Patients' Security and Confidentiality of Clinical Trial Data

Taking part in clinical trials happens voluntarily and it is entirely up to the subject to decide whether to continue their participation in the trial or to terminate it completely. Of course, such participations are surrounded by unavoidable formalities and requirements. One such requirement is for people to submit personal data to the board of researchers before the start date. This **information along with the medical records of the patient are supposed to be adequately maintained and preserved during and after the trial**. Investigators, then, are to make sure that all sensitive specifics are safeguarded so that no harm or violation could occur when promoting the research. Considering the modern research settings and the movement towards digitalization of clinical trials, Pharmaceutical companies largely integrate electronic methods into their daily medical care routines. This includes maintaining personal data equally on paper and electronically. However, privacy issues and concerns seem to accompany precisely this use of electronic techniques for data collection and preservation. With potential threats in front of them, researchers are challenged to come up with advanced approaches in order to avoid data misuses.

Privacy of patients and confidentiality of clinical trials information are important. Any discrepancy or fraud could have severe negative repercussions on different levels. Participants may be exposed to social damages or embarrassments, staff members could lose their position and employment, while organizations might even lose their legal licenses which allow them to carry out researches. Trying to not only guide institutional administrators, investigators, research performers and so on, regulators have stipulated and continue to stipulate different guiding principles, rules and laws.

Examples of similar statements are: HIPAA Privacy Rule (Health Insurance Portability and Accountability Act), the Code of Federal Regulations and even The Belmont Report published back in 1979. All of them stand for protection of privacy and confidentiality of trial participants and their medical records.

But what exactly stays behind the two words "privacy" and "confidentiality"? **When talking about privacy of someone in regards to clinical studies, the term refers to the right of a person to limit the access of other people to his or her personal information. Confidentiality, on the other hand, is defined by the process of protecting people's privacy.** This process includes deciding upon whether to keep patients' information without sharing it or to share it, knowing that it will benefit the public good. Nevertheless, any public distribution or transparency of data should be done only after trial participants have been informed about the procedure and have given their written consents. Going further, there are several advantages of ensuring that confidentiality is kept.

1. It builds up trust between the trial participant and the researchers

2. It gives autonomy and control to people who participate in a trial

3. They feel secure

Still, this type of sensitive data often turns into a product which can be sold and bought on the open market. The reasons for this trend are many but some of them are justified by the statement that it is done to achieve common goods that are in the public health interest. Unfortunately, there are many incidents of unauthorized personal medical information that has been used for inappropriate reasons. In Florida, for instance, an employee working for the state health department distributed confidential

information to two newspapers – The Tampa Tribune and The St. Petersburg Times. The forwarded data included the names of 4,000 people who tested positive for HIV. Some of the ways to avoid similar crisis and prevent their future occurrences, suggest limiting the access to personal data as well as anonymizing data and excluding specifics which might put trial participants at risk.

In summary, more and more practices in the Medical, Pharmaceutical and Clinical sector become digitalized. This includes keeping patients' medical records too. Even though such electronic tendencies save time and resources, they are likely to put privacy of patients and confidentiality of clinical trials information at risk. For this reason, those **people who are involved in all study procedures and phases (from approving to carrying it out) are expected to find the balance between data accessibility, usability and disclosure without jeopardizing patients' privacy and rights.**

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