Site Based Clinical Research at Duke

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Clinical Research Success: 2013

- ClinicalTrials.gov
- RDSP compliance in all clinical research projects
- HSR Training Program in place (89% compliant)
- Omics Expertise (scientific and ethical components)
- FDA CDRH/Office of Device Evaluation training at Duke
- Peking University IRB training at Duke
- Study initiation program
- MaestroCare Build Office
- Survived Go Live!
- We all got Flu Shots!

Duke Clinical Research

- HRPP Compliance
  - Institutional Review Board
  - Regulatory Affairs
  - Conflict of Interest
- Protocol Compliance
- Data Compliance
- Statistical Compliance
- Financial Compliance
Clinical Research Goals

• Develop and promote practices that
  – Standardize researcher experience at Duke
  – Demonstrate efficiencies in
    • Institutional review
    • Contract and Budget negotiations
    • Administrative sign off
• Explain the costs of research administration
  – Cooperative triage with CRU’s
  – Efficient, auditable data management
  – Study specific research education
• Teach the benefit of internal compliance review

Site Based Research Finances

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8.6% increase in studies 2011-2013
Site Based Research Paradigm Shift

• 1999: IRB shut down
• 2006: Systems Audit for Billing concern
  – Site Based Research Units and CRSO initiated
• 2007: CTQA reviews begun
  – Training deficiencies
  – Dolphin, consent, data management problems
• 2009: Genomics Cancer Protocol Crisis
  – IOM review; DukeQuest
  – Duke-HRPP initially by AAHRPP (re-accreditation 2012)
• 2011: Vice Dean for Clinical Research Office
  – IRB, COI, Regulatory Affairs moved to this umbrella
  – DOCR created; Clinical Research Unit rebranded

Board of Trustees Mandate Certain Program Requirements

• Retired uncounted numbers of policies
• Developed 100’s of new policies
• Met with RPMs, Directors, FPMs 1,000’s of times
• Attempted to politely address 10,000’s of complaints
• Trained and trained and trained
• Developed relationships with the Duke, Duke Regional,
  Duke Raleigh Hospitals; PDC, PRMO, Billing,
  Compliance, CTQA, Department Chairs, Business
  Administrators, Institute Directors, DMRI, DCRI...
• Kept research growing through all of these transitions

Clinical Research Unit
Human Research Protection Program

Vice Dean for Clinical Research

Conflict of Interest
Associate Dean for Clinical Research
Institutional Review Board
Regulatory Affairs

MaestroCare Build Team
Research Operations
Education and Training
Contracts Liaison

Data Management
Study Start-up
Research Support

http://docr.som.duke.edu/

Clinical Research Project Map

Study Submissions and Approval - High Level Overview

Site Based Research Paradigm Shift

- 2013: MaestroCare
  - The Go-Live team for research was awesome
  - Developed a great "need to know" video library
  - Designed training for EPIC
    - It was not enough, and EPIC is complicated
      - We are now in a patient centered environment;
        it can no longer be a study/investigator centered world
  - Built a Study Start-Up Team
  - Developing an Order Set Team
  - Working with Julie McCauley (hero!) on a daily basis
Epic 2012 @ Duke (Maestro Care)

Goals

- Single encounter with split-billing
- Excel usage being phased out
- Consent and scheduling driven by EPIC
- Role-based security
- Research data available in data warehouse
- Improvement of Compliance capabilities
- Duke Office of Clinical Research (DOCR)
  - Study initiation
  - User training
  - Order set build and validation
  - Beacon Build
- Patient Revenue Management Office (PRMO)
  - Billing calendar creation and maintenance
  - RSH record instantiation and security access

Enterprise Wide Planning 3:
Site Based Research

Rob Califf: Vice Chancellor for Clinical and Translational Research
Mark Stacy: Vice Dean for Clinical Research
Process: What facilitates research success?

- Institutional Initiatives
  - Streamline IRB and central sign-off process
  - Improve contracting process
  - Stabilize/define regulatory/compliance criteria
  - Review "unnecessary" regulatory barriers?
  - Unify enrollment programs
  - Provide resources: statisticians, grant writers
- Faculty Development
  - Support research project development
  - Incentivize/reward successful research activity
  - Simplify communication avenues for potential for collaboration
  - Harmonize educational initiative

Balanced Scorecard for Metrics

- Productivity
  - Are we generating and sharing knowledge?
  - Are our operations efficient?
- Finance
  - What are the costs and revenue of our efforts?
- Quality
  - Are we conducting research of the highest possible standard?
- Human capital
  - Are we building a cadre of investigators and study personnel with the right competencies, knowledge, job satisfaction and commitment to the enterprise?

Challenges 2014

- MaestroCare Billing
  - Educate coordinators to link visits
  - Develop consistent business practices and reporting
  - Define gaps in MaestroCare and research processes
- Continue growing into our new research environment
- Develop a research pathway for residents and fellows
  - Rapid initiation
  - Care and feeding
- Determine need for eIRB, eResearch
- Shift resources from apology to growth...
- Find the fun again!