



Shaping a European innovation ecosystem: EU-Innovation network multi-stakeholder meeting

26th September 2023, Madrid
Hotel Meliá Castilla

Objectives

The European Innovation Network (EU-IN) and the Spanish Agency of Medicines and Medical Devices (AEMPS) are organising a multi-stakeholders meeting under the Spanish 2023 EU-Presidency to promote research and development of innovative medicines and related technologies & methodologies in the European Union.

The main objectives of the meeting are:

- To **inform stakeholders** on EU-IN activities and available EU regulatory support to developers and to gather feedback on how to further optimise these support tools;
- **To exchange knowledge**, experience and good practices among stakeholders involved in medicines research and development and explore opportunities for collaboration;
- To **collect inputs from multiple stakeholders**, in particular from academic innovators, to identify gaps in regulatory science and discuss options to address them;

The feedback gathered during this meeting will inform recommendations and follow-up actions with the aim to further **catalyse innovative medicines development** in the EU.

Agenda details

08:00 Registration

08:30 Joining and Technical Checks

09:00 Welcome and Opening Speech

Silvia Calzón , Secretary of State for Health, ES	
María Lamas , Executive Director, AEMPS	
Emer Cooke , Executive Director, EMA	10'

09:15 Session 1: EU-IN in support of European Research

Chair/Co-chair: Laurence O'Dwyer (HPRA)/ Falk Ehmann (EMA)	5'
EU-IN Network activities and available EU regulatory support	
Speaker(s):	
Falk Ehmann (EMA) . European innovation ecosystem - EU Innovation Network activities	10'
Yoana Nuevo-Ordóñez (AEMPS) . AEMPS innovation Office	10'
Bettina Ziegele (PEI) . Simultaneous National Scientific Advice (SNSA)	10'
Ana Zanoletty (EMA) . Accelerating Clinical Trials in the EU (ACT-EU)	20'
Discussion	

10:30 Coffee break

11:00 Session 2: Promoting Academic-based clinical research and product development

Chair/Co-chair: Robert Klaus (AGES)/ Eleonora Agricola (AIFA)	5'
Academia experiences on engaging with EMA and National Competent Authorities, the earlier the better	
Speaker(s):	
Viktoriiia Starokozhko (CBG-MEB) . Update on the recommendations from STARS	10'
Damián García-Olmo (UAM) . Alofisel case	10'
Gonzalo Calvo (Clinic Barcelona) . Car T case	10'
Sean Russell (Telethon Foundation) . Telethon Case.	10'
Discussion	20'

12:15 Session 3: Academia and Regulators - The benefits of working together

Chair/Co-chair: Yoana Nuevo-Ordóñez (AEMPS)/ Ralf Herold (EMA)	5'
Sharing of expertise and opportunities for collaboration	
Speaker(s):	
Marta Puyol (Spanish Association against Cancer Scientific Foundation (FC AECC)). Experience on regulatory pre grant Advice	10'
Momir Radulović (JAZMP). IncreaseNET-Joint Action on Capacity Building	10'
Maribel Rico-Salas (EMA). Regulatory Science Research Needs (RSRN)	10'
Juan Luque (CIBER). Bidirectional training regulators-Academia	10'
Discussion	20'

13:30 Networking Lunch

15:00 Session 4: Other stakeholders -The benefits of working together

Chair/Co-chair: Esa Heinonen (FIMEA)/Bettina Ziegele (PEI)	5'
Sharing of expertise and opportunities for collaboration	
Speaker(s):	
Julián Isla (Foundation 29). Collaboration with patients	10'
Denis Lacombe (EORTC). Collaboration with health professionals	10'
Domingo Gargallo-Viola (ABAC Therapeutics S.L. Member of Beam Alliance Executive Board). Collaboration with SME's.	10'
Padraic Ward (Roche Pharma Europe & International). Collaboration with innovators.	10'
Discussion	20'

16:10 Coffee break

16:30 Session 5 – Looking towards the future

Chair/Co-chair: María Lamas (AEMPS)/Laurence O'Dwyer (HPRA)	5'
Speaker(s):	
Sara Rafael Almeida (DG SANTÉ. Medical Products and Innovation) Innovation within new pharmaceutical legislation. Funding for public researchers. Best use of data	15'
Panel discussion:	
Falk Ehmann (EU-IN Co-Chair). EMA	45'
César Hernández (General Director NHS Portfolio and Pharmacy). Ministry of Health	
Cristobal Belda (General Director). ISCIII	
Roberto Saldaña (Innovation Director). EUPATI-ES	
Roisin Adams (Head at HTA Strategy National centre for Pharmacoeconomics). HTA	
Juan Yermo. (General Director). Farmaindustria	
Discussion	10'

17:45 **Closing remarks**

María Lamas, Executive Director, AEMPS. Wrap up

10'

18:00 **End of the meeting**