

Welcome and introduction

Introduction to the Platform and agenda topics



Liese Barbier

European Platform for
Regulatory Science
Research Lead

EMA

Join at
slido.com
#RSR2025

🕒 Passcode: 20052025

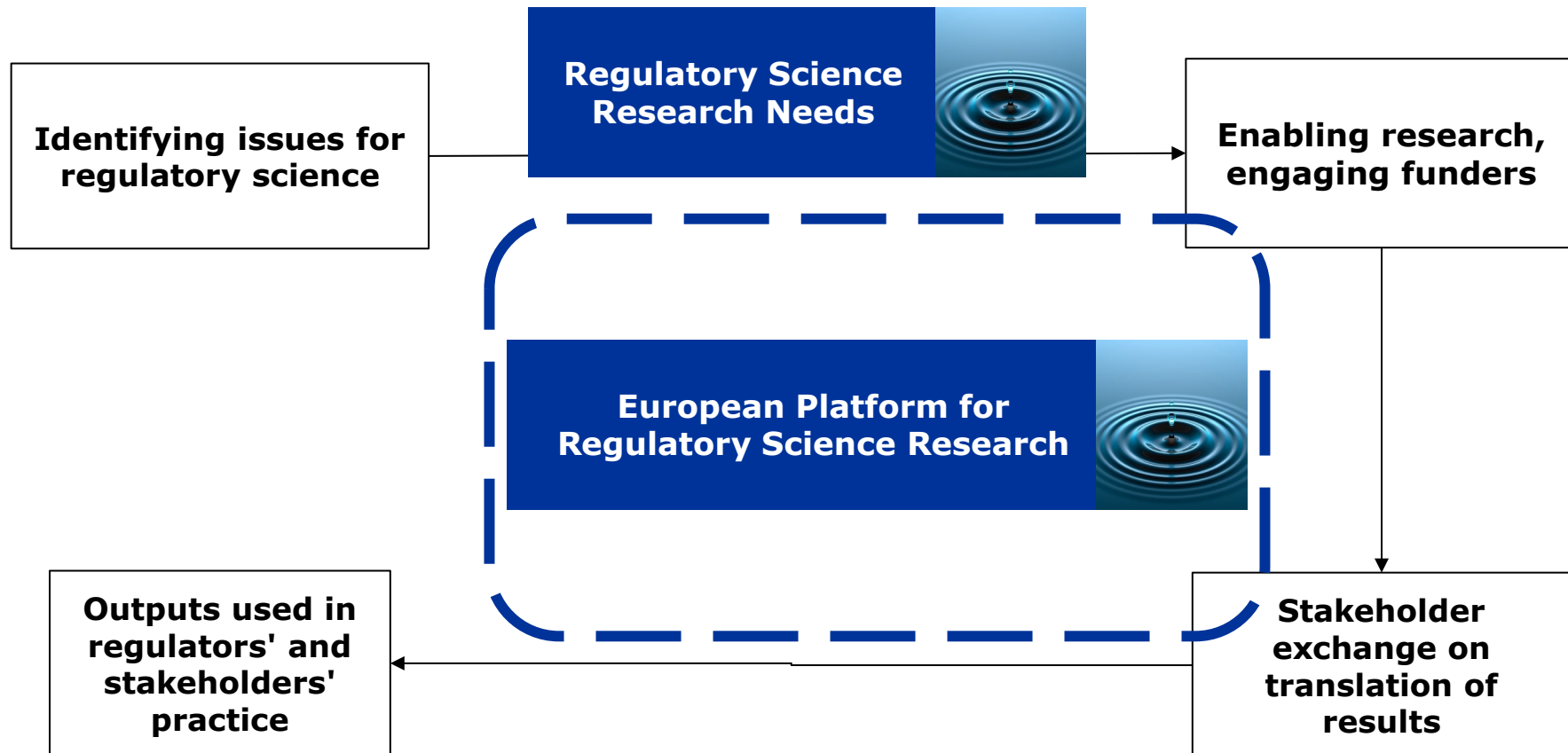


Introduction to the European Platform for Regulatory Science Research and Agenda topics

Liese Barbier

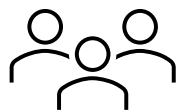


A strategic approach to Advancing regulatory science research



- Develop partnerships with academic / research centers to undertake research in strategic areas of regulatory science
- Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions





Q1 2024

Landscaping of
academic groups



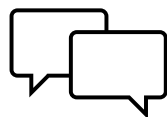
Q2-3 2024

EMA and network
consultations



Q2-3 2024

Draft concept
paper development



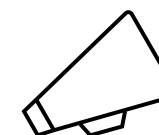
Q4 2024

Public event
18 November 2024



Q4 2024

Public consultation
concept paper



Q4 2024

Call for Expression
of Interest



Q1 2025

Nomination of
Steering group
members



Q1-2 2025

Steering group
meetings



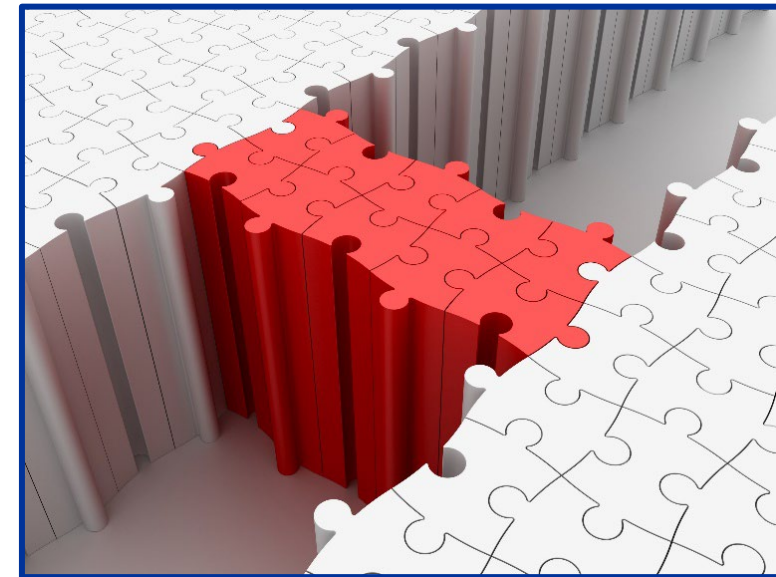
Q2 2025

**First Platform
meeting**

European Platform for Regulatory Science Research

A mechanism for dialogue and collaboration between academic, public and not-for-profit regulatory science researchers and regulators

- To systematically **advance and accelerate research** addressing regulatory needs
- To refine and enrich regulatory topics with **research interests** and **methods expertise**
- To progress methodological standards and increase **usefulness** of research outputs for implementation
- To accelerate **translation of outputs** into improved R&D and regulatory practices
- To support **growth of academic researcher community** engaging on regulatory issues



Opportunities for researchers

- Inform **research agenda** with needs of regulators
- Increase **visibility** and **exchange** on scientific and regulatory science activities at EU level
- Facilitate **projects and collaborations** with researchers from other groups and regulators
- Increase **awareness and familiarity** with initiatives and support of European regulators
- Increase **awareness** on regulatory science research **within researchers' institutions**
- Increased **capacity and competencies** for regulatory science research

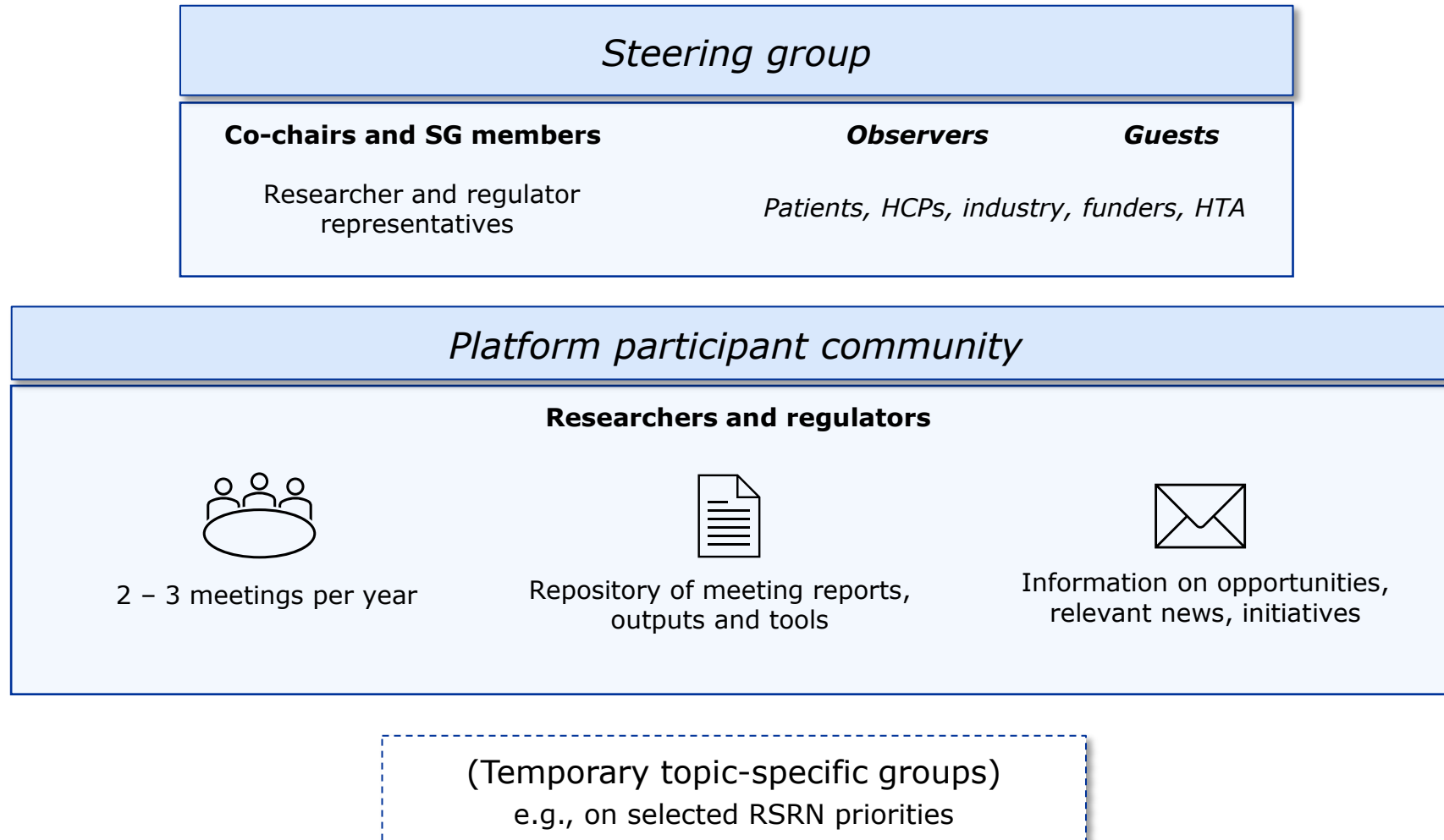
Research outputs with increased translational value and impact on regulatory practice *and public health*

Benefits for the regulatory system

- Enrich regulatory science needs with **views** from **stakeholders** including scientists and researchers
- Stimulate researchers to address and take up **regulatory science research questions deemed important by regulators** into their work (e.g., in grant proposals, PhD programs, collaborations...)
- **Streamlined** research **efforts**, increased efficiency, and outputs consolidation



Working model



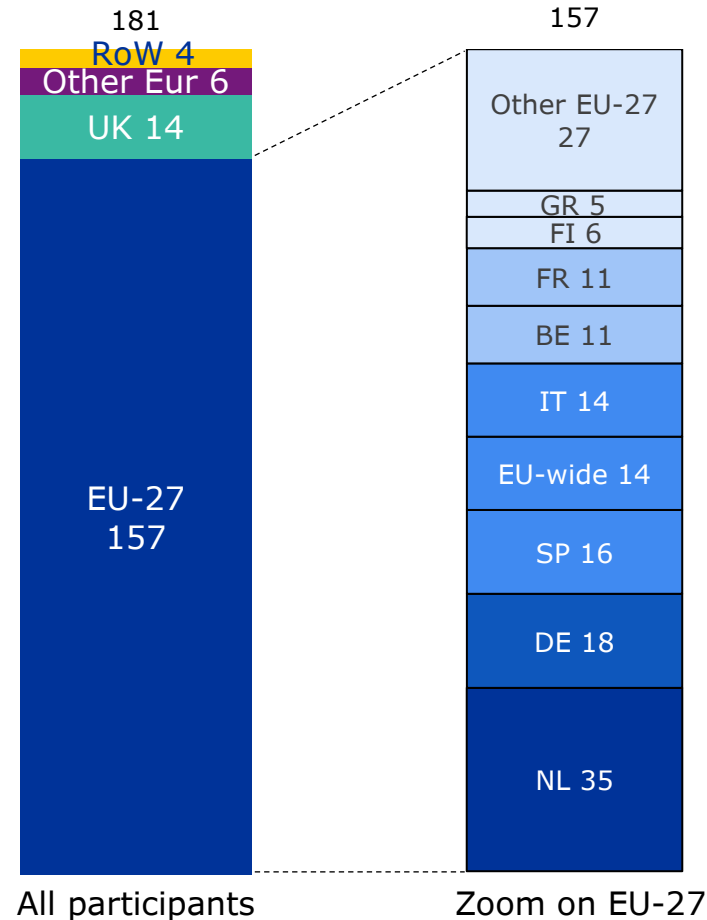
The Platform's Steering group

- Adam Hacker (CEPI) (Co-chair)
- Ronette Gehring (Utrecht University)
- Madeline Pe (EORTC)
- Marjon Pasmooij (MEB, Co-chair)
- Kit Roes (MEB, Methodology WP)
- Günter Waxenecker (AGES)
- Ralf Herold (EMA, Co-chair)
- Liese Barbier (EMA, Platform Lead)
- Ivana Silva (EMA)
- Frank Petavy / Andrew Thomson (EMA)
- Steffen Thirstrup (EMA)



The Platform's growing community

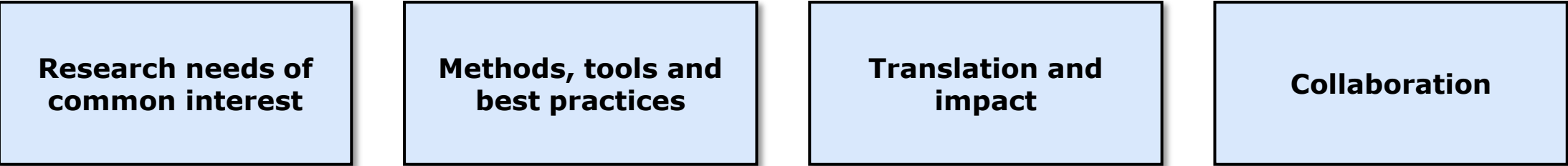
Around 180 and counting



Pharmacometrics Regulatory – academic
Platform trials Regulatory sandbox collaboration
Funding opportunities Medical devices
Digital technologies Modeling
Patient experience data ATMPs Rare diseases
Real world data Accelerated pathways
Clinical trial methodology New approach methodologies
Nanomedicines Academic drug development
Regulatory – HTA interface AI & machine learning
Uncertainty communication
Benefit risk methodologies
Antimicrobial resistance Vaccines
Data availability and sharing
Biomarker validation
...

Discussion topics for Platform meetings

Platform topic repository



EMA RSRN



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 November 2024
EMA/510633/2024

Regulatory Science Research Needs
2024 update - DRAFT

Table 1: Overview on 2024 updated of RSRNs

Sections with Research needs to ...
2.2. ...improve clinical research
2.3. ...improve regulatory system evolution
2.4. ... foster technologies for development of specific types of medicines
2.5. ... advance specifically animal health and the regulation of veterinary medicines

1.2. RSRN opportunities for researchers

Your input

Form for Expression of interest to participate in the Platform participant group and meetings

Your name	
Your organization	
Your institutional email address and website	
The EU/EEA member state where your organisation is located	
Information on your (regulatory science) research lines	
Proposed topic(s) to bring into and hear about in the platform	
Any additional information you would like to include	

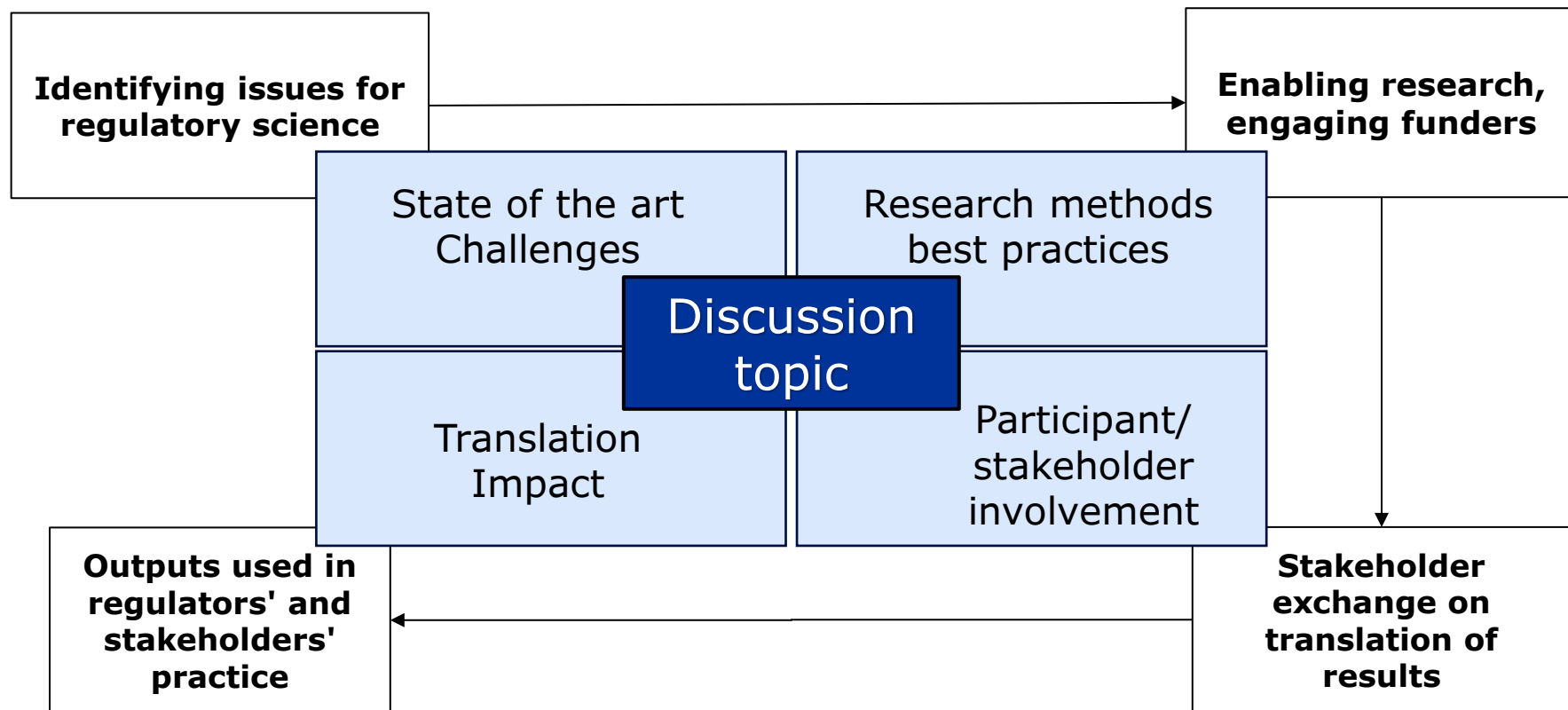
The submission of the completed form to regulatory.science@ema.europa.eu is encouraged by 24 January 2025, but the call will remain open over the course of 2025.

All personal data provided within this questionnaire will be processed in accordance with Regulation (EU) 2018/1725 on the protection of individuals regarding the processing of personal data by the Union institutions and bodies on the free movement of such data.

This data protection statement provides details on how the Agency, in its capacity as data controller, will process the information that you have given in your questionnaire.

Your consent to the processing of your data

A structured discussion approach



Today's discussion topics

Research need of common interest (EMA RSRN)

Session 1:

Perform studies to develop optimal PK (and PD) designs in children to support extrapolation from adults': *starting point* pharmacological modelling research

- Topic mapping and introduction
- Researcher perspective on state, gaps and opportunities
- Open discussion and questions

Methods, tools and best practices

Session 2:

Use of regulatory data in research projects: *spotlight on the assessment report*

- Topic mapping and introduction
- Methodological learnings from case examples
- Open discussion and questions