

Welcome to the Swedish health care ATMP ecosystem!

The Swedish university hospitals are supported by ATMP centers in their clinical research and implementation of ATMPs. The ATMP centers have close contact with the clinics and hospital research units and act as coordinators and single-entry point for all hospital ATMP activities. They also provide local regulatory support for the implementation of ATMPs. For more information and contact with the ATMP centers: [NACNET / Hospital ATMP Centers](#) | [ATMP Sweden](#).

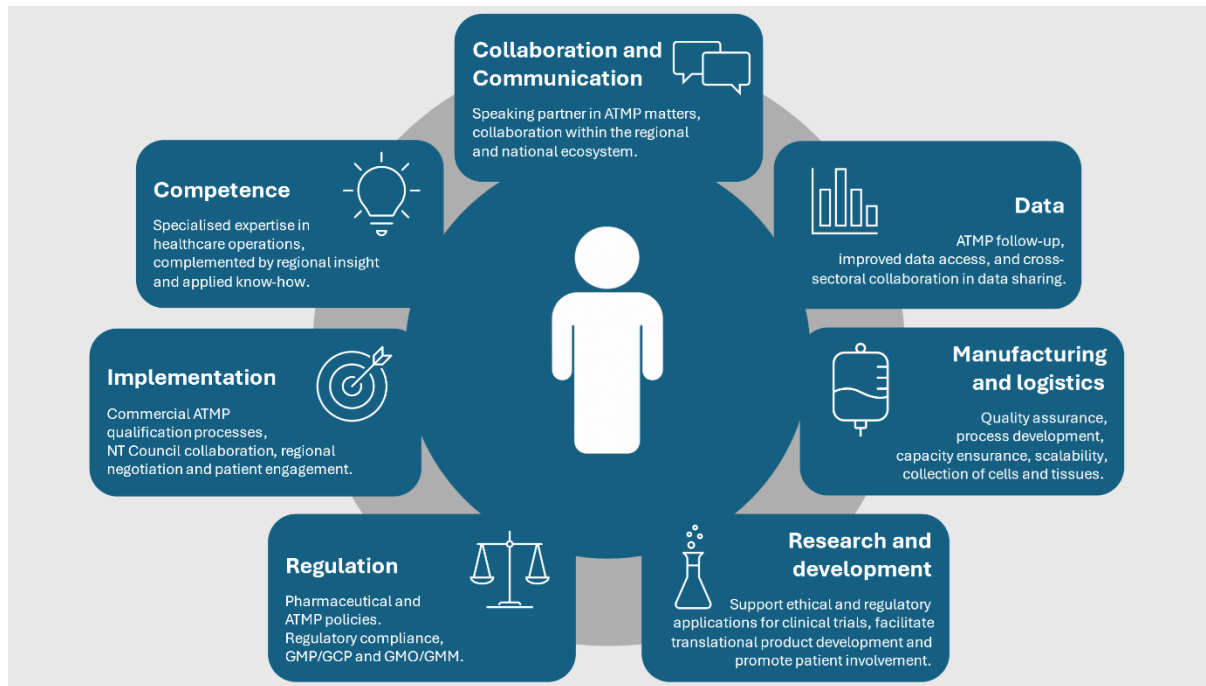


Figure 1. Overview of the multifaceted role of the ATMP centers.

Hospital research support structures

In Sweden, many clinical departments at the university hospitals have their own clinical research units, several of these have units dedicated to conduct of First-in-Human clinical trials.

[Clinical trial units | Kliniska Studier Sverige](#)

Feasibility requests for clinical trials are recommended to send to Feasibility Sweden: [English](#) | [Feasibility Sweden](#) for a nation-wide spread or for contact with a specific region or hospital. Check the box 'ATMP' in the request form and all ATMP centers will review your request.

Hospital facilities relevant for ATMPs

All Swedish university hospitals have intensive care units close to the clinical trials units. Apheresis is generally performed in-house and linked to a licensed tissue establishment with permits for handling starting material for ATMP manufacturing. Treatment with ATMP is carried out, much like standard of care, at the relevant hospital department based on diagnosis. Also, several hospitals have pediatric facilities for treatment with ATMP.

Swedish hospital regions use different pharmacy operators to handle ATMPs for hospital delivery. Most pharmacies can store products in freezers down to -80°C. For cryogenic storage, most hospitals have a cell therapy lab with a special pharmacy agreement for receipt and storage of ATMPs.

In general, GMO/GMM up to Biosafety level 2 can be handled in hospital facilities, yet some cases require both the pharmacy and hospital to notify the Swedish work environment authority.

Accreditations and certificates

Sweden has a long and broad experience of ATMPs, see Table 1 below for examples of clinical research. All clinical trials undergo regulatory and ethical review via CTIS (EMA). Sweden also has several commercial ATMPs recommended by the NT council and implemented in Swedish health care, for more information on the process: [National Joint Introduction - Samverkanläkemedel](#).

Furthermore, most Swedish university hospitals also have extensive experience of hematopoietic stem cell transplantation (HSCT, autologous and allogenic) for both adults and children. For transplantation of hematopoietic cells and immunomodulatory cells most university hospitals have JACIE accreditation [JACIE | EBMT](#), for a complete list: [JACIE Accredited Centres | EBMT](#).

All hospitals have a tissue establishment for procurement of tissues and/or cells to be used as start material in manufacturing of medicinal products. There is also experience, processes and equipment to be able to treat patients with other types of ATMP (in addition to *ex vivo* CAR-T therapies), such as *in vivo* gene therapies and cell therapies that require local administration and/or complex surgery, see table below for information of clinical experience.

Swedish hospital-based laboratories have ISO 15189 and/or ISO 17025 accreditation.

Clinical experience of ATMPs in Sweden	
Gene therapies	
<i>In vivo</i>	Oncolytic viruses
	CRISPR/Cas-based gene therapies
	Viral vector gene delivery
	Cancer vaccines (RNA, DNA)
<i>Ex vivo</i>	CAR T cells
	Engineered T cells
	NK cells
	CD34+ cells modified to express a specific gene
	Genetically modified pancreatic islet cells
Somatic cell therapies	
	Dendritic cells
	TILs
	Virus-specific T cells
	Mesenchymal stromal/stem cells
	Decidua stromal cells
	Human embryonic stem cell (hESC) derived cells
Tissue engineered products	
	Keratinocytes
	Chondrocytes

Table 1. Examples of clinical experience of ATMPs in Sweden.

For an overview of the Swedish clinical trials experience and more information about ongoing trials with ATMPs, see the Swedish ATMP Clinical Trials list [Swedish ATMP Clinical Trials | ATMP Sweden](#) (updated every six months).

If you have any questions or would like more information, please contact an ATMP center: [NACNET / Hospital ATMP Centers | ATMP Sweden](#).