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Designed by Strategikon's visionaries, Clinical Maestro is revolutionizing clinical trial operations with SaaS excellence and unrivaled transparency

Clinical Maestro is an innovative, cloud-based platform meticulously designed by the experts at Strategikon to streamline the intricate processes of budgeting, sourcing, and overseeing complex clinical programs. It emerged from a fusion of passion and exasperation. Developed and nurtured by seasoned financial and clinical business operations executives with experience on both Sponsor and Provider fronts, the founders embarked on a journey fueled by the conviction that there had to be a superior way. In response to their belief, they took matters into their own hands and created a solution that transcended conventional boundaries.

Clinical Maestro stands as a testament to the belief that the integration of intuitive technology, absolute transparency, and seamless communication between biopharmaceutical companies and providers will usher in a new era of heightened productivity in clinical research.

Anca Copasecu, CEO of Clinical Maestro, spoke exclusively to CIO Bulletin about how her company is at the forefront of minimizing the time and effort required for planning, budgeting, and outsourcing clinical trials.

Interview Highlights

Q. How has Clinical Maestro evolved since its founding, and what key milestones have marked the company's journey in the clinical trial budgeting and management industry?

The inauguration of our transformative journey came with the introduction of our inaugural commercial solution, the Clinical Maestro PORTFOLIO module, in 2019. From the onset, our vision was to create an end-to-end platform catering to the unique needs of the clinical business operations segment—an ambitious undertaking given the inherent complexity of core business processes. These processes span from planning and budgeting trials to managing high-value clinical RFPs for vendor selection, change order management, tracking, reforecasting actual completed and out-of-scope activities, and overseeing clinical vendor performance.

Over the past four years, guided by invaluable insights from industry stakeholders, we have diligently expanded our offerings, achieving our vision in record time. We delivered additional modules within the Clinical Maestro platform to our discerning clientele. Our commitment to innovation remains unwavering, as we continue to release breakthrough features at a high cadence.

We consider ourselves fortunate for the unwavering commitment of our dedicated group of employees, partners, customers, and investors. They not only share our vision but also believe in our mission to revolutionize the landscape of clinical operations with the Clinical Maestro platform.

Q. Can you provide a comprehensive overview of the services and solutions offered by Clinical Maestro for professionals involved in clinical trial budgeting, proposal, contracting, and vendor management?

Clinical Maestro Sponsor Edition, a pioneering solution in the pharmaceutical and biotech landscape, has emerged as a catalyst for transformative change in clinical business operations. It is meticulously crafted to empower professionals engaged in budgeting, proposal development, contracting, and vendor management. Its visionary approach resolves longstanding challenges and sets new benchmarks for operational efficiency and industry excellence.

At the heart of Clinical Maestro Sponsor lies its ability to create a virtual common ground that simplifies clinical business operation transactions. This is a paradigm shift from traditional methods, where stakeholders grapple with time-consuming and non-standardized document handovers. The elegant user interface of the platform ensures users have a great experience in navigating through the complexities of clinical business operations.

Clinical Maestro Sponsor is structured around four integrated modules, each supporting the overarching goal of enhancing operational efficiency and collaboration.

- 1. PORTFOLIO:** Unlocking Financial Modeling Efficiency PORTFOLIO empowers clinical operations professionals by providing an intuitive platform to design study budgets without the need for advanced financial modeling expertise or extensive Excel skills. The module's sophisticated budgeting capabilities extend to modeling with Provider pre-negotiated rate cards or fixed unit agreements, mapping the output to Sponsor's unique bid grid or GL account structure, creating dynamic payment schedules and tying them to unique study milestones, or modeling complex multi-cohort oncology studies. The ability to conduct unlimited scenario modeling enables users to explore various possibilities, fostering a more proactive and adaptive approach to clinical business operations. Simply put, PORTFOLIO has become the industry's most advanced and accurate clinical study modeling, budgeting, and benchmarking engine, providing fact-based insights to R&D finance, outsourcing, and clinical operations professionals.
- 2. SOURCE:** Innovating R&D Procurement SOURCE replaces outdated Excel-based workbooks and generic procurement systems. It centralizes all R&D outsourcing needs, ensuring that sourcing decisions adhere to best practices and are informed, objective, and fair. An exciting new feature of SOURCE enables Sponsors to effortlessly generate contracting documents, such as Statement(s) of Work (SOW) and Change Order(s) directly in the sourcing platform. SOURCE provides an unparalleled experience with an industry-first AI-enabled bid grid mapping functionality, delivering transparency in study assumptions and fostering collaborative responsibilities between sponsors and clinical service providers. One of SOURCE's standout features is its side-by-side comparison, allowing users to benchmark against provider proposals, rate cards, industry benchmarks, or previous prices paid. This valuable insight during negotiations saves on average >10% of the proposal cost and brings >75% efficiency in sourcing activities.
- 3. LEAD:** Navigating Contract Complexities Clinical Maestro LEAD stands as the pharmaceutical industry's first automated platform for contract activity reporting at the unit level. It dynamically tracks study progress, activities completed, and study forecasting using CRO or service provider reporting. LEAD brings order to the forecast process by facilitating the management of contract complexities, change orders, re-forecasting of clinical study budgets, and performance metrics. With features like Earned Value Analysis, tracking of actual units and milestones, LEAD offers unprecedented visibility into study progress. Stakeholders can easily measure the study's position relative to cost, time, and operational drivers, facilitating data-driven decision-making.

4. **VISION:** Revolutionizing Vendor Governance VISION, the first-to-market clinical vendor governance solution, pioneers R&D oversight and performance management and brings an array of unparalleled benefits. With a focus on transparency, VISION offers 100% visibility into vendor category specifics, work orders, and general contracts, governance, qualification status, and performance, acting as a central hub for comprehensive vendor management. The platform accelerates processes, achieving over 90% elimination of manual activities, such as Excel trackers, qualification surveys, and data entry. Communication is streamlined with VISION serving as the single source of truth for all stakeholders, uniting disparate sources of critical data for vendor performance management, including operational, financial, contractual, IT, security, and innovation. VISION delivers significant savings by eliminating duplicate systems and reducing internal efforts and boasts a remarkable >75% reduction in the current cost of centrally managing vendors.

Q. Can you share a notable success story where Clinical Maestro's products and services made a significant positive impact on a client's clinical trial processes or outcomes?

Challenge: Overcoming Outsourcing Hurdles

A West Coast-based Biotech faced significant challenges in outsourcing their previous clinical trial, leading them to seek a more efficient solution for their Phase II respiratory study.

Solution: Clinical Maestro's Game-Changing Approach

Clinical Maestro emerged as the game-changer, alleviating pain points and driving substantial benefits throughout the process. In their prior experience, negotiations were protracted, and seven months post-RFP, a finalized budget and contract were still elusive. Clinical Maestro revolutionized their approach by leveraging technology for financial study models and RFP automation.

Outcome: Transformative Results beyond Expectations

The results were nothing short of transformative. Bid-to-spec and bid-to-expertise scenarios, made possible by Clinical Maestro, narrowed CRO bid ranges, reduced activity-level variances through clear RFP specifications, and provided clarity through benchmarking to industry expectations. This streamlined approach enabled us to select a winning CRO promptly.

The impact? A finalized budget just five weeks post-negotiation, estimated savings of >\$800K in direct costs through effective negotiation, completion of outsourcing at least two months sooner, and an impressive four-month reduction in the contract period for each trial in our pipeline. The Biotech's Head of Clinical Operations emphasized the unparalleled value, highlighting that the savings achieved were over 25 times their investment in just four months.

Q. What is Clinical Maestro's vision for future innovations and developments? Are there specific areas or features the company is looking to enhance or introduce in the coming years?

Our roadmap is rich with new features stemming from our customer-led product advancement approach that puts user feedback at the center of new development. Exciting new features include expansion of our governance model in VISION with KPI-tracking and category-centric qualification processes, adding new benchmarks in PORTFOLIO and creating an AI-enabled marketplace in SOURCE.

Q. What message would you like to convey to the CIO Bulletin readers, your current and future clients?

As you lead your organization towards digital transformation, there are a few key points to keep in mind. Look for solutions that automate repetitive tasks, coupled with real-time data visibility. Empower your teams to make informed decisions and focus on customer success through efficiency, savings, and quality. Solutions should integrate seamlessly into existing systems, ensuring minimal disruption to current IT infrastructures. Perhaps most importantly, concentrate on a user-friendly interface to contribute to a positive user experience, facilitating quick onboarding and maximizing the platform's utility across your organization.

With its cloud-based SaaS architecture, Clinical Maestro has delivered all these components, as demonstrated by our growing success.

Anca Copasecu | Founder & CEO

Frustrated by existing solutions, Anca Copasecu created the Clinical Maestro platform based on more than 15 years of experience in clinical research, working with both sponsors and service providers. As the Head of Clinical Outsourcing at BioMarin and with experience at two global CROs, Anca gained unique insights into clinical business operations.

“Strategikon's Clinical Maestro platform, featuring its Sponsor modules—PORTFOLIO, SOURCE, LEAD, and VISION—effectively minimizes both time and expenses throughout the entire lifecycle of developing clinical trials.”