lead compounds for a study. The use of this technology has been shown to provide competent and efficient associations between implications and biomarkers. AI &ML would help in identifying promising lead candidates that have a higher likelihood of success during clinical trials, helping in eliminating candidates which may fail.

Connecting the dots

Thus, AI & ML can be used to enhance certain aspects in a clinical trial, or could also be used to create a seamless structure across the clinical trial, which would provide real time and high-quality data, allowing better optimization. With clear systems in place, it becomes easier to recognize bottle necks or fault areas which could affect timelines and cost. OneClinical is a platform that monitors the progress of a trial, providing near-real-time data and insights to sponsors, enabling proactive decision making to improve outcomes and enhance efficiencies. Such platforms give sponsors better control over the clinical trials process and impact the time and cost of running a trial significantly.

AI could significantly improve multiple facets of clinical trials, right from design, to setup, to conduct, to closure, improving quality and efficiency, and lowering failure rates and cost. Thus AI & ML could help in bringing lifesaving medicines faster to the market, with a greater onus on patient safety. BS

5 TRENDS IN CLINICAL TRIALS

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1. Clinical Trials are Becoming More Global and More Diverse

Patient scarcity, a shift towards more personalized medicine, a growing focus on rare diseases, as well as rising trial costs are all driving a movement towards the globalization of clinical trials. We anticipate seeing more pharma companies and clinical research organizations (CROs) look to new areas across the globe to run their trials to benefit from a broader pool of potential patients and lower operating costs, therein accelerating their therapies to market. Almost half of clinical trials currently take place outside of the US, and the number of patients enrolled in trials is increasing abroad. We are seeing emerging countries invest in healthcare and their life sciences infrastructure.

In tandem with this positive trend towards globalization comes greater diversity. The life science industry has traditionally lagged in diversity, but diversity will become a key to successful recruitment, retention and promotion strategies. Although it takes resources to educate people on the benefits, risks, and process of clinical trials, the gains are valuable. Having a more diverse patient population increases patient sourcing, while making trials more global and diverse will help build trust and communications into often overlooked communities. There is a growing movement towards making sure drugs are safe and effective across many demographics (age, race, and gender), rather than enrolling only the “perfect patients” for a given trial design. Furthermore, rare disease research is on the rise, and rare diseases often affect portions of the population outside the middle-class and Caucasian groups.

2. Data and Technology are Enhancing Patient Identification

In today’s clinical research landscape, the same challenges still prevail; 11-30 per cent of sites fail to recruit a single patient and as many as 50 per cent of trials are delayed due to recruitment issues. The costs incurred because of delays are momentous, amounting to as much as $8 million per day, along with detrimental setbacks in access to cures. Traditionally, patient recruitment has followed the same process for years; we ask research sites identify patients, then we fill in any gaps with advertising. While we have made progress in developing

more effective social and digital media campaigns, recruitment has historically been one-dimensional. That's been changing over the past few years, as patient recruitment companies are turning up with powerful technology to transform the way we identify and enroll patients. We are seeing more companies emerge, leveraging artificial intelligence (AI) and natural language processing to "crawl" medical records to find qualified patients for trials. Not only is this a smarter way to find the right patients for ongoing trials, it may lay the foundation for identifying entire cohorts of patients before a trial is even designed.

3. Patient Inputs are Driving Improved Engagement (Including a Rise in Virtual Trials)

Just as patient recruitment is undergoing a revolution, so is patient retention. In the growing wave of patient centricity, we are seeing a much needed shift in companies seeking input from patients and patient advocacy groups to incorporate into their drug development plan. Patient feedback is helping sponsors and CROs identify appropriate clinical trial endpoints, recognize feasibility, and understand patient burden to shape and improve the trial's protocol design. Furthermore, engagement is extending beyond patients to include feedback from payers and providers in guiding the development plan. Together, this feedback will benefit trials by enhancing the delivery of patient care, improving retention, and enabling sponsors and CROs to better execute the plan.

In conjunction with this growing trend in patient engagement is a shift towards more virtual trials. While some programs make for better virtual trial candidates than others, advances in technology such as wearable monitoring devices and the use of smartphones to transmit real-time patient data, are making virtual trials a reality. We will see virtual trials that allow patients to record data remotely, often from the comfort of their own homes, increase in number over the coming years. For those who live far distances from hospitals, or for sensitive populations such as children who may feel scared in a hospital setting, virtual trials are a critical means of making treatments accessible to as many patients as possible. Overall, virtual trials are the way of the future, helping reduce patient burden and improve participant convenience.

4. Streamlined Data Flow Between Clinical Trial Systems and Stakeholders

The number of data sources in clinical trials is on the rise, and sponsors, CROs, and clinical research centers have access to more technology than ever before. All these disparate systems historically made it difficult to share information among clinical trial collaborators, and as a result, companies are seeking to streamline the flow of information between stakeholders and systems. We are seeing the industry unite their technology and processes to automate the exchange of clinical data. Sponsors, CROs, and clinical research centers have made it a priority to eliminate communication barriers and automate clinical information exchange with cloud-based technology. Much like the airline industry where flight information is shared in real time on airport displays, mobile apps, and online, the life science industry is heading towards sharing real-time data across multiple channels and locations. Cloud-based technology is improving connectivity and the flow of information, allowing clinical teams to see all of their data in real-time and easily share information with stakeholders. More drug development companies are working towards risk-based trials (where information is accumulated and evaluated throughout a trial's lifecycle) for an up-to-date, integrated view of the patient. The outcome is improved collaboration between clinical trial sponsors, CROs, investigators, regulators, and even patients.

5. The Surge of Digital Medicine

Digital medicine is proving that it is here to stay, becoming progressively more integrated into new treatments alongside traditional drug therapies. Digital therapeutics have been already been in use for treating certain conditions such as mental health diseases, including alcohol addiction, from gamifying addiction management to the introduction of digital therapists. For many chronic conditions where treatment is focused on disease management, real-time monitoring is required, allowing for the perfect addition of digital therapeutics. For example, integrated blood sugar monitors could help automate insulin delivery, reducing the risk of dangerous fluctuations or hospital visits.

In 2018, the FDA approved perhaps the most innovative use of digital technology in healthcare: a pill integrated with an ingestible sensor that captures information about whether the patient has complied with their medication regimen. The sensor on the ingested pill works in tandem with a patch worn on the patient, digitally transmitting information to a mobile app, allowing both patient and physician to track how the patient is using and responding to their medication. Digital therapeutics help increase patient compliance, benefitting trial costs and timelines as well as the overall quality of the patient care. We expect to see ongoing innovations in the digital medicine space in the years ahead. BS