

PROTECT

Preparing for Optimal Phase III/IV maTernal
Group B StreptococCal vaccine Trials in Africa

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FACT SHEET

PRTECT

ACRONYM

PROTECT

FULL TITLE

PREparing for Optimal Phase III/IV maTernal Group B
StreptococCal vaccine Trials in Africa

PROGRAMME

EDCTP3

CONTRACT NUMBER

101145724

DURATION

36 months (01/03/2024 – 28/02/2027)

PROJECT FUNDING

3,271,990.50 EUR

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CONSORTIUM

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- MU-JHU Care Ltd (MU JHU), Uganda
- Aga Khan University Kenya (AKU), Kenya
- Kamuzu University of Health Sciences (KUHeS), Malawi
- Fundaçao Manhiça (FM), Mozambique
- Universiteit Antwerpen (UANTWERPEN), Belgium
- LINQ management GmbH (LINQ), Germany
- St George's Hospital Medical School (SGUL), United Kingdom
- The University of Liverpool (UoL), United Kingdom
- The Chancellor, Masters and Scholars of the University of Oxford (UOXF), United Kingdom

PROJECT WEBSITE

www.protect-network.org

ABSTRACT

Two vaccines designed for pregnant women, to protect their unborn infant, are entering late phase development and will prevent infections from group B Streptococcus and respiratory syncytial virus, respectively. For these vaccines to be approved, they must work effectively without causing any unwanted responses. To implement these vaccines in countries with low resources, healthcare systems must be strengthened by improving vaccine safety monitoring and surveillance of infection, and advancing vaccine delivery, vaccine confidence, and patient participation. The rapid rollout of electronic health records (EHR) in Kenya, Mozambique, Malawi, and Uganda offers an opportunity to use routine data to strengthen reporting of rates of adverse pregnancy, neonatal and infant outcomes, and any adverse events following immunisation; this will be imperative in informing and preparing for future large scale vaccination rollout campaigns.

Our approach will address key gaps in EHR to develop pregnancy registries embedded within national reporting systems to establish this data, including baseline rates of pregnancy and infancy outcomes for Tetanus and COVID19 vaccines currently in use. These reporting systems will allow monitoring of potential safety signals once new vaccines are introduced. Experts in EHR, obstetrics and gynaecology, paediatrics, microbiology, clinical trials, and implementation research will develop the motivation and tools needed to monitor and evaluate current and future maternal vaccines.

We will work closely with the WHO, African Medicines Agency and Country Stakeholders, co-developing pregnancy registries, sentinel site microbiological surveillance systems, and maternal vaccination communications toolkits in preparation for the decade of maternal vaccines. Our programme of work culminates in a network of maternal vaccine trial sites that can rapidly evaluate vaccines in pregnancy from late-stage trials through to introduction on a national level.