Virtual control groups in toxicity studies

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In systemic toxicity studies, replacement of concurrent control animals by so-called *Virtual Control Groups (VCGs)* may reduce the use of animals thus contributing to the 3R's principle of animal experimentation: Reduce, Refine, Replace. Although VCGs are an established concept in clinical trials, the idea of replacing animals with virtual data from historical data sets has so far not been introduced into the design of regulatory animal studies [1]. However, major steps facilitating review of methodology for derivation of VCGs from historical control data and performance testing in statistical analysis, are the collection, curation and sharing of suitable sets of historical control data from preclinical toxicity studies.
This talk will summarize accomplished and ongoing efforts for cross-industry provision of data resources and the planned activities within the framework of the *Innovative Health Initiative (IHI)* project **VICT3R** - Developing and implementing Virtual Control Groups to reduce animal use in preclinical safety assessment [2]. Besides key aspects of data collection, standardization and curation activities plus piloting general and specific methodologies for derivation of VCGs, the undertaking is dedicated to achieving scientific uptake and regulatory acceptance of VCGs, paving the way for their widespread adoption in toxicology research. A scientific advice procedure has been initiated for VCG at European Medicines Agency (EMA) Scientific Advice Working Party (SWAP). This talk will shed light on the objectives of the scientific advice and discuss the scientific approaches to achieve regulatory acceptance with a focus on currently performed and envisaged statistical analyses.

[1] Steger-Hartmann, T., Kreuchwig, A., Vaas, L., Wichard, J., Bringezu, F., Amberg, A., Muster, W., Pognan, F. and Barber, C. (2020) Introducing the concept of virtual control groups into preclinical toxicology testing, ALTEX - Alternatives to animal experimentation, 37(3), pp. 343–349. doi: 10.14573/altex.2001311.
[2] https://www.vict3r.eu/ VICT3R - Developing and implementing Virtual Control Groups to reduce animal use in Toxicology Research

This project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No 101172693. The JU receives support from the European Union’s Horizon Europe research and innovation programme and COCIR, EFPIA, Europa Bío, MedTech Europe, and Vaccines Europe and Instem Scientific Limited