IVA | Swedish Futures

Advanced therapy medicinal products

A technical report about ATMPs as part of the *Swedish Futures* series

Contents

Foreword

IVA is spearheading the *Swedish Futures* initiative to formulate a vision for Sweden as a leader in technology and innovation by 2035. Since autumn 2025, *Swedish Futures* has brought together stakeholders from academia, industry, and the public sector to identify opportunities, challenges and strategic directions for competitiveness and sustainable development.

Among other things, the initiative convenes working groups that quickly and systematically analyse challenges and opportunities in different technology areas and produce highly focused reports. These reports provide an overview of the status quo and outlook for the field under examination and present concrete proposals for action. They also serve as an important foundation for shaping an overarching vision for Sweden in 2035.

This report was written by the working group on advanced therapy medicinal products (ATMPs). ATMPs are a group of innovative treatments based on the use of genes, cells, or tissues to treat and cure diseases. The analysis shows that the ATMP field requires initiatives based on a shift in healthcare towards new medicines, innovative technologies, multidisciplinary environments, and economic innovation.

As is the case with all IVA projects, all participants contributed in their personal capacity and not as representatives of the organisations for which they work. The report's analyses, detailed proposals and to-the-point recommendations are based on the experience and knowledge they contributed and the discussions these inputs engendered. The working group endorses the report as a whole, although this does not mean that all members necessarily endorse every formulation.

The working group on ATMPs was active from February to May 2026.

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Summary

Advanced therapy medicinal products (ATMPs) are innovative cell-, gene- and tissue-based therapies that are in relatively early stages of development but advancing rapidly and gaining momentum worldwide. Sweden is well positioned to become a leader in selected areas of the ATMP sector, building on its strong research base, clinical excellence, advanced healthcare system and data-driven innovation ecosystem. But progress is constrained by fragmented national coordination, insufficient investment, and the need for clearer governance and support structures. The sector also faces high development costs, complex regulatory and implementation pathways, and the need for innovative business and reimbursement models to strengthen commercial viability and long-term growth.

ATMPs currently represent a relatively small share of the pharmaceutical market, but their importance is expected to grow significantly as scientific advances, technological progress and more efficient manufacturing solutions drive wider adoption. Realising this potential will require closer collaboration across sectors, stronger integration between research and clinical practice, and more effective technical, regulatory, and market frameworks. The proposals presented in this report address six key aspects: technology, healthcare transformation, innovation ecosystems, financing, regulatory development and incentives. Success in these areas will depend on bold ambition, strong leadership, and a shared commitment among stakeholders to collaboration and the delivery of tangible results.

The working group presents three recommendations on how Sweden should focus its efforts to strengthen industrial competitiveness, advance sustainability, and contribute to both national and global security. We believe that these recommendations will help unlock the full potential of ATMPs. In the long term, they can contribute to improved health outcomes, lower healthcare costs, and stronger incentives for private-sector investment and innovation.

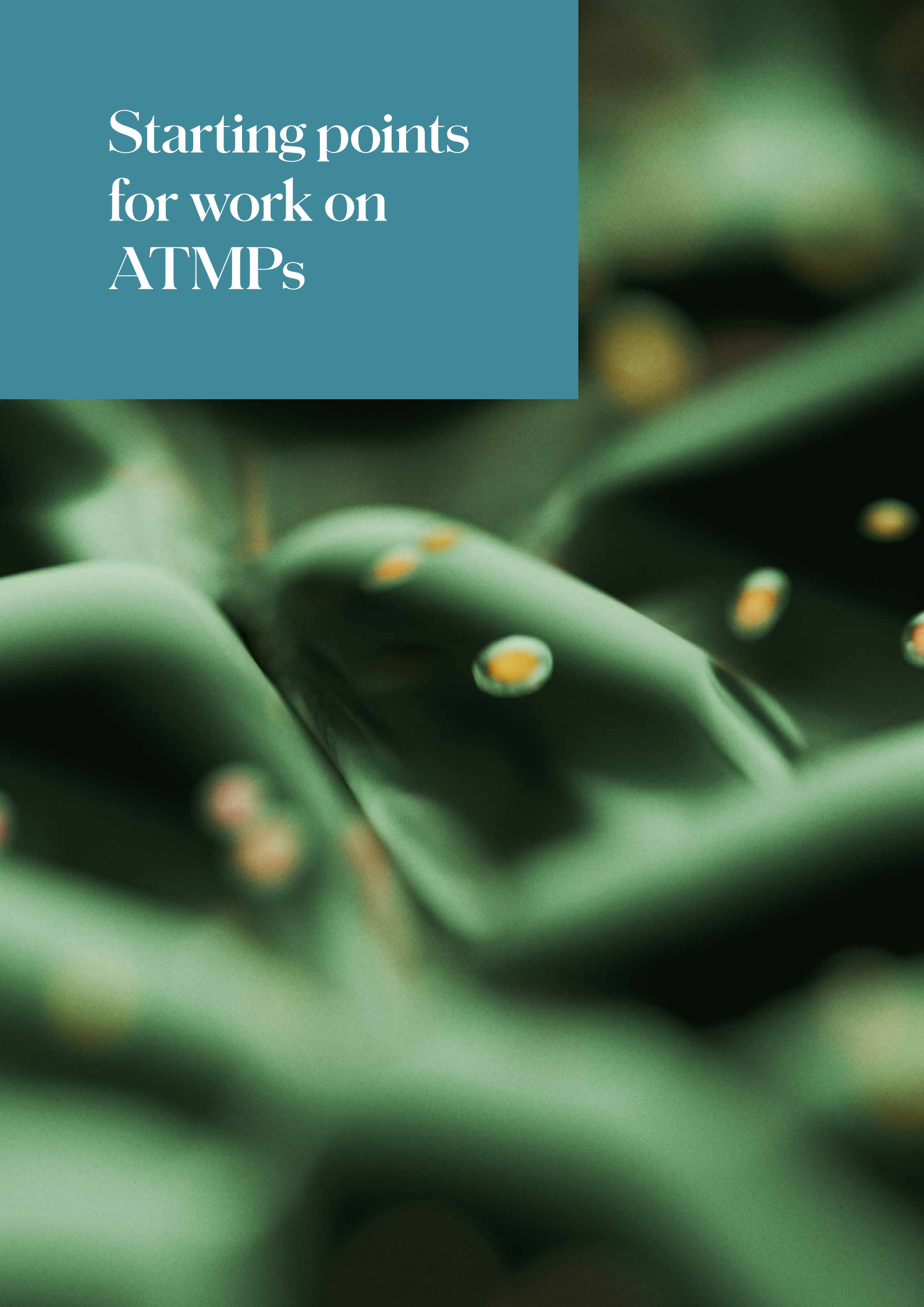
The recommendations are based on an analysis of Sweden's current position in ATMPs, international trends, and a review of key issues, identifying both obstacles and opportunities for continued development. They bring together a range of proposals and initiatives, which are set out in greater detail in the report.

1. Invest in multidisciplinary super-ecosystems with shared technology platforms where academia, industry, and healthcare collaborate to develop, test, and implement ATMPs.

2. Enable the healthcare sector to be an integrated, active part of research and innovation so that new treatments can reach patients more quickly and improve care outcomes.

3. Simplify regulations and strengthen incentives in Sweden and the EU and improve the coordination between public and private funding to mobilise capital and develop robust business models.

Starting points for work on ATMPs



Background

This report uses the term advanced therapy medicinal products, abbreviated as ATMPs. The report is based on the definition applied by the Swedish Medical Products Agency in its guidance and information on ATMPs, which is based on EU legislation: "Advanced therapy medicinal products (ATMPs) are medicinal products that include gene-therapy medicinal products, somatic cell-therapy medicinal products, and tissue-engineered products. These medicinal products are based on genes, cells, or tissues and are used to treat, cure, or prevent diseases by restoring, correcting, or modifying physiological functions."[1]

In this report, the term ATMP encompasses cell-, gene- and tissue-therapy. Cell- and gene-therapy are internationally recognised terms, while the term ATMP is primarily used within the EU. The United States and several other countries do not use the term ATMP.

ATMP is a part of the life sciences field, the latter being the overarching whole, the former a small subset of the most advanced therapies. ATMPs rely on the ecosystem that includes research, industry, regulation, and healthcare systems to develop and reach clinical use.

Scope of the technology report

The following limitations apply to this report: It is clear in scope and focused on ATMP, and does not cover broader prerequisites, conditions, and development opportunities relevant to the life sciences sector as a whole.

But it is also important to emphasise that ATMPs constitute an integral part of the life sciences sector. This means that discussions, analyses and proposals related to ATMPs are in many cases also relevant to the broader life sciences sector

Rationale for IVA's prioritisation of a technology report on ATMP

IVA has conducted a data-driven analysis of patents, scientific publications, and startup investments to map Sweden's global position in 48 technology areas that are of great strategic importance for national prosperity, economic resilience, and national security.[2]

Among other things, the analysis revealed that Sweden needs to adopt a more strategic approach to secure its position internationally. Against this backdrop, IVA has chosen to conduct an in-depth analysis of ATMPs and develop proposals for the desired future direction in this area. The selection is based on eight criteria (see Table 1).

Sweden is well-positioned to become a leader in certain areas of ATMPs, as we have strong research, clinical expertise, advanced healthcare, and a largely data-driven ecosystem. At the same time, there is currently a lack of strong coordination, clear strategy, and sufficient investment at national level. Meanwhile, develop-

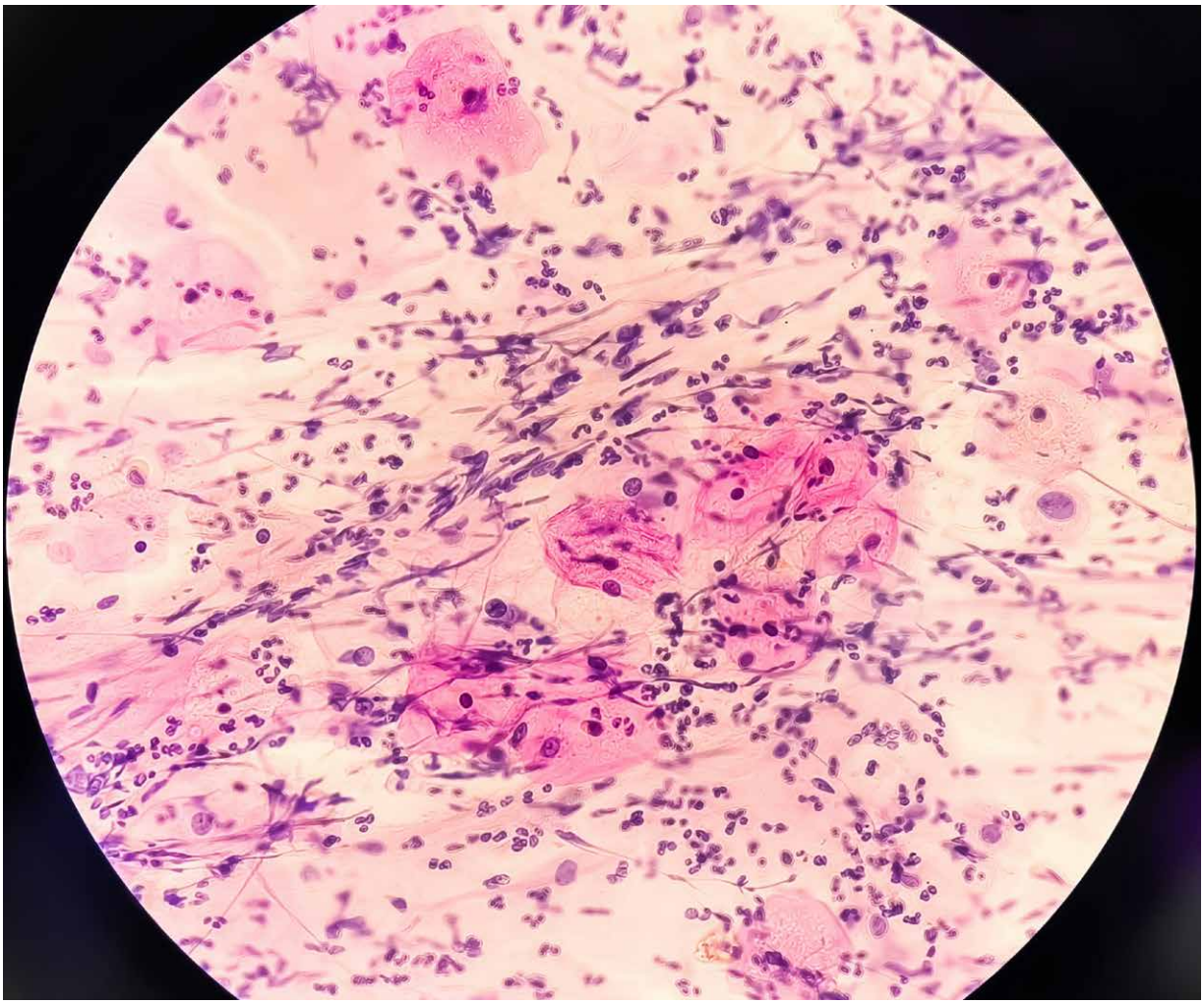
1 The Swedish Medical Products Agency. Advanced Therapy Medicinal Products (ATMP). Based on Regulation (EC) No 1394/2007 of the European Parliament and of the Council.

2 IVA (2025). Sweden's Position in Strategically Important Technologies. Investment Priorities, Strengths, and Challenges.

TABLE 1: IVA's decision to produce a technology report on ATMPs is based on eight criteria.

CRITERION	ATMPs IN SWEDEN
Global leadership	Strong research position and good clinical capacity, but not a global leader across the entire value chain.
Turnaround (opportunity to reverse current trends)	Good opportunity to strengthen the position thanks to existing expertise, infrastructure, and ongoing initiatives, but reversing the current trend requires, among other things, coordination and investments.
Position shift	Possible in selected niches (e.g., clinical trials, data, precision medicine), but international competition is fierce.
Enabling technology	Technical platforms and production capacity are crucial because the medicines of the future will be produced and monitored in new ways, where technology and industrial systems will play a decisive role.
International	Well integrated into international collaborations but losing investments and clinical trials to larger markets.
Megatrends	ATMPs align with global trends such as precision medicine, personalised treatments, and biologic drugs.
Geopolitics	Stable and attractive environment for research and innovation, but a small market.
Hot area	Generating significant interest due to its potential to transform the treatment of serious and previously difficult-to-treat diseases.

ments are moving rapidly on the international stage and show that ATMPs will transform how diseases are treated. ATMPs have been identified as a strategic area at the EU level. It is highlighted in the European Biotech Act as a priority area for strengthening Europe's biotechnology sector through faster innovation, simplified regulation, and improved opportunities for clinical



trials, production, and market access.[3] The field is also a high priority in China[4] and the United States.[5] The investments made in various parts of the world have contributed to the expansion of initiatives to promote the development of ATMPs.

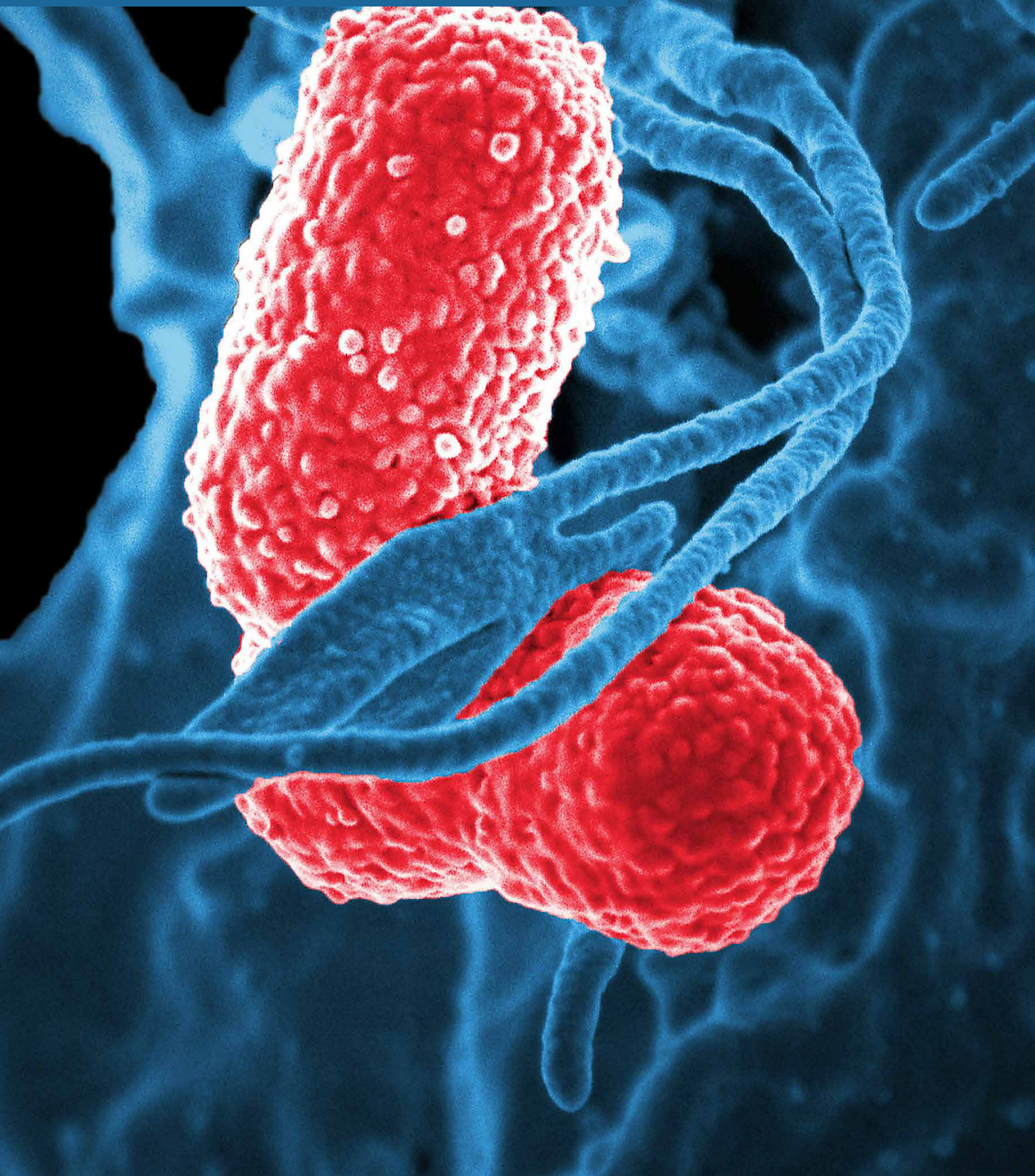
For this field to become attractive, the entire Swedish life-sciences system must be strengthened. If Sweden does not act now, there is a significant risk that the country will fall behind in an area that is crucial for the future of healthcare and the economy.

3 European Commission. (2025). *European Biotech Act*. 2025/0406(COD) 12/16/2025. European Commission. (2020). *Pharmaceutical Strategy for Europe*. European Medicines Agency. (2017). *Guideline on Advanced Therapy Medicinal Products (ATMPs)*. European Parliament and Council of the European Union. (2007). Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

4 State Council of the People's Republic of China. (2015). Made in China 2025. State Council of the People's Republic of China. (2016). *The 13th Five-Year Plan for Economic and Social Development of the People's Republic of China*.

5 U.S. Food and Drug Administration. (2019). *Framework for the regulation of regenerative medicine products*.

ATMPs today



ATMPs are innovative treatments that differ from traditional medicines

They are based on the use of genes, cells or tissue to treat and cure diseases.[6] Treatments based on ATMPs act directly on the underlying causes of disease.

ATMPs are currently used primarily for rare and serious genetic or life-threatening diseases where established treatments are often insufficient. One example is haemophilia, where gene therapy can replace or correct deficient clotting factors. Another example is sickle cell anaemia, where gene editing or cell therapy with modified stem cells is used. In the neuromuscular field, treatments target spinal muscular atrophy and Duchenne Muscular Dystrophy. In the field of eye diseases, the focus is primarily on hereditary retinal diseases. ATMPs in the form of CAR-T cell therapy are also used for haematological cancers (leukaemia and lymphoma) and for rare genetic diseases where specific mutations can be corrected. Furthermore, the scope also includes metabolic disorders, neurological disorders such as Parkinson's disease and other conditions linked to the central nervous system. ATMPs can also help treat heart disease, with tissue engineering therapies used to repair damaged heart tissue.

An important characteristic of ATMPs is that they are often administered as one-time treatments with potentially long-lasting or permanent effects. Many treatments are also personalised, particularly so-called autologous therapies where the patient's own cells are used. This makes production, logistics, and quality control more complex than for other medicines. ATMPs require specialised manufacturing and advanced clinical infrastructure that ensures traceability throughout the entire process, from manufacturing to patient treatment. The treatments also require patients to undergo careful and long-term follow-up examinations.

The development and use of ATMPs also differ from other medicines in that scientific and regulatory requirements often need to be adapted. For example, traditional animal models used to assess the safety and efficacy of medicines are not always relevant, while clinical studies and trials can be difficult to conduct on a large scale, especially for rare diseases where patient groups are small.

The complexity and potential risks of ATMPs create new challenges for healthcare in many areas, including regulation and financing. But they also improve the ability to deal with certain diseases and complement other forms of treatment, and drive the need for continued innovation, for example, to solve production challenges and reduce treatment risks. These challenges and risks can be both

DIFFERENT TYPES OF TREATMENTS

ATMPs primarily encompass three types of treatments. The first is gene therapies that alter or introduce genetic material into cells. The second is somatic cell therapies where living cells are used to repair or replace damaged tissue. The third type is tissue-engineered products aimed at recreating or replacing biological structures, such as skin or cartilage.

6 Texten i detta avsnitt bygger på en svensk översättning av denna artikel: Van Eldere J, Aiuti A, Lluesma S et al. (2026). *A roadmap for supporting the development of advanced therapy medicinal products in a European framework*. The Lancet Regional Health – Europe, 2026; 66.

specific to ATMPs or more general across several types of medicine.

Healthcare is a key part of the innovation chain. The use of ATMPs in healthcare has effects that ripple throughout the entire system. This will entail higher costs in the short run, but lower costs both for treatment and for society at large are expected in the long run. Realising these benefits will require sustainable business models and innovative economic approaches. These considerations must be taken into account to make the use of ATMPs sustainable and their adoption widespread.

Clinical development and access to healthcare infrastructure are necessary conditions for the successful development and use of ATMPs, but continued progress in industrial development and manufacturing will also be needed.

The development process for ATMPs

The development process for ATMPs from concept to clinical use involves several stages, including research, pre-clinical studies and trials, approval, and implementation in healthcare systems.

Stakeholders in ATMPs

In Europe, several stakeholders are involved in different aspects of the development and use of ATMPs.[7]

Regulatory authorities review the quality, safety, and efficacy of ATMPs. At European level, the European Medicines Agency (EMA) plays a key role, while in Sweden, responsibility lies with the Swedish Medical Products Agency. Regulatory processes include approval of manufacturing and review and authorisation of clinical study protocols for both academic studies and industry-sponsored clinical trials. Authorities also provide scientific advice throughout the development and approval process.

For commercial medicines approved by the EMA, the health economic evaluation in Sweden is conducted by the Dental and Pharmaceutical Benefits Agency (TLV), while recommendations on their use in the healthcare system are issued by a national collaborative body representing Sweden's regional governments, the Council for New Therapies (NT Council). This latter body's recommendations are not legally binding, but are of great practical importance, as the regions generally follow them collectively to ensure equitable and cost-effective use of medicines across the country.

Academic institutions and university hospitals conduct research, carry out preclinical studies and conduct clinical trials. They often collaborate with a wide range of stakeholders, including business.

Biotechnology, pharmaceutical, and medical-device companies represent a broad spectrum of companies, ranging from small startups to global corporations. These companies conduct research, run clinical trials, develop manufacturing technologies, and commercialise ATMPs. Contract development and manufacturing organisations (CDMOs), contract research organisations (CROs) and other specialised suppliers contribute expertise and services in research, clinical trials, good manufacturing practice (GMP), quality control, and production.

7 The text in this section is based in part on the following sources: European Medicines Agency (EMA). *Advanced therapy medicinal products overview and European Commission. Advanced therapies.*

FIGURE 1: The figure shows a schematic overview of the development process for ATMPs.

Basic research and concept phase	Identify biological mechanisms and potential therapeutic targets for treating a disease.
Proof of concept	Initial experiments to test whether the idea works in cells or animal models.
Preclinical development	A candidate product is tested for safety, efficacy, and biological properties.
GMP/Process development	Development of a controlled and reproducible manufacturing process that complies with the quality requirements applicable to pharmaceuticals.
Regulatory consulting	Dialogue with regulatory authorities to ensure that development complies with regulations.
Clinical Phase I	The product is tested on humans for the first time. The focus is on safety and dosing.
Phase II clinical trial	The treatment's efficacy and appropriate dose are evaluated in a larger patient group.
Clinical Phase III	Larger studies are conducted to confirm efficacy and safety, compared with standard treatment.
Review by the EMA	The European Medicines Agency (EMA) reviews the data and issues a scientific recommendation.
Formal decision	The European Commission makes the legally binding decision on whether the drug may be marketed throughout the EU.
HTA/price negotiations	National authorities assess cost-effectiveness and negotiate pricing and inclusion in the healthcare system.
Implementation in healthcare	Hospitals and other healthcare providers are establishing procedures, training, and logistics to be able to provide treatment.
Patient treatment	The patient receives ATMP treatment under close clinical supervision.
Long-term follow-up	All patients who have received ATMP treatment are followed over time to evaluate long-term effects and any late side effects.

The development of ATMPs is funded by government research and innovation funding agencies, research foundations, pharmaceutical companies, venture capital groups, and other organisations. A number of factors influence the attractiveness of investments, including intellectual property protection, business models, demand, willingness to pay, and regulatory and reimbursement issues. Given the particularly high-risk profile of the ATMP field, securing funding for early-stage projects is especially challenging. This is closely linked to the issue of pursuing sustainable business models and innovative economic approaches.

Healthcare systems and patient organisations play a vital role in defining clinical needs, setting priorities, and ensuring sustainable implementation.

Patient organisations contribute, among other things, by representing patient perspectives in decision making that is often shaped only by clinical, economic, and organisational factors. They do this by identifying the needs that are most urgent in patients' daily lives (for example, relating to symptoms, quality of life, or access to treatment), influencing which disease areas or interventions are perceived as highest priority for patients. In prac-

tice, these organisations often do this through participation in advisory groups, responses to public consultations, collaboration with authorities and regions, and attending various other forums for prioritisation and decision-making. Patient organisations can also contribute experience-based knowledge that complements clinical evidence, for example, they can say which treatments make the greatest difference in patients' lives or where healthcare falls short in terms of accessibility and equity.

These stakeholders together create an integrated ecosystem that supports innovation, regulation, manufacturing, and access to ATMPs. This ecosystem spans the entire value chain, from education and research to financing, manufacturing, and the market.

ATMPs in Sweden

Sweden has a range of stakeholders in the ATMP field.[8] At the national level, representatives from academia, university hospitals and business have formed the interest group Cell and Gene Therapy Sweden (CGT Sweden), which serves as a platform for collaboration. Another interest group is called ATMP Sweden, a membership-based organisation dedicated to promoting ATMPs in Sweden.

University hospitals and academic centres in medicine and technology play a central role in both research and clinical trials. The main players are Sweden's seven university hospitals and their ATMP centres. Stockholm focuses on gene- and cell-therapies and conducts early-stage clinical trials. Gothenburg works on immunotherapies and regenerative medicine. Malmö–Lund conducts research on stem cell therapies, neurodegenerative diseases, immunotherapy, and gene therapy (including haemophilia and oncology) and serves as a Nordic treatment centre for two rare genetic diseases. Uppsala focuses on stem cell therapies (CAR-T cells), while Linköping, Örebro, and Umeå conduct clinical studies and trials, among other things. Together, these centres cover much of the development chain, from preclinical research to clinical studies and trials, implementation and clinical care. They often collaborate closely with business.

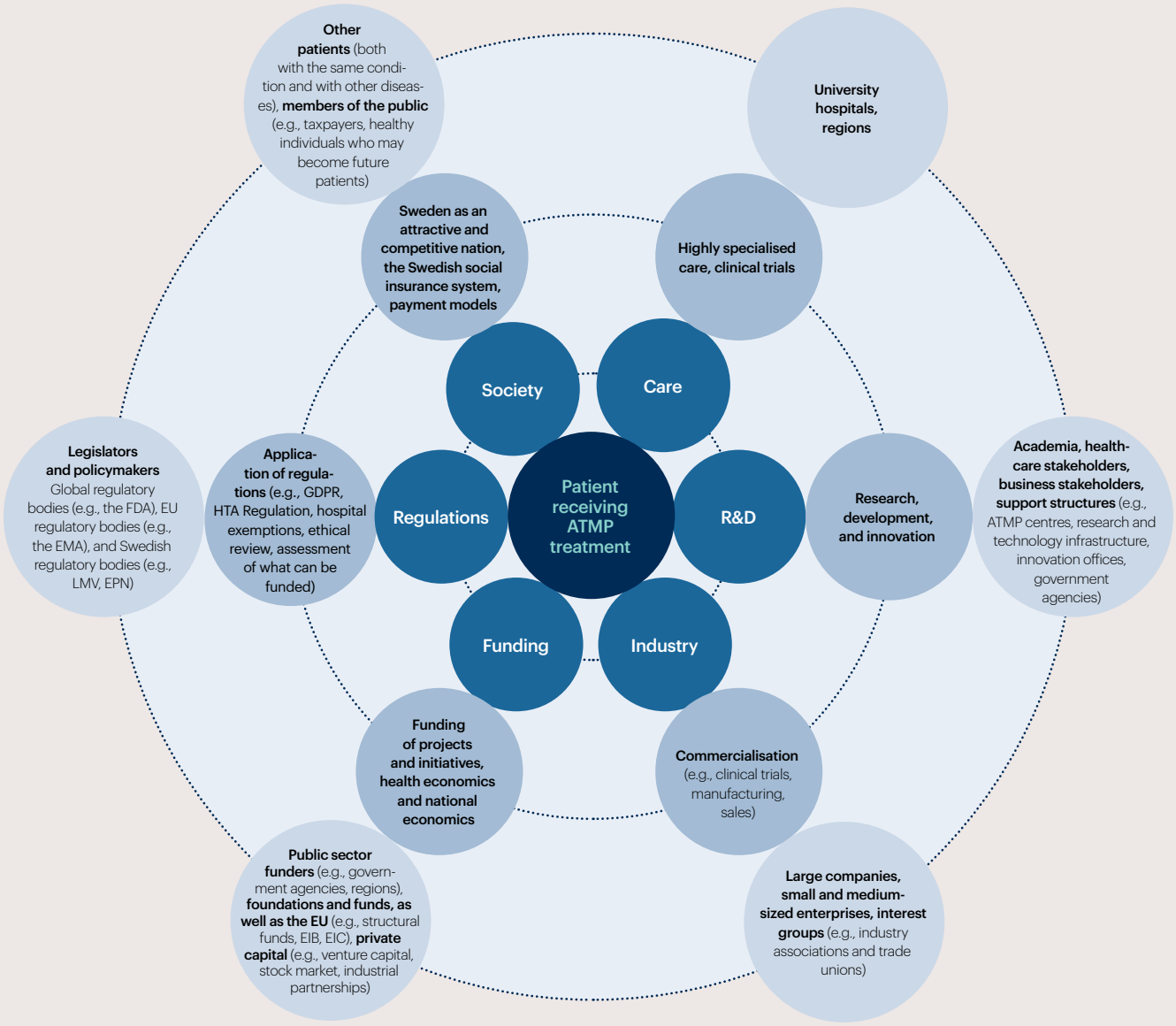
Companies and industry partners are also key components of the Swedish ATMP ecosystem. Sweden is home to a number of small and medium-sized ATMP companies, for example, developing cell-therapies for cancer and T-cell-based treatments. Several major international pharmaceutical companies are also active in Sweden that collaborate with academic centres and clinical trials. Their activities span research, clinical development, product and instrument development, analytical methods, GMP and the commercialisation of ATMPs. CDMOs contribute to production and quality control, including ensuring compliance with GMP standards and maintaining traceability of quality throughout the manufacturing process. In addition, national initiatives have established key innovation hubs like NorthX Biologics, Testa Center and CCRM Nordic.

Examples of funders that support ATMP projects include publicly funded programs such as Horizon Europe at EU-level and several national initiatives run by the Swedish Agency for Innovation Systems (Vinnova). Private venture capital groups also provide some funds.

In Sweden, several patient organisations are relevant to ATMPs. This is also a key issue discussed

8 The text in this section is based in part on the publication ATMP Sweden (2024). *ATMP2030 Swedish Annual ATMP Report 2024*.

FIGURE 2: The figure shows a schematic overview of stakeholders surrounding a patient receiving ATMP treatment. The inner circle shows the areas where collaboration is needed, while the middle circle shows examples of interventions within these areas. The outer circle illustrates examples of stakeholders involved. Collaboration among all stakeholders is crucial to providing the patient with the best possible care and to strengthen Sweden's attractiveness and competitiveness. Surrounding the patient is a private sphere that includes, for example, partners, family, and friends, as well as a social sphere that may consist of colleagues, classmates, and club members. There are also more formal support structures, such as patient and family associations.



SWEDISH COMPANY MANAGES A NEW EU FUND

The European Innovation Council has appointed a Swedish investment firm as investment advisor and fund manager for a new EUR 5 billion EU fund, the Scaleup Europe Fund, which will provide growth capital to European technology companies in areas such as biotechnology-related innovation. Although the fund is not specifically focused on ATMPs, the initiative is nonetheless relevant to developments in the field, as ATMPs often require significant investments in research and production to reach patients and the market in Europe.

Source: More information about the fund is available via the European Innovation Council, link: eic.ec.europa.eu/eic-fund/scaleup-europe-fund_en

in relation to the broader shift towards a new medicine paradigm.

ATMPs are governed by several regulatory frameworks

ATMPs within the EU fall under Regulation (EC) 1394/2007, which defines ATMPs and sets out how these therapies are assessed by the European Medicines Agency (EMA). Some treatments prepared for individual patients within an EU member state may be exempt from central authorisation under the so-called hospital exemption. But such treatments must still meet requirements for quality, traceability, and safety.

The hospital exemption means that under specific conditions, ATMPs can be manufactured and used within the healthcare system without central marketing authorization. The aim is to develop and offer individualised ATMP treatments in close proximity to clinical practice. In Sweden, this must take place within the framework of the legislation and in line with guidance from the Swedish Medical Products Agency to ensure a consistent and coherent regulatory system for ATMP development and approval. Making use of the exemption raises questions about how it should be applied and who bears responsibility, and its relationship to other regulatory frameworks. How the hospital exemption is applied in practice can have a significant impact on whether research, development, use, and implementation of ATMPs, as well as related research investments in Sweden.

The regulatory framework for the approval and use of medicines within the EU is changing. As of January 2025, ATMPs and new cancer medicines are subject to joint clinical assessments under the EU Health Technology Assessment (HTA) Regulation.[9] This may make requirements clearer and more predictable, but it also means that countries will have to adapt their national systems for pricing and provision.

International outlook

Targeted policy initiatives and regulatory frameworks have been developed in several countries to promote ATMP development. Examples include fast-track review processes, dual-track clinical trials, and strengthened reimbursement systems within health insurance schemes.

9 EU Regulation (EU) 2021/2282 on health technology assessment (HTA). Regulation of the European Parliament and of the Council of December 15, 2021.

The US is a global leader in ATMPs, with a growing number of approved cell- and gene-therapies.[10] A large number of clinical trials are also underway in the US, meaning that more therapies are in development, being tested on patients, or close to approval.[11] The US Food and Drug Administration (FDA) has introduced special fast-track programs to accelerate the development and review of regenerative medicines.[12] ATMPs also benefit from advanced regulatory mechanisms such as fast-track and accelerated approvals.[13] As a result, many new cell- and gene-therapies are first launched in the US. But the field remains highly resource-intensive, with substantial development costs and complex manufacturing requirements.[14] This means that patient access to ATMPs may be limited despite the availability of approved therapies.

China has rapidly built an expanding ATMP ecosystem, with a growing number of clinical studies and trials, new approvals and major government initiatives.[15] It has structured regulatory frameworks more clearly and aligned them with international standards, while investment in domestic production and supply chains has increased.[16] China has also introduced a dual-track system to accelerate trials.[17]

HOSPITAL EXEMPTION

The hospital exemption for ATMPs is regulated under EU pharmaceutical legislation, primarily in Regulation (EC) No. 1394/2007 on advanced therapy medicinal products. In Swedish law, the hospital exemption is implemented through the Medicines Act (2015:315) and supplementary regulations issued by the Swedish Medical Products Agency.

For more information, see the guidance on the Medical Products Agency's regulations (LVFS 2011:3) regarding medicinal products covered by the hospital exemption. Published May 13, 2024.

France has strengthened its position in ATMPs through strategic initiatives. As part of the *France 2030* programme, substantial investments have been made in biotherapies, biomanufacturing and advanced therapies.[18] ATMPs are a priority within France's broader effort to develop biological medicines of the future and strengthen domestic manufacturing capacity.

10 U.S. Food and Drug Administration. (2024). *Approved cellular and gene therapy products*. Link: www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products. Information retrieved May 7, 2026.

11 Vanhaeren, M., Gijsbers, R., Van Dyck, W., Huys, I., & Simoens, S. (2025). Advanced therapy medicinal products are coming of age: A pipeline analysis of the clinical trial landscape. *Drug Discovery Today, 30*(10). PMID: 40850492.

12 Food and Drug Administration. (2025). *Expedited Programs for Regenerative Medicine Therapies for Serious Conditions*. Draft guidance for industry. Docket Number: FDA-2017-D-6159. Food and Drug Administration. (2024). *Split real-time application review (STAR) pilot program*.

13 U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (2014). *Guidance for Industry. Expedited Programs for Serious Conditions – Drugs and Biologics*. OMB Control No. 0910-0765.

14 IQVIA Institute for Human Data Science (2025). *Global Trends in R&D 2025: Progress in recapturing momentum in biopharma innovation*. March 2025.

15 Tan, R., Hua, H., Zhou, S. et al. (2025) *Current landscape of innovative drug development and regulatory support in China*. Sig Transduct Target Ther 10, 220.

16 McKinsey's Life Sciences Practice (2022). *Vision 2028: How China could impact the global biopharma industry*. Article in a collaborative effort by Jeffrey Algazy et al.

17 Xu, L., Lu, W., Xie, Z., Hao, X. (2026) *The role of investigator-initiated trials in advancing cell and gene therapy under China's dual-track regulatory system: Opportunities and challenges*, Heliyon, Volume 12, Issue 7.

18 Government of the French Republic. (2021). *France 2030: A plan for innovation and industrial transformation*.

Germany has developed a national strategy for gene- and cell-therapies and strengthened reimbursement systems within its health insurance system.[19] A key element of the German approach is the assessment of the added value of new medicines and the determination of prices based on demonstrated clinical benefit. This requires robust evidence, which can be a challenge for ATMPs, particularly when patient populations are small and clinical data limited at the time of approval. To ensure continued patient access to ATMPs, more flexible assessments, better monitoring and new payment models that share risk between the health insurers and manufacturers are being explored.[20]

In Spain, access to ATMPs has long been slow and uneven due to cost considerations and different regulations across the country's regions. To address these challenges, Spain has introduced a national strategy for ATMPs, which has already led to better access to treatments such as CAR-T therapies. This work is supported by European initiatives, including RARE IMPACT, which brings together a wide range of stakeholders to improve the introduction and availability of advanced therapies. Despite this progress, however, problems persist with costs, assessment processes and approvals.[21]

The UK has invested in national networks and streamlined processes for clinical trials. The Medicines and Healthcare products Regulatory Agency (MHRA), the UK equivalent of Sweden's Medical Products Agency, has established the Innovative Licensing and Access Pathway to accelerate the development, approval and adoption of new medicines and treatments. The UK has also established the Advanced Therapy Treatment Centre Nework to support the development, implementation, and adoption of advanced therapies across the healthcare system.[22]

South Korea has established an advanced regulatory framework for ATMPs that is increasingly aligned with international standards. Among other measures, the country has introduced dedicated legislation for advanced therapies and developed regulatory guidelines through the Ministry of Food and Drug Safety (MFDS), South Korea's regulatory authority for medicines and medical devices.[23]

Japan has introduced flexible regulatory pathways that allow for conditional approvals and faster access to new therapies.[24] These conditional approvals are administered by Japan's Pharmaceuticals and Medical Devices Agency. In addition, Japan has passed legislation covering regenerative medicine, creating a distinct framework for ATMPs.

19 Federal Ministry of Health. (2024). *National Strategy for Gene and Cell Therapies.*

20 Rare Impact (2020). Country Report Germany. Improving patient access to gene and cell therapies for rare diseases in Europe. *A review of the challenges and proposals for improving patient access to advanced therapeutic medicinal products in Germany.* V1. January 2020.

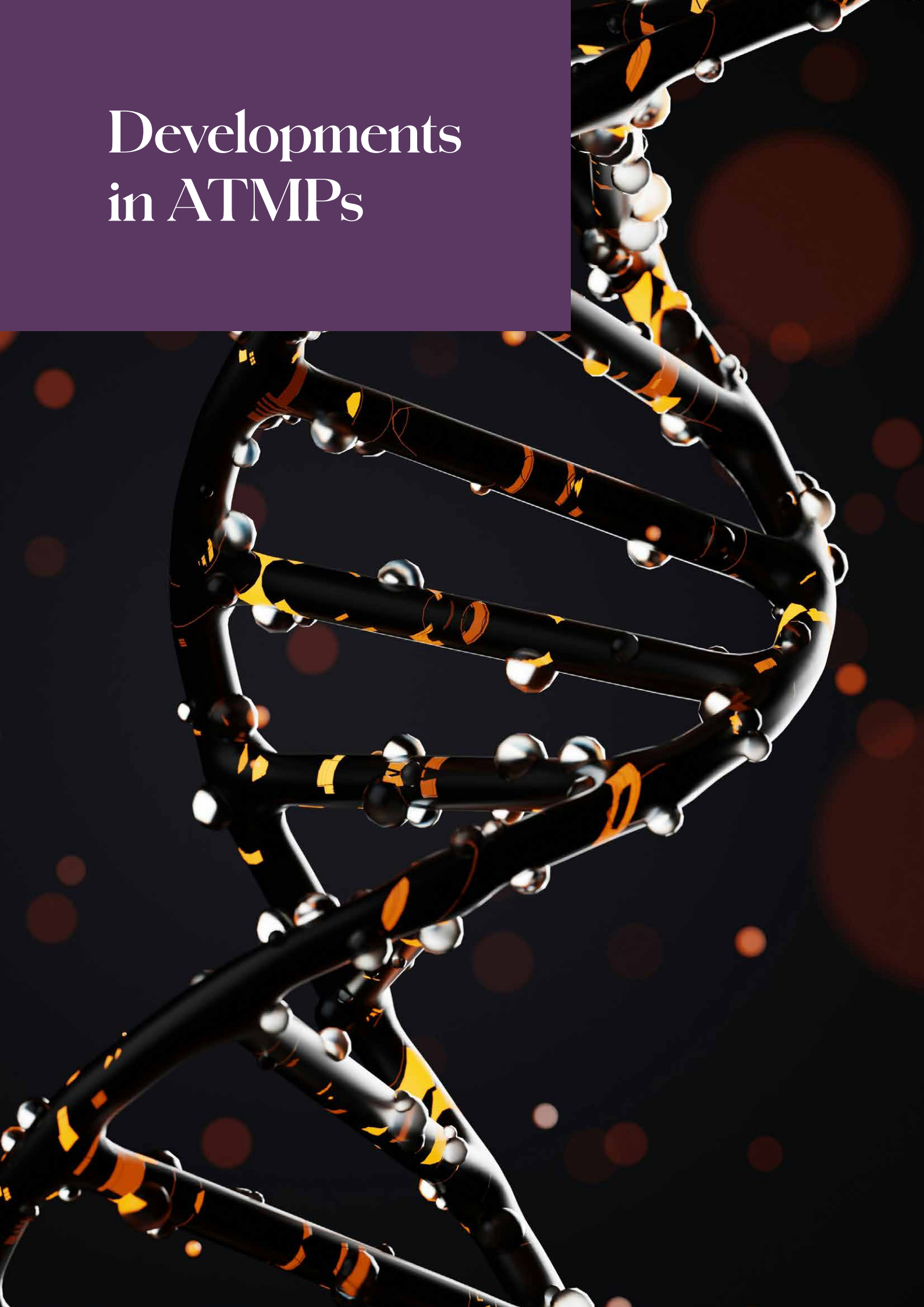
21 Rare Impact (2020). Country Report Spain. Improving patient access to gene and cell therapies for rare diseases in Europe. *A review of the challenges and proposals for improving patient access to advanced therapeutic medicinal products in Spain*. V1. January 2020.

22 Medicines and Healthcare products Regulatory Agency. (2022). *Innovative Licensing and Access Pathway (ILAP).*

23 Yoon, J., Lee, S., Kim, J-H. (2026). *New legal category of 'advanced regenerative medicine treatment' in Korea's amended regenerative medicine law: comparative lessons from Japan*, Stem Cell Reports, Volume 21, Issue 4.

24 Pharmaceuticals and Medical Devices Agency. (2023). *Regulatory framework for regenerative medicine products in Japan. Shinichi Noda, S. et al (2025). Regulatory advancements in Japan's conditional and time-limited approval scheme for regenerative medical products: the first guidance on the approval scheme and the second review for full approval of the first conditional and time-limited approved cellular product*, HeartSheet, Cytotherapy, Volume 27, Issue 6.

Developments in ATMPs



Current trends

The development of ATMPs has accelerated rapidly worldwide. Internationally, many ATMPs have entered clinical trials, but relatively few have progressed to market approval. A review conducted in 2018 found that over 500 clinical trials were conducted between 2009 and 2017, but that these resulted in only 19 applications for marketing authorisation and around 10 approved products in Europe.[25]

The expectation is that new treatments over the coming decade will expand beyond rare diseases and certain cancers to target solid tumours and more common diseases, including diabetes, autoimmune diseases and cardiovascular diseases.

From a health-economics perspective, this development has the potential to generate long-term benefits for patients and society by reducing the burden on healthcare systems and health insurance. At the same time, this will place increasing demands on regulatory frameworks and manufacturing platforms.[26] Sustainable reimbursement models will also be essential. Today's ATMP research is laying the groundwork for the next generation of treatments.

Sweden has long held a strong position in life sciences and biologics, supported by initiatives such as GoCo, NorthX Biologics, Testa Center and CCRM Nordic. Swedish ATMP projects often focus on small patient populations.[27] Experience gained from rare metabolic diseases, combined with a highly digitalised healthcare system and access to high-quality data, provides a strong foundation for the continued development of ATMPs.

Sweden has a unique program for screening all newborns for rare diseases, including long-term follow-up of all identified children.[28] This provides a foundation for a national strategy for both the development and introduction of new therapies, with an expansion of the screening program ensuring that all affected individuals in the population are identified and offered treatment before severe symptoms arise. The nationally coordinated initiative also creates opportunities to develop new, outcomes-based, economic, and reimbursement models. The program currently covers 26 treatable diseases. With the availability of a new gene therapy, one additional disease is expected to be added in 2026. Several other conditions are under consideration, and the potential for expansion is significant as new treatments, including ATMPs, become available.

However, there are not enough business models that adequately harness long-term value to make up for upfront costs, as well as a national roadmap that brings together existing initiatives and expert experience with ATMPs. These challenges are closely linked to broader issues of sustainable business models and economic innovation.

Sweden has integrated the development of ATMPs into its national life science strategy.[29] The strategy

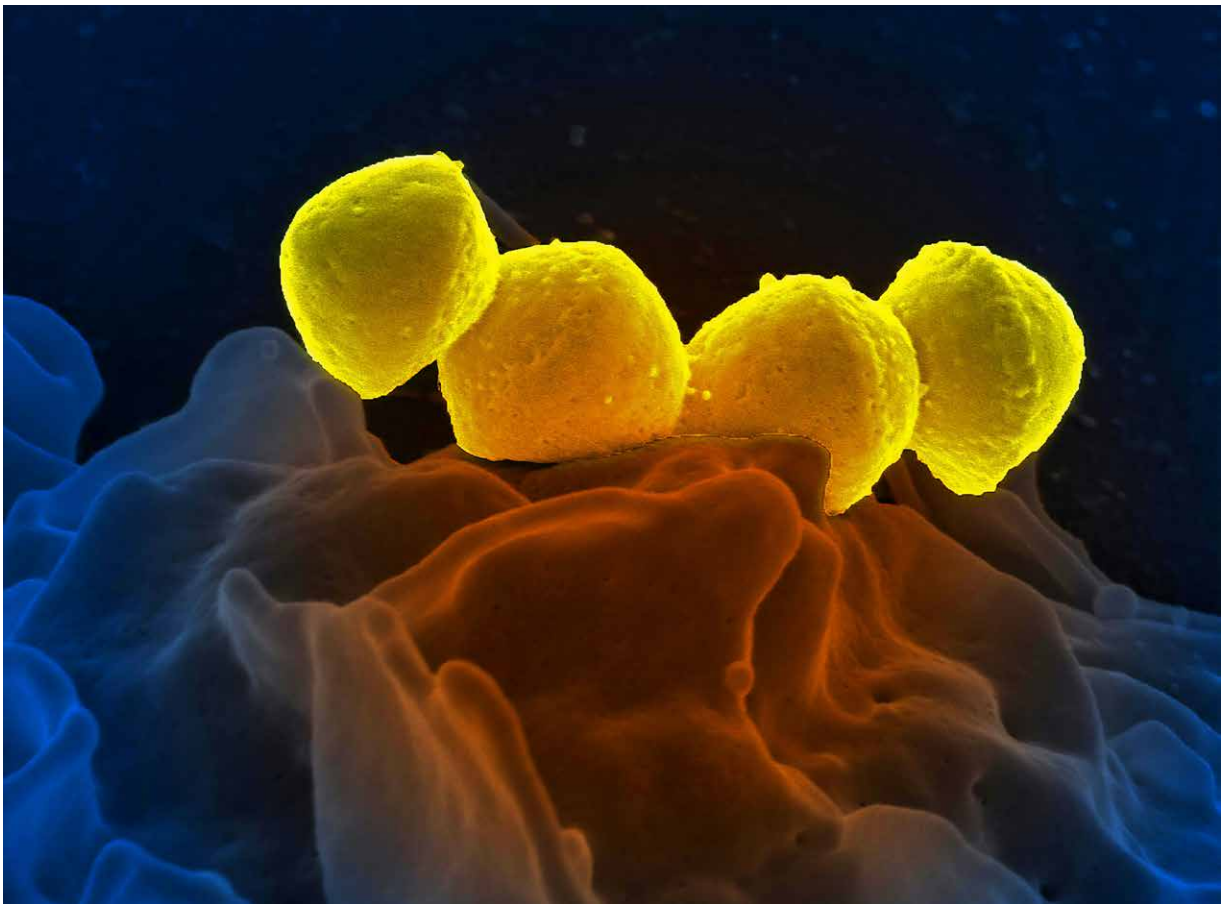
25 ten Ham, R. M. T. and co-authors. (2018). *Challenges in Advanced Therapy Medicinal Product Development: A Survey among Companies in Europe*. Molecular Therapy – Methods & Clinical Development, 11, 121–130.

26 Bucciarelli A. and Antonella Motta A. (2026). *Advanced therapy medicinal products: Emerging therapeutic frontiers and evolving regulatory landscapes*, Precision Medicine and Engineering, Volume 3, Issue 1, 2026.

27 Information on ATMPs in Europe is available via the European Medicines Agency (EMA). *Advanced therapy medicinal products: Overview.*

28 Link: www.karolinska.se/vard/funktion/funktion-medicinsk-diagnostik-karolinska/cmms/centrum-for-medfodda-metabola-sjukdomar/pku-prov/. Information retrieved April 24, 2026.

29 Government Offices of Sweden (2019). *National Life Sciences Strategy – for a strong life sciences sector in Sweden*. Stockholm: Ministry of Enterprise and Innovation.



identifies ATMPs as an important component of future healthcare and an area with great potential for advances in research and industrial development. The government has initiated support for national innovation clusters in advanced therapeutics through Vinnova, with a focus on commercialisation, skills development and manufacturing capacity. Additionally, the government has mandated Sweden's Dental and Pharmaceutical Benefits Agency (TLV) to press on with the development of methods for health-economic evaluations and payment models for precision medicine and ATMPs.

At the EU level, the European Medicines Agency (EMA) has established a dedicated scientific framework for ATMP development, including classification, scientific advice and approval processes tailored to these complex biological products.[30] The European Commission is also reviewing approval and monitoring mechanisms for advanced therapies as part of the EU's strategy for innovative medicines. The goal is to strengthen the internal market for ATMPs and improve access to innovative treatments across the member states.[31]

30 European Medicines Agency (EMA). (2026). *Advanced therapy medicinal products: Overview.*

31 European Commission. (2026). *Advanced therapies*. Link: health.ec.europa.eu/medicinal-products/product-types/advanced-therapies_en

EXAMPLES OF APPROVED ATMP TREATMENTS

CAR-T, TCR, and TIL therapies are different forms of immunotherapy. CAR-T involves modifying T cells in the laboratory so that they can recognise and kill cancer cells more effectively. TCR therapy works in a similar way but uses the T cell's natural receptor to identify cancer antigens inside the cells. TIL therapy relies on T cells that are already present in the tumour. These are isolated, multiplied in the laboratory, and returned to the patient to strengthen the immune system's attack on the cancer.

Today, these treatments are used almost exclusively for cancer, as they are particularly effective when there are clear targets to aim for.

ATMPs constitute a distinct segment of the pharmaceutical field

ATMPs still account for only a small share of medicines approved each year and currently reach relatively few patients worldwide. The field remains at an early stage of development, although the number of approvals has increased in recent years. For example, the US FDA in 2025 approved two cell therapies, three gene therapies and one tissue-engineered product. By comparison, 31 small-molecule drugs and 12 biologics were approved over the same time period. It is worth noting that nearly one-third of ATMPs approved in the EU were subsequently withdrawn, mainly because they were not commercially viable. Ten years after the first approval in 2015, there are currently 19 ATMPs authorised for the EU market.[32]

The number of new drugs approved annually is still dominated by small molecules and, to a lesser extent, biologics. Newer therapeutic modalities that have received regulatory approval alongside ATMPs are oligonucleotides, bispecific antibodies and antibody conjugates – and with theranostics using radioligands, for example, more are on the way. All of these therapies are not classified as ATMPs. Overall, the development of new therapeutic modalities provides additional ways to treat disease, potentially helping patient groups that currently lack satisfactory treatment options.

It is too early to determine whether cell and gene therapies will account for a growing share of approved medicines in the future. Depending on their underlying biological mechanisms and processes, and the diseases they target, different types of medicines may prove to be more or less suitable for achieving meaningful clinical benefits in specific patient populations.

Approved treatments based on ATMPs are currently available, for example, for rare diseases affecting the nervous system, the eye, and muscles. Currently approved ATMPs include CAR-T, TCR, and TIL modalities.

The global development portfolio includes several thousand ATMPs. Estimates vary between approximately 4,000 therapy candidates in development globally[33] and around 3,000 candidates,[34] depend-

32 Vanhaeren, M., Gijsbers, R., Van Dyck, W., Huys, I., & Simoens, S. (2025). Advanced therapy medicinal products are coming of age: A pipeline analysis of the clinical trial landscape. *Drug Discovery Today, 30*(10).

33 Alliance for Regenerative Medicine. (2025). *Q4 2025 Sector Snapshot. A Look into Cell and Gene Therapy Sector Trends*.

34 International Society for Cell & Gene Therapy. (2024). *Fourth global regulatory report: 2024 H2*.

ing on differences in terminology, definitions and dataset boundaries. According to one review article, just over 2,000 ATMPs were in clinical trials in the fall of 2025.[35] The majority of candidates remain in the preclinical or early clinical development.

About 40,000 clinical trials are initiated around the world every year, exact numbers varying depending on definitions and data sources.[36] But it is important to note that the number of clinical trials does not directly reflect the number of unique technologies or drug substances, as the same therapy or technology is often evaluated across multiple trials.

This suggests that about 5 percent of clinical trials in 2025 were focused on ATMPs.

At the same time, these therapies require substantial investment in manufacturing. For example, building enough production capacity to treat between 5,000 and 15,000 patients per year with so-called autologous cell therapy demands USD 4–6 billion (equivalent to SEK 40–65 billion) in investment.

ATMPs constitute a small part of the pharmaceutical field, but they could have a potentially significant clinical impact on specific patient groups, if a functioning market can be established.

Future potential

More and more diseases will become treatable with ATMPs as safety advances, delivery to the relevant tissues and organs improves and manufacturing becomes more cost-effective. There is hope that ATMPs could in the future be used to treat a wider range of conditions, from common diseases and various forms of cancer to very rare genetic disorders for which no treatment currently exists. Some examples are outlined below.

In the field of blood cancers, treatment options could be expanded to include more forms of leukaemia and myeloma, especially if cell therapies become more accessible and safer. To treat solid tumours as found in the lung, pancreas or brain, cell therapies will need to be improved to ensure better tumour targeting and to avoid side effects.

For autoimmune diseases such as rheumatic diseases, multiple sclerosis and systemic lupus erythematosus (SLE), ATMPs could in the future enable treatments that provide longer-lasting immune modulation compared with today's immunosuppressive drugs. Similar strategies may also help reduce the risk of organ transplants being rejected.

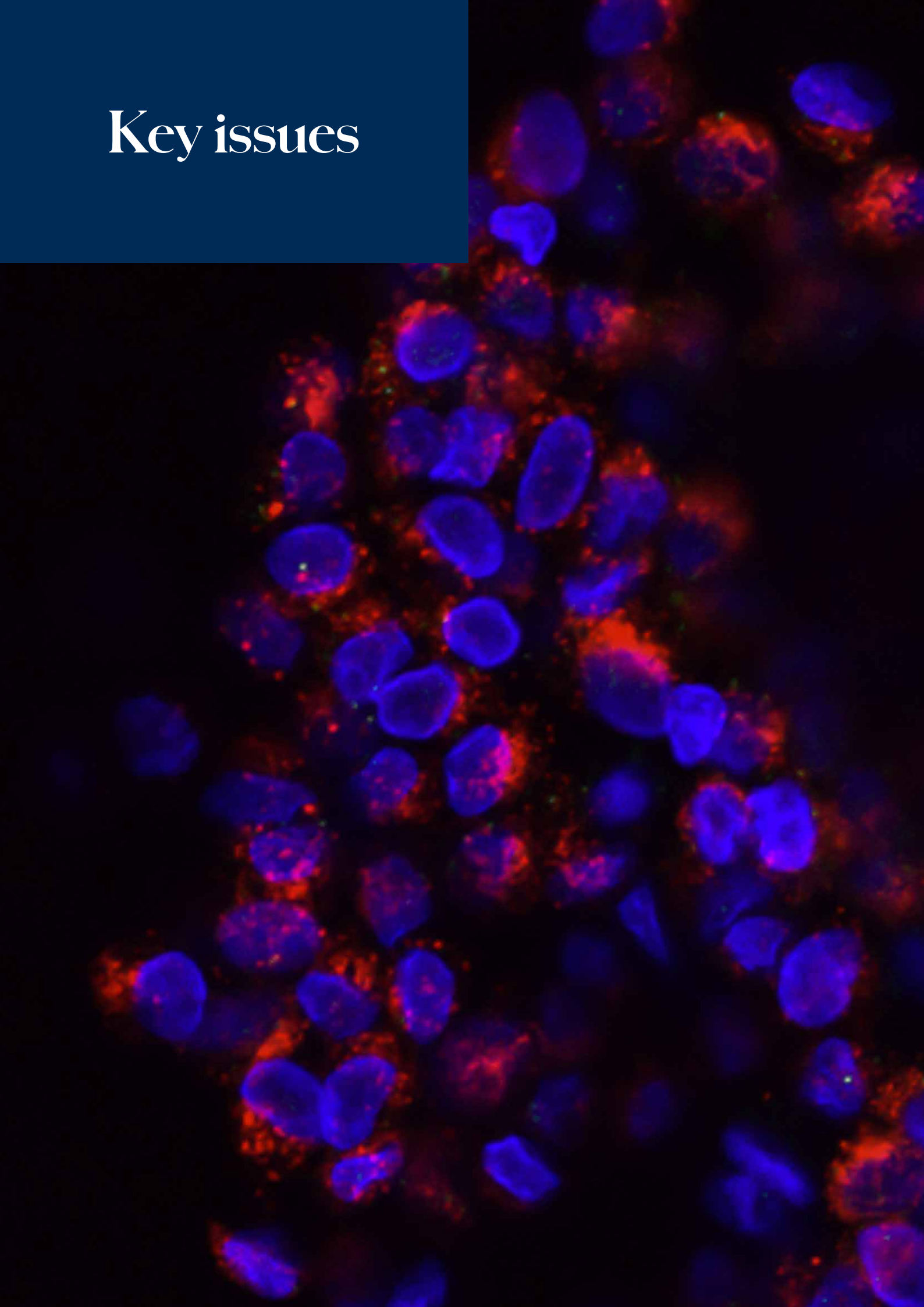
For inherited disorders of the blood, metabolism, and nervous system such as haemophilia, cystic fibrosis, Parkinson's disease, and muscular disorders, there is hope that one-time treatments could eventually replace lifelong medication.

Diseases affecting the eye, heart, lungs, hormones and skin could also potentially be treated more effectively through gene and cell therapies, for example by repairing or replacing damaged or dead cells.

35 Vanhaeren, M. och medförfattare. (2025). *Advanced therapy medicinal products are coming of age: A pipeline analysis of the clinical trial landscape*. Drug Discovery Today, 30(10), 104459.

36 Citeline (2025). *The Annual Clinical Trials Roundup 2025. Key Global Trends and Data Revealed*. Nov 17, 2025.

Key issues



Key issue 1: How can Sweden foster sustainable companies and innovative economic thinking?

There are several challenges to building companies in the ATMP field that have viable business models and are sustainable in the long term. ATMP development costs are very high, timelines long and patient populations often small, although there is potential for ATMPs to be used to treat broader indications and more common diseases in the future. In some cases, ATMP treatments can cost several hundred times more than standard treatments for the same condition. This implies that ATMP treatments must demonstrate greater efficacy with a single treatment or other benefits that justify their higher cost.

Even when ATMPs demonstrate strong medical efficacy, there is a risk that their price levels may limit widespread use within healthcare systems. A treatment has to be not only clinically effective, but also cost-effective and scalable. For this reason, industrialisation, automation and scalable production must be considered from the initial development phases.

Some companies are addressing these problems through business models based on dedicated production platforms, with the aim of reducing costs and enabling broader patient access to ATMP treatments over time. For these to be widely implemented, clinical efficacy alone is not sufficient – they must be deliverable at a cost that is sustainable for healthcare systems.

Obstacles to translating research results into commercial products or services also remain. Several ATMP products have received approval from the EMA but have still not reached the market. In some cases, companies withdrew products for commercial reasons. This typically reflects an assessment that expected sales are too low, meaning that the overall cost–benefit balance is not sufficiently favourable. High administrative costs and the design of reimbursement systems in Europe and Sweden also limit incentives to invest in ATMP development.

Sweden needs stronger integration into European and international funding structures to bridge the gap between clinical development and commercialisation. EU-level financing institutions play a key role in this effort., particularly the European Investment Fund, which provides venture capital to companies and other funds, and the European Investment Bank, which provides loans to larger investment projects.

Limited access to financing is one of the main challenges for smaller pharmaceutical companies, including those in the ATMP sector. Financing from government research and innovation funding bodies is mainly focused on early development phases, while later phases and the more expensive stages of development face greater difficulties attracting investment due to uncertainties related to business models, health insurers' willingness to pay and manufacturing costs. For example, companies in Sweden and elsewhere in Europe have less access to seed funding and early-stage investment than their US counterparts. By one estimate, the capital available for both seed and early-stage funding in Europe is 80% lower than in the US.[37] Lastly, the limited track record of successful ATMP projects also affects investors' willingness to invest in the field.

37 *Commission Staff Working Document – The EU Startup and Scaleup Strategy: Choose Europe to start and scale (SWD(2025) 138 final).* Brussels, 28 May 2025.

A key obstacle for the ATMP sector is the so-called "valley of death," the gap between research and the market entry, in which many projects fail. The challenge is particularly pronounced in Sweden, as its life-sciences sector is characterised by many small and often underfunded companies that struggle to push projects beyond early development.

This is linked to several factors, including perceptions that ATMP business models are particularly uncertain, sometimes small or poorly defined patient populations, potential risk of serious side effects, and difficulties in planning manufacturing at scale. Several factors influence the ability of companies to attract investment, including intellectual-property protections, business models, the size of the patient group, health insurers' willingness to pay, regulatory requirements and challenges related to production and scaling. To attract venture capital, projects generally need to demonstrate early on a credible production strategy and a clearly defined clinical and commercial patient population. Funding is often perceived as insufficient for projects to advance to clinical development and commercialisation. ATMPs remain high-risk investments, making early assessments of potential returns particularly important.

The EU has at the same time become less competitive in clinical trials, partly due to a fragmented and complex regulatory framework that makes trials multinational and thus more difficult and time-consuming to carry out.[38] A global review of clinical trials in cell therapy shows that the field is growing rapidly and is dominated by the US, China, and Europe. The US and China account for the majority of trials, while Europe maintains a strong research position and relatively high share of late-stage Phase III trials. Ongoing advances in research are driving the development of ATMPs towards broader clinical application, although significant regional differences remain in research focus and regulatory frameworks.[39]

The conditions for success are in place, provide circumstances prove favourable. At the same time, clinical research in Sweden is constrained by challenges such as healthcare waiting lists and the healthcare system prioritising routine care over research and clinical trials.

ATMP treatments are often very expensive in the short-term but can generate long-term savings by replacing lifelong treatment and care. Despite this potential, current reimbursement schemes do not always capture ATMPs' long-term value. Costs and benefits often accrue to different parts of society, complicating comprehensive assessments. Costs are frequently borne by the regions, while the savings accrue to health insurance systems or healthcare providers elsewhere, for example, through reduced demand for municipal care. Patients returning to work more quickly raise tax revenues that benefit the state.

Early and targeted interventions in diagnostics and treatment can reduce costs in other parts of the healthcare system and improve patient outcomes and quality of life. This is a central principle of precision medicine, which involves a shift from standardised treatment of large patient groups to more personalised diagnostics and treatment. This development is increasingly reflected in national policy initiatives, including a national roadmap and a government mandate for the National Board of

38 Draghi, M. (2024). *The future of European competitiveness: A competitiveness strategy for Europe*. European Commission, Brussels.

39 Wang M, et al (2026) *Global Panoramic analysis of clinical research in cell therapy: clinical trial landscape, marketed products, and regulatory trends*. Front. Pharmacol. 17:1715984.

Health and Welfare to pursue the implementation of precision health.[40] ATMPs play a central role in this transition, which is also reflected in Region Stockholm's action plan for precision medicine, where ATMPs are given special focus.[41]

The ATMP field is not only about creating individual therapies, but also about building a broader ecosystem. Sustainable companies can be built around manufacturing, infrastructure and technology platforms that support ATMP research, development and production. At the same time, access to capital is crucial throughout the value chain, and investment decisions are influenced not only by scientific merit but also by the potential to create a viable and profitable business models. There is a need for new financing models that better reflect the long-term value of treatments capable of delivering lasting benefits with a single application, including outcomes-based and pay-for-performance approaches. Debates about healthcare too often focus on immediate costs rather than broader economic and social benefits generated over time. Funding should be viewed not only as an expenditure, but also as an investment that can reduce future healthcare and long-term care costs.

Key issue 2: How can Sweden nurture creative and multidisciplinary environments?

Creative environments emerge when individuals, organisations, and educational institutions work closely together through frequent interactions within shared structures aimed at common goals. Interdisciplinary excellence, a strong innovation infrastructure, an open culture of collaboration, and investments in talent development and education are key components.

One example is collaboration between academia and industry across the entire development chain from research to patient care. This can generate new solutions that increase productivity in research and development and improve treatment safety, for example by ensuring the therapies are delivered to the appropriate target tissue or organ. Such collaboration can also improve product quality and reduce manufacturing costs (see box). In successful innovation environments, leading actors with ambitious and forward-looking – often dubbed "blue sky" – objectives in mind come together. Access to unique prototypes, specialised materials and reagents, early-stage analytical methods, advanced models and relevant machine learning techniques helps to continuously push the boundaries.

Experiences from GeneNova, a gene therapy consortium bringing together academia and industry, demonstrate how collaboration can drive innovation. The consortium has reduced produc-

40 Government Decision 2025-11-20. *Mandate to the National Board of Health and Welfare to carry out initiatives for an equitable and coordinated implementation of precision health*. S2025/01973 (in part)

41 Region Stockholm. *The Stockholm Region's life science strategy. Precision medicine*.

tion costs to approximately one-seventieth of those associated with traditional processes and brought three products to market. Each company in the consortium generates revenue within its respective product area, demonstrating that the model can combine innovation with commercial sustainability.

Organisational structure and working methods influence how well creative environments function. Short-term funding and an exclusive focus on academic credentials can encourage narrow specialisation, hamper interdisciplinary and translational research, and ultimately weaken innovation capacity. In practice, networks and collaboration across organisations and sectors play a major role, with smaller actors in particular often dependent on connections to larger contexts. The supply of talent is another critical factor. In addition to leading researchers, technical and operational expertise is also needed, for example in development and manufacturing. Educations and training at undergraduate, graduate, and professional levels should be an integral part of these environments.

Fostering creative and multidisciplinary environments within the ATMP field builds on experience gained through both national and international initiatives. Sweden already hosts several established innovation environments and ATMP activities at universities in Stockholm, Uppsala, Gothenburg, Lund, Linköping, Örebro and Umeå. These are also connected to networks and collaborations outside Sweden.

Sweden has several major clusters with a wide range of stakeholders in the ATMP field, including in the Stockholm–Uppsala, Västra Götaland–Oslo and Skåne–Copenhagen regions. These clusters – two of which include neighbouring Nordic countries – bring together several universities, academic hospitals, and biotechnology companies, enabling collaboration across the value chain from research to clinical application.

Innovation is driven by competition and collaboration. Experience shows that open innovation, where multiple actors collaborate and explore several ideas in parallel, can create synergies and strengthen development. At the same time, working methods and organisational structures have to be robust enough to manage situations in which national and regional actors have overlapping roles. It is important to establish collaboration early between research-based innovation, such as ATMP centres, and companies so that projects can mature and ultimately lead to treatments that can be implemented in healthcare. Highly specialised healthcare also serves as a driver of research and innovation, with national and international collaboration providing opportunities to develop and introduce advanced therapies for broader patient populations.

Advances in treating rare diseases show that integrated environments, in which research, clinical practice and technology are combined, are important both for advancing knowledge and helping patients. They also demonstrate that advanced therapies require new strategies and working models that combine highly specialised clinical medicine with experimental research. This requires a systems approach where the whole is greater than the sum of its parts. The medical profession should also be involved in decision-making and development. This requires continuous engagement within the healthcare system, including access to necessary resources. Multidisciplinary environments promote both foundational discoveries and advanced diagnostics and treatment, which require systematic collaboration and active engagement from the medical profession. Integrated data management, a patient-centred approach, and long-term learning enhance quality and efficiency within these environments.

Creative and multidisciplinary environments require not only funding but also effective collaboration, clear structures, a long-term perspective and strong leadership.

Key issue 3: How can Sweden drive innovative technologies?

Innovative technologies refer to the technical capabilities and infrastructure required for ATMPs. The development of ATMPs differs from that of conventional pharmaceuticals in that the processes are more complex and costly, while market potential remains more uncertain. As a result, technical innovation is not only about developing new equipment, but also about engaging healthcare stakeholders and optimising development and production end to end. Scientific excellence alone is not enough. Knowledge generated through research must also be translated into industrial production and clinical use.

Technology platforms, for example, present an important opportunity to adapt and develop solutions for different applications, reducing costs and increasing efficiency. Many of the technical solutions for cell handling are similar to those used in other fields. In practice, this means that common methods and platforms can support the development and production of several different therapies, saving time and resources. Realising such benefits requires well-functioning processes that integrate research, clinical practice, and industry and ensure logistics and workflows operate smoothly.

Digitalisation and data management are central to technological development in the ATMP field. Digital infrastructure enables the handling of large volumes of data from research and clinical trials, strengthening both scientific progress and the foundations for sustainable business models.

Tools and technologies used to study, develop and manufacture both conventional pharmaceuticals and cell and gene therapies are an area in which Sweden holds a strong position internationally. Several Swedish innovations originating in academic research have evolved into successful global companies. Rather than developing pharmaceuticals themselves, they provide the technologies that enable other companies to drive research, development and manufacturing. Such technology-focused companies are often perceived as less risky investors, which means their drug development projects can reach the market more quickly.

Demand for technology platforms is expected to grow rapidly, as ATMPs require new approaches to manufacturing, quality control, and logistics. The medicines of the future will be produced and controlled through increasingly advanced technological and industrial systems.

Sweden's strength lies in its broad ecosystem of companies developing these solutions. Examples include companies that manufacture bioprocessing equipment, equipment for the separation of cells and biological materials, bioreactors, purification and automation solutions, and sterile components. In the future, these companies will may also develop technologies focused on ATMP production, even if this is not one of their current business areas. Sweden also has number of smaller technology companies developing new methods for cell culture, analysis, and quality assurance, as well as companies specialising in analytical and quality-control technologies used to assess and ensure the quality of cell and gene therapies.

Sweden's historically strong position in the development of advanced technologies and instruments is a strategic advantage. Innovative technologies are not merely tools, they form the foundation for long-term competitiveness and the development of advanced therapies, including ATMPs.

Key issue 4: Can Sweden shift to the new medicine?

The development and introduction of new therapies require access to well-defined patient populations. Clinical medicine is currently undergoing a paradigm shift driven by technological advances that enable large-scale diagnostic approaches, so-called precision diagnostics. A key example is genomics, which makes it possible to identify patients with rare diseases at scale. In the interdisciplinary environment created by Karolinska University Hospital and Karolinska Institutet, whole-genome sequencing is tailored to different clinical questions and integrated into highly specialised clinical care through patient pathways where academic and clinical staff work side by side. In this multidisciplinary environment, patients with a range of rare diseases are increasingly identified early in the disease course, enabling more personalised treatments that also lay the basis for clinical trials.[42] In addition, new biological disease mechanisms are being uncovered, opening up opportunities for the development of entirely new therapies. This raises the need for new organisational models that have the potential to bring together advanced healthcare, research, and innovation to sustain these types of environments.

National initiatives are underway to implement so-called precision medicine in healthcare, including joint initiatives for precision medicine by the regions home to university hospitals[43] and a government mandate to the National Board of Health and Welfare to support the equitable and coordinated implementation of precision health.[44]

Another example is the Skåne Region's initiative to develop precision medicine toward so-called precision prevention, with a focus on preventing diseases more rigorously rather than merely treating them. A rapid whole-genome sequencing method was developed as part of this work, enabling the screening of larger populations to identify problems at an earlier stage.

One strategic issue concerns the locations of clinical studies and trials, as this influences where companies choose to establish operations. Companies are more likely to conduct clinical trials in countries where they expect rapid implementation and adoption. For Swedish stakeholders, it is important to maintain control over technological platforms and key parts of the development chain to ensure that value creation and expertise remain within the country. Although its patient populations are relatively small, Sweden benefits from high clinical expertise and an attractive environment for medical research. This also supports the development of platforms that combine ATMP expertise in clinical practice, research, and technology.

42 Lindstrand et al: *The Genomic Medicine Center Karolinska 10-year report on genome sequencing for rare diseases and a strategy for stepwise clinical implementation.* Genome Med. (2026) Mar 30;18(1):30.

43 Region Skåne, Region Stockholm, Region Uppsala, Region Västerbotten, Region Östergötland, Region Örebro County, and Region Västra Götaland. (2025). *Increased precision together.*

44 Government Decision, November 20, 2025. *Mandate to the National Board of Health and Welfare to carry out measures for an equitable and coordinated implementation of precision health*. S2025/01973 (in part).

Adequate healthcare capacity is essential for clinical studies and clinical trials. These provide patients with access to new treatments while simultaneously strengthening expertise in and understanding of ATMPs within the healthcare system. They can also increase the likelihood that research investment will be directed to Sweden.

Pharmaceutical companies invest about SEK 13 billion in research and development in Sweden every year, with SEK 5.2 billion or about 40 percent going into basic research. For example, clinical trials in cell therapy are conducted the country, which often lead to subsequent product launches and can serve as a model for other therapies. Clinical research and clinical trials are crucial to Sweden's attractiveness for investment, its capacity for innovation, and its overall competitiveness.

Implementation in healthcare systems is a critical part of the innovation chain. Ongoing efforts to integrate research and new technologies into everyday clinical practice, which generates benefits, but also entails costs – for example, related to the introduction of new technology. As a result, multidisciplinary environments that integrate research, clinical practice and innovation are of great importance. Concepts such as "first in healthcare," improved understanding of treatment risks, integration of diagnostics and treatment, and multidisciplinary environments can create the conditions to develop and implement ATMPs successfully.

Access to adequate data is a central issue in Swedish healthcare and research. Despite large volumes of data, information is often difficult to use in clinical settings because it is not available in the right format or in real time. This also applies to Swedish quality registries, which continue to have problems with incomplete data and varying data quality, partly because of continued manual data entry. Other countries face similar issues, but Sweden's high level of digitalisation provides a solid foundation for addressing them. Ethical and legal considerations related to health data, such as the use of opt-out models and interpretation of the EU's General Data Protection Regulation (GDPR), are also important. New EU legislation regarding the European Health Data Space introduces the possibility of opt-out models in certain contexts.

Communication – with policymakers, patient organisations, and the general public – is essential for raising awareness about ATMPs. The goal should be to strengthen understanding of Sweden's position and capabilities in the field.

FIRST IN HEALTHCARE

"First in healthcare" refers to the first-time use of a new medical treatment, technology, or method for treating patients in a healthcare setting. This often occurs following laboratory and animal studies, when the innovation is tested in a clinical environment. Examples include new drugs, medical devices, or diagnostic methods. The term is used to describe the early introduction of innovations in healthcare, where both benefits and risks are still being evaluated in real-world clinical use.

A description of how new treatments are introduced and used in healthcare is available from the Swedish Medical Products Agency; see the summary information on How a drug is approved.

The way forward

Vision

Sweden by 2035 will have developed a cohesive and internationally competitive ecosystem for ATMPs in which research, clinical development, industry, and healthcare collaborate closely. Sweden is now recognised as an attractive player in the ATMP field, which is strengthening the supply of expertise and contributing to growth. The path from scientific discovery to patient treatment is now short, predictable and efficient, enabling new therapies to reach patients more quickly and enhancing Sweden's appeal for clinical research, clinical trials, investment, and ATMP companies. Sweden is a leading and sought-after player in parts of the ATMP field, with international companies actively pursuing collaborations, investment and business development in the country.

Innovation ecosystems are organised into strong national and cross-border super-ecosystems in which stakeholders from medicine and technology work closely together on joint projects. These ecosystems have clear roles, effective coordination, and are sufficiently large to scale up innovations quickly and cost-effectively. When enough stakeholders come together, they form a critical mass that makes the system more resilient, robust, and better able to withstand disruptions.

Healthcare is an integrated, active part of the innovation system, with real-time data being used securely and systematically to support the development, monitoring, and improvement of treatments. Coordinated working methods and common rules make clinical trials and the introduction of new therapies routine. This means that patients gain earlier access to effective treatments, while unnecessary or ineffective interventions are being reduced.

There are clear regulatory frameworks that support ATMP innovation, with faster and more predictable approval processes both in Sweden and across the EU. Sweden actively advocates at EU-level for incentives that reward innovation that produce a meaningful clinical benefit. At the same time, the regulatory systems are designed to enable continuous learning and the gradual introduction of new treatments into healthcare systems.

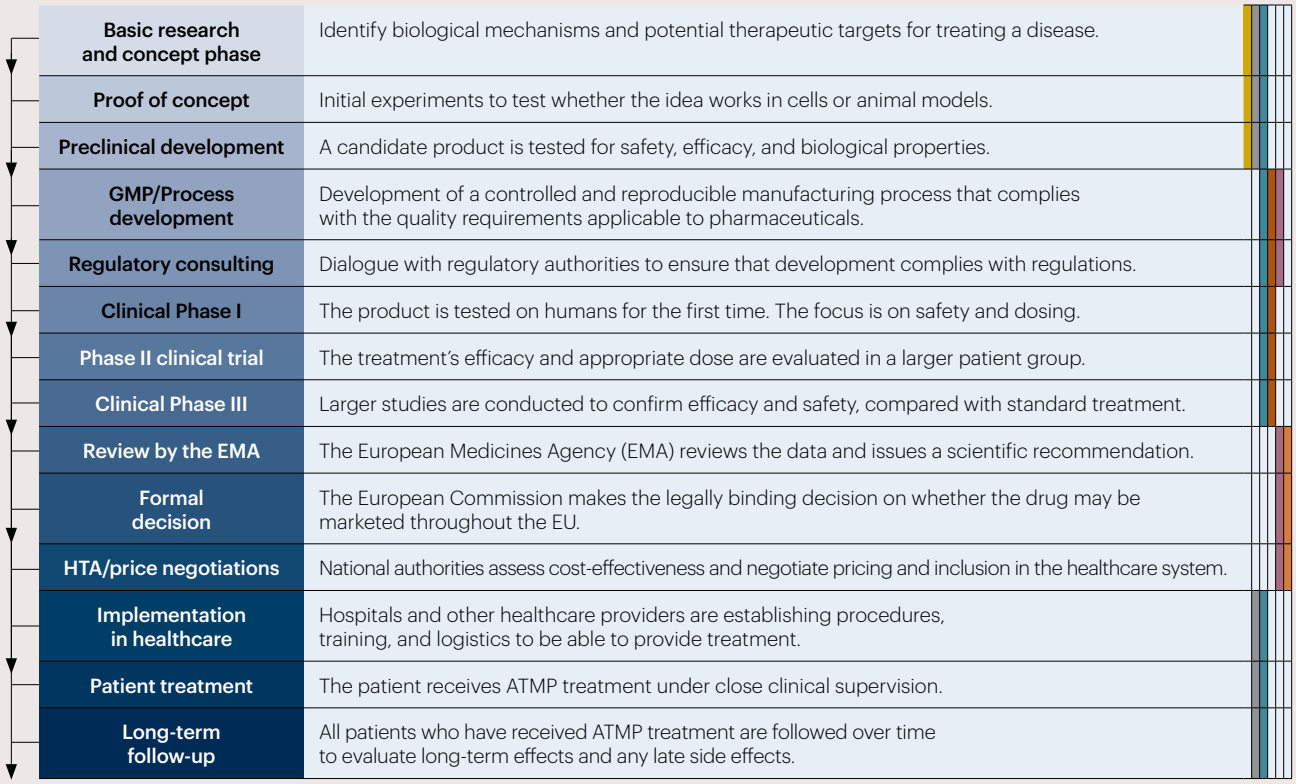
The financing system is designed so that the public and private sectors share risk in a structured manner, which allows more capital to be mobilised for ATMP projects in all phases of development. This leads to more projects and faster scaling up, and it reduces the risk that promising therapies will not reach patients.

Overall, patients receive faster and more targeted treatment, especially for serious and difficult-to-treat diseases. ATMPs help lower the societal costs of disease by cutting the number of complications, limiting disease progression, reducing the need for long-term care, and using healthcare resources more efficiently. This strengthens Sweden's international competitiveness and the efficiency and sustainability of it healthcare system.

Six proposals for the future of ATMPs in Sweden

The following are six overarching proposals to strengthen Sweden's competitiveness in ATMP, each consisting of a number of concrete measures that must be taken. The starting point is that Sweden is well-positioned to become an international leader in certain areas of ATMP. It has a strong research base, excellent clinical expertise, an advanced healthcare system, and a highly data-driven ecosystem. High quality research, technology development, and healthcare, and a strong framework for collaboration create favourable conditions for both development and implementation. However, significant gaps remain in national coordination, strategic direction, and long-term investment.

FIGURE 3: The proposals cover all stages of the ATMP development process.



Sweden cannot be a leader in all areas of ATMP. Resources must be concentrated in areas with strong ecosystems and clear competitive advantages. Particular emphasis should be placed on areas in which there are strong prospects of achieving a leading global position and access to world markets. This will ensure that resources are not spread too thinly. All six interrelated proposals were drawn up in this context. Several of them are expected to generate significant value for the broader life science sector. Their implementation will require high ambition, proactive drive, and a clear focus on translating ideas into concrete results.

Each proposal is of equal priority. All must be implemented and work should begin immediately. Sweden must:

- Strengthen the development of technology platforms
- Transform healthcare and improve data utilisation to move towards new medicine
- Invest in ATMP super-environments and creative innovation environments
- Strengthen funding and build a more effective investment structure

FIGURE 4: The proposals cover all areas related to a patient receiving ATMP treatment.

- Develop suitable regulation and drive innovative rule-making
- Strengthen EU and national incentive structures to drive innovation

Implementing these six proposals will be easier if the relevant government ministries – especially those responsible for research, healthcare, business, and funding – enhance collaboration. This would strengthen Sweden's position by enabling a more unified national approach and a more coherent national strategy. More consistent official messaging and government action would greatly help ATMP stakeholders.

However, the need for strengthened collaboration does not apply solely to the government. All ATMP stakeholders need to work in a more collaborative and open manner. This means not merely introducing new structures, but also fundamentally changing working methods and fostering genuine collaboration across organisational boundaries.

Proposal: Strengthen the development of technology platforms

Sweden should strengthen the development of technology platforms that can be used for multiple ATMP applications, as detailed in the key issue section on innovative technologies.

The focus should be on diagnostics, cell technology, and so-called industry-agnostic production systems that can be applied in various industries to address the challenge of raising production efficiency.

Action points to strengthen the development of technology platforms:

- **Support the establishment of national technology platforms within the ATMP** field by combining existing research and industrial expertise into emerging platforms designed for reuse across different therapies and disease areas. Universities, industry partners, and national public and private research funders would share responsibility for them.
- **Establish cross-sector collaborations** in which medicine, technology and industry work closely together, drawing on relevant international models. This can be achieved through shared research and educational environments. Education and technology development are integrated in industry-relevant testing environments and technical sandboxes. Leading universities, key research and technology organisations and relevant companies should be the key drivers of these efforts.
- **Harmonise processes** and create conditions for the technical adaptation and repurposing of existing solutions to reduce costs and increase scalability in ATMP development. This should primarily include processes related to automation, cell culture, sensor technology, bioproduction and digital control systems. Responsibility should lie with a combination of stakeholders from the private sector, government authorities and national ATMP centres.

In the short term, implementation involves identifying and consolidating existing technical strengths in diagnostics, cell technology, and production, as well as initiating joint pilot projects between academia and industry. The focus should be on connecting existing stakeholders rather than building entirely new structures, and on testing how technical solutions can be reused across different ATMP applications.

In a second step, more structured technology platforms can be established, in which diagnostics, cell culture, automation, and production systems are integrated into a shared environment. Collaboration with industry players developing manufacturing facilities and other stakeholders should be deepened, particularly in areas such as sensor technology, automation and bioprocesses. Processes should be harmonised to enable upscaling. Cross-industry collaborations should be established as a practical standardised approach.

The cost of infrastructure and reagents for ATMP production are high and need to be funded in education and research, from undergraduate to graduate and professional levels. Such funding has proven crucial for attracting pharmaceutical companies and strengthening collaboration between academia and industry. Examples of this include NIBRT in Dublin and iBET in Lisbon, two research and education hubs in biopharmaceuticals that maintain close links to industry and serve as vital hubs for expertise, education and development.

Within ten years, Sweden should have developed robust, scalable, and reusable technology platforms that can be used in various types of advanced ATMP treatments. These platforms, exportable products, and services should serve as a foundation for both national and international ATMP development and have the potential to significantly reduce development costs and shorten lead times.

Proposal: Transform healthcare and improve data utilisation to move towards new medicine

Healthcare needs to become multidisciplinary, connecting diagnostics, treatment, clinical studies, and clinical trials and integrating research and innovation.

Large volumes of health data must be available in healthcare systems in real time and integrated with traditional healthcare data along common standards. This enables multimodal analyses, reuse, and more sharing of data with relevant stakeholders. Access to data and data management must be integrated into research and development processes early. Scalable systems for patient data and process development are crucial for the advanced therapies of the future. In future, easier data-sharing through the EHDS and the use of pseudonymised health data could improve access to health data.

The transition to this new form of medicine must be addressed step by step, as healthcare encompasses a wide range of activities and levels of care with different needs. Particular attention should be given to the emerging model of medicine enabled by modern, large-scale diagnostic technologies and advanced therapies, which require access to infrastructure that individual regions cannot always pro-

vide. The state should take responsibility for ensuring a long-term, coordinated national effort to realise this transformation, which depends on seamless collaboration between academia and healthcare, with university hospitals playing a central role.

Sweden needs better ways to evaluate and pay for new treatments based on real-world results, and ATMPs could be used as a testing ground for improving the whole healthcare system.

Today's healthcare system lacks clear mandates with regard to innovation, commercialisation, and regional development. To successfully transform healthcare, key healthcare sector stakeholders need to be given a broader mandate for driving innovation.

Action points to transform healthcare and improve data utilisation:

- **Integrate clinical expertise into innovation and development work.** To bridge the gap between research and clinical practice, structures that free up time for clinicians to participate in development projects are needed. This can be achieved through dedicated roles, clinical innovation units, and incentive systems. University hospitals and regions should take responsibility.

- **Establish national clinical trial networks and learning healthcare structures.** Sweden should develop structures that connect screening, diagnostics, treatment and follow-up within a unified system. Such structures enable faster clinical trials and continuous improvement of healthcare. University hospitals and regions are key actors in implementation, with government support needed to enable cross-regional coordination.

- **Strengthen national digital infrastructure** by developing shared data platforms that enable the collection, standardisation and secondary use of health data. These systems should support real-time analysis and learning healthcare. Responsibility should be shared between regions, the National Board of Health and Welfare and the eHealth Agency in collaboration with academia. This aligns with Sweden's ongoing efforts to adapt to the EHDS, promoting interoperability, common standards, and improved data accessibility across organisational boundaries to support better care, stronger research, and increased innovation.

In the short term, implementation should focus on strengthening healthcare data infrastructure, establishing common standards, identifying regulatory barriers and launching pilot projects for real-time data collection in selected regions. At the same time, test environments for the new multidisciplinary model of medicine should be established, enabling closer collaboration between academia and healthcare and increased clinical involvement in innovation.

Over the next three years, national data infrastructures can be built to support the standardised collection, sharing and secondary use of health data in line with Sweden's adaptation to the EHDS. These infrastructures should be linked to national clinical trial networks in which screening, diagnostics, treatment, and follow-up are integrated into systems that support learning, operational development, and research. Healthcare should gradually evolve toward a more data-driven and multidisciplinary structure with seamless collaboration between academia and university hospitals.

Within ten years, Swedish healthcare should have evolved into a fully integrated learning system in which clinical practice, research, and innovation are connected in real time. Data should be used continuously to improve treatments, enable precision medicine, and support both clinical decision-making and system-level development.

Proposal: Invest in ATMP super-ecosystems and creative innovation environments

Sweden should develop a handful of strong ATMP super-ecosystems that connect existing innovation environments to attract EU funding. The aim is to create critical mass, better coordination and clear specialisation. These ecosystems should build upon existing structures rather than replace them. In cross-border environments involving Swedish and Norwegian or Danish partners, it is important that all parties contribute to investment.

Super clusters are becoming increasingly attractive for both investment and talent acquisition. Around the world, innovation activities are increasingly being organised into larger, more cohesive, and stronger clusters.

One model for organising such ecosystems is the internationally established hub-and-spoke model, in which a central hub provides coordination, infrastructure, and specialised capabilities, while a network of connected nodes carries out more applied and operational activities. The model combines strategic coordination with proximity to clinical practice, research, and innovation.

A national hub-and-spoke platform for ATMPs would include central hubs that provide advanced infrastructure and production support, such as manufacturing facilities, quality-control laboratories, quality-assurance systems, digital traceability, and frozen-product handling. Connected nodes, such as hospital-based ATMP centres and academic research groups, would be responsible for patient recruitment, sampling, treatment, follow-up and the early evaluation of new methods and treatments. Such a shared system would enable experts in advanced manufacturing and clinical activities to collaborate effectively. Super-ecosystems could also serve as national hubs for clinical trials, creating simpler, faster, and more coordinated processes.

Concrete action points for investing in super-ecosystems and creative innovation environments:

- **Establish three national super-ecosystems and integrate existing clusters.** The clusters in Stockholm–Uppsala, Västra Götaland–Oslo and Skåne–Öresund should be developed as major hubs, while existing ecosystems around other university areas and innovation platforms should also form structured networks. National coordination helps clarify roles, specialisations and responsibilities and to drive Nordic cooperation where relevant. Responsibility for collaboration should rest with a governing board where representatives from university hospitals and the regions can participate, supported by funding from bodies like Vinnova and the Swedish Agency for Economic and Regional Growth. Additional support can also be sought from the EU's structural funds via the Swedish Agency for Economic and Regional Growth. Collaboration should ensure that promising initiatives receive sufficient long-term support to mature, while allowing different approaches to be tested in parallel during early development. Once an initiative has become established, the stakeholders should jointly assess whether certain functions should be concentrated in a single location. Coordination between the ecosystems must be designed in a way that enjoys broad legitimacy and trust across the ATMP sector.
- **Develop common working methods** and integrate project structures. The super-ecosystems should be organised so that

medicine, technology, data, and industry collaborate on joint projects rather than working in silos. This requires shared technology platforms, interdisciplinary teams, and researcher networks. University hospitals, academia and industry stakeholders should play active roles.

- **Clarify roles and responsibilities among stakeholders** to avoid fragmentation. National research infrastructures, technology platforms, regional actors, and healthcare providers should have clearly defined responsibilities in research, clinical development, manufacturing, and innovation. Over time, different research and disease areas should be distributed across the ecosystems to build critical mass, international competitiveness, and complementary strengths. These specialisations should emerge gradually through collaboration rather than being predetermined.

- **Establish a national investment support function.** Sweden should create a permanent function that helps connect ATMP projects with domestic and international investors and supports companies in becoming investment-ready. This function could provide expertise in areas such as intellectual property, data strategy, regulatory pathways, and project structuring in line with international investment standards. Relevant actors include Vinnova, university innovation departments, and other innovation-support organisations.

In the short term, implementation should focus on mapping existing innovation environments in Sweden and neighbouring regions and developing a shared understanding of how they complement one another and contribute to the ATMP ecosystem. This includes taking stock of ongoing initiatives in Stockholm–Uppsala, Västra Götaland–Oslo, and Skåne–Öresund and identifying strengths, overlaps, and gaps. In parallel, a simple national coordination mechanism should be established to strengthen collaboration between regions, university hospitals, and innovation actors and reduce fragmentation. This could build on existing structures, such as Cell & Gene Therapy Sweden or the collaboration framework among Sweden's university hospital regions (SUHA) focused on strengthening cooperation in highly specialised care, research, education, and innovation.

In the coming years, these three super-ecosystems should be formalised as strategic hubs that bring together universities, university hospitals, and industry stakeholders in more structured networks. Existing environments should be incorporated into these networks and given clearer roles, particularly in relation to clinical trials, data-driven innovation, and industrial development. The emphasis should be on creating effective networks rather than new physical structures, with particular attention to interoperability and shared ways of working.

In the longer term, these super-ecosystems should evolve into fully integrated innovation and implementation environments spanning the entire value chain – from research and development to clinical application and industrial production. Sweden would then function as a coordinated network of internationally competitive ecosystems in which new ATMPs can be developed, tested, manufactured, and implemented within a connected system.

Proposal: Strengthen funding and build a more effective investment structure

Better coordination between public and private funding is needed to strengthen the ATMP sector and reduce investment risk. The focus should be on mobilising capital rather than creating new cost structures and on making later development stages more attractive to investors. The financing system should combine risk-sharing, long-term incentives, and stronger links between innovation, clinical value and reimbursement. To support the long-term development of ATMPs, Sweden also needs to adapt its value-based reimbursement system to new types of therapies.

Long-term development of ATMPs depends on access to private capital, viable business models, and investors willing to engage early in the development process. Without this kind of investment, all projects risk failing, despite good research and promising projects.

Concrete action points to strengthen funding and build a more effective investment structure:

- **Develop outcome-based reimbursement** by health insurers by introducing payment models linked to real-world patient outcomes over time, particularly for one-time treatments and advanced therapies. This requires structures for recording outcomes, as well as agreements between regions and companies to share risk between the healthcare systems and the private sector. The TLV and the regions can be key players alongside stakeholders in the private sector.
- **Create adequate conditions for upscaling and production.** To make it easier to invest in expensive manufacturing equipment, the government should consider providing credit guarantees or other support that reduces the risk associated with building and upscaling production capacity in accordance with GMP. This would make it easier for banks and private investors to finance the industrial scaling up of ATMPs. The Swedish National Debt Office could be responsible for credit guarantees for major industrial investments, while the European Investment Bank (EIB) could supplement this with loans and risk-sharing for smaller players. This is in line with the EIB and the European Commission's announcement of a joint initiative under TechEU to mobilise approximately EUR 10 billion in investments for Europe's biotechnology sector during 2026–2027.[45]
- **Introduce risk-sharing mechanism solutions linked to supply-chain and treatment risks.** This could be achieved by developing insurance models that cover risks related to logistics and traceability, as well as models in which payments are partially refunded if the treatment does not produce the expected results. This would reduce uncertainty for healthcare providers and funders and could increase their willingness to adopt new ATMP-based therapies. The government could develop these models in collaboration with insurance companies, regions and private-sector stakeholders.

45 European Investment Bank (2025). *European Commission and EIB Group announce new initiative to mobilize €10 billion in investment for Europe's biotech sector.* Link: www.eib.org/en/press/news/european-commission-and-eib-group-announce-new-initiative-to-mobilise-eur10-billion-investment-for-europe-s-biotech-sector

- **Establish public-private co-investment models** in which the government shares part of the financial risk during early and particularly uncertain development stages. The aim is to reduce investment uncertainty and attract more private capital to both the ATMP sector and the life sciences more generally. One risk-sharing instrument could be portfolio-based fund with a first-loss-like structure, in which public funds take the initial risk while private actors provide the majority of the capital and receive the largest share of any returns. The instrument can also be designed with other forms of risk sharing. The structure would have two levels – the fund-of-funds level, at which public capital absorbs part of the initial risk while private investors provide most of the capital and receive the majority of potential returns, and the fund level, at which the actual investments are made. Risk-sharing between public and private actors can be applied at both levels. Management responsibility for the underlying investment fund should be entrusted to professional managers, with access to institutional capital from both public and private sources.

Some form of public–private co-investment model could also be used to strengthen government co-financing of late-stage clinical trials and product launches. If applied in late-stage and implementation studies, where the risk is high, but the societal benefit is significant, dependence on private funding in the most capital-intensive part of development would decrease. This would raise the likelihood that more Swedish projects reach the market, benefiting societal welfare.

In the short term, the focus should be on identifying shortfalls in capital, particularly in late development stages, and on developing models for risk-sharing between the public and private sectors. At the same time, the state, the regions, and investors should discuss how to design guarantee models to cover investment losses, co-investment structures, and new compensation mechanisms.

In the coming years, more structured financing instruments will be found thanks to the state sharing risks through investment funds and guarantees that mobilise private capital. Sweden and Swedish companies should be more closely linked to European financing instruments, and structures to support companies through scaling up should be established. Outcome-based reimbursement models should also be introduced in healthcare.

Over the next ten years, a coherent financing system is expected to emerge. It will cover the entire value chain from early-stage research to commercial production. The public and private sectors will share risk in a structured manner, so that financing no longer constitutes a decisive barrier to the development of ATMPs in Sweden.

There is scope to design measures in line with state aid rules

Strengthened funding and an improved investment structure for ATMPs must comply with EU state aid rules. Experience from several member states shows that this regulatory framework allows for significant practical leeway in practice when measures are well designed.

State aid issues arise when public interventions provide companies selective economic advantages on terms that are not market-based, for example, when the state assumes greater risk without corresponding compensation in co-investment models, or offers guarantees and insurance below market rates. They can also arise from targeted support to individual companies, overfunding in late-stage development, or combinations of support that lead to overcompensation. This does not mean such support should be avoided, but that instruments must be designed within EU legal frameworks.

Several countries have demonstrated how this can be done. Belgium and the Netherlands channel public investment into ATMPs through research infrastructure, academic centres and open platforms. This reduces the risk of selective state aid and creates more robust and open innovation environments. Spain has integrated parts of ATMP development and production into the healthcare system, meaning that funding is delivered through public healthcare structures rather than direct company support. These examples show that state aid rules shape design rather than prevent action.

Against this background, a more detailed analysis should be conducted, but it is clear that the focus should be on using the flexibility within the regulatory framework. This document outlines a general direction rather than fully detailed proposals.

The preliminary assessment is that several sub-proposals carry a low risk of state aid. Outcome-based reimbursement models are generally considered payment for clinical value and fall outside state aid rules, especially when implemented through established actors such as TLV. Cooperation with the EIB and European Investment Fund operates within established frameworks and is therefore low risk. National coordination and matching functions, for example through Vinnova, can also be designed to avoid selective economic advantage. Insurance solutions may also fall into a low-risk category if premiums are set at market levels.

Other sub-proposals require more careful consideration but are still feasible within the regulatory framework. Public-private co-investment models in which the state assumes part of the initial risk are already used in several EU countries, provided market practices are included, like adjusting returns according to risk. State-backed guarantees can also be compatible if pricing reflects actual risk. Co-financing of late-stage clinical trials is closer to market practice but can be structured under EU rules for research, development and innovation, as long as proportionality and avoidance of overcompensation are respected.

Experience from other member states shows that the focus should be on designing measures within state aid rules rather than avoiding them. A more pragmatic approach – focused on system-level support, infrastructure, and market-based risk-sharing – can enable a more proactive investment strategy in Sweden.

Proposal: Develop suitable regulation and drive innovative rule-making

The regulatory framework must be developed to better support rapid innovation, international competitiveness, and new types of treatments.

Concrete action points for developing regulations and regulatory innovation:

- **Develop faster regulatory pathways for ATMPs in the EU and Sweden.** Sweden should work more actively within the EU to make the approval processes for ATMPs faster and more predictable. This involves promoting the development of fast-track procedures for

advanced therapies and supporting incentives such as "fast-track vouchers", whereby companies that receive approval for an ATMP would receive priority for the review of other drugs (see separate proposal below). The aim is to reduce regulatory uncertainty and shorten development timelines, while creating stronger incentives for investment in new treatments. This requires Swedish stakeholders not only to adapt to EU processes but also to actively influence them. The Swedish Medical Products Agency should take a leading role in regulatory work and advocate for Swedish priorities within European regulatory networks, while the government should be responsible for political coordination and for ensuring that Swedish positions are reflected in EU negotiations. Collaboration with industry stakeholders is important to ensure that incentives are designed to incentivise development decisions and investments.

- **Boost testing within healthcare systems** by establishing controlled environments in which new therapies, working methods and data-driven solutions can be tried out on a small scale before being wider implementation. The aim is to accelerate learning, improve opportunities to evaluate regulations in practice, and adapt clinical and regulatory processes in the light of new insights. This is particularly important for ATMPs, as development and implementation often occur in parallel and clinical data has to be shared quickly with researchers and healthcare professionals. Responsibility for the regulatory framework should lie with the Swedish Medical Products Agency and the Swedish Dental and Pharmaceutical Benefits Agency, working in close collaboration with the regions and university hospitals, which are responsible for clinical environments and patient-centred implementation. The Swedish Dental and Pharmaceutical Benefits Agency should be involved to ensure that reimbursement and implementation issues can be handled in parallel, while academia and industry contribute technology, data and methodological development.

- **Clarify and harmonise the interpretation of existing regulations.** Sweden must reduce the uncertainty about application of existing regulations in clinical innovation, particularly regarding the hospital exemption and the EU's GDPR. Varying interpretations lead to different approaches by countries, regions, and stakeholders, which hinders the implementation of new therapies and the use of health data in research and development. This can be addressed by developing common national guidelines that clarify how regulations should be applied in practice within the ATMP field. At the same time, the relevant authorities need to co-operate more closely to ensure more consistent application across the country and reduce differences in practice, both regionally and at the level of healthcare providers. The Swedish Medical Products Agency should be responsible for medical and regulatory interpretation, while the Swedish Authority for Privacy Protection should be responsible for issues related to data protection and the secondary use of health data.

In the short term, implementation should focus on identifying regulatory barriers and establishing a structured dialogue between Swedish authorities and the EU on regulatory issues and processes relevant to ATMPs. Pilot projects for healthcare testing environments should be launched to evaluate more flexible working methods.

In the coming years, structured testing environments should be introduced in healthcare where new therapies, data-sharing models and

clinical approaches can be tested in controlled settings. Sweden will actively engage within the EU to influence regulations relevant to ATMPs and health technology assessments (HTA). It should also streamline national processes for clinical trials.

Within ten years, Sweden should have established an adaptive and innovation-friendly regulatory framework in which regulatory and clinical development are closely integrated. Approval processes should be faster, more data-driven, and better suited to ATMPs.

Proposal: Strengthen European and national incentive structures to drive innovation

To boost the development of ATMPs, Sweden needs to actively utilise and influence the EU's incentive system and supplement it with national tools that make it more attractive to develop ATMPs. The focus should be on reducing uncertainty in approval processes, increasing predictability, and providing clearer rewards for innovation that leads to clinical benefit. This requires coordination between Swedish authorities, EU institutions, and industry stakeholders to ensure that incentives actually influence development decisions and investments.

Concrete action points to strengthen the incentive structures of the EU and Sweden for innovation:

- **Introduce a "fast-track voucher" for ATMPs.** Sweden should work to ensure that companies whose ATMPs are approved by the European Medicines Agency (EMA) can receive a "fast-track voucher" for priority review of another drug in development. It is important that this accelerates regulatory review substantially and that the fast-track voucher is transferable. This means that a company that develops an ATMP, obtains marketing authorisation, and receives a fast-track voucher would be able to sell it to another company. Faster market access — potentially by several months — can be extremely valuable, and companies may therefore be willing to pay substantial sums for such a voucher. In some cases, the proceeds from selling the voucher could offset a significant share of the development costs of the ATMP. Swedish stakeholders, including the government and the Medical Products Agency, should advocate for this policy at EU level to ensure that such a system is designed and implemented effectively. The private sector should also be involved at an early stage to ensure that the incentive leads to increased investment in clinically useful treatments.
- **Create incentives for early clinical adoption.** Sweden should introduce incentives for companies that conduct clinical trials and make new treatments available in Swedish healthcare at an early stage, for example through faster uptake in healthcare or more favourable reimbursement arrangements. Such incentives could be linked to conducting studies in Sweden and generating data useful to the Swedish healthcare system. Responsibility should lie with the TLV and the regions, working in collaboration with university hospitals.

- **Link approval and reimbursement more closely to patient outcomes and data generation.** Incentives should increasingly be based on whether medicines and treatments are not only approved but also systematically monitored in clinical practice and demonstrate real-world clinical benefit. To enable this, EU health technology assessments (HTAs) and Swedish quality registries should be linked so that outcomes can be tracked over time. The Swedish Medical Products Agency, TLV, the EU's HTA cooperation framework, and Swedish quality registries should collaborate to implement this approach in practice.

In the short term, implementation should focus on strengthening Sweden's influence on EU initiatives related to incentives for innovation, including proposals such as fast-track vouchers for ATMPs. An analysis should also be conducted of how national incentives can be strengthened to increase the number of clinical trials in Sweden. Dialogue between authorities, regions and the private sector should be intensified to identify opportunities for near-term improvements.

In the coming years, national incentives for clinical implementation and data generation should be introduced, while Sweden actively engages with and helps shape the EU's new HTA framework. The link between clinical trials, data collection and reimbursement should be strengthened so that financial incentives are increasingly based on demonstrated patient benefit.

Within ten years, Sweden should have established a well-coordinated system of national and EU-level incentives for innovation. Regulatory and economic drivers should work together to bring effective ATMP treatments to patients more quickly while strengthening Sweden's role as a leading innovation nation.

Recommendations

The working group has three overarching recommendations to strengthen Sweden's competitiveness and attractiveness, while contributing to the country's sustainable development. Together, they are meant to strengthen national coordination and increase the development, production, and use of ATMPs in Sweden and internationally.

We believe that these recommendations will accelerate the development and implementation of ATMPs. In the long term, they have the potential to generate significant socioeconomic benefits through improved health outcomes, lower healthcare costs, and more attractive conditions for business investment.

The recommendations are based on an analysis of Sweden's position in the ATMP field, international development trends and a review of key issues highlighting obstacles and opportunities for Sweden's continued development. They summarise a number of proposals and action points that are described in more detail above.

- Invest in multidisciplinary super-ecosystems with shared technology platforms where academia, industry, and healthcare collaborate to develop, test, and implement ATMPs.

- Enable the healthcare sector to be an integrated, active part of research and innovation so that new treatments can reach patients more quickly and improve care outcomes.

- Simplify regulations and strengthen incentives in Sweden and the EU and improve the coordination between public and private funding to mobilise capital and develop robust business models.

Appendix

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Glossary

Antibody conjugate
A drug in which an antibody is linked to an active substance, often a cytotoxic agent, allowing the treatment to target diseased cells directly and thereby reduce the impact on healthy cells.

ATMPs (Advanced Therapy Medicinal Products)
Advanced therapy medicinal products.

Autologous therapy
Personalized treatment in which the patient's own cells are used, reducing the risk that the introduced cells will be rejected by the body.

Biological medicines
Medicines produced in living cells, such as bacteria, yeast, or animal cells grown in laboratories. They consist of large and complex molecules such as proteins and target specific processes in the body.

Bioreactor
A container in which cells or microorganisms are grown under controlled conditions to produce, for example, drugs or biological substances.

Bispecific antibodies
Antibodies that can bind to two different targets simultaneously, thereby bringing together, for example, immune cells and cancer cells to help the immune system recognise and kill disease-causing cells more effectively.

CDMO (Contract Development and Manufacturing Organization)
Companies that develop and manufacture drugs for others.

CRO (Contract Research Organization)
Companies that conduct parts of clinical research and development on behalf of pharmaceutical and biotechnology companies. This may include, for example, clinical studies, clinical trials, data analysis, and regulatory work.

EMA (European Medicines Agency)
The European Medicines Agency.

EPL
Act (2003:460) on the Ethical Review of Research Involving Humans, often referred to as the Ethical Review Act.

GDPR (General Data Protection Regulation)
An EU regulation governing the processing of personal data and aimed at protecting individuals' privacy by setting requirements for how organisations may collect, store, and use information about individuals. In Swedish, the term "EU Data Protection Regulation" is often used.

GMP (Good Manufacturing Practice)
Rules that ensure that medicines are manufactured in a safe and controlled manner with high quality.

LMV
The Swedish Medical Products Agency.

Oligonucleotides
Short chains of the building blocks of DNA or RNA that can be used as medicines to influence how genes are expressed in the body.

Opt-out
In so-called opt-out models, a person's data may be used automatically, but the person has the option to actively choose not to participate or to object to the use of the data.

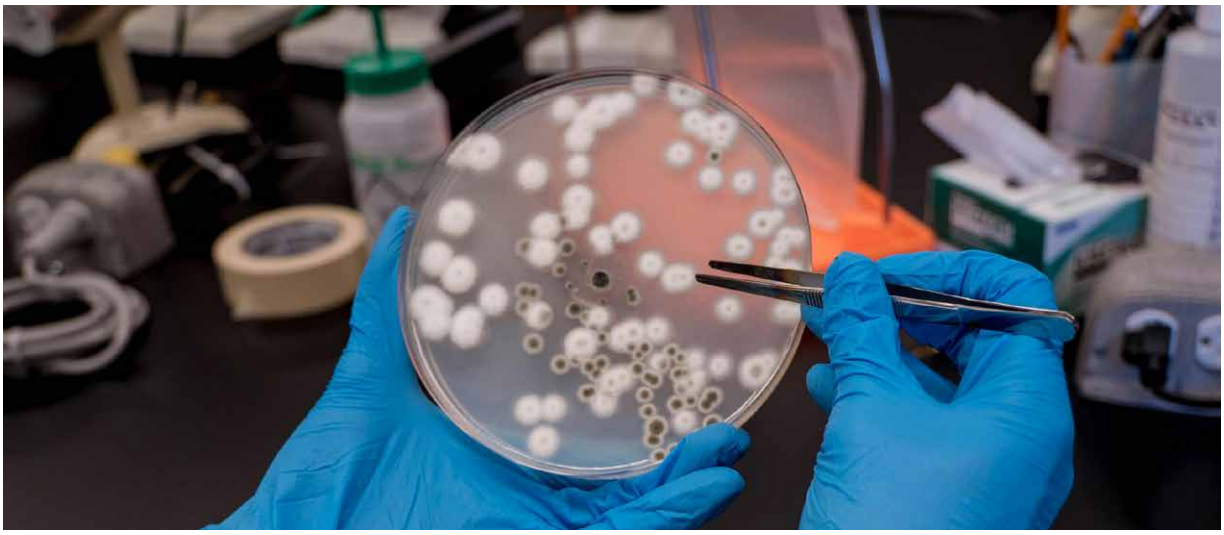
Pseudonymised data
Data in which information that can be linked to a person has been replaced with a code so that the individual cannot be directly identified without access to separate supplementary information.

SLE (systemic lupus erythematosus)
An autoimmune inflammatory disease that can affect the entire body.

Small-molecule drugs
Drugs consisting of very small chemical substances that can be absorbed by the body and affect specific processes in cells.

Radioligand-based theranostics
A method in which radioactive molecules are used for both the diagnosis and treatment of disease, often cancer. The same (or similar) substance is first used to image where the disease is located in the body and then to direct radiation directly at the diseased cells.

TLV
The Swedish Dental and Pharmaceutical Benefits Agency.



Examples of Swedish companies in the ATMP field

Swedish companies and stakeholders are active in various ways within the ATMP field, with different roles and functions in the ecosystem surrounding cell and gene therapies. The list below should be viewed as examples and not as a complete list.

Examples of companies working with T-cell-based therapies include **Anocca**, **Elicera Therapeutics**, **CuraCell**, **Strike Pharma**, and **Neogap Therapeutics**.

Several major pharmaceutical companies also have operations in the ATMP field in Sweden, such as **AstraZeneca**, **Thermo Fisher Scientific**, **Novartis**, and **Bristol Myers Squibb**.

There are also companies that directly support the development and production of cell and gene therapies through bioprocessing, materials, and manufacturing, such as **Cytiva**, **NorthX Biologics**, **BioLamina**, **Biotage**, and **Cellevate**.

In the field of analysis and biological tools for ATMP research, examples include **QuTEM** and **Mabtech**.

The Swedish ATMP ecosystem also consists of players who do not directly develop therapies but are important for industrialisation, scaling, and building the ecosystem around the sector.

This includes infrastructure and innovation hubs such as **Testa Center**, **CCRM Nordic**, **GoCo Health**, and **Vectura Fastigheter**, which facilitate testing, scaling up, and the establishment of life science operations in Sweden.

This also includes broader industrial companies that contribute to processes and infrastructure, such as **Alfa Laval** (separation of cells and biological materials), **Getinge** (bioreactors), and **Trelleborg** (sterile components).

Some examples of research and innovation collaborations between universities, healthcare, and industry in the ATMP field are **AdBIOPRO**, **GeneNova**, and **IndiCell**. These are not traditional companies but collaborative initiatives that are often funded through Swedish innovation programs, such as **Vinnova**.

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