

NCI CTRP Attachment 3a

NCI CTRP Registration Workflow and Screen Shots

Step 1: User accesses the NCI Clinical Trials Reporting Program website at <http://trials.nci.nih.gov> – see screenshot, page 2

Step 2: User enters “Username” and “Password” – see screenshot, page 2

Step 3: User reviews NCI Clinical Trials Reporting Program burden statement – see screenshot, page 3

Step 4: System displays “Search Submitted Clinical Trials” page – see screenshot, page 4

Step 5: User selects to perform “Initial Trial Registration” and completes initial registration – see screenshots, pages 5 - 7

CTRP Home and Login page



Welcome to NCI's Clinical Trials Reporting Program

This site enables you to register a trial with NCI's Clinical Trials Reporting Program. You can:

- ✓ Register clinical trials
- ✓ Register multiple trials at one time using a [batch upload template](#)
- ✓ Search registered trials by Title, Phase, Trial Identifiers and Organizations

Want to learn more about the Reporting Program? Visit the [NCI Clinical Trials Reporting Program](#) website. You can also email CBIIT Application Support at ncicbiit@mail.nih.gov if you have questions or need assistance.

➔ Sign In	✍ Sign Up	🔍 Forgot Your Password
Username	<input type="text" value="Enter your username"/>	
Password	<input type="password" value="Enter your password"/>	
Sign In ➔		



CTRP Burden Statement



NCI CLINICAL TRIALS REPORTING PROGRAM (CTRP) SYSTEM

This is a U.S. Government computer system, which may be accessed and used only for authorized Government business by authorized personnel. Unauthorized access or use of this computer system may subject violators to criminal, civil, and/or administrative action.

All information on this computer system may be intercepted, recorded, read, copied, and disclosed by and to authorized personnel for official purposes, including criminal investigations. Such information includes sensitive data encrypted to comply with confidentiality and privacy requirements. Access or use of this computer system by any person, whether authorized or unauthorized, constitutes consent to these terms. There is no right of privacy in this system.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

OMB#: 0925-0600 EXP. DATE: 5/31/16

Public reporting burden for this collection of information is estimated to average sixty (60) minutes for this questionnaire, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current, valid OMB control number.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0600).

Do not return the completed form to this address.

Accept

Reject

Search Submitted Clinical Trials

National Cancer Institute at the National Institutes of Health | www.cancer.gov

NCI CTRP Registration David Loose ▾

Search ▾ Register Trial ▾ Quick Links ▾ Contact Us Help

Search Clinical Trials | Search Persons | Search Organizations

Enter information for at least one of the criteria and then click Search.

Title: <input type="text" value="Enter keywords"/>	Purpose: <input type="text" value="--Select--"/>
Phase: <input type="text" value="--Select--"/>	Identifier: <input type="text" value="Examples: NCI-2008-00015; ECOG-1234"/>
Pilot Trial?: <input type="text" value="--Select--"/>	Organization: <input type="text" value="Enter keyword and select an organization from the list"/>
Identifier Type: <input type="text" value="--Select--"/>	Search By Trial Category: <input type="text" value="--Select--"/>
Organization Type: <input type="text" value="--Select--"/> <small>Please select an organization type before selecting an organization</small>	
Principal Investigator: <input type="text" value="Enter keyword and select a PI from the list"/>	

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NIH...Turning Discovery Into Health

Initial Trial Registration



Search

Register Trial

Quick Links

Contact Us

Help

Register Trial

Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked by asterisks (*).

XML Required, Enable "Upload from NCI CTRP" in [ClinicalTrials.gov?](#) Yes No [?](#)

[Collapse All](#)

Trial Identifiers*

Lead Organization Trial Identifier:*



30 characters left

ClinicalTrials.gov Identifier:



Other Identifiers

Other Trial Identifier:

[+ Add Other Identifier](#)



Trial Details*

Title:*



4000 characters left

Phase:*



Trial Type:*

Interventional Non-interventional

Primary Purpose:*



Secondary Purpose:

Accrual Disease Terminology:*

Lead Organization/Principal Investigator*

Lead Organization:*

[Please Select the Lead Organization -](#)

Principal Investigator:*

[Look Up Person](#)



Sponsor/Responsible Party*

Sponsor: * [Please Select the Sponsor Organization -](#)

Responsible Party: *

Data Table 4 Information*

Data Table 4 Funding Sponsor Type: ?

Data Table 4 Funding Sponsor: * [Please Select the Data Table 4 Sponsor Organization -](#) ?

Program code: ?

NIH Grant Information (for NIH funded Trials)*

To record grant information, provide values for all fields, and then click the **Add Grant** button.

Is this trial funded by an NCI grant? * Yes No

Funding Mechanism ?	Institute Code ?	Serial Number ?	NCI Division/Program Code ?	
<input type="text" value="--Select--"/>	<input type="text" value="--Select--"/>	<input type="text"/>	<input type="text" value="--Select--"/>	+ Add Grant

Trial Status*

Status Date ?	Status ?	Why Study Stopped? ?	
<input type="text" value="mm/dd/yyyy"/>	<input type="text" value="--Select--"/>	<input style="width: 95%; height: 40px;" type="text"/> <p style="font-size: small; text-align: right;">1000 characters left <i>Administratively Complete, Withdrawn and Temporarily Closed statuses only</i></p>	+ Add Status

Please refer to the [Trial Status Transition Rules](#).

Trial Dates*

Trial Start Date: * Actual Anticipated ?

Primary Completion Date: * Actual Anticipated ?

Completion Date: * Actual Anticipated ?

FDA IND/IDE Information for applicable trials

To record IND/IDE information, provide values for all fields, and then click the **Add IND/IDE** button.

IND/IDE Types	IND/IDE Number	IND/IDE Grantor	IND/IDE Holder Type	NIH Institution, NCI Division/Program Code (if applicable)	Expanded Access?	Expanded Access Type (if applicable)	Exempt? (if applicable)	
-Select		-Select	-Select	-Select	<input type="checkbox"/> Yes	-Select	<input type="checkbox"/> Yes	+ Add IND/IDE

< Scroll left/right to view full table >

Regulatory Information

Trial Oversight Authority Country: ?

Trial Oversight Authority Organization Name: ?

FDA Regulated Intervention Indicator: No Yes ?

Section 801 Indicator: No Yes ?

Data Monitoring Committee Appointed Indicator: No Yes ?

Trial Related Documents

To ensure successful registration, upload a Protocol document and an IRB Approval document. If the Protocol document does not include the informed Consent and/or participating sites, upload the Informed Consent document and a list of participating sites separately. You can use the [Participating Sites template](#) to submit your list of participating sites.

CTRP accepts most standard document types. For additional information about what document types are accepted, please refer to the Help section.

Protocol Document: No file selected. ?

IRB Approval: No file selected. ?

List of Participating Sites: No file selected. ?

Informed Consent Document: No file selected. ?

Other: No file selected. ?

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