

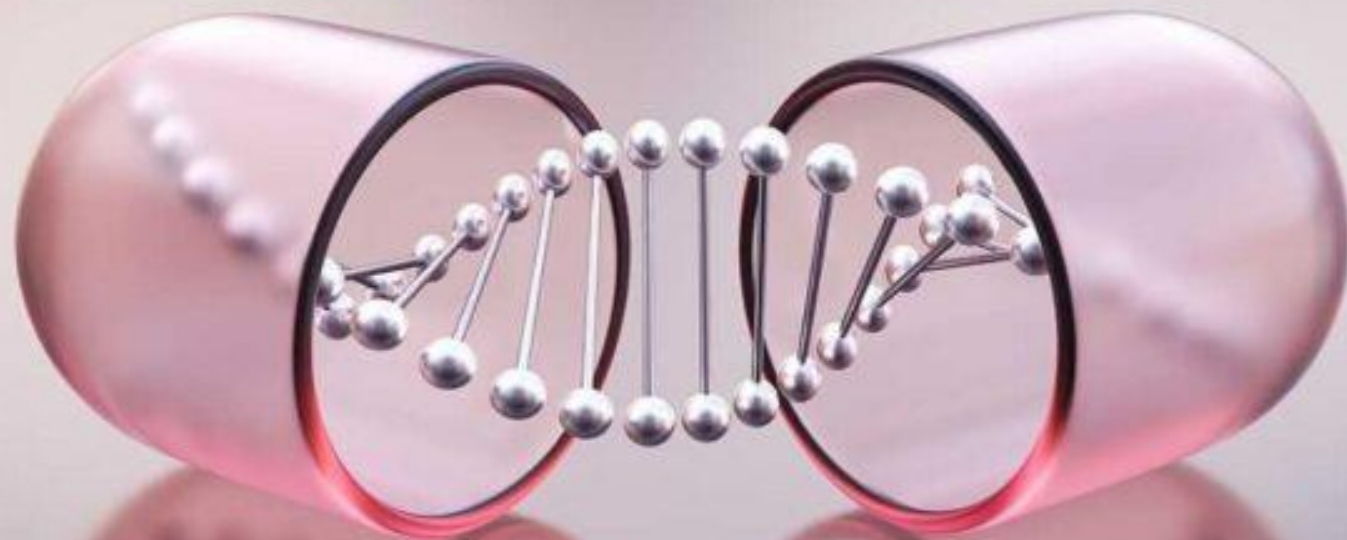


**ERA4Health
Partnership**

"Nano and advanced technologies for disease prevention, diagnostic and therapy call"

#NANOTECMCMEC_E4H



NANOTECMCMEC INFO DAY



21st of November
10h-12h CET, online



**Co-funded by
the European Union**

Follow us:  

Joint Transnational Call on Nanomedicine

« Nano and advanced technologies for disease prevention,
diagnostic and therapy »

NANOTECEMEC

Dr Anaïs Fradet and Dr Mérick Machouri

November 21th, 2023

<https://era4health.eu/nanotecmec-2024/>



Co-funded by
the European Union

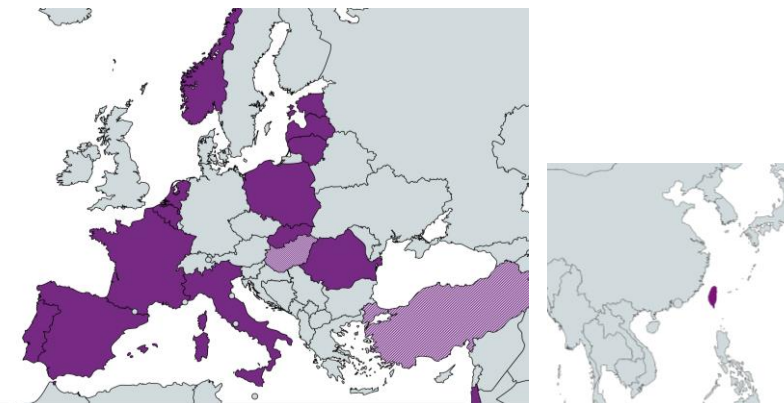
NANOTECMEC – ERA4Health 2024

21 funding organisations

17,7 M€

18 countries: BE, ES, FR, IL, IT, LV, LT, NL, NO, PO, PT, RO, SV, SP, TW
(2 pending countries: HU, TR)

3 EU regions: BE (Wallonia-Brussels, Flanders), ES (Andalusia)



Joint Call Secretariat (JCS):
The French National Research Agency (ANR)
Dr. Anaïs Fradet and Dr. Mérick Machouri :
nanotecmec@agencerecherche.fr
+33 1 73 54 81 74/ +33 1 72 73 06 72

Summary

Scope of the call

Eligibility criteria

Partner search

**Pre-proposal
template**

Submission tool

“

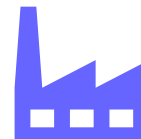
The scope of the call

Scope of the call



Aims of the call:

1. To support **translational research** projects that combine innovative approaches in the field of nanomedicine
2. To encourage and enable **transnational collaboration** between academic and clinical or private R&D research teams



Scope of the call



Topics addressed:

- a. Regenerative medicine
- b. Diagnostic
- c. Nanotherapy

Proposals based on nanoscale naturally occurring processes or structures will be rejected

Scope of the call



Proposals may include, but not limited to:

- 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
- 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

Scope of the call



Categories according to Technology Readiness levels:

1. Innovation applied research projects : TRL 3-4

→ 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.

2. Projects with high potential of applicability at short/ medium term : TRL 5-6

→ 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).

At the end, projects should fall within, but are not limited to, TRL 3-6 ; advancement of 2 TRL max

Scope of the call



Important points: studies

- Study of **other Key Enabling Technologies only in complement or combination** with nanotechnologies (Micro- and nano-electronics, advanced materials, biotechnology, photonics, advanced manufacturing systems, artificial intelligence, other digital technologies)
- When applicable, make use of **existing biobanks and existing cohorts**
- Must consider **potential moderators of effects** such as age, sex, gender and ethnic or other demographic features/differences
- Use of approaches from **precision medicine and personalized medicine** is encouraged

Scope of the call



Types of studies:

- ✓ Cellular, 3D and patient models (preferred to animal models)
- ✓ *In vitro* studies
- ✓ *In silico* studies
- ✓ Small-scale clinical studies (up to phase 2)
- ⊘ Other clinical studies

Scope of the call



Important points: general

- Duration of **36 months**
- Must demonstrate **potential health impact and/or economic impact** and **added-value of transnational collaboration**
- Must promote **translational research**
- Must follow and respect **RRI (Responsible Research and Innovation)**, application of **bedside to bench to bedside approach** is strongly recommended
- Should consider **gender balance** and the participation of **early career scientists** in the consortium

“

Eligibility criteria

Funding Modalities

National/Regional Rules

- Applicants funded by respective national/regional funding organisations
- Check their eligibility according to the funding organisation rules: Annex I of the call text (p26)
- Reach the national contact person



A partner non-eligible by a funding organisation can lead to rejection of the entire proposal

➔ A non-eligible partner can participate as a Collaborator, on its own funds

Country	France
Funding organisation	French Research Funding Agency
National person contact	Anais Fradet/Mérick Machouri 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	ANR funding will be limited to 250 000 € per French applicant. For a French Partner taking over the coordination of the project, the maximum budget can be increased up to 300 000 €. Minimum amount per partner: 15 000 €. 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 « Modalités pour les partenaires sollicitant une aide de l'ANR ». These rules are specified in ANR's "ANR Funding regulations" along with the

National/Regional funding organisations

Points of attention

- Funded entity : Academia, Clinical/public health sector, Enterprises and/or Operational stakeholders
- Type of studies : pre-clinical, up to phase 2 of the clinical trials
- Maximum funding per partner/coordinator, per project
- Eligible costs
- Required the submission of additional document(s)/process at the national/regional level



Any doubts, reach your national/regional contact person

General Rules

Composition of a consortium

- A. Academia
- B. Clinical/public health sector
- C. Enterprises
- D. Operational stakeholders

Each consortium must include partners from **at least two of the three categories A, B and C.**

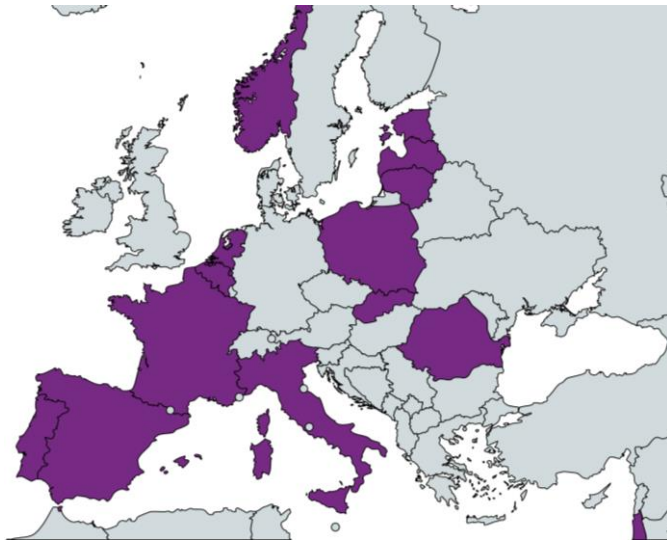
General Rules

Composition of a consortium

Minimum of 3 eligible partners
Maximum of 5 eligible partners

From 3 different countries participating to the call

No more than 2 eligible partners from the same country



- Belgium – Flanders
- Belgium – French
- Estonia
- France
- Israel
- Italy
- Latvia
- Lithuania
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Spain (national level)
- Spain – Andalusia
- Taiwan
- The Netherlands

General Rules

Composition of a consortium

Eligible partner **from under-representated countries** in the consortium allow to increase the total number of partners

- Latvia
- Lithuania
- Slovakia
- Türkiye (pending)

1 partner from an under-representated country

Up to 6 partners in the consortium

2 partners from an under-representated country

Up to 7 partners in the consortium

General Rules

Composition of a consortium

Collaborators: self-funded partners

- From non-funding countries
- Partners which are not fundable according to national/regional regulations of the participating funding organizations

Application conditions:

- Maximum of 2 collaborators
- Clear added value for the research project.
- Secure own funding for participation.
- A letter of commitment of the collaborator(s)
- A collaborator cannot be work package leader.

General Rules – Composition of the consortium

The smallest consortium

3 eligible partners

- From 3 different countries

The biggest consortium

7 eligible partners + 2 collaborators

- Eligible partners from at least 3 different participating countries
- Including 2 eligible partners from 2 under-represented countries

General Rules - Other

- Number of proposals allowed to be submitted by a principal investigator:
 - Submission of one proposal as project coordinator
 - Or up to two proposals as mere partner
- Submission of the proposal only through the submission Pt-outline before January 30th, 2024 at 16:00 CET
- Respect of the pre-proposal template

Checklist for the eligibility criteria

Pre-proposal template

Checklist for the Coordinator

In order to make sure that your proposal will be eligible for this call, please collect the information required to tick all the sections below. Please consult the call text for further details.

- Topic of the proposal:

- The project proposal addresses the aims of the call.
- The project proposal meets the topics in this call.

- The composition of the consortium:

- The project proposal involves at least 3 eligible project partners requesting funding from at least 3 different countries participating in the call.
- The project proposal does not include more than 2 eligible project partners from the same country participating in the call.
- The project proposal does not exceed the maximum of 5 project partners (6 or 7 if the consortium includes 1 or 2 partners, respectively, from the following countries Latvia, Lithuania, Romania, Slovakia, Turkey).
- Each eligible partner is represented by a single principle investigator.
- The coordinator is eligible for funding.
- The project proposal does not exceed the maximum of 2 collaborators (self-funded partners) and the letter of intent is included in the joint pre-proposal PDF for each collaborator.
- The coordinator and the majority of partners in the consortium are eligible partners (not collaborators).

- **Eligibility of project partners:**

- Each project partner involved in the proposal has checked its eligibility to receive funding by its funding organisation (see Annex I of the call text).
- All partners should sign the pre-proposal application form and declare they did not receive other public funding to perform the described tasks.
- If my consortium includes a partner funded by F.R.S.-FNRS, only pre-clinical studies can be funded for this partner.
- If my consortium includes a partner funded by FWO, only pre-clinical studies can be funded for this partner.
- If my consortium includes a partner funded by AEI, clinical trials are eligible but only up to phase 1 for this partner.
- If my consortium includes a partner funded by FWF, F.R.S.-FNRS, FWO, CSO-MoH, It-MoH, MUR, FCT, CSCJA, or TUBITAK, I made sure that this partner performed the national requirements / sent required information (submission of national documents to its funding organization).

- **National general conditions:**

Please check the national and regional rules applicable to each project partner in the Annex I of the call text.



“

Questions about the general rules

Joint Call Secretariat (JCS):
The French National Research Agency (ANR)
Dr. Anaïs Fradet and Dr. Méric Machouri :
nanotecmec@agencerecherche.fr
+33 1 73 54 81 74/ +33 1 72 73 06 72

“

Partner search tool

PART FINDER: <https://era4health.eu/partner-search/>



The Partnership

Preannouncements

Funding Opportunities

Results

News, Events & Newsletters

Publications & Resources

Partner Search

Contact



Partner Search

[ERA4HEALTH](#) > Partner Search

PART FINDER

PARTFINDER is a solution for research groups that are actively looking for partners or are interested in establishing cooperation with other partners from all around the world. The tool significantly facilitates the creation of national and international research consortia and joint participation in grant competitions.

Access to the PARTFINDER does not require logging in and in such a basic view the tool offers a preview of the basic data. However, by creating a unique user account, the functionality will be expanded to include the ability to view details of announcements (such as contact details), add your own announcements, create a list of favorite entities or personalize your profile.

can pick "ERA4Health Partnership". You can also pick one or all of the Calls that lie within your interest such as e.g. JTC3 or JTC4. You can pick more than one item in this field.

PARTNER SEARCH TOOL ACCESS


PART FINDER: <https://era4health.eu/partner-search/>

PART FINDER Welcome to Partner Search Tool - PartFinder New announcement 🔍 🔊 👤 Your account

🔍 Type minimum 3 letters Advanced filters ↓ Sort ↕

<p>Looking for: Partner Partner name: Lua Biosciences Partner type: Enterprise Status: Published</p>	<p>Novel Technologies and Approaches for Cancer Screening and Early... Lua Biosciences is a life science technology company based in Gdansk, Poland. Our focus is on building cutting-edge technologies...</p> <p>🕒 Published on 2023-11-16</p>	<p>Announcing country: Poland Countries searched: Austria, Belgium, Estonia, Greece, Spain, Netherlands, Israel, Lithuania, Latvia, Germany, Romania, Slovakia, Taiwan, Turkiye, Italy</p> <p>Observations: 0 Details</p>
<p>Looking for: Partner Partner name: Research Companion in Taipei Partner type: Research organization Status: Published</p>	<p>Modulation of brain ageing through nutrition and healthy... We are committed to improving population well-being through participatory and multidisciplinary interventions. Our primary goals...</p> <p>🕒 Published on 2023-11-16</p>	<p>Announcing country: Taiwan Countries searched: Austria, Belgium, Denmark, Finland, France, Greece, Netherlands, Ireland, Germany, Norway, Poland, Portugal, Sweden, United Kingdom, Italy</p> <p>Observations: 0 Details</p>
<p>Looking for: Partner Partner name: experts on cognition (older adults), brain function, partners with biobanks or cohorts in this regard Partner type: Research organization Status: Published</p>	<p>User-centred development of health technologies for monitoring... We offer expertise on the user-centred development and evaluation of health technologies such as apps and assistive systems for the target group of older adults with deficits in nutritional status and physical function. We have also expertise on the...</p> <p>🕒 Published on 2023-11-14</p>	<p>Announcing country: Germany Countries searched: Austria, Belgium, Denmark, Estonia, France, Spain, Netherlands, Ireland, Israel, Canada, Lithuania, Latvia, Norway, Poland, Switzerland, Taiwan, Turkiye, Hungary, Italy</p> <p>Observations: 0 Details</p>
<p>Looking for: Project Partner name: HOLISUN SRL Partner type: Enterprise Status: Published</p>	<p>HOLISUN SRL Holisun is a software company with 22 years of experience and expertise in: • Artificial Intelligence • Machine...</p> <p>🕒 Published on 2023-11-14</p>	<p>Announcing country: Romania Countries searched: Austria, Belgium, Denmark, Estonia, France, Spain, Netherlands, Israel, Lithuania, Germany, Norway, Poland, Slovakia, Italy</p> <p>Observations: 1 Details</p>

PART FINDER: <https://era4health.eu/partner-search/>


Welcome to Partner Search Tool - PartFinder

New announcement
♡
📢
👤 Your account

Advanced filters ↑
Sort ▾

Type of collaboration

Announcing country

Status

Classification areas

Programme / Call name

Not specified

M-ERA.NET 3

ERA4Health Partnership

TRANSCAN 3

Neuron Cofund 2

ERA4Health JTC3 NutriBrain

ERA4Health JTC4 NANOTECMEC

Partner type

Countries searched

Keywords

From the date of publication

Looking for: Partner

Partner name: Lua Biosciences

Partner type: Enterprise

Status: Published

[Novel Technologies and Approaches for Cancer Screening and Early...](#)

Lua Biosciences is a life science technology company based in Gdansk, Poland. Our focus is on building cutting-edge technologies...

🕒 Published on 2023-11-16

Announcing country: Romania

Countries searched: Greece, Spain, Germany, Romania

Observations: 1

Looking for: Partner

Partner name: Research Companion in Taipei

Partner type: Research organization

Status: Published

[Modulation of brain ageing through nutrition and healthy...](#)

We are committed to improving population well-being through participatory and multidisciplinary interventions. Our primary goals...

🕒 Published on 2023-11-16

Announcing country: Taiwan

Countries searched: Austria, Belgium, Denmark, Finland, France, Greece, Netherlands, Ireland, Germany, Norway, Poland, Portugal, Sweden, United Kingdom, Italy

Observations: 0

Details

Looking for: Partner

Partner name: experts on cognition (older adults), brain function, partners with biobanks or cohorts in this regard

Partner type: Research organization

Status: Published

[User-centred development of health technologies for monitoring...](#)

We offer expertise on the user-centred development and evaluation of health technologies such as apps and assistive systems for the target group of older adults with deficits in nutritional status and physical function. We have also expertise on the...

🕒 Published on 2023-11-14

Announcing country: Germany

Countries searched: Austria, Belgium, Denmark, Estonia, France, Spain, Netherlands, Ireland, Israel, Canada, Lithuania, Latvia, Norway, Poland, Switzerland, Taiwan, Turkiye, Hungary, Italy

Observations: 0

Details

Looking for: Project

Partner name: HOLISUN SRL

Partner type: Enterprise

Status: Published

[HOLISUN SRL](#)

Holisun is a software company with 22 years of experience and expertise in:

- Artificial Intelligence
- Machine...

🕒 Published on 2023-11-14

Announcing country: Romania

Countries searched: Austria, Belgium, Denmark, Estonia, France, Spain, Netherlands, Israel, Lithuania, Germany, Norway, Poland, Slovakia, Italy

Observations: 1

Details



“

Submission process

Steps for the submission of an application

- Complete the submission tool (PT-Outline)
- Complete the pre-proposal template
- Upload the pre-proposal template on PT-Outline

DEADLINE PRE-PROPOSAL SUBMISSION:
January 30th, 2024, 16:00 CET

“

Pre-proposal template

Template of pre-proposals

- **One joint proposal (in English)**, submitted only by the coordinator by uploading on the electronic submission system <https://ptoutline.eu/app/era4healthnano>
- **Only proposals using the official templates will be accepted**
 - Complete all fields, and respect the format of each section
 - "Arial font, size 11" characters. Paper format: A4 with all margins minimum 1.27 cm
- **Same indications in PT-Outline and proposal templates.** In case of inconsistency, the information registered in the electronic submission tool shall prevail.
- Respect the submission deadlines (avoid submissions on the last moment). **No proposal will be accepted after the deadline!**

DEADLINE PRE-PROPOSAL SUBMISSION:
January 30th, 2024, 16:00 CET



Template of pre-proposals

A. General information

Title, Acronym, Duration, Budget

1. TRL
2. Sub-topic selection
3. Keywords
4. Abstract

B. The consortium

1. Coordinator
2. Research partners
3. Collaborators not asking for funding

C. Project description

1. Project background
2. Description of the aims
3. Relevance of the aims of the call
4. Work plan
5. Work plan and timeline as diagram
6. Added value of transnational collaboration
7. Responsible Research and Innovation (RRI) and other cutting issues (including ethical considerations)
8. References
9. Scientific justification of requested budget

D. Budget

E. Annexes

1. Brief CV of each PI
2. Project collaborators: letter of intent
3. ³² Date and signature of all partners and collaborators



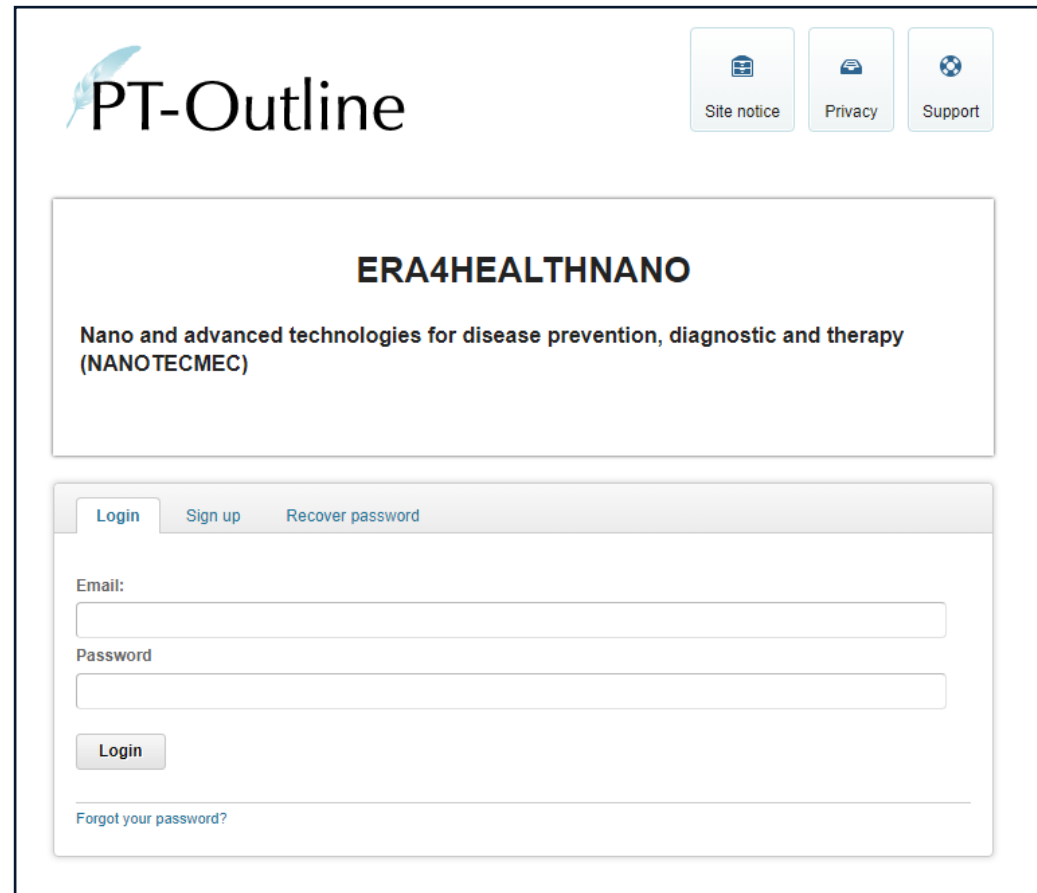
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Submission platform

Submission platform

Login

<https://ptoutline.eu/app/era4healthnano>



The screenshot shows the PT-Outline website interface. At the top left is the PT-Outline logo. To the right are three navigation buttons: 'Site notice', 'Privacy', and 'Support'. The main content area features the title 'ERA4HEALTHNANO' and a subtitle 'Nano and advanced technologies for disease prevention, diagnostic and therapy (NANOTECEMEC)'. Below this is a login section with three tabs: 'Login' (selected), 'Sign up', and 'Recover password'. The login form includes an 'Email:' field, a 'Password' field, and a 'Login' button. At the bottom of the form is a link for 'Forgot your password?'.

Submission platform

<https://ptoutline.eu/app/era4healthnano>

Upload your proposal (use the template!)

Verify your proposal and submit it

Overview
Privacy
General Information
Project Coordinator
Project Partner
Project description
Final Check and Submission



Please note that submission is definitive and no proposal will be accepted after the deadline!

What's next?



ETPN - ERA4Health matchmaking event:
get prepared for NANOTECEMEC!

«Nano and advanced technologies for disease prevention, diagnostic and therapy»

Register for free Dec. 7, 2023 - 2PM (CET) Get involved






December 7 th , 2023	ETPN – ERA4Health matchmaking event
January 30 th , 2024 - 4PM (CET)	Deadline for pre-proposal submission
April 23 rd , 2024	Results of pre-proposal assessment (invitation for full proposal)
June 13 th , 2024 - 4PM (CET)	Deadline for full proposal submission
August 23 rd – September 3 rd , 2024	Rebuttal stage
Mid-October 2024	Communication of the funding decisions
December 2024 – May 2025	Expected project start date (subject to national procedures)

RRI in ERA4Health

- Information meeting NANOTECMEC call
- 21 November 2023
- Ellen-Marie Forsberg (NORSUS) & Robert Smith (UniEdinburgh)



THE UNIVERSITY
of EDINBURGH



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the European Union

- Responsible Research and Innovation (RRI) is about doing the *right* science *right*
- RRI is included into ERA4Health (and other Eranet programmes) because funders believe it is important to make sure that taxpayers' money are going into research and innovation that actually benefits society and does no significant harm.
- RRI involves engagement of publics and societal stakeholders because science communities alone should not decide what is good for society or what is acceptable harm

The social responsibility of science involves reflecting on

- I. the potential directions of research being taken;
- II. who might benefit and who might experience new risks from new research and inventions; and
- III. how the potential social, environmental and ethical issues can be considered throughout the science and innovation process.

RRI offers techniques, tools and frameworks to think about questions of social responsibility and ensure scientists, funders and technologies don't lose sight of the context in which they do science, technology and innovation.

Definitions – European Commission, Horizon 2020

Responsible research and innovation is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation.

Responsible Research and Innovation (RRI) implies that societal actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society.

In practice, RRI is implemented as a package that includes multi-actor and [public engagement in research and innovation](#), enabling easier access to scientific results, the take up of gender and ethics in the research and innovation content and process, and formal and informal science education.



What is Responsible Research and Innovation (RRI) about?

- In an inclusive and deliberative way:
 - **Addressing societal needs**
 - **Avoiding undesirable side effects (Ref. also Do No Significant Harm principle of Horizon Europe)**
 - **Integrating responsibility into research and innovation practices**
 - **Engaging with stakeholders – without ‘outsourcing’ responsibility to others**
- **Responsibility related to**
 - *social, environmental, ethical, political or cultural issues*

Definitions → Approach in UK, Norway, and several Era-nets (including ERA4Health's guidelines)

EPSRC

Engineering and Physical Sciences
Research Council

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Research >

Home / Research / Framework for Responsible Innovation

Framework for Responsible
Innovation

Framework for Responsible Innovation

Anticipate, reflect, engage and act
(AREA)

EPSRC is committed to develop and promote Responsible Innovation. This site reaffirms our own commitment and sets out our expectations for the researchers we fund and their research organisations.

Support

Introduction

Expectations

Responsible Innovation is a process that seeks to promote creativity and opportunities for science and innovation that are socially desirable and undertaken in the public interest. Responsible Innovation acknowledges, that innovation can raise questions and dilemmas, is often ambiguous in terms of purposes and motivations and unpredictable in terms of impacts, beneficial or otherwise. Responsible Innovation creates spaces and processes to explore these aspects of innovation in an open, inclusive and timely way. This is a collective responsibility, where funders, researchers, stakeholders and the public all have an important role to play. It includes, but goes beyond, considerations of risk and regulation, important though these are.

Acknowledgements and resources

As a public funder of research, we have a responsibility to ensure that our activities and the research we fund, are aligned with the principles of Responsible Innovation, creating value for society in an ethical and responsible way. EPSRC does not wish to be prescriptive about how Responsible Innovation is embedded in the research and innovation process. We recognise that some researchers are already well engaged with this agenda. We also recognise that different approaches might be required for different research areas. There may be instances where detailed consideration is premature or even unwarranted. In other areas of research, a responsible innovation approach may be highly recommended, or even required. As such we recommend that all researchers demonstrate awareness of and commitment to, the principles of Responsible Innovation. Taking an approach that encompasses the following steps, should



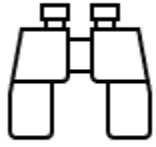
The NANOTECMEC call has RRI requirements

- «Proposals should follow the principles of Responsible Research and Innovation (RRI). All consortia **should** demonstrate a commitment for 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.»



ERA4Health Responsible Research and Innovation (RRI) Guidelines

ERA4Health approach to RRI = AIRR



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? 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 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.



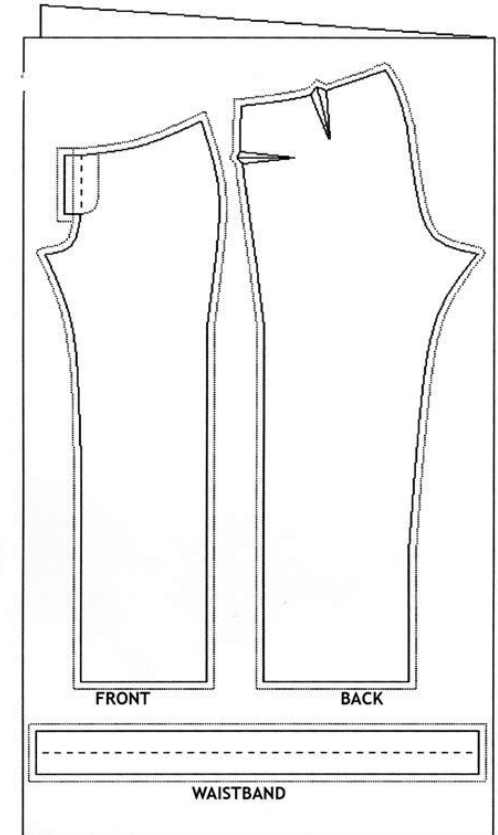
Reflection. Are there opportunities for you and your team to pause and 'take stock' about what you're doing? Would everyone agree with your goals and the decisions you've taken so far? Reflection is about making sure there is space and time to collectively ask hard questions about a project's foundations.



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.

HOW SHOULD YOU INCLUDE RRI IN YOUR PROJECT?

- ★ The approach to RRI must be adapted to the actual social and ethical issues raised by the R&I activities in the project.
- ★ Foundational, exploratory research will require a different (more exploratory) approach than applied, high-TRL research.
- ★ Disruptive, pathbreaking research may require a more substantive approach to RRI than incremental research.



Practical guidance – consider the following when developing your proposal:

1. Who will **benefit** from your project, who will not, and who may experience new **risks**? Are those answers **acceptable** to you?
2. Have you identified and involved relevant **stakeholders** and have you considered **public** engagement activities?
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?
4. Have you reflected on/considered adapting your **choice of research methods** regarding, for example ethical issues in the project?
5. Have you engaged with important aspects of your research environment such as **gender** and diversity, career progression and precarity, or **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?
7. Have you considered and evaluated **environmental** impacts and sustainable solutions, in line with the Do No Significant Harm principle?

Practical guidance – consider the following when developing your proposal:

1. Who will **benefit** from your project, who will not, and who may experience new **risks**? Are those answers acceptable to you?
2. Have you identified and involved relevant **stakeholders** and have you considered public engagement activities?
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?
4. Have you reflected on/considered adapting your **choice of research methods** regarding, for example ethical issues in the project?
5. Have you engaged with important aspects of your research environment such as **gender** and diversity, career progression and precarity, og **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?
7. Have you considered and evaluated **environmental** impacts and sustainable solutions, in line with the Do No Significant Harm principle?

More detailed advice is given in the RRI guidelines

HOW SHOULD YOU INCLUDE RRI IN YOUR PROJECT?

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.

Examples of RRI activities

- A separate work package on ethical issues?
- Societal stakeholders in your advisory group?
- A citizen's panel?
- Workshops with societal stakeholders?
- Etc

Evaluation of RRI in ERA4Health

- 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.
- 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.

Evaluation

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?

Further resources

- www.rri-tools.eu
- The Societal Readiness Thinking Tool: <https://thinkingtool.eu/>
- The Centre for Digital Life Norway: <https://www.digitallifenorway.org/services/rri/>
- Tools for public engagement: <https://www.publicengagement.ac.uk/resources> and <http://actioncatalogue.eu/>
- Further examples specific to health science and innovation will in the future be provided on the RRI webpage of ERA4Health (coming).



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Evaluation criteria

Dr Martine Batoux

Evaluation criteria

1. Excellence

2. Impact

3. Quality and efficiency of the implementation

1. Excellence

1. Excellence

a) Scientific quality of the proposal

- Significance of the research question
- Clarity and relevance of the objectives
- Credibility of the proposed approach and methodology
- Expected progress beyond the state of the art and clear demonstration of innovation potential

- Clear demonstration of the nano-value of the proposed approach compared to other approaches (antibodies, gels, natural vesicles..)

e.g. designed to possess improved and, often, novel physical, chemical and/or biological properties for different applications : potential to enable early detection and prevention of diseases, significantly improve diagnosis, treatment and follow-up of diseases



1. Excellence

- 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.
 - Demonstration of previous collaborative efforts (scientific papers, grants,...)
 - Demonstration of the benefit of working together and the unique contribution of each partner
 - Gender balance

1. Excellence

b) Novelty and ambition (including translatability of the proposed research to human health).

- To generate a credible roadmap how the results will contribute to a solution for the disease studied



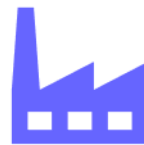
Solution in clinical setting

Results of the proposal

2. Impact

2. Impact

- a) Unmet public and societal need and potential impact for future clinical, public health, and/or other socio-economic health relevant applications including patients' needs and/or for industry.
- Details on the medical need and societal impact and costs
 - Patents, documented experience in translational research (at the PI level in addition to Institution)
 - Involvement of Industry as partner, collaborator, advisory board
 - Inclusion of clinical scientists/experts



2. Impact



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.

- Sharing resources and harmonizing data

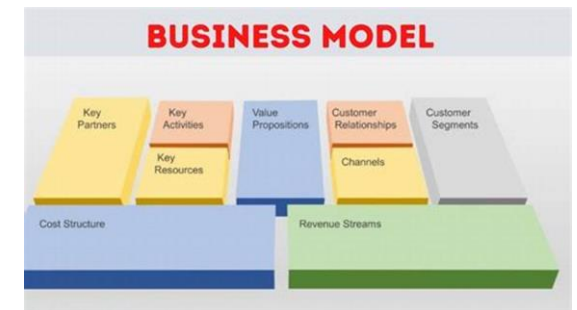
→ Use existing data/human biological material rather than producing new when it is already available

- Complementary of the consortium : avoid redundancy of expertise

2. Impact

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.

- Plans for regulatory approval, for patenting, clinical testing
- Business model (awareness of existing patents and competitors)
- Scaling-up strategy



2. Impact



- 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.
 - Engage end-users in the research process from conception of the study to implementation and dissemination and (ref RRI presentation)
 - End-users can participate as partners (when eligible for funding by a national/regional funding organisation), as collaborator (participation with own budget) or as part of an advisory board.

3. Quality and efficiency of the implementation plan

3. Quality and efficiency of the implementation plan

a) Feasibility of proposal and likelihood of successful completion of proposed research.

- Brief recap on the unmet medical need (approach bedside, bench, bedside)
- The main idea and - technology readiness levels, contribution to solution for patients

Be ambitious but not overambitious!

- Convince the reviewers with preliminary results
 - Basic/in-vitro for “innovative projects”
 - In-vivo/in-human for “projects with high potential of applicability”

3. Quality and efficiency of the implementation plan

b) Coherence and effectiveness of the work plan.

- Clearly state the aims, appropriate numbers according to the size of the consortium
- Clearly present Work Packages as connected to the aims
- Specify WP leader and structure
- Specify role of each Partner in the WP (balanced)

3. Quality and efficiency of the implementation plan

- c) Use of existing biobanks and existing cohorts (when applicable/appropriate).

Otherwise it must be very well justified!

3. Quality and efficiency of the implementation plan

- d) Appropriateness of the management structures and procedures
- e) Adequacy of the budget
- f) Sustainability of the research capacities initiated by the project

- Risk assessment (pitfalls and mitigations)

- Co-funding always necessary/desirable (salaries from Institution, partial coverage of consumables, intramural funding,)

- Co-funding from Industrial Partners always desirable



Thank you