NEXT-GENERATION CLINICAL DEVELOPMENT

Driving success and time-to-market in clinical drug development

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The clinical drug development market is teeming with innovation, including cell and gene therapies, digital therapeutics, personalized medicine and biomarkers, and the integration of drugs and medical devices. However, despite these breakthroughs, many life sciences organizations are not able to fully capitalize on the advancements.

A dramatic increase in the number of clinical trials, compounded by the intricacies of new therapeutic platforms, increased regulatory constraints, and intensified competition, has created unprecedented complexity for life sciences organizations. As a result, the drug development success rate remains stubbornly low, with just 10-15% of new treatments making it to market.

In this article, we explore one key element of the development cycle—the clinical trial—and how the emergence of powerful new digital and data capabilities, as well as new trial designs, can help companies increase program efficiency, speed, and access, driving outcomes for both the business and patients.

What is a next-generation clinical development?

A next-generation clinical trial is a project that leverages advanced digital and data capabilities, including AI and generative AI, to manage multiple data sources, enable new design formats, and unlock new analysis methods.

The value of next-generation clinical development

2+ years
Reduction in time to market

>15%
Probably of success

20% to 50%
Drug pipeline value increase

15% to 20%
Reduce cost

BREAKING THROUGH THE CHALLENGES OF BREAKTHROUGH INNOVATIONS

Despite the life sciences industry's collective focus on bringing new, proven medicines to patients quickly, clinical trials remain a costly and time-consuming process. In today's landscape, teams contend with the age-old industry challenges of recruitment and supply chain optimization as well as those stemming from new medical innovations, competition from emerging players and a exponential increase in data.

Most clinical trial challenges relate to one of three main dimensions:

Access

- Only 5% of eligible patients have access to a clinical trial.
- Recruiting a diverse set of patients remains a core challenge.

Speed

- The average clinical trial lasts 6-10 years.
- Digital tools are not being used to their full potential to enable end-to-end integration that would accelerate the entire process.

Effectiveness

- Overall cost for drug development is between $1-2 billion.
- High cost is to large degree driven by low probability of success (PoS)

3 STEPS TO ENABLING NEXT-GEN CLINICAL TRIALS

In the world of clinical trials, so much is changing and yet one thing remains the same: to advance the healthcare industry and improve patient outcomes through research and innovation.

To overcome the current challenges within the life sciences landscape, companies must reevaluate and adapt long-standing traditional clinical trial practices to make them more efficient, engaging, and accessible. We recommend companies take the following three actions to enable next generation clinical trial operations:

1 Integrate and simplify traditional clinical trial processes to accelerate process execution and data flows across the whole value chain.

When evaluating the efficiency and effectiveness of a clinical trial, organizations must consider three distinct, but interconnected, elements:

- The process
- The supporting organization
- Data and the enabling technology

In reviewing these dimensions, companies are likely to see that there are obstacles to efficiency and effectiveness that are common across all three areas.

For example, one common challenge related to clinical trial operation stems from data silos, which are often the result of disparate systems or legacy applications. At first glance, this would be considered a technology challenge. However, it becomes an organizational issue since it often means that teams are unable to share data with one another, or that the data is of limited use since it is not in a standard format. This not only creates pockets of inefficiency, but can also contribute to poor decision-making since teams do not have visibility into other areas of the process. This affects the overall efficiency and effectiveness of the process itself.

By evaluating these three areas individually and interdependently, organizations can identify and eliminate core challenges that are hindering overall performance. In so doing, organizations are able to create a more agile and resilient process, which accelerates process elements, optimizes resources, and often lowers costs.

We have recently helped a global pharma in setting up their unified clinical platform with end-to-end data flow from Protocol to Submission and secondary analysis addressing these three areas and through high value process steps prioritization. This has led to significant time reduction in system setup (50 to 75%) and database lock (50%).

2 Enable a multi-modal approach to accommodate new engagement forms, platforms, and data sources.

Given the challenges in today's landscape around patient access and diversity of participants, companies must rethink traditional trial design and execution strategies and instead consider how to use technology and alternative engagement methods to reach a wider range of patients, often across a broader geography.

For example, instead of relying exclusively on on-site trials where patients must frequently visit a hospital or other facility, they can consider developing a hybrid trial, which would allow participants to complete some trial activity from their home through telehealth applications and remote data capture from connected health devices.

Taking a multi-modal approach requires trial operators to collect, process, integrate and analyze a wider variety of data sources. These can include traditional clinical data, as well as patient-reported outcomes, digital biomarkers, connected device data, genomic data, and more.

While this increases the complexity of the trial, it provides the company with a far better understanding of results, as well as patient engagement and behavior. This data can be used to further refine and adapt the patient experience to ensure consistent, correct participation and reduce the risk of drop off.

We have been supporting a large pharma company with hybrid trials scaling, simplifying the experience for everyone with a unified, easy-to-use solution for patients and sites while reducing patient burden by collecting patient data from home, increasing statistical power using innovative endpoints and improving outcomes with remote patient monitoring.

3 Enable self-learning and insight-driven clinical trials to accelerate decision-making and shift from reactive to proactive.

Finally, pharmaceutical companies must be able to monitor the execution of the clinical trial and proactively address issues as they arise. This is done by leveraging advanced technologies to monitor KPIs across different domains.

One example for self-learning, that we have achieved with one of our clients, is connecting the clinical control tower that monitors trial execution with a feedback loop to protocol design. This way, new protocols can be AI generated using live experience especially on the operational dimension (e.g. milestones, best recruiting sites, etc.) and also on the medical dimension (e.g. best end points).

Another example is clinical supply chain operations which represent one of the biggest challenges in clinical development, aside from participant recruitment. In most cases, the products used in a clinical trial are not available via a pharmacy or store. Rather, companies are manufacturing specific, investigational products, often in small quantities that are then shipped to a hospital or, in the case of a hybrid trial, possibly directly to the home of the participant. These kits are often extremely expensive to produce and may have specific parameters around how the package must be stored or shipped. This means that any unexpected delay or disruption within the supply chain could potentially destroy products that cannot be easily replaced.

One of the core components of a next-generation clinical trial is an intelligent supply chain. An intelligent supply chain is an integrated, collaborative, responsive ecosystem that leverages advanced digital technologies, including cloud and AI, to provide end-to-end visibility of the entire value chain, enable the frictionless flow of information among partners, and seamlessly orchestrate all stakeholders.

Download our related paper, **Resilient and Sustainable Life Sciences Supply Chains: Good for business. Good for patients**, to learn more about how an intelligent supply chain can help your business unleash the power of your supply chain data to improve efficiency, avoid disruptions and manage delays.

Creating a better patient experience – and better results – with next-gen clinical trials

10-20%
Improved patient retention

25%
Reduced patient recruitment times

10-30%
Improve patient satisfaction

50-75%
Reduce system setup time

While next-generation clinical trials represent a significant opportunity for life sciences organizations, their ability to deliver value to the business and patients is based on several underlying factors:

CLEAN DATA FOUNDATION

- Ensure access to high-quality, clean, complete, and timely data to inform decision-making and enable proactive operations.
- Establish robust clinical data hubs, data lakes, or data mesh architectures for efficient data management.

DEMOCRATIZED DATA

- Ensure all relevant members of the clinical team can access the data they need to make accurate, timely, and informed decisions.
- Enable self-service data exploration and self-learning to empower users.
- Enable robust data dashboards that offer timely, complete, accurate data, in a digestible and accessible format, from all relevant domains.

MODELING AND SCENARIO PLANNING

- Leverage data and advanced technologies, such as digital twins, to perform simulations and what-if scenarios to improve operations and de-risk certain elements.
- Use data to inform mitigation plans to proactively address key issues.

PATIENT-CENTRICITY AND HUMAN-CENTRIC DESIGN

- Develop mechanisms to monitor patient behavior throughout the patient journey and identify points of friction or stress.
- Design clinical trial protocols that are reasonable and intuitive, helping to ensure patients remain engaged and active throughout the trial period.
- Leverage remote data capture, connected health devices, and telemedicine applications to enable hybrid or other non-traditional formats to increase trial accessibility, diversity, and engagement.

TAKING THE NEXT STEP TOWARD NEXT-GEN CLINICAL DEVELOPMENT

Innovation promises to usher in a new era of opportunity for life sciences companies. However, it will also add new levels of complexity to the development process, heightening the need to solve core challenges related to access, speed and effectiveness.

As the clinical landscape becomes both more complex and more competitive, now is the time to embrace the transformative strategies, advanced digital and data capabilities, and innovative trial designs that will enable a true next-gen clinical trial function—driving success and time-to-market across the drug development lifecycle.

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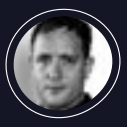

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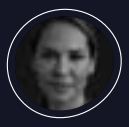

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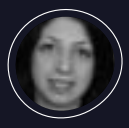

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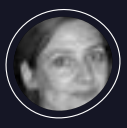

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