



Optimize Your Site's Clinical Trial Budgets: Tactics for a Swift and Successful Negotiation



Introductions



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Polling Question #1:
What type of organization do you represent?

Today's Agenda

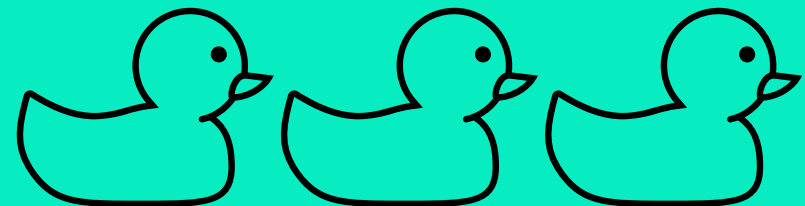


- 1 Establishing Clear Parameters
- 2 Site Documentation
- 3 Red Flags
- 4 First Outreach
- 5 Dealing With Denials
- 6 Finalization
- 7 Conclusion and Audience Questions



Budget Preparation: Crafting Your Approach for Streamlined Negotiations

(i.e. GETTING YOUR DUCKS IN A ROW)



Establishing Standardized and Clear Parameters

Variability or Ambiguity Will Lead to Questions and Delays Later From Sponsors Who Will Expect Clear and Consistent Application of Budgeting Standards.



Per Patient Costs

- Chargemaster vs. Medicare rates for CPT coded items
- Negotiation ranges
- Understanding time/effort ratios based on staff hourly rates



Administrative Fees

- Understanding which fees are non-negotiable vs. fees that may have some flexibility during negotiations
- Start-Up and pharmacy fees
- IND safety reports and SAE reports

Parameters help to come to agreement and expedite the negotiation!

Optimizing Site Documentation

- Fees should remain relatively consistent across all trials performed at the site.
- Each fee should be well delineated to avoid appearance of duplicative fees.
- Ensure that documentation is up to date.
- Document high-dollar items.

Site Administrative Fee Justification Should Include:

- A detailed description of what the fee is intended to cover
- Exact cost of fee and if overhead applies
- Documenting frequency of fee
- Demonstrate standardization
- Study-specific fees
 - i.e., delineating if there are fees that are applicable only to studies in certain therapeutic areas

Site Documentation Dos and Don'ts

Opportunity for Improvement

- Administrative Study Start-Up and Billing Compliance \$10,000

Very Strong, Ideal Justification

Non-Refundable Administrative Start-Up and Billing Compliance Fee

This one-time fee is inclusive of but not limited to:

- Site qualification and initiation visits
- Regulatory review (preparation and submission of documents to IRB, negotiation of informed consent)
- Protocol review and training
- Development of the coverage analysis and budget
- Contract and budget negotiations
- Feasibility review

\$10,000*

*cost inclusive of site 30% overhead

Getting there...

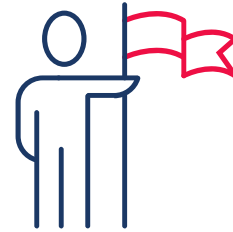
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Identify Red Flags Early On

- Identify root cause for large cost discrepancies between sponsor's initial offer and site's initial counter:
 - Standard of care vs. research related
 - Gaps in sponsor initial offer and site cost for procedures/assessments
 - Conditional vs. required items
 - Visit frequencies and structure
- What precedent has been set with sponsor? Is there an opportunity to mirror past budgets?



- **Verify you are negotiating under the most recent protocol version**
 - Can lead to substantial delays in finalization if there is a protocol amendment during negotiations

**Communicate
Effectively and
Get Ahead of
the Game!**



Communicating Effectively and Getting Ahead of the Game

- Budget negotiations often represent the biggest portion of the overall study start-up timeline.
- Much of that time is lost in the “white space” between handoffs waiting in queues to be reviewed.
- Building a plan focused on limiting time lost in each round is critical to shortening budget negotiation and overall study start-up timelines.



First Outreach

- Be as up front as possible.
- Provide all materials (admin fee schedule, IRB fee schedule, any supporting documentation).
- Cite protocol, billing justification, or site documentation for any edits.
- Anticipate questions.

Follow-up complete physical examination (includes weight, vital signs and BP pre-dose)	338.00		338.00	338.00
Blood pressure outside physical examination	65.00		390.00	65.00
Concomitant medications	70.00	70.00	70.00	70.00
Subsequent Anti-Tumor Therapy	45.00			
PRO(s) Assessment	50.00		50.00	
Drug Accountability for IMP1734	100.00		100.00	
Creatinine Clearance Calculation	20.00	20.00		
Survival Status (Phone)	75.00			
ECOG performance status	59.00	59.00	59.00	
12-lead Safety ECG - Triplicate	429.00	429.00	1,287.00	429.00
Continuous 12-lead ECG recording monitoring for up to 48 hours (Halter	406.00	406.00	406.00	

A Author E17

The site will need to perform a PE at these timepoints per site policy to monitor patient safety. We will need explicit timepoints in the budget and not labeled as invoice. Please refer to the document "Physical Exam-CBC policy signed [redacted] for further justification

September 19, 2024, 8:50 AM

245.00
100.00
3,215.26
1,125.34
4,340.60
3,215.26
1,125.34
4,340.60

A Author U66

Added a timepoint for the Physician Oversight Fee here as this visit requires a physical exam and extensive study related procedures (protocol p. 33) that will require investigator oversight

September 19, 2024, 9:04 AM

Attached is the budget for your review. Here is the rationalization from our coverage analysis:

Magnesium: The guidelines do not include a recommendation for magnesium testing at the frequency required by the protocol (NSCLC Guidelines: Immunotherapy Guidelines). Although the study regimen is known to cause a change in electrolytes, there is no recommendations for performing a magnesium test in addition to the electrolytes already being measured as part of the comprehensive metabolic panel (DailyMed). Therefore, the magnesium test is being used for research purposes and is not billable.

Edits Received - Dealing with Denials

Get to the Root Cause of Discrepancies - Help Sponsors Understand Your Site's Requirements.

- Balance budget need with impact to enrollment timelines.
- Look to previous agreements between your site and sponsor to justify similar rates or fair increases.
- Identify the disconnect in costs and be transparent.
- Delineate requirement vs. "nice-to-have."
- **Example:** Pre-screening tech fee may help process but does the benefit outweigh the potential loss in recruitment timeline if it adds weeks to the budget negotiation?

Copy of Scans \$135.00

TOTAL, RADIOLOGY FEES

Requires manual request for payment; see reimbursement for imaging will be paid up(s), where not standard MRI Scans are maximum costs incurred as a multi-reg week 56 response assessments, every 12 ± 2 weeks. At start of new anticancer therapy, disease occurs first. Scan or MRI is required for all subjects brain performed. All

Connor Wandle F116

This item is necessary to account for CRC time and effort to collect imaging of CT/MRI Scans, redact patient identifying data, and send the images to the central vendor in accordance with the protocol p. 51. Estimating 1 hour CRC time at a rate of \$100, inclusive of 35% OH

October 22, 2024, 1:24 PM

Recruitment Technology Fee	4	\$2,000.00	Max of:	\$2,000.00	Use of High Enroll has not been approved for this study. It has already been considered for other sites and declined.
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Recognize Downstream Impact



- **Appropriately aligning budget can prevent delays in subsequent processes.**

- Timepoints, designations, should align across budgets and coverage analysis
- All protocol required services are captured
- Language in the budget should align with the Clinical Trial Agreement

Ex. The screen failure reimbursement language agreed to in the budget should be reflected in the financial appendix.

- **Document and leave notes for future reference. i.e., why certain decisions were made, how are certain items being represented across budgets.**
- **More time invested now will save far more time down the road with CTMS build out, avoid compliance issues, and set the stage for quicker amendment executions in the future.**



Audience Questions

Polling Question #2:

**Would you like to learn more about WCG's
budget build & negotiation services for
research sites?**

**To learn more about our solutions,
visit our website at:**

www.wcgclinical.com/solutions/budget-development-negotiation

Thank you!



www.wcgclinical.com