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PRECISEU

DELIVERABLE D5.3

Multi-stakeholder Infrastructure Service Catalogue

bioRN

30/06/2026

Co-funded by the European Union

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*Legend = **R –** Report // **DEM –** Demonstrator, pilot, prototype, plan designs // **DEC –** Websites, patents filing, press & media actions, videos, etc. // **DMP –** Data management plan // **OTHER –** Software, technical diagram, algorithms, models, etc.	

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CONSORTIUM PARTNERS

	Name of the Entity	Acronym	Role	Country
1	BIORN CLUSTER MANAGEMENT GMBH	**BIORN**	B	Germany
2	EATRIS ERIC	**EATRIS**	B	Netherlands
3	BIOPRO BADEN-WUERTTEMBERG GMBH	**BIOPRO**	B	Germany
4	CLUST ER INDUSTRIE DELLA SALUTE E DEL BENESSERE	**Clust-ER Health**	B	Italy

***Legend** = Role in the Project: **C** – Coordinator // **B** – Beneficiary // **AP** – Associated Partner // Organization Type: **RTD** – Research and Technological

Tab. 1 Work Package Partners

	Name of the Entity	Acronym	Role	Country
1	Biocat LA FUNDACIO BIOREGIO DE CATALUNYA	**Biocat**	COORDINATOR	ES
2	DEPARTAMENT DE SALUT - GENERALITAT DE CATALUNYA	**SALUT**	BENIFICIARY	ES
3	BARCELONA SUPERCOMPUTING CENTER CENTRO NACIONAL DE SUPERCOMPUTACION	**BSC-CNS**	BENIFICIARY	ES
4	BIORN CLUSTER MANAGEMENT GMBH	**BIORN**	BENIFICIARY	DE
5	BIOPRO BADEN-WUERTTEMBERG GMBH	**BIOPRO**	BENIFICIARY	DE
6	AGENTIA PENTRU DEZVOLTARE REGIONALA NORD-EST	**NE RDA**	BENIFICIARY	RO
7	ASOCIATIA DIGITAL INNOVATION ZONE ZONA DE INOVARE DIGITALA	**DIZNE**	BENIFICIARY	RO
8	CLUSTERUL REGIONAL INOVATIV DE IMAGISTICA MOLECULARA SI STRUCTURALA NORD-EST (IMAGO-MOL)	**IMAGO-MOL**	BENIFICIARY	RO
9	BIOTEHNOLOGICHEN I ZDRAVEN KLASTER	**HLSCB**	BENIFICIARY	BG
10	CLUST ER INDUSTRIE DELLA SALUTE E DEL BENESSERE	**CLUST-ER HEALTH**	BENIFICIARY	IT
11	REGIONE EMILIA ROMAGNA	**RER**	BENIFICIARY	IT
12	ART-ER-SOCIETA CONSORTILE PER AZIONI	**ART-ER**	BENIFICIARY	IT
13	VLAAMSE GEWEST	**EWI**	BENIFICIARY	BE
14	BIOVIA	**BIOVIA**	BENIFICIARY	BE
15	VIESOJI ISTAIGA INOVACIJU AGENTURA	**IA LITHUANIA**	BENIFICIARY	LT
16	BRG, BUSINESS REGION GOTEBORG AB	**BRG**	BENIFICIARY	SE
17	EATRIS ERIC	**EATRIS**	BENIFICIARY	NL
18	PLATAFORMA DE ORGANIZACIONES DE PACIENTES	**POP**	BENIFICIARY	ES
19	AGENCIA PER A LA COMPETITIVITAT DE LA	**ACCIO**	BENIFICIARY	ES

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	EMPRESA			
20	IDRYMA TECHNOLOGIAS KAI EREVNAS	**FORTH-ICS**	BENIFICIARY	EL
21	REGION OF CRETE	**CRETE**	BENIFICIARY	EL
22	SAHLGRENSKA SCIENCE PARK AB	**SSP**	BENIFICIARY	SE
23	RIVNE INTERREGIONAL MEDICAL CLUSTER	**RIVNE**	BENIFICIARY	UA
24	ASTRAZENECA FARMACEUTICA SPAIN S.A.	**ASTRA ZENECA**	BENIFICIARY	ES
25	AGENCIA DE TRANSFORMACIÓN DIGITAL DE CASTILLA – LA MANCHA	**ATD**	BENIFICIARY	ES
26	LAZIO INNOVA	**LI**	BENIFICIARY	IT
27	NATIONAL INSTITUTE FOR BIOPROCESSING RESEARCH AND TRAINING	**NIBRT**	BENIFICIARY	IE

Tab. 2 The PRECISEU Consortium

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WORK PACKAGES AND LEADERS

Work Packages Name		WP Leader
WP 1	Project Management and Coordination	Biocat
WP 2	Communication and Dissemination	NE RDA
WP 3	Interregional Collaboration and Partnership Bridging	IA Lithuania
WP 4	Use of Health Data	ART-ER
WP 5	Multistakeholder infrastructure to enable access to ATMP on large scale	BIO PRO
WP 6	Market and Patient Access	SSP
WP 7	Training and Cultural Change	HLSCB
WP 8	Adoption of PM innovations in the HealthCare System	SALUT
WP 9	Innovation Support Program	Biocat

Tab. 3 The PRECISEU'S Work Packages

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LIST OF ACRONYMS AND ABBREVIATIONS

Abbreviation	Description
AAV	Adeno-associated Virus
ADA	Anti-drug Antibodies
ATMP	Advanced Therapy Medicinal Product
BSL	Biosafety Level
CDMO	Contract Development and Manufacturing Organization
CMC	Chemistry, Manufacturing, Controls
CRS	Cytokine Release Syndrome
CT	Computer Tomography
CTA	Clinical Trial Application
CyTOF	Cytometry by Time of Flight
D	Deliverable
ELISpot	Enzyme-linked Immunosorbent Spot Assay
EMA	European Medicines Agency
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IMPD	Investigational Medicinal Product Dossier
IP	Intellectual Property
MRI	Magnetic Resonance Imaging
mRNA	Messenger Ribonucleic Acid
Nab	Neutralizing Antibodies
NGS	Next Generation Sequencing
PCR	Polymerase Chain Reaction
PET	Positron Emission Tomography

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PRECISEU	Personalised medicine empowerment connecting innovation ecosystems across Europe
RNA	Ribonucleic Acid
siRNA	Small Interfering Ribonucleic Acid
SPECT	Single Photon Emission Computed Tomography
T	Task
TALEN	Transcription Activator-like Effector Nucleases
TPP	Target Product Profile
WP	Work Package

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LIST OF FIGURES AND TABLES

Figure/Table	Description
Figure 1	*Number of ATMP centers offering certain services broken down by category*
Table 1	*Organisations that filled out the ATMP services checklist and opted for publication*

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EXECUTIVE SUMMARY

This deliverable D5.3 is part of PRECISEU's strategy for establishing a coordinated, multi-stakeholder infrastructure to accelerate the development, manufacturing, and implementation of Advanced Therapy Medicinal Products (ATMPs) across Europe. The particular focus is on improving access to GMP capacities and expertise for smaller developers as accessible GMP manufacturing capacity remains one of the main bottlenecks for them, making infrastructures particularly important for innovation across Europe.

To catalogue services offered by ATMP centers, which are an integral part of the multi-stakeholder infrastructure as defined by PRECISEU, we developed an ATMP services checklist by compiling information from different sources. The different categories and items on this checklist are explained in this deliverable to support ATMP centers in filling in the checklist. In addition, filled-in checklist from various ATMP centers from across Europe are provided to facilitate collaboration between these ATMP centers and ATMP developers.

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1. Introduction

1.1 Objectives of Work Package 5 and Task 5.2

Work package 5 (WP5) – Multistakeholder infrastructure to enable access to ATMP on large scale – is one of the central WPs of PRECISEU with multiple interconnections with other WPs, such as with the mapping of ATMP initiatives in WP3, ATMP-related health data usage in WP4, content for capacity building in WP7, adoption of ATMP in healthcare systems in WP8 and as topic provider for the Joint Interregional Projects (JIPs) call in WP9.

In WP5, the partners seek to enhance visibility of and access to European ATMPs (Advanced Therapy Medicinal Products) infrastructure and resources. Key goals include connecting ATMP stakeholders and hubs across Europe, addressing bottlenecks, and supporting the development of safer, more effective gene therapies for rare diseases and indications with a critical need. It aims to accelerate the path from research and development (R&D) to market, expand education on regulatory, manufacturing, and research processes, and close the skills gap in the ATMP sector through targeted training programs. WP5 is split into four tasks to achieve this goal. Task 5.1 (T5.1) maps stakeholders in the ATMP space across Europe and will help to identify strengths but also weaknesses within the European ATMP value chain. T5.2 establishes a coordinated Multistakeholder Infrastructure (see below). T5.3 supports ATMP developers by helping them to use the Multistakeholder Infrastructure identified and defined in T5.2, and by fostering collaboration among key stakeholders—academia, industry, hospitals, and patients—from the earliest stages of research and development. T5.4 facilitates patients' access to ATMP particularly by involving regulators and health economics aspects.

The main aim of Task 5.2 is to establish a coordinated Multistakeholder Infrastructure that leverages existing resources, services, and expertise to support the development, production, and implementation of Advanced Therapy Medicinal Products across Europe. To that end, efforts were focused on ATMP centers because such structures were recognized as potentially instrumental in solving a main bottleneck identified in several national studies[1-3], the lack of GMP capacities accessible for smaller ATMP developers. By facilitating access to existing capacities and expertise, this initiative aims to ultimately accelerate patient access to ATMP.

Thus, rather than building new infrastructure, this task focuses on connecting and optimizing already available platforms, facilities, and networks to create a more efficient, accessible, and collaborative virtual ecosystem for ATMP innovation.
Central aspects are a) the design and dissemination of a service catalogue that maps available technologies, expert support, and training opportunities across partner organizations and regions, b) the definition of a governance and access model to ensure transparent use of the infrastructure within the PRECISEU regions and beyond, and c) the development of a blueprint for ATMP centers whose basics were developed during a dedicated workshop which simultaneously marked the start of a collaborative virtual ecosystem for ATMP innovation formed by ATMP centers.

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1.2 Objectives of this deliverable

Complementary to deliverables D5.4 and D5.2, this deliverable aims to provide a catalogue of services that the multi-stakeholder infrastructure, and as integral part of this the ATMP centers, offer. This catalogue is presented in the form of a checklist comprising the most relevant services. It is therefore targeted at managers and employees of such centers, regardless of whether they are already established, in development or in planning. It aims to give an overview of services to be integrated into the center's portfolio and supports in positioning the center along the value chain. The deliverable should also help users/clients of ATMP centers with understanding their position along the value chain, and as it includes checklists filled in by ATMP centers, should facilitate the search for potential partners.

2. Methods

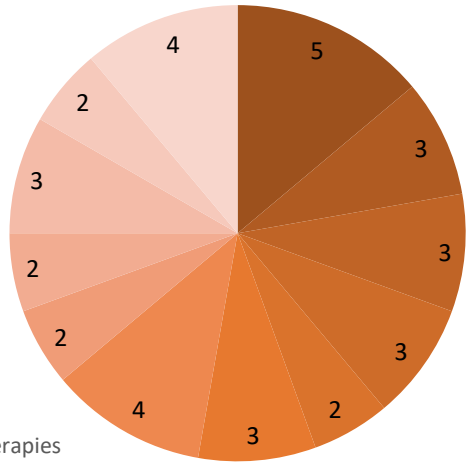
The checklist for ATMP services (Appendix 1 and below) was compiled by integration of the results from interviews with ATMP center representatives regarding services offered (see D5.4), the results of the discussion around services during the workshop "A Blueprint for ATMP Center", and platforms/services offered by EATRIS. The checklist was then verified by ATMP center representatives and EATRIS experts. It is open for modifications and extensions in the future, for instance, operational and logistics aspects might be included as well as they are highly relevant for ATMPs.
ATMP center representatives were then asked to fill in the ATMP services checklist, and indicate if publication of their capabilities was desired. The filled-in checklists are provided in Appendix 2.

Table 1 – Organisations that filled out the ATMP services checklist and opted for publication

Organization	Region and Country	Type of ATMP Center
CCRM Nordic	Gothenburg, Sweden	CDMO-like
CellGENTherapies	Gent, Belgium	Academic center
Center for Innovative Therapies (CIT) Heidelberg	Baden Württemberg, Germany	Academic center
CidStem of University of Modena and Reggio Emilia	Emilia-Romagna, Italy	Academic center
Hospital Sant Joan de Déu	Catalonia, Spain	Academic center
IRET Foundation	Emilia-Romagna, Italy	CDMO-like
Leitat-GeneVector	Catalonia, Spain	CDMO-like
Sahlgrenska/Gothenburg University	Gothenburg, Sweden	Academic center

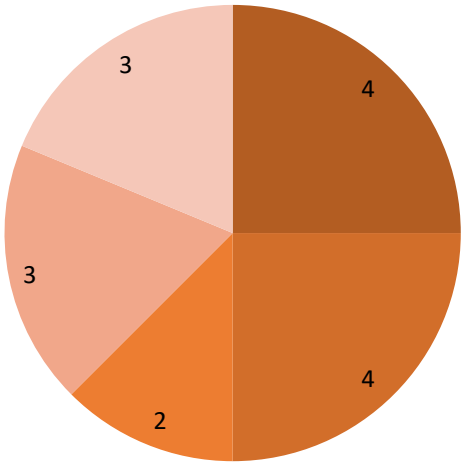
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Target Revalidation and Pre-Clinical Development



- General expertise in cell and gene therapies
- General expertise in genome engineering
- General expertise in RNA-based therapeutics
- State-of-the-art genomics platforms
- State-of-the-art proteomics platforms
- State-of-the-art vectorology and cell biotechnology platforms
- Animal facilities
- Disease-specific animal models
- Pre-clinical imaging (e.g. µPET, µCT, µMRI, US, µSPECT, optical, hybrid systems)
- Advanced disease models (organoids, organ-on-chip)
- Pre-clinical safety, efficacy and toxicology, and immunogenicity
- Immune monitoring services for ATMP development (e.g. CAR-T or gene therapy), to combine:

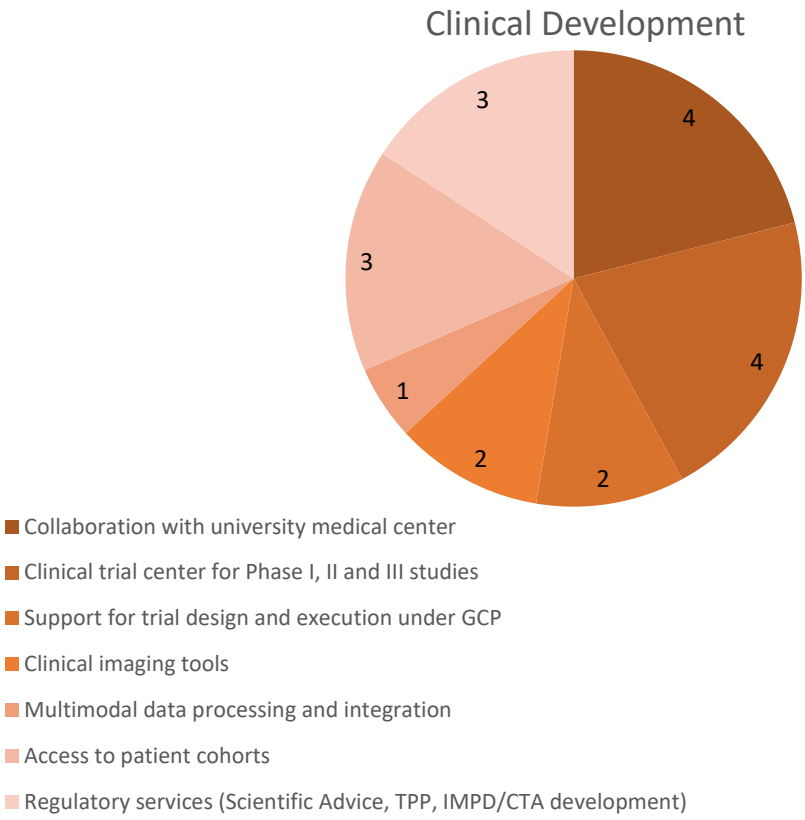
GMP Production of ATMPs



- General expertise in cell and gene therapy manufacturing
- GMP production authorized by competent authorities
- Vector production (e.g., AAV and recombinant vectors)
- Upscaling and GMP product/process development
- Analytical development

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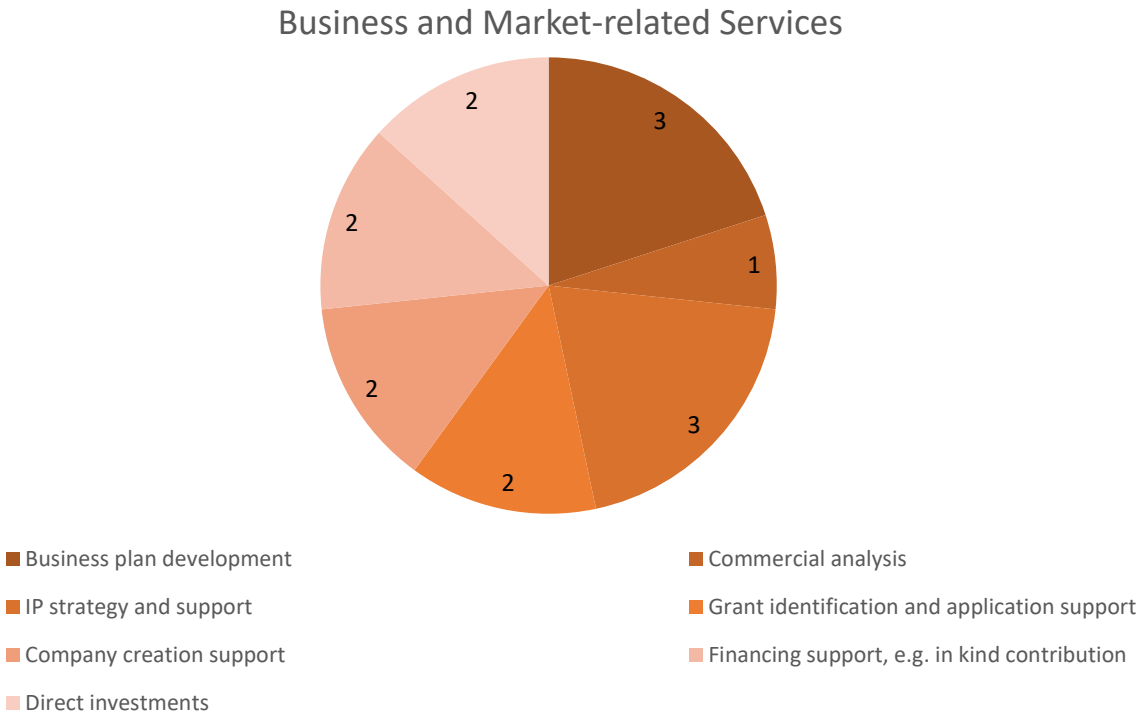


Figure 1 (pages 14-15) - *Number of ATMP centers offering certain services broken down by category*

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3. The ATMP Services Checklist Explained

Below is an explanation of the different sections and services mentioned in the checklist provided in Appendix 1. This comprehensive guide serves as a framework to map out the capabilities required across the entire value chain of ATMP development. By breaking down these complex requirements, the document provides the essential infrastructure, methodologies, and expertise needed to successfully develop ATMPs. It is open for modification and extensions in the future. Ultimately, this detailed breakdown should enable ATMP centers to evaluate their institutional readiness, as well as assess operational capacities. ATMP developers on the other hand will understand the value chain better and have a first idea of potential partners.

1. Target Revalidation and Pre-Clinical Development

General expertise in cell and gene therapies

Demonstrated scientific and translational expertise in the development of ATMPs, including autologous and allogeneic cell therapies, ex vivo and in vivo gene therapies, and genetically modified cellular products.

General expertise in genome engineering

Capabilities in targeted genome modification technologies, including CRISPR/Cas systems, TALENs, zinc finger nucleases, base editing, and related engineering platforms.

General expertise in RNA-based therapeutics

Experience in the development and evaluation of RNA therapeutics, including mRNA, siRNA, antisense oligonucleotides, and RNA delivery systems.

State-of-the-art genomics platforms

Availability of advanced genomics infrastructure supporting high-throughput sequencing, transcriptomics, epigenomics, single-cell sequencing, and bioinformatics analysis relevant to ATMP development.

State-of-the-art proteomics platforms

Availability of proteomics technologies for biomarker discovery, protein characterization, mechanism-of-action studies, and translational research, including mass spectrometry-based approaches.

State-of-the-art vectorology and cell biotechnology platforms

Infrastructure and know-how for viral and non-viral vector engineering, vector characterization, cell engineering, cell expansion, transduction optimization, and related biotechnological processes.

Animal facilities

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Access to accredited in vivo research facilities supporting ATMP-related studies under appropriate biosafety and ethical standards.

Which safety level

Specification of available biosafety containment levels (e.g. BSL-1 to BSL-3) relevant to vector handling and genetically modified organisms.

Which species

Identification of animal species available for preclinical studies (e.g. murine, canine, porcine, non-human primate).

Disease-specific animal models

Availability of validated disease-relevant in vivo models suitable for efficacy, biodistribution, toxicology, and translational studies.

Which ones

Specification of available disease models by therapeutic area or indication.

Including primates

Access to non-human primate models where required for advanced translational or toxicology studies.

Pre-clinical imaging

Availability of preclinical imaging modalities supporting biodistribution, efficacy, and mechanistic studies.

Which ones

Specification of available technologies, such as PET, CT, MRI, ultrasound, SPECT, optical imaging, or hybrid systems.

Advanced disease models (organoids, organ-on-chip)

Availability of advanced human-relevant in vitro or ex vivo disease models, including organoids, microphysiological systems, and organ-on-chip platforms.

Which ones (examples)

Specification of available organoid systems or engineered tissue platforms.

Pre-clinical safety, efficacy and toxicology, and immunogenicity

Capability to conduct GLP or non-GLP preclinical studies assessing therapeutic activity, biodistribution, toxicity, safety pharmacology, and immunogenicity.

Immune Monitoring Services for ATMP Development

Safety aspects:

Cytokines (CRS risk)

Assessment of cytokine profiles and inflammatory biomarkers associated with cytokine release syndrome (CRS) and related immune-mediated toxicities.

Clinical labs

Access to accredited clinical laboratory testing supporting translational and clinical studies.

Immunogenicity (ADA/NAb)

Assessment of anti-drug antibodies (ADA) and neutralizing antibodies (NAb) relevant to biologics, vectors, and gene therapies.

Integration site analysis (gene therapy)

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Analytical capabilities to characterize vector integration patterns and assess insertional mutagenesis risks.

Efficacy aspects:

Cell persistence (PCR, flow)

Methods to quantify persistence, expansion, and biodistribution of therapeutic cells using molecular and flow cytometry approaches.

Functional assays (killing activity)

Availability of potency and functional assays evaluating biological activity, including cytotoxicity and target-cell killing assays.

Antigen-specific responses (ELISpot)

Assays assessing antigen-specific cellular immune responses, including ELISpot and related immunomonitoring platforms.

Mechanism of action:

Immune phenotyping

Comprehensive characterization of immune cell subsets, activation states, and immune signatures using flow cytometry, CyTOF, or related technologies.

Single-cell and NGS approaches

Use of single-cell omics and next-generation sequencing (NGS) approaches for mechanistic, translational, and biomarker analyses.

CMC support

Support for Chemistry, Manufacturing and Controls (CMC) activities, including process characterization, analytical strategy, comparability, and documentation.

Regulatory requirements assessment for clinical development

Advisory support regarding regulatory expectations for preclinical and clinical ATMP development, including alignment with EMA/FDA requirements.

2. GMP Production of ATMPs

General expertise in cell and gene therapy manufacturing

Operational experience in GMP-compliant manufacturing of cell and gene therapy products.

GMP production authorized by competent authorities

Possession of relevant manufacturing authorizations and certifications issued by competent regulatory authorities.

Vector production (e.g., AAV and recombinant vectors)

Capabilities for development and GMP production of viral and recombinant vectors, including AAV, lentiviral, retroviral, or plasmid-based systems.

Upscaling and GMP product/process development

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Capabilities in process optimization, scale-up, technology transfer, and manufacturing process development for clinical and commercial production.

Analytical development
Development and validation of analytical methods supporting identity, purity, potency, safety, and stability testing.

3. Clinical Development

Collaboration with university medical center
Established collaborations with academic hospitals or university medical centers supporting translational and clinical activities.

Clinical trial center for Phase I, II and III studies
Availability of infrastructure and operational capabilities for conducting early- and late-phase clinical studies.

Support for trial design and execution under GCP
Support for protocol design, trial management, monitoring, and execution in compliance with Good Clinical Practice (GCP).

Clinical imaging tools
Availability of clinical imaging modalities supporting patient stratification, monitoring, and endpoint assessment.

Multimodal data processing and integration
Capabilities for integration and analysis of heterogeneous datasets, including clinical, imaging, omics, and biomarker data.

Access to patient cohorts
Established access to disease-specific patient populations, registries, or recruitment networks.

Regulatory services (Scientific Advice, TPP, IMPD/CTA development)
Support for regulatory strategy and preparation of documentation, including Scientific Advice procedures, Target Product Profiles (TPP), Investigational Medicinal Product Dossiers (IMPD), and Clinical Trial Applications (CTA).

4. Business and Market-related Services

Business plan development

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Support for business model development, strategic planning, and commercialization roadmaps.

Commercial analysis
Assessment of market landscape, competitive positioning, reimbursement environment, and commercialization potential.

IP strategy and support
Support for intellectual property strategy, patent landscaping, freedom-to-operate analyses, and licensing considerations.

Grant identification and application support
Identification of relevant national and international funding opportunities and support in grant preparation and submission.

Company creation support
Support for company formation, governance structuring, and early-stage operational setup.

Financing support, e.g. in kind contribution
Provision of financial or non-financial support mechanisms, including infrastructure access, personnel support, or co-development arrangements.

Direct investments
Capability to provide direct financial investment into ATMP development programs or spin-out companies.

5. Additional Services Comments

Additional services not mentioned above
Description of complementary capabilities, specialized services, or unique infrastructure not otherwise mentioned in the checklist.

Comments
Additional remarks, limitations, or contextual information relevant to interpretation of the provided information.

1. PRECISEU D6.1, https://preciseu.eu/wp-content/uploads/2025/10/D6.1-Cross-Regional-Report.pdf
2. National Strategy Gene- and Cell- based Therapies, https://www.nationale-strategie-gct.de/fileadmin/gct/01_Ueber/NEU_250619_Strategiepapier_EN.pdf
3. ATMP Sweden – A national Infrastructure for ATMP, https://atmpsweden.se/wp-content/uploads/2021/04/20210406-ATMPInfrastructure-final.pdf

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ATMP Services Checklist

1. Target Revalidation and Pre-Clinical Development

☐ General expertise in cell and gene therapies

☐ General expertise in genome engineering

☐ General expertise in RNA-based therapeutics

☐ State-of-the-art genomics platforms

☐ State-of-the-art proteomics platforms

☐ State-of-the-art vectorology and cell biotechnology platforms

☐ Animal facilities

Which safety level:

Which species:

☐ Disease-specific animal models

Which ones:

☐ Including primates

☐ Pre-clinical imaging (e.g. µPET, µCT, µMRI, US, µSPECT, optical, hybrid systems)

Which ones:

☐ Advanced disease models (organoids, organ-on-chip)

Which ones (examples):

☐ Pre-clinical safety, efficacy and toxicology, and immunogenicity

☐ lmmune monitoring services for ATMP development (e.g. CAR-T or gene therapy), to combine:

Safety:

☐ Cytokines (CRS risk)

☐ Clinical labs

☐ Immunogenicity (ADA/Nab)

☐ Integration site analysis (gene therapy)

Efficacy:

☐ Cell persistence (PCR, flow)

☐ Functional assays (killing activity)

☐ Antigen-specific responses (ELISpot)

Mechanism of Action:

☐ Immune phenotyping

☐ Single-cell and NGS approaches

☐ CMC support

☐ Regulatory requirements assessment for clinical development

2. GMP Production of ATMPs

☐ General expertise in cell and gene therapy manufacturing
☐ GMP production authorized by competent authorities
☐ Vector production (e.g., AAV and recombinant vectors)
☐ Upscaling and GMP product/process development
☐ Analytical development

3. Clinical Development

☐ Collaboration with university medical center
☐ Clinical trial center for Phase I, II and III studies
☐ Support for trial design and execution under GCP
☐ Clinical imaging tools
☐ Multimodal data processing and integration
☐ Access to patient cohorts
☐ Regulatory services (Scientific Advice, TPP, IMPD/CTA development)

4. Business and Market-related Services

☐ Business plan development
☐ Commercial analysis
☐ IP strategy and support
☐ Grant identification and application support
☐ Company creation support
☐ Financing support, e.g. in kind contribution
☐ Direct investments

5. Additional Services Comments

Additional services not mentioned above:

Comments:

Appendix 2

Ticked services are available at the respective ATMP Center.

Struck-through and greyed out services are not or not yet available at the respective ATMP Center.

ATMP Services Checklist CCRM Nordic

https://ccrmnordic.se/

1. Target Revalidation and Pre-Clinical Development

✓ General expertise in cell and gene therapies

☐ General expertise in genome engineering
☐ General expertise in RNA-based therapeutics
☐ State-of-the-art genomics platforms
☐ State-of-the-art proteomics platforms

✓ State-of-the-art vectorology and cell biotechnology platforms

☐ Animal facilities
    Which safety level:
    Which species:
☐ Disease-specific animal models
    Which ones:
    ☐ Including primates
☐ Pre-clinical imaging (e.g. µPET, µCT, µMRI, US, µSPECT, optical, hybrid systems)
    Which ones:
☐ Advanced disease models (organoids, organ-on-chip)
    Which ones (examples):
☐ Pre-clinical safety, efficacy and toxicology, and immunogenicity
☐ Immune monitoring services for ATMP development (e.g. CAR-T or gene therapy), to combine:
    Safety:
    ☐ Cytokines (CRS risk)
    ☐ Clinical labs
    ☐ Immunogenicity (ADA/Nab)
    ☐ Integration site analysis (gene therapy)
    Efficacy:
    ☐ Cell persistence (PCR, flow)
    ☐ Functional assays (killing activity)
    ☐ Antigen-specific responses (ELISpot)
    Mechanism of Action:
    ☐ Immune phenotyping
    ☐ Single-cell and NGS approaches

✓ CMC support

☐ Regulatory requirements assessment for clinical development

2. GMP Production of ATMPs

✓ General expertise in cell and gene therapy manufacturing

☐ GMP production authorized by competent authorities
☐ Vector production (e.g., AAV and recombinant vectors)

✓ Upscaling and GMP product/process development

✓ Analytical development

3. Clinical Development

✓ Collaboration with university medical center

☐ ~~Clinical trial center for Phase I, II and III studies~~
☐ ~~Support for trial design and execution under GCP~~
☐ ~~Clinical imaging tools~~
☐ ~~Multimodal data processing and integration~~
☐ ~~Access to patient cohorts~~

✓ Regulatory services (Scientific Advice, TPP, IMPD/CTA development)

4. Business and Market-related Services

✓ Business plan development

✓ Commercial analysis

✓ IP strategy and support

✓ Grant identification and application support

✓ Company creation support

✓ Financing support, e.g. in kind contribution

☐ ~~Direct investments~~

5. Additional Services Comments

~~Additional services not mentioned above:~~

Comments:

We would like to highlight that additional capabilities are planned in the near future, including expertise in genome engineering, process and analytical development for non-viral genetic engineering, GMP production authorized by competent authorities, and vector production (e.g. lentiviral vectors). In addition, we will be well positioned to support regulatory requirements assessment for clinical development through specialized collaborations with experienced partners.

ATMP Services Checklist CellGENTherapies

https://gmp-unit.be/

1. Target Revalidation and Pre-Clinical Development

✓ **General expertise in cell and gene therapies**

☐ ~~General expertise in genome engineering~~

✓ **General expertise in RNA-based therapeutics**

☐ ~~State-of-the-art genomics platforms~~
☐ ~~State-of-the-art proteomics platforms~~
☐ ~~State-of-the-art vectorology and cell biotechnology platforms~~
☐ ~~Animal facilities~~
~~Which safety level:~~
~~Which species:~~
☐ ~~Disease-specific animal models~~
~~Which ones:~~
☐ ~~Including primates~~
☐ ~~Pre-clinical imaging (e.g. µPET, µCT, µMRI, US, µSPECT, optical, hybrid systems)~~
~~Which ones:~~
☐ ~~Advanced disease models (organoids, organ-on-chip)~~
~~Which ones (examples):~~
☐ ~~Pre-clinical safety, efficacy and toxicology, and immunogenicity~~
☐ ~~Immune monitoring services for ATMP development (e.g. CAR-T or gene therapy), to combine:~~

Safety:
☐ ~~Cytokines (CRS risk)~~
☐ ~~Clinical labs~~
☐ ~~Immunogenicity (ADA/Nab)~~
☐ ~~Integration site analysis (gene therapy)~~

Efficacy:
☐ ~~Cell persistence (PCR, flow)~~
☐ ~~Functional assays (killing activity)~~
☐ ~~Antigen-specific responses (ELISpot)~~

Mechanism of Action:
☐ ~~Immune phenotyping~~
☐ ~~Single-cell and NGS approaches~~

☐ ~~CMC support~~
☐ ~~Regulatory requirements assessment for clinical development~~

2. GMP Production of ATMPs

✓ **General expertise in cell and gene therapy manufacturing**

✓ **GMP production authorized by competent authorities**

✓ **Vector production (e.g., AAV and recombinant vectors)**

✓ **Upscaling and GMP product/process development**

✓ **Analytical development**

3. Clinical Development

✓ Collaboration with university medical center

☐ ~~Clinical trial center for Phase I, II and III studies~~
☐ ~~Support for trial design and execution under GCP~~
☐ ~~Clinical imaging tools~~
☐ ~~Multimodal data processing and integration~~
☐ ~~Access to patient cohorts~~

✓ Regulatory services (Scientific Advice, TPP, IMPD/CTA development)

4. Business and Market-related Services

☐ ~~Business plan development~~
☐ ~~Commercial analysis~~
☐ ~~IP strategy and support~~
☐ ~~Grant identification and application support~~
☐ ~~Company creation support~~
☐ ~~Financing support, e.g. in kind contribution~~
☐ ~~Direct investments~~

5. Additional Services Comments

~~Additional services not mentioned above:~~

~~Comments:~~

ATMP Services Checklist Centre for Innovative Therapies Heidelberg https://nct.dkfz.de/

1. Target Revalidation and Pre-Clinical Development

✓ **General expertise in cell and gene therapies**

✓ **General expertise in genome engineering**

☐ ~~General expertise in RNA-based therapeutics~~
☐ ~~State-of-the-art genomics platforms~~
☐ ~~State-of-the-art proteomics platforms~~
☐ ~~State-of-the-art vectorology and cell biotechnology platforms~~
☐ ~~Animal facilities~~
~~Which safety level:~~
~~Which species:~~
☐ ~~Disease-specific animal models~~
~~Which ones:~~
☐ ~~Including primates~~
☐ ~~Pre-clinical imaging (e.g. µPET, µCT, µMRI, US, µSPECT, optical, hybrid systems)~~
~~Which ones:~~
☐ ~~Advanced disease models (organoids, organ-on-chip)~~
~~Which ones (examples):~~
☐ ~~Pre-clinical safety, efficacy and toxicology, and immunogenicity~~

✓ **Immune monitoring services for ATMP development (e.g. CAR-T or gene therapy), to combine:**

Safety:

✓ **Cytokines (CRS risk)**

✓ **Clinical labs**

☐ ~~Immunogenicity (ADA/Nab)~~

✓ **Integration site analysis (gene therapy)**

Efficacy:

✓ **Cell persistence (PCR, flow)**

✓ **Functional assays (killing activity)**

✓ **Antigen-specific responses (ELISpot)**

Mechanism of Action:

✓ **Immune phenotyping**

✓ **Single-cell and NGS approaches**

✓ **CMC support**

✓ **Regulatory requirements assessment for clinical development**

2. GMP Production of ATMPs

✓ **General expertise in cell and gene therapy manufacturing**

✓ **GMP production authorized by competent authorities – in progress**

☐ ~~Vector production (e.g., AAV and recombinant vectors)~~

✓ **Upscaling and GMP product/process development**

☐ ~~Analytical development~~

3. Clinical Development

✓ **Collaboration with university medical center**

☐ ~~Clinical trial center for Phase I, II and III studies~~
☐ ~~Support for trial design and execution under GCP~~
☐ ~~Clinical imaging tools~~
☐ ~~Multimodal data processing and integration~~

✓ **Access to patient cohorts**

☐ ~~Regulatory services (Scientific Advice, TPP, IMPD/CTA development)~~

4. Business and Market-related Services

☐ ~~Business plan development~~
☐ ~~Commercial analysis~~
☐ ~~IP strategy and support~~

✓ **Grant identification and application support**

☐ ~~Company creation support~~
☐ ~~Financing support, e.g. in kind contribution~~
☐ ~~Direct investments~~

5. Additional Services Comments

Additional services not mentioned above:
Expertise in Point-of-care Manufacturing

~~Comments:~~

ATMP Services Checklist CidStem University of Modena and Reggio Emilia https://www.cidstem.unimore.it/

1. Target Revalidation and Pre-Clinical Development

✓ **General expertise in cell and gene therapies**

✓ **General expertise in genome engineering**

✓ **General expertise in RNA-based therapeutics**

✓ **State-of-the-art genomics platforms**

☐ ~~State-of-the-art proteomics platforms~~

✓ **State-of-the-art vectorology and cell biotechnology platforms**

☐ ~~Animal facilities~~

~~Which safety level:~~

~~Which species:~~

☐ ~~Disease-specific animal models~~

~~Which ones:~~

☐ ~~Including primates~~

☐ ~~Pre-clinical imaging (e.g. μPET, μCT, μMRI, US, μSPECT, optical, hybrid systems)~~

~~Which ones:~~

✓ **Advanced disease models (organoids, organ-on-chip)**

Which ones (examples): **organoids**

✓ **Pre-clinical safety, efficacy and toxicology**, ~~and immunogenicity~~

✓ **Immune monitoring services for ATMP development (e.g. CAR-T or gene therapy), to combine:**

Safety:

☐ ~~Cytokines (CRS risk)~~

☐ ~~Clinical labs~~

☐ ~~Immunogenicity (ADA/Nab)~~

☐ ~~Integration site analysis (gene therapy)~~

Efficacy:

☐ ~~Cell persistence (PCR, flow)~~

✓ **Functional assays (killing activity)**

☐ ~~Antigen-specific responses (ELISpot)~~

Mechanism of Action:

✓ **Immune phenotyping**

✓ **Single-cell and NGS approaches**

✓ **CMC support**

☐ ~~Regulatory requirements assessment for clinical development~~

2. GMP Production of ATMPs

✓ **General expertise in cell and gene therapy manufacturing**

✓ **GMP production authorized by competent authorities (consultancy)**

☐ ~~Vector production (e.g., AAV and recombinant vectors)~~

✓ **Upscaling and GMP product/process development (consultancy)**

✓ **Analytical development (consultancy)**

3. Clinical Development

✓ **Collaboration with university medical center**

☐ ~~Clinical trial center for Phase I, II and III studies~~
☐ ~~Support for trial design and execution under GCP~~
☐ ~~Clinical imaging tools~~
☐ ~~Multimodal data processing and integration~~

✓ **Access to patient cohorts**

✓ **Regulatory services (Scientific Advice, TPP, IMPD/CTA development) (consultancy)**

4. Business and Market-related Services

☐ ~~Business plan development~~
☐ ~~Commercial analysis~~
☐ ~~IP strategy and support~~
☐ ~~Grant identification and application support~~
☐ ~~Company creation support~~
☐ ~~Financing support, e.g. in kind contribution~~
☐ ~~Direct investments~~

5. Additional Services Comments

Additional services not mentioned above:

✓ **Biocompatibility assays for materials**

✓ **Scientific disseminations**

✓ **Tissue engineering with multiple cell types**

✓ **Hosting People/ experiments in cell culture rooms, sharing of instruments (cell observer; automated microscope with image analysis; Chromium Ex; Tapestry; Cytofluorimetry; Digital PCR Biorad; Radgil; Elutriation; Cytocentrifuge; Vyvacyte)**

~~Comments:~~

ATMP Services Checklist Hospital San Joan de Déu

https://www.sjdhospitalbarcelona.org/en

1. Target Revalidation and Pre-Clinical Development

✓ **General expertise in cell and gene therapies**

✓ **General expertise in genome engineering**

☐ ~~General expertise in RNA-based therapeutics~~

✓ **State-of-the-art genomics platforms**

☐ ~~State-of-the-art proteomics platforms~~

✓ **State-of-the-art vectorology and cell biotechnology platforms**

✓ **Animal facilities**

Which safety level: I (A/ES/25/I-27)
Which species: **Immunosuppressed mice, and areas for sheep and pig**

☐ ~~Disease-specific animal models~~
~~Which ones:~~
☐ ~~Including primates~~

☐ ~~Pre-clinical imaging (e.g. µPET, µCT, µMRI, US, µSPECT, optical, hybrid systems)~~
~~Which ones:~~

☐ ~~Advanced disease models (organoids, organ-on-chip)~~
~~Which ones (examples):~~

☐ ~~Pre-clinical safety, efficacy and toxicology, and immunogenicity~~

✓ **Immune monitoring services for ATMP development (e.g. CAR-T or gene therapy), to combine:**

Safety:
☐ ~~Cytokines (CRS risk)~~
☐ ~~Clinical labs~~
☐ ~~Immunogenicity (ADA/Nab)~~
☐ ~~Integration site analysis (gene therapy)~~

Efficacy:
✓ **Cell persistence (PCR, flow)**
✓ **Functional assays (killing activity)**
☐ ~~Antigen-specific responses (ELISpot)~~

Mechanism of Action:
☐ ~~Immune phenotyping~~
☐ ~~Single-cell and NGS approaches~~

✓ **CMC support**

✓ **Regulatory requirements assessment for clinical development**

2. GMP Production of ATMPs

✓ **General expertise in cell and gene therapy manufacturing**

✓ **GMP production authorized by competent authorities**

✓ **Vector production (e.g., AAV and recombinant vectors)**

✓ **Upscaling and GMP product/process development**

✓ **Analytical development**

3. Clinical Development

✓ **Collaboration with university medical center**

✓ **Clinical trial center for Phase I, II and III studies**

✓ **Support for trial design and execution under GCP**

✓ **Clinical imaging tools**

✓ **Multimodal data processing and integration**

✓ **Access to patient cohorts**

✓ **Regulatory services (Scientific Advice, TPP, IMPD/CTA development)**

4. Business and Market-related Services

✓ **Business plan development**

✓ **Commercial analysis**

✓ **IP strategy and support**

✓ **Grant identification and application support**

✓ **Company creation support**

✓ **Financing support, e.g. in kind contribution**

✓ **Direct investments**

5. Additional Services Comments

Additional services not mentioned above:

Advanced Clinical Trial Simulation Unit

~~Comments:~~

ATMP Services Checklist IRET Foundation

https://iret-foundation.org/

1. Target Revalidation and Pre-Clinical Development

✓ **General expertise in cell and gene therapies**

☐ ~~General expertise in genome engineering~~

✓ **General expertise in RNA-based therapeutics**

☐ ~~State-of-the-art genomics platforms~~

✓ **State-of-the-art proteomics platforms**

☐ ~~State-of-the-art vectorology and cell biotechnology platforms~~

✓ **Animal facilities**

Which safety level: **SPF**
Which species: **mouse, rat**

✓ **Disease-specific animal models**

Which ones: **see Technopole Rita Levi-Montalcini service charter**

☐ ~~Including primates~~

☐ ~~Pre-clinical imaging (e.g. µPET, µCT, µMRI, US, µSPECT, optical, hybrid systems)~~
~~Which ones:~~

✓ **Advanced disease models (organoids, organ-on-chip)**

Which ones (examples): **see Technopole Rita Levi-Montalcini service charter**

✓ **Pre-clinical safety, efficacy and toxicology, and immunogenicity**

✓ **Immune monitoring services for ATMP development (e.g. CAR-T or gene therapy), to combine:**

Safety:

✓ **Cytokines (CRS risk)**

☐ ~~Clinical labs~~

✓ **Immunogenicity (ADA/Nab)**

☐ ~~Integration site analysis (gene therapy)~~

Efficacy:

✓ **Cell persistence (PCR, flow)**

☐ ~~Functional assays (killing activity)~~
☐ ~~Antigen-specific responses (ELISpot)~~

Mechanism of Action:

✓ **Immune phenotyping**

✓ **Single-cell and NGS approaches**

☐ ~~CMC support~~
☐ ~~Regulatory requirements assessment for clinical development~~

2. GMP Production of ATMPs

☐ ~~General expertise in cell and gene therapy manufacturing~~
☐ ~~GMP production authorized by competent authorities~~
☐ ~~Vector production (e.g., AAV and recombinant vectors)~~
☐ ~~Upscaling and GMP product/process development~~
☐ ~~Analytical development~~

3. Clinical Development

☐ ~~Collaboration with university medical center~~

✓ **Clinical trial center for Phase I, II and III studies**

☐ ~~Support for trial design and execution under GCP~~

☐ ~~Clinical imaging tools~~

☐ ~~Multimodal data processing and integration~~

☐ ~~Access to patient cohorts~~

☐ ~~Regulatory services (Scientific Advice, TPP, IMPD/CTA development)~~

4. Business and Market-related Services

☐ ~~Business plan development~~

☐ ~~Commercial analysis~~

☐ ~~IP strategy and support~~

☐ ~~Grant identification and application support~~

☐ ~~Company creation support~~

☐ ~~Financing support, e.g. in kind contribution~~

☐ ~~Direct investments~~

5. Additional Services Comments

Additional services not mentioned above:
see Technopole Rita Levi-Montalcini service charter

~~Comments:~~

ATMP Services Checklist Leitat Technological Center

https://leitat.org/en/

1. Target Revalidation and Pre-Clinical Development

✓ **General expertise in cell and gene therapies**

✓ **General expertise in genome engineering**

☐ ~~General expertise in RNA-based therapeutics~~
☐ ~~State-of-the-art genomics platforms~~
☐ ~~State-of-the-art proteomics platforms~~

✓ **State-of-the-art vectorology and cell biotechnology platforms**

✓ **Animal facilities**

Which safety level:
Which species: **Rodents**

✓ **Disease-specific animal models**

Which ones: **Rodent xenografts, advanced models for oncology, CNS, IBD and osteoarticular pathologies and in vivo microbiome models**

☐ ~~Including primates~~

✓ **Pre-clinical imaging (e.g. µPET, µCT, µMRI, US, µSPECT, optical, hybrid systems)**

Which ones: **IVIS**

✓ **Advanced disease models (organoids, organ-on-chip)**

Which ones (examples): **Organoids, organ-on-chip**

✓ **Pre-clinical safety, efficacy and toxicology, and immunogenicity**

✓ **Immune monitoring services for ATMP development (e.g. CAR-T or gene therapy), to combine:**

Safety:

✓ **Cytokines (CRS risk) (preclinical development)**

☐ ~~Clinical labs~~
☐ ~~Immunogenicity (ADA/Nab)~~
☐ ~~Integration site analysis (gene therapy)~~

Efficacy:

☐ ~~Cell persistence (PCR, flow)~~

✓ **Functional assays (killing activity)**

✓ **Antigen-specific responses (ELISpot)**

Mechanism of Action:

✓ **Immune phenotyping**

☐ ~~Single-cell and NGS approaches~~

✓ **CMC support**

☐ ~~Regulatory requirements assessment for clinical development~~

2. GMP Production of ATMPs

✓ **General expertise in cell and gene therapy manufacturing**

✓ **GMP production authorized by competent authorities**

✓ **Vector production (e.g., AAV and recombinant vectors)**

✓ **Upscaling and GMP product/process development**

☐ ~~Analytical development~~

3. Clinical Development

✓ **Collaboration with university medical center**

✓ **Clinical trial center for Phase I, II and III studies**

☐ ~~Support for trial design and execution under GCP~~
☐ ~~Clinical imaging tools~~
☐ ~~Multimodal data processing and integration~~
☐ ~~Access to patient cohorts~~
☐ ~~Regulatory services (Scientific Advice, TPP, IMPD/CTA development)~~

4. Business and Market-related Services

✓ **Business plan development**

☐ ~~Commercial analysis~~

✓ **IP strategy and support**

☐ ~~Grant identification and application support~~
☐ ~~Company creation support~~
☐ ~~Financing support, e.g. in kind contribution~~
☐ ~~Direct investments~~

5. Additional Services Comments

~~Additional services not mentioned above:~~

~~Comments:~~

ATMP Services Checklist Sahlgrenska Academy & University Hospital https://www.sahlgrenska.se/en

1. Target Revalidation and Pre-Clinical Development

✓ **General expertise in cell and gene therapies**

☐ ~~General expertise in genome engineering~~

✓ **General expertise in RNA-based therapeutics**

✓ **State-of-the-art genomics platforms**

✓ **State-of-the-art proteomics platforms**

☐ ~~State-of-the-art vectorology and cell biotechnology platforms~~

✓ **Animal facilities**

Which safety level: **BSL2**
Which species: **Rodents and large animals**

☐ ~~Disease-specific animal models~~
~~Which ones:~~
☐ ~~Including primates~~

✓ **Pre-clinical imaging (e.g. µPET, µCT, µMRI, US, µSPECT, optical, hybrid systems)**

Which ones: **MR, PET, SPECT**

☐ ~~Advanced disease models (organoids, organ-on-chip)~~
~~Which ones (examples):~~
☐ ~~Pre-clinical safety, efficacy and toxicology, and immunogenicity~~
☐ ~~Immune monitoring services for ATMP development (e.g. CAR-T or gene therapy), to combine:~~

Safety:
☐ ~~Cytokines (CRS risk)~~
☐ ~~Clinical labs~~
☐ ~~Immunogenicity (ADA/Nab)~~
☐ ~~Integration site analysis (gene therapy)~~

Efficacy:
☐ ~~Cell persistence (PCR, flow)~~
☐ ~~Functional assays (killing activity)~~
☐ ~~Antigen-specific responses (ELISpot)~~

Mechanism of Action:
☐ ~~Immune phenotyping~~
☐ ~~Single-cell and NGS approaches~~

☐ ~~CMC support~~
☐ ~~Regulatory requirements assessment for clinical development~~

2. GMP Production of ATMPs

✓ **General expertise in cell and gene therapy manufacturing**

✓ **GMP production authorized by competent authorities**

☐ ~~Vector production (e.g., AAV and recombinant vectors)~~
☐ ~~Upscaling and GMP product/process development~~

✓ **Analytical development**

3. Clinical Development

✓ **Collaboration with university medical center**

✓ **Clinical trial center for Phase I, II and III studies**

✓ **Support for trial design and execution under GCP**

✓ **Clinical imaging tools**

☐ ~~Multimodal data processing and integration~~

✓ **Access to patient cohorts**

✓ **Regulatory services (Scientific Advice, TPP, IMPD/CTA development)**

4. Business and Market-related Services

✓ **Business plan development**

☐ ~~Commercial analysis~~

✓ **IP strategy and support**

✓ **Grant identification and application support**

✓ **Company creation support**

✓ **Financing support, e.g. in kind contribution**

✓ **Direct investments**

5. Additional Services Comments

~~Additional services not mentioned above:~~

~~Comments:~~