Fundamentals of Clinical Trial Financial Management

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COURSE OBJECTIVES

- Understand the life cycle of a clinical study from a financial perspective
- Understand the purpose of an Internal Cost Assessment (ICA) and how it impacts budget negotiations
- Learn how revenue is earned during a clinical study life cycle
- Understand what type of costs are incurred and the concept of effort management
- Learn the importance of financial and management reporting
Agenda

☑ Overview of a clinical research portfolio
   ▪ What is considered clinical research
   ▪ Roles and responsibilities

☑ Pre-Award Activities
   ▪ Understanding the study protocol and what the contract illustrates
   ▪ Why is an internal cost assessment needed, and what does it entail to build?

☑ Post-Award Activities
   ▪ Revenue management: what is it, and why is it important to manage?
   ▪ Effort management: planned versus expended
   ▪ How effort ties to study activities for all study team personnel

☑ Financial & Management Reporting
   ▪ How to use reports to make better informed decisions
   ▪ What are typical management type reports?
What is considered clinical research?

- Patient-oriented research conducted with human subjects or on material with human origin for which an investigator interacts with human subjects
  - mechanisms of human disease
  - therapeutic interventions
  - clinical trials
  - development of new technologies
- Epidemiological and behavioral studies
- Outcomes research and health services research

Funding Sources for Clinical Research

<table>
<thead>
<tr>
<th>Fund Codes</th>
<th>FY12</th>
<th>FY13</th>
<th>Revenues*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal</td>
<td>714</td>
<td>876</td>
<td>$59,500</td>
</tr>
<tr>
<td>State</td>
<td>123</td>
<td>114</td>
<td>$4,936</td>
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<tr>
<td>Foundation</td>
<td>355</td>
<td>380</td>
<td>$14,777</td>
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<tr>
<td>Industry</td>
<td>1,727</td>
<td>1,594</td>
<td>$45,859</td>
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<tr>
<td>Internal</td>
<td>283</td>
<td>283</td>
<td>$857</td>
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</table>

<table>
<thead>
<tr>
<th>Total # of Codes</th>
<th>FY12</th>
<th>FY13</th>
<th>Total Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,202</td>
<td></td>
<td>3,247</td>
<td>$125,909</td>
</tr>
<tr>
<td>In Deficit</td>
<td>438</td>
<td>540</td>
<td>$138,159</td>
</tr>
</tbody>
</table>

*In dollars in 000's
Clinical Research Structure

- All clinical research should have oversight by an assigned Clinical Research Unit (CRU), regardless of a department’s research infrastructure.
- CRUs are the organization and functional structures that provide oversight for clinical research.
  - CRU Leadership: CRU Director, Research Practice Manager (RPM), and Financial Practice Manager (FPM)

Roles and Responsibilities of PI and Study Team

- Provide oversight of human subjects research
- Ensure study feasibility (scientific and financial)
- Ensure studies maintain regulatory compliance and staff are properly trained
- Ensure financial activities are properly managed
- Ensure target enrollment is understood and monitored
“Pre-Award” Activities

- Reviewing sponsor documents
- Preparing for IRB submission
- Developing internal cost assessment and external budget
- Negotiating with sponsor (if industry-funded)

Timeline for Industry-funded Studies

- After confidential disclosure agreement has been signed and you have received the protocol, draft budget, and draft contract from sponsor:
  1) Begin preparing internal cost assessment (ICA)
  2) Complete feasibility assessment (scientific, enrollment, financial)
  3) Begin preparation for submission to IRB
  4) Send draft contract to OCRC

- Even if you have a foundation or federally-sponsored study, it is still useful to know your costs and determine feasibility
Internal Cost Assessment: Why is it important?

- To determine “true” costs of performing the research
- To determine if the sponsor’s proposed budget is adequate to cover your costs (want cost + margin on industry-funded studies)
- To assist in capturing other potential unexpected costs
- To assist in the determination of whether the study is feasible from a financial perspective
- To assist in calculating the external budget
- Establishes consistent methodology for estimating costs (useful for future studies)
- Required per Duke policy

Items to Review in Preparing ICA

- Protocol
  - Don’t forget to read the footnotes!
  - Have Investigator, CRC, Regulatory, and Finance review as each has a different perspective
- Lab manual/Imaging acquisition manual
- Informed Consent
- Sponsor budget
- Clinical Trial Agreement/Contract
  - Key sections to review (next slide)
- CRF
  - Also consider the amount of time required for online data entry, particularly if the sponsor software operates slowly
- Investigational Drug/Device Brochure
Key Sections of Contract To Review

- **Compensation**
  - Will often direct you to Appendix/Exhibit budget
- **Supply of trial drug/device (if applicable)**
  - Are they providing drug? Where must it be stored? How will you return unused drug?
- **Document Retention**
  - How long will you need to maintain files?
- **Term**
  - How long will the study stay open?
- **Enrollment**
- **Payment Schedule**
- **Proposed Budget**

Staff Time to Consider

- Consentning
- Evaluation of inclusion/exclusion criteria
- Patient registration
- CRF completion/data entry
- Adverse event monitoring/recording
- Disease history
- Concomitant meds
- Phone calls/ follow-ups
- IVRS Calls/randomization
- Procurement (slides, samples)
- Enrollment log completion and submission
- EKG Transmissions/Scans to central lab
- Photographs
- Administration/collection of surveys and evaluations
- Clinician completed assessments and evaluations
- Diary training/review
- Medication compliance
- Initiation visit
- Monitor visits and query resolution
- Reviewing study subject bills for accuracy
- Time spent with patients that need additional assistance
Various Costs to Consider

- **Fixed Costs** (will occur regardless of how many subjects you enroll)
  - Study start-up
  - Maintenance
  - Closeout

- **Variable Costs** (generally invoiceable based on whether they occur)
  - Amendment fees
  - Screen failures
  - CRF changes

- **Per Patient Costs** (will occur for each subject enrolled)
  - Personnel time (screening, enrollment, CRF completion, etc.)
  - Phone calls, mailings, etc.
  - Labs and procedures
  - Facility fee (room charges)

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**Fixed Costs**

- Costs the project will incur regardless of how many subjects are enrolled

- **Start-up Costs**
  - Should be non-refundable, one-time charges
  - Examples:
    - Administrative start-up
    - PI and staff training
    - Pharmacy set-up fees
    - IRB fees
    - CRU fees
    - Language translation fees for informed consent
    - Training/certification expenses

- **Study Maintenance**
  - Yearly renewals for IRB, pharmacy, etc.

- **Study Closeout**
  - Document storage
  - Closeout fees
Variable Costs

- Generally invoiceable, some may require more negotiating than others
- Examples:
  - Amendment fees
    - Pharmacy and lab review
    - Reconsenting subjects, if necessary, requires staff time
  - Screen failures
  - Excessive SAE submissions
  - Project conference calls, reports, etc.
  - CRF changes
  - Advertising
  - Monitoring visit costs
    - Consider an extra fee if additional monitoring visits occur or if the sponsor wants to change the monitor which requires additional training

Example Budget: Fixed/Variable Costs

<table>
<thead>
<tr>
<th>Start-up Activities (excluding overhead)</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Set-Up Fee</td>
<td>2,000.00</td>
</tr>
<tr>
<td>3D fee (not overhead)</td>
<td>2,000.00</td>
</tr>
<tr>
<td>Scientific Review, R/BB Reg Prop, data prep, financial review, IT Database charges, Protocol Management Fee</td>
<td>10,000.00</td>
</tr>
<tr>
<td><strong>TOTAL START-UP</strong></td>
<td>$ 14,000.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pass Through Costs, Invoiceable to Sponsor (not including overhead)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>BBE Amendments requiring Consent R/BB</td>
<td>$25,000.00</td>
</tr>
<tr>
<td>IRB Annual Renewal Fee</td>
<td>$2,000.00</td>
</tr>
<tr>
<td>Annual pharmacy inventory fee</td>
<td>$150.00</td>
</tr>
<tr>
<td>IND Safety Letters - SAE processing fee</td>
<td>$500/quarter</td>
</tr>
<tr>
<td>3D screen failures will be monitored to site for patient cohort. On-site data monitoring due to central path and central pathology upon completion of screening CRF’s up to 3 patients</td>
<td>$1000 per patient</td>
</tr>
<tr>
<td>Sponsor initiated audit if applicable</td>
<td>$2,000.00</td>
</tr>
<tr>
<td>Additional, duplicate scans requested by Sponsor during and after treatment period (and are subject to review by Dept. of Radiology)</td>
<td>$1.50 per (DVU), per request</td>
</tr>
<tr>
<td>Sponsor Monitor Change Fee</td>
<td>$500 per change</td>
</tr>
<tr>
<td>Study Close-out Fee</td>
<td>$1,500.00</td>
</tr>
</tbody>
</table>
Per-patient Costs

- Supplies
- Tests and procedures (including interpretation)
  - Consider associated tests that may be required based on protocol-specified tests
- Packaging and shipping
- Pharmacy dispensing and storage
- Subject reimbursement
- Effort (PI, CRC, Data Manager)

*Tip: Consider the “cost” vs “charge”

- What you charge the sponsor should be cost + margin (for industry-funded studies)
- Charge for effort and services should be fair market value
- Residuals should be reasonable (revenue ≥ expenses)
  - Excessive residuals could be considered a kickback (illegal) or contrary to Duke’s non-profit status
  - Insufficient revenue could be considered a subsidy to the commercial sponsor which is also contrary to Duke’s non-profit status

Example Budget: Per Patient Costs

<table>
<thead>
<tr>
<th>Study Measurements</th>
<th>Mkt Cost</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
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<tbody>
<tr>
<td>Per Patient Costs</td>
<td>$1200</td>
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<td>$125</td>
<td>$75</td>
<td>$50</td>
<td>$25</td>
<td>$12</td>
<td>$7</td>
<td>$5</td>
<td>$2</td>
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<tr>
<td>Supplies</td>
<td>$2500</td>
<td>$1500</td>
<td>$900</td>
<td>$500</td>
<td>$300</td>
<td>$200</td>
<td>$150</td>
<td>$90</td>
<td>$50</td>
<td>$30</td>
<td>$20</td>
<td>$15</td>
</tr>
<tr>
<td>Tests and procedures (including interpretation)</td>
<td>$100</td>
<td>$50</td>
<td>$30</td>
<td>$20</td>
<td>$15</td>
<td>$12</td>
<td>$10</td>
<td>$9</td>
<td>$8</td>
<td>$7</td>
<td>$6</td>
<td>$5</td>
</tr>
<tr>
<td>Packaging and shipping</td>
<td>$2000</td>
<td>$1500</td>
<td>$1000</td>
<td>$500</td>
<td>$250</td>
<td>$125</td>
<td>$75</td>
<td>$50</td>
<td>$25</td>
<td>$12</td>
<td>$7</td>
<td>$5</td>
</tr>
<tr>
<td>Pharmacy dispensing and storage</td>
<td>$1500</td>
<td>$1000</td>
<td>$500</td>
<td>$250</td>
<td>$125</td>
<td>$75</td>
<td>$50</td>
<td>$25</td>
<td>$12</td>
<td>$7</td>
<td>$5</td>
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<td>Subject reimbursement</td>
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<td>$500</td>
<td>$250</td>
<td>$125</td>
<td>$75</td>
<td>$50</td>
<td>$25</td>
<td>$12</td>
<td>$7</td>
<td>$5</td>
<td>$2</td>
</tr>
<tr>
<td>Effort (PI, CRC, Data Manager)</td>
<td>$2500</td>
<td>$1500</td>
<td>$1000</td>
<td>$500</td>
<td>$250</td>
<td>$125</td>
<td>$75</td>
<td>$50</td>
<td>$25</td>
<td>$12</td>
<td>$7</td>
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Indirect Cost Recovery

- The published Duke University School of Medicine Facilities & Administrative (F&A) rate is:
  - 28% for Industry-sponsored clinical trials only
  - 57% On-campus research (Federal and industry, except clinical trials)
  - [http://research.som.duke.edu/research-administration/financial-administration/indirect-costs](http://research.som.duke.edu/research-administration/financial-administration/indirect-costs)

- Additionally, each CRU should incorporate a separate, additional CRU Management Charge of at least 10% on Industry-sponsored clinical trials.
  - This should be separated from institutional overhead on the budget (i.e., do not list the overhead as 38%)
  - This additional CRU Management Charge should be transferred to the appropriate hub code within the CRU as monies are received on the study

Completed ICA: Next Steps

- Provide completed ICA to your CRU for review
- Make sure the study is financially feasible
- Compare with sponsor’s draft budget (if industry-funded)
  - Generally their first offer—can negotiate higher
  - How much higher would be necessary to meet your costs?
  - Add appropriate margin and overhead to your costs
  - Perform breakeven analysis. What happens if you don’t enroll as many subjects as predicted?
- Fill in sponsor’s draft budget, making sure you account for every dollar on your ICA (categories may not align, so make sure you’re not leaving anything out)
- Begin budget and payment term negotiations with sponsors
Post-Award Activities

Activities that occur after the sponsor agreement is signed and recruitment and enrollment can begin

- Revenue Management and Invoicing Activities
- Managing the Effort of the Study Team – PI & Staff
- Financial Reconciliation and Analysis
- Financial and Management Reporting

Why is managing revenue so important?

- Provides a more realistic picture of the financial status of a study by showing not only the cash collected, but also what is billable on work performed
- Allows identification and resolution of issues before they become major concerns
- Ensures the PI has vital information to make sound decisions associated with work to be carried out on the study
- Ensures we are paid for the work performed
Why is managing revenue so important?

- Allows the Finance Practice Manager/Grants 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 Department
  - Ensures money earned on a project is actually recognized and collected

How is revenue managed?

- Understand the essential components of the contract/NOA
  - What are the specific contracted study activities?
  - What does the contract state the sponsor will pay for?
  - What has to happen to receive a payment?
    - Are we waiting on a monitor visit?
    - Does a Case Report Form (CRF) have to be completed?

- Understand the importance of enrollment data and the study protocol
  - What activities are required by the protocol?
  - What is the schedule of visits or events?
  - When do milestones, invoiceables, or out of scope activities occur?
Managing Federal/Foundation Revenue

Letter of Credit (LOC) – Federal
- Revenue is posted when an (LOC) drawdown is processed in R3
- Outstanding revenue is cash received minus expenses (not to exceed the awarded amount)

Invoiced Project
- Revenue is posted to a fund code when an invoice is generated in R3
- Outstanding revenue (accounts receivable) is amount invoiced minus cash received against the invoices

Managing Industry Revenue with Trial Trackers

A trial tracker is an Excel worksheet that connects subject encounters with contract payment terms. It includes:

- Study Demographics
  - IRB information
  - Fund code information
  - Sponsor information
  - Contract and payment terms information
- Study Budget
  - External
- Study Activity/Deliverables
  - Visits and milestones – such as the Schedule of Events
  - Subject visit tracking
  - Enrollment log
- Financial Activity/Deliverables
  - Visit and milestone payments
  - Invoice information
**Trial Tracker Example**  
**Tab 1**

- This tab can be formatted to mirror the Enrollment Log or it can be set up to automatically pull information from an Enrollment Log.
- Visit dates and/or milestones are entered here.
- This tool will tally the count of each visit (event).

**Trial Tracker Example**  
**Tab 2**

- Calculates Subject/Milestone Earned Revenue
  - Links the count of visitors or milestones from Tab 1
  - Ties in the payment amounts per event
- Tracks, Tallies, and Calculates Invoiceable Items
  - Ability to track invoices sent and collected
  - Provides a place to record earned amounts for out of scope events, invoiced milestones, or fees
- Totals the Amount Earned for the Project
Trial Tracker Example
Tab 3

- Tracks payments/cash received from the sponsor

- Summarizes and provides three key figures
  - Total Earned Revenue (from Tab 2)
  - Total Cash Received (from Tab 3)
  - The difference between these two is the amount of money still owed to Duke for the project (Accounts Receivable).

Loading Revenue in R3 for Industry-Sponsored Projects

- Each CRU links the A/R balances for each study (from the trial trackers) to a summary spreadsheet

- At the end of each month, using the summary spreadsheet, a JV is processed to upload the A/R amount in R3 using GL 326650

- This is similar to the invoice process in R3, which creates revenue and A/R for 20x – 389 codes
Monitoring Accounts Receivable

The financial analyst, grant manager, or FPM continuously monitors each project to see how much revenue is outstanding or owed by the sponsor on the study.

The above amount is called Accounts Receivable.

Accounts Receivable (A/R) equals the revenue earned minus cash received to date on the study.

Effort Management

Effort Allocation

Duke requires a minimum of 1% effort by the PI be reflected in SPS (Duke’s Sponsored Proposal System)

- The institutional base salary will vary based on PI

If DUHS employees are involved in a study, it may be necessary to negotiate payment with DUHS.
Effort Management

- Effort listed in the ICA, or federal/foundation budget, is an estimate of planned effort to complete the study for staff involved – PI and research team
- Effort allocated to a fund code should equal actual effort contributed to the project
  - Lab research effort is usually consistent throughout the project. Unlike lab effort, clinical research effort may not be consistent, since it is based on actual enrollment.
- Actual effort must be reviewed and revisions made, if necessary
  - Best Practice is to review effort at least monthly
  - Changes can be made retroactively
  - Consider if prospective changes to effort are needed

Financial Management & Reporting

Why is financial reporting so important?

- It tells a story of study/project performance based on the revenue earned and expenses (costs) incurred at a point in time.
- Provides a snapshot of the financial status of a study/project.
- Strengthens decision making capabilities for future studies and outcomes on an individual study/project.
What information is reflected on a financial report?

- The amount of revenue earned for each project
- The expenses incurred (direct and indirect costs)
- Transfers made in or out of fund codes
- The amount of cash still owed by sponsors (accounts receivable)

Financial Reporting and Analysis

- Financial reports can be run for different periods of time
  - Inception to Date (ITD) shows the financial activities of a study since its inception.
  - Fiscal Year to Date (YTD) shows the activities for a particular fiscal year
  - By Month shows the activity which occurred for a particular month you are reconciling
- Financial reports can be run multiple ways, such as summary or detailed level
  - Summary level shows a one line summary of all studies for a PI, BFR, or group of entered codes.
  - Detailed level reporting shows each transaction that has occurred on a study by G/L account.
How does reporting help the study team make better decisions?

- Assists in monitoring the portfolio performance at the department, division, or PI level
- Assists in managing margins (industry) and overdrafts
- Assists in preparing CRU operations budgets
- Assists in identifying areas of concerns, such as collection issues
- Assists in identifying trends in monthly expenses

How does a financial report assist the financial analyst/grant manager in performing their duties?

- Allows one to reconcile revenues and expenses to ensure the proper activity has been posted to the study
- Allows one to confirm the correct effort for faculty and staff has been recorded to the study
- Allows one to determine if the proper F&A rate is being assessed to the study
- Allows one to determine if the study is in overdraft and what could be the cause of the overdraft
- Allows one to measure against the budget to determine progress
What questions should the financial analyst/grant manager ask when reviewing reports?

- Is there a large A/R balance on the project? If so, is cash coming in on a continuous and appropriate basis?
- Do salaries look in line with the revenue being generated?
- Are the projects generating profit or loss? If so, are transfers playing a role in what is reflected?
- Are the transfers in and out appropriate?
- Are there major swings in activity from period to period?

SAP Management Reports List and Definitions

- ZFR1E, Project/WBS: Inception to Date w/ Plan – This report can be run on one or more fund codes at a time and also at the BFR level. It shows the revenue, ITD plan, current month actuals, YTD actuals, and the ITD actuals and balance.
- ZF109AR, Sponsored Programs AR One Line Summary – Identical to ZF109, but it has one extra column to display the outstanding A/R. Drills down to ZFR1E.
- ZF109, Sponsored Projects One Line Summary – ITD summary balance of each code that can be used to provide an overall view of fund codes. Can be run by BFR or a group of fund codes and then further narrowed by PI.
SAP Management Reports List and Definitions

- CJI3, Actual Cost Line Items – Shows the line item activity for a specific date range selected. Can be narrowed down by GL account or Cost Element Group.
- CJ03 Project/Work Breakdown Structure – Contains master data for a fund code, such as PI, start date, finish date, BFR, and F&A rate. It also confirms if a project is open (REL) or closed (CLSD) in R3.
- ZF110, Projects Ending with Three Months – A reports that shows which projects are ending within the next three periods. This is a great tool to use to determine if a WBSE extension should be requested.

- ZH223, Accounting View of Payroll – payroll report
- ZH33, Payroll Activity Detail (Multi-Period) – Shows payroll information for several periods and also provides fringe and fringe supplement amounts.
Summary

Pre-Award
- Important to review protocol, informed consent, and contract to know expected activities
- The Internal Cost Assessment reflects the true costs of performing the research and ensures the sponsor’s budget is adequate to cover all costs and defray CRU operational expenses

Post-Award
- Managing revenue allows for identification and resolution of issues
- Managing effort ensures effort is being appropriately allocated as expended
- Financial and management reporting assists in monitoring the overall financial performance of studies, including trending, overdrafts, reconciliations, and effort

Resources

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