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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).
CEN ATMP PS-25-04-052414 INITIAL (Part I + Part II)	DHF-22-VAP-001 Interventistico con dispositivo medico PRE MARKET - Profit Promotore: Precision for Medicine Inc. Multinational	Clinical Performance Study of the AAVS3 Neutralizing Antibody Test in Testing Samples from Subjects Being Screened for FLT201-03
CEN ATMP RD007855 INITIAL	RD007855 IVDR - Profit Promotore: Roche Multinational	Evaluation of clinical performance of Elecsys Anti-AAVrh74 using serum samples from the associated pharma Phase III BN46648 trial
CEN ATMP CLARIY-201 (RCD982) INITIAL	CLARIY-201 (RCD982) IVDR - Profit Promotore: Allogene Therapeutics Inc. Multinational	Clinical Performance Study for the Foresight CLARITY™ IUO for the Assessment of Molecular Residual Disease in Subjects Screened Under Clinical Trial ALPHA3
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

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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 - 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
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 - MS 2025-520765-50-00 ADDED MEMBER STATE AM-1 (Part I + Part II)	FLT201-03 Interventistico con farmaco - Profit Phase III Promotore: Spur Therapeutics Limited Multinational	A Phase 3 Safety and Efficacy Trial of FLT201 Gene Therapy in Patients with Gaucher Disease Type 1
CTIS ITALY - MS 2023-508784-68-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	RP2-202 Interventistico con farmaco - Profit Phase II/III Promotore: Replimune Inc. Multinational	A Randomized, Phase 2/3, Open-Label Study to Investigate the Efficacy and Safety of RP2 in Combination with Nivolumab versus Ipilimumab in Combination with Nivolumab in Immune Checkpoint Inhibitor-Naïve Adult Patients with Metastatic Uveal Melanoma

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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 - MS 2022-500747-21-00 SUBSTANTIAL MODIFICATION SM-10 (Part I + Part II)	81201887MDG3002 Interventistico con farmaco - Profit Phase II Promotore: Janssen - Cilag International Multinational	Long-term Extension Study for Participants with Geographic Atrophy (GA) Secondary to Age-related Macular Degeneration (AMD) in JNJ-81201887 Parent Clinical Studies
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)
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)
CTIS ITALY - RMS 2025-520902-37-00 SUBSTANTIAL MODIFICATION SM-4 (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)

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CTIS ITALY - MS 2026-526865-36-00 INITIAL (Part I + Part II)	BN46648 Interventistico con farmaco - Profit Phase III Promotore: F. Hoffmann-La Roche AG Multinational	A Phase 3 Multinational, Randomized, Double-Blind, Placebo Controlled Systemic Gene Therapy Delivery Study to Evaluate the Safety and Efficacy of SRP-9001 in Ambulatory Patients 4 to 6 Years of Age with Duchenne Muscular Dystrophy