

Goals/ Definitions

Track clinical trial start date.

Track the dosing of the first subject enrolled thereby indicating the beginning of the clinical trial.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none">Track first dosing event for a patient recruited to the Phase 3 clinical trial	<ul style="list-style-type: none">a) Conduct recruitment analysis and compare study starts to the clinical planb) Inform impact on other planned downstream activities in the case of study start delays	<ul style="list-style-type: none">Notification of date first subject dosed and any delay, if incurred