Introduction to Clinical Trial Budgets

Budget Development and Approaches to Successful Budget Negotiations

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What Is Our Product?

**KNOWLEDGE**

- **Basic Science**
  - Knowing what has been tried, what does work, what does not work and what may work
- **Expertise**
  - Ability of moving from the bench to the bedside with theories, questions and ideas
- **Clinical Experience**
  - Unavailable in industry
- **Leadership**
  - Faculty are leaders in their field and maintain relationships with peers and peer institutions
- **Broad Base**
  - Access to over 1,800 faculty and 28 clinical and basic science departments under one roof
Why Do Companies Buy From Penn?

- **High Quality** – Top medical school and health system
- **Competitive Cost** – Less expensive than corporate in-house
- **Brand Name** – Provides objectivity, credibility and credence to corporations
- **Patients / Facilities** – Millions of visits, broad array of patients, close facilities with cutting edge technology
- **Single Campus / Single System** – Geographically close system all with same reporting structure
What is the Price v. Cost?

**PRICE** is…

…the value the market places on your product – the amount of money paid for the product.

**COST** is…

…the total amount of dollars incurred to produce the product.

Companies pay a **PRICE** when buying Penn’s product
How Do I Price Penn’s Product?

- All direct costs to perform the work
- All F&A costs to support the work
- All value-added costs, such as:
  - PI consultation
  - Protocol development
- All “hidden costs,” such as:
  - Conducting / hosting meetings
  - Publication costs
  - Administrative oversight
  - Upfront implementation fee for CTAs
What are F&A Costs?

F&A are the costs above direct costs to make your product and get it out the door

At Penn…
- Light bulbs for the labs
- Get the trash emptied
- Security personnel
- General Counsel/contracting
- Supporting our ‘knowledge’
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At Companies…
- Light bulbs for the offices
- Get the trash emptied
- Security personnel
- General Counsel/contracting
- Product sales/advertising
The core elements of efficient & accurate study budgeting

- Protocol
- Study requirements flowchart
- Standard task activity categories & time assumptions
- Start-up cost assumptions
- Research team / Business Office collaboration & communication
The Cycle of Negotiating

START

Prepare

Dialog

Evaluate

Conclude

FINISH
What is Penn’s Corporate F&A Rate?

Study Budget:

- Direct price: $100,000
- Total price: ___________
### Study Budget:

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
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<tbody>
<tr>
<td>Direct price</td>
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</tr>
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What is Penn’s Corporate F&A Rate?
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<th>Study Budget:</th>
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Corporate F&A rates: % of TOTAL price
Preparation – Key for Negotiation Success

<table>
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<th>The Budget</th>
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<tbody>
<tr>
<td>• Utilize the Core Financial Practices</td>
</tr>
<tr>
<td>• Include “hidden” costs</td>
</tr>
<tr>
<td>• Familiarize yourself with the detail</td>
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<th>Your Counterpart</th>
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<td>• Their position &amp; motivation to place the trial at Penn</td>
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<tr>
<td>• Their previous experience working with Penn / your Department / this PI</td>
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Preparation – Key for Negotiation Success

**Yourself**

- What if they balk at the Penn price?
  - Let me tell you how the price was determined; what parts do not seem reasonable to you; are other sites doing the study, too?
- What if they refuse some of the prices?
  - What parts of the study do you not want Penn to do; can we break it into phases?
- What is our walk-away position?
  - Penn and the PI really want to do this study, but at your price, Penn would lose money – how can we close the gap?
Negotiating Rules of Thumb

1. Sponsors come for Penn’s product: knowledge
2. Include all expenses in the budget
3. Discuss F&A as a percent of total costs (20.6%)
4. It is all about price
5. Prepare, prepare, prepare!!
6. Work is negotiated – not value
7. Trade, don’t yield
8. Know your walk-away point