Duke Maestro Care and Clinical Research: 1st Town Hall Meeting

Dean Nancy Andrews, MD, PhD
Dr. Iain Sanderson, Chief Research and Academic Information Officer.
Dr. Mark Stacy, Vice-Dean for Clinical Research

Tuesday 11th June 2013

Panelists

Terry Ainsworth, MS, RN, NP, Associate Director of Research Operations, Duke Office of Clinical Research (DOCR)
Leigh A. Burgess, MHA, MEd, MA, Chief Research Operations Officer
Duke Cancer Institute

Cory Ennis, MS, Senior Manager, IT

Denise Snyder, MS, RD, CSO, LDN, Assistant Dean for Clinical Research, Duke Office of Clinical Research (DOCR)

Mark Stacy, MD, Vice Dean for Clinical Research

Fabian Stone, MBA, MHA, MT(ASCP), Senior Director, Revenue Cycle Management, PRMO

Town Hall - Format

• Introduction – Dean Nancy Andrews, MD, PhD
• Epic for Research - How did we get here?
  • Questions for the Panel
• What does this mean for me and what happens at Go-live?
  • Questions for the Panel
• What does this mean for Clinical Research and patients at Duke?
  • Questions for the Panel
How did we get here?

We mapped Current Workflow for Managing Clinical Research...

It's complicated... but this started a valuable collaboration!

We examined the Workflow of Research Billing...

Retiring Systems!
We decided to use Model Epic 2012 Research Functionality

RAC Executive Committee Nov 2012

We agreed to a Future State Workflow in a large workgroup of the Research Advisory Council

Result – Much Simplification and Integration
Clinical Research and Maestro Timeline

Research Systems Discovery Start

Current State Future State Validation

Aug Sept Oct Nov Dec Jan Feb

2012 2013

Research Workflow Validation – February 6th 2012

- Stop Light Evaluations
- 90+ Subject Matter Experts and Stakeholders from across the Research Enterprise – feedback

We are going to need some 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": the collection of clinically relevant actions, comments and notes that accompany the cycles of an oncology protocol and are used by providers as part of clinical care.
- "Grillendar": 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 research protocol. Created by a combination of the PRMO and DOCR, it is the necessary substrate for a "study calendar."
- "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.
How Does it Work?

Which studies need order sets and billing calendars by Go-live?

Maestro for Research – Timeline since Validation...
...Questions for the Panel...

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What does this mean for me and What happens at Go-live?

Training
- 550+ Clinical Research Coordinators have registered and will receive 4 hours classroom training
  - 50 of these have received Medication Administration Training
- Online training for over 500 research staff who need view only access to Maestro for Chart Review
- Online Training for PI's, faculty and other research staff
- Over 30 PRMO and Compliance Office Staff will have received classroom training

Maestro.duke.edu, “Clinical Research”
What Happens at Go-live?

- Maestro IS ALREADY LIVE IN PRODUCTION
  - All new appointments are in Maestro
  - CRCs are associating encounters with the research flag
- June 22nd is a Saturday
- Command Center
  - "Blue Shirts" are 1st Level of User Support in the field and are dispersed across clinics.
  - Zone Captains liaise with Command Center.
  - DHTS Helpdesk & Maestro Care Command Center staff perform 1st level of centralized support.
  - Research "Super Users" perform 2nd level of support and interface with builders and other Maestro Care support teams in the Command Center.

Help will be close at Hand

Building JUST-IN-TIME order sets and Beacon Protocols

- It’s been hard to build and validate order sets and Beacon Protocols in Maestro
  - Much harder than the clinical build
  - Requires QA and validation at every step
  - Study calendars are all built
- ...So we have been building order sets and Beacon Protocols JUST-IN-TIME based on criteria such as “inpatient study” or “study has an appointment in June and July” as we improve our build velocity
Contingency Planning. Ad-Hoc Ordering....

...Questions for the Panel...

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What does this mean for Clinical Research and patients at Duke?
Beacon Build Process for an oncology protocol.

Building these is HARD and requires multiple steps...

- Establish & Prioritize Protocol Arms
- Clinical Build Review
- Study Teams Rotation
- Auditors & OpCom Complete
- Billing Build
- Ready for Billing Build
- Technical QA Complete
- Protocol Arms Successfully Validated
- Billing Build Ready for Beacon Review
- In Beacon Review
- DOCR/PMO Review Needed
- Study Team Review Needed
- DG Pharmacist Review Needed
- ICS Pharmacist Review Needed

Protocol Arms Successfully Reconciled & QA Complete

Successfully Reconciled & QA Complete

Building Protocol Arms Ready for End User Validation

Protocol Arms Successfully Validated

Clinical and Billing Build

Validation

Non-Oncology Research Studies that involve Inpatients enrolling in June/July

- Most Moved from "build" to "validate" • We are increasing our velocity • Next up: Just in Time August studies, then JIT September... Then hopefully catch up.

... But the hard work is worth it!

Overall IP Just In Time Content Design and Build Progression (Manual Weekly Update)

Total: 23
Fiscal Result of Research Bill Hold...

- 100% research bill hold

- Jun
- Jul
- Aug
- Sept

Clinical and Research Revenue

Revenue

- Temporary Revenue Gap and increase in Accounts Receivable for both research revenues (from sponsor) and from payers (for standard of care charges)
- PRMO has hired 17 temporary staff to process research related charges
- Hopefully our new system will make it very easy to manage and reduce the need for 100% bill hold and any delay!

Longer term effects of Maestro for Clinical Research

- Maestro has forced a degree of discipline and precision in study planning/coding/ordering not seen before
- We will need to build guidelines, order sets or beacon protocols, and study calendars for all new studies
  - This will start on IRB submission
  - An investment by the SOM and DOCR in the central management of Site-Based Research at Duke
- Maestro will become the final common path to study initiation and patient enrollment
- Maestro will become our Research Patient Management System
- Patients should see a streamlined process with more opportunities to participate in research

Maestro's Potential for Clinical Research

- Epic's Research Patient Management improve research efficiency, conduct and workflow, and facilitate compliant study billing
- Maestro will simplify data stewardship at the enterprise scale (vs. 135 separate systems)
- Maestro'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 Maestro's My Chart patient portal. Maestro’s clinical Registries provide opportunities for focused research.
- We will explore Maestro'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)
- Coming Soon in “Optimization” – BPD’s MyChart Questionnaires, REDCap forms as services provided by DOCR (similar to REDCap services).
### Questions for the Panel

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