10 YEARS OF BREAKTHROUGHS A HEALTHIER FUTURE

EQIPD

53

A systematic review of guidelines for rigour in the design, conduct and analysis of biomedical experiments involving laboratory animals.

Vollert J[1], Schenker E[2], Macleod M[3], Bespalov A[4,5], Wuerbel H[6], Michel MC[4,7], Dirnagl U[8], Potschka H[9], Wever KE[10], Steckler T[11], Altevogt B[12], Rice ASC[1] on behalf of the EQIPD WP3 study group

[1]Pain Medicine, Imperial College London, London, UK, [2]Institut de Recherches Servier, Croissy-sur- Seine, France, [3]Centre for Clinical Brain Sciences, University of Edinburgh, UK, [4]Partnership for Assessment and Accreditation of Scientific Practice, Heidelberg, Germany, [5]Valdman Institute of Pharmacology, Pavlov Medical University, St. Petersburg, Russia, [6]Division of Animal Welfare, VPH Institute, Vetsuisse Faculty, University of Bern, Switzerland, [7]Universitätsmedizin Mainz, Johannes Gutenberg-Universität Mainz, Mainz, Germany, [8]Department of Experimental Neurology, Charité Universitätsmedizin Berlin, Germany, [9]Institute of Pharmacology, Toxicology, and Pharmacy, Ludwig-Maximilians- University, Munich, Germany, [10]Systematic Review Centre for Laboratory animal Experimentation, Department for Health Evidence, Radboud university medical center, Nijmegen, The Netherlands, [11]Janssen Pharmaceutica NV, Beerse, Belgium, [12]Pfizer Inc.

Challenge

Within the last years, there has been growing awareness of the negative repercussions of unstandardized planning, conduct and reporting of preclinical research. Several initiatives have set the aim of increasing validity and reliability in reporting of (not only preclinical) studies and publications, such as CAMARADES [*Hirst et al., 2014*], NC3Rs [*Percie du Sert et al., 2017*], SYRCLE [*Hooijmans et al., 2014*] and the EQUATOR network [*Simera et al., 2010*]. Additionally, several groups of experts across the biomedical spectrum, both clinical and preclinical, have published experience and opinion-based guidelines and guidance on potential standardized reporting [*Kilkenny et al., 2010; Smith et al., 2017; Hooijmans et al., 2010*].

While many of the points raised are identical or similar between these various guidelines (in fact many experts on the field are part of more than one initiative), they differ in detail, rigour, and show especially distinct variance in generalizability or specific challenges for a single field. While all these guidelines cover reporting of experiments, an important step prior to this should be rigours planning and conduct of studies, which face a similar situation [*Henderson et al., 2013*]. Consequently, it is hard for researchers to decide which guidelines to follow, especially at the stage of planning future studies.

Facts & Figures

Start date:	1.10.2017
End date:	30.9.2020
Contributions	
IMI funding:	4 495 523 €
EFPIA in kind:	300 000 €
Total Cost:	4 833 023 €
Project website:	www.eqipd.org

www.twitter.com/ECNPtweets

www.linkedin.com/groups/12074241/profile

www.facebook.com/EQIPD

The aim of this systematic review is to identify existing experimental design, conduct and analysis guidelines relating to preclinical animal research. The review also identified literature describing the prevalence and impact of risks of bias pertaining to the design, conduct and analysis and reporting of preclinical biomedical research.

Results

The systematic database search found 13,863 results, after abstract screening, 613 papers entered the final stage, in which 59 papers were included. From these, we extracted 58 items, eleven additional items were brought up in a Delphi process among consortium members.

Outlook & next steps

A final decision on a shortlist of items that the project members find valuable is currently made and will be prospectively tested by industry and academia for feasibility.

imi innovative medicines initiative efpia

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777364. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA