



Annual report 2024

September 2024





Content

- 1. ATMP landscape overview and developments
- 2. Company landscape
- 3. Research and publications
- 4. ATMP in healthcare
- 5. Clinical trials and horizon scanning
- 6. Job opportunity analysis
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Executive summary

Since 2018, the ATMP field in Sweden has witnessed substantial progress with a rapidly evolving infrastructure, clinical activity and industrial landscape

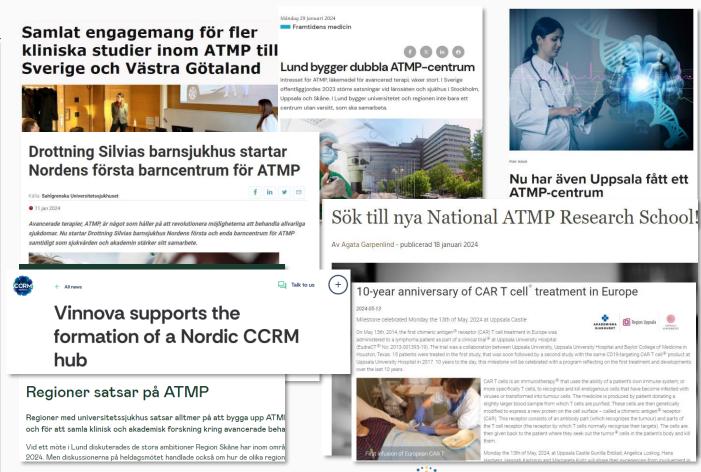
- An expanding infrastructure including today's 4 ATMP centers and numerous ATMP initiatives both on national and regional level
- 25 SME ATMP Developers in Sweden, +4 new companies from 2018
- +183% growth employees among SME ATMP developers (+220 employees)
- 48 active ATMP clinical trials in Sweden, 14 Ph III
- 7 ATMPs recommended by NT-rådet
- 6 ATMPs currently investigated by TLV
- High research activity and increasing number of publications
- On a global level, there are +1700 active ATMP clinical trials, including almost 100 in phase III





Since 2018, the ATMP field in Sweden has witnessed substantial progress with a rapidly evolving infrastructure and clinical use

ATMP development in Sweden (2018-2024*) **ATMP centres** inaugurated Started clinical ATMP trials 39 (2018 - 2024*)New **ATMP SME Developers** in Sweden Active ATMP related initiatives in Sweden



III triathlon



ATMP2030 in short

- The ATMP2030 project was established in 2019, as one of several initiatives under ATMP Sweden
- The project aims to establish a 'Vision Driven Innovation Milieu' for long-term transformation of the systems required for successful development and implementation of advanced therapy gene and cell therapeutic products, Advanced Therapy Medicinal Products (ATMP)
- Expected effects following the project are that Swedish healthcare and patients can access the developments within ATMP and make Sweden more attractive for future investments in the area

Subgoals of ATMP 2030



National coordination and strengthening of the network, as well as increased international contacts and collaborations



Increased capacity for industrial development and manufacture of ATMPs in Sweden



Effective processes for availability of cost-effective ATMPs within Swedish healthcare



Increase knowledge and secure future competence needs



Organization and financing model for sustainable continuation

Partners to ATMP2030





























CombiGene















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The Swedish ATMP landscape – a multi-cluster

landscape with strong links across the regions **Göteborg** Umeå ATMP Centre University hospital Center for Gene and Cell therapies CAMP Coordinator University hospital

ATMP 2030 Coordinator

¿ CCRM Nordic

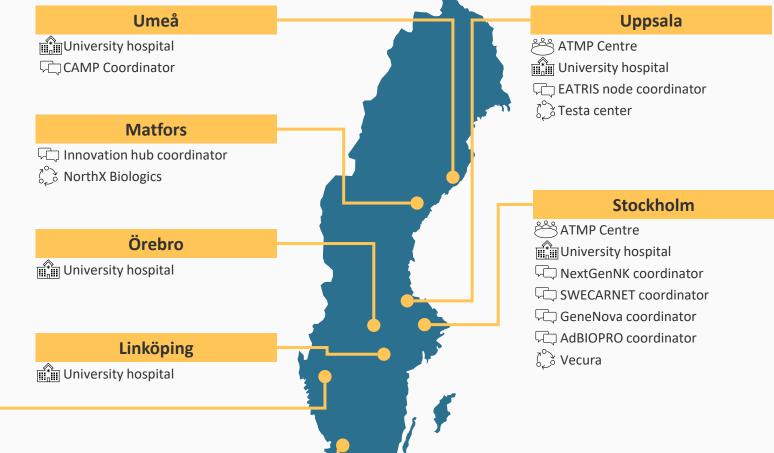


ATMP Centre

University hospital

IndiCell Coordinator

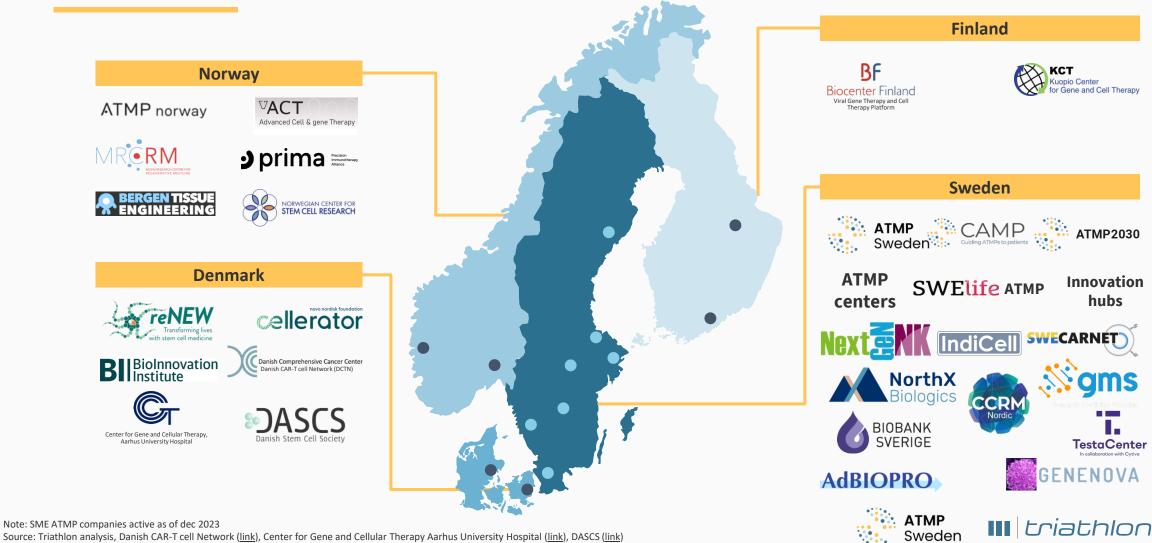
ATMP Research School coordinator







An expanding ATMP ecosystem in the Nordics



Selected highlights of ATMP field in Sweden 2018 to 2024 show many important events over the years

- ATMP Sweden started
- Testa Center opened
- CAMP (Centre for Advanced Medicinal Products) - an ATMP Sweden initiative started

- Karolinska University Hospital opened first Swedish Comprehensive Cancer Centre
- Sahlgrenska ATMP center inaugurated

2020

NextGenNK – an ATMP Sweden initiative started

- ATMP2030 entered second phase
- Creation of **ATMP center network**
- Report on ATMP education and future competence needs released

2022

- Advanced Cell and Gene therapies for Children **center** opened in Sahlgrenska
- Genomic Medicine Sweden (GMS) received 49 MSEK for research related to precision medicine
- Coordination function for ATMP inauguated



2021



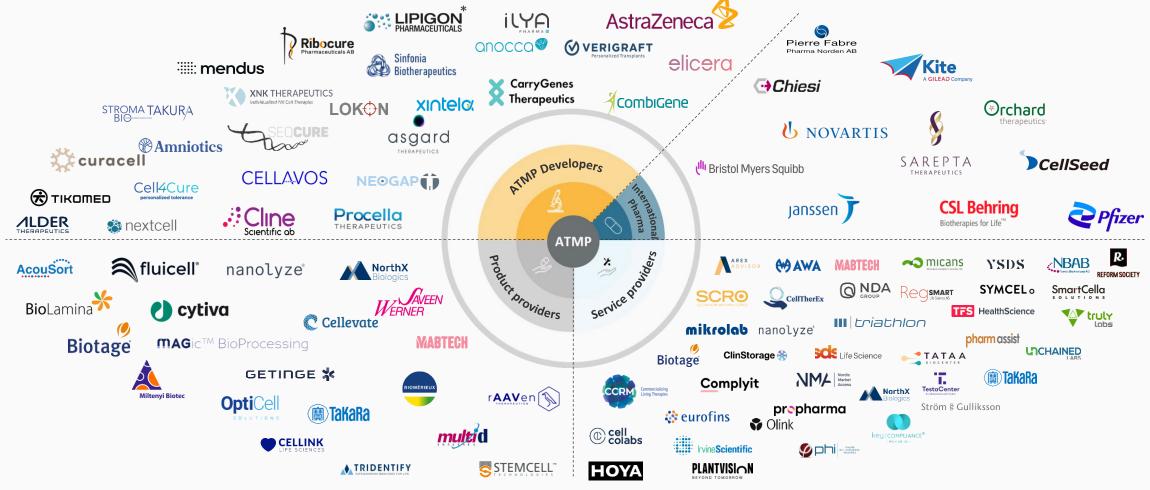


2024

2018

2019

A vibrant and diverse ATMP industrial landscape



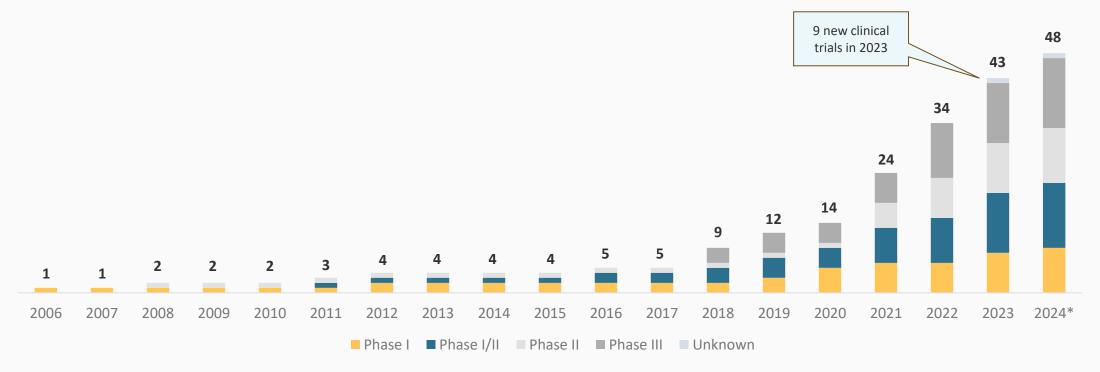




Development of clinical ATMP trials in Sweden

Cumulative # started clinical ATMP trials in Sweden 2006 to 2024*

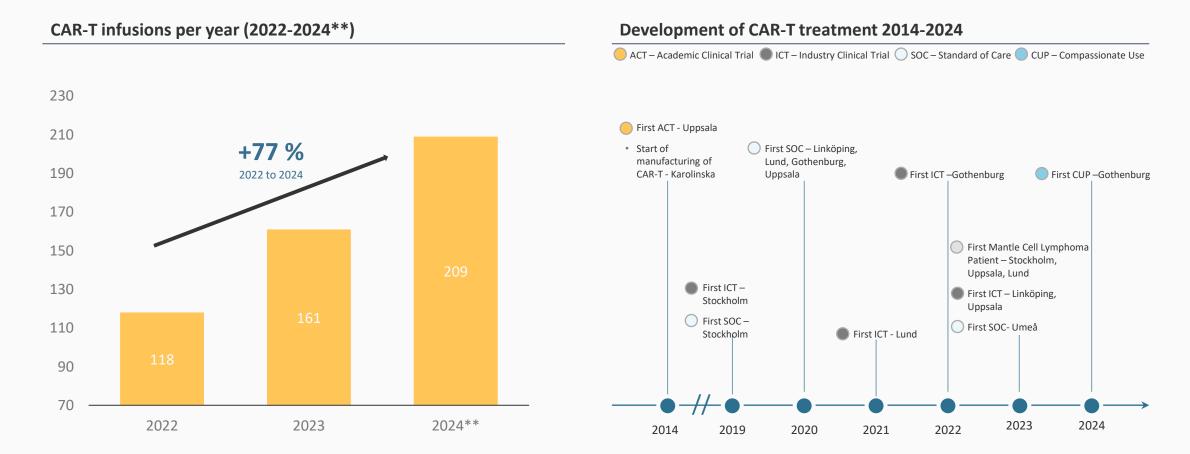
Based on start year for currently active trials







Significant increase of number of CAR-T treatments since the first at Uppsala University Hospital* in 2014





ATMP





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Company landscape Selected highlights

- 25 SME ATMP developers in Sweden, 4 new since 2018
- Swedish ATMP developers are spread across the country with most SME developers found in Stockholm, followed by Lund/Skåne
- 311 employees were reported for Swedish SME ATMP developers in 2022
- From 2018 to 2022, there was an 183% increase in employees for ATMP SME developers in Sweden
- Sweden makes up the majority of SME developers in the Nordic countries with 25 out of 46 companies
- A multitude of international pharmaceutical companies have presence at some level in the Nordics
- 15 out of 25 Swedish SME developers have their research focus area on sCTMP, followed by GTMP with 8 companies







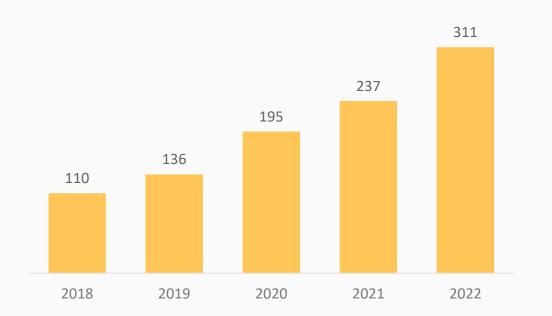
The ATMP SME developer field in Sweden is growing

of employees of SME drug developer companies

of SME drug developer companies

+183 % employees

since 2018



+4 companies*

since 2018



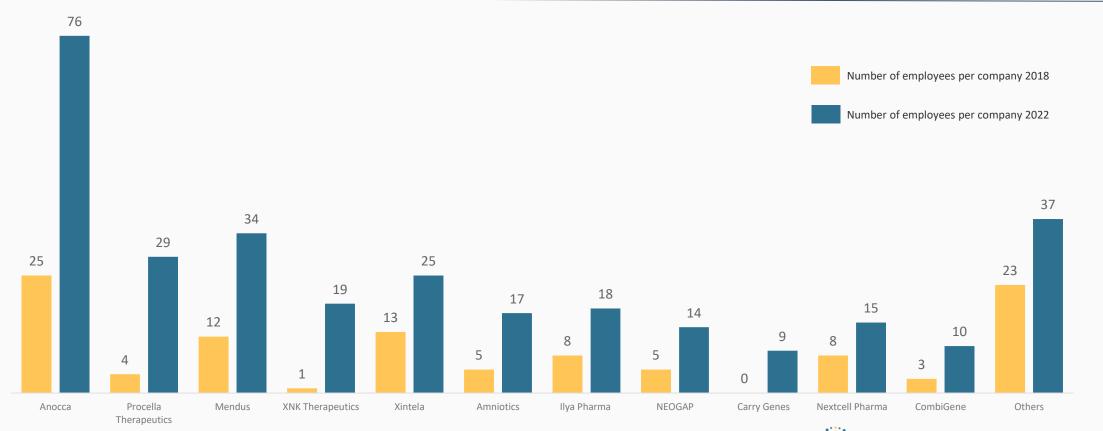
Note: *ldogen filed for bankruptcy in 2023 and Cell4Cure was created and acquired Idogen's technology platform in the end of 2023. Number of employees as per direct employees in Swedish AB, i.e. not taking into account e.g. consultants. Only companies regarded as active in dec 2023 were used for data collection, i.e. company data from Idogen was not used for employee count. Source: Triathlon analysis, Business Retriever

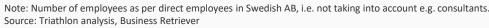




SME ATMP developers experienced high employee growth 2018-2022, collectively adding 201 employees

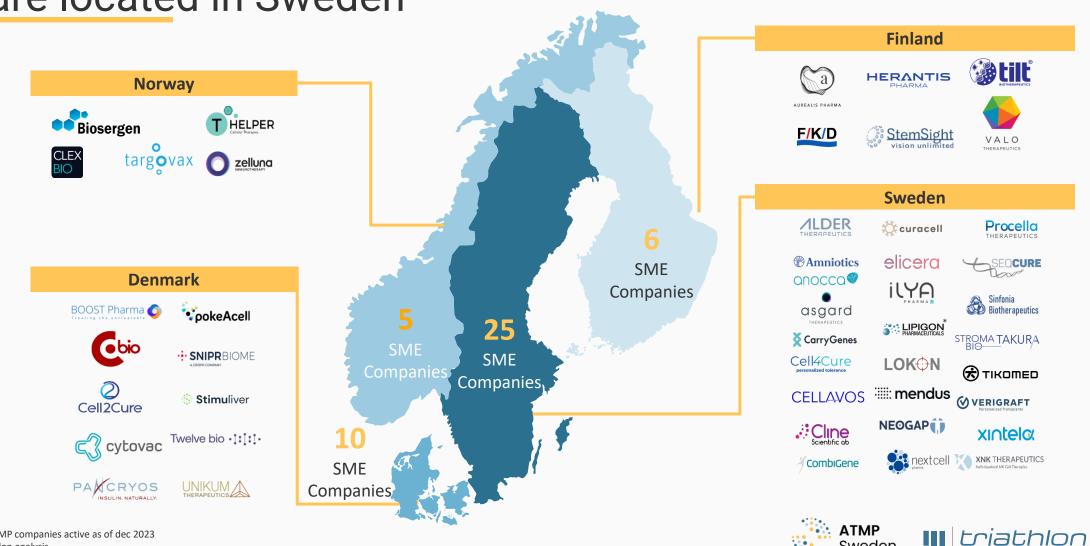
Employee growth per company







Out of 46 identified Nordic SME ATMP developers, 54% are located in Sweden

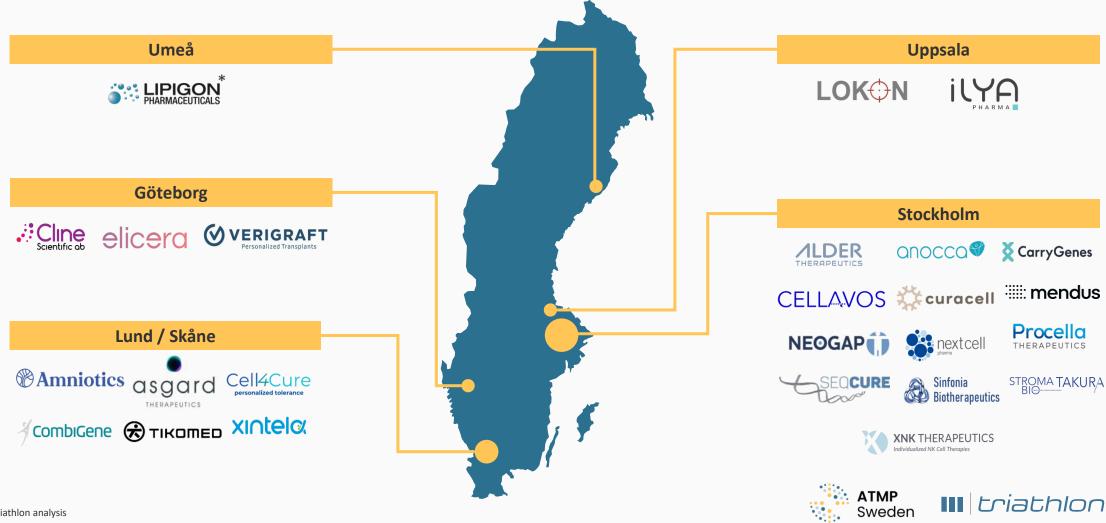


Note: SME ATMP companies active as of dec 2023 Source: Triathlon analysis

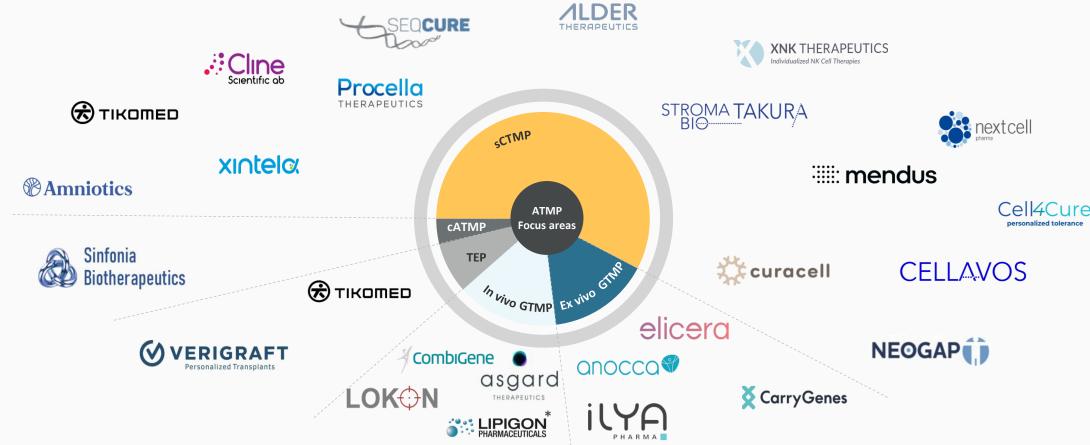
Several international companies with ATMP-related R&D have R&D and/or marketing activities in the Nordics



Swedish ATMP SME developers are divided across the country, with a majority of companies in Stockholm



sCTMP is the leading focus area of ATMP SME developers in Sweden; 15 of 25 companies develops sCTMP



Note: Tikomed has 2 reported focus areas, scTMP and TEP, and was therefore added twice. Categorization for Cellavos, Curacell, Cell4Cure and Sequre estimated based on descriptions on company websites

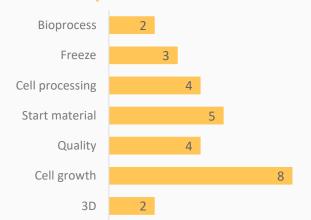






Important support functions for ATMP developers are covered by the widespread service and product providers in Sweden

Product providers







? cytiva

Miltenyi Biotec



multi d











GETINGE *



CELLINK









Service providers











HOYA









key2compliance6









SCRO

































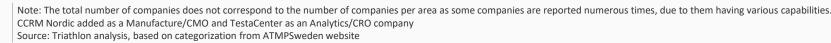
NBAB















Swedish SMEs ATMP developers have received 16+ MEUR in funding from EISMEA programs

Identified Swedish ATMP SMEs that received funding from EISMEA

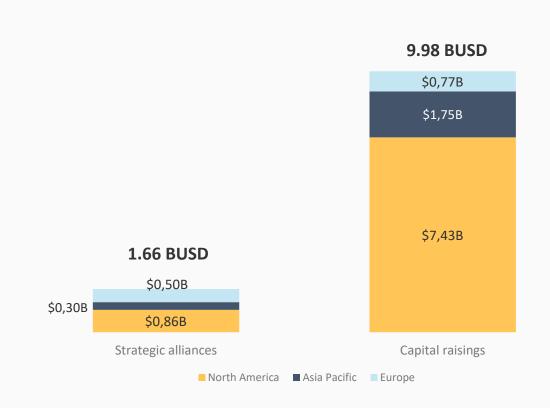
SME	Project	Program	Project timeline	Funding received by project
elicera	iTANK: a universal technology to boost the efficacy of CAR T cell therapies by inducing dual mode-of-action	EIC Accelerator	n/a	2 500 000 €
NEOGAP (1)	Innovative approach to an individualized T-Cell immunotherapy for cancer using Personalized Tumor Trained Lymphocytes (pTTL) that is reliable, costeffective, scalable and easy to implement	EIC Accelerator	n/a	8 119 920 €
⊘ VERIGRAFT	Personalized Tissue-Engineered Veins as the first Cure for Patients with Chronic Venous Insufficency	EIC Accelerator	2017–2019	2 184 604 €
Sinfonia Biotherapeutics	Tailored cell-based therapies for frontotemporal dementia and related genetically definded CNS orphan indications	EIC Accelerator	2018–2019	50 000 €
asgard THERAPEUTICS	TrojanDC; gene therapy that delivers immune-genes into the tumor and reeducates cancer cells to become anti-tumor immunne cells	EIC Accelerator	2019–2020	50 000 €
asgard THERAPEUTICS	TrojanDC - A BREAKTHROUGH DEEP-TECH INNOVATION FOR CANCER IMMUNOTHERAPY	European Innovation Ecosystems	2023–2024	75 000 €
CombiGene	A novel gene therapy for epilepsy; Clincal validation of CG01 as a novel gene therapy for the treatment of drug-resistant epilepsy patients	EIC Accelerator	2018–2021	50 000 €
ILYA	Wound healing ILYA-style; developing the EV100 drug candidate to heal chronic wounds in patients with diabetes	EIC Accelerator	2018–2019	2 992 575 €
ILYA	Wound healing ILYA-style 2; conduct exploratory clinical trials (Phase IIa) of their drug candidate, ILP100 Tropical, in treatment of non-healing wounds	EIC Accelerator	2020–2023	50 000 €





The global ATMP funding of 2023 was ~10 BUSD, with only 8% raised in Europe

Total deal values of 2023 in ATMP field





A total of **9. 98 BUSD** was raised as **capital** in 2023 in the field of regenerative medicine



1.66 BUSD was raised through strategic alliances, more specifically partnerships and licensing agreements



Majority of funding was raised in North America (74%). **8% of funding was raised in Europe**







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Publications Selected highlights

- Steady growth of number of ATMP related publications for 10 selected European countries (EU10*) since 2009, peaking in 2021 with 5 064 publications
- With 20,5 publications per capita, Sweden had the highest publication productivity among EU10 in 2023
- UK holds the majority of ATMP publications between 2009-2024, followed by Germany and Italy
- Sweden had a 42% increase in annual ATMP related publications from 2020 to 2022, going from 189 to 268
- CAR-T related publications in Sweden have increased with +350% between 2023 and 2018, going from 10 to 46 annual publications



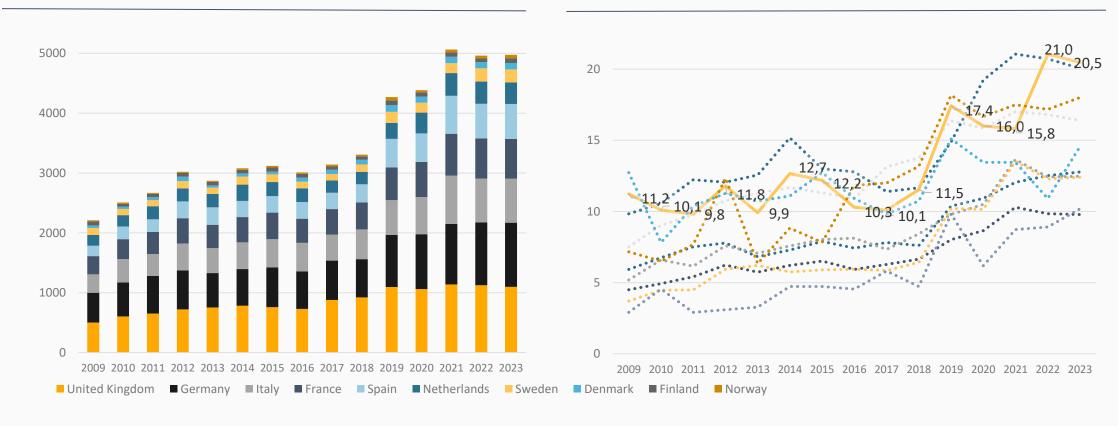




Steady growth of number of publications within ATMP in EU10* since 2009, with a peak in 2021

Total number of publications per year, per country**

Publication productivity per million inhabitants (as of 2024)

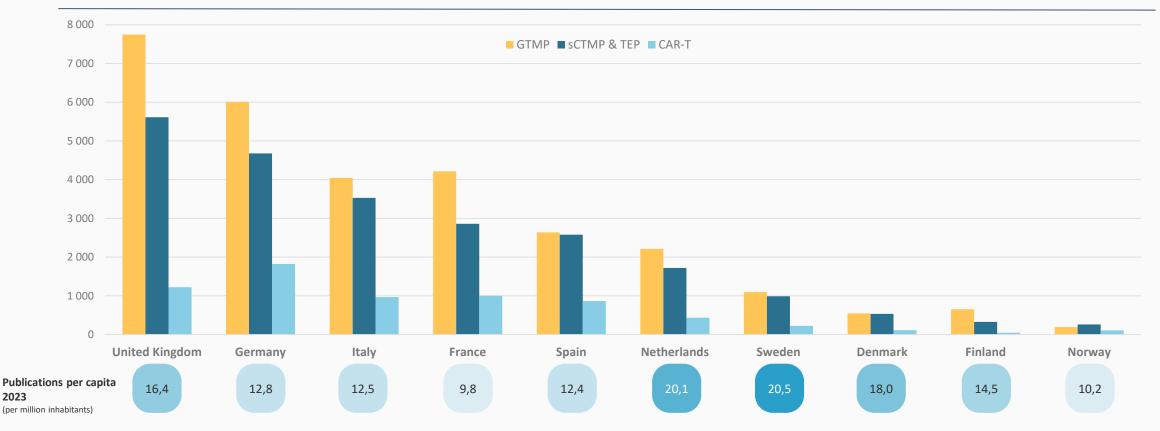






UK is a leading country in EU10* in terms of publications** in the ATMP field between 2009-2024

Total published research articles** within ATMP, between 2009-2024



Note: *EU10 covers Scandinavia and top 6 countries in Europe. **Publications can cover multiple topics and have collaborating authors in multiple countries – sum of total publications will not be equivalent to topic / country total. For searches boolean search string was used, see details in appendix.

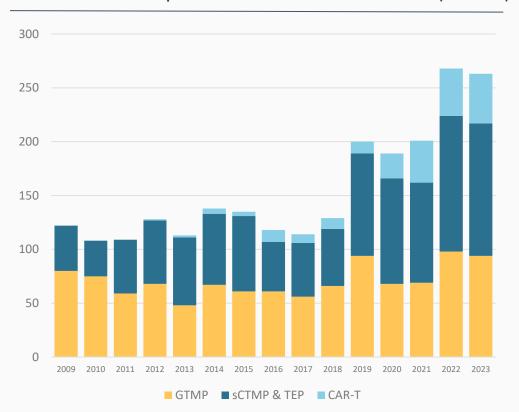
Source: Web of Science



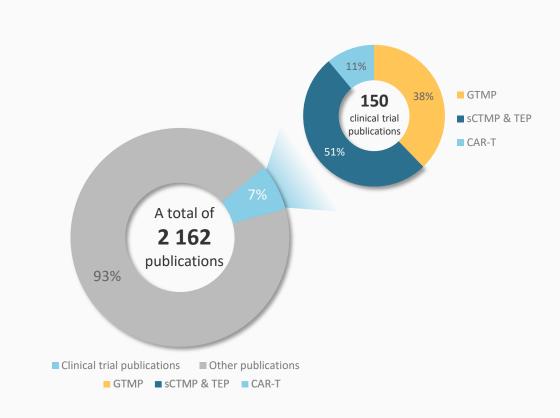


Unlike for full EU10*, the number of ATMP related publications continue to increase in Sweden

Number of ATMP related publications** from Sweden affiliated sources (2009-2023)



Total publications** of ATMP in Sweden and the different types (2009-2023)



Note: *EU10 covers Scandinavia and top 6 countries in Europe. **Publications can cover multiple topics – sum of total publications will not be equivalent to total for all topics individually. For searches boolean search string was used, see details in appendix.

Source: Web of Science







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ATMP in Healthcare

Selected highlights

- 4 ATMP centers have been established at four of the seven university hospitals in Sweden located in Gothenburg, Lund, Stockholm and Uppsala
- 7 approved and NT-recommended ATMP therapies available in Sweden, where 4 are CAR-T therapies and 3 are gene therapies
- 146 CAR-T infusions given to patients as standard of care
- 5 ATMPs were approved by EMA in 2022
- 19 out 26 of EMA approved therapies are gene therapies
- The timeline from EMA approval to NT-rådet first indication recommendation varies, with a seen minimal length of 8 months
- 6 EMA approved ATMPs are currently under investigation by TLV and NT-rådet







Current ATMP healthcare in Sweden

Nation-wide on approved ATMPs

7 approved therapies recommended by NT-rådet

146 CAR-T infusions*

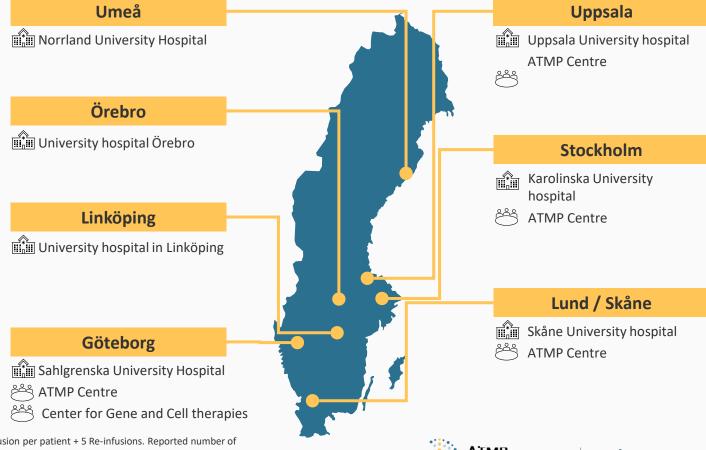
- Zolgensma
- Luxturna
- Yescarta
- Kymriah
- Tecartus
- Libmeldy
- Breyzani

- 8 Luxturna treatments
- Zolgensma patients
- 1 Libmeldy patient

Hospitals providing treatment

7 Hospitals providing treatments

4 Active ATMP centers



Note: CAR-T numbers as those reported as standard of care according to SweCarnet, assuming 1 infusion per patient + 5 Re-infusions. Reported number of treatments outside CAR-T infusions are from April 2024

Source: Triathlon analysis, SWECARNET, CAR-T treatments May 2024 (link), other treatment data based on presentation on ATMP treatment held in April 2024



Sweden now has 4 ATMP centers, creating a strong infrastructure to support ATMP clinical use

Uppsala University Hospital

(Uppsala)

- First in Europe to give CAR-T treatment in May of 2014 → Celebrated 10 year anniversary 13/5
- ATMP centre collaboration between UU, UUH, RU. Inaugurated sept 2023



Karolinska University Hospital

(Stockholm)

- Vecura facility GMP manufacturing of 50+ different ATMP products for more than 800 patients in clinical trials since 1996
- The first pre-GMP facility in the Nordics inaugurated 2019



Sahlgrenska University Hospital

(Gothenburg)

- ATMP Center created in 2020, including Center for Cell- and Gene Therapies from 2024
- GMP manufacturing of 3 ATMP products for approx. 2200 patients since 1987, with tissue establishment for start materials



Skåne University Hospital (Lund)

- LU-ATMP, university linked ATMP center inaugurated June 2023
- Lund Stem Cell Center

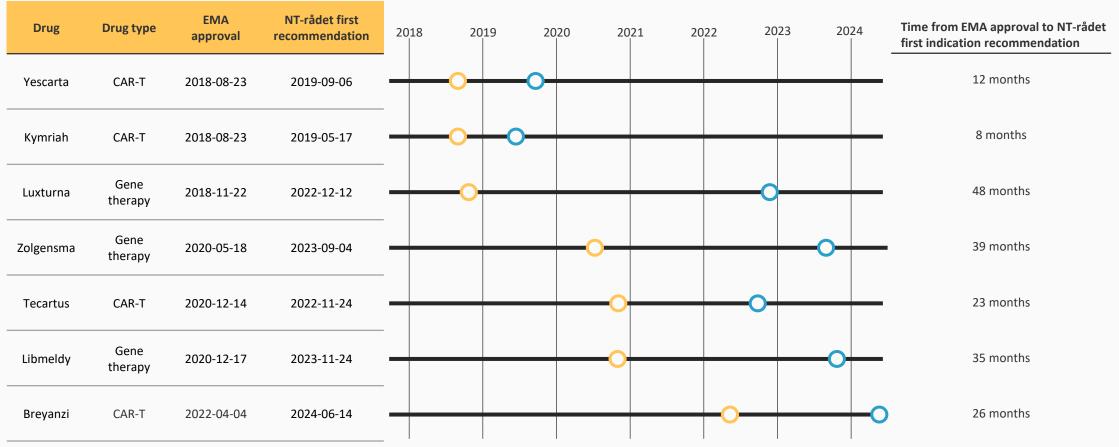






The time from EMA approval to NT-rådet recommendation varies between 8-48 months

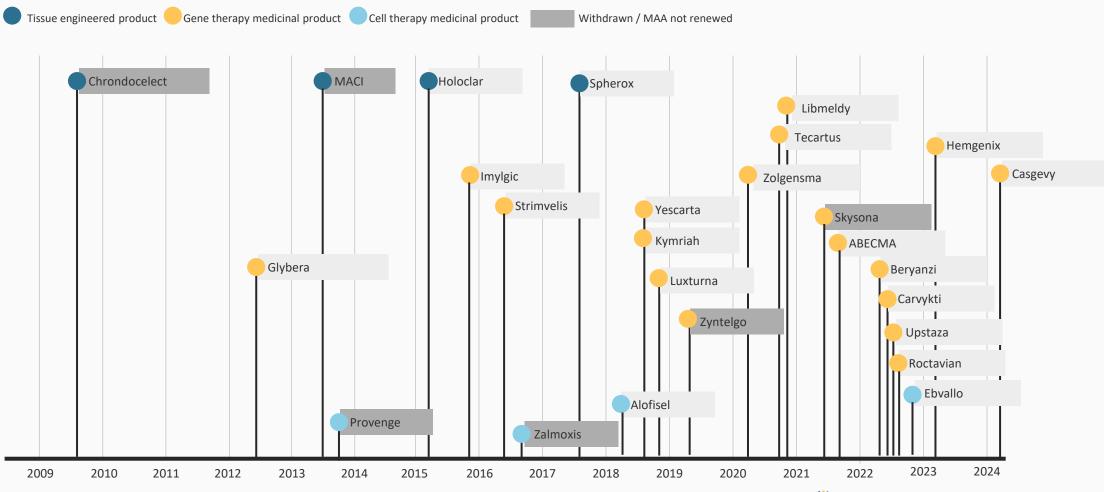








EMA approved ATMPs have expanded over the last six years, with 17 approvals between 2018 to 2024





Six therapies recently approved by EMA are under investigation or have planned assessment by NT-rådet











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Clinical trials and horizon scanning Selected highlights

- Currently 48 active clinical ATMP trials via the ATMP centers in Sweden, with 9 new clinical trials initiated in 2023
- Swedish companies have 60 ongoing ATMP projects, where 58% are in the preclinical phase
- 33 out of 44 ATMP classified clinical trials are GTMP
- 1 751 active ATMP clinical trials globally, with 43% in Phase I
- Over 400 industrial clinical ATMP trials initiated in 2023 globally, +300% compared to 2013
- China has grown from close to no studies in 2008 to >40% of all industrial clinical ATMP trial sites in 2023
- 99 ATMPs are in clinical phase III globally
- At least 6 ATMPs are in the final stages of the drug pipeline for approval in EU

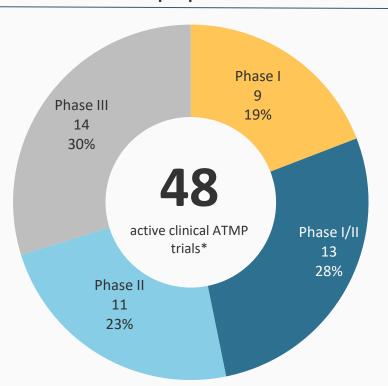




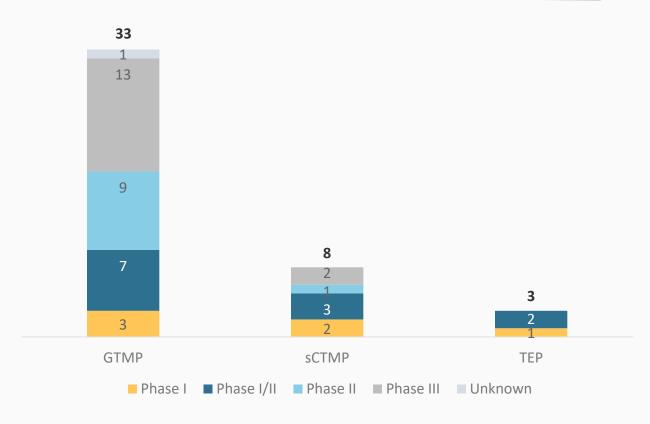


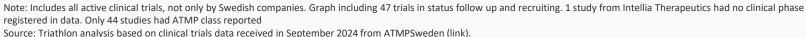
In total, there are currently 48 active clinical ATMP trials via the ATMP centers in Sweden

Clinical ATMP trials per phase



ATMP classes of active clinical ATMP trials





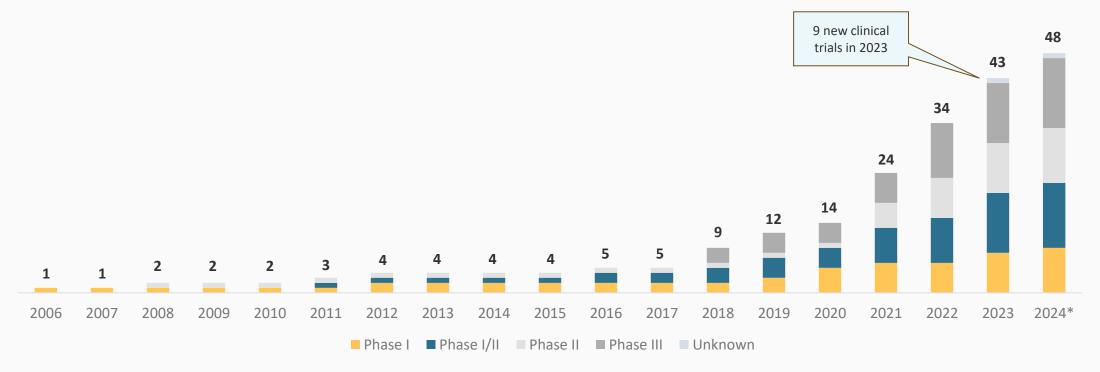




Development of clinical ATMP trials in Sweden

Cumulative # started clinical ATMP trials in Sweden 2006 to 2024*

Based on start year for currently active trials

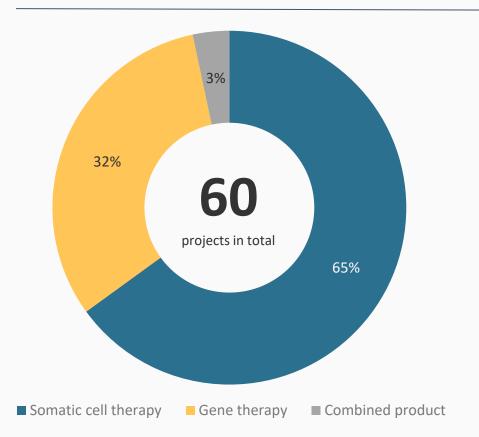




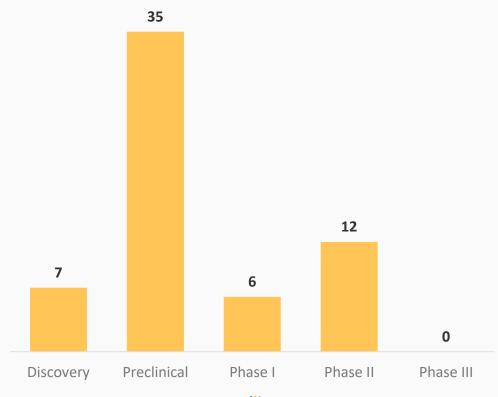


As of March 2023, Swedish companies had 60 ongoing ATMP projects, with majority in the preclinical phase

Ongoing Swedish ATMP projects as of March 2023, divided by therapy



Ongoing Swedish ATMP projects as of March 2023, divided by phase





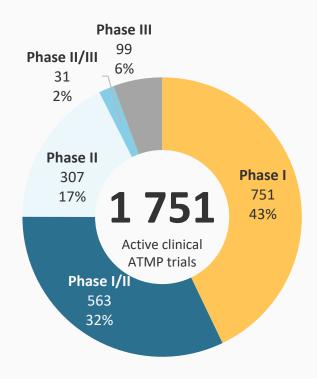


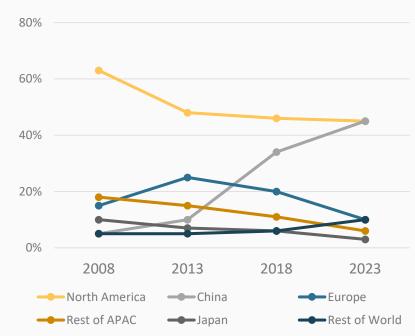
Global clinical ATMP trials are growing, with about +300% industrial trial starts in 2023 compared to 2013

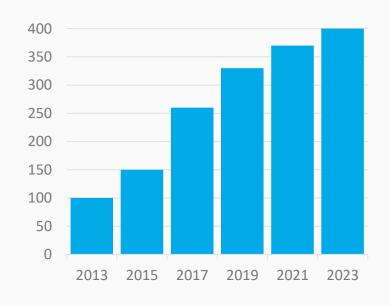
Clinical ATMP trials per phase

Sites of industrial clinical ATMP trials (2008-2023)*

Started industrial clinical ATMP trials*





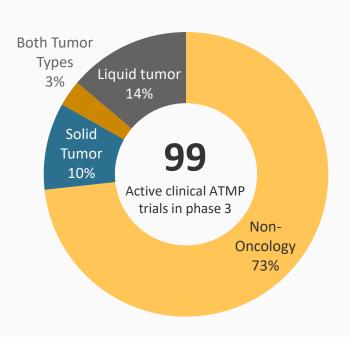






Horizon scan: On the verge of contributing to available therapies for patients, nearly 100 ATMPs are in late clinical stage globally

Indications for global clinical phase 3 trials



Examples of therapies in final stages of the drug pipeline for 2024

Therapy	Developer	Indication	Status
Casgevy	Vertex Pharmaceuticals	beta-Thalassemia Anemia, Sickle Cell	Feb 13 2024: Approved in the EU
BEQVEZ	Pfizer	Hemophilia B	2024 decision possible in the EU
Vyjuvek	Krystal Biotech	dystrophic epidermolysis bullosa (DEB)	2024 EU approval decision possible in H2 2024
RP-L102	Rocket Pharma	Fanconi Anemia	2024 decision possible in EU
Elevidys	Sarepta therapeutics	Duchenne muscular dystrophy (DMD)	2024 EMA MAA submission possible
Giroctogene fitelparvovec	Pfizer & Sangamo	Hemophilia A	EMA MAA submissions possible in 2024







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Job opportunity analysis Selected highlights

- 700+ identified ATMP job postings in Nordics 2020-2024
- With 519 job postings, Denmark takes the lead in the Nordics, followed by Sweden with 156 postings between 2020 to May 2024
- Novo Nordisk is the main employer with 362 job postings, Astra Zeneca follows with 97 postings
- Swedish job postings are dominated by jobs in Gothenburg with 60% out of all jobs
- Astra Zeneca has 60% of all ATMP job postings in Sweden

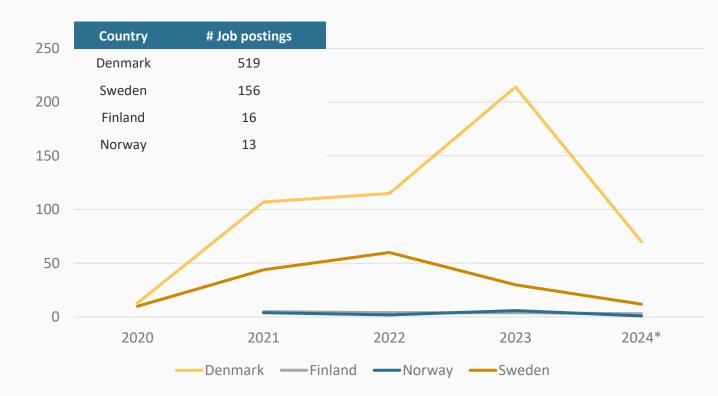






Denmark and Novo Nordisk AS leads job postings in the Nordic countries (2020-2024*)

Total job posting count for Nordic countries (2020-2024*)



Top 10 organizations, in # of job postings

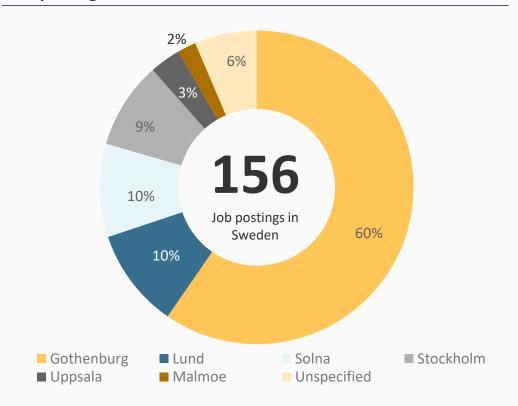
Organization	# Job postings
Novo Nordisk AS	362
AstraZeneca Plc	97
Fujifilm Diosynth Biotechnologies Uk Ltd	68
Bristol-Myers Squibb Co	30
Ferring Pharmaceuticals SA	30
AGC Biologics Inc	27
Gilead Sciences Inc	17
Hansa Biopharma AB	16
PPD Inc	8
Novartis AG	7





A majority of Swedish ATMP job postings were found in Gothenburg, with Astra Zeneca as a main employer

Job posting division of cities in Sweden



Division of job postings per organization (2021-2024*)

Organization	# Job postings
AstraZeneca Plc	94
Hansa Biopharma AB	16
Bristol-Myers Squibb Co	13
ProPharma Group Holdings LLC	7
Eurofins Scientific SE	5
Gilead Sciences Inc	5
Parexel International Corp	5
Johnson & Johnson	3
Novartis AG	3
GSK / MaxCyte / Pfizer/ PPD/ PTC Therapeutics	1 / company







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Glossary

- ATMP: Advanced Therapy Medicinal Products, including Gene therapy, Cell therapy and Tissue engineering
- CAR-T Therapy: Chimeric Antigen Receptor T-cell therapy; immunotherapy that modifies a patient's T-cells to target & destroy cancer cells
- cATMP: Combined Advanced Therapy Medicinal Product. Medicinal product incorporating an advanced therapy medicinal product (ATMP) plus one or more medical devices as an integral part of the product
- Cell therapy: Addition of healthy cells to replace disease/damaged cells in the patient
- CMO: Contract Manufacture Organization
- Combined product: See cATMP
- CRO: Contract Research Organization
- EISMEA: European Innovation Council and SMEs Executive Agency
- EMA: European Medicines Agency
- EU10: In this report Germany, UK, France, Spain, Italy, Netherlands and the Nordics
- **Ex vivo:** Occurring outside a living organism
- Gene therapy: Technique to deliver recombinant nucleic acids, typically an entire gene, into cells in order to modify gene expression with the aim of treating or preventing disease

- **GTMP:** Type of advanced therapy medicinal product (ATMP) containing an active substance consisting of or containing a recombinant nucleic acid, which is administered as a gene therapy for therapeutic, prophylactic or diagnostic purposes
- In vivo: Within the normal biological context of a living organism
- NT-rådet: An expert group with hospital-regional representation that is part of the collaborative model for medicines. Decides which medicines should be included in the national process for orderly introduction and has a mandate from the regions to make recommendations on the use of these medicines
- Regenerative medicine: Medical approaches aimed to repair, replace or regenerating damaged tissue, including cell therapy, gene therapy, tissue engineering, organ transplants etc
- sCTMP: Somatic cell therapy see cell therapy medicinal product
- **SME:** Small and medium-sized enterprises
- Tissue engineering: An array of techniques used to create artificial organs for transplantation into the body to repair or improve bodily functions
- **TEP:** Tissue Engineered Product. A medicine containing engineered cells or tissues, which is intended to regenerate, repair or replace a human tissue





Search strategy - Business Retriever

To analyze development of Swedish ATMP Developers, Business Retriever was used to retrieve data from annual reports via allabolag.se.

Since the annual reports of 2023 was not released for most of the chosen companies during the time for retrieving data, 2022 was given as the final year.

Data extraction method

- Identified ATMP SME developers
- ID numbers for companies identified
- Data download to Excel of annual reports 2018-2022 via business retriever based on ID numbers
- Data was managed based on download
- Data was crosschecked with annual reports on allabolag.se and company websites in cases where annual reports were missing

The Business Retriever database was accessed 2024-04-23





Search strategy - WebOfScience

The general search strategy and search terms have been kept similar to previous reports with smaller corrections in order to provide comparable results to previous ATMP Sweden reports. Due to more details provided in the Web of Science data, this database was used (instead of PubMed as in previous reports).

The strategy aims to include three ATMP types:

- Gene therapy medicines
- Somatic-cell therapy medicines & Tissue engineered products
- Tissue-engineered medicines.

Web of Science strategy for published research within advanced therapies

- Gene therapy medicinal product (GTMP):
 "gene therapy" (Topic) or "genetic therapy" (Topic) or "GTMP" (Topic)
- Somatic-cell therapy medicinal product (sCTMP) & Tissue engineered product (TEP):

"cell therapy" (Topic) or "cell-based therapy" (Topic) or "somatic cell therapy" (Topic) or "tissue engineered product"

- Chimeric Antigen Receptor (CAR) T-Cell therapy:
 "CAR-T" (Topic) or "CAR T-cell therapy" (Topic) or "chimeric antigen receptor T-cell therapy" (Topic)
- Clinical trials: "clinical trial" (Topic)

Web of Science strategy for countries

The following countries were included for separate analysis:

- Sweden
- Norway
- Finland
- Denmark
- United Kingdom (including England, Wales, Scotland, Northern Ireland)
- Germany
- The Netherlands
- Italy
- Spain
- France

The countries included were the same countries included in previous reports and were originally selected by RISE. France has been added due to a high activity

The published research per country was found by searching country per country.

The searches were filtered for type of article and publication dates between 2009-12-31 and 2024-12-31.

Web of Science was accessed 2024-06-12





Search strategy – EISMEA Swedish SMEs

EISMEAs datahubs for the following websites

- <u>European Innovation Ecosystems</u> datahub (eismea.eu)
- Horizon 2020 INNOSUP data hub (eismea.eu)
- COSME data hub (eismea.eu)

- EIC Pathfinder data hub (eismea.eu)
- <u>EIC Accelerator data hub (eismea.eu)</u>
- EIC Fast Track to Innovation data hub (eismea.eu)

The projects were filtered by searching for the Swedish SMEs*

CombiGene

Cline

ProCella

asgard

Amniotics

Cellavos

Ilya

TIKOMED

SeqCure

Sinfonia

Cell4Cure

Curacell

Verigraft

Xintela

Stroma

Elicera

Lokon

XNK

Mendus

Alder

CarryGenes

NEOGAP

NextCell

Lipigon

Anocca

* Full company names were not used to avoid irrelevant search results for terms such as "therapeutics"

EISMEA search method

- All Sweden ATMP SME developer companies was searched for in each respective database using the noted search terms
- Results where the Sweden ATMP SME developer companies received funding were compiled into a single common list
- The projects start and end year was noted together with funding received by the project (EU contribution)

The databases were accessed 2024-06-27





Search strategy - Global Data database

The following search criteria were used

- Focus on Nordic countries (Sweden, Norway, Finland, Denmark, Iceland)
- Regenerative Medicine Job Postings; AND
- Job Postings with "cell therapy", "gene therapy", "ATMP", "advanced therapy medicinal products", "tissue engineering" in Description
- Date Range: 1 Jan-2021 till 4-May-2024
- It was noted in the quote from Global Data that data was limited for small biotech companies

Data received from Global Data consisted of the following data

- Job ID
- Posted
- Closed
- Title
- Company
- City
- Country
- Seniority
- Theme
- Soft Skills

- Technical Skills
- Education Stream
- Occupation
- Min Salary(USD)
- Max Salary(USD)
- Salary(LCU)
- Min Salary(LCU)
- Max Salary(LCU)
- Job Descriptions

Data extraction method

- Retrieved data was checked to see if postings were relevant to ATMP;
 Out of 52 checked postings, 9 were marked as unclear, giving an approximate uncertainty of 20%
- Based on data, graphs were created to visualize retrieved input

Most of companies in the Global Data database job postings were international pharma companies. In the data, it was stated that SME companies were not



