

Goals / Definition

Business case for developing a deliverable product.

Identification of commercial partner(s) for launch and full-scale manufacturing of the product.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> ▪ Deliverability Assessment 	<p>The delivery plan will summarize:</p> <ol style="list-style-type: none"> a) Regulatory plan and first-wave country partners b) Production/manufacturing partners with projected product price, volume, and revenue c) Country supply chain and user targeting methodology d) Roll-out plans for first-wave countries e) Country decision support plans that verify capacity, resources, and new technologies for introduction f) Global policy and initiative opportunities/partnerships g) Benefits over current standard of care h) Global policy milestones and pathway identified to reach critical registration (i.e., PQ, EMA) 	<ul style="list-style-type: none"> ▪ Summary report
<ul style="list-style-type: none"> ▪ Strategic Demand Forecast 	<p>The demand forecast at EP2 will include:</p> <ol style="list-style-type: none"> a) Target countries for introduction b) Target populations/sub-populations c) Timing and speed of introduction specific to identified countries d) Product accessibility and availability e) Predicted coverage rate f) Expected volumes and pricing g) Sensitivity analysis based on key assumptions and drivers of forecast 	<ul style="list-style-type: none"> ▪ BMGF provides methodology

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<ul style="list-style-type: none"> ▪ COGS 	<p>A COGS analysis at EP2 will identify:</p> <ul style="list-style-type: none"> a) Product price, volume, and revenue based on commercial scale production b) Variable and fixed costs for R&D, facilities, equipment, labor, and raw materials c) Licensing expenses and incomes d) Grants, loans and outstanding debts related to the product e) Related product sales f) 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 	<p>A cost-effectiveness analysis at EP2 will identify:</p> <ul style="list-style-type: none"> a) Limitations of economic evaluations performed b) Comparators and mean costs and effects of the product and the competitor c) Cost and effects of the product on sub-populations d) Groups that may be disproportionately impacted positively or negatively 	<ul style="list-style-type: none"> ▪ BMGF provides methodology
<ul style="list-style-type: none"> ▪ Launch Budget Prediction 	<p>The first iteration of the launch budget prediction will include:</p> <ul style="list-style-type: none"> a) An estimate of the scale of launch support and budget for successful uptake b) Detailed budget for pre-launch activities 	<ul style="list-style-type: none"> ▪ Draft launch budget