

## Goals/ Definitions

**Candidate Target Product Profile Agreed.**

**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>Updated cTPP with further details</li></ul> | <ul style="list-style-type: none"><li>a) Indication, use case, and target population</li><li>b) Global health impact</li><li>c) Proposed mechanism of action</li><li>d) Primary endpoints and secondary endpoints</li><li>e) Manufacturability</li><li>f) Formulation, dosing, and stability</li><li>g) Route of administration</li><li>h) Shelf-life and storage</li><li>i) Cost and delivery considerations</li><li>j) Product registration strategy</li></ul> | <ul style="list-style-type: none"><li>Use cTPP template – should reflect the desired Intervention TPP (iTPP)</li></ul> |