CLINICAL DEVELOPMENT PLAN UPDATED

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Clinical safety data and rationale for registration.

Clinical Development Plan initiated.

(*Clinical Development Plan is initiated prior to the FIH gave review and is updated & reviewed during development through to the DTF gate review)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Clinical development plan initiated	a) Overview of planned clinical activities post-approval: • Study phase, objectives/research rationale • Duration of the studies, number of subjects, recruitment criteria (e.g.,. study arms, patient cohorts, comparators for non-inferiority trials, power calculations etc.) • **Special populations dosing & dosing modeling strategies** • **New formulation assessment & plan** b) Clinical partners, proposed target countries, and study sites (based on criteria including clinical expertise, sustainability, site capacity, and disease incidence/epidemiology studies, etc.) c) Post-marketed product surveillance/Phase 4 trial strategy d) Mass product administration considerations (e.g., trial design, safety requirements, etc.) e) Off-label use considerations f) Trial size considerations for diseases with limited incidence rates g) Potential risks and mitigation strategies h) Timelines and budgets for post-approval clinical development	▪ Detailed post approval clinical plan with timeline ▪ Risk identification and mitigation needed for post approval phase of development ▪ **Post approval Clinical Development Plan should be finalized prior to the DTF gate review (i.e., prior to registration)** ▪ Clinical Development Plan extends beyond DTF gate to accommodate time needed to report Phase 3 results and also to cover additional plans for pediatric studies and post-market surveillance

* Items in **bold** font reflect suggested reporting guidelines for this stage gate