

RECOMMENDATIONS FROM THE RET-A THINK TANK FOR THE MANAGEMENT AND IMPLEMENTATION OF ADVANCED THERAPIES IN SPAIN



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CONTEXT

The CAR-T cells therapy represents a therapeutic revolution for patients with some types of cancer, but it also poses healthcare, regulatory and economic challenges to the system. The **objective** of the **RET-A** think tank was to develop a **strategic reflection** on the short, medium and long-term challenges of managing CAR-T in Spain, and to propose improvement opportunities.

METHODS

Forty experts participated in this **multidisciplinary reflection**. A CORE group was responsible for the design and overall approach of the project. Four thematic working groups agreed on relevant aspects related to the strategic starting point, the integrated care pathway, the innovative economic assessment and funding models, and future projections.

RESULTS

The **three main challenges** identified were to increase the number of qualified centers for the management of CAR-T; to simplify the processes in order to reduce the average time of access to the therapy; and to advocate for therapeutic individualization with a multidisciplinary approach.



Figure 1. Proposed geographic location for the CAR-T qualified centers in the Spanish National Health System



▪ Increase the number of qualified centers for the management of CAR-T:

Faced with the 10 centers currently qualified for the management of CAR-T in the NHS, the experts proposed moving towards a scenario of 17-24 centers in the short term and 32 centers in the medium/long term, taking into account a wider geographic representativeness (Figure 1).

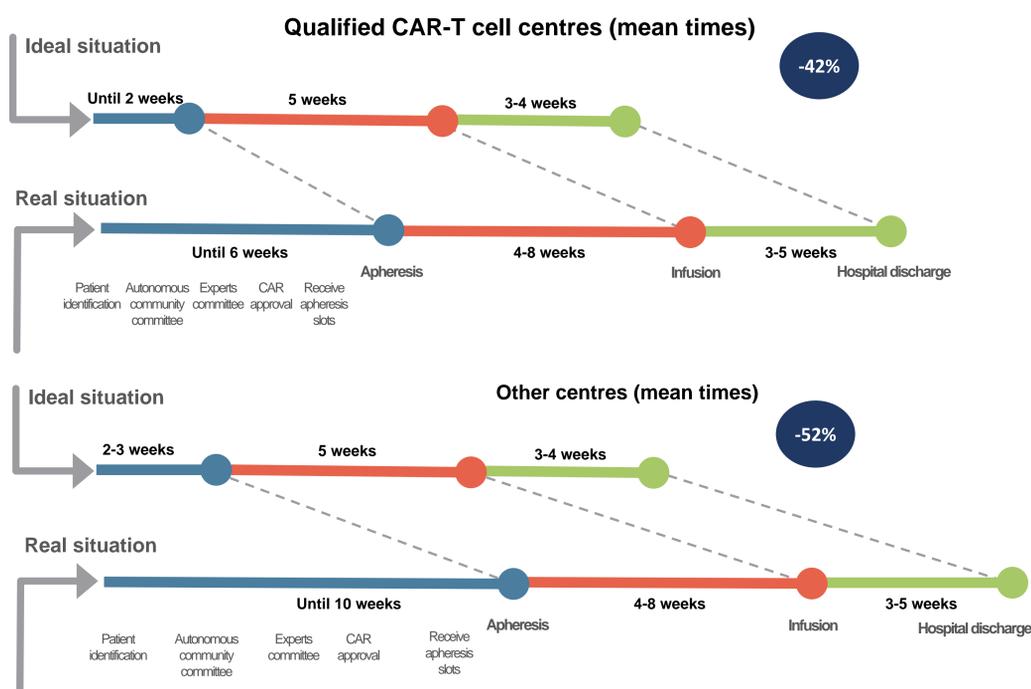
▪ Simplify processes to reduce the average time of access to CAR-T therapies:

Currently, the patient must wait up to 6 or 10 weeks, depending on the centre, from the time he/she is identified as a candidate for these therapies until the apheresis is finally performed. The experts believe that this stage could be optimised to achieve a duration of 2 weeks, speeding up the approval of the CAR and the arrival of slots for apheresis and, above all, shortening the time until the patient can undergo this practice. The time between apheresis and infusion could be shortened by up to 3 weeks, while the final phase between infusion and discharge from hospital could be reduced by up to 1 week. There is margin of time improvement of 42% in qualified centres and 52% in non-qualified ones (Figure 2).

▪ Therapeutic individualization, with a multidisciplinary approach:

CAR-T therapies should be differentiated based on their efficacy, safety, uncertainty and cost-effectiveness. The management of CAR-T must necessarily be multidisciplinary, with interaction between the different medical specialties, as well as the hospital pharmacy, nursing and medical management, among others.

Figure 2. Real and ideal times of each stage of the CAR-T management care pathway in Spain



In the **economic sphere**, some of the proposals were to develop alternative value-based payment models, considering the individual benefit of each indication, conditioned to real world evidence; to establish explicit and differential cost-utility thresholds; to consider the creation of a potential specific fund for emerging therapies; to establish an explicit expenditure ceiling; to apply a more long-term decision-making vision; and to monitor the results obtained through the use of adequate information systems.

The experts agreed on a decalogue of recommendations (Figure 3).

Figure 3. Decalogue of recommendations on the management of CAR-T in Spain

- 1 Acknowledge the **multidisciplinary nature** in the management of CAR-T, involving different medical disciplines, as well as nurses, hospital pharmacy and medical management, with continuous coordination among all parties.
- 2 **Improve training** of all professionals involved, also at non-qualified sites, by means of individualised and continuing training, as well as of patients.
- 3 **Position patients at the centre of the system**, meeting their needs, taking care of the human dimension, and allowing a greater involvement in the processes.
- 4 **Speed up bureaucratic processes**, identifying bottlenecks, shortening the times of each phase and automating as much as possible the processes to guarantee their appropriate and efficient access.
- 5 **Increase the number of qualified sites** for management of CAR-T in the NHS, with a more homogeneous geographic distribution.
- 6 **Therapeutic individualisation** of patients, differentiating each CAR-T based on its efficacy, safety, uncertainty and cost-effectiveness reason.
- 7 **Pay for performance agreements** associated with all CAR-T to better manage between the two parties clinical and economic uncertainty.
- 8 Use of a **broader scope in the economic assessments** incorporating society's perspective and longer-term vision in financing decisions, with the possibility to define a potential specific, purpose-determined fund for emerging therapies.
- 9 **Appropriate information systems** for follow up of clinical and economic results: simplification, automation, interoperability and feedback to professionals.
- 10 **Promote public-private collaboration** in a context where industrial and academic CAR-T have their own differentiated space.

CONCLUSIONS

CAR-T represent an opportunity to redefine the management of the whole Spanish healthcare system, but additional efforts are needed to ensure access and sustainability.