Scaling biotech innovation: Germany's opportunity in a shifting global order

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Collaboration for cure: why cell therapy biotechs need consortia to thrive

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The promise vs. reality gap in cell therapy

Chimeric antigen receptor T-cell (CAR-T) therapies represent the pinnacle of innovation in life sciences, delivering unmatched promise for hematological cancers and beyond – with seven approved products and growing early-line use – yet posing the greatest manufacturing challenges and costs. Biologically, they engineer patient T cells to express chimeric antigen receptors (CARs) that trigger tumor cell death. Beyond blood cancers, CAR-T shows potential for treating many other diseases, including solid tumors and autoimmune diseases.

CAR-T therapies, despite their transformative potential in oncology and immunology – with a global market valued at US$7.31b in 2024, projected to reach US$189b by 2034 at a CAGR of 36.8% – remain severely limited by per-patient costs averaging US$300,000-US$475,000.

Access to CAR-T therapy lags scientific progress. Despite eight regulatory approvals since 2018 only an estimated 11% to 30% of eligible patients received treatment as of 2023. Central to this gap are systemic bottlenecks, including manufacturing constraints due to leukapheresis coordination, complex logistics and prolonged vein-to-vein timelines that often exceed 40 days.

These delays heighten clinical uncertainty, with real-world data showing many patients deteriorating or dying while awaiting treatment.

TQ Therapeutics' pioneering fast cell therapy delivery

TQ Therapeutics (TQx) is a Munich, Germany-based biotechnology company advancing next-generation cellular therapies using innovative technologies to deliver them at the patient's point of care. The team developed a T-cell selection technology that isolates them directly from whole blood, enabling a one-day cell therapy delivery timeline versus several weeks. This CAR-T therapy process revolution will enable a future in which cell therapies are no longer niche treatments but scalable, life-changing interventions that reach patients efficiently and safely.

Built around TQx's proprietary cell selection technology, the company spans its modular CELLfinity Platform that unlocks infinite possibilities for clinical programs across diseases. Central to this vision is an ultra-short hybrid in vivo process that bridges conventional cell manufacturing concepts with direct in vivo therapy delivery. Clinically, this transforms cell therapy delivery by enabling device-based processing next to the patient, automates processing, reduces dependence on centralized facilities and lowers supply chain complexity. The technology is cost-efficient and highly scalable, with processing times under one day to meet growing demand.

While TQx advances next-generation cell therapies with an ultra-short process, transforming CAR-T requires broad collaboration across Europe; coordinated clinical, industrial and academic consortial efforts are key to overcoming bottlenecks and delivering benefits to patients.

EASYGEN – a collaborative blueprint for why consortia are essential in the cell therapy space

European health systems have begun addressing CAR-T access bottlenecks through national initiatives, but progress remains fragmented. Efforts largely operate in isolation, creating silos, data gaps and uneven access. Pan-European coordination is needed, including expanded capacity, digitalized quality management and harmonized data infrastructures to unlock the full potential of CAR-T and future advanced therapies.

The EASYGEN "EASY workflow integration for GENe therapy" consortium, led by Fresenius, Bad Homburg, Germany, provides a pan-European blueprint for hospital-integrated CAR-T manufacturing, that addresses persistent bottlenecks and fragmented delivery. It comprises 18 partners across eight countries, including key players such as TQx, Helios Klinikum Berlin-Buch, the Fraunhofer-Gesellschaft and the European Society for Blood and Marrow Transplantation (EBMT), supported by €8m in Innovative Health Initiative funding. The consortium unites clinical, industrial and academic expertise across work packages that cover process management, regulatory strategy, device optimization using Quality by Digital Design (QbDD), next-generation CAR-T development and point-of-care deployment. By linking technology providers and clinical experts, and embedding regulatory and health-technology expertise, EASYGEN creates a translatable framework for an advanced therapy production ecosystem across Europe.

Cell and gene therapies are complex and require collaboration. European consortia such as T2EVOLVE, GoCART, AIDPATH and JOIN4ATMP show how multi-stakeholder initiatives accelerate innovation, standardize processes and expand patient access. For startups, consortia provide access to Good Manufacturing Practices (GMP) facilities, clinical expertise, regulatory guidance and shared-risk frameworks. For corporates entering later, partnerships de-risk engagement with key technologies.

This is reinforced by internationally recognized academic and clinical leaders whose experience spans discovery research, GMP translation and real-world implementation. Within EASYGEN, for example, Prof. Dr. Ulrike Köhl, Manager of the Fraunhofer Institute for Cell Therapy and Immunology (Fraunhofer IZI), is a pioneer in GMP-compliant CAR-T development and manufacturing as well as clinical deployment, with extensive leadership experience at Fraunhofer IZI as well as within EBMT, Certainty, AIDPATH, JOIN4ATMP and as the coordinator of ImSAVAR and the cluster for future SaxoCell. In addition, Prof. Dr. Michael Hudecek, Head of the Cellular Immunotherapy Branch at Fraunhofer IZI in Würzburg and coordinator of T2EVOLVE, is a leading authority in CAR-T and T-cell receptor (TCR)-engineered therapies, driving pioneering clinical translation in oncology and autoimmune diseases. Consortia also strengthen interactions with regulators and payers by consolidating clinical, manufacturing and health-economic evidence into a coherent framework, supporting aligned regulatory evaluation and reimbursement.

Outlook for cell therapies leveraging consortial efforts

The future of CAR-T and advanced cell therapies envisions a shift from bespoke experimental manufacturing to scalable point-of-care production. Advances in automation, non-viral gene delivery and in vivo engineering promise faster, more efficient workflows, reducing reliance on specialized centers, enabling timely treatment and improving patient survival and quality of life. European consortia have laid the groundwork for regulatory harmonization and shared infrastructure, but sustained policy support, investment in digital competencies and ecosystem collaboration remain essential to turn breakthroughs into real-world access.