



2025 Theme Day:

Broadening and Securing Access to ATMPs

Bambino Gesù Hospital Rome, Italy | 6 June 2025

Programme

Friday 6 June

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| 09:00-10:00 | Registration and welcome coffee |
| 10:00-10:30 | Welcome <u>Chairs:</u> Luigi Naldini, Franco Locatelli, Concetta Quintarelli, Alberto Auricchio Welcome address & objectives of the workshop |
| 10:30-10:50 | The CAT and the regulatory development of an ATMP Barbara Bonamassa, AIFA, Rome INV01: CAT and the regulatory development of an ATMP <ul style="list-style-type: none">• State of the art• Points of implementation |
| 10:50-11:50 | Difficulty of access to the ATMP drugs 10:50-11:10: Stefano Benvenuti, Telethon Foundation, Milan INV02: New development and distribution models <ul style="list-style-type: none">• Drugs approved in Italy to date• Drugs not available in Italy whilst approved in EU• Drugs not available in EU whilst approved in US• Cost and economic sustainability: Academic and non profit models 11:10-11:30: Alessandro Aiuti, SR-Tiget, IRCCS San Raffaele Hospital, Milan INV03: Innovative regulatory solutions <ul style="list-style-type: none">• Regulatory and administrative barriers• Technology platforms, pilot initiatives for academic developers and "regulatory sandboxes" 11:30 - 11:50: Annalisa Scopinaro, Unimao, Rome (virtual) INV04: Patient Perspective |
| 11:50-12:20 | Experience in the field Franco Locatelli, Bambino Gesù Children's Hospital, Rome INV04: Point of care in Italy <ul style="list-style-type: none">• Evolution of manufacturing to reduce barriers• Successes and shortcomings in the application of CART therapies• The Italian network on ATMPs, PNRR and PNC projects |

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| 12:20-12:40 | Round table discussion <u>Moderator:</u> Concetta Quintarelli , <i>Bambino Gesù Children's Hospital, Rome</i> |
| 12:40-13:30 | Lunch Break |
| 13:30-14:00 | The role of AIFA to support innovation and access to ATMP therapies Paolo Foggi , <i>AIFA, Rome</i> INV06: Collaboration through institutions, industry and healthcare facilities |
| 14:00-14:20 | HTA Regulation Pia Rivetti di Val Cervo , <i>AIFA, Rome</i> INV07: Impact of joint scientific consultation and joint clinical evaluation on the future development of ATMPs |
| 14:20-14:40 | Innovative pricing & reimbursement models: managing uncertainty and facilitating access Oriana Ciani , <i>Bicocca University, Milan</i> INV08: Innovative price & reimbursement models: managing uncertainty and facilitating access |
| 14:40-15:10 | Role of the Ministry of Health: economic and organisational challenges in the evolution towards personalised medicine Americo Cicchetti , <i>Ministry of Health</i> INV09: |
| 15:10-15:45 | Round table discussion on strategies to improve accessibility <u>Moderators:</u> Alessandro Aiuti , Alberto Auricchio <u>Panel:</u> All speakers, plus Michela Gabaldo , <i>VP ATMP Global Regulatory Affairs, Evotec</i> Paolo Morgese , <i>VP Public Affairs, Alliance for Regenerative Medicine</i> Graziella Pellegrini , <i>University of Modena and Reggio Emilia</i> <ul style="list-style-type: none"> • Collaboration between institutions, industry and healthcare facilities • Proposals for regulatory simplification • Innovative financing models |
| 15:45-16:00 | Closing words <u>Chairs:</u> Luigi Naldini , Franco Locatelli , Concetta Quintarelli |