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

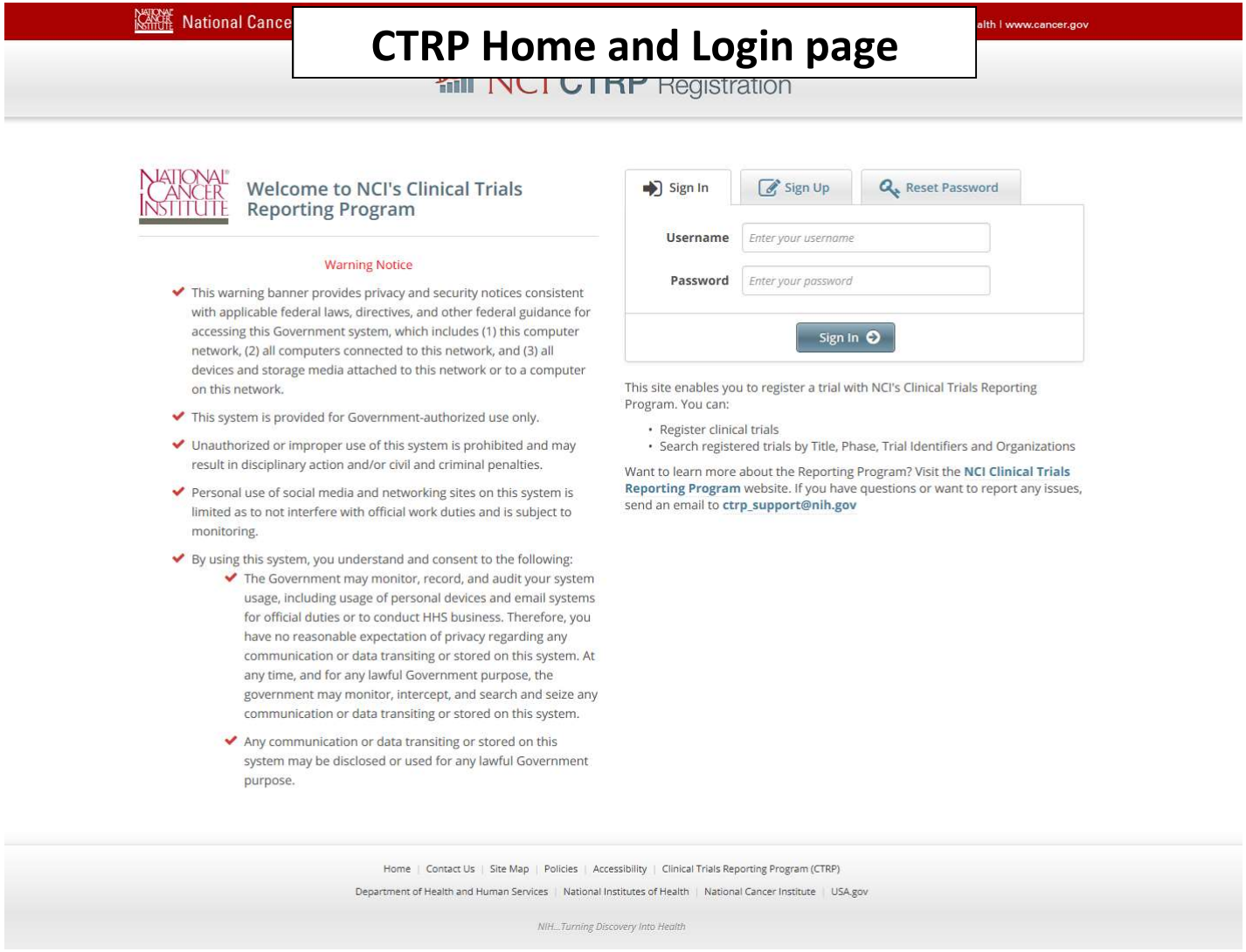
Step 2: User enters “Username” and “Password” – see screenshot, page 2

Step 3: User reviews NCI Clinical Trials Reporting Program burden statement – see screenshot, page 3

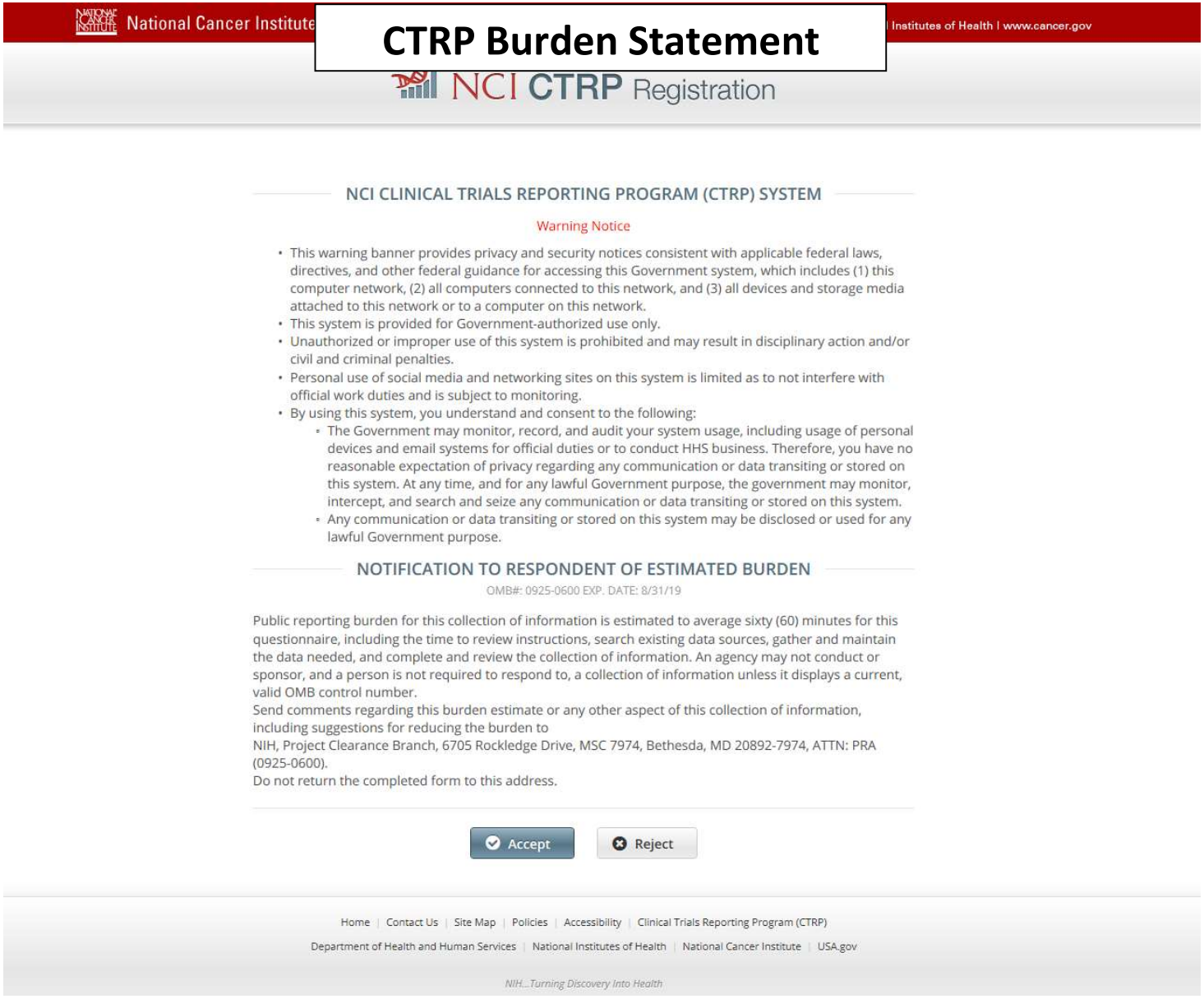
Step 4: System displays “Search Submitted Clinical Trials” page – see screenshot, page 4

Step 5: User selects to “Submit Trial Amendment” and amends an existing trial record – see screenshots, pages 5 – 10

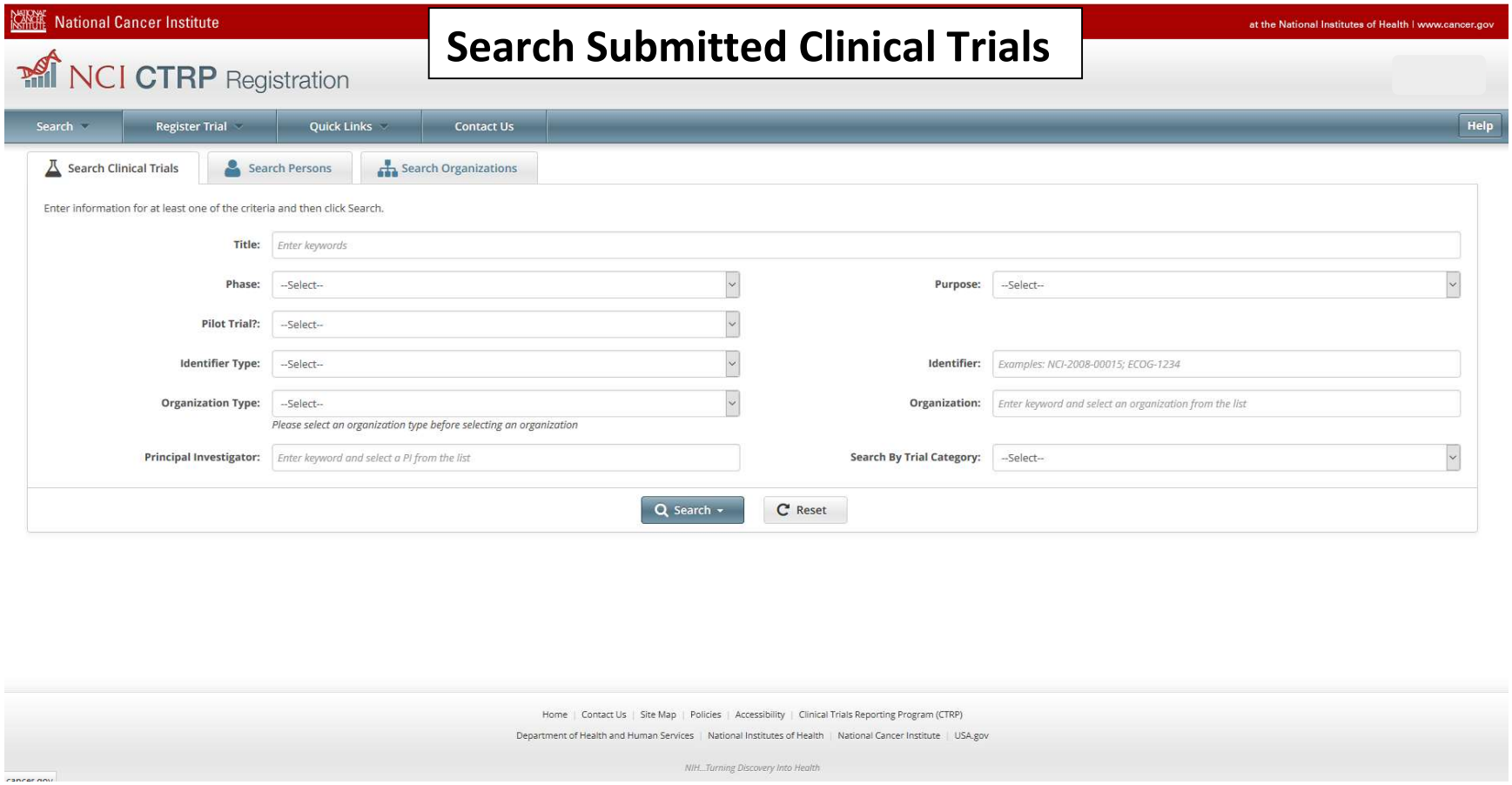
CTRP Home and Login page

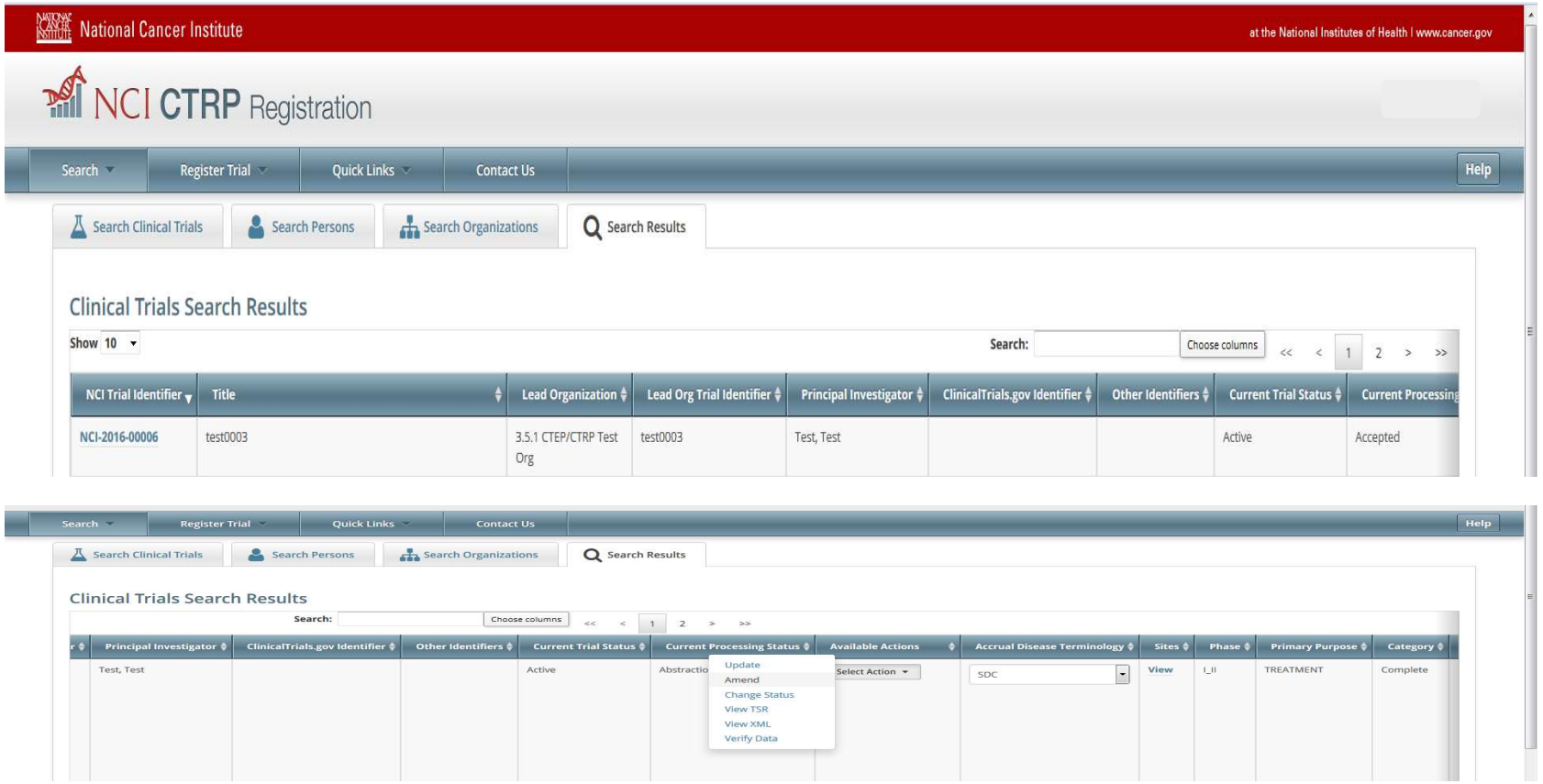


CTRP Burden Statement

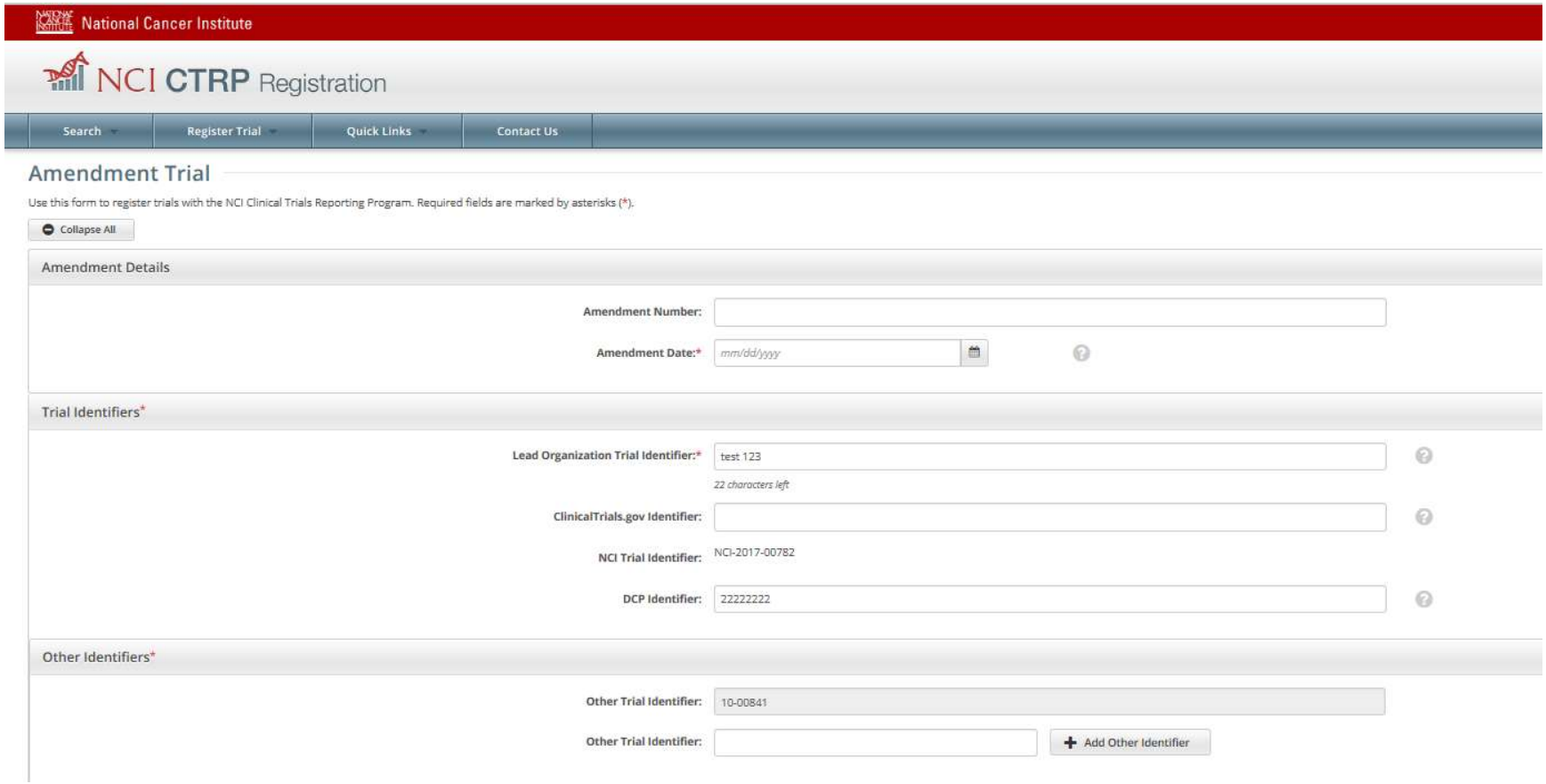


Search Submitted Clinical Trials




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

Search
Register Trial
Quick Links
Contact Us
Help
Search Clinical Trials
Search Persons
Search Organizations
Search Results
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
Select Action
SDC
View
I_II
TREATMENT
Complete


National Cancer Institute
NCI CTRP Registration
Search
Register Trial
Quick Links
Contact Us
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:*
mm/dd/yyyy
Trial Identifiers*
Lead Organization Trial Identifier:*
test 123
22 characters left
ClinicalTrials.gov Identifier:
NCI Trial Identifier:
NCI-2017-00782
DCP Identifier:
22222222
Other Identifiers*
Other Trial Identifier:
10-00841
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

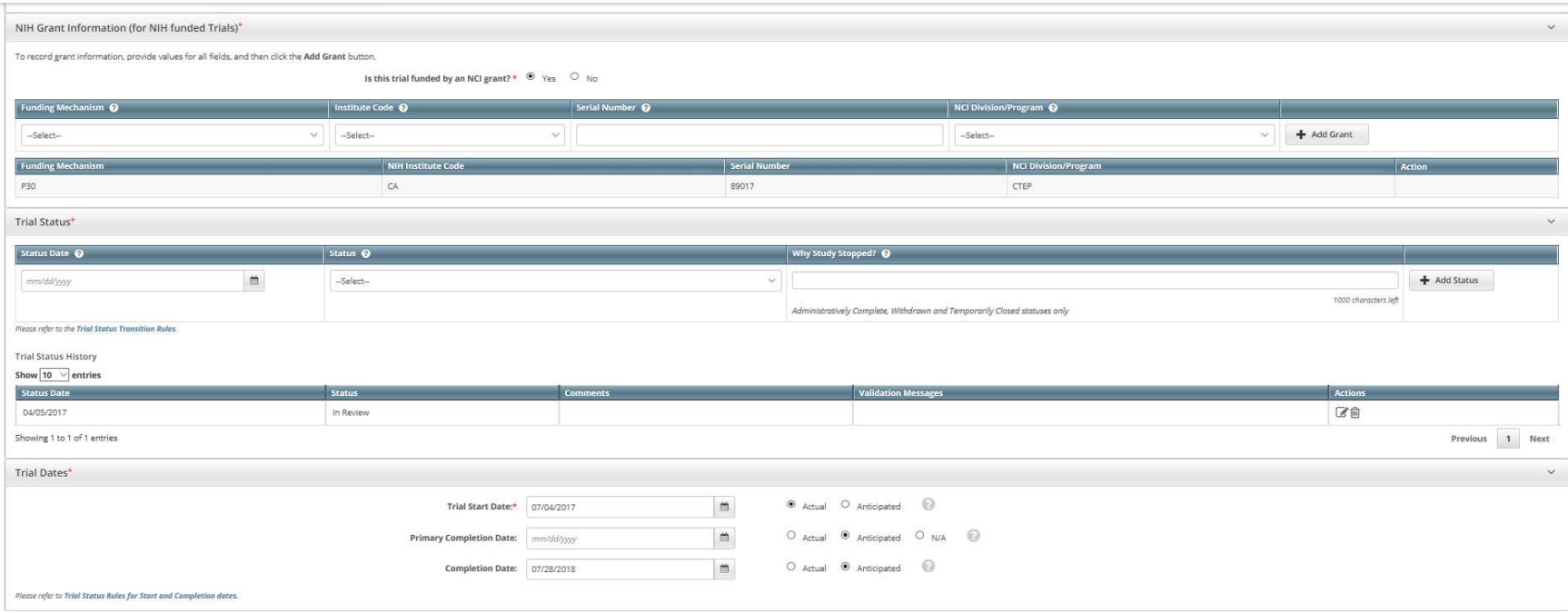
Data Table 4 Information*

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--
1000 characters left
Administratively Complete, Withdrawn and Temporarily Closed statuses only
Add Status
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
Actual Anticipated
Primary Completion Date:
mm/dd/yyyy
Actual Anticipated N/A
Completion Date:
07/28/2018
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**

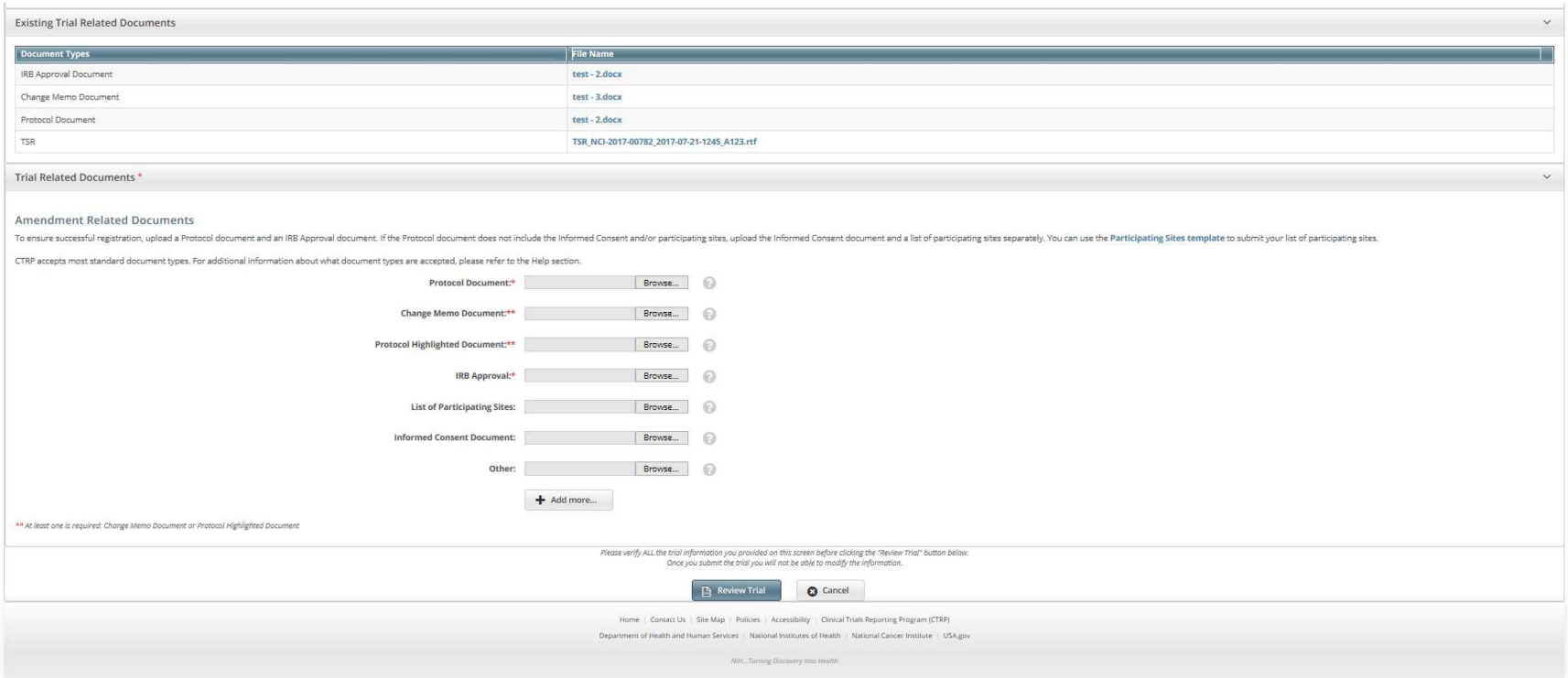
Pediatric Post-market Surveillance :

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:*
Change Memo Document:**
Protocol Highlighted Document:**
IRB Approval:*
List of Participating Sites:
Informed Consent Document:
Other:
Browse...
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 "Review Trial" button below.
Once you submit the trial you will not be able to modify the information.
Review Trial
Cancel
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Department of Health and Human Services | National Institutes of Health | National Cancer Institute | USA.gov
NIH...Turning Discovery Into Health