

# Assigning Pregnancy Outcomes and Gestational Age at Outcome for Robust Pregnancy Safety Analyses Application in US Claims

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## Background

- Pregnancy related drug safety data prior to marketing approval and authorization is limited.
- Real-world data sources can support robust risk-benefit evaluation taking advantage of episodes where contraindicated drugs are prescribed to unaware pregnant women or when no alternatives exist for treating maternal conditions.
- To produce robust results from claims-based pregnancy safety analyses there is a need for valid code algorithms.

## Objective

This study aimed to apply published algorithms in a large representative closed-claims database in the US to identify pregnancy outcomes.

## Methods

### Study design:



Observational retrospective cohort study using closed-claims database from USA.

### Study period:



This study included data from January 2022 to January 2023.

### Study population:



Women aged 15-49 with at least one pregnancy episode during study period.

### Index date:



First pregnancy outcome identified in the database.

### Pregnancy outcomes:



The following outcomes were identified using diagnosis and procedure codes:

- Live birth (LB), full term birth (FTB), preterm birth (PTB), and still birth (SB)
- Spontaneous abortion (SA) and elective abortion (AB)
- Ectopic pregnancy (ETC)

### Gestational age:

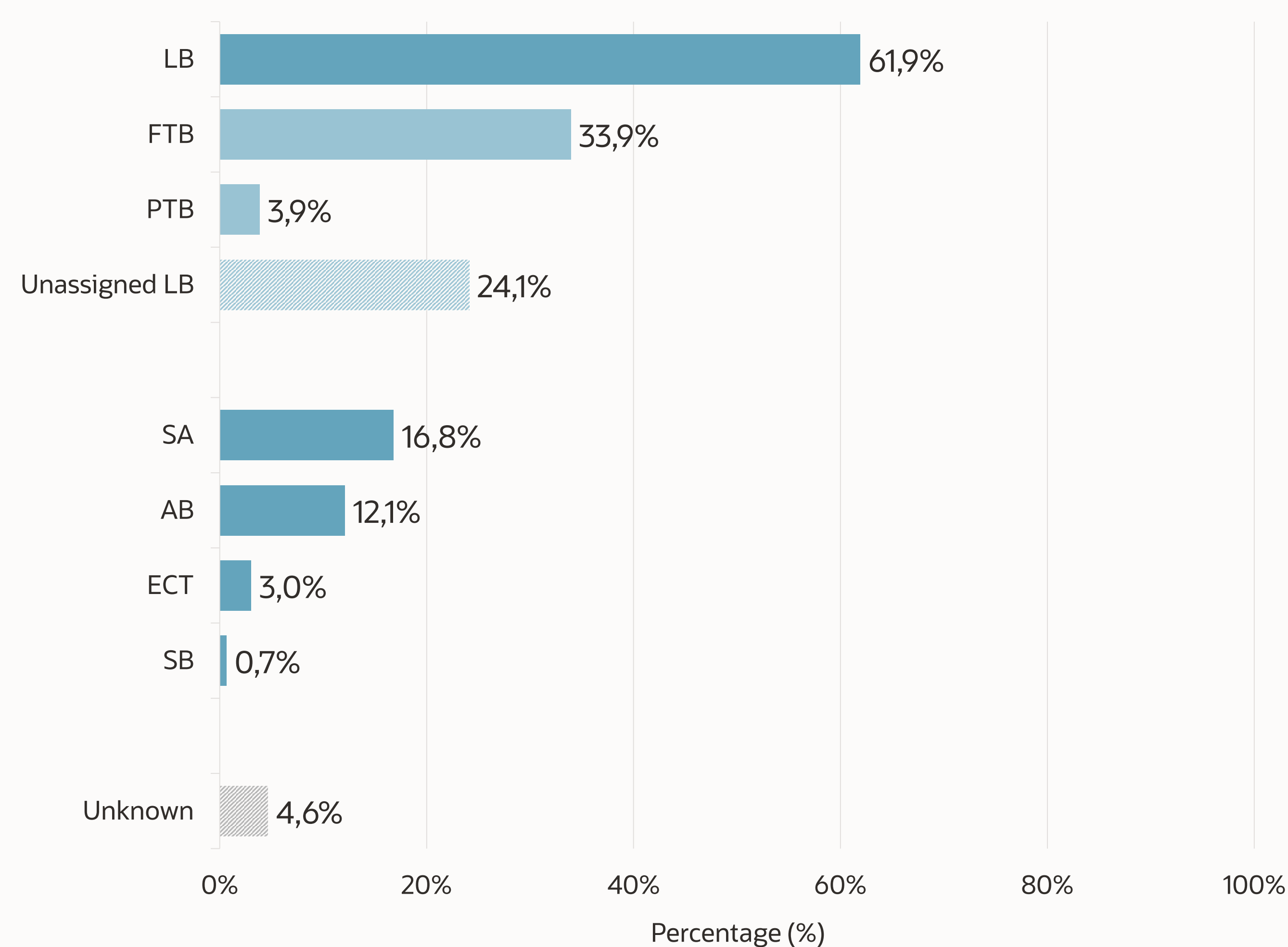


Estimated date of conception and gestational age (GA) at outcome was assigned using a hierarchical code algorithm.

## Results

- 842,583 pregnancy episodes were assigned an outcome by the algorithm.
- 77.1% (N = 649,995) pregnancy episodes were assigned a GA at outcome.

Pregnancy outcomes among validated pregnancy episodes (N = 842,583)



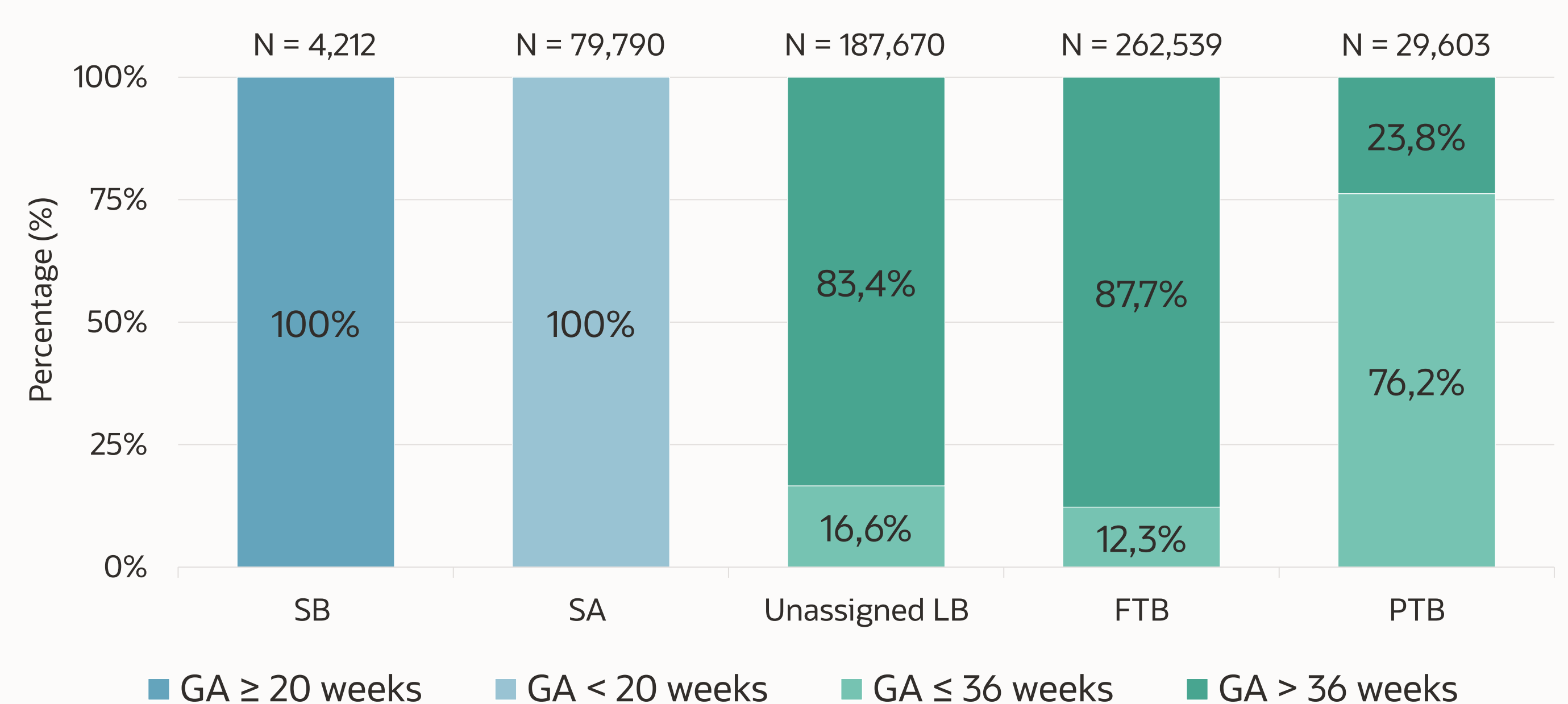
### Strengths:

- 74.9% (N = 4,212) of SB outcomes were assigned a GA, all of which were correctly identified as  $\geq 20$  weeks.
- 56.4% (N = 79,790) of SA outcomes were assigned a GA, all of which were correctly identified as  $< 20$  weeks.
- 92.3% (N = 187,670) of unassigned LB outcomes were assigned a GA, of which 16.6% (N = 31,123) were identified as  $\leq 36$  weeks and 83.4% (N = 156,547) were identified as  $> 36$  weeks.

### Inconsistencies:

- Among FTB outcomes with an assigned GA, 12.3% (N = 32,191) were identified as  $\leq 36$  weeks.
- Among PTB outcomes with an assigned GA, 23.8% (N = 7,039) were identified as  $> 36$  weeks.

Gestational age assignment



## Conclusion

Estimating date of conception and gestational age at outcome with code algorithms is crucial for defining pregnancy episode trimesters as exposure windows in claims data for inferential safety analyses. Linkage with electronic health record (EHR) data to validate a proportion of assigned outcomes and GA at outcome is needed.

## References

Moll K. et al., Validating Claims-Based Algorithms Determining Pregnancy Outcomes and Gestational Age Using a Linked Claims-Electronic Medical Record Database. Drug Saf. 2021 Nov;44(11):1151-1164. doi: 10.1007/s40264-021-01113-8. Epub 2021 Sep 30. PMID: 34591264; PMCID: PMC8481319.