RESEARCH PROTOCOLS: ARE THEY REALLY NECESSARY OR ARE THEY JUST FORMALITIES?

Planning is essential to prolific clinical studies. The description of various external and internal factors can serve as guidance to sponsors, physicians, researchers and other members of stuff. Therefore, every clinical research starts with the preparation of a detailed study plan. In the Pharmaceutical, Clinical and Medical sector, this study plan is most commonly referred to as research protocol. And just as any other required study procedure and documentation, the development of a protocol must also adhere to Good Clinical Practice (GCP) stipulations and other fundamental conditions. But are research protocols really important or are they just some sort of unnecessary formalities? The answers to those and many other questions can be found bellow.

Definition

Before providing you with an answer as to whether or not protocols have any essential role in trials, we would like to present you with a definition of what precisely protocols are. In essence, research protocols represent written specifications of the research plan. In other words, they underline how the trial should be performed in all of its stages. Protocols also make sure that the safety, privacy, confidentiality and rights of trial participants are preserved, while subjects' and study's data is accurately and rigorously collected. Such thorough outline of the intended

program offers the protocol receivers a summary of the whole information which has been previously discussed.

Particularities

Of course there are some quite pivotal distinctions or patterns which should be followed by anyone when creating a study protocol. In this regard, research protocols are written in future tense. Moreover, they cover distinguished focalized points and indicate different sections. These particular sections include information about the study organization, methodology, background, schedules of tests, design, objective(s), purpose, patients' definition (criteria for patients' inclusion and exclusion), statistical considerations, drug-products to be used and, lastly dosages.

Topics

The ICH Good Clinical Practice guidelines indicates that protocols should include the topics listed below:

- Title Page (General Information)
- Background Information
- Objectives/Purpose
- Study Design
- Selection and Exclusion of Subjects
- Treatment of Subjects
- Assessment of Efficacy
- Assessment of Safety
- Adverse Events
- Discontinuation of the Study
- Statistics
- Quality Control and Assurance
- Ethics
- Data handling and Recordkeeping
- Publication Policy
- Project Timetable/Flowchart
- References
- Supplements/Appendices


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Protocol deviations and violations

A protocol deviation is any kind of variation that differs from the processes or procedures which have been explained in the protocol. Even though almost every clinical trial experience deviations (some of them consequential and others inconsequential), their number should be minimum. In case there is a severe deviation that puts the safety or patients at risk, the event should be immediately reported to the IRB. A protocol variation, on the other hand, represents serious departures from acknowledged processes and procedures which may negatively affect the validity of the trial, as well as its evaluability and results.

Trying to avoid such disadvantages and hindrances to the study progress, experts have suggested several good practices.

They include:

• Providing adequate information and proper training to all technologists that may be participating in the scanning of research volunteers

• Keeping and providing a copy of the research protocol not only to the research department but to the technologists as well

• Reviewing the protocol on a regular basis

With all of this being said, writing and having a study protocol turns out to be really important when it comes to conducting successful researches. This kind of detailed protocols contain crucial information about the trial participants and the study itself. Going back to this data and plan will reassure practitioners that things are going the right direction. To put it differently, they will know that they are carrying out the procedures in accordance with all of the requirements which will really save them time, cost and efforts.

Article originally posted here: https://crotraining.co.uk/research-protocols-are-they-really-necessary-or-are-they-just-formalities/