The Evolution and Complexity of Revenue Management of Industry Funded Clinical Trials at Duke

Cathy O’Neill, Department of Medicine
Christeen Butler, Department of Pediatrics

Agenda & Objectives

- What is “Revenue Management” and what are we trying to accomplish
- Why is it important to your Department and its respective Clinical Research Unit (CRU)
- How does it work, who is involved and what is a “Trial Tracker”
- What are best practices for Reviewing, Verifying and Validating the data?
- What are the critical analyses that should be done?
- Who is responsible?
- What tools and resources are available?
What is Revenue Management?

• A process of aligning the funding within the Sponsor Agreement/Contract to an activity or event that takes place on the project
  • Start up activities
  • Number of Subject Visits
  • Reaching a milestone
  • An adverse event

• A School of Medicine Initiative to systematically track & record revenue earned on industry funded projects normally driven by milestones and visits

What is Revenue Management?

• Sometimes you may hear this process referred to as “Accrual Based Accounting”

• In simple terms; the primary accounting purpose of revenue management is to:
  • Match the revenue earned from the sponsor with the costs of performing the activity
  • In the same time frame the costs are incurred
Why is Managing your Revenue so Important?

- Provides a more realistic picture of the financial health of a study.
- Profit and Loss statement reflects not only the cash collected to date, but also what is billable on the work performed.
- Proactive management of clinical studies; Identify and resolve issues before they become problems.
- Ensures Principle Investigators have key information to make sound decisions associated with the work to be carried out on the study.

Why is Managing your Revenue so Important?

- Allows the Finance Practice Manager/Study Team to clearly identify when monies are owed for work performed.
  - Ability to determine when an Invoice is required
  - Better control over the collection of funds
  - Recognition of when a Study is operating in a true deficit situation
  - Isolates problems associated with cash lags

- Further Supports the Research mission of the Clinical Research Unit and their Department
How Do We Manage the Revenue Process?

• Have a strong understanding of the essential aspects of the contract
  – What are you being asked to do?
  – What are you being paid for?
  – What has to happen to get a check in the door?

• Understand the importance of enrollment data and the study protocol
  – What does the protocol require to be done?
  – When do visits or events happen?
  – When do milestones, invoiceables or out of scope’s occur?

These principles must be integrated to create a mechanism to manage revenue

Background on Trial Tracker Concept

• Late 2010 SOM Finance approached Departments and CRU’s with a new initiative to systematically track Industry Sponsored Revenue streams

• Process was phased in beginning with smaller departments

• Each Department and CRU developed a “Trial Tracking” tool manage the process
  – Many areas enhanced this tool to track invoicing, subject payments and other study related administration

• Full implementation for all Clinical Research Units (CRU) was July 1, 2011
The Trial Tracker

• At Duke today this mechanism is essentially a worksheet

• An Excel tool nicknamed the “Trial Tracker” developed and in use within the majority of the Clinical Research Units (CRU’s)

• “A Trial Tracker” connects the subject encounters with the contract payment terms

• It lays the foundation for the key concepts that are normally found within a Clinical Trial Management System

The Trial Tracker

• “Key Concepts” captured on Trial Trackers and would be included within a CTMS for these types of studies:
  – Study Demographics
    • IRB information
    • Fund Code Information
    • Sponsor Information
    • Contract & Payment Terms Information
  – Study Budget
    • Internal & External
  – Study Activity / Deliverables
    • Visits & Milestones – such as the Schedule of Events
    • Subject Visit Tracking
    • Enrollment Log
  – Financial Activity / Deliverables
    • Visit & Milestone payments
    • Invoice information
The Trial Tracker

• The Trial Tracker incorporates the critical information a Clinical Research Coordinator gathers (such as the subject encounters or visit dates) and combines it with the finances associated with those events

• The Trial Tracker allows the Finance Practices Manager to closely monitor the financial aspects of the project

In Summary

• The business process has evolved to compare earned/billable revenue versus expenditures incurred

• For every study related activity, there is usually a payment associated with it
  – Subject Visits/Procedures
  – Milestones
  – An adverse event
  – IRB renewal
  – Pharmacy charges

• In addition, Trial Trackers:
  • Simplify invoicing by providing a place to track when and what to bill
  • Tracks funding received on project since inception
Trial Trackers - Visits & Milestones

• Trackers usually revolve around patient visits or milestones
  – Visit dates and/or milestones are entered here
  – This tool will tally the revenue earned on the occurrence of each visit

• Simple approach – the tracker should serve as or mirror the Enrollment Log and/or visit logs study teams already maintain

• Tracks, Tallies and Calculates Invoiceable items
  – Ability to track invoices sent and collected
  – Place to record earned amounts for “Out Of Scopes”, Invoiced Milestones or Fees

When visits are confirmed or milestones are achieved, the revenue is then considered earned

Trial Trackers – Determining the “Accounts Receivable”

• Payments / Cash received from the Sponsor
• Summarizes & Provides three Key Figures
  – Total Earned Revenue
  – Total Cash Received
  – The difference between the two is the amount of money still owed to Duke for the work performed for the Project

This represents the Accounts Receivable on the Project
Important Steps - Review, Verify and Validate the Information

• Summary Report
  – View month to month trending for the entire fiscal year
  • Trends of Earned, Cash & AR
  – Easy way to validate cash

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What are the responsibilities?

• Depending on the size of the CRU Portfolio, the Finance Practice Manager and the Research Practice Manager may be responsible for detailed aspects on each Project/Study
  ➢ They are responsible for the overall support & management of this activity for their CRU
  • The success of managing the revenue process depends on the relationship & synchronized communication between the CRC, FM, CRU FPM and CRU RPM
What are the responsibilities?

• **The Financial Manager**
  
  – Must have an awareness of study protocol
  – Must have a strong working knowledge of the Sponsor contract
  – Is the Creator and Owner of the Trial Tracker Tool for each project, maintains may components of it
  – Responsible for monthly financial reporting of the Earned Revenue, Cash received and outstanding Accounts Receivable to the School of Medicine

• **Clinical Research Coordinator**
  
  – Has a strong knowledge of the Study Protocol
  – Must have an awareness of the contract terms of the Sponsor agreement
  – Recruits and Enrolls the Subjects into the Study
  – Tracks and logs the subject visits and milestones on a timely basis, enters into tracker or provides info to finance regularly
The Number One Critical Success Factor

The Relationship between the

Clinical Research Coordinator

and the

Financial Manager

Goal of CRU Finance Staff

– Ensure all money earned on a trial is recorded, collected, and reconciled
– No study is closed unless all payments owed have been received
– Proactive management of clinical studies; Identify and resolve issues before they become problems
– Use systems intelligently to reduce repetition and/or duplication of effort for CRCs
– Be flexible enough to work with CRCs in the way best suited for them
– Expedite internal processes to avoid administrative snags
“Tools” Finance Team Uses

- Contract
- Schedule of Events
- CTOV reports
- Trackers
- eIRB
- eResearch
- Visit Logs
- IDS invoices
- SAP
- Regular communication w/ Sponsors
- Regular communication w/ CRCs

How do we use these tools?

- Contract – we pick it apart
  - What comes in automatically? When?
  - Is there a holdback on patient related payments?
  - What do we invoice for? When?

- Schedule of Events – we look at it
  - Anticipate future visit dates as patients are enrolled

- CTOV reports – we see scheduled visits
  - Which study patient is coming in
  - Review against SoE, determine if timing coincides with a particular visit, confirm w/ CRC
How do we use these tools?

• Tracker – we track the money and its status
  • Calculate revenue earned in “real time”
  • Track what we’ve invoiced for and when
  • Ensure all items are marked “Payment Received” before we begin fund code closeout procedures

• eIRB – we see things that might need invoicing
  • Approval
  • Renewals
  • Amendments (expedited/full IRB)
  • Safety Reports

How do we use these tools?

• eResearch – we see enrollment
  • Patients enrolled
  • Screen Failures
  • Visits (future - calendaring being tested)

• Visit logs – we see what’s real
  • Confirm/Validate visits that have occurred
  • Note/confirm visits missed

• IDS Invoice – we see charges
  • CRU listed as Business Admin, informed of charges via email

• SAP – we see what’s posted to the code
  • Monitor funds in account, confirm deposits
  • Reconcile expenses
  • Monitor IDS charges to spur invoicing (if not receiving IDS email)
How do we use these tools?

- **Communication with CRCs**
  - Clarification on procedures to ensure we are paid appropriately
  - Confirmation of visits/invoiceables
  - Check in regularly to assure we know what’s going on with a study before we contact a sponsor
  - Facilitate the study and fund code closeout process

- **Communication with Sponsors**
  - Work with sponsors to understand nuances of contract budget
  - Submit invoices and required documentation
  - Determine why a payment may be held up

Who else is involved?

- **Department Leadership**
  - Responsibility over the monthly financial reporting and overdraft management

- **CRU Medical Director**
  - Oversight of the Studies within the CRU portfolio from a fiscal and regulatory perspective
  - Supports this initiative

- **Duke Office of Clinical Research**
  - Support and Education of Policies and Procedures

- **School of Medicine Finance**
  - Validation of AR and entry into the Financial Systems
  - CRU Monthly Financial Reporting to Senior Leadership
QUESTIONS/DISCUSSION?