Goals/ Definitions

Candidate Target Product Profile Agreed.

Identification of commercial partner(s) for launch and full-scale manufacturing of the product.

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>SAMPLE CONTENT REQUIREMENT</th>
<th>GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE</th>
</tr>
</thead>
</table>
| Updated cTPP with further details | a) Indication, use case, and target population  
   b) Global health impact  
   c) Proposed mechanism of action  
   d) Primary endpoints and secondary endpoints  
   e) Manufacturability  
   f) Formulation, dosing, and stability  
   g) Route of administration  
   h) Shelf-life and storage  
   i) Cost and delivery considerations  
   j) Product registration strategy | Use cTPP template – should reflect the desired Intervention TPP (iTPP) |