84th Advisory Forum meeting
Virtual Meeting, 08-09 June 2022

Update on SPIDO: NAMs (New approach methodologies)

George Kass

Lead Expert

Trusted science for safe food

efsa
European Food Safety Authority

Changing the way to do Risk Assessment

European Food Safety Authority

SCIENCE-POLICY INTERFACE

The Commission will:

- foster multidisciplinary research and digital innovations for **advanced tools, methods and models, and data analysis capacities**[102] to also move away from animal testing;

EUROPEAN COMMISSION

Brussels, 14.10.2020
COM(2020) 667 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Chemicals Strategy for Sustainability
Towards a Toxic-Free Environment

EC policy

Safety testing and chemical risk assessment need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments.

EFSA strategy 2027

STRATEGIC OBJECTIVE 2

Ensure preparedness for future risk analysis needs

KEY ACTIONS

- Develop and integrate new approach methodologies (NAMs) and omics for regulatory risk assessment

NAMs landscape

European Partnership for the Assessment of Risks from Chemicals
Horizon Europe

EURL ECVAM
European Union Reference Laboratory for Alternatives to Animal Testing

APCRA

ASPIS Consortium (RISK-HUNT3R, ONTOX and PrecisionTOX)

efsa
European Food Safety Authority

OECD

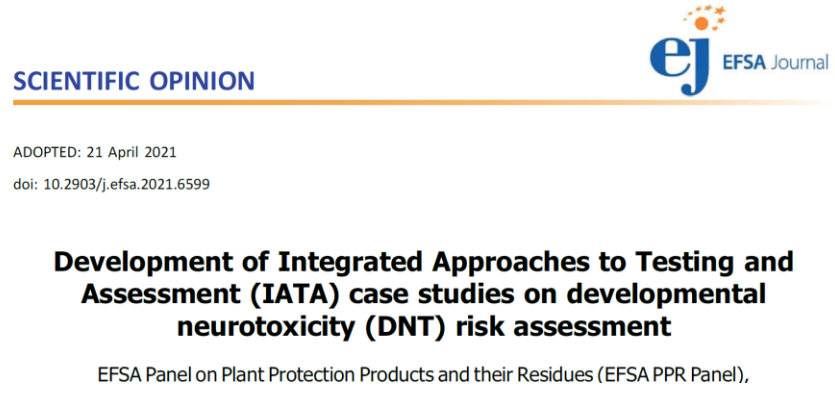
ECHA

Global Coalition for Regulatory Science Research

ILMERAC

EUTOXRISK

EFSA projects on NAMs


SCIENTIFIC OPINION

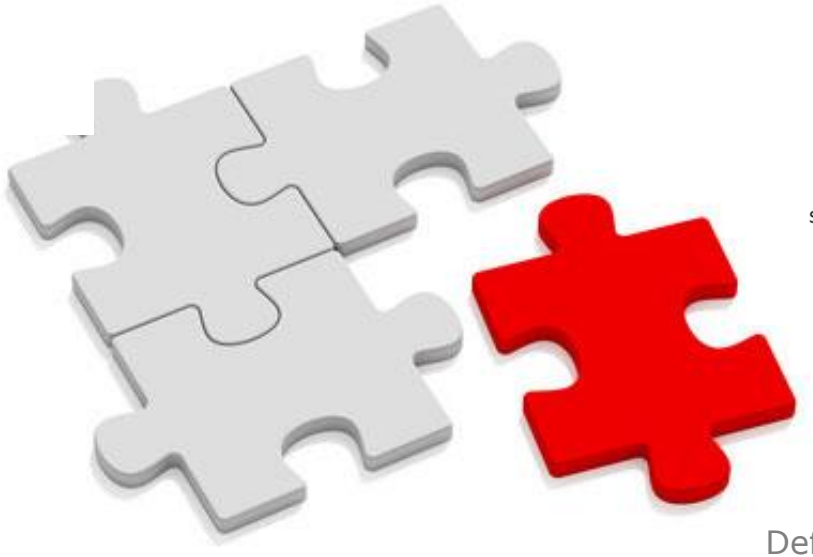
EFSA Journal

ADOPTED: 21 April 2021

doi: 10.2903/j.efsa.2021.6599

Development of Integrated Approaches to Testing and Assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment

EFSA Panel on Plant Protection Products and their Residues (EFSA PPR Panel),




EXTERNAL SCIENTIFIC REPORT

APPROVED: 2 May 2022

doi:10.2903/sp.efsa.2022.EN-7341

Development of a Roadmap for Action on New Approach Methodologies in Risk Assessment

Sylvia E. Escher[1], Falko Partosch[1], Sebastian Konzok[1], Paul Jennings[2], Mirjam Luijten[3], Anne Kienhuis[3], Victoria de Leeuw[3], Rosmarie Reuss[4], Katrina-Magdalena Lindemann[4], Susanne Hougaard Bennekou[5]

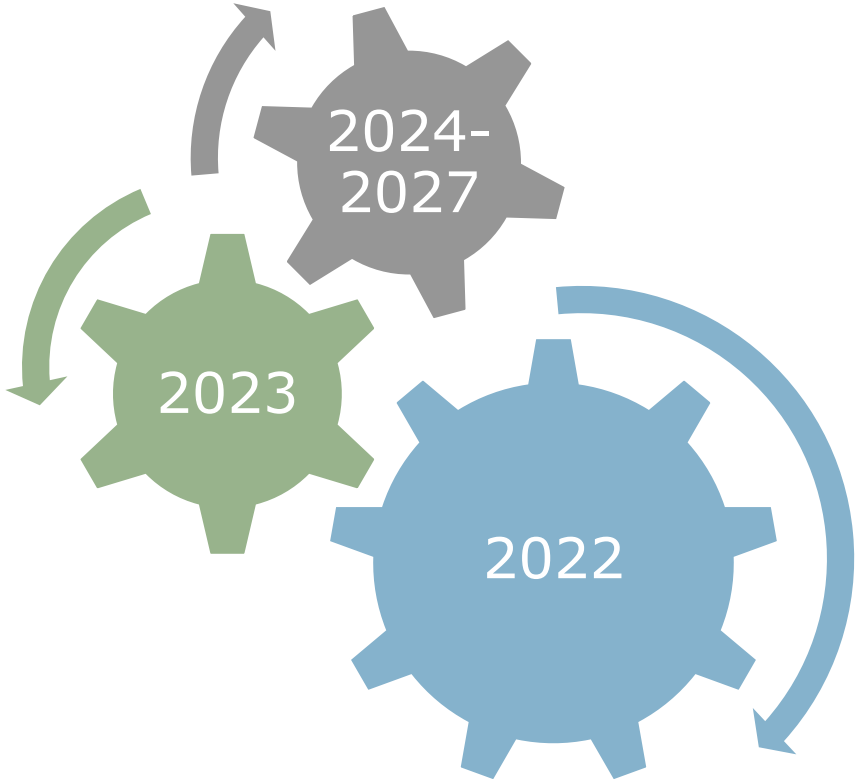
[1] Fraunhofer ITEM, [2] Vrije Universiteit Amsterdam, [3] National Institute for Public Health and the Environment, [4] Eura AG, [5] The National Food Institute Denmark

Projects

- Pesticides: neurodegenerative diseases
- Nanomaterials: GI uptake and genotoxicity
- PFAS: immunotoxicity
- Feed additives: essential oils interspecies metabolic differences
- Artificial intelligence for NAMs

Define **priorities** and **multiannual strategy** for the incorporation of NAMs in regulatory hazard and exposure assessment of chemicals in food and feed

NAMs – draft multi-annual plan



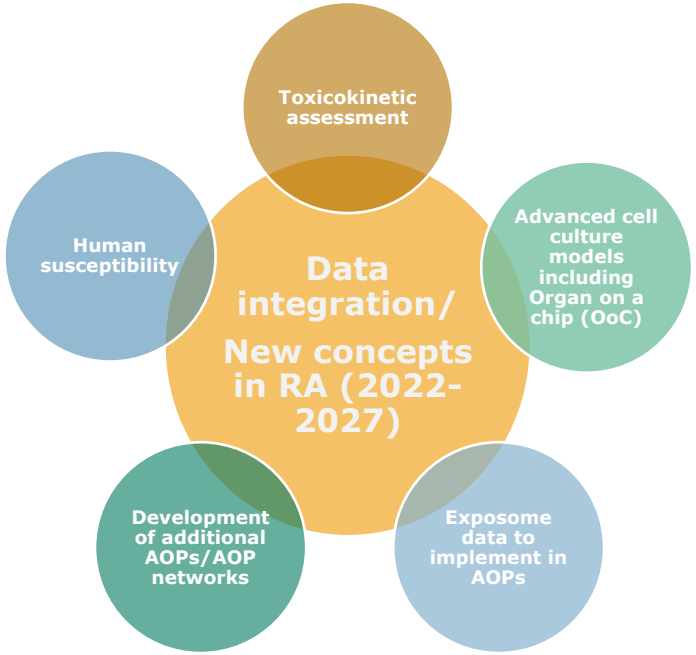
Proof-of-concept case studies

Generating data and tools

SC/Panel Guidance

International alignment (OECD, APCRA)

NAM Project calls: 2022



Project call 2022 (NAMs4NANO):
Data integration: case studies nanomaterial, tools for reporting NAMs data in IUCLID

Case studies

- Specific case studies proposed by MSs in the area of **nanomaterials**
- International collaboration (e.g. ILMERAC)

Guidance and tools

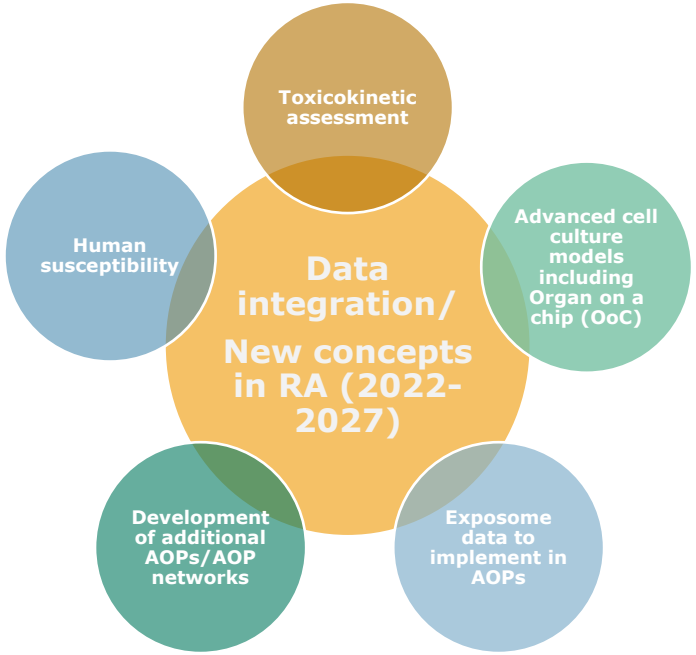
- Integration of NAMs/animal/human data. Guidance supported by examples
- Tools for reporting NAMs data in IUCLID

Launch: June 2022

€5.3M

Grant

NAM Project calls: 2022



Project call 2022 (ADME4NGRA):
Case studies to advance *in vitro* ADME models for use in IVIVE-PBK models, open access reference database

Case studies

- To support the development of **advanced in vitro/in silico ADME models** which can be used in QIVIVE-PBK models
- Develop **advanced in silico models & (open-access) databases** with in vitro and in vivo ADME data to depicted ADME processes

Guidance and tools

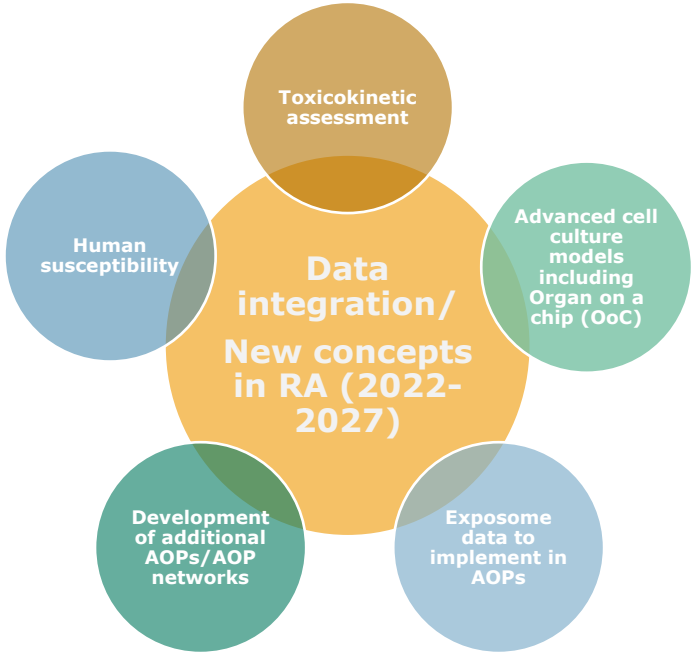
- Integrate QIVIVE and PBK models in human RAs (review/update Guidance)

Launch: June 2022

€3M

Open call

NAM Project calls: 2022



Project call 2022

(call for proposals):
case studies: AOP and transcriptomics to predict target organ toxicity

New AOPs/AOP networks

- Relevant to EFSA's remit
  - Developmental neurotoxicity
  - Endocrine disruption: metabolic syndrome, adrenal axis
  - Oxidative stress-mediated neurotoxicity

In vitro transcriptomics

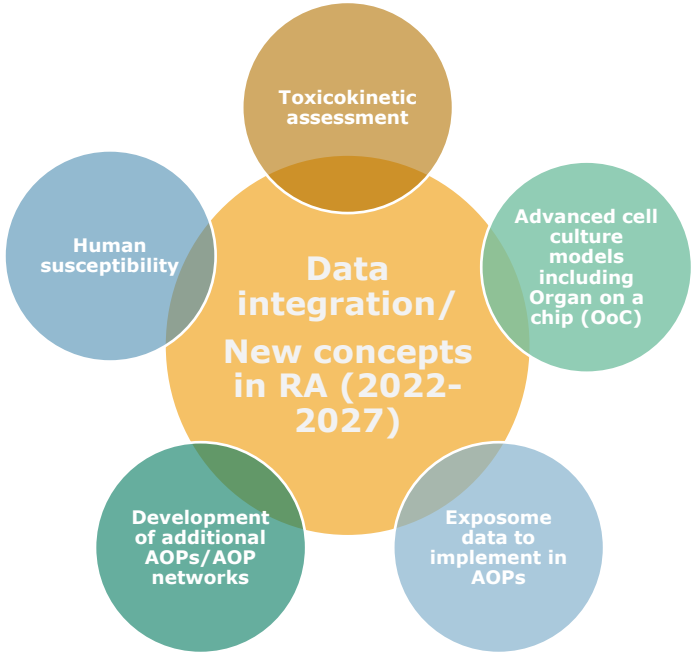
- To predict target organ toxicity and adversity

Launch: June-July 2022

€10M

Grant

NAM Project calls: 2022



Project call 2022
(call for proposals):
case studies: AOP and transcriptomics to predict target organ toxicity

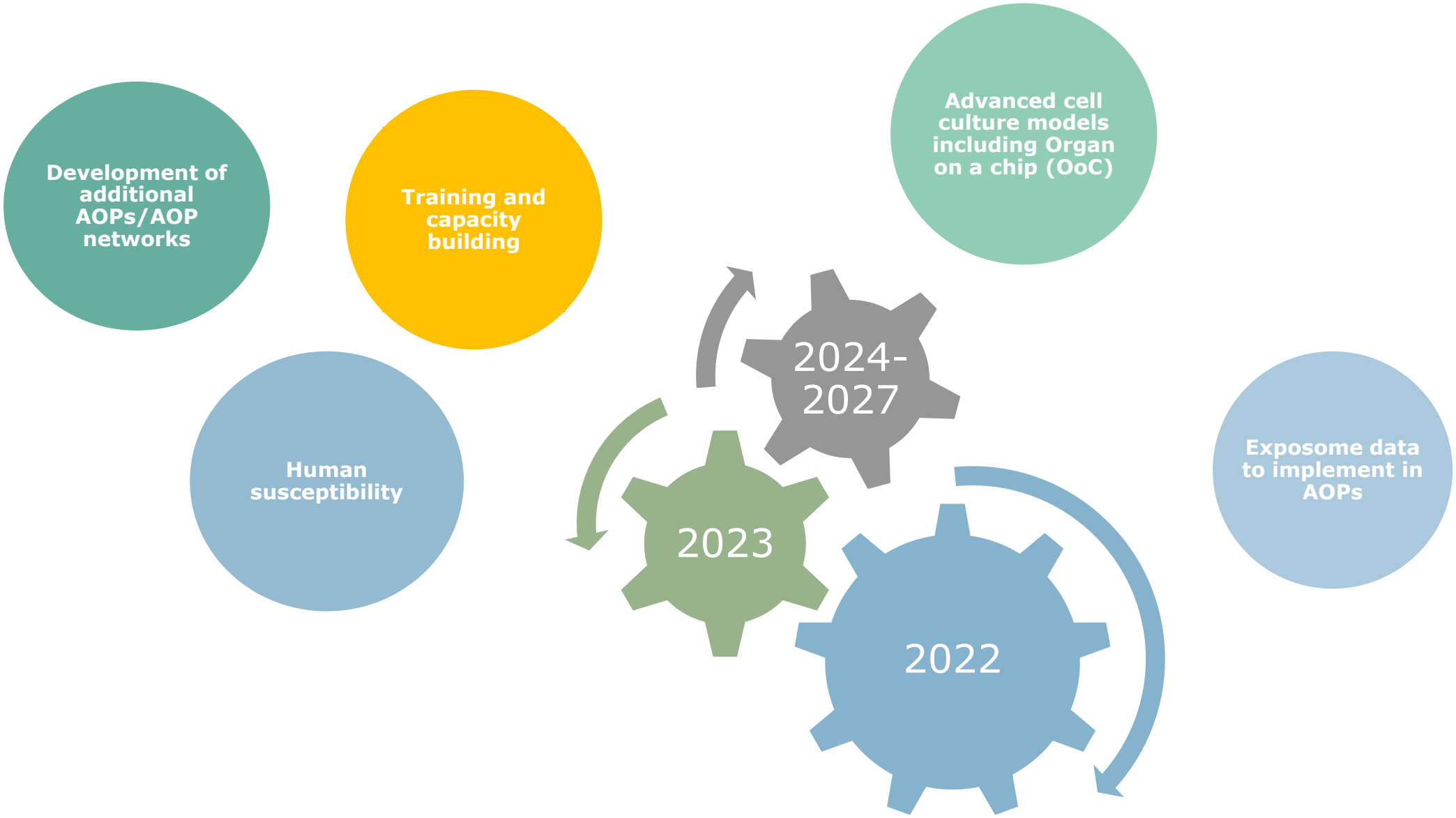
New Procedure

- Two-step procedure
  - **First Step:** Submission of an outline proposal that addresses the problem formulated in the call
  - **Second Step:** Full applications for highest ranked are invited

Why this approach?

- Greater flexibility for innovative ideas that will have an impact of the proposed work on regulatory science
- Co-creation with MS and Art 36 organisations
- More time to identify partners and organise submission of proposal

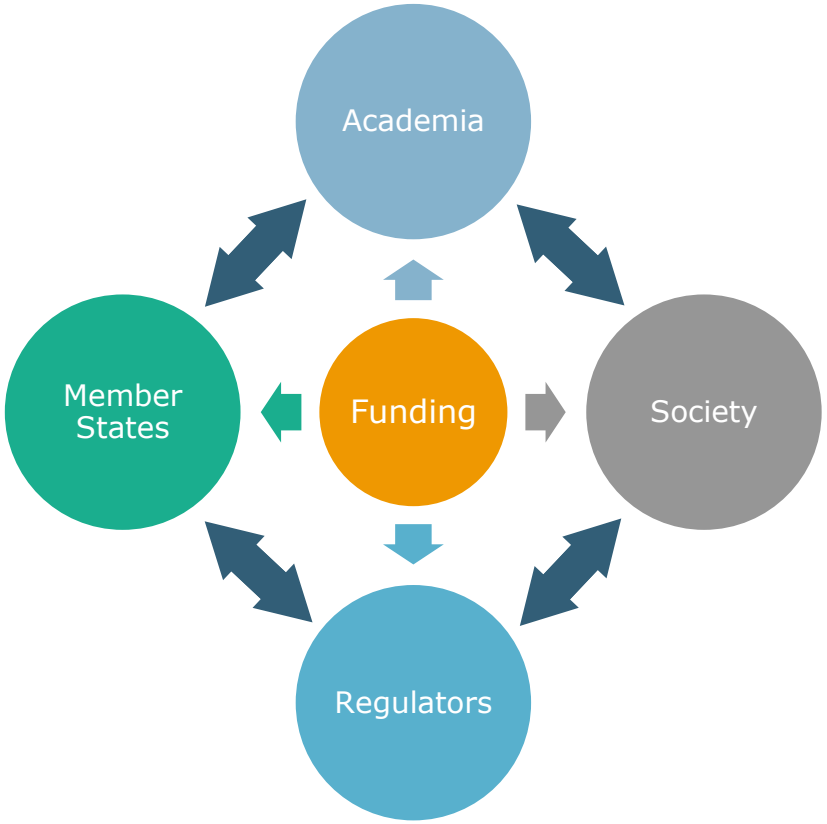
NAMs – draft Multiannual Plan



Opportunities and challenges

Vision, expectations and opportunities

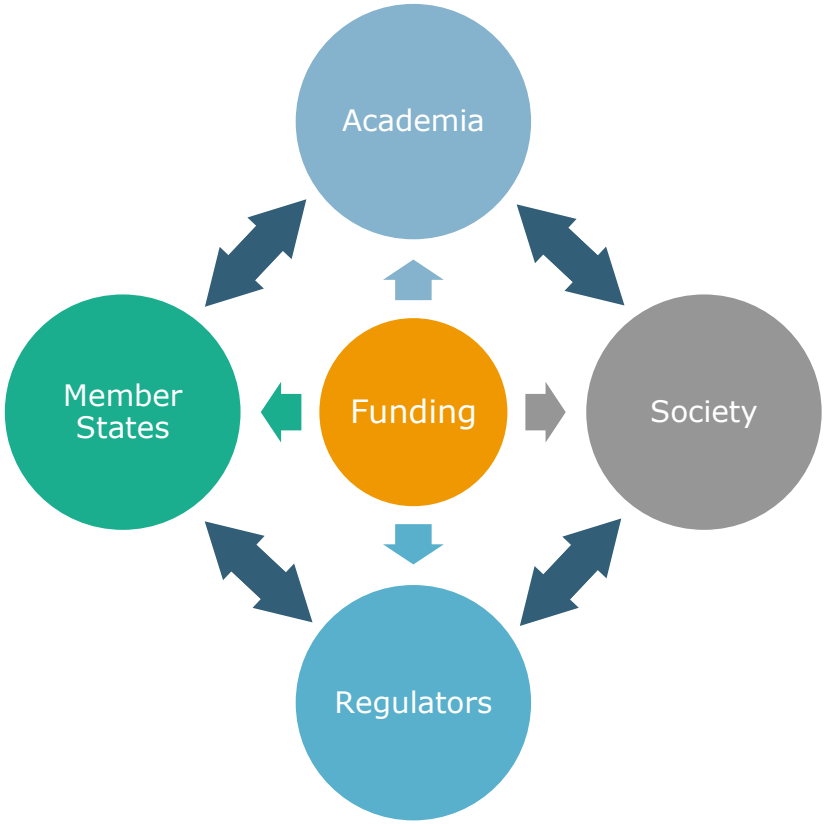
Collaboration, acceptability and sustainability



Opportunities and challenges

- First feedback received from 83rd AF Meeting: Many thanks!
- How can we **optimise** the interaction with ongoing and future projects
  - ILMERAC
  - APCRA
  - PARC
  - ASPIS cluster
  - EFSA calls
- How can we **strengthen** our collaborations and work together for NAM integration and capacity building?

Collaboration, acceptability and sustainability



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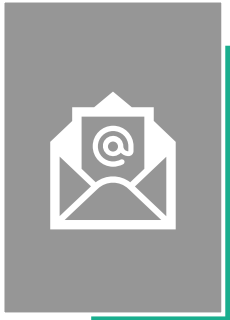

Contact us

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One2022.eu

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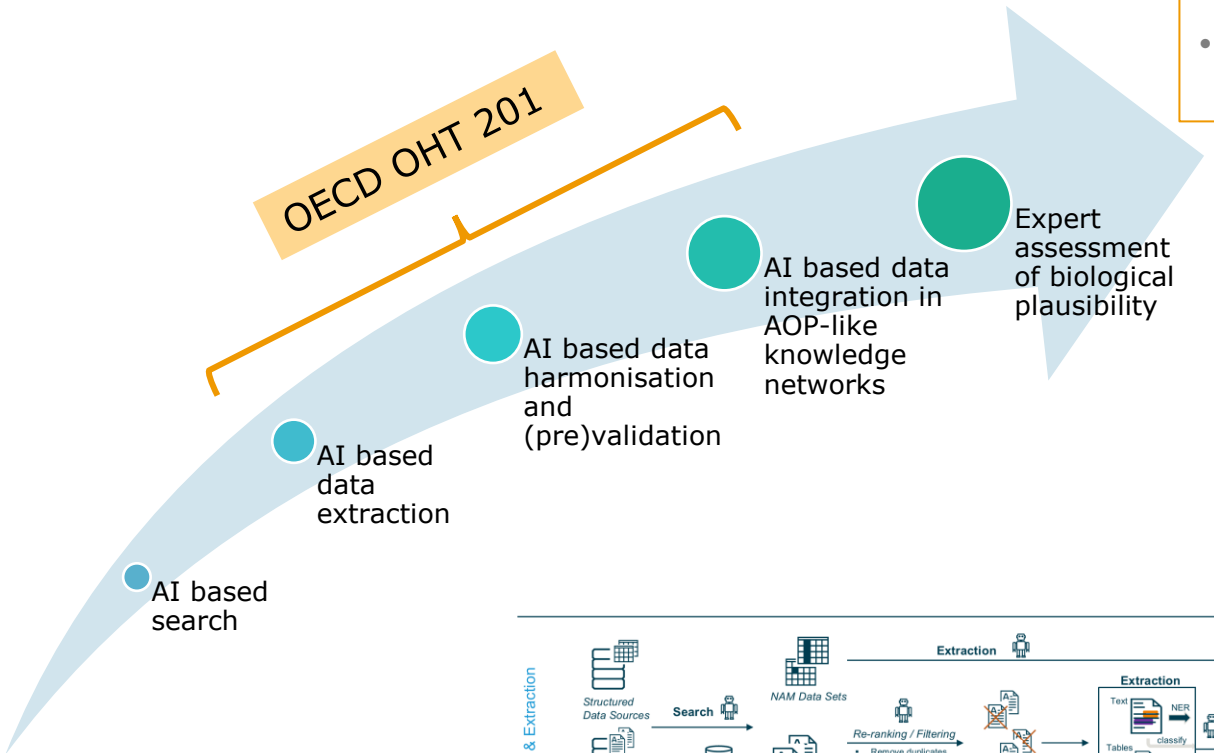
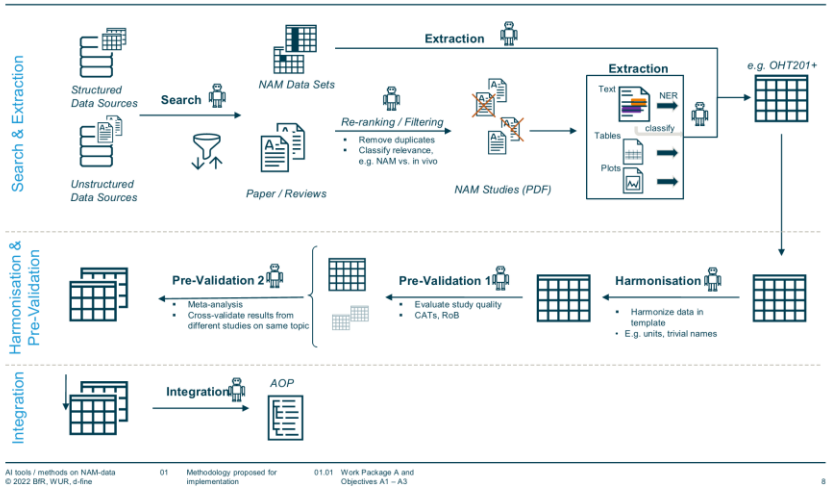
Annex: High-level details on ongoing NAMs projects
(slide 3)

- Pesticides, tebufenpyrad, neurotoxicity: AOP on Parkinsonian motor deficiencies
  - *In vitro* neurotox Reference Point + PBPK model for QIVIVE
- Nanofibres/GIT nanocellulose uptake and genotoxicity
  - "Classical" *in vitro* models and exploring Gut-on-a-Chip models
- Contaminants, PFAS, immunotoxicity
  - Identification of mode of action and relative potency
- Feed additives, essential oils, interspecies metabolic differences
  - Bioactivation and mixture effects

Annex: High-level details on ongoing NAMs projects
(slide 3 – AI for NAMs)

- Mechanistic knowledge
- Identification of data gaps





Cases focused on chemicals
- Pyrethroids (focus on neurotoxicity)
- Dioxins (covering the full group with TEFs)
- Phthalates
- Bisphenols

Cases focused on endpoints
- Liver toxicity (focus on pesticides)
- Hypothyroidism linked to endocrine disruption (focus on pesticides)

Next step:
Case study designs to be presented in June 2022

Annex: Written feedback received by AF on NAMs

MS	GENERAL	Project calls 2022	Collaboration Forum Platform
DK	Interest to apply to the calls and the platform depending on*	*the final call content	Yes (also in light of PARC)
GR		*deadline for submission *timelines *flexibility with non Art.36 Org	Yes
DE		Yes as a partner (not as coordinator)	Yes
FI		----	
IT		Interest from several Italian Art 36 Org and beyond	Yes