



International Alliance for  
Biological Standardization

*Europe*



**Workshop on Assessing Consequences  
of Maternal Immunization on Foetal Outcomes**  
June 8-9, 2026  
Zürich, Switzerland

**Title: Planned safety assessment in Pfizer's Phase-3 GBS trial, BEATRIX**  
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Pfizer has started enrollment into BEATRIX (group **B** strEptococcus mATeRnal and Infant vaX study), a Phase 3 study of its GBS vaccine, which is expected to continue until 2028. Enrollment is planned to occur in 18 countries globally, with significant LMIC representation. The study design will be reviewed, with particular focus on the elements intended to generate robust findings with respect to infant safety outcomes. These include: rigorous inclusion/exclusion criteria for the assessment of gestational age; staged enrollment by gestational age at vaccination; frequent DMC monitoring; and standardized classification of pathways to preterm delivery.

