

CTEP-Sponsored Cooperative Group Phase III trials: Early Stopping Guidelines for Slow Accruing Trials

The following guidelines are stated in terms of percentage of projected accrual during given quarter(s). For example, quarter 5-6 accrual is the number of patients enrolled on trial during quarters 5 and 6 after activation divided by the number of patients that were projected to be enrolled in that period based on the accrual rate specified in the protocol design.

Guidelines:

If quarter 5-6 accrual is:

≤ 20% of projected, then stop the trial

<50% and >20% of projected, then the study team is given 6 months to improve accrual. If the average accrual rate in quarter 8 is below 50% then the trial will have to be amended to reflect actual accrual. The implications of this new accrual rate on study relevance and feasibility should be discussed in the proposed amendment.

Implementation

The Group statistical office will provide to the Group Chair and the CTEP Clinical Investigations Branch Chief the average accrual for quarters 5 and 6 (and the projected accrual from the protocol) as soon as they become available. The Group Chair will close the trial or notify the investigators that they have another six months to improve accrual according to the guidelines described above. For trials that are closed or amended, the Group will notify the Group Data Monitoring Committee of the closure or amendment at their next regularly scheduled meeting. Group Chairs may consult with their DSMC in the early closure decision if so desired. In the unusual circumstance that the Group Chair believes that the guidelines are inappropriate for the given trial, he or she will initiate a discussion with the Cooperative Group Program Officer (CIB Branch Chief for Adult Groups or CIB Pediatric Section Head for COG) to reach a joint decision concerning what to do about the trial.

These guidelines apply only to the trials that have not had a formal interim efficacy analysis presented to the DSMC before the end of the 6th quarter from study activation.

These guidelines apply to all randomized CTEP-sponsored Cooperative Group phase III trials that were activated after April 1, 2004.