

ROLE OF INFORMATION TECHNOLOGY ON PATIENT CENTRICITY IN CLINICAL TRIALS

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Article Received on
31 Dec. 2018,

Revised on 21 Jan. 2019,
Accepted on 10 Feb. 2019

DOI: 10.20959/wjpr20193-14340

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ABSTRACT

Patient-centricity is about ensuring that the patient's needs and perspectives are considered while maintaining scientific rigor during the conduct of a clinical trial. Pharmaceutical companies are now employing newer electronic technologies to engage patients in the trial design by seeking and acknowledging their input in conducting a successful trial. There has been a rapid growth in e-technologies to improve data collection, patient recruitment and retention, study medicine tracking, delivery and dissemination. While clinical trials

have been slow at incorporating e-technology into the design and execution of clinical trials, there has certainly been an increase in its use to reach a wider audience, making clinical trials more effective and reducing costs. This paper gives a general overview of the use of information technology in improving patient communication and engagement at different stages of a clinical trial. The paper provides a brief insight on how newer software solutions have begun to transform patient engagement at different stages of the clinical trial. In the not so distant future, the extensive use of information technology would make data capture, post-operative observation and quality-of-life assessments in real time much easier for both the patient and the healthcare professional.

KEYWORDS: Information technology, patient centricity, digital technologies, e-consent, software-as-a-service.

INTRODUCTION

Patient centricity is no longer just a best practice. It is presently the bare minimum standard for conducting a clinical trial. Almost all aspects of a clinical trial, right from regulations, insurance and core scientific research now require that patient centricity be seen as a core tenet of any clinical trial design.

Increasing trial costs and the need to engage patients effectively has driven pharmaceutical companies to use digital technologies for facilitating a smooth clinical trial. Society may benefit from the lower costs as medicines and treatments are better understood and focused to patients' needs. An early case of a positive impact in such manner originates from a recent publication by CTTI citing significant cost reductions to clinical trial sponsors as a result of implementing its recommendations.^[1]

The use of digital technologies can ensure that correct and simplified trial information can make swift trial recruitment, ensure that qualified participants get the information they need to self-qualify and then ultimately enroll themselves.

Digital Technologies in Clinical Trial Design

Some researchers have implemented e-technology using the Internet to recruit study participants and create Internet-based interventions.^[2,3,4] For the last two decades, researchers are employing electronic tools to communicate with study personnel, randomize participants, develop protocols, collect data and analyze results.^[5,6,7]

Digital Technologies for Patient Recruitment

In the early stages involving incorporation of digital technologies, communication with trial subjects involved directing study participants to a website for detailed trial information and giving contact information for the purpose of recruitment and retention.^[8] Websites later moved on to distribute and collect information from online questionnaires to seek eligible candidates and obtain their consent. In recent years, clinical trials have started using social media (e.g. Twitter, Facebook), blogs, emails and text messaging to recruit and improve patient retention.^[9] Investigators are now integrating innovative patient data collection approaches through use of apps, GPS and wearable devices.^[10,11,12]

Patient Engagement in Clinical Trials

To build a patient-focused trial, sponsors need to understand the needs of the target patient population, how patients manage their disease, potential management burdens pertaining to study procedures and visits. The insights obtained from patients, caregivers and advocacy groups can give sponsors unique insights that can assist in designing a clinical trial that will engage the patient from start to finish.

The clinical trial workspace has been slow to adopt digital technologies. For example, in the time it takes to design, implement, and publish findings from a research study (approximately 6 years), technology evolved from playing interactive video games to using voice-activated personal assistants (Siri, Alexa, Cortana, Google Assistant).^[13,14]

However, the use of digital technologies in study designs, influenced by the use of mobile phones, wearable devices and Internet-based communication is now the new norm for patients. Creating a patient-centric culture involves creating an environment of communication that integrates the internet, smartphones and social media into all aspects of their lives.

Digital Technology for obtaining Consent (e-Consent)

With the evolving nature of clinical trials, informed consent forms (ICFs) have become increasingly complex and more difficult for patients to understand the clinical trial objectives.

Variability in literacy levels, cultural diversity and complicated study designs have made the development of ICFs an overly intricate and inefficient at conveying trial information to the patient.

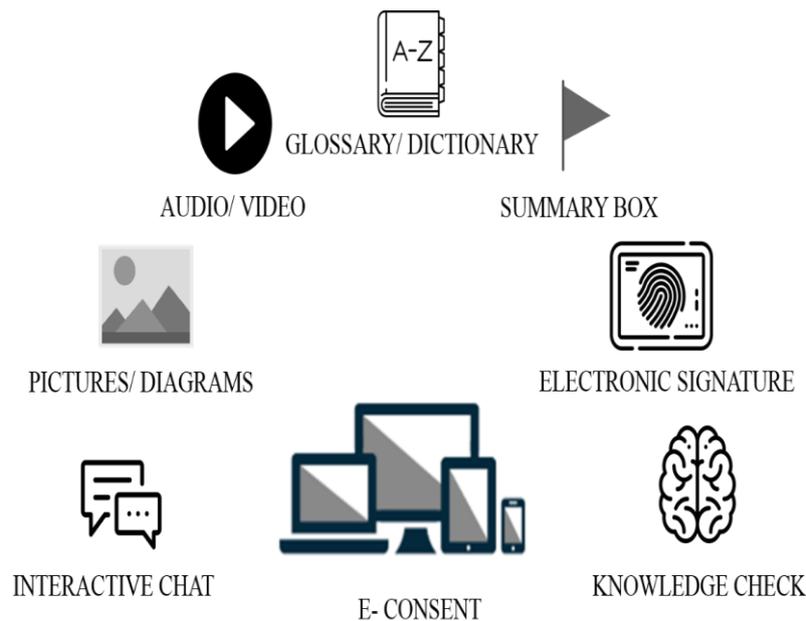


Fig 1: Multifaceted approach of the e-Consent process.

The use of digital technology for obtaining consent (e-Consent) is not just a paper document that is transcribed onto a mobile device. It is dynamic and includes multimedia components

that can be used to make an engaging and interactive engaging informed consent experience. Despite the challenges, e-Consent offers flexibility for diverse learning styles, both auditory and visual. Images, audio, video, diagrams, call out boxes, reports and a digital signature may aid the e-Consent process.^[15]

m-Health Technology in Clinical Trials

The advent of cloud-based data capture and management has transformed the clinical research landscape. While these new technologies have simplified data collection, management and trial outcomes; new challenges pertaining to the scale (trials across geographical barriers and languages), complexity and patient engagement throughout the trial needed to be addressed.

This propelled the need for sponsors, research organizations and sites to look for solutions that help improve medication dispensation, tracking and adherence; regulatory and trial compliance, and patient communication.

The emergence of patient-centric applications provides an opportunity to engage patients effectively and build a personalized relationship with them. The integration of mobile technologies in the clinical trial process can help align patient and clinical trial site needs by fast-tracking study execution and bringing cost reduction.

With the objective of seamlessly connecting with different stakeholders in a clinical trial, m-Health technologies can be integrated with existing systems such as:

- Electronic patient record outcomes (ePRO)
- Electronic medical records (EMR)
- Electronic Case report forms (eCRFs)
- Electronic health records (EHF)
- Clinical trial management system (CTMS)

Additionally, cloud-server technology has evolved to allow for more data storage with improved safety and security.

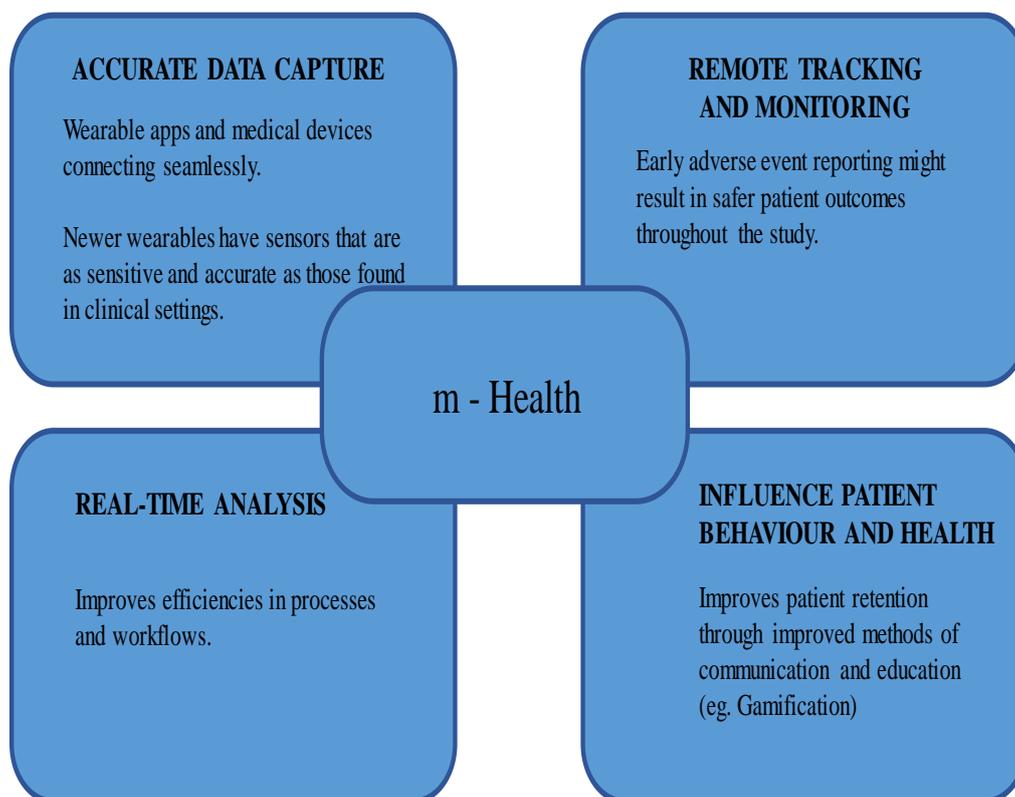


Fig 2: Advantages of using m-health technology.

A major service provider in the clinical space has recently developed a software-as-a-service (SaaS) platform that enables life sciences companies to significantly improve patient engagement in clinical trials and improve the efficiency and accountability of the clinical supply process.^[16,17,18]

This SaaS platform has 2 advantages:

1. 24/7/365 access to clinical trial data.
2. Centralized updates that provide researchers with the most recent software releases.

SaaS applications can be scaled and configured to meet individual trial needs and support operational growth and workflows. This platform can assist pharmaceutical firms in improving patient communication and engaging them throughout the clinical trial while bringing efficiency and accountability in the clinical supply process.

Cognitive engines [software that uses artificial intelligence (AI)] in these SaaS applications can automate complex business processes. They leverage the best of cloud architecture and intuitive user experience design in compliance with 'Good Clinical Practice' quality guidelines (GCP) and privacy norms.

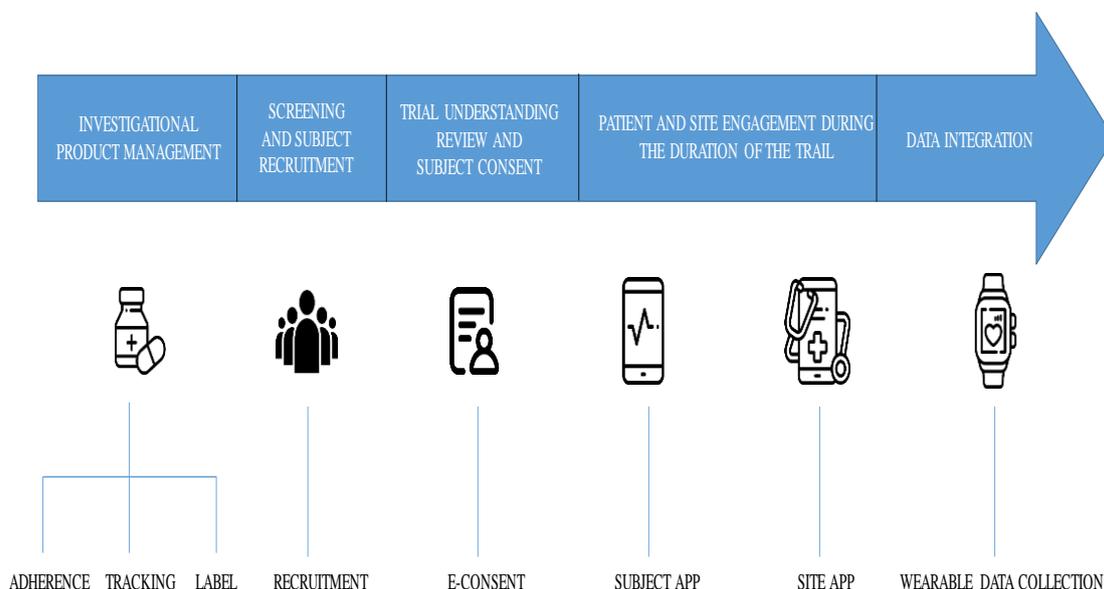


Fig 3: Information technology at different aspects of a clinical trial

The Not So Distant Future

Information technology could pave the way for capturing patient health data at home via tablets and iPads. Mobile technology could be used for post-operative observation and quality-of-life assessments that could now be done at home instead of going onsite. Real-time monitoring of patient data through remote monitoring apps that integrate wearable devices will reduce patient reliance to collect important data points. Apps that provide visit reminders, disease and trial information can increase patient compliance during the duration of the trial. Investigation product tracking, management and adherence (use of smart blisters that send a message to the App when broken) can help improve patient compliance to study medicine.

CONCLUSION

Technology is the currency of our day-to-day lives that will allow us to focus and meet the humanness of the patient whose life we aspire to change for the better. Patient feedback is the enabler of change. By using information technology and using patient feedback, we can drive meaningful improvements in clinical trials. This will enable technology to be more efficient and effective in engaging the patient. Patient-centricity is about human empathy. Being patient-centric in a clinical trial setting would mean employing technology to accompany the patient through his/her journey during each stage of the clinical trial.

ACKNOWLEDGEMENTS

I thank Mr. Snehal Suradkar, Senior Graphic Designer, for helping me with the graphic designing of the figures used in this paper.

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