

## **NCI CTRP Attachment 3**

### **NCI CTRP Registration, Update, Amendment, Accrual 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 “Username” 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 19

Step 6: Alternative workflows, a – f, 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 - 8, OR
- b. User selects to “Update Trial” and updates an existing trial record – see screenshots, pages 9 - 13, OR
- c. User selects to “Submit Trial Amendment” and amends an existing trial record – see screenshots, pages 14 - 19, OR
- d. User selects to “Search Submitted Clinical Trials” and searches for an existing trial – see screenshot, page 20
- e. User selects to “Submit Study Subject Accrual Information” and submits subject level accrual information on a registered trial – see screenshots, pages 21 - 24
- f. User selects to “Update Study Subject Accrual Information” and updates subject level accrual information on a registered trial – see screenshot, page 25
- g. User selects to “Submit Aggregate Study Subject Accrual Information” and submits aggregate accrual information on a registered trial – see screenshot, page 26

**CTRP Home page**



# CTRP Login Screen



## NCI CTRP Registration Site

Log In

### 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 have not yet registered, you may do so by clicking [here](#).

Username:

Password:

- [Create an Account](#)
- [Forgot your password?](#)
- [Forgot your username?](#)

 Log In

[CONTACT US](#)

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# CTRP Burden Statement

### NCI CTRP

- Home
- My Account
- Register Trial
- Search
  - Trials
  - Persons
  - Organizations
- Site Administration
  - Display Trial Ownership
  - Manage Trial Ownership
  - Manage Site Record Ownership
  - Manage Accrual Access
    - Assign & Un-assign Access
    - Assignment History
    - Assignment By Trial
  - Log Out
  - 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™

### NCI CLINICAL TRIALS REPORTING PROGRAM (CTRP) SYSTEM

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OMB#: 0925-0600 EXP. DATE: 3/31/2013

### NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

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.



# Initial Trial Registration



### NCI CTRP

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- caBIG™ - Cancer Biomedical Informatics Grid™

### Register Trial

[Help](#)

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

XML required for [ClinicalTrials.gov](#)?  Yes  No

#### Trial Identifiers

Lead Organization Trial Identifier: \*

NCT Number:

#### Other Identifiers

Other Identifier  [Add Other Identifier](#)

#### Trial Details

Title: \*

4000 characters left

Phase: \*

Trial Type: \*  Interventional  Observational

Purpose: \*

**Lead Organization/Principal Investigator**

Lead Organization: \*

 **Look Up Org**

Principal Investigator: \*

 **Look Up Person**

**Sponsor/Responsible Party**

Sponsor: \*

 **Look Up Sponsor**

Responsible Party: \*  PI  Sponsor

*Please provide professional contact information only.*

Responsible Party Email Address: \*

Responsible Party Phone Number: \*  Ext:

*Contact information is required for internal administrative use only; it is not revealed to the public.*

**Summary 4 Information**

Summary 4 Funding Sponsor Type:

Summary 4 Funding Sponsor: \*

 **Look Up Sponsor**

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.

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

**Status/Dates**

Current Trial Status: \* --Select--

Why the Study Stopped:

160 characters left

Required for Administratively Complete, Withdrawn and Temporarily Closed statuses only

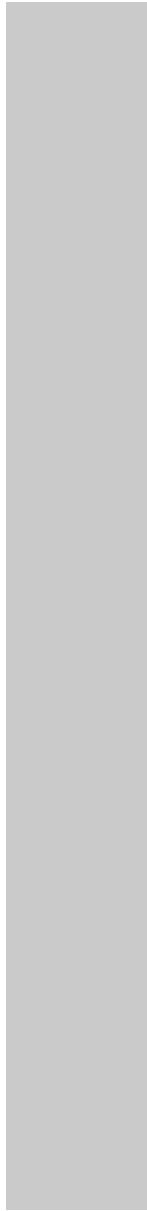
Current Trial Status Date: \*  (mm/dd/yyyy)

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

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

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

Please refer to the [Trial Status Rules for Start and Completion dates.](#)







# Update Trial



### NCI CTRP

- Home
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## Update Trial

[Help](#)

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

### Trial Identifiers

**Lead Organization Trial Identifier:\*** 1111

**NCT Number:**

**NCI Trial Identifier:** NCI-2012-00429

### Other Identifiers

**Other Identifier**

[Add Other Identifier](#)

### Trial Details

**Title:\*** Title of the trial from the protocol document

**Phase:\*** I

**Trial Type:\*** Interventional

**Purpose:\*** Treatment

### Lead Organization/Principal Investigator

**Lead Organization:\*** Mercy Anderson Hospital

**Principal Investigator:\*** Audet, Isabelle

### Sponsor/Responsible Party

Sponsor:\* American International Hospital

Responsible Party:\* sponsor

Responsible Party Contact: Audet, Isabelle

Responsible Party Generic Contact:

Responsible Party Email Address:\* iaudet@aih.org

Responsible Party Phone Number:\* 123-123-1234

### Summary 4 Information

Summary 4 Funding Sponsor Type:\* National

Summary 4 Funding Sponsor: \* National Cancer Institute

Program code:

### 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	
<input type="text" value="--Select--"/>	<input type="text" value="--Select--"/>	<input type="text"/>	<input type="text" value="--Select--"/>	<input type="button" value="Add Grant"/>

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code
B09	AA	123456	N/A

Status/Dates

Current Trial Status: \*

*Participants are being (or will be) selected from a predetermined population.*

Why the Study Stopped:

*160 characters left*

*Required for Administratively Complete, Withdrawn and Temporarily Closed statuses only*

Current Trial Status Date: \*

Trial Start Date: \*    Actual  Anticipated

Primary Completion Date: \*    Actual  Anticipated

Completion Date:    Actual  Anticipated

*Please refer to the [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 : \* No

Delayed Posting Indicator : \*

Data Monitoring Committee Appointed Indicator : Yes

### Participating Sites

Site	Recruitment Status	Date	Program Code
Banner MD Anderson Cancer Center	Enrolling by Invitation	10/31/2012	

### Collaborators

Collaborator	Functional Role
National Cancer Institute	Funding Source

### Existing Trial Related Documents

Document Type	File Name
Protocol Document	<a href="#">protocol.doc</a>
IRB Approval Document	<a href="#">irb_approval.doc</a>
TSR	<a href="#">TSR_NCI-2012-00429_2012-10-31-1946_O.rtf</a>

## 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:

IRB Approval:

List of Participating Sites:

Informed Consent Document:

Other:

[Add more...](#)

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

[CONTACT US](#)

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# Submit Trial Amendment

Welcome, [Edmond Mulaire](#) | [Log Out](#)

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### QUICK LINKS

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- caBIG™ - Cancer Biomedical Informatics Grid™

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## Amendment Trial

[Help](#)

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

[ClinicalTrials.gov XML required?](#)  Yes  No

### Amendment Details

Amendment Number:

Amendment Date: \*  (mm/dd/yyyy)

### Trial Identifiers

Lead Organization Trial Identifier: \*

NCT Number:

NCI Trial Identifier: NCI-2012-00429

### Other Identifiers

Other Identifier  [Add Other Identifier](#)

### Trial Details

Title: \*  3955 characters left

Phase: \*

Trial Type: \*  Interventional  Observational

Purpose: \*

### Lead Organization/Principal Investigator

Lead Organization:\*  

Principal Investigator:\*  


### Sponsor/Responsible Party

Sponsor:\*  

Responsible Party:\*  PI  Sponsor

Responsible Party Personal Contact: *Select Either Personal Contact or Generic Contact*



Responsible Party Generic Contact:  

**Please provide professional contact information only.**


Responsible Party Email Address:\*

Responsible Party Phone Number:\*  Extn:

**Contact information required for internal administrative use only; not revealed to public**

### Summary 4 Information

Summary 4 Funding Sponsor Type: \*

Summary 4 Funding Sponsor: \*  

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.

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

Funding Mechanism	NIH Institute Code	Serial Number	NCI Division/Program Code	Action
B09	AA	123456	N/A	

Status/Dates

Current Trial Status: \*

*Participants are being (or will be) selected from a predetermined population.*

Why the Study Stopped:

*160 characters left*

*Required for Administratively Complete, Withdrawn 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

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

*Please refer to the [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)	Expanded Access?	Expanded Access Type (if applicable)	Exempt? (if applicable)
-Select-		-Select-	-Select-	-Select-	<input type="checkbox"/> Yes	-Select-	<input type="checkbox"/> Yes

IND/IDE Type	Number	Grantor	Holder	Program Code	Expanded Access?	Expanded Access Type	Exempt?
IND	123	CDER	Investigator		No		No

Regulatory Information

Trial Oversight Authority Country :\*

Trial Oversight Authority Organization Name :\*

FDA Regulated Intervention Indicator :\*

Section 801 Indicator :\*

Delayed Posting Indicator :\*

Data Monitoring Committee Appointed Indicator :

### Exiting Trial Related Documents

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[Tips for creating CTRP compatible PDF documents](#)

Amendment Protocol Document: \*

Change Memo Document: \*\*

Protocol Highlighted Document: \*\*

IRB Approval: \*

List of Participating Sites:

Informed Consent Document:

Other:

[Add more...](#)

\*\* At least one is required: Change Memo Document or Protocol Highlighted Document

*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.*

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NATIONAL





# Search Submitted Clinical Trials

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**Search Clinical Trials** [Help](#)

Title:

Phase:

Purpose:

Pilot Trial?:

Identifier Type:

Identifier:

*(Examples: NCI-2008-00015; ECOG-1234)*

Organization Type:

Organization:

Principal Investigator:

Search By Trial Category:

[Search My Trials](#) [Search All Trials](#) [Reset](#) [Search Saved Drafts](#)

*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.  
 Search Saved Drafts: Search my saved drafts.*





# CTRP Accrual Burden Statement

Log Out

## QUICK LINKS

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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).

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# Submit Study Subject Accrual Information

## NCI CTRP

- Home
- ▾ Trial Search
- Study Subject Search
- Batch Upload
- Prior Submissions
- Log Out

## QUICK LINKS

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## Trial Search

[Help](#)

NCI Trial Identifier:

NCT Number:

Official Title:

## List of Trials

2 items found, displaying all items. 1

NCI Trial Identifier	Official Title	Current Trial Status
<a href="#">NCI-2012-00028</a>	A Phase II, Multi-center, Open-label Study Evaluating the Efficacy and Safety of GRN1005 in Non-Small Cell Lung Cancer Patients with Brain Metastases	
<a href="#">NCI-2012-00429</a>	Title of the trial from the protocol document	Enrolling by Invitation

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Welcome, | [Log Out](#)

- NCI CTRP**
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- caBIG™ - Cancer Biomedical Informatics Grid™

NCI-2012-00429: Title of the trial from the protocol document

Lead Organization Trial ID: 1111      Principal Investigator: Audet, Isabelle

Lead Organization: Mercy Anderson Hospital

## Search Study Subject

[Help](#)

Study Subject ID

Participating Site

Study Subject Birth Date (MM/YYYY):

[Search](#)

[+ Add New Study Subject](#)

## List of Study Subjects

3 items found, displaying all items.1

Study Subject ID	Registration Date	Participating Site	Last Update Date/Time	Update	Delete
<a href="#">SUBID_012345</a>	10/10/2012	Banner MD Anderson Cancer Center	10/31/2012 20:09		
<a href="#">SUBID_012346</a>	10/24/2012	Banner MD Anderson Cancer Center	10/31/2012 20:10		
<a href="#">SUBID_012347</a>	10/31/2012	Banner MD Anderson Cancer Center	10/31/2012 20:12		

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**NCI CTRP**

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- [Batch Upload](#)
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**QUICK LINKS**

- [Clinical Trials Reporting Program \(CTRP\)](#)
- [National Cancer Institute \(NCI\)](#)
- [NCI Center for Bioinformatics \(NCICB\)](#)
- [caBIG™ - Cancer Biomedical Informatics Grid™](#)

NCI-2012-00429: Title of the trial from the protocol document

Lead Organization Trial ID: 1111

Principal Investigator: Audet, Isabelle

Lead Organization: Mercy Anderson Hospital

**Add Study Subject**

[Help](#)

Study Subject ID:

Study Subject Birth Date (MM/YYYY):

Study Subject Gender:

Study Subject Race: 

- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- Not Reported
- Unknown
- White

To select multiple races, select one race, and then press and hold the CTRL key as you select the other(s).

Study Subject Ethnicity:

Study Subject Country:

Study Subject Zip Code:

Registration Date:  (mm/dd/yyyy)

Study Subject method of payment:

Disease:  [Look Up](#)

Participating Site:





# Update Study Subject Accrual Information

**NCI CTRP**

- Home
- Trial Search
- Study Subject Search
- Batch Upload
- Prior Submissions
- Log Out

**QUICK LINKS**

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NCI-2012-00429: Title of the trial from the protocol document

Lead Organization Trial ID: 1111

Principal Investigator: Audet, Isabelle

Lead Organization: Mercy Anderson Hospital

## Update Study Subject

[Help](#)

Study Subject ID: \* SUBID\_012345

Study Subject Birth Date (MM/YYYY): \* 01/2000

Study Subject Gender: \* Male

Study Subject Race: \* American Indian or Alaska Native

- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- Not Reported
- Unknown
- White

*To select multiple races, select one race, and then press and hold the CTRL key as you select the other(s).*

Study Subject Ethnicity: \* Not Hispanic or Latino

Study Subject Country: \* United States

Study Subject Zip Code: 12345

Registration Date: \* 10/10/2012 (mm/dd/yyyy)

Study Subject method of payment: Private Insurance

Disease: \* Acute erythremia and erythroleukemia (207.0) [Look Up](#)

Participating Site: \* Banner MD Anderson Cancer Center

[Save](#) [Cancel](#)

# Submit Aggregate Study Subject Accrual Information

- NCI CTRP**
- Home
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- Record Accrual Count
- Batch Upload
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**NCI-2012-00028:** A Phase II, Multi-center, Open-label Study Evaluating the Efficacy and Safety of GRN1005 in Non-Small Cell Lung Cancer Patients with Brain Metastases

**Lead Organization Trial ID:** CP1005B017

**Principal Investigator:**

**Lead Organization:** Geron Corporation

### Participating Site Subject Accrual Count

One item found.1

Save	PO Id	Site Name	# of Subjects Enrolled	Date Last Updated
<input type="checkbox"/>	71815	Moffitt Cancer Center and Research Institute	25	10/31/2012 20:48

Save

Reset