

Trial Status Information

Status Updates

For CTEP-supported trials using the CTSU, all trial statuses except Administratively Complete must be set by lead protocol organization (LPO) in the CTSU Protocol application (<https://protocol.ctsu.org/>). LPOs should update statuses in the CTSU Protocol application in a timely manner. For trials that are under LPO IND or are IND exempt, the LPOs are also responsible for updating the ClinicalTrials.gov record within 30 calendar days of the change.

To ask for a trial status to be set to Administratively Complete or update the status for a study not using the CTSU, contact the appropriate Protocol and Information Office (CTEP or DCP PIO).

Status Mapping, Definitions, and Implications

CTEP Status	CT.gov Status	CTEP Definition	Implications
Active	Recruiting	Trial is open to accrual.	<ul style="list-style-type: none"> ▪ Prior to setting a trial to active status, the LPO must attest in the CTSU Protocols application that all start-up activities are complete. System will check for IRB approval.
Temporarily Closed to Accrual	Suspended	Trial is temporarily not accruing. Must select: <ul style="list-style-type: none"> ▪ Scheduled interim monitoring ▪ Unacceptable toxicity ▪ Drug Supply ▪ Other (specify): 	<ul style="list-style-type: none"> ▪ No new participant enrollments permitted in OPEN in this status ▪ Status may be set back to Active and the trial can continue enrollment ▪ Participants continue to receive therapy / intervention
Temporarily Closed to Accrual and Treatment	Suspended	Trial is temporarily not accruing and participants are not receiving therapy / intervention. Must select: <ul style="list-style-type: none"> ▪ Scheduled interim monitoring ▪ Unacceptable toxicity ▪ Drug Supply ▪ Other (specify): 	<ul style="list-style-type: none"> ▪ No new participant enrollments permitted in OPEN in this status ▪ Status may be set back to Active and the trial can continue enrollment ▪ Participants must stop therapy / intervention
Closed to Accrual	Active, Not Recruiting	The study is closed to accrual. Participants are still receiving trial therapy / intervention. Must select: <ol style="list-style-type: none"> 1) Study has 90% of projected total accrual OR Recommended Phase 2 Dose (RP2D) established, OR 	<ul style="list-style-type: none"> ▪ No new participant enrollments will be permitted in OPEN ▪ Participants are still receiving trial therapy / intervention ▪ Status may not be set back to Active

CTEP Status	CT.gov Status	CTEP Definition	Implications
		2) Study has less than 90% of projected total accrual or RP2D not established. Must select: <ul style="list-style-type: none"> ▪ Interim monitoring ▪ Drug supply issues ▪ Inadequate accrual rate ▪ External information ▪ Unacceptable toxicity ▪ Other (specify): 	
Closed to Accrual and Treatment	Active, Not Recruiting	The trial is closed to accrual. All participants have completed therapy / intervention, but participants are still being followed according to the primary objectives of the study. No additional investigational agents are needed for this study.	<ul style="list-style-type: none"> ▪ Can only be set after a trial has reached Closed to Accrual Status ▪ All trial participants are off trial therapy / intervention ▪ Status may not be set back to Active
Complete	Active, Not Recruiting	The trial is closed to accrual, all participants have completed therapy, and the trial has met its primary objectives.	<ul style="list-style-type: none"> ▪ IND can be withdrawn ▪ Trial team can still access data ▪ CIRB continuous review can still occur for long term follow up and analysis of identifiable data/biospecimens
FDAAA/IRB Complete	Completed	The trial has concluded normally; participants are no longer being examined (including any long-term follow-up) or treated (i.e., last participant's last visit has occurred) and analysis of data has been completed.	<ul style="list-style-type: none"> ▪ No further analysis of identifiable data/biospecimens as part of study ▪ Trial is closed at CIRB ▪ All patients set to off study in RSS ▪ Removal of site access to Rave
Administratively Complete	Terminated	The trial has been completed prematurely (e.g., due to poor accrual, insufficient drug supply). The trial is closed to further accrual and all participants have completed trial treatment. Terminal status in lieu of "Complete" or "FDAAA/IRB Complete".	<ul style="list-style-type: none"> ▪ LPO must ask PIO to set this status ▪ IND can be withdrawn ▪ Results reporting to CT.gov still must occur if ≥ 1 participant was accrued ▪ No further analysis of identifiable data/biospecimens as part of trial ▪ trial is closed to CIRB ▪ All patients set to off study in RSS ▪ Removal of site access to Rave