

NCI CTRP Attachment 3c

NCI CTRP Amendment Portal 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 “Submit Trial Amendment” and amends an existing trial record – see screenshots, pages 5 – 10

CTRP Home and Login page

Clinical Trials Reporting Program Login

Clinical Trials Reporting Program

 NIH Login

OR

Username

Password

☐ Remember me

SIGN IN

Need help signing in?

Don't have an account? Sign up

You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. By using this information system, you understand and consent to the following:

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National Cancer Institute
at the National Institutes of Health

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HELP AND SUPPORT

ctrp_support@mail.nih.gov

LAST BUILD

04-19-22 10:51
[API Build Details](#)

CTRP Burden Statement



Clinical Trials Reporting Program Registration

NCI CLINICAL TRIALS REPORTING PROGRAM (CTRP) SYSTEM

Warning Notice

- This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.
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NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

OMB#: 0925-0600 EXP. DATE: 10/31/22

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

National Cancer Institute

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

NCI CTRP Registration

Search Submitted Clinical Trials

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:

Enter keywords

Phase:

--Select--

Pilot Trial?:

--Select--

Identifier Type:

--Select--

Organization Type:

--Select--

Principal Investigator:

Enter keyword and select a PI from the list

Purpose:

--Select--

Identifier:

Examples: NCI-2008-00015; ECOG-1234

Organization:

Enter keyword and select an organization from the list

Search By Trial Category:

--Select--

Search

Reset

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NCI CTRP Registration

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
NCI-2016-00006	test0003	3.5.1 CTEP/CTRP Test Org	test0003	Test, Test			Active	Accepted

Clinical Trials Search Results

Search: Choose columns << < 1 2 > >>

Principal Investigator	ClinicalTrials.gov Identifier	Other Identifiers	Current Trial Status	Current Processing Status	Available Actions	Accrual Disease Terminology	Sites	Phase	Primary Purpose	Category
Test, Test			Active	Abstractio	Update Amend Change Status View TSR View XML Verify Data	SDC	View	I,II	TREATMENT	Complete

Amendment Trial

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

⊖ Collapse All

Amendment Details

Amendment Number:

Amendment Date:* 



Trial Identifiers*

Lead Organization Trial Identifier:* 

22 characters left

ClinicalTrials.gov Identifier: 

NCI Trial Identifier: NCI-2017-00782

DCP Identifier: 

Other Identifiers*

Other Trial Identifier:

Other Trial Identifier:  Add Other Identifier

Trial Details*

Title:*
test test test test test
3976 characters left

Phase:*
I/II

Is this a Pilot? --Select--

Trial Type:*
☒ Interventional ☐ Non-interventional

Primary Purpose:*
Prevention

Secondary Purpose: --Select--

Accrual Disease Terminology: ICD10

Lead Organization/Principal Investigator*

Lead Organization:* Dana-Farber Cancer Institute

Principal Investigator:* Izbicki, Michael Look Up Person

Sponsor/Responsible Party

The information in this section is REQUIRED to enable "Upload from NCI CTRP" in ClinicalTrials.gov

Sponsor: Dana-Farber Cancer Institute

Responsible Party: Sponsor

Data Table 4 Information*

Data Table 4 Funding Sponsor Type:* National

Data Table 4 Funding Sponsor:* Please Select the Data Table 4 Sponsor Organization
Dana-Farber Cancer Institute Delete Sponsor

Program Code: ZZZ296

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 ?	
--Select--	--Select--		--Select--	+ Add Grant

Funding Mechanism	NIH Institute Code	Serial Number	NCI Division/Program	Action
P30	CA	89017	CTEP	

Trial Status*

Status Date ?	Status ?	Why Study Stopped? ?	
mm/dd/yyyy	--Select--		+ Add Status

Administratively Complete, Withdrawn and Temporarily Closed statuses only

1000 characters left

Please refer to the Trial Status Transition Rules.

Trial Status History

Show 10 entries

Status Date	Status	Comments	Validation Messages	Actions
04/05/2017	In Review			 

Showing 1 to 1 of 1 entries

Previous 1 Next

Trial Dates*

Trial Start Date: 07/04/2017

Primary Completion Date: mm/dd/yyyy

Completion Date: 07/28/2018

☒ Actual ☐ Anticipated ?
☐ Actual ☒ Anticipated ☐ N/A ?
☐ Actual ☒ Anticipated ?

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

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)	Availability of Expanded Access	Expanded Access Record (if applicable)	
-Select-		-Select-	-Select-	-Select-	Unknown		+ Add IND/IDE

IND/IDE Type	Number	Grantor	Holder	Program Code	Availability of Expanded Access	Expanded Access Record	Action
IND	132024	CDER	NCI	DEA	Yes	NCT12345678	
IDE	48176	CDRH	Investigator		Unknown		
IND	153116	CDER	Investigator				

< Scroll left/right to view full table >

Regulatory Information

The information in this section is REQUIRED to enable "Upload from NCI CTRP" in [ClinicalTrials.gov](#)

Studies a U.S. FDA-regulated Drug Product : Yes ?

Studies a U.S. FDA-regulated Device Product : Yes ?

Unapproved/Uncleared Device : No ? To modify this indicator's value please submit a request to the CTRO at ncictro@mail.nih.gov

Pediatric Post-market Surveillance : ?

Product Exported from the U.S : No ?

FDA Regulated Intervention Indicator : Yes ?

Section 801 Indicator : ?

Data Monitoring Committee Appointed Indicator : Yes ?

Existing Trial Related Documents

Document Types	File Name
IRB Approval Document	test - 2.docx
Change Memo Document	test - 3.docx
Protocol Document	test - 2.docx
TSR	TSR_NCI-2017-00782_2017-07-21-1245_A123.rtf

Trial Related Documents *

Amendment 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:*

Browse...

?

Change Memo Document:**

Browse...

?

Protocol Highlighted Document:**

Browse...

?

IRB Approval:*

Browse...

?

List of Participating Sites:

Browse...

?

Informed Consent Document:

Browse...

?

Other:

Browse...

?

+ Add more...

Review Trial

Cancel

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