CAR-T and Advanced Cell Therapies

Organisational aspects and quality requirements for CAR-T therapy centres

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CHAPTER 1

The ATMP — context

Advanced Therapy Medicinal Products

CAR-T therapies fall within the category of Advanced Therapy Medicinal Products (ATMPs), which are revolutionising the treatment of refractory lymphomas, acute lymphoblastic leukaemias, multiple myelomas and other haematological malignancies resistant to conventional therapies.

Unlike traditional pharmaceuticals, a CAR-T product is a "living drug" manufactured from the patient's own cells. T lymphocytes are collected, sent to a pharmaceutical facility where they are genetically engineered to express a chimeric antigen receptor (CAR) capable of recognising a specific antigen on tumour cells, and then reinfused into the patient.

An organisational challenge

The complexity of CAR-T therapy is not only scientific: it is organisational. It requires the simultaneous coordination of multiple operational units, compliance with stringent GMP requirements, management of a cellular product supply chain that tolerates no errors, and a post-infusion monitoring system for potentially life-threatening complications.

Pharmaceutical companies

The leading manufacturers of approved CAR-T therapies — Novartis (Kymriah), Gilead/Kite (Yescarta, Tecartus) and Bristol Myers Squibb (Abecma, Breyanzi) — impose specific qualification requirements on treatment centres. ICMED supports centres in meeting these requirements.

CHAPTER 2

The complete — CAR-T workflow

From indication to infusion

The CAR-T pathway is an articulated workflow involving the patient, the cellular product and multiple organisational actors. Each phase has specific quality, documentation and traceability requirements.

- Patient selection: eligibility assessment according to clinical and organisational criteria, disease staging, verification of programme-specific requirements
- Leukapheresis: collection of the patient's T lymphocytes via apheresis. Requires a qualified collection unit and staff trained on the specific procedure
- Tissue establishment: processing and preparation of the apheresis material, packaging and shipment to the pharmaceutical facility under controlled conditions
- Pharmaceutical manufacturing: the facility receives the cells, engineers them, expands them, tests them and produces the CAR-T drug. This phase is external to the centre
- Product reception: the centre receives the CAR-T product, verifies integrity, documentation and transport conditions. The product is stored according to specifications

- Lymphodepletion: preparative chemotherapy to create optimal immunological conditions for CAR-T cell engraftment
- Infusion: administration of the CAR-T product to the patient, with intensive monitoring in the following hours
- Post-infusion monitoring: management of complications, particularly Cytokine Release Syndrome (CRS) and neurological toxicity (ICANS), which may require intensive care intervention

Bidirectional product traceability — from patient to facility and back — is an absolute requirement. Any break in the chain of custody compromises patient safety.

CHAPTER 3

Direct and — indirect entities

CAR-T therapy requires the coordinated involvement of multiple operational units. Clarity of roles and responsibilities is fundamental to patient safety.

Direct entities

These are the operational units directly involved in the patient and product pathway:

- Haematology/Oncology: patient selection, clinical management, follow-up. This is the decision-making hub of the pathway
- Apheresis Unit: T lymphocyte collection. Must have staff trained specifically on CAR-T leukapheresis
- Cell Processing Laboratory: processing of apheresis material, quality controls, shipment management
- Hospital Pharmacy: CAR-T drug product management, traceability, storage, dispensation

Indirect entities

These are the operational units that intervene in complication management or in support of the pathway:

- Intensive Care Unit: management of severe CRS (grade 3-4) and complications requiring intensive support
- Cardiology: consultation for cardiovascular complications related to CRS
- Neurology: assessment and management of ICANS (Immune Effector Cell-Associated Neurotoxicity Syndrome)

CHAPTER 4

The CAR-T — Specialist

A key role

The CAR-T Specialist is the person who coordinates all organisational aspects of the CAR-T Unit. It is not a clinical role in the traditional sense: it is a coordinator who ensures that every phase of the pathway proceeds on time, in the correct manner and with the required documentation.

Key responsibilities

- Organisational coordination: ensures that all involved entities operate synchronously and with proper documentation
- Manufacturing requirements verification: checks that the apheresis material and documentation meet the pharmaceutical facility's specifications
- Audit and qualification coordination: manages the centre's qualification process with pharmaceutical companies
- Clinical team support: accompanies the pathway from collection to infusion, ensuring procedural compliance
- Documentation management: ensures that every phase is recorded and traceable according to centre and facility requirements

CAR-T Specialist training

ICMED offers specific training pathways for the CAR-T Specialist role, with modules on organisation, ATMP regulations, GMP requirements, documentation management and multi-unit coordination. The training is ECM-accredited.

CHAPTER 5

Requirements for — a CAR-T Centre

Qualification criteria

To administer CAR-T therapies, a centre must meet a series of organisational, structural and competency requirements. Requirements vary partly between pharmaceutical companies but share a common foundation.

- JACIE accreditation: preferably 7th edition, which includes specific requirements for advanced cellular therapies. This is the most stringent and qualifying requirement
- On-site Intensive Care Unit: the facility must have an ICU within the same premises for immediate management of acute complications
- Allogeneic transplant experience: documented with volumes and outcomes. CAR-T complexity requires consolidated competencies in managing immunocompromised patients
- Staff trained on CRS/ICANS: physicians and nurses must know the grading systems, treatment protocols (tocilizumab, corticosteroids) and escalation criteria
- Formal agreements with all involved entities: shared protocols, defined responsibilities, structured communication flows

GMP infrastructure

If the centre has a cell processing laboratory operating as a tissue establishment, it must meet GMP requirements: classified clean rooms (Class A, B, C, D per EU GMP Annex 1), qualified HVAC system, IQ/OQ/PQ equipment qualification and continuous environmental monitoring.

CHAPTER 6

The ICMED — experience

ICMED supports centres at every stage of the CAR-T Centre qualification pathway, integrating organisational consulting, staff training and digital tools.

Consulting and qualification

- Requirements assessment against JACIE standards and pharmaceutical company specifications
- Development of procedures, operational workflows and documentation dedicated to CAR-T
- Support in the qualification process with Novartis, Gilead/Kite, Bristol Myers Squibb
- JACIE inspection preparation with focus on advanced cellular therapy requirements

Training

- ECM courses for CAR-T Specialists, physicians, nurses, biologists
- Specific modules on CRS/ICANS: grading, treatment, escalation
- Training on multi-unit coordination and chain of custody management

IAAPP

The IAAPP platform includes modules specific to advanced cellular therapies: product traceability, qualification documentation management, performance indicators and complete audit trail.

LEARN MORE

Want to explore this topic further?

ICMED offers accredited ECM training programmes, specialised consulting and the IAAPP platform for complete quality management system oversight.

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