CLINICAL EXAMINATION METHODS

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Abstract: Clinical trials can be conducted on the basis of one research center in one country, or they can be multicenter and take place simultaneously in many countries.

Key words: Clinical trial, Types, trials.

A clinical trial is a scientific study involving people that is conducted to evaluate the effectiveness and safety of a new drug or to expand the indications for the use of an already known drug. Clinical studies may also examine the efficacy and safety of new invasive (including surgical) and non-invasive treatments and diagnostics. Clinical trials all over the world are an integral stage of drug development, which precedes its registration and widespread medical use. During clinical trials, a new drug is being studied to obtain data on its effectiveness and safety. Based on these data, the authorized health authority decides whether to register the drug or refuse registration. A drug that has not passed clinical trials cannot be registered and put on the market. When developing a new drug, it is impossible to do without clinical studies, since extrapolation of research results in animals and biological models to humans is possible only in general, and sometimes impossible at all. For example, pharmacokinetics (how a drug enters the bloodstream, is distributed in the body and is excreted from it) In humans, it differs even from pharmacokinetics in primates. However, the analysis of preclinical studies is very important for assessing the likelihood of the development and nature of side effects, calculating the starting dose to study the properties of the drug in humans. Clinical trials can be initiated only after encouraging results have been obtained in the course of preclinical studies (studies on biological models and laboratory animals), as well as the approval of the ethics committee and a positive decision of the authorized health authority of the country where the study is planned. Initially, an experimental drug is studied with the participation of a small number of patients and (or) healthy volunteers. As data on its safety and effectiveness accumulate, the number of patients involved in the study increases, and the drug itself is compared with drugs already known and widely used in medical practice. A study in which the researcher knows who belongs to the test group and who belongs to the control group, but the participants of the groups themselves do not know this is called a simple blind. If neither the group members nor the researcher know about

the division into groups, but only the external controller, such a study is called double—blind.

Types of clinical trials

The first way to classify clinical trials is by the presence of interference in the usual tactics of patient management, that is, in standard procedures for examination and treatment of the patient. An observational study is a clinical study in which a researcher collects data by simply observing events in their natural course without actively interfering with them. A controlled infection study, on the contrary, assumes the deliberate infection of healthy volunteers. A non-interventional study ("non—intervention study") is a study in which a drug is prescribed in the usual way in accordance with the conditions set out in the market authorization. The issue of "attributing" a patient to a specific treatment strategy is not resolved in advance in the study protocol. This issue is being resolved in accordance with current practice, and the prescription of the drug is clearly separated from the decision to include the patient in the study. No other diagnostic or monitoring procedures are used for patients, and epidemiological methods are used to analyze the collected data. An interventional study is a study of new, unregistered medicines, immunobiological agents, medical equipment, or a study in which medicines, immunobiological agents, medical equipment are prescribed or applied in a manner other than the conditions set out in the registered instructions for use (whether it is a new indication, a new dosage of the drug, a new route of administration, a new method of application or a new category of patients). The criterion of another classification method is the purpose of the study. This classification method was proposed by the U.S. National Institutes of Health (NIH) and identifies six different types of clinical trials: Preventive trials are conducted to find the best ways to prevent diseases in people who have never suffered from them, or to prevent a recurrence of the disease in patients. Such studies may examine medications, vaccines, vitamins, minerals, and lifestyle changes. Screening trials are conducted to find the best way to identify certain diseases or conditions. Diagnostic trials are conducted to find the best way to diagnose a particular disease or condition. Therapeutic trials are conducted to study the efficacy and safety of experimental drugs, new drug combinations, or new methods in surgery or radiation therapy. Quality of life trials are conducted to explore ways to improve the quality of life of patients suffering from chronic diseases. Extended access programs (in exceptional circumstances, compassionate use trials or expanded access) involve the use of an experimental drug in patients with serious or life—threatening diseases that cannot be included in a clinical trial because they do not meet the inclusion criteria. Usually, such programs involve

patients for whom there are no effective treatments for diseases, or those who have tried all the standard, well-known methods of treatment, and for whom they have not helped.

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