Systemic Barriers to CAR-T Access: Insights from a Certified German Center – first results from the EASYGEN consortium

D. Narres[1], R. Scheiwe[1], A. Ossami Saidy[2], B. Glass[2], C. Wegener[3], B. Lipp[4], J.O. Brunner[4], D. Krones[5], K. Mestermann[5], M. Hudecek[5], U. Köhl[6], S.Steppan[1], EASYGEN – EASY workflow integration for GENe therapy

[1] Fresenius SE & Co. KGaA, Bad Homburg, Germany, [2] Helios Klinikum Berlin-Buch GmbH, Berlin, Germany, [3] Fresenius Kabi, Lake Zurich USA, [4] Danmarks Tekniske Universitet – DTU, Lyngby, Denmark, [5] Fraunhofer Institute for Cell Therapy and Immunology, Würzburg, Germany, [6] Fraunhofer Institute for Cell Therapy and Immunology, Leipzig, Germany

Background

Chimeric antigen receptor T-cell (CAR-T) therapies are clinically effective but remain limited in real-world access due to highly complex, resource-intensive delivery processes. The EASYGEN consortium is a five-year collaboration of 18 academic, clinical, and industry partners, led by Fresenius, aiming to develop a scalable point-of-care framework for CAR-T delivery to improve sustainable implementation and patient access. The consortium is funded under the Innovative Health Initiative (IHI) Call 7.2 (Project No. 101194710) and structured within 8 core working packages jointly working together (fig. 1).

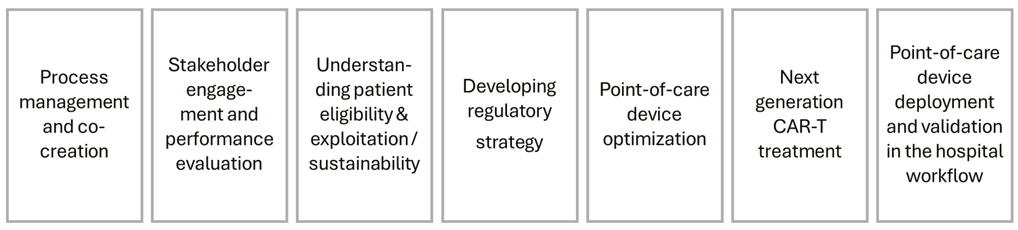

Figure 1. Core work packages of the EASYGEN consortium to enable scalable and sustainable CAR-T delivery at the hospital level.

Objectives

- To map current systemic barriers to CAR-T access in hospitals
- To establish a real-world baseline for comparison with decentralized, rapid point-of-care manufacturing models

Methods

A qualitative workflow analysis at a certified German CAR-T center identified key delivery barriers. Based on these findings, a structured survey was conducted among certified CAR-T centers in Germany (n=14). Centers allocated perceived effort (%) across eight predefined barrier domains for both implementation and routine phases. Results were summarized descriptively using medians, interquartile ranges (IQR), and aggregated ranking scores.

Results

Across German CAR-T centers, eight systemic barriers to CAR-T access were identified along the end-to-end care pathway, spanning both stage-specific (orange boxes) and cross-cutting (blue boxes) hurdles (fig. 2).

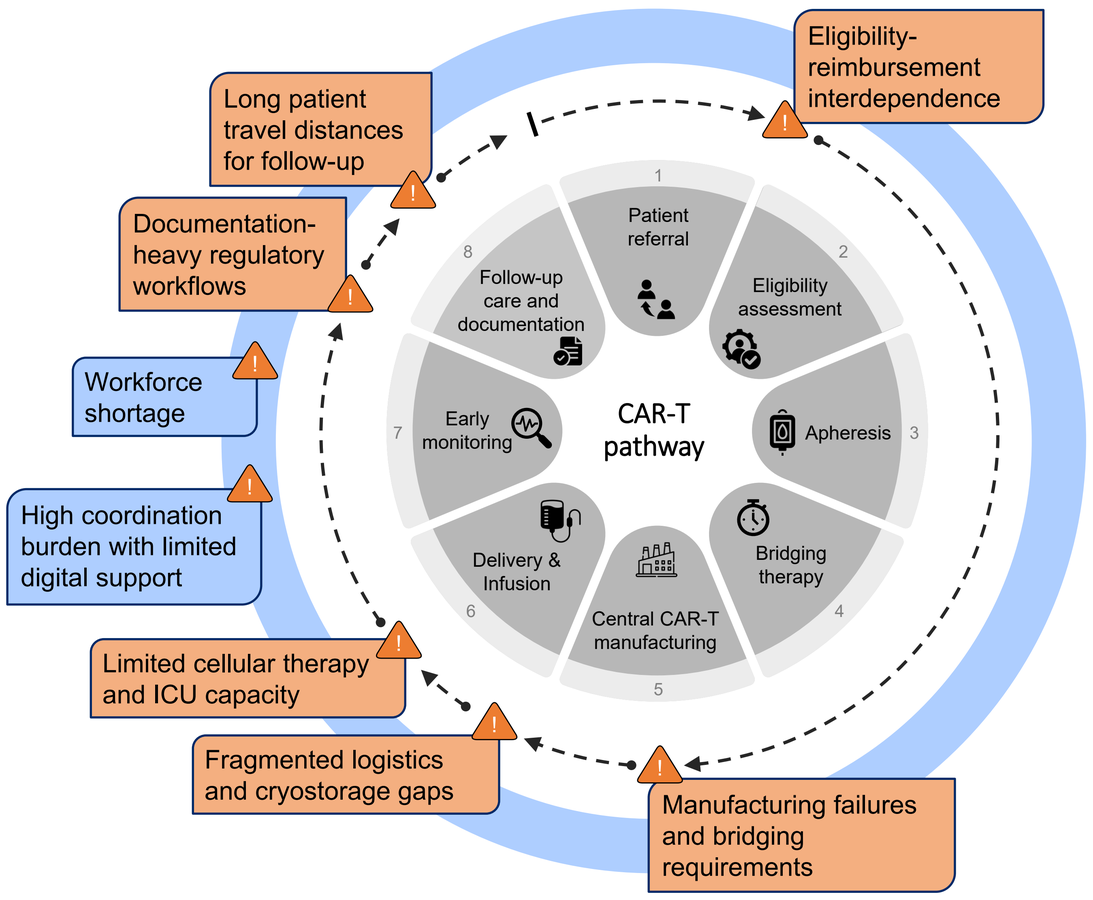

Figure 2 End-to-end CAR-T care pathway from patient referral to follow-up and documentation, structured into eight sequential process steps (grey boxes). Eight systemic barriers to CAR-T access were identified (orange triangles). Six barriers are linked to specific stages of the pathway (orange boxes), while two represent cross-cutting, omnipresent hurdles affecting all stages of CAR-T delivery (outer blue circle; light blue boxes).

These barriers span clinical, organizational, regulatory, and infrastructural domains and affect both center establishment and routine delivery, while the barriers “High coordination burden with limited digital support“ and „Workforce shortages in specialised roles“ were overarching throughout the whole CAR-T pathway.

Building on the qualitative mapping of the CAR-T pathway and the identified systemic barriers (fig. 2), we quantified how centers allocate relative effort across these hurdles (table 1) and how they prioritize them in routine practice (fig. 3). Eligibility, reimbursement, and documentation-related processes consistently ranked highest, accounting for the largest median workload shares and the highest ranking scores across centers. In contrast, logistics, manufacturing coordination, and referral pathways contributed smaller but more variable proportions of effort and ranked lower overall. Workforce shortages were excluded from this allocation analysis, as staffing constraints represent a structural boundary condition rather than an operational lever within the CAR-T process.

Table 1. Relative workload allocation across systemic CAR-T barriers during implementation and routine care. Median percentage allocation and interquartile range (IQR) of reported workload across eight predefined systemic barriers during CAR-T center implementation and routine operation (n = 14 centers). Δ represents the median difference between routine and implementation allocation (routine minus implementation). Positive Δ values indicate a higher relative workload in routine care, whereas negative values indicate higher allocation during implementation.

Barrier	Implementation Median (IQR), n=14	Routine Median (IQR), n=14	Δ (Routine-Implementation)
Eligibility-reimbursement interdependence	27,5% (13,75)	32,5% (15)	5
Documentation-heavy regulatory workflows	20,5% (16,25)	20% (5)	-0,5
Fragmented logistics and cryostorage gaps	10% (7,5)	10% (0)	0
Limited cellular therapy and ICU capacity	10% (1,25)	10 (7,5)	0
Manufacturing failures and bridging requirements	10% (0)	10% (11,25)	0
High coordination burden with limited digital support	10% (3)	5% (5)	-5
Long patient travel distances for follow-up	5% (5)	5% (5)	0

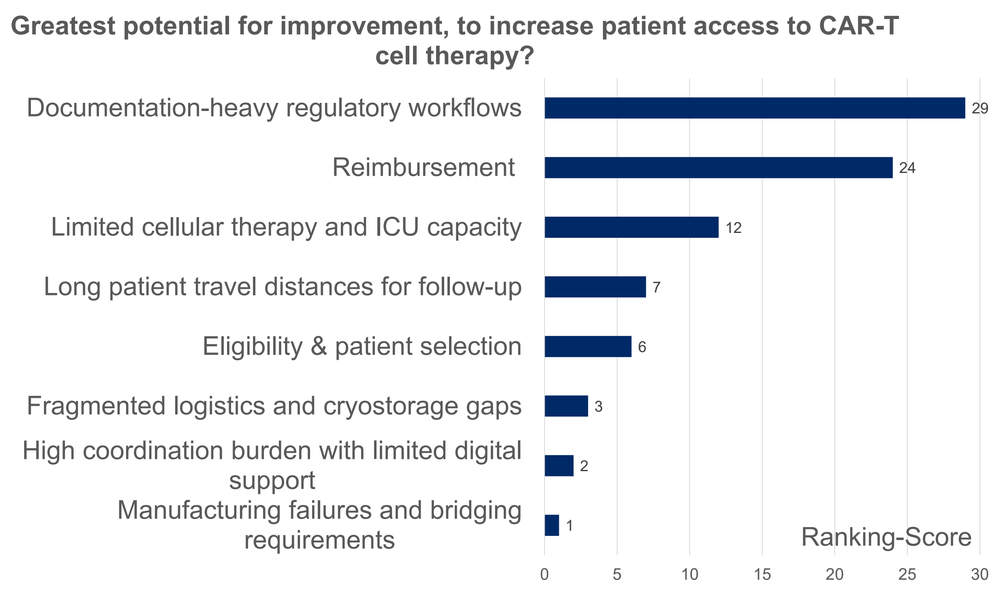

Figure 3. Ranking of systemic barriers to CAR-T delivery across German centers.
In a multicenter survey of German CAR-T centers (n=14), centers ranked the three barriers most in need of improvement. Rankings were weighted (rank 1 = 3 points, rank 2 = 2 points, rank 3 = 1 point) and summed to generate an overall ranking score per barrier, reflecting perceived relevance across centers.

Outlook

Building on these results, the study will be expanded to additional centers and rolled out at a European level to capture cross-country differences in regulation, reimbursement, and manufacturing models. The findings aim to inform evidence-based decision-making for policy makers and health system planners and complement ongoing translational and technological research within the EASYGEN consortium.

Acknowledgement

The EASYGEN „EASY workflow integration for GENe therapy“ consortium (Grant ID: 101194710) is funded by the European Union, the private members, and those contributing partners of the IHI JU. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the aforementioned parties. Neither of the aforementioned parties can be held responsible for them.