Agenda

• Recap December Presentation – J. Schmelz

• Example: New CT from HSC Investigator
  • Non-Cancer Clinical Trial - J. Bates, P. Miranda

• Example: New CT from External Entity
  • Non-Cancer Clinical Trial - J. Bates, P. Miranda

• Questions
Recap

Improving the "Time to First Subject Enrolled"

NIH definition of a "Clinical Trial"
(1.1) Initial request & PI Identified [10 days]

(1.2) Targeting
- Preliminary Survey [5 days]
- Decision to Target [EXT]
- PSV/QSV Visit [EXT]
- CDA Signed [10 days]

(1.3) Site Selected [EXT]

(1.4) Reg Package Sent: Contract, Budget & Protocol [EXT]

(2.1) OSP Negotiate Contract [5 days/round]

(2.2) Sponsor Approved Revisions [EXT]

(2.3) UT System Approved Exception [EXT]

(2.4) Executed Contract [EXT]

(2.5) CTO Negotiate Budget [7 days]

(2.6) Draft billing grid

(2.7) Roles & Responsibilities

(2.8) Inst. Services Dev [5 days]

(2.9) Staff/Devel Training [5 days]

(2.10) Recruit Plan Dev. [5 days]

(2.11) Final Budget

(3.1) Inst Approval Dev. (Step 1 & 2)

Lead: CTO

Leads: OSP & CTO
Timeline – CTO Expanded Services

February 2018
- Phase 1 – Support for **NEW** Clinical Trials
  - Coordinate start-up activities for all new “industry sponsored” trials
  - Provide budget review service for all new grant applications

2019
- Phase 2 – Support for all **On-Going** Clinical Trials (Legacy and New)
  - Coordinate modification of budgets/contracts
CTO Expanded Service

**CURRENT**

- Billing Risk Assessment
- Research Coverage Analysis
- Management of Participant Payments
- Study build & training for Velos eResearch

**EXPANDED**

- Initial feasibility assessment, preliminary communication with sponsor
- Coordinate CDAs & CTAs with OSP
- Price quotes from service providers
- Budget development and negotiation with sponsor
- Invoice and collect initial start-up fees from sponsor
Clinical Trial
• Randomize to one of two approved drugs to compare effects on blood level of a protein.
• Participants will receive an investigational compound to assess:
  • pharmacokinetics
  • safety
  • maximum tolerated dose
  • relieve disease symptoms
  • disease progression

Not a Clinical Trial
• Participants currently being treated with drug A are surveyed to ascertain whether they experience improvement [not prospectively assigned]
• Participants with disease X to evaluate the ability of a new task to evaluate executive function [not evaluating the intervention on the participants]
Investigational *in vitro* diagnostic device involving participants with disease X

- Study is designed to evaluate how the knowledge of certain antibody levels impacts clinical management of disease.

**Clinical trial:**
Measurement of an antibody is the intervention. The study is designed to evaluate how knowledge of the level of an antibody might inform treatment.

- Study is designed to test the ability of the device to measure the level of an antibody in blood.

**Not a clinical trial:**
IVD would not be considered an intervention. The IVD is being used to test its ability to measure antibody levels, but not to test its effects on any health-related biomedical or behavioral outcomes.
Two approved *in vitro* diagnostic devices involving participants with disease X

- Study is designed to compare the ability of approved devices A and B to diagnose the disease and inform the clinical management of disease X.

**Clinical trial:**
Measurement of an antibody is the intervention. The study is designed to evaluate how knowledge of the level of an antibody might inform treatment

**Not a clinical trial:**
IVD would not be considered an intervention. The study is to evaluate performance, but not to determine their effects on any health-related biomedical or behavioral outcomes.

- Study is designed to compare the diagnostic performance of each device which are used in clinical practice to measure disease markers.
New CT from HSC Investigator
Non-Cancer
Case Study: New CT from HSC Investigator
HSC Investigator (*con't*)

Contact Information
  • Investigator and assistant as applicable

<table>
<thead>
<tr>
<th>Local Administrative Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Admin Contact's Name:</strong></td>
</tr>
<tr>
<td>e.g., coordinator, administrative assistant, delegate, etc.</td>
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<tr>
<td><strong>Admin Contact's email</strong></td>
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<tr>
<td><strong>Admin Contact's Phone</strong></td>
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### Study Demos
- **Type**
- **Phase**
- **Working Title or Brief Description**
- **Indication**

<table>
<thead>
<tr>
<th><strong>Project Information</strong></th>
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<tr>
<td><strong>Working Title:</strong></td>
<td>CV events in subjects at high risk</td>
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<td>* must provide value</td>
<td>Please include drug/compound name in the working title.</td>
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<td><strong>Official Study Title</strong></td>
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<td>Study title listed on protocol</td>
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<td><strong>Brief description of study indications</strong></td>
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<tr>
<td>* must provide value</td>
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<td><strong>Who is the Regulatory Sponsor for this clinical trial?</strong></td>
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<tr>
<td>Local PI</td>
<td>An external entity</td>
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<td><strong>NCT Number</strong></td>
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<td><strong>Age range</strong></td>
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<tr>
<td><strong>Projected number of subjects</strong></td>
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<tr>
<td>Local enrollment only</td>
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HSC Investigator (con't)

Performance Sites

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<tbody>
<tr>
<td>UT Health San Antonio</td>
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<td>University Health System (UHS/University Hospital)</td>
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<tr>
<td>South Texas Veterans Healthcare System (VA)</td>
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<tr>
<td>Baptist Health System</td>
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<tr>
<td>Methodist Health System</td>
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<td>Christus Santa Rosa</td>
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<td>⬜</td>
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<tr>
<td>San Antonio Military Medical Center (SAMMC)</td>
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<tr>
<td>Other</td>
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</table>
HSC Investigator (con't)

External Contact Information
• Regulatory Sponsor
• CRO - Contract Research Organization

<table>
<thead>
<tr>
<th>Regulatory Sponsor Information</th>
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<tbody>
<tr>
<td>Regulatory Sponsor's name:</td>
<td>Research Sponsor, Inc.</td>
</tr>
<tr>
<td>Regulatory Sponsor POC name</td>
<td>Jason Bates</td>
</tr>
<tr>
<td>Sponsor POC email</td>
<td><a href="mailto:batesjr@uthscsa.edu">batesjr@uthscsa.edu</a></td>
</tr>
<tr>
<td>Sponsor POC phone</td>
<td>(210) 562-6818</td>
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HSC Investigator (con't)

Electronic File Upload

- How many “other” types of files would you like to upload? 5
  Maximum is 5

<table>
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<th>What is “Other File 1”?</th>
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HSC Investigator (con't)

Prior to submission

Thank you for completing the Clinical Trials Submission form.

The CTO staff will contact you within two to three business days to begin the project planning phase.
New CT from External Entity

Non-Cancer
Submissions can come from...

- Pharmaceutical sponsor
- Device sponsor
- Contract Research Organization (CRO)
- Research Network or Cooperative Group
- External (unaffiliated) Investigator
- Other

There are a few differences in the submission fields compared to HSC Investigator submitted:

- Information about who submitted the project
- Information relevant to finding a local PI
- Shorter list of file types to upload
New Process
Start-up Process

Study team and CTO collaborate to reach Site Selection

CTO works with OSP and Study Team to Finalize CTA & Budget preparing for IRB submission
Navigator Process

Complete all applicable milestones:

• Sponsor site survey
• Feasibility assessment
• Targeting decision
• Confidentiality agreement
• Site qualification visit
• Receipt of protocol, contract and budget
Pertinent Study Information

• Contract Research Organization (CRO), if applicable
• Research Network or Cooperative Group, if applicable
• Primary study contact?
• Regulatory sponsor?
• Study Team contact?
• Other entities involved in the project
CTO – Development Phase

• Triage Phase
  • CTO Budget Analyst Team complete:
    • Registration of clinical trial into Velos eResearch
    • Development of Draft Coverage Analysis
    • Obtain pharmacy or lab manuals/imaging protocols

• Budget Development Phase
  • Budget Negotiation Begins
    • Obtain Site Affiliation Contracts
    • Finalize Coverage Analysis*
    • Participant Payment Plan Created

• Release Phase
  • Notification Email to the PI and Research Team – Green Light!!!
    • Ready to submit to the IRB
Recap
Recap

- Case examples of Clinical Trials
- Clinical Trial Submission Process
- CTO Navigator role
- CTO Budget Analyst role
Recap

CTO Provides:
• Research Coverage Analysis – Final
• Institutional B (Participant Payment Plan) if applicable
• Clinical Trial Application

Research Team Responsibilities:
• Complete & Submit the Clinical Trial Application to OCR/OIRB
• Study Team Development and applicable trainings
• Develop Study Documentation (Regulatory documents, CRFs, logs)
• Track study progress in eResearch
  • Enrollment Status & Patient Activity
Continued CTO Effort

• Follow CTA & Budget to execution
• Invoice & Collect the Initial Start-up costs for the trial
• Release the eResearch Study build to track study progress
Questions?