



### Call for proposals 2024 – JTC4

# Nano and advanced technologies for disease prevention, diagnostic and therapy

(NANOTECMEC)

#### **Call Text**

#### **DEADLINES**

January 30, 2024 (16:00, CET) - SUBMISSION OF PRE-PROPOSALS

June 13, 2024 (16:00, CEST) - SUBMISSION OF INVITED FULL-PROPOSALS

Link to electronic proposal submission

https://ptoutline.eu/app/era4healthnano

For further information, please visit us on the website: <a href="https://era4health.eu/">https://era4health.eu/</a>

or contact the Joint Call Secretariat (JCS):

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### <u>History of modifications</u>:

#### 27/11/2023:

- Inclusion of TUBITAK (Turkey) and as participating funding organisations.

#### <u>29/11/2023</u>:

- Modification of the « Eligibility of Partners » section in RCN National Annex
- Modification of ANR National Annex : link in « Further guidance » section

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#### Aim and ambition of ERA4Health

The Partnership "Fostering a European Research Area for Health" (ERA4Health) aims at establishing a flexible and effective coordination between funding organisations in the European Research Area (ERA) for Health and Well-being. This Partnership brings the opportunity to increase European transnational collaborative research funding by creating a funding body for joint programming in priority areas addressing European Public Health Needs.

The general objective of ERA4Health is to reach an effective joint approach and generate knowledge and products (e.g. preventive guidelines, medical protocols) in the identified research areas as outlined in ERA4health Strategic Research and Innovation Agenda (SRIA)<sup>1</sup>. To achieve this, a comprehensive network will be created which aims at strengthening and expanding the existing conducive eco-system.

In this light, ERA4Health gathers public funders of health research in the European Research Area including the European Commission that jointly identify and implement a common funding strategy in priority areas to advance health research and develop innovation.

#### ERA4Health has 4 specific objectives:

- SO1. Support relevant medical research including clinical fields and intervention areas (prevention, diagnosis, treatment),
- SO2. Improve the utilisation of existing health technologies in clinical practice,
- SO3. Build capacity, in particular in conducting IICSs at European scale,
- SO4. Implement and advance the practice of Responsible Research and Innovation (RRI) across the breadth of the programme.

<sup>&</sup>lt;sup>1</sup>https://era4health.eu/wp-content/uploads/2022/11/ec rtd he-partnerships-era-for-health-1.pdf

#### Rationale

Nanomedicine is the application of nanotechnology to achieve breakthroughs in healthcare. It exploits materials and methods at the nanometer scale (from one nanometer to hundreds of nanometers) that are designed to possess improved and, often, novel physical, chemical and/or biological properties and applications.

Nanomedicine has the potential to enable early detection and prevention of diseases, and to significantly improve diagnosis, treatment and follow-up of diseases. The area has a natural transdisciplinary basis and is perceived as embracing six main sub-disciplines that in many ways are overlapping and underpinned by the following common technical issues:

- analytical tools
- nanoimaging
- nanomaterials and nanodevices, including nano-enabled implants
- novel therapeutics and drug delivery systems
- regulatory, safety and toxicological issues. In addition, the integration of Key Enabling Technologies (KET) to nanotechnologies will offer even greater possibilities of nanomedicine to foster innovation for new medical applications.
  - up-scalable production processes, including GMP production

Indeed, the concept of "cross-cutting KETs" refers to the integration of different KETs in a way that creates value beyond the sum of the individual technologies. Thus, cross-cutting KET have the potential to lead to unforeseen breakthroughs and new markets and make an important contribution to the development of new technological components and products. In Europe, the enabling technologies identified include economic analyses of market trends and their contribution to solve societal challenges, advanced materials, micro- and nano-electronics, photonics, biotechnology, advanced manufacturing systems, artificial intelligence and other digital technologies.

Nanotechnology research could also benefit from advances in artificial intelligence in the near future. However, to take advantage of this opportunity, efforts should be made to generate standardized data and to develop data management and stewardship plans for the data generated in nanotechnology research. Therefore, gathered data need to adhere to the FAIR principles, i.e. data must be findable, accessible, interoperable and reusable.

Over the last few years, Europe has successfully contributed to many of the achievements of the basic research dedicated to nanotechnologies. However, regarding the nanomedicine field in Europe, a critical issue concerns the capability of the research and technology development players to effectively move basic knowledge toward innovation into either industrial or clinical applications, i.e. translational research. In order to bridge this gap between research and clinical/commercial applications in nanomedicine it is essential that the efforts are made, so that a critical size in terms of R&D projects portfolio and scientific excellence is reached, a sufficient level of competitiveness is achieved, and academia, industry and clinical sectors work together.

#### Aim of the call

The aims of the call are:

- to support **translational research projects** that combine innovative approaches in the field of nanomedicine and

- to encourage and enable **transnational collaboration** between academic research (public and private partners i.e. research teams from universities, higher education institutions, public research institutions) and clinical/public health research (research teams from hospital, healthcare settings and other healthcare organisations) or R&D activities from industrial enterprises (all size). **The participation of Medical Doctors and clinicians is strongly encouraged. SMEs (Small and Medium-size Enterprises) are also strongly encouraged to participate**.

Project proposals will address multidisciplinary and translational research. The applications must cover at least one of the following nanomedicine areas that are of equal relevance for this call:

- a) Regenerative medicine
- b) **Diagnostics**
- c) Nanotherapy

Proposals may include, but are not limited to the identification, characterisation and validation of biomarkers, early diagnosis, convergence of nanotechnology and stem cell technology, cell biology applied to nanomedicine, multimodal imaging agents or techniques, point of care diagnostics (on site sensors), standardised procedures for preparation & characterisation of drug delivery systems, green production processes for nanomedical products, nanoparticles for hyperthermia, regenerative, gene or cell therapies using nanotechnology. **Pre-clinical and clinical studies are eligible subject to national/regional regulations**.

In order to use nanomedicines/nanodevices in clinical practice, additional advances and further understanding are, therefore, still needed and achievable. The aim of the call is to advance nanomedicine toward any translational focus with anticipated impact relative to the risk and investment. The call also invites applications that focus on improving outcomes e.g. improve the current drug development process, consistency and reproducibility studies, studies such as safety surveillance, studies to support use in special populations.

For a better understanding of the objectives and a more efficient evaluation, applicants are asked to specify in which of the two categories described below the project falls, according to its Technology Readiness Levels (TRL), i.e. its degree of innovation and expected time to market:

- 1) Innovation applied research projects: Proof of concept projects for innovative applications with analytical/experimental research and/or implementation and integration of components and test in laboratory and/or animal models. Safety and nanotoxicity should be taken into account when relevant. The viability of a path that may lead the experimental and/or analytical results (for TRL 3) and/or demonstrators (for TRL 4) to a future application at medium/long term shall also be demonstrated.
- 2) Projects with high potential of applicability at short/medium term: Projects closer to the market for the validation of demonstrators and prototypes in a realistic laboratory (for TRL 5) and/or relevant simulated operational field environment (for TRL-6). The viability of a path that may lead the validated systems and results to real products shall be demonstrated. Industrial engagement is crucial in this type of projects. Medical regulatory aspects have to be properly considered.

At the end, projects should fall within, but are not limited to, TRL 3-6, although for being realistic and coherent with the characteristics of the call, projects should propose advancements for a maximum of two TRL levels during their lifetime. TRL level must be understood as the level achieved by the end of the three-year-project. Industry engagement should be appropriate for the TRL range being investigated.

Beyond the research topics the following points should be taken into account, including approaches to responsible research and innovation:

- Proposals must clearly demonstrate the potential health and/or economic impact(s) as well as the added-value of transnational collaboration: sharing of expertise and resources (models, databases...), harmonization of data, access to innovative technologies, etc.
- Proposals should clearly promote translational research and demonstrate the benefit of working together and the unique contribution of each partner.
- Studies of other KET is possible only if they are used in complement or in combination with nanotechnologies.
- Where relevant, cellular, 3D and patients' models should be preferred to animal models. The use of animal models must be justified<sup>2</sup>. In the framework of this call small-scale clinical studies (up to phase 2), in vitro (e.g. human cells) and in silico (e.g. bioinformatics) are allowed.
- Applicants should make use of existing biobanks and existing cohorts, if applicable. Otherwise, it should be explained why existing biobanks/ cohorts are not used.
- Except for small-scale clinical studies up to phase 2. All other clinical studies are excluded in this call.
- The involvement of relevant stakeholders (e.g. patient organisations) in the project, application of bedside to bench to bedside approach is strongly recommended from the conception stage to the implementation and the dissemination. End-users can participate as partners (if eligible for funding by a national/regional funding organisation), as collaborators (participation with own budget) or as part of an or as advisory board.
- Applicants should consider potential moderators of effects such as age, sex, gender and ethnic or other demographic features/differences in the respective research approaches.
- The use of approaches from precision medicine and personalized medicine are encouraged.
- The consortia are encouraged to consider the gender balance in the composition of the consortia and to balance the responsibilities between genders.
- Early Career Scientists (Master, PhD and post-docs) are encouraged to participate in the consortium.

**Exclusion**: proposals based on nanoscale naturally occurring processes or structures and proposals focus on KET without nanotechnologies.

### Expected Impact

The collaboration between transnational research teams will contribute to important research-related activities such as the harmonisation of protocols, the standardisation of data, the establishment and sharing of data and guidelines, the sharing of research facilities and capacities and/or the development of a nanotechnology toolbox. The toolbox will include, but not limited to, nanotechnologies targeting specific organs, tissues, cell types or organelles, knowledge on the biodistribution of nanoparticles, the nanopharmacokinetics and protocols for reproducible scale up of the nanotechnology.

The development of nanotechnologies, alone or in combination with other KETs, will make it possible to guide clinical decision making and to find solutions to unmet medical needs (UMN). UMNs are either

<sup>&</sup>lt;sup>2</sup> https://www.eara.eu/animal-research-law

medical conditions for which there is no satisfactory method of diagnosis, prevention or treatment, or diseases for which there is a solution, but where nanotechnology-based applications will significantly improve patients' living conditions and/or prove cost-effective through new medical innovations in healthcare systems.

Outcomes in nanomedicine research will have significant potential impact on the European industries of the health sector. It can lead to risk reduction in clinical trials, new production, faster adoption of innovation and increased their market competitiveness.

### General conditions for application

The initial duration of the projects will be 36 months.

Proposals must clearly demonstrate the potential health, economic, and/or policy impacts, as well as the added-value of transnational collaboration i.e. sharing of resources (models, registries, diagnosis, etc.), harmonisation of data, sharing of specific know-how and/or innovative technologies.

Proposals should follow the principles of Responsible Research and Innovation (RRI). All consortia should demonstrate a commitment to investigating and addressing social, ethical, political, environmental or cultural dimensions of the proposed research. The proposal template further elaborates on this and how RRI dimensions can be approached (see our guidelines p18-26).

Research supported by ERA4Health must respect fundamental ethical principles. Applicants have to fill an ethical grid and describe any potential ethical aspects of the work to be carried out, and how the project will fulfil applicable requirements in institutional, national and European Union legislation (including the ethical standards and guidelines of Horizon 2020/Europe<sup>3</sup>).

The individual project partners of the joint applications should be complementary and the proposed work should contain novel, innovative and ambitious ideas with a high application potential for the end-users and/or with a high implementation potential to benefit of end-users/patients/citizens.

Furthermore, additional aspects need to be considered in the application:

- If appropriate: the design of the study (sample collection, statistical power, interpretation, relevant models for hypothesis validation) must be well justified and should be part of the proposal.
- For small-scale clinical studies up to phase 2: strategies for recruitment, retention, assessment, and analysis must be included. The study design and objectives should take into consideration the population that would be needed to reach the objective of the study. Data supporting the recruitment numbers is recommended.
- In case of an exploratory animal/small-scale clinical study up to phase 2, a detailed description is required as part of the full proposal application form (requirements are included in the Guidelines for Pre-clinical and small-scale clinical studies up to phase 2). The review panel will scrutinize this information as part of the formal evaluation criteria (1-Excellence) of full proposals. Assistance for provision of the information on experimental design can be found in the general ARRIVE guidelines<sup>4</sup>.

<sup>&</sup>lt;sup>3</sup> https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics\_en.htm

<sup>&</sup>lt;sup>4</sup> https://journals.plos.org/plosbiology/article/file?id=10.1371/journal.pbio.1000412&type=printable

### Participating countries and respective funding organisations

The following participating funding organisations have agreed to fund this call for transnational research projects:

| Countries   | Funding organisations   | Acronym   | Contribution (€) |
|-------------|---|-----------|------------------|
| Belgium     | Fund for Scientific Research-FNRS   | F.R.SFNRS | 300 000          |
| Belgium     | The Research Foundation - Flanders  | FWO       | 700 000          |
| Estonia     | Estonian Research Council   | ETAG      | 150 000          |
| France      | French Research Funding Agency  | ANR       | 2 000 000        |
| Israel      | Ministry of Health  | CSO-MOH   | 320 000          |
| Italy       | Ministry of Health  | IT MOH    | 1 500 000        |
| Italy       | Italian Ministry of Universities and Research                                       | MUR       | 1 000 000        |
| Latvia      | Latvian Council of Science  | LCS       | 600 000          |
| Lithuania   | Research Council of Lithuania   | LMT       | 300 000          |
| Norway      | The Research Council of Norway  | RCN       | 1 600 000        |
| Poland      | National Centre for Research and Development  | NCBR      | 1 250 000        |
| Portugal    | Foundation for Science and Technology   | FCT       | 500 000          |
| Romania     | Executive Agency for Higher Education, Research, Development and Innovation Funding | UEFISCDI  | 1 000 000        |
| Slovakia    | Slovak Academy of Sciences  | SAS       | 240 000          |
| Spain       | State Research Agency   | AEI       | 1 000 000        |
| Spain       | Regional Ministry of Health and Consumer<br>Affairs of Andalusia                    | CSCJA     | 250 000          |
| Spain       | Institute of Health Carlos III  | ISCIII    | 1 600 000        |
| Taiwan      | National Science and Technology Council   | NSTC      | 810 000          |
| The         | Dutch Research Council  | NWO       | 2 600 000        |
| Netherlands |   |           |                  |
| Türkiye     | The scientific and technological research council of Türkiye                        | TUBITAK   | 600 000          |

Table 1: Participating funding organisations

Project partners will be funded by their relevant national/regional funding organisations. Eligible costs and funding rules vary between the respective funding organisations (see Annex I).

#### Support for Earlier Career Scientists

All project coordinators and principal investigators (PI) are asked to encourage the Early Career Scientists (ECS) that will be involved in the research projects to actively engage in the upcoming ERA4Health Early Career Network (ECN). The aim of the ECN is to foster the interaction, capacity and growth of Early Career Scientists (ECS) involved in ERA4Health-funded projects. Different networking, training and capacity building activities dedicated to ECS will be organised and implemented during the runtime of the projects.

To facilitate participation of the ECS in the ECN, the coordinators and PIs should (I) include travel costs for the project's ECS dedicated to the ECN activities in the proposal and (II) allow the ECS to dedicate a certain amount of their working time to the ECN. In addition, the research consortia are invited to include training activities for Early Career Scientists into their proposals. Examples of training activities are mobility and lab visits of ECS between partners of the consortium or implementation of summer school(s).

### **Application**

#### **ELIGIBILITY CRITERIA**

Joint research proposals may be submitted by applicants belonging to one of the following categories (according to national/regional regulations; certain categories may not be eligible for funding by a specific funding organisation, please see Annex I):

- **A. Academia** research teams working in public and private universities, other higher education institutions or research institutes.
- **B. Clinical/public health sector** research teams working in hospitals/public health and/or other health care settings and health organisations, including primary health care.
- C. Enterprises private companies of all sizes involved in health research and innovation.
- and **D. Operational stakeholders** e.g. patient advocacy organisations, municipalities and local governments, local/national NGO's. In line with the concept of RRI, operational stakeholders should be in a position to provide useful knowledge to the consortium, ensure the consortium's research is useful and translatable to their (or other) organizational contexts, and/or influence decision making or create change within their organisations. Operational stakeholders should be engaged in the research process from conception of the study to dissemination.

Each application must include partners from at least two of the three categories A, B and C. The number of participants and their research contribution should be appropriate for the aims of the transnational research project and be reasonably balanced in terms of international participation. Each transnational collaborative project should represent the critical mass to achieve ambitious scientific goals and should clearly demonstrate an added value from working together. It is important to integrate partners from the category D in line with the aims of the proposal.

A partner search tool, available on ERA4Health website<sup>5</sup>, can be used to offer your support or look for a partner (associate your announce with the call name ERA4Health JTC4 Nanomedicine).

#### Size of the consortium

The number of participants and their research contribution should be appropriate for the aims of the transnational research project and be reasonably balanced in terms of international participation. Each transnational collaborative project should represent the critical mass to achieve ambitious scientific goals and should clearly demonstrate an added value from working together.

Only transnational projects will be funded. The following conditions apply to the composition of consortia:

- A minimum of 3 (three) eligible and a maximum of 5 (five) eligible partners from at least 3 (three) different countries participating in the call.
- The maximum number of eligible partners can be increased up to 6 (six) or 7 (seven) if they include 1 (one) or 2 (two) partners, respectively, from the following participating countries: Latvia, Lithuania, Slovakia and Türkiye.
- No more than 2 (two) eligible partners from the same country participating in the call will be accepted within one consortium.

A maximum of 2 (two) collaborators per consortium. Collaborators are self-funded partners: i.e., partners that do not request funds to any of the participating funding organisations (i.e., partners from non-funding countries or partners which are not fundable according to national/regional regulations of the participating funding organisations). The following conditions apply for collaborators:

- Clear added value for the research project. This should be demonstrated in the proposal.
- Secure own funding for participation with clear evidence in the proposal that this is already in place.
- A letter of commitment of the collaborator(s) needs to be included as an annex to the pre-proposal/ full proposal.
- A collaborator cannot be work package leader.

| Number of partners requesting funding (eligible partners) | 3-5            | 6          | 7          |
|---|----------------|------------|------------|
| Partners from underrepresented countries                  | No constraints | At least 1 | At least 2 |
| Maximum number of collaborators                           | 2              | 2          | 2          |

Table 3: Possible composition of a research consortium

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<sup>&</sup>lt;sup>5</sup> <u>https://era4health.eu/partner-search/</u>

Each project consortium must nominate a project coordinator from the participating principal investigators (NOT a collaborator). The project coordinator will represent the consortium externally and will act as contact person for the Joint Call Secretariat (JCS) and will be responsible during the entire process for the internal scientific management such as controlling, overseeing IPR issues, reporting, and contact with the JCS.

Each principal investigator can submit either 1 (one) proposal as project coordinator or up to 2 (two) proposals as simple partner (i.e. the coordinator of a proposal cannot be partner in another proposal). Please note that this rule may be subject to national/regional regulations. Applicants are consequently strongly encouraged to contact their national/regional contact points to check their national/regional eligibility rules before submission (see Annex I).

#### Financial and legal modalities

Project partners will be funded by their relevant national/regional funding organisation. Therefore, eligible costs, funding rules and the type of studies allowed will vary between the respective funding organisations (see Annex I). Due to these differences, it is recommended that each project partner defines its own budget in accordance with the funding rules of its own country/region.

For information on the specific funding rules and eligibility criteria of the national/regional funding organization :

- Carefully read Annex I and the national/regional announcements of the call
- In addition, applicants are strongly advised to reach out to their relevant funding organisation contact person before applying; please note that for some countries/regions it might be mandatory.

Please note that if a partner is found to be non-eligible at any step of the process by one of the funding organisations, the entire proposal could be rejected without further review.

#### Submission of joint proposals

There will be a two-step submission and evaluation procedure for joint applications, i.e. pre-proposals and full proposals, and the full proposal review process will be complemented by a rebuttal stage. For both submission steps, one joint proposal document (in English) shall be prepared by the partners of a joint transnational proposal and must be submitted to the JCS by uploading it on the electronic <u>submission system</u> by the project coordinator.

The two-step application process will have the following timeline:

| 14 November, 2023                  | Publication of NANOMEDICINE call   |  |
|------------------------------------|--|--|
| 21 November, 2023                  | Webinar Infoday  |  |
| 30 January, 2024, before 16h00 CET | Deadline for pre-proposal submission   |  |
| 23 April, 2024                     | Communication of the results of the pre-proposal assessment (invitation for full proposal) |  |
| 13 June, 2024, before 16h00 CEST   | Deadline for full proposal submission  |  |
| 23 August – 3 September, 2024      | Rebuttal stage   |  |
| Mid of October                     | Communication of the funding decisions to the applicants                                   |  |
| December 2024 – May 2025           | Expected project start (subject to national procedures)                                    |  |

Table 1: Timeline application process

The pre-proposal template will be available on the ERA4Health website (https://era4health.eu/nanotecmec-2024/).

An application template for the full proposal stage will be sent to the project coordinator by the JCS with the invitation to submit a full proposal.

Pre-proposals or full proposals submitted without using the relevant template will be declared noneligible.

If applicable, a proposal should be submitted together with a legal/ethical approval document according to the concerned country's/region's regulations.

For applicants from specific countries/regions it might be mandatory to submit the additional national/regional proposal and/or other information, in some cases before the deadline of this call, directly to the national/regional funding organisations. Therefore, applicants are strongly advised to check their funding organisations specific regulations. See Annex I for more details.

The Call Steering Committee (CSC, composed of one representative from each funding organisation participating in the call with funds) will take all lawful steps to ensure confidentiality of the information and documents obtained during the evaluation and selection procedure of the joint call.

For the submission of full proposals, the widening concept will be applied. It will therefore be possible, but not mandatory, to add partners that are eligible for funding by certain funding organisations (wit low number of eligible applicants at the first step). The inclusion of a new partner should be relevant for your proposal, and the new partner should be well integrated in your consortium. The list of funding organisations/countries will be provided by the JCS when the results of the first step will be communicated to the coordinators. The maximum of 7 partners within the consortium should still be respected. Finally, it is mandatory for the new partner to contact her/his national funding organizations prior to submission of the full proposal and receive approval (see contact details in Annex I of the call text).

#### Further information

For additional information, please contact the JCS, or your national/regional funding organisation Contact Person (see Annex I).

#### Evaluation and decision

#### Eligibility check and evaluation procedure

#### Formal check and evaluation of pre-proposals

The JCS will check all proposals to ensure that they meet the call's formal criteria (date of submission; number and category of participating countries; inclusion of all necessary information in English; appropriate limits on length). In parallel, the JCS will forward the proposals to the national/regional funding organisations, which will perform a check for compliance with national/regional regulations.

Each proposal passing the eligibility check (JCS and country/region) will be evaluated by three reviewers for a first evaluation (see evaluation criteria below). The reviewers will perform the assessment of the pre-proposal and complete a written evaluation form with scores and comments for each evaluation criterion. Based on the scores in the written evaluations a ranking list will be established. Potential conflicts of interests of the evaluators will be taken into consideration during the allocation of the proposals. The CSC members will meet to decide which proposals will be invited to submit a full proposal based on the reviewers' recommendations and to ensure a reasonable balance of requested and available national/regional budgets. Pre-proposals which do not pass this assessment will not be invited for the full proposal stage. The consortia will receive the evaluation reports, including advice on their RRI approach where appropriate.

#### Formal check and evaluation of full proposals.

The JCS will check the full proposals to ensure that they meet the call's formal criteria and have not changed substantially from the respective pre-proposals before sending them to the reviewers. Any fundamental change between pre- and full proposals, e.g. concerning the composition of the consortium, the objectives of the project or the requested budget must be communicated to the JCS and to the national/regional involved funding organisations. In exceptional cases, these changes may be admitted if detailed justification is provided <u>and</u> if they are accepted by CSC.

Each full proposal will be allocated to three reviewers taking into consideration the potential conflicts of interest. The reviewers will perform the assessment of the full proposal and complete a written evaluation form with scores and comments for each criterion (see evaluation criteria below). During a Peer Review Panel (PRP) meeting, the reviewers will discuss all proposals and produce a ranking list of proposals recommended for funding.

Before the PRP members meet to discuss each **full proposal** in a PRP meeting, each coordinator is provided with the opportunity of getting acquainted with the assessments and commenting on the arguments and evaluations of the reviewers (see section "Rebuttal").

#### **Evaluation Criteria**

#### 1. Excellence

- a. Scientific quality of the proposal:
  - Significance of the research question.
  - Clarity and relevance of the objectives.
  - Credibility and clarity of the proposed approach and methodology (including power calculations, randomisation, blinding and bias, target group(s) studied, as well as approach to responsible research and innovation).
  - Expected progress beyond the state-of-the-art, clearly demonstrating an innovation potential.
  - Quality of the project consortium: international competitiveness of participants in the field(s), previous work and specific expertise of the participants, complementarity of the participants, benefit of the transnational collaboration.
- b. Novelty and ambition (including translatability of the proposed research to human health).

#### 2. Impact

- a. Unmet public and societal need and potential impact of the expected research results for future clinical, public health, and/or other socio-economic health relevant applications including patients' needs and/or for industry (i.e. product development).
- b. Added-value of transnational collaboration and potential for fostering international network: gathering a critical mass of patients, sharing of resources (biological material, models, databases, etc.), harmonization of data, sharing of specific know-how and/or innovative technologies, etc.
- c. Projects with high potential of applicability at short/medium term: expected time for market and transfer to patient towards clinical and public health applications, pharmaceutical/health device applications, other industrial applications including market and end user's scenario, quality of dissemination, exploitation and business plan. (when appropriate/applicable).
- d. Participation/engagement with end-users such as patients, industry, clinicians (when appropriate/applicable).
- e. Effectiveness of the proposed measures to exploit and disseminate the project results (including management of intellectual property rights), to communicate the project results in a tailored manner to the different audiences (e.g. policy makers, industry, patients), and to manage research data where relevant.

Sub-criterion 2e will be evaluated at the full proposal evaluation stage.

#### 3. Quality and efficiency of the implementation

- a. Feasibility of proposal and likelihood of successful completion of proposed research.
- b. Coherence and effectiveness of the work plan (including appropriateness of the allocation of tasks, resources and timeframe).
  - c. Use of existing biobanks and existing cohorts (when appropriate/applicable).
- d. Appropriateness of the management structures and procedures, including risk, innovation management and RRI and ethical considerations.

- e. Adequacy of the budget: appropriate distribution of resources in relation to project activities, partner's responsibilities and time frame.
- f. Sustainability of the research capacities initiated by the project (e.g. FAIR data management, Open Science practices). Quality of Intellectual Property management.

Sub-criterion 3e and 3f will be evaluated at the full proposal evaluation stage.

Proposals not relevant to the call topic and objectives (out of the scope) will not be funded, independently of their scientific quality. Evaluation scores will be awarded for the three main criteria. Each criterion will be scored out of five. The weight of each of the three main criteria is equal.

#### Scoring system

Evaluation scores will be awarded for the three main criteria. Each criterion will be scored out of five. The weight of each of the three main criteria is equal.

- **0 = Failure.** The proposal fails to address the criterion or cannot be assessed due to missing or incomplete information.
- **1 = Poor.** The criterion is inadequately addressed, or there are serious inherent weaknesses.
- **2 = Fair.** The proposal broadly addresses the criterion, but there are significant weaknesses.
- **3 = Good.** The proposal addresses the criterion well, but a number of shortcomings are present.
- **4 = Very Good.** The proposal addresses the criterion very well, but a small number of shortcomings are present.
- **5** = **Excellent.** The proposal successfully addresses all relevant aspects of the criterion. Any shortcomings are minor.

Only integer values are accepted.

A full proposal will be considered fundable if the threshold score for individual criterion is 3 points and the overall score at least 10 points.

#### Rebuttal stage

Before the PRP members meet to discuss the full proposals in a PRP meeting, each coordinator is provided with the reviewers' assessments. This stage allows applicants to comment on factual errors or misunderstandings that may have occurred in the review process and to reply to reviewers' questions. However, issues not related to reviewers' comments or questions cannot be addressed and the work plan cannot be modified at this stage.

The applicants will have up to 12 days (23 August – 3 September, 2024) for this optional response to the reviewers' comments. Answers sent after the notified deadline, or not related with reviewers' comments or questions will be disregarded.

#### PRP meeting

The JCS will give the PRP members access to full proposals, reviews and rebuttals, avoiding any conflicts of interest. The PRP will meet to discuss each proposal and, after consideration of the evaluation criteria, external reviews, rebuttals, and their own reviews and discussions, the PRP will assign final scores, make a classification of the proposals, and rank proposals recommended for funding. The final summary review report prepared by the PRP members will be sent to the respective project coordinators.

#### Ethical clearance

After the PRP meeting, Ethical experts will remotely check the full proposals, which are recommended for funding by the PRP and selected for funding by the CSC, for alignment with ethical norms and regulations<sup>6</sup>. A meeting will also be organised for a discussion between the various ethics experts. If necessary, the ethics experts may ask the consortium for clarifications on the ethical points related to the proposed research approaches and for documents such as the patient consent form. The Ethics experts may highlight some vigilance points that need to be monitored during the implementation of the funded project. Only those proposals approved by both the scientific evaluation and ethical assessment (complying with all central Horizon Europe and regional/national ethical requirements), will be funded.

#### Decision

A final decision, based on the ranking list established by the PRP, available funding and the ethical clearance, will be taken by the national/regional funding organisations.

Project coordinators having submitted an eligible proposal will be informed about the funding recommendation regarding their proposal by the JCS. The projects coordinators are responsible to communicate this information to their project partners.

#### Redress procedure

Applicants can appeal against the evaluation outcome if they suspect a breach in the application of the evaluation and selection procedures. This redress procedure only covers the procedural aspects of the evaluation and/or eligibility checks, including the national eligibility checks. The redress will not call into question the scientific or technical judgement of appropriately qualified experts.

In this case they shall submit their appeal to the JCS via email (nanotecmec@agencerecherche.fr), up to 7 calendar days after the date of dispatch of the evaluation outcome email by the call secretariat at the end of each stage (first or second step). The proposal outcome email containing the results of the evaluation will give information on the appeals procedure, which is described below.

#### **Admissibility of appeals**

For an appeal to be admissible the following conditions must be met:

- The appeal must be submitted by the coordinator of the proposal to which the appeal relates
- Only one appeal per proposal will be considered

<sup>&</sup>lt;sup>6</sup> Reference to EU Regulation 2021/695 and how-to-complete-your-ethics-self-assessment\_en.pdf (europa.eu)

- The appeal must be submitted via email within the 7 calendar days deadline. The appeal must contain the following minimum information:
  - The name of the call for proposals;
  - The proposal acronym;
  - The title of the proposal;
  - A description of the alleged shortcomings of the evaluation procedure.

The appeal must demonstrate a procedural irregularity, factual error, manifest error of assessment, misuse of powers, or a conflict of interests. Appeals that do not meet the above conditions, or do not deal with the evaluation of a specific proposal or express mere disagreement with the result or the reasoning of the evaluation might be judged as not suitable for redress.

#### **Procedure**

Upon receipt of an appeal, an acknowledgement of receipt will be sent by the call secretariat within 7 calendar days. The acknowledgement shall report the redress process and the anticipated date by which a decision on the appeal will be communicated to the appellant.

All appeals received by the 7 calendar days deadline will be processed together and the decision will be communicated to the appellant within 7 calendar days from the deadline for submitting the appeals.

#### Responsibilities, Reporting requirements and Dissemination

#### Consortium Agreement

It will be the responsibility of the project coordinator to draw up a Consortium Agreement (CA) suitable to the project partners in order to manage the delivery of the project activities, finances, intellectual property rights (IPR), to handle confidential data (e.g. patient data) and to avoid disputes which might be detrimental to the completion of the project. The project consortium is strongly encouraged to sign this CA before the official project start date, and in any case the CA should be signed in the first 6 months of the project. Please note that national regulations may apply concerning the requirement for a CA (e.g. certain funding organisations may need the signed CA to release some funds). Further instructions will be provided by the JCS to the coordinators of the projects selected for funding.

#### Open Science

Importantly, all funding recipients must ensure that all outcomes (publications, etc.) of transnational ERA4Health-funded projects are published with Open Access. All research projects funded by ERA4Health are eligible to publish on **Open Research Europe (ORE)**, the <u>Platform of the EC<sup>7</sup></u> at no cost.

The new research data resulting from the project should be treated according to the <u>FAIR</u><sup>8</sup> principles, and deposited and shared, according to the national rules of the countries involved. To make research data findable, accessible, interoperable and re-usable (FAIR), a Data Management strategy for the proposed full projects is mandatory in the second evaluation stage. Projects selected to receive funding in the current call, will be requested to present a more detailed Data Management Plan (DMP) before month 6 from the official start of the project and an update of the DMP will be asked at the end of the projects.

<sup>&</sup>lt;sup>7</sup>https://open-research-europe.ec.europa.eu/

<sup>8</sup> https://www.nature.com/articles/sdata201618

#### Progress report

The project coordinator is required to submit an annual scientific progress report on behalf of the consortium to the JCS in March of each year, detailing how the project is progressing in relation to planned objectives. Furthermore, a final scientific report must be sent to the JCS within a period of two months after the project has ended. In addition to the reports, information related to some indicators related to the project may be collected on a platform/survey.

National funding organisations may also request financial and/or scientific annual progress reports and/or a final report on the project from the partners from their respective country.

In addition, the coordinators of each consortium may be asked to participate in a kick-off meeting and present two progress updates, one mid-term and one final status symposium. An appropriate travel budget should be included and justified in the financial plan for the proposal. In case some of the events are organised as an online conference, all partners of the consortia will be encouraged to participate.

#### Communication

The project coordinator will represent the consortium externally and will be responsible for all communication with the relevant ERA4Health bodies. The coordinator must promptly inform the JCS in case of ANY significant changes in the work plan or the consortium's composition. The JCS will inform the relevant funding organisations, who will decide upon the proper action to be taken.

Project coordinators, upon notification, are required to deliver an abstract of their project suitable for communication and dissemination purposes.

For the effective contribution of the project to the objectives of the ERA4Health, the project coordinator should be available to participate in meetings/workshops with the aim of:

- exchanging project results;
- developing a joint strategy to coordinate and facilitate integration of the planned activities of ERA4Health;
- communicating results across ERA4Health.

Importantly, all funding recipients must ensure that all outcomes (publications, etc.) of transnational ERA4Health funded projects include proper acknowledgement of the ERA4Health partnership and the respective funding partner organisations.

"This project received funding from [name of funding organisations, or an acknowledgment as requested by your national/regional funding organisations] under the umbrella of the Partnership Fostering a European Research Area for Health (ERA4Health) (GA N° 101095426 of the EU Horizon Europe Research and Innovation Programme)."

### Confidentiality

The ERA4Health JCS takes all reasonable steps to ensure that information provided in the application is treated confidential.

The proposals will be handled confidentially by the JCS and by the national/regional funding organisations. In selecting the international experts for the PRP, the JCS shall endeavour to avoid any possible conflicts of interest (CoI).

Each expert will have to sign a declaration of confidentiality and absence of conflict of interest. In case of a CoI the reviewer will be withdrawn from evaluating the respective proposal. Conflicts of interest are managed and recorded throughout the evaluation process.

#### General Data Protection Regulation

The following Data Privacy Notice applies:

By submitting an application, the applicants consent to the use, processing and retention of their personal data<sup>9</sup>, in accordance with article 6.1 (e) and (c) of the General Data Protection Regulation (GDPR) (2016/679) and for the purposes of:

- processing and evaluating the application where processing shall be lawful only if and to the
  extent that processing is necessary for the performance of a task carried out in the public
  interest or in the exercise of official authority vested in the controller,
- administering any subsequent funding award,
- managing the funding organisations relationship with them,
- analysing and evaluating the call,
- providing aggregate data to national and European surveys and analyses on the funded projects,
- and complying with audits that may be initiated by the funding organisations and the European Commission (or its agencies).

The members of the CSC may share applicant's data with third parties (some of which may be based outside the European Economic Area) in relation to the above activities including evaluators, auditors and the European Commission (or its agencies).

The members of the CSC may link the data that funding recipients provide in the application with national, bibliographic or external research funding data which are available through public subscription-based databases (e.g. Scopus, Web of Science, etc.) or other national / open datasets.

### ERA4Health Responsible Research and Innovation (RRI) Guidelines

#### What is RRI and why do we need it?

Health research and innovation is crucial for maintaining and improving European public health. In this context, it is easy to acknowledge that science is not separate from society but part of it, which confers an important social responsibility on science. It is important, therefore, that funders, researchers and

<sup>&</sup>lt;sup>9</sup> Last name, first name of the researchers, date of birth, professional contact information, degree(s), position (current and previous), fields of activity, place of work, organisation, address(es), curriculum vitae, ORCID number, name and reference of projects, pre-proposals, project proposals (scientific document, administrative and financial appendix).

other key groups involved in the development of science, technology and innovation think about: (i) the potential directions of research being taken; (ii) who might benefit from new research and inventions and who might not; and (iii) how consideration of the potential social, environmental and ethical issues can be considered throughout the science and innovation process. Responsible research and innovation (RRI) is not about adjudicating what is 'good 'or 'bad', 'positive 'or 'negative', or 'responsible 'or 'irresponsible'. Instead, RRI offers techniques, tools and frameworks to think about questions of social responsibility and ensure scientists, funders and technologists don't lose sight of the context in which they do science, technology and innovation.

RRI is closely related to other cross-cutting issues, and actions can be taken that address both RRI and other important values, such as public/user engagement, open science or ethical assessments.

#### What is ERA4Health's approach to RRI?

ERA4Health's approach to RRI is focused on improving the quality of research and innovation by keeping the broader context of your work visible. It encourages you to embed methodologies and processes to consider four important dimensions related to research and innovation:



**Anticipation**. What might the future desirable and undesirable effects of your work be? Who will benefit from it, and who might not? Can decisions be made now to encourage the good, while minimising the bad effects? This isn't about exhaustive prediction but about building a sense of preparedness for the future.



**Inclusion**. Whose voices and knowledge are shaping your research project? In health research, much evidence shows that patient organisations, health care users and health professionals (amongst others) can improve the quality of innovation. Inclusion is about creating opportunities for two-way exchange of information, co-design or knowledge co-production to draw important outside voices into the research process.



**Reflection**. Are there opportunities for you and your team to pause and take stock' about what you're doing? Would everyone agree with your goals and the decisions you've taken so far? Reflection is about making sure there is space and time to collectively ask hard questions about a project's foundations.

**Responsiveness**. What are the key decision points in your project? Are there opportunities to change course, if you need to? The final dimension is a reminder that the work you do under the label of RRI needs to shape the design, governance or use of your research or innovation.

In sum RRI provides a framework to ask how research and innovation should be carried out in order to ensure that we achieve the societal goals of research and innovation in an open and inclusive way. ERA4Health believes that the RRI methodology improves the quality of research proposals and projects, and substantively engaging with this framework will therefore be rewarded in the proposal evaluation process.

#### How should you include RRI in your project?

Experience with past funding programmes shows that these four dimensions – anticipation, inclusion, reflection and responsiveness – provide a useful heuristic to think about social responsibility across a range of domains. However, the diversity of health science and the range of local contexts engaged within ERA4Health means that there cannot be a one size fits all approach. The specific approach to RRI must be tailored to the actual social, environmental and ethical issues raised by a project's research and innovation activities.

This means that *the commitment* to RRI is clear and fixed in the programme, but there is an openness about the issues addressed and the specific ways to practise responsibility – these must be adapted to each project. In general, your approach to RRI should be proportionate to your proposal – disruptive, ground-breaking or high-TRL (Technology Readiness Level) work is likely to require a more substantive engagement with RRI. If the research is exploratory then RRI components can also be exploratory – teasing out the potential visions, goals and end uses of a project. Overall, the goal is to demonstrate that you have engaged and seriously considered the tensions and meaningful societal benefits associated with health research and innovation.

The text below therefore provides overall ideas and advice but cannot give a recipe that all potential applicants may use. However, the following four points will provide a good foundation as to how develop your approach to RRI in your proposal:

- 1. Treat **RRI** as an integrated part of the project involving as many project members as possible. Do not think of RRI as distinct from the science but as central to it. It is a process that will increase the likelihood of delivering applications with real utility, fair accessibility and concrete value for citizens.
- 2. It is important to develop a **shared understanding of the project's RRI aspects** as early as possible, and for the work plan to be specific to the project. Avoid writing generic, boiler-plate text. By 'RRI aspects' we mean implications or characteristics of your research that touch upon societal, ethical and environmental values.
- 3. **Develop the scientific and RRI components in tandem.** This means you will need to have conversations about the goals, uncertainties and assumptions associated with the scientific ideas. It is important to continue these conversations if the project is funded.
- 4. **Make sure you adequately resource RRI.** It takes time, effort, expertise and money to do RRI well. While there is no one approach to operationalising RRI within a project, ideally RRI needs to be coordinated and should have a lead.

#### BUT WHAT SHOULD YOU ACTUALLY DO?

Starting points to help you identify the most relevant dimensions for your project.

The following questions will direct you to different RRI perspectives applicable for health research and innovation projects. Many of these perspectives can be explored in a structured way with a range of methodologies (for additional resources, see box below).

Please be aware that these options neither represent a complete list of examples, nor the mandated approaches to RRI by ERA4Health.

- 1. **Who will benefit from your project**, who will not, and who may experience new risks? Are those answers acceptable to you?
  - a. Does your project address a specific health-related or societal problem or need?
  - b. Will your innovation be affordable and accessible? If not, is that a problem?
  - c. Does your framing of the problem fit with other people's understanding of it? Can you access these alternative framings?
  - d. How does your approach to the health challenge compare to others approaches?
  - e. What is the most appropriate form of intellectual property (IP) for your project goals and affordability aspirations? Do classical IP strategies deliver the broadest benefit? Can new strategies (e.g. Open Material Transfer Agreements) be adopted at certain points of the research process?
  - f. How could commercial or non-commercial organisations benefit from your research?
  - g. Are there foreseeable risks that you can mitigate now? For instance, what are the potential risks of data being released? How can you take care to ensure these data are interpreted appropriately?
- 2. Have you identified and involved **relevant stakeholders and have you considered public engagement activities**? Are there opportunities for stakeholders and the public to contribute to your work? Stakeholders are people or organisations with a vested interest in the project (both positive and negative), who may also contribute knowledge to it. They could be patients, minorities and marginalised groups, health system users, special interest groups, health professionals, companies, nonprofits, or advocacy organisations. A number of different considerations for stakeholder engagement are important:
  - a. Think about the methodology you will use. For instance, 'co-design' and 'knowledge co-production' methodologies are good at generating trust and allowing stakeholders, including the public, to contribute their knowledge to the problem your project is trying to address.
  - b. Think also about the appropriate timing of different stakeholders' inclusion: certain kinds of knowledge may be more useful early on, whereas other knowledge may be useful later.
  - c. It will likely be valuable (but not obligatory) to **include expertise beyond the medical and health sciences** such as lawyers, social scientists or philosophers to provide anticipatory and reflective methodologies or to address key challenges. Approach them early in your project design.
  - d. Think about **how best to formalise and include stakeholder knowledge** in your project. Are they best placed as scientific collaborators, as members of an advisory board, or as consultants to deliver only specific tasks? Check if your approach is in line with the national/regional funding rules before designing your proposal.

- 3. **Have you created good deliberative spaces** for your project team, partners and aforementioned stakeholders, including the public, to anticipate and reflect on the broader social, political, ethical or environmental context of your research? If not, RRI experts in Science and Technology Studies, medical sociology, bioethics and science communication may be able to help you with this in project design and implementation. A number of different approaches are possible, e.g.:
  - a. Focusing on your day-to-day research work ("philosopher in the lab approach").
  - b. Using foresight and critical futures methodologies.
  - c. Utilising a diverse advisory board.
  - d. Trans-disciplinary reflection at consortium meetings.
  - e. Using stage-gate approaches where explicit decisions about technological choices are taken.
- 4. Have you reflected on/considered adapting **your choice of research methods** regarding, for example:
  - a. Ethical issues in the project (including ethical considerations in the design of participatory science and possibly broader than the "ethics self-assessment")?
  - b. The use of data in your project where does it come from, how will it be used and where will it go? How will ethical use be ensured?
  - c. In vivo/in vitro experiments and need for use of animals in experiments?
  - d. Use of new approaches such as "Safe(r) by Design"?
  - e. Your ability to increase the likelihood of translation by outlining e.g. strategies of scientific rigour, and strategies to reduce bias, inclusion of sex/gender as a biological variable in study design?
  - f. Open Science (such as open data, open code, open protocol or other low barrier data sharing practices) and other publication practices (including report all results, also negative or so-called null results)?
  - g. And are there ways that your project can advance common practices on these issues?
- 5. Have you engaged with important aspects of **your research environment** such as:
  - a. gender, ethnicity and intersectional equality, diversity and inclusivity?
  - b. career progression and precarity?
  - c. equity between partners in your research consortium?
- 6. Have you shown how the project (and product) satisfy requirements for **patient and production safety** and efficiency? Will there be clear benefits for the patient by, for example by:
  - a. listening to/satisfying user needs and safety concerns, or involving them in design;
  - b. involving regulatory affairs professionals (toxicity tests, etc.),
  - c. communicating with regulatory entities as early as possible (the <u>Food and Drug Administration</u> (FDA) or the <u>European Medicines Agency</u> (pharmaceuticals and medical devices), etc.
- 7. Have you considered and evaluated **environmental impacts and sustainable solutions**, in line with the **Do No Significant Harm principle**<sup>10</sup>, by including, for example:
  - a. lifecycle analysis (LCA)?
  - b. ecotoxicology studies?

c. safer- sustainable-, or recyclable-by-design methodologies?

#### How does ERA4Health support and evaluate RRI?

Health research and innovation happens in many different locations (e.g. universities, hospitals, care homes, companies, policy organisations), involves different stages of research (i.e. across the TRL spectrum) and different research cultures. Responsibility for innovation must be shared, and RRI therefore requires a multi-level approach.

ERA4Health is taking a systemic approach to RRI, considering it in the development of the annual work programme and the resulting funding calls. These guidelines were developed in collaboration with members of the ERA4Health community, and will be updated on a rolling basis. The programme's capacity building activities will also facilitate a dialogue among stakeholders in health research about RRI and ethical issues.

At the level of research projects, ERA4Health requires that all proposers explain how their projects demonstrate a commitment to investigating and addressing the social, environmental, ethical, political or cultural dimensions of the proposed research. Integration of RRI should lead to an improved understanding and awareness of the possible benefits, risks, and uncertainties of health science across a broad cross-section of society. This may include (but is not limited to) any of the approaches described in the above section.

**In the (pre-)proposal templates**, three sections/points refer to RRI and ethics considerations and leave space for you to explain your approaches:

- General RRI aspects
- Involvement of stakeholders and the public
- Ethical considerations (in your ethics self-assessment)

RRI components will be given advise on/evaluated by experts as integral components within the scope of all evaluation criteria (Excellence, Impact, and Implementation). RRI does not detract from the overall scoring but contributes to it: Proposals that explicitly aim to advance processes of anticipation, reflection, inclusion and responsiveness by developing new analyses or methodologies will be rewarded in the review process and the scores will be adjusted accordingly. In pre-proposals: The research consortia will receive advice on the RRI dimension from their proposal via written comments from an RRI Adviser that will be shared with the reviewers. In full proposals: RRI Advisers will comment on proposals before the Per Review Panel (PRP) meeting and be invited to give additional advice RRI and the discussions support during meeting. The kinds of questions the RRI Advisers/reviewers will ask regarding RRI are:

#### Relating to Excellence

- Is the RRI approach proportionate to the content of the scientific proposal?
- Does RRI extend across the lifespan of the project? (e.g. as a sub-project, an advisory board or to be considered in annual meetings)
- Are there clear deliverables associated with the RRI work, with ambitions to contribute to RRI scholarship and/or new knowledge of the social, political, ethical or environmental dimensions of health science?

#### Relating to Impact

- Are there clear opportunities for the RRI work to shape the project's scientific trajectories?
- Does the RRI work help align the project's research better to the needs and values of society?

#### Relating to Implementation

- Is there appropriate RRI expertise in the project?
- Is RRI work adequately resourced? Is it clear how the objectives will be achieved?
- Is it clear how the work is organised? (e.g. as a work package, a cross-cutting issue, outsourced etc.)
- Is it clear who is doing the work and what they will do?

#### WEB RESOURCES FOR INCLUDING RRI IN YOUR PROJECT:

www.rri-tools.eu provide numerous resources for practical RRI.

https://thinkingtool.eu/: The Societal Readiness Thinking Tool guides you through the steps of including RRI in a project.

The Centre for Digital Life Norway <u>has also compiled a range of resources</u> that may help develop your approach.

Tools for public engagement: <a href="https://www.publicengagement.ac.uk/resources">https://www.publicengagement.ac.uk/resources</a> and <a href="https://actioncatalogue.eu/">https://www.publicengagement.ac.uk/resources</a> and <a href="https://www.publicengagement.ac.uk/resources">https://www.publicengagement.ac.uk/resources</a> and <a href="https://www.publicengagement.ac.uk/resources">https://www.publicengagement.ac.uk/resources</a> and <a href="https://www.publicengagement.ac.uk/resources">https://www.publicengagement.ac.uk/resources</a> and <a href="https://www.publicengagement.ac.uk/resources">https://www.publicengagement.ac.uk/resources</a>

Further examples specific to health science and innovation will in the future be provided on the RRI webpage of ERA4Health (coming).

ERA4HEALTH's approach to RRI builds on previous frameworks published by the UK's <u>EPSRC</u>, the Research Council of Norway, the <u>European Commission</u> and funding programmes such as <u>M-ERA.NET</u>, <u>ERA CoBioTech</u> and <u>EuroNanoMed3</u>.

### **ANNEX I**

| Country                     | Belgium   |
|-----------------------------|---|
| Funding organisation        | Fund for Scientific Research-FNRS   |
|                             | Dr. Agnès Roba (+32 2 504 9236)   |
| National contact person     | Dr. Florence Quist (+32 2 504 9351)   |
|                             | international@frs-fnrs.be   |
|                             | 300.000€  |
| Anticipated number of       | 1   |
| fundable proposals          | 1   |
| Maximum/ Minimum            |   |
| funding per grant           | 300.000 € per project for 3 years   |
| awarded to a project        | , and a per project for a years   |
| partner                     |   |
|                             | All eligibility rules and criteria can be found in the PINT-MULTI regulations.                                    |
|                             | All eligibility rules and criteria can be found in the PINT-MULTI regulations.                                    |
|                             | Please note that personnel costs (Article III.6) have an annual average cap of                                    |
| Eligibility of costs, types | 80,000 euros for this call.  Clinical studies are not eligible for funding by the F.R.SFNRS                       |
| and their caps              | Clinical studies are not eligible for funding by the F.K.SFNKS  |
|                             | "Overhead" is not an eligible cost. If the project is selected for funding,                                       |
|                             | these costs will be subject to a separate agreement between the institution of the beneficiary and the F.R.SFNRS. |
|                             | Applicants to F.R.SFNRS funding must provide basic administrative data by   |
|                             | submitting an administrative application on e-space within 5 working days   |
|                             | after the general deadline of the ERA4Health JTC4 call to be eligible. Please                                     |
|                             | select the "PINT-MULTI" funding instrument when creating the  |
| -                           | administrative application. Proposals invited to the second stage will be able                                    |
|                             | to complete the pre-proposal form and provide information for the full  |
|                             | proposal upon validation by the F.R.SFNRS.  |
| Submission of other         |   |
|                             | As described in the PINT-MULTI regulations.   |
| national level              |   |
| Submission of financial     |   |
| •                           | As described in the PINT-MULTI regulations.   |
| the national level          |   |
| Further guidance            | https://www.frs-fnrs.be/fr/calendrier-des-appels  |

| Country   | Belgium  |  |
|---|--|--|
| Funding organisation  | The Research Foundation – Flanders (FWO)   |  |
| National contact person   | Toon Monbaliu (FO)       Kristien Peeters (SBO)         europe@fwo.be       europe@fwo.be         +32 (0)2 550 15 70       +32 (0)2 550 15 95  |  |
| Funding commitment  | 700.000 EUR  |  |
| Anticipated number of fundable proposals                        | 2-3  |  |
| Maximum/ Minimum funding per grant awarded to a project partner | Maximum 350.000 EUR per project/consortium (overhead included).  |  |
|   | The FWO integrates two of its <u>funding channels</u> within this multilateral framework. The choice of funding channel depends on the <u>type of project</u> the researchers from Flanders wish to undertake.   |  |
| Eligibility of partners   | The eligibility of research institutions and its researchers can be verified in the relevant and respective chosen funding channels regulations, which can be consulted on the FWO website:  |  |
|   | - <u>FWO Research Projects (FO)</u>  |  |
|   | - <u>Strategic Basic Research (SBO)</u>  |  |
|   | The respective funding channel regulations apply (see links to national rules above), and both are capped at max. 350.000 EUR per project/consortium (incl. overhead, for which the calculation method diverges per funding channel).  |  |
|   | The FWO foresees a budget of 700.000 EUR, which allows for the funding of at least 2 projects.   |  |
| Eligibility of costs, types and their caps                      | For the overhead calculation, the fundamental (FO) and strategic research projects (SBO) entail the same approach: a structural overhead rate should be applied on the total project costs, with an overhead rate of 6% for 'FO' projects, and a 17% overhead rate for 'SBO' projects. Some practical examples:  |  |
|   | <ul> <li>FO: the sum of all costs (personnel, consumables, travel, subcontracting, etc.) amounts to 200.000 EUR, then the overhead will amount to 12.000 EUR (6% of 200.000 EUR) and the total requested cost is 212.000 EUR. This total requested cost may never exceed the max. available amount of 350.000 EUR.</li> <li>SBO: the sum of all costs (personnel, consumables, travel, subcontracting, etc.) amounts to 200.000 EUR, then the overhead will amount to 34.000 EUR (17% of 200.000 EUR) and the total</li> </ul> |  |

|  | requested cost is 234.000 EUR. This total requested cost may never exceed the max. available amount of 350.000 EUR.   |  |
|--|---|--|
|  |   |  |
|  | The FWO funds up to <u>pre-clinical research.</u>   |  |
| Submission of the proposal at the national level                     | The deadline to submit the administrative application to the FWO is identical to the deadline of the joint transnational call (preproposal stage). To ensure the eligibility of the proposal, it is recommended to consult the  |  |
|  | FWO administration at least one week in advance.  |  |
|  | Failure to comply with these requirements can lead to ineligibility.  |  |
| Submission of financial and scientific reports at the national level | <ul> <li>No additional, national scientific reporting is required: the ERA4Health 'NANOTECMEC' call reporting requirements suffice in this regard.</li> <li>Financial reporting is similar to the national framework. One additional feature: at the end of the project the FWO will ask for a cost statement, in the light of its own reporting requirements.</li> </ul> |  |

- Participation in this call does not interfere with the 'regular/national' project submission framework, and is consequently not taken into account for calculating the max. available number of new applications and running projects combined. However, researchers can only participate within 2 different international consortia in this call (and only once if they act as coordinator in one of the proposals).
- Projects aiming at the development of a spin-off company are not eligible in this context.

## Additional eligibility rulesFurther guidance

- The project duration is limited to 36 months, which implies the
  funding has to be budgeted and spent accordingly. An automatic
  prolongation and using positive (financial) balances after the end
  date is not applicable in this framework. As such article 28 of the
  FWO Research Projects and article 14 of the Strategic Basic
  Research (SBO) regulations do not apply in this context.
- The PI, for each of the participating institutions applying for FWO funds, must hold an appointment that fully covers the duration of the research project. Linked to this, and when it comes to the FWO research project regulations (FO): article 10, §7 is not applicable in this framework. I.e. supervisors (-spokespersons), or coordinators/consortium partners who are granted emeritus status during the calendar year of submission of the project application or during the duration of the project are not eligible.
- It is strongly advised to contact the FWO contact persons mentioned above, in order not to jeopardize any research projects/consortia.

| Country   | Estonia  |
|---|--|
| Funding organisation  | Estonian Research council  |
| National contact person   | Margit Suuroja margit.suuroja@etag,ee +372 731 7360  Argo Soon argo.soon@etag.ee +372 515 3424   |
| Funding commitment  | 150 000 €  |
| Anticipated number of fundable proposals                        | 1  |
| Maximum/ Minimum funding per grant awarded to a project partner | 150 000 €  |
| Eligibility of partners   | The Host Institution may be any legal entity that is registered and located in Estonia and has an Estonian bank account.  The Principal Investigator:  1.2.1 must have an updated public profile in the Estonian Research Information System (ETIS) by the submission deadline;  1.2.2 must hold a doctoral degree or an equivalent qualification. The degree must be awarded by the submission deadline of the grant application at the latest;  1.2.3 must have published at least three articles that comply with the requirements of Clause 1.1 of the ETIS classification of publications, or at least five articles that comply with the requirements of Clauses 1.1, 1.2, 2.1 or 3.1, within the last five calendar years prior to the proposal submission deadline. International patents are equalled with publications specified under Clause 1.1. A monograph (ETIS Clause 2.1) is equalled with three publications specified in Clause 1.1 if the number of authors is three or fewer. If the applicant has been on pregnancy and maternity or parental leave or performed compulsory service in the Defence Forces, or has another good reason, they can request the publication period requirement to be extended by the relevant period of time.  If the Principal Investigator has received the PhD degree outside Estonia, its correspondence to an Estonian doctoral degree must be recognised by either the Estonian ENIC-NARIC Centre or the Host Institution in accordance with the Regulation of the Government of the Republic of April |

the foreign education system terms and conditions of use". The Funding Organisation may ask for a relevant Evaluation Report. 1 Personnel costs are monthly salaries with social security charges and all other statutory costs of the project participants, calculated according to their commitment and in proportion to their total workload at their Host Institution. 2. Other direct costs are: - travel costs that may cover expenses for transport, accommodation, daily allowances and travel Insurance; - consumables and minor equipment related to the project; - publication and dissemination of project results; - organising meetings, seminars or conferences (room rent, catering); - fees for participating in scientific forums, conferences and other events related to the project; - patent costs; - all other costs that are identifiable as clearly required for carrying out the project (e.g. translation, copy editing, webpage hosting, etc.) and comply with the eligible costs. Eligibility of costs, 3. Subcontracting costs should cover only additional or complementary types and their caps research related tasks (e.g. analyses, conducting surveys, building a prototype, etc.) performed by third parties. Subcontracting costs should not be included in the overhead calculation. The activities and budget should be described in the proposal. Core project tasks should not be subcontracted. Subcontracting costs may not exceed 15% of the total costs. 4, Indirect costs (overhead) may not exceed 15% of the personnel costs and should cover the general expenses of the Host Institution. Costs for equipment and services intended for public use (e.g. a copy machine or a printer that is publicly used, phone bills, copy service, etc.) should be covered from the overhead. 5. Double funding of activities is not acceptable. 6. If several Estonian institutions participate in one proposal, the sum of their requested budgets may not exceed the maximum contribution of the respective national Funding Organisation indicated in the call documents. 7. State Aid

EU Regulations on State aid and de minimis aid must be taken into account

when requesting funding.

| Submission of the proposal at the national level                     | No additional documents should be submitted to ETAG during the submission phase                  |
|--|--|
| Submission of other information at the national level                | No additional documents should be submitted to ETAG during the submission phase                  |
| Submission of financial and scientific reports at the national level | Financial reports are required   |
| Further guidance   | https://etag.ee/wp-content/uploads/2022/07/Vastavusnouded-RV-uhiskonkurssidel -EN veebr.2023.pdf |

| Country                                    | France  |
|--|---|
| Funding organisation                       | French Research Funding Agency  |
|  | Anais Fradet/Mérick Machouri  |
| National contact person                    | Phone number: +33 1 73 54 81 74 /+33 1 72 73 06 72  |
|  | nanotecmec@agencerecherche.fr   |
| Funding commitment                         | 2 000 000 €   |
| Anticipated number of fundable proposals   | 5-7   |
| Maximum/ Minimum funding per grant         |   |
| awarded to a project partner               | Minimum amount per partner: 15 000 €.   |
| partite                                    | Maximum amount per project: 400 000 €.  |
| Eligibility of partners                    | ANR may finance fundamental research, industrial research and experimental developments. ANR may fund research organisations and undertakings, as defined by the EC regulation on State aid for research, development and innovation (see the ANR Funding regulations for further reference). Only research organisations that have their primary establishment in France may be funded. As for undertakings, ANR may fund those that have their real head office in an EU member State and an establishment (primary or secondary) in France.  Within this framework, research institutions such as EPST, EPIC, Universities, Hospitals as well as most Foundations, Associations and Enterprises can apply. Entities leading research are entitled to apply (eg: EPST, EPIC, Universities, Hospitals as well as most Foundations, Associations and Enterprises). This list is not comprehensive and funding rates vary. Please fill the form related to economical activities to identify your funding rate and consult the ANR Funding regulations for more details: |
|  | http://www.agence-nationale-recherche.fr/RF   |
|  | Please note that companies with economic difficulties are excluded from ANR subventions.  Countries subject to sanctions applicable to the research field by the European Union authorities are excluded from this call. Projects involving Partners established in these countries will be declared ineligible by the ANR. At the date of publication, these exclusions concern partners from the following countries Russia, Belarus. This list may evolve in case of new sanctions decided by the European Union.  |
| Eligibility of costs, types and their caps | Standard ANR funding rules apply for eligible costs, unless stated otherwise in the Annex « <i>Modalités pour les partenaires sollicitant une aide de l'ANR</i> ». These rules are specified in ANR's "ANR Funding regulations" along with the  |

|  | an explanatory note available at: <a href="https://anr.fr/fileadmin/documents/2017/ANR-RF-Fiche-COUTS.pdf">https://anr.fr/fileadmin/documents/2017/ANR-RF-Fiche-COUTS.pdf</a> Eligible costs (e.g.: personnel costs, costs of instruments and equipment, additional overheads and other operating expenses incurred directly as a result of the research project such as, for instance: travel costs) and funding rates vary based on the type of research and research partner. Please note that expenses related to permanent staff stipends are not eligible for the Beneficiaries "à coût marginal".                                      |
|--|---|
| Submission of the proposal at the national level                     | No additional documents should be submitted to ANR during the submission phase.   |
| Submission of other information at the national level                | When a project is selected for funding, administrative and financial data of the partners funded by ANR must be entered by the applicant on the ANR platform.   |
| Submission of financial and scientific reports at the national level | The ANR funded partners must communicate to ANR the required Scientific reports, Consortium Agreement, Data management plans according to the funding contract and as required to the project coordinator by ERA4Health.  Financial reports must be communicated to ANR according to the provisions of ANR Funding regulations.  If applicable, Declarations of Due Diligence for the financed projects (Nagoya Protocol) must also be transmitted to ANR in due time.  |
| Further guidance   | ANR does not allow double application nor double funding and will not finance projects or part of projects that have been funded through other calls.  See Annex « Modalités pour les partenaires sollicitant une aide de l'ANR » for additional ANR rules at https://anr.fr/fileadmin/aap/2024/aap-era4health-nanotecmec-2024-annexe-fr.pdf  The above-mentioned terms and conditions are only summarized translations of those entailed in the ANR Funding regulations and in the Annex. In case of inconsistencies, the terms of the ANR Funding regulations and the Annex shall prevail. Please consult these documents for more details. |

| Country  | Israel  |
|--|---|
| •  | Ministry of Health  |
| National contact person  | Dr. Irit Allon Phone: +972 (0)2 5082167; Email: irit.allon@moh.health.gov.il Chief Scientist Office, Ministry of Health Dr.Adelina Ovcharenko Phone: +972 (0) 543138655; Email: adelina@midgam.org Chief Scientist Office, Ministry of Health |
| Funding commitment   | 320,000 €   |
| Anticipated number of<br>fundable proposals                                | Up to 2 Projects  |
| Maximum/ Minimum funding per grant awarded to a project partner            | Up to 140,000 € Additional 40,000 € for coordination  |
| Eligibility of partners  | Position in a university, research center or hospital. Research authority must approve position prior to submission.  |
| and their caps   | Materials and consumables; Travel and hosting (up to 10%); No salaries for applicants; No heavy equipment, Institutional overhead 10%.  |
| proposal at the national   | Prior to submission, researchers will submit to CSO-MOH an abstract approved by their research authority including budget distribution. No submission of abstract can result in declaration of the consortium as ineligible.                  |
| Submission of other<br>information at the<br>national level                | If the application involves human or animal experiments, bioethics approvals must be submitted with the application.  |
| Submission of financial<br>and scientific reports at<br>the national level | Required annually.  |
| Filliner Sillnance   | Please see detailed instructions of application at the national level and reporting at http://www.health.gov.il/research-fund   |

| Country   | Italy   |  |
|---|---|--|
| Funding organisation  | Italian Ministry of Health (IT-MoH) <u>www.salute.gov.it</u>  |  |
| National contact person   | <ul> <li>Gaetano Guglielmi – Head Office 3 – Health Research g.guglielmi@sanita.it</li> <li>Francesca Turco – Scientific Officer - f.turco@sanita.it</li> <li>Chiara Ciccarelli – NCP and Programme Officer c.ciccarelli@sanita.it</li> </ul>   |  |
| Funding commitment  | 1,5 M €   |  |
| Anticipated number of fundable proposals                        | 4   |  |
| Maximum/ Minimum funding per grant awarded to a project partner | Max. 400K € per project   |  |
| Eligibility of partners   | Only IRCCS (Istituti di Ricovero e Cura a Carattere Scientifico) researchers are eligible to apply.  Not fundable: Universities, other research Institutes, companies.  No more than two Italian PIs (Principal Investigators) are eligible to apply for the same project.  Simultaneous PI participation in different 2024 JTCs funded by the Ministry of Health is not allowed. |  |
| Eligibility of costs, types and their caps                      | Traver (max 10%),   |  |

|   | Subcontracts are allowed only upon approval, by presenting via Workflow – code ER, a request together with the National pre-elegibility form, the latest 20 days before the deadline of the pre-proposal submission.  |
|---|---|
|   | Italian PAOs can be funded as a sub-contractor of an IRCCS if they fulfil the eligibility criteria of the EC. The maximum cost eligible for a sub-contract is 25.000 Euros (from the IRCCS Budget).   |
|   | Italian PAOs can still participate in Consortia as "Collaborators" with their own funds.  |
| Submission of   | In order to expedite the eligibility check process, the Ministry of Health will grant an eligibility clearance to the applicant prior to the submission of the proposals. To this end, it is mandatory that the applicants fill out and return to the IT-MoH a pre-submission eligibility check form through their IRCCS, using WFR System-> ER communication code, before submitting their proposal to the Joint Call Secretariat. |
| the proposal at<br>the nationallevel                                | It is strongly recommended that the form, completed and duly signed, is returned at least 10 working days before the proposal submission deadline. Applicants will be sent written notification of their eligibility status. Changes in acronyms and budgets provided in the pre-submission eligibility check are not allowed.  |
|   | The pre-eligibility form can be downloaded here: <a href="https://www.salute.gov.it/imgs/C">https://www.salute.gov.it/imgs/C</a> 17 pagineAree 4441 0 file.pdf  |
| Submission of other information at the national level               | _   |
| Submission of financial and scientific reports at thenational level | Submission of annual scientific and financial reports at the national level will be required according to the rules of the Ministry of Health (Ricerca Corrente).   |
| Further guidance  | Further information on the rules of the Ministry of Health can be requested to the national contact persons.  |

| Country   | Italy   |
|---|---|
| Funding organisation  | Ministero dell'Università e della Ricerca (MUR)   |
| National contact person   | Sara Cella: sara.cella@est.mur.gov.it Aldo Covello: aldo.covello@mur.gov.it   |
| Funding commitment  | 1.000.000 €   |
| Anticipated number of fundable proposals                        | 4   |
| Maximum/ Minimum funding per grant awarded to a project partner | 250.000 € per project (not per partner)   |
| Eligibility of partners   | The following entities are eligible, providing that they have stable organization in Italy: enterprises including foundations and non-economic entities, universities, research institutions, research organizations in accordance with EU Reg. n. 651/2014 of the European Commission - June 17, 2014, patient advocacy organizations, local and regional administrations; |
|   | Any participant, in order to be eligible, must comply with the eligibility criteria listed in the "Avviso integrativo nazionale".   |
|   | All costs incurred during the lifetime of the project under the following categories are eligible:  |
|   | A) Personnel,   |
|   | B) Consulting and equivalent services (subcontracting)  |
|   | C.1) Travel and subsistence   |
|   | C.2) Equipment  |
|   | C.3) Other goods and Services   |
| Eligibility of costs, types and their caps                      | E) Indirect Costs/Overheads ("Spese generali") calculated at 25% flat rate of all direct costs excluding cost category B) Consulting and equivalent services [E) = 25% of A) + C.1) + C.2) + C.3].  |
|   | All activities classifiable as Basic research, Industrial research and Experimental development are eligible for funding. Furthermore, Basic Research and Industrial research activities must be predominant with respect to Experimental development activities (in terms of costs).   |
|   | The amount of funding which can be granted to each beneficiary is calculated multiplying the eligible costs for the funding rates lister hereafter:   |
|   | Basic research: 70%   |

|  | Industrial Research: 70%  |
|--|---|
|  | ilidustriai Researcii. 70%  |
|  | Experimental Development: 25%   |
| Submission of the proposal at the national level                     | In addition to the project proposal, which shall be submitted at European level, the Italian participants are requested to submit a national additional application to MUR, through the national web platform, available at the following link: <a href="https://banditransnazionali-miur.cineca.it">https://banditransnazionali-miur.cineca.it</a> This national additional application must be submitted by the same deadline established in the international joint call for pre-proposal submission. Any participant who does not submit its national documents by the deadline will be considered not eligible for funding.  More information on the national documentation to be submitted to MUR is available at the web page dedicated to the partnership ERA4Health: <a href="http://www.ricercainternazionale.miur.it/era/european-partnership-2021-">http://www.ricercainternazionale.miur.it/era/european-partnership-2021-</a> |
| Submission of other information at the national level                | Other information may be requested for the preparation and signature of the contract  |
| Submission of financial and scientific reports at the national level | During the project execution and after the end of the projects, financial and scientific reports are requested to verify the project advancement and the achievement of the project results.  |
| Further guidance   | Relevant documents:  - Decreto legge n. 83/2012 - Decreto Ministeriale n. 1314 del 14 dicembre 2021 - Decreto Ministeriale n. 1368 del 24 dicembre 2021 - Avviso integrativo nazionale  |

Useful Links:

# National website:

 $\frac{http://www.ricercainternazionale.miur.it/era/european-partnership-2021-27/era4health.aspx}{27/era4health.aspx}$ 

 $\textbf{National submission platform:} \ \underline{\text{https://banditransnazionali-miur.cineca.it}}$ 

| Country   | Latvia   |
|---|--|
| Funding organisation  | Latvian Council of Science   |
| National contact person   | Maija Bundule E-mail: Maija.Bundule@lzp.gov.lv Tel: +371- 26514481  Uldis Berkis E-mail: Uldis.Berkis@lzp.gov.lv Tel.: +371-29472349   |
| Funding commitment  | 0,6M EUR   |
| Anticipated number of fundable proposals                        | 2  |
| Maximum/ Minimum funding per grant awarded to a project partner | 300.000 Euros per partner, not exceeding 100.000 EUR per year Funding rates under Regulation EC 651/2014 shall be respected in case of state aid.  Maximum 2 Latvian partners per proposal   |
| Eligibility of partners   | Only the following legal persons only  1) Research institutions registered in the Latvian Registry of Scientific Institutions, e.g.  - Research Institutes  - Universities  And must have the status of Research and knowledge dissemination organization (Regulation EC 651/2014)  2) Business enterprises entered into the Latvian Commercial registry as companies, assumed they are eligible to do the specific research and have specific capacity and resources to do the research in Latvia and have their main activity in Latvia. Limitations of EU legislation apply (R651/2014) together with financial reporting requirements, in this case this is state aid. Two previous statements with sworn auditor's approval should be provided and they must reflect the correspondence to the regulation as well as evidence of previous scientific activity and presence of capacity. |
| Eligibility of costs,<br>types and their caps                   | <ul> <li>Personnel costs incl. taxes;</li> <li>Consumables;</li> <li>Subcontracts (up to 25% of direct costs), needs detailed justification, includes all external services, project core activities cannot be subcontracted;</li> </ul>   |

|  | <ul> <li>Equipment (only depreciation costs during project directly attributable to project tasks);</li> <li>Replaceable and fully consumable during project elements of equipment (e.g. electrodes);</li> <li>Travels (according to travel plan);</li> <li>Indirect costs (up to 25% of direct costs excluding subcontracting).</li> </ul>  |
|--|--|
| Submission of the proposal at the national level                     | No   |
| Submission of other information at the national level                | To receive funding by LCS, Consortium agreement duly signed should be presented. Enterprises shall provide audited statements of 2 previous closed financial periods on request.  Final audit according to the LCS regulations.  |
| Submission of financial and scientific reports at the national level | Annual or in some cases half-annual financial and scientific reporting is mandatory.   |
| Further guidance   | Support is provided according to Provisions Nr 259, 26.05.2015 of the Latvian Cabinet of Ministers ( <a href="http://likumi.lv/ta/id/274671-atbalsta-pieskirsanas-kartiba-dalibaistarptautiskas-sadarbibas-programmas-petniecibas-un-tehnologiju-joma">http://likumi.lv/ta/id/274671-atbalsta-pieskirsanas-kartiba-dalibaistarptautiskas-sadarbibas-programmas-petniecibas-un-tehnologiju-joma</a> ) These provisions should be respected without exceptions. The maximum rates should respect the Provisions. The requirements in the provisions to specific applicant groups must be respected.  LCS cannot fund implementation support, nor training activities.  LCS is funding only research. |

| Funding organisation Research Council of Lithuania (Lietuvos mokslo taryba), LMT   |              |
|--|--------------|
|  |              |
| Živilė Ruželė  |              |
| National contact person E-mail: zivile.ruzele@lmt.lt;  |              |
| Tel. +37067614383  |              |
| Funding commitment 300 000 Eur   |              |
| Anticipated number of fundable proposals  1-2 projects   |              |
| Maximum/ Minimum Within a single project proposal, the maximum funding can be used to the control of the contro |              |
| <b>funding per grant</b> 150 000 for a consortium partner; up to EUR 200 000 for a coor <b>awarded to a project</b> eligible LT partners in a consortium or up to EUR 250 000 for a co   | · ·          |
| partner and 1 eligible LT partner in a consortium  |              |
| Eligible for funding institutions are Lithuanian research and highe  | r            |
| education institutions that are included in the Register of Education  |              |
| Research institutions, public healthcare institutions, academy of s  |              |
| mentioned in the state Law on Science and Studies, other state pu  |              |
| Eligibility of partners institutions such as National libraries, archives, museums. Benefic  | ·            |
| institution (grant holder) manage the state budget funds allocated   |              |
| project following the rules stated in the legal acts, as well as repreting the project partners (if applicable 'project partner' means public or project partner' mea | - 1          |
| legal entity that, together with the eligible institution, created the   | ·            |
| conditions for project implementation).  |              |
| Only costs (direct) generated during the lifetime of the project,  | related to   |
| Eligibility of costs, project are eligible. Direct costs: personnel, travel, purchase  | e (assets,   |
| types and their caps services, consumables), subcontracting.   |              |
| Overheads (indirect costs): up to 20 % from direct costs.  |              |
| Submission of the  |              |
| proposal at the Not required national level  |              |
| national level   |              |
| Submission of other If proposal is granted Lithuanian partner must submit the detailed   | ed budget    |
| for the project implementation prior to the grant agreement sign:  | - 1          |
| national level   |              |
| Submission of financial Quarterly and yearly financial reports and two (2) scientific reports  | orts (mid-   |
| and scientific reports at term and final) are required   | 2.00 (////00 |
| the national level   |              |
| Please contact National contact person and consult national cal  |              |
| Further guidance the webpage <a href="https://www.lmt.lt/lt/mokslo-finansavimas">https://www.lmt.lt/lt/mokslo-finansavimas</a>   |              |
| partnerystes-era-net-ir-kitos-koordinavimo-veiklos/era4health/40   | <u>15/</u>   |

| Country  | The Netherlands  |
|--|--|
| Funding organisation                                   | The funds for this call are provided by the Dutch Research Council (NWO)   |
| National contact person                                | Dr. Rob Hermans, NWO domain Applied Engineering Science,<br><u>ERA4Health@nwo.nl</u> , +31 30 6001 317   |
| Funding commitment                                     | € 2.600.000 in total   |
| Anticipated number of fundable proposals               | 8  |
| Maximum funding per grant awarded to a project partner | € 325.000 (= total amount for all Dutch partners per consortium project)   |
| Eligibility of partners                                | In this National Annex an Applicant is defined as a researcher from the Netherlands applying for funding (i.e. the Dutch part of a European consortium).  Full, associate and assistant professors, and other researchers with a comparable position* may submit an application (i.e. participate in a consortium and request NWO funding) if they have a tenured position (and therefore a paid position for an indefinite period) or a tenure track agreement at one of the following research organisations:  • Universities located in the Kingdom of the Netherlands;  • University medical centres;  • Institutes affiliated to the Royal Netherlands Academy of Arts and Sciences (KNAW) or NWO;  • The Netherlands Cancer Institute;  • The Max Planck Institute for Psycholinguistics in Nijmegen;  • Naturalis Biodiversity Center;  • Advanced Research Centre for NanoLithography (ARCNL);  • Princess Máxima Center.  *A comparable position refers to a researcher that has a demonstrable and comparable number of years of experience in carrying out scientific research and supervising other researchers as a full, associate or assistant professor.  Persons with a zero-hour employment agreement or with a contract for a limited period of time (other than a tenure track appointment) may not submit a proposal.  It could be the case that a tenure track agreement ends before the intended completion date of the project for which funding is applied for, or that before that date, the tenured contract ends due to a researcher reaching retirement age. In that case, the researcher needs to include a statement from their employer in which the organisation concerned guarantees that the project and all project members for whom funding has been requested will receive adequate supervision for the full duration of the project.  Employees with a part-time contract should guarantee adequate supervision of the project and all project members for whom funding is requested.  An application for funding (i.e. the Dutch partner or Coordinator in the |
|  | supervision of the project and all project members for whom funding is requested.  |

| Eligibility of costs, types and their caps            | <ul> <li>An applicant may only request NWO funding for one project (part of a European consortium) in this call.</li> <li>Applicants may not apply for a scientific position for themselves.</li> <li>Please note, in this call NWO only accepts applicants belonging to category 'A. Academia' and 'B. Clinical/public health sector' as eligible for funding, insofar as these applicants are employed at the research organisations described above in this National Annex.</li> <li>Applicants belonging to categories 'C. Enterprises' and 'D. Operational stakeholders' are not eligible for funding by NWO. If fitting in the project scope, collaboration with partner(s) from categories C and/or D is encouraged in a co-funding capacity (in cash or in kind contribution by that partner).</li> <li>See 'Application, Eligibility criteria' (page 9) of the call text.</li> <li>Please note, NWO does not fund clinical studies.</li> <li>The NWO budget modules (including the maximum amount) available for this call for proposals are listed below. Apply only for funding that is vital to realise the project.</li> <li>Available budget modules</li> <li>Postdoc – at least 12 full-time months and at most 36 full-time months, according to UNL or NFU rates</li> <li>Research leave – max. 5 months, 1 FTE, according to UNL or NFU rates</li> <li>Material costs – max. € 15.000 per year per full-time scientific position (postdoc)</li> <li>Knowledge utilisation - max. € 25.000</li> <li>Internationalisation - max. € 25.000</li> <li>Please, note the following:</li> <li>Proposals are required to have at least one personnel position of 12 full-time months.</li> <li>For the budget module "Postdoc", a one-off individual bench fee of € 5.000 is added on top of the salary costs to encourage the scientific career of the project employee funded by NWO.</li> <li>PhD positions cannot be applied for in this call, due to the maximum project duration of 3 years.</li> <li>Overhead costs are not eligible</li></ul> |
|---|--|
| Submission of the proposal at the national level      | Once proposals are selected for funding, the consortia will be notified by the Joint Call Secretariat and subsequently the national granting process will be initiated by NWO.   |
| Submission of other information at the national level | Applicants are required to submit a mandatory NWO budget form in the full proposal stage separately per email to <a href="mailto:ERA4Health@nwo.nl">ERA4Health@nwo.nl</a> . Please refer to the detailed explanation of NWO budget modules to see which costs are eligible for NWO funding.  It is recommended to use the NWO financial details form already in the preproposal stage to confirm eligibility of budget items.  |
| Submission of financial and                           | Submission of financial and scientific reports at national level is required in accordance with the rules of NWO.  |

| scientific reports at the national level |  |
|--|--|
| Further guidance                         | Postdoc salary costs and Research leave are funded in accordance with the UNL or NFU salary tables applicable at the moment the grant is awarded (https://www.nwo.nl/en/funding/funding+process+explained/salary+tables).  The NWO Grant Rules 2017 (www.nwo.nl/en/nwo-grant-rules) and the Approval of funding for scientific research 2008 (www.nwo.nl/en/approval-funding-scientific-research-2008) are applicable to the part of the project's budget covered by the grant from NWO. Any arrangements made regarding the part of the project's budget covered by the grant from NWO, for instance in a consortium agreement, must comply with the NWO Grant Rules 2017 and the European legislation on state aid.  Under the Dutch General Administrative Law Act, any interested party has the right to lodge an objection to the decision taken by NWO within six weeks of the date of the decision letter. Further information about the objections procedure can be found on the NWO website: https://www.nwo.nl/en/lodging-objection. |

| Country  | Norway  |
|--|---|
| Funding organisation   | Research Council of Norway  |
| National contact person  | Cecilie A. Mathiesen  |
|  | cam@rcn.no  |
|  | +47 45690357  |
| Funding commitment   | 1 600 000 euro  |
| Anticipated number of fundable proposals                             | 4-6   |
| Maximum/ Minimum funding per grant awarded to a project partner      | If the Norwegian participant is a partner, maximum budget is 300 000 € If the Norwegian participant has a coordinator role, maximum budget is 400.000 €.  Total budget for Norwegian partners in a single project is 400 000 €.   |
|  | Norwegian universities, university colleges, hospitals, research institutes, public sector, user organisations, NGOs, SME and other private industry.   |
| Eligibility of partners  | The Research Council cannot award support to an enterprise that is defined as an "undertaking in difficulty" under the state aid rules (see the "Definition of 'undertaking in difficulty" on our website).   |
|  | "Enkeltpersonforetak", that is Norwegian companies with sole proprietorship, cannot participate as coordinator.   |
|  | Technology Transfer Offices (TTOs) are not eligible partners in this call   |
|  | Payroll expenses, procurement of R&D services, consumables, network measures. The RCN research project budget rules should be followed. However, PhD fellowships are not eligible within the RCN funding and if a postdoc fellowship is included, it must be sought for 2 years                         |
| Eligibility of costs, types and their caps                           | The overhead cost is included in the rates for personnel.   |
|  | SME or other industrial partner is funded with up to 50 % of their eligible project costs. Se details in the State aid rules  |
|  | For funded projects, the contractual budget will be in NOK using the exchange rate from the pre-proposal deadline.  |
| Submission of the proposal at the national level                     | If the proposal is granted, information about national registration will be given.  |
| Submission of other information at the national level                | No  |
| Submission of financial and scientific reports at the national level | Yes, if funded  |
| Further guidance   | We encourage you to learn about and use our "PartFinder" (Partner Search Tool), which allows you to match science and industry entities from around the World with each other. The search engine is available here: <a href="Partner">Partner</a> <a href="Search - ERA4HEALTH">Search - ERA4HEALTH</a> |

| Country   | Poland   |
|---|--|
| Funding organisation  | National Centre for Research and Development   |
| National agreement  | Dr Marcin Chmielewski T: +48 22 39 07 109 M: +48 571 226 666 marcin.chmielewski@ncbr.gov.pl  |
| National contact person   | Mateusz Skutnik  T: +48 22 39 07 148  M: +48 515 339 175  mateusz.skutnik@ncbr.gov.pl  Department of International Cooperation, ul. Chmielna 69, 00-801 Warszawa, Poland   |
| Funding commitment  | 1 250 000 €  |
| Anticipated number of fundable proposals                        | 3  |
| Maximum/ Minimum funding per grant awarded to a project partner | 400 000 € per project  |
| Eligibility of partners   | <ul> <li>Micro, Small, Medium and Large enterprise;</li> <li>Research organisation;</li> <li>Group of entities (within the meaning of art. 37 section 1, point 1a of The Act of 30 April 2010 on the National Centre for Research and Development, published in Journal of Laws item 2279, 2022;).</li> <li>Entity must be registered in Poland;</li> <li>For enterprises it is strongly advised to state in the Pre-proposal application form the KRS number of the enterprise and the size of the enterprise (micro/small, medium, large);</li> <li>A condition for the participation of a group of entities as the Applicant in the competition is its formal existence on the date of submission of the pre-proposal, confirmed by its members concluding, at least conditionally, agreement on the creation of a group of entities;</li> <li>Please note that group of entities counts as at least two project partners from Poland (it meets the limit on the number of participants from the same country, please refer to call text for details).</li> </ul> |
| Eligibility of costs,<br>types and their caps                   | The eligible costs shall be the following:  1. personnel costs (researchers, technicians and other supporting staff to the extent employed on the research project);   |

- 2. operating costs including costs of instruments, equipment, technical knowledge, patents, costs for buildings and land, costs of materials, supplies and similar products incurred directly as a result of the research activity.
- 3. cost of contractual research, costs of consultancy and equivalent services used exclusively for the research activity; this cost type cannot account for more than 70% of all eligible costs of a project; the subcontracting can be obtained from consortium partner only in justified case, this need will be verified by a national expert panel.
- 4. additional overheads incurred indirectly as a result of the research project; that costs are exactly 25% of eligible project costs and are counted as a multiplication by percentage given above and the rest of direct costs, excluding subcontracting (3); It means 4 = (1+2)\*25%.

Funding quota of Polish participants can be up to 100% for research organisations. In the case of enterprises, funding quota will be decided on a caseby-case basis depending on the size of the company, type of research/development, risk associated with the research activities and commercial perspective of exploitation, under the Regulation of the Minister of Science and Higher Education of 19 August 2020 on criteria and rules on granting state aid by the National Centre for Research and Development, published in Journal of Laws item 1456, 2020.

|                    | Large        | Medium       | Small        | Research      |
|--------------------|--------------|--------------|--------------|---------------|
|                    | Enterprises  | Enterprises  | Enterprises  | organizations |
| Fundamental/Basic  | Not eligible | Not eligible | Not eligible | Not eligible  |
| Research           |              |              |              |               |
| Industrial/Applied | Up to        | Up to        | Up to        | Up to         |
| Research           | 50+15        | 50+10+15     | 50+20+15     | 100 %         |
|                    | (max 65 %)   | (max 75 %)   | (max 80 %)   |               |
| Experimental       | Up to        | Up to        | Up to        | Up to         |
| development        | 25+15        | 25+10+15     | 25+20+15     | 100 %         |
|                    | (max 40 %)   | (max 50 %)   | (max 60 %)   |               |

Only Industrial/Applied Research and Experimental Development will be funded. Other type of activities (e.g. coordination, dissemination, management) is not eligible for funding as separate research tasks in the project schedule.

#### Submission of the the proposal at national level

Polish Participants will be informed and invited to submit Polish proposal once the international evaluation and the ranking list will be established.

### Submission of other information at the national level

and scientific reports at | Annual scientific reports are obligatory.

Submission of financial the national level

|                  | Sample documents are available at: <a href="https://www.gov.pl/web/ncbr/wniosek-krajowy">https://www.gov.pl/web/ncbr/wniosek-krajowy</a>  |
|------------------|---|
| Further guidance | We encourage you to learn about and use our "PartFinder" (Partner Search Tool), which allows you to match science and industry entities from around the World with each other. The search engine is available at: <a href="https://partfinder.ncbr.gov.pl/">https://partfinder.ncbr.gov.pl/</a> |

| Country   | Portugal   |  |  |
|---|--|--|--|
| Funding organisation  | Fundação para a Ciência e a Tecnologia (FCT)   |  |  |
| National contact person   | Rita Cavaleiro   |  |  |
| Funding commitment  | 500.000 €  |  |  |
| Anticipated number of fundable proposals                        | 2-3 proposals  |  |  |
| Maximum/ Minimum funding per grant awarded to a project partner | Maximum 250.000 € for PT coordination and maximum 150.000 € for PT participation.  Note: if more than one Portuguese institution participates in each consortium, the budget must be shared.   |  |  |
| Eligibility of partners   | For eligible institutions, please consult Article 3 of FCT's Regulation on projects funded solely by national funds.  Payments made to companies cannot exceed 50% of the total cost of the company shareholding ( Article 7 of FCT's Regulation on projects funded solely by national funds).  For eligibility criteria of beneficiaries and projects, please consult Articles 5 and 6 of FCT's Regulation on projects funded solely by national funds.   |  |  |
| Eligibility of costs, types and their caps                      | For eligible costs and non-eligible costs, please consult Articles 8 and 9 of FCT's Regulation on projects funded solely by national funds.  Please note that costs indicated in paragraph x of 1a) from Article 8 (In-kind contributions) of FCT's Regulation on projects funded solely by national funds do not apply to this call. For eligible costs, please also consult FCT's Financial Execution Rules.   |  |  |
| Submission of the proposal at the national level                | Yes, but only for full proposals selected for funding.   |  |  |
| Submission of other information at the national level           | Up to 10 working days after the deadline for submission of pre-proposals, Portuguese teams (coordinators and/or partners) must send the Statement of Commitment to the National Contact Points for the call (ERA4Health@fct.pt), duly signed by the Researcher in Charge and by the legal representative of the Proposing Institution and stamped (valid electronic signatures are accepted and in this case the institutional stamp is not required). The original must be kept, as it may be requested by the FCT. Portuguese applicants of transnational consortia that do not apply for funding from FCT do not need to submit the Statement of Commitment to FCT. |  |  |
|   | For purposes of follow-up and final assessment, beneficiaries submit annual scientific progress report(s) and one final scientific report through the FCT, I.P. portal.  |  |  |
| Further guidance  | For additional information, please check <u>FCT's Regulation on projects funded</u> solely by national funds and <u>Financial execution rules</u> .  The percentage of time dedicated to transnational projects is not considered to the percentage of time dedicated to existing national projects.   |  |  |

| Country   | Romania  |
|---|--|
| Funding organisation  | Executive Agency for Higher Education, Research, Development and Innovation Funding  |
| National contact person   | Mihaela Manole  E-mail: mihaela.manole@uefiscdi.ro  Phone: +40 21 302 38 63  Nicoleta Dumitrache  E-mail: nicoleta.dumitrache@uefiscdi.ro  Phone: +40 21 302 38 86   |
| Funding commitment  | 1 000 000 euro   |
| Anticipated number of fundable proposals                        | 4-5  |
| Maximum/ Minimum funding per grant awarded to a project partner | Funding rates vary in accordance with state aid legislation.  For more information: <a href="https://uefiscdi.ro/pachet-de-informatii-suprogramul-3-2-orizont-2020">https://uefiscdi.ro/pachet-de-informatii-suprogramul-3-2-orizont-2020</a> • 250.000 euro for all romanian partners in case a Romanian institution is the Coordinator;  • 200.000 for all romanian partners in case a Romanian institution is not the Coordinator.  |
| Eligibility of partners   | Eligible entities for funding are universities, public institutions, R&D national institutions, joint-stock companies, SME's and Large companies, NGOs (associations, foundations, etc.), others.  |
| Eligibility of costs,<br>types and their caps                   | a. Staff costs; b. Logistics expenses  - Capital expenditure; - Expenditure on stocks - supplies and inventory items; - Expenditure on services performed by third parties cannot exceed 25 % of the funding from the public budget. The subcontracted parts should not be core/substantial parts of the project work;  c. Travel expenses; d. Overhead (indirect costs) is calculated as a percentage of direct costs: staff costs, logistics costs (excluding capital costs and cost for subcontracting) and travel expenses. Indirect costs will not exceed 20 % of direct costs. |

| Submission of the proposal at the national level                     | NO                                 |                      |                          |                            |   |
|--|------------------------------------|----------------------|--------------------------|----------------------------|---|
| Submission of other information at the national level                | NO                                 |                      |                          |                            |   |
| Submission of financial and scientific reports at the national level | NO                                 |                      |                          |                            |   |
|  | Maximum funding perc               | Large<br>Enterprises | Medium<br>Enterprises    | Small<br>Enterprises       | Universities and research organisations |
| Further guidance   | Fundamental/<br>Basic Research     | 100                  | 100                      | 100                        | 100                                     |
| 3  | Industrial/<br>Applied<br>Research | Up to 50+15 (max 65) | Up to<br>60+15 (max 75%) | Up to<br>70+10<br>(max 85) | 100                                     |
|  | Experimental development           | Up to 25+15 (max 40) | Up to<br>35+15 (max 50)  | Up to<br>40+15<br>(max 65) | 100                                     |

| Country   | Slovakia  |  |  |
|---|---|--|--|
| Funding organisation  | Slovak Academy of Sciences  |  |  |
| National contact  | Katarina Bibova   |  |  |
| person  | bibova@up.upsav.sk  |  |  |
| Funding commitment  | 240.000€  |  |  |
| Anticipated number of fundable proposals                        | 2   |  |  |
| Maximum/ Minimum funding per grant awarded to a project partner | t<br>Up to 120 000€ per project   |  |  |
|   | Only research Institutes of the Slovak Academy of Sciences are eligible organisations for funding by SAS (up to 100%).  |  |  |
|   | 1. The Slovak principal investigator must have a job contract for more than 50% working hours in the SAS organization for which the project proposal or participation in the project proposal is submitted.   |  |  |
| Eligibility of partners   | 2. Other researchers, except for doctoral students, must have a working relationship with the SAS organization.   |  |  |
|   | 3. Each researcher of the Slovak partner research team of a project consortium (other than the Slovak Principal Investigator) must have a job contract with or a fellowship with the Slovak Principal Investigator, lasting until the end of the project or beyond. |  |  |
|   | Total eligible costs = Permanent salaries + Other costs (DC + IC)   |  |  |
|   | • Permanent salaries 45 000 € (36 months)   |  |  |
|   | • Other costs: 75 000 € (36 months)   |  |  |
| Eligibility of costs, types and their caps                      | Direct costs (DC): Personnel (max. 15% of DC), Consumables, Equipment (max. 40% of DC) and Travel costs   |  |  |
|   | Indirect costs (IC, Overheads): max. 20 % of DC.  |  |  |
|   | Limitations and specifications are available: (https://oms.sav.sk/wp-content/uploads/Financne-pravidla-od-1.12023-schvalene-P-SAV-15.12.2022.pdf)   |  |  |
| Submission of the proposal at the national level                | ,   |  |  |

| Submission of other information at the national level                | no                         |
|--|----------------------------|
| Submission of financial and scientific reports at the national level | Annual financial reporting |
| Further guidance   |                            |

| Country   | Spain  |   |   |   |
|---|--|---|---|---|
| Funding organisation  | Agencia Estatal de Investigación   |   |   |   |
| National contact person   | María Gavira Era4Health@aei.gob.es   |   |   |   |
| Funding commitment  | 1.000.000 €  |   |   |   |
|   |  |   |   |   |
| Anticipated number of fundable proposals                        | 6-8  |   |   |   |
|   | The following <b>funding limit</b> eligibility criteria. Proposals ineligible.   | not respecting t  |   | d be declared                                     |
|   |  | Direct costs  | Indirect costs  | Total costs                                       |
|   |  | (€)*  | (€)*  | (€)   |
|   | Applicant (not coordinator)  | 140.000   | 35.000  | 175.000   |
|   | Coordinator applicant  | 220.000   | 55.000  | 275.000   |
|   | Coordinator applicant and one more applicant   | 260.000   | 65.000  | 325.000   |
| Maximum/ Minimum funding per grant awarded to a project partner | * The direct costs in the application must be rounded to the thousands. Indirect costs are 25% of direct costs requested  • Additional £ 30,000 (direct costs) can be granted for the entire |   | are only national s, see below). ication work for AEI                             |   |
| Eligibility of partners   | For this NANOTECMEC corganizations (such as uncenters and other private notin Spain). They must have becalls and they must ensure Investigator during the who                                | all the AEI w<br>niversities, reso<br>on-profit institu<br>een previously<br>e contractual re | ill fund non-prearch centers, tions performing beneficiaries of a lationship with | technological<br>RDI activities<br>any of the AEI |

Be aware that applicants from the Accredited Health Research Institutes (IIS), hospitals, primary health care or public health administration of the Spanish National Health System (SNS) and CIBER need to apply for funding to the Instituto de Salud Carlos III (ISCIII), also participating in this call.

After the evaluation process and based on their budgetary availability and requested funding of selected projects, AEI and ISCIII reserve the right to exchange applicants to each other in order to optimize the available funds, provided the respective eligibility rules are met.

IMPORTANT: Spanish legal entities which are part of mixed centres will be considered as a unique beneficiary, and thus the maximum funding should not exceed the limits per proposal established above.

Although not foundable by the AEI, the private sector is encouraged to participate in consortia with academic groups, using their own funds or applying to national or regional calls by CDTI or regional innovation agencies. This is especially encouraged when there are for profit companies from other countries in the consortium or for projects coordinated by Spanish PIs.

## **Eligibility criteria for PIs**

The Spanish Principal Investigators (PIs) must hold a PhD degree.

PIs must be eligible according to the requirements of <u>PCI 2023-1</u> call and must have experience as investigators (not necessarily as PIs) in projects funded by the Plan Nacional I+D+i 2008-2011, the Plan Estatal I+D+i 2013-2016, the Plan Estatal I+D+i 2017-2020, ERC Grants, European Framework Programmes or other relevant national or international programmes.

# Incompatibilities (these must be taken into account when participating in different ERA-Nets or other international initiatives):

- PIs will not be eligible for funding if they apply as PIs to more than one proposal in this transnational joint call (including those requesting to the ISCIII), to more than one proposal in the same Spanish PCI call and/or to PCI calls of consecutive years.
- If the same PI submits two or more proposals to the present call, all but one will be declared ineligible, without the possibility of changing the PI.
- A PI that has been granted a PCI the previous year will be declared ineligible, without the possibility of changing the PI.
- PIs must remain unchanged between the pre and full proposal of this transnational joint call, and the national PCI call.

The AEI will avoid double funding and will not grant projects or parts of projects already funded through other national or EU calls.

| Eligibility of costs,<br>types and their caps                        | <ul> <li>Only personnel costs for exclusive dedication to the project are eligible. The costs of permanent staff linked to the beneficiary entity or members of the research team will not be considered eligible costs.</li> <li>Direct costs such as current costs, small scientific equipment, disposable materials, travelling expenses, coordination costs, and other costs that can be justified as necessary to carry out the proposed activities.</li> <li>Indirect costs (overheads) are eligible costs (25% of total direct costs, including subcontracting).</li> <li>Subcontracting should not exceed 25% of total requested budget.</li> <li>Clinical trials are eligible up to phase 1, with a maximum of 50% of the total budget</li> <li>Please consult "Artículo 8. Conceptos financiables" in PCI 2023-1 resolution since eligible cost will be similar.</li> </ul> |  |
|--|---|--|
|  | Submission of the pre and full proposal at the national level:  |  |
| Submission of the proposal at the national level                     | Not mandatory. However, PIs and beneficiaries are strongly encouraged to check eligibility before submitting a pre-proposal, since <b>no changes will be accepted afterwords</b> . No PI or beneficiary changes will be accepted between pre and full proposal and the national call.  Funding Programme:  The framework for this funding action is the Plan Estatal de Investigación Científica, Técnica e Innovación 2021-2023. On a national level, the Call will be managed by the Subdivisión de Programas Científico-Técnicos Transversales, Fortalecimiento y Excelencia (STRAN) of the AEI.  Instrument for funding  The instrument for funding the Spanish groups is the call for "Proyectos de Calabaración Interposicional (PCI)" Applicants, are encouraged to  |  |
|  | de Colaboración Internacional (PCI)". Applicants are encouraged to carefully read the call PCI 2023-1 and the general requirements.   |  |
| Submission of other information at the national level                | Applicants are encouraged to carefully read the call PCI 2023-1 and the general requirements  |  |
| Submission of financial and scientific reports at the national level |   |  |
|  | Acknowledgement:  |  |
| Further guidance   | Any publication or dissemination activity resulting from the granted projects <a href="must"><u>must</u></a> acknowledge funding by the Agencia Estatal de Investigación according to AEI's web <u>guidelines</u> .  Beneficiaries are obliged by these requirements and those of the internacional call.   |  |

## **Data Protection:**

By submitting a grant application, the applicants consent to communication of the data contained in the application to other public administrations, with the aim of further processing of the data for historical, statistical or scientific purposes, within the framework of the Organic Law 3/2018, of December 5, on Personal Data

| Country  | Spain  |
|--|--|
| Funding organisation   | Institute of Health Carlos III (Instituto de Salud Carlos III- ISCIII)   |
| National contact person  | Astrid Valencia Quiñónez<br>email: <u>ma.valencia@isciii.es</u><br>Tel: (+34) 91 822 2227  |
| Funding commitment   | National Programme: Acción Estratégica en Salud (AES 2024)<br>1.600.000 € (pending of approval of Spanish State Budget)  |
| Anticipated number of fundable proposals                                 | 5-6  |
| Maximum/ Minimum<br>funding per grant<br>awarded to a project<br>partner | Maximum funding from ISCIII per awarded Spanish project:  If a Spanish Partner requesting funding to the ISCIII IS NOT the Coordinator of the transnational project:  • 220.000€ (overheads included), if there is only one Spanish Partner requesting funding to the ISCIII in the proposal.  • 275.000€ (overheads included), if there are two Spanish Partners requesting funding to the ISCIII in the proposal.  If a Spanish Partner requesting funding to the ISCIII IS the Coordinator of the transnational project:  • 320.000€ (overheads included), if there is only one Spanish Partner in the proposal, acting as a coordinator.  • 400.000€ (overheads included), if there is one Spanish Partner in addition to the Spanish Coordinator in the proposal, both requesting funding to the ISCIII.  Overheads according to AES 2024: 25%  Projects' duration: from 24 months to 36 months  The level of funding will take into account the evaluation of the collaborative proposal, the scientific quality of the Spanish group, the added value of the international collaboration, the participation of the primary health care and the financial resources available. |
| Eligibility of partners  | A maximum of two partners requesting funding from ISCIII may participate in the same project proposal.   |

### **Eligible Institutions:**

- Accredited Health Research Institutes (Institutos de Investigación Sanitaria acreditados, IIS). Accredited according to the RD 279/2016 (These institutions may manage research via a foundation regulated according to the Spanish Act 50/ 2002, of December 26th). See the list of IIS in this link.
- Hospitals, primary health care or public health administration of the Spanish National Health System (SNS). These institutions may manage research via a foundation regulated in accordance to the Spanish Act 50/2002, of December 26th (a copy of the foundation's statutes may be submitted).
- CIBER: team members applying to the call must be from at least two groups belonging to CIBER in two different home institutions and one of these two should be a hospital, primary health care or public health administration of the Spanish National Health System (SNS) or Accredited Health Research Institutes (Institutos de Investigación Sanitaria acreditados, IIS). Please contact Cristina Rodríguez (cristina.rodriguez@ciberisciii.es) for more information related to CIBER's eligibility.
- Private health entities and institutions and Public Research Institutions (OPIs) as defined in article 47 of Law 14/2011, of 1 June, in accordance with the provisions of Royal Decree 202/2021, of 30 March. These entities can only participate if they apply together with hospitals, primary health care or public health administration of the Spanish National Health System (or Accredited Health Research Institutes (IIS) in the same proposal. It is not allowed for these entities to apply independently, thus there must be two beneficiary Spanish institutions requesting funding to ISCIII in the same proposal.
- Applicants not related with the National Health System from non-profit research organizations such as universities, technological centres and other private nonprofit institutions performing RDI activities in Spain need to apply for funding to the Agencia Estatal de Investigación (AEI), following their eligibility criteria. It is highly recommended to this type of members to integrate in their consortium other Spanish clinical partner (IIS/SNS/CIBER) eligible for funding by ISCIII.

|   | NOT eligible institutions:   |  |
|---|--|--|
|   | - Those declared by AES 2024 as ineligible to receive funds by ISCIII.   |  |
| Additional clause regarding available grant | After the evaluation process and based on their budgetary availability and requested funding of selected projects, AEI and ISCIII may exchange applicants to each other in order to optimize the available funds, provided the respective eligibility rules are met.   |  |
|   | <ul> <li>Principal Investigators (PI) shall mandatory have PhD degree.</li> </ul>  |  |
|   | <ul> <li>Principal Investigators (PI) can only participate in one<br/>project proposal per call.</li> </ul>  |  |
|   | <ul> <li>Principal Investigators (PIs) belonging to an Accredited<br/>Health Research Institutes (IIS) could apply only from the<br/>IIS.</li> </ul>   |  |
|   | <ul> <li>The Principal Investigator (PI) and all members of the<br/>research group must belong to the eligible institutions in<br/>the call.</li> </ul>  |  |
|   | <ul> <li>Only one PI per beneficiary institution may be funded<br/>within the same proposal.</li> </ul>  |  |
| Eligibility of PI and team members          | <ul> <li>PIs that has an ongoing International Collaboration (PCIN) project of the same initiative and purpose that this call and that the project has an ending date after the 31st December 2024 will not be able to apply for this call. This incompatibility will affect only to the PI. And this incompatibility will not apply in the case that the PI participate as coordinator in the new application or in the ongoing project.</li> </ul> |  |
|   | For additional incompatibilities please review AES 2024.   |  |
|   | Excluded personnel as Principal Investigator (PI):   |  |
|   | <ul> <li>Those undergoing a postgraduate training in Health<br/>Specialization (MIR, EIR, FIR, QIR, BIR, PIR, RFIR).</li> </ul>  |  |
|   | <ul> <li>Those undergoing research training (e.g. PhD students, or<br/>"Río Hortega" contracts).</li> </ul>  |  |

|  | <ul> <li>Those undergoing postdoctoral training (e.g. "Sara Borrell" or "Juan de la Cierva" contracts).</li> <li>Researchers contracted by a RICORs and platforms funded by ISCIII.</li> </ul>   |
|--|--|
|  | Personnel costs:   |
|  | <ul> <li>Personnel costs will be eligible for contracts with the<br/>needed professional category (superior technician, BSc<br/>(grado), MSc (máster), PhD (doctor) for the project<br/>development accordingly to the published salary tables in<br/>ISCIII's webpage / AES2024.</li> </ul>   |
|  | <ul> <li>Contracts for PhD students will be done in the framework<br/>of National Subprogramme for Training (scholarships are<br/>not eligible).</li> </ul>  |
| Eligibility of costs, types                            | <ul> <li>Personnel costs will NOT be eligible when they correspond<br/>to civil servants or the equivalent personnel (as specified in<br/>the Art. 3.4 of AES2024) either employed by the beneficiary<br/>entities or belonging to the research team.</li> </ul>   |
| and their caps   | <ul> <li>Personnel costs will be eligible when corresponding to<br/>contracts under the frame of Art. 23bis of Law 14/2011, 1st<br/>June, following the specifications established in AES2024.</li> </ul>  |
|  | <ul> <li>Other eligible costs: Current costs, small scientific equipment,<br/>disposable materials, travelling expenses, complementary<br/>expenses (use of central and general research support services<br/>of the beneficiary entity), publication and dissemination of<br/>results and other costs as included in AES 2024 that can be<br/>justified as necessary to carry out the proposed activities.</li> </ul> |
|  | • Overheads, according to AES 2024 (25%)   |
|  | Double funding of the same concept is not allowed.   |
|  | National applications will be required by ISCIII.  |
| Submission of the<br>proposal at the national<br>level | Due to administrative and legal regulations, the Institute of Health Carlos III establishes the <b>31st October 2024</b> as the national deadline for the decision on fundable project consortia which includes Spanish partners to be funded by ISCIII, which must present their national application in the period stated in AES 2024.   |
|  | Any concerned applicant in a proposal for which no final decision has been made by the deadline of <b>31/10/2024</b> , could be declared not fundable by ISCIII.   |

| Submission of other information at the national level                    | As specified by AES 2024.  |
|--|--|
| Submission of financial and scientific reports at the national level     | As specified by ISCIII's instructions (please check ISCIII's webpage).   |
| Submission of a pre-<br>eligibility document<br>needed at national level | In order to expedite the eligibility check process, it is mandatory that all the applicants submit the <a href="mailto:CVA-ISCIII">CVA-ISCIII</a> of the PI.  This document shall be submitted by the PI by electronic email before the proposal submission deadline to: <a href="mailto:ma.valencia@isciii.es">ma.valencia@isciii.es</a>  |
| Requirements on data and repositories                                    | <ul> <li>Researchers funded by ISCIII must make public the human genomic data, as well as relevant data (phenotype and exposition data) generated inside the funded project and will use open access repositories. Researchers must also make public all the necessary information for the interpretation of these genomic data, including lab protocols, data instruments survey tools. Regarding genomic data it is understood: association of complete genomes (GWAS), matrixes of polymorphism of a single nucleotide (SNP) and sequence of genome, and transcriptomic, metagenomic, epigenomic and gene expression data. The researchers whose projects are funded by ISCIII are recommended to store their scientific data at the "ELIXIR Core Data Resources", or if non-European repositories or data bases are to be used they must be certified by ELIXIR or the US National Center for Biotechnology Information (NCBI).</li> <li>ISCIII may not fund any project that may require a repository and/or a data base without a plan ensuring sustainability and decommissioning after the end of funding</li> </ul> |
| Requirements for clinical studies  | Spanish groups that are involved on the performance of a clinical trial in the proposal, are recommended to include in their team a member from their scientific node of the EU Clinical Trials Network (SCReN or ECRIN-ERIC) or if it does not exist, a member from the personnel of their Clinical Research Supporting Platform of their institutions (UIC).   |
| Use of Research infrastructures and platforms                            | Researchers funded by ISCIII are encouraged to make use of the resources available through the European Research Infrastructures and the Spanish Platforms funded by ISCIII for supporting the biomedical and health R&I.  |

# Acknowledgements

Any publication, data base, product or event protected with IPR or not, resulting from the granted project must acknowledge "Award no. XX by Instituto de Salud Carlos III (ISCIII) through AES 2024 and within the ERA4Health Partnership" even after the end of the project, including other specific acknowledgments that could be requested by ISCIII to the granted project. For more information please see ISCIII's ROR here.

| Country   | Spain   |
|---|---|
| Funding organisation  | Consejería de Salud y Consumo de la Junta de Andalucía  |
| National contact person   | Alicia Milano Curto Tel: +34 955040450 email convocatorias.fps@juntadeandalucia.es  |
| Funding commitment  | 250.000,00 €  |
| Anticipated number of fundable proposals                        | 1-2   |
| Maximum/ Minimum funding per grant awarded to a project partner | 125.000€, 250.000€ if coordinator (including 21% indirect costs)  |
| Eligibility of partners   | <ul> <li>Eligibility criteria established in Orden de 10 de agosto de 2023 de la Consejería de Salud y Consumo de la Junta de Andalucía.</li> <li>Eligible organisation must be Andalusian Non-profit entities registered as Agents of the Andalusian Knowledge System (Registro de Agentes Andaluces del Conocimiento) with research and innovation activity in Biomedicine and Health Sciences, ie: Research managing foundations of the Andalusian Public Health System</li> <li>Principal investigators must be linked through a civil servant, statutory or labour relationship with the applicant or performing centre. For Health Research Institutes (Institutos de Investigación Sanitaria, IIS), the link may be with any of the public or private law entities that are part of the IIS provided that the entity meets all the specific requirements determined in each action, and, in any case, be personnel assigned to the IIS.</li> <li>More than one partner from Andalusia may participate in the same project</li> <li>A PI can only participate in one application per call.</li> <li>For receiving regional funding, the final funding decision issued by the corresponding program's decision-making body must be accredited</li> <li>The duration of the projects shall be determined by the corresponding JTC. In any case, this period shall be stated in the award resolution.</li> </ul> |
| Eligibility of costs,<br>types and their caps                   | a) Goods and services: consumables, bibliographic material, equipment rentals, software licenses and external services. b) Personnel costs: specifically hired for the project, including salaries, employer Social Security contributions, legally established compensation and other duly justified expenses derived. c) Travel, accommodation and subsistence according to the maximum amounts of compensation for service established in Decree 54/1989, of March 21, on compensation for service of the Junta de Andalucía, exclusively for people who are part of the research group or hired under the funded project. Exceptionally, any expense outside these amounts, or for people other than those listed before, must be authorised by the granting  |

body. d) Registration fees for congresses or conferences for the presentation and dissemination of the results. Publication costs: e) Other expenses duly justified and necessary for carrying out the project. f) Indirect costs 21% g) Subcontracting costs: cannot exceed 50% of the funding and need prior authorization from the granting body. Nor Scientific aspects nor the management of the project should be subcontracted. The following are not considered eligible expenses - Equipment or Equipment repair and maintenance - Items or amounts that, after analysis, are not considered justified - Amounts paid to persons participating in the project, with the exception of expenses necessary for special attention to patients that involve compensation for their participation in the project not derived from an employment relationship. The sum of the funding or income received for the same purpose may in no case exceed the cost of the funded activity. Regional applications must be submitted to the General Secretariat of of Public Health and R&D&I in Health exclusively by telematic means Submission the (please see section 10.c Orden de 10 de agosto de 2023). proposal at the The deadline for the submission of regional applications will be national level established in the regional call and will be informed through the website of the Regional Ministry of Health and Consumer Affairs. The documents to be provided are detailed in section 14 of the Orden de 10 de agosto de 2023) Submission of other For projects involving invasive procedures on human beings, their information at the biological material and/or clinical data, a favourable report or a national level document accrediting the request for its evaluation by the Biomedical Research Ethics Committee has to be provided Submission of financial Beneficiaries must submit financial and scientific reports to Consejería de and scientific reports at Salud y Consumo de la Junta de Andalucía (please see section 22.b) 3º and the national level 25.f) 1º Orden de 10 de agosto de 2023) The projects must respect the fundamental principles established in national and international declarations, protocols and conventions on research ethics, as well as respect the requirements established in national and regional legislation in the field of biomedical research, development and innovation, personal data protection and bioethics. **Further guidance** When the results are not susceptible to protection of industrial or intellectual property rights, the scientific publications resulting from the funding granted must be made available in open access, in accordance with article 37 of Law 14/2011, of June 1.

| Country  | Taiwan  |
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| Funding organisation   | National Science and Technology Council   |
| National contact person  | Dr. Ching-Mei Tang  |
|  | Email: cmtom@nstc.gov.tw  |
|  | Tel: +886-2-2737-7557   |
| Funding commitment   | 810,000€  |
| Anticipated number of fundable proposals                             | 2-3   |
| Maximum/ Minimum funding per grant awarded to a project partner      | -The maximum amount per year per project is €90,000.00 (about NTD3,000,000).  |
|  | -The decision regarding the exact amount of the grant is dependent on the result of the NSTC's internal reviews.  |
|  | -The number of grants of every principal investigator must comply with NSTC's regulation of the max number of two international cooperation projects granted by NSTC for the same duration.   |
| Eligibility of partners  | All research institutes, universities, hospitals, public organisations in Taiwan endorsed by the National Science and Technology Council (NSTC) as eligible institutions  |
| Eligibility of costs, types and their caps                           | Including personnel, consumables, hosting expenses for foreign researchers, and travel expenses for international destinations-joint research & overseas studies, for more information please refer to: https://www.nstc.gov.tw/folksonomy/list/f6d5c23c-b3ce-438e-911b-12a705dbac5a?l=ch                   |
| Submission of the proposal at the national level                     | No official national application is needed in the pre-proposal or full proposal phase. But must notify the national contact person in the National Science and Technology Council of your submission to the ERA4Health joint transnational call via email, together with your application as an attachment. |
| Submission of other information at the national level                | -Taiwanese project partners shall submit a proposal to the NSTC for national financing after the project has been selected and approved for funding through the ERA4Health evaluation and selection process.  |
|  | -The proposals are required to be submitted to NSTC for funding as soon as possible as the internal process of the NSTC generally takes 6 months.   |
| Submission of financial and scientific reports at the national level | please refer to: https://www.nstc.gov.tw/folksonomy/list/f6d5c23c-b3ce-438e-911b-12a705dbac5a?l=ch  |

| Country  | Türkiye  |
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| Funding organisation   | TUBITAK  |
| National contact   | Şükran Alpdemir  |
| person   | sukran.alpdemir@tubitak.gov.tr   |
| Funding commitment   | 600 000 Euros (TBC)  |
| Anticipated number of fundable proposals                             | 2-3 projects   |
| Maximum/ Minimum funding per grant awarded to a project partner      |  |
| Eligibility of partners  | For further information about application rules and procedures, please refer to the related TUBITAK website.   |
| Eligibility of costs, types and their caps                           | For further information about application rules and procedures, please refer to the related TUBITAK webpage.   |
| Submission of the proposal at the national level                     | Yes  |
| Submission of other information at the national level                | Yes  |
| Submission of financial and scientific reports at the national level | Yes  |
| Further guidance   | Participants from Türkiye should also submit their proposals to TUBITAK electronically via ( <a href="https://uidb-pbs.tubitak.gov.tr/">https://uidb-pbs.tubitak.gov.tr/</a> ) for the pre-proposal phase. Only the PIs from successful projects that are listed for funding after the second stage of international evaluation are required to submit their full proposals. The applications should be completed via e-signature. |