CCTS Lunch and Learn: Important UAB updates
26 Sept 2017

Penelope M Jester, BSN MPH
Program Manager
pennyjester@uabmc.edu
CCTS Lunch and Learn    September 26, 2017    11:30am – 12:45pm

Introduction- Penny Jester
OnCore and Powertrials Updates- Lisa Williams
CT.gov Update- Denise McKenzie
CBR Update- Dawn Bryant
CTAO Update- Mark Marchant
CCTS – Education and other updates – Penny Jester
OnCore Enterprise Update

Lisa Williams MSHI
OnCore Enterprise Administrator
26 SEP 2017
OnCore Project Updates

- Timeline
- Implementation Activities for Management Groups (aka Therapeutic Areas)
- Working Group Activity
- Technical System Activity
- Training Activity and Plans
- Communications
- PowerTrials
- Next Steps
Timeline

- OnCore expansion completed in Three Waves
  - Wave 1: Department of Medicine, December 2017
  - Wave 2: Obtaining Departmental Confirmation, April 2018
  - Wave 3: Obtaining Departmental Confirmation, September 2018

- Working to confirm the composition of Waves 2 & 3
- SiteMinder will be turned off after Wave 3 go-live.
Implementation Activities (Data Migration)

• Review of SiteMinder fields completed – mapped to OnCore fields
• Main Focus - Any trials currently managed by SiteMinder
  • Existing trials with AND without clinical billables
  • Some existing trials that will complete lifecycle in SiteMinder
• Request migrating study documents and protocol specific information
• Both internal and external sources used to re-create trials in OnCore
• Research units will validate/confirm accuracy of SiteMinder data once migrated to OnCore assisted by Super Users.
Implementation Activities (Roles Requested)

• Departments/Divisions identify Super Users and Calendar Builders

  **Super Users**
  » Expected to provide system support to users in their department/division or sometimes to another management group
  » Broader system training provided to this support group
  » Final validation of calendars with study team

  **Calendar Builders**
  » Review calendars built in OnCore and resolve discrepancies
    • Similar to SiteMinder build only with more study details
  » Link activities to charge master for CTBN creation (billing)
Working Groups

• Members selected from various departments and administrative entities

• Reviewed and modified Reference Codes (drop list options) and documented workflows
  
  Protocol Subject Management
  Financial Budgeting
  Reporting/Administration

• Continue to meet on ad hoc basis
Technical Systems

• Upgraded database hardware and operating systems
• Created new system environments for
  • Testing workflows
  • Training end users
• Testing system interfaces
  • Billing (both PowerTrials and CTBNs)
  • EMMI
Training

• Ideally within 6 weeks prior to go live
• Broken down by role e.g. coordinator, regulatory staff, administration
• Estimate 3 hour sessions per role training
• Sessions will cover
  • Protocol Management
  • Subject Management
  • Calendars (similar to SiteMinder study build)
  • Financials (Budgets)
  • Reports /Searches
Training

• Training Team has developed and conducted training sessions for Super Users, Calendar Builders.

• Currently developing end user training and scheduling classes at various locations

Dept. of Medicine (Wave 1) End User training expected to begin mid-October.
OnCore Support Team

• New staff hired to support OnCore end users
  • OnCore Coordinator - maintain and support system changes, general end user support
  • Business Analyst - identify and maintain information workflows
  • Two Calendar Builders - support calendar building for all departments
  • Report Writer – manages standard reports and creates custom reports
Communication

• Articles in weekly emails such as from CCTS & Research Administration
• School of Medicine – Dean’s Message
• Department and Division meetings
• CCTS Lunch and Learns
• OneUABmedicine.org/faculty-staff
• Development of the CTAO website – Training information; access forms; contact information; updates
What is PowerTrials?

A module within the IMPACT EHR

PowerTrials Relation to OnCore?

“Bridge” (interface) links the two systems

“Push” will happen behind-the-scenes avoiding duplicate entry into both systems.
Goals of PowerTrials

- Enhance patient safety
  - On/Off Study in IMPACT
  - Clinical Summary of Trial
  - Contact Information

- Automate research billing
  - Reduce, automate paper-based research processes

- Enhance research billing compliance
  - Pre-coded PowerPlans decrease billing errors
PowerTrials Implementation Plan

- Phase 1 – Cancer Center (OnCore) studies; RAD and LAB clinical billable services – Live
- Phase 2 – Include new studies (DOM) from OnCore; consider additional clinical billable services
- Information will be forthcoming
Next Steps

• OnCore team is in process of communicating with departmental leadership slated for Waves 2 & 3.
• Specific implementation strategy will be discussed with Wave 2 participants.
• DOM – Identify OnCore end users and their roles for training and access logistics.
• DOM - End User training for Wave 1 to begin around mid-October
• SiteMinder data migration
Questions?

From the OnCore Enterprise Team

OnCore@uabmc.edu
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*UAB The University of Alabama at Birmingham*  
Knowledge that will change your world
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From the OnCore Enterprise Team

OnCore@uabmc.edu
ClinicalTrials.gov

What’s New??
What’s New?

- Uploading Protocol & Statistical Analysis
- Uploading available June 29, 2017

**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:
What’s New?

• “Full Study Protocol & Statistical Analysis” plan must be uploaded, as part of results information submission, for studies with a Primary Completion Date on or after...

• January 18, 2017

• Full Study Protocol is defined as “Including All Amendments.”
What’s New?

• Only Certain Studies? Any study that meets the definition of an Applicable Clinical Trial (ACT) on or after January 18, 2017

• Protocol & Statistical Analysis are due with Results (1-year after the Primary Completion)

• Under the Voluntary Submissions (PDF) provision, a Responsible Party who submits results for such a clinical trial must submit complete clinical trial results information and must also submit results for each Applicable Clinical Trial that is required to be submitted to FDA
What’s New?

- 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).
What’s Coming?

• Clinical Trial Disclosure and Data Transparency Conference, Washington DC, Sept 14-15
• FDA, NIH, ClinicalTrials.gov presentations
• Clinical Trial Reporting
  - How Do We Measure Up?
  - Where Are We Headed

• Meeting Theme: More Reporting
A surprising amount of medical research isn’t made public. That’s dangerous.
What’s Coming?

• Individual Data Sharing Transparency
  – EMA 0070 went “live” with the public October, 2016
    Still working through implementation, redaction
  – US Industry – accepted policy and pro-active in beginning the process
  – Industry is defining this as a real “Game Changer” challenge

• ICMJE will require the following as conditions of consideration for publication of a clinical trial report in our member journals:
  • 1. As of July 1, 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as described below
  • 2. Clinical trials that begin enrolling participants on or after January 1, 2019, must include a data sharing plan in the trial’s registration.
What’s Coming?

• Summaries For Patients
  – Plain Language

• Study Design Integrity
  – Outcome Switching
Registering/Reporting

• 3 Key Facts To Remember:
  – Register - early
  – Update - annually
  – Report – 12 months post-completion

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

When To Register

- ICMJE - (International Committee of Medical Journal Editors) requires registration of clinical trials in a public trials registry BEFORE the time of first patient enrollment as a condition of consideration for publication.

- Recent experience: NEJM would not even consider...investigator adhered to the FDAA criteria (21 days) but not ICMJE’s. No exception.
Need Assistance?

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

• Denise McKenzie, dhmckenzie@uabmc.edu

• Penny Jester, pennyjester@uabmc.edu
Questions?
Clinical Billing Review

Dawn Matthews, MPA, CCRC, CPC, CNM
Manager-Office of Clinical Billing Review

dbryant@uab.edu
996-7573
REMINDERS/UPDATES

• Just a reminder that SiteMinder trainings are done every other month rather than monthly. The next training is scheduled for November 3rd.

• Note that when studies are finalized in SiteMinder with the new IRB# format, CBR will use the letter “I” followed by the nine digits in the new format.
  (i.e. I3000000256)
If you have any problems using the CBR Workbook, please call your FAP Analyst and she can send you the Excel document with additional instructions. The latest Microsoft updates to Excel have caused some computer systems to have issues with the document.
CLINICAL BILLING REVIEW

For FAP/SiteMinder questions, please Email fap@uab.edu.
Upcoming Initiatives

Mark Marchant, MPH, MBA, CCRP
Director, CTAO
• Electronic Subject Payment System
• Utilizes ClinCards
• Replaces Checks, Visa Debit Cards, Petty Cash
• Web Portal for Subject Entry and Visit Keeping
• Cards have no value until study visits kept in system
• Reporting capabilities
• Test Sites
  – Lung Health Center & Psychiatry
  – Completed TEST environment in August
  – Start PROD environment in October

• Phased Roll-out
  – Starts in January ‘18
  – Contacting Departments over next several weeks
UAB CRSP: General updates

Penelope M Jester, BSN MPH
Program Manager
pennyjester@uabmc.edu
Education! Where are we:

- CITP: Responsibilities and Implementation - for investigators: next session started September 2017
- ROP: The Basics – all staff: Offering every other month
- RTP: Implementation and tools for conducting research – support staff
- Roundtable Discussions: each month – Tuesday after First Thursday (12 -1) – in West Pavilion
- Every other month: building a budget
# 2017-2018 Sessions

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• Questions?

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  – chouser@uabmc.edu
  – pennyjester@uabmc.edu