

Goals/Definitions

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/ MILESTONE EXPECTATIONS | GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE |
|---|---|--|
| <ul style="list-style-type: none"> ▪ Deliverability Assessment | <ul style="list-style-type: none"> • A deliverability assessment will provide a high-level assessment of risks and opportunities for: <ul style="list-style-type: none"> • Improvement relative to standard of care • Considerations around the global and country awareness of the intervention, possibility of financing, • Global policy and regulatory pathway • Supply chain and user targeting • Frequency and mode of delivery and any special handling required • Novelty relative to existing products • Manufacturing considerations • Provider-related issues including workflow and training (ex: maintenance and calibration) • Patient access, perception of value and economics • Disease risk awareness in population | <ul style="list-style-type: none"> ▪ Summary report |