Biannual newsletter

March 2026

DARE-NL videos: explaining ATMPs and the DARE-NL platform

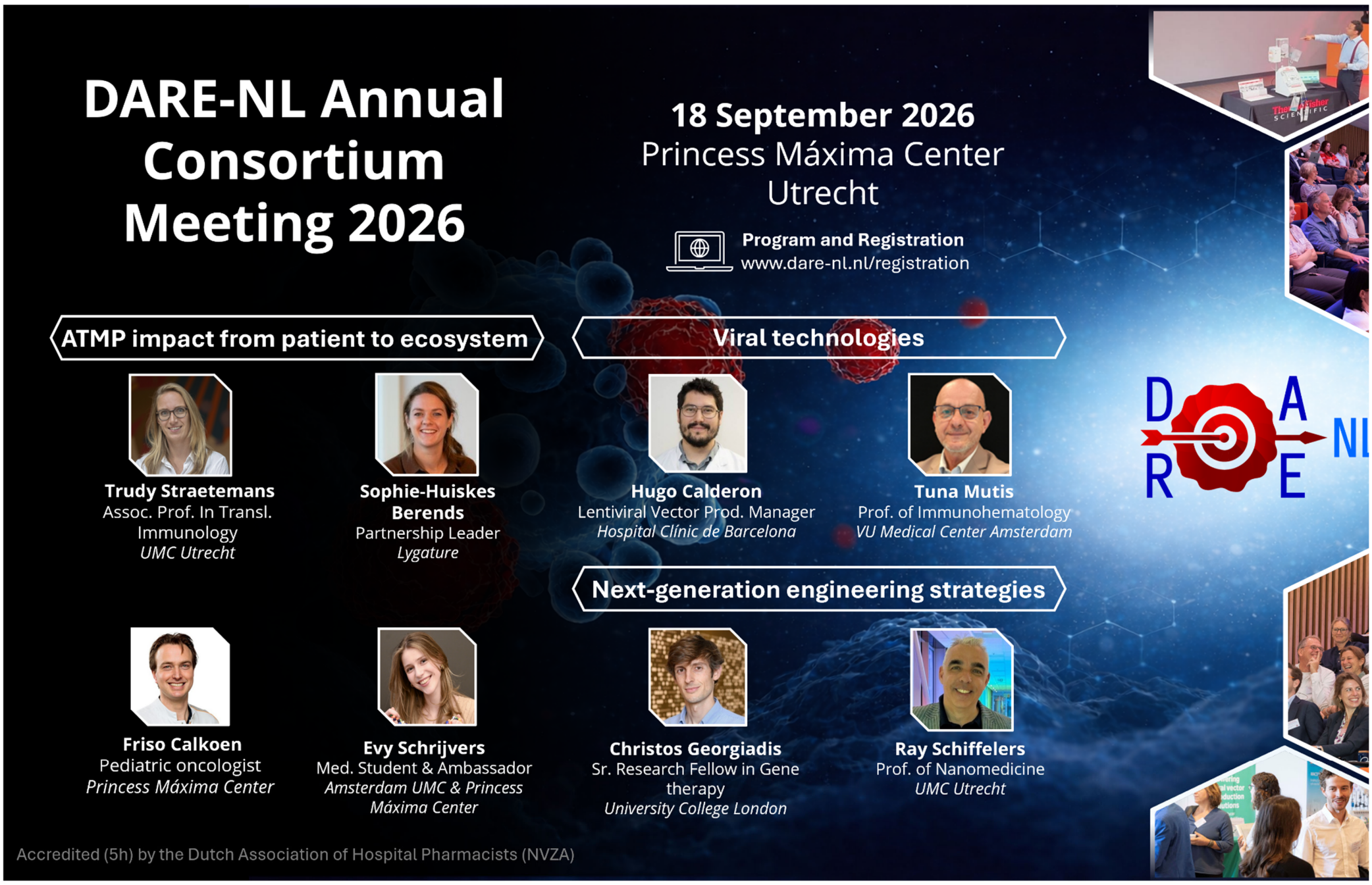
We are excited to announce the launch of a set of videos to share the DARE-NL story with a broad audience.

The first video, "What are ATMPs?", explains the concept of Advanced Therapy Medicinal Products, detailing how these revolutionary (living) medicines differ from traditional treatments and why they hold such promise for patients. The second video, "What is DARE-NL?", explains why the platform was founded, highlighting how we bring together researchers, clinicians and institutions to accelerate the development and implementation of these complex therapies. A pitch version to present at events is also in development.

And remember our videographer Bas van Leeuwen at the annual meetings last year? He also made a video about the annual meetings that you can already see on our website. Notice also that the website received a make-over – let us know your thoughts! The other videos will follow very soon.

We invite you to share these videos with your network. The videos are in Dutch and available with Dutch or English subtitles, intended for patients, patient representatives, clinicians, scientists, policymakers, regulators, funders and (potential) partners. Sharing helps to make these complex concepts understandable for a broad audience, so we can create support and facilitate acceptance of ATMPs together. Your help in spreading the word is greatly appreciated!

DARE-NL ANNUAL CONSORTIUM MEETING 2026

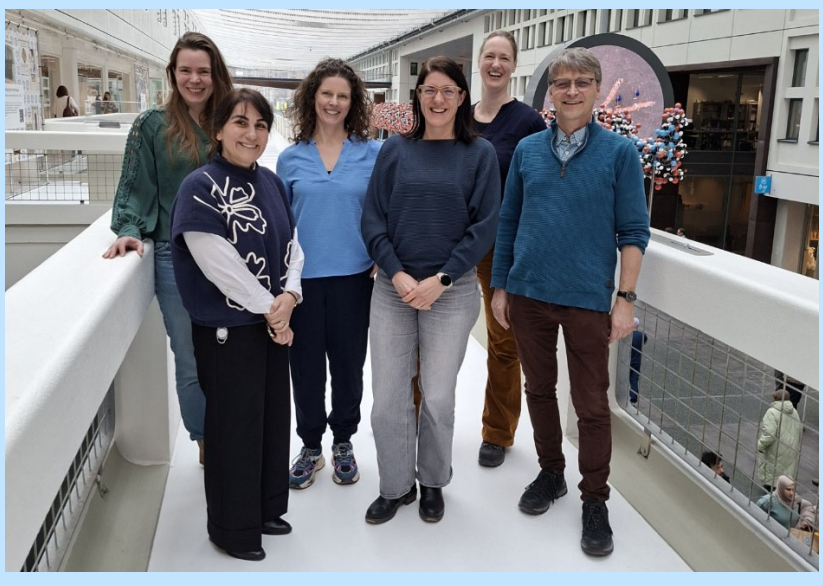


Registration for our fourth annual meeting is now open!
Click here for more information and to register.

DARE-NL PROJECT HIGHLIGHTS

WP1: Setup of DARE-NL data, training and valorization platform

Lead: Emma de Pater, Erasmus Medical Center



ATMP education

Emma de Pater has been awarded a **PharmaNL Human Capital Growth** grant application entitled 'Toekomstgerichte Training voor Cel- en Gentherapie Professionals'. The project kicked off in February (captured in the picture) and entails the development of three post-HBO courses and five workshops for operators that will be provided annually.

Two workshops were organized jointly with the CCMO, one on ATMP trial registries and one on obstacles in trial submissions (see WP6).
The next DARE-NL **workshop on comparability** is scheduled on 14 April.

The second edition of the DARE-NL **operator workshop** is scheduled at the Netherlands Cancer Institute on Friday 3 July. This workshop is organized by and for enthusiastic operators, technicians and other experts that develop and produce ATMPs at the DARE-NL partner sites. The goal of this workshop is to exchange experiences and common practices, discuss challenges and gain new insights. The program and invitation to register will follow soon.

Sustainability
We are proud to share that **DARE-NL by design** has been awarded funding by KWF Kankerbestrijding. This support enables the next crucial step toward a durable, structurally embedded national infrastructure for ATMP development. In this new phase we will focus on:

- strategic positioning and collaboration with all stakeholders
- long-term financial and legal sustainability
- professional project management, impact and quality

DARE-NL by design aims to transform DARE-NL into an infrastructure that is broadly supported, technically sound, financially sustainable and embedded in the innovation ecosystem. Together with our partners, we work toward one goal: accelerated access to innovative cell and gene therapies (ATMPs) for patients.
Lygature, an expert in developing partnerships and sustainable organizations in the life sciences, will be our partner in shaping the strategic and financial foundations of this next phase. We also welcome our new project manager Merle Hattink to support the growing number of activities starting in April, welcome to the team Merle!

WP2: Harmonizing GMP processes for the manufacturing of cancer-specific ATMPs

Lead: Trudy Straetemans, University Medical Center Utrecht

Harmonization of GMP procedures (WP2.3)
The third **harmonized procedure** on the validation of closed, automated culture systems is nearing finalization. Writing of the next procedure on Tech Transfer has initiated and will kick-off in April. Writing of the following procedures on Validation of material disinfection and Segregation of production in place and time are scheduled to initiate in June and September of this year, respectively.
Details on more than ten **ATMP inspections** at all partner sites by the IGJ have already been shared and this registry is continuously being expanded.

Production data (WP2.4)
The working group developed a user requirement specification for **digital batch record systems**. Based on this, demo sessions were scheduled with the software systems MyCellHub, COSMAS by MAK-system and Autolomous. A comparison document outlining in which situation which system may be beneficial is under development.

We contribute to the Oncode Accelerator data production task force that is inventorying partner registries for production and clinical data to be shared. Production variables in different registries at partner sites have been mapped. The clinical parameters collected in two clinical trials are mapped and compared with the variables in the EBMT CAR T registry. The next step is to match these variables and identify critical ones to continue to register.
An introduction to different trial registries was provided at the trial registry symposium on 29 January, see WP6 updates.

WP3: QC harmonization and assay development

Lead: Inge Jedema, NKI/AVL

Development and implementation of QC assays is ongoing (WP3.1/3.2)
Cryopreserved PMBCs will be sent to participating centers to be counted both manually and automatically (if available on site) in a new round robin assay.

A workshop on the practical application of Quality by Design (QbD) and the critical challenges of process comparability and tech transfer of ATMPs is organized for DARE-NL members at the Princess Máxima Center on 14 April. Since regulations for ATMPs provide a framework rather than a strict checklist, developers must learn to navigate these guidelines. Expert consultants will kick off by aligning the playing field: explaining the essential QbD concepts (TPP, CQAs, process controls) using an established model and discussing how to translate these to the intrinsic variability of ATMPs. To bridge the gap between theory and clinical reality, hospital pharmacist Bahez Gareb will present a comprehensive set of real-world scenarios. Ranging from cross-border comparability and mid-study vector changes to the current multi-center tech transfer within the Netherlands, he will illustrate the approach, obstacles and lessons learned.

WP4: Setup of a Dutch academic GMP vector manufacturing platform

Lead: Edwin Bremer, University Medical Center Groningen

Lentiviral production platform is under development (WP4.1/4.5)
The GMP-grade Master Cell Bank and mapping of the manufacturing and purification process for lentiviruses has been completed. We have established a complete package of quality control tests to ensure the lentiviral vehicles are safe and effective.

We are currently in the process of transferring these procedures into the GMP facility. Three manufacturing projects are developed in close collaboration with different academic institutes and a small biotech company and the first **GMP-grade lentiviral batch** (for the ligand-based CAR UMCG-001 for T-ALL) is scheduled in the summer or early fall of this year.

Edwin Bremer leads WP1: 'Manufacturing, scale-up, standardization and quality control' of the COST Action Connecting an INternational Network of Academic Manufacturers of ONcoimmunotherapies (CINNAMON). The objectives in this work package are:

- To develop and implement standardized protocols for CAR-T cell manufacturing across network centers;
- To stablish a common quality control protocol;
- To address challenges in manufacturing scale-up;
- To build new collaborative projects on addressing manufacturing hurdles.

Find more details in the Action Description MOU and when interested to join this action contact Edwin or apply to join online.

Successful establishment of GMP-ready retroviral production platform (WP4.2)
For the retroviral vectors, we have successfully established the initial production steps. Excitingly, yields of the retroviral vector have been optimized to 10^8/ml. We are setting up similar process controls as for the lentiviral vectors.

WP5: Identification and implementation of new technologies for the development and GMP-compliant manufacturing of ATMPs

Lead: Harry Dolstra, Radboud University Medical Center

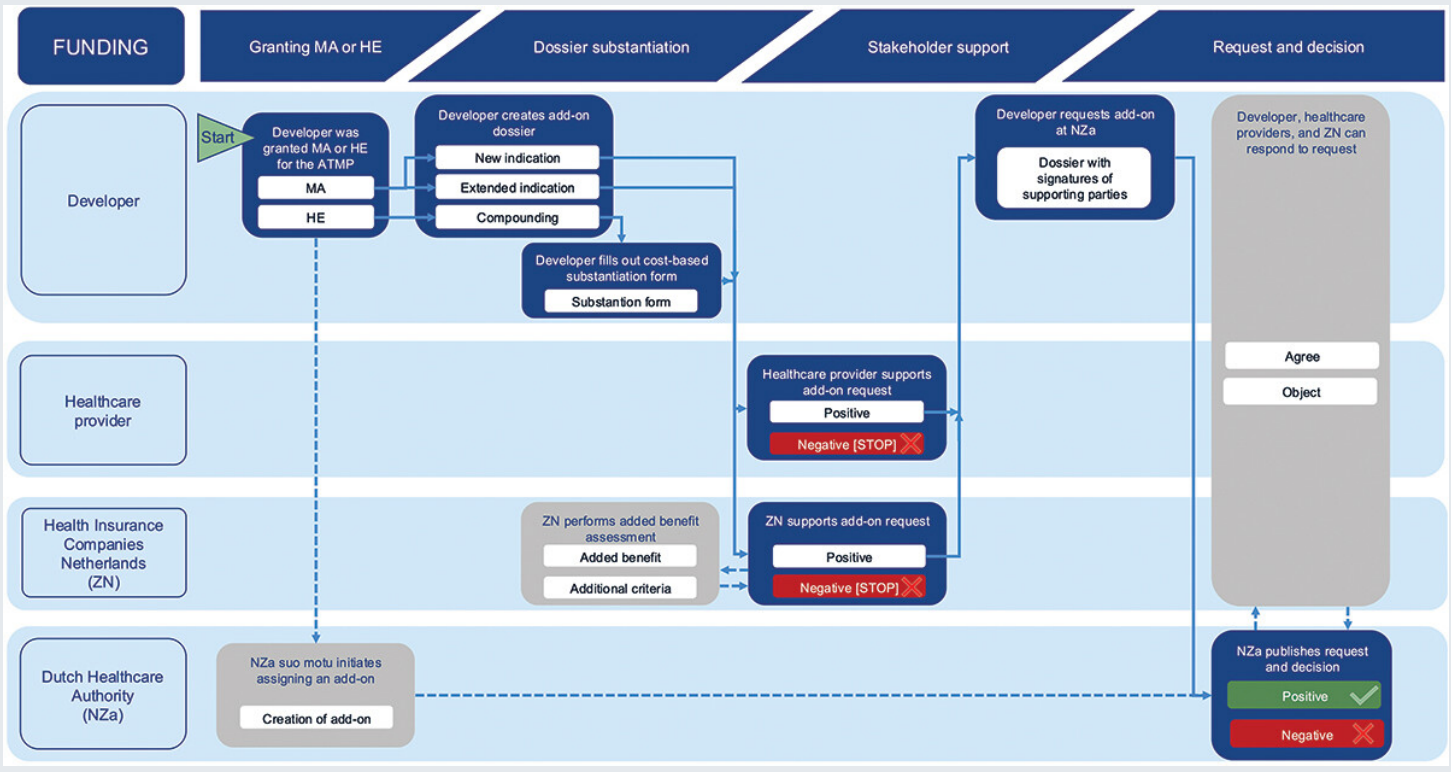
Roadmap for new technologies implementation is under development (WP5.1)
Iris Hagemans returned this month to coordinate the work package again, great to have you back Iris!

A practical guide paper on *ex vivo* CRISPR-based GTMPs for first-in-human trials is under development. This will be a general roadmap on gene editing techniques and drug products to potentially also cater for researchers outside the field of cancer drug development.

WP6: Regulation, health economics, health technology assessment and patient access

Lead: Pauline Meij, Leiden University Medical Center

Overview of manufacturing, evidence, HTA and regulatory pathways (WP6.1)



Achieving market access for ATMPs is a complex challenge, particularly for academic developers and SMEs. Patient access to these potentially life-saving therapies depends on whether they are reimbursed or not. In a recently published paper, team members Jurriaan Gort, Christine van Hattem, Lourens Bloem and Renske ten Ham conducted a comprehensive scoping review of **reimbursement routes** for ATMPs in the Netherlands. By analyzing legal documents and reviewing a cohort of ATMPs (both those that obtained marketing authorization and available under the Hospital Exemption) from 2008–2024, the team has created a clear visual roadmap that demystifies the process and shows how ATMPs have obtained reimbursement in the past.

Key insights from the study include:

- Obtaining reimbursement is not a single step; it involves two partially parallel processes: obtaining entitlement to reimbursement and securing funding.
- ATMPs that obtained marketing authorization undergo an assessment similar to non-ATMPs, often leading to a temporary exclusion from reimbursement, until health technology assessment (HTA), negotiations, and an add-on request have taken place.

- ATMPs available under the hospital exemption are not treated like other medicines and therefore undergo neither an HTA nor negotiations. While they can obtain an additional code for funding, for which they are considered pharmaceutical compounds, no HE-ATMP has obtained one so far. Based on this study, no uniform assessment and reimbursement policy seems to be currently in place for HE-ATMPs.

This publication is a vital tool for developers looking to bridge the "valley of death" between clinical success and patient access.

WP6 worked together with the CCMO on organizing a workshop on the Clinical Trials Information System (CTIS). Suzanna Huppelschoten (CCMO) presented data and perspectives on the submission procedure of ATMP trials at the DARE-NL **workshop on recurring challenges in CCMO and CTIS reviews** for ATMP trials on 30 October. In a very inviting setting, questions and challenges at every part of the submission process were openly discussed.

Set-up of a voluntary HE and trial registry for ATMPs (WP6.4)
We also organized a joint workshop on ATMP trial registries with the CCMO at the UMCU on 29 January. The symposium brought together a broad variety of experts to explore how clinical trial registries can better serve patients, clinicians, researchers, regulatory authorities and other stakeholders. CCMO staff member medical affairs Paula Vossebeld provided an overview of clinical trial registries and the basics of the OMON registry. Antonia Müller and Nara Marella from University Hospital Vienna presented the tools they have developed as part of the JOIN4ATMP project to get an overview of the European centers that develop ATMPs. The morning concluded with a patient perspective provided by Joost Groen on behalf of the Sarcoma Patient platform and Mara Tihaya also on behalf of the DARE-NL patient advisory board. After lunch participants learned how to navigate the OMON registry hands-on and discussed best practices and expectations moving forward. The feedback and discussions were incredibly valuable and will directly inform the further development of the OMON registry.

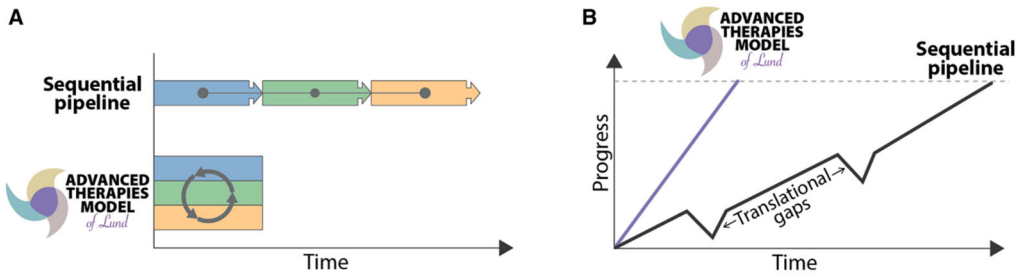
PUBLICATION HIGHLIGHTS

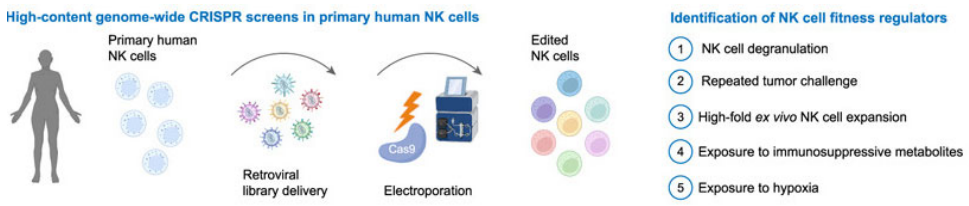
Table 1. **Approved ATMPs in the EU with indications related to hematology/immunology**

Medicine	MA date and status	Prevalence (in 10 000 people in the EU)	Orphan designation	High-level
Strimvelis	Authorized 26 May 2016	0.04	Yes	Children wit matched r
Zalmoxis	Withdrawn	0.32	Yes	Adults with l
Kymriah	Authorized 23 August 2018	1.2 (B-AAL), 4.6 (DLBCL)	Yes	Children, yo types of le
Yescarta	Authorized 23 August 2018	4.6 (DLCBL), 0.5 (PMBCL)	Yes	Adults with s
Zynteglo	Withdrawn	0.7	Yes	Patients age β-thalasse

Hidalgo Simon and Booth provide a high-level analysis of why many academically developed ATMPs fail to achieve sustainable clinical implementation. The paper dissects structural bottlenecks across regulatory strategy, GMP manufacturing, clinical development and reimbursement, and critically evaluates emerging translational models (e.g. public-benefit entities, academic–industry hybrids and pan-European consortia). It offers a timely framework for rethinking **role allocation between patients, clinicians, academia, industry, regulators and payers** to enable scalable, long-term access to ATMPs in rare indications (Blood, Mar 2026).

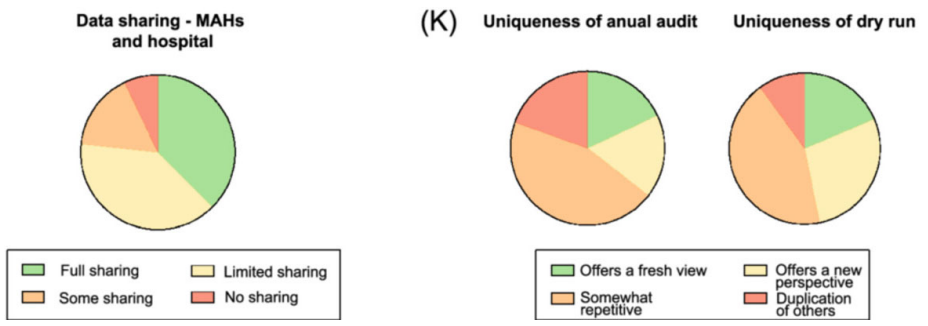
Researchers at Lund University have introduced a new integrated development framework designed to shorten the path from discovery to patient access for cell and gene therapies. The Advanced Therapies model of Lund promotes **parallel development of technical, clinical, and commercial tracks** from an early stage, supported by a structured Cell & Gene Therapy Navigator to identify bottlenecks proactively. The approach may serve as a blueprint for accelerating ATMP translation in other regions (Mol. Ther. Methods Clin. Dev., Dec 2025).





Biederstädt and Basar, et al. developed a genome-wide CRISPR screening platform for primary human NK cells to identify regulators of function under tumor challenge. They pinpointed MED12, ARIH2, and CCNC as critical checkpoints; deletion of these genes enhanced metabolic fitness, cytokine secretion and expansion in both **innate and CAR-NK cells**. Notably, dual **editing of ARIH2 and CCNC** further augmented proliferation and activation, leading to **enhanced clearance of treatment-refractory tumors** in xenograft models (Cancer Cell, Nov 2025).

While clinical efficacy is well-documented, the logistical cost of delivering CAR T-cell therapy remains high. A **multinational survey** by the GoCART Coalition and the JACIE Quality Managers Committee quantified that burden. Based on responses from 142 hospitals, the authors report on the fragmented nature of current **implementation strategies** and the heavy administrative workload. It serves as a call to action for stakeholders to align on standardized frameworks that reduce operational inefficiencies and enhance care delivery (HemaSphere, Oct 2025).



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 March 2026
EMA/53733/2026
Human Medicines Division

CAT quarterly highlights and approved ATMPs
March 2026

Quarterly highlights and approved ATMPs by the Committee for Advanced Therapies

ATMP LANDSCAPE: WHAT HAPPENS IN THE NETWORK

Explore ATMP Sites

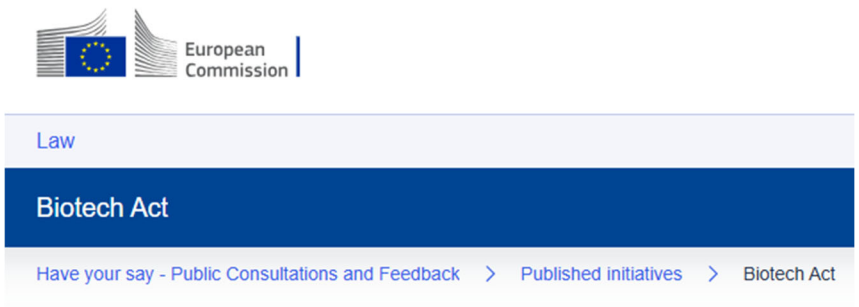
JOIN4ATMP launched a website to browse the location of ATMP capacities in Europe. How to navigate the website:

1. Use the filters on the top to select specific countries, types, products or status of manufacturing sites.
2. The table and map below will update accordingly, showing the relevant manufacturing sites.
3. Click on any row in the table or a location on the map to view further details about the manufacturing site.

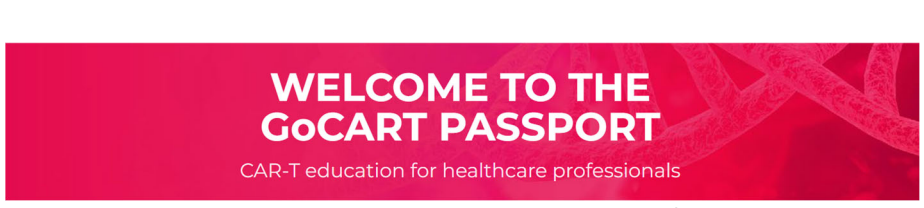
Provide your feedback on manufacturing site accuracy and completenes, functionality and easy of navigation to further refine the website and make it most useful to the community. They aim to include this map in a web portal to connect ATMP stakeholders for networking, collaboration and knowledge sharing.

ATMP-NL

ATMP-NL has officially launched their logo and website. ATMP-NL focuses on the overarching importance of connecting intersectoral, academic, business and government parties to strengthen the ATMP field in the Netherlands. With their focus on connecting and strengthening existing initiatives with their own identity and on identifying gaps in the ecosystem that can then be addressed by existing initiatives or new collaborations, parties can further improve the national ATMP ecosystem together. DARE-NL has been involved with ATMP-NL since its initiation and we will continue to coordinate our joint interests on a regular basis.



The EU biotechnology industry is one of the most economically productive industries, having grown more than twice as fast as the overall EU economy over the past decade. However, the EU lags behind other global regions when it comes to translating its worldclass science and innovation into commercially viable products. The necessity to boost the EU's technological advancement, competitiveness and economic growth was addressed in reports by Enrico Letta (April 2024) and Mario Draghi (September 2024). Peter Wennink wrote a report to translate the Draghi report into a Dutch context.
Following these reports, the EU Life Sciences Strategy was launched on 2 July 2025 to position the EU as the world's most attractive place for life sciences by 2030. This comes with an unprecedented amount of legislation presented in the European Biotech Act, with the aim of creating an enabling environment to make it easier to bring biotechnology products from the laboratory to the factory and then onto the market, while maintaining the highest safety standards for the protection of the population and the environment. Europe's leadership in ATMPs depends on hubs to centralize development, manufacturing, scalability, funding, training, regulation and access. The Biotech Act introduces a broad set of measures relevant to advanced therapies, including concepts related to centers of excellence and biotech accelerators and clusters. The Dutch government published an official assessment, on which Hollandbio published their analysis, following their overall position and detailed assessment of the Biotech Act Part I. The ATMP-relevant articles were also discussed with representatives of European ATMP hubs in two online meetings organized by the Alliance for Regenerative Medicine in November and January. A workshop exploring how the EU Biotech Act should support the development, translation and scale-up of advanced therapies in Europe was held in Brussels on 10 March. The Dutch ATMP hubs RegMedXB and DARE-NL were represented to share perspectives and explore the definition of a successful hub model and how these hubs could collaborate to reinforce Europe's leadership in advanced therapies. This offered a great opportunity to collectively shape how the EU defines, connects and funds ATMP hubs. While every country and hub has their own approach, ARM took the lead in collecting feedback and putting together a joint high-level statement on shared concerns and discussing this with the European commission. The time to act is now as the commission is currently seeking input.



The GoCART Coalition has introduced the GoCART passport: a standardized training program designed for physicians working in CAR-T and other cell therapies. A comprehensive set of 10 interactive e-learning modules — based on the EU CAR-T Handbook — that help clinicians demonstrate core training and clinical proficiency while reducing duplicated efforts and ensuring consistent competency across centers. Free access to 6 of 10 modules is available now, the rest will follow later this year.

CALENDAR

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