Overarching conclusions - 2021 Workshop Report

In this guide

75. The overall conclusions from the workshop were as follows:

- PBPK modelling tools were applicable in the explored areas of use, and that expertise was available (though numbers are small).
- PBPK modelling offers opportunities from which to address questions for compounds that are otherwise not possible (e.g., considerations of human variability in kinetics) and allows identification of “at risk” subpopulations.
- The use of PBPK modelling tends to be applied on a case-by-case basis and there appears to be a barrier to widespread acceptance amongst regulatory bodies due to the lack of available in-house expertise (apart from some medical and environmental agencies such as the EMA, US FDA, and the US EPA, respectively).

- Familiarisation and further training opportunities on the application of PBPK modelling using real world case studies would help in generating interest and developing more experts in the field, as well as furthering acceptance.
- In a regulatory context, establishing fitness for purpose for the use of PBPK models requires transparent discussion between regulatory agencies, government bodies, academics, and industry and the development of harmonised guidance such as that from the OECD would provide a starting point.
- Finally, PBPK modelling is part of the wider “NAMs” for risk assessment, and there needs to be emphasis in modelling not just toxicokinetics but also toxicodynamics.

Appendix

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