STUDY START-UP ACTIVITIES INITIATED

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Start-up activities are initiated to enable timely Phase 2 start

Clinical study start-up plan initiated with consideration of feasibility and identification of risks.t

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Clinical trial designed	a) Protocol design and scope for the next phase of development (including study plans, medical monitoring plans, timelines and budgets) to support both NRA approval and WHO PQ b) Proposed clinical development path (i.e., request for conditional approval) and rationales c) Investigator's Brochure updated for the next phase of development. (e.g., prior to First in Human include Core Safety Information from toxicology study) d) At EP2 ensure that feedback/recommendations from engagement with WHO (on target population etc.) are addressed in Phase 3 trial design	▪ Protocol synopsis ▪ Investigator Brochure
▪ Clinical trial site feasibility completed	a) Plan for conducting epidemiology study to understand patient population and identifying potential study sites b) Existing network of investigators and study sites c) Plan for site validation (may include audit) including considerations such as infrastructure, capability, supply chain feasibility, capacity, cGCP certification, etc. d) Understanding of required approval process to conduct clinical studies at all potential study sites and identifying risks e) Data integrity and confidentiality practices	▪ Summary report
▪ Clinical vendors/CRO identified and site initiation activities conducted	a) Scope of work required (e.g., site selection, site initiation, data management, process & method development, etc.) and agreed metrics to monitor trial progress b) Partner engagement strategy (e.g., outsourced activity, insourced activity, consultation, etc.) c) Relationship with local regulatory body, and authorities d) Existing network of investigators and study sites e) Ensure completion of site initiation activities such as: 1) Plan for obtaining Ethical Committee approvals and completing all administrative tasks required to start a clinical study at all study sites; 2) Plan for training of investigators and staff to ensure GCP compliance and protocol compliance (i.e., drug administration, dosing regimen, etc.); 3) Plan for educating patients on protocol compliance (i.e., sample collection, adverse event reporting, etc.); 4) Plan for obtaining Informed Consent with consideration of staff availability and patient literacy	▪ Summary report
▪ Clinical assay readiness	a) Clinical lab identified b) Clinical assays in place prior to entering clinical studies	▪ Summary of assay qualification