CONCEPT SCREENING AND IDENTIFICATION

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

To define and select device concept(s) for drug-device combination product candidate with viable capability to meet the TPP

Concept(s) generated based on based on initial market and user needs and TPP.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Hazard identification initiated	a) Use related hazard analysis and assessment, either by application of analytical techniques or by user-based evaluations b) Evaluation of prototype (if prototype is available) c) Potential risk mitigation strategies that may be employed given the product concept and application	▪ Summary of key data / information or information to substantiate conclusions ▪ Illustrative data tables or figures may be reported in an appendix
▪ Concept assessed	a) Evaluation of whether TPP goals can be achieved with an already approved device. If not, definition of the product concept(s) and "proof" that this product, as defined, can be developed and manufactured (based on early testing and existing product data) b) High level assessment of manufacturing capability (changes/new) needed and data suggesting that COGS target can be met c) Anticipated technical risks (high level) and how CMC Development plan for FIH stage gate addresses these risks	

*Candidate progression is discussed at standing grantee update meetings with the investment team