HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

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

Health Care Compliance Association
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888-580-8373 | www.hcca-info.org

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 web site
- **1 CTMS deployed!**

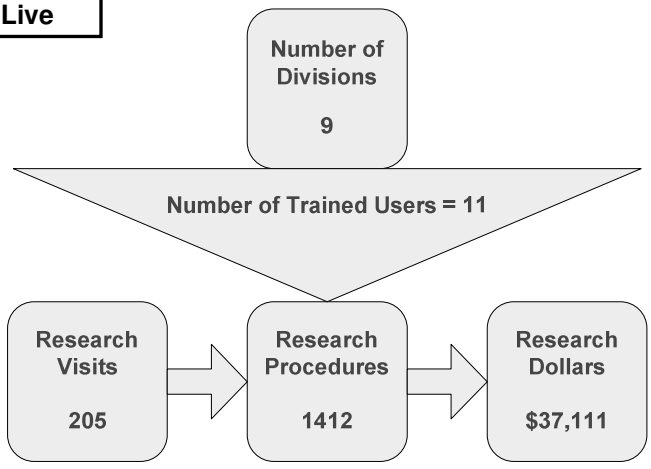
Time to Launch = 18 months

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

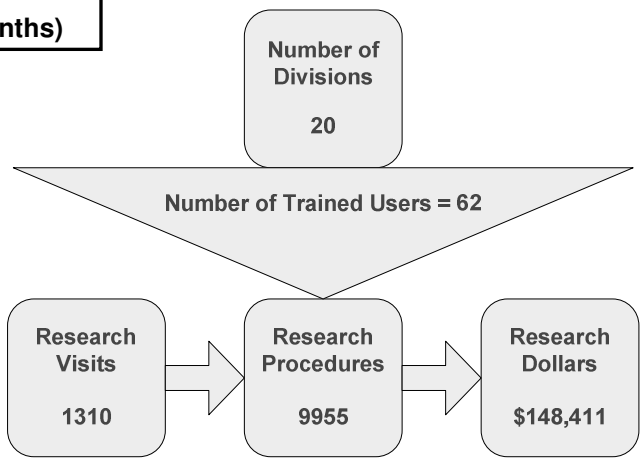
StudyManager™ Utilization

First 6 Months of Go Live

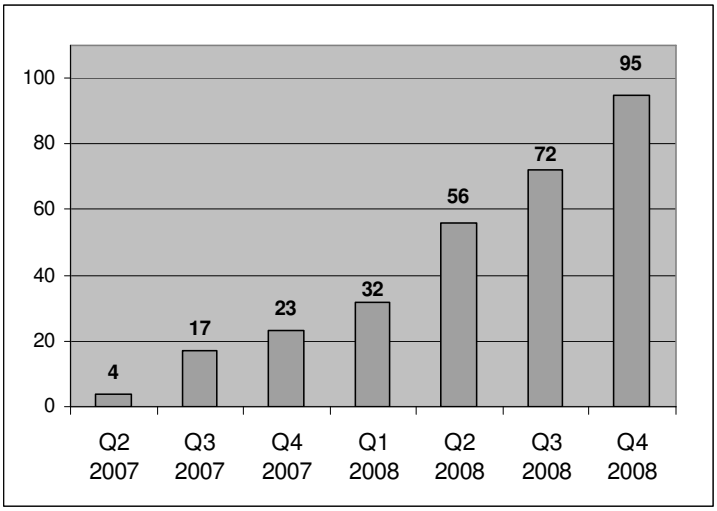


StudyManager™ Utilization

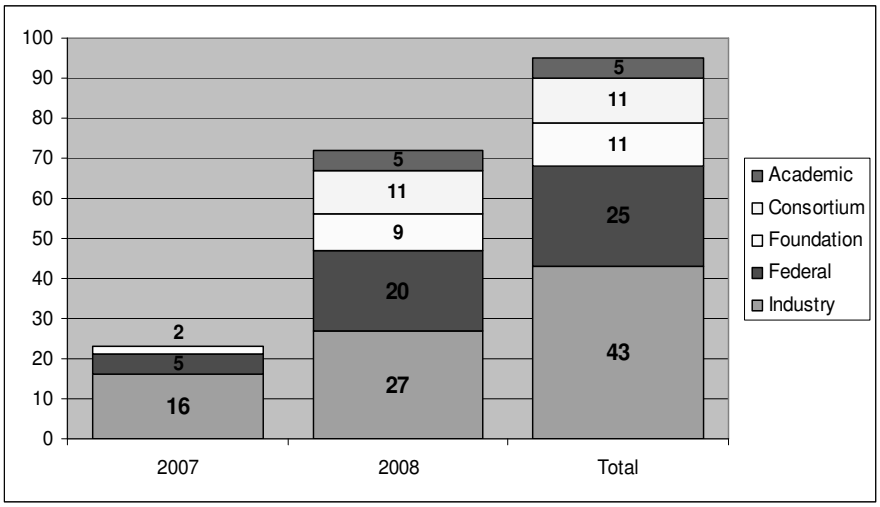
Current
(21 Months)



95 total studies in StudyManager™



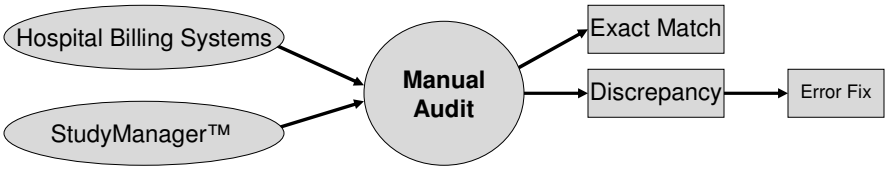
Sponsor Distribution



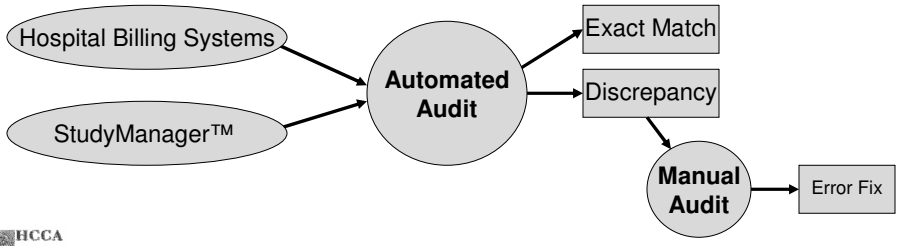
Research Billing Compliance

Compliance System Model

Parallel System - Original Manual Process



Parallel System – Current Semi-Automated Process



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.

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 IRB & SAC (if applicable) approval.
- Executed contract or grant.
- Designated research staff with required training completed.
- Lawson 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 OSR.

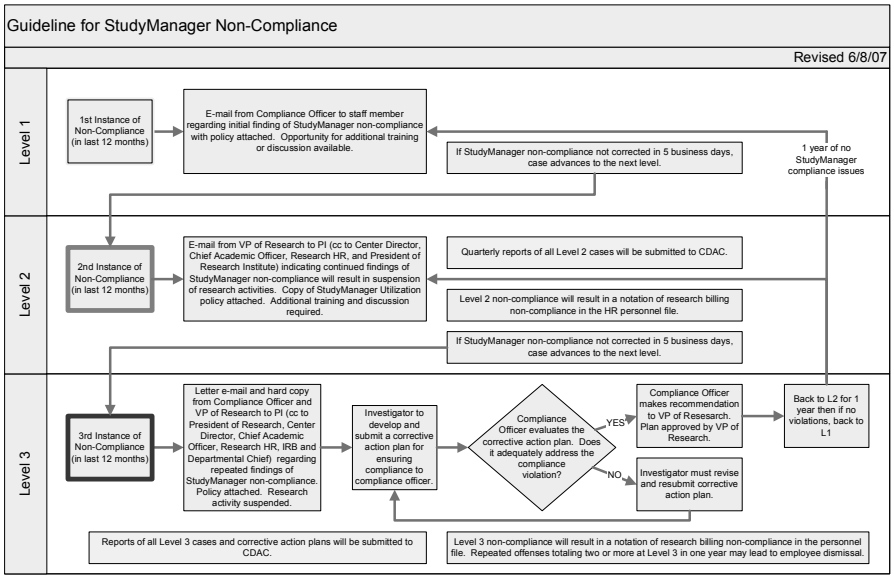
Compliance Issues

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



StudyManager™ Utilization Non-Compliance Memo

StudyManager Compliance Notice

Date:
To:
From: Pam Joy
Re: First Notice of StudyManager Non-Compliance
Attachments: CTM-100 StudyManager Utilization & Compliance Policy

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A recent review of StudyManager data indicates that there may be a non-compliance issue.

Study Reviewed:
Principal Investigator:
Patient(s) Reviewed:
Visit(s)/Visit Date(s) Reviewed:
Compliance Issue:

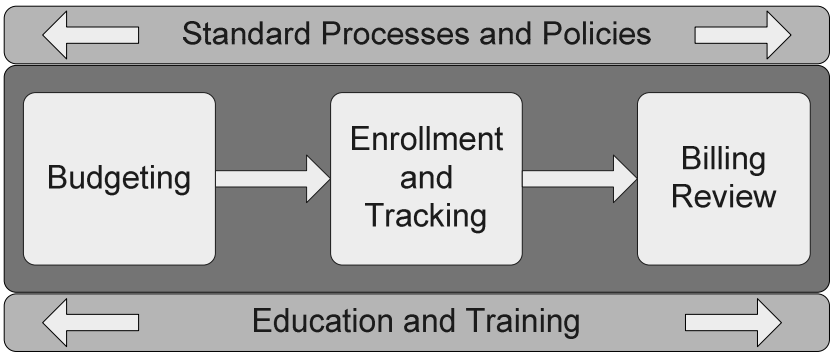
Please make any corrections, update StudyManager, and/or respond to this notice by . Please contact Clint Vickers, Study Manager Administrator if you have question or require assistance with data entry.

Failure to respond to this notice may result in disciplinary action as described in the attached policy. Feel free to contact me if you have any questions regarding the policy or this notice.

Thank you, Pam

Pam Joy, RN, MN, PNP
Director, Office of Clinical Research
Seattle Children's Hospital Research Institute

Key Areas



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

Elements

1. Defines a standard process for generating the SM budget document consistent w/ pricing policy, financial responsibility analysis policy, and other information.
2. Requires Investigator review and approval of same.

Compliance Issues

1. Implements compliance elements, consistently performed and consistently documented.
2. System enforced Investigator approval.

Impact

1. Standard budget document with standard (known, predictable, equitable) pricing is produced.
2. All research costs are considered, included and computed in a budget
3. Industry sponsored research will not be subsidized by Children's Hospital
4. Investigator involvement in process (approval requirement).

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

Pt: Pepper Sponsor: NCI Protocol # : RS_HEV0100 Dates: 9/6/06	Pre-Screening	Cycle 1 Day 1	Cycle 1 Day 2	Cycle 1 Day 5	Cycle 1 Day 7	Cycle 1 Day 27-28	Cycle 4	Cycle 7	Cycle 10
Procedures[1]									
Pharmacokinetics	Research	Research x8	Research x2	Research	Research	Research			
VEGF & VEGFR-2	Research					Research			
Circulating endothelial cells	Research					Research			
Tumor blocks	Resesarch								
DEMRI	Research billable				Research billable				
DEMRI pro-fee	Research billable				Research billable				
Pharmacogenetic studies	Research								
Tibial growth plate x-ray 2v	Research billable						Research billable	Research billable	Research billable
Tibial pro-fee	Research billable						Research billable	Research billable	Research billable
CBC	SOC	SOC					SOC	SOC	SOC
Urinalysis	SOC	SOC					SOC	SOC	SOC
Electrolytes	SOC	SOC					SOC	SOC	SOC
Coags	SOC						SOC	SOC	SOC
HCG	SOC						SOC	SOC	SOC
Fees									
CRC		Research billable	Research billable	Research billable	Research billable	Research billable			
Pharmacy dispensing		Research billable				Research billable	Research billable	Research billable	Research billable
Visit Time Activities									
Consent	Research								
Eligibility review	Research								
History	SOC	SOC					SOC	SOC	SOC
Physical exam & vital signs	SOC	SOC					SOC	SOC	SOC
Height, weight & BSA	SOC						SOC	SOC	SOC
Performance status	SOC						SOC	SOC	SOC
Tumor disease evaluation	SOC							SOC	SOC
Subject diary	SOC						SOC	SOC	SOC

Standard of Care vs. Research Care

StudyManager™ Report Screenshot

Change to Standard of Care in Screenshot

Visit Date: 06/11/2008	Visit Name: screening	
Adverse Events Review	Research	$0.00
BNP	Research	$85.07
Chemistry panel	Standard of Care	$0.00
Coagulation profile	Standard of Care	$0.00
CRA Case Report Form (CRF) Completion/Submission	Research	$0.00
Echocardiogram or MUGA	Standard of Care	$0.00
Electrocardiogram (ECG) (EKG)	Standard of Care	$0.00
GGT	Research	$19.14
Height & Weight	Standard of Care	$0.00
Hematology panel	Standard of Care	$0.00
hGH	Research	$48.72
IGF-1	Research	$46.72

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

Date:

To: **PI:**
Primary Study Contact:

From: Michelle Palmer, RN, BSN
Clinical Trial Budget Analyst
Office of Sponsored Research

Re:

Attachments: CTM-100 StudyManager Utilization & Compliance Policy
Schedule of visits and procedures report

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.

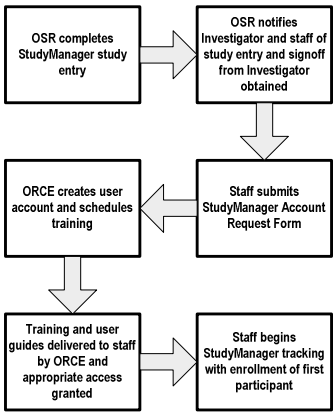
Per policy CTM-100, all clinical research studies that involve billable research care events are required to utilize StudyManager. Additionally, patient enrollment, status and documentation of completed study procedures in StudyManager should occur immediately during the research participant visit. Please see attached 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.seattlechildrens.org/assets/docs/studymanager_account_request_form.doc) and e-mail it to Clint Vickers, Study Manager Administrator. Upon receipt of the StudyManager Account Request Form, you will be notified to set up a training session.

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

Additional information about StudyManager is located on the OCR StudyManager Web site located on the Children's Research Web site at: http://research.seattlechildrens.org/rss/studymanager.asp.

Training: Getting Started



StudyManager
ACCOUNT REQUEST FORM

Instructions

1. All of the fields below are required to obtain a StudyManager account
2. Have Supervisor/Investigator* email the completed form to Clinton Vickers for account set up: clinton.vickers@seattlechildrens.org.
   *Supervisors/Investigators: Forwarding this form via e-mail to Clinton Vickers indicates your authorization of the actions requested in this form.
3. Account will not be activated until requestor has completed StudyManager training. You will be contacted by the Office of Clinical Research to schedule training.
4. For help with questions about this form, email: clinton.vickers@seattlechildrens.org.

Requestor Information

Name: [redacted] Phone:

New Account ☐ Modify Account ☐ Termination ☐

Department(s):

Role: (select one) If other selected, define role:

Date Account Needed or Account Modification/Termination Effective:

Name of Supervisor/Investigator of Requestor:

Training Checklist

StudyManager Training Checklist

User Trained: _____ Training Date: _____

- User account request form received ☐
- Distributed StudyManager User Guide ☐
- Distributed StudyManager Pocket Reference ☐
- StudyManager external web page location ☐
- Presented the training overview slideshow (Includes StudyManager overview, goal of research billing compliance, StudyManager compliance, processes and policies) ☐

Navigating StudyManager
- URL location of StudyManager program ☐
- Logging in/Passwords/Security ☐
- Automatic time out after 20 mins inactivity ☐
- Filters and Lists ☐

Adding a patient to StudyManager
- Entering and saving data ☐
- Field descriptions ☐
- Editing data ☐

Enrolling a patient to a study
- Add patient to study ☐
- Select investigator, coordinator, site ☐

- Reviewed studies currently in StudyManager ☐
  _____
  _____
  _____
- Reviewed process for determining which studies will be added to StudyManager. ☐
- Reviewed process that OSR will notify coordinator of new studies added to StudyManager. ☐
- Reviewed policy that all data should be entered within 2 business days of when events occurred (patient enrollment, visits, procedures completed, and patient study status). ☐
- Reviewed scope of what coordinators are expected to enter into StudyManager. ☐
  1. Enter patients in StudyManager
  2. Enroll patients to the appropriate study in StudyManager
  3. Add visits and check off completed procedures in StudyManager
  4. Keep patient status current

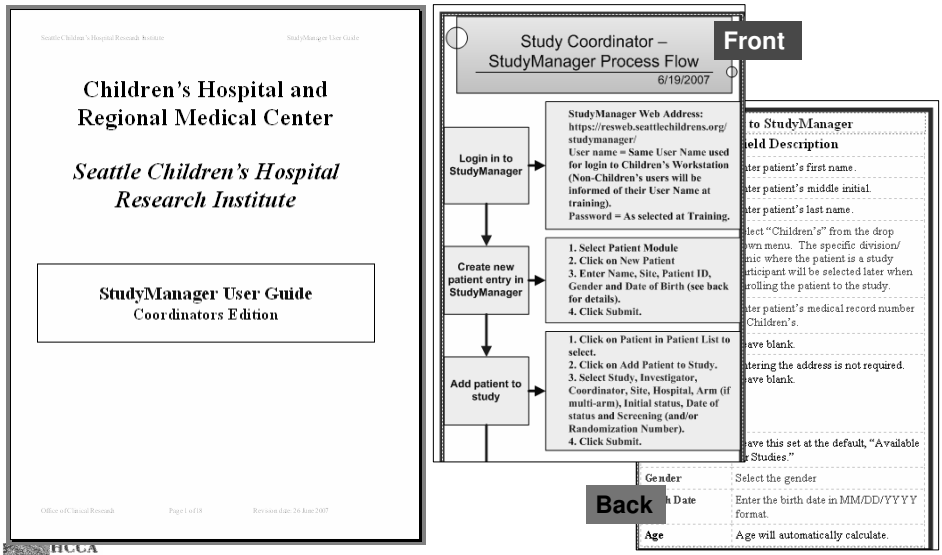
The items of information checked off have been conveyed to the research team member being trained, the research team member has expressed an understanding of this information and all questions have been answered.

Trainer Signature **Date**

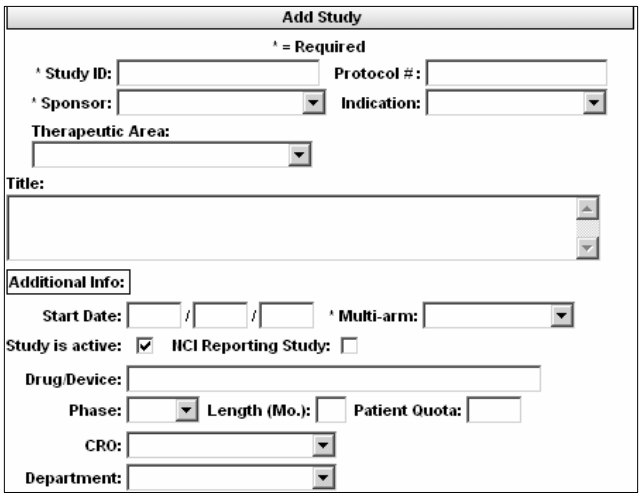
The items of information checked off have been conveyed to me and all of my questions have been answered.

Trainee Signature **Date**

User Guides

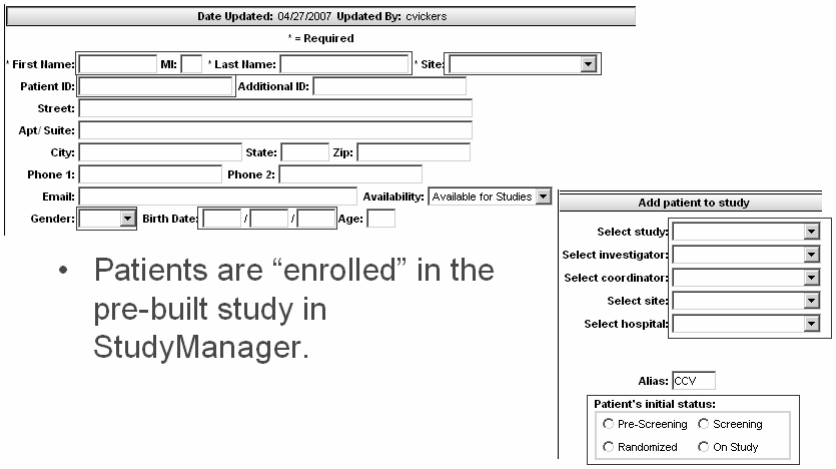


Study Entry



Enrolling Participants

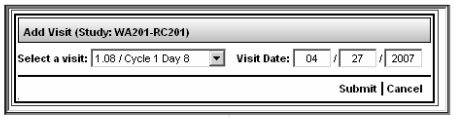
- Basic patient information is added to the StudyManager patient database.



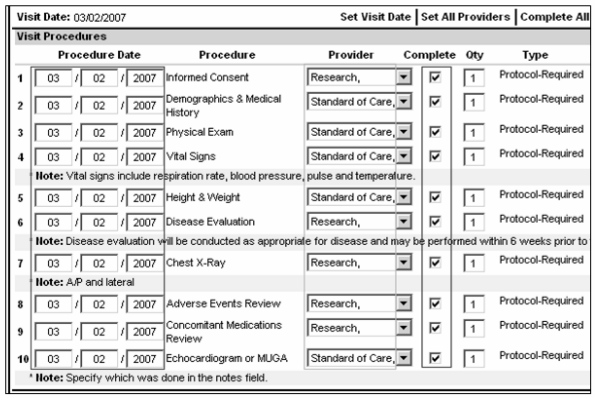
  - Patients are "enrolled" in the pre-built study in StudyManager.

Tracking Participant Activity

- Research participant visits are recorded by adding visits.



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



Patient Activity Report

Study Summary: Visit

Heading 2

Heading 3

Study ID: AG-100 Protocol Number: AG-03422 Sponsor: AG Pharma

Site ID: 1 Site Name: Clinical Trials Office (CTO)

Alias	Total Visits for Patient	Week 24	Complete	Visit 9	Week 4	Week 6	Week 12	Screen	Rand.	Week 2
ATA	9	04/29/2003	12/30/2003	05/18/2004	03/28/2003	04/07/2003	04/16/2003	01/12/2002	01/28/2002	02/14/2002
B-G	6				11/18/2004	12/07/2004	03/23/2005	11/12/2004	11/16/2004	11/16/2004
B-J	6				06/13/2003	06/17/2003	07/15/2004	03/05/2002	03/22/2002	06/13/2003
B-M	4				12/16/2004			04/03/2002	01/07/2004	12/16/2004
B-S	6				08/12/2004	08/17/2004	08/23/2004	08/09/2004	08/10/2004	08/11/2004
BKJ	2							03/02/2005	03/04/2005	
C-T	5				07/23/2003	08/23/2004		01/06/2002	01/28/2002	06/25/2003
D-K	2							12/15/2004	12/15/2004	
D-M	5				08/05/2004	01/18/2005		06/23/2004	06/23/2004	06/23/2004
E-M	1							03/12/2002		
FJH	8	05/27/2003	05/17/2004		06/11/2002	05/20/2003	05/21/2003	02/01/2002	02/14/2002	06/06/2002
G-A	7	05/17/2004			09/04/2002	01/10/2003	06/30/2003	07/25/2002	08/08/2002	08/29/2002
G-J	8	12/10/2004	12/14/2004		05/21/2003	06/05/2003	05/25/2004	02/01/2002	02/22/2002	05/20/2003
G-P	2							03/10/2005	03/11/2005	
GJR	4				02/16/2005			02/02/2005	02/07/2005	02/08/2005
H-H	8	05/18/2004	05/25/2004		02/04/2003	02/05/2003	05/20/2003	01/14/2002	02/04/2002	08/22/2002

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

Research Requisition

Children's Hospital & Regional Medical Center

Research Requisition - Radiology

To schedule call **(206) 987-2089,** then fax form to **(206) 987-2730**.
Form with patient label attached must accompany study participant to Radiology.
All sections must be completed

Patient Name:	Patient DOB:
Patient MRN: (6 digits)	Case/Encounter # (8 digits)
Attach Patient Label Here	

Today's Date:
Procedure Date:
Study Code: RS_
Investigator Name:
Research Coordinator Name:
Research Coordinator Phone:
Research Coordinator Pager:
Parent/Guardian Name:
Parent/Guardian Phone:

Please check off the requested procedures

☐ CT ☐ DEXA ☐ DX ☐ MRI (see MRI questions below) ☐ PET ☐ NM ☐ US

Exam Requested:

Diagnosis: *Radiology (research) Exam, not elsewhere classified*

ICD9 Code: *V72.6*

☐ **Sedation needed** ☐ **Labs:**
☐ **Contrast needed** ☐ **Allergies:**

Please consider when ordering exams for female patients 11 years and older that radiation can be harmful to the patient and fetus. Start date of last menstrual period:

For MRI, does the patient have any of the following:

☐ Pacemaker	☐ Orthodontia (Braces)	☐ Previous Surgery, Date/Location:
☐ Aneurysm clips	☐ Implant	☐ Previous MR, Date/Location:
☐ Metal Fragments	☐ Sedation needed	☐ Neurostimulator Type:

Comments/Special Instructions:

Assigned Radiologist *(if applicable)*:

CUMG If this requisition includes professional fees, check here to alert staff to submit charges to CUMG. ☐
Provider: CPT Codes:
Clinicians already charging effort to a study should not charge professional fees through CUMG for services related to that study.

Ordering Physician *(include first and last name, please print)*:

Ordering Physician signature (Required):

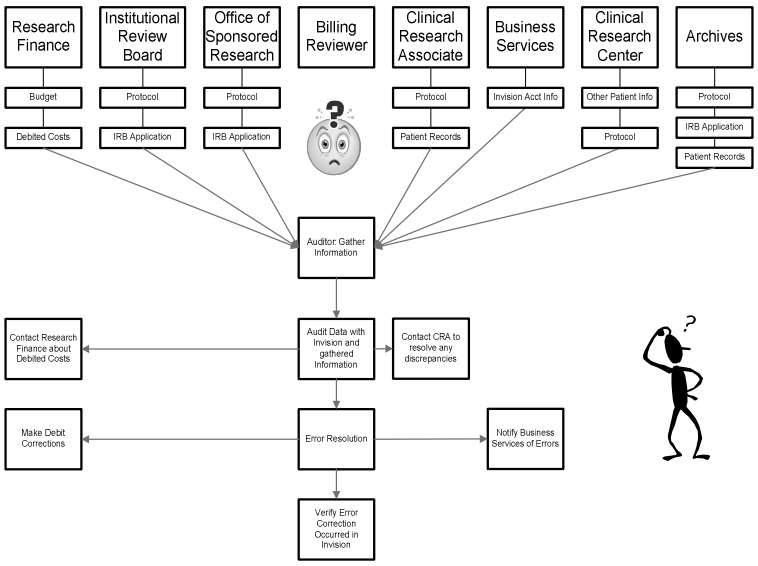
Best contact number for critical findings: ( ) -

Billing Review

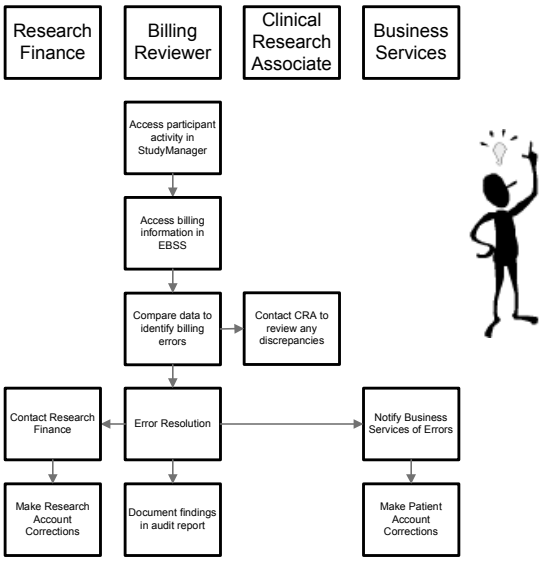
Billing Review: Essential Elements

- 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



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.

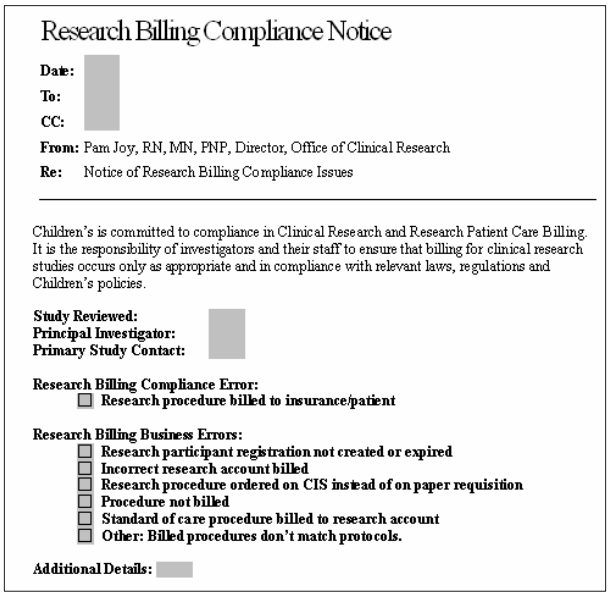
Compliance Issues

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 error.
3. Ensures appropriate clinical trial account residual.

Research Billing Compliance



Research Billing Compliance Notice

Date:
To:
CC:
From: Pam Joy, RN, MN, PNP, 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 occurs 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:
- ☐ **Research participant registration not created or expired**
- ☐ **Incorrect research account billed**
- ☐ **Research procedure ordered on CIS instead of on paper requisition**
- ☐ **Procedure not billed**
- ☐ **Standard of care procedure billed to research account**
- ☐ **Other: Billed procedures don't match protocols.**

Additional Details:

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 Vickers.

StudyManager Links:

StudyManager Program

Launch Children's StudyManager Program

Overview of StudyManager

StudyManager Overview Presentation (PDF 802KB)

StudyManager FAQs

Find answers to your questions about StudyManager.
StudyManager FAQs (PDF 16KB)

StudyManager Forms

StudyManager Account Request Form (DOC 62KB)

StudyManager Policies

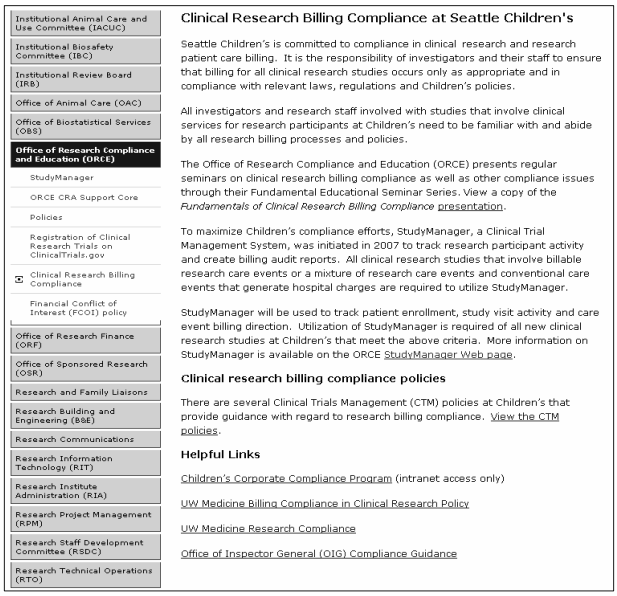
- CTM-100 StudyManager Utilization and Compliance (PDF 88KB)
- CTM-101 StudyManager Security (PDF 449KB)
- CTM-202 Clinical Trial Budget Creation (PDF 206KB)
- CTM-207 Auditing Research Patient Care Cost Compliance (PDF 87KB)
- CTM-300 Clinical Research Staff Qualifications (PDF 65KB)

StudyManager User Guidance

User Guide documentation is provided for reference.

- User Guide (Complete) (PDF 358KB)
- User Guide - Navigating StudyManager (PDF 405KB)
- User Guide - Adding a Patient to the StudyManager Database (PDF 29KB)
- User Guide - Enrolling a Patient in StudyManager (PDF 52KB)
- User Guide - Tracking Patient Visits (PDF 141KB)
- User Guide - Printing a Visit Checklist (PDF 62KB)
- User Guide - Using Reports (PDF 51KB)
- Printable Foldout Guide (PDF 286KB)
- Changing or Resetting Passwords (PDF 28KB)
- Glossary of StudyManager Terms (PDF 1MB)
- System Requirements (PDF 204KB)

Research Billing Compliance Webpage



- Institutional Animal Care and Use Committee (IACUC)
- Institutional Biosafety Committee (IBC)
- Institutional Review Board (IRB)
- Office of Animal Care (OAC)
- Office of Biostatistical Services (OBS)
- **Office of Research Compliance and Education (ORCE)**
  - StudyManager
  - ORCE CRA Support Core
  - Policies
  - Registration of Clinical Research Trials on ClinicalTrials.gov
  - Clinical Research Billing Compliance
  - Financial Conflict of Interest (FCOI) policy
- Office of Research Finance (ORF)
- Office of Sponsored Research (OSR)
- Research and Family Liaisons
- Research Building and Engineering (BSE)
- Research Communications
- Research Information Technology (RIT)
- Research Institute Administration (RIA)
- Research Project Management (RPM)
- Research Staff Development Committee (RSDC)
- Research Technical Operations (RTO)

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 only as appropriate and in compliance with relevant laws, regulations and Children's policies.

All investigators and research staff involved with studies that involve clinical services for research participants at Children's need to be familiar with and abide by all research billing processes and policies.

The Office of Research Compliance and Education (ORCE) presents regular seminars on clinical research billing compliance as well as other compliance issues through their Fundamental Educational Seminar Series. View a copy of the *Fundamentals of Clinical Research Billing Compliance* presentation.

To maximize Children's compliance efforts, StudyManager, a Clinical Trial Management System, was initiated in 2007 to track research participant activity and create billing audit reports. All clinical research studies that involve billable research care events or a mixture of research care events and conventional care events that generate hospital charges are required to utilize StudyManager.

StudyManager will be used to track patient enrollment, study visit activity and care event billing direction. Utilization of StudyManager is required of all new clinical research studies at Children's that meet the above criteria. More information on StudyManager is available on the ORCE StudyManager Web page.

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

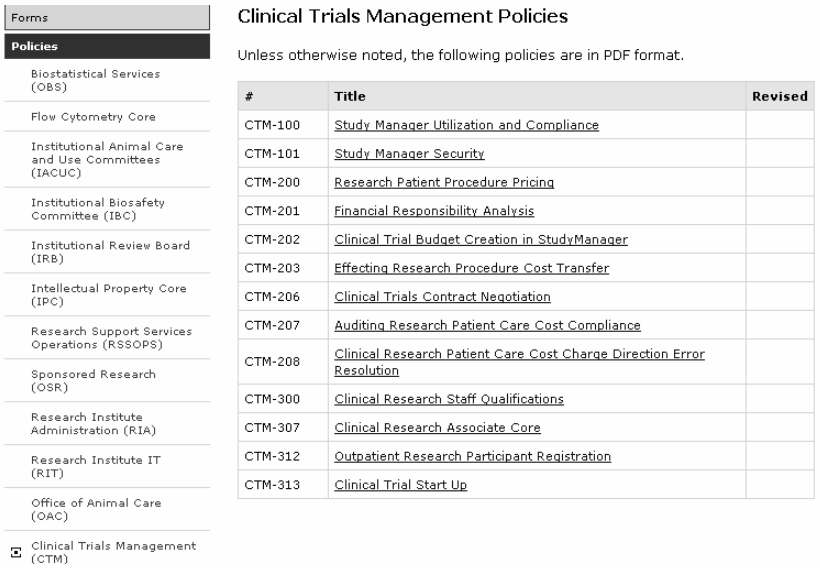
Children's Corporate Compliance Program (intranet access only)

UW Medicine Billing Compliance in Clinical Research Policy

UW Medicine Research Compliance

Office of Inspector General (OIG) Compliance Guidance

Clinical Trials Management Policies



- Forms
- **Policies**
  - Biostatistical Services (OBS)
  - Flow Cytometry Core
  - Institutional Animal Care and Use Committees (IACUC)
  - Institutional Biosafety Committee (IBC)
  - Institutional Review Board (IRB)
  - Intellectual Property Core (IPC)
  - Research Support Services Operations (RSSOPS)
  - Sponsored Research (OSR)
  - Research Institute Administration (RIA)
  - Research Institute IT (RIT)
  - Office of Animal Care (OAC)
  - Clinical Trials Management (CTM)

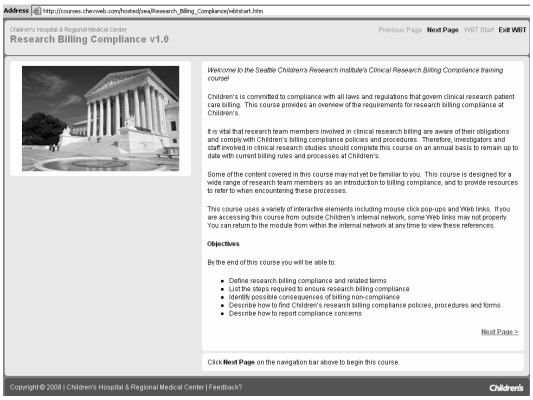
Clinical Trials Management Policies

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

#	Title	Revised
CTM-100	Study Manager Utilization and Compliance	
CTM-101	Study Manager Security	
CTM-200	Research Patient Procedure Pricing	
CTM-201	Financial Responsibility Analysis	
CTM-202	Clinical Trial Budget Creation in StudyManager	
CTM-203	Effecting Research Procedure Cost Transfer	
CTM-206	Clinical Trials Contract Negotiation	
CTM-207	Auditing Research Patient Care Cost Compliance	
CTM-208	Clinical Research Patient Care Cost Charge Direction Error Resolution	
CTM-300	Clinical Research Staff Qualifications	
CTM-307	Clinical Research Associate Core	
CTM-312	Outpatient Research Participant Registration	
CTM-313	Clinical Trial Start Up	

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



- Mandatory for CCTR research staff.
- Plan to create version for investigators.

Summary

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

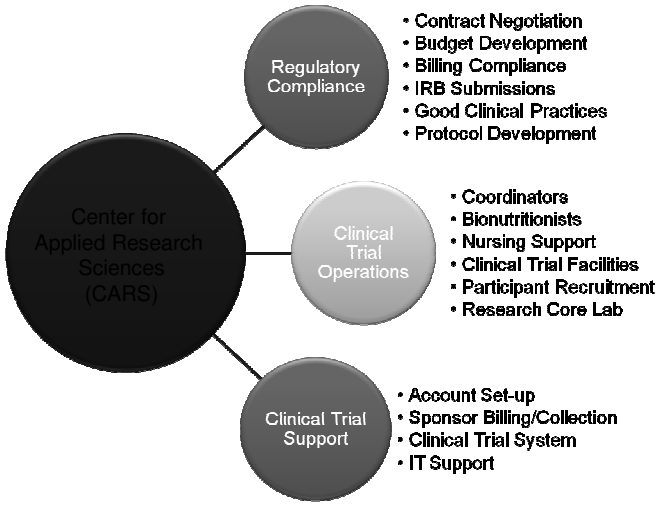
Implementation and Utilization of A Clinical Studies Management System in Support of Clinical Research Billing Compliance

Sara Kukuljan, RN
Washington University in St. Louis
Center for Applied Research Sciences

Jim Moran JD, CPA
Huron Consulting Group, L.L.P.
Clinical Research Service & Healthcare Compliance Practice

Health Care Compliance Association
6500 Barrie Road, Suite 250, Minneapolis, MN 55435
888-580-8373 | www.hcca-info.org

The Washington University Clinical Trial Support Infrastructure



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:

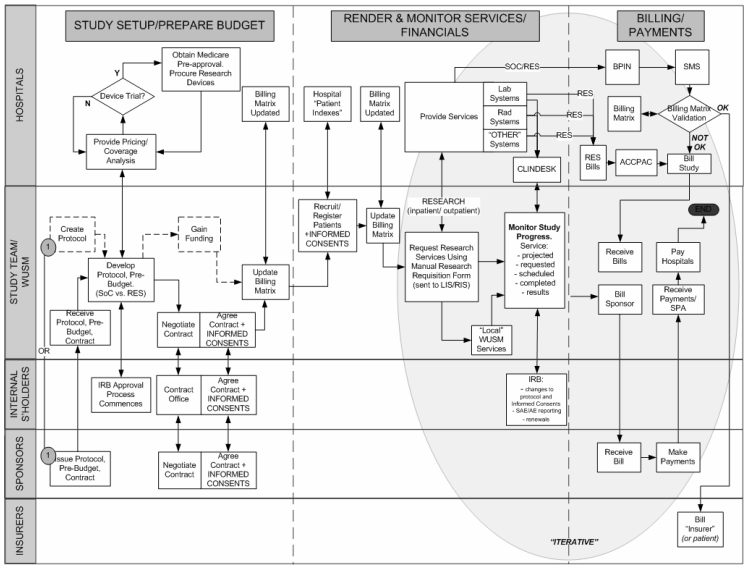
- enhances work flow and decreases the manual and often redundant processes required to manage clinical research
- meets the increasing compliance demands
- anticipates growth in clinical research based on NIH's Clinical and Translational Science Award (CTSA) model

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

End to End Clinical Trials Process



mdlogix

- mdlogix, (www.mdlogix.com), was chosen as WUSTL's software partner. The mdlogix Clinical Research Mangement 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:

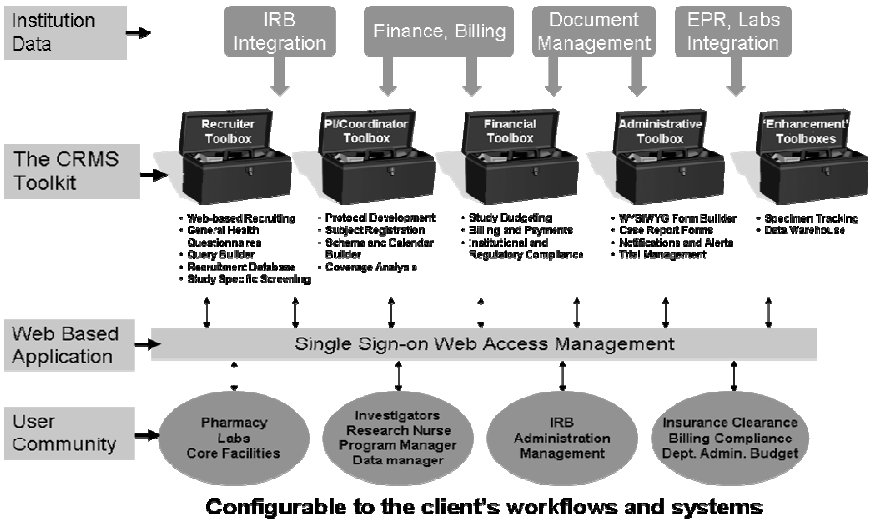
- Subject Recruitment
- Subject & Protocol Registry
- Protocol Schema & Subject Calendar
- Financial Management
- Data Capture/Forms Builder

mdlogix
accelerating clinical research

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

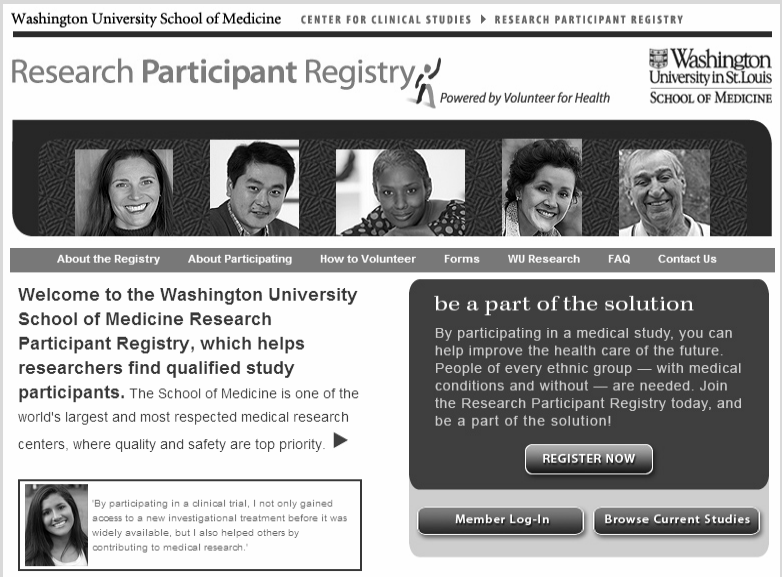


Financial Tools

- 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


Washington University School of Medicine
CENTER FOR CLINICAL STUDIES ▸ RESEARCH PARTICIPANT REGISTRY
Research Participant Registry
Powered by Volunteer for Health
Washington University in St. Louis
SCHOOL OF MEDICINE
About the Registry
About Participating
How to Volunteer
Forms
WU Research
FAQ
Contact Us
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, I not only gained access to a new investigational treatment before it was widely available, but I also helped others by contributing to medical research.'
be a part of the solution
By participating in a medical study, you can help improve the health care of the future. People of every ethnic group — with medical conditions and without — are needed. Join the Research Participant Registry today, and be a part of the solution!
REGISTER NOW
Member Log-In
Browse Current Studies
Washington University HIPAA Privacy Policy
Trials Feedback
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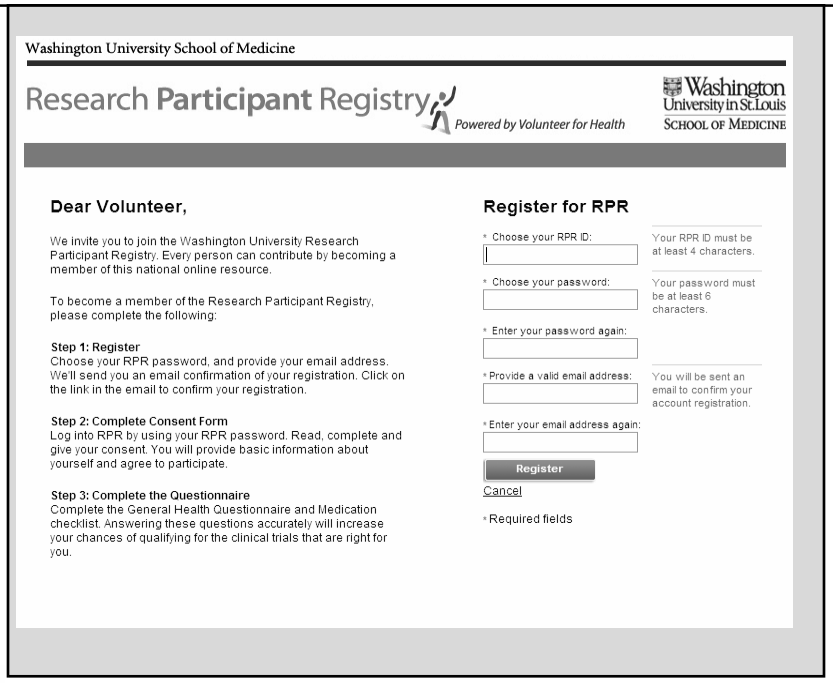
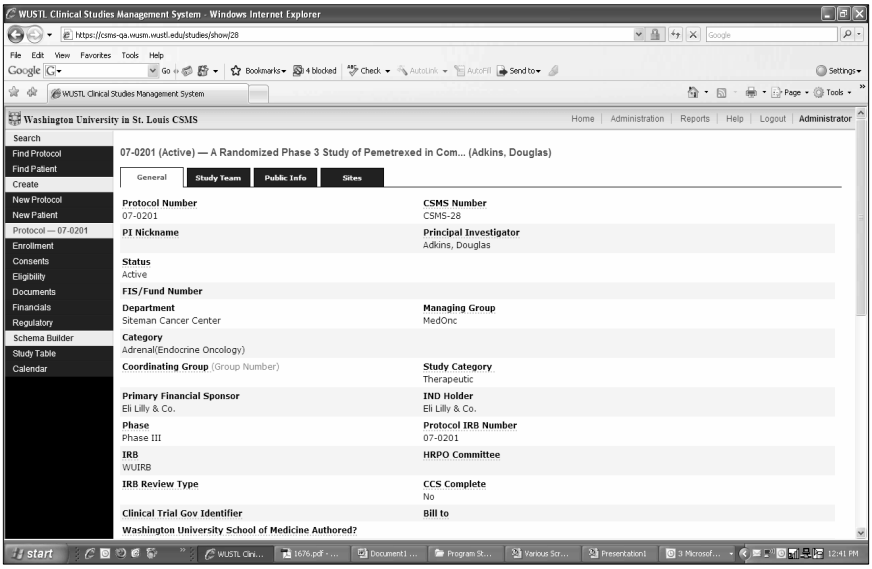
CENTER FOR CLINICAL STUDIES ▸ RESEARCH PARTICIPANT REGISTRY
Research Participant Registry
Powered by Volunteer for Health
Washington University in St. Louis
SCHOOL OF MEDICINE
Home
About the Registry
About Participating
How to Volunteer
Forms
WU Research
FAQ
Contact Us
be a part of the solution
REGISTER NOW
Member Log-In
Browse Current Studies
About the Registry
Affiliates
Welcome to the Research Participant Registry of Washington University School of Medicine. The Registry gives individuals the opportunity to participate in clinical studies and play a vital role in improving health care.
At Washington University, more than 1000 clinical studies begin every year to evaluate new investigational therapies or devices. For every study, also called a trial, investigators need volunteers to serve as research participants. The Registry helps researchers find people who are interested and who meet study qualifications. People who are healthy and those who have medical conditions are needed, from every ethnic and age group.
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 whatever mode of communication you choose, i.e., phone, fax, or e-mail at vfh@wustl.edu. You can also ask us to modify your information or you can do this on your own by accessing the website All of 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 one of many research recruitment services offered by the Recruitment Enhancement Core of Washington University School of Medicine's Center for Clinical Studies.
Frequently asked questions about the registry?
Washington University HIPAA Privacy Policy
Trials Feedback
© Copyright 2008, Washington University School of Medicine



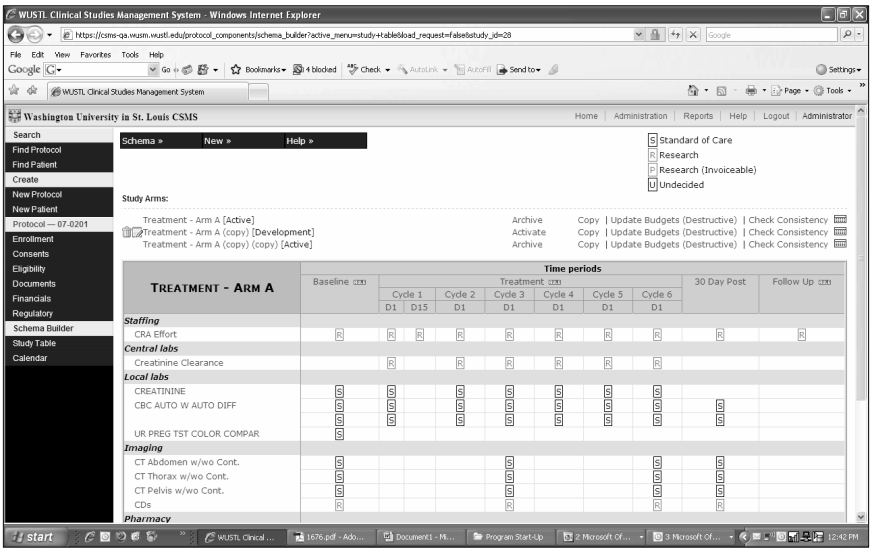
Subject & Protocol Registry



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

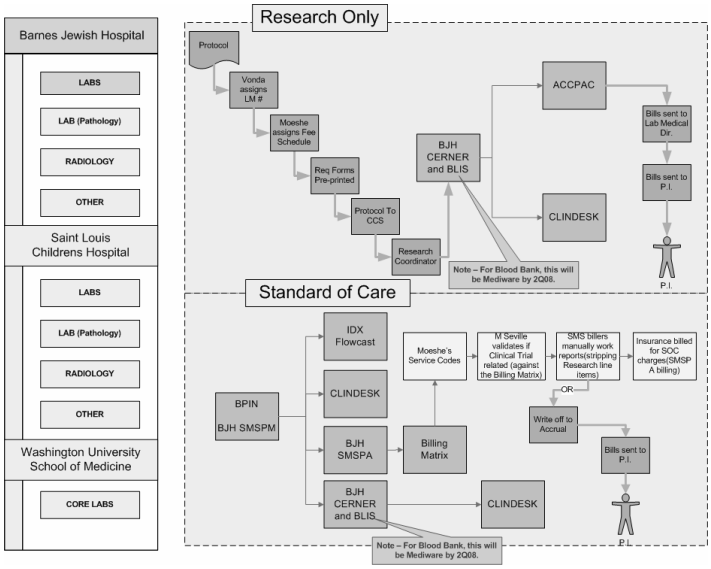
- The mdlogix system helps institutions prevent billing irregularities, comply with audits, and avoid penalties.
- Manages separation of charges between research and standard of care.
- Handles the billing process from study design to knowing the status of each subject's events for the research institution.
- 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

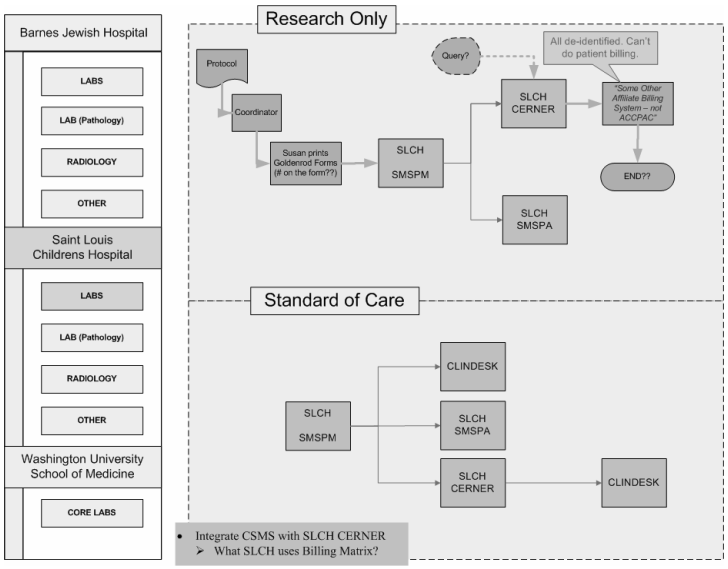
Issues addressed with this software include:

- 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'.

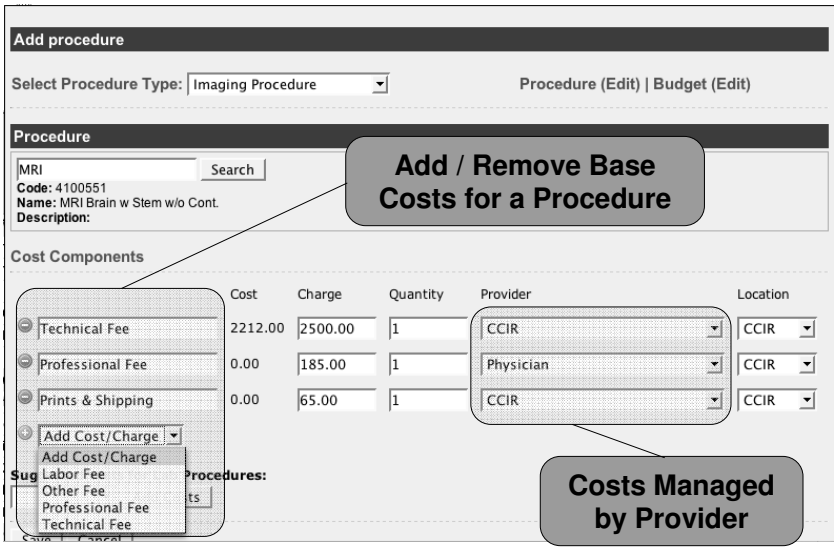
Barnes Jewish Hospital Research Workflow - Financials Example



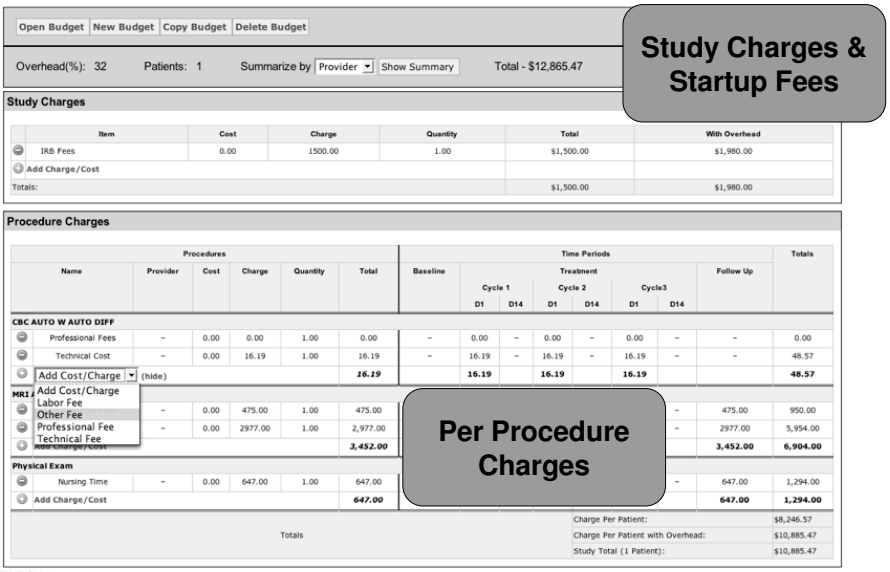
St. Louis Children's Hospital Research Workflow – Financials Example



Set Base Costs in Schema Builder



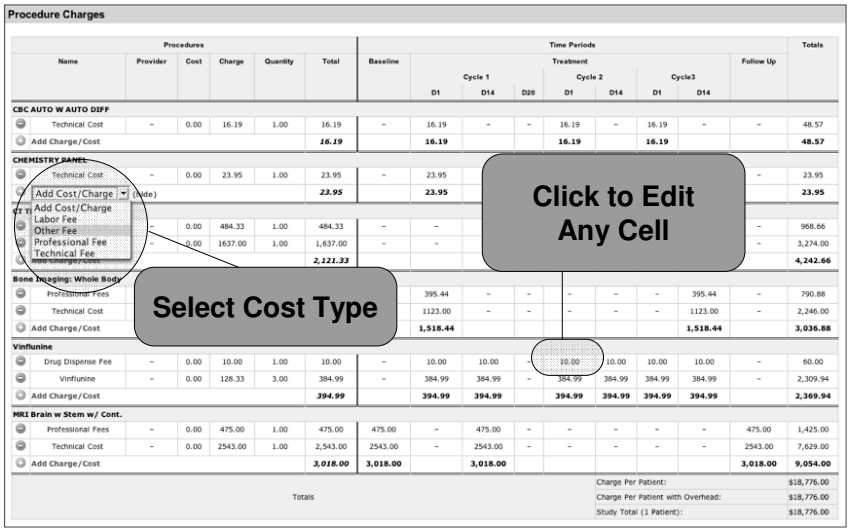
Generate a Study Budget



Study Charges & Startup Fees

Per Procedure Charges

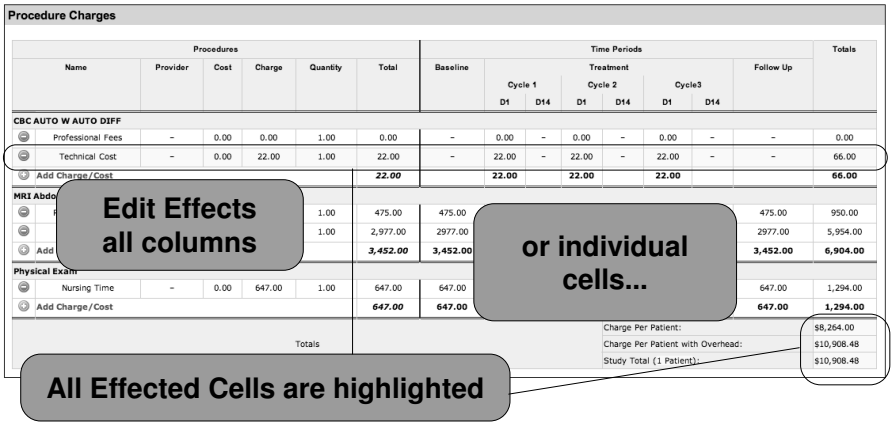
Add Costs to a Procedure



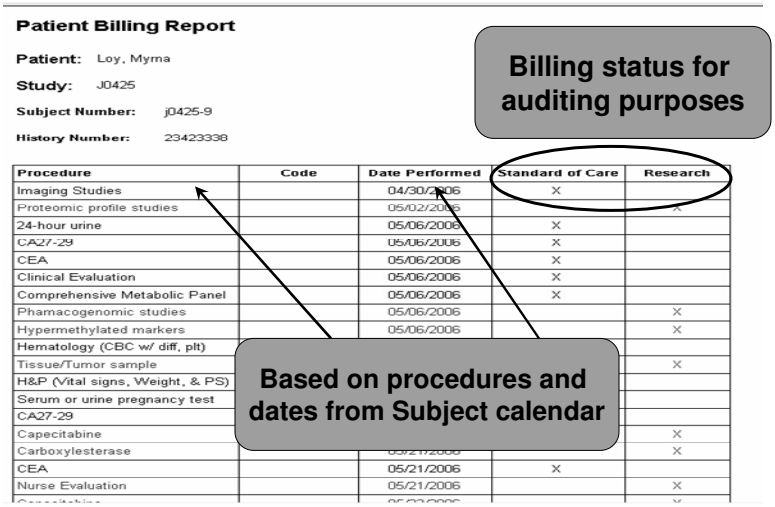
Click to Edit Any Cell

Select Cost Type

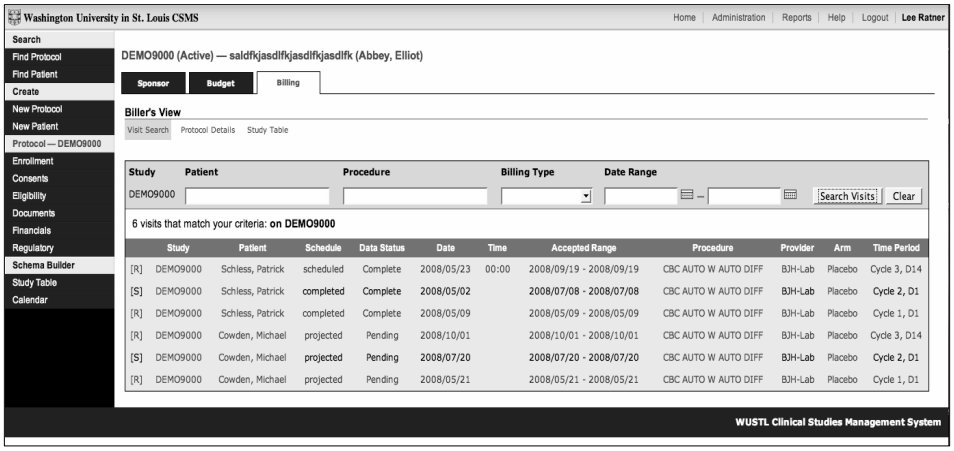
Change Costs & Update Budget



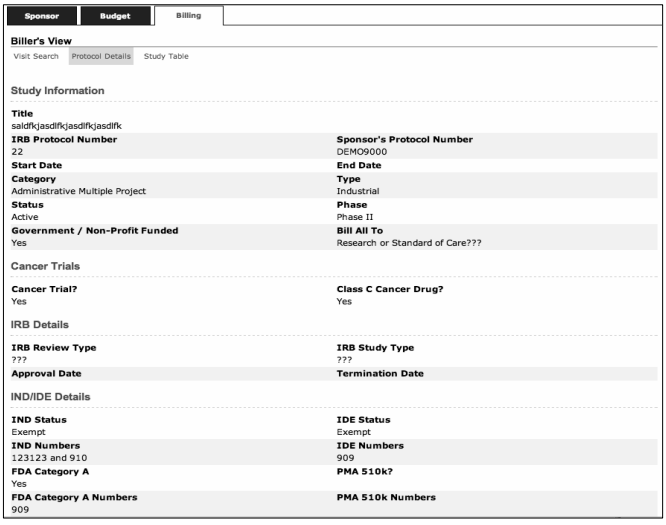
Subject Billing Report



Billers' View



Billers' View



Billers' View

Study Contacts

Principal Investigator Abbey, Elliot	**E-Mail** abbeye@msnotes.wustl.edu	**Phone** 314-361-5744
Address		**Fax** 314-362-0051
Study Coordinator Ratner, Lee	**E-Mail** lratner@im.wustl.edu	**Phone** 314-362-1171
Address		**Fax** 314-747-2797
Billing Coordinator ???	**E-Mail** ???	**Phone** ???
Address ???		**Fax** ???

Sponsors

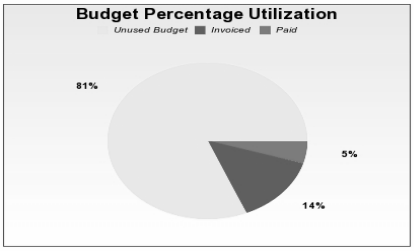
Dashboard

Budget | Sponsors | Milestones | Invoicing | Dashboard | Compliance

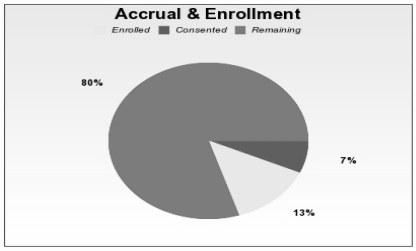
Reconciliation Dashboard for PITT002

07/23/2008

Budgeted, Invoiced, & Paid



Accrual & Enrollment Status



Details

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

Budgeted vs. Invoiced

Details

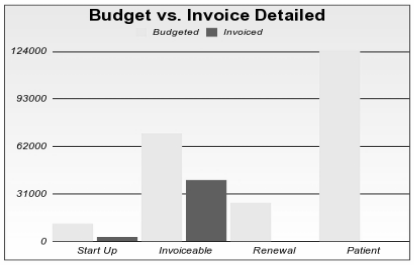
Enrollment Status	Count
Enrolled	2
Consented	1
*Remaining	12
Projected Accrual (All Sites)	**15**

Budgeted vs. Invoice

Total Invoiced	$43,349
Total Budgeted	$232,639

Enrolled	2
Consented	1
*Remaining	12
Projected Accrual (All Sites)	**15**

Budgeted vs. Invoiced



Details

	Budgeted	Invoiced
Startup Costs	$11,657	$3,000
Invoiceables	$70,795	$40,300
Renewal Fees	$25,327	
Patient Costs	$124,860	
Total	**$232,639**	**$43,349**

Invoices

Budget | Sponsors | Milestones | Invoicing | Dashboard | Compliance

Invoices for PITT002

Payment List | Create an Invoice for... | Enter Payment for... | Other actions... | Submit

	Invoice Number	In	Payment Amount	Balance Due	Payment Comments
☐	00230	07/	$0.00	$2,000.00	
☐	00229	07/	$0.00	$10,800.00	
☐	00228	07/	$10,800.00	$0.00	*Paid with Cash #111*
☐	00227	07/	$0.00	$3,875.00	
☐	00226	07/	$0.00	$5,000.00	
☐	00224	07/	$0.00	$10,873.50	

Enter Payment

Sponsor: PFIZER

Payment Method	Payment Number	Payment Amount
Cash		

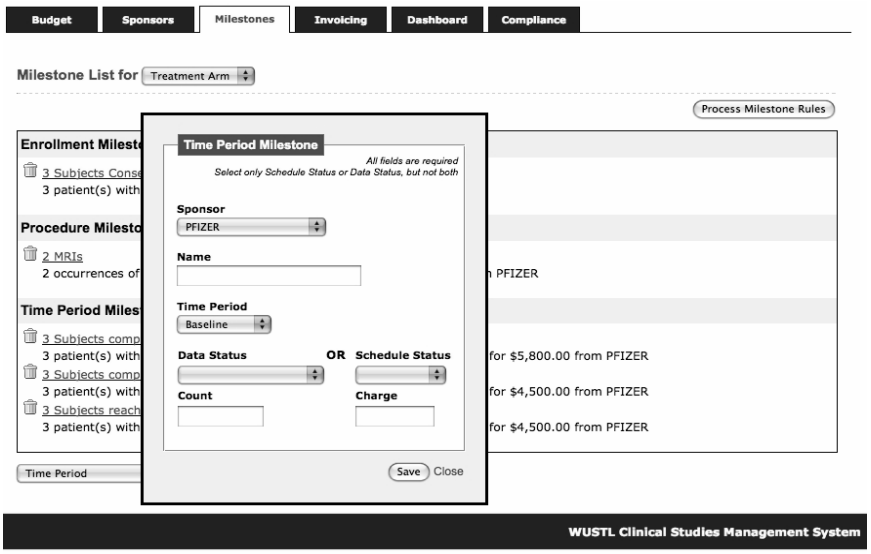
Date Issued	Date Received	Date Deposited

☐ Apply full amount to invoice number

Enter Payment | Close

WUSTL Clinical Studies Management System

Milestones



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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