# Better Data, Better Decisions

## Achieve Greater Certainty in Clinical Trial Financial Management by Leveraging Adaptive, Accurate, and Defendable Fair Market Value

**by Shelley Douros**

Pharmaceutical research and development is facing many opportunities and challenges, including an emphasis on improving the efficiency of clinical trials, which are becoming increasingly expensive, complex, and decentralized. The surging quantity of data, outcomes, and protocol amendments can slow or completely forestall research programs. Furthermore, volatile global financial markets inject uncertainty into budget forecasts.

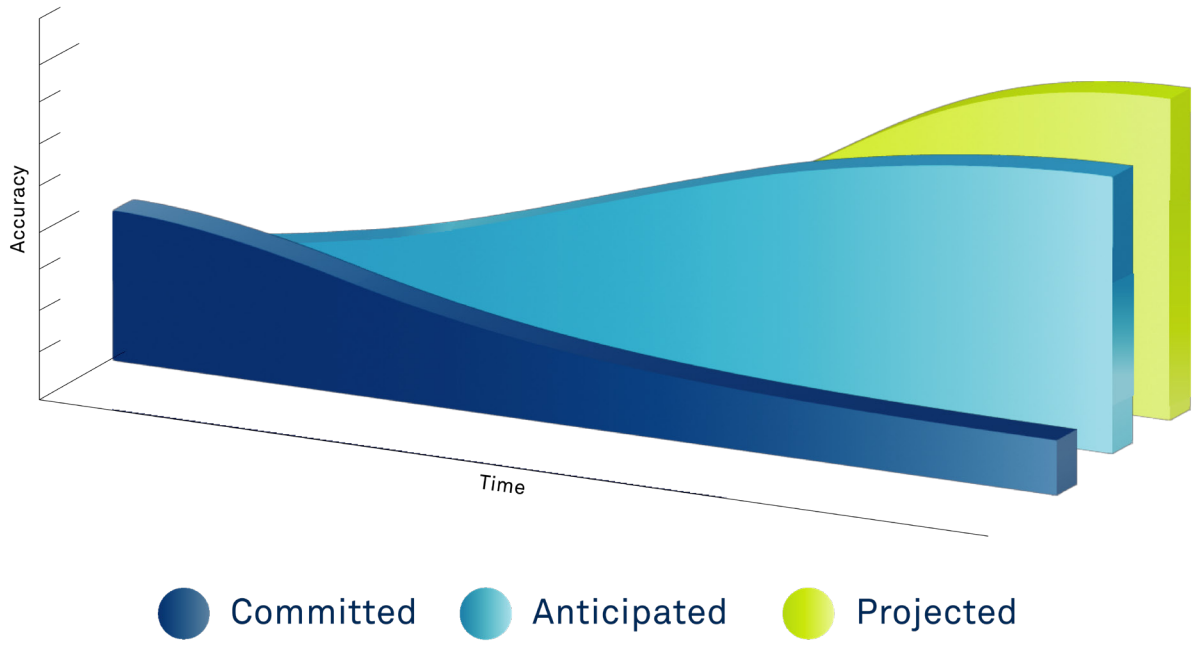
Fair market value (FMV) is an accepted standard for determining costs. It is often described as how much a buyer or sponsor is willing to pay and how much the seller or site is willing to accept. While it is simple in concept, establishing a defendable FMV requires trial operational metadata, economic drivers for context, and future projections. Determining FMV for investigator grants and sufficient funding for clinical trials has become increasingly complex since key variables like protocol endpoints, trial designs, and financial markets intersect and fluctuate over time. Thus, developing accurate budgets requires a multidimensional approach that adapts to evolving markets and anticipates future changes.

Navigating the complexity of clinical trial budgeting requires a smart budgeting framework that operates across a multidimensional approach for FMV. The committed-anticipated-projected (CAP) principle provides the flexibility and foresight to confidently optimize your budget amidst shifting variables (Figure 1). By considering committed costs, analyzing anticipated adjustments, and projecting future impacts, this framework helps build budgets attuned to unique trial requirements while poised for the road ahead. This saves time, money, and resources while fostering better relationships between sites and sponsors. Simpler, rigid methods are no longer adequate to support budgeting in the modern and dynamic world of clinical trials.

**Figure 1: The Committed-Anticipated-Projected (CAP) Principle.**

Figure 2 shows the accuracy of the different methods used to determine the FMV for clinical trial costs over time. Based solely on the costs specified in the Clinical Trial Agreement (CTA), the Committed curve does not consider any causal relationship with economic factors and cannot reliably forecast costs. On the other hand, the Anticipated and Projected curves are calibrated to reflect the true market value, considering both current and future economic conditions.

**Figure 2: Achieving Greater Accuracy in Forecasting with CAP.**




The following sections discuss the relevance of each of these factors.

## **Committed:** Evaluate Historically Committed Costs.

Committed costs or executed agreements are protocol and site-specific contracts with agreed-upon costs at the time of start-up or contract amendment, including costs for start-up and the principal investigator.

Despite the utility of executed site contracts, solely relying on them can lead to inaccurate FMV when budgeting for future studies. One of the most common issues of this approach is using outdated data. Additionally, geographical differences can lead to inaccurate measurements, as labor prices and competition for participants may vary significantly between locations. To overcome concerns about a single data source, FMV must be established via multiple data sources and a wide range of statistical techniques to ensure accuracy. However, as noted above, the accuracy associated with a proposed FMV wanes over time if only the "committed" variable is used.

## **Anticipated:** Apply economic factors for reliable anticipated adjustments.

Clinical trials and industry expectations on managing them and developing budgets are changing. The industry is demanding scalable and trustworthy data. Executed contracts provide helpful information to inform FMV. However, FMV is not static and is subject to external factors, such as economic conditions, exchange rates, inflation, and other influences required to budget confidently. Establishing FMV from prices in executed contracts is difficult at best and unreliable at worst. Thus, it is imperative to have accessible anticipated costs to ensure a defendable and fair budget.

Many companies use price list data or introduce purchasing power parity (PPP) to provide better FMV. However, PPP is not enough. It assumes that all countries function at the same efficiency and that clinical study activity in two countries costs the same. PPP does not consider other cost influencers, such as volatile exchange rates or the availability of services and equipment needed in different countries.

Creating anticipated FMV costs can be challenging but vital to ensure accuracy. Accurate 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, third-party data sources, country ratios, exchange rates, inflation, and statistical models to create accurate and current benchmarks. Medidata's anticipated analysis ensures the industry can obtain current FMV benchmarks effectively for better financial decisions and improved outcomes.

## **Projected:** Project the impact of future shifts in economic and business factors.

Financial strategic planning for future clinical trials is vital for all stakeholders, especially clinical operations and finance. This complex process involves understanding the company's strategic goals, assessing its financial state, and forecasting. Teams must create realistic and accurate budgets to help the company achieve its goals.

Historically, future costs were derived using descriptive analytics to estimate a budget. The average cost and growth rates were calculated and 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 become increasingly important for future clinical studies. The industry insists on accurately reflecting investigator grant budgets by assessing creditable, direct, and indirect costs and evaluating the current and future economic environment, not solely depending on historical data. Additionally, study planning often happens a year or more in advance, so having reliable future costs is imperative.

Medidata's CAP introduces intelligent algorithms to project FMV. This process considers complex, dynamic factors, such as inflation, and provides a more accurate and predictive estimate for future costs. One key advantage is that it provides a reasonable estimate to aid in budget planning and allocating resources in advance. This approach helps sponsors reassess their budgets and make better-informed fiscal planning decisions. It also gives sites confidence that they are negotiating with sponsors and CROs that are using applications that provide accurate and predictive FMV benchmarks.

## Budgeting Forward

As clinical trials become more complex and decentralized, determining FMV for investigator grants and ensuring adequate funding for studies is becoming increasingly challenging. The increasing variety and volume of data and protocol amendments further complicate the process. This article offers a comprehensive and forward-looking framework that not only improves budget certainty over time but also fosters stronger relationships between sites and sponsors.

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 FMV for their investigator grant budgets. Focusing on applications that generate current and future costs ensures sufficient funds are allocated appropriately, making it possible to budget accurately and secure financial viability.

## Clinical Trial Budgeting with CAP. Better Data, Better Decisions.

Medidata CTFM Grants Manager combines its wealth of clinical cost data and third-party data with advanced analytics to provide an accurate and defendable trial cost. We provide Sponsors/CROs with FMV benchmarks aligned with market conditions for better decisions to accelerate trial negotiation and build financial strength. Visit the Rave Grants Manager to learn more.