Use of the Epic Electronic Health Record for Comprehensive Clinical Research Management at Duke

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Disclosure

Dr. Iain Sanderson has no relationships with commercial interests.

Learning Objective

Understand the steps to implementing a management system for clinical research as part of the Electronic Health Record in a major academic medical center.
Topics

• A few facts and figures about Duke Clinical Research
• Describe our implementation of Epic 2012 for research administration at Duke
  – Planning, training, testing, go-live
• Current state and CTMS plans
• What next?
Duke Medicine Facts and Figures

- 3 Integrated hospitals using a single instance of Epic 2012
  - Duke University Hospital 924 beds (live June 22\textsuperscript{nd} 2013)
  - Duke Raleigh Hospital 186 beds (March 1\textsuperscript{st} 2014)
  - Duke Regional Hospital 369 beds (March 1\textsuperscript{st} 2014)
- 16,318 employees
- >7,000 simultaneous users of Epic (Epic’s largest big bang go-live)
- 2013 Clinical revenues $2.54B, 1.2m outpatient visits
- 2013 Total research revenues - $651m
- 2013 NIH funding $284m - ranked 10\textsuperscript{th}
- 2012 Industry funded research $215m (DCRI ++)
None of that Counted for Very Much, With Substantial Risk….

Epic was coming whether we were ready or not…
Our existing systems would be swept away..

Research Billing Processes – Current Data Systems and Linkages

<table>
<thead>
<tr>
<th>CPT Code/Price Request</th>
<th>Billing Designation</th>
<th>Fund Code Setup</th>
<th>Subject Study Association</th>
<th>Scheduling</th>
<th>Ordering</th>
<th>Encounter</th>
<th>Charge Review</th>
</tr>
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</table>

- **CPT Code/Price Request Form (E-mail)**
- **Internal Cost Summary (Excel)**
- **Charge Assignment Grid (Excel)**

- **Data Used - Human**
- **Data Flow - Human Intervention Needed**
- **Data Flow**

**Retiring Systems**

**No paper system for scheduling, orders, billing!**
Drivers in our Implementation

- No interfaces possible with Velos eResearch or eIRB
- Robust split charge billing mechanism for research and standard of care charges
- Robust study and subject registry
- Improved role based security
- Compliant and efficient research workflow
- Platform for BPAs, MyChart etc
- Support central management of research through Duke Office of Clinical Research (DOCR)

Explored and found considerable functionality for managing clinical studies in model Epic 2012
Model Epic 2012 Research Functionality, but also with an Order Set for each study Protocol

*Study Cycles As an Order Set

- Epic needs to know about the STUDY (Study Administrative Record)
- Recruit Patients
- Which PATIENTS are associated with the study
- Place Release Restriction on Research Patient Records
- Which ENCOUNTERS are associated with the study
- Which ORDERS are associated with the study
- Study Approved
- Visit charges generated from clinical activity and/or manual charge entry
- Which CHARGES should be routed to which account
- Research Billing Review
- Charges Billed Appropriately

* = New in Epic 2012
* = Duke configuration choice, not a customization
Desired Result – Systems Integration and simplified workflow for Research.

Epic becomes the reference study and subject registry. Enrollment, visit schedule, study drugs, orders, documentation and revenue cycle managed in Epic. For over 1000 users……
Initial Timeline..

Clinical Systems Discovery Start

Research Systems Discovery Start

Aug 2011

Aug 2012

Aug 2013

Validation

Research Calendaring and Ordering Workgroup

Current State

Future State

RAC

RAC

RAC

RAC
Research Workflow Validation – February 6th

• Stop Light Evaluations
• 90+ Subject Matter Experts and Stakeholders from across the Research Enterprise – A success based on Feedback.
Epic and Research - Timeline

- **Validation**: Feb 6th
- **Billing Calendar And Smart Set Build (ongoing)**
- **Send DOCR staff for Epic order set certification**
- **Wave 4 Go Live June 22nd**
- **Maintenance Build**

- **Feb**: Example build
- **Mar**: Curriculum development
- **Apr**: Super User Training 800 CRCs
Which Studies need Order Sets and Billing Calendars by Go-live?

**Excluding:**
- Exempt studies
- No CRU oversight (i.e. DCRI)
- Data analysis only
- Retrospective Studies
- Completed but data analysis ongoing
- Completed but subject follow-up

**4047**  
Active studies in eIRB

**815**

**357**  
High Priority Non-oncology

**552**  
PRMO feedback:
1. High charges AND IDEs
2. Blue grids (other payers)
3. Striped grids
4. Charges > $40,000
5. Yellow/green/pink grids
6. Two color grids
7. One color grids

**787**

**195**  
High Priority Oncology (Beacon)

**CRU feedback:**
- External sponsors
- Recent enrollment? Total Enrollment? Active after June 2013?
Epic Build for Research

• Had to define the build workflow and coordinate across build teams
  – RSH record, study calendar, order set, Beacon Protocols

• Created a “war room” team of co-located staff
  – 6 staff from DOCR
  – 8 staff from PRMO (Revenue staff)
  – Contractors – 4 order set builders, 2 willow builders, 1 coordinator
  – 2 Beacon build team contractors

• 500+ study calendars on time
• But Order sets and Beacon protocols were much harder….
• A $2m investment over 18 months…
Order Set Build Progress

Build burndown up to go-live

16 stage build, validate, QA and release process
Training

• Three course curricula required to support Epic clinical research:
  – Clinical Research Coordinator (410 staff)
  – General Researcher (read only access) (438 staff)
  – Research Billing and Compliance (35 staff)
• All users would need 4 hours “Introduction to Epic” classroom training as well as specific training
• 64 staff needed dual role training.
• Required steps – Develop curriculum, secure resources, train, go-live and maintain
• A $165k investment
Other Preparations for Go-live

• Go live and training website and materials
  – Tip Sheets, videos, command center information
  – PI research order “sign off” instructions
  – CRC training documentation
• Testing – needed to create test scripts
• Town Halls, “Research Wednesdays”, and a communication blitz
• Create the command center and staff it
• Cut over activities (500 appointments, 2000 security profiles, 9000 enrolled subjects)
• Go-live June 22\textsuperscript{nd} 2013
Go-live June 22nd 2013 Command Center
Where are we now?

- **We did successfully implement a new workflow for over 1000 people at the core of our research enterprise**
  - Some issues with compliance for study linking to visit schedules, but we can measure that for the first time and retrain.
- Split billing with a complete revenue cycle for research
- Study-related totals since 6/22/2013:
  - 1,978 active research studies in EPIC
  - 14,805 enrollments
  - 25,803 encounters
- Duke Office of Clinical Research (DOCR) established as central administrative/operational body for research support
- Epic as a **Clinical Research Patient Management System**
What have we done?

- Concept of CTMS functionality at Duke has changed.

**Epic EHR**
- Study registry
- Subject Registry
- Consent repository
- Research appointments
- Research Orders
- Study Calendaring
- CRC workflow
- Split Billing
- Reporting

**CTMS**
- Non billing risk study registry
- Randomization
- Study Financial Management
- Accrual Based Accounting
- Sponsor Invoicing
- Volunteer Subject registry
- Adverse event management
- Electronic Data Capture
- Study sample management
- Reporting across all studies
Duke’s Planned CTMS Landscape

**Epic:**
- Clinical Research workflow
  - Clinical Studies, Subjects, Research Charges, MyChart, BPAs

**Velos eResearch:**
- CTMS
  - All clinical and non-clinical study registry,
  - All subjects registry,
  - Volunteer registry,
  - Sample tracking,
  - Invoicing, AE Management, Financial mgt

**EDC:**
- REDCap
- RFD

**EDW/ Research Management Data Mart:**
- All Velos data,
- All Epic data,
- All eIRB data,
- All Reporting,
  - (NCI reporting)

**SAP:**
- FCs

**Click eIRB:**
- Studies, Named Personnel

**Duke Office of Clinical Research**

Custom Interface

**ETL**
What Next?

• Integrate Epic with Velos eResearch for non-clinical research subjects and advanced CTMS functionality
• Leverage EPIC functionality for research
  – Best Practice Advisories for recruitment
  – Smart Forms, Retrieve Form for Data Capture for
  – MyChart patient questionnaires and device data capture
  – Provide services for these through the Duke Office of Clinical Research