Symposium for Research Administrators
Reengineering Research Administration

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

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2012 Symposium for Research Administrators

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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?

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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

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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

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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

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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

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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 <u>earned</u>

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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

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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

Fund Code	Oct FY12			Nov FY12			Dec FY12			Jan FY12			Feb FY12			Current Month - Prior Month		
	ITD Rev Earned	ITD Actual Receipts	Current Period A/R	ITD Rev Earned	ITD Actual Receipts	Current Period A/R	ITD Rev Earned	ITD Actual Receipts	Current Period A/R	ITD Rev Earned	ITD Actual Receipts	Current Period A/R	ITD Rev Earned	ITD Actual Receipts	Current Period A/R	Rev Earned	Actual Receipts	Current Period A/R
3931111	34,782	31,898	2,884	35,972	31,898	4,074	35,972	31,898	4,074	37,221	34,278	2,943	37,221	35,028	2,193	-	750	(750)
3931112	58,973	58,973	-	58,973	58,973	-	58,973	58,973		58,973	58,973	-	58,973	58,973	-	-	-	-
3931113	40,791	31,395	9,396	42,001	31,395	10,606	42,621	31,395	11,226	42,621	31,395	11,226	42,621	31,395	11,226	-	-	-
3931114	9,750	6,750	3,000	9,750	7,500	2,250	9,750	7,500	2,250	9,750	7,500	2,250	9,750	7,500	2,250	-	-	-
3931115	11,591	-	5,319	12,445	-	3,675	12,445	-	12,445	15,007	-	15,007	17,509	-	17,509	2,502	-	2,502
3931116										14,000	-	14,000	14,000	11,000	3,000	-	11,000	(11,000)
Totals	155,887	129,016	20,598	159,141	129,766	20,605	159,761	129,766	29,995	177,572	132,146	45,426	180,074	143,896	36,178	2,502	11,750	(9,248)

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

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What are the responsibilities?

- *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

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The Number One Critical Success Factor

The Relationship between the

Clinical Research Coordinator

and the

Financial Manager

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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

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"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

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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)

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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?