Virtual clinical trials: Story of the 'site-less' model!

The journey of bringing a novel drug into the market is a costly and time-consuming affair. It has been estimated that only 1 out of every 10 investigational drugs are able to make it to the market. As a result, Pharma companies are constantly in search for means of lowering the costs involved in the whole drug discovery and development process, especially the clinical trial process.

Virtual clinical trials have come out to be a concept which can speed up the drug development timeline and at the same time, take some of the costs out of the whole process. Virtual trials utilize novel technologies like monitoring devices, various apps, and the social media to conduct various stages of the trial.

It offers a more patient-centered approach by utilizing technologies like Fitbit, Apple Watch, Telcare, and Scanadu to execute the trial. Patient recruitment, informed consent process, data collection as well as adverse event reporting are executed from the comfort of the patient's home. Real-time data like blood pressure, blood glucose, heart rate, quality and duration of sleep, are directly transmitted by the patients to the main study site via the various devices. Patient interaction with the investigators is via telemedicine devices and mobile phones. Study personnel visit the patient's home for providing the medication or they receive their medications in the mail.

Some of the pioneers in virtual clinical trials

1. Pfizer

Pfizer was the first to venture into the virtual trial world with its REMOTE (Research On Electronic Monitoring of Overactive Bladder Treatment Experience) trial in

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2011. Patient recruitment, enrolment, and data collection were carried by using web and smartphones. The main purpose of the REMOTE trial was to predict the feasibility of the virtual approach. The trial to study overactive bladder treatment was, however, a failure and encountered numerous challenges, with patient recruitment being the main issue.

2. Sanofi

In 2016, Sanofi initiated the VERKKO trial in Europe to test a wireless glucose meter. The remote, online Phase IV clinical trial for diabetes was conducted in collaboration with eClinicalHealth- a technology and consulting company, Langland-a UK based healthcare advertising agency and Mendor- a Finnish health technology company. The Facebook recruited study, demonstrated positive outcomes and also highlighted the operational feasibility of virtual trials.

In March 2017, Sanofi partnered with Science 37, a California based clinical research services and technology company, to develop and launch new remote trials.

3. Novartis

Novartis has also partnered alliance with Science 37 and expects its decentralized trials to begin by late 2018 in the areas of dermatology, neuroscience, and oncology. Network Oriented Research Assistant (NORA) technology platform of Science 37 will be utilized for the same. Non-alcoholic steatohepatitis (NASH), acne and cluster headache are some of the indications in which virtual trials have already been initiated.

Advantages in comparison to the traditional method

- The most obvious and important advantage of a virtual trial is the requirement of just a single study site which leads to decreased infrastructure and overhead costs.
- Remote trials offer the benefit of increased patient recruitment which ultimately decreases the overall duration of the trial. It enables participation of patients from various socioeconomic backgrounds and also provides the opportunity to those whose participation is restricted by geographies.
- Virtual trial offers the benefit of automated data collection, decreased site-visits and therefore result in increased patient engagement and better retention.

A plethora of challenges ahead

- With critical patient data collected electronically, these trials pose the risk of inadvertent disclosure of vital data.
- Low computer literacy, especially amongst the elderly patients is another matter of concern.

- Phase I studies and trials involving sophisticated monitoring are not good applicants for these trials as such studies require constant observation of the trial patients by expert medical professionals.
- Conducting such trials requires robust systems to efficiently deal with the large amounts of data collected. However many service providers like Science 37, eClinical Health, QuintilesIMS (MediGuard), Clinical Ink, Medpoint Digital and SnapMD have proved to be front-runners in this field.

Long way to go!

Site-less trials have the potential to tremendously reduce clinical timelines and ultimately reduce costs for sponsors. However, these trials currently may not be the best choice for complex or specialized trials, and have limitations when the study patients involve older populations.

Hybrid trials, which give patients the choice to select the mode of interaction with the study personnel, will increasingly be popular and are more likely to be common. Patients may interact via various mHealth technologies or attend in-person appointments.

The ultimate beneficiary of the virtual model will be the patient population as it makes trial participation more convenient and leads to speedy approval and commercialization of lifesaving drugs.

Although totally remote research is still a relatively new concept, advancements in technologies are re-shaping the way developers conduct clinical trials, and these could revolutionize the future of the trial structure.

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