



This project is part of the EDCTP2 programme supported by the European Union



MTBVAC against TB, reaching its last stages

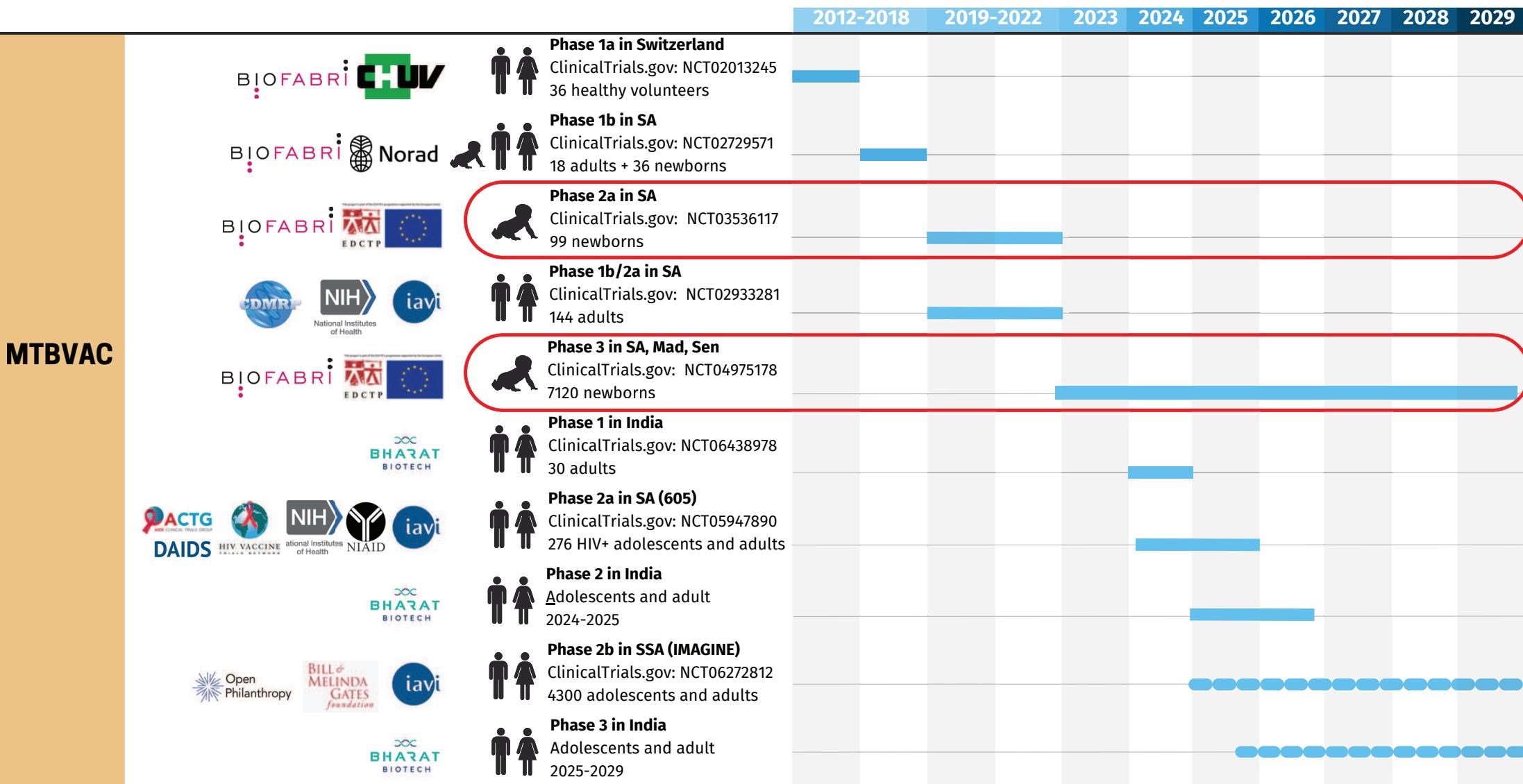
Jornada informativa de las convocatorias 2025 del
Partenariado en Salud Global

Ingrid Murillo Jelsbak

24 February 2025



MTBVAC Timeline



MTBVAC in newborns - Phase 2a RIA2016V-1637 - Completed



A Phase 2a Randomised Controlled Dose-Defining Trial of the **Safety** and **Immunogenicity** of MTBVAC in Healthy, BCG Naïve, HIV Unexposed, South African Newborns



European & Development Countries Clinical
Trial Partnership (EDCTP)



Coordinator - Biofabri Spain



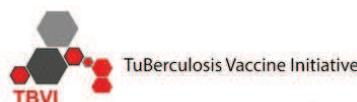
The University of Zaragoza (Unizar)
Spain



The University of Cape Town (UCT)
South Africa



Center de Recherche Biomédicale
Espoir Pour La Santé (CRB-EPLS)
Senegal



TuBerculosis Vaccine Initiative (TBVI)
The Netherlands



Institut Pasteur de Madagascar (IPM)
Madagascar

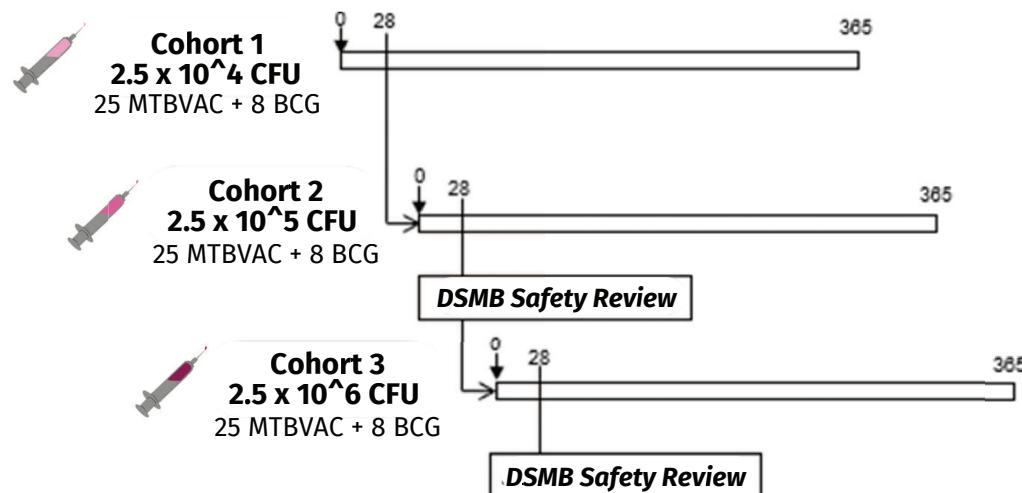
MTBVAC in newborns - Phase 2a RIA2016V-1637 - Completed



A Phase 2a Randomised Controlled Dose-Defining Trial of the **Safety** and **Immunogenicity** of MTBVAC in Healthy, BCG Naïve, HIV Unexposed, South African Newborns

Key points:

- Sample size - **99** ppts **in 1 site**
- Single dose, intradermal (**ID**)



Study Site



Main conclusions:

- All three doses seemed safe and well tolerated.
- No significant differences in immunogenicity between the 2.5×10^5 CFU and 2.5×10^6 CFU doses of MTBVAC were detected, but both these doses were more immunogenic than BCG and the 2.5×10^4 CFU dose of MTBVAC.

Dose selected for the Phase 3 ↗ **2.5×10^5 CFU**

Study publication submitted, pending approval.



In concordance with WHO recommendations, the 2.5×10^5 CFU MTBVAC dose was selected for phase 3 efficacy evaluation compared to BCG vaccination in infants.

MTBVAC in newborns - Phase 2a RIA2016V-1637 - Completed



Last in-person meeting of the partners involved in the project Phase 2a

Spain- Bayona - May 2022



TuBerculosis Vaccine Initiative



MTBVACN3 in newborns - Phase 3 RIA2019S-2652 - Ongoing



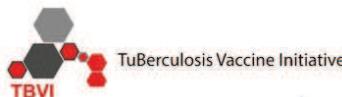
Randomized, Double blind, Controlled Phase 3 to evaluate the Efficacy, Safety and Immunogenicity of MTBVAC administered in healthy HIV unexposed uninfected and HIV exposed uninfected newborns in Tuberculosis-Endemic Regions of Sub-Saharan Africa



European & Development
Countries Clinical Trial Partnership (EDCTP)



Coordinator - Biofabri Spain



TuBerculosis Vaccine Initiative (TBVI)
The Netherland



The University of Cape Town (UCT)
South Africa



Wits VIDA Health Consortium (WHC)
South Africa



Stellenbosch University (SUN)
South Africa



The University of Zaragoza (Unizar)
Spain



Enhancing Care Foundation (ECF)
South Africa



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Senegal



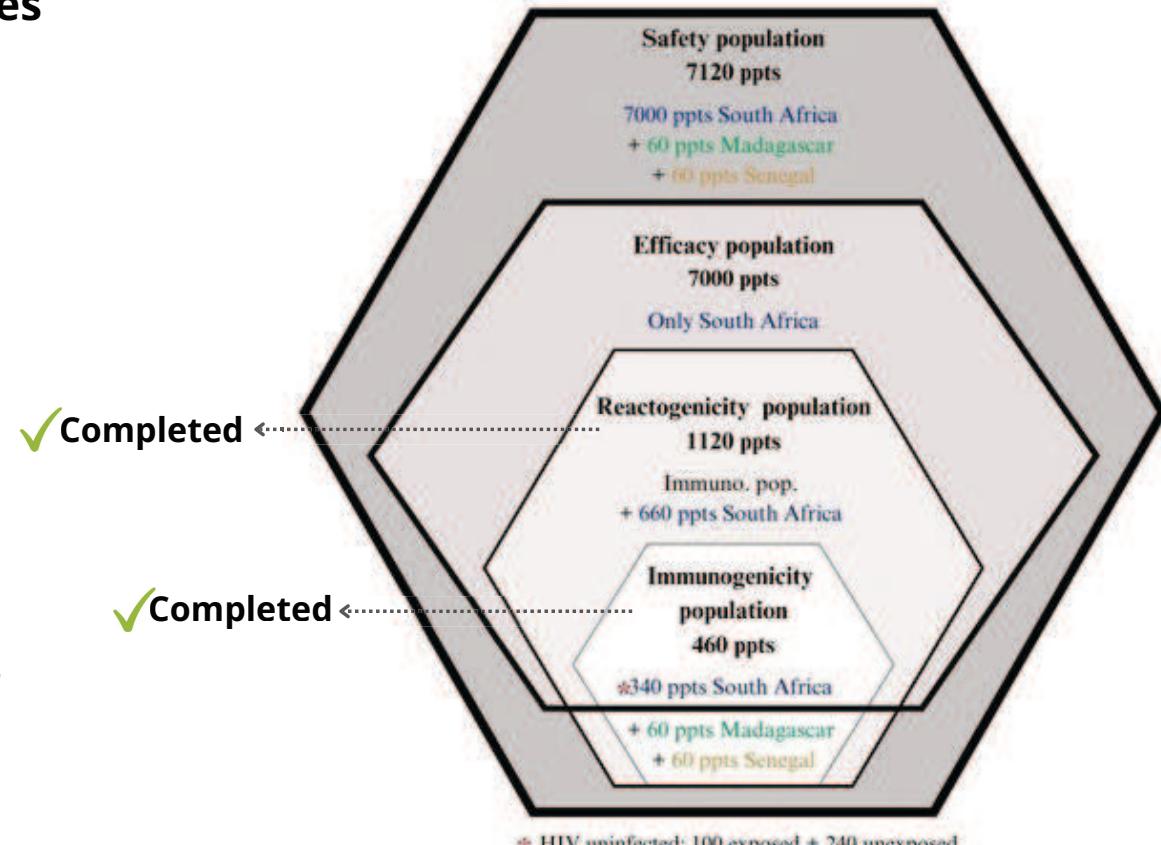
Institut Pasteur de Madagascar (IPM)
Madagascar

Key points:

- Sample size - **7120 ppts in 6 sites**
- Single dose, intradermal (**ID**)
- Control - BCG vaccine
- Follow up - 2- 6 years



Study Population



3787 vaccinated babies
53.1% of total target
by 18 February
2025

Madagascar and Senegal
have completed recruitment
by end 2024.



MTBVACN3 in newborns - Phase 3 RIA2019S-2652 - Ongoing



2nd Annual Project Progress Meeting - South Africa - Johannesburg - 27 to 29 May 2024

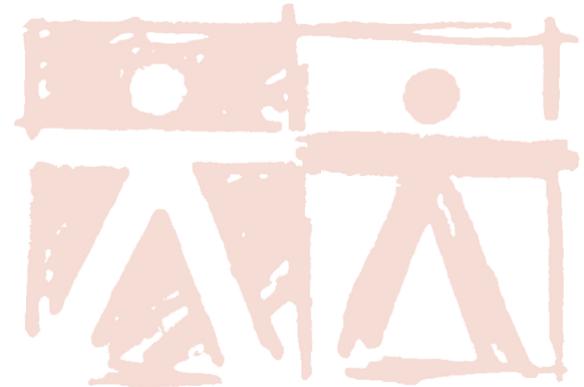


3rd Annual Project Progress Meeting - to be held in Spain - May 2025



Procedures, Opportunities and Benefits Offered by EDCTP

- Funding Support
- Additional Procedures and methodology:
 1. Non-cost Extension. Phase 2a.
 2. Annual training in project management and finances
 3. In-person Annual Progress Meetings of the projects
 4. EDCTP Annual Reporting: Technical and Financial Review - Interim Payments
 5. Fluent communication and support throughout the EDCTP project length





Thank you for the attention!

BIOFABRI

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Institut Pasteur
de Madagascar



TuBerculosis Vaccine Initiative



Centre de Recherche Biomédicale
Espoir Pour La Santé



WITS VIDA

UNIVERSITY OF THE WITWATERSTAND
VACCINES AND INFECTIOUS DISEASES
ANALYTICS RESEARCH



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