Goals/ Definition

Safety, efficacy, and desired outcomes in humans demonstrated in pivotal trial.

Safety, efficacy, and desired outcomes in humans (full analysis) demonstrated.

<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>
| ▪ Safety (includes clinical and laboratory abnormalities) profile of candidate aligns with TPP | Satisfactory safety profile using validated clinical endpoint assays and adequate statistical analyses:  
   a) Safety signal detection (e.g., adverse events (AEs) which may include serious adverse events (SAEs))  
   b) Fully characterized drug-drug interactions  
   c) Management of any adverse events (reporting of the events to the applicable ethical committees and regulatory agencies) | ▪ Summary of Phase 3 clinical trial data |
| ▪ Efficacy profile of candidate aligns with TPP | Clinical efficacy demonstrated using validated clinical endpoint assays and adequate statistical analyses:  
   1) Sufficient efficacy duration to achieve impact  
   2) Superiority or non-inferiority data in comparative studies against licensed drug (or treatment) control (if applicable) | ▪ Summary of Phase 3 clinical trial data |
| ▪ Other TPP characteristics met | Assessment of whether candidate meets target product profile | ▪ Use cTPP template |