

Translating Innovation to access for ATMPs
3rd EU-Innovation Network multi-stakeholder meeting
Rome, 15 November 2024
Piazza della Pilotta, 4 - 00187 Rome Italy

DRAFT AGENDA

- 8.30- 9.00 Registration on site/Joining remotely with technical checks**
- 9.00-9.30 Setting the scene**
- 9.00-9.10 Welcome introduction
- 9.10-9.20 The landscape for ATMPs in Europe 15 years after coming into force of the ATMP Regulation
- 9.20-9.30 Challenges and opportunities in ATMP development: survey results
- 9.30-11.00 Session 1 - The journey of ATMPs from early development to access in EU: challenges and opportunities**
- 9.30-9.40 Patients perspective
- 9.40 -9.55 Researchers perspective
- 9.55-10.10 No-profit organisation perspective
- 10.10-10.25 SMEs perspective
- 10.25-10.40 Industry perspective
- 10.40 - 11.00 Discussion and wrap-up of the session
- 11.00-11.30 Coffee Break**
- 11.30-13.00 Session 2 – EU regulatory and HTA support tools to developers**
- 11.30-11.45 Support and incentives
- 11.45-12.05 Scientific support on development
- 12.05-12.20 HTA regulation – joint scientific consultation and joint clinical assessment
- 12.20-13.00 Discussion and wrap-up of the session
- 13.00-14.00 Lunch Break**
- 14.00-14.20 Lecture**
- 14.20-15.15 Session 3 Hot topics: opportunities for improvements**
- 14.20-14.30 GMO framework
- 14.30-14.40 Combined developments
- 14.40-14.50 Hospital Exemption
- 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**
- 15.15-15.25 Case study 1
- 15.25-15.35 Case study 2



15.35-15.45 Case study 3

15.45-16.50 Round Table – The most pressing needs – proposal for the next concrete actions

16.50-17.00 Wrap up and conclusion