Objectives

- Evaluate leading practices for establishing a clinical research revenue cycle (CRRC)
- Distinguish pitfalls and techniques for managing regulatory risks throughout the revenue cycle
- Construct the high-level framework for effective and complaint CRRC management
Clinical Research Revenue Cycle

<table>
<thead>
<tr>
<th>Focus Area</th>
<th>Sub Area</th>
<th>Regulatory Agency</th>
<th>Risk Description</th>
<th>Proposed Approach</th>
</tr>
</thead>
</table>
| Billing Compliance       | Coverage Analysis                 | CMS               | Without a documented coverage analysis, the institution is at risk of potentially billing Medicare for non-qualifying clinical trials and/or potentially inaccurate clinical research billing. In addition, this step is key to the successful execution of the remaining steps in the billing compliance continuum. The institution may also be losing revenue due to billing denials by third party for services billable to a sponsor, | The following controls should be incorporated into operational procedures:  
• Consolidate coverage analysis, oversight and enforcement into a central office  
• A documented coverage analysis should be used for all the current clinical research studies (with billable procedures) |
| Billing Compliance       | Patient Tracking / Enrollment Registration | CMS               | Without a centralized location for recording all enrolled clinical research participants, registration and scheduling of these participants is difficult and could lead to errors.                                      | • A central database for patient billing compliance should be used that identifies all clinical research participants, and which has mechanisms for recording whether an individual procedure charge is considered Standard of Care (SOC) or Research related (RS). |
| Billing Compliance       | Coding and Billing                | CMS               | Without appropriate routing of SOC vs. RS charges, the institution is at risk for:  
• Improper billing  
• Loss of revenue due to denials  
• Non-compliance with Medicare clinical research coding and billing regulations                                                                 | The following controls should be incorporated into operational procedures:  
• Standardized coverage analysis billing grids should be used  
• Billing grids should be centrally available and shared with coding and billing teams within each ancillary department. |
### CRRC Risks & Mitigation

<table>
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<tr>
<th>Focus Area</th>
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</tr>
</thead>
</table>
| Billing Compliance| Reconciliation | CMS               | Without a periodic reconciliation process, there is a risk of:                                        | • A centralized, single source of clinical research billing data should be used (SOC and RS charges).  
  • The centralized clinical trials office staff should generate monthly or quarterly reconciliation report utilizing this data.                                                                                       |
| Financial         | Sponsor        | Invoicing         | An inconsistent invoicing and tracking process may result in unbilled invoices and loss of potential revenue. | • A centralized AR invoice tracking system should be used for sponsor invoices. Alternatively, an enterprise-wide clinical research management system (CTMS) could be used. |

### Defining the regulatory landscape & impact

Although the regulatory landscape for research remains relatively constant, determining the institutional risk impact is challenging.

<table>
<thead>
<tr>
<th>IMPACT</th>
<th>SCORE</th>
<th>RATING</th>
<th>FINANCIAL</th>
<th>OPERATIONS</th>
<th>GOVERNANCE</th>
<th>EXTERNAL</th>
<th>PEOPLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophic</td>
<td>5</td>
<td>Greater than 25% increase in costs</td>
<td>Increased financial burden, decreased institutional profit, damage to the reputation of the institution</td>
<td>Criminal sanctions, civil penalties, loss of government contract or accreditation</td>
<td>Serious damage to reputation, increased scrutiny by regulatory agencies</td>
<td>Requires senior management and BOD oversight</td>
<td>There is a leadership vacuum so severe it would require fundamental, large scale changes involving senior management, board of directors, and other key stakeholders.</td>
</tr>
<tr>
<td>Significant</td>
<td>4</td>
<td>Greater than 15% increase in costs</td>
<td>Increased financial burden, decreased institutional profit, damage to the reputation of the institution</td>
<td>Sanctions $50K to $100K</td>
<td>Broad and extended negative media coverage, loss of business opportunities</td>
<td>Requires high level of senior management attention and involvement</td>
<td>May involve changes to management team and other key stakeholders.</td>
</tr>
<tr>
<td>Moderate</td>
<td>3</td>
<td>Greater than 5% increase in costs</td>
<td>Increased financial burden, decreased institutional profit, damage to the reputation of the institution</td>
<td>Sanctions $5K to $50K</td>
<td>Negative press/social media mentions limited to one area/department, or one segment of the institution</td>
<td>Requires management team focus and some senior management oversight</td>
<td>May involve changes to management team and other key stakeholders.</td>
</tr>
<tr>
<td>Limited</td>
<td>2</td>
<td>Greater than 2% increase in costs</td>
<td>Increased financial burden, decreased institutional profit, damage to the reputation of the institution</td>
<td>Sanctions no financial penalties, or fines, or regulatory citations, or worsening of reputation</td>
<td>No negative press/social media mentions, no media coverage, no loss of business opportunities</td>
<td>Limited management team focus and some senior management oversight</td>
<td>Limited management team focus and some senior management oversight.</td>
</tr>
<tr>
<td>Minimal</td>
<td>1</td>
<td>Less than 2% increase in costs</td>
<td>Increased financial burden, decreased institutional profit, damage to the reputation of the institution</td>
<td>No financial penalties, or fines, or regulatory citations, or worsening of reputation</td>
<td>No negative press/social media mentions, no media coverage, no loss of business opportunities</td>
<td>Minimal, if any, management team focus required</td>
<td>Limited management team focus and some senior management oversight.</td>
</tr>
</tbody>
</table>

A risk may be assigned a rating of 1-5 by meeting one or more of the criteria associated to that rating; it is not necessary to meet all associated criteria for a given rating.
VL1  Erika - I would like to talk about this slide. Need to fully understand it. How can we make it easier to read?
Veazie, Mary L, 5/15/2020
### Prioritizing CRRC risks

<table>
<thead>
<tr>
<th>Understanding Sources of CRRC Risks</th>
<th>Developing CRRC Risk Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What goals must we achieve?</td>
<td>• Define the business objectives</td>
</tr>
<tr>
<td>2. What must go right to achieve our goals?</td>
<td>• Identify legal and regulatory requirements</td>
</tr>
<tr>
<td>3. What process would we connect this to?</td>
<td>• Identify risks to the objectives and requirements</td>
</tr>
<tr>
<td>4. Where in the organization is this owned?</td>
<td>• Determine the significance of the risk impact</td>
</tr>
<tr>
<td>5. What activities and controls must exist?</td>
<td>• Define the process where the risk is managed</td>
</tr>
<tr>
<td>6. What dependence exists on IT systems?</td>
<td>• Recognize business requirements for the process</td>
</tr>
<tr>
<td>7. What action must we take in response?</td>
<td>• Where in the organization is the process managed</td>
</tr>
<tr>
<td></td>
<td>• Who is accountable for the process</td>
</tr>
</tbody>
</table>

### RISK MITIGATION STEPS

**Understanding the Regulations**
On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Services to "explicitly authorize [Medicare] payment for routine patient care costs...and costs due to medical complications associated with participation in clinical trials."

Understanding the Regulation (cont.)

In response to the Presidential order the Center for Medicare and Medicaid Services (CMS) issued the clinical trial policy national coverage determination (NCD)

- NCD 310.1 Routine Costs in Clinical Trials
  - (CMS Internet Only Manual (IOM) Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 4, Section 310.1 "Routine Costs in Clinical Trials")
- Effective September 19, 2000
- Revised July 9, 2007
Understanding the Regulations

Patient Protection and Affordable Care Act (PPACA) became law in March 2010.
In 2014, new and non-grandfathered health plans will be required to cover clinical trials.
Plans may not:

• Deny the individual participation in the clinical trial
• Deny, limit, or impose additional conditions on the coverage of routine patient costs for items & services furnished in connection with participation in the trial; and
• Discriminate against the individual based on their participation

For this act, an individual is eligible to participate in an approved clinical trial according to the trial protocol for cancer or life threatening disease and if referred by a participating health care provider.

Local Regulations

Medicare Administrative Contractors works on behalf of Medicare to manage and process claims and implement state/regional coverage rules called:

• Local Coverage Determinations (LCD)

LCDs detail requirements necessary for reimbursement for certain services including

• Applicability, frequency, and exceptions
• Off-Label Drug Use in Clinical Trials
• Reimbursement requirements for IDE (investigational device exemptions)
RESOURCE TOOLS USED TO DETERMINE ROUTINE CARE

- Centers for Medicare and Medicaid Services (CMS)  
  www.cms.hhs.gov
- Novitas (LCD) – Texas  
  www.novitas-solutions.com

For oncology:
- National Comprehensive Cancer Network (NCCN)

Other disease groups:
- Utilize the national compendia applicable for the disease being investigated
- Review of coverage policies of common insurance carriers (Blue Cross, Aetna, Cigna, and United Healthcare)

RISK MITIGATION STEPS

The Medicare Coverage Analysis – a Multiuse Document
Clinical Trial Routine Cost Coverage

CMS has specific rules that must be met to qualify for coverage of the Routine Costs associated with the trial.

Cannot bill for Routine Services if the trial fails to meet CMS criteria
  • Some items/services never can qualify to bill to CMS

Items that cannot be billed must be covered by the trial funding source such as the sponsor.
NCD 310.1 - Routine Costs for Clinical Trials

National Coverage Determination 310.1 explains that specific requirements must be met in order to:

• Qualify for coverage
• Submit a claim properly and
• Receive reimbursement for claims submitted

Qualifying for Coverage

Three (3) Mandatory Requirements:

1. Trial must:
   • Evaluate an item or service within a benefit category and
   • Not be statutorily excluded from coverage

   Example: What Meets this Criteria?
   • Diagnostic tests, drugs, & biologics
     o Yes!
   • Hearing aids, cosmetic surgery, dental exams
     o No!
Qualifying for Coverage

2. The Trial must:
   • Not be designed exclusively to
     o Test toxicity or
     o Disease pathophysiology
   • Have therapeutic intent

Example: What Meets this Criteria?
• Phase 2 clinical trial testing FDA investigational new drug
  • Yes!
• Prospective lab trial to test tumor signal pathways
  • No!

Qualifying for Coverage

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

Example: What Meets this Criteria?
• Phase 2, two-arm comparison trial testing use of endoscopy dye to detect colon polyps. Will enroll participants with known polyp hx scheduled for follow-up colonoscopy, and pts with no known colon hx scheduled for initial colon screening.
  • Yes!
  
• Phase 1 study of the general population testing new cholesterol lowering medicine. Will enroll healthy volunteers ages 40-65.
  • No!
Qualifying for Coverage

3 Requirements Are Not Enough

Trial **Must ALSO** meet 7 characteristics (synopsis)
- potentially improves health outcomes
- well-supported by scientific & medical information
- does not unjustifiably duplicate existing studies
- is appropriate to answer the research question
- sponsored by a credible organization
- in compliance with Federal regulations
- conducted with scientific integrity

Qualifying for Coverage

Some trials will meet the 7 characteristics automatically if:
- Funded by NIH, CDC, AHRQ, CMS, DOD and VA;
- FDA IND & IRB Deem IND Exempt Drug Trials: or
- Supported by Centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA
Qualifying Clinical Trial

If the trial:
- Meets all 3 mandatory criteria and
- The 7 desirable characteristics (synopsis)

Then the trial is considered to be a
- Qualifying Clinical Trial
- Thereby meets the requirements for coverage of Routine Costs

Covered Services/Routine Costs

- What Does CMS consider to be Routine Costs?
- Routine costs of a qualifying clinical trial is defined as:
  - Reasonable & necessary items and services used to diagnose and treat complications
  - All other Medicare rules apply
  - All items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arms of a clinical trial
  - Items or services that are typically provided absent a clinical trial
Routine Costs (cont.)

- Items or services required solely for:
  - The provision of the investigational item or service
    - Covers the administration of an investigational product
  - Clinically appropriate monitoring of the effects of the item or service, or
  - Clinically appropriate monitoring for the prevention of complications

- Items or services needed for reasonable and necessary care for the diagnosis and/or treatment of complications.

---

Routine Care/Cost Decision Tree

Would the participant receive the item or service if they were not enrolled in a clinical trial?  
**Routine Care/Cost**

- Yes
- No

Is the item or service required to provide a research item or service?  
**Example:** Administration of non-chemotherapeutic agent, or a medically necessary inpatient admission for an investigational surgery

- Yes
- No

Is the service rendered required for the monitoring of the effects of the investigational item or service?  

- Yes
- No

Is the service rendered for the prevention of complications related to the investigational item or service?  

- Yes
- No

Is the item or service medically necessary for the diagnosis or treatment of complications arising from the investigational service?  
**Example:** Participant in an arm of the study develops a complication requiring a medically necessary admission

- Yes
- No

The item is covered and considered "Routine Care/Cost"
CMS Defined Research Costs

What does CMS consider to be Research?
The investigational item or service itself
  • Unless otherwise covered outside of the clinical trial
    • Example: Some items or services are covered but are also part of the trial investigation
    • Off-Label Use of approved drugs
      • Provided these meet CMS criteria usage requirements

Research Costs Include

• Items and services provided solely to:
  • Satisfy data collection and analysis needs
  • Services not used in the direct clinical management of the patient
    • Example: Monthly CT Scans for a condition usually requiring only a single scan

• Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial
  • If sponsor covers the cost of the service, CMS cannot be billed
## What To Bill?

<table>
<thead>
<tr>
<th>Covered</th>
<th>Non-covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Administration of drug</td>
<td>o Satisfy data collection</td>
</tr>
<tr>
<td>o Labs to monitor effects of drug</td>
<td>o Absent a clinical trial the service or item that provided solely for the purpose of the study.</td>
</tr>
<tr>
<td>o Complications</td>
<td></td>
</tr>
<tr>
<td>o All items and services are subject to LCDs and NCDs.</td>
<td></td>
</tr>
</tbody>
</table>

## What Does This Mean?

For each item or service, ask the question, why is this being done?

What is the reason / diagnosis for this service?
- o Assign the diagnosis and determine if it is covered under the terms of an LCD or NCD.
Facts

The billing mechanics are easy
Communication is key
The hard part is:

Getting the right information to the billing department!

Financial Life Cycle of Clinical Research Study - CTMS
Clinical Research Billing (CRB)
Research Charge Review Process - EHR

Patient is seen in clinic

Encounter is closed & charges are entered

Charges enter research billing review WQ

Research charge review and make determination

Link study activities to study

Q0 & Q1

Bill to patient/insurance

Not Related

Bill to Sponsor

PB Gross Revenue Recognized

RISK MITIGATION STEPS
Building Controls in Systems
Building Controls in Systems

• Centralize the study calendar & coverage analysis (CA)
  • Drives standards
  • Ensures compliance with CMS billing guidelines
  • Validate build with PI and/or designee
    • Provides assurances build matches IRB approved study
    • Obtain signature and date
• Electronically transfer coverage analysis to EHR
  • Becomes billing grid in EHR
  • Drives research billing process
• Create study note templates in EHR
  • Include study number; date of service; cycle & day; treatment provided; adverse events, if any
  • Drives standardization
  • Aid with research billing review

Building Controls in Systems

• Consent patient
  • Electronically transmit the consent date to CTMS and/or EHR
    • Associates the patient to the study
  • Central office creates initial patient timeline
• Associate to treatment plan and link encounters
  • PI and/or designee associates patient to treatment plan & timeline
    • Adjust as needed; based on patient
  • Generated research orders
    • Link encounters, as needed
• Patient treatment occurs
  • PI and/or designee ensure encounter is linked appropriately
  • Document study notes in patient’s chart
    • Include cycle and day; treatment; adverse event, if any
Building Controls in Systems

- Study Revisions
  - Revise the CA
    - Validate with PI and/or designee (obtain signature & date)
  - Migrate revised CA to EHR
    - Revise billing grid at study level
  - PI and/or designee re-associate patient treatment plan and timelines, as needed

Building Controls in Systems

- Research Billing Review
  - Centralized process
  - Utilize the CA in CTMS to aid with determination of appropriate charge routing
  - Monthly reconciliation of sponsor paid charges
    - Validation process between central office and department personnel
    - Utilize work queues in EHR to drive process
    - Post charges to general ledger within 30 days of month end
    - Mitigates risk of inappropriate billing

- Clear Effective Communication
RISK MITIGATION STEPS
Checks and Balances

Checks & Balances

• Reports
  • Research patient appointment report (linked encounters)
  • Patient timelines in CTMS vs. linked encounters in EHR
  • Patients with missing timelines & treatment plans report
  • Copy forward report (Beacon treatment plans)
• Productivity reports:
  • Research billing review productivity report
  • Research reconciliation productivity report
• Research billing reports
  • Study charges by department
Checks & Balances

• Monitoring
  • Monthly review of reports
    • Run queries to perform reasonableness checks
  • Review patient timeline in CTMS vs. linked encounters
• Reconciliation process
  • Validate centralized charge review
  • Shared learning – central office and department personnel
• Milestone achievements
  • Timely sponsor invoicing
• Close out process
  • Review research billing
    • Ensures appropriate billing prior to closing
    • Reasonableness checks for other budget categories

BEST PRACTICES
Best Practices

Differentiate covered services from non-covered (research related) services for major payers.

Creation of Coverage Analysis utilizing CMS guidelines

Once study is approved, enroll study [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and obtain 8 digit number.

Best Practices

Define how study enrollees will be identified on the front end.

Determine if internal systems can “talk” to one another for data transmission purposes.
  • Study number
  • Coverage by service
  • Diagnosis codes
Best Practices

At enrollment, informed consent should list out services that are non-covered.

At time of registration, obtain ABN for non-covered services.
  o Work with finance dept to inform patient of financial responsibilities associated with the trial.

If patient receives services at another institution, facility or entity that does their own billing, ensure that the services are identified appropriately. (i.e. national lab)

Conduct audits after the first 10-20 group of enrollees meet their first benchmark to ensure process is working correctly.

Best Practices

If problems are identified, fix it before it becomes out of hand.

End of trial procedures:
  • Perform post-study audit to ensure funds have been invoices, received and appropriated correctly.
  • Determine cause of credit balance
  • Review contract to determine what happens to excess funds.
Questions

Contact Information

Mary Veazie
Executive Director, Clinical Research Finance
The University of Texas MD Anderson Cancer Center
mlveazie@mdanderson.org