MEDIDATA

WHITE PAPER

Unveiling Clinical Trial Financial Management Patterns:

Harnessing Data Science for Better Data and Better Decisions

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Introduction

Sponsor and CRO business operation teams face tremendous pressure to develop accurate budget plans that reflect therapeutic considerations, global variances, and site-specific differences while ensuring that spending stays within budget. Once approved, the budgets drive contract negotiations with the sites and become the payable items once the study is underway.

Research has uncovered that 71% of sites are experiencing financial stress and are resorting to loans and other measures to cover expenses for completed work while waiting for reimbursement.[1] This financial strain significantly impacts the site's ability to sustain involvement in clinical research. In late 2022, the Society for Clinical Research Sites (SCRS), the world's foremost site advocacy group representing over 10,500 clinical research sites from 52 countries, published an Open Letter to Sponsors and CROs. This letter brought attention to the unprecedented financial pressures that sites face in conducting clinical trials. Specifically, the letter highlighted workforce retention and inflationary pressures as significant contributors to the escalating overhead costs at these sites. Through its advocacy efforts, the SCRS aims to raise awareness across the industry about the challenges faced by clinical research sites.

Managing clinical trial finances has always been a complex task, but the global changes and challenges experienced since 2020 have compounded existing issues for all stakeholders. Clients and sites frequently inquire about the impact of the COVID-19 pandemic on grant payments. Given the prevailing macroeconomic climate, there is a growing sentiment that the costs associated with conducting research have risen and should be duly reflected in study forecasts.

To shed light on the volatile period surrounding COVID-19, the Clinical Trial Financial Management team collaborated with colleagues in the Medidata AI Platform Data Science team. Leveraging the robust data available in our Site Payments application, we seek scalable data science solutions to address pressing questions. The Data Science team, with their profound industry expertise, diverse perspectives, and skilled data scientists, proved instrumental in tackling significant challenges on the Medidata platform.

Through meticulous examination of the extensive dataset on clinical trial payments, we have identified trends and patterns that illuminate how payments are made and managed within the clinical trials industry. This white paper aims to share some of our findings and explore how they can inform budgeting and contract decisions, streamline the payment process, and enhance the site experience. We firmly believe that our unique perspective and expertise position us well to provide this analysis, and we are confident that the insights presented in this white paper will prove invaluable to all individuals involved in the clinical trials industry.

Friction in Financial Health

The Budgeting, Transparency, and Oversight Dilemma

Financial difficulties and the threat of closure are pressing issues for over 50% of research sites. Sites urgently need sponsors and CROs to implement effective financial processes and system changes to ensure sustainability.

Traditional methods of disbursing funds to a Principal Investigator (PI) or site involve 20+ handoffs, cross-verification in multiple systems, manual data entry, and approvals. One Sponsor client has revealed that manual processes and checks consume 80% of their time and effort in financial planning. This intricate and disjointed workflow places a considerable burden on personnel, who must dedicate significant hours to analyzing budget versus expenditure, tracking accruals, and generating portfolio-level reports. Consequently, unnecessary overheads, time-consuming tasks, and analytical and visibility inaccuracies emerge, hindering decision-making and impeding effective oversight.

In the case of studies involving global sites, an additional layer of complexity arises as each country presents unique challenges that necessitate extensive local knowledge and expertise. This undertaking can become resource-intensive, time-consuming, and expensive.

Evolving Study Methodology

For over a decade, research sites have grappled with financial challenges, an issue that the Society for Clinical Research Sites (SCRS) has actively brought to light. Annual surveys, studies, and statistical analyses conducted by the SCRS consistently reveal a distressing reality: more than half of research sites (53% and 66%) operate with less than three months' worth of operating cash, exacerbated by delayed payments and extended 90-day payment terms. The situation has deteriorated, with 58% of sites reporting less than three months' operating cash in 2022.

The COVID-19 pandemic in 2020 left an indelible impact on the industry, resulting in the suspension, adaptation, or cancellation of numerous studies. Decentralized trials (DCT) gained prominence as the industry shifted its focus toward virtual and hybrid studies, necessitating the introduction of new technologies, processes, and services that research sites have readily embraced. In 2021, according to an SCRS Site Landscape Survey, 82% of sites experienced year-over-year profit declines.

Study Site Cost

Financial arrangements outlined in the Clinical Trial Agreement (CTA) between sites and sponsors encompass various aspects, including payment frequency, start-up and close-out costs, patient recruitment, patient reimbursement, and procedural expenses. During the initial phase of a study, sites make substantial investments in activities such as patient recruitment, advertising, staff recruitment and training, implementation and training for new systems, regulatory compliance, and the procurement of equipment and consumables.

Among the critical financial management issues sites face, payment frequency and delays take center stage. According to the latest survey conducted by the SCRS, this issue affects 58% of sites.[1] Payments to sites are typically subject to delays averaging 4.5 to 6 months, and the quarterly payment structure may contribute to these extended delays. The ongoing cash flow deficit becomes unsustainable as sites continuously incur expenses such as staff salaries, patient recruitment costs, recruitment and training expenditures, and preparatory costs for upcoming studies.

Analysis

Our analysis examined cost transactions spanning from January 2020 to June 2023. It consisted of approximately 7.6 million individual transactions. All costs were normalized to USD, adjusted for inflation for comparison purposes, and aggregated into a categorical classification.

Payment Cycles

The Medidata AI team conducted an in-depth analysis utilizing data from our Site Payments application. This application has supported over 2,500 global studies, facilitating grant payments totaling over $5.8 billion across 74 countries. By examining cost transactions from various customers from January 2020 to June 2023, we obtained a rich dataset comprising approximately 7.6 million individual transactions.

One notable finding from our analysis was the significant variation in payment cycle lengths. We defined the payment cycle as the days between creating a cost and the payment date. As illustrated in the histograms presented in Figure 1, individual payment cycles exhibited a wide range, spanning from less than 30 days to over a year. The mean payment cycle time between 2020 and 2021 was 138 days, while between 2022 and 2023, it reduced to 68 days. Notably, our data indicates that 16% of payments were made within 14 days of cost creation, and 49% were made within 60 days. However, approximately 39% of the analyzed records had a payment cycle longer than 90 days.

The substantial percentage of payments overdue by 90 days or more highlights the pressing need for sponsors to enhance the efficiency of their clinical trial financial management processes. It also suggests sponsors may require site assistance addressing underlying process and system issues.

Inflation and escalating operational and trial costs have emerged as significant challenges. In the United States, inflation reached its highest level in four decades during 2021 and 2022, while 69% of 29 countries, as reported by the Office for National Statistics, are grappling with “high” or “very high” inflation compared to their long-term trends.[2] These circumstances have disproportionately impacted clinical research sites, exacerbating their financial issues.

To tackle the inflationary pressures, increased costs, and the consequences of high staff turnover, the SCRS issued an open letter in late 2022, urging for open dialogue and collaboration. The rising costs associated with studies have significantly eroded the already narrow profit margins of research sites, pushing some to operate at a loss. According to the SCRS 2022 Landscape Survey, one-third of respondents from their membership reported experiencing a net loss or a profit margin of no more than 5%.

To enhance the accuracy of budgeting and forecasting, it is crucial to have access to reliable study cost information that is adjusted for economic conditions. Conventional methods often lead to inaccurate budgets, resulting in the issues discussed in this paper. However, by gaining access to an accurate and anonymized global clinical trials data repository that provides information on country, site, therapeutic area, industry-level costs, and patient-level data, it becomes possible to significantly improve the precision of planning, scenario development, forecasting, and budgeting.

Figure 1A

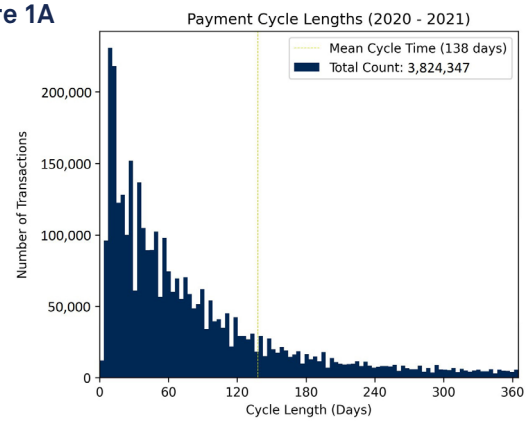


Figure 1B

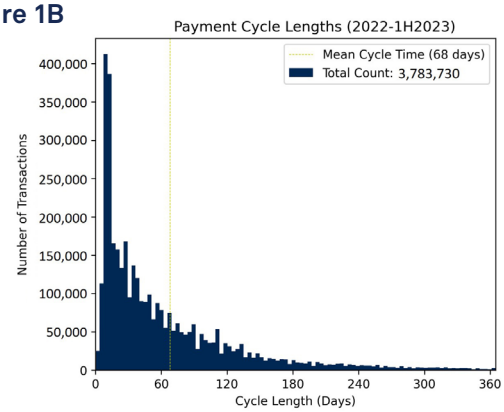
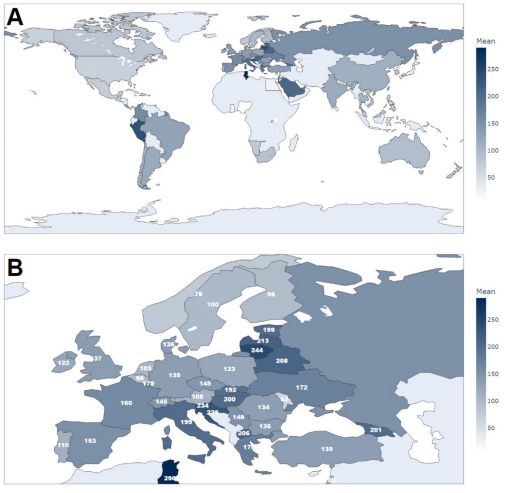


Figure 1, shows the distribution of the payment cycle lengths between 2020 and 2023. The horizontal axis represents the cycle length in days, while the vertical axis represents the number of payment transactions. Payment transactions that took 2020 and 2021 are considered "during COVID-19" and plotted in Figure 1A. Payment transactions between 2022 and 2023 identified as "after COVID-19" are in Figure 1B. The average cycle time for all transactions between 2020 and 2021 is 138 days, while the mean cycle time is 68 days. Our investigation found that the mean cycle time for all completed transactions was 127 days.

Global-View

In Figure 2, we have employed a color-coded system to represent the mean payment cycle length for each country. Countries shaded in darker blue indicate longer mean payment cycles, whereas lighter shades represent shorter cycles. It is worth noting that there is a considerable variation in mean payment cycle lengths among different countries. Specifically, Tunisia, Lithuania, Peru, and Slovenia demonstrate the longest average payment cycles, exceeding 234 days. This data suggests that during this period, Tunisia, Lithuania, and Peru had the longest payment cycles globally. Investigating the reasons behind this discrepancy could involve exploring in-country regulations and practices, the pace of hybrid implementation, or regional macroeconomic differences. These factors warrant further investigation to determine whether process refinement or additional site support is necessary.

Figure 2



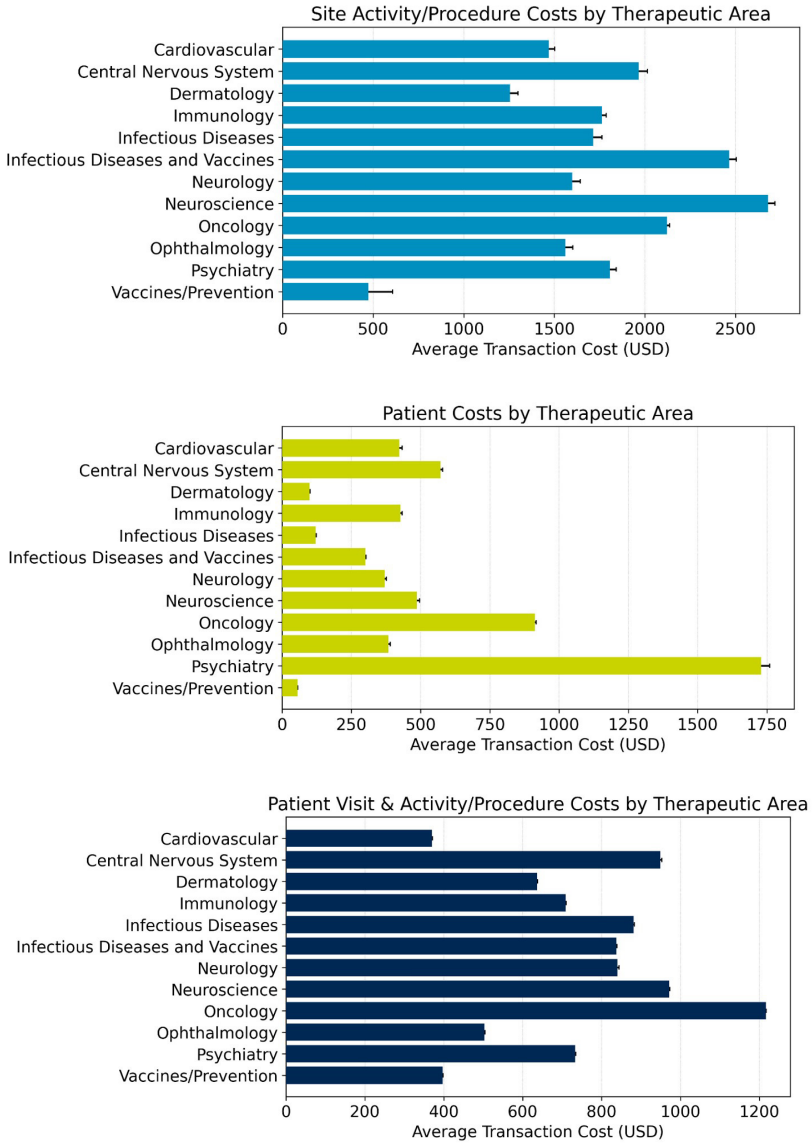
Rank	Country	Mean Payment Cycle Length (days)
1	Tunisia	290
2	Lithuania	244
3	Peru	236
4	Slovenia	234
5	Croatia	228
6	Latvia	213
7	Belarus	208
8	North Macedonia	206
9	Saudi Arabia	206
10	Georgia	201

Figure 2 displays a choropleth map that shows the mean payment cycle length of clinical trials across different countries. The countries are represented by varying shades of blue, with darker shades indicating longer mean payment cycle lengths. The mean payment cycle length for the countries highlighted in 2B is displayed as a text label. Figure 2A shows the entire world, while Figure 2B is a zoomed-in view of Europe. The color scale indicates the mean payment cycle length, and the table on the right displays the top 10 countries with the most prolonged mean payment cycles.

Cross-Sectional View of Cost Differences

We aggregated the 7.6 million transactions into their respective groups for analysis. The groups were Site Activity, Patient Cost, and Patient Visit & Activity Cost. Site Activity covered all startup and study close-out related expenses. Patient costs include patient travel expenses and reimbursements. Patient Visit & Activity covered site-related procedural activity costs. Figure 3 provides a snapshot of costs analyzed, indicating the variances across the three categories attributed to factors such as patient pool, cost efficiency, regulatory conditions, infrastructure, study expertise, exchange rates, and inflation.

Figure 3



In Figure 3, the bar charts show the average costs for the 12 most common therapeutic areas. The figure includes three bar charts, each representing the average cost for a different type of cost - Site Activity/Procedure Costs, Patient Costs, and Patient Visit and Activity/Procedure Costs, respectively. The length of each bar shows the average cost for a specific therapeutic area, and the error bars indicate the standard error of the mean.

The top bar chart displays site activity/procedure costs, the center bar chart shows patient costs, and the bottom chart reflects Patient Visit and Activity Procedure costs. Each bar in the chart represents a different therapeutic area, and its length shows the average cost for that therapeutic area.

Among the three types of costs, site activity/procedure costs emerge as the highest. This can be attributed to the significant payments associated with site-related expenses during the startup and closeout phases. Analyzing the plot for patient costs reveals that psychiatry trials exhibit the highest average patient cost. In contrast, oncology trials tend to have the highest costs for patient visits and activities/procedures. These findings underscore the burden placed on both sites and patients in these specific therapeutic areas.

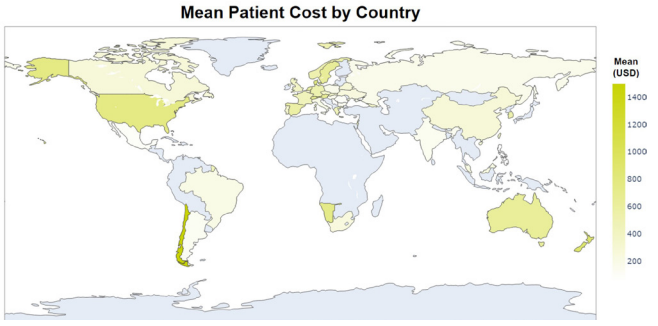
We also analyzed how the cost types varied across different countries. Figure 4 shows three choropleth maps that display the mean cost for the three different types of costs in other countries worldwide. The darker-shaded countries indicate higher average costs. The tables at the bottom of Figure 4 show the five countries with the highest mean costs for each cost type.

The differences in mean costs between countries could reflect differences in billing practices, such as making lump payments for multiple patients or procedures versus billing individually. Understanding these differences could be of great value to organizations involved in clinical trial financial management as it could help them better understand how costs vary across different countries and inform budgeting and cost management decisions.

Figure 4

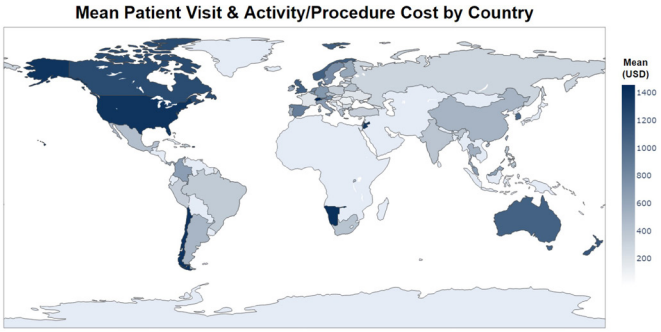
Site Activity / Procedure Costs

Rank	Country	Mean Cost (USD)
1	South Korea	6577
2	Denmark	4689
3	Singapore	3667
4	New Zealand	3297
5	Netherlands	3248



Patient Costs

Rank	Country	Mean Cost (USD)
1	Chile	1507
2	New Zealand	889
3	Denmark	789
4	USA	746
5	Namibia	727



Patient Visit Activity/Procedure

Rank	Country	Mean Cost (USD)
1	Switzerland	1465
2	Namibia	1406
3	Chile	1388
4	USA	1377
5	Jordan	1368

Figure 4 presents a choropleth map that displays the average costs of three categories across various countries. The color scale on the map denotes the mean cost, with darker shades indicating higher costs. Three separate maps are displayed for each cost group, along with tables that list the countries with the highest mean costs for each category.

Another cross-sectional analysis of the cost category variances was conducted by layering therapeutic area-specific costs by country, site, and patient-level information to analyze the cost variations.

Figure 5

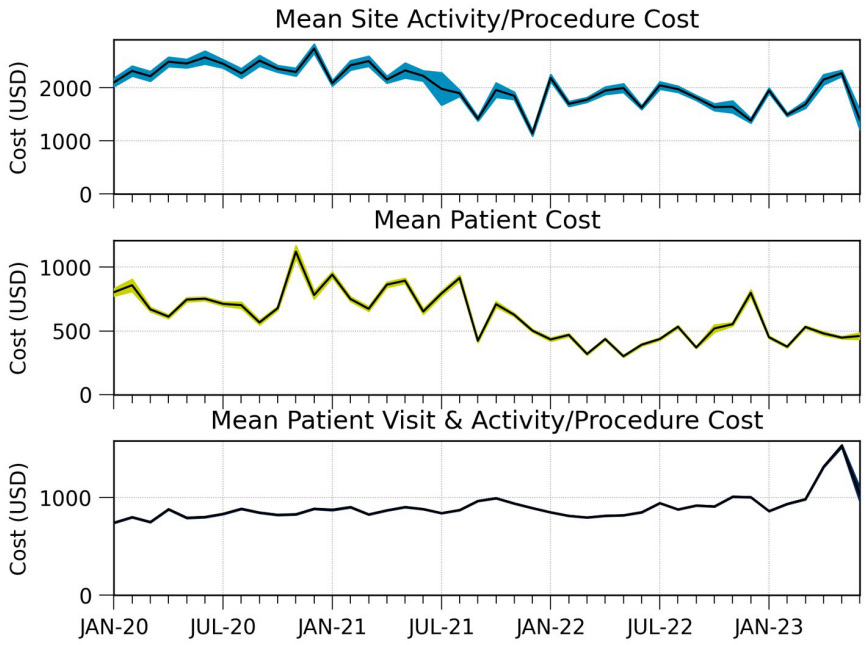


Figure 5 The line graphs show the average cost in USD for each cost type over time, with shaded regions indicating the standard error. Site Activity/Procedure Cost is represented in light blue, Patient Cost in green, and Patient Visit & Activity/Procedure Cost in dark blue. The y-axis displays the mean cost amount in USD.

It is evident from Figure 5 that, on average, the Mean Site Activity/Procedure Cost is greater than the Mean Patient Cost and Mean Patient Visit & Activity/Procedure Cost. Notably, Patient Visit & Activity/Procedure Cost demonstrates a consistent growth pattern over time. During 2021, The Mean Site Activity Procedure Cost and Mean Patient Cost exhibited a higher frequency of change, the most significant monthly variance, and the greatest highest standard error. This increased variability can be attributed to vaccination initiatives and the widespread implementation of hybrid research activities.

The volatile variances in these costs can create a margin of error that hinders negotiations. To avoid or reduce mistakes in budgets and forecasts, deep data insights are essential. A scalable system that provides global capabilities, multi-language interfaces, multi-currency and multi-tax capabilities, and global customer support is critical for finance management and decision-making in global clinical trials.

Conclusion

The collaboration between the Clinical Trial Financial Management and Data Science teams revealed significant differences in global payment practices between 2020 and 2023. During the early stages of the COVID-19 pandemic (January 2020 - December 2021), there was a 70-day reduction in mean payment cycle times compared to the latter stages (January 2022 - June 2023) after widespread vaccination was reached. Tunisia, Lithuania, and Peru had the most prolonged payment cycles globally during this period, which may be due to in-country regulations and practices, slower operationalization of research activities, or regional macroeconomic differences. Further investigation is needed to determine if process refinement or additional site support is required.

Our data also revealed that site activity and procedure costs, such as start-up and close-out, carry the highest average cost across different clinical trial spend categories. Start-up costs often account for lower-than-desired line-item costs in the grant budget, perpetuating a cycle of inaccurate fair market value for site activities. Obtaining insight into actual costs through a modern fair market value tool and building a trusting and transparent relationship with sites can elevate a company to a Sponsor of choice with sites.

Finally, there are regional and therapeutic area differences in grant costs, and the variance of these costs over time is of interest. Data can reveal these variances and serve as a call to action to determine whether intervention is required.

The ability to surface deep data insights within budgeting and payment activities can transform forecasting budget negotiations, inform study changes, or mitigate site escalations, helping better manage costs, cash flow, and risk. Our data science and product teams will continue to mine the wealth of data within Medidata payments datasets and dig deeper into how these analytics can be intelligently surfaced to the right end user at the right time.

When we leverage Medidata's financial suite of products and strengthen it with the computational power and methods of data sciences, data analytics in the workflow approach can be realized for the customers. This partnership of technology, insights, and customer input is the foundation from which sponsors and sites can focus on delivering exceptional patient care. This is only possible with the rich historical and cross-industry data available through Medidata Site Payments.

Better data, better decisions.

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2. Economics Daily. US Bureau of Labor Statistics. https://www.bls.gov/opub/ted/2022/consumer-prices-up-9-1-percent-over-the-year-ended-june-2022-largest-increase-in-40-years.htm