EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment

8 – 9 October 2025

Hybrid meeting - Room 1C/ Webex, EMA, Amsterdam

Background and objectives

Mechanistic models are increasingly being used to support the development of medicinal products for human use. The regulatory assessment of mechanistic models is focussed on determining whether the models are qualified for their intended use. Guidance documents on the requirements for reporting on and qualification of mechanistic models, covering different types of models (physiologically based pharmacokinetic models and quantitative systems pharmacology models) are currently being developed or updated.

This multistakeholder workshop will bring together academia, regulators and industry to discuss the experience with the current regulatory landscape around the application of mechanistic models to support drug development.

The aims of the workshop are to:

- Hear the views of stakeholders and experts on the current regulatory framework around the assessment of mechanistic models.

- Share the regulatory challenges associated with the assessment of mechanistic models with stakeholders and experts.
- Identify opportunities for future regulatory qualification of mechanistic models.
- Define how the current EU regulatory framework can be refined to streamline the use and assessment of mechanistic models.

A video recording will be published after the event.

EMA Multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment

Day 1 – 8 October 2025, 10:00 – 17:00 (CEST)

Chaired by Flora Musuamba Tshinanu (FAMHP, BE)

09:30 Joining and technical checks

10:00 Welcome and opening speech

Welcome **5'**
Iordanis Gravanis (EMA)

Presentation **5'**
Peter Arlett (EMA)

10:10 Session 1: Regulatory assessment of mechanistic models

This session will introduce key concepts and paths for regulatory assessment and acceptance of mechanistic models.

Chairs: Efthymios Manolis (EMA) & Flora Musuamba Tshinanu (FAMHP, BE)

Risk-based approach for model assessment **20'**
Flora Musuamba Tshinanu (FAMHP, BE)

EU regulatory paths to acceptance of a mechanistic model **10'**
Efthymios Manolis (EMA)

10:40 Session 2: Evaluation of predictive performance of mechanistic models for regulatory decision making: acceptance criteria, performance metrics, uncertainty quantification

In this session topics related to methods and tools used for platform qualification will be addressed.

Chair: Pieter Colin (EMA)

Topics to be confirmed **60'**
tbc

Panel discussion **50'**

Additional panellists:
tbc

12:30 **Lunch**

13:30 **Session 3: The qualification of mechanistic models through the EMA qualification framework and beyond.**

In this session EMA wishes to interact with its stakeholders on the current landscape around the qualification of mechanistic models to support regulatory decision making. Topics covered during the session may include: Evaluation of platform performance and qualification for specific Context-of-Use (for definition see EMA PBPK guideline) including the standards for benchmarking performance and reproducibility, required level of external evidence, reporting SOPs, version control and software product life cycle.

Chairs: tbc

Topics to be confirmed **60'**
tbc

Panel discussion **30'**

Additional panellists:
tbc

15:00 **Coffee break**

15:30 **Session 3: continued.**

Topics to be confirmed **60'**
tbc

Panel discussion **30'**

Additional Panellists:

tbc

17:00 **Closing remarks**

Wrap up **5'**
Pieter Colin

17:05 **End of day 1**

Day 2 – 9 October 2025, 9:00 – 16:10 (CET)

Chaired by Flora Musuamba Tshinanu (FAMHP, BE)

08:45 Joining and technical checks

09:00 Session 4: Mechanistic models for the future; challenges & opportunities in the context of Model-Informed Drug Development & risk assessment

In this session applications of mechanistic models that are expected to have a high impact in future regulatory submissions will be discussed. Topics covered may include: PBPK for special populations (e.g. pregnancy, lactation, children), QSP for rare diseases, other.

Chair: tbc

Topics to be confirmed **90'**
tbc

10:30 Coffee break

11:00 Session 4: continued

Chair: tbc

Topics to be confirmed **30'**
tbc

Panel discussion **60'**

Additional panellists:
tbc

12:30 Lunch

13:30 Session 5: Regulatory guidance on mechanistic models, gaps & challenges in guidance documents

The aim of this session is to critically review the current EMA guidance on mechanistic models and identify areas for improvement.

Chairs: tbc

EMA/EMRN perspective **20'**
tbc

Academic perspective **20'**
tbc

Industry perspective **20'**
tbc

International regulator's perspective **20'**
tbc

	Panel discussion	**60’**
	Additional panellists: *tbc*	

15:50 Closing remarks

	Wrap up *tbc*	**20’**

16:10 End of day 2