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Adoption of Electronic Forms and Mobile Technology to Improve Data Quality in Clinical Trials

Kelvin Onoka*

Department of Human Health, International Centre of Insect Physiology and Ecology, Kenya, Nairobi

E-mail: kaonoka@yahoo.com

Abstract: Clinical trials play an important role in the life cycle of drug development, timely and accurate data is very critical. Despite the high coverage of a smartphone and android powered tablets all over the world, mobile technology is yet to be used up to its full potential in clinical trials due to issues like participant's data is security and safety among other issues. The success of clinical trials is highly dependent on effective patient recruitment, engagement and protection of their rights. Data collected from subjects or patients during the course of a clinical trial is critical to determine the safety and efficacy of a drug, hence accurate real-time data is very important. The integration of web based and mobile technology in clinical trials can offer capabilities to collect continuous and accurate data in real time. The application of mobile technology can also decrease patient and investigator burden by reducing clinic visits, which may lead to increased patient recruitment and decreased loss to follow up of participants. The other advantage is that it is easy to share research information with various stakeholders making it possible to monitor research progress remotely. In addition, mobile technology offers an opportunity to potentially reduce the overall costs of performing clinical trials unlike traditionally paper based system which is manual, bulky and expensive. The adoption of electronic forms and mobile technology practices can increase the quality and efficiency of clinical trials activities. This paper reviews some challenges that should be addressed for successful implementation of mobile technology and electronic data capture in clinical trials research.

Keywords: Clinical trials; mHealth; Electronic forms mobile technology; Mobile applications; Mobile devices; Patient engagement; Data quality

I. INTRODUCTION

Despite the high coverage of a smartphone all over the world, mobile technology is yet to be used up to its full potential in clinical trials due to some issues like participant's data is security and safety. The clinical trials have persistently used the traditional paper based methods, which prone to errors and the overall cost is also very expensive. This had also lead to slowing down the sharing dissemination of results with stakeholders [1]. The paper-based requires that data be entered manually by hand, typically on a three-part paper case report form even if it is already in an electronic record form. The standards web-based and technology-enabled single-source process can reduce transcription errors, increase efficiency, and facilitate information flow and timeliness of data, thus improving data quality and patient safety [2]. The designing of electronic patient registries has made clinical research to be potentially faster and more feasible. Different approached can be used for instance, electronic forms (eForms) can be used to efficiently enrol, monitor and treat participant in a clinical trial, leading to production of quality results. Conversely, patients can engage in larger scale clinical trials, seeking to gain active participation in clinical trials with more patient centered feedback as patient empowerment and engagement in their own healthcare and clinical research development. This is due to increased development of software and device technology, and expanding use mobile by the population and patients, the researchers to collect and access available information [3]. Technology innovations have changed the way clinic trials are being conducted in the developing countries. The adoption of technology by various clinical trial collaborators requires willingness by regulatory authorities to allow new approaches to clinical trial operations [1]. Previous clinical trials have used smartphones as a delivery mechanism via short message service. For example a recent partnership between GlaxoSmithKline with Vodafone, the use of mobile technology helped to vaccinate more children against common infectious disease in Mozambique, Africa. The first pilot study was conducted in Mozambique by use of short

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message service to schedule vaccination appointments proved to be cost effective. In addition the use of SMS also ensured that children complete the full schedule and become fully immunized. The mobile phones also provided access to multiple systems through a single viewer with patient-context pro-cesses being used to open information at the appropriate point in the data [4].

II. STATEMENT OF THE PROBLEM

Most of research institutions have realized that the traditional paper-based system is bulky, time consuming and expensive in the long run. This has also resulted to poor understanding by participants information due errors generated during manual data entry. Despite the high coverage of a smartphone all over the world, the application of mobile technology in clinical trials is still facing some challenges. Adoption of new technology can play a crucial role in improving data quality of clinical trials if these challenges are successfully addressed to reduce or eliminate the expensive traditional paper based sys-tem. This will also improve the process of clinical trial monitoring from the beginning to end of study to achieve quality results and to provide a solution in time.

III. OBJECTIVE

The main objective is to address the outlined technological challenges inhibiting the widespread use of electronic forms and mobile technology in clinical trials data collection.

3.1 Opportunities and Existing Challenges

According to International Telecommunications Union, more than two-thirds of the world's population owned a mobile phone in the year 2009. The mobile devices have features that may make them particularly appropriate for improving clinical trials delivery processes due to their popularity, their mobility and their technological capabilities. The popularity of mobile technologies has led to high and increasing ownership of mobile technologies, which means interventions can be delivered to large numbers of people anywhere. The quality of data can also be improved due to development of software that can be downloaded and used on smartphone by researchers to collect and synchronize data remotely. Additionally, research participants can be sent appointment reminders to alert them for their appointment. Mobile health (mHealth) is the emerging technology for data collection and also calling patients when they not adhere to the study protocol. This is possible due to technology which has really moved to advance level in the 21st century [5]. It is crucial that a clinical trial study must be conducted in accordance to Good Clinical Practices (GCP) guidelines, which makes it mandatory for the sponsors of clinical trials to ensure subject protection and data integrity. The quality and integrity of data in clinical trials can be highly influenced by patient reported outcomes (PRO), quality of patient care and satisfaction of patients with clinical trial participation. There is need for vigorous discussion to address these challenges in order to make clinical research better and easy to manage in a cost effective manner [6]. The use of health information technology, especially at the point of care, is often considered as a better way to improve care coordination and data quality. Collection of information at the care site would be especially important in home health and hospital care, where care is provided predominantly at the patient's home rather than in an institutional. Functionalities such as clinical decision support systems or computerized physician order entry may lead to improved coordination of care delivered at the point of care among home health [7]. Despite the high coverage of mobile devices, there is need to consider broad use of electronic forms and mobile technologies by various research institutions to collect and submit data to central web server, where sponsors can have access. This can ensure that there is a continuous monitoring and compliance to protocol by study personnel. The use of web based technology will also improve delivery of quality care, data accuracy and quick feedback to the participants. In order to successfully adopt electronic forms and mobile technology the following challenges must be addressed; data security, regulatory acceptance and internet cost for non-offline data collection tools [8].

IV. POSSIBLE SOLUTIONS TO THE CHALLENGES

The identified challenges in the adoption of electronic forms and mobile technology in clinical trial can be addressed as follows:

The high coverage of mobile phones worldwide should an opportunity for internet providers to establish and improve existing internet infrastructure that can lead to quality of services in remote areas. The internet companies will be able to increase their revenue through internet users and research institutions will use these resource deploy a secure web-based portal where clinical trials data can be stored and updated by only authorized study personnel from anywhere. In addition any study participant identification such as names should not be included in the portal [9]. The mobile

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software applications should also have capabilities to protect data privacy during data collection and securely uploading data to specific study database. In addition, efforts should be made to improve mobile-based technology software to allow for offline data collection in areas where there is no internet and only use internet for data synchronization to reduce internet cost. Providing adequate computer training and defining user access levels based on your roles in the study can data quality and monitoring of the study activities. The access to a stable wifi/internet at study site is also very important in the implementation of any web based and mobile technology platform [10].

According a study done by Cascade, about 70% of investigators electronic signatures were extremely or very likely to be used as gold standard in clinical trials. This makes it also possible to design electronic informed consent forms that can be signed study participants to reduce paper-based systems and time taken for consenting process during participant enrolment. The electronic informed consent form can provide searchable data, such as the date and time that a subject signed the consent (Figure 1).

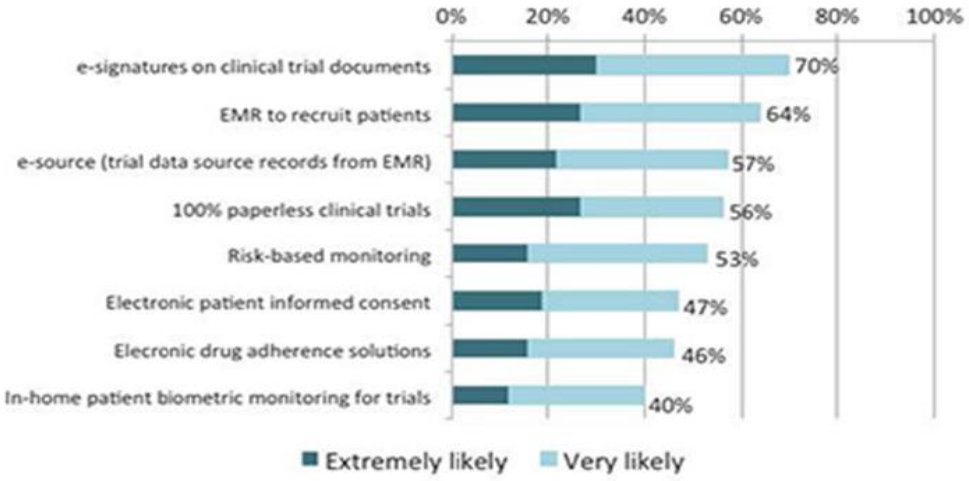

Figure 1: Technology extremely or very likely to become a gold standard within 3 years (Cascade, 2015).

About 75% of clinical trials are conducted using paper data collection as the primary tool despite the fact that electronic data collection tools have been available for more than 2 decades. Biopharmaceutical companies (93%) feel that standards are very important for efficient interchange of clinical data among different parties, and 90% feel that these standards should be extended to facilitate data collection at the investigative site. Site personnel (89%) feel that sponsors of clinical trials should collaborate in the standardization of electronic data collection practices and systems for investigative sites. Some of the critical factors that been outlined by to achieve a higher level of information sharing should include: the development and adoption of global data interchange standards that are harmonized between health care and clinical trials; the use of technology that is more acceptable to users and stakeholders; clarification of and adherence to regulatory requirements for health care and clinical trials; and implementation of new technologies that are being employed by other industries to facilitate data interchange, specifically the use of the extensible Mark-up Language (XML), which is much simpler and easier to design web-based applications [2].

V. CONCLUSION

Advancements of internet and mobile technology play a major role to improve the quality of data collection in clinical trials and field of mobile health in general. There is need to develop secure and standardized tools for data collection of self-reported patient outcomes. Some research institutions are already using mobile applications such as ODK Collect, ComCare, SurveyCTO, REDCap, KoboCollect and other software that can be downloaded and installed on a mobile smartphone or tablets for data collection. These applications should be improved further to allow for clinical trial design and information strategy development that can help in aligning site and patient needs with faster execution of study processes at reduced costs. This should also allow investigative site staff to have a secure authorized access to centralized system to data synchronization to smartphone or tablets to mirrors the data stored in the server after performing the right configuration. It is possible to use mobile phone to remotely collect and submit data to centralized

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secure web server database in real-time, software developers should focus trial applications in the context of the participant's data privacy per GCP guidelines and also fix the existing technological challenges such as offline data collection, data synchronization and security issues.

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