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Decentralized Clinical Trials - Need, Challenges and Prospects

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Abstract: ***Clinical trials, as currently conducted, are expensive, inefficient, and inaccessible. Furthermore, they fail to represent the patient population adequately. Currently, clinical trials are conducted centrally (at one trial site), at multiple individual trial sites, and/or remotely (via digital health technologies), depending on the type of data needed. Decentralized trials or Virtual clinical trials (VCT) can increase participant access and geographic representation, improve participant experience, and enhance recruitment of patient subpopulations. While decentralized trial is not new to the Pharma companies and CROs, the industry saw a surge in the adoption of decentralized clinical trials during COVID-19 times. This model allowed pharma companies to continue their clinical trials while keeping patients safe and out of clinical site. As the pandemic winds down, most researchers expect the decentralized model to be the new norm going forward. Study patients are being monitored from their homes and does that creates challenges for sponsor companies to track that data? What are the challenges of transitioning to hybrid, decentralized trial model, that companies need to overcome to succeed. This article identifies the challenges faced by the industry-in terms of technology, regulations and patient engagement adapting to the decentralized trials and the potential prospects to overcome the same.***

Keywords: Virtual Trials, DCTs, VCTs, D2P

1. Introduction

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While decentralized trial is not new to the Pharma companies and CROs, the industry saw a surge in the adoption of decentralized clinical trials during COVID-19 times. This model allowed pharma companies to continue their clinical trials while keeping patients safe and out of clinical site. As the pandemic winds down, most researchers expect the decentralized model to be the new norm going forward. Study patients are being monitored from their homes and does that creates challenges for sponsor companies to track that data? What are the challenges of transitioning to hybrid, decentralized trial model, that companies need to overcome to succeed. This article identifies the challenges faced by the industry-in terms of technology, regulations and patient engagement adapting to the decentralized trials and the potential prospects to overcome the same.

Some Facts:

- The average cost of bringing a new drug to market ~ $2.6 billion
- Two-thirds of the cost going to clinical trials - about 90% of which end in failure.

Need of Virtual Clinical trials:

In order to streamline the process during ongoing Covid-19 pandemic, researchers, pharmaceutical companies, and a handful of tech start-ups are experimenting with a new model: virtual clinical trials or also known as remote trials. Covid-19 has accelerated the adoption of decentralized trials, but the traditional model is not likely to disappear anytime soon.

A quality clinical trial is one that generates the minimal amount of credible, replicable, and evaluable data needed to answer meaningful questions with the least time and cost burden on participants. As more virtual clinical trials are conducted and patient communities are better engaged, the quality of endpoints and outcome measurements will improve such that trials can more effectively address questions about a patient's quality of life. These types of trials offer opportunities to foster ongoing relationships with participants, better understand clinical conditions longitudinally, and generate new and relevant research questions.

Lessons Learnt from Virtual Clinical Trials

Three main challenges associated with remote management of chronic conditions: (1) attributing digitally collected data to the individual under observation, (2) providing meaningful data for the participant being monitored (e. g., instant feedback on blood glucose levels for people living with diabetes), and (3) coordinating care for people with chronic conditions. Leveraging real-world evidence in a research setting may be complicated by the Hawthorne effect-the alteration of behavior by the subjects of a study due to their awareness of being observed.

Longitudinal research on large cohorts that aggregates data from a variety of sources (e. g. electronic health records, participant provided data, collected biospecimens, claims data), can facilitate trials. The combination of data that emerge from cohort studies could be leveraged to conduct a wide range of clinical research activities, including the identification of new disease targets and pharmacogenomic discovery, testing for adverse drug events, and identifying disease subtypes. Large, diverse observational cohort studies can enable direct and targeted recruitment of diverse populations, in addition to more intelligent trial design.

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VCTs also known as "Direct-to-Participant" (D2P) trials, as having no physical clinical sites, and thus no geographic limits on recruitment. The term 'D2P trials' more aptly captures the importance of building relationships with participants and that this approach can simplify trial design (i. e., improve enrollment, screening, data collection and reporting, etc.), thus increasing the likelihood of trial success. Recruitment from trusted communities and providers could lend D2P trials more success than solely web-based recruitment.

Opportunities that decentralized trials provide are increased geographic flexibility and reduced burden for participants; continuous data collection for faster and more accurate detection of health signals; and improved long-term follow-up with participants. Also there are challenges that decentralized trials can pose, such as operational (e. g., integration of emerging types of data and maintaining a temperature-controlled supply chain, especially for Covid-19 vaccines which requires temperatures between the range-20 degree to-80 degree), regulatory (e. g., endpoint and digital health technology validation), and change management (e. g., integration of decentralized trials into medical product development).

Virtual clinical trials can use unique designs to create new insights and increase participation rates of those who are typically excluded from clinical trials.

VCTs provide opportunities to use mobile technologies and engage local providers to promote inclusivity and convenience for trial participants, and for gathering information on real-world patient experience. These opportunities will require policies and regulations to address patient safety, privacy, the integrity of the data produced by remote technologies, and the responsibilities of the investigators involved in technology-enabled decentralized trials. Ensuring participant safety in a decentralized trial is no different than in a traditional clinical trial. However, digital health technologies are creating opportunities for greater safety oversight by replacing episodic monitoring with continuous monitoring of variables, such as blood glucose levels, heart rate, and rhythm. At the same time, it is important to ensure that technology failure does not jeopardize participant safety, or the integrity of the data and that technical support is available for when a digital health technology malfunction.

There are multiple benefits to decentralized trials, such as faster trial participant recruitment; improved retention; greater control, convenience, and comfort for participants; and increased participant diversity. To achieve these benefits, following are the recommendations: (1) Engage early with FDA and those who have already conducted a decentralized trial can be important for developing the trial protocol and trial success; (2) Maintain licensed investigators in each active trial site or use investigators licensed in multiple states, given state-by-state variations in regulations governing physician licensure; (3) Use mobile health care providers to facilitate participant protocol contributions, such as blood draws or administration of the investigational product, as a decentralized trial can cover a wide geographic area; (4) Review laws governing D2P shipment of drugs as these laws can also vary from state to state; (5) Consider differences between a standard and decentralized trial when delegating responsibilities to investigators, sub-investigators, and local providers; (6) Ensure that trial participants and trial staff are aware of procedures related to adverse events.

Projected market size for Virtual Clinical Trials

The global virtual clinical trials market size is expected to reach USD 13.78 billion by 2027. The market is **anticipated to register a CAGR: 12.6% from 2022 to 2027**. Growing adoption of telehealth, the necessity for patient diversity, and growing healthcare digitization increased the demand for the virtual clinical trials market. In addition to this, they enable the elimination of challenges associated with the traditional trials such as high trial cost, time-consuming procedures, and delay in patient recruitment, further boosting the growth of the market. Furthermore, the current **COVID-19 outbreak** across the world enabling regulatory agencies and biopharma companies to focus on the creation of digital technologies and virtual trials as they are seen as the potential solutions for limiting the spread of the virus, augmenting demand for the global market.

COVID-19 Pandemic Impact on traditional Trials: The COVID-19 pandemic has made a huge impact on the domestic as well as global market. A large number of trials that are primarily created for traditional setting are being forced to switch to virtual trials platform.

Virtual Clinical Trials Outlook

Design	Indication	Phases	Regions
• Observational Trials • Interventional Trials • Expanded Access Trials	• CNS • Autoimmune/Inflammation • Cardiovascular Disease • Metabolic/Endocrinology • Infectious Disease • Oncology • Genitourinary • Ophthalmology	• Phase I • Phase II • Phase III • Phase IV	• North America (U. S., Canada) • Europe (France, Germany, UK, Italy, Spain, Netherlands, Austria) • Asia Pacific (Japan, China, India, Malaysia, Indonesia. South Korea) • Latin America (Brazil, Mexico, Argentina) • MEA (Saudi Arabia, UAE, Israel, South Africa)

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List of Key Players of Virtual Clinical Trials Market

- Science 37, Inc.
- Covance Inc.
- CRF Health
- Oracle Corporation
- Medidata
- Veeva Vault
- ICON Plc
- IQVIA
- Medable, Inc.
- Paraxel International
- PRA Health Sciences
- LEO Innovation Lab

Key Stakeholders

- Raw material suppliers
- Distributors/traders/wholesalers/suppliers
- Regulatory bodies, including government agencies and NGO
- Commercial research and development (R&D) institutions
- Importers and exporters
- Government organizations, research organizations, and consulting firms
- Trade associations and industry bodies
- End-use industries

2. Conclusion

It is important of using human-centered design and seeking input from participants early in the trial design process. There is a need to have more visibility regarding current virtual clinical trials so that lessons learned are shared and D2P trials can move beyond the pilot-stage and towards 3 mainstream clinical trial methodology. Few of other points of importance are relaxing exclusion criteria to increase equitable participation in trials and community engagement, and how returning data to community members in real time can empower participants and help build trust in the trial process. It is important to understand the consent as an ongoing relationship-not a one-time transaction-especially when digital health technologies are passively collecting data. There is a need for development of ontology to describe the variety of studies occurring in the virtual clinical trial space. While regulatory issues were raised as a barrier to conducting virtual clinical trials, policy analysis and advocacy could facilitate implementation of reform. Virtual clinical trials may require greater inclusion of participants in study design, governance, as well as drug safety monitoring boards.

Virtual clinical trials are not a “one-size-fits-all” model and only a fraction of clinical trials might be considered fully virtual. In the near term, digital health technologies may only be applicable in a few settings, such as disease areas for which telemedicine is already an accepted practice or for evaluating medical products with a known safety profile and endpoints that can be measured remotely. However, in the longer term, virtual clinical trials have the potential to streamline the process of drug development and may offer new opportunities for a modern, more patient-centric clinical trial enterprise.

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