

## Goals / Definition

Rationale and justification for selection of commercial partner.

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"> <li>▪ Partner (commercial, government, non-profit, etc.) assessments to determine the fit for collaboration completed</li> </ul>	<ul style="list-style-type: none"> <li>a) Respective expectations and business model (i.e., pricing of drug pricing upon licensure, IP control, etc.)</li> <li>b) Mid- to long-term strategic fit (i.e., intent for pursuit of the product over mid/long term to ensure the viability of the product development and partnership)</li> <li>c) Assess whether the NRA in the manufacturer’s country is considered a functional NRA by the WHO</li> <li>d) Identify timing of decision points where contingency plan needs to be triggered if suitable commercial partner is not selected</li> </ul>	<ul style="list-style-type: none"> <li>▪ Summary of key data and rationale to support partner selection</li> <li>▪ Additional detail may be reported in an appendix</li> </ul>