

END OF PHASE 2 MEETING PLANNED OR SCHEDULED*

Goals/ Definitions

Gain concurrence with Regulatory Authority on Phase 3 study design.

End of Phase 2 Meeting with NRAs (if applicable) completed.

(*Specific communication requirements of NRAs should be identified upon initiation of the Regulatory Strategy Plan)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> ▪ Data package necessary for End of Phase 2 meeting completed and submitted to NRA 	<ul style="list-style-type: none"> a) Summaries of Phase 1/2 trial results b) Design and scope of Phase 3 study protocol (including study plans, medical monitoring plans, timelines and, if required by NRA, budgets) c) Plans for any additional nonclinical studies d) Review/update plans for pediatric studies (including a time line for protocol finalization, enrollment, completion, and data analysis, or information to support any planned request for waiver or deferral of pediatric studies) e) Identification of relevant product issues (i.e., plans to manufacturing scale-up to produce product for commercial scale and the need for comparability testing relative to the product used in Phase 1/2 clinical studies) f) Planned label, especially highlighting desired wording for indications (s) and any safety claims desired to make <p>If a Special Protocol Assessment agreement is desired (US specific), also requires:</p> <ul style="list-style-type: none"> a) Detailed protocol design (i.e., proposed size, power calculation, choice of study endpoints, choice of control, duration, methods of assessment) b) Data analysis plan c) Role of the study in the overall development plan 	<ul style="list-style-type: none"> ▪ End of Phase 2 briefing package
<ul style="list-style-type: none"> ▪ End of Phase 2 meeting outcomes summarized and development plan modified (if needed) 	<ul style="list-style-type: none"> a) Meeting minutes prepared by sponsor and shared with NRA; get NRA minutes (if possible). Document agreements achieved and next steps/actions agreed at end of Phase 2 meeting b) Revised Phase 3 study protocol c) Revised plans for nonclinical studies or pediatric studies 	<ul style="list-style-type: none"> ▪ Regulatory responses to questions