

End-to-End Clinical Support for Meningitis Vaccine Development

DiagnoSearch collaborated with SIIPL and WHO-PATH on a multi-phase, multi-country clinical program that led to the successful rollout of a meningococcal vaccine across sub-Saharan Africa.

Situation and Challenge

Serum Institute of India Pvt. Ltd. (SIIPL), in collaboration with WHO-PATH, initiated a global vaccine development program targeting meningococcal disease in sub-Saharan Africa's "meningitis belt." The initiative required:

- Full-service clinical trial execution across Phases I-IV
- Coordination across India and multiple African countries
- Standardization of global laboratory processes across leading international institutions
- Extensive pharmacovigilance and central laboratory support
- Strategic quality assurance partnerships at a global scale

Our Solution

DiagnoSearch provided comprehensive services across multiple geographies and trial phases:

- Clinical & Operational Services
- Full-service Data Management and Biostatistics
- Pharmacovigilance support across all trial phases
- Central Laboratory Services across all sites
- Project Management and Clinical Monitoring for India-based studies

Scientific Leadership & Global QA

DiagnoSearch played a strategic role in assay standardization and quality assurance for global immunoanalytical laboratories:

- Centers for Disease Control and Prevention (CDC), Atlanta
- Health Protection Agency (HPA), Manchester, UK
- Robert Koch Institute (RKI), Berlin, Germany

Appointed Quality Assurance Partner for the Meningitis Vaccine Laboratory (CDC) for a two-year tenure

Results and Impact

The clinical program enrolled approximately 15,400 subjects across both India and sub-Saharan Africa. This included around 14,200 participants in 8 projects across Africa (Phases II-IV) and 1,252 subjects across 3 India-based studies (Phases I and III). Over 325,000 CRF pages were processed with rigorous quality control and data integrity standards.

DiagnoSearch's global coordination, scientific leadership, and operational excellence were central to the success of this multi-country collaboration. The project directly contributed to the successful development and introduction of a life-saving meningococcal vaccine, protecting millions across Africa's meningitis belt.

Preview Version

Meningitis Vaccine Program in India & sub-Saharan Africa

Phases I-IV | 15,400 subjects | Multi-Country Collaboration

DiagnoSearch supported SIIPL and WHO-PATH across the full clinical development lifecycle of a meningococcal vaccine, providing full-spectrum services and global lab standardization. The program helped enable the vaccine's successful introduction across Africa.