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Risk assessment with the help of failure mode and effects analysis (FMEA) in BE studies

Kateryna Zupanets

National University of Pharmacy, Ukraine

Nowadays, bioequivalence (BE) study of drugs is considered to be a complex and multistage process where groups of professionals from different branches of pharmacy, medicine, and biostatistics are involved. It is a long way from the trial design and the enrollment of the first study object to the point the first results are entered into the corresponding documents. For that matter, even in case of planning the study accurately there may be issues that can emerge during the study and that require mobilizing all the parties/participants of clinical trial of a given drug to discuss, approve and solve possible problems. Such problems can include assessing abnormal ranges, registering and processing data entry, verifying source data, interpreting study data concerning adverse events/reactions (AE/AR). Consequently, we have decided to carry out the assessment of the above mentioned risks with the help of FMEA methodology that functions as a modern tool of risk assessment, helping to identify potential errors of any clinical trial. The experts of Clinical and Diagnostics Center of the National University of Pharmacy (Ukraine) which specializes in conducting BA/BE studies have been interviewed for them to assess the risk probability (P) and the level of its influence on the quality of clinical trial with the help of a five-rating scale. The risk value has been determined by means of priority risk parameter (PRP). As a result, it has been found out that the risk "AE/AR data missing due to incorrect conclusions about its significance" has been found among the highest values (PRP=5.07). Thus, during the BA/BE study it is desirable that investigators should pay their special attention to the revealed risk and make the relevant attempts at its minimization.

Biography

Kateryna Zupanets has completed her PhD from National University of Pharmacy, Kharkiv, Ukraine. Currently, she is pursuing her Post-doctoral studies at Clinical and Diagnostics Center of the National University of Pharmacy. She is the author of more than 25 papers in reputed journals (5 articles for SCOPUS journals). She has been working as a Co-Investigator in more than 40 trials of Bioequivalence studies and Phase I at Clinical and Diagnostics Center of the National University of Pharmacy.

katyaz@list.ru

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