



ATMP
Sweden

Who is ATMP Sweden?

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Summary

- What are ATMPs?
- Swedish ATMP developers
- Swedish ATMP immunotherapies
- Swedish service and product providers
- Who is ATMP Sweden?
- National projects/distribution
- Brief origin of Swedish ATMP
- SWECARNET implementation

What are ATMPs?

- Pharmaceuticals based on;
 - Manufactured therapeutic cells
 - Therapeutic cells used in non-homologous setting
 - Recombinant therapeutic nucleic acids

”

.. to understand what something is, you may need to understand what it isn't.

Medical Devices
(93/42/EEC)

Biologics

Medicinal Products (2001/83/EC)

Type of treatment/product modality

Medical Devices	Tissue Therapy	Cell Therapy	Gene Therapy	Vaccines	Biotech	Chemicals
Combined ATMP medical device plus a TEP, sCTMP or GTMP	Tissue Engineered Product (TEP) eg. Spherox, lab grown skin for burns treatment, P-TEV (VERIGRAFT)	Somatic cell therapy medicinal product (sCTMP) eg. Holoclar, Alofisel, lab expanded blood stem cells.....MSC for arthritis	Gene Therapy Medicinal Product (GTMP) eg. Kymriah, Imlygic, EV with recombinant mRNA, ILP100, in-vitro transcribed mRNA	eg. DNA vaccines or recombinant virus AGAINST infectious disease	eg. Insulin, antibodies, EV with transgenic protein	eg. Aspirin, Spinraza

Advanced Therapy Medicinal Products (ATMP) (1394/2007)

By EMA legal classification all gene therapies are GTMPs

Synthetic oligonucleotide, legally speaking, are not gene therapies

eg. medical device only, deceullarised scaffold

eg. skin transplant for burns treatment

eg. bone marrow transplant, blood transfusions

Tissues and Cells (2004/23/EC),
Blood (2002/98/EC)

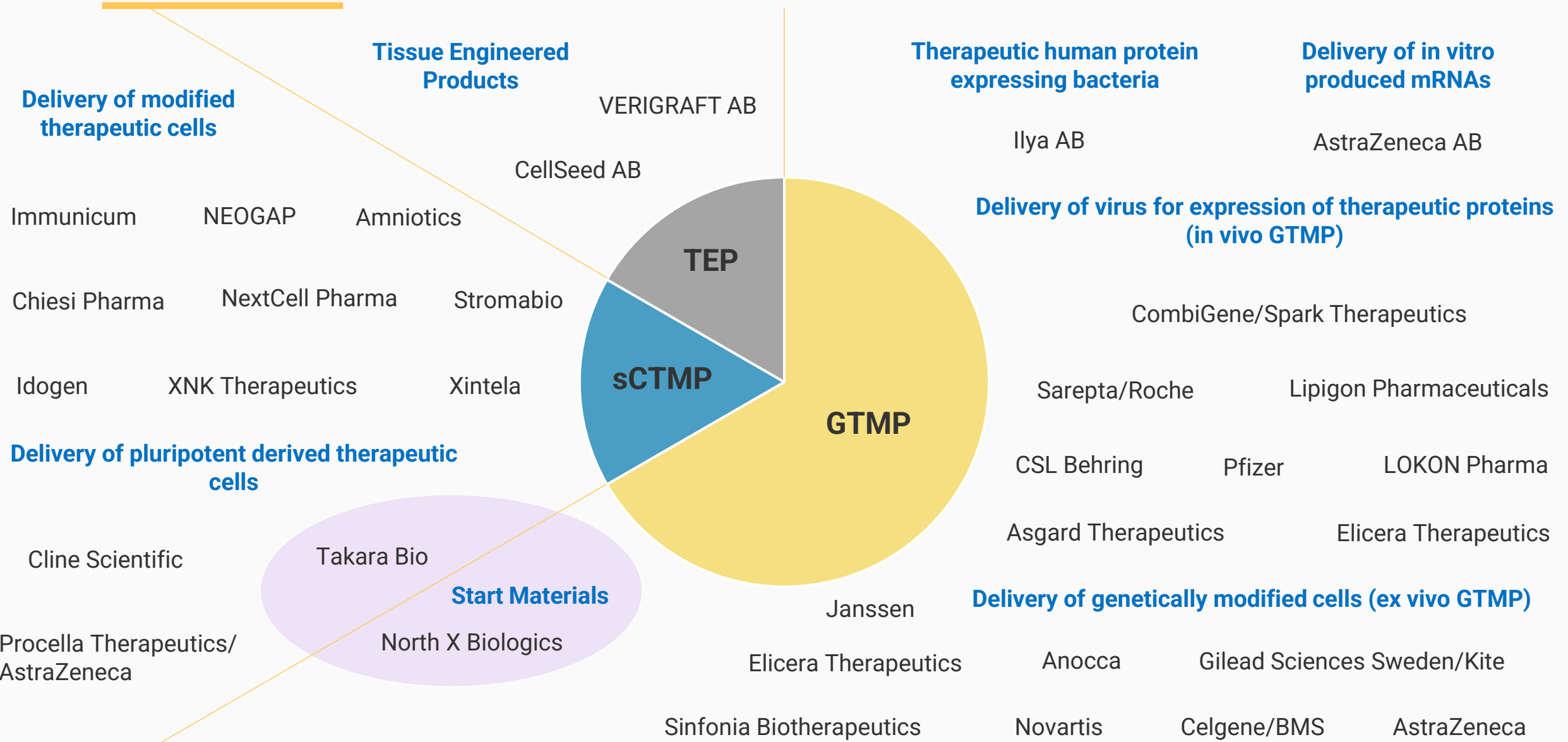
ATMPs

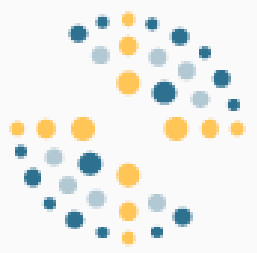
NOT ATMPs



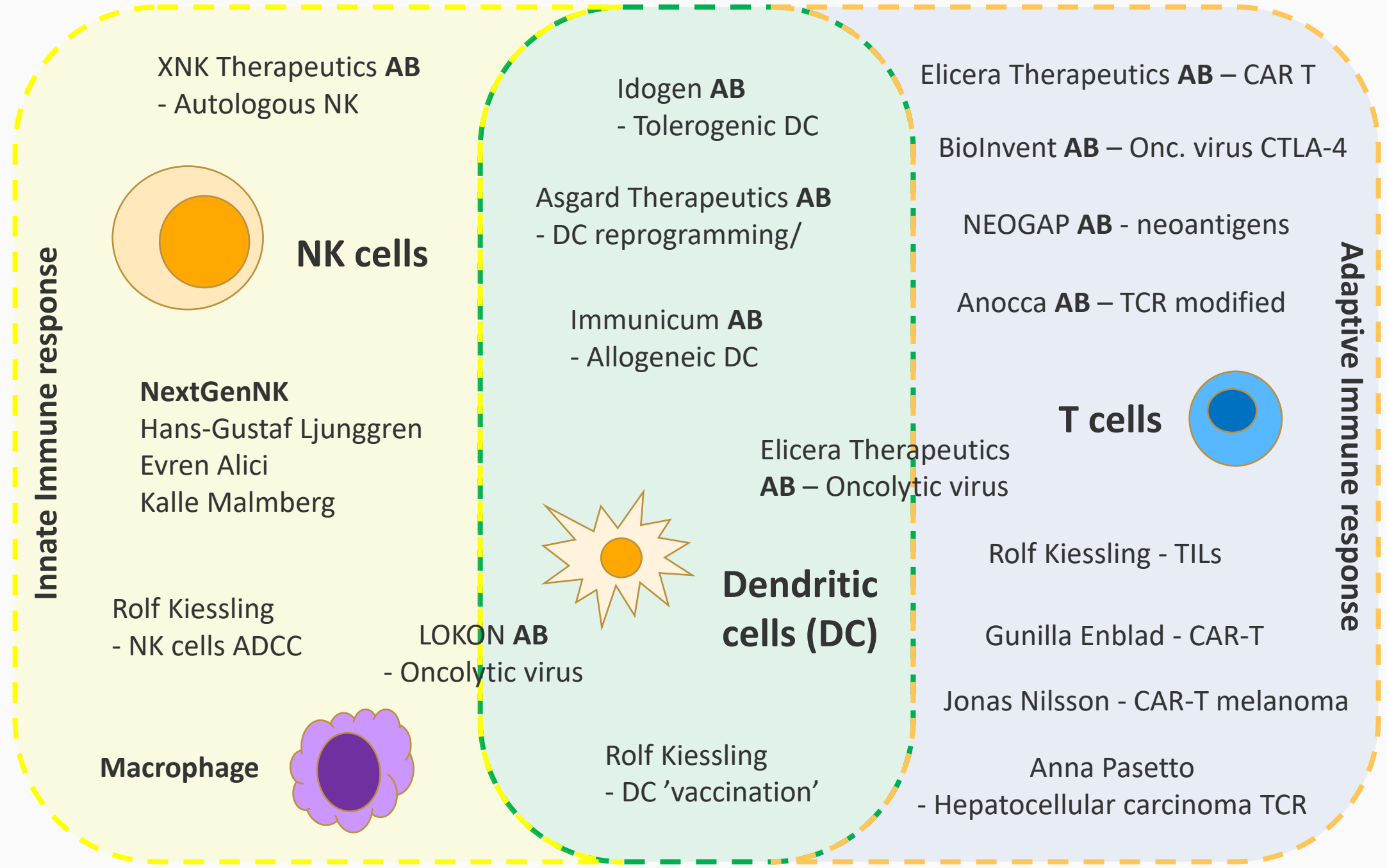
ATMP
Sweden

Swedish companies by ATMP type





Swedish ATMP immunotherapies



Swedish ATMP service providers



Documentation

Propharma group

Regulatory

NDA group

Sterility/endotoxin

Mikrolab

PCR

Tataa Biocenter

QMS

Quality Management
Stockholm

ELISA

ABC labs



HQ/GMP plasmid DNA

NorthX Biologics

Transport

YSDS

Storage

ClinStorage

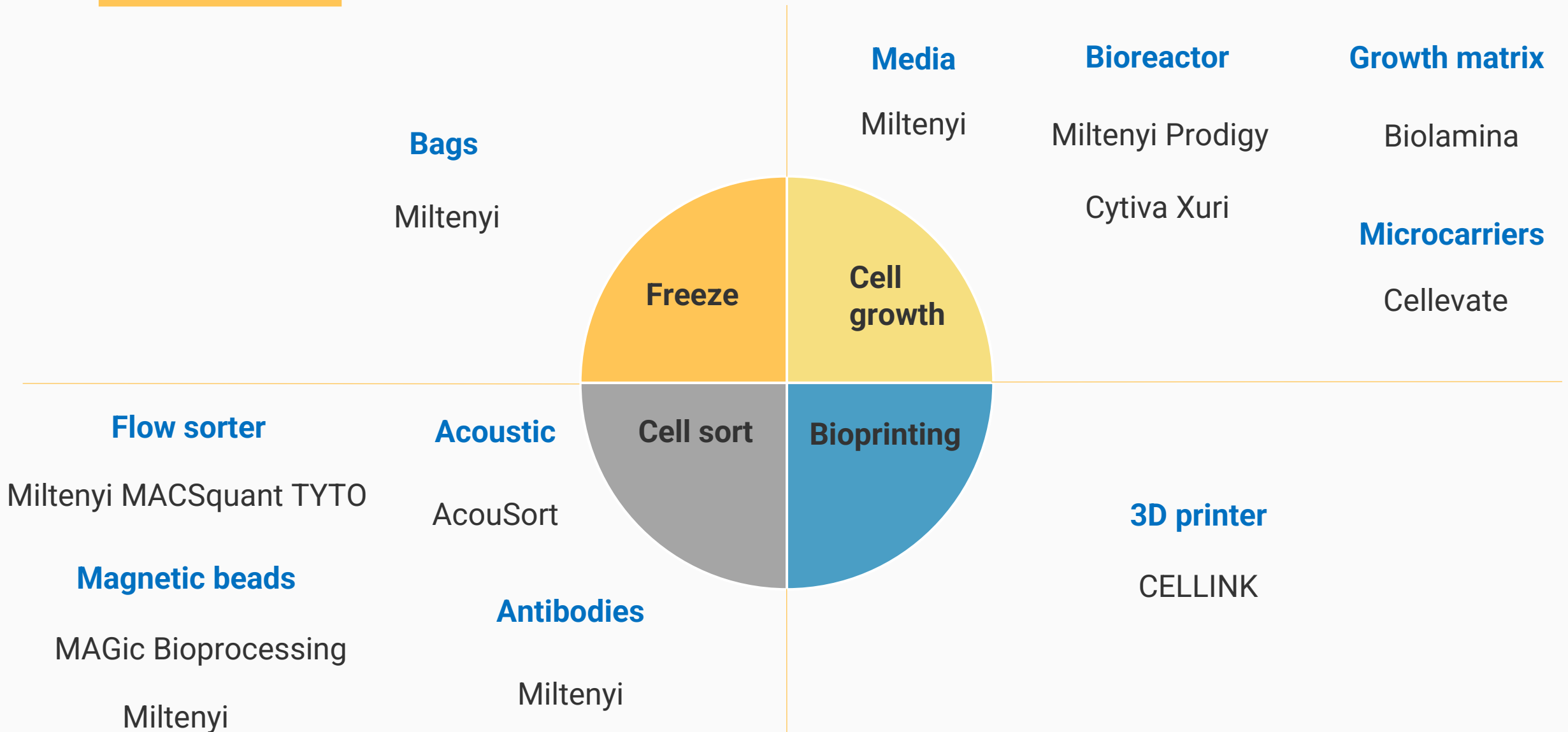
Pluripotent stem cells

Takara Bio

MSC manufacture

Cellco labs

Swedish ATMP product providers



Who is ATMP Sweden?

- The Swedish National network for ATMP activities
 - Coordinating communication and engagement between activities
 - Assist in the networking/information exchange of various stakeholder groups
 - Website atmpsweden.se
 - Conferences – National “ATMP Sweden” and International “ATMP world tour”
 - Run by National projects for the whole ecosystem

Our National projects



National network for ATMP
Communications, media, events



NK based ATMPs



Science and technology

Innovation Hub

Industrial scale
manufacture



**ATMP
2030**

'Innovation Millieu'

System innovation to be world leading in ATMP by 2030

SWELife

Opportunities and challenges
(completed Dec 2021)

ATMP Centres
Hospital functions

CCRM Nordic
Commercialisation
support

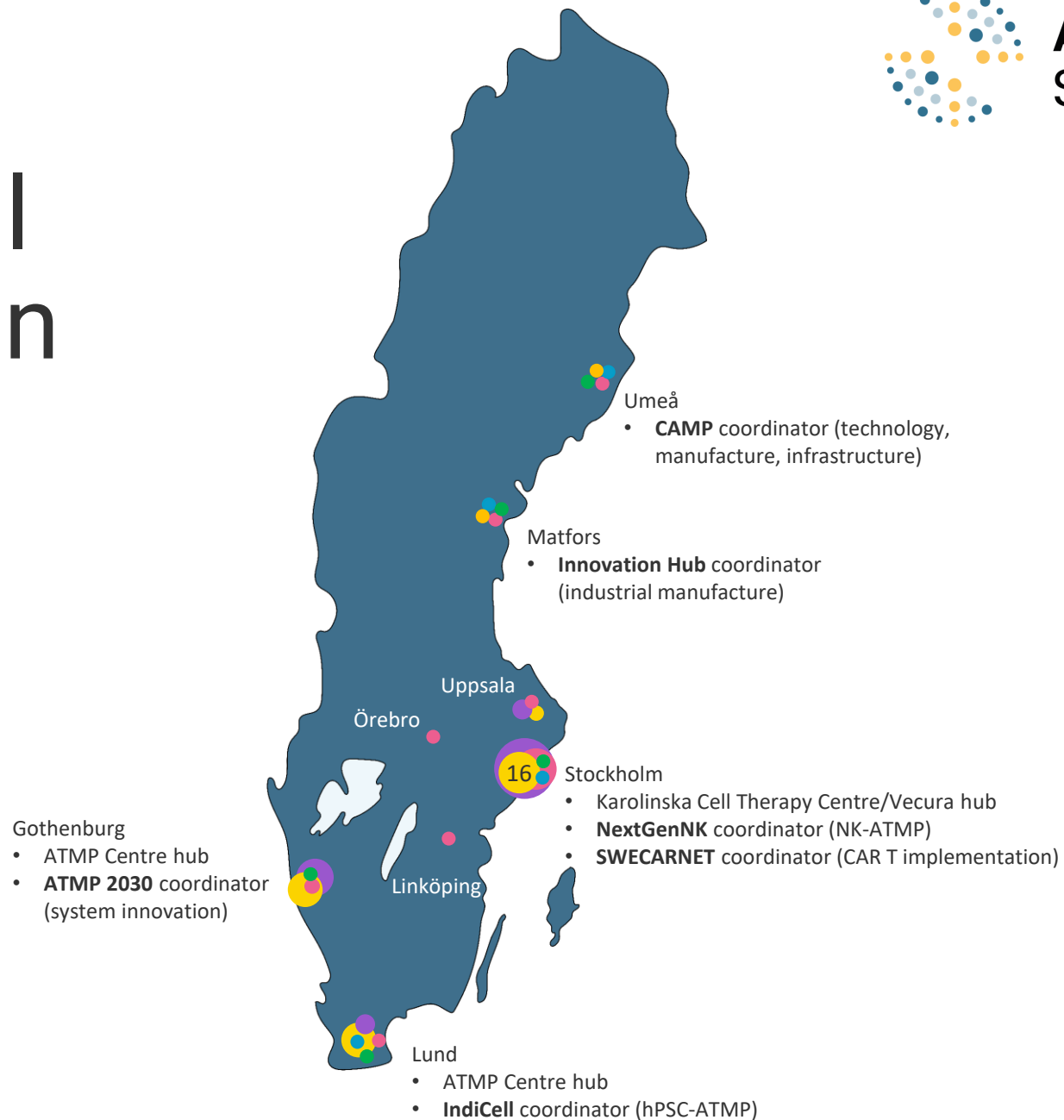
SWECARNET
CAR T implementation



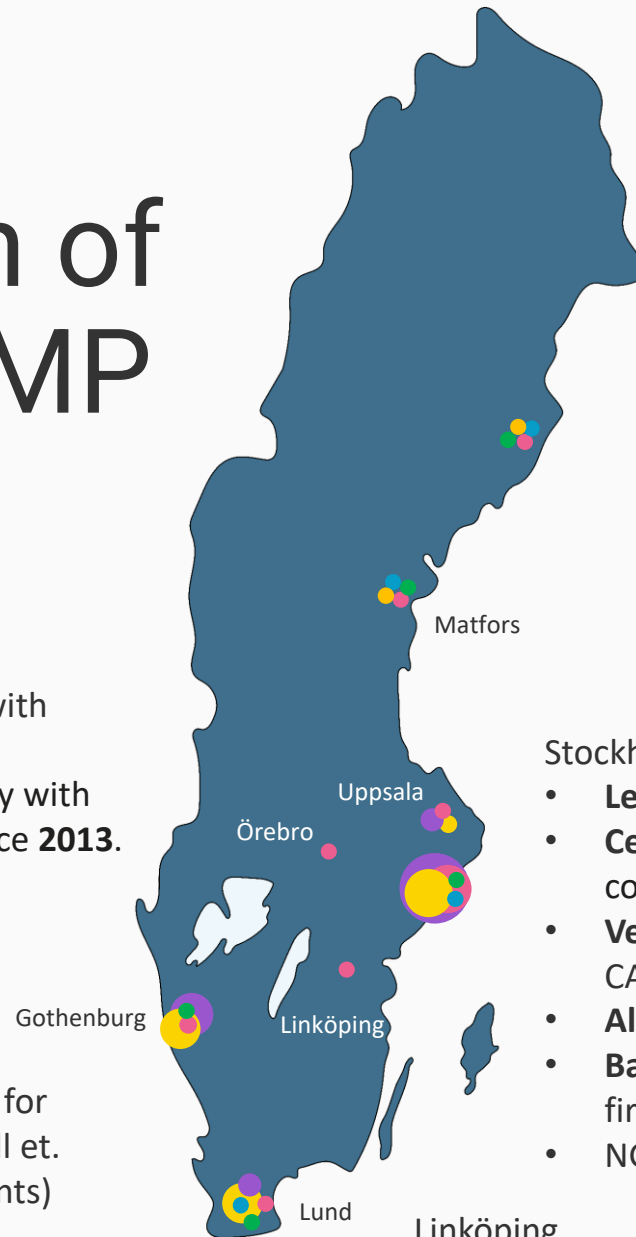
hPSC based ATMPs

Swedish National ATMP distribution

- ATMP companies
- Clean rooms/manufacture
- Treating clinicians
- National initiative
- ATMP hub for implementation



A brief origin of Swedish ATMP



Gothenburg

- **Brittberg et. al. 1994** – first patient treated with autologous cultured chondrocytes **1987**
- **Tataa Biocenter** - Supporting Pharma industry with molecular services since **2001**. ISO 17025 since **2013**.
- **Cellartis** – world first commercialization of pluripotent stem cells established **2001**

Lund

- **Malin Parmar** - hPSC derived DA progenitors for Parkinsons Disease (progression from Lindvall et. al. **1990** fetal derived DA progenitor transplants)

Matfors

- **NorthX Bio** – manufacturing GMP grade biologics since **1998**, HQ grade pDNA since **2018** and GMP grade pDNA since **2020**

Uppsala

- **Enblad et. al. 2018** - 3rd generation CAR T treatment since **2014**
- **Malstrom et. al. 2010** - immunostimulatory gene therapy with viral vectors in patients with solid malignancies since **2006**
- **Cytiva** – 70% of the world's biopharmaceuticals are produced with Cytiva products
- **Alexandra Karström** – first patients treated with autologous cultured skin for burns **late 1980s** in Stockholm/Uppsala

Stockholm

- **Le Blanc et. al. 2004** – first patient treated with cultured MSC for GVHD
- **Cecilia Götherström** - first prenatal treatment using a cell based ATMP, compassionate use **2002**
- **Vecura** – first gene therapy manufacture **1998**, first continental europe CAR T manufacture **2014**
- **Alici et. al. 2006** – first patient treated with gene modified infusion **1995**
- **Barkholt et. al. 2009** – infusion of cultured NK cells for cancer treatment, first patient treated **2003**
- NGF modified cells for alzheimers disease – first patient treated **2008**

Linköping

- **Folke Sjöberg** - first patient treated with autologous cultured skin for burns **2012**

SWECARNET CAR T implementation

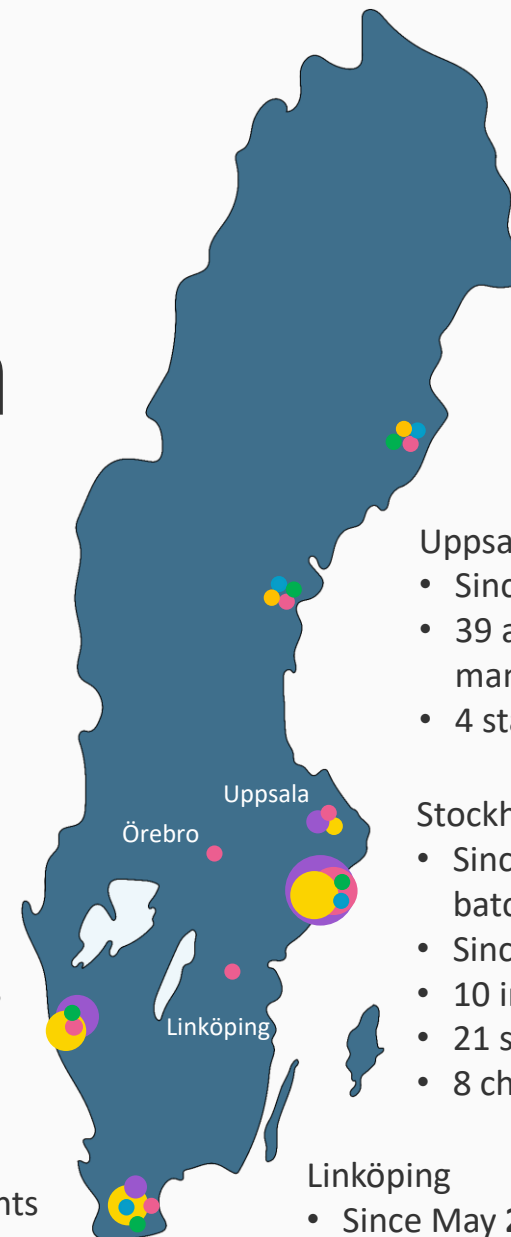
- **100 CAR T/TCR treatments in Sweden**
- **Last updated 17th March 2022**

Gothenburg

- Since October **2020** – 4 treatments
- Standard of care – 2 drugs

Lund

- Since January **2020** – 18 treatments
- Standard of care – 2 drugs



Uppsala

- Since May **2014** - 43 treatments
- 39 academic trial 3rd generation CAR T (cells manufacture in Vecura/Stockholm)
- 4 standard of care

Stockholm

- Since May **2014** - manufactured 39 patient batches 3rd generation (clinical trial in Uppsala)
- Since August **2019** - 31 treatments
- 10 industry driven trial – 2 drugs
- 21 standard of care – 2 drugs
- 8 child treatments

Linköping

- Since May **2021** – 2 treatments
- Standard of care

Get in touch

<https://atmpsweden.se/>



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Questions?

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