UK Government cross cutting themes on NAMS, data and emerging technologies - NAMS Roadmap (2023)

In this guide

In this guide

- 1. Cover NAMS Roadmap (2023)
- 2. Executive summary NAMS Roadmap (2023)
- 3. Introduction & Background NAMs Roadmap Draft Version 3 (2023)
- 4. What are NAMs and why is there a drive in the regulatory context? NAMS Roadmap (2023)
- 5. Who are the UK FSA and the COT? NAMS Roadmap (2023)
- 6. <u>Worldwide perspectives on emerging technologies NAMS Roadmap (2023)</u>
- 7. <u>UK Government cross cutting themes on NAMS, data and emerging</u> technologies - NAMS Roadmap (2023)
- 8. Future Government cross themes NAMS Roadmap (2023)
- 9. What have the FSA/COT done so far? NAMS Roadmap (2023)
- 10. Exploring Dose Response (EDR) Workshop Summary NAMS Roadmap (2023)
- 11. PBPK for Regulators Workshop Summary NAMS Roadmap (2023)
- 12. <u>The proposal: How does the FSA plan to integrate NAMs in the regulatory</u> <u>space? - NAMS Roadmap (2023)</u>
- 13. The 7 Steps to Integration & Acceptance NAMS Roadmap (2023)
- 14. Future Visions: The new normal chemical landscape NAMS Roadmap (2023)
- 15. <u>References NAMS Roadmap (2023)</u>
- 16. Abbreviations NAMS Roadmap (2023)
- 17. Technical information NAMS Roadmap (2023)
- 18. Acknowledgments NAMS Roadmap (2023)
- 19. More information NAMS Roadmap (2023)

There are numerous examples of work happening in government and beyond, currently surrounding NAMs and data capabilities needs. Therefore this roadmap fits in well, feeding and integrating valuable information into the wider remit to progress scientific and technical capabilities towards benefiting society and protection of human safety.

- The Alliance for Human Relevant Science formed a <u>new Parliamentary group</u> <u>which calls for human relevant science moonshot</u>. The purpose is for MPs and Peers of all parties to accelerate the development and uptake of human relevant life sciences in the UK on medicines development. The report <u>Bringing back the human: transitioning from animal research to human</u> <u>relevant science in the UK</u> highlights its desire to use NAMs, and under regulatory recommendations suggested a NAMs MHRA working group. The FSA have established a Cross-Whitehall group in which various government departments and agencies are involved.
- In the <u>'Rebuilding a Resilient Britain'</u> programme one of the departmental Areas of Research Interest (ARIs) marked as a priority was "data science and digital technologies" in the "Changing Systems" theme.
- In the "<u>The Integrated Review of Security, Defence, Development and</u> <u>Foreign Policy Global Britain in a competitive age</u>" it requests a collaborateaccess framework to guide government activity in priority areas of Science & Technology (such as AI, quantum technologies and engineering biology) which has the potential to unlock a step-change in wide ranging applications, which include chemicals.
- The volume of data produced in the world is growing ever more rapidly, from 33 zettabytes in 2018 to an expected 175 zettabytes in 2025 (IDC, 2018) (Food Systems and Data). The Department for Business, Energy and Industrial Strategy (BEIS) white paper on <u>Regulation for the Fourth Industrial</u> <u>Revolution</u> notes that changes in technology are occurring at a "scale, speed and complexity that is unprecedented". The use of such technologies can help improve regulatory processes in several ways. These include the improvement of the efficiency of data collection and to better exploit data already held by agencies to support improved analysis and risk assessment.
- DEFRA's <u>science research program</u> on <u>integrating systems thinking approach</u> includes Food systems in which NAMs, when used in the food system, could compliment in a regulatory context.
- Life Science Vision 2021 states that Life Sciences will be one of the great drivers of growth in the twenty first century. Through innovation and technological advances, we will diagnose, treat, cure and prevent a much wider range of disease than is currently possible. One of the strategic goals

is in the genomics field to harness the UK's prior investments to fully integrate genomics into health service delivery through the Genomic Medicine Service, and deliver significant advancements in the understanding, diagnosis, and treatment of disease. In addition, health data will be used in a secure and transparent manner, harness the NHS's unique health data to understand and tackle population health challenges, and drive advances in Life Science research and innovation. NAMs includes omics approaches and other tools that are also used in the health setting. Therefore, the new approaches and technologies that are developed can be shared across different settings and used towards improving knowledge and harnessing powerful collaborations.

- This UK COT FSA NAMs roadmap would complement the already existing <u>UKRI Non-animal technologies in the UK: a roadmap, strategy and vision</u> (2015) which recommends a need for early engagement with regulators to ensure that non-animal technologies can be used in regulatory risk assessments.
- The COT FSA NAMs roadmap will also will also help support various research strategies and priorities in the new <u>UKRI strategy 2022 to 2027</u> such as Priority 5.2 in the UKRI Strategy: Harness the opportunities from tomorrow's technologies, AI, digital and advanced computing. This supports the "development and use of cutting-edge tools, technologies and infrastructures- and in particular leverage the rapid advances in digital, data driven and computational approaches – that enable researchers and innovators to push boundaries"
- DHSC Better, broader, safer: using health data for research and analysis independent report states that its aims are: to facilitate substantially wider access to data; facilitate modern open working methods; and create a rapid explosion in the efficiency, openness, and quality of analytic work. NAMs can leverage the process of the harmonisation of a wide variety of data to predict human relevant data safety predictions including using AI and machine learning tools.
- The COT FSA NAMs roadmap will cross pollinate with government activity and <u>The UK's National AI Strategy</u> the vision of which is to remain an AI and science superpower, fit for the next decade.