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MTBVAC vaccine: Challenges in Establishing Phase III Trial Capacity in Antananarivo

Arimanitra Razafimahefa[1], Paulo Ranaivomanana[1], Niaina Rakotosamimanana[1]

[1]*Mycobacteria Unit, Institut Pasteur de Madagascar, Antananarivo, Madagascar*

Background: Tuberculosis (TB) remains one of the world's deadliest infectious diseases, claiming over 1.4 million lives each year. Preclinical studies and early phase clinical trials have shown promising results, demonstrating the safety and immunogenicity profile of MTBVAC in preventing tuberculosis (TB) infection and disease progression. To assess its safety, efficacy and effectiveness in large populations, a randomized, double-blind, Bacillus Calmette-Guérin (BCG)-controlled phase III trial is being conducted in South Africa, Senegal and Madagascar. The aim of this study was to identify/recognize strengths during a comprehensive capacity building initiative, particularly in a low-income country such as Madagascar.

Methods: To ensure capacity building, various criteria were evaluated, in accordance to Good Clinical Practice (GCP), Good Clinical Laboratory Practice (GCLP) and recommendation by External Quality Control. At the end of the methodological approach, a check-list was established to validate the necessary requirements for phase III trial.

Results: The main challenge concerns the implementation of strict quality control measures and reinforcing quality assurance. The level of GCP and GCLP certified training staff was 100%. Based on the standard guidelines, 90% of the standard operating procedures (SOPs) and protocols were rewritten.

Conclusions: This study provides the importance of capacity building initiatives and the significantly collaborations with international research institutions for the successful implementation of a Phase III clinical trials.

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Conflicts of Interest
None