

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"> ▪ COGS 	A COGS analysis at EP2 will identify: <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 	A cost-effectiveness analysis at EP2 will identify: <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 	The first iteration of the launch budget prediction will include: <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