Budgeting, Tracking and Invoicing for a Clinical Trial

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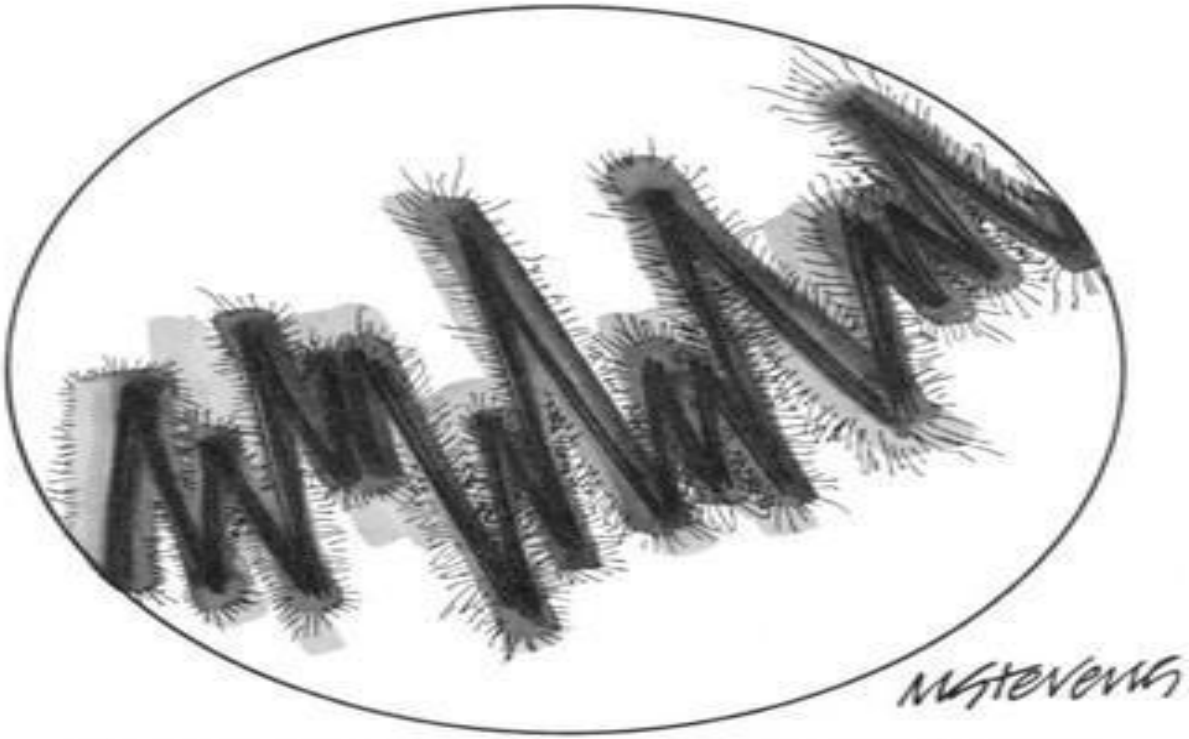
Course Objectives

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 in to 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!

Standard Payment Terms

- Non-refundable, start-up funds paid upon Agreement execution
- IRB and MCA fees payable 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

Whose Responsibility is it?

- 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?

Example of Protocol Status Report

REPORT DATE: 12/ 17/2015
Protocol: BAY-2008A-US XXXXXXXXX
Fund number : 1200-XXXXXX
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.

Invoice Details

- 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%20Postings/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