Developing Comprehensive & Defensible Industry Sponsored Clinical Trial Site Budgets

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Introduction

Clinical research is vital to the goals of:

- Improving Patients' Quality of Life
- Patient Survival
- The Ultimate Goal, finding a Cure

An integral part of clinical research is the costs associated with conducting clinical trials.

A successful clinical trial proposal is inclusive of a budget that adequately meets the trials financial needs and study requirements of both the Sponsor and Investigative Sites.

Compliance issues (IRB approval & Consent Forms) essential in clinical studies should be resolved in conjunction with the budget process.

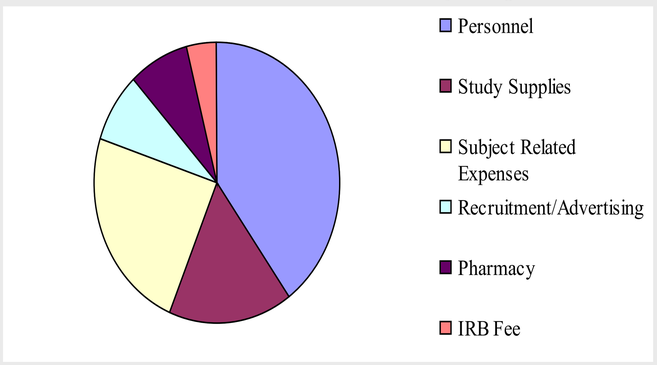
Methods

Confidential Disclosure Agreement (CDA) is a legal contract that governs the exchange of proprietary or confidential information. The agreement is used when there is a need to share proprietary information with an external party for a limited purpose while protecting it from being disclosed to others or the public.

A **Clinical Trial Agreement** (CTA) is used to ensure each participating site's compliance with:

- Agency-specific and award-specific policies and regulations
- Applicable FDA, federal, and state regulations
- The policies and procedures of your institution

- The PI is typically presented with the study protocol which will include:
  - Schedule of Subject Assessments
  - Per Subject Cost reimbursement
  - Payment schedule.
    - These are the most valuable tools to help develop a realistic clinical trial study budget. They provide details of procedures that need to be included in the study budget.



Personnel Salaries and Benefits are typically the largest category of a budget. Make sure the include:

- Salary for all who will devote effort
- Annual Salary Increases
- Do Not Underestimate the Time & Effort To Recruit Subjects

Methods

When building a Clinical Trial Budget some essential things to consider include:

- Study Start-up Non-Refundable
- Salary support for all study staff (PI, Specialty Physicians, Consultants, Project Manager, Statisticians, Data Managers, Coordinators, Grant Administrators and Administration)
- Per Subject Cost
- Study Related Supplies
- Parking and Meals for Study Subject
- Hospital Room Charges and Clinical Fees
- Per Subject Cost Annual Increases
- IRB Preparation and Amendment Fee
- Storage of Study Documents
- Dry Ice and/or Freezer Fee
- Recruitment/Advertising Fee
- Publication Cost
- Institutional Overhead as Appropriate.

Checklist for Industry Sponsored Clinical Research Budgeting

☐ Start with Final Protocol

Per Subject Cost
- ☐ Compensation for salary support for all study activities (including eCRF and AE/SAE completion)
  - ☐ PI and co-investigators
  - ☐ Other Physician(s)
  - ☐ Research Nurse(s)
  - ☐ Research Coordinator(s)/Data managers
- ☐ Determine Research Related vs. Standard of Care
- ☐ Correct lab/ procedure charges
  - ☐ Radiology charges confirmed with department
  - ☐ Include potential future charge increases
  - ☐ Include applicable professional fees
- ☐ Parking/travel for subjects and/or subject remuneration
- ☐ Hospital room charges/clinic fees
- ☐ Research Pharmacy
  - ☐ Drug Storage
  - ☐ Monthly Dispensing

One Time Cost
- ☐ Administrative/start-up fees to initiate the study
- ☐ Medicare Coverage Analyst
- ☐ Travel to Investigator Meeting
- ☐ Document Translation Costs
- ☐ Freezer/dry ice fee if samples need to be stored at cooler temperature
- ☐ Supply costs
- ☐ Recruitment/advertising costs
- ☐ Travel to Close-out Meeting
- ☐ Long Term Document Storage

Invoicable to Sponsor Cost
- ☐ Protocol amendment preparation
- ☐ SAEs
- ☐ Safety Reports
- ☐ IRB Fees – Initial; Amendment & Annual Renewal
- ☐ FDA Audits –time and effort of PI and coordinator
- ☐ Screen failure
  - ☐ Quantity allowed _____
  - ☐ Amount per screen fail $_____

Payment Schedule
- ☐ Start-up costs at execution of Contract
- ☐ Advance subject fees for first subject(s)
- ☐ Payment schedule complies with Institutional policy on payments

Institutional Policy
- ☐ Overhead rate at ___% (standard industry sponsored clinical trial research rate as determined by Institutions Sponsored Research Management)
- ☐ Overhead applied to all costs (including subcontracts; excluding only IRB fee)
- ☐ IRB review fee of $_____

Developing Clinical Trial Study Budgets serves two primary purposes:

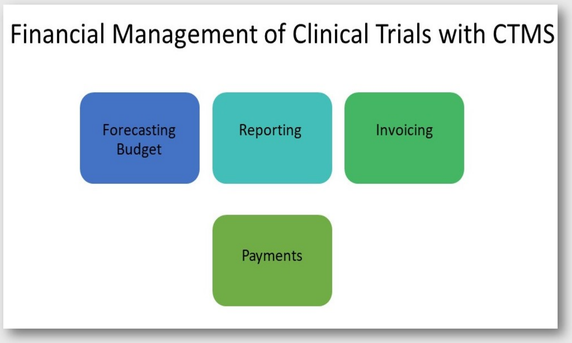
- Ensuring sufficient funds are available to perform the study start to finish
- Identifying procedures that are research-related and must be billed to the grant account vs. Standard of Care and billable to the subjects insurance per Medicare Coverage Analysis as applicable.
  - Carefully Review the Protocol – including any footnotes in SOA
  - Input from Investigator, coordinator, sponsor
  - Provide Justification for Start up fees
  - Ask for more than you think you need
  - Know institutional requirements – finance and compliance

<u>Under budgeting will result in fund deficit regardless of recruitment</u>

Review the protocol to make certain that the per subject reimbursement covers all of the trial expenses, that the payment schedule minimizes cash deficits and the sponsor has set realistic milestones.

Clinical Trials that include multiple participating study sites typically have a need for payments to study sites.

- Site Payments are calculated based on case report forms (CRF) that study sites complete per visit and enter into a database maintained by the study coordination center or sponsor and are based on work performed.
- For larger multi-center studies with high projected enrollment generating invoices can present challenges when trying to calculate and issue site payment.
- The ability to issue payment to participating sites with an accurate efficient process is critical to participating sites continued involvement and continued subject enrollment.
- Every protocol is different; the management of sites, vendor's, subject's and other costs/payments/invoicing can be extremely difficult. Other than a paper-based spreadsheet method, another more modern approach is the use of financial management accounting software or Clinical Trial Management System (CTMS).



Financial Outcomes/Effects

- Clinical trials that are well-designed, well-executed and well-funded are the best approach for advancements in medical care at health care research facilities around the world.
- Preparing Clinical Trial budgets is time-consuming and requires significant attention to detail. The time and effort invested upfront will ensure appropriate financial support for the life of the study.
- Develop a realistic budget; Justify your needs; Keep it reasonable
- <u>One size does not fit all</u>. Customize budgets taking local realities and study complexity into consideration
- Never agree to the Sponsor's initial offer no matter how incredible the dollar amount sounds without a thorough analysis of the specific protocol
- Successful Study Team communication is an integral role in the successful financial management of clinical research studies.

Conclusions

- Successful budgeting for all types of clinical trials is essential to ensure all costs are covered.
- Budgeting is a difficult part of the negotiation process and is a necessary task to ensure cost coverage. The close collaboration between the PI, CRA, site study staff and sponsor will ensure a successfully negotiated Fair Market Value clinical trial budget.
- Negotiate, if it's not in the contract you are not guaranteed to be paid for it.
- Budgeting for the successful performance of an industry sponsored clinical trial requires a comprehensive understanding of the budget preparation process.