

## Background

Cell and gene therapies are among the most expensive therapies within the healthcare sector<sup>1</sup>. Systematic reviews of economic evaluations of Chimeric antigen receptor T-cell (CAR-T) therapies for cancer treatment show that CAR-T therapies tend to be more costly, but also more effective than comparative treatments<sup>1,2</sup>. As CAR-T therapy use increases and large numbers of new advanced cell therapies are developed, the CAR-T therapy management process needs to be optimized in order to reduce the diagnosis to treatment time (turnaround process). This reduces therapy manufacturing time and associated costs, facilitating better access for patients.

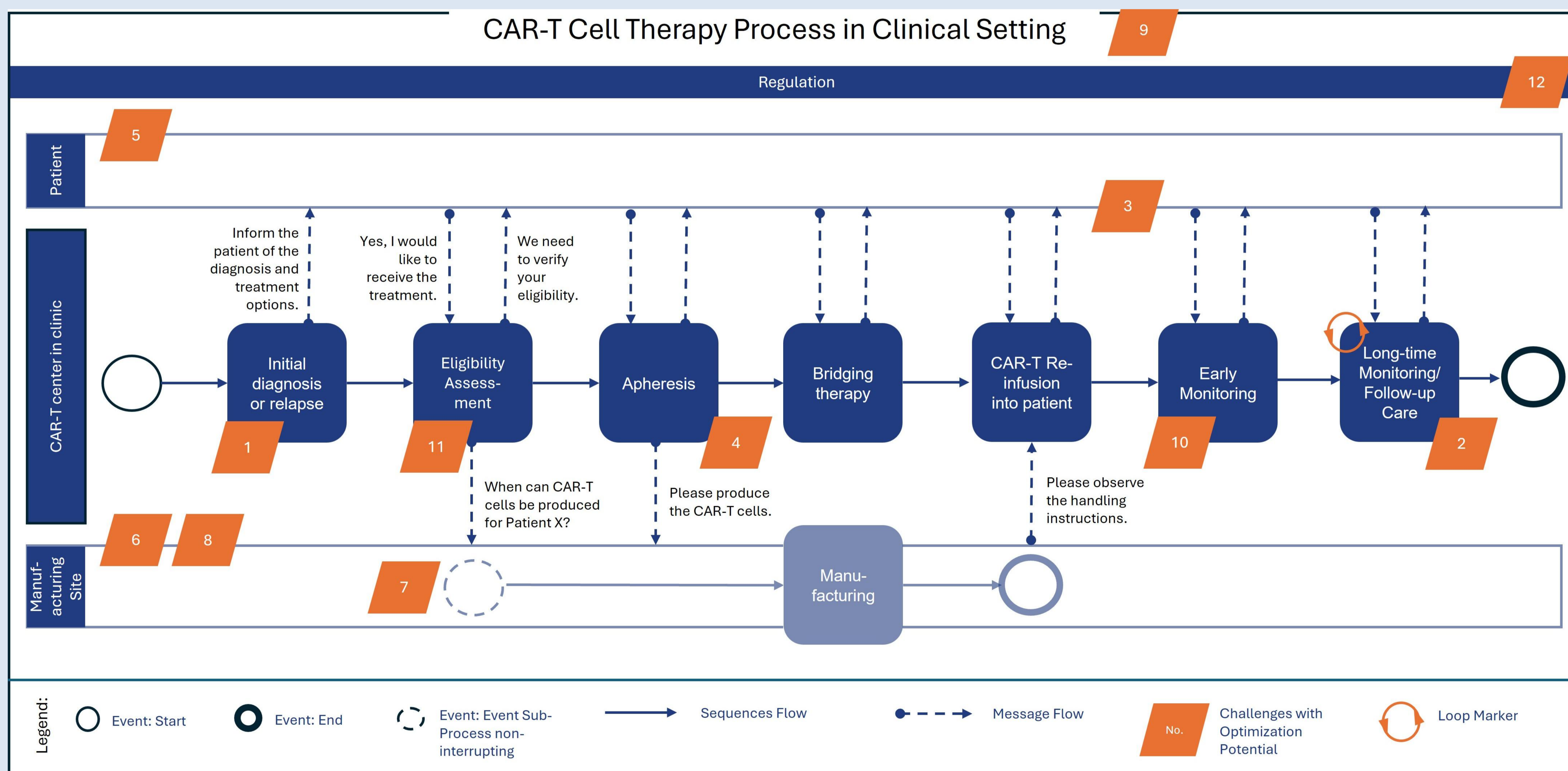
## Methods

We conduct eleven semi-structured expert interviews with clinicians, pharmacists, nurses, and coordinators with a CAR-T cell background from Germany, Ireland and Spain. Based on the interview results, we map the CAR-T cell therapy process using Business Process Model and Notation (BPMN)<sup>3</sup> and identify the optimization potentials.

## Results

Based on the interviews, we map the entire CAR-T cell therapy process and derive 12 challenges with potential for optimization (no specific order):

1. Indication - deciding on the right cancer therapy regimen for the individual patient
2. High response rate vs. low long-term remission rate of CAR-T therapies
3. Adverse events - resulting in a revolving door effect between outpatient care and hospitalization in the CAR-T center
4. Poor patient health before or after apheresis
5. Patient access – e.g. due to limited number of CAR-T cell centers patients must travel great distances to receive treatment and be monitored
6. High drug manufacturing cost due to centralized manufacturing and long production time
7. No standardization in terms of contracting between CAR-T manufacturing partners
8. High variety of CAR-T product specifications (different premedication, thawing procedures, treatment of side effects) requires extensive training and process management
9. Highly complex process management including logistics and coordination due to multi-stakeholder involvement
10. High staff workload due to continuous neurological testing
11. Limited number of beds at CAR-T and local centers - increased availability required for the expected scaling of CAR-T therapies
12. Complex regulation on regional, national and European levels



## Conclusions

The presented findings lay important groundwork for the definition of an optimized CAR-T cell therapy management process. The project EASYGEN aims to enable an automated, modular manufacturing platform for CAR-T cell production at the point-of-care and thereby reduce treatment cost by 50%, reduce manufacturing time significantly, broaden eligibility for new European patient groups and enable seamless integration of CAR-T cell manufacturing into routine hospital workflows.

### Sources:

- <sup>1</sup>Cliff, E. R. S., Kelkar, A. H., Russler-Germain, D. A., Tessema, F. A., Raymakers, A. J., Feldman, W. B., & Kesselheim, A. S. (2023). High cost of chimeric antigen receptor T-cells: challenges and solutions. *American Society of Clinical Oncology Educational Book*, 43, e397912.
- <sup>2</sup>Thavorn, K., Thompson, E.R., Kumar, S. et al. (2024) Economic evaluations of chimeric antigen receptor T-Cell therapies for hematologic and solid malignancies: a systematic review, *Value Health*, 27, pp. 1149-1173
- <sup>3</sup>Von Rosing, M., White, S., Cummins, F., & De Man, H. (2015). *Business Process Model and Notation-BPMN*.

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