How To Register A Protocol

ClinicalTrials.gov

Getting Started

- ClinicalTrials.gov account:
  - Establish an account
  - Connect With CT.gov Administrator
  - Blazer ID, Email, Phone Number

- CT.gov Website:
  - https://clinicaltrials.gov/
  - https://register.clinicaltrials.gov/

CT.gov Public Website

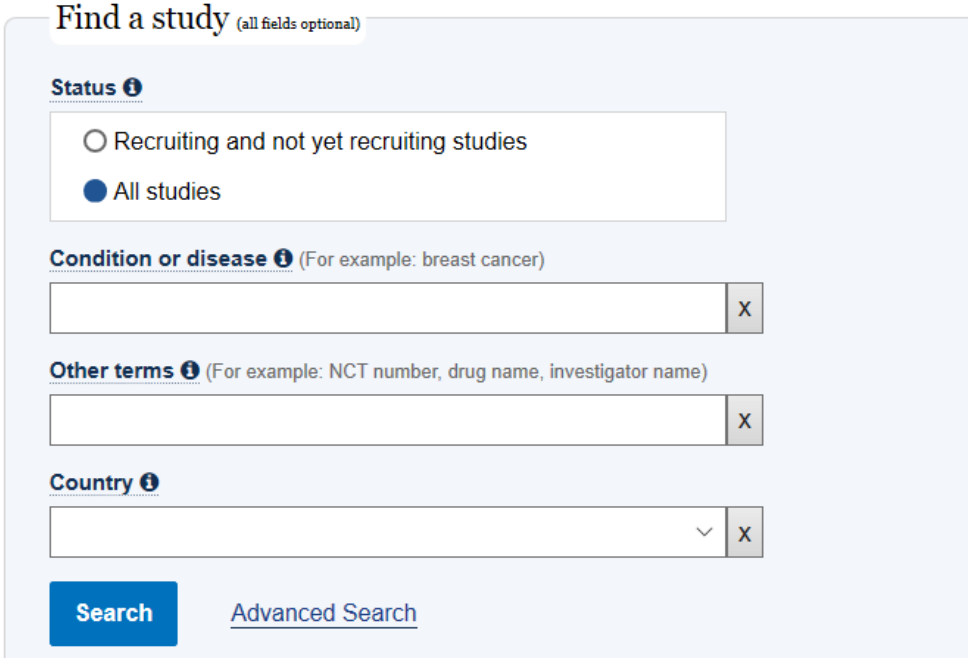
ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 327,786 research studies in all 50 states and in 209 countries.

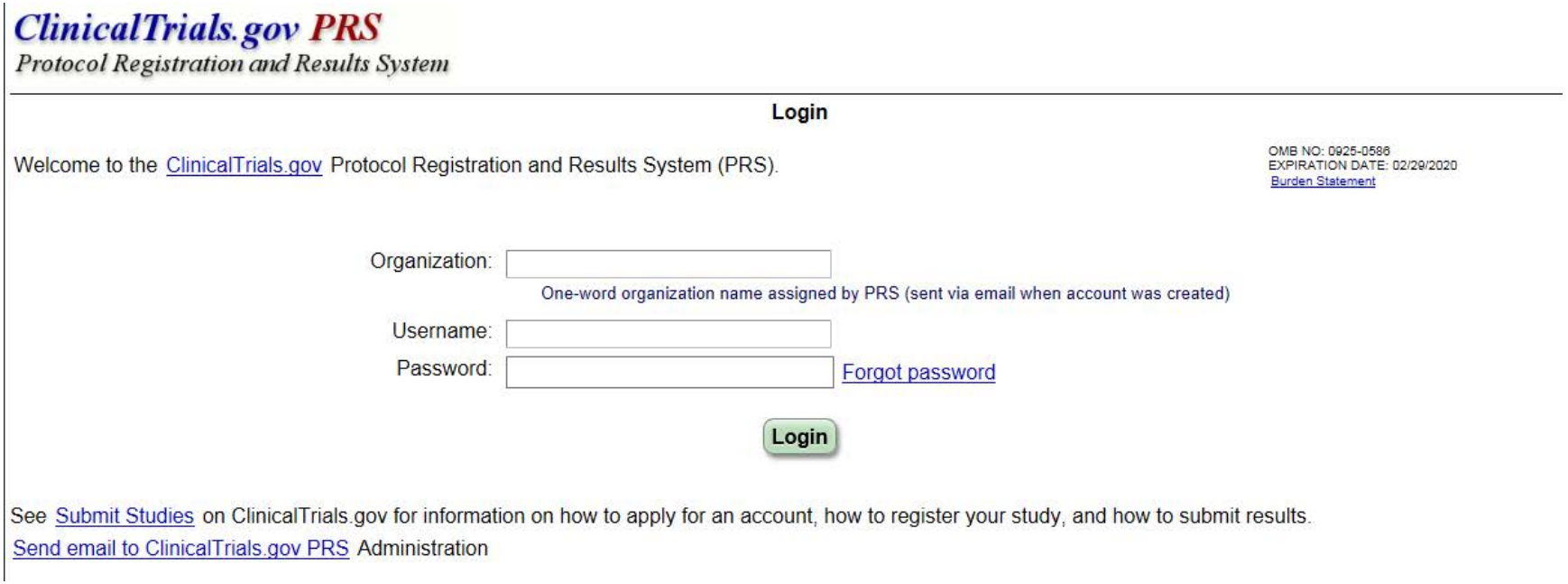
ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

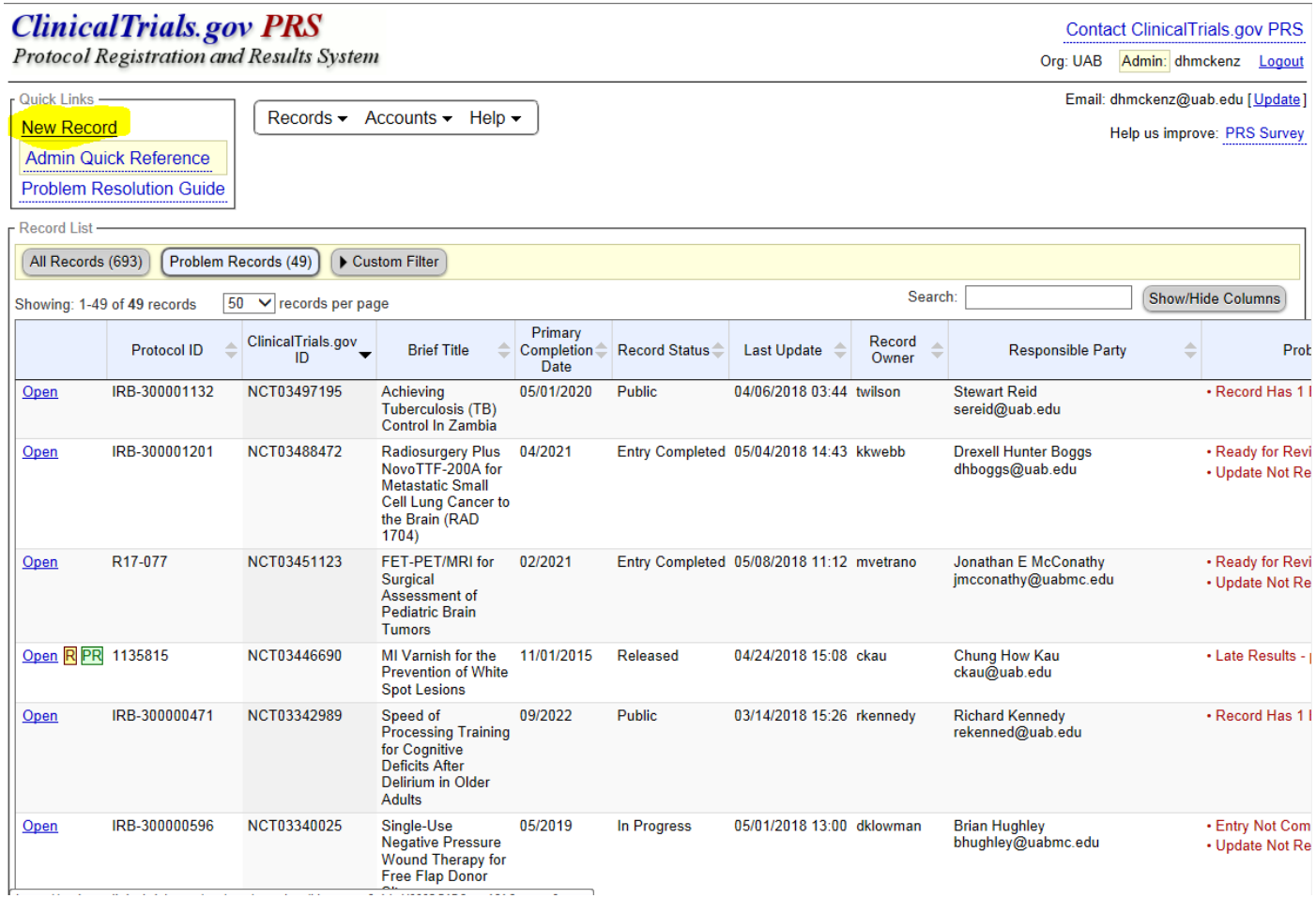
Before participating in a study, talk to your health care provider and learn about the risks and potential benefits.



CT.gov Registration Website



Registering A New Record



IRB – Clinical Trial Definition

6. Clinical Trial

Does this protocol meet the following definition of a clinical trial? ☐Yes ☐No

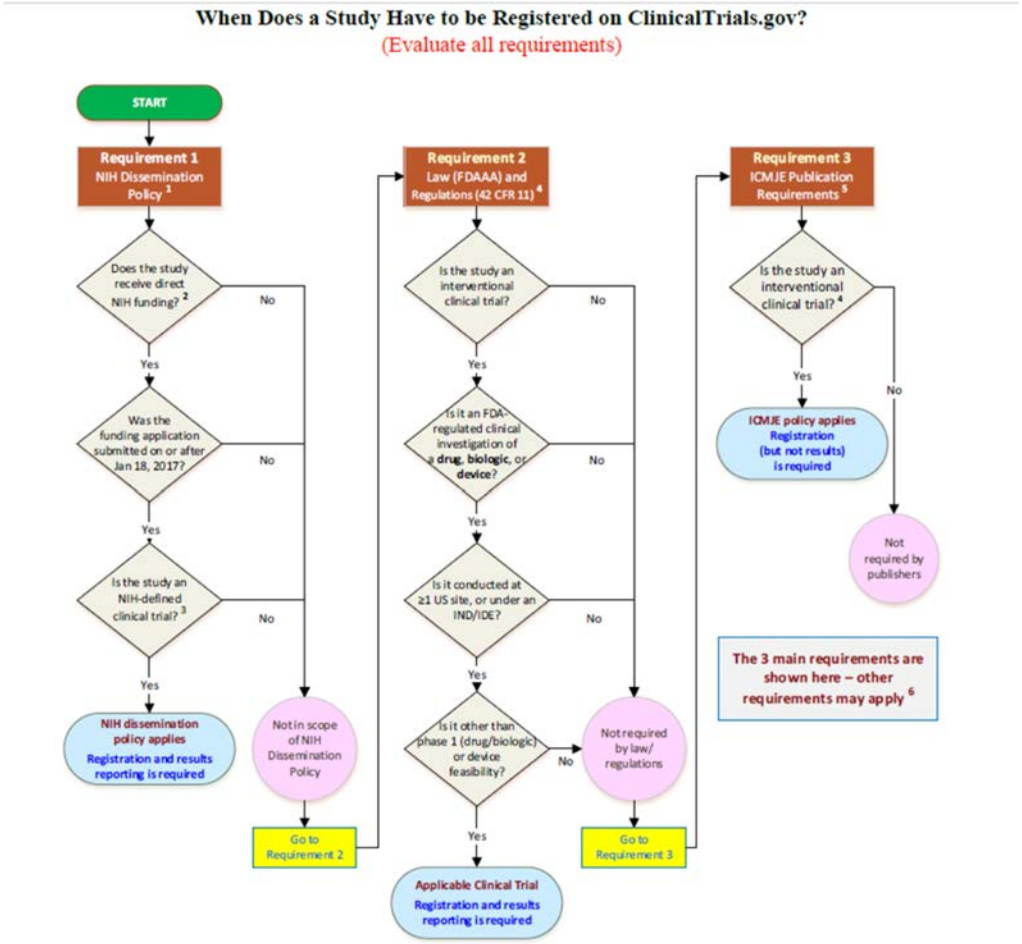
**A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. For more information, see the full definition of clinical trial here.*

If Yes, you will need to fulfill the following requirements (regardless of funding):

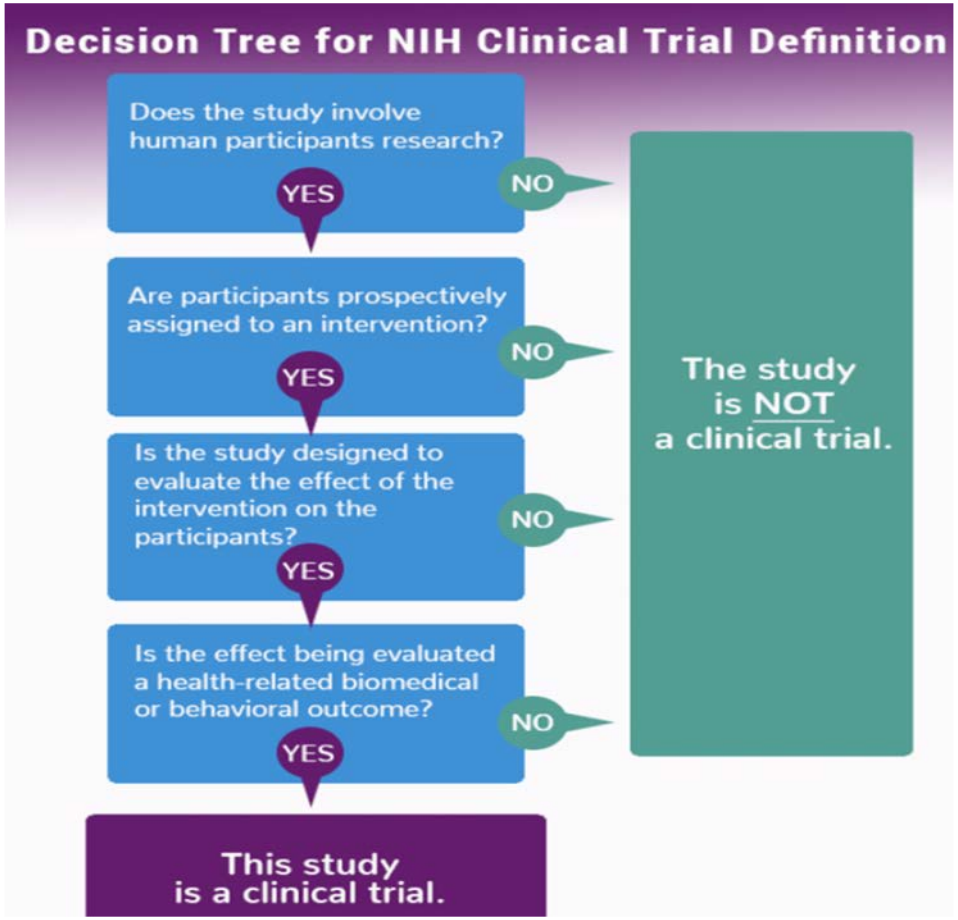
Determining Registration

- Who is funding the study?
- Interventional Study?
- Are there plans to publish?
- Have you checked with your contract officer or sponsor?
- If studies include Medicare patients, an NCT number is needed for billing purposes.

Registering & Reporting Requirements



Decision Tree for NIH Clinical Trial Definition



NIH Interventions

- An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.
- Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

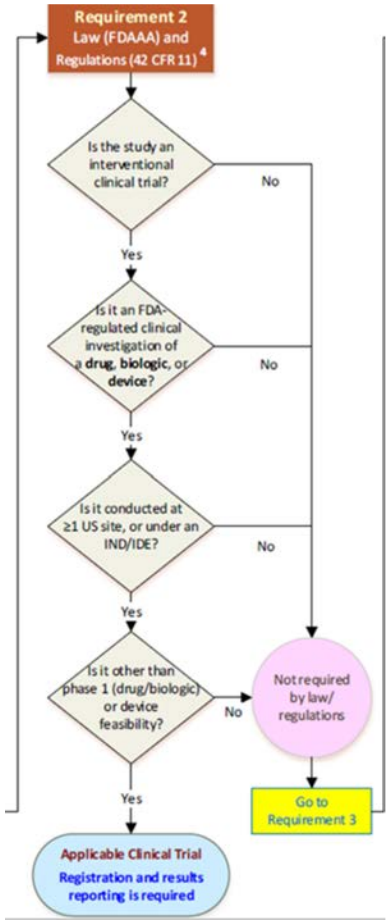
NIH Health-Related Biomedical or Behavioral Outcome

- Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life.
- Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

NIH Non-Clinical Trials

- Studies that involve secondary research with biological specimens or health information, or studies that are intended solely to refine measures are not considered clinical trials.
- Review extensive list of "***Case Studies***"
- NIH advises to consult with your program officer should your research fall into a gray area

FDAAA 801 Registering & Reporting?



- Is the study an interventional clinical trial?
- Is it an FDA-regulated clinical investigation of a drug, biologic, or device?
- One or more sites?
- Is it conducted under an IND/IDE?
- Is it other than a phase 1 or device feasibility?

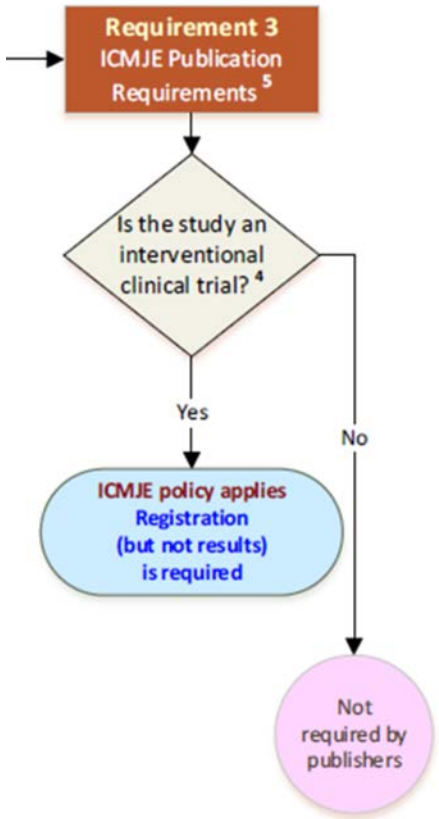
FDAAA & Other Regulations (42 CFR 11)

- Inclusions:
- Trials of drugs and biologics – All controlled clinical investigations, other than phase 1 (all Interventional Studies that meet established criteria).
- One or more sites, IND, involves a drug, biologic, or device
- Trials of devices – Controlled trials with health outcomes of devices, other than small feasibility studies and 2) pediatric post-market surveillance required by the FDA

FDAAA & Other Regulations (42 CFR 11)

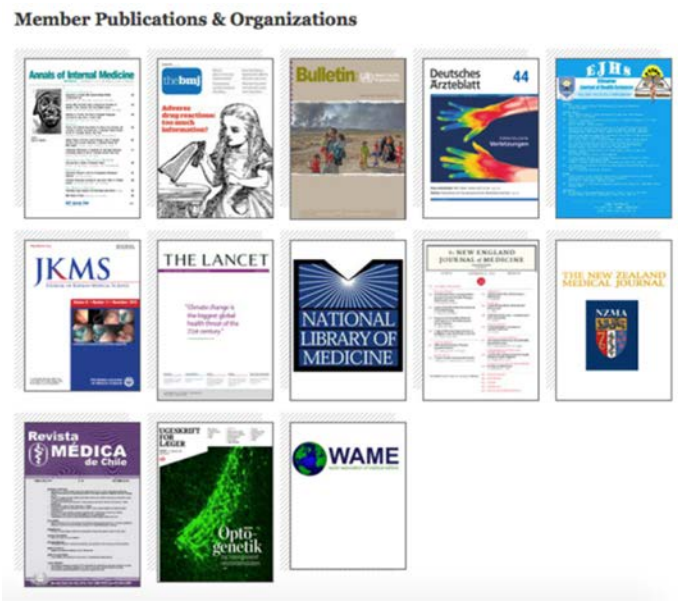
- Exclusions:
- Trials that do not include drugs, biologics, or devices (such as behavioral interventions)
- Phase 1 drug trials, including studies in which investigational drugs are used as research tools
- Non-interventional (observational) clinical research (such as cohort or case-control studies)
- Small clinical trials to determine the feasibility of a device, where the primary outcome measure relates to feasibility and not to health outcomes

ICMJE Registering & Reporting?



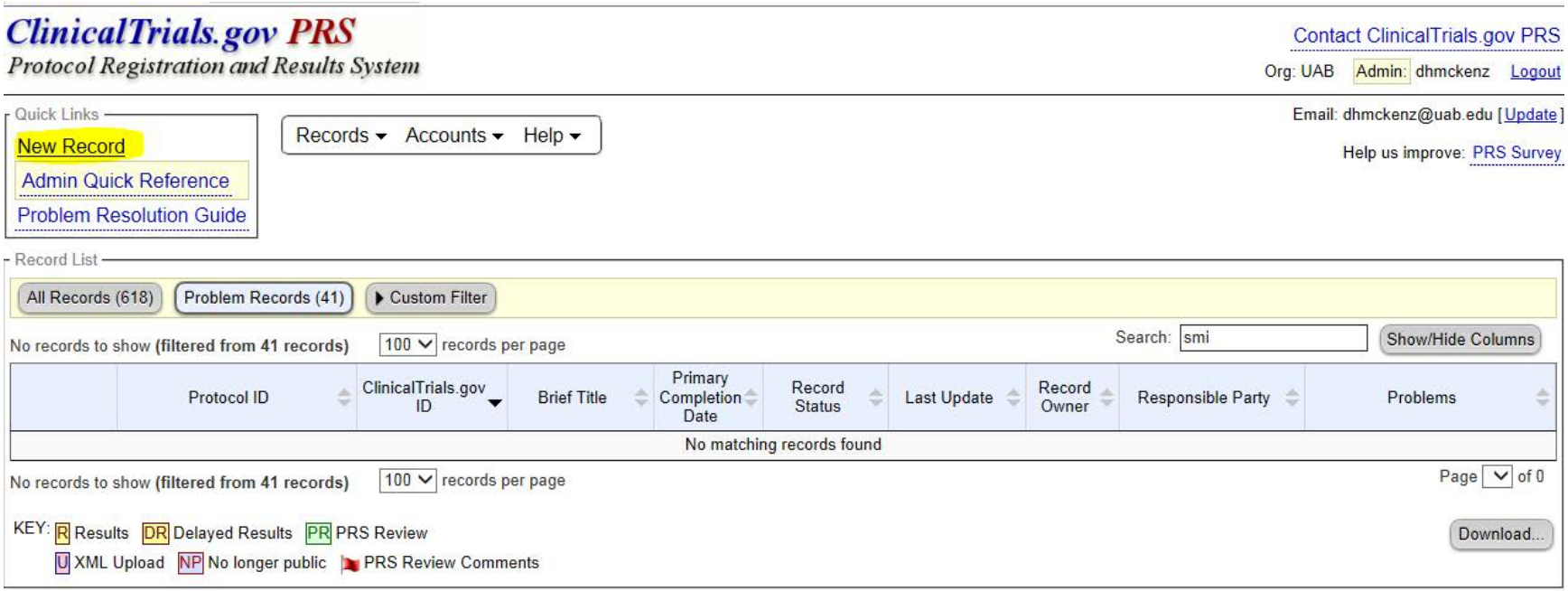
- Prospectively assigns individuals to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome.
- Includes drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes.

International Committee of Medical Journal Editors (ICMJE)



- The ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry "***at or before the time of first patient enrollment as a condition of consideration for publication.***"

New Record


ClinicalTrials.gov PRS
Protocol Registration and Results System
Contact ClinicalTrials.gov PRS
Org: UAB Admin: dhmckenz Logout
Quick Links
New Record
Admin Quick Reference
Problem Resolution Guide
Records Accounts Help
Email: dhmckenz@uab.edu [Update]
Help us improve: PRS Survey
Record List
All Records (618)
Problem Records (41)
Custom Filter
No records to show (filtered from 41 records)
100 records per page
Search: smi
Show/Hide Columns
Protocol ID
ClinicalTrials.gov ID
Brief Title
Primary Completion Date
Record Status
Last Update
Record Owner
Responsible Party
Problems
No matching records found
No records to show (filtered from 41 records)
100 records per page
Page of 0
KEY: R Results DR Delayed Results PR PRS Review
U XML Upload NP No longer public PRS Review Comments
Download...

Title Page

Help Definitions

* Organization's Unique Protocol ID: F00123456

* Brief Title: Efficacy of Drug X vs Drug Y in Non-Small Lung Cell Lung Cancer

Special Characters

[*] Acronym: (if any) NSCLC

If specified, will be included at end of Brief Title in parentheses.

* Study Type:

- (•) Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol
- ( ) Observational participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care
- ( ) Expanded Access availability of an experimental drug or device outside of a clinical trial protocol

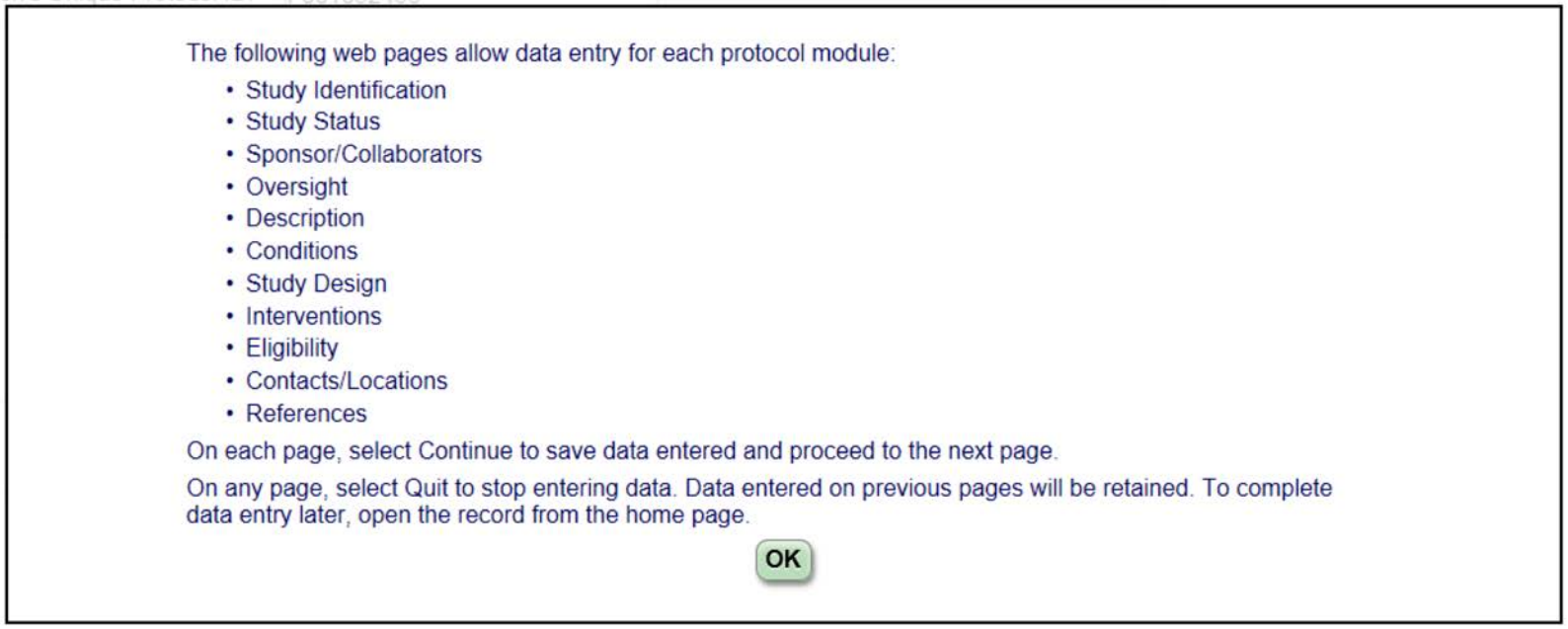
Continue Cancel

* Required

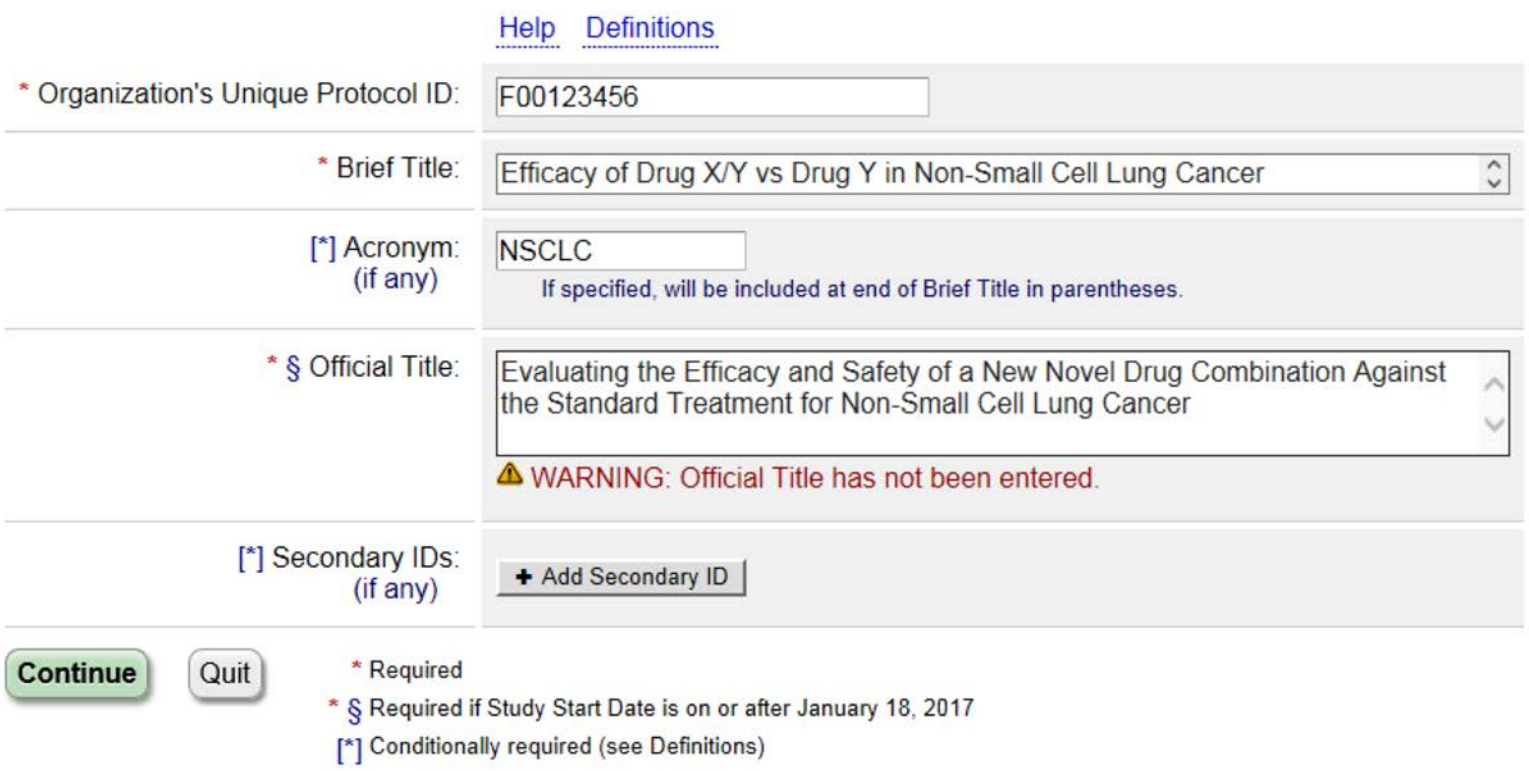
* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

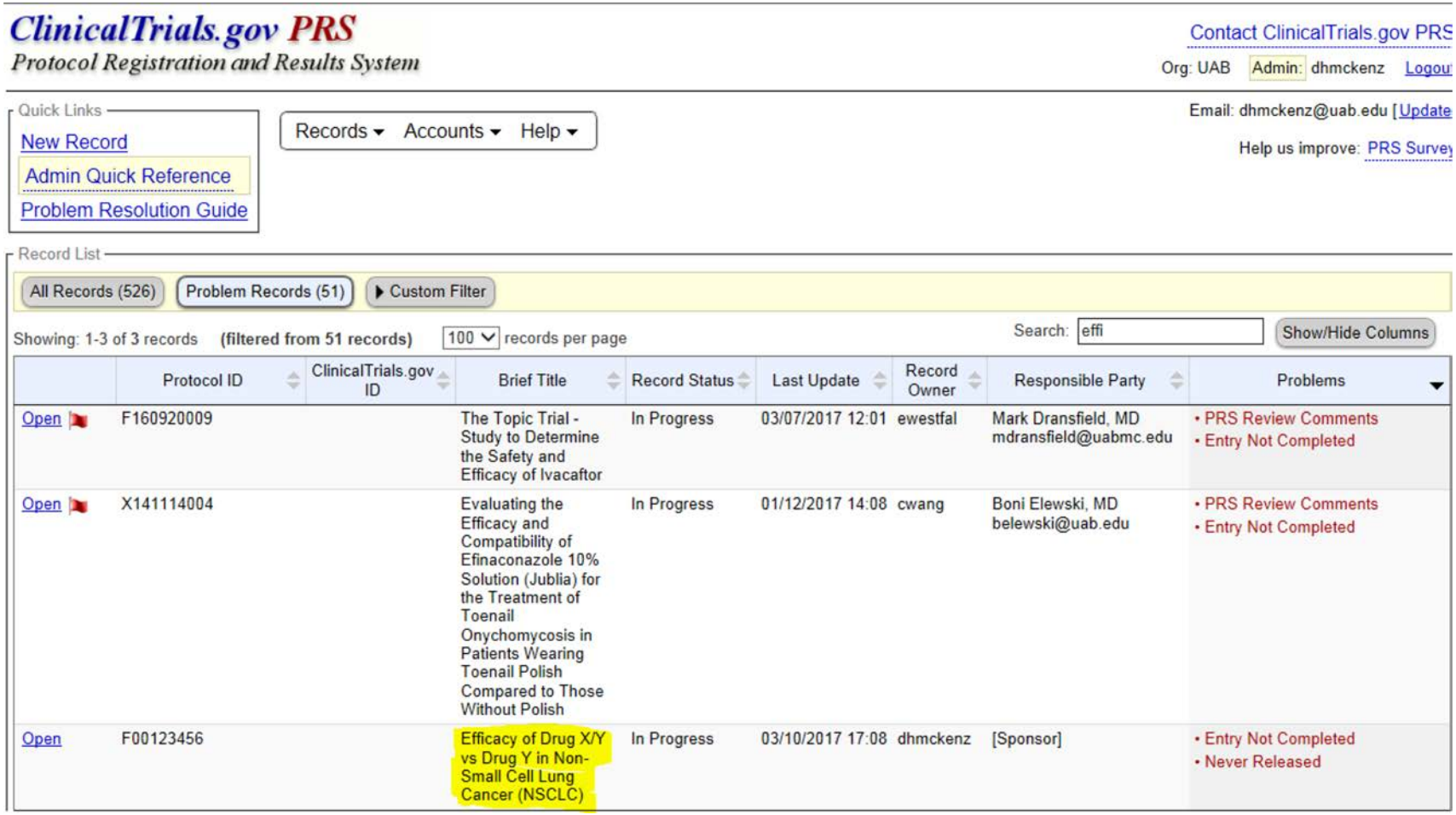
Agenda of Information



Official Title



CT.gov View



ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: UAB Admin: dhmckenz Logou

Quick Links
New Record
Admin Quick Reference
Problem Resolution Guide

Records Accounts Help

Email: dhmckenz@uab.edu [Update
Help us improve: PRS Survey

Record List

All Records (526) | Problem Records (51) | Custom Filter

Showing: 1-3 of 3 records (filtered from 51 records) 100 records per page

Search: effi | Show/Hide Columns

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	Record Owner	Responsible Party	Problems
Open	F160920009		The Topic Trial - Study to Determine the Safety and Efficacy of Ivacaftor	In Progress	03/07/2017 12:01	ewestfal	Mark Dransfield, MD mdransfield@uabmc.edu	• PRS Review Comments • Entry Not Completed
Open	X141114004		Evaluating the Efficacy and Compatibility of Efinaconazole 10% Solution (Jublia) for the Treatment of Toenail Onychomycosis in Patients Wearing Toenail Polish Compared to Those Without Polish	In Progress	01/12/2017 14:08	cwang	Boni Elewski, MD belewski@uab.edu	• PRS Review Comments • Entry Not Completed
Open	F00123456		Efficacy of Drug X/Y vs Drug Y in Non-Small Cell Lung Cancer (NSCLC)	In Progress	03/10/2017 17:08	dhmckenz	[Sponsor]	• Entry Not Completed • Never Released

Study Dates & Recruitment Completed

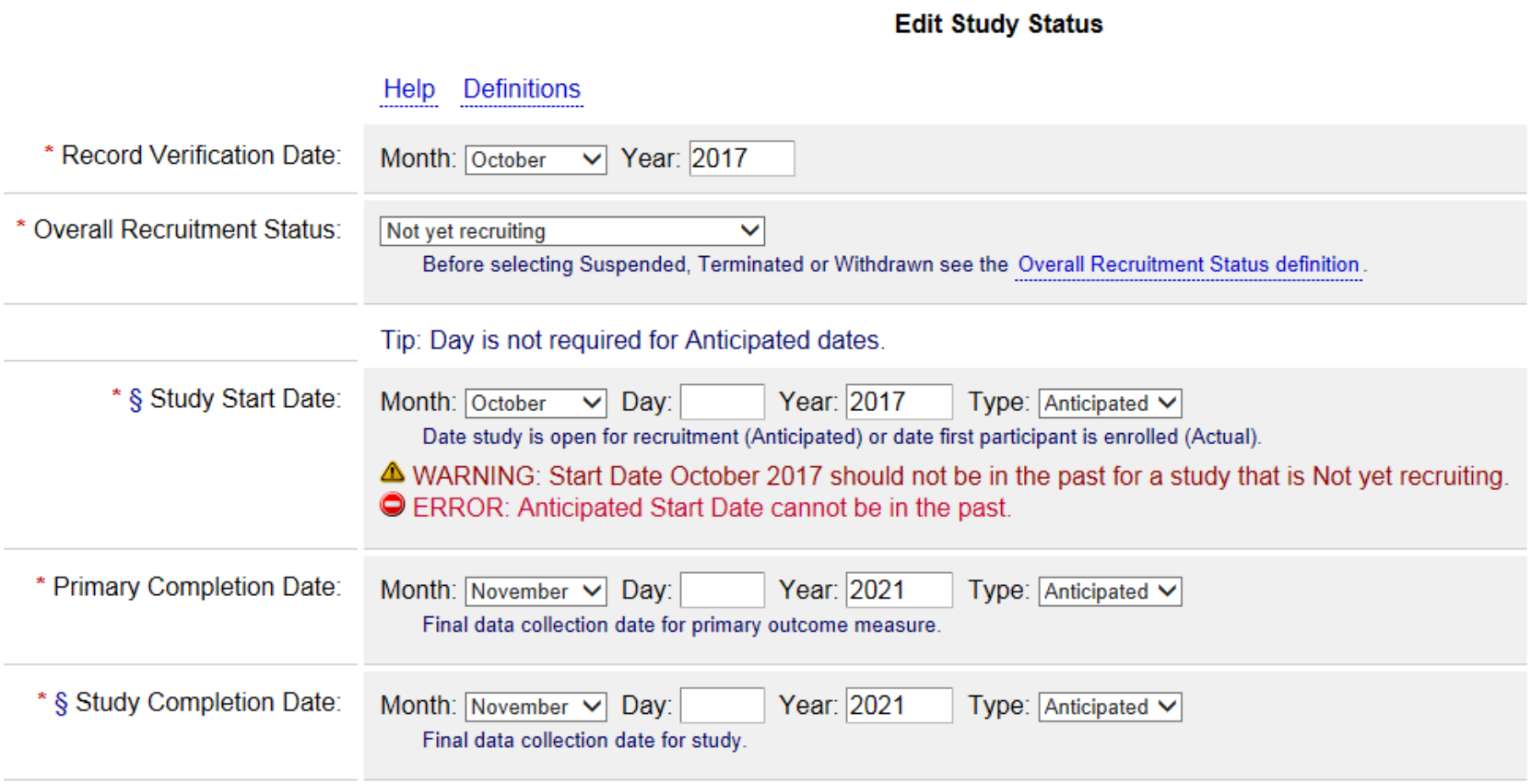
Help Definitions

* Record Verification Date:	Month: March Year: 2017
* Overall Recruitment Status:	Recruiting Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.
	Tip: Day is not required for Anticipated dates.
* § Study Start Date:	Month: April Day: 1 Year: 2017 Type: Actual Beginning of participant enrollment.
* Primary Completion Date:	Month: December Day: 31 Year: 2017 Type: Anticipated Final data collection date for primary outcome measure.
* § Study Completion Date:	Month: December Day: 31 Year: 2017 Type: Anticipated Final data collection date for study.

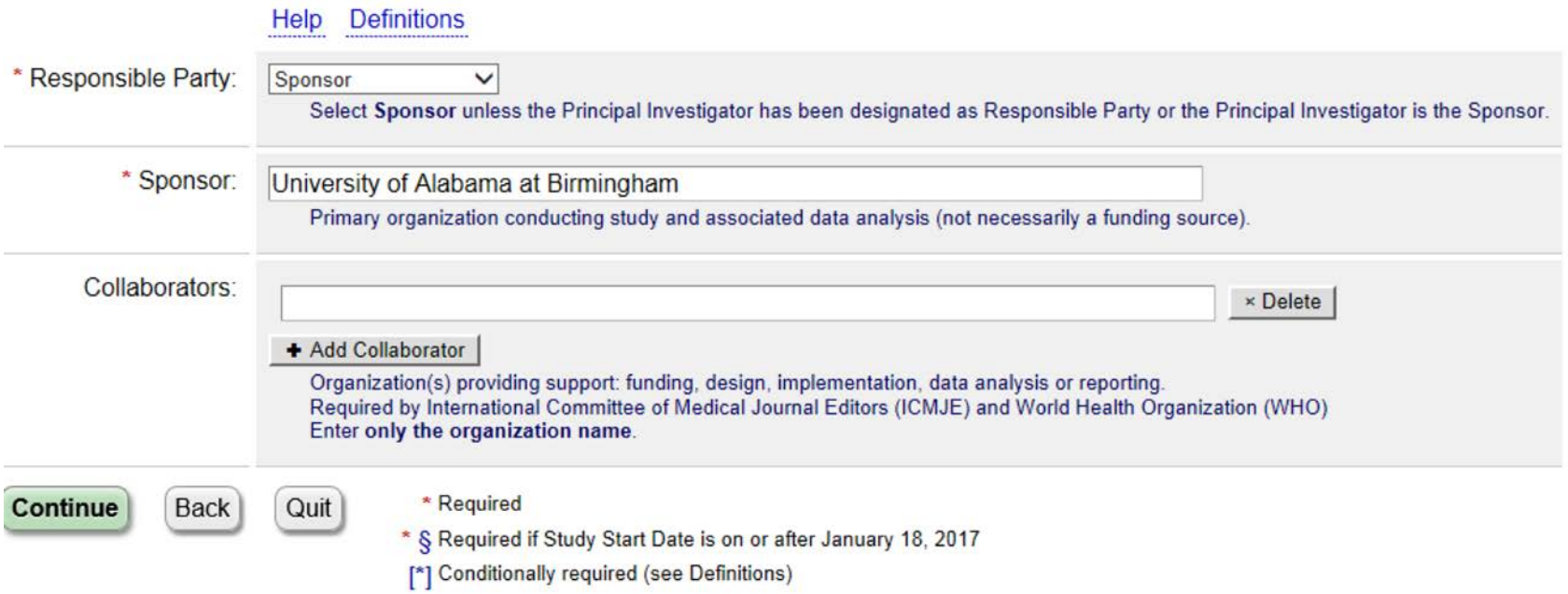
Continue Back Quit

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

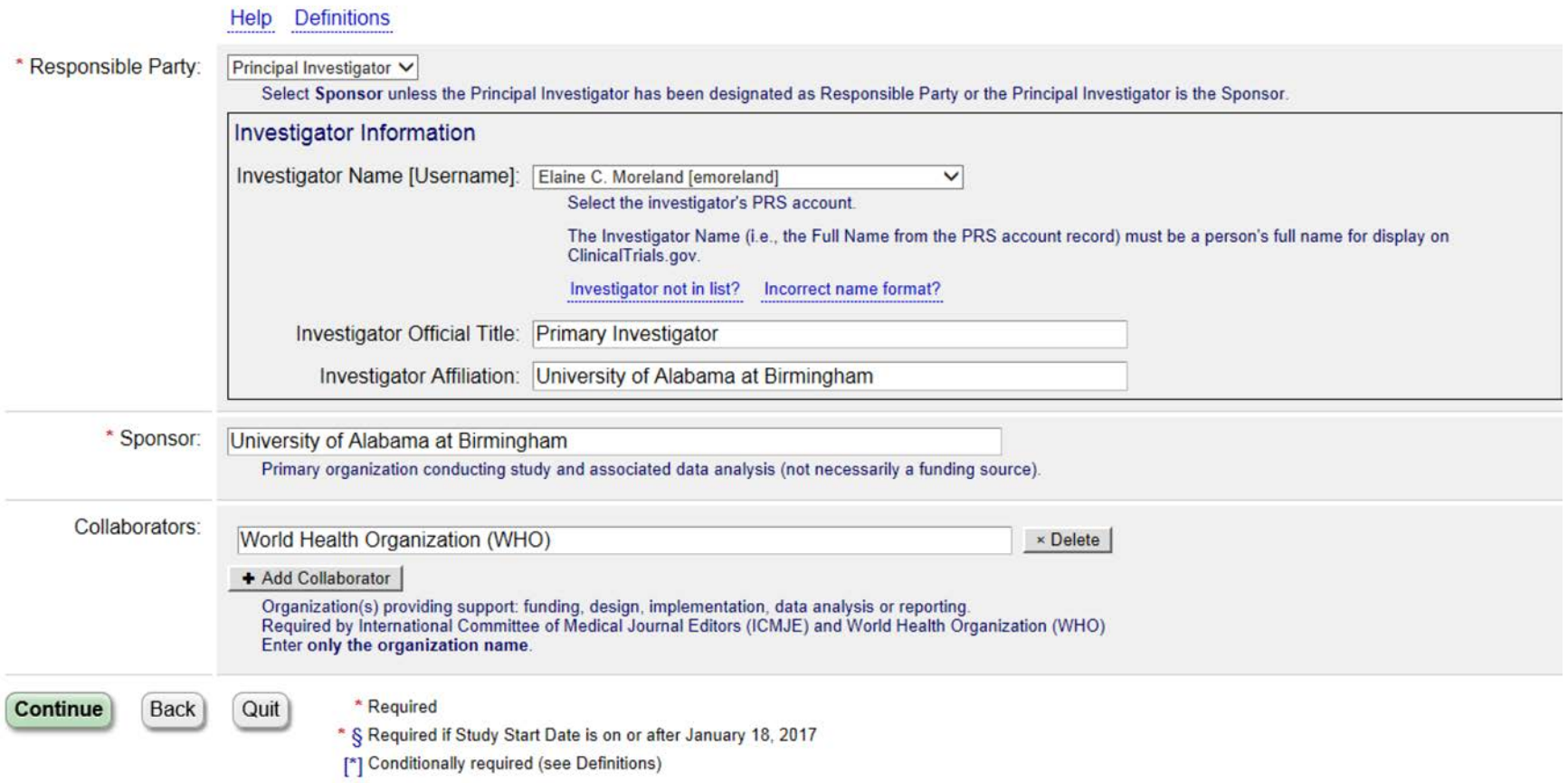
Study Dates - ERROR



Sponsor/Collaborators



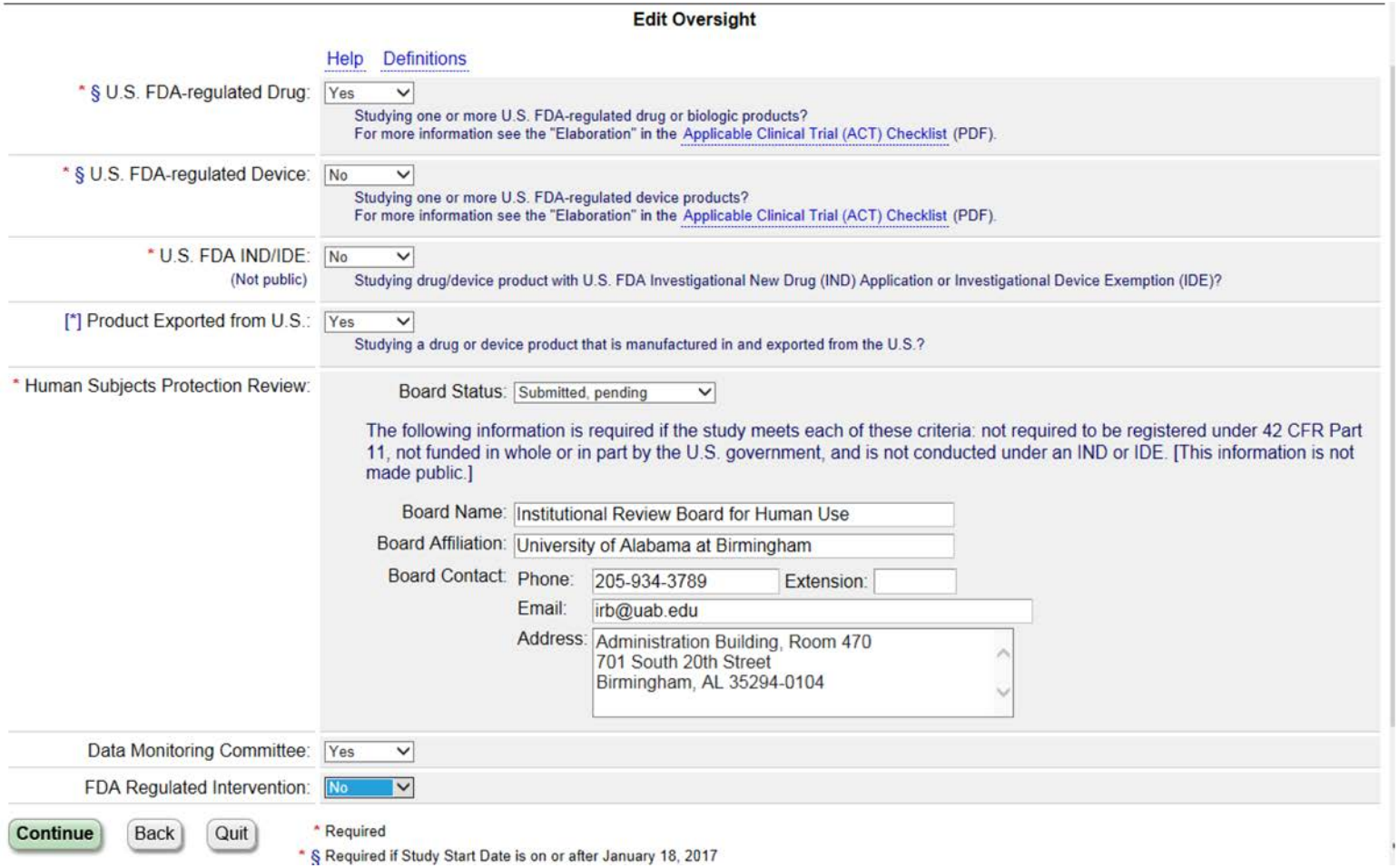
Sponsor/Collaborators Completed



Oversight


Help
Definitions
* § U.S. FDA-regulated Drug:
--Select--
Studying one or more U.S. FDA-regulated drug or biologic products?
* § U.S. FDA-regulated Device:
--Select--
Studying one or more U.S. FDA-regulated device products?
* U.S. FDA IND/IDE Study:
(Not public)
--Select--
Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?
* Human Subjects Protection Review:
Board Status:
--Select--
Data Monitoring Committee:
--Select--
Plan to Share IPD:
--Select--
Indicate if there is a plan to make individual participant data (IPD) available to other researchers.
FDA Regulated Intervention:
--Select--
Continue
Back
Quit
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Oversight Completed



Edit Oversight

Help Definitions

* § U.S. FDA-regulated Drug: Yes
Studying one or more U.S. FDA-regulated drug or biologic products?
For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF).

* § U.S. FDA-regulated Device: No
Studying one or more U.S. FDA-regulated device products?
For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF).

* U.S. FDA IND/IDE: (Not public) No
Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

[*] Product Exported from U.S.: Yes
Studying a drug or device product that is manufactured in and exported from the U.S.?

* Human Subjects Protection Review:
Board Status: Submitted, pending

The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not funded in whole or in part by the U.S. government, and is not conducted under an IND or IDE. [This information is not made public.]

Board Name: Institutional Review Board for Human Use
Board Affiliation: University of Alabama at Birmingham
Board Contact: Phone: 205-934-3789 Extension:
Email: irb@uab.edu
Address: Administration Building, Room 470
701 South 20th Street
Birmingham, AL 35294-0104

Data Monitoring Committee: Yes

FDA Regulated Intervention: No

Continue Back Quit

* Required
* § Required if Study Start Date is on or after January 18, 2017

Study Description Completed

Help Definitions

* Brief Summary:

This study is being done to determine the overall progression-free survival (PFS) in patients with advanced or metastatic (Stage IIIB - pleural effusion/IV), non-squamous histology NSCLC treated with standard chemotherapy treatment vs combination chemotherapy.

Special Characters

Detailed Description:

Subjects will be treated with chemotherapy with Drug X and Drug Y weekly for 3 out of 4 weeks. Treatment with chemotherapy will be expressed as a 4-week cycle. Tumor response to treatment will be evaluated every 8 weeks.

Treatment with chemotherapy will continue for a total of 6 cycles unless there is evidence of disease progression, intolerable toxicity, or withdrawal of consent. Maintenance therapy will then continue until disease progression, intolerable toxicity or withdrawal of consent.

Potential biologic parameters to monitor anti-tumor activity of metronomic chemotherapy will be evaluated in 10 subjects. These biomarkers include: sequential determination of blood levels of VEGF, VEGFR2, thrombospondin-1, E-selectin, ICAM-1, and circulating endothelial cells and endothelial precursor cells.

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

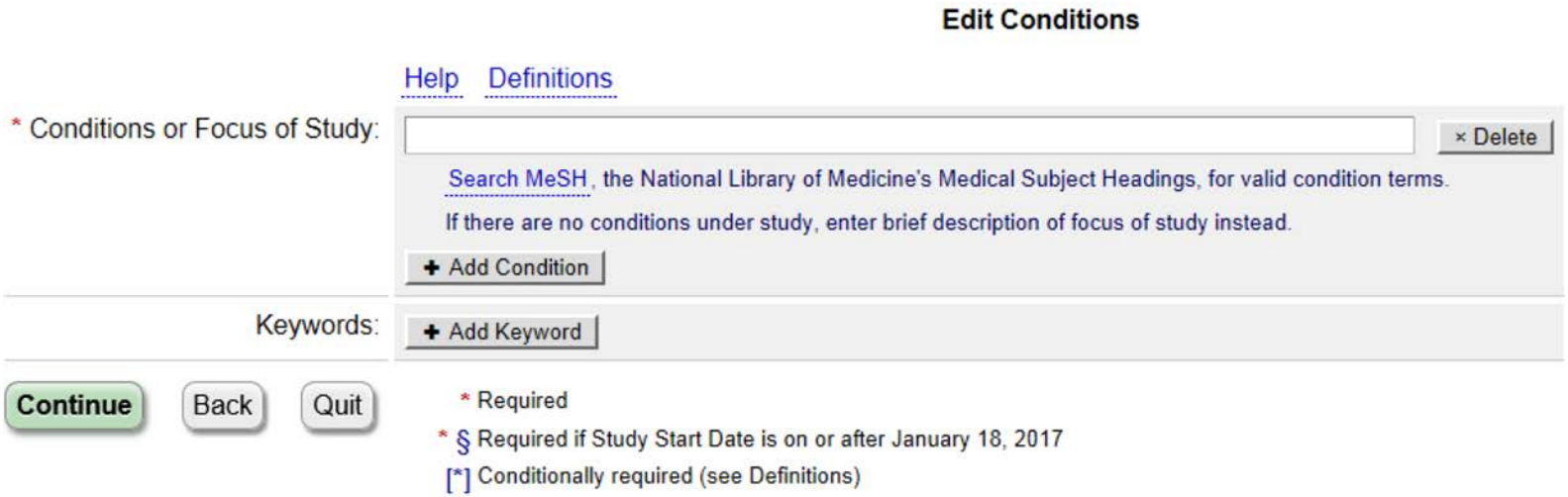
Continue Back Quit

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Conditions


Edit Conditions
Help
Definitions
* Conditions or Focus of Study:
× Delete
Search MeSH, the National Library of Medicine's Medical Subject Headings, for valid condition terms.
If there are no conditions under study, enter brief description of focus of study instead.
+ Add Condition
Keywords:
+ Add Keyword
Continue
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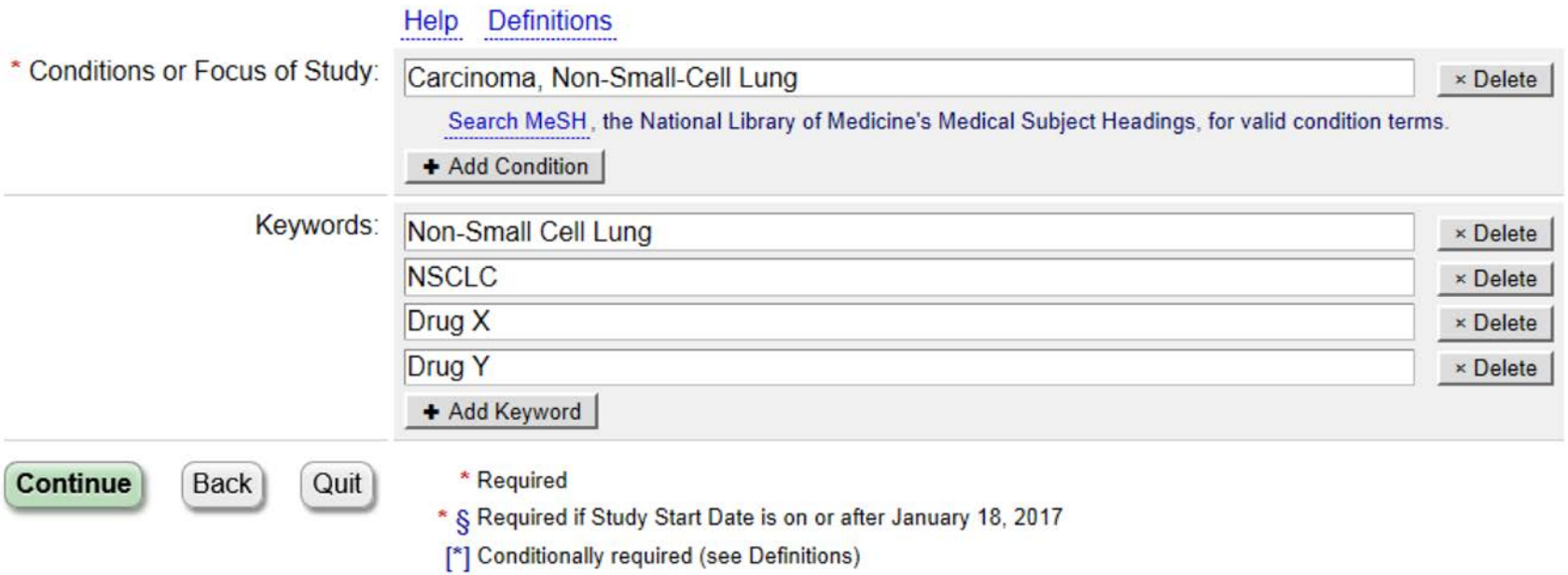
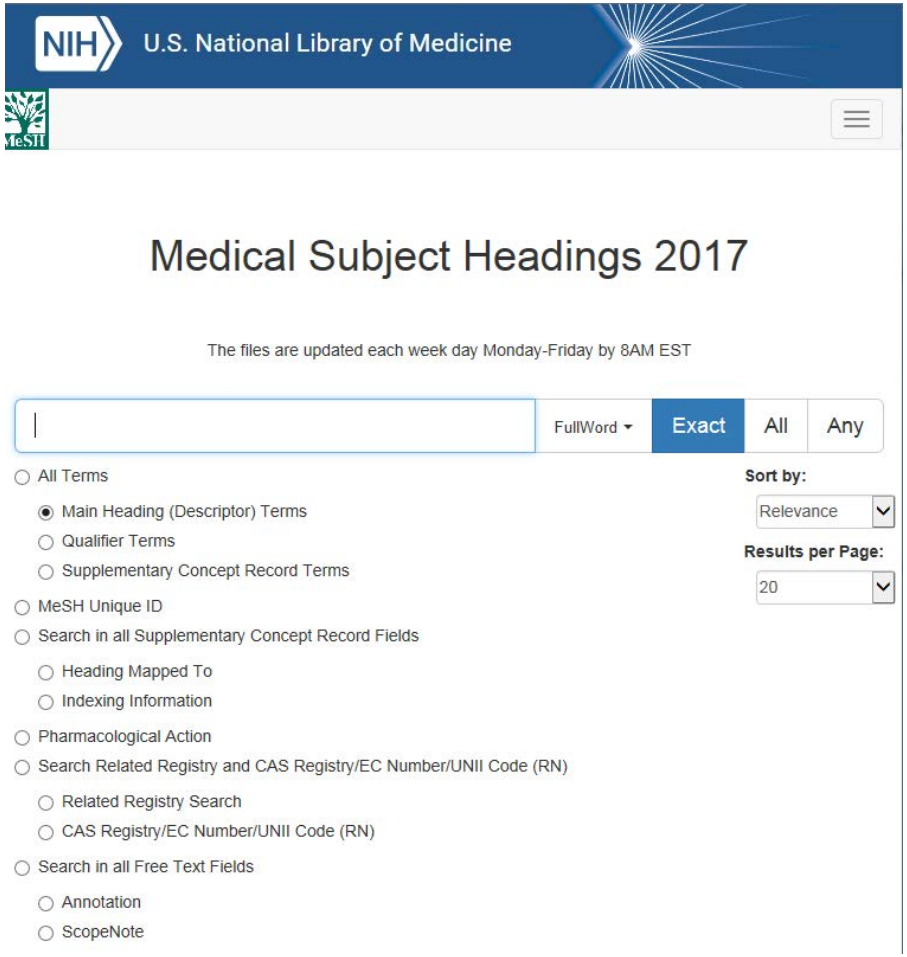
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

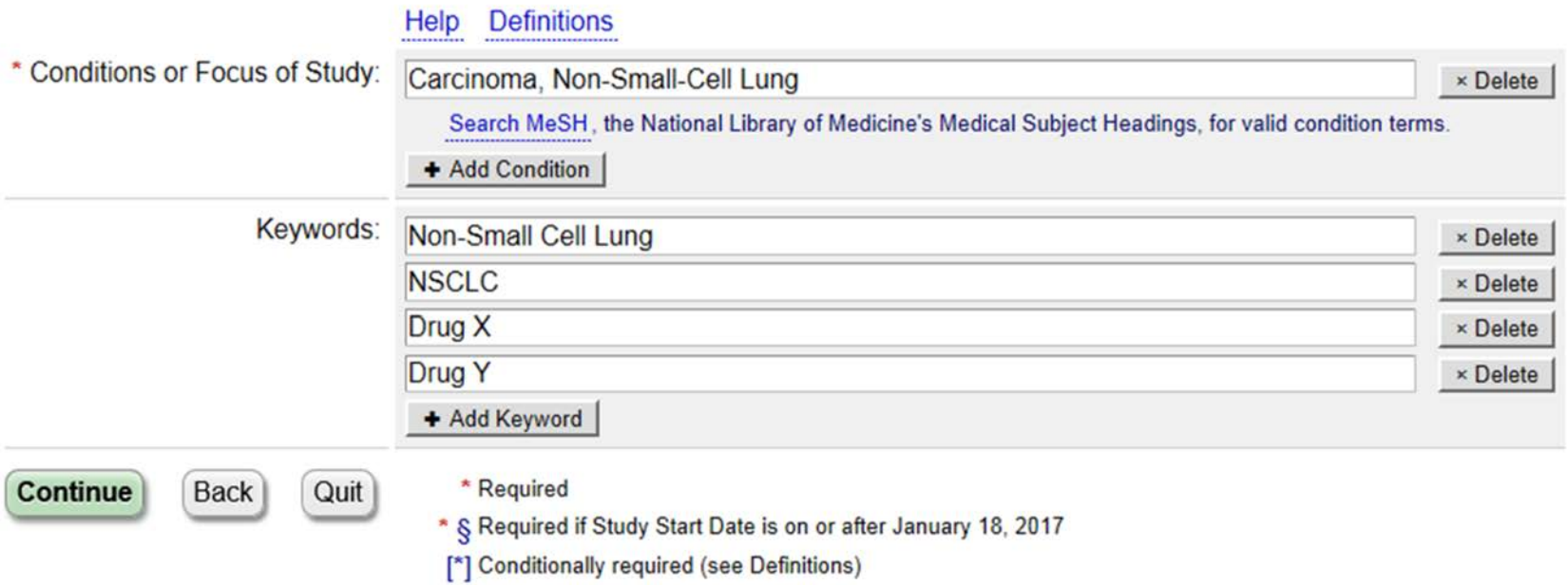
Conditions Complete



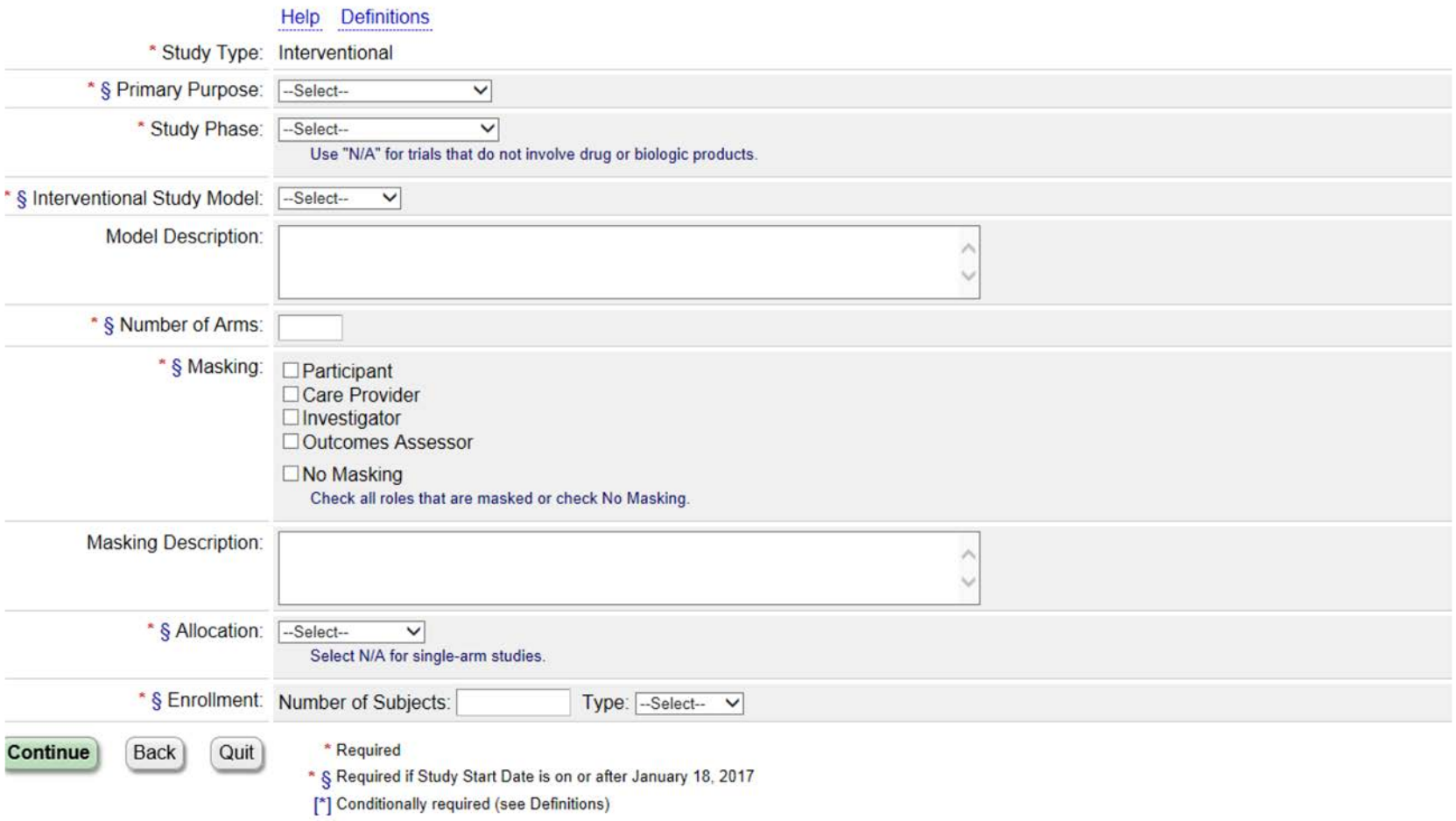
Medical Subject Headings



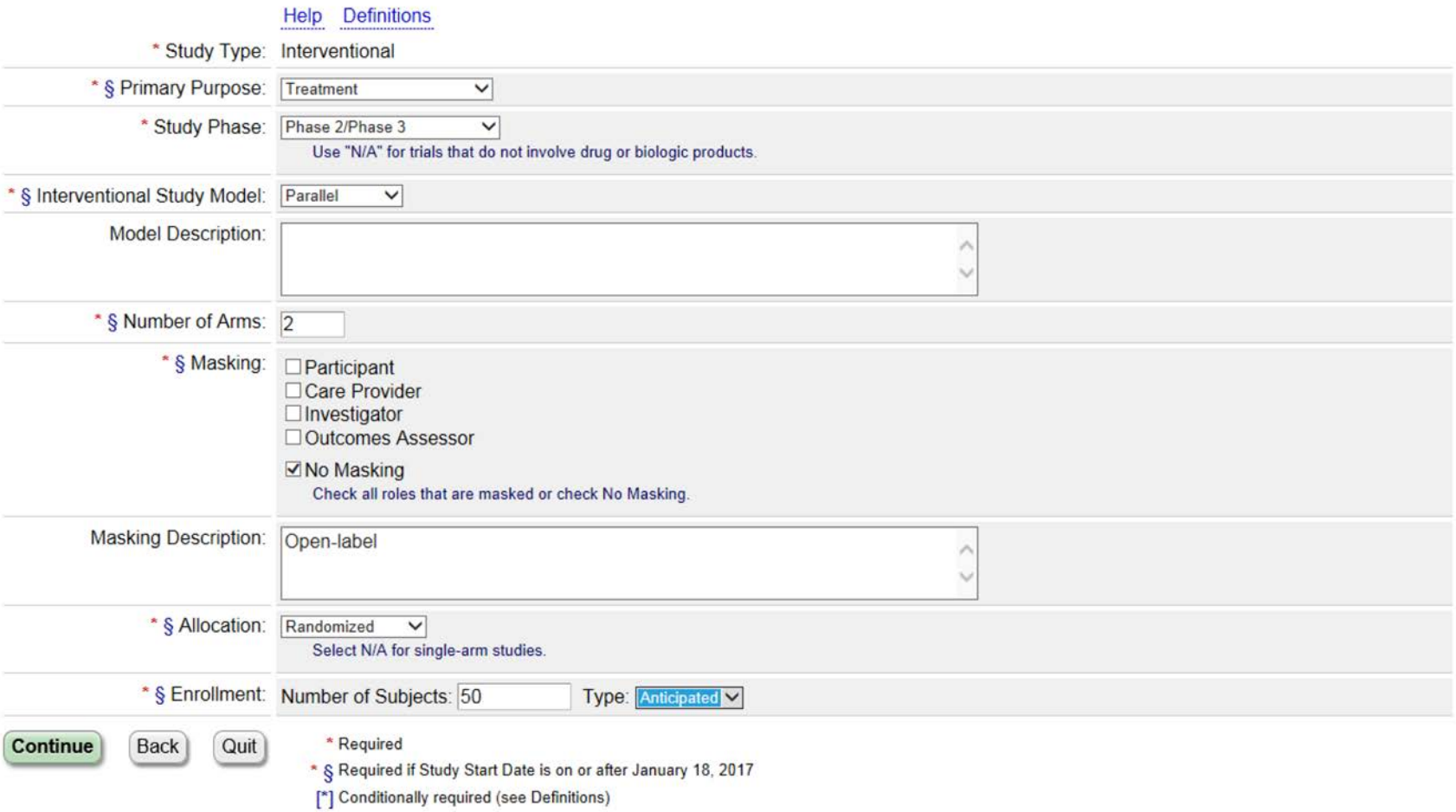
Keywords Used For Search



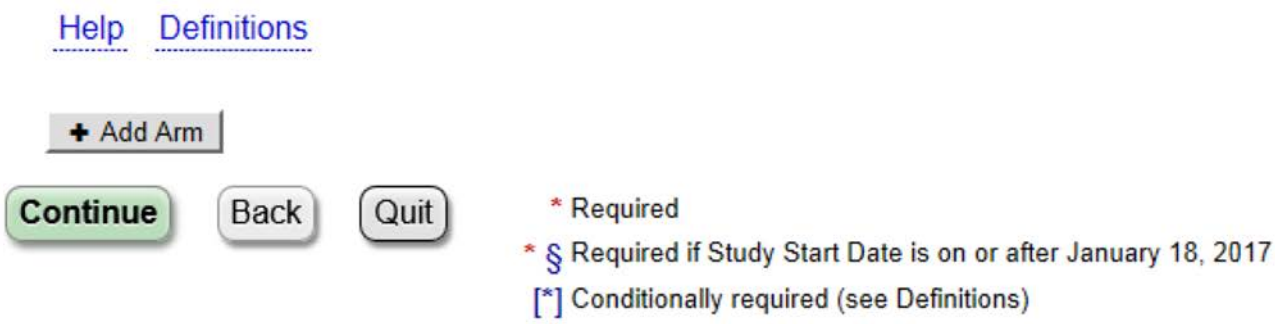
Interventional Study Design



Interventional Study Design Completed



Arms


Help
Definitions
+ Add Arm
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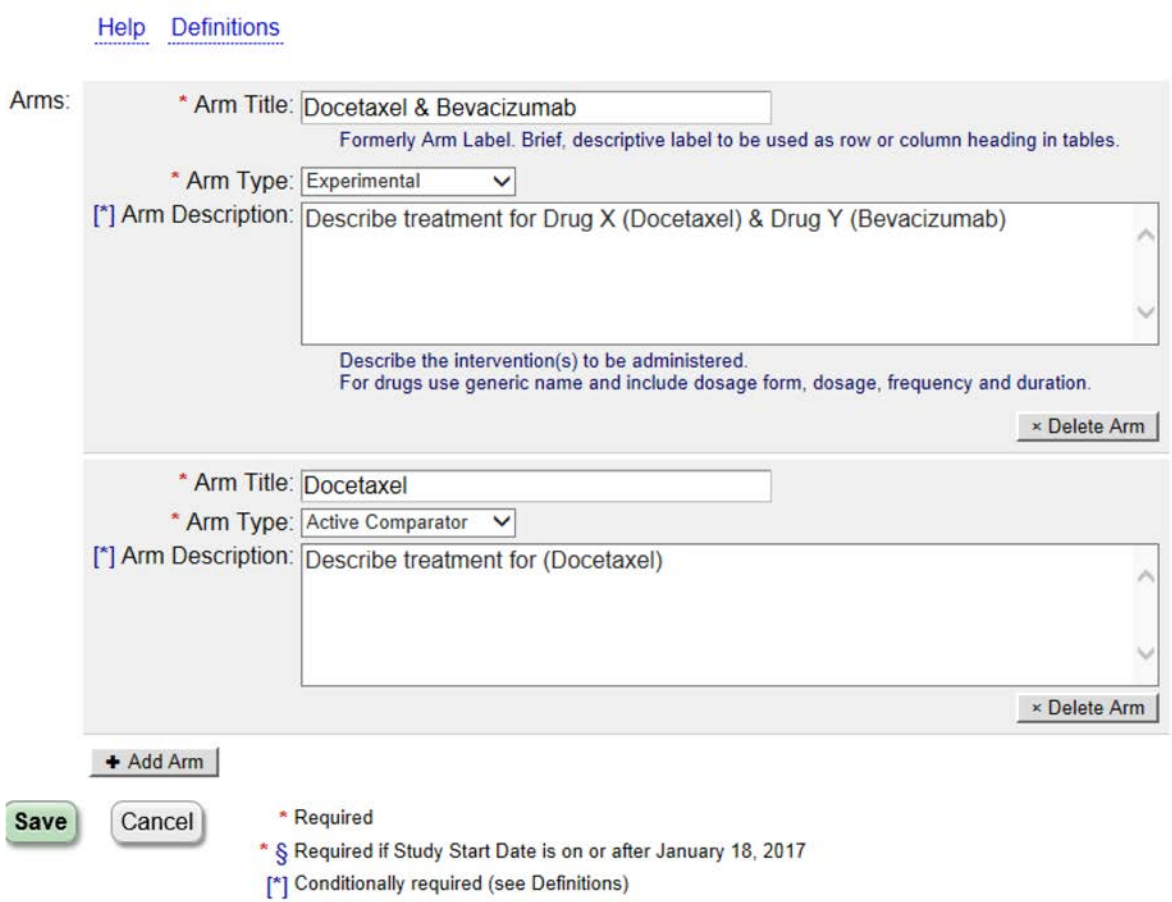
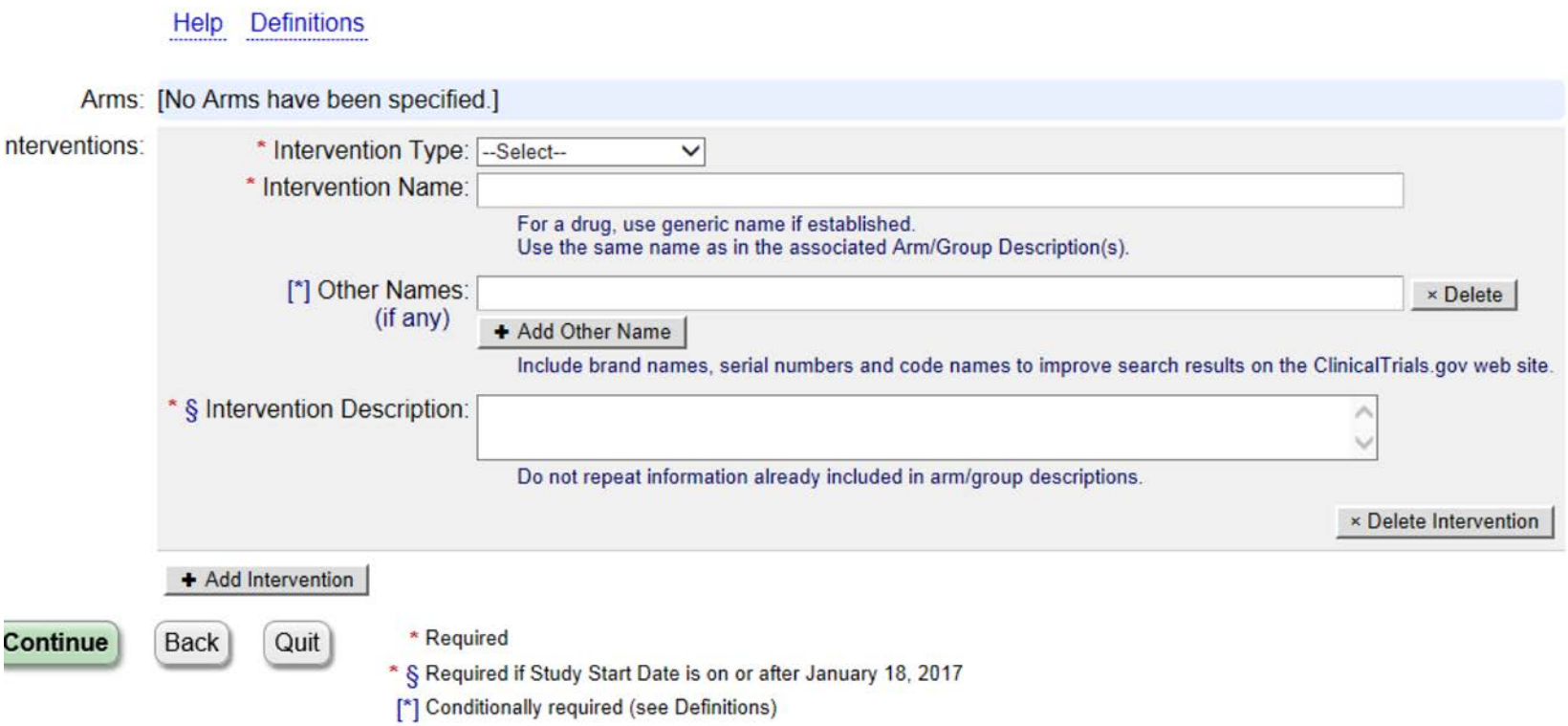
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

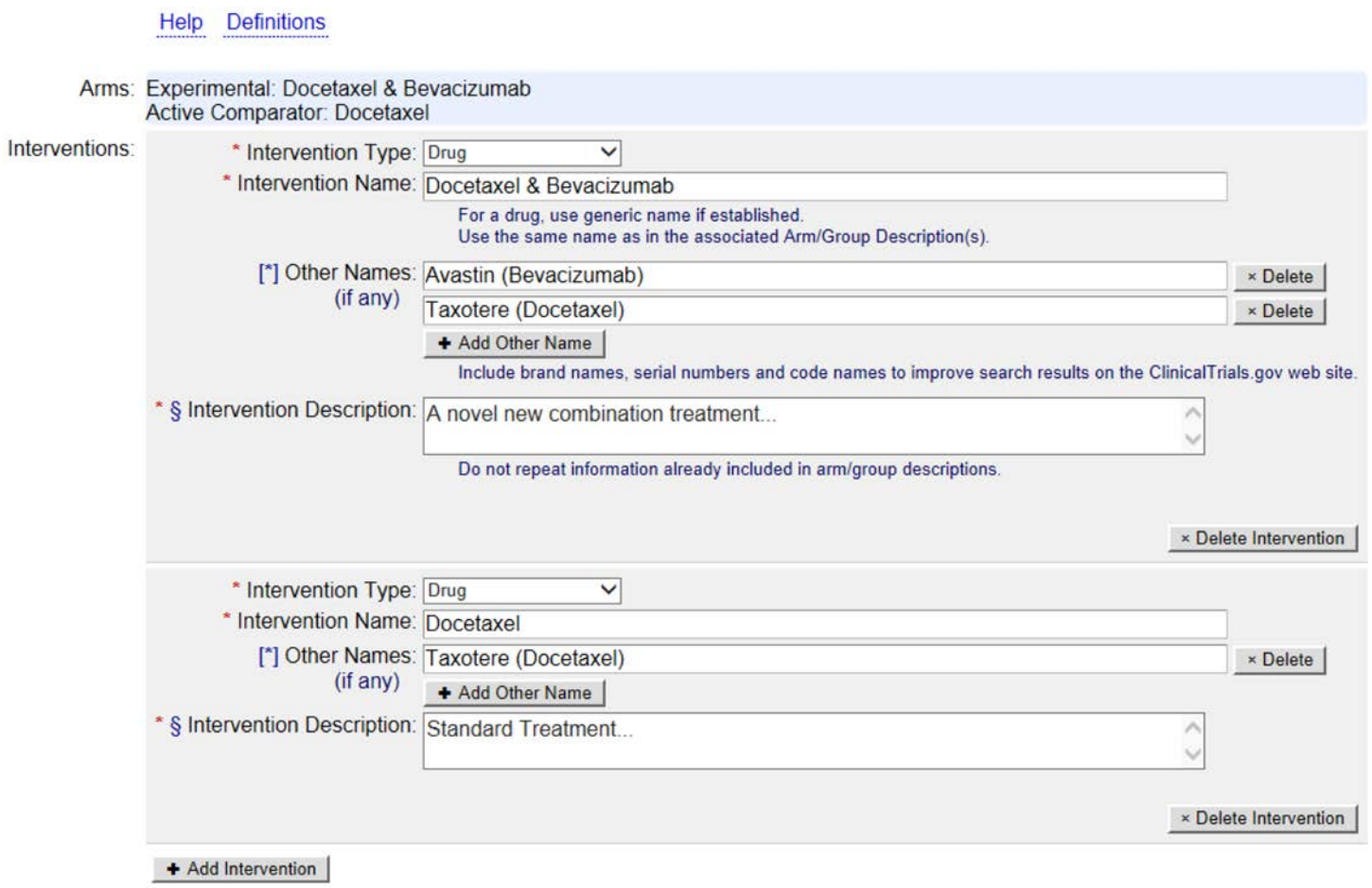
Arms Defined



Interventions



Intervention Defined



Arms & Interventions

Edit

Arms

Arm: Experimental: Docetaxel & Bevacizumab
Describe treatment for Drug X (Docetaxel) & Drug Y (Bevacizumab)

Arm: Active Comparator: Docetaxel
Describe treatment for (Docetaxel)

Edit

Interventions

Intervention: Drug: Docetaxel & Bevacizumab
Other Names:
Avastin (Bevacizumab)
Taxotere (Docetaxel)
A novel new combination treatment...

Intervention: Drug: Docetaxel
Other Names:
Taxotere (Docetaxel)
Standard Treatment...

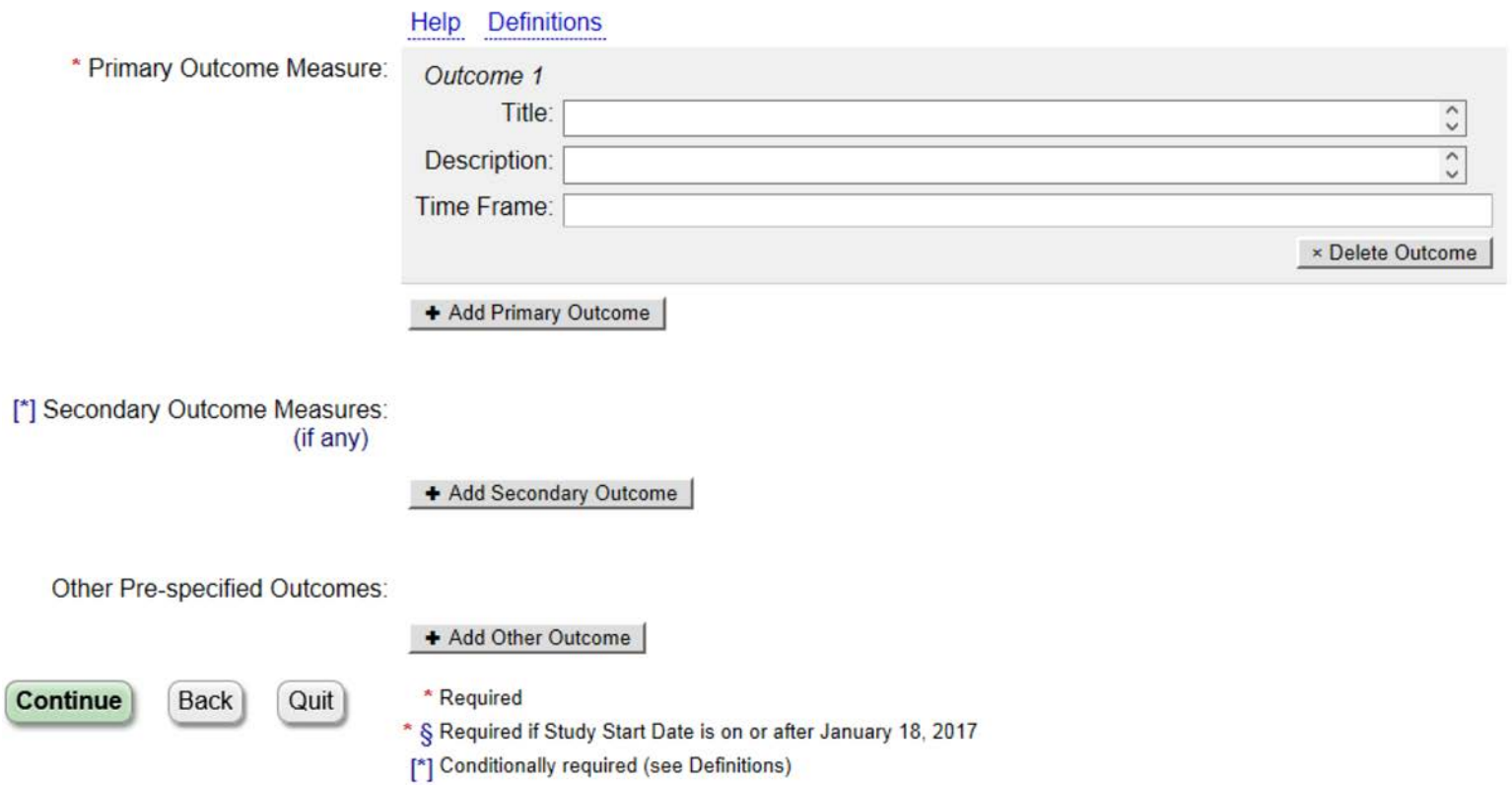
Edit

Cross-Reference

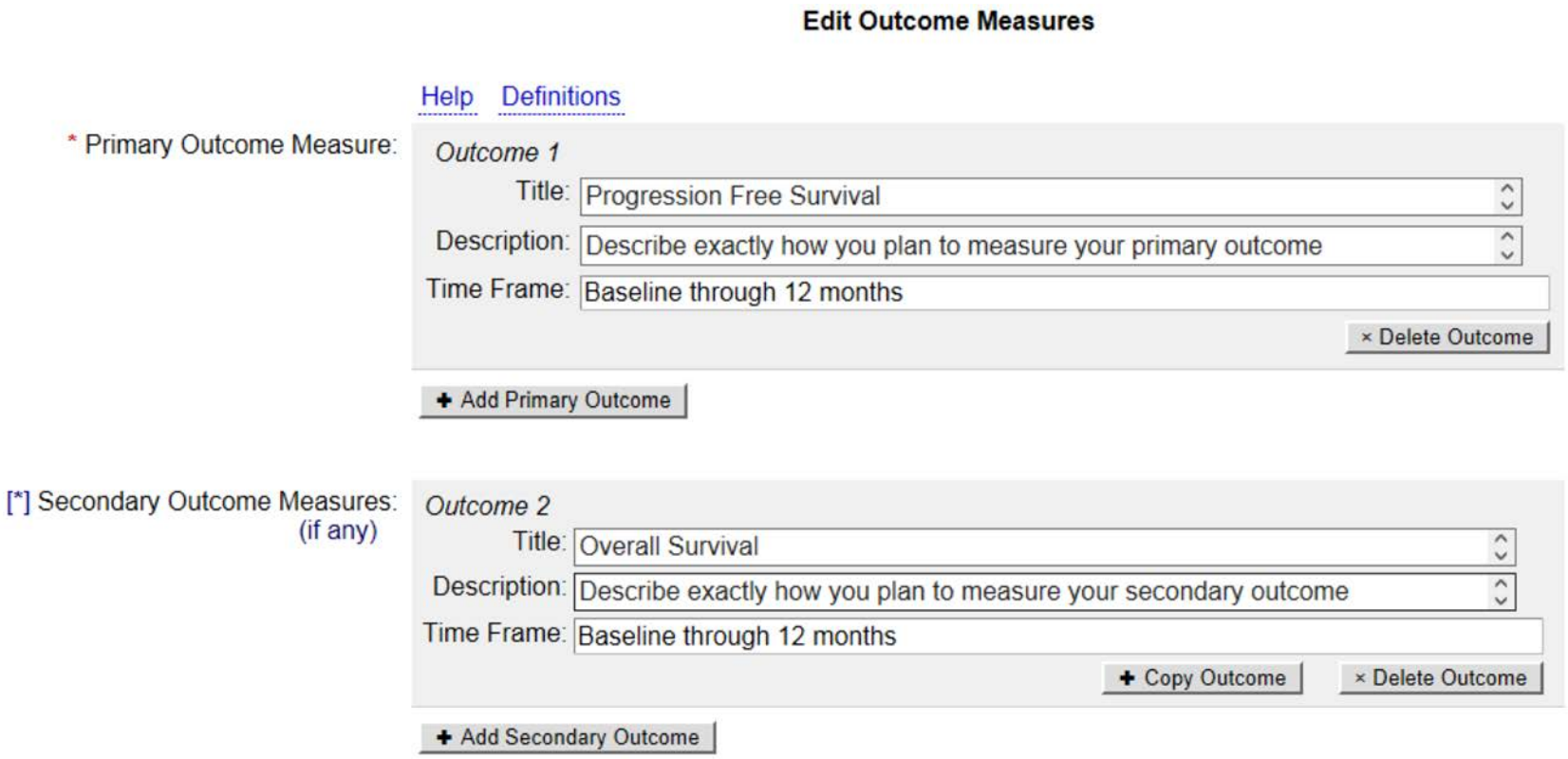
Arms	Interventions	
	Drug: Docetaxel & Bevacizumab	Drug: Docetaxel
Experimental: Docetaxel & Bevacizumab Describe treatment for Drug X (Docetaxel) & Drug Y (Bevacizumab)	✓	
Active Comparator: Docetaxel Describe treatment for (Docetaxel)		✓

✓ - Intervention is administered to patients in this Arm.

Outcome Measures



Outcome Measures



Major & Advisory Issues

- Problems are now addressed by:
- Advisory – are suggestions to improve the clarity of the record
- Major Issues have to be addressed
- Priority for the participants to understand the language

Advisory Issues:

The Investigator's information in the Responsible Party data element is not properly formatted. Please provide the investigator's Official Title (e.g., Director, Head of Otolaryngology, Principal Investigator, Clinical Professor).

Major Issues:

1) The Time Frame does not appear to be specific and/or in the correct format.

The Time Frame "1 most" is not specific. Measures of change should specify two or more time points in the Time Frame to indicate the time points over which the change is assessed (e.g., baseline and 6 months).

Outcome Measure – Major Issue

hide

7. TBS adjustment of FRAX scores for an enhanced fracture risk probability in pre and post-menopausal women undergoing bariatric surgery (Roux en Y vs. Gastric Sleeve).

The Trabecular Bone Score (TBS) is derived from the texture of the DXA image and has been shown to be related to fracture risk. Trabecular Bone Score (TBS) software will be used to adjust FRAX scores for an enhanced 10-year fracture risk probability (in %). FRAX adjusted for TBS is an algorithm derived from WHO FRAX calculation tool to adjust probability of fracture from clinical risk factors and BMD to account for TBS. The calculated probabilities of fracture have been shown to be more accurate when computed including TBS. TBS scores (in gradient of risk) ranges from 1.1% -1.9% coefficient of variation (C.V.)

[Time Frame: Baseline]

Comments [1]

Major Issues:

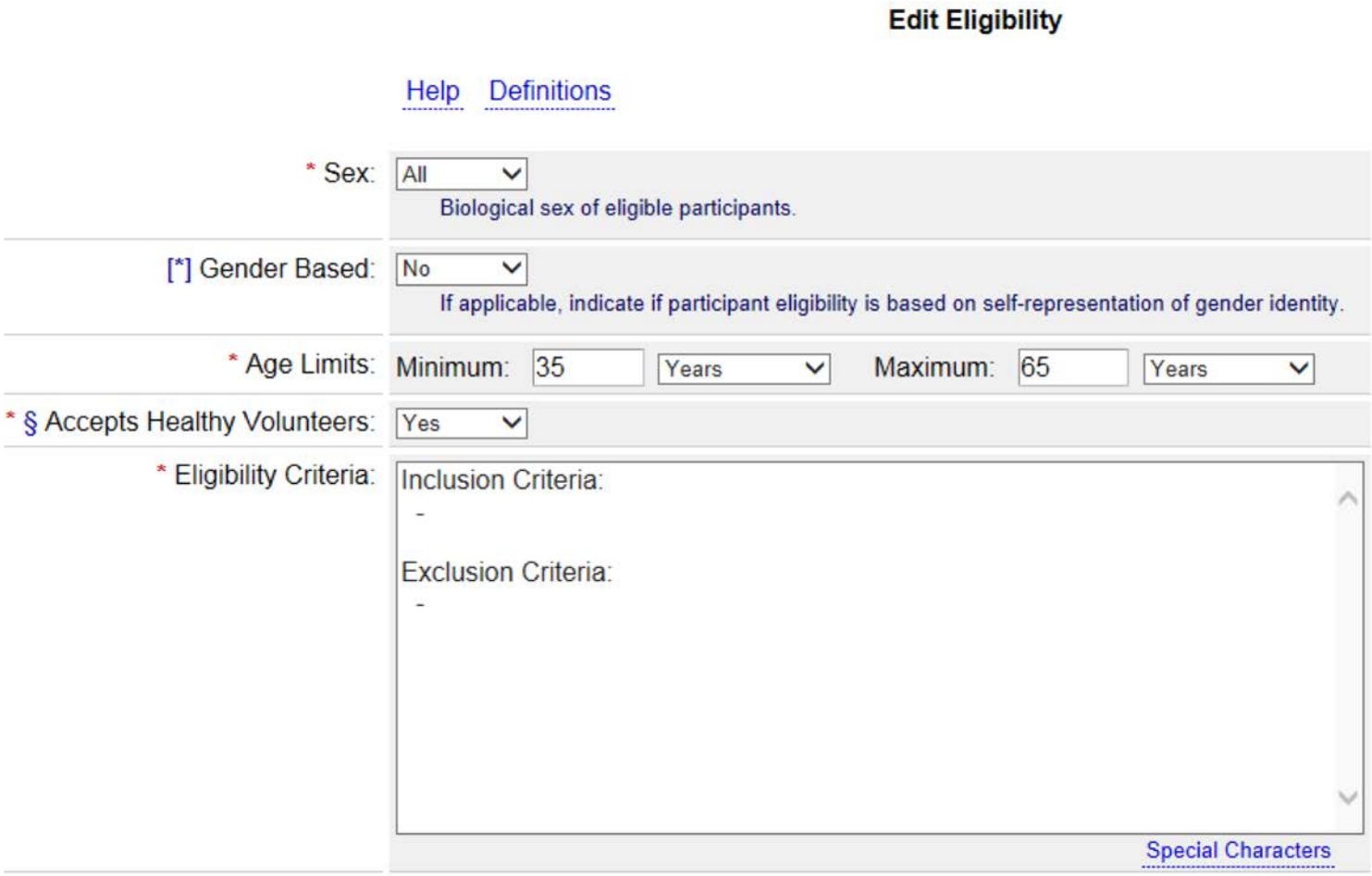
1) The Time Frame appears to be inconsistent with information provided here or in other parts of the record.

The Time Frame appears to be inconsistent with information provided in the Measure Description. Please review and revise as appropriate.

2) The Primary Outcome Measure Time Frame includes more than one time point, each of which appears to describe a separate measure.

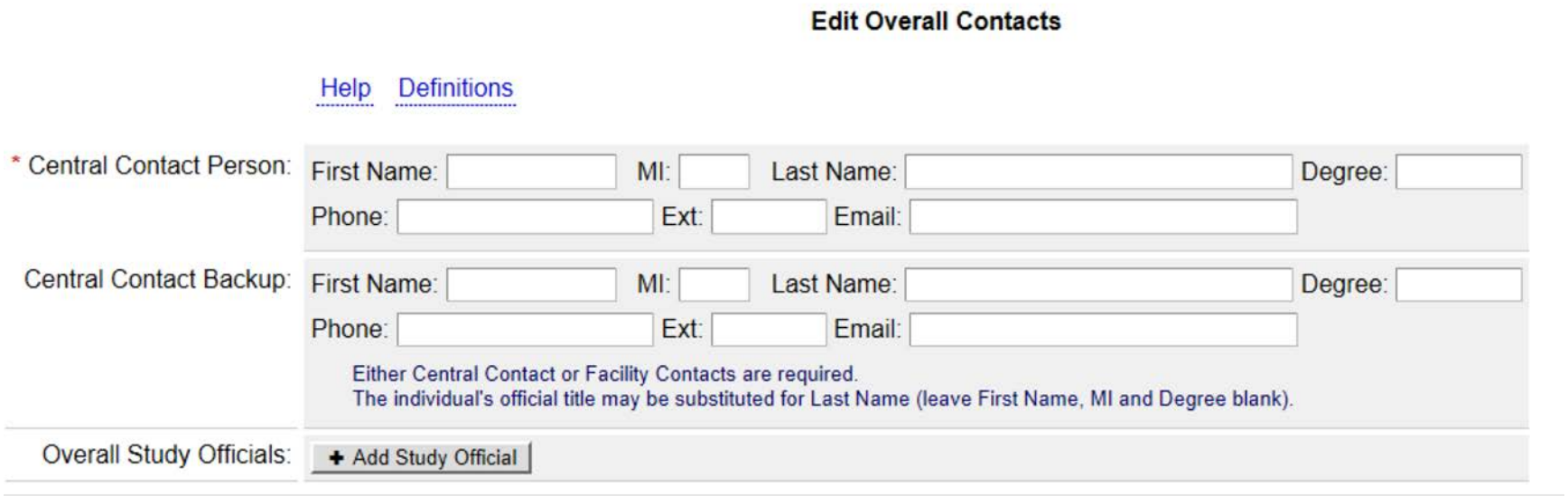
The Primary Outcome Measure Title includes more than one time point. Each Outcome Measure should typically only specify a single time point of assessment. A common exception to this is a measure assessing change between two time points (e.g., "Change from Baseline Systolic Blood Pressure at 6 months"). If the Outcome Measure(s) are assessing a change, please revise the Outcome Measure Title(s) to specify that "change" is being assessed. If not assessing change, please revise and enter additional Outcome Measures so that there is only one Time Frame per Outcome Measure.

Eligibility: Inclusion & Exclusion

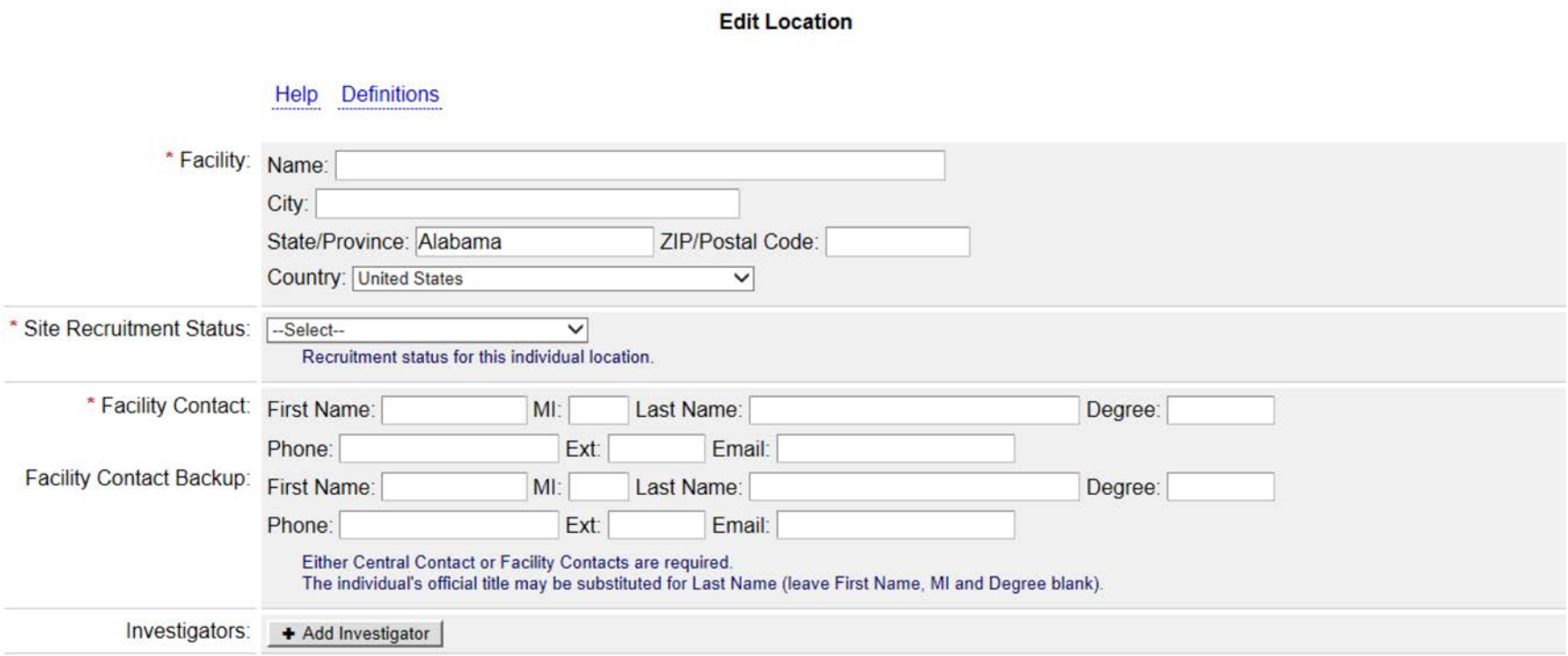


Overall Contacts

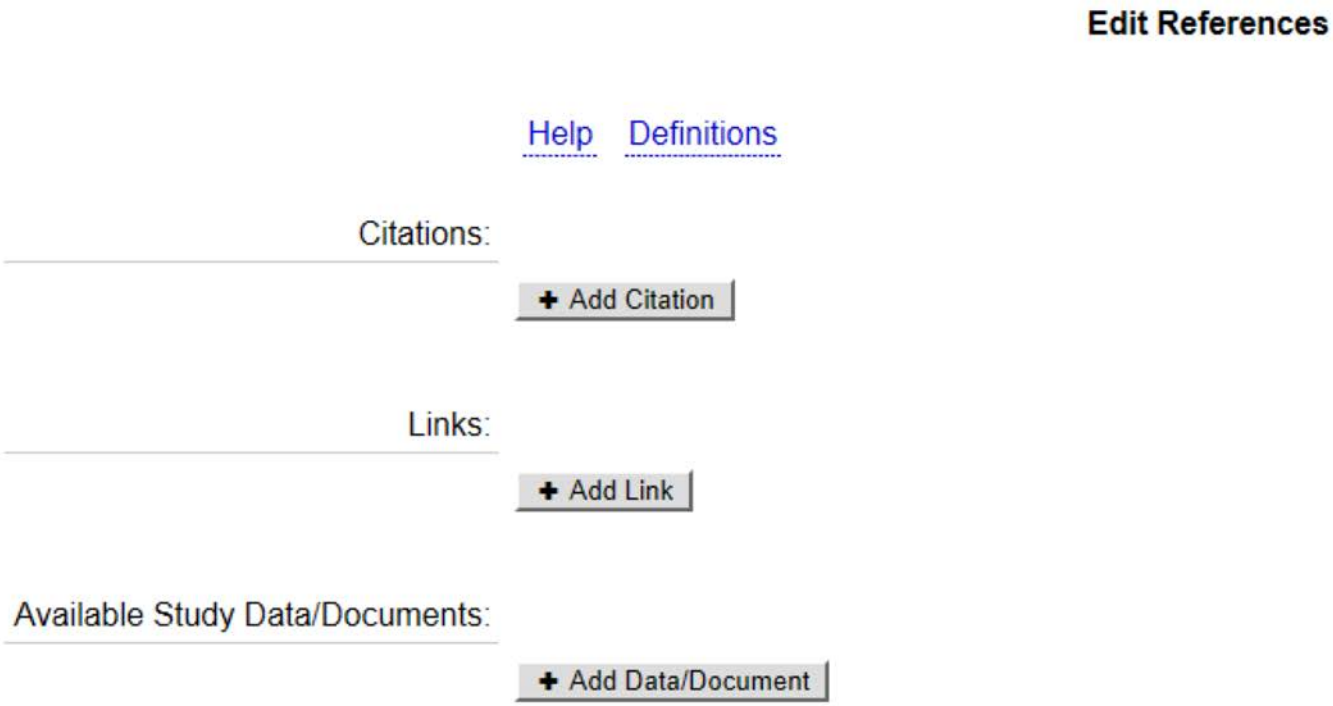
Overall Contacts



Study Location



Study References



References

Citations
Definition: Citations to publications related to the protocol: background and/or results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation.

PubMed Identifier
Definition: PMID for the citation in MEDLINE

Citation
Definition: bibliographic reference in NLM's MEDLINE format
Limit: 2000 characters.

Results Reference
Definition: Indicate if the reference provided reports on results from this clinical study.

Links
Definition: A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

URL
Definition: complete URL, including http:// or https://
Limit: 3999 characters.

Description
Definition: title or brief description of the linked page.
Limit: 254 characters.

Study Data/Documents

Available Study Data/Documents
Definition: Study data sets and documents that are being shared. Provide the following information for each:

Type
Definition: The type of data set or document being shared.

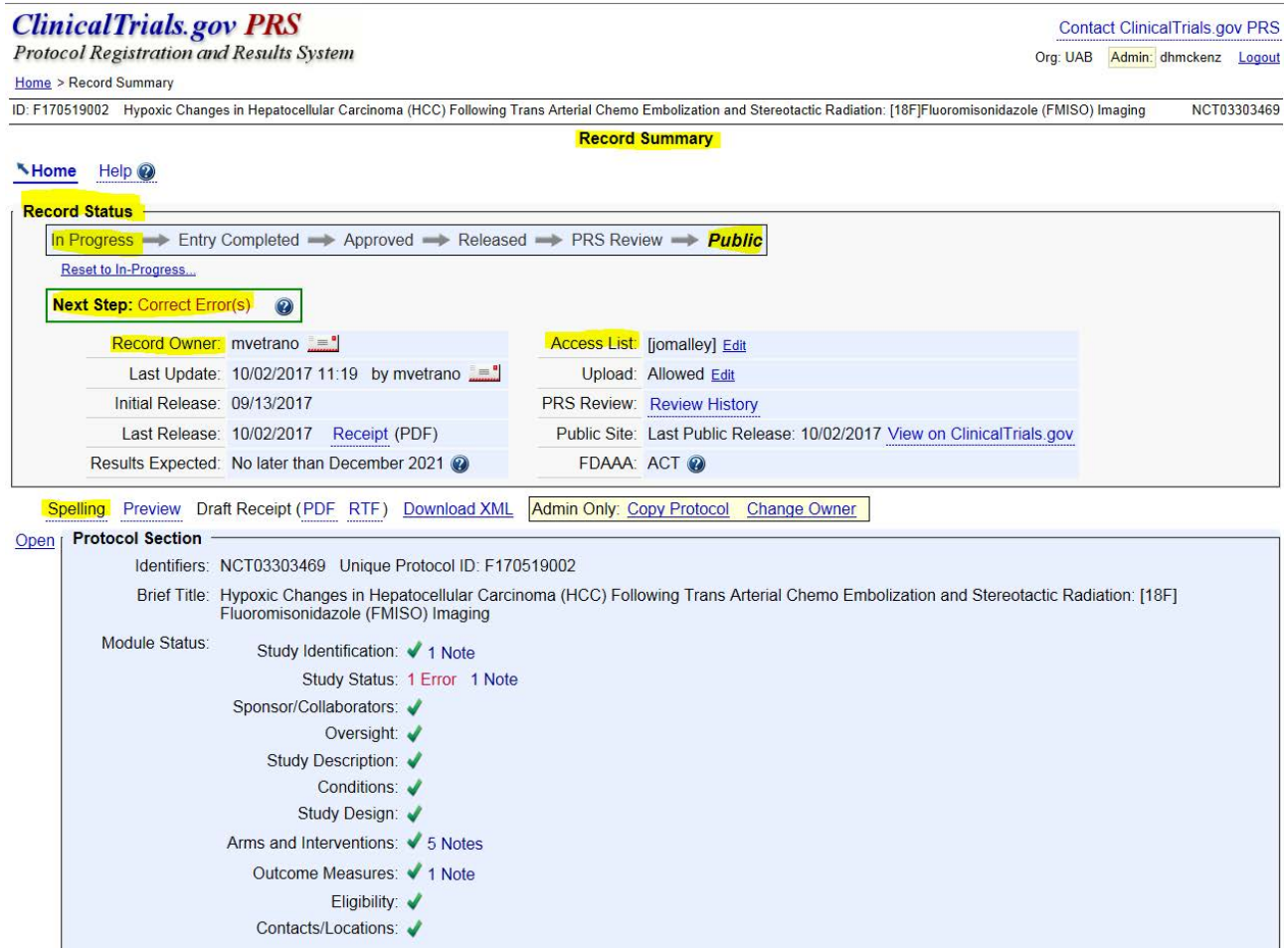
- Individual Participant Data Set
- Study Protocol
- Statistical Analysis Plan
- Informed Consent Form
- Clinical Study Report
- Analytic Code
- Other (specify)

URL
Definition: The Web address used to request or access the data set or document.
Limit: 3999 characters.

Identifier
Definition: The unique identifier used by a data repository for the data set or document.
Limit: 30 characters.

Comments
Definition: Additional information including the name of the data repository or other location where the data set or document is available. Provide any additional explanations about the data set or document and instructions for obtaining access, particularly if a URL is not provided.
Limit: 1000 characters.

Record Summary



Protocol Section

Open **Protocol Section**

Identifiers: NCT03303469 Unique Protocol ID: F170519002

Brief Title: Hypoxic Changes in Hepatocellular Carcinoma (HCC) Following Trans Arterial Chemo Embolization and Stereotactic Radiation: [18F] Fluoromisonidazole (FMISO) Imaging

Module Status:

- Study Identification: ✓ 1 Note
- Study Status: 1 Error 1 Note
- Sponsor/Collaborators: ✓
- Oversight: ✓
- Study Description: ✓
- Conditions: ✓
- Study Design: ✓
- Arms and Interventions: ✓ 5 Notes
- Outcome Measures: ✓ 1 Note
- Eligibility: ✓
- Contacts/Locations: ✓
- IPD Sharing Statement:
- References:

Protocol Section

Record Summary | Preview | Edit All | Help | Definitions

Edit

Study Identification

Unique Protocol ID: F170519002

Brief Title: Hypoxic Changes in Hepatocellular Carcinoma (HCC) Following Trans Arterial Chemo Embolization and Stereotactic Radiation: [18F] Fluoromisonidazole (FMISO) Imaging

NOTE: Brief Title should have no more than 120 characters.

Official Title: Hypoxic Changes in Hepatocellular Carcinoma (HCC) Following Trans Arterial Chemo Embolization and Stereotactic Radiation: [18F] Fluoromisonidazole (FMISO) Imaging

Secondary IDs:

Edit

Study Status

Record Verification: October 2017

Overall Status: Recruiting

Study Start: October 30, 2017 [Anticipated]

NOTE: Study Start Date should be updated and changed to Actual once the first participant is enrolled.

ERROR: Anticipated Start Date cannot be in the past.

Primary Completion: December 2020 [Anticipated]

Study Completion: December 2021 [Anticipated]

Edit

Sponsor/Collaborators

Sponsor: University of Alabama at Birmingham

Responsible Party: Principal Investigator
Investigator: Janis P. O'Malley [jomalley]
Official Title: Principal Investigator, Professor of Radiology
Affiliation: University of Alabama at Birmingham

Collaborators:

Edit

Oversight

U.S. FDA-regulated Drug: Yes

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: Yes

IND/IDE Information: FDA Center: CDER
IND/IDE Number: 136281
IND Serial Number:
Has Expanded Access No

Human Subjects Review: Board Status: Approved Approval Number: 170519002
Board Name: University of Alabama at Birmingham IRB

Edit

Study Design

Study Type: Interventional [Change...]
Primary Purpose: Diagnostic
Study Phase: Phase 2
Interventional Study Model: Single Group Assignment
Number of Arms: 1
Masking: None (Open Label)
Allocation: N/A
Enrollment: 20 [Anticipated]

Open

Arms and Interventions

Arms	Assigned Interventions
Experimental: FMISO PET imaging post TACE and SBRT FMISO imaging at baseline, post-TACE and post-SBRT	Drug: FMISO FMISO PET/CT imaging at baseline Drug: FMISO FMISO PET/CT post TACE Drug: FMISO FMISO PET/CT post SBRT

NOTE: Intervention Other Names have not been specified
NOTE: Intervention Other Names have not been specified
NOTE: Intervention Other Names have not been specified
NOTE: More than one Intervention has the name 'FMISO'
NOTE: More than one Intervention has the name 'FMISO'

Edit

Reorder

Outcome Measures

Primary Outcome Measure:

1. Quantitate HCC tumor hypoxia at baseline using FMISO PET.
   Perform PET/CT imaging using FMISO at baseline to measure tumor hypoxia
   [Time Frame: At baseline]
2. Measure changes in HCC tumor hypoxia and blood flow after TACE, prior to radiotherapy.
   Perform PET/CT imaging using FMISO post-TACE and prior to SBRT to determine tumor hypoxia
   [Time Frame: 1 month post-TACE procedures and prior to SBRT]
3. Measure changes in treated HCC tumor hypoxia following TACE and radiotherapy
   Perform PET/CT imaging using FMISO post-SBRT to determine tumor hypoxia
   [Time Frame: 1 month post-SBRT]

NOTE: Normally only one Primary Outcome Measure is specified.

Results Section

Open

Document Section

Documents that may be uploaded include:

- Study Protocol and Statistical Analysis Plan - only required with results information for studies with a Primary Completion Date on or after January 18, 2017
- Informed Consent Form - optional under 42 CFR Part 11, but may be required by funder, including if study is conducted or supported by a Common Rule (45 CFR 46) department or agency

Uploaded PDF/A Documents:

Results Section

Enter Results — Results submission is required by FDAAA 801 for certain applicable clinical trials of drugs, biologics and devices. Note: other clinical trials may need to have results submitted based on other funder or sponsor policies.

Delay Results — For applicable clinical trials subject to FDAAA 801, results submission may be delayed (in limited circumstances) with a Certification or Extension Request.

For more information see: When Do I Need to Register and Submit Results?

Need help with Results? Contact ClinicalTrials.gov PRS to request one-on-one assistance from one of our experts.

Results Section

Open **Document Section**

Only certain studies need to have study documents uploaded.

- Full study protocol and statistical analysis plan -- required with results information submission for studies with a Primary Completion Date on or after January 18, 2017
- Informed consent forms - optional for all studies

Uploaded PDF/A Documents:

Open **Results Section**

Module Status:

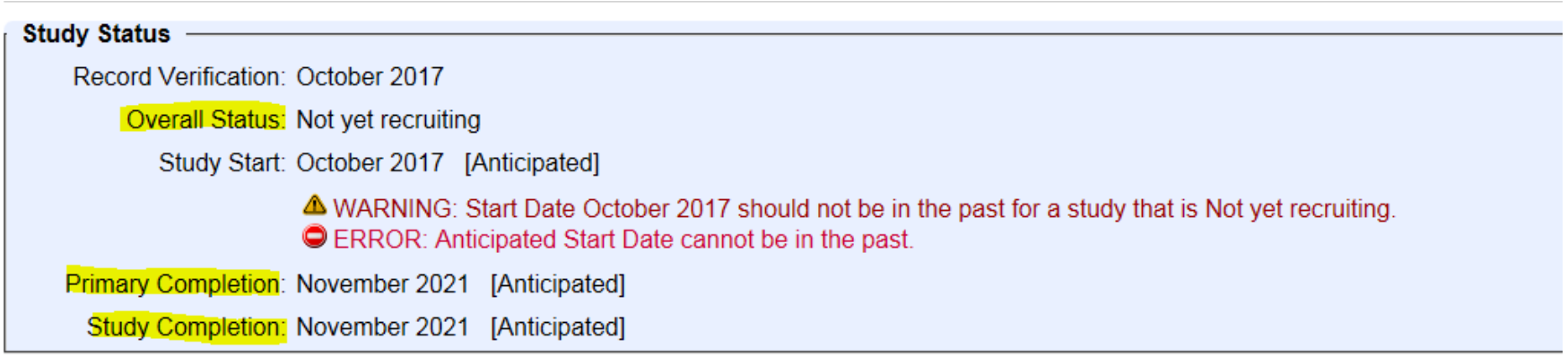
Participant Flow:	✓
Baseline Characteristics:	✓
Outcome Measures:	✓
Adverse Events:	✓ 1 Note
Certain Agreements:	✓
Limitations and Caveats:	
Results Point of Contact:	✓

Registration Updates

- Required annually (12months)
- “Record Verification” indicates the study data is correct and current.

Registration Updates

- Responsible Parties should update their records within ***30 days of a change*** to any of the following:
- ***Recruitment Status*** and ***Overall Recruitment Status*** data elements on ClinicalTrials.gov
- ***Completion Date*** (See ***Primary Completion Date*** data element on ClinicalTrials.gov)



Recent & Upcoming Changes

- ICMJE data sharing plan requirements:

  *Include a data sharing statement in all manuscripts submitted to member journals as of 7/1/18, and

  *Include a data sharing plan in all trial registrations (on ClinicalTrials.gov) for trials enrolling participants on or after 1/1/19

New ICMJE Policy

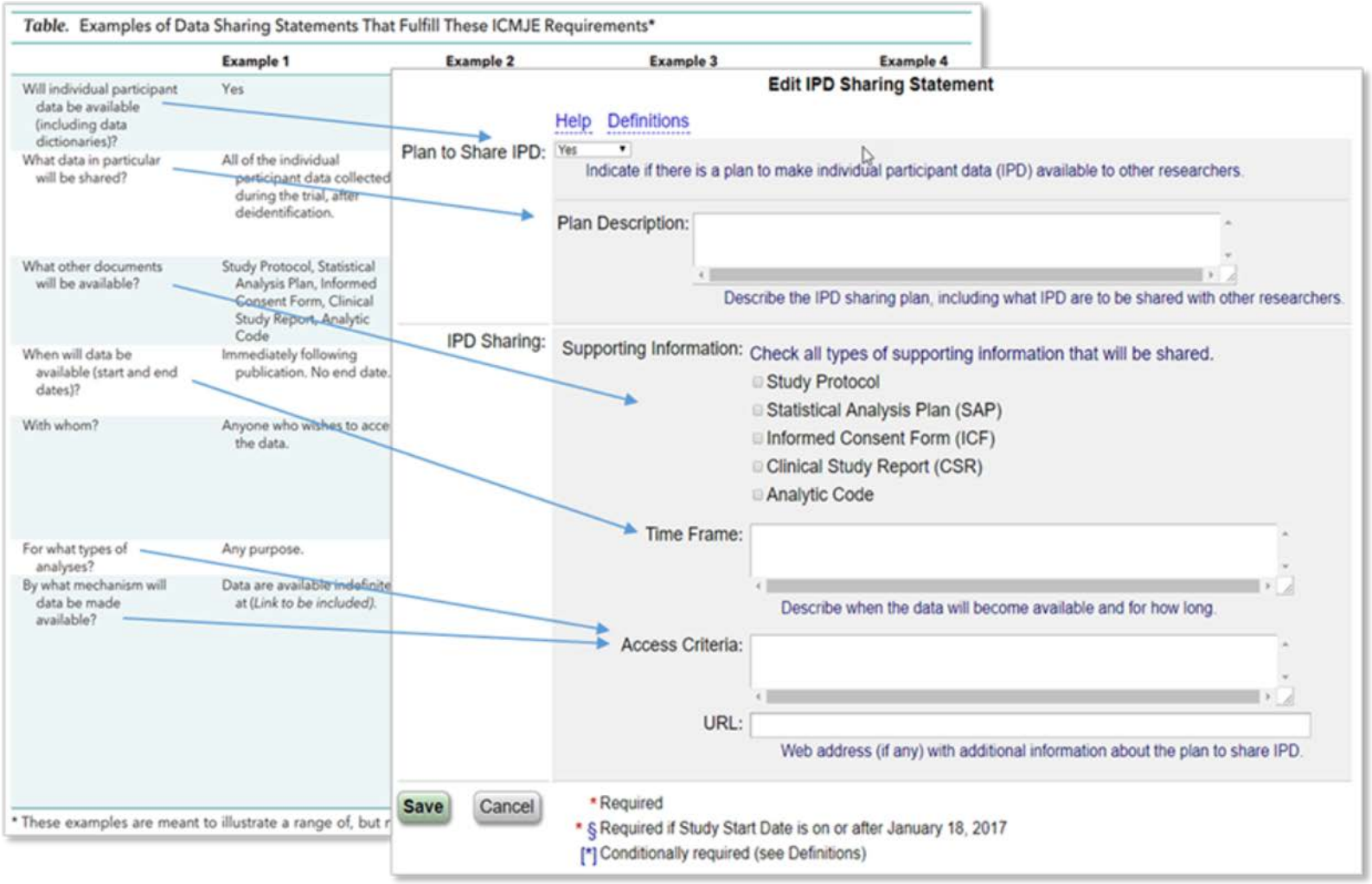


Table. Examples of Data Sharing Statements That Fulfill These ICMJE Requirements*

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes			
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.			
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code			
When will data be available (start and end dates)?	Immediately following publication. No end date.			
With whom?	Anyone who wishes to acce the data.			
For what types of analyses?	Any purpose.			
By what mechanism will data be made available?	Data are available indefinite at (*Link to be included*).			

* These examples are meant to illustrate a range of, but r

Edit IPD Sharing Statement

Help Definitions

Plan to Share IPD: Yes

Indicate if there is a plan to make individual participant data (IPD) available to other researchers.

Plan Description:

Describe the IPD sharing plan, including what IPD are to be shared with other researchers.

IPD Sharing:

Supporting Information: Check all types of supporting information that will be shared.

- Study Protocol
- Statistical Analysis Plan (SAP)
- Informed Consent Form (ICF)
- Clinical Study Report (CSR)
- Analytic Code

Time Frame:

Describe when the data will become available and for how long.

Access Criteria:

URL:

Web address (if any) with additional information about the plan to share IPD.

Save Cancel

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

IPD Sharing Statements

- Required in manuscripts starting in July 2018
- Required in the CTgov Registration for studies than begin enrolling on/after January 1, 2019
- Point to ICMJE link (above) for types of entries ICMJE expects
- Why it matters to investigators who want to publish – “editors may take into consideration data sharing statements when making editorial decisions”
- Once education material is ready, we will send it to the investigators we have been tracking, and ask them to review their entries and update as necessary
- We will continue sending education material for the near term as entries are made in this module
- We don’t intend to do this indefinitely, but the publication issue is important enough to investigators that we plan to keep with it for at least the near future

Common Rule

- Effective date of the revised Common Rule is January 19, 2019
- First time since it was issued in 1991
- Effort started in 2011 with 2 primary goals:
- Modernize and enhance the protections for human research participants
- Reduce the unnecessary burden/ambiguity for researchers

Common Rule

- Single Institutional Review Board (IRB) for multi-institutional research studies
- Improved consent forms and the process of obtaining consent:
- Begin with a “Concise & Focused” presentation of this key information that will most likely help someone make a decision about whether to participate in a study.
- Provide potential research subjects with a better understanding of a project’s scope, including its risks and benefits, so they can make a more fully informed decision about whether to participate.
- One version of the consent form used to enroll participants in federally funded clinical trials will be posted on a public website (CT.gov).

Common Rule

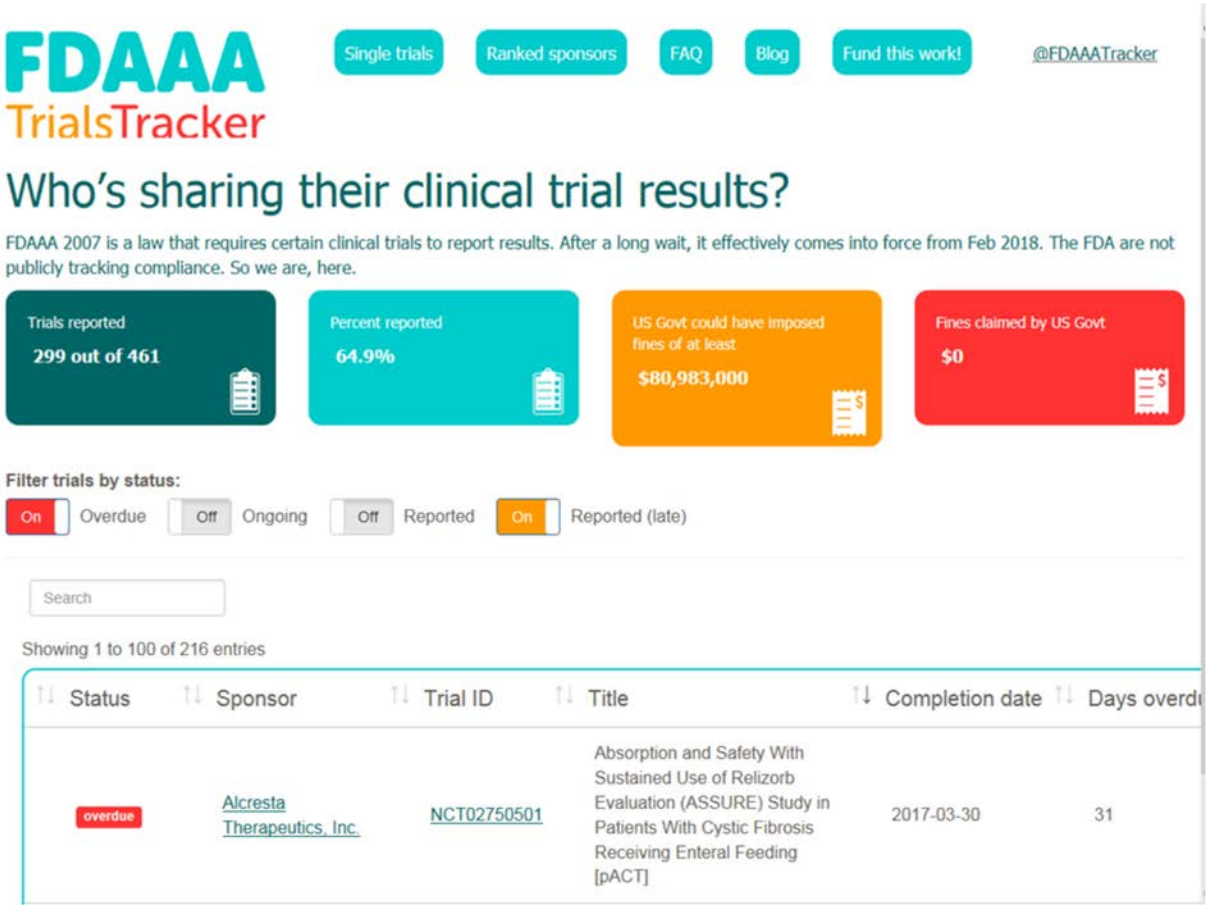
- For studies on stored identifiable data or biospecimens, researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement. As under the current rule, researchers will still not have to obtain consent for studies on non-identified stored data or biospecimens.
- Establishment of new exempt categories of research based on the level of risk they pose to participants (allows IRBs to focus their attention on higher risk studies).
- Removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such reviews do very little to protect subjects.

FDAAA Noncompliance


[New] Tracking FDAAA Noncompliance: AllTrials Calls on FDA to Levy Fines 19 February 2018
The international initiative AllTrials on Monday unveiled a new tracking tool to highlight clinical trial sponsors who fail to publish results as required by the FDA Amendments Act of 2007 (FDAAA). [Read More...]

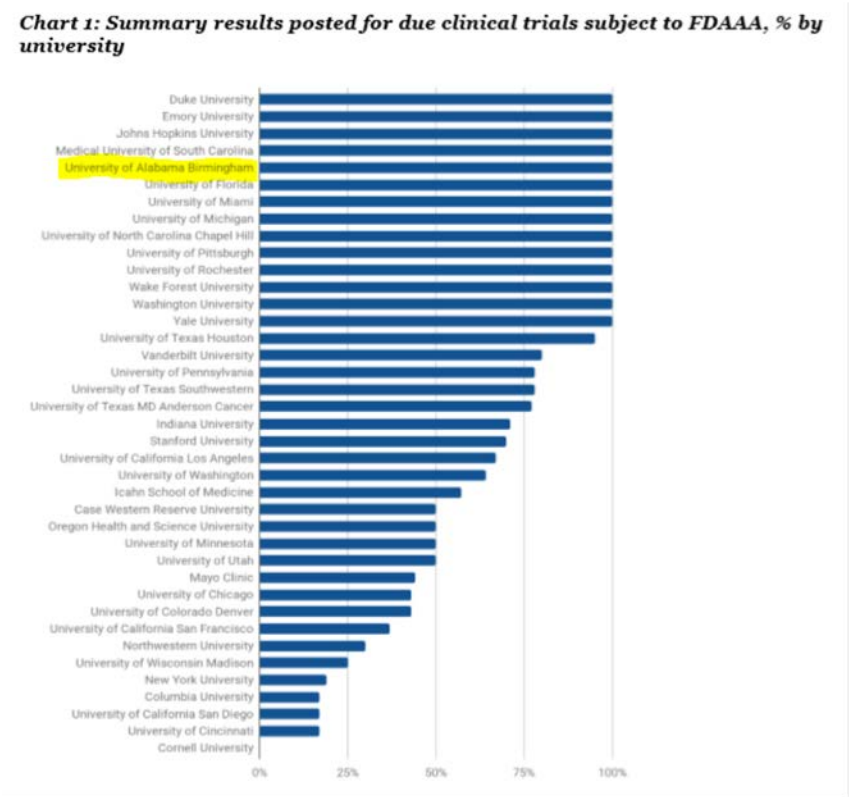
- https://www.raps.org/news-and-articles/news-articles/2018/2/tracking-fdaaa-noncompliance-alltrials-calls-on-f?utm_source=Email&utm_medium=Informz&utm_campaign=Informz-Emails&_zs=kQ0jK1&_zl=vhMJ4

FDAAA TrialsTracker



Reporting Results - 2019

Legal Compliance by US Universities



Reporting Results Since 2017

- 14 universities achieved a reporting rate of 10%
- 31% of those trials are still missing results
- Violators:
  - MD Anderson – 77%
  - Mayo – 42%
  - UC SF -37%
  - New York – 21%

Reporting Results - 2019

Continued… "Sharing Results Should Not Be Optional"

OPINION POLICY-ISH

Academic Medical Centers Get An F In Sharing Research Results

February 23, 2016 · 1:59 PM ET

HARLAN KRUMHOLZ

Who will check the study results if they aren't made public?

"Not reporting results violates the basic principle of the scientific method. It hurts patients, society and science. It dishonors the people who gave their consent and bore the risk of participating...

The holding back of the results impedes progress toward scientific breakthroughs, corrupts the medical literature and wastes research funding."

National Institutes of Health
Office of Extramural Research

http://www.npr.org/sections/health-shots/2016/02/23/467712481/academic-medical-centers-get-an-f-in-sharing-research-results

Registering/Reporting

- 3 Key Facts To Remember:
- Register
- Update
- Report

- Policy specifies that "the registration/reporting of all interventional trials is a scientific, ethical and moral responsibility.“

Need Assistance??

- We are always available, please call if in doubt:

- Denise McKenzie, dhmckenzie@uabmc.edu
  Phone: 934-9360
- Dorothy Shaw, dshaw@peds.uab.edu
  Phone: 996-7832
- Hina Amanullah, hamanullah@uabmc.edu
  Phone: 934-3796