

## 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"><li>Statistical analyses using preliminary or final data are completed</li></ul>	<ul style="list-style-type: none"><li>a) Pharmacokinetic and pharmacodynamics (PK/PD) analyses of data completed</li><li>b) Comparison of the observed results to the minimum criteria in the candidate TPP</li><li>c) Working data sets delivered</li><li>d) Tables, listings, figures produced to support topline report writing</li></ul>	<ul style="list-style-type: none"><li>Notification of milestone achievement, any delay, mitigations and revised timeline</li></ul>