

Utilization of Digital Technology in conduction of Clinical Trials in India: Issues and Perspectives

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Abstract- The conventional clinical trial system demands a change of evaluating new drugs, treatments, devices and health system intercession. Digital technologies have the ability to alter the whole clinical trial procedure through automatic mechanism, better data analysis and storage and better bond and relationship with patients. The year 2020 has schooled India as well as the world that an active functioning healthcare structure and healthy people are crucial to the economic and social welfare of a country.

The paper discusses about the role and importance of digital technologies which are used in clinical trials. It discusses about the key elements of digitizing the clinical trial process. It also focusses on the barriers of digitizing the clinical trial process. The paper concludes by throwing light in the concern area which needs to be overcome in order to enhance the efficiency and efficacy of digital clinical trial in India.

Index Terms- Digital clinical trials, Digital Recruitment, Digital Health Data Collection, Digital Analytics.

I. INTRODUCTION

On March 11, 2020, the World Health organization (WHO) announced the coronavirus disease 2019 outburst as a pandemic. The Covid-19 pandemic has significantly changed the society, economies of the countries, and consequently a vital need

arises for new inventions and innovations in the field of medicines, medical devices and development technology to provide high-quality patient-care following the Covid-19 protocols. Thus, it is very important to link the digital technology to medical software applications to grab health related information of the patients. Similarly digital technology should be used in the process of clinical trials as well so that the recruitment process can be raced up and the process of data analysis and recording and monitoring activities can also be done at a faster pace.¹

As per the Symposium organized by Parexel, Global Clinical Research Organization (CRO) in association with ET Health World, 2022, only 1.2% of the population participate in clinical trials in India. Large number of people's medical need are still unmet in India, which shows a strong necessity of clinical trials in India so that all new therapies and medicines are accessible to all the patients.²

According to the Accenture Digital Health Technology Vision 2020 report, 90% of health executives believes that for competing in the market, smooth and harmonious relations of organization with their customers is a primary requirement and this task is made easy with the help of digital technology. In 2000, only 8 clinical trials used digital health technologies which increased to 1100 trials by 2017. It is estimated that 70% of clinical trials will be backed by digital sensors and technology by 2025. Relationship of the technology and clinical research has given an opportunity to enter the Global clinical research market.³

¹ Anthony Jnr. Bokolo, 'Exploring The Adoption Of Telemedicine And Virtual Software For Care Of Outpatients During And After COVID-19 Pandemic' (2020) 190 Irish Journal of Medical Science (1971 -).

² 'India's Clinical Research Advancements: Trends Witnessed across Technology and Patient-Centricity - ET Healthworld' (ETHealthworld.com, 2022)
<<https://health.economictimes.indiatimes.com/news/industry/india-as-clinical-research-advancements-trends-witnessed-across->

[technology-and-patient-centricity/89790819](https://health.economictimes.indiatimes.com/news/industry/india-as-clinical-research-advancements-trends-witnessed-across-technology-and-patient-centricity/89790819)> accessed 11 April 2022.

³ Nikita Rana, 'Technology Is Going to Play a Key Role in India's Roadmap for Health Infrastructure: ETILC Members' (*The Economic Times*, 2022)
<<https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/technology-is-going-to-play-a-key-role-in-indias-roadmap-for-health-infrastructure-etilc-members/articleshow/81683674.cms>> accessed 5 January 2022.

II. DEFINITION OF CLINICAL TRIAL

A Clinical Trial is defined as a systematic study of new drugs in human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamics and pharmacokinetic), and/or adverse effects with the objective of determining safety and/or efficacy of the new drugs.⁴

Clinical trials form a link between preclinical testing and actual medical practice. With the help of clinical trial the efficacy and safety of a drug or treatment is tested which is a primary requirement for market authorization. Clinical trials are the only key through which lock of new medicines including drugs, therapeutic treatments, vaccines, medical devices are open for the public at large which helps in curing their diseases.⁵

III. CONCEPT OF DIGITAL CLINICAL TRIAL

A digital trial is defined by the procedure, methods and techniques that are used to obtain the clinical trial data. A digital clinical trial is the one where all types of data which are required for the study is collected through the use of digital technology and utilization of paper forms are to the minimum.⁶

The concept of digital clinical trials is useful to accelerate the process and improve the recruitment, data collection and data analysis which are available during the clinical trial procedure. Digital technology is very beneficial for speeding up the regulatory approval process which ultimately results in cost effective and less burdensome clinical trials. Various experts, professionals, and officials have accepted the potential of using digital technology to accelerate the pace at which various data and results is being obtained through clinical trials.⁷

IV. KEY ELEMENTS OF DIGITAL CLINICAL TRIAL

A digital trial is one that uses technology to improve recruitment process, pacing up the data collection procedure and help in the analysis of the data. So the key elements of a digital clinical trial are Digital Recruitment, Digital Health Data Collection and Data Analytics.⁸

V. DIGITAL RECRUITMENT

Recruitment and informed consent of participants for the clinical trial is a major hurdle because of which the clinical trials are not completed in time. Many a times the enrollment procedure are so complex that the participants hesitate in enrolling for the trial. Other reasons like the travelling expenses, financial constraints, lack of knowledge regarding the clinical trial of the drug may also hinder the recruitment process.⁹

The solution to such problems is the use of digital technology in the recruitment process of the participants which will make their work easy, quick, and economical and less time consuming. Recruitment of participants by using internet, certain software or social media applications, smartphones, laptops or such other virtual gadgets becomes quite easy, fast and cost efficient. Digital marketing with the help of online advertising can be useful in targeting the appropriate patient group which are required for the trial.¹⁰

VI. DIGITAL HEALTH DATA COLLECTION:

The second step after the recruitment of participants is the collection of data which are necessary in the clinical trial process. The data may include medical or demographic data, physiological

⁴ Sec. 122DAA of Drugs and Cosmetics Rules, 1945.

⁵ M Flather, Hazel Aston and Rod Stables, *Handbook of Clinical Trials* (ReMEDICA Pub 2001).

⁶ 'Decentralized Vs Digital Clinical Trials: There Is a Difference | Concertai' (*ConcertAI*, 2022) <<https://www.concertai.com/news/2021/11/decentralized-vs-digital-clinical-trials-there-is-a-difference/>> accessed 12 April 2022.

⁷ 'Accelerating Momentum: Digital Innovation in Clinical Trials' (*Accenture.com*, 2022) <[https://www.accenture.com/_acnmedia/PDF-171/Accenture-](https://www.accenture.com/_acnmedia/PDF-171/Accenture-90976792-Infographic-Accelerating-Momentum.pdf)

[90976792-Infographic-Accelerating-Momentum.pdf](https://www.accenture.com/_acnmedia/PDF-171/Accenture-90976792-Infographic-Accelerating-Momentum.pdf)> accessed 12 April 2022.

⁸ 'Accelerating Momentum: Digital Innovation in Clinical Trials' (*Accenture.com*, 2022) <https://www.accenture.com/_acnmedia/PDF-171/Accenture-90976792-Infographic-Accelerating-Momentum.pdf> accessed 12 April 2022.

⁹ Geoff K. Frampton and others, 'Digital Tools for the Recruitment and Retention of Participants in Randomised Controlled Trials: A Systematic Map' (2020) 21 *Trials*.

¹⁰ ClinEdge (en-US), 'Digital Recruitment: Changing the Face of Clinical Trials' (*Clin-edge.com*, 2022) <<https://clin-edge.com/news/digital-recruitment-changing-face-clinical-trials>> accessed 13 April 2022.

data or certain types of activity details which a patient or trial subject may be performing as a part of their routine, data regarding the patient reported outcomes and images etc. are required in a clinical trial process. These types of health data of a patient can be obtained with the help of wearable devices, digital biomarkers and by the use of smart phones and digital watches etc.¹¹

The digital biomarker can be used to collect information about the physiological, behavioral, pathological and overall bodily function of the patients. Some of the examples of digital bio markers are pocket ECG, fitness trackers, step counters, glucometer, blood pressure measuring device, oximeter etc. can provide with immense amount of data about the patients and even the outcome of a medicine or drug or any kind of treatment which is administered on them. As these data are collected continuously, a regular watch can be done on the patients and in case of any unfavorable events treatment can be given at the earliest and as a result it will also increase the reporting process of clinical trials.¹²

VII. DATA ANALYTICS

The digital transformation of health related data gives amazing opportunities to improve clinical trials, from trial complementing to collection of data, using medical instruments, internet facilities, using the real world data stored in EHR (Electronic Health Record) as well as other sources. A flexible, adaptable and measurable clinical trial infrastructure which employs the EHR is now possible. For example, The Substitutable Medical Application, Reusable Technologies known as SMART or The Fast Health Interoperability Resources i.e. FHIR enable the researchers, clinical technicians, doctors and patients to connect digital apps with the health system across the Electronic Health Record centers.¹³

The new Artificial Intelligence (AI) tools has become a boon to the healthcare industries. It transforms clinical trial and drug discovery process. AI intends to understand human

intelligence which includes human skills of understanding things, speaking, listening, performing social and cultural activities or creative work, so that it can reproduce this intelligence in machines. AI technique can combine treatment data, personal data, lab testing data etc. to identify any undesirable situation, or any particular pattern which will help in prediction of treatment and behavior of the patients.¹⁴

Thus data related to clinical trial can be analyzed quickly, cost efficiently and with less time consumption by digitizing the process of clinical trial and favorable outcome of the trial can also be obtained. But the pivotal point that needs to be remembered while analyzing the data digitally is to be extra cautious and extraordinarily vigilant in matter of the quality of the data as well as maintaining the privacy of the trial participants.¹⁵

VIII. IMPORTANCE/BENEFITS OF DIGITIZING CLINICAL TRIAL PROCESS

With advancement and development in technology various pharmaceutical companies and clinical research industries started using digital technology in the clinical trial process. The vast data which are produced during the process of clinical trials, analyzation of these data, compilation and recording of the data becomes a challenging task. Digitization helps in analyzing the data effectively, obtaining more understanding and knowledge from available data, developing and analyzing the data in product's safety and efficacy. It minimizes the risk related to the subject and also are cost effective.¹⁶

Digital technology is also useful in converting the raw data into smart data. The use of algorithms is a new milestone which have created a positive impact on clinical trial. With the adoption of technology the production cost of a drug will reduce tremendously and it will positively affect the value-based health care system. Some of the benefits are:

¹¹ 'Better Data Collection And Convenience For Remote Monitoring Of Patients The Main Benefits Of Using Digital Health Technologies In Clinical Trials: Poll' (*Clinical Trials Arena*, 2022) <<https://www.clinicaltrialsarena.com/news/better-data-collection-main-benefit-of-digital-technologies-in-clinical-trials/>> accessed 13 April 2022.

¹² Andrea Coravos, Sean Khozin and Kenneth D. Mandl, 'Developing and Adopting Safe and Effective Digital Biomarkers to Improve Patient Outcomes' (2019) 2 npj Digital Medicine.

¹³ O. T. Inan and others, 'Digitizing Clinical Trials' (2020) 3 npj Digital Medicine.

¹⁴ 'The Future of Advanced Analytics in Clinical Trials | Medidata Solutions' (*Medidata Solutions*, 2022)

<<https://www.medidata.com/en/life-science-resources/medidata-blog/the-future-of-advanced-analytics-in-clinical-research>> accessed 14 April 2022.

¹⁵ Roundtable Care and Institute Medicine, 'Digital Health Data Uses: Leveraging Data for Better Health' (*Ncbi.nlm.nih.gov*, 2022) <<https://www.ncbi.nlm.nih.gov/books/NBK207330/>> accessed 14 April 2022.

¹⁶ 'Better Data Collection And Convenience For Remote Monitoring Of Patients The Main Benefits Of Using Digital Health Technologies In Clinical Trials: Poll' (*Clinical Trials Arena*, 2022) <<https://www.clinicaltrialsarena.com/news/better-data-collection-main-benefit-of-digital-technologies-in-clinical-trials/>> accessed 13 April 2022.

- It will improve the results in commercial area related to the clinical trial.
- It will provide a new dimension in the clinical research industries.
- It will ameliorate patient's recruitment and retention. It will improve the patient's privacy and data protection.
- Digital clinical trials will lead to patient centric trials.
- Use of digital and smart analytics helps in making decision better and desired patient outcomes can be achieved easily.
- It also makes collaboration easy with big pharma companies through virtual platforms.
- Cost-effective and less time consuming.
- Focus will be more on individual care.¹⁷

IX. BARRIERS OF USING DIGITAL TECHNOLOGIES IN CLINICAL TRIAL PROCESS

The Covid-19 pandemic has forced the life science industries for adopting digital technologies in their medical operating systems. As a result many companies changed their traditional method of clinical trials to digital clinical trials using digital health technologies. But as it is rightly said that every coin has two sides, along with the entrance of digital technology in clinical trials, barriers and hindrances are also in its path.¹⁸ These are some of the hurdles in digitizing clinical trials.

- Ensuring genuineness, honorableness and confidentiality of the data becomes the greatest challenge.
- Selection of suitable technique to be applied in the clinical trial is also an area of concern.
- Reliability of the data, from where it is collected either from the internet or through social media is also a hindrance of the digital technology.
- Accessing the data from Electronic Health Records (EHR) and other data related to genetics can raise question on the security and privacy of the patients.
- Data collection by using the digital technologies can create uncertainty in matters of the regulatory requirement as the laws, regulations and rules are different from one country to another.

- Another challenge is in the process of recruiting the participants, whether the sample selected is a representative sample and the selection of the sample is conducted without any kind of biasness.¹⁹

X. CONCLUSION

Digital technology is very useful in making the clinical trial cost-effective, speedy and less vexatious. Digitizing clinical trial helps in improving the recruitment and sustainability of the trial participants taking part in the clinical trial. It also increase the pace of data collection and recording as well as through the use of digital tools like digital biomarkers, wearables, smartphones etc. analysis of data can be done easily and quickly. Though using of digital technology in all the fields have now become a necessity and specially in times of the pandemic, digital technology have played a vital role in the process of clinical trial but there are some challenges also in the path of digitizing clinical trials which need to be fixed. The problem of a representative sample, issue of privacy and confidentiality of health information of the participants, regulatory requirements for conducting a clinical trial, knowledge and understanding of the digital technology etc. are the barriers in the path of digitizing clinical trials and proper check and attention is required to be made in these areas in order to overcome these challenges.

The clinical research teams in the future should be well equipped with technological and data science knowledge so that they can implement digital clinical trials successfully. There is also a requirement of creating such software where the private and confidential data of the trial participants are absolutely secured and there are no chances of any cheating or tampering with the private information of the trial subject. Recruitment of trial participant should be done with great caution and free from biasness so that a representative sample may be selected for the trial and as a result the desired outcome of the trial can be achieved. Thus challenges may come in the way as the digital technology will enter in the clinical research stream but learning about the numerous benefits it will provide to the clinical research area there is a need to enforce digital technology which will enhance the efficiency of the clinical trials in India.

¹⁷ Dr. Ganesh Divekar, 'Technology's Role in Re-Shaping India's Clinical Research Sector' (*Healthcare Radius*, 2022)
<<https://www.healthcareradius.in/features/technology/27716-technologies-role-in-reshaping-indias-clinical-research-sector>>
accessed 19 January 2022.

¹⁸ 'Ensuring Data Authenticity, Integrity, And Confidentiality Biggest Barrier to Using Digital Technologies in Clinical Trials:

Poll' (*Clinical Trials Arena*, 2022)

<<https://www.clinicaltrialsarena.com/news/ensuring-data-authenticity-integrity-and-confidentiality-barrier-to-digital-technologies-in-clinical-trials/>> accessed 1 February 2022.

¹⁹ Carmen Rosa and others, 'Using Digital Technologies in Clinical Trials: Current and Future Applications' (2021) 100 *Contemporary Clinical Trials*.

REFERENCES

- [1] Anthony Jnr. Bokolo, 'Exploring The Adoption Of Telemedicine And Virtual Software For Care Of Outpatients During And After COVID-19 Pandemic' (2020) 190 Irish Journal of Medical Science (1971 -).
- [2] 'India's Clinical Research Advancements: Trends Witnessed across Technology and Patient-Centricity - ET Healthworld' (ETHealthworld.com, 2022) <<https://health.economicstimes.indiatimes.com/news/industry/indias-clinical-research-advancements-trends-witnessed-across-technology-and-patient-centricity/89790819>> accessed 11 April 2022.
- [3] Nikita Rana, 'Technology Is Going to Play a Key Role in India's Roadmap for Health Infrastructure: ETILC Members' (The Economic Times, 2022) <<https://economicstimes.indiatimes.com/industry/healthcare/biotech/healthcare/technology-is-going-to-play-a-key-role-in-indias-roadmap-for-health-infrastructure-etilc-members/articleshow/81683674.cms>> accessed 5 January 2022.
- [4] 4. Sec. 122DAA of Drugs and Cosmetics Rules, 1945.
- [5] 5. M Flather, Hazel Aston and Rod Stables, Handbook of Clinical Trials (ReMEDICA Pub 2001).
- [6] 6. 'Decentralized Vs Digital Clinical Trials: There Is a Difference | ConcertAI' (ConcertAI, 2022) <<https://www.concertai.com/news/2021/11/decentralized-vs-digital-clinical-trials-there-is-a-difference/>> accessed 12 April 2022.
- [7] 7. 'Accelerating Momentum: Digital Innovation in Clinical Trials' (Accenture.com, 2022) <https://www.accenture.com/_acnmedia/PDF-171/Accenture-90976792-Infographic-Accelerating-Momentum.pdf> accessed 12 April 2022.
- [8] 8. Geoff K. Frampton and others, 'Digital Tools for the Recruitment and Retention of Participants in Randomised Controlled Trials: A Systematic Map' (2020) 21 Trials.
- [9] 9. ClinEdge (en-US), 'Digital Recruitment: Changing the Face of Clinical Trials' (Clin-edge.com, 2022) <<https://clin-edge.com/news/digital-recruitment-changing-face-clinical-trials>> accessed 13 April 2022.
- [10] 10. 'Better Data Collection And Convenience For Remote Monitoring Of Patients The Main Benefits Of Using Digital Health Technologies In Clinical Trials: Poll' (Clinical Trials Arena, 2022) <<https://www.clinicaltrialsarena.com/news/better-data-collection-main-benefit-of-digital-technologies-in-clinical-trials/>> accessed 13 April 2022.
- [11] 11. Andrea Coravos, Sean Khozin and Kenneth D. Mandl, 'Developing and Adopting Safe and Effective Digital Biomarkers to Improve Patient Outcomes' (2019) 2 npj Digital Medicine.
- [12] 12. O. T. Inan and others, 'Digitizing Clinical Trials' (2020) 3 npj Digital Medicine.
- [13] 13. 'The Future of Advanced Analytics in Clinical Trials | Medidata Solutions' (Medidata Solutions, 2022) <<https://www.medidata.com/en/life-science-resources/medidata-blog/the-future-of-advanced-analytics-in-clinical-research>> accessed 14 April 2022.
- [14] 14. Roundtable Care and Institute Medicine, 'Digital Health Data Uses: Leveraging Data for Better Health' (Ncbi.nlm.nih.gov, 2022) <<https://www.ncbi.nlm.nih.gov/books/NBK207330/>> accessed 14 April 2022.
- [15] 15. 'Better Data Collection And Convenience For Remote Monitoring Of Patients The Main Benefits Of Using Digital Health Technologies In Clinical Trials: Poll' (Clinical Trials Arena, 2022) <<https://www.clinicaltrialsarena.com/news/better-data-collection-main-benefit-of-digital-technologies-in-clinical-trials/>> accessed 13 April 2022.
- [16] 16. Dr. Ganesh Divekar, 'Technology's Role in Re-Shaping India's Clinical Research Sector' (Healthcare Radius, 2022) <<https://www.healthcareradius.in/features/technology/27716-technologys-role-in-reshaping-indias-clinical-research-sector>> accessed 19 January 2022.
- [17] 17. 'Ensuring Data Authenticity, Integrity, And Confidentiality Biggest Barrier to Using Digital Technologies in Clinical Trials: Poll' (Clinical Trials Arena, 2022) <<https://www.clinicaltrialsarena.com/news/ensuring-data-authenticity-integrity-and-confidentiality-barrier-to-digital-technologies-in-clinical-trials/>> accessed 1 February 2022.
- [18] 18. Carmen Rosa and others, 'Using Digital Technologies in Clinical Trials: Current and Future Applications' (2021) 100 Contemporary Clinical Trials.

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