NCI CTRP Attachment 3a

NCI CTRP Trial Registration Workflow and Screen Shots

Step 1: User accesses the NCI Clinical Trials Reporting Program website at https://trials.nci.nih.gov/login – 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 to 7

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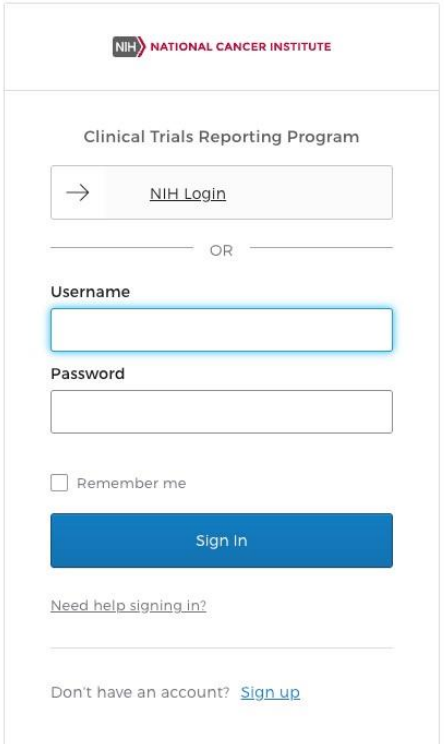
CTRP Login & Home page

Clinical Trials Reporting Program Login



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:

You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, record, and search and seize any communication or data transiting or stored on this information system.

Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

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CTRP Burden Statement

Clinical Trials Reporting Program Registration

NCI CLINICAL TRIALS REPORTING PROGRAM (CTRP) SYSTEM

Warning Notice

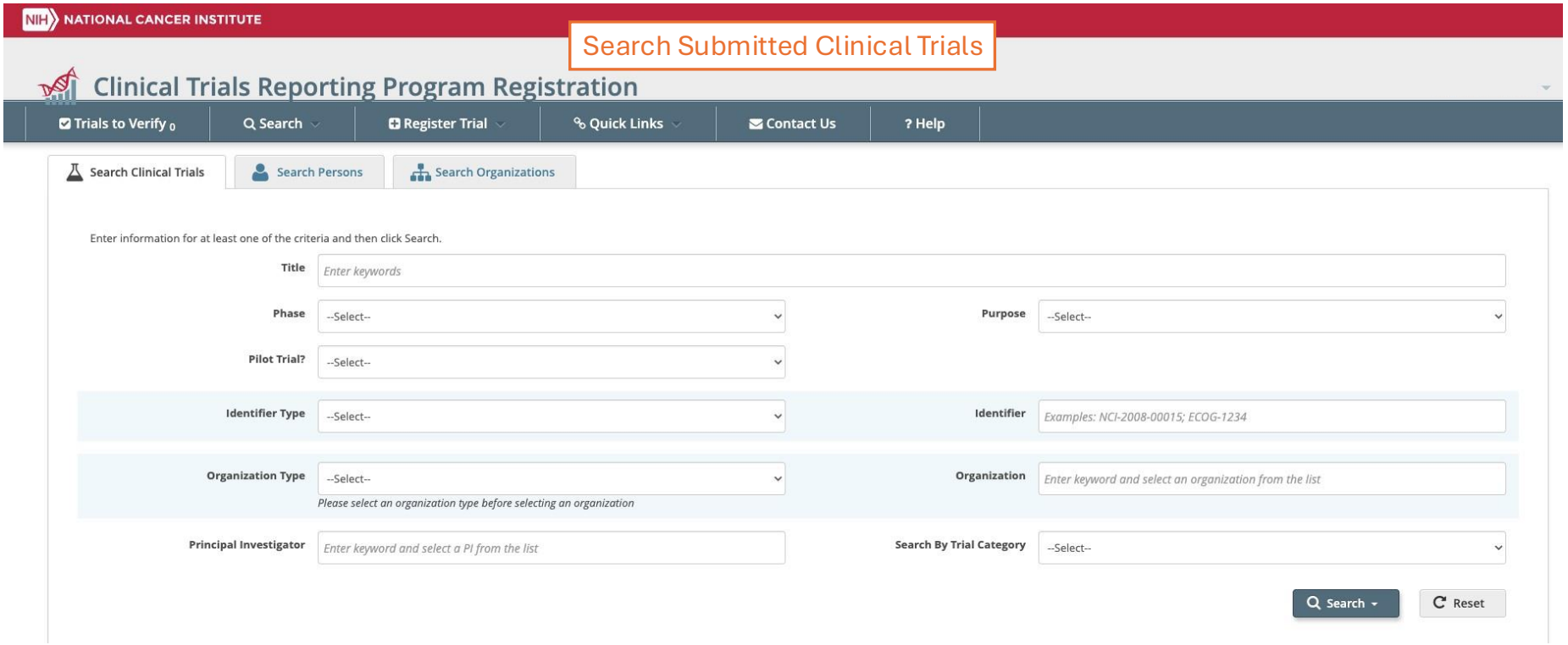
- This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.
- This system is provided for Government-authorized use only.
- Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties.
- Personal use of social media and networking sites on this system is limited as to not interfere with official work duties and is subject to monitoring.
- By using this system, you understand and consent to the following:
  - The Government may monitor, record, and audit your system usage, including usage of personal devices and email systems for official duties or to conduct HHS business. Therefore, you have no reasonable expectation of privacy regarding any communication or data transiting or stored on this system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this system.
  - Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

OMB#: 0925-0600 EXP. DATE: 2/28/26

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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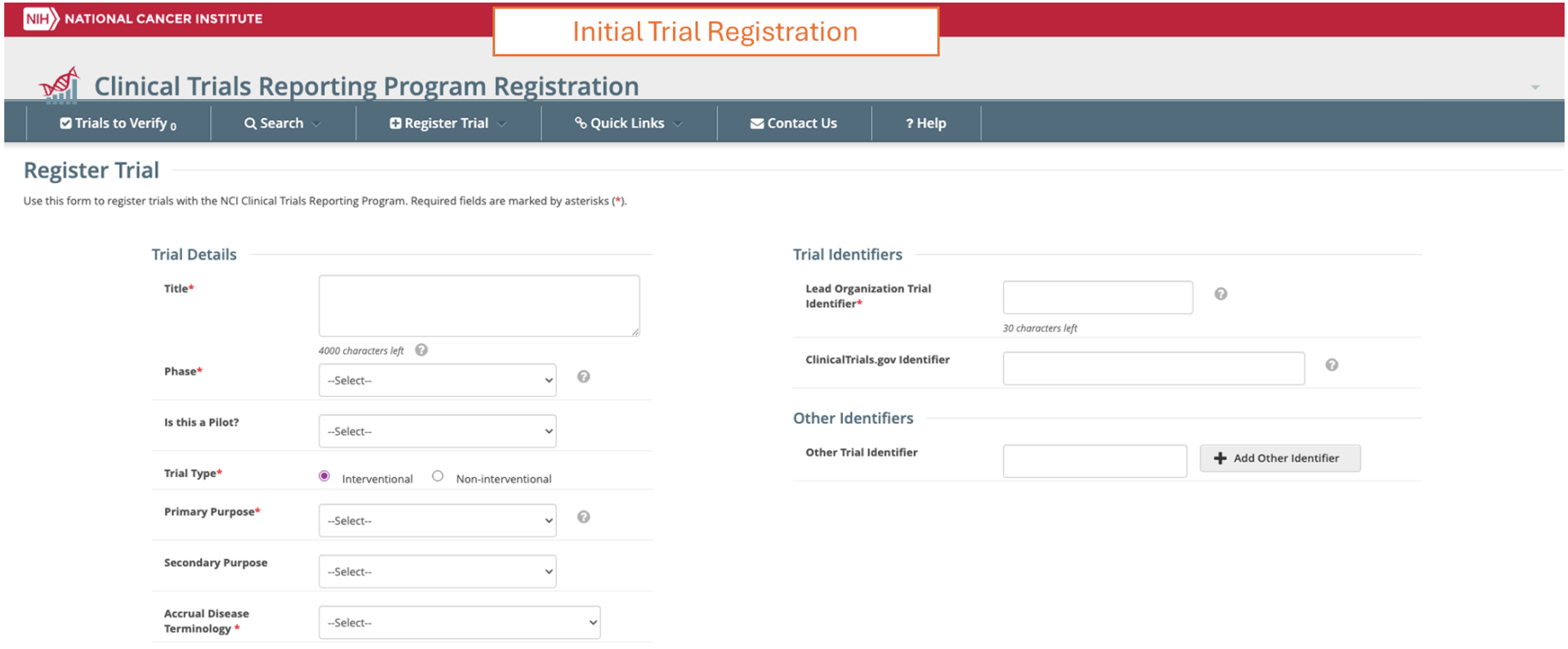
Search Submitted Clinical Trials
Clinical Trials Reporting Program Registration
Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
Search Clinical Trials
Search Persons
Search Organizations
Enter information for at least one of the criteria and then click Search.
Title
Enter keywords
Phase
--Select--
Purpose
--Select--
Pilot Trial?
--Select--
Identifier Type
--Select--
Identifier
Examples: NCI-2008-00015; ECOG-1234
Organization Type
--Select--
Please select an organization type before selecting an organization
Organization
Enter keyword and select an organization from the list
Principal Investigator
Enter keyword and select a PI from the list
Search By Trial Category
--Select--
Search
Reset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Initial Trial Registration
Clinical Trials Reporting Program Registration
Trials to Verify 0
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 (*).
Trial Details
Title*
4000 characters left
Phase*
--Select--
Is this a Pilot?
--Select--
Trial Type*
Interventional
Non-interventional
Primary Purpose*
--Select--
Secondary Purpose
--Select--
Accrual Disease Terminology *
--Select--
Trial Identifiers
Lead Organization Trial Identifier*
30 characters left
ClinicalTrials.gov Identifier
Other Identifiers
Other Trial Identifier
Add Other Identifier

Lead Organization/Principal Investigator

Lead Organization* Please Select the Lead Organization

Principal Investigator* Look Up

Sponsor/Responsible Party

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

Sponsor: Please Select the Sponsor Organization

Responsible Party --Select--

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

Studies a U.S. FDA-regulated Device Product

Product Exported from the U.S

FDA Regulated Intervention Indicator

Data Monitoring Committee Appointed Indicator

Data Table 4 Information

Data Table 4 Funding Sponsor Type* National

Data Table 4 Funding Sponsor* Please Select the Data Table 4 Sponsor Organization

Trial Status*

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

1000 characters left

Administratively Complete, Withdrawn and Temporarily Closed statuses only

*Please refer to the **Trial Status Transition Rules**.*

Trial Dates

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 **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

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 NCI funded? * Direct — Indirect — No

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

*Please refer to **Recording NIH Grants**.*

Institutional Review Board (IRB)

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

Board Affiliation: Look Up

Board Contact Mailing Address:

Board Contact City:

Board Contact State/Province:

Board Contact Zip/Postal Code:

Board Contact Country: --Select--

Board Contact Phone: Either a contact phone or an email address is required

Board Contact Email Address:

Board Name:

200 characters left

Clear IRB

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* Choose File No file chosen

IRB Approval* Choose File No file chosen

List of Participating Sites Choose File No file chosen

Informed Consent Document Choose File No file chosen

Other Choose File No file chosen

Add more...

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

Save as Draft | Submit Trial | Cancel