

## 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)
- Q&A and short discussion (10 min)

**10:15**

### 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)
- Q&A and short discussion (15 min)

**11:45**

### Lunch Break

**12:30**

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

*Chair: Hannah Morgan (Novartis)*

- "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)
- “From Mechanism to Prediction: Integrating NAMs with AOPs in Complex Immunopathologies”- *Hannah Morgan (Novartis) and Miriam Alb (University of Wurzburg)* (25 min)

**13:35**

### **Coffee Break**

**13:45**

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

*Chair: Hannah Morgan (Novartis)*

- 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)* (25 min)
- “Synergies between Immunotherapy Safety and AOP/NAM Development”- *Scott Wagers (BioSci)* (25 min)
- Q&A and short discussion (25 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.