2023 Clinical Trials Trends

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The COVID-19 pandemic has been the single largest factor in changes in clinical trials, impacting the processes to achieve them, the people who take part in them, and the technologies that are evaluated. Over the past few years, the world has seen the massive benefits of clinical trials through booming medical innovation that helped to diminish the danger of the pandemic, but those benefits are also applicable far outside the realm of COVID-19.

There has been a distinct shift in the values of the clinical trial industry, pushing the patient to the center of focus as they continue to increase their own awareness of their health and well-being, including their medical treatments. Much of the innovation and creation that emerged as a result of the COVID-19 pandemic has given the patient a more prominent voice throughout the clinical trial process and enabled them to take a larger role in the process.

In this piece, we outline five clinical trial trends that the industry should be watching in 2023:

DIGITAL TRANSFORMATION: TECHNOLOGIES TO SUPPORT DECENTRALIZATION

OVERCOMING THE TALENT SHORTAGE

ACCESS TO REAL-WORLD DATA

BLOCKCHAIN: RELIABLE AND SECURE

HUMAN AND MACHINE COLLABORATION

DIGITAL TRANSFORMATION: TECHNOLOGIES TO SUPPORT DECENTRALIZATION

Decentralization of clinical trials has been a continuing trend since the start of the pandemic in 2020. Decentralized trials have proven to be a successful method of trial delivery in the past several years; however, it has demonstrated a technological gap that is now being filled to support further decentralization.

Evolving innovations are becoming the core of clinical trials in a way never possible before, and clinical trials are struggling to keep up with the ever-changing digital technologies. Passive data collection, such as wearable devices that can track heart rate, blood pressure, oxygen, and much more, are starting to be incorporated into clinical trials to collect a vast range of data over long periods of time, improving trial accuracy and increasing the speed at which the trial can be completed.

Mobile applications are also being utilized to create a single resource for patient interaction, which increases patient clarity in trial functionality as well as compliance. Direct-to-patient shipments decrease compliance burdens and increase patient participation, and virtual visits with physicians allow patients to participate from far away from trial sites. These are only a few examples of the creative innovations that the clinical trial industry has taken to navigate this decentralized model while still achieving their goals.

While this evolving climate has major advantages for clinical trials, it leaves a gap in compliance for the FDA to fill. As a result, the FDA is implementing remote regulatory assessments (RRA) to evaluate documentation and ensure conformation with FDA data regulations. Sponsors must be able to prove that data is secure, reliable, and consistent, all while de-identifying patient information to retain privacy in order to pass these assessments .

It's essential to note that the success of the implementation of new technologies is dependent on the ability of human resources to keep up with these changes. This is a massive undertaking with respect to training, IT services, and execution, and the skills and mindset of employees will determine the efficacy of these changes. These resources must be fully equipped to adapt to these innovations through the implementation process to execute these technologies effectively and stay ahead of the ever-changing technological landscape.

2 OVERCOMING THE TALENT SHORTAGE

Throughout the past several years, the medical industry has proven to be even more robust and dynamic than anyone had thought. The pandemic has proven that innovation can happen quickly and safely, inspiring the medical community.

Trials are moving so quickly, in fact, that there aren't enough resources to perform them at the industry's desired speed. This issue is largely resulting from the talent shortage within the clinical trial field. Entry-level clinical research associate positions aren't filled quickly enough, and it's impacting every stage of clinical trials, from enrollment to testing, and even paperwork submission.

Not only is the labor shortage affecting standard trial functionality, but it's also limiting the deployment of new technologies that can increase trial speed. With resources low, it's difficult to pull employees from daily responsibilities to be trained on new software, technologies, or protocols. Moreover, there are often insufficient resources for an implementation team to take ownership of projects like these.

As a result of this shortage, many trials are turning to outsourcing when they don't have the resources to accomplish a standard task. This outsourced organization can provide a reliable function to clinical trials across various job responsibilities. With the labor shortage at a high right now, dependable talent resources are a commodity that clinical trials don't have, yet are essential to the speed of these trials. Outsourcing provides a solution that allows trials to complete the necessary functions for success.

The labor shortage is a massive burden on the clinical trial industry that will continue to disrupt trial functionality. Trials must continue to pursue innovative methods of working around these gaps to be successful in the future.

In the first quarter of 2022, more than 50% of clinical trial sites cited staffing as their top issue.

SOURCE

3 ACCESS TO REAL-WORLD DATA

Real-world data (RWD) usage is rapidly increasing, and its application will only be amplified in the year to come. Passive data collection, such as wearables and biosensors, are a continuing source of gathering information; however, this trend is shifting to include user-inputted data as well. Mobile applications that allow patients involved in clinical trials to input their symptoms, describe qualitative circumstances, and better analyze trial environments are being introduced to the clinical trial sphere.

This vast collection of both passive and user-driven RWD enhances the quality of results that trials are generating. With RWD, trials are creating a database of real-world clinical observations and measures that would be otherwise difficult to obtain. This information can be used to drive their research questions and identify clinical patterns under real-world conditions, especially when analyzed with artificial intelligence (AI).

With AI, the impact of clinical trials' work will become even more significant, as it allows them to process and analyze these large sums of complex data. This means increased application and insights, as well as a decreased financial burden on the trial sponsor. Through this process, however, it's essential to protect patient data and ensure patient privacy, as this is crucial to creating patient trust.

The global real world evidence solutions market size in healthcare is anticipated to reach USD $78.8 billion by 2030 and is expected to expand at a compound annual growth rate of 8.1% from 2022 to 2030.

SOURCE

4 BLOCKCHAIN: RELIABLE AND SECURE

In the new world of decentralized clinical trials, it's more important than ever to have reliable, consistent data sets across an entire organization. This is where blockchain technology comes in, a system that records data entries across multiple computers that are all linked in a peer-to-peer network, allowing all users to see the exact same data at all times.

Blockchain is one of the most secure methods of data collection, as the technology protects patient anonymity – increasing patient confidence in participation and decreasing bias within the analysis of trial results. This, in turn, will likely also increase the patient pool and the accuracy of trial results. This is critical to ensure that the trials have dependent, consistent information across all sites and methods of communication with their patients.

Blockchain technology is also one of the most reliable sources of data sharing and has significant application in clinical trials outside of security alone. Data collected in blockchain can't be edited or modified, and it provides exact reporting of drug delivery details, user-inputted data, information collected from wearables, and much more. This increases the reliability of clinical trials and decreases opportunity for modification or misrepresentation of results.

The blockchain technology in the healthcare market is expected to attain a valuation of USD $121 billion, at a compound annual growth rate of 68.3%, between 2022 and 2030.

SOURCE

HUMAN AND MACHINE COLLABORATION

Many of the trends in the years to come will revolve around the creation and innovation of new technology. Technological innovation is at the core of the clinical trial community; however, it would be wrong to overlook the importance of human thought processes and decision-making in this space.

While data-driven diagnostics will prove to be essential in the years to come, clinician awareness will lead to decisions that result in better health outcomes for the patients. To fully utilize AI and clinical decision support tools, it's essential that human experts take part in the process. It's up to them to take confusing, numeric results determined by data analysis software and explain these conclusions in tangible, understandable fragments of information that have application to the medical community.

It's especially important for these human users to understand the inputs and algorithms that the software is using to ensure that the determined results align with expected outcomes and to confirm the assumptions made with real-world clinical observations. Moreover, humans must work alongside AI to ensure compliance with GDPR (General Data Protection Regulation) and data privacy protection in order to avoid discriminatory results and security issues relating to an individual's personal data.

While technology and innovation are the only way to move forward in the clinical trial industry, we can't leave our humans behind. The collaboration between humans and machines will become essential in the year to come, and the importance of this relationship will only continue to grow as our technology advances further.

CONCLUSION

The pandemic will have a lasting impact on clinical trials for years to come, as its new innovative methods of delivery have shifted to focus on the needs of the patient. Many of the trends seen above are catered to be beneficial to the patient, promoting participation and valuing their insights as a part of the process, while still benefiting the trial and sponsors. In this decentralized format, the use of real-world data and blockchain technology improves both the data collection capabilities and reliability of the trial by increasing the data quantity and quality, all while operating in a hybrid format. The talent shortage is a key factor that may limit trials' ability to keep up with these evolving technologies, and organizations must be mindful of this. Moving forward, the key to success in clinical trials will be a successful collaboration between machines and the humans who designed them.

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