

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

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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

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Rolling Migration Approach

Cohort #1	Oct-17			Nov-17			Dec-17			
	16-Oct	23-Oct	30-Oct	6-Nov	13-Nov	20-Nov	27-Nov	4-Dec	11-Dec	18-Dec
#1	CRAO	CTSU	StudyTeam validation							
#2		CRAO	CTSU	StudyTeam validation						
#3			CRAO	CTSU	StudyTeam	break	validation			
#4				CRAO	CTSU	break	StudyTeam validation			
#5					CRAO	break	CTSU	StudyTeam validation		
#6						break	CRAO	CTSU	StudyTeam validation	
#7								CRAO	CTSU	StudyTeam validation
#8 - #31...									CRAO	CTSU

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Constituents' Line of Sight

Trial Migration Progress Tracker - Updated 11/10/2017

The Trial Migration Progress Tracker provides a high-level status of where a clinical trial is in its migration into OnCore and transition to CTSU support. Once a migration date has been confirmed with the Principal Investigator, the trial is added to the Tracker. Completion of key milestones are indicated by checkmark. A list of trials with tentative migration dates that have not been confirmed is available at the OnCore Migration Preliminary Schedule.

How to Search: You can search this tracker by using the "Find" (Ctrl+F) function in Excel.

Questions? Information about the migration of a trial(s) is available through the CTSU Administrator listed below:

- Ambulatory & Chronic Disease (ACD): Kate Huffman
- Acute, Critical Care, Surgery & Transplant (ACCT): Barbara Munsey
- Behavior, Function, Pain (BFP): Tracy Naylor
- Children's (CH): Tracy Naylor
- Heart, Vessel, Blood (HVB): Ann Conicelli
- Neurosciences & Sensory (NSS): Diana Miller

Target Date for Study Team Go-Live	Cohort	PI Last Name	PI First Name	HUMM	PAF#	Parent FYG	Department	CTSU	Migration Date Confirmed	OnCore Training Completed	Financials Build Completed	Study Team Validation Completed	Target Date for Validation Complete	Transition to CTSU and OnCore Complete
October 2017														
10/30/17	1	Khalil	Carlton	HUMM0118240	17-PAF01840		Internal Medicine	ACCT	✓	✓	✓	✓	TBD	✓
10/30/17	1	Centano	Robert	HUMM0122010	17-PAF01840	N022483	Internal Medicine	ACD	✓	✓	✓	✓	11/13/17	✓
10/30/17	1	Olney	William	HUMM0108826	16-PAF08842	N021464	Internal Medicine	ACD	✓	✓	✓	✓	N/A, study withdrawn by sponsor	
10/30/17	1	Miller	Bruce	HUMM0109957	16-PAF08445	N0213951	Orthopaedic Surgery	BFP	✓	✓	✓	✓	11/13/17	✓
10/30/17	1	Hummel	Scott	HUMM0113302	16-PAF06454	N021824	Internal Medicine	HVB	✓	✓	✓	✓	11/13/17	✓
10/30/17	1	Hummel	Scott	HUMM0113988	16-PAF09462	N021790	Internal Medicine	HVB	✓	✓	✓	✓	11/13/17	✓
10/30/17	1	Hoffrich	Valanda	HUMM0115672	17-PAF05449	N021913	Dermatology	NSS	✓	✓	✓	✓	11/13/17	✓
10/30/17	1	Hoffrich	Valanda	HUMM0112125	17-PAF05449	N021913	Dermatology	NSS	✓	✓	✓	✓	11/13/17	✓
10/30/17	1	Zaburonec	Dario	HUMM0118298	16-PAF04548		Neurology	NSS	✓	✓	✓	✓	TBD	
November 2017														
11/1/17	2	Sorenson	Christopher	HUMM0114882		N023027	Surgery	ACCT	✓	✓	✓	✓	11/20/17	✓
11/1/17	2	Dean	Erin	HUMM0108140			Orthopaedic Surgery	BFP	✓	✓	✓	✓	11/20/17	✓
11/1/17	2	Shanahan	Harold	HUMM0107054			Int Med-Cardiology	HVB	✓	✓	✓	✓	11/20/17	✓
11/1/17	2	Shanahan	Harold	HUMM0113822			Int Med-Cardiology	HVB	✓	✓	✓	✓	11/20/17	✓
11/1/17	2	Stamataki	Sofya	HUMM0113902		N021220, N021249	Neurology	NSS	✓	✓	✓	✓	11/20/17	✓
11/1/17	2	Muhar	Erman	HUMM0116853	17-PAF09094	N022473	Neurogeriatrics	NSS	✓	✓	✓	✓	11/27/17	✓
11/1/17	2	Huber	Gary	HUMM0113555			Dermatology	NSS	✓	✓	✓	✓	11/28/17	✓
11/1/17	3	Santamaria-Piñata	Milagros	HUMM0102985		R041366	Int Med-Neurology	ACCT	✓	✓	✓	✓	11/27/17	✓
11/1/17	3	Nguyen	Binh	HUMM0109812			Internal Medicine	ACD	✓	✓	✓	✓	11/27/17	✓
11/1/17	3	Perdue	Jason	HUMM0095475		N021859	Orthopaedic Surgery	BFP	✓	✓	✓	✓	11/27/17	✓
11/1/17	3	Smith	Jason	HUMM0093892	16-PAF04482	N023076	Neurosurgery	NSS	✓	✓	✓	✓	11/27/17	✓
11/1/17	3	Shanahan	Harold	HUMM0072449			Int Med-Cardiology	HVB	✓	✓	✓	✓	11/27/17	✓
11/27/17	3	McIntyre	Michael	HUMM0119888		N021717	Int Med-Neurology	ACCT	✓	✓	✓	✓	11/27/17	✓

<https://clinicaltrials.med.umich.edu/oncore-migration>

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Financial Principles



Financial Approach

- Achieve the goal and strategies of the transformation through a fiscally sound and sustainable model.
 - Maximize cost recovery from sponsors
 - Don't cost shift: Department ↔ PI
 - Contain costs to Departments and PI's
- Dean's Office funds central infrastructure.
 - IRB, Contracting, Research Pharmacy, CTSO Administration, OnCore, UH South space, DataDirect, Training, etc.
- Departments fund Clinical Trials Support Units (after UMMG start-up phase).
 - 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 \leftrightarrow PI

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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.

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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:
 - Feasibility review
 - During negotiations
 - Monthly project- and department-level financial reports

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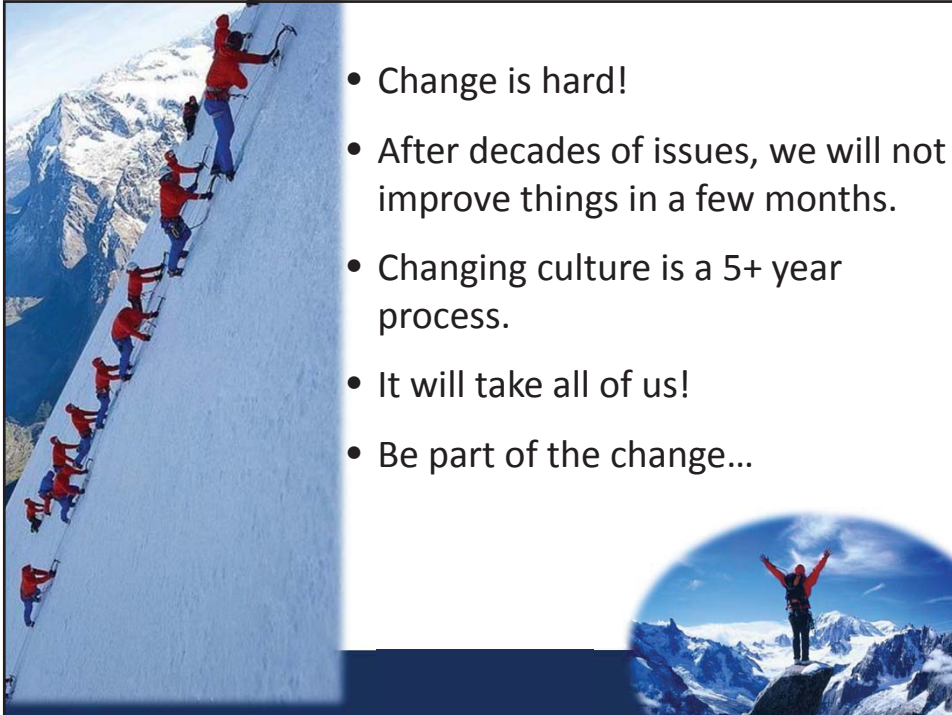


Practically Speaking....

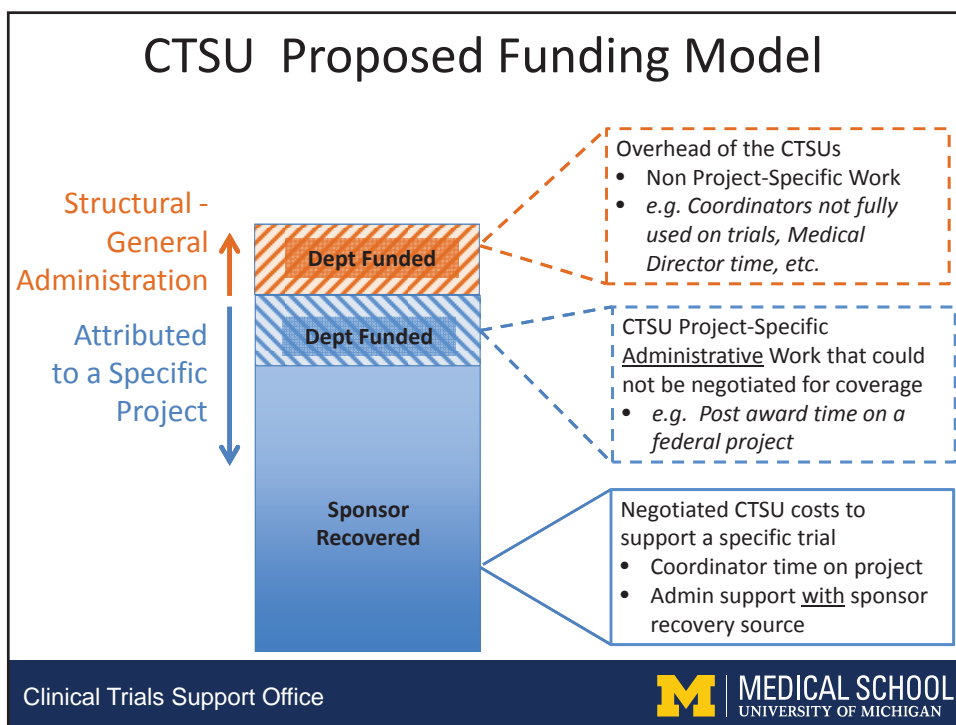
- CTSUs will track all expenses related to CTSU operation to develop an understanding of the cost of doing business.
 - Track and report project-specific activity and assign by specific Department
 - Track and report “general” administrative/overhead activity and assign by proportionate use
- Type of Sponsor or recovery is immaterial
No more “Project can’t afford it”

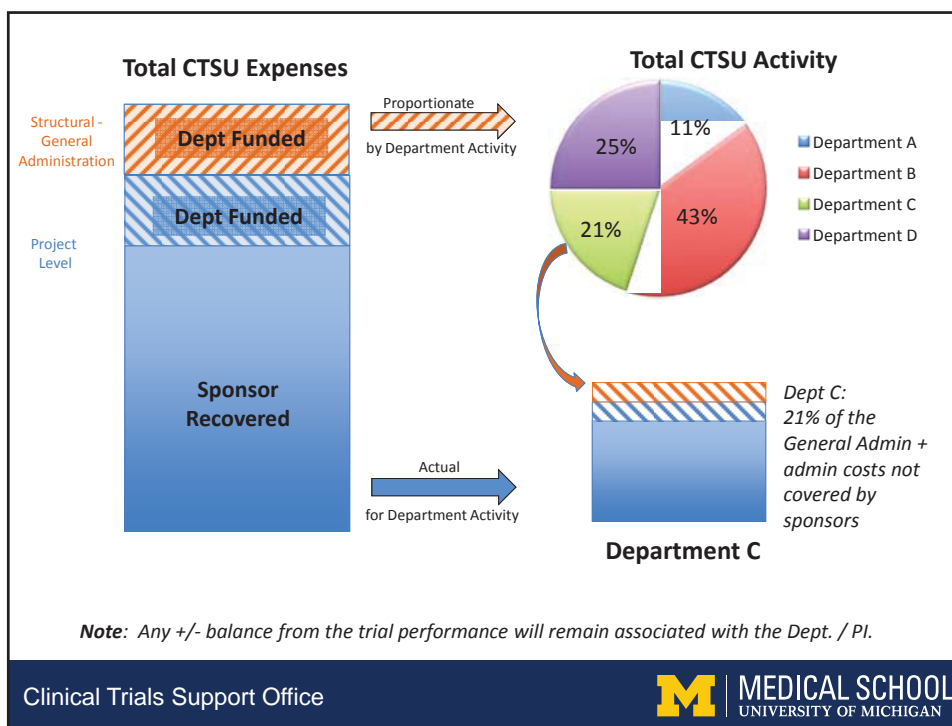
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- Change is hard!
- After decades of issues, we will not improve things in a few months.
- Changing culture is a 5+ year process.
- It will take all of us!
- Be part of the change...





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.