



**Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate**

**Giorno 09 Settembre ore 11:00 – 14:00**

## **ORDINE DEL GIORNO**

1. Comunicazioni del Presidente
2. Approvazione del verbale n. 9/2025 della seduta del 26.08.2025
3. Procedure in valutazione  
(dalla pagina seguente)

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - RMS 2024-512898-27-00 SUBSTANTIAL MODIFICATION SM-2 (Part I + Part II) Mononational	TEM-GU Interventistico con farmaco - Profit Phase I/II	An open-label phase 1/2 study to evaluate the safety, biological response and efficacy of a single dose of Temferon (autologous CD34+- enriched hematopoietic stem and progenitors cells genetically modified with human Interferon- $\alpha$ 2) in patients with metastatic renal cell carcinoma
CTIS ITALY - MS 2022-500747-21-00 SUBSTANTIAL MODIFICATION SM-7 (Part II) Multinational	81201887MDG300 2 Interventistico con farmaco - Profit Phase II	Long-term Extension Study for Participants with Geographic Atrophy (GA) Secondary to Age-related Macular Degeneration (AMD) in JNJ-81201887 Parent Clinical Studies
CTIS ITALY - RMS 2024-516019-26-00 SUBSTANTIAL MODIFICATION SM-2 (Part I + Part II) Mononational	SNIPER Interventistico con farmaco - Profit Phase I/II	RR001 in Combination with Chemotherapy for Patients with Locally Advanced Pancreatic Adenocarcinoma: Open-label, Non-randomized Dose Escalation Phase I/IIa Study
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.
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.
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

CTIS ITALY - MS 2024-517580-23-00 ADDED 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
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)
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
CEN ATPM RSO 3462 INITIAL Mononational	Tale_Car_T	Car-T Therapy: analisi del cambiamento dei costi sanitari, della “patient experience” e degli “Incident Reporting System” - uno studio retrospettivo monocentrico
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
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)
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.

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

5. Varie ed eventuali