

Sky-High Inflation and the Great Resignation: The Impact on Clinical Site Budgeting

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Disagreements about budgets can delay or stall drug development. As the clinical research industry experiences unprecedented rises in costs, having the most current data available when creating and negotiating your budget is more critical than ever. Understanding all the benchmarking tools available, updating your benchmarks and exchange rates regularly, and considering the use of benchmarks above the median may provide you with a better framework for negotiations.

In the three years since the start of the COVID-19 pandemic, inflation has skyrocketed at rates unseen in decades, and now the Great Resignation has led to staffing shortages across the pharmaceutical industry. For clinical trial sites, attrition rates have climbed from 10%-37% pre-pandemic to the current rate of 35%-61%. To recruit and retain staff, sites are experiencing 30%-50% staffing budget increases.¹ Meanwhile, operational costs have rocketed as supply chain shortages and inflation drive lab materials and disposable personal protective equipment prices.

Given the twin pressures of inflation and attrition, clinical trial sites are asking for much higher budgets, leading to prolonged negotiations. Sponsors need reliable data to negotiate fair market value (FMV) budgets with sites.

WHAT ARE SPONSORS SEEING?

Jenn Hill, Director of Clinical Site Contracting and Payments for Vertex Pharmaceuticals, recently shared her perspective on how inflation affects budget negotiations.

“We have many site-staffing-related queries and requests for increased hourly rates for staff,” Hill explained.

“We’ve even had sites request that we reimburse entire salaries for study coordinators and for vendor-related delays. So, when we think about the supply chain and the impacts on shipping, we ask, ‘How can we help support sites with vendor issues? How do we account for that in the budget?’ We see global queries around inflation more broadly, and we’re taking that on a site-by-site consideration right now. But budgets are coming in markedly higher than the benchmarking numbers.”

Jenn explained that, typically, sites request annual pricing increase, but now sites are requesting higher prices ad hoc. Also, sites are requesting amended contracts with increases for ongoing studies, and some now submit annual price sheets, which are more common in Europe, with new pricing effective immediately. It’s also taking longer to review and approve budgets. While some delays are due to sponsors taking time to research and follow up on information, staffing issues at sites have slowed down their response rate.

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Jenn Hill
Director, Clinical Site
Contracting and Payments,
Vertex Pharmaceuticals

“Our site activations are seeing lags, and we’re rethinking the conversations we’re having and how we’re engaging sites. Negotiating budgets and contracts is no longer business as usual. Relationships are the most critical aspect of our work, so we want to ensure that we’re having honest conversations sooner and are transparent about our expectations.”

Jenn recommends sponsors keep in mind these four tips to improve their relationships with sites:

- Remember that frustrations are rising along with prices
- Business as usual isn’t working
- Have live conversations sooner
- Consider engagement meetings after the award

“For example, suppose the feasibility questionnaire a site provided indicated they could do the study in a certain timeframe. Once that site is selected, we ask them if that’s still true or if we need to make different accommodations. We ask them if this will impact our timelines to target activation. We want to get everybody on the same page more quickly and adjust in real time. We must do more than just send emails and wait on responses. We must follow through, touching each site, ensuring they understand what we’re asking, and listening when they speak.”

1. Source: [Open Letter to Sponsor and CRO Colleagues Regarding the Workforce Retention and Inflationary Pressures Affecting Clinical Trial Sites – Society for Clinical Research Sites \(myscrs.org\)](#)

WHAT IS THE ROLE OF BENCHMARKING TOOLS?

Sponsors like Vertex have used benchmarking products such as IQVIA GrantPlan for many years to guide budget creation. Benchmarks show pricing trends in detail and help sponsors anticipate costs based on real-world data. With the rise in inflation and attrition, negotiators on both sides seek a better understanding of how benchmarks keep up.

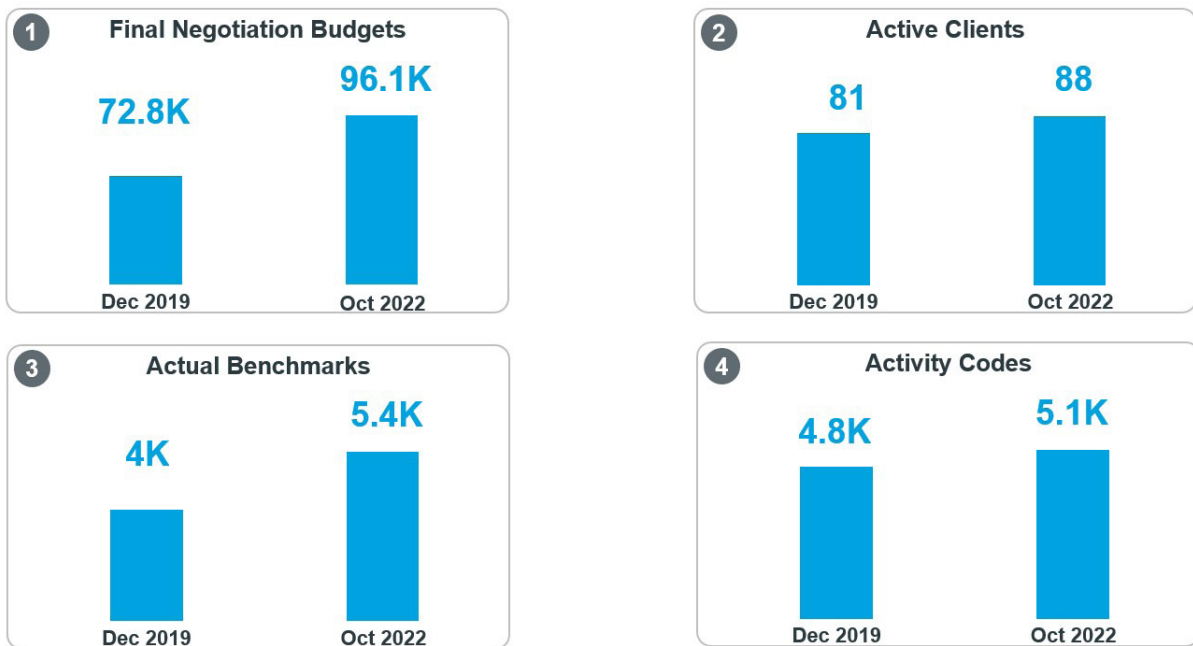
At IQVIA Technologies, we've seen a 32% rise in the number of negotiated budgets since 2020 in our GrantPlan platform. This robust flow of new client data allows us to create industry-leading benchmarks based on percentiles to help pharmaceutical sponsors establish FMV for clinical trial budget items.

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rise in the number of negotiated budgets in IQVIA GrantPlan platform since 2020

FIGURE 1: GRANTPLAN PRE-PANDEMIC DATA VOLUME V. TODAY

GrantPlan Pre-Pandemic Data Volume Compared to Today's



Source: IQVIA Technologies.

We collect data across more than 60 countries and 5,000 medical codes, and we've seen about 55,000 country/medical code combinations used in the past two years (see Figure 1). The intersection of country and codes informs benchmark costs. For example, a simple blood draw in Germany will have a different cost benchmark than the same procedure in the United States. Since 2020, we've seen costs rise across the board in all our markets, even accounting for these local variations.

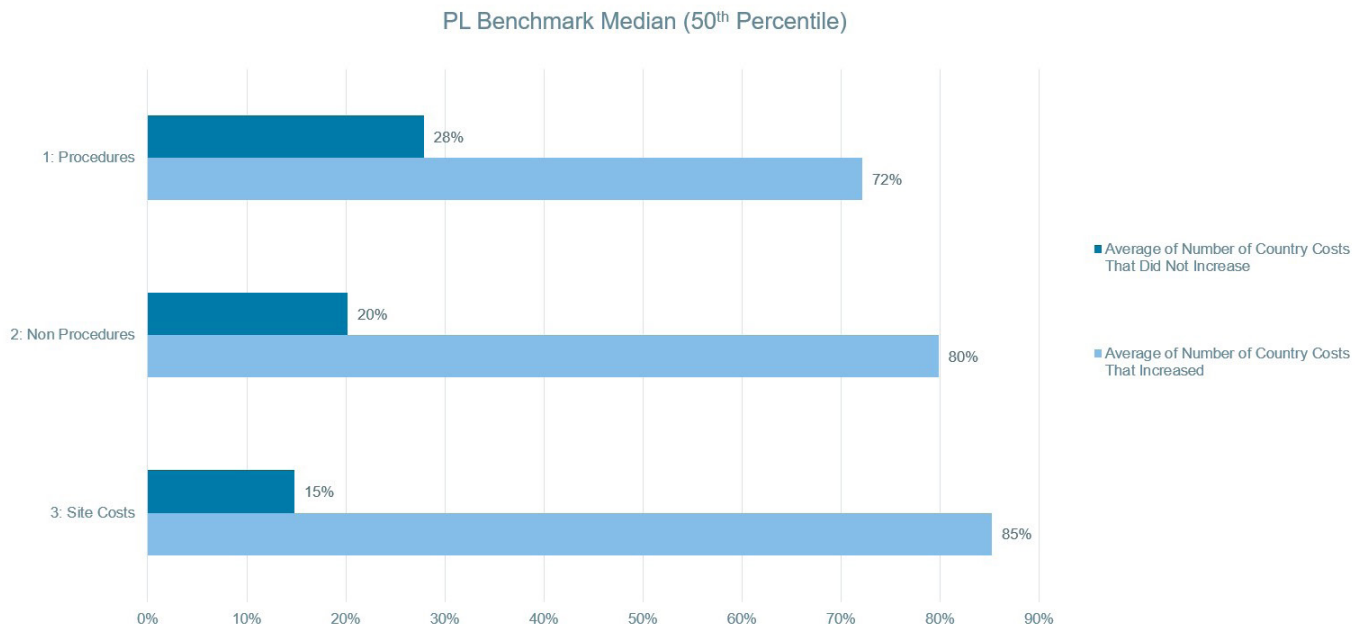
GrantPlan reports data back on final negotiated budgets in percentiles. The most used benchmarks include the median (50th), high (75th), and ninetieth (90th) percentiles. Most of our clients use the 50th percentile to formulate their FMV budgets, with the 75th percentile being the second-highest used benchmark. When we look at each of these benchmarks, we realize that the story of site FMV budgeting is more complex than national inflation.

First, Figure 2 illustrates the 50th percentile's costs across all countries, divided into three categories: procedures (physical exam, informed consent, etc.), non-procedures (personnel, materials, etc.), and total site costs (pharmacy fees, archive fees, etc.). This table shows that 72% of countries indicated higher procedure costs, 80% reported higher non-procedure costs, and 85% showed total site cost increases.

However, these numbers are not uniform across all benchmarks. When we examine the numbers for the 75th percentile in Figure 3, we see a similar trend but not as pronounced. For this benchmark, 64% of procedure costs across all countries saw increases; 71% of non-procedure costs saw increases, and 79% of total site costs showed increases.

FIGURE 2: GRANTPLAN BENCHMARKS, 50TH PERCENTILE

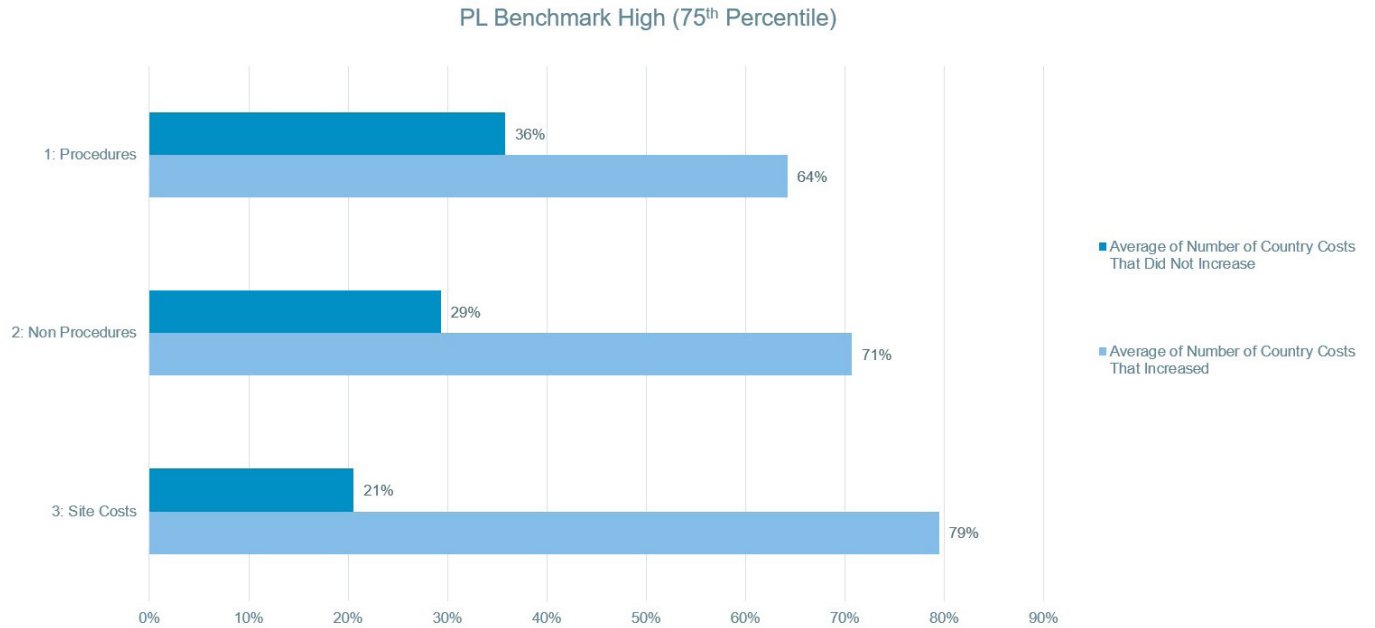
GrantPlan Benchmarks Pre-Pandemic Dec 2019 v. Oct 2022



Source: IQVIA Technologies.

FIGURE 3: GRANTPLAN BENCHMARKS, 75TH PERCENTILE

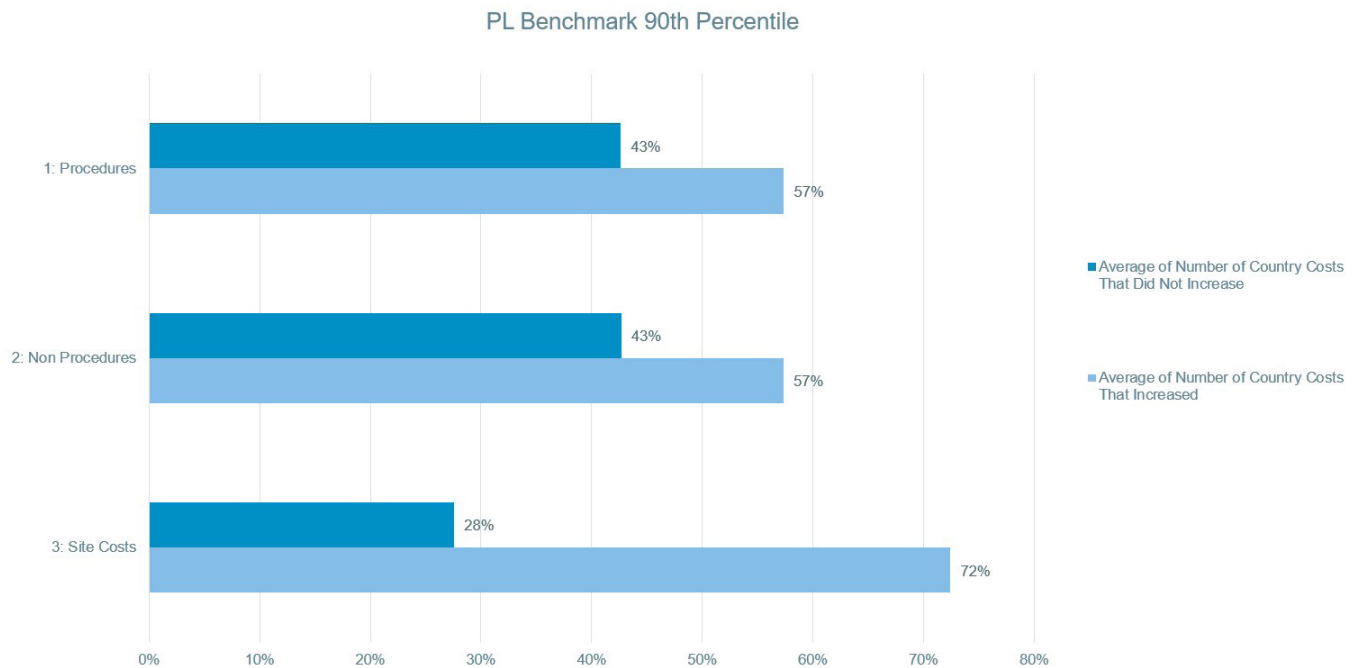
GrantPlan Benchmarks Pre-Pandemic Dec 2019 v. Oct 2022



Source: IQVIA Technologies.

FIGURE 4: GRANTPLAN BENCHMARKS, 90TH PERCENTILE

GrantPlan Benchmarks Pre-Pandemic Dec 2019 v. Oct 2022



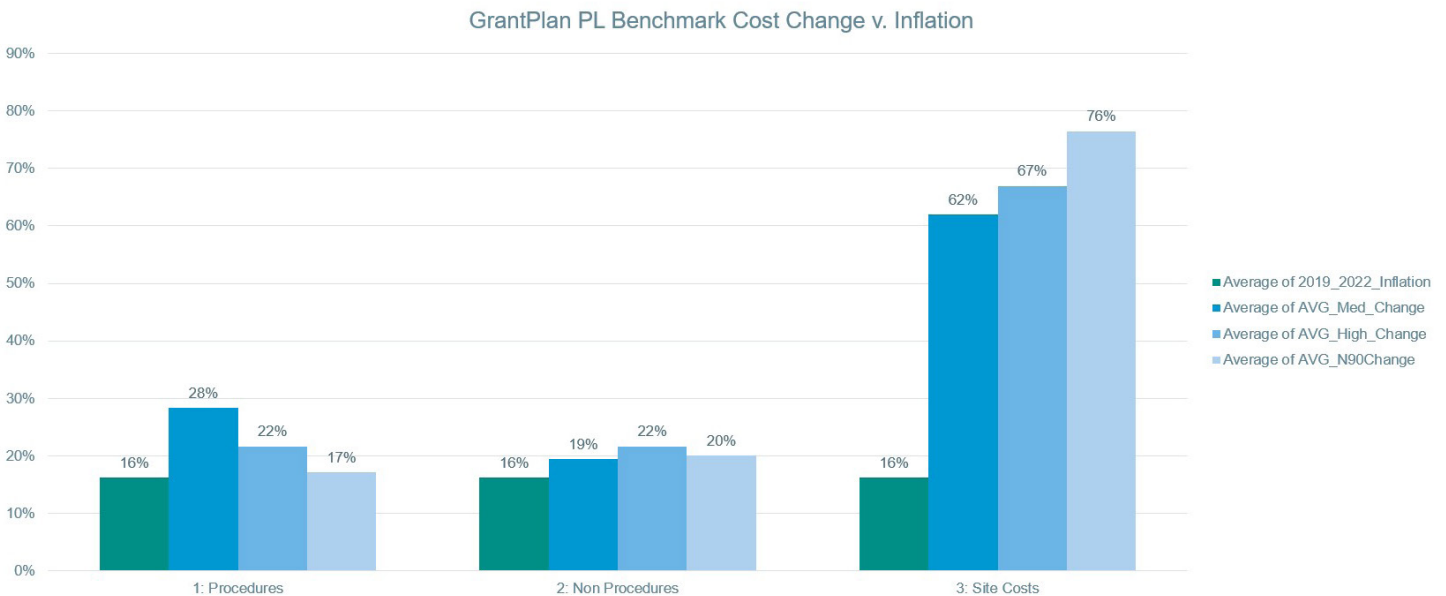
Source: IQVIA Technologies.

This trend continues through the 90th percentile benchmarks reported with even less pronounced increases than their median and high counterparts, as illustrated in Figure 4. Only 57% of country benchmarks saw a rise in procedure and non-procedure costs, while 72% indicated higher total site costs.

Comparing these three benchmarks helps us understand that cost increases are not uniform, with the highest percentiles experiencing the least significant changes. Regardless of the benchmark, we must also look at each country individually when we compare these costs to inflation. For example, in the United States, we've seen a dramatic change in total site costs vs. the current inflation rate, as illustrated in Figure 5.

FIGURE 5: GRANTPLAN BENCHMARKS V. INFLATION, UNITED STATES

GrantPlan's Benchmarks Compared to Dec 2019 - Oct 2022 Inflation *United States*



Source: IQVIA Technologies.

Interestingly, the 90th percentile benchmark tracked closely to inflation when we look again at procedure costs. Site costs, on the other hand, were far above inflation in every percentile. These numbers suggest that inflation and staffing shortages have significantly

raised the cost of clinical trials in the United States. They illustrate the complexity inherent in the data and highlight the importance of looking beyond the median benchmark to fully understand how your study may be affected by recent inflation and staffing costs.

CASE STUDY:

GERMANY, AN EXAMPLE OF COUNTRY VARIABILITY

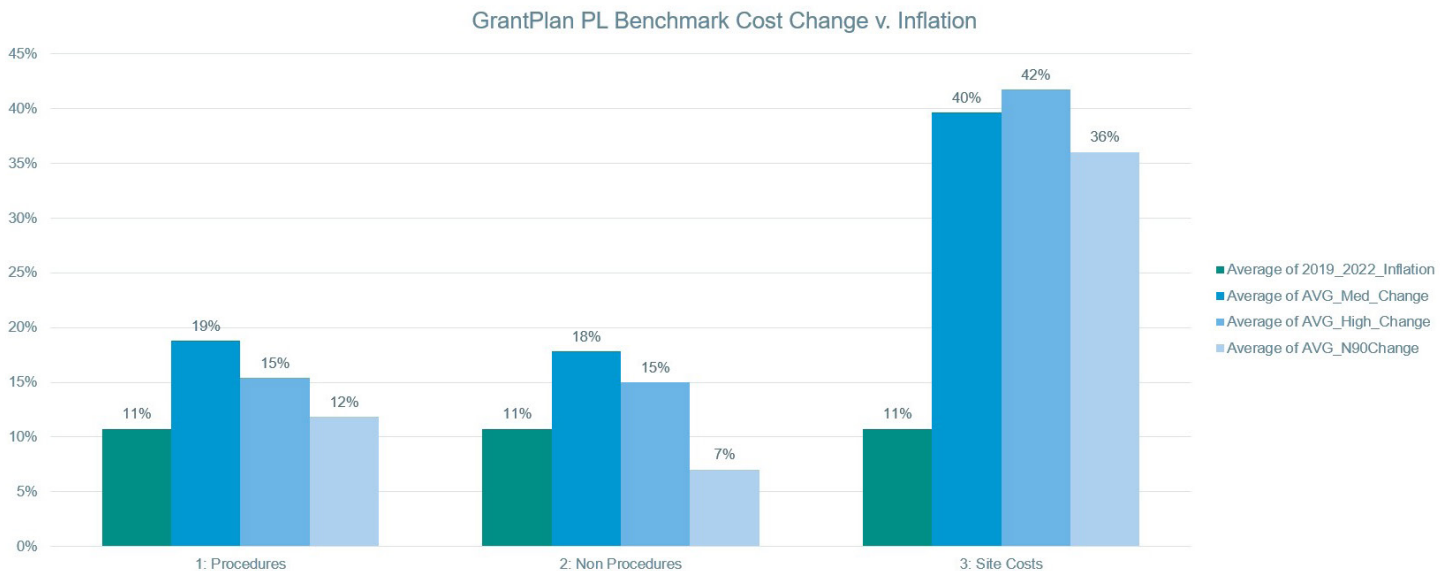
Data gathered from clients in Germany tell yet another story about inflation and high costs. We can see in Figure 6 that Germany's 2022 inflation rate was 11%; and, similar to the United States, procedure costs tracked closely to inflation in the 90th percentile. Site costs rose significantly but less dramatically than in the United States, with the 90th percentile reporting the smallest increase instead of the largest.

The non-procedure cost changes for the 90th percentile is at 7%, lower than Germany's 2022 cumulative inflation. Anomalies like this deserve a deep dive to understand their origin. Looking at Germany's staffing costs across the range of percentiles, we see an interesting phenomenon in Figure 7.

Although study coordinators' salaries expanded from 50 to 69 euros per hour in the 50th percentile and 59 to 86 euros per hour in the 75th percentile, they dropped from 106 to 99 euros per hour in the 90th percentile. However, nurses' and physicians' salaries are higher in all three benchmarks. Given these complexities and the range of salary changes by benchmark, determining FMV for staff salaries becomes complicated. This staffing cost difference helps explain the lower growth in non-procedure costs for this percentile, but sponsors must also consider the overall operating costs. Nuanced information such as this is invaluable for sponsors as they determine their FMV budgets.

FIGURE 6: GRANTPLAN BENCHMARKS V. INFLATION, GERMANY

GrantPlan's Benchmarks Compared to Dec 2019 - Oct 2022 Inflation *Germany*



Source: IQVIA Technologies.

FIGURE 7: GRANTPLAN BENCHMARK STAFFING COSTS, GERMANY

Understanding Benchmark Cost Changes

Country	Activity Name	Benchmark Version	Benchmark PL Median	Benchmark PL High	Benchmark PL 90 th
Germany	Study Coordinator - Per Hour	December of 2019	50	59	106
Germany	Study Coordinator - Per Hour	October of 2022	69	86	99
Germany	Nurse - Per Hour	December of 2019	34	41	60
Germany	Nurse - Per Hour	October of 2022	44	52	80
Germany	Physician - Per Hour	December of 2019	107	125	176
Germany	Physician - Per Hour	October of 2022	133	161	200

Source: IQVIA Technologies.

WAYS TO REDUCE FRICTION IN YOUR NEGOTIATION PROCESS

Figure 8 indicates the most popular benchmark percentiles our clients use and which version of the benchmarks they use. Only 14% of the studies created or modified in 2022 use the latest benchmarks from August and October 2022. Essentially, 86% of current studies use benchmark versions that don't incorporate the newest methodology or the most recent inflation rates, making them less relevant to today's volatile market.

Disagreements about budgets can delay or stall drug development. As the clinical research industry experiences unprecedented rises in costs, having the most current data available when creating and

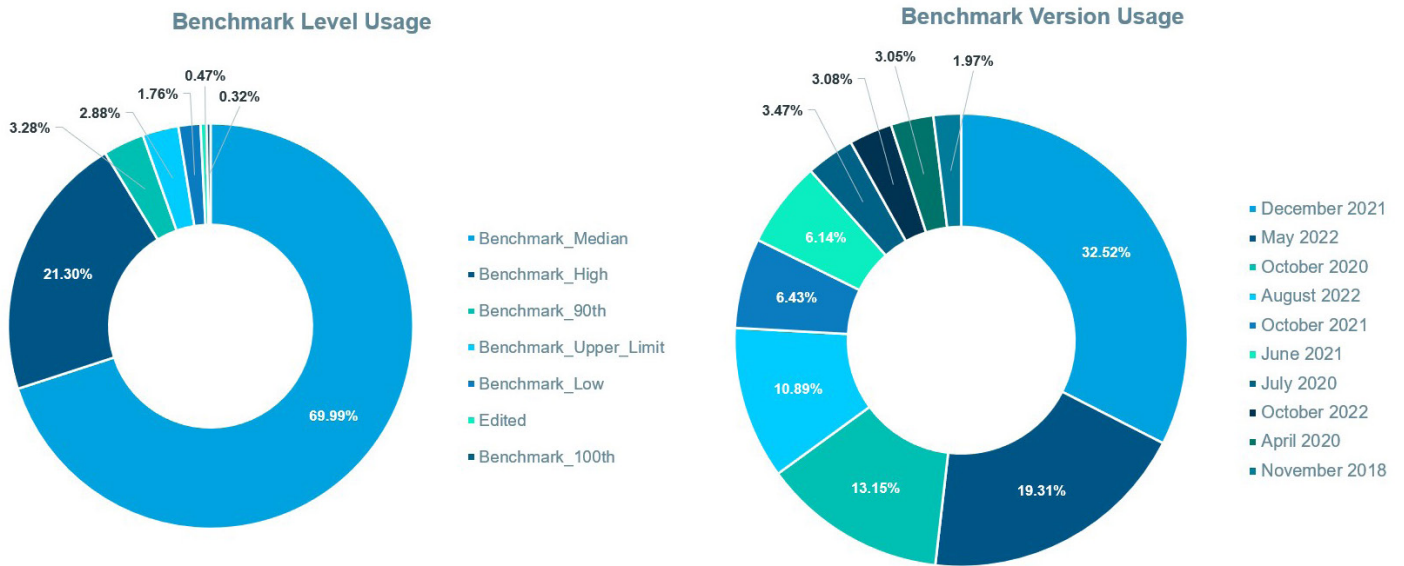
negotiating your budget is more critical than ever. Understanding all the benchmarking tools available, updating your benchmarks and exchange rates regularly, and considering the use of benchmarks above the median may provide you with a better framework for negotiations.

HOW GRANTPLAN MITIGATES INFLATION AND EXCHANGE RATE VOLATILITY

GrantPlan represents a strategic partnership between IQVIA and sponsors. Providing updated budget information and other feedback is an important aspect of maintaining and improving GrantPlan's application and processes for both the Pricelist (PL) and Actuals/Internal Budget (AIB) sources of benchmarks. Figure 9 demonstrates recent actions that we've taken to enhance our product.

FIGURE 8: CLIENT USAGE OF BENCHMARKS IN 2022

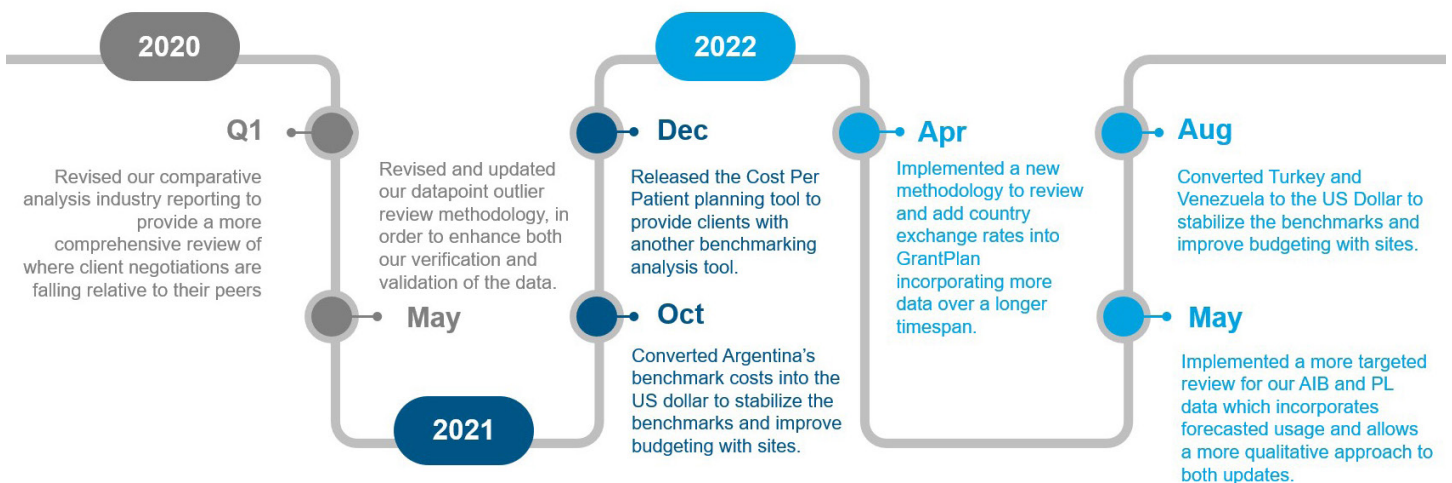
Client Usage of the Benchmarks Created or Modified (2022)



Source: IQVIA Technologies.

FIGURE 9: 9: EXAMPLES OF RECENT ACTIONS TAKEN TO ENHANCE GRANTPLAN

Examples of Recent Actions



Source: IQVIA Technologies.

“By applying novel approaches to confidence ranges pertaining to percentiles,” explained Jesse Glasse, Ph.D., Manager of Data Science for IQVIA GrantPlan, “we can leverage the full extent of GrantPlan’s data and provide the most accurate benchmarks possible.”

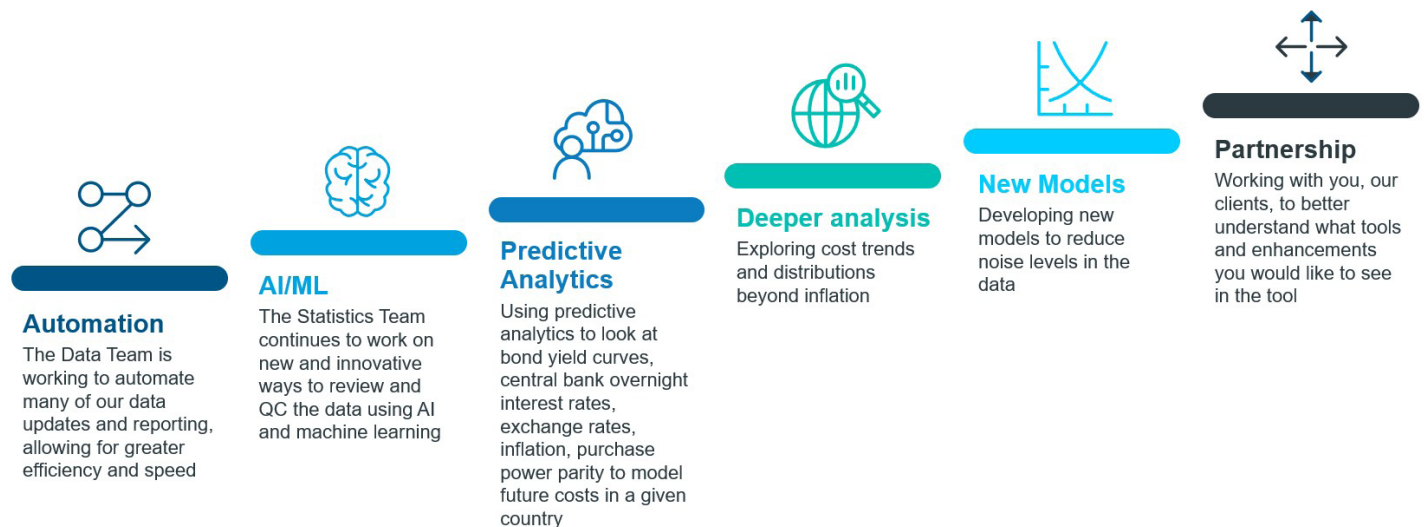
“Regarding predictive analytics, given a strong foundation of high data quality, we’re expanding our analysis and integrating more macroeconomic data,” Glasse continued. “We seek deeper analysis to provide trends within corporate inflation adjustments, sponsor-specific trends, or any other breakdown of countries, country groups, or macroeconomic factors. Additionally, we’re integrating new models to expand and integrate the scope of negotiation data captured with the Site Budget Capture tool.”

Figure 10 summarizes GrantPlan data scientists’ methods to continually grow confidence in the tool’s benchmarks, even in the face of inflation and exchange rate volatility.

Remember to update your benchmark version and update your exchange rates when copying a study, and consider updating benchmarks at key timeframes in a study life cycle.

FIGURE 10: WAYS GRANTPLAN CONTINUES TO MITIGATE INFLATION AND EXCHANGE RATE VOLATILITY

Ways GrantPlan Continues to Mitigate Inflation and Exchange Rate Volatility



Source: IQVIA Technologies.

FIGURE 11: WAYS GRANTPLAN USERS CAN MITIGATE INFLATION AND EXCHANGE RATE VOLATILITY

Ways GrantPlan Users Can Mitigate Inflation and Exchange Rate Volatility



Source: IQVIA Technologies.

Just as importantly, GrantPlan users can take steps to make sure they use the most relevant benchmarks and take advantage of all the tools available to build their budgets. First, you should leverage the Pricelist (PL) benchmark, use the Upper Limit tool, and use the Cost Per Patient Tool as an additional comparison against your Cost Per Patient amounts before or after building your detailed line-item budgets. Secondly, remember to update your benchmark version and update your exchange rates when copying a study. In this step, consider updating benchmarks at key timeframes in a study life cycle, e.g., when starting a new cohort. Finally, account for additional site effort and personnel time in this environment (e.g., supply chain issues, sponsor/vendor turnover, etc.). Remember that FMV does not mean one size fits all. These recommendations are illustrated in Figure 11.

IQVIA Technologies seeks to aid a frictionless negotiation process, ensuring the drug development ecosystem will continue to thrive. Cost data and benchmarks are tools to help these negotiations. We focus on our benchmarks' accuracy while listening to our clients and assessing

how they use the data. As the post-pandemic landscape continues to evolve, our data will evolve with it, allowing our clients to build mutually beneficial partnerships with principal investigators and sites while safeguarding their investment. High-quality data is a win-win for the entire industry.

ABOUT IQVIA TECHNOLOGIES

IQVIA Technologies develops purpose-built solutions on a future-state architecture to enable connected intelligence across the entire life sciences product life cycle. Under our Orchestrated Clinical Trials (OCT) platform, we're driving smarter, faster trials for sponsors, sites, and patients with more than 20 market-leading, cloud-based products, and tech-enabled services. These best-of-breed technologies are grouped as Digital Suites and are available independently of our CRO services, with support models customized to meet your specific business needs.

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Morgan King has been a part of the Data Services and Analytics team with the Cost Benchmarking group since 2017. He is passionate about the synergistic blend of both quantitative and qualitative data to understand the complex and quite often nuanced story it can convey.

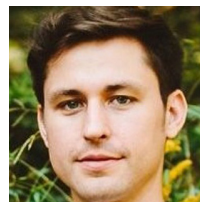
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