MEDIDATA

POP

Power of Partnership

ISSUE 02

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

POP ISSUE 02 CONTENTS

POP VOICE

Creating Budget & CTA Contracting Partnerships

by Shelley Douros

Many factors increase the challenges of reaching an agreement on Clinical Trial Agreements (CTA) and budgets, including inflation, hidden costs, and difficulty accessing fair-market-value data. Impacts on trial timelines, poor patient enrollment, and site financial instability can often directly correlate with an inadequate budget and contract processes. A lack of visibility and a central audit trail for sites, sponsors, and CROs leads to confusion, inaccurate budgets, and dissatisfied parties.

To discover the most significant pain points for sponsors, CROs, and sites Medidata recently surveyed sites within their site advocacy groups provided by the Society of Clinical Research Sites (SCRS). Medidata conducted a separate survey with their wide client base of sponsors and CROs.

The results showed that 53 percent of site respondents say the most significant concerns involve a lack of transparency into the itemized budget and sponsors trying to make apples-to-oranges comparisons among sites. They explained that sponsors often send templated location budgets asking one site to match the per-patient rate at another site, and they do not consider the specialty differences between sites, location distinctions, and possible discrepancies in healthcare coverage. All of the sites surveyed requested budgets at the per procedure level, and CTA contracts using the updated language used in their previous trial's executed CTA. Sites responded that receiving budgets at the visit level makes the negotiation process nearly impossible and leads to mistrust and confusion.

On the sponsor side, nearly half (46 percent) of the sponsors surveyed said that budget rules and the budget planning process are significant areas of concern. There are multiple process pain points, including systems and data that are often siloed and disconnected from systems at trial sites. Quality control and auditing are challenging in an environment where many sites negotiate and communicate manually using email and spreadsheets. Sponsors explained that it is a daunting task, and they struggle to decipher opaque cost structures that differ from one site to the next, all while trying to stay within the planned study budget and keep everyone happy.

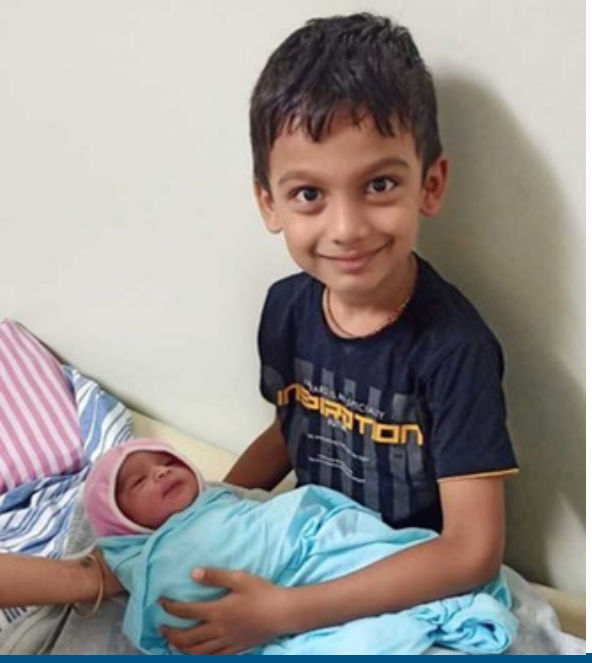
Concerned that an itemized budget can slow the negotiation process, sponsors often negotiate budgets at the visit level with the intention to help facilitate a smoother and faster negotiation.

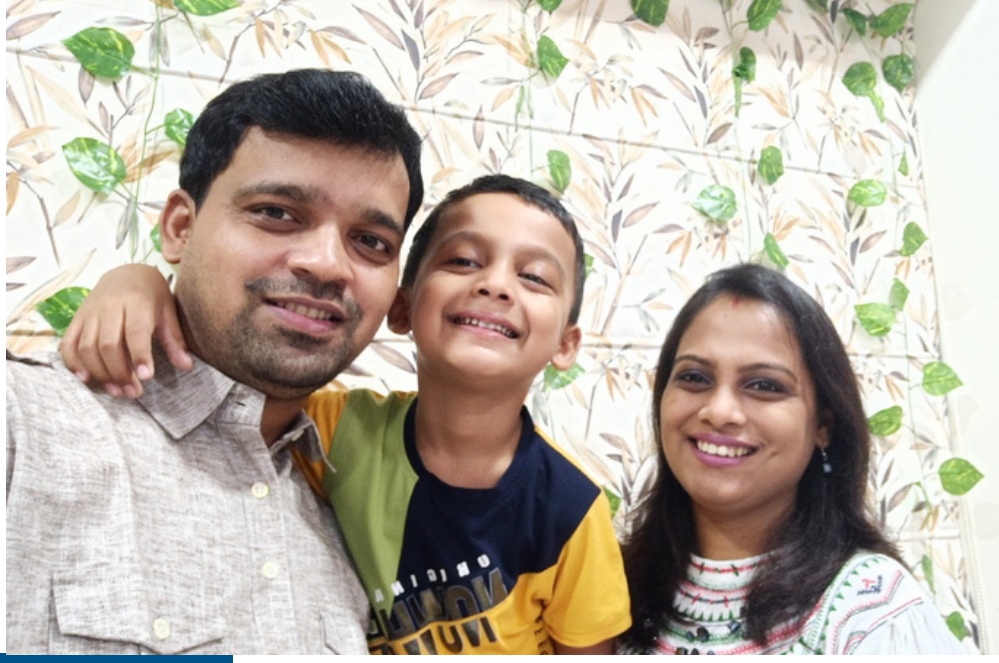
However, sites explain that an itemized budget makes it easier to review visible and hidden costs, which speeds up negotiations and provides more visibility into the process. Many of the concerns that sites, sponsors, and CROs have can be resolved by increasing the overall visibility of the budget negotiation process to ensure that all parties receive appropriate remuneration for their roles in advancing clinical research. They all agree that the correct use of technology and automation can help systematize and streamline the process while strengthening communication and relationships.

Ultimately, Medidata's survey found that sites, sponsors, and CROs crave more budget transparency. Each side feels the other does not understand its budgeting rules and processes. To the extent that sites, sponsors, and CROs can clarify those rules and explain their budgeting processes, they may well be able to eliminate confusion, foster goodwill, and expedite negotiations for the benefit of all involved.

"Coming together is a beginning; keeping together is progress; working together is success."

– Henry Ford





POP PERSONALITY

SANDIP DILIP HIRWALE

Meet Sandip Dilip Hirwale, a valued and crucial Clinical Trial Financial Management team member working as an Applications Engineer. He has his masters in computer science, and before joining the Medidata, Dassault Systèmes family, he worked 11+ years at ENOVIA within Dassault Systèmes, as an R&D Development Manager. Sandip attributes much of his technical and personal growth to Dassault Systèmes and the "brilliant brains" in the industry.

In Sandip's personal life, he loves to listen to music, primarily energetic pop and sometimes deep house. He spends time on music websites to search for the latest artists and albums in his favorite genres. Sandip has been married to his wife, Pallavi, for seven years. They have two children, a six-year-old and a new baby girl, born at the end of August. He says that Pallai is his "better half" and his support system. She inspires Sandip to do 1% better than the previous day.

Sandip's day starts with dropping his son off at school. Sandip says his son's high energy keeps him charged an entire day. After office hours, his family watches TV, eats dinner, and takes long walks. And yes, currently, his day now includes changing nappies.

We asked Sandip to answer a round of "Would you rather" questions, and here's what he said:

Would you rather...

live twice as long or win the lottery?
Live twice as long

watch a movie or read a book?
Read a book

spend the night camping or at a luxury hotel?
Camping

explore space or the ocean?
Space

be a child or an adult your entire life?
Child for my entire life

time travel to the future or the past?
Time travel to past

IMPACT REPORT

Medidata's Full-Service Site Payment Solution: Mid-sized Sponsor Manages Study Finances across Hundreds of Sites

A sponsor is on a mission to conquer cancer with data, empowering patients and providers to act decisively in fighting the disease. Shortly after the sponsor became publicly traded, the company planned to sponsor its first large clinical trial. Recognizing that the financial management of the study would be as critical to the trial's success as data management, the sponsor turned to Medidata's Rave Site Payments solution to track and manage timely payments to research sites triggered by entries in Medidata's Rave EDC (Electronic Data Capture) solution.

> **"I'm not sure that we could've done it without Rave Site Payments and without relying on a team of experts."**
>
> Vice President of Outcomes and Evidence at the Sponsor

THE CHALLENGE

When the sponsor was about to launch its large study its resources were constrained. The company, having just gone public, had just 350 employees and was in the process of installing and integrating several enterprise-wide systems.

The study is one the largest cancer screening studies of its kind. The sheer scope of the study, which would be challenging even for an industry giant, was daunting for the sponsor's clinical team of six people.

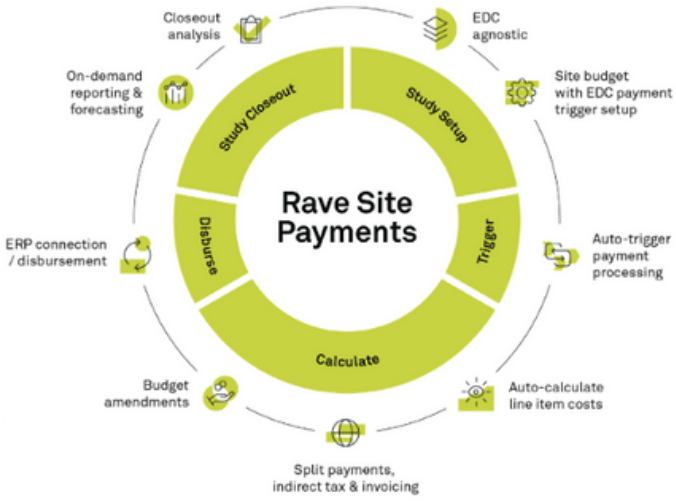
The sponsor's chief financial officer was keenly aware that it would be essential to know, minute by minute, what investigator payments had been processed and what charges from sites had been accrued. Otherwise, the company could have a distorted view of its cash flow and future liabilities, which could be devastating to its financial health. Meanwhile, the small clinical team couldn't devote two or three people - half of its headcount – to building the budget templates, ensuring that sites were paid on time, and creating an audit trail of payment activities. Technology would, therefore, be key to working efficiently and managing the company's resources wisely

THE SOLUTION

The sponsor's clinical team subscribed to Medidata's full-service, site payment model to ensure that they had a unified platform to manage the trial's finances and could call on a cadre of site payment experts at Medidata for support. Rave Site Payments is a cloud-based, smart solution that provides real-time payment processing triggered by data in the trial's electronic data capture (EDC) system, which in this case, was Medidata's market-leading Rave EDC.

The study was designed to pay sites upon their entry of critical data points, rather than on a per-visit basis. When certain fields are completed in Rave EDC, Rave Site Payments automatically calculates what is owed to each site, converts that amount to accrual, and disburses the payment due according to schedule.

Medidata payment experts worked as an extension of the sponsor's staff in helping set up the system. Critically, they helped the sponsor's financial and clinical teams come to a consensus over requirements and processes. "We desperately needed Medidata in the middle to help us negotiate and understand one another," explained Vice President of Outcomes and Evidence at the sponsor. "The Medidata team also advised us as we customized our reporting. They knew what the auditors would want to see."



In addition to executing payments based on the contract terms, Rave Site Payments offers the sponsor's team visibility into the status of payments and accruals and allows sites to track what they have been paid and what they are owed.

THE RESULTS

At the time of this writing, the study has been ongoing for multiple years and has captured data on more than 14,000 patients. Running such an expansive study has meant that the sponsor's clinical team is always in "start-up" mode with little time to devote to financial management. This has posed no difficulty as Medidata's technology automates the payment process, and Medidata's staff are always on call.

The sponsor reports that the full-service solution has delivered:

Confidence in financial tracking. The Medidata payments solution has earned the trust of the sponsor's financial team, eliminating any anxiety about the trial's finances. The system's transparency means that every line item can be tracked and checked. Lang said, "I don't sit up at night worrying that my accruals are wrong."

THE RESULTS

I**mproved site relationships**. Before Rave Site Payments was installed, the team extracted payment data manually and paid sites without a particular schedule. Consequently, at least three early sites experienced payment delays and stopped recruiting patients. “Once we adopted Rave Site Payments, complaints from sites went down to zero,” said VP of Outcomes and Evidence at the sponsor. “Our ability to communicate to sites how much they’ll be paid on an exact date is second to none. This has strengthened their trust in us.

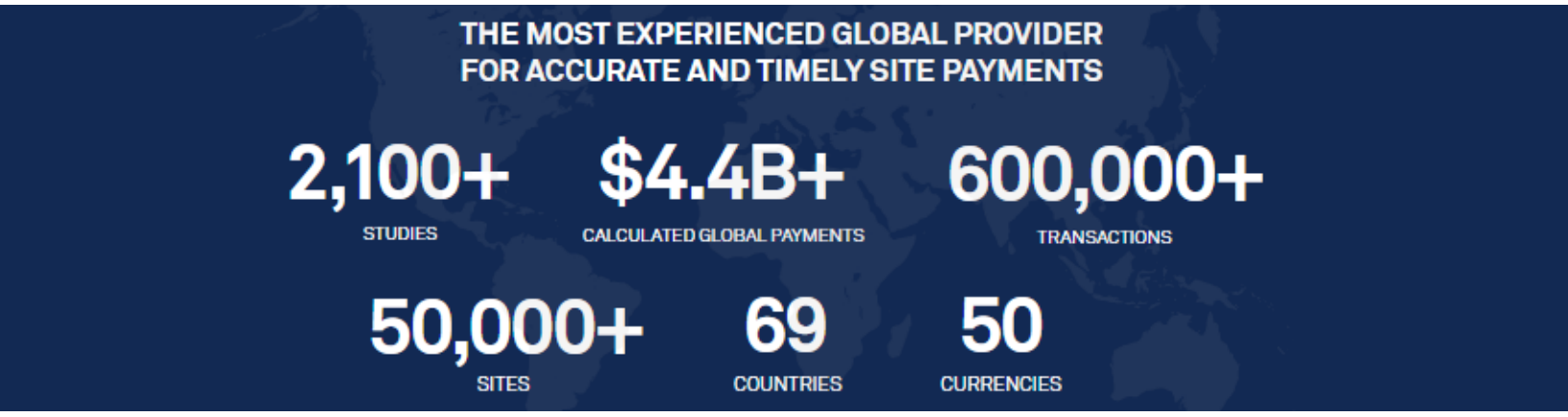
Audit readiness. The system generates evidence easily and produces customized reports that answer auditors’ very specific questions. And, because the system is so understandable, it has been easy to orient new auditors.

Strengthened corporate reputation. The company has built a reputation for paying sites on time, which will benefit its site recruitment in the future.

Redistributed internal resources. “We were able to rely entirely on Medidata’s very responsive team,” said VP of Outcomes and Evidence at the sponsor. “Our Clinical Research Coordinators (CRCs) and Clinical Research Associates (CRAs) have been able to devote their time to data management rather than to onerous, repetitive tasks and to chasing down site payments. They’re not entering data, but are providing oversight.” Alone, the automated purchase order and approval system save us “countless hours” each month, and collectively, the efficiencies and support have not only made the study manageable but have led to a reduction in full-time employees devoted to the study.

Streamlined communications with sites. Because payment dates are standardized across sites, messaging to sites can also be standardized.

In discussing the sponsor’s overall experience with Medidata’s payment technology and support, the VP of Outcomes and Evidence at the sponsor said, “I’m not sure that we could’ve done it without Rave Site Payments and without relying on a team of experts.” Perhaps the best indication of the solution’s success is that Medidata’s financial management solution has receded into the background; the fact that no one talks about it means it’s working flawlessly. As the sponsor pointed out, “Most study investigators don’t know how payments work, but they sure know when they’ve not been paid. Their silence speaks to how successful this has been.”



HAVE YOU HEARD

CTFM has already had a record-breaking year with the release of >21 feature enhancements! Check out some of the highlights from those releases.

GRANTS MANAGER

Upgrades to patient & site burden
Compare industry median & burden scores to your trial-specific cost, site burden, & patient burden

Redesigned study trial header
The new and improved odometer style visualization for better analysis of the trial metrics

Adaptive country, region, & site search
Improved country, region, and site search capabilities

Internal and technical updates
Technology updates to ensure that the product meets the latest technology standards

Enhanced GMC API
Inclusion of all budgets in negotiation in the list view, filter budgets by currency code, and increased currency filters

Grants Manager Knowledge Space

RAVE SITE PAYMENTS

Standard of care enablement
Expanded processing capabilities to capture standard of care line items to increase visibility and provide robust reporting

Batch exports implementation
Efficiencies with exporting and reporting

Email single remittance to multiple recipients
Enables multiple stakeholders at each site/payee to gain visibility into site payment details

Enhanced payment & invoicing workflow
Expanded workflow capabilities to allow for every situation with the back and forth during the electronic invoicing process with sites

Disbursement validation enhancements
Reduces errors and enables faster payment cycles with additional automated audit checks to ensure accurate payee information

Rave Site Payments Knowledge Space

GROW WITH US

WEBCAST & VIDEOS

Hot Topics in Clinical Finance

Innovative Clinical Finance Video Series

Tea with Pete & Laura Bousfield

Tea with Pete & Laura Bousfield Cont.

PUBLICATIONS

Translating Your Protocol into Clinical Financial Management

Clinical Trials Arena Article: How a well-planned clinical trial budget can help prevent burning bridges

BLOGS

Financial Effects of Site & Patient Burden

Site Dissatisfaction and Challenges in Clinical Trial Financial Management

How to Manage Global Tax

Investigator Grants Clinical Trial Forecasting

CASE STUDIES

Medidata's Full-Service Site Payment Solution: Mid-sized Sponsor Manages Study Finances across Hundreds of Sites

Regenerative Medicine Pioneer Issues Site Payments Accurately, on Time, and Transparently

WHAT'S COMING

Don't miss NEXT New York 2022! Register here.

Join us at the Power of Partnership Webinar Series w/ SCRS on Oct 25th! Register here.

Register here to join us at the SCRS Global Summit