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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
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 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
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

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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)
CTIS ITALY - MS 2022-503140-41-00 SUBSTANTIAL MODIFICATION SM-15 (Part I + Part II)	IOV-MEL-301 Interventistico con farmaco - Profit Phase III Promotore: Iovance Biotherapeutics Inc. Multinational	A Phase 3, multicenter, randomized, open-label, parallel group, treatment study to assess the efficacy and safety of the lifileucel (LN-144, autologous tumor-infiltrating lymphocytes [TIL]) regimen in combination with pembrolizumab compared with pembrolizumab monotherapy in participants with untreated, unresectable or metastatic melanoma
CTIS ITALY - MS 2024-512504-19-00 SUBSTANTIAL MODIFICATION SM-12 (Part I + Part II)	1456-0001 Interventistico con farmaco - Profit Phase I Promotore: Boehringer Ingelheim International GmbH Multinational	Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with an anti-PD-1 mAb in patients with advanced or metastatic solid tumors.
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

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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
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 - 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)
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

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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)