Budgeting, Tracking and Invoicing for a Clinical Trial

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Course Objectives

1. Outline the challenges of developing a study budget.
2. Provide instruction on tracking and invoicing for study-related expenses.
3. Caveats
FREE-FLOATING ANXIETY
(MAGNIFIED 200,000,000 TIMES)
Budgeting for a Study
New Study Protocol

First, upload the following documents in InfoEd for CTO to start budget and contract review:
- Proposed contract
- Protocol
- Sponsor’s budget offer
- Sponsor contact information
- Have PI complete PIQ

Second, submit study to IRB to initiate Medicare Cost Analysis

Third, begin developing your study budget
Why do I need to develop a budget if the Industry Sponsor sent one and CTO is reviewing/approving it?
PI is responsible for managing the study fund. If the Sponsor budget does not cover costs – deficit!

PI is responsible for any deficit in his/her fund!

~11% of MGH Clinical Research study funds are in deficit – some over $100,000.
Helps to Have Many People Review

- Previously, it was easier to develop a budget
- Costs change by location, research fees vs. global fees
- Helps to have those with clinical experience review the protocol for time needed for procedures
Look at the Big Picture

- What is being done?
  - Review the contract, protocol, informed consent and flow chart of activities

- Who will be doing the work?
  - PI, CRC, RN?

- How long will it take?
Step 1: Start with your One-Time Fees

- Clinical Trials Office - $5,000

- IRB Fees (Industry sponsored only)
  - $3,500 initial review, $1,000 for continuing reviews

- MCA (Industry and NIH)
  - $1,500 for a drug study, $2,000 for a device study

(no overhead applied to these fees)
Step 1: Start with your One-Time Fees

- Start-up fees for Investigator:
  - Upfront support of effort to be expended in study set-up
    - Protocol review
    - IRB preparation
    - Regulatory/safety
    - Training
    - Site initiation
  - Depending on the complexity of the study $1,500 - $6,500, IDC-inclusive ($4,000 is reasonable average)
Step 2: Determine Invoiceable Costs

- Events not applied to every subject:
  - Research Pharmacy (contact Cheryl Reilly-Tremblay)
  - Sponsor Amendments
  - Site Monitoring Visits
  - Adverse Events (includes PI/CRC time)
  - Safety Reports (need to be reviewed by PI)
  - Archiving
  - Screen Fails (cost of screening visit per subject, i.e. 10-20% is average but can be as high as 80% depending on the complexity of the study)
Step 3: Determine Per-Subject Charge

- Review your study documents for all subject related visits, procedures, labs and radiology

- Create a spreadsheet with the procedures (first column) and number of visits (top row)

- Use Procedure Picker and MGH Rate Book to identify charges
Step 4: Determine Pro Fees and Any Discounts

- Check to see what procedures have pro fees.
- Clarify with CTO if there is any discount. If so, what is the pro fee discounted percentage.
- Make certain the location you have selected is where you will be doing the test. Don’t change the location without checking the price.
Study Related Consults with Other Depts.

- Determine cost of procedures
- Ask department if they have extra administrative/start-up fees
  - Clinical Research Center has an application fee. ($2500)
  - Other departments set their own administrative start-up costs
Other Things to Consider

- Even if labs are being sent to a central lab
  - Need supplies (needles, gauze, alcohol wipes, band aids)
  - Need CRC time to process, package, & ship
  - Dry ice or -20/-80 refrigerator space
  - May have to pay to use lab space to process
  - Phlebotomy charges for blood draws
Data Entry Issues

How long will data entry take?

- Look at the protocol/flow chart to determine the data that need to be collected and entered into the database – it is an estimate.
- Will the sponsor provide source documents? If not, development of these forms can take many hours.
- Will they provide subject binders? (3” binders can run $10-15 each)
Subject Reimbursement

- Are you providing subject remuneration?
  - If so, how much per visit?

- Are you paying for parking?
  - 0-4 hours - $250/book (20 coupons)
  - 0-24 hours - $300/book

- Are you paying for mileage

- Are you paying for food?
Step 5: Compare Budgets

- Compare your budget with the budget reviewed by CTO and identify discrepancies
  - If the sponsor’s final offer is comes under budget and the PI wants to accept the offer, PI will need to identify other funds to support the study

- Discuss discrepancies and suggested revisions with your CTO analyst

- CTO will negotiate for you!
Non-refundable, start-up funds paid upon Agreement execution

IRB and MCA fees payable upon upon invoice

Subject charges payable for completed visits based on CRF reports filed or quarterly invoice
- 10-20% hold-back to be paid at study completion is standard

Invoiceable charges payable upon invoice with documentation of occurrence
When is it Time to Renegotiate?

- Despite best attempts, budget costs are often imprecise. If the budget turns out to be under budgeted, talk to the sponsor.

- Sponsor amendment adds test, procedure, or amends tasks that increases staff effort.

- New monitor with new queries
When is it Time to Renegotiate? (cont)

- Study Close Out - new queries!
- Study closed, final payment received and then sponsor starts FDA NDA: more queries
- FDA inspection (routine)- negotiate payment for staff to support inspection (MD, RN, CRC)
Expense Tracking
The PI is ultimately responsible for the research fund – often monthly fund review is delegated to the grants manager, department administrator or CRC.

The delegate needs to:

- Invoice sponsors based on achieving milestones set-forth in the contract
- Track payments received from sponsor
- Review monthly financial reports
- Review patient care charges in EPIC
- Prepare monthly Protocol Status Report
- Complete patient care correction forms
Monthly Protocol Status Report

- Review funds mid-month when General Ledger is updated

- Use Study Milestone Tracker
  - Basis of monthly Protocol Status Report to PI
    (dependent on CRC/grant manager teamwork)
  - Update fund cash balance, sponsor invoices & payments, visits, variable costs

- Create a written report
  - Cash received; expenses appropriate?
  - Amount due from sponsor; who will invoice
  - Estimated fund balance
  - Monitor queries: all resolved? Any still outstanding?
REPORT DATE: 12/17/2015
Fund number : 1200-XXXXXXX
Charges to fund: no corrections
Last Payment to the fund: $1,625.00 on 5/31/15.
SUMMARY: Projected Fund Balance: 12/2015
Total Revenue: $180,273.96
Total Expenses: $162,233.11
Current Balance: $18,040.85
Projected Fund Balance $4,007.50
Invoice submitted for closeout visit & archiving: $2450
Invoicing
Invoicing for Trial Payments

- Invoices originate at study staff level when milestones are achieved.

- Payment details and invoiceable charges are included in body of contract and budget exhibit. Be sure to check both!

- Study staff are responsible for invoicing for all start-up charges including CTO fee, MCA, IRB.
Any invoice submitted to a sponsor for payment should at a minimum include:

- Department name
- PI name
- Sponsor name and contact
- Date of the invoice
- Sponsor protocol number
- Study Fund Number
- Study title
- Itemized activities submitted for payment
- Total amount due
- Payment information and contact information if the sponsor has questions regarding the invoice. Invoiceable items are usually listed in the budget/payment schedule under invoiceable items.
Payments

- **Subcontract payments only:**
  - Mass General Hospital, Research Bank of America N.A. P.O. Box 3829 Boston, MA 02241-3829

- **Industry clinical trial payments, foundation payments, expense reimbursements, etc.**
  - Massachusetts General Hospital (MGH), Research Finance c/o the Bank of America PO Box 414876 Boston MA 02241-4876

- The check should reference the PeopleSoft fund number or InfoEd proposal number (grant), the name of the Principal Investigator and the protocol number.

- Federal Tax Identification Number for MGH: 04-2697983
Links

- **Procedure Picker**
  - Partners Applications>Microstrategy>Insight Analytics>Shared Reports>Procedure Picker

- **Lockbox**
  - [https://partnershealthcare.sharepoint.com/sites/phrmManage/mffs/br/Lists/Cash%20Posting/AllItems.aspx](https://partnershealthcare.sharepoint.com/sites/phrmManage/mffs/br/Lists/Cash%20Posting/AllItems.aspx)
Links (cont)

- MGH Division of Clinical Research (DCR)
  - 617-726-5500 Fax:617-726-5501
  - http://www.massgeneral.org/research/dcr/
  - E-mail:clinicalresearch@partners.org

- Partners Clinical Trials Office
  - https://partnershealthcare.sharepoint.com/sites/phrmdepartments/prd/pcro
Final Thoughts

- The system is messy, confusing and subject to change

- Ask sponsor for CPT code they used when budgeting for expensive tests

- Be prepared to renegotiate