

Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate
O.d.G Seduta del 24/03/2026

Gli studi vengono inseriti all'Ordine del Giorno esclusivamente nel momento in cui risulta disponibile l'intera documentazione validata e ritenuta idonea per avviare la fase di valutazione.

È importante sottolineare che l'inserimento in O.d.G. non garantisce che la valutazione venga completata o deliberata nella stessa seduta: esso rappresenta invece l'avvio formale dell'iter valutativo della procedura, che potrà richiedere ulteriori approfondimenti, integrazioni o successive discussioni in riunioni future.

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2025-522949-22-00 INITIAL (Part I + Part II)	SGT-003-301 Interventistico con farmaco - Profit Phase III Promotore: Solid Biosciences Inc Multinational	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy of a Single Intravenous Dose of SGT-003 in Ambulant Males With Duchenne Muscular Dystrophy
CEN ATMP RSO - 3770 INITIAL (Part I + Part II)	QOL-ONE PRO-CT Osservazionale con farmaco - No Profit Promotore: Associazione Culturale e di Ricerca QOL-ONE Mononational	A Real-World Observational Study on Patient-Reported Outcomes in Allogeneic Stem Cell Transplantation (Allo-SCT) and CAR-T Therapy
CTIS ITALY - MS 2025-523285-25-00 INITIAL (Part I + Part II)	D8311C00001 Interventistico con farmaco - Profit Phase III Promotore: AstraZeneca AB Multinational	A Phase III Open-label, Randomised, Multicentre Study Comparing AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Standard Regimens in Participants with Relapsed Refractory Multiple Myeloma (DURGA-4)
CTIS ITALY - MS 2023-504909-37-00 SUBSTANTIAL MODIFICATION SM-3 (Part I + Part II)	1504-0003 Interventistico con farmaco - Profit Phase I/II Promotore: Boehringer Ingelheim International GmbH Multinational	A clinical trial to evaluate the long-term safety and durability of efficacy of BI 3720931, an inhaled lentiviral vector gene therapy, after single dose administration in a previous clinical trial in people with cystic fibrosis rolled-over from a previous clinical trial with BI 3720931 (Lenticlair™-ON).
CTIS ITALY - RMS 2024-514053-30-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	IRST153.09 Interventistico con farmaco - No Profit Phase II Promotore: Istituto Romagnolo Per Lo Studio Dei Tumori Dino Amadori IRST S.r.l. Mononational	Sequential immunochemotherapy treatment with Pembrolizumab plus Dendritic Cell (DC) Vaccine followed by Trifluridine/Tipiracil plus Bevacizumab in refractory mismatch-repair-proficient (pMMR) or microsatellite-stable (MSS) metastatic colorectal cancer

Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate
O.d.G Seduta del 24/03/2026

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2025-522054-40-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	IOV-MEL-202 Interventistico con farmaco - Profit Phase II Promotore: Iovance Biotherapeutics Inc. Multinational	A Phase 2, multicenter, open-label study of lifileucel (tumor-infiltrating lymphocytes [TIL]) in participants with previously treated advanced melanoma
CTIS ITALY - MS 2023-505177-32-00 SUBSTANTIAL MODIFICATION SM-7 (Part I + Part II)	V940-004 Interventistico con farmaco - Profit Phase II Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 2, Randomized, Double-blind, Clinical Study of V940 (mRNA-4157) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab in the Adjuvant Treatment of Participants With Renal Cell Carcinoma (INTerpath-004)
CTIS ITALY - MS 2023-506267-33-00 SUBSTANTIAL MODIFICATION SM-8 (Part I + Part II)	90014496LYM1001 Interventistico con farmaco - Profit Phase I/II Promotore: Janssen - Cilag International Multinational	A Phase 1b Multicenter, Open-label, Study of JNJ-90014496, an Autologous CD19/CD20 Bi-specific CAR-T Cell Therapy in Adult Participants with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma
CTIS ITALY - MS 2023-505658-17-00 SUBSTANTIAL MODIFICATION SM-6 (Part I + Part II)	V940-005 Interventistico con farmaco - Profit Phase I/II Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 1/2 Study of V940 Plus Pembrolizumab With or Without Enfortumab Vedotin in Muscle-Invasive Urothelial Carcinoma (MIUC) (INTerpath-005)
CTIS ITALY - MS 2022-501607-27-00 SUBSTANTIAL MODIFICATION SM-13 (Part II)	NA Interventistico con farmaco - Profit Phase I/II Promotore: Collectis Multinational	Open-label dose-finding and dose-expansion study to evaluate the safety, expansion, persistence, and clinical activity of UCART20x22 in subjects with relapsed or refractory B-cell Non-Hodgkin Lymphoma (B-NHL)
CTIS ITALY - MS 2024-514137-38-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	CYTB323L12201 Interventistico con farmaco - Profit Phase II Promotore: Novartis Pharma AG Multinational	A Phase 2, randomized, open-label, controlled study to evaluate the efficacy and safety of rapcabtagene autoleucel versus comparator in participants with severe refractory idiopathic inflammatory myopathies

Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate
O.d.G Seduta del 24/03/2026

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - RMS 2024-514501-57-00 SUBSTANTIAL MODIFICATION SM-3 (Part I + Part II)	SGT-003-101 Interventistico con farmaco - Profit Phase I/II Promotore: Solid Biosciences Inc. Mononational	A Phase 1/2, Multicenter, Open-Label Study to Investigate the Safety, Tolerability, and Efficacy of a Single Intravenous Dose of SGT-003 in Ambulant Males with Duchenne Muscular Dystrophy
CEN ATMP RSO - 4260 INITIAL	DISH-SCC Osservazionale senza farmaco e dispositivo - No Profit Promotore: Fondazione Policlinico Universitario Agostino Gemelli IRCCS Mononational	Development of immunotherapy strategies in head and neck squamous cell carcinoma
CTIS ITALY - MS 2025-521349-25-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	4D-150-C004 Interventistico con farmaco - Profit Phase III Promotore: 4d Molecular Therapeutics Inc. Multinational	A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of 4D-150 in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration (4FRONT-2)
CTIS ITALY - MS 2025-523660-21-00 INITIAL (Part I + Part II)	C0371017 Interventistico con farmaco - Profit Phase III Promotore: Pfizer Inc. Multinational	A Phase 3, Non-Investigational Product, Multi Country Cohort Study to Describe the Long-Term Safety and Effectiveness of a Prior Single-Dose Treatment With Investigative Giroctocogene Fitelparvovec or Fidanacogene Elaparvovec in Participants With Hemophilia A or Hemophilia B, Respectively
CTIS ITALY - RMS 2025-522647-17-00 INITIAL (Part I + Part II)	FB Plus-01-23 Interventistico con farmaco - Profit Phase I Promotore: Hmg Biologics S.r.l. Mononational	A two-part study: open label, dose escalation phase aimed to evaluate the safety and tolerability of two different doses of allogeneic fibroblasts for the treatment of chronic refractory wounds and identifying the best dose for subsequent cohort expansion phase aimed to assess efficacy and confirm safety and tolerability
CTIS ITALY - RMS 2025-524635-39-00 INITIAL (Part I + Part II)	HIGM1-FT018-01 Interventistico con farmaco - Profit Phase I/II Promotore: San Raffaele Hospital Fondazione Telethon Ets Mononational	A Single Arm, Open Label, Single Center, Phase I/II Clinical Study evaluating Safety and Efficacy of gene therapy using Autologous CD4+ T-Cells Edited ExVivo at the CD40LG Locus by CRISPR/Cas9 and IDLV-based vector in Patients with Xlinked Hyper IgM Syndrome Type 1 (HIGM1).

Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate
O.d.G Seduta del 24/03/2026

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2024-514596-18-00 ADDED MEMBER STATE AM-2 (Part I + Part II)	U1111-1325-1245 Interventistico con farmaco - Profit Phase I/II Promotore: Novartis Pharma AG Multinational	An open-label, multi-center, phase 1/2 study to assess safety, cellular kinetics and exploratory efficacy of rapcabtagene autoleucel in participants with difficult-to-treat rheumatoid arthritis and severe, refractory Sjogren's disease with organ involvement
CTIS ITALY - MS 2023-503666-23-00 SUBSTANTIAL MODIFICATION SM-6 (Part I + Part II)	RGX-314-3101/M23-409 Interventistico con farmaco - Profit Phase III Promotore: Abbvie Deutschland GmbH & Co. KG Multinational	A Randomized, Partially Masked, Controlled, Phase 3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ASCENT)
CTIS ITALY - RMS 2025-522160-32-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	BTHAL-FT007-01 Interventistico con farmaco - Profit Phase II Promotore: Fondazione Telethon Ets Mononational	A single arm, open label, multicenter, single-dose, phase 2b clinical study evaluating efficacy and safety of gene therapy using autologous CD34+ hematopoietic stem cells transduced with the GLOBE lentiviral vector using an improved transduction protocol in subjects with transfusion-dependent beta-thalassemia.
CTIS ITALY - MS 2025-523448-10-00 INITIAL (Part I + Part II)	KTE-C19-104 Interventistico con farmaco - Profit Phase II Promotore: Gvhd Resistant to ruxolitinib and steroids Multinational	Efficacy of cell therapy with allo-MSCs in patients with gvhd resistant to ruxolitinib second line therapy: a Phase IIB Clinical Trial - MSC-GRR2 Study
CTIS ITALY - MS 2023-504786-23-00 SUBSTANTIAL MODIFICATION SM-15 (Part I + Part II)	VX21-522-001 Interventistico con farmaco - Profit Phase I/II Promotore: Vertex Pharmaceuticals Inc. Multinational	A Phase 1/2 Dose-escalation Study Evaluating the Safety, Tolerability, and Efficacy of VX-522 in Subjects 18 Years of Age and Older With Cystic Fibrosis and a CFTR Genotype Not Responsive to CFTR Modulator Therapy
CTIS ITALY - MS 2025-521145-24-01 INITIAL (Part I + Part II)	CAB-201-002 Interventistico con farmaco - Profit Phase I/II Promotore: Cabaletta Bio Inc. Multinational	A Phase 1/2, Open-Label Study to Evaluate the Safety and Efficacy of Autologous CD19-specific Chimeric Antigen Receptor T cells (CABA-201) in Subjects with Active Idiopathic Inflammatory Myopathy or Active Juvenile Idiopathic Inflammatory Myopathy

Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate
O.d.G Seduta del 24/03/2026

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - RMS 2023-505511-20-00 SUBSTANTIAL MODIFICATION SM-2 (Part II)	FT04CARCIK Interventistico con farmaco - No Profit Phase I/II Promotore: Fondazione Tettamanti Mononational	Phase I/II Trial to Determine Persistence, Safety and Clinical Activity of Allogeneic CIK Cells Transduced with a Transposon CD19-chimeric Antigen Receptor (CARCIK- CD19) in Adult and Pediatric Patients with Relapsed/Refractory B-cell Non-Hodgkin Lymphoma and B-cell Chronic Lymphocytic Leukemia