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Best Practices for Budget Justifications

Site Enablement League

Budgets Working Group

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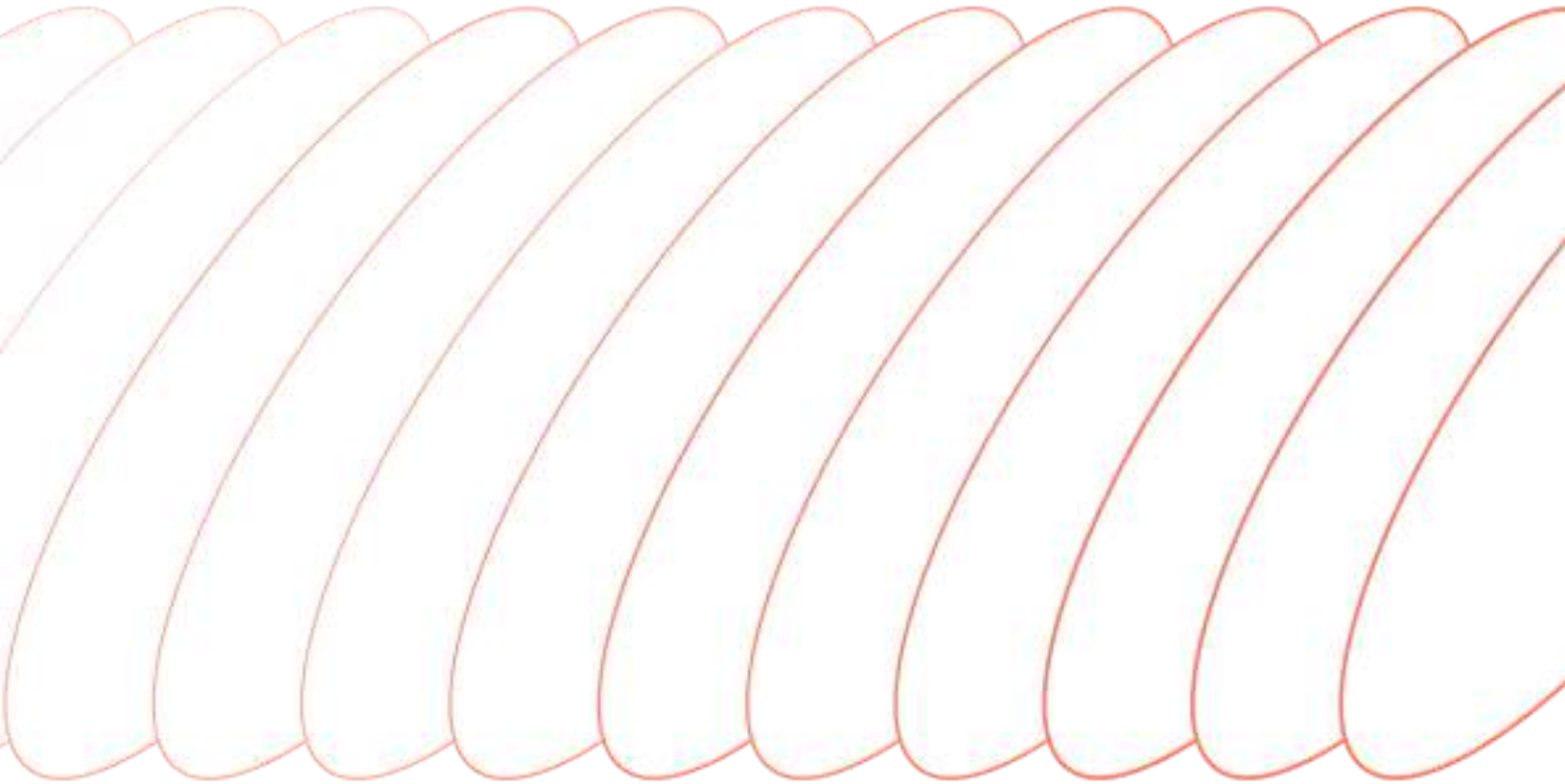

About this document

The clinical trial startup process is complex and involves many stakeholders. This document provides best practice recommendations for Budget Justifications from the Budgets Working Group of the Site Enablement League. By implementing these best practices, stakeholders can improve startup success rates, reduce timelines, and enhance overall trial efficiency.

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Introduction

Budget justification is the written explanation provided for each cost included in a clinical trial budget. It supports the financial value assigned to protocol procedures and operational site services during budget negotiations. Clinical trial budgeting is a complex, collaborative process involving multiple stakeholders at the site level, from study coordinators and investigators to finance and contract staff. Each protocol activity must be clearly identified and the cost must be estimated [See the Best Practices for Budget Estimations document for more details]. Providing detailed justifications for those requested costs can significantly streamline the negotiation process.

For research teams—especially those newer to budget development—this step can be challenging, but it is critical. Well-crafted justifications promote transparency, reduce negotiation back-and-forth, and build trust between sponsors, CROs, and sites. The goal of this document is to educate stakeholders on the value of budget justifications, highlight common pitfalls, and offer best practices for improving accuracy and efficiency. When all parties understand each other's perspectives and expectations, the entire budgeting process becomes more collaborative and effective.

Understanding Budget Justifications

What is a Budget Justification?

A budget justification is a written explanation from a site to the sponsor/CRO that supports why a specific payment is being requested for a line item in the clinical trial budget. Justifications are particularly important when budget line items are added by the site, or when the amount is changed significantly from the budget template. Budget justifications can be used to support clinical procedure costs or site operational costs and should explain how the cost was derived and why it is appropriate.

Why Justification Matters for Sponsors/CROs

When sponsors accept budget requests without adequate justification, they assume financial and compliance risks. Without clear rationale, there's no assurance that costs are fair, necessary, or aligned with actual study activities. This increases the likelihood of budget inflation, inconsistent payments, and audit vulnerability.

Justification is particularly critical when site-requested fees are bundled together, vary widely across sites, are unique or country-specific, or exceed sponsor's expectation for "fair market value" (FMV) [See "Fair Market Value" in the Appendix]. Sponsor/CRO staff may lack the training, tools or authority to properly evaluate and approve such budget requests without justification documentation.

Budget justifications are often saved in sponsor records for audit/inspection readiness. When sites send clear justifications early in budget negotiations it reduces the back-and-forth communication required to gather the documentation. Sponsor staff consistently report that clear, early justification from sites saves significant time in the negotiation process.

Why Justification Matters for Sites

For clinical research sites, thorough budget justifications are useful in reducing negotiation time, but are also essential for internal compliance and operational integrity. The process of assessing and justifying which protocol activities are clinical care (billable) versus clinical research (sponsor-paid), is critical for billing compliance. Clear justifications can help prevent billing errors that could lead to double billing, Medicare non-compliance, and potential fines, protecting both the site's reputation and its audit readiness [See "Billing Compliance" in the Appendix]. Clear estimations and justifications help sites ensure they are covering their costs and reduce the risk of budget renegotiation later if the site realizes its costs are not being covered. Moreover, well-documented justifications serve as an internal record that supports continuity during staff turnover, helping new team members understand prior decisions and maintain compliance across the trial lifecycle.

Mutual Benefits of Budget Justification

- **Clarity:** Justification documentation helps sponsors and CROs understand the rationale behind requested costs, and helps sites assess study finances
- **Efficiency:** Well-supported justifications can reduce negotiation cycles and prevent unnecessary delays
- **Trust:** Transparency in cost estimations and justification improves everyone's understanding of the protocol and fosters stronger sponsor-site relationships
- **Alignment:** Helps ensure that the site is fairly compensated for its work and that budgeted activities match actual workload

Writing Budget Justifications

Site staff involved in budget negotiations are responsible for including the justifications for budget items. These can be written in a justification document and/or added as comments in the budget template. Because budgeting is a complex process, often requiring cross-departmental collaboration [See the Best Practices for Study Startup document for more details], they may need to rely on other staff to create or explain the justification.

As discussed in depth in Best Practices for Budget Estimations, there are two main types of costs in a clinical trial budget, Procedure and Hospital Costs and Operational Costs. The justifications for these types of costs will be slightly different:

1. **Procedure and Hospital Costs**
   These are typically tied to medical services outlined in the protocol and based on Medicare Coverage Analysis (MCA) and institutional fee schedules. Justification here often references standard billing practices, CPT codes, and regulatory guidance. This aspect of cost justification is often more standardized and regulated.

2. **Operational Costs**
   These include the site's internal labor (time and effort) associated with running the trial, including protocol activities and administrative tasks. Unlike procedure costs, justification for these operational costs is specific to each site and requires an explanation of the time and effort for each task. Note that Procedure and Hospital activities may also require research staff time and effort, and so may have an operational cost associated with them.

Justification for Procedure and Hospital Costs

Sites can analyze and justify procedure and hospital costs by conducting a Medicare Coverage Analysis (MCA) [See the Best Practices for Study Startup document for more details about how this fits into the process]. The MCA process should assess each procedure required by the protocol to understand if the cost is reimbursable by the study sponsor or third-party payors. Justification from the MCA can be shared with the sponsor to support budget negotiations. The MCA analysis should consider reimbursement guidelines based on national standards of clinical practice, local standards, the routine clinical care practice at that site as well as special circumstances. Because of these many considerations, the final determination for any one

study procedure may vary widely across sites. Sponsor staff with less experience often do not understand this point and expect all site analyses to yield the same results.

The MCA process is complex and time consuming, and takes specialized skills. When it is overlooked or underperformed sites are at risk for billing compliance. Some sites have billing specialists who can help with the process, but others rely on the research team. Sponsors should note that every site structure is different and some sites might need more support on discussions that include coverage analysis. For a detailed explanation of the MCA process, see the Appendix of this document.

Justification for Operational Costs

Operational costs reflect the time, effort, and infrastructure required by research staff to execute the study effectively and compliantly. These include fixed costs like IRB submission fees, supply costs, and technology platform costs, as well as variable, effort-based costs for staff time for activities like recruiting, participant visits, data review and entry, and regulatory tasks. Time and effort costs can vary widely across sites depending on their organization, processes and location. These costs must be identified and estimated as described in Best Practices for Budget Estimations. When writing budget justifications for these items, sites should describe the associated tasks and explain why each activity is necessary for the conduct of the trial. Clear justifications help sponsors understand the value and resource burden of these activities, ensuring fair compensation and reducing negotiation delays. While many of these tasks are not visible in the protocol schedule of events, they are essential for study compliance, quality, and oversight, and must be documented accordingly.

Best Practices for Budget Justification

Effective budget justifications help clinical research sites communicate the value and necessity of their requested costs, ensuring fair compensation for study activities. The following best practices are designed to promote consistency, transparency, and efficiency in the negotiation process.

Standardization and Efficiency

- **Develop a standard approach:** Create institutional templates and promote a unified institutional approach, especially when departments operate independently. Consistency builds credibility with sponsors and CROs.

- **Maintain a reusable research chargemaster/rate sheet:** Use a central, study-agnostic document that outlines common justifications and standard time-and-effort rates for different staff roles and seniority levels, as described in Best Practices for Budget Estimations. Reference these standard rates in the justification for each protocol activity.
- **Identify non-negotiable fees early:** Clearly specify non-negotiable institutional fees at the start of negotiations to reduce confusion.

Clarity and Transparency

- **Be clear and detailed:** Always include rationale and details for what the cost covers and why it is needed for this particular protocol . Explain the number of hours, staff roles and seniority level, and any unique task logistics. For example, clarify if a coordination fee for a visit includes lab vendor setup or imaging logistics.
- **Use categories and examples:** For non-billable costs, list common activities ("including but not limited to...") to help sponsors understand scope.

Appropriate Level of Detail

- **Balance completeness with confidentiality:** Avoid sharing proprietary or overly sensitive information, but provide enough detail to justify the cost. Use the estimations and justifications internally for financial assessments and future study budgeting.
- **Focus on budget additions and major changes:** Not every budget line item requires justification. Focus on new items in the budget and line items that are significantly different from the original sponsor template.
- **Avoid overjustifying standard rates:** For recurring fees like annual admin costs, describe the scope but avoid overwhelming the sponsor with granular internal details unless challenged.

Justification for Unique or Study-Specific Costs

- **Use one-off templates for special circumstances:** Create a flexible template that can be adapted for study-specific needs like extra personnel (e.g., for pediatrics) or additional training.
- **Adjust for study complexity:** Highlight deviations from standard time/effort, such as longer visits, higher screen failure risk, or use of specialized equipment.

Conclusion

Budget justification is not just a formality, it is a critical tool for ensuring fairness, transparency, and mutual understanding between research sites and sponsors. By clearly articulating the rationale behind both procedural and operational costs, sites can advocate for appropriate funding while reducing delays and miscommunication during budget negotiations. Implementing consistent, well-documented justification practices empowers sites to operate sustainably and compliantly, while supporting successful sponsor partnerships and high-quality trial execution.

APPENDIX

Medicare Coverage Analysis (MCA)

The MCA is a systematic clinical trial protocol review based on the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) 310.1. The MCA determines which clinical procedures and services are eligible or not to be billed to third-party payors. The MCA evaluation assesses the Federal definition of a Qualifying Clinical Trial based on NCD 310.1; please reference the CMS database for further information on qualifying clinical trials. NCD - Routine Costs in Clinical Trials (310.1). The MCA is an internal tool that is effective for documenting the justification of procedures or services in a budget.

The MCA for procedures and services also requires assessment of the study site location, referred to as a local coverage determination (LCD). Based on a site's geographical location, LCD coverage for procedures and services is variable. A site in the Midwest may qualify at one rate for a procedure, whereas a different site on the East Coast may not qualify for third-party billing based on location. Clinical practices at the site can also impact MCA determinations [See “Clinical Considerations for Routine, Reasonable and Necessary Costs” in the Appendix of this document]. These differences can create variable payment schedules for study sites within one study for the sponsor, which can lead to confusion and delay negotiations.

A thorough MCA can provide the detailed information needed to support budget negotiations and ensure all parties are reviewing the same billing details and supporting information. For example sites should list the source used to justify the procedure in the MCA, along with any citations to national or local coverage determinations from CMS.

Example of a budget line item with thorough MCA details

Procedure or Service	Justification	CPT/HCPCS Codes	Identify Frequency and Timepoints
Pregnancy Test (urine/serum)	May be reasonable and necessary when used for monitoring and diagnosis of germ cell neoplasia; it may also be used to monitor pregnancy in patients who experience hypertension, vaginal bleeding, or suspected fetal loss	84703/ 81025	Every 6 months per protocol
Reference https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=125			
https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&calid=200			

Special Cases

There are many special circumstances that impact budget negotiations. For example, who is responsible for patient copays for experimental treatments? Who pays for adverse events and clinical care required to treat those? Who pays for billable costs for indigent participants, and are they even able to be enrolled? Some states have rules preventing Medicaid patients from participating in clinical trials. Does excluding that population change enrollment expectations? Would including that population and paying for their costs mean that covered participants receive inequitable treatment? Such rules vary by state and institution and can impact enrollment goals and equity/discrimination guidelines. There is also an additional administrative burden for any study with complex pre-authorization requirements, where insurance is likely to deny coverage and require an appeal. Decisions on these types of special cases need to be considered during budget negotiations.

Clinical Considerations for Routine, Reasonable and Necessary Costs

In addition to the MCA and LCD assessment for each protocol activity, there are clinical considerations such as the site's routine clinical care practice and the timing of clinical activities.

For example, if a protocol requires an Echocardiogram the MCA and LCD may show that this is billable. However, if the test is required to confirm inclusion/exclusion criteria and is required

to occur within a specific time period before enrollment then the timing of the research test might not align with the clinical billing cycle. In this example, if a patient had a clinical Echo 4 months ago then it's not clinically appropriate to repeat the echo even if the protocol requires an up to date Echo for screening. In that case the test would be a research cost.

Another example might be video visits versus in person visits. A protocol may require an in person visit when a site would routinely offer a video visit. This discrepancy means the site is likely to ask for that visit to be considered a research cost.

There are also important differences from protocol to protocol for the same type of test. For example, a pregnancy test performed on a woman of childbearing potential who is receiving anticarcinogenic (chemo/radiation) treatment per the guidelines is considered a reasonable and necessary test prior to treatment, and would therefore be billable to insurance. However, pregnancy screening for a woman on a standard cardiovascular trial may not be reasonable and necessary, and in that case the sponsor should cover the cost of the test.

Fair Market Value

Fair market value (FMV) is a term often used during budget negotiations. According to 42CFR411.351, fair market value is "the value in an arm's length transaction consistent with the *general market value* of the subject transaction." General market value concerning compensation for services is defined as "compensation that would be paid at the time the parties enter into the service arrangement as the result of a *bonafide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other." In other words, FMV refers to the reasonable price a sponsor should pay for a clinical trial-related service, based on what a typical, similarly qualified site would charge under normal circumstances.

FMV assessments are intended to ensure that site payments are not excessive, inappropriate, or construed as inducements for subject recruitment. This is especially important in protecting sponsors against violations of anti-kickback and fraud regulations. Sponsors often use third-party databases, benchmarking tools, and national averages to determine acceptable FMV ranges for clinical procedures and administrative tasks during budget negotiations. Although this data is relied on for budget planning and negotiation decisions, many industry veterans report that the data is often stale and inaccurate.

Sponsors/CROs and sites all express concerns about misunderstanding and undertrained staff when considering the role of FMV data during negotiations. Cost estimations and billing decisions are complex, and are dependent on geographical variables, therapy area considerations, and site processes. FMV database rates may apply to the clinical cost but may

not account for research staff time and effort specific to each protocol or institution. Sponsor and CRO staff should be clear on the applicability of FMV data compared to what sites are requesting in the budget. Sites should understand that detailed estimations with justification can help support budget requests that appear to be outside of FMV.

Billing Compliance

Billing compliance is the systematic review of all claims, billing, and coding for procedures or services in a clinical trial to ensure compliance with federal and state requirements. Ensuring services are appropriately entered on insurance claims is the responsibility of the research site or covered entity for which services will be rendered. The rationale is that the research site or the covered entity submitting claims to third-party services under NCD 310.1 is liable to comply with federal regulations when submitting claims for services. Additionally, the research site is at risk of revocation to bill CMS according to 45CFR424.535 should billing compliance misconduct be identified. Findings can be based on knowingly or unknowingly submitting false claims according to 42 U.S.C. § 1320a-7a(a)(5) and 45CFR424.535. The MCA documentation and final clinical trial budget provide guidelines for billing and coding for procedures or services when submitting claims.

Additional Resources

- Attend the Clinical Research Billing Compliance Summit
    - https://momentumevents.com/clinicalbilling/
- Browse a variety of industry resources online:
    - https://about.citiprogram.org/course/clinical-trial-billing-compliance/
    - https://about.citiprogram.org/blog/on-research-podcast-coverage-analysis-in-clinical-research/
    - https://www.advarra.com/blog/beginners-guide-to-medicare-coverage-analysis/
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