CLINICAL DEVELOPMENT PLAN IN PLACE

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Detailed plan for Phase 1 and high level plan for Phase 2 and 3 in place.

Clinical Development Plan initiated.

(*Clinical Development Plan is initiated 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 initiated	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.) • Dosing & dosing modeling strategies • Detailed rationale for Phase 1 dose range, and target clinical exposures • Toxicology and toxic kinetic results to support doses and dosing duration in Phase 2 • Drug combination assessment & plan • Toxicology plan to support Phase 2 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 plan with timeline for Phase 1 • High-level / draft plan for Phase 2 and Phase 3 risk identification and mitigation • Plans should reflect approaches to accelerate decision making (e.g., adaptive designs, real-time data analysis of clinical trials etc.) • Phase 2 plan is modified during Phase 1 trial as Phase 1 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