SCOPE

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 minimize 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, orthopedic 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 specialized 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

PROVEN RESULTS IN ATMP

★ ★ ★ ★ ★

"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

SCOPE International AG
Konrad-Zuse-Ring 18
68163 Mannheim, Germany
Phone +49 621 42939 0

For further information please contact
SCOPE's Business Development Team:
contact@scope-international.com

www.scope-international.com

Follow us on