RUN CLINICAL PROGRAM (4/7)

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Obtain an early read-out on the Phase 3 (if applicable) that may enable acceleration of regulatory submission.

Phase 3 interim analysis completed (preferably by independent committees).

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Safety assessment completed	a) Rate of severe adverse events (SAEs)	▪ Interim clinical study report
▪ Efficacy assessment completed	a) Statistically significant efficacy	▪ As above
▪ Futility assessment (inability of trial to meet its objectives) completed	a) Futility of trial effects (unlikely to achieve statistical significant efficacy) b) Operational futility (i.e., poor execution, lack of adequate resources, low adherence, poor quality of data)	▪ As above
▪ Clinical trial strategy adjustment (if needed)	a) Sample size re-adjustment b) Additional testing requirements	▪ Updated IPDP
▪ TPP achievement assessed	a) Probability assessment of whether candidate will meet target product profile	▪ Use cTPP template