NEGOTIATING CLINICAL TRIAL BUDGETS

Debbie Williams
R.N., C.C.R.C.,
C.R.A., A.B.N.
OVERVIEW

- Budget Types
- Analyzing the Protocol
- Negotiating the Contract
- Discussion / Tips
Goals

- Participate in the development of new treatments and medicines
- Recognition
- Part of Hospital Mission Statement
And.....

Profit Margins
The Bottom Line…

…Is Not Always The Bottom Line
TYPES OF BUDGET

- ITEMIZED PER SUBJECT
- STUDY BUDGET (Set-up, Investigator Fees, Pharmacy fees etc.)
- PRESET BUDGET (Lump sum)
3 “EASY” STEPS

- Review  *(What is involved with this study?)*
- Determine Profit  *(What is the profit margin?)*
- Revise  *(Negotiate)*
ANALYZING THE PROTOCOL

- Feasibility
- Focus quickly on whether or not you can/want to do study
Investigator Motto

- Just Do It

[Image of the Nike logo]
Available Resources

- Patient Population
- Staff to properly conduct study – Study Coordinator and Nurses
- Access to specialized tests / equipment such as CT, MRI, refrigerated centrifuge etc.
- Is Medical Coverage required?
Do you have the patient population?

If not:
Cost of Recruitment
Advertising
Stipends
Staffing

- Principal Investigator
- Sub-Investigators
- Study Coordinators
- Nurses
- Lab
- Pharmacy
- Etc.
Specialized Equipment / Tests

- MRI
- CT
- Cardio
- Pulmonary Function tests
- Day beds
- Refrigerated centrifuge
STUDY SCHEMATIC
Schedule of Assessments

- Good synopsis of study requirements
- Create a template to roughly estimate costs
<table>
<thead>
<tr>
<th>Assessments</th>
<th>Screening</th>
<th>Treatment Phase</th>
<th>Costing</th>
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<td>Day 2</td>
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<td>Pregnancy Test</td>
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<td>DCR's CRF Corrections</td>
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Institutional Costs

25% Overhead
Cost and Charge

- Find out what a procedure or test actually costs
- Charge a higher rate to sponsor
Staffing Costs

- Do not quote actual hourly rate.

- Inflate salary to cover benefits, vacation pay, sick pay coverage, overtime, raise increases for study personnel (for studies of long duration)
Investigator Fees

- Need to factor this in with itemized budget formats (as well as lump sum budget)
- Follow MSP rates for physicals, medical histories – usually $150 - $200 / hour
- Consider time for meetings, reviewing and signing CRFs, DCRs, etc.
Pharmacy Fees

- Set-up fee of $1000 – whether or not you actually enroll subjects
- Dispensing fee – approximately $15 (could be more depending upon workload)
Coordinator Time – Pre study

- Read protocol
- Prepare budget
- Pre-Site visit
- Obtain hospital approval
- Prepare submission to IRB
- Train study staff / nursing staff
- Attend Investigator’s meeting
- Organize Initiation meeting
Coordinator – during study

- Screening
- Consenting
- Enrolling subjects
- Subject visits and procedures
- CRF completion
- DCRs
- MedWatch reports / SAEs
- Enrollment logs
Coordinator – during study

- Make sure to ask for at least the draft CRF before signing budget
- CRF could be very lengthy and complicated
- On-call for study enrollment
Coordinator – study close

- Preparation for site close-out visit
- Storage of documents – what is this going to cost you?
- Letter to IRB
Possibility of Audit (Sponsor or Regulatory) is great – especially if you are a high enrolling site.

- What is the time involved?
- Ask for a amount up and above the “lump sum” dollar figure.
Other Costs to Consider

- Screen failures – common
  - Coordinator time – consents, arranging appointments
  - Lab costs
  - Investigator time
  - Screen failure CRF completion
  - Clerical time
Solution

- Ask for screen failure reimbursement
- Some companies are okay with this, others have policy not to pay
- Doesn’t hurt to ask
## PER PATIENT COSTS

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<th>Assessment</th>
<th>Number of Times</th>
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Profit Margin per subject = >40%
Other Costs continued…

- Redraw or repeat of blood samples/tests (budgeted for only one)
- SAEs can be costly in time – ask for reimbursement in budget.
- Copying and shipping of films
- Preparation of study specific blood samples
- Dry ice
- Patients not compliant or do not finish study
- Protocol amendments
# START UP COSTS

<table>
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<tr>
<th>Description</th>
<th>Cost</th>
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<td>Pharmacy Fee</td>
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<td>Submission to IRB</td>
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<tr>
<td>Study Set-up</td>
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<td>Attendance at Meetings</td>
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<tr>
<td>(Investigator’s and Site Initiation)</td>
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<tr>
<td>Administrative Expenses</td>
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<td>(Phone calls, Faxes, FEDEX, includes Coordinator time)</td>
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</table>

**TOTAL = $4250**
Alternate Solution

- Ask for study start-up fee apart from patient enrollment fee
- One time charge
- $5000 ?
Get Definition of Subjects for Payment Purposes!

- Consented
- Enrolled – Randomized
- Randomized but did not receive drug
- Subject withdraws consent
- Subject lost to follow-up
- Subject completes study
BIG COST TO SITE

- Premature cancellation of study due to safety or efficacy concerns!
- Need to ask for compensation in budget to cover this.
Other Pass-Thru Costs to Negotiate

- 25% overhead
- Screen failure reimbursement
- SAEs (if expecting several)
- Copying and Shipping of Films
- Dry Ice for Shipping
- Audits – What’s your time worth?
- Document Long-term Storage
ADDITIONAL REQUESTS

- Screen failure $25.00
- SAEs $100.00
- Film Copying $25.00
- Dry Ice $25.00
- Audit $200.00
Other Costs continued…

- “Incentives” to staff
  - Increases compliance with study protocol
  - Makes staff more aware of research being conducted
  - Good attitude adjuster

*Can generally ask monitor to get permission from sponsor during study for these perks.*
Get On The Phone

- Talk to other sites conducting study
- Try to go in together with same budget expectations – power in numbers
- Talk to Sponsor budget department – state your case for more money with specific examples
- Involve PI
U.S. Sponsor

Ask for U.S. Dollars
50% profit immediately
IT DOESN’T HURT TO ASK

All they can do is say no!
ASK YOUR COLLEAGUES

Share Information
Draw on Experience