✉ ATMP-centrum@skane.se

Skånes satsning på ATMP

Petra Johnels, *ATMP-koordinator - SUS ATMP-centrum, Region Skåne* [PP slide 2-6]

Josefina Dykes, *överläkare - KIT, Region Skåne* [PP slide 7-14]

Gisela Helenius, *enhetschef - SUS ATMP-centrum Region Skåne* [PP slide 15-21]

Linnéa Kruse, *laboratorieingenjör - Pre-GMP-faciliteten, LU-ATMP-center* [PP slide 22-26]

Skånedagarna 2026-09-03

LUND UNIVERSITY

REGION SKÅNE

ATMP Advanced Therapy Medicinal Product

Ett **läkemedel** som består av **gener**, **celler** eller **vävnader** som har genomgått *substantiell manipulering* så att dess **egenskaper förändrats** *eller* att cellen/vävnaden ska användas **icke-homologt**

4 klasser:
- Cellterapi
- Vävnadsteknisk produkt
- Genterapi: a) *in vivo; b) ex vivo*
- Kombinationsläkemedel

→ **Heterogen grupp, olika behov**

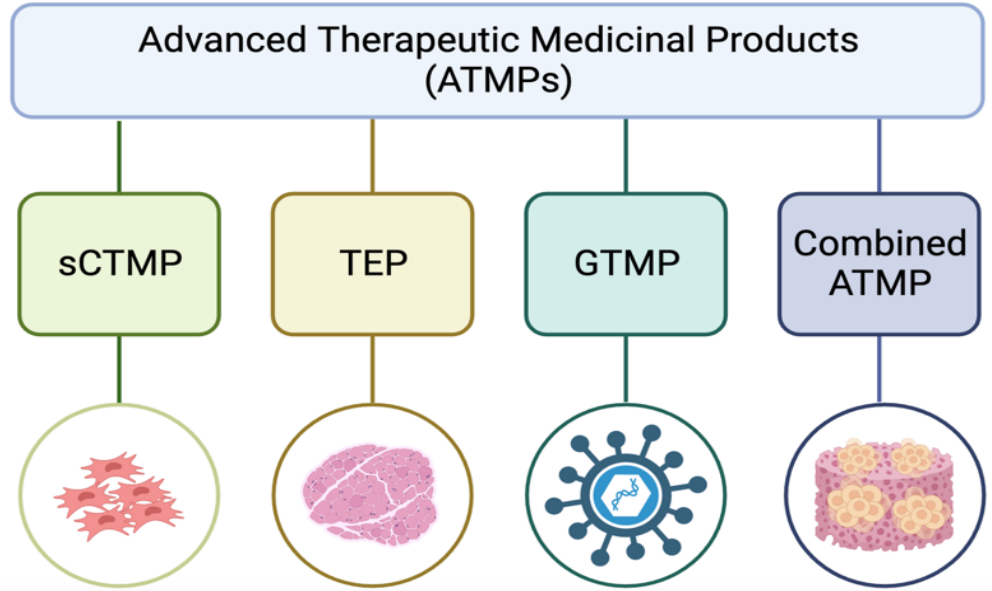


Bild från: Advancing Tomorrow´s Therapies, 2023, Lund University

Skånes satsning på infrastruktur

Utveckling och tillverkning av cell- och genterapiläkemedel — 2025

Klinisk implementering av ATMP i prövning samt av marknadsgodkända terapier — 2019

Linnéa

pre-GMP
produkt- & process-utveckling

LU ATMP

Gisela

GMP
tillverkning & sjukhusapoteks-funktion

Petra

En väg in – koordinering & stöd

2021

Josefina

KIT
tillvaratagande, vävnadsinrättning & mottagande

SCT verksamheten

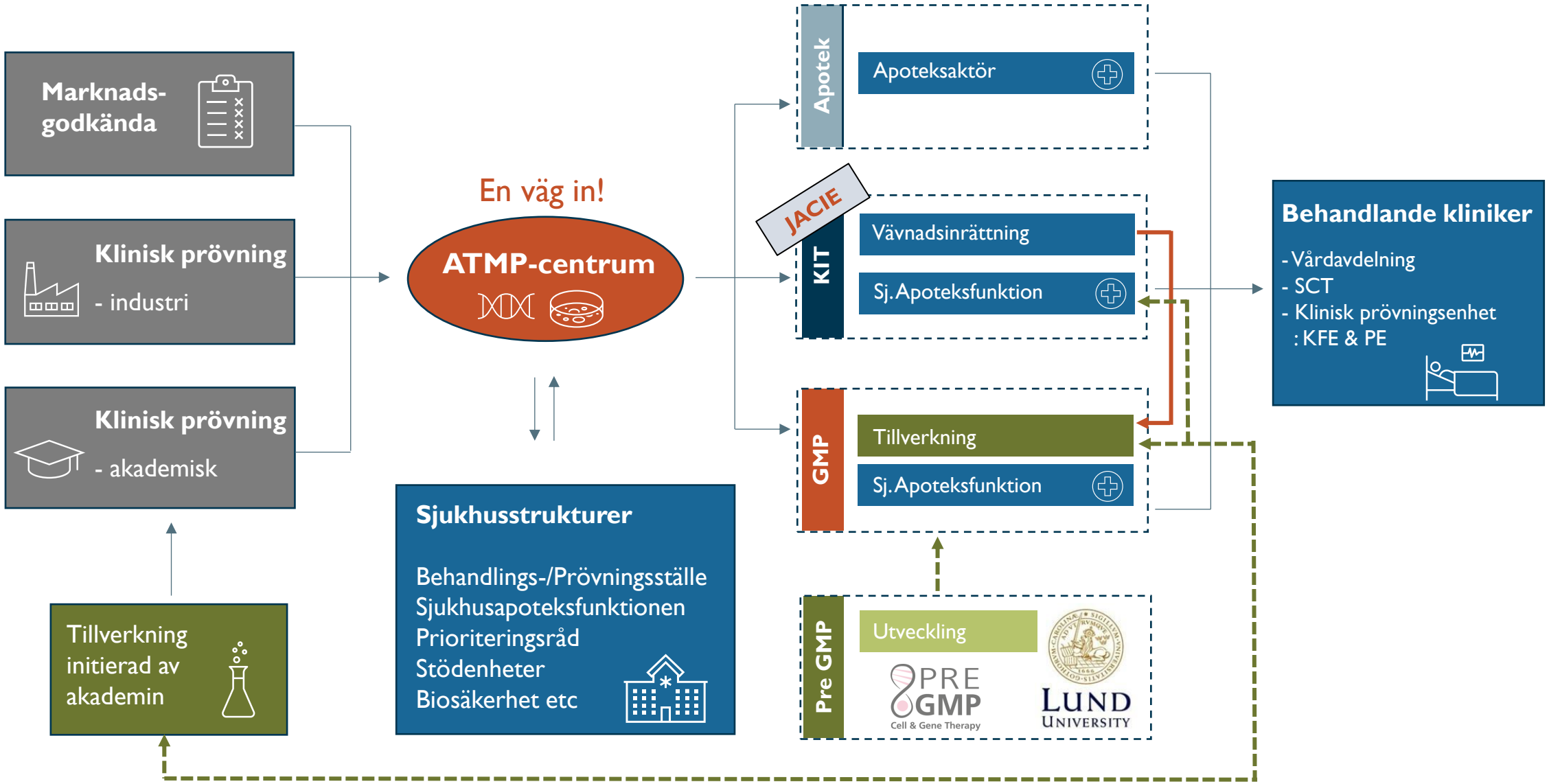
Enhet cell- och genterapi,
Region Skånes **ATMP-centrum**

En väg in Stöd för Industri - Akademi - Sjukvård

- Koordinering & kunskapsstöd
  - uppstart av kliniska ATMP prövningar
  - implementering av marknadsgodkända ATMP (bistår)
- Läkemedelsflöde & vårdprocesser
  - deltar i SCT prioriteringsråd & arbetsgrupp ATMP
- Regulatoriska anmälningar & kvalitetssäkring
  - GMO/GMM anmälningar
  - specifika avtal (kvalitets- & leveransavtal)

→ Helhetsbild – bygger på befintliga strukturer – nå patient snabbare

ATMP flöde i Skåne

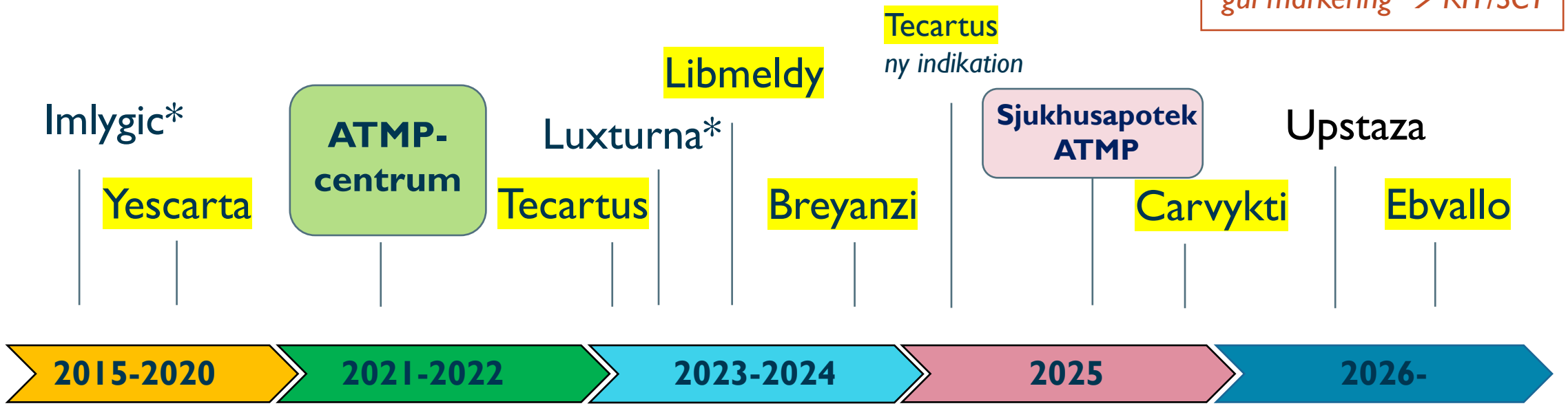


ATMP-behandlingar i Skåne

gul markering → KIT/SCT

Marknadsgodkända

Kliniska prövningar



- ZUMA7
- AMT-061[B]
- Cartitude-4

- BeneGene2[B]
- Cartitude-5
- BROMS
- VIR303
- Situ-Heal[GMM]
- AmnioPul
- Affine[A]

- stemPD
- BNT-122[mRNA]
- V940[mRNA]
- XIN-STEM
- Cartitude-6

- AVB-101
- Quintessential

- CAR-T (hema)
- genterapi (neuro)
- cellterapi (neuro)

GMP tillverkning:

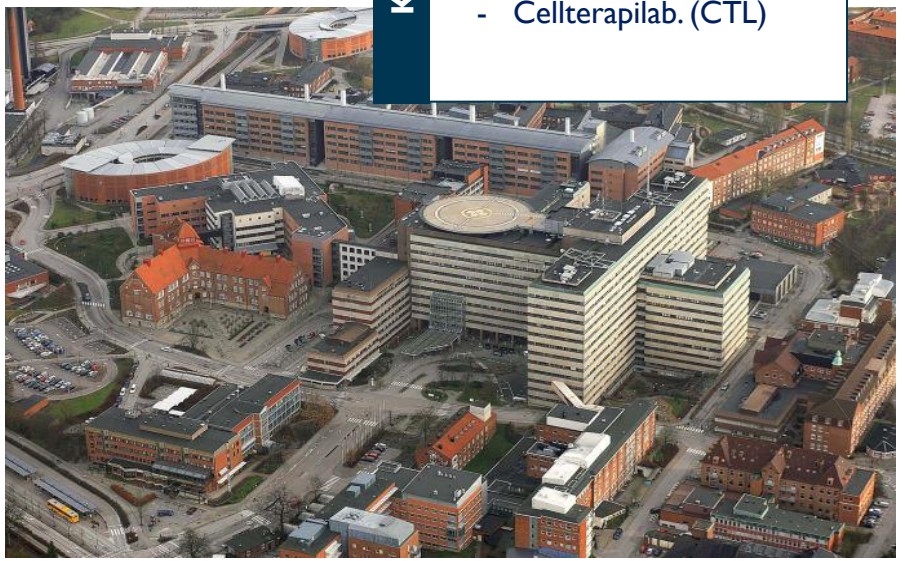
- CAR-T (onk)
- CAR-T (barn)
- cellterapi (onk)

Uppdaterad 2026-09-02/PJ

Cellterapiverksamheten i Lund

1986 - 2019

- Hematopoetisk stamcellstransplantation (SCT)



KIT

Vävnadsinrättning

- Aferes
- Cellterapilab. (CTL)

Hematologi/Onkologi
Pediatrisk onkologi

- Avdelning
- SCT

Cellterapiverksamheten i Lund

2019 - 2025

- Hematopoetisk stamcellstransplantation (SCT)
- ATMP cell-/genterapi

Marknads-godkända

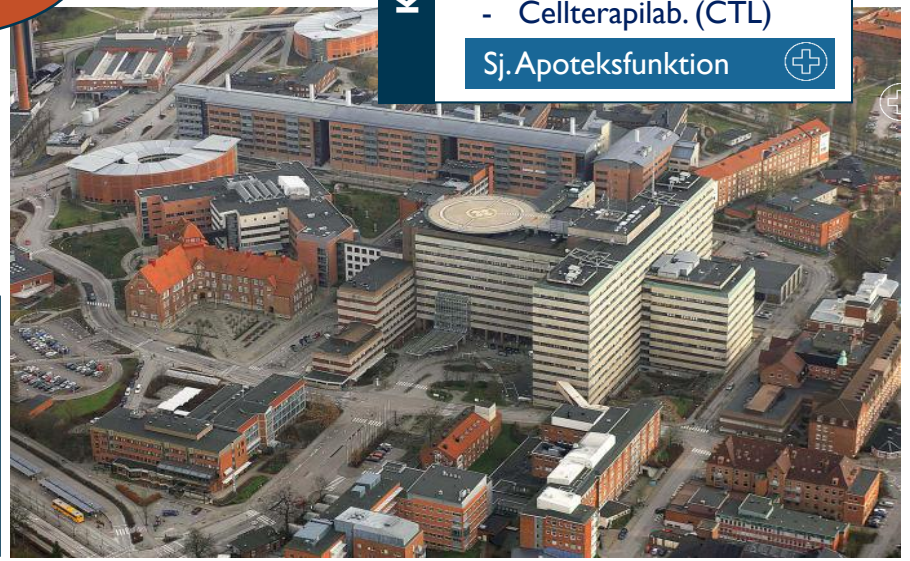
Klinisk prövn.
- Industri

Klinisk prövn.
- Akademi

ATMP Centrum

Sjukhusstrukturer

Prioriterigsråd
Sjukhusapoteksfunktion
Biosäkerhet etc



Apotek
- Apoteksaktör

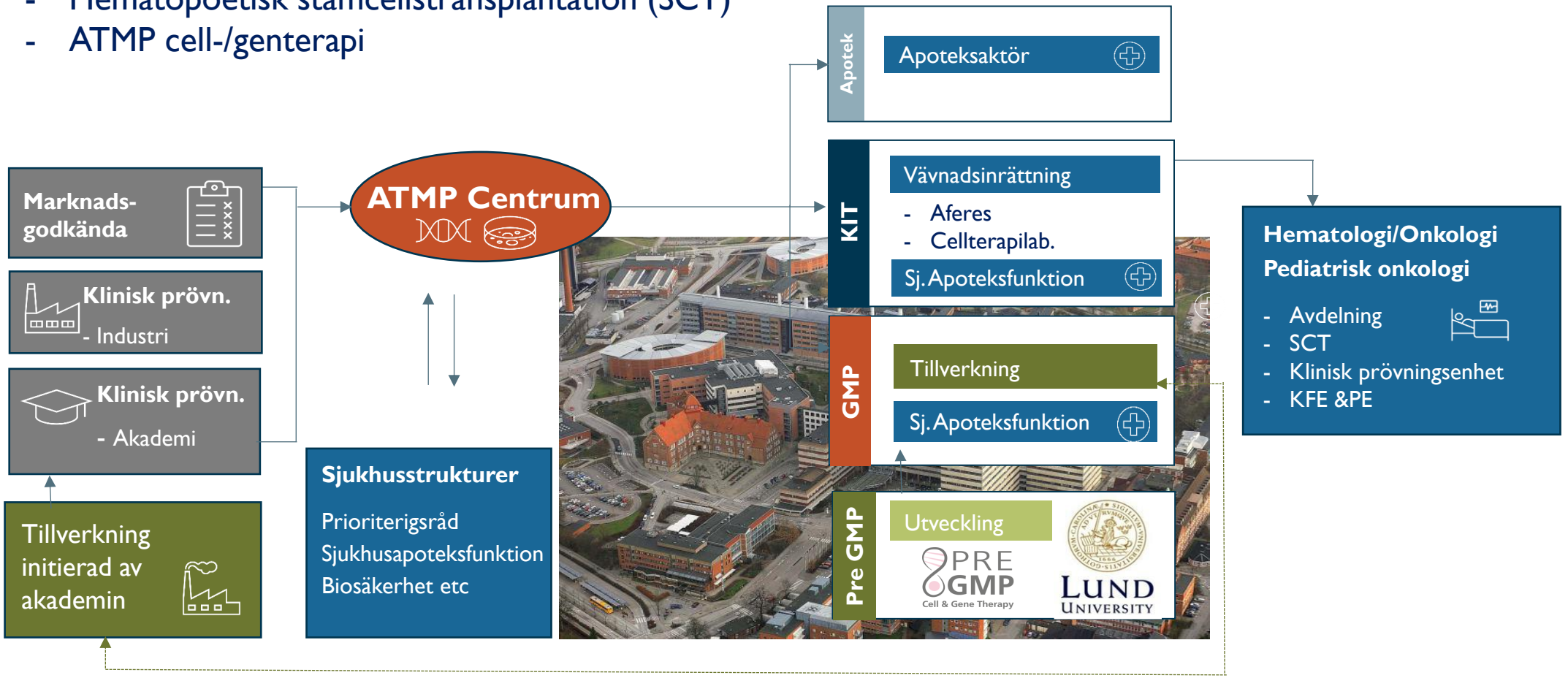
KIT
- Vävnadsinrättning
  - Aferes
  - Cellterapilab. (CTL)
- Sj. Apoteksfunktion

Hematologi/Onkologi
Pediatrisk onkologi
- Avdelning
- SCT
- Klinisk prövningsenhet
- KFE &PE

Cellterapiverksamheten i Lund

2025……..

- Hematopoetisk stamcellstransplantation (SCT)
- ATMP cell-/genterapi



Kvalificeringsprocessen

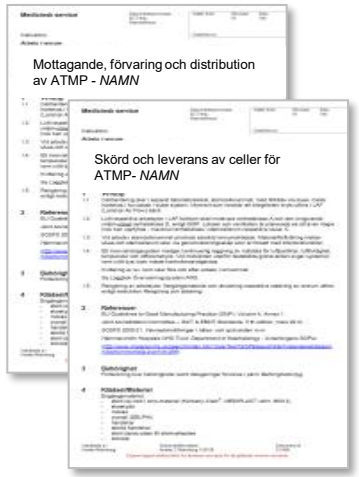
Site Assessment
Document Request
On site Audit (1-2 dagar)

QM TE KIT
SOP index
Avtal
Organisationsschema

Dry Run
Aferes, märkning och leverans av råvara
Mottagande ATMP
Logistik och kommunikation

Training Log

Implementera produktspecifika instruktioner



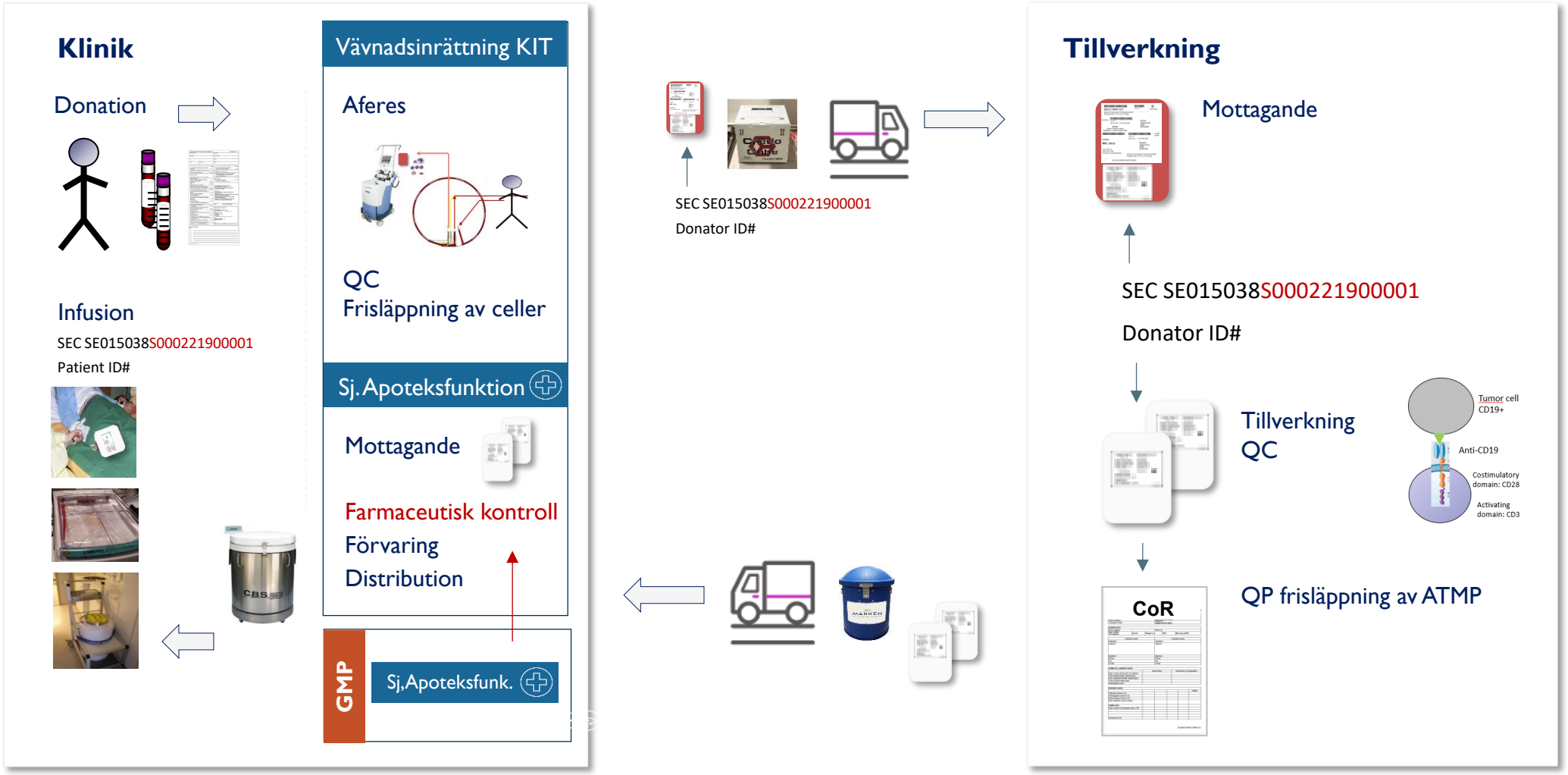
Re-Audit

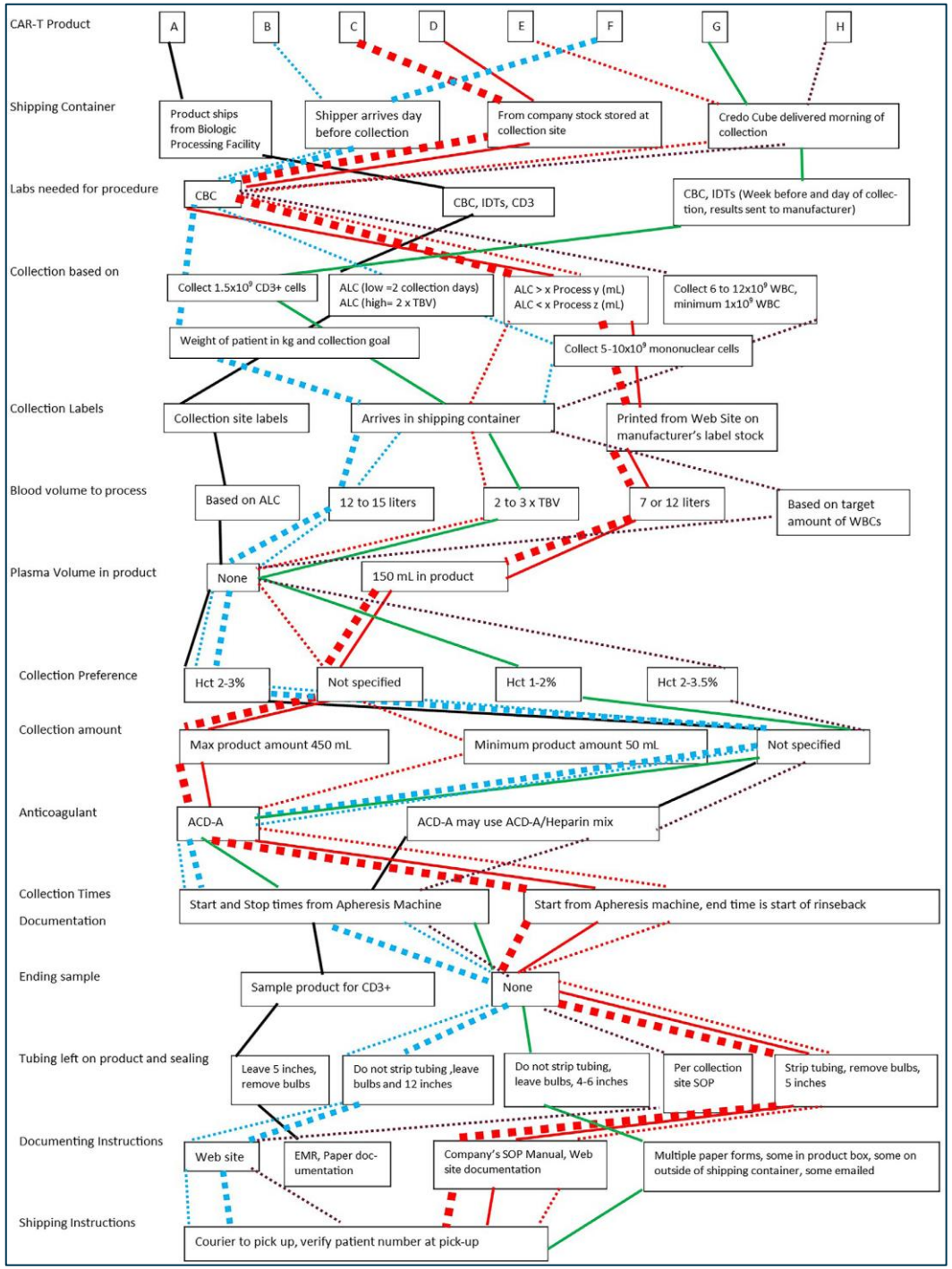
Rapportering
Allvarlig avvikande händelse/biverkning
Väsentlig förändring

6-9 mån

CAR-T-celler

ex vivo autolog genterapi vid B-cellsmalignitet (CD19) eller myelom (BMCA)





Cytotherapy 26 (2024) 948–953

Contents lists available at ScienceDirect

CYTOTHERAPY

journal homepage: www.isct-cytotherapy.org

ELSEVIER

International Society ISCT Cell & Gene Therapy®

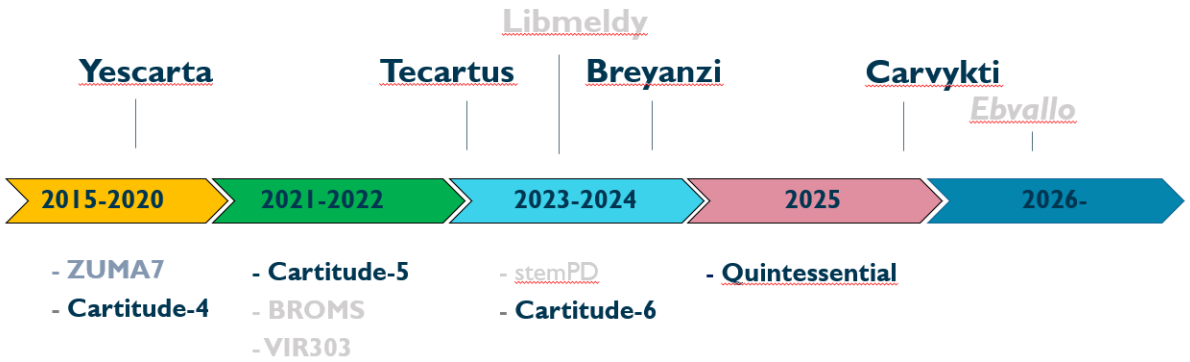
FULL-LENGTH ARTICLE

Regulatory Practice

Handling the different requirements for commercial and investigational MNC collections by apheresis

Aleh Bobr[1,*], Timothy Roberts[1], Scott Koepsell[1], Shelly M. Williams[1], Joseph Schwartz[2]

[1] Department of Pathology, Microbiology and Immunology, University of Nebraska Medical Center/Nebraska Medicine, Omaha, Nebraska, USA
[2] Department of Pathology/Hematopathology and Laboratory Medicine, Moffitt Cancer Center, Tampa, Florida, USA

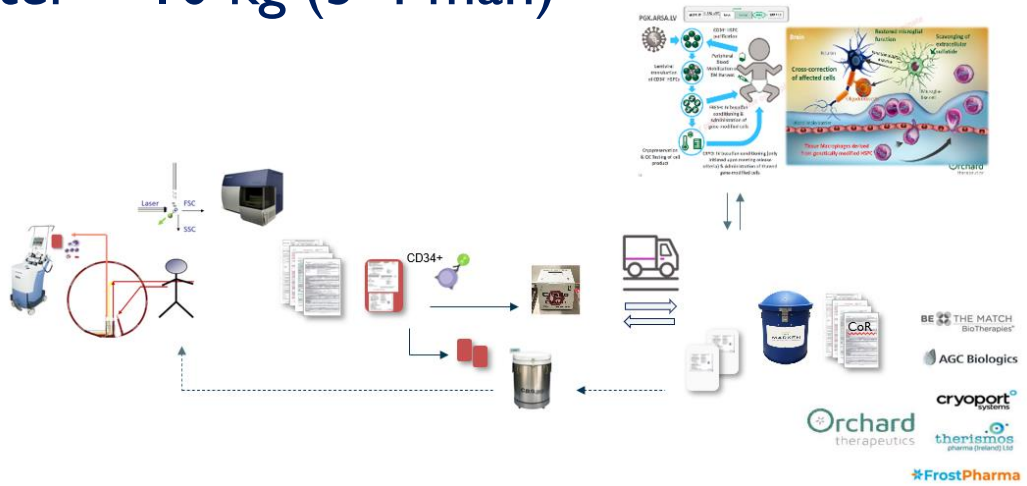


Nordic QTC Libmeldy (arsa-cel)

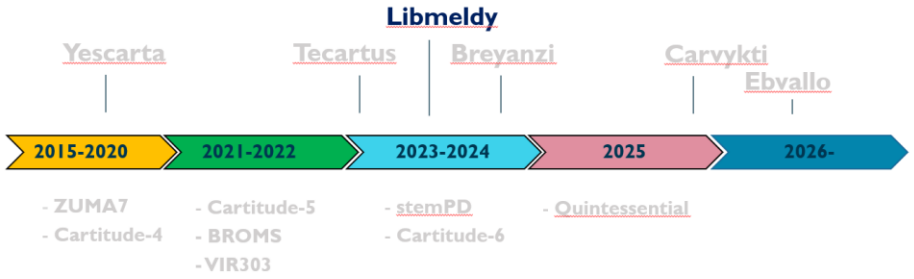
ex vivo autolog HSC genterapi vid metachromatic leukodystrophy MLD

Insamling av celler med aferes hos små patienter < 10 kg (3-4 mån)

- Kärlaccess
- Hemodynamik och vätskebalans
- Antikoagulantia
- Tekniska begränsningar aferesinstrument
- ”Megados” CD34+ HSC som råvara för ATMP



Nyföddhetsscreening MLD start under år 2026 i Norge och Sverige (31/9)



Somatiska cellterapier

Libmeldy

Yescarta | Tecartus | Breyanzi | Carvykti | Ebvallo

2015-2020 | **2021-2022** | **2023-2024** | **2025** | **2026-**

- ZUMA7
- Cartitude-4
- Cartitude-5
- **BROMS**
- **stemPD**
- Cartitude-6
- Quintessential

EBV T-celler vid PTLD

Laboratoires Pierre Fabre

Deciduaceller vid GvHD

Uppsala Universitet

Oslo universitetssykehus

Dopamin progenitorer vid Parkinson

STEM-PD

Lunds Universitet

NHS Royal Free London NHS Foundation Trust

KIT

Sj. Apoteksfunktion

Mottagande

Farmaceutisk kontroll

Förvaring

Distribution

GMP

Sj,Apoteksfunk.

GMP

Sjukhusapoteksfunktion

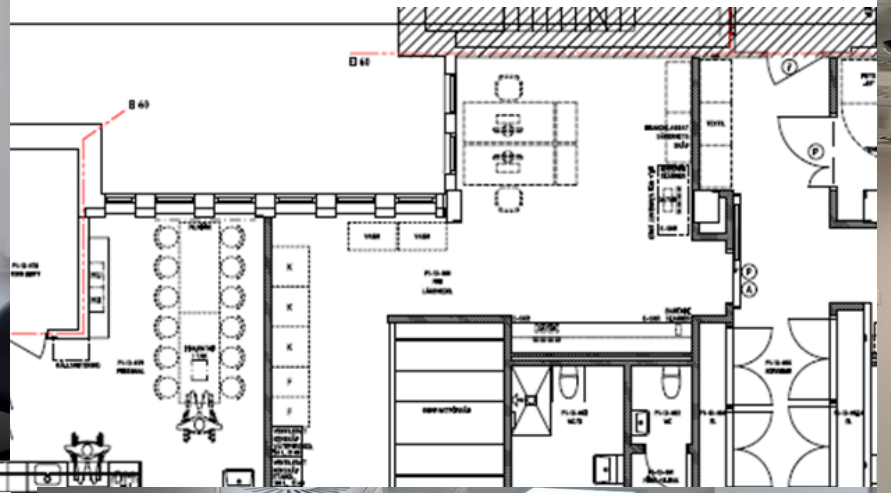
Beredning

Distribution

Functions at the ATMP center

GMP facility at ATMP center Skåne University Hospital

center Skåne University



Current projects at the GMP-facility

- Manufacturing platform for ex vivo gene therapies
  - Autologous CAR-T cells
  - Autologous gene therapy
- Autologous tumor infiltrating lymphocytes
- Pluripotent derived NK cells
- Pluripotent derived betacells
- Establishment of iPSC lines

LUND UNIVERSITY

Skåne University Hospital

Molecular Therapy
Methods & Clinical Development
In the Spotlight

The Advanced Therapies model of Lund an integrated approach to accelerate access for many patients

Gisela Helenius,[1] Stefan Jovinge,[3,4,5] and Anna Falk[2,6]

https://doi.org/10.1016/j.omtm.2025.101637

Scientific breakthroughs in the field of cell and gene therapy lay the groundwork for therapeutic innovation, but their translation and integration into routine care is delayed by systemic inefficiencies and limited cross-sector alignment. The Advanced Therapies model of Lund is a proactive and integrated approach designed to accelerate the development of advanced therapies from discovery to reimbursement, facilitating close collaboration among three main entities: university, hospital, and the iActors (a coalition of the innovation system, incubators, investors, and industry). Unlocking the full potential of therapeutic innovation requires inclusive and proactive engagement from all entities to accelerate development practices (GMP) transfer, fewer re-works, faster time to first-in-human, and the creation of more viable biotech companies.

THE ADVANCED THERAPIES MODEL OF LUND, AN INTEGRATED AND PROACTIVE WAY OF WORKING

Cell and gene therapy research is rapidly advancing, but the process of translating research to clinical trials and further into commercially viable and market-approved drugs is immature and slow. Many cell and gene therapies are reaching neither clinical trials nor the market, despite yielding promising preclinical results.[1] A significant challenge for developers is the complexity and difficulty of overseeing the process from disproactively (Figure 1). The clear division of responsibilities is important to create an optimal process (Table 1). Courage is needed to be bold and open with the division of responsibilities based on knowledge and avoid prestige being a determinant. When all actors have a comprehensive overview of all steps early in the Advanced Therapies development process, it is possible to act proactively and prepare for support and responsibility handover.

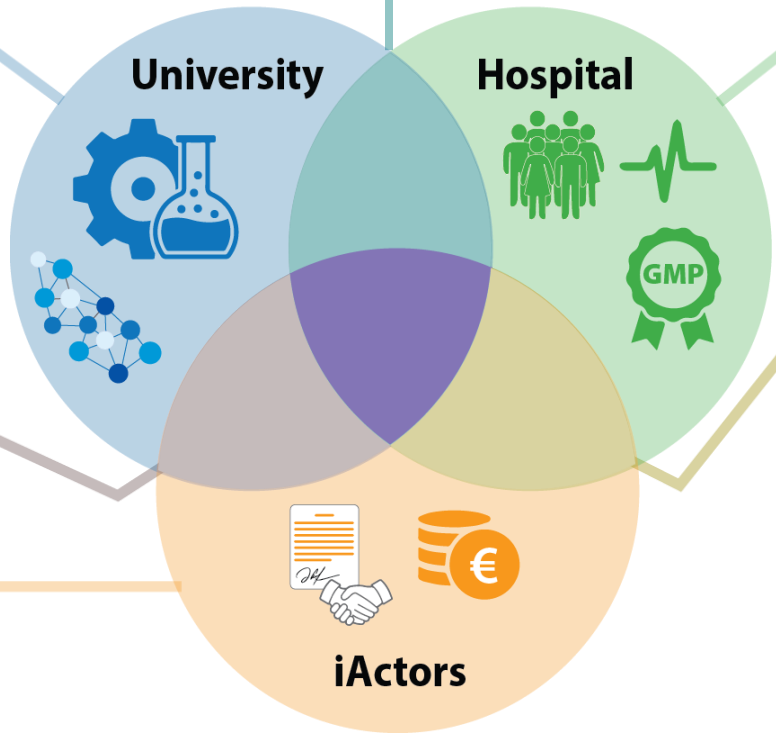
Within the framework of the Advanced Therapies model, a dedicated team of experts is assembled across sectors and organizations, each with a comprehensive understanding of the overall project timeline. When their specific expertise is called for, they will claim responsibility. This ensures that responsibility for project outcomes is shared among team members in an integrated, rather than linear, manner (Figure 2). As a result, the workflow is characterized by a circular and iterative process rather than a one-directional flow as Advanced Therapy projects are typically developed. This multidirectional approach allows for continuous feedback and adaptations as the project progresses, enhancing the team's ability to respond to new information and challenges effectively. Work will be performed by regular brainstorming

- ATMP research
- Process development
- Multidisciplinary collaborations
- Research grant
- Pre-clinical testing
- Feasibility manufacturing
- Networks National and international

- Tech transfer GMP processes
- Education
- SOP derivations
- QC development

- GMP manufacturing
- Patient enrolment
- Clinical Trials
- Health monitoring and follow up
- Regulatory compliance and support
- Clinical PI support

- Patents
- FTO - freedom to operate analyses
- Upscaling
- Entrepreneurship
- Mentoring
- Talent retention and acquisition



- Extended clean room availability
- Clinical phase II/III
- Implementation
- Market access feasibility

- Business models
- Financing
- Legal support
- Incubators
- Align and synergies
- Networks and training

Integrated 3-part model

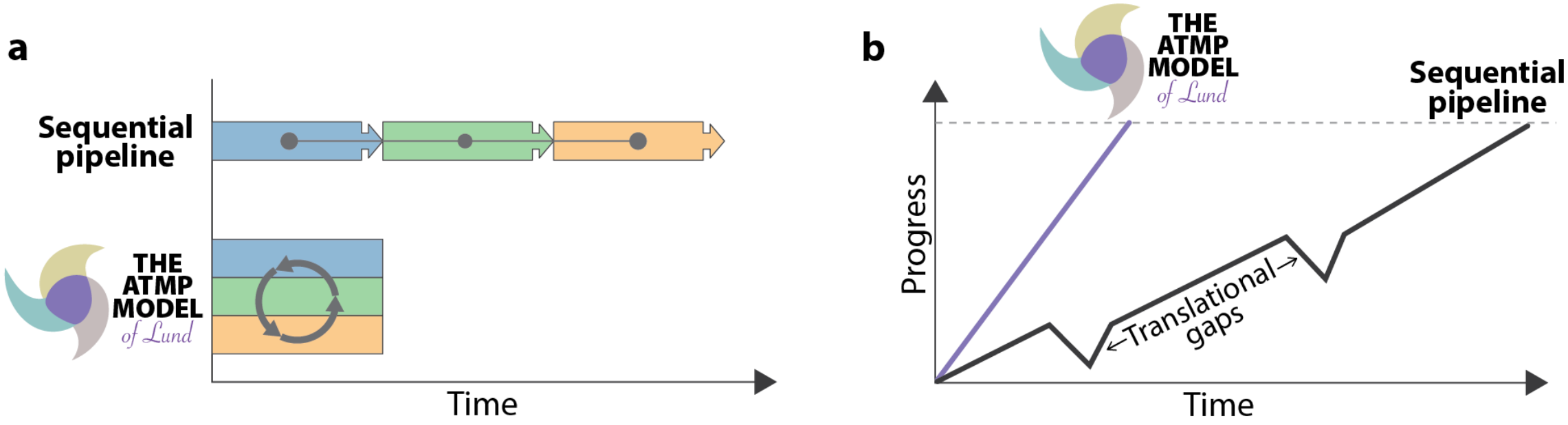
Acceleration from research to reimbursement

Sustainability

Proactive work

Innovation

Integrated model accelerate ATMP development



Lunds Universitets Pre-GMP Facilitet

LINNEA KRUSE – LABORATORIEINGENJÖR PRE-GMP

3 SEPTEMBER 2026

Vad är pre-GMP?
– en brygga mellan forskning och GMP-produktion

- Ett fysiskt labb i ”simulerad” GMP miljö på Lunds Universitet
- Etablerat i nära samarbete med GMP faciliteten på SUS

183 m^2

LUND STEM CELL CENTER

PRE GMP Cell & Gene Therapy

Pre-GMP i Skånes ATMP-ekosystem

Lund University

Skåne University Hospital

Life Science Industry

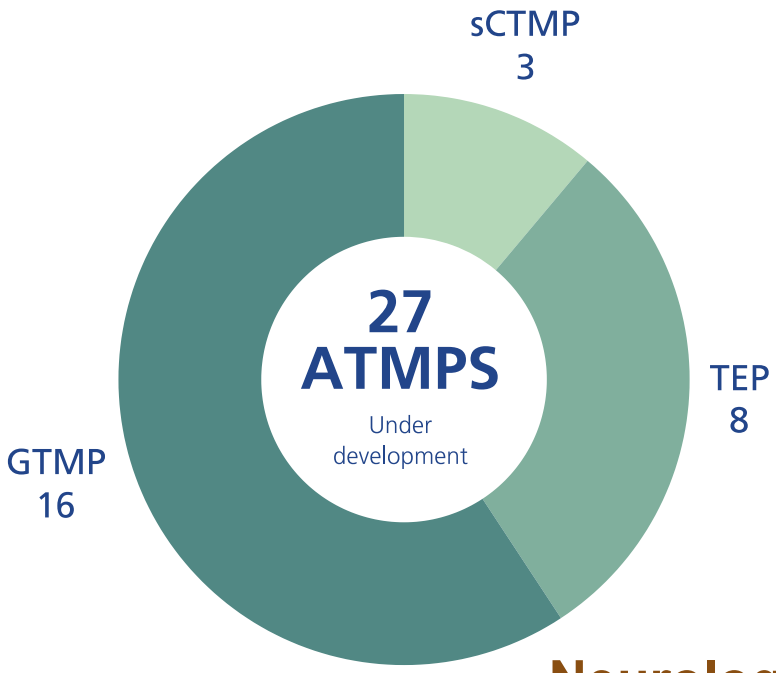
Research → ATMP Candidates → Pre-GMP → GMP Manufacture → ATMP → Approved Product

LUND STEM CELL CENTER

LUND UNIVERSITY

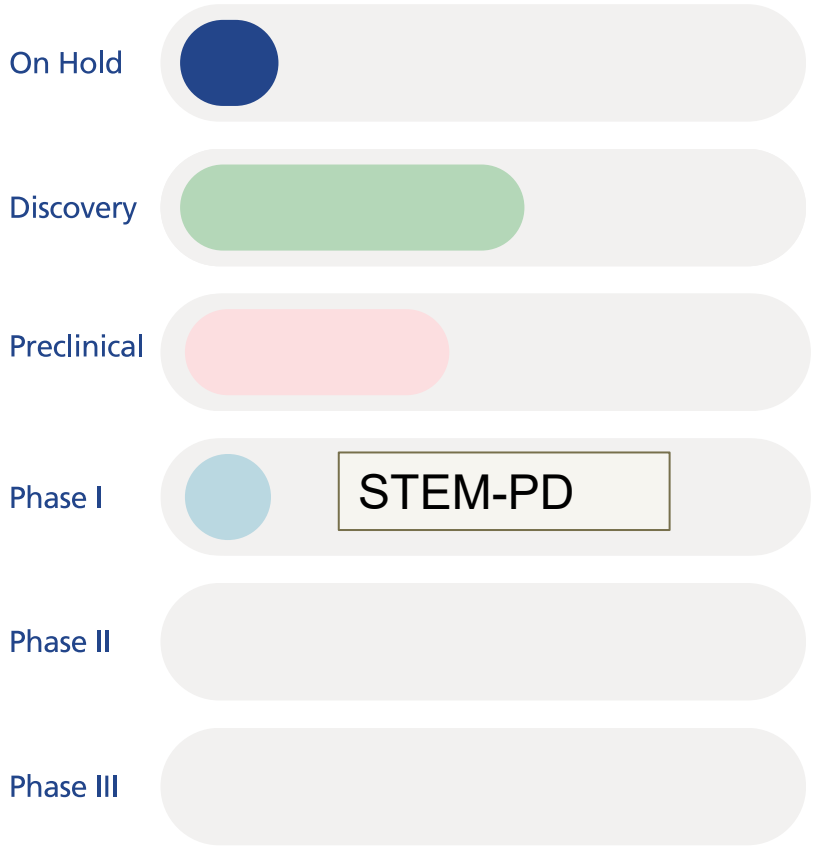
ATMP-utveckling på Medicinska Fakulteten

Antalet ATMPs:
(2024)



Neurology
Oncology
Hematology

Var i utvecklingen:

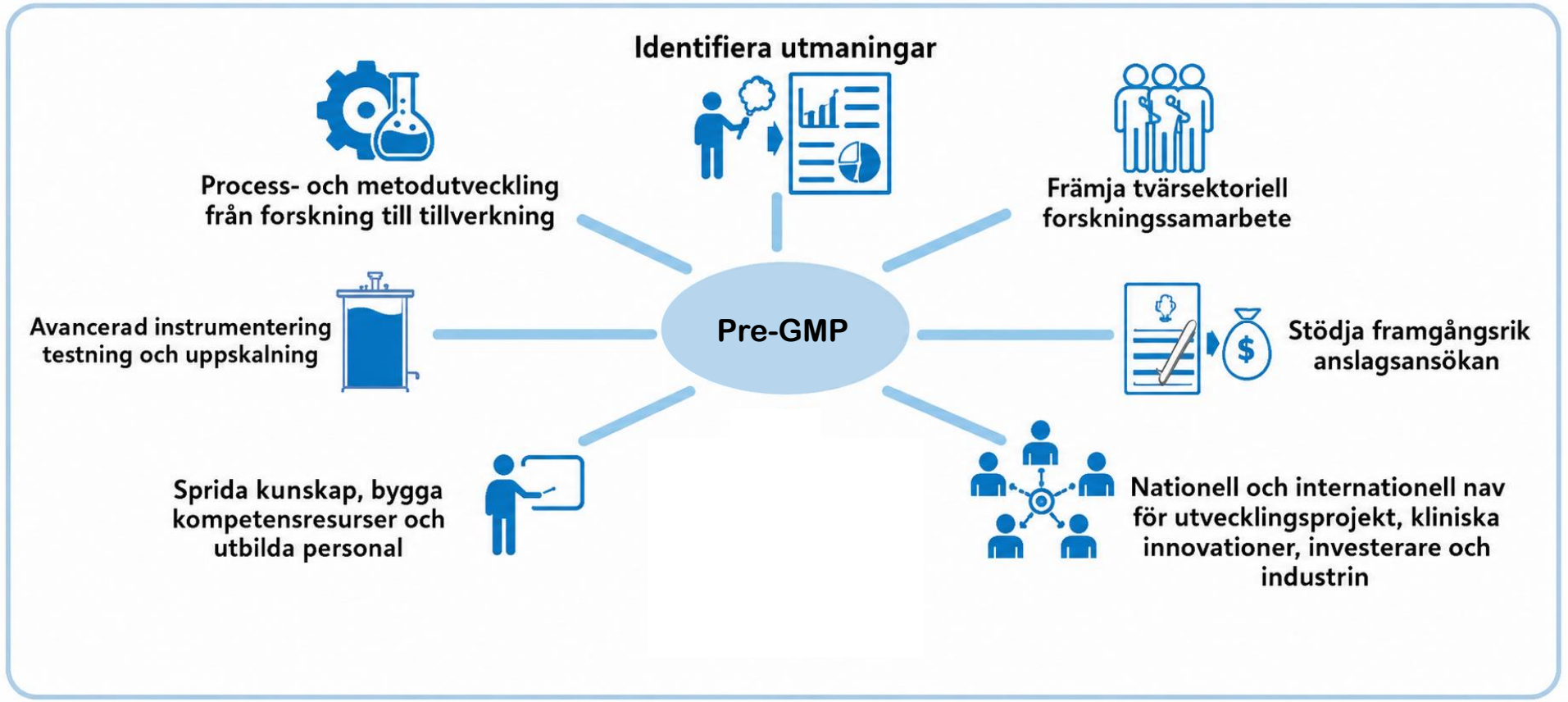


LUND STEM CELL CENTER

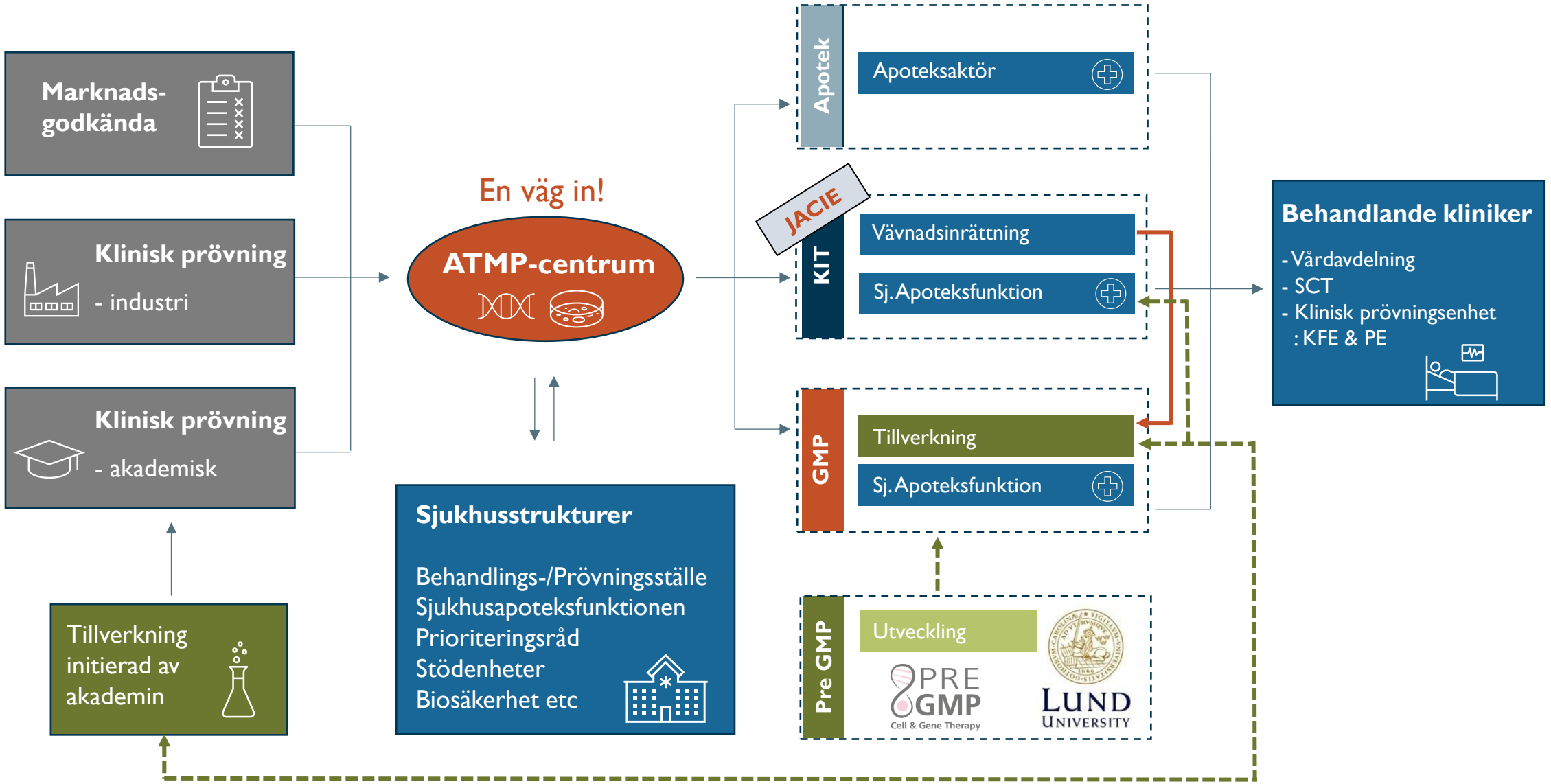
LUND UNIVERSITY

Källa:The ATMP pipeline report, Elias Uhlin

Pre-GMPs ansvarsområden:



Samarbeten och nätverkande

LUND UNIVERSITY

FRÅGOR? ATMP-centrum@skane.se