



**PRECISEU**

## Frequently Asked Questions

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*This FAQ document is a living document and will be subject to continuous revision and updates. The version number will be updated accordingly each time modifications are introduced. Applicants are encouraged to consult the latest available version regularly.*



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# 1. Call scope and topics

## 1.1. Can a proposal focus on only one topic of the call?

Yes. A proposal may focus on one topic only, provided it clearly fits the scope, eligible activities, expected outcomes and TRL requirements of that topic. The two call topics are Topic 1 – Advanced therapeutics, and Topic 2 – Health Data for Personalised Medicine.

## 1.2. Are personalised software solutions eligible?

Potentially yes. Software, AI-enabled tools, digital health solutions and data-driven platforms can fit the call, especially under Topic 2 – Health Data for Personalised Medicine, provided they are already developed and tested, fall within TRL 6–8, and are positioned as validation / demonstration / implementation projects rather than early-stage development.

## 1.3. Can a project based on AI, health data and decision-support systems fit the call?

Potentially yes, especially under Topic 2, provided the proposal is clearly linked to personalised medicine, experimental development and implementation-oriented validation.

## 1.4. Can non-EU developed technology be used in a PRECISEU project?

Potentially yes. The key issue is not the origin of the technology itself, but whether the applicants are eligible and whether the project is centred on adaptation, integration, validation and implementation in Europe, within the scope and TRL requirements of the call.

## 1.5. Can digital health or non-pharmacological personalised care solutions fit PRECISEU?

Potentially yes, if they are presented as data-driven personalised medicine solutions, with a strong health-data or deep-tech component, and with credible TRL 6–8 implementation and validation activities.

## 1.6. Would an IVD oncology solution fit the call?

Potentially yes. Diagnostic or IVD solutions may fit, especially where they contribute to personalised medicine, generate implementation-ready evidence, and are validated in relevant environments within TRL 6–8.

## 1.7. Can decentralised manufacturing models fit the call?

Potentially yes, provided they are clearly linked to the call's objectives on implementation, patient access, operational efficiency or advanced therapeutics, and provided the project remains within the call's maturity and scope requirements.

# 2. TRL and type of activities supported



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### 2.1. What TRL is required by PRECISEU?

Projects must be centred on experimental development activities in the TRL 6–8 range. The project core is expected to start at TRL 6 or above and progress to a higher maturity level within that range.

### 2.2. Must every project start exactly at TRL 6 and end at TRL 8?

No. The key requirement is that the project is already within the TRL 6–8 range and advances further within that range. For example, a project could move from TRL 6 to 7 or from TRL 7 towards 8.

### 2.3. Can a lower-TRL module be included inside a broader TRL 6–8 project?

Potentially yes, but only if that element is ancillary, clearly justified and subordinate to a project whose centre of gravity is clearly TRL 6–8. If the lower-TRL module is a core unresolved part of the project, eligibility becomes much more difficult to defend.

### 2.4. Are Phase I clinical trials eligible?

A Phase I clinical trial is not automatically excluded. However, a project centred mainly on Phase I may face difficulties if it cannot convincingly demonstrate that the project already starts at the maturity level expected by the call and advances further within the TRL 6–8 logic.

### 2.5. Can clinical validation activities be included?

Yes, in principle, if they are part of an eligible TRL 6–8 experimental development project and comply with the applicable ethics, data protection and regulatory requirements.

## 3. Consortium composition and partner eligibility

### 3.1. What are the minimum consortium requirements?

At least 3 applicants located in 3 different Funding Agency regions, with at least 2 of them in 2 different EU Member States, and at least 1 SME from a Funding Agency region. The coordinator must be established in a Funding Agency region.

### 3.2. Can two partners from the same region be in the consortium?

Yes, but they do not by themselves satisfy the minimum regional-diversity requirement. The minimum requirement is at least 3 applicants from 3 different Funding Agency regions.

### 3.3. Can a SME be coordinator?

Yes, a SME can be coordinator, provided it is established in a Funding Agency region and the consortium otherwise complies with the call rules.



### **3.4. Is there a limit on how many projects one institution can join?**

The general call text allows entities to participate in more than one proposal, provided they coordinate only one, the proposals are different, and different teams are involved. However, some regional authorities may apply stricter regional rules.

### **3.5. Can PRECISEU partners join a JIP consortium?**

Yes, but if a PRECISEU project partner joins a JIP, it is excluded from receiving PRECISEU funds for that action and should be treated as self-funded.

### **3.6. Can a spin-off and an academic institution linked to the same PI join the same consortium?**

Potentially yes, provided they are distinct legal entities, their roles and budgets are clearly differentiated, and the relationship is managed transparently to avoid conflicts of interest or double funding concerns.

### **3.7. Can affiliated entities participate as in standard Horizon Europe?**

The PRECISEU JIP rules do not foresee affiliated entities as clearly as standard Horizon Europe grants do. If an organisation needs its own tasks and budget, the cleanest approach is usually for it to participate as an independent beneficiary, subject to its own PIC and eligibility.

### **3.8. Can a non-profit entity fulfil the SME requirement?**

Potentially yes, but only if it meets the EU SME definition and carries out economic activity. A non-profit entity may count as an SME only if it remains within the EU SME thresholds (staff and financial criteria) and is engaged in economic activity, for example through market-based services or other commercial operations. If, for example, a CRO operates commercially, even under a hospital's non-profit umbrella, it may in principle qualify as an SME and be treated under the funding logic applicable to economic operators. By contrast, if the entity is purely non-profit and does not carry out economic activity, it should not be considered to fulfil the SME requirement, even if it may still be eligible as a non-profit entity under the call. For legal certainty, applicants should be prepared to provide evidence such as an SME self-declaration and documentation showing the existence of economic activity. Where relevant, the final interpretation should be confirmed by the competent Funding Agency.

## **4. Funding regions, non-funding regions and self-funded partners**

### **4.1. Can entities from PRECISEU non-funding regions participate?**

Yes, but only on a self-funded basis and subject to the composition limits set by the call.

### **4.2. How many entities from a PRECISEU non-funding region can be included?**



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Maximum one applicant from a PRECISEU non-funding region per project.

#### **4.3. How many entities from a non-PRECISEU region can be included?**

Maximum one applicant from a non-PRECISEU region (EU Member State or Horizon Europe Associated Country) per project, subject to the specific added-value and budget conditions set out in the call.

#### **4.4. If an organisation is located outside the territories of the Funding Agencies, is there no chance to apply?**

There may still be a possibility to participate, but generally on a self-funded basis and subject to strict limits. A consortium may include at most one applicant from a PRECISEU non-funding region and at most one applicant from a non-PRECISEU EU Member State or Horizon Europe Associated Country, subject to the conditions of the call. Such entities cannot lead the consortium.

#### **4.5. If an invention has already reached TRL 8, is it ineligible to participate in the project?**

Not automatically, but it may be more difficult to demonstrate fit with the call if the core innovation is already fully mature. PRECISEU is mainly designed to support projects in the TRL 6–8 range that still need validation, demonstration, implementation-oriented development or scale-up. A proposal centred on a technology already fully at TRL 8 would need to show clearly what eligible remaining innovation and implementation challenges the project addresses.

#### **4.6. Can the SME be from the same region as one of the other partners?**

Yes. The call requires at least one SME from a Funding Agency region, but it does not require that the SME be from a different region than all other partners. What is required overall is that the consortium includes at least three applicants established in three different Funding Agency regions.

## **5. Budget, funding rates and State aid**

### **5.1. What are the general funding rates?**

Unless Annex 1 provides otherwise, the general call rates are 100% for non-profit legal entities and up to 70% for profit-making legal entities established in Funding Agency regions.

### **5.2. How does GBER Article 25(6)(d) relate to PRECISEU?**

The relevant aid intensity logic for experimental development may be used. This is particularly relevant for interregional collaborative projects selected through an open call involving at least 3 EU/EEA countries and the other conditions of that provision. Where a question depends on State aid, regional payment rules, legal establishment, or region-specific eligibility, applicants should always consult the relevant Annex 1 and, where needed, contact the competent Funding Agency directly.



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### 5.3. What is the maximum contribution per beneficiary?

As a general rule, up to EUR 600,000 per beneficiary.

### 5.4. Can the work of SME owners without salary be budgeted?

Yes, in principle, following the Horizon-style logic for SME owners without salary, provided the relevant methodology and supporting conditions are respected.

### 5.5. Can different Funding Agencies fund personnel costs differently?

Yes. The general call provides common cost categories, but Annex 1 and the regional framework may restrict or specify eligible personnel costs differently for different regions.

## 6. Eligible costs: subcontracting, equipment and indirect costs

### 6.1. What is the subcontracting limit?

Subcontracting costs may not exceed 20% of the total eligible costs of the project.

### 6.2. Can core project tasks be subcontracted?

No. Subcontracting should cover only additional or complementary tasks performed by third parties. Core project tasks should not be subcontracted, and subcontracting to another project partner is not allowed.

### 6.3. Are whole equipment purchase costs eligible?

No, as a general rule equipment is eligible only through depreciation costs, not through the full purchase price.

### 6.4. What are depreciation costs?

Depreciation costs are the portion of the value of an asset that is attributable to the period and extent of its use for the project, according to the beneficiary's usual accounting rules.

### 6.5. What indirect cost rate applies?

The general call rule follows a 25% flat rate on eligible direct costs, excluding subcontracting and certain other items, unless Annex 1 provides otherwise. Some regional annexes, such as SALUT in Catalonia, specify a different rate.

## 7. Regional issues and Annex 1 practicalities



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### **7.1. Do all regions follow the same payment logic?**

No. The call provides a general framework, but payment arrangements may differ by region under Annex 1. Some regions provide detailed regional conditions; others leave operational specifics to the later grant agreement.

### **7.2. Can one applicant participate in only one project in Emilia-Romagna?**

Under its regional eligibility requirements, each applicant can apply for only one project, and each AOU is treated as a single entity.

### **7.3. Is a national/regional application required?**

It depends on the region. The PRECISEU application is submitted through the common call process, but some regions may require additional documentation, parallel submission, or a later regional grant step. Applicants must check Annex 1 carefully for each funded beneficiary.

## **8. Hospitals, clinics and healthcare providers**

### **8.1. Are hospitals eligible?**

Yes, hospitals are expressly mentioned among the target organisations of the call.

### **8.2. What funding rate applies to hospitals or healthcare providers?**

The funding rate depends on the legal nature of the entity, not simply on being a hospital. In general, 100% applies to non-profit legal entities and up to 70% to profit-making legal entities, unless Annex 1 provides otherwise.

## **9. IP, conflict of interest and special compliance questions**

### **9.1. Does the lump-sum funding mean that a specifically owed contractual result is expected?**

No. The better reading is that the payments are grant-type staged payments linked to reporting and compliance, not a procurement contract for a specifically owed result.

### **9.2. Does the funder acquire IP or transfer rights that would indicate contract research?**

No. The grant-style framework is based on beneficiaries retaining ownership of the results they generate, while the funder retains only limited rights of use for policy, communication or dissemination purposes.



## 10. Practical application issues

### 10.1. Would participation in a JIP count as participation in a Horizon Europe project?

Not as a direct Horizon Europe beneficiary. The most accurate description is participation in a JIP funded under a Horizon Europe-funded project.



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