

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 clicks “Login”

Step 3: User enters “Email Address” and “Password” – see screenshot, page 3

Step 4: User reviews NCI Clinical Trials Reporting Program burden statement – see screenshot, page 4

Step 5: System displays “Search Submitted Clinical Trials” page – see screenshot, page 15

Step 6: Alternative workflows, a – c, a user may perform any of these actions upon entering the system:

- a. User selects to perform “Initial Trial Registration” and completes initial registration – see screenshots, pages 5 - 9, OR
- b. User selects to “Submit Trial Amendment” and amends an existing trial record – see screenshots, pages 10 - 14, OR**
- c. User selects to “Search Submitted Clinical Trials” and searches for an existing trial – see screenshot, page 15

CTRP Home page

NCI Registry - Mozilla Firefox

File Edit View History Bookmarks Tools Help

CTRP Login Screen

National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov

NCI CTRP Registration Site

Log In

NCI CTRP

- Home
- Create Account
- Register Trial
- Search Trials
- Log In**
- Help

QUICK LINKS

- Clinical Trials Reporting Program (CTRP)
- Useful Templates and Documentation
- National Cancer Institute (NCI)
- NCI Center for Bioinformatics (NCICB)
- caBIG™ - Cancer Biomedical Informatics Grid™

Login

Help

Please log in to search, view and register clinical trial details. If you do not have an account, you may [create an account](#).





Email Address:

Password:

[\(Forgot Your Password?\)](#)
[\(Create an Account\)](#)

Log In

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CTRP Burden Statement

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Welcome to NCI's Clinical Trials Reporting Program

Help



OMB#: 0925-XXXX EXP. DATE: XX/XX/XXXX

NCI CLINICAL TRIALS REPORTING PROGRAM NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average one (1) to two (2) hours 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-XXXX). Do not return the completed form to this address.

Continue to CTRP

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Register Trial - Mozilla Firefox

Initial Trial Registration

File Edit View History Bookmarks Tools Help

https://trials-qa.nci.nih.gov/registry/protected/submitTrial.action

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National Cancer Institute U.S. National Institutes of Health

NCI CTRP Registration Site

Welcome, nshimko@scenpro

NCI CTRP

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Register Trial

Register trial with NCI's Clinical Trials Reporting Program. Required fields are marked by asterisks(*).

Trial Details

Lead Organization Trial Identifier: *

NCT Number:

Title: * Max 4000 characters

Phase: * --Select--

Phase Comment: Required if Phase equals 'Other'

Trial Type: * Interventional Observational

Purpose: * --Select--

Purpose Comment: Required if Purpose equals 'Other'


Lead Organization/Principal Investigator

Lead Organization/Principal Investigator

Lead Organization:* 

Principal Investigator:* 

Sponsor/Responsible Party

Sponsor:* 


Responsible Party:* PI Sponsor

Responsible Party Email Address:* (work information)

Responsible Party Phone Number:* (work information)

Summary 4 Information (for trials at NCI-designated cancer centers)

Summary 4 Funding Sponsor Type: 

Summary 4 Funding Sponsor: 

NIH Grant Information (for NIH funded Trials)

Assign values to all editable grant elements and click 'Add Grant' button for adding this grant to the trial. Note that the button becomes active when all required grant attributes are assigned.

Register Trial - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://trials-qa.nci.nih.gov/registry/protected/submitTrial.action

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NIH Grant Information (for NIH funded Trials)

Assign values to all editable grant elements and click 'Add Grant' button for adding this grant to the trial. Note that the button becomes active when all required grant attributes are assigned.

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code
--Select--	--Select--		--Select--

Add Grant

Status/Dates

Current Trial Status:* --Select--

Why Study Stopped?: Required for Administratively Complete and Temporarily Closed statuses only

Current Trial Status Date:* (mm/dd/yyyy)

Trial Start Date:* (mm/dd/yyyy) Actual Anticipated

Primary Completion Date:* (mm/dd/yyyy) Actual Anticipated

FDA IND/IDE Information for applicable trials

Assign values to all editable IND/IDE elements and click 'Add IND/IDE' button for adding this IND/IDE to the trial. Note that the button becomes active when all required IND/IDE attributes are assigned.

Done trials-qa.nci.nih.gov

Register Trial - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://trials-qa.nci.nih.gov/registry/protected/submitTrial.action

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FDA IND/IDE Information for applicable trials

Assign values to all editable IND/IDE elements and click 'Add IND/IDE' button for adding this IND/IDE to the trial. Note that the button becomes active when all required IND/IDE attributes are assigned.

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)	
<input type="radio"/> IND <input type="radio"/> IDE	<input type="text"/>	-Select- ▾	-Select- ▾	-Select- ▾	<input type="radio"/> Yes <input checked="" type="radio"/> No	-Select- ▾	<input type="button" value="Add IND/IDE"/>

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, please submit them separately using the fields below.

Protocol Document:

IRB Approval:

List of Participating Sites:

Informed Consent Document:

Other:

*Please verify ALL the trial information you provided on this screen before clicking the "Submit Trial" button below.
Once you submit the trial you will not be able to modify the information.*

Register Trial - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://trials-qa.nci.nih.gov/registry/protected/submitTrial.action

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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)	
<input type="radio"/> IND <input type="radio"/> IDE	<input type="text"/>	-Select- ▾	-Select- ▾	-Select- ▾	<input type="radio"/> Yes <input checked="" type="radio"/> No	-Select- ▾	Add IND/IDE

Trial Related Documents

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Protocol Document: *

IRB Approval: *

List of Participating Sites:

Informed Consent Document:

Other:

Please verify ALL the trial information you provided on this screen before clicking the "Submit Trial" button below. Once you submit the trial you will not be able to modify the information.

Amend Trial - Mozilla Firefox

Submit Trial Amendment

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https://trials-qa.nci.nih.gov/registry/protected/amendTrialview.action?studyProtocolId=120318

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NCI CTRP Registration Site

Welcome, nshimko@scenpro

NCI CTRP

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- Search Trials
- Log Out
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QUICK LINKS

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Amendment Trial

Register trial with NCI's Clinical Trials Reporting Program. Required fields are marked by asterisks(*).

Amendment Details

Amendment Number:

Amendment Date: * (mm/dd/yyyy)

Trial Details

NCI Trial Identifier: NCI-2009-00753

Lead Organization Trial Identifier: *

NCT Number:

Title: * Max 4000 characters

Phase: *

Phase Comment: Required if Phase equals 'Other'

Trial Type: * Interventional Observational

Done trials-qa.nci.nih.gov

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Required if Phase equals 'Other'

Trial Type: Interventional Observational

Purpose: Treatment

Purpose Comment: Required if Purpose equals 'Other'

Lead Organization/Principal Investigator

Lead Organization: Mercy Hospital

Principal Investigator: Kraft, Andrew

Sponsor/Responsible Party

Sponsor: National Cancer Institute Medicine

Responsible Party: PI Sponsor

Responsible Party Email Address: (work information)

Responsible Party Phone Number: (work information)

Summary 4 Information (for trials at NCI-designated cancer centers)

Summary 4 Funding Sponsor Type: --Select--

Summary 4 Funding Sponsor:

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Amend Trial - Mozilla Firefox

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https://trials-qa.nci.nih.gov/registry/protected/amendTrialview.action?studyProtocolId=120318

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Summary 4 Information (for trials at NCI-designated cancer centers)

Summary 4 Funding Sponsor Type: --Select--

Summary 4 Funding Sponsor:

NIH Grant Information (for NIH funded Trials)

Assign values to all editable grant elements and click 'Add Grant' button for adding this grant to the trial. Note that the button becomes active when all required grant attributes are assigned.

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code	
B09	AA	123456	N/A	<input type="button" value="Add Grant"/>

Status/Dates

Current Trial Status: Temporarily Closed to Accrual and

Why Study Stopped?: Required for Administratively Complete, Withdrawn and Temporarily Closed statuses only

Current Trial Status Date: 04/02/2009 (mm/dd/yyyy)

Trial Start Date: 03/31/2009 (mm/dd/yyyy) Actual Anticipated

Primary Completion Date: 03/31/2011 (mm/dd/yyyy) Actual Anticipated

Done trials-qa.nci.nih.gov

Amend Trial - Mozilla Firefox

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https://trials-qa.nci.nih.gov/registry/protected/amendTrialview.action?studyProtocolId=120318

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FDA IND/IDE Information for applicable trials

Assign values to all editable IND/IDE elements and click 'Add IND/IDE' button for adding this IND/IDE to the trial. Note that the button becomes active when all required IND/IDE attributes are assigned.

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)	
<input checked="" type="radio"/> IND <input type="radio"/> IDE	123	CDER	Organizat	-Select-	<input type="radio"/> Yes <input checked="" type="radio"/> No	-Select-	Add IND/IDE

Exiting Trial Related Documents

Document Types	File Name
Protocol Document	PD.doc
IRB Approval Document	PD.doc
Change Memo Document	PD.doc

Amendment 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, please submit them separately using the fields below.

Amendment Protocol Document: *

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Amend Trial - Mozilla Firefox

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https://trials-qa.nci.nih.gov/registry/protected/amendTrialview.action?studyProtocolId=120318

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Protocol Document	PD.doc
IRB Approval Document	PD.doc
Change Memo Document	PD.doc

Amendment 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, please submit them separately using the fields below.

Amendment Protocol Document:

Change Memo Document:

Protocol Highlighted Document:

IRB Approval:

List of Participating Sites:

Informed Consent Document:

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NATIONAL CANCER INSTITUTE USA.gov

Search Submitted Clinical Trials - Mozilla Firefox

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https://trials- **Search Submitted Clinical Trials** Google

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NATIONAL CANCER INSTITUTE National Cancer Institute U.S. National Inst

NCI CTRP Registration Site Welcome, nshimko@scenpro.com

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Search Submitted Clinical Trials

Title:

Phase: --Select--

Identifier Type: --Select--

Organization Type: --Select--

Purpose: --Select--

Identifier:
(e.g. NCI-2008-00015; ECOG-1234, etc)

Organization: --Select--

Search My Trials: Search the trials I have submitted.
Search All Trials: Search all trials I have submitted as well as those registered by others.

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