

## 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
<ul style="list-style-type: none"><li>▪ Delivery Plan</li></ul>	<ul style="list-style-type: none"><li>• The delivery plan will summarize:<ul style="list-style-type: none"><li>• Completed regulatory dossier ready for submission</li><li>• Production/manufacturing supply chain and user targeting</li><li>• Frequency and mode of delivery, e.g., special handling</li><li>• Roll out plans for first-wave countries</li><li>• Country decision support plans that verify capacity, resources, and new technologies for introduction</li><li>• Considerations around global and country awareness of the intervention</li><li>• Comparators with current standard of care</li><li>• Patient access and perception of value and economics</li><li>• Progress of government partnerships</li><li>• Assessment of implementation capabilities and gaps</li><li>• Provider-related issues, e.g., workflow and training</li><li>• Coverage tracker metrics</li></ul></li></ul>	<ul style="list-style-type: none"><li>▪ Summary report</li></ul>