

Programme

Workshop: Mapping Inflammation – Towards Predictive AOPs for Immune-Related Adverse Outcomes for Pharmaceuticals

9 September 2025, 9:00 – 16:00 CEST

Representation of Lower Saxony to the European Union, Rue Montoyer 61, B-1000 Brussels, Belgium

08:30

Registration & Coffee

09:00

Welcome & Introduction

Workshop goals, agenda & expected outcomes

Katherina Sewald (Fraunhofer ITEM) & Laure-Alix Clerbaux (UCLouvain)

09:15

Session 1: AOPs as Strategic Tools for Inflammatory Responses: Regulatory Point of View

Chair: Laure-Alix Clerbaux (UCLouvain)

- “The AOP Framework: Strategic Tools for Elucidating Biological Mechanisms” - *Clemens Wittwehr (JRC)* (25 min)
- “OECD’s Experience in AOP and NAMs Development: Regulatory Insights and Case Studies” - *Magdalini Sachana (OECD)* (25 min)

10:05

Coffee Break

10:30

Session 2: Inflammatory AOPs Used for Risk Assessment of Chemicals

Chair: Katherina Sewald (Fraunhofer ITEM)

- “Development of Immune-Related AOPs in PARC” - *Birgitte Lindeman (Norwegian Institute of Public Health)* (25 min)
- “Integrative Analysis of Silica-Associated Disease Mechanisms in the EXIMIOUS Project” - *Manosij Ghosh (KULeuven)* (25 min)
- “Nanoparticle-Induced Inflammation: Linking Exposure to Chronic Outcomes via AOPs” - *Sabina Halappanavar (Health Canada)* (25 min)

11:45

Session 3: Mapping inflammation with AOPs and NAMs for Biomedical Stressors - Part 1

Chair: Hannah Morgan (Novartis)

- “Inflammation – the next frontier in NAM development” *Thomas Hartung (John Hopkins Bloomberg School of Public Health)* (25 min)
- “Leveraging inflammatory AOPs in pandemic times: Insights from the CIAO COVID-19 Initiative” - *Laure-Alix Clerbaux (UCLouvain)* (25 min)

- “Developing In Vitro Models for Immune-Related Adverse Outcome Prediction: An Introduction to imSAVAR”- *Katherina Sewald (Fraunhofer ITEM)* (15 min)

12:45

Lunch Break

13:45

Session 3: Mapping inflammation with AOPs and NAMs for Biomedical Stressors - Part 2

Chair: Hannah Morgan (Novartis)

- “From Mechanism to Prediction: Integrating NAMs with AOPs in Complex Immunopathologies”- *Hannah Morgan (Novartis) and Miriam Alb (University of Wurzburg)* (20 min)
- “AOPs as an Integral Part of Labs-in-the-Loop for Improved Biomarkers in CAR T Cell Therapy” – *Kristin Reiche (Fraunhofer IZI)* (15 min)
- An explorable model of an adverse outcome pathway of cytokine release syndrome related to the administration of immunomodulatory biotherapeutics and cellular therapies – *Marek Ostaszewski (University of Luxembourg)* (15 min)
- “Synergies between Immunotherapy Safety and AOP/NAM Development” - *Scott Wagers (BioSci)* (15 min)
- Q&A and short discussion (10 min)

15:00

Breakout Session: Towards a Joint Perspectives Workshop Paper

Facilitated small groups work on:

- Mapping inflammation-related AOPs
- Mechanistic gaps & challenges
- NAMs integration
- Regulatory applicability

15:45

Wrap-Up & Next Step

Katherina Sewald (Fraunhofer ITEM) & Laure-Alix Clerbaux (UCLouvain)

- Summary from breakout groups
- Paper coordination
- Outlook for future collaboration

16:00

End

Join us as international experts to explore the **AOP framework** for predicting inflammation-driven toxicities by pharmaceuticals.