

Integrated clinical research center selection for phase 2b MTBVAC TB prevention efficacy trial in African adolescents and adults.

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Background: Both epidemiological and operational feasibility assessments are crucial for selecting clinical research centers (CRCs) in high tuberculosis (TB) incidence areas. This study aimed to integrate epidemiological data to identify high-burden regions, navigate feasibility-related CRC selection considerations, and address challenges in data-driven selection for a Phase 2b TB vaccine trial (NCT06272812).

Methods: CRC selection activities commenced in June 2023. The aim was to select at least 15 CRCs for adequate trial recruitment, considering data validity and completeness, and CRC experience and capacity. CRCs in sub-Saharan Africa were identified. Feasibility data was collected and captured CRC-specific information and epidemiology data. A comprehensive review evaluated epidemiology, CRC resources, experience, and capacity. We engaged with CRCs to map TB case notifications and improve the quality of available data. Composite Scoring was conducted to assign scores based on assessed components. This allowed focusing on experienced CRCs in endemic regions with high TB incidence, high IGRA prevalence, and low HIV prevalence. Extensive data review and cleaning were conducted during the feasibility phase.

Results: Feasibility forms were sent to 51 CRCs, and 22 were shortlisted for on-site assessment based on epidemiology and capacity data. Out of the 15 CRCs selected, the majority (12) were in South Africa, due to high TB incidence, one in Tanzania, and two in Kenya. 15 additional backup CRCs were identified for further exploration.

Conclusion: Key epidemiology and operational scoring indicators were systematically developed, providing a structured framework for investigating the primary endpoint (pulmonary TB in IGRA+ and HIV- participants) while considering the context of additional endpoints (adequate experience to successfully execute a clinical trial). While limitations existed due to available data, many case notification rates exceed

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Conflicts of Interest

None

