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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 - RMS 2024-513978-22-00 SUBSTANTIAL MODIFICATION SM-3 (Part I)	VX21-CTX001-151 Interventistico con farmaco - Profit Phase III Promotore: Vertex Pharmaceuticals Inc. Multinational	A Phase 3 Study to Evaluate the Safety and Efficacy of a Single Dose of CTX001 in Pediatric Subjects With Severe Sickle Cell Disease
CTIS ITALY - MS 2024-512029-10-00 SUBSTANTIAL MODIFICATION SM-4 (Part I)	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)
CEN ATMP RSO - 4408 INITIAL	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
CEN ATMP RSO - 4260 INITIAL	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

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CTIS ITALY - RMS 2024-514053-30-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	IRST153.09 Interventistico con farmaco - No Profit Phase II Promotore: Istituto Romagnolo Per Lo Studio Dei Tumori Dino Amadori IRST S.r.l. Mononational	Sequential immunochemotherapy treatment with Pembrolizumab plus Dendritic Cell (DC) Vaccine followed by Trifluridine/Tipiracil plus Bevacizumab in refractory mismatch-repair-proficient (pMMR) or microsatellite-stable (MSS) metastatic colorectal cancer
CTIS ITALY - MS 2023-507041-28-00 SUBSTANTIAL MODIFICATION SM-8 (Part I)	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
CTIS ITALY - MS 2023-506327-29-00 SUBSTANTIAL MODIFICATION SM-5 (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 2022-503112-17-00 SUBSTANTIAL MODIFICATION SM- 4 (Part I + Part II)	SRP-9003-301 Interventistico con farmaco - Profit Phase III Promotore: Sarepta Therapeutics Inc. Multinational	A Phase 3 Multinational, Open-label, Systemic Gene Delivery Study to Evaluate the Safety and Efficacy of SRP-9003 in Subjects with Limb Girdle Muscular Dystrophy 2E/R4
CTIS ITALY - MS 2025-524337-11-00 INITIAL (Part I + Part II)	U1111-1330-3381 Interventistico con farmaco - Profit Phase III Promotore: Celgene Corporation Multinational	A Phase 3, Randomized, Open-label, Multicenter Study to Compare the Efficacy and Safety of BMS-986353, CD19-targeted NEX-T CAR T Cells, Versus Standard of Care in Participants with Active Systemic Sclerosis (Breakfree-SSc)
CTIS ITALY - MS 2022-501607-27-00 SUBSTANTIAL MODIFICATION SM-13 (Part II)	NA Interventistico con farmaco - Profit Phase I/II Promotore: Cellectis Multinational	Open-label dose-finding and dose-expansion study to evaluate the safety, expansion, persistence, and clinical activity of UCART20x22 in subjects with relapsed or refractory B-cell Non-Hodgkin Lymphoma (B-NHL)

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CTIS ITALY - RMS 2025-522643-18-00 INITIAL (Part I + Part II)	V940-014 Interventistico con farmaco - Profit Phase III Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 3, Randomized, Placebo-Controlled Study of Adjuvant Intismeran Autogene Plus Subcutaneous Pembrolizumab and Berahyaluronidase Alfa (MK-3475A) or Intismeran Autogene Monotherapy Versus Placebo in Participants With Completely Resected High-Risk Stage I Non-Small Cell Lung Cancer (INTerpath-014)
CTIS ITALY - MS 2025-522275-28-00 INITIAL (Part I + Part II)	OTL-200-11 Interventistico con farmaco - Profit Phase IV Promotore: Orchard Therapeutics (Europe) Ltd Multinational	Sample Collection Study to Monitor the Risk of Malignancy Due to Insertional Oncogenesis in Early Onset Patients with Metachromatic Leukodystrophy Treated with OTL-200 in the Clinical Development Program
CTIS ITALY - RMS 2023-505511-20-00 SUBSTANTIAL MODIFICATION SM-2 (Part II)	FT04CARCIK Interventistico con farmaco - No Profit Phase I/II Promotore: Fondazione Tettamanti Mononational	Phase I/II Trial to Determine Persistence, Safety and Clinical Activity of Allogeneic CIK Cells Transduced with a Transposon CD19-chimeric Antigen Receptor (CARCIK-CD19) in Adult and Pediatric Patients with Relapsed/Refractory B-cell Non-Hodgkin Lymphoma and B-cell Chronic Lymphocytic Leukemia
CTIS ITALY - MS 2024-514596-18-00 ADDED MEMBER STATE AM-2 (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
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 - MS 2023-504923-20-00 SUBSTANTIAL MODIFICATION SM-6 (Part I + Part II)	V940-002 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 Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer (INTerpath-002)

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CTIS ITALY - RMS 2022-502305-15-00 SUBSTANTIAL MODIFICATION SM-6 (Part I + Part II)	UCART22_01 Interventistico con farmaco - Profit Phase I/II Promotore: Cellectis Multinational	Open label dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCART22 (allogeneic engineered T-cells expressing Anti-CD22 Chimeric Antigen Receptor) in patients with relapsed or refractory CD22+ B-cell Acute Lymphoblastic Leukemia (B-ALL)
CTIS ITALY - MS 2024-517335-46-00 SUBSTANTIAL MODIFICATION SM-3 (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)
CTIS ITALY - RMS 2025-522160-32-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II)	BTHAL-FT007-01 Interventistico con farmaco - Profit Phase II Promotore: Fondazione Telethon Ets Mononational	A single arm, open label, multicenter, single-dose, phase 2b clinical study evaluating efficacy and safety of gene therapy using autologous CD34+ hematopoietic stem cells transduced with the GLOBE lentiviral vector using an improved transduction protocol in subjects with transfusion-dependent beta-thalassemia.
CEN ATMP RSO - 4562 INITIAL	PROJ111905 Osservazionale con farmaco - Profit Promotore: Miltenyi Biomedicine GmbH Friedrich-Ebert-Straße 68, 51429 Bergisch Gladbach Germany Multinational	Zamtoacabtagene Autoleucel External Comparator Study