Clinical Trials Management System (CTMS) Overview

8.DEC.2011    |    Biomedical Informatics Core (BIC) Retreat

Elizabeth Micalizzi, Director, Communications and Integrated Technology, Research Affairs and VCU Institutional Liaison for ResearchMatch
VCU Office of the Vice President for Health Sciences
Riddle Me This

• How many subjects have an “on treatment” or “on study” status today?
• What does your (personal, division, department, school) clinical trial “profile” look like?
• How many places, and separate documents, do you use to store all of your protocol information?
• Who do I contact about study “X” if there has been staff turnover?
CTMS Benefits

- Better strategic planning
- Strengthened compliance
- Overall reporting
- Improved workflow / processes
- Real time accurate online study information portal
- Improved human subject research activity throughput / volume
- Risk mitigation
Objectives

• Enhance clinical research infrastructures and support via IT-driven enterprise integration
  – Offer enterprise-wide solution to the VCU clinical research community
  – serve as the system of record for VCU
• Replace current decentralized methods of recording clinical research activity
• Support process and workflows to strengthen and support institutional oversight
• Ultimately reduce administrative redundancy
• Strive for the goal of institution-wide mandate
CTMS Options

• Since 2009 explored available CTMS options with market research, demos, committees (oh my!)
  – OnCore, REDCap, Velos, Click Commerce, Homegrown, etc

• And....
Why OnCore?

• Full spectrum (CTMS)
  – Doesn’t focus on just one function
  – Has ability to streamline CT administrative functions and workflows
  – Commercially available database management system originally developed for cancer centers
    • Has 40% CC market share; expanding rapidly to multidisciplinary AHCs
    • Proven track record
  – Ability to provide centralized oversight and operate within various research areas
  – System that will allow us to do our jobs
• by Forte (formerly known as PercipEnz)
• Use by Massey Cancer Center since 2006
Secure web based access to application

Clinical trials

Every revolutionary medical discovery starts with clinical research. The vaccines, medicines, surgical procedures and therapies we rely on to keep us healthy, help us recover from sickness, injuries and diseases and resume our normal lives – they all exist because they were proven effective in clinical trials. At VCU Massey Cancer Center, volunteers from our public communities join our doctors and scientists in this research process and share the pride in helping to discover medical breakthroughs.
Organizational Placement

MCC
(Massey Cancer Center)

CCTR
(Center for Clinical and Translational Research)

OVPHS
(Office of the VP for Health Sciences)

Enterprise OnCore

Operational/Application Support and Oversight for cancer protocols

Operational and Application Support For non-cancer protocols

Institutional oversight
Anticipated OnCore Functions

• Protocol management
  – initiation, status and portfolio reporting, start-up tracking

• Workflow routing/approvals
  – role based, integrating with email, other alerts

• Staff and faculty tracking
  – Training (CITI) and CV management

• Compliance
  – tracking of IRB approvals, FDA and monitor reports, contract compliance

• Subject enrollment and tracking
  – subject status
How Did We Get Here?

• Current cancer center contract amended to expand OnCore beyond Cancer Center, July, 2011
• Stakeholder registry and steering committee developed, August, 2011
  – CCTR, MCC, OVPHS, SoM, VCUHS Financial and Support Services, other SMEs PRN
• Demos and presentations December, 2011
• Initial Kickoff meeting slated for January, 2012
• Implementation of Phase I in pilot department will start shortly after kickoff
Phase I OnCore Expansion (1/2)

- Strive for the goal of institution-wide mandate
  - Protocol registration
    - For all human subjects studies
    - SoM, Non-Cancer
    - Interventional therapeutic
    - Regardless of funding/location of study conduct
  - Subject registration
    - Minimum subject data points
Phase I OnCore Expansion (2/2)

• Pilot department (Jan, 2012)
  – Training and education
  – Global protocol information
  – Subject tracking

• +9-12 months (Jan, 2013)
  – Additional SoM departments

• +12-18 months (Jan, 2014)
  – Additional schools
  – Additional functionality
Continued Implementation

• Phases II and III
  – Non therapeutic human subjects protocols
  – Interoperability
  – Customized reporting
  – Continued enhancements
What’s in it for you…. 

• Better access to information
• More efficient processes
• Lower compliance risk
• Delivery of high-quality data
Other reasons why VCU is moving this direction

HIPAA Authorization Forms
Protocol
Clinical Trial Agreement
Medical License
Research Billing Slip
Payment Tracking
Enrollment Log
Consent Forms

Subject
Chart

Slide credit: Tracy Ohrt, University of Wisconsin Madison