VICT3R IHI: Replacing Concurrent Control Animals with Virtual Control Groups in Animal Studies

Description

VICT3R aims to significantly reduce the number of animals used in experimental studies performed during the nonclinical drug andchemical safety evaluation by replacing the animals of the concurrent controls groups (CCGs) with Virtual Control Groups (VCGs). These VCGs will be generated by means of state-of-the-art statistical or artificial intelligence (AI) approaches that optimally exploit the wealth of historical data from control animals accumulated over decades by pharmaceutical companies and other relevant industrial and academic sectors. The VCG concept was conceived and prototyped during the recently finished eTRANSAFE IMI2 project for its application in the nonclinical safety assessment of the pharmaceutical industry. A preliminary evaluation of the VCG concept carried out in the eTRANSAFE project demonstrated that it is generally feasible, yet scientifically and operationally challenging and must therefore be refined before its adoption for regulatory hazard and risk assessment.

The main challenges consist of adequate datac ollection and curation, identification of key variables to achieve optimal matching between VCGs and CCGs, and validation of procedures including compliance with Good Laboratory Practice (GLP). These challenges will be systematically tackled in VICT3R for achieving the full development and regulatory acceptance of the VCG concept. VICT3R will collect, curate and analyse large data sets of control animals from different species to produce a large high-quality database. The database will be made available to VICT3R partners, regulators, and policy makers with the purpose to allow maturation of the VCG concept and to prove its validity, reproducibility and robustness.

While VICT3R will be primarily focused on repeated dose toxicity studies, the extension of the VCG concept to other types of studies involving animals will also be tackled. VICT3R will promote that its database and software platform ismaintained and expanded long term.

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