

Early Phase Trial Slow Accrual Guidelines

CTEP has implemented slow accrual guidelines for phase I, I/II, and II trials it supports. This notice will serve to update the early phase slow accrual guidelines and should serve as minimum accrual expectations for all early phase trials, whether or not they are conducted under a CTEP IND. At the LOI/Concept stage, CTEP and study investigators must agree upon realistic projected accrual rates, as trials may be terminated if the agreed upon accrual projections at the time of study approval are not met.

Early Phase Trial Monitoring

- Studies will be monitored for accrual starting with completion of Quarter 2 until study closure. A Corrective Action Plan (CAP) request will be issued if the study is accruing less than 50% of the projected accrual rate during active enrollment (excluding time closed for toxicity evaluation for Phase I trials).

Corrective Action Plan Reassessment for Early Phase Trials

- Once the CAP is received, it will be reviewed by IDB/CIB Branch Chiefs and other CTEP staff. If CTEP staff concurs with the CAP, the site will be notified and study accrual monitored and reevaluated after a specified reassessment timeframe, typically six (6) months.
 - A study will be allowed to continue if its projected quarterly accrual rate is at least 75% of projected during the reassessment timeframe. Accrual will continue to be monitored monthly, and a CAP may be issued again should the accrual fall below 50% of the projected accrual rate.
 - A study will be considered for administrative closure if it has not reached 75% of its planned enrollment at the end of the reassessment timeframe.
- If closure of a study is necessary, an administrative closure memo will be sent to the site and CTEP will administratively close the study on the date specified in the closure memo.