Advancing clinical trial efficiency: Merck's blueprint for AI-Enabled patient and site matching

Jennifer Sheller, Head of Global Clinical Trial Operations, Merck

The challenge we face

Clinical trials are the foundation of modern medicine – they help us discover potential treatments to improve people's health and save lives. Yet, the industry faces persistent challenges in clinical trial enrollment. **Across the industry, approximately 20% of sites activated fail to enroll a single patient**.[1] This issue is especially pronounced for oncology trials in the United States. In fact, in a study evaluating drug approvals in oncology from 2013-2017, of the 42 approved drugs, 14 of these were based on pivotal clinical data with less than 20% of patients from the U.S. Among these 14 trials, the average percent of U.S. patients was just 8%.[2] These inefficiencies slow our progress, increase costs, limit patient access to potential therapies and ultimately impact our ability to deliver on the promise of innovation.

While there are several factors that contribute to the inefficiencies in trial execution, including protocol complexity, heavily customized and siloed systems, site saturation and barriers to access, a primary challenge is the fragmented ecosystem of data that forces operational teams to rely on manual processes and cumbersome spreadsheets. Similarly, clinical trial sites are inundated with the task of identifying patients that match the eligibility criteria of each trial. Even when we do find the right sites and recruit patients into the trials, predicting patient dropout and retaining patients remains a major hurdle.

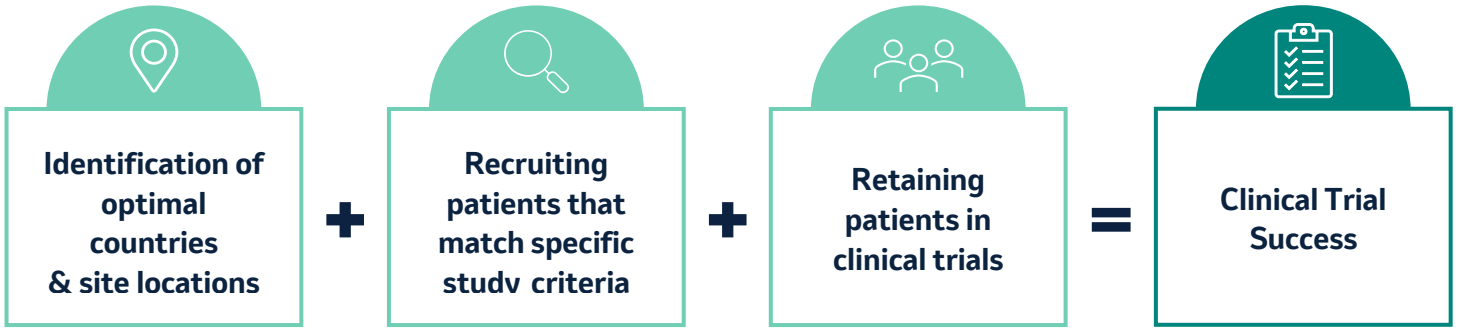
These challenges are not unique to Merck; it's an industry-wide challenge. However, given the evolution in the tech landscape, and maturity of innovative solutions, we recognize a unique opportunity to leverage data and technology to drive meaningful changes in trial delivery.

Transforming enrollment through data- and AI-powered innovations

We are deploying a thoughtful approach at Merck to address enrollment challenges by focusing on key areas of opportunity:

[1] **Lokavant** : https://blog.lokavant.com/mythbusters-20-of-sites-fail-to-enroll-a-single-patient#:~:text=Based%20on%20our%20analysis%20of,of%20sites%20will%20under%20enroll
[2] **WCG Clinical:** https://www.wcgclinical.com/insights/ensuring-representative-us-enrollment-in-oncology-clinical-trials-navigating-the-rising-tide-of-regulatory-scrutiny/

1. **Data-driven site selection:** We're harnessing AI and data-driven business insights, complemented by human expertise, to generate prioritized sites and locations most likely to deliver successful trial outcomes.
2. **Enhancing patient-site matching with AI:** Sites are being equipped with AI vendor solutions and added resources to quickly identify patients within their networks and expand awareness throughout referral channels.
3. **Improving retention through predictive insights:** We're working to build models leveraging our historical data to predict patients at the highest risk of drop out and deploying targeted interventions to improve retention



CHALLENGE:
Limited ability to effectively leverage both internal and external data for informed decisions due to missing, fragmented and scattered data

CHALLENGE:
Tedious and time-consuming process for sites to review all patient profiles and identify matches; lack of access to patients within the vicinity who are outside of their network

CHALLENGE:
To adequately answer research hypotheses, patient retention is as important (if not more) than recruitment

Visual representation of the key steps to execute a successful clinical trial, and the primary challenge

Strategic partnerships to accelerate innovation

We believe in rapid experimentation and learning. Rather than spending years building proprietary solutions, we are starting with partnerships and specialized vendors who bring deep expertise, curated and standardized analysis-ready datasets and proven **AI/ML models for site selection and AI ML & NLP for patient matching**.
This partnership-first approach allows us to:

- **Accelerate implementation:** We're learning and deploying solutions in real-time that combine external and internal data to inform site selection without lengthy development.
- **Adapting technology over time:** We're starting simple with the flexibility to layer in greater complexity and innovation to create incremental value as our needs evolve.

- **Leveraging external data:** We're able to access broader data ecosystems that would otherwise remain out of reach, while maintaining strict privacy and compliance.
  - **Protection**: Across our partnerships our internal operational data remains protected; we are clear about what data can be shared and what must remain within our walls. Every partnership is vetted for credibility, intentionality and alignment with our company's values.
- **Benefitting from industry best practices:** We're applying proven models and insights from vendors who work with multiple sponsors, enabling Merck to integrate best-in-class practices into our approach.

Building the future together

At Merck, our ambition is focused on what we do best: advancing science and serving patients. By working with external partners, we can move faster, adapt more nimbly and ensure our solutions are built for the real-world needs of trial teams and patients. The blueprint is clear:

- **Collaborate:** Pharma companies, technology vendors and research organizations must work together to develop shared standards and solutions.
- **Invest in data-driven innovation:** Embrace AI/ML/NLP as tools for real-world impact - improving site selection, patient matching and retention.
- **Integrate technology and process:** Recognize that solving enrollment & retention challenges requires not only advanced technology, but also thoughtful business process improvements to unlock lasting value.
- **Champion patient-centricity:** Every innovation should ultimately serve patients, making trials more accessible, efficient and responsive to their needs.

Though our journey is still unfolding, we are committed to bringing others along as we learn. As we continue to experiment, learn, and refine our approach, we call on the industry to move beyond isolated efforts and toward a collaborative, data-enabled future. Together, we can reduce site failures, accelerate enrollment and deliver better outcomes for patients everywhere.

For more information on Merck's data science and artificial intelligence, please click here.