Bridging the Gaps:
Understanding and Managing the Regulatory, Financial, and Clinical Risks through Implementation of a Sustainable Clinical Trial Management System

HCCA Research Compliance Conference
October 19, 2009

Objectives

• Overview of clinical trial management challenges

• Typical Process Challenges: Understanding your institutional clinical trial management and billing landscape

• CTMS: How they can help & what to look for

• Key elements for a successful implementation of a CTMS

• Questions & Answers
Clinical Trial Management Challenges

“Clinical trials administration and compliance at academic health centers nationwide has been rapidly changing in recent years as a result of increased research activity, mounting regulatory requirements, and escalating costs”.


Clinical Trial Management Challenges

Market Condition - Compliant Management of Clinical Research

- The Department of Health and Human Services – Office of the Inspector General (“OIG”) draft research compliance program guidance specifically highlights billing as an area of risk that should be managed through a formal compliance process
- Medicare “double billing” has been the subject of numerous OIG and Department of Justice (“DOJ”) investigations/settlement

Who is accountable and how do you do it compliantly?
Clinical Trial Management Challenges

Compliant Management of Clinical Research – Two Major Cases

- Case at Rush University Medical Center has brought substantial attention to the need for compliant, efficient clinical trial billing
  - First settlement associated solely with the National Coverage Decision on Clinical Trials
  - Focused on cancer clinical trial overpayments
  - Repaid $1 million in overpayments (50% penalty)
  - Entered into 3 year Certificate of Compliance Agreement
  - Re-organized clinical trials billing management:
    - Established a centralized office
    - Required all clinical trials to receive a “coverage analysis”
    - Developed new auditing and monitoring program

- Settlement at the University of Alabama at Birmingham resulted from 9 year review of billing improprieties
  - Investigation of research grants and Medicare billing between 1996 and 2004
  - Repaid $3,390,000, of the more than $3.5 billion the government paid UAB during this period for research funding and healthcare services
  - Focused on allegations involving research compliance and billing, including:
    - The manner in which UAB investigators accounted for their overall effort and research support
    - Charging practices for grant-related services
    - Billing practices for services provided to patients participating in clinical studies

Clinical Trial Management Challenges

Clinical & Translational Science Award (CTSA)

- Clinical and Translational Research Programs are critical to advancing the quality of patient care in the United States yet institutions that manage them often face tremendous challenges.
- The Clinical and Translational Science Awards (CTSA) managed by select institutions seek to facilitate research innovation across the continuum of bench to bedside and improve the practice of medicine.
- The CTSA presents a unique opportunity to invest in an infrastructure to better support and improve clinical trial management and speed innovations from bench to bedside.
Clinical Trial Management Challenges

CTSA Goals and Objectives

- The goal of the CTSA is to transform how clinical and translational research is conducted and managed, ultimately enabling researchers to provide new treatments more efficiently and quickly to patients.
- CTSAs now comprise 46 academic health centers in 26 states. The consortium *ultimately will link about 60 institutions together* to energize the discipline of clinical and translational science.
- In order to achieve the objective, the NCRR provides funding that ranges from $10M to $100M+ to establish clinical and translational infrastructure. In addition, the recipient institutions have committed matching funds in the $10’s of millions.

Clinical Trial Management Challenges

CTSA Implications

- The CTSA requires a new approach for facilitating efficient clinical trials, where tools are necessary for managing clinical trials at an enterprise-wide level.
- Many organizations are looking to establish central support in an effort to better manage the intricacies of the CTSA across the entire institution.
Clinical Trial Management Challenges

Current Institution Environment

For most institutions, the clinical trial environment might be characterized as:

- **Decentralized** – a federation of departments/divisions or even PIs
- **Highly manual** – few integrated systems or processes
- **Variable** – few institutional standards, few written policies and procedures
- **Under-invested** – in administrative / support resources
- **Individual-centric** – controls (e.g. budgeting, billing compliance, etc.) depend on the efforts of a specific person
- **Limited in scope** – as this relates to the level and sophistication of administrative and management services

### Clinical Trial Management Challenges

#### Common Management Challenges

<table>
<thead>
<tr>
<th>Organization</th>
<th>Information Technology</th>
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<tbody>
<tr>
<td>✷ Multiple clinical trial support groups with redundant / overlapping functions (often department based)</td>
<td>✷ No common system for many aspects of Clinical Research – many “shadow systems”</td>
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<tr>
<td>✷ “Silos” of responsibility dispersed / unclear among the AMC entities (University, Med School, Hospital)</td>
<td>✷ No central registry with comprehensive clinical research study and participant data</td>
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<tr>
<td>✷ No single person or group responsible for coordinating clinical research administration across the organizational silos</td>
<td>✷ Often the main technologies used are Excel spreadsheets and MS Word documents – and these tools are not standardized across departments</td>
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<td>✷ In many cases the silos compete with each other</td>
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<table>
<thead>
<tr>
<th>Personnel</th>
<th>Processes</th>
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<tr>
<td>✷ Numerous individuals supporting clinical research administration (in the hundred’s) but…</td>
<td>✷ Few policies and procedures governing how institution-wide clinical research should be conducted</td>
</tr>
<tr>
<td>✷ …variable experience and expertise among these individuals</td>
<td>✷ No overall enterprise-wide authority to develop standards, systems, or processes</td>
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<tr>
<td></td>
<td>✷ Often no system-wide contracting authority</td>
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</table>
Clinical Trial Management Challenges

Simple Concerns are Often Extremely Complicated

- I do not know how many clinical trials I currently have.
- How much money do we make or lose on clinical trials?
- The number of clinical trial patients at my institution makes me uneasy knowing how difficult it is to bill for patient care services.
- How can I improve the performance of the clinical trials business and reduce time consuming, but necessary, administrative functions?
- Is there a way to better integrate technology to aid in the management of clinical trials?
- How many patients are enrolled in clinical trials?
- Do we make or loose money on clinical trials?
- Are the activities on the clinical trial being billed correctly to either the research study or the patient’s insurance?
- Have the sponsors paid us what we are owed?
- How much clinical revenue is derived from clinical research?

Clinical Trial Management Challenges

Essential Components to Clinical Trial Management

<table>
<thead>
<tr>
<th>Medical School</th>
<th>Physician Practice Plan</th>
<th>Hospital Partners</th>
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<tbody>
<tr>
<td>Strategic Plan</td>
<td>Infrastructure</td>
<td>Process</td>
</tr>
</tbody>
</table>

1. Institutional buy-in
   - Vision aligned with institutional capabilities
   - Forward looking & sustainable
   - Widely communicated
   - Continuous leadership and support

2. Decentralized, Centralized, Hybrid
   - Buy In from Stakeholders (University, School of Medicine, Faculty Practice Plan, Hospital)
   - Proper Accountability
   - Overburdened / misaligned resources

3. Efficient business processes
   - Reduce duplicative work
   - Centralize key business processes
   - Leverage to ancillary and SOM departments
   - Performance metrics driven

4. Built on top of sound strategic vision, infrastructure and processes
   - Personnel understand how to use technology
   - Reduce / Eliminate redundant data entry
   - High Degree of Integration with other systems
Typical Process Challenges

Typical Process Deficiencies

* Billing Compliance

- As research billing compliance remains complex and fragmented due to continuous scientific innovation and an ever-changing regulatory environment, manual and reactive based management incurs greater risk, and missed opportunities.

- The current, independent departmental methods and manual systems used to enroll, register, schedule, track, and bill patients in clinical trials is of a greater risk of compliance breakdown.

Key Billing Compliance Components

- Budget Development
- Segregating Costs
- Research Registration / Scheduling
- Research Billing
Typical Process Deficiencies

Introduction

• The rules for billing standard care to research patients are subject to different interpretations
• For many trials, it is difficult to distinguish research from standard care
• The clinical trials process involves many units and people
• Historically, systems have been geared to patient care only, not research
• Problems create publicity as well as financial risk
• The government is paying attention

Typical Process Deficiencies

Segregating Research from Standard of Care Charges

• No formal process for reviewing the study to determine which tests and procedures could be billed to patient insurance vs. those that should be billed to the study
• Need to consider:
  – What does the Clinical Trial Policy (CTP) allow (e.g. what could be billed?)
  – What is the sponsor covering
• Many institutions are making this a function of a central clinical trials office
  – Affords consistency & helps mitigate compliance risk

Just because the Clinical Trial Policy allows a charge to be billed as standard of care, doesn’t mean it should. Could be a “double dip.”
• Tools to support accurate budget development are often lacking
  – Standard rates for clinical charges have not been developed and/or a
    research rate schedule is not available
  – As a result, discounts for research costs may not be applied appropriately
• With a good study budget, the institution can use the budget to
  identify significant variations from plan and monitor billing compliance
  – For example, if patient care costs charged to the study account are
    significantly less than planned, the study team can investigate to
    determine whether:
    • Patient care charges were incorrectly billed to the participant and/or third party
     insurer
    • Patient care charges were not billed to anyone (e.g., remain on hold)
    • Patient care charges were billed at lower rates than anticipated

Typical Process Deficiencies
Research Registration

• Information collected at the time of registration is insufficient to
  identify a patient as a research subject
  – Difficult to manage the appointment scheduling and registration processes
    for research encounters
  – Difficult to effectively manage research-related encounter flow and billing
    efforts
Typical Process Deficiencies

Other Issues Related to Research Billing Compliance

- Clinical trials-related hospital accounts receivable had missing or incorrect research account information
- “Patient Financial Services” may not have a system to monitor the status of bills which have been forwarded to hospital accounting / departments for review / payment.
- PFS may not maintain an accounts receivable aging report for clinical trials.

*Clinical trial billing is cumbersome and there are many opportunities in the process to make mistakes. The keys to reducing risks are coordination, communication, and culture.*

- No procedures to handle disputed charges
  - An audit trail to support charges is often lacking making it difficult to determine whether the specific item was charged to the patient in error
  - Moreover, there is no person or process to ensure the issue is resolved timely / correctly

- No formal policy to handle residual balances
  - If amount is greater than expected (per budget) the institution should investigate to ensure clinical charges were not billed to the patient incorrectly
CTMS: How They Can Help

- Develop protocols in a consistent, standard manner
- Capture all protocol information and leverage to:
  - Negotiate contract & budget
  - Gain regulatory approvals
  - Perform coverage analysis
  - Identify procedures and services providers, and validate CPT codes
- Enroll study subjects and add to Patient Registry database
- Build protocol schema and study and patient calendars
  - Procedures
  - Service providers, locations
  - Dates, times
  - Coverage
- Generate study budget template (Financial Management)
- Monitor and manage study and subject progress
- Record adverse events
- Maintain and manage study documentation
Clinical Trial Management System (CTMS)

How they can help

- High Degree of Integration; CTMS bridge gaps between all arms of clinical research while providing a high degree of integration with other systems.

- Provides a Comprehensive Clinical Research Structure; Pre-Planning and Feasibility, Budget Development, Coverage Analysis Support (treatment grids), Clinical Trial and Subject Tracking, Complete Study Financial Management

- Increased Communication; All research roles are able to communicate in a central location.

*ADT Feed: A streamlined messaging system for providing admission, discharge, and transfer information from a hospital information system to another system.

Clinical Trial Management System (CTMS)

What to Look For

An Enterprise-Wide Solution Should Include:

- Protocol Management - Workflow management, study lifecycle tracking, treatment plans & patient calendar creation.
- Patient Management - Patient recruitment, enrollment, scheduling, & tracking
- Financial Management - Budget creation, milestone tracking, invoicing, cost segregation (research vs. standard of care), & compliant research billing
- Data Management - Adverse event documentation, data capture, study-related event documentation
- Reporting - Data & Safety monitoring reporting, financial dashboards, NCI reporting.

Compliant & Systematic Clinical Research Process
Clinical Trial Management System (CTMS)

CTMS Budget Example

Clinical Trial Management System (CTMS)

CTMS Cost Segregation
Clinical Trial Management System (CTMS)

CTMS Patient Tracking Example

<table>
<thead>
<tr>
<th>Patient Study Status</th>
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<tbody>
<tr>
<td><strong>Patient ID:</strong> demo-A123</td>
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<tr>
<td>Please enter Status details</td>
</tr>
<tr>
<td><strong>Status:</strong> Select an Option</td>
</tr>
<tr>
<td><strong>Reason:</strong> Select an Option</td>
</tr>
<tr>
<td><strong>Status Date:</strong> Select Date</td>
</tr>
<tr>
<td>☑ This is patient's current status in this study</td>
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<tr>
<td><strong>Notes</strong></td>
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<table>
<thead>
<tr>
<th>Additional Information</th>
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<tbody>
<tr>
<td><strong>Patient Study ID:</strong> <em>(system-generated)</em></td>
</tr>
<tr>
<td><strong>Enrolling Site</strong></td>
</tr>
<tr>
<td><strong>Assigned To</strong></td>
</tr>
<tr>
<td><strong>Physician</strong></td>
</tr>
<tr>
<td><strong>Treatment Location</strong></td>
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<tr>
<td><strong>Treating Organization</strong></td>
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Key Elements for a Successful CTMS Implementation
CTMS Implementation Considerations

Improve Within Clinical Research

The primary purpose of using technology is to provide an administrative “nervous center” to support the growth and tracking of clinical research programs. When implemented correctly, a Clinical Trial Management Systems (CTMS) could help to streamline and standardize the planning, execution, and tracking of clinical trials/research activities with a focus on operational best practices, metrics, and compliance improvement.

<table>
<thead>
<tr>
<th>Pre-CTMS Environment</th>
<th>Post-CTMS Environment</th>
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<tr>
<td>Decentralized</td>
<td>More Defined Structure &amp; Process</td>
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<tr>
<td></td>
<td>– Once implemented, the system will direct and support the process</td>
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<tr>
<td></td>
<td>Standards – Standard practices and tools are rolled out across the institution (with some modifications to accommodate the differences in research in various therapeutic areas)</td>
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<td></td>
<td>New Workflow – New processes that often require new communications</td>
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<td></td>
<td>Improved Management – Management can monitor, providing better support for PIs and study teams</td>
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<td></td>
<td>Best Practices – Institutional best practices in clinical trial management can be identified in the organizations “areas of excellence” and instituted across the organization</td>
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Common Issues

Likely Implications when CTMS is Implemented

Given these implications, institutions implementing a CTMS should consider each of the following issues:

1. Role of the CTMS
2. Assignment of roles and responsibilities
3. Level of centralization / standardization desired
4. Staffing requirements
5. Organizational placement
6. Financing and funds flow
7. Workflow / configuration decisions
8. Engaging the Entire Enterprise
Questions & Answers

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Jim has more than 15 years of experience working with universities, hospitals, and academic medical centers as a research operating officer, chief compliance officer, and consultant. Prior to joining Huron, Jim served as the clinical research operating officer for Washington University in St. Louis, implemented a compliance program at the University of Pennsylvania, and worked as a consultant for PricewaterhouseCoopers.

Professional experience
Representative examples of Jim’s engagement experience include:

Clinical Research Strategic Planning & Business Development
- Authored sections of the Clinical & Translational Science Award (CTSA) granted to Washington University. Directed the regulatory knowledge and support as well as the clinical interaction resource sections.
- Developed strategic research partnerships with pharmaceutical sponsors and peer academic medical centers. Grew clinical trial revenue by 20% in a two-year period.
- Combined two general clinical research centers (GCRCs) with a pharmaceutical clinical trial unit to become the CTSA’s clinical interaction resource.

Clinical Trial Office Operations
- Directed a staff of 85 individuals including registered nurse coordinators, lawyers, medical assistants, regulatory support personnel, contract specialists, recruitment coordinators, and dieticians.
- Managed a dedicated clinical and translational research space of 31,000 square feet.
- Developed and implemented a plan to address the National Coverage Decision outlining the Medicare/Medicaid billing requirements for clinical trials.
- Led an effort to reduce clinical trial contract processing time.

Clinical Studies Management System Selection & Implementation
- Selected and implemented an enterprise wide clinical research management system for Washington University and BJC Healthcare, a health system made up of 13 hospitals across the St. Louis region.

University Compliance
- Designed, implemented, and operated a compliance program to address the complex regulatory requirements of the University of Pennsylvania’s teaching, research, and patient care activities.
- Designed and implemented a Web-based certification and training program for all principal investigators performing human subject research.
- Led a comprehensive restructuring of the oversight of human subject research at the University of Pennsylvania including institutional review board oversight; FDA good clinical practices quality assurance and monitoring; adverse event reporting; clinical protocol development; principal investigator training; and conflict of interest.
- Led an initiative to implement the HIPAA privacy regulation to meet the requirements of federal and state laws while preserving the institution’s ability to conduct human subject research.
- Developed and implemented a comprehensive auditing program for research grants.

Education and certification
- Juris Doctorate, Health Care, Widener University School of Law, Wilmington, Delaware
- Bachelor of Science, Accounting, Pennsylvania State University, State College, Pennsylvania
- Certified Public Accountant, Pennsylvania

Speaking engagements
- Frequent speaker at national and regional conferences on clinical research operations and regulatory compliance topics such as CTSA management, clinical trial billing compliance, clinical trial management systems, clinical trial office operations, effort reporting, and grant charging practices.
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Manager
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Salman has more than eight years of experience in the clinical research industry.

Professional Experience
Prior to joining Huron, Salman was an associate for Covance’s strategy and marketing consulting practice and previously founded and managed a healthcare clinical research management consulting company. Representative examples of Salman’s engagement experience include:

Hospital/Information Technology
• Led an engagement at a large Academic Medical Center (AMC) to strategize and plan for integration and implementation of a proprietary clinical trial management system (CTMS) at three large, prestigious academic medical centers.
• Conducted training sessions on clinical trials management systems.
• Designed and developed a cost-effective clinical trial management system for better management of clinical research data.

Clinical Research Administration and Compliance
• Led a large engagement with multiple projects to develop and support an academic medical center.
• Led an engagement to monitor and audit hospital and professional billing for an established academic medical center in the Midwest. Presented findings and recommendations based on the review.
• Performed Medicare coverage analyses at large academic medical centers. Determined the billable nature of services provided in a clinical study based upon the CMS Final National Coverage determination (NCD).
• Assisted with the preparation of a training module on the conduct of Medicare coverage analyses for medical device and pharmaceutical companies.
• Conducted rigorous analysis of a client’s operations and recommended a strategy and solution to enhance performance.

• Designed, developed, and implemented three user-friendly and efficient patient data collection and analysis systems for research studies within the department of head and neck cancer.
• Introduced an effective way to collect research data and created reporting tools while working within limited grant budgets.
• Designed, developed, and implemented a user-friendly information system for a collaborative clinical and life sciences research study.

Clinical/Research Administration and Compliance
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Strategic Planning
• Led a large engagement to plan and strategize development of a clinical trials office for a large academic medical center.
• Developed strategies for medical technologies to maximize payer coverage and reimbursement. Conducted market research, commercial analysis, and competitive intelligence. Defined problem sets, identified issues, and developed integrated analysis plans.
• Consulted with healthcare thought leaders including practicing clinicians, medical and pharmacy directors. Gathered information from knowledgeable individuals, reference texts, on-line databases, and other research materials in order to develop product market access strategy and planning.
• Worked with project teams to support product launches by training pharmaceutical/biotech hotline staff and pharmaceutical sales force.

Hospital Information Technology
• Led an engagement at a large Academic Medical Center (AMC) to strategize and plan for integration and implementation of two proprietary clinical trial management system (CTMS) multiple projects to develop and support and clinical trials office at a large academic medical center.
• Managed and supported the implementation of a proprietary CTMS at three large, prestigious academic medical centers.
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Education
• Bachelor of Science, Cellular and Molecular Biology and Economics, University of Michigan, Ann Arbor, Michigan

Publications
• Contributed industry articles for Health Care Compliance Association’s Compliance Today and Association of Clinical Research professionals (ACRP) Wire.