

Goals/ Definition

Track availability of clinical trial data for decision making.

Track the availability of top line results that enable real-time discussions of clinical trial data analysis and earlier investment decisions.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none">Statistical analyses using preliminary or final data are completed	<ul style="list-style-type: none">a) Pharmacokinetic and pharmacodynamics (PK/PD) analyses of data completedb) Comparison of the observed results to the minimum criteria in the candidate TPPc) Working data sets deliveredd) Tables, listings, figures produced to support topline report writing	<ul style="list-style-type: none">Notification of milestone achievement, any delay, mitigations and revised timeline