OmniScience

Field Guide for Modern Clinical Trial Teams: Navigating the Opportunity Landscape

Clinical trial complexity is growing. Modern trial teams are managing more than triple the data compared to a decade ago. Despite this, the methods and technologies for handling this data remain largely unchanged, heavily relying on manual processes and disparate systems. This inefficiency hampers clinical trial operations and jeopardizes data quality, pressing the need for innovation.

At OmniScience, we believe data unification is the most critical source of innovation from which numerous opportunities emerge. **Here we summarize market trends that have led us to this conclusion and ways that our team is laying the foundation for the future of clinical development.**

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Keeping pace with the clinical trial data explosion

It is an exciting time for clinical research. Clinical trial teams now have access to over 3x the volume of data that was available 10 years ago. Additionally, the complexity of data is increasing, with more inclusion and exclusion criteria, more sources of data, and more endpoints, including a growing number of digital endpoints from digital health technologies.

The value and knowledge behind this data is limitless. However, there are a host of limitations standing in the way of clinical trial teams optimizing this wealth of data.

Clinical trial teams have access to over 3x the volume of data available 10 years ago:

- Total endpoints increased **69.2%**
- Total procedures increased **40.5%**
- Total countries increased **66.7%**
- Total sites increased **60.1%**
- Total data points collected went from 929,203 to 3,560,201 (↑ **384.2%**)

Ken Getz, *Tufts Center for the Study of Drug Development, presented at Marcus Evans Evolution Summit Dec. 4, 2023*

Clinical trial operations and data management, and the technologies to support them, have remained relatively unchanged over the past decade. The work is still largely manual and reliant on spreadsheets. To compound the issue, over 70% of clinical trial data is now being collected outside of electronic data capture (EDC) systems, meaning that the high volume of data is spread across even more systems.

Sponsors and CROs do not have the luxury of taking a pause to innovate and fix the root-cause problem on their own. Most are stuck with collecting, cleaning, aggregating, and making sense of all this data using spreadsheets.

Clinical trials represent the longest and most expensive phase of drug development and most clinical trials fail. The Pharma industry needs innovation in clinical trials.

So where do we begin?

Step 1: Situational awareness

The first step in decision science is situational awareness. The “Catch-22” is that situational awareness requires collaboration and mind space, which is impossible if your clinical trial team is already operating at maximum human capacity, juggling multiple spreadsheets capturing many data sources and at varying frequencies in non-standardized formats. The lack of a trustworthy, real-time “control tower” of information causes a domino effect of impaired visibility and decision making.

Today 85% of clinical trials are delayed, and 95% of those trials are delayed by more than 1 month. The cost of delays is high. Recent reports estimate that for every day a trial is delayed, sponsors lose $40,000 in direct costs and $500,000 in unrealized sales.

Delays stem from numerous sources ranging from challenges with enrollment and site engagement, to protocol adherence, to data reconciliation. To combat these root causes, sponsors need enhanced oversight with AI automation to pinpoint problems across the full breadth of data gathered during clinical trials. Accomplishing this requires the unification of clinical trial data across all sources and deep domain knowledge distilled into AI systems designed for collaborative use.

> “Clinical trial operations will look entirely different in another decade. Our shared burden and opportunity, as modern clinical research scientists and clinical trial innovators, is to stick with it through this period of exponential change.”
>
> - **Ken Getz**, *Tufts Center for the Study of Drug Development, presented at Marcus Evans Evolution Summit Dec. 4, 2023*

Step 2: From disparate data to a cohesive narrative

Knowing what questions to ask to unlock opportunities for innovation, efficiency, and impact.

At the heart of modern clinical R&D lies a complex web of data – diverse in format, origin, and application. For biopharma teams that rely on reports from their ongoing clinical development initiatives to make critical decisions, the fragmentation of clinical trial data can make it challenging to get clear answers to important questions. Even asking simple questions like “What data have we collected to date?”, “Is data quality sufficient to achieve our analysis objectives?”, or “How many patients have we recruited compared to expectations?” are not easily answered without significant communication and work.

The unification of clinical trial data is more than a technical detail. It is a strategic imperative that holds the key to accelerating and advancing clinical research.

One ‘obvious’ solution is to unify trial data to offer more comprehensive oversight of study progress and outcomes throughout the clinical development process. While every clinical trial is unique, representing data in internally consistent ways enables companies to learn not only from individual studies but also assess trends across them.

The unification of clinical trial data is more than a technical detail. It is a strategic imperative that holds the key to accelerating and advancing clinical research. Embracing this approach has the power to transform disparate data points into a cohesive, analyzable, and more valuable data asset.

During trials, a unified approach enables clinical researchers to elevate the quality and depth of data and analyses to enhance outcomes. This improves the likelihood and rate at which a new therapy will ultimately reach the patients it was designed to benefit.

Likewise, during interim and post-hoc analyses, unified data can be leveraged to better measure the efficacy and safety of therapeutics within and across subpopulations. This additional perspective can help guide portfolio strategy in a variety of valuable ways, from informing future clinical research directions, to optimizing trial designs, to improving regulatory strategies, to surfacing new pathways to bring therapies to market.

Step 3:
From fragmentation to fusion

Rethinking information access in clinical trials

The need to navigate a multitude of clinical trial vendor portals imposes a heavy burden on clinical development teams, highlighting the necessity for innovation to streamline processes and expedite trials.

Modern clinical trials involve gathering data from participants not only during each site visit, but also increasingly between site visits using a variety of non-invasive digital health technologies such as mobile applications and wearable devices.

The more data we collect during clinical trials, the more we can learn about human disease in order to make more informed decisions and bring novel therapeutics to market. However, the increasing number and complexity of clinical trial endpoints poses protocol adherence, patient engagement, data management, and trial oversight challenges for clinical development teams

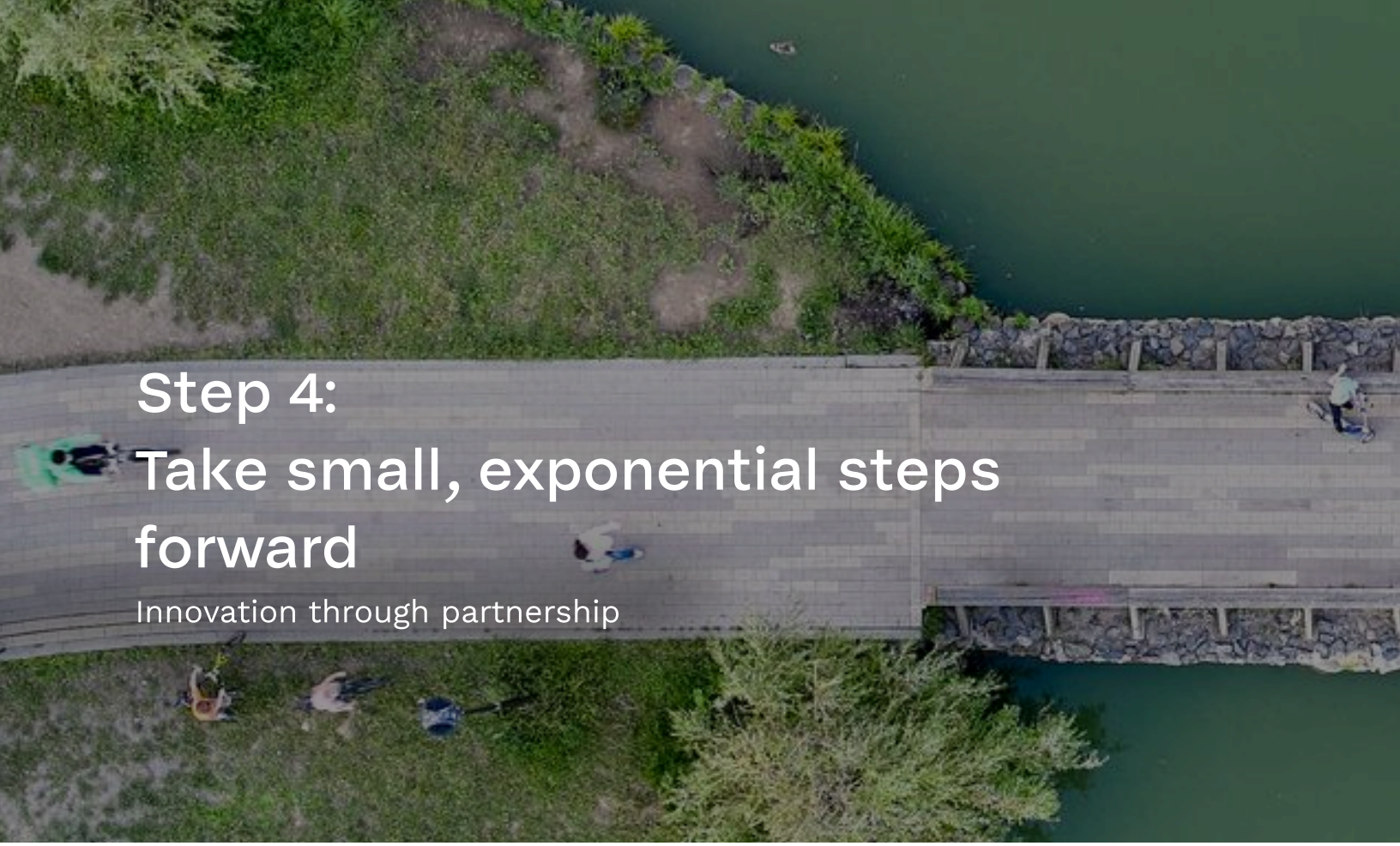
> Total data points collected in phase 3 studies went from 929,203 in 2010 to 3,560,201 in 2020
>
> - **Ken Getz**, *Tufts Center for the Study of Drug Development, presented at Marcus Evans Evolution*

For example, in many trials, generating performance reports can no longer be accomplished by simply logging into a single electronic data capture system (EDC) or clinical trial management system (CTMS). Instead, reports require visiting numerous vendor portals and software systems to gather the data needed to summarize overall trial status and obtain operational insights.

This patchwork of portals and the manual effort required to extract and synthesize information from them is a source of frustration, for both clinical operations and clinical research teams, and causes delayed timelines.

Unfortunately, these challenges are expected to worsen as trial designs and discovery pipelines embrace AI-driven drug discovery, novel diagnostics, and personalized therapies. Significant innovation is needed to keep up with the new pace of discovery.

Failure to innovate on our current clinical trial processes will slow and even prevent the progression of numerous therapies through clinical trials, placing financial strain on biopharma and leaving patients without needed treatments.



Step 4:
Take small, exponential steps forward

Innovation through partnership

Pharma is facing a $183B patent cliff in annual sales by 2030. Under these market conditions, innovation and partnership to dial-up the volume on this need are the only paths forward.

AI holds potential to solve this seemingly intractable challenge of lower costs while simultaneously increasing productivity. McKinsey has cited that clinical control tower and copilot solutions leveraging gen AI can create $13-$25B in annual value in clinical development.

At OmniScience, we are empowering clinical trial sponsors with AI-enhanced study oversight.

Vivo
BY OMNISCIENCE

Our platform, Vivo, unifies clinical trial data to create a clinical trial control tower with actionable notifications, and leverages intelligent chat to answer questions about site performance, data quality, and patient outcomes.

If you are running or planning a clinical trial or want to glean more from past clinical trial data, let's talk. We take pride in partnering with leading life science organizations and would love to help your company tackle pressing data unification and analysis challenges through our platforms and services.

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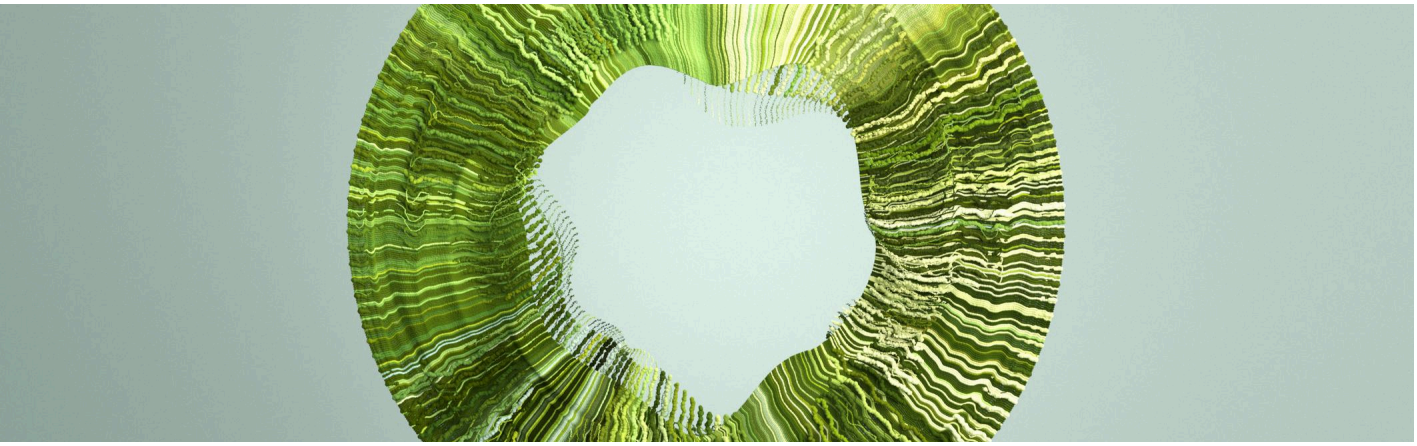

OmniScience is a trusted partner to leading life science organizations advancing Clinical R&D missions through unparalleled expertise in clinical data science.

Learn more at: omniscience.bio