END OF PHASE 1 MEETING SCHEDULED

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Gain concurrence with Regulatory Authority on Phase 2 study design.

End of Phase 1 Meeting (if needed) with FDA/ other NRAs (if applicable) completed.
(*Specific communication requirements of NRAS should be identified upon initiation of the Regulatory Strategy Plan, if pre-IND meeting (or similar NRA meeting) includes a discussion of Phase 2 plans and there is certainty in the path forward/ no protocol adjustments needed based on Phase 1 data / nop regulatory requirement, there may not be a need to conduct a formal End of Phase 1 Meeting with NRAS)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Data package necessary for End of Phase 1 meeting completed, endorsed, and submitted to NRA	a) Summary of Phase 1 trial results b) Design and scope of Phase 2 study protocol (including study plans, medical monitoring plans, timelines budgets, if required by NRA) c) Proposed clinical development path (e.g. request to use alternate development/authorization pathways (e.g., conditional approval, accelerated, approval, breakthrough designation, orphan designation) and rationale d) Plans for additional nonclinical studies (if any) e) Plans for pediatric studies (including a timeline for protocol finalization, enrollment, completion, and data analysis, or information to support any planned request for waiver or deferral of pediatric studies)	▪ End of Phase 1 briefing package
▪ End of Phase 1 meeting outcomes summarized and development plan modified (if needed)	a) Meeting minutes developed by sponsor and also received from NRA (if possible) with documentation on agreements achieved and agreed next steps/actions in End of Phase 1 meeting b) Revised Phase 2 study protocol c) Revised plans for nonclinical studies, pediatric studies, etc.	▪ Regulatory responses to questions