

PRECISEU Best Practice Recognition

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Winner in the Category EXCELLENCE

PragmaTIL

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The PragmaTIL trial aims to optimize TIL-ACT for cancer and enhance its clinical use in academic hospitals.

Launched in 2023 and funded by the EU's Horizon Europe program (Grant Agreement No. 101104684), PragmaTIL is a multi-center, open-label, phase II randomized clinical trial spanning 12 partners across 6 countries. Its goal is to optimize and expand Tumor-Infiltrating Lymphocyte Adoptive Cell Therapy (TIL-ACT) for patients with melanoma, non-small cell lung cancer (NSCLC), and cervical cancer by comparing ANV419, a novel IL-2 agonist, with the current high-dose IL-2 regimen. Objectives include determining if treatment-related toxicities can be reduced by 35%, and compare the quality of life of patients during their hospitalization period using ANV419 vs HD-IL-2. It is addressing cost-effectiveness, reimbursement strategies, and social return on investment.

Patient engagement is central, with trial participants acting as co-researchers through validated questionnaires and a Patient Advisory Committee composed of cancer survivors ensuring perspectives are integrated via Living Lab methodology.

Patients undergo preparative chemotherapy with cyclophosphamide and fludarabine before receiving TILs manufactured in-house by participating institutions. PragmaTIL demonstrates innovation through its regulatory approach, prioritizing product attributes—such as cell composition, viability, sterility, and potency—over rigid manufacturing protocols. Supported by meta-analyses showing no significant efficacy differences across varying manufacturing methods, this model accelerates trial implementation, enhances scalability, and democratizes access to advanced personalized therapies.

The PragmaTIL trial uses the WeShare platform (<https://weshare.unicancer.com/>), a digital infrastructure funded by the French National Research Agency (ANR) and coordinated by UNICANCER, to manage patient-reported data and ensure privacy compliance. WeShare provides researchers with secure technical tools for quantitative and qualitative data collection, study management, and interventional research, all aligned with FAIR standards. It functions as a public, standardized repository of patient-reported outcomes, clinical, behavioral, and socioeconomic data, enabling large-scale ancillary and secondary studies in oncology. Available in multiple languages, the platform allows patients across different countries to actively and passively report treatment-related toxicities, quality of life, and behavioral information. Its design emphasizes harmonisation, interoperability, and inclusivity while supporting digitally enabled trial procedures and patient engagement.

The use of the WeShare platform in PragmaTIL is outstanding because it supports digitally enabled clinical trial procedures that facilitate patient engagement and the collection of patient-generated data, while ensuring privacy, equity, inclusion, diversity, and multilingual access to advance patient-centered oncology research across Europe.