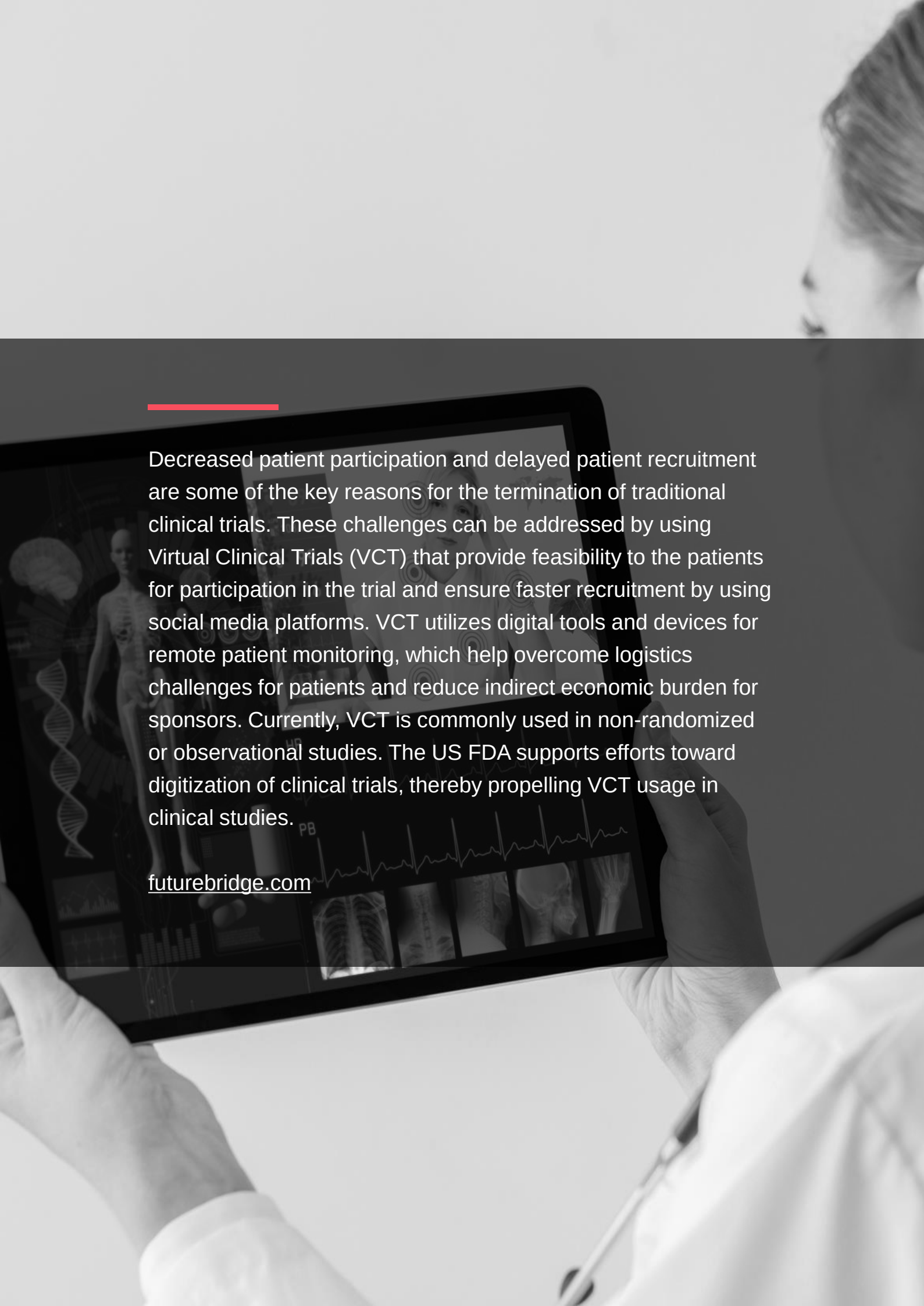
WHITE PAPER

Virtual Clinical Trials – Patient-Focused Approach

FutureBridge



Decreased patient participation and delayed patient recruitment are some of the key reasons for the termination of traditional clinical trials. These challenges can be addressed by using Virtual Clinical Trials (VCT) that provide feasibility to the patients for participation in the trial and ensure faster recruitment by using social media platforms. VCT utilizes digital tools and devices for remote patient monitoring, which help overcome logistics challenges for patients and reduce indirect economic burden for sponsors. Currently, VCT is commonly used in non-randomized or observational studies. The US FDA supports efforts toward digitization of clinical trials, thereby propelling VCT usage in clinical studies.

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Summary

Virtual or decentralized clinical trials make use of apps, monitoring devices, and online social media platforms. These trials enable patients to participate from home or be attended at a local physician's office, without the trouble of personally visiting the study center. This can increase a trial's reach to remote or underserved communities and may provide up to 30 times faster patient recruitment. Virtual clinical trials help enhance the satisfaction level of patients and physicians, thereby improving the patient retention rate.

Virtual clinical trials provide patients with the feasibility to participate when they do not have the proper logistics to reach the site physically. Multiple stakeholders, including sponsors, sites, and healthcare professionals, can provide real-time support through solutions, such as online chats, call centers, or email. The site operator can interact with multiple patients in a short period, resulting in less burdensome work schedule and more time allocated for research. Long recruitment timelines and under-performing sites are the most frequently encountered challenges in the clinical trials sector. Hence, adopting the virtual route may solve some of these problems. Virtual clinical trials prove to be cost-efficient, owing to faster patient recruitment, high patient retention, and reduced maintained cost of the clinical site.

Currently, virtual clinical trials are used for non-randomized or observational studies. In 2011, Pfizer conducted the first-ever virtual clinical trial. Novartis, in partnership with Science 37 is already conducting clinical trials for cluster headache, acne, and Non-alcoholic Steatohepatitis (NASH). In March 2018, Novartis extended its partnership with Science 37 for 10 more virtual clinical trial programs in the field of dermatology, neuroscience, and oncology. Presently, many companies such as Sage Bionetworks and EmpiraMed conduct full virtual clinical trials, including patient recruitment as well as data collection and analysis.

The involvement of patients due to the use of digital tools has improved significantly as compared to traditional clinical trials. Empowering patients is essential to create awareness among them regarding ongoing and relevant clinical trials.

The use of electronic medical records can help identify subjects with specifically targeted characteristics and increase awareness of experimentations and recruit subjects directly. A continuous data recording benefits patients by monitoring their safety, allowing a more specific study design and limiting costs in case of study failure. Therapeutic areas such as endocrinology, Central Nervous System (CNS), dermatology, respiratory, gastrointestinal, immunology, cardiovascular, and rare diseases present the best opportunities for a virtual approach.

The Food and Drug Administration (FDA) of the US has also undertaken efforts towards the development of the current clinical trial process, thereby propelling the adoption of digital tools in clinical trials to collect Real-world Data (RWD) and Real-world Evidence (RWE).

Virtual Clinical Trials

Introduction

A novel disruptive technology has made it likely to drive the limits of traditional clinical trial models—one such disruptor is the Virtual Clinical Trial (VCT). In the past, it was difficult to carry out a large-scale virtual trial; however, established pharmaceutical companies are using VCT and have reported success.

VCT is a new method of carrying out a trial with the help of digitization to collect data so as to assess the safety and efficacy of a molecular or medical device. VCT involves the use of videoconferencing, wearable technology, mobile apps, etc., which interlinks with patients and collects data. The requirement of visiting a clinical trial center for several times is negated, and the patient data is collected remotely. Patients in VCT have access to their study team via video-conference or chat.

Once successfully applied, the VCT offers the ability to enroll numerous patients at a faster rate, improvise patient retention, and enroll a diverse population. However, it is impossible to enroll pediatric and geriatric people for VCT.

VCT enables patients to participate in the trial, especially the ones who do not have proper logistics to reach the clinical site. Digital technology is quick and less complicated to set up; VCT mostly relies on digital technology to offer a more patient-centric approach.

History

In 2001, the first virtual study by Eli Lilly was carried out; the study involved testing of Tadalafil, a PDE5 inhibitor used to treat erectile dysfunction. An online questionnaire was filled up by study participants; this was considered as the first attempt for a site-less clinical trial. After 10 years, Pfizer carried out a VCT model with Research on Electronic Monitoring of Overactive Bladder Treatment Experience (REMOTE) for bladder study (*as mentioned in Exhibit 1*). This was the first virtual study wherein patient data was collected via mobile or over internet. The primary objective of this study was to compare the VCT with a traditional Phase IV study model to assess whether VCT can be successful for future studies. The study failed to recruit adequate number of participants, and most of the recruited patients were aged individuals with limited skill to use the technology.

EXHIBIT 1: First Virtual Clinical Trial

PFIZER'S REMOTE TRIAL

Research on electronic monitoring of overactive bladder, treatment experience

Patients could participate in the trial from their home via smartphones or web. The objective of the trial was to improve patient compliance and gather quick and quality data.

Pfizer planned to recruit ~600 patients from 10 states; however, this recruitment target was not achieved, and the trial was halted in 2012.

Even though the trial failed to recruit sufficient patients, Pfizer developed an effective, informed consent methodology and a successful way to engage with potential trial recruitment patients.

KEY TAKEAWAYS

Social media channels proved to be successful in generating awareness; however, the reason for the failure was identified as the unwillingness of patients to trust or respond via Facebook.

Source: Pfizer

Sanofi carried out a virtual diabetes trial (VERKKO) that was conducted remotely in Finland in 2015. Rather than testing a drug like Pfizer, Sanofi used a medical device such as a wireless glucose meter for patients with diabetes. This was also the first clinical trial that acquired patients consent electronically and was approved by the European regulatory bodies.

The outcome of the study highlighted a 97% retention rate and a 30% higher recruitment rate as compared to the traditional trial.

Remote research is still a new concept and has its own limitations. For example, it is not possible to carry out Phase 1 studies due to some acute problems, such as stroke, which is perhaps impossible to screen at home.

In 2015, Genentech conducted a head-to-head trial on rituximab and mycophenolate mofetil in patients with Pemphigus Vulgaris, a rare autoimmune skin disease. The comparison between virtual recruitment channels and traditional recruitment channels observed that Facebook and Google AdWords was faster in recruiting patients than the traditional channel, which comprised of 21 clinical trial centers. An announcement was made by Novartis in March 2019 that the company will introduce 10 VCT over the next 3 years in partnership with Science 37.

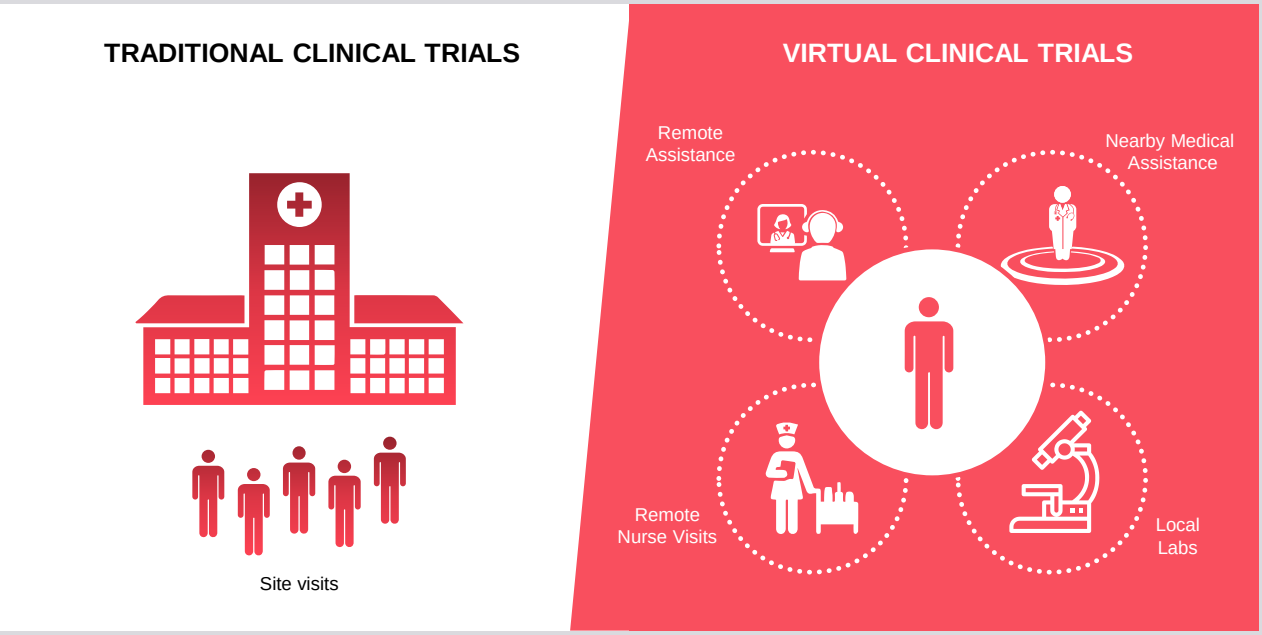
Opportunity to improve existing clinical trials

Traditional clinical trials have accessibility obstacles for patients, especially for those who often need to travel long distances to visit the clinical trial site and have to make time commitments for multiple trial-related site visits. Due to this challenge, many clinical researchers find it difficult to enroll and maintain participants. According to

statistics, 87% of patients are willing to participate in a relevant clinical trial; however, approximately 70% of the potential patient lives more than 2 hours away from home. As a result, 33% of clinical trials fail to enroll sufficient patients; a 30% drop-out rate is observed in a standard clinical trial, whereas a virtual clinical trial has recorded a drop-out rate of 5%. ~77% of patients who have tried virtual visits report high satisfaction.

Long recruitment timelines and under-performing sites are the most frequently encountered challenges in the clinical trials sector. New technological advances are expected to overcome these challenges in the near future. The difference between traditional and virtual clinical trial is depicted in the *Exhibit 2* below.

EXHIBIT 2: Traditional vs. Virtual Clinical Trial



Source: FutureBridge analysis

Apart from time and enrollment challenges, other challenges associated with traditional clinical trials include increased cost and complexity. Another burden of traditional clinical trials is the cost associated with supporting a network of study sites. Current clinical trials have stringent eligibility criteria, Patient-Recorded-Outcomes (PRO) assessments, detailed procedures, and complex endpoints.

Consideration for virtual clinical trials

Virtual clinical trials cannot be applied to all existing clinical trial models. There need to be some criteria before considering the shift from traditional to virtual model.

Scientific considerations

Age: The age of the patient population to be enrolled offers insight on whether or not remote research would be a successful alternative to a traditional study. For example, in elderly population, proficiency with technology may prove a hurdle to participation.

Technology Adoption & Training: Site staff and participants are critical for proper data collection and device management device training for field nurses.

Study Design: Appropriate study design is essential for the desired outcome.

Integrity of the Data: Selecting the best technology to support a remote study is imperative. Without checkpoints to ensure clean and quality data at the source, data verification becomes a significant burden on-site staff.

Remote Monitoring: When selecting technology to support the study, the ability to monitor data remotely offers additional optimal efficiency and cost savings.

Adverse Events: Adverse event reports are often made by phone, email, or in-person at study visits in traditional approach. With remote studies, the technology must be able to capture adverse event reports and relay them in a timely manner for follow-up by the site staff.

Device Delivery or Bring Your Own Device (BYOD): Careful selection of the best devices, which will be used as a platform that can work on multiple devices (smartphone, laptop, tablet, etc.), is essential.

Global Studies: Data with respect to country-specific privacy regulations, relevant languages, and local cultures must be embedded in the software.

Operational considerations

Online systems can be utilized to support clinical operations. In a remote study, participants share data via the Internet from their home using a study portal or website on their computer or mobile device. Multiple stakeholders, including sponsors, sites, and healthcare professionals, can provide real-time support through solutions, such as online chats, call centers, or email.

Important operational considerations include:

Need for Specialized Equipment: Need for MRI and CT scan as well as in-depth assessment can be performed only by a trained clinician. In addition, there is a need for a physician to be present during drug administration.

Patient Care and Data Collection: Not all data collection can be passively transmitted back to the study site. However, home health nurses may collect the specimen, conduct physical exams, and undergo drug administration.

Patient Recruitment: A hassle-free online patient recruitment procedure involves a minimum number of clicks for a relevant clinical trial.

Advantages of virtual clinical trials

In recent years, the cost of conducting a clinical trial for developing a product has increased, whereas, clinical trial patient involvement and withholding have decreased. However, to overcome these challenges, sponsors are seeking and undertaking new and state-of-the-art methods such as site-less trails or virtual trials to reduce costs while increasing patient participation.

Virtual clinical trials or site-less clinical trials offer the clinical trial experience to the patient's home via a central, virtual coordinating site without having to travel to the clinical site. This mostly works for individuals with rare diseases and other serious illnesses where patients are bedridden. Enlisted below are some of the advantages of virtual clinical trials.

- Reducing the overall trial cost: With the virtual clinical trial, the need for multiple physical sites to conduct study procedures, a full staff complement, or storage facilities, and investigator grant payments reduces intensely, ultimately reducing the overall trial cost.
- Large geographic reach and more diverse patient population: Patients living in remote, rural areas have an opportunity to participate in clinical trials. Thus, having a larger and wider population for trial recruitment magnifies the saturated pool of patients interested in trial participation.
- Flexibility for patients: Site-less clinical trials are performed at home without having the patient to visit the clinical trial site. This enables patients with rare diseases and other serious illnesses, especially those who are bedridden, to consult physicians without having to visit the clinical trial site.
- Improved data quality: A majority of data is automatically transferred from smartphones or other wearable devices to the clinical trial database, negating the involvement of site staff and improving data quality by avoiding manual errors.
- Resourcefulness: Improved quality and effective service to patients are achieved by having one-site handling capability to manage higher volumes, thereby allowing for a more flexible and efficient resourcing of professional staffing and better training.

Advanced development of technology will allow site-less clinical trials to become more popular in the near future.

Application of virtual clinical trials

A virtual clinical trial is dependent on patient-reported outcomes and the quality of life measures. Studies indicate that drugs or devices not considered as life-threatening or invasive, such as in dermatology, could be conducted virtually. An overview of the components and procedures is illustrated in *Exhibit 3*.

EXHIBIT 3: Application of Virtual Clinical Trials

Source: FutureBridge analysis

TABLE 1: Technologies Employed at Various Stages in Virtual Clinical Trial

Requires Stages/Steps	Technologies Employed
Patient Recruitment	Social media (Twitter/Facebook/You tube/Apps, etc.)
Patient Retention	Social media, mobility, remote patient monitoring
Patient Compliance	Mobility, Remote Patient Monitoring, e-PROs/e-diaries, Interactive Response Technology (IRT)
Patient Engagement	Social media, mobility, and IRT
Patient-driven Data Collection	Remote patient monitoring, e-patient reported outcomes/e-diaries, and IRT

Source: FutureBridge analysis

A recent example of a virtual clinical trial is AOBiome's site-less phase 2b clinical trial conducted to assess safety details and determine the effectiveness of in-development acne treatment. AOBiome, a Boston biotech firm, started by recruiting patients through social media and online ads. It continued by conducting screening programs and gaining consent of patients via calls. An app on loaned iPhones was used by patients to report treatment effects, submit pictures of acne, and ask questions.

At the conclusion of the study, AOBiome reported positive safety and efficacy data. It also enrolled 372 patients in seven months—about half the time of a typical, similar trial. Additionally, the study recruited 41% of minority patients, partly because those patients could participate no matter where they lived. The firm observed that dropout rates were lower, compliance was better, and the trial was cheaper to administer than a traditional trial.

Key challenges of virtual clinical trials

Virtual trials make up only a fraction of the several registered US-based clinical trials, despite the adoption by some of the established biopharma and medical device companies. Digital technology platform adoption stands as a major challenge and results in the slow adoption of the technology in clinical trials. As virtual clinical trials have recently been adopted, evidence on whether these technologies improve clinical trial design is unavailable.

Key challenges for these trials include:

- Higher amounts of data to collect, manage, and prove reliability to regulators
- Requirement of in-hospital attention or equipment (e.g., cancer studies, diagnostic imaging, etc.)
- A phase I clinical trial, which finds the best dose of the drug with minimum side-effects
- Regulatory hurdles for eConsent in different countries and shipping of drugs directly to patients
- The FDA accepts eConsent as a valid patient consent method
- Investigational products with an unknown safety profile
- Assessment of the new protocol may take more time and effort
- Slow adoption of the technology in clinical trials
- Computer literacy is yet to be adopted by the elderly population; for example, only one in ten Americans aged 55-65 could complete an online task, such as filling out a form using an app (recruiting older adults with low computer literacy could impact trial data and patient retention)
- Data integrity; maintain the secrecy of the patient data

Patient-focused Approach

A patient-centric approach puts individuals rather than investigative sites at the center of the research process. In a study, it is stated that if the challenge of traveling far distances to reach a clinical trial site is removed, the patient involvement will increase significantly. In a patient-focused approach, it is imperative to reduce the discomfort associated with travel and simplify the data collection process.

Several studies have stated that virtual trials can reduce the high drop-out rates of patients involved in phase III studies (~40%). Current healthcare technologies increase the compliance of patients in the study. Companies have services such as remote visits for patients, who have limited locomotive ability and need to be attended by caregivers.

The patient-centered remote approach, more commonly used in non-interventional studies, predominantly follows a patient with a particular disease. By the use of technology, electronic medical records can help identify subjects with specific targeted characteristics to increase awareness of experimentations and recruit subjects directly.

Although a remote approach needs strong technological resources, it is believed that savings can be achieved both by saving time and eliminating the traditional multi-site study set-up. A continuous data recording benefits patients by monitoring their safety, allowing a more specific study design and limiting costs in case of study failure. Sharing of the educational information frequently with patients and their relatives enhances patient awareness, ultimately improving patient retention.

Patient empowerment

Individuals living with chronic, acute, or terminal illnesses often use the Internet for information with the purpose of empowering themselves to make better healthcare decisions.

According to a 2015 survey, 62% of smartphone owners used their phones to access information regarding a health condition. Patients are becoming more tech-savvy and are engaging in patient-driven research initiatives.

Engagement of patients in clinical research initiatives is more convenient at present as compared to 10 years before. Organizations such as Patient-centered Outcomes Research Institute (PCORI) educate patients regarding clinical trials

specific to the patient condition in their surroundings. Patients, nowadays, are leveraging technology to stay engaged and remain informed about ongoing events in the pharmaceutical sector.

With increased access to healthcare facilities, and awareness in patients regarding clinical trials, the hurdle for participation in clinical studies will be minimized as compared to traditional clinical trials. Owing to advocacy groups, trial finder websites, and social media campaigns, the amount of patient participation from any geographical region of the world is high.

Patient empowerment and easy accessibility to relevant clinical trial sites have resulted in lowering the overall burden on patients and their families. Improvement of up to 60% inpatient recruitment is expected by minimizing the impact on a patient's lifestyle, while >90% participants are expected to complete the study.

Challenges of patient-centric trial

Physicians included in Phase III or Phase IV clinical studies are the key prescribers/adopters of drugs upon approval. If a patient-centric study is employed where the involvement of the physician is limited or none, the sponsor may lose on early-adopting physicians, thereby impacting the initial sale of drugs.

Monitoring patient progress using a remote trial might not be a feasible option each time, as the physician is required to determine the drug's novelty, line of therapy, and other parameters. This will have an impact on the physician's observations during a remote clinical trial.

A superficial physical examination can be performed using video conferencing tools, such as Skype; however, unless other vital signs are recorded via the technology used as part of the study (smartphone apps and electronic devices), site visits, or home health nurses may need to be employed.

The limited role of the caregiver in a remote trial may make the caregiver feel less important. Hence, provisions of making the role of caregivers significant should be made. These provisions include awareness regarding the technology being used in the study and incorporation of caregiver reminder notifications that improve the compliance towards taking medications.

Policy Consideration

As the healthcare industry grapples with the increased cost of innovation and development of new drugs, policymakers have been receptive to different ways of cost-cutting. The use of virtual approach may help clinical trials become more agile, efficient, and cost-effective. The FDA has extended support to decentralized clinical trials with the aim of making these trials cost-effective and productive. In January 2019, the FDA designed a policy to expand discussion and debate over how Real-world Data (RWD) and Real-world Evidence (RWE) can be utilized to support a range of drug development goals. *Table 2* showcases responsibilities of principal investigators and how they may be delegated in a virtual trial.

TABLE 2: Responsibilities of Principal Investigators and their Delegation in Virtual Clinical Trials

Responsibility of Principal Investigator	Transfer to
Obtain informed consent	Virtual PI
Randomization and unblinding	Sponsor/CRO
Ensure that procedures follow GCP and the protocol	Virtual PI
Give medical attention and make medical decisions	PCP and virtual PI
Review safety events and report SAEs	PCP and virtual PI
Document deviations	PCP and virtual PI
Ensure that patients receive appropriate therapy and follow-up	PCP and virtual PI
Inform patients of updates to trial and/or IP	Sponsor/CRO or PCP
Communicate with the IRB	Sponsor/CRO
Oversee study staff	Sponsor/CRO*
Store and account for IP	Sponsor/CRO

Source: Biorasi: Revolutionizing Clinical Research

Novel virtual technology helps improve compliance with regulations. Cloud-based analytical tools can analyze documentation for non-compliant elements in a report and ensure that a trial meets all required standards, prior to the trial start date. This helps save time and money needed for revising and supplementing previously submitted documents. The FDA participates in the Clinical Trials Transformation Initiative (CTTI) to develop new opportunities to incorporate mobile technology in clinical trials with a focus on novel end-point design.

Moreover, the FDA has planned a stakeholder meeting to develop an advanced framework in certain areas. It has aimed to utilize remote monitoring technologies to

reduce the need for traditional on-site monitoring while assuring the integrity of data needed to assess patient safety and product efficacy. Such programs conducted by the FDA are vital in assessing new cancer treatments and rare disease therapies affecting small patient populations. Further, FDA is launching a two-year fellowship program in artificial intelligence and machine learning that will bring in academic fellows to support advances in clinical trials. FDA has held public workshops on defining RWD and developing innovative medical devices for collecting patient-relevant information. Decentralized clinical trials fit broader initiatives promoting patient centricity in clinical research. FDA has supported modern approaches of collecting RWD, as it is a key towards modernization of clinical trials. In 2018, the FDA launched a digital tool via mobile devices to facilitate collection of RWE.

Virtual Clinical Trial Companies and Patient Recruitment Platform

Virtual clinical trial companies

A step towards innovation in traditional clinical trials is being taken in the form of virtual clinical trials. These trials are comparatively cheaper, provide access to wider population, and offers lucrative opportunities to capture real-world data from participants.

Reduction in the cost of conducting a clinical trial, increased patient engagement, and quick results are the topmost priorities of biopharma and medical device companies (*refer Exhibit 4*). With these virtual clinical trials, several sponsors have partnered with virtual trial providers, such as Science 37, IQVIA, and VirTrial, etc.

EXHIBIT 4: Virtual Clinical Trial Companies

Source: FutureBridge Analysis

EmpiraMed, which serves Merck, Biogen, Janssen, Sanofi Genzyme, UT, and TEVA, has successfully completed three virtual studies by enrolling patients directly into its PRO Portal platform and followed participants for one year. Follow-up of patients was completely anonymous in these studies. Another organization, Science 37, provides a digital platform named NORA for conducting clinical trials. The established "digital CRO" has raised USD 67 million in the year 2017-18 to support site-less trials.

An e-consent platform organization, Mytrus, which was acquired by Medidata, assists pharmaceutical companies in obtaining the consent of patients. The company has assisted Pfizer launch, the first-ever virtual trial in 2011.

Patient recruitment platforms

Patient recruitment is an essential part of a clinical trial. Most patients are willing to participate in a clinical trial; however, they have limited knowledge regarding the ongoing clinical trials. These platforms engage patients so they could know about a relevant clinical trial by the new software-led approaches. There are many different approaches to finding better ways to recruit patients (*refer Exhibit 5*).

EXHIBIT 5: Patient Recruitment Platforms

Source: FutureBridge Analysis

Artificial Intelligence platforms such as Mendel.ai and Deep6 AI have developed algorithms that match an individual's medical record to find a suitable patient for the relevant clinical trial. Among major players in this market, Clara Health developed a software platform to streamline the process of participating in clinical trials.

Conclusion

The introduction of new tools for clinical trials and the accessibility of Big Data offer vast prospects for investigators; however, several challenges still remain unresolved. The clinical trial team should bear in mind that e-technologies are supplementary tools and not supplant traditional methods. The time consumed by these technologies is immense and requires refinements to overcome numerous challenges. Upcoming research can develop an understanding regarding the impact of e-technologies on VCT and their interpretation, with respect to the strength of results, randomization, and blinding.

A lot of work still remains to fine-tune the virtual clinical trial model; however, looking forward, CROs and pharmaceutical players will have a significant impact on obligatory changes in regulations, infrastructure, and conventions. Participants are benefited from the virtual trial by being able to participate more easily without disturbing routines and being better characterized in clinical trial data.

Even though there is good support offered by players in healthcare, the journey for VCT is not an easy one. The establishment of new entities and logistics policies to accommodate all of the far-off parties involved in VCT will require a considerable amount of work and intelligence, in addition to regular updates. As individual constituents are all available, a significant portion of the task needs to be performed by enterprises, who can tie everything into an efficient, working system.

Focusing firmly on the patient, digital approaches can theoretically transform the research landscape, enabling better, faster, and more efficient trials. These technologies will help in the execution of a less complex, interventional, and observational study involving chronic disease. Key advantages for patients include diverse clinical care options, improved trial accessibility, and increased retention. Whereas for investigators, richer data from a diverse population will provide deeper insights into the clinical condition of patients.

Virtual clinical trials are likely to enhance the patient and investigator satisfaction in the clinical study. Moreover, these trials demand various complex regulatory requirements and in-depth clinical understanding.

As the FDA directs the involvement of diverse patient groups, virtual clinical trials can potentially include hard-to-reach populations, such as people living in rural locations and extremely sick individuals. Patient-centric trials can ease the burden on the patient and allow patients, especially in remote locations, to have access to clinical research. If executed successfully, virtual clinical trials can be significantly cost-effective, efficient, and a patient-friendly model for clinical research programs globally.

References

1. Alper J. et al. Virtual clinical trials: Challenges and opportunity (accessed on 8th Aug 2019)
2. Pfizer REMOTE the first virtual clinical trial (accessed on 12th Aug 2019)
3. Hand S. et al. Xtalks Blog. Can virtual clinical trial change clinical trial landscape (accessed on 12th Aug 2019)
4. Novartis and Science 37 collaboration for virtual clinical trials, 2018 (Accessed on 12th Aug 2019)
5. VirTrial company website (accessed on 12th Aug 2019)
6. Global Public and Patient Perceptions and Insights 2015
7. Lamberti M.et al. Profiles of New Approaches to Improving the Efficiency and Performance of Pharmaceutical Drug Development, 2015
8. White paper: Direct to patient remote search; Clinipal, 2017
9. Jaramillo C. et al., Virtual clinical trials: A tool for the study transmission of nosocomial infection
10. Novartis Global Drug Development, decentralized clinical trials, 2019
11. Clinical Leader, The benefit and challenges of siteless clinical trials, 2019
12. McCarty M. et al. A guide to conducting late phase research directly, June 2018
13. Holloway J. et al. Siteless Clinical Trials Are Changing the Game for Patients, Feb 2019
14. Rosa C. et al. using e-technologies in clinical trials, 2015
15. Lucchini C. et al. industry embraces the virtual platform, 2018
16. White paper: Direct to patient remote search; Clinipal, 2017
17. Terry M. Virtual clinical trials, 2019
18. Wechsler J. et al. FDA policies shift support decentralized clinical trials
19. Coravos A. et al. Software enabled clinical trials, 2017

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