

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"> ▪ Cost-Effectiveness Analysis | <p>A cost-effectiveness analysis at EP2 will identify:</p> <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 |