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

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<td>María Lamas, Executive Director, AEMPS</td>
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### 09:15  Session 1: EU-IN in support of European Research

**Chair/Co-chair:** Laurence O'Dwyer (HPRA)/ Falk Ehmann (EMA)  

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| Speaker(s):  
  - Laurence O'Dwyer (HPRA) / Falk Ehmann (EMA)  
  - Yoana Nuevo-Ordóñez (AEMPS)  
  - Bettina Ziegele (PEI)/Christophe Lahorte (FAMHP) | 10’ |
| Ana Zanoletty (EMA)  
  - ACT-EU | 10’ |

**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)  

**Academia experiences on engaging with EMA and National Competent Authorities, the earlier the better**

**Speaker(s):**

- TBC. Update on the recommendations from STARS  
- Damián García-Olmo,(UAM) Alofisel case  
- Gonzalo Calvo, Car T case. Clinic Barcelona  
- Sean Russell Telethon Case. Telethon Foundation  

**Discussion**  

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

**Chair/Co-chair:** Yoana Nuevo-Ordóñez (AEMPS)/ TBC  
**Sharing of expertise and opportunities for collaboration**

**Speaker(s):**

- **Marta Puyol** (Fundación científica Asociación Española Contra el Cáncer). Experience on regulatory pre grant Advice  
- **Regulator** CHMP representative (TBC)  
- **Maribel Rico-Salas** (EMA) RSRN  
- **Juan Luque** (CIBER). Bidirectional training regulators-Academia

**Discussion**

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### 13:30 Networking Lunch

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

**Chair/Co-chair:** Esa Heinonen (FIMEA)  
**Sharing of expertise and opportunities for collaboration**

**Speaker(s):**

- **Julián Isla.** Foundation 29. Collaboration with patients  
- **Denis Lacombe.** EORTC. Collaboration with health professionals  
- **Domingo Gargallo-Viola** ABAC Therapeutics S.L. Member of Beam Alliance Executive Board. Collaboration with SME’s.  
- **Farmaindustria.** Collaboration with innovators. Representative TBC

**Discussion**

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### 16:10 Coffee break

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

**Chair/Co-chair:** María Lamas (AEMPS)/Laurence O’Dwyer (HPRA)  
**Speaker(s):**

- **Sara Rafael Almeida (DG SANTÉ. Medical Products and Innovation)** Innovation within new pharmaceutical legislation. Funding for public researchers. Best use of data

**Panel discussion**

- **Falk Ehmann** EMA  
- **César Hernández** General Director NHS Portfolio and Pharmacy  
- **Cristobal Belda** Director General. ISCIII  
- **Roberto Saldaña** EUPATI-ES  
- **HTA representative** Farmaindustria TBC

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Discussion

17:45  Closing remarks

Wrap up

18:00  End of the meeting