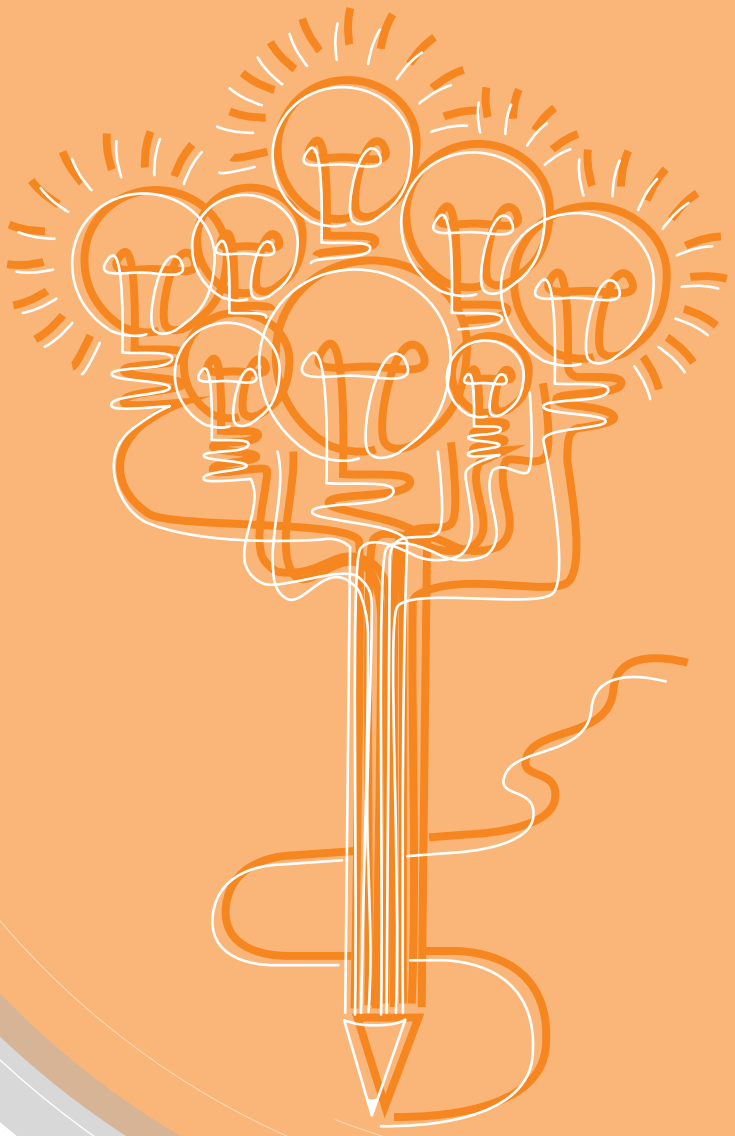


EMA Regulatory Science to 2025
Post-Public Consultation Human Stakeholders Workshop

18 – 19 November 2019

European Medicines Agency
Amsterdam, The Netherlands

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Objectives of the meeting

Further to last year's workshop and a very successful public consultation, we are pleased to inform you of the upcoming multi-stakeholders workshop entitled "EMA Regulatory Science to 2025" which will take place on 18th and 19th November 2019.

The objectives of this workshop are to:

- share the outcome and key messages from the analysis of the public consultation;
- reflect on the likely prioritisation of core recommendations EMA's Regulatory Science Strategy to 2025; and
- identify concrete actions in order to implement the key core recommendations.

Please note that only a sub-set of core recommendations and actions across the strategic goals have been selected to be discussed within the workshop format. These have been selected primarily based on stakeholders' priority ranking of the core recommendations as well as the degree of comments/suggestions received on the underlying actions and proposals for further actions. However, very constructive feedback has also been received on the remaining core recommendations and underlying actions. These will be addressed post workshop such that the final RSS strategy document will present a holistic outcome of the public consultation as well as revised/extended action listings for all core recommendations.

Programme Overview

Session 1	Overview of the outcome of the public consultation on EMA's Regulatory Science Strategy to 2025
Session 2	ATMPs and precision medicine
Session 3	Developing scientific advice/assessment pathways and optimising evidence incl. RWD for decision making and communication
Session 4	Clinical trials, digital therapeutics and modelling & simulation
Session 5	Reinforcing patient relevance in evidence generation and developing research partnerships with academia
Session 6	Feedback from breakout sessions
Session 7	Emerging health threats, AMR and vaccines
Session 8	Feedback from breakout sessions

Organising Committee

Scientific Coordination Board (SciCoBo):

Martina Schussler-Lenz	CAT Chair, *Paul-Ehrlich-Institut (PEI), Germany*
Harald Enzmann	CHMP Chair, *Federal Institute for Drugs and Medical Devices (BfArM), Germany*
Laura Oliveira Santamaria	CMDh Chair, *Agencia Española del Medicamento y Productos Sanitarios (AEMPS), Spain*
Violeta Stoyanova-Beninska	COMP Chair, *Medicines Evaluation Board (MEB), Netherlands*
Marisa Delbò	HMPC Chair, *Agenzia Italiana del Farmaco (AIFA), Italy*
Koenraad Norga	PDCO Chair, *Universitair Ziekenhuis Antwerpen, Belgium*
Sabine Straus	PRAC Chair, *Medicines Evaluation Board (MEB), Netherlands*
Anja Schiel	SAWP Chair, *Norwegian Medicines Agency (NOMA), Norway*

European Medicines Agency (EMA):

Hans-Georg Eichler	Senior Medical Officer
Enrica Alteri	Human Medicines Research & Development Support Division
Zaïde Frias	Human Medicines Evaluation Division
Fergus Sweeney	Inspections, Human Medicines Pharmacovigilance & Committees Division
Melanie Carr	Stakeholders & Communication Division
Tony Humphreys	Scientific Committees Regulatory Science Strategy Division

DAY ONE

18 November 2019 – meeting room 2A

13:00 – 13:20 Welcome and introductions

***Guido Rasi**, Executive Director, EMA*
***Florian Schmidt**, DG Santé, EC*

13:20 – 14:10 Session 1: Overview of the outcome of the public consultation on Regulatory Science Strategy to 2025

***Tony Humphreys**, EMA*

14:10 – 15:30 Session 2: ATMPs and precision medicine

Overview of underlying actions for the following core recommendations

- Support developments in precision medicine, biomarkers and 'omics
- Support translation of advanced therapy medicinal products (ATMPs) into patient treatments

Discussion session to review underlying actions

***Martina Schussler-Lenz**, CAT*
***Ana Hidalgo-Simon**, EMA*

15:30 – 15:50 Coffee break

15:50 – 18:00 Session 3: Developing scientific advice/assessment pathways and optimising evidence incl. RWD for decision making and communication

Parallel breakout sessions A & B

Breakout session A: Developing scientific advice/assessment pathways

- Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products
- Diversify and integrate the provision of regulatory advice along the development continuum

***Anja Schiel**, SAWP / **Koenraad Norga**, PDCO*
***Spiros Vamvakas**, EMA / **Armin Ritzhaupt**, EMA*

Breakout session B: Optimising evidence incl. RWD for decision making and communication

- Contribute to HTAs' preparedness and downstream decision making for innovative medicines
- Bridge from evaluation to access through collaboration with payers
- Expand benefit-risk assessment and communication
- Promote use of high-quality real-world data (RWD) in decision making

***Sabine Straus**, PRAC / **Violeta Stoyanova-Beninska**, COMP*
***Peter Arlett**, EMA / **Michael Berntgen**, EMA*

18:00 – 20:00 Refreshments

DAY TWO

19 November 2019 – meeting room 2A

08:30 – 10:00 Session 4: Clinical trials, digital therapeutics and modelling & simulation

Overview of underlying actions for the following core recommendations

- Foster innovation in clinical trials
- Develop the regulatory framework for emerging clinical data generation
- Optimise capabilities in modelling, simulation and extrapolation

Discussion session to review underlying actions

***Bruno Sepodes**, CHMP / **Anja Schiel**, SAWP*
***Francesca Cerreta**, EMA / **Efthymios Manolis**, EMA / **Ina-Christine Rondak** , EMA*

10:00 – 10:20 Coffee break

10:20 – 12:30 Session 5: Reinforcing patient relevance in evidence generation and developing research partnerships with academia

Parallel breakout sessions C & D

Breakout session C: Reinforcing patient relevance in evidence generation

- Reinforce patient relevance in evidence generation
  ***Bruno Sepodes**, CHMP / **Koenraad Norga**, PDCO*
  ***Juan García Burgos**, EMA / **Ralf Herold**, EMA*

Breakout session D: Developing research partnerships with academia

- Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science
  ***Sabine Straus**, PRAC / **Violeta Stoyanova-Beninska**, COMP*
  ***Hans Georg Eichler**, EMA / **Corinne de Vries**, EMA*

12:30 – 13:30 Lunch break

13:30 – 14:40 Session 6: Feedback from breakout sessions

Feedback of Breakout session A

***Anja Schiel**, SAWP / **Koenraad Norga**, PDCO*

Feedback of Breakout session B

***Sabine Straus**, PRAC / **Violeta Stoyanova-Beninska**, COMP*

DAY TWO

19 November 2019 – meeting room 2A

14:40 – 16:10 Session 7: Emerging health threats, AMR and vaccines

Overview of underlying actions for the following core recommendations

- Continue to support development of new antibacterial agents and their alternatives
- Support innovative approaches to the development, approval and post-authorisation monitoring of vaccines

Discussion session to review underlying actions

***César Hernández García**, HMA*
***Marco Cavaleri**, EMA*

16:10 – 16:30 Coffee break

16:30 – 17:40 Session 8: Feedback from breakout sessions

Feedback of Breakout session C

***Bruno Sepodes**, CHMP / **Koenraad Norga**, PDCO*

Feedback of Breakout session D

***Sabine Straus**, PRAC / **Violeta Stoyanova-Beninska**, COMP*

17:40 – 18:00 Delivering the strategy

Practical information

Attendance in breakout sessions

Please note that the breakout sessions will be held as follows:

- Breakout sessions A & B will be held in parallel on Monday 18 November 2019
- Breakout sessions C & D will be held in parallel on Tuesday 19 November 2019

Live broadcast

- The workshop will be live streamed (both the plenary and the breakout sessions). Please follow the link in the Multimedia tab on the event page. No registration or password is required.
- Please note that Remote participants are encouraged to submit comments by email to RegulatoryScience2025@ema.europa.eu or via Twitter on #RegScience2025.

Recording and photography

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on the European Union. By attending this meeting you consent to any photographing, recording, broadcast and publication of presentations on EMA website.

WiFI Access

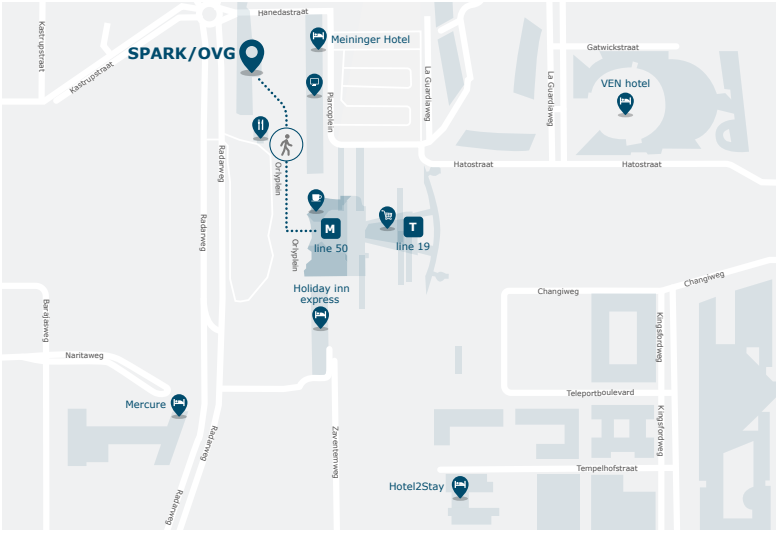
WiFi is available throughout EMA. Login details can be found on the back of your EMA access pass.

Getting to the Spark

EMA is located in Amsterdam Sloterdijk.

Please find below a map of the area.

Directions to European Medicines Agency and map of the area



Practical information

Contact

Should you have any questions, please contact Laetitia Kpenou via RegulatoryScience2025@ema.europa.eu

Physical disability

Let us know if you would like any specific help or information that would make your stay more comfortable. We will be very happy to help.

Registration

We advise you to arrive at least half an hour before the start of the workshop (i.e. at 12:30) to allow sufficient time for registration and settling down.

Presentations

We will not circulate printouts of speakers' presentations beforehand. However, a workshop brief including the details of the core recommendations for discussion as well as the underlying actions identified in the draft strategy document and in the public consultation will be circulated.

Catering

Drinks will be provided on 18th November 2019 and lunch will be provided on the 19th November 2019 for all delegates free of charge to allow opportunities for discussion and networking.

Workshop venue

European Medicines Agency
Spark building
Orlyplein 24
1043 DP Amsterdam
The Netherlands
Telephone: +31 (0)88 781 6000
Organiser: RegulatoryScience2025@ema.europa.eu