GLOBAL DRUG DEVELOPMENT

Goals/ Definition

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

▪ Delivery Plan	• The delivery plan will summarize:
	   • Completed regulatory dossier ready for submission
	   • Production/manufacturing supply chain and user targeting
	   • Frequency and mode of delivery, e.g., special handling
	   • Roll out plans for first-wave countries
	   • Country decision support plans that verify capacity, resources, and new technologies for introduction
	   • Considerations around global and country awareness of the intervention
	   • Comparators with current standard of care
	   • Patient access and perception of value and economics
	   • Progress of government partnerships
	   • Assessment of implementation capabilities and gaps
	   • Provider-related issues, e.g., workflow and training
	   • Coverage tracker metrics
		▪ Summary report

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▪ Strategic demand Forecast	• The demand forecast will include refined iterations of : • Target countries for introduction • Target populations/sub-populations • Timing and speed of introduction specific to identified countries • Product accessibility and availability • Predicted coverage rate • Expected volumes and pricing • Sensitivity analysis based on key assumptions and drivers of forecast	▪ BMGF provides methodology
▪ COGS	• The COGS analysis will include refined iterations of: • Product price, volume, and revenue based on commercial scale production • Variable and fixed costs (for all areas in COGS methodology) • Licensing expenses and incomes • Grants, loans and outstanding debts related to the product • Related product sales • Expected price, aligned with TPP & BMGF strategy • Initial allocation and partner negotiation around shared and indirect costs	▪ BMGF provides methodology

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▪ Cost-effectiveness analysis	The cost-effectiveness analysis will include refined iterations of: 1. Limitations of economic evaluations performed 2. Comparators and mean costs and effects of the product and the competitor 3. Cost and effects of the product on sub-populations 4. Groups that may be disproportionally impacted positively or negatively Note: Additional inputs expected from Delivery team	▪ BMGF provides methodology
▪ Launch Budget Prediction	The refined launch budget prediction will provide: 1. A detailed and accurate estimation of the scale of launch support and budget for successful uptake	▪ Refined launch budget
▪ Coverage and Financial Tracker	The first iteration of the coverage and financial tracker should: 1. Develop target metrics for number of countries launched, coverage, average procurement price, and incremental costs to deliver *At PQ/LR these metrics should be refined.	▪ Draft target metrics