



International Alliance for  
Biological Standardization

Europe



**Workshop on Assessing Consequences  
of Maternal Immunization on Foetal Outcomes**  
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Zürich, Switzerland

**Title: Immunogenicity and Safety assessment of GBS-NN/NN2 in Pregnant Women**  
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MinervaX' AlpN GBS vaccine is developed to address the important medical need for a novel prophylactic vaccine against Group B Streptococcus (GBS). AlpN GBS, is an Alum adjuvanted, protein-only vaccine based on fusions of highly immunogenic and protective protein domains from selected surface proteins of GBS - the Alpha-like protein family (AlpN). It is being tested in the clinic for use in pregnancy and in older people.

Vaccination during pregnancy will protect infants against devastating invasive GBS disease in the first months of life. When given early enough during pregnancy, the vaccine could potentially also protect against Adverse Pregnancy Outcomes such as Stillbirth and Preterm Delivery, which can be caused by GBS. AlpN GBS vaccine was shown to have an acceptable safety profile in both vaccinated mothers as their infants, after administration as a two-dose schedule to pregnant women in two completed Phase 2 trials. Antibodies induced in the mother were successfully transferred to the infant. The pivotal trial to support licensure of this vaccine, the MOTIVATION Trial (MOther To Infant protection by VAccinaTION), is under preparation.

