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