DIA 2022: Progress on modern approaches for clinical trial design, execution, and wider engagement

By Mark Maietta, President, YPrime

Discussions at the recent DIA Annual meeting celebrated industry successes, while also reminding attendees of the unfinished work needed to improve trial inclusivity and efficiency, while reducing burdens on patients and sites. These same discussions focused on the untapped potential for technology to have a greater role as a connector and enabler. As the clinical research ecosystem continues to expand and include more research partners, stakeholders and a range of patient and caregiver perspectives, collaboration and connection is essential to future clinical trial success and next-generation medicine.

Patient representation

Recent diversity guidance issued by the FDA in April reinforced the public health urgency of expanded clinical trial representation. As sponsors prepare for trial-specific diversity planning, multiple sessions and panel discussions featured thoughtful recommendations on ways to expand inclusivity and bring clinical trials into communities. This is an intrinsic challenge that requires major changes to the existing site research network, among other long-term solutions. The good news is that many efforts are already underway.

The burgeoning integrated research organization model (led by Javara, Elligo Health and Circuit Clinical) bridges clinical research and clinical care, by enabling research to take place in the physicians' office.

Research is resource-intensive and technology is critical for providing resource and compliance support to community practices, new investigators, and patients, so everyone can participate with a lower burden.

Retail pharmacies such as CVS Health and Walgreens are pursuing clinical trial opportunities, promoting their abilities to reach historically underrepresented segments of the population through their extensive patient databases, vast geographical coverage and physical locations in hard-to-reach communities.

Both models offset the advertising-led approach to patient recruitment with pre-identification of patients more representative of broader disease populations through electronic health record () and pharmacy data.

Protocol optimization

While there is more recognition of self-imposed and unnecessary complexity, cutting and pasting protocol templates from 20 years ago remains a widespread practice, along with restrictive eligibility criteria. Lessons from the pandemic demonstrated the necessity of flexibility and practicality for recruitment and enrollment performance (Are the lab values required for inclusion based on current or past standards?). Looking ahead, the abundance of real-world data can inform better protocols with fit-for-purpose eligibility criteria and replace outdated practices that impose unnecessary burdens on participation. (Are those weekly required blood draws scientifically necessary or based on historical precedent?) Data-driven site selection based on EHR, insurance claims, and custom predictive analytics can replace outdated practices of using the same sites, with the same demographics.

Data quality

In the opening keynote, Ken Getz revealed the growth in data collection for a single trial is four times the volume it was 10 years ago. Bringing disparate sources and types of data together, such as medical records, insurance claims and social determinants of disease with trial-specific data collection require enterprise solutions to directly embed technology solutions into site workflows to eliminate manual processes and reduce site burden. Increased uses of structured data also minimize the need for physical auditing.

Trial execution

As trial models move from traditional site-based execution to patient-centric models, patient-facing technology required for remote participation – from eCOA, to sensors and telehealth -- must be unified and designed for intuitive user navigation. Clunky technology will not promote engagement or compliance.

Effective use of technology strengthens collaboration. When discussing optimal ways to advance clinical trial evidence generation, honorary chair and FDA Commissioner Rob Califf urged the drug development audience to "develop connected ecosystems where patients or families and clinicians can be engaged to both participate in relevant trials, to play an essential role in study design, and implement findings of studies into practice. Consider how effective we could be if we revamped the foundation system for sharing data."

When applied thoughtfully, technology can help solve some of our toughest data questions and fundamental engagement challenges as we find practical ways to work across communities to make clinical trials more accessible to all people.