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.

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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’
17:45	**Closing remarks**	
	Wrap up	10’
18:00	**End of the meeting**	

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