STUDY START-UP ACTIVITIES INITIATED

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Start-up activities are initiated to enable timely. Phase 1 start.

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

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Clinical trial designed	a) Protocol design and scope for Phase 1 (including study plans, medical monitoring plans, timelines and budgets) to support both NRA approval and WHO PQ b) An overview of the clinical development path (i.e., request for conditional approval) and rationales c) Updates to Investigator's Brochure for the next phase of development. (e.g., prior to First in Human include Core Safety Information from toxicology study)	▪ Protocol synopsis ▪ Investigator Brochure
▪ Clinical trial site feasibility completed	a) Plan for site assessment (may include audit) including considerations such as infrastructure, capability, supply chain feasibility, capacity, etc. b) Understanding of required approval process to conduct clinical studies at all potential study sites and identifying risks	▪ 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) Examples of past vaccine trial experience in the disease area/geographic area d) Understanding of the stepwise clinical trial approval process, engaging with local regulatory authorities, ethics committee etc. e) Existing network of investigators and study sites f) Audit record of clinical study sites and track record of staff GCP training g) Completion of site initiation activities	▪ Summary report
▪ Clinical assay readiness	a) Relevant clinical assays need to be available prior to entering clinical studies	▪ Summary of assay qualification