



Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate

Giorno 26 AGOSTO ore 16:30 – 18:30

ORDINE DEL GIORNO

1. Comunicazioni del Presidente
2. Approvazione del verbale n.7 della seduta del 05.08.2025
3. Procedure in valutazione
(dalla pagina seguente)

INFO GENERALI	Info Studio	Titolo	Scadenze
CTIS ITALY - RMS 2024-519317-66-00 INITIAL (Part I + Part II) Mononational	AT-W-CLI-2024-10 Interventistico con farmaco - Profit Phase II	(ESMERALD) A phase-2A, single-centre, prospective, uncontrolled, open label, single arm, exploratory clinical study to evaluate the safety and efficacy of cutaneous AUP1602-C with foam dressing as a treatment for non-healing neuroischemic diabetic foot ulcers	Primo O.d.G: 24/06/2025 Data Fine: 28/08/2025 (Secondo Round)
CTIS ITALY - MS 2024-513683-25-00 INITIAL (Part I + Part II) Multinational	NA Interventistico con farmaco - No Profit Phase II	Randomized, controlled, multi-center phase II clinical trial for the treatment of patellofemoral osteoarthritis with nasal chondrocyte-based tissue engineered cartilage implantation vs current standard of care (ENCANTO)	Primo O.d.G: 08/07/2025 Data Fine: 28/08/2025 (Secondo Round)
CTIS ITALY - MS 2025-521349-25-00 INITIAL (Part I + Part II) Multinational	4D-150-C004 Interventistico con farmaco - Profit Phase III	A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of 4D-150 in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration (4FRONT-2)	Primo O.d.G: 05/08/2025 Data Fine: 29/08/2025 (Primo Round)
CTIS ITALY - MS 2023-505658-17-00 SUBSTANTIAL MODIFICATION SM-5 (Part I + Part II) Multinational	V940-005 Interventistico con farmaco - Profit Phase I/II	A Phase 1/2 Study of V940 Plus Pembrolizumab With or Without Enfortumab Vedotin in Muscle-Invasive Urothelial Carcinoma (MIUC) (INTTerpath-005)	Primo O.d.G: 26/08/2025 Data Fine: 08/09/2025 (Primo Round)
CTIS ITALY - MS 2023-505043-39-00 SUBSTANTIAL MODIFICATION SM-5 (Part I + Part II) Multinational	SRP-9001-305 Interventistico con farmaco - Profit Phase III	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	Primo O.d.G: 26/08/2025 Data Fine: 08/09/2025 (Primo Round)
CTIS ITALY - MS 2022-503140-41-00 SUBSTANTIAL MODIFICATION SM-12 (Part I + Part II) Multinational	IOV-MEL-301 Interventistico con farmaco - Profit Phase III	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	Primo O.d.G: 26/08/2025 Data Fine: 11/09/2025 (Primo Round)

CTIS ITALY - MS 2022-500746-16-00 SUBSTANTIAL MODIFICATION SM-8 (Part I + Part II) Multinational	81201887MDG2001 Interventistico con farmaco - Profit Phase II	A Phase 2b, Randomized, Double-masked, Multicenter, Dose-ranging, Sham-controlled Clinical Trial to Evaluate Intravitreal JNJ-81201887 (AAVCAGsCD59) Compared to Sham Procedure for the Treatment of Geographic Atrophy (GA) Secondary to Age-related Macular Degeneration (AMD)	Primo O.d.G: Data Fine: 09/06/2025 (Secondo Round)
CTIS ITALY - MS 2023-503666-23-00 SUBSTANTIAL MODIFICATION SM-5 (Part I + Part II) Multinational	RGX-314-3101/M23-409 Interventistico con farmaco - Profit Phase III	A Randomized, Partially Masked, Controlled, Phase 3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ASCENT)	Primo O.d.G: 05/08/2025 Data Fine: 15/07/2025 (Primo Round)
CTIS ITALY - MS 2023-510150-17-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II) Multinational	CYTB323J12201 Interventistico con farmaco - Profit Phase II	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).	Primo O.d.G: 08/07/2025 Data Fine: 19/06/2025 (Secondo Round)
CTIS ITALY - RMS 2025-522160-32-00 INITIAL (Part I + Part II) Mononational	BTHAL-FT007-01 Interventistico con farmaco - Profit Phase II	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.	Primo O.d.G: 26/08/2025 Data Fine: 19/09/2025 (Primo Round)
CTIS ITALY - MS 2023-504786-23-00 SUBSTANTIAL MODIFICATION SM-14 (Part I + Part II) Multinational	VX21-522-001 Interventistico con farmaco - Profit Phase I/II	A Phase 1/2 Dose-escalation Study Evaluating the Safety, Tolerability, and Efficacy of VX-522 in Subjects 18 Years of Age and Older With Cystic Fibrosis and a CFTR Genotype Not Responsive to CFTR Modulator Therapy	Primo O.d.G: 26/08/2025 Data Fine: 22/09/2025 (Primo Round)
CTIS ITALY - MS2024-517580-23-00ADDED MEMBER STATE AM-2 (Part I + Part II) Multinational	VALO-001 Interventistico con farmaco - Profit Phase I	A Phase I, open-label, non-randomized study to evaluate the safety and immune activity of PeptiCRAd-1, a tumor-specific peptide coated conditionally replicating adenovirus, in combination with immune checkpoint inhibitor pembrolizumab in patients with injectable solid tumors in indications known to express NY-ESO-1 and MAGE-A3	Primo O.d.G:26/08/2025 Data Fine:22/09/2025 (Primo Round)

CTIS ITALY - MS 2024-515279-37-00 SUBSTANTIAL MODIFICATION SM-6 (Part I + Part II) Multinational	CA0881007 Interventistico con farmaco - Profit Phase II/III	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	Primo O.d.G: Data Fine: 29/09/2025 (Primo Round)
CTIS ITALY - MS 2024-512298-28-00 INITIAL (Part I + Part II) Multinational	M24-528 Interventistico con farmaco - Profit Phase III	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)	Primo O.d.G: 26/08/2025 Data Fine: 29/09/2025 (Primo Round)
CTIS ITALY - MS 2025-522054-40-00 INITIAL (Part I + Part II) Multinational	IOV-MEL-202 Interventistico con farmaco - Profit Phase II	A Phase 2, multicenter, open-label study of lifileucel (tumor-infiltrating lymphocytes [TIL]) in participants with previously treated advanced melanoma	Primo O.d.G: 26/08/2025 Data Fine: 03/10/2025 (Primo Round)
CTIS ITALY - MS 2024-517335-46-00 INITIAL (Part I + Part II) Multinational	V940-011 Interventistico con farmaco - Profit Phase II	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)	Primo O.d.G: 08/07/2025 Data Fine: 17/03/2025 (Secondo Round)
CTIS ITALY - MS 2024-517335-46-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II) Multinational	V940-011 Interventistico con farmaco - Profit Phase II	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)	Primo O.d.G: 08/07/2025 Data Fine: 01/09/2025 (Secondo Round)
CTIS ITALY - MS 2024-519278-37-00 INITIAL (Part I + Part II) Multinational	CA061-1011 Interventistico con farmaco - Profit Phase II	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	Primo O.d.G: Data Fine: 29/08/2025 (Primo Round)

CTIS ITALY - MS 2024-512504-19-00 ADDED MEMBER STATE AM-1 (Part I + Part II) Multinational	1456-0001 Interventistico con farmaco - Profit Phase I	Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with an anti-PD-1 mAb in patients with advanced or metastatic solid tumors.	Primo O.d.G: Data Fine: 02/04/2025 (Secondo Round)
CTIS ITALY - MS 2024-512504-19-00 SUBSTANTIAL MODIFICATION SM-7 (Part I + Part II) Multinational	1456-0001 Interventistico con farmaco - Profit Phase I	Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with an anti-PD-1 mAb in patients with advanced or metastatic solid tumors.	Primo O.d.G: 05/08/2025 Data Fine: 18/08/2025 (Primo Round)

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

5. Varie ed eventuali