Agenda

- Introductions
  - Center for Applied Research Sciences
  - Barnes Jewish Hospital Compliance Department
- Current State: The Billing Matrix
- Future State: Clinical Studies Management System
Washington University in St. Louis
Center for Applied Research Sciences

Assistant Dean Clinical Trials Operations Officer CTSA

• Contract Negotiation
• Budget Development
• Billing Compliance
• IRB Submissions
• Good Clinical Practices
• Protocol Development

Center for Applied Research Sciences (CARS)

Regulatory Compliance

Clinical Trial Operations

Clinical Trial Support

Washington University in St. Louis
Center for Applied Research Sciences

Assistant Dean Clinical Trials Operations Officer CTSA

Administration (6 FTEs)

Cash Receipts, Sponsor Billing, Department Operations

Regulatory / Compliance (11 FTEs)

Research Patient Care Units (42 FTEs)

Coordinators (12 FTEs)

Research Pt. Recruitment (7 FTEs)

• Reports to the Assoc Vice Chancellor Admin & Finance
• Central contracting, budgeting and billing compliance
• Optional services include patient recruitment and study coordination support
Current State: The Billing Matrix
The Front End Process to Identify Clinical Trials & Register Patients

MAIN MENU

Create a New Study Profile
Create a New Billing Matrix
Find/Edit an Existing Profile & Matrix
Enroll a Patient
View Procedure & Event Tree
View Report

User: MEDPRO/Temp/Admin [SERVER INDEPENDENT]
Current State: The Billing Matrix
The Front End Process to Identify Clinical Trials & Register Patients

**Center for Applied Research Sciences (CARS)**

888-580-8373 | www.hcca-info.org
### Study Information

- **Study Type**: 114
- **Endpoint Target (number of patients)**: 
- **NET Enrollment Number of Patients**: 
- **NET Randomized Enrollment Number**: 
- **NET Randomized Enrollment Start Date**: 
- **NET Randomized Enrollment End Date**: 
- **Total Phase**: FULL BOARD
- **Protocol Type**: FULL BOARD
- **TBS Submission Date**: 12/07
- **IATA Category A (drug only)**: 
- **IATA Category A (device only)**: 
- **IATA Category A (drug + device)**: 
- **ENR Drug Overall**: 
- **ENR Device Overall**: 
- **Class 1 Cancer Drug**: 
- **Class 2 Cancer Drug**: 
- **Class 3 Cancer Drug**: 
- **Class 4 Cancer Drug**: 
- **Class 5 Cancer Drug**: 
- **EMI, impact, IMRT, or Exact**: 
- **Significant Risk**: 
- **Significant Risk Device**: 
- **Significant Risk Device**: 
- **Federal Funds Being Requested for the Study**: 
- **RD 209A by Patient (Insurance)**: 
- ** RD 209A in Research Fund**: 
- **FIS Fund Number**: 041000
- **Study Number**: 0410000
- **Study Start Date (mm/dd/yyyy)**: 01/01/0001
- **Projected Study (grant or contract) End Date**: 01/01/0001
- **Actual Study End Date**: 01/01/0001
- **Approved Memorial Date**: 01/01/0001
- **Study Coordinator or Contact Name**: TERESA ARB
- **Study Contact Email**: arb@monastix.wustl.edu
- **Study Contact Phone**: 314-447-1237
- **Study Contact Fax**: 314-447-1404
- **Billing or Financial Contact Name**: COURTNEY AGREE
- **Billing Contact Email**: acnec@monastix.wustl.edu
- **Billing Contact Phone**: 314-402-6518
- **Billing Contact Fax**: 314-402-6518
- **Sponsor Contact Name**: 
- **Sponsor Contact Email**: 
- **Sponsor Contact Phone**: 
- **CTS Complete Flag**: 
- **Form Last Modified Date**: 05/06/2006 16:34:30
- **Form Last Modified By**: MEDPRIV/unknown

### Other Information

- **Save**
- **New**
- **Clone**
- **Refresh**
- **Updated By**: [User]
Current State: The Billing Matrix

The Front End Process to Identify Clinical Trials & Register Patients
Current State: The Billing Matrix
The Front End Process to Identify Clinical Trials & Register Patients

Names of patients that would populate these fields have been intentionally left blank to protect patient privacy.

Note: The patient information in this screen shot is fictitious data.
Current State: The Billing Matrix
The Back End Process to Screen Patient Bills

• Insurance Plan Code Creation & Application

[Illustration of form with fields filled in]

1. Principal Investigator is the guarantor of payments to BIM on Patient Accounts Bills. Therefore, Bills are mailed to the PI.

Please return requested information to BIM Clinical Trial Compliance Manager, CAS Finance, Room 120A, 2:00-00
Current State: The Billing Matrix
The Back End Process to Screen Patient Bills

- Protocol Adaptation (Clinical Trial Profile)

Current State: The Billing Matrix
The Back End Process to Screen Patient Bills

- Protocol Adaptation (Protocol to Service Code Mapping)
Current State: The Billing Matrix  
The Back End Process to Screen Patient Bills

- Protocol Adaptation (Protocol to Calendar Mapping)

PROTOCOL MAINTENANCE

TRIAL ID: 000000000029
TIMEFRAME: Possible repeat 3 times o

(protocol maintenance details)

ENTER TO EDIT OR USE KEYS TO UPDATE
ENTER-EDIT HELP PRE-NEXT PRE-PREV PRI-DC PRI-FRESH

Protocol Adaptation Summary

Current State: The Billing Matrix  
The Back End Process to Screen Patient Bills

- Protocol Adaptation Summary
Current State: The Billing Matrix
The Back End Process to Screen Patient Bills

- Data Management & Claims Suspension Processes

### Current State: The Billing Matrix - The Back End Process to Screen Patient Bills

#### Data Management & Claims Suspension Processes

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<th>Comments</th>
<th>TimeFrame</th>
<th>CPBD</th>
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# Current State: The Billing Matrix - The Back End Process to Screen Patient Bills

#### Clinical Trial Work Aid for Patient Financial Services - Biller

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Future State

Future State: Clinical Studies Management System

For Washington University and BJC Healthcare 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 BJC Healthcare 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

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
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

Fully Integrated CSMS

Configurable to the client’s workflows and systems
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
Welcome to the Washington University School of Medicine Research Participant Registry, which helps researchers find qualified study participants. The School of Medicine is one of the world's largest and most respected medical research centers, where quality and safety are top priority.

By participating in a clinical trial, you not only gain access to a new investigational treatment before it becomes widely available, but also help others by contributing to medical research.

By registering, you inform us that you are interested in participating. When a study comes up for which you may be qualified, you may be contacted to determine your interest and eligibility.

Membership in the registry does not obligate you to participate in any study; you are always free to say no. You may remove or modify your registry entry at any time. You can ask us to remove your information by using either mode of communication you choose, i.e., phone, fax, or email at ihcavolunteers@wustl.edu. You can also ask us to modify your information or you can do this on your own by accessing the website with the information you provide in the registry is kept completely confidential, in compliance with federal law and Washington University policies.

The Research Participant Registry is a one of many research recruitment services offered by the Recruitment Enhancement Core of the Washington University School of Medicine Center for Clinical Studies.

Frequently asked questions about the registry:

Washington University HIPAA Privacy Policy | Terms of Use | Copyright 2000, Washington University School of Medicine
Dear Volunteer,

We invite you to join the Washington University Research Participant Registry. Every person can contribute by becoming a member of this national online resource.

To become a member of the Research Participant Registry, please complete the following:

Step 1: Register
Choose your RPR password, and provide your email address. You'll receive an email confirmation of your registration. Click on the link in the email to confirm your registration.

Step 2: Complete Consent Form
Log into RPR by using your RPR password. Read, complete and give your consent. You will provide basic information about yourself and agree to participate.

Step 3: Complete Questionnaire
Complete the General Health Questionnaire and Medication checklist. Answering these questions accurately will increase your chances of qualifying for the clinical trials that are right for you.

Register for RPR

- Choose your RPR ID
- Choose your password
  - Password must be at least 6 characters.
- Enter your email address
  - You will be sent an email to confirm your account registration.
- Enter your email address again
- Register

Subject & Protocol Registry

[Image of a web interface for Subject & Protocol Registry]

HCCA - Research Participants

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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'.

Barnes Jewish Hospital Research Workflow - Financials Example
St. Louis Children’s Hospital Research Workflow – Financials Example

Set Base Costs in Schema Builder

Add procedure

Select Procedure Type: Imaging Procedure

Procedure

Add / Remove Base Costs for a Procedure

Cost Components

Technical Fee
Professional Fee
Prints & Shipping
Add Cost/Charge
Labor Fee
Other Fee

Cost
2.112.00
0.00
0.00
0.00
0.00

Charge
125.00
1
1
1

Quantity
CCIR
Physician
CCIR

Provider
CCIR

Location

Procedure (Edit) | Budget (Edit)

Costs Managed by Provider
### Generate a Study Budget

#### Study Charges

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<tr>
<th>Name</th>
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<th>Start</th>
<th>Change</th>
<th>Budget</th>
<th>Total</th>
<th>Add On</th>
<th>Total</th>
<th>Add On</th>
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#### Procedure Charges

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### Add Costs to a Procedure

#### Procedure Charges

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**Select Cost Type**

**Click to Edit Any Cell**

**Per Procedure Charges**

**Study Charges & Startup Fees**
Change Costs & Update Budget

Subject Billing Report

Based on procedures and dates from Subject calendar

Billing status for auditing purposes

All Effected Cells are highlighted

Edit Effects all columns or individual cells...
# Billers' View

## Study Information

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<tr>
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<th>Value</th>
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<td>Sponsor</td>
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<td>Category</td>
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<td>Status</td>
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<td>Phase</td>
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<td>Research / Standard of Care?</td>
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<td>Cancer Trial?</td>
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<tr>
<td>Class C Cancer Drug?</td>
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## Study Contacts

### Principal Investigator

<table>
<thead>
<tr>
<th>Name</th>
<th>E-Mail</th>
<th>Phone</th>
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</thead>
<tbody>
<tr>
<td>Abbe, Gisele</td>
<td><a href="mailto:abbeve@manothes.wustl.edu">abbeve@manothes.wustl.edu</a></td>
<td>314-365-5744</td>
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### Study Coordinator

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<tr>
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<td><a href="mailto:iratner@im.wustl.edu">iratner@im.wustl.edu</a></td>
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### Billing Coordinator

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<tbody>
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<td>???</td>
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## Sponsors
Billers’ View

Billing Automation

CSIMS
Clinical Trial System Manager

BPHN
Barnes Jewish Hospital Patient Registration System

SOF MED
Health Information Management

SMS
Patient Accounts System

Comparison

Trial Data

Q and Q Modifiers (Instruction on Claims Splitting)

BM
Claims Scrubber

Quality Review

Sponsor

Payer

8371 Claim Split Modifiers Appended

Charge Corrections

8371

EMIA

EMIA

EMIA

Trial Site

BPHN

SOF MED

Billers’ View

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Dashboard

Reconciliation Dashboard for PIT7922

Budgeted, Invoiced, & Paid

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<th>Budgeted</th>
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Budget vs. Invoiced

<table>
<thead>
<tr>
<th>Budget vs. Invoice Detailed</th>
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</table>

Accrual & Enrollment Status

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<tr>
<th>Enrollment Status</th>
<th>Count</th>
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<tbody>
<tr>
<td>Enrolled</td>
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<tr>
<td>Consented</td>
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<tr>
<td>Remaining</td>
<td>12</td>
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<tr>
<td>Projected Accrual (All Sites)</td>
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</tbody>
</table>

Budgeted vs. Invoice

<table>
<thead>
<tr>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Invoiced</td>
</tr>
<tr>
<td>Total Budgeted</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Budget vs. Invoice Detailed</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Startup Costs</td>
</tr>
<tr>
<td>Invoiciable</td>
</tr>
<tr>
<td>Manual Fees</td>
</tr>
<tr>
<td>Patient Costs</td>
</tr>
<tr>
<td>Total</td>
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</tbody>
</table>
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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