It’s a Marathon Not a Sprint – Improving Clinical Research Support and Lessons Learned from Maestro Care Implementation

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“Strive not to be a success, but rather to be of value.”
-- Albert Einstein
“OK, I’m now going to read out loud every single slide to you, word for word, until you all wish you’d just die.”
Questions for Today

- Why are we here?
- How do we establish trust?
- How can we help you?
- What’s the best way to become partners?
- What’s one thing we can learn from you?
- Should we expect more from each other?
Why do we do what we do?
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)
- Revenues $2.54B, 1.2m outpatient visits
- 1,780 clinical faculty and clinician scientists
- 203 basic scientists (our first homegrown Nobel Laureate)
Clinical Research at Duke

- 2013 NIH funding $284m - ranked 10th
- 2012 Industry funded research $215m - nearly double that of the next highest academic institution
- 2013 total research revenues - $651m
- NIH studies since 2006:
  - 80 Phase 1, with 5,126 participants
  - 345 Site based, with 16,634 participants
  - 75 multi site, with 87,432 participants
- Duke Clinical Research Institute is the largest Academic CRO in the world with over 1000 employees
- Duke is the Coordinating Center for PCORI
- Our CTSA was renewed in 2013
- Duke School of Medicine Ranked 8th 2014
**Exceptional grant success**

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ARRA effect?
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<td>331</td>
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<td><strong>3124</strong></td>
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<td><strong>3782</strong></td>
<td><strong>3542</strong></td>
<td><strong>4108</strong></td>
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8.6% increase in studies 2011-2013
Core Values - School of Medicine

▪ Excellence in education, research and patient care
▪ Respect for and inclusion of people from all backgrounds
▪ Commitment to service, solving real world problems
▪ Sense of urgency in transforming discoveries into improved human health
Ten strategic objectives serve as a roadmap for the activities of the School of Medicine leadership:

- To educate clinicians and scientists who will be future leaders in improving human health through discovery, innovation and implementation of new knowledge.
- To accelerate translation of basic and clinical discoveries to improvements in human health.
- To have a collection of signature areas in research and in clinical care for which we are known world-wide.
- To provide an infrastructure that will help our research portfolio reach its full potential, and provide fertile soil for new ideas and initiatives to grow.
- To take full advantage of being part of a great university through collaborations and multidisciplinary/interdisciplinary initiatives.
- To improve our local community through contributions to health care, education, the economy.
- To extend our reach and our contributions around the world.
- To attract the best people from the largest possible pool of talent, achieving diversity in every layer of our organization.
- To live within our means and find resources to support our individual and collective visions.
- To be accountable and transparent to our stakeholders.
ALL of YOU are part of this infrastructure and the success of improving patient care!
What is DOCR and how can we help?

▪ **FREE SUPPORT – GET HELP BEFORE YOU NEED IT**
  ▫ Supports all research at Duke with an emphasis on clinical research by developing the “navigation, tools, and training” where Duke serves as an investigative site

▪ **SAVE TIME – NAVIGATE DUKE (it’s not easy)**
  ▫ Home for resources and services for the investigative site-based research community

▪ **SAVE MONEY – PAY FOR JUST WHAT YOU NEED**
  ▫ Direct effort cost only from shared effort pool
  ▫ Supported by the CTSA grant UL1TR001117 from the National Center for Advancing Translational Sciences (NCATS)
Help! I need training... ? January 2000

FY2014 Attendance
114 sessions (1625)
17 Research Wednesdays (859)
Clinical Research Update
>8000 subscribers
Supports all faculty, staff, and students by developing the "navigation, tools, and training" for the conduct of clinical research in which Duke serves as an investigative site.

Duke Office of Clinical Research
Taking on Site Based Contract Signature

What changed?

- 1 day turnaround (compared to 5 days)
- Making the process electronic (only hard copy if you need it)
- More streamlined SPS entries
- One-on-one training
- 508 agreements/amendments signed since 8/21/13
***DHTS is currently working to fix access to documents (including DOCR policies and procedures) that are located behind the firewall on the DOCR website. In the meantime, please use this link to access these documents (will need VPN access if outside of Duke network). Alternatively, please contact DOCR.Help@dm.duke.edu if you are still having problems accessing the documents.***

The Duke Office of Clinical Research (DOCR) is responsible for developing the "rules, tools, and training" for the conduct of clinical research in which Duke serves as an investigative site, and for fostering an identifiable, cohesive community of clinical investigators and research staff. DOCR’s core values include flexibility, service, creativity, collaboration, quality and integrity.
Clinical Research Success: 2013

- ClinicalTrials.gov (5055 old studies complete!)
- More than 500 attendees at 1st ever clinical research appreciation event
- RDSP compliance in all clinical research projects
- HSR Training Program
- Study initiation meetings
- MaestroCare Build
- Survived Go Live!
- We all got Flu Shots!
### ClinicalTrials.gov at Duke:

<table>
<thead>
<tr>
<th>Where We Were: (Oct, 2012)</th>
<th>Where We Are: (5/15/2014)</th>
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<tbody>
<tr>
<td>• 528 study records published</td>
<td>• 862 study records published</td>
</tr>
<tr>
<td>• 58 study records started, never released</td>
<td>• 12 study records started, never released</td>
</tr>
<tr>
<td>• 330 study records identified on problem reports (62%)</td>
<td>• 91 study records identified on problem reports (11%)</td>
</tr>
<tr>
<td>• Minimum of 70 records identified as overdue for reporting results according to FDAAA</td>
<td>• 20 records identified as overdue for reporting results according to FDAAA – 8 of those have been submitted and are under review</td>
</tr>
<tr>
<td>• 23 records published with posted results</td>
<td>• 145 records published with posted results – another 10 are pending QA</td>
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Duke numbers (rolled out May 2013)
36 researchers (20 recruiting, 16 feasibility)
295 “yes” respondents
1,703 volunteers within 50 miles of Duke
Available for IRBs through both DUHS and Campus
The REDCap Consortium is composed of 914 active institutional partners from CTSA, GCRC, and other institutions in 74 countries. The consortium supports a secure web application (REDCap) designed exclusively to support data capture for research studies.

The REDCap application allows users to build and manage online surveys and databases quickly and securely, and is currently in production use or development/build-status for more than 92,000 projects with over 121,000 users spanning numerous research focus areas across the consortium. To find out if your institution is already running REDCap, you will find contact information on the Consortium FAQs page.

Learn more about REDCap by watching a brief summary video (4 min).

**Map of REDCap Consortium Partners**

**REDCap Numbers**

<p>| | |</p>
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<tr>
<td>Users</td>
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<tr>
<td>Databases</td>
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<td>Surveys</td>
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Plans for FY2015

- Research professional job description
- Research professionals network
  - Internal listserv
  - Recruitment tools
  - Shared templates
  - More training, certification & competencies
- Maestro Care – Duke Med Link access for external monitors
- Pre-award grant assistance for faculty (operational, budgets etc)
- More online education
- More Reports for CRUs
- This isn’t it…there will be much more…
Evolved DOCR Model
(influenced by Epic EHR Implementation)

Departments, Institutes, and Centers
- Feasibility determination
- Recruitment
- Enrollment
- Study conduct
- Monitoring
- RO6 – manage research staff
- A/R activities
- Monitor IRB renewals
- Monitor training
- Grant submissions

SOM Research Support
- Study initiation meetings
  - PI Initiated
  - Industry Sponsored
  - Federal & other
- Maestro Care research build
- Research Management Team
- Liaison to other central offices (DHTS, PRMO, etc.)
- CTSA navigation & support
- ClinicalTrials.gov
- Contract signature process
- Study Close out
- A/R monitoring
- Device Expertise
- Dissemination
- Monitoring
- Reports
Why Clinical Research IT?
None of that Counted for Very Much..

Clinical Systems
Discovery
Start

Research Systems
Discovery
Start

Go-Live

Aug
2011

Aug
2012

June
2013

Epic was coming whether we were ready or not…
Lessons Learned (1)

▪ Early, detailed planning with Study Teams VITAL
  ▫ Began study initiation visits for each protocol to map out the build (orderables and chargeables)

▪ We need to train our own staff. (Contractors & rework are expensive – duh.)
  ▫ Migration study builds performed by contractors avg. $10,000 per study (already down to $7500 with goal of $3000)
  ▫ Planned budget of $1.8M to sustain effort going forward
    ▪ Includes all support staff and build teams
    ▪ 300 new studies requiring build per year – FY14 & FY15
Lessons Learned (2)

- Training was not as effective as we had hoped
  - Linking timelines to encounters was a problem – much improved!
  - Targeted training underway
  - Centralizing some functions is under consideration
Lessons Learned (3)

- Communication and research representation is not as inclusive as needed.
  - Upgrades have impacted our functionality ("highlight")
  - Research often was overlooked
  - Research Optimization Council being formed
  - Now have research representation on other committees

- Studies requiring pharmacy involvement require additional attention
  - The Research Pharmacy remains under-resourced
  - Paper was still a viable fallback for study teams
  - Users would contact the pharmacy directly for assistance, which occurred outside the system
Lessons Learned (4)

- Research continues to lobby for EPIC resources
- Few research related reports available for go live
  - The reports team remains under-resourced and had a lack of research knowledge
    - Report writer now working with DOCR/PRMO
  - Partially addressed by ensuring research data was copied into data warehouse
Lessons Learned (5)

- Ending 100% bill hold is taking longer than expected
  - Holding steady at $11M since go live
Where are we now?

- **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**
  - Expand the availability of sophisticated clinical research operations by building a leadership team of experts
  - Fostering relationships across research enterprise
- **Surveying research leadership and staff to determine reporting and CTMS needs**
Where are we now?

- 76% of migration order sets are live in production
  - 99% have been built
- 59% of migration Beacon treatment plans are live in production
  - 83% are built
- Why the gap in build vs. live?
  - Need to complete validations with study teams
  - Balancing remaining migration builds with new study builds
- Study submission and build process defined
- Staffing of build team underway
DOCR/ORI Incident Trend by Type for the Last 6 Months

Maestro Care accounts for 83% of all incidents
Creating the Centralized Build Team

- Needed to adjust from migration build effort
- Approx. 1200 new studies submitted to IRB per year
  - 53% of all studies require RSH record
  - 36% of all studies require RSH and Study Calendar build
  - 19% of all studies require Research Order Set build
  - 13% of all studies require Research Order Set build with Research ERX build
  - 12% of all studies require Beacon build with Research ERX build
- Approx. 400 will require Order Set or Beacon build
Study Build Timeframes

Build Time Required in Weeks

0 1 2 3 4 5 6 7 8 9 10

Order Set No Med
Order Set With Med
Order Set With Device
Low/Medium Complexity Beacon
High Complexity Beacon (or study team delay)
Recognized Benefits

- EPIC implementation has shone a light on long standing operational, compliance and financial administration shortcomings and enabled us to address
  - No standards applied across CRUs
  - Individuals performing jobs they were not trained/qualified to perform
- Research at Duke finally has a “cornerstone” system with which to build an infrastructure around
- Data supplied to School of Medicine Leadership for decision making has much higher level of integrity
Recognized Benefits

- Potential to leverage EPIC functionality for research is enormous
  - Best Practice Advisories
  - Smart Forms
  - Retrieve Form Data Capture
Challenges 2014 and beyond

- MaestroCare
- Develop consistent business practices and reporting
- Continue growing into our new research environment
- Mapping coordinator positions – central report
- Develop a research pathway for residents and fellows
  - Rapid initiation
  - Care and feeding
- IT applications and support (bandwidth!)
- Raise the bar professional partnership (that’s you!)
- Shift resources to growth...
- Have fun!
Thank you!

Duke University School of Medicine

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