

Goals/ Definitions

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"> ▪ Business Case 	<ul style="list-style-type: none"> • Business case provides overview of product candidate’s strategic value and market viability, including: <ul style="list-style-type: none"> • Value proposition against foundation’s disease strategy and other interventions in market • Estimate of overall costs to launch and drive uptake • Summary of market understanding (e.g., size, segments, user needs, etc.) 	<ul style="list-style-type: none"> ▪ Provide key assumptions and rationale for business case
<ul style="list-style-type: none"> ▪ Deliverability Assessment 	<ul style="list-style-type: none"> • A deliverability assessment will provide a high-level assessment of risks and opportunities for: <ul style="list-style-type: none"> • Improvement relative to standard of care • Considerations around the global and country awareness of the intervention, possibility of financing, • Global policy and regulatory pathway • Supply chain and user targeting • Frequency and mode of delivery and any special handling required • Novelty relative to existing products • Manufacturing considerations • Provider-related issues including workflow and training (ex: maintenance and calibration) • Patient access, perception of value and economics • Disease risk awareness in population 	<ul style="list-style-type: none"> ▪ Summary report