CLINICAL DEVELOPMENT PLAN UPDATED

GLOBAL DRUG DEVELOPMENT

Goals/ Definitions

Plan for clinical studies for licensure and post-marketing.

Clinical Development Plan initiated

(*Clinical Development Pan is initiated prior to the FIH gate 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 updated	a) Overview of planned clinical activities:
	• 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.)
	• Complete drug-drug interaction and special population place in place
	  • Dosing & dosing modeling strategies
	  • Detailed rationale for Phase 3 dose selection
	  • Toxicology and toxicokinetic results to support doses and dosing duration in Phase 3
	  • Drug combination assessment & plan
	  • Toxicology plan to support submission (e.g., carcinogenicity, reproductive toxicology)
	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) Definition of clinical endpoints (primary & secondary), methodology (clinical endpoint assays, data collection plan, statistical methods, etc.), adverse event reporting, stopping rules, etc.
	d) Monitoring, data management, and biostatistics strategies
	e) Post-marketed product surveillance/Phase 4 trial strategy
	f) Mass product administration considerations (e.g., trial design, safety requirements, etc.)
	g) Off-label use considerations
	h) Trial size considerations for diseases with limited incidence rates
	i) Potential risks and mitigation strategies
	j) Timelines and budgets for clinical development
		▪ Detailed Phase 3 clinical plan with timeline
		▪ Updated risk identification and mitigation needed for all subsequent phases of development
		▪ Plans should reflect approaches to accelerate decision making (e.g., adaptive designs, real-time data analysis of clinical trials etc.)
		▪ Phase 3 plan is modified during Phase 2 trial as Phase 2 data become available
		▪ Clinical development plan extends beyond DTF to accommodate the time needed to report Phase 3 results and also cover additional plans for pediatric studies and post-market surveillance