



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"> 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