INTEGRATE ATMP
Building a nationwide Data Ecosystem for advanced Therapies

Background

INTEGRATE ATMP stands for:
Integrated care for New Therapies through Empowerment, Gene therapeutics, Registry establishment, Adverse-event management, Treatment pathways & Economic models for:

Advanced | Therapy | Medicinal | Products

ATMPs, such as CAR-T cells, gene therapies, and tissue-engineered products, are transforming modern medicine. As their use expands, Germany faces the challenge of integrating these complex therapies into a fragmented healthcare ecosystem characterized by:

- Isolated electronic health record systems
- Manual data entry processes
- Multiple national and European registries
- Regulatory demands for high-quality post-marketing data
- Poor inter-sectoral communication

To address these gaps, the INTEGRATE-ATMP project was launched as a G-BA Innovation Fund initiative (2022–2026). It brings together 24 German CAR-T treatment centers to harmonize outpatient ATMP care and create a cross-product, cross-indication treatment registry.

How MARVIN EDC Enabled High-Quality, Cross-Center Registry Documentation

The University of Heidelberg, our client, oversaw this project, developed the digital infrastructure, managed the data, coordinated clinical routes, assessed results, and made sure ATMP care structures were implemented across Germany over the long term.

Building such an ATMP registry requires an EDC platform capable of handling complex therapies, diverse data sources, and strict regulatory expectations.

Marvin EDC provided exactly this foundation: a secure, interoperable system that enables standardized documentation and seamless collaboration among all treatment centers.

Marvin enabled the creation of a cross-product, cross-indication registry with consistent data structures across all 24 centers. Its electronic query system and audit trails supported the requirement for high data quality.

Requirements and Challenges

The INTEGRATE-ATMP consortium defined a set of criteria essential for a modern ATMP registry.

Clinical & Operational Requirements

- Harmonized documentation across all participating centers
- Structured treatment plans for pre- and post-care
- Integration of patient-reported outcomes and subjective endpoints
- Support for telemedicine workflows

Technical Requirements

- High data quality (audit trails, electronic queries, monitoring)
- Modular and expandable data structures
- Automated remote data capture (through Telemed-Platform Integration)
- User access to center-level dashboards
- Interoperability with other European registries
- Capability to manage cross-indicational and industry-independent datasets

Regulatory & Ethical Requirements

- Transparent data access rules
- Reimbursement-compatible documentation
- Compatibility with post-marketing surveillance (PASS/PAES)
- End-to-end encrypted documentation transfer

"Working with Quickbird Medical on the Telemed-Platform integration to develop the ATMP App has been an exceptional collaboration. Their expertise in telemedicine combined with our EDC platform Marvin created something truly innovative. Together, we've built a solution that not only streamlines advanced therapy medicinal product management but also bridges the gap between clinical data capture and real-time patient care coordination."

Dr. Xiao Li, Project Data Manager Marvin Team Munich

How MARVIN EDC Supported the Registry

Marvin's flexible form and module structure allowed seamless integration of new ATMP types, expansion into further indications, and updates to treatment algorithms without any system downtime. This modular approach ensures the platform can evolve alongside advancing therapies and changing clinical needs.

Furthermore Marvin enabled the incorporation of patient-reported outcomes (PROs) and subjective endpoints captured via telemedicine. This integration ensures that the patient's voice is directly reflected in the clinical data, providing a more holistic view of treatment effectiveness and quality of life.

This ensured that real-world patient experience was included, not only clinical parameters.

Key Features:

INTEROPERABILITY WITH EXTERNAL REGISTRIES:
The ATMP registry required interfaces to existing European registries. Marvin's API and data-export abilities allowed this integration.

CENTER-LEVEL DASHBOARDS:
Marvin supported transparent access rules and enabled each treatment center to access its own structured data and analytics.

SUPPORT FOR REMOTE & AUTOMATED WORKFLOWS
Linking Marvin with the telemedicine platform enabled:
- Remote data capture
- Automated data flows into the registry
- Real-time visualization for clinicians

COMPLIANCE & LONG-TERM SUSTAINABILITY
Marvin contributed to meeting regulatory documentation needs related to:

- Post-authorization safety studies
- The German AMNOG benefit assessment
- G-BA quality assurance guidelines

Its compatibility with these processes reinforced the long-term sustainability of the registry.

Benefits

NATIONWIDE HARMONIZED ATMP AFTERCARE
All centers use a unified treatment and documentation model, enabling comparable data across Germany.

IMPROVED CROSS-SECTOR COMMUNICATION
Telemedicine integration via Marvin enables dynamic collaboration, shared patient pathway views, and digital scheduling.

AUTOMATED, HIGH-QUALITY DATA CAPTURE
Automation reduces manual workload and improves completeness and data quality.

GREATER TRANSPARENCY FOR CENTERS
Clinicians can now access their own center's performance data thus closing a longstanding information gap.

FOUNDATION FOR FUTURE "EVIDENCE AT A GLANCE" MODELS
The ecosystem supports continuous evidence generation from clinical trials through post-marketing phases.

Since implementing Marvin EDC, communication across all centers has been transformed. The telemedicine integration allows our teams to collaborate in real-time like never before. We can all view patient pathways together, coordinate care seamlessly, and manage scheduling digitally.

Dr. Andreas Ziegler, Senior Consultant in the Section of Neuropediatrics and Metabolic Medicine at Heidelberg University, Germany

In line with the Bundesverband der Pharmazeutischen Industrie (BPI)'s recommendations to strengthen Europe as a biotech hub, we support key priorities such as more efficient regulatory pathways — particularly for ATMPs — faster approvals, and the use of AI in clinical trials. Our software enables regulatory and clinical processes to be data-driven, transparent, and scalable.

Contact us to learn more

marvin

We are a leading provider of modern eClinical solutions designed specifically for experts in clinical research. Our eClinical software, Marvin, is an effective CDISC-certified EDC system that includes numerous modules such as randomization, patient-reported outcomes (ePRO), IWRS, CDISC tabulation, reporting, medical coding, and more.