IDENTIFICATION OF RISKS TYPES THAT INFLUENCE THE QUALITY OF DATA IN CLINICAL RESEARCH

Bondarchuk I.S., Ratushna K.L.

The National University of Pharmacy, Kharkiv, Ukraine

irinabondarchuk@icloud.com

Globalization, growth of number and complexity of clinical researches (CR) creates circumstances that make it hard to reach a high quality level because of lack of resources. In such condition it becomes especially crucial to implement a risk oriented approach in the CR control system.

The goal of our research was to study the typical risks for data control system (DCS) in CR. During the study we have used the methods of abstraction, logical analysis and structured system analysis. The first step of risks assessment is their identification where it is important to discover factors that can badly influence on some data quality and the analysis of this influence with further identification of risks for DCS in CR. As a result of a conducted analysis of national and foreign literary sources, clinical trial protocols and study designs we have pinpointed main types of risks that lead to loss of data quality in CR during their planning and organization. Thus, risks connected with the data processing and conduction of biostatical analysis and also with clinical data control have a negative influence on a clinical data quality. As last risks we describe the following: irregular getting of informed consent; incompatibility o insertion criteria, inadequate recognition of side reactions and by-effects; false estimating of efficiency and security indicator of medicinal product ; improper randomization and use of blind design.

The analysis of the pinpointed risks types enables to properly determine prior directions in risks control for DCS in CR at the stage of its planning and to guarantee its high efficiency.