

How Much Money Do you Ask for When Submitting Grant Budgets?

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Goals of Today's Program

- Understand Cost Elements of Clinical Studies/Trials
- Understand How to Estimate Costs Associated With Protocol Events

Types of Trials/Studies

Investigator-initiated Single Site

- NIH
- Foundations
- Industry

Multi Site – Sponsor Initiated

- NIH: R01s; R03s; RFAs; Contracts
- Industry

Common Thread: Need to understand costs

Clinical Trials/Studies: Are They Worth the Effort?

Assess

Opportunity Cost

- Dilute time from other academic activities
- Take a long time from start, to finish, to publication
- Minimal margin: **You're not doing this for the \$**

Access to Infrastructure

- Study Coordinators - available?, new hire? or part time CRP?
- IRB Submission - departmental or CRP help
- Space: exam rooms, cabinets for CRFs, staff study agents

Why Participate in Clinical Studies/trials

AHC Mission - Patient Care, Research & Education

Patient Care - Pts might benefit

Research - Protocol's scientific merit

Add-on studies: data mining

Build patient cohorts for future studies

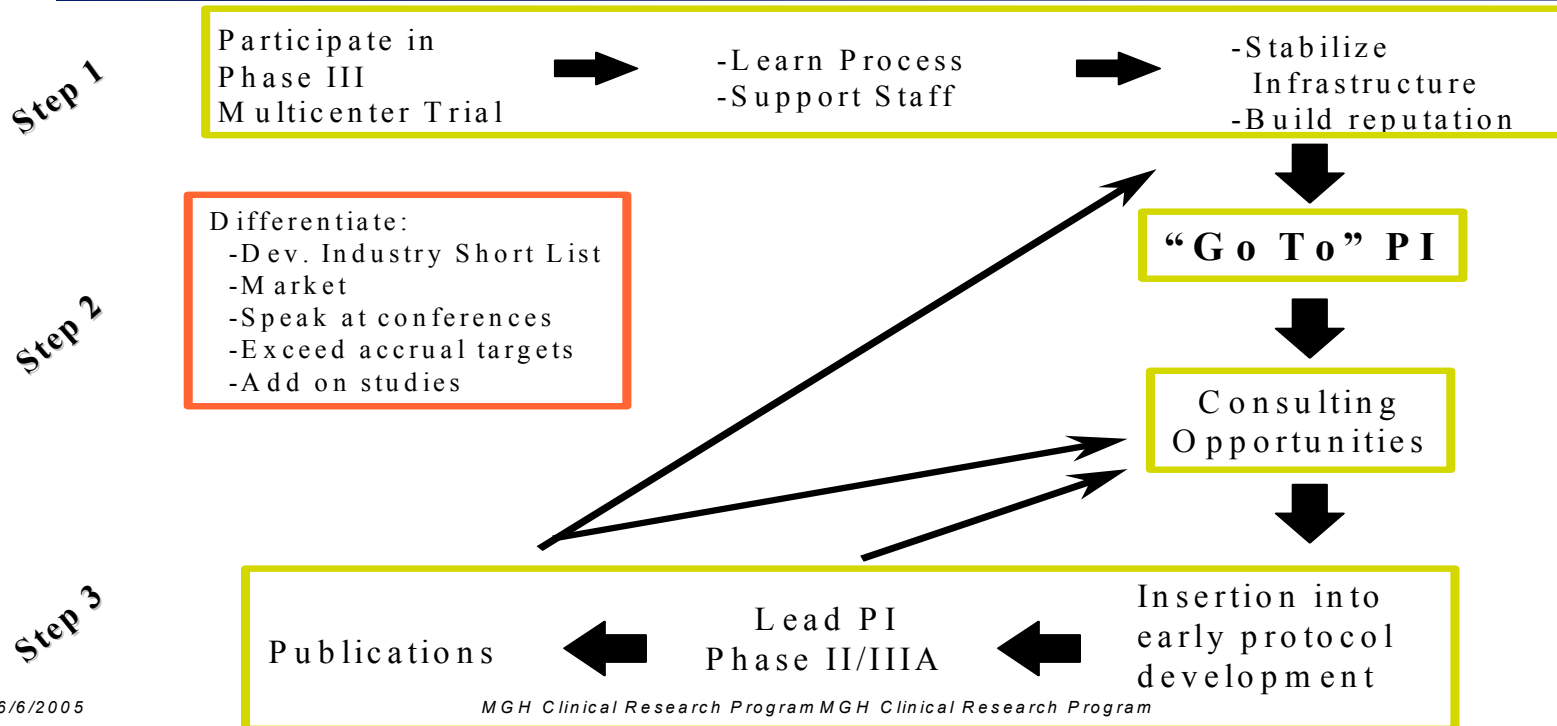
Education - Therapeutic potential of intervention, NCE,

Our Competitive Advantage Over Other AHC

- RPDR
- RSVP
- CSRL – RVL
 - Master Agreements

Industry-Sponsored Trials: Why Participate?

One possible strategy



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Industry Sponsored Studies/Trials

2nd strategy – Build Track Record

NIH Roadmap Initiatives

Show recruitment and retention /each study
Build databases of potential subjects

Enhance study management skills

Manage parallel IRB, contract & budget review
Competitive enrollment dilemma (NIH and industry)
Early IRB review vs. just-in-time review

Protocol Assessment

- Feasibility
- Degree of difficulty
- Study Costs

Feasibility

- Do we have access to this population or can we recruit them?
- Does the budget support the work to be performed?
- Do you have trained support staff?

Determine Degree of Difficulty

- Easy
- Moderate
- Difficult

Study Costs

- Realistic
- Consistent
- Flexible
- Justifiable

✓ Budget tip -
Don't look at
proposed budget.

Figure your costs
first!!!

Study Costs

- Start-up costs
- Per-patient costs
- Variable costs (as needed)

Study Costs

Start-up costs

- Non - refundable
- One time charges
- Examples include: coordinator time, IRB and pharmacy setup fees

Study Costs Procedures

- ✓ Read protocol and list all procedures/tests
- ✓ Include associated professional fees
- ✓ Include room rates
- ✓ Verify “Standard of Care” items
- ✓ Use pricing guide/chargemaster as a reference only
- ✓ Verify/Negotiate charges with each departments research administrator

Study Costs Tasks

- ✓ Read protocol and list all tasks
- ✓ Determine the personnel costs associated with each study task
- ✓ Items may have both a procedure cost and an associated personnel cost

Per-patient Costs

- Direct costs
- Supplies
- Tests/procedures
- Stipends/transportation costs
- Staff time

Variable Costs (as needed)

- Bill (invoice) only if they occur
- Not included in list of per-patient costs

Commonly Overlooked Budget Items

- Start-up & close-out costs
- Increase in operating cost for multi-year study
- Visits not considered visits by the sponsor
- Advertising
- Record storage
- Payments for unscheduled procedures, adverse events, visits, test, screen failure compensation
- Audits from sponsors, CRO, or FDA

Underestimated Budget Items

- Consent “Process”
- Start-up costs
- Administrative costs
- Miscellaneous supplies
- Equipment use and depreciation

- Support staff time - #1

Top Five Budget Mistakes

- # 5 - Accepting the Sponsor's proposed budget
- # 4 - Ignoring details of the protocol
- # 3 - Not seeing case report forms before finalizing budget
- # 2 - Not obtaining accurate professional and technical fees for procedures/tests
- # 1 - Accepting any loss- no matter how small

Summary

NEVER accept initial proposed budget

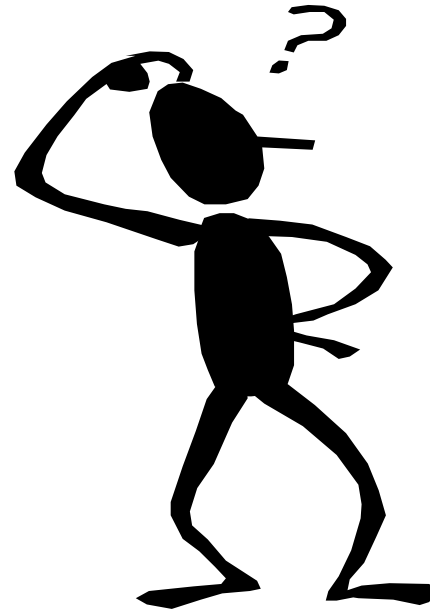
ALWAYS figure costs of study procedures

DON'T rely on sponsor template of costs

FIND hidden costs in protocol

Budget Building Exercise

Where to begin



Questions

Should you have any questions regarding any information on this presentation, please contact us.

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