ONCOGEN CENTER | SCJUPBT TIMIȘOARA, ROMANIA

PARTNER PROFILE & CAPABILITY DECK — Horizon Europe & IHI Call 14 (Topic 4)

Institution: Pius Brînzeu County Clinical Emergency Hospital (SCJUPBT)	**PIC:** 895586451	**Location:** Timișoara, Romania (CEE / Widening)
Centre: OncoGen – Center for Gene & Cellular Therapies	**Director:** Prof. Dr. Virgil Păunescu	**Contact:** virgil.paunescu@oncogen.ro | www.oncogen.ro

1. Executive Profile & Strategic Positioning

OncoGen is an advanced research and hospital-based bioprocessing centre for cell and gene therapies, built through ERDF funding within a 3,000 m² specialized complex directly integrated into a tertiary university hospital (SCJUPBT). OncoGen bridges preclinical translational research with clinical-scale manufacturing capabilities. Positioned in a Central and Eastern European (CEE / Widening) member state, OncoGen offers consortia preparing full proposals for IHI Call 14, Topic 4 (ATMP: Supporting manufacturing and clinical centre readiness in Europe) a fully equipped real-world pilot site for decentralized manufacturing validation, pre-GMP release testing, and clinical care pathway harmonization.

2. Key Infrastructure & Bioprocessing Assets

Domain	Infrastructure & Technical Capabilities	Strategic Readiness Value
Cleanroom Complex (160 m²)	• 2 × 12 m² Grade A workstations in Grade B background cleanrooms. • 1 × 20 m² Grade B (BSL-2) cleanroom for viral/vector work. • Grade C & D supporting airlocks and gowning zones. • Equipped with 3 incubators, 3 laminar-flow cabinets, 3 centrifuges. • National GMP licensing pathway underway (projected in ~12 months).	Enables clinical-scale, aseptic ATMP micro-production, environmental monitoring SOP validation, and pre-licensing workflow piloting.
Automated Closed Processing	• Miltenyi CliniMACS Prodigy platform installed and fully operational. • Protocols for automated cell separation, genetic transduction, and formulation. • Capacity to integrate and benchmark alternative closed-system bioreactors.	Standardized point-of-care manufacturing; elimination of cleanroom operator variability; modular scalability.
Analytical Suites & Biobanking	• Multi-parametric flow cytometry & comprehensive immune-profiling. • NGS, genomics, qPCR, proteomics, microarray, and HLA typing. • Dedicated QC, ELISA, chemistry, and release-testing laboratories. • Certified human tissue and cell biobank; in vivo animal facility.	Full in-house analytical release testing, identity/purity assays, potency testing, and translational biomarker tracking.
Clinical Ecosystem (SCJUPBT)	• On-site therapeutic leukapheresis unit for starting material harvest. • Intensive Care Units (ICU) prepared for post-infusion toxicity management. • Affiliated university oncology & hematology networks (IC Fundeni, IOCN Cluj).	Full patient care pathway readiness: leukapheresis SOPs, cryogenic chain logistics, infusion monitoring, and multi-centre referral.

3. Research Pipeline & Intellectual Property

• **Engineered Cellular Immunotherapy:** Generation and validation of anti-EGFR CAR-PBMC platforms [Biomedicines 2025], anti-HER2 CAR-NK92 cells and their selective cytotoxic exosomes [Int J Mol Sci 2025], and transition models toward cell-free immunotherapy [Cells 2026].
• **Proprietary Patent Portfolio:** Published patent applications for cytotoxic cells bearing universal chimeric receptors for multiple antigens

(RO135043 A0) and selective bispecific CAR-T cells tailored for solid tumors (RO135040 A0).
• **Preclinical & Target Validation:** Target validation platforms (TheraFast), erythrocyte-based immune engagers (REAKT), and translational oncology models.

4. Proposed Contributions to IHI Call 14 (Topic 4) Consortia

Work Package / Focus Area	OncoGen Contribution & Deliverables
WP: Manufacturing Readiness & Decentralized Piloting	Hospital-based pilot site for closed-system automated cell processing (CliniMACS Prodigy); benchmarking environmental monitoring and batch release SOPs under pre-GMP / hospital exemption conditions.
WP: Clinical Centre Readiness & Care Pathways	Harmonization of clinical procedures: standardized leukapheresis, cold-chain transport, clinical-grade thawing/handling, and ICU management of cytokine release syndrome (CRS) / neurotoxicity.
WP: Regulatory Harmonization & Health Economics	Real-world case studies of national competent authority interactions in CEE; cost-of-goods (CoG) and capacity models comparing centralized vs. decentralized hospital-scale bioprocessing.
WP: Preclinical & Analytical Release Testing	Translational validation, flow-cytometric immunomonitoring, potency testing, genomics, and biobanking of patient and product samples.

5. Partnership Profile & Network Engagement

• **Sought Partners:** Industrial/biotech developers of ATMP technologies, closed-system automation providers, EFPIA/EuropaBio members seeking European pilot validation sites, academic proposal coordinators, and clinical networks.
• **Established Academic & Clinical Network:** Victor Babeș University of Medicine and Pharmacy Timișoara, Fundeni Clinical Institute (Bucharest), The Oncology Institute 'Prof. Dr. Ion Chiricuță' (IOCN Cluj-Napoca), Louis Țurcanu Children's Emergency Hospital, and academic collaborations with TU Dresden and Medical University of Vienna.