CASE STUDY

The Barcelona Blueprint for Scaling CAR-T Collection

A Case Study from Barcelona Cell Therapy Services

Based on SCTbio's discussion with Jesus Fernandez-Sojo, Director of Barcelona Cell Therapy Services

Barcelona Cell Therapy Services, coordinated by the Catalan Blood and Tissue Bank, operates one of the most advanced CAR-T starting-material collection networks in Europe. Their experience shows that scaling CAR-T collection is not simply a matter of adding more sites, staff, or equipment, but a systems-design problem: the elements that determine quality, training, documentation, qualification, and performance monitoring must be centralized, while patient-facing collection and care remain distributed across hospitals.

Using an existing hematopoietic stem cell transplantation (HSCT) infrastructure and organizing it through a hub-and-spoke model, the network grew from 6 CAR-T starting-material collections in 2016 to 190 in 2025, with 1,054 leukocytapheresis procedures and 836 CAR-T products received over the 2016–2025 period.

The central lesson for biotech companies, CGT developers, research groups, and KOL partners is that collection-network scale depends less on site count alone than on operational coherence. In this case, a centralized cell therapy processing laboratory, shared quality system, common SOPs, unified training, coordinated site initiation visits, and structured manufacturer integration allowed the network to absorb increasing clinical and commercial demand without requiring duplication at each hospital. The case is therefore best understood as an example of how existing transplant infrastructure can be adapted into a resilient CGT collection platform.

To understand why this model proved effective, it is important to consider the regulatory and operational context in which it emerged.

The Road to Operational Readiness

When CAR-T therapies received European regulatory approval in 2018, healthcare systems across Europe faced a common challenge: how to expand access to highly individualized therapies while maintaining quality, traceability, and compliance across multiple institutions. The inflection point came with the approval of the first commercial CAR-T therapies, including Kymriah and Yescarta, which rapidly increased demand for qualified collection capacity.

In November 2018, Spain’s Ministry of Health approved the Management Plan for Advanced Therapies, establishing criteria for CAR-T treatment centers, including clinical experience in apheresis and cell processing, JACIE quality certification, professional coordination, and GMP ATMP manufacturing capabilities.

Regulatory authorization, however, did not automatically create operational readiness. Many hospitals were authorized to treat CAR-T patients but were not yet technically qualified by manufacturers to collect starting material. The Barcelona network had to coordinate 11 transplant centers, multiple hospital-based collection sites, and eventually seven ATMP manufacturers, each with distinct technical and documentation requirements.

The challenge was therefore not only volume, but operational complexity. The network needed to align manufacturers, clinical teams, pharmacy services, apheresis staff, and patient pathways while maintaining uniform standards throughout the network.

Its advantage was that CAR-T expansion did not start from scratch. The participating centers already operated under shared SOPs, training programs, and a common processing infrastructure. This prior standardization enabled rapid manufacturer qualification and positioned the network to respond immediately as demand increased.

Against this backdrop, the network expanded by formalizing a centralized, redundancy-free operating model.

The Hub-and-Spoke Operating Model

The Barcelona model is organized around a single cell therapy processing laboratory at the Catalan Blood and Tissue Bank, acting as the hub, connected to hospital-based collection and delivery sites acting as spokes. The hub concentrates functions that benefit from standardization: tissue establishment licensing (license ES000049), JACIE-accredited processing, centralized quality control, cryogenic storage, a master quality manual, and unified training and qualification. The hospital-based sites retain patient-facing activities, including apheresis procedures, clinical care, and pharmacy operations.

Hub-and-spoke model of the Barcelona apheresis network.

This structure enabled the network to sustain more than 500 HSCT procedures annually while simultaneously absorbing rapid growth in CAR-T activity.

Operationally, the model relies on five interconnected mechanisms:

Shared resources: A backup apheresis device is available across sites, quality control testing is centralized, and clinical trial coordinators support trial initiation across the network. Starting-material collections undergo standardized testing regardless of site, including viability, white blood cell counts, and CD3+ cell counts. This setup naturally streamlines network operations and concentrates technical expertise.

Standardized performance management: All sites operate under common SOPs and performance metrics. Collection Efficiency Type 2 (CE2) is tracked across centers as a key performance indicator, enabling early intervention when

performance falls below the network median. Regular performance reviews ensure that variability is identified and addressed before it affects outcomes.

Integrated quality system: A single master quality manual governs workflows, while manufacturer-specific documentation is incorporated into the electronic quality management system (Qualiteasy 7.21). Technical quality agreements define responsibilities across hospitals, the central processing facility, and manufacturers, allowing the network to manage multiple ATMP partners.

Structured network learning: Regular cross-site meetings allow teams to share operational challenges and update SOPs accordingly, converting individual issues into system-wide improvements. For example, complications such as clotting during leukapheresis are discussed and translated into updated procedures across all centers.

Operational flexibility: Patient transfer protocols and centralized scheduling enable load balancing across sites, ensuring that local constraints do not compromise quality or timelines.

The impact of this model becomes clear when examining how the network evolved over time.

Quantifying Network Growth and Scale

Barcelona's hub-and-spoke model has demonstrated sustained growth over nearly a decade, scaling from early-stage clinical trials to supporting both investigational and commercial CAR-T programs simultaneously.

Year	Clinical Trials Active	New SIVs	Total Collections	CAR-T Products Received
2016	1	1	6	5
2017	2	7	9	3
2018	4	6	106	19
2019	6	6	66	57
2020	10	13	79	53
2021	10	5	83	64
2022	-	17	140	126
2023	-	14	181	163
2024	-	22	194	175
2025 (YTD)	-	24	190	171
Total	**10+**	**115**	**1,054**	**836**

SIV = Site Initiation Visit *"Clinical trials active" not reported after 2021*

The data show a transition from early clinical trial activity to sustained high-volume operations. Collections increased from 15 total procedures in 2016–2017 to 106 in 2018 following regulatory approval and stabilized at 140–194 annual collections from 2022 onwards.

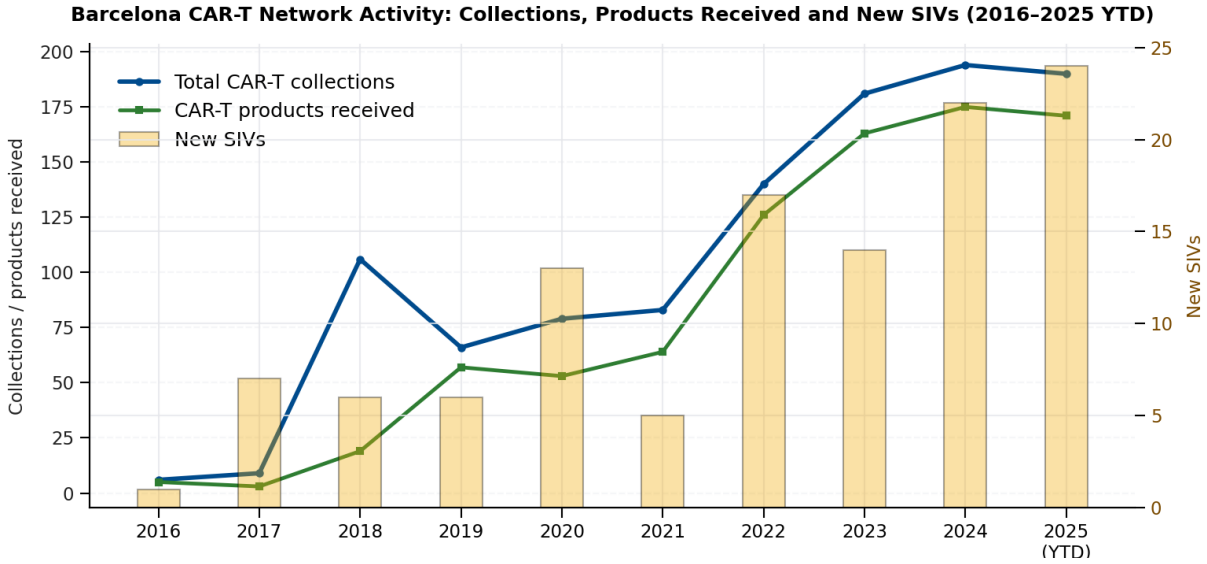
Site initiation visits provide an additional indicator of complexity. The number of new SIVs increased from 1 in 2016 to 24 in 2025, with 115 conducted over the period. Each SIV requires training, qualification, documentation, and risk assessment. The network absorbed this increase efficiently, supported by centralized training and quality systems.

This ability to scale under pressure is particularly visible in the 2021–2024 period, when collections increased by approximately 130% (from 83 to 194 annually) while new SIV activity more than quadrupled. Despite this combined increase in volume and operational burden, performance remained consistent across the network.

Across the full period, the network performed 1,054 leukocytapheresis procedures, supporting more than seven ATMP manufacturers. Approximately 61% of collections were cryopreserved and 39% delivered fresh. A total of 836 CAR-T products were received at the central warehouse and administered across five CAR-T treatment centers.

A separate administration-rate example shows 281 of 313 products infused, corresponding to a 90% administration rate. This reflects coordination across collection, manufacturing, storage, and clinical delivery.

At the same time, the network maintained more than 500 HSCT procedures annually, supporting 11 transplant centers while scaling CAR-T activity. Importantly, this activity was coordinated across 9 HSCT collection centers and 5 CAR-T-qualified centers.



Barcelona CAR-T Network Activity (2016–2025 YTD)

The key observation is not a single growth metric, but the combination of sustained volume, increasing SIV load, multi-manufacturer support, and consistent quality. Together, these demonstrate that the hub-and-spoke model enabled scaling without proportional increases in resources at the site level.

These results have direct implications for CGT stakeholders.

Lessons for Scalable Cell Therapy Networks

For biotech and pharmaceutical sponsors, the Barcelona Cell Therapy Services case highlights that evaluating collection networks requires more than counting sites. What matters is whether the underlying operating model can absorb both volume and complexity. In this case, centralized quality systems, harmonized SOPs, shared training, and integrated manufacturer documentation enabled the network to support multiple ATMP partners and repeated site initiation visits without fragmenting operations.

A key enabler was the use of existing HSCT infrastructure. Established quality systems, trained personnel, logistics for temperature-sensitive materials, and JACIE accreditation provided a foundation that significantly reduced implementation timelines and avoided the need for parallel investment. This allowed the network to respond rapidly when commercial CAR-T therapies were introduced.

For cell therapy developers and research groups, the findings emphasize that clinical translation depends on operational readiness as much as scientific progress. The Barcelona network was able to achieve rapid manufacturer qualification because standardized processes, documentation, and training were already in place. When Spain designated CAR-T treatment centers in 2019, five of six affiliated hospitals were immediately manufacturer-qualified, while other institutions were still building capabilities.

The case also highlights the importance of coordination across functions that are often managed separately. Clinical teams, pharmacy services, apheresis staff, quality units, and clinical trial coordinators must operate within a shared framework. The hub-and-spoke structure provides a central point of coordination that aligns these stakeholders around common protocols and performance expectations.

For healthcare systems, the experience demonstrates that expanding CAR-T access does not necessarily require building new infrastructure from scratch. The overlap between HSCT and CAR-T workflows—including leukapheresis, cryopreservation, quality control, and infusion—creates opportunities to reuse existing capabilities. This reduces financial barriers and shortens time to implementation.

Finally, the Barcelona model illustrates that quality and efficiency are not competing objectives. Standardized processes, proactive performance monitoring, and shared learning mechanisms reduce variability, minimize product loss, and enable predictable scheduling. The result is a system that can scale while maintaining control of critical quality parameters.

The central implication is that scalable CAR-T access depends on how networks are organized, not only on how many sites they include. Centralized coordination combined with distributed execution allows systems to grow without duplicating infrastructure or compromising quality.

About the network

Jesus Fernandez-Sojo is Director of the Cell Processing Laboratory at the Catalan Blood and Tissue Bank in Barcelona, Spain, coordinating 11 transplant centers and 9 HSCT collection centers. Since 2016, the network has performed over 1,000 CAR-T starting material collections and managed 115 site initiation visits. The model has been published in Cytotherapy (2022) and presented at international conferences.

This case study is based on insights from SCTbio's webinar on global apheresis network management for cell and gene therapies. Watch the full discussion on demand to explore further.

Sources

[1] Ministerio de Sanidad, Gobierno de España. Management Plan for Advanced Therapies in the National Health System: CAR T-Cell Medicinal Products. Nov 2018: www.sanidad.gob.es/profesionales/farmacia/Terapias_Avanzadas.htm

[2] Fernandez-Sojo J, et al. A hub-and-spoke model to deliver effective access to chimeric antigen receptor T-cell therapy in a public health network: the Catalan Blood and Tissue Bank experience. Cytotherapy. 2022. DOI: 10.1016/j.jcyt.2022.07.011