



Power of Partnership

ISSUE 09

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

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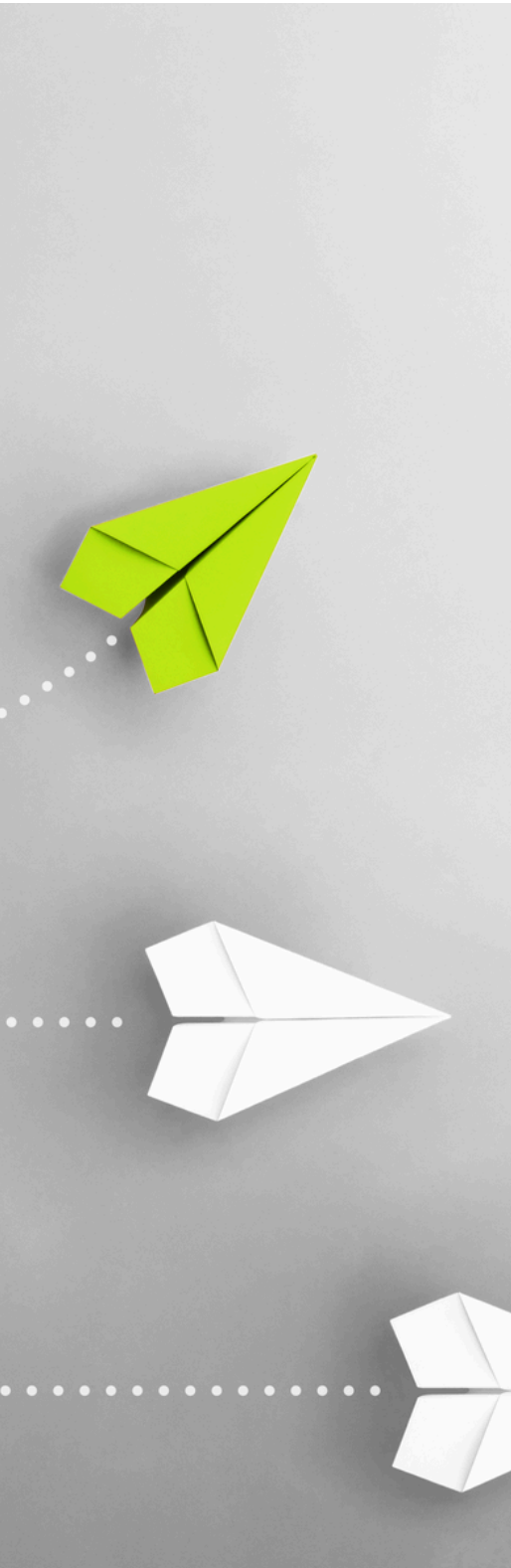
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POP VOICE

Follow the Money - Innovations in End-to end Clinical Trial Financial Management

Unsurprisingly, clinical trial financial management (CTFM) is complex. Surprisingly, a proper end-to-end CTFM solution does not exist... yet. At [Medidata NEXT New York 2023](#), Meghan Harrington, VP, Clinical Trial Financial Management, outlined why an actual end-to-end financial process is needed and shared an exciting announcement.

CTFM Complexity in Context

While the focus of any sponsor will be on meeting their clinical milestones, as Meghan stated:

“Financial management is the engine that drives clinical research activity.”

A study’s financial model mirrors a study’s operational complexity. Costs are compartmentalized according to operating models—usually employing disparate systems, services, and solutions. That complexity is exacerbated by using a mix of manual processes and workarounds, specialized clinical trial financial management software, and services, generating unique financial data sets within their functional remits. Critical areas impacted include site payments, patient payments and reimbursements, clinical trial supply management, vendor management, and overall study budget management.

In a Medidata survey, a sponsor shared the following:

“Manual processes and workarounds consume 80% of sponsors’ time and effort in their financial planning.”

This comment should be shocking, but it’s widely accepted as ‘normal.’ Sponsors apply a disparate mixture of solutions to address challenges—the equivalent of one hundred band-aids for one hundred problems. Without an end-to-end CTFM platform, this practice of using disparate systems and processes (the band-aids) has its positives and negatives.

On the positive side, many independent specialized solutions are available to address specific problems within each operational layer. But implementing these disparate systems creates challenges—interoperability, integration with multiple systems, gaps or duplication of data, gaps in features, multiple user interfaces and logins, scalability, long-term software support issues (for heavily customized systems), and variable quality and availability of training (especially at a global level).

Disjointed processes lead to significant direct and indirect financial impact, so what can be done about this?

The Future of End-to-End Financial Management Is within Reach

Meghan announced that meaningful innovations are on the horizon, as the Medidata Platform is expanding to deliver a single, harmonized, end-to-end financial management experience for clinical trials.

Medidata Rave EDC is already an industry-standard solution integrated with Medidata’s suite of financial offerings. By adding patient payments and reimbursements in the second half of this year and further enhancements to its existing solutions, a sponsor’s financial team will be able to track every single dollar across the lifetime of a study—from early budget planning before draft protocols, all the way to a study close-out—an actual end-to-end financial experience (Figure 1).

Follow the Money: Realizing a True End-to-End Financial Experience

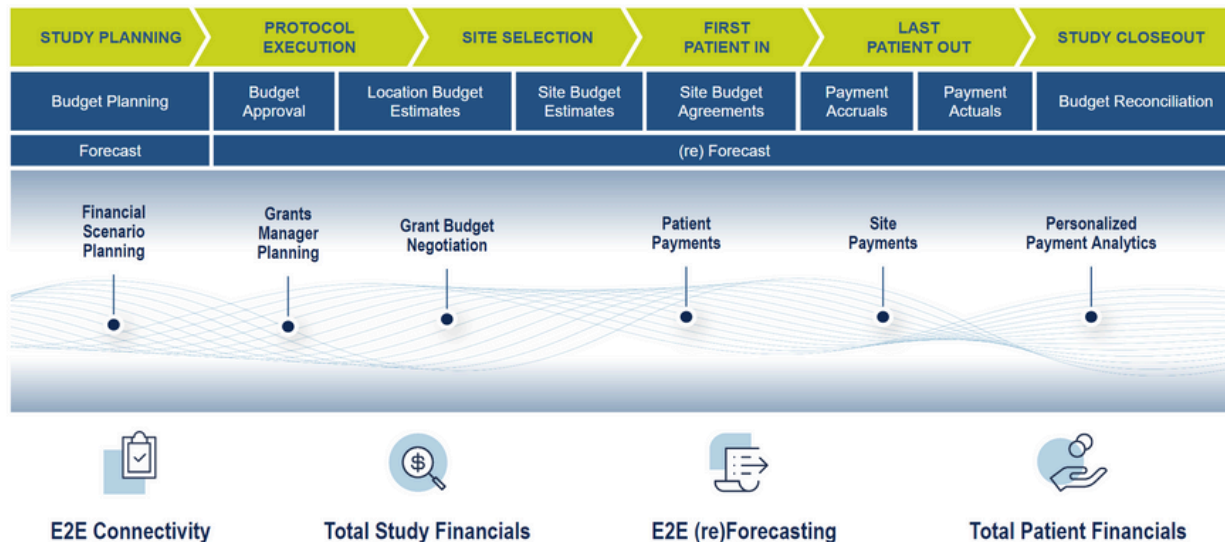


Figure 1. CTFM across the entire lifecycle of a clinical trial.

Meghan shared insights into three key innovations that make an end-to-end CTFM experience a reality.

At its core is data, the critical enabler on the path to innovation.

The site payments application has been used for almost \$6 billion in grant payments in 52 unique currencies. It has generated benchmarking data that reflects 3.5 million itemized costs from over 450 sponsors and contributing partners in over 200 countries and regions.

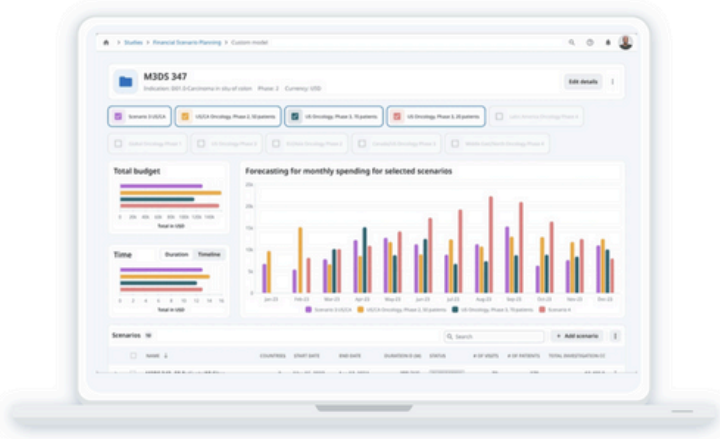
This data has been leveraged to innovate across Financial Scenario Planning, dynamic fair market value (FMV), and patient payments solutions.

Financial Scenario Planning

Clinical trial budget planning complexities are in a league of their own compared to other industries. In this dynamic environment, some essential information is often unavailable, so finance teams rely heavily on other data sources or their own experience, filling gaps with estimated data for many scenarios.

Financial Scenario Planning Overview

Innovation #1



Budget with Confidence



Scenario Modeling



Funding Optimization



Collaboration & Reporting

Figure 2. Financial Scenario Planning overview.

Medidata’s Financial Scenario Planning solution (Figure 2) addresses the current gap in the industry by aligning early budget modeling with feasibility-aligned forecasting, leveraging vast volumes of benchmark data. Advanced analytics and statistical modeling empower users to build, assess, and optimize multiple scenario models, ensuring stakeholders can make decisions based on data-driven insights and forecasts.

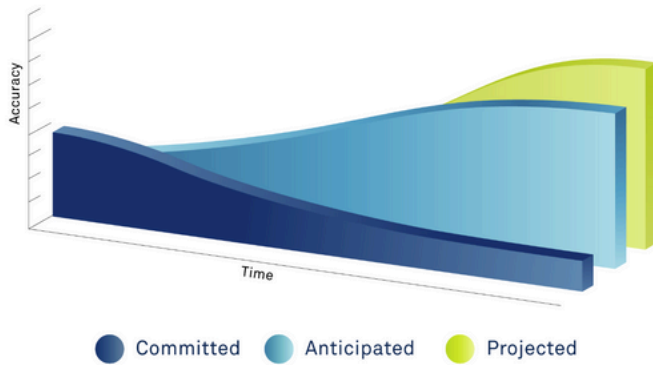
Dynamic Fair Market Value (FMV)

Assessing what constitutes fair payments for sites within the clinical ecosystem has been a long-standing challenge. Industry averages are not enough. Variations globally, nationally, and locally need to be considered when creating defensible financial benchmarking for clinical studies. Meghan shared insights into how Medidata applies innovative approaches to leveraging data, empowering users to make better decisions. For the FMV applied within Medidata Rave Grants Manager Planning, this included using committed data (extracted data from executed contracts), anticipated data (committed data and third-party data sources), country ratios, exchange rates, inflation & statistical models, and projected data (predicted data based on the length of the study) (Figure 3).

Budget for Your Future

Better Data, Better Decisions

Innovation #2



Get access to data that takes a multidimensional approach to FMV

Achieve optimal budget planning and execution

Safeguard against future financial uncertainties

Nurture site relationships

Figure 3. Fair market value.

AI is used to help conduct complex and deep analyses and projections, adapting to dynamic financial changes like inflation rates. Medidata’s Grants Manager is already recognized as an industry standard, so the innovations have enhanced this leading solution even further as part of the CTFM end-to-end offering.

Patient Payments

Patient payments/reimbursements will be introduced in the second half of 2024. This solution builds on the strengths of the myMedidata application and existing Medidata products (Figure 4). A system preview was shown, demonstrating that it’s been built with the patient experience in mind.

Patient Payments Experience

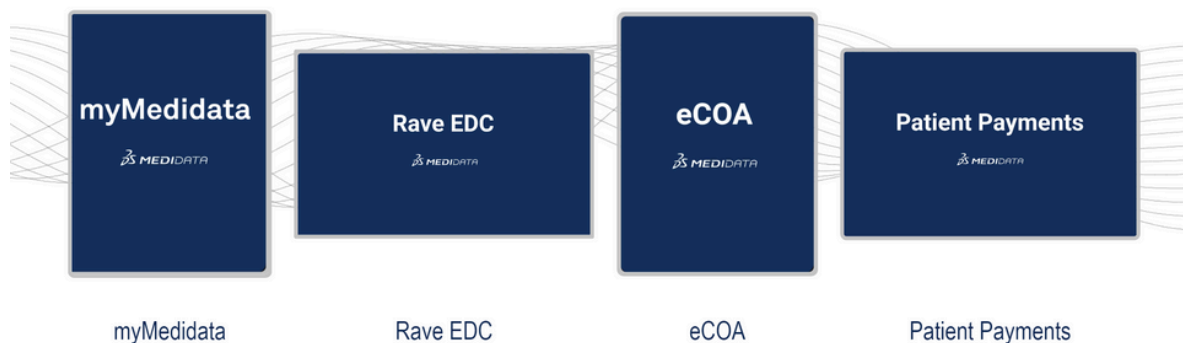


Figure 4. The patient payments experience.

Patient payment and reimbursement solutions reduce patient burdens and aid retention. By leveraging its entire solution—the most widely adopted clinical data platform—Medidata aims to remove any inconvenience from the process.

In Conclusion

The industry has tried its best to create harmonized financial and operational environments for decades by piecing together a jigsaw puzzle of disparate systems and processes. But sponsors have made it clear—a unified, harmonized end-to-end financial management platform is needed. And it's finally on the horizon.

[Watch the full presentation here.](#)

To learn more about the innovative things the Medidata Clinical Trial Financial Management team is doing, visit the [CTFM Resources page.](#)



IMPACT REPORT

Watch the Financial Scenario Planning Video

Your request, our commitment: We asked, you clarified, we delivered!

“Before a protocol is finalized, we need to forecast the potential study.”

“During the RFP process, we need to create multiple budget proposals that go through a review process. Doing this outside of the system is a lot of work.”

“Currently, we are giving forecasting to our partners & its not working well. We need to bring that in-house.”

“It would be helpful if it was possible to select a comparison annual span so that I could compare.”

Innovation Lab and Q1 Summary

Budget Innovation Lab Discussion

- **Worldwide Costing Practises - Featuring Special Guest Speaker Dr Thorsten Ruppert, PhD**
 - Different cost structures for different countries are being used, the issues are with time lag in costing tools. They are trying to mimic the real world, but real pricing has significant differences.
- **Drug Costs**
 - Best practises for how to include 'drug costs' when building a budget
- **Standard of Care**
 - Inclusion of SoC in Grants Manager

Payments Innovation Lab Discussion

- **Impact Assessments**
 - How CTFM can evolve the current Payments process
- **Payments Complexities**
 - Payments are complex because of actions downstream.
 - Holdback and how to manage
 - Additional Maintenance Fees

Data Innovation Lab Discussion

- **What's the Industry Saying**
 - Sites are adding more costs as the typical visit is longer and they need to be compensated appropriately.
- **Site Cost Line Items**
 - Site costs have evolved over time. In the past ten years CTFM has seen an 80% increase in new line items added to budgets.
- **CAP (Committed, Anticipated and Projected) Data**
 - The new generation of benchmarking data.



Global Costing Task Force Summary

Since the initial meeting in October 2023, vast strides have been made on the Global Costing Task Force mission to conquer some of the worldwide costing challenges. Being highlighted in a thought leadership piece [What's the true price of negotiation?](#) And investigating the top areas of concern. The first question we are addressing is 'What is the definition of Fair Market Value' and what does FMV actually mean to each stakeholder. Watch this space for outcomes of the first GCTF 2024 Meeting.

[Join the GCTF LinkedIn community](#)

For more information about the Innovation Labs or the Global Costing Task Force, contact Tina Mincher, Director, CTFM Client Strategy at [**tina.mincher@3ds.com**](mailto:tina.mincher@3ds.com)



“IF YOU BELIEVE IT’LL
WORK OUT, YOU’LL SEE
OPPORTUNITIES. IF YOU
DON’T BELIEVE IT’LL WORK
OUT, YOU’LL SEE
OBSTACLES.”

WAYNE DYER

HAVE YOU HEARD



RAVE GRANTS MANAGER

Data Release

Cost Data for 26 Sponsors, 45 Countries, 42 Indication Groups and 4 new 'Other Direct' activities.

Enhanced Data Build

- 15+ new procedures
- 5 Questionnaire, Scales and Assessments (QSA) related procedures
- 7 Other Direct Costs (ODC) procedures associated with medical personnel hourly rates

The updated cost data volume now comprises of:

- 2953 site budgets
- 123,454 unique payments
- 188,601 total payments (inclusive of multiple indications)



RAVE SITE PAYMENTS

Payment APIs, Phase One Implementation - Users utilize APIs instead of (FTP) imports and UI workflows, improving the security and reducing the manual intervention required.

Localisation for Event, Date & Cost Category in PFI/RFI templates, Phase One Implementation - Providing sites with invoices in their required language, including translation for line item descriptions within the invoice, like procedure names. This makes the invoices more coherent for site users.

Limiting display of Invoiceable Categories on Cost view - Helping to identify the correct invoiceables easily and enhancing the payment setup process.

Cost and Payment Summary/Overview Report, Phase Two - Study, Site & Country based payment information presented in a tabular format in a report. Clarity on payments for the study, in clear report format, provides a better experience than an export.

Convera Disbursement - Batch option - Allowing for more control on how the payments are batched together for disbursing, thus providing better operational control.

- Batches will be created per Funding Account Number and Currency. So that approval is sent to the specific customer only for those respective payments.
- Batches will be created irrespective of Study, Site, Payee.

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Resources

- [CTFM Resource Page](#)
- [Dynamic Benchmarks Podcast](#)
- [Global Costing Task Force Highlight - What's the true price of negotiation?](#)
- [UK NIHR News](#)
- [FSP Fact Sheet](#)



For CTFM POP questions, comments, and collaborations, contact Tina Mincher at Tina.Mincher@3DS.com.



CLINICAL TRIAL FINANCIAL MANAGEMENT



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