



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



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<ul style="list-style-type: none"> Strategic Demand Forecast 	<ul style="list-style-type: none"> An initial, high-level demand forecast will identify: <ul style="list-style-type: none"> Target countries Target sub populations Timing of introduction specific to identified countries 	<ul style="list-style-type: none"> BMGF provides methodology
<ul style="list-style-type: none"> COGS 	<ul style="list-style-type: none"> An initial, high-level COGS analysis at EP1 will identify: <ul style="list-style-type: none"> Key cost drivers Cost estimate assumptions for equipment needed, processes Projected price (within 30% of TPP target) 	<ul style="list-style-type: none"> BMGF provides methodology
<ul style="list-style-type: none"> Cost-Effectiveness Analysis 	<ul style="list-style-type: none"> An initial, high-level cost-effectiveness analysis will identify: <ul style="list-style-type: none"> Anticipated health and economic benefits of the product Projected health and economic costs to achieve the benefits Comparisons to existing standards of care 	<ul style="list-style-type: none"> BMGF provides methodology