters. Other concomitant medication exposure during pregnancy included NSAIDs (n=2, 16.7%); one across all trimesters, and one in the third trimester) and methotrexate (n=1, 8.3%, at first trimester).

Of the overall 61 live birth infants in the prospective cohort, four (6.6%) reported a serious infection during the first year of life (five events); 2 infants at outcome visit and 2 at 12-month visit. Fourteen (23.0%) of the 61 live birth infants reported non-serious infection/fevers (clinically significant per protocol definition) with a total of 16 events; two infants were identified at outcome visit, 7 infants at 4 month, and 6 infants at 12 months.

In total, 28 maternal serious adverse events (SAEs) were reported in 19 (31.1%) pregnant individuals in the prospective cohort and 18 (29.5%) pregnant individuals reported at least one maternal non-serious AE. In infants, 46 SAEs were reported in 26 pregnant individuals and there were 21 reports of individuals whose infants experienced at least one solicited non-serious AE.

A total of 11 retrospective pregnancies were enrolled within the BPR of which no confirmed major birth defects were identified in live birth infants as well no serious infections and/or non-serious infection/fevers (clinically significant per protocol) during infant one year follow-up. Pregnancy loss, excluding elective termination, occurred in 40% (4/10) pregnancies. These results should be interpreted with caution as the retrospective reports would be subject to biases since pregnancy outcome was known prior to enrollment.

Discussion

Of the sample size of 500 prospective pregnancies with a known outcome, only 61 (12%) were enrolled and considered evaluable for the study. Despite multiple awareness efforts to enroll patients into the BPR, enrollment targets were not achieved, and the registry was terminated early due to insufficient sample size. Based on the yearly enrollment rate (average of seven participants per year), the study as it was designed would need to be extended for 20 or more years to meet the targeted sample size. Coupled with the lack of an internal comparison group design, the BPR could not provide timely or clinically meaningful information to HCPs and patients.

Considering the limitations associated with the BPR, it was not possible to draw conclusions about any relationship between belimumab exposure and major birth defects using these data alone. However, the BPR did not identify any pattern of defects that would suggest an unusual cluster or plausible drug-induced mechanism of birth defects in individuals receiving belimumab within the data reported here or when observed in the wider context of limited case reports. The prevalence of other pregnancy and infant outcomes of interest align with published rates of these outcomes in pregnant women with SLE; however, due to the low number of outcomes accumulated in BPR to date, data should be interpreted with caution.

Conclusions

On 18 April 2023, the Belimumab Scientific Advisory Committee independently reviewed all data reported to the BPR as well as supplemental data and concluded that there are insufficient pregnancy outcomes to ascertain the risks of birth defects and the secondary endpoints of intent for pregnancy exposed to commercially supplied belimumab.

Marketing authorization holder

GSK (Ireland) Limited.

Names and affiliations of principal investigators

Name	Institution
Nancy Agmon-Levin, MD	Allergy and Immunology, Chaim Sheba Medical Center
Zahir Amoura, MD	Internal Medicine, Groupe Hospitalier Pitié Salpétrière
Ronna Chan, PhD, MPH	Epidemiology and Scientific Affairs, PPD
Rebecca Fischer-Betz, MD	Internal Medicine, Universitatsklinikum Dusseldorf
Iva Gunnarsson, MD	Internal Medicine, Karolinska Universitetssjukhuset Solna
Jozef Lukac, MD	Internal Medicine, Narodny ustav reumatickych chorob
Michel Malaise, MD	Internal Medicine, CHU de Liège
Esther Ruiz Lucea, MD	Internal Medicine, Hospital Universitario Basurto
Maria Jose Santos, MD	Internal Medicine, Hospital Garcia de Orta
Michael Schirmer, MD	Internal Medicine, Medizinische Universitat Innsbruck

3. AMENDMENTS AND UPDATES

GSK Document Number	Date	Version, Section of study protocol, Amendment or update
2010N108011_00	21 July 2011	Original
2010N108011_01	24 February 2012	Amendment No. 01 Global: Update HGS Sponsor Signatory information Update Abbreviations Update Protocol Summary Update Methodology (Section 4) Update Summary Table of Evaluations, including addition of breastfeeding status Update Reporting of Adverse Events (Section 7.4) Update References Update Appendices Minor typographical errors corrected
2010N108011_02	11 April 2013	Amendment No.02: Global Registry name change to use generic in title vs. brand name Update Sponsor Signatory Page Delete HGS Sponsor Signatory Page Delete HGS Sponsor Contact Information Delete HGS Protocol Number Delete HGS Study Number Update Investigator Protocol Agreement Page Remove HGS throughout body of protocol Update Trademark Information Update Protocol Summary Revise definition for retrospective reports of pregnancy; addition of definitions for traditional prospective and pure prospective reports of pregnancy per the EMA in the following sections: Protocol Summary Update Section 4.1 Update Section 4.2 Update Section 4.6 Update Section 4.8

GSK Document Number	Date	Version, Section of study protocol, Amendment or update
		Update Section 5 Update Section 6 Update Glossary Update Section 4.5 Update Section 7.2 Update Section 7.4 Update Section 7.7 Update Section 7.9 Update References Update Appendices Minor typographical errors corrected
2010N108011_03	13 November 2015	Amendment No. 3: Global Update Sponsor Signatory Page Update Sponsor Information Page Update List of Abbreviations Revise study population to reflect inclusion of unexposed participants from SABLE per the EMA in the following sections: Protocol summary Update Section 1.1. Update Section 1.2 Update Section 2.1 Update Section 4.1 Update Section 4.4 Update Section 4.6 Update Section 4.6.1. Update Section 4.6.2 Update Section 4.6.3 Update Section 4.6.3.1 Update Section 4.6.3.2 Update Section 4.6.4 Update Section 4.6.8.4 Update Section 4.8 Update Section 4.8.1 Update Section 4.8.2 Update Section 4.8.2.1

GSK Document Number	Date	Version, Section of study protocol, Amendment or update
		Update Section 4.8.2.2 Update Section 4.8.3 Update Section 4.8.4 Update Section 4.8.5 Update Section 6 Update Section 7.4 Update Section 7.10 Update Section 7.11 Update Section 7.12 Update Section 3 Update Section 4.3.1 Update Table of Evaluations (Section 4.6.1) Update Section 4.6.3 Update Section 4.6.4 Update Section 4.6.8.1 Update Section 4.6.8.2 Update Section 7.13 Update References Update Appendices Update Glossary Minor typographical errors corrected
2010N108011_04	17 March 2020	Amendment No. 4: Global Update Sponsor Information Page Updates to Sponsor Legal Address required due to sponsor site closure Update Section 4.6.8.3 to clarify outcome information from HCP was considered to be valid Update Section 7.4 to include lack of efficacy text Minor typographical errors corrected

Abbreviations: EMA = European Medicines Agency; HCP = healthcare provider; HGS = Human Genome Sciences; SABLE = Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus

4. MILESTONES

Milestone	Planned date	Actual date	Comments
Start of data collection	01 January 2013	01 July 2013	N/A
End of data collection	26 November 2011	11 November 2022	Last regulatory agency approval to close BPR was received on 28 October 2022
Registration in the EU PAS register	19 May 2014		
Study progress report 1	30 September 2019	02 October 2019	N/A
Final report of study results	28 April 2022	26 June 2023	BPR closure date changed due to receipt of last regulatory agency approval for closure; final analysis completed on 16 February 2023

Abbreviations: BPR = Belimumab Pregnancy Registry; EU = European Union; N/A = not available; PAS = Post Authorization Study

5. RATIONALE AND BACKGROUND

Systemic lupus erythematosus (SLE) is a disabling and life-threatening chronic autoimmune condition that can impact any organ system [Barber, 2021; Von, 1995]. This disease is highly variable from person to person and is characteristically difficult to diagnose. SLE does not have a cure, and people with SLE may experience a heavy clinical burden of poor or untimely diagnosis, use of multiple toxic medications, and significant impacts on quality of life and activities of daily living.

As many as 4 million people may be affected worldwide by SLE. In the United States (US), the estimated prevalence of SLE is 53.5 to 84.8 per 100,000 persons [Dall'Era, 2017; Izmirly, 2017; Jarukitsopa, 2015, Lim, 2014; Somers, 2014]. Similar prevalence rates were reported in Canada (90.0 per 100,000 [Fatoye, 2018]), while reported prevalence ranged from 28.3 to 97.0 per 100,000 persons in Europe [Arnaud, 2014; Ingvarsson, 2016; Laustrup, 2009; Simard, 2014], and varied from 26.5 to 80.0 per 100,000 in Asian countries [Chiu, 2010; Yeh, 2013; Yu, 2013; Zou, 2014]. SLE prevalence may be four to 15 times higher among women (range: 45.8 to 162.4 per 100,000) than among men (range: 6.4 to 24.8 per 100,000) [Chiu, 2010; Dall'Era, 2017; Fatoye, 2018; Flower, 2012; Izmirly, 2017; Jarukitsopa, 2015; Lim, 2014; Rees, 2016; Shim, 2014; Simard, 2014; Somers, 2014; Zou, 2014]. The female-to-male ratio of SLE in the childbearing years has been reported to be as high as 12:1 [Danchenko, 2006]. Women with SLE may have as much as a 20-fold higher risk of mortality compared with women without SLE [Moroni, 2016]. Although maternal mortality has improved significantly in the past decades, improvement is still needed, according to a recent large retrospective study that examined SLE and non-SLE pregnancies over 18 years (1998 through 2015) [Mehta, 2019]. Women with SLE have historically experienced poorer maternal and fetal pregnancy outcomes, including a greater likelihood of lupus flares, hypertension, nephritis, and pre-eclampsia (maternal outcomes) as well as pregnancy loss, preterm deliveries, intrauterine growth restriction, congenital malformation [Bundhun, 2017; Nili, 2013; Rowaiee, 2019; Vinet, 2015; Wallenius, 2014], stillbirth, and neonatal lupus syndrome due to transplacental passage of antibodies (fetal outcomes) [Lateef, 2013; Smyth, 2010; Chakravarty, 2006; Clowse, 2008; Ruiz-Irastorza, 2011; Tani, 2021]. Considering the impact of SLE disease severity on women of childbearing age, as well as several SLE treatments being known or suspected teratogens, pregnancy is generally discouraged in affected patients [Tani, 2021; Taulaigo, 2021; Petri, 2020).

Belimumab is a recombinant, human, immunoglobulin G1λ monoclonal antibody that binds soluble B lymphocyte stimulator (BLyS) with high affinity and inhibits its biological activity [Baker, 2003]. Following in vitro and animal model studies [Belimumab, 2019], belimumab was identified as a potential therapeutic agent for autoimmune diseases in which BLyS may play a role in disease pathogenesis. Belimumab was the first biologic agent approved for the treatment of SLE. Treatment with intravenous (IV) or subcutaneous belimumab as an add-on to standard therapy was shown to be effective and tolerable in phase III trials among patients with SLE [Furie,2011; Navarra, 2011; Stohl, 2017; Zhang, 2018]. Belimumab is approved in the US as an add-on therapy in patients five years and older who have active, autoantibody-positive SLE or active lupus nephritis and are receiving standard therapy [GSK, 2022] as add-on therapy in patients aged five years and older with active, autoantibody-positive

SLE with a high degree of disease activity (e.g., positive anti-double-stranded deoxyribonucleic acid [dsDNA] and low complement) despite standard therapy in the European Union (EU) [EMA, 2011]. Before the global Belimumab Pregnancy Registry (BPR) began (July 2012), no data were available from human subjects who received substantial exposure to belimumab during pregnancy [Calligaro, 2014; Skorpen, 2016], as women who became pregnant in belimumab clinical trials were withdrawn from treatment as soon as the pregnancy was detected through monthly pregnancy screenings. In preclinical studies, treatment with belimumab was not associated with direct or indirect harmful effects with respect to maternal toxicity, developmental toxicity, or teratogenicity. Similarly, in a 2014 case report, a woman taking belimumab during pregnancy had well-controlled SLE and an uneventful pregnancy [Danve, 2014]. Due to limited available data on the effects of belimumab on maternal and fetal outcomes during pregnancy, the European Alliance of Associations for Rheumatology and British Society for Rheumatology advise caution when treating with belimumab during pregnancy, and the American College of Rheumatology recommends discontinuation of belimumab in women who become pregnant [Andreoli, 2017; Flint, 2016; Sammaritano, 2020]. Additional data are needed on the effects of belimumab on pregnancy outcomes for physicians to make informed decisions when assessing the benefits and risks of treating women with belimumab.

The BPR added to the current clinical experience with commercially supplied belimumab and to complement reproductive data from animal toxicology studies. The BPR also assisted clinicians in weighing the potential risks against the benefits of treatment with belimumab for pregnant individuals with SLE.

6. RESEARCH QUESTION AND OBJECTIVES

As a post-authorization requirement, the BPR was conducted to evaluate pregnancy and infant outcomes for pregnancies in women with SLE who were exposed to commercially supplied belimumab within the four months prior to and/or during pregnancy.

To help contextualize pregnancy outcomes within the SLE population as the BPR did not include an unexposed comparator group, enrollment into the BPR was offered to pregnancy participants with SLE from the SABLE (Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus) study who were not exposed to belimumab. The SABLE study is an ongoing observational cohort study to evaluate the incidence of adverse events of special interest and effectiveness in participants with active, autoantibody positive SLE treated with and without belimumab [GSK, 2012]. The BPR protocol planned to collect pregnancy and infant outcomes for pregnant women in the SABLE cohort and enrolled in the BPR.

The primary endpoint was birth defects. Secondary endpoints included spontaneous miscarriage (also referred to as spontaneous abortion [SAB]), live birth (including preterm birth, small-for-gestational-age [SGA], and neonatal death), stillbirth, elective termination, molar pregnancies, ectopic pregnancies, and serious infections and/or non-serious infection/fevers (clinically significant as per protocol) met in infants through one year of age.

7. RESEARCH METHODS

7.1. Study design

The BPR was a global, multi-center, prospective cohort study with voluntary participant registration following informed consent by the pregnant woman for her participation and assent for participation of her infant. Confirmation of exposure to commercially supplied belimumab was obtained from the healthcare provider (HCP), typically the belimumab prescriber or the infusion center, but this was also acceptable from alternate HCPs such as obstetricians or pediatricians. The BPR involved the primary data collection of maternal and infant data, and it was strictly observational. The schedule of office visits and all treatment regimens were determined by the treating HCP. The BPR collected data that were routinely documented in the participant's medical record during usual care, and where available, information of SLE disease activity using the Physician Global Assessment (PGA) (Protocol – Appendix 1) [GSK Document Number 2010N108011_04, 2020] and the Systemic Lupus Erythematosus International Collaborating Clinic (SLICC)/American College of Rheumatology (ACR) Damage Index (SDI; Protocol – Appendix 2) [GSK Document Number 2010N108011_04, 2020].

The BPR was designed to enroll participants with SLE who had been exposed to commercially supplied belimumab within the four months' preconception and/or during pregnancy. Details regarding the inclusion and exclusion criteria are presented in Section 7.2. Data were collected at registration (early in pregnancy to include preconception SLE disease severity), at the end of the second trimester (approximately 26 weeks' gestation), and at pregnancy outcome (delivery or early termination). For live births, infant outcomes at the time of birth were reported. Data on infants were obtained from medical record during usual care visit at outcome, at four months and 12 months of age visits. Targeted follow-up also took place to gather additional information, if required, to assist data interpretation on events and outcomes of interest.

Prospective reports of pregnancy included all women with an active pregnancy at time of enrollment who were exposed to commercially available belimumab from four months prior to and/or during pregnancy, known as the overall prospective cohort. This cohort was further stratified into two sub-cohorts: 1) Traditional prospective reports of pregnancy regardless of known normal or abnormal prenatal test results, or if prenatal testing was not known and 2) Pure prospective reports of pregnancy for which (a) the enrollee did not know at the time of enrollment whether the fetus had a malformation, and (b) no prenatal testing was completed prior to enrollment.

Retrospective reports of pregnancy were those in which the pregnancy ended (live birth, fetal loss, etc.) before enrollment or at the time of first contact with the BPR. All retrospective cases reported to the BPR had data collected and entered in the database (as appropriate for the underlying disease) using the same procedures as prospective cases; however, retrospective cases were summarized separately. If a pregnancy was reported to the BPR from a woman who had been exposed to commercially supplied belimumab within the four months prior to and/or during pregnancy but was not diagnosed with SLE, the BPR collected that data but summarized them separately from pregnancies in

participants diagnosed with SLE (Protocol – Section 4.6.8.6) [GSK Document Number 2010N108011_04, 2020].

Because participants were enrolled in the BPR on a voluntary basis, it was important for the HCPs and participants to be aware of the BPR. To increase awareness among the HCPs, awareness activities, as described in Appendix C, were carried out between 16 July 2012 and 28 October 2022.

7.2. Study population/participants and setting

Women with SLE who had been exposed to commercially supplied belimumab within the four months' preconception and/or during pregnancy or those participating in the SABLE registry were eligible to participate in the BPR.

Minimum criteria for enrollment included the following:

- Exposure classification:

  For belimumab-exposed pregnant women:

  - Sufficient evidence to confirm that exposure to commercially supplied belimumab occurred within the four months' preconception and/or during pregnancy ("belimumab exposed")

  OR

  For belimumab-unexposed pregnant women:

  - Sufficient evidence to confirm the exposure to belimumab did not occur within the four months prior to and/or during pregnancy ("unexposed")
- Sufficient information to classify the pregnancy as prospective or retrospective (i.e., whether the outcome of pregnancy was known at the time of first contact with the BPR). Retrospective reports of pregnancy were those in which the pregnancy ended before enrollment or at the time of first contact with the BPR. Overall prospective reports of pregnancy included all participants who enrolled in the BPR before the end of the pregnancy and was further stratified into two subcategories:
  - Traditional prospective reports of pregnancy included all women who enrolled in the BPR before the end of pregnancy (live birth, fetal loss, etc.), regardless of known normal or abnormal prenatal test results or if prenatal testing was not known.
  - Pure prospective reports of pregnancy included all women who enrolled in the BPR before the end of pregnancy for which (a) the enrollee did not know at the time of enrollment whether the fetus had a malformation, and (b) no prenatal testing was completed prior to enrollment.
- Full initial reporter (i.e., pregnant woman or HCP) contact information to allow for follow-up (name, address, telephone number/email address), and contact information for applicable HCPs if initial reporter was the pregnant woman.

- Consent provided by the pregnant woman for her participation and assent for participation of her infant.

Reported cases that did not meet the minimum criteria for BPR enrollment were ineligible for inclusion in the BPR and were not entered into the database. In such cases, the report was forwarded to the GSK Global Clinical Safety and Pharmacovigilance (GCSP) Case Management Group (CMG), which handled these reports using routine pharmacovigilance measures.

7.3. Variables

7.3.1. Exposure definition

Belimumab-exposed participants were defined as: one complete or partial dose of commercially supplied belimumab, administered within the four months' (i.e., a period of approximately five belimumab terminal half-lives) preconception and/or during pregnancy, constituted exposure. Belimumab exposure was further categorized by earliest trimester of exposure. Overall belimumab exposure is presented by the number of days exposed, which is calculated by adding four months (100 days) to the non-missing exposure treatment date to reflect the half-life of the drug.

Belimumab-unexposed participants were defined as: treatment with any immunosuppressants (azathioprine, methotrexate, cyclophosphamide, mycophenolate, biologics, or others) as defined in the SABLE protocol as SLE treatment, excluding belimumab (Protocol HGS1006-C1124), constituted non-exposure. There needed to be sufficient evidence to confirm that exposure to belimumab did not occur within the four months' preconception and/or during pregnancy for a woman to be classified within this group.

7.3.2. Baseline characteristics and potential confounders

Demographic and baseline characteristics were collected for the BPR participants, and they included maternal age at enrollment, race, ethnicity, region, country, height, pre-pregnancy weight, pre-pregnancy body mass index, pregnancy history (number of previous pregnancies, outcomes of previous pregnancies, and medical conditions in previous pregnancies), comorbidities, trimester at enrollment, gestational age at enrollment, and current pregnancy type. Exposure to concomitant medications was also collected for each participant, where available, and by timing of exposure. Participants may be presented in one or several time points (preconception and during pregnancy). Participants may also had been exposed to one or several medications; therefore, the percentages may not add to 100%. Drug names and classes were also presented.

Additionally, information was also collected on whether any prenatal tests were taken prior to enrollment and where available, information on ultrasounds and other prenatal testing such as amniocentesis, maternal serum alpha-fetoprotein, quad screen, and chorionic villus sampling, and results of any fetal abnormality was noted from the ultrasounds or from other prenatal tests were also obtained. Pregnancy complications, where noted, were collected at the end of the second trimester of pregnancy. Information

on maternal alcohol, tobacco, and recreational drug use was obtained at enrollment and through the pregnancy.

Disease activity for SLE was assessed using the PGA scores. The PGA is a simple, concise global index of disease activity [Petri, 1992] that was completed at registration (including a preconception assessment), around the end of the second trimester and at pregnancy outcome for BPR participants with SLE. The SDI score, where available, recorded irreversible organ system damage that occurred in participants with SLE regardless of etiology. Damage may be attributed to active SLE disease, concomitant medication, or intercurrent illness [Gladman1996].

7.3.3. Outcome definitions

7.3.3.1. Pregnancy outcomes of interest

The following pregnancy outcomes were collected by the BPR.

- Spontaneous miscarriage: fetal death or expulsion of products of conception prior to $20^{0/7}$ weeks' (<$20^{0/7}$ weeks) gestational age
- Live birth: the birth of a living fetus at $20^{0/7}$ weeks' gestational age or greater (≥$20^{0/7}$ weeks) or, if gestational age was unknown, a fetus weighing 500 g or more (≥500 g).
  - Full-term birth: an infant born at gestational age greater than or equal to $37^{0/7}$ weeks. Full-term birth was further categorized into the following categories:
    - Early term ($37^{0/7}$ weeks – $38^{6/7}$ weeks)
    - Full-term ($39^{0/7}$ weeks – $40^{6/7}$ weeks)
    - Late-term ($41^{0/7}$ weeks – $41^{6/7}$ weeks)
    - Post-term (≥$42^{0/7}$ weeks)
  - Preterm birth: an infant born at a gestational age less than $37^{0/7}$ weeks (<$37^{0/7}$ weeks). Preterm birth was further categorized into the following categories:
    - Extremely preterm, born at less than $28^{0/7}$ weeks of pregnancy
    - Very/severely preterm, born between $28^{0/7}$ and $31^{6/7}$ weeks of pregnancy
    - Moderate preterm, born between $32^{0/7}$ and $33^{6/7}$ weeks of pregnancy
    - Late preterm, born between $34^{0/7}$ and $36^{6/7}$ of pregnancy, inclusive
  - SGA: an infant whose birth weight was less than the 10^{th} percentile for the gestational age. SGA was based on data derived from an appropriate reference population. The BPR utilized the sex-specific international growth reference standards from the International Fetal and Newborn Growth Consortium for the 21^{st} Century (INTERGROWTH-21^{st}) for those born ≥33 weeks' gestation [Villar, 2014]. As the INTERGROWTH-21^{st} standards were valid for infants born between $33^{0/7}$ weeks' and $42^{6/7}$ weeks' gestation, SGA was additionally classified using the referenced standard endorsed by the American Congress

of Obstetricians and Gynecologists (ACOG) [ACOG, 2013], which was applicable for the entire range of gestational age [Alexander, 1996]

- Neonatal death: an infant who, after live birth, expired within the first 28 days (≤28 days) of life

- Stillbirth: A fetal death occurring at $20^{0/7}$ weeks' gestational age or greater (≥20 weeks), or, if gestational age was unknown, death of a fetus weighing 500 g or more (≥500 g)
- Elective termination: voluntary interruption of pregnancy, including pregnancy termination that occurred electively, to preserve maternal health, or due to fetal abnormalities
- Ectopic pregnancy: implantation of a conception outside of the uterus
- Molar pregnancy: a conception that resulted in a gestational trophoblastic tumor

7.3.3.2. Birth defects

The BPR defined and coded birth defects with criteria specified by the Centers for Disease Control and Prevention (CDC)'s Metropolitan Atlanta Congenital Defects Program (MACDP) (Birth Defects and Genetic Diseases Branch 6 – Digit Code for Reportable Congenital Anomalies, Version 08/07) [CDC, 2007].

Newborn and infant conditions that were not necessarily considered birth defects appeared in the Exclusion List for MACDP. These conditions were included under certain circumstances by CDC criteria and were considered "conditional defects" in the BPR. Birth defect was defined by the BPR as any major structural or chromosomal defect or combination of two or more of the conditional defects in live-born infants, stillbirths, or fetal losses of any gestational age, including outcomes prior to 20 weeks' gestation or a fetus weighing <500 g. This definition was consistent with, but not restricted to, the MACDP definition. As defined by MACDP, clusters of conditional defects and data from aborted fetuses of less than 20 weeks' gestation, when available, were included to increase sensitivity of monitoring. While MACDP included conditional defects only if in the presence of a major structural defect, the BPR considered reports of two or more conditional defects as a birth defect case in efforts to increase potential signal generation and to capture instances where a combination of conditional defects might constitute a major birth defect or syndrome.

The BPR conformed to MACDP guidelines in disqualifying birth defects if those findings were present in infants born at less than $36^{0/7}$ weeks' gestation and were attributable to prematurity itself, such as patent ductus arteriosus, patent foramen ovale, or inguinal hernias. The MACDP classification included chromosomal defects. Although these defects were not likely to contribute to a risk for a drug exposure, the BPR included these birth defects to maintain this consistency with MACDP. Live-born infants with only transient or infectious conditions or with biochemical abnormalities (e.g., jaundice) were classified as being without reported birth defects unless there was a possibility that the condition reflected an unrecognized birth defect. Detected and reported transient or infectious conditions or biochemical abnormalities in infants without reported birth

defects and defects that were excluded by the CDC guidelines were reviewed and noted in the BPR reports as they occurred.

Because the BPR was conducted in North America and Europe, the BPR used the European Surveillance of Congenital Anomalies (EUROCAT) in addition to the US-based CDC MACDP in subgroup analyses and/or with specific SLE comparator cohorts if data were available or applicable.

Because the BPR was conducted to identify potential signals that may indicate an increased risk of major birth defects in offspring of women diagnosed with SLE following exposure to commercially supplied belimumab, it was necessary to monitor the cumulative data to identify patterns of potential signals and to determine the necessary course of action if a signal was suspected. The BPR utilized the strategy of "threshold" based on the method recommended by the Council for International Organizations of Medical Sciences (CIOMS) [CIOMS, 1999]. The threshold for action was determined by the extent of certainty about the cases and tempered by the specifics of each case, and using this approach, BPR did not formally detect an increased risk of a specific rare outcome following exposure to commercially supplied belimumab within the four months' preconception and/or during pregnancy. To aid in hypothesis generation, the birth defect evaluator (BDE) reviewed all birth defects in an aggregate manner and on an ongoing basis to identify any possible reporting patterns and any potential patterns that were identified were discussed with the Scientific Advisory Committee (SAC).

7.3.3.3. Infant follow-up

The BPR collected detailed information for live birth infants at outcome and up through one year of age. Information collected on infants included weight, length, head circumference, breastfeeding status, participants' exposure to belimumab during breastfeeding, achievement of developmental milestones (provided by a pediatrician at usual four- and 12-month visits for the five main areas of development: gross motor, fine motor, language, cognitive, and socio-emotional), and serious infections and/or non-serious infection/fevers (clinically significant as per protocol) (definition in Section 7.3.3.4).

7.3.3.4. Serious infections and/or non-serious infection/fevers-clinically significant as per protocol in infants

The following definitions were used for infant infections:

Any infection/fever: Any infection requiring treatment or any fever of unknown origin or fever on known infections etiology reported in infants.

Serious infection: Any infection that met the serious adverse event (SAE) criteria (Infections that resulted in death; were life-threatening; required inpatient hospitalization, prolonged hospitalization, resulted in significant disability or incapacity and/or were considered medically important to date) (Section 7.3.3).

Non-serious infection/fever (clinically significant per protocol definition): Non-serious infection/fevers where:

- Infections requiring treatment in infants from birth through six months of age (infection onset date from zero to ≤ 26 weeks)
- Fevers of unknown origin or of known infectious etiology in infants from birth through three months of age (onset date zero to ≤ 13 weeks)
- Infant infection with missing age of onset date will be included within this definition

7.3.4. Solicited adverse events and serious adverse events

Solicited adverse events (AEs) and SAEs were documented at each follow-up period for both the mother and infant and included, but were not limited to, the following:

- Reports of congenital anomalies in the fetus or infant
- Reports of adverse pregnancy outcomes, including spontaneous miscarriages and stillbirths
- Reports of serious and/or other clinically significant infections in the infant
- Reports of SAEs in the mother or infant

Solicited SAEs were defined as those AEs that resulted in death; were life-threatening; required inpatient hospitalization or prolongation of existing hospitalization; resulted in persistent or significant disability/incapacity; or were congenital anomalies/birth defects. In addition, based upon appropriate medical judgment, important medical events that might not have been immediately life-threatening or resulted in death or hospitalization but might have jeopardized the participant or might have required intervention to prevent one of the other outcomes listed above were considered SAEs. All solicited AEs and SAEs were reported in a listing for the mother and a separate listing for the infant. In addition, counts and percentages of the solicited AEs and SAEs were summarized for all available cases.

7.4. Data sources

This voluntary registry was conducted between 16 July 2012 and 11 November 2022, and the registry awareness program was carried out for the duration of the BPR to encourage enrollment as early in pregnancy as possible to minimize bias resulting due to left truncation. In addition, all investigators from the SABLE protocol were made aware of the BPR and informed eligible women of their option to participate in the BPR. The BPR protocol planned for the collection of pregnancy and infant outcome information for pregnancies in women with SLE from the SABLE protocol who were not exposed to belimumab and enrolled in the BPR.

The pregnant woman and appropriate members of her healthcare team served as data reporters to the BPR. A hierarchy for source data was established to maximize the collection of key data points for the BPR. For example, data regarding participants' SLE

disease severity were sought from the belimumab prescriber or other HCP and were captured at four different time points (preconception, registration, end of second trimester, and pregnancy outcome). Data regarding the pregnancy and pregnancy outcome were sought primarily from the obstetrical (OB) HCP and secondarily from alternate HCPs (SLE prescriber or pediatric HCP), and data on live-born infants were sought from the pediatric HCP and alternatively from the OB HCP or SLE prescriber. Appropriate members of the woman's and infant's healthcare team were contacted to complete missing data as needed. Participant-reported data were verified from the HCP overseeing that component of the participant's care.

Data from participants or relevant HCPs were collected on case report forms (CRFs). Medical records were not requested by the BPR unless considered appropriate during targeted follow-up of specific events and outcomes. Depending on the gestational age at time of enrollment and gestational age at pregnancy outcome, not all CRFs were completed for each participant. For example, a participant who enrolled late in pregnancy and delivered early, there may be no completed second trimester data collection form. To ensure maximum collection of data, the BPR accepted data from clinicians at any time from the day a participant was enrolled in the BPR through the day that the BPR was closed. No date for cessation of data entry into the BPR on any specific participant was specified.

7.5. Bias

Despite numerous awareness activities throughout the conduct of the BPR and efforts to recruit participants from 13 countries, enrollment target was not met (Figure 1, Appendix B). Recruitment in pregnancy registries, particularly in the enrollment of pregnant women early in pregnancy, is known to be challenging. This could be due to the voluntary enrollment of the BPR, and pregnant women or women of reproductive age who are planning a pregnancy not being prescribed or being reluctant to use some medications; thereby, BPR participants may not be representative of the overall SLE pregnant population. Even with having more than half of the BPR participants in the prospective cohort enrolled during the first trimester of pregnancy, potential bias due to left truncation may exist.

Although numerous efforts were made to recruit and enroll belimumab-exposed pregnant women with SLE, the BPR was designed as an exposure-only registry without a comparator group of unexposed pregnant participants with SLE. To help contextualize pregnancy outcomes within the SLE population as the BPR did not include an unexposed comparator, enrollment into the BPR was offered to participants with SLE from the SABLE study who were not exposed to belimumab. Due to no enrollment of pregnant participants with SLE who were unexposed to belimumab from SABLE, the lack of a comparator group was an added limitation; no women with SLE who were unexposed to belimumab were recruited into the BPR from the SABLE protocol.

The design of the BPR allowed for the collection of maternal and infant health outcome data across multiple time points. However, the reporting of pregnancies and other maternal and infant data was voluntary and based on reporting from the HCPs, it is possible that recall bias exists. The BPR did not access medical records for its

participants unless considered appropriate during targeted follow-up of specific events. Per protocol and as appropriate, multiple contact attempts with the HCP were made by the BPR project team at each follow-up time point. Missing data in key parameters such as SLE disease severity and SLE laboratory test results was an additional limitation to allow for a complete evaluation of clinically relevant metrics in relation to maternal belimumab exposure and maternal and infant health outcomes. Although a small number of participants was in the retrospective cohort, their pregnancy outcomes occurred prior to enrollment into the BPR; thereby, information bias, primarily enrollment bias, was a concern for maternal data, as participants were more likely to enroll with adverse pregnancy outcomes. To further minimize potential biases, the main analysis for the BPR was conducted on prospective cohort data.

7.6. Study size

The BPR was descriptive and sought to enroll approximately 500 prospective pregnancies exposed to commercially supplied belimumab. Research indicates that approximately 83% to 95% of pregnancies enrolled in pregnancy exposure registries result in live births [Covington, 2010] and approximately 20% to 25% are lost to follow-up [Covington, 2007], resulting in an upper estimate of 380 live births and a lower estimate of 311 live births.

The study design allowed the birth defect prevalence in belimumab-exposed participants to be estimated with an exact 95% confidence interval (CI) of 1.32% – 5.09%, assuming 350 live births and an observed belimumab birth defect prevalence equivalent to the MACDP general population birth defect prevalence of 2.78%.

7.7. Data management

All data were collected from the participant or the relevant HCP on CRFs. Medical records were not requested by the BPR unless considered appropriate during targeted follow-up of specific events and outcomes. The raw and analyses datasets were stored on the appropriate shared drive. As GSK requested for the BPR to be closed on 28 October 2022, data entry for all participant and infant data was carried out through 11 November 2022 and the database lock occurred on 15 February 2023.

Study data were managed with a 21 Code of Federal Regulations Part 11 compliant electronic database. The database was backed up as part of the routine back-up process. The server was also backed up to tape daily as an incremental back-up (i.e., only files with changes since the last back-up are backed up). A full back-up of the database was performed weekly and stored securely off-site for one year. One full back-up per month was stored off-site for three years; however, every six months, back-ups were stored for the duration of the BPR. The contract research organization was responsible for retaining back-ups of the electronic database for the duration of the BPR. Upon closure of all BPR activities, the database will be retained by the vendor (Merative) for 15 years. All electronic files will be transferred to GSK for archiving.

SAS Enterprise Guide 7.1 was used for data transformation and statistical analysis.

7.7.1. Case disposition

7.7.1.1. Evaluable registry reports

An evaluable registry report was a case with data submitted or confirmed by an HCP that met the minimum criteria for a registry report, as described in Section 7.2, and for which the pregnancy outcome was known.

Overall prospective reported evaluable cases are included in Section 7.8.1.1. Evaluable belimumab-exposed prospective cases (pure prospective and traditional prospective) and retrospective cases were summarized separately.

7.7.1.2. Invalid registry reports

An invalid case was a report for which the minimum eligibility criteria were never obtained despite requests for the missing data. This included participants who met the enrollment criteria and consented but whose belimumab exposure was not confirmed by an SLE prescriber, an infusion center, an OB HCP, or any other reporter approved by GSK (i.e., determination of exposure was solely based on participant report). This also included participants in the unexposed population who met the enrollment criteria and consented but whose participation in SABLE was not confirmed.

If the minimum data to determine eligibility were not provided initially, the case was considered pending until all attempts to obtain missing data and requests for follow-up after the initial contact were complete. If, after all attempts at follow-up were made, the minimum criteria for registration (detailed in Section 7.2) were still not met, the case was considered invalid due to insufficient information. Invalid reports were not included in the BPR analyses.

7.7.1.3. Lost to follow-up

Cases that were lost to follow-up were defined as all prospective reports (pure or traditional) for which the pregnancy outcome (live birth, stillbirth, fetal loss) was never obtained, unavailable, and/or where the indication of a birth defect was designated as unknown. When no pregnancy outcome data were available, the participant was assumed to be lost to follow-up for both the pregnancy outcome endpoints and the infant outcome endpoints. Participants who had data available at pregnancy outcome but were missing data at the four-month follow-up and/or the 12-month follow-up were not considered lost to follow-up; however, the infants were considered lost to follow-up. Participants who decided to withdraw from the BPR were considered as drop-outs.

7.8. Data analyses

The BPR was descriptive and designed to detect potential safety signals rather than test hypotheses. The BPR was specifically interested in detecting whether the prevalence estimates of birth defects among the live births of pregnant women exposed to

belimumab were greater than the prevalence of these outcomes among the general population, however, given the sample size this could not be achieved.

7.8.1. Analysis cohorts

7.8.1.1. Primary analysis cohort

Overall prospective cohort (also referred to as the prospective cohort) is the primary analysis cohort. The overall prospective evaluable cases were evaluable participants in the traditional prospective cohort and pure prospective cohort, who had SLE and were exposed to belimumab (i.e., who received one complete or partial dose of commercially supplied belimumab) within the four months' (i.e., a period of approximately five belimumab terminal half-lives) preconception and/or during pregnancy and who were not lost to follow-up (i.e., cases with appropriate outcome information that met the minimum criteria for evaluation as previously specified). Results from the prospective cohort are presented in this study report with referent tables/listing located in Section 15.

7.8.1.2. Additional analysis cohorts

Additional analysis cohorts included belimumab-exposed participants (as described in the Section 7.8.1.1) according to the following definitions of pregnancy reports:

- Traditional prospective reports of pregnancy included all women who enrolled in the BPR before the end of pregnancy (live birth, fetal loss, etc.), regardless of known normal or abnormal prenatal test results at the time of enrollment, or if prenatal testing was not known.
- Pure prospective reports of pregnancy included all women who enrolled in the BPR before the end of pregnancy for which (a) the enrollee did not know at the time of enrollment whether the fetus had a malformation, and (b) no prenatal testing was completed prior to enrollment.
- Retrospective reports of pregnancy included evaluable cases for which the enrollees made first contact with the BPR after the end of pregnancy (i.e., live birth, stillbirth, or fetal loss). The cases needed to have SLE.
- Non-SLE reports of pregnancy included retrospectively and prospectively enrolled (pure or traditional) evaluable cases where the participant had not been diagnosed with SLE upon entry into the BPR.

In this report, participant registry status is presented for the overall prospective cohort and retrospective cohort. Results for each additional prospective sub-cohorts are referenced under Section 15.

7.8.2. Primary analysis

7.8.2.1. Main analytical approach

All data were summarized using descriptive statistics where applicable. Continuous variables were reported with the number of participants (n), mean, standard deviation (SD), median, lower quartile, upper quartile, minimum, maximum, and number of unknown/missing observations unless otherwise stated. Categorical variables were reported as number and percentage (n, %) in each category. Missing data were displayed as a separate category where appropriate. The denominator for all percentages reflected the number of participants within the cohort or the number of infants within the cohort, unless another denominator was stated.

7.8.2.1.1. Birth defects

Overall point estimates and 95% CIs were calculated using the exact binomial distribution for prevalence rates of birth defects among pregnant women exposed to belimumab and their live births. Most structural defects have their origins in the first trimester of pregnancy, the period of organogenesis. In addition to overall prevalence of birth defects, the analysis of birth defects was stratified by trimester of exposure to belimumab.

The prevalence rate of birth defects reported to the BPR for the main analysis was calculated as the proportion within the live birth infant cohort (numerator: live birth infants with any birth defects [MACDP criteria]; denominator: all live birth infants). Further defect prevalence rates by MACDP/EUROCAT or separately, were also calculated within the live birth infant cohort. Additionally, defect prevalence rates were also calculated within the live birth pregnancy cohort (numerator: live birth pregnancy with any birth defects [MACDP and/or EUROCAT]; denominator: all live birth pregnancies)

Pregnancy losses with reported defects occurring at or after 20 weeks' gestation were included in the numerator prevalence estimates for defects to increase sensitivity and to allow comparison of outcomes with the MACDP and EUROCAT, which calculated rates by this convention. A secondary analysis was carried as a sensitivity analysis to include any pregnancy losses with reported defects occurring at less than 20 weeks' gestation in the calculation of prevalence (Section 7.8.2.3).

The prevalence rate of combined defects in exposed cases was compared with that reported by MACDP and EUROCAT [Correa, 2007; EUROCAT, 2023.].

Only cases meeting the MACDP criteria for a defect or with two or more conditional defects were included in the primary analysis. Single minor defects did not constitute a defect per the MACDP classification; therefore, they were listed in the report but not included in the primary analysis.

7.8.2.2. Data handling conventions/data transformations

There were occurrences of partial missing dates for exposures or medical conditions of interest. No date imputation was conducted for calculating summary estimate outcomes. It was of interest in this study to evaluate the frequency of birth defects based on timing of belimumab exposure. As a conservative estimate of the number of birth defects in this study, a missing date was imputed to correspond to the first trimester of exposure when belimumab exposure was assessed.

As there were occurrences of missing data, data were obtained from the participant or from any HCP. Therefore, during the analysis, a hierarchal approach was taken to summarize the data, presented in Table A. For example, outcome data provided by the OB HCP were summarized. However, if data were not obtained from the OB HCP, any outcome data provided by the pediatric HCP, or the prescribing HCP was used in the analysis summaries. Participant-reported data received for the primary and secondary outcomes that were not confirmed by an HCP were summarized separately.

Per the Reporting and Analysis Plan (RAP) [PPD, 2022] and as shown in Table A, the approach in the handling of partially or completely missing data involved the following:

Table A. Handling of Missing Data

Element	Reporting Detail
General	Missing data occurred when any requested data were not provided, leading to blank or unknown fields: • These data were indicated by a "not reported" or "unknown" in participant listing displays, unless all data for a specific visit were missing, in which case the data were excluded from the table. • Answers such as "not applicable," "not evaluable," and "unknown" were not considered to be missing data and were not displayed as such.
Dates	In listings, the dates were presented as entered on the data collection form, unaltered. No date imputation was conducted for calculating except as described below. • It was of interest in this study to evaluate the frequency of birth defects based on timing of belimumab exposure. As a conservative estimate, a missing date for belimumab exposure was imputed to correspond to the first trimester.
Comorbidity, Belimumab Exposure, Concomitant Medication, and Laboratory Start/Stop Dates	Partial dates for data listed to the left recorded in the CRF were imputed using the following convention: • If the partial date was a start date, a "01" was used for the day and/or "Jan" was used for the month. • If the partial date was a stop date, a "28/29/30/31" was used for the day (dependent on the month and year) and/or "Dec" was used for the month. • As a conservative estimate, if preconception was not indicated, a missing start date was imputed to correspond to occur during the first trimester, and a missing stop date was imputed to correspond to occur during the third trimester. • The recorded partial date was displayed in listings.

Abbreviation: CRF = case report form

Data derivations for analysis are presented in Table B.

Table B. Data Derivation for Analysis

mEDD – Estimated Date of Delivery		
The mEDD was: • An estimate provided by the obstetric reporter based upon ultrasound examination or known date of conception (e.g., in vitro fertilization) If an mEDD was not provided: • cEDD = LMP + 280 days		
DoC – Date of Conception		
The DoC was estimated from the mEDD as DoC = mEDD – 266 days		
GA – Gestational Age		
GA expressed as a continuous result with a decimal on a particular date was calculated as: GA = [280 days – (mEDD – reference date)] / 7 If GA expressed in weeks + days: • Weeks = INT{[280 days – (mEDD – reference date)] / 7} • Days = 7 * {[280 days – (mEDD – reference date)] / 7} – INT{[280 days – (mEDD – reference date)] / 7}		
Pregnancy Intervals		
Interval	**Interval Start**	**Interval End**
Preconception (4 months prior)	DoC – 120 days	DoC – 1 day
1st trimester	DoC	DoC + 83 days ($13^{6/7}$ weeks)
2nd trimester	DoC + 84 days ($14^{0/7}$ weeks)	DoC + 181 days ($27^{6/7}$ weeks)
3rd trimester	DoC + 182 days ($28^{0/7}$ weeks)	>DoC + 182 days (>$28^{0/7}$ weeks) through date of birth
Post-pregnancy outcome	≥ date of outcome + 1 day	None specified
Pregnancy Categories		
Category	**Interval Start**	**Interval End**
Early term	DoC + 245 days ($37^{0/7}$ weeks)	DoC + 258 days (<$39^{0/7}$ weeks)
Full-term	DoC + 259 days ($39^{0/7}$ weeks)	DoC + 272 days (<$41^{0/7}$ weeks)
Late-term	DoC + 273 days ($41^{0/7}$ weeks)	DoC + 279 days (<$42^{0/7}$ weeks)
Post-term	DoC + 280 days ($42^{0/7}$ weeks)	>DoC + 280 days (>$42^{0/7}$ weeks)
Preterm	DoC + 126 days ($20^{0/7}$ weeks)	DoC + 244 days ($36^{6/7}$ weeks)
Extremely preterm	DoC + 126 days ($20^{0/7}$ weeks)	DoC + 181 days ($27^{6/7}$ weeks)
Very/severely preterm	DoC + 182 days ($28^{0/7}$ weeks)	DoC + 209 days ($31^{6/7}$ weeks)
Moderate preterm	DoC + 210 days ($32^{0/7}$ weeks)	DoC + 223 days ($33^{6/7}$ weeks)
Late preterm	DoC + 224 days ($34^{0/7}$ weeks)	DoC + 244 days ($36^{6/7}$ weeks)

Abbreviations: cEDD = corrected estimated date of delivery; DoC = date of conception; GA = gestational age; LMP = last menstrual period; mEDD = most accurate estimated due date

Belimumab exposure was calculated as described in Table C:

Table C. Belimumab Exposure Calculation

Cumulative Belimumab Exposure (days)
For each exposed participant regardless of route, the total number of days exposed to belimumab was calculated as: ([last non-missing belimumab treatment date] – [first non-missing belimumab treatment date]) + 100 days. (100 days were added to account for five half-lives; 20 day half-live*5 half-lives of belimumab). Dose dates > 120 days prior to DoC and Dose dates > delivery date was excluded.
Days of treatment were compared to the windows defined above to define timing of each dose. The overall timing of exposure was grouped by preconception and through each trimester during pregnancy. Exposure starting and ending prior to the preconception period was excluded from the analysis.
Timing of Belimumab Exposure Relative to Conception
For each exposure record for each exposed participant regardless of route, the following was calculated for the timing of belimumab exposure: • Start day of exposure = (first belimumab treatment date – DoC) + 1 • Stop day of exposure = (last belimumab treatment date – DoC) + 100 (100 days were added to account for five half-lives; 20 day half-live*5 half-lives of belimumab.)

Abbreviation: DoC = date of conception

7.8.2.3. Sensitivity analyses

One sensitivity analysis was performed among live birth infants and live birth pregnancies including fetal losses with reported birth defects occurring at less than 20 weeks' gestation (See Section 7.8.2.1.1).

The sensitivity analysis was used to determine how stable the primary study finding was and if any bias in study interpretation was recognized with excluding this subpopulation. The sensitivity analysis of the birth defect prevalence rates was compared with the MACDP and EUROCAT prevalence estimates.

7.8.3. Secondary analysis/Exploratory analysis

7.8.3.1. Adverse pregnancy outcomes

As specified in the protocol, the BPR identified the number of cases of spontaneous miscarriages, SGAs (denominator: any pregnancies enrolled prior to the 20th week of gestation), as well as elective terminations, stillbirths (denominator: any pregnancies enrolled), and preterm births (denominator: live birth infants); proportions of these outcomes were calculated with 95% CIs.

7.8.3.2. Serious infections and/or non-serious infection/fevers (clinically significant as per protocol) in infants

As specified in the protocol, the frequency and proportion of serious infection and/or non-serious infection/fevers (clinically significant as per protocol) during the infant's first year of life, with the number of live birth infants as the denominator. These frequencies and proportions were stratified according to the timing of infant follow-up.

7.8.4. Amendments to the statistical analysis plan

The amendments to the statistical analyses are outlined in Table D.

Table D. Amendments to the Statistical Analysis Plan

Protocol	**RAP**	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
Primary Endpoint: • Birth defects **Secondary Endpoints:** <u>Other pregnancy outcomes</u> • Spontaneous miscarriage • Live birth (preterm birth and SGA) • Stillbirth • Elective termination <u>Infant outcomes through age 1 year</u> • Serious and/or clinically significant infections	**Primary Endpoint:** • Birth defects **Secondary Endpoints:** <u>Other pregnancy outcomes</u> • Spontaneous miscarriage • Molar and ectopic pregnancies • Live birth (full-term birth, preterm birth, SGA, neonatal death) • Stillbirth • Elective termination <u>Infant outcomes through age 1 year</u> • Serious and/or clinically significant infections[1]	Represents all pregnancy outcomes collected by BPR
Further categorization of preterm was not defined.	Preterm birth may be further sub-categorized as: • Extremely preterm, born prior to $28^{0/7}$ weeks of pregnancy • Very/severely preterm, born between $28^{0/7}$ and $31^{6/7}$ weeks of pregnancy • Moderate preterm, born between $32^{0/7}$ and $33^{6/7}$ weeks of pregnancy • Late preterm, born between $34^{0/7}$ and $36^{6/7}$ weeks of pregnancy, inclusive	Further breakdown was added to better understand adverse pregnancy outcomes.
Full-term birth not defined	Full-term infant is an infant born at gestational age greater than or equal to $37^{0/7}$ weeks. Full-term births may be further sub-categorized as: • Early term ($37^{0/7}$ weeks – $38^{6/7}$ weeks)	Further breakdown was added to better understand adverse pregnancy outcomes.

Protocol	RAP	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
	• Full-term ($39^{0/7}$ weeks– $40^{6/7}$ weeks) • Late-term ($41^{0/7}$ weeks – $41^{6/7}$ weeks) • Post-term (≥$42^{0/7}$ weeks)	
An invalid case is a report for which the minimum eligibility criteria are never obtained despite requests for the missing data.	Invalid - Participants who meet the enrollment criteria and consent, but belimumab exposure is not confirmed by an SLE prescriber, an infusion center, an OB HCP, or an "other" reporter approved by GSK, who has medically confirmed the exposure (not solely based on patient report) Invalid - Participants inthe unexposed populationwho meet the enrollment criteria and consent, but participation in SABLE is not confirmed.	Detail added to provide clarity.
Length and head circumference will be considered along with birth weight when determining SGA.	Only birth weight will be used in the calculation per the sex-specific international growth reference currently recommended by the INTERGROWTH-21st Project standards (applicable for those born at $33^{0/7}$ and over [Villar, 2014; Alexander, 1996]).	GSK and the scientific advisory board reviewed the available references and agreed that those included were appropriate to meet the objectives of the registry.
Prior to and/or during pregnancy	Preconception and/or during pregnancy	Detail added to provide clarity. Sponsor preference
Included only those patients exposed to belimumab	The registry includes unexposed participants from the SABLE protocol; however, as the likely number of these participants will be small, formal comparisons of primary and secondary outcomes between belimumab-exposed and unexposed participants will not be conducted.	Required by EMA
Reporting of prospective pregnancy: • **Traditional Prospective:** Traditional prospective reports of pregnancy will include all women who enroll in the registry before the end of	• **Traditional Prospective:** Evaluable participants are classified as traditional prospective if they have a diagnosis of SLE that meets ACR criteria, have an ongoing pregnancy at the time of enrollment (defined as delivery date greater than informed consent date),	Details added to provide clarity and sponsor preference

Protocol	RAP	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
pregnancy (live birth, fetal loss, etc.), regardless of known normal or abnormal prenatal test results. • **Pure Prospective:** Pure prospective reports of pregnancy are a subset of traditional prospective reports and include those where (a) the enrollee did not know at the time of enrollment whether the fetus had a malformation, and (b) no prenatal testing was completed prior to enrollment.	whose fetal test date is on or before informed consent date but may or may not have known fetal test results at the time of enrolment[2] and with known pregnancy outcome confirmed by HCP. • **Pure Prospective:** Evaluable participants are classified as pure prospective if they have a diagnosis of SLE that meets ACR criteria, have an ongoing pregnancy at the time of enrollment (defined as delivery date greater than informed consent date), did not know at the time of enrollment whether the fetus had a malformation, and had no prenatal testing completed prior to enrollment (fetal test date is after informed consent date or is missing), and with known pregnancy outcome confirmed by HCP. Traditional prospective and pure prospective cohorts' results will be reported combined and separately. Overall prospective cohort will be reported for all tables and the definitions for traditional and prospective cohorts will be based on actual derivations.	
SABLE protocol: Pregnant women with SLE from the SABLE protocol who are not exposed to belimumab, with sufficient evidence to confirm that exposure to belimumab did not occur within four months prior to and/or during pregnancy	Evaluable pregnant women who are unexposed to belimumab, as defined as within four months prior to and/or during pregnancy, from the SABLE protocol	Sponsor preference

Abbreviations: ACR = American College of Rheumatology; BPR = Belimumab Pregnancy Registry; EMA = European Medicines Agency; HCP = healthcare provider; INTERGROWTH-21st = International Fetal and Newborn Growth Consortium for the 21st Century; OB = obstetrical; RAP = reporting and analysis

plan; SABLE = Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus; SGA = small-for-gestational-age; SLE = systemic lupus erythematosus

[1]Text further updated to "Serious infections and/or non-serious infection/fevers (clinically significant as per protocol)" in the final report to clarify differences between serious infection/SAE and other infections/fevers.

[2]The following statement was added to definition of Traditional Prospect within the final report to clarify participants with where prenatal testing was unknown: "or if prenatal testing was not known and with known pregnancy outcome confirmed by HCP."

7.9. Quality control and quality assurance

Ensuring that the data collected were of high quality was an ongoing, multistep process involving programming of edit checks for critical data variables in the data management system and secondary visual review by the clinical research coordinator for completeness, logic, consistency, and accuracy.

Single Pass Data entry was performed by PPD Data Entry personnel through the Merative electronic data capture (EDC) application within three days of receipt of the CRF data. The global project manager then performed visual verification. Any discrepancies between the source document and EDC were corrected by the project manager and/or the data entry personnel. Additionally, the global project manager raised queries to the attention of the data entry personnel.

Manual queries were generated by data entry personnel and Clinical Data Management at any time and were immediately available for review. All manual query resolutions were reviewed and closed by the group that created the query. It was expected that EDC discrepancies were to be resolved within five days of query receipt.

As part of the ongoing quality control process, the project team monitored the type and number of queries experienced across the study on an ongoing basis.

As is recommended in regulatory guidance documents [FDA, 2019; EMA, 2005], CRFs were carefully designed to ensure data quality and integrity. When required, participant-reported data were verified by the appropriate HCP.

8. PROTECTION OF HUMAN SUBJECTS

8.1. Ethical approval and participant consent

In North America, the study was reviewed and granted approval by an institutional review board (IRB). Approval included a waiver of documentation of signed informed consent for participation based on the BPR's process for collecting data and protecting participant privacy. The IRB approval also included a Health Insurance Portability and Accountability Act authorization waiver. In Europe, Ethics Committee (EC) approval or notification had been obtained or performed, respectively, in countries where this was required.

8.2. Participant confidentiality

Each participant's identity was known only to the third-party vendor (Virtual Research Coordination Center; PPD), the BPR site, enrolling individual (i.e., participant or HCP), and relevant HCPs (i.e., belimumab prescriber, obstetrician, pediatrician). The BPR assigned participant and infant identification numbers, which were used to identify BPR participants and their infant offspring. The dataset used in each analysis of data from the BPR contained coded BPR participant identifiers for both the pregnant mothers and infants. In North America, the registry received an exemption from the US Health Insurance Portability and Accountability Act Authorization. In Europe, the Data Protection Directive 1995/46/EU was implemented with different national data protection laws in each country based on the directive and subsequently replaced in 2018 by the EU General Data Protection Regulation.

9. RESULTS

9.1. Participants

9.1.1. Participant enrollment

From 16 July 2012 through 28 October 2022, 87 pregnant individuals enrolled into the BPR. The study did meet the expected sample size target of 500 prospective pregnancies with confirmed pregnancy outcome. As such, the registry was terminated early due to low enrollment.

Table 1.1 describes the distribution of evaluable and unevaluable pregnant individuals based on trimester of enrollment.

Of the 87 pregnant individuals who consented and enrolled into the BPR, 72 (82.8%) were considered evaluable with confirmed outcomes and 15 (17.2%) were considered unevaluable, either invalid/ineligible or lost to follow-up prior to outcome (Figure A). No pregnant individuals had ongoing pregnancies or a medically unconfirmed outcome at study closure. The 72 evaluable individuals with confirmed pregnancy outcomes ranged in age from 21 to 42 years (mean 31.7 years) and were enrolled from six countries: US (n=56, 77.8%), Canada (n=4, 5.6%), France (n=3, 4.2%), Spain (n=3, 4.2%), Austria (n=3, 4.2%), and Germany (n=2, 2.8%)[1] (Table 10.1); no individuals were enrolled from the seven other countries in which the BPR was opened. Among the 72 evaluable pregnant individuals with confirmed pregnancy outcomes, 61 (84.7%) individuals were pregnant at the time of enrollment and were prospectively enrolled into the BPR cohort to

[1] Country was missing for n=1 participant (1.4%)

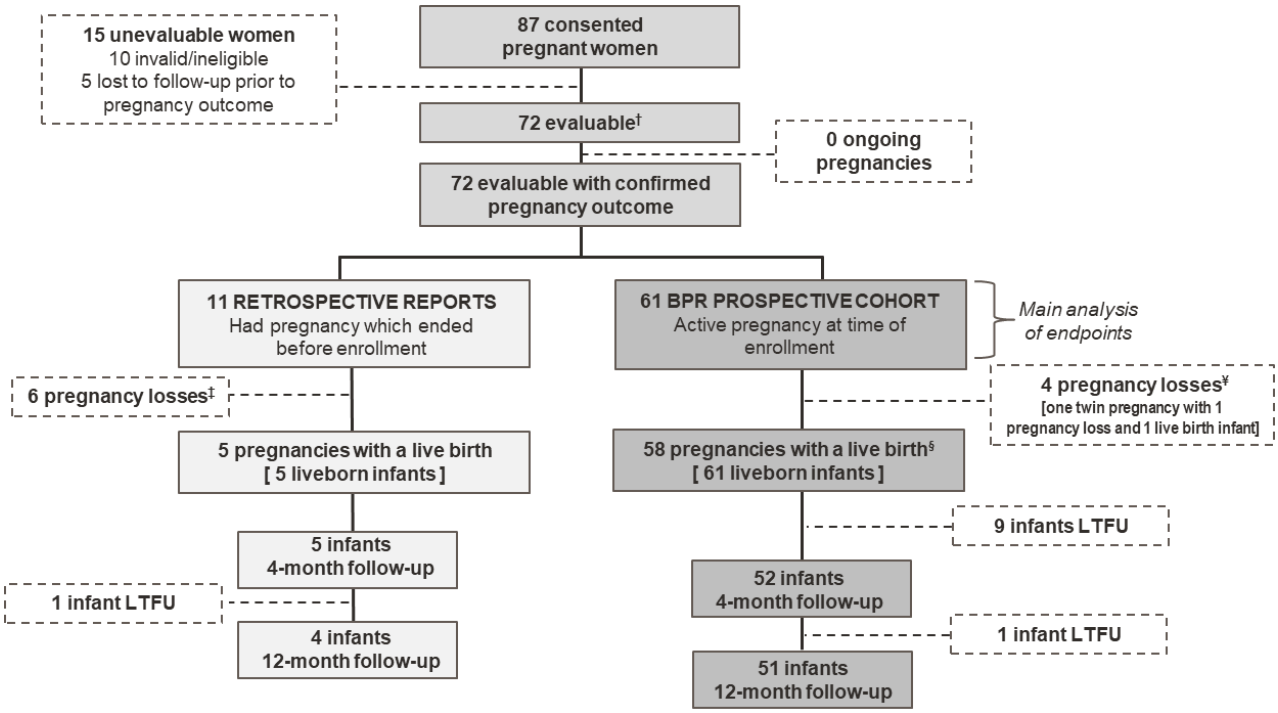
assess the main outcomes of the study. Among these individuals (n=61), 17 (27.9%) were considered pure prospective cases, as they enrolled into the BPR before the end of pregnancy, they did not know at the time of enrollment whether the fetus had malformation, and no prenatal testing was completed prior to enrollment; 44 (72.1%) were considered traditional prospective cases, as the women enrolled into the BPR before the end of pregnancy, regardless of known normal or abnormal prenatal test results at the time of enrollment, or if prenatal testing was not known (Table 1.1).

Of the 61 individuals, 44 (72.1%) had prenatal testing prior to enrollment (e.g., ultrasound, amniocentesis, maternal serum alpha-fetoprotein test, Quad Screen, chorionic villus sampling, and other tests, as available), five (8.2%) had missing/unknown prenatal testing status, and 12 (19.7%) had no prenatal testing prior to enrollment (Table 10.1).

Eleven (15.3%) of 72 individuals with completed pregnancies (such as live birth or spontaneous miscarriage) prior to enrollment were included as retrospective reports. No individuals from the SABLE study (the unexposed cohort) were enrolled into the BPR; no individuals were enrolled into the non-SLE cohort (i.e., individuals who received belimumab for an indication other than SLE). There was no eligible pregnant individual with an unconfirmed pregnancy and exposure (Table 1.1).

Five of 87 enrolled pregnant individuals were considered unevaluable because they were lost to follow-up prior to pregnancy outcome, and 10 cases were considered invalid because they lacked confirmation to meet minimum criteria for enrollment. These cases were not included in the BPR analysis. They were included in the GSK Safety Database (ARGUS) and were followed by routine pharmacovigilance by GSK.

Figure A. BPR Study Population and Enrollment Attrition Status



Source: Table 1.1, Table 2.1, Table 4.1

Abbreviations: LTFU = lost to follow-up.
[†]A participant was considered evaluable and included in the study if the data submitted or confirmed by an HCP met the minimum criteria for a registry report, which included: confirmed belimumab exposure, sufficient information to classify the pregnancy as prospective or retrospective, the pregnancy outcome, contact information for follow-up and consent from the pregnant individual to participate in the registry; [‡]Included two elective terminations and four spontaneous miscarriages; [§]four pregnancies with twins that resulted in seven live-born infants; [¥]included one stillbirth and three spontaneous miscarriages

9.2. Descriptive data including baseline characteristics

9.2.1. Demographics and baseline characteristics (prospective cohort)

Demographic and baseline characteristics of evaluable pregnant individuals in the prospective cohort are described in Table 10.1. Evaluable prospective pregnant individuals with confirmed outcomes (n=61) were recruited from North America (n=53, 86.9%) and Europe (n=7, 11.5%). One had missing information on region. The majority (n=49, 80.3%) of the prospective cohort were participants from the US, followed by Canada (6.6%), Austria (3.3%), France (3.3%), Germany (3.3%), and Spain (1.6%).

Of the 61 pregnant individuals in the prospective cohort, four (6.6%) were in the 20- to 24-year age group, 13 (21.3%) in the 25- to 29-year age group, 26 (42.6%) in the 30- to 34-year age group, 16 (26.2%) in the 35- to 39-year age group, and two (3.3%) in the ≥40-year age group. The mean maternal age (SD) was 31.9 (4.60) years (range: 21 to 42). Nearly three-quarters (n=45, 73.8%) were White or Caucasian and 9.8% (n=6) were Black or African American; only 10 (16.4%) were of Hispanic ethnicity.

Slightly more than half (n=32, 52.5%) of the individuals in the prospective cohort enrolled in the BPR during the first trimester of pregnancy, while over one-quarter (n=18, 29.5%) enrolled in the second trimester of pregnancy and 18.0% (n=11) enrolled in the third trimester of pregnancy. The mean (SD) gestational age at enrollment was 16.6 (9.09) weeks' gestation (range: 5 to 38) (Table 10.1). Among the 61 pregnant individuals, 44 (72.1%) had prenatal testing prior to enrollment, 5 (8.2%) had unknown or missing prenatal testing status, and 12 (19.7%) had no prenatal testing prior to enrollment.

Demographic and baseline clinical characteristics for the overall, pure prospective, traditional prospective, and retrospective cohorts are also presented in Table 10.1.

9.2.2. Pregnancy history (prospective cohort)

Table 10.1 describes the previous pregnancy history for all evaluable pregnant individuals in the prospective cohort. Thirty (49.2%) pregnant individuals in the prospective cohort were nulligravida, 13 (21.3%) had one previous pregnancy, 12 (19.7%) had two or more previous pregnancies, and 6 (9.8%) had missing information. Among the 25 (41.0%) of 61 pregnant individuals with previous pregnancies, 20 (80.0%) reported previous pregnancy outcomes of live births. Seven (28.0%) previous spontaneous miscarriages and three (12.0%) elective terminations were also reported. One reported a previous pregnancy resulted in a child with a birth defect.

Table 10.1 also summarizes prenatal testing including ultrasound, amniocentesis, and chorionic villus sampling. Fetal abnormality was noted in five (8.2%) of the 61 evaluable prospective pregnant individuals with confirmed outcomes.

Pregnancy history for the overall, pure prospective, traditional prospective, and retrospective cohorts is also presented in Table 10.1.

9.2.3. Characteristics of SLE

9.2.3.1. SLE disease activity (prospective cohort)

Table 11.1 summarizes the HCP-reported SLE disease activity in the prospective cohort. using the PGA scores. Figure 2 in Appendix B shows the distribution of PGA score at the time of enrollment and at pregnancy outcome.

More than half (n=36, 59.0%) of the PGA scores were either missing or not done at preconception. Among pregnant individuals with available PGA data during the preconception period (n=25), seven (28.0%) had no disease activity (PGA=0), 10 (40.0%) had mild disease activity (PGA=1), seven (28.0%) had moderate disease activity (PGA=2), and one (4.0%) had severe disease activity (PGA=3).

At the time of enrollment, nearly half (n=30, 49.2%) had available PGA data (Table 11.1). Of these, nine (30.0%) had no disease activity, 13 (43.3%) had mild disease activity, six (20.0%) had moderate disease activity, and two (6.7%) had severe disease activity. Thirty-one (50.8%) participants had PGA assessments that were either missing or not done.

Twenty-three (37.7%) pregnant individuals in the prospective cohort had available PGA data at the second trimester follow-up (Table 11.1). Eight (34.8%) had PGA scores indicating no disease activity, 12 (52.2%) had mild disease activity, and three (13.0%) had moderate disease activity. No individual had severe disease activity. Thirty-eight (62.3%) pregnant individuals had PGA assessments that were either missing or not done for this time period.

At the time of the pregnancy outcome, 15 (24.6%) pregnant individuals had available PGA data (Table 11.1). Of those, nine (60.0%) had no disease activity, three (20.0%) had mild disease activity, two (13.3%) had moderate disease activity, and one (6.7%) had severe disease activity. Forty-six (75.4%) pregnant individuals had PGA assessments that were either missing or not done at the time of pregnancy outcome.

Among the 61 evaluable pregnant individuals with confirmed pregnancy outcomes in the prospective cohort, the SDI score was recorded at baseline for 15 (24.6%) individuals, with a mean score of 1.5 (SD: 4.36; median: 0; range: 0 to 17) (Table 10.1).

All SDI score and PGA scores are also available in Table 11.0 - Table 11.4 (PGA) and Table 10.1 – Table 10.3 (SDI) by cohorts (overall, overall prospective, pure prospective, traditional prospective, and retrospective)

9.2.3.2. SLE laboratory parameters (prospective cohort)

SLE laboratory results for the prospective cohort are shown in Table 13.1.

Anti-dsDNA laboratory results were available for 46 pregnant individuals in the prospective cohort during preconception and/or during pregnancy, with 28 (60.9%) having an abnormal test result (Table 13.0). Thirty-two pregnant individuals had a laboratory result for lupus anticoagulant during preconception and/or during pregnancy, with six (18.8%) having an abnormal test result. The mean (SD) serum creatinine across the 79 tests was 0.72 mg/dL (0.54) (range: 0.4 - 5.3).

SLE laboratory tests are also summarized in Table 13.0 – Table 13.4 by cohort (overall, overall prospective, pure prospective, traditional prospective, and retrospective).

9.2.4. Comorbidities and pregnancy complications (prospective cohort)

Table 12.1 summarizes comorbidities and pregnancy complications for the prospective cohort. For these pregnant individuals, severe lupus flare requiring pulse steroids was the most commonly reported comorbidity or pregnancy-related complications (n=12, 19.7%), followed by hypertensive-hypertension (n=11, 18.0%) and hypothyroidism (n=9, 14.8%). Other reported comorbidities and pregnancy complications experienced by pregnant individuals in the prospective cohort are shown in Table 12.1. Table 12.0 - Table 12.4 provide the comorbidities and pregnancy complications by cohort (overall, overall prospective, pure prospective, traditional prospective, and retrospective), with the frequency of individuals for each condition reported overall and across four time points (preconception, first trimester, second trimester, and third trimester).

9.2.5. Belimumab exposure (prospective cohort)

Among the 61 pregnant individuals in the prospective cohort, the earliest date of belimumab exposure for the majority (n=57, 93.4%) was during the preconception period (Table 3.1). Four (6.6%) individuals had the earliest date of belimumab exposure during the first (n=2) or second (n=2) trimester.

The last belimumab exposure was reported for all prospective cohort individuals, with the timing of last exposure in the first trimester for nine (14.8%) individuals, in the second trimester for 32 (52.5%) individuals, in the third trimester for one (1.6%) individual, and in the post-pregnancy period for 19 (31.1%) individuals (Table 3.1). Among the 57 individuals whose first belimumab exposure occurred in the preconception period, over half (n=31, 54.4%) were exposed to belimumab from preconception through the second trimester of the pregnancy; over one-quarter (n=16, 28.1%) of the individuals were exposed from preconception through post-pregnancy. Exposure occurred from preconception through the first trimester for nine (15.8%) individuals and from preconception through the third trimester for one individual. For the remaining four individuals, belimumab exposure occurred: (1) from the first trimester through the second trimester (n=1); (2) from the first trimester through post-pregnancy (n=1); or (3) from the second trimester through post-pregnancy (n=2). Overall, mean (SD) cumulative exposure was 250.1 (110.29) days (range: 100 - 464). The majority (n=52, 85.2%) received

belimumab via the intravenous route; seven (11.5%) individuals received belimumab subcutaneously and two (3.3%) switched between formulations (intravenous to subcutaneous) (Table 3.1).

Table 3.0 – Table 3.4 describe the belimumab exposure overall and by timing of exposure for the overall, prospective, pure prospective, traditional prospective, and retrospective cohorts.

9.2.6. Concomitant medication exposures (prospective cohort)

Table 3.1 summarizes exposure to concomitant medications either within the six months preconception or during pregnancy for pregnant individuals in the overall prospective cohort. The most common concomitant medications reported during pregnancy were antimalarials (n=50, 82.0%), corticosteroids for SLE (n=30, 49.2%), folate (n=28, 45.9%), aspirin (n=24, 39.3%), immunosuppressants such as azathioprine, cyclophosphamide, methotrexate, mycophenolate, cyclosporin, and rituximab (n=17, 27.9%), and non-steroidal anti-inflammatory drugs (NSAIDs) (n=9, 14.8%). Concomitant medications use was similar during preconception. Eleven (18.0%) of the 61 pregnant individuals were exposed to azathioprine preconception, and 10 (16.4%) individuals were exposed during pregnancy. Eight (13.1%) and five (8.2%) individuals used methotrexate during preconception and pregnancy, respectively.

Complete results for the concomitant medication exposure including by overall, pure prospective, traditional prospective, and retrospective cohorts are presented in Table 3.0 to Table 3.4.

9.2.7. Tobacco, alcohol, and recreational drug exposure (prospective cohort)

As shown in Table 10.1, 18 (29.5%) pregnant individuals from the prospective cohort reported any alcohol, tobacco, or recreational drug use any time during preconception and/or during pregnancy. Three (4.9%) individuals reported tobacco use at preconception only; three (4.9%) individuals reported tobacco use at preconception and during pregnancy; none reported tobacco use during pregnancy only and most (n=49, 80.3%) reported never using tobacco. Eleven (18.0%) individuals reported alcohol use preconception; none reported that they used alcohol during pregnancy and nearly two-thirds (n=40, 65.6%) reported never drinking alcohol. One individual reported recreational drug use during preconception and during pregnancy and one individual reported recreational drug use during pregnancy only, while most (n=53, 86.9%) of the pregnant individuals have never used recreational drugs. Marijuana was the recreational drug reported during preconception; marijuana and heroin were recreational drugs reported during pregnancy (Table 10.1).

Tobacco, alcohol, and recreational drug use are also presented for additional cohorts in Table 10.1.

9.3. Outcome data (prospective cohort)

There was a total of 61 pregnant individuals in the prospective cohort with a confirmed pregnancy outcome (Figure A and Table 1.1), of which one was a stillbirth, three spontaneous miscarriages (one from one set of twin pregnancies and the other resulted in a live birth) and 58 resulted in a live birth. Of the 58 pregnancies with a live birth there were 61 live birth infants (54 infants from 54 singleton pregnancies and seven infants from four twin pregnancies) (Table 4.1). Of the 61 live birth infants, 42 (68.9%) were full-term infants and 19 (31.1%) were preterm infants. Four (6.6%) live birth infants were classified as SGA based on the INTERGROWTH-21st criteria and 12 (19.7%) live birth infants were classified as SGA based on Alexander criteria. Among the 58 live birth pregnancies in the prospective cohort, 12 (20.7%) resulted in birth defects that were confirmed using either MACDP or EUROCAT criteria.

More detailed analyses about the main outcomes of interest are presented in Section 9.4 and Section 9.5.

Pregnancy and infant outcome results and characteristics for pure prospective, traditional prospective, and retrospective cohorts are also presented in Table 2.1, Table 4.0, Table 4.1, Table 5.1, Table 7.0, Table 7.2, Table 7.3, and Table 7.4, Table 8.01, Table 8.02, and Listing 1.0, Listing 2.0, Listing 6.0, and Listing 8.0.

9.4. Results of primary analyses

9.4.1. Birth defects (prospective cohort)

Among the 61 live birth infants from 58 prospective live birth pregnancies (Table 8.01), 11 resulted in a confirmed major birth defect (using MACDP definition) as confirmed by the BDE (18.0%; 95% CI: 8.4% – 27.7 %). Sensitivity analyses of birth defects among the same primary population using either MACDP or EUROCAT definitions of defects indicates prevalence of 19.7% (12/61) with 95% CI (9.7% to 29.6%) and in EUROCAT only indicated prevalence of 14.8% (9/61) with 95% CI (5.9% – 23.7%). Sensitivity analyses of birth defects among prospective pregnancies with a live birth, either MACDP or EUROCAT definitions of defects, indicates prevalence of 20.7% (12/58;) with 95% CI (9.7% to 29.6%). No confirmed birth defects were identified in the retrospective cohort.

There were 17 defect events among the 12 infants using either/or MACDP/EUROCAT (five infants had two defects) (Table E). Four infants had four defect events that only met the classification criteria of MACDP: one with non-descending testis, one with congenital heart block, one with pelviectasis, one with ankyloglossia. One infant (with a small fenestrated atrial septal defect) met the classification criteria of EUROCAT but was classified as an exclusionary defect by MACDP. Five infants had defect events [bilateral club foot (one infant), congenital heart block (one infant), plagiocephaly (three infants), and torticollis (three infants)] considered to be defects of known cause or no temporal association, and two infants had defect events (non-descending testis and small ventricular septal defect) with insufficient data on defect and/or belimumab exposure window for proper assessment (Table E).

Of the 12 live birth pregnancies with major birth defects, the earliest belimumab exposure occurred pre-conceptionally in 11 (91.7%) individuals (Table 3.1). Mean (SD) cumulative belimumab exposure was 223.3 (79.03) days, and the majority (n=10, 83.3%) received belimumab via the IV route (Table 3.1). For the 12 pregnancies with major birth defects, six (50.0%) were enrolled in the first trimester, five (41.7%) in the second trimester, and one (8.3%) in the third trimester (Table 10.2). Eleven (91.7%) had prenatal testing prior to enrollment (Table 10.2) of which one had an abnormal result (infant with atrial septal defect) (Table 6.2, Listing 2.0) and one where results were not available (Arnold Chiari type II malformation) (Table E). All 12 (100.0%) pregnancies had prenatal testing results post-enrollment, of which two defects (bilateral club foot and congenital heart block) were detected prenatally and one was suspected (hydronephrosis) by ultrasound or abnormal prenatal screening post-enrollment. Six (50.0%) were of advanced maternal age (35 to 39 years), one (8.3%) with twins, and one (8.3%) reported an elective termination in a previous pregnancy (Table 10.2). Of the 12 pregnancies with major birth defects, 11 (91.7%) had anti-dsDNA tests available (five abnormal), six (50.0%) had lupus anticoagulant tests available (two abnormal), two (16.7%) had anti-Ro/SSA and anti-La/SSB tests available (none abnormal), and one (8.3%) had proteinuria tests available (none abnormal) (Table 13.1).

Of the 12 live birth pregnancies associated with major birth defects, seven (58.3%, ad hoc analysis) pregnancies had the presence of one or more comorbidity and/or pregnancy complication, including severe lupus flare, pre-existing hypertension, hypothyroidism, thrombocytopenia, thrombotic event, pre-eclampsia, placental abruption and neurological manifestation of lupus (Table 12.1). Lupus nephritis and antiphospholipid syndrome were noted in one individual within the BDE case assessment (Table 12.1, Listing 2.0). Five (41.7%) infants from the 12 live birth pregnancies were a preterm birth (Listing 2.0) and two were SGA (Listing 2.0).

Exposure to concomitant medications of interest during pregnancy in the 12 live birth pregnancies included antimalarials (n=10, 83.3%), corticosteroids (n=6, 50.0%), aspirin (n=4, 33.3%), azathioprine (n=2, 16.7%), heparin (n=2, 16.7%), antiepileptics (n=2, 16.7%), cyclosporin (n=1, 8.3%); exposure of these drugs occurred in all three trimesters. Other concomitant medication exposure during pregnancy included NSAIDs (n=2, 16.7%); one across all trimesters, and one in the third trimester) and methotrexate (n=1, 8.3%, at first trimester) (Table 3.1). Any alcohol, tobacco, or recreational drug use was reported for six (50.0%) of 12 pregnancies associated with a major birth defect. Tobacco use was reported preconception and during pregnancy for two (16.7%) pregnancies and recreational drug use during pregnancy only for one (8.3%) case (Table 10.2).

All HCP-reported birth defects are provided in Listing 1.0. Listing 2.0 provides the assessments conducted by the BDE, including MACDP and EUROCAT classification. HCP-reported events and conditions that were determined not to be birth defects by either the MACDP or EUROCAT classification were excluded from the birth defect summaries (Table 8.01 and Table 8.02). Summary report for each birth defect case including belimumab exposure and potential confounders are presented in Appendix D.

No fetal loss or live birth infants with a confirmed birth defect were reported in the retrospective cohort (Listing 2). Additionally, no major birth defects were detected in any fetal loss cases (Table 8.02 versus Table 8.01).

Table E. Assessments of Birth Defect Cases

Reported infant cases	Birth defect event reported	Classified by MACDP	Classified by EUROCAT	Organ system	Belimumab exposure timing[a,i]	Additional considerations[e,i]
CONFIRMED BY BDE [ALL FROM PROSPECTIVE COHORT]						
1	Bilateral club foot[b,c]	Yes	Yes	Musculoskeletal	Preconception to 2nd trimester	**Defect with known cause[f]**. Can occur due to mechanical factors that take place within the pregnancy[g].
2	Non-descending testis	Yes	No	Male reproductive	Preconception to 2nd trimester	Insufficient data[h]. Exposure may not have occurred during critical window of development[g].
3	Very mild Ebstein's anomaly of the tricuspid[b]	Yes	Yes	Cardiovascular	Preconception to postpartum	---
4	Congenital heart block[b]	Yes	No	Cardiovascular	Preconception to 2nd trimester	**Defect with known cause[j].** Associated with SLE disease itself (presence of anti-Ro/SSA and anti-La/SSB antibodies)[g].
5	Small ventricular septal defect	Yes	Yes	Cardiovascular	Preconception to 2nd trimester	Insufficient data[g]. Described as tiny atypical ventricular septal defect and muscular. Size not known [h].
	Congenital hydronephrosis	Yes	Yes	Renal		---
6	Low-lying conus medullaris	Yes	Yes	CNS	Preconception to 2nd trimester	---
	Pelviectasis	Yes	No	Renal		---
7	Positional plagiocephaly[b,d]	Yes	Yes	Face	Preconception to 1st trimester	**Defect with known cause[f]**. Can occur due to mechanical factors that take place within the pregnancy [g].
	Positional torticollis[b,d]	Yes	Yes	Face		**Defect with known cause[f]**. Can occur due to mechanical factors that take place within the pregnancy[g]. twin pregnancy[h].
8	Small fenestrated atrial septal defect	ED	Yes	Cardiovascular	Preconception to 1st trimester	Prenatal testing prior to enrollment with abnormal results [h].

Reported infant cases	Birth defect event reported	Classified by MACDP	Classified by EUROCAT	Organ system	Belimumab exposure timing[a,i]	Additional considerations[e,i]
9	Severe Arnold Chiari type II malformation[d]	Yes	Yes	CNS	Preconception to 2nd trimester	Enrolled in 3rd trimester, prenatal testing done prior to enrollment but results unknown[h,k].
10	Ankyloglossia	Yes	No	Gastrointestinal	1st trimester to postpartum	---
11	Plagiocephaly	Yes	Yes	Face	Preconception to 1st trimester	**Defect with known cause[f].** Can occur due to mechanical factors that take place within the pregnancy[h].
	Torticollis	Yes	Yes	Face		**Defect with known cause.[f]** Can occur due to mechanical factors that take place within the pregnancy[h].
12	Left-sided positional plagiocephaly	Yes	Yes	Face	Preconception to 2nd trimester	**No temporal association.** Can occur due to mechanical factors that take place within the pregnancy[h].
	Torticollis	Yes	Yes	Face		**No temporal association.** Can occur due to mechanical factors that take place within the pregnancy[h]
NOT A DEFECT (CONFIRMED BY BDE)						
2	Inflammation of tricuspid valve	No	No		No; not a defect case by BDE evaluation (prospective)	
	Patent ductus arteriosus	No	No		No; not a defect case by BDE evaluation (prospective)	
7	Patent ductus arteriosus	No	No		No; not a defect case (prospective)	
	Patent foramen ovale	No	No		No; not a defect case (prospective)	
10	Dacryostenosis of nasolacrimal ducts	No	No		No; not a defect case (prospective)	
13	Right nasal lacrimal duct obstruction	ED	No		No; not a defect case (prospective)	

Reported infant cases	Birth defect event reported	Classified by MACDP	Classified by EUROCAT	Organ system	Belimumab exposure timing[a,i]	Additional considerations[e,i]

Source: Listing 2.0, Juliao, 2022, and Case summary report Appendix D.

Abbreviations: BDE = Birth defect evaluator; CNS = central nervous system; ED = exclusionary defect; EUROCAT = European Surveillance of Congenital Anomalies; MACDP = Metropolitan Atlanta Congenital Defects Program

Note: ED; single EDs within an infant are not considered to be birth defect cases.

[a]Preconception is defined as 4 months prior to pregnancy for belimumab

[b]Patient was positive for anti-Ro/SSA and anti-La/SSB antibodies (all noted at preconception) [Source: Case summary report Appendix D]

[c]Defect detected prenatally by ultrasound or abnormal prenatal screening in two cases [Source: Case summary report Appendix D]

[d]Defect noted after pregnancy outcome (during infant follow-up) [Source: Case summary report Appendix D]

[e]Approved by SAC (Scientific Advisory Committee)

[f]Initially noted by BDE

[g]Initially noted by internal GSK pregnancy safety panel (POAP: GSK Pregnancy Outcome Advisory Panel)

[h]Initially noted by PPD and GSK study team [Source: Case summary report Appendix D]

[i]Included in Juliao, 2022 publication

[j]Yildirim A, Tunaoolu FS, Karaaoac AT. Neonatal congenital health block. Indian Pediatr. 2013;50(5):483-8

[k]Per hospital's Medical Records Department [Source: Case summary report Appendix D]

9.5. Results of secondary analyses/exploratory analyses

9.5.1. Pregnancy outcomes (prospective cohort)

Between 16 July 2012 and 11 November 2022, pregnancy outcomes were reported for 61 pregnant individuals in the prospective cohort. A summary of the pregnancy outcomes is presented in Section 9.3 and Table 5.1 for the prospective cohort, and in Table 5.1 for pure prospective, traditional prospective, and retrospective cohorts.

9.5.1.1. Live births (prospective cohort)

Of the 61 pregnancies in the prospective cohort, 58 resulted in a live birth (54 singleton live birth infants and seven live birth infants from four sets of twins). Therefore, there were 61 live birth infants in total (Table 4.1). Of the live birth infants, nearly two-thirds (n=39, 63.9%) were male and the mean (SD) gestational age at birth was 37.7 (1.96) weeks. Nineteen (31.1%) were preterm births and 16 (26.2%) were low birthweight births.

Table 4.0 and Table 4.1 also present details regarding the live birth infants for participants in the overall, pure prospective, traditional prospective, and retrospective cohorts.

9.5.1.2. Preterm births (prospective cohort)

Of the 61 live birth infants, 19 (31.1%; 95% CI: 19.5% – 42.8%) were considered preterm in the prospective cohort (Table 4.1 and Table 8.01). Among the 19 preterm infants, the majority (n=17, 89.5%) were considered late preterm ($34^{0/7}$ - $36^{6/7}$ weeks' gestation), one (5.3%) was considered moderately preterm ($32^{0/7}$ - $33^{6/7}$ weeks' gestation), and one (5.3%) was considered very/severely preterm ($28^{0/7}$ - $31^{6/7}$ weeks) (Table 4.1).

Belimumab exposures occurred at the following time points for pregnancies with preterm infants (n=17): preconception through the first trimester (n=5, 29.4%), preconception through the second trimester (n=8, 47.1%), and preconception through post-pregnancy (n=4, 23.5%) (Table 3.1). Pregnancies with preterm infants were also exposed to antimalarials (n=13, 76.5%), aspirin (n=8, 47.1%), folate (n=8, 47.1%), corticosteroids (n=8, 47.1%), immunosuppressants (n=7, 41.2%), angiotensin-converting enzyme inhibitors (n=3, 17.6%), and NSAIDs (n=3, 17.6%) during preconception and/or throughout pregnancy (Table 3.1).

For pregnancies with preterm infants in the prospective cohort, over one-third (n=6, 35.3%) had available PGA data at preconception (Table 11.1). Of these, one (16.7%) had no disease activity (PGA=0), four (66.7%) had mild disease activity (PGA=1), none had moderate disease activity (PGA=2), and one (16.7%) had severe disease activity (PGA=3). At the time of enrollment, over half (n=10, 58.8%) had available PGA data. Of these, three (30.0%) had no disease activity, four (40.0%) had mild disease activity, two (20.0%) had moderate disease activity, and one (10.0%) had severe disease activity. Six (35.3%) pregnancies with preterm infants had available PGA data at the second trimester

follow-up. Two (33.3%) had no disease activity, three (50.0%) had mild disease activity, one (16.7%) had moderate disease activity, and none had severe disease. At the time of pregnancy outcome, three (17.6%) pregnancies with preterm infants had available PGA data. Among these, one (33.3%) had no disease activity, one (33.3%) had mild disease activity, one (33.3%) had moderate disease activity, and none reported severe disease (Table 11.1).

Where available, most preterm infants also met appropriate developmental milestones for gross motor skills, fine motor skills, language development milestone, cognitive, and social/emotional domains (details described in Section 9.6.1 and Table 7.1). One preterm infant (5.3%) reported at least one serious infection at the outcome visit and one infant (5.9%) at the 12-month visit. For non-serious infection/fever (clinically significant per protocol), one preterm infant (5.3%) reported at least one event at the outcome visit and one infant (17.6%) at the 12-month visit (Table 7.6).

Table 4.0 and Table 4.1 also present details regarding preterm infants in the overall, pure prospective, traditional prospective, and retrospective cohorts. Belimumab and concomitant medication exposures among pregnancies with preterm births are presented in Table 3.0, Table 3.1, Table 3.2, Table 3.3, Table 3.4, Table 4.1, and Table 8.01. Infant outcomes are detailed by cohort in Table 7.0 - Table 7.9.

9.5.1.3. SGA (prospective cohort)

Among the 61 pregnancies in the prospective cohort enrolled prior to 20 weeks' gestation, four live birth pregnancies (6.6%; 95% CI: 0.3% – 12.8%) resulted in infants considered as SGA based on INTERGROWTH-21st [Villar, 2014] criteria, and 12 live birth pregnancies (19.7%; 95% CI: 9.7% – 29.6%) resulted in infants considered as SGA based on Alexander criteria (Table 8.01). As shown in Table 4.1, among the four live birth infants that were classified as SGA by INTERGROWTH-21st standards, all were low birthweight infants, defined as an infant with birth weight less than 2,500 grams; for those classified based on the Alexander criteria, eight (66.7%) of 12 were low birthweight infants.

For the live birth pregnancies (n=4) that resulted in infants that were considered as SGA based on INTERGROWTH-21st standards, belimumab exposures occurred at the following time points: preconception through the second trimester (n=2, 50.0%), preconception through post-pregnancy (n=1, 25.0%), and second trimester through post-pregnancy (n=1, 25.0%). Exposure to concomitant medications of interest during pregnancy included antimalarials (n=4, 100.0%), folate (n=3, 75.0%), aspirin, (n=3, 75.0%), immunosuppressants (n=2, 50.0%), NSAIDs (n=2, 50.0%), and corticosteroids (n=2, 50.0%) (Table 3.1).

Of the 12 live birth pregnancies with infants considered as SGA based on Alexander criteria, belimumab exposures occurred at the following time points: preconception through first trimester (n=1, 8.3%), preconception through the second trimester (n=8, 66.7%), preconception through post-pregnancy (n=2, 16.7%), and second trimester through post-pregnancy (n=1, 8.3%). Exposure to concomitant medications of interest during pregnancy included antimalarials (n=11, 91.7%), aspirin, (n=7, 58.3%), folate

(n=7, 58.3%), corticosteroids (n=5, 41.7%), immunosuppressants (n=4, 33.3%), and NSAIDs (n=3, 25.0%) (Table 3.1).

Table 4.1 also presents the number of live birth infants considered as SGA in the overall, pure prospective, traditional prospective, and retrospective cohorts. Belimumab and concomitant medication exposures among live birth pregnancies with infants that were considered as SGAs are presented in Table 3.0, Table 3.1, Table 3.2, Table 3.3, Table 3.4, Table 4.1, and Table 8.01.

9.5.1.4. Stillbirths (prospective cohort)

Among the 61 pregnancies in the prospective cohort, one (1.6%; 95% CI: 0.0% – 4.7%) stillbirth was reported (Table 2.1 and Table 8.01). For the pregnancy that ended as a stillbirth, belimumab exposure occurred from second trimester through post-pregnancy. Exposure to concomitant medications of interest during pregnancy included corticosteroids (during the second and third trimesters of pregnancy), antimalarials (throughout the first, second, and third trimesters of pregnancy), beta-blockers (throughout the first, second, and third trimesters of pregnancy), and aspirin (during the second and third trimesters of pregnancy) (Table 3.1).

The one pregnancy that resulted in a stillbirth was in the traditional prospective cohort; no pregnancies in other cohorts ended in a stillbirth. Belimumab exposure and concomitant medication exposures in pregnancies that ended in stillbirths are presented in Table 3.0,Table 3.2,Table 3.3,Table 3.4, and Table 8.01 in the overall, pure prospective, traditional prospective, and retrospective cohorts. Characteristics of evaluable pregnancies that resulted stillbirth, stratified by cohort, are described in Table 10.3.

No birth defects were reported in the one stillbirth (Source: OB HCP).

9.5.1.5. Spontaneous miscarriages (prospective cohort)

In the prospective cohort, three (3/61, 4.9%) pregnancies ended in a spontaneous miscarriage (Table 2.1). Among the pregnancies in the prospective cohort enrolled prior to 20 weeks' gestation, the spontaneous miscarriage occurrence rate in the BPR was 7.0% (3/43, 95% CI: 0.0% – 14.3%) (Table 8.01).

For the three pregnancies that ended in a spontaneous miscarriage, the earliest belimumab exposure occurred during preconception. The last belimumab exposure occurred during the second trimester for one pregnancy (33.3%) and in the post-pregnancy period for two (66.7%) pregnancies (Table 3.1 and Table 8.01). One of three participants who had a spontaneous miscarriage was exposed to corticosteroids preconception but not during pregnancy. Exposure to concomitant medications of interest included antimalarials during preconception (n=2, 66.7%) and throughout pregnancy (n=2, 66.7%), as well as immunosuppressants during preconception (n=1, 33.3%) but not during pregnancy; methotrexate was the immunosuppressant reported (Table 3.1).

Table 2.1 also presents the number of pregnancies that resulted in spontaneous miscarriages in the overall, pure prospective, traditional prospective, and retrospective

cohorts. Belimumab and concomitant medication exposures in pregnancies that ended in spontaneous miscarriages are presented in Table 3.0, Table 3.1, Table 3.2, Table 3.3, Table 3.4, and Table 8.01. Characteristics of evaluable pregnancies that ended in a spontaneous miscarriage or stillbirth, stratified by cohort, are described in Table 10.3.

No birth defects were reported in the three spontaneous miscarriages (Source: Table 8.01 and Table 8.02).

9.5.1.6. Elective terminations (prospective cohort)

No elective termination was reported for participants in the prospective cohort. Table 2.1 presents the number of pregnancies that ended in elective terminations in the overall, pure prospective, traditional prospective, and retrospective cohorts.

9.5.1.7. Ectopic and molar pregnancy (prospective cohort)

No ectopic or molar pregnancy was reported for participants in the prospective cohort. Table 2.1 presents the number of pregnancies that resulted in either an ectopic pregnancy or a molar pregnancy in the overall, pure prospective, traditional prospective, and retrospective cohorts.

9.5.2. Infant outcomes (prospective cohort)

9.5.2.1. Pediatric infections (prospective cohort)

Any infection and/or fever. Of the 61 live birth infants with data outcome visit, four (n = 4/61, 6.6%) infants had at least one infection/fever event (five events total) (Table 7.1). At the four-month follow-up visit, seven (n = 7/52, 13.5%) infants with complete data reported at least one infection/fever (seven events total). At the 12-month follow-up visit, 18 (n = 18/51, 35.3%) infants with complete data reported any infection/fever (25 events total).

Serious infections. Of the overall 61 live birth infants, four (n = 4/61, 6.6%; 95% CI: 0.3 – 12.8) reported a serious infection during the first year of life (five events) (Table 7.6, Table 8.01, and Listing 8.0, Listing 9.4). When reporting by follow-up visit, of the 61 live birth infants with complete data at the outcome visit, two (n = 2/61, 3.3%) had any serious infections (two events) (Table 7.6). Both infections (viral meningitis and endocarditis, Listing 9.4) within the two infants were resolved but attributability with belimumab could not be ruled out in one infection and it was unknown for the other infection. No serious infections were reported at the four-month visit. At the 12-month follow-up visit two (n = 2/51, 3.9%) infants reported a serious infection (three events). The two serious infections from the first infant (rhinovirus and gastroenteritis, Listing 8.0 and Listing 9.4) were resolved and were not attributable to belimumab. The serious infection from the second infant (respiratory syncytial virus, Listing 8.0 and Listing 9.4) was resolved but it was unknown if attributable to belimumab (Listing 8.0 and Listing 9.4).

Non-serious infection/fever (clinically significant per protocol): Of all 61 live birth infants, 14 (n=14/61, 23.0%) reported non-serious infection/fevers(clinically significant per protocol) during the first year of life (16 events) (Table 7.6). When reporting by infant with data on each follow-up visit, of the 61 live birth infants with complete data at the outcome visit, two (n = 2/61, 3.3%) had non-serious infection/fever (clinically significant per protocol) (three events) with age of onset ranging from 7.3 – 10.9 weeks (Table 7.6). Of the three events, two were resolved and one status was ongoing. Attributability to belimumab was unknow for all three events. At the four-month visit, seven (n= 7/52, 13.5%) infants with complete data had a non-serious infection/fever (clinically significant per protocol) (seven events total) with age of onset ranging from 11.0 – 21.9 weeks. Of the seven events, five events were not attributable to belimumab, and two events were unknown. All seven events were resolved. At the 12-month follow-up visit there were six infants (n=6/51, 11.8%) with a non-serious infection/fever (clinically significant per protocol) (6 events) (Table 7.6). Of the six events, two were not attributable to belimumab and 4 was unknown. Five of the events were resolved and the status of one was unknown.

Table 7.0, Table 7.2, Table 7.3, and Table 7.4 present details regarding infants experiencing at least one infection or fever and the total number of infections or fever in the overall, pure prospective, traditional prospective, and retrospective cohorts. Infant serious infection and non-serious infection/fever (clinically significant per protocol) are presented by cohort in Table 7.5 – Table 7.9.

9.6. Other analyses

9.6.1. Developmental milestones (prospective cohort)

Table 7.1 describes infant outcomes across time points among prospective cohort participants. There were 61 live-born infants (42 full-term; 19 preterm infants) from the prospective cohort.

Data at the four-month follow-up visit:

- Fifty-two infants (33 full-term; 19 preterm) had data for the four-month follow-up visit.
    - Where data were available, all full-term infants met their milestones in gross motor, fine motor, language, cognitive, and social/emotional skills. For infants with data at the four-month follow-up, data were missing for the following milestones: language (n=3, 9.1%), cognitive (n=3, 9.1%), fine motor (n=2, 6.1%), social/emotional (n=2, 6.1%), and gross motor skills (n=1, 3.0%).
    - Where data were available, all preterm infants met age-appropriate developmental milestones for fine motor, language, cognitive, and social/emotional skills; data were missing for the following milestones: language (n=4, 21.1%), fine motor (n=2, 10.5%), social/emotional (n=2, 10.5%), and cognitive (n=2,10.5%) skills. Milestone for gross motor skills was not met for one (5.3%) infant.

Data at the 12-month study period:

- Fifty-one infants (34 full-term; 17 preterm) had data for the 12-month follow-up visit.
    - Where data were available, all full-term infants met their milestones in gross motor, language, cognitive, and social/emotional skills. Milestone for fine motor skills was not met for one (2.9%) infant. Data were missing for the following milestones: social/emotional (n=2, 5.9%), cognitive (n=2, 5.9%), gross motor (n=1, 2.9%), fine motor (n=1, 2.9%), and language skills (n=1, 2.9%).
    - All 17 preterm infants met their milestones for cognitive and fine motor skills. Milestones for gross motor and language skills were not met for two (11.8%) infants, and milestone for the social/emotional skills was not met for one (5.9%) infant.

Results at the four-month and at 12-month visits for infants in the overall, pure prospective, traditional prospective, and retrospective cohorts are presented in Table 7.0, Table 7.2, Table 7.3, and Table 7.4, respectively.

9.6.2. Breastfeeding (prospective cohort)

Ten (16.4%) live birth pregnancies in the prospective cohort were exposed to belimumab while breastfeeding; this information was missing or was unknown for nearly half (n=28, 45.9%) of the live birth pregnancies and 37.7% (n=23) were not exposed to belimumab at the time of breastfeeding (Table 7.1).

Of the live birth infants in the prospective cohort with follow-up visit data at four months of age (n=52; 33 full-term and 19 preterm), the pediatric HCPs confirmed that 22 (66.7%) full-term infants and 18 (94.7%) preterm infants had ever been breastfed. Where data were available on belimumab exposure during breastfeeding at the four-month follow-up, three pregnancies that resulted in full-term births and two pregnancies that resulted in preterm births had belimumab administered during breastfeeding (Table 7.1).

Among infants with follow-up visit data available at 12 months of age, 24 (70.6%) of 34 full-term infants and 16 (94.1%) of the 17 preterm infants had been breastfed. Where data were available on belimumab exposure during breastfeeding at the 12-month follow-up, belimumab exposure during breastfeeding occurred in six pregnancies (resulted in three full-term and three preterm infants) (Table 7.1).

Results for breastfeeding and belimumab exposure while breastfeeding for the overall, pure prospective, traditional prospective, and retrospective cohorts are presented in Table 7.0, Table 7.2, Table 7.3, and Table 7.4, respectively.

9.6.3. Zika virus

In February 2016, the World Health Organization (WHO) declared the emerging Zika virus epidemic as a “Public Health Emergency of International Concern” because of clusters of microcephaly and other neurological disorders in newborns in some areas

affected by the Zika virus. Since then, Zika virus has become a nationally reportable condition in the US, and a registry has been established by the CDC to track pregnancies in the US in women exposed to the Zika virus and their outcomes [Simeone, 2016]. A risk detection and monitoring strategy for Zika virus infections in the BPR was put in place after discussion with the BPR Steering Committee, effective 24 January 2017. The aim of the strategy was to identify and document possible exposure to Zika virus when birth defects were noted, so that this confounding factor could be considered. From 24 January 2017 until 28 October 2022, exposure to Zika virus had not been reported in any confirmed defect cases.

9.6.4. SARS-CoV-2 virus

In March 2020, the WHO declared the coronavirus disease 2019 (COVID-19) outbreak, caused by the severe acute respiratory syndrome coronavirus-2, as a pandemic due to spread, severity, and global presence. There had been no data to suggest if COVID-19 infections can lead to adverse pregnancy outcomes. Due to limited data and as such, several COVID-19 pregnancy registries were set up to explore this concern and monitor periodically to determine if a possible link could be identified [Mullins, 2022; PRIORITY, 2020]. For the BPR specifically, a COVID-19 component was added to the existing Zika virus risk detection and monitoring strategy after discussion with the BPR SAC in June 2020. From June 2020 until 28 October 2022, COVID-19 exposure had not been reported for the confirmed defect cases.

9.6.5. Retrospective reports

A total of 11 retrospective pregnancies were enrolled within the BPR of which no confirmed major birth defects were identified in live birth infants (Table E) as well no serious infections and/or non-serious infection/fevers (clinically significant per protocol) during infant one year follow-up (Table 7.9). Pregnancy loss, excluding elective termination, occurred in 40% (4/10) (Table 2.1) of the pregnancies; as these were retrospective cases, it was not feasible to restrict analysis to enrollment prior to 20 weeks' gestation. All other pregnancy and infant outcomes, patient characteristics and adverse events in the retrospective reports are found in Table 2.1, Table 3.4, Table 4.1, Table 4.1, Table 5.1, Table 6.1, Table 6.2, Table 7.4, Table 10.1-Table 10.3, Table 11.4 and Table 12.4.

9.7. Adverse events/adverse reactions

9.7.1. Maternal and infant-solicited adverse events and solicited serious adverse events (prospective cohort)

Maternal and infant-solicited AEs and solicited SAEs are reported in Table 6.1 and Table 6.2, respectively, for pregnant individuals in the overall, prospective, pure prospective, traditional prospective, and retrospective cohorts. Listing 9.1 – Listing 9.4 detail maternal and infant-solicited AEs and solicited SAEs.

Thirty-one (50.8%) of 61 pregnant individuals in the prospective cohort had at least one solicited maternal non-serious AE and/or SAE. In total, 28 maternal SAEs had been reported in 19 (31.1%) pregnant individuals, and 18 (29.5%) pregnant individuals reported at least one maternal non-serious AE; among these, 16 pregnant individuals experienced pregnancy, puerperium, and perinatal conditions, six pregnant individuals experienced gastrointestinal disorders, and six pregnant individuals experienced infections (Table 6.1, Listing 9.1 and Listing 9.2).

Thirty-five (57.4%) of 61 individuals had at least one solicited infant non-serious AE and/or SAE. In total, 46 infant SAEs had been reported in 26 pregnant individuals who experienced infant SAEs (42.6%) and there were 21 reports (34.4%) of individuals whose infants experienced at least one solicited non-serious infant AE; among these, 14 events were congenital, familial, and genetic disorders, 11 were pregnancy, puerperium, and perinatal conditions, 10 were gastrointestinal disorders, six were musculoskeletal and connective tissue disorders, and six were infections (Table 6.2, Listing 9.3 and Table 9.4).

In summary, these maternal and infant solicited AEs and SAEs did not indicate a trend or safety signal with belimumab. No new important safety information regarding use in pregnancy has been identified from the BPR.

10. DISCUSSION

10.1. Key results

10.1.1. Overview

The BPR aimed to evaluate pregnancy and infant outcomes for pregnancies in women with SLE who were exposed to commercially supplied belimumab within four months' preconception and/or during pregnancy. Between 16 July 2012 and 28 October 2022, 87 women consented to participate of which 72 participants (82.8%) were considered evaluable with a confirmed pregnancy outcome. Of the 72 participants, 61 were from main analysis cohort (overall prospective cohort) which was over 80% below the target sample size of 500 pregnancies (Figure A, Figure 1 under Appendix B). Additionally, the small sample size of the retrospective cohort (n=11) and its risk of enrollment bias also limits the interpretation of the results. Lastly, no non-exposed SLE participants were enrolled within the external comparator group from SABLE to contextualize these outcomes in the overall SLE population. These limitations resulted in imprecise estimates for the study outcomes making it challenging to draw inferences on the available data.

10.1.2. Participant characteristics and follow-up

Of the 61 prospective participants, more than half (52.5%) were enrolled into the BPR during the first trimester of pregnancy; fewer participants were recruited in the second and third trimester (29.5% and 18.0%, respectively), with a mean of 16.6 weeks' gestation. There were no lost to follow-up prior to pregnancies outcomes and the LTFU for the infants first year of life was 17% =10/58, Figure A).

Nearly three-quarters of the pregnant participants were White or Caucasian, which are similar characteristic of patients prescribed belimumab within the US [Ke, 2015]. Over 80% of participants were from the US.

Disease activity scales such as Systemic Lupus Erythematosus National Assessment Systemic Lupus Erythematosus Disease Activity Index, Systemic Lupus Erythematosus Disease Activity Index 2K, or British Isles Lupus Assessment Group were not systematically collected, and data were reported using the PGA. Missing information makes it difficult to assess the representativeness of the BPR population in terms of disease severity as 45% to 68% were missing a PGA score depending on timing of assessment.

Similar SLE-related comorbidities and pregnancy complication were reported in BPR participants as in the general SLE pregnant population including hypertension, hypothyroidism, pre-eclampsia [Gergianaki, 2021]. However, the impact of missing data must be considered when interpreting these results.

The most common concomitant medications within the BPR were antimalarials and corticosteroids, which is consistent with SLE treatment recommendations [Andreoli, 2017; Sammaritano, 2020]. Immunosuppressants were also reported for many pregnancies including azathioprine, cyclophosphamide, methotrexate (MTX), mycophenolate (MMF), cyclosporin, and rituximab. Evidence that suggests certain immunosuppressant medications should be avoided during pregnancy, including MMF, cyclophosphamide and MTX [Taulaigo, 2021].

10.1.3. Live births

Most pregnancies in the BPR for prospective cohort participants resulted in live birth, 95.1% overall. This percentage is consistent with results from other studies that utilized various study designs and methodologies to examine birth outcomes in SLE populations, which showed that 54.9% to 94.5% of SLE pregnancies resulted in live birth [Andrade, 2008; Borella, 2014; Cervera, 2002; Clowse, 2005; Georgiou, 2000; Hwang, 2018; Normand, 2019]. The timing of enrollment for many is likely after most spontaneous miscarriages would have occurred, as such, live birth estimates may be overestimated in registries [Howards, 2007].

10.1.4. Birth defects

The prevalence of birth defects (using MACDP definition) reported in the *primary study population* (live birth infants from prospectively enrolled pregnancies) of the BPR is 18% (11/61 95% CI 8.4% - 27.7 %). The wide CIs suggest imprecision in the prevalence estimates and, as such, should be interpreted with caution. Prevalence estimates varied based on available causality information for the defect. If we remove those infants with defects with a known cause or no temporal associations, it will result in a prevalence estimate of 9.8% (6/61). Prevalence estimates also varied based on the defect criteria used with a prevalence of 19.7% (12/61, 95% CI: 9.7% - 29.6%) using MACDP or EUROCAT definitions; a wide confidence interval was also noted in this sensitivity

analysis. No confirmed birth defects were identified in live birth infants within the retrospective reports.

Although the proportion of infants with a major birth defect was higher (18-19.7%) than previously reported for an SLE cohort (3% to 13%) [Barnabe, 2011; Clowse, 2006; Nili, 2013; Zhang, 2012; Vinet, 2012a ; Vinet, 2015; Wallenius, 2014], this estimate should be interpreted with caution as the study did not have sufficient sample size (target sample size: N = 500 pregnancies) to provide estimates with adequate precision. This is evident with the wide CI's provided for the main outcome estimates.

There were 17 defects events among 12 infants using either/or MACDP/EUROCAT (five infants had two defects). However, most infant cases contained factors other than belimumab exposure that can contribute to the presence of birth defects (Juliao, 2022). For example, one pregnancy with an infant case was receiving methotrexate, which has been associated with birth defects [Sammaritano, 2020; Food and Drug Administration (FDA), 2020; Østensen, 2013; Taulaigo, 2021].

Additionally, 10 out of the 17 defect events (58.8%) had other explanatory factors or insufficient data for proper assessment. Seven defects events from four infants were considered to be defects of known cause or no temporal associations (one bilateral club foot, three positional plagiocephaly, and three torticollis events), as these may occur due to mechanical factors during the pregnancy [Moh, 2012; Sharon-Weiner, 2017]. Congenital heart block, which was observed in one infant in this study, is also a defect of known cause as it is associated with SLE and anti-Ro/SSA and anti-La/SBB antibodies [Buyon, 2015; Lateef, 2013], the presence of which had been confirmed in this participant by laboratory testing. One infant case of non-descending testis may not have been exposed to belimumab during the critical window of development. There were missing defect details (e.g., septal size) that are required to properly classify as a major defect for the infant case with ventricular septal defect. Additionally, there is no reason to predict an immunoglobulin G antibody would affect interventricular septum development (which completes by seven weeks in humans) because belimumab is highly specific for BLyS, which binds to receptors primarily localized to B lymphocytes, and because there is very little placental transfer of immunoglobulin G antibodies during the first trimester [Simister, 2003; Dhanantwari, 2009]. Lastly, there was misalignment of defect classifications between MACDP and EUROCAT in five defect events from five infants.

In recent real-world evaluation of 13 patients who received belimumab during pregnancy in Taiwan, 11 resulted in live births and there were no reported fetal anomalies or cases of leukopenia, lymphopenia, neutropenia, or thrombocytopenia [Kao, 2021]. A single episode of omphalitis was reported, but the fetus recovered following treatment. These patients had a median age of 38 and reported a median of two belimumab courses; almost half also had a history of recurrent pregnancy loss [Kao, 2021]. Similarly, no major birth defects were observed in an analysis of 12 live births that resulted from 13 pregnancies in patients with SLE who were exposed to belimumab from across three Italian centers [Crisafulli, 2021]. Additional reports of belimumab exposure during pregnancy have been published as case studies, detailing successful outcomes of three belimumab-exposed pregnancies, with no reported defects [Danve, 2014; Emmi, 2016; Kumthekar, 2017; Chehab, 2019], as well as providing further details on the BPR case with mild Ebstein's

anomaly that was also included in our study [Danve 2014]. From the review of all available data including the BPR, no multiple defects of a common nature or type were identified that would suggest a pattern or common mechanism of birth defects in individuals receiving belimumab.

On 18 April 2023, the Belimumab Scientific Advisory Committee independently reviewed all data reported to the BPR as well as supplemental data and concluded that there are insufficient pregnancy outcomes to ascertain the risks of birth defects and the secondary endpoints of intent for pregnancy exposed to commercially supplied belimumab.

10.1.5. Spontaneous miscarriage and stillbirth (Pregnancy Loss)

Of the 61 prospective pregnancies with known outcomes, pregnancy loss occurred in 6.6% with three miscarriages and one stillbirth (no elective terminations were reported within the prospective cohort). When restricting to pregnancies enrolled prior to 20 weeks' gestation, the fetal loss occurrence rate in the BPR was 3/57 (5.3%; 95%CI 0.0% – 10.9%) (Table 8.01). Of the 11 retrospective pregnancies, 2 reported an elective loss. Pregnancy loss, excluding elective termination, occurred in 40% (4/10); as these were retrospective cases, we could not restrict analysis to enrollment prior to 20 weeks' gestation. The number of fetal losses reported in the BPR is within the range found reported in the literature with the SLE population with estimates among women with SLE ranging from 2.9%-52.6% [Yan, 2008; Clowse, 2013; Park, 2014; Egbe, 2015; Zamani, 2020; Petri, 2023]. Due to low sample size, proportions should be interpreted with caution, especially within the retrospective reports with a cohort size of 11 pregnancies. Additionally, there is also a potential bias in reporting within the retrospective as the cases were enrolled after the outcome was known.

10.1.6. Preterm births

Preterm birth is a common complication in patients with SLE [Bundhun, 2017; Wei, 2017] that occurs more frequently in multiple gestation pregnancies than in singleton pregnancies [Goldenberg, 2008]. In the BPR, 58 prospective participants reported live births, of which 54 were singleton and seven live births were from four sets of twins (Table 4.1). Of these, 42 births were full-term (68.9%) and 19 were preterm (31.1%). Preterm live births occurred in 14 of the 54 singleton pregnancies (25.9%) and five of the seven twin pregnancies (71.4%).

The BPR identified that 19 (31.1%; 95% CI: 19.5% – 42.8%) of 61 live births in the prospective cohort were preterm. This prevalence rate is consistent with results for preterm births reported by other studies in SLE populations (range: 5.1% to 39.4%) Andrade, 2008; Borella, 2014; Bundhun, 2017; Cervera, 2002; Clowse, 2005; Georgiou, 2000; Hwang, 2018; Normand, 2019; Smyth, 2010]. These results also corroborate the findings of a prospective study among 77 women with SLE, which found that maternal flares, among other risk factors, were associated with increased risk of prematurity (odds ratio: 9.18; 95% CI: 1.59 – 53.08; p=0.013) [Hwang, 2018].

These reports are also in line with a meta-analysis of SLE studies, which showed that infants born to mothers with SLE were at significantly higher risk of, among other

outcomes, prematurity (risk ratio: 3.05; 95% CI: 2.56 – 3.63) and congenital anomalies (risk ratio: 2.63, 95% CI: 1.93 – 3.58) as compared with infants born from healthy mothers [Bundhun, 2017]. In summary, data from BPR on both mothers and infants, and the published literature, do not indicate a trend or safety signal with belimumab.

10.1.7. Small-for-gestational-age

Among the 61 live births in the prospective cohort enrolled prior to 20 weeks' gestation, four (6.6%) infants were considered SGA based on INTERGROWTH-21st criteria and 12 (19.7%) infants were considered SGA based on Alexander criteria. The rate of SGA outcomes reported in the BPR was higher based on Alexander criteria and lower based on INTERGROWTH-21st standards when compared with the rate of SGA reported in a study among 385 patients (10%) [Buyon, 2015], but both were similar to or lower than rates found in other published literature. The Hopkins Lupus Pregnancy Cohort prospective follow-up of 257 pregnancies in 197 women with SLE reported that 20% of infants were SGA [Clowse, 2006]. Growth disturbances such as SGA are common neonatal outcomes reported in numerous studies among women with SLE (rates ranging between 20% and 70%) [Barnabe, 2011; Bundhun, 2017; Clowse, 2005; de Jesus, 2017; Nili, 2013; Smyth, 2010].

10.1.8. Serious infections and/or non-serious infection/fevers (clinically significant as per protocol) in infants

Of the overall 61 live birth infants in the prospective cohort, four (6.6%) reported a serious infection during the first year of life (five events); 2 infants at outcome visit and 2 at 12-month visit. Fourteen (23.0%) of the 61 live birth infants reported non-serious infection/fevers (clinically significant per protocol definition) with a total of 16 events; two infants were identified at outcome visit, 7 infants at 4 month, and 6 infants at 12 months.

There is a high degree of variation in the reporting of infant infections rates in the literature, which varies based on age of assessment following birth (e.g., within 30 days, 3 months, 1 year, and 2 years), the definition and severity of the infection, source of data (e.g., physician data vs hospital data, national data vs center data), as well as the presence of other confounding factors such as maternal age, preterm birth, and gestational age.

Infant infection rates are higher among mothers with SLE compared to mothers without SLE [Quan, 2013; Arkema, 2016; Bender, 2018; Gernaat, 2022], most of which has been attributed to preterm birth.

A study examining data from the Swedish birth registers found that 21% of infants born to women with SLE had an infection during their first 12 months of life compared with 14% of infants in the general population [Arkema, 2016]. A US-based study found the risk of any infant infection during the neonatal period (birth to 30 days) was 1.8 times higher in infants born to women with SLE than in infants born to women without SLE [Bender, 2018].

Recent reports of serious/clinically relevant infant infections among mothers with SLE who received belimumab in pregnancy (10.8% – 23.0%) [BPR, Ghalandari, 2023] are similar to rates observed in published studies among women with SLE who did not receive belimumab in pregnancy (3.9% – 47.6%) [Quan, 2013; Bender, 2018; Acevedo, 2017; Gernaat, 2022], (evaluated within 6 months of birth).

10.1.9. Other analyses and adverse events

Breastfeeding. US data show that 83% of mothers initiate breastfeeding, with 69% exclusively breastfeeding at three months [CDC, 2022]. In women with SLE, it has been previously shown that 50% choose to breastfeed, with postpartum lupus disease activity being a significant factor influencing breastfeeding status. Mothers with SLE have also shown decreased breastfeeding duration due to over-inflated perceived risk of medications [Acevedo, 2017], highlighting a need for breastfeeding education. Rates of prospective participants who reported having ever breastfed in BPR were slightly higher compared with rates in previous work, both at four months (n=40; 76.9%) and at 12 months (n=40; 78.4%). However, only 9.6% and 11.8% of participants reported belimumab exposure during breastfeeding at four months and at 12 months, respectively. Duration of breastfeeding was not known in the BPR participants and information on belimumab exposure during breastfeeding were missing for the majority of participants with follow-up visit data, so conclusions cannot be drawn.

Maternal SAEs. In total, 28 maternal SAEs have been reported in 19 participants in the prospective cohort. As was previously reported in patients with SLE, phase II and III clinical studies have shown that rates of SAEs for belimumab patients (18%) were similar to rates for placebo patients (16.6%) [Wallace, 2013]. Importantly, however, this trial was in men and women and did not focus on pregnancy-related outcomes. Additional similar work in men and women, following patients up to seven years of treatment, has highlighted that belimumab is generally well tolerated [Ginzler, 2014]. It has been well documented that the risk of complications in pregnant women with SLE is at least twice as high overall as in healthy women [Nahal, 2018]. Specific complications, including pre-eclampsia, spontaneous miscarriage, and postpartum infection, occur at significantly greater rates in women with SLE (risk ratios: 1.5 - 11.3) as compared with healthy women. Though little previous data had been generated for pregnant women treated with belimumab, preclinical research in cynomolgus monkeys had shown that belimumab was well tolerated at pharmacological doses during pregnancy [Auyeung-Kim, 2009; Ginzler, 2014; Srivastava, 2016]. Similarly, a 2014 case report showed belimumab being well tolerated during pregnancy [Danve, 2014].

Infant SAEs In infants, 46 SAEs had been reported in 26 pregnant individuals who experienced an infant SAE and there were 21 reports (34.4%) of pregnant individuals whose infants experience at least one solicited non-serious AE. Most of the SAEs were congenital anomalies, prematurity, and infections. As was discussed above, infants of mothers with SLE are more likely than infants of mothers without SLE to have congenital anomalies [Barnabe, 2011; Bundhun, 2017; Nili, 2013; Vinet, 2012b; Vinet, 2015], prematurity [Bundhun, 2017; Hwang, 2018; Normand, 2019; Smyth, 2010], and infections [Arkema, 2016; Bender, 2018].

Infant Developmental Milestones. The study design of the BPR allowed for the collection of detailed maternal clinical characteristics across multiple time points during pregnancy and live birth infant outcomes through 1 year of age allowed for the assessment of key maternal and infant health outcomes. As part of the infant follow-up, information on development milestones was also collected for infants through 1 year of age. Where data were available, all full-term infants met the milestones for gross motor, language, cognitive, and social/emotional skills. Only one infant did not meet the milestones for fine motor skills at 12 months. In preterm infants and where data were available, all met their milestones for cognitive and fine motor skills. Milestones were not met in gross motor and language skills for two infants, and in social/emotional skills for one infant. Though the sample size for BPR was small, results suggested that infant development was not affected by maternal exposure to belimumab treatment.

Retrospective reports. Data from retrospective reports were collected separately to provide additional pregnancy outcome pattern, rather than assessing of pregnancy outcome proportions as this cohort would be subject to biases since pregnancy outcome was known prior to enrollment. A total of 11 retrospective pregnancies were enrolled within the BPR of which no confirmed major birth defects were identified in live birth infants as well no serious infections and/or non-serious infection/fevers (clinically significant per protocol) during infant one year follow-up. Pregnancy loss, excluding elective termination, occurred in 40% (4/10) of pregnancies; as these were retrospective cases, it was not feasible to restrict analysis to enrollment prior to 20 weeks' gestation. The number of fetal losses reported in the retrospective cases is within the range reported in the literature with the SLE population with estimates among women with SLE ranging from 2.9% to 52.6% [Yan, 2008; Clowse, 2013; Park, 2014; Egbe, 2015; Zamani, 2020; Petri, 2023]. Due to extremely low sample size and the presence of selection and recall biases, results should be interpreted with caution.

10.2. Limitations

The sample size of 500 prospective pregnancies with a known outcome, only 61 were enrolled in the study. Despite multiple awareness efforts to enroll patients into the BPR, enrollment target was not achieved, and the registry was terminated early due to low enrollment. In 10 years (since 2012 to 2022), 72 evaluable pregnant women had enrolled out of the original target of 500. This represents an average enrollment rate of seven evaluable participants per year and none enrolled into the unexposed external comparator group, resulting in an insufficient sample size to allow for any meaningful conclusions to be drawn. Based on the yearly enrollment rate (Figure 1), the study as it was designed would need to be extended for 20 or more years to meet the targeted sample size. Coupled with the lack of enrollment of unexposed SLE pregnancies and lack of an internal comparison group design, the BPR cannot provide either timely or clinically meaningful information to healthcare providers and patients.

Despite numerous awareness activities throughout the duration of the BPR, in addition to approvals for new formulation and efforts to recruit participants into the BPR from 11 countries, enrollment target was not met (Figure 1 in Appendix B). No women with SLE who were unexposed to belimumab were recruited into the BPR from the SABLE protocol. Recruitment in pregnancy registries, particularly in the enrollment of pregnant

women early in pregnancy, is known to be challenging. This could be due to the voluntary enrollment of the BPR and pregnant women or women of reproductive age who are planning a pregnancy may not be prescribed or are reluctant to use some medications; thereby, BPR participants may not be representative of the overall SLE pregnant population. Even with having more than half of the participants in the prospective cohort enrolled in the BPR during the first trimester of pregnancy, potential bias due to left truncation may exist.

Although numerous efforts were made to recruit and enroll belimumab-exposed pregnant women with SLE, the BPR was designed as an exposure-only registry without a comparator group of unexposed pregnant participants with SLE. The lack of a comparator group was an added limitation; no women with SLE who were unexposed to belimumab was recruited into the BPR from the SABLE protocol.

The design of the BPR allowed for the collection of maternal and infant health and health outcome data across multiple time points. However, the reporting of pregnancies and other maternal and infant data was voluntary and based on the reporting from HCPs, it is possible that recall bias exists. The BPR did not access medical records for its participants unless considered appropriate during targeted follow-up of specific events. Per protocol and as appropriate, multiple contact attempts with the HCP were made by the BPR team at each follow-up time point for each participant. Missing data in key parameters such as SLE disease severity and SLE laboratory test results was an additional limitation to allow for a complete evaluation of clinically relevant metrics in relation to maternal belimumab exposure and maternal and infant health outcomes.

10.3. Interpretation of results

In summary, considering the limitations associated with the BPR, it was not possible to draw conclusions about any relationship between belimumab exposure and major birth defects using these data alone. However, the BPR did not identify any pattern of defects that would suggest an unusual cluster or plausible drug-induced mechanism of birth defects in individuals receiving belimumab within the data reported here or when observed in the wider context of limited case reports.

In regard to the prevalence of other pregnancy and infant outcomes of interest (live births, spontaneous miscarriages, preterm births, serious infant infections) align with published rates of these outcomes in pregnant women with SLE; however, due to the low number of outcomes accumulated in BPR to date, data should be interpreted with caution.

10.4. Generalizability

Although data from the BPR are limited to due small sample size, the information collected adds to the body of existing literature on belimumab use at preconception and during pregnancy, and on maternal and infant health and health outcomes. Given the inherent limitation of small sample size and the exposure-only design, participants in the BPR may not be representative of pregnant women with SLE in the general population; thereby, limiting the generalizability of the study results.

11. OTHER INFORMATION

None.

12. CONCLUSIONS

On 18 April 2023, the Belimumab Scientific Advisory Committee independently reviewed all data reported to the BPR as well as supplemental data and concluded that there are insufficient pregnancy outcomes to ascertain the risks of birth defects and the secondary endpoints of intent for pregnancy exposed to commercially supplied belimumab.

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14. APPENDICES

14.1. Appendix A: Glossary of Terms (Per Protocol and RAP)

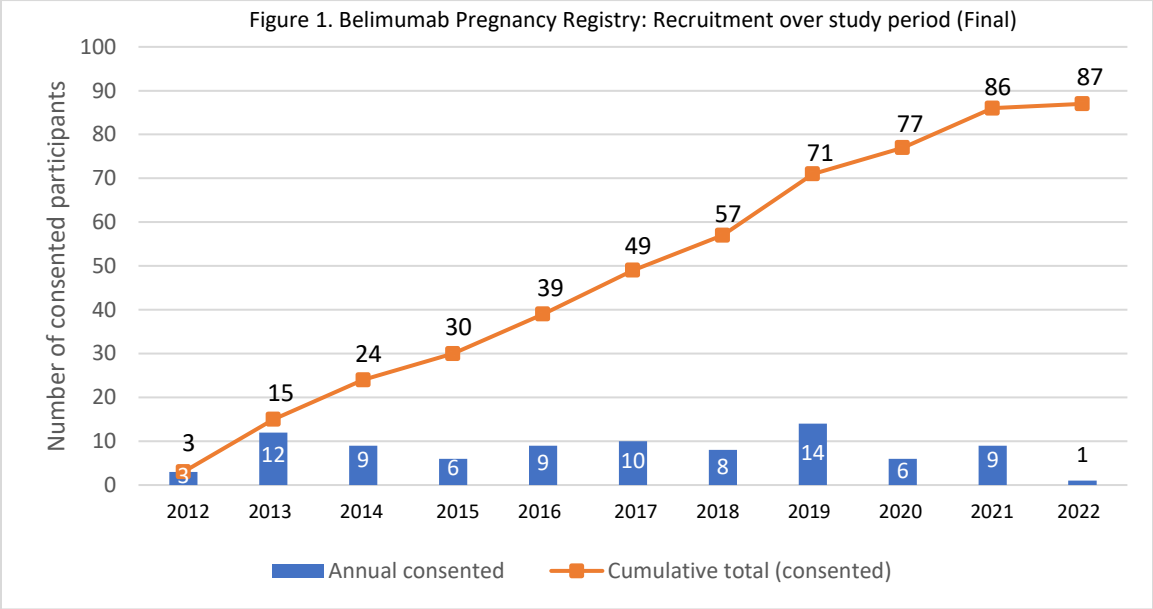
Term	Registry Definition
Birth Defect Evaluator (BDE)	The BDE is an expert in teratology and reviewed, evaluated, and classified all birth defects reported in the Registry. In addition, the BDE provided an opinion regarding the possible temporal association of the belimumab exposure or other SLE treatment exposure to the development of observed defects.
Evaluable participant	A participant was considered evaluable if they had confirmed exposure to commercial belimumab within the four months preconception and/or during pregnancy and that were confirmed pregnant by any HCP, as well as unexposed participants from SABLE with confirmation of pregnancy. In addition, if lost to follow-up prior to outcome was identified, the patient was not evaluable.
Traditional prospective report	Traditional prospective reports of pregnancy included all women who enrolled in the BPR before the end of pregnancy (live birth, fetal loss, etc.), regardless of known normal or abnormal prenatal test results, or if prenatal testing was not known.[1]
Pure prospective report	Pure prospective reports of pregnancy included all women who enrolled in the BPR before the end of the pregnancy for which (a) the enrollee did not know at the time of enrollment whether the fetus had a malformation, and (b) no prenatal testing was completed prior to enrollment[1]
Retrospective report	Retrospective reports of pregnancy were those in which the pregnancy ended before enrollment or at the time of first contact with the registry.

[1]Minor updates to text from RAP to final report to improve clarity. See footnote of Table D in Section 7.8.4

Abbreviations; BDE = birth defect evaluator; BPR = Belimumab Pregnancy Registry; HCP = healthcare provider; RAP = reporting and analysis plan; SABLE = Safety and Effectiveness of Belimumab in Systemic Lupus Erythematosus; SLE = systemic lupus erythematosus

14.2. Appendix B: Additional Figures – All Registry Participants

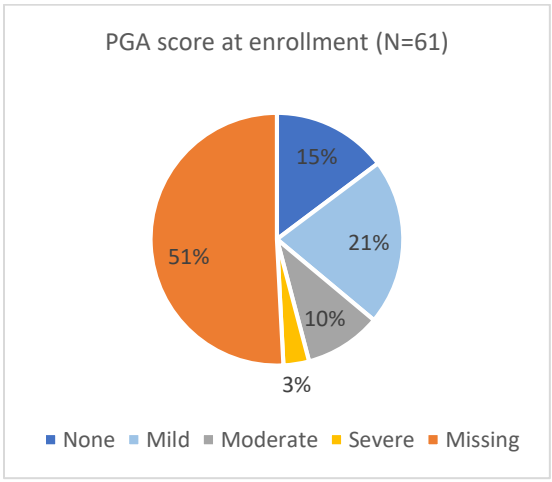
Figure 1. Belimumab Pregnancy Registry: Recruitment over Study Period (Final)

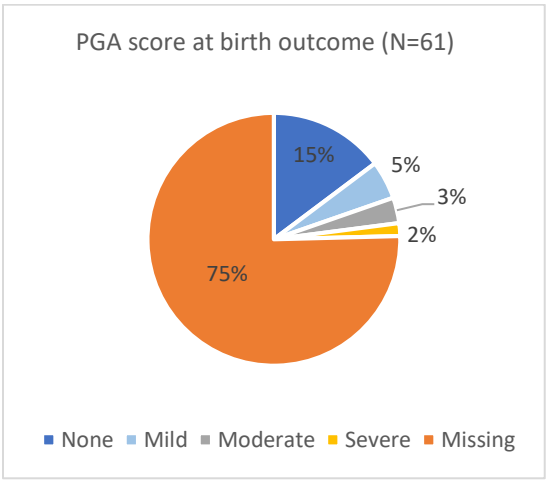


Note: Numbers reflect all consented participants and were further classified as evaluable (n=61 in the prospective cohort and n=11 in the retrospective cohort) and unevaluable (n=15). Refer to Figure A for more details.

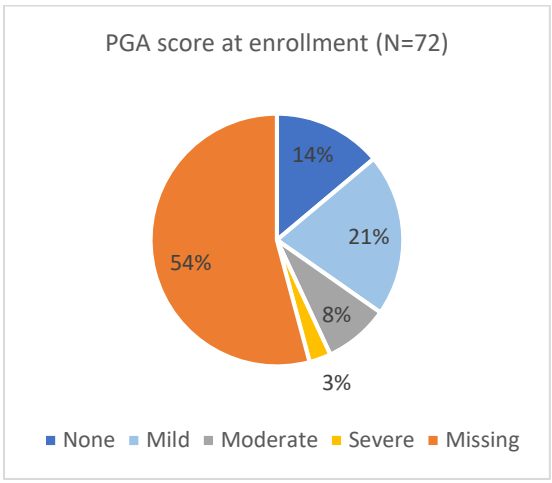
Figure 2. Distribution of PGA at Enrollment and at Pregnancy Outcome (n=61) for Evaluable Pregnant Individuals with Confirmed Pregnancy Outcomes in Prospective Cohort (n=61) and in all Cohorts (n=72)

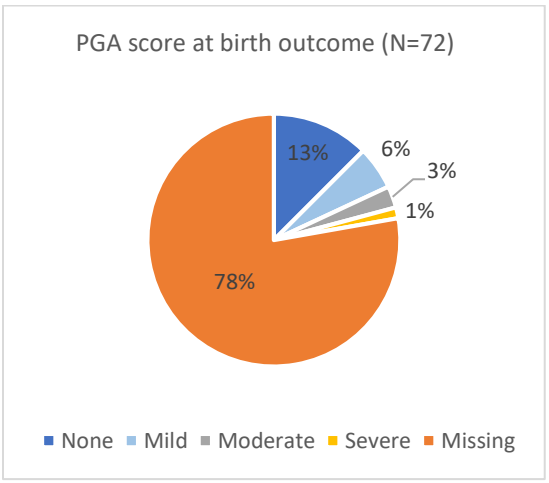
Evaluable pregnant individuals with confirmed pregnancy outcomes in prospective cohort (n=61)





Evaluable individuals with confirmed pregnancy outcomes in all cohorts (n=72)





Abbreviation: PGA = Physician Global Assessment

14.3. Appendix C: Awareness Activities

Overview of Recruitment Activities into the Pregnancy Registry

The BPR attempted to collect data on women who had been exposed to commercially prescribed BENLYSTA; therefore, the registry was not set up like a clinical research trial with study sites. Our expectation was that pregnant patients would seek care from their regular health care provider; therefore, most awareness was physician focused.

In Europe, pre-identified principal investigators in each country were responsible for registry awareness. Key awareness activities included distributing brochures to HCPs and lupus clinics, attending medical meetings, contacting fellow rheumatologists, presenting at educational seminars, providing BPR information in hospital newsletters, discussing BPR with local lupus community groups and attending conferences. Conferences included ACR, European Alliance of Associations for Rheumatology, Rheumatology Conference Austria, Prague, Bilbano and Zaragoza Spain, Focus OGR Jahrestagung, European Rheumatology Congress, Pregnancy Conference in Norway, Lupus Academy Conference, Lupus Congress in Greece and Paris, Spring Rheumatology Meeting in Slovakia, Congress of Rheumatology in Czech Republic, National Rheumatology Conference in Spain, Scandinavian SLE conference, American Society of Rheumatologists, Central European Congress of Rheumatology Congress of Rheumatology Austria, International Lupus Meeting Austria, the Inbar Conference in Israel, Reproduction, National/Rheumatologist Congress in Portugal, Congress of Internists in Rheinland Westphalia, Gynecologists and Immunologists Conference, Pregnancy and Autoimmune Conference, and Pregnancy and Rheumatic Disease Conference in Bern, Switzerland.

GSK had undertaken a significant level of awareness and other activities to optimize the level of recruitment as described below:

- The registry and contact information were announced in the prescribing information documents (HCP and patient) and product websites (US package insert and Daily Med).
- Free phone access was provided to the BPR Registry Coordinating Center in all North American and European countries, in operation since September 2011, which was prior to the registry officially opening in each country.
- The BPR Coordinating Center staff were trained to address patient questions, provide an overview of the study objectives, and register interested/potentially eligible patients.
- BPR contact information was included on BENLYSTA Consumer webpage.
- Targeted distribution of awareness materials was sent to HCPs who had referred patients to the GSK US gateway payer assistance hub.
- HCP and patient brochure (combined where permissible by country/local laws) had been in place since October 2011 and included in the Western IRB applications (US and Canada boards) and country-specific EC applications.

- A dedicated website was created to provide BPR information to HCPs and patients: www.bprgsk.com and included contact information and downloadable information about the BPR (brochure, Participant Consent to Contact Card, Registration Form, etc.).
- The BPR was listed on the GSK Pregnancy Registry website (www.pregnancyregistry.gsk.com) and included recruitment information.
- BPR information was available via internet search engines (i.e., Google) and other online media since November 2011.
- Non-branded banner and online media advertisements appeared on relevant websites (i.e., Association of Women's Health, Obstetric and Neonatal Nurses, Alliance for Lupus Research, Reprotox).
- BPR information was included on the US lupus advocacy's group Alliance for Lupus Research website (http://www.lupusresearch.org), including their clinical trials website Lupustrials.org.
- BPR received referral from calls made to the hotlines for the Organization of Teratology Information of Specialists (OTIS) and Motherisk (Canada). OTIS was retained in May 2019 and belimumab fact sheets were published in English and Spanish.
- BPR information was on the ACR website (http://www.rheumatology.org/I-Am-A/Rheumatologist/Research/Clinical-Trials/Share-My-Clinical-Trials).
- GSK had utilized advisory boards and steering committees in part to increase awareness about the BPR among physician networks including the SLE International Coordinating Clinics and Canadian Perinatal Network. The BPR Steering Committee was set up in January 2012, with a SAC comprised of rheumatology, obstetrical, and pediatric infectious disease specialists with epidemiologist and pregnancy registry expertise.
- GSK staff had attended numerous international conferences to share BPR information. The BPR had been presented as a scientific abstract/poster, tabletop exhibit or part of a "trials in progress" booth at several scientific congresses.
- Targeted awareness of the BPR had been implemented through mass mailing activities to prescribing HCPs and investigators taking part in the SABLE protocol.
- Bi-annually, prescribing HCPs were identified using a patient data provider called TriNetX. Awareness materials were sent to the sites that prescribed belimumab to female patients.
- The SABLE study quarterly newsletter included an advert for the BPR.
- GSK Medical Science Liaison personnel had been trained in the BPR so they can raise awareness during meetings with HCPs.
- Refresher training was provided to GSK Medical, Safety, and Clinical Operations Staff in local operating countries.

- Brochures were distributed to the Lupus Foundation of America, North Carolina Chapter.
- Crowdsourcing projects using Amazon Turk (female lupus patients of childbearing age) and SERMO (Rheumatologist and Obstetricians) have assessed awareness of the BPR, willingness to refer to the BPR, and barriers to enrollment.

14.4. Appendix D: Major Birth Defect Case Summary Reports

Table F below provides a summary for all 12 infant cases with a major birth defect event using either/or MACDP/ EUROCAT criteria (17 defect events) within the BPR (114256). Details for each infant/pregnancy and defect are also included within the table including belimumab exposure, concomitant medication, Physician's Global Assessment (PGA) of SLE disease activity, maternal comorbidities, maternal autoantibody status, the outcome of prenatal testing and other confounding factors are presented on an individual level. Where available, national-level, population estimates of background rates of congenital anomalies are presented with US-based estimates from the National Birth Defects Prevention Network, 2010-2014 [Mai, 2019] and European estimates from the EUROCAT Network, 2011-2020 [EUROCAT, 2023].

Table F Summary Table for All 12 Infant Cases of Birth Defects

	BPR
Case 1	US0011/ Bilateral Club Foot
Maternal age	36 years-old
Belimumab exposure (timing of dose)	Preconception (approximately 2 months) to 1 2/7 weeks gestation
Concomitant medication (timing of dose)	Preconception and all trimesters: Prednisone (6 months preconception), Plaquenil (hydroxychloroquine sulfate) All trimesters: Folate started at 8 weeks At least during 1st trimester (2nd & 3rd trimester exposure unknown): Hydrocodone Unknown timing: pre-natal vitamin
PGA of SLE disease activity	Moderate (15 weeks), Not provided (1st or 3rd trimester)
Maternal comorbidities/ Events	Preconception: Renal tubular acidosis, nephrolithiasis (preconception and unknown Preconception and during pregnancy: Nephrolithiasis (unknown timing during pregnancy) All trimesters: Tobacco user 1st and 2nd trimesters: moderate SLE activity
Maternal autoantibody tests	~12 years preconception: Anti-Ro and/or Anti-La positive ~5 years preconception: Anti-ds DNA + ~1 year preconception: Anti-ds DNA negative
Prenatal tests	Unknown dates: Anti-cardiolipin antibodies negative Prenatal ultrasounds: 12-32 weeks – bilateral club foot Echo: 36 weeks – negative Maternal labs Proteinuria: preconception to 26 weeks – normal SCr: 4 months preconception – 0.5; 38 weeks – 0.6
Post-delivery tests (Neonatal)	None provided

	BPR
Gestation Age at delivery/ / Route of delivery	383/7 weeks/ Caesarean
Gender of neonate/ Birth weight/ Apgar	Male/ 2950 grams
Age at time of congenital anomaly diagnosis	12 3/7 weeks gestation
Treatment of congenital anomaly	Weekly casting from birth until surgical repair at 2 months of age followed by braces. Infant to wear braces until walking.
Status of congenital anomaly	13 months postpartum: Recovering, infant not walking
Defect Classification (per Birth Defect Evaluator)	MACDP – defect EUROCAT – defect
Defect Classification (per GSK Pregnancy Outcomes Panel)	MACDP – defect EUROCAT – Conditional: Yes because surgery required
Confounding factors (per Birth Defect Evaluator)	Cigarette smoker (70 per week reported), Other maternal medications (Prednisone, Plaquenil), Advanced Maternal Age, SLE
Etiology/Comments (per Birth Defect Evaluator)	Club foot considered a deformation rather than a malformation due to trapping the foot (feet) in the uterus which can be due to low amniotic fluid volume (no report of oligohydramnios) resulting in the altered shape. Etiology was unknown, however, defect known to be more common in males. An association with smoking has been made. If one parent has clubfoot more likely child will also. Incidence approximately 1/1000.
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	Confounders: Smoker (70 cigs/day); advanced maternal age; steroid use; moderate disease activity. EUROCAT: Excluded as major congenital anomaly where there is no further specification of whether malformation or postural origin
Other Details	Previous maternal pregnancy history: G3P2002. 12 months postpartum: Infant meeting all developmental milestones.
Background rate of anomaly	US data: 16.87 per 10,000 live births (95% 16.46-17.30) [Mai 2019] Europe data: 9.42 per 10,000 live births (95%CI 9.20-9.64) [EUROCAT 2023]
Case 2	DE0002/ non-descending Testis (Left)
Maternal age	38 years-old
Belimumab exposure (timing of dose)	Preconception (> 6 months) to 1 2/7 weeks gestation
Concomitant medication (timing of dose)	Preconception only: Azathioprine (6 years to 2.5 years preconception)

	BPR
PGA of SLE disease activity	Preconception and all trimesters: Cyclosporin started 5 years preconception, Quensyl (hydroxychloroquine sulfate) started 6 years preconception 1st to 3rd trimester: Folate (started at 4 weeks), DeCartin (prednisone) 3 mg (6 months preconception and ongoing)
Maternal comorbidities/ Events	Not provided (1st trimester), Mild (19 weeks), None (30 weeks, 1 week post-delivery) Preconception (at least): Thrombocytopenia (platelets normal at 27 weeks and outcome), severe lupus flare requiring pulse steroids, smoker (stopped 6 years prior to pregnancy) Prior to conception and 1st trimester: proteinuria requiring treatment 2nd Trimester: lupus flare requiring pulse steroids, mild SLE activity Unknown timing: HPV infection
Maternal autoantibody tests	3 weeks to 34 weeks gestation: anti-ds DNA + Unknown dates: anti-cardiolipin antibody positive (IgG positive, IgM negative, IgA unknown); lupus anticoagulant negative; Anti-Ro negative; anti-La negative
Prenatal tests	Prenatal ultrasounds: 14-39 weeks – no fetal abnormalities
Post-delivery tests (Neonatal)	Maternal labs SCr: 25 weeks and pregnancy outcome (weeks not provided) – normal Platelets: 27 weeks and pregnancy outcome (weeks not provided) – normal Proteinuria: 25 weeks and pregnancy outcome (weeks not provided) – normal
Gestation Age at delivery/ Route of delivery	None provided
Gender of neonate/ Birth weight/Apgar	40 4/7 weeks/ Vacuum pump assistance
Age at time of congenital anomaly diagnosis	Male/ 3130 grams/ Not provided
Treatment of congenital anomaly	2 days post-delivery
Status of congenital anomaly	Orchidopexy left side surgical repair
Defect Classification (per Birth Defect Evaluator)	12.5 months post-delivery: Resolved MACDP – defect EUROCAT – not a defect
Defect Classification (per GSK Pregnancy Outcomes Panel)	MACDP – defect, but exposure outside of critical window for causality EUROCAT – not a defect
Confounding factors (per Birth Defect Evaluator)	Azathioprine (discontinued 2.5 years preconception), Quensyl, Tobacco use (stopped 6 years preconception)

	BPR
Etiology/Comments (per Birth Defect Evaluator)	Isolated undescended testicle should be reported as a minor anomaly under EUROCAT Guidelines. MACDP - is dependent upon multiple factors for reporting including the need for surgical repair. Reportable because of surgical intervention which was successful.
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	Exposure timing does not match up (descent occurs late in pregnancy or after birth). Confounders: Steroid use; lupus flare requiring pulse steroids in 2nd trimester of pregnancy; MACDP: If > 36 weeks at birth, code only if a medical or surgical intervention was done. EUROCAT: Not coded as a major congenital anomaly.
Other Details	Maternal American College of Rheumatology (ACR) criteria included photosensitivity, renal disorder, hematologic disorder, immunologic disorder, and antinuclear antibodies. 12 months postpartum – infant meeting all developmental milestones.
Background rate of anomaly	1% to 4% in full-term newborns and in up to 45% of preterm male babies (based on systematic literature review [Sijstermans, 2008])
Case 3	US0005/ Mild Ebstein's anomaly
Maternal age	37 years-old
Belimumab exposure (timing of dose)	Preconception (approximately 1.5 years) to post conception
Concomitant medication (timing of dose)	Weeks of exposure not available Preconception only: Warfarin (unknown timing), Lisinopril (5 years to 4 months preconception) Preconception to at least the 2nd trimester (3rd trimester exposure unknown): Lovenox (enoxaparin sodium), Tylenol (paracetamol) and Benadryl (diphenhydramine) as premedication for belimumab Preconception and all trimesters: Plaquenil (hydroxychloroquine sulfate), Synthroid (levothyroxine), Deltasone (Prednisone) started 3 years preconception, Aspirin 81 mg, heparin All trimesters: Iron supplement At least during 3rd trimester (1st & 2nd trimester exposure unknown): Colace
Physician's Global Assessment (PGA) of SLE disease activity	Mild (within 6 months preconception, 13 weeks, 30 weeks, 2 weeks post-delivery)
Maternal comorbidities/ Events	Preconception: Thrombotic event and severe lupus flare requiring pulse steroids, leukopenia/neutropenia (started 10 years prior to conception, unknown if continued into pregnancy), aspartate aminotransferase and alanine aminotransferase increased (started several months prior to conception), thrombocytopenia (not within 6 months preconception or during pregnancy) Preconception and all trimesters: Hypothyroidism, proteinuria (reported as within 6 months preconception and throughout pregnancy; however conflicting labs provided – see Prenatal tests below)
Maternal autoantibody tests	Unknown timing: Lupus nephritis, antiphospholipid syndrome, pancytopenia ~5 years preconception: Anti-Ro +; Anti-La negative

	BPR
Prenatal tests	~1.5 years preconception: anti-dsDNA +, IgG, IgA or IgM one or more positive 2 months preconception and 8 weeks gestation: Anti-ds DNA negative 15 weeks gestation: IgG and IgM negative per Obstetrical (OB) Nurse and IgG, IgA or IgM one or more positive per Prescriber 17 weeks gestation: Anti-ds DNA negative 26 weeks gestation: Anti-ds DNA + per OB nurse and negative per Prescriber 35 weeks gestation: Anti-ds DNA + Unknown dates: ANA + Prenatal ultrasounds/sequential screen: 7-36 weeks – no fetal abnormality Fetal echocardiograms: 15 and 17 weeks – negative Echo: Unknown date – tricuspid regurgitation and fetal arrythmia
Post-delivery tests (Neonatal)	Maternal labs Proteinuria: 1 month preconception to 15 weeks – normal; 17 weeks – noted as both normal and abnormal (trace protein); 19 weeks – normal; 22 weeks – abnormal; 23 to 36 weeks – normal Urine protein/creatinine ratio (mg/mg): 6 to 15 weeks – 0.14 to 0.25 17 weeks - 0.19; 19 weeks - 0.27; 22 weeks - 0.30; 25 weeks - 0.22 Platelets: 3 days post LMP - 172,000; 25 weeks - 149,000 SCr: 0 weeks - 0.7; 24 weeks - 0.6
Gestation Age at delivery/ Route of delivery	Echocardiogram: 1 day post-delivery – mild to moderate tricuspid valve regurgitation with possible mild Ebstein's Abnormality, Patent Ductus Arteriosus (PDA) and patent foramen ovale (PFO). Echo: 2.5 months post-delivery – minimal displacement of septal leaflet of tricuspid valve. Diagnosed with mild Ebstein anomaly of tricuspid valve. Tricuspid valve functioning normally.
Gender of neonate/ Birth weight/ Apgar	366/7 weeks/ Caesarean
Age at time of congenital anomaly diagnosis	Female/ 2680 grams/ Not provided
Treatment of congenital anomaly	1 day post-delivery
Status of congenital anomaly	Not reported
Defect Classification (per Birth Defect Evaluator)	2-years postpartum: Continuing, no murmur and condition not causing problems
Defect Classification (per GSK Pregnancy Outcomes Panel)	MACDP – defect; EUROCAT - defect
Confounding factors (per Birth Defect Evaluator)	MACDP – defect; EUROCAT - defect
Etiology/Comments (per Birth Defect Evaluator)	

	BPR
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary Other Details Background rate of anomaly	Maternal Age (37), Maternal SLE, Maternal Lupus Nephritis, Maternal Antiphospholipid Syndrome, Prednisone Very mild functional cardiac defect with follow up in 2 years. No genetic screening testing performed for cardiac transcription factor NKX2.5 mutations, 10p13p14 deletion or 1p34-3-36.11 deletion. The genetic evaluation is not essential at this moment to the health of the child. However, the genetics is a possible etiology for understanding the defects. Prednisone, maternal age or autoimmune disease have not been associated with Ebstein anomaly as has lithium therapy. The defect is mild and should not impair function according to the cardiologist caring for the child. Confounders: concomitant medications; Advanced Maternal Age; Lupus Nephritis; Family history of sibling with extrarenal pelvis, mother with unspecified thromboembolic event raising consideration for tricuspid valve etiology 12 months postpartum: Infant meeting all developmental milestones US data: 0.77 per 10,000 live births (95%CI 0.69-0.85) [Mai 2019] Europe data: 0.39 per 10,000 live births (95%CI 0.35 - 0.44) [EUROCAT 2023]
Case 4 Maternal age Belimumab exposure (timing of dose) Concomitant medication (timing of dose) PGA of SLE disease activity Maternal comorbidities/ Events Maternal autoantibody tests Prenatal tests	**US0014/ Heart Block** 29 years-old Preconception (1 year) to $2^{2/7}$ weeks gestation **Preconception to 2nd trimester:** Prednisone (until 26 weeks) **Preconception and all trimesters:** Imuran (Azathrioprine) started 4 months preconception, Plaquenil (hydroxychloroquine) started 14 months preconception **1st to 3rd trimester:** folate started at 13 weeks; vitamin D, vitamin C and iron all started at 11 weeks, Prenatal vitamin started at 9 weeks **2nd and 3rd trimester:** Dexamethasone since 26 weeks **Day of delivery:** Motrin Not provided **3rd trimester:** hypertension **Unknown timing:** obesity 1 year preconception: Anti-cardiolipin antibodies IgG and IgA +; Anti-Ro and Anti-La +; Anti-ds DNA + ~23-27 weeks gestation: Anti-ds DNA negative 22 days post-conception: Anti-Ro highly +; Anti- La highly + Prenatal ultrasounds: 9 to 22 weeks – no fetal abnormality; 27 weeks – fetal arrhythmia, fetal complete heart blocks Echocardiogram: 26 weeks – heart block: possible 2 to 1 – ventricular rate was 1/2 the atrial rate. Ultrasound and echo with doppler: 30 to 38 weeks – heart block <u>Maternal labs</u> SCr: 36 weeks – 0.5 mg/dL

	BPR
Post-delivery tests (Neonatal)	Proteinuria: 36 weeks – normal Electrocardiogram (ECG): 3 days post-delivery – congenital heart block. Heart rate was 90 beats/minute
Gestation Age at delivery/ Route of delivery	$39^{1/7}$ weeks/ Caesarean
Gender of neonate/ Birth weight/ Apgar	Male/ 2449 grams/ Not provided
Age at time of congenital anomaly diagnosis	26 $^{1/7}$ weeks gestation
Treatment of congenital anomaly	Treatment: Dexamethasone and IVIG in utero
Status of congenital anomaly	4 months post-delivery: No report of continuation of heart block by Cardiologist
Defect Classification (per Birth Defect Evaluator)	MACDP – defect EUROCAT – not a defect
Defect Classification (per GSK Pregnancy Outcomes Panel)	MACDP – known alternative cause EUROCAT – known alternative cause
Confounding factors (per Birth Defect Evaluator)	Azathioprine, Plaquenil, Prednisone
Etiology/Comments (per Birth Defect Evaluator)	Fetal congenital heart block is associated with autoimmune disease itself. Babies at high risk for morbidity and mortality. Treatment adrenocorticosteroids is standard for reduction of inflammatory insult. Patient had prednisone. One etiology is IgG antibodies against Ro and La intracellular ribonuclear proteins are transported across the placenta and bind to specific cells of the fetal conduction system. It should be noted that mother did test positive for anti-Ro and anti-La antibodies strengthening the association of heart block with autoimmune disease. Azathioprine – no reports of fetal heart block. Only one report of ASD among many studies. Could be by chance. Plaquenil – no studies of heart block
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	Other more likely established cause is the presence of anti-Ro/anti-La antibodies (highly positive). Confounders: Steroid
Other Details	
Background rate of anomaly	12 months postpartum: Infant meeting all developmental milestones Autoimmune CHB occurs nearly exclusively in infants whose mothers have autoantibodies to Ro/SSA, most frequently in conjunction with La/SSB. No US/European estimates are available, but incidence has been estimated at 1 in 15,000 live births in Finland and the incidence of autoantibody related

	BPR
	CHB in Stockholm County was approximately 1 in 23,300 live births [Wainwright, 2019]
Case 5	**US0016/ Small Ventricular Septal Defect and Hydronephrosis (left side)**
Maternal age	32 years-old
Belimumab exposure (timing of dose)	Preconception (~3.5 months) to $1^{3/7}$ weeks
Concomitant medication (timing of dose)	**Preconception:** NSAIDS preconception (stop date not provided) **Preconception and all trimesters:** Deltasone (prednisone) (3.5months preconception), anti-malarial (4 years preconception), folic with prenatal vitamin (1 month preconception) **1st trimester to outcome:** Heparin (13 weeks to outcome), aspirin (5 to 14 weeks and 22 weeks to outcome), **2nd trimester to outcome:** Prednisone (22 weeks to outcome)
PGA of SLE disease activity	None (15 weeks, 2.5 months post-delivery), Not provided (1st trimester)
Maternal comorbidities/ Events	**Preconception:** Thrombocytopenia **1st trimester:** Bladder infection (5-7 weeks), irritable bowel syndrome (5-7 weeks)
Maternal autoantibody tests	Anti-Cardiolipin Antibodies, Lupus Anticoagulant, Anti-Ro or Anti-La never noted to be positive during the pregnancy. Lupus Anticoagulant was positive in 2008. 36 weeks gestation – Anti-Ro and Anti-La negative
Prenatal tests	Prenatal Ultrasounds: 6 weeks to 34 weeks – no fetal abnormality, 34 weeks – 11.4 mm left renal pelvis 35 weeks -11.3 mm left renal pelvis, 37 weeks – 12 mm left renal pylectasis, $37^{2/7}$ weeks – no fetal abnormality <u>Maternal labs</u> Proteinuria: 37 weeks – normal
Post-delivery tests (Neonatal)	Echo: Unknown date – small VSD, 1-year post-delivery – normal Renal sonogram: 15 months post-delivery – normal
Gestation Age at delivery/ Route of delivery	$37^{5/7}$ weeks/ Caesarean
Gender of neonate/ Birth weight/ Apgar	Male/ 2381 grams/ Not provided
Age at time of congenital anomaly diagnosis	0 days post-partum
Treatment of congenital anomaly	Not reported
Status of congenital anomaly	12 months post-delivery: VSD resolved 15 months post-delivery: Hydronephrosis resolved

	BPR
Defect Classification (per Birth Defect Evaluator)	MACDP: VSD – defect; Hydronephrosis – defect EUROCAT: VSD – defect; Hydronephrosis – defect
Defect Classification (per GSK Pregnancy Outcomes Panel)	MACDP: VSD – defect; Hydronephrosis – not a defect EUROCAT: VSD – defect; Hydronephrosis – not a defect
Confounding factors (per Birth Defect Evaluator)	Maternal medications (heparin, aspirin, prednisone, Deltasone, anti-malarial), lupus anticoagulant positive (6 years preconception)
Etiology/Comments (per Birth Defect Evaluator)	VSD incidence in approximately 2 per 1000 live births (more common in premature infants). A number of small VSDs naturally close within the first 6 months to 1 year without incident. No further neonatal symptoms reported. Autoantibody screening negative.
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	Echo after birth (unknown timing) showed a "small" VSD and echo at 1 year of ago was normal. Confounders: Steroid use. History of lupus anticoagulant positive status. MACDP: If hydronephrosis is diagnosed or suspected on a prenatal U/S and a renal U/S is done after the 2nd week of life and is normal, do not code hydronephrosis. EUROCAT: Pyelecaliectasis/ hydronephrosis documented to be <10mm considered minor anomaly.
Other Details	VSD described as "a tiny atypical VSD" and muscular. 12 months postpartum: Infant meeting all developmental milestones
Background rate of anomaly	VSD: US data: 41.8 per 10,000 live births (prevalence from Metropolitan Atlanta, 1998–2005) [Reller, 2008] European data: 35.94 per 10,000 live births (95%CI 35.51-36.37) [EUROCAT, 2023] Congenital hydronephrosis: US data: Hydronephrosis found in up to 1 in 100 live births in the US [Thotakura, 2023] European data: 13.80 per 10,000 live births (95%CI 13.53-14.07 – 14.36) [EUROCAT 2023]
Case 6	**US0023/ Low lying conus medullaris and Pelviectasis**
Maternal age	36 years-old
Belimumab exposure (timing of dose)	Preconception (3 months) to $2^{5/7}$ weeks
Concomitant medication (timing of dose)	**Preconception and 1st trimester:** Methotrexate (until between 1-5 weeks) **Preconception and all trimesters:** Hydroxychloroquine, corticosteroids for SLE, folate, unspecified epilepsy medication **2nd trimester** (1st & 3rd trimester exposure unknown)**:** Prenatal Vitamins, stool softener **Unknown timing:** Penicillin, Xanax, Vyvanse, Nicoderm Patch
PGA of SLE disease activity	Moderate (within 6 months preconception), Mild (18 weeks), Not reported (1st and 3rd trimesters)
Maternal comorbidities/ Events	**Preconception and throughout pregnancy:** neurological manifestations of lupus (i.e., psychosis, seizures), epilepsy **Preconception and during pregnancy (unknown timing):** Tobacco user

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	During pregnancy (unknown timing): drug abuser (heroin)
Maternal autoantibody tests	3 months preconception: Anti-ds DNA negative
Prenatal tests	Maternal serum alpha-fetoprotein (MSAFP): 18 weeks – no abnormality Prenatal Ultrasounds: 10 to 25 weeks – no abnormality <u>Maternal labs</u> Toxicology screen: Unknown date – negative Proteinuria: 3 months preconception – normal SCr: 3 months preconception – 0.7
Post-delivery tests (Neonatal)	Renal U/S: 7 months post-delivery – resolution of left pelviectasis
Gestation Age at delivery/ Route of delivery	$38^{4/7}$ weeks/ Vaginal
Gender of neonate/ Birth weight/ Apgars	Male/ 2777 grams/ 8-9
Age at time of congenital anomaly diagnosis	2 days post-delivery (low lying conus medullaris), 3 days post-delivery (pelviectasis)
Treatment of congenital anomaly	Not reported
Status of congenital anomaly	7 months post-delivery: Left pelviectasis resolved Low lying conus medullaris: Outcome unknown
Defect Classification (per Birth Defect Evaluator)	MACDP: Low lying conus medullaris – defect; Pelviectasis – defect EUROCAT: Low lying conus medullaris – defect; Pelviectasis – not a defect
Defect Classification (per GSK Pregnancy Outcomes Panel)	MACDP: Low lying conus medullaris – not a defect; Pelviectasis – Conditional: No EUROCAT: Low lying conus medullaris – not a defect; Pelviectasis – Conditional: Maybe
Confounding factors (per Birth Defect Evaluator)	Maternal lupus, seizures, smoking, maternal medications (Percocet, Plaquenil, Lamictal, Xanax, Vyvanse, Nicoderm Patch, in utero heroin use
Etiology/Comments (per Birth Defect Evaluator)	**Low lying conus medullaris:** Incidence estimated as 2-4/1000 in postnatal life indicates an inappropriate ascent of the spine. Etiology proposed: traction injury, ischemic damage due to compression of radial perforating vessels. **Pelviectasis:** Very high incidence of newborns with pelviectasis during pregnancy resolving. No information provided as to diagnosis of pelviectasis and its timing. Primarily postnatal identification.
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	

	BPR
Other Details	Confounders: Methotrexate and unspecified antiepileptic medication exposure; steroid use; tobacco, alprazolam, methamphetamine (Vyvanse) and heroin use in pregnancy. MACDP: If hydronephrosis is diagnosed or suspected on a prenatal U/S and a renal U/S is done after the 2nd week of life and is normal, do not code hydronephrosis. EUROCAT: Pyelecaliectasis/ hydronephrosis documented to be <10mm considered minor anomaly
Background rate of anomaly	4 months postpartum: Infant meeting gross and fine motor and language developmental milestones. Unknown if meeting cognitive and social/emotional milestones. 12-month milestones not provided. National estimates are not available.
Case 7	**US0027 (Twin A)/ Positional Plagiocephaly and Positional Torticollis**
Maternal age	30 years-old
Belimumab exposure (timing of dose)	Preconception (7 months to 1 month preconception)
Concomitant medication (timing of dose)	**Preconception only:** Azathioprine (8 months to1 month preconception) **Preconception and all trimesters:** Folate (folic acid), anti-malarials (4 years preconception), **1st trimester:** Diclegis (doxylamine succinate + pyridoxine hydrochloride) starting at 10 weeks (unknown stop date) **2nd trimester:** Augmentin (amoxicillin + clavulanic acid) at 24 weeks, prenatal vitamins (at least 1st and 2nd trimester exposure unknown)
PGA of SLE disease activity	Mild (11 weeks), Mild/Moderate (28 weeks), Not provided (3rd trimester)
Maternal comorbidities/ Events	**1st trimester:** Morning sickness (starting at 10 weeks, unknown stop date) **2nd trimester:** Sinus infection (24 weeks gestation) **3rd trimester:** Spontaneous rupture of membranes (36 weeks)
Maternal autoantibody tests	3 years preconception: Anti-Ro and/or Anti-La +, lupus anticoagulant + 1.5 years preconception: lupus anticoagulant +, Anti-cardiolipin antibodies negative 2 months preconception: Anti-ds DNA negative,
Prenatal tests	5 months preconception: lupus anticoagulant negative 11 weeks gestation: Anti-ds DNA + MSAFP: 18 weeks – no abnormality Genetic Screening Test: 10 weeks – normal Prenatal ultrasounds (10 to 35 weeks) – no fetal abnormality
Post-delivery tests (Neonatal)	<u>Maternal labs</u> Proteinuria: 2 months preconception and 11 weeks – normal SCr: 2 months preconception and 11 weeks – 0.8 and 0.7
Gestation Age at delivery/ Route of delivery	None provided $36^{1/7}$ weeks/ Caesarean
Gender of neonate/ Birth weight/ Apgar	

	BPR
Age at time of congenital anomaly diagnosis	Male/ Not provided/ 9-9
Treatment of congenital anomaly	9 months post-delivery
Status of congenital anomaly	Stretching exercises
Defect Classification (per Birth Defect Evaluator)	12 month post-delivery: Plagiocephaly and torticollis recovered
Defect Classification (per GSK Pregnancy Outcomes Panel)	MACDP: Positional Plagiocephaly/Positional Torticollis – defect EUROCAT: Positional Plagiocephaly/Positional Torticollis – not a defect
Confounding factors (per Birth Defect Evaluator)	MACDP: Positional Plagiocephaly/Positional Torticollis – not a defect EUROCAT: Positional Plagiocephaly/Positional Torticollis – not a defect
Etiology/Comments (per Birth Defect Evaluator)	Maternal medications, SLE, male, caesarean section, spontaneous rupture of membranes
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	**Positional Plagiocephaly:** Intrauterine malposition is considered to be the cause of flat head, especially noted in multiple pregnancies. Due to intrauterine malposition would indicate a deformation rather than malformation. **Positional Torticollis:** Birth trauma or intrauterine malposition is considered to be the cause of damage to the sternocleidomastoid muscle in the neck. Incidence is 0.3-3.0 percent. Due to intrauterine malposition would indicate a deformation rather than malformation.
Other Details	Diagnosis made at 9 months of age and consistent with positional torticollis and plagiocephaly as reported (rather than congenital)
Background rate of anomaly	Spontaneous rupture of membranes following uterine contractions beginning at 36 weeks gestation. Healthy male twins were delivered. Twin A was diagnosed with perianal abscess/anal fistula at approximately 1.5 months of age. Treated with Augmentin and metronidazole. Experienced bronchiolitis and respiratory syncytial virus infection at 2 months of age and treated with albuterol. 12 months postpartum: Infant meeting all developmental milestones. Positional plagiocephaly prevalence can range from 16 to 48% in infants less than 1 year of age [Ballardini, 2018]
Case 8	**US0032/ Small fenestrated Atrial septal defect**
Maternal age	35 years-old
Belimumab exposure (timing of dose)	Preconception (unknown start date until 1.5 months preconception)

	BPR
Concomitant medication (timing of dose)	**Preconception only:** NSAIDs (4 months preconception) **Preconception and all trimesters:** Anti-malarials **1st to 2nd trimester** (3rd trimester exposure unknown)**:** Prenatal Vitamins + Folic acid (started at 2 weeks), Baby aspirin (started at 2 weeks)
PGA of SLE disease activity	None (22 weeks, 1.5 months post-delivery), Not provided (1st and 3rd trimesters)
Maternal comorbidities/ Events	**2nd and 3rd trimester:** Thrombocytopenia (starting at 20 weeks) **3rd trimester:** Placental abruption (34 weeks)
Maternal autoantibody tests	1.5 years preconception: Anti-ds DNA negative 1.5 months preconception: Anti-Ro, anti-La, anti-cardiolipin antibodies, lupus anticoagulant – negative 2 weeks gestation: Anti-ds DNA – negative 20 weeks gestation: Anti-ds DNA – negative
Prenatal tests	Prenatal ultrasound: 20 weeks – echogenic intracardiac focus Echocardiogram with doppler: 20 weeks – small muscular ventricular septal defect suspected (not confirmed at birth) <u>Maternal labs</u> SCr: 1.5 months preconception, 20 weeks, 34 weeks: 1, 0.8, 0.8 Proteinuria: 1.5 months preconception and 27 weeks – normal
Post-delivery tests (Neonatal)	Echocardiogram: 2 weeks post-delivery – two small atrial shunt (left to right), small fenestrated ASD Echocardiogram: 4.5 months post-delivery – possible atrial shunt left to right. Five pulmonary veins visualized. Normal left ventricle with normal thickness and size. Normal right ventricle with normal thickness and size. Normal valve.
Gestation Age at delivery/ Route of delivery	$34^{3/7}$ weeks/ Caesarean
Gender of neonate/ Birth weight/ Apgar	Male/ 2268 grams/ 1^{1}-6^{5}-8^{10}
Age at time of congenital anomaly diagnosis	2 weeks post-delivery
Treatment of congenital anomaly	Not reported
Status of congenital anomaly	10 months post-delivery: Resolved
Defect Classification (per Birth Defect Evaluator)	MACDP: exclusionary (conditional defect) EUROCAT – defect MACDP/ EUROCAT: Conditional: Unlikely (without actual "small" defect measurement, inconclusive)

	BPR
Defect Classification (per GSK Pregnancy Outcomes Panel)	Placental abruption
Confounding factors (per Birth Defect Evaluator)	4 month visit no reported birth defects by pediatrician. Fetal echo identified small VSD; ASD diagnosed shortly after birth with natural closure of small ASD; many ASDs resolve in this manner, especially in premature infants.
Etiology/Comments (per Birth Defect Evaluator)	At a 20 week in utero U/S, a small muscular VSD was suspected. At 2 weeks of age, two small left to right atrial shunts were noted (small, fenestrated ASD) and at 4.5 months of age, echo showed "possible" atrial shunt left to right with other anatomy normal (pulmonary veins, L/R ventricles and valves) and at 10 months echo showed resolution. "Possible" small VSD noted on 20-week prenatal U/S never confirmed after delivery. Confounders: Prematurity (34-week delivery due to placental abruption). MACDP: If defect size by echo is $\leq$ 4mm, follow instructions for patent 100 foramen ovale even if the record says secundum ASD. For PFO, if < 36 weeks at birth, never code as a congenital anomaly. EUROCAT: A persistent or patent foramen ovale is considered a minor or other exclusionary congenital anomaly and is not coded.
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	
Other Details	Fall leading to placental abruption and premature delivery. Neonate sent to Neonatal Intensive Care Unit. VSD not confirmed at birth. 12 months postpartum: Infant not meeting gross motor skill milestones but meeting fine motor skills, language, cognitive and social or emotional milestones.
Background rate of anomaly	US data: 13.1 per 10,000 live births (prevalence from Metropolitan Atlanta, 1998–2005) [Reller, 2008] European data: 15.73 per 10,000 live births (95%CI 15.45 – 16.01) [EUROCAT, 2023]
Case 9	**US0035/ Arnold Chiari Type II Malformation**
Maternal age	31 years-old
Belimumab exposure (timing of dose)	Preconception (~ 1 year) to $1^{4/7}$ weeks
Concomitant medication (timing of dose)	Unknown
PGA of SLE disease activity	Not provided
Maternal comorbidities/ Events	Obesity
Maternal autoantibody tests	Unknown
Prenatal tests	Prenatal ultrasound: 6 weeks – unknown
Post-delivery tests (Neonatal)	Rapid brain MRI: 4 months post-delivery – Chiari Malformation Full MRI: 4 months post-delivery – patient reported severe Chiari I Malformation (later noted by pediatric medical assistant as type II)
	$37^{5/7}$ weeks/ Not provided

	BPR
Gestation Age at delivery/ Route of delivery	Male/ 2630.8 grams/ Not provided
Gender of neonate/ Birth weight/ Apgar	4 months post-delivery
Age at time of congenital anomaly diagnosis	Brain surgery and C1/C2 laminectomy at 4 months post-delivery
Treatment of congenital anomaly	12 months post-delivery: Ongoing
Status of congenital anomaly	MACDP – defect EUROCAT – defect
Defect Classification (per Birth Defect Evaluator)	MACDP – defect EUROCAT – defect
Defect Classification (per GSK Pregnancy Outcomes Panel)	Black race, 38-week delivery, birth weight 5.8 lbs, birth length 49.5 cm, obesity
Confounding factors (per Birth Defect Evaluator)	Prevalence rate is 0.1-0.5% slightly higher in females; Linkage to chromosomes 9 and 15. Also proposed association with deficient nutrition vitamins. Pathophysiology associated with 1- Compression of medulla and upper spinal cord, 2- Compression of cerebellum, 3- Disruption of CSF flow through foramen magnum. Confounders: Obesity; Black Race
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	4 months postpartum: Infant taken to the emergency room for difficulty breathing and diagnosed with respiratory infection. Admitted to hospital the following day due to continuing to struggle with breathing and not eating and was diagnosed with Chiari II Malformation. The infant immediately underwent brain surgery and was scheduled to be discharged with a feeding tube. C1/C2 laminectomy was performed. 12 months: Infant meeting all developmental milestones.
Other Details	
Background rate of anomaly	National level estimates are not available.
Case 10	**US0053/ Ankyloglossia**
Maternal age	35 years-old
Belimumab exposure (timing of dose)	Preconception (approximately 7 years) to post conception
Concomitant medication (timing of dose)	**Preconception (at least):** Azathioprine (7 years preconception to unknown date), Trazodone ‘’ (unknown dates)

	BPR
PGA of SLE disease activity	**Preconception and 1st trimester:** Topamax (until 5 weeks), Zomig (until 5 weeks) **Preconception to post-delivery:** Plaquenil (until at least 33 weeks) **2nd trimester** (1st and 3rd trimester exposure unknown)**:** Iron and magnesium (unknown timing, at least during week 21)**,** Prednisone (21 weeks to at least 25 weeks)
Maternal comorbidities/ Events	Not available
Maternal autoantibody tests	**Preconception:** Two prior pregnancies (1 belimumab-exposed live birth of healthy full-term female with minor speech delay, 1 elective termination), alcohol use **Preconception to at least the 2nd trimester:** Raynaud's Syndrome, chronic migraines without aurora, anxiety disorder **2nd trimester:** Palpitations, chest rash
Prenatal tests	~3 months preconception: Anti-ds DNA negative Prenatal ultrasounds: 8 weeks to 21 weeks– no fetal abnormality Genetic screening: 11 weeks – no fetal abnormality
Post-delivery tests (Neonatal)	<u>Maternal labs</u> Proteinuria: 3 months preconception – normal SCr: 3 months preconception – 0.74 (normal) Urine creatinine: 3 months preconception – 96.2 (normal)
Gestation Age at delivery/ Route of delivery	Not available
Gender of neonate/ Birth weight/ Apgar	37 6/7 weeks/ Cesarean
Age at time of congenital anomaly diagnosis	Male/ 3255 grams/ Not provided
Treatment of congenital anomaly	0 days post-partum
Status of congenital anomaly	Frenectomy (laser) 9 days post-delivery
Defect Classification (per Birth Defect Evaluator)	9 days post-delivery: Resolved
Defect Classification (per GSK Pregnancy Outcomes Panel)	MACDP: Ankyloglossia – defect; Lip adhesion – not a defect EUROCAT: Ankyloglossia – not a defect; Lip adhesion – not a defect
Confounding factors (per Birth Defect Evaluator)	Not available not part of POAP review Male infant. Very common issue

	BPR
Etiology/Comments (per Birth Defect Evaluator)	
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	No family history. Very common and increasing – reports have ranged from 4-10% of newborns. More males are affected than females (2:1). Not specifically associated with any exposures. Laser Frenectomy is commonly used. The development of this defect and the timing of exposure to drug cannot rule out a possible association.
Other Details	Not applicable, not part of POAP review
Background rate of anomaly	Lip Adhesion also noted at birth but not considered a defect per MACDP or EUROCAT criteria. Recovered with frenectomy. No family history and no known causes of ankyloglossia or lip adhesion. Problem breastfeeding which resolved after frenectomy. Mother reported at 1 month no problems with akyloglossia other than some difficulty latching. Feeding difficulties with solids since 8-9 months of age (referred for occupational therapy). 12 months postpartum: Meeting all developmental milestones except fine motor skills. Prevalence of ankyloglossia can range from 4.2% to 10.7% in infants [Segal, 2007]
Case 11	**US0062/ Torticollis/Plagiocephaly**
Maternal age	32 years-old
Belimumab exposure (timing of dose)	Preconception to $2^{1/7}$ weeks
Concomitant medication (timing of dose)	**Preconception to at least the 1st trimester:** Folate **At least during the 1st trimester (2nd and 3rd trimester exposure unknown):** Aspirin (starting at 8 weeks)
PGA of SLE disease activity	Mild (7 months preconception, 7 weeks, 30 weeks)
Maternal comorbidities/ Events	None provided
Maternal autoantibody tests	7 weeks: Anti-ds DNA negative, lupus anticoagulant negative, Anti-Ro and Anti-La negative 23 weeks: Anti-ds DNA negative, IgG, IgA, IgM negative, lupus anticoagulant negative, Anti-Ro and Anti-La negative 36 weeks: Anti-ds DNA negative
Prenatal tests	Prenatal ultrasounds: 8 weeks and 20 weeks - no fetal abnormality <u>Maternal labs</u> Proteinuria: 7 weeks to 30 weeks - normal; 36 weeks - abnormal SCr: 7 weeks - 0.5; 23 weeks 0.7; 30 and 36 weeks - 0.5 Protein/creatinine: 36 weeks - 0.207
Post-delivery tests (Neonatal)	None provided

	BPR
Gestation Age at delivery/ Route of delivery	$36^{4/7}$ weeks/ Cesarean
Gender of neonate/ Birth weight/ Apgar	Male/ Not provided/ Not provided
Age at time of congenital anomaly diagnosis	2 months post-delivery
Treatment of congenital anomaly	Referred for physical therapy (no documentation that appointment was kept)
Status of congenital anomaly	Unknown (No notation of condition at 4-month pediatric visit)
Defect Classification (per Birth Defect Evaluator)	MACDP: Torticollis - defect; Plagiocephaly - defect EUROCAT: Torticollis - defect; Plagiocephaly - defect
Defect Classification (per GSK Pregnancy Outcomes Panel)	Not available not part of POAP review
Confounding factors (per Birth Defect Evaluator)	None provided
Etiology/Comments (per Birth Defect Evaluator)	**Torticollis:** Postnatal contributions are very high. **Plagiocephaly:** Postnatal sleep patterns have been highly associated with flat head. **Torticollis and Plagiocephaly:** Not diagnosed until 2 months of age. Parents did not consider this condition a major problem. Defect with known cause, temporality may be irrelevant.
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	Not applicable, not part of POAP review
Other Details	Also diagnosed with single scalp hemangioma (not cavernous, size = 0.5 cm) at 2 months old. 4 months postpartum: Infant meeting all developmental milestones. 12-month pediatric follow-up data not obtained.
Background rate of anomaly	Positional plagiocephaly prevalence can range from 16 to 48% in infants less than 1 year of age [Ballardini 2018]
Case 12	**US0065/ Mild Torticollis/Left-sided Positional Plagiocephaly**
Maternal age	30 years-old
Belimumab exposure (timing of dose)	Preconception to 3-4 weeks gestation
Concomitant medication (timing of dose)	**Preconception and 1st trimester (at least):** Prenatal vitamins **Preconception and all trimesters:** Lamictal

	BPR
	1st trimester (at least): Vitamin B6 (started at 8 weeks), Folate **2nd trimester (at least):** Plaquenil (started at 22 weeks)
PGA of SLE disease activity	Not available
Maternal comorbidities/ Events	**Preconception:** Blood clotting disorder, generalized anxiety disorder **3rd Trimester:** Preeclampsia (36 weeks)
Maternal autoantibody tests	5 months preconception: Anti-ds DNA negative
Prenatal tests	Prenatal ultrasounds: 8-34 weeks – no fetal abnormality <u>Maternal labs</u> SCr: 5 months preconception – 0.78
Post-delivery tests (Neonatal)	None provided
Gestation Age at delivery/ Route of delivery	$36^{4/7}$ weeks/ Cesarean
Gender of neonate/ Birth weight/ Apgar	Male/ 3230 grams/ Not provided
Age at time of congenital anomaly diagnosis	4 Months post-delivery
Treatment of congenital anomaly	Referred for physical therapy/increased tummy time (Unknown if physical therapy received)
Status of congenital anomaly	6-month assessment: Resolved
Defect Classification (per Birth Defect Evaluator)	MACDP: Torticollis – defect; Plagiocephaly – defect EUROCAT: Torticollis – defect; Plagiocephaly – defect
Defect Classification (per GSK Pregnancy Outcomes Panel)	Not available not part of POAP review
Confounding factors (per Birth Defect Evaluator)	SLE; No birth defect at birth (cesarean section); Male – 3230 grams; preeclampsia; no observed fetal abnormalities on ultrasound; normal growth and landmarks at 4 months of age; epilepsy medication with folate; belimumab; no reported alcohol, tobacco or recreational drug use
Etiology/Comments (per Birth Defect Evaluator)	**Plagiocephaly:** Not noted at birth and may be the result of the torticollis especially since it is one sided, which is consistent with being the result of torticollis. **Torticollis:** Often wryneck is not diagnosed until a few weeks after birth. Can be congenital or acquired. May be associated with positional

	BPR
	plagiocephaly on one side. May be associated in utero with the head being malpositioned and cramped. No evidence described from ultrasounds that malposition is evident or no oligohydramnios. Often will resolve with time. First reported at 4 months of age. Temporality in question because noted at 4 months of age.
GSK Pregnancy Outcomes Panel (POAP) Conclusion/Commentary	Not applicable, not part of POAP review
Other Details	Per Pediatric nurse: Possible cause of plagiocephaly and torticollis was infant positioning. Nurse did not consider conditions as birth defects. Belimumab received while breastfeeding. 12 months postpartum: Meeting all developmental milestones except fine motor skills.
Background rate of anomaly	Positional plagiocephaly prevalence can range from 16 to 48% in infants less than 1 year of age [Ballardini, 2018]

15. TABLES AND FIGURES

Table 1.1 – Table 14.0 and Listing 1.0-Listing 10.0 will be appended in this section.

Protocol: BEL114256
Population: All Registry Participants

Table 1.1
Exposed Enrollment Status

Note: Denominator is the total number of participants in each column (N),unless otherwise noted.
[1]This table includes retrospective participants and participants with insufficient dosing data to determine timing of exposure. In some cases, the trimester of enrollment cannot be determined and columns/rows may not total accordingly.
[2]Includes participants previously participating in a belimumab study. Participants in these rows are not counted in the overall N for each column as they are included elsewhere in the table.
[3]Includes participants who meet the enrollment criteria and consent but commercial belimumab exposure is never confirmed.
[4]Includes eligible participants where critical data remains pending, resulting in a temporary pending status. Due to BPR closure, pending reflective at the time of the closure. BPR will not collect additional information.
[5]Evaluable cases are cases with confirmed exposure to commercial belimumab administered within the four months preconception and/or during pregnancy and that are confirmed pregnant by any HCP.
[6]Pure Prospective cases are evaluable participants with a diagnosis of SLE that meets ACR criteria, have an ongoing pregnancy at the time of enrollment (defined as delivery date greater than informed consent date), did not know at the time of enrollment whether the fetus had a malformation, and had no prenatal testing completed prior to enrollment (fetal test date is after informed consent date or is missing), and with known pregnancy outcome confirmed by HCP.
[7]Traditional prospective cases are evaluable participants with a diagnosis of SLE that meets ACR criteria, have an ongoing pregnancy at the time of enrollment (defined as delivery date greater than informed consent date), whose fetal test date is on or before informed consent date but may or may not have known fetal test results at the time of enrolment, and with known pregnancy outcome confirmed by HCP.
[8]Non SLE cases are any evaluable cases where the participant has not been diagnosed with SLE upon entry into the registry.
[9]Retrospective cases are reports of pregnancy in which the pregnancy ended before enrollment or at the time of the first contact with the registry.
[10]Includes evaluable participants without a medically confirmed outcome, resulting in a temporary pending status. Due to BPR closure, pending reflective at the time of the closure. BPR will not collect additional information.
[11]Intravenous administration includes missing route participants.

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Protocol: BEL114256
Population: All Registry Participants

Table 1.1
Exposed Enrollment Status

	All Registry Participants[1] (N=87)	Trimester of Enrollment		
		1st trimester (N=39)	2nd trimester (N=20)	3rd trimester (N=14)
Previous belimumab study participation[2]				
Participants previously enrolled in belimumab clinical trial	2 (2.3%)	0	2 (10.0%)	0
Participants previously enrolled in belimumab pregnancy registry	5 (5.7%)	2 (5.1%)	1 (5.0%)	1 (7.1%)
Invalid/ineligible participants[3]	10 (11.5%)	4 (10.3%)	1 (5.0%)	2 (14.3%)
Eligible participants with an unconfirmed pregnancy and exposure[4]	0	0	0	0
Evaluable patients with an on-going pregnancy[5]	0	0	0	0
Evaluable participants with a confirmed outcome[5]	72 (82.8%)	32 (82.1%)	18 (90.0%)	11 (78.6%)
Pure prospective cohort[6]	17 (19.5%)	12 (30.8%)	1 (5.0%)	4 (28.6%)
Traditional prospective cohort[7]	44 (50.6%)	20 (51.3%)	17 (85.0%)	7 (50.0%)
Non SLE cohort[8]	0	0	0	0
Retrospective cohort[9]	11 (12.6%)	NA	NA	NA
Evaluable participants with a medically unconfirmed outcome[10]	0	0	0	0
Participants considered lost to follow-up before pregnancy outcome	5 (5.7%)	3 (7.7%)	1 (5.0%)	1 (7.1%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 1.1
Exposed Enrollment Status

	All Registry Participants[1] (N=87)	Trimester of Enrollment 1st trimester (N=39)	2nd trimester (N=20)	3rd trimester (N=14)
Participants route of belimumab administration				
Intravenous administration[11]	74 (85.1%)	33 (84.6%)	16 (80.0%)	12 (85.7%)
Subcutaneous administration	9 (10.3%)	5 (12.8%)	3 (15.0%)	0
Switched route	2 (2.3%)	1 (2.6%)	1 (5.0%)	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 2.1
Exposed Registry Status
(Evaluable Participants with a Confirmed Outcome)

Note: Denominator is the total number of participants in each column (N), unless otherwise noted.
Live birth: the birth of a living fetus at $20^{0/7}$ weeks' gestational age or greater (>=20 weeks), or, if gestational age is unknown, a fetus weighing 500 g or more (>=500 g).
Neonatal death: an infant who after live birth expired within the first 28 days (<= 28 days) of life.
Stillbirth: a fetal death occurring at $20^{0/7}$ weeks' gestational age or greater (>=20 weeks) or, if gestational age is unknown, a fetus weighing 500 g or more (>=500 g).
Spontaneous miscarriage: fetal death or expulsion of products of conception prior to 20 weeks' (< 20 weeks) gestation.
Elective termination: voluntary interruption of pregnancy, including pregnancy termination that occurs electively, to preserve maternal health, or due to fetal abnormalities.
Ectopic pregnancy: implantation of a conception outside of the uterus.
Molar pregnancy: a conception that results in a gestational trophoblastic tumor.
[1]Completed registry participation is defined as pregnancy outcome is known and if a live birth, follow-up has been completed through month 12.
[2]Denominator is the number of participants completing the registry.
[3]Pediatric follow-up time points are not mutually exclusive. Therefore, percentages may add up to more than 100%. Due to BPR closure, the number of follow-up pending at each follow-up time point is reflective at the time of the closure; BPR will not collect pediatric follow-up information on these infants.
[4]Denominator is the number of live births, pediatric follow-up pending.
[5]Denominator is the number of live births.
[6]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in two subcategories of pregnancy outcomes. This participant is counted once under Total (N) and Pure Prospective (N).

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Protocol: BEL114256
Population: All Registry Participants

Table 2.1
Exposed Registry Status
(Evaluable Participants with a Confirmed Outcome)

	Total (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non-SLE (N=0)	Retrospective (N=11)
Registry participation complete[1]	60 (83.3%)	12 (70.6%)	38 (86.4%)	0	10 (90.9%)
Live birth, pediatric follow-up complete[2]	50 (83.3%)	10 (83.3%)	36 (94.7%)	0	4 (40.0%)
Neonatal death[2]	0	0	0	0	0
Stillbirth[2]	1 (1.7%)	0	1 (2.6%)	0	0
Spontaneous miscarriage[2,6]	7 (11.7%)	2 (16.7%)	1 (2.6%)	0	4 (40.0%)
Elective termination[2]	2 (3.3%)	0	0	0	2 (20.0%)
Ectopic pregnancy[2]	0	0	0	0	0
Molar pregnancy[2]	0	0	0	0	0
Live birth, pediatric follow-up pending[3]	3 (4.2%)	0	2 (4.5%)	0	1 (9.1%)
Pediatric outcome pending[4]	0	0	0	0	0
4 month follow-up pending[4]	2 (66.7%)	0	2 (100.0%)	0	0
12 month follow-up pending[4]	1 (33.3%)	0	0	0	1 (100.0%)
Live Birth: Lost to follow-up after pregnancy outcome/incomplete pediatric follow-up[5,6]	10 (13.9%)	6 (35.3%)	4 (9.1%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Note: Denominator is the total number of participants in each column (N). ACE inhibitors=angiotensin-converting-enzyme inhibitors; NSAIDs=non-steroidal anti-inflammatory drugs; SAB=spontaneous miscarriage; SGA=small for gestational age.
Exposure is defined as at least one dose during the period of observation (6 months prior to/during pregnancy for concomitant medications and 4 months prior to/during pregnancy for commercial belimumab) and does not imply continued use throughout the period of observation. Preconception is defined as six months prior to pregnancy for concomitant medications and 4 months prior to/during pregnancy for commercial belimumab. Participants may be presented in one or several time points and may be exposed to one or several medications; therefore, percentages may not add to 100%. For Rituximab and Anti-Malarials half-lives are assessed to determine the trimester of exposure.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births. Ectopic and molar pregnancies have not been reported to date.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st reference. Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Preconception occurs within 4 months prior to conception. The first trimester begins the day after date of conception, the second trimester begins at week $14^{0/7}$ after the date of conception, and the third trimester begins at week $28^{0/7}$.
[5]Defined by the first or last recorded exposure with a non-missing treatment date.
[6]Considering timing of enrollment, participants with unknown routes of exposure are summarized under intravenous route.
[7]Includes azathioprine, cyclophosphamide, methotrexate, mycophenolate, cyclosporin, and rituximab.
[8]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.

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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Earliest Belimumab exposure [4,5]				
Preconception	65(90.3%)	6(85.7%)	2(100%)	0
1st trimester	5(6.9%)	1(14.3%)	0	0
2nd trimester	2(2.8%)	0	0	1(100%)
3rd trimester	0	0	0	0
Last Belimumab exposure [4,5]				
Preconception	0	0	0	0
1st trimester	10(13.9%)	0	0	0
2nd trimester	34(47.2%)	1(14.3%)	0	0
3rd trimester	1(1.4%)	0	0	0
Postpartum	27(37.5%)	6(85.7%)	2(100%)	1(100%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Earliest Belimumab exposure [4,5]					
Preconception	58(92.1%)	18(94.7%)	3(75.0%)	11(91.7%)	11(91.7%)
1st trimester	4(6.3%)	1(5.3%)	0	0	1(8.3%)
2nd trimester	1(1.6%)	0	1(25.0%)	1(8.3%)	0
3rd trimester	0	0	0	0	0
Last Belimumab exposure [4,5]					
Preconception	0	0	0	0	0
1st trimester	10(15.9%)	6(31.6%)	0	1(8.3%)	3(25.0%)
2nd trimester	34(54.0%)	9(47.4%)	2(50.0%)	8(66.7%)	7(58.3%)
3rd trimester	1(1.6%)	0	0	0	0
Postpartum	18(28.6%)	4(21.1%)	2(50.0%)	3(25.0%)	2(16.7%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Exposure by study timepoints [4,5]				
Preconception through 1st trimester	10(13.9%)	0	0	0
Preconception through 2nd trimester	32(44.4%)	1(14.3%)	0	0
Preconception through 3rd trimester	1(1.4%)	0	0	0
Preconception through post-pregnancy	22(30.6%)	5(71.4%)	2(100%)	0
1st trimester through 2nd trimester	2(2.8%)	0	0	0
1st trimester through 3rd trimester	0	0	0	0
1st trimester through post-pregnancy	3(4.2%)	1(14.3%)	0	0
2nd trimester through 3rd trimester	0	0	0	0
2nd trimester through post-pregnancy	2(2.8%)	0	0	1(100%)
3rd trimester through post-pregnancy	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Exposure by study timepoints [4,5]					
Preconception through 1st trimester	10(15.9%)	6(31.6%)	0	1(8.3%)	3(25.0%)
Preconception through 2nd trimester	32(50.8%)	8(42.1%)	2(50.0%)	8(66.7%)	7(58.3%)
Preconception through 3rd trimester	1(1.6%)	0	0	0	0
Preconception through post-pregnancy	15(23.8%)	4(21.1%)	1(25.0%)	2(16.7%)	1(8.3%)
1st trimester through 2nd trimester	2(3.2%)	1(5.3%)	0	0	0
1st trimester through 3rd trimester	0	0	0	0	0
1st trimester through post-pregnancy	2(3.2%)	0	0	0	1(8.3%)
2nd trimester through 3rd trimester	0	0	0	0	0
2nd trimester through post-pregnancy	1(1.6%)	0	1(25.0%)	1(8.3%)	0
3rd trimester through post-pregnancy	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Cumulative exposure (days)				
n	72	7	2	1
Mean (SD)	245.4(108.27)	208.0(45.91)	230.5(43.13)	142.0 (-)
Median	211.5	219.0	230.5	142.0
Min - Max	100 - 464	128 - 261	200 - 261	142 - 142
Q1, Q3	166.0,303.5	183.0,241.0	200.0,261.0	142.0,142.0
Route of administration[6]				
Intravenous	62(86.1%)	7(100%)	2(100%)	0
Subcutaneous	8(11.1%)	0	0	1(100%)
Switched route	2(2.8%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Cumulative exposure (days)					
n	63	19	4	12	12
Mean (SD)	251.6(113.20)	238.3(110.58)	272.8(113.64)	235.2(101.77)	223.3(79.03)
Median	212.0	202.0	218.0	211.5	197.5
Min - Max	100 - 464	130 - 443	212 - 443	130 - 443	155 - 409
Q1, Q3	166.0,350.0	156.0,282.0	212.0,333.5	179.5,236.5	171.0,232.0
Route of administration[6]					
Intravenous	54(85.7%)	15(78.9%)	4(100%)	11(91.7%)	10(83.3%)
Subcutaneous	7(11.1%)	4(21.1%)	0	1(8.3%)	2(16.7%)
Switched route	2(3.2%)	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Other exposures during pregnancy				
Corticosteroids (For SLE ONLY)	38(52.8%)	4(57.1%)	1(50.0%)	1(100%)
Preconception	37(51.4%)	4(57.1%)	1(50.0%)	1(100%)
During pregnancy	36(50.0%)	3(42.9%)	1(50.0%)	1(100%)
1st trimester	34(47.2%)	3(42.9%)	1(50.0%)	0
2nd trimester	35(48.6%)	3(42.9%)	1(50.0%)	1(100%)
3rd trimester	33(45.8%)	3(42.9%)	1(50.0%)	1(100%)
NSAIDs	14(19.4%)	2(28.6%)	0	0
Preconception	13(18.1%)	2(28.6%)	0	0
During pregnancy	10(13.9%)	1(14.3%)	0	0
1st trimester	9(12.5%)	1(14.3%)	0	0
2nd trimester	6(8.3%)	1(14.3%)	0	0
3rd trimester	6(8.3%)	1(14.3%)	0	0

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Other exposures during pregnancy					
Corticosteroids (For SLE ONLY)	32(50.8%)	9(47.4%)	2(50.0%)	5(41.7%)	6(50.0%)
Preconception	31(49.2%)	9(47.4%)	2(50.0%)	5(41.7%)	6(50.0%)
During pregnancy	31(49.2%)	9(47.4%)	2(50.0%)	5(41.7%)	6(50.0%)
1st trimester	30(47.6%)	9(47.4%)	2(50.0%)	5(41.7%)	6(50.0%)
2nd trimester	30(47.6%)	9(47.4%)	2(50.0%)	5(41.7%)	6(50.0%)
3rd trimester	28(44.4%)	9(47.4%)	2(50.0%)	5(41.7%)	6(50.0%)
NSAIDs	12(19.0%)	3(15.8%)	2(50.0%)	4(33.3%)	3(25.0%)
Preconception	11(17.5%)	2(10.5%)	2(50.0%)	4(33.3%)	3(25.0%)
During pregnancy	9(14.3%)	1(5.3%)	1(25.0%)	3(25.0%)	2(16.7%)
1st trimester	8(12.7%)	1(5.3%)	0	2(16.7%)	1(8.3%)
2nd trimester	5(7.9%)	1(5.3%)	0	2(16.7%)	1(8.3%)
3rd trimester	5(7.9%)	1(5.3%)	1(25.0%)	3(25.0%)	2(16.7%)

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Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Anti-malarials	55(76.4%)	3(42.9%)	1(50.0%)	1(100%)
Preconception	55(76.4%)	3(42.9%)	1(50.0%)	1(100%)
During pregnancy	55(76.4%)	3(42.9%)	1(50.0%)	1(100%)
1st trimester	54(75.0%)	3(42.9%)	1(50.0%)	1(100%)
2nd trimester	55(76.4%)	3(42.9%)	1(50.0%)	1(100%)
3rd trimester	55(76.4%)	3(42.9%)	1(50.0%)	1(100%)
Folate	35(48.6%)	3(42.9%)	0	0
Preconception	29(40.3%)	3(42.9%)	0	0
During pregnancy	33(45.8%)	2(28.6%)	0	0
1st trimester	33(45.8%)	2(28.6%)	0	0
2nd trimester	33(45.8%)	2(28.6%)	0	0
3rd trimester	33(45.8%)	2(28.6%)	0	0

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Anti-malarials	50(79.4%)	14(73.7%)	4(100%)	11(91.7%)	10(83.3%)
Preconception	50(79.4%)	14(73.7%)	4(100%)	11(91.7%)	10(83.3%)
During pregnancy	50(79.4%)	14(73.7%)	4(100%)	11(91.7%)	10(83.3%)
1st trimester	49(77.8%)	13(68.4%)	4(100%)	11(91.7%)	9(75.0%)
2nd trimester	50(79.4%)	14(73.7%)	4(100%)	11(91.7%)	10(83.3%)
3rd trimester	50(79.4%)	14(73.7%)	4(100%)	11(91.7%)	10(83.3%)
Folate	32(50.8%)	10(52.6%)	3(75.0%)	7(58.3%)	9(75.0%)
Preconception	26(41.3%)	8(42.1%)	1(25.0%)	5(41.7%)	8(66.7%)
During pregnancy	31(49.2%)	10(52.6%)	3(75.0%)	7(58.3%)	9(75.0%)
1st trimester	31(49.2%)	10(52.6%)	3(75.0%)	7(58.3%)	9(75.0%)
2nd trimester	31(49.2%)	10(52.6%)	3(75.0%)	7(58.3%)	9(75.0%)
3rd trimester	31(49.2%)	10(52.6%)	3(75.0%)	7(58.3%)	9(75.0%)

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
ACE Inhibitors	3(4.2%)	0	0	0
Preconception	3(4.2%)	0	0	0
During pregnancy	2(2.8%)	0	0	0
1st trimester	2(2.8%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Calcium Channel Blockers	6(8.3%)	1(14.3%)	0	0
Preconception	5(6.9%)	1(14.3%)	0	0
During pregnancy	6(8.3%)	1(14.3%)	0	0
1st trimester	5(6.9%)	1(14.3%)	0	0
2nd trimester	5(6.9%)	1(14.3%)	0	0
3rd trimester	5(6.9%)	1(14.3%)	0	0

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Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
ACE Inhibitors	3(4.8%)	3(15.8%)	0	0	1(8.3%)
Preconception	3(4.8%)	3(15.8%)	0	0	1(8.3%)
During pregnancy	2(3.2%)	2(10.5%)	0	0	0
1st trimester	2(3.2%)	2(10.5%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Calcium Channel Blockers	5(7.9%)	1(5.3%)	0	0	0
Preconception	4(6.3%)	0	0	0	0
During pregnancy	5(7.9%)	1(5.3%)	0	0	0
1st trimester	4(6.3%)	0	0	0	0
2nd trimester	4(6.3%)	0	0	0	0
3rd trimester	4(6.3%)	1(5.3%)	0	0	0

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Beta Blockers	6(8.3%)	1(14.3%)	0	1(100%)
Preconception	6(8.3%)	1(14.3%)	0	1(100%)
During pregnancy	6(8.3%)	1(14.3%)	0	1(100%)
1st trimester	4(5.6%)	1(14.3%)	0	1(100%)
2nd trimester	5(6.9%)	0	0	1(100%)
3rd trimester	5(6.9%)	0	0	1(100%)
Angiotensin II Receptor Antagonists	3(4.2%)	0	0	0
Preconception	3(4.2%)	0	0	0
During pregnancy	2(2.8%)	0	0	0
1st trimester	2(2.8%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Beta Blockers	4(6.3%)	2(10.5%)	0	1(8.3%)	0
Preconception	4(6.3%)	2(10.5%)	0	1(8.3%)	0
During pregnancy	4(6.3%)	2(10.5%)	0	1(8.3%)	0
1st trimester	2(3.2%)	1(5.3%)	0	1(8.3%)	0
2nd trimester	4(6.3%)	2(10.5%)	0	1(8.3%)	0
3rd trimester	4(6.3%)	2(10.5%)	0	1(8.3%)	0
Angiotensin II Receptor Antagonists	3(4.8%)	2(10.5%)	0	0	0
Preconception	3(4.8%)	2(10.5%)	0	0	0
During pregnancy	2(3.2%)	1(5.3%)	0	0	0
1st trimester	2(3.2%)	1(5.3%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Insulin	2(2.8%)	0	0	0
Preconception	0	0	0	0
During pregnancy	2(2.8%)	0	0	0
1st trimester	2(2.8%)	0	0	0
2nd trimester	1(1.4%)	0	0	0
3rd trimester	1(1.4%)	0	0	0
Heparin	7(9.7%)	0	0	0
Preconception	4(5.6%)	0	0	0
During pregnancy	7(9.7%)	0	0	0
1st trimester	6(8.3%)	0	0	0
2nd trimester	6(8.3%)	0	0	0
3rd trimester	6(8.3%)	0	0	0

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Insulin	2(3.2%)	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	2(3.2%)	0	0	0	0
1st trimester	2(3.2%)	0	0	0	0
2nd trimester	1(1.6%)	0	0	0	0
3rd trimester	1(1.6%)	0	0	0	0
Heparin	7(11.1%)	1(5.3%)	0	1(8.3%)	2(16.7%)
Preconception	4(6.3%)	1(5.3%)	0	1(8.3%)	2(16.7%)
During pregnancy	7(11.1%)	1(5.3%)	0	1(8.3%)	2(16.7%)
1st trimester	6(9.5%)	1(5.3%)	0	1(8.3%)	2(16.7%)
2nd trimester	6(9.5%)	1(5.3%)	0	1(8.3%)	2(16.7%)
3rd trimester	6(9.5%)	1(5.3%)	0	1(8.3%)	2(16.7%)

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Aspirin	28(38.9%)	1(14.3%)	0	1(100%)
Preconception	18(25.0%)	1(14.3%)	0	1(100%)
During pregnancy	28(38.9%)	1(14.3%)	0	1(100%)
1st trimester	26(36.1%)	1(14.3%)	0	0
2nd trimester	28(38.9%)	1(14.3%)	0	1(100%)
3rd trimester	28(38.9%)	1(14.3%)	0	1(100%)
Epilepsy	6(8.3%)	0	0	0
Medication				
Preconception	6(8.3%)	0	0	0
During pregnancy	6(8.3%)	0	0	0
1st trimester	6(8.3%)	0	0	0
2nd trimester	5(6.9%)	0	0	0
3rd trimester	5(6.9%)	0	0	0

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Aspirin	26(41.3%)	10(52.6%)	3(75.0%)	7(58.3%)	4(33.3%)
Preconception	16(25.4%)	5(26.3%)	2(50.0%)	5(41.7%)	2(16.7%)
During pregnancy	26(41.3%)	10(52.6%)	3(75.0%)	7(58.3%)	4(33.3%)
1st trimester	25(39.7%)	10(52.6%)	3(75.0%)	7(58.3%)	4(33.3%)
2nd trimester	26(41.3%)	10(52.6%)	3(75.0%)	7(58.3%)	4(33.3%)
3rd trimester	26(41.3%)	10(52.6%)	3(75.0%)	7(58.3%)	4(33.3%)
Epilepsy	6(9.5%)	2(10.5%)	0	0	2(16.7%)
Medication					
Preconception	6(9.5%)	2(10.5%)	0	0	2(16.7%)
During pregnancy	6(9.5%)	2(10.5%)	0	0	2(16.7%)
1st trimester	6(9.5%)	2(10.5%)	0	0	2(16.7%)
2nd trimester	5(7.9%)	2(10.5%)	0	0	2(16.7%)
3rd trimester	5(7.9%)	2(10.5%)	0	0	2(16.7%)

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Other Immunosuppressants[7]	30(41.7%)	5(71.4%)	0	0
Preconception	29(40.3%)	5(71.4%)	0	0
During pregnancy	21(29.2%)	3(42.9%)	0	0
1st trimester	21(29.2%)	3(42.9%)	0	0
2nd trimester	12(16.7%)	1(14.3%)	0	0
3rd trimester	11(15.3%)	1(14.3%)	0	0
Azathioprine	16(22.2%)	1(14.3%)	0	0
Preconception	13(18.1%)	1(14.3%)	0	0
During pregnancy	11(15.3%)	0	0	0
1st trimester	11(15.3%)	0	0	0
2nd trimester	9(12.5%)	0	0	0
3rd trimester	9(12.5%)	0	0	0

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Other Immunosuppressants[7]	25(39.7%)	7(36.8%)	4(100%)	7(58.3%)	5(41.7%)
Preconception	24(38.1%)	6(31.6%)	4(100%)	7(58.3%)	5(41.7%)
During pregnancy	18(28.6%)	4(21.1%)	2(50.0%)	4(33.3%)	4(33.3%)
1st trimester	18(28.6%)	4(21.1%)	2(50.0%)	4(33.3%)	4(33.3%)
2nd trimester	11(17.5%)	1(5.3%)	2(50.0%)	4(33.3%)	3(25.0%)
3rd trimester	10(15.9%)	1(5.3%)	2(50.0%)	4(33.3%)	3(25.0%)
Azathioprine	15(23.8%)	3(15.8%)	2(50.0%)	4(33.3%)	4(33.3%)
Preconception	12(19.0%)	2(10.5%)	2(50.0%)	4(33.3%)	3(25.0%)
During pregnancy	11(17.5%)	1(5.3%)	2(50.0%)	4(33.3%)	2(16.7%)
1st trimester	11(17.5%)	1(5.3%)	2(50.0%)	4(33.3%)	2(16.7%)
2nd trimester	9(14.3%)	1(5.3%)	2(50.0%)	4(33.3%)	2(16.7%)
3rd trimester	9(14.3%)	1(5.3%)	2(50.0%)	4(33.3%)	2(16.7%)

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Cyclophosphamide	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Methotrexate	9(12.5%)	2(28.6%)	0	0
Preconception	9(12.5%)	2(28.6%)	0	0
During pregnancy	6(8.3%)	1(14.3%)	0	0
1st trimester	6(8.3%)	1(14.3%)	0	0
2nd trimester	1(1.4%)	0	0	0
3rd trimester	0	0	0	0

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Cyclophosphamide	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Methotrexate	7(11.1%)	2(10.5%)	0	0	1(8.3%)
Preconception	7(11.1%)	2(10.5%)	0	0	1(8.3%)
During pregnancy	5(7.9%)	2(10.5%)	0	0	1(8.3%)
1st trimester	5(7.9%)	2(10.5%)	0	0	1(8.3%)
2nd trimester	1(1.6%)	0	0	0	0
3rd trimester	0	0	0	0	0

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Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Mycophenolate	8(11.1%)	1(14.3%)	0	0
Preconception	7(9.7%)	1(14.3%)	0	0
During pregnancy	3(4.2%)	1(14.3%)	0	0
1st trimester	3(4.2%)	1(14.3%)	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Cyclosporin	3(4.2%)	1(14.3%)	0	0
Preconception	3(4.2%)	1(14.3%)	0	0
During pregnancy	3(4.2%)	1(14.3%)	0	0
1st trimester	3(4.2%)	1(14.3%)	0	0
2nd trimester	2(2.8%)	1(14.3%)	0	0
3rd trimester	2(2.8%)	1(14.3%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Mycophenolate	7(11.1%)	3(15.8%)	2(50.0%)	4(33.3%)	0
Preconception	6(9.5%)	3(15.8%)	2(50.0%)	3(25.0%)	0
During pregnancy	2(3.2%)	2(10.5%)	0	0	0
1st trimester	2(3.2%)	2(10.5%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Cyclosporin	2(3.2%)	0	0	1(8.3%)	1(8.3%)
Preconception	2(3.2%)	0	0	1(8.3%)	1(8.3%)
During pregnancy	2(3.2%)	0	0	1(8.3%)	1(8.3%)
1st trimester	2(3.2%)	0	0	1(8.3%)	1(8.3%)
2nd trimester	1(1.6%)	0	0	0	1(8.3%)
3rd trimester	1(1.6%)	0	0	0	1(8.3%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Total[1,8] (N=72)	SAB[8] (N=7)	Elective terms (N=2)	Still-births (N=1)
Rituximab	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

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Protocol: BEL114256
Population: All Registry Participants

Table 3.0
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

	Live Births [8] (N=63)	Preterm[8] (N=19)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Rituximab	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Note: Denominator is the total number of participants in each column (N). ACE inhibitors=angiotensin-converting-enzyme inhibitors; NSAIDs=non-steroidal anti-inflammatory drugs; SAB=spontaneous miscarriage; SGA=small for gestational age.
Exposure is defined as at least one dose during the period of observation (6 months prior to/during pregnancy for concomitant medications and 4 months prior to/during pregnancy for commercial belimumab) and does not imply continued use throughout the period of observation. Preconception is defined as six months prior to pregnancy for concomitant medications and 4 months prior to/during pregnancy for commercial belimumab. Participants may be presented in one or several time points and may be exposed to one or several medications; therefore, percentages may not add to 100%. For Rituximab and Anti-Malarials half-lives are assessed to determine the trimester of exposure.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births. Ectopic and molar pregnancies have not been reported to date.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st reference. Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Preconception occurs within 4 months prior to conception. The first trimester begins the day after date of conception, the second trimester begins at week $14^{0/7}$ after the date of conception, and the third trimester begins at week $28^{0/7}$.
[5]Defined by the first or last recorded exposure with a non-missing treatment date.
[6]Considering timing of enrollment, participants with unknown routes of exposure are summarized under intravenous route.
[7]Includes azathioprine, cyclophosphamide, methotrexate, mycophenolate, cyclosporin, and rituximab.
[8]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.

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Protocol: BEL114256
Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Earliest Belimumab exposure [4,5]				
Preconception	57(93.4%)	3(100%)	0	0
1st trimester	2(3.3%)	0	0	0
2nd trimester	2(3.3%)	0	0	1(100%)
3rd trimester	0	0	0	0
Last Belimumab exposure [4,5]				
Preconception	0	0	0	0
1st trimester	9(14.8%)	0	0	0
2nd trimester	32(52.5%)	1(33.3%)	0	0
3rd trimester	1(1.6%)	0	0	0
Postpartum	19(31.1%)	2(66.7%)	0	1(100%)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Earliest Belimumab exposure [4,5]					
Preconception	55(94.8%)	17(100%)	3(75.0%)	11(91.7%)	11(91.7%)
1st trimester	2(3.4%)	0	0	0	1(8.3%)
2nd trimester	1(1.7%)	0	1(25.0%)	1(8.3%)	0
3rd trimester	0	0	0	0	0
Last Belimumab exposure [4,5]					
Preconception	0	0	0	0	0
1st trimester	9(15.5%)	5(29.4%)	0	1(8.3%)	3(25.0%)
2nd trimester	32(55.2%)	8(47.1%)	2(50.0%)	8(66.7%)	7(58.3%)
3rd trimester	1(1.7%)	0	0	0	0
Postpartum	16(27.6%)	4(23.5%)	2(50.0%)	3(25.0%)	2(16.7%)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Exposure by study timepoints [4,5]				
Preconception through 1st trimester	9(14.8%)	0	0	0
Preconception through 2nd trimester	31(50.8%)	1(33.3%)	0	0
Preconception through 3rd trimester	1(1.6%)	0	0	0
Preconception through post-pregnancy	16(26.2%)	2(66.7%)	0	0
1st trimester through 2nd trimester	1(1.6%)	0	0	0
1st trimester through 3rd trimester	0	0	0	0
1st trimester through post-pregnancy	1(1.6%)	0	0	0
2nd trimester through 3rd trimester	0	0	0	0
2nd trimester through post-pregnancy	2(3.3%)	0	0	1(100%)
3rd trimester through post-pregnancy	0	0	0	0

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Exposure by study timepoints [4,5]					
Preconception through 1st trimester	9(15.5%)	5(29.4%)	0	1(8.3%)	3(25.0%)
Preconception through 2nd trimester	31(53.4%)	8(47.1%)	2(50.0%)	8(66.7%)	7(58.3%)
Preconception through 3rd trimester	1(1.7%)	0	0	0	0
Preconception through post-pregnancy	14(24.1%)	4(23.5%)	1(25.0%)	2(16.7%)	1(8.3%)
1st trimester through 2nd trimester	1(1.7%)	0	0	0	0
1st trimester through 3rd trimester	0	0	0	0	0
1st trimester through post-pregnancy	1(1.7%)	0	0	0	1(8.3%)
2nd trimester through 3rd trimester	0	0	0	0	0
2nd trimester through post-pregnancy	1(1.7%)	0	1(25.0%)	1(8.3%)	0
3rd trimester through post-pregnancy	0	0	0	0	0

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Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Cumulative exposure (days)				
n	61	3	0	1
Mean (SD)	250.1(110.29)	221.3(33.20)	-	142.0 (-)
Median	212.0	240.0	-	142.0
Min - Max	100 - 464	183 - 241	-	142 - 142
Q1, Q3	183.0,325.0	183.0,241.0	-	142.0,142.0
Route of administration[6]				
Intravenous	52(85.2%)	3(100%)	0	0
Subcutaneous	7(11.5%)	0	0	1(100%)
Switched route	2(3.3%)	0	0	0

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Cumulative exposure (days)					
n	58	17	4	12	12
Mean (SD)	253.3(111.83)	251.0(110.08)	272.8(113.64)	235.2(101.77)	223.3(79.03)
Median	212.0	211.0	218.0	211.5	197.5
Min - Max	100 - 464	130 - 443	212 - 443	130 - 443	155 - 409
Q1, Q3	184.0,350.0	184.0,282.0	212.0,333.5	179.5,236.5	171.0,232.0
Route of administration[6]					
Intravenous	50(86.2%)	13(76.5%)	4(100%)	11(91.7%)	10(83.3%)
Subcutaneous	6(10.3%)	4(23.5%)	0	1(8.3%)	2(16.7%)
Switched route	2(3.4%)	0	0	0	0

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Other exposures during pregnancy				
Corticosteroids (For SLE ONLY)	32(52.5%)	1(33.3%)	0	1(100%)
Preconception	31(50.8%)	1(33.3%)	0	1(100%)
During pregnancy	30(49.2%)	0	0	1(100%)
1st trimester	28(45.9%)	0	0	0
2nd trimester	29(47.5%)	0	0	1(100%)
3rd trimester	27(44.3%)	0	0	1(100%)
NSAIDs	12(19.7%)	0	0	0
Preconception	11(18.0%)	0	0	0
During pregnancy	9(14.8%)	0	0	0
1st trimester	8(13.1%)	0	0	0
2nd trimester	5(8.2%)	0	0	0
3rd trimester	5(8.2%)	0	0	0

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Other exposures during pregnancy					
Corticosteroids (For SLE ONLY)	30(51.7%)	8(47.1%)	2(50.0%)	5(41.7%)	6(50.0%)
Preconception	29(50.0%)	8(47.1%)	2(50.0%)	5(41.7%)	6(50.0%)
During pregnancy	29(50.0%)	8(47.1%)	2(50.0%)	5(41.7%)	6(50.0%)
1st trimester	28(48.3%)	8(47.1%)	2(50.0%)	5(41.7%)	6(50.0%)
2nd trimester	28(48.3%)	8(47.1%)	2(50.0%)	5(41.7%)	6(50.0%)
3rd trimester	26(44.8%)	8(47.1%)	2(50.0%)	5(41.7%)	6(50.0%)
NSAIDs	12(20.7%)	3(17.6%)	2(50.0%)	4(33.3%)	3(25.0%)
Preconception	11(19.0%)	2(11.8%)	2(50.0%)	4(33.3%)	3(25.0%)
During pregnancy	9(15.5%)	1(5.9%)	1(25.0%)	3(25.0%)	2(16.7%)
1st trimester	8(13.8%)	1(5.9%)	0	2(16.7%)	1(8.3%)
2nd trimester	5(8.6%)	1(5.9%)	0	2(16.7%)	1(8.3%)
3rd trimester	5(8.6%)	1(5.9%)	1(25.0%)	3(25.0%)	2(16.7%)

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Anti-malarials	50(82.0%)	2(66.7%)	0	1(100%)
Preconception	50(82.0%)	2(66.7%)	0	1(100%)
During pregnancy	50(82.0%)	2(66.7%)	0	1(100%)
1st trimester	49(80.3%)	2(66.7%)	0	1(100%)
2nd trimester	50(82.0%)	2(66.7%)	0	1(100%)
3rd trimester	50(82.0%)	2(66.7%)	0	1(100%)
Folate	30(49.2%)	2(66.7%)	0	0
Preconception	26(42.6%)	2(66.7%)	0	0
During pregnancy	28(45.9%)	1(33.3%)	0	0
1st trimester	28(45.9%)	1(33.3%)	0	0
2nd trimester	28(45.9%)	1(33.3%)	0	0
3rd trimester	28(45.9%)	1(33.3%)	0	0

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Anti-malarials	47(81.0%)	13(76.5%)	4(100%)	11(91.7%)	10(83.3%)
Preconception	47(81.0%)	13(76.5%)	4(100%)	11(91.7%)	10(83.3%)
During pregnancy	47(81.0%)	13(76.5%)	4(100%)	11(91.7%)	10(83.3%)
1st trimester	46(79.3%)	12(70.6%)	4(100%)	11(91.7%)	9(75.0%)
2nd trimester	47(81.0%)	13(76.5%)	4(100%)	11(91.7%)	10(83.3%)
3rd trimester	47(81.0%)	13(76.5%)	4(100%)	11(91.7%)	10(83.3%)
Folate	28(48.3%)	8(47.1%)	3(75.0%)	7(58.3%)	9(75.0%)
Preconception	24(41.4%)	8(47.1%)	1(25.0%)	5(41.7%)	8(66.7%)
During pregnancy	27(46.6%)	8(47.1%)	3(75.0%)	7(58.3%)	9(75.0%)
1st trimester	27(46.6%)	8(47.1%)	3(75.0%)	7(58.3%)	9(75.0%)
2nd trimester	27(46.6%)	8(47.1%)	3(75.0%)	7(58.3%)	9(75.0%)
3rd trimester	27(46.6%)	8(47.1%)	3(75.0%)	7(58.3%)	9(75.0%)

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
ACE Inhibitors	3(4.9%)	0	0	0
Preconception	3(4.9%)	0	0	0
During pregnancy	2(3.3%)	0	0	0
1st trimester	2(3.3%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Calcium Channel Blockers	5(8.2%)	1(33.3%)	0	0
Preconception	5(8.2%)	1(33.3%)	0	0
During pregnancy	5(8.2%)	1(33.3%)	0	0
1st trimester	5(8.2%)	1(33.3%)	0	0
2nd trimester	5(8.2%)	1(33.3%)	0	0
3rd trimester	4(6.6%)	1(33.3%)	0	0

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
ACE Inhibitors	3(5.2%)	3(17.6%)	0	0	1(8.3%)
Preconception	3(5.2%)	3(17.6%)	0	0	1(8.3%)
During pregnancy	2(3.4%)	2(11.8%)	0	0	0
1st trimester	2(3.4%)	2(11.8%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Calcium Channel Blockers	4(6.9%)	0	0	0	0
Preconception	4(6.9%)	0	0	0	0
During pregnancy	4(6.9%)	0	0	0	0
1st trimester	4(6.9%)	0	0	0	0
2nd trimester	4(6.9%)	0	0	0	0
3rd trimester	3(5.2%)	0	0	0	0

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Beta Blockers	4(6.6%)	0	0	1(100%)
Preconception	4(6.6%)	0	0	1(100%)
During pregnancy	4(6.6%)	0	0	1(100%)
1st trimester	3(4.9%)	0	0	1(100%)
2nd trimester	4(6.6%)	0	0	1(100%)
3rd trimester	4(6.6%)	0	0	1(100%)
Angiotensin II Receptor Antagonists	3(4.9%)	0	0	0
Preconception	3(4.9%)	0	0	0
During pregnancy	2(3.3%)	0	0	0
1st trimester	2(3.3%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Beta Blockers	3(5.2%)	1(5.9%)	0	1(8.3%)	0
Preconception	3(5.2%)	1(5.9%)	0	1(8.3%)	0
During pregnancy	3(5.2%)	1(5.9%)	0	1(8.3%)	0
1st trimester	2(3.4%)	1(5.9%)	0	1(8.3%)	0
2nd trimester	3(5.2%)	1(5.9%)	0	1(8.3%)	0
3rd trimester	3(5.2%)	1(5.9%)	0	1(8.3%)	0
Angiotensin II Receptor Antagonists	3(5.2%)	2(11.8%)	0	0	0
Preconception	3(5.2%)	2(11.8%)	0	0	0
During pregnancy	2(3.4%)	1(5.9%)	0	0	0
1st trimester	2(3.4%)	1(5.9%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Insulin	2(3.3%)	0	0	0
Preconception	0	0	0	0
During pregnancy	2(3.3%)	0	0	0
1st trimester	2(3.3%)	0	0	0
2nd trimester	1(1.6%)	0	0	0
3rd trimester	1(1.6%)	0	0	0
Heparin	6(9.8%)	0	0	0
Preconception	3(4.9%)	0	0	0
During pregnancy	6(9.8%)	0	0	0
1st trimester	5(8.2%)	0	0	0
2nd trimester	5(8.2%)	0	0	0
3rd trimester	5(8.2%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Insulin	2(3.4%)	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	2(3.4%)	0	0	0	0
1st trimester	2(3.4%)	0	0	0	0
2nd trimester	1(1.7%)	0	0	0	0
3rd trimester	1(1.7%)	0	0	0	0
Heparin	6(10.3%)	1(5.9%)	0	1(8.3%)	2(16.7%)
Preconception	3(5.2%)	1(5.9%)	0	1(8.3%)	2(16.7%)
During pregnancy	6(10.3%)	1(5.9%)	0	1(8.3%)	2(16.7%)
1st trimester	5(8.6%)	1(5.9%)	0	1(8.3%)	2(16.7%)
2nd trimester	5(8.6%)	1(5.9%)	0	1(8.3%)	2(16.7%)
3rd trimester	5(8.6%)	1(5.9%)	0	1(8.3%)	2(16.7%)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Aspirin	24(39.3%)	0	0	1(100%)
Preconception	16(26.2%)	0	0	1(100%)
During pregnancy	24(39.3%)	0	0	1(100%)
1st trimester	22(36.1%)	0	0	0
2nd trimester	24(39.3%)	0	0	1(100%)
3rd trimester	24(39.3%)	0	0	1(100%)
Epilepsy	6(9.8%)	0	0	0
Medication				
Preconception	6(9.8%)	0	0	0
During pregnancy	6(9.8%)	0	0	0
1st trimester	6(9.8%)	0	0	0
2nd trimester	5(8.2%)	0	0	0
3rd trimester	5(8.2%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Aspirin	23(39.7%)	8(47.1%)	3(75.0%)	7(58.3%)	4(33.3%)
Preconception	15(25.9%)	5(29.4%)	2(50.0%)	5(41.7%)	2(16.7%)
During pregnancy	23(39.7%)	8(47.1%)	3(75.0%)	7(58.3%)	4(33.3%)
1st trimester	22(37.9%)	8(47.1%)	3(75.0%)	7(58.3%)	4(33.3%)
2nd trimester	23(39.7%)	8(47.1%)	3(75.0%)	7(58.3%)	4(33.3%)
3rd trimester	23(39.7%)	8(47.1%)	3(75.0%)	7(58.3%)	4(33.3%)
Epilepsy	6(10.3%)	2(11.8%)	0	0	2(16.7%)
Medication					
Preconception	6(10.3%)	2(11.8%)	0	0	2(16.7%)
During pregnancy	6(10.3%)	2(11.8%)	0	0	2(16.7%)
1st trimester	6(10.3%)	2(11.8%)	0	0	2(16.7%)
2nd trimester	5(8.6%)	2(11.8%)	0	0	2(16.7%)
3rd trimester	5(8.6%)	2(11.8%)	0	0	2(16.7%)

Note: See footnotes on Page 1.
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Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Other Immunosuppressants[7]	24(39.3%)	1(33.3%)	0	0
Preconception	23(37.7%)	1(33.3%)	0	0
During pregnancy	17(27.9%)	0	0	0
1st trimester	17(27.9%)	0	0	0
2nd trimester	10(16.4%)	0	0	0
3rd trimester	9(14.8%)	0	0	0
Azathioprine	14(23.0%)	0	0	0
Preconception	11(18.0%)	0	0	0
During pregnancy	10(16.4%)	0	0	0
1st trimester	10(16.4%)	0	0	0
2nd trimester	8(13.1%)	0	0	0
3rd trimester	8(13.1%)	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Other Immunosuppressants[7]	23(39.7%)	7(41.2%)	4(100%)	7(58.3%)	5(41.7%)
Preconception	22(37.9%)	6(35.3%)	4(100%)	7(58.3%)	5(41.7%)
During pregnancy	17(29.3%)	4(23.5%)	2(50.0%)	4(33.3%)	4(33.3%)
1st trimester	17(29.3%)	4(23.5%)	2(50.0%)	4(33.3%)	4(33.3%)
2nd trimester	10(17.2%)	1(5.9%)	2(50.0%)	4(33.3%)	3(25.0%)
3rd trimester	9(15.5%)	1(5.9%)	2(50.0%)	4(33.3%)	3(25.0%)
Azathioprine	14(24.1%)	3(17.6%)	2(50.0%)	4(33.3%)	4(33.3%)
Preconception	11(19.0%)	2(11.8%)	2(50.0%)	4(33.3%)	3(25.0%)
During pregnancy	10(17.2%)	1(5.9%)	2(50.0%)	4(33.3%)	2(16.7%)
1st trimester	10(17.2%)	1(5.9%)	2(50.0%)	4(33.3%)	2(16.7%)
2nd trimester	8(13.8%)	1(5.9%)	2(50.0%)	4(33.3%)	2(16.7%)
3rd trimester	8(13.8%)	1(5.9%)	2(50.0%)	4(33.3%)	2(16.7%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Cyclophosphamide	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Methotrexate	8(13.1%)	1(33.3%)	0	0
Preconception	8(13.1%)	1(33.3%)	0	0
During pregnancy	5(8.2%)	0	0	0
1st trimester	5(8.2%)	0	0	0
2nd trimester	1(1.6%)	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Cyclophosphamide	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Methotrexate	7(12.1%)	2(11.8%)	0	0	1(8.3%)
Preconception	7(12.1%)	2(11.8%)	0	0	1(8.3%)
During pregnancy	5(8.6%)	2(11.8%)	0	0	1(8.3%)
1st trimester	5(8.6%)	2(11.8%)	0	0	1(8.3%)
2nd trimester	1(1.7%)	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Mycophenolate	6(9.8%)	0	0	0
Preconception	5(8.2%)	0	0	0
During pregnancy	2(3.3%)	0	0	0
1st trimester	2(3.3%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Cyclosporin	2(3.3%)	0	0	0
Preconception	2(3.3%)	0	0	0
During pregnancy	2(3.3%)	0	0	0
1st trimester	2(3.3%)	0	0	0
2nd trimester	1(1.6%)	0	0	0
3rd trimester	1(1.6%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Mycophenolate	6(10.3%)	3(17.6%)	2(50.0%)	4(33.3%)	0
Preconception	5(8.6%)	3(17.6%)	2(50.0%)	3(25.0%)	0
During pregnancy	2(3.4%)	2(11.8%)	0	0	0
1st trimester	2(3.4%)	2(11.8%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Cyclosporin	2(3.4%)	0	0	1(8.3%)	1(8.3%)
Preconception	2(3.4%)	0	0	1(8.3%)	1(8.3%)
During pregnancy	2(3.4%)	0	0	1(8.3%)	1(8.3%)
1st trimester	2(3.4%)	0	0	1(8.3%)	1(8.3%)
2nd trimester	1(1.7%)	0	0	0	1(8.3%)
3rd trimester	1(1.7%)	0	0	0	1(8.3%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Total[1,8] (N=61)	SAB[8] (N=3)	Elective terms (N=0)	Still-births (N=1)
Rituximab	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.1
Exposures of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

	Live Births [8] (N=58)	Preterm[8] (N=17)	SGA[2] (N=4)	SGA[3] (N=12)	Birth Defects (N=12)
Rituximab	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Note: Denominator is the total number of participants in each column (N). ACE inhibitors=angiotensin-converting-enzyme inhibitors; NSAIDs=non-steroidal anti-inflammatory drugs; SAB=spontaneous miscarriage; SGA=small for gestational age.
Exposure is defined as at least one dose during the period of observation (6 months prior to/during pregnancy for concomitant medications and 4 months prior to/during pregnancy for commercial belimumab) and does not imply continued use throughout the period of observation. Preconception is defined as six months prior to pregnancy for concomitant medications and 4 months prior to/during pregnancy for commercial belimumab. Participants may be presented in one or several time points and may be exposed to one or several medications; therefore, percentages may not add to 100%. For Rituximab and Anti-Malarials half-lives are assessed to determine the trimester of exposure.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births. Ectopic and molar pregnancies have not been reported to date.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Preconception occurs within 4 months prior to conception. The first trimester begins the day after date of conception, the second trimester begins at week $14^{0/7}$ after the date of conception, and the third trimester begins at week $28^{0/7}$.
[5]Defined by the last recorded exposure with a non-missing treatment date.
[6]Considering timing of enrollment, participants with unknown routes of exposure are summarized under intravenous route.
[7]Includes azathioprine, cyclophosphamide, methotrexate, mycophenolate, cyclosporin, and rituximab.
[8]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.

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Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Earliest Belimumab exposure [4,5]				
Preconception	17(100%)	2(100%)	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Last Belimumab exposure [4,5]				
Preconception	0	0	0	0
1st trimester	2(11.8%)	0	0	0
2nd trimester	8(47.1%)	1(50.0%)	0	0
3rd trimester	0	0	0	0
Postpartum	7(41.2%)	1(50.0%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Earliest Belimumab exposure [4,5]					
Preconception	16(100%)	6(100%)	0	2(100%)	1(100%)
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Last Belimumab exposure [4,5]					
Preconception	0	0	0	0	0
1st trimester	2(12.5%)	0	0	0	0
2nd trimester	8(50.0%)	4(66.7%)	0	2(100%)	1(100%)
3rd trimester	0	0	0	0	0
Postpartum	6(37.5%)	2(33.3%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Exposure by study timepoints [4,5]				
Preconception through 1st trimester	2(11.8%)	0	0	0
Preconception through 2nd trimester	8(47.1%)	1(50.0%)	0	0
Preconception through 3rd trimester	0	0	0	0
Preconception through post-pregnancy	7(41.2%)	1(50.0%)	0	0
1st trimester through 2nd trimester	0	0	0	0
1st trimester through 3rd trimester	0	0	0	0
1st trimester through post-pregnancy	0	0	0	0
2nd trimester through 3rd trimester	0	0	0	0
2nd trimester through post-pregnancy	0	0	0	0
3rd trimester through post-pregnancy	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Exposure by study timepoints [4,5]					
Preconception through 1st trimester	2(12.5%)	0	0	0	0
Preconception through 2nd trimester	8(50.0%)	4(66.7%)	0	2(100%)	1(100%)
Preconception through 3rd trimester	0	0	0	0	0
Preconception through post-pregnancy	6(37.5%)	2(33.3%)	0	0	0
1st trimester through 2nd trimester	0	0	0	0	0
1st trimester through 3rd trimester	0	0	0	0	0
1st trimester through post-pregnancy	0	0	0	0	0
2nd trimester through 3rd trimester	0	0	0	0	0
2nd trimester through post-pregnancy	0	0	0	0	0
3rd trimester through post-pregnancy	0	0	0	0	0

Note: See footnotes on Page 1.
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Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Cumulative exposure (days)				
n	17	2	0	0
Mean (SD)	285.4(109.78)	240.5(0.71)	-	-
Median	241.0	240.5	-	-
Min - Max	142 - 461	240 - 241	-	-
Q1, Q3	211.0,404.0	240.0,241.0	-	-
Route of administration[6]				
Intravenous	15(88.2%)	2(100%)	0	0
Subcutaneous	2(11.8%)	0	0	0
Switched route	0	0	0	0

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Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Cumulative exposure (days)					
n	16	6	0	2	1
Mean (SD)	288.2(112.73)	300.8(107.24)	-	230.0(26.87)	155.0 (-)
Median	245.0	261.5	-	230.0	155.0
Min - Max	142 - 461	202 - 435	-	211 - 249	155 - 155
Q1, Q3	206.5,419.0	211.0,434.0	-	211.0,249.0	155.0,155.0
Route of administration[6]					
Intravenous	14(87.5%)	4(66.7%)	0	2(100%)	1(100%)
Subcutaneous	2(12.5%)	2(33.3%)	0	0	0
Switched route	0	0	0	0	0

Note: See footnotes on Page 1.
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Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Other exposures during pregnancy				
Corticosteroids (For SLE ONLY)	9(52.9%)	0	0	0
Preconception	9(52.9%)	0	0	0
During pregnancy	8(47.1%)	0	0	0
1st trimester	8(47.1%)	0	0	0
2nd trimester	8(47.1%)	0	0	0
3rd trimester	8(47.1%)	0	0	0
NSAIDs	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Other exposures during pregnancy					
Corticosteroids (For SLE ONLY)	9(56.3%)	3(50.0%)	0	1(50.0%)	1(100%)
Preconception	9(56.3%)	3(50.0%)	0	1(50.0%)	1(100%)
During pregnancy	8(50.0%)	3(50.0%)	0	1(50.0%)	1(100%)
1st trimester	8(50.0%)	3(50.0%)	0	1(50.0%)	1(100%)
2nd trimester	8(50.0%)	3(50.0%)	0	1(50.0%)	1(100%)
3rd trimester	8(50.0%)	3(50.0%)	0	1(50.0%)	1(100%)
NSAIDs	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Anti-malarials	13(76.5%)	1(50.0%)	0	0
Preconception	13(76.5%)	1(50.0%)	0	0
During pregnancy	13(76.5%)	1(50.0%)	0	0
1st trimester	13(76.5%)	1(50.0%)	0	0
2nd trimester	13(76.5%)	1(50.0%)	0	0
3rd trimester	13(76.5%)	1(50.0%)	0	0
Folate	7(41.2%)	1(50.0%)	0	0
Preconception	6(35.3%)	1(50.0%)	0	0
During pregnancy	7(41.2%)	1(50.0%)	0	0
1st trimester	7(41.2%)	1(50.0%)	0	0
2nd trimester	7(41.2%)	1(50.0%)	0	0
3rd trimester	7(41.2%)	1(50.0%)	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Anti-malarials	12(75.0%)	3(50.0%)	0	2(100%)	1(100%)
Preconception	12(75.0%)	3(50.0%)	0	2(100%)	1(100%)
During pregnancy	12(75.0%)	3(50.0%)	0	2(100%)	1(100%)
1st trimester	12(75.0%)	3(50.0%)	0	2(100%)	1(100%)
2nd trimester	12(75.0%)	3(50.0%)	0	2(100%)	1(100%)
3rd trimester	12(75.0%)	3(50.0%)	0	2(100%)	1(100%)
Folate	6(37.5%)	2(33.3%)	0	1(50.0%)	1(100%)
Preconception	5(31.3%)	2(33.3%)	0	1(50.0%)	1(100%)
During pregnancy	6(37.5%)	2(33.3%)	0	1(50.0%)	1(100%)
1st trimester	6(37.5%)	2(33.3%)	0	1(50.0%)	1(100%)
2nd trimester	6(37.5%)	2(33.3%)	0	1(50.0%)	1(100%)
3rd trimester	6(37.5%)	2(33.3%)	0	1(50.0%)	1(100%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
ACE Inhibitors	1(5.9%)	0	0	0
Preconception	1(5.9%)	0	0	0
During pregnancy	1(5.9%)	0	0	0
1st trimester	1(5.9%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Calcium Channel Blockers	2(11.8%)	1(50.0%)	0	0
Preconception	2(11.8%)	1(50.0%)	0	0
During pregnancy	2(11.8%)	1(50.0%)	0	0
1st trimester	2(11.8%)	1(50.0%)	0	0
2nd trimester	2(11.8%)	1(50.0%)	0	0
3rd trimester	2(11.8%)	1(50.0%)	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
ACE Inhibitors	1(6.3%)	1(16.7%)	0	0	0
Preconception	1(6.3%)	1(16.7%)	0	0	0
During pregnancy	1(6.3%)	1(16.7%)	0	0	0
1st trimester	1(6.3%)	1(16.7%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Calcium Channel Blockers	1(6.3%)	0	0	0	0
Preconception	1(6.3%)	0	0	0	0
During pregnancy	1(6.3%)	0	0	0	0
1st trimester	1(6.3%)	0	0	0	0
2nd trimester	1(6.3%)	0	0	0	0
3rd trimester	1(6.3%)	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Beta Blockers	1(5.9%)	0	0	0
Preconception	1(5.9%)	0	0	0
During pregnancy	1(5.9%)	0	0	0
1st trimester	1(5.9%)	0	0	0
2nd trimester	1(5.9%)	0	0	0
3rd trimester	1(5.9%)	0	0	0
Angiotensin II Receptor Antagonists	2(11.8%)	0	0	0
Preconception	2(11.8%)	0	0	0
During pregnancy	2(11.8%)	0	0	0
1st trimester	2(11.8%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Beta Blockers	1(6.3%)	1(16.7%)	0	1(50.0%)	0
Preconception	1(6.3%)	1(16.7%)	0	1(50.0%)	0
During pregnancy	1(6.3%)	1(16.7%)	0	1(50.0%)	0
1st trimester	1(6.3%)	1(16.7%)	0	1(50.0%)	0
2nd trimester	1(6.3%)	1(16.7%)	0	1(50.0%)	0
3rd trimester	1(6.3%)	1(16.7%)	0	1(50.0%)	0
Angiotensin II Receptor Antagonists	2(12.5%)	1(16.7%)	0	0	0
Preconception	2(12.5%)	1(16.7%)	0	0	0
During pregnancy	2(12.5%)	1(16.7%)	0	0	0
1st trimester	2(12.5%)	1(16.7%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Insulin	1(5.9%)	0	0	0
Preconception	0	0	0	0
During pregnancy	1(5.9%)	0	0	0
1st trimester	1(5.9%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Heparin	1(5.9%)	0	0	0
Preconception	0	0	0	0
During pregnancy	1(5.9%)	0	0	0
1st trimester	1(5.9%)	0	0	0
2nd trimester	1(5.9%)	0	0	0
3rd trimester	1(5.9%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Insulin	1(6.3%)	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	1(6.3%)	0	0	0	0
1st trimester	1(6.3%)	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Heparin	1(6.3%)	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	1(6.3%)	0	0	0	0
1st trimester	1(6.3%)	0	0	0	0
2nd trimester	1(6.3%)	0	0	0	0
3rd trimester	1(6.3%)	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Aspirin	4(23.5%)	0	0	0
Preconception	3(17.6%)	0	0	0
During pregnancy	4(23.5%)	0	0	0
1st trimester	4(23.5%)	0	0	0
2nd trimester	4(23.5%)	0	0	0
3rd trimester	4(23.5%)	0	0	0
Epilepsy	1(5.9%)	0	0	0
Medication				
Preconception	1(5.9%)	0	0	0
During pregnancy	1(5.9%)	0	0	0
1st trimester	1(5.9%)	0	0	0
2nd trimester	1(5.9%)	0	0	0
3rd trimester	1(5.9%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Aspirin	4(25.0%)	3(50.0%)	0	1(50.0%)	0
Preconception	3(18.8%)	2(33.3%)	0	1(50.0%)	0
During pregnancy	4(25.0%)	3(50.0%)	0	1(50.0%)	0
1st trimester	4(25.0%)	3(50.0%)	0	1(50.0%)	0
2nd trimester	4(25.0%)	3(50.0%)	0	1(50.0%)	0
3rd trimester	4(25.0%)	3(50.0%)	0	1(50.0%)	0
Epilepsy	1(6.3%)	1(16.7%)	0	0	0
Medication					
Preconception	1(6.3%)	1(16.7%)	0	0	0
During pregnancy	1(6.3%)	1(16.7%)	0	0	0
1st trimester	1(6.3%)	1(16.7%)	0	0	0
2nd trimester	1(6.3%)	1(16.7%)	0	0	0
3rd trimester	1(6.3%)	1(16.7%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Other Immunosuppressants[7]	2(11.8%)	0	0	0
Preconception	2(11.8%)	0	0	0
During pregnancy	2(11.8%)	0	0	0
1st trimester	2(11.8%)	0	0	0
2nd trimester	1(5.9%)	0	0	0
3rd trimester	1(5.9%)	0	0	0
Azathioprine	1(5.9%)	0	0	0
Preconception	1(5.9%)	0	0	0
During pregnancy	1(5.9%)	0	0	0
1st trimester	1(5.9%)	0	0	0
2nd trimester	1(5.9%)	0	0	0
3rd trimester	1(5.9%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Other Immunosuppressants[7]	2(12.5%)	1(16.7%)	0	1(50.0%)	0
Preconception	2(12.5%)	1(16.7%)	0	1(50.0%)	0
During pregnancy	2(12.5%)	1(16.7%)	0	1(50.0%)	0
1st trimester	2(12.5%)	1(16.7%)	0	1(50.0%)	0
2nd trimester	1(6.3%)	0	0	1(50.0%)	0
3rd trimester	1(6.3%)	0	0	1(50.0%)	0
Azathioprine	1(6.3%)	0	0	1(50.0%)	0
Preconception	1(6.3%)	0	0	1(50.0%)	0
During pregnancy	1(6.3%)	0	0	1(50.0%)	0
1st trimester	1(6.3%)	0	0	1(50.0%)	0
2nd trimester	1(6.3%)	0	0	1(50.0%)	0
3rd trimester	1(6.3%)	0	0	1(50.0%)	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Cyclophosphamide	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Methotrexate	1(5.9%)	0	0	0
Preconception	1(5.9%)	0	0	0
During pregnancy	1(5.9%)	0	0	0
1st trimester	1(5.9%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
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Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Cyclophosphamide	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Methotrexate	1(6.3%)	1(16.7%)	0	0	0
Preconception	1(6.3%)	1(16.7%)	0	0	0
During pregnancy	1(6.3%)	1(16.7%)	0	0	0
1st trimester	1(6.3%)	1(16.7%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Mycophenolate	2(11.8%)	0	0	0
Preconception	1(5.9%)	0	0	0
During pregnancy	1(5.9%)	0	0	0
1st trimester	1(5.9%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Cyclosporin	1(5.9%)	0	0	0
Preconception	1(5.9%)	0	0	0
During pregnancy	1(5.9%)	0	0	0
1st trimester	1(5.9%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Mycophenolate	2(12.5%)	1(16.7%)	0	1(50.0%)	0
Preconception	1(6.3%)	1(16.7%)	0	0	0
During pregnancy	1(6.3%)	1(16.7%)	0	0	0
1st trimester	1(6.3%)	1(16.7%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Cyclosporin	1(6.3%)	0	0	1(50.0%)	0
Preconception	1(6.3%)	0	0	1(50.0%)	0
During pregnancy	1(6.3%)	0	0	1(50.0%)	0
1st trimester	1(6.3%)	0	0	1(50.0%)	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Total[1,8] (N=17)	SAB[8] (N=2)	Elective terms (N=0)	Still-births (N=0)
Rituximab	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.2
Exposures of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

	Live Births [8] (N=16)	Preterm[8] (N=6)	SGA[2] (N=0)	SGA[3] (N=2)	Birth Defects (N=1)
Rituximab	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Note: Denominator is the total number of participants in each column (N). ACE inhibitors=angiotensin-converting-enzyme inhibitors; NSAIDs=non-steroidal anti-inflammatory drugs; SAB=spontaneous miscarriage; SGA=small for gestational age.
Exposure is defined as at least one dose during the period of observation (6 months prior to/during pregnancy for concomitant medications and 4 months prior to/during pregnancy for commercial belimumab) and does not imply continued use throughout the period of observation. Preconception is defined as six months prior to pregnancy for concomitant medications and 4 months prior to/during pregnancy for commercial belimumab. Participants may be presented in one or several time points and may be exposed to one or several medications; therefore, percentages may not add to 100%. For Rituximab and Anti-Malarials half-lives are assessed to determine the trimester of exposure.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births. Ectopic and molar pregnancies have not been reported to date.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Preconception occurs within 4 months prior to conception. The first trimester begins the day after date of conception, the second trimester begins at week $14^{0/7}$ after the date of conception, and the third trimester begins at week $28^{0/7}$.
[5]Defined by the last recorded exposure with a non-missing treatment date.
[6]Considering timing of enrollment, participants with unknown routes of exposure are summarized under intravenous route.
[7]Includes azathioprine, cyclophosphamide, methotrexate, mycophenolate, cyclosporin, and rituximab.

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Protocol: BEL114256
Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Earliest Belimumab exposure [4,5]				
Preconception	40(90.9%)	1(100%)	0	0
1st trimester	2(4.5%)	0	0	0
2nd trimester	2(4.5%)	0	0	1(100%)
3rd trimester	0	0	0	0
Last Belimumab exposure [4,5]				
Preconception	0	0	0	0
1st trimester	7(15.9%)	0	0	0
2nd trimester	24(54.5%)	0	0	0
3rd trimester	1(2.3%)	0	0	0
Postpartum	12(27.3%)	1(100%)	0	1(100%)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Earliest Belimumab exposure [4,5]					
Preconception	39(92.9%)	11(100%)	3(75.0%)	9(90.0%)	10(90.9%)
1st trimester	2(4.8%)	0	0	0	1(9.1%)
2nd trimester	1(2.4%)	0	1(25.0%)	1(10.0%)	0
3rd trimester	0	0	0	0	0
Last Belimumab exposure [4,5]					
Preconception	0	0	0	0	0
1st trimester	7(16.7%)	5(45.5%)	0	1(10.0%)	3(27.3%)
2nd trimester	24(57.1%)	4(36.4%)	2(50.0%)	6(60.0%)	6(54.5%)
3rd trimester	1(2.4%)	0	0	0	0
Postpartum	10(23.8%)	2(18.2%)	2(50.0%)	3(30.0%)	2(18.2%)

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Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Exposure by study timepoints [4,5]				
Preconception through 1st trimester	7(15.9%)	0	0	0
Preconception through 2nd trimester	23(52.3%)	0	0	0
Preconception through 3rd trimester	1(2.3%)	0	0	0
Preconception through post-pregnancy	9(20.5%)	1(100%)	0	0
1st trimester through 2nd trimester	1(2.3%)	0	0	0
1st trimester through 3rd trimester	0	0	0	0
1st trimester through post-pregnancy	1(2.3%)	0	0	0
2nd trimester through 3rd trimester	0	0	0	0
2nd trimester through post-pregnancy	2(4.5%)	0	0	1(100%)
3rd trimester through post-pregnancy	0	0	0	0

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Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Exposure by study timepoints [4,5]					
Preconception through 1st trimester	7(16.7%)	5(45.5%)	0	1(10.0%)	3(27.3%)
Preconception through 2nd trimester	23(54.8%)	4(36.4%)	2(50.0%)	6(60.0%)	6(54.5%)
Preconception through 3rd trimester	1(2.4%)	0	0	0	0
Preconception through post-pregnancy	8(19.0%)	2(18.2%)	1(25.0%)	2(20.0%)	1(9.1%)
1st trimester through 2nd trimester	1(2.4%)	0	0	0	0
1st trimester through 3rd trimester	0	0	0	0	0
1st trimester through post-pregnancy	1(2.4%)	0	0	0	1(9.1%)
2nd trimester through 3rd trimester	0	0	0	0	0
2nd trimester through post-pregnancy	1(2.4%)	0	1(25.0%)	1(10.0%)	0
3rd trimester through post-pregnancy	0	0	0	0	0

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Protocol: BEL114256
Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Cumulative exposure (days)				
n	44	1	0	1
Mean (SD)	236.5(108.66)	183.0 (-)	-	142.0 (-)
Median	197.5	183.0	-	142.0
Min - Max	100 - 464	183 - 183	-	142 - 142
Q1, Q3	164.5,238.0	183.0,183.0	-	142.0,142.0
Route of administration[6]				
Intravenous	37(84.1%)	1(100%)	0	0
Subcutaneous	5(11.4%)	0	0	1(100%)
Switched route	2(4.5%)	0	0	0

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Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Cumulative exposure (days)					
n	42	11	4	10	11
Mean (SD)	240.0(109.92)	223.8(106.47)	272.8(113.64)	236.2(112.12)	229.5(79.76)
Median	203.0	184.0	218.0	211.5	198.0
Min - Max	100 - 464	130 - 443	212 - 443	130 - 443	156 - 409
Q1, Q3	166.0,252.0	156.0,252.0	212.0,333.5	163.0,224.0	184.0,252.0
Route of administration[6]					
Intravenous	36(85.7%)	9(81.8%)	4(100%)	9(90.0%)	9(81.8%)
Subcutaneous	4(9.5%)	2(18.2%)	0	1(10.0%)	2(18.2%)
Switched route	2(4.8%)	0	0	0	0

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Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Other exposures during pregnancy				
Corticosteroids	23(52.3%)	1(100%)	0	1(100%)
(For SLE ONLY)				
Preconception	22(50.0%)	1(100%)	0	1(100%)
During pregnancy	22(50.0%)	0	0	1(100%)
1st trimester	20(45.5%)	0	0	0
2nd trimester	21(47.7%)	0	0	1(100%)
3rd trimester	19(43.2%)	0	0	1(100%)
NSAIDs	12(27.3%)	0	0	0
Preconception	11(25.0%)	0	0	0
During pregnancy	9(20.5%)	0	0	0
1st trimester	8(18.2%)	0	0	0
2nd trimester	5(11.4%)	0	0	0
3rd trimester	5(11.4%)	0	0	0

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Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Other exposures during pregnancy					
Corticosteroids (For SLE ONLY)	21(50.0%)	5(45.5%)	2(50.0%)	4(40.0%)	5(45.5%)
Preconception	20(47.6%)	5(45.5%)	2(50.0%)	4(40.0%)	5(45.5%)
During pregnancy	21(50.0%)	5(45.5%)	2(50.0%)	4(40.0%)	5(45.5%)
1st trimester	20(47.6%)	5(45.5%)	2(50.0%)	4(40.0%)	5(45.5%)
2nd trimester	20(47.6%)	5(45.5%)	2(50.0%)	4(40.0%)	5(45.5%)
3rd trimester	18(42.9%)	5(45.5%)	2(50.0%)	4(40.0%)	5(45.5%)
NSAIDs	12(28.6%)	3(27.3%)	2(50.0%)	4(40.0%)	3(27.3%)
Preconception	11(26.2%)	2(18.2%)	2(50.0%)	4(40.0%)	3(27.3%)
During pregnancy	9(21.4%)	1(9.1%)	1(25.0%)	3(30.0%)	2(18.2%)
1st trimester	8(19.0%)	1(9.1%)	0	2(20.0%)	1(9.1%)
2nd trimester	5(11.9%)	1(9.1%)	0	2(20.0%)	1(9.1%)
3rd trimester	5(11.9%)	1(9.1%)	1(25.0%)	3(30.0%)	2(18.2%)

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Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Anti-malarials	37(84.1%)	1(100%)	0	1(100%)
Preconception	37(84.1%)	1(100%)	0	1(100%)
During pregnancy	37(84.1%)	1(100%)	0	1(100%)
1st trimester	36(81.8%)	1(100%)	0	1(100%)
2nd trimester	37(84.1%)	1(100%)	0	1(100%)
3rd trimester	37(84.1%)	1(100%)	0	1(100%)
Folate	23(52.3%)	1(100%)	0	0
Preconception	20(45.5%)	1(100%)	0	0
During pregnancy	21(47.7%)	0	0	0
1st trimester	21(47.7%)	0	0	0
2nd trimester	21(47.7%)	0	0	0
3rd trimester	21(47.7%)	0	0	0

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Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Anti-malarials	35(83.3%)	10(90.9%)	4(100%)	9(90.0%)	9(81.8%)
Preconception	35(83.3%)	10(90.9%)	4(100%)	9(90.0%)	9(81.8%)
During pregnancy	35(83.3%)	10(90.9%)	4(100%)	9(90.0%)	9(81.8%)
1st trimester	34(81.0%)	9(81.8%)	4(100%)	9(90.0%)	8(72.7%)
2nd trimester	35(83.3%)	10(90.9%)	4(100%)	9(90.0%)	9(81.8%)
3rd trimester	35(83.3%)	10(90.9%)	4(100%)	9(90.0%)	9(81.8%)
Folate	22(52.4%)	6(54.5%)	3(75.0%)	6(60.0%)	8(72.7%)
Preconception	19(45.2%)	6(54.5%)	1(25.0%)	4(40.0%)	7(63.6%)
During pregnancy	21(50.0%)	6(54.5%)	3(75.0%)	6(60.0%)	8(72.7%)
1st trimester	21(50.0%)	6(54.5%)	3(75.0%)	6(60.0%)	8(72.7%)
2nd trimester	21(50.0%)	6(54.5%)	3(75.0%)	6(60.0%)	8(72.7%)
3rd trimester	21(50.0%)	6(54.5%)	3(75.0%)	6(60.0%)	8(72.7%)

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Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
ACE Inhibitors	2(4.5%)	0	0	0
Preconception	2(4.5%)	0	0	0
During pregnancy	1(2.3%)	0	0	0
1st trimester	1(2.3%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Calcium Channel Blockers	3(6.8%)	0	0	0
Preconception	3(6.8%)	0	0	0
During pregnancy	3(6.8%)	0	0	0
1st trimester	3(6.8%)	0	0	0
2nd trimester	3(6.8%)	0	0	0
3rd trimester	2(4.5%)	0	0	0

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Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
ACE Inhibitors	2(4.8%)	2(18.2%)	0	0	1(9.1%)
Preconception	2(4.8%)	2(18.2%)	0	0	1(9.1%)
During pregnancy	1(2.4%)	1(9.1%)	0	0	0
1st trimester	1(2.4%)	1(9.1%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Calcium Channel Blockers	3(7.1%)	0	0	0	0
Preconception	3(7.1%)	0	0	0	0
During pregnancy	3(7.1%)	0	0	0	0
1st trimester	3(7.1%)	0	0	0	0
2nd trimester	3(7.1%)	0	0	0	0
3rd trimester	2(4.8%)	0	0	0	0

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Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Beta Blockers	3(6.8%)	0	0	1(100%)
Preconception	3(6.8%)	0	0	1(100%)
During pregnancy	3(6.8%)	0	0	1(100%)
1st trimester	2(4.5%)	0	0	1(100%)
2nd trimester	3(6.8%)	0	0	1(100%)
3rd trimester	3(6.8%)	0	0	1(100%)
Angiotensin II Receptor Antagonists	1(2.3%)	0	0	0
Preconception	1(2.3%)	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

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Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Beta Blockers	2(4.8%)	0	0	0	0
Preconception	2(4.8%)	0	0	0	0
During pregnancy	2(4.8%)	0	0	0	0
1st trimester	1(2.4%)	0	0	0	0
2nd trimester	2(4.8%)	0	0	0	0
3rd trimester	2(4.8%)	0	0	0	0
Angiotensin II Receptor Antagonists	1(2.4%)	1(9.1%)	0	0	0
Preconception	1(2.4%)	1(9.1%)	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

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Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Insulin	1(2.3%)	0	0	0
Preconception	0	0	0	0
During pregnancy	1(2.3%)	0	0	0
1st trimester	1(2.3%)	0	0	0
2nd trimester	1(2.3%)	0	0	0
3rd trimester	1(2.3%)	0	0	0
Heparin	5(11.4%)	0	0	0
Preconception	3(6.8%)	0	0	0
During pregnancy	5(11.4%)	0	0	0
1st trimester	4(9.1%)	0	0	0
2nd trimester	4(9.1%)	0	0	0
3rd trimester	4(9.1%)	0	0	0

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Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Insulin	1(2.4%)	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	1(2.4%)	0	0	0	0
1st trimester	1(2.4%)	0	0	0	0
2nd trimester	1(2.4%)	0	0	0	0
3rd trimester	1(2.4%)	0	0	0	0
Heparin	5(11.9%)	1(9.1%)	0	1(10.0%)	2(18.2%)
Preconception	3(7.1%)	1(9.1%)	0	1(10.0%)	2(18.2%)
During pregnancy	5(11.9%)	1(9.1%)	0	1(10.0%)	2(18.2%)
1st trimester	4(9.5%)	1(9.1%)	0	1(10.0%)	2(18.2%)
2nd trimester	4(9.5%)	1(9.1%)	0	1(10.0%)	2(18.2%)
3rd trimester	4(9.5%)	1(9.1%)	0	1(10.0%)	2(18.2%)

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Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Aspirin	20(45.5%)	0	0	1(100%)
Preconception	13(29.5%)	0	0	1(100%)
During pregnancy	20(45.5%)	0	0	1(100%)
1st trimester	18(40.9%)	0	0	0
2nd trimester	20(45.5%)	0	0	1(100%)
3rd trimester	20(45.5%)	0	0	1(100%)
Epilepsy	5(11.4%)	0	0	0
Medication				
Preconception	5(11.4%)	0	0	0
During pregnancy	5(11.4%)	0	0	0
1st trimester	5(11.4%)	0	0	0
2nd trimester	4(9.1%)	0	0	0
3rd trimester	4(9.1%)	0	0	0

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Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Aspirin	19(45.2%)	5(45.5%)	3(75.0%)	6(60.0%)	4(36.4%)
Preconception	12(28.6%)	3(27.3%)	2(50.0%)	4(40.0%)	2(18.2%)
During pregnancy	19(45.2%)	5(45.5%)	3(75.0%)	6(60.0%)	4(36.4%)
1st trimester	18(42.9%)	5(45.5%)	3(75.0%)	6(60.0%)	4(36.4%)
2nd trimester	19(45.2%)	5(45.5%)	3(75.0%)	6(60.0%)	4(36.4%)
3rd trimester	19(45.2%)	5(45.5%)	3(75.0%)	6(60.0%)	4(36.4%)
Epilepsy	5(11.9%)	1(9.1%)	0	0	2(18.2%)
Medication					
Preconception	5(11.9%)	1(9.1%)	0	0	2(18.2%)
During pregnancy	5(11.9%)	1(9.1%)	0	0	2(18.2%)
1st trimester	5(11.9%)	1(9.1%)	0	0	2(18.2%)
2nd trimester	4(9.5%)	1(9.1%)	0	0	2(18.2%)
3rd trimester	4(9.5%)	1(9.1%)	0	0	2(18.2%)

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Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Other Immunosuppressants[7]	22(50.0%)	1(100%)	0	0
Preconception	21(47.7%)	1(100%)	0	0
During pregnancy	15(34.1%)	0	0	0
1st trimester	15(34.1%)	0	0	0
2nd trimester	9(20.5%)	0	0	0
3rd trimester	8(18.2%)	0	0	0
Azathioprine	13(29.5%)	0	0	0
Preconception	10(22.7%)	0	0	0
During pregnancy	9(20.5%)	0	0	0
1st trimester	9(20.5%)	0	0	0
2nd trimester	7(15.9%)	0	0	0
3rd trimester	7(15.9%)	0	0	0

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Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Other Immunosuppressants[7]	21(50.0%)	6(54.5%)	4(100%)	6(60.0%)	5(45.5%)
Preconception	20(47.6%)	5(45.5%)	4(100%)	6(60.0%)	5(45.5%)
During pregnancy	15(35.7%)	3(27.3%)	2(50.0%)	3(30.0%)	4(36.4%)
1st trimester	15(35.7%)	3(27.3%)	2(50.0%)	3(30.0%)	4(36.4%)
2nd trimester	9(21.4%)	1(9.1%)	2(50.0%)	3(30.0%)	3(27.3%)
3rd trimester	8(19.0%)	1(9.1%)	2(50.0%)	3(30.0%)	3(27.3%)
Azathioprine	13(31.0%)	3(27.3%)	2(50.0%)	3(30.0%)	4(36.4%)
Preconception	10(23.8%)	2(18.2%)	2(50.0%)	3(30.0%)	3(27.3%)
During pregnancy	9(21.4%)	1(9.1%)	2(50.0%)	3(30.0%)	2(18.2%)
1st trimester	9(21.4%)	1(9.1%)	2(50.0%)	3(30.0%)	2(18.2%)
2nd trimester	7(16.7%)	1(9.1%)	2(50.0%)	3(30.0%)	2(18.2%)
3rd trimester	7(16.7%)	1(9.1%)	2(50.0%)	3(30.0%)	2(18.2%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Cyclophosphamide	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Methotrexate	7(15.9%)	1(100%)	0	0
Preconception	7(15.9%)	1(100%)	0	0
During pregnancy	4(9.1%)	0	0	0
1st trimester	4(9.1%)	0	0	0
2nd trimester	1(2.3%)	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Cyclophosphamide	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Methotrexate	6(14.3%)	1(9.1%)	0	0	1(9.1%)
Preconception	6(14.3%)	1(9.1%)	0	0	1(9.1%)
During pregnancy	4(9.5%)	1(9.1%)	0	0	1(9.1%)
1st trimester	4(9.5%)	1(9.1%)	0	0	1(9.1%)
2nd trimester	1(2.4%)	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Mycophenolate	4(9.1%)	0	0	0
Preconception	4(9.1%)	0	0	0
During pregnancy	1(2.3%)	0	0	0
1st trimester	1(2.3%)	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Cyclosporin	1(2.3%)	0	0	0
Preconception	1(2.3%)	0	0	0
During pregnancy	1(2.3%)	0	0	0
1st trimester	1(2.3%)	0	0	0
2nd trimester	1(2.3%)	0	0	0
3rd trimester	1(2.3%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Mycophenolate	4(9.5%)	2(18.2%)	2(50.0%)	3(30.0%)	0
Preconception	4(9.5%)	2(18.2%)	2(50.0%)	3(30.0%)	0
During pregnancy	1(2.4%)	1(9.1%)	0	0	0
1st trimester	1(2.4%)	1(9.1%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Cyclosporin	1(2.4%)	0	0	0	1(9.1%)
Preconception	1(2.4%)	0	0	0	1(9.1%)
During pregnancy	1(2.4%)	0	0	0	1(9.1%)
1st trimester	1(2.4%)	0	0	0	1(9.1%)
2nd trimester	1(2.4%)	0	0	0	1(9.1%)
3rd trimester	1(2.4%)	0	0	0	1(9.1%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still-births (N=1)
Rituximab	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.3
Exposures of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

	Live Births (N=42)	Preterm (N=11)	SGA[2] (N=4)	SGA[3] (N=10)	Birth Defects (N=11)
Rituximab	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Note: Denominator is the total number of participants in each column (N). ACE inhibitors=angiotensin-converting-enzyme inhibitors; NSAIDs=non-steroidal anti-inflammatory drugs; SAB=spontaneous miscarriage; SGA=small for gestational age.
Exposure is defined as at least one dose during the period of observation (6 months prior to/during pregnancy for concomitant medications and 4 months prior to/during pregnancy for commercial belimumab) and does not imply continued use throughout the period of observation. Preconception is defined as six months prior to pregnancy for concomitant medications and 4 months prior to/during pregnancy for commercial belimumab. Participants may be presented in one or several time points and may be exposed to one or several medications; therefore, percentages may not add to 100%. For Rituximab and Anti-Malarials half-lives are assessed to determine the trimester of exposure.
Reports of pregnancy in which the pregnancy outcome or anticipated outcome is already known before enrollment can be biased toward the reporting of more unusual or severe cases compared to women whose pregnancy outcome is not yet known at the time of enrollment into the pregnancy registry. Therefore, rates of outcomes cannot be calculated from these data. However, a series of reported birth defects can be evaluated to detect patterns of specific birth defects and can assist with identification of potential early signals of therapy risks.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births. Ectopic and molar pregnancies have not been reported to date.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Preconception occurs within 4 months prior to conception. The first trimester begins the day after date of conception, the second trimester begins at week $14^{0/7}$ after the date of conception, and the third trimester begins at week $28^{0/7}$.
[5]Defined by the last recorded exposure with a non-missing treatment date.
[6]Considering timing of enrollment, participants with unknown routes of exposure are summarized under intravenous route.
[7]Includes azathioprine, cyclophosphamide, methotrexate, mycophenolate, cyclosporin, and rituximab.

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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Earliest Belimumab exposure [4,5]				
Preconception	8(72.7%)	3(75.0%)	2(100%)	0
1st trimester	3(27.3%)	1(25.0%)	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Last Belimumab exposure [4,5]				
Preconception	0	0	0	0
1st trimester	1(9.1%)	0	0	0
2nd trimester	2(18.2%)	0	0	0
3rd trimester	0	0	0	0
Postpartum	8(72.7%)	4(100%)	2(100%)	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Earliest Belimumab exposure [4,5]					
Preconception	3(60.0%)	1(50.0%)	0	0	0
1st trimester	2(40.0%)	1(50.0%)	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Last Belimumab exposure [4,5]					
Preconception	0	0	0	0	0
1st trimester	1(20.0%)	1(50.0%)	0	0	0
2nd trimester	2(40.0%)	1(50.0%)	0	0	0
3rd trimester	0	0	0	0	0
Postpartum	2(40.0%)	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Exposure by study timepoints [4,5]				
Preconception through 1st trimester	1(9.1%)	0	0	0
Preconception through 2nd trimester	1(9.1%)	0	0	0
Preconception through 3rd trimester	0	0	0	0
Preconception through post-pregnancy	6(54.5%)	3(75.0%)	2(100%)	0
1st trimester through 2nd trimester	1(9.1%)	0	0	0
1st trimester through 3rd trimester	0	0	0	0
1st trimester through post-pregnancy	2(18.2%)	1(25.0%)	0	0
2nd trimester through 3rd trimester	0	0	0	0
2nd trimester through post-pregnancy	0	0	0	0
3rd trimester through post-pregnancy	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Exposure by study timepoints [4,5]					
Preconception through 1st trimester	1(20.0%)	1(50.0%)	0	0	0
Preconception through 2nd trimester	1(20.0%)	0	0	0	0
Preconception through 3rd trimester	0	0	0	0	0
Preconception through post-pregnancy	1(20.0%)	0	0	0	0
1st trimester through 2nd trimester	1(20.0%)	1(50.0%)	0	0	0
1st trimester through 3rd trimester	0	0	0	0	0
1st trimester through post-pregnancy	1(20.0%)	0	0	0	0
2nd trimester through 3rd trimester	0	0	0	0	0
2nd trimester through post-pregnancy	0	0	0	0	0
3rd trimester through post-pregnancy	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Cumulative exposure (days)				
n	11	4	2	0
Mean (SD)	219.2(96.77)	198.0(56.29)	230.5(43.13)	-
Median	200.0	201.5	230.5	-
Min - Max	128 - 422	128 - 261	200 - 261	-
Q1, Q3	130.0,261.0	156.0,240.0	200.0,261.0	-
Route of administration[6]				
Intravenous	10(90.9%)	4(100%)	2(100%)	0
Subcutaneous	1(9.1%)	0	0	0
Switched route	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Cumulative exposure (days)					
n	5	2	0	0	0
Mean (SD)	231.6(140.94)	130.0(0.00)	-	-	-
Median	132.0	130.0	-	-	-
Min - Max	130 - 422	130 - 130	-	-	-
Q1, Q3	130.0,344.0	130.0,130.0	-	-	-
Route of administration[6]					
Intravenous	4(80.0%)	2(100%)	0	0	0
Subcutaneous	1(20.0%)	0	0	0	0
Switched route	0	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Other exposures during pregnancy				
Corticosteroids (For SLE ONLY)	6(54.5%)	3(75.0%)	1(50.0%)	0
Preconception	6(54.5%)	3(75.0%)	1(50.0%)	0
During pregnancy	6(54.5%)	3(75.0%)	1(50.0%)	0
1st trimester	6(54.5%)	3(75.0%)	1(50.0%)	0
2nd trimester	6(54.5%)	3(75.0%)	1(50.0%)	0
3rd trimester	6(54.5%)	3(75.0%)	1(50.0%)	0
NSAIDs	2(18.2%)	2(50.0%)	0	0
Preconception	2(18.2%)	2(50.0%)	0	0
During pregnancy	1(9.1%)	1(25.0%)	0	0
1st trimester	1(9.1%)	1(25.0%)	0	0
2nd trimester	1(9.1%)	1(25.0%)	0	0
3rd trimester	1(9.1%)	1(25.0%)	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Other exposures during pregnancy					
Corticosteroids (For SLE ONLY)	2(40.0%)	1(50.0%)	0	0	0
Preconception	2(40.0%)	1(50.0%)	0	0	0
During pregnancy	2(40.0%)	1(50.0%)	0	0	0
1st trimester	2(40.0%)	1(50.0%)	0	0	0
2nd trimester	2(40.0%)	1(50.0%)	0	0	0
3rd trimester	2(40.0%)	1(50.0%)	0	0	0
NSAIDs	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Anti-malarials	5(45.5%)	1(25.0%)	1(50.0%)	0
Preconception	5(45.5%)	1(25.0%)	1(50.0%)	0
During pregnancy	5(45.5%)	1(25.0%)	1(50.0%)	0
1st trimester	5(45.5%)	1(25.0%)	1(50.0%)	0
2nd trimester	5(45.5%)	1(25.0%)	1(50.0%)	0
3rd trimester	5(45.5%)	1(25.0%)	1(50.0%)	0
Folate	5(45.5%)	1(25.0%)	0	0
Preconception	3(27.3%)	1(25.0%)	0	0
During pregnancy	5(45.5%)	1(25.0%)	0	0
1st trimester	5(45.5%)	1(25.0%)	0	0
2nd trimester	5(45.5%)	1(25.0%)	0	0
3rd trimester	5(45.5%)	1(25.0%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Anti-malarials	3(60.0%)	1(50.0%)	0	0	0
Preconception	3(60.0%)	1(50.0%)	0	0	0
During pregnancy	3(60.0%)	1(50.0%)	0	0	0
1st trimester	3(60.0%)	1(50.0%)	0	0	0
2nd trimester	3(60.0%)	1(50.0%)	0	0	0
3rd trimester	3(60.0%)	1(50.0%)	0	0	0
Folate	4(80.0%)	2(100%)	0	0	0
Preconception	2(40.0%)	0	0	0	0
During pregnancy	4(80.0%)	2(100%)	0	0	0
1st trimester	4(80.0%)	2(100%)	0	0	0
2nd trimester	4(80.0%)	2(100%)	0	0	0
3rd trimester	4(80.0%)	2(100%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
ACE Inhibitors	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Calcium Channel Blockers	1(9.1%)	0	0	0
Preconception	0	0	0	0
During pregnancy	1(9.1%)	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	1(9.1%)	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
ACE Inhibitors	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Calcium Channel Blockers	1(20.0%)	1(50.0%)	0	0	0
Preconception	0	0	0	0	0
During pregnancy	1(20.0%)	1(50.0%)	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	1(20.0%)	1(50.0%)	0	0	0

Note: See footnotes on Page 1.
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Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Beta Blockers	2(18.2%)	1(25.0%)	0	0
Preconception	2(18.2%)	1(25.0%)	0	0
During pregnancy	2(18.2%)	1(25.0%)	0	0
1st trimester	1(9.1%)	1(25.0%)	0	0
2nd trimester	1(9.1%)	0	0	0
3rd trimester	1(9.1%)	0	0	0
Angiotensin II Receptor Antagonists	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0304
BEL114256 Final Analysis: Generated: 16FEB2023 16:52

Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Beta Blockers	1(20.0%)	1(50.0%)	0	0	0
Preconception	1(20.0%)	1(50.0%)	0	0	0
During pregnancy	1(20.0%)	1(50.0%)	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	1(20.0%)	1(50.0%)	0	0	0
3rd trimester	1(20.0%)	1(50.0%)	0	0	0
Angiotensin II Receptor Antagonists	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0304
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Insulin	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Heparin	1(9.1%)	0	0	0
Preconception	1(9.1%)	0	0	0
During pregnancy	1(9.1%)	0	0	0
1st trimester	1(9.1%)	0	0	0
2nd trimester	1(9.1%)	0	0	0
3rd trimester	1(9.1%)	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0304
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Insulin	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Heparin	1(20.0%)	0	0	0	0
Preconception	1(20.0%)	0	0	0	0
During pregnancy	1(20.0%)	0	0	0	0
1st trimester	1(20.0%)	0	0	0	0
2nd trimester	1(20.0%)	0	0	0	0
3rd trimester	1(20.0%)	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0304
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Aspirin	4(36.4%)	1(25.0%)	0	0
Preconception	2(18.2%)	1(25.0%)	0	0
During pregnancy	4(36.4%)	1(25.0%)	0	0
1st trimester	4(36.4%)	1(25.0%)	0	0
2nd trimester	4(36.4%)	1(25.0%)	0	0
3rd trimester	4(36.4%)	1(25.0%)	0	0
Epilepsy	0	0	0	0
Medication				
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0304
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Aspirin	3(60.0%)	2(100%)	0	0	0
Preconception	1(20.0%)	0	0	0	0
During pregnancy	3(60.0%)	2(100%)	0	0	0
1st trimester	3(60.0%)	2(100%)	0	0	0
2nd trimester	3(60.0%)	2(100%)	0	0	0
3rd trimester	3(60.0%)	2(100%)	0	0	0
Epilepsy Medication	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0304
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Other Immunosuppressants[7]	6(54.5%)	4(100%)	0	0
Preconception	6(54.5%)	4(100%)	0	0
During pregnancy	4(36.4%)	3(75.0%)	0	0
1st trimester	4(36.4%)	3(75.0%)	0	0
2nd trimester	2(18.2%)	1(25.0%)	0	0
3rd trimester	2(18.2%)	1(25.0%)	0	0
Azathioprine	2(18.2%)	1(25.0%)	0	0
Preconception	2(18.2%)	1(25.0%)	0	0
During pregnancy	1(9.1%)	0	0	0
1st trimester	1(9.1%)	0	0	0
2nd trimester	1(9.1%)	0	0	0
3rd trimester	1(9.1%)	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0304
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Other Immunosuppressants[7]	2(40.0%)	0	0	0	0
Preconception	2(40.0%)	0	0	0	0
During pregnancy	1(20.0%)	0	0	0	0
1st trimester	1(20.0%)	0	0	0	0
2nd trimester	1(20.0%)	0	0	0	0
3rd trimester	1(20.0%)	0	0	0	0
Azathioprine	1(20.0%)	0	0	0	0
Preconception	1(20.0%)	0	0	0	0
During pregnancy	1(20.0%)	0	0	0	0
1st trimester	1(20.0%)	0	0	0	0
2nd trimester	1(20.0%)	0	0	0	0
3rd trimester	1(20.0%)	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0304
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Cyclophosphamide	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Methotrexate	1(9.1%)	1(25.0%)	0	0
Preconception	1(9.1%)	1(25.0%)	0	0
During pregnancy	1(9.1%)	1(25.0%)	0	0
1st trimester	1(9.1%)	1(25.0%)	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0304
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Cyclophosphamide	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Methotrexate	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Mycophenolate	2(18.2%)	1(25.0%)	0	0
Preconception	2(18.2%)	1(25.0%)	0	0
During pregnancy	1(9.1%)	1(25.0%)	0	0
1st trimester	1(9.1%)	1(25.0%)	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0
Cyclosporin	1(9.1%)	1(25.0%)	0	0
Preconception	1(9.1%)	1(25.0%)	0	0
During pregnancy	1(9.1%)	1(25.0%)	0	0
1st trimester	1(9.1%)	1(25.0%)	0	0
2nd trimester	1(9.1%)	1(25.0%)	0	0
3rd trimester	1(9.1%)	1(25.0%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Mycophenolate	1(20.0%)	0	0	0	0
Preconception	1(20.0%)	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Cyclosporin	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still-births (N=0)
Rituximab	0	0	0	0
Preconception	0	0	0	0
During pregnancy	0	0	0	0
1st trimester	0	0	0	0
2nd trimester	0	0	0	0
3rd trimester	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 3.4
Exposures of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

	Live Births (N=5)	Preterm (N=2)	SGA[2] (N=0)	SGA[3] (N=0)	Birth Defects (N=0)
Rituximab	0	0	0	0	0
Preconception	0	0	0	0	0
During pregnancy	0	0	0	0	0
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0304
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Protocol: BEL114256
Population: All Registry Participants

Table 4.0
Live Birth Outcome Characteristics for Exposed Participants
(Overall Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses. Anti-ds=anti-double-stranded; max=maximum; min=minimum; Q=quartile; NSAIDs=non-steroidal anti-inflammatory drugs; SD= standard deviation.
[1]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[3]Denominator is the number of live births per cohort. Each infant of a multiple live birth will be counted separately.
[4]Full-Term low birth weight defined as infants born at >=$37^{0/7}$ weeks' gestational age weighing less than 2500 grams. Preterm low birth weight is defined as infants born at <$37^{0/7}$ weeks' gestational age weighing less than 2500 grams. Multiple gestations are excluded.
[5]Low birth weight is defined as a birth weight less than 2500 grams among infants.
[6]Defined by the last recorded exposure with a non-missing treatment date.

Protocol: BEL114256
Population: All Registry Participants

Table 4.0
Live Birth Outcome Characteristics for Exposed Participants
(Overall Cohort)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Overall Cohort	66	44	21	4	12
Delivery method[3]					
Normal vaginal	29 (43.9%)	23 (52.3%)	5 (23.8%)	2 (50.0%)	5 (41.7%)
Cesarean	35 (53.0%)	19 (43.2%)	16 (76.2%)	2 (50.0%)	7 (58.3%)
Missing/unknown	2 (3.0%)	2 (4.5%)	0	0	0
Live births[3]					
Singleton	59 (89.4%)	42 (95.5%)	16 (76.2%)	4 (100.0%)	12 (100.0%)
Twin	7 (10.6%)	2 (4.5%)	5 (23.8%)	0	0
Triplet	0	0	0	0	0
Other	0	0	0	0	0
Gender[3]					
Male	40 (60.6%)	29 (65.9%)	11 (52.4%)	2 (50.0%)	6 (50.0%)
Female	25 (37.9%)	15 (34.1%)	9 (42.9%)	2 (50.0%)	6 (50.0%)
Ambiguous Gender	0	0	0	0	0
Missing Gender	1 (1.5%)	0	1 (4.8%)	0	0
Gestational age at birth (weeks)					
n	65	44	21	4	12
Mean (SD)	37.70 (1.935)	38.70 (0.913)	35.60 (1.826)	37.39 (1.402)	37.64 (1.150)
Median	38.14	38.57	36.29	37.36	37.57
Min - Max	29.1 - 40.6	37.0 - 40.6	29.1 - 36.9	35.7 - 39.1	35.7 - 39.6
Q1, Q3	36.71, 39.14	38.00, 39.29	35.71, 36.57	36.50, 38.29	36.86, 38.43

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0400
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Protocol: BEL114256
Population: All Registry Participants

Table 4.0
Live Birth Outcome Characteristics for Exposed Participants
(Overall Cohort)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Overall Cohort	66	44	21	4	12
Preterm[4]	21 (31.8%)	NA	21 (100.0%)	1 (25.0%)	3 (25.0%)
Extremely preterm (<$28^{0/7}$ weeks)	0		0	0	0
Very/severely preterm ($28^{0/7}$ weeks - $31^{6/7}$ weeks)	1 (1.5%)		1 (4.8%)	0	0
Moderate preterm ($32^{0/7}$ weeks - $33^{6/7}$ weeks)	1 (1.5%)		1 (4.8%)	0	0
Late preterm ($34^{0/7}$ weeks - $36^{6/7}$ weeks)	19 (28.8%)		19 (90.5%)	1 (25.0%)	3 (25.0%)
Full-Term[4]	44 (66.7%)	44 (100.0%)	NA	3 (75.0%)	9 (75.0%)
Early term ($37^{0/7}$ weeks – $38^{6/7}$ weeks)	24 (36.4%)	24 (54.5%)		2 (50.0%)	7 (58.3%)
Full term ($39^{0/7}$ weeks – $40^{6/7}$ weeks)	20 (30.3%)	20 (45.5%)		1 (25.0%)	2 (16.7%)
Late term ($41^{0/7}$ weeks – $41^{6/7}$ weeks)	0	0		0	0
Post term (>=$42^{0/7}$ weeks)	0	0		0	0
Low birth weight[5]	19 (28.8%)	6 (13.6%)	12 (57.1%)	4 (100.0%)	8 (66.7%)
Male	7 (10.6%)	3 (6.8%)	4 (19.0%)	2 (50.0%)	3 (25.0%)
Female	11 (16.7%)	3 (6.8%)	7 (33.3%)	2 (50.0%)	5 (41.7%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 4.0
Live Birth Outcome Characteristics for Exposed Participants
(Overall Cohort)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Overall Cohort	66	44	21	4	12
Earliest trimester of belimumab exposure by infusion date					
Preconception (within 4 months prior to conception)	61 (92.4%)	41 (93.2%)	20 (95.2%)	3 (75.0%)	11 (91.7%)
1st trimester	4 (6.1%)	2 (4.5%)	1 (4.8%)	0	0
2nd trimester	1 (1.5%)	1 (2.3%)	0	1 (25.0%)	1 (8.3%)
3rd trimester	0	0	0	0	0
Last belimumab exposure by infusion date[6]					
Preconception (within 4 months prior to conception)	0	0	0	0	0
1st trimester	11 (16.7%)	4 (9.1%)	7 (33.3%)	0	1 (8.3%)
2nd trimester	35 (53.0%)	26 (59.1%)	9 (42.9%)	2 (50.0%)	8 (66.7%)
3rd trimester	1 (1.5%)	1 (2.3%)	0	0	0
Postpartum	19 (28.8%)	13 (29.5%)	5 (23.8%)	2 (50.0%)	3 (25.0%)
Other exposures during pregnancy	62 (93.9%)	41 (93.2%)	20 (95.2%)	4 (100.0%)	11 (91.7%)
Corticosteroids	33 (50.0%)	23 (52.3%)	10 (47.6%)	2 (50.0%)	5 (41.7%)
NSAIDs	9 (13.6%)	8 (18.2%)	1 (4.8%)	1 (25.0%)	3 (25.0%)
Other immunosuppressants	51 (77.3%)	32 (72.7%)	18 (85.7%)	4 (100.0%)	10 (83.3%)
Anti-malarial drugs	52 (78.8%)	35 (79.5%)	16 (76.2%)	4 (100.0%)	11 (91.7%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses. Anti-ds=anti-double-stranded; max=maximum; min=minimum; Q=quartile; NSAIDs=non-steroidal anti-inflammatory drugs; SD= standard deviation.
[1]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[3]Denominator is the number of live births per cohort. Each infant of a multiple live birth will be counted separately.
[4]Full-Term low birth weight defined as infants born at >=$37^{0/7}$ weeks' gestational age weighing less than 2500 grams. Preterm low birth weight is defined as infants born at <$37^{0/7}$ weeks' gestational age weighing less than 2500 grams. Multiple gestations are excluded.
[5]Low birth weight is defined as a birth weight less than 2500 grams among infants.
[6]Defined by the last recorded exposure with a non-missing treatment date.

Protocol: BEL114256
Population: All Registry Participants

Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Overall Prospective Cohort	61	42	19	4	12
Delivery method[3]					
Normal vaginal	25 (41.0%)	21 (50.0%)	4 (21.1%)	2 (50.0%)	5 (41.7%)
Cesarean	34 (55.7%)	19 (45.2%)	15 (78.9%)	2 (50.0%)	7 (58.3%)
Missing/unknown	2 (3.3%)	2 (4.8%)	0	0	0
Live births[3]					
Singleton	54 (88.5%)	40 (95.2%)	14 (73.7%)	4 (100.0%)	12 (100.0%)
Twin	7 (11.5%)	2 (4.8%)	5 (26.3%)	0	0
Triplet	0	0	0	0	0
Other	0	0	0	0	0
Gender[3]					
Male	39 (63.9%)	28 (66.7%)	11 (57.9%)	2 (50.0%)	6 (50.0%)
Female	21 (34.4%)	14 (33.3%)	7 (36.8%)	2 (50.0%)	6 (50.0%)
Ambiguous Gender	0	0	0	0	0
Missing Gender	1 (1.6%)	0	1 (5.3%)	0	0
Gestational age at birth (weeks)					
n	61	42	19	4	12
Mean (SD)	37.70 (1.958)	38.69 (0.915)	35.53 (1.909)	37.39 (1.402)	37.64 (1.150)
Median	38.14	38.57	36.29	37.36	37.57
Min - Max	29.1 - 40.6	37.0 - 40.6	29.1 - 36.9	35.7 - 39.1	35.7 - 39.6
Q1, Q3	36.86, 39.14	37.86, 39.29	34.86, 36.71	36.50, 38.29	36.86, 38.43

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Overall Prospective Cohort	61	42	19	4	12
Preterm[4]	19 (31.1%)	NA	19 (100.0%)	1 (25.0%)	3 (25.0%)
Extremely preterm (<$28^{0/7}$ weeks)	0		0	0	0
Very/severely preterm ($28^{0/7}$ weeks - $31^{6/7}$ weeks)	1 (1.6%)		1 (5.3%)	0	0
Moderate preterm ($32^{0/7}$ weeks - $33^{6/7}$ weeks)	1 (1.6%)		1 (5.3%)	0	0
Late preterm ($34^{0/7}$ weeks - $36^{6/7}$ weeks)	17 (27.9%)		17 (89.5%)	1 (25.0%)	3 (25.0%)
Full-Term[4]	42 (68.9%)	42 (100.0%)	NA	3 (75.0%)	9 (75.0%)
Early term ($37^{0/7}$ weeks – $38^{6/7}$ weeks)	23 (37.7%)	23 (54.8%)		2 (50.0%)	7 (58.3%)
Full term ($39^{0/7}$ weeks – $40^{6/7}$ weeks)	19 (31.1%)	19 (45.2%)		1 (25.0%)	2 (16.7%)
Late term ($41^{0/7}$ weeks – $41^{6/7}$ weeks)	0	0		0	0
Post term (>=$42^{0/7}$ weeks)	0	0		0	0
Low birth weight[5]	16 (26.2%)	6 (14.3%)	10 (52.6%)	4 (100.0%)	8 (66.7%)
Male	7 (11.5%)	3 (7.1%)	4 (21.1%)	2 (50.0%)	3 (25.0%)
Female	8 (13.1%)	3 (7.1%)	5 (26.3%)	2 (50.0%)	5 (41.7%)

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Overall Prospective Cohort	61	42	19	4	12
Earliest trimester of belimumab exposure by infusion date					
Preconception (within 4 months prior to conception)	58 (95.1%)	39 (92.9%)	19 (100.0%)	3 (75.0%)	11 (91.7%)
1st trimester	2 (3.3%)	2 (4.8%)	0	0	0
2nd trimester	1 (1.6%)	1 (2.4%)	0	1 (25.0%)	1 (8.3%)
3rd trimester	0	0	0	0	0
Last belimumab exposure by infusion date[6]					
Preconception (within 4 months prior to conception)	0	0	0	0	0
1st trimester	10 (16.4%)	4 (9.5%)	6 (31.6%)	0	1 (8.3%)
2nd trimester	33 (54.1%)	25 (59.5%)	8 (42.1%)	2 (50.0%)	8 (66.7%)
3rd trimester	1 (1.6%)	1 (2.4%)	0	0	0
Postpartum	17 (27.9%)	12 (28.6%)	5 (26.3%)	2 (50.0%)	3 (25.0%)

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Other exposures during pregnancy	57 (93.4%)	39 (92.9%)	18 (94.7%)	4 (100.0%)	11 (91.7%)
Corticosteroids	31 (50.8%)	22 (52.4%)	9 (47.4%)	2 (50.0%)	5 (41.7%)
NSAIDs	9 (14.8%)	8 (19.0%)	1 (5.3%)	1 (25.0%)	3 (25.0%)
Other immunosuppressants	46 (75.4%)	30 (71.4%)	16 (84.2%)	4 (100.0%)	10 (83.3%)
Anti-malarial drugs	49 (80.3%)	34 (81.0%)	15 (78.9%)	4 (100.0%)	11 (91.7%)

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Pure Prospective Cohort	17	10	7	0	2
Delivery method[3]					
Normal vaginal	7 (41.2%)	4 (40.0%)	3 (42.9%)	0	1 (50.0%)
Cesarean	9 (52.9%)	5 (50.0%)	4 (57.1%)	0	1 (50.0%)
Missing/unknown	1 (5.9%)	1 (10.0%)	0	0	0
Live births[3]					
Singleton	14 (82.4%)	10 (100.0%)	4 (57.1%)	0	2 (100.0%)
Twin	3 (17.6%)	0	3 (42.9%)	0	0
Triplet	0	0	0	0	0
Other	0	0	0	0	0
Gender[3]					
Male	11 (64.7%)	7 (70.0%)	4 (57.1%)	0	0
Female	5 (29.4%)	3 (30.0%)	2 (28.6%)	0	2 (100.0%)
Ambiguous Gender	0	0	0	0	0
Missing Gender	1 (5.9%)	0	1 (14.3%)	0	0
Gestational age at birth (weeks)					
n	17	10	7	0	2
Mean (SD)	37.54 (1.458)	38.39 (1.094)	36.33 (0.982)	-	36.93 (0.707)
Median	37.14	38.21	36.71	-	36.93
Min - Max	34.1 - 40.1	37.0 - 40.1	34.1 - 36.9	-	36.4 - 37.4
Q1, Q3	36.86, 38.29	37.43, 39.14	36.43, 36.86	-	36.43, 37.43

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Pure Prospective Cohort	17	10	7	0	2
Preterm[4]	7 (41.2%)	NA	7 (100.0%)	0	1 (50.0%)
Extremely preterm (<$28^{0/7}$ weeks)	0		0	0	0
Very/severely preterm ($28^{0/7}$ weeks - $31^{6/7}$ weeks)	0		0	0	0
Moderate preterm ($32^{0/7}$ weeks - $33^{6/7}$ weeks)	0		0	0	0
Late preterm ($34^{0/7}$ weeks - $36^{6/7}$ weeks)	7 (41.2%)		7 (100.0%)	0	1 (50.0%)
Full-Term[4]	10 (58.8%)	10 (100.0%)	NA	0	1 (50.0%)
Early term ($37^{0/7}$ weeks – $38^{6/7}$ weeks)	7 (41.2%)	7 (70.0%)		0	1 (50.0%)
Full term ($39^{0/7}$ weeks – $40^{6/7}$ weeks)	3 (17.6%)	3 (30.0%)		0	0
Late term ($41^{0/7}$ weeks – $41^{6/7}$ weeks)	0	0		0	0
Post term (>=$42^{0/7}$ weeks)	0	0		0	0
Low birth weight[5]	4 (23.5%)	1 (10.0%)	3 (42.9%)	0	2 (100.0%)
Male	1 (5.9%)	0	1 (14.3%)	0	0
Female	2 (11.8%)	1 (10.0%)	1 (14.3%)	0	2 (100.0%)

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Pure Prospective Cohort	17	10	7	0	2
Earliest trimester of belimumab exposure by infusion date					
Preconception (within 4 months prior to conception)	17 (100.0%)	10 (100.0%)	7 (100.0%)	0	2 (100.0%)
1st trimester	0	0	0	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Last belimumab exposure by infusion date[6]					
Preconception (within 4 months prior to conception)	0	0	0	0	0
1st trimester	2 (11.8%)	2 (20.0%)	0	0	0
2nd trimester	8 (47.1%)	4 (40.0%)	4 (57.1%)	0	2 (100.0%)
3rd trimester	0	0	0	0	0
Postpartum	7 (41.2%)	4 (40.0%)	3 (42.9%)	0	0

Note: See footnotes on Page 1.
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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Other exposures during pregnancy	16 (94.1%)	10 (100.0%)	6 (85.7%)	0	2 (100.0%)
Corticosteroids	9 (52.9%)	5 (50.0%)	4 (57.1%)	0	1 (50.0%)
NSAIDs	0	0	0	0	0
Other immunosuppressants	10 (58.8%)	5 (50.0%)	5 (71.4%)	0	2 (100.0%)
Anti-malarial drugs	13 (76.5%)	9 (90.0%)	4 (57.1%)	0	2 (100.0%)

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Traditional Prospective Cohort	44	32	12	4	10
Delivery method[3]					
Normal vaginal	18 (40.9%)	17 (53.1%)	1 (8.3%)	2 (50.0%)	4 (40.0%)
Cesarean	25 (56.8%)	14 (43.8%)	11 (91.7%)	2 (50.0%)	6 (60.0%)
Missing/unknown	1 (2.3%)	1 (3.1%)	0	0	0
Live births[3]					
Singleton	40 (90.9%)	30 (93.8%)	10 (83.3%)	4 (100.0%)	10 (100.0%)
Twin	4 (9.1%)	2 (6.3%)	2 (16.7%)	0	0
Triplet	0	0	0	0	0
Other	0	0	0	0	0
Gender[3]					
Male	28 (63.6%)	21 (65.6%)	7 (58.3%)	2 (50.0%)	6 (60.0%)
Female	16 (36.4%)	11 (34.4%)	5 (41.7%)	2 (50.0%)	4 (40.0%)
Ambiguous Gender	0	0	0	0	0
Missing Gender	0	0	0	0	0
Gestational age at birth (weeks)					
n	44	32	12	4	10
Mean (SD)	37.77 (2.131)	38.78 (0.849)	35.07 (2.192)	37.39 (1.402)	37.79 (1.194)
Median	38.29	38.93	35.86	37.36	37.79
Min - Max	29.1 - 40.6	37.3 - 40.6	29.1 - 36.9	35.7 - 39.1	35.7 - 39.6
Q1, Q3	36.71, 39.14	38.07, 39.29	34.64, 36.43	36.50, 38.29	37.29, 38.57

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Traditional Prospective Cohort	44	32	12	4	10
Preterm[4]	12 (27.3%)	NA	12 (100.0%)	1 (25.0%)	2 (20.0%)
Extremely preterm (<$28^{0/7}$ weeks)	0		0	0	0
Very/severely preterm ($28^{0/7}$ weeks - $31^{6/7}$ weeks)	1 (2.3%)		1 (8.3%)	0	0
Moderate preterm ($32^{0/7}$ weeks - $33^{6/7}$ weeks)	1 (2.3%)		1 (8.3%)	0	0
Late preterm ($34^{0/7}$ weeks - $36^{6/7}$ weeks)	10 (22.7%)		10 (83.3%)	1 (25.0%)	2 (20.0%)
Full-Term[4]	32 (72.7%)	32 (100.0%)	NA	3 (75.0%)	8 (80.0%)
Early term ($37^{0/7}$ weeks – $38^{6/7}$ weeks)	16 (36.4%)	16 (50.0%)		2 (50.0%)	6 (60.0%)
Full term ($39^{0/7}$ weeks – $40^{6/7}$ weeks)	16 (36.4%)	16 (50.0%)		1 (25.0%)	2 (20.0%)
Late term ($41^{0/7}$ weeks – $41^{6/7}$ weeks)	0	0		0	0
Post term (>=$42^{0/7}$ weeks)	0	0		0	0
Low birth weight[5]	12 (27.3%)	5 (15.6%)	7 (58.3%)	4 (100.0%)	6 (60.0%)
Male	6 (13.6%)	3 (9.4%)	3 (25.0%)	2 (50.0%)	3 (30.0%)
Female	6 (13.6%)	2 (6.3%)	4 (33.3%)	2 (50.0%)	3 (30.0%)

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Traditional Prospective Cohort	44	32	12	4	10
Earliest trimester of belimumab exposure by infusion date					
Preconception (within 4 months prior to conception)	41 (93.2%)	29 (90.6%)	12 (100.0%)	3 (75.0%)	9 (90.0%)
1st trimester	2 (4.5%)	2 (6.3%)	0	0	0
2nd trimester	1 (2.3%)	1 (3.1%)	0	1 (25.0%)	1 (10.0%)
3rd trimester	0	0	0	0	0
Last belimumab exposure by infusion date[6]					
Preconception (within 4 months prior to conception)	0	0	0	0	0
1st trimester	8 (18.2%)	2 (6.3%)	6 (50.0%)	0	1 (10.0%)
2nd trimester	25 (56.8%)	21 (65.6%)	4 (33.3%)	2 (50.0%)	6 (60.0%)
3rd trimester	1 (2.3%)	1 (3.1%)	0	0	0
Postpartum	10 (22.7%)	8 (25.0%)	2 (16.7%)	2 (50.0%)	3 (30.0%)

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Other exposures during pregnancy	41 (93.2%)	29 (90.6%)	12 (100.0%)	4 (100.0%)	9 (90.0%)
Corticosteroids	22 (50.0%)	17 (53.1%)	5 (41.7%)	2 (50.0%)	4 (40.0%)
NSAIDs	9 (20.5%)	8 (25.0%)	1 (8.3%)	1 (25.0%)	3 (30.0%)
Other immunosuppressants	36 (81.8%)	25 (78.1%)	11 (91.7%)	4 (100.0%)	8 (80.0%)
Anti-malarial drugs	36 (81.8%)	25 (78.1%)	11 (91.7%)	4 (100.0%)	9 (90.0%)

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Retrospective Cohort	5	2	2	0	0
Delivery method[3]					
Normal vaginal	4 (80.0%)	2 (100.0%)	1 (50.0%)	0	0
Cesarean	1 (20.0%)	0	1 (50.0%)	0	0
Missing/unknown	0	0	0	0	0
Live births[3]					
Singleton	5 (100.0%)	2 (100.0%)	2 (100.0%)	0	0
Twin	0	0	0	0	0
Triplet	0	0	0	0	0
Other	0	0	0	0	0
Gender[3]					
Male	1 (20.0%)	1 (50.0%)	0	0	0
Female	4 (80.0%)	1 (50.0%)	2 (100.0%)	0	0
Ambiguous Gender	0	0	0	0	0
Missing Gender	0	0	0	0	0
Gestational age at birth (weeks)					
n	4	2	2	0	0
Mean (SD)	37.64 (1.794)	39.07 (1.111)	36.21 (0.505)	-	-
Median	37.43	39.07	36.21	-	-
Min - Max	35.9 - 39.9	38.3 - 39.9	35.9 - 36.6	-	-
Q1, Q3	36.21, 39.07	38.29, 39.86	35.86, 36.57	-	-

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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Retrospective Cohort	5	2	2	0	0
Preterm[4]	2 (40.0%)	NA	2 (100.0%)	0	0
Extremely preterm (<$28^{0/7}$ weeks)	0		0	0	0
Very/severely preterm ($28^{0/7}$ weeks - $31^{6/7}$ weeks)	0		0	0	0
Moderate preterm ($32^{0/7}$ weeks - $33^{6/7}$ weeks)	0		0	0	0
Late preterm ($34^{0/7}$ weeks - $36^{6/7}$ weeks)	2 (40.0%)		2 (100.0%)	0	0
Full-Term[4]	2 (40.0%)	2 (100.0%)	NA	0	0
Early term ($37^{0/7}$ weeks – $38^{6/7}$ weeks)	1 (20.0%)	1 (50.0%)		0	0
Full term ($39^{0/7}$ weeks – $40^{6/7}$ weeks)	1 (20.0%)	1 (50.0%)		0	0
Late term ($41^{0/7}$ weeks – $41^{6/7}$ weeks)	0	0		0	0
Post term (>=$42^{0/7}$ weeks)	0	0		0	0
Low birth weight[5]	3 (60.0%)	0	2 (100.0%)	0	0
Male	0	0	0	0	0
Female	3 (60.0%)	0	2 (100.0%)	0	0

Note: See footnotes on Page 1.
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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Retrospective Cohort	5	2	2	0	0
Earliest trimester of belimumab exposure by infusion date					
Preconception (within 4 months prior to conception)	3 (60.0%)	2 (100.0%)	1 (50.0%)	0	0
1st trimester	2 (40.0%)	0	1 (50.0%)	0	0
2nd trimester	0	0	0	0	0
3rd trimester	0	0	0	0	0
Last belimumab exposure by infusion date[6]					
Preconception (within 4 months prior to conception)	0	0	0	0	0
1st trimester	1 (20.0%)	0	1 (50.0%)	0	0
2nd trimester	2 (40.0%)	1 (50.0%)	1 (50.0%)	0	0
3rd trimester	0	0	0	0	0
Postpartum	2 (40.0%)	1 (50.0%)	0	0	0

Note: See footnotes on Page 1.
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Table 4.1
Live Birth Outcome Characteristics for Exposed Participants
(Overall Prospective, Pure Prospective, Traditional Prospective, Retrospective Cohorts)

		Live Births			
	All Live Births	Full-Term	Preterm	SGA[1]	SGA[2]
Other exposures during pregnancy	5 (100.0%)	2 (100.0%)	2 (100.0%)	0	0
Corticosteroids	2 (40.0%)	1 (50.0%)	1 (50.0%)	0	0
NSAIDs	0	0	0	0	0
Other immunosuppressants	5 (100.0%)	2 (100.0%)	2 (100.0%)	0	0
Anti-malarial drugs	3 (60.0%)	1 (50.0%)	1 (50.0%)	0	0

Note: See footnotes on Page 1.
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Table 5.0
Pregnancy Outcome Characteristics by Earliest Period of Exposure
(Overall Cohort)

Note: Denominator is the total number of participants in each column (N) cohort by trimester of exposure unless otherwise indicated. First trimester begins day after date of conception to $13^{6/7}$, second trimester begins at week $14^{0/7}$ – $27^{6/7}$ weeks, and the third trimester begins at week $28^{0/7}$.
Live birth: the birth of a living fetus at $20^{0/7}$ weeks' gestational age or greater (>=20 weeks), or, if gestational age is unknown, a fetus weighing 500 g or more (>=500 g);
Elective termination: voluntary interruption of pregnancy, including pregnancy termination that occurs electively, to preserve maternal health, or due to fetal abnormalities;
Spontaneous miscarriage: fetal death or expulsion of products of conception prior to 20 weeks' (< 20 weeks) gestation;
Neonatal death: an infant who after live birth expired within the first 28 days (<= 28 days) of life;
Stillbirth: a fetal death occurring at $20^{0/7}$ weeks' gestational age or greater (>=20 weeks), or, if gestational age is unknown, a fetus weighing 500 g or more (>=500 g);
Ectopic pregnancy: implantation of a conception outside of the uterus;
Molar pregnancy: a conception that results in a gestational trophoblastic tumor.
[1]Denominator is the total number of participants with a pregnancy outcome. Participants in retrospective cohort do not contribute to the counts and frequencies under 'gestation age at enrollment'.
[2]Includes the number of participants with a pregnancy outcome of spontaneous abortion or stillbirth.
[3]Denominator is the total number of participants with a pregnancy outcome minus the number of participants with an elective termination.
[4]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in two subcategories of pregnancy outcomes.

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Table 5.0
Pregnancy Outcome Characteristics by Earliest Period of Exposure
(Overall Cohort)

			Earliest Trimester of Exposure		
	Total	Preconception	Trimester 1	Trimester 2	Trimester 3
Overall Cohort[4]	72	65	5	2	0
Number of participants with a pregnancy outcome	72 (100.0%)	65 (100.0%)	5 (100.0%)	2 (100.0%)	0
Live Birth[1]	63 (87.5%)	58 (89.2%)	4 (80.0%)	1 (50.0%)	0
Neonatal death[1]	0	0	0	0	0
Elective termination[1]	2 (2.8%)	2 (3.1%)	0	0	0
Fetal loss[2,3]	8 (11.4%)	6 (9.5%)	1 (20.0%)	1 (50.0%)	0
Spontaneous miscarriage[1]	7 (9.7%)	6 (9.2%)	1 (20.0%)	0	0
Gestation Age at enrollment					
<8 weeks' gestation	1 (1.4%)	1 (1.5%)	0	0	0
$8^{0/7}$ - $11^{6/7}$ weeks' gestation	2 (2.8%)	2 (3.1%)	0	0	0
$12^{0/7}$ - $13^{6/7}$ weeks' gestation	1 (1.4%)	1 (1.5%)	0	0	0
$14^{0/7}$ - $19^{6/7}$ weeks' gestation	0	0	0	0	0
Stillbirth[1]	1 (1.4%)	0	0	1 (50.0%)	0
Ectopic pregnancy[1]	0	0	0	0	0
Molar pregnancy[1]	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 5.1
Pregnancy Outcome Characteristics by Earliest Period of Exposure
(Overall Prospective, Pure Prospective, Traditional Prospective, and Retrospective Cohorts)

Note: Denominator is the total number of participants in each column (N) cohort by trimester of exposure unless otherwise indicated. First trimester begins day after date of conception to $13^{6/7}$, second trimester begins at week $14^{0/7}$ – $27^{6/7}$ weeks, and the third trimester begins at week $28^{0/7}$.
Live birth: the birth of a living fetus at $20^{0/7}$ weeks' gestational age or greater (>=20 weeks), or, if gestational age is unknown, a fetus weighing 500 g or more (>=500 g);
Elective termination: voluntary interruption of pregnancy, including pregnancy termination that occurs electively, to preserve maternal health, or due to fetal abnormalities;
Spontaneous miscarriage: fetal death or expulsion of products of conception prior to 20 weeks' (< 20 weeks) gestation;
Neonatal death: an infant who after live birth expired within the first 28 days (<= 28 days) of life;
Stillbirth: a fetal death occurring at $20^{0/7}$ weeks' gestational age or greater (>=20 weeks), or, if gestational age is unknown, a fetus weighing 500 g or more (>=500 g);
Ectopic pregnancy: implantation of a conception outside of the uterus;
Molar pregnancy: a conception that results in a gestational trophoblastic tumor.
[1]Denominator is the total number of participants with a pregnancy outcome.
[2]Includes the number of participants with a pregnancy outcome of spontaneous abortion or stillbirth.
[3]Denominator is the total number of participants with a pregnancy outcome minus the number of participants with an elective termination.
[4]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in two subcategories of pregnancy outcomes.

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Protocol: BEL114256
Population: All Registry Participants

Table 5.1
Pregnancy Outcome Characteristics by Earliest Period of Exposure
(Overall Prospective, Pure Prospective, Traditional Prospective, and Retrospective Cohorts)

		Earliest Trimester of Exposure			
	Total	Preconception	Trimester 1	Trimester 2	Trimester 3
Overall Prospective[4]	61	57	2	2	0
Number of participants with a pregnancy outcome	61 (100.0%)	57 (100.0%)	2 (100.0%)	2 (100.0%)	0
Live Birth[1]	58 (95.1%)	55 (96.5%)	2 (100.0%)	1 (50.0%)	0
Neonatal death[1]	0	0	0	0	0
Elective termination[1]	0	0	0	0	0
Fetal loss[2,3]	4 (6.6%)	3 (5.3%)	0	1 (50.0%)	0
Spontaneous miscarriage[1]	3 (4.9%)	3 (5.3%)	0	0	0
Gestation Age at enrollment					
<8 weeks' gestation	1 (1.6%)	1 (1.8%)	0	0	0
$8^{0/7}$ - $11^{6/7}$ weeks' gestation	2 (3.3%)	2 (3.5%)	0	0	0
$12^{0/7}$ - $13^{6/7}$ weeks' gestation	0	0	0	0	0
$14^{0/7}$ - $19^{6/7}$ weeks' gestation	0	0	0	0	0
Stillbirth[1]	1 (1.6%)	0	0	1 (50.0%)	0
Ectopic pregnancy[1]	0	0	0	0	0
Molar pregnancy[1]	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 5.1
Pregnancy Outcome Characteristics by Earliest Period of Exposure
(Overall Prospective, Pure Prospective, Traditional Prospective, and Retrospective Cohorts)

			Earliest Trimester of Exposure		
	Total	Preconception	Trimester 1	Trimester 2	Trimester 3
Pure Prospective Cohort[4]	17	17	0	0	0
Number of participants with a pregnancy outcome	17 (100.0%)	17 (100.0%)	0	0	0
Live Birth[1]	16 (94.1%)	16 (94.1%)	0	0	0
Neonatal death[1]	0	0	0	0	0
Elective termination[1]	0	0	0	0	0
Fetal loss[2,3]	2 (11.8%)	2 (11.8%)	0	0	0
Spontaneous miscarriage[1]	2 (11.8%)	2 (11.8%)	0	0	0
Gestation Age at enrollment					
<8 weeks' gestation	1 (5.9%)	1 (5.9%)	0	0	0
$8^{0/7}$ - $11^{6/7}$ weeks' gestation	1 (5.9%)	1 (5.9%)	0	0	0
$12^{0/7}$ - $13^{6/7}$ weeks' gestation	0	0	0	0	0
$14^{0/7}$ - $19^{6/7}$ weeks' gestation	0	0	0	0	0
Stillbirth[1]	0	0	0	0	0
Ectopic pregnancy[1]	0	0	0	0	0
Molar pregnancy[1]	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 5.1
Pregnancy Outcome Characteristics by Earliest Period of Exposure
(Overall Prospective, Pure Prospective, Traditional Prospective, and Retrospective Cohorts)

		Earliest Trimester of Exposure		
	Total	Preconception	Trimester 1	Trimester 2	Trimester 3
Traditional Prospective Cohort	44	40	2	2	0
Number of participants with a pregnancy outcome	44 (100.0%)	40 (100.0%)	2 (100.0%)	2 (100.0%)	0
Live Birth[1]	42 (95.5%)	39 (97.5%)	2 (100.0%)	1 (50.0%)	0
Neonatal death[1]	0	0	0	0	0
Elective termination[1]	0	0	0	0	0
Fetal loss[2,3]	2 (4.5%)	1 (2.5%)	0	1 (50.0%)	0
Spontaneous miscarriage[1]	1 (2.3%)	1 (2.5%)	0	0	0
Gestation Age at enrollment					
<8 weeks' gestation	0	0	0	0	0
$8^{0/7}$ - $11^{6/7}$ weeks' gestation	1 (2.3%)	1 (2.5%)	0	0	0
$12^{0/7}$ - $13^{6/7}$ weeks' gestation	0	0	0	0	0
$14^{0/7}$ - $19^{6/7}$ weeks' gestation	0	0	0	0	0
Stillbirth[1]	1 (2.3%)	0	0	1 (50.0%)	0
Ectopic pregnancy[1]	0	0	0	0	0
Molar pregnancy[1]	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 5.1
Pregnancy Outcome Characteristics by Earliest Period of Exposure
(Overall Prospective, Pure Prospective, Traditional Prospective, and Retrospective Cohorts)

		Earliest Trimester of Exposure			
	Total	Preconception	Trimester 1	Trimester 2	Trimester 3
Retrospective Cohort	11	8	3	0	0
Number of participants with a pregnancy outcome	11 (100.0%)	8 (100.0%)	3 (100.0%)	0	0
Live Birth[1]	5 (45.5%)	3 (37.5%)	2 (66.7%)	0	0
Neonatal death[1]	0	0	0	0	0
Elective termination[1]	2 (18.2%)	2 (25.0%)	0	0	0
Fetal loss[2,3]	4 (44.4%)	3 (50.0%)	1 (33.3%)	0	0
Spontaneous miscarriage[1]	4 (36.4%)	3 (37.5%)	1 (33.3%)	0	0
Gestation Age at enrollment					
<8 weeks' gestation	0	0	0	0	0
$8^{0/7}$ - $11^{6/7}$ weeks' gestation	0	0	0	0	0
$12^{0/7}$ - $13^{6/7}$ weeks' gestation	1 (9.1%)	1 (12.5%)	0	0	0
$14^{0/7}$ - $19^{6/7}$ weeks' gestation	0	0	0	0	0
Stillbirth[1]	0	0	0	0	0
Ectopic pregnancy[1]	0	0	0	0	0
Molar pregnancy[1]	0	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0501
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Protocol: BEL114256
Population: All Registry Participants

Table 6.1
Solicited Maternal AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Number of participants with at least one solicited maternal non-serious AE	20(27.8%)	3(17.6%)	15(34.1%)	0	2(18.2%)
Number of participants with at least one solicited maternal SAE	28(38.9%)	4(23.5%)	15(34.1%)	0	9(81.8%)
Total number of solicited maternal SAEs	39	5	23	0	11
Number of participants with at least one solicited maternal non-serious AE and/or SAE	40(55.6%)	6(35.3%)	25(56.8%)	0	9(81.8%)
Blood and lymphatic system disorders	4(5.6%)	0	2(4.5%)	0	2(18.2%)
Anaemia	1(1.4%)	0	0	0	1(9.1%)
Anaemia of pregnancy	1(1.4%)	0	1(2.3%)	0	0
Hypercoagulation	1(1.4%)	0	0	0	1(9.1%)
Thrombocytopenia	1(1.4%)	0	1(2.3%)	0	0
Cardiac disorders	3(4.2%)	0	2(4.5%)	0	1(9.1%)
Arteriosclerosis coronary artery	1(1.4%)	0	0	0	1(9.1%)

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
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Protocol: BEL114256
Population: All Registry Participants

Table 6.1
Solicited Maternal AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Cardiac disorders (Cont'd)					
Cardiomegaly	1(1.4%)	0	0	0	1(9.1%)
Palpitations	1(1.4%)	0	1(2.3%)	0	0
Sinus tachycardia	1(1.4%)	0	1(2.3%)	0	0
Ear and labyrinth disorders	1(1.4%)	0	1(2.3%)	0	0
Hyperacusis	1(1.4%)	0	1(2.3%)	0	0
Eye disorders	1(1.4%)	0	1(2.3%)	0	0
Eye pain	1(1.4%)	0	1(2.3%)	0	0
Photophobia	1(1.4%)	0	1(2.3%)	0	0
Gastrointestinal disorders	6(8.3%)	1(5.9%)	5(11.4%)	0	0
Irritable bowel syndrome	1(1.4%)	0	1(2.3%)	0	0
Nausea	4(5.6%)	1(5.9%)	3(6.8%)	0	0
Vomiting	4(5.6%)	1(5.9%)	3(6.8%)	0	0
General disorders and administration site conditions	1(1.4%)	0	0	0	1(9.1%)
Fatigue	1(1.4%)	0	0	0	1(9.1%)

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
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Protocol: BEL114256
Population: All Registry Participants

Table 6.1
Solicited Maternal AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
General disorders and administration site conditions (Cont'd)					
Mass	1(1.4%)	0	0	0	1(9.1%)
Infections and infestations	7(9.7%)	1(5.9%)	5(11.4%)	0	1(9.1%)
Cystitis	1(1.4%)	0	1(2.3%)	0	0
Endometritis decidual	1(1.4%)	0	1(2.3%)	0	0
Herpes zoster	1(1.4%)	0	1(2.3%)	0	0
Mastitis	2(2.8%)	1(5.9%)	1(2.3%)	0	0
Sinusitis	1(1.4%)	0	1(2.3%)	0	0
Staphylococcal infection	1(1.4%)	0	0	0	1(9.1%)
Urinary tract infection	1(1.4%)	0	0	0	1(9.1%)
Injury, poisoning and procedural complications	1(1.4%)	0	1(2.3%)	0	0
Ligament sprain	1(1.4%)	0	1(2.3%)	0	0
Metabolism and nutrition disorders	1(1.4%)	0	1(2.3%)	0	0
Type 2 diabetes mellitus	1(1.4%)	0	1(2.3%)	0	0
Musculoskeletal and connective tissue disorders	6(8.3%)	1(5.9%)	4(9.1%)	0	1(9.1%)
Arthralgia	3(4.2%)	1(5.9%)	2(4.5%)	0	0

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
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Protocol: BEL114256
Population: All Registry Participants

Table 6.1
Solicited Maternal AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Musculoskeletal and connective tissue disorders (Cont'd)					
Connective tissue disorder	1(1.4%)	0	1(2.3%)	0	0
Fibromyalgia	1(1.4%)	0	1(2.3%)	0	0
Osteoporosis	1(1.4%)	0	0	0	1(9.1%)
Systemic lupus erythematosus	2(2.8%)	0	2(4.5%)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1(1.4%)	0	1(2.3%)	0	0
Neoplasm malignant	1(1.4%)	0	1(2.3%)	0	0
Nervous system disorders	1(1.4%)	0	1(2.3%)	0	0
Headache	1(1.4%)	0	1(2.3%)	0	0
Pregnancy, puerperium and perinatal conditions	22(30.6%)	3(17.6%)	13(29.5%)	0	6(54.5%)
Abortion spontaneous	5(6.9%)	1(5.9%)	0	0	4(36.4%)
Arrested labour	1(1.4%)	0	1(2.3%)	0	0
Cephalo-pelvic disproportion	1(1.4%)	0	1(2.3%)	0	0
Cervical incompetence	1(1.4%)	1(5.9%)	0	0	0
Foetal death	2(2.8%)	1(5.9%)	1(2.3%)	0	0

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
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Protocol: BEL114256
Population: All Registry Participants

Table 6.1
Solicited Maternal AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Pregnancy, puerperium and perinatal conditions (Cont'd)					
Gestational hypertension	1(1.4%)	0	1(2.3%)	0	0
Morning sickness	1(1.4%)	0	1(2.3%)	0	0
Oligohydramnios	2(2.8%)	0	2(4.5%)	0	0
Pelvic haematoma obstetric	1(1.4%)	0	1(2.3%)	0	0
Placental insufficiency	1(1.4%)	0	1(2.3%)	0	0
Postpartum haemorrhage	2(2.8%)	0	1(2.3%)	0	1(9.1%)
Pre-eclampsia	5(6.9%)	1(5.9%)	3(6.8%)	0	1(9.1%)
Premature labour	1(1.4%)	0	1(2.3%)	0	0
Premature separation of placenta	2(2.8%)	0	2(4.5%)	0	0
Preterm premature rupture of membranes	1(1.4%)	0	0	0	1(9.1%)
Prolonged labour	1(1.4%)	0	1(2.3%)	0	0
Psychiatric disorders	1(1.4%)	0	1(2.3%)	0	0
Insomnia	1(1.4%)	0	1(2.3%)	0	0
Renal and urinary disorders	1(1.4%)	1(5.9%)	0	0	0
Nephrolithiasis	1(1.4%)	1(5.9%)	0	0	0
Reproductive system and breast disorders	2(2.8%)	0	2(4.5%)	0	0
Vaginal haemorrhage	2(2.8%)	0	2(4.5%)	0	0

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0601
BEL114256 Final Analysis: Generated: 16FEB2023 16:55

Protocol: BEL114256
Population: All Registry Participants

Table 6.1
Solicited Maternal AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Skin and subcutaneous tissue disorders	3(4.2%)	0	2(4.5%)	0	1(9.1%)
Acne	1(1.4%)	0	0	0	1(9.1%)
Rash	1(1.4%)	0	1(2.3%)	0	0
Skin irritation	1(1.4%)	0	1(2.3%)	0	0
Surgical and medical procedures	2(2.8%)	0	0	0	2(18.2%)
Abortion induced	2(2.8%)	0	0	0	2(18.2%)
Vascular disorders	2(2.8%)	0	1(2.3%)	0	1(9.1%)
Hypertension	2(2.8%)	0	1(2.3%)	0	1(9.1%)

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0601
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Protocol: BEL114256
Population: All Registry Participants

Table 6.2
Solicited Infant AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Number of participants with at least one solicited infant non-serious AE	21(29.2%)	6(35.3%)	15(34.1%)	0	0
Number of participants with at least one solicited infant SAE	27(37.5%)	5(29.4%)	21(47.7%)	0	1(9.1%)
Total number of solicited infant SAEs	49	8	38	0	3
Number of participants with at least one solicited infant non-serious AE and/or SAE	36(50.0%)	9(52.9%)	26(59.1%)	0	1(9.1%)
Blood and lymphatic system disorders	2(2.8%)	1(5.9%)	1(2.3%)	0	0
Anaemia	1(1.4%)	1(5.9%)	0	0	0
Hypochromic anaemia	1(1.4%)	0	1(2.3%)	0	0
Cardiac disorders	4(5.6%)	0	4(9.1%)	0	0
Atrioventricular block	1(1.4%)	0	1(2.3%)	0	0
Nonreassuring foetal heart rate pattern	1(1.4%)	0	1(2.3%)	0	0
Supraventricular tachycardia	1(1.4%)	0	1(2.3%)	0	0

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0602
BEL114256 Final Analysis: Generated: 16FEB2023 16:56

Protocol: BEL114256
Population: All Registry Participants

Table 6.2
Solicited Infant AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Cardiac disorders (Cont'd)					
Tricuspid valve incompetence	1(1.4%)	0	1(2.3%)	0	0
Ventricular extrasystoles	1(1.4%)	0	1(2.3%)	0	0
Congenital, familial and genetic disorders	15(20.8%)	4(23.5%)	10(22.7%)	0	1(9.1%)
Ankyloglossia congenital	1(1.4%)	0	1(2.3%)	0	0
Arnold-Chiari malformation	1(1.4%)	0	1(2.3%)	0	0
Atrial septal defect	3(4.2%)	0	2(4.5%)	0	1(9.1%)
Cryptorchism	1(1.4%)	0	1(2.3%)	0	0
Ebstein's anomaly	1(1.4%)	0	1(2.3%)	0	0
Hydrocele	1(1.4%)	0	1(2.3%)	0	0
Labial tie	1(1.4%)	0	1(2.3%)	0	0
Macrocephaly	1(1.4%)	1(5.9%)	0	0	0
Neonatal lupus erythematosus	1(1.4%)	1(5.9%)	0	0	0
Patent ductus arteriosus	3(4.2%)	0	2(4.5%)	0	1(9.1%)
Phimosis	1(1.4%)	1(5.9%)	0	0	0
Plagiocephaly	1(1.4%)	0	1(2.3%)	0	0
Talipes	1(1.4%)	1(5.9%)	0	0	0
Ventricular septal defect	2(2.8%)	0	2(4.5%)	0	0

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0602
BEL114256 Final Analysis: Generated: 16FEB2023 16:56

Protocol: BEL114256
Population: All Registry Participants

Table 6.2
Solicited Infant AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Eye disorders	2(2.8%)	0	2(4.5%)	0	0
Dacryostenosis acquired	2(2.8%)	0	2(4.5%)	0	0
Gastrointestinal disorders	10(13.9%)	2(11.8%)	8(18.2%)	0	0
Abdominal pain	1(1.4%)	0	1(2.3%)	0	0
Anal fistula	1(1.4%)	0	1(2.3%)	0	0
Constipation	2(2.8%)	1(5.9%)	1(2.3%)	0	0
Diarrhoea	1(1.4%)	0	1(2.3%)	0	0
Dysphagia	2(2.8%)	0	2(4.5%)	0	0
Food protein-induced enterocolitis syndrome	1(1.4%)	0	1(2.3%)	0	0
Gastrooesophageal reflux disease	2(2.8%)	1(5.9%)	1(2.3%)	0	0
Haematochezia	1(1.4%)	0	1(2.3%)	0	0
Oesophageal obstruction	1(1.4%)	0	1(2.3%)	0	0
Umbilical hernia	1(1.4%)	1(5.9%)	0	0	0
General disorders and administration site conditions	2(2.8%)	1(5.9%)	1(2.3%)	0	0
Developmental delay	1(1.4%)	1(5.9%)	0	0	0
Pyrexia	1(1.4%)	0	1(2.3%)	0	0
Hepatobiliary disorders	1(1.4%)	0	1(2.3%)	0	0
Jaundice	1(1.4%)	0	1(2.3%)	0	0

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0602
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Protocol: BEL114256
Population: All Registry Participants

Table 6.2
Solicited Infant AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Immune system disorders	1(1.4%)	0	1(2.3%)	0	0
Food allergy	1(1.4%)	0	1(2.3%)	0	0
Infections and infestations	6(8.3%)	2(11.8%)	4(9.1%)	0	0
Endocarditis	1(1.4%)	0	1(2.3%)	0	0
Gastroenteritis rotavirus	1(1.4%)	0	1(2.3%)	0	0
Meningitis viral	1(1.4%)	1(5.9%)	0	0	0
Respiratory syncytial virus infection	1(1.4%)	0	1(2.3%)	0	0
Rhinovirus infection	1(1.4%)	0	1(2.3%)	0	0
Upper respiratory tract infection	2(2.8%)	1(5.9%)	1(2.3%)	0	0
Investigations	2(2.8%)	0	2(4.5%)	0	0
Acoustic stimulation tests abnormal	1(1.4%)	0	1(2.3%)	0	0
Cardiac murmur	1(1.4%)	0	1(2.3%)	0	0
Echocardiogram abnormal	1(1.4%)	0	1(2.3%)	0	0
Metabolism and nutrition disorders	5(6.9%)	2(11.8%)	3(6.8%)	0	0
Feeding disorder	1(1.4%)	1(5.9%)	0	0	0
Hypercalcaemia	1(1.4%)	1(5.9%)	0	0	0

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_0602
BEL114256 Final Analysis: Generated: 16FEB2023 16:56

Protocol: BEL114256
Population: All Registry Participants

Table 6.2
Solicited Infant AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Metabolism and nutrition disorders (Cont'd)					
Hypophagia	1(1.4%)	0	1(2.3%)	0	0
Underweight	1(1.4%)	0	1(2.3%)	0	0
Weight gain poor	2(2.8%)	0	2(4.5%)	0	0
Musculoskeletal and connective tissue disorders	6(8.3%)	0	6(13.6%)	0	0
Acquired plagiocephaly	2(2.8%)	0	2(4.5%)	0	0
Head deformity	1(1.4%)	0	1(2.3%)	0	0
Joint noise	1(1.4%)	0	1(2.3%)	0	0
Rib deformity	1(1.4%)	0	1(2.3%)	0	0
Torticollis	4(5.6%)	0	4(9.1%)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2(2.8%)	0	2(4.5%)	0	0
Haemangioma	1(1.4%)	0	1(2.3%)	0	0
Haemangioma of skin	1(1.4%)	0	1(2.3%)	0	0
Nervous system disorders	5(6.9%)	2(11.8%)	3(6.8%)	0	0
Clonus	1(1.4%)	1(5.9%)	0	0	0

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
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Protocol: BEL114256
Population: All Registry Participants

Table 6.2
Solicited Infant AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Nervous system disorders (Cont'd)					
Gross motor delay	1(1.4%)	0	1(2.3%)	0	0
Hypertonia	1(1.4%)	1(5.9%)	0	0	0
Intraventricular haemorrhage neonatal	1(1.4%)	0	1(2.3%)	0	0
Spinal cord disorder	1(1.4%)	0	1(2.3%)	0	0
Pregnancy, puerperium and perinatal conditions	12(16.7%)	4(23.5%)	7(15.9%)	0	1(9.1%)
Foetal cardiac disorder	1(1.4%)	1(5.9%)	0	0	0
Foetal distress syndrome	1(1.4%)	1(5.9%)	0	0	0
Foetal growth restriction	1(1.4%)	0	1(2.3%)	0	0
Hydrops foetalis	2(2.8%)	0	2(4.5%)	0	0
Jaundice neonatal	1(1.4%)	1(5.9%)	0	0	0
Premature baby	6(8.3%)	1(5.9%)	4(9.1%)	0	1(9.1%)
Small for dates baby	1(1.4%)	1(5.9%)	0	0	0
Renal and urinary disorders	2(2.8%)	0	2(4.5%)	0	0
Hydronephrosis	1(1.4%)	0	1(2.3%)	0	0
Pyelocaliectasis	2(2.8%)	0	2(4.5%)	0	0
Reproductive system and breast disorders	1(1.4%)	0	1(2.3%)	0	0
Penile adhesion	1(1.4%)	0	1(2.3%)	0	0

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
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Protocol: BEL114256
Population: All Registry Participants

Table 6.2
Solicited Infant AEs and SAEs by Cohort for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Skin and subcutaneous tissue disorders	4(5.6%)	1(5.9%)	3(6.8%)	0	0
Dermatitis diaper	3(4.2%)	1(5.9%)	2(4.5%)	0	0
Rash	1(1.4%)	0	1(2.3%)	0	0

Note: A subject with multiple occurrences of a system organ class or preferred term is counted only once.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.0
Infant Follow-up by Visit for Exposed Participants
(Overall Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses.
N= the number of live births with data at each time point.
[1]Full-Term is defined as infants born >=$37^{0/7}$ weeks' gestational age.
[2]Preterm is defined as delivery <$37^{0/7}$ weeks' gestational age; late preterm is defined as $34^{0/7}$ and $36^{6/7}$ weeks' gestational age; moderate preterm is defined as $32^{0/7}$ and $33^{6/7}$ weeks' gestational age; very/severely preterm defined as $28^{0/7}$ and $31^{6/7}$ weeks' gestational age; extremely preterm is defined as <$28^{0/7}$ weeks' gestational age.
[3]Includes both previously and currently breastfed infants. Participants with no breastfeeding records available are not presented; therefore numbers may not add to total numbers presented in the column headers.
[4]Includes all defects noted during infant Outcome and follow-up and not defects confirmed by the birth defect evaluator. Birth Defect status may not be reported at Outcome, but may be reported or confirmed at a later visit. Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.
[5]Any infant with a reported infection requiring treatment OR a reported fever of unknown origin or fever of known infectious etiology reported at designated follow-up visit (regardless of age of onset or severity). Denominator is total number of infants with a designated follow-up visit
[6]Participants DE0001 and US0003 will never have a pediatric outcome form and therefore are categorized as 'pending/missing/unknown'. Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the outcome column within their respective table

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Protocol: BEL114256
Population: All Registry Participants

Table 7.0
Infant Follow-up by Visit for Exposed Participants
(Overall Cohort)

	All Live Births (N=66)			Full-Term Live Births[1] (N=44)			Preterm Live Births[2] (N=21)		
	Outcome (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Outcome (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Region									
N. America	57(86.4%)	49(86.0%)	48(87.3%)	39(88.6%)	31(88.6%)	33(91.7%)	18(85.7%)	18(85.7%)	15(83.3%)
Europe	8(12.1%)	7(12.3%)	7(12.7%)	4(9.1%)	3(8.6%)	3(8.3%)	3(14.3%)	3(14.3%)	3(16.7%)
Missing/Unk	1(1.5%)	1(1.8%)	0	1(2.3%)	1(2.9%)	0	0	0	0
Length(cm)									
n	50	57	54	34	35	35	15	21	18
Mean (SD)	47.78 (3.172)	62.40 (3.212)	75.19 (3.804)	48.74 (2.662)	63.23 (2.766)	75.90 (3.653)	45.72 (3.388)	61.12 (3.557)	73.94 (3.932)
Median	48.00	62.23	75.65	48.26	63.50	76.20	45.72	61.00	74.08
Min - Max	38.0 - 53.3	50.5 - 68.6	64.8 - 83.1	43.2 - 53.3	58.4 - 68.6	64.8 - 83.1	38.0 - 52.0	50.5 - 65.5	67.0 - 80.0
Q1, Q3	45.72, 50.80	60.96, 64.77	73.00, 78.23	47.50, 50.80	60.96, 65.53	73.50, 78.74	43.80, 48.26	59.69, 63.50	71.12, 77.47

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 7.0
Infant Follow-up by Visit for Exposed Participants
(Overall Cohort)

	All Live Births (N=66)			Full-Term Live Births[1] (N=44)			Preterm Live Births[2] (N=21)		
	Outcome (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Outcome (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Weight(kg)									
n	63	57	55	44	35	36	18	21	18
Mean (SD)	2.83 (0.586)	6.33 (0.796)	9.82 (1.219)	3.06 (0.485)	6.54 (0.709)	10.14 (1.282)	2.31 (0.477)	5.99 (0.849)	9.25 (0.837)
Median	2.81	6.26	9.71	3.06	6.53	9.98	2.27	6.00	9.41
Min - Max	1.4 - 4.3	4.0 - 7.8	7.5 - 14.6	2.0 - 4.3	5.0 - 7.8	7.6 - 14.6	1.4 - 3.2	4.0 - 7.4	7.5 - 10.8
Q1, Q3	2.42, 3.30	5.90, 7.03	9.34, 10.34	2.71, 3.34	6.00, 7.26	9.50, 10.66	2.09, 2.63	5.62, 6.40	9.21, 9.62

Note: See footnotes on Page 1.
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Protocol: BEL114256
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Table 7.0
Infant Follow-up by Visit for Exposed Participants
(Overall Cohort)

	All Live Births (N=66)			Full-Term Live Births[1] (N=44)			Preterm Live Births[2] (N=21)		
	Outcome (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Outcome (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Head circumference (cm)									
n	45	57	53	29	35	34	15	21	18
Mean (SD)	33.32 (1.874)	41.37 (1.653)	46.27 (1.449)	33.95 (1.520)	41.82 (1.681)	46.73 (1.560)	31.99 (1.871)	40.61 (1.372)	45.47 (0.713)
Median	33.50	41.28	46.00	34.00	41.50	46.99	32.00	40.64	45.50
Min - Max	27.0 - 36.8	37.5 - 45.2	42.5 - 50.0	31.0 - 36.8	38.2 - 45.2	42.5 - 50.0	27.0 - 34.3	37.5 - 43.4	44.0 - 46.5
Q1, Q3	32.00, 34.50	40.50, 42.50	45.50, 47.00	33.00, 35.00	40.64, 43.00	45.72, 47.50	32.00, 33.00	40.01, 41.50	45.00, 46.00
Currently breastfed?[3]									
Yes	42(63.6%)	30(52.6%)	11(20.0%)	26(59.1%)	14(40.0%)	9(25.0%)	16(76.2%)	15(71.4%)	2(11.1%)
No	17(25.8%)	27(47.4%)	43(78.2%)	16(36.4%)	21(60.0%)	26(72.2%)	1(4.8%)	6(28.6%)	16(88.9%)
Missing/Unk	7(10.6%)	0	1(1.8%)	2(4.5%)	0	1(2.8%)	4(19.0%)	0	0

Note: See footnotes on Page 1.
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Table 7.0
Infant Follow-up by Visit for Exposed Participants
(Overall Cohort)

	All Live Births (N=66)			Full-Term Live Births[1] (N=44)			Preterm Live Births[2] (N=21)		
	Outcome (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Outcome (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Ever breastfed?									
Yes[3]	45(68.2%)	45(78.9%)	44(80.0%)	29(65.9%)	24(68.6%)	26(72.2%)	16(76.2%)	20(95.2%)	17(94.4%)
No	14(21.2%)	12(21.1%)	11(20.0%)	13(29.5%)	11(31.4%)	10(27.8%)	1(4.8%)	1(4.8%)	1(5.6%)
Missing/Unk	7(10.6%)	0	0	2(4.5%)	0	0	4(19.0%)	0	0
Belimumab exposure during breast-feeding?[3]									
Yes	11(16.7%)	6(10.5%)	7(12.7%)	6(13.6%)	3(8.6%)	3(8.3%)	5(23.8%)	2(9.5%)	3(16.7%)
No	26(39.4%)	10(17.5%)	9(16.4%)	18(40.9%)	6(17.1%)	5(13.9%)	8(38.1%)	4(19.0%)	4(22.2%)
Missing/Unk	29(43.9%)	41(71.9%)	39(70.9%)	20(45.5%)	26(74.3%)	28(77.8%)	8(38.1%)	15(71.4%)	11(61.1%)

Note: See footnotes on Page 1.
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Table 7.0
Infant Follow-up by Visit for Exposed Participants
(Overall Cohort)

	All Live Births (N=66)			Full-Term Live Births[1] (N=44)			Preterm Live Births[2] (N=21)		
	Outcome (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Outcome (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Birth Defect Noted[4]									
Yes	9(13.6%)	2(3.5%)	1(1.8%)	7(15.9%)	1(2.9%)	0	2(9.5%)	1(4.8%)	1(5.6%)
No	55(83.3%)	54(94.7%)	54(98.2%)	37(84.1%)	33(94.3%)	36(100.0%)	17(81.0%)	20(95.2%)	17(94.4%)
Pending/ Missing/Unk[6]	2(3.0%)	1(1.8%)	0	0	1(2.9%)	0	2(9.5%)	0	0
Earliest Belimumab Exposure									
Preconception	61(92.4%)	52(91.2%)	50(90.9%)	41(93.2%)	32(91.4%)	33(91.7%)	20(95.2%)	20(95.2%)	17(94.4%)
1st trimester	4(6.1%)	4(7.0%)	4(7.3%)	2(4.5%)	2(5.7%)	2(5.6%)	1(4.8%)	1(4.8%)	1(5.6%)
2nd trimester	1(1.5%)	1(1.8%)	1(1.8%)	1(2.3%)	1(2.9%)	1(2.8%)	0	0	0
3rd trimester	0	0	0	0	0	0	0	0	0
Postpartum	0	0	0	0	0	0	0	0	0

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Table 7.0
Infant Follow-up by Visit for Exposed Participants
(Overall Cohort)

	All Live Births (N=66)			Full-Term Live Births[1] (N=44)			Preterm Live Births[2] (N=21)		
	Outcome (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Outcome (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Last Belimumab Exposure									
Preconception	0	0	0	0	0	0	0	0	0
1st trimester	11(16.7%)	9(15.8%)	8(14.5%)	4(9.1%)	2(5.7%)	3(8.3%)	7(33.3%)	7(33.3%)	5(27.8%)
2nd trimester	35(53.0%)	29(50.9%)	28(50.9%)	26(59.1%)	20(57.1%)	20(55.6%)	9(42.9%)	9(42.9%)	8(44.4%)
3rd trimester	1(1.5%)	1(1.8%)	1(1.8%)	1(2.3%)	1(2.9%)	1(2.8%)	0	0	0
Postpartum	19(28.8%)	18(31.6%)	18(32.7%)	13(29.5%)	12(34.3%)	12(33.3%)	5(23.8%)	5(23.8%)	5(27.8%)
Maternal Age									
<35 years	48(72.7%)	42(73.7%)	39(70.9%)	33(75.0%)	27(77.1%)	26(72.2%)	14(66.7%)	14(66.7%)	12(66.7%)
>=35 years	18(27.3%)	15(26.3%)	16(29.1%)	11(25.0%)	8(22.9%)	10(27.8%)	7(33.3%)	7(33.3%)	6(33.3%)
Meeting Dev. Milestones?									
Gross Motor	NA			NA			NA		
Yes		54(94.7%)	51(92.7%)		34(97.1%)	35(97.2%)		20(95.2%)	16(88.9%)
No		1(1.8%)	2(3.6%)		0	0		1(4.8%)	2(11.1%)
Missing/Unk		2(3.5%)	2(3.6%)		1(2.9%)	1(2.8%)		0	0

Note: See footnotes on Page 1.
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Table 7.0
Infant Follow-up by Visit for Exposed Participants
(Overall Cohort)

	All Live Births (N=66)			Full-Term Live Births[1] (N=44)			Preterm Live Births[2] (N=21)		
	Outcome (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Outcome (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Fine Motor	NA			NA			NA		
Yes		52(91.2%)	52(94.5%)		33(94.3%)	34(94.4%)		19(90.5%)	18(100.0%)
No		0	1(1.8%)		0	1(2.8%)		0	0
Missing/Unk		5(8.8%)	2(3.6%)		2(5.7%)	1(2.8%)		2(9.5%)	0
Language	NA			NA			NA		
Yes		49(86.0%)	51(92.7%)		32(91.4%)	35(97.2%)		17(81.0%)	16(88.9%)
No		0	2(3.6%)		0	0		0	2(11.1%)
Missing/Unk		8(14.0%)	2(3.6%)		3(8.6%)	1(2.8%)		4(19.0%)	0
Cognitive	NA			NA			NA		
Yes		51(89.5%)	52(94.5%)		32(91.4%)	34(94.4%)		19(90.5%)	18(100.0%)
No		0	0		0	0		0	0
Missing/Unk		6(10.5%)	3(5.5%)		3(8.6%)	2(5.6%)		2(9.5%)	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.0
Infant Follow-up by Visit for Exposed Participants
(Overall Cohort)

	All Live Births (N=66)			Full-Term Live Births[1] (N=44)			Preterm Live Births[2] (N=21)		
	Outcome[*] (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Outcome[*] (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Social/ Emotional	NA			NA			NA		
Yes		52(91.2%)	51(92.7%)		33(94.3%)	34(94.4%)		19(90.5%)	17(94.4%)
No		0	1(1.8%)		0	0		0	1(5.6%)
Missing/Unk		5(8.8%)	3(5.5%)		2(5.7%)	2(5.6%)		2(9.5%)	0
Infants experiencing at least one infection or fever regardless of severity[5]	4(6.1%)	7(12.3%)	20(36.4%)	3(6.8%)	7(20.0%)	13(36.1%)	1(4.8%)	0	7(38.9%)
Total number infections or fever?	5	7	28	3	7	18	2	0	10

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.1
Infant Follow-up by Visit for Exposed Participants
(Overall Prospective Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses.
N= the number of live births with data at each time point.
[1]Full-Term is defined as infants born >=$37^{0/7}$ weeks' gestational age.
[2]Preterm is defined as delivery <$37^{0/7}$ weeks' gestational age; late preterm is defined as $34^{0/7}$ and $36^{6/7}$ weeks' gestational age; moderate preterm is defined as $32^{0/7}$ and $33^{6/7}$ weeks' gestational age; very/severely preterm defined as $28^{0/7}$ and $31^{6/7}$ weeks' gestational age; extremely preterm is defined as <$28^{0/7}$ weeks' gestational age.
[3]Includes both previously and currently breastfed infants. Participants with no breastfeeding records available are not presented; therefore numbers may not add to total numbers presented in the column headers.
[4]Includes all defects noted during infant Outcome and follow-up and not defects confirmed by the birth defect evaluator. Birth Defect status may not be reported at Outcome, but may be reported or confirmed at a later visit. Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.
[5]Any infant with a reported infection requiring treatment OR a reported fever of unknown origin or fever of known infectious etiology reported at designated follow-up visit (regardless of age of onset or severity). Denominator is total number of infants with a designated follow-up visit
[6]Participants DE0001 and US0003 will never have a pediatric outcome form and therefore are categorized as 'pending/missing/unknown'. Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the outcome column within their respective table

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Protocol: BEL114256
Population: All Registry Participants

Table 7.1
Infant Follow-up by Visit for Exposed Participants
(Overall Prospective Cohort)

	All Live Births (N=61)			Full-Term Live Births[1] (N=42)			Preterm Live Births[2] (N=19)		
	Outcome (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Outcome (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Region									
N. America	53(86.9%)	45(86.5%)	45(88.2%)	37(88.1%)	29(87.9%)	31(91.2%)	16(84.2%)	16(84.2%)	14(82.4%)
Europe	7(11.5%)	6(11.5%)	6(11.8%)	4(9.5%)	3(9.1%)	3(8.8%)	3(15.8%)	3(15.8%)	3(17.6%)
Missing/Unk	1(1.6%)	1(1.9%)	0	1(2.4%)	1(3.0%)	0	0	0	0
Length(cm)									
n	46	52	50	33	33	33	13	19	17
Mean (SD)	47.81 (3.298)	62.40 (3.210)	75.11 (3.780)	48.78 (2.696)	63.14 (2.658)	75.86 (3.568)	45.35 (3.503)	61.12 (3.730)	73.66 (3.861)
Median	48.13	62.47	75.65	48.26	63.50	76.20	45.70	61.00	73.66
Min - Max	38.0 - 53.3	50.5 - 68.6	64.8 - 83.1	43.2 - 53.3	58.4 - 68.6	64.8 - 83.1	38.0 - 52.0	50.5 - 65.5	67.0 - 80.0
Q1, Q3	45.70, 50.80	60.96, 64.79	73.15, 77.47	47.50, 50.80	60.96, 65.53	73.66, 78.74	43.80, 47.00	59.00, 64.77	71.12, 76.20

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.1
Infant Follow-up by Visit for Exposed Participants
(Overall Prospective Cohort)

	All Live Births (N=61)			Full-Term Live Births[1] (N=42)			Preterm Live Births[2] (N=19)		
	Outcome (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Outcome (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Weight(kg)									
n	58	52	51	42	33	34	16	19	17
Mean (SD)	2.84 (0.600)	6.30 (0.804)	9.80 (1.243)	3.05 (0.495)	6.52 (0.718)	10.13 (1.318)	2.29 (0.498)	5.92 (0.823)	9.16 (0.766)
Median	2.83	6.26	9.66	3.06	6.53	9.96	2.25	6.00	9.40
Min - Max	1.4 - 4.3	4.0 - 7.8	7.5 - 14.6	2.0 - 4.3	5.0 - 7.8	7.6 - 14.6	1.4 - 3.2	4.0 - 7.3	7.5 - 10.2
Q1, Q3	2.42, 3.30	5.87, 7.01	9.34, 10.21	2.69, 3.36	6.00, 7.08	9.48, 10.75	2.04, 2.52	5.46, 6.40	9.21, 9.50

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Population: All Registry Participants

Table 7.1
Infant Follow-up by Visit for Exposed Participants
(Overall Prospective Cohort)

	All Live Births (N=61)			Full-Term Live Births[1] (N=42)			Preterm Live Births[2] (N=19)		
	Outcome (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Outcome (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Head circumference (cm)									
n	41	52	49	28	33	32	13	19	17
Mean (SD)	33.26 (1.935)	41.36 (1.728)	46.29 (1.491)	33.95 (1.547)	41.83 (1.732)	46.75 (1.599)	31.77 (1.889)	40.55 (1.429)	45.44 (0.723)
Median	33.50	41.24	46.00	34.02	41.50	46.99	32.00	40.50	45.50
Min - Max	27.0 - 36.8	37.5 - 45.2	42.5 - 50.0	31.0 - 36.8	38.2 - 45.2	42.5 - 50.0	27.0 - 34.0	37.5 - 43.4	44.0 - 46.5
Q1, Q3	32.00, 34.50	40.49, 42.50	45.50, 47.00	33.00, 35.00	40.64, 43.00	45.72, 47.60	32.00, 33.00	40.00, 41.50	45.00, 46.00
Currently breastfed?[3]									
Yes	38(62.3%)	26(50.0%)	10(19.6%)	24(57.1%)	13(39.4%)	8(23.5%)	14(73.7%)	13(68.4%)	2(11.8%)
No	17(27.9%)	26(50.0%)	40(78.4%)	16(38.1%)	20(60.6%)	25(73.5%)	1(5.3%)	6(31.6%)	15(88.2%)
Missing/Unk	6(9.8%)	0	1(2.0%)	2(4.8%)	0	1(2.9%)	4(21.1%)	0	0

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Table 7.1
Infant Follow-up by Visit for Exposed Participants
(Overall Prospective Cohort)

	All Live Births (N=61)			Full-Term Live Births[1] (N=42)			Preterm Live Births[2] (N=19)		
	Outcome (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Outcome (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Ever breastfed?									
Yes[3]	41(67.2%)	40(76.9%)	40(78.4%)	27(64.3%)	22(66.7%)	24(70.6%)	14(73.7%)	18(94.7%)	16(94.1%)
No	14(23.0%)	12(23.1%)	11(21.6%)	13(31.0%)	11(33.3%)	10(29.4%)	1(5.3%)	1(5.3%)	1(5.9%)
Missing/Unk	6(9.8%)	0	0	2(4.8%)	0	0	4(21.1%)	0	0
Belimumab exposure during breast-feeding?[3]									
Yes	10(16.4%)	5(9.6%)	6(11.8%)	5(11.9%)	3(9.1%)	3(8.8%)	5(26.3%)	2(10.5%)	3(17.6%)
No	23(37.7%)	8(15.4%)	8(15.7%)	17(40.5%)	5(15.2%)	4(11.8%)	6(31.6%)	3(15.8%)	4(23.5%)
Missing/Unk	28(45.9%)	39(75.0%)	37(72.5%)	20(47.6%)	25(75.8%)	27(79.4%)	8(42.1%)	14(73.7%)	10(58.8%)

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Table 7.1
Infant Follow-up by Visit for Exposed Participants
(Overall Prospective Cohort)

	All Live Births (N=61)			Full-Term Live Births[1] (N=42)			Preterm Live Births[2] (N=19)		
	Outcome (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Outcome (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Birth Defect Noted[4]									
Yes	9(14.8%)	2(3.8%)	1(2.0%)	7(16.7%)	1(3.0%)	0	2(10.5%)	1(5.3%)	1(5.9%)
No	50(82.0%)	49(94.2%)	50(98.0%)	35(83.3%)	31(93.9%)	34(100.0%)	15(78.9%)	18(94.7%)	16(94.1%)
Pending/ Missing/Unk[6]	2(3.3%)	1(1.9%)	0	0	1(3.0%)	0	2(10.5%)	0	0
Earliest Belimumab Exposure									
Preconception	58(95.1%)	49(94.2%)	48(94.1%)	39(92.9%)	30(90.9%)	31(91.2%)	19(100.0%)	19(100.0%)	17(100.0%)
1st trimester	2(3.3%)	2(3.8%)	2(3.9%)	2(4.8%)	2(6.1%)	2(5.9%)	0	0	0
2nd trimester	1(1.6%)	1(1.9%)	1(2.0%)	1(2.4%)	1(3.0%)	1(2.9%)	0	0	0
3rd trimester	0	0	0	0	0	0	0	0	0
Postpartum	0	0	0	0	0	0	0	0	0

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Table 7.1
Infant Follow-up by Visit for Exposed Participants
(Overall Prospective Cohort)

	All Live Births (N=61)			Full-Term Live Births[1] (N=42)			Preterm Live Births[2] (N=19)		
	Outcome (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Outcome (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Last Belimumab Exposure									
Preconception	0	0	0	0	0	0	0	0	0
1st trimester	10(16.4%)	8(15.4%)	8(15.7%)	4(9.5%)	2(6.1%)	3(8.8%)	6(31.6%)	6(31.6%)	5(29.4%)
2nd trimester	33(54.1%)	27(51.9%)	26(51.0%)	25(59.5%)	19(57.6%)	19(55.9%)	8(42.1%)	8(42.1%)	7(41.2%)
3rd trimester	1(1.6%)	1(1.9%)	1(2.0%)	1(2.4%)	1(3.0%)	1(2.9%)	0	0	0
Postpartum	17(27.9%)	16(30.8%)	16(31.4%)	12(28.6%)	11(33.3%)	11(32.4%)	5(26.3%)	5(26.3%)	5(29.4%)
Maternal Age									
<35 years	43(70.5%)	37(71.2%)	35(68.6%)	31(73.8%)	25(75.8%)	24(70.6%)	12(63.2%)	12(63.2%)	11(64.7%)
>=35 years	18(29.5%)	15(28.8%)	16(31.4%)	11(26.2%)	8(24.2%)	10(29.4%)	7(36.8%)	7(36.8%)	6(35.3%)
Meeting Dev. Milestones?									
Gross Motor	NA			NA			NA		
Yes		50(96.2%)	48(94.1%)		32(97.0%)	33(97.1%)		18(94.7%)	15(88.2%)
No		1(1.9%)	2(3.9%)		0	0		1(5.3%)	2(11.8%)
Missing/Unk		1(1.9%)	1(2.0%)		1(3.0%)	1(2.9%)		0	0

Note: See footnotes on Page 1.
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Table 7.1
Infant Follow-up by Visit for Exposed Participants
(Overall Prospective Cohort)

	All Live Births (N=61)			Full-Term Live Births[1] (N=42)			Preterm Live Births[2] (N=19)		
	Outcome (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Outcome (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Fine Motor	NA			NA			NA		
Yes		48(92.3%)	49(96.1%)		31(93.9%)	32(94.1%)		17(89.5%)	17(100.0%)
No		0	1(2.0%)		0	1(2.9%)		0	0
Missing/Unk		4(7.7%)	1(2.0%)		2(6.1%)	1(2.9%)		2(10.5%)	0
Language	NA			NA			NA		
Yes		45(86.5%)	48(94.1%)		30(90.9%)	33(97.1%)		15(78.9%)	15(88.2%)
No		0	2(3.9%)		0	0		0	2(11.8%)
Missing/Unk		7(13.5%)	1(2.0%)		3(9.1%)	1(2.9%)		4(21.1%)	0
Cognitive	NA			NA			NA		
Yes		47(90.4%)	49(96.1%)		30(90.9%)	32(94.1%)		17(89.5%)	17(100.0%)
No		0	0		0	0		0	0
Missing/Unk		5(9.6%)	2(3.9%)		3(9.1%)	2(5.9%)		2(10.5%)	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 7.1
Infant Follow-up by Visit for Exposed Participants
(Overall Prospective Cohort)

	All Live Births (N=61)			Full-Term Live Births[1] (N=42)			Preterm Live Births[2] (N=19)		
	Outcome[*] (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Outcome[*] (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Social/ Emotional	NA			NA			NA		
Yes		48(92.3%)	48(94.1%)		31(93.9%)	32(94.1%)		17(89.5%)	16(94.1%)
No		0	1(2.0%)		0	0		0	1(5.9%)
Missing/Unk		4(7.7%)	2(3.9%)		2(6.1%)	2(5.9%)		2(10.5%)	0
Infants experiencing at least one infection or fever regardless of severity[5]	4(6.6%)	7(13.5%)	18(35.3%)	3(7.1%)	7(21.2%)	12(35.3%)	1(5.3%)	0	6(35.3%)
Total number infections or fever?	5	7	25	3	7	16	2	0	9

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Population: All Registry Participants

Table 7.2
Infant Follow-up by Visit for Exposed Participants
(Pure Prospective Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses.
N= the number of live births with data at each time point.
[1]Full-Term is defined as infants born >=$37^{0/7}$ weeks' gestational age.
[2]Preterm is defined as delivery <$37^{0/7}$ weeks' gestational age; late preterm is defined as $34^{0/7}$ and $36^{6/7}$ weeks' gestational age; moderate preterm is defined as $32^{0/7}$ and $33^{6/7}$ weeks' gestational age; very/severely preterm defined as $28^{0/7}$ and $31^{6/7}$ weeks' gestational age; extremely preterm is defined as <$28^{0/7}$ weeks' gestational age.
[3]Includes both previously and currently breastfed infants. Participants with no breastfeeding records available are not presented; therefore numbers may not add to total numbers presented in the column headers.
[4]Includes all defects noted during infant Outcome and follow-up and not defects confirmed by the birth defect evaluator. Birth Defect status may not be reported at Outcome, but may be reported or confirmed at a later visit. Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.
[5]Any infant with a reported infection requiring treatment OR a reported fever of unknown origin or fever of known infectious etiology reported at designated follow-up visit (regardless of age of onset or severity). Denominator is total number of infants with a designated follow-up visit
[6]Participants DE0001 and US0003 will never have a pediatric outcome form and therefore are categorized as 'pending/missing/unknown'. Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the outcome column within their respective table

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Protocol: BEL114256
Population: All Registry Participants

Table 7.2
Infant Follow-up by Visit for Exposed Participants
(Pure Prospective Cohort)

	All Live Births (N=17)			Full-Term Live Births[1] (N=10)			Preterm Live Births[2] (N=7)		
	Outcome (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Outcome (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Region									
N. America	14(82.4%)	10(76.9%)	9(81.8%)	8(80.0%)	4(66.7%)	4(80.0%)	6(85.7%)	6(85.7%)	5(83.3%)
Europe	2(11.8%)	2(15.4%)	2(18.2%)	1(10.0%)	1(16.7%)	1(20.0%)	1(14.3%)	1(14.3%)	1(16.7%)
Missing/Unk	1(5.9%)	1(7.7%)	0	1(10.0%)	1(16.7%)	0	0	0	0
Length(cm)									
n	12	13	11	5	6	5	7	7	6
Mean (SD)	47.26 (3.132)	62.89 (3.205)	75.58 (3.674)	48.57 (3.001)	63.60 (3.004)	76.75 (2.549)	46.32 (3.083)	62.27 (3.475)	74.60 (4.392)
Median	47.00	63.50	75.50	48.26	64.52	77.47	45.72	62.87	74.58
Min - Max	42.5 - 53.3	55.9 - 66.5	68.6 - 80.0	45.0 - 53.3	59.1 - 66.5	73.7 - 79.4	42.5 - 52.0	55.9 - 65.5	68.6 - 80.0
Q1, Q3	45.35, 48.28	60.96, 65.50	73.66, 78.74	48.00, 48.26	60.96, 66.00	74.50, 78.74	43.99, 48.30	60.50, 65.41	71.12, 78.74

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Table 7.2
Infant Follow-up by Visit for Exposed Participants
(Pure Prospective Cohort)

	All Live Births (N=17)			Full-Term Live Births[1] (N=10)			Preterm Live Births[2] (N=7)		
	Outcome (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Outcome (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Weight(kg)									
n	17	13	11	10	6	5	7	7	6
Mean (SD)	2.75 (0.578)	6.23 (0.927)	9.79 (1.161)	3.05 (0.407)	6.41 (0.966)	10.51 (1.220)	2.32 (0.524)	6.08 (0.940)	9.19 (0.743)
Median	2.77	6.26	9.60	2.97	6.29	10.02	2.22	6.26	9.42
Min - Max	1.5 - 3.8	4.6 - 7.5	7.7 - 12.2	2.4 - 3.8	5.0 - 7.5	9.4 - 12.2	1.5 - 3.2	4.6 - 7.3	7.7 - 9.7
Q1, Q3	2.42, 3.20	5.99, 6.71	9.34, 10.02	2.77, 3.36	5.99, 7.39	9.60, 11.29	2.09, 2.63	5.08, 6.71	9.25, 9.62

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 7.2
Infant Follow-up by Visit for Exposed Participants
(Pure Prospective Cohort)

	All Live Births (N=17)			Full-Term Live Births[1] (N=10)			Preterm Live Births[2] (N=7)		
	Outcome (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Outcome (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Head circumference (cm)									
n	12	13	11	5	6	5	7	7	6
Mean (SD)	33.02 (1.842)	41.55 (2.192)	46.47 (1.823)	34.25 (1.504)	42.34 (2.585)	47.85 (1.866)	32.14 (1.600)	40.86 (1.693)	45.32 (0.619)
Median	33.01	41.50	46.00	34.93	42.75	47.50	32.00	40.70	45.25
Min - Max	29.0 - 35.6	38.0 - 45.2	44.5 - 50.0	31.8 - 35.6	38.2 - 45.2	45.7 - 50.0	29.0 - 34.0	38.0 - 43.4	44.5 - 46.0
Q1, Q3	32.00, 34.46	40.50, 43.00	45.00, 47.50	34.00, 35.00	40.64, 44.50	46.50, 49.53	32.00, 33.50	40.01, 41.91	45.00, 46.00
Currently breastfed?[3]									
Yes	9(52.9%)	4(30.8%)	0	4(40.0%)	0	0	5(71.4%)	4(57.1%)	0
No	6(35.3%)	9(69.2%)	11(100.0%)	5(50.0%)	6(100.0%)	5(100.0%)	1(14.3%)	3(42.9%)	6(100.0%)
Missing/Unk	2(11.8%)	0	0	1(10.0%)	0	0	1(14.3%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.2
Infant Follow-up by Visit for Exposed Participants
(Pure Prospective Cohort)

	All Live Births (N=17)			Full-Term Live Births[1] (N=10)			Preterm Live Births[2] (N=7)		
	Outcome (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Outcome (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Ever breastfed?									
Yes[3]	10(58.8%)	9(69.2%)	8(72.7%)	5(50.0%)	3(50.0%)	3(60.0%)	5(71.4%)	6(85.7%)	5(83.3%)
No	5(29.4%)	4(30.8%)	3(27.3%)	4(40.0%)	3(50.0%)	2(40.0%)	1(14.3%)	1(14.3%)	1(16.7%)
Missing/Unk	2(11.8%)	0	0	1(10.0%)	0	0	1(14.3%)	0	0
Belimumab exposure during breast-feeding?[3]									
Yes	4(23.5%)	3(23.1%)	3(27.3%)	1(10.0%)	1(16.7%)	1(20.0%)	3(42.9%)	2(28.6%)	2(33.3%)
No	6(35.3%)	2(15.4%)	1(9.1%)	4(40.0%)	1(16.7%)	0	2(28.6%)	1(14.3%)	1(16.7%)
Missing/Unk	7(41.2%)	8(61.5%)	7(63.6%)	5(50.0%)	4(66.7%)	4(80.0%)	2(28.6%)	4(57.1%)	3(50.0%)
Birth Defect Noted[4]									
Yes	1(5.9%)	0	0	1(10.0%)	0	0	0	0	0
No	15(88.2%)	13(100.0%)	11(100.0%)	9(90.0%)	6(100.0%)	5(100.0%)	6(85.7%)	7(100.0%)	6(100.0%)
Pending/ Missing/Unk[6]	1(5.9%)	0	0	0	0	0	1(14.3%)	0	0

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Protocol: BEL114256
Population: All Registry Participants

Table 7.2
Infant Follow-up by Visit for Exposed Participants
(Pure Prospective Cohort)

	All Live Births (N=17)			Full-Term Live Births[1] (N=10)			Preterm Live Births[2] (N=7)		
	Outcome (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Outcome (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Earliest Belimumab Exposure									
Preconception	17(100.0%)	13(100.0%)	11(100.0%)	10(100.0%)	6(100.0%)	5(100.0%)	7(100.0%)	7(100.0%)	6(100.0%)
1st trimester	0	0	0	0	0	0	0	0	0
2nd trimester	0	0	0	0	0	0	0	0	0
3rd trimester	0	0	0	0	0	0	0	0	0
Postpartum	0	0	0	0	0	0	0	0	0
Last Belimumab Exposure									
Preconception	0	0	0	0	0	0	0	0	0
1st trimester	2(11.8%)	1(7.7%)	1(9.1%)	2(20.0%)	1(16.7%)	1(20.0%)	0	0	0
2nd trimester	8(47.1%)	6(46.2%)	4(36.4%)	4(40.0%)	2(33.3%)	1(20.0%)	4(57.1%)	4(57.1%)	3(50.0%)
3rd trimester	0	0	0	0	0	0	0	0	0
Postpartum	7(41.2%)	6(46.2%)	6(54.5%)	4(40.0%)	3(50.0%)	3(60.0%)	3(42.9%)	3(42.9%)	3(50.0%)

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Population: All Registry Participants

Table 7.2
Infant Follow-up by Visit for Exposed Participants
(Pure Prospective Cohort)

	All Live Births (N=17)			Full-Term Live Births[1] (N=10)			Preterm Live Births[2] (N=7)		
	Outcome (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Outcome (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Maternal Age									
<35 years	12(70.6%)	8(61.5%)	7(63.6%)	9(90.0%)	5(83.3%)	4(80.0%)	3(42.9%)	3(42.9%)	3(50.0%)
>=35 years	5(29.4%)	5(38.5%)	4(36.4%)	1(10.0%)	1(16.7%)	1(20.0%)	4(57.1%)	4(57.1%)	3(50.0%)
Meeting Dev. Milestones?									
Gross Motor	NA			NA			NA		
Yes		12(92.3%)	11(100.0%)		5(83.3%)	5(100.0%)		7(100.0%)	6(100.0%)
No		0	0		0	0		0	0
Missing/Unk		1(7.7%)	0		1(16.7%)	0		0	0
Fine Motor	NA			NA			NA		
Yes		10(76.9%)	11(100.0%)		5(83.3%)	5(100.0%)		5(71.4%)	6(100.0%)
No		0	0		0	0		0	0
Missing/Unk		3(23.1%)	0		1(16.7%)	0		2(28.6%)	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 7.2
Infant Follow-up by Visit for Exposed Participants
(Pure Prospective Cohort)

	All Live Births (N=17)			Full-Term Live Births[1] (N=10)			Preterm Live Births[2] (N=7)		
	Outcome (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Outcome (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Language	NA			NA			NA		
Yes		9(69.2%)	10(90.9%)		5(83.3%)	5(100.0%)		4(57.1%)	5(83.3%)
No		0	1(9.1%)		0	0		0	1(16.7%)
Missing/Unk		4(30.8%)	0		1(16.7%)	0		3(42.9%)	0
Cognitive	NA			NA			NA		
Yes		10(76.9%)	11(100.0%)		5(83.3%)	5(100.0%)		5(71.4%)	6(100.0%)
No		0	0		0	0		0	0
Missing/Unk		3(23.1%)	0		1(16.7%)	0		2(28.6%)	0
Social/ Emotional	NA			NA			NA		
Yes		10(76.9%)	11(100.0%)		5(83.3%)	5(100.0%)		5(71.4%)	6(100.0%)
No		0	0		0	0		0	0
Missing/Unk		3(23.1%)	0		1(16.7%)	0		2(28.6%)	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.2
Infant Follow-up by Visit for Exposed Participants
(Pure Prospective Cohort)

	All Live Births (N=17)			Full-Term Live Births[1] (N=10)			Preterm Live Births[2] (N=7)		
	Outcome[*] (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Outcome[*] (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Infants experiencing at least one infection or fever regardless of severity[5]	1(5.9%)	2(15.4%)	5(45.5%)	1(10.0%)	2(33.3%)	2(40.0%)	0	0	3(50.0%)
Total number infections or fever?	1	2	5	1	2	2	0	0	3

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Protocol: BEL114256
Population: All Registry Participants

Table 7.3
Infant Follow-up by Visit for Exposed Participants
(Traditional Prospective Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses.
N= the number of live births with data at each time point.
[1]Full-Term is defined as infants born >=$37^{0/7}$ weeks' gestational age.
[2]Preterm is defined as delivery <$37^{0/7}$ weeks' gestational age; late preterm is defined as $34^{0/7}$ and $36^{6/7}$ weeks' gestational age; moderate preterm is defined as $32^{0/7}$ and $33^{6/7}$ weeks' gestational age; very/severely preterm defined as $28^{0/7}$ and $31^{6/7}$ weeks' gestational age; extremely preterm is defined as <$28^{0/7}$ weeks' gestational age.
[3]Includes both previously and currently breastfed infants. Participants with no breastfeeding records available are not presented; therefore numbers may not add to total numbers presented in the column headers.
[4]Includes all defects noted during infant Outcome and follow-up and not defects confirmed by the birth defect evaluator. Birth Defect status may not be reported at Outcome, but may be reported or confirmed at a later visit. Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.
[5]Any infant with a reported infection requiring treatment OR a reported fever of unknown origin or fever of known infectious etiology reported at designated follow-up visit (regardless of age of onset or severity). Denominator is total number of infants with a designated follow-up visit
[6]Participants DE0001 and US0003 will never have a pediatric outcome form and therefore are categorized as 'pending/missing/unknown'. Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the outcome column within their respective table

Protocol: BEL114256
Population: All Registry Participants

Table 7.3
Infant Follow-up by Visit for Exposed Participants
(Traditional Prospective Cohort)

	All Live Births (N=44)			Full-Term Live Births[1] (N=32)			Preterm Live Births[2] (N=12)		
	Outcome (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Outcome (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Region									
N. America	39(88.6%)	35(89.7%)	36(90.0%)	29(90.6%)	25(92.6%)	27(93.1%)	10(83.3%)	10(83.3%)	9(81.8%)
Europe	5(11.4%)	4(10.3%)	4(10.0%)	3(9.4%)	2(7.4%)	2(6.9%)	2(16.7%)	2(16.7%)	2(18.2%)
Length(cm)									
n	34	39	39	28	27	28	6	12	11
Mean (SD)	48.00 (3.379)	62.24 (3.237)	74.98 (3.846)	48.81 (2.696)	63.04 (2.627)	75.70 (3.736)	44.22 (3.899)	60.45 (3.854)	73.14 (3.658)
Median	48.26	62.23	75.69	49.50	62.79	76.20	43.90	60.96	73.66
Min - Max	38.0 - 53.3	50.5 - 68.6	64.8 - 83.1	43.2 - 53.3	58.4 - 68.6	64.8 - 83.1	38.0 - 49.5	50.5 - 64.8	67.0 - 78.2
Q1, Q3	45.72, 50.80	60.96, 64.77	72.39, 77.47	47.25, 50.80	60.96, 65.00	73.35, 78.10	43.00, 47.00	58.71, 62.87	70.51, 76.20

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 7.3
Infant Follow-up by Visit for Exposed Participants
(Traditional Prospective Cohort)

	All Live Births (N=44)			Full-Term Live Births[1] (N=32)			Preterm Live Births[2] (N=12)		
	Outcome (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Outcome (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Weight(kg)									
n	41	39	40	32	27	29	9	12	11
Mean (SD)	2.88 (0.613)	6.33 (0.771)	9.81 (1.279)	3.05 (0.525)	6.54 (0.672)	10.06 (1.343)	2.26 (0.508)	5.83 (0.775)	9.15 (0.814)
Median	2.89	6.17	9.77	3.13	6.53	9.93	2.27	5.94	9.40
Min - Max	1.4 - 4.3	4.0 - 7.8	7.5 - 14.6	2.0 - 4.3	5.3 - 7.8	7.6 - 14.6	1.4 - 3.2	4.0 - 7.2	7.5 - 10.2
Q1, Q3	2.45, 3.30	5.85, 7.03	9.28, 10.27	2.63, 3.32	6.01, 7.08	9.48, 10.50	2.00, 2.33	5.54, 6.12	8.67, 9.50

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Population: All Registry Participants

Table 7.3
Infant Follow-up by Visit for Exposed Participants
(Traditional Prospective Cohort)

	All Live Births (N=44)			Full-Term Live Births[1] (N=32)			Preterm Live Births[2] (N=12)		
	Outcome (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Outcome (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Head circumference (cm)									
n	29	39	38	23	27	27	6	12	11
Mean (SD)	33.36 (1.995)	41.30 (1.574)	46.24 (1.405)	33.89 (1.581)	41.71 (1.527)	46.55 (1.495)	31.33 (2.251)	40.37 (1.295)	45.50 (0.795)
Median	33.50	41.20	46.40	34.00	41.28	46.99	32.00	40.49	45.50
Min - Max	27.0 - 36.8	37.5 - 44.5	42.5 - 50.0	31.0 - 36.8	38.5 - 44.5	42.5 - 50.0	27.0 - 33.0	37.5 - 42.0	44.0 - 46.5
Q1, Q3	32.00, 34.50	40.49, 42.50	45.50, 47.00	33.00, 35.00	40.64, 43.00	45.72, 47.40	31.00, 33.00	39.65, 41.35	45.00, 46.40
Currently breastfed?[3]									
Yes	29(65.9%)	22(56.4%)	10(25.0%)	20(62.5%)	13(48.1%)	8(27.6%)	9(75.0%)	9(75.0%)	2(18.2%)
No	11(25.0%)	17(43.6%)	29(72.5%)	11(34.4%)	14(51.9%)	20(69.0%)	0	3(25.0%)	9(81.8%)
Missing/Unk	4(9.1%)	0	1(2.5%)	1(3.1%)	0	1(3.4%)	3(25.0%)	0	0

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Table 7.3
Infant Follow-up by Visit for Exposed Participants
(Traditional Prospective Cohort)

	All Live Births (N=44)			Full-Term Live Births[1] (N=32)			Preterm Live Births[2] (N=12)		
	Outcome (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Outcome (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Ever breastfed?									
Yes[3]	31(70.5%)	31(79.5%)	32(80.0%)	22(68.8%)	19(70.4%)	21(72.4%)	9(75.0%)	12(100.0%)	11(100.0%)
No	9(20.5%)	8(20.5%)	8(20.0%)	9(28.1%)	8(29.6%)	8(27.6%)	0	0	0
Missing/Unk	4(9.1%)	0	0	1(3.1%)	0	0	3(25.0%)	0	0
Belimumab exposure during breast-feeding?[3]									
Yes	6(13.6%)	2(5.1%)	3(7.5%)	4(12.5%)	2(7.4%)	2(6.9%)	2(16.7%)	0	1(9.1%)
No	17(38.6%)	6(15.4%)	7(17.5%)	13(40.6%)	4(14.8%)	4(13.8%)	4(33.3%)	2(16.7%)	3(27.3%)
Missing/Unk	21(47.7%)	31(79.5%)	30(75.0%)	15(46.9%)	21(77.8%)	23(79.3%)	6(50.0%)	10(83.3%)	7(63.6%)

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Table 7.3
Infant Follow-up by Visit for Exposed Participants
(Traditional Prospective Cohort)

	All Live Births (N=44)			Full-Term Live Births[1] (N=32)			Preterm Live Births[2] (N=12)		
	Outcome (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Outcome (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Birth Defect Noted[4]									
Yes	8(18.2%)	2(5.1%)	1(2.5%)	6(18.8%)	1(3.7%)	0	2(16.7%)	1(8.3%)	1(9.1%)
No	35(79.5%)	36(92.3%)	39(97.5%)	26(81.3%)	25(92.6%)	29(100.0%)	9(75.0%)	11(91.7%)	10(90.9%)
Pending/ Missing/Unk[6]	1(2.3%)	1(2.6%)	0	0	1(3.7%)	0	1(8.3%)	0	0
Earliest Belimumab Exposure									
Preconception	41(93.2%)	36(92.3%)	37(92.5%)	29(90.6%)	24(88.9%)	26(89.7%)	12(100.0%)	12(100.0%)	11(100.0%)
1st trimester	2(4.5%)	2(5.1%)	2(5.0%)	2(6.3%)	2(7.4%)	2(6.9%)	0	0	0
2nd trimester	1(2.3%)	1(2.6%)	1(2.5%)	1(3.1%)	1(3.7%)	1(3.4%)	0	0	0
3rd trimester	0	0	0	0	0	0	0	0	0
Postpartum	0	0	0	0	0	0	0	0	0

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Table 7.3
Infant Follow-up by Visit for Exposed Participants
(Traditional Prospective Cohort)

	All Live Births (N=44)			Full-Term Live Births[1] (N=32)			Preterm Live Births[2] (N=12)		
	Outcome (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Outcome (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Last Belimumab Exposure									
Preconception	0	0	0	0	0	0	0	0	0
1st trimester	8(18.2%)	7(17.9%)	7(17.5%)	2(6.3%)	1(3.7%)	2(6.9%)	6(50.0%)	6(50.0%)	5(45.5%)
2nd trimester	25(56.8%)	21(53.8%)	22(55.0%)	21(65.6%)	17(63.0%)	18(62.1%)	4(33.3%)	4(33.3%)	4(36.4%)
3rd trimester	1(2.3%)	1(2.6%)	1(2.5%)	1(3.1%)	1(3.7%)	1(3.4%)	0	0	0
Postpartum	10(22.7%)	10(25.6%)	10(25.0%)	8(25.0%)	8(29.6%)	8(27.6%)	2(16.7%)	2(16.7%)	2(18.2%)
Maternal Age									
<35 years	31(70.5%)	29(74.4%)	28(70.0%)	22(68.8%)	20(74.1%)	20(69.0%)	9(75.0%)	9(75.0%)	8(72.7%)
>=35 years	13(29.5%)	10(25.6%)	12(30.0%)	10(31.3%)	7(25.9%)	9(31.0%)	3(25.0%)	3(25.0%)	3(27.3%)
Meeting Dev. Milestones?									
Gross Motor	NA			NA			NA		
Yes		38(97.4%)	37(92.5%)		27(100.0%)	28(96.6%)		11(91.7%)	9(81.8%)
No		1(2.6%)	2(5.0%)		0	0		1(8.3%)	2(18.2%)
Missing/Unk		0	0		0	0		0	0

Note: See footnotes on Page 1.
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Table 7.3
Infant Follow-up by Visit for Exposed Participants
(Traditional Prospective Cohort)

	All Live Births (N=44)			Full-Term Live Births[1] (N=32)			Preterm Live Births[2] (N=12)		
	Outcome (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Outcome (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Fine Motor	NA			NA			NA		
Yes		38(97.4%)	38(95.0%)		26(96.3%)	27(93.1%)		12(100.0%)	11(100.0%)
No		0	1(2.5%)		0	1(3.4%)		0	0
Missing/Unk		1(2.6%)	0		1(3.7%)	0		0	0
Language	NA			NA			NA		
Yes		36(92.3%)	38(95.0%)		25(92.6%)	28(96.6%)		11(91.7%)	10(90.9%)
No		0	1(2.5%)		0	0		0	1(9.1%)
Missing/Unk		3(7.7%)	0		2(7.4%)	0		1(8.3%)	0
Cognitive	NA			NA			NA		
Yes		37(94.9%)	38(95.0%)		25(92.6%)	27(93.1%)		12(100.0%)	11(100.0%)
No		0	0		0	0		0	0
Missing/Unk		2(5.1%)	2(5.0%)		2(7.4%)	2(6.9%)		0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.3
Infant Follow-up by Visit for Exposed Participants
(Traditional Prospective Cohort)

	All Live Births (N=44)			Full-Term Live Births[1] (N=32)			Preterm Live Births[2] (N=12)		
	Outcome[*] (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Outcome[*] (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Social/ Emotional	NA			NA			NA		
Yes		38(97.4%)	37(92.5%)		26(96.3%)	27(93.1%)		12(100.0%)	10(90.9%)
No		0	1(2.5%)		0	0		0	1(9.1%)
Missing/Unk		1(2.6%)	2(5.0%)		1(3.7%)	2(6.9%)		0	0
Infants experiencing at least one infection or fever regardless of severity[5]	3(6.8%)	5(12.8%)	13(32.5%)	2(6.3%)	5(18.5%)	10(34.5%)	1(8.3%)	0	3(27.3%)
Total number infections or fever?	4	5	20	2	5	14	2	0	6

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.4
Infant Follow-up by Visit for Exposed Participants
(Retrospective Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses.
N= the number of live births with data at each time point.
[1]Full-Term is defined as infants born >=$37^{0/7}$ weeks' gestational age.
[2]Preterm is defined as delivery <$37^{0/7}$ weeks' gestational age; late preterm is defined as $34^{0/7}$ and $36^{6/7}$ weeks' gestational age; moderate preterm is defined as $32^{0/7}$ and $33^{6/7}$ weeks' gestational age; very/severely preterm defined as $28^{0/7}$ and $31^{6/7}$ weeks' gestational age; extremely preterm is defined as <$28^{0/7}$ weeks' gestational age.
[3]Includes both previously and currently breastfed infants. Participants with no breastfeeding records available are not presented; therefore numbers may not add to total numbers presented in the column headers.
[4]Includes all defects noted during infant Outcome and follow-up and not defects confirmed by the birth defect evaluator. Birth Defect status may not be reported at Outcome, but may be reported or confirmed at a later visit. Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.
[5]Any infant with a reported infection requiring treatment OR a reported fever of unknown origin or fever of known infectious etiology reported at designated follow-up visit (regardless of age of onset or severity). Denominator is total number of infants with a designated follow-up visit
[6]Participants DE0001 and US0003 will never have a pediatric outcome form and therefore are categorized as 'pending/missing/unknown'. Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the outcome column within their respective table

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Protocol: BEL114256
Population: All Registry Participants

Table 7.4
Infant Follow-up by Visit for Exposed Participants
(Retrospective Cohort)

	All Live Births (N=5)			Full-Term Live Births[1] (N=2)			Preterm Live Births[2] (N=2)		
	Outcome (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Region									
N. America	4(80.0%)	4(80.0%)	3(75.0%)	2(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	1(100.0%)
Europe	1(20.0%)	1(20.0%)	1(25.0%)	0	0	0	0	0	0
Length(cm)									
n	4	5	4	1	2	2	2	2	1
Mean (SD)	47.47 (1.014)	62.34 (3.608)	76.19 (4.555)	47.60 (-)	64.77 (5.388)	76.52 (6.735)	48.13 (0.184)	61.09 (1.616)	78.74 (-)
Median	47.80	60.96	75.87	47.60	64.77	76.52	48.13	61.09	78.74
Min - Max	46.0 - 48.3	59.9 - 68.6	71.8 - 81.3	47.6 - 47.6	61.0 - 68.6	71.8 - 81.3	48.0 - 48.3	59.9 - 62.2	78.7 - 78.7
Q1, Q3	46.80, 48.13	60.00, 62.23	72.38, 80.01	47.60, 47.60	60.96, 68.58	71.76, 81.28	48.00, 48.26	59.94, 62.23	78.74, 78.74

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.4
Infant Follow-up by Visit for Exposed Participants
(Retrospective Cohort)

	All Live Births (N=5)			Full-Term Live Births[1] (N=2)			Preterm Live Births[2] (N=2)		
	Outcome (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Weight(kg)									
n	5	5	4	2	2	2	2	2	1
Mean (SD)	2.74 (0.418)	6.63 (0.719)	10.08 (0.947)	3.15 (0.225)	6.89 (0.577)	10.42 (0.215)	2.47 (0.281)	6.62 (1.155)	10.80 (-)
Median	2.67	6.49	10.42	3.15	6.89	10.42	2.47	6.62	10.80
Min - Max	2.3 - 3.3	5.8 - 7.4	8.7 - 10.8	3.0 - 3.3	6.5 - 7.3	10.3 - 10.6	2.3 - 2.7	5.8 - 7.4	10.8 - 10.8
Q1, Q3	2.46, 2.99	6.12, 7.30	9.48, 10.68	2.99, 3.31	6.49, 7.30	10.26, 10.57	2.27, 2.67	5.81, 7.44	10.80, 10.80

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 7.4
Infant Follow-up by Visit for Exposed Participants
(Retrospective Cohort)

	All Live Births (N=5)			Full-Term Live Births[1] (N=2)			Preterm Live Births[2] (N=2)		
	Outcome (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Head circumference (cm)									
n	4	5	4	1	2	2	2	2	1
Mean (SD)	33.87 (1.058)	41.44 (0.401)	45.94 (0.822)	33.70 (-)	41.71 (0.287)	46.37 (0.877)	33.40 (1.266)	41.15 (0.495)	46.00 (-)
Median	34.00	41.50	45.88	33.70	41.71	46.37	33.40	41.15	46.00
Min - Max	32.5 - 35.0	40.8 - 41.9	45.0 - 47.0	33.7 - 33.7	41.5 - 41.9	45.8 - 47.0	32.5 - 34.3	40.8 - 41.5	46.0 - 46.0
Q1, Q3	33.10, 34.65	41.50, 41.50	45.38, 46.50	33.70, 33.70	41.50, 41.91	45.75, 46.99	32.50, 34.29	40.80, 41.50	46.00, 46.00
Currently breastfed?[3]									
Yes	4(80.0%)	4(80.0%)	1(25.0%)	2(100.0%)	1(50.0%)	1(50.0%)	2(100.0%)	2(100.0%)	0
No	0	1(20.0%)	3(75.0%)	0	1(50.0%)	1(50.0%)	0	0	1(100.0%)
Missing/Unk	0	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Table 7.4
Infant Follow-up by Visit for Exposed Participants
(Retrospective Cohort)

	All Live Births (N=5)			Full-Term Live Births[1] (N=2)			Preterm Live Births[2] (N=2)		
	Outcome (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Ever breastfed?									
Yes[3]	4(80.0%)	5(100.0%)	4(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	1(100.0%)
No	0	0	0	0	0	0	0	0	0
Missing/Unk	0	0	0	0	0	0	0	0	0
Belimumab exposure during breast-feeding?[3]									
Yes	1(20.0%)	1(20.0%)	1(25.0%)	1(50.0%)	0	0	0	0	0
No	3(60.0%)	2(40.0%)	1(25.0%)	1(50.0%)	1(50.0%)	1(50.0%)	2(100.0%)	1(50.0%)	0
Missing/Unk	0	2(40.0%)	2(50.0%)	0	1(50.0%)	1(50.0%)	0	1(50.0%)	1(100.0%)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 7.4
Infant Follow-up by Visit for Exposed Participants
(Retrospective Cohort)

	All Live Births (N=5)			Full-Term Live Births[1] (N=2)			Preterm Live Births[2] (N=2)		
	Outcome (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Birth Defect Noted[4]									
Yes	0	0	0	0	0	0	0	0	0
No	5(100.0%)	5(100.0%)	4(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	1(100.0%)
Pending/ Missing/Unk[6]	0	0	0	0	0	0	0	0	0
Earliest Belimumab Exposure									
Preconception	3(60.0%)	3(60.0%)	2(50.0%)	2(100.0%)	2(100.0%)	2(100.0%)	1(50.0%)	1(50.0%)	0
1st trimester	2(40.0%)	2(40.0%)	2(50.0%)	0	0	0	1(50.0%)	1(50.0%)	1(100.0%)
2nd trimester	0	0	0	0	0	0	0	0	0
3rd trimester	0	0	0	0	0	0	0	0	0
Postpartum	0	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 7.4
Infant Follow-up by Visit for Exposed Participants
(Retrospective Cohort)

	All Live Births (N=5)			Full-Term Live Births[1] (N=2)			Preterm Live Births[2] (N=2)		
	Outcome (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Last Belimumab Exposure									
Preconception	0	0	0	0	0	0	0	0	0
1st trimester	1(20.0%)	1(20.0%)	0	0	0	0	1(50.0%)	1(50.0%)	0
2nd trimester	2(40.0%)	2(40.0%)	2(50.0%)	1(50.0%)	1(50.0%)	1(50.0%)	1(50.0%)	1(50.0%)	1(100.0%)
3rd trimester	0	0	0	0	0	0	0	0	0
Postpartum	2(40.0%)	2(40.0%)	2(50.0%)	1(50.0%)	1(50.0%)	1(50.0%)	0	0	0
Maternal Age									
<35 years	5(100.0%)	5(100.0%)	4(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	2(100.0%)	1(100.0%)
>=35 years	0	0	0	0	0	0	0	0	0
Meeting Dev. Milestones?									
Gross Motor	NA			NA			NA		
Yes		4(80.0%)	3(75.0%)		2(100.0%)	2(100.0%)		2(100.0%)	1(100.0%)
No		0	0		0	0		0	0
Missing/Unk		0	0		0	0		0	0

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Protocol: BEL114256
Population: All Registry Participants

Table 7.4
Infant Follow-up by Visit for Exposed Participants
(Retrospective Cohort)

	All Live Births (N=5)			Full-Term Live Births[1] (N=2)			Preterm Live Births[2] (N=2)		
	Outcome (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Fine Motor	NA			NA			NA		
Yes		4(80.0%)	3(75.0%)		2(100.0%)	2(100.0%)		2(100.0%)	1(100.0%)
No		0	0		0	0		0	0
Missing/Unk		0	0		0	0		0	0
Language	NA			NA			NA		
Yes		4(80.0%)	3(75.0%)		2(100.0%)	2(100.0%)		2(100.0%)	1(100.0%)
No		0	0		0	0		0	0
Missing/Unk		0	0		0	0		0	0
Cognitive	NA			NA			NA		
Yes		4(80.0%)	3(75.0%)		2(100.0%)	2(100.0%)		2(100.0%)	1(100.0%)
No		0	0		0	0		0	0
Missing/Unk		0	0		0	0		0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.4
Infant Follow-up by Visit for Exposed Participants
(Retrospective Cohort)

	All Live Births (N=5)			Full-Term Live Births[1] (N=2)			Preterm Live Births[2] (N=2)		
	Outcome[*] (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Outcome[*] (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Social/ Emotional	NA			NA			NA		
Yes		4(80.0%)	3(75.0%)		2(100.0%)	2(100.0%)		2(100.0%)	1(100.0%)
No		0	0		0	0		0	0
Missing/Unk		0	0		0	0		0	0
Infants experiencing at least one infection or fever regardless of severity[5]	0	0	2(50.0%)	0	0	1(50.0%)	0	0	1(100.0%)
Total number infections or fever?	0	0	3	0	0	2	0	0	1

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.5
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses.
N= the number of live births with data at each time point.
[1]Full-Term is defined as infants born >=$37^{0/7}$ weeks' gestational age.
[2]Preterm is defined as delivery <$37^{0/7}$ weeks' gestational age; late preterm is defined as $34^{0/7}$ and $36^{6/7}$ weeks' gestational age; moderate preterm is defined as $32^{0/7}$ and $33^{6/7}$ weeks' gestational age; very/severely preterm defined as $28^{0/7}$ and $31^{6/7}$ weeks' gestational age; extremely preterm is defined as <$28^{0/7}$ weeks' gestational age.
[3]Infant infection at designated follow-up visit that meet the serious adverse event (SAE) criteria [Infections that resulted in death; were life-threatening; required inpatient hospitalization, prolonged hospitalization, resulted in significant disability or incapacity and/or were considered medically important to date]
[4]Reported infant infection/fever at designated follow-up visit with any of the following criteria: 1) Fever of unknown origin or of known infectious etiology in infants from birth through three months of age [onset date from 0 to <= 13 weeks]; 2) Infections requiring treatment in infants from birth through six months of age (infection onset date from 0 to <= 26 weeks). Infant infection with missing age of onset will be included within this definition
[5]Unknown or missing data were classified as unknown
[6]Age of onset date was missing from 3 events for serious infections and 4 events for non-serious infections
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the outcome column within their respective table

Protocol: BEL114256
Population: All Registry Participants

Table 7.5
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Cohort)

	All Live Births (N=66)				Full-Term Live Births[1] (N=44)			
	Overall[*] (N=66)	Outcome[*] (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Overall[*] (N=44)	Outcome[*] (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)
Infants with at least one serious infection[3]	4(6.1%)	2(3.0%)	0	2(3.6%)	3(6.8%)	2(4.5%)	0	1(2.8%)
Total number of serious infections[3]	5	2	0	3	4	2	0	2
Attributable to belimumab?								
Yes	1(20.0%)	1(50.0%)	0	0	1(25.0%)	1(50.0%)	0	0
No	2(40.0%)	0	0	2(66.7%)	2(50.0%)	0	0	2(100%)
Unknown[5]	2(40.0%)	1(50.0%)	0	1(33.3%)	1(25.0%)	1(50.0%)	0	0
Requiring txt?								
Yes	3(60.0%)	0	0	3(100%)	2(50.0%)	0	0	2(100%)
No	0	0	0	0	0	0	0	0
Unknown[5]	2(40.0%)	2(100%)	0	0	2(50.0%)	2(100%)	0	0

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Protocol: BEL114256
Population: All Registry Participants

Table 7.5
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Cohort)

	Preterm Live Births[2] (N=21)			
	Overall (N=21)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Infants with at least one serious infection[3]	1(4.8%)	0	0	1(5.6%)
Total number of serious infections[3]	1	0	0	1
Attributable to belimumab?				
Yes	0	0	0	0
No	0	0	0	0
Unknown[5]	1(100%)	0	0	1(100%)
Requiring txt?				
Yes	1(100%)	0	0	1(100%)
No	0	0	0	0
Unknown[5]	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 7.5
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol (Overall Cohort)

	All Live Births (N=66)				Full-Term Live Births[1] (N=44)			
	Overall[*] (N=66)	Outcome[*] (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Overall[*] (N=44)	Outcome[*] (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)
Status								
Resolved	5(100%)	2(100%)	0	3(100%)	4(100%)	2(100%)	0	2(100%)
Ongoing	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Age of onset range (weeks)[6]	38.9-47.1	-	-	38.9-47.1	47.1-47.1	-	-	47.1-47.1
Infants with at least one non-serious infection/fever [clinically significant per protocol][4]	14(21.2%)	2(3.0%)	7(12.3%)	6(10.9%)	10(22.7%)	1(2.3%)	7(20.0%)	3(8.3%)
Total number of non-serious infection/fever [clinically significant per protocol][4]	16	3	7	6	11	1	7	3

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.5
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Cohort)

	Preterm Live Births[2] (N=21)			
	Overall (N=21)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Status				
Resolved	1(100%)	0	0	1(100%)
Ongoing	0	0	0	0
Death	0	0	0	0
Unknown[5]	0	0	0	0
Age of onset range (weeks)[6]	38.9-38.9	-	-	38.9-38.9
Infants with at least one non-serious infection/fever [clinically significant per protocol][4]	4(19.0%)	1(4.8%)	0	3(16.7%)
Total number of non-serious infection/fever [clinically significant per protocol][4]	5	2	0	3

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.5
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Cohort)

	All Live Births (N=66)				Full-Term Live Births[1] (N=44)			
	Overall[*] (N=66)	Outcome[*] (N=66)	4 Month Follow-up (N=57)	12 Month Follow-up (N=55)	Overall[*] (N=44)	Outcome[*] (N=44)	4 Month Follow-up (N=35)	12 Month Follow-up (N=36)
Attributable to belimumab?								
Yes	0	0	0	0	0	0	0	0
No	7(43.8%)	0	5(71.4%)	2(33.3%)	6(54.5%)	0	5(71.4%)	1(33.3%)
Unknown[5]	9(56.3%)	3(100%)	2(28.6%)	4(66.7%)	5(45.5%)	1(100%)	2(28.6%)	2(66.7%)
Requiring txt?								
Yes	16(100%)	3(100%)	7(100%)	6(100%)	11(100%)	1(100%)	7(100%)	3(100%)
No	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Status								
Resolved	14(87.5%)	2(66.7%)	7(100%)	5(83.3%)	10(90.9%)	1(100%)	7(100%)	2(66.7%)
Ongoing	1(6.3%)	1(33.3%)	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Unknown[5]	1(6.3%)	0	0	1(16.7%)	1(9.1%)	0	0	1(33.3%)
Age of onset range (weeks)[6]	7.3-25.1	7.3-10.9	11.0-21.9	23.1-25.1	10.9-24.1	10.9-10.9	11.0-21.9	24.1-24.1

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.5
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Cohort)

	Preterm Live Births[2] (N=21)			
	Overall (N=21)	Outcome (N=21)	4 Month Follow-up (N=21)	12 Month Follow-up (N=18)
Attributable to belimumab?				
Yes	0	0	0	0
No	1(20.0%)	0	0	1(33.3%)
Unknown[5]	4(80.0%)	2(100%)	0	2(66.7%)
Requiring txt?				
Yes	5(100%)	2(100%)	0	3(100%)
No	0	0	0	0
Unknown[5]	0	0	0	0
Status				
Resolved	4(80.0%)	1(50.0%)	0	3(100%)
Ongoing	1(20.0%)	1(50.0%)	0	0
Death	0	0	0	0
Unknown[5]	0	0	0	0
Age of onset range (weeks)[6]	7.3-25.1	7.3-9.1	-	23.1-25.1

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.6
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Prospective Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses.
N= the number of live births with data at each time point.
[1]Full-Term is defined as infants born >=$37^{0/7}$ weeks' gestational age.
[2]Preterm is defined as delivery <$37^{0/7}$ weeks' gestational age; late preterm is defined as $34^{0/7}$ and $36^{6/7}$ weeks' gestational age; moderate preterm is defined as $32^{0/7}$ and $33^{6/7}$ weeks' gestational age; very/severely preterm defined as $28^{0/7}$ and $31^{6/7}$ weeks' gestational age; extremely preterm is defined as <$28^{0/7}$ weeks' gestational age.
[3]Infant infection at designated follow-up visit that meet the serious adverse event (SAE) criteria [Infections that resulted in death; were life-threatening; required inpatient hospitalization, prolonged hospitalization, resulted in significant disability or incapacity and/or were considered medically important to date]
[4]Reported infant infection/fever at designated follow-up visit with any of the following criteria: 1) Fever of unknown origin or of known infectious etiology in infants from birth through three months of age [onset date from 0 to <= 13 weeks]; 2) Infections requiring treatment in infants from birth through six months of age (infection onset date from 0 to <= 26 weeks). Infant infection with missing age of onset will be included within this definition
[5]Unknown or missing data were classified as unknown
[6]Age of onset date was missing from 3 events for serious infections and 4 events for non-serious infections
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the outcome column within their respective table

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Protocol: BEL114256
Population: All Registry Participants

Table 7.6
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Prospective Cohort)

	All Live Births (N=61)				Full-Term Live Births[1] (N=42)			
	Overall[*] (N=61)	Outcome[*] (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Overall[*] (N=42)	Outcome[*] (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)
Infants with at least one serious infection[3]	4(6.6%)	2(3.3%)	0	2(3.9%)	3(7.1%)	2(4.8%)	0	1(2.9%)
Total number of serious infections[3]	5	2	0	3	4	2	0	2
Attributable to belimumab?								
Yes	1(20.0%)	1(50.0%)	0	0	1(25.0%)	1(50.0%)	0	0
No	2(40.0%)	0	0	2(66.7%)	2(50.0%)	0	0	2(100%)
Unknown[5]	2(40.0%)	1(50.0%)	0	1(33.3%)	1(25.0%)	1(50.0%)	0	0
Requiring txt?								
Yes	3(60.0%)	0	0	3(100%)	2(50.0%)	0	0	2(100%)
No	0	0	0	0	0	0	0	0
Unknown[5]	2(40.0%)	2(100%)	0	0	2(50.0%)	2(100%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.6
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Prospective Cohort)

	Preterm Live Births[2] (N=19)			
	Overall (N=19)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Infants with at least one serious infection[3]	1(5.3%)	0	0	1(5.9%)
Total number of serious infections[3]	1	0	0	1
Attributable to belimumab?				
Yes	0	0	0	0
No	0	0	0	0
Unknown[5]	1(100%)	0	0	1(100%)
Requiring txt?				
Yes	1(100%)	0	0	1(100%)
No	0	0	0	0
Unknown[5]	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.6
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Prospective Cohort)

	All Live Births (N=61)				Full-Term Live Births[1] (N=42)			
	Overall[*] (N=61)	Outcome[*] (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Overall[*] (N=42)	Outcome[*] (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)
Status								
Resolved	5(100%)	2(100%)	0	3(100%)	4(100%)	2(100%)	0	2(100%)
Ongoing	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Age of onset range (weeks)[6]	38.9-47.1	-	-	38.9-47.1	47.1-47.1	-	-	47.1-47.1
Infants with at least one non-serious infection/fever [clinically significant per protocol][4]	14(23.0%)	2(3.3%)	7(13.5%)	6(11.8%)	10(23.8%)	1(2.4%)	7(21.2%)	3(8.8%)
Total number of non-serious infection/fever [clinically significant per protocol][4]	16	3	7	6	11	1	7	3

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.6
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Prospective Cohort)

	Preterm Live Births[2] (N=19)			
	Overall (N=19)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Status				
Resolved	1(100%)	0	0	1(100%)
Ongoing	0	0	0	0
Death	0	0	0	0
Unknown[5]	0	0	0	0
Age of onset range (weeks)[6]	38.9-38.9	-	-	38.9-38.9
Infants with at least one non-serious infection/fever [clinically significant per protocol][4]	4(21.1%)	1(5.3%)	0	3(17.6%)
Total number of non-serious infection/fever [clinically significant per protocol][4]	5	2	0	3

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.6
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Prospective Cohort)

	All Live Births (N=61)				Full-Term Live Births[1] (N=42)			
	Overall[*] (N=61)	Outcome[*] (N=61)	4 Month Follow-up (N=52)	12 Month Follow-up (N=51)	Overall[*] (N=42)	Outcome[*] (N=42)	4 Month Follow-up (N=33)	12 Month Follow-up (N=34)
Attributable to belimumab?								
Yes	0	0	0	0	0	0	0	0
No	7(43.8%)	0	5(71.4%)	2(33.3%)	6(54.5%)	0	5(71.4%)	1(33.3%)
Unknown[5]	9(56.3%)	3(100%)	2(28.6%)	4(66.7%)	5(45.5%)	1(100%)	2(28.6%)	2(66.7%)
Requiring txt?								
Yes	16(100%)	3(100%)	7(100%)	6(100%)	11(100%)	1(100%)	7(100%)	3(100%)
No	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Status								
Resolved	14(87.5%)	2(66.7%)	7(100%)	5(83.3%)	10(90.9%)	1(100%)	7(100%)	2(66.7%)
Ongoing	1(6.3%)	1(33.3%)	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Unknown[5]	1(6.3%)	0	0	1(16.7%)	1(9.1%)	0	0	1(33.3%)
Age of onset range (weeks)[6]	7.3-25.1	7.3-10.9	11.0-21.9	23.1-25.1	10.9-24.1	10.9-10.9	11.0-21.9	24.1-24.1

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.6
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Overall Prospective Cohort)

	Preterm Live Births[2] (N=19)			
	Overall (N=19)	Outcome (N=19)	4 Month Follow-up (N=19)	12 Month Follow-up (N=17)
Attributable to belimumab?				
Yes	0	0	0	0
No	1(20.0%)	0	0	1(33.3%)
Unknown[5]	4(80.0%)	2(100%)	0	2(66.7%)
Requiring txt?				
Yes	5(100%)	2(100%)	0	3(100%)
No	0	0	0	0
Unknown[5]	0	0	0	0
Status				
Resolved	4(80.0%)	1(50.0%)	0	3(100%)
Ongoing	1(20.0%)	1(50.0%)	0	0
Death	0	0	0	0
Unknown[5]	0	0	0	0
Age of onset range (weeks)[6]	7.3-25.1	7.3-9.1	-	23.1-25.1

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.7
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Pure Prospective Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses.
N= the number of live births with data at each time point.
[1]Full-Term is defined as infants born >=$37^{0/7}$ weeks' gestational age.
[2]Preterm is defined as delivery <$37^{0/7}$ weeks' gestational age; late preterm is defined as $34^{0/7}$ and $36^{6/7}$ weeks' gestational age; moderate preterm is defined as $32^{0/7}$ and $33^{6/7}$ weeks' gestational age; very/severely preterm defined as $28^{0/7}$ and $31^{6/7}$ weeks' gestational age; extremely preterm is defined as <$28^{0/7}$ weeks' gestational age.
[3]Infant infection at designated follow-up visit that meet the serious adverse event (SAE) criteria [Infections that resulted in death; were life-threatening; required inpatient hospitalization, prolonged hospitalization, resulted in significant disability or incapacity and/or were considered medically important to date]
[4]Reported infant infection/fever at designated follow-up visit with any of the following criteria: 1) Fever of unknown origin or of known infectious etiology in infants from birth through three months of age [onset date from 0 to <= 13 weeks]; 2) Infections requiring treatment in infants from birth through six months of age (infection onset date from 0 to <= 26 weeks). Infant infection with missing age of onset will be included within this definition
[5]Unknown or missing data were classified as unknown
[6]Age of onset date was missing from 2 events for serious infections and 3 events for non-serious infections
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the outcome column within their respective table

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Protocol: BEL114256
Population: All Registry Participants

Table 7.7
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Pure Prospective Cohort)

	All Live Births (N=17)				Full-Term Live Births[1] (N=10)			
	Overall[*] (N=17)	Outcome[*] (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Overall[*] (N=10)	Outcome[*] (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)
Infants with at least one serious infection[3]	1(5.9%)	1(5.9%)	0	0	1(10.0%)	1(10.0%)	0	0
Total number of serious infections[3]	1	1	0	0	1	1	0	0
Attributable to belimumab?								
Yes	1(100%)	1(100%)	0	0	1(100%)	1(100%)	0	0
No	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Requiring txt?								
Yes	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0
Unknown[5]	1(100%)	1(100%)	0	0	1(100%)	1(100%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.7
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Pure Prospective Cohort)

	Preterm Live Births[2] (N=7)			
	Overall (N=7)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Infants with at least one serious infection[3]	0	0	0	0
Total number of serious infections[3]	0	0	0	0
Attributable to belimumab?				
Yes	0	0	0	0
No	0	0	0	0
Unknown[5]	0	0	0	0
Requiring txt?				
Yes	0	0	0	0
No	0	0	0	0
Unknown[5]	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.7
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Pure Prospective Cohort)

	All Live Births (N=17)				Full-Term Live Births[1] (N=10)			
	Overall[*] (N=17)	Outcome[*] (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Overall[*] (N=10)	Outcome[*] (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)
Status								
Resolved	1(100%)	1(100%)	0	0	1(100%)	1(100%)	0	0
Ongoing	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Age of onset range (weeks)[6]	-	-	-	-	-	-	-	-
Infants with at least one non-serious infection/fever [clinically significant per protocol][4]	3(17.6%)	0	2(15.4%)	1(9.1%)	2(20.0%)	0	2(33.3%)	0
Total number of non-serious infection/fever [clinically significant per protocol][4]	3	0	2	1	2	0	2	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.7
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Pure Prospective Cohort)

	Preterm Live Births[2] (N=7)			
	Overall (N=7)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Status				
Resolved	0	0	0	0
Ongoing	0	0	0	0
Death	0	0	0	0
Unknown[5]	0	0	0	0
Age of onset range (weeks)[6]	-	-	-	-
Infants with at least one non-serious infection/fever [clinically significant per protocol][4]	1(14.3%)	0	0	1(16.7%)
Total number of non-serious infection/fever [clinically significant per protocol][4]	1	0	0	1

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.7
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Pure Prospective Cohort)

	All Live Births (N=17)				Full-Term Live Births[1] (N=10)			
	Overall[*] (N=17)	Outcome[*] (N=17)	4 Month Follow-up (N=13)	12 Month Follow-up (N=11)	Overall[*] (N=10)	Outcome[*] (N=10)	4 Month Follow-up (N=6)	12 Month Follow-up (N=5)
Attributable to belimumab?								
Yes	0	0	0	0	0	0	0	0
No	3(100%)	0	2(100%)	1(100%)	2(100%)	0	2(100%)	0
Unknown[5]	0	0	0	0	0	0	0	0
Requiring txt?								
Yes	3(100%)	0	2(100%)	1(100%)	2(100%)	0	2(100%)	0
No	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Status								
Resolved	3(100%)	0	2(100%)	1(100%)	2(100%)	0	2(100%)	0
Ongoing	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Age of onset range (weeks)[6]	21.9-23.1	-	21.9-21.9	23.1-23.1	21.9-21.9	-	21.9-21.9	-

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.7
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Pure Prospective Cohort)

	Preterm Live Births[2] (N=7)			
	Overall (N=7)	Outcome (N=7)	4 Month Follow-up (N=7)	12 Month Follow-up (N=6)
Attributable to belimumab?				
Yes	0	0	0	0
No	1(100%)	0	0	1(100%)
Unknown[5]	0	0	0	0
Requiring txt?				
Yes	1(100%)	0	0	1(100%)
No	0	0	0	0
Unknown[5]	0	0	0	0
Status				
Resolved	1(100%)	0	0	1(100%)
Ongoing	0	0	0	0
Death	0	0	0	0
Unknown[5]	0	0	0	0
Age of onset range (weeks)[6]	23.1-23.1	-	-	23.1-23.1

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.8
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Traditional Prospective Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses.
N= the number of live births with data at each time point.
[1]Full-Term is defined as infants born >=$37^{0/7}$ weeks' gestational age.
[2]Preterm is defined as delivery <$37^{0/7}$ weeks' gestational age; late preterm is defined as $34^{0/7}$ and $36^{6/7}$ weeks' gestational age; moderate preterm is defined as $32^{0/7}$ and $33^{6/7}$ weeks' gestational age; very/severely preterm defined as $28^{0/7}$ and $31^{6/7}$ weeks' gestational age; extremely preterm is defined as <$28^{0/7}$ weeks' gestational age.
[3]Infant infection at designated follow-up visit that meet the serious adverse event (SAE) criteria [Infections that resulted in death; were life-threatening; required inpatient hospitalization, prolonged hospitalization, resulted in significant disability or incapacity and/or were considered medically important to date]
[4]Reported infant infection/fever at designated follow-up visit with any of the following criteria: 1) Fever of unknown origin or of known infectious etiology in infants from birth through three months of age [onset date from 0 to <= 13 weeks]; 2) Infections requiring treatment in infants from birth through six months of age (infection onset date from 0 to <= 26 weeks). Infant infection with missing age of onset will be included within this definition
[5]Unknown or missing data were classified as unknown
[6]Age of onset date was missing from 1 events for serious infections and 1 events for non-serious infections
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the outcome column within their respective table

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Protocol: BEL114256
Population: All Registry Participants

Table 7.8
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Traditional Prospective Cohort)

	All Live Births (N=44)				Full-Term Live Births[1] (N=32)			
	Overall[*] (N=44)	Outcome[*] (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Overall[*] (N=32)	Outcome[*] (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)
Infants with at least one serious infection[3]	3(6.8%)	1(2.3%)	0	2(5.0%)	2(6.3%)	1(3.1%)	0	1(3.4%)
Total number of serious infections[3]	4	1	0	3	3	1	0	2
Attributable to belimumab?								
Yes	0	0	0	0	0	0	0	0
No	2(50.0%)	0	0	2(66.7%)	2(66.7%)	0	0	2(100%)
Unknown[5]	2(50.0%)	1(100%)	0	1(33.3%)	1(33.3%)	1(100%)	0	0
Requiring txt?								
Yes	3(75.0%)	0	0	3(100%)	2(66.7%)	0	0	2(100%)
No	0	0	0	0	0	0	0	0
Unknown[5]	1(25.0%)	1(100%)	0	0	1(33.3%)	1(100%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.8
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Traditional Prospective Cohort)

	Preterm Live Births[2] (N=12)			
	Overall (N=12)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Infants with at least one serious infection[3]	1(8.3%)	0	0	1(9.1%)
Total number of serious infections[3]	1	0	0	1
Attributable to belimumab?				
Yes	0	0	0	0
No	0	0	0	0
Unknown[5]	1(100%)	0	0	1(100%)
Requiring txt?				
Yes	1(100%)	0	0	1(100%)
No	0	0	0	0
Unknown[5]	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.8
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Traditional Prospective Cohort)

	All Live Births (N=44)				Full-Term Live Births[1] (N=32)			
	Overall[*] (N=44)	Outcome[*] (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Overall[*] (N=32)	Outcome[*] (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)
Status								
Resolved	4(100%)	1(100%)	0	3(100%)	3(100%)	1(100%)	0	2(100%)
Ongoing	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Age of onset range (weeks)[6]	38.9-47.1	-	-	38.9-47.1	47.1-47.1	-	-	47.1-47.1
Infants with at least one non-serious infection/fever [clinically significant per protocol][4]	11(25.0%)	2(4.5%)	5(12.8%)	5(12.5%)	8(25.0%)	1(3.1%)	5(18.5%)	3(10.3%)
Total number of non-serious infection/fever [clinically significant per protocol][4]	13	3	5	5	9	1	5	3

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.8
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Traditional Prospective Cohort)

	Preterm Live Births[2] (N=12)			
	Overall (N=12)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Status				
Resolved	1(100%)	0	0	1(100%)
Ongoing	0	0	0	0
Death	0	0	0	0
Unknown[5]	0	0	0	0
Age of onset range (weeks)[6]	38.9-38.9	-	-	38.9-38.9
Infants with at least one non-serious infection/fever [clinically significant per protocol][4]	3(25.0%)	1(8.3%)	0	2(18.2%)
Total number of non-serious infection/fever [clinically significant per protocol][4]	4	2	0	2

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.8
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Traditional Prospective Cohort)

	All Live Births (N=44)				Full-Term Live Births[1] (N=32)			
	Overall[*] (N=44)	Outcome[*] (N=44)	4 Month Follow-up (N=39)	12 Month Follow-up (N=40)	Overall[*] (N=32)	Outcome[*] (N=32)	4 Month Follow-up (N=27)	12 Month Follow-up (N=29)
Attributable to belimumab?								
Yes	0	0	0	0	0	0	0	0
No	4(30.8%)	0	3(60.0%)	1(20.0%)	4(44.4%)	0	3(60.0%)	1(33.3%)
Unknown[5]	9(69.2%)	3(100%)	2(40.0%)	4(80.0%)	5(55.6%)	1(100%)	2(40.0%)	2(66.7%)
Requiring txt?								
Yes	13(100%)	3(100%)	5(100%)	5(100%)	9(100%)	1(100%)	5(100%)	3(100%)
No	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Status								
Resolved	11(84.6%)	2(66.7%)	5(100%)	4(80.0%)	8(88.9%)	1(100%)	5(100%)	2(66.7%)
Ongoing	1(7.7%)	1(33.3%)	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Unknown[5]	1(7.7%)	0	0	1(20.0%)	1(11.1%)	0	0	1(33.3%)
Age of onset range (weeks)[6]	7.3-25.1	7.3-10.9	11.0-20.3	24.1-25.1	10.9-24.1	10.9-10.9	11.0-20.3	24.1-24.1

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.8
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Traditional Prospective Cohort)

	Preterm Live Births[2] (N=12)			
	Overall (N=12)	Outcome (N=12)	4 Month Follow-up (N=12)	12 Month Follow-up (N=11)
Attributable to belimumab?				
Yes	0	0	0	0
No	0	0	0	0
Unknown[5]	4(100%)	2(100%)	0	2(100%)
Requiring txt?				
Yes	4(100%)	2(100%)	0	2(100%)
No	0	0	0	0
Unknown[5]	0	0	0	0
Status				
Resolved	3(75.0%)	1(50.0%)	0	2(100%)
Ongoing	1(25.0%)	1(50.0%)	0	0
Death	0	0	0	0
Unknown[5]	0	0	0	0
Age of onset range (weeks)[6]	7.3-25.1	7.3-9.1	-	25.1-25.1

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.9
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Retrospective Cohort)

Note: Each infant of a multiple live birth is counted separately. n is the total number of non-missing responses.
N= the number of live births with data at each time point.
[1]Full-Term is defined as infants born >=$37^{0/7}$ weeks' gestational age.
[2]Preterm is defined as delivery <$37^{0/7}$ weeks' gestational age; late preterm is defined as $34^{0/7}$ and $36^{6/7}$ weeks' gestational age; moderate preterm is defined as $32^{0/7}$ and $33^{6/7}$ weeks' gestational age; very/severely preterm defined as $28^{0/7}$ and $31^{6/7}$ weeks' gestational age; extremely preterm is defined as <$28^{0/7}$ weeks' gestational age.
[3]Infant infection at designated follow-up visit that meet the serious adverse event (SAE) criteria [Infections that resulted in death; were life-threatening; required inpatient hospitalization, prolonged hospitalization, resulted in significant disability or incapacity and/or were considered medically important to date]
[4]Reported infant infection/fever at designated follow-up visit with any of the following criteria: 1) Fever of unknown origin or of known infectious etiology in infants from birth through three months of age [onset date from 0 to <= 13 weeks]; 2) Infections requiring treatment in infants from birth through six months of age (infection onset date from 0 to <= 26 weeks). Infant infection with missing age of onset will be included within this definition
[5]Unknown or missing data were classified as unknown
[6]Age of onset date was missing from 0 events for serious infections and 0 events for non-serious infections
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the outcome column within their respective table

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Protocol: BEL114256
Population: All Registry Participants

Table 7.9
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Retrospective Cohort)

	All Live Births (N=5)				Full-Term Live Births[1] (N=2)			
	Overall[*] (N=5)	Outcome[*] (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Overall[*] (N=2)	Outcome[*] (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)
Infants with at least one serious infection[3]	0	0	0	0	0	0	0	0
Total number of serious infections[3]	0	0	0	0	0	0	0	0
Attributable to belimumab?								
Yes	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Requiring txt?								
Yes	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.9
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Retrospective Cohort)

	Preterm Live Births[2] (N=2)			
	Overall (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Infants with at least one serious infection[3]	0	0	0	0
Total number of serious infections[3]	0	0	0	0
Attributable to belimumab?				
Yes	0	0	0	0
No	0	0	0	0
Unknown[5]	0	0	0	0
Requiring txt?				
Yes	0	0	0	0
No	0	0	0	0
Unknown[5]	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.9
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Retrospective Cohort)

	All Live Births (N=5)				Full-Term Live Births[1] (N=2)			
	Overall[*] (N=5)	Outcome[*] (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Overall[*] (N=2)	Outcome[*] (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)
Status								
Resolved	0	0	0	0	0	0	0	0
Ongoing	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Age of onset range (weeks)[6]	-	-	-	-	-	-	-	-
Infants with at least one non-serious infection/fever [clinically significant per protocol][4]	0	0	0	0	0	0	0	0
Total number of non-serious infection/fever [clinically significant per protocol][4]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.9
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Retrospective Cohort)

	Preterm Live Births[2] (N=2)			
	Overall (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Status				
Resolved	0	0	0	0
Ongoing	0	0	0	0
Death	0	0	0	0
Unknown[5]	0	0	0	0
Age of onset range (weeks)[6]	-	-	-	-
Infants with at least one non-serious infection/fever [clinically significant per protocol][4]	0	0	0	0
Total number of non-serious infection/fever [clinically significant per protocol][4]	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.9
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Retrospective Cohort)

	All Live Births (N=5)				Full-Term Live Births[1] (N=2)			
	Overall[*] (N=5)	Outcome[*] (N=5)	4 Month Follow-up (N=5)	12 Month Follow-up (N=4)	Overall[*] (N=2)	Outcome[*] (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=2)
Attributable to belimumab?								
Yes	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Requiring txt?								
Yes	0	0	0	0	0	0	0	0
No	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Status								
Resolved	0	0	0	0	0	0	0	0
Ongoing	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Unknown[5]	0	0	0	0	0	0	0	0
Age of onset range (weeks)[6]	-	-	-	-	-	-	-	-

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 7.9
Infant Follow-up by Visit for Exposed Participants, serious and/or non-serious-clinically significant per protocol
(Retrospective Cohort)

	Preterm Live Births[2] (N=2)			
	Overall (N=2)	Outcome (N=2)	4 Month Follow-up (N=2)	12 Month Follow-up (N=1)
Attributable to belimumab?				
Yes	0	0	0	0
No	0	0	0	0
Unknown[5]	0	0	0	0
Requiring txt?				
Yes	0	0	0	0
No	0	0	0	0
Unknown[5]	0	0	0	0
Status				
Resolved	0	0	0	0
Ongoing	0	0	0	0
Death	0	0	0	0
Unknown[5]	0	0	0	0
Age of onset range (weeks)[6]	-	-	-	-

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.01
Outcomes of Interest for Exposed Participants, excluding Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

Note: Reports of pregnancy in which the pregnancy outcome or anticipated outcome is already known before enrollment can be biased toward the reporting of more unusual or severe cases compared to women whose pregnancy outcome is not yet known at the time of enrollment into the pregnancy registry. Therefore, rates of outcomes cannot be calculated from these data. However, a series of reported birth defects can be evaluated to detect patterns of specific birth defects and can assist with identification of potential early signals of therapy risks.
[0]Denominator is number of live birth pregnancies.
[1]Denominator is number of live births. A denominator greater than N is an indicator of multiple births.
[2]MACDP birth defect prevalence (Correa, 2007); MACDP calculates birth defect prevalence as the proportion of live birth outcomes or fetal death outcomes at 20 weeks or more with confirmed birth defects relative to the number of live births. Cases are also considered defects if the infant or fetus has two or more conditional defects.
[3]EUROCAT birth defect prevalence (eurocat-network.eu); EUROCAT calculates birth defect prevalence as the proportion of live birth outcomes with birth defects relative to the number of live births.
[4]Denominator is number of live birth infants overall and by each time point of earliest exposure.
[5]Any trimester includes those occurring during the first, second, or third trimesters.
[6]Denominator is the number of unique participants enrolling prior to 20 weeks gestation overall and by each timepoint of earliest exposure.
[7]Denominator is number of unique participants overall and by each timepoint of earliest exposure.
[8]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[9]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[10]Denominator is number of live birth infants who were breastfed overall and at each timepoint of infant follow-up.
[11]Denominator is number of live birth infants overall and at each timepoint of infant follow-up.
[12]On 15Mar2022, EUROCAT classification was changed for two participants (US0027A and US0062A).
[13]Includes the number of participants with a pregnancy outcome of spontaneous abortion or stillbirth.

Protocol: BEL114256
Population: All Registry Participants

Table 8.01
Outcomes of Interest for Exposed Participants, excluding Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

[14]Denominator is the total number of participants with a pregnancy outcome minus the number of participants with an elective termination overall and by each time point of earliest exposure.
[15]Numerator: Infant with an infection that meet the serious adverse event (SAE) criteria [Infections that resulted in death; were life-threatening; required inpatient hospitalization, prolonged hospitalization, resulted in significant disability or incapacity and/or were considered medically important to date]
[16]No birth defects were noted in the three spontaneous miscarriages
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the table in overall count and in the outcome visit within the table

Protocol: BEL114256
Population: All Registry Participants

Table 8.01
Outcomes of Interest for Exposed Participants, excluding Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Total confirmed birth defects using MACDP or EUROCAT criteria[0,2,3,12]	12/58 (20.7% 95%CI 9.7%-29.6%)	1/16 (6.3% 95%CI 0.0%-17.1%)	11/42 (26.2% 95%CI 12.2%-37.8%)
Total confirmed birth defects using MACDP or EUROCAT criteria[1,2,3,12]	12/61 (19.7% 95%CI 9.7%-29.6%)	1/17 (5.9% 95%CI 0.0%-17.1%)	11/44 (25.0% 95%CI 12.2%-37.8%)
Confirmed birth defect prevalence using MACDP criteria [2,4]	11/61 (18.0% 95%CI 8.4%-27.7%)	1/17 (5.9% 95%CI 0.0%-17.1%)	10/44 (22.7% 95%CI 10.3%-35.1%)
By Earliest Belimumab Exposure			
Preconception	10/58 (17.2% 95%CI 7.5%-27.0%)	1/17 (5.9% 95%CI 0.0%-17.1%)	9/41 (22.0% 95%CI 9.3%-34.6%)
1st Trimester	1/2 (50.0% 95%CI 0.0%-100.0%)	0/0	1/2 (50.0% 95%CI 0.0%-100.0%)
2nd/3rd Trimester	0/1	0/0	0/1
Any Trimester[5]	1/3 (33.3% 95%CI 0.0%-86.7%)	0/0	1/3 (33.3% 95%CI 0.0%-86.7%)
MACDP birth defect prevalence for most recent 5-year period[2]	11/61 (18.0% 95%CI 8.4%-27.7%)	1/17 (5.9% 95%CI 0.0%-17.1%)	10/44 (22.7% 95%CI 10.3%-35.1%)

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.01
Outcomes of Interest for Exposed Participants, excluding Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Confirmed birth defect prevalence using EUROCAT Criteria [3,4,12]	9/61 (14.8% 95%CI 5.9%-23.7%)	1/17 (5.9% 95%CI 0.0%-17.1%)	8/44 (18.2% 95%CI 6.8%-29.6%)
By Earliest Belimumab Exposure			
Preconception	9/58 (15.5% 95%CI 6.2%-24.8%)	1/17 (5.9% 95%CI 0.0%-17.1%)	8/41 (19.5% 95%CI 7.4%-31.6%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	0/1	0/0	0/1
Any Trimester[5]	0/3	0/0	0/3
EUROCAT birth defect prevalence for most recent 5-year period[3]	9/61 (14.8% 95%CI 5.9%-23.7%)	1/17 (5.9% 95%CI 0.0%-17.1%)	8/44 (18.2% 95%CI 6.8%-29.6%)
Spontaneous Miscarriage Prevalence[6,16]	3/43 (7.0% 95%CI 0.0%-14.3%)	2/13 (15.4% 95%CI 0.0%-32.6%)	1/30 (3.3% 95%CI 0.0%-9.8%)
By Earliest Belimumab Exposure			
Preconception	3/41 (7.3% 95%CI 0.0%-14.9%)	2/13 (15.4% 95%CI 0.0%-32.6%)	1/28 (3.6% 95%CI 0.0%-10.4%)
1st Trimester	0/1	0/0	0/1
2nd/3rd Trimester	0/1	0/0	0/1
Any Trimester[5]	0/2	0/0	0/2

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.01
Outcomes of Interest for Exposed Participants, excluding Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Elective Termination Prevalence[7]	0/61	0/17	0/44
By Earliest Belimumab Exposure			
Preconception	0/57	0/17	0/40
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	0/2	0/0	0/2
Any Trimester[5]	0/4	0/0	0/4
Stillbirth Prevalence[7]	1/61 (1.6% 95%CI 0.0%-4.7%)	0/17	1/44 (2.3% 95%CI 0.0%-6.7%)
By Earliest Belimumab Exposure			
Preconception	0/57	0/17	0/40
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	1/2 (50.0% 95%CI 0.0%-100.0%)	0/0	1/2 (50.0% 95%CI 0.0%-100.0%)
Any Trimester[5]	1/4 (25.0% 95%CI 0.0%-67.4%)	0/0	1/4 (25.0% 95%CI 0.0%-67.4%)

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.01
Outcomes of Interest for Exposed Participants, excluding Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Fetal Loss Prevalence [13,14]	4/61 (6.6% 95%CI 0.3%-12.6%)	2/17 (11.8% 95%CI 0.0%-25.6%)	2/44 (4.5% 95%CI 0.0%-10.7%)
By Earliest Belimumab Exposure			
Preconception	3/57 (5.3% 95%CI 0.0%-10.9%)	2/17 (11.8% 95%CI 0.0%-25.6%)	1/40 (2.5% 95%CI 0.0%-7.3%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	1/2 (50.0% 95%CI 0.0%-100.0%)	0/0	1/2 (50.0% 95%CI 0.0%-100.0%)
Any Trimester[5]	1/4 (25.0% 95%CI 0.0%-67.4%)	0/0	1/4 (25.0% 95%CI 0.0%-67.4%)
Preterm Prevalence[4]	19/61 (31.1% 95%CI 19.5%-42.8%)	7/17 (41.2% 95%CI 17.8%-64.6%)	12/44 (27.3% 95%CI 14.1%-40.4%)
By Earliest Belimumab Exposure			
Preconception	19/58 (32.8% 95%CI 20.7%-44.8%)	7/17 (41.2% 95%CI 17.8%-64.6%)	12/41 (29.3% 95%CI 15.3%-43.2%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	0/1	0/0	0/1
Any Trimester[5]	0/3	0/0	0/3

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.01
Outcomes of Interest for Exposed Participants, excluding Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
SGA[6,8] Prevalence	4/61 (6.6% 95%CI 0.3%-12.8%)	0/17	4/44 (9.1% 95%CI 0.6%-17.6%)
By Earliest Belimumab Exposure			
Preconception	3/58 (5.2% 95%CI 0.0%-10.9%)	0/17	3/41 (7.3% 95%CI 0.0%-15.3%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	1/1 (100.0% 95%CI 100.0%-100.0%)	0/0	1/1 (100.0% 95%CI 100.0%-100.0%)
Any Trimester[5]	1/3 (33.3% 95%CI 0.0%-86.7%)	0/0	1/3 (33.3% 95%CI 0.0%-86.7%)
SGA[6,9] Prevalence	12/61 (19.7% 95%CI 9.7%-29.6%)	2/17 (11.8% 95%CI 0.0%-27.1%)	10/44 (22.7% 95%CI 10.3%-35.1%)
By Earliest Belimumab Exposure			
Preconception	11/58 (19.0% 95%CI 8.9%-29.1%)	2/17 (11.8% 95%CI 0.0%-27.1%)	9/41 (22.0% 95%CI 9.3%-34.6%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	1/1 (100.0% 95%CI 100.0%-100.0%)	0/0	1/1 (100.0% 95%CI 100.0%-100.0%)
Any Trimester[5]	1/3 (33.3% 95%CI 0.0%-86.7%)	0/0	1/3 (33.3% 95%CI 0.0%-86.7%)

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.01
Outcomes of Interest for Exposed Participants, excluding Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Infant with serious Infection Prevalence[4,15]	4/61 (6.6% 95%CI 0.3%-12.8%)	1/17 (5.9% 95%CI 0.0%-17.1%)	3/44 (6.8% 95%CI 0.0%-14.3%)
By Earliest Belimumab Exposure			
Preconception	4/58 (6.9% 95%CI 0.4%-13.4%)	1/17 (5.9% 95%CI 0.0%-17.1%)	3/41 (7.3% 95%CI 0.0%-15.3%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	0/1	0/0	0/1
Any Trimester[5]	0/3	0/0	0/3
Infant with serious Infection Prevalence for Breastfed Infants at[10,15]	1/40 (2.5% 95%CI 0.0%-7.3%)	1/9 (11.1% 95%CI 0.0%-31.6%)	0/31
Outcome	1/38 (2.6% 95%CI 0.0%-7.7%)	1/9 (11.1% 95%CI 0.0%-31.6%)	0/29
Four Month Follow-up	0/26	0/4	0/22
Twelve Month Follow-up	0/10	0/0	0/10

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.01
Outcomes of Interest for Exposed Participants, excluding Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Infant with serious Infection Prevalence for Infants Completing Outcome[11,15,*]	4/61 (6.6% 95%CI 0.3%-12.8%)	1/17 (5.9% 95%CI 0.0%-17.1%)	3/44 (6.8% 95%CI 0.0%-14.3%)
Outcome	2/61 (3.3% 95%CI 0.0%-7.7%)	1/17 (5.9% 95%CI 0.0%-17.1%)	1/44 (2.3% 95%CI 0.0%-6.7%)
Four Month Follow-up	0/52	0/13	0/39
Twelve Month Follow-up	2/51 (3.9% 95%CI 0.0%-9.2%)	0/11	2/40 (5.0% 95%CI 0.0%-11.8%)

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.02
Outcomes of Interest for Exposed Participants, including Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

Note: Reports of pregnancy in which the pregnancy outcome or anticipated outcome is already known before enrollment can be biased toward the reporting of more unusual or severe cases compared to women whose pregnancy outcome is not yet known at the time of enrollment into the pregnancy registry. Therefore, rates of outcomes cannot be calculated from these data. However, a series of reported birth defects can be evaluated to detect patterns of specific birth defects and can assist with identification of potential early signals of therapy risks.
[0]Denominator is number of live birth participants.
[1]Denominator is number of live births. A denominator greater than N is an indicator of multiple births.
[2]MACDP birth defect prevalence (Correa, 2007); MACDP calculates birth defect prevalence as the proportion of live birth outcomes or fetal death outcomes at 20 weeks or more with confirmed birth defects relative to the number of live births. Cases are also considered defects if the infant or fetus has two or more conditional defects. This table includes sensitivity analysis; therefore, fetal death outcomes less than 20 weeks with confirmed birth defects are also counted in the numerators.
[3]EUROCAT birth defect prevalence (eurocat-network.eu); EUROCAT calculates birth defect prevalence as the proportion of live birth outcomes with birth defects relative to the number of live births. This table includes sensitivity analysis; therefore, fetal death outcomes less than 20 weeks with confirmed birth defects are also counted in the numerators.
[4]Denominator is number of live birth infants overall and by each time point of earliest exposure.
[5]Any trimester includes those occurring during the first, second, or third trimesters.
[6]Denominator is the number of unique participants enrolling prior to 20 weeks gestation overall and by each timepoint of earliest exposure.
[7]Denominator is number of unique participants overall and by each timepoint of earliest exposure.
[8]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[9]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[10]Denominator is number of live birth infants who were breastfed overall and at each timepoint of infant follow-up.
[11]Denominator is number of live birth infants overall and at each timepoint of infant follow-up.

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Table 8.02
Outcomes of Interest for Exposed Participants, including Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

[12]On 15Mar2022, EUROCAT classification was changed for two participants (US0027A and US0062A).
[13]Includes the number of participants with a pregnancy outcome of spontaneous abortion or stillbirth.
[14]Denominator is the total number of participants with a pregnancy outcome minus the number of participants with an elective termination overall and by each time point of earliest exposure.
[15]Numerator: Infant with an infection that meet the serious adverse event (SAE) criteria [Infections that resulted in death; were life-threatening; required inpatient hospitalization, prolonged hospitalization, resulted in significant disability or incapacity and/or were considered medically important to date]
[16]No birth defects were noted in the three spontaneous miscarriages
[*]2 infants with SAE infection [1 infant from the pure prospective and 1 from traditional prospective] reported through AE process within the first 3 months of life (line listing 9.4) but no infant visit data available. These cases had been pulled in and included in the table in overall count and in the outcome visit within the table

Protocol: BEL114256
Population: All Registry Participants

Table 8.02
Outcomes of Interest for Exposed Participants, including Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Total confirmed birth defects using MACDP or EUROCAT criteria[0,2,3,12]	12/58 (20.7% 95%CI 9.7%-29.6%)	1/16 (6.3% 95%CI 0.0%-17.1%)	11/42 (26.2% 95%CI 12.2%-37.8%)
Total confirmed birth defects using MACDP or EUROCAT criteria[1,2,3,12]	12/61 (19.7% 95%CI 9.7%-29.6%)	1/17 (5.9% 95%CI 0.0%-17.1%)	11/44 (25.0% 95%CI 12.2%-37.8%)
Confirmed birth defect prevalence using MACDP criteria [2,4]	11/61 (18.0% 95%CI 8.4%-27.7%)	1/17 (5.9% 95%CI 0.0%-17.1%)	10/44 (22.7% 95%CI 10.3%-35.1%)
By Earliest Belimumab Exposure			
Preconception	10/58 (17.2% 95%CI 7.5%-27.0%)	1/17 (5.9% 95%CI 0.0%-17.1%)	9/41 (22.0% 95%CI 9.3%-34.6%)
1st Trimester	1/2 (50.0% 95%CI 0.0%-100.0%)	0/0	1/2 (50.0% 95%CI 0.0%-100.0%)
2nd/3rd Trimester	0/1	0/0	0/1
Any Trimester[5]	1/3 (33.3% 95%CI 0.0%-86.7%)	0/0	1/3 (33.3% 95%CI 0.0%-86.7%)
MACDP birth defect prevalence for most recent 5-year period[2]	11/61 (18.0% 95%CI 8.4%-27.7%)	1/17 (5.9% 95%CI 0.0%-17.1%)	10/44 (22.7% 95%CI 10.3%-35.1%)

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.02
Outcomes of Interest for Exposed Participants, including Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Confirmed birth defect prevalence using EUROCAT Criteria [3,4,12]	9/61 (14.8% 95%CI 5.9%-23.7%)	1/17 (5.9% 95%CI 0.0%-17.1%)	8/44 (18.2% 95%CI 6.8%-29.6%)
By Earliest Belimumab Exposure			
Preconception	9/58 (15.5% 95%CI 6.2%-24.8%)	1/17 (5.9% 95%CI 0.0%-17.1%)	8/41 (19.5% 95%CI 7.4%-31.6%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	0/1	0/0	0/1
Any Trimester[5]	0/3	0/0	0/3
EUROCAT birth defect prevalence for most recent 5-year period[3]	9/61 (14.8% 95%CI 5.9%-23.7%)	1/17 (5.9% 95%CI 0.0%-17.1%)	8/44 (18.2% 95%CI 6.8%-29.6%)
Spontaneous Miscarriage Prevalence[6,16]	3/43 (7.0% 95%CI 0.0%-14.3%)	2/13 (15.4% 95%CI 0.0%-32.6%)	1/30 (3.3% 95%CI 0.0%-9.8%)
By Earliest Belimumab Exposure			
Preconception	3/41 (7.3% 95%CI 0.0%-14.9%)	2/13 (15.4% 95%CI 0.0%-32.6%)	1/28 (3.6% 95%CI 0.0%-10.4%)
1st Trimester	0/1	0/0	0/1
2nd/3rd Trimester	0/1	0/0	0/1
Any Trimester[5]	0/2	0/0	0/2

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.02
Outcomes of Interest for Exposed Participants, including Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Elective Termination Prevalence[7]	0/61	0/17	0/44
By Earliest Belimumab Exposure			
Preconception	0/57	0/17	0/40
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	0/2	0/0	0/2
Any Trimester[5]	0/4	0/0	0/4
Stillbirth Prevalence[7]	1/61 (1.6% 95%CI 0.0%-4.7%)	0/17	1/44 (2.3% 95%CI 0.0%-6.7%)
By Earliest Belimumab Exposure			
Preconception	0/57	0/17	0/40
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	1/2 (50.0% 95%CI 0.0%-100.0%)	0/0	1/2 (50.0% 95%CI 0.0%-100.0%)
Any Trimester[5]	1/4 (25.0% 95%CI 0.0%-67.4%)	0/0	1/4 (25.0% 95%CI 0.0%-67.4%)

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.02
Outcomes of Interest for Exposed Participants, including Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Fetal Loss Prevalence [13,14]	4/61 (6.6% 95%CI 0.3%-12.6%)	2/17 (11.8% 95%CI 0.0%-25.6%)	2/44 (4.5% 95%CI 0.0%-10.7%)
By Earliest Belimumab Exposure			
Preconception	3/57 (5.3% 95%CI 0.0%-10.9%)	2/17 (11.8% 95%CI 0.0%-25.6%)	1/40 (2.5% 95%CI 0.0%-7.3%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	1/2 (50.0% 95%CI 0.0%-100.0%)	0/0	1/2 (50.0% 95%CI 0.0%-100.0%)
Any Trimester[5]	1/4 (25.0% 95%CI 0.0%-67.4%)	0/0	1/4 (25.0% 95%CI 0.0%-67.4%)
Preterm Prevalence[4]	19/61 (31.1% 95%CI 19.5%-42.8%)	7/17 (41.2% 95%CI 17.8%-64.6%)	12/44 (27.3% 95%CI 14.1%-40.4%)
By Earliest Belimumab Exposure			
Preconception	19/58 (32.8% 95%CI 20.7%-44.8%)	7/17 (41.2% 95%CI 17.8%-64.6%)	12/41 (29.3% 95%CI 15.3%-43.2%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	0/1	0/0	0/1
Any Trimester[5]	0/3	0/0	0/3

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.02
Outcomes of Interest for Exposed Participants, including Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
SGA[6,8] Prevalence	4/61 (6.6% 95%CI 0.3%-12.8%)	0/17	4/44 (9.1% 95%CI 0.6%-17.6%)
By Earliest Belimumab Exposure			
Preconception	3/58 (5.2% 95%CI 0.0%-10.9%)	0/17	3/41 (7.3% 95%CI 0.0%-15.3%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	1/1 (100.0% 95%CI 100.0%-100.0%)	0/0	1/1 (100.0% 95%CI 100.0%-100.0%)
Any Trimester[5]	1/3 (33.3% 95%CI 0.0%-86.7%)	0/0	1/3 (33.3% 95%CI 0.0%-86.7%)
SGA[6,9] Prevalence	12/61 (19.7% 95%CI 9.7%-29.6%)	2/17 (11.8% 95%CI 0.0%-27.1%)	10/44 (22.7% 95%CI 10.3%-35.1%)
By Earliest Belimumab Exposure			
Preconception	11/58 (19.0% 95%CI 8.9%-29.1%)	2/17 (11.8% 95%CI 0.0%-27.1%)	9/41 (22.0% 95%CI 9.3%-34.6%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	1/1 (100.0% 95%CI 100.0%-100.0%)	0/0	1/1 (100.0% 95%CI 100.0%-100.0%)
Any Trimester[5]	1/3 (33.3% 95%CI 0.0%-86.7%)	0/0	1/3 (33.3% 95%CI 0.0%-86.7%)

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.02
Outcomes of Interest for Exposed Participants, including Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Infant with serious Infection Prevalence[4,15]	4/61 (6.6% 95%CI 0.3%-12.8%)	1/17 (5.9% 95%CI 0.0%-17.1%)	3/44 (6.8% 95%CI 0.0%-14.3%)
By Earliest Belimumab Exposure			
Preconception	4/58 (6.9% 95%CI 0.4%-13.4%)	1/17 (5.9% 95%CI 0.0%-17.1%)	3/41 (7.3% 95%CI 0.0%-15.3%)
1st Trimester	0/2	0/0	0/2
2nd/3rd Trimester	0/1	0/0	0/1
Any Trimester[5]	0/3	0/0	0/3
Infant with serious Infection Prevalence for Breastfed Infants at[10,15]	1/40 (2.5% 95%CI 0.0%-7.3%)	1/9 (11.1% 95%CI 0.0%-31.6%)	0/31
Outcome	1/38 (2.6% 95%CI 0.0%-7.7%)	1/9 (11.1% 95%CI 0.0%-31.6%)	0/29
Four Month Follow-up	0/26	0/4	0/22
Twelve Month Follow-up	0/10	0/0	0/10

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 8.02
Outcomes of Interest for Exposed Participants, including Defects of a Fetal Loss <20 Weeks
(Overall Prospective, Pure Prospective and Traditional Prospective Cohorts)

	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)
Infant with serious Infection Prevalence for Infants Completing Outcome[11,15,*]	4/61 (6.6% 95%CI 0.3%-12.8%)	1/17 (5.9% 95%CI 0.0%-17.1%)	3/44 (6.8% 95%CI 0.0%-14.3%)
Outcome	2/61 (3.3% 95%CI 0.0%-7.7%)	1/17 (5.9% 95%CI 0.0%-17.1%)	1/44 (2.3% 95%CI 0.0%-6.7%)
Four Month Follow-up	0/52	0/13	0/39
Twelve Month Follow-up	2/51 (3.9% 95%CI 0.0%-9.2%)	0/11	2/40 (5.0% 95%CI 0.0%-11.8%)

Note: See footnotes on Page 1 and 2.
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Protocol: BEL114256
Population: All Registry Participants

Table 9.1
Reasons for Study Discontinuation for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

Note: Denominator is the total number of participants in each column (N).
[1]Denominator is the number of participants discontinuing post-pregnancy outcome.

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Protocol: BEL114256
Population: All Registry Participants

Table 9.1
Reasons for Study Discontinuation for Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Number that discontinued post-pregnancy outcome	10 (13.9%)	6 (35.3%)	4 (9.1%)	0	0
Reason(s) for early discontinuation post-pregnancy outcome					
Maternal Death[1]	0	0	0	0	0
Neonatal Death[1]	0	0	0	0	0
Serious adverse event[1]	0	0	0	0	0
No response from HCPs[1]	1 (10.0%)	0	1 (25.0%)	0	0
No response from participant[1]	3 (30.0%)	2 (33.3%)	1 (25.0%)	0	0
Participant's decision to withdraw from registry[1]	0	0	0	0	0
Sponsor's decision to terminate registry[1]	2 (20.0%)	2 (33.3%)	0	0	0
Other[1]	4 (40.0%)	2 (33.3%)	2 (50.0%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 9.2
Reasons for Study Discontinuation for Exposed Participants
(Non-evaluable Participants Considered Lost to Follow-up before Pregnancy Outcome)

Note: Denominator is the total number of participants in each column (N).
[1]Denominator is the number of participants discontinuing prior to pregnancy outcome.

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Protocol: BEL114256
Population: All Registry Participants

Table 9.2
Reasons for Study Discontinuation for Exposed Participants
(Non-evaluable Participants Considered Lost to Follow-up before Pregnancy Outcome)

	Overall (N=5)
Number that discontinued prior to pregnancy outcome	5 (100.0%)
Reason(s) for early discontinuation prior to pregnancy outcome	
Maternal Death[1]	0
Serious adverse event[1]	0
Birth defect unknown[1]	2 (40.0%)
No response from HCPs[1]	3 (60.0%)
No response from participant[1]	0
Participant's decision to withdraw from registry[1]	0
Sponsor's decision to terminate registry[1]	0
Other[1]	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

Note: Denominator is the total number of participants in each column (N) unless otherwise indicated. n is the number of non-missing responses. Prospective Lost to Follow-up Participants are excluded due to unknown pregnancy outcome.
BMI = Body mass index; HELLP=hemolysis, elevated liver enzyme levels, and low platelet count; max=maximum; min=minimum; N/A=not applicable; Q=quartile; SD=standard deviation; SLE=systemic lupus erythematosus.
[1]If the woman has more than one race assigned, then race is summarized under multi-racial.
[2]Body mass index (BMI) is calculated based on pre-pregnancy weight.
[3]First trimester begins on date of conception, second trimester begins at week $14^{0/7}$ after the date of conception, and the third trimester begins at week $28^{0/7}$.
[4]Gestational age (weeks) is calculated as (280 days - [mEDD — reference date])/7.
[5]Denominator is the number of reported previous pregnancy outcomes. Includes reports of birth defects from previous pregnancies. These reports from previous pregnancies were not review and confirmed by the birth defect evaluator.
[6]Denominator is the number of reported previous pregnancy outcomes of a live birth.
[7]Summarizes all recorded tests. All other prenatal tests may include amniocentesis, MSAFP, Quad Screen, CVS, and any other tests, as available.
[8]SLICC/ACR Damage Index Score is assessed at Enrollment, but data may be obtained at any registry time point.
[9]Retrospective cohort patients are excluded.
[10]Denominator is the number of current pregnancies.
[11]Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.

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Protocol: BEL114256
Population: All Registry Participants

Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Age at Enrollment (years)						
n	72	61	17	44	0	11
Mean (SD)	31.7 (4.61)	31.9 (4.60)	32.4 (3.77)	31.7 (4.91)		30.7 (4.73)
Median	32.0	32.0	33.0	32.0		30.0
Min - Max	21 - 42	21 - 42	25 - 39	21 - 42		21 - 38
Q1, Q3	29.0, 36.0	29.0, 36.0	31.0, 36.0	28.5, 36.0		28.0, 33.0
Age group at Enrollment						
<20 years	0	0	0	0	0	0
20 - 24 years	5 (6.9%)	4 (6.6%)	0	4 (9.1%)	0	1 (9.1%)
25 - 29 years	16 (22.2%)	13 (21.3%)	3 (17.6%)	10 (22.7%)	0	3 (27.3%)
30 - 34 years	31 (43.1%)	26 (42.6%)	9 (52.9%)	17 (38.6%)	0	5 (45.5%)
35 - 39 years	18 (25.0%)	16 (26.2%)	5 (29.4%)	11 (25.0%)	0	2 (18.2%)
>=40 years	2 (2.8%)	2 (3.3%)	0	2 (4.5%)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Race						
American Indian/Alaskan Native	1 (1.4%)	1 (1.6%)	0	1 (2.3%)	0	0
Asian	4 (5.6%)	4 (6.6%)	3 (17.6%)	1 (2.3%)	0	0
Black/African American	7 (9.7%)	6 (9.8%)	0	6 (13.6%)	0	1 (9.1%)
Native Hawaiian/Oth Pacific Islander	0	0	0	0	0	0
White/Caucasian	54 (75.0%)	45 (73.8%)	11 (64.7%)	34 (77.3%)	0	9 (81.8%)
Other	5 (6.9%)	5 (8.2%)	3 (17.6%)	2 (4.5%)	0	0
Multi-racial[1]	0	0	0	0	0	0
Missing	1 (1.4%)	0	0	0	0	1 (9.1%)
Ethnicity						
Hispanic or Latino	12 (16.7%)	10 (16.4%)	3 (17.6%)	7 (15.9%)	0	2 (18.2%)
Not Hispanic or Latino	58 (80.6%)	50 (82.0%)	14 (82.4%)	36 (81.8%)	0	8 (72.7%)
Missing	2 (2.8%)	1 (1.6%)	0	1 (2.3%)	0	1 (9.1%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Region						
North America	60 (83.3%)	53 (86.9%)	14 (82.4%)	39 (88.6%)	0	7 (63.6%)
Europe	11 (15.3%)	7 (11.5%)	2 (11.8%)	5 (11.4%)	0	4 (36.4%)
Missing	1 (1.4%)	1 (1.6%)	1 (5.9%)	0	0	0
Country						
Austria	3 (4.2%)	2 (3.3%)	1 (5.9%)	1 (2.3%)	0	1 (9.1%)
Canada	4 (5.6%)	4 (6.6%)	2 (11.8%)	2 (4.5%)	0	0
France	3 (4.2%)	2 (3.3%)	0	2 (4.5%)	0	1 (9.1%)
Germany	2 (2.8%)	2 (3.3%)	1 (5.9%)	1 (2.3%)	0	0
Israel	0	0	0	0	0	0
Spain	3 (4.2%)	1 (1.6%)	0	1 (2.3%)	0	2 (18.2%)
USA	56 (77.8%)	49 (80.3%)	12 (70.6%)	37 (84.1%)	0	7 (63.6%)
Missing	1 (1.4%)	1 (1.6%)	1 (5.9%)	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Height(cm)						
n	71	61	17	44	0	10
Mean (SD)	165.0 (6.74)	164.7 (7.10)	164.9 (7.28)	164.6 (7.11)		166.7 (3.70)
Median	164.6	161.5	164.6	161.5		167.6
Min - Max	149 - 183	149 - 183	149 - 183	152 - 183		159 - 174
Pre-pregnancy weight(kg)						
n	71	61	17	44	0	10
Mean (SD)	70.8 (18.97)	71.0 (20.11)	65.5 (13.60)	73.2 (21.89)		69.4 (9.90)
Median	67.1	67.1	61.2	68.0		66.9
Min - Max	43 - 154	43 - 154	47 - 90	43 - 154		57 - 87

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Population: All Registry Participants

Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Pre-pregnancy BMI (kg/m2)[2]						
n	71	61	17	44	0	10
Mean (SD)	25.9 (6.11)	26.0 (6.36)	24.1 (4.72)	26.8 (6.79)		25.1 (4.40)
Median	25.1	25.2	22.1	25.8		23.8
Min - Max	18 - 49	18 - 49	19 - 35	18 - 49		20 - 34
Q1, Q3	21.7, 28.4	21.7, 28.4	20.2, 27.8	22.6, 28.7		21.8, 27.8
Pre-pregnancy BMI weight categories[2]						
Underweight (BMI <18.5 kg/m^2)	3 (4.2%)	3 (4.9%)	0	3 (6.8%)	0	0
Normal weight (BMI >= 18.5 and <25 kg/m^2)	31 (43.1%)	25 (41.0%)	10 (58.8%)	15 (34.1%)	0	6 (54.5%)
Overweight (BMI >=25 and <30kg/m^2)	26 (36.1%)	23 (37.7%)	5 (29.4%)	18 (40.9%)	0	3 (27.3%)
Obese (BMI >=30kg/m^2)	11 (15.3%)	10 (16.4%)	2 (11.8%)	8 (18.2%)	0	1 (9.1%)
Missing	1 (1.4%)	0	0	0	0	1 (9.1%)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Trimester of enrollment [3]						
First	32 (44.4%)	32 (52.5%)	12 (70.6%)	20 (45.5%)	0	NA
Second	18 (25.0%)	18 (29.5%)	1 (5.9%)	17 (38.6%)	0	NA
Third	11 (15.3%)	11 (18.0%)	4 (23.5%)	7 (15.9%)	0	NA
Gestational age at enrollment[4,9] (weeks)						
n	61	61	17	44	0	NA
Mean (SD)	16.6 (9.09)	16.6 (9.09)	14.5 (10.35)	17.4 (8.55)		NA
Median	13.1	13.1	9.6	15.6		NA
Min - Max	5 - 38	5 - 38	5 - 33	5 - 38		NA
Q1, Q3	9.3, 22.7	9.3, 22.7	6.7, 19.9	10.6, 22.9		NA
Multiple pregnancy type						
Twin (Complete Separate Outcome Forms)	4 (5.6%)	4 (6.6%)	2 (11.8%)	2 (4.5%)	0	0

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Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Participant pregnancy history						
Number of previous pregnancies						
0	32 (44.4%)	30 (49.2%)	5 (29.4%)	25 (56.8%)	0	2 (18.2%)
1	17 (23.6%)	13 (21.3%)	6 (35.3%)	7 (15.9%)	0	4 (36.4%)
2	7 (9.7%)	7 (11.5%)	2 (11.8%)	5 (11.4%)	0	0
3	3 (4.2%)	3 (4.9%)	0	3 (6.8%)	0	0
4 or more	3 (4.2%)	2 (3.3%)	0	2 (4.5%)	0	1 (9.1%)
Missing	10 (13.9%)	6 (9.8%)	4 (23.5%)	2 (4.5%)	0	4 (36.4%)
Previous pregnancies	30	25	8	17	0	5
Live birth[5]	24 (80.0%)	20 (80.0%)	6 (75.0%)	14 (82.4%)	0	4 (80.0%)
Full-Term birth[6]	19 (79.2%)	16 (80.0%)	6 (100.0%)	10 (71.4%)	0	3 (75.0%)
Preterm birth[6]	4 (16.7%)	4 (20.0%)	0	4 (28.6%)	0	0
Neonatal death[6]	0	0	0	0	0	0
Missing[6]	2 (8.3%)	1 (5.0%)	0	1 (7.1%)	0	1 (25.0%)
Stillborn[5]	0	0	0	0	0	0
Spontaneous miscarriage[5]	9 (30.0%)	7 (28.0%)	1 (12.5%)	6 (35.3%)	0	2 (40.0%)
Elective termination[5]	3 (10.0%)	3 (12.0%)	0	3 (17.6%)	0	0

Note: See footnotes on Page 1.
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Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Ectopic Pregnancy[5]	1 (3.3%)	1 (4.0%)	0	1 (5.9%)	0	0
Molar Pregnancy[5]	0	0	0	0	0	0
Outcomes with a birth defect[5]	1 (3.3%)	1 (4.0%)	0	1 (5.9%)	0	0
Multiple gestation pregnancy[5]	0	0	0	0	0	0
Missing[5]	1 (3.3%)	1 (4.0%)	1 (12.5%)	0	0	0
Current pregnancy						
Multiple gestation pregnancy [10]	4 (5.6%)	4 (6.6%)	2 (11.8%)	2 (4.5%)	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Medical Conditions occurring in a previous pregnancy						
Gestational Diabetes[5]	1 (3.3%)	1 (4.0%)	1 (12.5%)	0	0	0
Preeclampsia[5]	1 (3.3%)	0	0	0	0	1 (20.0%)
Eclampsia[5]	0	0	0	0	0	0
HELLP syndrome[5]	0	0	0	0	0	0
Prenatal testing prior to enrollment?						
Yes	53 (73.6%)	44 (72.1%)	0	44 (100.0%)	0	NA
No	12 (16.7%)	12 (19.7%)	12 (70.6%)	0	0	0
Missing/Unknown	7 (9.7%)	5 (8.2%)	5 (29.4%)	0	0	2 (18.2%)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Ultrasound[7]						
Gestational age (weeks)[4]						
n	62	54	12	42	0	8
Mean (SD)	10.3 (5.19)	10.6 (5.11)	12.5 (4.22)	10.1 (5.25)		8.4 (5.70)
Median	8.7	8.9	12.4	8.6		6.9
Min - Max	1 - 30	1 - 30	8 - 22	1 - 30		2 - 21
Q1, Q3	7.3, 11.7	7.6, 12.4	9.1, 13.1	7.3, 11.4		5.3, 10.1
Fetal Abnormality noted?[11]						
Yes	5 (6.9%)	5 (8.2%)	3 (17.6%)	2 (4.5%)	0	0
No	54 (75.0%)	48 (78.7%)	9 (52.9%)	39 (88.6%)	0	6 (54.5%)
Result pending	0	0	0	0	0	0
Missing/Unknown	13 (18.1%)	8 (13.1%)	5 (29.4%)	3 (6.8%)	0	5 (45.5%)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
All other prenatal tests[7]						
Gestational age (weeks)[4]						
n	36	32	5	27	0	4
Mean (SD)	13.6 (4.76)	13.6 (5.03)	19.5 (9.55)	12.4 (2.82)		13.6 (1.63)
Median	12.4	12.2	13.1	11.7		13.0
Min - Max	9 - 33	9 - 33	12 - 33	9 - 21		12 - 16
Q1, Q3	11.1, 13.4	11.0, 13.4	13.0, 26.1	11.0, 12.7		12.6, 14.6
Fetal Abnormality noted?[11]						
Yes	2 (2.8%)	2 (3.3%)	1 (5.9%)	1 (2.3%)	0	0
No	32 (44.4%)	28 (45.9%)	3 (17.6%)	25 (56.8%)	0	4 (36.4%)
Result pending	2 (2.8%)	2 (3.3%)	1 (5.9%)	1 (2.3%)	0	0
Missing/Unknown	36 (50.0%)	29 (47.5%)	12 (70.6%)	17 (38.6%)	0	7 (63.6%)

Note: See footnotes on Page 1.
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Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Participants with alcohol, tobacco, or rec. drug use	20 (27.8%)	18 (29.5%)	5 (29.4%)	13 (29.5%)	0	2 (18.2%)
Tobacco use (cigarettes, cigars, smokeless)						
Preconception and during pregnancy	3 (4.2%)	3 (4.9%)	1 (5.9%)	2 (4.5%)	0	0
Preconception only	3 (4.2%)	3 (4.9%)	0	3 (6.8%)	0	0
During pregnancy	0	0	0	0	0	0
Never	58 (80.6%)	49 (80.3%)	15 (88.2%)	34 (77.3%)	0	9 (81.8%)
Unknown/missing	8 (11.1%)	6 (9.8%)	1 (5.9%)	5 (11.4%)	0	2 (18.2%)
Alcohol use						
Preconception and during pregnancy	0	0	0	0	0	0
Preconception only	13 (18.1%)	11 (18.0%)	4 (23.5%)	7 (15.9%)	0	2 (18.2%)
During pregnancy	0	0	0	0	0	0
Never	47 (65.3%)	40 (65.6%)	11 (64.7%)	29 (65.9%)	0	7 (63.6%)
Unknown/missing	12 (16.7%)	10 (16.4%)	2 (11.8%)	8 (18.2%)	0	2 (18.2%)

Note: See footnotes on Page 1.
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Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Recreational drug use						
Preconception and during pregnancy	1 (1.4%)	1 (1.6%)	0	1 (2.3%)	0	0
Preconception only	0	0	0	0	0	0
During pregnancy	1 (1.4%)	1 (1.6%)	0	1 (2.3%)	0	0
Never	62 (86.1%)	53 (86.9%)	16 (94.1%)	37 (84.1%)	0	9 (81.8%)
Unknown/missing	8 (11.1%)	6 (9.8%)	1 (5.9%)	5 (11.4%)	0	2 (18.2%)
Recreational drug reported preconception						
Heroin	0	0	0	0	0	0
Cocaine	0	0	0	0	0	0
Marijuana	1 (1.4%)	1 (1.6%)	0	1 (2.3%)	0	0
Other	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Table 10.1
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with a Confirmed Outcome)

	Overall (N=72)	Overall Prospective (N=61)	Pure Prospective (N=17)	Traditional Prospective (N=44)	Non SLE (N=0)	Retrospective (N=11)
Recreational drug reported during pregnancy						
Heroin	1 (1.4%)	1 (1.6%)	0	1 (2.3%)	0	0
Cocaine	0	0	0	0	0	0
Marijuana	1 (1.4%)	1 (1.6%)	0	1 (2.3%)	0	0
Other	0	0	0	0	0	0
SLE Diagnosis per ACR criteria						
Yes	72 (100.0%)	61 (100.0%)	17 (100.0%)	44 (100.0%)	NA	11 (100.0%)
No	0	NA	NA	NA	0	0
SLICC/ACR Damage Index (SDI)Cumulative Score[8]						
n	16	15	3	12	NA	1
Mean (SD)	1.4 (4.21)	1.5 (4.36)	0.7 (1.15)	1.7 (4.87)		1.0 (NA)
Median	0.0	0.0	0.0	0.0		1.0
Min - Max	0 - 17	0 - 17	0 - 2	0 - 17		1 - 1
Q1, Q3	0.0, 1.0	0.0, 1.0	0.0, 2.0	0.0, 0.5		1.0, 1.0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1001
BEL114256 Final Analysis: Generated: 16FEB2023 17:02

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

Note: Denominator is the total number of participants in each column (N) unless otherwise indicated. n is the number of non-missing responses. Prospective Lost to Follow-up Participants are excluded due to unknown pregnancy outcome.
BMI = Body mass index; HELLP=hemolysis, elevated liver enzyme levels, and low platelet count; max=maximum; min=minimum; N/A=not applicable; Q=quartile; SD=standard deviation; SLE=systemic lupus erythematosus.
[1]If the woman has more than one race assigned, then race is summarized under multi-racial.
[2]Body mass index (BMI) is calculated based on pre-pregnancy weight.
[3]First trimester begins on date of conception, second trimester begins at week $14^{0/7}$ after the date of conception, and the third trimester begins at week $28^{0/7}$.
[4]Gestational age (weeks) is calculated as (280 days - [mEDD — reference date])/7.
[5]Denominator is the number of reported previous pregnancy outcomes. Includes reports of birth defects from previous pregnancies. These reports from previous pregnancies were not review and confirmed by the birth defect evaluator.
[6]Denominator is the number of reported previous pregnancy outcomes of a live birth.
[7]Summarizes all recorded tests. All other prenatal tests may include amniocentesis, MSAFP, Quad Screen, CVS, and any other tests, as available.
[8]SLICC/ACR Damage Index Score is assessed at Enrollment, but data may be obtained at any registry time point.
[9]Retrospective cohort patients are excluded.
[10]Denominator is the number of current pregnancies.
[11]Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.

Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Age at Enrollment (years)						
n	12	12	1	11	0	0
Mean (SD)	33.8 (3.05)	33.8 (3.05)	36.0 (NA)	33.5 (3.11)		
Median	33.5	33.5	36.0	32.0		
Min - Max	29 - 38	29 - 38	36 - 36	29 - 38		
Q1, Q3	31.0, 36.5	31.0, 36.5	36.0, 36.0	31.0, 37.0		
Age group at Enrollment						
<20 years	0	0	0	0	0	0
20 - 24 years	0	0	0	0	0	0
25 - 29 years	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
30 - 34 years	5 (41.7%)	5 (41.7%)	0	5 (45.5%)	0	0
35 - 39 years	6 (50.0%)	6 (50.0%)	1 (100.0%)	5 (45.5%)	0	0
>=40 years	0	0	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Race						
American Indian/Alaskan Native	0	0	0	0	0	0
Asian	0	0	0	0	0	0
Black/African American	2 (16.7%)	2 (16.7%)	0	2 (18.2%)	0	0
Native Hawaiian/Oth Pacific Islander	0	0	0	0	0	0
White/Caucasian	10 (83.3%)	10 (83.3%)	1 (100.0%)	9 (81.8%)	0	0
Other	0	0	0	0	0	0
Multi-racial[1]	0	0	0	0	0	0
Ethnicity						
Hispanic or Latino	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
Not Hispanic or Latino	11 (91.7%)	11 (91.7%)	1 (100.0%)	10 (90.9%)	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Region						
North America	11 (91.7%)	11 (91.7%)	1 (100.0%)	10 (90.9%)	0	0
Europe	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
Country						
Austria	0	0	0	0	0	0
Canada	0	0	0	0	0	0
France	0	0	0	0	0	0
Germany	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
Israel	0	0	0	0	0	0
Spain	0	0	0	0	0	0
USA	11 (91.7%)	11 (91.7%)	1 (100.0%)	10 (90.9%)	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Height(cm)						
n	12	12	1	11	0	0
Mean (SD)	165.4 (5.83)	165.4 (5.83)	167.6 (NA)	165.1 (6.07)		
Median	163.1	163.1	167.6	161.5		
Min - Max	158 - 177	158 - 177	168 - 168	158 - 177		
Pre-pregnancy weight(kg)						
n	12	12	1	11	0	0
Mean (SD)	76.0 (27.77)	76.0 (27.77)	86.2 (NA)	75.1 (28.94)		
Median	71.2	71.2	86.2	69.9		
Min - Max	46 - 154	46 - 154	86 - 86	46 - 154		

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Pre-pregnancy BMI (kg/m2)[2]						
n	12	12	1	11	0	0
Mean (SD)	27.4 (8.03)	27.4 (8.03)	30.7 (NA)	27.1 (8.35)		
Median	27.0	27.0	30.7	26.8		
Min - Max	18 - 49	18 - 49	31 - 31	18 - 49		
Q1, Q3	22.6, 29.6	22.6, 29.6	30.7, 30.7	21.7, 29.0		
Pre-pregnancy BMI weight categories[2]						
Underweight (BMI <18.5 kg/m^2)	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
Normal weight (BMI >= 18.5 and <25 kg/m^2)	3 (25.0%)	3 (25.0%)	0	3 (27.3%)	0	0
Overweight (BMI >=25 and <30kg/m^2)	5 (41.7%)	5 (41.7%)	0	5 (45.5%)	0	0
Obese (BMI >=30kg/m^2)	3 (25.0%)	3 (25.0%)	1 (100.0%)	2 (18.2%)	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Trimester of enrollment [3]						
First	6 (50.0%)	6 (50.0%)	1 (100.0%)	5 (45.5%)	0	NA
Second	5 (41.7%)	5 (41.7%)	0	5 (45.5%)	0	NA
Third	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	NA
Gestational age at enrollment[4,9] (weeks)						
n	12	12	1	11	0	NA
Mean (SD)	16.5 (6.78)	16.5 (6.78)	8.4 (NA)	17.3 (6.58)		NA
Median	13.9	13.9	8.4	14.7		NA
Min - Max	8 - 29	8 - 29	8 - 8	9 - 29		NA
Q1, Q3	11.2, 22.5	11.2, 22.5	8.4, 8.4	11.4, 23.1		NA
Multiple pregnancy type						
Twin (Complete Separate Outcome Forms)	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Participant pregnancy history						
Number of previous pregnancies						
0	7 (58.3%)	7 (58.3%)	0	7 (63.6%)	0	0
1	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
2	2 (16.7%)	2 (16.7%)	1 (100.0%)	1 (9.1%)	0	0
3	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
4 or more	0	0	0	0	0	0
Missing	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
Previous pregnancies	4	4	1	3	0	0
Live birth[5]	4 (100.0%)	4 (100.0%)	1 (100.0%)	3 (100.0%)	0	0
Full-Term birth[6]	4 (100.0%)	4 (100.0%)	1 (100.0%)	3 (100.0%)	0	0
Preterm birth[6]	0	0	0	0	0	0
Neonatal death[6]	0	0	0	0	0	0
Stillborn[5]	0	0	0	0	0	0
Spontaneous miscarriage[5]	0	0	0	0	0	0
Elective termination[5]	1 (25.0%)	1 (25.0%)	0	1 (33.3%)	0	0
Ectopic Pregnancy[5]	0	0	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Molar Pregnancy[5]	0	0	0	0	0	0
Outcomes with a birth defect[5]	0	0	0	0	0	0
Multiple gestation pregnancy[5]	0	0	0	0	0	0
Current pregnancy						
Multiple gestation pregnancy [10]	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
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Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Medical Conditions occurring in a previous pregnancy						
Gestational Diabetes[5]	0	0	0	0	0	0
Preeclampsia[5]	0	0	0	0	0	0
Eclampsia[5]	0	0	0	0	0	0
HELLP syndrome[5]	0	0	0	0	0	0
Prenatal testing prior to enrollment?						
Yes	11 (91.7%)	11 (91.7%)	0	11 (100.0%)	0	NA
No	1 (8.3%)	1 (8.3%)	1 (100.0%)	0	0	0
Missing/Unknown	0	0	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Ultrasound[7]						
Gestational age (weeks)[4]						
n	12	12	1	11	0	0
Mean (SD)	10.3 (4.08)	10.3 (4.08)	12.4 (NA)	10.1 (4.21)		
Median	9.0	9.0	12.4	8.7		
Min - Max	6 - 21	6 - 21	12 - 12	6 - 21		
Q1, Q3	7.8, 11.6	7.8, 11.6	12.4, 12.4	7.7, 10.9		
Fetal Abnormality noted?[11]						
Yes	2 (16.7%)	2 (16.7%)	1 (100.0%)	1 (9.1%)	0	0
No	9 (75.0%)	9 (75.0%)	0	9 (81.8%)	0	0
Result pending	0	0	0	0	0	0
Missing/Unknown	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
All other prenatal tests[7]						
Gestational age (weeks)[4]						
n	7	7	1	6	0	0
Mean (SD)	15.8 (6.03)	15.8 (6.03)	26.1 (NA)	14.1 (4.34)		
Median	12.6	12.6	26.1	12.1		
Min - Max	10 - 26	10 - 26	26 - 26	10 - 21		
Q1, Q3	11.0, 20.6	11.0, 20.6	26.1, 26.1	11.0, 18.6		
Fetal Abnormality noted?[11]						
Yes	2 (16.7%)	2 (16.7%)	1 (100.0%)	1 (9.1%)	0	0
No	5 (41.7%)	5 (41.7%)	0	5 (45.5%)	0	0
Result pending	0	0	0	0	0	0
Missing/Unknown	5 (41.7%)	5 (41.7%)	0	5 (45.5%)	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Participants with alcohol, tobacco, or rec. drug use	6 (50.0%)	6 (50.0%)	1 (100.0%)	5 (45.5%)	0	0
Tobacco use (cigarettes, cigars, smokeless)						
Preconception and during pregnancy	2 (16.7%)	2 (16.7%)	1 (100.0%)	1 (9.1%)	0	0
Preconception only	0	0	0	0	0	0
During pregnancy	0	0	0	0	0	0
Never	9 (75.0%)	9 (75.0%)	0	9 (81.8%)	0	0
Unknown/missing	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
Alcohol use						
Preconception and during pregnancy	0	0	0	0	0	0
Preconception only	4 (33.3%)	4 (33.3%)	0	4 (36.4%)	0	0
During pregnancy	0	0	0	0	0	0
Never	6 (50.0%)	6 (50.0%)	1 (100.0%)	5 (45.5%)	0	0
Unknown/missing	2 (16.7%)	2 (16.7%)	0	2 (18.2%)	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Recreational drug use						
Preconception and during pregnancy	0	0	0	0	0	0
Preconception only	0	0	0	0	0	0
During pregnancy	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
Never	10 (83.3%)	10 (83.3%)	1 (100.0%)	9 (81.8%)	0	0
Unknown/missing	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
Recreational drug reported preconception						
Heroin	0	0	0	0	0	0
Cocaine	0	0	0	0	0	0
Marijuana	0	0	0	0	0	0
Other	0	0	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.2
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of Birth Defect(s))

	Overall (N=12)	Overall Prospective (N=12)	Pure Prospective (N=1)	Traditional Prospective (N=11)	Non SLE (N=0)	Retrospective (N=0)
Recreational drug reported during pregnancy						
Heroin	1 (8.3%)	1 (8.3%)	0	1 (9.1%)	0	0
Cocaine	0	0	0	0	0	0
Marijuana	0	0	0	0	0	0
Other	0	0	0	0	0	0
SLE Diagnosis per ACR criteria						
Yes	12 (100.0%)	12 (100.0%)	1 (100.0%)	11 (100.0%)	NA	0
No	0	NA	NA	NA	0	0
SLICC/ACR Damage Index (SDI)Cumulative Score[8]						
n	4	4	1	3	NA	0
Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (NA)	0.0 (0.00)		
Median	0.0	0.0	0.0	0.0		
Min - Max	0 - 0	0 - 0	0 - 0	0 - 0		
Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0		

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1002
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

Note: Denominator is the total number of participants in each column (N) unless otherwise indicated. n is the number of non-missing responses. Prospective Lost to Follow-up Participants are excluded due to unknown pregnancy outcome.
BMI = Body mass index; HELLP=hemolysis, elevated liver enzyme levels, and low platelet count; max=maximum; min=minimum; N/A=not applicable; Q=quartile; SD=standard deviation; SLE=systemic lupus erythematosus.
[1]If the woman has more than one race assigned, then race is summarized under multi-racial.
[2]Body mass index (BMI) is calculated based on pre-pregnancy weight.
[3]First trimester begins on date of conception, second trimester begins at week $14^{0/7}$ after the date of conception, and the third trimester begins at week $28^{0/7}$.
[4]Gestational age (weeks) is calculated as (280 days - [mEDD — reference date])/7.
[5]Denominator is the number of reported previous pregnancy outcomes. Includes reports of birth defects from previous pregnancies. These reports from previous pregnancies were not review and confirmed by the birth defect evaluator.
[6]Denominator is the number of reported previous pregnancy outcomes of a live birth.
[7]Summarizes all recorded tests. All other prenatal tests may include amniocentesis, MSAFP, Quad Screen, CVS, and any other tests, as available.
[8]SLICC/ACR Damage Index Score is assessed at Enrollment, but data may be obtained at any registry time point.
[9]Retrospective cohort patients are excluded.
[10]Denominator is the number of current pregnancies.
[11]Due to BPR closure, pending is reflective at the time of the closure. BPR will not collect additional information.

Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1003
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Age at Enrollment (years)						
n	8	4	2	2	0	4
Mean (SD)	34.5 (3.42)	34.8 (3.50)	37.5 (2.12)	32.0 (1.41)		34.3 (3.86)
Median	34.5	34.5	37.5	32.0		34.5
Min - Max	30 - 39	31 - 39	36 - 39	31 - 33		30 - 38
Q1, Q3	31.5, 37.5	32.0, 37.5	36.0, 39.0	31.0, 33.0		31.0, 37.5
Age group at Enrollment						
<20 years	0	0	0	0	0	0
20 - 24 years	0	0	0	0	0	0
25 - 29 years	0	0	0	0	0	0
30 - 34 years	4 (50.0%)	2 (50.0%)	0	2 (100.0%)	0	2 (50.0%)
35 - 39 years	4 (50.0%)	2 (50.0%)	2 (100.0%)	0	0	2 (50.0%)
>=40 years	0	0	0	0	0	0

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1003
BEL114256 Final Analysis: Generated: 16FEB2023 17:04

Protocol: BEL114256
Population: All Registry Participants

Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Race						
American Indian/Alaskan Native	0	0	0	0	0	0
Asian	0	0	0	0	0	0
Black/African American	0	0	0	0	0	0
Native Hawaiian/Oth Pacific Islander	0	0	0	0	0	0
White/Caucasian	6 (75.0%)	3 (75.0%)	1 (50.0%)	2 (100.0%)	0	3 (75.0%)
Other	1 (12.5%)	1 (25.0%)	1 (50.0%)	0	0	0
Multi-racial[1]	0	0	0	0	0	0
Missing	1 (12.5%)	0	0	0	0	1 (25.0%)
Ethnicity						
Hispanic or Latino	1 (12.5%)	1 (25.0%)	1 (50.0%)	0	0	0
Not Hispanic or Latino	6 (75.0%)	3 (75.0%)	1 (50.0%)	2 (100.0%)	0	3 (75.0%)
Missing	1 (12.5%)	0	0	0	0	1 (25.0%)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Region						
North America	7 (87.5%)	4 (100.0%)	2 (100.0%)	2 (100.0%)	0	3 (75.0%)
Europe	1 (12.5%)	0	0	0	0	1 (25.0%)
Country						
Austria	0	0	0	0	0	0
Canada	1 (12.5%)	1 (25.0%)	1 (50.0%)	0	0	0
France	0	0	0	0	0	0
Germany	0	0	0	0	0	0
Israel	0	0	0	0	0	0
Spain	1 (12.5%)	0	0	0	0	1 (25.0%)
USA	6 (75.0%)	3 (75.0%)	1 (50.0%)	2 (100.0%)	0	3 (75.0%)

Note: See footnotes on Page 1.
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Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Height(cm)						
n	7	4	2	2	0	3
Mean (SD)	167.2 (7.13)	166.1 (9.14)	167.6 (8.62)	164.6 (12.93)		168.7 (4.66)
Median	167.6	167.6	167.6	164.6		167.6
Min - Max	155 - 174	155 - 174	162 - 174	155 - 174		165 - 174
Pre-pregnancy weight(kg)						
n	7	4	2	2	0	3
Mean (SD)	77.3 (25.59)	83.6 (34.16)	66.2 (11.55)	100.9 (46.51)		68.9 (5.50)
Median	68.0	71.2	66.2	100.9		65.8
Min - Max	58 - 134	58 - 134	58 - 74	68 - 134		66 - 75

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Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Pre-pregnancy BMI (kg/m2)[2]						
n	7	4	2	2	0	3
Mean (SD)	27.6 (8.19)	30.1 (10.44)	23.9 (6.56)	36.2 (11.44)		24.3 (3.11)
Median	27.8	28.3	23.9	36.2		23.4
Min - Max	19 - 44	19 - 44	19 - 29	28 - 44		22 - 28
Q1, Q3	21.8, 28.5	23.7, 36.4	19.2, 28.5	28.2, 44.3		21.8, 27.8
Pre-pregnancy BMI weight categories[2]						
Underweight (BMI <18.5 kg/m^2)	0	0	0	0	0	0
Normal weight (BMI >= 18.5 and <25 kg/m^2)	3 (37.5%)	1 (25.0%)	1 (50.0%)	0	0	2 (50.0%)
Overweight (BMI >=25 and <30kg/m^2)	3 (37.5%)	2 (50.0%)	1 (50.0%)	1 (50.0%)	0	1 (25.0%)
Obese (BMI >=30kg/m^2)	1 (12.5%)	1 (25.0%)	0	1 (50.0%)	0	0
Missing	1 (12.5%)	0	0	0	0	1 (25.0%)

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Population: All Registry Participants

Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Trimester of enrollment [3]						
First	3 (37.5%)	3 (75.0%)	2 (100.0%)	1 (50.0%)	0	NA
Second	1 (12.5%)	1 (25.0%)	0	1 (50.0%)	0	NA
Third	0	0	0	0	0	NA
Gestational age at enrollment[4,9] (weeks)						
n	4	4	2	2	0	NA
Mean (SD)	10.7 (5.39)	10.7 (5.39)	7.3 (3.23)	14.1 (5.45)		NA
Median	9.9	9.9	7.3	14.1		NA
Min - Max	5 - 18	5 - 18	5 - 10	10 - 18		NA
Q1, Q3	7.3, 14.1	7.3, 14.1	5.0, 9.6	10.3, 18.0		NA
Multiple pregnancy type						
Twin (Complete Separate Outcome Forms)	1 (12.5%)	1 (25.0%)	1 (50.0%)	0	0	0

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Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Participant pregnancy history						
Number of previous pregnancies						
0	2 (25.0%)	2 (50.0%)	1 (50.0%)	1 (50.0%)	0	0
1	3 (37.5%)	2 (50.0%)	1 (50.0%)	1 (50.0%)	0	1 (25.0%)
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4 or more	1 (12.5%)	0	0	0	0	1 (25.0%)
Missing	2 (25.0%)	0	0	0	0	2 (50.0%)
Previous pregnancies	4	2	1	1	0	2
Live birth[5]	3 (75.0%)	2 (100.0%)	1 (100.0%)	1 (100.0%)	0	1 (50.0%)
Full-Term birth[6]	2 (66.7%)	2 (100.0%)	1 (100.0%)	1 (100.0%)	0	0
Preterm birth[6]	0	0	0	0	0	0
Neonatal death[6]	0	0	0	0	0	0
Missing[6]	1 (33.3%)	0	0	0	0	1 (100.0%)
Stillborn[5]	0	0	0	0	0	0
Spontaneous miscarriage[5]	2 (50.0%)	0	0	0	0	2 (100.0%)
Elective termination[5]	0	0	0	0	0	0

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Population: All Registry Participants

Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Ectopic Pregnancy[5]	0	0	0	0	0	0
Molar Pregnancy[5]	0	0	0	0	0	0
Outcomes with a birth defect[5]	0	0	0	0	0	0
Multiple gestation pregnancy[5]	0	0	0	0	0	0
Current pregnancy						
Multiple gestation pregnancy [10]	1 (12.5%)	1 (25.0%)	1 (50.0%)	0	0	0

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Population: All Registry Participants

Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Medical Conditions occurring in a previous pregnancy						
Gestational Diabetes[5]	0	0	0	0	0	0
Preeclampsia[5]	0	0	0	0	0	0
Eclampsia[5]	0	0	0	0	0	0
HELLP syndrome[5]	0	0	0	0	0	0
Prenatal testing prior to enrollment?						
Yes	5 (62.5%)	2 (50.0%)	0	2 (100.0%)	0	NA
No	2 (25.0%)	2 (50.0%)	2 (100.0%)	0	0	0
Missing/Unknown	1 (12.5%)	0	0	0	0	1 (25.0%)

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Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Ultrasound[7]						
Gestational age (weeks)[4]						
n	7	4	2	2	0	3
Mean (SD)	7.4 (3.80)	9.9 (2.80)	10.4 (3.74)	9.4 (2.93)		4.2 (2.03)
Median	7.3	9.6	10.4	9.4		4.6
Min - Max	2 - 13	7 - 13	8 - 13	7 - 11		2 - 6
Q1, Q3	4.6, 11.4	7.5, 12.2	7.7, 13.0	7.3, 11.4		2.0, 6.0
Fetal Abnormality noted?[11]						
Yes	2 (25.0%)	2 (50.0%)	2 (100.0%)	0	0	0
No	4 (50.0%)	2 (50.0%)	0	2 (100.0%)	0	2 (50.0%)
Result pending	0	0	0	0	0	0
Missing/Unknown	2 (25.0%)	0	0	0	0	2 (50.0%)

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Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
All other prenatal tests[7]						
Gestational age (weeks)[4]						
n	0	0	0	0	0	0
Mean (SD)						
Median						
Min - Max						
Q1, Q3						
Fetal Abnormality noted?[11]						
Yes	0	0	0	0	0	0
No	0	0	0	0	0	0
Result pending	0	0	0	0	0	0
Missing/Unknown	8 (100.0%)	4 (100.0%)	2 (100.0%)	2 (100.0%)	0	4 (100.0%)

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Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Participants with alcohol, tobacco, or rec. drug use	2 (25.0%)	1 (25.0%)	1 (50.0%)	0	0	1 (25.0%)
Tobacco use (cigarettes, cigars, smokeless)						
Preconception and during pregnancy	0	0	0	0	0	0
Preconception only	0	0	0	0	0	0
During pregnancy	0	0	0	0	0	0
Never	7 (87.5%)	4 (100.0%)	2 (100.0%)	2 (100.0%)	0	3 (75.0%)
Unknown/missing	1 (12.5%)	0	0	0	0	1 (25.0%)
Alcohol use						
Preconception and during pregnancy	0	0	0	0	0	0
Preconception only	2 (25.0%)	1 (25.0%)	1 (50.0%)	0	0	1 (25.0%)
During pregnancy	0	0	0	0	0	0
Never	5 (62.5%)	3 (75.0%)	1 (50.0%)	2 (100.0%)	0	2 (50.0%)
Unknown/missing	1 (12.5%)	0	0	0	0	1 (25.0%)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Recreational drug use						
Preconception and during pregnancy	0	0	0	0	0	0
Preconception only	0	0	0	0	0	0
During pregnancy	0	0	0	0	0	0
Never	7 (87.5%)	4 (100.0%)	2 (100.0%)	2 (100.0%)	0	3 (75.0%)
Unknown/missing	1 (12.5%)	0	0	0	0	1 (25.0%)
Recreational drug reported preconception						
Heroin	0	0	0	0	0	0
Cocaine	0	0	0	0	0	0
Marijuana	0	0	0	0	0	0
Other	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 10.3
Characteristics of All Evaluable Exposed Participants
(Evaluable Participants with Outcome of SAB or Stillbirth)

	Overall (N=8)	Overall Prospective (N=4)	Pure Prospective (N=2)	Traditional Prospective (N=2)	Non SLE (N=0)	Retrospective (N=4)
Recreational drug reported during pregnancy						
Heroin	0	0	0	0	0	0
Cocaine	0	0	0	0	0	0
Marijuana	0	0	0	0	0	0
Other	0	0	0	0	0	0
SLE Diagnosis per ACR criteria						
Yes	8 (100.0%)	4 (100.0%)	2 (100.0%)	2 (100.0%)	NA	4 (100.0%)
No	0	NA	NA	NA	0	0
SLICC/ACR Damage Index (SDI)Cumulative Score[8]						
n	0	0	0	0	NA	0
Mean (SD)						
Median						
Min - Max						
Q1, Q3						

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 11.0
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Note: Multiple gestations may be reported by a participant. Therefore N includes all reported outcomes. PGA=physician global assessment; SGA=small for gestational age; SAB=Spontaneous Miscarriages.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births. Preterm, SGA, and birth defects are all subsets of live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Denominator is N for each outcome.
[5]Denominator is the number of non-missing responses at each timepoint.
[6]Second trimester begins at week $14^{0/7}$ after the date of conception to week $28^{0/7}$.
[7]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.

Protocol: BEL114256
Population: All Registry Participants

Table 11.0
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Disease Severity (PGA)	Total[1,7] (N=72) n(%)	SAB[7] (N=7) n(%)	Elective terms (N=2) n(%)	Still-births (N=1) n(%)	Live Births [7] (N=63) n(%)	Preterm [7] (N=19) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Preconception									
Nonmissing[4]	30(41.7)	3(42.9)	1(50.0)	0	26(41.3)	6(31.6)	1(25.0)	4(33.3)	2(16.7)
0=None[5]	9(30.0)	1(33.3)	0	0	8(30.8)	1(16.7)	1(100)	1(25.0)	0
1=Mild[5]	12(40.0)	1(33.3)	1(100)	0	10(38.5)	4(66.7)	0	1(25.0)	1(50.0)
2=Moderate[5]	8(26.7)	1(33.3)	0	0	7(26.9)	0	0	2(50.0)	1(50.0)
3=Severe[5]	1(3.3)	0	0	0	1(3.8)	1(16.7)	0	0	0
Missing[4]	42(58.3)	4(57.1)	1(50.0)	1(100)	37(58.7)	13(68.4)	3(75.0)	8(66.7)	10(83.3)
At enrollment									
Nonmissing[4]	33(45.8)	1(14.3)	1(50.0)	1(100)	30(47.6)	10(52.6)	1(25.0)	4(33.3)	6(50.0)
0=None[5]	10(30.3)	0	0	0	10(33.3)	3(30.0)	1(100)	2(50.0)	2(33.3)
1=Mild[5]	15(45.5)	1(100)	1(100)	0	13(43.3)	4(40.0)	0	2(50.0)	4(66.7)
2=Moderate[5]	6(18.2)	0	0	0	6(20.0)	2(20.0)	0	0	0
3=Severe[5]	2(6.1)	0	0	1(100)	1(3.3)	1(10.0)	0	0	0
Missing[4]	39(54.2)	6(85.7)	1(50.0)	0	33(52.4)	9(47.4)	3(75.0)	8(66.7)	6(50.0)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 11.0
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Disease Severity (PGA)	Total[1,7] (N=72) n(%)	SAB[7] (N=7) n(%)	Elective terms (N=2) n(%)	Still-births (N=1) n(%)	Live Births [7] (N=63) n(%)	Preterm [7] (N=19) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
At end of second trimester[6]									
Nonmissing[4]	23(31.9)	0	0	0	23(36.5)	6(31.6)	1(25.0)	3(25.0)	6(50.0)
0=None[5]	8(34.8)	0	0	0	8(34.8)	2(33.3)	1(100)	2(66.7)	1(16.7)
1=Mild[5]	12(52.2)	0	0	0	12(52.2)	3(50.0)	0	1(33.3)	3(50.0)
2=Moderate[5]	3(13.0)	0	0	0	3(13.0)	1(16.7)	0	0	2(33.3)
3=Severe[5]	0	0	0	0	0	0	0	0	0
Missing[4]	49(68.1)	7(100)	2(100)	1(100)	40(63.5)	13(68.4)	3(75.0)	9(75.0)	6(50.0)
At outcome									
Nonmissing[4]	16(22.2)	1(14.3)	0	0	15(23.8)	3(15.8)	1(25.0)	4(33.3)	4(33.3)
0=None[5]	9(56.3)	0	0	0	9(60.0)	1(33.3)	1(100)	4(100)	3(75.0)
1=Mild[5]	4(25.0)	1(100)	0	0	3(20.0)	1(33.3)	0	0	1(25.0)
2=Moderate[5]	2(12.5)	0	0	0	2(13.3)	1(33.3)	0	0	0
3=Severe[5]	1(6.3)	0	0	0	1(6.7)	0	0	0	0
Missing[4]	56(77.8)	6(85.7)	2(100)	1(100)	48(76.2)	16(84.2)	3(75.0)	8(66.7)	8(66.7)

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 11.1
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Note: Multiple gestations may be reported by a participant. Therefore N includes all reported outcomes. PGA=physician global assessment; SGA=small for gestational age; SAB=Spontaneous Miscarriages.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births. Preterm, SGA, and birth defects are all subsets of live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Denominator is N for each outcome.
[5]Denominator is the number of non-missing responses at each timepoint.
[6]Second trimester begins at week $14^{0/7}$ after the date of conception to week $28^{0/7}$.
[7]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.

Protocol: BEL114256
Population: All Registry Participants

Table 11.1
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Disease Severity (PGA)	Total[1,7] (N=61) n(%)	SAB[7] (N=3) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births [7] (N=58) n(%)	Preterm [7] (N=17) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Preconception									
Nonmissing[4]	25(41.0)	0	0	0	25(43.1)	6(35.3)	1(25.0)	4(33.3)	2(16.7)
0=None[5]	7(28.0)	0	0	0	7(28.0)	1(16.7)	1(100)	1(25.0)	0
1=Mild[5]	10(40.0)	0	0	0	10(40.0)	4(66.7)	0	1(25.0)	1(50.0)
2=Moderate[5]	7(28.0)	0	0	0	7(28.0)	0	0	2(50.0)	1(50.0)
3=Severe[5]	1(4.0)	0	0	0	1(4.0)	1(16.7)	0	0	0
Missing[4]	36(59.0)	3(100)	0	1(100)	33(56.9)	11(64.7)	3(75.0)	8(66.7)	10(83.3)
At enrollment									
Nonmissing[4]	30(49.2)	0	0	1(100)	29(50.0)	10(58.8)	1(25.0)	4(33.3)	6(50.0)
0=None[5]	9(30.0)	0	0	0	9(31.0)	3(30.0)	1(100)	2(50.0)	2(33.3)
1=Mild[5]	13(43.3)	0	0	0	13(44.8)	4(40.0)	0	2(50.0)	4(66.7)
2=Moderate[5]	6(20.0)	0	0	0	6(20.7)	2(20.0)	0	0	0
3=Severe[5]	2(6.7)	0	0	1(100)	1(3.4)	1(10.0)	0	0	0
Missing[4]	31(50.8)	3(100)	0	0	29(50.0)	7(41.2)	3(75.0)	8(66.7)	6(50.0)

Note: See footnotes on Page 1.
BEL114256 Final Analysis: Generated: 16FEB2023 17:06

Protocol: BEL114256
Population: All Registry Participants

Table 11.1
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Disease Severity (PGA)	Total[1,7] (N=61) n(%)	SAB[7] (N=3) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births [7] (N=58) n(%)	Preterm [7] (N=17) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
At end of second trimester[6]									
Nonmissing[4]	23(37.7)	0	0	0	23(39.7)	6(35.3)	1(25.0)	3(25.0)	6(50.0)
0=None[5]	8(34.8)	0	0	0	8(34.8)	2(33.3)	1(100)	2(66.7)	1(16.7)
1=Mild[5]	12(52.2)	0	0	0	12(52.2)	3(50.0)	0	1(33.3)	3(50.0)
2=Moderate[5]	3(13.0)	0	0	0	3(13.0)	1(16.7)	0	0	2(33.3)
3=Severe[5]	0	0	0	0	0	0	0	0	0
Missing[4]	38(62.3)	3(100)	0	1(100)	35(60.3)	11(64.7)	3(75.0)	9(75.0)	6(50.0)
At outcome									
Nonmissing[4]	15(24.6)	0	0	0	15(25.9)	3(17.6)	1(25.0)	4(33.3)	4(33.3)
0=None[5]	9(60.0)	0	0	0	9(60.0)	1(33.3)	1(100)	4(100)	3(75.0)
1=Mild[5]	3(20.0)	0	0	0	3(20.0)	1(33.3)	0	0	1(25.0)
2=Moderate[5]	2(13.3)	0	0	0	2(13.3)	1(33.3)	0	0	0
3=Severe[5]	1(6.7)	0	0	0	1(6.7)	0	0	0	0
Missing[4]	46(75.4)	3(100)	0	1(100)	43(74.1)	14(82.4)	3(75.0)	8(66.7)	8(66.7)

Note: See footnotes on Page 1.
BEL114256 Final Analysis: Generated: 16FEB2023 17:06

Protocol: BEL114256
Population: All Registry Participants

Table 11.2
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Note: Multiple gestations may be reported by a participant. Therefore N includes all reported outcomes. PGA=physician global assessment; SGA=small for gestational age; SAB=Spontaneous Miscarriages.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births. Preterm, SGA, and birth defects are all subsets of live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Denominator is N for each outcome.
[5]Denominator is the number of non-missing responses at each timepoint.
[6]Second trimester begins at week $14^{0/7}$ after the date of conception to week $28^{0/7}$.
[7]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.

Protocol: BEL114256
Population: All Registry Participants

Table 11.2
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Disease Severity (PGA)	Total[1,7] (N=17) n(%)	SAB[7] (N=2) n(%)	Elective terms (N=0) n(%)	Still-births (N=0) n(%)	Live Births [7] (N=16) n(%)	Preterm [7] (N=6) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=2) n(%)	Birth Defects (N=1) n(%)
Preconception									
Nonmissing[4]	8(47.1)	0	0	0	8(50.0)	2(33.3)	0	1(50.0)	0
0=None[5]	2(25.0)	0	0	0	2(25.0)	0	0	0	0
1=Mild[5]	3(37.5)	0	0	0	3(37.5)	1(50.0)	0	0	0
2=Moderate[5]	2(25.0)	0	0	0	2(25.0)	0	0	1(100)	0
3=Severe[5]	1(12.5)	0	0	0	1(12.5)	1(50.0)	0	0	0
Missing[4]	9(52.9)	2(100)	0	0	8(50.0)	4(66.7)	0	1(50.0)	1(100)
At enrollment									
Nonmissing[4]	6(35.3)	0	0	0	6(37.5)	2(33.3)	0	1(50.0)	0
0=None[5]	3(50.0)	0	0	0	3(50.0)	0	0	0	0
1=Mild[5]	2(33.3)	0	0	0	2(33.3)	1(50.0)	0	1(100)	0
2=Moderate[5]	0	0	0	0	0	0	0	0	0
3=Severe[5]	1(16.7)	0	0	0	1(16.7)	1(50.0)	0	0	0
Missing[4]	11(64.7)	2(100)	0	0	10(62.5)	4(66.7)	0	1(50.0)	1(100)

Note: See footnotes on Page 1.
BEL114256 Final Analysis: Generated: 16FEB2023 17:07

Protocol: BEL114256
Population: All Registry Participants

Table 11.2
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Disease Severity (PGA)	Total[1,7] (N=17) n(%)	SAB[7] (N=2) n(%)	Elective terms (N=0) n(%)	Still-births (N=0) n(%)	Live Births [7] (N=16) n(%)	Preterm [7] (N=6) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=2) n(%)	Birth Defects (N=1) n(%)
At end of second trimester[6]									
Nonmissing[4]	6(35.3)	0	0	0	6(37.5)	0	0	1(50.0)	1(100)
0=None[5]	3(50.0)	0	0	0	3(50.0)	0	0	1(100)	0
1=Mild[5]	2(33.3)	0	0	0	2(33.3)	0	0	0	0
2=Moderate[5]	1(16.7)	0	0	0	1(16.7)	0	0	0	1(100)
3=Severe[5]	0	0	0	0	0	0	0	0	0
Missing[4]	11(64.7)	2(100)	0	0	10(62.5)	6(100)	0	1(50.0)	0
At outcome									
Nonmissing[4]	2(11.8)	0	0	0	2(12.5)	0	0	1(50.0)	0
0=None[5]	2(100)	0	0	0	2(100)	0	0	1(100)	0
1=Mild[5]	0	0	0	0	0	0	0	0	0
2=Moderate[5]	0	0	0	0	0	0	0	0	0
3=Severe[5]	0	0	0	0	0	0	0	0	0
Missing[4]	15(88.2)	2(100)	0	0	14(87.5)	6(100)	0	1(50.0)	1(100)

Note: See footnotes on Page 1.
BEL114256 Final Analysis: Generated: 16FEB2023 17:07

Protocol: BEL114256
Population: All Registry Participants

Table 11.3
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Note: Multiple gestations may be reported by a participant. Therefore N includes all reported outcomes. PGA=physician global assessment; SGA=small for gestational age; SAB=Spontaneous Miscarriages.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births. Preterm, SGA, and birth defects are all subsets of live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Denominator is N for each outcome.
[5]Denominator is the number of non-missing responses at each timepoint.
[6]Second trimester begins at week $14^{0/7}$ after the date of conception to week $28^{0/7}$.

Protocol: BEL114256
Population: All Registry Participants

Table 11.3
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Disease Severity (PGA)	Total[1] (N=44) n(%)	SAB (N=1) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births (N=42) n(%)	Preterm (N=11) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=10) n(%)	Birth Defects (N=11) n(%)
Preconception									
Nonmissing[4]	17(38.6)	0	0	0	17(40.5)	4(36.4)	1(25.0)	3(30.0)	2(18.2)
0=None[5]	5(29.4)	0	0	0	5(29.4)	1(25.0)	1(100)	1(33.3)	0
1=Mild[5]	7(41.2)	0	0	0	7(41.2)	3(75.0)	0	1(33.3)	1(50.0)
2=Moderate[5]	5(29.4)	0	0	0	5(29.4)	0	0	1(33.3)	1(50.0)
3=Severe[5]	0	0	0	0	0	0	0	0	0
Missing[4]	27(61.4)	1(100)	0	1(100)	25(59.5)	7(63.6)	3(75.0)	7(70.0)	9(81.8)
At enrollment									
Nonmissing[4]	24(54.5)	0	0	1(100)	23(54.8)	8(72.7)	1(25.0)	3(30.0)	6(54.5)
0=None[5]	6(25.0)	0	0	0	6(26.1)	3(37.5)	1(100)	2(66.7)	2(33.3)
1=Mild[5]	11(45.8)	0	0	0	11(47.8)	3(37.5)	0	1(33.3)	4(66.7)
2=Moderate[5]	6(25.0)	0	0	0	6(26.1)	2(25.0)	0	0	0
3=Severe[5]	1(4.2)	0	0	1(100)	0	0	0	0	0
Missing[4]	20(45.5)	1(100)	0	0	19(45.2)	3(27.3)	3(75.0)	7(70.0)	5(45.5)

Note: See footnotes on Page 1.
BEL114256 Final Analysis: Generated: 16FEB2023 17:07

Protocol: BEL114256
Population: All Registry Participants

Table 11.3
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Disease Severity (PGA)	Total[1] (N=44) n(%)	SAB (N=1) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births (N=42) n(%)	Preterm (N=11) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=10) n(%)	Birth Defects (N=11) n(%)
At end of second trimester[6]									
Nonmissing[4]	17(38.6)	0	0	0	17(40.5)	6(54.5)	1(25.0)	2(20.0)	5(45.5)
0=None[5]	5(29.4)	0	0	0	5(29.4)	2(33.3)	1(100)	1(50.0)	1(20.0)
1=Mild[5]	10(58.8)	0	0	0	10(58.8)	3(50.0)	0	1(50.0)	3(60.0)
2=Moderate[5]	2(11.8)	0	0	0	2(11.8)	1(16.7)	0	0	1(20.0)
3=Severe[5]	0	0	0	0	0	0	0	0	0
Missing[4]	27(61.4)	1(100)	0	1(100)	25(59.5)	5(45.5)	3(75.0)	8(80.0)	6(54.5)
At outcome									
Nonmissing[4]	13(29.5)	0	0	0	13(31.0)	3(27.3)	1(25.0)	3(30.0)	4(36.4)
0=None[5]	7(53.8)	0	0	0	7(53.8)	1(33.3)	1(100)	3(100)	3(75.0)
1=Mild[5]	3(23.1)	0	0	0	3(23.1)	1(33.3)	0	0	1(25.0)
2=Moderate[5]	2(15.4)	0	0	0	2(15.4)	1(33.3)	0	0	0
3=Severe[5]	1(7.7)	0	0	0	1(7.7)	0	0	0	0
Missing[4]	31(70.5)	1(100)	0	1(100)	29(69.0)	8(72.7)	3(75.0)	7(70.0)	7(63.6)

Note: See footnotes on Page 1.
BEL114256 Final Analysis: Generated: 16FEB2023 17:07

Protocol: BEL114256
Population: All Registry Participants

Table 11.4
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Note: Multiple gestations may be reported by a participant. Therefore N includes all reported outcomes. PGA=physician global assessment; SGA=small for gestational age; SAB=Spontaneous Miscarriages.
Reports of pregnancy in which the pregnancy outcome or anticipated outcome is already known before enrollment can be biased toward the reporting of more unusual or severe cases compared to women whose pregnancy outcome is not yet known at the time of enrollment into the pregnancy registry. Therefore, rates of outcomes cannot be calculated from these data. However, a series of reported birth defects can be evaluated to detect patterns of specific birth defects and can assist with identification of potential early signals of therapy risks.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births. Preterm, SGA, and birth defects are all subsets of live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Denominator is N for each outcome.
[5]Denominator is the number of non-missing responses at each timepoint.
[6]Second trimester begins at week $14^{0/7}$ after the date of conception to week $28^{0/7}$.

Protocol: BEL114256
Population: All Registry Participants

Table 11.4
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Disease Severity (PGA)	Total[1] (N=11) n(%)	SAB (N=4) n(%)	Elective terms (N=2) n(%)	Still-births (N=0) n(%)	Live Births (N=5) n(%)	Preterm (N=2) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=0) n(%)	Birth Defects (N=0) n(%)
Preconception									
Nonmissing[4]	5(45.5)	3(75.0)	1(50.0)	0	1(20.0)	0	0	0	0
0=None[5]	2(40.0)	1(33.3)	0	0	1(100)	0	0	0	0
1=Mild[5]	2(40.0)	1(33.3)	1(100)	0	0	0	0	0	0
2=Moderate[5]	1(20.0)	1(33.3)	0	0	0	0	0	0	0
3=Severe[5]	0	0	0	0	0	0	0	0	0
Missing[4]	6(54.5)	1(25.0)	1(50.0)	0	4(80.0)	2(100)	0	0	0
At enrollment									
Nonmissing[4]	3(27.3)	1(25.0)	1(50.0)	0	1(20.0)	0	0	0	0
0=None[5]	1(33.3)	0	0	0	1(100)	0	0	0	0
1=Mild[5]	2(66.7)	1(100)	1(100)	0	0	0	0	0	0
2=Moderate[5]	0	0	0	0	0	0	0	0	0
3=Severe[5]	0	0	0	0	0	0	0	0	0
Missing[4]	8(72.7)	3(75.0)	1(50.0)	0	4(80.0)	2(100)	0	0	0

Note: See footnotes on Page 1.
BEL114256 Final Analysis: Generated: 16FEB2023 17:08

Protocol: BEL114256
Population: All Registry Participants

Table 11.4
Disease Severity of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Disease Severity (PGA)	Total[1] (N=11) n(%)	SAB (N=4) n(%)	Elective terms (N=2) n(%)	Still-births (N=0) n(%)	Live Births (N=5) n(%)	Preterm (N=2) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=0) n(%)	Birth Defects (N=0) n(%)
At end of second trimester[6]									
Nonmissing[4]	0	0	0	0	0	0	0	0	0
0=None[5]	0	0	0	0	0	0	0	0	0
1=Mild[5]	0	0	0	0	0	0	0	0	0
2=Moderate[5]	0	0	0	0	0	0	0	0	0
3=Severe[5]	0	0	0	0	0	0	0	0	0
Missing[4]	11(100)	4(100)	2(100)	0	5(100)	2(100)	0	0	0
At outcome									
Nonmissing[4]	1(9.1)	1(25.0)	0	0	0	0	0	0	0
0=None[5]	0	0	0	0	0	0	0	0	0
1=Mild[5]	1(100)	1(100)	0	0	0	0	0	0	0
2=Moderate[5]	0	0	0	0	0	0	0	0	0
3=Severe[5]	0	0	0	0	0	0	0	0	0
Missing[4]	10(90.9)	3(75.0)	2(100)	0	5(100)	2(100)	0	0	0

Note: See footnotes on Page 1.
BEL114256 Final Analysis: Generated: 16FEB2023 17:08

Protocol: BEL114256
Population: All Registry Participants

Table 12.0
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.
SAB=Spontaneous Miscarriages.

Protocol: BEL114256
Population: All Registry Participants

Table 12.0
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Comorbidities	Total[1,4] (N=72) n(%)	SAB[4] (N=7) n(%)	Elective terms (N=2) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=63) n(%)	Preterm [4] (N=19) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Chronic Renal Failure	1(1.4)	0	0	0	1(1.6)	0	0	0	0
Preconception	1(1.4)	0	0	0	1(1.6)	0	0	0	0
1st Trimester	1(1.4)	0	0	0	1(1.6)	0	0	0	0
2nd Trimester	1(1.4)	0	0	0	1(1.6)	0	0	0	0
3rd Trimester	1(1.4)	0	0	0	1(1.6)	0	0	0	0
Restrictive Lung Disease	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Severe Lupus Flare requiring pulse-steroids	13(18.1)	0	1(50.0)	1(100)	11(17.5)	3(15.8)	0	1(8.3)	2(16.7)
Preconception	11(15.3)	0	1(50.0)	0	10(15.9)	3(15.8)	0	1(8.3)	2(16.7)
1st Trimester	11(15.3)	0	1(50.0)	0	10(15.9)	3(15.8)	0	1(8.3)	2(16.7)
2nd Trimester	12(16.7)	0	1(50.0)	1(100)	10(15.9)	3(15.8)	0	1(8.3)	2(16.7)
3rd Trimester	11(15.3)	0	1(50.0)	0	10(15.9)	3(15.8)	0	1(8.3)	2(16.7)

Note: See footnotes on Page 1.
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BEL114256 Final Analysis: Generated: 16FEB2023 17:09

Protocol: BEL114256
Population: All Registry Participants

Table 12.0
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Comorbidities	Total[1,4] (N=72) n(%)	SAB[4] (N=7) n(%)	Elective terms (N=2) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=63) n(%)	Preterm [4] (N=19) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Hypertensive-Hypertension	12(16.7)	1(14.3)	1(50.0)	1(100)	9(14.3)	0	2(50.0)	2(16.7)	1(8.3)
Preconception	11(15.3)	1(14.3)	1(50.0)	1(100)	8(12.7)	0	1(25.0)	1(8.3)	0
1st Trimester	11(15.3)	1(14.3)	1(50.0)	1(100)	8(12.7)	0	2(50.0)	2(16.7)	1(8.3)
2nd Trimester	11(15.3)	1(14.3)	1(50.0)	1(100)	8(12.7)	0	1(25.0)	1(8.3)	1(8.3)
3rd Trimester	11(15.3)	1(14.3)	1(50.0)	1(100)	8(12.7)	0	1(25.0)	1(8.3)	1(8.3)
Hypertensive- Gest Hypertension	1(1.4)	0	0	0	1(1.6)	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	1(1.4)	0	0	0	1(1.6)	0	0	0	0
Diabetes Type I	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 12.0
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Comorbidities	Total[1,4] (N=72) n(%)	SAB[4] (N=7) n(%)	Elective terms (N=2) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=63) n(%)	Preterm [4] (N=19) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Diabetes Type 2	2(2.8)	0	0	0	2(3.2)	0	0	0	0
Preconception	2(2.8)	0	0	0	2(3.2)	0	0	0	0
1st Trimester	2(2.8)	0	0	0	2(3.2)	0	0	0	0
2nd Trimester	2(2.8)	0	0	0	2(3.2)	0	0	0	0
3rd Trimester	2(2.8)	0	0	0	2(3.2)	0	0	0	0
Gestational diabetes mellitus	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Hyperthyroidism	1(1.4)	0	0	0	1(1.6)	1(5.3)	0	0	0
Preconception	1(1.4)	0	0	0	1(1.6)	1(5.3)	0	0	0
1st Trimester	1(1.4)	0	0	0	1(1.6)	1(5.3)	0	0	0
2nd Trimester	1(1.4)	0	0	0	1(1.6)	1(5.3)	0	0	0
3rd Trimester	1(1.4)	0	0	0	1(1.6)	1(5.3)	0	0	0

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Protocol: BEL114256
Population: All Registry Participants

Table 12.0
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Comorbidities	Total[1,4] (N=72) n(%)	SAB[4] (N=7) n(%)	Elective terms (N=2) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=63) n(%)	Preterm [4] (N=19) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Hypothyroidism	10(13.9)	2(28.6)	0	0	8(12.7)	1(5.3)	0	0	1(8.3)
Preconception	10(13.9)	2(28.6)	0	0	8(12.7)	1(5.3)	0	0	1(8.3)
1st Trimester	10(13.9)	2(28.6)	0	0	8(12.7)	1(5.3)	0	0	1(8.3)
2nd Trimester	10(13.9)	2(28.6)	0	0	8(12.7)	1(5.3)	0	0	1(8.3)
3rd Trimester	10(13.9)	2(28.6)	0	0	8(12.7)	1(5.3)	0	0	1(8.3)
Thrombocytopenia	6(8.3)	0	0	0	6(9.5)	1(5.3)	0	1(8.3)	3(25.0)
Preconception	5(6.9)	0	0	0	5(7.9)	0	0	1(8.3)	2(16.7)
1st Trimester	5(6.9)	0	0	0	5(7.9)	0	0	1(8.3)	2(16.7)
2nd Trimester	6(8.3)	0	0	0	6(9.5)	1(5.3)	0	1(8.3)	3(25.0)
3rd Trimester	6(8.3)	0	0	0	6(9.5)	1(5.3)	0	1(8.3)	3(25.0)
Thrombotic event(s)	3(4.2)	0	0	0	3(4.8)	2(10.5)	0	0	1(8.3)
Preconception	3(4.2)	0	0	0	3(4.8)	2(10.5)	0	0	1(8.3)
1st Trimester	3(4.2)	0	0	0	3(4.8)	2(10.5)	0	0	1(8.3)
2nd Trimester	3(4.2)	0	0	0	3(4.8)	2(10.5)	0	0	1(8.3)
3rd Trimester	3(4.2)	0	0	0	3(4.8)	2(10.5)	0	0	1(8.3)

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Protocol: BEL114256
Population: All Registry Participants

Table 12.0
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Comorbidities	Total[1,4] (N=72) n(%)	SAB[4] (N=7) n(%)	Elective terms (N=2) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=63) n(%)	Preterm [4] (N=19) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Pre-eclampsia	4(5.6)	1(14.3)	0	0	4(6.3)	4(21.1)	0	0	1(8.3)
Preconception	1(1.4)	0	0	0	1(1.6)	1(5.3)	0	0	0
1st Trimester	1(1.4)	0	0	0	1(1.6)	1(5.3)	0	0	0
2nd Trimester	1(1.4)	0	0	0	1(1.6)	1(5.3)	0	0	0
3rd Trimester	4(5.6)	1(14.3)	0	0	4(6.3)	4(21.1)	0	0	1(8.3)
Placental Abruption	2(2.8)	0	0	0	2(3.2)	2(10.5)	0	0	1(8.3)
Preconception	1(1.4)	0	0	0	1(1.6)	1(5.3)	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	2(2.8)	0	0	0	2(3.2)	2(10.5)	0	0	1(8.3)
Eclampsia	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

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Protocol: BEL114256
Population: All Registry Participants

Table 12.0
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Comorbidities	Total[1,4] (N=72) n(%)	SAB[4] (N=7) n(%)	Elective terms (N=2) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=63) n(%)	Preterm [4] (N=19) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Chorioamnionitis	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Neurological Manifestation of Lupus (i.e., psychosis, seizures)	3(4.2)	0	0	0	3(4.8)	0	0	0	1(8.3)
Preconception	3(4.2)	0	0	0	3(4.8)	0	0	0	1(8.3)
1st Trimester	3(4.2)	0	0	0	3(4.8)	0	0	0	1(8.3)
2nd Trimester	3(4.2)	0	0	0	3(4.8)	0	0	0	1(8.3)
3rd Trimester	3(4.2)	0	0	0	3(4.8)	0	0	0	1(8.3)

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Protocol: BEL114256
Population: All Registry Participants

Table 12.1
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.
SAB=Spontaneous Miscarriages.

Protocol: BEL114256
Population: All Registry Participants

Table 12.1
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Comorbidities	Total[1,4] (N=61) n(%)	SAB[4] (N=3) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=58) n(%)	Preterm [4] (N=17) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Chronic Renal Failure	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Restrictive Lung Disease	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Severe Lupus Flare requiring pulse-steroids	12(19.7)	0	0	1(100)	11(19.0)	3(17.6)	0	1(8.3)	2(16.7)
Preconception	10(16.4)	0	0	0	10(17.2)	3(17.6)	0	1(8.3)	2(16.7)
1st Trimester	10(16.4)	0	0	0	10(17.2)	3(17.6)	0	1(8.3)	2(16.7)
2nd Trimester	11(18.0)	0	0	1(100)	10(17.2)	3(17.6)	0	1(8.3)	2(16.7)
3rd Trimester	10(16.4)	0	0	0	10(17.2)	3(17.6)	0	1(8.3)	2(16.7)

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Population: All Registry Participants

Table 12.1
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Comorbidities	Total[1,4] (N=61) n(%)	SAB[4] (N=3) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=58) n(%)	Preterm [4] (N=17) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Hypertensive-Hypertension	11(18.0)	1(33.3)	0	1(100)	9(15.5)	0	2(50.0)	2(16.7)	1(8.3)
Preconception	10(16.4)	1(33.3)	0	1(100)	8(13.8)	0	1(25.0)	1(8.3)	0
1st Trimester	10(16.4)	1(33.3)	0	1(100)	8(13.8)	0	2(50.0)	2(16.7)	1(8.3)
2nd Trimester	10(16.4)	1(33.3)	0	1(100)	8(13.8)	0	1(25.0)	1(8.3)	1(8.3)
3rd Trimester	10(16.4)	1(33.3)	0	1(100)	8(13.8)	0	1(25.0)	1(8.3)	1(8.3)
Hypertensive- Gest Hypertension	1(1.6)	0	0	0	1(1.7)	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	1(1.6)	0	0	0	1(1.7)	0	0	0	0
Diabetes Type I	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

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Table 12.1
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Comorbidities	Total[1,4] (N=61) n(%)	SAB[4] (N=3) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=58) n(%)	Preterm [4] (N=17) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Diabetes Type 2	2(3.3)	0	0	0	2(3.4)	0	0	0	0
Preconception	2(3.3)	0	0	0	2(3.4)	0	0	0	0
1st Trimester	2(3.3)	0	0	0	2(3.4)	0	0	0	0
2nd Trimester	2(3.3)	0	0	0	2(3.4)	0	0	0	0
3rd Trimester	2(3.3)	0	0	0	2(3.4)	0	0	0	0
Gestational diabetes mellitus	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Hyperthyroidism	1(1.6)	0	0	0	1(1.7)	1(5.9)	0	0	0
Preconception	1(1.6)	0	0	0	1(1.7)	1(5.9)	0	0	0
1st Trimester	1(1.6)	0	0	0	1(1.7)	1(5.9)	0	0	0
2nd Trimester	1(1.6)	0	0	0	1(1.7)	1(5.9)	0	0	0
3rd Trimester	1(1.6)	0	0	0	1(1.7)	1(5.9)	0	0	0

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Table 12.1
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Comorbidities	Total[1,4] (N=61) n(%)	SAB[4] (N=3) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=58) n(%)	Preterm [4] (N=17) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Hypothyroidism	9(14.8)	1(33.3)	0	0	8(13.8)	1(5.9)	0	0	1(8.3)
Preconception	9(14.8)	1(33.3)	0	0	8(13.8)	1(5.9)	0	0	1(8.3)
1st Trimester	9(14.8)	1(33.3)	0	0	8(13.8)	1(5.9)	0	0	1(8.3)
2nd Trimester	9(14.8)	1(33.3)	0	0	8(13.8)	1(5.9)	0	0	1(8.3)
3rd Trimester	9(14.8)	1(33.3)	0	0	8(13.8)	1(5.9)	0	0	1(8.3)
Thrombocytopenia	6(9.8)	0	0	0	6(10.3)	1(5.9)	0	1(8.3)	3(25.0)
Preconception	5(8.2)	0	0	0	5(8.6)	0	0	1(8.3)	2(16.7)
1st Trimester	5(8.2)	0	0	0	5(8.6)	0	0	1(8.3)	2(16.7)
2nd Trimester	6(9.8)	0	0	0	6(10.3)	1(5.9)	0	1(8.3)	3(25.0)
3rd Trimester	6(9.8)	0	0	0	6(10.3)	1(5.9)	0	1(8.3)	3(25.0)
Thrombotic event(s)	3(4.9)	0	0	0	3(5.2)	2(11.8)	0	0	1(8.3)
Preconception	3(4.9)	0	0	0	3(5.2)	2(11.8)	0	0	1(8.3)
1st Trimester	3(4.9)	0	0	0	3(5.2)	2(11.8)	0	0	1(8.3)
2nd Trimester	3(4.9)	0	0	0	3(5.2)	2(11.8)	0	0	1(8.3)
3rd Trimester	3(4.9)	0	0	0	3(5.2)	2(11.8)	0	0	1(8.3)

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Table 12.1
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Comorbidities	Total[1,4] (N=61) n(%)	SAB[4] (N=3) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=58) n(%)	Preterm [4] (N=17) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Pre-eclampsia	3(4.9)	1(33.3)	0	0	3(5.2)	3(17.6)	0	0	1(8.3)
Preconception	1(1.6)	0	0	0	1(1.7)	1(5.9)	0	0	0
1st Trimester	1(1.6)	0	0	0	1(1.7)	1(5.9)	0	0	0
2nd Trimester	1(1.6)	0	0	0	1(1.7)	1(5.9)	0	0	0
3rd Trimester	3(4.9)	1(33.3)	0	0	3(5.2)	3(17.6)	0	0	1(8.3)
Placental Abruption	2(3.3)	0	0	0	2(3.4)	2(11.8)	0	0	1(8.3)
Preconception	1(1.6)	0	0	0	1(1.7)	1(5.9)	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	2(3.3)	0	0	0	2(3.4)	2(11.8)	0	0	1(8.3)
Eclampsia	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

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Population: All Registry Participants

Table 12.1
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Comorbidities	Total[1,4] (N=61) n(%)	SAB[4] (N=3) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births[4] (N=58) n(%)	Preterm [4] (N=17) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=12) n(%)	Birth Defects (N=12) n(%)
Chorioamnionitis	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Neurological Manifestation of Lupus (i.e., psychosis, seizures)	3(4.9)	0	0	0	3(5.2)	0	0	0	1(8.3)
Preconception	3(4.9)	0	0	0	3(5.2)	0	0	0	1(8.3)
1st Trimester	3(4.9)	0	0	0	3(5.2)	0	0	0	1(8.3)
2nd Trimester	3(4.9)	0	0	0	3(5.2)	0	0	0	1(8.3)
3rd Trimester	3(4.9)	0	0	0	3(5.2)	0	0	0	1(8.3)

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Protocol: BEL114256
Population: All Registry Participants

Table 12.2
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.
SAB=Spontaneous Miscarriages.

Protocol: BEL114256
Population: All Registry Participants

Table 12.2
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Comorbidities	Total[1,4] (N=17) n(%)	SAB[4] (N=2) n(%)	Elective terms (N=0) n(%)	Still-births (N=0) n(%)	Live Births[4] (N=16) n(%)	Preterm [4] (N=6) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=2) n(%)	Birth Defects (N=1) n(%)
Chronic Renal Failure	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Restrictive Lung Disease	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Severe Lupus Flare requiring pulse-steroids	2(11.8)	0	0	0	2(12.5)	0	0	0	0
Preconception	1(5.9)	0	0	0	1(6.3)	0	0	0	0
1st Trimester	1(5.9)	0	0	0	1(6.3)	0	0	0	0
2nd Trimester	1(5.9)	0	0	0	1(6.3)	0	0	0	0
3rd Trimester	1(5.9)	0	0	0	1(6.3)	0	0	0	0

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Protocol: BEL114256
Population: All Registry Participants

Table 12.2
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Comorbidities	Total[1,4] (N=17) n(%)	SAB[4] (N=2) n(%)	Elective terms (N=0) n(%)	Still-births (N=0) n(%)	Live Births[4] (N=16) n(%)	Preterm [4] (N=6) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=2) n(%)	Birth Defects (N=1) n(%)
Hypertensive-	3(17.6)	1(50.0)	0	0	2(12.5)	0	0	0	0
Hypertension									
Preconception	3(17.6)	1(50.0)	0	0	2(12.5)	0	0	0	0
1st Trimester	3(17.6)	1(50.0)	0	0	2(12.5)	0	0	0	0
2nd Trimester	3(17.6)	1(50.0)	0	0	2(12.5)	0	0	0	0
3rd Trimester	3(17.6)	1(50.0)	0	0	2(12.5)	0	0	0	0
Hypertensive- Gest	0	0	0	0	0	0	0	0	0
Hypertension									
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Diabetes Type I	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

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Population: All Registry Participants

Table 12.2
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Comorbidities	Total[1,4] (N=17) n(%)	SAB[4] (N=2) n(%)	Elective terms (N=0) n(%)	Still-births (N=0) n(%)	Live Births[4] (N=16) n(%)	Preterm [4] (N=6) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=2) n(%)	Birth Defects (N=1) n(%)
Diabetes Type 2	1(5.9)	0	0	0	1(6.3)	0	0	0	0
Preconception	1(5.9)	0	0	0	1(6.3)	0	0	0	0
1st Trimester	1(5.9)	0	0	0	1(6.3)	0	0	0	0
2nd Trimester	1(5.9)	0	0	0	1(6.3)	0	0	0	0
3rd Trimester	1(5.9)	0	0	0	1(6.3)	0	0	0	0
Gestational diabetes mellitus	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Hyperthyroidism	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

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Population: All Registry Participants

Table 12.2
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Comorbidities	Total[1,4] (N=17) n(%)	SAB[4] (N=2) n(%)	Elective terms (N=0) n(%)	Still-births (N=0) n(%)	Live Births[4] (N=16) n(%)	Preterm [4] (N=6) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=2) n(%)	Birth Defects (N=1) n(%)
Hypothyroidism	2(11.8)	0	0	0	2(12.5)	0	0	0	0
Preconception	2(11.8)	0	0	0	2(12.5)	0	0	0	0
1st Trimester	2(11.8)	0	0	0	2(12.5)	0	0	0	0
2nd Trimester	2(11.8)	0	0	0	2(12.5)	0	0	0	0
3rd Trimester	2(11.8)	0	0	0	2(12.5)	0	0	0	0
Thrombocytopenia	1(5.9)	0	0	0	1(6.3)	0	0	0	0
Preconception	1(5.9)	0	0	0	1(6.3)	0	0	0	0
1st Trimester	1(5.9)	0	0	0	1(6.3)	0	0	0	0
2nd Trimester	1(5.9)	0	0	0	1(6.3)	0	0	0	0
3rd Trimester	1(5.9)	0	0	0	1(6.3)	0	0	0	0
Thrombotic event(s)	1(5.9)	0	0	0	1(6.3)	1(16.7)	0	0	0
Preconception	1(5.9)	0	0	0	1(6.3)	1(16.7)	0	0	0
1st Trimester	1(5.9)	0	0	0	1(6.3)	1(16.7)	0	0	0
2nd Trimester	1(5.9)	0	0	0	1(6.3)	1(16.7)	0	0	0
3rd Trimester	1(5.9)	0	0	0	1(6.3)	1(16.7)	0	0	0

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Population: All Registry Participants

Table 12.2
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Comorbidities	Total[1,4] (N=17) n(%)	SAB[4] (N=2) n(%)	Elective terms (N=0) n(%)	Still-births (N=0) n(%)	Live Births[4] (N=16) n(%)	Preterm [4] (N=6) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=2) n(%)	Birth Defects (N=1) n(%)
Pre-eclampsia	2(11.8)	1(50.0)	0	0	2(12.5)	2(33.3)	0	0	0
Preconception	1(5.9)	0	0	0	1(6.3)	1(16.7)	0	0	0
1st Trimester	1(5.9)	0	0	0	1(6.3)	1(16.7)	0	0	0
2nd Trimester	1(5.9)	0	0	0	1(6.3)	1(16.7)	0	0	0
3rd Trimester	2(11.8)	1(50.0)	0	0	2(12.5)	2(33.3)	0	0	0
Placental Abruption	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Eclampsia	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

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Population: All Registry Participants

Table 12.2
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Comorbidities	Total[1,4] (N=17) n(%)	SAB[4] (N=2) n(%)	Elective terms (N=0) n(%)	Still-births (N=0) n(%)	Live Births[4] (N=16) n(%)	Preterm [4] (N=6) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=2) n(%)	Birth Defects (N=1) n(%)
Chorioamnionitis	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Neurological Manifestation of Lupus (i.e., psychosis, seizures)	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

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Population: All Registry Participants

Table 12.3
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
SAB=Spontaneous Miscarriages.

Protocol: BEL114256
Population: All Registry Participants

Table 12.3
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Comorbidities	Total[1] (N=44) n(%)	SAB (N=1) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births (N=42) n(%)	Preterm (N=11) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=10) n(%)	Birth Defects (N=11) n(%)
Chronic Renal Failure	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Restrictive Lung Disease	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Severe Lupus Flare requiring pulse-steroids	10(22.7)	0	0	1(100)	9(21.4)	3(27.3)	0	1(10.0)	2(18.2)
Preconception	9(20.5)	0	0	0	9(21.4)	3(27.3)	0	1(10.0)	2(18.2)
1st Trimester	9(20.5)	0	0	0	9(21.4)	3(27.3)	0	1(10.0)	2(18.2)
2nd Trimester	10(22.7)	0	0	1(100)	9(21.4)	3(27.3)	0	1(10.0)	2(18.2)
3rd Trimester	9(20.5)	0	0	0	9(21.4)	3(27.3)	0	1(10.0)	2(18.2)

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Population: All Registry Participants

Table 12.3
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Comorbidities	Total[1] (N=44) n(%)	SAB (N=1) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births (N=42) n(%)	Preterm (N=11) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=10) n(%)	Birth Defects (N=11) n(%)
Hypertensive-	8(18.2)	0	0	1(100)	7(16.7)	0	2(50.0)	2(20.0)	1(9.1)
Hypertension									
Preconception	7(15.9)	0	0	1(100)	6(14.3)	0	1(25.0)	1(10.0)	0
1st Trimester	7(15.9)	0	0	1(100)	6(14.3)	0	2(50.0)	2(20.0)	1(9.1)
2nd Trimester	7(15.9)	0	0	1(100)	6(14.3)	0	1(25.0)	1(10.0)	1(9.1)
3rd Trimester	7(15.9)	0	0	1(100)	6(14.3)	0	1(25.0)	1(10.0)	1(9.1)
Hypertensive- Gest	1(2.3)	0	0	0	1(2.4)	0	0	0	0
Hypertension									
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	1(2.3)	0	0	0	1(2.4)	0	0	0	0
Diabetes Type I	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

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Population: All Registry Participants

Table 12.3
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Comorbidities	Total[1] (N=44) n(%)	SAB (N=1) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births (N=42) n(%)	Preterm (N=11) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=10) n(%)	Birth Defects (N=11) n(%)
Diabetes Type 2	1(2.3)	0	0	0	1(2.4)	0	0	0	0
Preconception	1(2.3)	0	0	0	1(2.4)	0	0	0	0
1st Trimester	1(2.3)	0	0	0	1(2.4)	0	0	0	0
2nd Trimester	1(2.3)	0	0	0	1(2.4)	0	0	0	0
3rd Trimester	1(2.3)	0	0	0	1(2.4)	0	0	0	0
Gestational diabetes mellitus	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Hyperthyroidism	1(2.3)	0	0	0	1(2.4)	1(9.1)	0	0	0
Preconception	1(2.3)	0	0	0	1(2.4)	1(9.1)	0	0	0
1st Trimester	1(2.3)	0	0	0	1(2.4)	1(9.1)	0	0	0
2nd Trimester	1(2.3)	0	0	0	1(2.4)	1(9.1)	0	0	0
3rd Trimester	1(2.3)	0	0	0	1(2.4)	1(9.1)	0	0	0

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Table 12.3
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Comorbidities	Total[1] (N=44) n(%)	SAB (N=1) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births (N=42) n(%)	Preterm (N=11) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=10) n(%)	Birth Defects (N=11) n(%)
Hypothyroidism	7(15.9)	1(100)	0	0	6(14.3)	1(9.1)	0	0	1(9.1)
Preconception	7(15.9)	1(100)	0	0	6(14.3)	1(9.1)	0	0	1(9.1)
1st Trimester	7(15.9)	1(100)	0	0	6(14.3)	1(9.1)	0	0	1(9.1)
2nd Trimester	7(15.9)	1(100)	0	0	6(14.3)	1(9.1)	0	0	1(9.1)
3rd Trimester	7(15.9)	1(100)	0	0	6(14.3)	1(9.1)	0	0	1(9.1)
Thrombocytopenia	5(11.4)	0	0	0	5(11.9)	1(9.1)	0	1(10.0)	3(27.3)
Preconception	4(9.1)	0	0	0	4(9.5)	0	0	1(10.0)	2(18.2)
1st Trimester	4(9.1)	0	0	0	4(9.5)	0	0	1(10.0)	2(18.2)
2nd Trimester	5(11.4)	0	0	0	5(11.9)	1(9.1)	0	1(10.0)	3(27.3)
3rd Trimester	5(11.4)	0	0	0	5(11.9)	1(9.1)	0	1(10.0)	3(27.3)
Thrombotic event(s)	2(4.5)	0	0	0	2(4.8)	1(9.1)	0	0	1(9.1)
Preconception	2(4.5)	0	0	0	2(4.8)	1(9.1)	0	0	1(9.1)
1st Trimester	2(4.5)	0	0	0	2(4.8)	1(9.1)	0	0	1(9.1)
2nd Trimester	2(4.5)	0	0	0	2(4.8)	1(9.1)	0	0	1(9.1)
3rd Trimester	2(4.5)	0	0	0	2(4.8)	1(9.1)	0	0	1(9.1)

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Population: All Registry Participants

Table 12.3
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Comorbidities	Total[1] (N=44) n(%)	SAB (N=1) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births (N=42) n(%)	Preterm (N=11) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=10) n(%)	Birth Defects (N=11) n(%)
Pre-eclampsia	1(2.3)	0	0	0	1(2.4)	1(9.1)	0	0	1(9.1)
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	1(2.3)	0	0	0	1(2.4)	1(9.1)	0	0	1(9.1)
Placental Abruption	2(4.5)	0	0	0	2(4.8)	2(18.2)	0	0	1(9.1)
Preconception	1(2.3)	0	0	0	1(2.4)	1(9.1)	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	2(4.5)	0	0	0	2(4.8)	2(18.2)	0	0	1(9.1)
Eclampsia	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

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Table 12.3
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Comorbidities	Total[1] (N=44) n(%)	SAB (N=1) n(%)	Elective terms (N=0) n(%)	Still-births (N=1) n(%)	Live Births (N=42) n(%)	Preterm (N=11) n(%)	SGA[2] (N=4) n(%)	SGA[3] (N=10) n(%)	Birth Defects (N=11) n(%)
Chorioamnionitis	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Neurological Manifestation of Lupus (i.e., psychosis, seizures)	3(6.8)	0	0	0	3(7.1)	0	0	0	1(9.1)
Preconception	3(6.8)	0	0	0	3(7.1)	0	0	0	1(9.1)
1st Trimester	3(6.8)	0	0	0	3(7.1)	0	0	0	1(9.1)
2nd Trimester	3(6.8)	0	0	0	3(7.1)	0	0	0	1(9.1)
3rd Trimester	3(6.8)	0	0	0	3(7.1)	0	0	0	1(9.1)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 12.4
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Note: Reports of pregnancy in which the pregnancy outcome or anticipated outcome is already known before enrollment can be biased toward the reporting of more unusual or severe cases compared to women whose pregnancy outcome is not yet known at the time of enrollment into the pregnancy registry. Therefore, rates of outcomes cannot be calculated from these data. However, a series of reported birth defects can be evaluated to detect patterns of specific birth defects and can assist with identification of potential early signals of therapy risks.
[1]Total includes spontaneous miscarriages, stillbirths, elective terminations, and live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
SAB=Spontaneous Miscarriages.
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].

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Protocol: BEL114256
Population: All Registry Participants

Table 12.4
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Comorbidities	Total[1] (N=11) n(%)	SAB (N=4) n(%)	Elective terms (N=2) n(%)	Still-births (N=0) n(%)	Live Births (N=5) n(%)	Preterm (N=2) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=0) n(%)	Birth Defects (N=0) n(%)
Chronic Renal Failure	1(9.1)	0	0	0	1(20.0)	0	0	0	0
Preconception	1(9.1)	0	0	0	1(20.0)	0	0	0	0
1st Trimester	1(9.1)	0	0	0	1(20.0)	0	0	0	0
2nd Trimester	1(9.1)	0	0	0	1(20.0)	0	0	0	0
3rd Trimester	1(9.1)	0	0	0	1(20.0)	0	0	0	0
Restrictive Lung Disease	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Severe Lupus Flare requiring pulse-steroids	1(9.1)	0	1(50.0)	0	0	0	0	0	0
Preconception	1(9.1)	0	1(50.0)	0	0	0	0	0	0
1st Trimester	1(9.1)	0	1(50.0)	0	0	0	0	0	0
2nd Trimester	1(9.1)	0	1(50.0)	0	0	0	0	0	0
3rd Trimester	1(9.1)	0	1(50.0)	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 12.4
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Comorbidities	Total[1] (N=11) n(%)	SAB (N=4) n(%)	Elective terms (N=2) n(%)	Still-births (N=0) n(%)	Live Births (N=5) n(%)	Preterm (N=2) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=0) n(%)	Birth Defects (N=0) n(%)
Hypertensive-	1(9.1)	0	1(50.0)	0	0	0	0	0	0
Hypertension									
Preconception	1(9.1)	0	1(50.0)	0	0	0	0	0	0
1st Trimester	1(9.1)	0	1(50.0)	0	0	0	0	0	0
2nd Trimester	1(9.1)	0	1(50.0)	0	0	0	0	0	0
3rd Trimester	1(9.1)	0	1(50.0)	0	0	0	0	0	0
Hypertensive- Gest	0	0	0	0	0	0	0	0	0
Hypertension									
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Diabetes Type I	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 12.4
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Comorbidities	Total[1] (N=11) n(%)	SAB (N=4) n(%)	Elective terms (N=2) n(%)	Still-births (N=0) n(%)	Live Births (N=5) n(%)	Preterm (N=2) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=0) n(%)	Birth Defects (N=0) n(%)
Diabetes Type 2	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Gestational diabetes mellitus	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Hyperthyroidism	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 12.4
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Comorbidities	Total[1] (N=11) n(%)	SAB (N=4) n(%)	Elective terms (N=2) n(%)	Still-births (N=0) n(%)	Live Births (N=5) n(%)	Preterm (N=2) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=0) n(%)	Birth Defects (N=0) n(%)
Hypothyroidism	1(9.1)	1(25.0)	0	0	0	0	0	0	0
Preconception	1(9.1)	1(25.0)	0	0	0	0	0	0	0
1st Trimester	1(9.1)	1(25.0)	0	0	0	0	0	0	0
2nd Trimester	1(9.1)	1(25.0)	0	0	0	0	0	0	0
3rd Trimester	1(9.1)	1(25.0)	0	0	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Thrombotic event(s)	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

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Protocol: BEL114256
Population: All Registry Participants

Table 12.4
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Comorbidities	Total[1] (N=11) n(%)	SAB (N=4) n(%)	Elective terms (N=2) n(%)	Still-births (N=0) n(%)	Live Births (N=5) n(%)	Preterm (N=2) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=0) n(%)	Birth Defects (N=0) n(%)
Pre-eclampsia	1(9.1)	0	0	0	1(20.0)	1(50.0)	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	1(9.1)	0	0	0	1(20.0)	1(50.0)	0	0	0
Placental Abruption	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Eclampsia	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 12.4
Comorbidities of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Comorbidities	Total[1] (N=11) n(%)	SAB (N=4) n(%)	Elective terms (N=2) n(%)	Still-births (N=0) n(%)	Live Births (N=5) n(%)	Preterm (N=2) n(%)	SGA[2] (N=0) n(%)	SGA[3] (N=0) n(%)	Birth Defects (N=0) n(%)
Chorioamnionitis	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0
Neurological Manifestation of Lupus (i.e., psychosis, seizures)	0	0	0	0	0	0	0	0	0
Preconception	0	0	0	0	0	0	0	0	0
1st Trimester	0	0	0	0	0	0	0	0	0
2nd Trimester	0	0	0	0	0	0	0	0	0
3rd Trimester	0	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.0
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Note: Anti-ds=anti-double-stranded; C3=complement 3; C4=complement 4; SGA=small for gestational age; SAB = spontaneous abortion.
[1]Total includes spontaneous abortion, stillbirths, elective terminations, and live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Denominator is the number of non missing test results during pregnancy.
[5]Denominator is the number of non missing test results in preconception and/or during pregnancy.
[6]n and the summary statistics are across all serum creatinine results, and an individual subject may have contributed 0, 1, 2, or more results.
[7]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.

Protocol: BEL114256
Population: All Registry Participants

Table 13.0
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Laboratory Test	Total[1,7] (N=72)	SAB[7] (N=7)	Elective terms (N=2)	Still births (N=1)	Live Births [7] (N=63)	Preterm[7] (N=19)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Anti-ds DNA								
Number of subjects with test results during pregnancy	36	2	1	1	33	11	6	7
Number of subjects with at least one abnormal test result during pregnancy [4]	19 (52.8)	0	0	1 (100.0)	18 (54.5)	5 (45.5)	3 (50.0)	3 (42.9)
Number of subjects with test results in preconception and/or during pregnancy	52	5	1	1	46	15	6	11
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	31 (59.6)	1 (20.0)	0	1 (100.0)	29 (63.0)	7 (46.7)	4 (66.7)	5 (45.5)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.0
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Laboratory Test	Total[1,7] (N=72)	SAB[7] (N=7)	Elective terms (N=2)	Still births (N=1)	Live Births [7] (N=63)	Preterm[7] (N=19)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Complement(C3 and C4)								
Number of subjects with test results during pregnancy	3	1	0	0	2	1	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	3	1	0	0	2	1	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.0
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Laboratory Test	Total[1,7] (N=72)	SAB[7] (N=7)	Elective terms (N=2)	Still births (N=1)	Live Births [7] (N=63)	Preterm[7] (N=19)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Anti-Cardiolipin Antibodies IgG, IgA, IgM								
Number of subjects with test results during pregnancy	6	1	0	0	5	0	1	2
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	6	1	0	0	5	0	1	2
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.0
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Laboratory Test	Total[1,7] (N=72)	SAB[7] (N=7)	Elective terms (N=2)	Still births (N=1)	Live Births [7] (N=63)	Preterm[7] (N=19)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Lupus Anticoagulant								
Number of subjects with test results during pregnancy	19	1	0	0	18	6	2	4
Number of subjects with at least one abnormal test result during pregnancy [4]	2 (10.5)	0	0	0	2 (11.1)	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	34	2	0	0	32	11	5	6
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	7 (20.6)	1 (50.0)	0	0	6 (18.8)	2 (18.2)	1 (20.0)	2 (33.3)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.0
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Laboratory Test	Total[1,7] (N=72)	SAB[7] (N=7)	Elective terms (N=2)	Still births (N=1)	Live Births [7] (N=63)	Preterm[7] (N=19)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Anti-Ro (Anti-SS-A) and Anti-La (Anti-SS-B)								
Number of subjects with test results during pregnancy	3	1	0	0	2	0	1	2
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	3	1	0	0	2	0	1	2
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.0
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Laboratory Test	Total[1,7] (N=72)	SAB[7] (N=7)	Elective terms (N=2)	Still births (N=1)	Live Births [7] (N=63)	Preterm[7] (N=19)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Proteinuria								
Number of subjects with test results during pregnancy	3	1	0	0	2	0	0	1
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	3	1	0	0	2	0	0	1
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.0
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Cohort)

Laboratory Test	Total[1,7] (N=72)	SAB[7] (N=7)	Elective terms (N=2)	Still births (N=1)	Live Births [7] (N=63)	Preterm[7] (N=19)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Serum Creatinine (mg/dL) [6]								
n	93	4	2	1	86	26	9	17
Mean (SD)	0.77 (0.529)	0.90 (0.115)	0.55 (0.071)	1.00 (NA)	0.77 (0.548)	0.88 (0.915)	0.68 (0.130)	0.67 (0.145)
Median	0.70	0.90	0.55	1.00	0.60	0.75	0.60	0.70
Min - Max	0.4 - 5.3	0.8 - 1.0	0.5 - 0.6	1.0 - 1.0	0.4 - 5.3	0.4 - 5.3	0.5 - 0.9	0.5 - 1.0
Q1, Q3	0.60, 0.80	0.80, 1.00	0.50, 0.60	1.00, 1.00	0.60, 0.80	0.60, 0.80	0.60, 0.80	0.50, 0.80

Note: See footnotes on Page 1.
Source: \\wilbtib\wilbtib04\GSK GSKBEL114256\Post_Lock_2023\TLF\t_1300
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Protocol: BEL114256
Population: All Registry Participants

Table 13.1
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Note: Anti-ds=anti-double-stranded; C3=complement 3; C4=complement 4; SGA=small for gestational age; SAB = spontaneous abortion.
[1]Total includes spontaneous abortion, stillbirths, elective terminations, and live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Denominator is the number of non missing test results during pregnancy.
[5]Denominator is the number of non missing test results in preconception and/or during pregnancy.
[6]n and the summary statistics are across all serum creatinine results, and an individual subject may have contributed 0, 1, 2, or more results.
[7]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.

Protocol: BEL114256
Population: All Registry Participants

Table 13.1
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Laboratory Test	Total[1,7] (N=61)	SAB[7] (N=3)	Elective terms (N=0)	Still births (N=1)	Live Births [7] (N=58)	Preterm[7] (N=17)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Anti-ds DNA								
Number of subjects with test results during pregnancy	33	1	0	1	32	10	6	7
Number of subjects with at least one abnormal test result during pregnancy [4]	18 (54.5)	0	0	1 (100.0)	17 (53.1)	4 (40.0)	3 (50.0)	3 (42.9)
Number of subjects with test results in preconception and/or during pregnancy	46	2	0	1	44	14	6	11
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	28 (60.9)	0	0	1 (100.0)	27 (61.4)	6 (42.9)	4 (66.7)	5 (45.5)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.1
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Laboratory Test	Total[1,7] (N=61)	SAB[7] (N=3)	Elective terms (N=0)	Still births (N=1)	Live Births [7] (N=58)	Preterm[7] (N=17)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Complement(C3 and C4)								
Number of subjects with test results during pregnancy	2	0	0	0	2	1	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	2	0	0	0	2	1	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.1
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Laboratory Test	Total[1,7] (N=61)	SAB[7] (N=3)	Elective terms (N=0)	Still births (N=1)	Live Births [7] (N=58)	Preterm[7] (N=17)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Anti-Cardiolipin Antibodies IgG, IgA, IgM								
Number of subjects with test results during pregnancy	5	0	0	0	5	0	1	2
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	5	0	0	0	5	0	1	2
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.1
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Laboratory Test	Total[1,7] (N=61)	SAB[7] (N=3)	Elective terms (N=0)	Still births (N=1)	Live Births [7] (N=58)	Preterm[7] (N=17)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Lupus Anticoagulant								
Number of subjects with test results during pregnancy	18	0	0	0	18	6	2	4
Number of subjects with at least one abnormal test result during pregnancy [4]	2 (11.1)	0	0	0	2 (11.1)	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	32	0	0	0	32	11	5	6
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	6 (18.8)	0	0	0	6 (18.8)	2 (18.2)	1 (20.0)	2 (33.3)

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Population: All Registry Participants

Table 13.1
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Laboratory Test	Total[1,7] (N=61)	SAB[7] (N=3)	Elective terms (N=0)	Still births (N=1)	Live Births [7] (N=58)	Preterm[7] (N=17)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Anti-Ro (Anti-SS-A) and Anti-La (Anti-SS-B)								
Number of subjects with test results during pregnancy	2	0	0	0	2	0	1	2
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	2	0	0	0	2	0	1	2
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

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Table 13.1
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Laboratory Test	Total[1,7] (N=61)	SAB[7] (N=3)	Elective terms (N=0)	Still births (N=1)	Live Births [7] (N=58)	Preterm[7] (N=17)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Proteinuria								
Number of subjects with test results during pregnancy	2	0	0	0	2	0	0	1
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	2	0	0	0	2	0	0	1
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

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Table 13.1
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Overall Prospective Cohort)

Laboratory Test	Total[1,7] (N=61)	SAB[7] (N=3)	Elective terms (N=0)	Still births (N=1)	Live Births [7] (N=58)	Preterm[7] (N=17)	SGA[2]/ SGA[3] (N=12)	Birth Defects (N=12)
Serum Creatinine (mg/dL) [6]								
n	79	2	0	1	76	26	9	17
Mean (SD)	0.72 (0.544)	1.00 (0.000)	0	1.00 (NA)	0.71 (0.552)	0.88 (0.915)	0.68 (0.130)	0.67 (0.145)
Median	0.60	1.00	0	1.00	0.60	0.75	0.60	0.70
Min - Max	0.4 - 5.3	1.0 - 1.0	0	1.0 - 1.0	0.4 - 5.3	0.4 - 5.3	0.5 - 0.9	0.5 - 1.0
Q1, Q3	0.60, 0.80	1.00, 1.00	0	1.00, 1.00	0.55, 0.80	0.60, 0.80	0.60, 0.80	0.50, 0.80

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Protocol: BEL114256
Population: All Registry Participants

Table 13.2
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Note: Anti-ds=anti-double-stranded; C3=complement 3; C4=complement 4; SGA=small for gestational age; SAB = spontaneous abortion.
[1]Total includes spontaneous abortion, stillbirths, elective terminations, and live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Denominator is the number of non missing test results during pregnancy.
[5]Denominator is the number of non missing test results in preconception and/or during pregnancy.
[6]n and the summary statistics are across all serum creatinine results, and an individual subject may have contributed 0, 1, 2, or more results.
[7]One participant had a multiple gestational pregnancy that resulted in two different pregnancy outcomes. Thereby, each pregnancy outcome of this participant is represented in subcategories of pregnancy outcomes. This participant is counted once under Total.

Protocol: BEL114256
Population: All Registry Participants

Table 13.2
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Laboratory Test	Total[1,7] (N=17)	SAB[7] (N=2)	Elective terms (N=0)	Still births (N=0)	Live Births [7] (N=16)	Preterm[7] (N=6)	SGA[2]/ SGA[3] (N=2)	Birth Defects (N=1)
Anti-ds DNA								
Number of subjects with test results during pregnancy	9	1	0	0	9	3	1	0
Number of subjects with at least one abnormal test result during pregnancy [4]	4 (44.4)	0	0	0	4 (44.4)	1 (33.3)	1 (100.0)	0
Number of subjects with test results in preconception and/or during pregnancy	12	1	0	0	12	4	1	1
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	8 (66.7)	0	0	0	8 (66.7)	2 (50.0)	1 (100.0)	1 (100.0)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.2
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Laboratory Test	Total[1,7] (N=17)	SAB[7] (N=2)	Elective terms (N=0)	Still births (N=0)	Live Births [7] (N=16)	Preterm[7] (N=6)	SGA[2]/ SGA[3] (N=2)	Birth Defects (N=1)
Complement(C3 and C4)								
Number of subjects with test results during pregnancy	0	0	0	0	0	0	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	0	0	0	0	0	0	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

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Population: All Registry Participants

Table 13.2
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Laboratory Test	Total[1,7] (N=17)	SAB[7] (N=2)	Elective terms (N=0)	Still births (N=0)	Live Births [7] (N=16)	Preterm[7] (N=6)	SGA[2]/ SGA[3] (N=2)	Birth Defects (N=1)
Anti-Cardiolipin Antibodies IgG, IgA, IgM								
Number of subjects with test results during pregnancy	0	0	0	0	0	0	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	0	0	0	0	0	0	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 13.2
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Laboratory Test	Total[1,7] (N=17)	SAB[7] (N=2)	Elective terms (N=0)	Still births (N=0)	Live Births [7] (N=16)	Preterm[7] (N=6)	SGA[2]/ SGA[3] (N=2)	Birth Defects (N=1)
Lupus Anticoagulant								
Number of subjects with test results during pregnancy	4	0	0	0	4	1	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	1 (25.0)	0	0	0	1 (25.0)	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	8	0	0	0	8	2	1	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	1 (12.5)	0	0	0	1 (12.5)	0	0	0

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Population: All Registry Participants

Table 13.2
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Laboratory Test	Total[1,7] (N=17)	SAB[7] (N=2)	Elective terms (N=0)	Still births (N=0)	Live Births [7] (N=16)	Preterm[7] (N=6)	SGA[2]/ SGA[3] (N=2)	Birth Defects (N=1)
Anti-Ro (Anti-SS-A) and Anti-La (Anti-SS-B)								
Number of subjects with test results during pregnancy	0	0	0	0	0	0	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	0	0	0	0	0	0	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

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Table 13.2
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Laboratory Test	Total[1,7] (N=17)	SAB[7] (N=2)	Elective terms (N=0)	Still births (N=0)	Live Births [7] (N=16)	Preterm[7] (N=6)	SGA[2]/ SGA[3] (N=2)	Birth Defects (N=1)
Proteinuria								
Number of subjects with test results during pregnancy	1	0	0	0	1	0	0	1
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	1	0	0	0	1	0	0	1
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

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Table 13.2
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Pure Prospective Cohort)

Laboratory Test	Total[1,7] (N=17)	SAB[7] (N=2)	Elective terms (N=0)	Still births (N=0)	Live Births [7] (N=16)	Preterm[7] (N=6)	SGA[2]/ SGA[3] (N=2)	Birth Defects (N=1)
Serum Creatinine (mg/dL) [6]								
n	21	0	0	0	21	5	2	2
Mean (SD)	0.57 (0.101)	0	0	0	0.57 (0.101)	0.62 (0.179)	0.65 (0.071)	0.55 (0.071)
Median	0.60	0	0	0	0.60	0.60	0.65	0.55
Min - Max	0.4 - 0.8	0	0	0	0.4 - 0.8	0.4 - 0.8	0.6 - 0.7	0.5 - 0.6
Q1, Q3	0.50, 0.60	0	0	0	0.50, 0.60	0.50, 0.80	0.60, 0.70	0.50, 0.60

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Protocol: BEL114256
Population: All Registry Participants

Table 13.3
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Note: Anti-ds=anti-double-stranded; C3=complement 3; C4=complement 4; SGA=small for gestational age; SAB = spontaneous abortion.
[1]Total includes spontaneous abortion, stillbirths, elective terminations, and live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Denominator is the number of non missing test results during pregnancy.
[5]Denominator is the number of non missing test results in preconception and/or during pregnancy.
[6]n and the summary statistics are across all serum creatinine results, and an individual subject may have contributed 0, 1, 2, or more results.

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Population: All Registry Participants

Table 13.3
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Laboratory Test	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still births (N=1)	Live Births (N=42)	Preterm (N=11)	SGA[2]/ SGA[3] (N=10)	Birth Defects (N=11)
Anti-ds DNA								
Number of subjects with test results during pregnancy	24	0	0	1	23	7	5	7
Number of subjects with at least one abnormal test result during pregnancy [4]	14 (58.3)	0	0	1 (100.0)	13 (56.5)	3 (42.9)	2 (40.0)	3 (42.9)
Number of subjects with test results in preconception and/or during pregnancy	34	1	0	1	32	10	5	10
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	20 (58.8)	0	0	1 (100.0)	19 (59.4)	4 (40.0)	3 (60.0)	4 (40.0)

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.3
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Laboratory Test	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still births (N=1)	Live Births (N=42)	Preterm (N=11)	SGA[2]/ SGA[3] (N=10)	Birth Defects (N=11)
Complement(C3 and C4)								
Number of subjects with test results during pregnancy	2	0	0	0	2	1	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	2	0	0	0	2	1	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 13.3
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Laboratory Test	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still births (N=1)	Live Births (N=42)	Preterm (N=11)	SGA[2]/ SGA[3] (N=10)	Birth Defects (N=11)
Anti-Cardiolipin Antibodies IgG, IgA, IgM								
Number of subjects with test results during pregnancy	5	0	0	0	5	0	1	2
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	5	0	0	0	5	0	1	2
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 13.3
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Laboratory Test	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still births (N=1)	Live Births (N=42)	Preterm (N=11)	SGA[2]/ SGA[3] (N=10)	Birth Defects (N=11)
Lupus Anticoagulant								
Number of subjects with test results during pregnancy	14	0	0	0	14	5	2	4
Number of subjects with at least one abnormal test result during pregnancy [4]	1 (7.1)	0	0	0	1 (7.1)	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	24	0	0	0	24	9	4	6
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	5 (20.8)	0	0	0	5 (20.8)	2 (22.2)	1 (25.0)	2 (33.3)

Note: See footnotes on Page 1.
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Table 13.3
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Laboratory Test	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still births (N=1)	Live Births (N=42)	Preterm (N=11)	SGA[2]/ SGA[3] (N=10)	Birth Defects (N=11)
Anti-Ro (Anti-SS-A) and Anti-La (Anti-SS-B)								
Number of subjects with test results during pregnancy	2	0	0	0	2	0	1	2
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	2	0	0	0	2	0	1	2
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Population: All Registry Participants

Table 13.3
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Laboratory Test	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still births (N=1)	Live Births (N=42)	Preterm (N=11)	SGA[2]/ SGA[3] (N=10)	Birth Defects (N=11)
Proteinuria								
Number of subjects with test results during pregnancy	1	0	0	0	1	0	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	1	0	0	0	1	0	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Table 13.3
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Traditional Prospective Cohort)

Laboratory Test	Total[1] (N=44)	SAB (N=1)	Elective terms (N=0)	Still births (N=1)	Live Births (N=42)	Preterm (N=11)	SGA[2]/ SGA[3] (N=10)	Birth Defects (N=11)
Serum Creatinine (mg/dL) [6]								
n	58	2	0	1	55	21	7	15
Mean (SD)	0.78 (0.624)	1.00 (0.000)	0	1.00 (NA)	0.76 (0.639)	0.95 (1.009)	0.69 (0.146)	0.69 (0.146)
Median	0.70	1.00	0	1.00	0.70	0.80	0.60	0.70
Min - Max	0.4 - 5.3	1.0 - 1.0	0	1.0 - 1.0	0.4 - 5.3	0.5 - 5.3	0.5 - 0.9	0.5 - 1.0
Q1, Q3	0.60, 0.80	1.00, 1.00	0	1.00, 1.00	0.60, 0.80	0.60, 0.80	0.60, 0.80	0.50, 0.80

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.4
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Note: Anti-ds=anti-double-stranded; C3=complement 3; C4=complement 4; SGA=small for gestational age; SAB = spontaneous abortion.
[1]Total includes spontaneous abortion, stillbirths, elective terminations, and live births.
[2]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on Intergrowth-21st Project reference data [Villar].
[3]Small for gestational age is defined as live births whose birth weight lies below the 10th percentile for that gestational age based on reference data [Alexander].
[4]Denominator is the number of non missing test results during pregnancy.
[5]Denominator is the number of non missing test results in preconception and/or during pregnancy.
[6]n and the summary statistics are across all serum creatinine results, and an individual subject may have contributed 0, 1, 2, or more results.

Protocol: BEL114256
Population: All Registry Participants

Table 13.4
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Laboratory Test	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still births (N=0)	Live Births (N=5)	Preterm (N=2)	SGA[2]/ SGA[3] (N=0)	Birth Defects (N=0)
Anti-ds DNA								
Number of subjects with test results during pregnancy	3	1	1	0	1	1	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	1 (33.3)	0	0	0	1 (100.0)	1 (100.0)	0	0
Number of subjects with test results in preconception and/or during pregnancy	6	3	1	0	2	1	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	3 (50.0)	1 (33.3)	0	0	2 (100.0)	1 (100.0)	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.4
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Laboratory Test	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still births (N=0)	Live Births (N=5)	Preterm (N=2)	SGA[2]/ SGA[3] (N=0)	Birth Defects (N=0)
Complement(C3 and C4)								
Number of subjects with test results during pregnancy	1	1	0	0	0	0	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	1	1	0	0	0	0	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.4
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Laboratory Test	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still births (N=0)	Live Births (N=5)	Preterm (N=2)	SGA[2]/ SGA[3] (N=0)	Birth Defects (N=0)
Anti-Cardiolipin Antibodies IgG, IgA, IgM								
Number of subjects with test results during pregnancy	1	1	0	0	0	0	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	1	1	0	0	0	0	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Protocol: BEL114256
Population: All Registry Participants

Table 13.4
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Laboratory Test	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still births (N=0)	Live Births (N=5)	Preterm (N=2)	SGA[2]/ SGA[3] (N=0)	Birth Defects (N=0)
Lupus Anticoagulant								
Number of subjects with test results during pregnancy	1	1	0	0	0	0	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	2	2	0	0	0	0	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	1 (50.0)	1 (50.0)	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Table 13.4
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Laboratory Test	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still births (N=0)	Live Births (N=5)	Preterm (N=2)	SGA[2]/ SGA[3] (N=0)	Birth Defects (N=0)
Anti-Ro (Anti-SS-A) and Anti-La (Anti-SS-B)								
Number of subjects with test results during pregnancy	1	1	0	0	0	0	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	1	1	0	0	0	0	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Table 13.4
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Laboratory Test	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still births (N=0)	Live Births (N=5)	Preterm (N=2)	SGA[2]/ SGA[3] (N=0)	Birth Defects (N=0)
Proteinuria								
Number of subjects with test results during pregnancy	1	1	0	0	0	0	0	0
Number of subjects with at least one abnormal test result during pregnancy [4]	0	0	0	0	0	0	0	0
Number of subjects with test results in preconception and/or during pregnancy	1	1	0	0	0	0	0	0
Number of subjects with at least one abnormal test result in preconception and/or during pregnancy [5]	0	0	0	0	0	0	0	0

Note: See footnotes on Page 1.
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Table 13.4
Laboratory Results of Exposed Participants with Known Pregnancy Outcome
(Retrospective Cohort)

Laboratory Test	Total[1] (N=11)	SAB (N=4)	Elective terms (N=2)	Still births (N=0)	Live Births (N=5)	Preterm (N=2)	SGA[2]/ SGA[3] (N=0)	Birth Defects (N=0)
Serum Creatinine (mg/dL) [6]								
n	14	2	2	0	10	0	0	0
Mean (SD)	1.04 (0.334)	0.80 (0.000)	0.55 (0.071)	0	1.19 (0.264)	0	0	0
Median	1.20	0.80	0.55	0	1.25	0	0	0
Min - Max	0.5 - 1.5	0.8 - 0.8	0.5 - 0.6	0	0.5 - 1.5	0	0	0
Q1, Q3	0.80, 1.30	0.80, 0.80	0.50, 0.60	0	1.20, 1.30	0	0	0

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ANNEX 1. LIST OF STANDALONE DOCUMENTS

Number	Document reference number	Date	Title
1	2010N108011_04	17 March 2020	Belimumab (BENLYSTA) Pregnancy Registry
2	CB261CED-0259-4991-968C-844E4FB36A7C	02 November 2022	Reporting and Analysis Plan for the Belimumab Pregnancy Registry (BPR)