

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/ MILESTONE EXPECTATIONS	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