Addressing the ATMP competency gap:

A cross-sectoral report and roadmap for West Sweden.

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We extend our heartfelt appreciation to all individuals and organizations that contributed to the successful completion of this pre-study and report. Your expertise, insights, and support have been invaluable throughout this project. Thank you!

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VERIGRAFT
Yrgo

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Table of contents

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1 Executive summary

This report addresses the critical need for specialized competencies in Advanced Therapy Medicinal Products (ATMP), outlining the required skills, as well as key activities required to bridge the ATMP competency gap in West Sweden in the medium-long term from 2024 to 2027.

Recognizing the rapid advancements and complexity inherent in ATMP development, organizations in Sweden across healthcare, academia, and industry have committed to a cohesive and forward-looking action plan.

Background

Sweden aims to establish itself as a global leader in Advanced Therapy Medicinal Products (ATMP) by 2030. This ambition is supported by a joint declaration of intent between Region Västra Götaland, the University of Gothenburg, the Sahlgrenska Academy, Sahlgrenska University Hospital, and Chalmers University of Technology. West Sweden has a great potential to be competitive in the ATMP field with key elements in place, including (but not limited to) the growing GoCo Health Innovation City (GoCo), newly established CCRM Nordic, the ATMP Center at Sahlgrenska University Hospital as a key healthcare resource linked to a GMP facility with advanced expertise. Further, West Sweden has strong track record of cross-sectoral collaboration between academia, healthcare and industry with strong science and industrial presence.

However, the complexity of ATMP, combined with global competition and a shortage of skilled professionals, challenges growth. A national survey revealed that ATMP-related education and training in Sweden is limited and fragmented. For example, universities lack relevant and updated programs focused on ATMPs, which are essential for supplying skilled labor to SMEs. Additionally, there is no structured system for continuing education, such as training centers, to support SMEs working in the ATMP field. To remain competitive, it is crucial to address regional skill gaps swiftly through a coordinated action plan involving industry, academia, and healthcare.

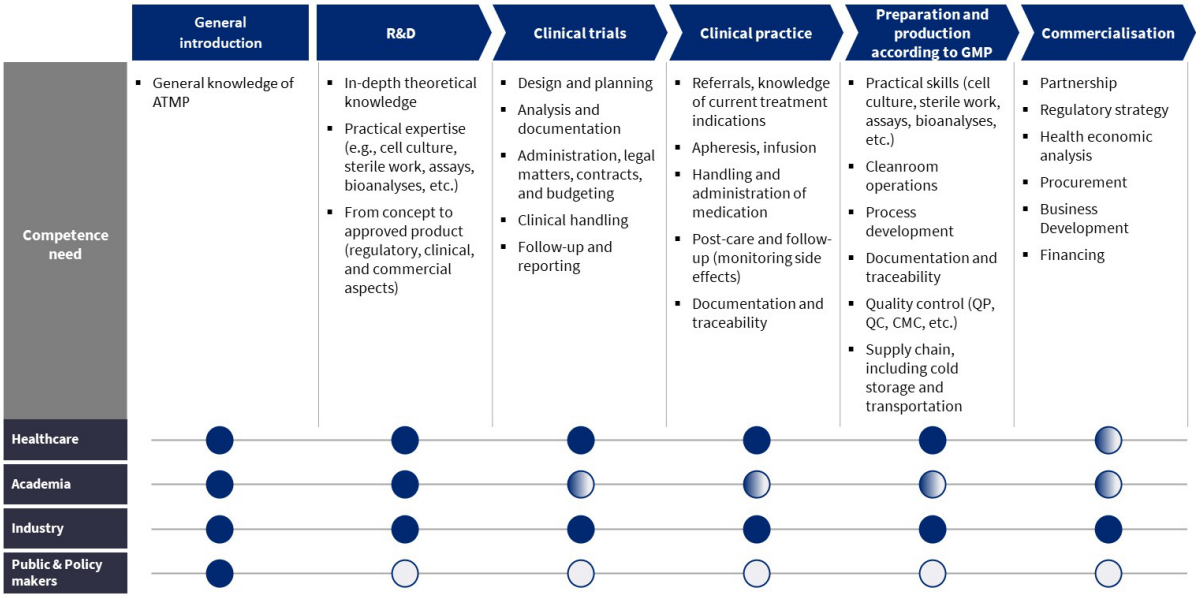
About the pre-study

The pre-study funded by the European Regional Development Fund and Region Västra Götaland aimed to: (1) define ATMP-related competence needs across sectors, and (2) develop a comprehensive action plan to address these needs from 2024 to 2027. This pre-study involved extensive collaboration, including workshops, interviews, and market analysis, engaging stakeholders from healthcare, academia, and industry.

Competence needs overview

The pre-study has clarified specific competency requirements for each sector, while also revealing that many of these needs are shared. All stakeholders, except the general public and policymakers, require skills development across all stages of advanced therapy development. For the private sector and healthcare, most areas of competency overlap. In terms of commercialization, the primary need for increased competence lies with industry and academia, whereas in healthcare, the focus is mainly on therapy development and health economic analysis. Researchers and students within academia require a basic understanding of clinical trials, healthcare application, and therapy production, which links to a broader systemic understanding of therapy development beyond the research phase.

The figure below illustrates specific areas of competency needs, highlighting that while many needs are shared across sectors, there are also distinct requirements.



Joint action plan with activities to address the ATMP competence needs in West Sweden 2024-2027

The preliminary study has identified a significant number of potential future activities. While progress is already underway in many areas, there is an urgent and compelling need to amplify and accelerate these efforts to fully realize West Sweden's potential and contribute to securing the competence needs in Sweden.

The joint action plan organizes ongoing and proposed initiatives into four strategic priorities. The action plan has been endorsed at the highest management level by all participating stakeholders: CCRM Nordic, Chalmers University of Technology, University of Gothenburg (Sahlgrenska Academy and the Faculty of Science for fundamental sciences), LIF, Sahlgrenska Science Park, Sahlgrenska University Hospital, SwedenBIO and YRGO.

The work outlined in this plan will unfold from 2024 to 2027, laying a foundation that will extend beyond this period. By driving this initiative forward, we are not only addressing critical needs but also aiming to position West Sweden as a frontrunner in the rapidly evolving ATMP landscape.

Strategic priority 1: Strengthen education and interdisciplinary research on ATMP at universities with the ambition of creating comprehensive academic environments.

1.1 Establish a framework for closer research collaboration in ATMP and related methods within and between universities to strengthen research and education
1.2 Develop and integrate ATMP into university curricula
1.3 Develop and offer vocational training in areas relevant to ATMP
1.4 Strengthen regulatory, clinical and commercial expertise among researchers
1.5 Assess and enhance the use of exchange agreements with leading international universities and university hospitals in the ATMP field

Strategic priority 2: Implement targeted initiatives to enhance competencies in healthcare and industry

2.1 Develop and implement targeted competence development initiatives for healthcare
2.2 Develop and implement targeted competence development initiatives for the industry

Strategic priority 3: Increase awareness of ATMP among the public and decision-makers.

3.1 Develop and make available an ATMP Introduction Course
3.2 Develop and offer ATMP educational courses at universities for the public and decision-makers
3.3 Establish collaborations with organizations that have direct communication with the public and decision-makers to raise awareness

Strategic priority 4: Drive the advancement of ATMP through long-term collaboration between industry, healthcare and academia.

4.1. Establish a cross-sector "ATMP Training" Center
4.2 Encourage and strengthen incentives for adjunct positions, affiliations and shared roles
4.3 Develop and formally establish a regional ATMP collaboration function, with competence development as a central focus

The plan emphasizes sustainability through gender equality and an inclusive approach to talent development.

The implementation of the action plan is supported by an approved application to the European Social Fund for SEK 10.4 million for competency development for healthcare personnel at Sahlgrenska University Hospital and the county hospitals. An application has also been submitted to the European Regional Development Fund to support implementation of activities in the plan related to industry competency development and strengthened collaboration between healthcare, industry, and academia. National and international collaboration will play a pivotal role in the implementation of the plan, and we welcome interested parties to contribute to this effort.

Conclusion

West Sweden recognizes both the significant potential and the urgent need to develop specialized competencies in Advanced Therapy Medicinal Products (ATMP) to maintain competitiveness. To address these needs, a comprehensive strategic action plan for 2024–2027 has been developed, involving close collaboration between healthcare, academia, and industry. The activities and outcomes are intended to be executed and disseminated in partnership with national and international stakeholders, thereby contributing to broader advancements in ATMP development.

2 Background

In West Sweden, there is a strong ambition to contribute to the vision of making Sweden a world leader in Advanced Therapy Medicinal Products (ATMP) by 2030. This goal is supported by a joint declaration of intent between Region Västra Götaland, the University of Gothenburg, the Sahlgrenska Academy, Sahlgrenska University Hospital and Chalmers University of Technology.

West Sweden has a great potential to be competitive in the ATMP field. GoCo Health Innovation City (GoCo) is a growing business cluster in the region, where a government- and industry-funded innovation hub, CCRM Nordic, has been established to support small and medium-sized enterprises (SMEs) in the development, production, and commercialization of ATMP. West Sweden has for a long time been an attractive location for SMEs in life sciences, with around ten companies already active within the ATMP field. The expectation is that GoCo and CCRM Nordic will help more SMEs grow and remain in the region. A key resource in healthcare is the ATMP Center at Sahlgrenska University Hospital, established in 2020, which includes a newly created center for cell and gene therapy for children at Queen Silvia's Children's Hospital. The Sahlgrenska ATMP Center is also linked to a well-established Good Manufacturing Practice (GMP) facility with high expertise in the field.

The complexity of ATMP requires many unique competencies throughout the various stages of development. Global and national investments, along with the rapid growth of the ATMP field, have resulted in a global shortage of skilled professionals. This global competition makes it difficult for Swedish companies, especially SMEs, to compete for talent. A national survey highlighted that the availability of ATMP-related education and training in Sweden, including West Sweden, is limited and fragmented (Mapping of education and competence needs in ATMP, 2022). For instance, universities lack relevant and updated programs featuring ATMPs, which are crucial for providing skilled labor to SMEs. Another example is the lack of structure for continuing education, such as training centers, to support SMEs working with ATMPs.

To stay competitive, it is essential to address the regional competence needs in West Sweden. In discussions with an ATMP coordination group in West Sweden, including representatives from industry, academia, and healthcare, a need was identified to clarify the skill requirements across sectors and mobilize all relevant stakeholders with a joint action plan to address the competency gap. This mobilization must be swift and decisive to prevent West Sweden from falling behind in the rapidly advancing field.

3 About the pre-study

Against this background, a pre-study has been conducted through extensive collaboration between healthcare, academia, and industry. The pre-study was funded by European Regional Development Fund (facilitated by the Swedish Agency for Economic and Regional Growth) and Region Västra Götaland (Regional Development). This report presents the findings and results of the pre-study. The results will benefit West Sweden in particular, and eventually also national and international actors.

The objective of the pre-study was to mobilize key stakeholders in West Sweden and develop a joint action plan that clearly defines the competence needs for Advanced Therapy Medicinal

Products (ATMP), as well as outlining the necessary activities for future efforts, with the potential to establish a joint competency platform.

The central question addressed in this report is:
In the next three years, what actions are required from stakeholders in West Sweden to address the ATMP competence gap?

This main question is broken down into two sub-questions:
i) What are the competence needs for ATMP?
ii) What activities are required by relevant actors in West Sweden from 2024 to 2027 to address the identified competency needs?

The two sub-questions are addressed in chapters 5 and 6, respectively.

The analysis emphasizes regional competence development in West Sweden, focusing on individuals who are currently working or studying in the area. As a result, the primary aim is to develop talent within universities, the healthcare sector, and in small and medium-sized enterprises. This approach stems from the problem statement, which highlights the intense global competition for talent and suggests that attracting international expertise will only address a small portion of the overall competence needs in West Sweden. Consequently, international talent attraction was considered only through a defined workshop series aimed at enhancing talent collaboration. The project primarily targets the short to medium term period (2024-2027).

To carry out the preliminary study, a project organization was established, consisting of project management, a core team, a reference group, and three focus groups with representatives from academia, healthcare, and industry. A separate focus group was formed to address the specific issue of strengthening talent collaboration.

See *Figure 1* below, which illustrates the project organization.

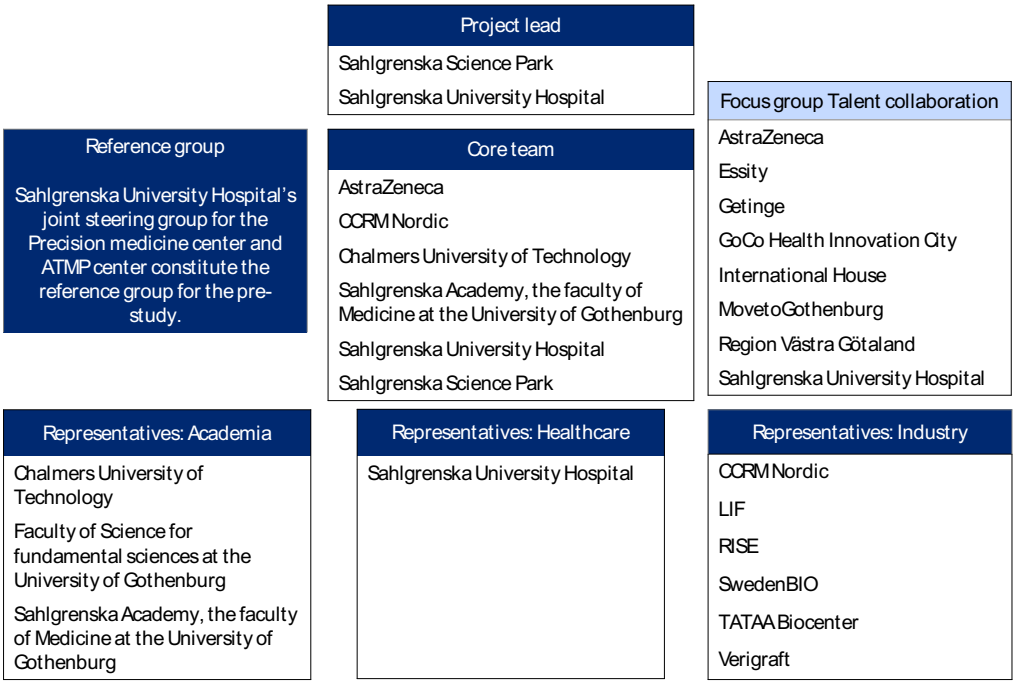


Figure 1. Project organization

The project was initiated and led by project managers from Sahlgrenska Science Park (Josefin Klingvall, Head of Project Partnerships) and Sahlgrenska University Hospital (Kristina Levan, Director of the ATMP Center and Chair of the National coordination function for ATMP). Kristina Levan's involvement ensured that the project benefitted from expert knowledge and an extensive regional, national, and international network. The project management team was supported by an operational project manager and external support from the consulting company Triathlon Group.

The reference group for this project was the same as the reference group for the joint steering committee of the Center for Precision medicine and ATMP Center at Sahlgrenska University Hospital, comprising key representatives from relevant organizations in the ATMP field in West Sweden. This setup provided strong project alignment and valuable guidance.

Through this project structure, all target groups were actively included in the feasibility study's execution. This involvement has contributed to growing interest and engagement in ATMP, particularly in terms of skills development. The cross-sector approach also strengthened the network and enhanced consensus among academia, healthcare, and industry.

The feasibility study was conducted from December 2023 through June 2024, in two primary phases. The first phase focused on mapping skills needs and identifying potential actions in close collaboration with involved stakeholders. Based on these results, a draft action plan was developed. The second phase aimed primarily at further aligning and refining the feasibility study results and proposed action plan.

Skills development in ATMP is a complex area with considerable variation in needs across different stakeholders. A central part of the work, therefore, involved collecting perspectives, needs, and suggestions from representatives from healthcare, industry, academia, and other stakeholders.

The project followed an iterative process, combining methods such as interviews and workshops with external data collection and market analysis, as illustrated in *Figure 2*. Involvement and alignment were guiding principles throughout the project, with cross-sector collaboration and participation in workshops. In addition to the elements shown in the figure, ongoing meetings were also held within the project management and core team.

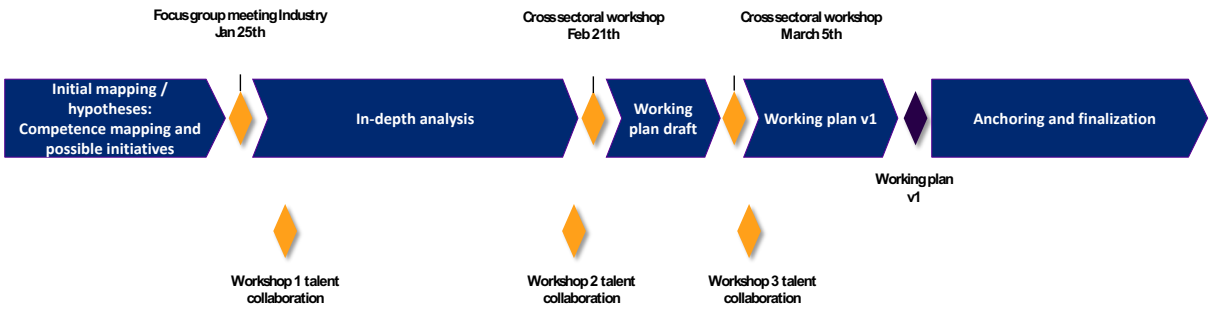


Figure 2. Overall Approach

Beyond securing alignment on the joint action plan with focus groups and the core team throughout the process, alignment meetings were held with representatives from senior management in each organization with responsibilities in the action plan (University of Gothenburg, Chalmers University of Technology, Sahlgrenska University Hospital, CCRM Nordic, Sahlgrenska Science Park, and the industry associations LIF and SwedenBIO), as well as with

representatives from small and medium-sized enterprises. This collectively agreed action plan formed the foundation for subsequent implementation work that commenced in August 2024.

4 National and regional overview of the ATMP field

The ATMP sector has experienced significant growth in Sweden over recent years with a rapidly evolving infrastructure. Key hubs have been established across the country, many in connection with university hospitals, including four dedicated ATMP centers. ATMP Sweden plays a central role and serves as a national network for activities related to advanced therapy medicinal products. *Figure 3* illustrates examples of national projects and organizations associated with ATMP Sweden.

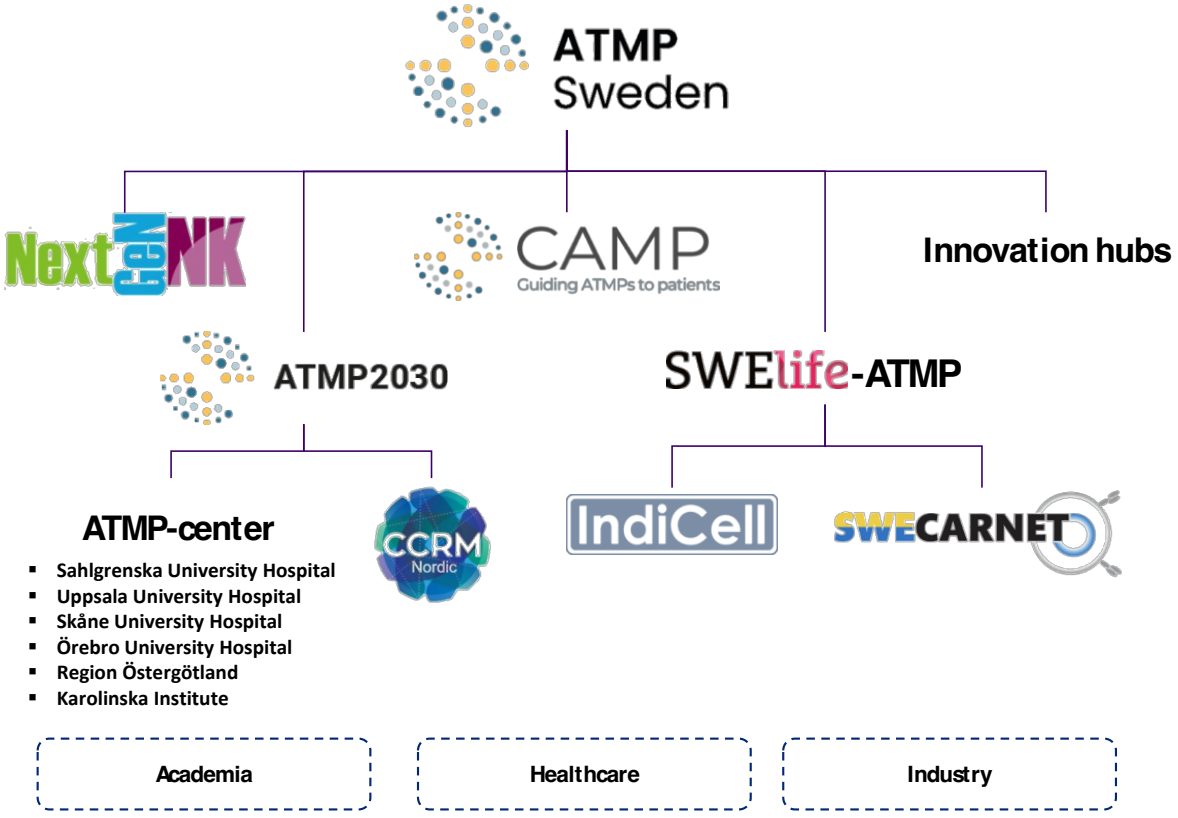


Figure 3. Examples of national initiatives and projects linked to ATMP

ATMP 2030 is a project supported by Vinnova, with the goal of making Sweden a global leader in advanced therapies by 2030. This will be achieved by creating a vision-driven innovation environment to develop ATMP in Sweden. Four ATMP centers have been established under this project, aiming to act as knowledge hubs and points of contact for integrating advanced therapies into the Swedish healthcare system. Along with various projects and initiatives from ATMP Sweden, there are also several development companies and product and service providers linked to ATMP.

In the context of West Sweden's ecosystem for advanced therapies, there are currently several actors with varying degrees of involvement in the field. *Figure 4* provides an illustration of these stakeholders, with healthcare institutions such as Sahlgrenska University Hospital, which houses an ATMP Center including a newly established center for cell and gene therapy for children at Queen Silvia's Children's Hospital, playing a central role.

Figure 4. Organizations within ATMP operating in Western Sweden

In addition to healthcare, several companies are developing new therapies, including AstraZeneca, as well as SMEs such as Elicera Therapeutics and VERIGRAFT. Research is being conducted at universities like the University of Gothenburg, Chalmers University of Technology, and the University of Skövde, supported by an established research infrastructure through organizations such as RISE, Oligonova, and SciLifeLab, among others.

Support and expertise functions related to ATMP, as well as product and service providers, are also contributing to the field, with many linked to later stages of therapy development. For example, Gothia Forum supports stakeholders in clinical trials, while CCRM Nordic will provide support related to the manufacturing of advanced therapies once laboratory facilities are established at GoCo.

The current national and regional ecosystem for ATMP addresses several key aspects of advanced therapies, from development and manufacturing to treatment. However, certain areas still require further development to ensure a competitive industry and a healthcare and academic sector at the forefront.

5 What are the competence needs for ATMP?

In West Sweden, there is a strong ambition to contribute to making Sweden a global leader in ATMP by 2030 through a joint declaration of intent between the Region Västra Götaland, Sahlgrenska University Hospital, University of Gothenburg, Sahlgrenska Academy, and Chalmers University of Technology. The goal is to consolidate efforts within the ATMP sector in West Sweden, providing a solid foundation as the region now needs to better position itself to meet the rapid advancements in the field.

West Sweden has strong potential to become a leader in ATMP but, to achieve this, substantial development is required across several interconnected areas. Currently, the Sahlgrenska ATMP

Center is a key player driving collaboration in the development of competence supply, clinical trials, and preparation for integration into healthcare, in cooperation with various stakeholders such as the University of Gothenburg, Chalmers University of Technology, CCRM Nordic, RISE, LIF, and AstraZeneca. Expanding collaboration with these and other actors will be crucial moving forward.

In summary, the pre-study has identified clear competence needs and an overarching requirement for strengthened, long-term collaboration between industry, healthcare, academia, and society at large, to achieve the goals outlined in the previously mentioned declaration of intent.

5.1 Healthcare competence needs

To meet the significant potential expected from the future development of ATMP, it is crucial that healthcare staff in West Sweden possess the necessary expertise in this area. As the field continues to advance, the demand for trained personnel is expected to increase substantially, driven by the growing number of therapies being developed and the acceleration of clinical usage. Competence development is needed both for the use of therapies in healthcare and to enable participation in research and development through clinical trials.

Through competence-enhancing initiatives related to ATMP in healthcare, more patients will eventually have access to these advanced therapies, which will contribute to both increased patient benefit and strengthen West Sweden's competitiveness in the field. To address identified needs, it is critical to act swiftly in developing competence-building measures for healthcare employees. ATMP is not only a new therapeutic area but also represents a significant shift in work processes and care pathways for several healthcare teams, requiring a wide spectrum of competence development efforts.

Sahlgrenska University Hospital already has several ATMP-related initiatives in place, with the ATMP Center, established in 2020, serving as the central hub. The ATMP Center also includes a dedicated center for cell and gene therapy for children at Queen Silvia's Children's Hospital, which opened in the spring of 2024. Together with competence-building initiatives, these efforts provide a strong foundation for further advancing Western Sweden's positioning within ATMP.

5.1.1 ATMP in healthcare – a transformation

ATMP is not mass-produced in the same way as traditional therapies, as each treatment is tailored to meet the unique needs and genetic profile of the patient. As a result, ATMP treatment involves a more complex care pathway that requires collaboration to ensure each patient receives the most effective and gentle treatment possible.

The ATMP Center at Sahlgrenska University Hospital plays a crucial role in ATMP treatments. It serves as a "single entry point" for advanced therapies, responsible for coordination and supporting the preparations necessary when new therapies are introduced. The ATMP Center's ATMP council is tasked with ensuring capacity and resources within the hospital to facilitate the use of advanced therapies, whether for clinical trials or recommended drugs. The center also functions as an independent advisory body, reviewing resources, feasibility, and compliance with regulations for ATMP. The ATMP Center has a representative in the national network for delivery and quality agreements.

For new treatments, the ATMP Center serves as a coordinating structure, providing support in areas such as permits and notifications for medicines containing or consisting of genetically modified organisms (GMO notification).

Care teams need interdisciplinary knowledge and an understanding of the potential of ATMP. All involved healthcare departments must therefore work closely together, develop their competencies, and stay updated to work with these new therapies as the field evolves.

The need for competence development in healthcare is broad, ranging from basic knowledge of ATMP to enable referral of patients for relevant therapies to more specialized knowledge for professionals who administer the treatments, with a deep understanding of their expected effects and side effects. The educational needs vary significantly across staff groups, but the common factor is that many will need some form of training in ATMP.

5.1.2 Primary professional roles involved with ATMP

The primary professional roles involved with ATMP are:

- Doctors, nurses, assistant nurses, pharmacists, and coordinators who work closely with patients in the relevant clinics and departments where ATMP is currently used, being developed, and implemented.
- Laboratory personnel (biologists, biomedical analysts, pharmacists, and certain roles such as Qualified Person - QP) who work in laboratory settings.
- Staff in research support roles working with, for example, the development and support of clinical trials in healthcare.

Additionally, managers and decision-makers within healthcare also require increased awareness and knowledge of ATMP and its potential to make informed strategic decisions about the development and use of ATMP in healthcare.

5.1.3 Competence needs in clinical operations

For personnel directly involved with ATMP, competence-building measures are needed to cover the full care chain. Given the diversity of personnel involved, it is desirable that healthcare professionals have some competence in ATMP from their initial education, whether as doctors, nurses, assistant nurses, etc.

To ensure that patients have access to the best possible care, clinicians at hospitals and regional hospitals in Western Sweden must be aware of ATMP and its current indications.

For patient treatment, healthcare personnel must be knowledgeable about the preparatory steps before therapy, such as apheresis, lymphocyte treatment (bridging), and the administration of the ATMP therapy.

Post-treatment care for patients is particularly important, especially as some side effects may arise long after treatment. Therefore, it is crucial that departments such as emergency care, intensive care units, primary care, and neurologists are familiar with the side effects of ATMP therapies, as well as other healthcare settings where follow-up checks are conducted after treatment.

5.1.4 Competence needs in hospital laboratories

A significant area with clear competence needs is in hospital laboratories and GMP facilities, specifically in Clinical Immunology and Transfusion Medicine (KITM). Resource shortages are already being experienced for handling current ATMP therapies at the hospital, as significant training efforts are required from existing staff to train new employees until they become independent, which results in a long learning curve of approximately 1-2 years. New hires must learn practical skills such as cell culturing, sterile work practices, conducting bioanalysis, and gaining theoretical knowledge of ATMP. A basic understanding and practical experience in related fields, such as biomedical analysis, are therefore desirable for new staff.

Currently, GMP-certified facilities are available at Sahlgrenska University Hospital, which require significant resources to operate and maintain. Quality control and equipment calibration are performed according to the same standards as pharmaceutical companies manufacturing drugs under GMP, though these tasks are currently carried out beyond the available resources. The KITM Cell and Tissue Lab has five employees, with three working operationally, one working as a QP, and one in administration. To increase the in-house production of ATMP at Sahlgrenska University Hospital, increased access to GMP facilities, as well as additional competence and resources for practical work and production of these therapies, is needed. A clear shortage of competence exists for specific roles such as QP, where specialized regulatory expertise for ATMP is highlighted as a need. General quality work needs to be performed by a broader portion of the department to reduce vulnerabilities associated with this.

The need for QP roles is also experienced at the pharmacy department (VO Läkemedel), where the handling and preparation of ATMP is managed. This department also experiences a need for other competence-building initiatives related to ATMP. Within the pharmacy department, ATMP preparations are carried out, and currently, staff are loaned from the region's extempore production facility. As ATMP becomes more common in healthcare, resource and competence needs will increase, requiring multiple professionals with similar expertise to reduce the risk of losing staff with the right skills if someone leaves.

5.1.5 Competence needs in clinical trials for research and development

Clinical trials are central to the research and development of new ATMP therapies. Sahlgrenska University Hospital can play a decisive role in the development of ATMP by participating in clinical trials in the field. Contributing to clinical trials in ATMP at the hospital will be significant for the advancement of healthcare and realizing the potential within this field. If sufficient competence is not available to manage clinical trials in ATMP in West Sweden, healthcare risks falling behind in development. Clinical trials are also crucial for the industry and, to remain competitive, it is vital that healthcare can serve as a competent and close partner to companies. This requires healthcare personnel to demonstrate high competence and capacity in the area. ATMP is subject to specific regulations, making knowledge of these rules, laws, and permit requirements essential for successful clinical trials. Furthermore, it is important that healthcare receives coverage for the costs associated with participating in clinical trials involving ATMP. This is currently seen as a challenging task, requiring increased competence and support for budgeting to ensure that the trial does not become too costly for the healthcare system to conduct.

5.1.6 Summary of identified competence needs at Sahlgrenska University Hospital

As part of the pre-study, an application was made to the European Social Fund (ESF) to develop and implement competence-building initiatives for ATMP in healthcare in Region Västra Götaland. Data was gathered from various departments within Sahlgrenska University Hospital to gain an understanding of the competence needs. The needs were categorized into seven competence areas: general knowledge of ATMP, research and development, clinical trials, clinical practice, preparation and production, QA/RA (Quality Assurance/Regulatory Affairs), and commercialization. *Table 1* illustrates the results of the survey.

Table 1. Summary results from an assessment of competence development needs by competency areas across different operational areas of Sahlgrenska University Hospital.

Competence area / Operational area	General knowledge of ATMP	R&D	Clinial trials	Clinical practice	Preparation and production	QA/RA	Commercial isation
Hematologen	85		44	115		15	
Onkologen	137		17	136			
Barnsjukhuset	170		23	175			
VO Läkemedel	10	10	3	7	8		5
KITM	60	29	30		25		20
Gothia Forum	35	2	29				
Total	497	41	146	473	33	15	25

The table clearly shows that a significant portion of the staff requires general knowledge, though there are differences across departments in terms of specific skill requirements. Not all employees need the same training, nor to the same extent. Allocating resources to strengthen both general competence and specialized expertise will contribute to making ATMP a leading field in Western Sweden's healthcare system.

5.1.7 ATMP training in healthcare

Training initiatives are underway at the hospital, primarily led by Gothia Forum and the ATMP Center, which provide professional development for various groups. For example, ATMP Center conducts training within clinical trial units for healthcare staff during focus weeks organized by the Strategic Council for Medicines, as well as through a clinical research school offered by the Regional Cancer Center West in collaboration with the University of Gothenburg. As the number of products and clinical studies increases, more staff will need to be involved, highlighting the need to expand training and knowledge-building initiatives within ATMP. Currently, much of the educational material is created by staff in addition to their regular duties. For sustainable competence development, a more systematic approach to professional growth is needed.

To ensure the success of competency-building efforts in healthcare, it is essential that these efforts are effective, well-planned, and well-integrated, especially given the high workload of healthcare professionals. This can be achieved, for example, by combining short courses such as one-hour lectures with longer series and more in-depth training sessions.

In addition to expanding the educational content itself, there is currently no designated physical space to conduct all training components. Some training sessions, for example, require access to

specific facilities such as laboratories and clean rooms to enable practical application of theoretical knowledge.

5.2 Industry competence needs

West Sweden currently has several companies in the ATMP sector, including development companies and product/service providers. The number of these companies, as well as their employees, has grown significantly in recent years and is expected to grow further in the coming years. Consequently, there is a substantial need for increased expertise among current employees to drive progress, as well as a need for skilled individuals who can join the workforce in the near future.

New hires will come from diverse backgrounds: other companies, healthcare, and/or academia. These individuals bring varied skills, meaning that initiatives linked to academia and healthcare will significantly benefit the industry. However, as some of these competencies may take years to reach the industry, short-term training efforts should also target the business sector directly.

5.2.1 Need for new hires

Currently, approximately 300 employees work in ATMP-related companies in West Sweden, with over 60% in research and development (R&D). Local development companies have been asked to estimate the number of new hires expected over the next five years, assuming business plans are realized. The responding companies, representing both service providers and ATMP pharmaceutical developers, indicate a projected increase of approximately 200–300 new hires. The company with the highest anticipated growth is CCRM Nordic, expecting around 75 new hires, primarily in production. Similarly, TATAA Biocenter plans to expand its staff in the coming years (with half of the number projected to have limited interaction with ATMP). The companies have also provided estimates on the distribution of new hires across different job categories. R&D staff is still expected to comprise a large share of the total, though production and QA/RA roles are anticipated to see the highest growth.

Beyond hiring within existing companies, there is a strong likelihood of new companies forming, contributing to the rising demand for personnel. An estimate suggests that five new companies with an average of five employees each will add about 25 new jobs.

As previously noted, employees in production and QA/RA roles are expected to make up an increasing proportion of the total workforce. For comparison, the current role distribution in the UK can serve as a reference, as it is several years ahead of Sweden in ATMP development. This comparison shows that the expected future distribution in West Sweden will increasingly resemble that in the UK, where production staff represent a larger share (UK Cell and Gene Therapy Skills Demand Report, 2023).

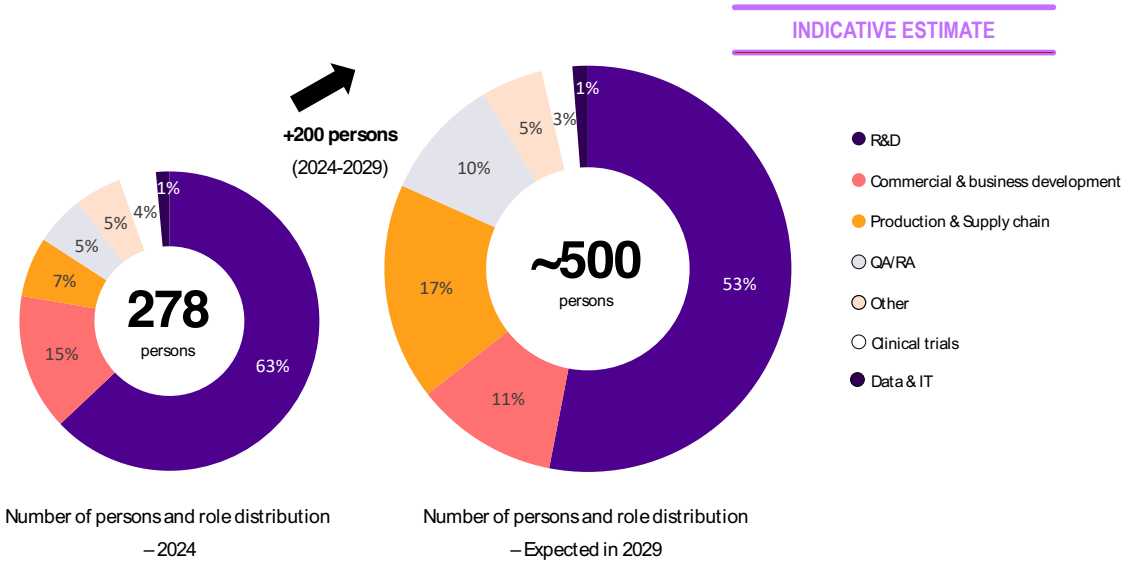


Figure 5. Future competence needs in West Sweden within ATMP, based on estimates from surveyed companies. In cases where role distribution was not estimated, the distribution has been based on the current role distribution within the company.

5.2.2 The future skills gap

With the expected increase in staffing and shifts among job categories, companies are likely to face a noticeable skills gap and a challenge in finding qualified personnel. Even now, companies report difficulty in sourcing candidates with relevant expertise. Larger companies can generally attract international talent and thus do not face as many challenges. However, small and medium-sized companies and healthcare manufacturing face greater difficulty in visibility to job seekers and in offering competitive salaries in the global market.

5.2.3 Enhanced theoretical and practical knowledge

As the field is relatively new, there is a need for a general skills enhancement, both theoretical and practical. A foundational ATMP training program would be beneficial for all staff, especially those with non-ATMP backgrounds. This introduction would provide a broad understanding, creating familiarity for those directly involved in development as well as for those indirectly supporting it, such as finance and HR. In addition to general knowledge, there is a need for more specialized skills.

Specific skills include both theoretical and practical knowledge in cell and molecular biology oriented towards ATMP, as well as bioinformatics and various omics techniques. Notable skill shortages include combinations such as molecular analysis and Good Laboratory Practice (GLP).

5.2.4 Working in GMP environments, production and associated processes

Production staff is among the job categories expected to grow most, with demand for various skill sets. Operators need qualifications, as the work, though often routine, requires high standards of quality. Academic training is not always essential, but practical experience is highly valued. ATMP production occurs in a GMP (Good Manufacturing Practice) environment, with stringent requirements for sterile work, protective clothing, documentation, traceability, analysis methods, and specific manufacturing techniques. Extensive training is required to become independent in

this setting. Practical skills are also needed in development and quality control of pharmaceuticals.

In addition to production personnel, roles related to regulatory and quality control aspects are necessary, as well as expertise in process development. Like other production sectors, ATMP manufacturing is expected to trend toward increased automation, raising skill requirements for those developing these processes.

5.2.5 Specialized regulatory expertise

ATMP regulations differ somewhat from other treatments and drugs, necessitating specific regulatory knowledge for early-stage development, production, clinical trials, market approval, and commercialization. Other areas of demand include CMC (Chemistry, Manufacturing, and Controls) and IP (Intellectual Property), which are particularly complex in the context of ATMP and more challenging to find relevant expertise for. Because ATMP is still considered new, there is often uncertainty around regulatory interpretation, and companies express difficulty in understanding compliance requirements. There is currently no established forum for companies to discuss these issues collaboratively.

5.2.6 From concept to commercially viable product

Developing pharmaceuticals is a lengthy and costly process, requiring specific skills across a broad range of fields. Beyond the specialized knowledge required for product R&D, stakeholders emphasize the importance of considering regulatory, clinical, and commercial aspects early in development. This is particularly relevant for innovation-driven startups, which often originate from academic research and may lack established structures and industrial expertise. In contrast, larger pharmaceutical companies have established processes to ensure development complies with strict regulatory, economic, and time-efficiency requirements. This includes selecting the right starting materials and manufacturing processes and ensuring thorough documentation and traceability from the outset. Adopting a clinical approach early on facilitates the transition from development to production and ensures practical application in clinical settings.

A critical need is to build commercial expertise within innovation-driven development companies and SMEs in the ATMP field, where a shift in focus is required — from aiming to develop an approved product to creating a commercially viable product. The need for commercial expertise is highlighted by the fact that several ATMP therapies have been withdrawn from the market. As of June 2024, the European Medicines Agency (EMA) has approved 25 ATMP therapies, seven of which have since been withdrawn. Unlike traditional drugs, these withdrawals are primarily due to commercial reasons, as profitability challenges arise from the complexity of processes and business models not being fully accounted for.

The need for commercial expertise can be divided into two areas:

- **Business strategy skills**, including development of a company's business model and partnership strategies. For instance, companies need to decide whether to bring their product to Phase 3, market entry, or to partner early in development — or a combination thereof. Different models demand diverse skill sets, and companies need strategic business expertise and the capacity to build a successful enterprise. This also includes the expertise necessary to secure funding across various stages of company growth.

- **Go-to-market expertise**, covering reimbursement, pricing, payment models, Health Technology Assessment (HTA), market strategy, distribution, logistics, and related areas.

By creating conditions for the right competencies to "get it right from the start," companies can reduce time and costs to achieve a commercially sustainable product, mitigating the risk of therapies being quickly withdrawn post-approval.

5.3 Academic competence needs

West Sweden has a strong tradition in education and world-leading research within life sciences, with the University of Gothenburg (GU), particularly the Sahlgrenska Academy for medical sciences and the Faculty of Science for fundamental sciences, along with Chalmers University of Technology (Chalmers), serving as the dominant academic players. Additional contributions from other institutions in the region, including the University of Skövde, the University of Borås, and the University West, enrich a robust academic environment in education, research, and innovation. This environment is vital for the development and talent supply in ATMP, serving both healthcare and the industry. Furthermore, vocational colleges like Yrgo (Higher Vocational Education in Gothenburg) and other educational institutions are also key contributors. A key factor across all areas is the importance of long-term investment in ATMP initiatives at universities and the aim to create comprehensive academic settings where education is interconnected with research. Since ATMP is an emerging field experiencing rapid development, long-term sustainability and a strong academic home for the discipline require that education be integrated into areas where active research is conducted, ensuring access to the needed expertise. This approach fosters interdisciplinary research and educational collaborations and strengthens partnerships with both public and private sector entities. Integrating ATMP-related content into established undergraduate programs of relevance will also raise awareness and interest among students, encouraging further education and specialization in this area.

Currently, there is ongoing ATMP research at universities in West Sweden, but full collaboration between research groups is not yet established. Additionally, these efforts are not well-promoted on research portals, making it challenging to identify active research groups without prior knowledge. A clearer overview of the regional research landscape would help clarify ongoing initiatives and highlight existing investments.

GU and Chalmers alone enroll over a thousand students annually in ATMP-related programs, such as pharmacy, pharmaceutical science, biomedical analysis, biotechnology, biochemistry, biology, molecular biology, pharmaceutical chemistry, and medical and nursing programs. Following the joint declaration of intent between the Region Västra Götaland, GU, and Chalmers on ATMP in 2023, work is underway to develop joint advanced-level courses in areas like biomedical analysis, pharmacy, and biotechnology education. By offering courses across multiple programs, interdisciplinary learning is enabled. This initiative, aligned with the needs assessment, has highlighted the importance of having accessible lecturers, suitable facilities for cleanroom training, and well-defined course content.

5.3.1 Updating university curricula

The development of course content for the pharmacy and biomedical analysis programs is underway. Continued discussions around formats and structures for sustaining this development are necessary. Given that new courses will be designed for students from various programs,

collaboration within and across institutions is essential to ensure the content aligns and courses are scheduled appropriately.

In addition to advanced-level courses, it's essential to integrate ATMP, and visualize the already existing ATMP content, into relevant undergraduate programs to increase general competency in the field. Exposing more students to ATMP will raise awareness and stimulate curiosity, potentially leading them to pursue further studies or careers in the field. In the long term, this integration should be considered across entire degree offerings rather than as isolated elective courses.

5.3.2 Long-term supply of lecturers with ATMP expertise

The needs assessment underscores the demand for lecturers with specialized ATMP related knowledge, particularly concerning advanced-level courses that are being developed. There is a notable need for expertise in regulatory affairs, as well as cell and gene therapy. While some expertise currently exists within academia, an inventory is required to specifically match these skills with requested course content. Strengthening research in these areas will assure building expertise over time.

Given ATMP's rapidly evolving nature, inviting external lecturers from clinical practice and industry would be beneficial. However, coordination is necessary to identify and involve these external experts. Adjunct and affiliated positions, as well as joint roles, would provide access to skilled individuals based outside of academia. Such collaborations with industry would also reinforce connections to the commercial sector. Ensuring long-term engagement is essential to avoid relying on individual lecturers. Clear contact pathways and a coordinating function are required to efficiently identify instructors from academia, healthcare, and industry.

5.3.3 Strengthened research collaboration

ATMP related research is currently conducted across multiple faculties and departments at GU and Chalmers, as well as in dedicated research centers like FormulaEx. However, collaboration among researchers in the field is underdeveloped, limiting knowledge exchange and opportunities for interdisciplinary and translational research. A contributing factor is the lack of established collaborative platforms, like the successful Lund Stem Cell Center established in 2003, which now includes over 300 affiliated researchers.

Stakeholders have expressed interest in consolidating research groups within the field to create a platform that would support collaboration and strengthen research. A research network could be a first step in raising awareness of ongoing research and regional collaboration opportunities. Initial inventories of research groups at the Sahlgrenska University Hospital and Sahlgrenska Academy have been completed, with similar efforts underway at Chalmers and the Faculty of Science for fundamental sciences at the University of Gothenburg.

5.3.4 Strengthening regulatory, clinical and commercial expertise among researchers

Moving academic research and innovation toward an industrially scalable, regulatory-approved, and commercially viable product requires specialized skills tailored to clinical, regulatory, and industry requirements. This need is particularly pronounced for ATMP, which introduces new requirements and business models compared to traditional pharmaceutical development. To "get it right from start" and reduce time and costs for drug approval, researchers, PhD students, and

post-docs require enhanced knowledge in regulatory, clinical, and commercial areas. This includes business strategy, company-building, selecting business models, and addressing health economics questions. It is critical to understand and address these requirements early to ease the transition from basic research to regulated industrial product development and GMP manufacturing.

The National ATMP Research School is an important initiative addressing these needs, with eight projects funded in 2024. It could serve as a foundation for broader educational initiatives and early introduction of ATMP concepts to researchers, building the necessary expertise to advance the field. Some of these courses will be documented digitally, which will allow broader access to content in the future.

5.3.5 Access to facilities

In addition to developing course content, there is a need for suitable training facilities, including laboratories and cleanrooms, where theoretical knowledge can be practically applied. Laboratory spaces don't necessarily need to be GMP-certified to meet educational needs, but access to facilities that mimic real-world environments is important for hands-on learning. Available options exist, but decisions are needed on which facilities to use and how.

5.3.6 Exchange agreements

An international benchmarking study identified over 30 dedicated master's programs in ATMP, with the UK particularly advanced in this field, as well as institutions in Canada and Andalusia offering dedicated programs and courses. Offering exchange opportunities would allow students to study at leading institutions in ATMP. However, a comprehensive overview of relevant agreements and opportunities is lacking, and there is a need to inventory and prioritize these possibilities. Existing agreements could be better utilized, with more information provided to students about available options.

5.4 Public and policymaker knowledge requirements

To support the growth of ATMP, there is also a need for increased awareness among the general public and policymakers.

For the public, increased awareness will support the development of healthcare. Some hesitation toward ATMP exists, as it remains a relatively new and unexplored treatment type. Patients need access to information to feel confident and understand the implications of undergoing such therapies.

Policymakers require a deeper understanding of the unique needs in ATMP development and implementation, including clear insights into how these therapies differ from traditional pharmaceuticals. Significant investments are required from regional and national levels to enable development, clinical trials, and availability in healthcare, as well as to address other prioritization or funding needs. ATMPs often involve different business models, and due to high development costs and smaller patient populations, they typically fall into a higher price category than traditional drugs. Furthermore, there are numerous regulations surrounding ATMPs, and there is a perception that authorities have not kept pace with developments, creating unnecessary obstacles, or making it difficult for companies and developers to understand what is permissible.

5.5 Cross-sectoral competence needs

The analysis clarified specific competency requirements for each sector, while also revealing that many of these needs are shared. All stakeholders, except the general public and policymakers, require skills development across all stages of advanced therapy development. For the private sector and healthcare, most areas of competency overlap. In terms of commercialization, the primary need for increased competence lies with industry and academia, whereas in healthcare, the focus is mainly on therapy development and health economic analysis. Researchers and students within academia require a basic understanding of clinical trials, healthcare application, and therapy production, which links to a broader systemic understanding of therapy development beyond the research phase.

Figure 6 illustrates specific areas of competency needs, highlighting that while many needs are shared across sectors, there are distinct requirements as well. For example, "Application in Healthcare" is primarily relevant for clinical healthcare personnel, whereas "Industrial GMP Manufacturing" is more pertinent to the private sector (and, to some extent, to laboratory activities within hospitals and academia). Foundational and advanced theoretical knowledge is relevant for many, creating opportunities to develop synergies through shared training initiatives.

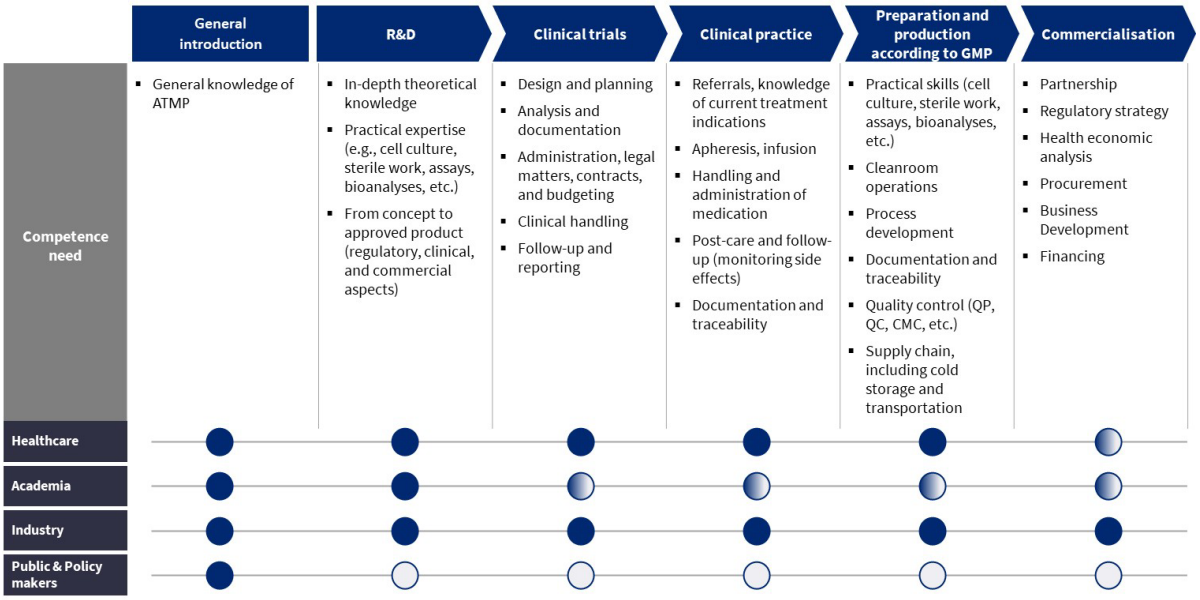


Figure 6. Overview of competence needs by competency area, highlighting several common needs across sectors.

5.5.1 Enhanced talent collaboration

The pre-study has focused on initiatives that can be implemented to meet regional competence needs in West Sweden, based on the people who are already working and studying here. This includes developing talent locally at universities, in healthcare, and within the business sector. The issue of attracting international talent to the region has therefore been addressed in a limited way, concentrating on whether enhanced talent collaboration between organizations in West Sweden could improve conditions for attracting international expertise. The following specific needs emerged from this workshop series:

- **Strengthening conditions for finding employment for accompanying partners**: A significant challenge in recruiting international talent within the life science sector is finding jobs for accompanying partners. Often, these partners are highly educated and seeking qualified work, frequently also within the life science sector. There is a need to highlight and showcase all available opportunities in the region, for instance, by identifying potential employers within life science and other sectors. An important aspect of this is demonstrating that career development does not have to be limited to the specific company that the talent initially joins upon arrival in West Sweden. The need for an updated website with comprehensive, accessible, and engaging information is clear. Ideally, an existing website should be used for this purpose.
- **Raising awareness of existing infrastructure and support**: There is a well-developed infrastructure and support system for international talent attraction, such as Move to Gothenburg and International House Gothenburg. For example, a job portal has been created, listing current job postings from the Swedish Public Employment Service and partner companies. However, it is evident that knowledge and awareness of this infrastructure are relatively low, so there is a need to raise awareness of the available resources. In addition, a need has been identified to further develop the existing job portal to enhance opportunities for both job seekers and employers. This includes features like allowing job seekers to create profiles with their skills and receive notifications about relevant job openings, as well as enabling employers to create profiles to search for potential candidates. Work on this is ongoing.
- **Strengthening the collaboration platform**: There is a demand for an expanded collaboration platform related to talent attraction among life science actors in the region, building on previous positive experiences. Currently, many companies are not part of the existing forums and networks. Participants in the workshop series highlighted the need to establish a network of recruitment/HR representatives with clear points of contact. This would improve conditions for talent collaboration and facilitate joint initiatives, information sharing, and quick interactions between organizations, such as assisting with recruitment processes, including support for job-seeking partners. The meetings held have clearly demonstrated the value of bringing together a wide range of representatives, and several dialogues have been initiated around potential joint initiatives and activities.

6 What activities are required by relevant actors in West Sweden from 2024 to 2027 to address the identified competence needs?

6.1 International outlook

The international outlook aimed to capture ongoing ATMP activities in other countries as a source of inspiration for development of a joint action plan in West Sweden. In this process, several university-affiliated ATMP training programs were identified (see Table 3 below). Other skill-building initiatives were also found, with an overview provided in Table 2.

Table 2. Examples of identified international skills development initiatives in ATMP

Organization	What	Short description
CGT Catapult, UK	Internship program ATAC - Advanced Therapies Apprenticeship Community	A tailored, paid apprenticeship program for training and upskilling individuals in ATMP development and manufacturing. Combines hands-on experience with ongoing academic training. Upon completion, participants receive a nationally recognized qualification.
ARM, US	Internship Program GROW RegenMed Internship Programme	A paid 12-week summer internship program for students, also aimed at promoting gender equality within the field.
CGT Catapult, UK	Training center ATSTN - The Advanced Therapy Skills Training Network	Two national training centers offering a wide range of training options, including in-person, online, virtual, and AR/VR technology for ATMP GMP manufacturing, analytical techniques, etc.
Canadian Advanced Therapy Training Institute (CATTI), Canada	Training center CATTI	Practical GMP training for workforce skill enhancement, such as the “Cell Therapy Bootcamp” — an intensive 5-day course in GMP-compliant human pluripotent stem cell manufacturing. Also offers online courses.
Andalusian Network for the design and translation of Advanced Therapies (And&AT), Spain	Online training Andalusian Network for the design and translation of Advanced Therapies (And&AT)	Accredited courses by the Agency for Healthcare Quality in Andalusia in GLP, GCP, and GDP, with course durations of approximately 6–11 weeks.
Stem Cell Network (Canada) och Medical Resarch Council (UK)	Exchange program UK-Canada Exchange Program Awards	A research exchange program between the UK and Canada in the ATMP field, with exchange periods lasting 6–12 weeks.
Utrecht Summer School, Netherlands	On-site course Utrecht Summer School - Regenerative Medicine	A 4-day intensive course featuring lectures and hands-on experiments for master’s-level students.

Table 3. International outlook – Examples of ATMP master's programs

Country	Organization	Education
Finland	Tampere University	▪ Master program – Biomaterials and Tissue Engineering
France	UPEC – University Paris-Est Créteil	▪ Master program – Biology and Health – Tissue, Cell and Gene Biotherapies
Ireland	Atlantic Technological University	▪ Master program – Advanced Therapy Medicinal Products (ATMP) Cell Manufacturing
	University of Galway	▪ Master program – Cellular Manufacturing and Therapy
Italy	Universita Cattolica de Sacro Cuore	▪ Master program – Innovations in Biotechnology Applied to Regenerative Medicine
Canada	University of Guelph	▪ Master program – Regenerative Medicine
Netherlands	Universiteit Leiden	▪ Master program – Transfusion Medicine and Cellular and Tissue Therapies
	Utrecht University	▪ Master program – Regenerative Medicine and Technology
	Eindhoven University of Technology	▪ Master program – Biomedical engineering: Regenerative Medicine och Technology
Spain	University of Granada	▪ Master program – Tissue Engineering and Advanced Therapies ▪ Master program – Master in Manufacturing ATMP
	Autonomous University of Barcelona	▪ Master program – Transfusion Medicine and Cellular and Tissue Therapies
UK	Aston University of Birmingham	▪ Master program – Stem Cells and Regenerative Medicine
	Edinburgh Medical School	▪ MSc by Research – Regenerative Medicine and Tissue Repair
	Imperial College London	▪ Master program – Genes, Drugs and Stem cells - Novel Therapies
	Keele University	▪ Master program – Cell and Tissue Engineering
	Kings College London	▪ MSc by Research – Research inom Tissue Engineering och Innovation Technology
	Newcastle University	▪ MSc by Research – Regenerative Medicine and Stem cells
	Queen Mary University of London	▪ Master program – Regenerative Medicine

Country	Organization	Education
	Swansea University	▪ Master program – Tissue Engineering and Regenerative Medicine
	UCL	▪ Master program – Manufacture and Commercialisation of Stem Cells and Gene therapy ▪ Master program – Cell and Gene Therapy ▪ Master program – Nanotechnology and Renerative Medicine
	University of Brighton	▪ MSc by Research – Regenerative Medicine and Devices
	University of Cardiff	▪ Master program – Tissue Engineering and Regenerative Medicine
	University of Glasgow	▪ Master program – Stem cell Engineering for regenerative medicine
	University of Manchester	▪ Master program – Advanced Therapy Medicinal Products ▪ MSc by Research – Tissue Engineering for Regenerative Medicine
	University Of Nottingham	▪ Master program – Stem cell Technology and Regenerative Medicine
	University of Sheffield	▪ Master program – Advanced Cell and Gene Therapies
United States	California Polytechnic State University	▪ Master program – Regenerative medicine
	University of Southern California	▪ Master program – Stem cell biology and regenerative medicine
	Northeastern University	▪ Master program – Cell and Gene therapies
	New Jersey Institute of Technology	▪ Master program – Pharmaceutical Chemistry – Cell and Gene Therapy Sciences
Austria	University of Applied Sciences Technikum Wien	▪ Master program – Tissue Engineering and Regenerative Medicine

6.2 Joint action plan with activities to address the ATMP competence needs in West Sweden 2024-2027

The preliminary study has identified a significant number of potential future activities. While work is already being carried out in many of these areas, efforts need to be intensified and enhanced to meet the identified needs.

Ongoing and proposed activities have been organized into four strategic priorities:

1. Strengthen education and interdisciplinary research on ATMP at universities with the ambition of creating comprehensive academic environments.
2. Implement targeted initiatives to enhance competencies in healthcare and industry.
3. Increase awareness of ATMP among the public and decision-makers.
4. Drive the advancement of ATMP through long-term collaboration between industry, healthcare, and academia.

Figure 7 below illustrates the connection between identified needs and the proposed strategic priorities.

Figure 7. Illustration of the connection between identified needs and proposed strategic priorities.

Activities and responsible stakeholders (organizations) for each activity are listed in the table below. The action plan has been endorsed at the highest management level by all participating stakeholders. All activities must be carried out during 2024-2027, and in many cases, the work will need to continue beyond this period. This is highlighted in the illustration of the action plan in section 6.2.3.

Abbreviations in the table:

CCRM Nordic	Centre for Commercialization of Regenerative Medicine (CCRM) Nordic
Chalmers	Chalmers University of Technology
GU	University of Gothenburg
SA	Sahlgrenska Academy, the faculty of Medicine at the University of Gothenburg

NatFak	Faculty of Science for fundamental sciences at the University of Gothenburg
LIF	Trade association for the research-based pharmaceutical industry in Sweden
SSP	Sahlgrenska Science Park
SU	Sahlgrenska University Hospital
SwedenBIO	National trade organization for life sciences in Sweden
YRGO	Higher vocational education Gothenburg

Strategic priority 1: Strengthen education and interdisciplinary research on ATMP at universities with the ambition of creating comprehensive academic environments.

Activity	Organization
1.1 **Establish a framework for closer research collaboration in ATMP and related methods within and between universities to strengthen research and education,** including ensuring long-term faculty competence. Conduct a survey of researchers at the University of Gothenburg and Chalmers University of Technology who are working in fields related to ATMP. Identify which researchers are active in the area, their motivations, and their specific competencies. A key group includes those who are also affiliated with Sahlgrenska University Hospital. Identify common interests and based on this, establish a structure such as a research network. The National ATMP Research School is an important component of this initiative. At Chalmers, leveraging the strengths of the university's strategic areas serves as an excellent entry point and catalyst for further development. Guest professors are a valuable addition to the network, bringing in international expertise. Strengthening the research framework will, in turn, enhance educational opportunities and ensure long-term supply of lecturers with ATMP expertise.	○ GU ○ Chalmers ○ SU
1.2 Develop and integrate ATMP into university curricula ○ **1.2.1 Raise awareness of ATMP among undergraduate students** For instance, offer inspiring lectures at both undergraduate and master's levels to make students aware of ATMP. Relevant programs include: Pharmacy, Biomedical Analysis (BMA), Biotechnology, Biology, Pharmaceutical Chemistry, Medicine, Nursing, and Assistant Nursing. ○ **1.2.2 Offer elective, interdisciplinary ATMP courses within relevant programs** Ongoing efforts are underway to develop elective courses. In the long term, these courses will be linked to current research at the institutions to provide academic grounding in the ATMP field and develop comprehensive academic environments. GU/SA: Advanced-level course in the Pharmacy program focusing on	○ GU ○ Chalmers ○ SU

fundamental theoretical knowledge of ATMP, including an introduction to regulatory issues. GU/SA: Advanced-level course in the Biomedical Analyst program (BMA), covering fundamental cell and molecular biology for cell culture, practical work in cleanrooms, handling patient material, quality control (QC), and documentation. GU/NatFak: Potential courses for the Biology program, Pharmaceutical Chemistry, and Prescriptionist program, with the possibility of an elective course in the Pharmacy program. Chalmers: Course for the Biotechnology program, potentially as a "Tracks" course. Key considerations include specifying the need for cleanroom facilities, assessing the feasibility of taking multiple elective courses across different study periods, and enabling courses for doctors, nurses, assistant nurses, and additional healthcare roles. In the longer term, the development of a master's program could be considered, potentially with a broader focus such as precision medicine/precision health, with ATMP as a significant component. Although this is not part of the current action plan, it is a matter to monitor and potentially begin planning early.	
1.3 **Develop and offer vocational training in areas relevant to ATMP** As part of competence-enhancing measures, a collaboration with Yrgo has been initiated. Vocational training programs are a crucial element of the joint action plan for securing competence. Vocational training programs develop career-oriented courses and programs with short lead times tailored to industry needs. Yrgo is conducting a needs assessment within Life Science, including precision medicine, to develop training programs from 2025 and for the next 3-5 years.	○ Yrgo
1.4 Strengthen regulatory, clinical and commercial expertise among researchers Two main areas of competence development have been identified: business model and strategy expertise, and "go-to-market" knowledge (market strategy, pricing, logistics, etc.). Explore opportunities to expand upon courses offered through the National ATMP Research School. For example, the health economics course in the National ATMP Research school could be broadened to be accessible to social sciences students. Depending on needs, leverage the opportunity to participate in professional development initiatives within healthcare and industry (see activity 2.1 and 2.2).	○ GU ○ Chalmers ○ SU ○ SSP ○ CCRM Nordic
1.5 Assess and enhance the use of exchange agreements with leading international universities and university hospitals in the ATMP field to foster relationships and strengthen research and education.	○ GU ○ Chalmers ○ SU

Strategic priority 2: Implement targeted initiatives to enhance competencies in healthcare and industry	
Activity	Organization
2.1 Develop and implement targeted competence development initiatives for healthcare Competence development efforts will be directed towards a broad range of personnel groups within healthcare: • Clinical staff working directly with patients in relevant departments and units at Sahlgrenska University Hospital where ATMP is currently used, implemented, and developed. • Laboratory personnel at Sahlgrenska University Hospital. • Health professionals in research support services, such as those involved in the development and support of clinical studies within healthcare. • Health professionals at county hospitals. Examples of these initiatives include various forms of educational programs based on a cross-sectoral catalog of ATMP-related competence development efforts (preliminary version, to be refined throughout the project). See section 6.2.1.1.	○ SU ○ County hospitals ○ CCRM Nordic ○ SSP Collaboration with GU, Chalmers, LIF, SwedenBIO
2.2 Develop and implement targeted competence development initiatives for the industry These initiatives will focus on small and medium-sized enterprises (SMEs) and current/potential entrepreneurs in ATMP connected to West Sweden, as well as roles within established businesses that engage with healthcare. Examples of initiatives include: • Training programs aimed at fostering the creation of new ATMP companies (targeting researchers, clinicians, and startups/entrepreneurs). • Enhanced competence supply and training for SMEs. • Coaching, strategic analysis, and dialogue for competence planning, such as supporting businesses by analyzing the skill requirements outlined in their business plans and creating a tailored competence development plan. Analyses may also include identifying skill gaps for companies looking to transition towards ATMP activities. • Competence development focused on specific skills required for ATMP development, based on the cross-sectoral catalog of ATMP-related competence development efforts (preliminary version, to be refined throughout the project). See section 6.2.1.1.	○ SU ○ CCRM Nordic ○ SSP ○ GU ○ Chalmers Collaboration with: ○ LIF ○ SwedenBIO

Strategic priority 3: Increase awareness of ATMP among the public and decision-makers.	
Activity	Organization
3.1 Develop and make available an ATMP Introduction Course for a wide range of target groups (e.g. decision-makers, professionals outside the ATMP field). The course should be "popular science" oriented and patient-centered, with no commercial affiliation. Duration: approximately 15-30 minutes, accompanied by relevant communication materials.	○ SU ○ CCRM Nordic Support from: ○ LIF ○ SwedenBIO
3.2 Develop and offer ATMP educational courses at universities for the public and decision-makers Courses would introduce ATMP, including ethical considerations, for example, earning 2.5/5 credits. Open to all, including students, professionals and retirees.	○ GU ○ Chalmers
3.3 Establish collaborations with organizations that have direct communication with the public and decision-makers to raise awareness For example, digital seminar series, leveraging existing collaborations such as between LIF and Sahlgrenska University Hospital.	○ SU/VGR ○ LIF ○ SwedenBIO

Strategic priority 4: Drive the advancement of ATMP through long-term collaboration between industry, healthcare and academia.	
Activity	Organization
4.1. Establish a cross-sector "ATMP Training" Center Establish an ATMP Training Center in collaboration with industry, academia, and healthcare (including CCRM Nordic, Sahlgrenska University Hospital, Chalmers University of Technology, the University of Gothenburg, and Sahlgrenska Science Park). The Center's activities will be conducted across multiple physical locations among the participating partners, depending on the facilities most suitable for the target audience and content, rather than being based in a single physical building. The Center's core mission is to provide competence development initiatives for industry and entrepreneurs (both existing and potential) and to coordinate collaboration efforts among all participating entities. This includes organizing speakers, facilitating connections for student projects or internships, coordinating the use of facilities, and systematically linking to national and international initiatives. The Center will serve as a "single point of entry" for skills development activities for businesses and ATMP stakeholders. Part of establishing the Center involves exploring collaboration opportunities with the simulation center at Sahlgrenska University Hospital.	○ CCRM Nordic ○ SU ○ GU ○ Chalmers ○ SSP Collaboration with: ○ LIF ○ SwedenBIO

4.2 Encourage and strengthen incentives for adjunct positions, affiliations and shared roles Promote more adjunct and affiliated positions related to ATMP at universities. Strengthen incentives for adjunct positions and affiliations within Region Västra Götaland (primarily Sahlgrenska University Hospital) and in established businesses (where some initiatives are already in place). This approach enhances access to expertise from healthcare and leading companies from a competence supply perspective. One suggestion is to explicitly emphasize ATMP as a priority area. Initially, these efforts will focus on established businesses, with potential expansion to healthcare depending on resource availability. Encouraging and providing incentives for shared roles is also essential, as they play a critical role in competence development. Shared roles are particularly relevant between universities and university hospitals, and between Sahlgrenska University Hospital and the nationally funded innovation infrastructure, CCRM Nordic.	○ VGR ○ GU ○ Chalmers ○ SU ○ CCRM Nordic ○ LIF (member companies) ○ SwedenBIO (member companies)
4.3 Develop and formally establish a regional ATMP collaboration function, with competence development as a central focus Establish a regional collaboration function for ATMP, mirroring the recently established national coordination function for ATMP. The aim is to intensify collaboration and build a formal structure that acts as a driving force, consolidating activities and developing a strategy for prioritized development areas within ATMP, with competence development being a top priority. The regional collaboration function can create specialized working groups to address various issues, with a planned group dedicated to competence development. Examples of tasks include: • Leading and driving the work outlined in this joint action plan to strengthen ATMP competence supply in West Sweden. • Coordinating the use of existing infrastructure, leveraging current collaborations between academic and public entities and expanding them to include industry. • Connecting existing research networks in ATMP, ensuring all relevant researchers are invited. The working group on competence development will also address the priority need for talent collaboration, updating and enhancing an existing website to provide a comprehensive overview of the life science sector in West Sweden. This includes information and links describing ATMP companies and the surrounding ecosystem. Coordination with ATMP Sweden, which compiles information on ATMP companies in Sweden, will be undertaken. *Additional identified needs related to enhanced talent collaboration will be addressed within existing structures for this purpose.*	○ GU ○ Chalmers ○ SU ○ SSP ○ CCRM Nordic Collaboration with: ○ LIF ○ SwedenBIO

An overall timeline for the implementation of the action plan has been developed; see 6.2.3.

6.2.1.1 Preliminary cross-sectoral catalog of competence development initiatives in ATMP

A. **General introduction** – An introduction to ATMP, including an overview of the healthcare sector's role as an innovation partner to industry, along with regular updates on news and advancements.
B. **Research & Development** – In-depth theoretical knowledge and the process of developing an idea into an approved product, covering regulatory, clinical, and commercial aspects.
C. **Clinical trials** – Management of clinical studies related to ATMP. This includes design and analysis of clinical trials, ATMP-specific administration, and legal considerations for clinical studies, including compliance with Clinical Trial Regulations (CTR), submissions to authorities, and the EU portal CTIS (Clinical Trial Information System). It also covers budget planning, contract drafting, and training for research nurses.
D. **Clinical practice** – Referral processes and knowledge of current indications, preparations such as donation and the collection of starting materials, drug administration, aftercare, and follow-up (managing side effects), routines, traceability, documentation, and agreements with pharmaceutical companies.
E. **Preparation and production** – Preparation of in-vivo gene therapies, GMP manufacturing and production (both practical and theoretical), cleanroom skills (practical skills, routines, and requirements, isolators), practical laboratory skills (cell culture, sterile work, assays, and bioanalysis), as well as supply chain and logistics (cold storage and transportation).

6.2.1.2 Gender equality and equal treatment – ATMP as an emerging field with potential for impact

The pre-study has mapped the skill requirements of existing personnel within healthcare, industry, and academia, as well as the future competencies needed in connection with ATMP, which will drive new hires, entirely new professional roles, and the establishment of new companies. This evolving field offers a unique opportunity to promote both gender equality and equitable treatment across the sector. By embedding awareness from the outset about how to communicate the ATMP field and the necessary skills to engage both men and women, we can ensure the field appeals to everyone, regardless of gender or background.

In summary, for continued progress in the ATMP field, promoting gender equality and equitable treatment is essential for both the structural development of the field and in building relevant competencies.

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In summary, for continued progress in the ATMP field, promoting gender equality and equitable treatment is essential for both the structural development of the field and in building relevant competencies. Thus, it will provide an integrated, central perspective on the implementation of the action plan.

6.2.2 Implementation of the action plan

During the development of the action plan, it became evident that certain activities fall within the regular mandates of the respective organizations and can therefore be managed within the scope of existing resources. However, for most activities outlined in the joint action plan, the pre-study concluded that additional resources will be needed for implementation. ATMP is a new field, and the identified competence needs cannot be met at the pace required without the infusion of additional resources.

Based on this, two funding applications have been submitted alongside the preliminary study:

1. **Application to the European Social Fund (ESF) for "Competence development ATMP, for healthcare professionals."** This application aims to secure resources to support the implementation of activity 2.1. The application was approved, and the project runs from August 2024 to August 2026.
2. **Application to the European Regional Development Fund (ERDF) for "Competence development in ATMP"** under the call "Strengthen the Competence of West Sweden's Business Sector" (submitted in September 2024). This application aims to secure resources to support the implementation of activities 1.1, 1.4, 2.2, 3.1, 3.3, and 4.1-4.3 from 2025 to 2028.

The two applications complement each other by jointly strengthening competencies in healthcare (ESF) as well as in industry and academia and enhancing structures for long-term competence development (ERDF). Enabling a parallel upskilling effort is highly valuable for elevating the so-called triple helix model (industry, academia, and healthcare), which is fundamental to competitiveness and success in the life science sector.

Both applications and the forward-looking plan reflect the pre-study's insights on gender equality, equity, and sustainability in the design of activities and the project setup.

Given that the scope of the preliminary study covers the years 2024-2027, the final year of 2027 is highlighted in the visualization below. As shown, several activities are planned to continue beyond 2027. Activities that visually start before the timeline are those that are already underway today.

6.2.3 Overall timeline for the implementation of the joint action plan

Figure 9. Overall timeline for the implementation of the joint action plan for 2024-2030.