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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
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
CTIS ITALY - MS 2023-503281-23-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	1504-0001 Interventistico con farmaco - Profit Phase I/II Promotore: Boehringer Ingelheim International GmbH Multinational	A seamless Phase I/II trial with an initial open-label dose escalation part and a subsequent randomised, double-blind, placebo-controlled expansion part to evaluate the safety, tolerability, and efficacy of a single dose of BI 3720931, an inhaled lentiviral vector gene therapy, in adult people with cystic fibrosis who are ineligible for CFTR modulators (LenticlairTM 1)
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 - MS 2024-515279-37-00 SUBSTANTIAL MODIFICATION SM-7 (Part I + Part II)	CA088-1007 Interventistico con farmaco - Profit Phase II/III Promotore: Celgene Corp. Multinational	A Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of BMS-986393, a GPRC5D-directed CAR-T Cell Therapy, Versus Standard Regimens in Adult Participants with Relapsed or Refractory and Lenalidomide-refractory Multiple Myeloma

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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 2023-510380-34-00 SUBSTANTIAL MODIFICATION SM-7 (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 2025-522054-40-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	IOV-MEL-202 Interventistico con farmaco - Profit Phase II Promotore: Iovance Biotherapeutics Inc. Multinational	A Phase 2, multicenter, open-label study of lifileucel (tumor-infiltrating lymphocytes [TIL]) in participants with previously treated advanced melanoma
CTIS ITALY - MS 2023-505658-17-00 SUBSTANTIAL MODIFICATION SM-6 (Part I + Part II)	V940-005 Interventistico con farmaco - Profit Phase I/II Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 1/2 Study of V940 Plus Pembrolizumab With or Without Enfortumab Vedotin in Muscle-Invasive Urothelial Carcinoma (MIUC) (INTerpath-005)
CTIS ITALY - MS 2023-503823-24-01 SUBSTANTIAL MODIFICATION SM-8 (Part I + Part II)	CA061-1001 Interventistico con farmaco - Profit Phase I Promotore: Celgene Corp. Multinational	A Phase 1 Study of CD19-targeted NEX-T CAR T Cells in Participants with Severe, Refractory Autoimmune Diseases
CTIS ITALY - MS 2024-519278-37-00 SUBSTANTIAL MODIFICATION SM-2 (Part I + Part II)	CA061-1011 Interventistico con farmaco - Profit Phase II Promotore: Celgene Corp. Multinational	A Phase 2, Multicenter, Open-Label Study of CC-97540 (BMS-986353), CD19-Targeted NEX-T CAR T Cells, in Participants with Active SLE (Including Lupus Nephritis) with Inadequate Response to Glucocorticoids and at Least 2 Immunosuppressants (Breakfree-SLE

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CTIS ITALY - RMS 2024-514501-57-00 SUBSTANTIAL MODIFICATION SM-3 (Part I + Part II)	SGT-003-101 Interventistico con farmaco - Profit Phase I/II Promotore: Solid Biosciences Inc. Mononational	A Phase 1/2, Multicenter, Open-Label Study to Investigate the Safety, Tolerability, and Efficacy of a Single Intravenous Dose of SGT-003 in Ambulant Males with Duchenne Muscular Dystrophy
CTIS ITALY - MS 2022-503140-41-00 SUBSTANTIAL MODIFICATION SM-13 (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 2023-505043-39-00 SUBSTANTIAL MODIFICATION SM-7 (Part I + Part II)	SRP-9001-305 Interventistico con farmaco - Profit Phase III Promotore: Serepta Therautics Inc. Multinational	A Phase 3, Multinational, Long-Term Follow-Up Study to Evaluate Safety and Efficacy in Subjects Who Have Previously Received SRP-9001 in a Clinical Study
CTIS ITALY - MS 2024-514137-38-00 SUBSTANTIAL MODIFICATION SM-4 (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 2025-522207-15-01 INITIAL (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 2024-512029-10-00 ADDED MEMBER STATE AM-2 (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)

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CTIS ITALY - MS 2025-523660-21-00 INITIAL (Part I + 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
CTIS ITALY - MS 2025-522647-17-00 INITIAL (Part I + Part II)	Interventistico con farmaco - Profit Promotore: Hmg Biologics S.r.l. Multinational	A two-part study: open label, dose escalation phase aimed to evaluate the safety and tolerability of two different doses of allogeneic fibroblasts for the treatment of chronic refractory wounds and identifying the best dose for subsequent cohort expansion phase aimed to assess efficacy and confirm safety and tolerability
CTIS ITALY - MS 2025-522949-22-00 INITIAL (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 2025-523285-25-00 INITIAL (Part I + Part II)	D8311C00001 Interventistico con farmaco - Profit Phase III Promotore: AstraZeneca AB Multinational	A Phase III Open-label, Randomised, Multicentre Study Comparing AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Standard Regimens in Participants with Relapsed Refractory Multiple Myeloma (DURGA-4)
CTIS ITALY - MS 2025-523448-10-00 INITIAL (Part I + Part II)	KTE-C19-104 Interventistico con farmaco - Profit Phase II Promotore: Gvhd Resistant to ruxolitinib and steroids Multinational	Efficacy of cell therapy with allo-MSCs in patients with gvhd resistant to ruxolitinib second line therapy: a Phase IIB Clinical Trial - MSC-GRR2 Study
CTIS ITALY - MS 2023-504909-37-00 SUBSTANTIAL MODIFICATION SM-3 (Part I + Part II)	1504-0003 Interventistico con farmaco - Profit Phase I/II Promotore: Boehringer Ingelheim International GmbH Multinational	A clinical trial to evaluate the long-term safety and durability of efficacy of BI 3720931, an inhaled lentiviral vector gene therapy, after single dose administration in a previous clinical trial in people with cystic fibrosis rolled-over from a previous clinical trial with BI 3720931 (LenticlairTM-ON).

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CTIS ITALY - MS 2025-521145-24-01 INITIAL (Part I + Part II)	CAB-201-002 Interventistico con farmaco - Profit Phase I/II Promotore: Cabaletta Bio Inc. Multinational	A Phase 1/2, Open-Label Study to Evaluate the Safety and Efficacy of Autologous CD19-specific Chimeric Antigen Receptor T cells (CABA-201) in Subjects with Active Idiopathic Inflammatory Myopathy or Active Juvenile Idiopathic Inflammatory Myopathy
CTIS ITALY - MS 2023-503652-27-00 SUBSTANTIAL MODIFICATION SM-9 (Part I)	V940-001 Interventistico con farmaco - Profit Phase III Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants with High-risk Stage II-IV Melanoma (INTerpath-001)