



PRECISEU

DELIVERABLE D5.2

Blueprint for Multi-Stakeholder ATMP Infrastructure Access

bioRN

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Project coordinator	Montse Daban (Biocat)
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Main authors	Friedemann Loos
Contributors	David Morrow, Clémence Foltz, Romy Wentenschuh
Reviewed by	Miquel Salas and Montse Daban (Biocat)
E-mail Contact for queries	fl@biorn.org
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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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CONTRIBUTING 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

CONSORTIUM 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 GOTEBOG 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 EMPRESA	ACCIO	BENIFICIARY	ES
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

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
ATMP	Advanced Therapy Medicinal Product
D	Deliverable
HTA	Health Technology Assessment
R&D	Research and Development
T	Task
WP	Work Package



LIST OF FIGURES

Figure	Description
Figure 1	<i>Flowchart depicting an exemplary access process to an ATMP center.</i>



EXECUTIVE SUMMARY

This deliverable D5.2 is part of PRECISEU's Task 5.2 and its 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 facilitate concrete access to these infrastructures and lower the threshold of potential users/clients to approach them, an exemplary flowchart was generated by compiling information from different sources. The different steps of an access process are explained in this deliverable to guide ATMP centers and support them with improving their processes. In addition, the flowchart provides background information for inexperienced users/clients likewise aiding with approaching ATMP centers for potential collaboration.



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 to help identify strengths but also weaknesses within the European ATMP value chain. Task 5.2 establishes a coordinated Multistakeholder Infrastructure (see below). Task 5.3 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. Task 5.4 ultimately 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 ATMPs across Europe. To that end, efforts were focused on ATMP centers (see definition below) because such structures were recognized as potentially instrumental in solving a main bottleneck identified in several national studies¹⁻¹³, 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.

1.2 Objectives of this deliverable

Complementary to deliverables D5.3 and D5.4, this deliverable D5.2 aims to provide an overview of how ATMP developers could access an ATMP center as an integral part of the multi-stakeholder infrastructure in an idealized setting. It is presented in the form of an exemplary flowchart depicting the recommended steps.

The infrastructure is not intended to fragment GMP manufacturing activities across multiple centers by default. Rather, it aims to route each project to the most suitable ATMP center or coordinated support pathway, based on expertise, capacity and project needs, while allowing complementary expertise or advisory support where appropriate. This blueprint for access to ATMP centers is targeted at managers of such centers, regardless of whether they are already established, in development or in planning, and should help them with reviewing and improving their access processes. Likewise, the deliverable will help users/clients of ATMP centers better understand access procedures and may thereby help overcome barriers to accessing and leveraging such infrastructures.

2. Methods

The blueprint for access to ATMP centers in the form of a flowchart (Figure 1) was created by integration of the results from interviews with ATMP center representatives regarding access procedures (see D5.4), and the results of the discussion around access procedures during the workshop “A Blueprint for ATMP Center”. It was then verified by the corresponding ATMP center representatives and by EATRIS experts.

3. The Access Flowchart Explained

1. Transparent Access Rules

The process starts with clearly defined access conditions. Potential users/clients should be able to easily identify eligibility criteria, available services, pricing structures, and the relevant contact point. A single point of entry ensures consistency and transparency throughout the process.

2. Request Submission

Interested users/clients submit an initial request through the designated entry point. This request should contain sufficient information to allow for a preliminary assessment of the project's scope, requirements, and feasibility.

3. Feedback

Within a predefined timeframe, the ATMP center provides feedback on the request. This typically includes an initial assessment of feasibility, estimated costs, expected timelines, and a list of additional information or documentation required for a formal application. This phase may include repeated exchanges between the parties.

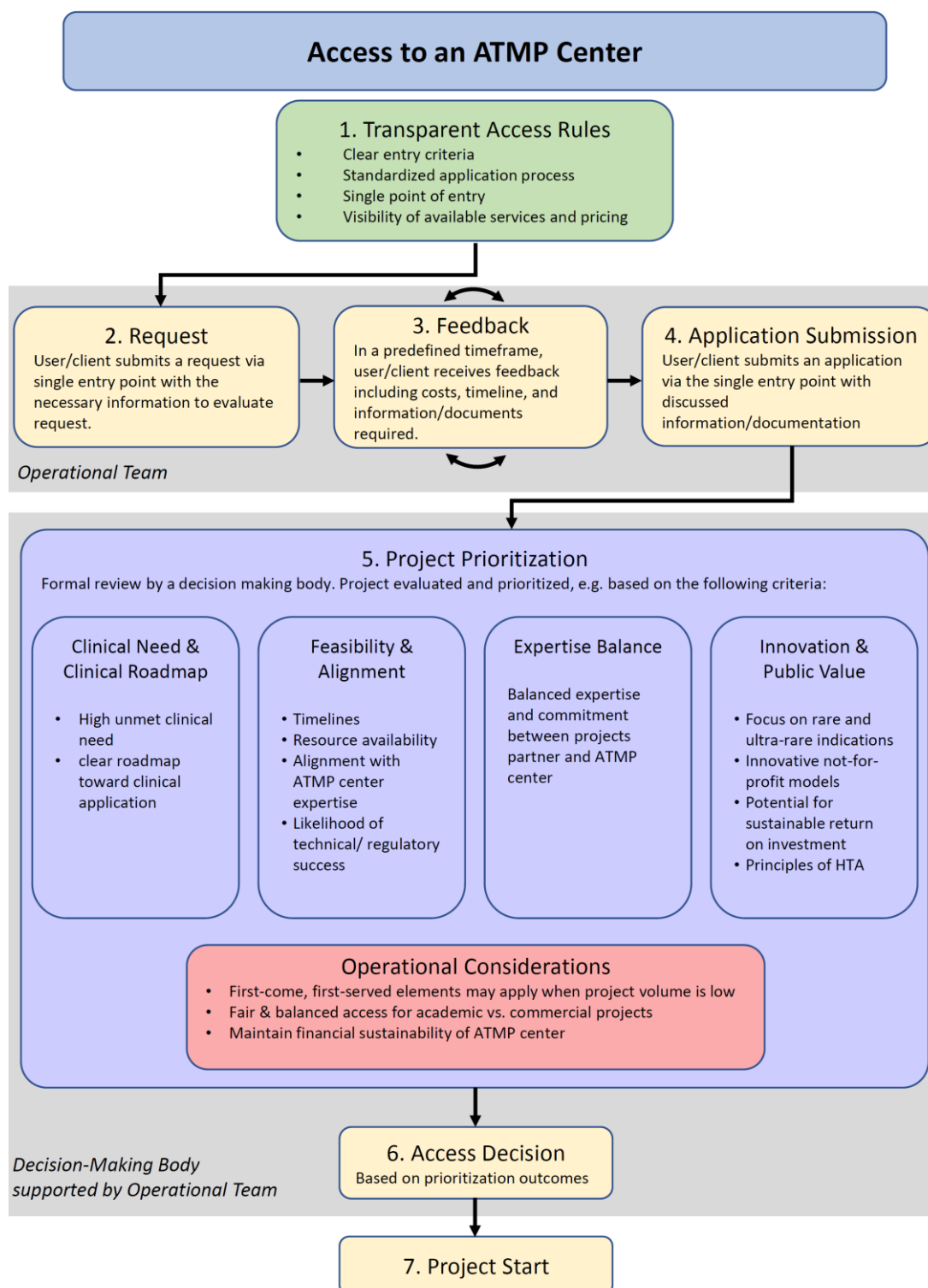


Figure 1 - Flowchart depicting an exemplary access process to an ATMP center. Numbered boxes give different steps whereas non-numbered boxes provide general considerations. Grey shaded area relates to body responsible for implementing steps in that area.

4. Application Submission

Based on the received feedback, the user submits a formal, complete application containing all requested documentation and project details. This forms the basis for the subsequent evaluation and prioritization process.

5. Project Prioritization

Following submission of the formal application, projects undergo a structured review by a designated decision-making body, supported by the operational team. The objective is to ensure that access to the ATMP center's resources, expertise, and infrastructure is allocated transparently and in line with strategic priorities.

Projects are evaluated based on several criteria, including:

- **Clinical Need and Clinical Roadmap:** Priority may be given to projects addressing high unmet medical needs and demonstrating a credible pathway toward clinical application and patient benefit.
- **Feasibility and Alignment:** Applications are evaluated regarding technical feasibility and general alignment with the ATMP center's capabilities and capacities, e.g. resource requirements, expected timelines, availability of infrastructure, alignment with the center's expertise, and the likelihood of achieving technical and regulatory milestones.
- **Expertise Balance:** Consideration is given to whether the user/client and the ATMP center collectively provide the necessary expertise, capabilities, and commitment to successfully execute the project.
- **Innovation and Public Value:** Projects may be prioritized based on their degree of innovation, their potential societal impact, their relevance for rare or ultra-rare diseases, the use of not-for-profit development models, and their ability to generate sustainable value. Considerations related to health technology assessment (HTA) and long-term healthcare impact may also be considered, as are general concerns regarding return on investment.
- **Operational Considerations:** In addition to scientific and clinical benefits, operational aspects must be always considered and may influence prioritization. These can include maintaining a balanced portfolio of academic and commercial projects, ensuring the financial sustainability of the ATMP center, and managing project throughput. When demand is low and capacity is available, first-come, first-served principles may also be applied.

The outcome of this assessment is a prioritized project ranking that forms the basis for the subsequent access decision.

6. Access Decision

Following the prioritization outcomes, a formal decision is made regarding project acceptance. The applicant is informed of the decision and conditions associated with access to the ATMP center's services and infrastructure are communicated.

7. Project Initiation

Approved projects enter the implementation phase. The user/client and the ATMP center establish the operational framework, finalize planning, contracting, and initiate the agreed activities.

8. Governance Structure

The process is overseen by a decision-making body responsible for strategic prioritization and access decisions. This body might be the general steering or executive board, or a separate body dedicated to access prioritization. It is supported by an operational team that manages the day-to-day administration of requests, communication with potential users/clients, and coordination of evaluations.

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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>

