2022 Clinical Trials Trends

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Clinical trials are a necessary, but frequently costly and burdensome, part of providing innovative treatments and improving health outcomes globally. In fact, conducting a clinical trial has been one of the greatest costs in bringing a new drug to market as part of the drug development process. Breakthroughs in science and changes in regulatory policies have enabled advancements that have increased the quality, speed, and design of clinical trials. Simultaneously, new and existing technologies are being employed to aid in matters ranging from patient health data collection to enrolling in a remote trial.

Here are five clinical trial trends the industry should be watching in 2022:

TREND #1

Clinical trials are increasingly being conducted in a decentralized model.

The COVID-19 pandemic caused the development of a plethora of novel technologies within the life sciences industry that enable researchers to work effectively and remotely. An imperative emerged that shifted the traditional hub-based research trial model, where participants gather for an on-site trial experience, to a new experience involving remote monitoring and telehealth with clinicians. Simultaneously, the onset of the pandemic in the spring of 2020 caused many ongoing trials to be placed on hold, or canceled altogether, as the original trial design proved impossible to conduct without the risk of contagion.

A decentralized trial can incorporate technology at different steps of the clinical development process as well as help to remove barriers that have historically led to a lack of diversity in trial participation. Web-based document signing removes a burden on trial participants by allowing the documentation, registration, and informed consent process to be done from a patient's home. Likewise, the widespread adoption of electronic health records among clinicians and researchers facilitates access to patient health records across sites and remote work settings.

The challenge to conducting decentralized trials is finding a balance between remote and on-site elements in the trial design. Ongoing decentralized trials may require a combination of in-person and remote activities, ranging from participation through a local health care practitioner to telehealth technologies delivering clinical contact at home.

The degree to which a trial can be decentralized is dependent on the factors of the clinical investigation. Trials that involve more serious illnesses, extensive procedures, advanced imaging, biopsies, and interventions with significant risk will still require close monitoring by clinicians and researchers. Trials involving more serious clinical attention may need to determine what elements of a decentralized design is best for the research and at what stages to implement such elements.

The global virtual clinical trial market is projected to grow at a rate of 5.8% CAGR between 2020 and 2027 to a market value of $14.5b USD. SOURCE

TREND #2

Digital tools are enabling clinical development processes and outcomes.

Digital tools and software are evolving and enabling clinical development. There is a growing trend of employing software and other digital tools to manage trial complexities, similar to the way ERP systems coordinate a business's operations.

Digital strategy is becoming an important part of a successful clinical trial design, and process review and possible re-engineering should be included within that strategy. Companies won't maximize the benefits of new technologies if they just layer them on top of current processes. Instead, they can harness the power of technology to be truly innovative and deliver more or new value.

30% of participants in a clinical trial fail to take their study medication correctly.
SOURCE

During a clinical trial, clinicians must coordinate a multitude of tasks among stakeholders, where the participants' actions are critical to the outcome of the study. Communication is a vital element, allowing clinicians to exchange information with trial participants. Communication with patients can be enhanced through an omnichannel approach, where they're contacted through social media, text messaging, or mobile ePro solutions.

There are novel ways of incorporating existing technologies into the trial design as well. According to PEW Research, 97% of Americans own a phone, 85% of which are smartphones. This can be especially helpful in supporting patients to adhere to trial regimens such as medication dosing or serving as a reminder to complete other tasks. Furthermore, applications, like eConsent, enable patients to sign documents related to the trial swiftly, securely, and with regulatory compliance.

TREND #3

Mobile technologies are improving end-point data collection in clinical trials.

Mobile technologies are taking on a greater role as practical tools in research data collection methodology. Mobile technologies include wearables, devices that are ingested, implants, portable sensors, and applications developed for electronic outcomes assessment.

The key benefit of mobile technologies in a clinical development setting is that they allow researchers to take direct measures from an individual. Within a clinical trial, these technologies enable the recording of continuous health data from participants over the course of the trial. While clinicians may be able to monitor participants at periodic check-ins, mobile technologies provide a more holistic outlook of a patient's health.

1,400 studies to date have been launched involving the use of mobile technologies to monitor patient populations, of which 540 have been completed.
SOURCE

In some cases, these technologies can even reduce data skewness. "White Coat Syndrome" is a phenomenon where people have higher than normal blood pressure during a doctor's visit coming from anxiety and other factors, and in this event, mobile technologies have clear benefits for assessing health data at a more consistent level.

Mobile technologies can also contribute to a better trial experience for participants. Rather than having to travel for health check-ins or stay at a site for the duration of the trial, participants are allowed to continue with their typical schedule.

This trend has the potential to influence other areas of clinical trials as well. By putting the patient at the forefront of the clinical trial participant experience, a number of people are able to consider taking part in a trial without it disrupting their working schedules or interfering with other responsibilities. Furthermore, historically underrepresented minority populations are able to consider taking part in a study with the help of these technologies.

TREND #4

Regulatory changes induced by the COVID-19 pandemic created lasting changes in clinical development.

The COVID-19 pandemic proved that it's possible to develop safe and effective medicines that combat disease in an accelerated time frame. The rapid development of COVID-19 vaccines was supported by Operation Warp Speed, an unprecedented collaborative effort between many government agencies including the FDA, the National Institutes of Health, the Centers for Disease Control, and the Biomedical Advanced Research and Development Authority, among others.

Key differences in the clinical trial development for COVID-19 treatments stemmed from the trial being conducted by the NIH, as opposed to traditional public-private partnerships. With the coronavirus, mass production of the vaccine began simultaneously with ongoing trial evaluation. U.S. regulatory agencies were focused on developing large-scale production capabilities prior to approval for any candidate medicine demonstrated by billions of dollars in investments in Pfizer, Moderna, and NovaVax among other firms.

While these specific government and regulatory responses emerged from the unique challenges of the COVID-19 pandemic, they have produced lasting changes in the regulatory process surrounding investigative medicines. Regulators had to take a more pragmatic approach to approval, resulting in the modernization of clinical trials, and these regulatory changes also included incorporating telemedicine and remote monitoring technologies to promote decentralized trials. For researchers, the use of real-world data from early phases of a trial should and can inform investment and planning for further stages of the trials.

TREND #5

Targeted strategies to reach patients are effective in increasing diversity in clinical trials.

Clinical trials do not always meet the needs of patient populations that researchers are seeking to study. Historically, patients from racial and ethnic minority groups have been and continue to be underrepresented in research studies compared to the overall population.

Racial and ethnic minorities make up 39% of the U.S. population but represent less than 16% of clinical trial participants.
SOURCE

In a pilot study at the Moffitt Cancer Center, researchers implemented a research site self-assessment tool and implicit bias training focused on improving trial diversity. Including bias training for clinicians and staff conducing the trial is one way to promote more cognizant inclusion of underrepresented populations. Masking patient demographic data where applicable is another strategy for including a breadth of trial participants.

Another factor contributing to the disproportionate representation is a lack of awareness of ongoing studies as well as distrust of the medical community. Improving the visibility of ongoing studies and explaining the research needs and methodologies is crucial to enrolling more participants. Direct-to-Consumer (DTC) marketing is a novel method to reach out to key patient populations, educate patients on trials, and allow for recruiting. The Follicular Lymphoma Foundation has used DTC marketing and social media to create a global online forum with over eight thousand members.

Furthermore, trends in decentralized clinical development will be key to improving diversity in studies as well. Barriers contributing to the lack of diversity have come from traditional trials that are defined by on-site gathering in hub cities. Socioeconomic factors, from being able to take leave from employment to having access to transportation and childcare, have impeded people from readily enrolling in a trial that requires a broad time commitment an

Conclusion

The future of clinical trials is enabled by technology adoption and lasting regulatory changes, prompted by the impact of the COVID-19 pandemic. Conducting decentralized trials became an innovative approach for regulators and Pharma companies to continue to research new and effective treatments while mitigating effects of viral spread. Within decentralized trials, mobile technologies allow for continuous data collection from patients and provide more holistic data for researchers. Another benefit of decentralized trials is that researchers can better recruit underrepresented patients through targeted strategies like direct marketing. All told, the future of clinical trials entails centering trial design and planning on the patient experience.

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