



Fact Sheet

ATMP





SCOPE has extensive experience in **Advanced Therapy Medicinal Products (ATMP)**, which involve **cells, gene therapy, or tissue engineering**. These products are used in indications such as immune diseases, Parkinson’s and Alzheimer’s disease, cartilage defects, cardiac repair, skin replacement, and cancer immunotherapy.

ATMPs differ from conventional medicines and require special regulatory knowledge due to their biological or biotechnological origin. SCOPE provides the experience and know-how necessary to navigate the complexities of ATMP trials successfully.



11 / Countries **650** / Subjects



Challenges & Best Practices in ATMP Trials

General Challenge	SCOPE Experience/Recommendation
Complex regulatory interactions	Deep knowledge of ATMP-specific regulatory frameworks and requirements in multiple countries
Country and site selection	Expertise in evaluating sites against country-specific criteria and requirements
Competent authority & ethics timelines	Experience in planning based on approval timelines to minimise delays
Tissue release	Strong collaboration with external partners and investigators to ensure timely tissue release
Traceability	Established networks, tracking systems, and documentation procedures to meet regulatory traceability
Safety – long-term data & tumorigenicity	Up-to-date safety management and monitoring procedures tailored to ATMP requirements

Your CRO of Choice for _____ **ATMP**



Phase III Trial Example – Cartilage Repair

The goal of this Phase III study was to demonstrate the efficacy of an ATMP in treating cartilage defects. Evaluation was performed through patients' subjective assessments and physicians' functional evaluations, while the cartilage regenerative effects and safety profile were also closely monitored.

With our structured and supportive approach, excellent communication with investigational sites, and experience in ATMP trials, SCOPE was able to maintain the proposed timelines despite unforeseen challenges.



Study Details

- Phase III, orthopaedic indication
- 100 subjects, 20 sites across 5 European countries
- Services provided by SCOPE: project management, clinical monitoring, budget planning, regulatory affairs, data management, EDC programming, safety management, pharmacovigilance, medical monitoring, statistical programming and analysis



Challenges included

- Only 10 sites active in the first six months; 7 sites had to be replaced
- One country excluded due to regulatory changes; added a new country with 3 sites
- Protocol update after initial submission required integration without delaying recruitment

Result:

All subjects were successfully recruited within projected timelines, and long-term follow-up and close cooperation with sites are ongoing as part of our current service.



ATMP Studies – Key Experience

SCOPE's experience ensures that your ATMP study benefits from specialised knowledge in regulatory requirements, proven processes for site selection, tissue release, and traceability, as well as effective safety management, including long-term monitoring.



SCOPE's Solutions

Clinical Operations

Medical Writing

Clinical Data Management

Biostatistics & SAS Programming

Safety Management

Quality Management

Regulatory Affairs

Strategic Development



“Confidence in a highly complex development area”

SCOPE's regulatory expertise and structured approach were critical in navigating the complexity of our ATMP programme and keeping timelines on track.

VP Clinical Operations, Biotech Company

PROVEN RESULTS IN ATMP

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