

BUDGET NEGOTIATIONS FOR INDUSTRY CLINICAL TRIALS

**Financial Administration of
Clinical Trials Services**



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Agenda

- Introduction
- Developing an Industry Sponsored Clinical Trial Budget
- Industry Sponsored Device Studies
- Medicare Coverage Analysis
- Indirect Cost Rate for Industry
- Ideal Payment Terms
- Budget Negotiations by FACTS
- New Process for Request of Industry Fund Numbers
- Discussion/ Questions

Introduction

- The Clinical Trial market is a competitive business.
- Developing a study budget that captures all of the costs associated with a clinical trial is essential to the financial success of site-conducted studies.
- Negotiating study budgets isn't always an easy task and is often a tense discussion between sponsors and research sites.
- This presentation hopefully will provide you with tools to ease the budget negotiation process and help you achieve financial success when conducting clinical trials.

Developing an Industry Sponsored Clinical Trial Budget



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Documents Required

- What you need:
 - Final protocol
 - Schedule of Events
 - Contract
 - Exhibit A or payment terms
 - Budget
 - Sponsor's template (every Sponsor will have a different template)
 - Informed Consent
- Items you may need:
 - Imaging manual
 - Laboratory manual
 - Pharmacy manual

Budget Development Process

Read the protocol including footnotes in the schedule of events table



Review the sponsors budget grid and payment terms



Develop internal study budget – accounting for all costs



Revise sponsors template based on the internal budget



Justify costs

In Preparing to Develop the Budget

- Review the final protocol with PI and/or study team
 - Identify items that will generate expenses for the site
 - ✓ Number and complexity of subject visits
 - ✓ Estimated time for study visits
 - ✓ Procedures to be performed
 - ✓ Staffing needs for duration of study
 - ✓ Number of patients expected to be enrolled
 - ✓ Location of study visits

Reviewing the Protocol

✓ Determine if there will be other affected areas

- Pharmacy
 - Drug dispensing
- Pathology
 - Reading fees
 - Additional Slides or Blocks
- Laboratory
 - Central vs local lab
 - Who's drawing the blood
 - Who will process the samples
 - If local what if a test is positive?
- Radiology
 - Copies of film
 - Who will read the films?
- Cardiology
 - Echos
 - Reading fees
- Pulmonary
 - Pulmonary Function Tests (PFTs)

Parts of a Study Budget

- **Fixed Costs**
- **Variable Costs**
- **Per Patient Costs**

Fixed Costs

➤ **Costs that will occur regardless of patient enrollment**

Start-Up costs (Non-Refundable)

- Initial IRB Preparation and Review Fees
- Pharmacy Review Fees
- Contract and Budget Review Fees
- PI and Staff Training
- Regulatory Document Preparation
- Pharmacy Initial Review Fee
- Clinical Research Center Set up Fee (if applicable)
- Departmental Review Fee (if applicable)

Other Fixed Costs to consider

- Document Storage Fee
- Medicare Coverage Analysis(if applicable)
- Close out Fee

Variable Costs

➤ Events that may or may not occur during the study

- Annual IRB Preparation and Review Fees
- Annual Pharmacy Fees
- IRB Amendment Preparation and Review Fees
- Advertising Fee
- Safety Report Preparation and Review Fee
- Contract Amendment Review Fees
- Monitoring Visit Fees
- Other fees applicable to your department
- Translation Fee

Per Patient Costs

➤ **Budget for one single completed subject**

- Patient Care
 - Procedures
 - Test
 - Labs
- Subject Costs
 - Stipends
- Personnel Costs
 - Physician
 - Coordinator
 - Nurse
 - Lab Tech
 - Pharmacist
 - Other Specialist

Institutional Fees

Administrative Fee

Start up Fee – Average \$6,000

Annual Regulatory Maintenance Fee – Average \$1,500

Close out Fee – Average \$1,000

PPHS IRB Fees

Initial IRB review \$2,500 once

Annual IRB review \$1,200 yearly

Modification IRB review \$500 each

External IRB review \$575 (if applicable)

IDS Fees

Investigational drug service review/start up \$1,500 once

Dispensing Fee (built into per patient budget)

Administrative Fee \$750/annually (Billed as \$62.50/month)

Close out Fee \$500 at end of study

FACTS Fees

MCA fee \$1,575 (if applicable)

Initial Review: Clinical Trial Agreement Fee \$1,000 or Site Agreement Fee \$800 or Work Orders to MCTA \$500

Amendments to CTA (minor) \$100/amendment

Amendments to CTA (substantial) \$200/amendment

Budget negotiation (if FACTS is used) \$600

CLINICAL RESEARCH UNIT (CRU) – if applicable

Application & Set up Fee – \$1,000

Per Visit Fee – see CRU application

Overhead (IDC) is 35% for all industry trials – it is applied to all costs except for IRB fees

What is the Most Important
Cost Element of a Budget?

Personnel Costs

Personnel Cost: Study Coordinator

- Estimating Coordinator Time
 - Protocol Required Activities
 - Informed Consent (2-3 hours)
 - Inclusion/Exclusion Criteria & Medical History
 - Questionnaires
 - Assessments
 - Additional Time waiting for subject
 - eCRFs (Electronic Case Report Forms)
 - Subject Recruitment & Pre-Screening
 - Coordinating the study visits- Scheduling
 - Amount of time at each study visit
 - Regulatory Paperwork
 - Training

Estimate that for every 1 hour spent with subject there is 1.5 hours of paperwork

Personnel Cost: Physician Fees

- Physical Exams
 - Initial
 - Complete
 - Limited
 - Follow-up
- Procedural Charges-Professional and Technical Component
- PI Fee – Responsible for the conduct of the study
- Length of Study Visits
- On-line training
- Investigator Meetings

Budgeting Personnel time in Budget

- Percent effort must be allocated to visits and number of subjects
- Percent Effort Calculation
 - $((\text{Salary} + \text{Fringe}) * \% \text{ Effort}) / \text{number of anticipated subjects}$
 - This formula calculates the amount that needs to be included per subject
 - The amount calculated is then allocated across the visits.

*Be realistic on the number of anticipated subjects

- If you base the calculation on more subjects than actual enrollment then the study will likely end in a loss

Helpful Tips

- Most sponsors require documentation/justification of costs.
 - Create Explanation of Fees on Institutional Letterhead
 - IRB, IDS, FACTS and Indirect Cost justification are available online
- Be prepared to justify
- Know what are the must have items, what items you want to have and what you are able to concede
- Be flexible
 - Sponsor may not be willing to add a fee that is titled a certain way but they may be willing to offer something else that would cover the fee
- Allow room for negotiation

Hidden Costs

- Increased salaries & operating costs over time.
- Unscheduled visits
- Screen failures/early termination
- Missing Procedures/Events
- Anesthesiology Cost for Procedures

Budget Revisions

- ❖ Renegotiation is an option, even mid-study
 - Change in visits / procedures / tests
 - Extension of study
 - Number of study subjects
 - Amendments

Contacts for Research Fee Schedule

- Ophthalmology – Jill Slutsky-Sanon
- Laboratory Fees – Frederick Adams
- Pathology- Daphne Semet
- Dermatology – Giselle Singer
- Anesthesiology – James Leader
- Medicine Divisions – Michele Cohen
- Cardiology – Debra Fitzpatrick
- Clinical Research Unit – Joanne Zephir
- Neurophysiology Lab - Mary-Catherine George
- Transplant – Brandy Haydel
- Radiology – Depends on where it's being done.
- Hospital Fees – Fee schedule available (ask FACTS)

Industry Sponsored Device Trials



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Device Trial Types

There are two basic types of device trials

- Investigational Device Exemption [IDE] studies
 - Not FDA approved for the indication
 - Category B
 - Category A
 - Both require Centers for Medicare & Medicaid Services [CMS] approval
 - Both require local MAC [National Government Services – NGS] approval
 - FDA approved for the indication
 - Generally post market approval studies for gathering additional ‘real world’ data
 - To satisfy FDA
 - To obtain additional claims information and obtain billing code[s]
 - Do not require Medicare approval

Include in Sponsor Budget

Additional time/effort is involved in these per patient / hidden budget items:

- Device Accountability
 - Account for and track:
 - Product receipt/storage
 - Documentation of lot number / expiration date
 - Subject who received device
 - Date device implemented
- Imaging data to core lab
 - Converting imaging data from standard of care systems
 - De-identify data
 - Have access to sponsor system
 - Download/upload or copy data to CD and mail
- SAE reporting
 - Investigator oversight and sign off on eCRF
 - IRB notification
 - Data entry for both the sponsor eCRF and IRB notification
 - Source document retrieval (internal EMR or external sources)
 - Send source docs to sponsor -de-identified HIPAA compliant format.

Device Provision

- Devices are:
 - **FREE** - Provided at no cost by the sponsor
 - This should be clearly stated in the study agreement
 - “Sponsor will provide, without charge, the Study Device to Study Center to be used in the Study”, or something similar
 - **NOT FREE** - provided by the sponsor at a cost to hospital
 - This should also be clearly stated in the study agreement
 - “Sponsor will not provide Study Device to Participating Institution at no charge“, or something similar
- Devices ‘not free’ must be purchased by the Hospital
 - Determine if device is already being purchased by hospital
 - If not, initiate the Purchase Agreement negotiation process

Device Purchase Agreement

Devices not currently purchased by hospital, must have Purchase Agreement

- Notify Hospital Administration / Compliance / Purchasing
 - Device purchase for clinical trials must be approved by hospital
 - Michael McCarry, Senior VP Hospital Administration
 - Inna Bender, Senior Director, Finance
 - The following hospital purchasing personnel should be contacted:
 - Fred Silva, Director Operating Room
- Should be requested in parallel to submission of CTA to FACTS office

Medicare Approval

IDE trials require Medicare approval to qualify for billing reimbursement

- Industry sponsors are required to register the IDE trials with CMS
- Category B trials qualify for reimbursement of both device and routine clinical services
- Category A trials only qualify for reimbursement of routine clinical services – but not the device
- Registered trials can be found at:
<https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html>

NO patients should be scheduled for a procedure under an IDE protocol until institution has received acknowledgement/approval from NGS

Medicare approval is not required for FDA approved device trials or Drug trials

Medicare Coverage Analysis



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Medicare Coverage Analysis MCA

An MCA is required for all clinical trials in which any tests, procedures and interventions performed on study subjects may be a combination of bill-to third party payers and paid-for by sponsor

- Done to determine eligibility of study for Medicare reimbursement
- Done to ensure compliance for clinical billing in research
- Based on Medicare coverage rules

MCA

Why Medicare?

Services determined to qualify for insurance reimbursement follow Medicare rules because:

- Medicare reimbursement rules are standardized
- Many commercial payors follow rules similar to Medicare

Services determined to qualify for sponsor's reimbursement:

- Use of Medicare rules for budgeting allows a set minimum amount from which to initiate negotiation with sponsor

MCA

What qualifies for Medicare reimbursement

Under Medicare's Clinical Trial Policy, 'routine costs' are covered when a research study meets the criteria for a qualifying clinical trial

Routine costs are those medically necessary items/services that would be normally covered by Medicare in the absence of a clinical trial

Routine costs [Medicare's definition] are not always synonymous with Standard of Care(SOC) [Physician definition]

MCA

What Medicare does NOT pay for

The following are the items/services that the sponsor is responsible for paying for:

- Investigational item or service itself(ex: many investigational drugs, devices and diagnostic tests)
- Items and services provided solely for the purpose of determining eligibility and not related to medically necessary clinical care
- Items and services not ordinarily covered under Medicare (ex: cosmetic surgery)
- Items and services provided solely to satisfy data collection and analysis needs and not necessary for clinical management (ex: Monthly CT scans for a condition usually requiring only a single scan)
- Items and services provided by the research sponsors free of charge

MCA example

Protocol Title: The Study Catheter Clinical Trial: Prevention of Pulmonary Embolism in High Risk Subjects											
Protocol Number: QD-230		NCT#: NCT02186223		PI Name: John Smith							
ASSESSMENT/EVENT	CPT Code	NCD/LCD/ References	Qo/Qi Modifier? Y/N	Comments		Screening / Enrollment / Baseline	Day of Catheter Insertion	Daily Follow Up While the Catheter is in Place	Day of Catheter Removal	Daily Follow Up Post-Catheter Removal	Final Visit
Study Visit											
Enter Y/N at each visit timepoint if diagnosis Code V70.7 (and Condition Code 30, where applicable)						Y	Y	Y	Y	Y	Y
Non procedures and forms											
Informed consent	None	N/R	N			F					
Eligibility Criteria	None	N/R	N			F					
Baseline Assessment	None	N/R	N			S					
Adverse Events	None	N/R	N				S	S	S	S	S
Study Exit	None	N/R	N								F
Antibiotic, Thrombolytic, Antiplatelet, Anticoagulant, and Vasopressor Medications	None	N/R	N			S	S	S	S	S	S
Daily assessment with device in place	None	N/R	N					S			
Daily Follow-up after device removal	None	N/R	N							S	
Central Venous Catheter Status	None	N/R	N			S	S	S	S	S	S
Procedures and tests											
Device insertion	36556; 36558; 36561; 36563; 36565; 36566; 368569; 36574; 75998; 76937	Footnote 1; Footnote 2	Y				M				
Device removal	36589; 36590; 75998; 76937	Footnote 2	Y						M		
Imaging Assessments											
Compression Ultrasound of the lower extremities according to the Imaging Acquisition Guidelines	93921-26	None	N			S	S	S	S		
Compression Ultrasound of the upper and lower extremities according to the Imaging Acquisition Guidelines	93970-93971	None	N					S	S	S	S
Echocardiogram	93303-93308 (APC 0269, 93320-93325	Footnote 4	Y	*If subject has a confirmed diagnosis of PE per protocol definition		M	M	M	M	M	M
KUB	74000	None	N				S				
Spot Films	None	None	N						S		
Cavogram through the Proximal Sheath Port of the Study Catheter	75825	None	N						S		
Laboratory Assessments											
Venipuncture	36415	None	Y	Service performed to obtain samples for processing at a local lab and patient management.		M	M	M	M	M	M
CBC (including WBC, HGB, HCT, Platelets)	85025	NCD 190.15	Y	Footnote 3		M					
INR, PT	85610 (PT); 3555F (INR)	NCD 190.16 (aPTT); NCD 190.17 (PT)	Y	After screening, PTT and INR if subject has major/fatal bleeding as per protocol's schedule of events table 6.1		M	M	M	M	M	M
Pregnancy test	84702; 84703	None	N			S					
Troponin I or T	84484	Footnote 5	Y	*If subject has a confirmed diagnosis of PE per protocol definition		M	M	M	M	M	M
Device											
Study Catheter	G12020266	None	N	Being provided by Sponsor free of charge.			NB				

MCA Budgets

For Budget negotiation, an MCA can be a tool to appropriately identify which items are research, to be paid for by sponsor and which are SOC, can be billed to subject insurance

A billing grid is developed and will:

- Summarize protocol schedule of events
- Validate CMS National & Local coverage decisions for clinical items identified in protocol as SOC
- Apply a determination of reimbursement to individual protocol events - ie: what sponsor should pay for, what may be billable to insurance

Learn more about MCA - [Clinical Research Billing Rules for Investigators](http://peak.mountsinai.org) training course in PEAK at <http://peak.mountsinai.org>

Indirect Cost Rate for Industry –Clinical Trial Fund

- All industry sponsored expenses are subject to the indirect cost rate of 35% except IRB fees which are paid directly to the IRB and do not get charged to the fund.
- The indirect cost rate is non-negotiable.
- If the pharmaceutical company will not pay the 35% rate, a waiver is required from the Dean or the CFO.
- If the waiver is not granted, the department will need to supplement the difference.

Ideal Payment Terms

- Initial payment for start-up costs, which is non-refundable, should be paid upon the full execution of CTA. No invoicing should be necessary. If an invoice is required, it should be sent out immediately.
- If possible, payments should be processed through wire transfers.
- Regular payments made with realistic milestones. If possible, payments should be monthly instead of quarterly.
- Payments should not be held up due to monitoring visits. Payments should be based on CRF completion.
- There should be no holdback since all the reporting now is done electronically. Holdback is more of a trust issue. In Europe it is illegal. If necessary, keep hold back to a minimum.

FACTS Offers Budget Negotiation Services

- If your department does not have the expertise in negotiating clinical trial budgets or you have too many budgets at one time to negotiate, the FACTS office will negotiate the budget for you.
- The fee will be \$600 which is built into the budget and charged to the sponsor.

New Process for Request of Industry Fund Numbers

- Effective May 1, 2018, The department will no longer need to request fund number from SPA for industry studies.
 - FACTS will request a fund number for all studies that have IRB approval and are negotiated by FACTS*.
 - The request that will go to SPA will copy the PI and department initiator so that when SPA creates the fund number, the department will be notified.
 - FACTS will request a fund number once the study receives IRB approval and has a final contract signed.
 - In order for FACTS to request the fund number, Meditract will have extra fields requesting default account along with location of study.
- *All agreements that are negotiated by MSIP that require fund number would still need to be requested by department.

Questions

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