

Request for assessment, clinical trial

The ATMP council at Sahlgrenska University Hospital assess all new treatments at the hospital that include Advanced Therapy Medicinal Products (ATMP). In order to be able to process a "Request for Assessment" it is required that the information requested in the document be submitted to the ATMP Council at least two weeks prior to scheduled meeting. Dates for the ATMP Council meetings, which is scheduled once a month, are announced on the ATMP Center's website [ATMP-råd - Sahlgrenska Universitetssjukhuset](#). The ATMP Council's activities are covered by the confidentiality rules set out in the Publicity and Confidentiality Act (2009:400) The document, "Request for assessment" can be completed electronically and is limited to a maximum of 16 pages including help text and signature page. The document must be signed by the investigator at Sahlgrenska University Hospital and/or the sponsor (in the case of a clinical trial) or the responsible physician (in the case of hospital exemption), researcher and Director/Head of department at the treating clinic. The document including attachments is sent via email to su.atmpcenter@vgregion.se. The assessment by the ATMP council is communicated via the ATMP Center to the person or persons who signed the document.

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Section 1. Confidentiality

1.1 Is there a need for confidentiality?

No

Yes

If yes, please indicate which sections of this application are concerned

Section 2. Information about sponsor, investigator and clinic

2.1 Sponsor

Enter sponsor if it is a clinical trial

Name:

Title:

Company/University/college:

Health care affiliation:

Address:

Email:

Phone:

2.2 Principal investigator/investigator or responsible physician

In the case of clinical trial, the principal investigator and, where applicable, investigator at Sahlgrenska University Hospital are indicated. In the case of hospital exemption or other use, the responsible physician and researcher are indicated.

Name:
Title:
University/college:
Health care affiliation:
Address:
Email:
Phone:

Name:
Title:
University/college:
Health care affiliation:
Address:
Email:
Phone:

2.3 Treating clinic and Director/Head of department

State at which clinic(s) the treatments will take place as well as the name and contact details of Director/Head of department.

Clinic:
Director/Head of department name:
Address:
Email:
Phone:

2.4 Agreement

2.4.1 Is there an agreement between the sponsor and the Director/Head of department (in the case of clinical trial) or between the responsible physician/Director/Head of department and the manufacturing unit (in the case of hospital exemption/transplantation)

- No
 Yes

2.4.2 Is there an agreement between the Department and other departments at the hospital?

- No
 Yes

Section 3. Information about the project/preclinical data/clinical data

3.1 Project title, and short title

3.2 Patient treatment

Specify the type of treatment intended:

- Clinical trial (ATMP)
 Hospital exemption treatment (ATMP)
 Transplantation (established treatment, not drugs)
 Clinical study (not clinical trial involving drug)

3.3 Indication and patient group

State the indication and patient group the product is intended for.

3.4 How many patients will be treated?

3.5 Biobank samples

Does the project include biobank samples?

No

Yes

If yes, describe how these samples are handled

3.6 Scientific background

Describe the scientific background to the project.

3.7 Preclinical data

Please provide available preclinical data (in vitro and in vivo).

3.8 Clinical data

Are there clinical data from previously completed studies?

3.9 Allocation of responsibilities

Describe the responsibilities within the research project at the hospital.

3.10 Are there other stakeholders in this project?

E.g. company, other healthcare provider, academy.

3.11 Need for resources

Describe the resources needed at Sahlgrenska University Hospital. E.g. resources for recovery, manufacturing, treatment, or legal resources.

- Harvest- apheresis will take place on XXX
- Drugs are manufactured at supplier xxx alternatively xxx
- Receipt of drugs will be performed by xxx (for clinical trial it can be performed at the clinic with a routine established by a hospital pharmacist) alternatively by the hospital pharmacy
- Dispensing of medicine is performed by xxx (e.g. hospital pharmacy)
- Preparation will be carried out by Preparation unit Hospital Pharmacy/preparation at the clinic
- Treatment will take place at clinic xx
- Legal support when writing contracts will be needed.

3.12 Need for special equipment

3.13 Summary of the project

Briefly describe the project's practical layout and rationale. Describe the entire process/flow and who is responsible for each step – harvest (where and how does harvest take place?), manufacturing (where does manufacturing take place?), treatment (where and how does treatment take place?), evaluation/follow up.

Section 4. Information about the product

4.1 Classification of product

4.1.1 Is the product an ATMP? Enter the associated subgroup

- CTMP
- GTMP
- TEP
- Combined ATMP describe how

4.1.2 Is the product classified in consultation with the Swedish Medical Products Agency or European Medicines Agency?

- No
- Yes

4.1.3 Provide a brief summary of the reasoning

The following can be used for guidance: Article 17 of Regulation (EC) No 1394/2007 and/or “Reflection paper on classification of advanced therapy medicinal products” 21 May 2015 EMA/CAT/600280/2010 rev.1 Committee for Advanced Therapies (CAT)

4.1.4 Is a medical device involved?

No

Yes

If Yes describe the product

4.2 Product description

Describe the product's characteristics and efficacy in patient (Please attach the Pharmacy Manual if available)

Product	
Manufacturer	
Is there a market approval for the product	
Indication	
Pharmaceutical formulation	
Dosage and route of administration	
Pharmacological properties <i>(Pharmacodynamics/Pharmacokinetics)</i>	
Qualitative and Quantitative composition	
Release criteria including limits and methods	
Primary endpoint <i>What is the primary clinical criterion?</i>	
Secondary endpoint <i>What is the secondary clinical criterion?</i>	

4.3 Manufacturing

4.3.1 Enter manufacturer

4.3.2 Is there a validated production process?

No

Yes

4.3.3 Process description – Manufacturing (scale/capacity, validation status, quality control), storage, packaging

Section 5. Information on licenses/financing

5.1 Licenses

5.1.1 Does the manufacturer have a manufacturing license or alternatively a tissue facility license or equivalent?

Manufacturing license Yes No

Tissue establishment license Yes No

5.1.2 Has the Department license from the Health Care Inspectorate (IVO) or the Medical Products Agency (LV)?

License from IVO Yes No

License for Hospital exemption from LV Yes No

5.1.3 Is there approval in CTIS? (The Swedish Medical Products Agency and the Ethics Review Authority) for clinical trial?

No

Yes

If Yes, enter the EU CT number and date of approval

5.1.4 Is the product GMM/GMO - if yes, attach SNIF/ERA or other equivalent documentation for risk assessment

No

Yes

5.2 Financing

5.2.1 How is the project/treatment financed?

Section 6. Benefit and health economic aspects

Describe the future benefit/use of the project for Sahlgrenska University Hospital. Are there health economic aspects to take into account?

Section 7. Other requests

Section 8. Signatures

Principal Investigator/Responsible physician

Physician: _____ Date: _____

Print name: _____

Director/Head of
department: _____ Date: _____

Print name: _____