

When a clinical trial closes unexpectedly

Although it is rare, a sponsor may unexpectedly halt the investigation of a new compound before studies are complete. Knowing the correct closure procedures in advance enables site workers to be ready to protect the safety – and continued motivation – of the volunteers.

Early trial terminations affect both the study and the study subjects. Site workers have to handle activities for all study subjects within a short time frame. Volunteers may miss out on a beneficial treatment; they may be concerned about their health if the drug has been found to be unsafe, and completing the study early can be inconvenient.

Communicating well with the sponsor and with the study subjects will ensure a reasonable resolution to an unexpected clinical trial termination.

CISCRP is offering a new brochure that tells site personnel how to properly conclude a clinical trial that has been terminated unexpectedly. To receive a copy of the brochure, please write to info@ciscrp.org.

When an early site closure occurs, the site director and personnel should ask:

- Is the study being closed for safety reasons?
- Do the subjects need to have their study medication tapered, or can it be withdrawn abruptly?

If the study is being closed for safety reasons, clinical trials personnel must contact the subjects immediately, tell subjects to stop their drug, and schedule them for a visit to return their unused drug and complete necessary final evaluations, lab tests, etc.

If the subjects' drugs need to be tapered off at the end of their use, this drug-dependent situation needs to be addressed. Clinicians will need to schedule all study subjects for a visit to explain and start the taper period.

Site personnel can make the closing process smoother by using a checklist of activities to perform when a trial is terminated early. Start with the basic checklist at right:

CHECKLIST OF ACTIVITIES FOR UNEXPECTED SITE CLOSURE

- ✓ **Ask the sponsor:**
 - Why the trial is being terminated
 - Is it for safety reasons?
 - Determine the need for any long term safety follow-up
- ✓ **Determine if subjects can have the drug stopped abruptly or does it need to be tapered.**
- ✓ **Arrange for the necessary time and personnel to handle the subject discontinuation visits**
- ✓ **Contact (telephone) each study subject:**
 - Explain why the trial is being stopped
 - Explain any safety concerns, and tell what is being done to ensure the subject's safety
 - Describe the process for tapering the drug, if applicable
 - Explain the need to come in for a final study visit and for any necessary tests, etc.
 - Reassure the subjects that their safety is of paramount importance
 - Schedule the discontinuation visit(s) for each subject
- ✓ **Complete the necessary study visit(s) for each subject.**
 - Answer any questions about the study and/or the termination
 - Thank the subjects for participating
- ✓ **Complete the final case report forms according to the sponsor's instructions.**
- ✓ **Stay in contact with the sponsor** throughout the closure process to ensure that all activities are completed and that any subject-specific concerns are addressed
- ✓ **Remember to complete all the usual study closure activities, including:**
 - Completion of case report forms (CRFs), including error corrections and data queries appropriate review, filing, and storage of all study documents
 - Return any unused study drug or materials to sponsor
 - Submission of a final report to the sponsor and to the IRB.