

POP



Power of Partnership

SITE SPOTLIGHT

Embedding the Site Voice into
Trial Execution Collaboration

POP VOICE

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

POP IMPACT

The Seasonal
Nature of the Client
Journey in Business



ISSUE 16

POP is devoted to providing transparent and collaborative clinical trial financial management news



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HAVE YOU HEARD

The Global Costing Task Force (GCTF)

Embedding the Site Voice into Trial Execution

Sites drive execution. Your technology should reflect that.

Sites carry the operational burden of clinical trials. When systems require duplicate entry, multiple logins, or manual reconciliation, execution slows and frustration rises.

Reducing site burden isn't optional. It directly affects data quality, timelines, and patient experience.

From Site Feedback to Product Design

Sites don't need more tools. They need systems that reflect their workflows.

Through its Site Voice partnership with the Society for Clinical Research Sites (SCRS), Medidata gathers structured site feedback through research projects, advocacy groups, and workshops. R&D teams incorporate that feedback directly into product roadmaps so solutions evolve with real operational demands.




Site insight shapes design decisions.



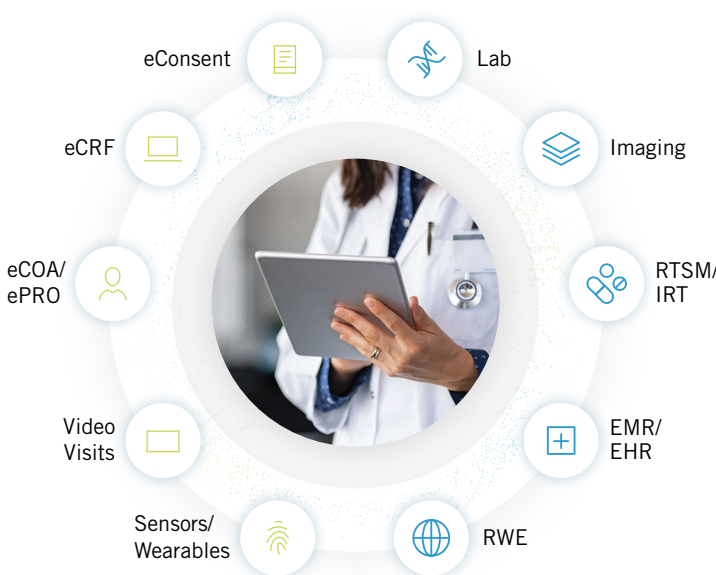
Proven at Scale

With over 715,000 site users and growing, Medidata Rave EDC is the most widely used electronic data capture solution in clinical research.

Sites describe Rave EDC as intuitive, faster than competing systems, easy to access, and aligned with daily tasks. Site personnel complete eLearning modules once across multiple trials, reducing repeat training and saving time.

-  "Of the 30+ studies I work on, over 20 are on Rave. It's by far the most user-friendly."
-  "Faster and easier than other EDCs"
-  "One login for multiple trials"

Where Site Alignment Becomes Operational Impact



One Environment, Not Multiple Workarounds

Sites access multiple trials through a single sign-on in Rave EDC, streamlining data entry and review across studies.

As part of the Medidata Platform, data from eConsent, eCOA, Imaging, RTSM (randomization and trial supply management), and eTMF (electronic trial master file) is available within the same environment. Working in one location reduces system switching and administrative effort.

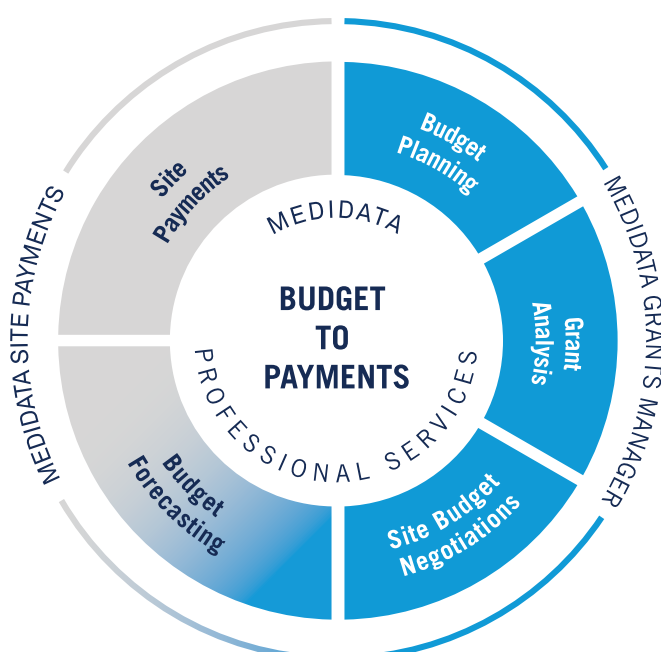
As trials expand into hybrid and decentralized models, remotely collected patient data, including eConsent, eCOA, and sensor data, is available alongside eCRF data at the site, supporting oversight without added complexity.

Transparent Financial Workflows Support Site Stability

Budget negotiations and site payments demand transparency.

Medidata Grants Manager provides site-specific budget benchmarks to support objective negotiation starting points.

Medidata Site Payments triggers payments based on work completed in EDC, improving payment accuracy and timeliness while giving sites visibility into cash flow.



Documentation and Support That Hold Up under Pressure

Medidata eTMF and Site Cloud: End of Study support structured electronic documentation from study start through closeout.

24-hour multilingual Help Desk support, along with the Success Center in iMedidata and the Medidata Knowledge Space, provide ongoing access to assistance.

Enhanced Technical Account Management services provide device and app reporting, proactive update outreach, and identification of critical issues or low compliance sites or patients. Average technical support turnaround time is 4.0 days, with site satisfaction at 94.9%.



Site Insights Are Built into the System

Sites aren't downstream users of sponsor technology. Their feedback informs how systems are designed, integrated, and supported.

Embedding the site voice into execution reduces friction that can delay enrollment, increase queries, or strain sponsor-site relationships.

*Survey conducted with Rave Imaging Site users in March 2020 n=343

Elevating the Site Voice through Action, Accountability, and Design

Medidata's Site Insights Program reflects a deliberate shift toward transparency, efficiency, and true site-centricity in clinical research. Built on the belief that better technology starts with better listening, the program embeds the site voice into product design, training, and strategy. Every insight gathered is tied to action, ensuring that collaboration leads to measurable improvements for sites and, ultimately, better experiences for patients.

This approach reinforces a simple but powerful principle: collaboration is only meaningful when it results in visible change. To achieve that, Medidata has moved beyond listening alone and focused on building the internal structures, behaviors, and accountability needed to act on what sites share.

Building Collaboration Into the Organization

Turning site insight into real-world impact requires alignment across the organization. Medidata's commitment to collaboration is reinforced by strong leadership engagement and clear accountability, ensuring that site feedback does not stop at discussion but informs decisions and priorities.

CEO Anthony Costello's background in patient-first technology sets the tone for an organization that values lived experience and operational reality. That mindset is translated into action in several tangible ways:

- **Thought Leadership:** Sites are positioned as partners, co-presenting alongside Medidata at conferences and client roundtables.
- **End-to-End Site Visits:** Product teams visit research sites to observe workflows, understand patient journeys, and identify challenges that directly inform product design.
- **Shared Accountability:** Feedback is not gathered for awareness alone. It is tracked, prioritized, and addressed with clear ownership across teams.

By embedding collaboration into daily work and leadership expectations, Medidata ensures that site insights influence decisions at every level of the organization.

From Patient Insights to a Site-Centered Collaboration Model

Medidata's collaboration journey began with a focus on patients. Through the Patient Insights Board and the Patient Centric Design Studio framework, Medidata partnered product teams with patient advocates to co-design solutions aimed at improving the clinical trial experience.

Those early efforts surfaced a critical insight. To achieve broader, real-world impact, clinical research sites needed to be part of these conversations. Sites sit at the intersection of technology, patients, and operations, making their perspective essential to scalable and sustainable improvement.

This realization led to the creation of the Site Insights Program and, as a foundational element, the Site Tech Board, formed approximately three years ago in partnership with the Society for Clinical Research Sites (SCRS). As the program matured, Medidata expanded its approach in March 2025 with the launch of an Executive Site Advisory Board and an online Site User Community, formalizing how site voices inform both day-to-day product decisions and long-term strategy.

Today, the Site Insights Program functions as an integrated ecosystem designed to capture, apply, and scale site feedback across the organization. Key components include:

- **Site Tech Board:** Enabling hands-on collaboration with product teams to refine existing technology and pilot new solutions.
- **Executive Site Advisory Board:** Engaging senior site leaders to inform strategic direction and future vision.
- **Site Partnerships:** Supporting ongoing collaboration beyond formal advisory roles.
- **Online Site User Community:** Providing sites with direct access to training, support, and structured feedback tools.

Together, these elements ensure that site perspectives are not only heard, but consistently translated into action, reinforcing Medidata's commitment to practical, site-driven innovation.

The Site Tech Board: Structure and Purpose

The Site Tech Board brings together approximately 15 sites to collaborate directly with Medidata's product development teams. Its structure is intentionally designed to reflect the diversity of the site ecosystem, including academic medical centers, independent sites, site networks, mobile research units, and retail-based sites.

The board meets six times per year and engages with teams across the organization to optimize existing technologies and

To achieve broader, real-world impact, clinical research sites needed to be part of these conversations.

pilot new solutions. Membership typically spans a two-year term, ensuring continuity while allowing for fresh input and rotating representation over time.

This structure balances depth of engagement with diversity of perspective, keeping feedback both actionable and representative.

How Insights Turn Into Action

A defining feature of the Site Insights Program is its closed-loop feedback model. After each Site Tech Board meeting, Medidata teams conduct structured briefing sessions to capture insights, align internally, and develop implementation plans.

Approximately three months later, those teams reconvene to demonstrate how site feedback has been applied. This includes product updates, workflow refinements, and process improvements, reinforcing transparency and trust.

Continuous feedback is further supported through end-of-session surveys and year-end summaries shared with participating sites, ensuring accountability and ongoing engagement.

Tangible Outcomes and Improvements

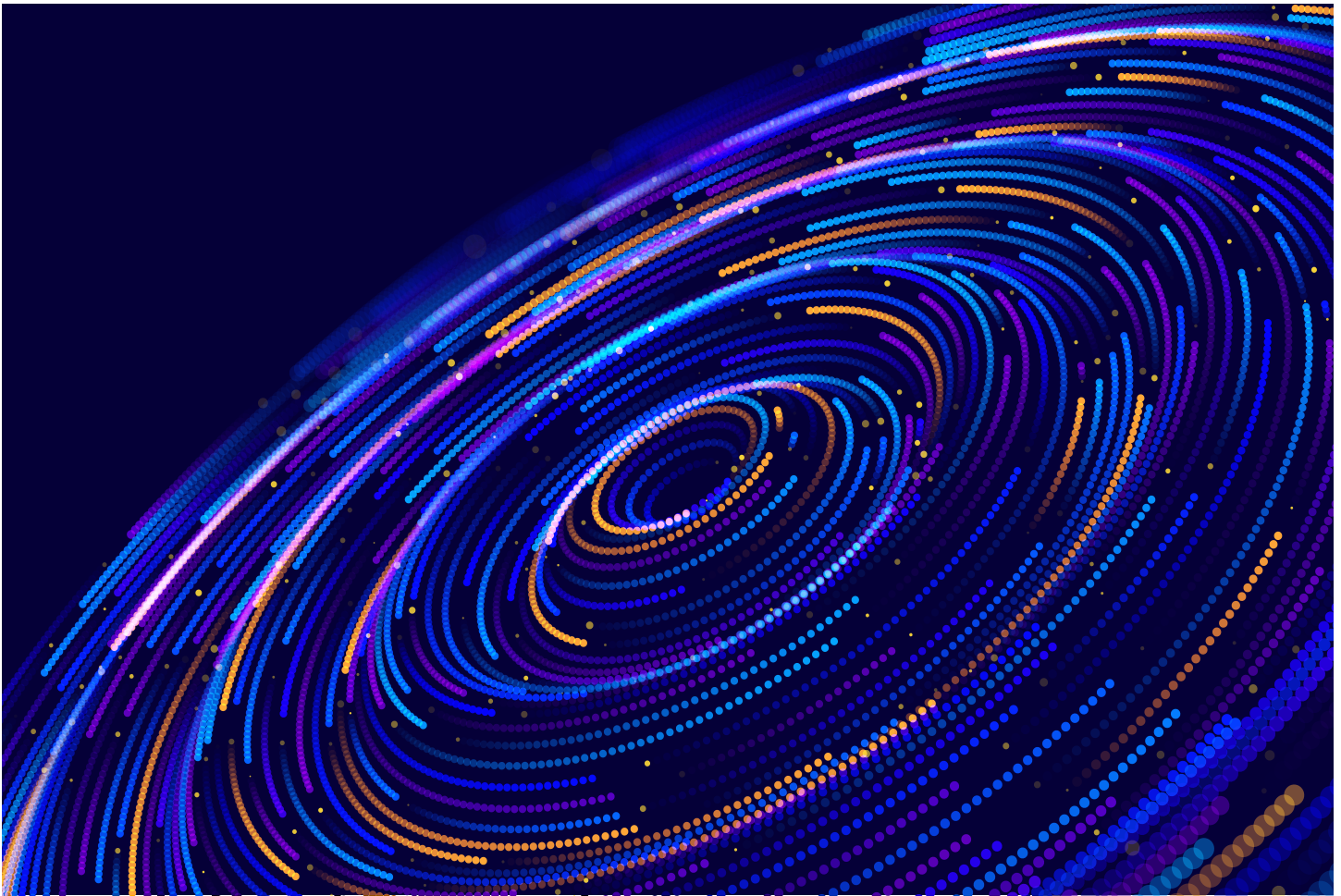
Product Enhancements

Site feedback has directly influenced enhancements across multiple Medidata solutions. Examples include refining informed consent workflows by separating education from signature, improving patient payment workflows to support timely payments and budget reconciliation, and enhancing the electronic clinical outcome assessments (eCOAs) solution functionality to better support raters. These changes reflect site input translated into practical, real-world improvements.

Training Evolution

Training has evolved from static, role-based modules to a just-in-time learning model. Sites now receive targeted information when it is most relevant, reducing redundancy and saving time. Investigator meetings allow sites to practice with devices in advance of patient visits, improving readiness and confidence.

Looking ahead, Medidata is exploring enhancements to the learning management system (LMS) that will prevent unnecessary repetition, improve compliance clarity, and further reduce site burden.



Scaling a Model That Works

At its core, Medidata's Site Insights Program demonstrates a simple truth the industry often overlooks: better products come from better relationships. By listening to sites, bringing them into decision-making, and holding itself accountable for acting on their feedback, Medidata is building technology that works in real-world settings. This is not theoretical collaboration. It is a repeatable model for how meaningful site engagement translates directly into stronger products, greater trust, and improved outcomes across clinical research.

The Site Insights Program continues to expand globally. Site engagement events were completed in Japan in November 2025, with additional regions planned throughout 2026. As the program grows, Medidata remains focused on maintaining consistency, accountability, and meaningful follow-through across geographies.

Collaborate Forward Takeaways

- Embedding the site voice requires intentional structure and sustained commitment.
- Tangible outcomes build trust when sites see how their input drives change.

- Diverse site representation leads to more practical, scalable solutions.
- Leadership alignment is critical to sustaining collaboration.
- Closed-loop feedback transforms insights into action and accountability into impact.

Contributors from GSK

- **Robin Douglas**, VP, Research Site Engagement
- **Lisa Moneymaker**, Chief Strategy Officer



The Collaborate Forward Team

A Multidisciplinary Team Dedicated to Industry Collaboration



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Forward

Let's keep moving
forward. **Together.**

[Learn more](#) about Collaborate Forward
Have a story to share? [Share it here.](#)



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

MASTERING DCT BUDGETS

The Challenge



Site Variability & Burden



Patient Payments & Engagement



Technology & Data Costs



Regulatory Compliance



Fair Compensation

The Medidata Solution



Integrated Platform



Automated Payment Processing



Unified Technology & Data Management



Compliance & Regulatory Support



Streamlined Compensation Management

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 defensible 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 defensible budgets that facilitate better decision-making, ensure financial transparency, and support the success of decentralized trials.

The Seasonal Nature of the Client Journey in Business

By Tina Mincher

A Client journey is not static. Just like the changing seasons, it has natural cycles that ebb and flow, driven by various factors ranging from consumer expectations to economic conditions, to personal circumstances. Understanding the seasonal nature of client experience is vital for businesses to remain relevant, responsive, and engaged with their customers throughout the year.



The Four Seasons of the Client Journey

SPRING – THE SEASON OF GROWTH AND EXPLORATION

Spring in the client journey cycle represents a period of renewal, discovery, and growth. Just as flowers bloom and new life emerges in nature, businesses experience a surge in new clients or opportunities. This season often begins after the initial acquisition of a client, during the exploration phase, where customers are excited to try new products, services, or experiences. It's a time of optimism, curiosity, and potential.

In this season, businesses must focus on making strong first impressions. It's when customers begin to develop trust and their initial feelings about a brand are formed. Companies can nurture this phase through:



Personalized onboarding experiences



Educational content that helps clients understand the product or service



Proactive customer support to answer questions early on



Building an emotional connection that fosters loyalty

In the spring of the client journey, businesses should take every opportunity to help their clients feel heard and understood, allowing them to explore the full value of what the company has to offer.

SUMMER – THE SEASON OF ENGAGEMENT AND PEAK CONNECTION

Summer represents the high energy, flourishing stage of the client journey cycle. In nature, summer is a time of abundance and vitality, and similarly, in business, it's when clients are fully engaged, enjoying the products or services, and experiencing satisfaction. This is when clients are at their most loyal and most communicative, ideally returning for repeat business and recommending the brand to others.

For businesses, summer is a season to capitalize on their established relationship with customers. Strategies for this stage include:



Encouraging feedback and gathering insights to improve service



Offering loyalty programs, upsell or cross-sell opportunities



Sharing exclusive content or early access to new features or products



Engaging customers through social media and personalized messaging

During this phase, the key is to deepen the relationship and provide added value that strengthens the connection between the brand and the client. Businesses that maintain excitement and satisfaction during the summer season are more likely to have a long term relationship with the customer.

AUTUMN – THE SEASON OF REFLECTION AND EVALUATION

As the leaves turn and the weather cools, autumn brings a period of transition and reflection. In the business world, this is often when clients reassess their needs, their budgets, and the value they are receiving. This is a time of evaluation, where clients begin to think more critically about their investments and whether the solutions they've adopted are still the best fit for their evolving needs.



Autumn may bring some challenges, but it also presents an opportunity for businesses to solidify their relevance. In this season, companies should:



Gather and act on client feedback to improve their offerings



Reaffirm the value of the service or product and its continued benefits



Offer personalized solutions for clients facing new challenges or shifts



Provide opportunities for clients to reconnect, perhaps through loyalty programs, customer appreciation events, or exclusive offers

Businesses that successfully navigate autumn can turn this evaluative phase into an opportunity for renewal and re-engagement, strengthening client relationships for the long term.

WINTER – THE SEASON OF HIBERNATION AND RETENTION

Winter represents a period of dormancy, slowing down, and sometimes even withdrawal. For businesses, this phase is marked by a potential drop in client engagement or a slowdown in activity. Clients might become less active, less vocal, or even consider shifting to competitors. Economic factors, seasonal shifts, or changing client priorities can contribute to this winter like phase.

However, just as nature doesn't stop in winter, neither does the potential for business growth. In the winter season of client experience, the focus shifts to retention and staying top of mind. Businesses should focus on:



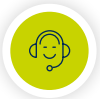
Keeping communication lines open with clients, even if they aren't currently active



Providing valuable content that helps clients solve problems or improve their business



Offering promotions or incentives to encourage re-engagement



Maintaining exceptional customer support to address any concerns

Winter is the time to nurture relationships at a slower, more intentional pace. By investing in retention strategies and maintaining client loyalty, businesses can emerge from this slower period stronger and ready for the next cycle of growth.

NAVIGATING THE CHANGING SEASONS

The beauty of the seasonal nature of the client journey is that each phase brings its own opportunities and challenges. By understanding these natural cycles, businesses can tailor their strategies to meet the needs of their clients at each stage. The key to success is not just in acquiring new clients, but in nurturing and retaining them throughout their entire journey with the brand.

Just like nature, the seasons of client journeys are cyclical. A well managed client journey strategy adapts to these changes, ensuring that businesses are equipped to handle the highs of summer, the evaluation of autumn, the dormancy of winter, and the growth of spring.

By paying attention to the rhythms of client engagement, businesses can create deeper, more lasting relationships and sustain a steady flow of growth throughout the year. After all, it's not just about getting through one season, it's about thriving through all of them.

At Medidata, the Client Strategy priority is to walk every season with our clients, partnering, evolving, and ensuring they always feel supported, heard, and valued as part of our shared journey.



A photograph of a person walking on a sand dune in a desert landscape. The person is small in the distance, walking along the crest of a dune. The sand is rippled and the lighting suggests a low sun, creating long shadows. The background is a vast, open desert under a clear sky.

“

Do not go where
the path may
lead, **go instead
where there
is no path and
leave a trail.**

Ralph Waldo Emerson



Budget InnoLabs Insights 2025

The 2025 Budget InnoLabs focused on refining financial planning tools, improving system integration, and addressing challenges in global budgeting and reporting across regions. Below are highlights from the 2025 Budget InnoLabs.

Strategic Focus Areas

AI & AUTOMATION READINESS

AMA 2026 Preparation

Preparing for the AMA 2026 update, which will introduce new AI-heavy procedural codes. Medidata plans to use AI to generate “defensible algorithms” for cost estimates.

Digital Protocol Initiative

A major enhancement is underway to move from manual data entry to uploading digital protocols. This system will automatically generate line-item budgets, with a phased rollout scheduled for 2026.

Fair Market Value (FMV) Enhancements

New AI layers are being added to FMV data to provide localized inflation adjustments and build stronger confidence in the data through synthetic modeling, particularly in the APAC region.

GLOBAL VS. LOCAL ALIGNMENT

UK & French Templates

Clients identified significant friction in translating global budget builds into mandatory local templates (e.g., UK iCT and French costing grids). The French template’s reliance on “unit costs” rather than visit structures makes direct mapping difficult.

The “One-Button” Solution

Stakeholders proposed a feature that would allow users to build a global budget and press a “button” to translate it into local formats.

Cost Per Patient (CPP) Benchmarking

An internal analysis used the US as a baseline to create global indices. Findings showed cost decreases in Chile, Norway, and South Korea.

PRODUCT MODERNIZATION & DATA INTEGRITY

Code Retirement

The team retired vague “bucket” codes in favor of granular options to improve data accuracy. This was driven by pandemic-era learnings where historical data proved insufficient for new procedure types.

Historical Data Limitations

To address client concerns about limited historical data for new therapies, GMP now incorporates third-party and payment data to model “anticipated costs” rather than relying solely on past benchmarks.

Strategic Outlook & Roadmap Recommendations

FSP Enhancement

Allow high-level estimates to be broken down into granular costs.

AI Code Communication

Execute a communication plan explaining the rationale for using AI-generated costs for new AMA codes.

Automated Budgeting

Launch the capability to recognize uploaded protocols and automatically build budgets.

KEY CHALLENGES & PAIN POINTS



French Template Complexity

The French template requires a line-by-line build that does not align with standard visit grid structures, creating a significant manual workload.



Code Granularity

Clients struggle to map retired codes to new options. There is a demand for clearer documentation mapping old “bucket” codes to their replacements.



Inflation Visibility

Clients questioned why budget inflation is not always reflected in quarterly benchmarks, necessitating better communication regarding data refresh cycles.

End-to-End Integration

Advance the goal of linking FSP and GMP to Payments and EDC/Data Management for a unified financial lifecycle.

Collaborative Workshops

Continue the InnoLabs and consider inviting sites to future meetings to address the 92% dissatisfaction rate regarding budget accuracy.

Data Refinement

Continue the biannual update of UK iCT codes and the annual analysis of code usage to retire obsolete data.





Site Payments InnoLabs Insights 2025

The 2025 Site Payments InnoLabs focused on aligning financial operations with clinical execution by modernizing audit trails, standardizing invoicing, and addressing global e-invoicing mandates. Below are highlights from the 2025 Site Payments InnoLabs.

Strategic Focus Areas

ELECTRONIC INVOICING (E-INVOICING) & COMPLIANCE

Global Shift

Governments, particularly in South America, Europe, and Italy, are mandating electronic invoicing via API. CTFM is monitoring these requirements closely.

Current Capabilities

The payments application currently calculates taxes. A roadmap enhancement is planned for next year to handle detailed e-invoice submissions to relevant authorities.

UK Focus

There is a specific initiative to better understand UK payment templates, as current formats require manual “deciphering” and do not align easily with global procedure-based budgets.

AUDIT TRAIL & SEGREGATION OF DUTIES

Granular Data Requirements

Clients require detailed, reportable audit trails for the entire contract lifecycle. This includes tracking who created/approved contracts, specific changes (cost/payee), and timestamps.

AI Scrutiny

Sponsors are increasingly using AI to analyze audit trails for anomalies. Current systems (CTMS Classic) struggle to export full study audit trails, which is a known limitation being tracked.

Segregation of Duties

Auditors are demanding proof of performance, specifically that the person setting up costs is different from the person approving them. Currently, clients use manual workarounds (custom Jasper reports) rather than system-enforced controls.

PARTNERSHIPS & INTEGRATION

“Edge” System Collaboration

A potential collaboration is being explored with “Edge,” a payment system used by approximately 95% of UK university trusts. An introductory meeting with Stevie Barr is planned.

Parexel Partnership

A joint success story article is being co-authored to highlight the end-to-end partnership involving Grant Managers and Payment leads.

Strategic Outlook & Roadmap Recommendations

Technical Fixes

Correct the date logic/labeling on payment reports regarding the Approved Date.

Audit Trail Export

Investigate long-term solutions to enable CTMS Classic audit trail export.

Strategic Meetings

Plan future Innolabs with a focus on Audit Support.

Content & Marketing

Gather intel on “Slow Payments.”

Process Improvement

Continue investigating system-based solutions to prove segregation of duties between cost setup and approval.

KEY CHALLENGES & PAIN POINTS

Finance vs. Clinical Disconnect

A major pain point is the disconnect between site finance teams and clinical operations. Finance staff often do not read protocols, leading to inaccurate invoices (e.g., billing for items that didn’t happen).

Documentation Issues

Sites frequently submit incomplete data or double-bill. “Throwing invoices against the wall is a waste of everyone’s time”.

Fee Complexity

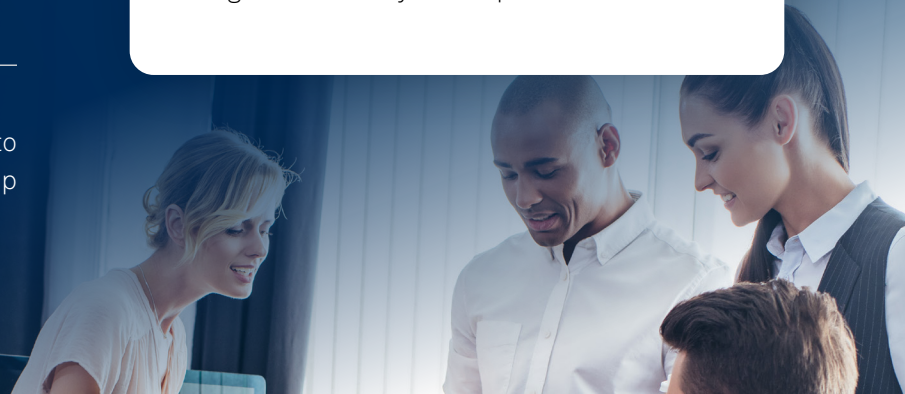
Sites are breaking costs down into granular fees (e.g., 5 different start-up fees), complicating standardization. There is a push to map these to CPT codes or unique identifiers to automate data entry.

Premature Payments

A recent Site Tech Board workshop raised concerns regarding “premature automated payments,” which will be a topic for future discussion.

Bug Fix

Users reported a “misaligned Approved Date” in payment reports (appearing earlier than the submission date), which has caused confusion during audits. This is currently being addressed by development teams.





Patient Payments InnoLabs Insights 2025

The 2025 Patient Payments InnoLab focused on reducing site administrative burdens, prioritizing upfront patient coverage, improving financial forecasting, ensuring global compliance, and enhancing platform flexibility. Below are highlights from the 2025 Patient Payments InnoLab.

Strategic Focus Areas

REQUIREMENTS

Reduce Burden

Sites strongly prefer to be taken out of the payment and travel logistics equation entirely to avoid administrative overhead.

Upfront Payments

Patients prefer to have expenses (lodging, meals, childcare) covered upfront rather than waiting for reimbursement.

Transparency

Patients require clear visibility into payment reasons and the availability of their balance.

Flexible Methods

There is a demand for diverse payment options, including Venmo, PayPal, direct deposit, and Cash App.

KEY CHALLENGES & PAIN POINTS



Budgeting and Forecasting

Unpredictability

Forecasting utilization for variable expenses (childcare, pet care, elder care) is extremely difficult. Even across nearly identical studies, utilization can swing wildly (e.g., 15% vs. 60%).

Cash Flow

Long payment terms (e.g., 60 days) force teams to hold large cash balances to avoid payment delays.



Regulatory and Global Complexity

Rapid Changes

The global regulatory landscape shifts constantly; information gathered in July may be outdated by December, requiring constant re-verification.

Compliance Conflicts

Issues arise when a vendor can support a service in a country, but the sponsor's internal policy forbids it.

Tax Thresholds

Managing tax limits (e.g., the \$600 threshold) is complex when combining standard stipends with micropayments for tasks like e-diary completion.



Defining Expense Types

Scope Expansion

Sponsors are moving beyond travel to cover childcare, pet care, elder care, and lost wages.

Language Strategy

Framing payments as compensation for "time and effort" (similar to jury duty) rather than "incentives" improves acceptance by ethics committees.



Platform Requirements

Required Metrics

Sponsors need utilization metrics (opt-in rates) and total cost reporting.

Failure Alerts

Sponsors want to be alerted only to service failures (e.g., no-shows) to manage site/patient frustration.

Hybrid Funding

Because site preferences vary (some refuse vendors, others depend on them), the platform must handle mixed funding sources without causing "double-dipping" budget errors.

Complex Conditions

The platform must support milestone payments and compliance-based incentives (e.g., paying upon 90% diary completion).

Strategic Outlook & Roadmap Recommendations

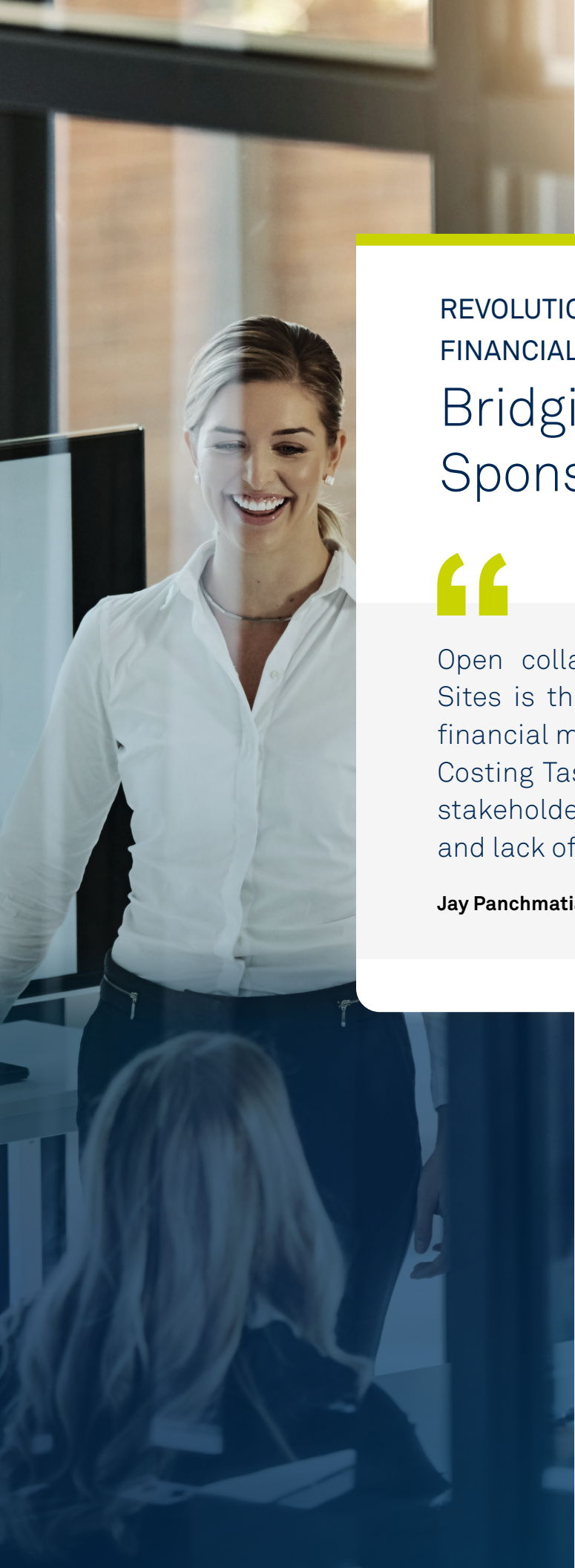
Vendor as Expert

Partners want the vendor to serve as the "source of truth" for country-specific regulations and best practices, rather than having the sponsor track changing laws.

Flexible Architecture

The system must be adaptable enough to support complex study designs and varying payment conditions.





REVOLUTIONIZING CLINICAL TRIAL FINANCIAL MANAGEMENT

Bridging the Gap Between Sponsors and Sites



Open collaboration between Sponsors, CRO's and Sites is the key to success for optimal clinical trial financial management across the industry. The Global Costing Task Force has created the space for all the stakeholders to improve poor communication flow and lack of responsiveness that previously existed.”

Jay Panchmatia

In the high stakes world of global clinical trials, the path to bringing life saving treatments to market is often blocked by a surprisingly mundane hurdle: financial administration. Specifically, the complex dance of budgeting, contract negotiations, and site payments continues to be one of the industry's most significant 'pain points'. Drawing from insights presented by industry veteran and Global Costing Task Force Member, Jay Panchmatia FCCA at the COG Conference, London 2026, let's explore the current challenges in clinical trial costing and the digital solutions designed to streamline the process.

THE FAIR MARKET VALUE (FMV) TUG OF WAR

At the heart of every trial budget is the concept of Fair Market Value (FMV). However, 'fairness' is often in the eye of the beholder. Jay highlighted the fundamental disconnect between stakeholders:

- Sites view FMV as critical for their operational sustainability and the ability to maintain quality research infrastructure.
- Sponsors see it as a mandatory element for regulatory compliance and justifying compensation.
- CROs treat it as a strategic tool to balance the conflicting needs of both sites and sponsors.

This disconnect, compounded by geographic variability and the lack of standardized global templates, often leads to protracted negotiations that delay site activation, the very step seen as the most 'rate limiting' by all parties.

TOP DRIVERS OF BUDGET OVERRUNS

It isn't just the initial negotiation that causes financial strain. Several factors frequently drive trial costs beyond original estimates:

- 1 Protocol Amendments**
Changes to study design often require significant rework for vendors.
- 2 Timeline Delays**
Trials are duration driven. Extending a timeline requires more resource time, not just spreading existing costs thinner.
- 3 Monitoring Strategies**
Face to face visits are expensive, often costing thousands of dollars per visit when travel and prep time are factored in.
- 4 Vendor Misalliances**
Selecting vendors based solely on price can backfire; changing vendors mid study is one of the costliest decisions a sponsor can make.

THE PATH TO OPTIMIZATION: TECHNOLOGY AS THE BRIDGE

How can the industry move past these systemic inefficiencies? One solution lies in shifting from manual, spreadsheet-based processes to unified digital platforms.

Platforms like Medidata's Clinical Trial Financial Management (CTFM) aim to unify study data and financial management to create a seamless 'Budget to Payment' lifecycle.

Key benefits include:



For Sponsors & CROs

Automated accruals and real time visibility into spend and forecasting reduce the administrative burden on study teams.



For Sites

Faster, more accurate payments and a 24/7 portal for payment statements help sites focus on what matters most: the patients.



For the Industry

Utilizing internal databases of negotiated costs to supplement FMV benchmarks can lead to more accurate initial budgets and reduced negotiation rounds.

CONCLUSION: 'PENNY WISE AND POUND FOOLISH'

Jay warns against an overly aggressive approach to site budgeting. An 'insufficient budget' often leads to repetitive negotiations, resulting in the high opportunity cost of delayed site activation. By prioritizing transparent communication, adopting accurate budgeting practices, and leveraging integrated technology, the industry can finally bridge the gap between financial compliance and operational excellence.

The **Global Costing Task Force (GCTF)** is an industry-focused group dedicated to optimizing financial management within clinical trials to drive global efficiency and sustainability.

CORE MISSION AND GOALS

The GCTF aims to empower the industry to make informed financial decisions and achieve ‘cost excellence’ by fostering collaboration and leveraging technology. Their primary objectives include:

Elevating the Conversation

Introducing industry experts to lead global discussions.

Sharing Best Practices

Distributing global clinical trial budgeting standards.

Building Partnerships

Involving a wider industry audience to create global connections.

Driving Innovation

Influencing the industry to promote stability and innovative practices.

PRIORITIZATION SURVEY RESULTS

The task force recently conducted a Priority Survey to identify and rank the most significant challenges in clinical trial budgeting based on their impact and the effort required to address them.

Rank	Problem Area	Avg. Impact Score	Avg. Effort Score
1	Inflation and Dynamic Cost Blind Spots	4	3.3
2	Inadequate Budget Coverage for True Costs	3.9	3.5
3	Site-Sponsor Relationship Erosion	3.7	3.3
4	Prolonged Budget Negotiations	3.4	3.4
5	Lack of Fair Market Value (FMV) Transparency	3.4	3.7
6	Site Payment Delays and Inefficiencies	3.4	3.7
7	Decentralised Trial (DCT) Cost Ambiguity	3.4	3.4
8	Financial Tracking Fragmentation	3.4	3.2
9	Billing Compliance Vulnerabilities	2.9	3
10	Participant Compensation Bottlenecks	2.9	2.9

We invite you to contribute your expertise to our global benchmarking efforts. By completing the GCTF Prioritization Survey, you ensure your perspectives are integrated into the strategies we are developing to address critical industry challenges like inflation and budget transparency.

GCTF Priority Survey