Implementation and Utilization of A Clinical Studies Management System in Support of Clinical Research Billing Compliance

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The Washington University Clinical Trial Support Infrastructure

Center for Applied Research Sciences (CARS)

- Regulatory Compliance
  - Contract Negotiation
  - Budget Development
  - Billing Compliance
  - IRB/Institutional
  - Good Clinical Practice
  - Protocol Development

Clinical Trial Operations

- Coordinator
- Investigators
- Nursing Support
- Clinical Trial Facilities
- Participant Recruitment
- Research Core Lab

Clinical Trial Support

- Account Setup
- Sponsor Billing/Collection
- Clinical Trial System
- IT Support
Washington University in St. Louis

For Washington University and our affiliated hospitals to advance as leaders in biomedical research and patient care, a world-class, highly integrated and multi-disciplinary clinical studies informational infrastructure became a necessity and a priority.

An electronically integrated clinical studies management system:
- enhances work flow and decreases the manual and often redundant processes required to manage clinical research
- meets the increasing compliance demands
- anticipates growth in clinical research based on NIH’s Clinical and Translational Science Award (CTSA) model

Enterprise-Wide Clinical Studies Management System

Washington University and our affiliated hospitals are deploying an enterprise-wide Clinical Studies Management System (CSMS) that:
- Enhances the use of Good Clinical Practices procedures and other best practices in conducting clinical studies
- Promotes compliance with regulatory authorities, sponsor requirements, and institutional policies
- Addresses the unique requirements of clinical trial billing compliance
- Produces tools and templates for budget and protocol development, study management, financial reconciliation, and data capturing and reporting through electronic case report forms
- Assists the recruitment and retention of clinical study participants and ensures an appropriate distribution of underserved minority participants
mdlogix

- mdlogix, ([www.mdlogix.com](http://www.mdlogix.com)), was chosen as WUSTL’s software partner. The mdlogix Clinical Research Management System provides a scalable, configurable, Web-based solution to facilitate effective collaboration within and between institutions. Other mdlogix clients include Johns Hopkins University.
- The mdlogix system supports the needs of ALL staff across the full clinical trials lifecycle
  - Recruiters
  - Study PIs/Coordinators
  - Regulatory staff
  - Service provider staff
  - Financial and administrative staff
- Addresses regulatory and billing compliance at all stages of the process
- Facilitates efficient and effective trials management and improved research outcomes
- Reduces manual effort and removes duplication of data entry and storage
- Facilitates CTSA collaboration
**System Product Suite**

The mdlogix software system consists of 7 products that integrate with existing institution and hospital systems. Washington University in St. Louis uses:

- Subject Recruitment
- Subject & Protocol Registry
- Protocol Schema & Subject Calendar
- Financial Management
- Data Capture/Forms Builder

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**CSMS**

- Develop protocols in a consistent, standard manner
- Capture all protocol information and leverage to:
  - Negotiate contract
  - 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
**Financial Tools**

- **Protocol Budgeting**: Allows study team to develop a protocol's budget by mapping out the study's procedures over time
  - Develop the study budget from study/patient calendars
  - Consistent application and validation of procedure/service codes and pricing
  - Break-even analysis
- **Billing Compliance**: Automates charge separation of Research and Standard of Care procedures
- **Contract Management**: Allows member of the study team to collaborate on contracts, protocol development, and financials
  - Unified application for managing all aspects of protocol development
- **Reconciliation & Reporting**: Reconciles the initial budget against the actual costs of the study
  - Improve the economies and efficiencies of clinical trials
Recruitment: Research Participant Registry

- Appealing and informative Web site
- Specific questions for improved matching to study inclusion/exclusion criteria
- Linked to institution CSMS, which will allow us to track participants once they have been put on a trial
- Facilitates increased recruitment and enrollment
- Increases the revenue to the institution when studies are filling with subjects
- Provides for attractive site selection to external sponsors knowing that recruitment is a priority in the competitive landscape of trial placement
IRB

- The mdlogix CSMS and Click Commerce eIRB share information on a real-time basis.
- The use of these systems will allow WashU to establish best practice strategies to improve the quality of IRB submissions and communications, thereby speeding the approval process.
- All fields are automatically populated into CSMS from the eIRB.
- Integrating these two systems will significantly reduce redundant data entry, reduce IRB approval times and ensure that there are strong compliance checks regarding IRB approval of protocols, amendments, and consent forms.
- These systems will also introduce a rational efficient and flexible workflow to a current process environment which is ad hoc and inefficient.
Protocol Schema & Subject Calendar

Data Capture/Forms Builder

- Electronic Data Capture: Web-based, user-friendly, scientifically rigorous tool that allows the creation of complex forms for electronic data capture.
  - Validation logic
  - Skip Logic
  - Associate forms with study
  - Forms library
- WYSIWYG (What You See Is What You Get) Editor: Build forms from existing forms/documents, with full feature editing capabilities.
  - Add items from existing form library
  - Set attributes, define validations, define navigation
  - Set comparator
  - Set error messages
- Workflow Management: Control the flow of events across the full clinical trials lifecycle.
  - Identify roles
  - Set permissions
  - Provide views
  - Set notifications and alerts
  - Manage exceptions
Billing and Regulatory Compliance

- The mdlogix system helps institutions prevent billing irregularities, comply with audits, and avoid penalties.
- Manages separation of charges between research and standard of care.
- Handles the billing process from study design to knowing the status of each subject’s events for the research institution.
- Builds a budget that shows the sponsor the component costs of a procedure.
- Allows users to set up billing milestones and track payments from sponsors.

Financial Management

Issues addressed with this software include:

- Regulatory and billing compliance
- Elimination of missed revenue opportunities
- Timely billing and payments
- Improved profitability in clinical trials
- Improved revenues from clinical research
- More effective and efficient processing of the financial aspects of clinical trials
- Improved use of technology-based automation and workflows
- Reduced administrative overhead
- Elimination of human dependencies
- A common framework deployed for the financial management of clinical trials across the ‘enterprise’.
Set Base Costs in Schema Builder

Add / Remove Base Costs for a Procedure

Costs Managed by Provider

Generate a Study Budget

Study Charges & Startup Fees

Per Procedure Charges
Add Costs to a Procedure

Select Cost Type

Click to Edit Any Cell

Change Costs & Update Budget

Edit Effects all columns

or individual cells...

All Effected Cells are highlighted
Subject Billing Report

Patient Billing Report

Patient: [Patient Name]
Study: [Study Name]
Subject Number: [Subject Number]
History Number: [History Number]

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Code</th>
<th>Date Performed</th>
<th>Standard of Care</th>
<th>Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging Studies</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prostate specific studies</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>24-hour urine</td>
<td></td>
<td>06/06/2009</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>CEA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Evaluation</td>
<td></td>
<td>06/06/2009</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Comprehensive Metabolic Panel</td>
<td></td>
<td>06/06/2009</td>
<td>x</td>
<td></td>
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<tr>
<td>Pharmacogenetic studies</td>
<td></td>
<td>06/06/2009</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Hematology (CBC w/diff, ptt)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tumor/Patient sample</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>H&amp;L (total serum, weight, &amp; PED)</td>
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<td></td>
<td></td>
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<tr>
<td>Serum or urine pregnancy test</td>
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<td></td>
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<tr>
<td>CEA</td>
<td></td>
<td>06/10/2009</td>
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<td></td>
</tr>
<tr>
<td>Nurse Evaluation</td>
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<td>06/10/2009</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Billing status for auditing purposes
Based on procedures and dates from Subject calendar

Billers’ View

[Image of Billers’ View interface]

[Image of Billers’ View interface]

[Image of Billers’ View interface]
Billers’ View

**Sponsor Budget Billing**

<table>
<thead>
<tr>
<th>Study Information</th>
<th>Sponsor’s Protocol Number</th>
<th>Study Information</th>
<th>Study Information</th>
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<tbody>
<tr>
<td>Title</td>
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<td>Study Information</td>
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<tr>
<td>Disease</td>
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<td>Study Information</td>
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**Study Contacts**

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<tr>
<td>Principal Investigator</td>
<td><a href="mailto:abbeye@msnotes.wustl.edu">abbeye@msnotes.wustl.edu</a></td>
<td>314-361-5744</td>
<td>314-362-0051</td>
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<tr>
<td>Study Coordinator</td>
<td><a href="mailto:ikratner@im.wustl.edu">ikratner@im.wustl.edu</a></td>
<td>314-362-1171</td>
<td>314-747-2797</td>
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Dashboard

**Budgeted, Invoiced, & Paid**
- **Budget Percentage Utilization**
  - Enrolled: 0%
  - Consented: 0%
  - Remaining: 100%

**Accrual & Enrollment Status**
- **Accrual & Enrollment**
  - Enrolled: 0%
  - Consented: 0%
  - Remaining: 100%

**Details**
- Total Paid: $10,000
- Total Invoiced: $43,349
- Total Budgeted: $232,639

**Budget vs. Invoiced**

**Budget vs. Invoice Detailed**

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**Budgeted vs. Invoice**

**Details**
- **Budgeted**
  - Startup Costs: $1,657
  - Onboarding: $75,793
  - Renewal Fees: $21,327
  - Patient Costs: $125,860
  - Total: $232,639

- **Invoiced**
  - Startup Costs: $5,000
  - Onboarding: $40,305
  - Renewal Fees: $40,305
  - Patient Costs: $43,349
  - Total: $232,639

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**Enrollment Status**
- Enrolled: 2
- Consented: 1
- Remaining: 13
- Projected Accrual (All Sites): 15
Invoices

Invoices for PITT002

Milestones

Milestone List for [Treatment Arm]

Time Period Milestones

Sponsor: PZGER
Name:
Time Period:
Data Status OR Schedule Status:
Count:
Charge:

WUSTL Clinical Studies Management System
Benefits

• A common framework for clinical trials financial workflows across the ‘enterprise’
• Minimized risk of compliance issues
• Study billing decision-making directed to the appropriate source of knowledge
• Significant reduction in manual administrative effort placed on non-clinical studies staff
• Reduced billing rework
• Process efficiencies through use of automated workflows
• Eliminates the need for siloed billing management/tracking systems
• The CSMS becomes the ‘golden source’ for ALL clinical trials data

Questions?

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