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

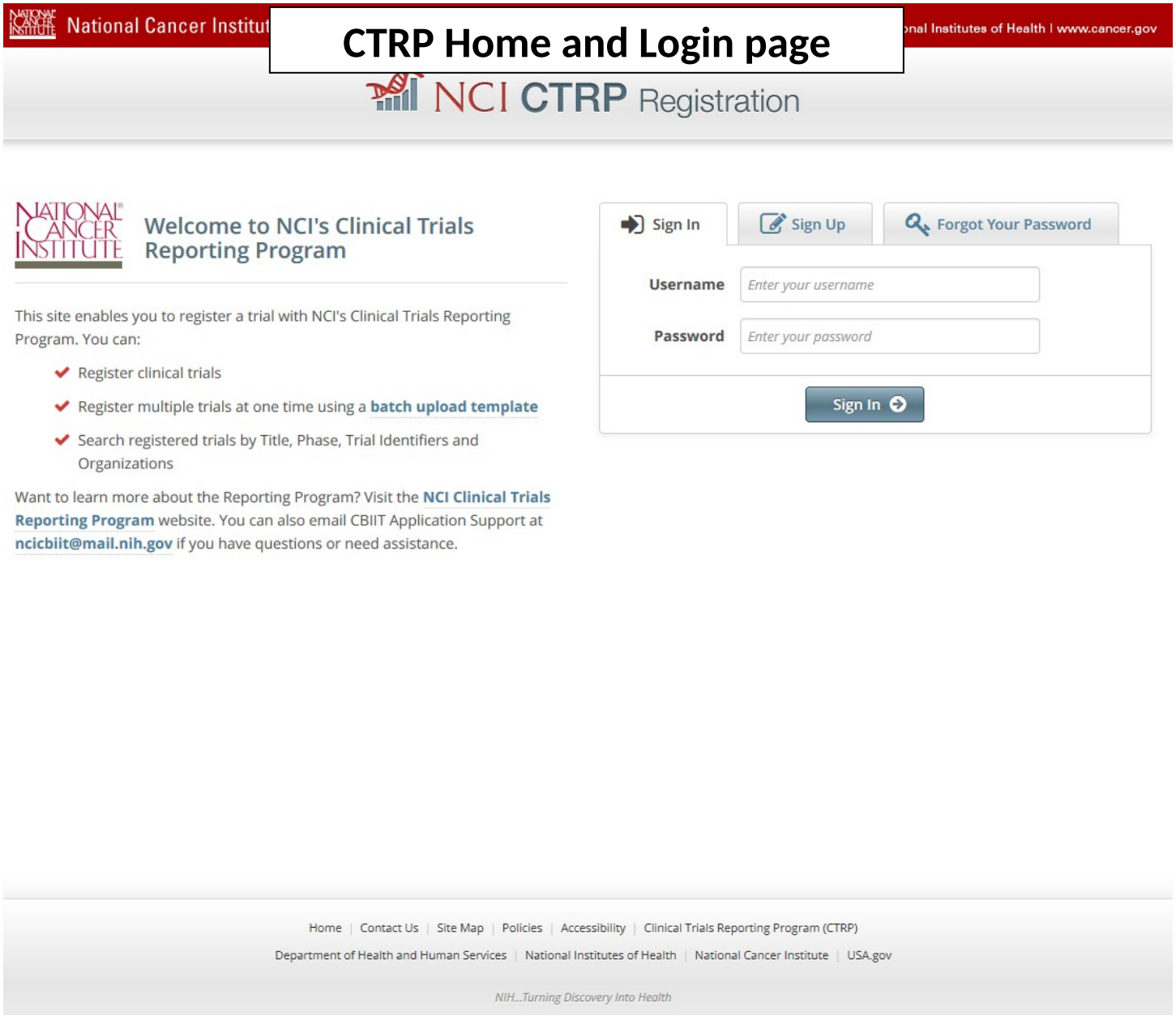
Step 2: User enters “Username” and “Password” – see screenshot, page 2

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

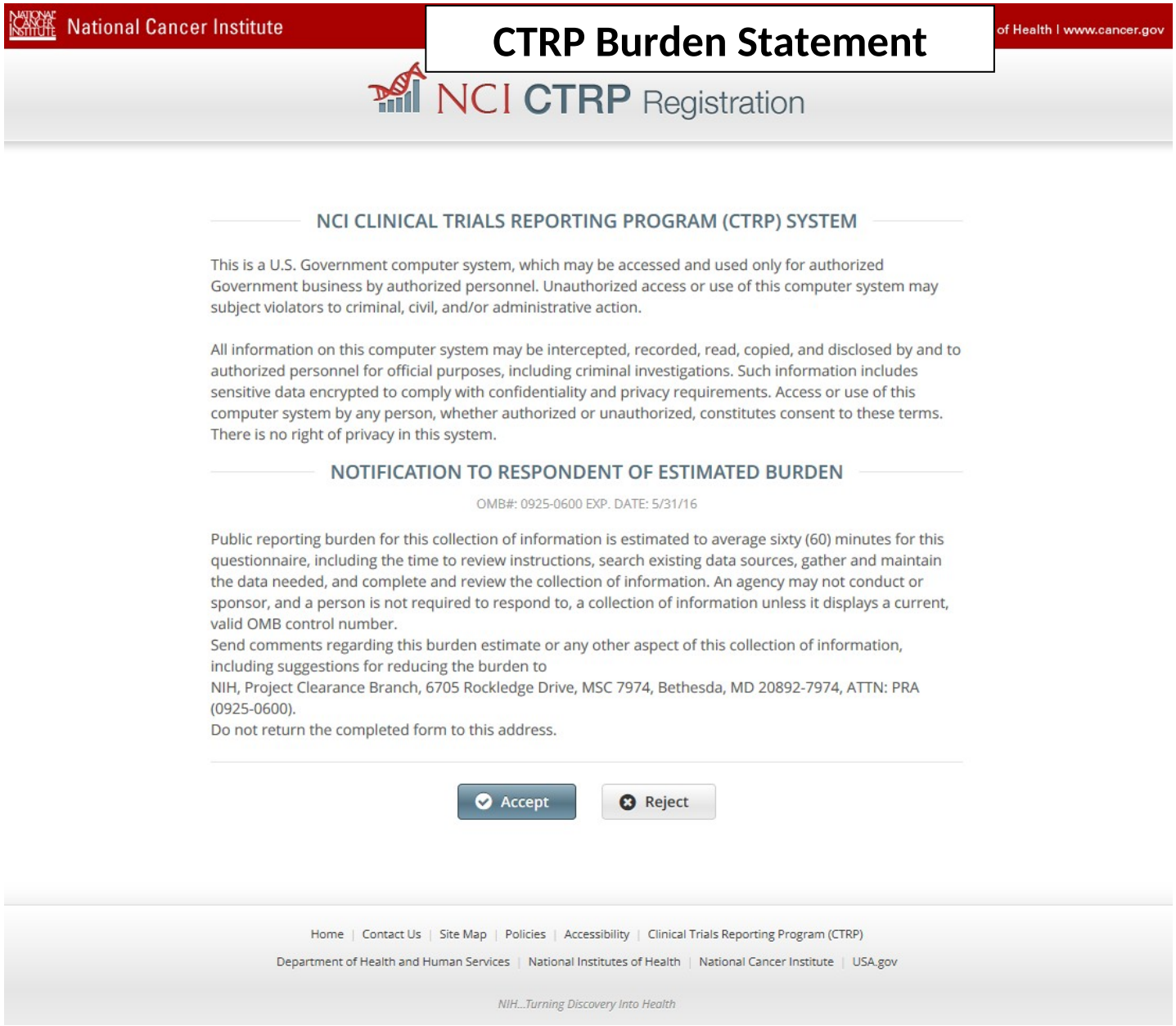
Step 4: System displays “Search Submitted Clinical Trials” page – see screenshot, page 4

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

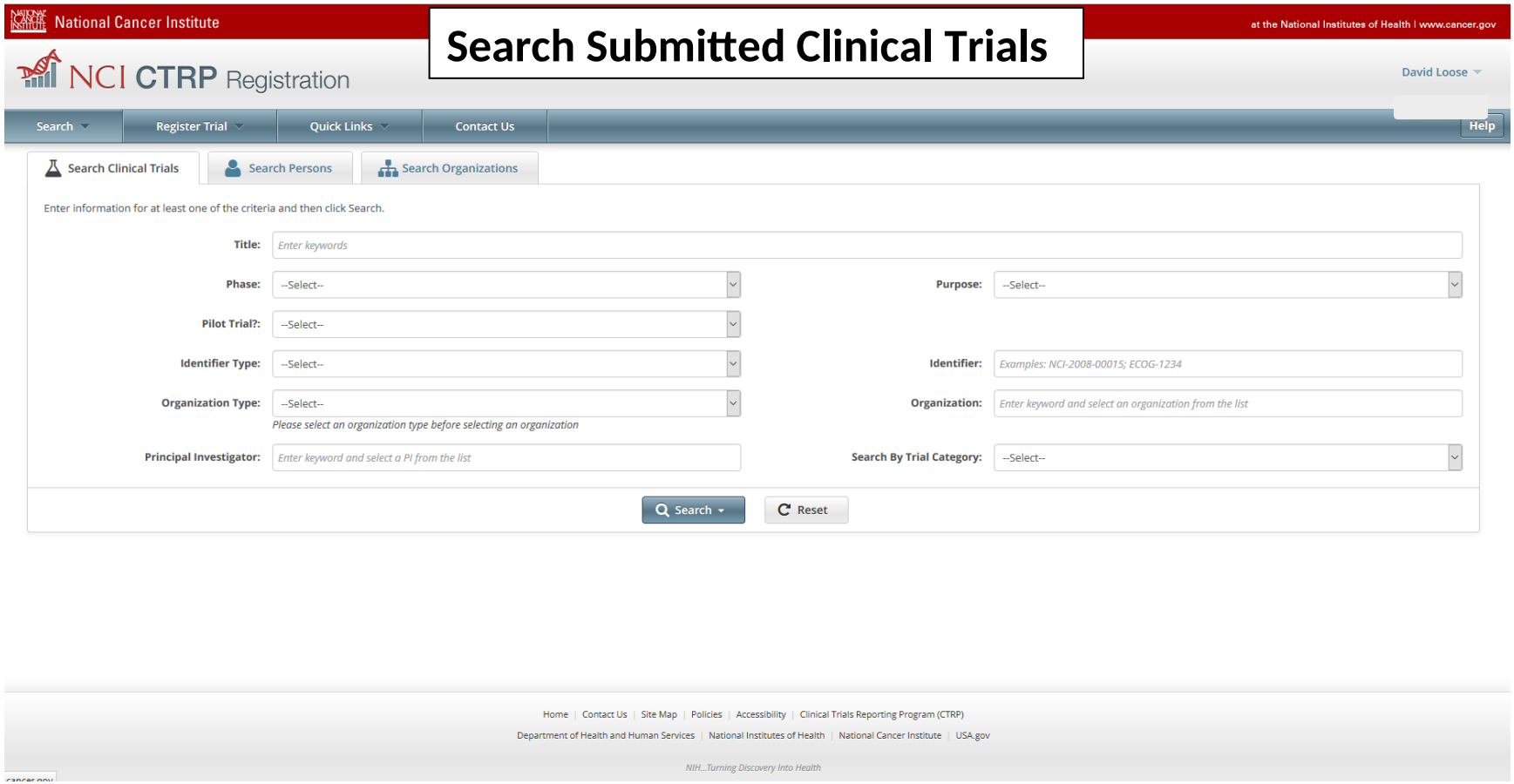
CTRP Home and Login page

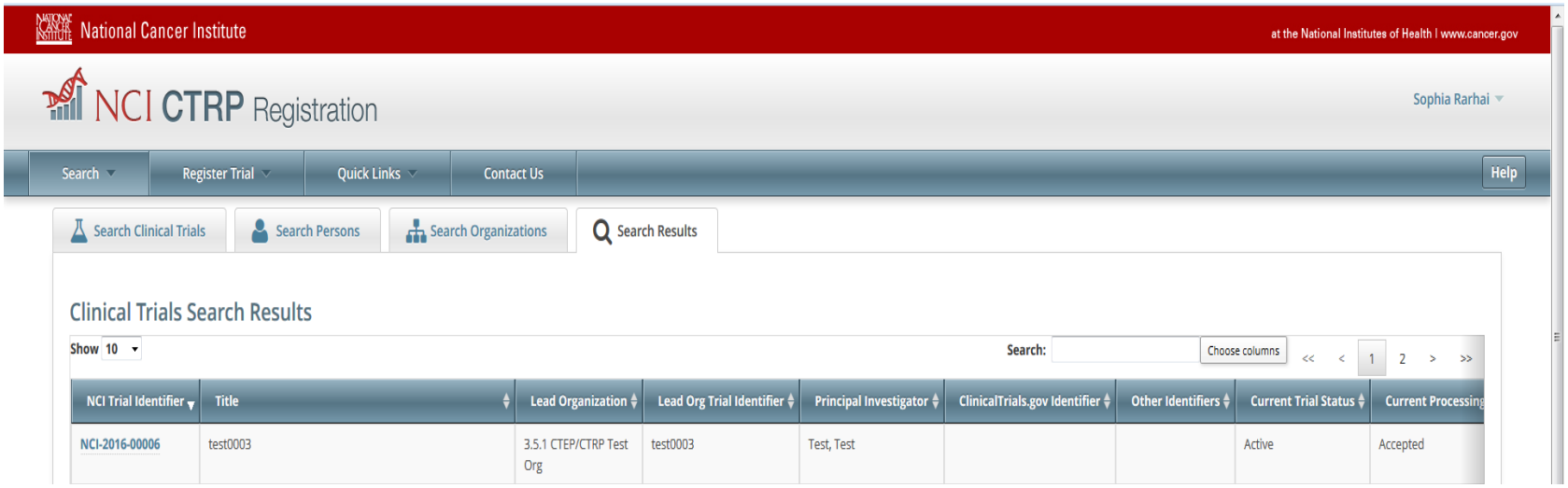


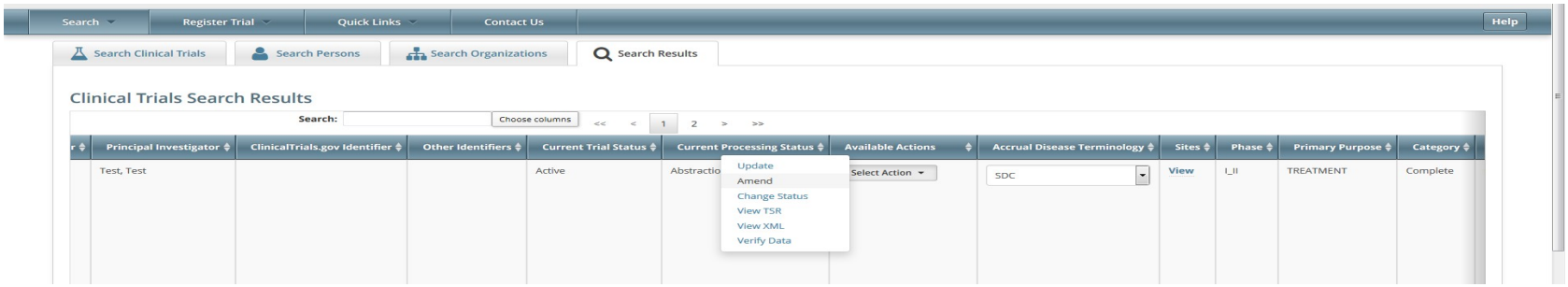
CTRP Burden Statement



Search Submitted Clinical Trials




National Cancer Institute
at the National Institutes of Health | www.cancer.gov
NCI CTRP Registration
Sophia Rarhai
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
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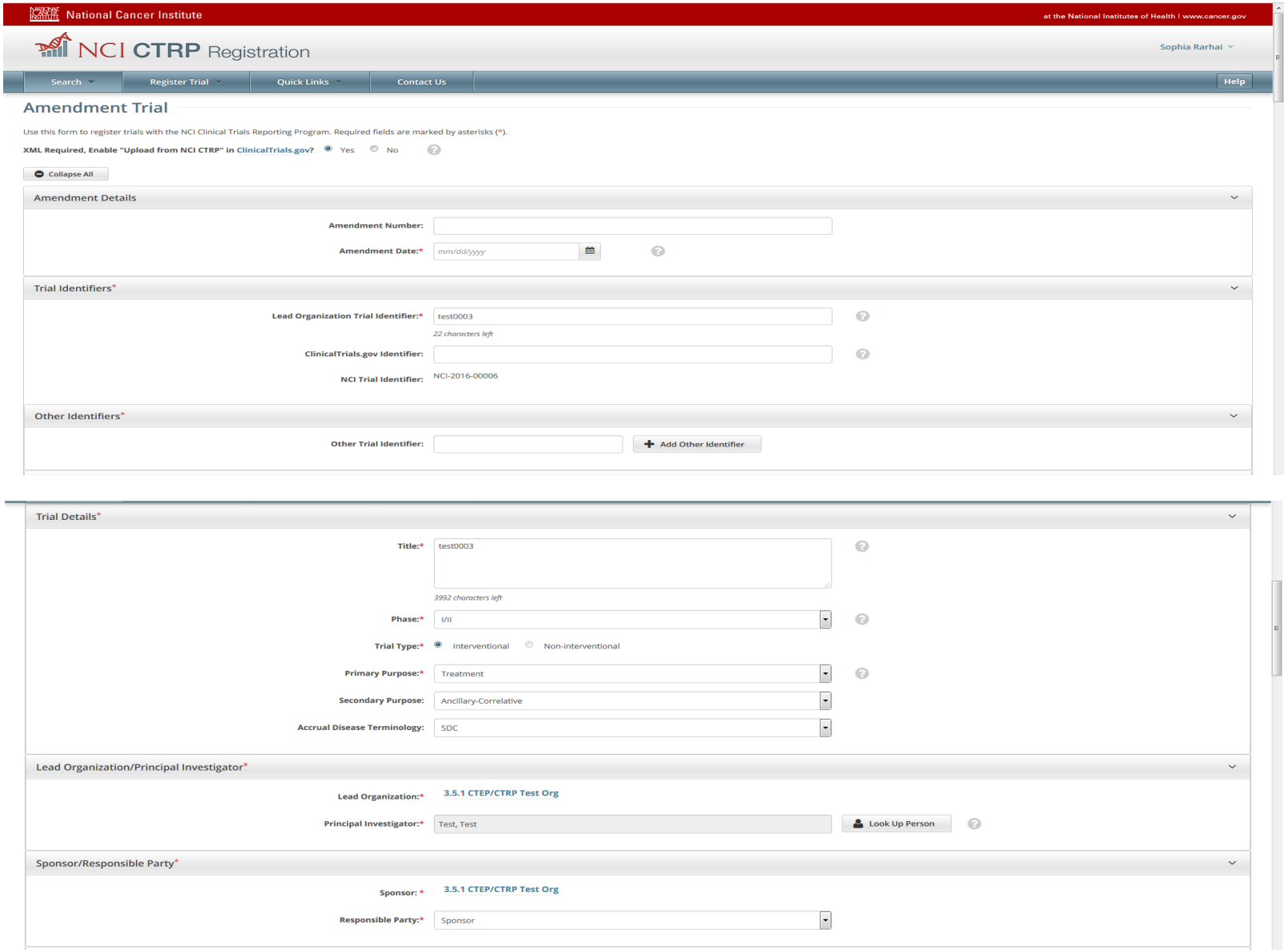
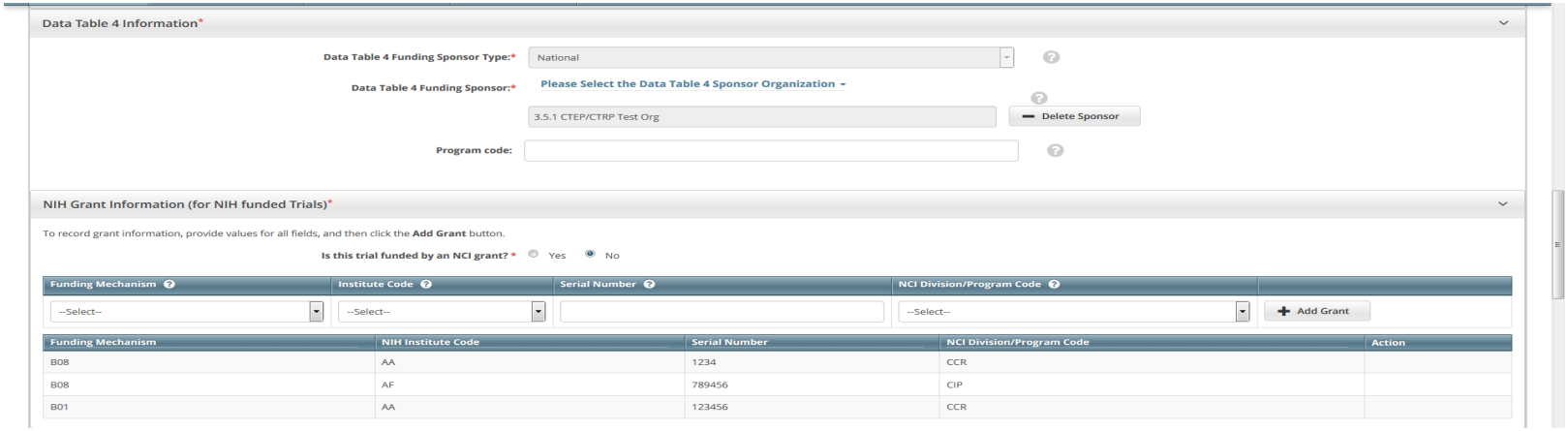
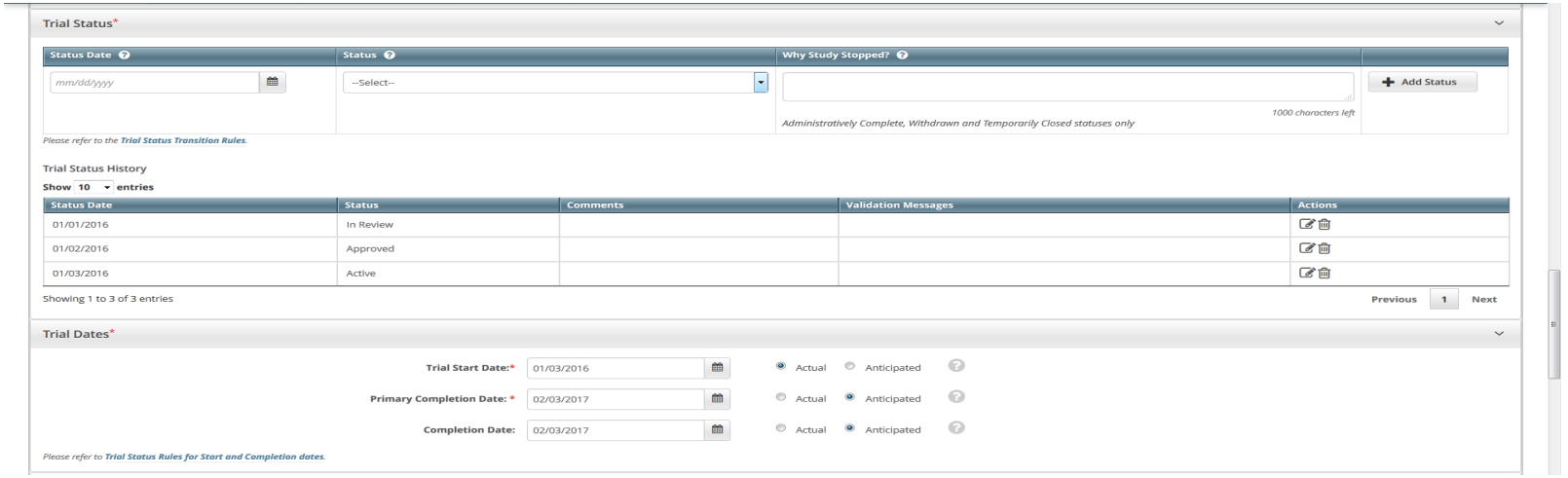
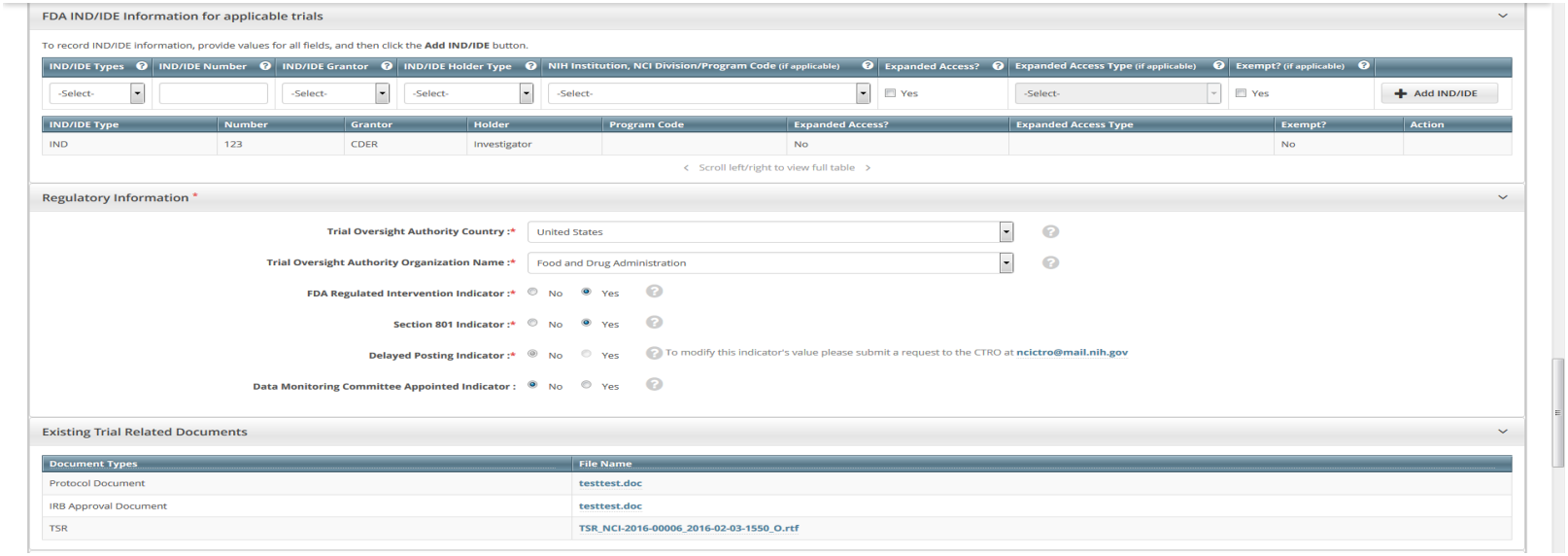
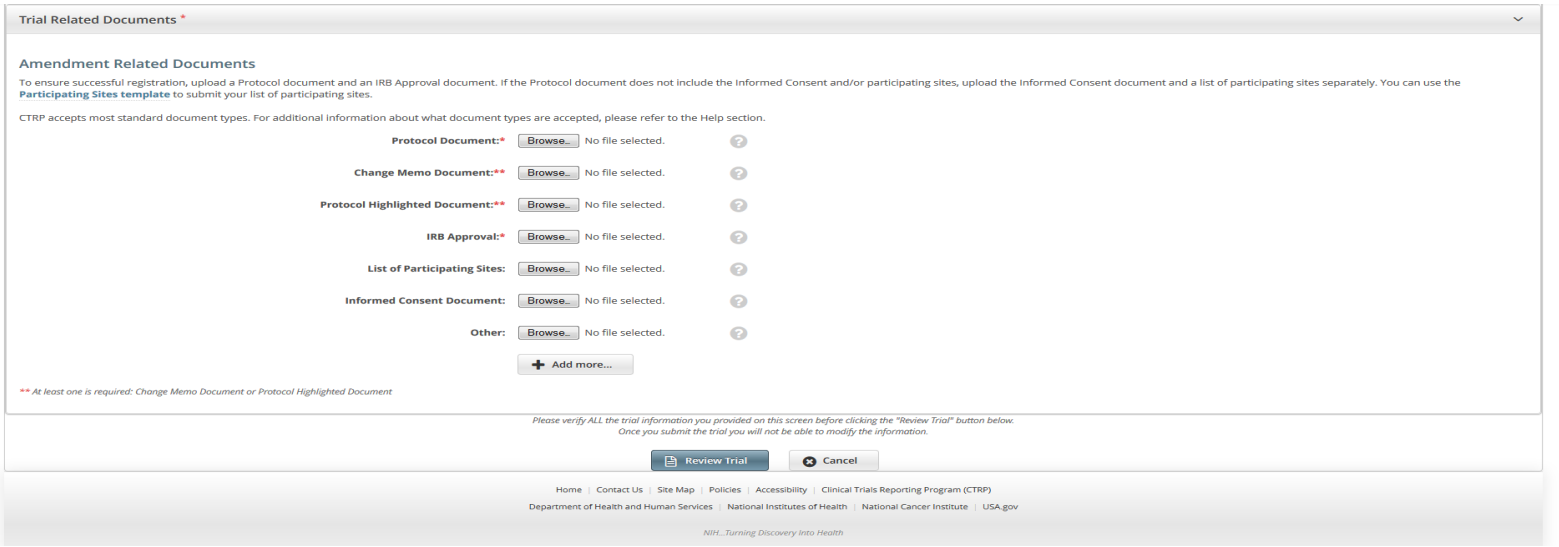
TREATMENT
Complete


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
Amendment Trial
Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked by asterisks (*).
XML Required, Enable "Upload from NCI CTRP" in ClinicalTrials.gov? Yes No
Collapse All
Amendment Details
Amendment Number:
Amendment Date:*
mm/dd/yyyy
Trial Identifiers*
Lead Organization Trial Identifier:*
test0003
22 characters left
ClinicalTrials.gov Identifier:
NCI Trial Identifier:
NCI-2016-00006
Other Identifiers*
Other Trial Identifier:
Add Other Identifier
Trial Details*
Title:*
test0003
3992 characters left
Phase:*
I/II
Trial Type:*
Interventional
Non-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
Look Up Person
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:*
Please Select the Data Table 4 Sponsor Organization
3.5.1 CTEP/CTRP Test Org
Delete 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.
Is this trial funded by an NCI grant? * Yes No
Funding Mechanism
Institute Code
Serial Number
NCI Division/Program Code
--Select--
Add Grant
Funding Mechanism
NIH Institute Code
Serial Number
NCI Division/Program Code
Action
B08 AA 1234 CCR
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
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-
Yes
Add IND/IDE
IND/IDE Type
Number
Grantor
Holder
Program Code
Expanded Access?
Expanded Access Type
Exempt?
Action
IND
123
CDER
Investigator
No
No
Scroll left/right to view full table
Regulatory Information *
Trial Oversight Authority Country :*
United States
Trial Oversight Authority Organization Name :*
Food and Drug Administration
FDA Regulated Intervention Indicator :*
Section 801 Indicator :*
Delayed Posting Indicator :*
To modify this indicator's value please submit a request to the CTRO at ncictro@mail.nih.gov
Data Monitoring Committee Appointed Indicator :
No
Yes
Existing Trial Related Documents
Document Types
File Name
Protocol Document
testtest.doc
IRB Approval Document
testtest.doc
TSR
TSR_NCI-2016-00006_2016-02-03-1550_O.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...
No file selected.
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