

Pregnancy Outcomes in Maternal Exposure to Guselkumab: Review of Cases Reported to the Company Global Safety Database

Uma Mahadevan,¹ Millie Long,² Mette Julsgaard,³ Connie Lin,⁴ Anja Geldhof,⁵ Miriam Zimmermann,⁶ Mauricio Rosas Ballina,⁷ Hewei Li,⁸ Javier P. Gisbert,⁹ Maria Chaparro⁹

¹University of California, San Francisco, San Francisco, CA, USA; ²University of North Carolina, Chapel Hill, Chapel Hill, NC, USA; ³Department of Hepatology and Gastroenterology, Aarhus University Hospital, Aarhus, Denmark; ⁴Johnson & Johnson, Horsham, PA, USA; ⁵Johnson & Johnson, Diegem, Belgium; ⁶Johnson & Johnson, Zurg, Switzerland; ⁷Johnson & Johnson, Basel, Switzerland; ⁸Johnson & Johnson, Titusville, NJ, USA; ⁹Hospital Universitario de La Princesa, Instituto de Investigación Sanitaria Princesa (IIS-Princesa), Universidad Autónoma de Madrid (UAM), and Centro de Investigación Biomédica en Red de Enfermedades Hepáticas y Digestivas (CIBEREHD), Madrid, Spain

*Presenting author



Scan the QR code. The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

P0410

Key Takeaways



These findings suggest no apparent impact of GUS on pregnancy outcomes; however, they should be interpreted cautiously given data limitations.



Further studies are warranted to confirm these observations and to better characterize the safety profile of GUS exposure during pregnancy.

The limitations of these findings include, but are not limited to, the lack of study control, a small sample size of pregnancies with known outcomes, and reported data with varying degrees of missing information.

Background



The Global Consensus Consortium statement on the management of pregnancy in inflammatory bowel disease suggests women can continue treatment with interleukin (IL)-23 inhibitors throughout pregnancy¹



Guselkumab (GUS) is a dual-acting selective p19 subunit-targeted IL-23 inhibitor that blocks IL-23 signaling and binds to CD64, a receptor on immune cells that produce IL-23²



GUS is approved to treat moderate-to-severe psoriasis (PsO), active psoriatic arthritis (PsA), and moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD)³

Objective



In this analysis, we report data on pregnancy cases with known outcomes in women exposed to GUS during pregnancy

Methods

- Pregnancy cases were reported to the Company Global Safety Database through 12 July 2025
 - Cases with known outcomes were reported from clinical studies and spontaneous sources
- Data were summarized descriptively for pregnancies reported prospectively and retrospectively
- GUS therapeutic indications in pregnancy cases were:
 - Psoriatic disease
 - CD
 - UC
 - Other/not reported

- Maternal GUS exposure was categorized as follows:
 - Before conception (within 3 months prior to conception)
 - During the first trimester (T1)
 - After the first trimester only (T2, T3)
 - Throughout pregnancy
 - Not reported

- Pregnancy outcomes were classified as:
 - Live births with or without congenital anomalies
 - Spontaneous abortions
 - Elective terminations with or without fetal defects or unknown
 - Ectopic pregnancies
 - Stillbirths with or without fetal defects
 - Unspecified abortions with or without fetal defects or unknown

Results

Figure 1. A total of 400 pregnancy events with known outcomes occurred among 396 women

- Maternal age was reported for 264/396 (67%) women, and the mean maternal age was 32 years

Figure 4. Proportions of pregnancy cases reported by geographic region, N=396

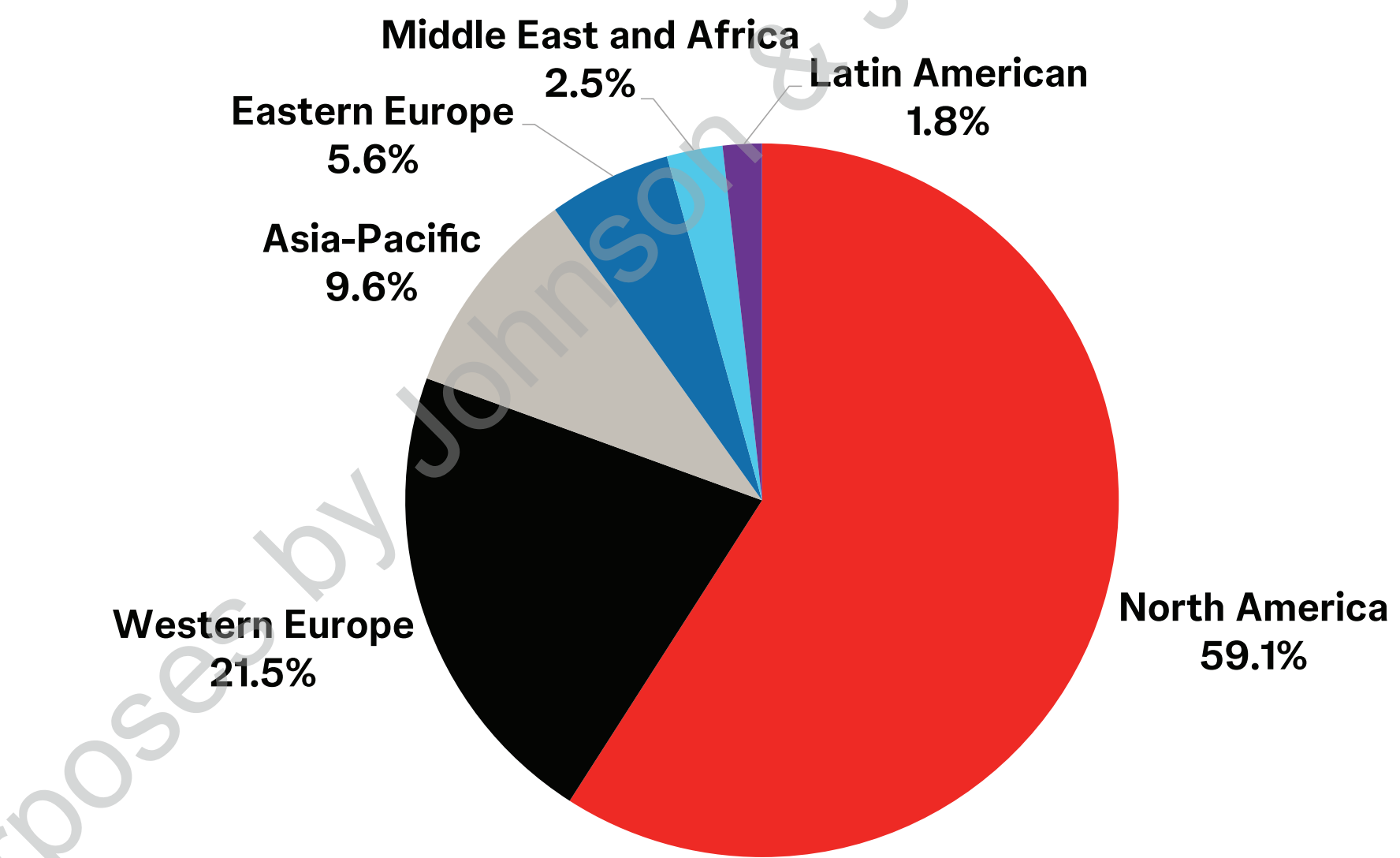


Figure 6. Proportions of Pregnancy Events by Outcome, N=400

- 66.5% of pregnancy events with maternal exposure to GUS resulted in live birth

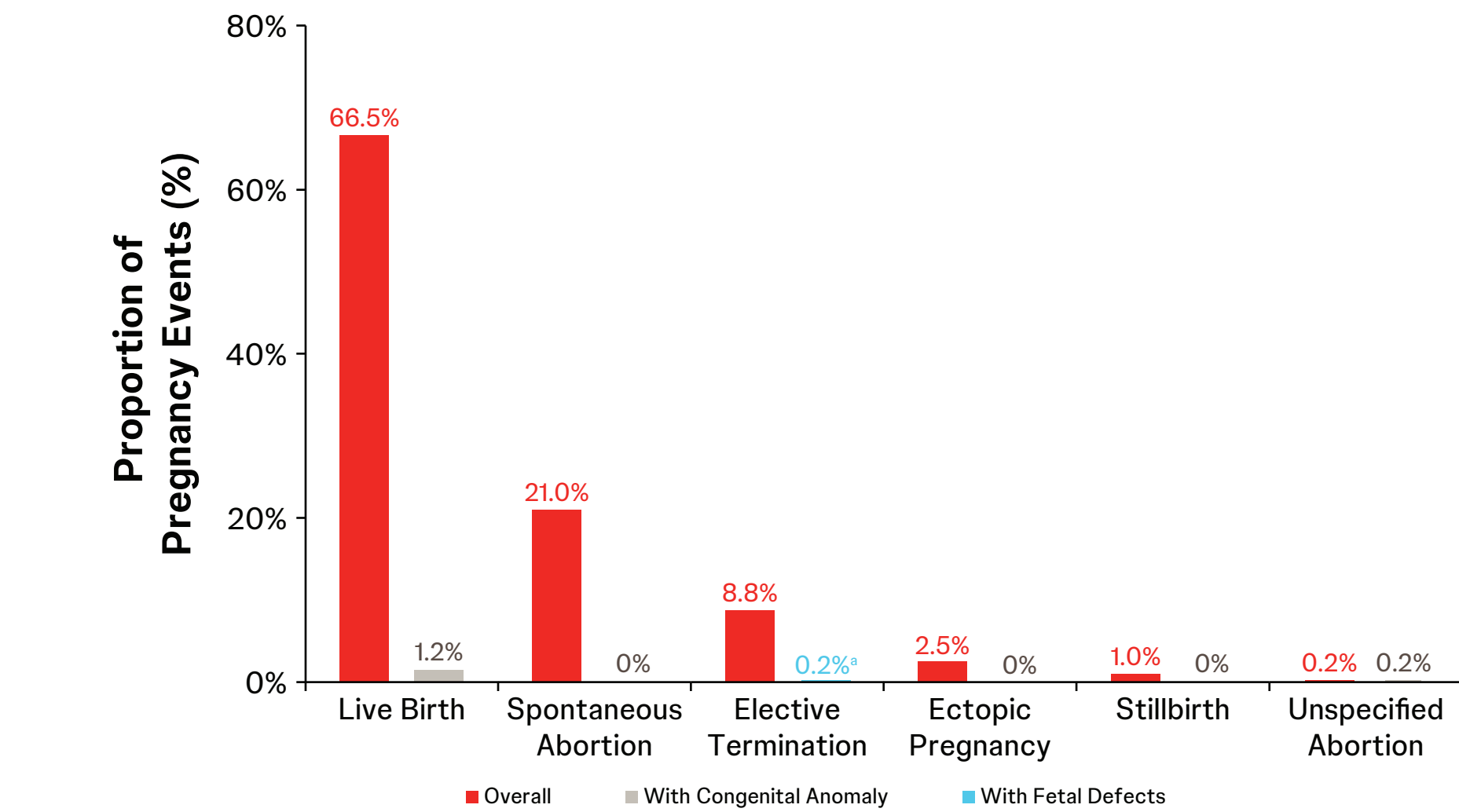


Figure 2. Proportions of prospectively and retrospectively reported pregnancy events, N=400

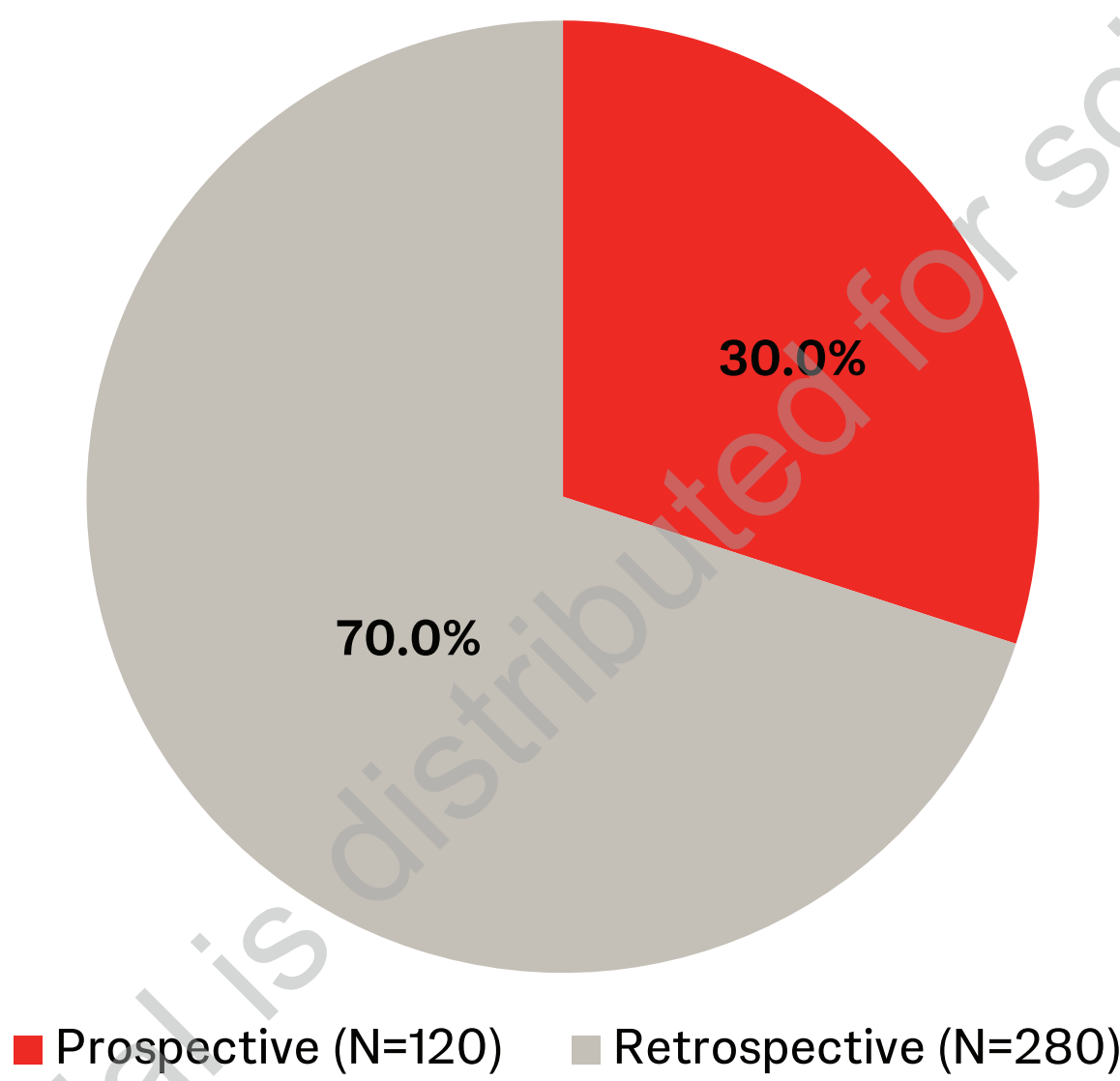


Table 1. Women exposed to GUS during pregnancy were treated for:

	Indication (N=396)	
	n-value	Percentage
Psoriatic Disease ^a	289	73.0%
Not Reported	70	17.7%
Inflammatory Bowel Disease	25	6.3%
CD	15	3.8%
UC	10	2.5%
Other ^b	12	3.0%

^aIncludes cases reported as psoriasis, psoriatic arthritis, and psoriasis + psoriatic arthritis. ^bOther indications included hidradenitis suppurativa, palmoplantar pustulosis, guttate psoriasis, pityriasis rubra pilaris, rheumatoid arthritis, and healthy individuals from Phase 1 studies. **CD**=Crohn's disease, **UC**=ulcerative colitis.

Table 2. Congenital Anomalies by Pregnancy Outcome and Timing of Exposure

- Of the 400 pregnancy events with known outcomes, 6 (1.5%) pregnancies were associated with congenital anomalies

Events of Interest ^a	Number of Events	Pregnancy Outcomes	Timing of Maternal Exposure	Classification ^b
Trisomy 13 ^c	1	Live Birth	Throughout pregnancy	Major anomaly Chromosomal
Congenital Heart Disease	1	Live Birth	Not reported	Major anomaly Nonchromosomal
Esophageal Atresia ^d	1	Live Birth	Not reported	Major anomaly Nonchromosomal
Cerebral Ventricle Dilation	1	Live Birth	During the first trimester	Minor anomaly Nonchromosomal
Single Umbilical Artery	1	Live Birth	During the first trimester	Minor anomaly Nonchromosomal
Fetal Malformation	1	Unspecified Abortion	During the first trimester	Termination of pregnancy due to fetal anomaly

^aMedical Dictionary for Regulatory Activities (MedDRA, version 28.0) was used to identify adverse events based on the System Organ Class of congenital, familial, or genetic disorders, which is sub-search of the Standardized MedDRA Query of pregnancy and neonatal topics. ^bMajor and chromosomal congenital anomalies per EUROCAT classification are reported unless otherwise specified. ^cPre-term delivery at less than 37 weeks; baby died due to Trisomy 13. ^dBaby adverse event of tracheomalacia was reported.

Figure 3. Proportions of pregnancy events by reporting source, N=400

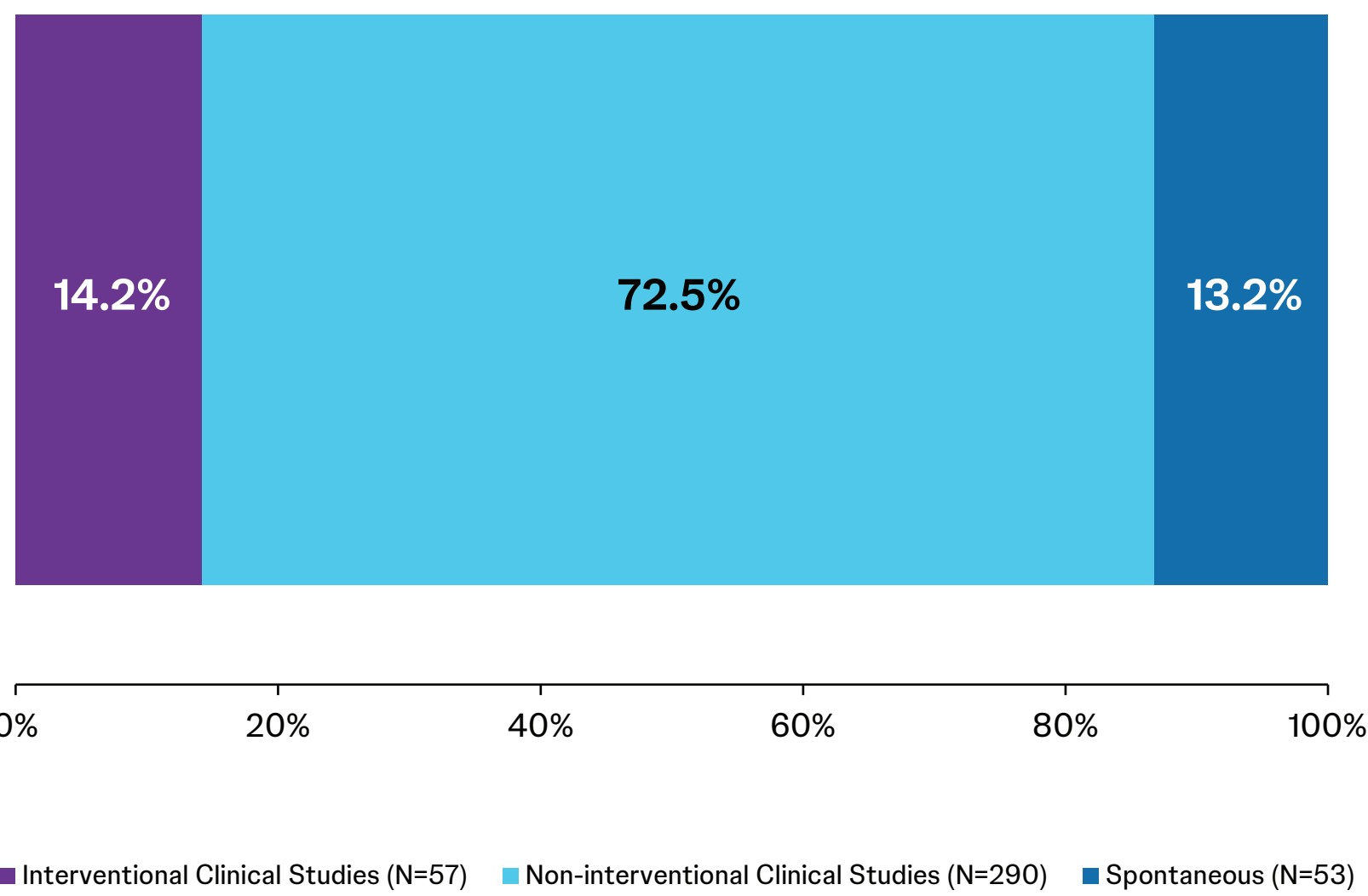
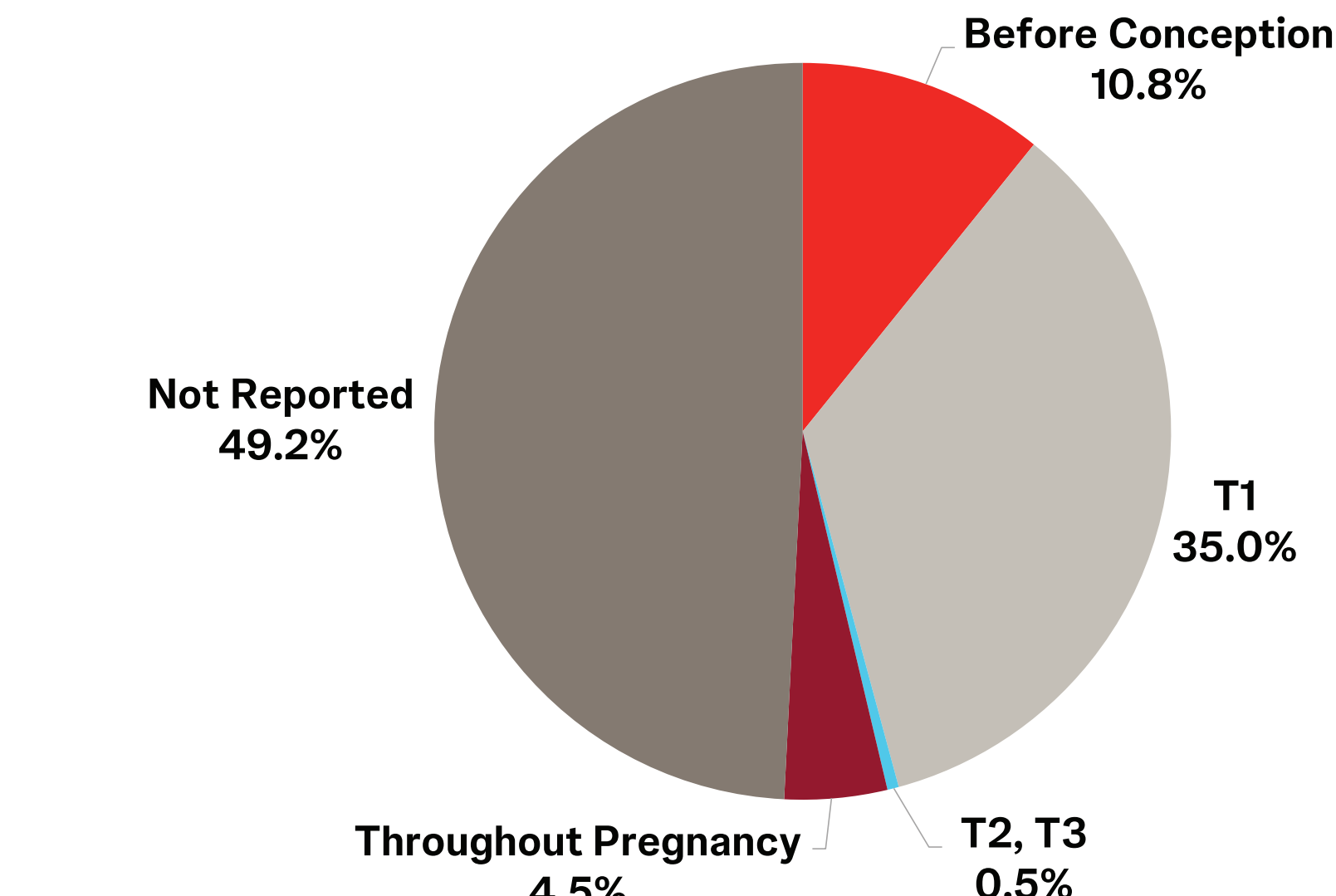


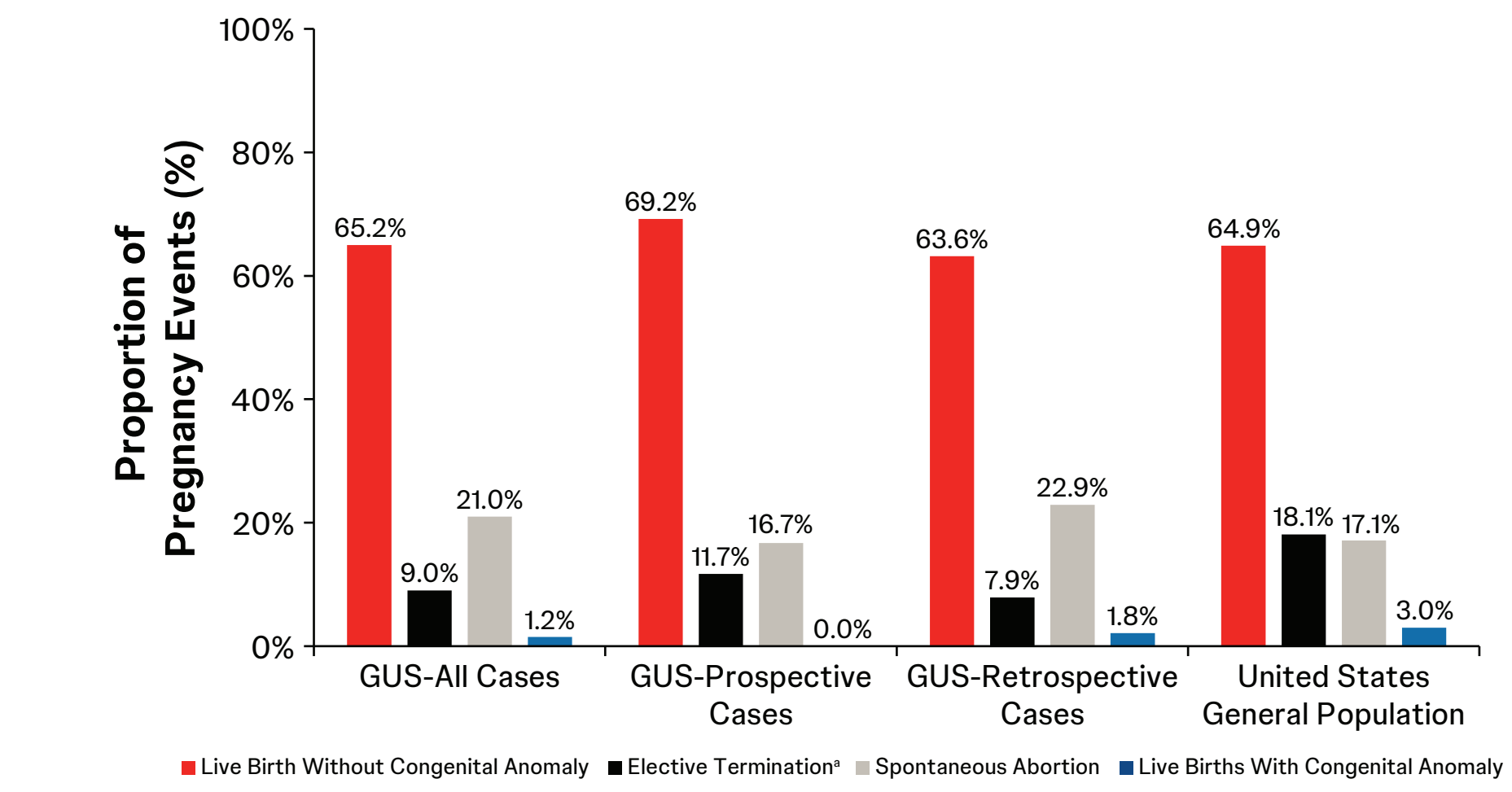
Figure 5. Proportions of pregnancy cases reported by timing of exposure, N=400



T1=first trimester, T2=second trimester, T3=third trimester.

Figure 7. Rates of Pregnancy Outcomes With Maternal Exposure vs United States General Population^{4,5}

- Rates of pregnancy outcomes in women exposed to GUS were consistent with those of the general US population



^aIncluded cases reporting unspecified abortions. **GUS**=guselkumab.