

CTRP Quick Start Guide

Step 1

Decide whether your organization's interventional trials need to be reported

- **Has the trial already been reported to NCI through its Cancer Therapy Evaluation Program (CTEP) or the Division of Cancer Prevention (DCP)?**

If yes, you do **not** have to register the trial with CTRP. NCI will transfer data for this trial to CTRP.

- **Is your organization an NCI-Designated Cancer Center that is not a CTRP original site?**

You are scheduled to begin registering new interventional trials beginning July 1, 2009

- **Are you a grantee who is not at an NCI-Designated Cancer Center?**

You are scheduled to begin registering new interventional trials on October 1, 2009

Step 2

Gather Required Information

Before you begin to register your trials with CTRP, it will be helpful to gather the following information for each trial:

- Lead Organization Trial Identifier
- Trial Title, Type, Phase, Purpose (prevention, treatment, diagnostic)
- Lead Organization and Principal Investigator
- Sponsor / Responsible Party
- Summary 4 Information (Funding Category and Funding Sponsor)
- Status and Status Date (Study Start and Completion Date)
- NIH Grant Information (Funding Mechanism, Institute Code, Serial Number, NCI Division or Program Code)
- IND/IDE Information (Number, Grantor, Holder Type)

You will also need to upload the following trial-related documents in support of each trial's registration:

- Protocol Document
- Informed Consent (if not embedded within the protocol document)
- IRB Approval
- List of participating Sites for Multi-Center Studies (if not already described within the protocol document)

Step 3

Create User Account

- **Create An Account.** Enter an email account and create a password. You will receive a confirmation email.
- **Account Profile.** Click on the link listed in your confirmation email to activate your account and to enter your Account Profile information.
- **Log In.** After entering the Account Profile info you will be asked to log in again. If you forgot your password, then reset it.
- **Search Screen.** You will be routed to a Search Screen after log-in.

Step 4

Search Trials

You may want to check if you or someone at your organization has already submitted the trial(s) that you are registering. Also, for multi-center trials you can check if other centers have already registered the trial.

Search My Trials. Use this feature to find trials that have been submitted through your account.

Search All Trials. Use this feature to view select data on all registered trials within CTRP from all submitting organizations.

Step 5

Submit Trials

Enter Trial Information. Complete the data fields for each trial. "Drop down" menus can help you make a selection. Fields marked with an asterisk are required. You will not be able to register the trial without completing these fields.

Upload Trial Documents. The following trial-related documents are required as part of your trial's registration to CTRP:

- Protocol document
- Informed consent (if not embedded within the protocol document)
- IRB approval
- List of participating sites for multi-center studies (if not already described within the protocol document)

You can attach these files just like you attach a file to an email. You can "browse" the files on your computer and select a file.

Submit. Review the trial information that you have entered and click “Submit.”

If you need to make any changes after you have submitted the trial, please contact the CTRP staff by email.

Step 6 Verify Trials Data

- **Review.** You will receive an email within 48 hours letting you know whether the trial has been accepted or rejected to CTRP.

CTRP will include reason(s) if the trial is rejected rejection in the email (e.g., a duplicate submission, missing documents). The email will also provide you with a unique identifier assigned by NCI for your trial.

- **Abstraction.** CTRP will abstract information from the protocol and the other supporting documents. CTRP will contact you via email if there are any questions or need for clarification.
-
- **Confirmation.** CTRP will send you an email with a Trial Summary Report for your review. You can email us with corrections or questions about the Trial Summary Report.

Verify that the trial has been abstracted correctly and respond within 5 business days to let CTRP know if the abstraction is correct.

If we have not heard from you within 5 business days, CTRP will assume the Trial Summary Report is acceptable.

You will also receive a file that includes the abstracted data elements in a format that may be used to submit the trial to the National Library of Medicine's ClinicalTrials.gov database.

For Assistance

If you have questions or comments regarding this document, or other CTRP topics, please contact NCICB Applications Support at:

Email: ncicb@pop.nci.nih.gov

Web site: <http://ncicb.nci.nih.gov/NCICB/support>

Toll-free: 888-478-4423

Phone 301-451-4384

Live telephone support is available Monday to Friday, 8 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

CTRP: <http://www.cancer.gov/ncictrp>