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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 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 - 4024 INITIAL (Part I + Part II)	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 - RMS 2026-525714-59-00 INITIAL (Part I + Part II)	SNIPER-LTFU Interventistico con farmaco - Profit Phase I/II Promotore: Eir Biotherapies S.r.l. Mononational	SNIPER-LTFU: Long-term follow-up study of patients administered with RR001 in the interventional Parent SNIPER study
CTIS ITALY - MS 2023-507041-28-00 SUBSTANTIAL MODIFICATION SM-9 (Part I + Part II)	KT-US-982-5968 Interventistico con farmaco - Profit Phase II Promotore: Kite Pharma Inc. Multinational	Long-term Follow-up Study for Participants of Kite-Sponsored Interventional Studies Treated With Gene-Modified Cells

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CTIS ITALY - RMS 2025-522821-37-00 INITIAL (Part I + Part II)	BETELGEUSE Interventistico con farmaco - No Profit Phase I Promotore: Azienda Ospedaliero-Universitaria Di Bologna IRCCS Istituto Di Ricerca E Di Cura A Carattere Scientifico Mononational	Basket trial for B-cEll driven severe auToimmunE and aLoimmune diseases (chronic Graft vErsUs host diseaSe) treated with anti-CD19 CAR T-cell thErapy
CTIS ITALY - RMS 2024-518369-92-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	WAS-TLT003-01 Interventistico con farmaco - No Profit Phase III Promotore: Fondazione Telethon Ets Mononational	A Long-term Follow-up Study for Subjects Previously Treated with Autologous ex vivo Lentiviral Hematopoietic Stem and Progenitor Cell Gene Therapy for Wiskott-Aldrich Syndrome (WAS)
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).
CTIS ITALY - MS 2024-512177-27-01 ADDED MEMBER STATE AM-3 (Part I + Part II)	000434 – ABLE-22 Interventistico con farmaco - Profit Phase III Promotore: Ferring Pharmaceuticals A/S Multinational	A phase 3, randomised, multi-center, open label trial to evaluate the safety and efficacy of intravesical nadofaragene firadenovec alone or in combination with chemotherapy (gemcitabine and docetaxel) or immunotherapy (pembrolizumab) in subjects with high-grade Bacillus Calmette-Guerin therapy (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC)
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

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CTIS ITALY - MS 2026-525367-40-00 INITIAL (Part I + Part II)	D8316C00001 (DURGA 6) Interventistico con farmaco - Profit Phase III Promotore: AstraZeneca AB Multinational	A Phase III, Open-label, Multicentre, Randomised Study Comparing Consolidation Treatment with AZD0120, an Autologous Dual Targeting Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Autologous Stem Cell Transplant (ASCT) in Participants with Newly Diagnosed Multiple Myeloma who are Transplant Eligible (TE NDMM) (DURGA-6)
CTIS ITALY - MS 2023-505177-32-00 SUBSTANTIAL MODIFICATION SM-8 (Part I + Part II)	V940-004 Interventistico con farmaco - Profit Phase II Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 2, Randomized, Double-blind, Clinical Study of V940 (mRNA-4157) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab in the Adjuvant Treatment of Participants With Renal Cell Carcinoma (INTerpath-004)
CTIS ITALY - MS 2023-510380-34-00 SUBSTANTIAL MODIFICATION SM-9 (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 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
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 - RMS 2023-508355-39-00 SUBSTANTIAL MODIFICATION SM-4 (Part II)	CD7-CAR01 Interventistico con farmaco - No Profit Phase I/II Promotore: Ospedale Pediatrico Bambino Gesu' Mononational	Phase I/II study of anti-CD7 Chimeric Antigen Receptor-Expressing T cells in pediatric patients/young adult affected by relapsed/refractory CD7+ T-cell Acute Lymphoblastic Leukemia/Lymphoma

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INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2024-517335-46-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	V940-011 Interventistico con farmaco - Profit Phase II Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 2 Open-label Randomized Study of V940 in Combination With BCG Versus BCG Monotherapy in Participants With High-risk Non-muscle Invasive Bladder Cancer (INTerpath-011)