

BEHIND THE BUDGET

What Sites Really Need to Run Trials Today

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Clinical trial sites have always been the operational backbone of research. However, as trials incorporate more complex protocols and decentralized technologies, the operational, technical, and administrative demands placed on these sites are escalating. One of the most visible signs of this evolution? Budgets.

In recent discussions with research professionals, we explored how clinical site needs are changing and how the budgeting process must adapt to keep pace. From the growing administrative burden on coordinators to the emergence of new line items like IT support and training time, it's clear that old budget models are no longer sufficient.

In this article, we unpack the 'why' behind these shifts, highlight the site perspective, advocate for stronger communication between all parties involved and feature some innovative site budget strategies sponsors are implementing.



BUDGET NEGOTIATION: A BROKEN PROCESS?

Sites consistently report that the budgets received from sponsors or CROs are often **inaccurate, inefficient, and fail to reflect the full complexity of site operations.**

These budgets frequently underestimate the time, resources, and administrative burden required to run a study effectively—particularly as protocols grow more complex and technology plays a larger role.

When it comes to participant reimbursement and/or stipends, it's important to get the details finalized as quickly as possible. This information is needed to submit to the IRB and finalize the ICF. However, this section is often delayed as the language in the budget surrounding participant compensation is often imprecise and budget negotiators lack understanding of the site needs and processes. This can be exacerbated when the sponsor uses a third-party service to compensate participants. The sponsor's budget negotiator often lacks the information and understanding of the third-party service being used. Confusion in this area can delay study start at the site.

SPONSOR INNOVATION: WHEN SITES REIMBURSE PARTICIPANTS DIRECTLY

Participant reimbursement/stipends identified clearly and incorporated in the per visit payment amount with overhead applied. This helps cover the expense of tracking and issuing payments.

If additional reimbursement is available (extensive travel, hotel etc.), the amounts are included along with information on how the site will be reimbursed for these expenses with no restriction for obtaining prior approval.

One promising initiative aimed at improving this process is the formation of the **Global Costing Task Force**, which brings together industry leaders to identify actionable strategies that help sites and sponsors better align on budget expectations. This collaboration is a positive step forward but it's not a complete solution.

Understanding site needs – *not just aligning on costs* – is critical to achieving real progress.

Medidata's **CTFM Grants Manager** continues to evolve its dataset to provide more accurate, real-world cost benchmarks. Beyond the numbers, the Clinical Trial Financial Management (CTFM) team works closely with customers through **Innovation Labs**, creating a forum for dialogue and deep listening across all stakeholders.

These efforts are designed to go beyond automation to foster mutual understanding and deliver **maximum impact** by addressing both the technical and human elements of budgeting in clinical trials.

THE EMERGENCE OF NEW BUDGET LINE ITEMS

Historically, clinical trial budgets have focused on well-defined, study-specific costs such as PI oversight, coordinator time, lab processing, and patient visit procedures. While these core elements remain essential, today's site budgets are increasingly being **supplemented and sometimes overshadowed by new operational demands**.

These emerging costs reflect the growing complexity of trial execution at the site level.

Two Diverging Perspectives



Sponsor/CRO Perspective:

There's a growing perception that sites are frequently requesting additional line items, sometimes seen as unjustified, which complicates budget negotiations and review processes.



Site Perspective:

From the site's point of view, these requests reflect **real, increasing costs** – driven by protocol complexity, technology burdens, and administrative tasks that were not part of clinical trials a decade ago. Sponsors often lack visibility into what it truly takes to run a study today, and how these evolving demands impact both timelines and staff capacity.



With the increase in clinical trial tech for sites and participants, there is extensive **unexpected workload**. *Wearables for participants, ePROs, eDiaries and 10+ portals per study require sites to deal with charging needs for large numbers of devices, software updates, training, portal interactions, malfunctions, and providing tech support for the participant.*

SPONSOR INNOVATION: TECHNOLOGY FEES

Some sponsors are now recognizing the impact that technology is having on the clinical trial site. Technology fees clearly labeled in the study budget at key time points can help address site time spent in this area. An alternative is having an hourly rate reimbursed, but this is not as ideal because it requires the site to track, invoice and chase down late payments.

As these differences in perception grow, so does the need for **transparent dialogue** and a shared understanding of what modern trial conduct entails. Without this alignment, budget negotiations risk becoming adversarial rather than collaborative and ultimately, patients and timelines suffer.

THE SITE BURDEN AND EXPENSE FOR INVOICING

As sponsors and CROs work for precision in budgeting and payments in clinical trials, the number of optional procedures and pass through items that sites need to invoice for are increasing dramatically.



This comes at a significant cost to the site as they must develop systems for tracking, invoicing and following up on delayed or missed reimbursements. All of this is done at the site's expense.

Take for example the potential for use of local labs if something goes wrong and the central lab can't be used. Most sponsors list each local lab test and assign a value to be invoiced if required. When reviewing the budget, if a site must reach out to a local lab to obtain an estimate for the study, this can cause delays in negotiating the study budget. All this work and delay and the local lab may never be used.



SPONSOR INNOVATION: CONTINGENCY FEES

In clinical trials, unanticipated things happen and there may be the need for additional funding for site expenses. It could be local lab fees as in the example above, supplies needed or any number of things. Forward thinking sponsors are adding an amount for Contingency Fees in the budget so that rather than having to amend the budget part way through the study, the site can simply request for approval of the new expense.

IT SUPPORT AND TRAINING: THE HIDDEN TIME SINK

Two of the fastest-growing cost drivers at the site level are IT support and training:



IT Support Needs

As digital platforms multiply, sites often spend significant time troubleshooting portals, resetting logins, or navigating technical errors, frequently while participants are onsite. That's real time, with real costs.



Training Demands

Training platforms are sometimes non-functional or need to be redone due to errors producing certificates. This can mean hours of lost productivity for already-stretched site staff.

These are not 'extras,' they're increasingly part of the day-to-day reality of running a study.



Imagine being in the room with a study participant and the ePRO tablet malfunctions. What if it then takes an hour with IT support to get the problem fixed, or even worse, what if it doesn't get fixed? The participant sitting there getting increasingly frustrated and if it happens at a screening visit, the participant may elect not to proceed. It also puts the CRC behind for the rest of the day. Time that was to be dedicated to recruitment activities now vanished for the day. Missed opportunities cost the site much more than the cost of the CRC's time.

SPONSOR INNOVATION: EARLY SITE INPUT ON VENDORS

The typical process for sponsors selecting tech vendors for a study overlooks the value that sites can provide. Engaging a select group of sites during vendor selection can help identify and avoid problematic vendors.

UNDERSTANDING THE 'WHY' BEHIND THE ASK

Most sponsors and CROs genuinely want sites to be compensated fairly. However, the challenge often lies in understanding **why** certain budget line items are being requested in the first place. Without context, these requests can seem excessive or arbitrary, especially when they deviate from standard templates or historical norms.

But for sites, these additions usually stem from **real operational needs**, needs driven by increased protocol complexity, technology burdens, regulatory requirements, and time-consuming administrative tasks that weren't present even a few years ago.

When this deeper context is missing, budget conversations can quickly become transactional

and sometimes contentious. This disconnect doesn't just delay negotiations—it fosters mistrust and contributes to the very inefficiencies all stakeholders are working to eliminate.

Take the example of funding for recruitment activities. Identifying and prescreening potential candidates for a clinical trial is an incredibly vital and highly skilled activity in clinical trials. However, in the budget, it's often represented as a small, token "chart review" fee. This doesn't come close to the hours of conversations that the investigators and staff will spend reviewing charts and speaking with candidates and their families or doctors.

SPONSOR INNOVATION: FUNDING RECRUITMENT PLANNING & EXECUTION

Budgets have start-up fees, pharmacy fees, but what about Recruitment fees. Fees aligned with establishing a study specific recruitment plan and funding associated with all aspects of execution. It may include hourly rates for both the CRC and investigator and potentially the use of site tech (i.e. AI protocol – EHR matching, AI pre-screening).

Understanding the **'why'** behind the ask isn't just about justifying a number - it's about building **a collaborative partnership** that supports trial quality, efficiency, and ultimately, better outcomes for patients.

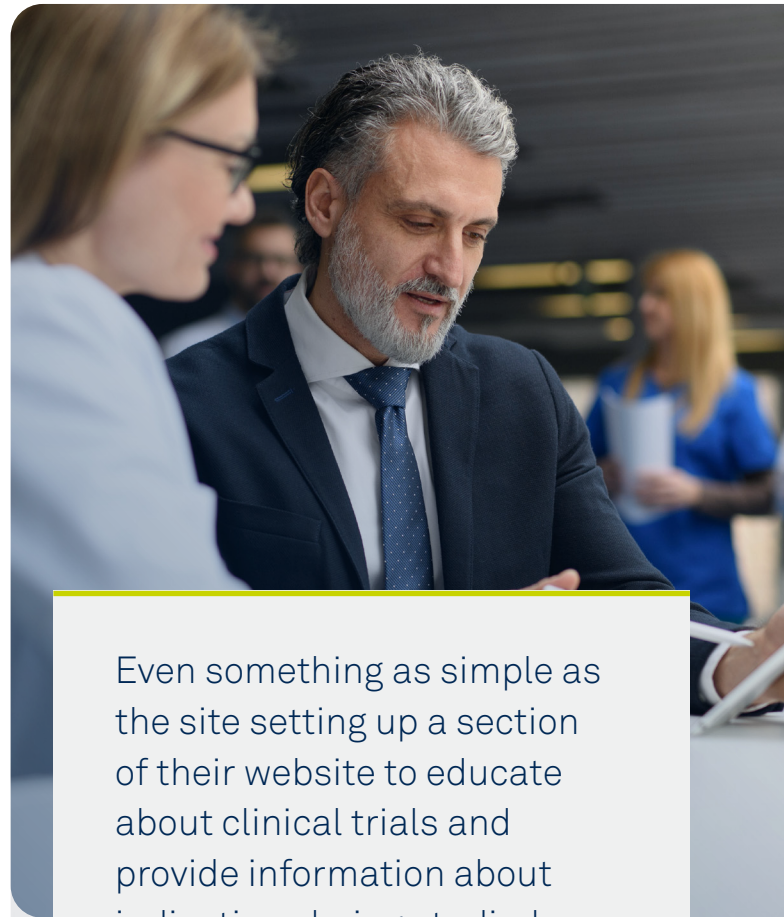
THE GREY AREA OF RECRUITMENT SUPPORT

A growing challenge for sites is securing funding for **broader recruitment initiatives**—efforts that extend beyond traditional, protocol-specific outreach. These include:

- Partnering with patient advocacy organizations
- Attending disease-specific community events
- Building relationships with local healthcare providers
- Engaging underrepresented or diverse populations through sustained outreach

These activities are not tied to a single study protocol, yet they are **essential to addressing the recruitment crisis** many trials are facing today. They build trust, raise awareness, and help ensure that clinical research is inclusive and accessible to the communities who need it most.

Unfortunately, these critical efforts often fall outside the boundaries of traditional study budgets, which typically cover only study-specific advertising or patient travel costs. As a result, sites are left to either absorb the cost or abandon the outreach—limiting the trial's reach and diversity.



Even something as simple as the site setting up a section of their website to educate about clinical trials and provide information about indications being studied can be a beneficial strategy. Costs for website design, content creation, and running general advertising to raise awareness is done at the site's expense.

SPONSOR INNOVATION: COMMUNITY OUTREACH

In addition to study specific local advertising, funding community outreach can be an important tool for educating about clinical trials and research activities in the local community.

This 'grey area' of recruitment funding needs to be brought into the light. Without meaningful support for these initiatives, we risk designing inclusive trials on paper, but not in practice.



WHERE DO WE GO FROM HERE?

This evolution in budgeting isn't just about numbers, it's about **respecting, understanding, and supporting the operational realities at clinical sites**. As the demands on sites continue to grow, so must our commitment to building more equitable and transparent partnerships.

To move the industry forward, several key steps can help strengthen collaboration and close the understanding gap:



Continue the Conversation

Ongoing, honest dialogue between sponsors, CROs, and sites is essential. These conversations must go beyond transactional negotiations and focus on long-term relationship-building.



Educate Both Sides

Sponsors need to understand the **true burden** of study conduct at the site level—while sites must be empowered and prepared to clearly articulate the **operational 'why'** behind budget requests.



Collaborate Transparently

A shared language and foundation of trust can transform budgeting from a point of friction into an opportunity for alignment, efficiency, and mutual respect.

Sponsors who understand site needs and how they review budgets can significantly reduce the burden and time required for a site to review and negotiate a budget. If the approach of the sponsor and site is one of partnership, significant advancements and time savings can be made.

SPONSOR INNOVATION: SIMPLICITY AND COLLABORATION

As the budget is prepared for sites, review from the lens of simplicity. Has everything been done to make the budget as simple as possible, as clear as possible and have strategies been employed that reduce site invoicing as much as possible? Most sites build a spreadsheet to evaluate the cost of procedures in a study. Some sponsors provide a spreadsheet as a tool for sites to save time and effort.

FINAL THOUGHTS

Clinical trials are evolving, and so are the demands placed on the sites that carry them out. To keep pace, **budgeting practices must evolve as well.**

By recognizing the need for new line items, supporting broader community engagement, and fostering open, ongoing communication between stakeholders, we have the opportunity to build a **more efficient, respectful, and sustainable clinical trial ecosystem.**

This isn't just about improving budgets. It's about creating the conditions for **stronger partnerships, faster startups, better recruitment, and ultimately better outcomes for patients.**

