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)

<table>
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<tr>
<th>CRITERIA</th>
<th>SAMPLE CONTENT REQUIREMENT</th>
<th>GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE</th>
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| ▪ 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 |