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Securing ASPIS sustainability through collaboration

Mathieu Vinken

Vrije Universiteit Brussel - Belgium

aspis-cluster.eu



Background

- Partnership for the assessment of risks from chemicals
- Public-public partnership (EU-national authorities)
- €400 million
- Over 200 partners
- 2022-2029

Objectives

- To establish an EU-wide sustainable cross-disciplinary network to identify and agree on research and innovation needs and to support research uptake into regulatory chemical risk assessment
- To set up joint EU research and innovation activities responding to identified priorities in support of current regulatory risk assessment processes for chemical substances and to emerging challenges
- To strengthen existing capacities and building new transdisciplinary platforms to support chemical risk assessment



Research collaborations

- SYNnet: various research projects
- ASPA workflow implementation
- Omics interpretation tools (TXG-MAPr)
- qAOPs
- Integration of NAMs in IATAs

Joint activities

- ASPIS Academy/PARC Junior Community



Background

- Developing and implementing virtual control groups to reduce animal use in toxicology Research
- Public-private partnership (Innovative Health Initiative)
- €27.8 million
- 33 partners
- 2024-2028



Objective

To replace animal control groups with virtual control groups by leveraging decades of historical data processed by statistics and cutting-edge artificial intelligence technologies



Research collaborations

- Benchmarking of *in vitro* tools
- Optimization of physiological maps
- Interspecies comparison
- Characterization of background pathologies
- Leveraging learning from regulatory qualification experience



Joint activities

- VICT3R-ASPIS webinars
- Joint conference session proposals

Background

- NAMS within integrated safety and efficacy evaluation of chemicals and pharmaceuticals
- €2 million
- 18 partners
- 2024-2027



Objective

To promote the adoption of NAMs for evaluating the safety and efficacy of chemicals and pharmaceuticals

Research collaborations

- PFOA probabilistic risk assessment
- PFAS multi-compound mechanistic study
- *In vitro*/AI liver steatosis and cholestasis prediction



Joint activities

- Joint workshop



Background

- Virtual human platform for safety assessment
- The Netherlands Organization for Scientific Research
- €11 million
- 33 partners
- 2021-2026



Objectives

- To improve the prediction of the potential harmful effects of chemicals and pharmaceuticals based on a holistic interdisciplinary definition of human health by developing the virtual human platform
- To accelerate the transition from animal-based testing to innovative safety assessment



Research collaborations (collaboration groups)

- qAOP
- TXG-MAPr integration (RISK-HUNT3R)
- Chemical selection
- Risk assessment
- Data management
- Stakeholder involvement
- IT-platforms



Joint activities

- VHP4Safety-ONTOX (early-stage researcher) webinars
- VHP4Safety-ONTOX meeting
- VHP4Safety-ONTOX hackathon
- VHP4Safety-ONTOX workshop



Background

- R&D for the EFSA NGRA regulatory framework
- Multiple projects
 - TD-TRAQ (€1.6 million)
 - ADME4NGRA (€3 million)
 - TXG-MAP (€5 million)
- 2022-2027

Objectives

- TD-TRAQ: to derive improved data-driven uncertainty/assessment factors for EFSA risk assessment reflecting human variability instead of conservative defaults
- ADME4NGRA: to improve human relevance of exposure and internal dose predictions to support NGRA with reduced animal testing
- TXG-MAP: to establish TXG-MAPr toolbox for *in vitro* test systems to support NAM-based gene-network-based metrics for hazard characterization, increasing confidence in NAM-based (non-animal) risk assessment



Research collaborations

- TXG-MAPr quantitative omics interpretation for hazard assessment
- Interindividual variability of hazard assessment
- QIVIVE methodologies for NGRA

Joint activities

- ASPA workflow integration
- Data interpretation tools
- Case study assessments



Other collaborations

- European Chemical Agency (ECHA)
- Organisation for Economic Co-operation and Development (OECD)
- US Food and Drug Administration (FDA)
- US Environmental Protection Agency (EPA)
- European Molecular Biology Laboratory (EMBL)
- US National Institutes of Health (NIH)
- Oak Ridge National Laboratory (ORNL)
- UK Department for Environment, Food & Rural Affairs (Defra)
- US National Toxicology Program (NTP)
- British Toxicological Society (BTS)
- European Partnership for Alternative Approaches to Animal Testing (EPAA)

Memorandum of understanding

- ASPIS-VICT3R
- ONTOX-University of Seoul-South Korea
- ONTOX-European Society of Toxicology *In Vitro*