



COVID-19 Site Readiness Project

DCVMN AGM

Pune, 20 October 2022



COVID-19 Vaccine Phase 3 Research Centre Preparation

Selected 11 low- and middle-income country (LMIC) sites having prior relevant experience and demonstrated success in implementing clinical vaccine trials

Goal: To **enhance capacity** at **LMIC clinical trial sites** in preparation for testing COVID-19 vaccine candidates alongside peer sites in high-income countries, including effectively **sustaining and managing high-volume (participants & specimens)** for **rapid enrolling trials** implemented in a **pandemic setting** while adhering to GCP guidelines and quality standards.



Burkina Faso - Institut de Recherche en Science de la Sant...



Costa Rica - Fundacion Inciensa (FUNIN), Biomédicas (ACIB)-...



Honduras: Inversiones en Investigación Médica S.A....



Malawi - Malawi-Liverpool-Wellcome Trust



Mozambique - Centro de Investigaçao em Saude de...



Pakistan - Aga Khan University Clinical Trials Unit



Colombia - Centro de Atención y Diagnóstico de Enfermedades...



Haiti - Les Centres GHEKIO



Kenya - KAVI University of Nairobi



Mali - Le Centre pour le Développement des Vaccins du...



Niger - Epicentre

COVID-19 Phase 3 Research Centre Preparation

- **Standard capacity improvements**

- Hiring and training a **core set of qualified trial management staff** in GCP and HSR and site-specific procedures
- Establishing a **core set of SOPs**, including COVID-19 specific SOPs promoting social distancing and infection prevention measures
- Identifying a reliable source of **COVID-19 surveillance data** for country and local area, consistent monthly reporting
- Consulting with National Regulatory Authorities (NRA) and Ethics Committees (EC) to **optimize timelines for NRA & EC review/approval**
- Conducting community/stakeholder consultation meetings to verify **community readiness** for a trial
- Completing financial reviews to verify **financial competency** to manage trial finances

COVID-19 Phase 3 Research Centre Preparation

- **Capacity improvements tailored by site**
 - **Improving infrastructure** to allow for **high-volume enrollment, physical distancing**, and preventing contact between suspected/confirmed patients and healthy study participants
 - **Renovating/expanding storage** and **workspace** in labs and pharmacies
 - Establishing **satellite sites**
 - **Purchasing and/or maintaining** refrigerators, freezers, and/or basic **COVID-19 clinical care and assessment tools** (e.g., oximeter, touchless thermometers, oxygen concentrators, etc.)

COVID-19 Phase 3 Research Centre Preparation

- **Food for thought:**
 - **Continuity, Sustainability, Capacity Building**
 - **De-colonization**
 - **Global cross-stakeholder coordination**