NCI CTRP Attachment 3b

NCI CTRP Update 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

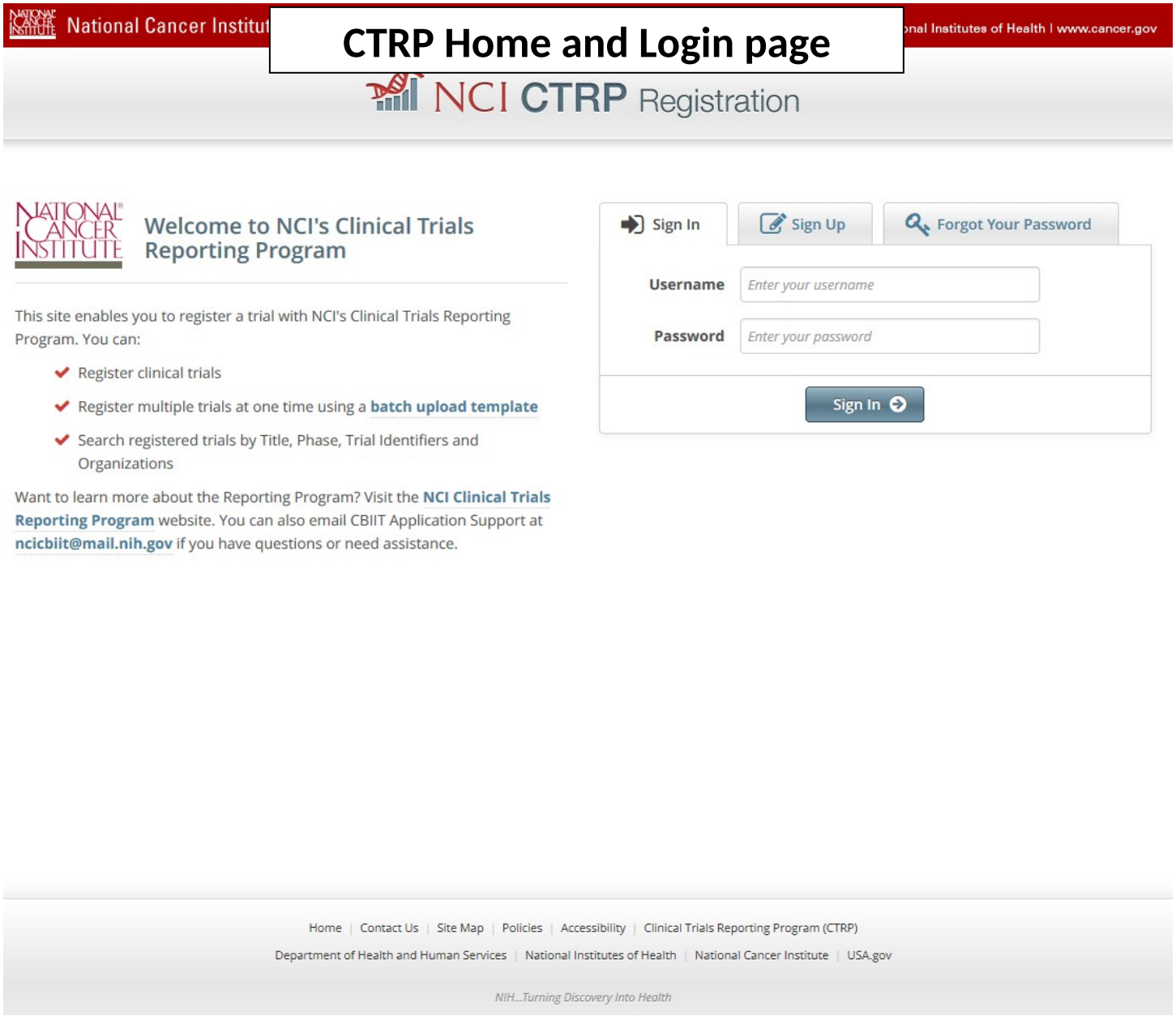
Step 2: User enters “Username” and “Password” – see screenshot, page 2

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

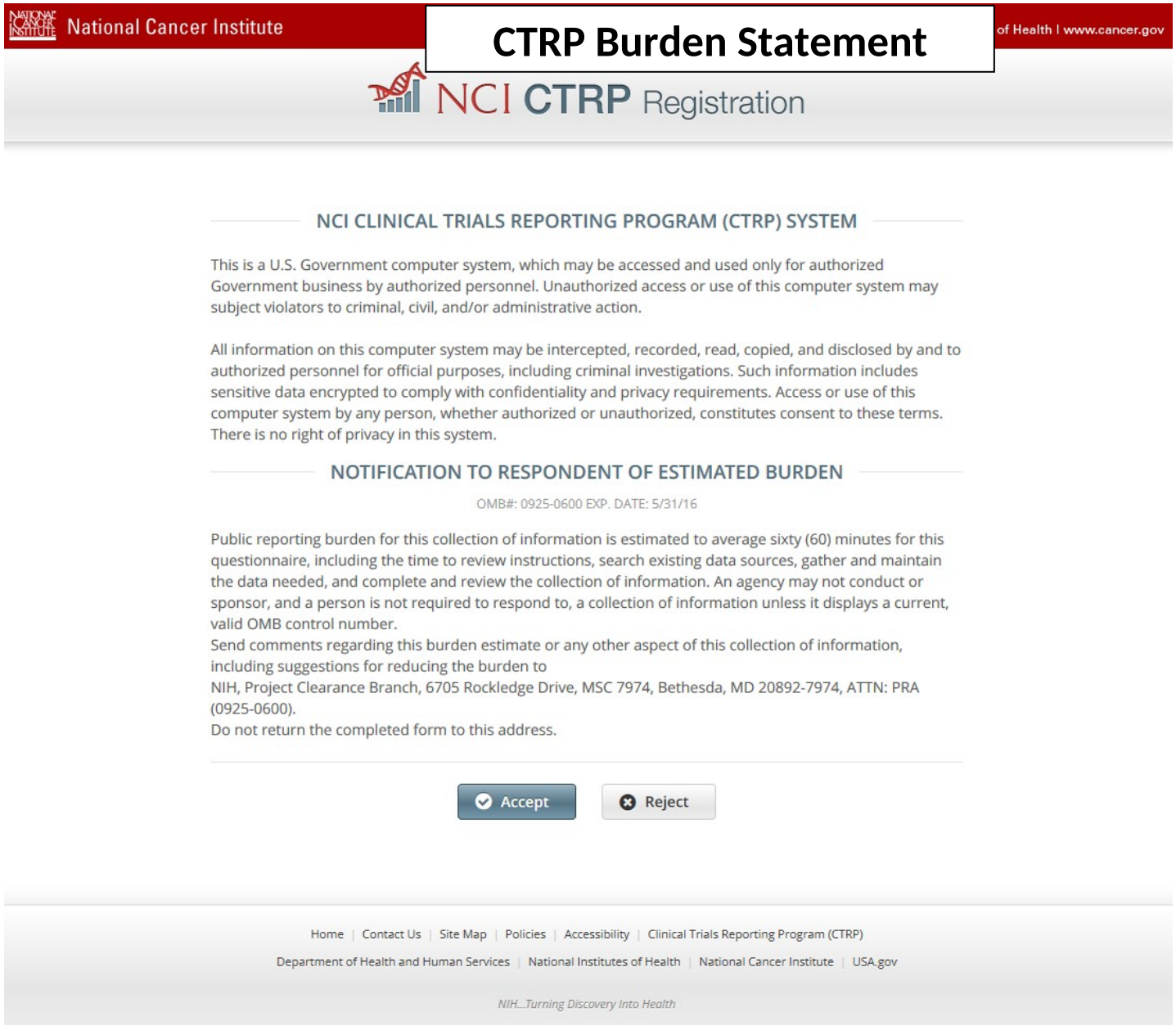
Step 4: System displays “Search Submitted Clinical Trials” page – see screenshot, page 4

Step 5: User selects to “Update Trial” and updates an existing trial record – see screenshots, pages 5 - 8

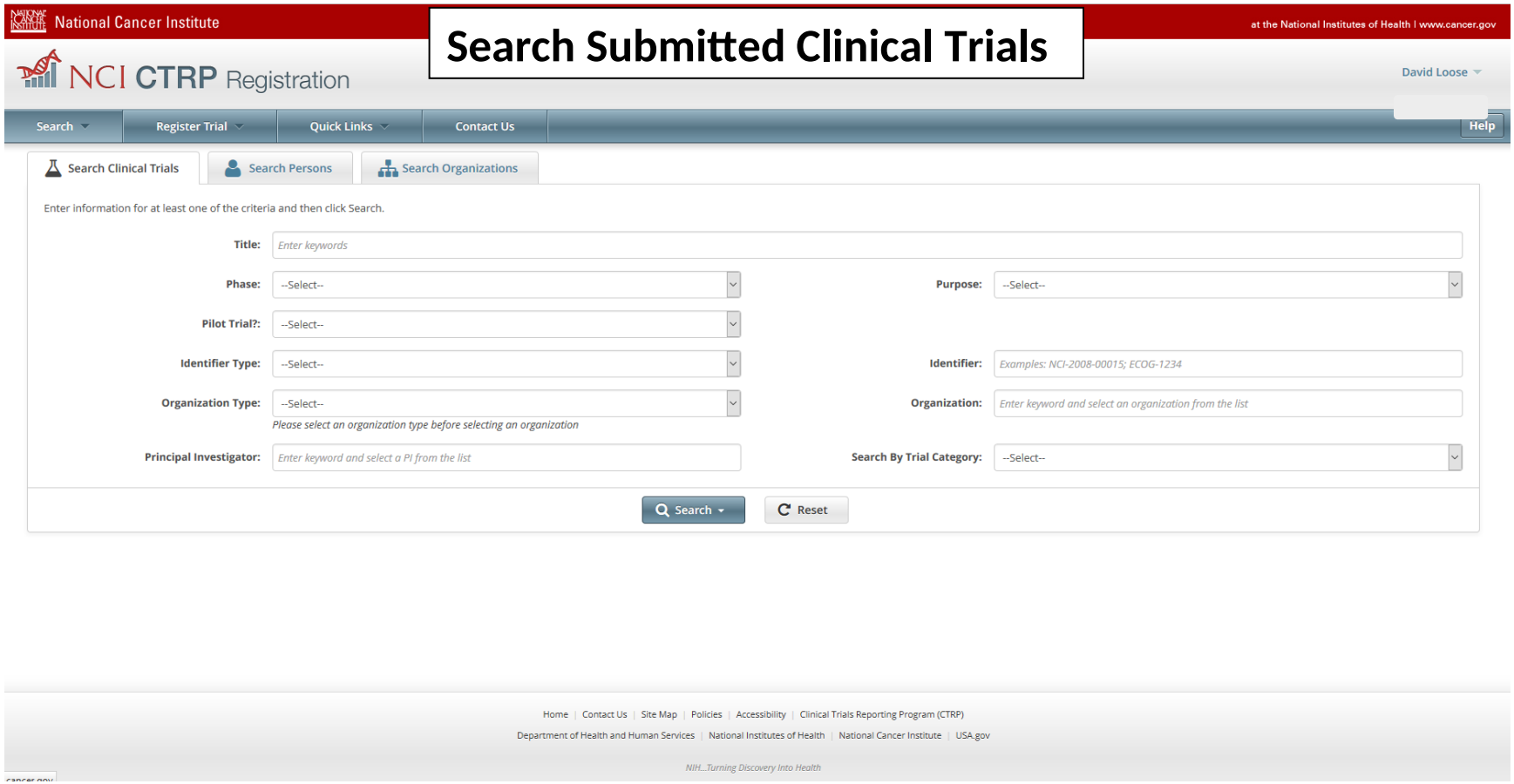
CTRP Home and Login page



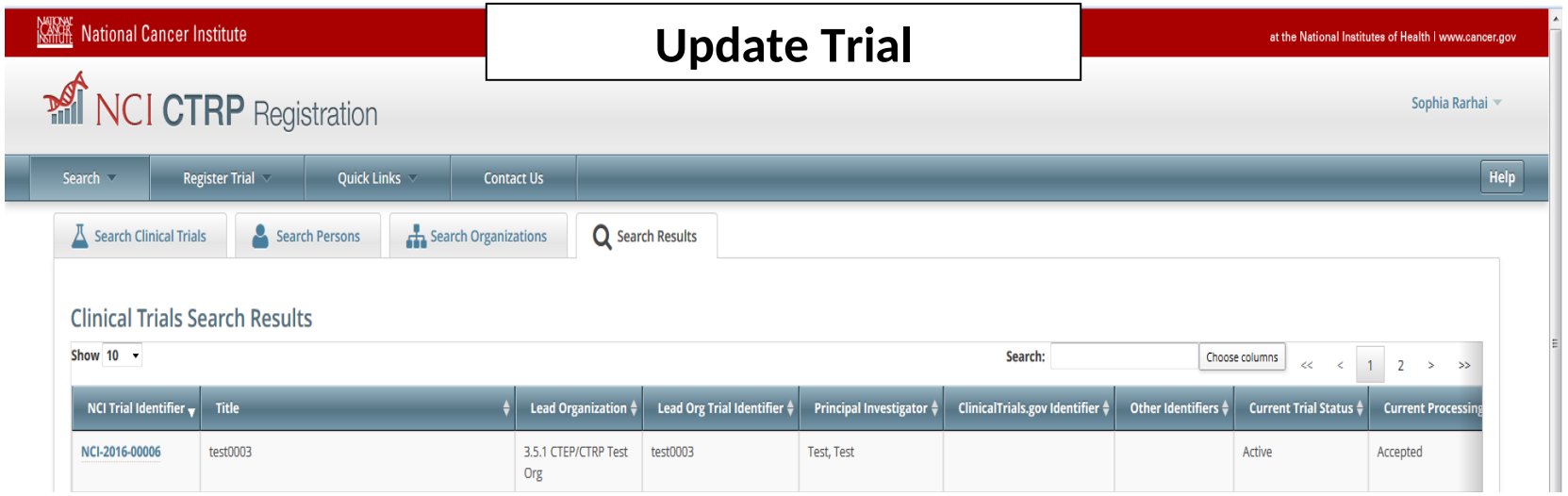
CTRP Burden Statement

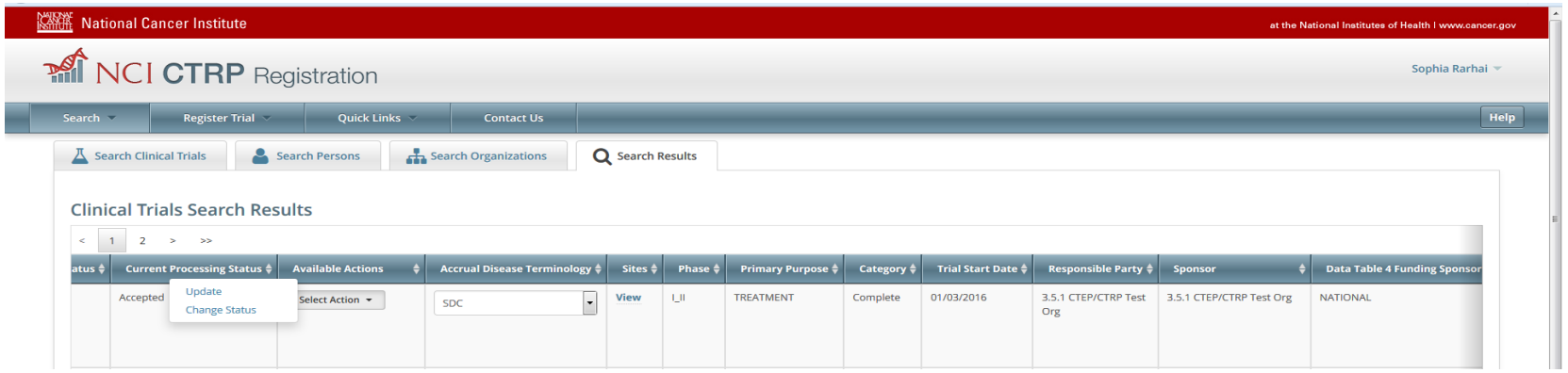


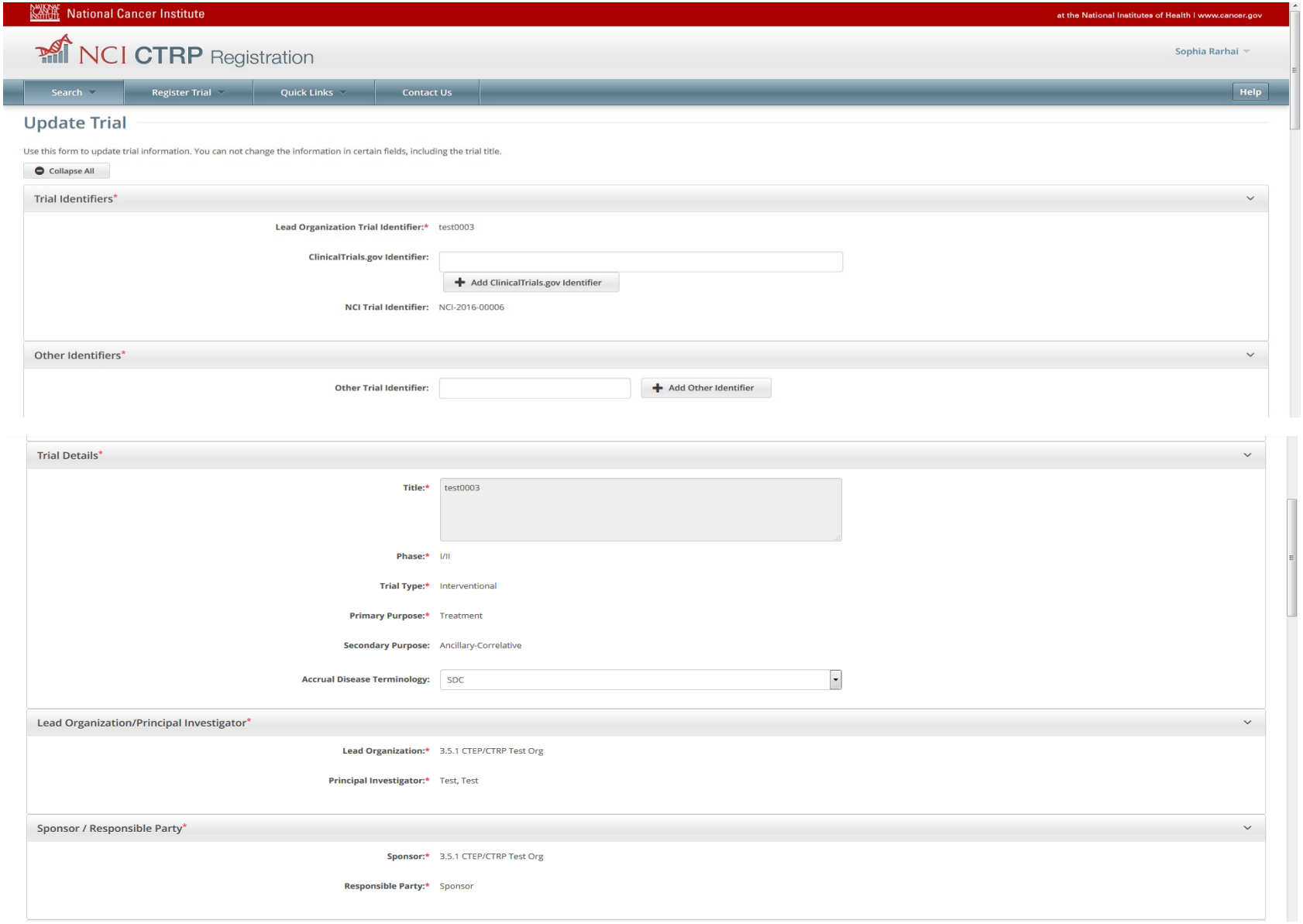
Search Submitted Clinical Trials

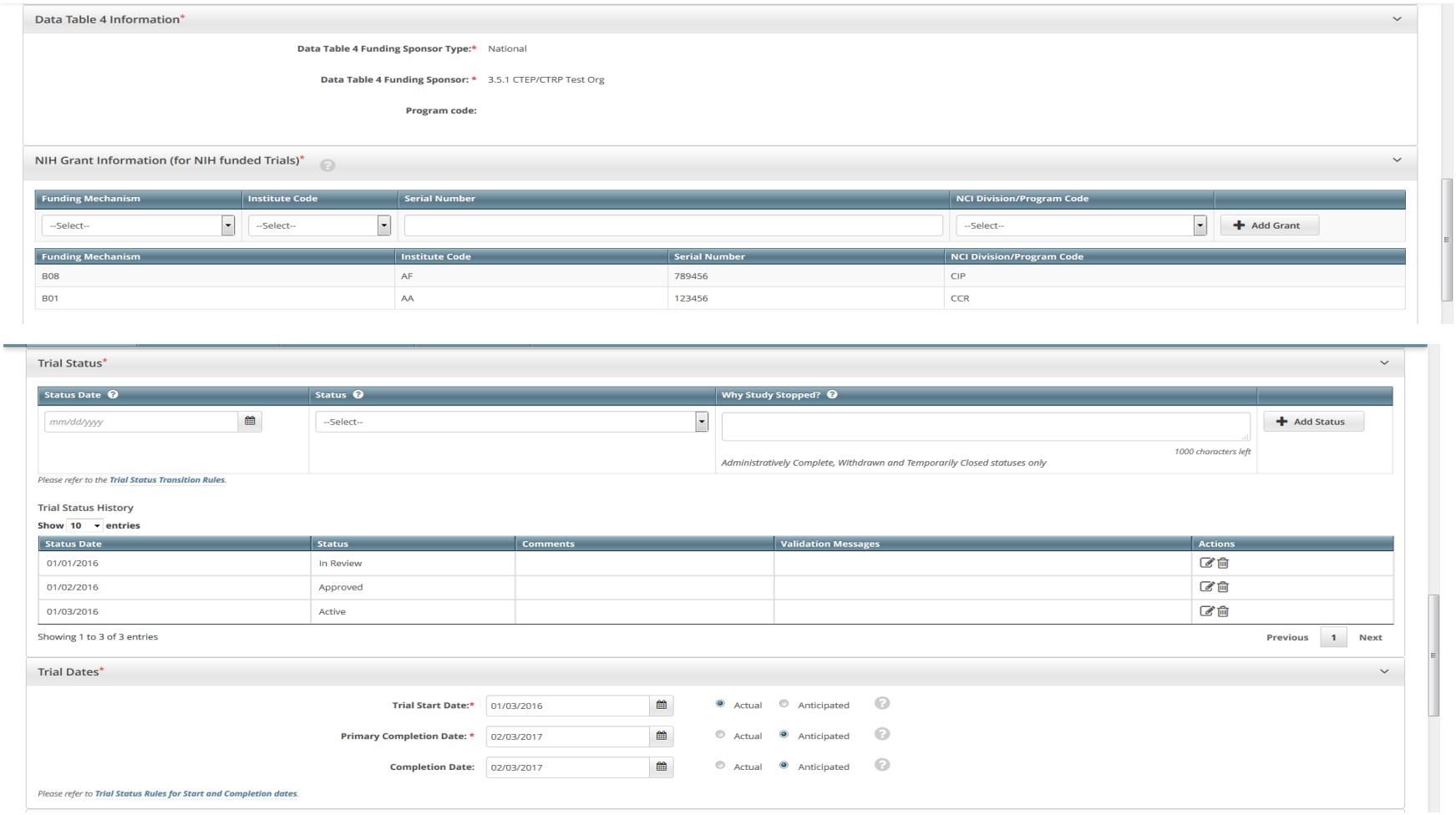


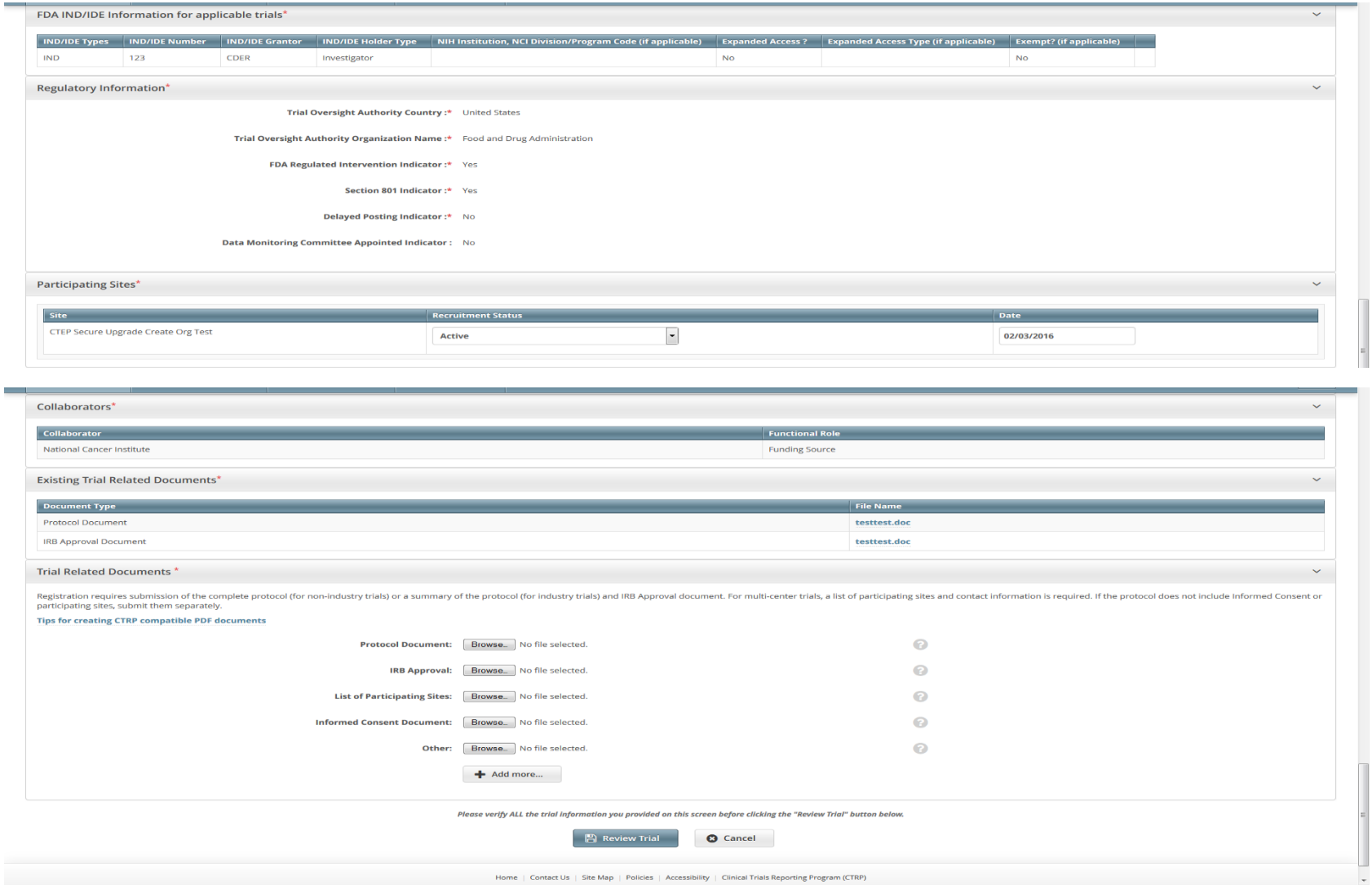
Update Trial






National Cancer Institute
at the National Institutes of Health | www.cancer.gov
NCI CTRP Registration
Sophia Rarhai
Search
Register Trial
Quick Links
Contact Us
Help
Update Trial
Use this form to update trial information. You can not change the information in certain fields, including the trial title.
Collapse All
Trial Identifiers*
Lead Organization Trial Identifier:* test0003
ClinicalTrials.gov Identifier:
Add ClinicalTrials.gov Identifier
NCI Trial Identifier: NCI-2016-00006
Other Identifiers*
Other Trial Identifier:
Add Other Identifier
Trial Details*
Title:* test0003
Phase:* I/II
Trial Type:* Interventional
Primary Purpose:* Treatment
Secondary Purpose: Ancillary-Correlative
Accrual Disease Terminology: SDC
Lead Organization/Principal Investigator*
Lead Organization:* 3.5.1 CTEP/CTRP Test Org
Principal Investigator:* Test, Test
Sponsor / Responsible Party*
Sponsor:* 3.5.1 CTEP/CTRP Test Org
Responsible Party:* Sponsor


Data Table 4 Information*
Data Table 4 Funding Sponsor Type:* National
Data Table 4 Funding Sponsor: * 3.5.1 CTEP/CTRP Test Org
Program code:
NIH Grant Information (for NIH funded Trials)*
Funding Mechanism
Institute Code
Serial Number
NCI Division/Program Code
--Select--
--Select--
--Select--
Add Grant
Funding Mechanism
Institute Code
Serial Number
NCI Division/Program Code
B08
AF
789456
CIP
B01
AA
123456
CCR
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
01/01/2016
In Review
01/02/2016
Approved
01/03/2016
Active
Showing 1 to 3 of 3 entries
Previous
1
Next
Trial Dates*
Trial Start Date:*
01/03/2016
Actual
Anticipated
Primary Completion Date: *
02/03/2017
Actual
Anticipated
Completion Date:
02/03/2017
Actual
Anticipated
Please refer to 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 :* Yes

Delayed Posting Indicator :* No

Data Monitoring Committee Appointed Indicator : No

Participating Sites*

Site	Recruitment Status	Date
CTEP Secure Upgrade Create Org Test	Active	02/03/2016

Collaborators*

Collaborator	Functional Role
National Cancer Institute	Funding Source

Existing Trial Related Documents*

Document Type	File Name
Protocol Document	testtest.doc
IRB Approval Document	testtest.doc

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: Browse... No file selected.

IRB Approval: Browse... No file selected.

List of Participating Sites: Browse... No file selected.

Informed Consent Document: Browse... No file selected.

Other: Browse... No file selected.

Add more...

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

Review Trial Cancel

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