Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate
O.d.G Seduta del 13/01/2026

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 2023-507041-28-00 SUBSTANTIAL MODIFICATION SM-7 (Part I)	KT-US-982-5968 Interventistico con farmaco - Profit Phase II Multinational	Long-term Follow-up Study for Participants of Kite-Sponsored Interventional Studies Treated With Gene-Modified Cells
CTIS ITALY - MS 2023-509440-97-00 SUBSTANTIAL MODIFICATION SM-3 (Part I)	KTE-C19-104 Interventistico con farmaco - Profit Phase I/II Multinational	A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-X19 in Pediatric and Adolescent Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia or Relapsed/Refractory BCell Non Hodgkin Lymphoma (ZUMA-4)
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 - 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 - 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 2024-514006-31-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	CYTB323R12101 Interventistico con farmaco - Profit Phase I/II Promotore: Novartis Pharma AG Multinational	An open-label, multi-center, phase I/II study to assess safety, disease progression, and cellular kinetics following YTB323 administration in participants with non-active Progressive Multiple Sclerosis (PMS)

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INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2023-506480-34-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	RP-A501-0123 Interventistico con farmaco - Profit Phase II Promotore: Merck Sharp & Dohme LLC Multinational	Gene Therapy for Danon Disease: A Phase 2 Study Evaluating the Efficacy and Safety of Intravenously Administered Adeno-Associated Virus Serotype 9 (rAAV9) Vector Containing the Human LAMP2 Isoform B Transgene (RP-A501; AAV9.LAMP2B) in Male Patients with Danon Disease
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
CEN ATMP RSO 3660 INITIAL (Part I + Part II)	BOOST Osservazionale con farmaco - No Profit Mononational	STUDIO MULTICENTRICO RETROSPETTIVO SULL'USO DI CELLULE STAMINALI AUTOLOGHE CRIOPRESERVATE IN PAZIENTI ADULTI SOTTOPOSTI A TERAPIA CON CELLULE CAR T CHE PRESENTINO CITOPENIA PROLUNGATA