Improving R&D Efforts: Clinical Trial Advancements to Watch in 2024

Research and development stakeholders continuously work to strengthen clinical development programs by evaluating trial activities from every angle to improve efficiencies and reduce participation burdens on patients, sites, study teams and sponsors. These ongoing efforts are necessary because the drug development landscape is not a straightforward pathway, and increasingly, innovative therapies mean added complexities for sponsors to consider. Also, global macroeconomic impacts are influencing how trial sponsors streamline their efforts to meet patient needs and support sites simultaneously.

When looking at ways to optimize clinical trials and meet development objectives, there are several anticipated advancements the industry should keep a close eye on as we push the boundaries for R&D innovation in 2024 and beyond.

GENERATIVE AI FOR DRUG DISCOVERY AND DEVELOPMENT

Interest in ChatGPT and generative artificial intelligence will only increase this year and afterward, especially as the healthcare industry further explores its possibilities for improving patient outcomes. Specifically, clinical trial sponsors are leveraging machine learning engineering expertise to optimize clinical trial activities via generative AI and large language models. Currently, there is a growing collection of evidence-based use cases for how these tech-enabled solutions can use the extensive breadth of data available to industry stakeholders to support and improve clinical trials and reduce the unknowns in research and development planning. Some key examples include:

- Drug repurposing: leveraging large amounts of data from various sources (e.g., scientific literature, clinical trial data and electronic health records) for analysis to determine new uses for an existing drug.
- Evaluating trial feasibility: generating trial scenarios to evaluate potential outcomes of each, including risk/benefit analysis.
- Optimized trial protocols: determining the best ways to enhance trial design and conduct trials to improve the patient experience, reduce site burden and enhance trial efficiencies.
- Patient recruitment/engagement: customizing communications to reach ideal patient populations and using GPT-powered chatbots to better match patients to trials of interest.

Additionally, ML experts are using generative AI and large language models to create "digital twins," patient avatars of trial participants, to allow study teams to simulate the impact of new drugs in terms of safety and efficacy and better predict potential outcomes for patients in the trial.

How generative AI can help sponsors secure valuable insights from what can be an overwhelming amount of data and expand opportunities to improve clinical trials is unknown. However, we do know that it will be vital to be responsible when implementing AI. It is critical to ensure testing and usage is underpinned by qualified and experienced ML engineers and that insights from therapeutic, clinical and operational experts who are critical to trial strategies are integrated into the process.

PATIENT-CENTERED DIAGNOSTIC TESTING

Because most clinical trials require the collection of biological samples, such as blood, urine and saliva, for laboratory testing, trial sponsors want to reduce participant burden through decentralized approaches as has been done for other trial-related activities.

During the COVID-19 pandemic, the industry experienced an increase in at-home specimen collection by phlebotomists for patient convenience and safety. Now, recent advances are allowing patients to collect their own specimens (e.g., blood and urine) with at-home collection devices in some cases. In late 2023, the U.S. Food and Drug Administration approved use of the first diagnostic test for chlamydia and gonorrhea with at-home sample collection. These at-home testing options are helping to reduce trial site visits for patients, which improves their experience. However, it will be equally important for spon-

sors, study teams and lab experts to ensure sites are adequately supported, given the shift in responsibilities, including a need for sites to teach patients correct self-collection methods.

Additionally, though clinical trial teams traditionally rely on blood, tissue, urine and stool collection for testing purposes, other established biological samples (e.g., saliva, sweat and hair) can be used in some instances. Applications for saliva-related diagnostic testing for clinical trials are expanding with advanced analytical methods, which can be a key advance for patient-centered approaches in trials since collection is non-invasive. Thanks to innovations in diagnostic instrumentation, saliva-related testing is regularly used to detect oral cancers, high-risk human papillomaviruses and autoimmune diseases. It is also proving to be a viable alternative for nasal swabs for infectious disease diagnosis, especially where there may be challenges to the nasal swab supply chain.

As we move ahead, the industry will continue to increase development of lay-person-usable devices for at-home lab collection and even at-home test results.

ENHANCING VACCINE ACCESS AND STABILITY GLOBALLY

The accelerated development of the COVID-19 vaccine reduced typical vaccine development timelines by 94% (from 13 years on average to less than one year). This rapid pace showed how the industry can leverage various transformative tools already in existence (e.g., decentralized trial solutions) to successfully fight global healthcare challenges and how regulatory agencies could accept key clinical trial design changes, allowing for activities historically done chronologically to happen in parallel.

What that time also demonstrated was the major difference in vaccination needs of high-income countries compared to low- and middle-income countries (LMICs), including those in Africa and the Asia-Pacific, and the variations among regions, which play a significant role in vaccine availability and speed of access to local residents.

To address the global disparities in vaccine access in LMICs, stakeholders across the healthcare industry are focused on making vaccines more stable and useful for all. One way is ensuring vaccine innovation accounts for supply chain nuances that differ per region. In vaccine manufacturing practices, developers are exploring solutions to account for heat susceptibility both in regions where they'll be used and during transportation and how vaccine techniques can be updated to meet the needs of specific regions. For example, if safe needle disposal is a greater concern for some regions, is there a nasal technique to offer instead? Also, can a vaccine be made more temperature-stable to decrease refrigeration requirements during transport and storage?

Stakeholders are also exploring creating more opportunities for local manufacturing in LMICs to ensure stronger access pathways and reduce supply chain challenges.

Several international organizations capture and publish infectious disease surveillance, and it has been quite useful in guiding which countries to include in clinical trials and trends in variants that inform interventional product development decisions. However, in recent years, global public health organizations, including the World Health Organization and other stakeholders, are also closely monitoring social media platforms (e.g., X) and other online commentary to secure earlier indications of regional and local disease traction. This added level of monitoring can help to accelerate vaccine manufacturing and/or supply fulfillment as well as provide trial sponsors indications of potential treatment development needs.

CONTINUING CREATIVE EXPLORATION

The advances and trends noted above are just a sample of what clinical trial sponsors and clinical research organizations are exploring and expanding upon to ensure global R&D efforts are impactful and ultimately improve patient outcomes while in the process tackle tangible challenges various industry stakeholders face. Whether integrating digitized solutions, deploying new testing methodologies or broadening treatment access to underserved communities, the industry is showing its commitment to continuously thinking outside of the box and evolving R&D practices to further accelerate drug development for those in need in 2024 and beyond. **CP**

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