

Translating Innovation into access for ATMPs 3rd EU-Innovation Network multi-stakeholder meeting

**Rome, 15 November 2024
Piazza della Pilotta, 4 - 00187 Rome Italy**

Objectives

The EU-Innovation Network (EU-IN) and the Italian Medicines Agency (AIFA) are organising a multi-stakeholder meeting to discuss on how innovation in the development of Advanced Therapy Medicinal Products (ATMPs) can be translated into effective and safe therapies at the point of care in Europe.

The objectives are to:

- seek feedback from developers on the main challenges and barriers currently encountered from early development to access,
- provide insights on scientific and regulatory advice tools available to innovative developers at European and national level,
- discuss opportunities for promoting mutual exchange and interactions between stakeholders with the aim of strengthening the European innovation ecosystem.

The meeting will provide an open forum for discussion with a view to raising awareness of existing initiatives, as well as identifying further actions that could help to foster collaboration between stakeholders and ultimately facilitate patient access to safe and effective ATMPs.

8.30- 9.00 Registration on site/Joining remotely with technical checks

9.00-9.30 Setting the scene

Chairs: Falk Ehmann, EMA

Paolo Foggi, AIFA, SAWP

9.00-9.10 Welcome and opening address

9.10-9.20 The landscape for ATMPs in Europe 15 years after coming into force of the ATMP Regulation.
Kieran Breen, St Andrew's Healthcare - Research Centre, CAT

9.20-9.30 A survey to gather developers' view on challenges and opportunities in ATMP development. *Maria Di Marzo, AIFA*

9.30-11.00 Session 1 - The journey of ATMPs from early development to access in EU: challenges and opportunities

Chairs: Barbara Bonamassa, AIFA, CAT

Marianne Lunzer, AGES, CTCG

9.30-9.40 Patients perspective. *Mencia de Lemus, SMA Europe, EURORDIS*

9.40-9.55 Researchers perspective. *Franco Locatelli, Bambino Gesù Children Hospital*

9.55-10.10 Academia/No-profit organisation perspective. *Leila Amini, BeCAT Therapies*

10.10-10.25 SMEs perspective. *Alexander Natz, EUCOPE*

10.25-10.40 Industry perspective. *Marcello Cattani, Farindustria*

10.40-11.00 Discussion and wrap-up of the session

11.00-11.30 Coffee Break

11.30-13.00 Session 2 – EU support tools to developers

Chairs: Viktoriia Starokozhko, CBG/MEB

Yoana Nuevo, AEMPS

11.30-11.45 EMA support to innovation, *Valentina Cordò, EMA*

11.45-12.00 National Competent Agencies support to innovation, *Eleonora Agricola, AIFA*

12.00-12.15 HTA regulation:

joint scientific consultation and joint clinical assessment, *Pia Rivetti di Val Cervo, AIFA, JSCSG*

12.15-12.25 EU4Health funding programme, *Giuseppe Simone, HaDEA*

12.25-12.35 Horizon Europe funding programme on ATMPs, *Anna-Pia Papageorgiou, EC DG Research & Innovation*

12.35-13.00 Discussion and wrap-up of the session

13.00-14.00 Lunch Break

14.00-14.20 Lecture

Strengthening the European innovation ecosystem, *Tony Humphreys*

14.20-15.00 Session 3 Hot topics: opportunities for improvements

Chairs: Marjon Pasmooij, CBG/MEB

Concetta Quintarelli, Bambino Gesù Children Hospital, CAT

- 14.20-14.30 GMO framework, *Claire Beuneu, FAMHP*
14.30-14.40 Combined developments, *Ilona Reischl, AGES, CAT*
14.40-14.50 Hospital Exemption, *Sandra Petraglia, AIFA, CTCG*
14.50-15.00 Discussion and wrap-up of the session

15.00-15.15 Coffee Break

15.15-15.55 Session 4 Reality check: case studies

Chairs: Paolo Gasparini, IRCCS\ Burlo Garofalo, CHMP

Barbara Bonamassa, AIFA, CAT

- 15.15-15.25 Case study 1: Hospital Clinic Barcelona, *Gonzalo Calvo, Hospital Clínic de Barcelona*
15.25-15.35 Case study 2: Telethon, *Celeste Scotti, Fondazione Telethon*
15.35-15.45 Case study 3: Holostem, *Maria Carmela Latella, Holostem*
15.45-15.55 Discussion and wrap-up of the session

15.55-16.50 Round Table – The most pressing needs – proposal for the next concrete actions

Chairs: Laurence O'Dwyer, HPRA

Paolo Foggi, AIFA, SAWP

Panellists:

- Regulator perspective, *Ilona Reischl, AGES, CAT*
European Commission perspective, *Filip Domański, EC DG Santé*
HTA perspective, *Pia Rivetti di Val Cervo, AIFA, JSCSG*
Patient perspective, *Mencia de Lemus, SMA Europe*
Academia/No-profit perspective, *Leila Amini, BeCAT Therapies*
Gonzalo Calvo, Hospital Clínic de Barcelona
Andrea Biondi, University of Milan
Alessandro Aiuti, Vita-Salute San Raffaele University of Milan
Industry perspective, *Riccardo Ena, Federchimica Assobiotec*

16.50-17.00 Wrap up and conclusion