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Clinical Research in USA and How to Maintain Quality of the Outcomes

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1. ABSTRACT

The clinical research known as well the pharmaceutical research is necessary and essential in enhancing medicine and in promoting health via conducting good quality trials or studies to test and ensure the efficacy, the safety, and the effectiveness of the investigational products or the study medications. These study medications or investigational products could be new medications or already approved medications.

The already approved medications then in clinical research will be tested for further indications. Therefore, the clinical research has a fundamental role to ensure the treatment availability for diseases and disorders.

The outcomes or the final results will be used then after the trials or the studies to seek the eligibility for the approval to be used for patients. The approval is done by certain authorized agency in each country for instance in USA, it is the FDA (The United States Food and Drug Administration).

2. KEYWORDS

Clinical research; Contract Research Organization (CRO); Principal Investigator (PI); Clinical Research Coordinator (CRC); Sponsor; Clinical Research Assistant; Clinical Research Associate (CRA)

3.INTRODUCTION

This paper will be discussing the qualifications and the requirements for the different positions in the clinical research to be occupied or fulfilled.

This paper is continuation for a previous short communication that I have published under the topic of "The Impact of Financial Profit Management on Clinical Research".[1] In my manuscript of that short communication, I have discussed how the financial profit sites that are conducting trials might impact badly and negatively on the outcomes of the trials of the clinical research via not accurate practices which might lead to unintegration in

conductions. Thus, nonprofit sites to be established to ensure integrity and accuracy. However, other solutions might be useful and effective via implementing standards and regulations in case the application of nonprofit sites is not applicable especially in country like USA although having nonprofit sites could be still a good form of resolution.

This paper will be a reflection of my experience in clinical research in USA discussing my overview, matters that I have faced, and issues that I have noticed while working in clinical research in USA.

Here in this paper, I will be discussing the Clinical Research field per my experience in working in this field and per my interactions with others in the same field in USA.

3.1. Sponsors and CROs in Clinical Research:

CRO is Contract Research Organization (CRO), known as also Clinical Research Organization, defined by the Promedica International as an organization contracted by another company to take the lead in managing that company's trials and complex medical testing responsibilities. Thus, Contract Research Organization reduces the cost of research and development to help businesses and institutions meet the needs of the evolving medical device and pharmaceutical industry [2].

However, sponsor in clinical research is defined by the center for advancing health outcomes as who is responsible for ensuring that the clinical study is conducted in accordance with the protocol, GCP (Good Clinical Practice), and applicable regulatory requirements. Furthermore, the sponsor is implementing a system to manage quality throughout all stages of the trial process. The sponsors should focus on trial activities essential to ensure protection of study participants and the reliability of trial results [3].

3.2. Principal Investigator (PI) in Clinical Research:

AMGEN defines the Principal Investigator (PI) as the physician who leads the conduct of a clinical trial at a study site. The leadership role of the PI helps to create the foundation of a successful clinical trial or study research (1).

3.3. Clinical Research Coordinator (CRC) in Clinical Research:

According to University of California San Francisco (UCSF), the CRC has a fundamental and a crucial role in Clinical Research as CRC works with and under the direction of the PI. Although the PI is legally responsible for all aspects of the research study, the CRC often handles the bulk of the daily study activities and plays a key role in the study conduct and management. The CRC is frequently responsible for organizing the documentation and files pertaining to a study and for coordinating the activities of the investigators and the study participants/ subjects. The responsibilities of the CRC in general include: protection of the rights and welfare of the subjects/ participants, evaluation of new protocols for feasibility, preparation site for study conduct, participation in the informed consent process, and management of the study conduct.[4]

3.4. Sub-Investigator (SI) in Clinical Research:

According to National Institutes of Health (NIH), Sub-Investigator (SI) also known as Co-Investigator (Co-I) refers to a senior or key investigator involved in a clinical study who does not have the overall responsibility and authority of the PI. SI is expected to devote a specified amount of time to the project, makes significant contributions, and may be involved in developing and/or carrying out the project.[5]

3.5. Site Manager in Clinical Research:

According to Johns Hopkins University, the Site Manager is the professional who is responsible for managing site investigator relationships and executing site start up and performance plans, assigning tasks and deadlines to site clinical teams, directing and monitoring clinical site work efforts on a daily basis, identifying resource needs, performing quality reviews, and escalate functional, quality and timeline issues appropriately.

3.6. Clinical Research Associate (CRA) in Clinical Research:

According to McMaster University, a Clinical Research Associate (CRA), also called a clinical monitor or trial monitor, is a professional who performs many activities related to medical research, particularly clinical trials. Clinical research associates work in various settings, such as pharmaceutical companies, medical research institutes and government agencies.[6]

3.7. Clinical Research Recruiter:

The Recruiter in Clinical Research focuses strongly on direct sourcing, is the one who will understand how to effectively leverage the employer brand to screen, attract, and hire top clinical research talent. The Clinical Research Recruiter is responsible for the full lifecycle recruitment while partnering in a very consultative manner with hiring managers throughout the hiring process. Clinical Research Recruiters are responsible for leading and communicating strategic recruitment updates to key leaders within the division that they support.

3.8. Clinical Data Manager in Clinical Research:

A clinical Data Manager is responsible for ensuring that statistical information and results from clinical trials are recorded and reported accurately, both during and after they are complete. This is achieved through the careful design of data collection tools and methodology for interrogating data, as well as liaising closely with other functions.[7]

3.9. Clinical Research Operations Manager:

Clinical Research Operations Manager role is to manage and supervise all activities necessary to operate one or more research work settings such as a laboratory, clinic, field and/or classroom. To fulfill such position then it requires knowledge of research concepts, practices and procedures, laboratory operations, regulatory requirements, and planning and budgeting.

3.10. Clinical Research assistant:

Clinical Research Assistants identify subjects or clinical trials, collect data, evaluate results, monitor clinical trials, and take notes on activities. They audit research trials and ensure all clinical trial protocols are in compliance. They transfer data to the computers, recorder, or scanner in organized spreadsheets with large numbers, curating data directly from clinical research.

3.11. Research Pharmacist:

Research Pharmacist works behind the scenes and plays a vital role in clinical research. Research pharmacists make the clinical trial part of drug development possible. They are part of multidisciplinary teams that investigate new pharmaceuticals developed for patient use.[8,9]

4. HOW QUALIFICATIONS ARE BEING USED IN CLINICAL RESEARCH

Through my overview in USA, I have noticed in general that the qualifications especially the foreign ones are not being used neither appropriately nor properly in their accurate fields, and this mostly applies to academic and educational qualifications when coming to USA looking for opportunities that do not require licensing but to use their academic and educational qualifications in seeking for hiring opportunities. Considering locals rather than foreigners, and local education rather than foreign education for good descent inclining future positions in the hiring process. However, social relations, networks and good connections might play influential role in the hiring process. Which ended up seeing and noticing less qualified individuals are being superiors and managers above highly qualified individuals.

This overview applies for the field of the clinical Research as well. Through my experience and my careers in Clinical Research in USA, I have noticed the controversial and the discrepancy in hiring individuals within neither uncertain related nor adequate backgrounds in the Clinical Research in positions like CRA, CRC, Site Manager, Clinical Operations Manager, and others except the positions that do require license to fulfill like PI and SI in which the valid medical license is a requirement that is being asked by the Sponsors, the CROs, and the authority.
I have dealt with CRAs who are monitoring the trials that I have been conducting that do not have any related medical or knowledge background into the medical clinical research field. For instance, I have been introduced to a CRA who used to be a police officer prior to be a CRA, and another CRA who used to be a cook/ chief prior to be a CRA. I have seen site managers and operations managers without neither any kind of academic nor higher educational qualifications being superiors for CRCs within master degrees into related medical fields.
I have dealt in clinical research with superiors including site manager, clinical research operations manager, and CEO with no related educational background to the clinical research field but their only concern was how to make financial profit from clinical research.
Unfortunately, there are neither solid regulations nor solid requirements by the authority or the sponsors for the individuals who are fulfilling important and essential positions in research although there are solid and clear requirements for some positions like PI, SI and clinical Pharmacists, however, the other positions are not less important so not to have any requirements or certifications or licenses to fulfill them.
However, there are some frameworks that might be available and some published recommendations, and some optional certifications that are available to acquire.

5. THE IMPORTANCE OF THE CLINICAL RESEARCH COORDINATOR IN CLINICAL TRIALS

According to a toolkit for NIH (National Institute of Health), the Clinical Research Coordinator (CRC) ensures the clinical trial maintains accordance with the protocol, applicable regulations, and (GCP) Good Clinical Practice and (IRB) Institutional Review Board requirements. The CRC manages and conducts the day-to-day activities of the clinical studies. CRC collects and reviews the data prior of entering the captured data into the study database.

Per CRC's Guide to Coordinating Clinical Research (4th edition) by Sandra "SAM" Sather, MS, CCRC, the CRC has multiple responsibilities which include reviewing protocols and other materials, looking at subject eligibility requirements, assessing the ability to meet study timelines, assessing the resources necessary to conduct the study, assessing the financial feasibility, preparing the site study team for conducting the study, participating in the informed consent process, managing study conduct throughout the trial, professionally representing the site, coordinating sponsor and/ or regulatory study audits, maintaining regular communications with sponsors and/ or CROs, and assisting the investigator with financial aspects of the trial.

Clinical Research Coordinator (CRC) roles and responsibilities in general include processing informed consents, maintaining trial timelines, creating data collection forms, protecting research participants, completing case report forms, performing administrative duties, reviewing protocols, performing patient preference studies, liaising with labs, recruiting participants, reporting adverse events, preparing budgets, and managing research budgets. However, these roles and responsibilities might reduce little bit depending on how big the research facilities are and in case those research facilities might have other sub specialities coordinators to support the CRCs. Therefore, the position of the CRC with the associated responsibilities that come with it is essential, crucial, important, and dynamic for each study trial to be conducted and performed. Thus, it is necessary to fulfill such position within individual who is adequately educated and then to be treating such individual who is fulfilling such position fairly via both personal respect and salary prospective. But what I have noticed continuously in USA in clinical research field that CRCs are not being respected fairly in compare to other clinical research positions which made the position of the CRC as a temporarily career by whoever fulfilling it to leave it as soon as possible within the first possibility to leave for better well paid positions in clinical research, and this led to the continuous turn overs of the CRCs in the clinical research facilities causing the instability of the steadiness in conducting trials.

6. RECOMMENDATIONS

Clinical research is essential, important and effective in medical field via conducting trials for the purpose of health promotion and improving medicine. Therefore, the individuals who are conducting such critical trials have to be adequately acknowledged and adequately qualified. Such individuals have to be qualified whether academically and/ or educationally to appreciate the importance of the research's outcomes that they are providing how necessity they are. Thus, such individuals despite the position in the clinical research field have to be at better level at the payroll scale as well after the qualification's assurance due to the major role that they are playing in the trials' conductions.

CRC positions have to be filled by well educated and acknowledged individuals to ensure the integrity in conducting trials, and CRCs have to be treated fairly enough to accommodate their education, their knowledge and their work to ensure the steady flow in the trials that are being conducted by the clinical research facilities.

However, the correction has to start from the top at first by making sure managerial positions to be filled by adequately educated individuals who have concern about the scientific value of the clinical research.

7. REFERENCES

1. Anas Malik Radif Alubaidi. The Impact of Financial Profit Management on Clinical Research. Ann Med Res Pub Health. 2023;1(1):1-3.
2. Promedica International, no date. What is a Contract Research Organization?.

3. Jneedham, 19th September 2017. Sponsor responsibilities 101.
4. UCSF, 27th September 2023. Human research protection program.
5. NIH, no date. Co-investigators (Co-I).
6. McMaster University, Certified Clinical Research Associate. Retrieved 28th April 2014. Accessed on: 1st November 2023.
7. ckgroup, no date. Clinical Data Manager job profile.
8. Mayo Clinic College of Medicine and Science staff, 28th March 2023.
9. AMGEN, no date. Investigator resources.