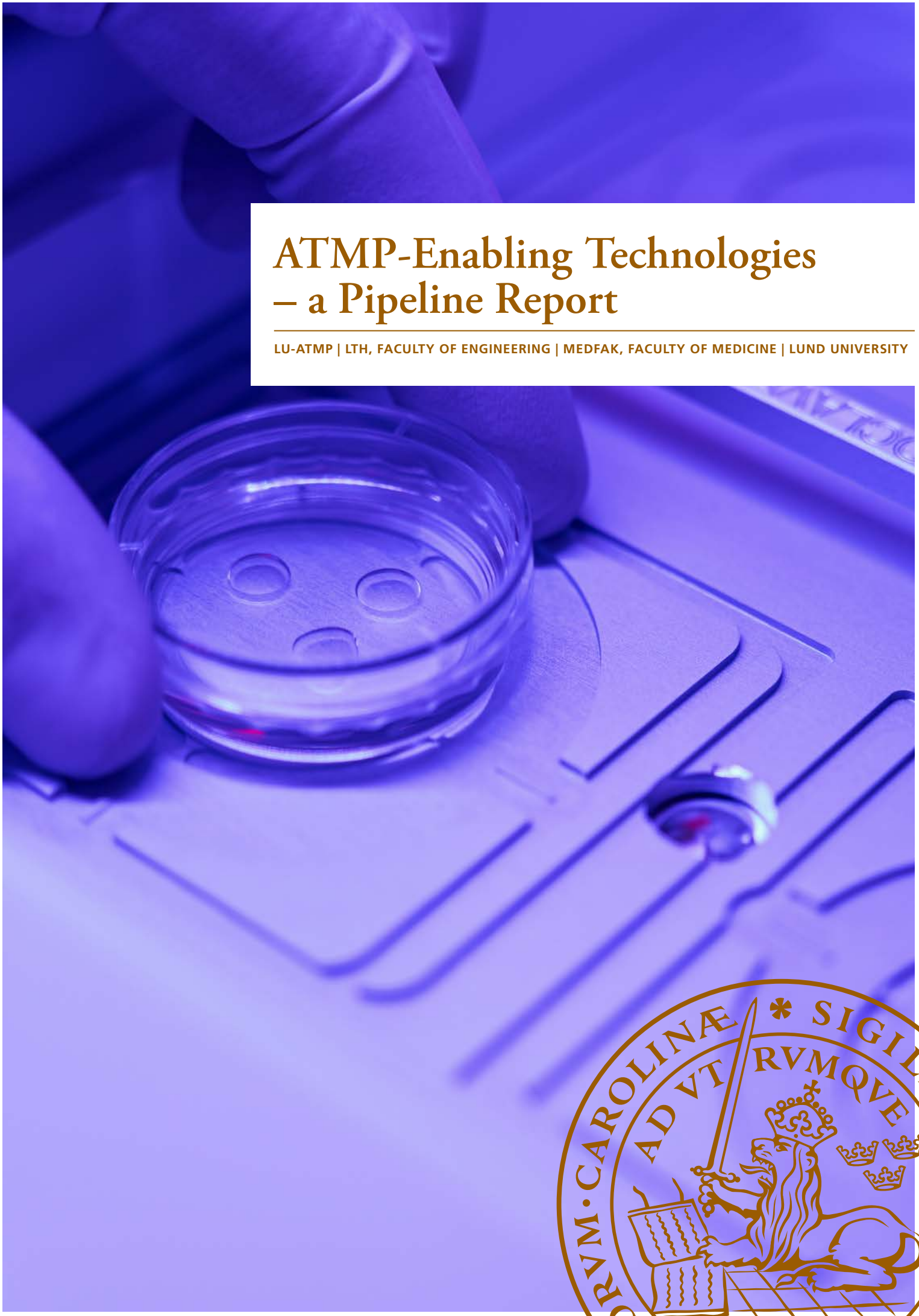


ATMP-Enabling Technologies – a Pipeline Report

LU-ATMP | LTH, FACULTY OF ENGINEERING | MEDFAK, FACULTY OF MEDICINE | LUND UNIVERSITY

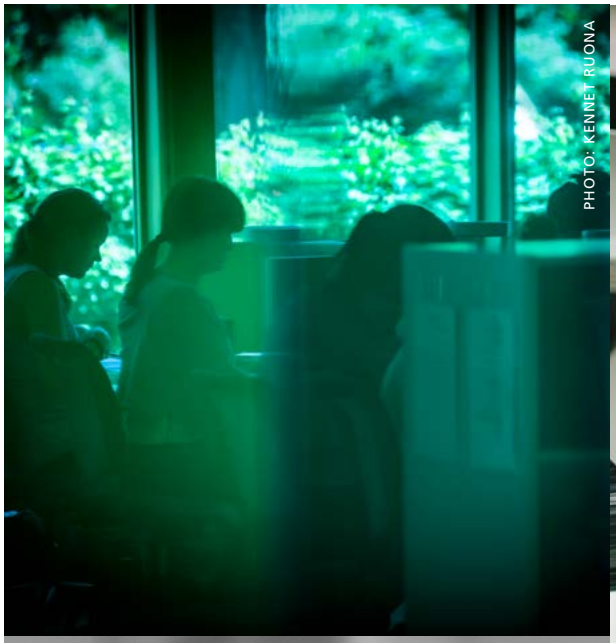


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PHOTO: RAGNHILD MÖLLER



PHOTO: JESPER LÖFMAN

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PHOTO: KENNET RUONA

From Molecules to Living Therapies: The Transformation of Modern Medicine

Modern medicine is evolving at a remarkable pace. Traditionally, most drugs have been based on small synthetic molecules that enter cells and alter biological processes by interacting with specific receptors or pathways in the body. In recent decades, a new generation of biological medicines, such as antibodies and recombinant proteins, has emerged. Unlike chemical compounds, these biologics are produced in living cells and can target disease mechanisms with greater precision.

Advanced Therapy Medicinal Products (ATMPs) represent the next leap in biomedical innovation. This new category of medicines includes gene therapies, and cell therapies (Fig. 1).

ATMPs have the potential to treat, or even cure, diseases that were previously untreatable by acting directly on a patient's own genes, cells, or tissues. However, they also introduce a new set of challenges, including economic, manufacturing, and medical challenges. Because ATMPs often involve complex modifications of biological material, production processes frequently need to be personalized for each patient.

This makes development expensive, time-consuming, and difficult to scale while maintaining consistency and quality. Moreover, critical questions remain about long-term safety, immune responses, and how these therapies can be effectively integrated into existing healthcare systems.

Traditionally, drug development has been driven by industry, even when discoveries originated in universities. In contrast, most ATMPs stem directly from academic research and are developed in close collaboration with academia. This shift underscores the need for new, sustainable financial and organizational models to support development.

The complexity of ATMPs also demands close cooperation among academic researchers, hospitals that manufacture these therapies, and industrial partners capable of large-scale production. Their inherently multidisciplinary nature also calls for integrated efforts across cell biology, engineering, and clinical science. In the coming years, we can expect rapid, technology-driven advances in cell-, gene-, and tissue-based therapies. Such synergy is crucial not only for pushing the boundaries of science but also for ensuring that these powerful new therapies become safe, sustainable, and accessible parts of future healthcare.

ILLUSTRATIONS CREATED IN BIORENDER

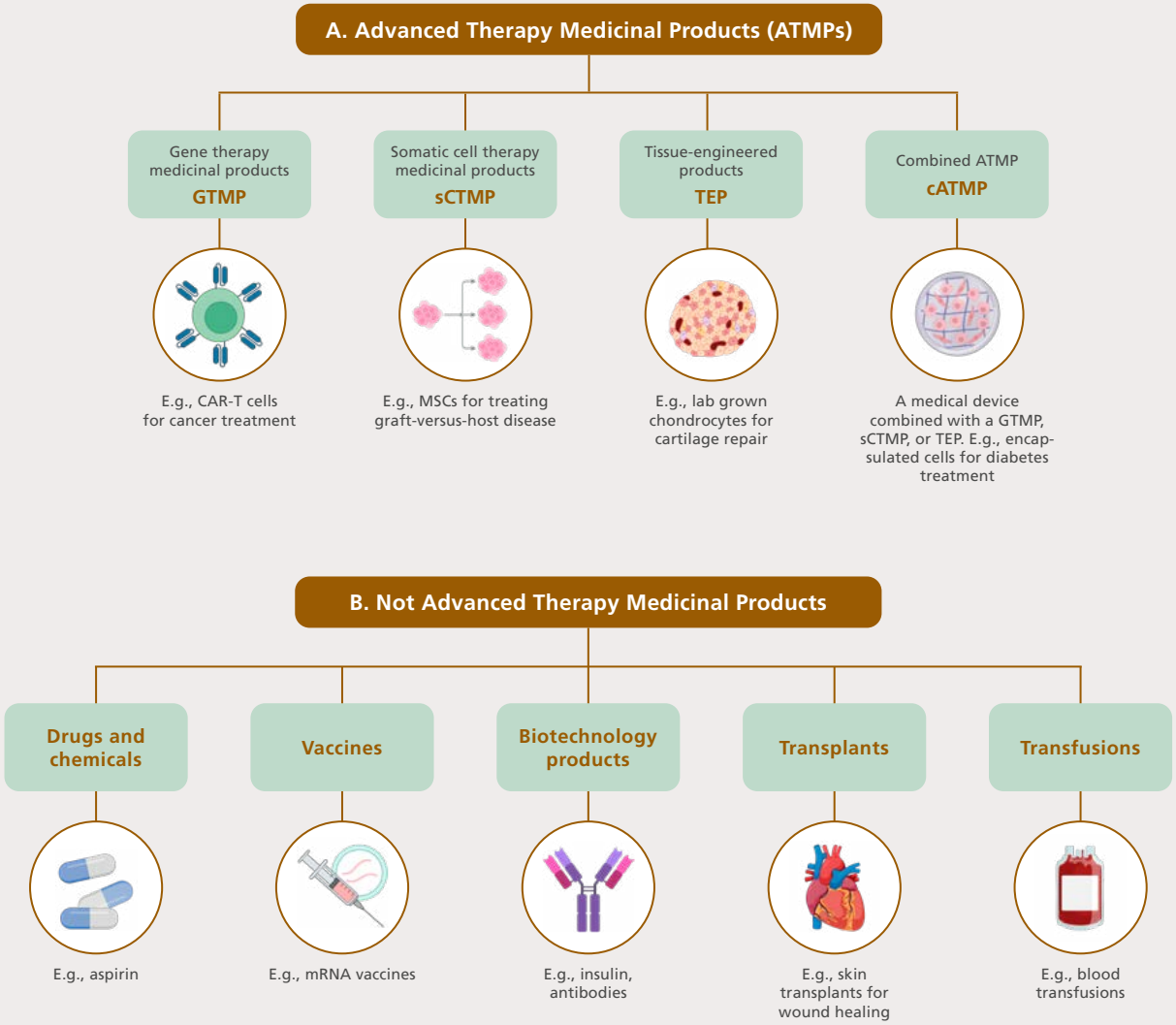


Figure 1. What are ATMPs?
A) The four categories of ATMPs illustrated with example. **B)** Select therapeutics not included within the ATMP categories.



PHOTO: JOHAN PERSSON

The Four Pillars of Advanced Therapy Medicinal Products

Advanced Therapy Medicinal Products are medicines based on gene therapy, somatic cell therapy or tissue-engineered products that provide new ways of treating, or even curing, previously untreatable and high-burden diseases. These innovative products require specialized production, handling, and regulatory oversight, which comes with unique challenges due to their living components.

ATMPs are divided into four different categories:

Gene therapy medicinal products (GTMPs) are products containing genes (DNA, RNA or other nucleic acid sequences) that can regulate, restore, replace, insert, or delete a gene sequence, or genetically modified cells, or viruses and leads to a therapeutic, prophylactic or diagnostic effect.

Somatic cell therapy medicinal products (sCTMPs) are products containing cells that have been modified to have different biological characteristics, physiological functions, or structure, and used to cure, diagnose or prevent diseases.

Tissue-engineered products (TEPs) are products containing processed cells or tissues intended to regenerate, repair, or replace human tissues.

Combined ATMPs (cATMPs) are products comprised of a medical device as an integral part of the medicine, combined with an ATMP from the above-described categories.

A Growing ATMP Ecosystem: From Academic Discovery to Clinical Delivery

Sweden's ATMP landscape is experiencing rapid growth, establishing the country as a leading force in Europe. RISE (Research Institutes of Sweden) identified nine European countries, United Kingdom, Germany, Sweden, Italy, Denmark, Spain, Norway, Finland, and the Netherlands, that are prominent in ATMP development.

Among these EU9, Sweden consistently ranks within the top three nations for the number of identified ATMP-focused companies, a position reinforced by targeted national investments[1]. Furthermore, the Royal Swedish Academy of Engineering Sciences (IVA) recently proposed 48 key strategic technologies crucial for Sweden's future prosperity, economic resilience, and national security, where ATMP was one of them, and determined that Sweden shows scientific leadership in ATMP[2].

Lund, located in southern Sweden within the Greater Copenhagen region, is at the heart of the Medicon Valley Life Science Cluster, an internationally renowned hub connecting 15 universities, 28 hospitals, and over 400 life science enterprises across Sweden and Denmark. Coupled with a strong emphasis on ATMP research at both the Faculty of Engineering and the Faculty of Medicine at Lund University, and with specialized training programs, comprising both undergraduate courses and national and international research schools on ATMP development, Lund is positioning itself as a centre of innovation in ATMPs, bridging research and clinical applications.

In 2023 the University-wide development centre focused on ATMPs; Lund University Advance Therapy Medicinal Products (LU-ATMP), was founded with a mission to translate novel medicinal therapeutics to patients when traditional therapies are not sufficient. It was recognized that to do this, dedicated resources and development of strategies are needed to take these novel cell and gene therapies from early development, through first-in-human trials and all the way to commercialization. As part of this initiative, all research group leaders at the Lund Stem Cell Center, and extended to the Faculty of Medicine, were invited to participate in interviews regarding their work within ATMP development. The results were published in the LU-ATMP pipeline report, that has since come out in an updated version, which outlines the scope of the 27 identified cell and gene therapies that are currently being developed at Lund University[3, 4]. The aim of the report was to map out and display ongoing ATMP development projects in Lund, and also to better define current and future needs of infrastructure and competence support for academic developers.

Current initiatives in establishing local, Lund-based, ATMP manufacturing infrastructure for both pre-good manufacturing practice (pre-GMP) and good manufacturing practice (GMP), will significantly increase production capacity of ATMPs in Sweden and accelerate the translation of research into clinical applications. The infrastructure support, the pre-GMP facility at Lund University and the GMP unit at Skåne University Hospital were inaugurated in 2025.

This expansion is complemented by a rising number of planned early-phase clinical trials, where a recent success story includes a stem cell-based cell therapy for Parkinson's disease (Stem-PD)[5], underscoring Lund's ability to bring innovative therapies from the laboratory to patients.

Lund University is also investing into the ATMP research area by recruiting up to four associate senior lecturers and one full professor during 2026.

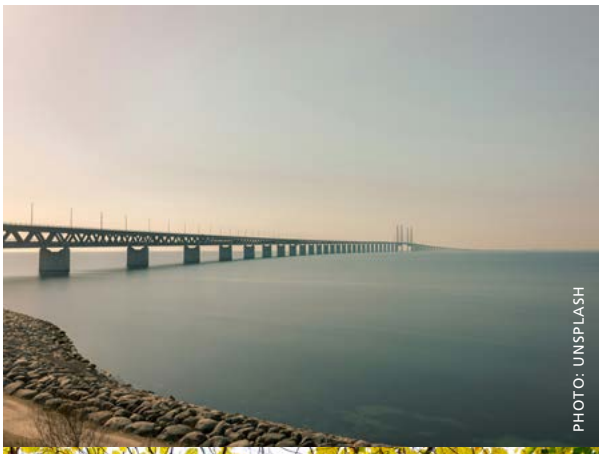


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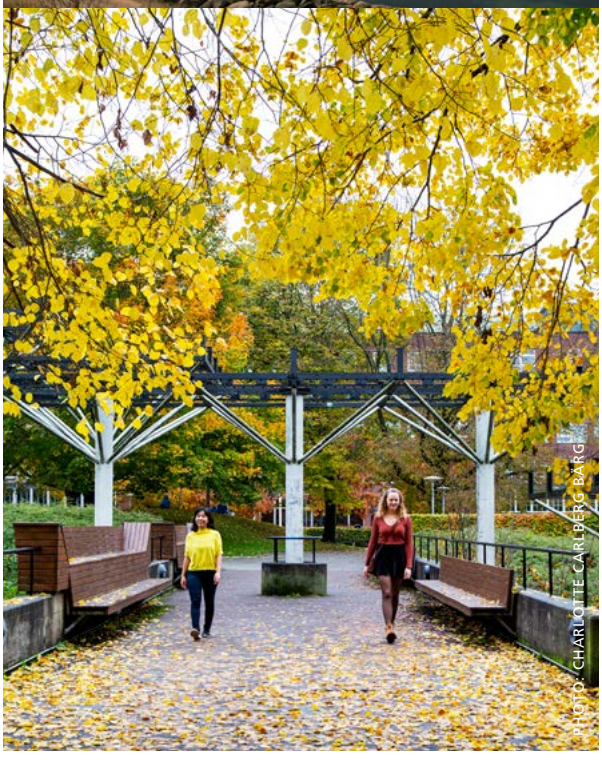


PHOTO: CHARLOTTE CARLBERG BARG

Engineering the Future of Medicine: Core Challenges in ATMP Development

The development of ATMPs involves a range of technical challenges that span the early pre-clinical development in the research laboratory to the clinical translation and application.

The heterogeneity of these products and the fact that the field is still relatively young poses many project-unique challenges and requires an active building of knowledge and experience.

For cell therapies, and preservation of cells, including freezing, thawing, and storage conditions, while maintaining cell viability and identity, remain challenging. Delivering genes or therapeutic agents effectively remains a critical hurdle, where ensuring the identity, purity, and potency of these products is essential.

For tissue engineering therapies and combined ATMPs, which often include both biomaterial scaffolds and cells, there is a need to upscale and automate the production process to move away from labour intensive and artisan protocols.

More generally, safety issues such as tumorigenesis, immunogenicity or tissue-engineered implant rejection are also concerning, as well as understanding of pharmacokinetics and pharmacodynamics.

Scaling Up ATMPs: Technical Barriers and Opportunities

Upscaling possesses additional technical challenges including major challenges in inconsistency in both cell and gene therapy products.

A lack of sophisticated preclinical testing models often leads to subsequent failure in animal or clinical trials of therapies that performed well in lab settings.

Stability is another major concern, encompassing cell viability, material degradation, packaging, and maintenance of therapeutic activity over time during storage.

Collectively, these challenges underscore the intricate, multidisciplinary nature of ATMP development and the need for integrated solutions across cell biology, engineering, and clinical science.

These technical challenges also highlight significant opportunities for technological expertise, as part of a technology-driven development of cell, gene and tissue-engineered therapies. By advancing technological innovations, researchers and engineers can accelerate the translation of ATMPs from bench to bedside.

The Power of Proximity: Lund University's Unique ATMP Environment

A major strength of Lund University in the Swedish ATMP field lies in its status as a multifaculty university, where the size and breadth of its faculties create unique opportunities for interdisciplinary collaboration.

Unlike single-faculty universities, Lund offers a distinct advantage by bringing together expertise from engineering, medicine, natural sciences, and beyond within a single academic environment. This is further supported by the geographical proximity of the faculties, which are located within walking distance of each other, enabling daily interaction and facilitating joint projects.

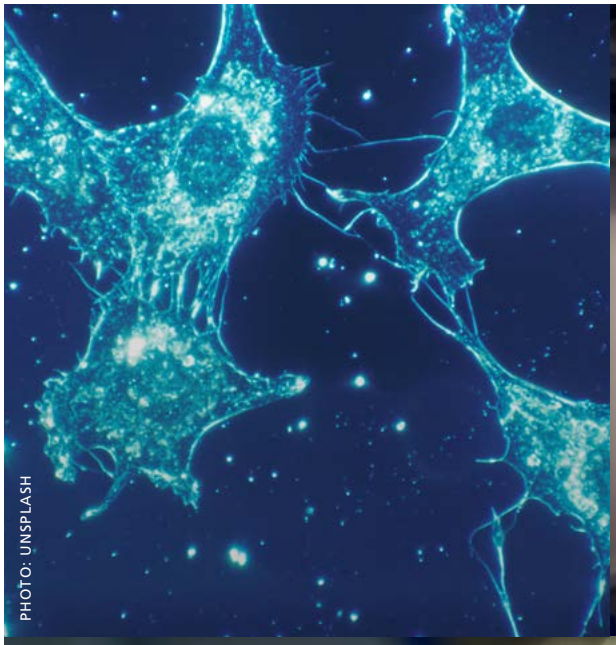
This structure has made it possible to merge technology and medicine at an early stage, fostering joint initiatives where engineers and medical researchers work side by side to address complex challenges in cell and gene therapies.

The Lund University Strategic Research Area StemTherapy within the Faculty of Medicine is a prominent research area that enables advanced basic, applied, and clinical research in diverse areas, including in the field of ATMPs.

In 2023, Lund University embarked on a route to leverage competences beyond the Faculty of Medicine to enable development of ATMPs from the research stage towards clinical translation at a time when the research community, pharmaceutical industry, and society is ready for such a development.

The formation of LU-ATMP, including the Faculties of Medicine and Engineering at Lund University, will facilitate joint collaboration and effective utilization of technological resources and innovations to achieve such end goals. Joint seminars, discussions, novel educational initiatives, grant applications, and technology and infrastructure sharing across faculties, will further enable this development.

Such integration not only accelerates the development of innovative ATMP solutions, but also cultivates a rich training environment for the next generation of scientists and clinicians.


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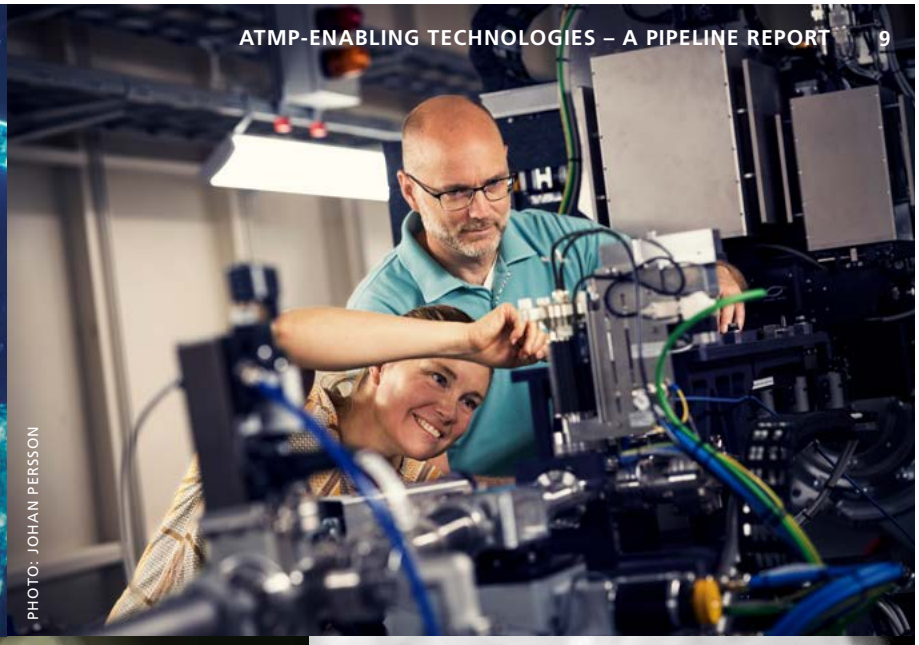
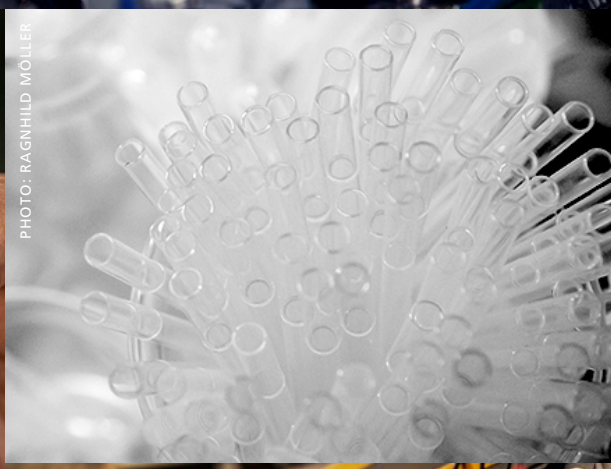

PHOTO: JOHAN PERSSON


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PHOTO: RAGNHILD MÖLLER

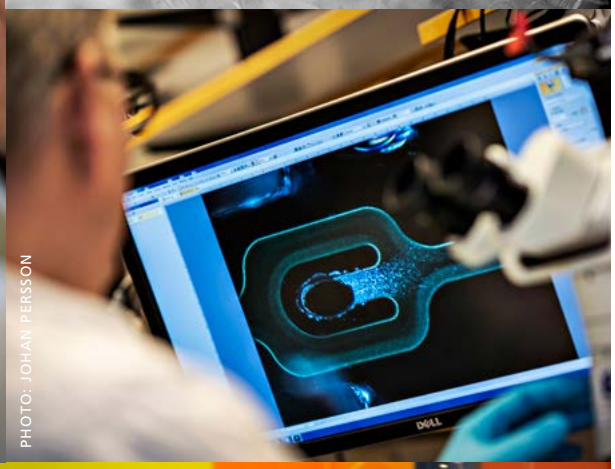

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About the Report

A substantial amount of research at the The Faculty of Engineering at Lund University is focused on developing technologies that can be used for ATMP development and production, spanning from early-stage research to late-stage GMP production.

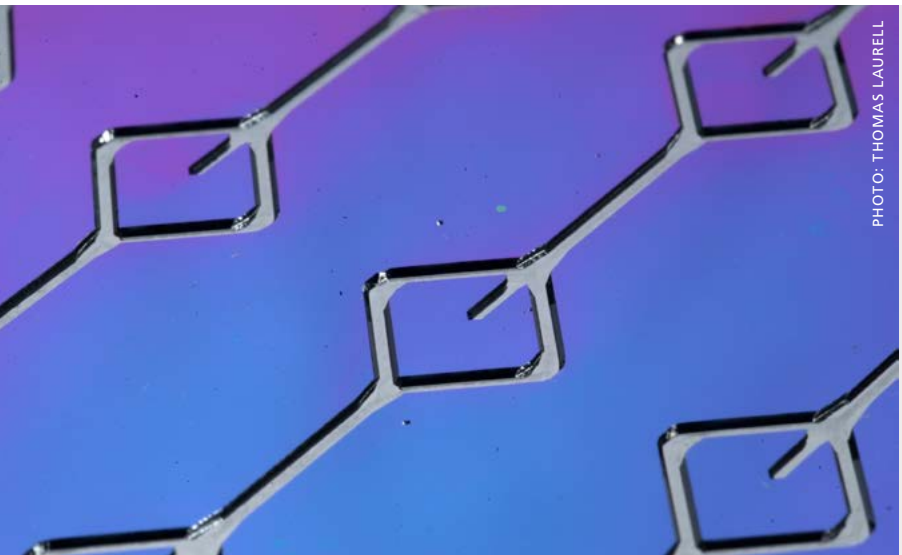
These technologies are crucial components in the advancement of technology-driven ATMP development, now and in the future.

The joint faculty initiative LU-ATMP initiated this report to map existing technologies at the Faculty of Engineering that could be applied to ATMP, as well as projects currently applied towards ATMP.

In this report, we aim to provide an outline of the existing technologies, including their development level and at what ATMP developmental stage the technologies can be applied to.

By mapping this we hope to enhance the visibility of these technologies and foster intra-faculty collaborative efforts that can accelerate the translation of ATMPs from bench to bedside.

Maria Nordin, main author


PHOTO: THOMAS LAURELL

Maria Nordin is an Associate Professor at the Department of Biomedical Engineering, LTH, Lund University, and leads the BioMicroSystems research group. Her research focuses on lab-on-a-chip technologies, microfluidics, biomaterials, and tissue engineering, with a particular emphasis on developing in vitro models of the intestine. She combines engineering approaches with cell and stem cell biology to study epithelial and endothelial systems, with applications ranging from basic biology to translational and regenerative medicine.


Maria Nordin.

Methodology

The data used for this report was gathered from 50 research groups at the Faculty of Engineering at Lund University. The collection of data was done through open interviews with researchers, during which they were questioned about their research activities on technologies that could enable ATMP development. Publicly available information was used in 14 cases of non-responders to interview requests.

Once data had been collected, a thematic analysis was performed. The ATMP category and the pipeline stage that the ATMP-enabling technologies could be applied to was coded using the following categories.

1. The classification of ATMP categories in case directly relatable was classified according to the definitions of European Medicines Agency (EMA)[6].

- **GTMPs** – Gene therapy medicinal products are products containing genes (DNA, RNA or other nucleic acid sequences) that can regulate, restore, replace, insert, or delete a gene sequence, or genetically modified cells, or viruses.
- **sCTMPs** – Somatic cell therapy medicinal products are products containing cells that have been modified to have different biological characteristics, physiological functions, or structure.
- **TEPs** – Tissue-engineered products are products containing processed cells or tissues intended to regenerate, repair, or replace human tissues.
- **cATMPs** – Combined ATMPs are products comprised of a medical device combined with and ATMP from the categories described above.

2. The developmental phase of the ATMP-enabling technologies was assigned as follows:

- **On hold** – A technology exists but no active development is ongoing. There is an intention to resume development when able.
- **Development** – The technology is being actively developed and could be used for ATMP purposes but has not yet been applied.
- **Active** – The technology is being used towards ATMP projects.
- **Commercial** – The technology has been commercialized.

3. The ATMP pipeline stage the enabling technologies can be applied to has been assigned as follows:

- **Basic/Discovery** – The project or technology provides a fundamental understanding of disease mechanisms or therapeutic targets or can be applied to projects of this stage (e.g., omics-technologies, fundamental biology, AI, and machine learning).
- **Translational/Preclinical** – The project or technology focuses on therapeutic feasibility, dosing, safety, or delivery mechanism (e.g., cell and gene therapy technologies, model systems).
- **Pre-GMP** – The project or technology focus on upscaling and manufacturing in larger scales (e.g., process development, standardising, and automation).
- **GMP** – The project or technology focuses on the regulatory environment for producing clinical-grade material (e.g., quality assurance and regulatory documentation).

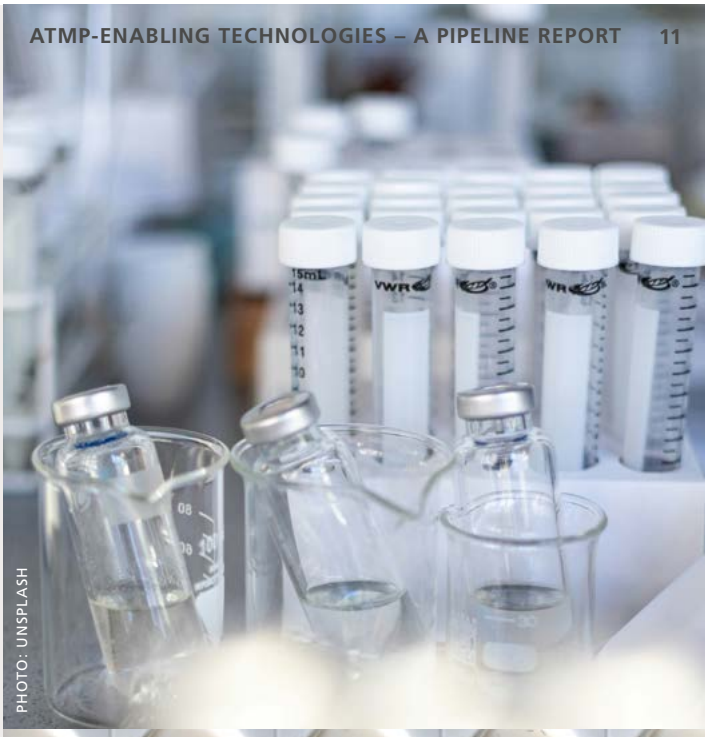
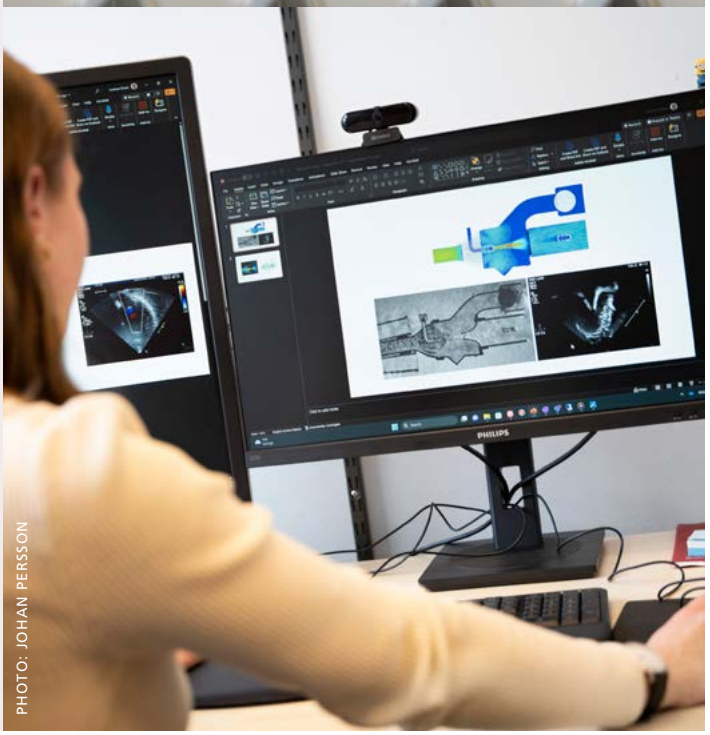

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PHOTO: JOHAN PERSSON

Results

In total 50 ATMP-enabling technologies were identified at the Faculty of Engineering at Lund University, where the majority of the projects are found in the developmental phase, although a few have even been commercialized (Fig. 2). Most of these technologies can be applied towards ATMP projects in the basic or developmental stage (40%) or the translational or preclinical stage (42%) (Fig. 3).

The identified ATMP-enabling projects cover a wide variety of research areas and categories from across the Faculty of Engineering (Fig. 4–5). Some of these projects are more generally applicable and 19 of them focus on specific target tissues or organs (Fig. 6).

Eight of the technologies are currently applied directly towards ATMP projects and found in the categories of Gene Therapy Medicinal Products (GTMP), or Tissue-Engineered Products (TEP) (Fig. 7–8).

This is not an exhaustive list of ATMP-enabling technologies at the Faculty of Engineering or Lund University as a whole. Additional less visible projects likely exist in the Faculty of Engineering as well as in other faculties of the university, with potential to further support development and use of ATMPs in a translational context.

Development Phases

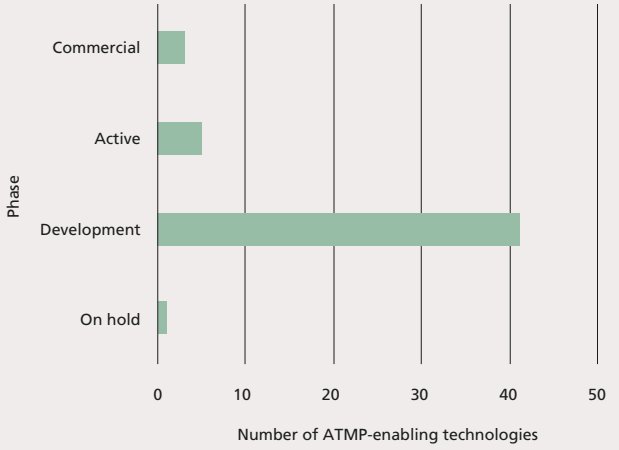


Figure 2. Stage of development of the ATMP-enabling technologies at the Faculty of Engineering at Lund University. The developmental phase of the ATMP-enabling technologies has been assigned as; *On hold* if a technology exists but no active development is ongoing. There is an intention to resume development when able.; *Development* if the technology is being actively developed and could be used for ATMP purposes but has not yet been applied; *Active* if the technology is being used towards ATMP projects; or *Commercial* if the technology has been commercialized.

Pipeline Stage

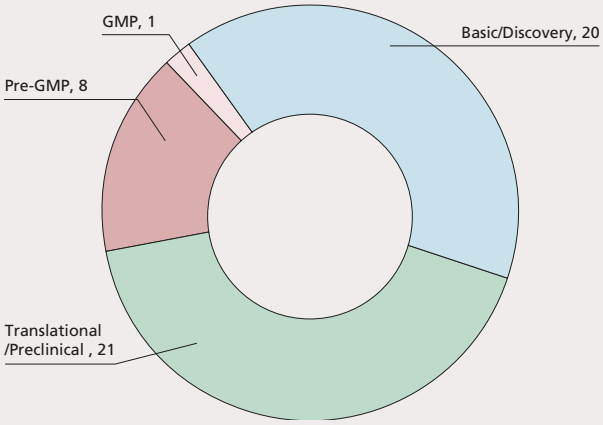


Figure 3. ATMP-enabling technologies in the pipeline in 2025 by where in the ATMP developmental phases they can be applied. The 50 ATMP-enabling technologies at the Faculty of Engineering at Lund University are predominantly applicable in the earlier pipeline stages. The ATMP pipeline stage the enabling technologies can be applied to has been assigned as; *Basic/Discovery* if the project or technology provides a fundamental understanding of disease mechanisms or therapeutic targets or can be applied to projects of this stage; *Translational/Preclinical* if the project or technology focuses on therapeutic feasibility, dosing, safety or delivery mechanism; *Pre-GMP* if the project or technology focus on upscaling and manufacturing in larger scales; or *GMP* if the project or technology focuses on the regulated environment for producing clinical-grade material.

Research Areas

Biomedical Engineering	7
Chemistry	21
Computer Science	1
Control Theory	2
Immunotechnology	9
Mathematics	4
Mechanical Engineering	1
Physics	5

Figure 4. The different research areas hosting the 50 ATMP-related technology development projects identified at the Faculty of Engineering at Lund University.

Category

AI/Machine learning	5
Biomaterials	4
Biosensors	2
Cell or Molecular Separation	6
Control Systems	2
Formulation Technology	4
Gene Technology	2
Imaging	2
Immunology	8
In silico Modelling	1
In vitro Modelling	2
Ligand Technology	1
Protein Technology	7
Proteomics	3
Quality Assurance	1

Figure 5. The different research categories of the 50 ATMP-enabling technology development projects identified at the Faculty of Engineering at Lund University.

Target Tissue

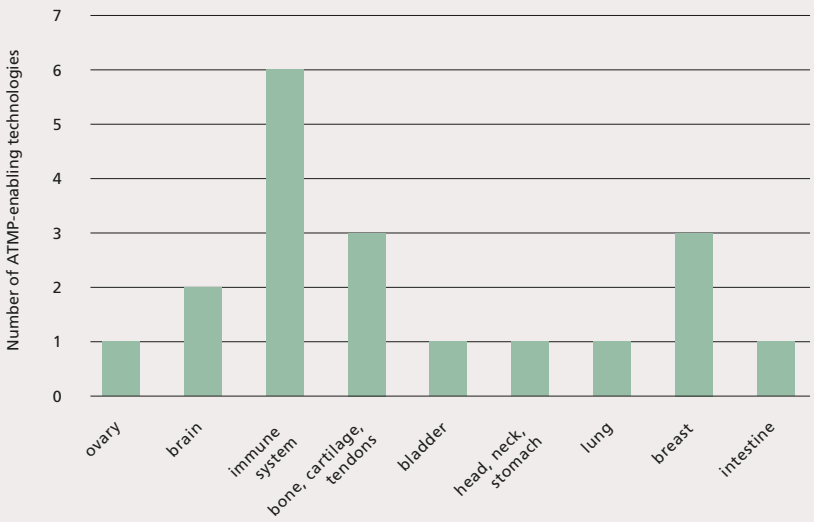


Figure 6. Of the 50 ATMP-enabling technologies identified at the Faculty of Engineering at Lund University 19 are directly applied to a specific tissues or organ.

ATMP Technologies in the Pipeline

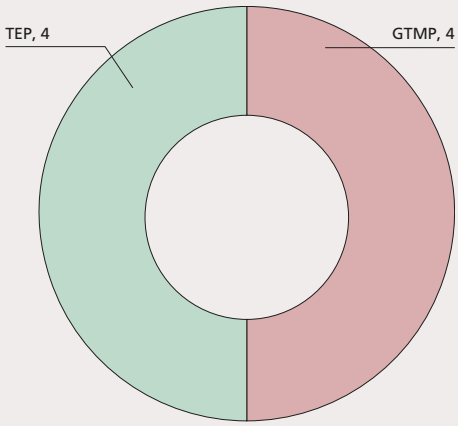


Figure 7. Among the 50 ATMP-enabling technologies identified at the Faculty of Engineering at Lund University, eight are directly focused on ATMP, including four Tissue-Engineered Products (TEP), and four Gene Therapy Medicinal Products (GTMP).

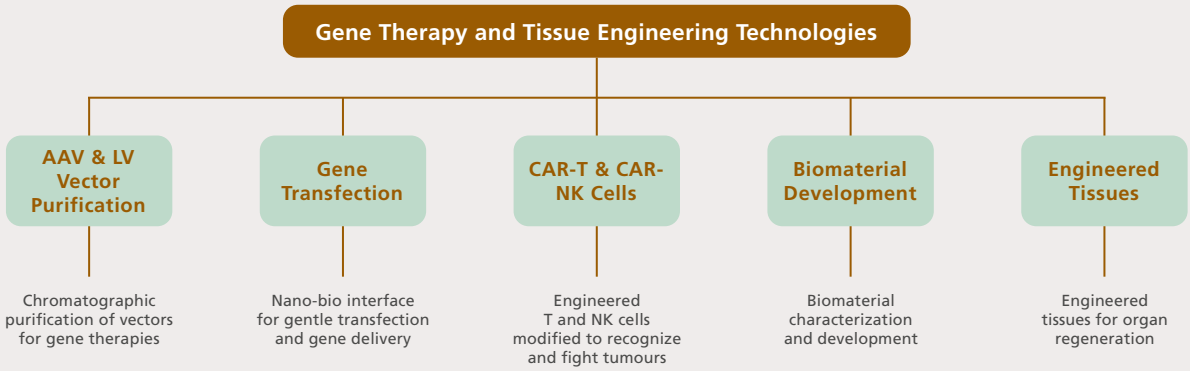


Figure 8. Among the 50 ATMP-enabling technologies identified at the Faculty of Engineering at Lund University, eight are directly focused on ATMP, including four Tissue-Engineered Products (TEP), and four Gene Therapy Medicinal Products (GTMP). Specifically, these TEP, and GTMP projects involved vector purification, gene transfection, CAR cell technology, biomaterial development and engineered tissues.

HIGHLIGHTED RESEARCH

Optimizing Viral Vector Purification for ATMPs

A technological challenge for the ATMP field is to produce and purify viral vectors for cell and gene therapy. Professor Bernt Nilsson's research focuses on solving this challenge by developing and optimizing this purification processes. Using chromatography combined with mathematical modelling, he predicts and controls how proteins or viral particles behave during purification depending on factors such as concentration, impurities, and contaminations.

This approach enables continuous, closed processes where material flows directly from cell culture to purified product. Inline fluorescence measurements allow real-time monitoring during separation and purification, and fractions can be automatically diverted for quality control.

The main applications are purification of antibodies and adeno-associated virus (AAV) particles, though lentivirus is also studied in collaborations. Although antibody purification is not part of the ATMP field, process and technology development is strongly related to purification of ATMP-enabling products. Bernt and his team has also run pilot projects at larger scale, and his team is advancing methods to exclude not only empty virus particles, but also particles of subpar quality, improving the quality of the subsequent therapy.

Mathematical models are central in this work, allowing predictions of binding behaviour between viruses, ligands, and impurities. These models make it possible to optimize operating conditions such as concentration, reducing trial-and-error and improving efficiency.

In the long run, this research contributes to more robust, automated, and scalable manufacturing processes that are essential for future cell and gene therapies.



Bernt Nilsson.
Photo: Håkan Röjder

Translational Cancer Research and ATMP Development

Professor Sara Ek conducts translational, clinically oriented cancer research with a focus on B-cell lymphomas. This work is based on patient-derived samples, enabling direct links between molecular findings and clinical outcomes.

A major focus of this research is the use of advanced omics technologies at the single-cell level. By analysing transcriptomes and gene expression in immune and tumour cells, it is possible to investigate cellular heterogeneity and identify subpopulations associated with treatment response or resistance. Using digital spatial profiling, Sara and her team can follow specific cell types in their native tissue context and characterize both protein expression and mRNA signatures.



Sara Ek. Photo: Kennet Ruona

These approaches are then combined with image analysis, digital pathology, and bioinformatics to study tumour-immune cell interactions within the tumour microenvironment.

By integrating morphological, molecular, and functional data, the aim is to identify biomarkers predicting therapeutic response and to uncover mechanisms driving resistance to targeted treatments. The goal is to develop personalised treatments and find novel molecular targets for biological medicines, as treatment of lymphoma moving away from chemotherapy and towards cellular therapies such as CAR-T, -NK, or -monocyte-based therapies.

As part of a novel initiative, the L2CancerBridge project, Sara contributes to CAR-T cell therapy development and to collaborative efforts between Lund University (Faculty of Engineering) and Skåne University Hospital (SUS) on clinical trials involving these ATMPs.

This large-scale initiative (supported by approximately 420 million SEK) also strengthens the ATMP-enabling infrastructure for functional single-cell analysis, spatial and image-based profiling, and *in vitro* functional modelling, enabling a broader translational research program in immuno-oncology.



PHOTO: HÅKAN RÖJDER

AcouSort: Acoustofluidic Automation for Cell Processing

AcouSort, spun out of research performed at the Faculty of Engineering at Lund University, uses acoustofluidics, combining sound waves with microfluidics to move target cells from one liquid to another based on the cells' size, density, and compressibility.

For ATMP applications, it can be used to prepare clinical samples or to automate purification steps in cell therapy manufacturing, enabling less manual handling.

By creating a standing acoustic wave in microfluidic channels, bioparticles can be moved by the ultrasound. This allows separation or trapping of different blood components, isolation of extracellular vesicles, or removal of contaminants from cells without physical contact. The technology operates gently and continuously, providing an alternative to conventional methods such as centrifugation or filtration.

Aligned Bio: Nanowire Optics for Ultra-sensitive Biomolecule Detection

Aligned Bio, also spun out of research performed at the Faculty of Engineering at Lund University, has developed a nanowire-based platform for DNA sequencing and biomolecular sensing.

For ATMP applications, the technology could be applied to biomarker detection in research or monitoring of cell and gene therapy production for early detection and quality control.

The platform uses aligned nanowires to increase sensitivity up to 200x using their waveguide technology, to detect targets such as DNA, proteins, other biomolecules, or pathogens. Functionalized nanowires emit a concentrated light signal when binding specific molecules, allowing single-molecule detection through using simple optical readers.

The nanowires then act as optical fibres that collect, guide, and direct emitted light from fluorescent molecules bound to their surface, enabling single molecule detection. The company is also developing a long-read DNA sequencing platform capable of providing 8x more genetic information at higher accuracy in less time and at lower cost than current methods.

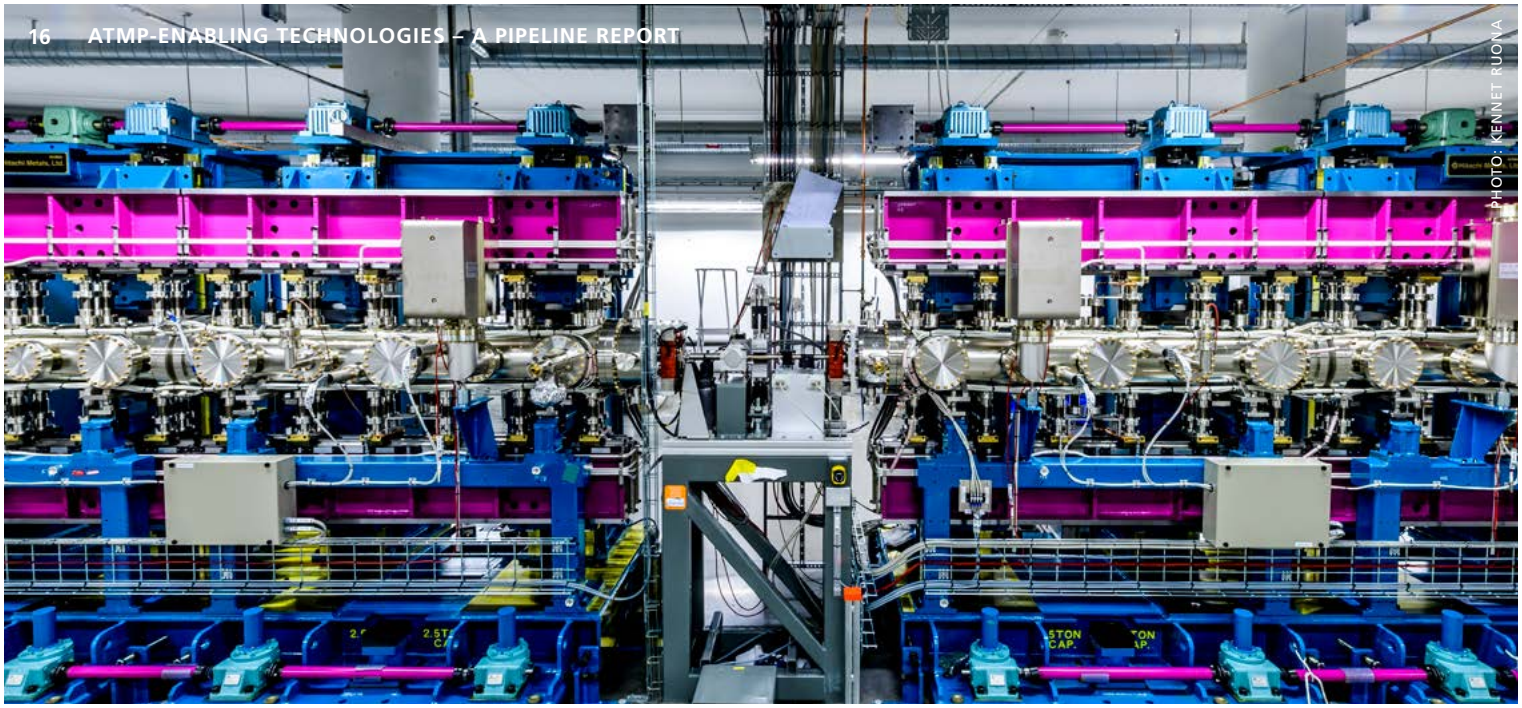


PHOTO: KENNET RUONA

Building the ATMP Pipeline: Lund's Integrated Pre-GMP and GMP Ecosystem

A key factor in accelerating ATMP development is access to dedicated environments where developers can meet, identify challenges, collaborate on solutions, and prepare therapies for clinical use. Furthermore, unlike typical drug development, ATMP therapies often remain within academia and the hospital for Phase I and II clinical trials, creating a need for small-scale manufacturing facilities. In Lund, this has recently been made possible through Region Skåne's new hospital based GMP facility and the LU-ATMP/StemTherapy pre-GMP facility at Lund University. The two facilities work in an integrated way to minimize translational gaps and avoid delayes. Their joint inauguration in April 2025 marked a major regional milestone and a significant investment in future therapies.

The pre-GMP facility provides space and support for both academic and industry projects requiring process development. It mirrors the hospital's GMP environment to ensure seamless technology transfer and close collaboration across development stages. As a simulated GMP facility, it enables cost efficient development of GMP compliant products and training in GMP workflows, serving as a natural meeting place for researchers and GMP staff.

The unit includes two simulated Grade B cell culture rooms and one Grade C process development room equipped with advanced systems such as bioreactors, quality control instruments, and automated imaging tools. Beyond infrastructure, it supports knowledge sharing, development of GMP compatible standard operating procedures (SOPs), and training of future ATMP experts through dedicated courses. By bringing together researchers from medicine and engineering, the facility aims to foster interdisciplinary collaborations and develop a strong pipeline of ATMP professionals. The long-term vision is to create a national and international hub where researchers, clinicians, and innovation partners can work proactively together to accelerate ATMP development.

The GMP facility will be opened in spring 2026 and the first manufacturing project and clinical trial will be CAR-T cells that engage researchers across faculties.



PHOTO: AGATA GARPENLIND

Sara Nolbrant is the director for the pre-GMP facility. During her PhD studies in the laboratory of Malin Parmar at Lund University, she gained first-hand experience in developing cell and gene-based therapies for Parkinson's disease. This work included protocol development, GMP adaptation and tech transfer of the protocol for generating dopamine progenitors from pluripotent stem cells in preparation for the STEM-PD clinical trial.

She subsequently received postdoctoral training at UCSF in San Francisco, developing new iPSC-based models to study development and disease. In addition, she has worked as scientific consultant within cell therapy development in the US. She is passionate about interdisciplinary collaborations, scientific communication, and translating cutting-edge research into impactful therapies.



Sara Nolbrant.

Path2Patient: Strengthening the Route From Discovery to Commercial ATMPs

Path2Patient was launched to accelerate the commercialization of next-generation ATMP therapies, aiming to reach more patients and find new ways to treat diseases that currently lack effective treatment options[7].

With substantial financing from the Swedish Agency for Economic and Regional Growth and Region Skåne, this LU Innovation-driven initiative will strengthen the ecosystem for the development and commercialization of cutting-edge ATMP research.

The project brings together academia, healthcare, and innovation actors (iActors), executed by LU Innovation, Smile Venture Hub, Medicon Village Innovation, LU-ATMP, pre-GMP, and Region Skåne's ATMP centre.

ATMP development and business models are more complex than for traditional drugs, which has limited the creation of new companies and prevented many projects from reaching patients. International experience shows that with the right support, the success rate of commercialization can increase significantly. Such support includes proactive guidance for academic projects and the identification of strategically important decisions early in the process, which increases the likelihood of therapies reaching patients.

In addition, Path2Patient will establish novel technological platforms for the production of cell and gene therapies in pre-GMP and GMP environments, facilitating the transition from fundamental research to clinical application.

World-Class Infrastructure Driving ATMP Innovation

In the vicinity of the Faculties of Engineering and Medicines' ATMP landscape, there are several infrastructures and institutes that are important for continuous ATMP development.

- **MAX IV** is a synchrotron light source producing X-rays. In this particle accelerator, electrons are shot and accelerated into near light-speed. The electrons produce X-ray beams through forced vibrations, which are delivered to different beamlines where material and life science experiments occur. Within life science, the platform is predominately used for protein structure determination, of single proteins or protein complexes, through crystallography. The platform can also be used for imaging through full field tomography where the organization of tissues or pathologies can be studied[8].

- **The European Spallation Source, ESS,** is a neutron spallation source, currently under construction. This infrastructure will enable research within a broad spectrum of fields including materials, life science, energy, environmental technology, cultural heritage, and fundamental physics. ESS long pulse source is attractive with several neutron techniques for biological samples. Possible investigations include macromolecular structures at an atomic level, structure of macromolecular complexes, biological membrane assemblies, protein clustering and aggregation, dynamics of biomolecules, and imaging organism-level complexity[9].

- **LINXS** is an advanced studies institute that is promoting science and education focused on neutrons and X-rays, accommodate short-term research visits of world-leading scientists, and host international networks. Furthermore, their goal is to help educate potential users of MAX IV and ESS. LINXS has three focus areas, soft matter, life science, and hard matter[10].

- **The Lund Protein Production Platform, LP3** is an interfaculty facility that serves researchers with recombinant protein production, crystallization, biophysical characterization, and structure determination. LP3 constitutes the Lund node of a national research infrastructure for protein production, Protein Production Sweden, and is also connected to both MAX IV and ESS. The different nodes of Protein Production Sweden use different expression systems which allows the production of different types of proteins. The Lund node mainly focuses on protein expression using insect cells, which provide better posttranslational modification such as glycosylation and disulfide bridges compared to bacteria[11].

- **The Cell and Gene Technologies (CAGT) Core Facility** at Lund Stem Cell Center provides services designed to support advanced ATMP research and development. These include the reprogramming of donor samples into induced pluripotent stem cells (iPSCs), gene-editing of iPSCs, production of master cell banks and quality control measures to ensure cell integrity and reproducibility. In addition, the CAGT core offers expertise in diverse delivery strategies, including mRNA-based approaches and the production of adeno-associated virus (AAV) and lentiviral vectors, enabling researchers to explore and optimize gene delivery systems for therapeutic development. Beyond technical assistance, the CAGT core also provides educational support and structured training[12].

The Advanced Therapies Model of Lund: Integrating Science, Technology, Healthcare & Innovation Actors

This report highlights the strong potential for technology-driven development of ATMPs within the Lund ecosystem. The aim of this report is to bridge the gap between technological and medical innovation, and increase the interdisciplinary communication, made possible by the close integration between the faculties.

This effort is further supported by the novel shared platforms of the pre-GMP and GMP facilities emerging as meeting points for researchers, clinicians, and industry partners. Together these factors create favourable conditions for addressing the unique challenges associated with translating ATMP research from bench to bedside.

This is further enabled by implementation of the Advanced Therapies model of Lund characterized by its unique integrated way of working between the University, the University Hospital and the local iActors (innovators, incubators, industry, and investments)[13].

Lund is building a strong and highly competent cross-sectorial team that together with large-scale investments in research, technology and infrastructure will accelerate ATMPs to many patients.

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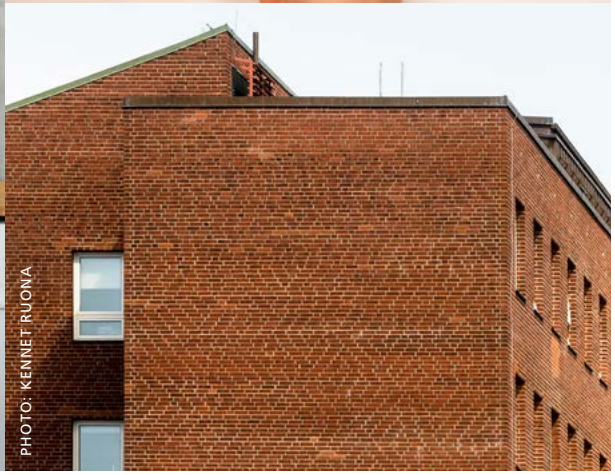

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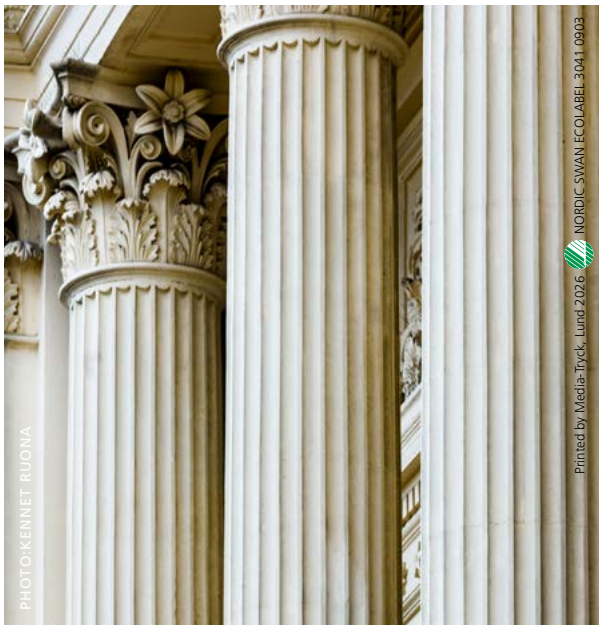


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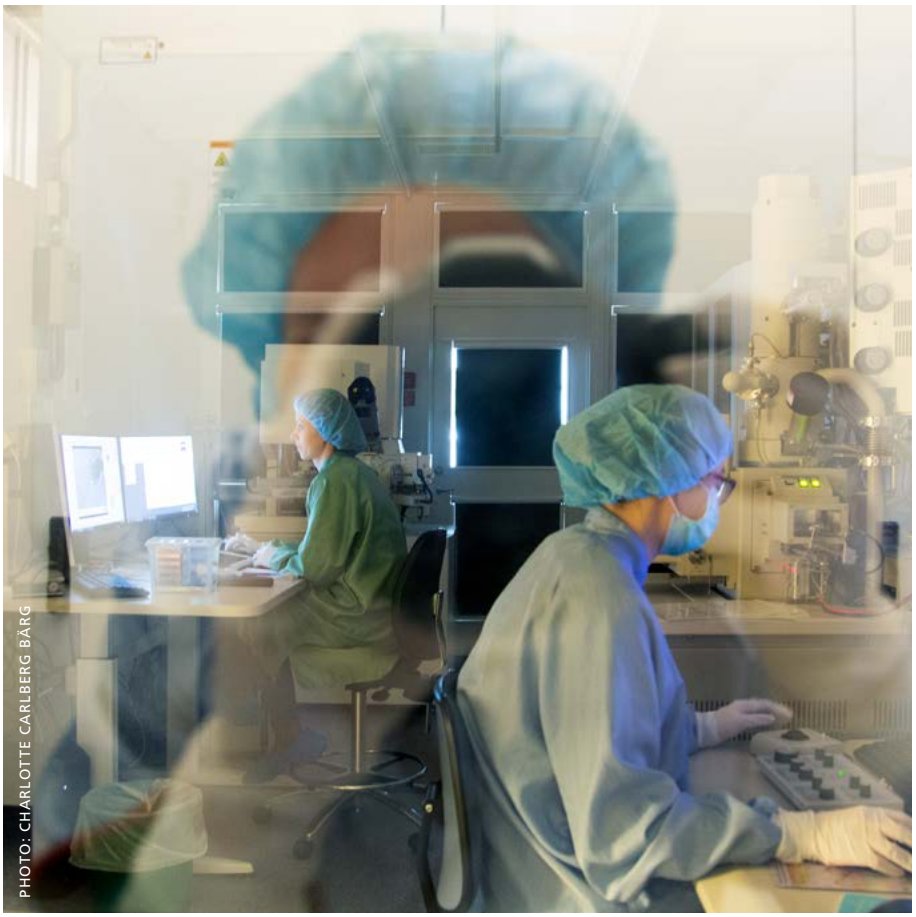


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