MEDIDATA

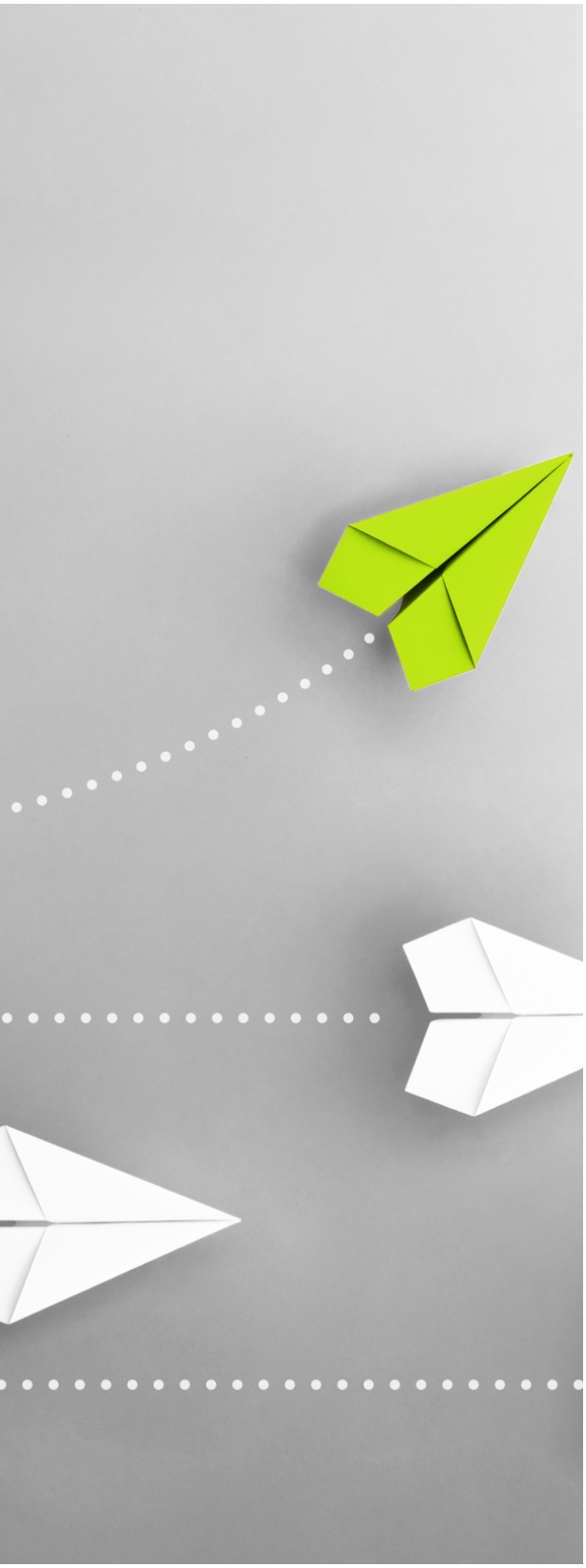
POP

Power of Partnership

ISSUE 06

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

POP ISSUE 06 CONTENTS



POP VOICE

Personalized Payment Analytics

By Meghan Harrington

Sponsor and CRO business operation teams face tremendous pressure to develop an accurate budget that reflects therapeutic considerations and site-specific differences while also ensuring that the spending stays within corporate constraints. The accuracy of the study and site-specific budgets are a critical planning step in the financial health of a study. The approved budgets then drive the contract negotiations with the sites, ultimately becoming the payable items to the site once the study is underway.

A recent survey by Medidata shows that 53 percent of sites, sponsors, and CROs agree that lack of transparency between the parties leads to inaccurate budgets and CTA agreements and causes financial instability for all parties.

Traditional methods of disbursing funds to a PI or site result from 20+ hand-offs and cross-verifications in multiple systems, manual data entry, and approvals. One Sponsor client has shared that manual processes and checks consume 80% of their time and effort in financial planning. This complicated and disjointed workflow makes it a resource-intensive effort to pull analytics on budget vs spend and to generate portfolio-level reporting.

Modern oversight is fluid and should be changing based on real-time data. Optimizing the financial oversight capability via an extended data reach brings tangible value during planning and execution by aligning budgets with corporate strategic objectives. A team can proactively analyze how procedural selection impacts study complexity, site, and patient burden, affecting the study budget and subsequent study start-up timelines.

Further, connected financial oversight gives Sponsors/CROs full transparency to the data to ask (and answer) questions such as: Where is study X's actual spend compared to budget? What are study/portfolio payment cycle timelines? What regions have the highest costs by therapeutic area? What is the relationship between differing quality strategies and site compliance with invoice submission? These insights gleaned from the data can be leveraged to adjust the financial strategy of a study, introduce mid-study changes, and plan for the future.

Our Site Payments application has been leveraged to support 2,500 global studies and facilitated over $5.8B in grant payments in 74 countries. There is rich data to mine regarding payment cycles, regional costing differences, site compliance with invoicing, and budget variance, to name a few. That said, a recurring question we receive from clients and sites is how COVID-19 has impacted grant payments. In the current macroeconomic climate, the sense is that the cost to conduct research has increased and should, therefore, be reflected in visit costs.

The Clinical Trial Financial Management team partnered with the Platform Data Science team in Medidata AI. We mined the wealth of data in our Site Payments solution to look for answers to questions that our clients and teams had about the volatile time surrounding the COVID-19 pandemic. The Platform Data Science team aims to be the first stop for Medidata teams that seek scalable data science solutions that leverage deep industry knowledge and a strong data science focus to solve high-impact Life Science challenges.

Individual cost transactions pooled from different customers were analyzed. Our analysis focused on costs incurred between January 2020 and June 2023, which resulted in approximately 7.6 million individual transactions. All costs were normalized to USD and adjusted for inflation for comparison purposes.

Figure 1: Distribution of Payment Cycle Lengths between 2020 and 2023. The horizontal axis represents the cycle length in days, while the vertical axis represents the number of payment transactions. Payment transactions in which payments were created between 2020 and 2021 are considered “during COVID-19” and plotted in Figure 1A. Payment transactions in which costs were created between 2022 and 2023 are considered “after COVID-19” and are shown in Figure 1B. The mean cycle time for all transactions from 2020-2021 is 138 days, while the mean cycle time for all transactions between 2022-2023 is 68 days. The mean cycle time for all completed transactions in our investigation was 127 days.

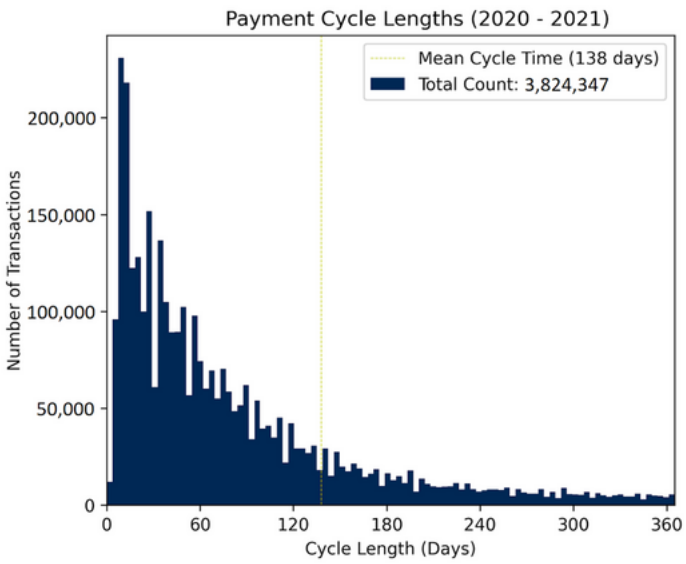


Figure 1A

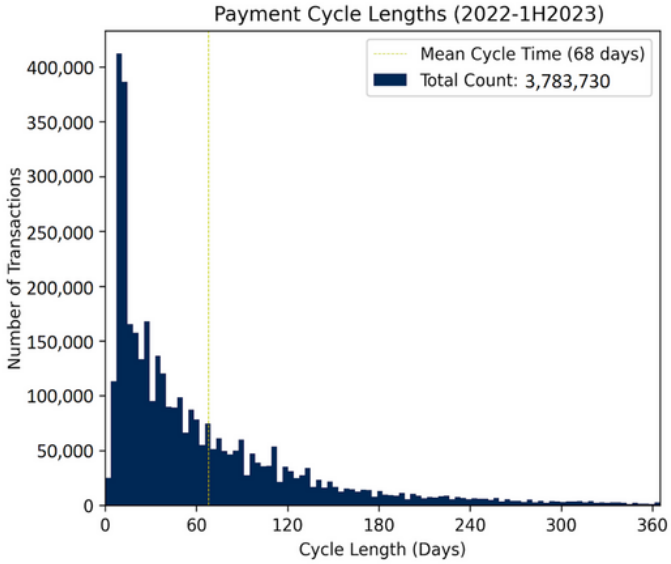


Figure 1B

One of the key findings of our analysis was the wide range of payment cycle lengths that we observed. We measured the payment cycle as the number of days between when a cost was created and the date that the cost was paid. As shown in the histograms in Figures 1, the lengths of individual payment cycles varied greatly, from less than 30 days to over one year. The mean payment cycle time between 2020 and 2021 was 138 days, and between 2022 and 2023 was 68 days. Our data shows that 16% of payments are made within 14 days of cost creation, and 49% of all payments are made within 60 days. However, approximately 39% of records analyzed had a payment cycle longer than 90 days.

The large proportion of costs that take longer than 90 days for payment indicates room for improvement in the efficiency of clinical trial financial management. With increased visibility into their payment cycle trends, organizations may identify opportunities to streamline their processes and reduce the time it takes to complete a payment cycle. This could lead to cost savings and improved outcomes for clinical trial sponsors, researchers, and participants. Additionally, reducing the length of payment cycles could improve the overall speed and efficiency of the clinical trials industry, enabling organizations to conduct more trials and potentially bring new treatments to market more quickly.

Rank	Country	Mean Payment Cycle Length (days)
1	Tunisia	290
2	Lithuania	244
3	Peru	236
4	Slovenia	234
5	Croatia	228
6	Latvia	213
7	Belarus	208
8	North Macedonia	206
9	Saudi Arabia	206
10	Georgia	201

Figure 2

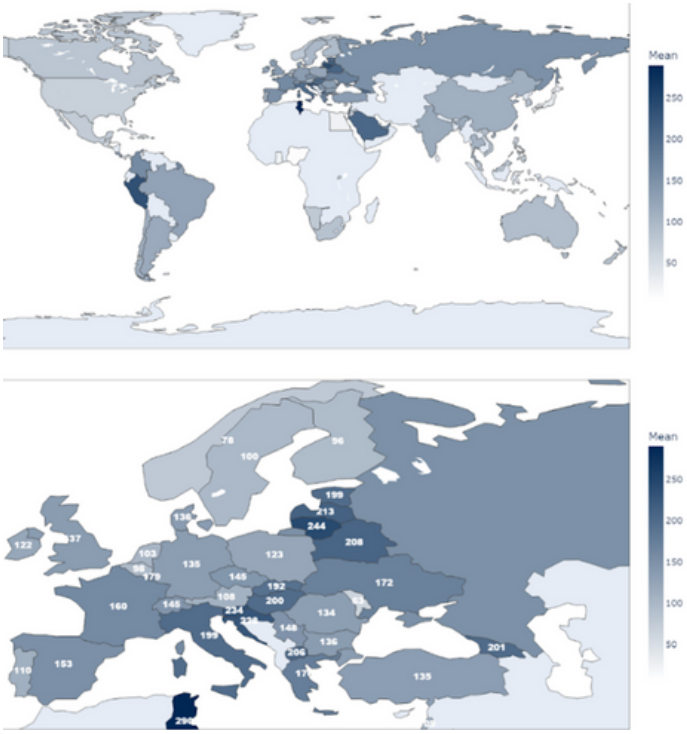


Figure 2 is a choropleth map that shows the mean payment cycle length for clinical trials in different countries worldwide. The map is color-coded, with countries with longer mean payment cycles in darker blue and countries with shorter mean payment cycles in lighter colors. Figure 2A shows the entire world, while Figure 2B is a zoomed-in view of Europe.

Notably, there is a wide variation in mean payment cycle lengths among different countries. Tunisia, Lithuania, Peru, and Slovenia lead the list, all having average payment cycles of 234 days or more. The data show that Tunisia, Lithuania, and Peru have the longest payment cycles globally during this period, which could reflect in-country regulations and practices, a slower operationalization of hybridization of research activities, or speak to regional macroeconomic differences. All are worthy of further inquiry to determine if process refinement or further support of sites is warranted.

The collaboration between the Clinical Trial Financial Management and Data Science teams uncovered meaningful differences in global payment practices from 2020 to 2023. In addition to payment cycle trends, the team analyzed trial cost variances by therapeutic area and geography. These additional data insights will be published in a forthcoming white paper.

When we leverage Medidata's financial suite of products as the engine that powers the financial health and management of the study and further strengthen it with the computational power and methods of data sciences, data analytics in the workflow approach can be realized for the customers. This partnership of technology, insights, and customer input is the foundation from which sponsors and sites can narrow their focus on researching and delivering exceptional patient care. This is only possible with the rich historical and cross-industry data available through the Medidata Site Payments.

Better data, better decisions.

"The most valuable commodity I know of is information. “

- Gordon Gekko

POP PERSONALITY

Meet Kevin Kappel

Tell us a little about yourself.
I have lived in the suburbs around the Twin Cities of Minneapolis and St. Paul, Minnesota, since 1999, and I will be moving into St. Paul “proper” this September. I have two rescue dogs, named Indy and Sasha, who I think spend most of their time silently judging me for not feeding them a steady diet of treats.

What do you do outside of work?

Outside of work, I enjoy cooking (more so if it’s for someone else), motorcycling (in the non-winter months, of course), and soaking in my record collection on a vintage audiophile stereo.

How long have you been at Medidata?

I joined Medidata in 2011 as part of the Clinical Force acquisition and have been part of the Professional Services team for my entire tenure here.

Would you rather...

be able to talk with animals or with plants?

Animals! I want to be able to explain the meaning of personal space to one of my dogs, and…well, I have a lot of questions for the other dog.

live twice as long or win the lottery?

I would rather win the lottery so I can use the proceeds to try and live longer.

explore space or the ocean?

Space for sure. I’m a sci-fi nerd and would love nothing more than to spend my days cruising around the galaxy.

lose your car keys or your smartphone?

Car keys. If someone else finds them, they’ll have a harder time stealing my identity than they would with my phone.

time travel to the future or the past?

Tough call, because the future probably has spaceships, but I’d probably go to the past because I’d love to experience the Roaring 20’s.

"I feel incredibly fortunate that I’ve spent my time at Medidata surrounded by teams of talented and motivated colleagues."

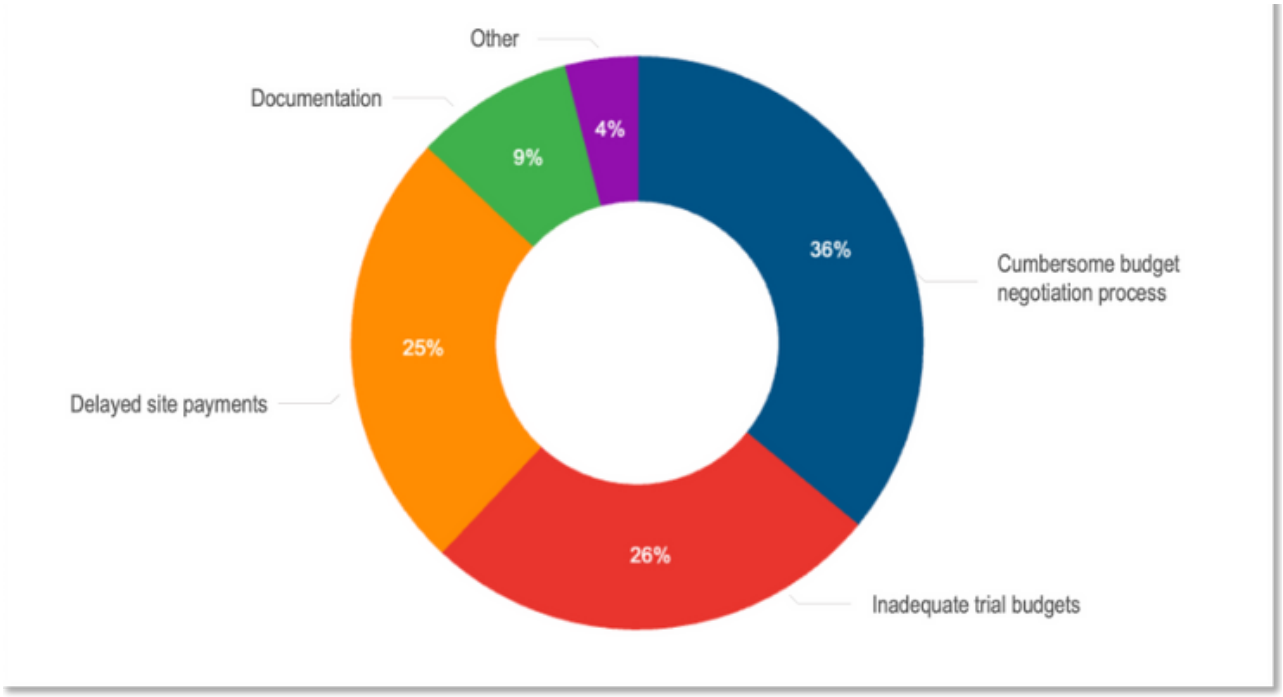
IMPACT REPORT

Perfecting the Partnership

By Tina Mincher

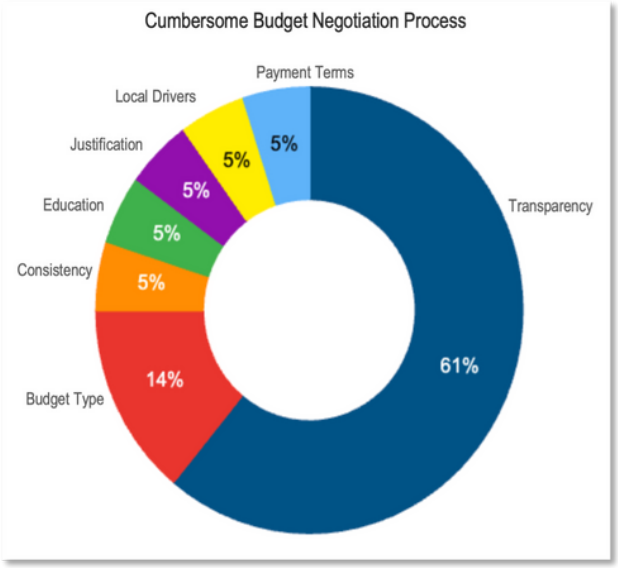
Effective clinical trial operations ensure harmony between sponsors, sites, patients, and CROs. It requires coordination, precision, communication, and a well-planned approach to achieve optimal outcomes. Having thoughtful budgets and timely payments helps facilitate a strong partnership between sponsors and sites.

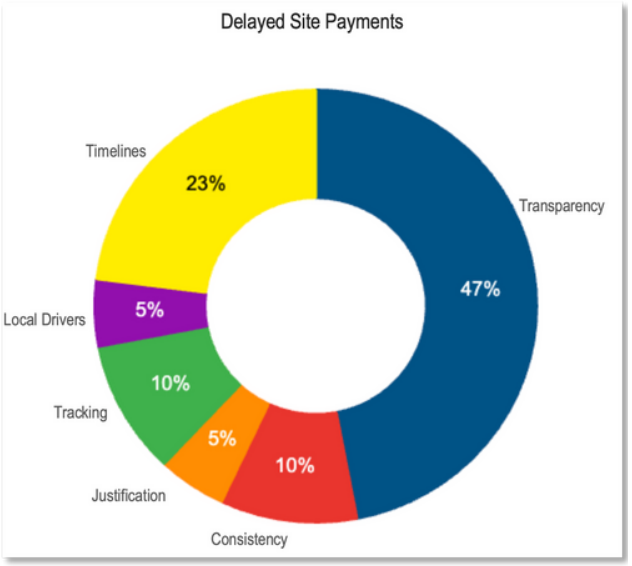
The Medidata Clinical Trial Financial Management (CTFM) team regularly meets with industry leaders, including sponsors, sites, patients, and CROs, to better understand the financial operational concerns. Our team often conducts global surveys, and a recent one highlights three main areas of concern specific to financial operations. Thirty-six percent (36%) stated that the cumbersome budget negotiation process was their primary concern, with 26% saying inadequate trial budgets and 25% contributing to delayed site payments.

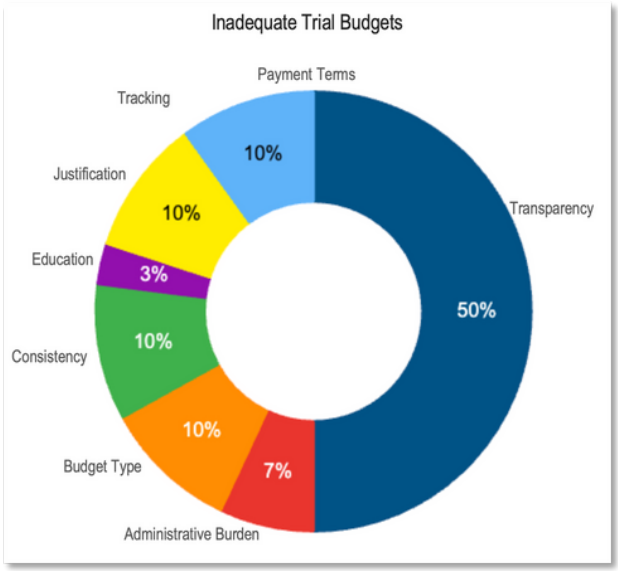


Curious and wanting to dig deeper, the CTFM team asked the surveyees to expand on the problems within each of those top three main areas. What we found was interesting. Both sponsors and sites cited a lack of transparency as the primary cause of issues in all three main concerns, leading by over a 45% margin.

After seeing the survey results, we returned to the surveyees and our broader Power of Partnership contributors to gain additional insights. We know that the successful execution of clinical trials heavily relies on effective financial operations, so we wanted to understand how the industry feels it can increase transparency and build better partnerships.







Sponsors & CROs Quotes

Sites do not understand the budgeting rules & process

Sites add costs without supporting documentation

Sites double count for fees already included in procedure costs

Site Quotes

Sponsor & CROs do not understand budgeting rules & process

Sponsors & CROs do not approve costs after supplying documentation

Budgets not broken down by procedure - too many activities bulked

Open & Transparent Communication

Set the strategy and goals for effective negotiations and contracting to align teams and departments. Ensure that the strategy and goals include escalation paths, timeline parameters, and schedule budget and contracting recurring meetings.

Defined Roles & Responsibilities

To avoid confusion and to streamline operations, it is crucial to establish clearly defined roles and responsibilities for sponsors, sites, and CROs. A clear understanding of responsibilities and timelines prevents duplication of efforts, ensures accountability, and promotes teamwork.

Effective and Accurate Implementation

Collaborating with sites during protocol development and operational planning is an effective way to establish fruitful partnerships. Sponsors who actively seek input from trial sites proactively address feasibility concerns and can openly collaborate on budgeting, contracting, and payment expectations.

Collaborative & Flexible Problem-Solving

Clinical trials often encounter unexpected challenges or amendments that require prompt resolutions. Sponsors, sites, and CROs must stay agile to changes in the industry, economic conditions, and site landscapes. Regularly scheduled meetings and forums that allow for collective communication and brainstorming can minimize the impact on trial timelines and increase efficiency in the execution of changes to the budgets and payments.

As the industry continues to foster an environment where clinical trial financial management can move seamlessly, embracing the spirit of collaboration and communication will enhance efficiency, accuracy, and ultimately lead to better healthcare outcomes. We thank everyone participating in our CTFM Innovation Labs and our Power of Partnership family. With you, Medidata's CTFM team will continue to bring the industry voice to the forefront and embrace the Power of Partnership to bring smarter treatments and inspire continuous innovation.

HAVE YOU HEARD

RAVE GRANTS MANAGER

Drug Pricing
The Grants Manager database consortium is growing with its latest UK and US drug pricing addition. Users can now access Medidata's drug pricing library to add comparator and therapy drugs to the visit schedule in their total budget.

Japan Data Improvement
Adding a current logic will allow users to access the entire anticipated library when building budgets in Japan. Users can now access the entire benchmark data elements to create more accurate budgets.

AMA CPT Standards Updates
CTFM annual maintenance to align the Grants Manager codes with the AMA CPT code set and update Medidata internal third-party reference cost sources. Maintaining current industry standards will give accurate and current information to the user when building budgets.

Site Payments Cost Data
Adding the additional dataset from CTFM's site payments solution allows another layer of accuracy to the Grants Manager data source set. Giving the user a greater level of trust in the costs.

Other Direct Costs Description Enhancement
Additional character enhancement allows Medidata to expand the Grants Manager ODC library descriptions to provide accurate and detailed content. This allows the users the visibility to more robust descriptions.

RAVE SITE PAYMENTS

Auto Email Communication Related to Site Payee Contract
Notifications for site payee contracts (SPC) when awaiting approval status to ensure costs are successfully generated without contract approval-related issues.

Auto Email Communication to Sites
Notifying site payees and sponsors in the site invoicing service to expedite the invoice approval workflow

Auto Email Notifications to Site in Local Language
Localized email notifications (multilingual email - supported Spanish and Turkish)

Usability Improvements Payments
Site payee dashboard displays faster as the view is no longer dependent on a refresh of the data from Site Invoicing. The site invoicing data is now refreshed every hour using a scheduled job and is independent of the Site Payee Dashboard.

Enhancements to Study Costs and Payments Export
Optimization to study costs and payments export when payment includes invoicing data. Also, includes additional columns for more relevant information to provide an overview of cost costs and payments.

Convera Disbursement Support
Send withholding tax (WHT) details to payment disbursement gateway (PDG) service as a part of the payment extract will allow withholding tax (WHT) detail to be displayed when remittance PDF is downloaded.

For more product information, visit the knowledge space

Rave Grants Manager Knowledge Hub

Rave Site Payments Knowledge Hub

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CTFM Resources

Clinical Trial Financial Management Resource Page

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

Translating Your Protocol into Clinical Financial Management

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

Blogs & Podcasts

Site Dissatisfaction and Challenges in Clinical Trial Financial Management

How to Manage Global Tax

Investigator Grants Clinical Trial Forecasting

Collaborating for Transparency: Site Budgets & Payments