

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

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<ul style="list-style-type: none"> <li>COGS</li> </ul>	A COGS analysis at EP2 will identify: <ul style="list-style-type: none"> <li>a) Product price, volume, and revenue based on commercial scale production</li> <li>b) Variable and fixed costs for R&amp;D, facilities, equipment, labor, and raw materials</li> <li>c) Licensing expenses and incomes</li> <li>d) Grants, loans and outstanding debts related to the product</li> <li>e) Related product sales</li> <li>f) Projected price (within 30% of TPP target)</li> </ul>	<ul style="list-style-type: none"> <li>BMGF provides methodology</li> </ul>
<ul style="list-style-type: none"> <li>Cost-Effectiveness Analysis</li> </ul>	A cost-effectiveness analysis at EP2 will identify: <ul style="list-style-type: none"> <li>a) Limitations of economic evaluations performed</li> <li>b) Comparators and mean costs and effects of the product and the competitor</li> <li>c) Cost and effects of the product on sub-populations</li> <li>d) Groups that may be disproportionately impacted positively or negatively</li> </ul>	<ul style="list-style-type: none"> <li>BMGF provides methodology</li> </ul>
<ul style="list-style-type: none"> <li>Launch Budget Prediction</li> </ul>	The first iteration of the launch budget prediction will include: <ul style="list-style-type: none"> <li>a) An estimate of the scale of launch support and budget for successful uptake</li> <li>b) Detailed budget for pre-launch activities</li> </ul>	<ul style="list-style-type: none"> <li>Draft launch budget</li> </ul>