Title:

Issues in reporting results of safety pharmacology studies according to new guidelines.

Authors:

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Short bios:

Dr. Ivan Semeniuk obtained his bachelor's and master's degrees in mathematics at Kyiv National Taras Shevchenko University in 2014 and 2016 respectively. He obtained a PhD degree in statistics in 2022 at European University Viadrina in Frankfurt (Oder) and works as a biostatistician in the preclinical research at a CRO Chrestos Concept in Essen since 2022. Current interests lie in the statistical analysis of pharmacology studies with beagle dogs.

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Short summary:

According to the best practice recommendations of the ICH E14/S7B, statistical methods of estimating treatment effects on the QTc interval in safety pharmacology studies with non-rodent species should have sufficient sensitivity to detect a QTc prolongation/shrinkage effect. Even though the best practice document contains nonbinding recommendations, researchers in the safety pharmacology field feel obliged to perform the suggested analysis and adjust the reports of the new studies to the recommended format. Some articles are published to support the implementation of the best practice recommendations. They discuss the topic of power analysis using historical data from former studies and a new way of reporting the statistical results in upcoming studies. Statistical analysis recommended in the literature (minimum detectable difference and least significant difference computation based on ANOVA-modelling, power estimation based on simulation studies with linear mixed models, etc.) needs a thorough discussion on its pros and cons for the results interpretation and reliability of findings. We would like to address this topic in our talk and present our ideas as possible alternatives to the existing statistical approaches.