

CORRECTIVE ACTION PLAN (CAP) CODE SHEET

Study Information: Protocol Number:

Protocol Title:

P.I.:

Lead Organization:

Trial Activation Date:

Accrual Information:

Planned accrual rate: patients per month; minimum, maximum

Enrollment to date: patients as of

Pattern of accrual:

To be completed by investigators:

Accrual Status

- If applicable, please provide the accrual status of each arm/cohort.

- If an interim analysis is planned, how many additional patients will be needed to reach that point and when might the interim analysis occur? (use the box below)
- If an interim analysis was recently completed, please discuss the results. (use the box below)

Assessment of Accrual Challenges

Based on a recent analysis of corrective action plans, CTEP has developed the following categories on the next two pages to track slow accrual reasons and corrective actions to be taken. **Please complete the following two pages for your trial.**

EARLY PHASE SLOW ACCRUAL REASONS

Instructions: Please use the following categories to indicate (via the checkboxes) the top reason(s) contributing to slow accrual to your trial. **Check no more than 5 boxes** on this page.

Eligibility

Strict eligibility criteria
Rare disease
High rate of screen failures

Safety/Toxicity

DLTs leading to dose reduction
FDA holds or amendments
Required CAEPR/ RRA/Action Letter
Pre-specified halt to enrollment (e.g., interim analyses, stopping rules, DMC, or RP2D)
Enrollment slowed (but not stopped) due to safety observation periods/safety run-in

Institutional/PI/administrative

Staffing/management/operational issues
Competing trials at institution(s)
Institutional scientific review
Site-initiated amendment(s)
Low rate of patient referrals to trial

Site Activation Delays

Delays with CIRB approval
Delays with local IRB approval
Delays with site activation at planned sites
Planned site(s) not activated or were removed
Trial open at too few or a limited number of institutions (limiting population access)

Study design/protocol

Trial complexity
Treatment schedule or procedures causing undue patient burden or trial delay

Environment/external issues

Newly approved drugs for diseases
Changes in standard of care

Drug supply

Lack of available drug supply
Drug discontinued
Company withdrew/ not willing to supply drug

Budget/insurance issues

Loss of study funding
Study procedures or drug not covered
Low reimbursement rate

CTEP administrative issues

CTEP request to halt enrollment
CTEP amendment request (not safety related)

Other (not listed above): (specify):

EARLY PHASE CORRECTIVE ACTIONS TO ADDRESS SLOW ACCRUAL

Instructions: Please use the following categories to indicate (via the checkboxes) the proposed corrective actions that you will be taking to address slow accrual to your trial. Multiple responses are acceptable, but only mark those actions you expect to **implement in the next 6 months.**

Addressing eligibility concerns

Broaden eligibility criteria

Broaden patient screening activities (by study team) to identify eligible patients

Addressing institutional/PI/administrative concerns

Increase study team review processes, meetings, conference calls around trial

Increase/change staffing

Change administrative processes (e.g., streamlining, increase efficiencies)

Close competing trial(s)

Addressing site activation delays

Activate/ receive IRB approval at planned participating institutions

Open at new institution(s) beyond those proposed in the protocol. If so, how many sites? Number of sites

Open network/group-wide

Place on CTSU

Addressing study design/protocol concerns

Amend the treatment design (i.e. decrease toxicity, statistical design, or revise schema). Please describe the proposed amendment in the box below.

Addressing budget/insurance concerns

Increase per case funding

Obtain additional funding

Promotion of trial

External (i.e., reach out to doctors or other cancer centers in your community to increase referrals)

Internal (i.e., promote trial within your own center/organization)

Group wide (i.e., promote across ETCTN)

Increase awareness through advocacy groups and professional societies

Other (not listed above)

Specify:

ADDITIONAL COMMENTS TO ADDRESS EARLY PHASE SLOW ACCRUAL

Instructions: Please use the space below to provide CTEP any additional comments you may want to add in relation to slow accrual.