UK FSA COT Paving the way for a UK Roadmap-Development, Validation and Acceptance of New Approach Methodologies Workshop summary (2021)

## **Lesson Learnt and Conclusions**

## 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
- 231. There is a clear sense that it is time to look carefully on how the UK can progress in this space especially since leaving the EU and learn from international agencies.
- 232. How do we assure ourselves that it is fit for purpose as we cannot simply fall back on the validation process of previous methods.
- 233. The general consensus is to gain confidence and be able to predict in a reliable manner with accurate transparency.

- One of the biggest challenges facing the toxicological landscape is organisational inertia. If the wrong decision is made using a new method, it is a big downside for the process. If a new method is used and the right decision is made, it is not likely to be highly publicised.
- 235. The ultimate aim is to protect public health rather than predict outcomes.
- We need to define what is wanted vs needed and that will be independent from an individual's opinion.
- 237. There needs to be communication and dialogue between regulators and industry.
- 238. There is a need to exploit the latest science, already available data, collaboration, safe-harbour approaches, and regulator buy-in.
- 239. More investment will be needed for upscaling particularly in fields in exposure assessment if the UK are to be world leaders in risk-based regulations.
- 240. Strategic priorities funding in the area of next generation toxicologists and training will be key.
- 241. There needs to be an incentive to assess objectively what these methods can do.
- 242. These new alternatives are not just for regulatory use. They are frontloading methods for pharma, green toxicology, and green chemistry.
- 243. The public needs to be made aware of the uncertainty in animal data as this could help towards acceptance of the uncertainty in NAMs i.e., do animals still remain the gold standard?
- 244. People are risk averse, so they tend to focus on losses more than gains. Perhaps NAMs need to be promoted in a way that emphasises what we stand to lose if we do not encourage their use and acceptance, rather than the gains.
- 245. Timelines on certain aspects of the roadmap might encourage activity in all areas.
- 246. The law is there but is sufficiently flexible and in theory does not stop NAMs and alternative testing methods being used.

- 247. Economics, training, and funding were key themes of the workshop with a strong emphasis on the gains/benefits and the loss in not using these new technologies to protect the public.
- 248. Insert integrated health metric values more such as DALY/QUALYs.
- 249. Identifying socio economic technologies barriers will be key to progressing an understanding the value or loss in not up taking these new technologies.
- 250. Exploration of social science /citizen science to engage public confidence.
- 251. Reviewing and discussing: Are animals the gold standard anymore?
- 252. A balancing act (Figure 6) needs to be found between current and future methodologies in risk assessment and accepting the new methodologies and showing they are just as safe as traditional methods.



Diagram of a balancing act between data derived from animals vs in silico. The Figure is a black and white image of a set of scales.

**Figure 6**. A balancing act. From Mice to Mouse. Discussions over virtual laboratory acceptance, weighing the options over animal data vs in silico.