Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate
O.d.G Seduta del 27/01/2026

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 2023-503652-27-00 SUBSTANTIAL MODIFICATION SM-9 (Part I)	V940-001 Interventistico con farmaco - Profit Phase III 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)
CEN ATMP RSO - 3770 INITIAL (Part I + Part II)	QOL-ONE PRO-CT Osservazionale con farmaco - No Profit Mononational	A Real-World Observational Study on Patient-Reported Outcomes in Allogeneic Stem Cell Transplantation (Allo-SCT) and CAR-T Therapy
CTIS ITALY - MS 2024-514137-38-00 SUBSTANTIAL MODIFICATION SM-3 (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 autoleucelversus comparator in participants with severe refractory idiopathic inflammatory myopathies
CTIS ITALY - RMS 2023-506348-17-00 SUBSTANTIAL MODIFICATION SM-3 (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 - MS 2024-512029-10-00 ADDED MEMBER STATE AM-2 (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)
CTIS ITALY - MS 2023-503281-23-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	1504-0001 Interventistico con farmaco - Profit Phase I/II Promotore: Boehringer Ingelheim International GmbH Multinational	A seamless Phase I/II trial with an initial open-label dose escalation part and a subsequent randomised, double-blind, placebo-controlled expansion part to evaluate the safety, tolerability, and efficacy of a single dose of BI 3720931, an inhaled lentiviral vector gene therapy, in adult people with cystic fibrosis who are ineligible for CFTR modulators (LenticlairTM 1)

Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate
O.d.G Seduta del 27/01/2026

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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 (LenticlairTM-ON).
CTIS ITALY - MS 2023-507717-94-00 SUBSTANTIAL MODIFICATION SM-2 (Part I + Part II)	dS-BA-PIII Interventistico con farmaco - Profit Phase III Promotore: Cutiss AG Multinational	A multicentre, intra-patient randomised controlled Phase III study to confirm the efficacy and safety of denovoSkin™, a bilayer engineered collagen-based skin graft composed of autologous fibroblasts and keratinocytes, for the treatment of patients with deep partial and full-thickness burns
CTIS ITALY - MS 2024-515279-37-00 SUBSTANTIAL MODIFICATION SM-7 (Part I + Part II)	CA088-1007 Interventistico con farmaco - Profit Phase II/III Promotore: Celgene Corp. Multinational	A Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of BMS-986393, a GPRC5D-directed CAR-T Cell Therapy, Versus Standard Regimens in Adult Participants with Relapsed or Refractory and Lenalidomide-refractory Multiple Myeloma
CTIS ITALY - RMS 2025-520902-37-00 INITIAL (Part I + Part II)	V940-013 Interventistico con farmaco - Profit Phase II Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of V940 in Combination With Pembrolizumab and Chemotherapy as First-Line Treatment for Participants With Metastatic Squamous NSCLC (INTerpath-013)
CTIS ITALY - MS 2023-510380-34-00 SUBSTANTIAL MODIFICATION SM-7 (Part I + Part II)	CYTB323K12201 Interventistico con farmaco - Profit Phase II Promotore: Novartis Pharma AG Multinational	A Phase II, multi-part, three-year, randomized, open-label, assessor-blinded, active-controlled, multicenter study to evaluate the efficacy and safety of rapcabtagene autoleucel versus rituximab treatment in participants with severe refractory diffuse cutaneous systemic sclerosis
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 2023-505658-17-00 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)

Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate
O.d.G Seduta del 27/01/2026

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CTIS ITALY - MS 2023-503823-24-01 SUBSTANTIAL MODIFICATION SM-8 (Part I + Part II)	CA061-1001 Interventistico con farmaco - Profit Phase I Promotore: Celgene Corp. Multinational	A Phase 1 Study of CD19-targeted NEX-T CAR T Cells in Participants with Severe, Refractory Autoimmune Diseases
CTIS ITALY - MS 2024-519278-37-00 SUBSTANTIAL MODIFICATION SM-2 (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 - RMS 2024-514501-57-00 SUBSTANTIAL MODIFICATION SM-3	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