Research and the EHR: Process Improvement Through Integration

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Conflict of Interest

Marti Arvin, JD
Arash Naeim, MD PhD

Have no real or apparent conflicts of interest to report.
Agenda

• Systems
• Processes
• Integration of Systems and Processes
• Impact on People
• Managing Risks
Learning Objectives

• Analyze the interplay between the IRB, CTMS and the EHR

• Describe the process used to assess the balance between end user satisfaction with an integrated set of systems and the compliance objectives of the integration of those systems.

• Assess the overall improvement to workflow, end user satisfaction and compliance after the implementation of integrated systems for a clinical research study
Opportunity

• Create a national model for efficient nimble clinical research study start-up and management

• Serve as a UC wide center of excellence, leveraging infrastructure investment into a future sustainability model

• Increase PI and research staff satisfaction and retention

• Improve compliance for privacy, security and clinician research billing
Focus

Deployment of Appropriate Technology

Change Management

People

Processes

Technology

Workflow Re-design
Systems
IRB and the Web-IRB System

• To ensure that the rights and welfare of research subjects are adequately protected
  – Review clinical research protocol and informed consent
    • Financial language
    • Therapeutic intent
  – Ensure clinical research is performed in accordance to federal and state regulations and guidance
  – Provide continuing review (annually)
  – HIPAA Compliance review
  – Significant risk determination
Clinical Trials Management System

- A clinical trial management system (CTMS) is a software system used by to manage clinical trials. The system maintains and manages planning, performing and reporting functions, along with participant contact information, tracking deadlines and milestones.
  - Study management
  - Subject management
  - Financial Management
Electronic Health Record System

• An Electronic Health Record (EHR) is a digital version of a patient’s medical history that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that person’s care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports.
  – Billing for services and associated documentation
  – Level of service
  – Research special billing rules
  – Clinicaltrials.gov registration (NCT#)
EHR
- SmartSets for Complex Studies
- Registration/Scheduling
- Research
- Charge Review

CTMS
- Study Start-Up Management:
  - Status Tracking
  - Hand-offs
  - Notifications
- Coverage Analysis
- Budgeting
- Sponsor Invoicing & A/R
- SAE & Deviations Mgmt
- Cancer Center Specific Features

- Study Creation
- Billing Grid
- Study Staff Management
- Patient Statuses
- Patient Timelines
- Reporting
Clinical Research Infrastructure Vision

Speed, Efficiency, Interoperability, Transparency, & Analytics

- Human Subjects
  - IRB
- Clinical Trials Management System
- Electronic Health Record
  - EHR/EMR
- Insurers/Payors
- Sponsors
- Contracts & Grants
Processes
Chaos
Potential Chaos – Limited Infrastructure Investment

- Sponsor
- Sponsor
- Coverage Analysis (CA)
- Contracting

IRB

IRB

IRB

Sub-contracting

HOSPITAL WRITE OFFS

NO RESEARCH PRICING
NO ANCILLARY REVIEW
NO DOCUMENT MANAGEMENT

MINIMAL STUDY DATA
NO SUBJECT DATA
NO TRACKING
DISCREPANCIES BETWEEN CONSENT, PROTOCOL, & BUDGET
Driver: Clinical Research Billing Compliance

• In June of 2013, Noridian, our region’s new Medicare Administrative Contractor, announced its expectation for compliant clinical research billing as a focused priority of interest.

• UCOP’s Office of Ethics, Compliance, and Audit Services issued a directive to all UC sites to develop clinical research billing readiness plans to prepare for the Noridian transition.

• This area, along with patient privacy, was a significant compliance risk area for the organization.
UCLA’s Research Billing Readiness Plan

• Appoint a Chief Medical Officer for Clinical Research.
• Establish a Clinical Research Governance Committee established with a broad charge to rapidly develop policies and procedures for proper clinical research management.
• Implement an enterprise-wide clinical trials management system integrated with the electronic health record system.
• Provide sufficient centralized support to study teams.
Setting Up a Committee

Clinical Research Governance Committee

- Research Pricing & Charges
- Research Compliance
- Precision Medicine
- Clinical Research Informatics
- Ancillary Services
Building a Committee

- 18 representatives, one each from the Clinical Chairs
- Cancer Center
- Chief Administrative Officer Liaison
- Precision Medicine
- Dentistry, Public Health, Nursing, and Psychiatry

- Psychology, Engineering
- Office of Research Administration
- Chief Compliance Officer
- IRB Director
- Health System
  - Hospital Finance, FPG
  - Finance, Charge Master, ISS
How Decisions are Made

• Analysis and options created by lead unit.
• Topics presented at a CRGC subcommittee, then to full CRGC.
• Key decisions also reviewed when appropriate by CTSI Governance, Health Science Enterprise Compliance Oversight Board, Clinical Chairs, Clinical CAOs, Research Deans, OVCR, and Academic Senate.
Clinical Research Info Systems

- Leveraging technology and workflow reengineering to ensure a compliant, yet nimble, clinical research business processes with transparency and actionable business metrics.
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HOSPITAL WRITE OFFS
Rational and Efficient Approach

- Fund Number
  Clinicaltrials.gov
  Open in EHR

- Calendar
- Coverage Analysis
- Coding/Pricing
- Budget Negotiation
- Quality Check
- Ancillaries
- Sponsor

IRB
Contracting
Integration of Systems & Processes
Leading the Nation

IRB
webIRB changes
Institutional Financial Fund Numbers

CTMS
Coverage Analysis
CPT Linking
Research Charge Master

EHR
Research Protocols
Security Access Per Protocol Ordering
CTMS Coverage Analysis
CPT Linking
Research Charge Master

Huge Efficiency Win for PIs
CTMS
Coverage Analysis
CPT Linking
Research Charge Master

EHR
Research Protocols
Security Access
Per Protocol Ordering

Data Mart/Reporting
Business of Clinical Research

Foundation for business metrics
Billing: an opportunity area

- Hospital versus faculty practice group
- Billing IT versus Billing staff
- Quality control and assurance
- Service-orientation toward researchers
- Coding versus Charge Review
Impact on People
Service-Oriented Culture

• Staff evaluated based on:
  – Productivity (volume/efficiency/metrics)
  – Competency & Quality
  – Client and user satisfaction
  – 360 evaluations of managers and directors

• Evaluation criteria tied to:
  – Merit increases
  – Career advancement
  – Salary adjustments
  – Performance reviews
Business Process Optimization

• Leverage sponsor invoicing functionality
  – Prevent unbilled events

• Optimize workflow for study closure
  – Ensure all campus-based service providers are reimbursed before a fund closes

• Close studies that don’t or won’t accrue
  – Maximize resources and minimize losses associated with study start-up

• Streamline adverse event and deviation submission and reporting
  – Minimize duplicate data collection effort and monitor for compliance issues

• Convert from paper to electronic regulatory binders
  – Save time, space and money for offsite storage
Change Management

- **Oncology**: Switch from cancer center controlled CTMS to institutional CTMS and a more centralized process.

- **Non-Oncology**: Faculty will require more optimization since moving from paper/excel spreadsheets to clinical research management system.

- **Departmental Differences**: processes, resources, roles, and responsibilities of research support staff.
Manage Risks
Blaming the Whole

• With any complex systems implementation, the expectation is that optimization of workflows is never ending with adjustments made based on real time feedback and adoption of more functionality and features.

• One should expect some additional increased risk associated with learning and following new workflows during implementation.

• However, there is increased risk that leadership and the workforce will also loosely blame a system’s implementation for lack of competency or poor work quality even when it is unrelated.
False Claims Act (FCA)

- Healthcare fraud and abuse is a top enforcement priority of government agencies
- HCCA estimated investigative recoveries for FY17 is $4.13 billion
- FCA establishes liability for anyone who submits a false claim for payment to the government - specific intent not required
- Federal penalties for violating the FCA are severe and include fines up to 3x the amount for each claim, plus a penalty of up to $21,562 per claim and possible exclusion from federal health care programs
- Obligation to act promptly when there is a reason to suspect potential overpayment (potential liability for reverse false claim)
False Claim Settlements with OIG

- University of Alabama at Birmingham
- Rush University Medical Center
- Emory
- University of Florida
- Columbia University
- Harvard
Data Privacy & Security Risks

• Research data compromises could result in
  – Breach notification to OCR and/or state entities
  – Civil lawsuits
  – Patient and subject distrust
FDA

• Clinicaltrials.gov
  – Civil monetary penalties of $10k per day for each study with late results reporting.
  – Withholding of NIH grants

• FDA audits
  – FDA 483
  – Warning Letter
  – Research Injunction
  – Sponsor Litigation
  – Criminal Prosecution
PI Satisfaction and Retention

• All academic medical centers need to implement systems and processes to mitigate the regulatory and compliance risks associated with performing clinical research.

• All academic medical centers will need to report metrics and demonstrate efficiency in study-start up and recruitment processes.

• PI satisfaction and retention is at risk when additional support services (study start-up, regulatory, FDA, research coordinator, navigation) are unavailable to help support and reduce the burden on PI’s and study teams in their efforts to perform cutting-edge clinical research.

• Need to demonstrate value to counterbalance the pain of adjusting to new systems and processes.
Specific Compliance Improvements

• Easier for researchers to follow the process which decreases non-compliance

• Transfer key processes to individuals with expertise to assure compliance

• Condense locations for data and structured process allows compliance to conduct appropriate and transparent audits and investigations

• Commitment by senior leadership to emphasize importance of compliance

• Involvement of all key stakeholders allowed buy-in to processes

• Increased transparency
Efficiency

• Trends in NIH accountability from cradle to grave of a clinical research study or trial
• Importance of parallel processing
• Being nimble to efficiently respond to new policies and regulations
• Educating young investigators and new research staff
• Accruing study participants after study-start-up investment
Questions

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