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Power of Partnership

SITE SPOTLIGHT

Why Site and Patient-Centric Design is the Future of Clinical Trials

POP VOICE

Mastering Investigator Grant Budgets: Cutting-Edge Strategies for Decentralized Clinical Trials

POP IMPACT

One Connected Experience. Countless Human Moments.

ISSUE 17

POP is devoted to providing transparent and collaborative study experience news

MEDIDATA

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Why the Industry Needs Medidata's Study Experience

THE GROWING CHALLENGES IN CLINICAL TRIALS: COMPLEXITY, DELAYS, AND FINANCIAL CONSEQUENCES

Clinical trials are the bedrock of medical innovation, enabling the evaluation and approval of new treatments that can transform lives. But over the years, the clinical trial landscape has shifted dramatically. What was once a primarily scientific endeavor has become an increasingly complex operational and logistical challenge.

As trial designs grow more intricate and globalized, the industry is grappling with a host of issues, from frequent protocol amendments and recruitment delays to ballooning costs and missed deadlines. These factors are straining resources and timelines, threatening not only the speed of drug development but also the financial viability of research programs.

Amid these rising challenges, the need for a unified, intelligent, and patient-centric solution has never been more urgent. Enter **Medidata's Study Experience**: an experience purpose-built to solve the inefficiencies plaguing today's clinical trials.

INCREASING TRIAL COMPLEXITY: MORE AMENDMENTS, MORE SITES

One of the most striking developments in recent clinical trial trends is the dramatic increase in trial complexity. Data shows that trials now undergo **60% more protocol amendments** than before. Each amendment, while sometimes necessary for scientific or regulatory reasons, adds layers of complexity, affecting trial timelines, regulatory submissions, data consistency, and patient recruitment.

In addition, the average trial today involves **100% more clinical sites** than a decade ago. While expanding the number of sites may seem like a strategy to increase participant recruitment or diversify the trial population, it also brings heightened logistical demands: coordinating across multiple regions, managing more vendors, training more site staff, and ensuring compliance across geographically dispersed teams.

OPERATIONAL COMPLEXITY: MISSED TARGETS AND DELAYS

This rising complexity isn't just theoretical, it has real-world consequences. A staggering **80% of clinical trials now miss their enrollment targets**, reflecting the increasing difficulty in recruiting and retaining qualified participants. Slow or insufficient enrollment is one of the primary drivers of delays in clinical research.

These delays are not short-lived either. On average, trials are now running **12 months behind schedule**. Whether due to regulatory bottlenecks, recruitment issues, or protocol amendments, this delay has cascading effects on all stakeholders, from patients waiting for novel therapies to investors backing biotech innovations.

FINANCIAL IMPACT: $500,000 PER DAY LOST

Perhaps the most alarming aspect of this trend is the financial cost of delays. Every day a clinical trial is delayed can cost sponsors an average of **$500,000** in lost revenue and increased operational expenses. This daily burn includes everything from continued site management costs to extended use of monitoring, data collection, and trial oversight systems.

Over a 12-month delay, that can translate to over **$180 million in financial impact for a single trial**, a cost that many smaller biotech firms cannot afford and that even large pharmaceutical companies are increasingly scrutinizing.

THE WAY FORWARD: ADDRESSING THE COMPLEXITY WITH MEDIDATA STUDY EXPERIENCE

To reverse these trends, the industry must adopt **smarter**, **more connected solutions** that are purpose-built for modern clinical trial demands. This is precisely where **Medidata Study Experience** makes a difference. With an ecosystem that brings together design, planning, execution, and oversight, Medidata allows sponsors to **regain control over complexity**, **timelines**, and **budgets**, without compromising scientific rigor or patient experience.

FINAL THOUGHTS

The clinical trial industry is facing a critical inflection point. While the ambition to develop more targeted, personalized, and global therapies is commendable, the current trajectory of increasing trial complexity is unsustainable. With **60% more amendments**, **double the number of sites**, **80% enrollment misses**, and **12-month delays**, the operational and financial consequences are mounting to the tune of **$500,000 per day**. To move forward, innovation in trial design and execution must match the pace of scientific discovery, or the entire drug development ecosystem risks becoming economically untenable.

For more information on **Study Experience**.

Why Site and Patient-Centric Design is the Future of Clinical Trials

By **Robin Douglas**

The clinical trial landscape is advancing rapidly, but this progress brings unprecedented complexity. Currently, 70% of site staff report that trials have become more difficult to manage over the past five years, and 60% are burdened by logging into more than 20 different systems daily. For sponsors and pharma companies, these site-level bottlenecks directly threaten study timelines and success. Fragmented technologies cause duplicated data entry, inconsistent patient experiences, and extra training requirements. Ultimately, this friction compounds a much larger issue: 80% of all clinical trials fail to meet their patient enrollment targets.

To overcome these hurdles, sponsors must shift their approach to site and patient-centric protocol and product design.

THE VALUE OF CO-CREATION AND INSIGHTS

By embedding the voices of clinical operational leaders and patients directly into the protocol or technology design process, sponsors can create solutions that reflect the practical, real-world needs of research professionals. Partnering with advisory boards, like Medidata's **Site Insights Program** and **Patient Insights Board** to co-design your study and its technology solutions offers massive strategic value for sponsors and CROs:

Accelerated Recruitment and Trial Adherence
Designing tools with direct patient input radically improves the patient experience. For instance, collaborating with patient advocates to design simplified patient payment options can exponentially improve patient satisfaction and lead to quicker trial accruals and greater adherence.

Reduced Site Burden and Faster Data Entry
Integrating site insights into product development eliminates the operational inefficiencies that delay trial execution. Unifying disparate systems into a single interface significantly reduces the number of daily logins required of site staff. Additionally, building deeply interoperable systems—such as technology that securely pulls electronic health record (EHR) data directly into data capture systems—can accelerate form completion by up to 90% and dramatically reduce transcription errors.

Financial Health and Transparency

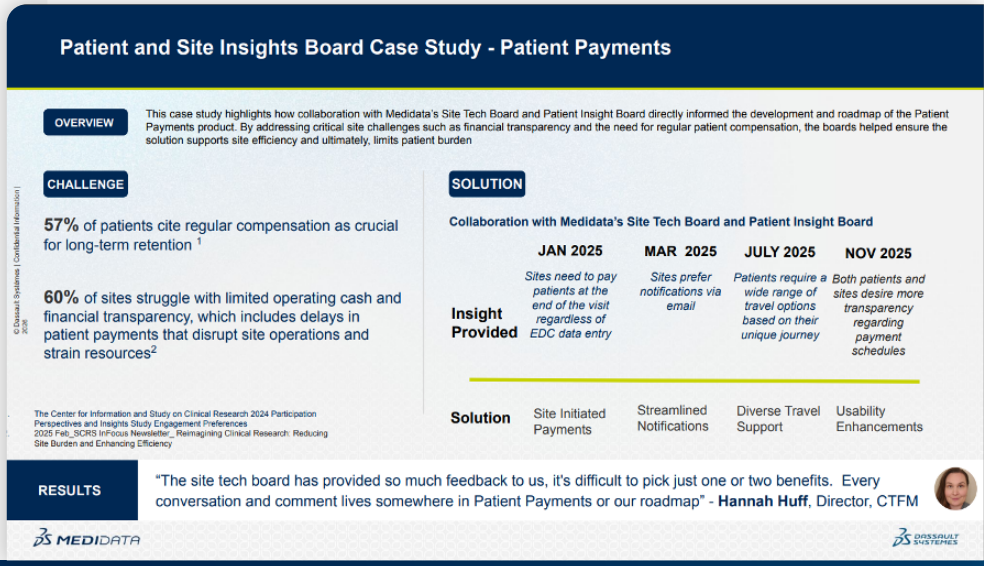
The most significant benefit to sponsors of paying on time is the uninterrupted continuation of their research, as sites can focus on recruitment and retention vs keeping the lights on. Furthermore, utilizing clinical trial financial management (CTFM) systems to ensure on-time payments reduces the heavy administrative and financial management burden for all parties involved, including the sponsors, CROs, and the sites. By streamlining automated approval processes and eliminating payment delays, sponsors allow site staff to redirect their focus and resources toward what matters most: efficient trial management and superior patient care.

Stronger Technology Adoption and Compliance

Technologies that actively address site pain points naturally drive stronger adoption, higher compliance, and superior overall performance.

Here is an example of site and patient centric design where feedback directly from sites and patients transformed outcomes.

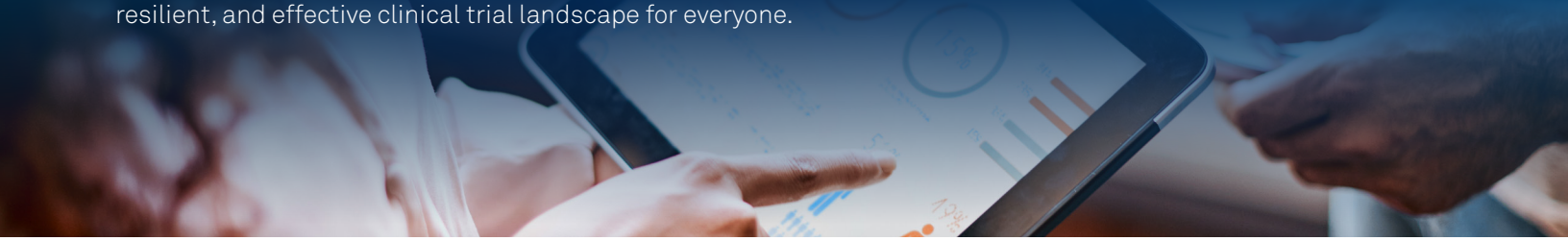
Medidata's Patient Payment's team met with both our Site Tech Board and our Patient Insights Board multiple times while designing our current solution. Feedback directly from sites and patients helped to optimize the product and provide the transparency both sites and patients want.



LOOKING AHEAD: THE EXPERIENCE PARADIGM

To drive faster, higher-quality outcomes, the industry must transition from merely providing technology products to delivering a cohesive, unified experience. By deeply embedding site and patient centricity into protocol optimization, study start-up, trial execution, and financial management, sponsors can dramatically reduce operational friction.

Moving forward, site and patient-centricity must be the foundation of our strategy. By co-creating with those who conduct and participate in trials, we don't just solve current operational challenges—we build a more sustainable, resilient, and effective clinical trial landscape for everyone.



One Connected Experience. Countless Human Moments.

By Tina Mincher

A clinical trial is often described in timelines, data points, and milestones. But for the people living it, it's something else entirely.

It's a **patient** searching for one more option.

A **family** holding onto hope.

A **physician** trying to make the right call with limited time.

A **nurse** offering reassurance in uncertain moments.

A **study coordinator** keeping everything together behind the scenes.

A **sponsor** carrying the responsibility to deliver something that could change lives.

This is where **Medidata's Study Experience** truly makes a difference.

By unifying design, planning, build, execution, finance, and closeout into one connected environment, it brings clarity where there was once fragmentation. Clinical, operational, and financial data work together from day one, so decisions are not delayed, and neither is progress.

And that matters.

Because when predictability improves, outcomes change. Risks are surfaced earlier before they become setbacks. Enrollment delays, budget pressures, quality concerns are seen, understood, and addressed in time. For the patient, that can mean getting access to a trial sooner. For their family, it means less waiting in the unknown.

When financial oversight is stronger, trials don't stall. Payments reach sites on time. Resources are where they need to be. The study coordinator isn't chasing discrepancies; they're supporting the study. The sponsor isn't reacting; they're leading with confidence. And the physician and nurse can focus less on process, more on people.

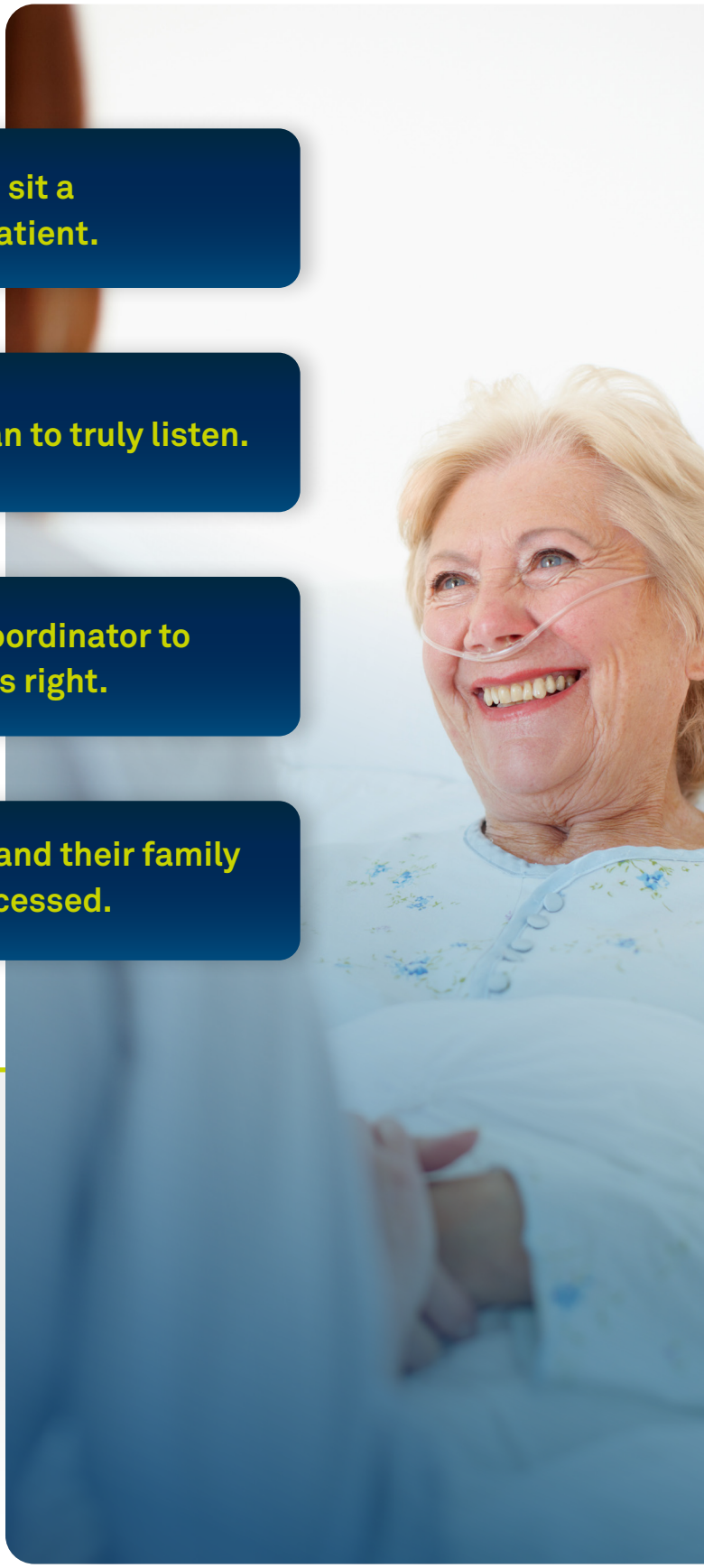
When operational complexity is reduced, something powerful happens: time is given back.

Time for the **nurse to sit a little longer with a patient.**

Time for the **physician to truly listen.**

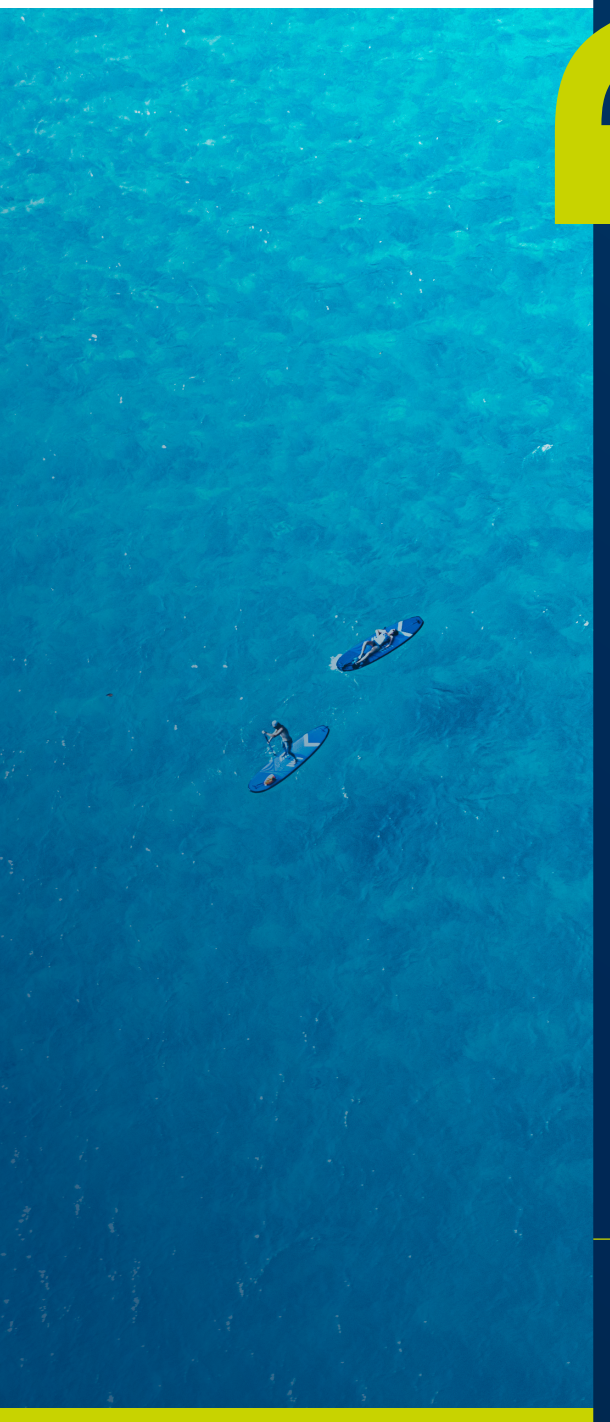
Time for the **study coordinator to ensure every detail is right.**

Time for the **patient and their family to feel seen, not processed.**



By connecting systems, aligning data, and embedding intelligence across the trial lifecycle, the Medidata Study Experience doesn't just make trials more efficient, it makes them more human. Because every improvement, every moment saved, every risk avoided echoes far beyond the system. It reaches the people who need it most.

And in those moments quiet, personal, and profound that's **where real change begins**.



Individually, we are one drop. **Together, we are an ocean.**

Ryunosuke Satoro

Mastering Investigator Grant Budgets: Cutting-Edge Strategies for Decentralized Clinical Trials

By Shelley Douros

INTRODUCTION

In the rapidly evolving clinical research landscape, decentralized trials (DCTs) have become a common and transformative approach, offering significant flexibility and accessibility. However, with this model now established, unique challenges persist, particularly in budgeting for investigator grants. Traditional budgeting models, designed for centralized trials, often fail to address the complexities and nuances of DCTs. The industry must be equipped with the necessary knowledge and technology to ensure smooth and effective budget-building, resulting in positive outcomes for all parties involved.

While the DCT model can optimize certain expenses, it is a misconception that they are always a cost-saving measure. In fact, they often introduce new financial complexities that require careful management. A significant technological investment is needed for remote data collection and patient monitoring, and enhanced patient support services like home healthcare visits add direct expenses. Furthermore, navigating diverse regional regulations can increase administrative costs. Therefore, a proactive and detailed budgeting strategy is essential to manage these unique financial demands effectively.

Medidata Clinical Trial Financial Management has been collaborating with our clients to better understand the financial needs surrounding DCTs. Through our Power of Partnership program and Innovation Labs, we have delved deep into the DCT landscape to identify specific needs and differences. We've explored cutting-edge methodologies to provide a comprehensive guide for optimizing financial management for DCTs.

BURDEN AND VARIABILITY

Decentralized trials often involve a greater number of sites, including remote and home-based settings. This variability in site types and locations adds complexity to budgeting, as investigator grant budgets must account for diverse operational costs and logistical challenges.

With Grants Manager, clients gain insights into site and patient burden scores, which are automatically calculated within the dashboard as you build your budget. These scores help streamline the budgeting process, particularly for decentralized trials, by clearly illustrating the burden and workload involved. This ensures accurate and informed budgeting decisions, effectively accommodating decentralized trial operations' unique challenges and costs.

TECHNOLOGY AND INFRASTRUCTURE

Decentralized trials typically require a significant technological investment to facilitate remote data collection, telehealth visits, and patient monitoring. This includes devices, software, training, and support costs, which must be incorporated into the grant budgets.

With Grants Manager Fair Market Value, clients can accurately determine costs for data collection, site management, telehealth visits, and all personnel time associated with decentralized trials.

PATIENT ENGAGEMENT AND RECRUITMENT

Decentralized trial recruitment and retention strategies often involve more extensive outreach efforts and enhanced patient support services, such as travel reimbursements, home healthcare visits, and direct-to-patient shipments. These initiatives are designed to make participation more convenient and accessible for patients, regardless of location. For example, travel reimbursements and home healthcare visits incur direct expenses, while implementing advanced technologies like wearable devices and telehealth platforms requires significant investment. These additional efforts and services come with increased costs that must be carefully factored into the budget.

However, it is important to recognize that not all patients may find the decentralized model more convenient. Factors such as a lack of technological familiarity, the responsibility of managing at-home medical devices, or a personal preference for in-person interaction with healthcare providers can be potential barriers. This makes budgeting for robust patient support services and training even more critical to ensure the trial is truly accessible and minimizes patient burden.

These direct-to-patient costs, especially travel reimbursements, can create a significant administrative burden for sites and patients, which must also be factored into the budget. A dedicated solution, such as Medidata's Patient Payments app, automates and streamlines this process, ensuring patients are compensated quickly while reducing the operational workload on clinical staff.

With all of these factors in mind, Grants Manager FMV allows clients to account for all patient engagement, travel, and recruitment costs, from chart reviews to shipping expenses and everything in between. By leveraging Medidata's Anticipated FMV in Grants Manager, clients can accurately budget for data collection, management, telehealth visits, and personnel time.

REGULATORY AND COMPLIANCE

Compliance with diverse regional regulations regarding remote data collection, telemedicine, and patient privacy can increase administrative costs in decentralized trials. Ensuring all investigators adhere to these regulations requires additional resources, which can increase budgets and add to operational needs. For example, different regions have unique regulatory requirements for DCTs, and understanding these variations in local laws is a necessity.

Navigating this complex environment is precisely where our Global Compliance & Strategy (GCS) and Patient Cloud teams provide critical support. Our GCS experts offer proactive guidance on the global regulatory landscape, helping you anticipate and plan for regional variations. In parallel, our Patient Cloud team configures the technology platform to align with specific local requirements for electronic consent, data privacy, and telemedicine, thereby reducing the administrative burden and ensuring compliance is built directly into your trial's workflow.

Finally, our Grants Manager platform helps you accurately budget for these activities. It provides a clear financial picture by incorporating regional regulatory requirements into automated cost calculations and tracking them in detail. By leveraging compliance cost benchmarking and calculating FMV for necessary resources, Grants Manager ensures you can confidently determine and incorporate all costs associated with a compliant decentralized trial.

WORKLOAD AND COMPENSATION

Decentralized trials often require Investigators to manage a broader range of activities, including coordinating with remote monitoring teams, ensuring data integrity from various sources, and maintaining patient engagement remotely. This can lead to increased compensation and the need for additional support staff.

With Grants Manager's dynamic benchmarking and the expansive personnel library, clients can utilize Anticipated FMV to create budgets that reflect current and fair costs tailored to the specific trial design. Anticipated FMV evaluates all necessary factors and resources for a successful clinical trial investigator grant budget, identifying the most critical and efficient elements. This approach analyzes data from committed and historically executed site contracts, third-party data sources, country ratios, exchange rates, inflation, and statistical models to generate accurate and up-to-date benchmarks. Having accessible anticipated costs is crucial for ensuring a defendable and equitable budget.

TRAINING & SUPPORT

Decentralized trials present unique challenges that require additional training and support costs for clinical staff and patients. For example, DCTs involve extensive outreach efforts and enhanced patient support services. Additionally, managing multiple remote sites can be challenging, making comprehensive training essential to reducing the likelihood of errors and inefficiencies.

With Grants Manager's dynamic benchmarking, clients can access anticipated benchmarks to understand future FMV, allowing for better financial scenario planning. This feature helps anticipate and mitigate financial risks associated with compliance and training in decentralized trials. Because of Grants Manager's groundbreaking benchmarking, clients receive a clear and detailed breakdown of

all costs and access to costs for all activities, even newly created ones. This forward-thinking process ensures financial transparency, facilitates better decision-making, and helps stakeholders understand the financial implications of additional training and support in decentralized trials.

DATA MANAGEMENT AND MONITORING

Decentralized trials often require integrating and managing data from multiple sources, such as wearable devices, telehealth platforms, and home visits. This warrants robust data management systems and real-time monitoring solutions. Accurately budgeting for these advanced data-handling capabilities is crucial to ensure decentralized trials' smooth and efficient operation.

Grants Manager facilitates managing data management costs and monitoring in decentralized trials through several key functionalities: budgeting accuracy, dynamic benchmarking, streamlined workflows, and data management and compliance benchmarking. With access to these functionalities, Grants Manager empowers clients to manage the complex data management and monitoring costs in decentralized trials, ensuring financial oversight and operational success.

CONCLUSION

Budgeting for investigator grants in decentralized trials requires a more flexible and comprehensive approach to accommodate the unique challenges and additional operational costs. While traditional trial budgets benefit from more standardized and predictable expense categories, DCTs require a more nuanced strategy. This includes accounting for advanced data management systems, real-time monitoring solutions, extensive patient support services, and compliance with diverse regional regulations. Medidata's Grants Manager provides the functionalities and benchmarks needed to navigate these complexities, offering accurate budgeting, streamlined workflows, and dynamic benchmarking capabilities. By leveraging Grants Manager, clients can create realistic and defendable budgets that facilitate better decision-making, ensure financial transparency, and support the success of decentralized trials.

MASTERING DCT BUDGETS

THE CHALLENGE	THE MEDIDATA SOLUTION
Site Variability & Burden	Integrated Platform
Patient Payments & Engagement	Automated Payment Processing
Technology & Data Costs	Unified Technology & Data Management
Regulatory Compliance	Compliance & Regulatory Support
Fair Compensation	Streamlined Compensation Management

Spring Budget InnoLabs

The Spring Budget InnoLab brought together product teams and industry stakeholders to focus on modernizing clinical trial financial management. The goal is to replace manual, time-consuming processes with an AI-driven workflow that connects budgeting, contracting, and payments. Broader challenges discussed included inflation, hidden costs, gaps in budget coverage, and applying fair market value (FMV).

KEY FEEDBACK & PAIN POINTS

Heavy reliance on manual work, including data entry, cost comparisons, and updating amendments

Difficulty maintaining consistency across budgets, contracts, and legal documents (e.g., aligning consent forms with budget items)

Complex coordination across sponsors, CROs, and sites with separate workflows

CONTRACTING NEEDS

Clear visibility of changes and negotiation history

Built-in FMV benchmarks within the workflow

Access to historical pricing data for better decision-making

WHAT'S NEXT

Prototype testing available asynchronously

Regular updates and quarterly roadmap integration to improve communication

Continued user feedback encouraged through surveys

Spring Site Payments InnoLabs

The session focused on designing a next-generation site payments platform to replace legacy systems and better support increasingly complex clinical trial financial workflows. The goal is a flexible, end-to-end solution connecting the full payments lifecycle.

KEY FEEDBACK & PAIN POINTS

Modernization Needed
Current tools create inefficiencies and don't reflect today's operational complexity

End-to-End Vision
Strong demand for a unified platform that reduces fragmentation across payment processes

User-Driven Design
Feedback is being gathered through structured methods to co-create solutions with users

Experience Gaps

- Preference for **interactive prototypes** over static screenshots
- Need for **real-time dashboards** to improve payment visibility
- Interest in **CTMS integration** to automate triggers like site initiation payments

Timeline

- **Early 2027**: Early adopter phase
- **Late 2027**: Global rollout

WHAT'S NEXT

- Share **follow-up questions** to **gather deeper input** on payment workflows and invoicing
- Introduce **interactive prototypes** in future sessions
- Include additional longer, **deep-dive workshops**

SCRS INFOCUS ARTICLE

Behind the Budget: What Sites Really Need to Know Today | Society for Clinical Research Sites