



Call Document

PRECISEU Best Practice Recognition Edition 2





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Changes

Chapter	Version 1	Version 2 for Edition 2
3. Objectives-	INNOVATION: SMEs and Startups that are	INNOVATION: Organizations that are
categories	revolutionizing	revolutionizing
5 Timetable		New dates for 2 nd edition
10 Other conditions - reward	The applicants will be informed in July 2025 if they are amongst the 12 finalists. The winning organizations will be informed in August and announced in September 2025, provided all the requested documents have been submitted. The winners will be asked to attend the Life Sciences Baltics Conference 2025, Vilnius. Special conditions apply, e.g. reduced registration fees and reduced hotel costs. The Recognition Ceremony will takt place on 18 September 2025 at the Life Science Baltics Conference, Vilnius.	dates and Location for Ceremony adjusted to 2nd Edition
10 Other conditions - dissemination	Reference to Grant No	Use disclaimer
	Version 2 for Edition 2	Version 3 for Edition 2
5 Timetable		dates for 2 nd edition
7 Eligibility	INNOVATION: They are groundbreaking in the sense of	INNOVATION: They are
- eligibility	originality and creativity in the application of health data.	groundbreaking in the sense of
conditions		originality and creativity in the
		application of health data and ATMP technologies
3 Objectives-	INNOVATION: Organizations that are revolutionizing	INNOVATION: Organizations that are
Themes and	patient care in the field of ATMPs through breakthrough	revolutionizing patient care in the field
priorities —	innovations, leveraging patient data to drive	of ATMPs through breakthrough
Activities—	transformative solutions.	innovations and leveraging patient data
Expected results -		to drive transformative solutions.
Categories		
9 Evaluation and	Three finalists in each category will be announced in July.	Three finalists in each category will be
Recognition	Jury members will decide afterwards who will receive the	announced in May .
procedure	recognition. The winner will be informed in July and	Jury members will decide afterwards
	announced in September.	who will receive the recognition. The
		winner will be informed in May and
		announced in June .
10 PRECISEU Best	Innovation: Originality and creativity in the application of	Innovation: Originality and creativity in
Practice Recognition	health data.	the application of health data and
criteria		ATMPs.



1. Introduction

The PRECISEU Best Practice Recognition is a promotion designed to inspire, motivate, and showcase exemplary practices in healthcare, particularly in the innovative use of health data.

This contest operates under the *PeRsonalised medicine Empowerment Connecting Innovation ecoSystems across EUrope* (PRECISEU) Programme. PRECISEU is co-funded by the European Union's Horizon Europe research and innovation programme under Grant Agreement No 101161301 as part of the <u>New European Innovation Agenda</u>, and capitalizes on the potential of deep-tech innovation in the different territories of the EU.

We encourage all participants to carefully review this document, which provides valuable guidance and answers to support the preparation of your application.

These documents provide clarifications and answers to questions you may have when preparing your application:

the Call Document (Rules of Contest) outlines the:

- background, objectives, scope, activities that can be funded and the expected results (sections 1 and 2)
- available timetable (sections 3 and 4)
- admissibility and eligibility conditions (including mandatory documents; sections 5 and
 6)
- criteria for exclusion (section 7)
- evaluation and Recognition procedure (section 8)
- Recognition Criteria (section 9)
- other conditions (section 10)
- how to submit an application (section 11)



2. Background

PRECISEU is a flagship project of the European Commission's Horizon Europe Program that will address the main challenges of Personalised Medicine in Europe defined in the Strategic Research & Innovation Agenda (SRIA) agreed upon by experts from the large European consortium EP Permed. PRECISEU will contribute to achieving the goals of a more preventive, personalized, predictive, patient-centered, and participatory medicine (5P) in a shorter time.

The consortium includes regional authorities, clusters, a European Research Infrastructure Consortium, global pharmaceutical companies, patient organizations, and European Digital Innovation Hubs. The project has a budget of 23 million euros and will run for five years, until June 30, 2029.

The general objective of PRECISEU is to increase the efficiency of the regional innovation ecosystems through strengthened collaboration and shared resources on strategic areas of regional strength and specialization, enabling the development and implementation of innovating initiatives, and facilitating the digital and sustainable transformation of the healthcare systems.

3. Objectives — Themes and priorities — Activities — Expected results

Objectives

PRECISEU is an initiative dedicated to connecting innovation ecosystems across Europe, with a focus on advancing personalized healthcare. It seeks to inspire, motivate, and highlight exemplary practices in the use of health data at various levels of healthcare. Despite the transformative potential of health data, significant barriers still hinder its effective utilization.

The PRECISEU Best Practice Recognition aims to address these challenges by providing Europe-wide promotion for the most innovative and successful solutions in overcoming these obstacles. By showcasing and transferring best practices between regions, the PRECISEU Best Practice Recognition accelerates progress toward truly personalized healthcare. It also promotes the scaling-up of deep-tech healthcare innovations, particularly those based on advanced therapy medicinal products and the strategic use of health data. Ultimately, PRECISEU seeks to strengthen connectivity among regional ecosystems across Europe, fostering collaboration and innovation for a healthier future.

Categories

The PRECISEU Best Practice Recognition will be awarded to organizations, and contestants can apply to one among the following four Categories:

 IMPACT: Collaborating organizations that can demonstrate significant impact in healthcare via a transformative academic/business partnership supported by evidence based results



- INNOVATION: Organizations that are revolutionizing patient care in the field of ATMPs through breakthrough innovations and leveraging patient data to drive transformative solutions.
- EXCELLENCE: Organizations of health data excellence with respect to best accessibility, interoperability, safety, data stratification, quality standards for raw data input and inclusivity when it comes to utilization of patient data for personalized medicine
- CULTURE: Organizations that have developed best patient involvement and public engagement and are an example for best practice in communication for cultural impact to society in health data use

Expected outcomes

Enable the implementation of best practice models in Europe by highlighting the promoted examples. By creating a European network of excellence, the introduction of personalized medicine will be accelerated and improve healthcare outcomes.

Expected results

The PRECISEU Best Practice Recognitions will drive positive change within innovators, policymakers, patients, SMEs and healthcare organizations and foster the culture of deep tech within health care regarding resistance and skepticism while encouraging the adoption of innovative approaches. The PRECISEU Best Practice Recognitions should recognize the commitment of individuals or teams that lead the advancement of personalized medicine, to inspire and advocate for the broader adoption of the model.

4. Benefits

Each winner will be featured prominently across social media platforms associated with the organization, reaching a diverse and engaged audience. This includes targeted promotion to raise awareness of their achievements in Europe and beyond, showcasing their success on a global stage. This widespread European and international promotion is an opportunity to connect with key stakeholders, professionals, and decision-makers in their field.

The winners are invited to join with two individuals an event hosted by a PRECISEU network member. This includes the opportunity to be celebrated on stage in a Recognition Ceremony and being showcased among an esteemed audience of peers and industry leaders.

As part of their promotion, the winner will have the unique opportunity to contribute their insights and knowledge by participating in high-level training sessions for decision-makers. This platform allows the winner to interact with policy, being a role model for industry practices, and solidify their reputation as a thought leader in their domain.



5. Timetable and deadlines

Timetable and Deadlines	netable and Deadlines		
Call opening	October 2025		
Deadline for Submission	1 March 2026		
Evaluation	March/April 2026		
Notification to finalists and winners	April 2026		
Public voting	May 2026		
Announcement of finalists	May 2026		
Recognition Ceremony	June 2026		

6. Admissibility and documents

Applications must be submitted before the call deadline (see timetable section 5).

Applications must be submitted electronically via the questionnaire provided on the PRECISEU platform. Paper submissions are NOT possible.

Applications (including annexes and supporting documents) must be submitted using the submission system.

All information provided must be in English.

Your application must be readable, accessible and printable.

An applicant can only apply to one category of the four PRECISEU Best Practice Recognition Categories with the same project.

In case you are amongst the finalists you will be asked at a later stage for further documents and a five-minute video presentation of your project. The winner will be asked for statements or a short video message on your achievements in the chosen category. These materials will be used for communication purposes only.

7. Eligibility

Eligible participants (eligible countries)

In order to be eligible, the applicant must:

- be a legal entity (public or private body)
- be a research performing organization, including a higher education establishment (e.g. university)
- be established in one of the eligible countries, i.e.:
 - o EU Member State (including overseas countries and territories (OCTs))





o non-EU country associated to the Horizon Europe (associated countries)

• comply with the mandatory requirements of the PRECISEU Best Practice Recognition eligibility criteria

Applicants cannot receive a second recognition for the same activities.

Eligibility conditions

Organizations apply with a published project and will not share confidential information.

A project is an innovative, scientific project or clinical trial, but it can also be the implementation of new tools of impact, e.g. landing page, infrastructure, personnel with scientific project supportive tasks.

Applicants must have published in the past two years such a project that and involves

- A) uses of health data for public health improvement or healthcare delivery, AND
- B) are innovative in the fields of Advanced Therapy Medicinal Products (ATMPs):

gene therapy medicines: these contain genes that lead to a therapeutic, prophylactic or diagnostic effect. They work by inserting 'recombinant' genes into the body, usually to treat a variety of diseases, including genetic disorders, cancer or long-term diseases. A recombinant gene is a stretch of DNA that is created in the laboratory, bringing together DNA from different sources;

somatic-cell therapy medicines: these contain cells or tissues that have been manipulated to change their biological characteristics or cells or tissues not intended to be used for the same essential functions in the body. They can be used to cure, diagnose or prevent diseases;

tissue-engineered medicines: these contain cells or tissues that have been modified so they can be used to repair, regenerate or replace human tissue;

Publishing in this context means at least one of the following: publication in a peer reviewed paper, initiation of clinical trial, homepage that provides public access to data infrastructure, or launched a patient resp. public engagement project.

All Categories request a broad spectrum of information to enable a jury to judge the best practice.

Category: "IMPACT"

The applicant must be a partner in an academic/industry collaborative project.

This category's focus lies on the demonstration of sustainable and inclusive impact on society and health care. Potential for the projects must be given to be scaled or adapted to other settings, and for long-term benefits.

The project has delivered evidence-based proof of improved patient outcomes (e.g., life span, quality of life). The number of current and future beneficiaries are well known. The applicants





can demonstrate sustainability of the project in the sense of established long-term data collection frameworks and scalability for future healthcare advancements.

Ideally projects ensure by implemented measures across genders, races, and cultural backgrounds, etc. inclusivity of data output. They also include patient participation in e.g. design and evaluation of the project.

These projects set a benchmark for transformative, inclusive, and sustainable patient care solutions.

One partner should apply and upload a letter of support from the collaboration partner(s).

Category: "INNOVATION"

Eligible applicants are academic translational projects or startups and SMEs with innovative projects.

This category focuses on groundbreaking projects that drive transformative change in healthcare. Submissions should showcase leap innovations that redefine patient care, integrating cutting-edge solutions with measurable impact. Projects must demonstrate novelty and utility, ideally by a patent application derived from the project. They are groundbreaking in the sense of originality and creativity in the application of health data and ATMP technologies.

Category: "EXCELLENCE"

This category recognizes projects that exemplify best practices in health data management.

Applicants must demonstrate excellence in accessibility, interoperability, data quality management, data security and best practice in respecting ethics.

Therefore, clear pathways for data access and collaboration (e.g., project landing page, contact person) should be available. Standardized frameworks for seamless data integration and harmonization must be core of the project; as well as robust quality control measures for raw data input. The adherence to stringent standards for data security, privacy, and ethical handling of patient information.

Submissions should highlight how these practices drive innovation while ensuring trust, inclusivity, and excellence in health data management.

Category: "CULTURE"

This category recognizes organizations that have demonstrated excellence in patient involvement and public engagement, serving as benchmarks for best practices in communication and cultural impact related to the use of health data.

The focus of this category lies in fostering a culture of trust, transparency, and collaboration between health data stakeholders and the broader public. Projects in this category must exemplify how patient perspectives and public engagement are integrated into the design, execution, and evaluation of initiatives, leading to meaningful cultural shifts in the understanding and utilization of health data.





Projects should demonstrate Co-creation with patients and the public in planning and decision-making, transparent communication of health data use and its impact and measurable benefits such as improved trust, understanding, and public participation.

All applicants must verify their legal status. For the validation, you will be requested to upload documents showing legal status and origin.

Eligible activities

Eligible activities are the ones set out in section 7 above.

Ethics and values

Activities must comply with the highest ethical standards and the applicable EU, international and national law on ethical principles. Moreover, they must respect basic EU values (such as respect for human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities).

The activities must comply with:

- ethical principles (including the highest standards of research integrity) and
- applicable international, EU and national law

and may not:

- aim at human cloning for reproductive purposes
- intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads which may be financed), or
- intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Moreover, activities must have an exclusive focus on civil applications and no recognition can be awarded for activities carried out outside the EU, if they are prohibited in all Member States.

Verification

In case of entering the round of the three best applications in one category, we may ask for additional documents like:

Legal Entity Validation Documents:

• SMEs and Startups: must provide a self-declaration that the company is sustainable and will be in operation at least for three months after the recognition

Ethics Review Documents:

 Ethics approval certificates for any data collection or clinical trials involved in your project.





• Documentation of compliance with data protection regulations (e.g., GDPR compliance statement).

Declaration of Honour:

• A signed declaration confirming the accuracy of the submitted information and adherence to the recognition's ethical and procedural standards.

8. Exclusion

Applicants which are subject to an EU exclusion decision or in one of the following exclusion situations that bar them from receiving EU funding can NOT participate23:

- bankruptcy, winding up, affairs administered by the courts, arrangements with creditors, suspended business activities or other similar procedures (including procedures for persons with unlimited liability for the applicant's debts)
- in breach of social security or tax obligations (including if done by persons with unlimited liability for the applicant's debts)
- guilty of grave professional misconduct24 (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the implementation of the Recognition)
- committed fraud, corruption, links to a criminal organization, money laundering, terrorism-related crimes (including terrorism financing), child labor or human trafficking during the Recognition procedure they misrepresented information required as a (including if done by persons having powers of representation, decisionmaking or control, beneficial owners or persons who are essential for the implementation of the Recognition)
- shown significant deficiencies in complying with main obligations under an EU
 procurement contract, grant agreement, prize, expert contract, or similar (including if
 done by persons having powers of representation, decision-making or control,
 beneficial owners or persons who are essential for the implementation of the
 Recognition)
- guilty of irregularities within the meaning of Article 1(2) of Regulation No 2988/95
 (including if done by persons having powers of representation, decision-making or
 control, beneficial owners or persons who are essential for the implementation of the
 Recognition) created under a different jurisdiction with the intent to circumvent fiscal,
 social or other legal obligations in the country of origin or created another entity with
 this purpose (including if done by persons having powers of representation, decision making or control, beneficial owners or persons who are essential for the
 implementation of the Recognition).

Applicants will also be refused if it turns out that:





- during the PRECISEU Best Practice Recognition procedure they misrepresented information required as a condition for participating or failed to supply that information
- they were previously involved in the preparation of the call and this entails a distortion of competition that cannot be remedied otherwise (conflict of interest).

9. Evaluation and Recognition procedure

Applications will undergo a formal evaluation by a jury.

Non-confidential information, including project details and supporting documents (e.g., papers, links), will be shared with the jury.

If there are more than 90 applications in a prize category, a pre-selection will narrow it down to the top 30, which will then be reviewed by the jury. If fewer than 30 applications are received, all will be reviewed. Each jury member will review no more than ten applications.

The pre-selection panel and jury may have different members, although jury members can be part of the pre-selection panel.

The pre-selection panel/jury will evaluate each application against the recognition criteria.

For applications in each of the four prize categories, the pre-selection panel/jury will determine a priority order according to the following approach:

Several parameters are evaluated for the four categories. The jury will rank each answer for a parameter on a scale from -2 (improvement needed), 0= (average) to +2 (excellent). Points are awarded based on several parameters, with a maximum of 44 points in all categories.

Based on the jury's evaluation (and after mandatory checks: ethics review, legal entity validation, non-exclusion) the Recognizing authority will identify 3 finalists for each category.

Three finalists in each category will be announced in May.

Jury members will decide afterwards who will receive the recognition. The winner will be informed in May and announced in June.



10. PRECISEU Best Practice Recognition criteria

If admissible and eligible, all applications will be evaluated and ranked against the following Recognition Criteria defined for each of the four Categories.

Innovation: Originality and creativity in the application of health data and ATMPs.

Impact: Demonstrable outcomes and contributions to public health, including quantifiable improvements in patient outcomes or health equity.

Scalability and Sustainability: Potential for the project to be scaled or adapted to other settings, and for long-term benefits.

Data Integrity and Ethical Standards: Adherence to high standards of data security, privacy, and ethical use in the handling and application of health data.

Patient involvement: Patient involvement and public engagement in the course of the project.

Impact of Criteria in the different Categories

In the different Categories the evaluation of some of the criteria will have more impact on the ranking:

INNOVATION: In this category the novelty and utility of the project is in focus and ranked higher in the evaluation. Demonstration of the generation of IP as evidence will be requested.

IMPACT: Demonstrable outcomes and contributions to public health. The projects must be scalable, sustainable and inclusive.

EXCELLENCE: Best practice for data integrity and fulfilling ethical standards are in the focus of this category.

CULTURE: projects will be evaluated for their excellence in patient involvement and public engagement.

11. Other conditions

Reward

The applicants will be informed in April 2026 if they are amongst the 12 finalists. The winning organizations will be informed in April 2026 and announced in June 2026, provided all the requested documents have been submitted. The winners will be asked to attend the 5th edition Spinoff Europa Conference 2026, 4-5 June 2026, Sofia, Bulgaria. Special conditions apply, e.g. reduced registration fees and reduced hotel costs.

The Recognition Ceremony will takt place in June 2026 at the Spinoff Europa Conference 2026, Sofia.



Communication — Dissemination — Visibility of funding

Winners are invited to promote the PRECISEU Best Practice Recognition and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

Communication activities related to the PRECISEU Best Practice Recognition (including media interviews, press statements, presentations, etc., in electronic form, via traditional or social media, etc.), must acknowledge EU support and display the European flag (emblem) and funding statement (translated into local languages, where appropriate) and PRECISEU logo:



Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Innovation Council and SMEs Executive Agency (EISMEA). Neither the European Union nor the granting authority can be held responsible for them.



The emblem must remain distinct and separate and cannot be modified by adding other visual marks, brands or text.

Apart from the emblem and the PRECISEU logo, no other visual identity or logo may be used to highlight the EU support.

When displayed in association with other logos (e.g. of winners or sponsors), the emblem must be displayed at least as prominently and visibly as the other logos

For the purposes of these obligations, the winners may use the emblem or logo without first obtaining approval from the PRECISEU Best Practice Recognition authority. This does not, however, give them the right to exclusive use. Moreover, they may not appropriate the emblem or any similar trademark or logo, either by registration or by any other means.

Any communication or dissemination activity related to the PRECISEU Best Practice Recognition must use factually accurate information.

Moreover, it must indicate the following disclaimer (translated into local languages where appropriate):

IPR — *Rights of use*

The PRECISEU Best Practice Recognition authority does not obtain ownership of the results produced in the context of the Recognition.





The PRECISEU Best Practice Recognition authority has the right to use non-sensitive information relating to the Recognition and materials and documents received from the winners (such as pictures or audio-visual material, in paper or electronic form) for information, communication, dissemination and publicity purposes.

Photos and videos taken by the PRECISEU Best Practice Recognition authority either in preparation of the Recognition Ceremony or during the Recognition Ceremony are the sole property of the PRECISEU Best Practice Recognition authority.

Checks, audits and investigations

The PRECISEU Best Practice Recognition authority, the members of the PRECISEU-project may carry out checks and investigations in relation to the Recognition.

Withdrawal of the Recognition

The PRECISEU Best Practice Recognition authority may withdraw the Recognition after its announcement, if it finds out that

- false information, fraud or corruption was used to obtain it
- the winners were not eligible or should have been excluded or
- the winners are in serious breach of their obligations under these Rules of Contest

12. How to submit an application

All applications must be submitted directly online via the PRESICEU registration portal. Paper applications are NOT accepted.

You can access the registration by clicking 'Apply now' on the official PRECISEU Best Practice Recognition webpage.

General information and Privacy Policy

For organizational reasons we will ask you about your institution and to upload personal information. These data will not go to the jury. With uploading this information, you agree that PRECISEU partners can handle the data according to their data protection policies.

Project related information

To evaluate if your project is outstanding in the sense of the Recognition Criteria, the jury members need information that describes your solution to existing problems in personalized medicine. In the questionnaire you will be asked stepwise to highlight different aspects of your project that refer to the evaluation criteria. PLEASE, SHARE NON-CONFIDENTIAL INFORMATION ONLY! Share information you want to be distributed and copied for you to become a role model in best practice of heath data use in ATMPs!



Deadline and **Platform**

- All applications must be submitted **before the call deadline**. Refer to the timetable in **Section 4** for the exact dates.
- Applications **must be submitted electronically** using the questionnaire on the PRECISEU platform.
- Paper submissions are NOT accepted.

Submission System Requirements

- Applications, including all annexes and supporting documents, must be submitted via the **Submission System**.
- All submitted information must be in English.
- Ensure your application is readable, accessible, and printable.

Project and Category Guidelines

- Applicants can apply to **only one category** of the prize categories per project.
- Published projects only: Applications must involve initiatives already published (e.g., peer-reviewed paper, initiated clinical trial, public data infrastructure).
- Applications must **not contain confidential information**.

Additional Requirements

When starting the application, the following documents and materials are available to expedite the process:

Supporting information to the project will be requested:

- Detailed project description, including:
 - Objectives, methods, and outcomes.
 - Information on scalability and sustainability.
- Evidence of project publication, such as:
 - Peer-reviewed journal articles.
 - Clinical trial registration details.
 - Publicly accessible webpages or platforms providing access to the project's data infrastructure.
 - Any patents, intellectual property (IP) documentation, or records of innovation where applicable.
 - Letters of support from partners, stakeholders, or collaborators.





By gathering all available materials beforehand, you can ensure a smoother and more efficient submission process.

For all categories the same questionnaire will be used. Some questions are more relevant for certain categories. E.g, patient involvement is of significantly more importance to the Category CULTURE. This will be reflected in the final evaluation as some criteria will have more impact on the category and the ranking than others.

In case you can't answer a question, please add "n/a" in the survey.

The application must be submitted before the call deadline (see section 5). After this deadline, the system is closed, and applications can no longer be submitted.

Once the application is submitted, you will receive a confirmation e-mail (with date and time of your application). If you do not receive this confirmation e-mail, it means your application has NOT been submitted. If you believe this is due to a fault in the submission system, you should immediately file a complaint via the technical support contact, explaining the circumstances and attaching a copy of the application (and, if possible, screenshots to show what happened).

13. Help

Additional information can be found here:

Supporting document "questionnaire": you can pre-read the questionnaire to prepare for the upload of the requested information.

PRECISEU website including an FAQ section

Contact

For individual questions on the application form, please

contact for technical support:
María Céjas: mcejas@biocat.cat

Non-IT related questions please contact

Daniela Weber: dw@biorn.org

