PRECISEU

Terms & Conditions

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This project has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement No 101161301

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1. ACRONYMS AND DEFINITIONS

1.1. ABBREVIATIONS AND ACRONYMS

AC	Associated country/countries associated with Horizon Europe
AI	Artificial Intelligence
ATMPs	Advanced therapy medicinal products
CMC	Chemistry, Manufacturing, and Control
C&G	Cell and Gene
DMP	Data Management Plan
DNSH	Do No Significant Harm
DoA	Description of Action
ECA	European Court of Auditors
EEA	European Economic Area
EHDS	European Health Data Space
EHR	Electronic Health Record
EISMEA	European Innovation Council and SMEs Executive Agency
EMA	European Medicines Agency
EP PerMed	European Partnership for Personalised Medicine, supported by the European Union under Horizon Europe, Grant Agreement N° 101137129
EPPO	European Public Prosecutor's Office
ERDF	European Regional Development Fund
EU	European Union
FAIR	Findability, Accessibility, Interoperability, and Reusability
FDA	U.S. Food and Drug Administration
FSTP	Financial Support to Third Parties
GA	Grant Agreement
GBER	General Block Exemption Regulation
GDPR	General Data Protection Regulation
GEDI	Gender Equality Diversity and Inclusion
HE	Horizon Europe Programme
IA	Innovation Action
IC Permed	International Consortium for Personalised Medicine
IP(R)	Intellectual property (rights)
JIP	Joint Interregional Project
JRC	European Commission Joint Research Centre
MS	Member State(s)
NEIA	New European Innovation Agenda
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
OLAF	European Anti-Fraud Office
PIC	Participant Identification Code
PM	Personalised Medicine

PRECISEU	PeRsonalised medicine Empowerment Connecting Innovation ecoSystems across EUrope
R&I	Research and Innovation
RP	Reporting Period
RRI	Responsible research and innovation
RTO	Research and Technology Organisation
S3	Smart Specialisation Strategies
SCO	Simplified Cost Option
SMEs	Small and Medium Enterprises
SRIA	Strategic Research and Innovation Agenda
SSH	Social Sciences and Humanities
TEHDAS	Towards the European Health Data Space
TFEU	Treaty of the Functioning of the European Union
ToA	Triplets of Action
TRL	Technology Readiness Level
WP	Work Package

1.2. RELEVANT TERMINOLOGY

Applicant	A legal entity, private or public, which takes part in a consortium applying to the PRECISEU Open Call.
Background	Any data, know-how, or information—whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights—that is held by the applicants before they acceded to the Grant Agreement and is needed to implement the action or exploit the results.
Beneficiary	A legal entity, private or public, that receives PRECISEU funding. The Coordinator of the proposal will be the signatory of the Grant Agreement and responsible for implementing the project complying with the agreement's obligations.
Call secretariat	Office responsible for managing and administering calls. The secretariat handles tasks like preparing call documents, promoting the call, receiving proposals, coordinating evaluations, and monitoring project implementation.
Court of auditors	EU's independent external auditor, ensuring the proper management of EU finances.

Deep tech innovation[1]	Innovation rooted in cutting edge science, technology and engineering, often combining advances in the physical, biological and digital spheres and with the potential to deliver transformative solutions in the face of global challenges.
Deliverable	A report to be sent to the PRECISEU Call Secretariat providing information to allow monitoring of the project.
Do No Significant Harm (DNSH)	A principle ensuring that economic activities do not cause significant harm to any of the six environmental objectives: climate change mitigation, climate change adaptation, sustainable use of water, circular economy, pollution prevention, and biodiversity protection.
Experimental Development	Systematic work of creating new or improved products, processes, or services by applying existing knowledge. It involves activities like building and testing prototypes, demonstrating new systems, and conducting pilots in real-world conditions to make further technical improvements. This stage uses results from research and practical experience to transform ideas into a usable, testable form[2].
Funding Agency	In the context of this call, a PRECISEU partner from a participating region providing funds for the FSTP in a EU co-funding scheme in the frame of the Horizon Europe project, and which undertakes an agreement with the JIPs beneficiaries to provide the awarded FSTP.
General Block Exemption Regulation (GBER)	EU regulation (Commission Regulation (EU) No 651/2014) that allows Member States to grant specific categories of aid without prior notification to the European Commission, provided they meet certain criteria .
Impact	Wider long-term effect on society (including the environment), the economy and science, enabled by the outcomes of R&I investments (long term). It refers to the specific contribution of the project to the PRECISEU expected impacts described in the Open Call text. Impacts generally occur sometime after the end of the project.
Innovation Action (IA)	A collaborative project that produces plans or designs for new or improved products, processes or services including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.
Legal entity	Any natural or legal person created and recognised as such under national, EU or international law.

[1] European Commission, *A New European Innovation Agenda*, COM(2022) 332 final. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022DC0332#page=2

[2] OECD: "Frascati Manual 2002: The measurement of scientific and technological activities - Proposed Standard Practice for Surveys on Research and Experimental Development", OECD, Paris, 2002 PDF

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Lump sum	A fixed amount of money which can be used by beneficiaries for several purposes related to the achievement of the project objectives.
New Drug Application	A formal proposal submitted to regulatory agencies (such as EMA or FDA) for the approval of a new pharmaceutical for sale and marketing. In the context of this call, the submission of an New Drug Application corresponds to TRL 8.
Non-Disclosure Agreement	A legally binding contract establishing a confidential relationship. In this call, it refers to the agreement signed by the members of the Expert Panel to protect the confidentiality of the proposals and materials received during the evaluation.
Objectives	Goals of the work performed within the project that will be translated into activities, depending on the type of action and the scope of the PRECISEU Open Call.
Outcomes	Expected effects, over the medium term, of projects supported. The results of a project should contribute to these outcomes, fostered in particular by the dissemination and exploitation measures. Outcomes generally occur during or shortly after the end of the project.
Outputs	Results generated by the action, in the form of validated prototypes, harmonised protocols and interoperable data infrastructures, clinical and real-world evidence on effectiveness and safety, regulatory and HTA-relevant documentation and strategies, sustainable business and implementation models, capacity-building activities and best-practice guidelines, or strengthened use of health data for clinical decision-making and regulatory acceptance.
Results	What is generated during the project implementation. Most JIP results are 'Intellectual Property', which may, if appropriate, be protected by formal 'Intellectual Property Rights'.
Scope	Specific area of R&I a project will address to achieve the expected outcomes, without dictating the methods to be used.
Technology Readiness Levels[3]	A scale from 1 to 9 that measures the maturity of a technology, with TRL 1 being the earliest stage and TRL 9 being the most advanced and commercialized. The scale helps stakeholders like engineers, investors, and funding bodies understand the current development stage of an innovation

[3] As defined in the HE General Annexes: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2025/wp-14-general-annexes_horizon-2025_en.pdf#page=14

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	and what steps are needed to reach market readiness. For this call, the relevant TRLs are: • TRL 6: Prototype demonstration. A prototype system or component is demonstrated in a relevant environment. • TRL 7: Full-scale prototype. A full-scale prototype is demonstrated in an operational environment. • TRL 8: Technology proven. The technology is proven to work in its final form and is considered ready for commercialization.
Topic	Specific area or issue within a funding call, outlining the specific research and innovation activities the agency wants to support.
Triplets of Action	Core elements of the SRIA, defining challenges, objectives, and expected outcomes for fostering personalised medicine research and implementation.

2. ABOUT THE PRECISEU PROJECT

2.1. GENERAL INFORMATION

Project acronym	PRECISEU
Project title	PeRsonalised medicine Empowerment Connecting Innovation ecoSystems across Europe
Project number	101161301
Project topic	HORIZON-EIE-2023-CONNECT-03-01
Project duration	60 months
Overall project budget	€22 730 100
Open call budget	€11 570 000
Website	www.preciseu.eu

Table 1. General information of the PRECISEU project

2.2. THE PRECISEU PROJECT AND ITS OBJECTIVES

PRECISEU's general objective is to enhance regional innovation ecosystems by promoting collaboration and shared resources in strategic areas of specialisation. It fosters innovative initiatives for the digital and sustainable transformation of healthcare and accelerates the uptake of Personalised Medicine (PM) across Europe. The project responds to the Strategic Research and Innovation Agenda (SRIA) for Personalised Medicine and aligns with the New European Innovation Agenda (NEIA) and the Smart Specialisation

Strategies (S3).

PRECISEU aims to:

a) Accelerate the adoption of PM in Europe, reducing fragmentation and inequalities in the European Union (EU) and facilitating the implementation of advanced technology innovations in various ecosystems with different levels of innovation, assets, strategies, and policies.

b) Connect innovation ecosystems across Europe to advance towards truly personalised healthcare through personalised medicine.

c) Contribute to the transfer of practices and solutions among European regions.

d) Support the scale up of advanced technological innovations in the health sector, grounded in two pillars of personalised medicine: 1) health data, which must be accessible, high-quality, and interoperable, and 2) advanced therapies —based on genes, tissues, and cells— which may include advanced medical devices (providing emerging diagnostics) and treatments aimed at curing and improving the treatment of severe diseases and complex injuries in a more tailored approach to patients' needs.

2.3. PRECISEU PARTICIPATING REGIONS AND FUNDING AGENCIES

PRECISEU is implemented by a multidisciplinary and geographically diverse consortium bringing together regional authorities, innovation agencies, research and technology organisations, clusters, and key ecosystem actors across Europe. The partnership reflects a strong commitment to interregional collaboration and to strengthening innovation capacity in the field of personalised medicine and related technologies.

Within the consortium, a subset of partners act as Funding Agencies, contributing financial resources to support projects selected under this Open Call through a joint interregional funding mechanism (FSTP). Joint Interregional Projects (JIP) to be granted under the PRECISEU Open Call will be co-funded by the European Union (EU) through the European Innovation Council and SMEs Executive Agency (EISMEA) and those partners of the PRECISEU project contributing to the Financial Support to Third Parties (FSTP). These Funding Agencies are responsible for defining and applying specific regional eligibility rules, as well as for managing the financial contribution to beneficiaries established in their respective regions. Other partners participate as ecosystem enablers, providing expertise, networking capacity, and support services, but do not directly provide funding.

The PRECISEU consortium covers a wide range of European regions, including both funding and non-funding territories. While participation in project consortia is open to entities from all represented regions (subject to the eligibility conditions of the call), only applicants established in regions with a participating Funding Agency are eligible to receive financial support.

The table below provides an overview of all PRECISEU partners, indicating their corresponding region, country, and whether they act as a Funding Agency within the framework of this Open Call.

Partner name	Region	Country	Funding Agency

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Biocat	Catalonia	Spain	No
Departament de Salut – Generalitat de Catalunya	Catalonia	Spain	Yes
ACCIÓ	Catalonia	Spain	Yes
Barcelona Supercomputing Center	Catalonia	Spain	No
BioRN Cluster Management GmbH	Baden-Württemberg	Germany	No
BIOPRO Baden-Württemberg GmbH	Baden-Württemberg	Germany	Yes
North-East Regional Development Agency	Nord-Est	Romania	Yes
Digital Innovation Zone	Nord-Est	Romania	No
IMAGO-MOL Cluster	Nord-Est	Romania	No
Health & Life Sciences Cluster Bulgaria	Bulgaria	Bulgaria	No
Clust-ER Health	Emilia-Romagna	Italy	No
Regione Emilia-Romagna	Emilia-Romagna	Italy	Yes
ART-ER	Emilia-Romagna	Italy	No
BIOVIA	Flanders	Belgium	No
Dept. Economy, Science & Innovation	Flanders	Belgium	No
Innovation Agency Lithuania	Lithuania	Lithuania	Yes
Business Region Göteborg	Gothenburg	Sweden	No
EATRIS	Netherlands	Netherlands	No
Plataforma de Organizaciones de Pacientes	Spain	Spain	No
Region of Crete	Crete	Greece	Yes
FORTH	Crete	Greece	No
Science & Technology Park of Crete	Crete	Greece	No
Rivne Interregional Medical Cluster	Rivne	Ukraine	No
AstraZeneca	Multi-country	Sweden/EU	No
Agencia de Transformación Digital Castilla-La Mancha	Castilla-La Mancha	Spain	Yes
Lazio Innova S.p.A.	Lazio	Italy	Yes
NIBRT	Ireland	Ireland	Yes

Table 2. Only entities established in regions covered by a participating Funding Agency are eligible to receive financial support under this Open Call. Entities from non-funding regions may participate on a self-funded basis.

3. OPEN CALL FOR PROPOSALS

3.1. SUMMARY OF THE CALL

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With this Open Call, the PRECISEU consortium will provide financial support to consortia implementing Joint Interregional Projects (JIPs). The evaluation of proposals will follow an IA-like logic inspired by Horizon Europe Innovation Actions, notably with regard to the award criteria of Excellence, Impact, and Quality and efficiency of the implementation. However, the PRECISEU Open Call is not a Horizon Europe call for proposals addressed directly by the European Commission or EISMEA; it is a Financial Support to Third Parties (FSTP) scheme implemented under the PRECISEU project and subject to these Terms and Conditions, Annex 1, and the applicable sub-grant agreement and regional rules.

Objectives	The general objectives of the PRECISEU Open Call are: • To competitively fund Joint Interregional Projects (JIPs) with a reasonable number of beneficiaries representing the largest possible number of participating regions from PRECISEU (at least three) and the best use of all committed national/regional funding. • To target deep tech innovation, including Advanced therapeutics and health data. • To enhance connections between the different PRECISEU innovation ecosystems across Europe and translating and sharing best practices and solutions. See section 3.2 for more details.
Type of activities to be funded	• Scale-up production • Optimisation, validation and standardisation of the analytical methods, protocols and methodologies • Mechanism-related studies necessary to resolve technical uncertainty directly linked to validation, scale-up, performance, safety, comparability or regulatory advancement of a technology already at TRL 6–8. • Development of suitable and (environmentally) relevant reference materials required for validation, comparability, quality control, release testing or regulatory readiness of a TRL 6–8 product, process or platform. • Development of improved in-vivo, in-silico and in-vitro models • Generation of evidence needed to resolve technical uncertainty directly linked to performance, safety, manufacturability, interoperability, comparability, regulatory readiness or implementation readiness in

	relevant settings. • End-user collaborative projects • Use of health data repositories to facilitate/support the clinical validation of a technology • Validation and demonstration activities in relevant or operational settings are eligible where they are necessary to resolve remaining technical uncertainty. • Activities related to regulatory considerations See section 3.5 for more details.
TRL requirement	Projects must help bring the technology or solution to a higher TRL level, from TRL6 to TRL8. See section 3.5.2 for more details.
Eligible applicants	Companies, research institutes, universities, technological centres, local authorities, public administration, associations, NGOs (including patient organisations), public and private research bodies, hospitals, and large companies, with a validated PIC number. Applicants can be located in any of the PRECISEU regions or any non-PRECISEU region from EU Member States and HE Associated Countries. Different conditions apply depending on the location and nature of the beneficiaries; in particular, only beneficiaries established in regions covered by a participating Funding Agency will be eligible for funding under this Call (see Section 5 and Annex 1).
Consortium requirements	Consortia must be composed by legal entities from European Union Member States and HE Associated Countries. The following requirements must be met: • At least three (3) applicants located in three (3) different regions of the Funding Agencies. At least two (2) of them must be in two (2) different Member States. • At least one (1) SME located from a region of a Funding Agency. • Maximum one (1) applicant from a PRECISEU non-funding region and maximum one (1) applicant from a non-PRECISEU region (EU Member State or Horizon Europe Associated Country), subject to the conditions set out in Section 3.7. Those entities cannot lead a consortium. • Each consortium must appoint a Coordinator established in the territory

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	of one of the Funding Agencies. See Sections 3.6 and 4.1 for more details.
Number of applications per organisation	Applicants can participate in more than one proposal provided that: • They only submit one as Coordinator • The proposals differ from each other. • The teams involved are different within the applicant entity. Otherwise, only the first submitted will be considered for evaluation.
Funding	The maximum amount committed for this call is €11 570 000, co-funded (50%) by the European Union through the Horizon Europe programme, under Grant Agreement No 101161301, and by the Funding Agencies of the contributing regions (50%).
Funding rate	Funding rates may differ depending on the region. For entities located in PRECISEU Funding Agencies' regions: • 70% co-fund for profit-making legal entities and 100% for non-profit legal entities for Innovation Actions-like projects. • Up to EUR 600.000 per beneficiary for all participating projects. Participants from regions different from the regions of the Funding Agencies may also apply, on the understanding that they will not receive funding from the PRECISEU Open Call for the implementation of their activities. State aid rules apply if the beneficiary of public funding granted from Member State resources, including the ERDF, is an undertaking (and if all other cumulative conditions for the presence of State aid, spelled of Article 107 (1) TFEU are met). GBER article 25(6)d might be applied to ensure compatibility with the internal market if all its conditions are met. Each applicant should refer to their region dedicated table in 0. See also Section 5.22 for more details.
Maximum funding amount	The maximum financial contribution per project is €3 000 000. A single entity can perceive a maximum amount of €600 000. If an entity participating in more than one project requests, in sum, a higher amount, it will enter in a negotiation process to meet this requirement. See section 5.1 for more details.
Payments	If not stated differently in 0, for all JIPs receiving financial support there will be a pre-financing of 50% of the granted contribution within the established term

	of each Funding Agency. The final payment (payment of the balance) will be made after completion of the assessment of the final progress performance report. See section 5 for more details.
Application calendar	The call for proposals will remain open between 13/04/2026 and 14/06/2026.
Projects implementation period	Projects implementation period: from October 2026 to March 2029 (overall implementation window). Please note that some Funding Agencies may apply stricter regional timelines, including earlier end dates, as specified in Annex 1 (Regional Specificities).

Table 3. Summary of the PRECISEU Open Call for Joint Interregional Projects.

Proposals could consider the involvement of the European Commission's Joint Research Centre (JRC) with respect to the value it could bring in providing an effective interface between innovation activities and regulatory aspects.

3.2. OBJECTIVE

The general objectives of the PRECISEU Open Call are:

a) To competitively fund Joint Interregional Projects (JIPs) with a reasonable number of beneficiaries representing the largest possible number of participating regions from PRECISEU (at least three) and the best use of all committed national/regional fundings.

b) To improve accessibility and affordability of personalised therapies, increase competitiveness and innovation capacity of European regions, strengthen European leadership in health data and advanced therapies, and contribute to the EU twin transition and open strategic autonomy in health technologies.

c) To target deep tech innovation, including Advanced Therapy Medicinal Products (novels) and health data (See Annex 2).

d) To enhance connections between the different PRECISEU innovation ecosystems across Europe and translating and sharing best practices and solutions.

More concretely, PRECISEU aims to fund innovation projects focused on the progress and implementation of PM diagnostics and treatments through experimentation, considering that:

- Projects must lead to innovations (TRL 6-8) advancing in the development of new PM diagnostic strategies and therapies and/or in the secondary use of health data for PM. Proposals should include a clear regulatory path to market.

- Projects should pursue strengthening collaboration between research, industry, healthcare providers, and regional authorities, for the uptake of PM innovations by the market

- Projects must ensure patient benefit, promoting equity in PM, particularly for underserved

populations.

- Projects must include activities promoting cross-regional innovation alliances and knowledge transfer between ecosystems.
- Proposals might address some of the following:
    - Data-driven platforms with AI and other advanced data analytics functionalities.
    - Innovative systems such as portable, faster, more compact or accurate devices and technologies, including the possibility to include point of care developments.
    - Innovative diagnostic methods bringing a significant improvement, such as less invasive sampling.
    - Hurdles, factors and situations that impede implementation of good practices and PM tools in real-life settings. Effectiveness and general applicability should be assessed and evaluated to provide enhanced real solutions in practice.
    - Social and health determinants, including sex, gender, age and other relevant variables, such as socio-economic status, living in rural or remote areas and education.
- Proposals should include a regional dimension and respond to the European dimension criteria (requisite based on HE General Annexes - B. Eligibility).

3.3. EXPECTED OUTCOMES AND IMPACTS

The expected outcomes of this call are:

- More innovation co-investments, mobilising other funding leverages, including European, national, or regional public funds and/or other private funds, to complement Horizon Europe support.
- Increased participation of all innovation ecosystems players across EU territories in technology and industrial value chains (existing and emerging ones) relevant to the EU twin green and digital transition to achieve broader sustainability and the EU's open strategic autonomy.
- Increased collaboration with relevant initiatives in the deep-tech and PM field.
- Strengthened positioning of European regions as leaders in precision health and deep tech.
- Contribution to the EU's strategic goals in health innovation, digital transformation, and sustainability.
- Efficient knowledge transfer, share of best practices, and co-development of innovative solutions.
- Advancement in deep tech innovation.
- Acceleration of cutting-edge developments in ATMPs and health data applications.

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- Strengthened research and development efforts leading to tangible technological advancements.
- Strengthened regulatory readiness of funded solutions, through robust regulatory strategies and early interactions with regulators/HTA bodies, de-risking the path to market access and clinical implementation.
- Strengthened use of health data for clinical applications.
- To increase the access of ATMPs to market and patients, independently of their region of residence: improved diagnostic accuracy, best patient-targeted therapy increasing the likelihood of success and reducing side effects, improved interventions disease prevention from patient to population cohorts.

The expected impacts of this call are:

- Increased competitiveness of public and private innovators, increased business volume and academic R&I breakthroughs.
- Efficient knowledge transfer, share of best practices, and co-development of innovative solutions.
- Advancement in deep tech innovation. Acceleration of cutting-edge developments in ATMPs and health data applications.
- Strengthened research and development efforts leading to tangible technological advancements.
- Increased utilization of health data repositories for clinical validation and decision-making.
- More effective and data-driven healthcare innovations benefiting patients and healthcare professionals.

3.4. TOPICS

Considering the detailed scope, eligible activities, and identified needs (see ANNEX 2), the call topics can be defined as follows:

- Topic 1 - Accelerating the development of Advanced therapeutics: innovations (TRL 6-8) advancing development of new personalised medicine diagnostic strategies and therapies: including development, testing, validation and scaling up of ATMPs, promoting the clinical and regulatory integration of new diagnostic and therapeutic solutions.
- Topic 2 – The use of Health Data for Personalised Medicine: innovations (TRL 6-8) advancing in the secondary use of health data for Personalised Medicine, including: facilitating the use of interoperable and high-quality health data in research and innovation; Data collection and management by healthcare professionals for PM; availability and accessibility of real-world data and real-world evidence for PM; connecting large-scale health databases to advance EHDS implementation.

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3.5. SCOPE OF THE CALL AND ELIGIBLE ACTIVITIES

Activities must be aligned with the EU State Aid R&D definitions, and the logic behind the GBER 25.6.d exemption, which typically refers to activities that qualify as Experimental Development. Here below, it can be found a non-exhaustive list of eligible activities:

- Scale-up production, when scale-up involves actual scientific or technical uncertainty that prevents the use of standard engineering solutions, or it requires new experimental work to understand or control biological, biochemical, or process behaviour at larger scale.

- Optimisation, validation and standardisation of the analytical methods, protocols and methodologies, if non-routine and needed to resolve scientific or technical uncertainty.

- Mechanism-related studies necessary to resolve technical uncertainty directly linked to validation, scale-up, performance, safety, comparability or regulatory advancement of a technology already at TRL 6–8.

- Development of suitable and (environmentally) relevant reference materials required for validation, comparability, quality control, release testing or regulatory readiness of a TRL 6–8 product, process or platform.

- Development of improved in-vivo, in-silico and in-vitro models, if the models are new or substantially improved and involve technical uncertainty

- Generation of evidence needed to resolve technical uncertainty directly linked to performance, safety, manufacturability, interoperability, comparability, regulatory readiness or implementation readiness in relevant settings.

- End-user collaborative projects (engagement of patients, healthcare practitioners, clinicians, and relevant healthcare authorities to support and enhance clinical development) when user engagement directly supports iterative experimental development.

- Use of health data repositories to facilitate/support the clinical validation of a technology when used to develop/validate algorithms, models or technologies with unresolved technical uncertainty.

- Validation and demonstration activities in relevant or operational settings are eligible where they are necessary to resolve remaining technical uncertainty. Pure market uptake, routine deployment, roll-out, commercialisation and distribution activities are not eligible.

- Activities related to regulatory considerations, for instance a regulatory strategy and interaction plan. This could include interactions with regulatory and/or Health Technology Assessment agencies using existing support services. Some regulatory support services offered by regulatory agencies attract fees, and the fees depend on the type of submitter (e.g. academic, SMEs). The costs of regulatory fees/interactions can be eligible costs under this call.

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As a general rule, projects must be centred on experimental development activities at TRL 6–8. Any activity outside that category must be ancillary, clearly justified, and remain subordinate to the project's experimental development core.

3.5.1. CLINICAL TRIALS

Clinical trials might entail great complexity, long periods of execution, high funding needs and might include sensitive materials and information. Though activities relative to clinical trials will not be excluded, they will be assessed case by case, and each project will be ensured to follow ethical and GDPR assessments before being awarded. Selected proposals envisaging to include clinical studies should be asked to provide further details of their clinical studies in the grant agreement preparation process.

3.5.2. TECHNOLOGY READINESS LEVEL (TRL) REQUIREMENT

The PRECISEU Open Call aims to contribute to activities that demonstrate an already developed and tested digital solution, product, process, service, or technology (TRL 6-8). It is important to note that TRL differ if referred to drugs or medical devices:

TRL	General definition	Pharmaceuticals / Advanced therapeutics	Medical Devices
TRL 6	Technology tested in a relevant environment	Completion of Phase I clinical trials, demonstrating initial safety in humans	Prototype demonstrated in an operational environment; clinical testing and safety demonstrated; regulatory accreditation process ongoing
TRL 7	Technology showing preliminary effectiveness	Completion of Phase II clinical trials, providing preliminary evidence of efficacy	Final product design validated; final prototypes intended for commercialisation produced and tested; regulatory accreditation completed where applicable
TRL 8	Technology showing broad effectiveness and readiness for market deployment	Completion of Phase III clinical trials; marketing authorisation application prepared and submitted to EMA/FDA	Manufacturing process validated; premarket application submitted and approved; device demonstrated in real-life conditions with technical support structures in place for technical problems

Table 4. TRL description

For pharmaceuticals and advanced therapeutics, TRL equivalences are indicative and may vary depending on modality, regulatory pathway and development model. Applicants must justify the starting and target TRL in a manner proportionate to the technology and the proposed work.

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3.6. GEOGRAPHICAL SCOPE

3.6.1. ELIGIBLE REGIONS (PRECISEU REGIONS)

The PRECISEU consortium covers a wide range of European regions, including both funding and non-funding territories. While participation in project consortia is open to entities from all represented regions (subject to the eligibility conditions of the call), only applicants established in regions with a participating Funding Agency are eligible to receive financial support.

Region	Country	Eligible to receive financial support
Catalonia	Spain	Yes
Baden-Württemberg	Germany	Yes
Nord-Est	Romania	Yes
Bulgaria	Bulgaria	No
Emilia-Romagna	Italy	Yes
Flanders	Belgium	No
Lithuania	Lithuania	Yes
Gothenburg	Sweden	No
Netherlands	Netherlands	No
Madrid	Spain	No
Crete	Greece	Yes
Rivne	Ukraine	No
Castilla-La Mancha	Spain	Yes
Lazio	Italy	Yes
Ireland	Ireland	Yes

Table 5. Eligibility of PRECISEU regions for financial support

3.6.2. PARTICIPATION FROM OTHER EU MS/ASSOCIATED COUNTRIES

Participation is open to legal entities established in the PRECISEU regions listed above, including both funding and non-funding regions. In addition, legal entities established in other EU Member States and/or Horizon Europe Associated Countries may participate, subject to the consortium composition and funding conditions set out in Section 3.7 (and any applicable regional requirements in Annex 1). Only entities established in regions covered by a participating Funding Agency are eligible to receive funding under this Call, as described in Section 5 and Annex 1.

3.7. TARGET BENEFICIARIES AND CONSORTIUM COMPOSITION RULES

This project has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement No 101161301

Legal entities[4] from regions in EU Member States and HE Associated Countries are invited to participate in the Open Call and join a consortium.

All participating entities must be registered in the Participant Register[5] at the EU Funding & Tenders Portal. They must have a PIC number which should be validated before the Grant Agreement Signature. The validated profiles serve as a guarantee for acknowledging that the participant is an active legal entity and it is financially viable in line with the criteria of the European Commission and its Agencies.

Target organisations include (but are not limited to) SMEs, start-ups, public and private research bodies, hospitals, NGOs (including patient organizations), and large companies.

Different conditions will apply for entities from the regions of the Funding Agencies (see Section 2.3), entities from other PRECISEU regions, and entities from other regions: participating entities may be eligible to receive funding from the PRECISEU Open call if they are established in any of the regions in which the authorities or investment agencies have committed funding for the Financial Support to Third Parties (FSTP). Otherwise, they may participate without receiving funding from PRECISEU Open call. In case of oversubscription (see Section 6.4), the Funding Agency will decide the % of funding.

Entities from regions of other EU Member States (MS) and HE Associated Countries (AC) can participate under particular conditions and without receiving funding from the PRECISEU Open call. These participants will be considered eligible if:

- They provide proven added value to the proposal by increasing the expected impact of the project in the PRECISEU regions and the EU as a whole.
- Their budget represents less than 20% of the consortium budget.
- Their participation and financial resources have been secured at the application phase by a commitment letter signed by the participant itself or by the corresponding funding organisation.
- Their financial resources are secured by a contract before the signature of the Grant Agreement.

Partners established in PRECISEU non-funding regions and in non-PRECISEU regions participate on a self-funded basis unless otherwise specified.

Only entities from PRECISEU funding regions can lead a consortium and receive funding from PRECISEU.

The participation of PRECISEU partners in the projects funded under this call is possible. However, in their participation, they will be excluded from receiving funds to execute the project from the PRECISEU Open Call funding.

[4] A 'legal entity' means any natural or legal person created and recognised as such under national, EU or international law.
[5] Detailed information on how to register and obtain a PIC number can be found in the Guide for applicants, available at the PRECISEU webpage.

3.8. TIMELINE

PRECISEU Open Call for proposals will remain open for two months (13/04/2026–14/06/2026), allowing participants to work with their consortia and submit applications for funding (following Horizon Europe Innovation Action (IA) scheme). After a standard evaluation (see Section 6), projects will be selected or rejected for funding, depending on their alignment with the call topic and selection criteria. Successful projects will be invited to proceed to the Grant Agreement Preparation phase, in which all contractual and administrative details will be finalised before implementation. This structured approach ensures an efficient and strategic allocation of resources, supporting only the most promising initiatives within the PRECISEU framework.

Launch of the open call	13/04/2026
Deadline	14/06/2026 at 17 h CEST
Evaluation	15/06/2026 – 31/07/2026
Announcement of results	31/07/2026
Grant Agreement preparation	01/08/2026 – 30/09/2026
GA signature date	Until 30/09/2026
Earliest project starting date	01/10/2026
Latest project end date	31/03/2029

Table 6. Timeline of the call.

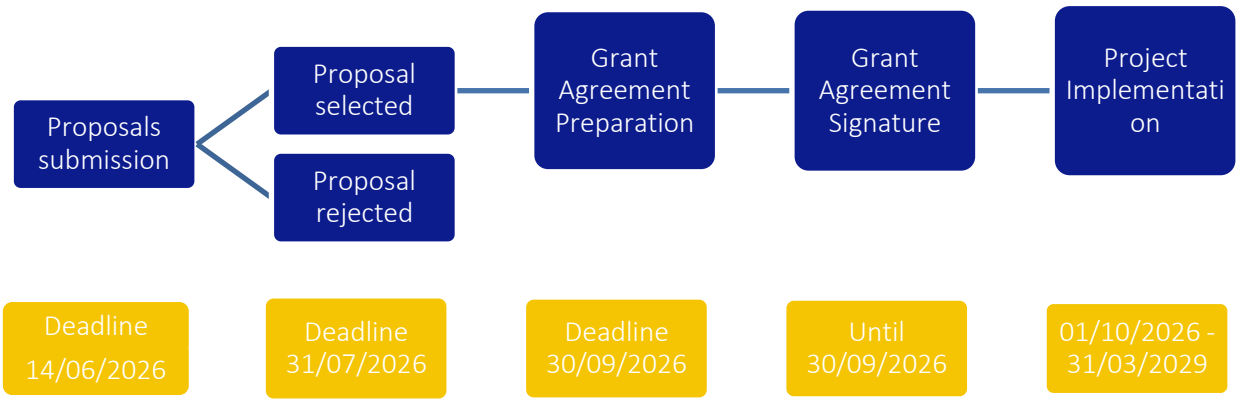

Figure 1. Timeline of the call.

4. APPLICATION AND ADMISSIBILITY

4.1. ADMISSIBILITY REQUIEREMENTS

The application process consists of a single stage. Applications can only be accepted if they are submitted with the templates provided, written exclusively in English, and through the online application form

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available on the PRECISEU website[6]. Applicants from some regions may be required to submit an additional regional/national proposal or other information directly to their relevant regional/national funding organisations[7]. For queries on that regard, applicants might get in touch with the respective Funding Agency contact persons (see 0). For general information, they may contact the Call Secretariat.

Applications will be composed of the following forms:

- Part A – Identification of project and consortium partners
- Part B – Description of the Action (DoA)
- Part C – Budget
- Declaration of Honour

The limit for Part B will be 30 pages. Pages exceeding this maximum will not be considered for the evaluation. All documents must be uploaded in PDF format.

PRECISEU Open Call for proposals will remain open for two months (13/04/2026–14/06/2026).

4.2. ELIGIBILITY CONDITIONS

Proposals will enter the evaluation phase only if all the following conditions are met:

- Each consortium must include at least three independent legal entities established in three different Funding Agency regions. At least two of those entities must be established in two different EU Member States. Each of those three entities must be eligible for, and request, funding from the respective participating Funding Agency.
- Each consortium must include, at least, one (1) SME from a PRECISEU region (see Section 3.6).
- A consortium may include a maximum of one (1) partner established in a PRECISEU non-funding region and/or one (1) partner established in a non-PRECISEU region (EU Member State or Horizon Europe Associated Country), subject to the conditions set out in Section 3.7. At least two (2) of them must be in two (2) different Member States.
- Entities can participate in more than one proposal provided that i) the entity only performs the role as coordinator for one consortium, ii) the proposals differ from each other and iii) the teams involved are different within the applicant entity (for example, different departments/teams within a university).
- Proposals must be aligned with the scope of the call, address the expected outcomes and impacts, and cover the specified activities and topic priorities.

[6] Paper submissions will not be accepted.
[7] Consult 0 with national/regional requirements to confirm whether an additional proposal submission will be required.

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- Applications must be written exclusively in English. Submissions written in any other language will be ineligible.

- Applications must comply with the provided template forms (administrative forms, description of action, budget, Declaration of Honour), including overall size, section page limits, and character restrictions, strictly adhering to the "Guide for Applicants."

- Applications must be submitted, at least, through the corresponding online application tool in the PRECISEU website before the deadline of the Open Call. Additional application mechanisms may be necessary upon request from regional funding agencies. 0 includes the list of regional specifications. Candidates need to look up this section to identify their regions' requirements, if any.

- Applicants must be transparent in disclosing which AI tools were used and how they were utilised.

- Applicants must pass Russian sanction checks to ensure full compliance with international and EU regulations[8].

4.2.1. EXCLUSION

Applicants participating in the PRECISEU Open Call can be excluded at any time if they are subject to EU administrative sanctions (i.e. exclusion[9]) or in one of the following exclusion situations[10]:

- 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).

- They are in breach of social security or tax obligations (including if done by persons with unlimited liability for the applicant's debts).

- They are guilty of grave professional misconduct (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant).

- They are guilty of fraud, corruption, having links to a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant).

- They have shown significant deficiencies in complying with main obligations under an EU procurement contract, subgrant agreement or subgrant decision (including if done by persons

[8] This implies that applicants must verify they are not subject to EU restrictive measures adopted under Article 29 of the Treaty on European Union (TEU) and Article 215 of the Treaty on the Functioning of the European Union (TFEU), specifically including Regulation (EU) No 833/2014.
[9] Article 136 of EU Financial Regulation
[10] Articles 136 and 141 of EU Financial Regulation banning them from receiving EU grants

having powers of representation, decision making or control, beneficial owners or persons who are essential for the award/implementation of the subgrant).

- They are 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 award/implementation of the subgrant).

- They have created under a different jurisdiction an entity 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 award/implementation of the grant).

Beneficiaries will also be refused if it turns out that, during the Grant Agreement Preparation process, they misrepresented information required as a condition for participating or failed to provide that information, or 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).

4.3. SUBMISSION OF PROPOSALS

Only the participant with the role of Coordinator is responsible for completing the online administrative information and uploading an electronically signed application with all required document

After submission, the Coordinator will receive a verification email indicating the date and time of submission.

Applicants are also reminded that some regions may require an additional submission of the proposal and/or other information directly to their respective Funding Agency; where applicable, applicants must follow the regional instructions and deadlines and contact the relevant Funding Agency contact persons listed in Annex 1.

For general enquiries, applicants may contact the Call Secretariat at preciseu@biocat.cat and consult the latest information and documents on the PRECISEU website.

5. FUNDING SCHEME AND FINANCIAL RULES

The monitoring and reporting procedures described in this section apply as a general framework to the PRECISEU Open Call. Nevertheless, beneficiaries may be required to comply with additional or specific reporting, audit, expenditure verification or documentation requirements imposed by the regional Funding Agency supporting them, as detailed in Annex 1 and the relevant regional annex to the Grant Agreement.

The distribution of funds will depend on the evaluation process' outputs considering the Excellence, Impact and Quality and Efficiency of the Implementation (See Section 6). The economic resources within each region and the type of participating organisation will also be considered. In case of oversubscription

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(see Section 6.4), the Funding Agency will decide the % of funding.

When defining the budget in the application drafting, partners should consider:

- The regional particularities (maximum funding, State aid rules and percentages, type of entities that can be funded —see 0)
- Max. amount provided by the regions.
- Prefinancing terms and other regional specifications.

It is encouraged to work transparently, allocate the funds to the activities and moments that better suit particular entities according to their location, and liaise as many times as necessary with their contacts at the local Funding Agencies for support and clarification.

All payments will be made in Euros (€).

5.1. FINANCIAL SUPPORT OFFERED

- The maximum financial contribution per project is €3 000 000.
- The amount of financial support varies based on the funding rate (see Section 5.2) and is limited to a maximum of €600 000 per beneficiary.
- If an entity participating in more than one project requests, in sum, a higher amount, it will enter a negotiation process with the Call Secretariat (with the supervision of the EC Project Officer) to match this requirement. As a general rule, the maximum funding will apply at the level of the legal entity identified by a single Participant Identification Code (PIC). In exceptional cases, the funding limit may be applied to a sub-unit of that legal entity instead, but only if the applicant can demonstrate that the sub-unit has clear operational and budgetary autonomy and will not receive double funding or duplicate costs with respect to any other proposals.
- The amount of financial support provided to every Beneficiary will be calculated by applying differentiated funding rates, depending on the legal status of the participants and regarding the Funding Agencies specific requirements[11] as detailed in Section 5.2.
- When no specific national/regional conditions apply, the funding rate of participants from regions with Funding Agency will depend (as in Horizon Europe Innovation Actions) on the legal status of the participant organisation: 70% for profit-making legal entities and 100% for non-profit legal entities.
- Partners established in PRECISEU non-funding regions and in non-PRECISEU regions participate on a self-funded basis unless otherwise specified.

[11] Review 0 with national/regional requirements for further information.

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- Submission of an application does not constitute an entitlement for funding.

The total funds provided by the Funding Agencies are distributed as follows:

Region	Funding organisation	Total funds
Baden-Württemberg (Germany)	BIOPRO BADEN-WUERTTEMBERG GMBH	€ 1.600.000
Castilla La Mancha (Spain)	AGENCIA DE TRANSFORMACIÓN DIGITAL CASTILLA-LA MANCHA	€ 1.100.000
Catalonia (Spain)	DEPARTAMENT DE SALUT – GENERALITAT DE CATALUNYA	€ 3.000.000
	AGÈNCIA PER A LA COMPETITIVITAT DE L'EMPRESA	€ 600.000
Crete (Greece)	REGION OF CRETE	€ 600.000
Emilia-Romagna (Italy)	REGIONE EMILIA-ROMAGNA	€ 1.800.000
Ireland	IRELAND'S NATIONAL INSTITUTE OF BIOPROCESSING RESEARCH AND TRAINING	€ 500.000
Lazio (Italy)	LAZIO INNOVA SpA	€ 1.100.000
Lithuania	VIESOJI ISTAIGA INOVACIJU AGENTURA	€ 200.000
North East (Romania)	AGENTIA PENTRU DEZVOLTARE REGIONALA NORD-EST	€ 1.070.000

Table 7. Funds provided by each Funding Agency.

5.2. FUNDING RATES

Funding rates may differ depending on the region[12]. Unless specified otherwise in the Annex 1, participants from the regions of the Funding Agencies (see Section 2.3) will be subject to a funding rate of 100%, in case of non-profit legal entities, and a funding rate of 70%, in case of profit-making legal entities[13]. Participants from regions different from the regions of the Funding Agencies may also apply, on the understanding that they will not receive funding from the PRECISEU Open Call for the implementation of their activities.

Participant type	Region	Funding rate
Non-profit legal entities	PRECISEU region (Funding Agency): Baden-Württemberg, Castilla-La Mancha, Catalonia, Emilia-Romagna, Ireland, Lazio, Nord East Region Romania, Region of Crete	100%
	PRECISEU region (Non-funding): Flanders, Gothenburg, Madrid, Rivne, Bulgaria, The Netherlands	0%
	EU region outside PRECISEU	0%

[12] Review ANNEX 1 for specific conditions.
[13] Funding rates may differ depending on the existence of a call at regional level. Review 0 with national/regional specific conditions.

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Profit-making legal entities	PRECISEU region (Funding Agency): Baden-Württemberg, Castilla-La Mancha, Catalonia, Emilia-Romagna, Ireland, Lazio, Lithuania, Nord East Region Romania, Region of Crete	70%
	PRECISEU region (Non-funding): Flanders, Gothenburg, Madrid, Rivne, Bulgaria, The Netherlands	0%
	EU region outside PRECISEU	0%

Table 8. Funding rates depending on the type of participant.

5.3. ELIGIBLE COSTS

Unless specified otherwise in the Annex 1, eligible costs are[14]:

- Direct staff costs: costs hours of the staff of the beneficiaries dedicated to actual work under the project.
- External expertise (subcontracting costs): work carried out by an external provider which has entered into an agreement on business conditions with the beneficiary. Subcontracting costs should cover only additional or complementary tasks performed by third parties. Core project tasks should not be subcontracted. Subcontracting to other partners participating in the same project is not permitted. Subcontracting costs may not exceed 20% of the total eligible costs of the project.
- Other direct costs: further direct incurred costs can be claimed for travel, consumables, equipment (only depreciation costs), etc. These costs must be incurred in connection with the action and necessary for and during its implementation. Proposals should include a budget for networking, attendance at meetings, and potential joint activities.
- Indirect costs (25% of eligible direct costs, excluding subcontracting, as in Horizon Europe[15]).

5.4. INELIGIBLE COSTS AND DOUBLE FUNDING

Double funding is strictly prohibited. The same cost item, activity, deliverable, output or result may not be financed twice from Union, national, regional or other public sources.

Irrespective of any potential audits, beneficiaries must comply with the applicable Horizon Europe rules on cost eligibility. Therefore, the following rules and limitations per project must be respected when declaring costs:

- Only costs during the lifetime of the project can be eligible. Expenses incurred before the entry into force of the Grant Agreement or after the project end date are not eligible for funding.
- Costs described in the submitted budget must be determined in accordance with the usual

[14] Review 0 with national/regional requirements for specific eligibility conditions.
[15] Horizon Europe Work programme 2025 – General Annexes

accounting and management principles and practices of the applicants.

- Costs incurred for the implementation of the project must be used for the sole and close purpose of achieving the objectives of the project and its expected results, in a transparent manner consistent with the principles of economy, efficiency and effectiveness.

5.5. FORM OF PAYMENT AND PAYMENT TERMS

Unless specified otherwise in the Annex 1, participants, successful proposals shall receive the requested financial contribution in the form of a lump sum[16]. A lump sum is a fixed amount of money which can be used by beneficiaries for several purposes related to the achievement of the project objectives.

4.3As a general rule, PRECISEU financial support is awarded as a lump sum and is monitored primarily against technical implementation and achievement of results. However, where required by a participating Funding Agency under Annex 1 and/or the regional annex to the Grant Agreement, beneficiaries may also be subject to additional regional financial control, audit, expenditure verification, or cost-reporting obligations. In such cases, those regional requirements apply only to the beneficiaries funded by the respective Funding Agency and do not alter the lump-sum nature of the PRECISEU grant at call level.

Payment modalities (including pre-financing, interim payments, reimbursement schedules and timelines for final payment) are defined by each participating Funding Agency and may vary by region. The applicable payment schedule and conditions for each beneficiary are those set out in **Annex 1 (Regional Specificities)** and, where applicable, in the corresponding regional annex to the Grant Agreement. Applicants must therefore consult Annex 1 carefully and comply with the relevant regional requirements.

If not stated differently in 0, which contains the national/regional specific requirements, for all projects receiving financial support there will be a pre-financing of 50% of the granted contribution within the established term of each funding agency, within a maximum of 30 days from the signature of the grant agreement[17]. The final payment (payment of the balance) will be made within 60 days from the completion of the assessment of the final progress performance report. In any case, the total amount paid will not exceed the total granted contribution per project according to the Grant Agreement in force. Each beneficiary will receive funding from the Funding Agency of its respective region.

Important note on lump sum and regional controls: The PRECISEU call uses a lump-sum funding model at call level. Nevertheless, some regional Funding Agencies may impose additional financial verification, audit, or expenditure-reporting requirements under their applicable regional legal framework. Applicants must therefore consult Annex 1 carefully. In case of conflict, the regional annex applies to the beneficiary funded by that Funding Agency.

5.6. BENEFICIARIES' OBLIGATIONS

Beneficiaries' obligations are as following[18]:

[16] Review 0 with national/regional requirements for specific forms of financial contribution.
[17] Review 0 with national/regional requirements for specific payment deadlines.
[18] Review 0 with national/regional requirements for additional obligations.

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- Beneficiaries must, for a period of five-years after the payment of the balance, keep records and other supporting documentation to prove the proper implementation of the action.

- The records and supporting documents must be made available upon request or in the context of checks, reviews, audits, or investigations.

- If there are on-going checks, reviews, audits, investigations, litigation, or other pursuits of claims under the consortium agreement, the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

- The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. Non-original documents may be accepted if they offer a comparable level of assurance.

- Beneficiaries must ensure that the European Innovation Council and SMEs Executive Agency (EISMEA), the European Commission, the European Anti-fraud Office (OLAF), the European Public Prosecutor's Office (EPPO) and the Court of Auditors (ECA) can exercise their powers of control, on documents, information, even stored on electronic media, or on the final recipient's premises as detailed in the Grant Agreement.

Further provisions on controls, verification mechanisms and supporting-document requirements applicable to beneficiaries under this Open Call are set out in Section 7.5 and, where applicable, in Annex 1 and the relevant regional annex.

5.7. ERDF COFUND

Some participating regions may support beneficiaries under this Open Call through funding subject to ERDF or other regional legal frameworks. In such cases, the applicable regional rules shall govern the corresponding beneficiaries, including rules on eligibility, payment, controls, reporting, audit, State aid, and avoidance of double funding. Applicants must consult Annex 1 carefully for the conditions applicable in each region.

Regional agencies that would select cascade-funding projects and act as bodies implementing ERDF funds (co-funded by Horizon Europe), must be designated as intermediate implementing bodies by ERDF programme Managing Authorities. The legal implementation mechanism is "cumulative funding" between EU direct and shared management programmes, which is possible for the same expenditure, provided specific arrangements are made to ensure prohibition of double declaration of expenditure[19], and reimbursement of not more than 100% of the eligible costs[20]. Practical steps for the implementation of "cumulative funding" are explained in the Commission Notice on Synergies between Horizon Europe and ERDF programmes.[21]

[19] Article 63(9) Common Provisions Regulation
[20] Article 191(3) Financial Regulation
[21] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52022XC1104(02)

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5.8. STATE AID

Financial support awarded under this Open Call must comply with the applicable State aid rules.

Where a beneficiary carries out an economic activity within the meaning of Article 107(1) TFEU, the relevant Funding Agency will determine the applicable legal basis for the support in accordance with the relevant EU, national and regional framework. This may include, where appropriate, Commission Regulation (EU) No 651/2014 (General Block Exemption Regulation, "GBER") or Commission Regulation (EU) 2023/2831 on de minimis aid. Aid may be granted without prior notification to the European Commission only where all the conditions of the relevant legal basis are fulfilled.

Under the de minimis regime, the total amount of de minimis aid granted per single entity must not exceed EUR 300 000 over any period of 3 years. Beneficiaries supported under that regime may therefore be required to declare other de minimis aid received.

For support granted under Article 25 GBER for research and development projects, the aid intensity for experimental development shall be determined on the basis of the beneficiary type and the applicable conditions. For the purposes of this Open Call, and assuming compliance with Article 25(6)(a) and Article 25(6)(d) GBER[22], the maximum aid intensities for experimental development shall be as follows:

Type of undertaking	Maximum aid intensity
Large enterprise	50%
Medium-sized enterprise	60%
Small enterprise	70%

Table 9. Maximum aid intensities for experimental development

Applicants must consult Annex 1 carefully, since the applicable aid regime, aid intensity, co-financing requirement, eligible-cost methodology, and supporting-document obligations may differ by region and by beneficiary type. The final funding conditions applicable to each beneficiary shall be those confirmed by the competent Funding Agency under the applicable legal framework.

Aid intensity for non-for-profit entities

100% funding applies to research and knowledge dissemination organisations that do not engage in economic activity, provided a separate accounting system is maintained for such activities. Eligible organisations include:

- Research institutes and centres, universities, and technology centres
- Clusters and innovation agencies
- Local authorities, public administrations, and public associations (including public companies)

[22] Projects selected through an open call, jointly designed by at least 3 Member States/EEA parties, with effective cross-border collaboration and wide dissemination or FRAND-like licensing under the terms of the applicable scheme.

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- Civil society actors (associations, NGOs, etc.)

6. EVALUATION AND SELECTION PROCESS

After the deadline of the call, a formal requirement check (admissibility and eligibility) of the submitted applications will be performed by the PRECISEU Call Secretariat. The selection of eligible proposals will be agreed in a single plenary meeting of the Call Secretariat.

Eligible proposals will undergo an independent evaluation carried out by an Expert Panel. The Expert Panel will be composed of relevant stakeholders of the Quadruple Helix (academia, government, industry and society) independent from and not affiliated with the PRECISEU consortium. All experts shall be appointed based on competence and impartiality and will be subject to Conflict of Interest (COI) checks and confidentiality obligations.

6.1. EVALUATION PROCESS

This evaluation will consist of a two-step process, aimed to ensure transparency and equal treatment:

- **Step 1:** Individual Evaluation. Each proposal shall be evaluated independently by a minimum of three experts, in accordance with the evaluation criteria set out in the call. A preliminary ranking will be set with the average score of the individual evaluators.

- **Step 2:** Consensus Evaluation. The Expert Panel will rank the proposals based on the call evaluation criteria and a list of full proposals recommended for funding will be submitted to the Call Secretariat.

The assessment period will last two months from the deadline of the Open Call for Proposals.

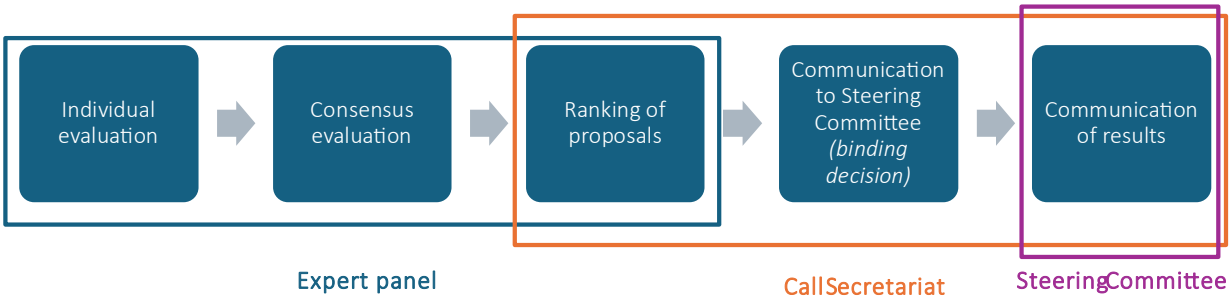

Figure 2. Evaluation process

6.2. EVALUATION CRITERIA

Proposals will be evaluated and ranked against the following award criteria:

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Relevance	• Clarity and pertinence of the project's objectives, and the extent to which the proposed work addresses the scope, priorities and expected outcomes of the Open Call. • Extent to which the proposed work is ambitious, responds to clearly identified needs, and goes beyond the state of the art.
Quality	• Soundness and feasibility of the proposed methodology, including the underlying concepts, models, assumptions, interdisciplinary approaches, and, where relevant, appropriate consideration of the gender dimension and open science practices. • Quality and efficiency of the implementation, including the work plan, allocation of resources, risk assessment, and the capacity and complementarity of the consortium.
Impact	• Credibility of the pathways to achieve the expected outcomes and impacts specified in Section 3.3, and the likely scale and significance of the project's contributions. • Suitability and quality of the measures to maximise expected outcomes and impacts, including dissemination, exploitation and communication activities.

Table 10. Evaluation criteria.

6.3. SCORING MECHANISM

The scores for each criterion will range from 0-5 with a minimum threshold of 3 (half marks may be given) and the overall minimum threshold for all three criteria is 10, as in Horizon Europe Innovation Actions.

In the event that two or more proposals obtain the same final score, proposals will be ranked according to their score under the Impact criterion, followed by Relevance. If a tie still remains, additional considerations aligned with the objectives of the call may be applied by the evaluation panel to determine the final ranking.

6.4. OVERSUBSCRIPTION

The financial contribution to the Open Call varies across participating regions. Consequently, the number of entities to be funded in each region depends on the budget allocated by the respective Funding Agency and is subject to its final funding decision.

Following the evaluation, proposals will be ranked based on their evaluation scores. Funding decisions will be taken by the relevant Funding Agencies, taking into account the ranking list and the available regional budgets. While Funding Agencies will generally follow the ranking order, final decisions remain subject to budgetary constraints.

In the event of oversubscription or funding limitations, additional criteria may be applied to optimise the

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allocation of funds, including the maximisation of the number of high-quality proposals funded, the efficient use of regional budgets, and the promotion of participation from underrepresented or undersubscribed regions. Where necessary, a priority order may be established between proposals with identical scores.

Where a proposal cannot be funded due to insufficient budget in one or more regions, possible solutions may be explored in agreement with the relevant Funding Agencies and the consortium. If such solutions cannot be identified, the selection process may continue down the ranking list.

As a result, the final funding awarded may differ from the amount initially requested and may require adjustments to the consortium composition or budget.

6.5. CONFLICT OF INTEREST

All members of the Expert Panel will be required to sign a Non-Disclosure Agreement before receiving any communications or materials.

All potential conflicts of interest will be carefully assessed in accordance with the European Commission's approach to managing conflict of interest risks and the applicable governing rules[23].

6.6. EVALUATION RESULTS, NOTIFICATION AND REVIEW PROCEDURE

Coordinators will receive by e-mail a letter with the evaluation result immediately after the assessment is finalised, along with indications for next steps in case the proposal is successful. Based on the ranking and considering the available funding, the Call Secretariat will propose a funding recommendation to the PRECISEU Steering Committee, which will be binding.

The Call Secretariat will communicate the results to the applicants. A formal Evaluation Review Procedure is available for coordinators who believe that a procedural error has occurred in the evaluation of their proposal (see Section 6.7). Instructions and deadlines will also be recalled in the Evaluation Result Letter.

The Evaluation Review Procedure allows coordinators to request a review of the way their proposal was evaluated, if they consider that a procedural error occurred.

6.7. ENQUIRIES AND COMPLAINTS

When applicants don't agree with the evaluation results, they may request a review of the way their proposal was evaluated, if they consider that a procedural error occurred. The Evaluation Review Procedure does not allow for a re-evaluation of the scientific/technical content of the proposal simply because the applicants disagree with the scores or comments received.

Who may appeal

- Only the Coordinator of a proposal may submit a request for review.

[23] Please see guidelines on avoiding and managing conflicts of interest for effective governance and sound financial management.

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- The procedure applies to proposals that have received an Evaluation Result Letter (ERL).

Grounds for appeal

A request for review must be based on one or more of the following grounds:

- A breach of the published evaluation rules (e.g. wrong eligibility or admissibility criterion applied, wrong funding region applied).
- A failure to follow the published evaluation procedure (e.g. number or type of evaluators not in line with rules, obvious inconsistency with the evaluation criteria described in the call).
- A clear procedural irregularity (e.g. proposal assessed under the wrong topic, wrong version of the proposal used, evident conflict of interest not managed according to the rules).

Requests based solely on disagreement with the experts' opinions, scores or funding decision (without a procedural error) will be rejected.

How to submit an appeal

- The coordinator may submit a written request for review by email to: preciseu@biocat.cat
- The request must:
    - Clearly identify the proposal ID and acronym;
    - State which procedural error(s) are alleged;
    - Refer to the relevant part(s) of the call text or evaluation rules;
    - Explain why the alleged error could have affected the evaluation outcome.

Deadlines and resolution timeframe

- The request must be submitted within 7 calendar days from the date of the Evaluation Result Letter. Late requests will not be considered.
- The PRECISEU coordination team will acknowledge receipt within 5 working days.
- A dedicated Review Committee (composed of coordination and regional representatives not involved in the original evaluation) will examine the request.
- A written answer will normally be provided within 20 calendar days from the acknowledgement of receipt. If, exceptionally, more time is needed, applicants will be informed of the extended deadline.

Process and possible outcomes

The Review Committee will:

1. Verify whether the evaluation was carried out in line with the published rules and the information provided in the call documents.

2. Decide one of the following outcomes:

    - No procedural error identified: the original evaluation and funding decision stand.

    - Procedural error identified but not affecting outcome: the error is recorded and, where relevant, internal procedures are adjusted; the original scores and ranking stand.

    - Procedural error identified that may have affected the outcome: the proposal may be subject to a partial or full re-evaluation by one or more new, independent experts. In such case:

        - The new evaluation will fully replace the previous one;

        - The scores and ranking of the proposal may go up, down or remain unchanged;

        - The overall funded list may be adjusted within the available budget envelope.

Decisions taken at the end of the Evaluation Review Procedure are final and will be communicated in writing to the coordinator.

7. SUB-GRANT AGREEMENT, IMPLEMENTATION, MONITORING AND REPORTING

7.1. SUB-GRANT AGREEMENT PREPARATION AND SIGNATURE

After receiving positive feedback, a sub-Grant Agreement preparation phase will be initiated to formalise the contractual obligations between the Call Secretariat and the selected Beneficiaries. Successful proposals will be requested to sign a sub-Grant Agreement between the PRECISEU Coordinator (on behalf of the PRECISEU consortium) and the Coordinator of the JIP. All participants in the JIP must adhere to this sub-Grant Agreement. In the event of non-compliance with specific requirements, Beneficiaries may be requested to introduce modifications (where possible) prior to the signature of the sub-Grant Agreement. In addition, a Consortium Agreement will be signed between the project coordinator and all beneficiaries.

The final awarded funding may differ from the requested funding, depending on the available funding of each Funding Agency. During the sub-Grant Agreement preparation phase, consortia may be offered the possibility to include additional partners from regions whose Funding Agency has not yet exhausted its available funding. New partners may be accepted provided that the project has not reached its maximum

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funding amount (€3.000.000).

7.2. REGIONAL ANNEXES AND FUNDING AGENCY-SPECIFIC CONDITIONS

When necessary, the sub-Grant Agreement will include specific annexes reflecting the funding conditions and regional specificities (Annex 1) applicable to each Funding Agency contributing to the project. These annexes, signed directly between the relevant Funding Agency and the beneficiary established in its region, set out the respective regional rules, obligations, and payment modalities, which are addressed bilaterally between each project partner and its funder.

7.3. PROJECT IMPLEMENTATION OBLIGATIONS

Consortia will have to set up internal consortium agreements regulating their cooperation.

PRECISEU will not be responsible for paying any costs applied for and incurred by beneficiaries in case of non-compliance with the terms and conditions of the PRECISEU's Open call.

7.4. MONITORING AND REPORTING PROCESS

The monitoring and reporting procedures described in this section apply as a general framework to the PRECISEU Open Call. Nevertheless, beneficiaries may be required to comply with additional or specific reporting, audit, expenditure verification or documentation requirements imposed by the regional Funding Agency supporting them, as detailed in Annex 1 and the relevant regional annex to the sub-Grant Agreement.

One mid-term interim report will be requested at month 18 to provide an overall performance report of the project, along with the respective deliverables validating the work (including a business and investment plan, list of remaining bottle necks, and materials for official communication). Consortia shall also provide a final technical report within 30 days after the end of the project.

The purpose of the reports is to evaluate:

- The degree of fulfilment of the project work plan for the relevant period and of the related deliverable(s).
- The continued relevance of the objectives and breakthrough potential with respect to the scientific and industrial state of the art.
- The expected potential impact in economic, competition and social terms, and the beneficiaries' cooperation to elaborate a dissemination of foreground plan.

Monitoring and reporting obligations may be complemented by additional verification or control requirements, as further described in Section 7.5 and, where applicable, in Annex 1 and the relevant regional annex.

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7.5. AUDITS, CHECKS AND CONTROLS

Beneficiaries must ensure that the European Innovation Council and SMEs Executive Agency (EISMEA), the European Commission, the European Anti-Fraud Office (OLAF), the European Public Prosecutor's Office (EPPO) and the European Court of Auditors (ECA) are able to exercise their powers of control, including checks, reviews, audits and investigations, on the basis of documents, information and data, including when stored in electronic format, and, where necessary, through access to the premises of the final recipients, as provided for in the Grant Agreement.

Recipients of funding under this Open Call must comply with the monitoring, reporting, verification and supporting-document obligations set out in this Call and, where applicable, in Annex 1, the relevant regional annex and the sub-grant agreement. As a general rule, PRECISEU support is awarded as a lump sum and will be monitored primarily through technical reporting and proportionate verification of the proper implementation of the funded action.

There is no automatic obligation for recipients of funding under this Open Call to submit a Certificate on the Financial Statements (CFS) solely because the amount of financial support awarded reaches or exceeds EUR 430 000. The CFS threshold established under the Horizon Europe Grant Agreement applies to the beneficiaries of the EU grant when declaring costs under that Grant Agreement and does not automatically apply to recipients of Financial Support to Third Parties (FSTP) under this Open Call.

Nevertheless, some participating Funding Agencies may require additional expenditure reporting, financial statements, audit certificates, or equivalent supporting documentation for the purposes of regional control, ERDF, State aid, or national compliance, as specified in Annex 1, the Regional Call, or the annex to the grant agreement. Recipients of funding under this Open Call must keep all records and supporting documentation necessary to demonstrate the proper use of funds, the achievement of milestones, deliverables or results, and compliance with the applicable eligibility and contractual requirements. Non-compliance with these obligations may result in suspension, reduction, recovery or other corrective measures in accordance with the applicable contractual provisions.

7.6. AMENDMENTS, SUSPENSION AND TERMINATION

Amendments to the sub-Grant Agreement, as well as any suspension or termination of the grant, will be governed by the provisions set out in the sub-Grant Agreement and, where applicable, by the specific conditions established by the relevant Funding Agencies in the regional annexes. Any request for changes affecting the scope of work, the consortium composition, the budget allocation, the implementation timeline, or any other material aspect of the project must be duly justified and submitted in writing through the channels indicated by the Call Secretariat, within the deadlines defined in the Grant Agreement. The grant may be suspended or terminated in cases such as non-compliance with contractual obligations, breach of eligibility or funding conditions, serious procedural or ethical breaches (including conflicts of interest), insolvency, or other circumstances that prevent proper implementation. In the event of suspension or termination, beneficiaries may be required to cease relevant activities, submit the necessary reports and supporting documentation, and reimburse unduly paid amounts in accordance with the Grant Agreement and applicable Funding Agency rules.

8. CALL GOVERNANCE AND SUPPORT

8.1. CALL SECRETARIAT

The Call Secretariat will be coordinated by Biocat (PRECISEU Project Coordinator) and composed by the regional Funding Agencies ACCIÓ (Catalonia), Salut (Catalonia), BIOPRO (Baden-Württemberg), AGENCIA DE TRANSFORMACIÓN DIGITAL (Castilla-La Mancha), RER (Emilia Romagna), Perifereia (Crete), NATIONAL INSTITUTE OF BIOPROCESSING RESEARCH AND TRAINING (Ireland), INNOVA SpA (Lazio), VIESOJI ISTAIGA INOVACIJU AGENTURA (Lithuania) and AGENTIA PENTRU DEZVOLTARE REGIONALA NORD-EST (Nord-East Romania).

The tasks of the Call Secretariat will be:

- Facilitating information to the PRECISEU Consortium for the announcement of the Open call launch, evaluation results and dissemination about interregional project progress.
- Managing access and submission rights to the electronic proposal submission system (PRECISEU Open Call Platform).
- Acting as main contact for queries related to the Call, the Expression of Interest and Funnelling Process and of the full proposal submissions to the Open Call, providing technical support to evaluators and applicants.
- Curating the Open Call Platform (in PRECISEU website) sections dedicated to information, submission, and reporting.
- Procurement of an external evaluation company to manage the Independent Expert Panel for proposal evaluation, including the selection of the pool of experts and the allocation of proposals.
- Providing administration procedures regarding members of the Expert Panel, guidelines for applicants, GDPR, and GEDI (Gender, Equity, Diversity, and Inclusion) considerations.
- Informing of the funding recommendation from the Expert Panel to the PRECISEU Steering Committee.
- Monitoring management of funds and funding transfers to the beneficiaries of the JIP).
- Acting as Help Desk, Regional Contact Points and Support teams on administrative, IT, Project Grant Agreement and reporting subjects.
- Connecting to EISMEA and European Institutions for correct and smooth management of JIPs.

8.2. COMMUNICATION CHANNELS AND HELPDESK

Applicants who have questions regarding the scope of the call, eligibility conditions or proposal preparation are encouraged to contact the PRECISEU Coordination Team via preciseu@biocat.cat. Questions related to

regional funding conditions should be addressed to the corresponding regional Funding Agency, as indicated in the relevant regional annex. Where appropriate, the Coordination Team may redirect enquiries to the competent regional authority to ensure consistent and accurate guidance.

9. CROSS-CUTTING REQUIREMENTS FOR PROPOSAL PREPARATION AND IMPLEMENTATION

9.1. INTEGRATION OF GENDER DIMENSION

As the integration of the gender dimension is a requirement under Horizon Europe, it will also be a requirement set in this FSTP call. Applicants are strongly encouraged to integrate sex and gender considerations, as well as underrepresented populations or underrepresented patient sub-groups. Applicants are invited to take all measures to promote equal opportunities between men and women in the implementation of the action, also when referring to validation methodologies and testing. Applicants must aim for better gender balance at all levels of the personnel assigned to the action, including supervisory and managerial levels to the full extent possible.

In the proposal template, applicants are invited to describe how the gender dimension is considered in the project's content and implementation.

If applicants do not consider such a gender dimension to be relevant in their specific project, they should provide a sound justification, which will be considered during evaluation of the proposal.

9.2. ETHICAL DIMENSION

For all activities funded by the EU, the ethical dimension is an integral part, and ethical compliance is seen as pivotal to achieve real excellence. It implies the application of fundamental ethical principles and legislation in all possible domains. The process to assess and address the ethical dimension of activities funded under Horizon Europe is called the Ethics Appraisal Procedure, and the submission forms will include a section covering this aspect, to be filled by applicants. Only ethically cleared proposals will be funded, after an Ethical Committee Screening.

Applicants must describe any potential ethical aspects of the work to be carried out, and how the project will fulfil applicable requirements in institutional, regional, national and European Union legislation.

Activities must not:

- aim at human cloning for reproductive purposes.
- intend to modify the genetic heritage of human beings which could make such changes heritable

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(except for research relating to cancer treatment of the gonads, which may be financed).

- 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.

- lead to the destruction of human embryos.

9.3. SECURITY

Activities carried out under this program must comply with the applicable security rules and in particular, rules on the protection of classified information against unauthorised disclosure, including compliance with any relevant EU and national law. The process to assess and address the security dimension of activities funded this call will follow Horizon Europe Security Appraisal Procedure.

9.4. INVOLVEMENT OF POTENTIAL END-USERS

PRECISEU also strongly encourages the active involvement of end-users in the projects (patient organisations, citizens, healthcare providers, and health and social care service users). The goal is to improve the success of the solutions to be developed within the projects and to raise awareness, share knowledge and improve dialogue between researchers, healthcare providers, policymakers, industry, citizens, and experts in ethics and legal field.

It will be recommended to seek the commitment of end users from early on in the project's implementation, as they may help guide the work towards specific applications of the project's results. End-users could come from the regional, national and international networks of consortium partners, or from the value chains they operate in. They could be involved as partners or as members of an advisory board or user group.

9.5. DISSEMINATION, COMMUNICATION AND EXPLOITATION

On this regard, it is relevant to recall the difference between dissemination/communication and exploitation activities:

- Dissemination/Communication: public disclosure of the results by appropriate means.

- Exploitation: use of results in further research and innovation activities other than those covered by the action concerned.

Unless otherwise agreed with the Funding Agency, beneficiaries must promote the project and its results by providing targeted information to multiple audiences (including the media and the public) in a strategic, coherent, and effective manner. Before engaging in a communication or dissemination activity expected to have a major media impact, beneficiaries must inform the Funding Agency.

Any communication or dissemination activity related to the action must use factually accurate information.

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Visibility

Unless otherwise agreed with the Funding Agency, communication activities of the beneficiaries related to the action (including media relations, conferences, seminars, information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via traditional or social media, etc.), dissemination activities and any infrastructure, equipment, vehicles, supplies or major result funded by the grant must acknowledge the support received from the Funding Agency, the PRECISEU project and the EU by displaying the Funding Agency and PRECISEU project logo and the European flag (emblem) and funding statement (translated into local languages, where appropriate).

The logos and the EU emblem must remain distinct and separate and cannot be modified by adding other visual marks, brands, or text. When displayed in association with other logos (e.g. of beneficiaries or sponsors), they must be displayed at least as prominently and visibly as the other logos.

Beneficiaries may use the emblem without first obtaining approval from the granting 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.

Use of disclaimer

Any communication or dissemination activity related to the action must use factually accurate information. Moreover, it must indicate the following disclaimer (translated into local languages where appropriate):

“Funded by the European Union and [name of the Funding Agency]. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or [name of the Funding Agency]. Neither the European Union nor the Funding Agency can be held responsible for them”.

9.6. OPEN SCIENCE AND OPEN ACCESS

Applicants must clearly describe all the methodological approach with the description of all the tools, technologies, digital supports, etc., employed in the project. In addition, descriptions should be included of how data from different sources (such as different institutions) will be combined, how different data streams will be merged and how the primary outcomes will be meaningful across different institutions. PRECISEU expects projects to develop data management plans (DMPs) early in the project (within the first 6 months) according to international state-of-the-art standards for data security.

Proposals should explain how the data, tools, code, or algorithms gathered, developed or used throughout the project will be maintained after the project end and will be available (findable, accessible, interoperable and re-usable) or communicated to the wider research community, during and after the end of the project period.

Open science practices are addressed and evaluated under ‘relevance’ as they are considered a part of the methodology. However, open access in particular also results in the broad dissemination of knowledge and is relevant in the context of dissemination.

Open access to generated research data is required under the premise ‘as open as possible as closed as

necessary', meaning that there can be exceptions to this. Data management plans are mandatory for all projects generating or reusing data. DMPs should address requirements related to making the data FAIR.

9.7. INTELLECTUAL PROPERTY MANAGEMENT

Applicants, in particular economic operators, should ensure that their IP, dissemination and exploitation strategy is consistent with the applicable State aid framework set out in Section 5.8.

Applicants must describe their strategy for the management of intellectual property (IP), including any planned protection measures (where relevant) and how these will support the exploitation of results (to be reflected in the Impact section of the proposal). In particular, for projects aiming at economic and/or societal exploitation, the IP management strategy must be proportionate to the expected outcomes and impacts.

Selected consortia must put in place a consortium agreement before grant signature, covering at least background, access rights, ownership of results, protection, exploitation, dissemination, confidentiality and dispute resolution. All participants in selected projects must comply with the Intellectual Property Rights (IPR) provisions set out in Article 16 of the Horizon Europe Model Grant Agreement.

Beneficiaries may also make use of the European IP Helpdesk, a free first-line support service of the European Commission that assists SMEs and EU-funded research teams in managing, protecting and exploiting IP in cross-border collaboration and EU research and innovation projects.

Background and access rights to background

Applicants should identify, at proposal stage, any critical background IP, data or know-how needed for implementation and exploitation, and disclose any known restrictions, encumbrances or third-party rights that may affect access or freedom to operate.

'Background' means any data, know-how or information —whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights— that is:

- held by the participants before they acceded to the Agreement and
- needed to implement the action or exploit the results.

If background is subject to rights of a third party, the party concerned must ensure that it is able to comply with its obligations under the project Grant Agreement.

Ownership of results

Funding Agencies do not obtain ownership of the results produced under the action. Results are owned by the beneficiaries that generate them (unless specified otherwise in a consortium agreement).

'Results' means any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.

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Rights of use of the granting authority on materials, documents and information received for policy, information, communication, dissemination, and publicity purposes.

Funding Agencies have the right to use non-sensitive information relating to the action and materials and documents received from the beneficiaries (notably summaries for publication, deliverables, as well as any other material, such as pictures or audio-visual material, in paper or electronic form) for policy, information, communication, dissemination and publicity purposes —during the action or afterwards. These rights do not affect ownership of results, patentability, trade secrets or confidential know-how.

For the avoidance of doubt, these rights of use apply only to non-sensitive and non-confidential materials submitted for reporting, communication or dissemination purposes, and do not affect ownership of results, confidential information, trade secrets, or patentability of foreground.

The right to use the beneficiaries' materials, documents and information is granted in the form of a royalty-free, non-exclusive, and irrevocable licence, which includes the following rights:

- use for its own purposes (in particular, making them available to persons working for the granting authority or any other EU service (including institutions, bodies, offices, agencies, etc.) or EU MS institution or body; copying or reproducing them in whole or in part, in unlimited numbers; and communication through press information services)

- distribution to the public (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes)

- editing or redrafting (including shortening, summarising, inserting other elements (e.g. meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation)

- translation

- storage in paper, electronic or other form

- archiving, in line with applicable document-management rules

- the right to authorise third parties to act on its behalf or sub-license to third parties the modes of use set out in Points (b), (c), (d) and (f), if needed for the information, communication, and publicity activity of the granting authority

- processing, analysing, aggregating the materials, documents and information received and producing derivative works.

- The rights of use are granted for the whole duration of the industrial or intellectual property rights concerned.

If materials or documents are subject to moral rights or third party rights (including intellectual property

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rights or rights of natural persons on their image and voice), the beneficiaries must ensure that they comply with their obligations under this Agreement (in particular, by obtaining the necessary licences and authorisations from the rights holders concerned).

9.8. DO NO SIGNIFICANT HARM (DNSH) PRINCIPLE [24]

The projects must comply with the DNSH to:

- climate change mitigation
- climate change adaptation
- the sustainable use and protection of water and marine resources
- the circular economy, including waste prevention and recycling
- to pollution prevention and control
- to the protection and restoration of biodiversity and ecosystems.

9.9. RESPONSIBLE RESEARCH AND INNOVATION

Proposals should adhere to the principles of Responsible Research and Innovation (RRI). Consortia are expected to:

- Demonstrate how they will identify and address relevant social, ethical, legal, political, environmental and/or cultural dimensions of the proposed innovation.
- Involve relevant stakeholders (e.g. patients, healthcare professionals, citizens, policy-makers, industry) in a meaningful way throughout the project lifecycle, where appropriate.
- Consider aspects such as equality, diversity and inclusion, data protection and privacy, transparency, accessibility, and sustainability in the design, implementation and deployment of their solutions.

Applicants should briefly describe their RRI approach in the proposal (e.g. within the impact section), explaining how these considerations will be integrated into project activities and governance.

9.10. COLLABORATION AND NETWORKS

All projects funded under this call are encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Therefore, proposals are expected to include a budget for the attendance at

[24] https://finance.ec.europa.eu/news/commission-provides-further-clarifications-eu-taxonomy-sustainable-economic-activities-2024-11-29_en. Please note that in 2025 the DNSH principle will no longer be considered for R&I activities (only applies to economic activities).

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regular joint meetings and may consider covering the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the first month of the project and they will be compiled in a Dissemination plan which will have to be provided as a Deliverable.

10. CONFIDENTIALITY AND DATA PROTECTION

The General Data Protection Regulation (2016/679/EU) guarantees that the processing of data is carried out in compliance with the fundamental rights and freedoms, as well as the dignity of the data subject with reference to confidentiality, personal identity, and the right to data protection.

By applying to the PRECISEU Open Call, the applicant agrees on the storage and use of its personal data for the execution of the PRECISEU objectives and work plan. The PRECISEU consortium commits to handling personal data confidentially except for the Open call results, which will contain the following information:

- Information about successful PRECISEU Open Call applications that will be made publicly available before the end of the project containing: project title and budget, names of project partners and short project description (as provided by the applicant in the application template).

- Information about the successfully completed PRECISEU Innovation Projects that will be publicly available after the completion of the projects: project title, names of project partners, awarded funding and updated short project description (as provided by the project partners in the Final Report).

The processing of data that PRECISEU intends to carry out will be based on lawfulness and correctness in the full protection of its rights and its confidentiality pursuant to the general principles of the GDPR and its art. 24. Therefore, the applicants are informed of the procedure that the data provided by the applicants will be treated exclusively with reference to the procedure for which they submitted the documentation.

Applications' selection and evaluation will be performed under the appropriate ethical conduct and will respect the confidentiality of the information received.

11. DISCLAIMER

Purpose: This text is explaining the PRECISEU Open Call for information purposes only. No rights can be claimed on the basis of this document. Views and opinions expressed are those of the author(s) only and do not necessarily reflect those of the European Union or EISMEA of the European Commission. Neither the European Union nor EISMEA and the European Commission can be held responsible for them.

Mistakes or inconsistencies: The PRECISEU consortium is not responsible for any mistakes or misinterpretations that this text may cause. In the case of inconsistencies, the PRECISEU Call Secretariat will determine the steps to be taken, in cooperation with the applicant concerned.

Modification of the PRECISEU Open call: The PRECISEU consortium partners, represented by the

Coordinator, are entitled to modify this document (including re-opening/closing dates of the Open call, in case of non-granting of funds and/or early depletion of the available funds, or as they see fit) at any time without notice. The current Open call will be published on the website always mentioning the version number. The most recent version of the PRECISEU Open Call applies and prevails.

Consequential damages: In no event shall either party be liable to the other or any of its affiliates for any consequential, incidental, indirect, special, punitive, or exemplary damages (including, without limitation, lost profits, business, or goodwill) suffered or incurred by such other party or its affiliates in connection with this funding scheme, even if advised of the possibility of such damages.

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ANNEX 1. REGIONAL ANNEX

This Annex sets out the regional rules and specific conditions applicable to Funding Agencies participating in the Call. Where regional provisions differ from the general provisions of this Call, the regional provisions shall apply to the beneficiaries funded by the respective Funding Agency. Where no additional regional provisions are listed for a given region, no additional regional conditions apply beyond these Terms and Conditions and the Call documents.

BADEN-WUERTTEMBERG (GERMANY)

Region / Funding Organisation	BIOPRO Baden-Württemberg GmbH
Contact (name, email, phone)	Dr. Claudia Luther luther@bio-pro.de +49 711 21818505
Legal scheme (e.g., ERDF OP, national programme if applicable)	Regional funding
Funding available (Intention letter and commitment letter)	1.6 M Euros (50% funded by EU)
Pre-financing (rate %, trigger)	25%
Interim reporting (if any specificities)	In addition to the reporting stated in chapter 7.4, beneficiaries must provide a 12-month reporting to BIOPRO Baden-Württemberg.
Final reporting & audit (deadlines; audit window)	Reporting according to PRECISEU Audit rights for: BIOPRO Baden-Württemberg GmbH, the Baden-Württemberg Ministry of Economic Affairs, Labor and Tourism and the Court of Auditors of Baden-Württemberg (Rechnungshof Baden-Württemberg)
Payment schedule (advance / interim / final; conditions)	Advance, 2026: 25% Interim, after 12-month reporting in 2027: 25% Final, after final reporting in 2029: 50%
State-aid framework (GBER article(s) or not-aid; de minimis?)	According to PRECISEU
Funding rates (by beneficiary type & activity) — e.g., SMEs/large, non-profit.	According to PRECISEU
Max funding (if any disparities with the PRECISEU Call)	According to PRECISEU
Eligible beneficiaries (if any disparities with the PRECISEU general requirements)	According to PRECISEU
Additional eligibility requirements	According to PRECISEU

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Eligible costs (in case of disparities)	According to PRECISEU
National pre-checks / parallel submission (pre-eligibility forms, national e-portal, letters)	None
Special singularities:	Each participant from Baden-Württemberg, that receives funding from BIOPRO Baden-Württemberg will sign an additional notice of grants (Zuwendungsbescheid) with BIOPRO Baden-Württemberg GmbH.
Contacts for queries (scientific / financial / legal)	Dr. Claudia Luther luther@bio-pro.de +49 711 21818505
Other documents for consultation	Administrative Regulation (Verwaltungsvorschrift) to § 44 of the State Budget Code (Landeshaushaltsordnung) Baden-Württemberg, Section 12 f.

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CASTILLA-LA MANCHA (SPAIN)

For Castilla-La Mancha, no additional regional specificities are set out at this stage in Annex 1. The applicable regional conditions, including financial and implementation provisions where relevant, will be specified in the Grant Agreement.

Co-funded by the European Union

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CATALONIA (SPAIN)

SALUT

Region / Funding Organisation	Departament de Salut – Generalitat de Catalunya (SALUT)
Contact (name, email, phone)	Carme Pérez peris@gencat.cat Tel: (+34) 935566103
Legal scheme (e.g., ERDF OP, national programme if applicable)	N/A
Funding available (Intention letter and commitment letter)	3.000.000,00 €
Pre-financing (rate %, trigger)	Established in the Grant Agreement
Interim reporting (if any specificities)	Established in the Grant Agreement
Final reporting & audit (deadlines; audit window)	Established in the Grant Agreement
Payment schedule (advance / interim / final; conditions)	Established in the Grant Agreement
State-aid framework (GBER article(s) or not-aid; de minimis?)	N/A
Funding rates (by beneficiary type & activity) — e.g., SMEs/large, non-profit.	Established in the call
Max funding (if any disparities with the PRECISEU Call)	N/A
Eligible beneficiaries (if any disparities with the PRECISEU general requirements)	SMEs, startups/spinoffs, public and private research bodies and large companies. NGOs and patient organisations are excluded
Additional eligibility requirements	None
Eligible costs (in case of disparities)	Personnel costs Consumables Core facilities Travel Other (direct costs). It is compulsory to include the cost of a financial audit certificate up to a maximum of € 2,000 Overhead (Flat rate 21% calculated on direct costs)
National pre-checks / parallel submission (pre-eligibility forms, national e-portal, letters)	None

Special singularities:	None
Contacts for queries (scientific / financial / legal)	peris@gencat.cat
Other documents for consultation	None

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ACCIÓ

Region / Funding Organisation	AGÈNCIA PER A LA COMPETITIVITAT DE L'EMPRESA (Catalonia)
Contact (name, email, phone)	preciseu.accio@gencat.cat
Legal scheme (e.g., ERDF OP, national programme if applicable)	Applicable legal provisions in Catalonia concerning subsidies
Funding available (Intention letter and commitment letter)	€600.000
Pre-financing (rate %, trigger)	Initial prefinancing, 50 % (30 days from entry into force of Grant Agreement).
Interim reporting (if any specificities)	One mid-term interim report.
Final reporting & audit (deadlines; audit window)	One final report (technical and financial statement with audit certificate) Audit rights for: Funding Agency and Catalan and Spanish competent Authorities (*Intervenció General de la Generalitat de Catalunya*, *Sindicatura de Comptes*, among others)
Payment schedule (advance / interim / final; conditions)	A pre-financing of 50 % of the granted contribution within a maximum of 60 days from the signature of the grant agreement. A final payment within 60 days from the completion of the assessment of the final progress performance report.
State-aid framework (GBER article(s) or not-aid; de minimis?)	Where applicable, GBER Article 25 (Experimental Development) applies *De minimis* provisions may be used where appropriate
Funding rates (by beneficiary type & activity) — e.g., SMEs/large, non-profit.	Companies up to a maximum of 70 % according to PRECISEU terms and conditions
Max funding (if any disparities with the PRECISEU Call)	N/A
Eligible beneficiaries (if any disparities with the PRECISEU general requirements)	Small, medium and large companies can be funded.
Additional eligibility requirements	Activity to be carried out from an operational establishment located in Catalonia.
Eligible costs (in case of disparities)	To be considered eligible, costs must be directly linked to the implementation of the project and comply with the general conditions of section 5.3 of PRECISEU terms and conditions. The following cost categories will be considered eligible: • **Personnel Costs**: Costs for employees (or equivalent) assigned to the action, limited to salaries, social security contributions, and taxes arising from national law or the employment contract. *Please note that the following concepts will **NOT** be eligible as personnel costs:* o Overtime. o Payments based on profits (including bonuses, entity dividends, and

	the achievement of commercial, sales, or fundraising targets). o Payments in kind. o Untaken annual leave (untaken holidays). o Per diems and travel expenses (these should be claimed under travel costs). o Death indemnities and corresponding transfer costs. o Severance pay or indemnities for suspensions, dismissals, or termination of employment. o Marriage allowances. • **Equipment (depreciation)**: Depreciation costs of equipment, infrastructure, or other assets used for the action. These must be written off in accordance with the entity's usual accounting practices. Only the portion of the costs that corresponds to the rate of actual use for the action during the project duration is eligible. • **Consumables and supplies**: Costs of consumables and supplies purchased specifically for the action. • **External services**: Subcontracting costs for tasks that are part of the action, as well as the purchase of other necessary services, provided they ensure best value for money and absence of conflict of interest. • **IPR activities**: Costs related to the protection of the intellectual property rights (IPR) generated by the project's results, such as consulting fees or patent office fees. • **Travel costs**: Travel, accommodation, and subsistence costs for personnel involved in the project, provided they are necessary for the action and align with the entity's usual practices. • **Other costs**: Costs of other goods, works, and services needed to implement the project, such as communication, dissemination, and translation activities. **Italso includes the costs for the mandatory audit report, which will be eligible up to a maximum of €2,000**. • **Indirect Costs**: Overheads and general running costs that cannot be directly attributed to the project. **These will be reimbursed as a flat rate of 25% of the eligible direct costs** (excluding subcontracting costs).
National pre-checks / parallel submission (pre-eligibility forms, national e-portal, letters)	Once the proposal has successfully passed the evaluation and selection process, beneficiary is to file the grant application with Agència per a la Competitivitat de l'Empresa as instructed by the latter for final approval of the grant. Documents to be submitted in Catalan.
Special singularities:	Funding is provided not provided as a lump sum: carrying out of financial control, audit and expenditure verification concerning eligible costs.
Contacts for queries (scientific / financial / legal)	preciseu.accio@gencat.cat
Other documents for consultation	None

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CRETE (GREECE)

Field	To be completed by region
Region / Funding Organisation	Region of Crete
Contact (name, email, phone)	Katerina Rousaki Head of Entrepreneurship Development and Innovation Unit/ Regional Economy Development and Openness Directorate/ Region of Crete Tel. No: +30 2813410171,180 E-mail: krousaki@crete.gov.gr Christos Bilios Executive Officer of Entrepreneurship Development and Innovation Unit / Regional Economy Development and Openness Directorate/ Region of Crete Tel. No: +30 2813410137 E-mail: cbilios@crete.gov.gr
Legal scheme (e.g., ERDF OP, national programme if applicable)	The budget is co-funded (50%) by the European Union through the Horizon Europe programme, under Grant Agreement No 101161301, and (50%) by the National Programme / Public Investment Programme (12055/28.11.2024 Decision of Deputy Minister of National Economy).
Funding available (commitment letter)	The maximum amount available is € 600.000. The budget is co-funded (50%) by the European Union through the Horizon Europe programme, under Grant Agreement No 101161301, and (50%) by the National Programme / Public Investment Programme (12055/28.11.2024 Decision of Deputy Minister of National Economy).
Pre-financing (rate %, trigger)	Pre-financing is provided (rate for Greek beneficiaries 40%)
Interim reporting (if any specificities)	As stated in the open call and according to the Regional Call to be issued by the Region of Crete.
Final reporting & audit (deadlines; audit window)	As stated in both the open and regional calls. Final report should be followed with a summary in Greek.
Payment schedule (advance / interim / final; conditions)	Greek beneficiaries will receive a pre-financing rate of 40%, with the remaining 60% paid as a final payment.
State-aid framework (GBER article(s) or not-aid; de minimis?)	A. For Economic Operators, in accordance with Regulation 651/2014 on the declaration of certain categories of aid as compatible with the internal market, pursuant to Articles 107 and 108 of the Treaty. The Regulation has been amended by Commission Regulation (EU) 2023/1315 of 23 June 2023 and is currently in force (O.J. EU L 167/1 of 30.6.2023) (GBER). The provisions of Article 25 shall apply. B. For Research Organisations: In accordance with the provisions set out in the European Commission Communication – 'Framework for State aid for research and development and innovation' [(2022/C 414/01)].

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Funding rates (by beneficiary type & activity) — e.g., SMEs/large, non-profit.	A. **For Economic Operators** As stated in the Open Call, the maximum aid intensities for experimental development range from 50% to 70%, depending on the type and size of the participating organisation, as per Article 25.6(d) of Commission Regulation (EU) No 651/2014. However, the aid intensities for industrial research and experimental development for SMEs may be increased up to a maximum aid intensity of 80 % of the eligible costs in accordance with points (a) to (d), where points (b), (c) and (d) must not be combined with each other. B. **For Research Organisations:** Up to 100%, in accordance with the Commission Notice 'Framework for State aid for research and development and innovation (2022/C 414/01).
Max funding (if any disparities with the PRECISEU Call)	**Total available funding is € 600.000.** **Maximum funding per beneficiary from Crete is € 600.000.**
Eligible beneficiaries (if any disparities with the PRECISEU general requirements)	The potential beneficiaries <u>at the time of their registration to the Open Call Platform</u> (in PRECISEU website), must have a legally operating installation or branch in the Region of Crete, possess a VAT number (AFM) and a validated PIC number. Offshore companies are not eligible to apply.
Additional eligibility requirements	In addition, the following categories of undertakings are not eligible: • An "undertaking in difficulty" (according to art.2 of Reg. (EU) 651/2014, as amended by Reg. (EU) 2021/1237 & Reg. (EU) 2023/1315). • Exclusions according to Articles 136 and 141 of EU Financial Regulation (EU, Euratom) 2018/1046. • An undertaking which is subject to an outstanding recovery order following a previous Commission decision declaring an aid illegal and incompatible with the internal market.
Eligible costs (in case of disparities)	(a) personnel costs: researchers, technicians and other supporting staff to the extent employed on the project; (b) costs of instruments and equipment to the extent and for the period used for the project. Where such instruments and equipment are not used for their full life for the project, only the depreciation costs corresponding to the life of the project, as calculated on the basis of generally accepted accounting principles are considered as eligible. (c) costs of contractual research, knowledge and patents bought or licensed from outside sources at arm's length conditions, as well as costs of consultancy and equivalent services used exclusively for the project; (d) additional overheads and other operating expenses, including costs of materials, supplies and similar products, incurred directly as a result of the project; without prejudice to Article 7(1), third sentence, such research and development project

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	costs may alternatively be calculated on the basis of a simplified cost approach in the form of a flat-rate of up to 20 %, applied to total eligible research and development project costs referred to in points (a) to (c). In this case, the research and development project costs used for the calculation of the indirect costs shall be established on the basis of normal accounting practices and shall comprise only eligible research and development project costs referred to in points (a) to (c).
National pre-checks / parallel submission (pre-eligibility forms, national e-portal, letters)	Beneficiaries from Crete that will participate in a successful consortium must apply for and comply with the Regional Call to be issued by the Region of Crete according to National Law.
Special singularities:	For non-public entities the pre-financing amount (40%) will be provided upon submission of a bank letter of guarantee.
Contacts for queries (scientific / financial / legal)	**Emmanouela Petrogianni** Executive Officer of Entrepreneurship Development and Innovation Unit / Regional Economy Development and Openness Directorate/ Region of Crete Tel. No: +30 2813410176 E-mail: epetrogianni@crete.gov.gr **George Pagkalos** Innovation Business Observatory Support Team Entrepreneurship Development and Innovation Unit/Regional Economy Development and Openness Directorate/Region of Crete Tel. No.: +30 2813 410180 Email: ibo4@creteregion.gr
Other documents for consultation	2023/C/6801 Regional aid map for Greece.

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EMILIA-ROMAGNA (ITALY)

Field	To be completed by region
Region / Funding Organisation	Regione Emilia-Romagna
Contact (name, email, phone)	Elisabetta Maini elisabetta.maini@regione.emilia-romagna.it +39 0515276551
Legal scheme (e.g., ERDF OP, national programme if applicable)	ERDF
Funding available (Intention letter and commitment letter)	€ 900.000,00 (ERDF) + € 900.000,00 (HORIZON)
Pre-financing (rate %, trigger)	0
Interim reporting (if any specificities)	EVERY 6 MONTHS reimbursements for the costs sustained
Final reporting & audit (deadlines; audit window)	Projects should end their activities in March 2029
Payment schedule (advance / interim / final; conditions)	INTERIM FORESEEN EVERY 6 MONTHS
State-aid framework (GBER article(s) or not-aid; de minimis?)	De Minimis; Not aid for research organization (as defined by Eu regulation)
Funding rates (by beneficiary type & activity) — e.g., SMEs/large, non-profit.	70% for beneficiary
Max funding (if any disparities with the PRECISEU Call)	Max € 200.000,00
Eligible beneficiaries (if any disparities with the PRECISEU general requirements)	Research Institutions, public and private, Center for innovations included in the Emilia-Romagna High Technology Network, SMEs, micro-enterprises, non-accredited healthcare companies, non-accredited IRCCS (Scientific Institutes for Research, Hospitalization and Care)
Additional eligibility requirements	
Eligible costs (in case of disparities)	Personnel cost, subcontracting, consumables, overheads
National pre-checks / parallel submission (pre-eligibility forms, national e-portal, letters)	
Special singularities:	
Contacts for queries (scientific / financial / legal)	infoporfesr@regione.emilia-romagna.it
Other documents for consultation	

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IRELAND

Region / Funding Organisation	Ireland / National Institute for Bioprocessing Research and Training (NIBRT)
Contact (name, email, phone)	Julia Rakovets, Business Manager for Research, NIBRT, Julia.Rakovets@nibrt.ie
Legal scheme (e.g., ERDF OP, national programme if applicable)	Funding is provided under the PRECISEU Horizon Europe project (Grant Agreement No. 101161301) through the Financial Support to Third Parties (FSTP) mechanism. No separate national or ERDF operational programme applies.
Funding available (Intention letter and commitment letter)	Ireland has an indicative allocation of €500,000 under the PRECISEU Open Call. This allocation is intended to support projects with strong translational and scale-up potential that advance technologies in the TRL 6-8 range and demonstrate clear pathways to implementation. Funding is subject to availability and final selection outcomes and will be formalised through the PRECISEU Grant Agreement process.
Pre-financing (rate %, trigger)	Pre-financing of up to 50% of the awarded grant will be provided following signature of the Grant Agreement, in line with PRECISEU general provisions.
Interim reporting (if any specificities)	No additional national interim reporting requirements apply beyond the PRECISEU monitoring and reporting framework. Progress reporting will be aligned with project milestones and deliverables, reflecting the focus on implementation and advancement through TRL 6-8.
Final reporting & audit (deadlines; audit window)	Final reporting will follow PRECISEU requirements, including submission of the final technical report and associated deliverables. Beneficiaries must retain supporting documentation for a minimum of five years following final payment, in line with Horizon Europe requirements
Payment schedule (advance / interim / final; conditions)	Pre-financing: up to 50% upon Grant Agreement signature Final payment: balance following approval of final report Payments are conditional on satisfactory project implementation and delivery of agreed outcomes, with particular emphasis on demonstrable progress towards scale-up and real-world application.
State-aid framework (GBER article(s) or not-aid; de minimis?)	Funding is provided in accordance with Horizon Europe cascade funding principles and relevant EU State aid frameworks. Where applicable: • GBER Article 25 (Experimental Development) applies • Non-aid applies to non-economic activities of research organisations De minimis provisions may be used where appropriate

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Funding rates (by beneficiary type & activity) — e.g., SMEs/large, non-profit.	Funding rates are aligned with PRECISEU provisions: • Non-profit entities: up to 100% • For-profit entities: up to 70% These rates reflect the focus on experimental development activities and the progression of innovations towards implementation
Max funding (if any disparities with the PRECISEU Call)	No additional national restrictions apply beyond PRECISEU rules
Eligible beneficiaries (if any disparities with the PRECISEU general requirements)	Ireland supports participation across SMEs, RPOs, healthcare providers, public bodies and industry. Particular encouragement is given to SME-led or SME-driven consortia, reflecting the central role of SMEs in driving translation, agility and commercialisation, while maintaining strong collaboration with academic and clinical partners.
Additional eligibility requirements	No additional national eligibility requirements apply. Proposals, however, are expected to align with the translational focus of the Irish ecosystem.
Eligible costs (in case of disparities)	Eligible costs follow PRECISEU and Horizon Europe rules. No national deviations apply.
National pre-checks / parallel submission (pre-eligibility forms, national e-portal, letters)	No additional national pre-checks or parallel submission processes apply. Applications are submitted solely through the PRECISEU call system. Applicants involving Irish partners are encouraged to notify NIBRT in advance of submission, to support coordination, provide guidance where appropriate, and facilitate connections within the Irish ecosystem where helpful.
Special singularities:	Ireland participates in PRECISEU as a nationally coordinated, industry-connected innovation ecosystem with a distinctive strength in the translation, scale-up and industrialisation of advanced therapeutics, underpinned by one of Europe's most established biopharmaceutical manufacturing bases. The Irish model is characterised by strong alignment between research, SMEs, industry and workforce development, enabling a direct pathway from late-stage research to manufacturable, scalable and regulatory-ready solutions. Ireland places a clear emphasis on SME-led and SME-driven innovation, supported by close collaboration with RPOs, clinical partners and industry. This ensures that projects are not only scientifically strong but positioned for implementation and real-world adoption from the outset. Ireland is particularly well positioned to contribute to: - advanced therapy medicinal products (ATMPs) and next-generation biologics - process development, scale-up and manufacturing innovation - integration of analytics, data and digital approaches - development of transferable standards and platforms for cross-regional deployment

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	Proposals involving Irish partners are expected to demonstrate: - clear progression within the TRL 6-8 range, with a strong focus on implementation and scale - credible and realistic pathways to manufacturability and supply readiness - early and proactive engagement with regulatory and quality requirements - effective collaboration across SMEs, academia, healthcare and industry NIBRT acts as both Funding Agency and national coordination point, providing a single interface into the Irish ecosystem and supporting projects to translate efficiently, scale effectively and contribute to European strategic priorities in ATMPs.
Contacts for queries (scientific / financial / legal)	Julia Rakovets, Business Manager for Research, NIBRT Julia.Rakovets@nibrt.ie
Other documents for consultation	PRECISEU Call Text and Terms & Conditions, Horizon Europe General Annexes, Relevant EU State Aid framework (GBER Article 25)

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LAZIO (ITALY)

Region / Funding Organisation	Region of Lazio / Lazio Innova SpA
Contact (name, email, phone)	**Ilaria Corsi** Head of European Projects Office and EEN contact point *Tel. No: +39 06 60516244* *E-mail: i.corsi@lazioinnova.it*
Legal scheme (e.g., ERDF OP, national programme if applicable)	ERDF 2021-2027 Lazio Programme (CCI 2021IT16RFPR008) S.O. 1.3 (SME Competitiveness). NB: *Lazio Innova reserves the right to change the source of regional support before the grant is awarded.*
Funding available (commitment letter)	**Maximum amount available 1.1M€,** co-funded (50%) by the European Union through the Horizon Europe programme, under Grant Agreement No 101161301-AMD-101161301-13, and (50%) by RP Lazio ERDF 2021-2027
Pre-financing (rate %, trigger)	40% of regional support upon submission of a bank or insurance guarantee (Lazio Innova Template)
Interim reporting (if any specificities)	After interim reporting to PrecisEU successfully evaluated, **with reporting of costs incurred**.
Final reporting & audit (deadlines; audit window)	As stated in the open call but **before the end of 2028**, with reporting of costs incurred.
Payment schedule (advance / interim / final; conditions)	Lazio beneficiaries will receive a pre-financing rate of 40%, an interim payment (up to max. 40%), with the remaining amount to be paid as final payment (min.20%)
State-aid framework (GBER article(s) or not-aid; de minimis?)	Art. 25 of GBER according to PRECISEU
Funding rates (by beneficiary type & activity) — e.g., SMEs/large, non-profit.	Art. 25 of GBER State aid intensity for Lazio SMEs
Max funding (if any disparities with the PRECISEU Call)	**Total available regional funding is € 550.000.** **Maximum funding per beneficiary from Lazio is € 300.000** (to be covered with RP Lazio ERDF 2021-2027).
Eligible beneficiaries (if any disparities with the PRECISEU general requirements)	**Lazio SMEs** Lazio beneficiaries at the time of their registration to the Open Call Platform (in PRECISEU website), must have a legally operating installation or branch in the Region of Lazio.
Additional eligibility requirements	State aids (UiD, Deggendorf) and national eligible requirements (mainly in D.Lgs. 184/25 "Codice degli Incentivi") will be applied as

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	stated in regional call.
Eligible costs (in case of disparities)	According to art. 25 GBER (a) personnel costs, standard Italian hourly rates for R&D projects will be applied (b) costs of instruments and equipment (c) costs of contractual research, knowledge, patents, consultancy and equivalent services (max 15%) (d) additional overheads and other operating expenses in the form of a 20% flat rate applied to total costs referred to in points (a), (b) and (c).
National pre-checks / parallel submission (pre-eligibility forms, national e-portal, letters)	Lazio beneficiaries that applied to PRECISEU call, must apply for and comply with the Regional Call to be published by Lazio Innova. Only successful proposals on PRECISEU call can be funded by regional funds. Lazio beneficiaries must apply for and comply with the Regional Call, to receive PRECISEU EU funding.
Special singularities:	The pre-financing amount (40%) will be provided upon submission of a bank letter of guarantee.
Contacts for queries (scientific / financial / legal)	infobandi@lazioinnova.it
Other documents for consultation	Regional Call to be published by Lazio Innova will be available on the institutional website www.lazioinnova.it, “Bandi” section.

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LITHUANIA

Region / Funding Organisation	Innovation Agency Lithuania
Contact (name, email, phone)	PhD Viktorija Šimanauskienė Project Leader | Innovation Development Department | Innovation Agency Lithuania E-mail: v.simanauskiene@inovacijuagentura.lt Tel. No: +370 687 27208
Legal scheme (e.g., ERDF OP, national programme if applicable)	50% by the European Union through the Horizon Europe programme, under Grant Agreement No 101161301. 50% by the state budget funds.
Funding available (Intention letter and commitment letter)	The maximum amount available is € 200,000, which is co-funded: 50% by the European Union through the Horizon Europe programme under Grant Agreement No 101161301 50% by the state budget funds
Pre-financing (rate %, trigger)	Pre-financing is provided (rate for Lithuanian beneficiaries 50%)
Interim reporting (if any specificities)	At least once a year during the project implementation period.
Final reporting & audit (deadlines; audit window)	A Final Project Activity and Financial Report
Payment schedule (advance / interim / final; conditions)	Lithuanian beneficiaries will receive a pre-financing rate of 50%, with the remaining 50% paid as a final payment.
State-aid framework (GBER article(s) or not-aid; de minimis?)	de minimis
Funding rates (by beneficiary type & activity) — e.g., SMEs/large, non-profit.	SMEs – up to 70 %
Max funding (if any disparities with the PRECISEU Call)	200 000 EUR
Eligible beneficiaries (if any disparities with the PRECISEU general requirements)	SMEs
Additional eligibility requirements	
Eligible costs (in case of disparities)	- VAT not applicable
National pre-checks / parallel submission (pre-eligibility forms, national e-portal, letters)	- In addition to the application, Lithuanian partners must submit the following documents: - "Single Entity" Declaration - SME Declaration
Special singularities:	-
Contacts for queries (scientific / financial / legal)	PhD Viktorija Šimanauskienė v.simanauskiene@inovacijuagentura.lt

	+370 687 27208
Other documents for consultation	National Call will published separately on the institutional website https://inovacijuagentura.lt/finansavimo-kvietimai?lang=lt

NORTH EAST ROMANIA (ROMANIA)

Region / Funding Organisation	North-East (RO21) / North-East Regional Development Agency
Contact (name, email, phone)	Lucian Sandu, Head of RIS3 Management Office lucian.sandu@adrnordest.ro bgris3@adrnordest.ro
Legal scheme (e.g., ERDF OP, national programme if applicable)	ERDF (European Regional Development Fund), North-East Regional Programme 2021-2027
Funding available (Intention letter and commitment letter)	500.000 euro (ERDF, North-East Regional Programme 2021-2027) + 570.000 euro (Horizon Europe)
Pre-financing (rate %, trigger)	40% of the total value of the aid (ERDF) will be provided upon submission of a bank letter of guarantee
Interim reporting (if any specificities)	Every 3 months
Final reporting & audit (deadlines; audit window)	Projects should end their activities on 31 December 2029
Payment schedule (advance / interim / final; conditions)	In accordance with regional call (Pre-financing/ payment/ reimbursement requests)
State-aid framework (GBER article(s) or not-aid; de minimis?)	De minimis aid
Funding rates (by beneficiary type & activity) — e.g., SMEs/large, non-profit.	100% (ERDF) ,70% (Horizon Europe)
Max funding (if any disparities with the PRECISEU Call)	Minimum 100.000 euro - maximum 300.000 euro per project
Eligible beneficiaries (if any disparities with the PRECISEU general requirements)	SMEs
Additional eligibility requirements	**To be eligible for the regional call for projects, the funding applicant must:** • be classified in the SME category following the EC definition; • be established as an enterprise according to Romanian Law 31/1990; • be registered (headquarter/ operational office) in the North-East region (at the latest at the time of the first payment of aid); • be active for a period corresponding to at least one full fiscal year, did not have the activity temporarily suspended at any time in the current year of submitting the financing request and in the previous fiscal year, and recorded operating profit (>0 lei) in the fiscal year preceding the submission of the financing request; • not to be excluded by de minimis aid regulation (Commission Regulation (EU) 2023/2831).

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	To be eligible for the regional call for projects, the project must: • have the financing decision from the Secretariat of the PRECISEU Interregional Call (JIP -Joint Interregional Project); • target at least one of the smart specialization domains of the North-East Region; • achieved minimum TRL (Technology Readiness Level) 5; • targets specific activities for advancing through TRL 5 → TRL 6, TRL 6 → TRL 7, and TRL 7 → TRL 8; • be implemented in the North-East Region; • not include activities in sectors excluded from the scope of de minimis aid regulation; • not include investments started prior to the submission of the financing application; respect the DNSH (Do No Significant Harm) principle.
Eligible costs (in case of disparities)	• Personnel costs (industrial research, experimental development, innovation) • Purchase costs (tangible and intangible assets, RDI services) Indirect cost (maximum 7% calculated on direct costs)
National pre-checks / parallel submission (pre-eligibility forms, national e-portal, letters)	SME partners in the consortium that have received the financing decision must submit a regional proposal in compliance with the PRECISEU regional call requirements under the North-East Regional Programme 2021-2027.
Special singularities:	
Contacts for queries (scientific / financial / legal)	bgris3@adrnordest.ro
Other documents for consultation	Separate regional call will be published https://regionordest.ro/prioritatea-1/

ANNEX 2. TECHNICAL SCOPE AND DEEP-TECH DEFINITION (Advanced Therapies and Health Data)

For the purpose of this call, the scope targets deep tech innovation in personalised medicine—i.e., innovations grounded in advanced scientific and engineering developments requiring substantial R&I efforts to reach clinical validation, implementation and/or market readiness (TRL 6–8).

Eligible project concepts must address at least one of the following topics:

Advanced therapeutics

This topic is used as a broad, technology-neutral umbrella and includes:

- Advanced Therapy Medicinal Products (ATMPs) as defined in EU legislation (gene therapy medicinal products, somatic cell therapy medicinal products, tissue engineered products, and combined ATMPs).
- RNA-based therapies and other advanced nucleic-acid-based therapeutics, including non-coding RNA therapies (e.g., antisense oligonucleotides, siRNA/RNAi, miRNA/lncRNA-based approaches and related modalities), regardless of whether they are classified as ATMPs or as chemically synthesised medicinal products.
- Enabling technologies that are integral to the translation of these therapies towards TRL 6–8 (e.g., delivery/formulation integral to the therapy, GMP/manufacturing scale-up, analytical/potency methods, comparability strategies, and regulatory/HTA interaction activities), provided the project's centre of gravity remains on advancing a "Medicines for Novel Therapies" modality.

Health Data for Personalised Medicine

This topic covers deep tech solutions that enable or accelerate the responsible secondary use and clinical use of health data to improve prevention, diagnosis, treatment and patient management, including (non-exhaustive):

- Interoperability and data integration across heterogeneous clinical and research environments (e.g., EHR, registries, biobanks, omics/genomics databases), including harmonisation of standards, semantics and metadata.
- Data quality, security and privacy-enhancing technologies, including governance-by-design approaches, access control, auditability, federated approaches and compliance-ready architectures.
- Real-world evidence generation and advanced analytics, including AI/ML-enabled tools for clinical validation, decision support, patient stratification and trial optimisation, where appropriate.
- Federated infrastructures, platforms and tools that reduce fragmentation and enable trustworthy cross-regional data sharing and validation aligned with European initiatives (e.g., EHDS readiness

where relevant).

Note: Digital health products and data-driven tools are in scope where they demonstrably contribute to deep tech innovation and to measurable clinical or system impact at TRL 6–8 (e.g., validated performance in relevant settings, implementation-ready integration, and clear governance/compliance pathway), rather than purely local, low-tech or non-scalable deployments.

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ANNEX 3. DEFINITION OF PRIORITIES AND IDENTIFICATION OF NEEDS

The topic priorities of the PRECISEU Call derive from the following:

Priorities defined by PRECISEU analysis

PRECISEU JIPs will need to tackle challenges identified during the implementation of activities in the first months of PRECISEU in different work packages (Interregional Collaboration and Partnership Bridging, Use of Health Data, Multistakeholder infrastructure to enable access to ATMP on large scale, Market and Patient Access, Adoption of PM innovations in the HealthCare System).

Alignment to SRIA's ToAs

The IC PerMed Strategic Research and Innovation Agenda for Personalised Medicine (published in 2023) presented in total 57 triplets of action (ToA), valuable recommendations, and conclusions to enable the future development and adaptation of personalised medicine approaches for the benefit of patients, citizens, and sustainable healthcare systems. The ToAs are presented in the SRIA along the main areas crucial for an effective development of personalised medicine: interdisciplinary research efforts, successful innovation and implementation of personalised medicine approaches into healthcare. PRECISEU JIP should address challenges included in the SRIA, such as (but not limited to):

- Data collection by healthcare professionals for PM
- Availability and accessibility of real-world data and real-world evidence
- Connected large-scale health databases
- Development of personalised preventive medicine strategies and therapies
- Promote the uptake of PM innovations by the market and ensure patient benefit
- Equity in PM, particularly for underserved populations

Other priorities

To contribute to PM advancement, the PRECISEU Open Call also build on the analysis of key EU initiatives like TEHDAS2 or EP PerMed, and the calls launched by the latter[25].

Identified needs

Regarding Health data:

- Data Integration Interoperability
- Data Quality and Security
- Real world evidence for clinical trials.
- Data Governance and Infrastructures
- Less fragmented EHR systems
- Machine learning for clinical trials
- Cancer registries or national genomic databases
- Enhancing data-sharing capabilities
- Data fragmentation and inconsistent standards
- Data quality for research and clinical decision-making
- Digital Infrastructure for health data management

- Federated architectures, platforms, and tools for validation

Regarding ATMPs:

- Equity in diagnostics and treatments
- CMC (Chemistry, Manufacturing, Control)
- Leverage robotics and AI for automation in manufacturing, logistics and quality control
- Novel biomarkers for monitoring therapy response to ATMPs in clinical settings
- Piloting decentralised manufacturing
- Platform Technologies for C&G Therapy
- Paediatric oncology and rare diseases
- Sandboxes for Regulatory Tools and Frameworks for Next-Generation ATMPs
- Toolboxes for Clinical integration of PM
- Clinics of genomics or molecular diagnostics
- Testbeds or scaling up support for ATMPs
- Research, infrastructure, reimbursement models, and economic incentives
- Specialized services in oncology
- Cost Reduction of diagnostics and ATMPs
- Address system inefficiencies, low-value health

Following these criteria, PRECISEU Open Call encourages collaboration of public and private stakeholders towards innovation and implementation of PM solutions in Europe contributing to transform Healthcare Systems. So, projects should pursue strengthening collaboration between research, industry, healthcare providers, and regional authorities, for the uptake of PM innovations by the market. They must also include activities promoting cross-regional innovation alliances and knowledge transfer between ecosystems. In addition, projects must ensure patient benefit, promoting equity in PM, particularly for underserved populations.

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