

Goals/ Definition

Business case for developing a deliverable product.

Business Case, deliverability assessment, strategic demand forecast and COGS reports and cost effectiveness report.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> ▪ Delivery Plan 	<ul style="list-style-type: none"> • The delivery plan will summarize: <ul style="list-style-type: none"> • Completed regulatory dossier ready for submission • Production/manufacturing supply chain and user targeting • Frequency and mode of delivery, e.g., special handling • Roll out plans for first-wave countries • Country decision support plans that verify capacity, resources, and new technologies for introduction • Considerations around global and country awareness of the intervention • Comparators with current standard of care • Patient access and perception of value and economics • Progress of government partnerships • Assessment of implementation capabilities and gaps • Provider-related issues, e.g., workflow and training • Coverage tracker metrics 	<ul style="list-style-type: none"> ▪ Summary report