Clinical Trials Update: Migration & Review of Financial Principles

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Existing Trials Migration

Partnership & Transparency
Lessons Learned

- Lessons learned from the first migration
  - Transparency: provide overview of process and roles & responsibilities well in advance
  - Support: arrange clear support and escalation paths for our migration teams as well as end users
  - Partnership: build relationships between our teams and end users
  - Size matters: small cohorts vs. big wave allows for focused service excellence

Migration Principles

- New trials are our first priority
- Rolling migration affords higher touch point
- Increase transparency
  - Meeting in person with each PI, Study Team, and Department Research/Grant Administrators
    - 98 meetings, September - November
    - Scheduling February 2018 meetings
  - Preliminary migration schedule and progress tracker on website
- CTSUs and OnCore teams have dedicated migration teams
- CRAO will provide contact for each calendar
- Deliver service excellence to PIs, Study Teams, and Department Research Administrators

Migration packet includes:
- Overview
- PI studies to migrate
- CTSU description
- Data Migration information
- CTSU Trial Transition Checklist
- OnCore Account Provisioning
- Training Schedule
### Rolling Migration Approach

<table>
<thead>
<tr>
<th>Oct-17</th>
<th>Nov-17</th>
<th>Dec-17</th>
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<tbody>
<tr>
<td>16-Oct</td>
<td>20-Oct</td>
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<td>6-Nov</td>
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<td>11-Dec</td>
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<tr>
<td>27-Nov</td>
<td>15-Dec</td>
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</tbody>
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Cohort #1
- CRAO
- CTBU
- StudyTeam validation

Cohort #2
- CRAO
- CTBU
- StudyTeam validation

Cohort #3
- CRAO
- CTBU
- StudyTeam validation

Cohort #4
- CRAO
- CTBU
- StudyTeam validation

Cohort #5
- CRAO
- CTBU
- StudyTeam validation

Cohort #6
- CRAO
- CTBU
- StudyTeam validation

Cohort #7
- CRAO
- CTBU
- StudyTeam validation

### Constituents’ Line of Sight

[Sample chart or table related to constituents’ line of sight]

[Link to online resource]

https://clinicaltrials.med.umich.edu/ongene-migration
Financial Principles

Financial Approach

• Achieve the goal and strategies of the transformation through a fiscally sound and sustainable model.
  o Maximize cost recovery from sponsors
  o Don’t cost shift: Department ←→ PI
  o Contain costs to Departments and PI’s

• Dean’s Office funds central infrastructure.
  o IRB, Contracting, Research Pharmacy, CTSO Administration, OnCore, UH South space, DataDirect, Training, etc.

• Departments fund Clinical Trials Support Units (after UMMG start-up phase).
  o Act as extensions of departments in providing pre- and post-award services that have traditionally been provided to faculty by departments
Underlying Principles

- We must understand the cost of supporting the clinical trial enterprise in a transparent way
- Employ equity of funding across departments
  - Alignment of cost with support to the department & investigator
  - Separately evaluating general infrastructure v. specific project support
- Recognition of previously existing costs to departments
  
  No cost shift in new model: Department ↔ PI

Financial Principles

- Indirects for projects flow to the investigators’ departments.
- Standardized cost recovery practices established across all CTSUs.
- Maximize cost recovery from sponsors as allowable.
- CTSU personnel will track effort at the project level.
- CTSU administrative effort that is not recoverable from the sponsor will be allocated to the project administrative department.
- Negotiated recovery above CTSU actual expenses will remain with the project to cover overall study costs.
Financial Principles

• Expenses will be charged as they occur which may lead to negative study balances at any given point in time.

• Study balances will carry over year-to-year, allowing time for revenue to catch up with expenses to determine final study balance at closeout.

• +/- project balances at time of study closeout will follow existing department policies and procedures.

• Checkpoints for departments and PI:
  o Feasibility review
  o During negotiations
  o Monthly project- and department-level financial reports

Practically Speaking....

• CTSUs will track all expenses related to CTSU operation to develop an understanding of the cost of doing business.
  – Track and report project-specific activity and assign by specific Department
  – Track and report “general” administrative/overhead activity and assign by proportionate use

• Type of Sponsor or recovery is immaterial
  No more “Project can’t afford it”
Change is hard!
• After decades of issues, we will not improve things in a few months.
• Changing culture is a 5+ year process.
• It will take all of us!
• Be part of the change...

CTSU Proposed Funding Model

- Overhead of the CTSUs
  - Non Project-Specific Work
  - *e.g.* Coordinators not fully used on trials, Medical Director time, etc.

- CTSU Project-Specific Administrative Work that could not be negotiated for coverage
  - *e.g.* Post award time on a federal project

- Negotiated CTSU costs to support a specific trial
  - Coordinator time on project
  - Admin support with sponsor recovery source
How are we going to map CTSU Costs (Blue)

- Maximize negotiation / cost recovery from sponsors
  
  *Reminder: Working on behalf of Dept & PI Interests*

- Delineate amount “earmarked” for CTSU support in department-approved budget

- Charge CTSU services to project until that agreed limit is reached
  
  *CTSU personnel will track effort and expenses at the project level.*

- CTSU expenses not provided by the sponsor are allocated to the home unit.