



White Paper:

CRPN's revenue recovery systems and services enhance clinical site revenue streams and financial stability at local community sites:

A Real-World Case Study

Daniel J. Fox, MPH, PhD

Founder and CEO – Clinical Research Payment Network

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Executive Summary

Introduction

Late clinical site payments are not a secret to the industry. Unfortunately, they are the norm. Sponsors and CROs become so overwhelmed with work that proper payment management systems are often compromised. The fault cannot be fully owned by global sponsors and CROs, but rather shared by every stakeholder, including the local community sites, who do not have the necessary financial management systems for optimal performance.

Problem

As an industry standard, clinical trial payments often have little to no accountability for noncompliance, they generate improper, unreliable, or no remittances, they are considered by many site personnel to be out of scope of their professional responsibilities, and they are plagued with delaying communication breaks across internal and external stakeholders.

Solution

At a site partner's request, CRPN may offer complete Site and Industry Communications, Negotiations, Grant Management and Bookkeeping, Aging and Query Resolution, and Forecasting and Financial Reporting services to establish a pathway to financial success throughout the clinical trial business cycle.

Case Study

The following case study measured a CRPN site partner's general financial metrics before and one year after requesting CRPN financial and revenue recovery services.

Results

The site partner experienced an increase in overall revenue and a notable increase in invoiced revenue with vs. without utilization of CRPN's financial and revenue recovery services. After correcting for annual study visit increases as an additional revenue-increasing variable, CRPN's services demonstrated a direct impact of 70% compared to the prior year. In addition, the site reported additional business enhancements in negotiated rates, increased data quality management, and reduced AR times of unpaid claims.

Conclusion

Grant management and financial processes are critical to successful clinical site businesses. CRPN's financial management and revenue recovery services successfully optimize site partner business models for reliable and dependable financial security. Once established, sites will have the tools necessary to optimize the utilization of the contracts in lieu of negotiating inflated and unused resources.

As a result, responsible financial management may assist in a proper and deflated clinical trial execution process that may benefit the entire industry.



Introduction

Payments are one of the most contentious challenges community research sites must face during their business operations. Far too often, Sponsors and CROs become so inundated with global-scale trials that they often do not have the processes in place to manage and operate responsible payment systems to our frontlines. As a result, clinical trial payments are late as an industry standard, invoiceables are missed, and communication with sites is scattered and unreliable due to inconsistent communication plans and personnel turnover. The fault, however, cannot be solely on the sites' consumers, but rather on the internal processes of each community research site.

It is imperative as a clinical research site to develop internal processes that are fast, accurate, and flexible to meet the needs of the global partners we work with.

As late or no payments for services continue to become a standard in our industry, community research sites need to establish thorough financial management processes to ensure they successfully receive all of the resources they have earned.

The following white paper discussion will explore the challenges behind site payments, introduce the Clinical Research Payment Network's solutions to these problems, and then present a real-world case study and testimonial from a CRPN site partner to demonstrate the earning power of fast, reliable, and managed accounts receivable processes for enhanced quality, improved industry connections, and stronger financial systems.

Background

Sponsors and CROs almost never comply with the agreed-upon contractual negotiations (Clinical Research News 2018), resulting in a mistrust between parties and substantial discouragement from physicians to continue future participation (SCRS 2014). Promises are broken, physicians avoid further damages, and the potential patients now and in the future who could receive innovative and life-saving care are no longer a potential.

As a result, Clinical research as an industry has a broken financial system that is critically impacting its mission to translate innovative technologies to patient care as quickly, efficiently, and safely as possible (McIntyre 2021; SCRS 2012, 2017).

For years now, sites and site advocates call for financial changes in the industry (SCRS 2014, 2017a, 2019). Sites are not paid according to contractual terms (Miseta 2017; Clinical Research News 2018) and, as a result, they experience limited operating cash, untimely payment, lack of financial transparency, and significantly underfunded contractual negotiations (SCRS 2019). Only one in three sites have sufficient resources to operate for 90 days (SCRS 2017) and, amidst the pandemic in 2020, 31% of sites reported to ACRP they feared permanently closing operations due to the pandemic (ACRP 2020). The industry is in a crisis, with health institutions finding fewer and fewer physicians interested in performing research, primarily, according to Robert Califf, the current commissioner of the FDA, "by erosions of system



efficiency, waning interest in clinical research among practitioners, and financial insolvency among participants in the clinical research enterprise” (Califf 2009; SCRS 2019).

Clinical sites have been frustrated with CRO mismanagement for years and have reported across conference circuits and among inner circles they experience CRO’s generally tend to ignore contractual obligations and avoid timely payments without accountability for their negligence and, as a result, compromise the clinical sites’ capacity to support quality clinical trials.

Problem

How is something as intuitively simple in business settings so challenging for the clinical trials industry to remediate?

Why, after years of concern and demonstration, aren’t these processes improving?

In an industry as complex and stakeholder-heavy as clinical research, there may be many reasons. To name a few of the most common culprits, the following are descriptions and observations are referenced from true stories, and real-world experiences from the voices of CRPN’s site partners.

No direct accountability for noncompliance

Every clinical trial comprises a negotiated budget and a clinical trial agreement (CTA), however the promises made when the contract is signed are often forgotten or ignored before the ink is dry. As an industry standard, CRPN site partners report Sponsors and CROs often do not adhere to the payment provisions in these contracts. Net30 terms may pay sites in 90 days. Net 90 (quarterly) terms may pay sites in as much as 140 days (Raghunandan 2019).

Unfortunately, the consequence of neglecting the promises made is minimal. CTAs do not have late fees in the US as they do in other countries (NHS 2006), and a site’s general protections from such non-compliance often escalates to extremes rapidly, such as withholding of data entry or delay of monitoring visits until sponsors can successfully achieve financial compliance per the CTA.

Site reports across the network are echoed across the industry; confirming that even now poor site payments continue to plague the industry (CenterWatch 2022; Montgomery 2022) with potential solutions that are currently under construction (DiCesare 2023; Parke 2023). However, although efforts continue to develop point solutions across niche sectors and specific vendors, a comprehensive and impactful industry-wide solution has yet to gain momentum in the overall industry to eliminate the failure culture of contractual payment terms.

Improper, unreliable, or no remittance tracking

In the uncommon event sites are paid on time, the challenges have only just begun. Sites report continuous difficulties accessing the itemized and correct remittances they need to properly account for and record payments for services provided. Remittances are sent across the industry through a number of venues and range from helpful and collaborative PDF documents to zero remittances without individual requests, bulk or lump sum remittances that do not align with agreed-upon CTA terminologies or values,



required portal logins for access, and even remittances that are not only incorrect, but also combined with numerous CTAs without defined separation or clear description of payments.

Depending on the CRO and Sponsor, sites report times to receive a remittance or remittance clarity is 4 weeks to 175 days (Montgomery 2022). And, in the event of an erroneous remittance, sites have little to no path to dispute or communicate the error and are instead funneled into global-wide e-mail boxes that may take months to receive a response.

Internal Site Misunderstandings – “It’s not my job”

Far too often, a site’s internal Administrative, Clinical Operations, and Regulatory teams create responsibility siloes that do not allow for the flow of financial information communication. Clinical operations and regulatory teams are so laser focused on the performance of a trial that they often do not prioritize financial billing communications to administrative teams until it is too late to claim revenue.

In fact, many of the sites visited by CRPN personnel demonstrate the same professional dynamic: Clinical Operations and Regulatory Teams often claim financial reporting is “not their job” and opt to continue their daily operations without adjusting communication pathways to ensure their site is capturing the revenue owed for each trial. Such voluntary siloing results in an internal inefficiency that can cost research sites hundreds of thousands of dollars in unclaimed revenue. Financial health must be just as important to every site staff member as their daily services to patients, sponsors, CROs, and regulatory bodies.

External Communication breaks

“Where’s our payment?”; “Where’s the remittance?”; “This is wrong, why?” – Thousands of questions arriving into the e-mail boxes of our global CRO payment specialists. The overwhelming amounts of work results in poor service quality, frustrated stakeholders, and overburdened CRO employees.

Consequentially – the long communication time periods that occur simply to achieve remittance or query resolution led to extensions in accounts receivable timelines and increased personnel time required to continue following up on small and answerable queries.

Further, in a world where CROs feel sites are “meddling in their business” when they contact sponsors directly (Moat 2023), the disconnect combined with the cultural expectation for sites to work directly with non-responsive CROs leads the industry toward a disastrous path of mistrust and expensive and unreliable services performed.

Solution

The industry’s projected ten-year growth and the clinical sites’ chronic dissatisfaction with current systems warrant a prime environment to establish a new industry financial standard. CRPN works in, out, and across the confines of the current clinical trial landscape to ensure its site partners and sponsors have access to the tools they need to succeed. Our expert team flexes to the financial processes and needs of any site from paper and spreadsheets all the way to commercial CTMS platforms. We customize our processes to create communication pathways and informative education to make financial management not the burden of a single staff member, but rather a holistic site effort.



In addition to CRPN’s streamlined financial processes that model up to 70% in cost savings and 98% in startup and grant management savings for our site partners and sponsor members, they also work directly with site partners to help them navigate and manage their current negotiation and financial management needs.

Case Study

Site partners across the world have experienced the power of strong financial management systems within their organizations. CRPN thanks its anonymous site partner who is willing to help share the successful message of our services in the analysis and promotion of their story for our network’s mission and the betterment of the industry.

To protect the identity and wellbeing of each site partner, data and testimonials are deidentified by organization and dollar value.

Site Introduction

The site partner successfully enrolled trial participants in the majority of its awarded trials. Although equipped with a standard CTMS platform and the necessary electronic systems, the site partner recognized a potential to claim additional revenue with optimized financial processes.

After joining CRPN, the site partner requested an initial **Financial Monitoring Visit** to assess financial health.

Following the visit, the site partner requested CRPN assume grant management, bookkeeping, negotiating, and overall financial management and forecasting of its trial portfolio to improve and enhance its revenue cycles.

CRPN Services

CRPN offered a comprehensive financial service customized to the strengths and needs of the requesting site partner:

Site and Industry Communications

CRPN ensured every stakeholder at the site who generated revenue opportunities was included into the necessary communication pathways. We developed systems and processes within the site’s CTMS to monitor invoiceable triggers and created systems with site personnel to inform them when to report invoiceable services as they are generated while, at the same time, remained conscious about sensitive financial and budgetary information among site personnel.

Negotiations

We utilized CRPN’s industry knowledge and experience to ensure contracts going forward were responsibly negotiated. CRPN personnel have successfully negotiated countless industry contracts and customize negotiation strategies to our site partner’s needs.

The result – strong contracts that are designed to protect our sites and ensure their study services are fully funded throughout the lifetime of the clinical trials.

Grant Management and Bookkeeping

The experienced CRPN team assumed all grant management and bookkeeping activities surrounding site payments and expenses. We not only assumed duties for current and future grant payments, remittances, and expenses, but we also utilized our industry connections to retrospectively request every remittance issued to the site for 100% payment reconciliation.

Aging and Queries

Complimentary to grant management – CRPN established routine aging reports and queries for late and incorrect payments. We confirmed each payment was fully compliant to each study’s CTA and utilized our knowledge and relationships throughout the industry to ensure the site was paid what they deserved when it was promised.

Forecasting and Financial Reporting

CRPN assisted the site with past, present, and future financial management services. In addition to retrospective payment reconciliation and current processes, we assisted the site with forecasting and prediction models for financial planning, staffing and resource management, and strategic growth.

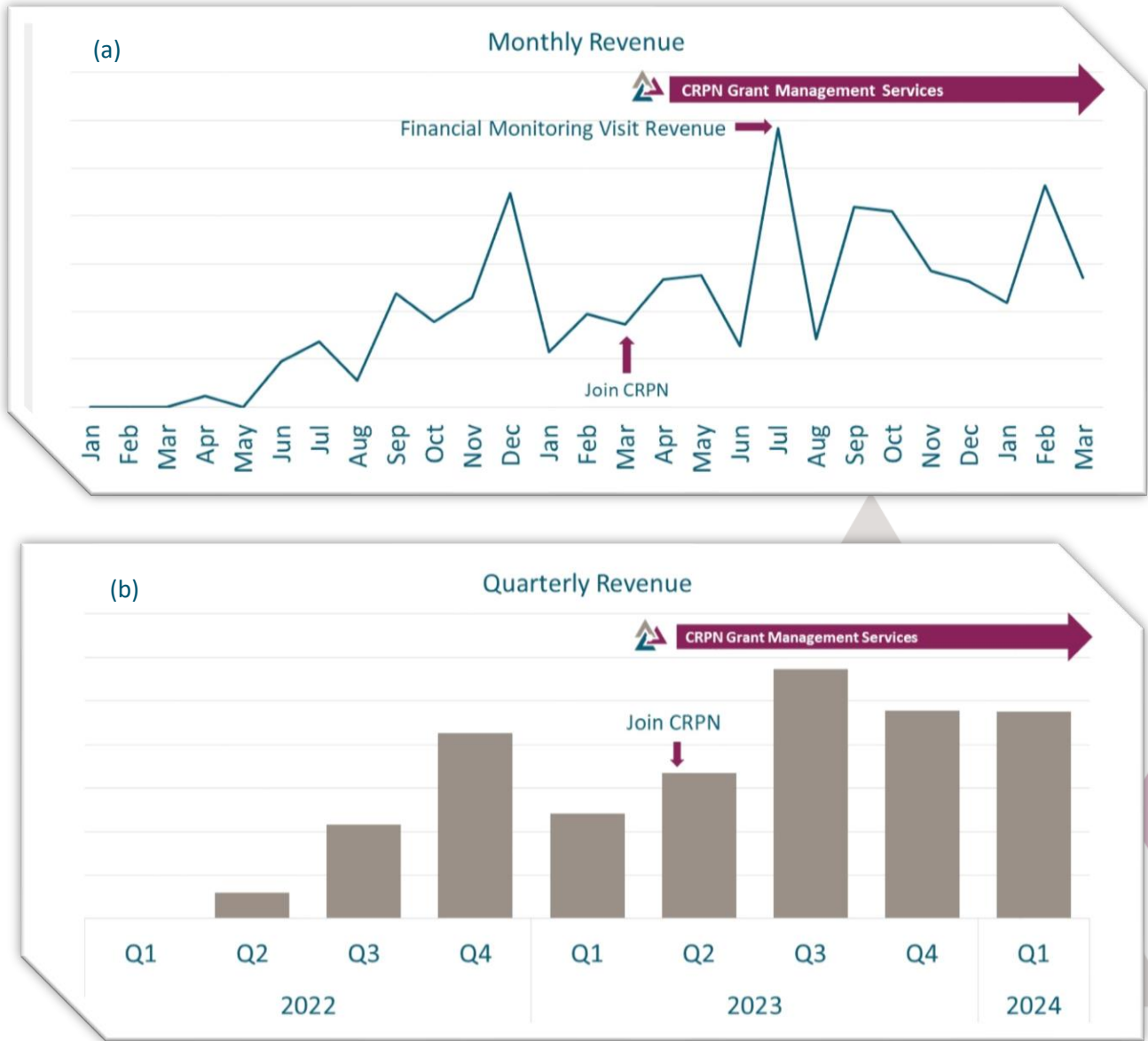
Results

Over the past year, CRPN’s services have demonstrated numerous measurable and reportable outcomes for our site partner.

Increases Overall Revenue

The site partner experienced an increase in overall revenue after joining CRPN and requesting financial services. Monthly revenue yielded highs and lows, with a record peak resulting from invoices and revenue recovered from the initial Financial Monitoring Visit. Even after the initial burst of unclaimed revenue was realized, no full quarterly report while under CRPN’s management fell below the highest reporting quarter before the site requested CRPN’s services (Figure 1 below).

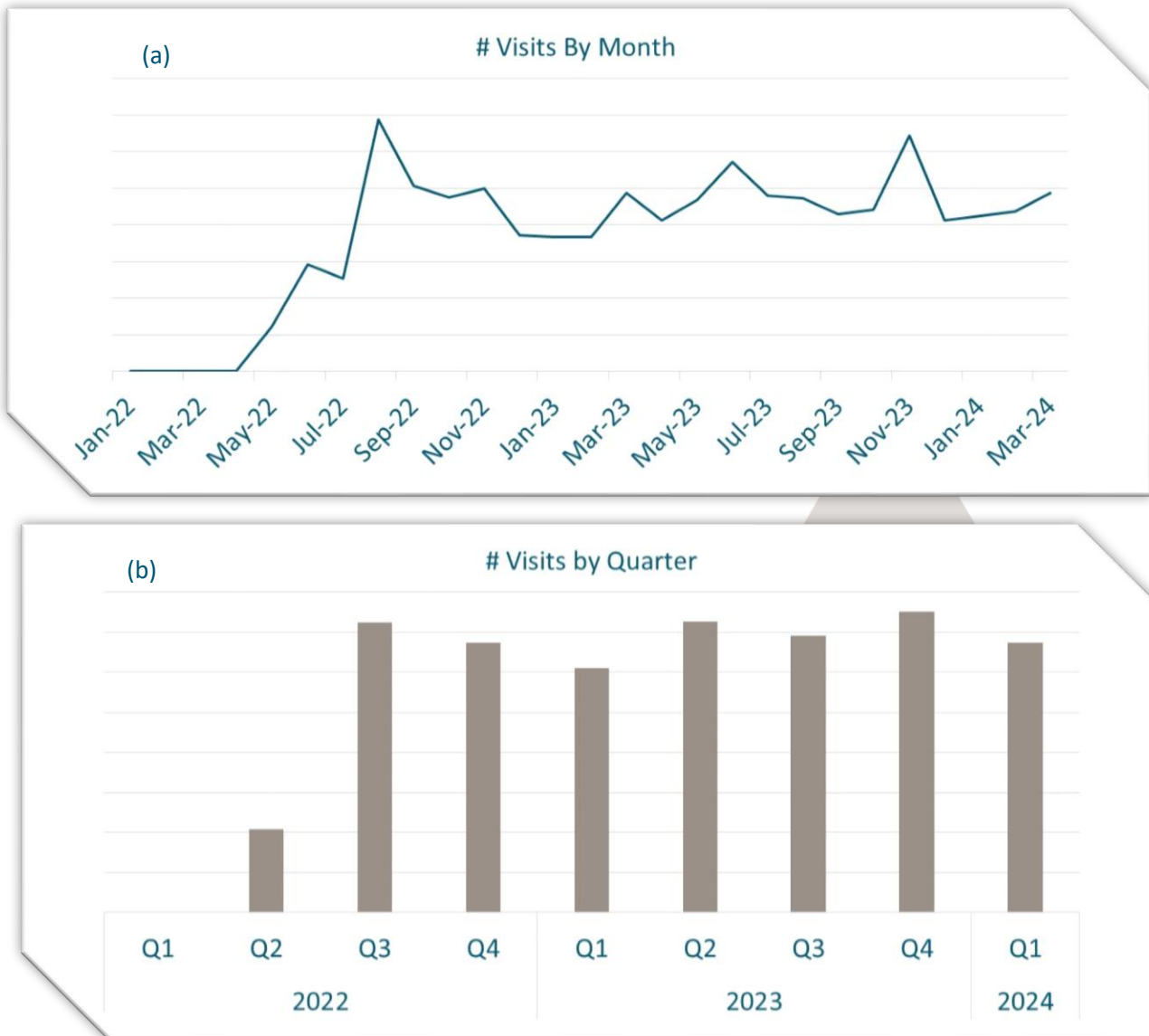
Figure 1(Below). Monthly (a) and quarterly (b) revenue over time. The site partner joined CRPN and requested services since March 2023. Received revenue noticeably increased and sustained when CRPN initiated site-wide revenue recovery systems and financial management services.



Combined, the site partner earned 1.98 times more revenue 12 months after joining CRPN than the 12 months prior to requesting services. The average number of visits in the same time period increased by 28%, whereas the average overall revenue in the same time period increased by 98%. The notable increase in revenue therefore did not appear to be a complete result from an increase in workload

(Figure 2 below). Rather, the 70% difference between percent work vs earned revenue was likely a direct result of CRPN’s financial management and revenue recovery services.

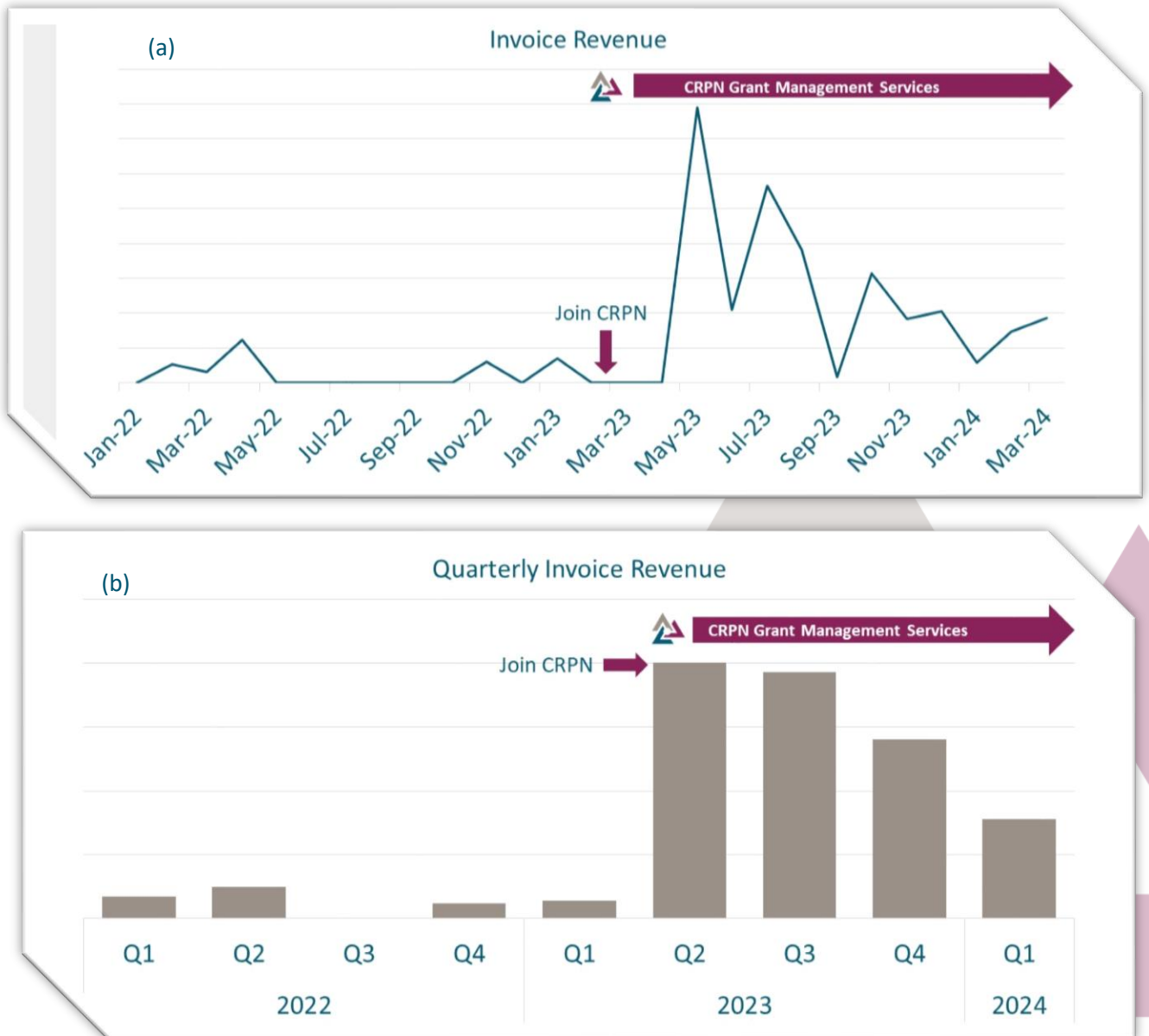
Figure 2 (Below). Monthly (a) and quarterly (b) number of study visits at the research site. Following ramp up, the # of visits in 2022 vs. 2023. While the number of visits sustained across the time periods, revenue notably increased. Thus, the noted increase was not necessarily a result of increased visits, but rather financial management and recovery services.



Increased Invoice Revenue

One of the most notable impacts from CRPN’s services resulted from a substantial increase in invoiced revenue (Figure 3 below). Although the site had sent a few initial startup invoices prior to joining CRPN, it was not claiming its invoiceable revenue to its entirety. Once established, CRPN’s financial management services yielded 16% of the overall revenue directly from invoices.

Figure 3 (Below). Monthly (a) and quarterly (b) invoice revenue over time. CRPN’s grant management and revenue claiming services notably increased the amount of invoice revenue requested and collected.



Increased Negotiated Rates

The site partner noted a substantial increase in CRPN-negotiated rates compared to previous budget negotiations. The difference in negotiation rates was a direct result of CRPN's industry knowledge of service rates and invoiceable line items that were not previously considered. In addition, CTA terms were notably improved toward site protection and adequate funding for services provided.

Increased Quality Assurance

The site found that continually-managed financial services provided an enhancement to data quality management and a reduction to data queries. Throughout the process, financial teams identified data entry queries before site monitoring visits. Further, with proper aging report and reconciliation processes, the financial services assisted to identify EDC entries, mis-entries, and/or omissions that were preventing service payments.

Reduced AR Times and Unpaid Claims

Prior to CRPN's services, the site was experiencing an average Accounts Receivable (AR) times near Net180 in payments, with some study visits and invoiceables being over one year old. Following extensive financial management and reconciliation with global organizations over the course of one year, the site is now averaging AR timelines near Net45 with one of the oldest unpaid visits being approximately 4.5 months old. To maintain this level of quality, the cycle must be continuous with routine follow-ups and late payment queries to ensure continued contractual accountability with the industry's payment counterparts.

Discussion

Case study results echoed the industry's recommendations to adopt Generally Accepted Accounting Principles (GAAP) and financial management for sound site business operations (Roy 2023; Monte 2023) and the impact of sound financial systems in clinical trial efficiency and viability (Sampson et al. 2022). They also validate recent recommendations for strong, functional, and compliant financial systems in clinical trial settings (Verma 2021) and the importance of trial financial managers to make significant and ethical contributions to the advancement of medical research (Emenze 2023).

By responsibly managing a site's contracts and ensuring sites receive everything owed for services provided, we see that negotiated contracts do not necessarily have to inflate into inflated budgets that are only partially utilized, but rather represent the true fair market value of the services provided.

Further, while the case study requires strict confidentiality to protect the site partner's business metrics and sensitive financial information, the preliminary results more than justify further studies and extended metrics to fully analyze the impact that CRPN's financial services may have on a clinical site's short- and long-term financial wellbeing.

Conclusion

A message from the site:

“CRPN’s grant management services made an enormous impact at my research sites. At one site, Dr. Fox performed a financial monitoring visit that uncovered and recovered more than six figures of owed monies we were unaware of. At a newly established site, the CRPN team’s vigilant attention to our accounts receivable made that business cash flow months sooner than it would have otherwise and possibly saved it from default.

The truth is most clinical research professionals are not familiar with the finance aspect of the industry. If you do not have a finance pro in your corner you need one and CRPN makes this accessible to everyone.”

CRPN successfully establishes customized financial management systems for each of its requesting site partners for optimal payment reconciliation, improved margins, and overall, a substantial increase in financial health.

This case study demonstrates only one of numerous examples comprising sites with strong and passionate clinical operations and limited knowledge, infrastructure, and/or industry connections required to thoroughly and properly manage clinical trial finances as a responsible business.

The payment challenges our sites face every day are multi-faceted and therefore require multi-pronged approaches to remediate. A healthy financial system must therefore establish strong negotiation strategies, solid grant management systems, transparent internal and external communication pathways, and multi-disciplinary support structures at the site level to holistically enhance not only financial operations, but also regulatory, data quality management, and clinical operations.



Questions or Comments?

Contact CRPN today to learn how we may help your site or your clinical program:

info@crpaynet.com

crpn.crpaynet.com

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