

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

26th September 2023, Madrid

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

08:30 Joining and Technical Checks

09:00 Welcome and Opening Speech

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):

Laurence O'Dwyer (HPRA) /Falk Ehmann (EMA). EU-IN activities and available supports 10'

Yoana Nuevo-Ordóñez (AEMPS). AEMPS innovation Office 10'

Bettina Ziegele (PEI)/Christophe Lahorte (FAMHP). SNSA 10'

Ana Zanoletty (EMA) ACT-EU 10'

Discussion 20'

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):

TBC. Update on the recommendations from STARS 10'

Damián García-Olmo.(UAM) Alofisel case 10'

Gonzalo Calvo. Car T case. Clinic Barcelona 10'

Sean Russell Telethon Case. Telethon Foundation 10'

Discussion 20'

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

Chair/Co-chair: Yoana Nuevo-Ordóñez (AEMPS)/ TBC	5'
Sharing of expertise and opportunities for collaboration	
Speaker(s):	
Marta Puyol (Fundación científica Asociación Española Contra el Cáncer). Experience on regulatory pre grant Advice	10'
Regulator CHMP representative (TBC)	10'
Maribel Rico-Salas (EMA) 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)	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'
Farmaindustria . Collaboration with innovators. Representative TBC	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	10'
Panel discussion	50'
Falk Ehmann EMA	
César Hernández General Director NHS Portfolio and Pharmacy	
Cristobal Belda Director General. ISCIII	
Roberto Saldaña EUPATI-ES HTA representative Farmaindustria TBC	

	Discussion	10'
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17:45

Closing remarks

	Wrap up	10'
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18:00

End of the meeting

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