Epic and Clinical Research at Duke: CTSA plans

Research Wednesdays
05/22/2013
Dr. Iain Sanderson, CRAIO
Other Academic Health Systems and Epic’s use for the management of Clinical Research

<table>
<thead>
<tr>
<th>Institution</th>
<th>Research Optimization Functionality Utilized</th>
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<td>UNC</td>
<td>• PLANNING EPIC – AT LEAST ONE YEAR BEHIND AND RESEARCH OR CLINICAL IMPLEMENTATION</td>
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| Northwestern             | • MYCHART -Subjects log into the research portal and their demographic data is pulled from EPIC.  
• Contact information that was entered into MyChart by the subject is also pulled thus avoiding duplicate data entry. No management of Research billing using Epic.                                                                                     |
| Cleveland Clinic         | • MYCHART and DISEASE REGISTRIES – but yet to use them specifically for research on a large scale. EPIC’s BPAs for subject recruiting.  
• They have seen a ten fold increase in the subject referral rate. More importantly have doubled subject enrollments since deploying BPAs.                                                                                                                   |
| Harvard (Partners HealthCare) | • Currently deploying EPIC and gathering data from other institutions regarding research capabilities.  
• Monthly calls with Duke since we are at least a year or two ahead.                                                                                                                                                                                                                                         |
| Johns Hopkins            | • MDlogic custom CTMS and interface to Epic. No billing through Epic/ordersets/Beacon.  
• They have moved forward with REGISTRIES and MYCHART for capture patient questionnaires related to research.                                                                                                                                                                                                                                              |
| Ohio State University    | • EPIC 2012, but no billing  
• Using BPA’s to assist in study recruiting.                                                                                                                                                                                                                                                                                                                        |

We will have the broadest and deepest implementation of Epic for Clinical Research in the US on June 22nd
Epic’s Potential for Clinical Research

- Epic will **simplify data stewardship** at the enterprise scale (vs. 135 separate systems).
- Epic’s **Best Practice Advisories** can be harnessed to search for inclusion and exclusion criteria for clinical studies, enhancing **recruitment** during clinical workflow.
- Collection of **patient-reported outcomes** will be enhanced by Epic’s **My Chart** patient portal. Epic’s clinical **Registries** provide opportunities for focused research.
- Epic will become Duke’s **platform for applied personalized medicine**. This will eventually enable Duke to translate genomics research findings into clinical care.
  - Collecting detailed family pedigrees, genotyping and sequence data
  - Integrate validated genomic indicators in clinical care
- Epic’s study registry, subject registry, Smart Set orders for study protocols, and streamlined clinical and scheduling processes will **improve research efficiency, conduct and workflow, and facilitate compliant study billing**. We are building 550+ active protocols and training 900+ study coordinators.
- We will explore Epic’s capability of **retrieving a case report form for a clinical trial participant during normal clinical workflow** using a standards based mechanism called Retrieve Form for Data Capture (RFD)
Our Build Process…
We Discovered our Current Workflow..
Current Research Billing Process - Systems

Research Billing Processes – Current Data Systems and Linkages

- Retiring Systems
- No paper system for scheduling, orders, billing!
- No choice but to embrace Epic!
Clinical Research and Epic. History

Clinical Systems Discovery Start

Research Systems Discovery Start

Research Calendaring and Ordering Workgroup

Current State

Future State

Validation

Aug 2011

Aug 2012

Sept 2012

Oct 2012

Nov 2012

Dec 2012

Jan 2013

Feb 2013
Decision to use Model Epic 2012 Research Functionality

RAC Executive Committee  Nov 2012

Order Sets And Billing Calendars

= New in Epic 2012
Drivers in Future State Research Workflow using Epic

• No interfaces possible with Velos eResearch or eIRB for Wave 4
  – Reserved for “Optimization”

• Paramount to create a robust split charge billing mechanism for research and standard of care charges
  – PRMO promoting a single encounter, split billing paradigm. We would have to adjust.

• Need a robust study and subject registry

• If possible promote central management of research through DOCR (Huron Report)

Explored and found considerable functionality for managing clinical studies in Epic 2012 model functionality
Future State Workflow Carefully Agreed..

Epic Screens

Study Grid
More Future State Workflow..

Epic Screens
Epic is becoming a Research Patient Management System and will own this space.
Result - Simplified Systems Integration.
Sticking Points Requiring Deep Review

• One Study: One Fund Code
  – Epic only allows one code per study.
• Central Grant Scheduling volume
  – Redirecting unusual schedule requests to peripheral schedulers
• Group signing of order sets
  – PI can sign an order set for the entire protocol – once
• Research “Flag” in the Maestro header
• The use of Billing Calendars vs single orders
  – Epic single orders cannot designate Payer
• Naming convention for research orders
• Role of Velos eResearch
  – Study/subject interface in optimization
  – Velos will be used manage the superset of all our clinical trials (with and without involvement of our clinical systems/billing risk)
Definitions

- **Study grid** - the mandated grid of cycles, actions, drugs and tests that is required for IRB approval of a clinical research protocol. Submitted by study teams and maintained by DOCR.

- **Clinical template** - is the collection of clinically relevant actions, comments and notes that accompany the cycles of an oncology protocol and used by providers as part of clinical care.

- **Grillindar** - a modified study grid, with added Epic-specific fields, charges, EAP and procedure codes verified by the PRMO and corresponding to the cycles of a protocols. Created by a combination of the PRMO and DOCR, it is the necessary substrate for a "billing calendar. The combination of a validated clinical template and a validated grillindar, as well as the necessary built study and therapeutic drugs in Willow, is necessary for the start of the Beacon build for any oncology protocol.

- **Study Calendar/AKA Billing calendar** - is the instantiation in Epic of a built research protocol, either through Beacon, or through an order set, combining the cycles of the protocol with detailed charge, payer and coding mapped so that as orders are fulfilled, charges are routed appropriately to the corresponding payer.
Decision to use Billing Calendars and Order Sets (Epic 2012 Model)

• Epic 2012 enables the creation of a Billing calendar for clinical trials
  – Maps to a visit schedule
  – Chargeable events and items identified, appropriately coded (eg V70.7 modifier) and mapped to Payer (sponsor, insurance)

• Linked at build time to an order set for the study
  – Maps orders to chargeable events and items in billing calendar

• As Charges drop, cross-checked against calendar, coded and routed appropriately

• Review process cleans up

Significant advance in billing compliance/reduction in complexity

But Billing Calendars and Order Sets need to be Pre-built…
Which Studies need Order Sets and Billing Calendars by Go-live?

4047
Active studies in eIRB

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

815

CRU feedback:
- External sponsors
- Recent enrollment?
- Total Enrollment?
- Active after June 2013?

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

357
High Priority Non-oncology

195
High Priority Oncology (Beacon)

787
Research Workflow Validation – February 6th

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

![Research Workflow Diagram]
Epic and Research - Timeline

- **Validation Feb 6th**
- **Example build**
- **Billing Calendar And Smart Set Build (10 weeks)**
- **Send DOCR staff for Epic order set certification**
- **Wave 4 Go Live June 22nd**
- **Maintenance Build**
- **Curriculum development**
- **Super User Training**
- **Train 800+ CRCs**
Building Order Sets and Study Calendars – Non-oncology

- 552 high priority studies have become 564 as new studies added, some closed.
- “war room” team assembled in Hock Plaza, jointly funded by DUHS and SOM.
  - 6 FTE + 3 temp FTE from PRMO (grillindar+ calendars)
  - 6.5 FTE from DOCR (grillindar + Validation)
  - 3 FTE from ORI, Project management from Maestro
  - Managers from PRMO, DOCR, ORI
  - Certified contractors – 3 Orderset build, 4 oncology build, 2 Willow pharmacy build, 1 Principle Trainer, 1 trainer.
Epic Order Set Build for Research

- **Now**: Build June July August visits
- **June 22nd**: Build JIT and for later visits and

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**To Do**

- Epic Order Set Build for Research
- June 22nd
- Build June July August visits
- Build JIT and for later visits and
# Research Dashboard

<table>
<thead>
<tr>
<th>Application</th>
<th>Status</th>
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<tbody>
<tr>
<td>Study Record Build</td>
<td>Green</td>
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<tr>
<td>Research Billing Workflow Build</td>
<td>Green</td>
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<tr>
<td>Study Calendars</td>
<td>Green</td>
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<tr>
<td>Order Set/Billing Calendar Build</td>
<td>Yellow</td>
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<tr>
<td>eRX Build</td>
<td>Yellow</td>
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<tr>
<td>Testing</td>
<td>Yellow</td>
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<tr>
<td>Training</td>
<td>Green</td>
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<tr>
<td>Reporting</td>
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Research: Order Sets

- **Status: Yellow**
  - **Remaining Work:**
    - In the process of assessing maximum number of order sets that can be built, per day to forecast content that will be validated in time for go-live and plan contingencies for un-built content. Also taking into consideration appointment dates around go-live to ensure impacted order sets are built.

- **Risks:** All Priority 1 order sets may not be built and / or validated in time for go-live.

- **Testing Challenges:** Not at this time

  - **Mitigation Plan:**
    - Unified tracker has been created to better manage hand offs between design and build activities as well as validation scheduling. Daily touch points with team leadership established to increase build/QA efficiencies.
    - Contingency planning meeting scheduled for Monday 05/20/2013
Non-oncology Research Build Progress

- Over 2000 study administrative records already built in Maestro (so it knows studies, PI’s, Fund codes etc)
- A mass upload of patients enrolled in studies performed on May 1\textsuperscript{st}, with periodic updates.
- Security templates and profiles built/uploaded
- 357 billing calendars built and couriered into production
- 141/451 Non-oncology drugs built
  - Starting order set validation with study teams
  - This will create more rework involving entire build team
CONTINGENCY

Grillindar

Visit 3

CRC places Ad Hoc orders based On Grillindar

Study Calendar

Charge code

CPT

CPT

Standard Of Care

Study Sponsor
Training, Testing, Reporting, Security and Cutover
Training Numbers by Role – 918 in Total

• Clinical Research Coordinators
  – 410 CRC’s for Wave 4 Go Live inpatient and clinics.

• General Researcher Training
  – 438 individuals will require View Only information. Depending on Maestro Care requirements, this can be an online module much like eBrowser instruction is today.

• Research Billing/Compliance Training
  – 35 will require training in the functions of research billing/compliance as part of the EPIC research build.

• Medication Administration Record Training
  – 35 CRC’s will require specialized MAR training for research medications in addition to the standard 18 hours of MAR clinical training.
Training and Communications

• Principle Trainers (Yolanda Rainey and Elizabeth Oreck) Have created CRC classroom training curriculum
  – Pilot training successful
  – Seely Mudd 104d secured for May 14th onwards through July with new workstations from DHTS
  – Twice daily classes of 15, 4 hours each
    • Al require basic Maestro proficiency first.
    • Extra hour for MAR training
  – “Augmented registration” managed by DOCR
• Online courses for view only mode training
• Billing – separate curriculum
• Communications – newsletter, posterboards, research wednesdays, Great Hall Trent/Siemens

We have a good plan for training, all the better for being late!
Testing - Integrated Test Scripts

- Establishing a Study Administrative Record
- Associating a Patient with a Study
- CRC Ordering Without Order Set
- CRC Ordering a Research Order Set
- No Study Orderables
- Associating a Visit with a Study - At Scheduling (Central Grant Scheduling)
- Associating a Visit with a Study - At Scheduling (Local Scheduler)
- Associating a Visit with a Study - During a Visit/Stay
- Discontinuing a Patient on a Study

- Charge Review
- Charge Review Corrections/Adjustments
- Post-Charge Review Corrections/Adjustments
## Integrated Test Scripts

<table>
<thead>
<tr>
<th>Script Name</th>
<th>ADT</th>
<th>ASAP</th>
<th>Beacon</th>
<th>Order s(Lab)</th>
<th>Cadence</th>
<th>Claims</th>
<th>Epic Anesthesia</th>
<th>EpicCare Ambulatory</th>
<th>EpicCare Inpatient</th>
<th>EpicCare Link</th>
<th>HIM/Identity</th>
<th>MyChart</th>
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Maestro - Reporting for Research Administration

• About 10 model Epic reports
  – Eg subject enrollment by study
  – PI’s associated with Study/ Study ID
• 3 custom reports are being built for the PRMO for research billing by the Maestro reporting team
• We don’t know what we don’t know.
  – Significant issue for the DCI
• Cory Ennis is investigating other potential custom reports needed by the research enterprise.

We are asking for an extract of all Epic Data for research, so we can write our own reports as we need them in an agile process.
Security Templates

• These are templates that define a role and the grid of modules/functions within Epic that the role will have access to.

• Templates can overlay, so will considerably help with management

Eg “RN + CRC” role or “billing + compliance role”

• So we are developing lists of names attached to each role/template for upload so on go live, after training, individuals will have their role pre-assigned.
Cutover

- “Cutover” is the management of tasks that are partially handled by the old and new system
  - Especially reporting and scheduling
  - 6000+ research appointments will be identified and rescheduled into Epic June 1st/2nd
  - CRC’s will associate studies with appointments.
Epic’s Potential for Clinical Research

• Epic will **simplify data stewardship** at the enterprise scale (vs. 135 separate systems).

• Epic’s **Best Practice Advisories** can be harnessed to search for inclusion and exclusion criteria for clinical studies, enhancing **recruitment** during clinical workflow.

• Collection of **patient-reported outcomes** will be enhanced by Epic’s **My Chart** patient portal. Epic’s clinical **Registries** provide opportunities for focused research.

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Duke’s CTSA 2.0 VISION

• High-quality research requires a nurturing academic environment with a pervasive culture of mentorship, continuous learning, and exchange of ideas.

• Research and clinical practice, linked by high-quality data, must power a complementary cycle of continuous learning and improvement.

• Duke must catalyze a measurable improvement in the health and healthcare of individuals and their communities.

• We must link discovery science to a creative engine that accelerates development of new technologies.

• Research must be continually evaluated for academic productivity, safety, efficiency, and cost.

• We must create a fabric of analyzable data and provide tools that help researchers locate and use resources.

• Train and develop the clinical and translational workforce of the future.

• Integrate clinical trials, registries, and electronic health records.
Duke’s Strengths

• Basic and early translational researchers …..leveraging creative technology development … expertise in regulatory strategy … commercialization..Duke’s leading role in public-private partnerships

• A unique structure for site based research ….15 Clinical Research Units (CRUs) … using common “rules, tools, and training” federated through the Duke Office of Clinical research (DOCR)

• DCRI’s 20-year history of coordinating high-impact, multi-site trials and NIH research networks, managing national databases and registries, and contributing to the development of data standards

• A large, diverse group of quantitative scientists with an emphasis on developing new methods and collaborating with clinical investigators

• A unique enterprise data warehouse that includes clinical, financial, and environmental data embedded in a geospatial framework to facilitate population health management and the investigation of interactions among biological, social, and environmental factors;

• Degree-granting programs with a record of producing graduates who sustain academic careers with funded research.

21,760 participants enrolled in 425 NIH protocols from 2006 - 2011
A Challenge for Duke’s CTSA 2.0 Vision: Our Diverse Research Communities and Hubs

These are connected through the vision and structures of the Integrated Research Home.
The Integrated Research Home

• Complement to the “Patient Centered Medical Home”
  – Presents an understandable, consistent and navigable face to the healthcare system in the context of a single patient despite its underlying complexity.

• The “Investigator Centered Research Home” needs to do the same, but for research.
  – It is our complex, but productive, academic and research environment, simplified and made more accessible for research.

DTMI will establish and operate our Integrated Home using CTSA funding
Overall Aims Proposed for Duke CTSA

Aim 1: Create an Integrated Research Home that stimulates and ensures high-quality innovation and discovery in clinical and translational research

Aim 2: Provide resources and services that will improve the quality, safety, efficiency, cost-effectiveness, and impact of clinical and translational research

Aim 3: Build the clinical and translational research workforce
What would an Investigator want from Duke’s Integrated Home?

- **A single point of entry** to Duke’s research infrastructure
  - For receiving news, managing studies, grant applications and IRB submissions
- **Access to mentors** and continuous learning opportunities
- **Access to research services, resources, expertise and tools**
  - **Self-service** access and human navigation if necessary
  - A searchable catalog of cores, resources, expertise, tools and services across Duke
- **Predictable and interoperable data and regulatory environments**
- **Adequate physical space** to foster team science
- Access to and **the ability to efficiently engage research participants**
- Access to **PILOT AND VOUCHER PROGRAMS**
The CTSA at Duke – The Integrated Home

Making it easier for researchers to find resources and collaborators
Aim 1: Integrated Research Home

Investigator Portal: *MyResearchHome@Duke*

- Single point of entry for obtaining support and assistance from the Research Hubs (call, email, online chat, web request)
- Locally managed, maintained web content
- “Single sign-on” to integrate applications launched from the portal
- Personalized dashboards for research administration
- Comprehensive, integrated suite of tools for data discovery and analysis
- Integration with our research networking suite (*Scholars@Duke*).
- Access to educational programs, credentialing and career development opportunities
- Document sharing, electronic forums, online chat sessions, and group messaging (including collaborators outside Duke)
Aim 1: Integrated Research
Home

Navigation Assistance: “MyResearchTeam@Duke”

• Expert “navigators” from each Research Hub, familiar with the full range of resources and services at Duke. Personalized assistance to investigators.
• Accessed through the portal and other points of contact (common mechanism for requesting research navigation services.)
  – Virtual service desk and ticketing system that routes and tracks all investigator requests.
• Navigators locate necessary resources or convene mentors from a group of established investigators to provide feedback and develop research ideas
  – Examples of resources include: biostatistics, biobanking, bioethics, core facilities, data management, pilot funding opportunities, and regulatory expertise.
Aim 1: Integrated Research Home

- Common services application (Services, Pricing, and Applications for Research Centers [SPARC])
  - Accessed through MyResearchHome@Duke
  - SPARC will provide a catalog of all research services available through Duke’s centers, institutes, and cores.
  - A common pricing mechanism.
  - SPARC has an intuitive user interface to browse resources and services, create proposals with realistic budgets, and route proposals for expert review by their local CRU and relevant Research Hub staff.
Aim 1: Integrated Research

Home

• An institutional commitment to scientific research networking, mentoring, and team science
  – Encourage collaborative opportunities both across our own investigator communities and those external to Duke.
  – Using investigator expertise codified in Scholars@Duke encourage mentorship and team science at the enterprise scale.
• An institutional commitment to data governance and data stewardship
  – A new Data Governance Oversight Committee
  – 6 Data Stewards to maintain Data dictionary/standards
• Significant investment in the data warehouse and Epic
  – to provide a robust and predictable data fabric for research
How it works

Combines broad access to services with a process designed to yield high-quality proposals, shaped by multiple stages of review and feedback for ensuring scientific quality, priority, and feasibility.
Questions?