

ADVANCE

Course on Cell and Gene Therapies 2025

24-28
February
2025

Co-organized by

Italian National Institute of Health, Department of Oncology and Molecular Medicine and

Takis Biotech Roma

General Information

The 5-day course will take place at the Italian National Institute of Health (ISS), Aula Marotta, Viale del Castro Laurenziano 10 – Rome, Italy

Aim and objectives

The aim of the course is to prepare students and early-career scientists to the scientific and regulatory principles fundamental for the development of ATMP through frontal lessons and group assignments

Registration

To register, complete the [Application Form \(link\)](#) by 30/11/2024.

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

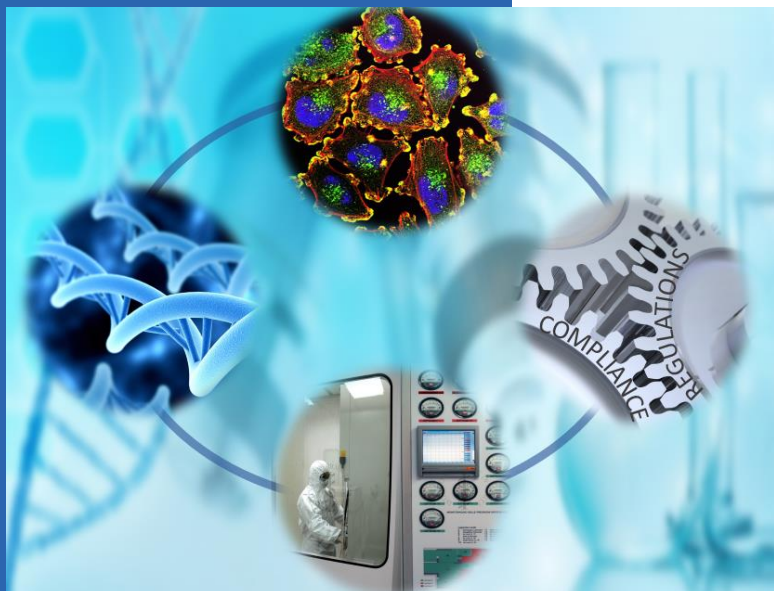
Learning outcomes will be assessed through a practical simulation and a multiple-choice questionnaire

Contacts

For any further information, visit

eatris.eu/events/ or contact:

advance.atmp@iss.it



Finanziato
dall'Unione europea
NextGenerationEU



Ministero
dell'Università
e della Ricerca



Italiadomani
PIANO NAZIONALE
DI RIPRESA E RESILIENZA



Preliminary program

Monday 24 February 2025

Preclinical and Clinical Development

Chair: L Gabriele, L Castiello



- 9.00 Registration and welcome
- 9.30 Introduction from the attendees
- 10.30 *Scientific basis and assessment of ATMPs*
J Zupan
- 11.00 Coffee break
- 11.30 *Dual CART cells for Multiple Myeloma: from bench to bedside*
T Mutis
- 12.00 *Bridging the gap: from research protocols to GMP standards in clinical trials*
A Pasetto
- 12.30 *Clinical ATMP development –*
G Pellegrini
- 13.00 Lunch
- 14.15 Assignments
- 14.30 Working groups
- 15.45 Coffee break
- 16.15 Discussion and Daily Wrap up

Tuesday 25 February 2025

Manufacturing and Regulatory

Chair: F Moretti, E Aricò

- 9.00 Daily introduction
- 9.15 *ATMP manufacturing challenges*
L Castiello
- 9.45 *QTTP in ATMP development*
M Gabaldo
- 10.15 *Cell and gene therapies versus monoclonal antibodies: are we facing the same challenges after 40 years?*
M Dominici

- 10.45 Coffee break
- 11.15 *ATMP Hospital Exemption: regulatory aspects and evaluation of the clinical setting*
M F Cometa - A Ambrosone
- 11.45 *New European regulation on HTA: objectives and contents for ATMPs*
To be defined
- 12.15 *ATMP, regulatory aspects from clinical trials to authorization*
M Biffoni
- 12.45 Lunch
- 13.45 GMP Facility tour
- 16.15 Discussion and Daily Wrap up

Wednesday 26 February 2025

New frontiers and Business in ATMP development

Chair: F Moretti, F Capone

- 9.00 Daily introduction
- 9.15 *ATMPs and Business Development*
L Aurisicchio
- 9.55 *Supporting new ideas: non dilutive funding*
Lazio Innova
- 10.35 Coffee break
- 11.05 *Veterinary ATMP*
A Conforti
- 11.45 *ATMPs: Life cycle and opportunities*
R Palmisano
- 12.25 Lunch
- 15.00 Tour
- 19.00 Workshop dinner

Thursday 27 February 2025

ATMP Automation, Digitalization, and Training

Chair: L Castiello, L Aurisicchio

- 9.00 Daily introduction
- 9.15 *Automation of Quality Control assays for ATMP batch release and characterization*
M Bocchi
- 9.55 *Real-time monitoring and control for dynamic manufacturing process*
P Gabaldi
- 10.35 Coffee break
- 11.05 *Virtual creation of a GMP laboratory*
G De Matthaeis
- 11.45 *ATMPs Biotech Academy*
L Sibilio
- 12.45 Lunch
- 13.45 Group Work
- 15.15 Coffee break
- 15.45 Group Work
- 16.15 Discussion and Daily Wrap up



Friday 28 February 2025

ATMP Reimbursement and Perspectives

Chair: L Gabriele, L Aurisicchio

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

Scientific Director

L Gabriele - Italian National Institute of Health
L Aurisicchio - Takis Biotech S.r.l.

Scientific Secretariat

F Capone - Italian National Institute of Health
F Moretti - Italian National Institute of Health
L Castiello - Italian National Institute of Health
L Le Pera - Italian National Institute of Health

Organizational Secretariat

M Fontana - Italian National Institute of Health
I Canini - Italian National Institute of Health
S Gualdi - Italian National Institute of Health
S Donati - Italian National Institute of Health
U Visconti - Italian National Institute of Health
A Ferrigno - Takis Biotech S.r.l.

Technical Moderator

S Guida - Italian National Institute of Health

Event produced within the Project “Rome Technopole” PNRR-NextGenerationEU “Innovation ecosystems for sustainability” and with an unconditional grant from Merck, Labozeta, CellPly, and Vitares