

## **NCI CTRP Attachment 3b**

### **NCI CTRP Update 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 “Update Trial” and updates an existing trial record – see screenshots, pages 5 - 8

# 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](mailto:ncicbiit@mail.nih.gov) if you have questions or need assistance.

Sign In

Sign Up

Forgot Your Password

**Username**

**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

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:**

**Phase:**

**Purpose:**

**Pilot Trial?:**

**Identifier Type:**

**Identifier:**

**Organization Type:**

**Organization:**

*Please select an organization type before selecting an organization*

**Principal Investigator:**

**Search By Trial Category:**

 Search ▾

 Reset

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

# Update Trial

NCI CTRP Registration Sophia Rarhai ▾

Search ▾ Register Trial ▾ Quick Links ▾ Contact Us Help

Search Clinical Trials
Search Persons
Search Organizations
Search Results

### Clinical Trials Search Results

Show 10 ▾ Search:  Choose columns << < 1 2 > >>

NCI Trial Identifier ▾	Title ▾	Lead Organization ▾	Lead Org Trial Identifier ▾	Principal Investigator ▾	ClinicalTrials.gov Identifier ▾	Other Identifiers ▾	Current Trial Status ▾	Current Processing
<a href="#">NCI-2016-00006</a>	test0003	3.5.1 CTEP/CTRP Test Org	test0003	Test, Test			Active	Accepted

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

# Update Trial

NCI CTRP Registration Sophia Rarhai ▾

Search ▾ Register Trial ▾ Quick Links ▾ Contact Us Help

Search Clinical Trials
Search Persons
Search Organizations
Search Results

### Clinical Trials Search Results

< 1 2 > >>

Status ▾	Current Processing Status ▾	Available Actions ▾	Accrual Disease Terminology ▾	Sites ▾	Phase ▾	Primary Purpose ▾	Category ▾	Trial Start Date ▾	Responsible Party ▾	Sponsor ▾	Data Table 4 Funding Sponsor
	Accepted	<div style="border: 1px solid gray; padding: 2px; display: inline-block;">           Update Change Status Select Action ▾         </div>	SDC ▾	View	I,II	TREATMENT	Complete	01/03/2016	3.5.1 CTEP/CTRP Test Org	3.5.1 CTEP/CTRP Test Org	NATIONAL

### Update Trial

Use this form to update trial information. You can not change the information in certain fields, including the trial title.

#### Trial Identifiers\*

Lead Organization Trial Identifier:\* test0003

ClinicalTrials.gov Identifier:

NCI Trial Identifier: NCI-2016-00006

#### Other Identifiers\*

Other Trial Identifier:

#### Trial Details\*

Title:\* test0003

Phase:\* I/II

Trial Type:\* Interventional

Primary Purpose:\* Treatment

Secondary Purpose: Ancillary-Correlative

Accrual Disease Terminology: SDC

#### Lead Organization/Principal Investigator\*

Lead Organization:\* 3.5.1 CTEP/CTRP Test Org

Principal Investigator:\* Test, Test

#### Sponsor / Responsible Party\*

Sponsor:\* 3.5.1 CTEP/CTRP Test Org

Responsible Party:\* Sponsor

Data Table 4 Information\*

Data Table 4 Funding Sponsor Type:\* National

Data Table 4 Funding Sponsor:\* 3.5.1 CTEP/CTRP Test Org

Program code:

NIH Grant Information (for NIH funded Trials)\* ?

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code	
--Select--	--Select--		--Select--	<input type="button" value="+ Add Grant"/>
Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code	
B08	AF	789456	CIP	
B01	AA	123456	CCR	

Trial Status\*

Status Date ?	Status ?	Why Study Stopped? ?	
<input type="text" value="mm/dd/yyyy"/>	--Select--	<input type="text"/>	<input type="button" value="+ Add Status"/>
		<small>Administratively Complete, Withdrawn and Temporarily Closed statuses only</small>	<small>1000 characters left</small>

Please refer to the Trial Status Transition Rules.

Trial Status History

Show 10 entries

Status Date	Status	Comments	Validation Messages	Actions
01/01/2016	In Review			
01/02/2016	Approved			
01/03/2016	Active			

Showing 1 to 3 of 3 entries

Previous **1** Next

Trial Dates\*

Trial Start Date:\*   Actual  Anticipated ?

Primary Completion Date:\*   Actual  Anticipated ?

Completion Date:   Actual  Anticipated ?

Please refer to Trial Status Rules for Start and Completion dates.

FDA IND/IDE Information for applicable trials\*

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)
IND	123	CDER	Investigator		No		No

Regulatory Information\*

Trial Oversight Authority Country :\* United States  
 Trial Oversight Authority Organization Name :\* Food and Drug Administration  
 FDA Regulated Intervention Indicator :\* Yes  
 Section 801 Indicator :\* Yes  
 Delayed Posting Indicator :\* No  
 Data Monitoring Committee Appointed Indicator : No

Participating Sites\*

Site	Recruitment Status	Date
CTEP Secure Upgrade Create Org Test	Active	02/03/2016

Collaborators\*

Collaborator	Functional Role
National Cancer Institute	Funding Source

Existing Trial Related Documents\*

Document Type	File Name
Protocol Document	testtest.doc
IRB Approval Document	testtest.doc

Trial Related Documents \*

Registration requires submission of the complete protocol (for non-industry trials) or a summary of the protocol (for industry trials) and IRB Approval document. For multi-center trials, a list of participating sites and contact information is required. If the protocol does not include Informed Consent or participating sites, submit them separately.

Tips for creating CTRP compatible PDF documents

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. ?

Please verify ALL the trial information you provided on this screen before clicking the "Review Trial" button below.