PRE-IND MEETING SCHEDULED* (OPTIONAL)

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Gain concurrence with Regulatory Authority on Phase 1 study design.

Data Package necessary for pre-IND and/or IND meeting (or NRA equivalent meeting) submission, and/or meeting opinion.
(*Specific communication requirements of National Regulatory Authorities (NRAs) should be identified upon initiation of the Regulatory Strategy Plan)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Package for pre-IND meeting submission (NRA equivalent meeting) prepared ▪ Ethics committee review process understood and interplay with pre-IND meeting understood	a) List of specific questions and input sought from regulatory agency b) Summary of drug characterization data (e.g., basic molecular properties, physicochemical properties, purity, stability, preliminary formulation concept, etc.) c) Summary of initial nonclinical assessments • PK, PD, ADME • Efficacy and activity • Safety d) Manufacture plan & initial specs developed as required for clinical trial supplies e) Outline of follow-on nonclinical studies f) Outline of clinical plan (which may leverage Clinical Development Plan and Clinical Readiness milestones content), including: • Rationale for intended use • Studies supporting dosing and duration • Appropriateness of safety monitoring techniques • Assurance of clinical trial supply quality • Phase 1 trial design & protocol • Inclusion / exclusion criteria; safety monitoring procedures • High-level plans for Phase 2 study	▪ Pre-IND briefing package
▪ Post-meeting debrief and development strategy adjustment (if required) completed	a) Review of decisions and recommendations made at the meeting b) Action plan to address highlighted development issues (if any) prior to filing of clinical trials application	▪ Regulatory responses to questions