



# Power of Partnership

# ISSUE 12

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

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## **POP VOICE**

## Medidata Becomes First Life Sciences Company to Integrate UK Mandated Health Costing Data into Its Financial Management Portfolio

Incorporating the UK integrated Costing Tool (iCT) pricing into Medidata Grants Manager is expected to amplify UK budget precision by up to 80%

<u>Medidata</u>, a Dassault Systèmes brand and leading provider of clinical trial solutions to the life sciences industry, has integrated data from the <u>UK interactive Costing Tool (iCT)</u>, hosted by the <u>National Institute for Health and Care Research</u> (NIHR), into Medidata <u>Grants Manager</u>, creating a first-of-its-kind offering in the life sciences space. This will consolidate study budgeting with consistent costs, coding, and processes.

"The ability for clinical trial teams to efficiently develop grant budgets and administer site negotiations is a crucial function of a trial," said Meghan Harrington, vice president, clinical financial management, Medidata. "Incorporating the UK iCT into Grants Manager streamlines the study start up process and improves budget precision by up to 80%."

The UK approach for commercial study costing and contracting relies on a standardized budget template with specific codes and costs to ensure efficient budget preparation. The manual transfer of data from the UK iCT system into budgeting applications creates inefficiencies, including delays and duplication of efforts that increase the risk of errors. Integrating UK iCT data directly into Grants Manager overcomes these challenges by eliminating the need for manual data entry, significantly reducing preparation time and supporting data consistency across platforms.



Our overarching mission as an organization is to advance the nation's health through groundbreaking research, and with Medidata's support, we are proudly positioning the UK as a global leader in this endeavor," said Laura Bousfield, national research delivery director, NIHR. "This Medidata solution empowers us to improve UK budget accuracy, creating a process that is more systematic and reliable. This empowers research sites, organizations, and sponsors to conduct impactful studies and accelerate the development of life-changing medicines."

Medidata has worked closely with the <u>NIHR</u> using insights to enhance Medidata's grant lifecycle services. Through relationships with NIHR and active participation on both the <u>National Contract Value Review Advisory</u> <u>Board</u> and UK Commercial Costing Reference Group, Medidata continues to amplify its Grants Manager platform while contributing to industry-wide breakthroughs.

Grants Manager is part of Medidata Clinical Trial Financial Manager, for more information:

**Visit here** 



# FIND A GROUP OF PEOPLE WHO CHALLENGE AND INSPIRE YOU, SPEND A LOT OF TIME WITH THEM, AND IT WILL CHANGE YOUR LIFE.

AMY POEHLER

## **IMPACT REPORT**

## Celebrating the Unsung Heroes: Medidata's Site Payments Managed Services Team

By Tina Mincher

Behind every successful clinical trial lies a network of dedicated individuals ensuring that the logistics and operations flow seamlessly. Among these is Medidata's Site Payments Managed Services Team, a group of humble yet impactful heroes who play a pivotal role in the clinical trial ecosystem. Their work goes beyond the numbers—they are the backbone of trust and reliability that keeps relationships with sites and investigators strong.

#### The Power of Teamwork and Expertise

Medidata's Site Payments Managed Services Team is more than just a group managing transactions; they are relationship-builders and problem-solvers. Their mission is clear: ensure that sites are paid in a timely and accurate manner, all while alleviating the administrative burden for sponsors.

Their work extends far beyond managing spreadsheets. They navigate the nuances of reconciling payments, forecasting costs, and processing disbursements—all while maintaining full visibility and transparency for sponsors. Their expertise not only prevents delays but also helps sponsors avoid the fractured relationships that can arise from missed or inaccurate payments. This reliability builds trust, fosters collaboration, and creates a foundation for success across studies.

#### A Snapshot of Their Impact

The numbers behind the team's work speak volumes about their dedication and efficiency. Here's a glimpse into what the team has achieved\*:

#### Over USD 1 billion

disbursed to sites and investigators worldwide

## More than **100,000 disbursements**

completed globally

# Supporting over **40 sponsors**

across industries

Funds distributed across

#### 68 countries

Transactions conducted in

36 currencies

#### **Total Payments Landscape:**



- Over USD 8 billion in payments approved to sites and investigators worldwide
- Over **975,000** total approved payments
- Over **2,700** studies
- Payments approved for over 74 countries
- Transactions made in 54 currencies

These achievements are a testament to the team's hard work, resilience, and ability to manage the complexity of global clinical trials. Every dollar disbursed, every currency converted, and every site paid represents a step toward advancing healthcare.

As Medidata continues to enhance and expand Site Payments Managed Services, we asked the experts to share some insights:

1

What are some of the biggest challenges you face in managing site payments across different currencies and regions? How do you overcome them?

I think site responsiveness is the biggest challenge, and it is not specific to any particular region. Sites are busy, and we understand that it can be easy to miss notifications and reminders. However, our process relies on being able to standardize communications, and handcrafting individual messages to thousands of sites is not a sustainable practice. This is where collaboration with our clients around educating sites about the process becomes critical, so sites understand what needs to be watched for and responded to ensure timely payments.

#### Kevin Kappel, Engagement Director

2

How do you ensure compliance with local regulations when processing payments in so many countries?

To ensure compliance when processing site payments, Medidata has partnered with Convera for disbursements. Our disbursement partner is a "regulated financial company" that must perform both internal and external financial audits, including a SOC2 review. Convera makes payments in 140+ currencies and 200+ countries, and they understand local laws, implement robust KYC (Know Your Customer) and AML (Anti-Money Laundering) procedures, regularly monitor regulatory updates, and leverage technology solutions to manage cross-border payment compliance.

#### Reana Rossi, Disbursement Manager

3

What steps do you take to maintain relationships with sites and investigators and build trust through payments?

Trust is hard-earned, easily lost, and difficult to reestablish. This is a commonly shared maxim, but especially true when actual money is involved. The ideal payments solution places the least burden on sites and investigators while ensuring payments are processed accurately, securely and in a timely manner. We have built robust processes in collaboration with our key vendor partners to process a high volume of payments mostly seamlessly.

However, when sites raise queries related to their payments, appropriate responses are essential to maintaining a good relationship. To achieve this, we apply a model that progressively engages more senior members of the Managed Services team and ultimately the Payments Operations PM when communications with the site are not leading to a resolution. This ensures that more complex issues are highlighted and receive the correct level of response that is satisfactory to the site. The character of a service provider shows best in how they handle situations where things don't go as expected. We look at these as opportunities to build trust with the sites and investigators by giving them confidence that while we strive for perfection, when things go wrong, we'll fix it.

#### Mitchell Munoko, Engagement Director

4

Are there trends or insights you've noticed in payment operations that could help us better support sponsors and sites in the future?

I think many things contribute to the smooth running of payments throughout the timeline of a study, particularly at times when there are changing requirements. Our adaptability and drive to find innovative solutions, big or small, as a team has always been our strength, along with our collective individual skill sets and experiences. When I consider the challenges of the past and the improvements we have made over time, I think it comes down to some simple core principles, with it all looping back to the word: clarity. Firstly, clarity is essential in the contracts. We do not always come in to a project at a stage where we can effect the contracts but when we do it is important to ensure the sponsors are aware of all the elements to include and best practices, the contract is the key driver for what comes after as the guideline throughout the study so getting this right in the beginning is imperative. An example of this is the innovation of the dynamic PAI (Payment Account Information) form which Mitchell Munoko designed and created. This intuitive form dynamically changes based on country and guides the site through entering all the details, some of which are not in a standard contract, from banking information to site contacts for invitations to the site portal, the form makes this process simple and clear for all. The second core principle relates to the clarity in the data. It is important that data is entered in the system in a uniformed and consistent way. This enables the ability to reconcile, understand, and explain what is happening with the costs and payments at any given time while creating reporting that aids us in managing the studies. This leads in to my final point and, perhaps the most important, clarity in communication is critical. A calm and patient approach is paramount to understanding the needs of sponsors and sites in a changing and progressive world which then feeds back to our drive to always find creative solutions and ties everything together along with our ability to communicate back, advise and educate where needed. These principles all link together to create a supportive and positive experience for the sponsor and site. Personally coming from a particularly data leaning perspective, I always resolve back to my mantra, making the complex simple... Clarity.

#### Richard Sparkes, Senior Project Manager, Payments Operations



What's the feedback you've received from sponsors or sites about our services, and how can we leverage this to improve even further?

We receive a lot of positive feedback about working with our managed services team, as well as the ability to process payments in many currencies. Most clients appreciate the time they receive back, knowing we are seamlessly managing payments once we are through implementation. Timely and accurate payments have always been high on our priority list, which clients appreciate. A major recent improvement to this has been implementing a new disbursement partner. With this new partner, we now have the flexibility to process payments within 24 hours and without any additional charge to the clients. This improved turnaround time does not add much additional work to the client approval process. Many clients have shared their happiness with this improvement, which gives us quite a bit of leverage over competitors in the industry.

Mary Kate McDermott, Senior Project Manager, Payments Operations

#### Final thoughts from Charles Meier, who leads the team:

The core of our strength is our teamwork. Seemingly every week, we are presented with new challenges that one teammate may not be able to solve alone. But once we come together to discuss the issue, we are always able to combine the broad array of knowledge, experience, and skillsets to find a solution and, most importantly, to satisfy the client by getting their payment or request executed.

**Charles Meier, Principal, Director Payment Operations** 

#### **Looking Ahead**

5

Medidata's Site Payments Managed Services Team exemplifies the company's commitment to innovation, reliability, and trust. Their expertise is essential to the success of clinical trials, and their adaptability is key as the global payments landscape continues to evolve. Together, we are driving meaningful progress and shaping the future of clinical research.

## **POP INNOVATIONS**

# Client Strategy Client Innovation and Collaboration Network (CICN)

#### **Unlocking Innovation and Collaboration**

In today's fast-paced world, staying ahead requires more than just adapting to change—it demands innovation, collaboration, and a commitment to shared learning. That's why the Client Innovation and Collaboration Network (CICN) was created. Designed with our clients at its heart, CICN is a dynamic network that transforms how we connect, engage, and innovate together.



#### What is CICN



#### A Network Built for You

CICN is a client-focused ecosystem built to inspire creativity, enhance collaboration, and foster innovation. Through a suite of targeted initiatives, CICN provides clients with multiple avenues to exchange ideas, explore cutting-edge solutions, and directly shape the future of our shared industry.

The CICN is a community where clients are at the forefront of innovation and collaboration. By combining micro labs, user clubs, blogs, podcasts and webinars, CICN creates a multi-touch engagement model that ensures you stay informed, connected, and empowered to drive success in your organisation.

InnoLabs

**Client ClubNet** 

**CICN Insights** 

**CICN Spotlight** 

#### **Innovation Doesn't Happen in Isolation**

By joining the Client Innovation and Collaboration Network, you'll gain access to a vibrant community dedicated to solving challenges, exploring new opportunities, and shaping the future—together. Let's innovate, collaborate, and grow. Your voice matters. Your ideas matter. And through CICN, they'll make a difference.

#### The New Era of Client Experience

Client Innovation and Collaboration Network (CICN)

## InnoLabs Hands-On Innovation

InnoLabs are brief, interactive sessions designed to drive dynamic discussions, brainstorm, and spark innovation quickly. These 30-minute labs offer collaborative problem-solving and allow clients to address specific challenges and explore different opportunities in a fast-paced format.

InnoLabs focus on innovation by exploring new ideas and solutions that directly address client needs and concerns.

## **CICN Insights**Thought Leadership at Your Fingertips

CICN Insights will capture key takeaways, solutions, and insights from the InnoLabs and ClubNet sessions. Specifically designed to be easily referenced by the CICN community, ensuring that innovation and knowledge sharing extend beyond InnoLabs and ClunNet.

The goal is to provide concise insights on innovation trends, outcomes, and other key updates and to serve as a valuable resource for clients and a way to keep everyone informed and engaged.

#### **ClubNet** Your Voice Amplified

ClubNet serves as a platform to showcase highlights and spotlights on key trends, innovations, and success stories. The User Clubs will facilitate deeper connections between clients and experts, allowing them to continue the innovation dialogue, refine ideas, and implement solutions.

ClubNet is designed to build community and create a space for active participation, allowing clients to share feedback and insights while learning from their peers.

## **CICN Spotlight**Learn, Share, Grow

CICN Spotlight serve as an outreach tool to highlight CICN's innovation capabilities, showcase success stories, and invite broader collaboration.

These sessions will demonstrate the value of the CICN with thought leaders, and industry experts sharing their experiences on relevant trends, challenges, and opportunities in innovation.

## SITE SPOTLIGHT

## Reimagining Clinical Research: Reducing Site Burden and Enhancing Efficiency

Clinical research sites play a crucial role in advancing medical science, but they face numerous challenges that can hinder their efficiency and effectiveness. According to ACRP, 70% of global investigative site staff reported that trials have become much more difficult to manage in the last five years<sup>1</sup>. From the burden of manual data entry to the complexities of managing placebo arms, these obstacles can be overwhelming. However, envisioning a future where these challenges are mitigated can inspire hope and drive innovation.

#### **Challenges Faced by Clinical Research Sites**

1 Manual Data Entry

58% of sites struggle with manual data entry and data management<sup>2</sup>. This process is not only labor-intensive but also prone to errors, which can compromise the integrity of the data collected.

Payment Delays

60% of sites struggle with limited operating cash and financial transparency<sup>3</sup>. Timely payment is essential for the smooth operation of clinical research sites. However, delays in payments can disrupt operations and strain resources, making it difficult for sites to maintain their high standards of research.

Placebo Arms

Managing placebo arms in clinical trials is another significant challenge. It requires meticulous planning and execution to ensure that the placebo effect does not skew the results, adding to the complexity and cost of trials.

**Technology Inefficiencies** 

47% of sites find it difficult to adopt new technologies and systems<sup>2</sup>. With the continued use of disparate technologies sites continue to feel the burden of managing multiple passwords and logins, increased training hours, and becoming the support desk to their staff and their patents.

#### A Vision for the Future

Imagine a world where these burdens are significantly reduced, allowing clinical research sites to focus more on their core mission of advancing medical science.



## Elimination of Manual Data Entry

With the advent of advanced technologies like Medidata's Rave Companion and Health Record Connect, the need for manual data entry can be eliminated. Rave Companion works like a data entry assistant and allows data to be captured once and automatically populated into Rave EDC. Health Record Connect connects EMR to EDC, decreasing the administrative burden of data entry and eliminating queries due to transcription errors.



#### Placebo Arm Alternatives

The use of virtual twins—digital replicas of patients—can revolutionize the way placebo arms are managed. By simulating the placebo effect, virtual twins can eliminate the need for actual placebo groups, making trials more efficient and appealing to study participants.



## Timely Payments with EDC Triggers

Our Medidata Site
Payments solution triggers
payments automatically
upon the completion of
specific EDC fields. This
ensures that sites are paid
on time, reducing financial
strain and allowing them to
focus on what's important—
their patients.



#### Technology built by sites and patients for sites and patients

Here at Medidata, we believe that to be patient centric, you must also be site centric. Sites and patients are our partners, not just our end users. Medidata has developed a multi-tier <u>Site Insights Program</u> to bring the site voice into everything we do. The program includes our:

#### **Site Advisory Board**

Top executives from all site types around the globe that support our strategy and innovation.

#### **Site Tech Board**

In partnership with the Society of Clinical Research Sites (SCRS), our site tech board includes operational leaders from sites around the globe that work directly with our product and design teams to optimize our current technology solutions and pilot innovations for the future.

#### **Engage Site User Community**

A community of site members where communication about Medidata is centralized, including access to training and support. The community shares best practices, and members are encouraged to be part of our thought leadership, joining us at industry events and our NEXT series.

#### Conclusion

The challenges faced by clinical research sites are significant, but they are not insurmountable. By embracing innovative solutions and advocating for site needs, we can create a future where the burden on clinical research sites is greatly reduced, allowing them to thrive and continue their vital work in bringing new treatments and therapies to those that need it most.



#### References

- https://acrpnet.org/2024/10/22/discover-the-top-site-challenges-of-2024-data-and-insights-on-site-barriers-and-trial-efficiency
- https://www.wcgclinical.com/wp-content/uploads/2023/05/WCGs-2023-Clinical-Research-Site-Challenges-Survey-Report.pdf
- 3 https://myscrs.org/learning-campus/white-papers/

## **HAVE YOU HEARD**

CTFM PRODUCT ENHANCEMENTS



#### **RAVE GRANTS MANAGER**

#### **NIHR Search Enhancement**

Improving the search functionality for UK iCT codes to reduce duplication and enhance efficiency.

## Other Direct Cost Search and Pagination Improvement

Enhancing the ODC code search and pagination for a more efficient and streamlined budgeting process.

#### NIHR Market Forces Factor & Capacity Building Adjustments

Automating MFF and Capacity Building Adjustments within the Grants Manager code set to align with the Interactive Costing Template (iCT), ensuring more accurate budgets.

#### **French Hourly Rates Additions**

Incorporating French hourly rates to improve accuracy and optimize the budgeting workflow.

#### SITE PAYMENTS

#### **Retrospective Cost Correction**

This new feature will highlight discrepancies between approved costs (whether paid or pending payment) and the original event cost.

#### **Split Invoices to Site Payees**

Users can now remove a split portion from an invoice. This enables corrections to be applied to split invoices. There is a new Related Split Invoices section on the Payments view that shows several split invoice attributes & the Associated Invoices section on the Payments view now has a new Split From Invoice column to show the parent Split Invoice.

#### **Contract and Cost Reconciliation Report**

This new budget report streamlines cost and contract validation, reducing the need to navigate multiple screens.

## **Enhancements to Date field labels for Rave Integrated Studies**

'Date' fields updated to enhance integration.

#### **Request for Invoice Enhancement**

A new "Request for Invoice/Invoice Number" field has been added to the Payments pages, allowing for easier payment searches by request or invoice number.

#### **Updates to Event Cost All Trigger Import**

New validations have been added to the Currency column in the Event Costs All Triggers import to ensure smooth cost setup and prevent issues in cost generation.

#### Slovakia Tax Update

The tax rate for Slovakia has been updated and is applicable to all invoices created from January 1, 2025.

#### **Cost Page Filter Enhancements**

The Activity and Subject filters on the Study Cost pages have been updated to ensure consistent record search across Cost pages with improved usability.

#### **Cost and Payment Summary Report update**

Two new filters, "Sponsor Filter" and "Start Date Filter," have been added to enhance usability.

#### **Disbursement Enhancement**

The BIC field is auto-populated with the Bank Swift Code on the Add Payee page. The BIC field is also editable.

#### **PATIENT PAYMENTS**

#### **Expanded Patient Choices**

Patients will have additional global payment options to choose from, including PayPal International, eDebit, eGiftcards, and Venmo.

#### Reimbursements on myMedidata Mobile App

In addition to all the other patient activities on the app, patients can use myMedidata app to request reimbursements.

#### **Tax Support: W-9 Collection**

US-based patients will be prompted to fill out a W-9 as part of the payment setup through myMedidata.



## **GROW WITH US**

NCVR - The True Price of Negotiation

New Methods to Budget Negotiations That Really Work - NEXT NY Session

POP Magazine Issue 11

**CTFM Resource Page** 

**UK NIHR News** 

#### **BLOGS**

Site Dissatisfaction and Challenges in Clinical Trial Financial Management

<u>Clinical Trial Financial Management: How to Manage Global Tax</u>

NIHR & Medidata: Working Towards a Global Clinical Trial Budgeting

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

Raising the Site Voice: The Future of Clinical Research Depends On It

Patient Payments Webinar

#### **PUBLICATIONS**

Better Data, Better Decisions

Creating Budget & CTA Contracting Partnerships

How a well-planned clinical trial budget can help prevent burning bridges

<u>How Sponsors and Sites Can Achieve a Harmonious and Optimized Site</u> Budget Negotiation Process

#### **PODCASTS**

Beyond Numbers: Revolutionizing Clinical Trial Budgeting

Collaborating for Transparency: Site Budgets & Payments





#### CLINICAL TRIAL FINANCIAL MANAGEMENT



Power of Partnership