Virtual Clinical Trials: Pathway to Attain Patient Centricity During the Current COVID 19 Pandemic

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INTRODUCTION

Industry Overview: Virtual Clinical Trials

- Virtual clinical trials represent a new way of gathering data from the comfort of the patients, taking complete advantage of technologies like wearables, sensors to conduct each stage of the trial starting from recruitment till measuring clinical endpoints and adverse reactions
- Virtual trial is one among the emerging trends in the clinical trials space

Conventional Clinical Trials

ROI in pharma R&D have decreased to 1.8 per cent in 2019, since 2010 when it was 10.1 per cent - a decline of 8.3 percentage points

Drug manufacturers spend around $2.6 billion to launch a new drug, according to a recent estimate from the Tufts Center for the Study of Drug Development

Virtual Clinical Trials

The global Digital Clinical Trials market is estimated to reach 7.61 Billion by 2022, at a CAGR of 12.4% during the forecast period (2017-2022)

A survey of participants from CROs, academia, and labs stated that the ~78 percent of them have been using mHealth in clinical trials for more than a year

INTRODUCTION

Industry Overview: Virtual Clinical Trials

Conventional Clinical Trials

Traditional recruitment mechanisms have ended up with 86% failure rate in meeting their recruitment timelines and one third of phase 3 trials fail owing to enrollment issues

Average dropout rate from trial protocols is 30% based on research by both the Tufts Center for the Study of Drug Development

40% of patients do not end up adhering to trial protocols.
Over two-thirds of sites fail to meet original patient enrollment for a given trial

Virtual Clinical Trials

Virtual clinical trials in phase 2- 4 have shown promising results

Not just operationally feasible but successful

Elderly and disabled can overcome their mobility issues

A broader digital technology ensures faster recruitment

LITERATURE REVIEW

Initiatives by the FDA

- 21st Century Cures Act
- Pilot pre-certification program
- CTTI
- RWE/RWD – Sentinel programs
- Remote monitoring programs

RWD

- Electronic health records (EHRs)
- Claims and billing activities
- Product and disease registries
- Patient-generated data including in home-use settings
- Data gathered from mobile devices, other wearables, ingestible, implantable, and portable technologies containing sensors for the remote capture of outcomes data

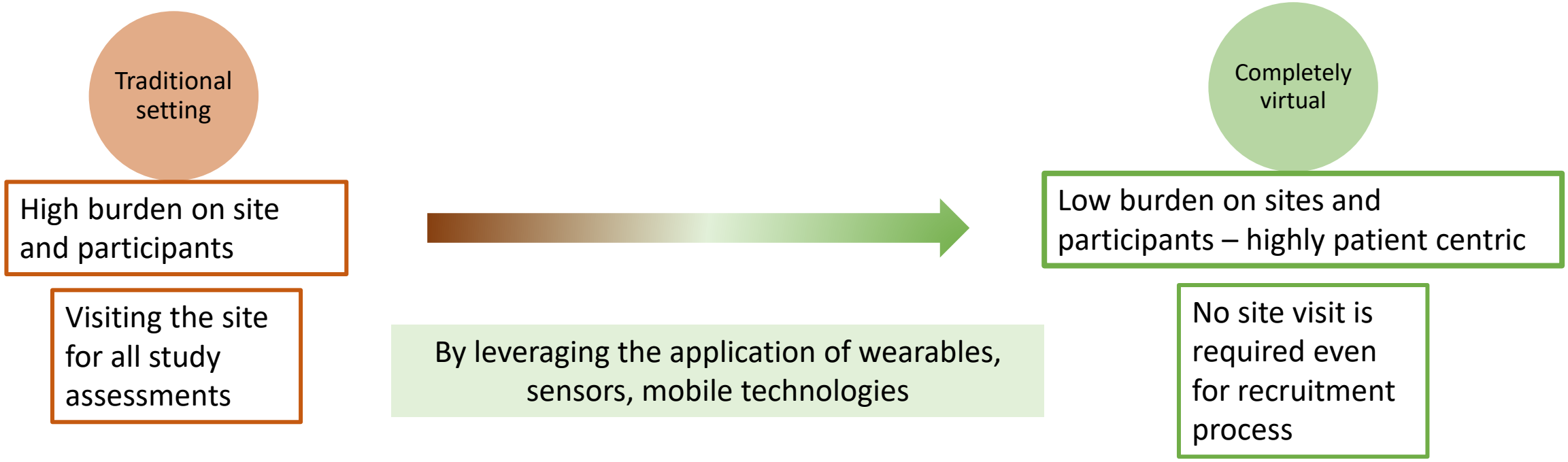
RWE

- Large simple trials
- Pragmatic trials
- Observational studies

The demand for the digital technologies has never been so high as now during the COVID19 outbreak since they can constantly monitor a patient's vital signs and integrate that data alongside patient reported subjective, this powerful device will change the way the trials are being conducted

BACKGROUND OF THE STUDY

In the current scenario of pandemic due to COVID 19, the industry needs to embrace virtual clinical trials like never before since the FDA also urges to take this path and has also released the guidelines on how to conduct visits remotely as to overcome the hurdles like interrupted supply chain and closure of sites along with research activities being temporarily ceased.



OBJECTIVES

General objective

- To map the current scenario of virtual clinical trials in the pharmaceutical industry in the USA through scoping analysis

Specific objectives

- To analyze the evolutionary trends in clinical trials to achieve patient centricity
- To determine the reasons for the emerging needs to adopt virtual clinical trials concept

RESEARCH METHODOLOGY

- Study design: Systematic review through qualitative secondary research
- Data collection: Secondary resources using various combinations of relevant strings and keywords using search engine like Google
- Duration of the study: 3rd Feb 2020 to 31st May 2020
- Source of information: Research studies and publications
- Method of analysis: Combination of content and narrative analysis.
- Process of research work: Keywords selected to search relevant articles – Virtual clinical trials, remote monitoring, decentralized clinical trials, site less monitoring, pragmatic trials, hybrid trials and direct to patient trials. From the vast list of around 100 articles in the search engine only relevant articles of about 4 that are applicable for the study such as use cases were taken for analysis and rest of about 20 articles were used for literature review.

FINDINGS: Case studies of virtual clinical trials

Pfizer's REMOTE trial (2011)

It is the first "virtual" clinical trial under an IND application that used digital technologies like to step into patient recruitment, enrollment, and collection of study data without requiring patients to visit a physical study site.

The clinical trial was designed to assess the safety and efficacy of Detrol LA (tolterodine tartrate), a treatment for overactive bladder.

But the trial failed to advance from pilot study since the patient population included mostly the elderly and they had very little acquaintance with the mobile phones facilities as compared to younger adults.

FINDINGS: Case studies of virtual clinical trials

Sanofi's VERKKO (2015)

It was the first study that used to test online platform, wireless glucose meter.

All the patients were recruited through Facebook. Before signing the electronic informed consent form the patients were selected and reviewed properly.

The selected patients could review the electronic consent form before reviewing and study materials and other training materials were delivered to patients through Clinpal account established by eClinical health Ltd.

FINDINGS: Case studies of virtual clinical trials

Janssen's CHIEF-HF (2020)

Janssen along with PRA Health Sciences recently designed the first completely decentralized clinical trial, to assess the effectiveness of INVOKANA in adults with heart failure.

The recruitment process will start recruiting in early 2020 and relies on PRA's patient facing mobile platform to remotely monitor and analyze patient healthcare data and patient – reported outcomes via smartphones and wearable devices.

This study setup will allow patients to engage well from their homes in the study as their routine physical activities will be recorded in the wearables and have facilities to connect with their healthcare stakeholders online. These integrated networks of technology will allow researchers to gather patient data in real time.

FINDINGS: Case studies of virtual clinical trials

LabCorp's virtual trial - 2020

LabCorp is partnering with software provider Medable to accelerate the acceptance of virtual clinical trials to reduce the dropout rate of study participants from clinical trials during the ongoing COVID 19 pandemic.

Labcorp's drug development unit Covance will expand its decentralized trials ecosystem by teaming up with Medable, a modular software platform to facilitate engagement between clinical research investigators and patients. This approach will help the organization to maintain the proposed timelines.

CONCLUSION

- The international bodies directly influencing the healthcare ecosystem are focusing on system efficiencies to deliver the healthcare services in a cost efficient and innovative way during this ongoing COVID 19 pandemic
- The ongoing pandemic has well demonstrated the benefits of virtual trails and made the stakeholders of clinical trials space to realize that its worthy enough to invest time and efforts in virtual clinical trials
- Virtual clinical trials symbolize a new way of collecting safety and efficacy data throughout the execution process by strengthening the data gathered from mobile apps, other social media platforms thereby the process from recruitment till analyzing the clinical endpoints are streamlined

RECOMMENDATIONS

- In the current dynamic situation that has evolved due to this COVID-19 pandemic, the need for proactive approach is highly appreciated by the regulatory bodies as well.
- On the same lines virtual trials are in high demand which can be implemented by the pharmaceutical industry since it resonates with the social distancing measures to a greater extent.
- For the same reason as mentioned above, a collaborative planning is required in order to mitigate the impact of COVID-19 on patient centricity.
- Virtual clinical trials should include telemedicine, real world data and evidence by leveraging digital technologies.
- The protocol for virtual clinical trials should be carried out electronically and must be compliant with HIPPA (The Health Insurance Portability and Accountability Act) guidelines.

LIMITATIONS

Not enough research articles are published around the scope of virtual clinical trials. The reasons could be lack of awareness amongst the stakeholders in the past and lack of understanding of the unmet needs of the participants. Thus, I could not deep dive to gather enormous data since the current articles are majorly focused on the scope of virtual concept and not the use cases of the same.