Streptococcus agalactiae, or Group B Streptococcus (GBS), is a gram-positive streptococcal bacteria that is well-recognized as one of the leading causes of infant death, particularly in the early neonatal period (the first week of life). An estimated one in five pregnant women around the world carry GBS bacteria in their gastrointestinal or genitourinary tracts and vertical transmission from colonized mothers can lead to invasive disease in their offspring. A recent study conservatively estimated that out of 410,000 GBS cases globally every year, there are at least 147,000 stillbirths and infant deaths. Despite being home to only 13 percent of the world's population, Africa has the highest GBS disease burden, with 54 percent of estimated cases and 65 percent of stillbirths and infant deaths.

An effective GBS vaccine, given during pregnancy, is a promising strategy to protect against infection. Currently, no licensed vaccine exists to prevent GBS disease, but scientific evaluation of feasibility is favorable. The leading vaccine candidates are capsular polysaccharide-protein conjugate vaccines. Evidence suggests maternal immunization with a safe and effective GBS vaccine may reduce the disease risk in neonates and young infants.

The Biovac Institute was established as a private-public partnership and is the only Southern African vaccine manufacturer. Located in Cape Town, South Africa, Biovac’s mission is to become a leading vaccine developer and producer in South Africa to increase capacity in Africa which only has 4 other vaccine manufacturers.

Biovac, in collaboration with PATH, an international health organization, and other partners, is developing a multivalent conjugate vaccine against GBS. The first stage of the project involves the development of biopharmaceutical manufacturing processes and analytical tests, the preparation of clinical trial product, and execution of a first-in-human clinical trial. This presentation will provide an overview of the project, progress to date, and the path to commercialization.