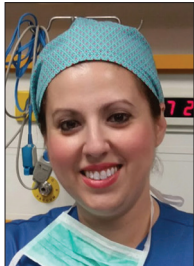


E-Clinical Trials: The Future of Clinical Trials and How Nurses Can Be Involved

Maria Kapritsou

Anesthesiology Department, Hellenic Anticancer Institute, "Saint Savvas" Hospital, Day Care Surgery N. Kourkoulos, Athens, Greece



Corresponding author: Maria Kapritsou, RN, BSN, MSc, MHM (c), PhD, Postdoc

Hellenic Anticancer Institute, Saint Savvas Hospital, Day Care Surgery N. Kourkoulos, Athens, Greece

Tel: 00306976523789; Fax: 0030213241159

E-mail: mariakaprit@gmail.com

Received: February 13, 2020; Accepted: April 10, 2020; Published: June 26, 2020

Clinical trials (CTs) are the cornerstone of the medical and nursing science evolution. They create or open the pathway for new treatments and medical devices that are safe and effective for patients and the general public. The use of CTs has led to the discovery of better treatments, which have fewer side effects and are more efficient for patients than the conventional method. Further, through the years, CTs have helped in preventing the spread of diseases and have been utilized by caregivers and support groups to improve patients' life.^[1]

Platforms have been created to secure the proper development of CTs worldwide. They should show favorable results that advance the medical and nursing science. Each country's Food and Drug Administration Organization (FDA) approves CTs on animals first. Then, the FDA gives its approval for CTs on humans.

Since 2010, a new kind of research has been developed, the E-Clinical Trials (eCTs). Originally, the term eClinical referred to the use of technology, such as electronic patients' applications, CT management systems, or trial supply management systems. Now, the term is used in automation technology and biopharmaceutical companies, for example, the merger of Electronic Data Capture/Electronic Case

Report Forms and the Interactive Voice Response System or Interactive Web Response System to assess the quality of healthcare.^[2]

Specifically, eCTs are the future of medical and nursing CTs because they promote personalized medicine and electronic health. They also offer increased data quality with decreased costs and can limit the time and efforts that researchers utilize for clinical services. Nevertheless, the scientific evolution has come up with a major challenge, such as the new general data protection regulation. Researchers should be very careful regarding data privacy regulations. The Declaration of Helsinki states that the patients' data should be secured and protected and should not be accessible to the sponsor, while clinical research associations should have limited access to the information and medical records. Contrarily, eCTs can enroll more patients who could not have access to these trials, evaluate the data faster, and generate the results earlier, so as to facilitate an earlier market release for new drugs.^[3]

In the field of nursing, research is a tool and an instrument to acquire knowledge about nursing care. Nursing contributes to the interpretation and resolution of

Access this article online

Quick Response Code:



Website: www.apjon.org

DOI:
10.4103/apjon.apjon_11_20

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

Cite this article as: Kapritsou M. E-Clinical Trials: The Future of Clinical Trials and How Nurses Can Be Involved. *Asia Pac J Oncol Nurs* 2020;7:235-6.

problems arising from the practice of the nursing profession, such as work environment and autonomy.

In the development of CTs and eCTs, the nurse researcher plays a vital role. Many studies have pointed out the importance of nurses' role in CTs. However, eCTs do not differ in their development to obtain access to the patients' data. Primarily, nurses could be responsible for obtaining informed consent and recruiting candidates for a research study.^[4] Furthermore, they could be involved in the collaboration and consultation with clinical researchers, ethics committees, medical staff, pharmacists, companies, and universities. Nurses could offer support for clinical colleagues and ensure good practice rules, simultaneously promoting research culture among colleagues.^[4]

During the CTs, they could administer the necessary medications and collect blood and other biological samples.^[5] Likewise, the nurses' role is essential for collecting data, filling document, or completing annual and other reports.

Over the past decades, health professionals have gradually increased their interest in CTs in Greece. However, Greek health professionals did not develop CTs due to limited resources or patients refusing to participate in CTs due to ignorance. Nowadays, Greek universities have developed postgraduate programs such as Masters of Science and Doctor of Philosophy which advance nursing Science, through CTs.

Furthermore, my personal experience in CTs not only helped me to improve as a health professional but also drew me closer to my patients. Their participation in

my CTs helped me to understand them better through discussions and assist them deal with their hospitalization. Patients should, first, trust the researchers and create a special bond to participate in CTs. CTs are the way for science evolution, which is revealed through reliable results.

In conclusion, nursing science has many clinical studies to demonstrate its research dimension. While Florence Nightingale was the pioneer in the research activities of the nursing profession, modern nurses have succeeded in evolving their role in science and the healthcare systems by providing multidimensional care to patients.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Dreier G, Löhler J. Evidence and evidence gaps – An introduction. *Laryngorhinootologie* 2016;95 Suppl 1:S6-12.
2. Ruikar V. Interactive Voice/Web response system in clinical research. *Perspect Clin Res* 2016;7:15-20.
3. Tu H, Lin Z, Lee K. Automation with intelligence in drug research. *Clin Ther* 2019;41:2436-44.
4. Regan E. Clinical trials informed consent. *Clin J Oncol Nurs* 2018;22:152-8.
5. Flocke SA, Antognoli E, Daly BJ, Jackson B, Fulton SE, Liu TM, *et al.* The role of oncology nurses in discussing clinical trials. *Oncol Nurs Forum* 2017;44:547-53.