



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