



Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate

O.d.G. Seduta del 13/10/2026

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 2025-524014-29-00 SUBSTANTIAL MODIFICATION SM-1 (Part I)	D8312C00002 Interventistico con farmaco - Profit Phase III Promotore: AstraZeneca AB Multinational	A Phase III Open-Label, Randomised, Multicentre Study of Consolidation with a Single Administration of AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR T) Therapy Directed Against BCMA and CD19, Compared with Continuous Standard Therapy in Participants with NDMM Who Are Ineligible to Receive ASCT as Initial Therapy (DURGA-5).

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2025-522761-29-00 INITIAL (Part I + Part II)	CA2590001 Interventistico con farmaco - Profit Phase I Promotore: Bristol-Myers Squibb Services Unlimited Company Multinational	A Phase 1, Multicenter, Open-label, Study of BMS-986527, Healthy Donor Allogenic CD70-targeted Chimeric Antigen Receptor (CAR) T Cells, as Monotherapy or in Novel Combinations in Participants with Clear Cell Renal Cell Carcinoma (ccRCC).
CEN ATMP RSO - 5362 INITIAL	CARTiER Osservazionale con farmaco - No Profit Promotore: IRCCS AOU di Bologna Policlinico Sant'Orsola Mononational	Studio CARTiER: Protocollo integrato di monitoraggio nei pazienti affetti da mieloma multiplo sottoposti a terapia con cellule CAR-T.
CTIS ITALY - RMS 2026-525847-34-00 INITIAL (Part I + Part II)	MPSVI-FT005-02 Interventistico con farmaco - Profit Phase I/II Promotore: Fondazione Telethon ETS Mononational	A Phase I/II Open-Label Extension of Study TIGEM1-MPSVI, Evaluating the Safety and Efficacy of FT005, an Adeno-Associated Viral Vector 8 to Deliver the Human ARSB Gene to the Liver of Subjects with Mucopolysaccharidosis type VI (MPS VI).

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2024-511188-26-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	KT-US-679-0788 Interventistico con farmaco - Profit Phase III Promotore: Kite Pharma Inc. Multinational	A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma.
CTIS ITALY - MS 2023-503652-27-00 SUBSTANTIAL MODIFICATION SM-20 (Part II)	V940-001 Interventistico con farmaco - Profit Phase III Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants with High-risk Stage II-IV Melanoma (INTerpath-001).
CTIS ITALY - MS 2023-507220-23-00 SUBSTANTIAL MODIFICATION SM-9 (Part I + Part II)	ITL-2001-CL-301 Interventistico con farmaco - Profit Phase III Promotore: Intellia Therapeutics Inc. Multinational	MAGNITUDE: A Phase 3, Multinational, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of NTLA-2001 in Participants with Transthyretin Amyloidosis with Cardiomyopathy (ATTR-CM).

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - RMS2024-511028-15-00SUBSTANTIAL MODIFICATION SM-4(Part II)	STEMS2Interventistico con farmaco - No ProfitPhase IIPromotore: Ospedale San Raffaele S.r.l.Mononational	A phase 2, randomized, patient and assessor blind, multicenter study comparing fetal neural stem cells transplantation to sham procedure in progressive multiple sclerosis (STEMS2).
CTIS ITALY - MS 2024-519278-37-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	CA061-1011 Interventistico con farmaco - Profit Phase II Promotore: Celgene Corp. Multinational	A Phase 2, Multicenter, Open-Label Study of CC-97540 (BMS-986353), CD19-Targeted NEX-T CAR T Cells, in Participants with Active SLE (Including Lupus Nephritis) with Inadequate Response to Glucocorticoids and at Least 2 Immunosuppressants (Breakfree-SLE).
CTIS ITALY - MS 2024-512029-10-00 SUBSTANTIAL MODIFICATION SM-5 (Part I + Part II)	000423 Interventistico con farmaco - Profit Phase III Promotore: Ferring Pharmaceuticals A/S Multinational	A phase 3b, Randomized, Controlled Trial of Nadofaragene Firadenovec vs. Observation in Subjects with Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR NMIBC).

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CEN ATMP RSO - 4024 SUBSTANTIAL MODIFICATION SM-1	iMMunoPro Osservazionale con farmaco - No Profit Promotore: AOU DI BOLOGNA POLICLINICO S.ORSOLAMALPIGHI Mononational	Multicenter, observational, prospective and retrospective Italian study on infections and anti-infective prophylaxis strategies in Relapsed/Refractory Multiple Myeloma patients undergoing immunotherapy with CAR-T cells or bispecific antibodies in real-life.
CTIS ITALY - MS 2022-500306-17-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	OTL-203-02 Interventistico con farmaco - Profit Phase III Promotore: Orchard Therapeutics (Europe) Limited Multinational	A multi-center, randomized, active controlled clinical trial to evaluate the efficacy and safety of OTL-203 in subjects with mucopolysaccharidosis type I, Hurler syndrome (MPS-IH) compared to standard of care with allogeneic hematopoietic stem cell transplantation (allo-HSCT).
CTIS ITALY - RMS 2024-514501-57-00 SUBSTANTIAL MODIFICATION SM-5 (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.

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - RMS 2023-506348-17-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	M-2021-389 Interventistico con farmaco - Profit Phase II Promotore: Miltenyi Biomedicine GmbH Multinational	A single-arm, multi-center, open-label Phase II study to determine the safety and efficacy of MB-CART2019.1 in pediatric subjects with relapsed/refractory (r/r) mature B-cell neoplasms who have relapsed after one or more prior therapies, including subjects with primary refractory disease.
CTIS ITALY - RMS 2025-521500-21-01 INITIAL (Part I + Part II)	RESTORE Interventistico con farmaco - Profit Phase II Promotore: Fondazione Policlinico Universitario Campus Bio-Medico Mononational	Allogenic Umbilical Cord-Derived Mesenchymal Stromal Cells as Therapeutic Approach for Chronic Lumbar Back Pain Due to Multilevel Intervertebral Disc Degeneration: A Phase IIB double-blind Randomized Controlled Trial.
CTIS ITALY - MS 2025-524970-40-00 INITIAL (Part I + Part II)	LX2006-03 Interventistico con farmaco - Profit Phase II Promotore: Lexeo Therapeutics, Inc. Multinational	A Phase 2, Multicenter, Open-label, Randomized, Controlled Study of LX2006 Gene Therapy in Participants with Friedreich Ataxia Cardiomyopathy (SUNRISE-FA 2).

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CEN ATMP RSO - 4408 INITIAL (Part I + Part II)	CART-T_PWH Osservazionale con farmaco - No Profit Promotore: Fondazione Policlinico Universitario A. Gemelli IRCCS Mononational	Sicurezza della terapia con CAR-T in persone con HIV e linfoma refrattario o recidivato: Studio retrospettivo multicentrico.
CTIS ITALY - MS 2023-505530-10-00 ADDED MEMBER STATE AM-4 (Part I + Part II)	68284528MMY4002 (CARTinue) Interventistico con farmaco - Profit Phase IV Promotore: Janssen - Cilag International Multinational	Long-term Follow-up Study for Participants Previously Treated with Ciltacabtagene Autoleucel.
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.