

# Effective Financial Management of Clinical Trials: Issues and Challenges

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# Background

- Clinical trial market is a competitive business
- Clinical trial budgets follow a business model vs. Federal-funding model
- Clinical trial hidden costs can be significant
- Typical payment schedules sluggish leaving sites to carry cost for months

# Outline

- Discuss clinical trial (CT) budgeting process
  - Define approach to define a comprehensive budget
- List issues and challenges in the CT budgeting process
- Discuss strategies to improve CT budgeting effectiveness

# Preparing the Budget: Defining “Real” Costs

- Common fixed costs: laboratory, x-ray, EKG, etc.
- Related costs: phlebotomy fees, supplies, specimen processing fees
- Drug costs: investigational drug management/dispensing, alternative or adjunct drugs
- Subject costs: travel, parking, time compensation
- Ancillary costs: travel, pager/phone, administrative (copying, long distance phone)
- Marketing costs: radio, newspaper ads, etc.

# Preparing the Budget: Defining “Real” Costs

- Study Personnel: research nurse/coordinator, investigator
  - budget by time estimate or milestone (per visit,etc)
  - use actual salary values
- Institutional Fees:
  - IRB
  - Contracting
  - Overhead or indirect costs
- Record Retention Fees

# Preparing the Budget: Defining “Real” Costs

- “Hidden” costs:
  - Time/cost to obtain special reports (UB 92)
  - Copy cost for X-rays, MRIs etc.
  - Cost increases for studies that go on later than one year
    - inflation, health system price increases, etc.
  - Personnel costs
    - screening, training of staff, failed enrollment, etc
  - Cost of starting enrollment late

# Preparing the Budget: Defining “Real” Costs

- “Hidden” costs:
  - Sponsor imposed costs -
    - monitoring visits
      - poorly trained monitors
      - monitor turn-over during course of study
    - inefficient handling of study queries and data corrections
    - processing amendments

# Evaluating the Trial Opportunity

- Business Analysis:
  - Financially sound study?
    - Cost of doing trial < Budget payments
- Academic Analysis:
  - Quality of the Science?
    - Phase I, II > Phase III, IV
- Right Answer: balance between the two



# Evaluating the Trial Opportunity

- Evaluate long term financial risk of the study
  - financially “positive” at first, financially “risky” later
- Participate in financially “risky” trial?
  - Interest in disease state or investigational agent
    - Investigator/Department decision
  - Novel therapeutic intervention
    - only accessible in clinical trial
  - Differentiate AMC within the community

# Clinical Trial Budgeting Issues

- Define study costs vs. standard of care
  - *a priori* determination works best
    - who does this?
      - Investigator, IRB, other committee?
  - specify major study costs in consent form
    - if grant will not support, notify subject they are responsible
  - billing process - document study payments
    - audit trail

# Clinical Trial Budgeting Issues

- Clinical trial budgets are usually fixed
  - usually broken into “per subject” payments
    - payments prorated based on subject completion
  - must “back into” sponsors bottom line
  - overhead/indirect costs may be included in fixed budget
- Study costs increase over the time the study is underway
  - study could become financially “risky”

# Clinical Trial Budgeting Challenges

- Accounting for subject screening costs
  - May be unpredictable
    - many times not listed in budget
  - Screening failures
    - reimburse as a ratio of enrolled subjects
    - reimburse only a fixed number
    - usually reimbursed at end of trial
- Understand payments for “partial” or “non-evaluable” subjects

# Clinical Trial Budgeting Challenges

- Recovering cost for sponsor decisions
  - placing studies “on-hold”
  - closing studies early
- Payment milestones based on monitor visits
  - dependent on monitor’s schedule and efficiency
- Differentiate study payments vs. normal charge/payments in billing system
  - list research as another “payor”

# Clinical Trial Budgeting Challenges

- Incentive payments
  - many times not included in study contract
  - how to handle appropriately?
    - Include in study contract
    - Conflict of interest issues
      - IRB concerns
    - Go directly to investigator?
    - Place in educational fund?
    - Institutional policy

# Clinical Trial Budgeting Challenges

- Study account residual dollars
  - Who controls disposition of left over \$s?
  - May be motivation for investigator to participate in trial
  - Incentive for investigator not to “cost account” study?
  - Tax consequences for non-profit AMCs?

# Clinical Trial Budgeting Strategies

- Budget development process
- Negotiating the budget
- During the course of conducting the study



# Clinical Trial Budgeting Strategies

- Budget Development Process
  - Understand costs at your site
    - Use standardized cost templates
    - Define “research costs” for procedures, etc.
  - Choose “good” studies
    - Financial outcome based on objective assessment

# Clinical Trial Budgeting Strategies

- Budget Development Process
  - Know your “break even” point
    - How long can you go without enrolling your 1st subject?
    - Plan to make periodic financial evaluations
  - Get insight from experienced clinical research staff
    - Expertise of the person creating the budget
      - need clinical and financial perspective

# Clinical Trial Budgeting Strategies

- Negotiating the Budget
  - Fixed per subject payment?
    - May still be negotiable
    - Overhead or indirect cost included?
    - Understand “one-time” costs
      - IRB fee, etc
  - Establish flexibility to cover “pass through” costs
    - Prn procedures (f/u CT scans, MRI, etc)

# Clinical Trial Budgeting Strategies

- Negotiating the Budget
  - Negotiation tools:
    - Past performance by investigator or site
    - Data base of potential subjects

# Clinical Trial Budgeting Strategies

- Negotiating the Contract
  - Initiation or start-up payment
    - Negotiate as “non-refundable” to cover screening/enrollment costs
  - Evaluate payment schedule/milestones based on your cost

# Clinical Trial Budgeting Strategies

- During the Conduct of the Study
  - Know where your costs are
    - Keep track of screening/enrollment costs
    - Use research “CPT codes” for study procedures
  - Evaluate “break even” point
  - Define criteria to end study at your site
    - Make a business decision

# Clinical Trial Budgeting

## Additional Strategies

- Timing the start of the study
  - Efficient start-up process
- Knowing when it is time to quit
  - Screening/enrollment costs >> reimbursement
- Utilize electronic budgeting software
  - SiteWorks Solutions
  - Study Manager

# Clinical Trial Budgeting

## Additional Strategies

- Negotiate your own incentives
  - Based on performance
    - rapid start-up time
    - rapid subject enrollment
- Select the best balance of studies
  - Target enrollment 3 subjects, 30 subjects



# Effective Financial Management of Clinical Trials Summary

- Identify all study-related costs *a priori*
- Address the issues specific to your site
- Experienced CT budgeting staff may be best strategy
  - however, maintain a relationship with investigator
- Continue to assess CT finances during the conduct of study