

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/ 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
<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

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CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> Strategic Demand Forecast 	<ul style="list-style-type: none"> Methodology to be used to assess potential demand adjusted for product availability, country introduction decisions, uptake timing (without any supply or financing constraints) BMGF provides a methodology grantees may use for demand forecasting Demand forecast methods should align with to the BMGF valuation model (in Integrated Portfolio Management tool) 	<ul style="list-style-type: none"> BMGF provides methodology
<ul style="list-style-type: none"> COGS 	<ul style="list-style-type: none"> Methodology to be used to build up COGS over the course of product development During FIH, an initial aspirational COGS should be set to drive TPP and goals for projected costs related to the product 	<ul style="list-style-type: none"> BMGF provides methodology
<ul style="list-style-type: none"> Cost-Effectiveness Analysis 	<ul style="list-style-type: none"> Methodology to be used to assess drivers of health and economic outcomes and interventions/product candidates BMGF provides a methodology grantees may use for cost-effectiveness analysis Cost-effectiveness methods should align with to the BMGF valuation model (in Integrated Portfolio Management tool) 	<ul style="list-style-type: none"> BMGF provides methodology