Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate

Giorno 09 dicembre 2025 ore 16:00 – 18:00

ORDINE DEL GIORNO

1. Verifica numero Legale

2. Approvazione del verbale n. 11/2025 della seduta del 25 novembre 2025

3. Procedure in valutazione
   (dalla pagina seguente)

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2023-508784-68-00 INITIAL (Part I + Part II) Multinational	RP2-202 Interventistico con farmaco - Profit Phase II/III	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 2023-506327-29-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II) Multinational	V940-009 Interventistico con farmaco - Profit Phase III	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 - RMS 2024-513978-22-00 SUBSTANTIAL MODIFICATION SM-2 (Part II) Multinational	VX21-CTX001-151 Interventistico con farmaco - Profit Phase III	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 2023-504923-20-00 SUBSTANTIAL MODIFICATION SM-5 (Part I + Part II) Multinational	V940-002 Interventistico con farmaco - Profit Phase III	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)

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2023-507717-94-00 SUBSTANTIAL MODIFICATION SM-2 (Part I + Part II) Multinational	dS-BA-PIII Interventistico con farmaco - Profit Phase III	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 2024-511188-26-00 SUBSTANTIAL MODIFICATION SM-3 (Part I + Part II) Multinational	KT-US-679-0788 Interventistico con farmaco - Profit Phase III	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 2025-520902-37-00 INITIAL (Part I + Part II) Multinational	V940-013 Interventistico con farmaco - Profit Phase II	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 2023-506480-34-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II) Multinational	RP-A501-0123 Interventistico con farmaco - Profit Phase II	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 2024-514006-31-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II) Multinational	CYTB323R12101 Interventistico con farmaco - Profit Phase I/II	An open-label, multi-center, phase I/II study to assess safety, disease progression, and cellular kinetics following YTB323 administration in participants with non-active Progressive Multiple Sclerosis (PMS)

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - RMS 2025-521500-21-00 INITIAL (Part I + Part II) Mononational	RESTORE Interventistico con farmaco - No Profit Phase II	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 2023-508081-15-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II) Multinational	CCTL019G2201J Interventistico con farmaco - Profit Phase II	A phase II trial of tisagenlecleucel in first-line high-risk (HR) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (B-ALL) who are minimal residual disease (MRD) positive at the end of consolidation (EOC) therapy
CTIS ITALY - MS2024-514137-38-00SUBSTANTIAL MODIFICATION SM-3(Part I + Part II)Multinational	CYTB323L12201Interventistico con farmaco - ProfitPhase II	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

Si specifica che gli studi vengono inseriti all'Ordine del Giorno (O.d.G.) 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.

4. Revisione/adozione Regolamento del CEN ATMP (Tutti i componenti)

5. Varie ed eventuali