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

Pam Joy, RN, MN
Seattle Children’s Hospital Research Institute

Seattle Children’s Research Institute

• Leadership Structure
  – President - James B. Hendricks, PhD
  – Vice President, Research Operations and Logistics - Erik M. Lausund
  – Chair, Center Directory Advisory Committee; Chief Academic Office; Senior Vice President, Children’s Hospital – F. Bruder Stapleton, MD
  – Research governance is organized around Research Centers with a common thematic focus and an identifiable core set of programs to promote and encourage interdisciplinary research.
    • Centers include faculty from multiple disciplines, departments and divisions.
    • The mission and programs of each center is aligned with the Hospital’s and Institute’s overall strategic goals and priority programs.
  – Research Executive Committee (REC) – the strategic, financial and policy-making body for the research enterprise.
  – Center Director Advisory Committee (CDAC) – Represents Research Centers in the governance structure through the Center Directors and ex-officio members.
Facts about the Research Institute

• Funding/Budget
  – The Institute receives about $33 million in extramural funding.
  – This year, approximately $20 million was funded by the NIH and other federal sources.

• Capital Investments
  – Initial investments procured approximately 500,000 square feet of research space in Seattle’s Downtown/South Lake Union area with proximity to other basic science facilities, including the Fred Hutchinson Cancer Research Center and the University of Washington’s South Lake Union development.
    • The Research Institute currently occupies approximately 200,000 square feet of that space, which includes a new 10,000 cage vivarium.
  – Subsequent investment is projected to contribute an additional 900,000 square feet.

Focus for Today

Practical, real world experience of what it takes for successful deployment of an off-the-shelf clinical trial management system (CTMS) to support clinical research billing compliance.

Seattle Children’s implemented StudyManager™ to:

• Manage research billing compliance with greater accuracy and fewer resources
• Centralize documentation of research visit activity
• Facilitate auditing of clinical research billing
StudyManager™

- Developed and distributed by Advanced Clinical Software (ACS)
  - Seattle-based leading provider of clinical trial software
  - 15 years in business
  - Mature & stable
    - Privately held, no venture capital
    - Large number of active, multi-year contracts
    - Flagship product is currently in its 13th generation
    - Thoroughly vetted & proven within the industry
  - Focus is exclusively clinical research management
  - Designed for multi-department operations with hundreds of users

Institutions Using StudyManager™

- Currently more than 1,800 unique and active installations including:
  - Seattle Children's
  - Baylor College of Medicine
  - National Institutes of Health
  - Indiana University / Perdue University
  - Swedish Hospital – Seattle
  - Medical College of Georgia
  - Children's Medical Center Dallas
  - University of North Texas - Health Science Center
  - Children's Hospital of Orange County
  - Ontario Institute for Cancer Research
  - Columbia University
What is StudyManager™?

- A Web-based clinical trial management system
  - Makes the process of conducting clinical trials more organized and efficient
  - CTMS Modules (Studies, Patient, Financial, Report Builder Modules)
  - Easy to use “point-and-click” application
  - Central, real-time record of research projects, enrollment statistics & financial status
    - Creates budgets, and tracks financial data associated with studies
    - Tracks research patient visits and procedures
  - Advanced security & compliance features
    - Authenticated system access & password aging
    - Data partitioning – role-based access & user permissions
    - Auditable record of all activity
  - Determine a project’s costs prior to sponsor negotiation
  - Source for reconciliation & compliance auditing
    - Automatic revenue accrual
    - Create & send sponsor invoices
    - Report Builder – easily customize & share results

Implementation – What Did It Take?

- Institutional support
- Well defined implementation plan
- 100+ meetings
- 12 new policies
- 11 articles in *interaction*
- 11 business processes (8 revised, 3 new)
- 6 Leadership presentations
- 5+ new forms
- 2 risk analysis consultations
- 2 user manuals
- 1 website
- 1 CTMS deployed!

Time to Launch = 18 months
What You Need

- Clear goals, consistently and visibly supported by Leadership
- A good team and realistic expectations
- Policies, processes and other tools necessary for success prior to Go Live
- Partnership with representatives of key areas and end users during implementation
- Ongoing monitoring of StudyManager™ utilization and enforceable consequences of non-compliance

StudyManager™ Utilization

First 6 Months of Go Live

<table>
<thead>
<tr>
<th>Number of Divisions</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Trained Users</td>
<td>11</td>
</tr>
<tr>
<td>Research Visits</td>
<td>205</td>
</tr>
<tr>
<td>Research Procedures</td>
<td>1412</td>
</tr>
<tr>
<td>Research Dollars</td>
<td>$37,111</td>
</tr>
</tbody>
</table>
StudyManager™ Utilization

Current
(21 Months)

Number of
Divisions
20

Number of Trained Users = 62

Research Visits
1310

Research Procedures
9955

Research Dollars
$148,411

95 total studies in StudyManager™

---|---|---|---|---|---|---
4 | 17 | 23 | 32 | 56 | 72 | 95
Sponsor Distribution

Research Billing Compliance
Research Compliance - Essential Elements

- Investigator maintains primary responsibility for study design, implementation & conduct
- **Compliance is not optional!**
  - Consistent communications from Leadership
  - Policies established to clarify processes
  - Processes are standardized
  - Centralized data systems
  - Regular education, communication & training
### StudyManager™ Utilization & Compliance Policy

#### Elements
1. All clinical Research Studies that involve billable patient procedures are required to utilize StudyManager to create budgets and track research participant activity.
2. All research participants will be entered in StudyManager and all activity tracked.

#### Compliance Issues
1. Creates database that allows for billing compliance QA audit activity.
2. Ensures adherence to billing compliance requirements of payers and federal policies, as well as institutional (Children's and UW) and practice plan requirements.

#### Impact
1. Allow research teams to monitor activity of their studies.
2. Clarifies Investigator and staff accountability: Failure to comply will result in corrective action up to and including suspension of an Investigator’s clinical research activity.
3. “Real time” research activity data will allow more efficient and complete auditing of research billing.

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### Clinical Trial Start Up Policy

#### Elements
1. It is the responsibility of the Investigator to ensure the following are in place prior to initiating a clinical trial:
   - Final IRS & SAC (if applicable) approval.
   - Executed contract or grant.
   - Designated research staff with required training completed.
   - Larson activity number.
   - Notification to and endorsement from the Hospital service area being utilized.
   - All study supplies, documents, and equipment available.
   - Completed Protocol Implementation Meeting (PIM).
   - Verification of study entry into Study Manager by the DSR.

#### Compliance Issues
1. Clinical research trials will be implemented in an efficient, organized and compliant manner.

#### Impact
1. All study start up requirements will be completed prior to study initiation.
2. Clinical services will be consulted with and made aware of research that will occur in their service area prior to initiation of the study.
StudyManager™ Utilization Non-Compliance Guideline

1st Instance of Non-Compliance (in last 12 months)

E-mail from Compliance Officer to staff member reporting initial finding of StudyManager non-compliance with policy attached. Opportunity for additional training or discussion available.

2nd Instance of Non-Compliance (in last 12 months)

E-mail from VP of Research to PI (cc to Center Director, Chief Academic Officer, Research HR, and President of Research Institute) indicating continued findings of StudyManager non-compliance will result in suspension of research activities. Copy of StudyManager Utilization policy attached. Additional training and discussion required.

3rd Instance of Non-Compliance (in last 12 months)

Letter e-mail and hard copy from Compliance Officer and VP of Research to PI (cc to President of Research, Center Director, Chief Academic Officer, Research HR, IRB and Departmental Chief) regarding repeated findings of StudyManager non-compliance. Policy attached. Research activity suspended.

Quarterly reports of all Level 2 cases will be submitted to CDAC.

Back to L2 for 1 year. If no violations, back to L1.

Investigator to develop and submit a corrective action plan for ensuring compliance to Compliance Officer. Compliance Officer evaluates the corrective action plan. Does it adequately address the compliance violation?

NO

YES

Investigator must revise and resubmit corrective action plan.

Quarterly reports of all Level 2 cases will be submitted to CDAC.

1st Instance of Non-Compliance (in last 12 months)

Level 2 non-compliance will result in a notation of research billing non-compliance in the HR personnel file.

Level 3 non-compliance will result in a notation of research billing non-compliance in the personnel file. Repeated offenses totaling two or more at Level 3 in one year may lead to employee dismissal.

Reports of all Level 2 cases and corrective action plans will be submitted to CDAC.

1 year of no StudyManager compliance issues

If StudyManager non-compliance not corrected in 5 business days, case advances to the next level.
Key Areas

Budgeting → Enrollment and Tracking → Billing Review

Accurate budgets and corresponding billing plans, together with accurate procedure data, are the foundation for billing compliance assurance.

Budgeting
Budgeting: Essential Elements

- Centralized process
  - Review of protocol
  - Identification of all procedures/costs
  - Delineation of Research Care vs. Standard of Care Event
  - Contract Negotiation
- Standardized pricing
- Investigator sign off on budget
- Notification of study entry in StudyManager™ to research team

Clinical Trial Budget Creation Policy

<table>
<thead>
<tr>
<th>Elements</th>
<th>Compliance Issues</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Defines a standard process for generating the SM budget document</td>
<td>1. Implements compliance elements, consistently performed and consistently</td>
<td>1. Standard budget document with standard (known, predictable, equitable) pricing is produced.</td>
</tr>
<tr>
<td>consistent w/ pricing policy, financial responsibility analysis</td>
<td>documented.</td>
<td>2. All research costs are considered, included and computed in a budget</td>
</tr>
<tr>
<td>policy, and other information.</td>
<td>2. System enforced Investigator approval.</td>
<td>3. Industry sponsored research will not be subsidized by Children’s Hospital</td>
</tr>
<tr>
<td>2. Requires Investigator review and approval of same.</td>
<td></td>
<td>4. Investigator involvement in process (approval requirement).</td>
</tr>
</tbody>
</table>
Financial Responsibility Analysis Policy

Elements

1. All research with billable events will be analyzed to determine which care events are standard of care vs. research.
2. Requires investigator review and approval of same.

Compliance Issues

1. Consistent method for determination performed by designated staff.
2. Consistent documentation.
3. System enforced investigator approval.

Impact

1. Correct delineation of patient care costs.
2. Investigator involvement in process (approval requirement).

The FRA

Financial Responsibility Analysis
## Standard of Care vs. Research Care

### StudyManager™ Report Screenshot

**Change to Standard of Care in Screenshot**

<table>
<thead>
<tr>
<th>Visit Date: 06/10/2003</th>
<th>Visit Name: screening</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse Events Review</strong></td>
<td>Research $93.00</td>
</tr>
<tr>
<td><strong>BNP</strong></td>
<td>Research $95.07</td>
</tr>
<tr>
<td><strong>Chemistry profile</strong></td>
<td>Standard of Care $0.00</td>
</tr>
<tr>
<td><strong>Coagulation profile</strong></td>
<td>Standard of Care $0.00</td>
</tr>
<tr>
<td><strong>CRA Case Report Form (CRF)</strong></td>
<td>Research $9.00</td>
</tr>
<tr>
<td><strong>Completion/Submission</strong></td>
<td>Research $9.00</td>
</tr>
<tr>
<td><strong>ECG/EKG or MRI</strong></td>
<td>Standard of Care $0.00</td>
</tr>
<tr>
<td><strong>Electrocardiogram (ECG)/EKG</strong></td>
<td>Standard of Care $0.00</td>
</tr>
<tr>
<td><strong>GGT</strong></td>
<td>Research $19.14</td>
</tr>
<tr>
<td><strong>Height &amp; Weight</strong></td>
<td>Standard of Care $0.00</td>
</tr>
<tr>
<td><strong>Hematology panel</strong></td>
<td>Standard of Care $0.00</td>
</tr>
<tr>
<td><strong>NOS</strong></td>
<td>Research $48.72</td>
</tr>
<tr>
<td><strong>OCT-1</strong></td>
<td>Research $48.72</td>
</tr>
</tbody>
</table>

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## Enrollment and Tracking
Enrollment & Tracking: Essential Elements

- Centralized Process
  - Entry of Study in StudyManager™
  - Enrollment of study participants in StudyManager™
  - Tracking visits/completed procedures in StudyManager™
  - Coordinator Training
- Standardized Research Requisitions

Notice of Study Entry in StudyManager™

Notice of Study Entry in StudyManager

<table>
<thead>
<tr>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To: PI: Primary Study Contact:</td>
</tr>
<tr>
<td>From: Michelle Dolan, RN, BSN Clinical Trial Coordinator Office of Sponsored Research</td>
</tr>
<tr>
<td>Re:</td>
</tr>
<tr>
<td>Attachments: CTM 100 Study Manager Utilization &amp; Compliance Policy Schedule of visits and procedures report</td>
</tr>
</tbody>
</table>

The above referenced study has been entered into StudyManager. Please review attached schedule of visits and procedures as they have been entered into StudyManager and notify me if there are any discrepancies with the protocol. Otherwise, tracking of all participants and completed procedures should commence with enrollment of the first research participant.

Per policy CTM-100, all clinical research studies that involve billable research tasks are required to utilize StudyManager. Additionally, patient enrollment status and documentation of completed study procedures in StudyManager should occur immediately during the research participant visit. Please refer to the policy for additional information regarding StudyManager utilization and compliance.

If you do not already have a StudyManager account you must complete a StudyManager Account Request Form located on the Children’s Research Web site at http://research.soundchildrens.org/studymanager_account_request_form.jsp and e-mail it to Clar Viadero, Study Manager Administrator. Upon receipt of the StudyManager Account Request Form, you will be notified to setup a Thanksgiving.

If you already have an account and have received training you may proceed with tracking participant data in StudyManager. Do not hesitate to contact Clar Viadero if you have any questions or require additional training.

Additional information about StudyManager is located on the DCEC StudyManager Web site located on the Children’s Research Web site at http://research.soundchildrens.org/studymanager.asp.
Enrolling Participants

- Basic patient information is added to the StudyManager patient database.

- Patients are “enrolled” in the pre-built study in StudyManager.

Tracking Participant Activity

- Research participant visits are recorded by adding visits.

- Procedures are checked off as complete and dates of service are recorded.
Revised Requisition Process

- New Research Requisitions
  - The new form has an easy to read layout with clear instructions regarding the information required.
  - Research Requisitions are used for:
    - Scheduling
    - Ordering
    - Billing
Billing Review: Essential Elements

- Centralized Process
  - Dedicated reviewer in a centralized office
    - Needs both clinical and research experience
  - Data is centrally located
  - Correcting errors

- Continuous Review Schedule
  - Quarterly & at study completion

- Participation of Investigator & Research Team
  - Process for education/training
  - Consistent consequences for non-compliance

Previous Review Process
StudyManager™ Review Process

Access participant activity in StudyManager

Access billing information in EBSS

Compare data to identify billing errors

Contact CRA to review any discrepancies

Notify Business Services of Errors

Document findings in audit report

Make Research Account Corrections

Make Patient Account Corrections

Reviewing Research Patient Care Cost Compliance Policy

**Elements**
1. Monitors all clinical trials activity conducted at Children’s.
2. Monitors clinical trials quarterly until completion.
3. Monitors to confirm successful transfer of research funds.

**Compliance Issues**
1. Ensures effectiveness of research patient procedure charge direction.
2. Provides data to enable correction of errors.
3. Identifies charge errors in a timely manner.

**Impact**
1. Errors (charge direction and dollar amounts) are corrected.
2. Mandates cooperation of Investigator and Research staff to assist in clarification when faced with apparent errors.
3. Ensures appropriate clinical trial account residual.
Research Billing Compliance

Research Billing Compliance Notice

Date:
To:
CC:
From: Pam Agy, RN, MN, NEA, Director, Office of Clinical Research
Re: Notice of Research Billing Compliance Issues

Children’s is committed to compliance in Clinical Research and Research Patient Care Billing. It is the responsibility of investigators and their staff to ensure that billing for clinical research studies accrues only as appropriate and in compliance with relevant laws, regulations and Children’s policies.

Study Reviewed:
Principal Investigator:
Primary Study Contact:

Research Billing Compliance Error:
☑ Research procedure billed to insurance/patient

Research Billing Business Errors:
☑ Incorrect research account billed
☑ Research participant registration not created or expired
☑ Research procedure ordered on CUS instead of as paper requisition
☑ Procedure not billed
☑ Incorrect research account billed to research account
☑ Other: Billed procedures don’t match protocols.

Additional Details:

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Research Billing Error Resolution Policy

Elements
1. Rectify any clinical research patient care cost charge direction errors immediately upon identification.

Compliance Issues
1. Corrects inappropriately billed activity.
2. Provides documentation of institutional commitment to compliance.

Impact
1. Billing errors will be corrected in a timely manner, reducing compliance risk and ensuring all Hospital costs are compensated.
Education and Training Resources

Children’s StudyManager™ Web Site

StudyManager

StudyManager is a widely used and proven Clinical Trials Management System (CTMS). A CTMS helps users manage all aspects of clinical trials planning, tracking, and reporting.

StudyManager has been deployed at Seattle Children's as a major tool for monitoring billing compliance related to research activity.

StudyManager is being used by investigators, research staff, and research support staff to develop budgets and track all study events for all new clinical research since January 1, 2007.

StudyManager is a web-based database that requires no installation on desktop computers. Study information can be accessed from anywhere using Internet Explorer and a Children’s StudyManager account.

Contact Us

If you have any questions related to the recent ACS webinar on Children’s implementation of StudyManager for research billing compliance, or if you would like to request forms or other documentation, please e-mail Research Help.

For Children’s Staff

If you have any questions about StudyManager, please contact Clinton Voices.

StudyManager Links:

- StudyManager Program
- Launch Children's StudyManager Program

Overview of StudyManager

- StudyManager Overview Presentation (PDF 1.8MB)
- StudyManager FAQ's
- StudyManager Policies
- CTR-215 Study Manager Utilization and Compliance (PDF 66KB)
- Clinical Research Across Sites (CRAC) (PDF 1.5MB)
- CTR-203 Clinical Trial Budget Creation (PDF 29KB)
- CTR-207 Auditing Research Patient Care Cost Compliance (PDF 17KB)
- CTR-208 Clinical Research Staff Qualifications (PDF 34KB)

StudyManager User Guidance

User Guide documentation is provided for reference:

- User Guide: Compliance (PDF 29KB)
- User Guide: Operating StudyManager (PDF 40KB)
- User Guide: Adding a Patient to the StudyManager Database (PDF 26KB)
- User Guide: Ongoing & Patient StudyManager (PDF 59KB)
- User Guide: Adding a Visit Checklist (PDF 6KB)
- User Guide: Ongoing Compliance (PDF 1.9MB)
- Formative Feedback Guide (PDF 20KB)
- Changing or Retrieving Information (PDF 23KB)
- Review of StudyManager Terms (PDF 34KB)
- System Requirements (PDF 20KB)
Research Billing Compliance Webpage

Clinical Research Billing Compliance at Seattle Children’s

Seattle Children’s is committed to compliance in clinical research and research patient care billing. It is the responsibility of investigators and their staff to ensure that billing for all clinical research studies occurs in an appropriate and in compliance with relevant laws, regulations, and Children’s policies.

All investigators and research staff involved with studies that include clinical services for research participants at Children’s need to be familiar with and adhere to all research billing processes and policies.

The Office of Research Compliance and Education (OCRE) presents regular seminars on clinical research billing compliance as well as other compliance issues through their Fundamentals of Clinical Research webinar series. View a copy of the webinars on the Clinical Research Billing Compliance page.

Tactical Children’s (TRC) offers a Clinical Trial Management Software, clinical trial research support and billing services. For more information, please visit the TRC website.

Clinical research billing compliance policies

There are several Clinical Trials Management (CTM) policies at Children’s that provide guidance with regard to research billing compliance. View the CTM policies.

Helpful Links

<table>
<thead>
<tr>
<th>Website/Resource</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Compliance Programs (<a href="http://www.ctr.gov">www.ctr.gov</a>)</td>
<td>Learn about clinical research compliance programs.</td>
</tr>
<tr>
<td>Unit Medicine Billing Compliance in Clinical Research Policy</td>
<td>Policies related to unit medicine billing.</td>
</tr>
<tr>
<td>Unit Medicine Research Compliance</td>
<td>Policies related to unit medicine research.</td>
</tr>
<tr>
<td>Office of Research General (ORG) Compliance</td>
<td>Policies related to research general compliance.</td>
</tr>
</tbody>
</table>

Clinical Trials Management Policies

Clinical Trials Management Policies

Unless otherwise noted, the following policies are in PDF format.

<table>
<thead>
<tr>
<th>#</th>
<th>Title</th>
<th>Revised</th>
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</thead>
<tbody>
<tr>
<td>CTR-100</td>
<td>Study Manager Utilization and Compliance</td>
<td></td>
</tr>
<tr>
<td>CTR-105</td>
<td>Study Manager Security</td>
<td></td>
</tr>
<tr>
<td>CTR-200</td>
<td>Research Patient Procedure Filing</td>
<td></td>
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<tr>
<td>CTR-204</td>
<td>Financial Responsibility Analysis</td>
<td></td>
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<tr>
<td>CTR-202</td>
<td>Clinical Trial Budget Creation in StudyManager</td>
<td></td>
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<td>CTR-203</td>
<td>Effecting Research Protocol Cost Transfer</td>
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<td>CTR-206</td>
<td>Clinical Trial Contract Negotiation</td>
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<tr>
<td>CTR-207</td>
<td>Subject Research Patient Case Cost Compliance</td>
<td></td>
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<tr>
<td>CTR-208</td>
<td>Clinical Research Patient Case Cost Change Review</td>
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<td>CTR-300</td>
<td>Clinical Research Staff Qualifications</td>
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<td>CTR-307</td>
<td>Clinical Research Associate Care</td>
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<tr>
<td>CTR-512</td>
<td>Outpatient Research Participant Registration</td>
<td></td>
</tr>
<tr>
<td>CTR-313</td>
<td>Clinical Trial Start Up</td>
<td></td>
</tr>
</tbody>
</table>
Research Billing Compliance Web Module

- **Research Billing Compliance v1.0**
- Created 20 min module
  - input from
    - research staff
    - research and hospital leadership,
    - Epic implementation team
    - research support services.
- Step by step information on:
  - Harmonizing study documents
  - Monitor blue sheets in Epic
- **Summary**
  - Mandatory for CCTR research staff.
  - Plan to create version for investigators.
What did Seattle Children’s gain?

• A systematic approach to research billing compliance
• Documented Standard of Care and Research Care Events
• Centralized repository of searchable study activity
• Standardized process for budgeting and pricing
• More efficient audit process using easily accessible, real time data

Pros and Cons of Out-of-box system

• Pros
  – Tested product
  – Vendor support resource with experience from other sites
  – Less need for institutional IT support
  – Focus more on institutional implementation vs. product development

• Cons
  – Decreased flexibility in functionality, workflow and appearance
  – Potential challenges working with vendors
  – Increased costs for additional licenses
  – System may not be as easy to integrate with other institutional systems
Questions/Comments
The Washington University Clinical Trial Support Infrastructure

Center for Applied Research Sciences (CARS)

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

Clinical Trial Operations

- Coordinators
- Biomarkers
- Nursing Support
- Clinical Trial Facilities
- Participant Recruitment
- Research Core Lab

Clinical Trial Support

- Account Set-up
- 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), 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
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
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.

Be a part of the solution

By participating in a clinical trial, you not only gain access to a new investigational treatment before it widely available, but also helping 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 refuse or modify your Registry entry at any time. You can ask us to remove your information by whichever mode of communication you choose, i.e., phone, fax, or email at info@hcca.org. You can also ask us to modify your information if you can do this on your own by accessing the website and the information you provide in the Registry is kept confidential, in compliance with federal and Washington University policies.

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

Frequently asked questions about the registry:

Washington University IRB 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 username and provide your email address. We'll send you 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 the 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.

---

Subject & Protocol Registry

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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<tbody>
<tr>
<td>Protocol Number</td>
<td>BT-035</td>
</tr>
<tr>
<td>PI's Name</td>
<td>P. J. McShane</td>
</tr>
<tr>
<td>Institution</td>
<td>Washington University</td>
</tr>
<tr>
<td>Study Category</td>
<td>Clinical Trials</td>
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<tr>
<td>Primary Sponsor</td>
<td>Washington University</td>
</tr>
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<td></td>
</tr>
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</tr>
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<td>End Date</td>
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<td>Clinical Trials</td>
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<td>Sites</td>
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<td>Primary Investigator</td>
<td></td>
</tr>
<tr>
<td>Secondary Investigator</td>
<td></td>
</tr>
<tr>
<td>Co-Investigators</td>
<td></td>
</tr>
<tr>
<td>Principal Investigator</td>
<td></td>
</tr>
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<td>Co-Investigator Type</td>
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</tr>
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<td>Clinical Trials Type</td>
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<td>Sponsor</td>
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</tr>
<tr>
<td>PI's Email</td>
<td><a href="mailto:pjmshane@washington.edu">pjmshane@washington.edu</a></td>
</tr>
<tr>
<td>.pi's Phone</td>
<td>301-265-3700</td>
</tr>
<tr>
<td>PI's Fax</td>
<td>301-265-3701</td>
</tr>
<tr>
<td>PI's Address</td>
<td>4601 California Ave</td>
</tr>
<tr>
<td>Country</td>
<td>United States</td>
</tr>
<tr>
<td>State</td>
<td>Washington</td>
</tr>
<tr>
<td>City</td>
<td>St. Louis</td>
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<td>CCR Number</td>
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<td>CCR Fax</td>
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<td>P. J. McShane</td>
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<tr>
<td>CCR PI Zip Code</td>
<td>63108</td>
</tr>
</tbody>
</table>
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 (Edit) | Budget (Edit)

Procedure

MRI: 0100501
Name: MRI Brain w Stem w Perf, Description:

Cost Components

<table>
<thead>
<tr>
<th>Cost</th>
<th>Charge</th>
<th>Quantity</th>
<th>Provider</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>2212.00</td>
<td>2500.00</td>
<td>1</td>
<td>CCIR</td>
<td>CCIR</td>
</tr>
<tr>
<td>0.00</td>
<td>185.00</td>
<td>1</td>
<td>Physician</td>
<td>CCIR</td>
</tr>
<tr>
<td>0.00</td>
<td>65.00</td>
<td>1</td>
<td>CCIR</td>
<td>CCIR</td>
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</table>

Add / Remove Base Costs for a Procedure

Costs Managed by Provider
Generate a Study Budget

Study Charges

<table>
<thead>
<tr>
<th>Item</th>
<th>Fixed Cost</th>
<th>Change</th>
<th>Total</th>
<th>Unit Cost</th>
<th>Total Cost</th>
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</thead>
<tbody>
<tr>
<td>Gross</td>
<td>0.00</td>
<td>200.00</td>
<td>200.00</td>
<td>0.00</td>
<td>200.00</td>
</tr>
<tr>
<td>Add Change/Cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>200.00</td>
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</tbody>
</table>

Study Charges & Startup Fees

Procedure Charges

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Provider</th>
<th>Cost</th>
<th>Change</th>
<th>Total</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle 3</th>
<th>Cycle 4</th>
<th>Cycle 5</th>
<th>Cycle 6</th>
<th>Cycle 7</th>
<th>Cycle 8</th>
<th>Cycle 9</th>
<th>Cycle 10</th>
<th>Cycle 11</th>
<th>Cycle 12</th>
</tr>
</thead>
</table>

Per Procedure Charges

Add Costs to a Procedure

Procedure Charges

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Provider</th>
<th>Cost</th>
<th>Change</th>
<th>Total</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle 3</th>
<th>Cycle 4</th>
<th>Cycle 5</th>
<th>Cycle 6</th>
<th>Cycle 7</th>
<th>Cycle 8</th>
<th>Cycle 9</th>
<th>Cycle 10</th>
<th>Cycle 11</th>
<th>Cycle 12</th>
</tr>
</thead>
</table>

Click to Edit Any Cell

Select Cost Type

Study Charges & Startup Fees

Per Procedure Charges
Change Costs & Update Budget

Procedure Changes

<table>
<thead>
<tr>
<th>Procedure Changes</th>
<th>Provider</th>
<th>Cost</th>
<th>Change</th>
<th>Quantity</th>
<th>Total</th>
<th>Details</th>
<th>Year Period</th>
<th>Follow up</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Q1</td>
<td>Q2</td>
</tr>
<tr>
<td>CBE AUTO MIN AUTO DEPT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>22.00</td>
<td>22.00</td>
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<tr>
<td>Technical Fees</td>
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<td>-</td>
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</table>

Edit Effects all columns or individual cells...

All Effected Cells are highlighted

Subject Billing Report

Patient Billing Report

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Date</th>
<th>billed</th>
<th>performed</th>
<th>billed</th>
<th>performed</th>
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<tbody>
<tr>
<td>Imaging Studies</td>
<td>04/03/2000</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Intravenous pyelogram</td>
<td>05/05/2000</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT Scan Upper</td>
<td>06/06/2000</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEA</td>
<td>05/05/2000</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Clinical Evaluation</td>
<td>06/06/2000</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comprehensive Metabolic Panel</td>
<td>05/05/2000</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phlebotomy/venipuncture</td>
<td>06/06/2000</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematology (CReW w/diff, p10)</td>
<td>05/05/2000</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treating/Consultant sample</td>
<td>06/06/2000</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>H&amp;P (Vital signs, Weight, &amp; PIS)</td>
<td>06/06/2000</td>
<td>X</td>
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<td></td>
<td></td>
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<tr>
<td>Serum or urine pregnancy test</td>
<td>06/06/2000</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Carcinoma antigen</td>
<td>06/06/2000</td>
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<td></td>
<td></td>
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<tr>
<td>CEA</td>
<td>05/05/2000</td>
<td>X</td>
<td></td>
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</tr>
<tr>
<td>Nurse Evaluation</td>
<td>06/06/2000</td>
<td>X</td>
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<td></td>
</tr>
</tbody>
</table>
| Based on procedures and dates from Subject calendar

Billing status for auditing purposes
# Billers’ View

## Study Contacts

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>E-Mail</th>
<th>Phone</th>
<th>Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>Abbey, Ebe</td>
<td><a href="mailto:abbeyle@marinotes.wustl.edu">abbeyle@marinotes.wustl.edu</a></td>
<td>314-361-5744</td>
<td>314-362-0051</td>
</tr>
<tr>
<td>Study Coordinator</td>
<td>Rauter, Lee</td>
<td><a href="mailto:krainer@email.wustl.edu">krainer@email.wustl.edu</a></td>
<td>314-362-1171</td>
<td>314-747-2797</td>
</tr>
<tr>
<td>Billing Coordinator</td>
<td>???</td>
<td>???</td>
<td>???</td>
<td>???</td>
</tr>
</tbody>
</table>

## Dashboard

### Budget, Invoiced, & Paid

**Budget Percentage Utilization**

- **Unspent Budget**: 81%
- **Invoiced**: 9%
- **Paid**: 14%

**Total Paid**: $10,800
**Total Invoiced**: $43,349
**Total Budgeted**: $232,639

### Accrual & Enrollment Status

**Accrual & Enrollment**

- **Enrolled**: 7%
- **Consented**: 11%
- **Remaining**: 13%

**Projected Accrual (All Sites)**: 13

### Details

<table>
<thead>
<tr>
<th>Enrollment Status</th>
<th>Count</th>
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<tbody>
<tr>
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<tr>
<td>Consented</td>
<td>1</td>
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<tr>
<td>Remaining</td>
<td>12</td>
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</table>
Budgeted vs. Invoice

<table>
<thead>
<tr>
<th></th>
<th>Budgeted</th>
<th>Invoiced</th>
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</thead>
<tbody>
<tr>
<td>Total Invoiced</td>
<td>$423,349</td>
<td></td>
</tr>
<tr>
<td>Total Budgeted</td>
<td>$232,639</td>
<td></td>
</tr>
</tbody>
</table>

Budgeted vs. Invoiced Details

<table>
<thead>
<tr>
<th></th>
<th>Budgeted</th>
<th>Invoiced</th>
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</thead>
<tbody>
<tr>
<td>Startup Costs</td>
<td>$11,657</td>
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</tr>
<tr>
<td>Invoicables</td>
<td>$70,795</td>
<td>$49,308</td>
</tr>
<tr>
<td>Renewal Fees</td>
<td>$75,327</td>
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</tr>
<tr>
<td>Patient Costs</td>
<td>$124,960</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>$232,639</td>
<td>$423,349</td>
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</tbody>
</table>

Invoices

Invoices for PITT02

<table>
<thead>
<tr>
<th>Invoice Number</th>
<th>Sponsor</th>
<th>Payment Method</th>
<th>Payment Number</th>
<th>Payment Amount</th>
<th>Balance Due</th>
<th>Payment Comments</th>
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<td>00220</td>
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<td>Cash</td>
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<td>00229</td>
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<td></td>
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<td>$10,800.00</td>
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<tr>
<td>00228</td>
<td></td>
<td></td>
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<td>$15,800.00</td>
<td>$0.00</td>
<td>Paid with Cash #111</td>
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<td>$0.00</td>
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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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Washington University in St. Louis
Center for Applied Research Sciences
Phone: (314) 362-xxxx
Email: kukuljas@wusm.wustl.edu

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Huron Consulting Group, L.L.P.
Phone: (312) 880-0559
Email: jmoran@huronconsultinggroup.com