

## 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<br>DETAIL NEEDED AT EACH<br>GATE              |
|--|---|---|
| <ul style="list-style-type: none"><li>▪ Launch Budget Prediction</li></ul> | The first iteration of the launch budget prediction will include: <ul style="list-style-type: none"><li>a) An estimate of the scale of launch support and budget for successful uptake</li><li>b) Detailed budget for pre-launch activities</li></ul> | <ul style="list-style-type: none"><li>▪ Draft launch budget</li></ul> |