MEDIDATA

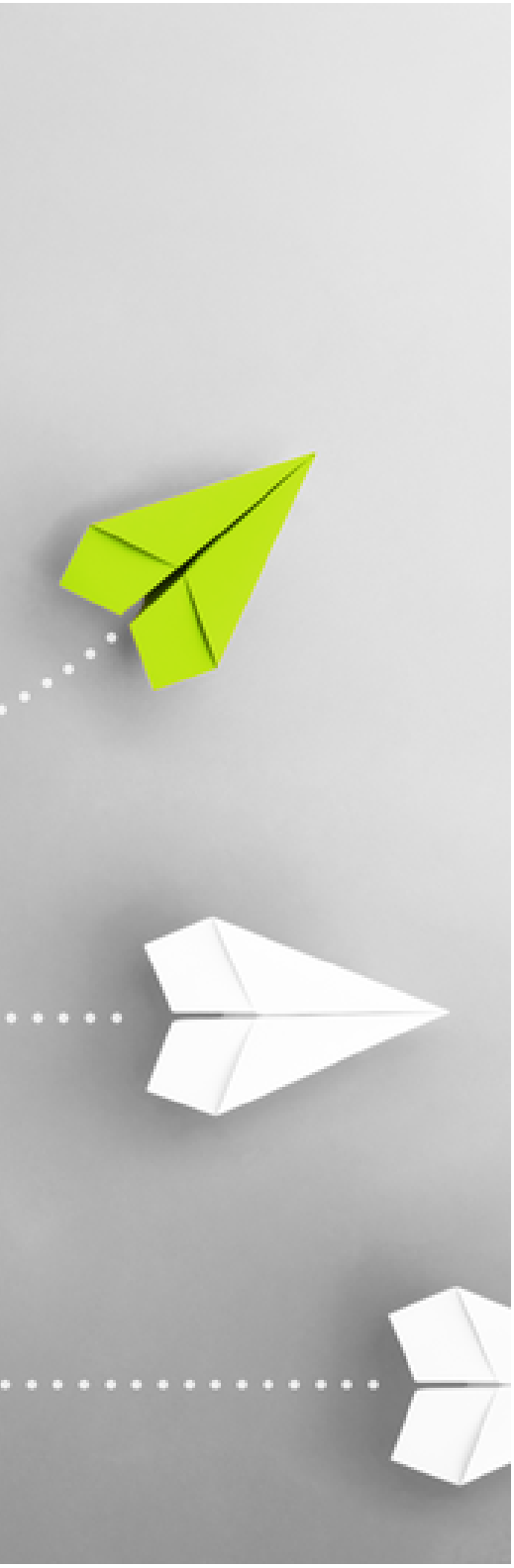
POP

Power of Partnership

ISSUE 08

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

POP ISSUE 08 CONTENTS



POP VOICE

By Shelley Douros

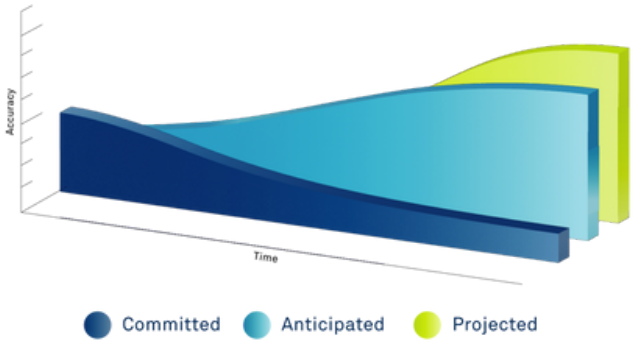
Better Data, Better Decisions

Smart Clinical Trial Budgets through Dynamic Benchmarking

Clinical trials can become costly and slow or halt discovery without adequate budgets and efficient workflows. Understanding and having accurate Fair Market Value (FMV) for investigator grants can lead to more successful clinical trials, ensuring the best and most accurate results, all within budget. However, establishing FMV is more complex than it may seem. Simply looking at executed contracts to generate FMV is insufficient to ensure reliable information. It is imperative to have better data to make better decisions. Dynamic budgeting with a multi-dimensional approach to FMV via Committed - Anticipated - Projected (CAP) for clinical trial investigator grants can help organizations save time, money, and resources, fostering better relationships between sites and sponsors.

Three critical factors for smart, successful budgeting include:

1. Evaluation of historically committed costs
2. Accessible anticipated costs
3. Capacity to project future spending



Committed: Evaluation of Historically Committed Costs

FMV is an accepted standard for determining costs and is often described as how much a buyer or sponsor is willing to pay and how much the seller or site is willing to accept. When creating budgets for investigator grants or planning for future site payments, neither the sponsor nor the site desires to pay or receive excessive funds. The expectation is to have a fair and appropriate budget that aligns with the protocol requirements. For clinical studies, committed costs or executed clinical trial agreements (CTA) are protocol and site-specific contracts with agreed-upon costs at the time of study start-up or at the time of a contract amendment. CTA-executed contracts can be a valuable tool for understanding historically committed costs to develop criteria for FMV. They can also provide a good foundation when establishing benchmarks for future pricing. The ability to surface historical pricing with associated terms and conditions also establishes financial trust between the parties and a baseline for ensuring that FMV is achieved in the future.

Despite the utility of executed site contracts, several issues of solely relying upon on-site contracts can lead to inaccurate fair market value when budgeting for future studies. One of the most common issues is the use of outdated data. Additionally, country and regional differences can lead to inaccurate measurements, as prices vary significantly between locations. To overcome single data source concerns, FMV must be established using multiple data sources while employing a wide range of statistical techniques to ensure accuracy.

Anticipated: Accessible Anticipated Costs

Clinical trials and industry expectations on managing trials and developing budgets are changing. The industry is demanding scalable and trustworthy data. Previously executed contracts provide helpful information that can inform FMV. However, FMV is not static and is subject to external factors like economic conditions, exchange rates, inflation, and other influences. These factors need to be considered in order to budget confidently. Establishing FMV at agreed-upon prices in executed contracts is difficult at best and unreliable at worst. For this reason, it's imperative to have accessible anticipated costs to ensure a defendable and fair budget.

Many companies use price list data or have introduced purchasing power parity (PPP) to their process to provide better FMV. However, PPP is not enough. When you use PPP, you assume that all countries function equally efficiently and that clinical study activity in two countries costs the same price. PPP does not consider other cost impactors, such as volatile exchange rates or the availability of services and equipment needed to complete the required assessments in different countries.

Creating anticipated FMV costs can be challenging but vital to ensure accuracy. Accurately anticipated FMV involves looking at all the factors and resources required for a successful clinical trial investigator grant budget and determining the most important and efficient ones. CAP Anticipated FMV analyzes data from executed site contracts, 3rd party data sources, country ratios, exchange rates, inflation, and statistical models to create accurate and current benchmarks. Dynamic budgeting with CAP ensures the industry can effectively obtain current, anticipated FMV benchmarks for better financial decisions and improved outcomes.

Projected: Ability to Project Future Spending

Financial strategic planning for future clinical trials is vital for all operational parties, including clinical operations and finance. It is a complex process that involves understanding the company's strategic goals, assessing the current financial state, and forecasting the future. Teams must create realistic and accurate budgets to help the company achieve its goals.

Historically, predicting future costs was done by combining a sample of past data sets with statistics or algorithms to produce a budget estimate. The average price was calculated and then applied to similar activities. This method has many shortcomings, including external factors, inflation, and algorithm limitations when using multiple variables.

Projecting future spending through predictive costs has increasingly become important when considering pricing for future clinical studies. The industry insists on accurately reflecting investigator grant budget costs by assessing creditable, direct, and indirect costs and evaluating the current and future economic environment. It is crucial that the industry no longer depends on historical data collected in the past. Additionally, planning for future clinical studies often happens a year or more in advance, so having reliable future costs is imperative.

Dynamic Budgeting with CAP introduces AI to project FMV. Using AI to project FMV considers complex, dynamic factors such as inflation and provides a more accurate and predictive estimate for future costs. One of the key advantages of using projected FMV to estimate the cost of investigator grant budgets is that it provides a reasonable idea of the expected costs to aid in budget planning and for allocating resources to the study in advance. This approach helps clinical trial sponsors reassess their budgets and make better-informed decisions during fiscal planning. It also gives sites confidence to negotiate with sponsors and CROs using applications that provide accurate and predictive FMV benchmarks.

CAP revolutionizes how the industry plans and budgets for investigator grants and focuses on ensuring that the industry has accurate, current, and predictive costs to gain an understanding of present and future fair market value for their investigator grant budgets. Focusing on applications that generate current and future costs ensure that sufficient funds are allocated appropriately, making it possible to budget accurately and secure financial viability.

Thank you for joining the 2023 CTFM Innovation Labs!

Your voice matters to CTFM!

> 16%	> 200	> 20
Enhancements From Labs	Total Attendees	Unique Clients Attended

Innovation Area	CTFM Enhancement
Inadequate Trial Budget & Cumbersome Budget Negotiation	• Dynamic search functionality (2023) • Upgrade of Site & Patient Burden Index (2023) • AMA Code Expansion and Third Party datasets (2023-2024) • NIHR iCT integration partnership (2023-2024)
What do Sites need? Transparency	• Inclusion of SCRS CLEAR into the product (2024 R02) • Adaptive location search functionality and country sets (2023) • Global Costing Task Force Topic: Site Discussion (2024)
Delayed Site Payments & Cash Flow Concerns	• Improvements to Site Invoice Workflow (2023) • Auto Email communication to Sites (2023) • Ongoing discussions for the potential of allowing sites to enter data (2024)
Language Barriers	• Email notifications to sites in local languages phase one Turkey and Spain (2023) • Localization of text and currency in Site Facing Pages (2023) • Ongoing user discussions on what countries for next stage (TBD)
Invoiceable Items & Cost of Operating	• Inclusion of SCRS Site Invoiceable tool kit into the product (2024 R02) • ODC Code Evaluation and Upgrade (2023) • Global Costing Task Force Topic: Site Discussion (2024)

Customer Feedback

"I value hearing we are all facing similar issues, and we can collaborate; instead of each of us solving independently, we can tackle issues and find universal solutions, with input from many."

GLOBAL COSTING TASK FORCE

MISSION

Medidata Clinical Trial Financial Management Global Costing Task Force optimizes trial financial management across the industry, driving efficiency and sustainability globally. By fostering collaboration, sharing best practices, and leveraging technology, our task force aims to empower the industry to make informed decisions, streamline operations, and achieve cost excellence while considering environmental and social impacts. Together, we will elevate the global network of clinical trial financial management professionals dedicated to driving financial stability and innovation.

GOALS

- Introduce industry experts to elevate the global conversation
- Share global clinical trial budgeting best practices
- Involve a wider industry audience, creating global partnerships
- Influence the industry, driving stability and innovation

“THE SINGLE MOST IMPORTANT INGREDIENT IN THE RECIPE FOR SUCCESS IS TRANSPARENCY BECAUSE TRANSPARENCY BUILDS TRUST”

DENISE MORRISON

HAVE YOU HEARD

RAVE GRANTS MANAGER

IIS Quick Price Lookup - For Investigator-Initiated users this allows access to a specific price set in QPL making sure IIS studies have accurate FMV.

Data Source Analysis - Incorporating Machine Learning and Medidata AI to analyze, predict, and weigh new and historical benchmarking sources. Providing the "Gold Standard" data with the most robust and accurate benchmarking in our industry. Customers should be and can be 100% confident in our offerings.

Updated Specificity Options - Provide users Anticipated (formerly Derived) specificity defaults to prevent manual intervention at the granular level.

RAVE SITE PAYMENTS

Tax Update - Ensuring accurate taxes are calculated for payees in Malaysia.

MySQL - 8.0 offers improved indexing, query execution, and security compared to MySQL 5.7. It ensures your database system stays up-to-date, efficient, and aligned with industry standards and advancements.

Refresh of Site Invoicing Cache - Allows gathering Site invoicing details in the CTMS database which will allow extracting invoicing data for payment with better performance and would also allow the refresh to be real-time and incremental

Enhancement to Study Cost & Payments Export - Allows an optimized experience for exporting payment data for studies with Site Invoicing and Invoiceables.

Asynchronous Export - Gives customers the ability to run large exports and avoid issues with exports timing out.

Cost and Payment Summary Overview Report - Part One - Clarity on payments taking place for the study, in a clear report format which provides a better experience than an export.

Country Filters - Better cost and payment management with the ability to filter data using the country association/membership.

Study Environment Selection - All Cloud Administration-configured study environments do not appear in CTMS, enabling a clearer selection of auxiliary environments.

Usability Enhancements - Auto mapping Site Invoice details to Payments will ensure manual efforts are reduced and also remove the error in capturing this information. It also eases payment troubleshooting/invoice reconciliation with payments. Ensures easier and more accurate interface for clients with EBS integration who are using the 'Payment Request File' export.

- Clearer feedback data regarding email notifications.
- Avoiding timeouts when updating many event cost records on event cost view and better search capability.
- Help to load studies faster on the Site Payee Dashboard when there is a large database. Better data load, consistency in the interface, and clearer search capability on the payment pages.

GROW WITH US

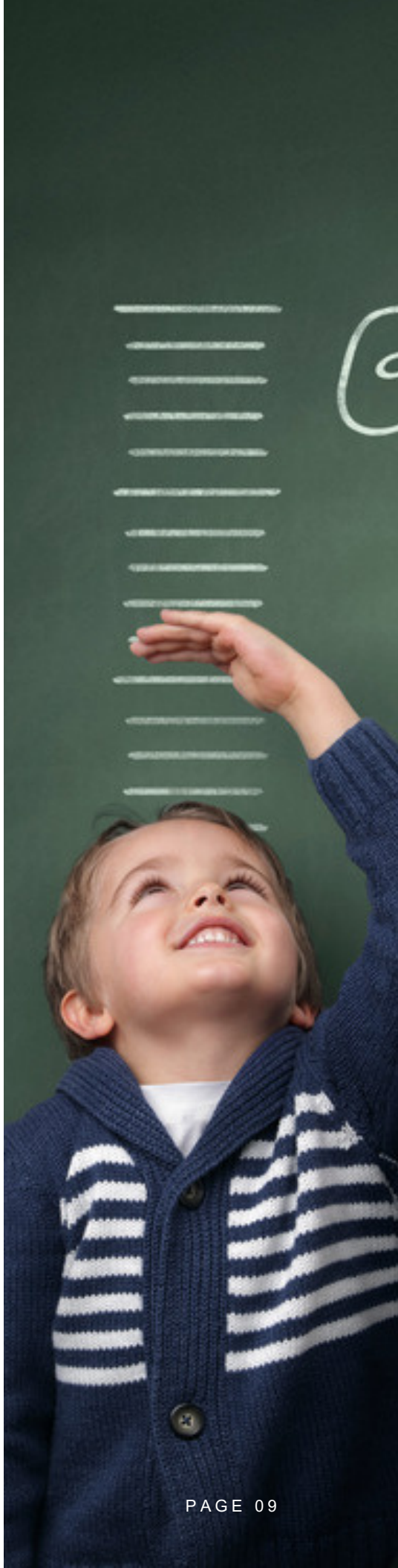
Medidata's Newest Innovation:
Clinical Data Studio

NIHR News

SiteTech Board Highlight

Medidata recently held two all-day SiteTech Board meetings at the New York City office, which took place on February 21st and 22nd. The first day included a joint session with members of our Patient Insights Board, while the second day was exclusively for the SiteTech Board. Both gatherings were marked by productive collaboration and lively discussions, generating valuable insights for Medidata's design team to incorporate in their future work.

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



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