

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

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

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 perspectives. *Mencia de Lemus, SMA Europe*

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

9.55-10.10 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, Farminindustria*

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 Support and incentives, *Valentina Cordò, EMA*

11.45-12.00 Scientific support on development, *Eleonora Agricola, AIFA*

12.00-12.15 HTA regulation – joint scientific consultation and joint clinical assessment, *Simona Montilla, AIFA*

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, *Anthony 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

15.15-15.45 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, *Simona Montilla, AIFA*

Patient perspective, *Mencia de Lemus, SMA Europe*

Academic perspective, *Leila Amini, BeCAT Therapies and Gonzalo Calvo, Hospital Clínic de Barcelona*

No profit perspective, *Andrea Biondi, University of Milan and Alessandro Aiuti, Vita-Salute San Raffaele University of Milan*

Industry perspective, *TBD*

16.50-17.00 Wrap up and conclusion