International Journal of Science and Research (IJSR)
ISSN: 2319-7064
ResearchGate Impact Factor (2018): 0.28 | SJIF (2018): 7.426

Emanating Technologies in Modern Era of Clinical Trials

Kanika[1], Raibarinder Singh[2], Ramica Sharma[3], Gurfateh Singh[4]

University School of Pharmaceutical Sciences, Rayat Bahra University, Sahauran, Kharar, Mohali, Punjab, India

Abstract: ***During the last decade, all clinical trial activities are conducted using paper system. But twenty first century is the era of Virtual Clinical Trials. The current progress in the field of research helps in breaking the stereotype of implementing paper system in research studies and modified this system into Electronic Data Capture System. The positive results of EDC system helps in accelerating the technologies used in clinical trials. Data safety in clinical trials can be guaranteed with e-technology by a series of softwares like Oracle clinical, Argus etc. Emerging technologies like social media, wearables, m-health technology and artificial intelligence can provide some specific benefits to the study participants. The process of data collection can be strengthening by using electronic patient diaries. Patient outcomes can be upgraded by using m-health apps. Researchers also use m-health technologies in order to decrease trial time and drug development costs. Instead of all these advantages, e-technology can face some challenges and to reduce these challenges researchers should concentrate on using e-technologies in a precise manner.***

Keywords: Technology, Virtual Clinical Trials, Artificial intelligence

1. Introduction

Clinical research is one of the most promising approach in the field of research and development. Clinical trial is a research study done in human participants with their consent to resolve specific health issues [1]. Clinical trials are done carefully in order to measure therapeutic effectiveness and enhance public health [1]. Clinical research covers a long period of time using paper system for doing all the research activities till 1990's [2]. Conventional "face-to-face" approach was used previously in order to conduct clinical trial activities like recruitment, retention, delivery of interventions and data collection [3]. But with the advancement of science and technology in healthcare, the clinical trials began to move from paper system to electronic data capture (EDC) system. EDC system is an alternative approach to clinical trial paper based data collection in which the stakeholders themselves enter the data directly into the electronic database [4]. EDC is considered to be the most promising and preferred technology than the manual system as it provides efficient methods of clinical data capture, analysis and better data quality although the conversion of manual system to EDC system has been a slow progression due to some barriers that come in the path of EDC system [5,6]. These barriers can be removed successfully once they understood and addressed at the initiation of the implementation process [6]. EDC system is used for routine clinical use which ultimately saves time for clinical documentation [7]. In order to avoid human errors and inefficiency in research, an EDC system needs to cooperate with electronic medical records system (EMR) in which the data needed for case report forms (CRF) is transcribed automatically from EMR to CRF [8]. In 2016, a web based EDC tool called as "Brocade" was developed in order to capture key data elements like histology, stage, patients and treatment characteristics that helps to create electronic health records and improves clinical documentation [9]. Almost all the clinical research activities like patient recruitment, retention, engagement etc. are done by using e-technologies. Twenty first century is the era of Virtual Clinical Trial in the field of R&D [8]. It can increase participation in the research by bringing studies directly to patients and to keep subjects engaged with the study [10]. Computer based technologies are the effective means of giving support to health care consumers and remove the burden of the health care system as mobile apps are portable, flexible and relatively of low cost [11]. Electronic informed consent for research shows a tremendous success in clinical trial model [12].

2. Emerging Technologies

Technology has a very massive impact on every area of science and healthcare like in R&D and also on clinical trials. It makes each and every stakeholder's jobs easier, streamlined and is also a less time consuming method [13]. Some of the emerging technologies used in clinical trials are:

Social media: Social media is an emerging platform in order to meet the requirements of patients with illness and helps in direct patient engagement with family, friends and community. "Smart Patients" and "Patient like Me" are the social media health related platforms which helps in providing peer-to-peer support to patients, families and becoming informed about the latest treatments. Social media also helps in knowing about global issues of emotional, financial and spiritual toxicities within a disease community. This platform also provide opportunities for patients to communicate with clinical investigators and other people across the world which helps clinical investigators in recruiting patients into the study. Patients can also have the opportunity to learn about latest research and contribute to scientific advancement [14]. Social media is a rostrum which is popularly used for subject recruitment by using some apps like Twitter, Facebook, YouTube, Blogs and patient community [3]. Twitter and facebook are the social media platforms that can help in patient recruitment by advertising specific clinical trials directly to patients [14]. Social media also offers some unique benefits that most of the traditional recruitment channels cannot do such as study participants go online routinely in order to exchange their experiences [17]. It

is an important platform for networking through blogs, facebook as it is used for rapid dispersion and acquirement of information [15].Social media is growing rapidly and it can transform people from content consumers into content producers [16].

Wearables: Wearable technology is one of the most valuable technology to patients as it can improve patient outcomes [18]. Wearables are used to measure or track physical and metabolic status [19]. Wearable devices like Fitbits, wristbands, electronic footwear, hearing aids and Smart watches offer great potential in collection of richer data [19].These devices help people for self-health tracking, detection and diagnosis of heart rate, blood pressure, sweat and emotions. New smartwatches generation is emerging with wireless and mobile communication which are able to provide more than 24 hours of vital monitoring [22,23]. Wearable devices are used to collect, evaluate, monitor multiple vital signs and are helpful in data storage and future diagnosis [20,21]. Data collection can be enhanced by using digital diaries or electronic patient diaries that portray the key component of patient's personal health and lifestyle [24].

m-health technology: m-health technology that includes mobile sensors, telemedicine and patient engagement apps can alter the way of collecting the clinical trial data and improve the efficiency of studies [10]. Researchers use m-health technologies in order to decrease trial times and drug development costs [25]. Apple software, Research kit are the recent apps developed in this area [38]. m-health apps also have the capability to enhance the patient outcomes [26]. In order to enhance self-management skills of persons with chronic conditions and disabilities, a mobile health system is used known as "iM Here". [27]. m-health apps are useful in raising self-awareness by reporting of symptoms [28]. In 2011, it was reported that more than 260 diabetes related iPhone applications were available for iPhone users [29].

Artificial Intelligence: Artificial Intelligence plays an important role in the progress of personalized medicines, reduce medical errors, improve subject enrollment into clinical trials and have reported a good accuracy for breast cancer detection [30,31,32]. Artificial Intelligence has the potential to change each stage of the clinical trial from enrollment to medication adherence. It can extracts specific information from patient's medical records and compares it with the ongoing trials. AI can also estimate which patients have a higher chance of dropping out or not following protocol [36]. AI can improve the quality of patient care in clinical practice and also helps in predicting the early stages of hypertension [33,34]. In AI, computers learn from data and imitate human thought processes [35]. AI like Watson (IBM's artificial intelligent supercomputer) is capable of doing research work within minutes which human researchers can take weeks and months to do [37].

3. Benefits of e-technology

- Online access to the clinical trial data can reduce errors [38].
- Technology allows for enhanced communication and information exchange [39].
- m-health apps have the capability to enhance the patient care with growing confirmation of effectiveness [40].
- e-technology can help in minimizing data redundancy [38].
- Data collected by Interactive Response Technology (IRT) automatically passed to EDC system.
- e-technology helps in eliminate duplication of efforts.
- By using e-technology one can save time and money.
- e-technology helps in eliminating possible mismatch between system [38].
- VCT are patient centric.
- It eliminates travel time to trial sites.
- It provide safe and more comfortable space to receive treatment.
- Patients with mobility issues can participate [39].
- The positive results of EDC system helps in accelerating this technology in clinical trials, eliminate data errors and also the duration of a trial [41].
- Computerized system helps in enhancing the patient recruitment criteria and eliminate errors [42].
- Social media helps in enhancing mutually beneficial interactions between public health professionals and the lay public [43].
- Wearable devices are used to measure the physical activities of human subjects and to make a real-time assessment of the physiological state of the subjects [44].
- EDC system helps in eliminating transcription errors, reduce paper management time and needs less physical storage space [45].

4. Challenges of e-technology

- There is a risk of failure of technology as it won't operate properly.
- Integrity and accuracy of data is the major concern of using e-technology.
- Privacy and confidentiality issues arises by using e-technology [39].
- Cyber stalking, location disclosure, social profiling are the risks involved using social media for people [16].
- The challenge EHR facing is quality of the data, so there is a need for better understanding of the factors behind poor data quality [48,49]
- The main aspect that needs attention in EHR quality assurance as it identifies the defects generated in the data and also minimize the risk of their occurrence in future [48].

5. Conclusion

Researchers serve e-technology as a blessing in the field of clinical research as it can helps in achieving many benefits so easily which cannot be achieved earlier such as it can improve efficiency and also lowers the cost of clinical trials. But still it can face many challenges like risk of failure of technology, privacy and confidentiality issues. To overcome these challenges, researchers need to focus on the proper planning and precise execution of e-technology. This overview enlightened the various useful technologies used in clinical trials and its challenges.

6. Acknowledgement

We wish to express our gratefulness to Sr. Gurvinder Singh Bahra Ji (Honorable Chancellor), Dr. Daljit Singh, Worthy Vice Chancellor of Rayat and Bahra University Mohali (Punjab) for their praiseworthy inspiration, platform and constant support for the completion of this study.

References

[1] Thorat S.B, Banarjee S.K, Gaikwad D.D, Jadhav S.L, Thorat R.M 2010, "Clinical Trial: A Review", *International Journal of Pharmaceutical Sciences Review and Research*, vol. 1, pp. 101-106.

[2] Curran A 2015, "Emerging Trends in Electronic Data Capture", *ArisGlobal*, pp. 1-12.

[3] SRG 2018, "What are the most promising Clinical trial technologies?"

[4] Pavlovic I, Kern T, Miklavcic D 2009, "Comparison of paper-based and electronic data collection process in clinical trials:costs stimulation study", *Contemp Clin Trials*, vol.30, pp.300-16.

[5] Sahoo U, Bhatt A 2003, "Electronic data capture (EDC)-a new mantra for clinical trials", *Qual Assur*, vol.10, pp.117-21.

[6] Welker J.A 2007, "Implementation of electronic data capture systems:barriers and solutions", *Contemp Clin Trials*, vol.28, pp.329-36.

[7] Pan H.Y, Shaitelman S.F, Perkins G.H, Schlembach P.J, Woodward W.A, Smith B.D 2016, "Implementing a real-time Electronic Data Capture System to Improve clinical documentation in radiation oncology", *J Am Coll Radiol*, vol.13, pp.401-7.

[8] Matsumura Y, Hatori A, Manane S, Takeda T, Tekahashi D, Yamamoto Y, Murata T, Mihara N 2014, "Internconnection of electronic medical record with clinical data management system by CDISC ODM", *Stud Health Technol Inform*, vol.205, pp.868-72.

[9] Pasalic D, Reddy J.P, Edward T, Pan H.Y, Smith B.D 2018, "Implementing an Electronic Data Capture System to Improve clinical workflow in a large Academic Radiation Oncology Practice", *JCO Clinical Cancer Informatics*, vol.2, pp.1-12.

[10] Palmer J 2018, "The Future of Mobility and Medicine", *Applied Clinical Trials*, vol. 27.

Hirt E, Schmid R, Vuskovic M 2004, "AMON:a wearable multiparameter medical monitoring and alert system", *IEEE Trans Inf Technol Biomed*, vol.8, pp.415-27.

[11] Chan K.L, Leung W.C, Tiwari A, Or K.L, Ip P. 2019, "Using smartphone-based Psychoeducation to Reduce postnatal depression among first-time mothers:Randomized Controlled Trial", JMIR Mhealth Uhealth, vol.7, e 12794.

[12] Frelich M.J, Bosler M.E, Gould J.C 2015, "Research Electronic data capture (REDCap) electronic Informed consent form (eICF) is complaint and feasible in a clinical research setting", *International Journal of clinical trials*, vol.2 pp.51-55.

[13] Mortimer S 2018, "Technology is Revolutionizing Clinical Trials: Here's How", *BioSpace*.

[14] Subbiah I.M, Hamilto E, Knoll M, Shanhan K, Meisel J 2019, "A Big World made small:Using social media to optimize paient care", *American Society of Clinical Oncology Educational Book*, vol.39, pp.212-218.

[15] Markham M.J, Gentile D, Graham D.L 2017, "Social media for Networking, Profesional Development and Patient Engagement", *Am Soc Clin Oucol Educ Book*, vol.37, pp.782-787.

[16] Kein M.E, Noji E 2011, "Emergent use of social media:a new age of opportunity for disaster resilience", Am J Disaster Med, vol.6, pp.47-54.

[17] Stempel D 2018, "Social Media and Clinical Trial Recruitment- New Insights and Best Practices", *Media Marketing Insights*.

[18] Bahadori S, Immins T, Wainweight T.W 2018, "A review of wearable motion tracking systems used in rehabilitation following hip and knee replacement", *J Rehabil Assist Technol Eng*, vol.18, pp.5.

[19] Yrtisen A.K, Martinez-Hurtado J.L, Unal B, Khademhosseini A, Butt H 2018, "Wearables in Medicine", *Adv. Mater*, vol.30.

[20] Haghi M, Thurow K, Stoll R 2017, "Wearable devices in medical internet of thins:Scientific research and commercially available devices", *Healthc Inform Res*, vol.23, pp.4-15.

[21] Anliker U, Ward J.A, Lukowicz P, Troster G, Dolveck F, Baer M, Keita F, Schenker E.B, Catarsi F, Coluccini L, Belardinelli A, Shklareki D, Alon M,

[22] Dias D, Paulo Silva Cunha J 2018, "Wearable Health devices-Vital Sign Monitoring systems and technologies", *Sensors*, vol.18; 2414.

[23] Jeong I.C, Bychkov D, Searson P.C 2019, "Wearable devices for precision medicine and health state monitoring", *IEEE Trans Biomed Eng*, vol.66, pp.1242-1258.

[24] Izmailova E.S., Wagner J.A., Perakslis E.D 2018, "Wearable Devices in Clinical Trials: Hype and Hypothesis", *Clin Pharmacol Ther*, vol.104, pp. 42-52.

[25] Suzanne M. Cox, Ashley L, Samuel L, Vlchenboum 2018, "Use of wearable mobile and sensor technology in cancer clinical trials", *JCO Clinical Cancer Informatics*, vol.2, pp.1-11.

[26] Bucklen K.W., Abbott B.M 2014, "Promise and challenges with the use of mobile applications to support and improve patient care: an industry perspective", *Clinical Pharmacology & Therapeutics*, vol. 95, pp. 469-471.

[27] Setiawan M.A, Zhou L, Alfikri Z, Saptono A, Fairman A.D, Dicianno B.E, Parmanto B 2019, "An adaptive mobile health system to support self-management for persons with chronic conditions and disabilities:usability and feasibility studies", *JMIR Form Res*, vol.3, 12982.

[28] M.A, LoPresti, M.E, Abraham G, Appelboom E.S, Connolly Jr, Slomian J 2015, "Clinical trials using mobile health aplications", *Pharm Med*, vol.29, pp.17-25.

[29] Kirwan M, Vandelanotte C, Fenning A, Duncan M.J 2013, "Diabetes self-management smartphone application for adults with Type 1 Diabetes:Randomized controlled trial", *Journal of Medical Internet Research*, vol.15, pp.1-14.

[30] Schork N.J 2019, "Artificial Inteligence and personalized medicine", *Cancer Treatment and research*, vol.178, pp.265-283.
[31] Miller D.D, Brown E.W 2018, "Artificial Intelligence in medical practice:The question to the answer?", *Am J. Med*, vol.131, pp.129-133.
[32] Houssami N, Jones G.K, Noguchi N, Lee C.I 2019, "Artificial Intelligence (AI) for the early detection of breast cancer:a scoping review to assess AI's potential in breast screening practice", *Expert Review of medical devices*, vol.16, pp.351-362.
[33] Krittanwong C 2018, "The rise of artificial intelligence and the uncertain future for physicians", *Eur J Intern Med*, vol.48, pp.13-14.
[34] Krittanawong C, Bomback, A.S, Baber U, Bangalore S, Messerli F.H, Tang W.H 2018, "Future direction for using Artificial Intelligence to predict and manage hypertension", *Curr Hypertens Rep*, vol.20, pp.-1.
[35] Noorbakhsh-Sabet N, Zand R, ZhangY, Abedi V 2019, "Artificial Intelligence Transforms the future of health care", *Am J. Med*, vol.19.
[36] Bookbinder M 2017, "The Intelligent Trial: All Comes To Clinical Trials".
[37] Nayak V.S., Khan M.S., Shukla B.K., Chaturvedi P.R 2016, "Artificial intelligence in clinical research", *International Journal of Clinical Trials*, vol. 3, pp. 187-193.
[38] Rosa C., Campbell A.N., Miele G.M., Brunner M., Winstanley E.L 2015, "Using e-technologies in clinical trials", *Contemporary clinical trials*, vol. 45, pp. 41-54.
[39] LoPresti M., Appelboom G.,Bruyere O., Reginster J.V., Klug E., Connolly E.S 2014, "Patient engagement in clinical research through mobile technology", *Clin Pract*, vol. 11, pp. 549-551.
[40] LoPresti M.A., Abraham M.E., Appelboom G.,Bruyere O., Slomian J., Reginster J.Y., Connolly E.S 2015, "Clinical Trials Using Mobile Health Applications", *Pharm Med*, vol. 29, pp.17-25.
[41] Emam K.E, Jonker E, Sampson M, Jeric K.E, Neisa A 2009, "The use of electronic data capture tools in clinical trials:web-survey of 259 canadian trials", *Journal of Medical Internet Research*, vol.11, pp.8.
[42] Johnson N, Lilford R.J 1990, "Computerized automation of clinical trials", *Baillieres Clin Obstet Gynaecol*, vol.4, pp.771-86.
[43] Keller B, Labrique A, Jain K.M, Prekosz A, Levine O 2014, "Mind the Gap:Social media engagement by public health researchers", *J Med Internet Res*, vol.16, pp-8.
[44] Gao W, Emaminejad S, Nyein H.Y.Y, Challa S, Chen K, Peck A, Fahad H.M, Ota H, Shiraki H, Kiriya D, Lein D.H, Brooks G.A, Davis R.W, Javey A 2016, "Fully integrated wearable sensor arrays for multiplexed in situ perspiration analysis", *Nature*, vol.28, pp.509-514.
[45] Malik I, Burnett S, Smith M.W, Morden J, Ereira S, Gillman A, Lewis R, Hall E, Bliss J, Snowdon C 2015, "Benefits and challenges of electronic data capture (EDC) systems versus paper case report forms", *BioMed Central*, vol.16, pp-37.
[46] "The Benefits and Challenges of Virtual Trials", *Life Sciences Software*.
[47] "The Future of Clinical Trials: How AI & Big Tech could make Drug Development Cheaper, Faster, & More Effective" 2018.
[48] Shabestari O, Roudsari A 2013, "Challenges in data quality assurance for electronic health records", *Stud Health Technol Inform*, vol.183, pp.37-41.
[49] Chan K.S, Fowles J.B, Weiner J.P 2010, "Review:electronic health records and the reliability and validity of quality measures:a review of the literature", *Med Care Rev*. vol.67, pp.503-27