

DOCUMENT FLOW AS A PART OF THE CLINICAL TRIALS ORGANIZING STAGE AND MANAGEMENT OF COMMUNICATION PROCESSES

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Introduction. In recent years, the field of clinical trials (CT) of medicinal products in Ukraine has moved from the phase of active formation to the phase of rapid development. In accordance with the principles of ICH GCP, the registration, processing and storage of information that is obtained during the CT should be carried out in such a way as to ensure the correct presentation, interpretation and verification of data. One of the means to implement this principle is proper communication. It is a key factor that ensures the proper organizing of CT, as well as obtaining reliable results. The communication process is confirmed by appropriate documenting, which is an important part of the quality system. Therefore, the document flow is a necessary and important part for the management of communications during the organizing of CT.

The aim of the research was to characterize the role of document management in the organizing of CT and its influence on communicative processes.

Materials and methods. Systematic analysis of scientific publications and normative acts and the method of summarizing the obtained information were used.

Research results. Communicative processes can be considered to be the basis of the CT organizing, because through them, the study protocol is created, the participation of researchers is confirmed, holding of the CT is approved by the regulatory authorities and etc., which is the organization of the research to be carried out. One of the simplest ways to track the communication is through the correspondence: it can confirm the telephone conversation, agreement on plans, protocols, etc. Signing and dating any document is considered as approval. Analysis of all approved documents allows to track all communication processes. The usual communication sequence: oral communication, written communication, signing and approval. Today, the introduction of electronic document flow allows to reduce the time of communication and speed up the coordination of documents or the information transfer from one party to another. Proper document management prevents the occurrence and spread of verbal communication errors and allows to monitor the relevant operations in the CT organizing.

Conclusions. Implementation of document flow during CT is an important process that allows tracking of communications and affects the quality and integrity of data obtained during the study.