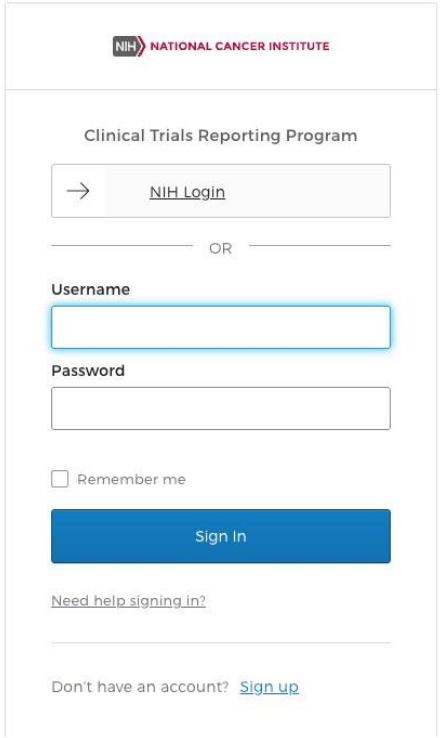
NCI CTRP Attachment 3b

NCI CTRP Trial Registration Update Workflow and Screen Shots

NIH NATIONAL CANCER INSTITUTE

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

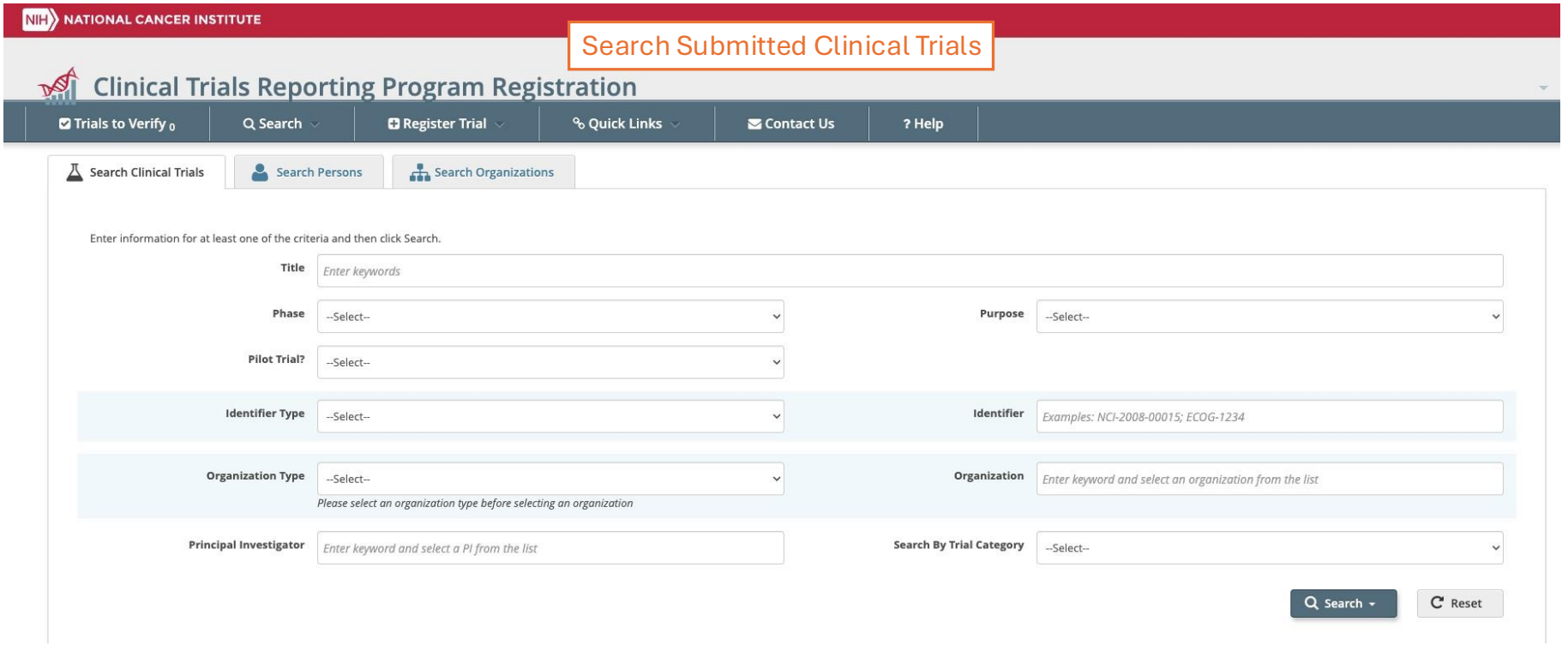
- This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media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

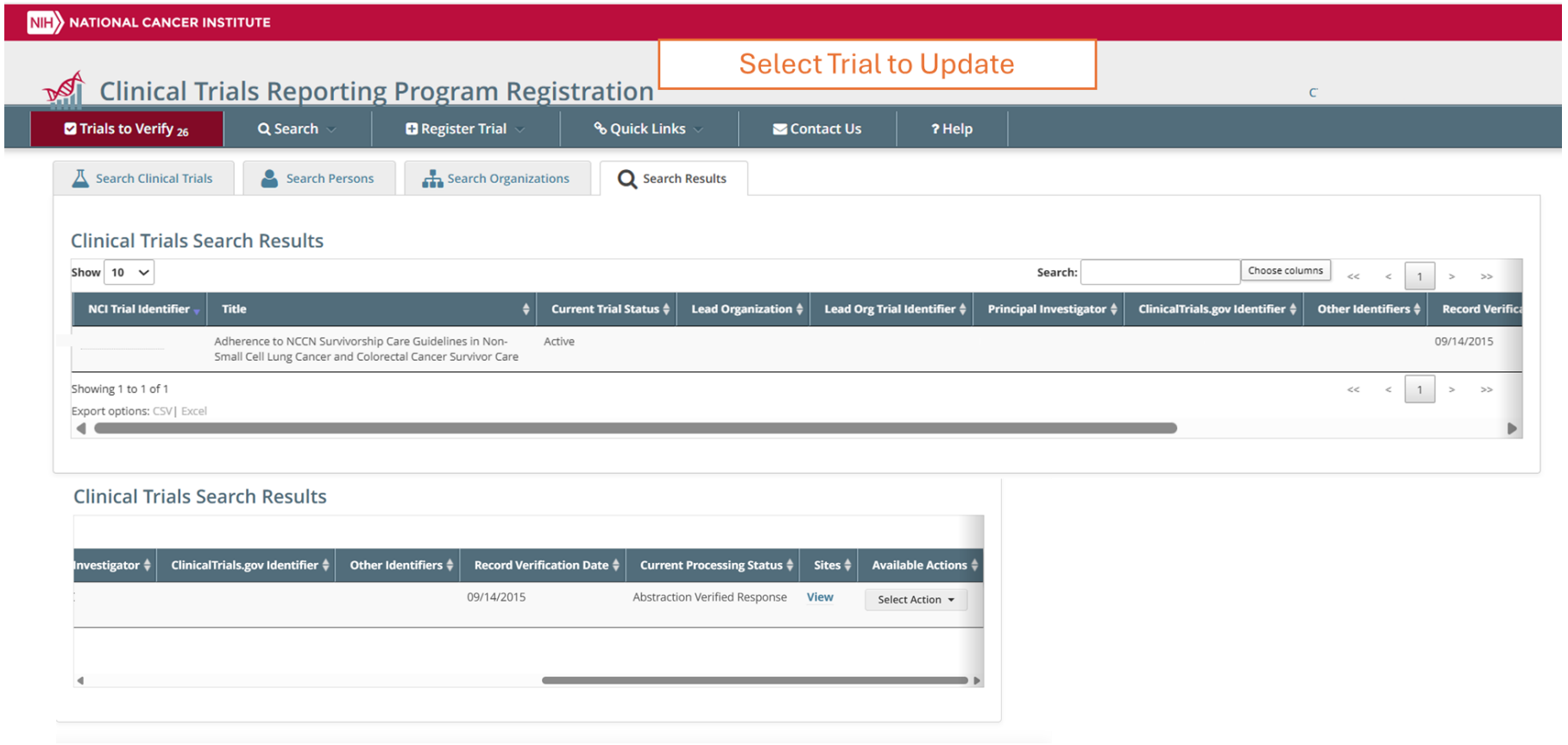
NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

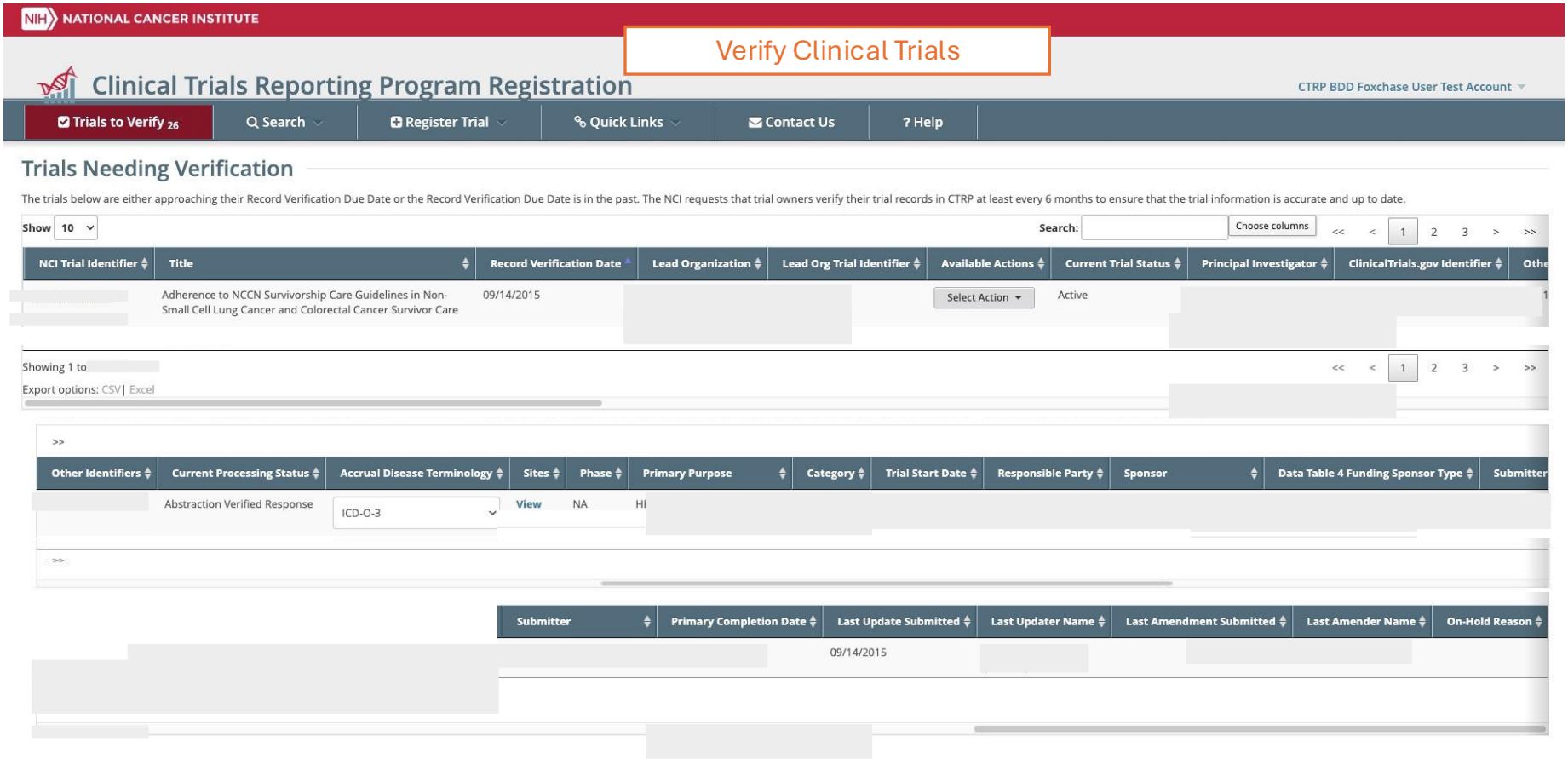
OMB#: 0925-0600 EXP. DATE: 2/28/26

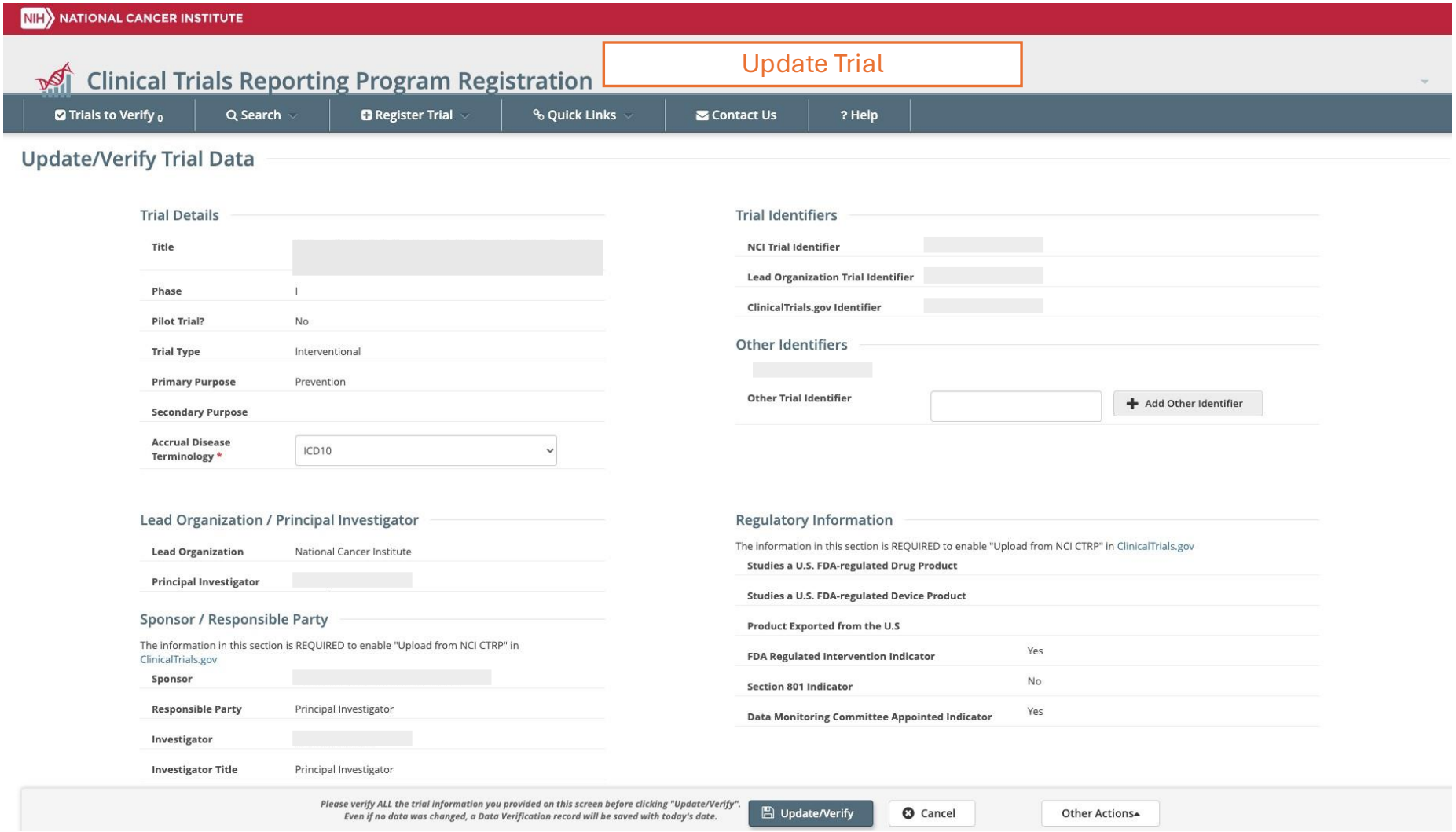
Public reporting burden for this collection of information is estimated to average sixty (60) minutes for this questionnaire, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. An agency 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.

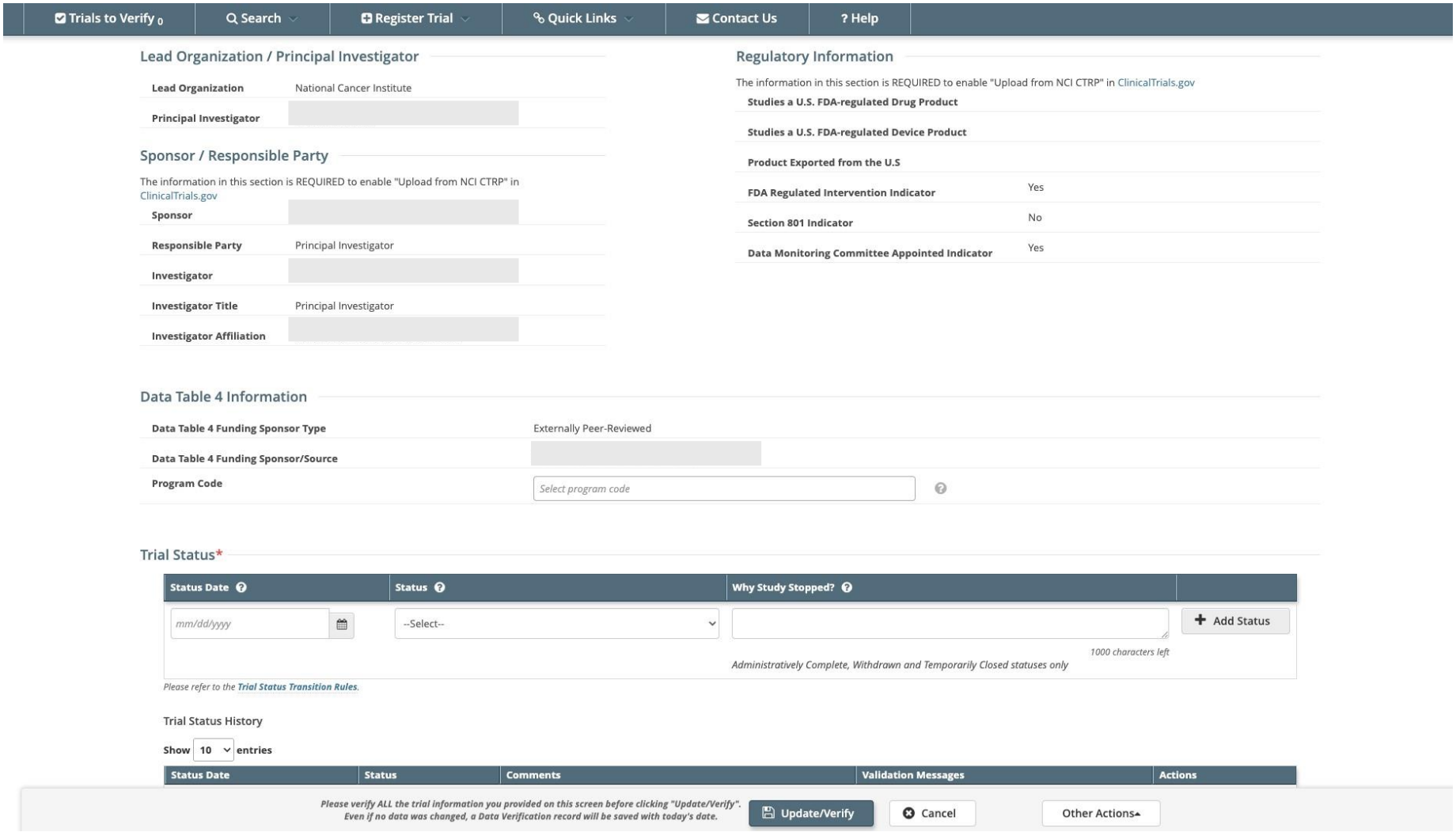
Accept Reject

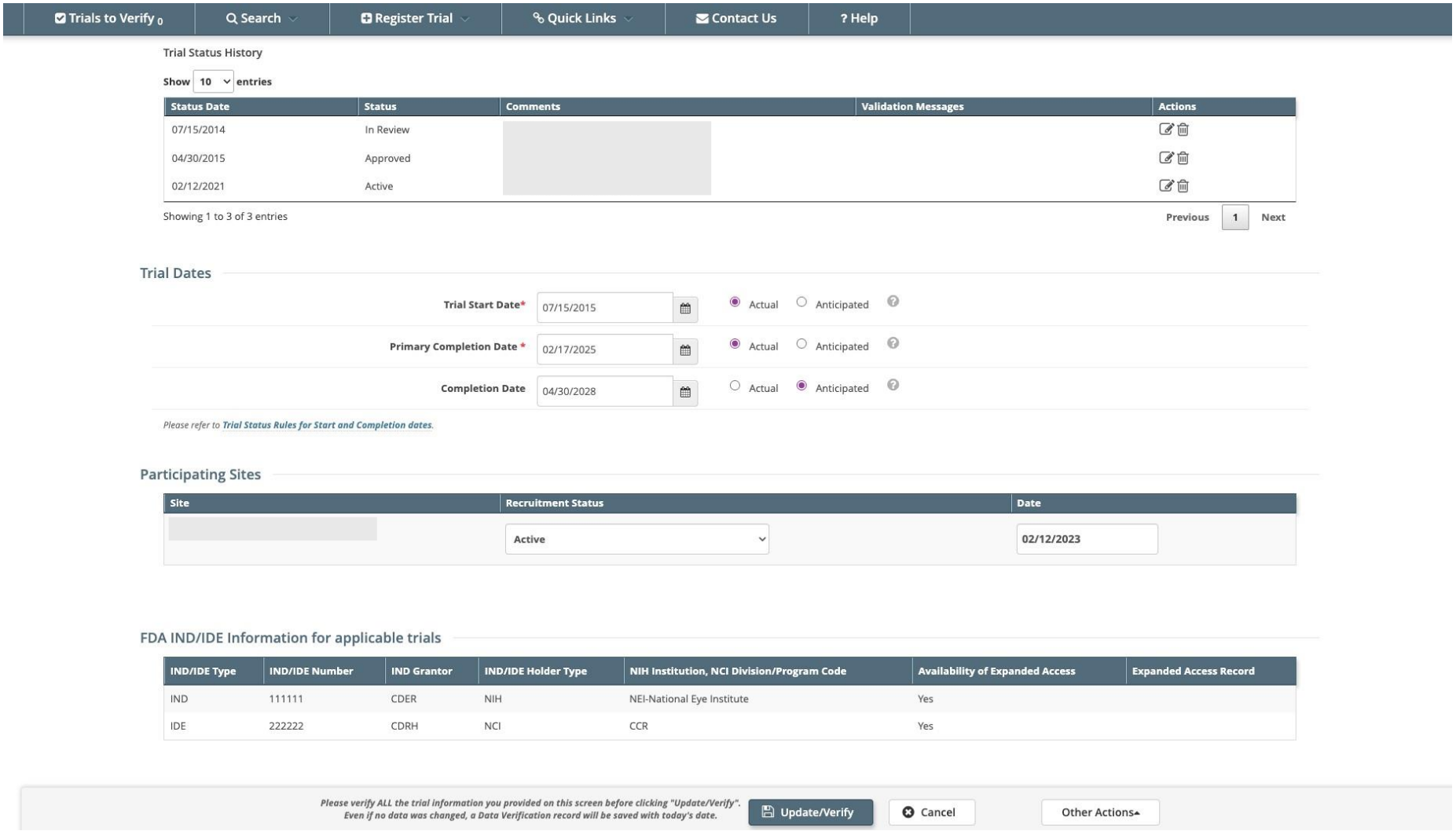

NATIONAL CANCER INSTITUTE
Search Submitted Clinical Trials
Clinical Trials Reporting Program Registration
Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
Search Clinical Trials
Search Persons
Search Organizations
Enter information for at least one of the criteria and then click 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

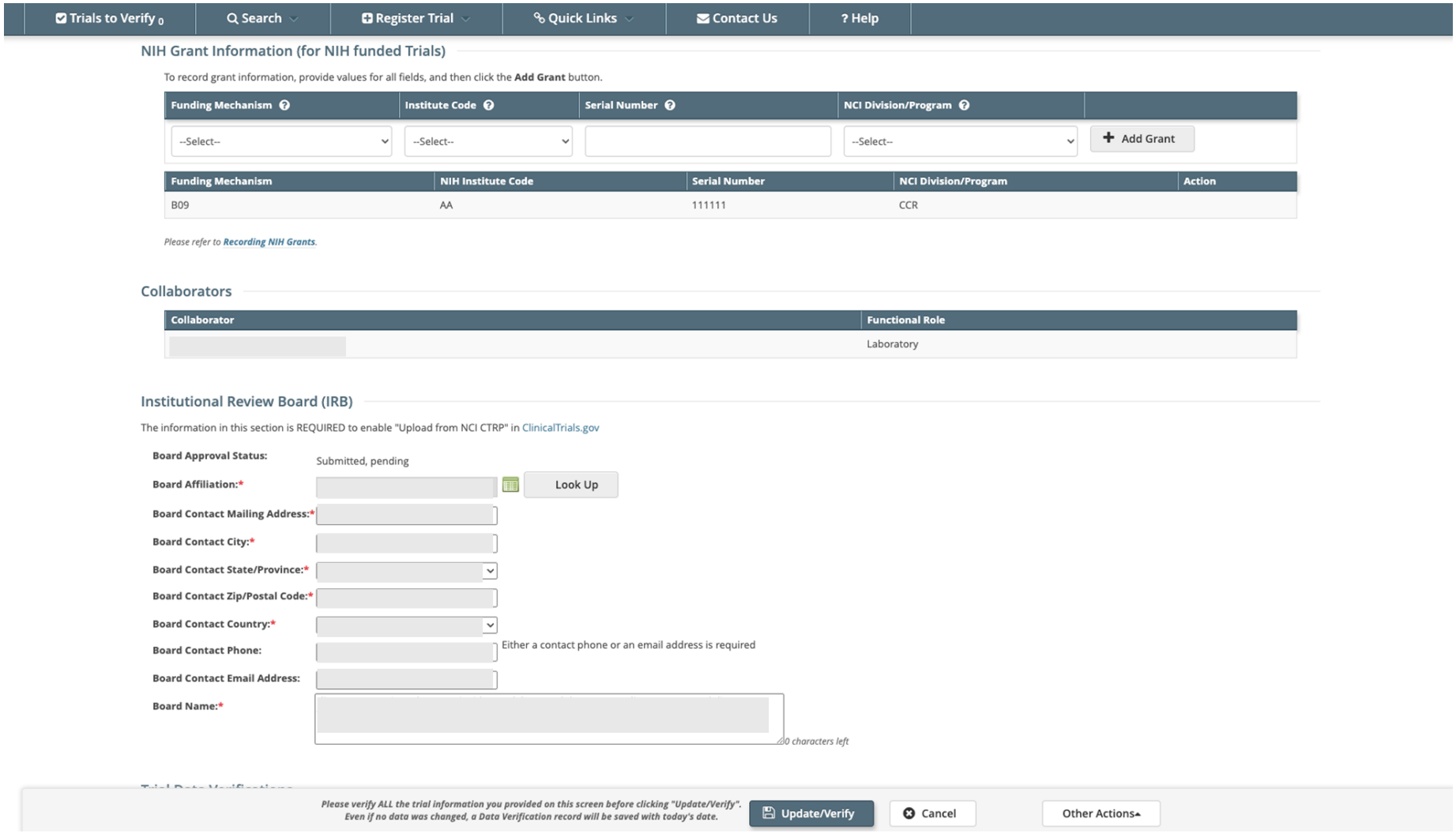

NATIONAL CANCER INSTITUTE
Clinical Trials Reporting Program Registration
Select Trial to Update
Trials to Verify 26
Search
Register Trial
Quick Links
Contact Us
Help
Search Clinical Trials
Search Persons
Search Organizations
Search Results
Clinical Trials Search Results
Show 10
Search:
Choose columns
NCI Trial Identifier
Title
Current Trial Status
Lead Organization
Lead Org Trial Identifier
Principal Investigator
ClinicalTrials.gov Identifier
Other Identifiers
Record Verifica
Adherence to NCCN Survivorship Care Guidelines in Non-Small Cell Lung Cancer and Colorectal Cancer Survivor Care
Active
09/14/2015
Showing 1 to 1 of 1
Export options: CSV | Excel
Clinical Trials Search Results
Investigator
ClinicalTrials.gov Identifier
Other Identifiers
Record Verification Date
Current Processing Status
Sites
Available Actions
09/14/2015
Abstraction Verified Response
View
Select Action

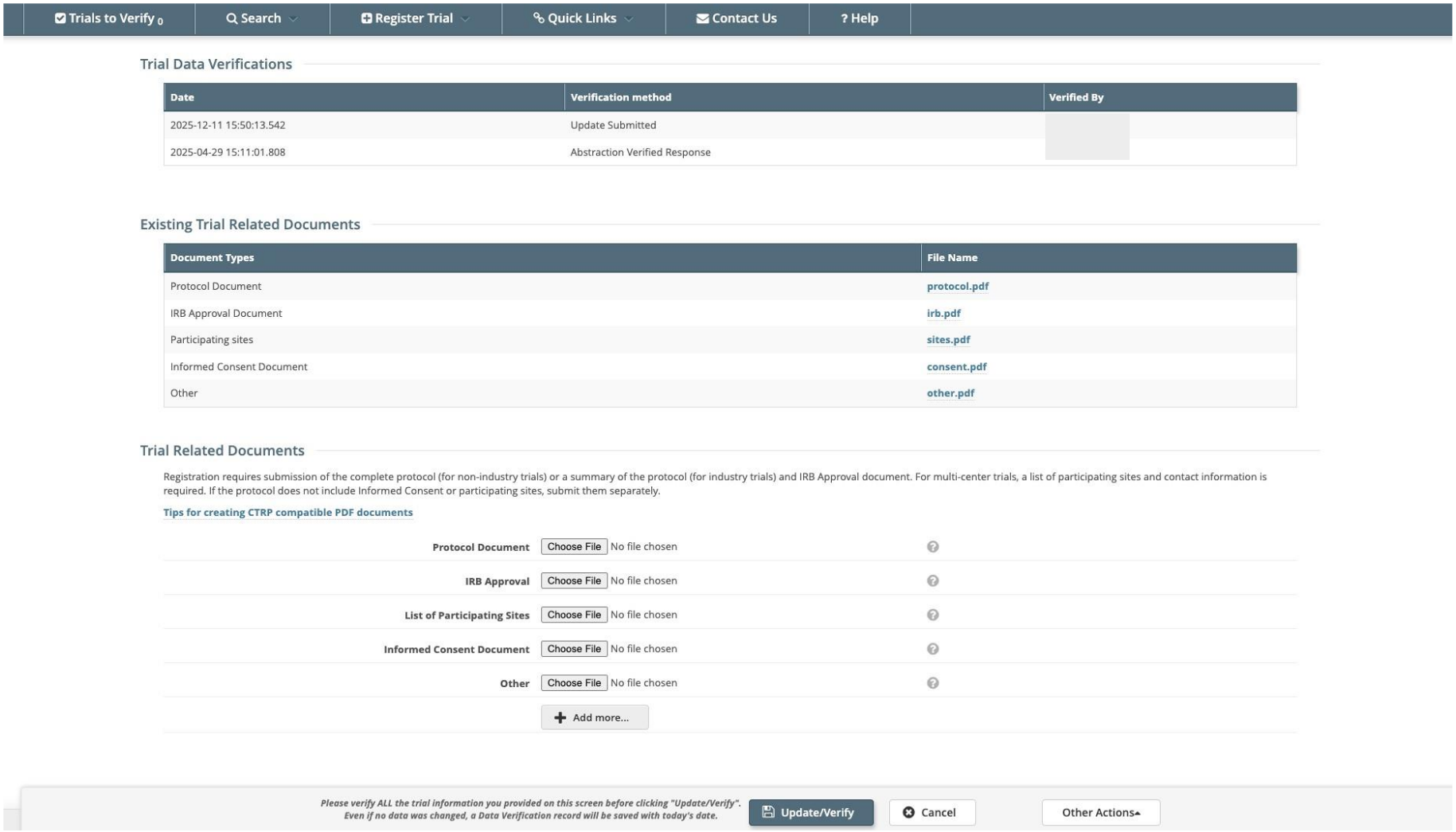

NATIONAL CANCER INSTITUTE
Verify Clinical Trials
Clinical Trials Reporting Program Registration
CTRP BDD Foxchase User Test Account
Trials to Verify 26
Search
Register Trial
Quick Links
Contact Us
Help
Trials Needing Verification
The trials below are either approaching their Record Verification Due Date or the Record Verification Due Date is in the past. The NCI requests that trial owners verify their trial records in CTRP at least every 6 months to ensure that the trial information is accurate and up to date.
Show 10
Search:
Choose columns
NCI Trial Identifier
Title
Record Verification Date
Lead Organization
Lead Org Trial Identifier
Available Actions
Current Trial Status
Principal Investigator
ClinicalTrials.gov Identifier
Adherence to NCCN Survivorship Care Guidelines in Non-Small Cell Lung Cancer and Colorectal Cancer Survivor Care
09/14/2015
Select Action
Active
Showing 1 to
Export options: CSV | Excel
Other Identifiers
Current Processing Status
Accrual Disease Terminology
Sites
Phase
Primary Purpose
Category
Trial Start Date
Responsible Party
Sponsor
Data Table 4 Funding Sponsor Type
Submitter
Abstraction Verified Response
ICD-O-3
View
NA
Submitter
Primary Completion Date
Last Update Submitted
Last Updater Name
Last Amendment Submitted
Last Amender Name
On-Hold Reason
09/14/2015


NIH NATIONAL CANCER INSTITUTE
Clinical Trials Reporting Program Registration
Update Trial
Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
Update/Verify Trial Data
Trial Details
Title
Phase
I
Pilot Trial?
No
Trial Type
Interventional
Primary Purpose
Prevention
Secondary Purpose
Accrual Disease Terminology *
ICD10
Trial Identifiers
NCI Trial Identifier
Lead Organization Trial Identifier
ClinicalTrials.gov Identifier
Other Identifiers
Other Trial Identifier
Add Other Identifier
Lead Organization / Principal Investigator
Lead Organization
National Cancer Institute
Principal Investigator
Sponsor / Responsible Party
The information in this section is REQUIRED to enable "Upload from NCI CTRP" in ClinicalTrials.gov
Sponsor
Responsible Party
Principal Investigator
Investigator
Investigator Title
Principal Investigator
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
Yes
Section 801 Indicator
No
Data Monitoring Committee Appointed Indicator
Yes
Please verify ALL the trial information you provided on this screen before clicking "Update/Verify".
Even if no data was changed, a Data Verification record will be saved with today's date.
Update/Verify
Cancel
Other Actions


Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
Lead Organization / Principal Investigator
Lead Organization
National Cancer Institute
Principal Investigator
Sponsor / Responsible Party
The information in this section is REQUIRED to enable "Upload from NCI CTRP" in ClinicalTrials.gov
Sponsor
Responsible Party
Principal Investigator
Investigator
Investigator Title
Principal Investigator
Investigator Affiliation
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
Yes
Section 801 Indicator
No
Data Monitoring Committee Appointed Indicator
Yes
Data Table 4 Information
Data Table 4 Funding Sponsor Type
Externally Peer-Reviewed
Data Table 4 Funding Sponsor/Source
Program Code
Select program code
Trial Status*
Status Date
Status
Why Study Stopped?
mm/dd/yyyy
--Select--
1000 characters left
Add Status
Administratively Complete, Withdrawn and Temporarily Closed statuses only
Please refer to the Trial Status Transition Rules.
Trial Status History
Show 10 entries
Status Date
Status
Comments
Validation Messages
Actions
Please verify ALL the trial information you provided on this screen before clicking "Update/Verify".
Even if no data was changed, a Data Verification record will be saved with today's date.
Update/Verify
Cancel
Other Actions


Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
Trial Status History
Show 10 entries
Status Date
Status
Comments
Validation Messages
Actions
07/15/2014
In Review
04/30/2015
Approved
02/12/2021
Active
Showing 1 to 3 of 3 entries
Previous
1
Next
Trial Dates
Trial Start Date*
07/15/2015
Actual
Anticipated
Primary Completion Date *
02/17/2025
Actual
Anticipated
Completion Date
04/30/2028
Actual
Anticipated
Please refer to Trial Status Rules for Start and Completion dates.
Participating Sites
Site
Recruitment Status
Date
Active
02/12/2023
FDA IND/IDE Information for applicable trials
IND/IDE Type
IND/IDE Number
IND Grantor
IND/IDE Holder Type
NIH Institution, NCI Division/Program Code
Availability of Expanded Access
Expanded Access Record
IND
111111
CDER
NIH
NEI-National Eye Institute
Yes
IDE
222222
CDRH
NCI
CCR
Yes
Please verify ALL the trial information you provided on this screen before clicking "Update/Verify".
Even if no data was changed, a Data Verification record will be saved with today's date.
Update/Verify
Cancel
Other Actions


Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
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
--Select--
--Select--
--Select--
Add Grant
Funding Mechanism
NIH Institute Code
Serial Number
NCI Division/Program
Action
B09
AA
111111
CCR
Please refer to Recording NIH Grants.
Collaborators
Collaborator
Functional Role
Laboratory
Institutional Review Board (IRB)
The information in this section is REQUIRED to enable "Upload from NCI CTRP" in ClinicalTrials.gov
Board Approval Status:
Submitted, pending
Board Affiliation:*
Look Up
Board Contact Mailing Address:*
Board Contact City:*
Board Contact State/Province:*
Board Contact Zip/Postal Code:*
Board Contact Country:*
Board Contact Phone:
Either a contact phone or an email address is required
Board Contact Email Address:
Board Name:*
0 characters left
Please verify ALL the trial information you provided on this screen before clicking "Update/Verify".
Even if no data was changed, a Data Verification record will be saved with today's date.
Update/Verify
Cancel
Other Actions


Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
Trial Data Verifications
Date
Verification method
Verified By
2025-12-11 15:50:13.542
Update Submitted
2025-04-29 15:11:01.808
Abstraction Verified Response
Existing Trial Related Documents
Document Types
File Name
Protocol Document
protocol.pdf
IRB Approval Document
irb.pdf
Participating sites
sites.pdf
Informed Consent Document
consent.pdf
Other
other.pdf
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
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 "Update/Verify".
Even if no data was changed, a Data Verification record will be saved with today's date.
Update/Verify
Cancel
Other Actions