

**Welcome to**

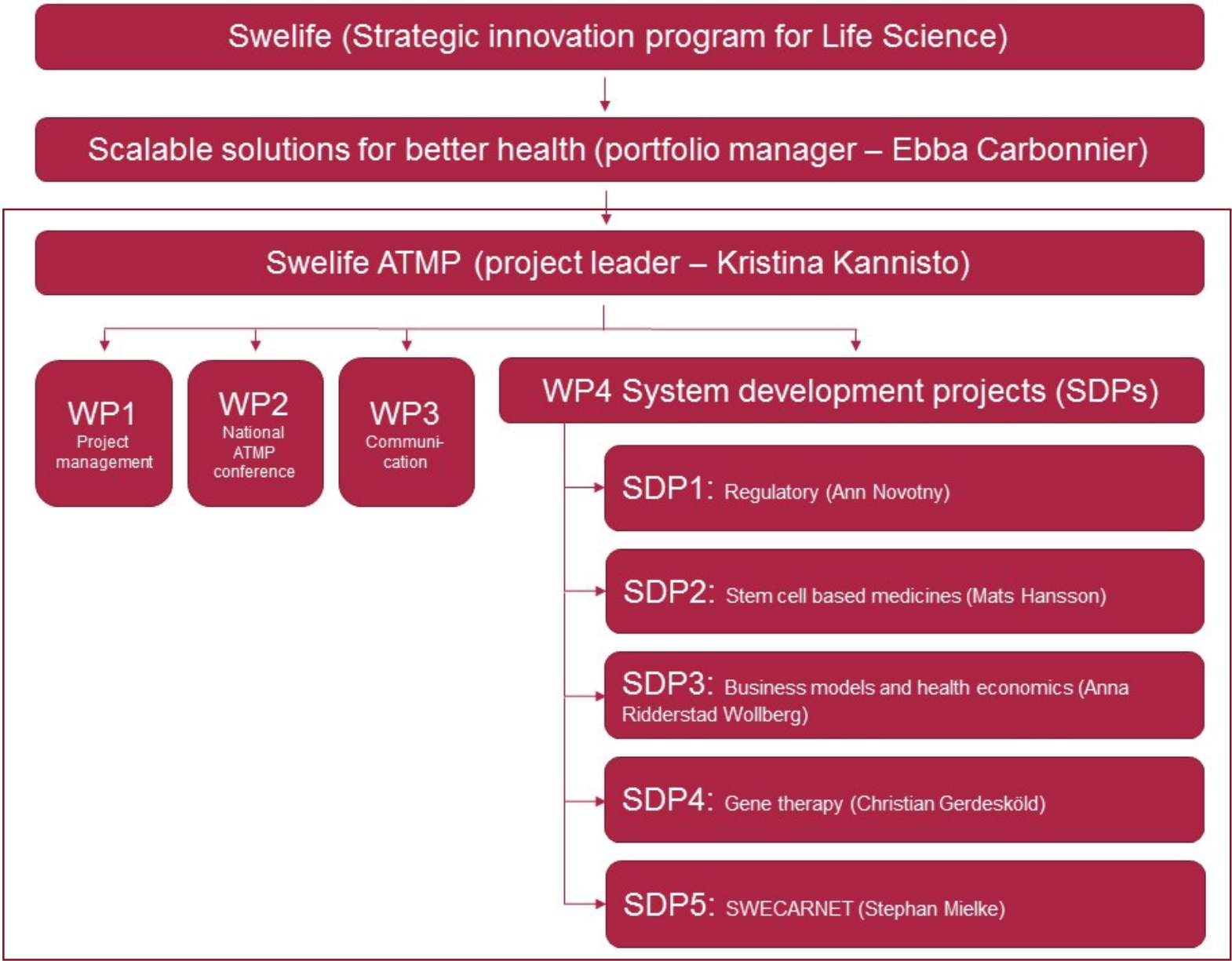
**Swelife ATMP wrap up webinar  
November 17<sup>th</sup> 2020**





## **Swelife ATMP - Increased competitiveness within cell and gene therapies**

- > A strategic national project aiming to increase Sweden's abilities and competitiveness within Advanced Therapy Medicinal Products (ATMPs)**
- > Started June 2017**
- > Total budget of 28 Mkr**
- > Since 2018, run in parallel with Centre for Advanced Medical products (CAMP)**
- > End date moved from May 2020 to June 2021, due to the ongoing pandemic**
- > Part of Swelife's portfolio "scalable solutions for better health"**







# Swelife-ATMP

## Nationally scalable solutions

Ebba Carbonnier, MSc MBA  
Portfolio Manager Nationally Scalable Solutions for Health, Swelife and Karolinska Institutet Innovations  
2020-11-17



Karolinska Institutet  
Innovations AB

SWElife

MED STÖD FRÅN

VINNOVA

FORMAS

 Energimyndigheten



# SWElife

## National Innovation program Life Science

- 20 Strategic projects and  
100 innovation projects

### E. g. Strategic projects

1. Prevention of childhood obesity
2. Cell- and gene therapy
3. National biobanking
4. Genomic Medicine Sweden - Informatics

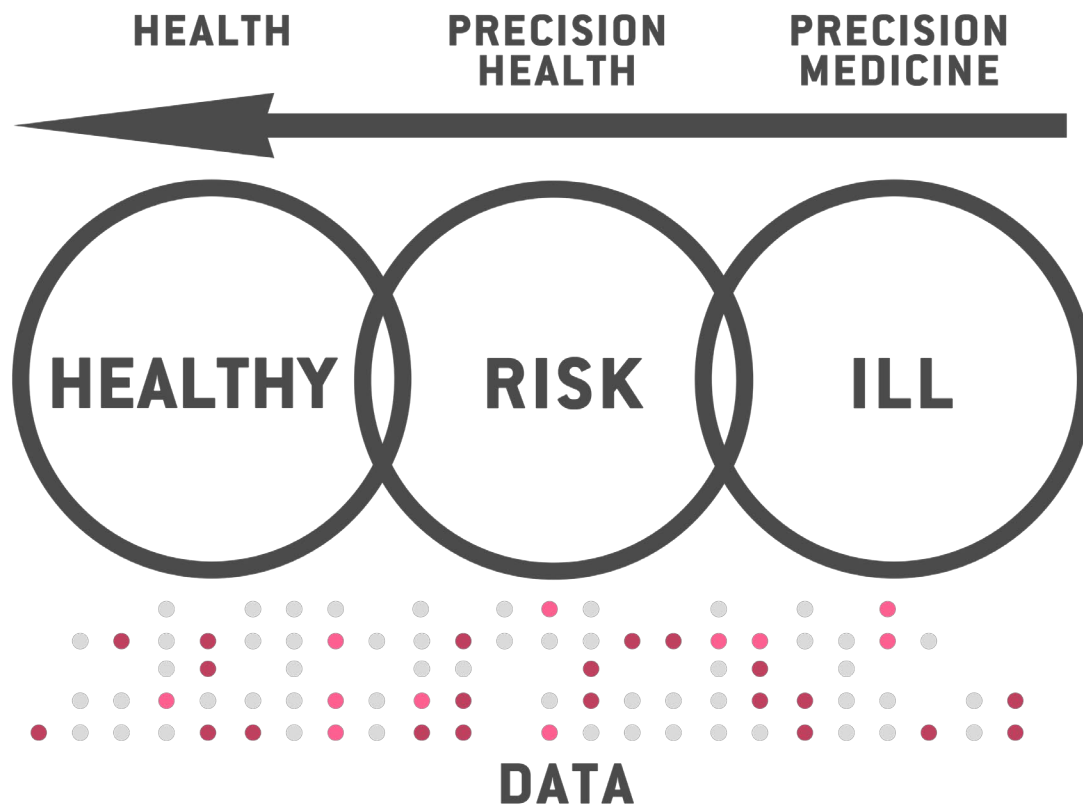




## Close cooperation between our large national projects

> Data, consent, legal and ethical aspects, health economy





# Thank you

Ebba Carbonnier

Portfolio Manager Nationally Scalable Solutions for Health

+46 730 82 56 54

[ebba.carbonnier@swelife.se](mailto:ebba.carbonnier@swelife.se)

[www.swelife.se](http://www.swelife.se)



**Karolinska Institutet  
Innovations AB**







## What is Swelife ATMP?

- > **Purpose:** to adress key challenges and system aspects of regulations and legislation, ethics, communication, education and know-how, health economics and more.
- > **Bringing partners together in networks around challenges, with the goal of collaboration and communication, inwards and outwards.**
- > **Deliverables and results:**
  - > Some intangible: networks and established contacts, mapping and formulation of challenges, communication
  - > Some tangible: web page and news letter, a national conference; ATMP Sweden, education and information, guides, checklists and templates



# Examples

The screenshot shows a web browser displaying the ATMP regulatory guide website. The browser's address bar shows the URL `atmpsweden.se/atmp-regulatory-guide/`. The page features a blue header with the slogan "MAKING THE IMPOSSIBLE POSSIBLE" and a "Partner login" button. A navigation menu is open, listing various sections. The "ATMP REGULATORY GUIDE" section is highlighted, and its content is visible on the right side of the page.

ATMP - ATMP regulatory guide x +

atmpsweden.se/atmp-regulatory-guide/

Partner login

MAKING THE IMPOSSIBLE POSSIBLE

HOME CONFERENCE NEWS EVENTS CONTACT

RESOURCES > ATMP REGULATORY GUIDE

ABOUT CAMP > PUBLICATIONS

ABOUT SWELIFE-ATMP > WHAT ARE ATMPs?

ABOUT INNOVATION> MILIEU SME COUNCIL

OPPORTUNITIES IN > SWEDEN ATMPs IN SWEDEN

ATMP Products (ATMPs, Clinical trials, Hospital Exemption

FOLKHÄLSODALEN 2020

ATMP REGULATORY GUIDE

This regulatory guide will provide useful information and insights throughout the Advanced Therapy Medicinal Product (ATMP) development process.

Contact [Läkemedelsverket](#) or the [European Medicines Agency \(EMA\)](#) at an early stage for advice on your process development plan.

This guide for ATMPs will help you through the important steps from process development to clinical use. In this guide you have the possibility to navigate through the general steps for clinical trial and all the different classifications.

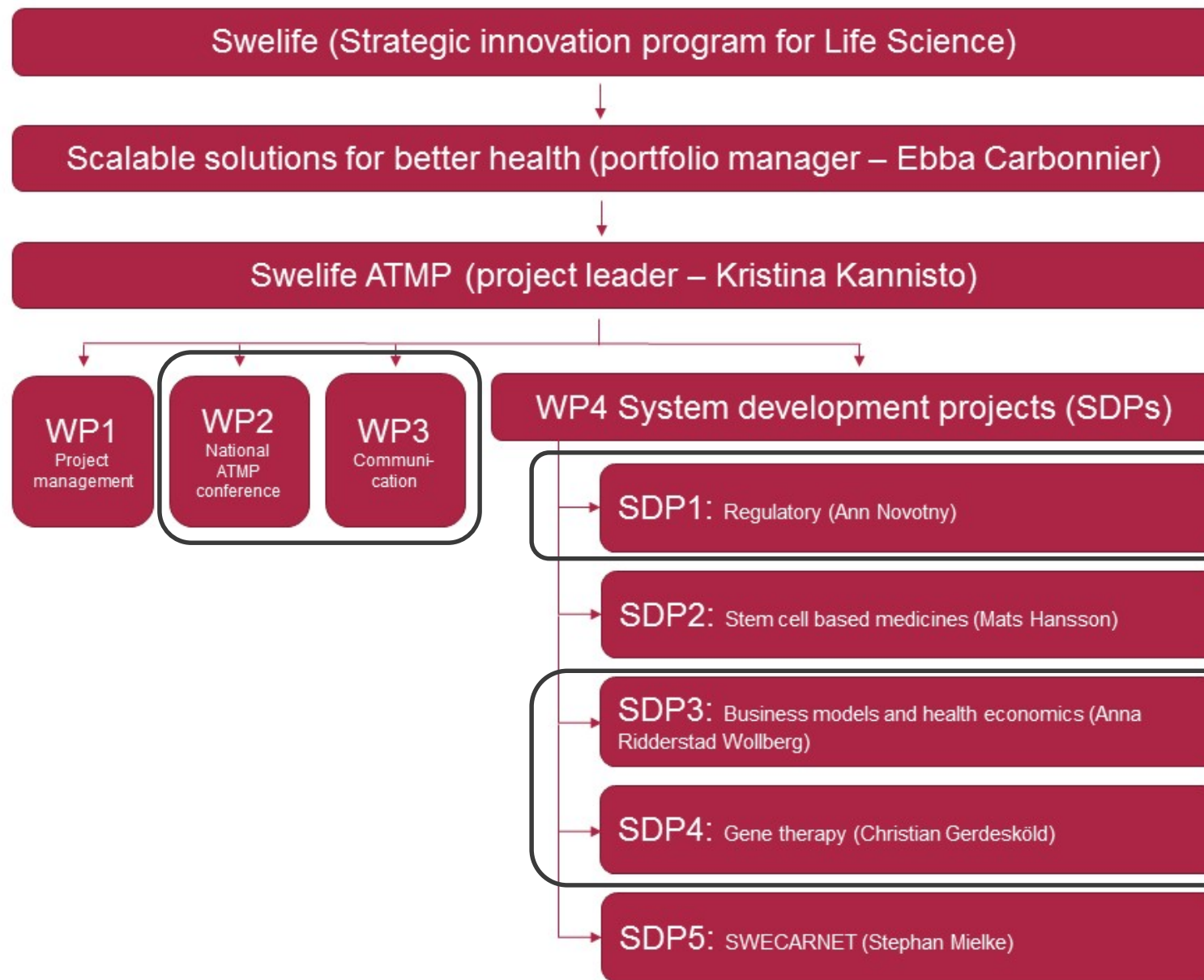
For more information on the guide or for comments and suggestions

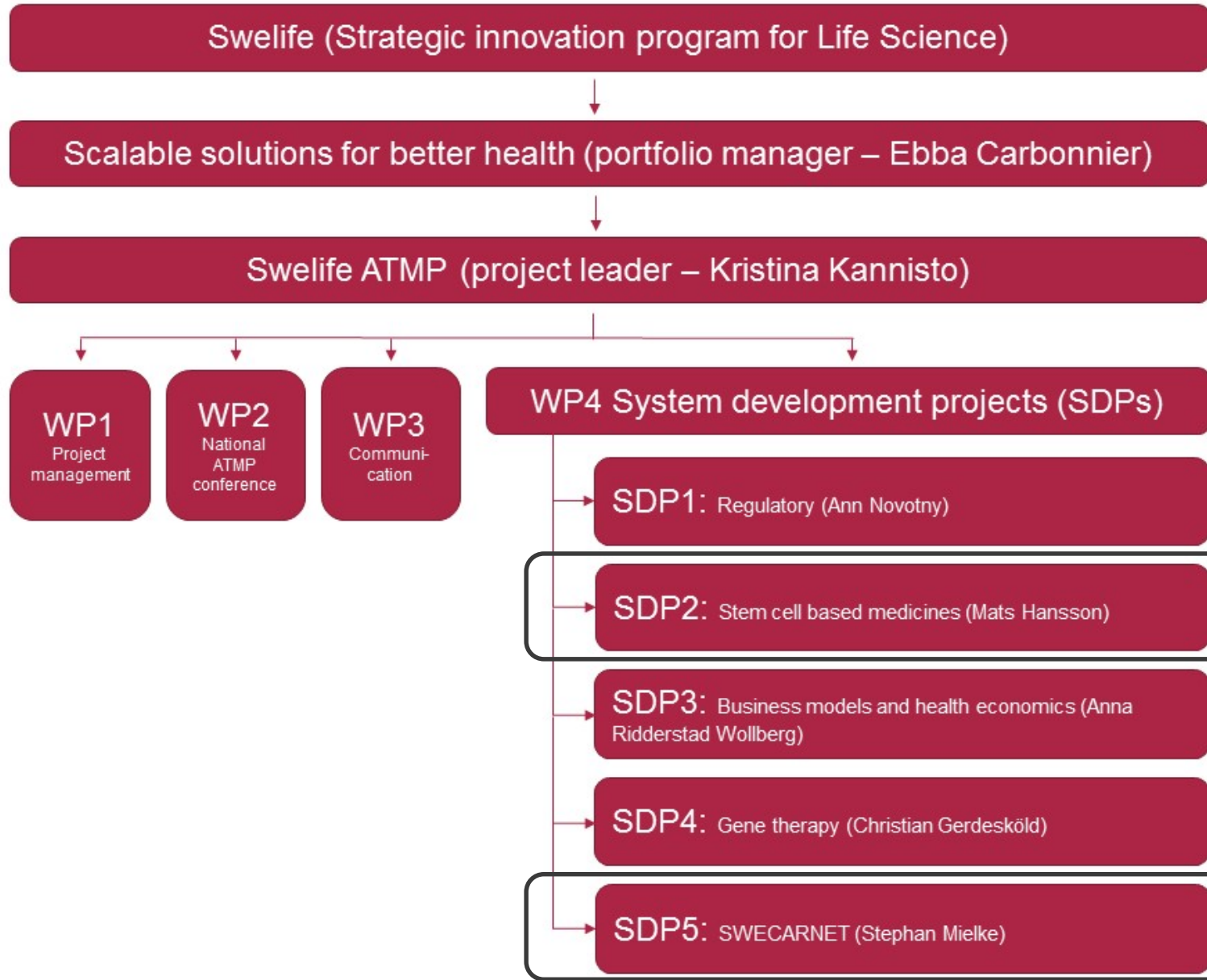


## Who are we?

- > **39+ partners representing Regions, University Hospitals, Academia, Small and Medium-sized Enterprises (SMEs) or Big Pharma**
- > **Project management from Karolinska Cell therapy Centre (KCC) – Kristina Kannisto**
- > **Swelife ATMP is part of a bigger collaborative network under the umbrella ATMP Sweden**
- > **Find out who is involved and more info at [www.atmpsweden.se](http://www.atmpsweden.se) -> about Swelife ATMP**  
**<https://atmpsweden.se/swelife-atmp-2/swelife-atmp/>**





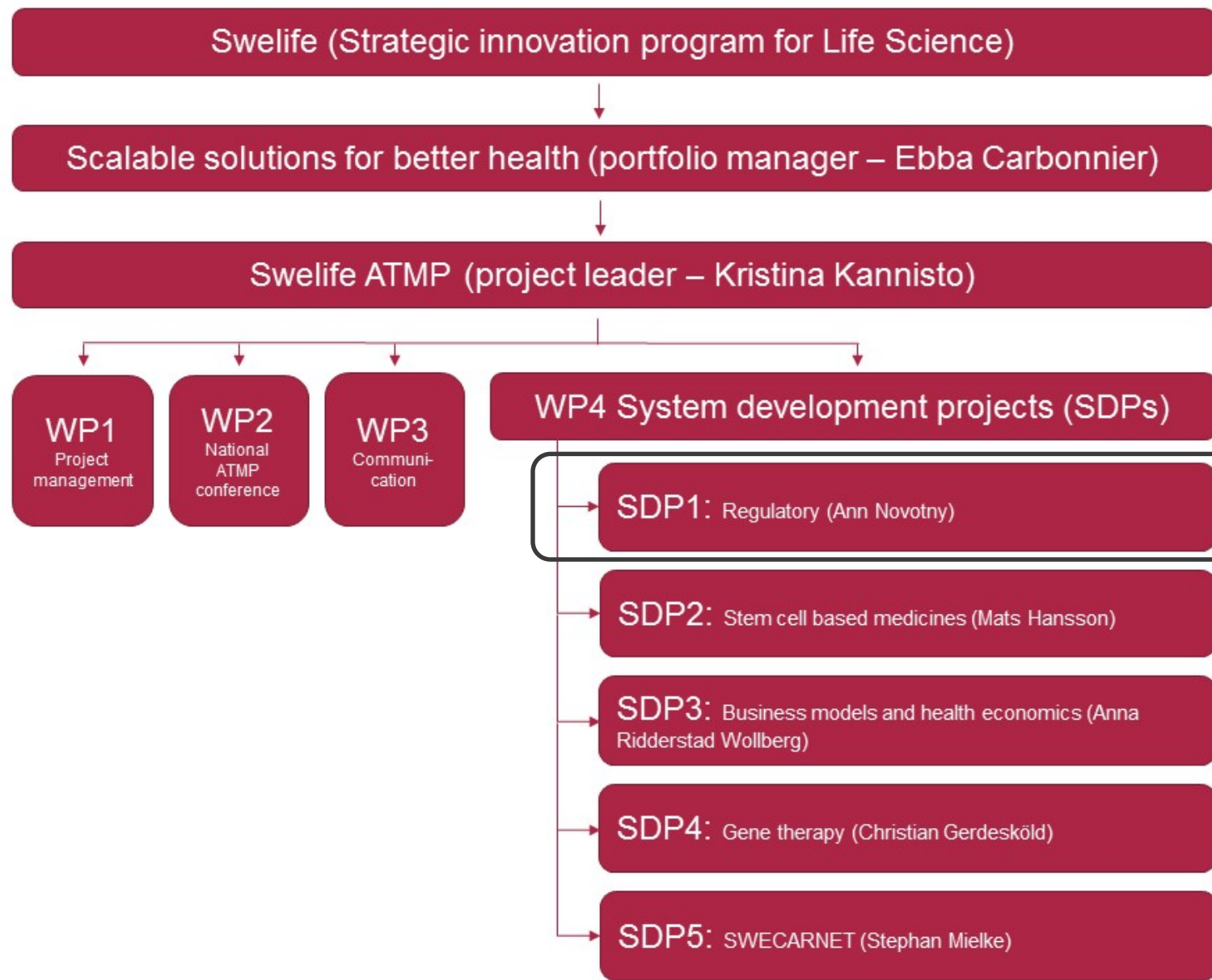


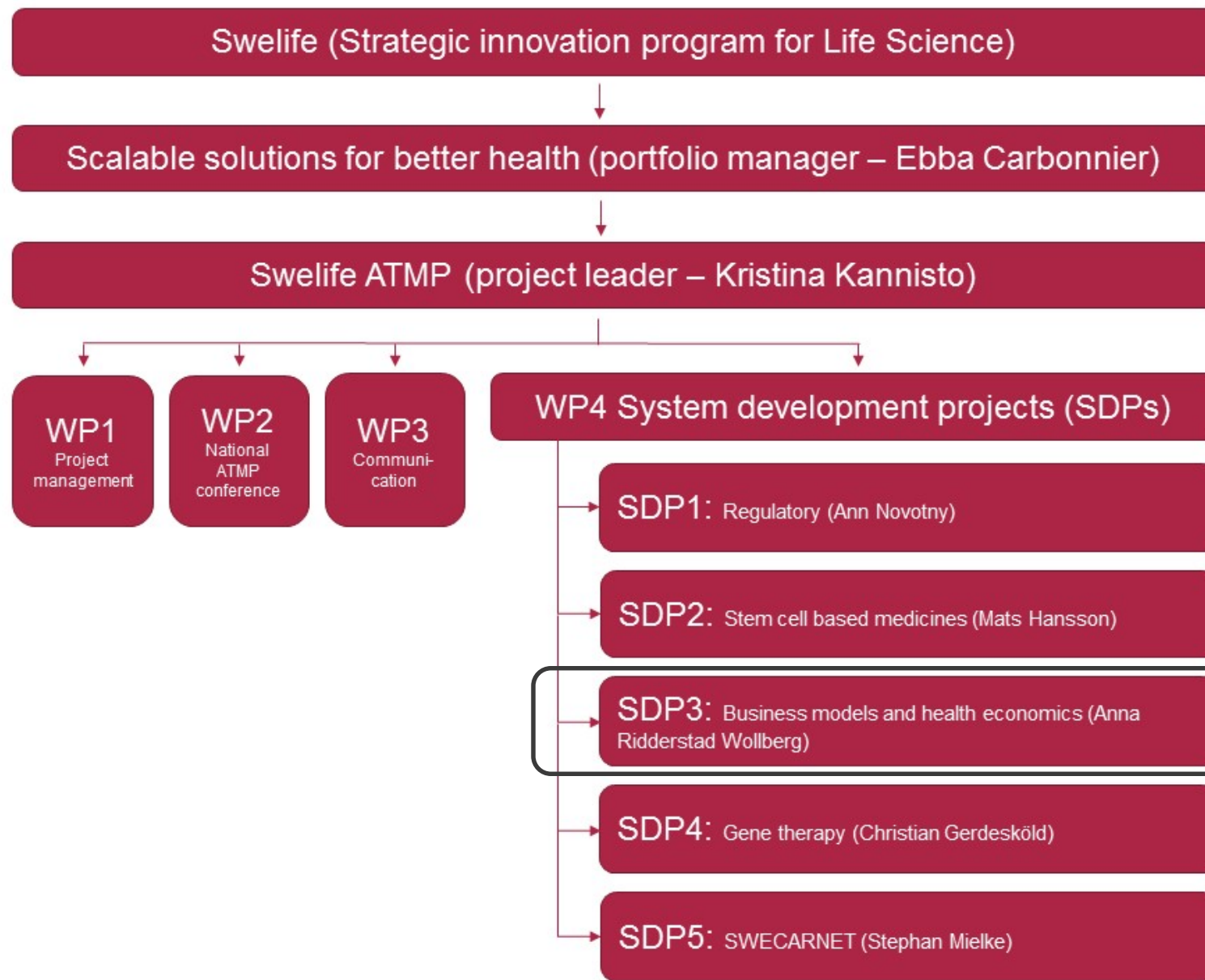


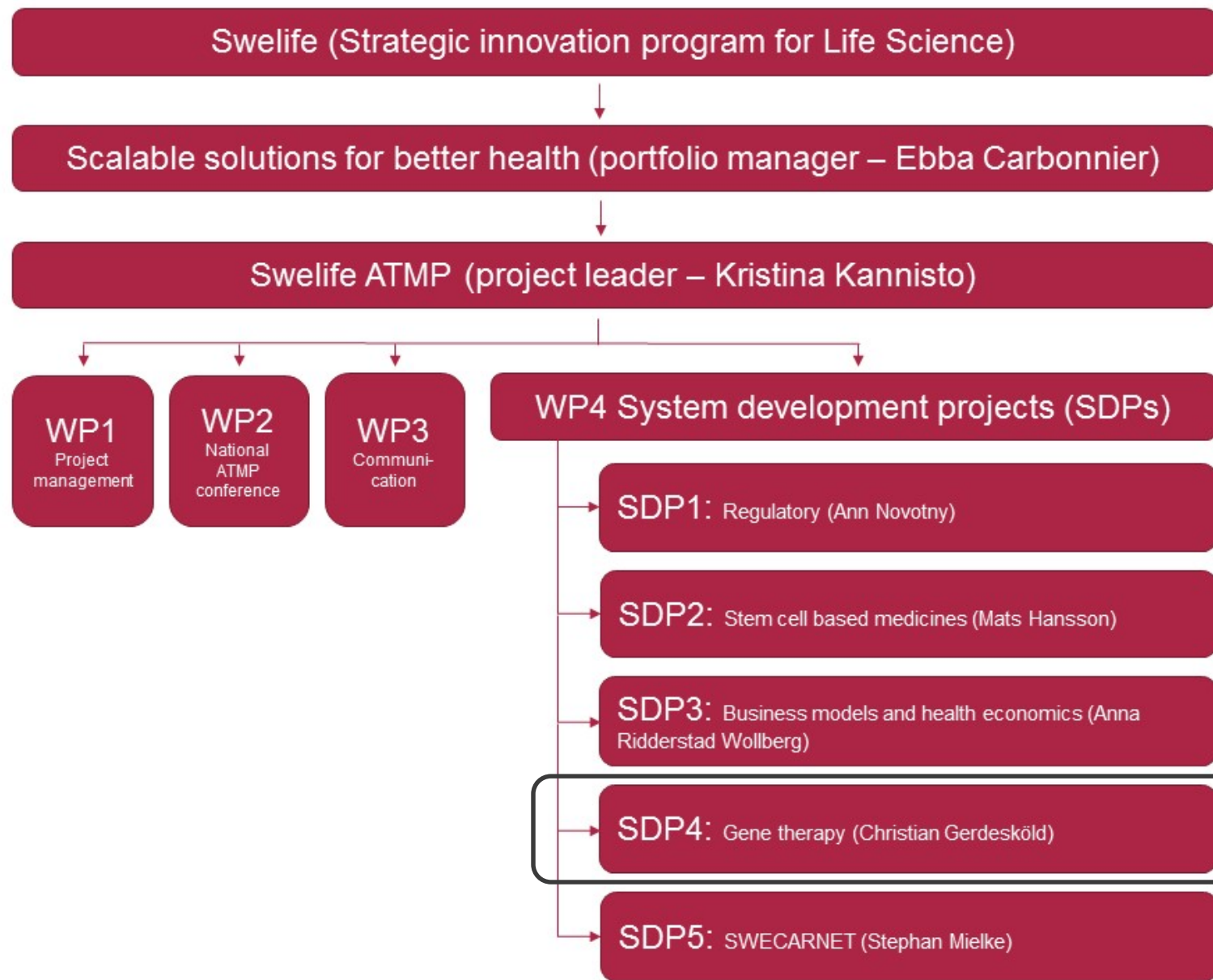
## About SDP2 and 5

- > **SDP2 addresses key issues around pluripotent stem cells and their use in research and manufacture of advanced therapies.**
  - > Results from value survey are delayed due to the ongoing pandemic but will be finalized and presented in 2021
  - > Report and other material summarizing the work within Swelife ATMP can be found at <https://atmpsweden.se/swelife-atmp-2/projects/road-map-for-setting-the-ethical-and-legal-framework-of-stem-cell-based-atmp-in-sweden/>
- > **SDP5 - SWECARNET is the national competence network for CAR T-cell therapies**
  - > The network is heavily affected by the ongoing pandemic and has been granted extended project time in 2021
  - > Films and info about Swecarnet and Swedish CAR T activities can be found at <https://atmpsweden.se/swelife-atmp-2/projects/sdp5-swecarnet/>

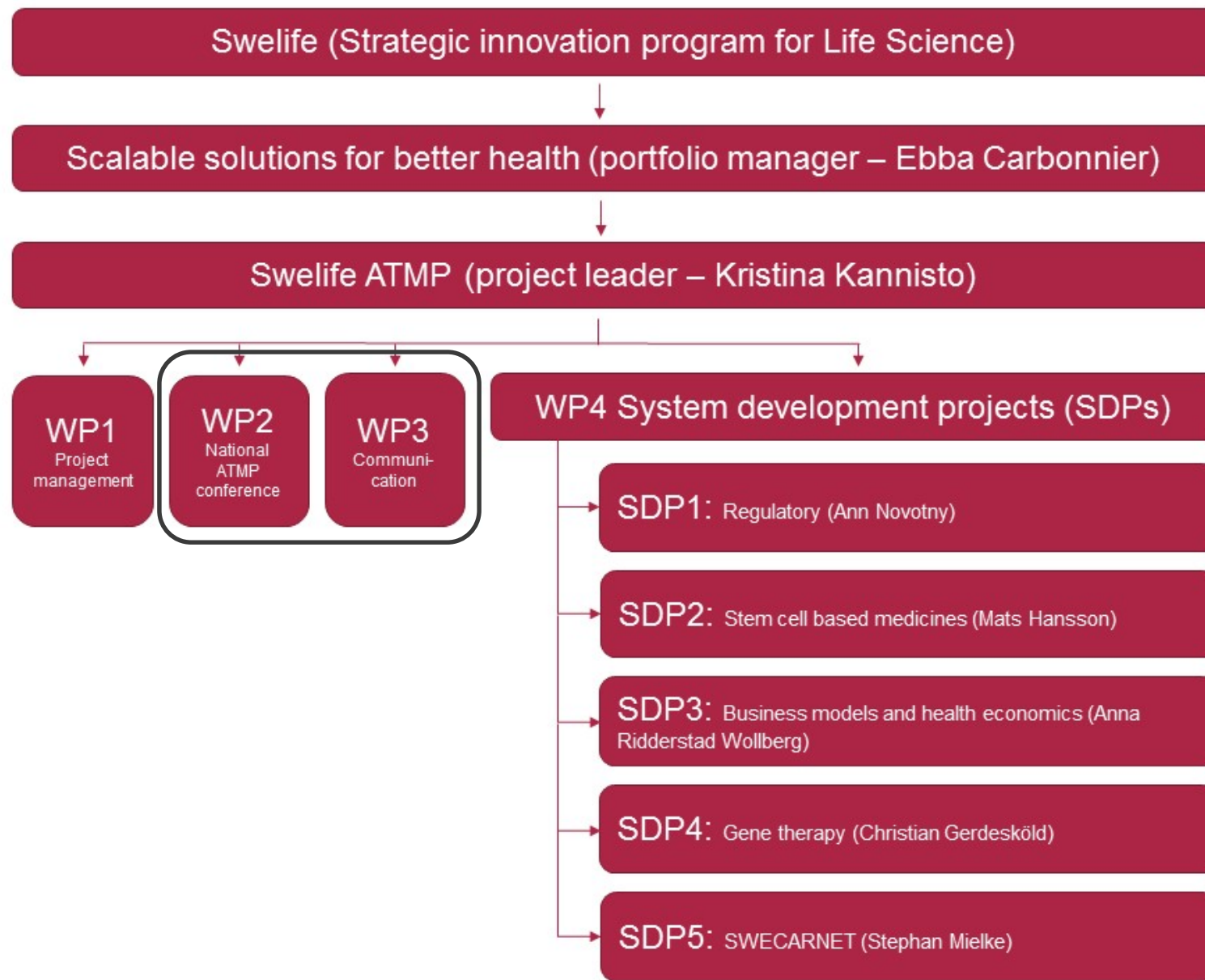












# Swelife ATMP

## Summary and future





## What is the value of Swelife ATMP?

- > **The network!**
- > **Visibility, collaboration, knowledge-sharing and communication**
- > **Understanding the "whole picture" of the system aspects affecting competitiveness within the field**
- > **Tangible and intangible results and deliverables in conjunction**
  - > Templates, reports, guides etc become valuable when they are used and communicated within and outside the network
  - > Communication within and outside the network becomes valuable when we use the knowledge accumulated in templates, reports, guides etc





# What will happen with results and deliverables when Swelife ATMP ends?

- > They will be continuously implemented and developed through Centre for Advanced Medical Products (CAMP), the vision-driven innovation milieu and other initiatives under **ATMP Sweden**
- > **For example:**
  - > Communication work and ATMP Sweden conference continues in the vision-driven innovation milieu
  - > SDP1 work group has transferred to CAMP and the network of emerging ATMP-centers at university hospitals will maintain the network
  - > SDP2 was unable to deliver in full within Swelife ATMP (due to Covid-19) but has transferred to CAMP and joined forces with the CAMP-project  
<https://atmpsweden.se/camp-2/projects/producing-gmp-hpsc-and-derivatives/>
  - > SDP3 report material will now be used in the continuation of SDP3, plans for incorporation of the material in education events and to be used in communication with stakeholders



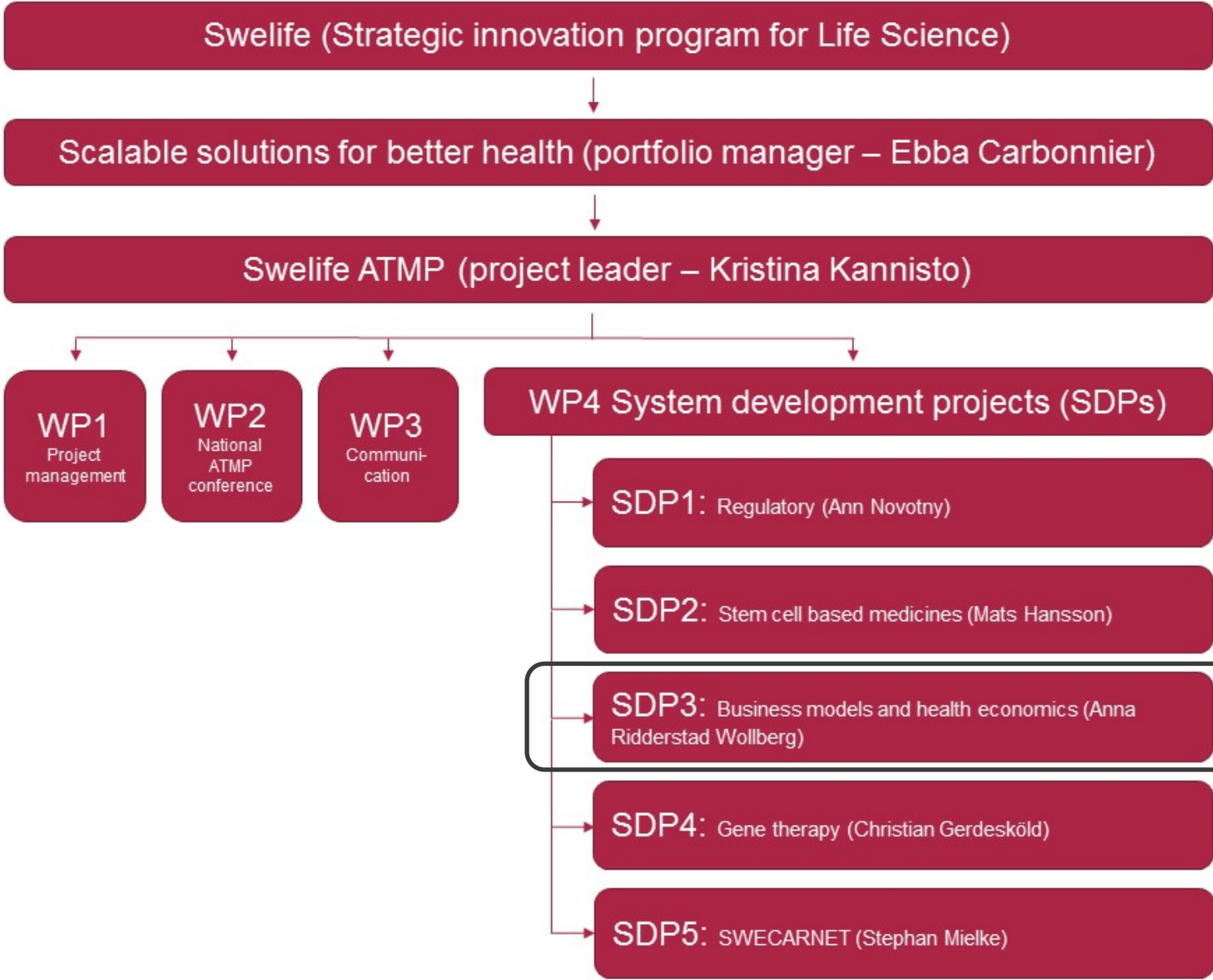
# What will happen with results and deliverables when Swelife ATMP ends?

## > Continued examples:

- > SDP4 report and partners have highlighted the need for Swedish capabilities in process development and manufacturing of *in vivo* gene therapies and the innovation milieu is addressing this in one of its strategic initiatives
- > SDP5 continues during 2021 and plans for further implementation and continued funding thereafter are under construction

## > Destination: ATMP Sweden and identified target groups

- > All results from Swelife ATMP are to be made publicly available (main source: [atmpsweden.se](http://atmpsweden.se))





## Swelife ATMP – SDP 3, continuation

Lead: Örjan Norberg, Region Västerbotten

> **Challenge**

> Regulatory approval does not ensure positive recommendation, reimbursement and implementation in healthcare in Sweden

> **Overall objective**

> To increase patients access to best possible treatment alternatives that are cost effective and affordable

> **Goal**

> In partnership with stakeholders identify, develop, test and evaluate new - long-term sustainable and nationally relevant and scalable – valuation- and payment models for advanced therapies

> **Deliverable**

> A "real world case study" - including results, lessons learned and possible solutions that are of relevance for the sector as a whole.





# The partners – the greatest value of Swelife ATMP!

Akademiska Sjukhuset

AstraZeneca AB

CELGENE AB

CELLSEED SWEDEN AB

CombiGene AB

GE Healthcare Aktiebolag

Gilead Sciences Sweden AB

Göteborgs Universitet

IDOGEN AB

IHE, INSTITUTET FÖR HÄLSO- OCH  
SJUKVÅRDSEKONOMI

KI - Department of Clinical Science, Intervention  
and Technology

KI - Department of Neuroscience

KI - Institutionen för laboratoriemedicin

Karolinska Universitetssjukhuset - Cellterapi och  
Allogen Stamcellstransplantation

Karolinska Universitetssjukhuset - KCC

Karolinska Universitetssjukhuset - KTA

Karolinska Universitetssjukhuset -  
Innovationsplatsen

Lunds universitet

Läkemedelsindustriföreningens Service  
Aktiebolag

Medicon Village Innovation AB

NEXTCELL PHARMA AB

NOVARTIS SVERIGE AKTIEBOLAG

PFIZER INNOVATIONS AB

Region Skåne - Enheten för Forskning och  
utveckling

Region Skåne - Neurologkliniken Lund

Region Västerbotten

Region Örebro län

RISE Research Institutes of Sweden AB

Skånes universitetssjukhus - Hematologi,  
onkologi och strålningsfysik

TAKARA BIO EUROPE AB

Uppsala universitet - Institutionen för folkhälso-  
och vårdvetenskap

Uppsala universitet - Institutionen för  
immunologi, genetik och patologi

Uppsala universitet - Juridiska institutionen

VERIGRAFT AB

VÄSTRA GÖTALANDSREGIONEN - Gothia Forum

VÄSTRA GÖTALANDSREGIONEN - VO Onkologi

XNK Therapeutics AB - CellProtect Nordic  
Pharmaceuticals AB

ÖSTERGÖTLANDS LÄNS LANDSTING - REGION  
ÖSTERGÖTLAND



## And a special thank you to Vinnova/Swelife and WP/SDP-leaders

### **Vinnova**

Mats Jarekrans

### **Swelife**

Ebba Carbonnier

Peter Nordström

Nils-Olof Jönsson

Karin Lilja

### **WP/SDP-leaders**

Heather Main, WP2-3 Communication

Ann Novotny, SDP1 Regulatory

Mats Hansson, SDP2 Stem cell-based

medicines

Anna Ridderstad Wollberg, SDP3 Business models and health economics

Christian Gerdesköld, SDP4 Gene therapy

Stephan Mielke, SDP5 Swecarnet





Thank you!



Kristina Kannisto

Karolinska Centrum för Cellterapi

kristina.kannisto@sll.se