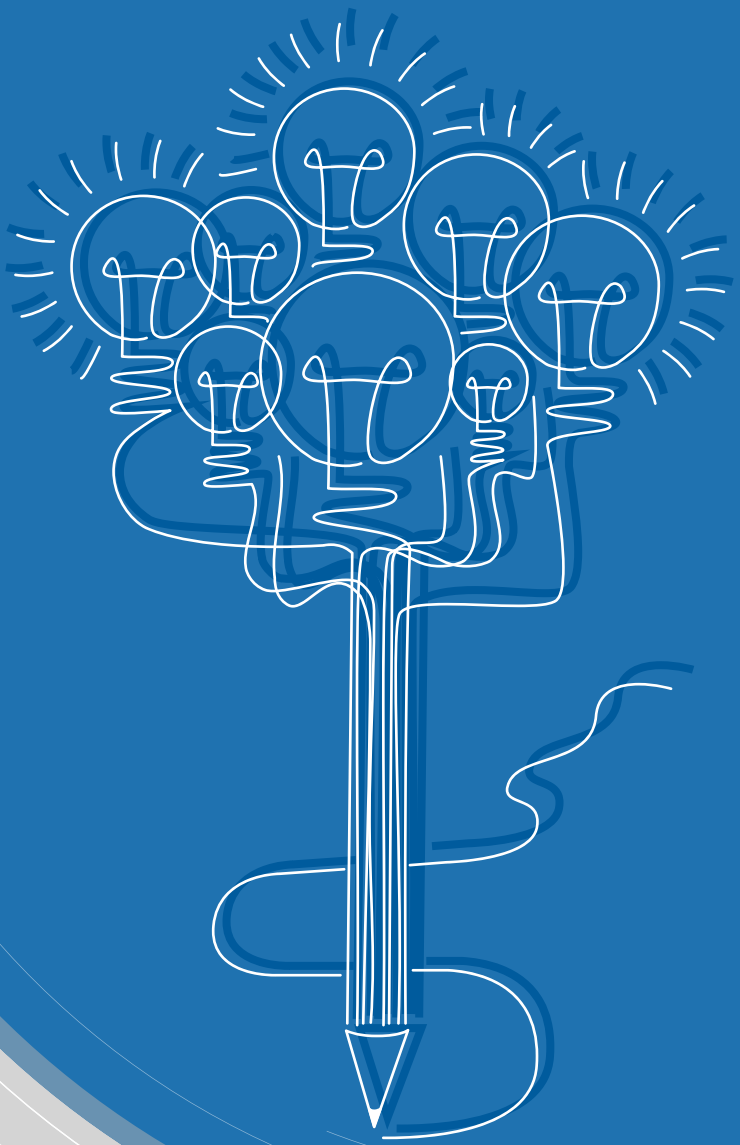

EMA - Regulatory Science to 2025

Launch of Human Stakeholder Consultation

Wednesday, 24 October 2018

European Medicines Agency
London, United Kingdom

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Background and objectives

The European Medicines Agency (EMA) is holding a multi-stakeholder workshop on 24 October 2018 aiming to gather initial thoughts on the key areas to be covered in the current reflection on EMA's Regulatory Science to 2025.

On this occasion, we will share the proposals for human medicines. This should facilitate:
1- a shared reflection on the key regulatory science challenges faced by the various scientific committees and working parties of the Agency and opportunities to address these;
2- an understanding of the process by which the proposed strategic goals and core recommendations were elaborated to date;
3- highlighting areas that are of particular relevance to various stakeholder groups to focus on during the public consultation.

Arrival at the Agency and registration

On arriving for your meeting at 30 Churchill Place, please report to reception where you will be issued with an access pass. This pass will allow you to enter our industry lounge, which you are welcome to utilise during your visit. The industry lounge is located through the sliding doors to the right of the reception desk past the security turnstiles. Your EMA contact point will meet you there.

We strongly advise you to arrive up to 30 minutes before the start of the info day, to allow you time for registration. Please note that the Agency requires all visitors to provide a valid photo ID on arrival, such as passport, identity card or driving licence. Participants without a valid photo ID may be turned away.

Media disclaimer

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 European Union.
The Agency herewith informs attendees that this particular meeting will be recorded and broadcast. For more information about processing of personal data by EMA, please visit the: www.ema.europa.eu or contact dataprotection@ema.europa.eu

By attending this meeting you consent to any recording or broadcast.

Venue

European Medicines Agency
30 Churchill Place, Canary Wharf
London E14 5EU,
United Kingdom

Telephone +44 (0)20 3660 6000
E-mail: RegulatoryScience2025@ema.europa.eu
Website: www.ema.europa.eu

Wednesday 24th October 2018, 08:30 - 17:30 - meeting room 3A and 3M

Welcome and introductions ..... / *8:30*

- *Guido Rasi, Executive Director, EMA / 10'*

Session 1: Responding to the needs of the 21st century Patient. Addressing challenges and opportunities across the European Regulatory Framework ..... / 8:40

- EMA's Regulatory Science Response / *20'*
  Hans-Georg Eichler, EMA
- View from the patient / *10'*
  Simone Boselli, EURORDIS
- *View from the European Parliament/ 10'*
  Biljana BORZAN, European Parliament
- *View from the European Commission / 10'*
  Olga Solomon, European Commission
- View from European Medicines Regulatory Network (EMRN) / *10'*
  Karl Broich, HMA Management Group
- View from the innovator / *10'*
  Alan Morrison, EFPIA

Session 2: Catalysing the integration of science & technology in drug development ..... / *09:50*

- Catalysing the integration of science & technology in drug development / 20'
  Enrica Alteri, EMA
- Questions and panel discussion / 50'
  Panellists:
  Sue Forda, EFPIA
  Emma Du Four, EuropaBio
  Maria Pascual, EBE
  Dario Pirovano, MedTechEurope
  Maud Perrudin, AESGP
  Esa Heinonen, Co-Chair EU Innovation Network

Coffee break ..... / *11:00*

Session 3: Driving collaborative evidence generation – Improving the scientific quality of evaluations ..... / 11:10

- Driving collaborative evidence generation through use of: Modern trials and Data and digitalisation - Improving the scientific quality of evaluations / 20'
  Zaide Frias, EMA
- Questions and panel discussion / *70'*
  Panellists:
  Kieran Breen, European Parkinson's Disease Association (EPDA)
  Giovanni Tafuri, EUnetHTA
  Daniel Swerdlow, BenevolentAI
  Jan Bogaerts, European Organisation for Research and Treatment of Cancer (EORTC)
  Peter van Meer, Regulatory Science Network Netherlands
  Mark Hope, EFPIA

Lunch break ..... / *12:40*

Session 4: Advancing patient-centred access to medicines in partnership with healthcare systems ..... / 13:40

- Advancing patient-centred access to medicines in partnership with healthcare systems / 20'
  Michael Berntgen, EMA
- Questions and panel discussion / 60'
  Panellists:
  Christine Meyer-Nicolai, EFPIA
  Fosca De Iorio, EUCOPE
  Francois Houyez, EURORDIS
  Beata Stepniewska, Medicines for Europe
  Gonzalo Calvo, HCPWP
  Niklas Hedberg, EUnetHTA
  Ad Schuurman, Medicine Evaluation Committee (MEDEV)

Session 5: Addressing emerging health threats and availability/therapeutic challenges / *15:00*

- Addressing emerging health threats and availability/therapeutic challenges / 20'
  Marco Cavaleri, EMA
- Questions and panel discussion / 30'
  Panellists:
  Marie-Pierre Preziosi, WHO
  Michel Stoffel, Vaccines Europe
  Henrik Kim Nielsen, EFPIA
  John Rex, F2G Limited
  Julien Veys, Medicines for Europe
  Helene Guillard, AESGP

Coffee break ..... / *15:50*

Session 6: Enabling and leveraging research and innovation in regulatory science...../ *16:10*

- Enabling and leveraging research and innovation in regulatory science / 20'
  Alison Cave, EMA
- Questions and panel discussion / 40'
  Panellists:
  Stéphane Hogan, European Commission
  Serena Scollen, ELIXIR
  Olaf Klungel, University of Utrecht
  Luca Sangiorgi, European Reference Networks Research Working Group
  Erik Steinfelder, BBMRI-ERIC
  Wiebke Löbker, EU Innovation Network

Closing remarks ..... / *17:10*

- *Tony Humphreys, EMA / 20'*

List of sessions & proposed core recommendations

Session 1 Responding to the needs of the 21st century Patient – Addressing challenges and opportunities across the European Regulatory Framework Enabling and leveraging research and innovation in regulatory science

Session 2 Catalysing the integration of science & technology in drug development

- *Diversify and integrate the provision of regulatory advice along the development continuum*
- *Promote and invest in the PRIME scheme*
- *Support developments in precision medicine, biomarkers and 'omics'*
- *Create an integrated evaluation framework for the assessment of Medical Devices, IVDs and borderline products*
- *Support the translation of cell, genes and tissue based products into patient treatments*
- *Facilitate the implementation of novel manufacturing technologies*
- *Develop understanding of and regulatory response to nanotechnology and new materials' utilisation in pharmaceuticals*

Session 3 Driving collaborative evidence generation – Improving the scientific quality of evaluations

- *Leverage novel non-clinical models and 3Rs*
- *Optimise capabilities in modelling and simulation and extrapolation*
- *Foster innovation in clinical trials*
- *Develop the regulatory framework for emerging clinical data generation*
- *Expand benefit-risk assessment and communication*
- *Invest in special populations initiatives*
- *Exploit digital technology and artificial intelligence in decision-making*

Session 4 Advancing patient-centred access to medicines in partnership with healthcare systems

- *Promote use of high quality real world data in decision-making*
- *Develop network competences and specialist collaborations to engage with "big data"*
- *Enable HTAs' preparedness and downstream decision-making for innovative medicines*
- *Share impact assessments of major therapeutic innovations with Payers*
- *Reinforce patients involvement in medicines development*
- *Deliver real-time electronic Product Information (ePI)*
- *Promote the uptake of biosimilars in the healthcare system*
- *Further develop external communications to promote trust and confidence in the EU regulatory system*

Session 5 Addressing emerging health threats and availability/therapeutic challenges

- *Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches*
- *Continue to support development of new antimicrobials and their alternatives*
- *Promote global cooperation to anticipate and address supply challenges*
- *Support innovative approaches to the development and post-authorisation monitoring of vaccines*
- *Support the development and implementation of a repurposing framework*

Session 6 Enabling and leveraging research and innovation in regulatory science

- *Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science*
- *Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions*
- *Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders*
- *Identify and enable access to the best expertise across Europe and internationally*

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*
Dirk Mentzer	*PDCO Chair, Paul-Ehrlich-Institut (PEI), Germany*
Sabine Straus	*PRAC Chair, Medicines Evaluation Board (MEB), Netherlands*
Robert James Hemmings	*SAWP Chair, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom*

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*
Alexis Nolte	*Information Management Division*
Melanie Carr	*Stakeholders & Communication Division*
Anthony Humphreys	*Scientific Committees Regulatory Science Strategy Division*
Marie-Helene Pinheiro	*Industry Stakeholders' Liaison - Corporate Stakeholders*

Practical information

WiFi access

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

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 08:00) to allow sufficient time for registration and settling down. Registration will take place in the foyer on the 3rd floor.

Meeting room

There is no seating plan in the room except for a number of reserved seats for the speakers, panellists and chairs of the workshop.

Presentations

We will not circulate printouts of speakers' presentations beforehand. However, you will be able to download the presentations from the workshop website approximately one week after the event.

Catering

Lunch will be provided on the 24th October for all delegates free of charge to allow opportunities for discussion and networking.

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Live broadcast

The workshop will be live streamed. Please follow the link in Multimedia tab on the event page. No registration or password is required.

Twitter

Participants interested in tweeting on this event are invited to use the hashtag **#RegScience2025**.

Getting to Canary Wharf

The EMA is located in Canary Wharf, a business district in the east of London.
Please find below the public transport options for travelling to Canary Wharf together with the approximate journey times and the map of the area.

Directions to European Medicines Agency and map of the area