



International Alliance for
Biological Standardization

Europe



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

Title: Data and Analysis from the Pfizer MATISSE Trial
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MATISSE was the phase 3 efficacy trial of Pfizer's RSVpreF vaccine, conducted from 2020 - 2023. Data relating to infant safety outcomes will be presented, with a focus on preterm birth and its sequelae (Madhi et al, *Obstet Gynecol.* 2025). A numerical imbalance in the incidence of preterm birth in the vaccine group compared to placebo was observed. Multivariable analysis will be presented to explore regional variations and the subject characteristics (demographics, obstetrical history) associated with preterm birth. Potential confounding issues will be discussed such as receipt of other vaccinations during pregnancy and the SARS-CoV-2 pandemic. The critical role of vaccination timing during the pregnancy, and the need for careful interpretation of this factor, will be described. The challenges inherent in the assessment of gestational age and the approaches that were taken to address them will be covered. There will be a general review of the interpretation of modest treatment effects and the sample sizes required for confirm/refute them.

