

**THE CLOSER: RESOLVE THE RISKY BUSINESS OF BILLING COMPLIANCE**  
Kelly Willenberg and Kathleen Hurtado

## OBJECTIVES

- What are current key billing compliance areas including device studies and how do you find solutions to some of your challenges
- Success strategy for a bill hold and how to expand a compliance billing network
- How to make an affordable investment and how do you link performance improvement into the billing compliance model

## KEY AREAS IN CLINICAL TRIAL BILLING

- Variety of information must be coordinated in order to manage research billing compliance
- Processes must be established to identify patients in billing systems
- Compliance databases must be developed
- Incorporating processes as early as possible in life of study helps:
  - Manage billing compliance risks
  - Budget appropriately




## CLINICAL TRIAL BILLING OBJECTIVES


- Financial: All costs of the clinical trial are covered by sponsor, third party payor or subject
- Compliance: All costs of the clinical trial are billed to the appropriate payer
  - Third party payors billed only if services not paid by sponsor
  - Third party payor billed only if services are covered
  - Patient billed in accordance with informed consent



## CLINICAL TRIAL BILLING CHALLENGES

- Coverage Principles More Complex
    - Need for common understanding
  - Coordination of Issues More Difficult
    - Need for communication and processes
  - Coding Issues Unique
    - Specific codes for clinical trial services
- 

## WHY SHOULD YOU CARE?

- Audits
  - Investigations
  - Whistleblowers
  - Industry expectations
  - Heightened stakeholder scrutiny
    - Is a study right for the organization?
    - What types of studies are financially viable at the organization?
  - Confronting historical decentralization in the U.S.
- 

## WHAT ARE THE RISKS OF BILLING NON-COMPLIANCE?

- Billing for services that are already paid by the sponsor (double billing)
- Billing for services promised free in the informed consent
- Billing for services that are for research-purposes only
- Billing for services that are part of a non-qualifying clinical trial


## CHALLENGES FACED

- Cause of most research billing non-compliance: Breakdown in coordination
- What are some historical things that might come into play?
  - History of institution
  - Culture
  - Existing structure
  - Size and availability of resources
  - Scope of the research program and scalability of it
- Important information to coordinate
  - What research studies are being conducted at a facility?
  - Which patients are enrolled in a research study?
  - Which services should be charged to payors and which charged to study account?

## MEDICARE COVERAGE PRINCIPLES

- Clinical Trials National Coverage Decision
  - Investigational Device Clinical Trials Mandate
  - All Clinical Trials: Medicare Secondary Payor Rules
  - All Clinical Trials: Payment Restrictions
- 

## HOW DO YOU FIND SOLUTIONS?

- Coordination of study information
    - MCA's and Billing Grids must be available to stakeholders
  - Communication of study information
    - Billing community must be included in the fold
  - Clarity of study documents
    - Medicare Coverage Analysis is a MUST for determining the Medicare billing status of both the study itself and the items and services provided to the research subjects that are outlined in the research documents over the course of the study
- 

## CONFIRM STATUS OF THE STUDY - DEVICE

- 1) Does the study have an IDE from the FDA? Is so, the IDE number should be listed and a copy of the FDA IDE letter should be provided.
- 2) If the study has an IDE, has the FDA assigned the device Category A or Category B status?
- 3) If the device is a Category A, is the device addressing a life-threatening condition?
- 4) If the study does not have an IDE, is the study one of the following:
  - Study involving a HDE device?
  - Study involving FDA approved device approved during PMA process or a 510(k) cleared device
- 5) Is the device being used on-label?

## DRUG OR BIOLOGICAL

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g. physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The trial must not be designed to exclusively test for toxicity or disease pathophysiology. ***It must have therapeutic intent.***
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
4. The research study must be one of the following types of studies:
  - a. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
  - b. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;
  - c. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
  - d. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1)


## MCA GOALS

- MCAs used for:
  - Synthesizing study information with rules
  - Managing study information and costs
  - A “translation” tool: dialogue between Medicare & Research
- MCAs are not:
  - Judgments on studies
  - Judgments on medical decision-making
- MCAs are:
  - tools to ensure billing is done appropriately

## HOW DO YOU KNOW IF YOU NEED AN MCA?


- Is it possible for a charge to be captured in the billing system?
- If possible for charge to be captured, then MCA created
- If study required services using existing specimens or involve collecting data based on the clinical progression of the patient, then no MCA developed

## IMPORTANT PARTS OF BILLING COMPLIANCE

1. Identify research being conducted
  2. Assemble documents to understand what is required by the study
  3. Synthesize relevant information in study under Medicare rules
  4. Identify patients enrolled in research study
  5. Determine how to apply rules and information to charge capture/claims processing system
  6. Develop a process to check the accuracy of development of billing tools
  7. Develop a process to check the accuracy of claims
  8. Ensure appropriate parties are being billed/invoiced
- 

## HOW DO YOU GET THERE?

Let's look at a successful strategy...



## ROLE OF HRA IN CLINICAL RESEARCH

- Fully owned subsidiary of the University of Southern California
- Functions as the research support office for all private industry-funded research on behalf of the USC Keck School of Medicine and other USC Schools conducting clinical research
  - Includes Investigator Initiated Studies
- HRA rarely handles federal, state, local or foundation grants and contracts for clinical and public health research studies
  - Managed by the USC Department of Contracts and Grants
- Responsible for ensuring that PIs and staff are in compliance with clinical trial regulations, including USC guidelines for research

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## HISTORICAL RECAP

- Started with a budgeting tool
- Met with Office of Compliance – joined at the hip for the next several years
- With Office of Compliance, conducted over 25 physician interviews
  - Gauged awareness
  - Assessed practices
- Convened a Process Improvement Task Force
  - HRA, OOC, Study Coordinators, Billers, Administrators from key provider areas – radiology, laboratory, IM, Admission managers, and IDX Director
  - Did not include Hospitals at this juncture
  - Met every other week for over a year
  - Team now meets monthly


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## HISTORICAL RECAP

- o Conducted Clinical Trial Billing Training
  - Three days – over 100 people trained
- o Identified key issues
  - Identifying study participants in a trial
  - Notifying all concerned parties
  - Identifying study related services
  - Ensuring bills dropped properly
- o Four Initiatives
  - TRUE – Trial Registration Update Entry
    - o Database of all ongoing studies on campus that also lists all active participants
  - Modified budget template that adds a Research Order Form
  - IDX flag that is turned on when a participant is consented to a trial
    - o Flag turned on/off by HRA only
  - Training rolled out to separate study teams to individualize as much as possible – 53 Presentations and 321 PI/Coordinators/Staff
    - o Training every Monday for new staff
  - Consistency Checklist

## HRA WEBSITE

The screenshot shows the HRA website homepage. At the top, there is a navigation bar with links for 'About Us', 'Contact Us', 'Investigators', 'Employees', and 'TRUE'. Below the navigation bar is the HRA logo and the text 'Health Research Association, Inc. an affiliate of University of Southern California'. The main content area is divided into two columns. The left column contains an 'OVERVIEW' section with text about HRA's history and services. The right column contains a 'SECTIONS' sidebar with a dropdown menu and a 'News' section with a photo of a building and contact information for the Human Resources Department.



**HEALTH RESEARCH ASSOCIATION, Inc.**  
Health Research Association, Inc.  
An affiliate of University of Southern California

**HEALTH RESEARCH ASSOCIATION, Inc.**

Welcome, Nancy H  
*Role: Diabetes Administrator*

**Participant**

[Home](#)

[Protocol](#)

[Participants](#)

[Study Coordinators](#)

[PI](#)

[Group Editor](#)

[User Editor](#)

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Search Participant
View Participant
Add New Participant

**View Participant**


Participant First Name: Participant F\_name  
 Participant Last Name: Participant L\_name  
 MRN#: 941076  
 MIRUN(LAC #): 6789989  
[Add Note:](#)

[Edit this Participant](#)

[Add Protocol to this Participant](#)

**List of Trials Associated with this Participant**

IRB No.	Protocol No.	Start Date	End Date	Consent Form	HPAA Form	
HS-001028		9/22/2007				<a href="#">Edit</a> <a href="#">Delete</a>



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**PROTOCOL**

[Home](#)

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Search Protocol
Add New Protocol
View Protocol

**View Protocol**

IRB No: HS-001044  
 Protocol Number: SWOG-S9921  
 PI: PI 11 Issue  
 Status: Active  
 Study Coordinator:

Study Coordinator	Phone	Location
Coordinator1	323-226-2452	LAC
Coordinator2	323-866-0469	Norris Cancer Center

Groups Associated with it:

Group Name
CSD
Oncology

Files Uploaded:  
[Study Calendar](#)  
[Research Order Form](#)  
[Medicare Coverage Analysis: Medicare Coverage Analysis](#)  
[MD Order Form](#)  
[Add Note:](#)

**Research Participants Associated with this Protocol:**

Participant Name	MRN #	MIRUN #	Start Date	End Date	Consent	HPAA
Participant 1	553004		5/20/2004			
Participant 2	569970		8/13/2004			
Participant 3		6618782	7/28/2005			
Participant 4	440723		02/10/02			

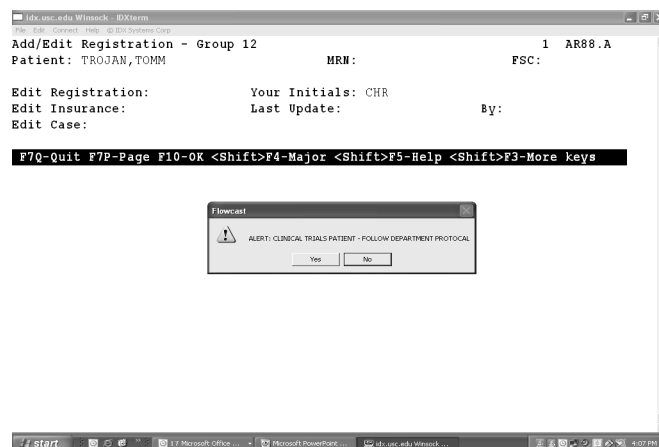
## BUDGET TEMPLATE

- Starts with a coverage analysis
- All tasks related to a study taken into consideration
- Need the sponsors protocol, IDB, lab manual, draft CTA and draft budget if available in order to develop
- Completed for every study regardless of sponsor
- Process is centralized
- EXAMPLE

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## IDX Flag

- IDX patient search
  - Pop-up alert that patients are in a research study



## IDX REGISTRATION SCREEN

- New screen in registration, page 8

The screenshot displays a terminal window titled 'idx.usc.edu Winsock: IDXterm'. The window content is as follows:

```

File Edit Connect Help © IDX Systems Corp
- Patient: TROJAN,TOMMY M08000001 1UR87.CT1
          CLINICAL TRIALS

CLINICAL TRIALS PATIENT? YES

DEPT INTERNAL MEDICINE CONTACT CONTACT 1 - X75820
IRB# HSA-012-000312 START DT: 02/26/2008 DT: 03/07/2008

DEPT INTERNAL MEDICINE CONTACT CONTACT 2
IRB# IRB#3 START DT: 03/01/2008 DT: 03/07/2008

DEPT DERMATOLOGY CONTACT CONTACT 3
IRB# IRB#3 START DT: 01/01/2008 DT: 01/02/2008

F7Q-Quit F7P-Page F10-OK <Shift>F4-Major <Shift>F5-Help <Shift>F3-More keys
  
```

The Windows taskbar at the bottom shows the 'start' button, several open applications including Microsoft Office and Microsoft PowerPoint, and the system clock indicating 4:12 PM.

## HRA CHECKLIST

- 
- Staff at HRA will review the iStar (IRB) application, sponsor contract or grant award and protocol
- HRA staff will upload a document indicating that the contract and iStar material, specifically the Informed Consent document are concordant or areas that require attention.

### Contract/Study Consistency Checklist

Issue	Agreement/ Contract	Informed Consent	Protocol	Reviewer
A. Confidentiality Describe how data or information will be shared between USC, or sites and the research sponsor.				
B. Research vs. Standard of Care The procedures that will be performed during the course of the trial that are considered to be part of the subjects' routine standard of care and that would be performed anyway notwithstanding the research study are differentiated from the procedures that will be performed during the course of the study that are for research purposes only.				
C. Subjects will be required to bear additional costs beyond those associated with their standard care as a result of participating in the study.				
D. Subject Compensation Subjects will be offered compensation for agreeing to participate in the trial.				
E. Research Related Injury Identify the individual or entity responsible for the costs of any research-related injuries to subjects.				
F. Futures Use Of Data Are subjects asked or expected to donate data, materials, samples etc to databases or tissue repositories and will the sponsor receive any future rights to the data or materials collected in the course of the study?				
G. Study is registered at clinicaltrials.gov				

## REVIEW OF CLINICAL TRIAL BILLING OPERATIONS

- Engaged outside legal consultant to conduct compliance assessment of clinical trial funding activities at HRA under attorney-client privilege
- Compliance assessment was “systems check” intended to identify “gaps” in the current system
  - General Consideration: Assess whether policies, procedures, practices and personnel are (1) effective in ensuring compliance with legal and contractual obligations, and (2) can be further enhanced
  - Specific Objective: Determine whether USC/HRA can reasonably ensure that appropriate parties are billed for clinical trial services

## CONSULTANT RECOMMENDATIONS

### ○ Categories for Action

- Personnel Response
- Policy Development and Implementation
  - Budget Policy
  - Contract Policy
  - Other Clinical Trial Policies



## CONSULTANT RECOMMENDATION

### ○ Personnel Response

- Reorganization
  - Layoff/Reorganization
  - Hiring of new staff with appropriate skills
    - Clinical, research, billing
  - Training
  - Coordination with Dept Contracts and Grants

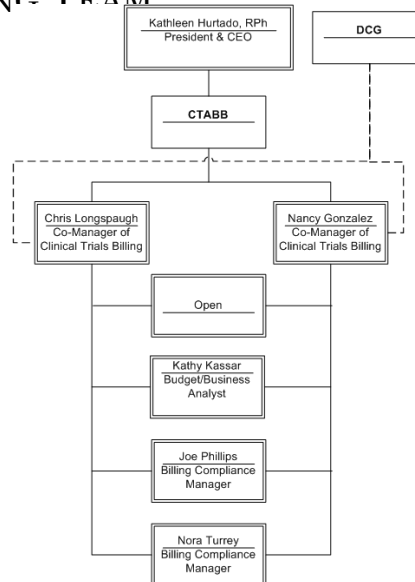


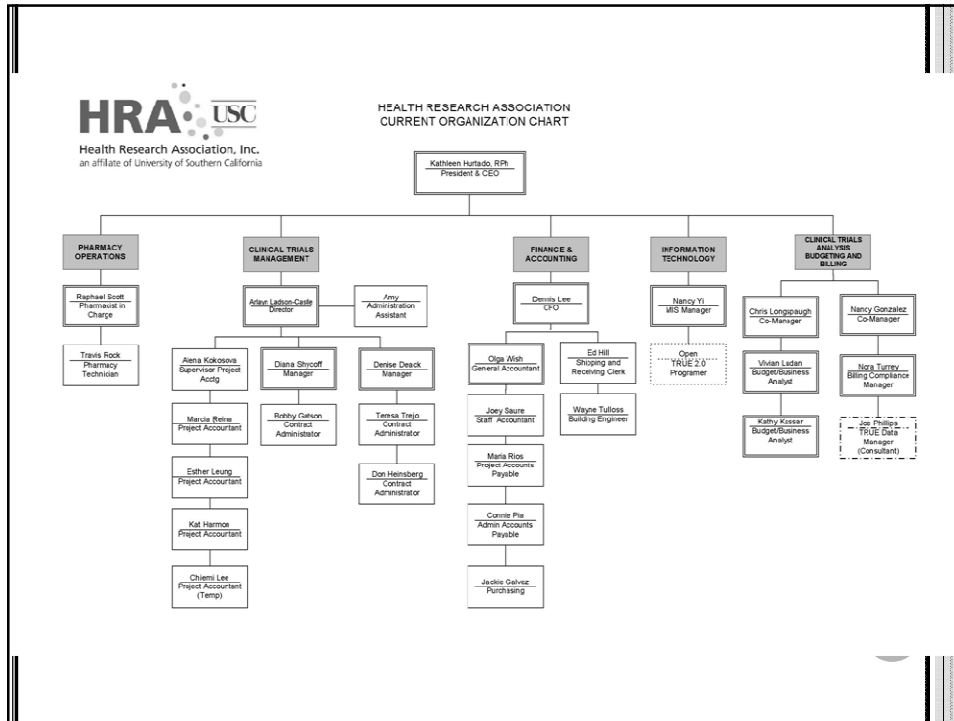
## HRA CTABB AND CTM

- CTABB
  - Two pharmacists and one certified coder doing budgets and MCAs
  - One billing reconciler/manager
  - One database manager
  - One budgeting and billing manager for CTU
- CTM
  - One Director with law degree
  - Five contract administrators

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## CLINICAL TRIAL ANALYSIS BUDGETING AND BILLING TEAM





## CONSULTANT RECOMMENDATION

### o Policy Development - BUDGETING

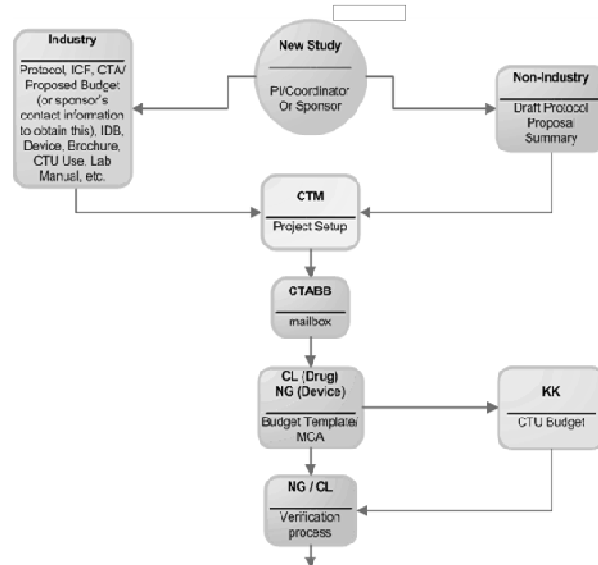
- Format by which to conduct a Medicare Coverage Analysis for EVERY clinical trial project regardless of funding source that will guide the budget development
  - o Includes MCA Worksheet
  - o Complement to the Budget Template

## CONSULTANT RECOMMENDATION

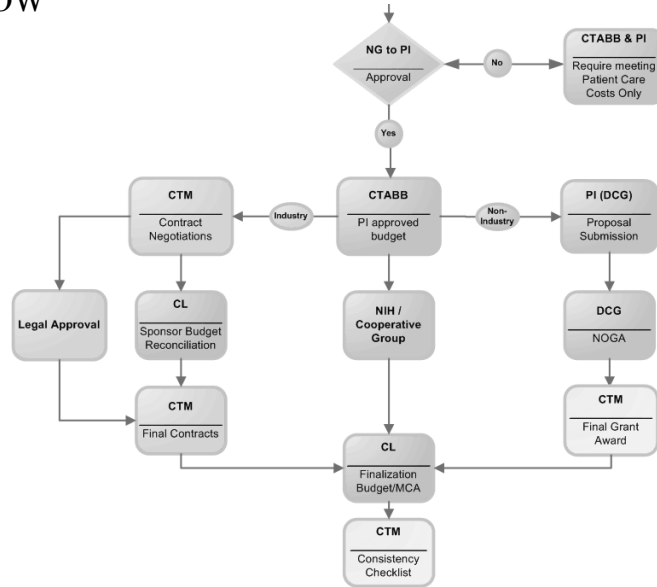
### o Policy Development - CONTRACTING

- A directive to the contract administrators with detailed instructions on how to use the Clinical Trial Agreement template
  - o Includes CTA Template and Guidelines
  - o Training
  - o Separate template for Investigator Initiated Studies

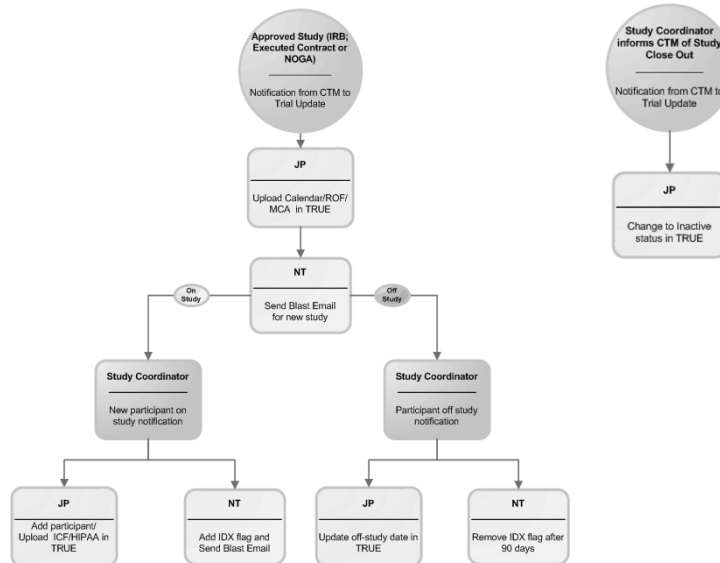
## CLINICAL RESEARCH BUDGETING WORK FLOW



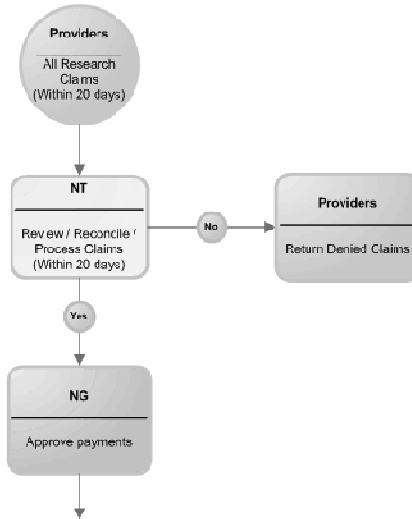
## CLINICAL RESEARCH BUDGETING WORK FLOW



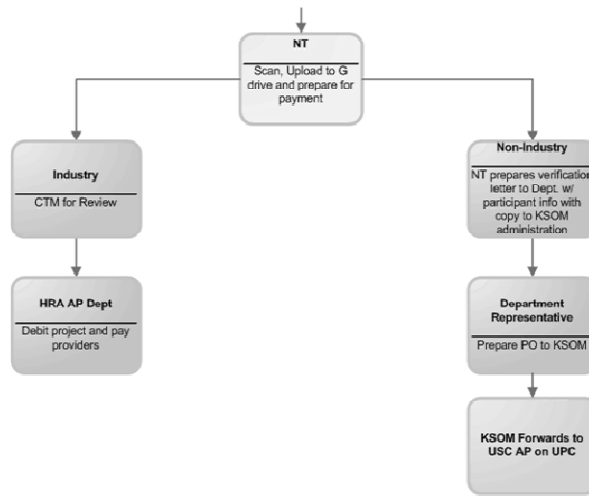
## RESEARCH PROJECT AND PARTICIPANT FLOW



## CLINICAL RESEARCH CLAIM PROCESSING



## CLINICAL RESEARCH CLAIM PROCESSING



## CLINICAL TRIAL BILLING INITIATIVES

- Process Improvement Team with Hospitals initiated
  - HRA, OOC, Admitting, Scheduling, Authorizations, Billing, Auditing, Medical Records and selected departments as needed
  - Meetings every two weeks initially for over a year and now monthly
- Problems identified via “Issues Log” and communication between groups; Intervention as necessary
- The recurrent themes:
  - Adding tests to the ROF
  - Not using the ROF
  - ROF not signed or missing diagnosis
  - Not communicating end or off study dates
  - New coordinators – not trained


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## TRUE 2.0 (CLICK PRODUCT)


- Will add further transparency to process
- Tie in with pre-award and IRB systems
- Real time tracking and email notification of exceptions
- Better workflow management and personnel management
- ROFs on a visit basis rather than study basis
- Participant tracking on a more granular level

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## KEYS TO SUCCESS

- COMMUNICATION
  - TEAM WORK
  - TRAINING
  - TECHNOLOGY
  - PATIENCE
  - SENSE OF HUMOR
- 

## MODELS FOR IDENTIFICATION OF SUBJECTS AND BILLS

- Front-end process
    - Study-specific order forms
    - Research check-off on all order forms
    - Medicare coverage analysis in charts
    - Central repository of coverage analyses checked
  
  - Back-end process
    - Temporary hold on research patient's accounts
    - Review held account against coverage analysis or billing plan
    - Designated reviewers
- 


## MODELS FOR IDENTIFICATION OF SUBJECTS AND BILLS

- Front-end process
  - Upside: no bill hold
  - Downside: heavy compliance auditing needed
  
- Back-end process
  - Upside: manages billing risk well
  - Downside: temporary bill hold can grow large if not managed efficiently


## MODELS FOR CHARGE DIRECTION

- Charges need to be directed to payor or to study account
  
- Identify protocol-required services
  
- Coverage analyses/billing plans:
  - Medicare Coverage Analysis to manually direct/flag charges
  - Billing plans for each study programmed into claims generation process

## STEPS IN PROCESS IMPROVEMENT

- Identify subjects
  - Hold bills associated with subjects
  - Know study documents including MCA and billing or budget grids
  - Review every item on schedule of events, confirm status and number of times being done
  - Know the CPT code, description, revenue code and item number (from the MCA and/or grid)
  - Frequency & date of service for each subject is key for review of a bill (study calendar and date of consent)
  - Know items that will be expenses against research funds and review all bills
- 

## STEPS TO MCA DEVELOPMENT

- Collect documents
    - Protocol
    - Lab Manual
    - Investigational Drug or Device Brochure
    - IND or IDE letter
    - Sponsor Proposed Budget
    - Draft Clinical Trial Agreement or Master Agreement
    - All Research Staff and Sites Involved in the Study
- 


## MCA STEPS

- Is the trial qualifying?
- What is the item or service being investigated and is it billable to Medicare?
- Categorize each item and service that is protocol related as “customary care” or “research”
- Review what sponsoring is covering in their budget and contract
- Confirm all services considered billable to Medicare according to the national and local coverage determinations under the guidelines
- Verify informed consent language and contract language


## BILL HOLD REVIEW STEPS

- Identify Subjects and place all bills and charges on hold for review
- Verify date of service within consent date and study calendar
- Identify and segregate charges against MCA and billing grid
- Ensure you have the following:
  - Correct bill
  - Correct amount
  - To the correct payer

## COMMON SHORT TERM SOLUTIONS

- Patient-level research flag
  - Visit-level research flag
  - Edit checks via patient registry / Clinical Research Management System
  - Dual registration
- 

## LINKING TO PERFORMANCE IMPROVEMENT

- Implications for staffing and daily workload assignment
  - Role delineation and job responsibilities must be clear
  - Training and monitoring must include workload measures
  - Solutions demand cooperation of all involved and a knowledge of what is expected at the beginning
- 

	Output	Critical Dimension	Indicator	Standard	Monitoring
1)	Review All Documents Assess "Qualifying" status	Accuracy	Verifies check list	100%	Audit
3)	Identifies item, service or device that is investigational	Accuracy	Reviews schedule of events or protocol calendar	Reviews FDA exemption letter and knows IDE and IND number	PI and Supervisor review
4)	Categorizes each item or service as "customary" or "research"	Accuracy	Reviews guidelines and standard practice for Institution	All items categorized and PI contacted if any questions arise	Review and denial history based on bill release
5)	Confirms services are billable under the NCD and all guidelines	Accuracy	Checks NCD and LCD and any pertinent guidelines	Documents all comments and references on MCA	Review and audit
6)	Documents findings appropriately on MCA	Accuracy	Provides billing grid and MCA finalized with appropriate features	Search and find and document from sources	Number of denials based on documentation
7)	Verifies consent, budget and MCA are congruent	Accuracy	Checklist completed	100%	Satisfactory findings upon audit
8)	Builds MCA within 8 working days of receipt		MCA completed within timeframe	85%	Logs time to completion

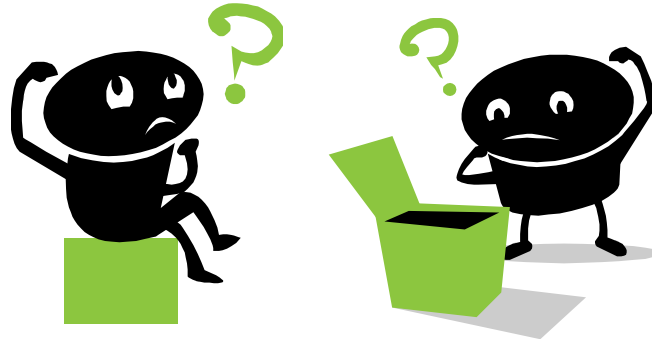
**JOB MODEL**

*The chart is a sample of monitoring and evaluating a Clinical Trials Billing/MCA Coordinator aimed at improving performance through training and supervision.*

## THE CLOSER – RESOLVE THE RISKY BUSINESS OF BILLING COMPLIANCE

- Identify billing errors
- Identify process improvement solutions
- Demonstrate system change effectiveness
- Provide metrics for evaluating process improvement
- Provide evidence of billing compliance
- Train and evaluate team
- Track progress
- Learn from your mistakes

## QUESTIONS?



## CONTACT INFORMATION

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