



Power of Partnership

# ISSUE 11

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

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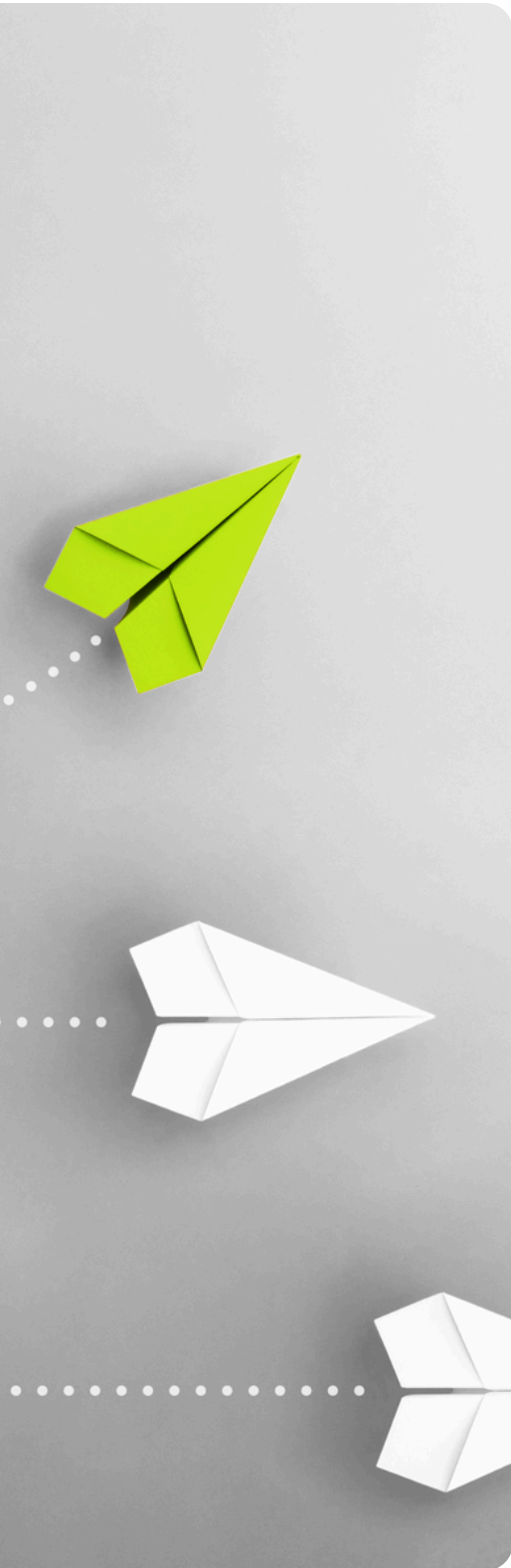
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# The Medidata Guide to Patient Reimbursements and Payments

## Introduction

Patient and site experiences are the key to understanding why clinical trial patient retention is challenging. Analyzing feedback from Medidata's **Patient Insights Program**, the Medidata SiteTech Board powered by the SCRS (**Society for Clinical Research Sites**), and the extensive 2023 industry survey conducted by Industry Standard Research (ISR) on behalf of Medidata, we can share insights that shape the patient, site, and sponsor experience regarding the financial aspects of patient-level engagement.

The Patient Insights Program was the first industry initiative to include patient feedback for patient-facing technology and solutions, and the SiteTech Board is a unique, exclusive panel of experienced site representatives that enables the site voice to be heard, impacting the way technology solutions and services are designed and implemented.

Feedback from the Patient Insights Board and Site Tech Board is analyzed and embedded into Medidata's product design and development process—the Patient Centricity by Design's "built for patients, by patients" framework. This ensures a true patient-centric experience.

Compensation in the form of patient reimbursements and stipends is an important part of the patient experience. Reimbursements repay expenses incurred by patients who pay for travel and meals associated with the study visit. Stipends are predetermined, fixed sums of money paid to patients in recognition of their time, effort, and burden of participating in clinical research activities.

From a patient perspective, if they are not reimbursed or paid on time, they may be unable to continue in a study, preventing them from receiving life-affecting—or even life-saving—treatment and impacting the study itself.

Another aspect of the patient experience is the additional non-medical financial cost of participation in certain therapeutic areas—inability to work, destitution, etc.—that leaves patients with unexpected burdens that have a devastating impact on their lives and their ability to participate in studies. This issue is known as financial toxicity and is often associated with cancer patients. The serious and often overlooked issue has been the subject of concern for decades, and we are shining a light on this in this paper with a call for sponsors to act (see below).

Research sites are the enabler and interface between patients, systems, and CROs/sponsors. Managing and facilitating the patient reimbursements and stipend process are essential, but they also add disproportionate time and resource burdens. Exactly how much of a burden depends on the level of financial system and solution support (if any) that sponsors provide for them. If sites are asked to carry out processes manually, the result is a slow, unscalable process open to human error. Technology solutions provided by sponsors are the potential answer, but not all systems are created equal, and many can add further burdens to sites inadvertently rather than reduce them.

From a sponsor perspective, even the most experienced project management team will say, "we don't know what we don't know" and acknowledge that having a complete understanding of the challenges faced is key to deciding on the best possible solution.

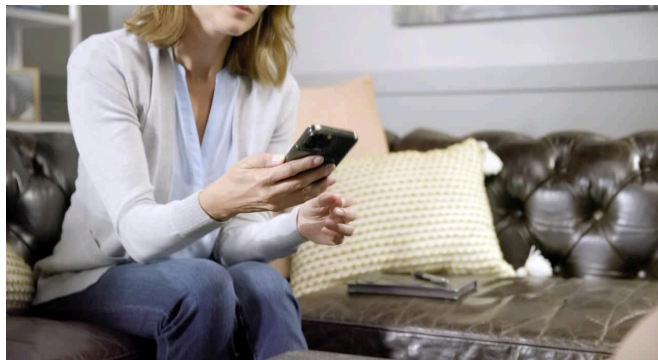
Typically, patient reimbursements and stipend implementations often include internal stakeholders from multiple departments: outsourcing, global studies, patient experience, country management, site management, finance, operations, data management, regulatory, IT, legal, and contract negotiations.

The expectations, experiences, and needs of patients, sites, and sponsors are linked but different, and understanding individual requirements is the key to creating a best-in-class experience for everyone.

## The Patient Experience

Each patient is unique—their circumstances, medical needs, and preferences shape their clinical trial experience. The conundrum is, how can we ensure that each patient has an exceptional clinical trial experience?

Clinical trial stakeholders should proactively seek feedback from patient advocates. The Medidata Patient Insights Board was formed to achieve this in conjunction with Site Tech Board feedback, driving patient-centric, empathetic technology product design and development through the Patient Centricity by Design framework. The Patient Insights Board is a diverse team of patient experts representing multiple therapeutic areas, personal and professional medical experiences, and hands-on caregiver knowledge.



Patient Payments Video - [Watch Here](#)

The feedback has uncovered common themes, including the need for intuitive design, ease of use, accessible help and support, transparency from study staff, data privacy, data security, and empowering patients to make informed decisions through transparent communication for improved health literacy and understanding. Being listened to, feeling cared for and comforted throughout the study is the foundation of the patient experience.

Expanding on how patient reimbursements and stipends play a significant and impactful part in the patient experience, one example would be that of a patient who, traveling from France to Switzerland for monthly site visits, needs to cover the costs of flights, hotel stays, food, cabs, etc. Covering these costs, to begin with, may be impactful for the patient; late reimbursement will impact their financial situation even more so and may eventually leave them unable to cover the costs of future travel to the site. Because the patient may well have a lot on their mind to begin with, what impact will adding a significant financial burden have on their ability or willingness to continue with a study?

When manual processes or less capable systems are used, late payments are not uncommon in clinical trials—there are cases where reimbursements or payments have taken months or more to process.

Financial management, stress, and motivation are all inextricably linked and are known to impact patient recruitment and retention in studies.

Summarizing specific Medidata Patient Design Studios feedback to understand the specific areas that impact patients from non-Medidata solutions and processes, the following concerns stand out: **a lack of choice in disbursement options, delayed payments, a lack of payment process transparency, unexpected bank or card fees, bad user experiences in apps and with help desks, privacy and security concerns, a need for simpler patient registration, a lack of local language and timezone support, and overall communication concerns.**

For US studies, stipends are more common than reimbursements, so patients should be informed that these payments are treated as income by the IRS. Not only are there current tax implications; stipends have the potential to disqualify patients from other government benefits like Medicaid, Supplemental Nutrition Assistance Program (SNAP), etc. Above the US\$600 threshold, patients are required to pay taxes and will also need to be provided with a 1099-MISC from the payor.

**The Harley Jacobsen Clinical Trial Participant Income Exemption Act** is a proposed bill that seeks to remove this tax liability—which affects an estimated 110 million Americans enrolled in social welfare programs—enabling them to participate in clinical trials without potentially losing benefits.

## The Site Experience

As the key interface between patients, technology, CROs, and sponsors, research sites are responsible for study setups, treatments, recruitment, retention, device setup, distribution and training, finance management, data entry and management, data storage, compliance, and more, but their connection with patients goes beyond all of this. Their part in the patient journey is significant, directly impacting the patients' overall experience, supporting them, building trust, keeping them informed, and motivating them.

Sponsors provide sites with a wide range of technologies and services that empower them to carry out studies, usually designed to automate processes, improve efficiencies, and reduce burdens. The irony is that if several disparate systems are provided, site burdens increase significantly in other areas, due to: the use of multiple user interfaces, increased logins, duplication in data entry, gaps in data between disparate systems, the lack of local time-zone and language support, duplication or insufficiency in training, integration issues, and inconsistent quality of helpdesk support, to name a few. On average, if a site is provided with five systems for a single study, this would equate to fifty different logins per day, taking research staff away from patients and important tasks. Typically, with multiple studies a site will need to access over twenty systems a day.

Viviënne van de Walle, co-founder of the independent clinical research site [PT&R](#) and a member of the leadership council for the SCRS, calls this "an escape room experience." The site experience with disparate systems is not a happy one.

In addition to the universal challenges listed above for manual processes and disparate systems, additional patient reimbursements and stipend processes sites have stated they would welcome alternatives, solutions, or support for, include: cross-checking expenses against sponsors' expense policies, scanning and uploading receipts, manual entry of journals, tracking and reconciling payments, checking detailed payment reports, reducing the additional impact on site finance management, handling patient questions and problems related to unpaid reimbursements, manual approvals processes, and managing additional follow-ups due to late payments.

SiteTech Board feedback pointed to the fact that many of these processes and actions have a domino effect on the sites, CROs, and sponsors, that can be triggered by just a single unpaid \$5 receipt. The burden is disproportionate and significant.

Sites are supportive of any technology designed to help them, but they must be pragmatic. If technology or a process causes problems, they are proactive in raising concerns and seeking ways to find better solutions. With that in mind, they have asked for more visibility, clarity, and transparency in the payment and invoicing process to enable them to be a proactive part of the change.

The wider financial challenges and burdens that sites face have been heavily publicized, so it is important that patient reimbursements and stipend challenges remain at the fore alongside those discussions. It is a critical element which directly impacts everyone.

## The Sponsors' Experience

For sponsors, a holistic perspective is necessary when deciding on the best strategies, solutions, and infrastructure to ensure study success. Analysis from the ISR survey provided a comprehensive view of sponsors' expectations and needs from patient reimbursements and stipend systems, budgeting, forecasting, and services. Additionally, with patient and site centrality in mind, how can sponsors provide support without overwhelming them with technology, whilst not providing an underwhelming, demotivating experience?

A firm foundation for any systems implementation is important, especially in clinical trials. Close alignment with strategic, philosophical (patient and site centric), technical, operational, and functional requirements is essential.

The ISR survey showed that 86% of survey respondents were likely or highly likely to be more interested in an end-to-end clinical trial financial management technology solution that offers budget planning, forecasting, approval, contract negotiation and processing tools, site/investigator and patient payment tools, and expense tracking/reconciliation.

With this in mind, a platform of unified solutions specifically designed with these attributes has significant advantages over the implementation of multiple disparate systems.

For high-level guidance, key functional and operational areas to consider when developing a patient payment system are listed in alphabetical order here. Some seem obvious, such as compliance, but not all independent systems have the essentials in place, so they are listed here to ensure they are not missed:

**Approvals Workflows** - A widely recognised issue that has led to delayed payments has been the use of manual approvals processes—as many as twenty-one touchpoints have been reported between the patient, site, CRO, and sponsor. Automated, user-friendly technology, advanced workflows, and rule-based approvals with manual interventions for any exceptions would overcome this while increasing adoption and compliance.

**Finance Management, Budgeting, and Forecasting** - Patient reimbursement and payment management, budgeting and forecasting is complex, even more so with global studies, higher visit schedule studies, and therapeutic areas where patients have special travel needs. The intricacies of multiple local banking models, currencies, preferred payment methods, differences in local travel and associated costs, bank charges, and other cost variables interweave further complexity into calculations.

Rather than guesswork or employing resources to carry out micro-analysis of every variable, using advanced systems with access to global data from previous and current clinical trials is the answer.

The ISR survey also reported that the ability to centralize and easily access end of study contracts and invoices was of high importance for 87% of respondents.

**Compliance** - FDA guideline adherence, HIPAA compliance for PII and Protected Health Information (PHI), IRS compliance, data privacy, data security, and regulatory compliance should all be standard, but it is always wise to check with each vendor, just in case.

**Data Interoperability and Systems Integration** - The ISR survey showed that systems integration and data interoperability are two of the most complex and difficult to achieve deliverables when implementing independent patient reimbursements and stipend systems with disparate eClinical systems. The deployment of disparate systems is an acute problem, often leading to delays, gaps in data, duplication of data, inconsistent user experiences, and varied support and helpdesk quality.

An advanced unified platform would address these issues, even more so if an end-to-end clinical trial financial management infrastructure is implemented.

**Global support** - Patients and sites need local time zone and language support. Without it, the negative impact on the study as a result of bad patient and site experiences can be significant. If a technical issue prevents a site visit from being completed and support isn't available while the patient is on-site, that visit cannot be completed.

In the ISR survey, 64% of respondents felt that a technology solution with multilingual materials and technical support would enable the improvement of diversity and inclusion in clinical trials.

Global, localized support is not just a nice to have, it's a critically important requirement.

**Recruitment** - Site feedback in the [2023 SCRS Site Landscape Survey](#) showed that whilst they are happy with their progress in meeting diversity, equality, and inclusion goals, they would welcome additional support from sponsors when recruiting within diverse and rare patient communities. Sponsors and CROs have also stated that the ability of a site to recruit within diverse populations is a contributing factor to site selection.



**Reimbursement and payment options** - Not everyone will want to share bank details for bank transfers; many prefer PayPal or Venmo, and others prefer e-Debit. Some patients will love reloadable cards while others will hate them. In some countries, banking processes and costs are a barrier to providing bank transfers for patient reimbursements. Sponsor responses in the ISR report indicated that addressing this issue is high on the list of their needs.

It is extremely important to work with a partner who has experience and expertise, and who excels in delivering patient and site experiences through human-centric design.

## Financial Toxicity and a Call to Action

The financial burden of non-medical costs and the consequences of trial participation in oncology studies can devastate patients' lives and their ability to continue participating in trials.

The 'financial toxicity' that they endure has been brought to the attention of oncology sponsors since the 1980s and has been addressed in papers ever since.<sup>2</sup> This has produced shockingly little effect.

Seven major themes in financial toxicity were highlighted in the Mayo Clinic paper, *The Faces of Financial Toxicity* (2023), believed to be the first survey of its kind. The paper serves to highlight the current issues and impact on patients' lives: the burden of travel, a willingness to pursue treatment despite the financial risk, fear of destitution, financial toxicity equaling physical toxicity, changes in food spending, reluctance to confide in the study investigator about financial toxicity, and difficulty navigating financial aid.<sup>3</sup>

One study respondent said, "I would say my physical symptoms are probably only about a ten percent and my financial strain is a lot worse than that."

56% of patients stated that out-of-pocket costs had become so high "that they had plans to, or had already undertaken, measures including selling their home and moving in with family members, selling vehicles or household goods, or completely depleting their savings."

In other papers, researchers stated that it was possible to "identify patients who may be at higher risk, including younger patients, minoritized racial groups, and patients in lower socioeconomic strata. Financial toxicity can cause patients to skip doses or not fill prescriptions altogether. Financial toxicity has a direct impact upon patients' quality of life, puts them at risk for bankruptcy, and may even increase mortality",<sup>4</sup> and "financial toxicity is disproportionately higher in patients with lower income and those who travel farther, and unexpected medical costs were more common among non-White or Hispanic patients. OOP costs can be substantial and are often unexpected for patients."<sup>5</sup>

The position cannot continue, it must be addressed, and we call out to sponsors to act now.

## Patient Reimbursements and Payments - More than Expense Management

Understanding patient reimbursements and stipend systems is not only about software, transactions, workflows, and data management systems. It is about people—patients, caregivers, and our valued site partners. Adopting a truly patient and site-centric approach is the secret to delivering the exceptional experiences needed to create an optimal environment for study success.



**For patients**, feedback from patient advocates and the Patient Insights Program flows into our Patient Centricity by Design framework, introducing patient-insight-driven actionable elements in product development.

Patient feedback has shown that a range of reimbursement and payment options is preferred. Medidata's patient-first principle means that we are committed to providing a wide range of payment options to cater to the individual preferences, circumstances, and needs of patients while making the back-end process as seamless and simple as possible for all other stakeholders.

The result is a rich, personalized patient reimbursement and stipend experience that addresses the issues that have been raised above. For patients, we've built on the familiar **MyMedidata app**, delivering an intuitive, user-friendly, and simple financial management experience that lowers burdens for them and provides visibility, security, and peace of mind.

**For sites**, we've worked extensively with the SCRS for many years and partnered with them to create the SiteTech Board, giving sites a voice to provide input and feedback regarding their needs and challenges, impacting the way Medidata's technology solutions and services are designed and implemented.

As the industry leader, Medidata has supported 33,000+ clinical trials, 10 million+ patients, 2,300+ customers, and had involvement in 65% of 2023 FDA novel drug approvals and 60% since 2015 (excluding vaccines and biologics). As a result, research sites are very familiar with the Medidata Platform, our intuitive, integrated, unified platform with a single log-in, and a consistent site experience that is supported by local time zone and multi-language support.

As a majority of sites and patients are already using our systems, calling them 'home' for their clinical trials, patient reimbursements and stipends are just a natural extension of that experience.

**For sponsors and CROs**, we address many challenges faced across the clinical trial ecosystem with our best-in-class platform and services. Addressing the specific issues highlighted in this paper, patient and site centricity has been embedded into our systems for years, and we continue to innovate, evolve, and adapt as the face of the industry changes, moving towards more complex trials in an ever-changing world.

In addressing the key points above, advanced and intelligent approvals workflows, compliance, and global support are standard within the foundations across our platform.

For data interoperability and systems integration, Medidata's unified platform, which underpins all of our products and solutions, has long been recognized for its excellence in these critical areas.

As has been evidenced by expert feedback from patient advocates, sites, and sponsors, patient reimbursement and payment challenges are far from straightforward. They can be exacerbated when disparate systems are implemented.

We can address and simplify these challenges while delivering the best possible experiences for all key stakeholders. Our CTFM team would be happy to have a conversation with you to see how we can help you with any aspect of your patient payment strategy.

Financial toxicity is crippling to oncology patients and is an issue that has persisted for almost forty years. It must be addressed, and we have the technology to ease the financial processes and mechanisms for sponsors—it is up to sponsors to take financial responsibility for the patients who participate and play a critical part in their studies.

Contact us, we can help you.

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2. [Controversies in Breast Cancer Disease: Diagnosis and Management. Edited by Sharon Grundfest-Broniatowski, MD, and Caldwell B. Esselstyn, Jr, MD, New York: Marcel Dekker, Inc, 1988](#)
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5. [Huey RW, George GC, Phillips P, White R, Fu S, Janku F, Karp DD, Naing A, Piha-Paul S, Subbiah V, Tsimberidou AM, Pant S, Yap TA, Rodon J, Meric-Bernstam F, Shih YT, Hong DS. Patient-Reported Out-of-Pocket Costs and Financial Toxicity During Early-Phase Oncology Clinical Trials. Oncologist. 2021 Jul;26\(7\):588-596. doi: 10.1002/onco.13767. Epub 2021 Apr 21. PMID: 33783054; PMCID: PMC8265355.](#)

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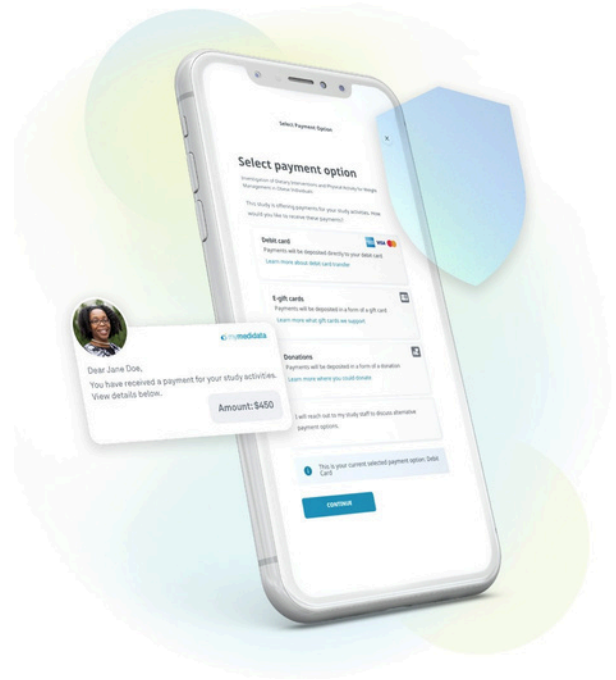
“PUTTING THE PATIENT FIRST  
IN AN OPEN AND SUSTAINED  
ENGAGEMENT OF THE  
PATIENT TO RESPECTFULLY  
AND COMPASSIONATELY  
ACHIEVE THE BEST  
EXPERIENCE AND OUTCOME  
FOR THAT PERSON AND  
THEIR FAMILY.”

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-YEOMAN G, FURLONG P, SERES M, ET AL, DEFINING  
PATIENT CENTRICITY WITH PATIENTS FOR PATIENTS AND  
CAREGIVERS: A COLLABORATIVE ENDEAVOUR. BMJ  
INNOVATIONS 2017;3:76-83.

# Patient Payments

## Streamline Payments on the Most Widely Adopted Clinical Data Platform



Medidata's Patient Payments enhances the experience of clinical trial participation by offering a stress-free, secure, and efficient reimbursement and payment process for trial participants within myMedidata. This patient-centered solution, built on the most widely adopted clinical data platform, empowers patients with choice and flexibility in managing their payments. For sites and sponsors, it brings unparalleled speed and seamless data integration, alleviating site administrative burdens so they can focus on what matters most – patient care and efficient trial management.

## Medidata's Patient Payments Solution Enables:



### Excellent Patient Experiences

Leverage myMedidata's patient portal and Help Desk for seamless trial engagement and patient assistance.



### Engaged Patients with Choice and Control

Put the patient in the driver's seat and offer flexible payment options and visibility into the process, meeting the patients where they are.



### Swift Payment Processing Within a Unified Data Flow

The Medidata Platform and integrated data facilitate automated payment processing.



### Elimination of Financial & Administrative Burden

Ensure no patient bears a financial burden in their clinical trials. Enhance site-patient relationships with reduced administrative tasks.

## Features at a Glance



Automated and secure payment processing



Integrated data flow from EDC and eCOA



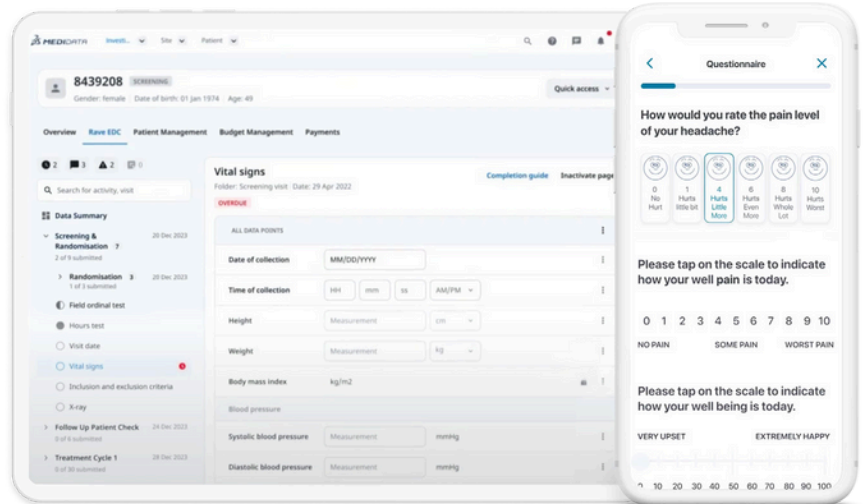
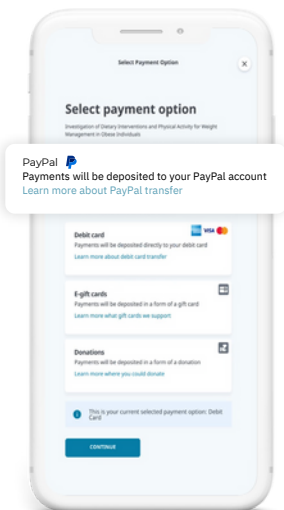
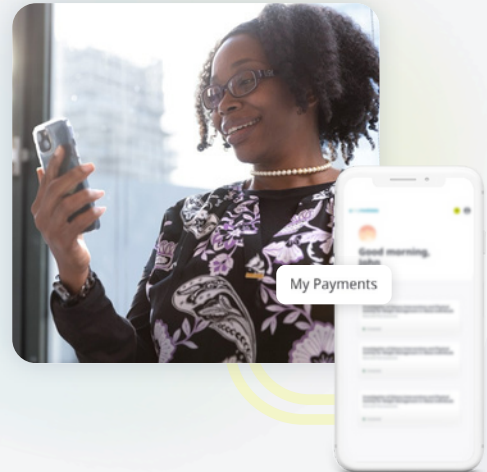
Easy access and full visibility for all users



Preferred payment options for patients



Detailed and transparent payment receipts



### Patient Choice & Visibility

Patients choose their preferred method of payment directly in myMedidata

### Data Integration, Transparency & Control

Sponsors and CROs gain a comprehensive view and management of patient payments, seamlessly integrated and automated through EDC and eCOA data

Empower your sites to provide a worry-free patient experience with Medidata's Patient Payments. Combining convenience with patient care, it's a straightforward solution for more efficient trials and delighted study participants.

With the Medidata Platform, Sponsors & CROs can experience an end-to-end clinical finance experience, while sites and patients can work within a flexible DCT experience.



# POP INNOVATIONS



## Patient Payments - SiteTech Board Insights

**Objective:** To analyze the patient processes at the site to identify opportunities to accelerate data-driven payments to patients.

Lessons Learned	Value
Sites have multiple data entry points which can delay patient payments	Validation of our approach against site and patient burden and experience
Sites have to check source systems against each other to verify data and process completion	Identifying opportunities for further features and enhancements
Sites prefer to use their own technology	An opportunity to gain a deeper understanding of the current approaches being used in the marketplace
Sites hold significant leverage in negotiating how patient payments are processed (site system vs. sponsor system)	Assess site perspectives on technology adoption





# HAVE YOU HEARD

## PRODUCT ENHANCEMENTS



### RAVE GRANTS MANAGER

#### [CTFM Data Release Dashboard](#)

- **Phasing Out Physician Salary Codes.** Gradually phasing out V1110 and V1111 codes to be replaced with codes that reduce variability, simplify FMV assessments without complex calculation, and improve the accuracy informed by the CTA line items.
- **Committed Data Adjustment** - To address quarterly fluctuations and unnecessary adaptations to modernize data points, we have implemented additional algorithmic adjustments and data consortium refinement.
- **Expanded Hourly Rates (UK)** - We are pleased to announce the expansion of our Hourly Rate offering to the United Kingdom. This enhancement will provide more comprehensive and localized rate information for clinical trials conducted in the UK.
- 
- **UK ICT Codes Integration** - We are thrilled to announce a groundbreaking partnership with the National Institute for Health and Care Research (NIHR) to integrate the UK interactive Costing Tool (iCT) directly into Grants Manager Planning. Providing users centralized access to both FMV global costs and UK ICT pricing, simplifying budgeting for clinical trials. For more information on the NIHR partnership and its impact on clinical trial budgeting, please visit our [blog post](#).

### RAVE SITE PAYMENTS

#### [Site Payments Knowledge Hub](#)

- **Implement splits at the time of invoice generation** - Faster payment processing with less manual input and workarounds involved, especially in Eastern European sites where this scenario is prevalent.
- **Ability to generate invoices or payments for auto-approved costs** - To increase efficiency and reduce the management of the cost approval process to an Invoice or a Payment.
- **Imports / Exports** - Support for Column Delimiter and Decimal Separator – Better support for European payment application users when mass importing and exporting data.
- **Update Israel tax rate** - To ensure accurate calculation of taxes for payments for Israeli payees.
- **Enhancement to event costs audit visibility on Site Payee Contracts** - To allow finance users to review updates to events costs without opting for the Site payee contract approval workflow.
- **Convera Enhancements** - Additional validations for IBAN, account number, and Bank Branch Sort Code (Routing Code)



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[UK NIHR News](#)



## Blogs

[Site Dissatisfaction and Challenges in Clinical Trial Financial Management](#)  
[Clinical Trial Financial Management: How to Manage Global Tax](#)  
[Clinical Trial Financial Management: Investigator Grants Clinical Trial Forecasting](#)  
[NIHR & Medidata: Working Towards a Global Clinical Trial Budgeting Approach](#)  
[NIHR & Medidata: Knowledge, Expertise & Collaboration Lead to Improved Clinical Trial Budgeting](#)

## Webinars & Videos

[Hot Topics in Clinical Finance](#)  
[Innovative Clinical Finance Video Series](#)  
[Medidata Elevating the Site Voice](#)  
[The Future of Site Budgeting & Payments: Turning Lessons Learned Into Solutions](#)  
[Raising the Site Voice: The Future of Clinical Research Depends On It](#)

## Publications

[Better Data, Better Decisions](#)  
[Creating Budget & CTA Contracting Partnerships](#)  
[Clinical Trials Arena Article: How a well-planned clinical trial budget can help prevent burning bridges](#)  
[How Sponsors and Sites Can Achieve a Harmonious and Optimized Site Budget Negotiation Process White Paper](#)  
[Translating Your Protocol into Clinical Financial Management](#)  
[NCVR - The True Price of Negotiation](#)

## Podcasts

[Beyond Numbers: Revolutionizing Clinical Trial Budgeting](#)  
[Collaborating for Transparency: Site Budgets & Payments](#)



CLINICAL TRIAL FINANCIAL MANAGEMENT



Power of Partnership