

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