MAXIS IT

Get Control of Your Data

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Transform Your Biotech Organization into a Data-Driven Powerhouse

Given the rising volume and complexity of clinical trials, it's no wonder biotech companies outsource most of their study activity to contract research organizations.

While sponsor-CRO partnerships are invaluable for bringing drugs and devices to market, the former are often left with less visibility into their data. Is there a way for sponsors to maintain more oversight of their data while maintaining a healthy CRO partnership?

By implementing an artificial intelligence-enabled data management and analytics platform, biotech sponsors can get visibility into and control of their data in real-time. If the platform has self-service capabilities, sponsors can use it to oversee trial progress and make decisions in the moment. Meanwhile, their CRO partners can continue to do what they do best—execute high-quality clinical trials.

Why Are CROs in High Demand?

Demand for CROs has skyrocketed over the past five years, as pharma and biotech companies seek comprehensive support for more clinical trials. Spending on contract clinical research services is growing at about triple the rate of non-outsourced clinical development spending. Both hiring and M&A activity among CROs are also high.[1]

The main reasons for the CRO boom stem from clinical trial quantity and complexity. The number of clinical trials has grown exponentially over the past 10 years. At the end of 2012, clinicaltrials.gov listed their numbers at 137,485, jumping to 437,536 by the end of 2022.[2]

Drug developers are also implementing more complex protocols, with an emphasis on large molecule therapies and oncology. A Tufts Center for the Study of Drug Development (CSDD) analysis from 2021 points out that oncology studies—which have nearly quadrupled over the past 20 years—typically involve more investigative sites and generate more data. The analysis also found oncology study durations are 30 to 40% longer than trials in other therapeutic areas, involving more protocol deviations and amendments.[3]

A Tufts CSDD report from 2023 built on the trend toward complexity, finding that more than 75% of clinical trial protocols involve at least one amendment. Amendments, which are, it said, associated with larger and more complex trials.[4] The more complex the clinical trial, the more data it generates. Today's complex clinical trials generate so much data, it's difficult—if not impossible—for study teams to timely collect, manage, analyze, and interpret that data.

With so much nuanced activity, it's no surprise that biotech sponsors are reaching out to CROs with increasing frequency. Biotech startups tend to operate lean, employing small teams that act fast. They rely on CROs for their industry expertise, their development capabilities, and their relationships with sites, investigators, and regulatory agencies.

1. https://www.centerwatch.com/articles/26334-cro-market-shows-signs-of-consolidation-amidst-record-levels-of-demand-and-growth
2. https://clinicaltrials.gov/ct2/resources/trends#RegisteredStudiesOverTime
3. https://acrpnet.org/2021/05/05/clinical-trial-complexity-levels-show-unrelenting-increase
4. https://csdd.tufts.edu/impact-reports

The Problem with Data Dependence

While CROs provide vital resources for biotech research, the relationship has its limitations. McKinsey research noted that the biotech companies it surveyed said CROs could do better when offering strategic advice and integrating technology providers. [5]

The McKinsey article advises CROs to position themselves as an end-to-end partner of choice. That same level of service applies to technology implementation.

A best-of-breed approach allows biotech sponsors to use a collection of sophisticated standalone systems. However, this approach introduces data compatibility issues and puts a significant burden on site staff. For sites that manage multiple trials concurrently, requiring them to learn five different systems for one study is a big ask. In the end, a best-of-breed approach results in an unnecessarily long cycle from data capture to submission.

Other CROs and/or sponsors work with clinical technology vendors that offer an end-to-end data capture and management platform. In the past, this approach meant users had to settle for generic, sub-standard systems, but advances in technology have changed that.

Many top-tier vendors offer best-in-class platforms with all or nearly all the modules needed to run a clinical trial. But if those platforms remain under the control of the CRO, biotech sponsors won't have what they need to move with the agility they're accustomed to. Instead, they fall into a frustrating pattern of moving fast and waiting long.

5. https://www.mckinsey.com/industries/life-sciences/our-insights/cros-and-biotech-companies-fine-tuning-the-partnership

Whether biotech organizations fully outsource clinical trials to CROs or outsource only specific functions, the data disconnect creates a type of black box for the sponsor, receving monthly or quarterly reports rather than real-time visibility.

If there's a discrepancy that requires an adjustment to the protocol, the CRO may initiate a change order. Change orders raise the cost of the services provided and may lead to trial delays. For companies focused on running time-and cost-efficient clinical trials, multiple change orders and "hiccups" are best avoided.

How Can Biotech Become More Data Independent?

Data management and transfer are part of the sponsor-CRO agreement; however, access to data could trigger additional costs. Biotech companies deserve visibility into their data throughout the trial lifecycle, not just at certain points in time.

An artificial intelligence-enabled data management and analytics platform brings trial data out of the black box that lies between the CRO and sponsor. With data accessible when needed, sponsors regain their control. They can make decisions in real-time, which helps the trial move forward, faster.

MaxisIT's Clinical Trial Oversight System (CTOS) is a purpose-built command center for biotech sponsors and CROs. It's designed to manage biopharma and life sciences clinical trials as mission-critical business processes.

As an AI-enabled analytics platform, the CTOS allows for "data-driven digital transformation" from data ingestion, processing, and analysis to timely clinical intelligence. Real-time data visibility, analytics, and visualization empower researchers to identify and mitigate errors as they occur.

The CTOS brings clinical operations and patient data together in a central data hub. Consider it a single source of truth for clinical operations, clinical data management, biostatistics, and clinical R&D portfolio management.

For biotech sponsors who prefer the best-of-breed approach, CTOS unifies trial data from disparate eClinical systems to support data quality, clinical review, patient safety, CRO performance, risk-assessment, and other functions, all the way to submission.

Using a platform like the CTOS, sponsors can take back control of their data. They gain more visibility, allowing for more informed decisions.

This level of data transparency allows biotech sponsors to work better together, partnering to execute more efficient, highly effective clinical trials for today's complex therapies.

About MaxisIT

MaxisIT's purpose-fit and intelligent clinical data analytics platform helps improve clinical trial performance, mitigate risk, and optimize clinical outcomes. We provide a centralized and reliable source of truth for diverse data types from various sources, giving life sciences companies real-time insight to shorten cycle time and increase return on investment.

Incorporating an end-to-end clinical data pipeline from intake to visualization, MaxisIT's solutions are powered by AI/ML and metadata-centric approaches. Our impressive portfolio of over 3,300 clinical trials and an unparalleled 100% customer retention rate affirm the quality and reliability of our services.

Moulik Shah
Founder & CEO, MaxisIT

Moulik Shah is a passionate healthcare technology entrepreneur and the visionary CEO of MaxisIT, where he has been at the forefront of leveraging technology to transform pharmaceutical and life sciences clinical trials.

His dedication to improving patient outcomes and his leadership in directing patient-centricity, patient diversity, interoperability, and real-world-data-led collaborations have been at the core of his vision of an integrated healthcare ecosystem based on effective use of data and analytics platforms.

He has been instrumental in driving innovation and progress in the industry. Under Moulik's leadership, MaxisIT has become a leading provider of clinical data and analytics which is driving real-world impact in the pharmaceutical and life sciences clinical trials.

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