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/
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.

Find a study (all fields optional)

Status

- Recruiting and not yet recruiting studies
- All studies

Condition or disease (For example: breast cancer)

Other terms (For example: NCT number, drug name, investigator name)

Country

Search

Advanced Search
CT.gov Registration Website

Welcome to the ClinicalTrials.gov Protocol Registration and Results System (PRS).

Organization: [Type organization name]

Username: [Type username]

Password: [Type password]  Forgot password

See Submit Studies on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.

Send email to ClinicalTrials.gov PRS Administration
Registering A New Record

<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>ClinicalTrials.gov ID</th>
<th>Brief Title</th>
<th>Primary Completion Date</th>
<th>Record Status</th>
<th>Last Update</th>
<th>Record Owner</th>
<th>Responsible Party</th>
<th>Prot</th>
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<tbody>
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<td>IRB-300091132</td>
<td>NCT03497195</td>
<td>Achieving Tuberculosis (TB) Control in Zambia</td>
<td>05/01/2020</td>
<td>Public</td>
<td>04/06/2018 03:44</td>
<td>twilloh</td>
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<td>NCT03485472</td>
<td>Radiosurgery Plus NovoTTF-200A for Metastatic Small Cell Lung Cancer to the Brain (RAD 1704)</td>
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<td>kkhwebb</td>
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<td>mvatran0</td>
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<td>04/24/2016 10:58</td>
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<td>03/14/2016 15:26</td>
<td>rkennedy</td>
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<td>Open</td>
<td>IRB-300090596</td>
<td>Single Use Negative Pressure Wound Therapy for Free Flap Donor</td>
<td>05/2019</td>
<td>In Progress</td>
<td>05/01/2018 13:00</td>
<td>dlklowman</td>
<td>Brian Hughley</td>
<td><a href="mailto:bhlughley@uabmc.edu">bhlughley@uabmc.edu</a></td>
</tr>
</tbody>
</table>
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

When Does a Study Have to be Registered on ClinicalTrials.gov?
(Evaluate all requirements)

START

Requirement 1
NIH Dissemination Policy

Does the study receive direct NIH funding?

No

Yes

Was the funding application submitted on or after Jan 18, 2017?

No

Yes

Is the study an NIH-defined clinical trial?

No

Yes

NIH dissemination policy applies
Registration and results reporting is required

Go to Requirement 2

Not in scope of NIH Dissemination Policy

Go to Requirement 2

Requirement 2
Law (FDAAA) and Regulations (82 CFR 111)*

Is the study an interventional clinical trial?

Yes

No

Not an FDA-regulated clinical investigation of drug, biologic, or device?

Yes

No

Is it conducted at a U.S. site, or under an IND/IDE?

Yes

No

Applicable Clinical Trial
Registration and results reporting is required

Go to Requirement 3

Not required by law/regulators

Go to Requirement 3

Requirement 3
ICMJE Publication Requirements

Is the study an interventional clinical trial?

Yes

No

ICMJE policy applies
Registration (but not results) is required

The 3 main requirements are shown here — other requirements may apply

Not required by publishers
Decision Tree for NIH Clinical Trial Definition

- Does the study involve human participants research?
  - YES
  - NO

- Are participants prospectively assigned to an intervention?
  - YES
  - NO

- Is the study designed to evaluate the effect of the intervention on the participants?
  - YES
  - NO

- Is the effect being evaluated a health-related biomedical or behavioral outcome?
  - YES
  - NO

The study is NOT a clinical trial.

This study is a clinical trial.
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.”
Title Page

* Organization’s Unique Protocol ID: F00123456

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

[*] Acronym: (if any) NSCLC

* Study Type: (required)

  - 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

* Required

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

[*] Conditionally required (see Definitions)
Agenda of Information

The following web pages allow data entry for each protocol module:

- Study Identification
- Study Status
- Sponsor/Collaborators
- Oversight
- Description
- Conditions
- Study Design
- Interventions
- Eligibility
- Contacts/Locations
- References

On each page, select Continue to save data entered and proceed to the next page.
On any page, select Quit to stop entering data. Data entered on previous pages will be retained. To complete data entry later, open the record from the home page.

OK
### Official Title

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Organization's Unique Protocol ID</td>
<td>F00123456</td>
</tr>
<tr>
<td>Brief Title</td>
<td>Efficacy of Drug X/Y vs Drug Y in Non-Small Cell Lung Cancer</td>
</tr>
<tr>
<td>Acronym (if any)</td>
<td>NSCLC</td>
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<tr>
<td>Official Title</td>
<td>Evaluating the Efficacy and Safety of a New Novel Drug Combination Against the Standard Treatment for Non-Small Cell Lung Cancer</td>
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**WARNING:** Official Title has not been entered.

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Secondary IDs (if any)</td>
<td>Add Secondary ID</td>
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</table>

* Required

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

[*] Conditionally required (see Definitions)
# ClinicalTrials.gov PRS

## Protocol Registration and Results System

### Quick Links
- New Record
- Admin Quick Reference
- Problem Resolution Guide

### Record List

<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>ClinicalTrials.gov ID</th>
<th>Brief Title</th>
<th>Record Status</th>
<th>Last Update</th>
<th>Record Owner</th>
<th>Responsible Party</th>
<th>Problems</th>
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<tbody>
<tr>
<td>Open</td>
<td>F160920009</td>
<td>The Topic Trial - Study to Determine the Safety and Efficacy of IVACAFOR</td>
<td>In Progress</td>
<td>03/07/2017 12:01</td>
<td>ewestf</td>
<td>Mark Dransfield, MD</td>
<td><a href="mailto:mdransfield@uabmc.edu">mdransfield@uabmc.edu</a></td>
</tr>
<tr>
<td>Open</td>
<td>X141114004</td>
<td>Evaluating the Efficacy and Compatibility of Eflornithine 10% Solution (Jublia) for the Treatment of Toenail Onychomycosis in Patients Wearing Toenail Polish Compared to Those Without Polish</td>
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<td>01/12/2017 14:08</td>
<td>cwang</td>
<td>Boni Elewski, MD</td>
<td><a href="mailto:belewski@uab.edu">belewski@uab.edu</a></td>
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<td>dhmckenz</td>
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</table>
Study Dates & Recruitment Completed

* Record Verification Date: Month: March, Year: 2017

* Overall Recruitment Status: Recruiting

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.

* Required

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

[*] Conditionally required (see Definitions)
# Study Dates - ERROR

## Edit Study Status

<table>
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<tbody>
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<td><strong>Month:</strong> October <strong>Year:</strong> 2017</td>
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<td><strong>Overall Recruitment Status:</strong></td>
<td>Not yet recruiting</td>
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<td><strong>Tip:</strong> Day is not required for Anticipated dates.</td>
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<tr>
<td><strong>§ Study Start Date:</strong></td>
<td><strong>Month:</strong> October <strong>Day:</strong> _ <strong>Year:</strong> 2017 <strong>Type:</strong> Anticipated</td>
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<tr>
<td><strong>WARNING:</strong> Start Date October 2017 should not be in the past for a study that is Not yet recruiting.</td>
<td></td>
</tr>
<tr>
<td><strong>ERROR:</strong> Anticipated Start Date cannot be in the past.</td>
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</tr>
<tr>
<td><strong>Primary Completion Date:</strong></td>
<td><strong>Month:</strong> November <strong>Day:</strong> _ <strong>Year:</strong> 2021 <strong>Type:</strong> Anticipated</td>
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<td>Final data collection date for primary outcome measure.</td>
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</tr>
<tr>
<td><strong>§ Study Completion Date:</strong></td>
<td><strong>Month:</strong> November <strong>Day:</strong> _ <strong>Year:</strong> 2021 <strong>Type:</strong> Anticipated</td>
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<tr>
<td>Final data collection date for study.</td>
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### Sponsor/Collaborators

<table>
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<tr>
<th><strong>Responsible Party:</strong></th>
<th>Sponsor</th>
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<tbody>
<tr>
<td><strong>Sponsor:</strong></td>
<td>University of Alabama at Birmingham</td>
</tr>
<tr>
<td></td>
<td>Primary organization conducting study and associated data analysis (not necessarily a funding source).</td>
</tr>
<tr>
<td><strong>Collaborators:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Add Collaborator</td>
</tr>
<tr>
<td></td>
<td>Organization(s) providing support: funding, design, implementation, data analysis or reporting. Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO). Enter only the organization name.</td>
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</tbody>
</table>

- **Required:**
  - $ Required if Study Start Date is on or after January 18, 2017
  - [*] Conditionally required (see Definitions)
Sponsor/Collaborators Completed

Investigator Information
- Investigator Name [Username]: Elaine C. Moreland [emoreland]
- Investigator Official Title: Primary Investigator
- Investigator Affiliation: University of Alabama at Birmingham

Sponsor:
- University of Alabama at Birmingham
  - Primary organization conducting study and associated data analysis (not necessarily a funding source).

Collaborators:
- World Health Organization (WHO)

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

- **U.S. FDA-regulated Drug**: Select if studying one or more U.S. FDA-regulated drug or biologic products.
- **U.S. FDA-regulated Device**: Select if studying one or more U.S. FDA-regulated device products.
- **U.S. FDA IND/IDE Study**: Select if 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.
- **FDA Regulated Intervention**: Select.

*Required

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

[ ] Conditionally required (see Definitions)
Oversight Completed
Study Description
Completed

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

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.

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

Conditions or Focus of Study:

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.

Keywords:

Required

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

The files are updated each week day Monday-Friday by 8AM EST

- All Terms
- Main Heading (Description) Terms
- Qualifier Terms
- Supplementary Concept Record Terms
- MeSH Unique ID
- Search in all Supplementary Concept Record Fields
- Heading Mapped To
- Indexing Information
- Pharmacological Action
- Search Related Registry and CAS Registry/EC Number/UNII Code (RN)
- Related Registry Search
- CAS Registry/EC Number/UNII Code (RN)
- Search in all Free Text Fields
- Annotation
- ScopeNote
Keywords Used For Search

Conditions or Focus of Study:
- Carcinoma, Non-Small-Cell Lung

Keywords:
- Non-Small Cell Lung
- NSCLC
- Drug X
- Drug Y

* Conditions or Focus of Study:
* Keywords:

Help
Definitions

× Delete

Continue  Back  Quit

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

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<td>Study Phase</td>
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<td>Interventional Study Model</td>
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<td>Model Description</td>
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<td>Number of Arms</td>
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<tr>
<td>Masking</td>
<td>Participant, Care Provider, Investigator,</td>
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<td></td>
<td>Outcomes Assessor</td>
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<td></td>
<td>No Masking</td>
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<tr>
<td>Masking Description</td>
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<td>Allocation</td>
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* Required
* Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)
**Interventional Study Design Completed**

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<td>Study Phase</td>
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<tr>
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<td>Allocation</td>
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<td>Enrollment Type</td>
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</tbody>
</table>

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

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

[Image of a form with fields for arms definition, including titles, types, and descriptions.]
Interventions
Intervention Defined
Arms & Interventions

Arms

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

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

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...

Cross-Reference

<table>
<thead>
<tr>
<th>Arms</th>
<th>Interventions</th>
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<tbody>
<tr>
<td>Experimental: Docetaxel &amp; Bevacizumab</td>
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</tr>
<tr>
<td>Describe treatment for Drug X (Docetaxel) &amp; Drug Y (Bevacizumab)</td>
<td></td>
</tr>
<tr>
<td>Active Comparator: Docetaxel</td>
<td></td>
</tr>
<tr>
<td>Describe treatment for (Docetaxel)</td>
<td></td>
</tr>
</tbody>
</table>

✓ - Intervention is administered to patients in this Arm.
Outcome Measures

* Primary Outcome Measure:
  - Title:
  - Description:
  - Time Frame:

[*] Secondary Outcome Measures:
  (if any)

Other Pre-specified Outcomes:

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

Primary Outcome Measure:
- **Title**: Progression Free Survival
- **Description**: Describe exactly how you plan to measure your primary outcome
- **Time Frame**: Baseline through 12 months

Secondary Outcome Measures:
- **Outcome 2**
  - **Title**: Overall Survival
  - **Description**: Describe exactly how you plan to measure your secondary outcome
  - **Time Frame**: Baseline through 12 months
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
Outcome Measure – Major Issue

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

<table>
<thead>
<tr>
<th>Field</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Sex:</td>
<td>All</td>
</tr>
<tr>
<td>Biological sex of eligible participants.</td>
<td></td>
</tr>
<tr>
<td>[*] Gender Based:</td>
<td>No</td>
</tr>
<tr>
<td>If applicable, indicate if participant eligibility is based on self-representation of gender identity.</td>
<td></td>
</tr>
<tr>
<td>* Age Limits: Minimum:</td>
<td>35 Years</td>
</tr>
<tr>
<td>Maximum:</td>
<td>65 Years</td>
</tr>
<tr>
<td>* Accepts Healthy Volunteers:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

* Eligibility Criteria:
- Inclusion Criteria:
- Exclusion Criteria:
Overall Contacts

Central Contact Person:
Central Contact Backup:
Overall Study Officials:

Copy locations... from a master list, extracted from this organization's records.

Information is required

Continue  Back  Quit
Overall Contacts

<table>
<thead>
<tr>
<th>Overall Study Officials:</th>
<th>+ Add Study Official</th>
</tr>
</thead>
</table>

* Central Contact Person:  
  First Name: [ ]  MI: [ ]  Last Name: [ ]  Degree: [ ]  Phone: [ ]  Ext: [ ]  Email: [ ]

Central Contact Backup:  
  First Name: [ ]  MI: [ ]  Last Name: [ ]  Degree: [ ]  Phone: [ ]  Ext: [ ]  Email: [ ]

Either Central Contact or Facility Contacts are required.  
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).
# Study Location

## Edit Location

**Facility:**
- Name: [Field]
- City: [Field]
- State/Province: Alabama
- ZIP/Postal Code: [Field]
- Country: United States

**Site Recruitment Status:**
- [Select] [Field]

**Facility Contact:**
- First Name: [Field]
- MI: [Field]
- Last Name: [Field]
- Phone: [Field]
- Ext: [Field]
- Email: [Field]

**Facility Contact Backup:**
- First Name: [Field]
- MI: [Field]
- Last Name: [Field]
- Degree: [Field]

Either Central Contact or Facility Contacts are required. The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

**Investigators:**
- [Add Investigator] [Button]
Study References

Edit References

Citations:

Links:

Available Study Data/Documents:

Help  Definitions
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.
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

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
Results 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:

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

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:

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)

<table>
<thead>
<tr>
<th>Study Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record Verification: October 2017</td>
</tr>
<tr>
<td><strong>Overall Status</strong>: Not yet recruiting</td>
</tr>
<tr>
<td><strong>Study Start</strong>: October 2017 [Anticipated]</td>
</tr>
<tr>
<td><strong>WARNING</strong>: Start Date October 2017 should not be in the past for a study that is Not yet recruiting.</td>
</tr>
<tr>
<td><strong>ERROR</strong>: Anticipated Start Date cannot be in the past</td>
</tr>
<tr>
<td><strong>Primary Completion</strong>: November 2021 [Anticipated]</td>
</tr>
<tr>
<td><strong>Study Completion</strong>: November 2021 [Anticipated]</td>
</tr>
</tbody>
</table>
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
IPD Sharing Statements

- Required in manuscripts starting in July 2018
- Required in the CTgov Registration for studies that 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

FDAAA TrialsTracker

Who’s sharing their clinical trial results?

FDAAA 2007 is a law that requires certain clinical trials to report results. After a long wait, it effectively comes into force from Feb 2018. The FDA are not publicly tracking compliance. So we are, here.

<table>
<thead>
<tr>
<th>Trials reported</th>
<th>Percent reported</th>
<th>US Govt could have imposed fines of at least</th>
<th>Fines claimed by US Govt</th>
</tr>
</thead>
<tbody>
<tr>
<td>299 out of 461</td>
<td>64.9%</td>
<td>$80,983,000</td>
<td>$0</td>
</tr>
</tbody>
</table>

Filter trials by status:
- On
- Overdue
- Off
- Ongoing
- Off
- Reported
- Off
- Reported (late)

Showing 1 to 100 of 216 entries

<table>
<thead>
<tr>
<th>Status</th>
<th>Sponsor</th>
<th>Trial ID</th>
<th>Title</th>
<th>Completion date</th>
<th>Days overdue</th>
</tr>
</thead>
<tbody>
<tr>
<td>overdue</td>
<td>Alcresta Therapeutics, Inc</td>
<td>NCT02750501</td>
<td>Absorption and Safety With Sustained Use of Relizorb Evaluation (ASSURE) Study in Patients With Cystic Fibrosis Receiving Enteral Feeding (pACT)</td>
<td>2017-03-30</td>
<td>31</td>
</tr>
</tbody>
</table>
Reporting Results - 2019

Legal Compliance by US Universities

Chart 1: Summary results posted for due clinical trials subject to FDAAA, % by university

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”

“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.”

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