

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

26<sup>th</sup> 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

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### 09:00 Welcome and Opening Speech

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**María Lamas**, Executive Director, AEMPS 10'  
**Emer Cooke**, Executive Director EMA

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

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Chair/Co-chair: **Laurence O'Dwyer and Falk Ehmann** 5'

#### EU-IN Network activities and available EU regulatory support

Speaker(s):

**Laurence O'Dwyer/Falk Ehmann.** EU-IN activities and available supports 10'  
**Yoana Nuevo-Ordóñez.** AEMPS innovation Office 10'  
**Bettina Ziegele/Christophe Lahorte.** SNSA 10'  
**TBC** ACT-EU 10'

**Discussion** 20'

### 10:30 Coffee break

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

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Chair/Co-chair: **Robert Klaus/TBC** 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'  
**TBC.** Alofisel case 10'  
**TBC.** Car T case. Clinic Barcelona 10'  
**TBC.** Other case 10'

**Discussion** 20'

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

Chair/Co-chair: <b>Yoana Nuevo-Ordóñez / TBC</b>	5'
<b>Sharing of expertise and opportunities for collaboration</b>	
Speaker(s):	
<b>Fundación científica Asociación Española Contra el Cáncer (Representative TBC).</b> Experience on regulatory pre grant Advice	10'
<b>Regulator</b> CHMP representative (TBC)	10'
<b>Maribel Rico-Salas, EMA (RSRN)</b>	10'
<b>CIBERER.</b> Bidirectional training regulators-Academia	10'
<b>Discussion</b>	20'

## 13:30 Networking Lunch

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

Chair/Co-chair: TBC	5'
<b>Sharing of expertise and opportunities for collaboration</b>	
Speaker(s):	
<b>Julián Isla.</b> Foundation 29. Collaboration with patients	10'
<b>Denis Lacombe. EORTC.</b> Collaboration with health professionals	10'
<b>Beam Alliance.</b> Collaboration with SME's. Representative TBC	10'
<b>Farmaindustria.</b> Collaboration with innovators. Representative TBC	10'
<b>Discussion</b>	20'

## 16:10 Coffee break

## 16:30 Session 5 – Looking towards the future

Chair/Co-chair: <b>María Lamas/Laurence O'Dwyer</b>	5'
Speaker(s):	
<b>TBC</b>	10'
Panel discussion	
<b>Falk Ehmann</b> EMA	50'
<b>AEMPS</b>	
<b>Other panelists to be confirmed</b>	
<b>Discussion</b>	10'

## 17:45 Closing remarks

<b>Wrap up</b>	10'
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## 18:00 End of the meeting