IND SUBMITTED TO REGULATORY AGENCY

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Gain concurrence with Regulatory Authority on Phase 1 study design.

Track the regulatory approval to enter to Phase 1 studies.
(*Specific communication requirements of National Regulatory Authorities (NRAs) should be identified in upon initiation of the Regulatory Strategy Plan)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE

▪ IND application package (or similar NRA clinical trials package) prepared, endorsed, submitted, and received by regulatory agency	• List of regulatory agency requirements (for example)
	  • Drug substance & drug product properties
	  • Stability data
	  • Relevant animal PK and disease model data
	  • Argument for acceptability of preclinical candidate safety profile
	  • Demonstrated in vitro and/or in vivo efficacy/activity, as applicable
	  • Argument for acceptability of drug interaction profile
	  • Feasibility of cGMP manufacture & CMC information relevant to clinical trial supplies
	  • Previous human exposure (if available)
	  • Argument for acceptability of clinical dosage form
	  • Clinical proof of concept plan
	  • Proposed clinical trial protocols
	• Application package aligned with agency requirements
	• Confirmation of application receipt by FDA / NRA
		▪ Notification of submission date

▪ US IND application response (if any) or similar NRA application approved	• If filed with US FDA, confirmation that no response from the US FDA was received within 30 days after the agency's receipt of the IND application • No response confirmation and/or approval confirmation from other NRAs as required for their clinical trials applications • Ethics Committee action	▪ Notification of Regulatory Authority response (if any) and any impact to timeline or study design