

Goals/Definitions

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> <ul 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