Building a Better Clinical Trial Budget Model

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Clinical research is a dynamic industry built around continuous learning from the successes and failures of process and science. As the clinical research industry has responded to the COVID-19 pandemic, we have found new urgency in identifying and overcoming barriers to successful clinical trial execution. One business-driven success factor that routinely comes under scrutiny is clinical research budgets and the planning or flexibility in their performance for all involved parties.

There are endless webinars, white papers, training modules, vendors, consultants, and conferences all seeking to "improve" clinical trial budgets for clinical research sites. Nicholas Slack, WCG Clinical Executive Vice President and Chief Commercial Officer, recently shared that, on average, sites subsidize approximately 38% of their clinical research costs from other operations (Ramsey, 2020). According to SCRS's 2020 Landscape Survey, 53% of sites have three months or less of operating cash available. This number reflects a steady decline from 2018, when 64% of sites had three months of operating cash (SCRS Landscape Survey, 2020). This opens the question, if we have all of these resources to help sites improve their budgets, why are they continuing to struggle?

Let's get the obvious culprits out of the way: quarterly payment terms, hidden budget items, and holdbacks. The industry has done a great job of changing these traditional models, especially in response to the COVID-19 pandemic. Sites want monthly payments, no holdbacks, and transparency in regard to acknowledging expenses that are identified after the budget is executed. For example, expenses may be identified from a lab processing manual that is not available until the site initiation visit. At this point, a budget amendment may be needed, and sponsors and clinical research organizations (CROs) have come to accept that reality. These issues are not the primary problem.

The main issue causing financial strain in site budgets is the use of commercial grant databases that set the standard for fair market value for sponsors and CROs. Sites' clinical trial budgets are compared to these tools, but sites are unable to evaluate these tools for themselves. This is the system we need to fix, as it is inherently flawed. These databases fail to account for contexts where budgets are below market value, and therefore create standards that are not sustainable for sites. Some of these contexts include:

- New sites with “loss leader” budgets trying to get their foot in the door.
- Inexperienced sites that don’t have an adequate budget review process.
- Sites undercutting budgets for competitive advantage knowing they have philanthropic subsidies for sustainability.
- Academic medical centers that are extremely cautious about creating an income stream that will detract from their sense of mission.
- Investigators that see research more in terms of career fulfillment and less as part of their site’s bottom line.

Some additional contexts that are created by the industry itself are:

- Pressuring sites to open quickly and accept low budgets.
- Finalizing the contract before ancillary materials that are necessary to review the budget, such as the laboratory manual, are available.

An additional issue faced by hospital systems doing research is that cost sheets may change as often as quarterly. At present, there is no effective way to update study budgets to match these cost sheet changes. Sites’ best strategy is to estimate cost increases based on the anticipated length of the trial, knowing that budget amendments without a protocol amendment will likely not be a priority.

There are many other flaws in the current design process that are too specific to go into here. In short, we have a process that models budgets solely on patient activity, study startup and expenses that can be invoiced (excluding all the non-billable work). This may not be the best way to model the budget, but as an industry we haven’t developed anything better.

Sponsors and CROs then add a layer of complexity to the budget process by sending out low budgets that they expect to require negotiation. The pressures of COVID-19 research have revealed this practice to be a charade, as sites report budgets that seem to have come in at a higher rate that could more quickly be finalized. A common saying in the industry is that “sponsors will not balk at sites asking for up to 20% increase from the original budget they send.” Why play this game when time is of the essence for all stakeholders – most importantly our patients?

Sponsors do need a tool to justify expenses, demonstrate fair market value, and protect themselves from perceptions of conflicts of interest or any malicious activity that could risk the integrity of the research. However, we also need to recognize that grant databases gather data from sites with varying business savvy, education, agendas, and geographic cost to do business. When sites that do not understand their own costs accept sub-standard budgets or when they are in low-cost zones, their budgets go into the average of the data that all sites are held to (but cannot see).

It is clear that a working group composed of the great minds in the industry (and outside the industry) is needed to develop an alternative model that addresses not only the inaccuracy of commercialized grant databases, but also the flaws in current clinical trial budget models. Having an accurate tool for all key stakeholders to use should decrease wasted time in budget negotiations, protect all parties involved, and help keep clinical research sites from closing due to financial unsustainability.

REFERENCES:

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