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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 2023-510150-17-00 SUBSTANTIAL MODIFICATION SM-7 (Part I + Part II)	CYTB323J12201 Interventistico con farmaco - Profit Phase II Promotore: Novartis Pharma AG Multinational	A Phase 2, adaptive, randomized, open-label, assessor-blinded active-controlled study to evaluate the efficacy and safety of rapcabtagene autoleucel versus Standard of Care in patients suffering from systemic lupus erythematosus (SLE) with active, refractory lupus nephritis (LN).
CTIS ITALY - MS 2024-512298-28-00 SUBSTANTIAL MODIFICATION SM-9 (Part I + Part II)	M24-528 Interventistico con farmaco - Profit Phase III Promotore: AbbVie Deutschland GmbH & Co. KG Multinational	A Randomized, Controlled, Partially Masked, Phase 3b Study to Assess the Injection Burden, Efficacy, Safety, and Long-Term Preservation of Visual Acuity of Surabgene Lomparvovec (ABBV-RGX-314) in a Real-World Context in Subjects with Neovascular Age-Related Macular Degeneration (nAMD)
CTIS ITALY - MS 2025-523845-90-00 ADDED MEMBER STATE AM-3 (Part I + Part II)	CRSP-AID-501 Interventistico con farmaco - No Profit Phase I/II Promotore: CRISPR Therapeutics AG Multinational	A Phase 1/2 Dose Evaluation Trial of the Safety and Preliminary Efficacy of AntiCD19 Allogeneic CRISPR-Cas9–Engineered T Cells (CTX112) in Adult Participants With Relapsed/Refractory Hematologic Autoimmune Disease
CTIS ITALY - MS 2026-525886-38-00 INITIAL (Part I + Part II)	ATSN-201-1 Interventistico con farmaco - Profit Phase I/II Promotore: Atsena Therapeutics Inc. Multinational	A Phase 1/2/3, Open-Label, Dose Escalation, Dose Expansion, and Randomized, Controlled Study to Evaluate the Safety and Efficacy of ATSN-201 Gene Therapy in Subjects with RS1-Associated X-linked Retinoschisis (LIGHTHOUSE)
CTIS ITALY - RMS 2025-524635-39-00 SUBSTANTIAL MODIFICATION SM-3 (Part I + Part II)	HIGM1-FT018-01 Interventistico con farmaco - Profit Phase I/II Promotore: San Raffaele Hospital Fondazione Telethon Ets Mononational	A Single Arm, Open Label, Single Center, Phase I/II Clinical Study evaluating Safety and Efficacy of gene therapy using Autologous CD4+ T-Cells Edited ExVivo at the CD40LG Locus by CRISPR/Cas9 and IDLV-based vector in Patients with Xlinked Hyper IgM Syndrome Type 1 (HIGM1).

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CTIS ITALY - MS 2022-503140-41-00 SUBSTANTIAL MODIFICATION SM-14 (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
CEN ATMP RSO - 4260 INITIAL (Part I + Part II)	DISH-SCC Osservazionale senza farmaco e dispositivo - No Profit Promotore: Fondazione Policlinico Universitario Agostino Gemelli IRCCS Mononational	Development of immunotherapy strategies in head and neck squamous cell carcinoma
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 2025-522949-22-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	SGT-003-301 Interventistico con farmaco - Profit Phase III Promotore: Solid Biosciences Inc Multinational	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy of a Single Intravenous Dose of SGT-003 in Ambulant Males With Duchenne Muscular Dystrophy
CTIS ITALY - MS 2025-522207-15-01 SUBSTANTIAL MODIFICATION SM-8 (Part I + Part II)	039-101 Interventistico con farmaco - Profit Phase I/II Promotore: Aavantgarde Bio S.r.l. Multinational	An Open-label, Multicenter, Two Part, Ascending Dose Followed by a Controlled Trial to Assess the Safety and Efficacy of a Subretinal Administration of AAVB-039 in Participants with Stargardt Disease (STGD1) (CELESTE)
CTIS ITALY - MS 2024-514596-18-00 SUBSTANTIAL MODIFICATION SM-3 (Part I + Part II)	U1111-1325-1245 Interventistico con farmaco - Profit Phase I/II Promotore: Novartis Pharma AG Multinational	An open-label, multi-center, phase 1/2 study to assess safety, cellular kinetics and exploratory efficacy of rapcabtagene autoleucel in participants with difficult-to-treat rheumatoid arthritis and severe, refractory Sjogren's disease with organ involvement

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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 2026-525847-34-00 INITIAL (Part I + Part II)	MPSVI-FT005-02 Interventistico con farmaco - Profit Phase I/II Promotore: Fondazione Telethon ETS Mononational	A Phase I/II Open-Label Extension of Study TIGEM1-MPSVI, Evaluating the Safety and Efficacy of FT005, an Adeno-Associated Viral Vector 8 to Deliver the Human ARSB Gene to the Liver of Subjects with Mucopolysaccharidosis type VI (MPS VI)
CTIS ITALY - MS 2023-506480-34-00 SUBSTANTIAL MODIFICATION SM-6 (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 - MS 2025-524014-29-00 INITIAL (Part I + Part II)	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).
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)

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CTIS ITALY - MS 2024-512714-18-00 SUBSTANTIAL MODIFICATION SM-3 (Part II)	CYTB323N12101 Interventistico con farmaco - Profit Phase I/II Promotore: Novartis Pharma AG Multinational	An open-label, multi-center, phase 1/2 study to assess safety, efficacy, and cellular kinetics of YTB323 in participants with Relapsing Multiple Sclerosis with breakthrough disease activity during previous treatment with a highly efficacious therapy
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)
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 2023-505177-32-00 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)

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CTIS ITALY - MS 2023-506327-29-00 SUBSTANTIAL MODIFICATION SM-6 (Part I + Part II)	V940-009 Interventistico con farmaco - Profit Phase III Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab With or Without V940 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy (INTerpath-009)
CTIS ITALY - MS 2025-523660-21-00 SUBSTANTIAL MODIFICATION SM-5 (Part II)	C0371017 Interventistico con farmaco - Profit Phase III Promotore: Pfizer Inc. Multinational	A Phase 3, Non-Investigational Product, Multi Country Cohort Study to Describe the Long-Term Safety and Effectiveness of a Prior Single-Dose Treatment With Investigative Giroctocogene Fitelparvovec or Fidanacogene Elaparvovec in Participants With Hemophilia A or Hemophilia B, Respectively