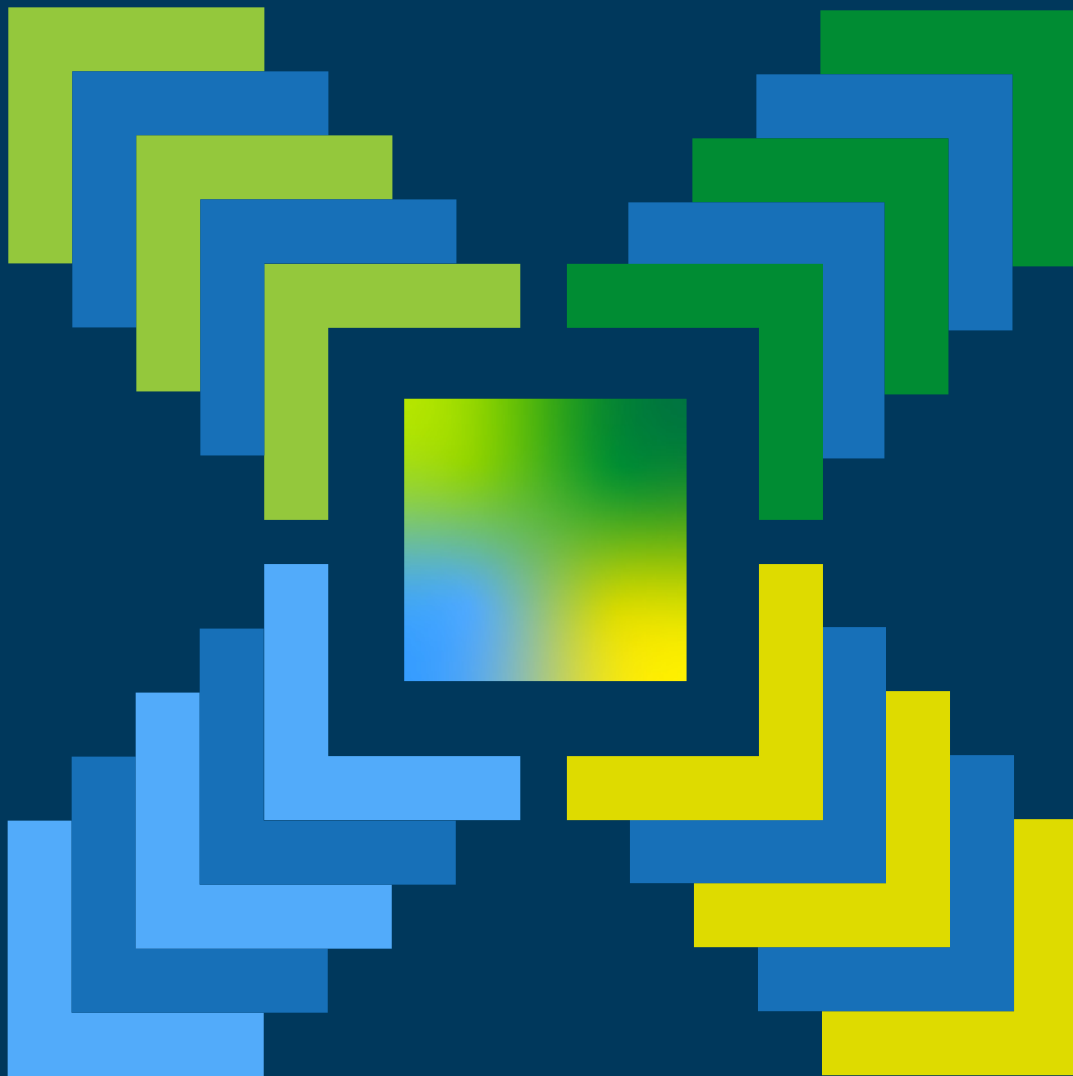


# Helping Clinical Research Sites Budget for Decentralized Trial Elements:

Ensuring Accurate and Adequate Compensation  
for Sites Implementing DCTs

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# HELPING CLINICAL RESEARCH SITES BUDGET FOR DECENTRALIZED TRIAL ELEMENTS:

## Ensuring Accurate and Adequate Compensation for Sites Implementing DCTs

### BACKGROUND

Decentralized clinical trials (DCTs) continue to be a focus of attention, whether as a way to improve clinical trial diversity or as a source of regulatory confusion. Driven by the COVID-19 pandemic, the number of trials worldwide that included a decentralized or virtual element increased by 50% from 2020 to 2021, and by a further 28% from 2021 to 2022.<sup>1,2</sup> Yet despite recent draft U.S. Food and Drug Administration (FDA) guidance on DCTs<sup>3</sup> stakeholder responsibilities (especially those of Principal Investigators [PIs]) remains unclear, and while decentralized study elements bring benefits for patients and enrollment diversity, they can be burdensome for sites.

As a result, there are challenges for facilities that already face staffing issues, rising protocol complexity, and longstanding cashflow challenges. Against this backdrop, site approaches to budgeting have remained unchanged for many years, reflecting primarily the tasks related to traditional trials at bricks-and-mortar sites, and based on a startup fee, a per-patient fee for all steps listed in the protocol, plus overheads. These site budgets typically fail to account for the time and cost involved in learning and implementing new systems, as well as in both traditional and newer remote study activities.

This paper examines recent work by the Association of Clinical Research Professionals (ACRP) and its members to build awareness of the need for a new

budget model for sites and to leverage the adoption of DCT elements to improve how sites are supported in their critical contribution to drug development. The authors describe how sites can be empowered to ask questions to clarify budgets, improve communication around budget negotiations, and be fairly compensated for implementing DCT elements in the studies and trials they lead.

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*“The development and negotiation of site budgets, including incorporation of DCT elements, is often viewed as a zero-sum game where one stakeholder’s gain is another’s loss—yet this does not have to be the case. This framework represents a starting point for alignment between site and sponsor on what components should be discussed when determining the scope of a DCT project and ultimately how to build more equitable site budgets.”*

**JOHN CAMPBELL**  
Head of Decentralized Trials, Walgreen Co.

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## Barriers to DCT Success: Regulatory Clarity and Budgets

An ACRP think tank in October 2022 identified the two leading barriers to DCT success as the need for regulatory clarity, including for PI oversight, and the existence of budgetary issues. Entitled, “From Trepidation to Trust: Documenting the Realities of Hybrid and Decentralized Clinical Trials Adoption,” the think tank included 42 participants from multiple clinical trial stakeholder groups, including sites, contract research organizations (CROs), academic research organizations, healthcare providers, pharmaceutical companies, and regulators.<sup>4</sup>

These barriers were in line with themes identified by a 2022 ACRP site survey, such as the fact that DCT technology use lags behind other trial technologies, with fewer than half of sites saying they have clinical trials that use DCT components/services; sites that use DCT elements spend more time on trial delivery activities than sites that do not; and sites often lack the training and budget necessary to implement DCTs effectively.<sup>5</sup> The survey was fielded online from August 24 to September 14, 2022, and the analysis was based on responses from 291 clinical research professionals employed in a broad range of roles at clinical sites.<sup>5</sup>

To help address the leading challenge identified by the think tank—the need for regulatory clarity—ACRP submitted comments to the FDA on the May 2023 Draft Guidance on Decentralized Clinical Trials.<sup>6</sup> ACRP asked the FDA for clarity on regulatory expectations for who among sponsors, investigators, and vendors will be held responsible for various aspects of DCTs.<sup>7</sup> The draft guidance was also the subject of an ACRP blog, highlighting questions about PI oversight of participant safety, protocols, and data handling.<sup>8</sup>

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*“From my experience in both the CRO and site space, sites struggle with budgets, regardless of the design of the trial. Considering the complexities of DCTs, this tool will help all sites to be able to have a level playing field when negotiating their budget needs without overlooking the nuances of a DCT.”*

**MELISSA HOLBROOK**  
Executive Vice President, Velocity  
Clinical Research

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## ACRP New Budget Model Working Group Goals and Achievements

In response to the second challenge—budgetary issues—ACRP established a New Budget Model (for industry-funded trials) Working Group. This was a first step to highlight that sites need to be accurately compensated for the extra efforts required to implement decentralized study components and to provide a resource for ensuring success. Decentralized elements add activities and responsibilities to study implementation, a cost in terms of both time and effort that is being absorbed by sites and not accounted for in their budgets. As examples, DCT-related activities can include:

- **Onboarding and managing third-party vendors,** including home health companies and pop-up trial sites

- **Training and management of multiple pre-determined technology platforms**, all with varying automated functionality and in addition to electronic data capture and electronic trial master file (eTMF) already required in trials
- **Provisioning digital health devices** to participants where required by the study protocol
- **Serving as the technology training and support team** for study participants in “bring your own device” (BYOD) studies
- **Managing payments** to study participants, either directly or through a patient concierge vendor
- **Coordinating direct-to-patient shipment logistics**, which is becoming more common and allows IP or devices to be shipped directly to patient homes

Some DCT elements, such as new technology training, should involve a ‘time and effort’ calculation. This

budgeting method is not applied universally when calculating the true cost of sites’ study management efforts, and is often assumed to be covered by the startup fee or overheads. The fact is that overhead budgets provided to sites are not built with transparency and are not based on true costs. They serve as a type of budget catch-all, a historical problem further exposed by the onset of adoption of decentralized elements.

There remain differences of opinion on what should be included in overheads—with some institutions including rent, lighting, and equipment costs, while others also include staff time to attend PI meetings. Each institution has its own definition, yet it would be helpful to align transparently with exactly what is covered within overheads. Another approach might be to move away from the concept of overheads and establish fees for facilities, staff time, and other items as directly invoiceable costs. Trials that are fully decentralized, with no bricks-and-mortar site, often do not have overheads, with payment for actual costs being covered via direct fees of this kind.

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*“Aligning site responsibilities with site budgets is long overdue, even in trials without DCT components. When you change the trial design to a decentralized format, facility overhead fees may not apply and certainly do not cover the new responsibilities at the site level. Sponsors have the benefits of DCTs providing more diverse populations and increasing the number of patients willing to participate; however, they must also account for the logistics, training, vendor onboarding and data integration activities that fall on the shoulders of the sites. Discussing these ‘grey areas’ or new responsibilities will be critical to protecting the study conduct quality and to ensuring site budgets are reflective of the work being performed.”*

**CAROLINE REDEKER**  
Senior Vice President, Corporate Development, Advanced Clinical

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Among other challenges is the fact that benchmarking tools used by sponsors for site budgeting are based on historical budgets, usually over the past five years, which did not account for decentralized elements. Utilizing the same format when the industry is changing the way research is managed is not sustainable. One option would be to use the benchmark only for protocol visit fees and procedures, which will not change in DCTs, and to add elements to account for the extra work now required outside the site. This will result in a budget that is truly reflective of the time and effort required from the site.

## Steps Toward a New Budgetary Approach

The New Budget Model Working Group aimed to leverage the adoption of DCTs to update and upgrade clinical research budget models for sites' benefit, specifically addressing the issues described above. As a first step, the group set out to develop a resource of considerations for site leaders to review as part of their feasibility assessments and budget negotiations. This new resource — [ACRP's DCT Budget Buddy™](#) — comprises a series of questions for sites to consider under each major topic. The resource identifies considerations to determine needs rather than indicating specific monetary values. This is intended to be used during planning stages to ensure that sites are asking and answering important questions that set them up for accurate and adequate compensation. The resource also allows sites to evaluate their role in managing and monitoring technology platforms and software to ensure that training, time, and efforts are sufficiently represented in the site budget. The [ACRP DCT Budget Buddy™](#) is organized by areas that reflect the most change ushered in with DCT components, including:

- **Planning:** This component ensures that the site asks and answers important overarching questions that plan for appropriate and adequate compensation for decentralized components. Key elements are: *decentralized component identification*, including which stakeholder is responsible for each component, and clarity on PI involvement; *staff resourcing*, with an evaluation of the need for more or different staff, or more time from existing staff; *communication pathways*, with clear definition of ownership of each decentralized component by the site, CRO, sponsor, or vendor; *vendor identification and roles*, including the site role in onboarding of vendors; *facilities*, with assessment of any changes needed and associated costs; and *baseline participant alignment* with any decentralized elements.

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*“Many sites struggle with basic budget development. Sites tend to underbudget for all types of trials—not just those involving decentralized elements. As a result, DCTs are layering onto an already-imperfect system. Sponsors should be responsible for the additional time and effort involved in decentralized elements, plus the costs of any additional supplies needed to treat the participant at home rather than in a clinic setting.”*

**MARY VEAZIE**  
Clinical Research Consulting & Education  
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- **Technology:** Since DCTs and hybrid trials depend on technology to collect and monitor data remotely, the site should carefully evaluate its role. This will help ensure that training, time, and effort are accurately represented in the site budget. Key areas include: *technology platforms* (how many, whether these are single sign-on [SSO] enabled, whether the site has worked with each vendor, and how many vendors are involved); *site technology needs*, including any digital tools and whether these will be provided or will require investment; extent of *site support* required for patient technology help desks, and whether the site is involved in device provisioning; whether patients are allowed to *use their own digital device*, and whether the site will be expected to provide training; and site familiarity with any electronic clinical outcome assessment (eCOA), electronic patient-reported outcome (ePRO), or electronic data capture (EDC) required.
- **Patient engagement and management:** This includes general elements such as the locations of potential study participants, and implications at the site level for managing patient communication, engagement, and study implementation. Based on inclusion/exclusion criteria, there may be special considerations for patient engagement, and an online screening tool may be required through the site or a vendor. Sites are often requested to work with appointment scheduling modules, telehealth platforms, and other forms of communication with the patient. Payments are another element, including whether the site will handle these or handle logistics working with a patient concierge.
- **Patient-focused technology:** Considerations here include whether the decentralized components require other groups to manage patients in the study (e.g., patient concierge, patient recruitment support, patient payment vendor). In cases where training and support will be needed, the roles and responsibilities of the various stakeholders should be clarified.
- **Data management and quality control:** This category includes consideration of whether the site budget currently covers the costs of data management activities, and whether sufficient specialized site staff are available. This can include study information from uploading eISF information into platforms to special requirements around patient/study data.
- **Clinical monitoring and site management:** Elements of this category include remote site monitoring, including support for information technology (IT)/internet/systems and whether the study calls for integration into the electronic medical record (EMR); any requirement for home health visits, whether a vendor will be used, and whether the site will manage the vendor; and any need for pop-up/mobile visits based on the location of potential study participants, and whether a vendor will be involved. More and more sites are being requested to upload or integrate data to reduce sponsor/CRO travel costs; however, this causes more work to be done at the site level.
- **Regulatory compliance:** Clinical research sites are well aware of the regulatory compliance activities that must be accounted for in support of trials and studies. Yet, certain decentralized elements may need additional support, such as assessing requirements for site locations for study conduct, potential responsibility for ensuring vendor qualifications, and additional time and effort to support PIs and Sub-Investigators. When sponsors choose third party vendors to perform activities that would otherwise be performed by site staff, this adds a level of oversight and training responsibilities to the site while increasing their risk as the ultimate responsible party to oversee the care of the patient.

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*“DCTs have exposed that today’s site budgets need a significant overhaul; it’s a real pain point for sites which serve as the implementation engine for clinical research. In the interim, sponsors, contract research organizations, and sites must work together to adapt existing budget models to ensure that sites are compensated for the breadth of work associated with managing DCT elements.”*

**CATHERINE GREGOR**  
Chief Clinical Trial Officer, Florence Healthcare

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## CONCLUSION

The ACRP New Budget Model Working Group brought together a diverse group from various types of sites (private practice, academic, networks, and mobile sites), CROs, and sponsors, enabling varied perspectives to be included. This unique effort was part of ACRP’s mission to promote excellence in clinical research, with the vision that clinical research is performed ethically, responsibly, and professionally everywhere in the world.

The working group successfully developed the [ACRP DCT Budget Buddy™](#) to support sites’ budgeting processes and to empower sites to facilitate budget discussions between themselves and sponsors. Gaps in understanding roles and responsibilities

between DCT providers, sites and patients create opportunity for quality issues or risk to data integrity. Eliminating these gaps clearly benefits sponsors as well as sites. This approach aligns site and sponsor interests by clearly identifying project scope early in the process of asking and rationalizing requests for compensation related to services in support of DCT study implementation and management.

The resource has potential to support more transparent decisions on scope of services and budget—and lead to a healthier clinical trials ecosystem.

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