References - Paving the way for a UK Roadmap

In this guide

In this guide

1. Cover Page
2. Background and Objectives
3. Overview
4. Day 1
5. Session I
6. Session II
7. Session III
8. Day 2
9. Session IV
10. Session V
11. Roadmap Discussions
12. Take home thoughts
13. Lesson Learnt and Conclusions
14. A New Hope
15. References - Paving the way for a UK Roadmap
16. Abbreviations - Paving the way for a UK Roadmap
17. Organizing Committee - Paving the way for a UK Roadmap

Accelerating the Pace of Chemical Risk Assessment (APCRA) Website: Accelerating the Pace of Chemical Risk Assessment (APCRA) | US EPA

AMBIT Website: AMBIT – Cheminformatics data management system – Cefic-Lri

Andersen ME, McMullen PD, Phillips MB, Yoon M, Pendse SN, Clewell HJ, Hartman JK, Moreau M, Becker RA, Clewell RA. 2019. Developing context appropriate toxicity testing approaches using new alternative methods (NAMs). ALTEX.

36(4):523-534.

ASPIS Cluster Website: Aspis – Project cluster for Implementation of novel Strategies (aspis-cluster.eu)

Bell, S., Abedini, J., Ceger, P., Chang, X., Cook, B., Karmaus, A.L., Lea, I., Mansouri, K., Phillips, J., McAfee, E. and Rai, R., 2020. An integrated chemical environment with tools for chemical safety testing. Toxicology *in vitro*, 67, p.104916.

The Crown Prosecution Service, 2019, Prosecution Guidance, Expert Evidence, updated 09/10/2019, Legal Guidance: Expert Evidence | The Crown Prosecution Service (cps.gov.uk)

Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment- Environmental, health and safety alternative testing strategies: Development of methods for potency estimation (TOX/2019/70): Developing methods for potency estimation (food.gov.uk)

CRACK IT Challenges Website: CRACK IT Challenges | Innovation Platform (nc3rs.org.uk)

ECHA read-across assessment framework (RAAF): 614e5d61-891d-4154-8a47-87efebd1851a (europa.eu)

ECETOC Website: Home - ECETOC

EFSA Alternatives to animal testing: Alternatives to animal testing | EFSA (europa.eu)

Environment Protection Agency Website: U.S. Environmental Protection Agency | US EPA

European Medical Agency Website: Homepage | European Medicines Agency (europa.eu)

EMA News release recently implementing new measures to minimise animal testing during medicines development (2021): EMA implements new measures to minimise animal testing during medicines development | European Medicines Agency (europa.eu)

EPA Memo on reducing animal testing (2019): Administrator Wheeler Signs Memo to Reduce Animal Testing, Awards $4.25 Million to Advance Research on Alternative Methods to Animal Testing | US EPA

European Union Chemical Strategy (2020): Chemicals strategy - European Commission (europa.eu)

EU Tox Risk Website: EU-ToxRisk - EU-ToxRisk – An Integrated European 'Flagship' Programme Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st century

Geels, F.W., 2002. Technological transitions as evolutionary reconfiguration processes: a multi-level perspective and a case-study. Research Policy 31 (8/9), 1257–1274

Geels, F.W. and Schot, J., 2007. Typology of sociotechnical transition pathways. Research policy, 36(3), pp.399-417.

Harrill, J.A., Viant, M.R., Yauk, C.L., Sachana, M., Gant, T.W., Auerbach, S.S., Beger, R.D., Bouhifd, M., O'Brien, J., Burgoon, L. and Caiment, F., 2021. Progress towards an OECD reporting framework for transcriptomics and metabolomics in regulatory toxicology. Regulatory Toxicology and Pharmacology, 125, p.105020.

Helman, G., Shah, I., Williams, A.J., Edwards, J., Dunne, J. and Patlewicz, G., 2019. Generalised read-across (GenRA): a workflow implemented into the EPA CompTox chemicals dashboard. Altex, 36(3), p.462.

ICCVAM (Interagency Coordinating Committee on the Validation of Alternative Methods). 2018. A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States: A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States (nih.gov)

Lowe, K., Dawson, J., Phillips, K., Minucci, J., Wambaugh, J.F., Qian, H., Ramanarayanan, T., Egeghy, P., Ingle, B., Brunner, R. and Mendez, E., 2021. Incorporating human exposure information in a weight of evidence approach to inform design of repeated dose animal studies. Regulatory Toxicology and Pharmacology, 127, p.105073.

Malloy, T. and Beryt, E., 2016. Leveraging the new predictive toxicology paradigm: alternative testing strategies in regulatory decision-making.

Environmental Science: Nano, 3(6), pp.1380-1395.

Moreau M, Mallick P, Smeltz M, Haider S, Nicolas CI, Pendse SN, Leonard JA, Linakis MW, McMullen PD, Clewell RA, Clewell HJ, and Yoon M. 2022. Considerations for improving metabolism predictions for in vitro to in vivo extrapolation (IVIVE). Frontiers in Toxicology, 4:894569.

National Research Council, 2007. Toxicity testing in the 21st century: a vision and a strategy. National Academies Press.

OECD QSAR ToolBox: The OECD QSAR Toolbox - OECD

ONTOX Website: ONTOX project (ontox-project.eu)

Partnership for the assessment of risks from chemicals (PARC) Website: Partnership for the Assessment of Risks from Chemicals | Parc (eu-parc.eu)

Precision Tox Website: PrecisionTox – The goal of PrecisionTox is to advance safety assessment of chemicals without the use of animal testing by establishing a new Precision Toxicology

Parish, S.T., Aschner, M., Casey, W., Corvaro, M., Embry, M.R., Fitzpatrick, S., Kidd, D., Kleinstreuer, N.C., Lima, B.S., Settivari, R.S. and Wolf, D.C., 2020. An evaluation framework for new approach methodologies (NAMs) for human health safety assessment. Regulatory Toxicology and Pharmacology, 112, p.104592.

Pestana, C.B., Firman, J.W. and Cronin, M.T., 2021. Incorporating lines of evidence from New Approach Methodologies (NAMs) to reduce uncertainties in a category based read-across: a case study for repeated dose toxicity. Regulatory Toxicology and Pharmacology, 120, p.104855.

Patlewicz, G., Cronin, M.T., Helman, G., Lambert, J.C., Lizarraga, L.E. and Shah, I., 2018. Navigating through the minefield of read-across frameworks: A commentary perspective. Computational Toxicology, 6, pp.39-54.

Punt, A., Bouwmeester, H., Blaauboer, B.J., Coecke, S., Hakkert, B., Hendriks, D.F., Jennings, P., Kramer, N.I., Neuhoff, S., Masereeuw, R. and Paini, A., 2020. New approach methodologies (NAMs) for human-relevant biokinetics predictions: Meeting the paradigm shift in toxicology towards an animal-free chemical risk assessment. ALTEX-Alternatives to animal experimentation, 37(4), pp.607-622.

RISK HUNT3R Website: Home - RISK-HUNT3R

Royal Society Chemistry Drivers and scope for a UK chemicals framework: rsc-uk-chemical-framework-drivers-scope-2020.pdf

Rotroff DM, Wetmore BA, Dix DJ, Ferguson SS, Clewell HJ, Houck KA, Lecluyse EL, Andersen ME, Judson RS, Smith CM, Sochaski MA, Kavlock RJ, Boellmann F, Martin MT, Reif DM, Wambaugh JF, Thomas RS. 2010. Incorporating Human Dosimetry and Exposure into High-Throughput In Vitro Toxicity Screening. Toxicol Sci, 117(2):348-358.

Rovida, C., Barton-Maclaren, T., Benfenati, E., Caloni, F., Chandrasekera, C., Dietrich, D.R., Kisitu, J., Leist, M., Pallocca, G. and Hartung, T., 2020. Internationalization of read-across as a validated new approach method (NAM) for regulatory toxicology. Alternatives to Animal Experimentation: ALTEX, 37(4), pp.579-606.

Schultz, T.W., Richarz, A.N. and Cronin, M.T., 2019. Assessing uncertainty in read-across: questions to evaluate toxicity predictions based on knowledge gained from case studies. Computational Toxicology, 9, pp.1-11.

Sostare, E., Lawson, T.N., Saunders, L.R., Colbourne, J.K., Weber, R.J., Sobanski, T. and Viant, M.R., 2022. Knowledge-driven approaches to create the MTox700+ metabolite panel for predicting toxicity. Toxicological Sciences, 186(2), pp.208-220.

Symcyp Website: Certara Simcyp™ PBPK Simulator | Predicting Drug Performance

ToxCast Website: Toxicity Forecasting (ToxCast) | US EPA

ToxRead Website: ToxRead – VEGA HUB

UK Innovation Strategy: leading the future by creating:
UK Innovation Strategy: leading the future by creating it (accessible webpage) - GOV.UK (www.gov.uk)

Viant, M.R., Ebbels, T., Beger, R.D., Ekman, D.R., Epps, D.J., Kamp, H., Leonards, P.E., Loizou, G.D., MacRae, J.I., Van Ravenzwaay, B. and Rocca-Serra, P., 2019. Use cases, best practice and reporting standards for metabolomics in regulatory toxicology. Nature communications, 10(1), pp.1-10.

Yoon, M, Campbell, JL, Andersen, ME, and HJ Clewell. 2012. Quantitative in vitro to in vivo extrapolation of cell-based toxicity assay results. Crit Rev Toxicol. 42(8):633-652.

Zaunbrecher, V., Beryt, E., Parodi, D., Telesca, D., Doherty, J., Malloy, T. and Allard, P., 2017. Has toxicity testing moved into the 21st century? A survey and analysis of perceptions in the field of toxicology. Environmental health perspectives, 125(8), p.087024.