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 “payer”
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