THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Knowledge that will change your world

CCTS Lunch and Learn: Important UAB updates 26 Sept 2017

Penelope M Jester, BSN MPH

Program Manager

pennyjester@uabmc.edu

Agenda

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

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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

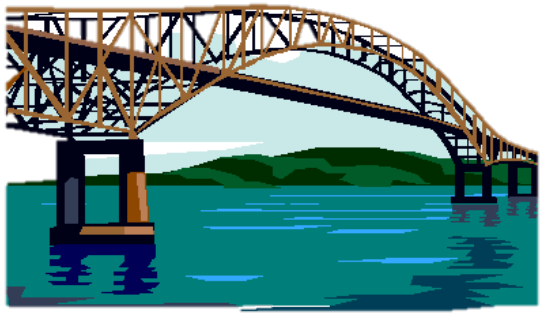
Communication

- 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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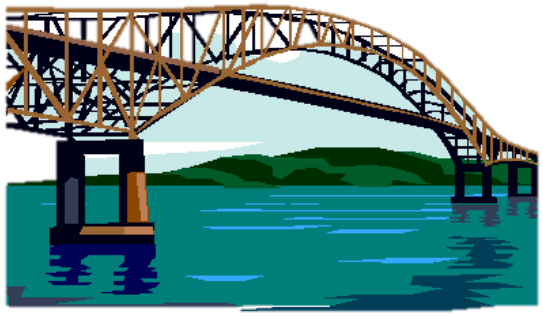

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From the OnCore Enterprise Team

OnCore@uabmc.edu

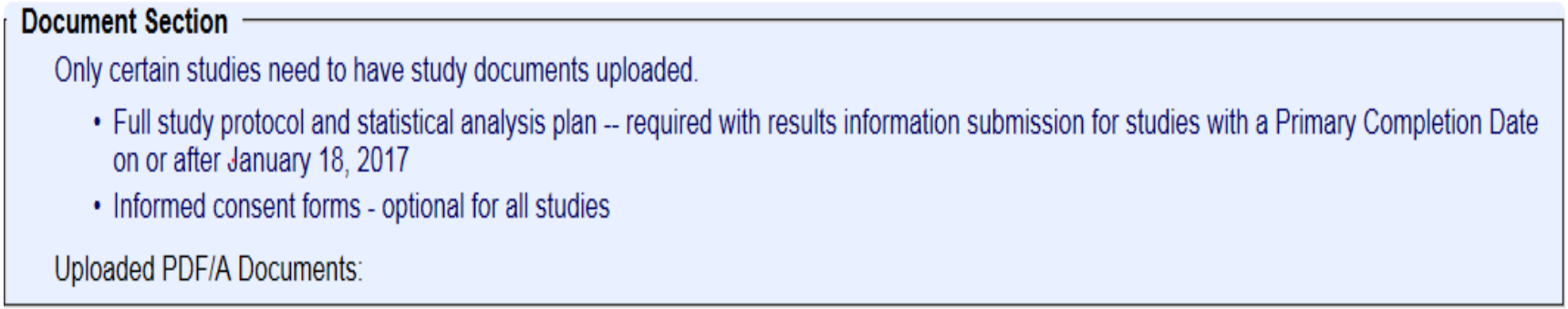
ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov

What's New??

What's New?

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



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

What's Coming?

Vox

EXPLAINERS POLITICS & POLICY WORLD CULTURE SCIENCE & HEALTH MORE

A surprising amount of medical research isn't made public. That's dangerous.

Updated by Stephanie Wykstra | Aug 1, 2017, 8:40am EDT

TWEET SHARE

Fast Cash Now
$100 - $10,000
Apply Now
>>> zloan.top <<<

Most Read

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 FDAAA 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. I300000256)

CBR WORKBOOK

- 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

greenphire

- 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

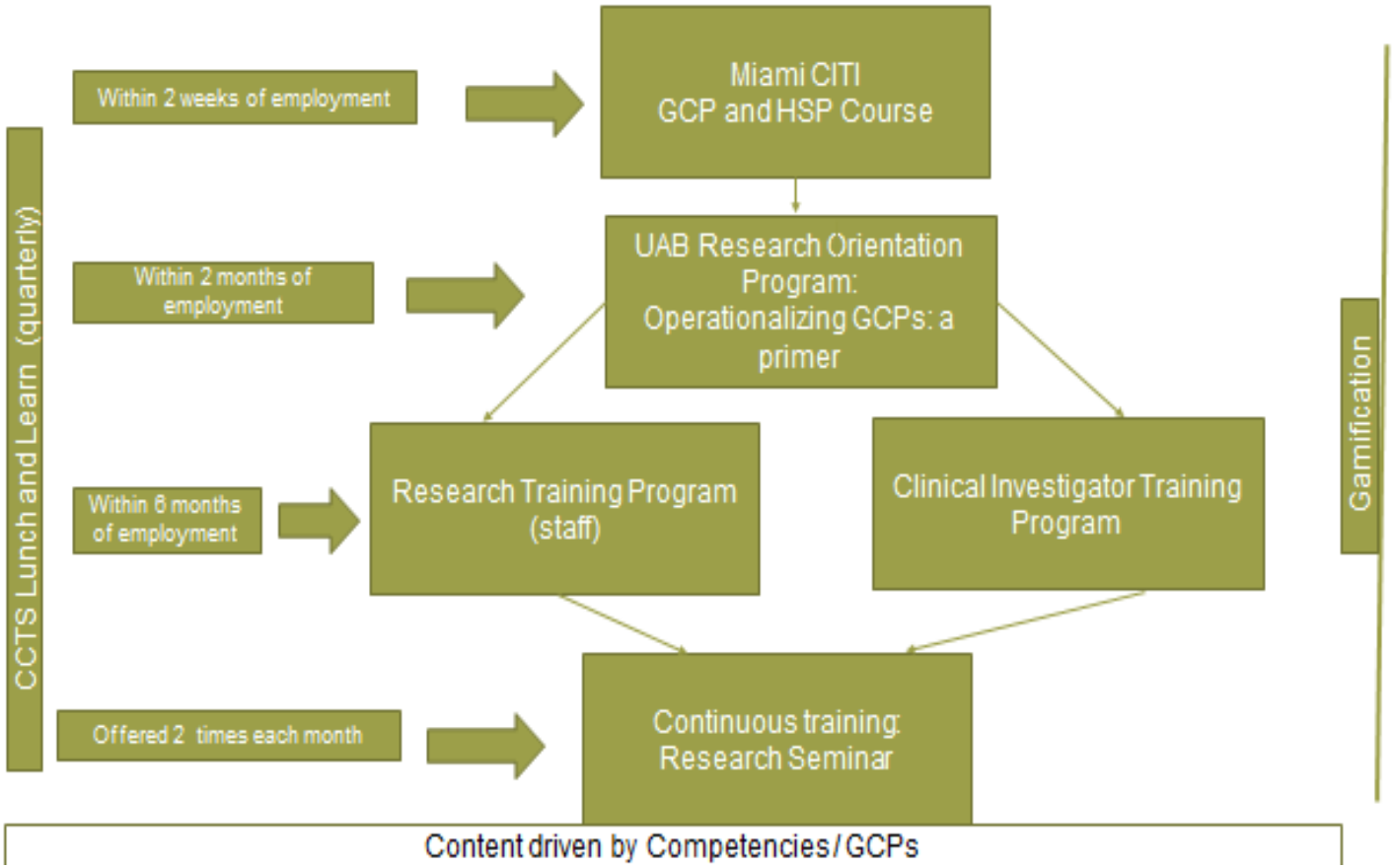
- Test Sites
  - Lung Health Center & Psychiatry
  - Completed TEST environment in August
  - Start PROD environment in October
- Phased Roll-out
  - Starts in January ‘18
  - Contacting Departments over next several weeks

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


Within 2 weeks of employment
Miami CITI
GCP and HSP Course
Within 2 months of employment
UAB Research Orientation Program:
Operationalizing GCPs: a primer
Within 6 months of employment
Research Training Program (staff)
Clinical Investigator Training Program
Offered 2 times each month
Continuous training:
Research Seminar
CCTS Lunch and Learn (quarterly)
Gamification
Content driven by Competencies / GCPs

2017-2018 Sessions

UAB Research Education Series 2017 - 2018 (may be updated)		version 9.3.17	
Topics	Month	Dates	Location
Research Orientation Program (8a - 12noon)	Aug	8/24/2017	PCAMS
Stress Management: how to keep from snorkeling (12 -1)	Sept	9/7/2017	PCAMS
Round Table: Brown Bag: How do you create Source Documents? (12 -1)	Sept	9/12/2017	WPCC-G
ClinicalTrials.gov: an update (12 -1)	Sept	9/21/2017	PCAMS
CCTS Lunch and Learn (CTAO, Oncore, CT.gov, ….) (11:30 - 12:45)	Sept	9/26/2017	MCSA
Being a mentor or being a resource…what is the difference? (12 -1)	Oct	10/5/2017	PCAMS
Round Table: Brown Bag: what do you need that you are not getting? (12 -1)	Oct	10/10/2017	WPCC-G
Research 101: Process To Get Started or How To Start a Study Workshop (Steps to Activation) (11 - 1)	Oct	10/19/2017	TBD
Building a Budget (11 -1)	Oct	10/24/2017	TBD
Research Orientation Program (8a - 12noon)	Oct	10/26/2017	PCAMS
Recruitment Workshop: where do we find the subjects? (12 -1)	Nov	11/2/2017	
Round Table: Brown Bag (12 -1)	Nov	11/7/2017	WPCC-C
Preparing for an FDA audit: what you should know (12 -1)	Nov	11/16/2017	
ACRES [Setting Standards] (12 -1)	Dec	12/7/2017	
Round Table: Brown Bag (12 -1)	Dec	12/12/2017	WPCC-B
Round Table: Brown Bag (12 -1)	Jan	1/9/2018	WPCC-G
Consenting Workshop (2 hours) (11 - 1)	Jan	1/18/2018	
Research Orientation Program (8a - 12noon)	Jan	1/25/2018	PCAMS

UAB Research Education Series 2017 - 2018 (may be updated)		version 9.3.17	
Topics	Month	Dates	Location
Internal Quality Control: measuring, assessing and correcting! (repeat!) (12 -1)	Feb	2/1/2018	PCAMS
Round Table: Brown Bag (12 -1)	Feb	2/6/2018	WPCC-B
Business Etiquette: you will get there stronger with the right approach (12 -1)	Feb	2/15/2018	PCAMS
Building a Budget (11 - 1)	Feb	2/27/2018	
Organizational Tools and Regulatory (12 -1)	Mar	3/1/2018	PCAMS
Round Table: Brown Bag (12 -1)	Mar	3/6/2018	WPCC-B
IRB workshop (11 -1)	Mar	3/15/2018	
Research Orientation Program (8a - 12noon)	Mar	3/22/2018	PCAMS
Monitor Visits: how to prepare (12-1)	Apr	4/5/2018	PCAMS
Round Table: Brown Bag (12 -1)	Apr	4/10/2018	WPCC-G
Herding cats: being organized and working with people (12 -1)	Apr	4/17/2018	PCAMS
Budget Negotiating (12 -1)	May	5/3/2018	PCAMS
Round Table: Brown Bag (12 -1)	May	5/8/2018	WPCC-G
Managing Research Account (12 -1)	May	5/17/2018	PCAMS
Research Orientation Program (8a - 12noon)	May	5/24/2018	PCAMS
Research Pharmacy (12-1)	Jun	6/7/2018	PCAMS
Round Table: Brown Bag (12-1)	Jun	6/12/2018	WPCC-B
Oncore Capabilities (12 -1)	Jun	6/21/2018	PCAMS
Building a Budget (11 - 1)	Jun	6/26/2018	

- Questions?

- Contact:

  - CCTS@uab.edu
  - chouser@uabmc.edu
  - pennyjester@uabmc.edu