



IDEAL VS. REALITY BUDGETING

Create & Negotiate the Best Clinical Trial Budget for Your Site

Real-World Budgeting

Ideally, you receive the sponsor's budget table, and your site has a standard cost for every protocol item. You send your site's cost request to the sponsor to initiate negotiations, and the sponsor accepts all budget requests. This situation is possible, but it is rare for the sponsor not to respond with questions, counteroffers or denials. The ideal negotiation turnaround time is 30 days from the start of negotiations to budget completion, but it is not always feasible.

In reality, most sites see at least one round of negotiation involving phone calls, clarification emails and justification requests. Do not expect the sponsor to agree to every initial cost proposed; they may be unwilling to pay certain administrative fees or have a maximum per-patient cost. Due to study complexity, you may need to update standard costs or add unique costs. Multiple rounds of budget negotiations can lead to start-up delays.

Ideal

- You receive an email back from the sponsor accepting all of your study budget costs as soon as you send the budget
- Your site has a standard cost for every item
- You can start a study in less than 30 days

Reality

- Most study budgets have at least one round of negotiation
- Sites can't expect the sponsor to agree to all costs
- Standard costs updates and some studies will have unique costs
- Budgets costs and process may be leading to start-up delays

Standard Fee Schedules

Having a general budgeting process for all studies ensures budget quality. As a result, site costs are covered, and you increase efficiency while speeding negotiation.

Standard items include:

Time and effort

- Hourly rates for study staff budgeting
- Baseline time estimates for common research activities

Patient care costs

- Chargemaster/s – single (technical and professional), research-specific or multiple
- Clear Medicare pricing documentation, including inflation rates
- Contractor rates for routine outside services (e.g., lab and radiology)
- Bottom-line and negotiation thresholds for items in the fee schedule

Administrative fees

- Standard administrative fee schedule per department or location
- Study-level internal site fees (e.g., pharmacy and radiology)
- Non-negotiable “must have” vs. “nice to have” fees

Cost Documentation

One of the most critical requirements for effective budget negotiations is cost documentation. If possible, this documentation should be available before beginning negotiations and should be part of the initial negotiation email or available in memo format.



Usually required for administrative fees

Some sites have separate documents for items such as overhead or IRB fees

Include the fee and an explanation of the fee on letterhead

May need more than one fee schedule

Important to update fee schedules change

Critical for faster negotiations

Study-Specific Considerations

Before building the budget, have a clear, defined process, including:

- Coverage analysis, if required
- Budget details from coverage analyst – such as difficult-to-price items to be sponsor-paid
- Notes from study team with any special protocol requirements or complex activities
- Study-specific departmental protocol reviews, so fees are ready for budget negotiation

- Request to mirror any recently negotiated sponsor budget
- Confirmation of sponsor and CRO budget contacts

Internal Budget Development

Each site's internal budget development process may look slightly different depending upon the process for obtaining costs. In general, these guidelines pay off: For example, if a sponsor's budget includes one follow-up visit, but four follow-ups are involved, ensure

1

Always develop your own internal budget – don't rely on the sponsor's template.

2

Site specific template allows you to show key details for your site (e.g., pro and tech fee breakdown) that the sponsor's template doesn't include.

3

If a coverage analysis is required, use the coverage analysis grid to develop the internal budget.

4

Create a standard internal budget template that incorporates your fee schedules

5

Avoid forgetting site standard budget items, such as a central image submission fees, by creating placeholder lines.

6

Prepare for negotiations by building in formulas that allow you to quickly calculate whether or not you can accept the sponsor's counteroffer.

that your internal budget captures those visits. You will then have an accurate picture of your internal costs compared to the sponsor's costs during negotiation. There are significant variable costs for complex device studies, so you may not be able to fix a standard rate across all studies. To avoid delays, reach out to the specific department or contact early. For items such as biopsies, negotiate an invoice "up to the amount" for these variable fees. Other examples of items to be priced per study are hospitalizations, medications and placebo supplies not provided by the sponsor, surgical procedures and anesthesia associated with those procedures. These items might have a different level of negotiability than other items in the budget.

Time & Effort Items

Work with the study team to identify activities with special timing or staffing requirements (e.g., additional nursing, coordinator, GI). They should confirm requirements for activity, including heavy visits, such as extended PK sampling days, observation days or protocols that require just an inpatient stay

Also, consider if your site must provide a stipend specific to long PK sampling days, for example. Observational studies may include CRF payments, so estimate the time and effort associated with protocol requirements and ask the sponsor to review those CRFs before budgeting. More generally, include data management costs within your budget

and ensure that you have appropriate PI and coordinator time allocated. Items may include informed consent, inclusion-exclusion criteria, concomitant medications, adverse events or follow-up calls.

Negotiations

Be prepared and provide clear expectations for the negotiation process. The steps covered so far will support efficient negotiation. Then, consider these tactics:

- When sending initial negotiations to the CRO or sponsor, include your ideal timeline for negotiation completion. Attach documentation and standard letters or memos. Let the contact know you will follow up in x days if you do not hear back.
- Create site standards for negotiation follow-up timelines when you can decrease prices and when approvals are required.
- Be prepared for situations where the sponsor counteroffer is below your bottom line. Who needs to be involved in phone calls and decisions? Are you willing to walk away from the study?

Certain topics come up in almost every negotiation, so prepare standard responses. Even better – add these to your documentation or create memos if certain fees are often challenged. FAQs include:

- Overhead – document what is or is not included

- Fair market value
- IRB fees – central vs. local requirements
- Start-up

Note that sponsors frequently see different start-up amounts for different sites. Having official documentation of the start-up costs will save multiple rounds of negotiations and help fast-track the budget to finalization.

Tip: Negotiate for start-up payments to be made automatically upon execution instead of invoicing. You'll save administrative time and effort.

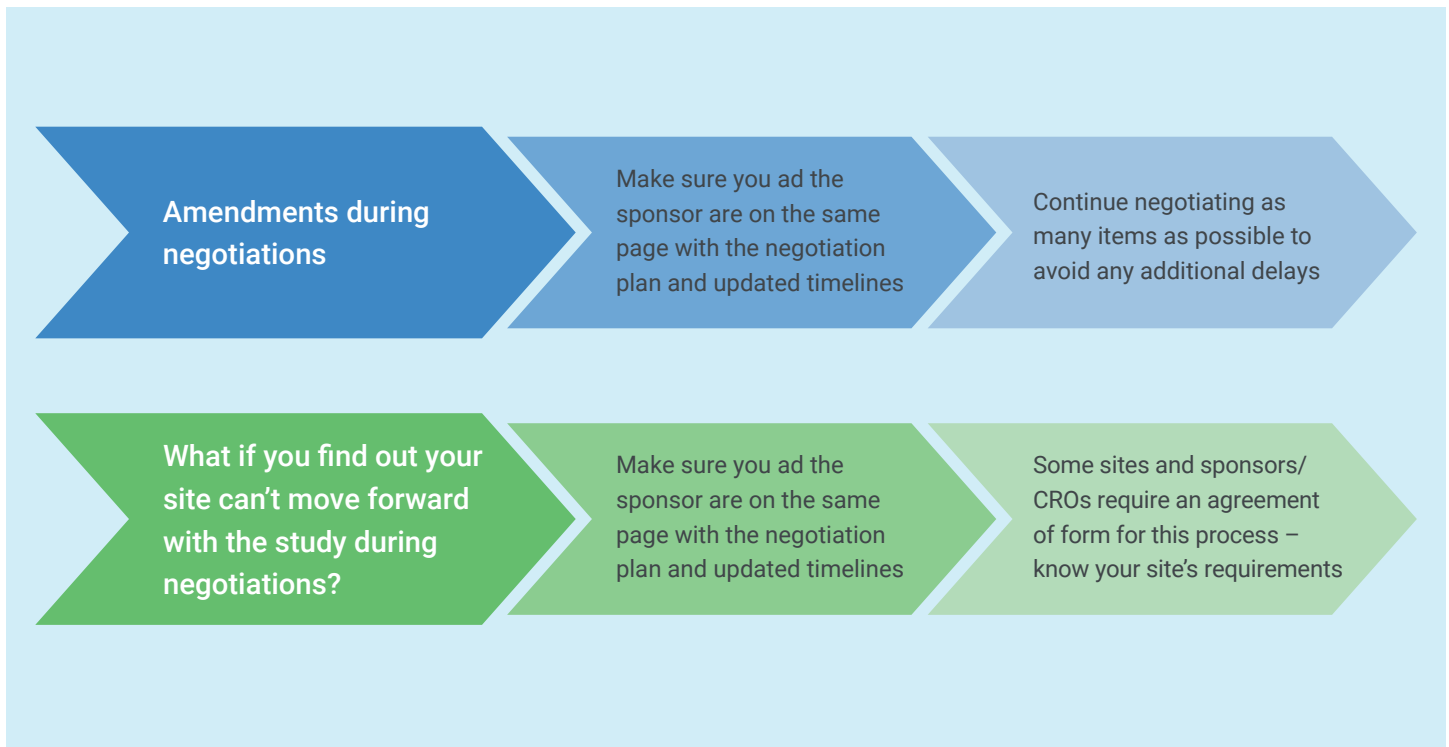
Payment Terms

Know which payment terms are high priorities for your site. Verify addresses and payment

contacts, especially for multiple locations, and ensure that the start-up payment has a timeline. Finally, review screen-fail requirements and work with the study team to determine if a study is likely to have high or low screen-fail rates.

Amendments & Cancellations During Negotiations

Understand your site's process and standards for these negotiation situations to ensure an efficient process and cover your financial bases. Follow these tips for problem solving:



Conclusion

Preparing for budget challenges avoids delays and leads to smoother negotiations. Be ready to justify costs, understanding that it is unrealistic to expect sponsors to agree to every line item. Having standards in place to address less-than-ideal scenarios helps you move through the budget process faster. In the end, reaching an ideal but realistic budget quickly allows you to get patients the treatment they need.



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