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Transforming Clinical Trials With Digital Tech, And What That Means For The Patient

Many stakeholders within the pharma and biotech industries are witnessing radical shifts taking place in how clinical trials are conceived, designed and conducted. This transformation relies heavily on applying the power of digital technologies.

As new technologies emerge, they will converge through networks and cloud-based platforms to create a new digital health care ecosystem. Collectively, they will have a greater impact on clinical trials than any one technology would achieve separately. At the center of this ecosystem is the patient, demonstrated by the uptick in personalized therapies and a growing emphasis on patient-reported outcomes.

While the mean projected return on new drug research and development (R&D) investments by a dozen large cap biopharma firms fell from 10.1% in 2010 to 1.9% in 2018,[1] an opportunity remains for emerging digital technologies to improve R&D productivity.

We predict the following four technology trends will impact the drug and device development industries and have the potential to transform pharma R&D:

- Rising use of the cloud
- Democratization of artificial intelligence (AI), data and algorithms
- Incorporation of the Internet of Medical Things (IoMT)
- Increased use of digital technology for patient-centered design

Understanding the potential of these emerging trends and technologies to increase returns on pharmaceutical R&D, how they interrelate, and a framework for successfully integrating them needs to be the single biggest priority for every stakeholder in 2020.

RISING USE OF THE CLOUD FOR CLINICAL TRIAL DESIGN AND EXECUTION

Cloud-based platforms offer the ability to access large pools of data that could improve patient recruitment during clinical trials through the enhanced ability to identify, select, onboard and monitor patients who may be eligible for clinical trials. Further, harnessing cloud-based technologies allows sponsors to implement end-to-end data management strategies to transform clinical development life cycles, including data acquisition, storage, aggregation and analysis.

Moreover, cloud-based platforms offer the ability to integrate different applications such as electronic data capture, clinical trial management systems, safety systems and data repositories. A central data storage location provides sponsors and sites access in real time, and increases productivity by allowing information to be quickly shared and managed in a secure fashion.

Additionally, the continuous streaming of data to cloud-based platforms could accelerate clinical trials and decrease protocol amendments, resulting in reduced clinical trial costs. Also, sponsors can use cloud-based platforms for data submission to regulatory agencies, which has the potential to accelerate drug development, streamline regulatory review and enhance regulatory decision-making.[2]

DEMOCRATIZATION OF AI, DATA AND ALGORITHMS

The influx of big data is fueling algorithms that are the building blocks of AI, machine learning and other technologies, such as blockchain. The democratization of data, especially real-world data, is inevitable as its use spreads across every aspect of drug and device development.

As analytic methods improve, these approaches will have a compounding effect on the industry, ultimately increasing efficiency. AI-powered capabilities, including pattern recognition and evolutionary modeling, are essential to gather, normalize, analyze and harness the growing masses of data. In ICON's industry survey, AI and advanced analytics were viewed as the digital technologies with the most potential to improve clinical R&D productivity.[3]

Other AI applications in clinical trials include automating routine data-entry functions, analyzing electronic health record (EHR) data to find suitable candidates and sites for clinical studies, and monitoring and encouraging patient compliance with study protocols. Robotic process automation will streamline or eliminate many costly, time-consuming and error-prone manual steps.

AI can filter and process quality data faster than any human, generating insights to support early decision-making with powerful predictive analytics and statistical models.[1,4–6] Moreover, this function has potential applications in adaptive dose finding, and discovering and modeling new molecules and therapies.

Increased use of machine learning, which is a type of AI, allows for greater power in processing complex data sets. Machine learning applications for increased clinical trial efficiency include remote monitoring

of therapies for adverse events, addressing and adapting to changes in sites for patient recruitment, and using EHRs to reduce data errors.[7]

Meanwhile, blockchain has potential in addressing a key concern in clinical trials – data integrity. Responding to queries from regulatory authorities regarding maintaining the integrity of trial results from data capture is often a time-consuming burden. Designing blockchain into a clinical trial – which can show data from their origin to the final report – has the potential to accelerate the regulatory approval process and reduce costs.[8]

INCREASED USE OF DIGITAL TECHNOLOGY FOR PATIENT-CENTERED DESIGN

Employing digital technologies can also simplify the patient experience in clinical trials. Real-time monitoring of data collected from devices and sensors could mean less frequent study visits for patients. In addition, collecting data points throughout a clinical trial could assist sponsors in making go/no-go decisions faster, saving time and costs.

Within clinical trials, patient data are transactional between stakeholders such as health care institutions, patients and regulators. As more patients become aware of how their data are being used, harnessing blockchain technology could help maintain patient confidentiality – an ethical and legal requirement – and will become more important in engaging and retaining patients.

Blockchain's potential to increase security, privacy and interoperability of health data could make EHRs more efficient and secure. With blockchain, an audit trail is built into the transaction of data, allowing verification of the original source of the information, as well as the ability to detect attempts to tamper with it.

Also, blockchain allows for greater data availability. When data are shared openly within a network, there are fewer issues with data system interoperability. For example, availability and accessibility of patient information could be used for patient feasibility analysis and population studies. Moreover, blockchain allows researchers to submit queries for data that are stored off chain, further protecting patient privacy.[9]

INCORPORATING THE INTERNET OF MEDICAL THINGS

Innovation in medtech has led to an increased number of connected medical devices that can generate, collect, analyze and transmit data. This connected infrastructure of devices, along with their software applications, data and health systems, are creating the Internet of Medical Things (IoMT).

Wearables and imaging are creating diagnostic insights into previously untreatable or undetectable indications. For example, the US Food and Drug Administration (FDA) recently granted breakthrough device designation for an AI technology that can analyze endoscopy images for signs of gastric cancer, a disease associated with a high rate of false-negatives.[10] Further, combining historical information from EHRs with imaging, genetic and molecular test data is driving the development of highly targeted oncology treatments, such as CAR-T.

Clinical trials are increasingly designed with mobile and sensor technologies – such as smartphone applications, wearables and implantables – to capture data. The reliability and accuracy of these devices could mean that real-time monitoring of patients participating in clinical trials could be used to demonstrate the health economic value of protocols, drugs and devices. For instance, a wearable might include an accelerometer. Applying various algorithms to the accelerometer signals could generate data on sleep quality, steps per day and other endpoints that reflects real-world experiences of trial participants.[11]

CONCLUSION

Despite the benefits of digital technologies, leveraging their potential requires the right infrastructure and expertise. In fact, applying advanced statistical and trial design to specific study needs was one of the top-three challenges sponsors identified that requires the skills and knowledge of contract research organizations (CROs) and other clinical trial experts.

CROs can develop platforms to securely capture, transmit and visualize medical device data and can support volumes of data collected by sensors. Identifying and addressing these current study needs using data, AI and other novel digital technologies not only improves trial efficiency significantly in the near term, but also builds competence and confidence in applying the digital technology needed to succeed and increase return on investment in the trial of the future.

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