National initiatives to facilitate clinical implementation of ATMPs



Competence centre for process and product development and manufacturing of ATMPs

SWElife

Strategic project for ATMPs, focusing on legislation, ethics, knowledge exchange and communication



SWElife

Production

WP1. Process development

WP2. Infrastructure for GMP-manufacturing

WP3. Quality control, shelf-life and logistics

Cross Cutting Priority 1: Legislation, regulatory and Health economical aspects Cross Cutting Priority 2: Swedish ATMP challenges and opportunities

/larket – Tools, consumables, services ATMP and healthcare

Clinical research & development in the different regions (academia and industry)

SWElife

ATMP

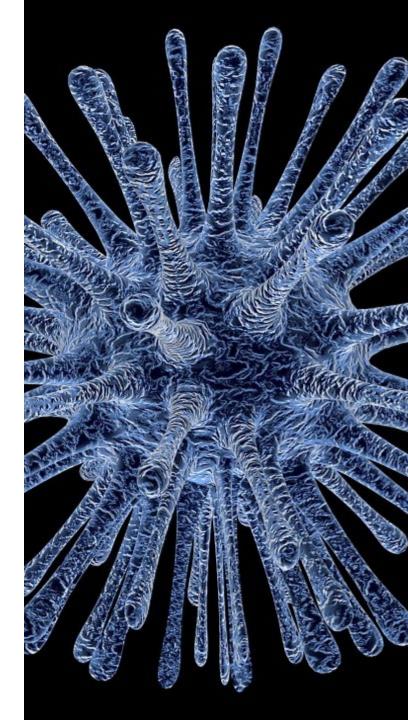
Increased competitiveness within cell and gene therapy

Aim

> Strengthen Sweden's competitiveness within advanced therapies (ATMP)

Objectives

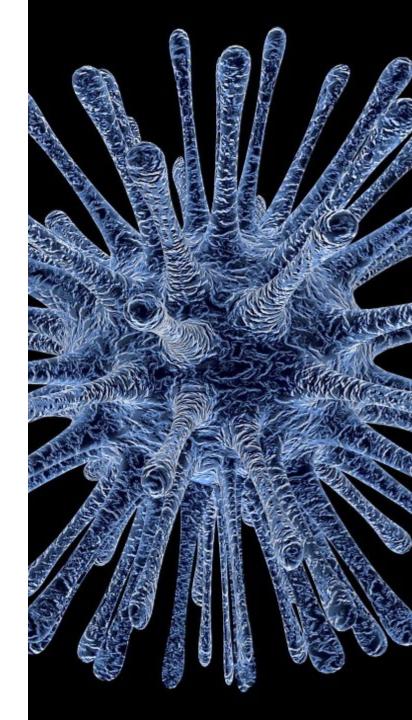
- > Increased national knowledge about and competence for development of ATMPs
- > Increased visibility and awareness of ATMPs in society and healthcare
- Speed up clinical translation (without loss of quality or safety)



> Increased national knowledge about and competence for development of ATMPs

How?

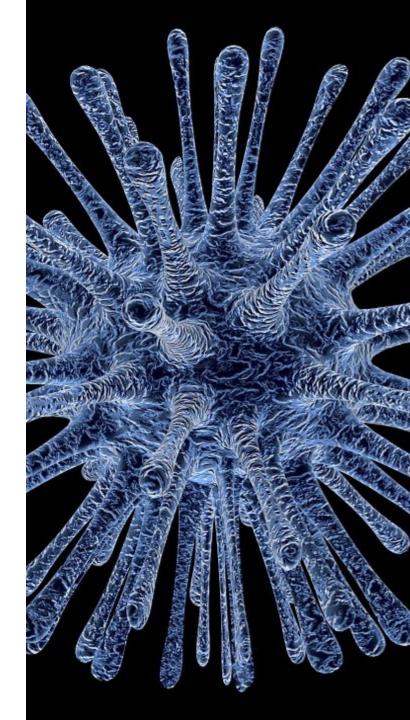
- National conference (April 4 2019)
- Educational seminars together with Vävnadsrådets VOG Cell (GMP for ATMP, May 2019)
- System development projects addressing regulatory, ethical and strategic issues (Regulatory guide available on Karolinska.se/kcc)
- Work shops gathering big pharma, SMEs, academia and healthcare in common dialogue



> Increased visibility and awareness of ATMPs in society and healthcare

How?

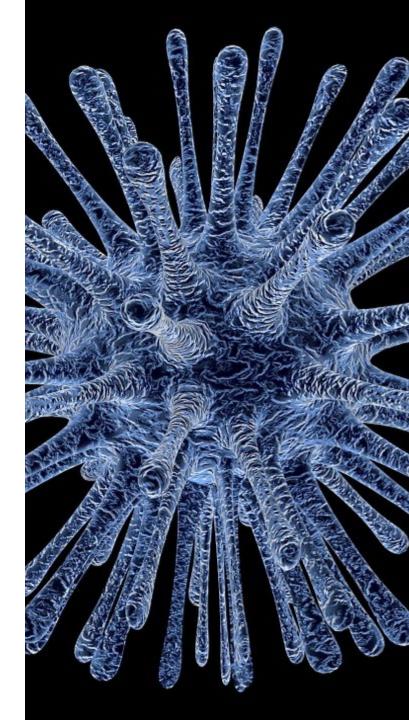
- Web page (under construction)
- LinkedIn (Centre for Advanced Medical Products)
- Patient organisations and participation in "public dialogue"



> Speed up clinical translation (without loss of quality or safety)

How?

- Compiled knowledge (Regulatory guide, support networks, web, seminars etc)
- Providing support for development of quality assured ATMPs for clinical trial
- Sharing knowledge between sites



Work packages:

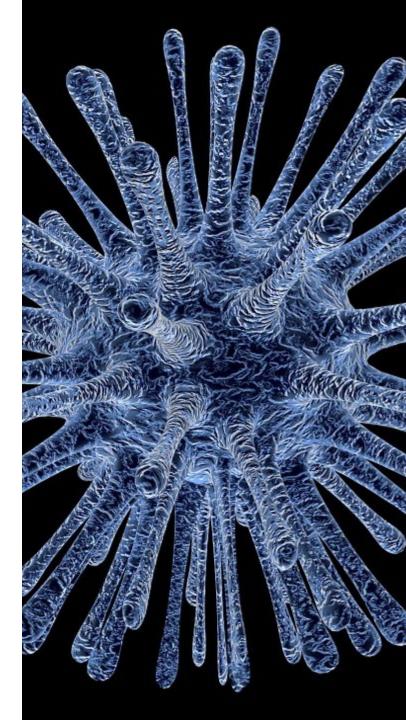
- 1. Project management
- 2. National conference
- 3. Communication
- 4. System development projects

SDP1 – regulatory

SDP2 – stem cell based medicines

SDP3 – business models and health economy

SDP4 – gene therapy





Thank you!

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www.swelife.se



FOR A COMPETITIVE LIFE SCIENCE ECOSYSTEM IN SWEDEN







