

## Goals/ Definitions

Track that enrolment in the clinical trial is proceeding according to plan.

Track the progress and feasibility of Phase 3 clinical trials.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"><li>Track recruitment and budget by comparing actual patient enrollment to previously established benchmarks at 25% of the projected recruitment period</li></ul>	<ul style="list-style-type: none"><li>a) Conduct recruitment analysis and report number of patients recruited and budget within 25% of the projected recruitment period</li><li>b) If suboptimal recruitment is identified, submit an analysis of recruitment barriers and a corrective recruitment plan with revised budget and timeline</li><li>c) If recruitment levels are below minimum acceptable levels: evaluate feasibility to complete study within acceptable budget or timeframe and submit corrective recruitment plan</li></ul>	<ul style="list-style-type: none"><li>Notification of milestone achievement, any delay, mitigations and revised timeline</li></ul>