



PROVIDER N.2224

# ADVANCE

## Course on Cell and Gene Therapies 2025

February 24 – 28, 2025

Co-organized by  
ISTITUTO SUPERIORE DI SANITÀ  
Department of Oncology and Molecular Medicine

and

TAKIS BIOTECH ROMA

Within the Project “Rome Technopole” PNRR-NextGenerationEU n. ECS 00000024, Mission 4 Education and Research, Component 2 From Research to Enterprise, Investment. 1.5 Creation and strengthening of “Innovation ecosystems for sustainability”

N° ID: 136C24\_P

### Rationale

The 5-day course will cover all the aspects related to Advanced Therapy Medicinal Products (ATMPs), one of the most promising and challenging therapies. The course aims at preparing the new generation of scientists on ATMP: from preclinical development phase to clinical and regulatory requirements, the course will prepare the attendants to overcome critical issues of the whole cycle of ATMP development. Moreover, during the course specific session will be held on funding scheme and facilitating programs specifically available for ATMP.

The course grounds on the experience of the now concluded Erasmus+ ADVANCE programme promoted and coordinated by the non-profit European Research Infrastructure Consortium EATRIS, the European Infrastructure for Translational Medicine. Given the remarkable success of past editions, a decision was made by the Consortium to carry forward this educational course within the project “Rome Technopole”.

### Aim and objectives

The aim of the course is to prepare students and early-career scientists from Italy and Europe to the scientific and regulatory principles fundamental for the development of ATMP through frontal lessons, held by leaders in the field, and group assignments. The program includes the visit to biotechnological facilities and networking events.

### Specific objectives

At the end of the course, the participants will:

1. Have a broader overview of the issues that have to be overcome in ATMP development, grounding on stronger quality of knowledge, skills and competences;
2. Know available tools, research infrastructures, and funding schemes that can facilitate the development of novel ATMP;
3. Rely on stronger regulatory knowledge needed for the clinical development phase and marketing authorization.

### Didactic method

Reports/lessons, exercises in small groups, interactive trainings and discussions.



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## PROGRAMME

**Monday 24 February 2025**

### *Preclinical and Clinical Development*

*Chair: Lucia Gabriele, Luciano Castiello*

- 9.00 *Registration and welcome*
- 9.30 *Introduction from the attendees*
- 10.30 *1<sup>st</sup> Lecture - Scientific basis and assessment of ATMPs*  
**Janja Zupan**
- 11.00 *Coffee break*
- 11.30 *2<sup>nd</sup> Lecture - Dual CART cells for Multiple Myeloma: from bench to bedside*  
**Tuna Mutis**
- 12.00 *3<sup>rd</sup> Lecture - Bridging the gap: from research protocols to GMP standards in clinical trials*  
**Anna Pasetto**
- 12.30 *4<sup>th</sup> Lecture - Clinical ATMP development*  
**Graziella Pellegrini**
- 13.00 *Lunch*
- 14.15 *Assignments*
- 14.30 *Working groups*
- 15.45 *Coffee break*
- 16.15 *Discussion and Daily Wrap up*



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**Tuesday 25 February 2025**

## ***Manufacturing and Regulatory***

**Chair: Franca Moretti, Eleonora Aricò**

- 9.00 *Daily introduction*
- 9.15 *1<sup>st</sup> Lecture - ATMP manufacturing challenges*  
**Luciano Castiello**
- 9.45 *2<sup>nd</sup> Lecture – QTTP in ATMP development*  
**Michela Gabaldo**
- 10.15 *3<sup>rd</sup> Lecture - Cell and gene therapies versus monoclonal antibodies: are we facing the same challenges after 40 years?*  
**Massimo Dominici**
- 10.45 *Coffee break*
- 11.15 *4<sup>th</sup> Lecture – ATMP Hospital Exemption: regulatory aspects and evaluation of the clinical setting*  
**Maria Francesca Cometa - Alessandra Ambrosone**
- 11.45 *5<sup>th</sup> Lecture - New European regulation on HTA: objectives and contents for ATMPs*  
**To be defined**
- 12.15 *6<sup>th</sup> Lecture - ATMP, regulatory aspects from clinical trials to authorization*  
**Mauro Biffoni**
- 12.45 *Lunch*
- 13.45 *GMP Facility tour*
- 16.15 *Discussion and Daily Wrap up*



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**Wednesday 26 February 2025**

***New frontiers and Business in ATMP development***

***Chair: Franca Moretti, Francesca Capone***

- 9.00 *Daily introduction*
- 9.15 *1<sup>st</sup> Lecture - ATMPs and Business Development*  
**Luigi Aurisicchio**
- 9.55 *2<sup>nd</sup> Lecture - Supporting new ideas: non dilutive funding*  
**Lazio Innova**
- 10.35 Coffee break
- 11.05 *3<sup>rd</sup> Lecture - Veterinary ATMP*  
**Antonella Conforti**
- 11.45 *4<sup>th</sup> Lecture - ATMPs: Life cycle and opportunities*  
**Riccardo Palmisano**
- 12.25 Lunch
- 15.00 Tour
- 19.00 Workshop dinner

Preliminary Program



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**Thursday 27 February 2025**

## ***ATMP Automation, Digitalization, and Training***

***Chair: Luciano Castiello, Luigi Aurisicchio***

- 9.00 *Daily introduction*
- 9.15 *1<sup>st</sup> Lecture - Automation of Quality Control assays for ATMP batch release and characterization*  
**Massimo Bocchi**
- 9.55 *2<sup>nd</sup> Lecture - Real-time monitoring and control for dynamic manufacturing process*  
**Paolo Gabaldi**
- 10.35 Coffee break
- 11.05 *3<sup>rd</sup> Lecture/Activity - Virtual creation of a GMP laboratory*  
**Giancarlo De Matthaëis**
- 11.45 *4<sup>th</sup> Lecture - ATMPs Biotech Academy*  
**Leonardo Sibilio**
- 12.45 Lunch
- 13.45 *Group Work*
- 15.15 Coffee break
- 15.45 *Group Work*
- 16.15 *Discussion and Daily Wrap up*



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**Friday 28 February 2025**

## ***ATMP Reimbursement and Perspectives***

***Chair: Lucia Gabriele, Luigi Aurisicchio***

- 9.00 *Daily introduction*
- 9.15 *1<sup>st</sup> Lecture - Pricing and reimbursement mechanisms for ATMPs*  
**Juan Carlos Rejon-Parrilla**
- 9.45 *2<sup>nd</sup> Lecture - The role of EATRIS in developing the next generation of ATMPs*  
**David Morrow**
- 10.15 *Presentation, Examination, Evaluation – 1<sup>st</sup> part*
- 11.15 *Coffee break*
- 11.45 *Presentation, Examination, Evaluation – 2<sup>nd</sup> part*
- 12.30 *Wrap up and Farewell*

Preliminary Program



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## TRAINERS and TUTORS

**Alessandra Ambrosone** - National Centre for Drug Research and Evaluation, Italian Institute of Health (ISS), Rome

**Eleonora Aricò** - Core Facilities, Italian Institute of Health (ISS), Rome

**Luigi Aurisicchio** - Takis; EvviVax; NeoMatrix; Vitares; Assobiotec; Rome Technopole, Rome

**Mauro Biffoni** - Department of Oncology and Molecular Medicine, Italian Institute of Health (ISS), Rome

**Massimo Bocchi** - Cellply, Bologna

**Francesca Capone** - Research Coordination and Promotion Service, Italian Institute of Health (ISS); Italian Advanced Translational Research Association (A\_IATRIS), Rome

**Luciano Castiello** - Core Facilities, Italian Institute of Health (ISS); Italian Advanced Translational Research Association (A\_IATRIS), Rome

**Maria Francesca Cometa** - National Centre for Drug Research and Evaluation, Italian Institute of Health (ISS), Rome

**Antonella Conforti** - EvviVax, Rome

**Giancarlo De Matthaeis** - Labozeta, Rome

**Massimo Dominici** - Department of Oncology and Hematology Azienda Ospedaliero-Universitaria di Modena, Modena

**Michela Gabaldo** - EVOTEC, Fondazione Telethon, Milan

**Paolo Gabaldi** - Merck, Milan

**Lucia Gabriele** - Department of Oncology and Molecular Medicine, Italian Institute of Health (ISS); Italian Advanced Translational Research Association (A\_IATRIS), Rome

**Franca Moretti** - Research Coordination and Promotion Service, Italian Institute of Health (ISS); Italian Advanced Translational Research Association (A\_IATRIS), Rome

**David Morrow** - EATRIS Translational Medicine and Drug Development, Amsterdam

**Tuna Mutis** - Amsterdam University Medical Centers, Amsterdam

**Anna Pasetto** - Department of Oncology, Oslo University Hospital, Oslo

**Riccardo Palmisano** - InnovaVector Srl, Pozzuoli, Naples

**Graziella Pellegrini** - Centre for Regenerative Medicine, University of Modena and Reggio Emilia, Modena

**Juan Carlos Rejon-Parrilla** - HTA and Health Policy Researcher at Andalusian Regional Department of Health (area of HTA, AETSA), Seville

**Leonardo Sibilio** - Biotech Academy, Rome; BetaPro Consulting, Rome

**Janja Zupan** - Faculty of Pharmacy, University of Ljubljana, Ljubljana

### Scientific Director

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Italian Institute of Health (ISS), Rome

LUIGI AURISICCHIO

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### Technical Moderator

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Dept. of Oncology and Molecular Medicine, Italian Institute of Health (ISS), Rome

## GENERAL INFORMATION

### Venue

Italian Institute of Health (ISS), Aula Marotta, Viale del Castro Laurenziano 10 – Rome, Italy

### Official language

The official language is **English**.

### Registration and attendance

To register, complete and send the form available at the following link by 30/11/2024: [Application Form](#) .  
Actual attendance at the event will be verified by recording entry and exit in the appropriate attendance register. Participation in the event is free. Travel and accommodation expenses are the responsibility of the participant.

Maximum 30 attendees will be selected. Ten attendees will be priority selected within the founder partner of Rome Technopole.

### Selection

Participants will be selected according to their CVs and motivation letter. Selected participants will be notified by 10/12/2024 and have to confirm participation by 15/12/2024.

### Learning assessment





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Learning outcomes will be assessed through a practical simulation and by filling out a multiple-choice questionnaire on the last day of the course. This final test is compulsory for all participants to obtain the certificate of attendance.

### Satisfaction questionnaire

At the end of the course, all participants should complete a quality assessment survey.

**This event does not provide any CME credits.**

### Certification

Attendance certificates indicating the hours of training will be issued on request to participants who complete at least 80% of the course and successfully pass the final test.

For any further information, please contact the Scientific Secretariat or send an email at [advance.atmp@iss.it](mailto:advance.atmp@iss.it).

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[Firma elettronica del Presidente]