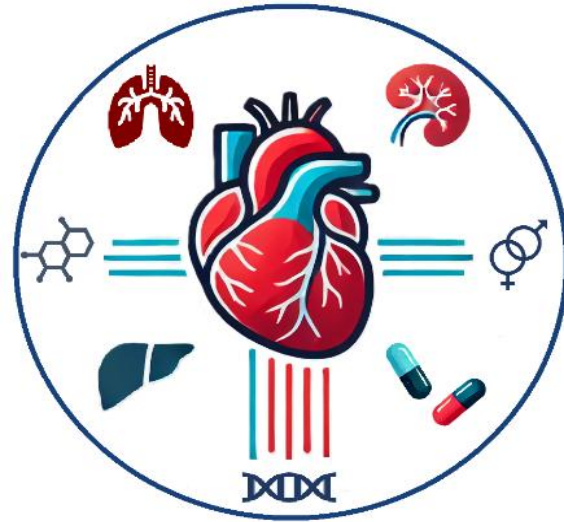


# ERA4Health InterHeart Call InfoDay

**Tuesday, 14 January 2025 14:00 - 16:00**

(UTC+01:00) Brussels, Copenhagen, Madrid, Paris



## Agenda

- o Welcome Words - (10 min) - Cristina Nieto, ERA4Health coordinator, ISCIII
- o Presentation of the InterHeart call (40 min) - Joint Call Secretariat
  - Scope of the call
  - Eligibility criteria
  - Partner Search
  - Template of pre-proposals
  - Submission tool
- o Principles of Responsible Research and Innovation (RRI) (20 min)
  - Ellen-Marie Forsberg, NORSUS
- o Evaluation Criteria (15 min) - Joint Call Secretariat
- o Q&A session (30 min)

# ERA4Health Partnership

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Cristina Nieto (ERA4Health Coordinator)

**INSTITUTE OF HEALTH CARLOS III (ISCIII)**

*InterHeart 2025 Infoday, 14<sup>th</sup> January 2025, online*

# ERA4Health Aim and Specific Objectives

ERA4Health fosters European collaborative research funding by creating a flexible funding body for joint programming in priority areas addressing European Public Health Needs and aims to set up Europe at the forefront of science and innovation in Health Research by 2050.

S01. Support relevant medical research including clinical fields and intervention areas

S02. Improve the utilisation of existing health technologies in clinical practice

S03. Build capacity, in particular in conducting IICs at European scale

S04. Implement and develop RRI in multiple ways

# ERA4Health Working Plan

Directly related with previous ERA-Nets (ERA-CVD, EuroNanoMed, ERA-HDHL and HDHL-INTIMIC)

## Phase 1

- Joint transnational calls in **nutrition, diet and healthy life-styles, cardiovascular diseases and nanomedicine**
- Framework to support multinational Investigator Initiated Clinical Studies (IICSs)
- Duration: **2 years (Nov. 2022- 2025)**

**PILOT CALL ON IICS (launched at the end of 2024):  
critical milestone for 2nd phase**

## Phase 2

- **Calls in research priority areas**
- **Calls for IICS in Health Technologies addressing public health needs**
- Duration: **expected 9 years**
- **Incorporation of new funders willing to fund Investigator-Initiated Clinical Studies**

# ERA4Health Consortia



37 Partners (mainly Funding Organisations) covering:

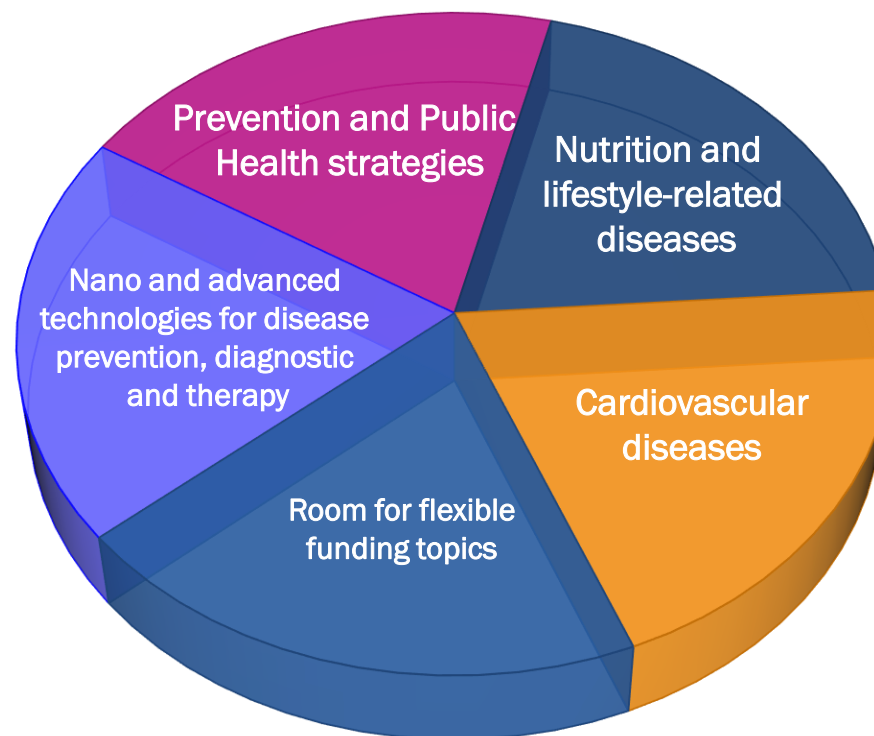
- 19 of the actual 27 members of the European Union
- 3 Third Countries associated to Horizon Europe (Israel, Norway, Turkey)
- 2 Third countries (Egypt, Taiwan)

# ERA4Health Strategic Research and Innovation Agenda

## ➤ High Priority research areas



[ec\\_rtd\\_he-partnerships-era-for-health-1.pdf \(era4health.eu\)](https://era4health.eu/ec_rtd_he-partnerships-era-for-health-1.pdf)



## ➤ Research Areas to be addressed with IICS (updating of the SRIA)

# ERA4Health Joint Transnational Calls

## HealthEquity

*“Increasing health equity through promoting healthy diets and physical activity” (JCS:DLR)*



10 funded projects with 13M€

## CARDINNOV

*“Research targeting development of innovative therapeutic strategies in cardiovascular disease” (JCS: ANR)*



17 funded projects with 19M€

## NutriBrain

*“Modulation of brain ageing through nutrition and healthy lifestyle” (JCS:MUR)*



15 funded projects with 20M€

## NANOTECMEC

*“Nano and advanced technologies for disease prevention, diagnostic and therapy” (JCS:ANR)*



19 funded projects with 19M€

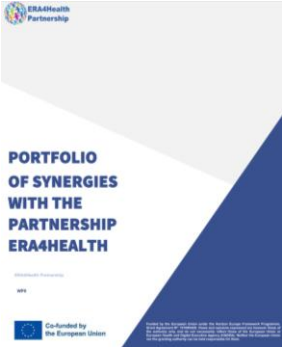
Calls in 2025: EffecTrial (IICS) and InterHeart 2025

# Other additional ERA4Health activities

## ERA4Health Early Career Network

Publications, Newsletters,  
Communication and  
dissemination activities

## Synergies Working Group



## Capacity Building Activities



**ERA4Health**  
1st webinar



**Calum MacRae M.D., PhD**  
Vice Chair for Scientific Innovation  
Department of Medicine  
Brigham & Women's Hospital (Boston)  
Professor of Medicine at Harvard Medical School

**Building Learning Health Systems for  
Discovery, Translation and Care**

**Sep 30 13:00-14:00 CET**  
Registration required



**ERA4Health**  
2nd webinar



**Frank Hulstaert M.D.**  
Senior Researcher  
The Belgian Health Care  
Knowledge Centre (KCE)

**Pragmatic Comparative-  
Effectiveness Randomized Trials:**

ERA4Health 2nd webinar Pragmatic Comparative-  
Effectiveness Randomized Trials: Real-World Evidence for  
Better Health Decisions

© 2024-11-11

Read More

## Identification of barriers in translating health research into practical applications



**Help Us Overcome Barriers in  
Health Research!**

YOUR INSIGHTS MATTER

**PARTICIPATE IN THE  
ERA4HEALTH SURVEY**



**Survey Open**



# ERA4Health RRI Guidelines



## Responsible Research and Innovation (RRI) - ERA4HEALTH

### 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? 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.



# Thank you!

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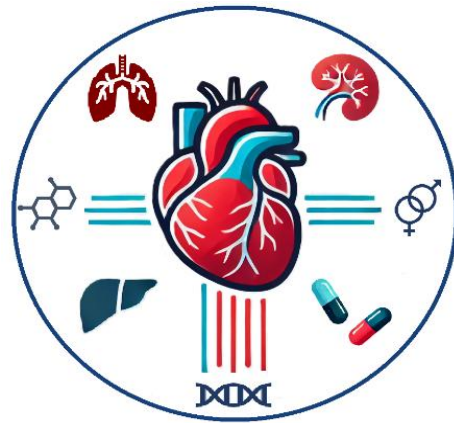
ERA4Health Coordinator

Institute of Health Carlos III (ISCIII)

[ERA4Health@isciii.es](mailto:ERA4Health@isciii.es)

# Joint Transnational Call 6

« Understanding the interactions between cardiovascular disorders and comorbidities and/or their therapeutic treatments »



## InterHeart

Dr Anaïs Fradet and Dr Martine Batoux

January 14th, 2025

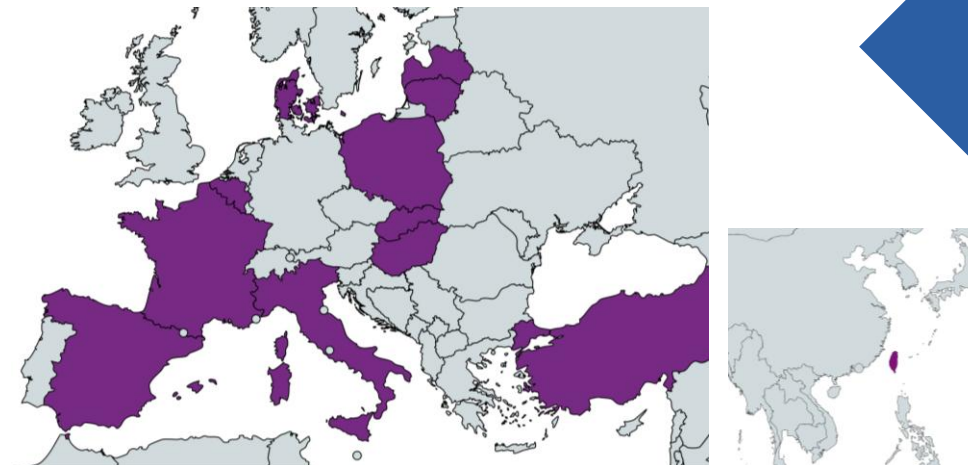
# InterHeart – ERA4Health 2025

14 funding organisations

~ 10,7 M€

12 countries: BE, DK, ES, FR, HU, IT, LV, LT, PO, SV, TR, TW

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



**Joint Call Secretariat (JCS):**  
**The French National Research Agency (ANR)**  
Dr. Anaïs Fradet and Dr. Martine Batoux :  
interheart@agencerecherche.fr  
+33 1 73 54 81 74/ +33 1 73 54 81 40

# Summary

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**Scope of the call**

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**Eligibility criteria**

---

**Partner search**

---

**Pre-proposal  
template**

---

**Submission tool**

“

# The scope of the call

# Scope of the call: Aims

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## To support research that:

- builds understanding of molecular and cellular mechanisms governing interactions between the heart and other organs during pathological state of either or both systems,
- builds comprehensive approaches to understanding cardiovascular disease interactions, combining basic research, clinical translation, and digital innovation through international collaboration.
- enables transnational collaboration of multidisciplinary scientists from different countries to work together across borders, taking advantage of complementary expertise and leveraging diverse patient populations and sets of data.

# Scope of the call: Focus

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Proposals should focus on:

- How CVD affect the performance of other organs/systems and/or their capacity to respond to treatments,
- How disorders other than CVD affect cardiovascular system performance including response to treatments,
- And/or how treatment(s) for disorders other than CVD affect positively or negatively the performance of the cardiovascular system.



# Scope of the call: Approach

---

Proposals should include one of the following approaches:

- Mechanistic / experimental research
- Identification and validation of biomarkers of organs/systems/disorders crosstalk (including epigenetic biomarkers)
- Generation of digital models of disease(s) to study disease-disease or/and disease-drug interactions.

# Scope of the call: exclusions

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- Except for small-scale clinical studies up to phase 2, all other clinical studies are excluded in this call
- Proposals that are not dealing with the cardiovascular system or CVD
- Proposals that only study the cardiovascular system or CVD without studying the interaction with other organs, systems, diseases or the response to their treatment
- Studies on how CVD treatments affect the performance of other system/organs
- Development of therapeutics
- Infectious diseases, even if studied with CVD

# Scope of the call

## Important points: studies

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- When applicable, make use of **existing biobanks and existing cohorts**
- Applicants should consider **potential social moderators** on effects such as age, sex, gender and ethnic or other demographic features/differences in the respective research approaches.
- **Cross-validation** of research results across different ethnic groups and different socio-cultural group is strongly encouraged.

# Scope of the call

## Important points: general

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- Duration of **36 months**
- Must demonstrate **potential health impact and/or economic impact** and **added-value of transnational collaboration**
- Must follow and respect **RRI (Responsible Research and Innovation)**, application of **bedside to bench approach** is strongly recommended
- Should **balance gender** and balance responsibilities between genders
- Should encourage 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
- 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

Country	Taiwan
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: <a href="https://www.nstc.gov.tw/folksonomy/list/f6d5c23c-b3ce-438e-911b-12a705dbac5a?l=ch">https://www.nstc.gov.tw/folksonomy/list/f6d5c23c-b3ce-438e-911b-12a705dbac5a?l=ch</a>
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: <a href="https://www.nstc.gov.tw/folksonomy/list/f6d5c23c-b3ce-438e-911b-12a705dbac5a?l=ch">https://www.nstc.gov.tw/folksonomy/list/f6d5c23c-b3ce-438e-911b-12a705dbac5a?l=ch</a>

# 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/**type of partners**

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

Recommended to include partners from **different categories according to the workplan.**



# General Rules

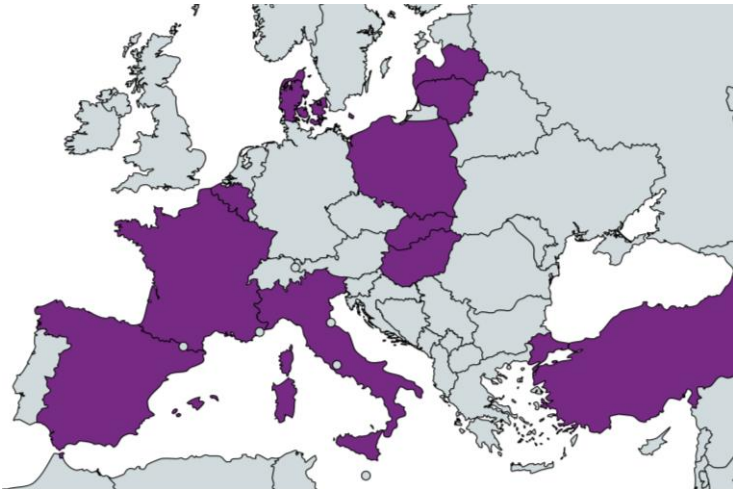
## Composition of a consortium/size

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
- Denmark
- France
- Hungary
- Italy
- Latvia
- Lithuania
- Poland
- Slovakia
- Spain – national
- Spain - Andalusia
- Türkiye
- Taiwan

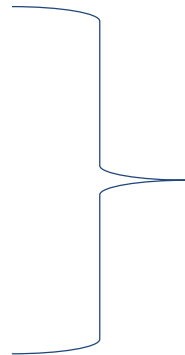


# General Rules

## Composition of a consortium/**under-represented countries**

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

- Hungary
- Latvia
- Lithuania
- Slovakia
- Türkiye



<b>1 partner from an under-represented country</b>	<b>2 partners from an under-represented country</b>
Up to 6 partners in the consortium	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/ **examples**

---

## 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 March 7th, 2025 at 12:00 CET
- Respect of the pre-proposal template: no figure except in the workplan, no supporting letters, no extra CV

# Checklist for the eligibility criteria

## Pre-proposal template

- 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: Lithuania or Slovakia).
  - 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. Collaborators are not WP leader.
  
- **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).
  - 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 F.R.S.- FNRS, FWO, It-MoH, CSCJA, TUBITAK, I made sure that this partner performed the national requirements / sent required information (submission of national documents to their funding organization).
  
- **Eligibility of the pre-proposal:**
  - The different sections of the pre-proposal strictly comply with the maximum length allowed for each section
  - There is no figure except eventually in the workplan (but still respect the maximum length allowed)
  - There is no extra document other than the collaborator's letter of commitment
  - The collaborator's letter of commitment is signed by the director of the institution (not by the researcher/PI himself)
  - All the PI representing the partners have signed the pre-proposal and declared they have not received other public funding to perform the described tasks



“

# Questions about the general rules

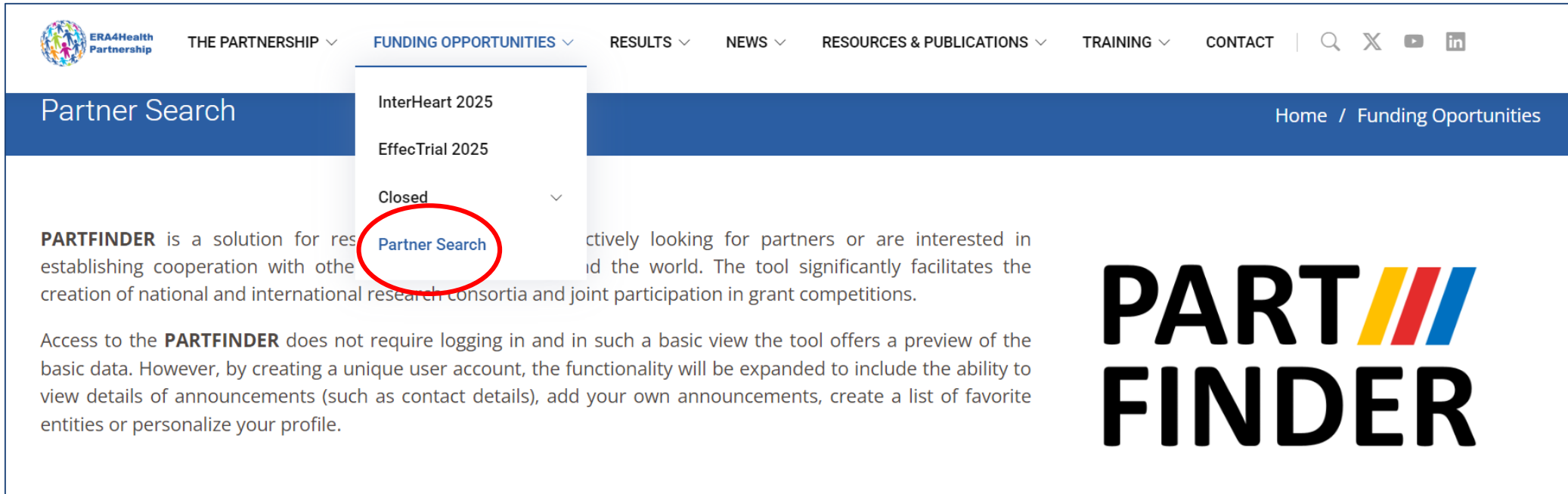
Joint Call Secretariat (JCS):  
The French National Research Agency (ANR)  
Dr. Anaïs Fradet and Dr. Martine Batoux:  
[interheart@agencerecherche.fr](mailto:interheart@agencerecherche.fr)  
+33 1 73 54 81 74/ +33 1 73 54 81 74

“

# Partner search tool



# PART FINDER: <https://era4health.eu/calls/partnersearch.php>



The screenshot shows the ERA4Health Partnership website. The navigation menu includes 'THE PARTNERSHIP', 'FUNDING OPPORTUNITIES', 'RESULTS', 'NEWS', 'RESOURCES & PUBLICATIONS', 'TRAINING', and 'CONTACT'. A dropdown menu under 'FUNDING OPPORTUNITIES' is open, listing 'InterHeart 2025', 'EffecTrial 2025', and 'Closed'. The 'Partner Search' link is circled in red. The main content area features the 'PART FINDER' logo and a description of the tool. The text states: 'PARTFINDER is a solution for researchers who are actively looking for partners or are interested in establishing cooperation with other researchers 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.'

Partners search tool access (open in a new window )

# PART FINDER: <https://era4health.eu/calls/partnersearch.php>

**PART FINDER** Welcome to PartFinder New feature - chat between users New announcement ♡ 📢 💬 👤 Your account

🔍 Type minimum 3 letters Advanced filters ↓ Sort ↕

<b>Looking for:</b> Partner <b>Partner name:</b> HEKA VR <b>Partner type:</b> Research organization <b>Call:</b> Not specified	<a href="#">We are looking for collaborations in mental health innovation...</a> In collaboration with mental health experts from Copenhagen Centre for Mental Health, we are pioneering virtual reality-based... 🕒 Published on 2025-01-13	<b>Announcing country:</b> United States of America <b>Countries searched:</b> Belgium, Czechia, Finland, France, Spain, Netherlands, Norway, Portugal, Slovakia, Switzerland, Sweden Observations: 0 <span>Details</span>
<b>Looking for:</b> Project <b>Partner name:</b> AIT Austrian Institute of Technology GmbH <b>Partner type:</b> Research organization <b>Call:</b> THCS Partnership, M-ERA.NET 3, ERA4Health Partnership, Horizon Europe	<a href="#">Painless smart patch for the continuous monitoring of...</a> We aim to apply our microneedle-based biosensor to specific applications in lifestyle and decentralised healthcare approaches. The device can be used for quantitative monitoring of up to three... 🕒 Published on 2025-01-13	<b>Announcing country:</b> Austria <b>Countries searched:</b> Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Finland, France, Greece, Spain, Netherlands, Ireland... Observations: 0 <span>Details</span>
<b>Looking for:</b> Project <b>Partner name:</b> Social Science Research Centre, Riga Stradins University <b>Partner type:</b> Research organization <b>Call:</b> THCS Partnership	<a href="#">Better care closer to home: Enhancing primary and community care</a> Who we are: Riga Stradiņš University (RSU) is the leading institution in Latvia for medical and health sciences education and research. With a strong focus on interdisciplinary... 🕒 Published on 2025-01-13	<b>Announcing country:</b> Latvia <b>Countries searched:</b> Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Greece, Spain, Netherlands... Observations: 0 <span>Details</span>
<b>Looking for:</b> Project <b>Partner name:</b> FH Campus Wien – University of Applied Sciences [...] <b>Partner type:</b> Research organization <b>Call:</b> THCS Partnership	<a href="#">FH Campus Wien – University of Applied Sciences   Research...</a> The interdisciplinary research center Digital Health and Care researches technologies at the intersection of health sciences, nursing, and engineering. Our mission is to connect these... 🕒 Published on 2025-01-13	<b>Announcing country:</b> Austria <b>Countries searched:</b> Belgium, Denmark, Finland, France, Greece, Spain, Netherlands, Ireland, Iceland, Lithuania, Latvia, Norway... Observations: 5 <span>Details</span>
<b>Looking for:</b> Project <b>Partner name:</b> European University of Tirana, Albania. <b>Partner type:</b> Research organization <b>Call:</b>	<a href="#">Project Search</a> Hello, My name is Jonila Gabrani PhD, Head of the Centre for Scientific Research in Public Health, Faculty of Medical Technical Sciences, European University of Tirana, Albania. Jonila... 🕒 Published on 2025-01-12	<b>Announcing country:</b> Albania <b>Countries searched:</b> Austria, Belgium, Finland, Greece, Spain, Ireland, Iceland, Lithuania, Portugal, Romania, Switzerland, Sweden... Observations: 0 <span>Details</span>

# PART FINDER: <https://era4health.eu/calls/partnersearch.php>



Welcome to PartFinder New feature - chat between users

New announcement



Your account

Q Type minimum 3 letters Advanced filters ↑ Sort ⇅

Type of collaboration Choose an option ▾	Announcing country <input type="text"/>	Status Choose an option ▾	Classification areas <input type="text"/>	Programme / Call name Not specified
Partner type Choose an option ▾	Countries searched <input type="text"/>	Keywords <input type="text"/>	From the date of publication jj/mm/aaaa <input type="text"/>	ERA4Health JTC3 NutriBrain ERA4Health JTC4 NANOTECMEC Horizon Europe ERA4Health JTC5 EffecTrial <b>ERA4Health JTC6 InterHeart</b>

**Looking for:** Partner  
**Partner name:** HEKA VR  
**Partner type:** Research organization  
**Call:** Not specified

[We are looking for collaborations in mental health innovation...](#)  
In collaboration with mental health experts from Copenhagen Centre for Mental Health, we are pioneering virtual reality-based...

Published on 2025-01-13

**Announcing country:** America  
**Countries searched:** Finland, Norway, Portugal, Switzerland, Sweden

Observations: 0 Details

**Looking for:** Project  
**Partner name:** AIT Austrian Institute of Technology GmbH

[Painless smart patch for the continuous monitoring of...](#)  
We aim to apply our microneedle-based biosensor to specific applications in lifestyle and decentralised healthcare approaches.

**Announcing country:** Austria  
**Countries searched:** Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Ireland, Israel, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom



“

# Submission process

# Steps for the submission of an application

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- Complete the consortium information on the submission tool (PT-Outline)
- Complete the pre-proposal template (available for download on ERA4Health website)
- Upload the pre-proposal template on PT-Outline

DEADLINE PRE-PROPOSAL SUBMISSION:  
March 7th, 2025, 12:00 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/era4healthinterheart>
- **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!**

“

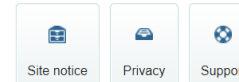
# Submission platform



# Submission platform

<https://ptoutline.eu/app/era4healthinterheart>

 PT-Outline



## ERA4HEALTHINTERHEART

Understanding the interactions between cardiovascular disorders and other disorders and/or their therapeutic treatments

Login Sign up Recover password

Email:

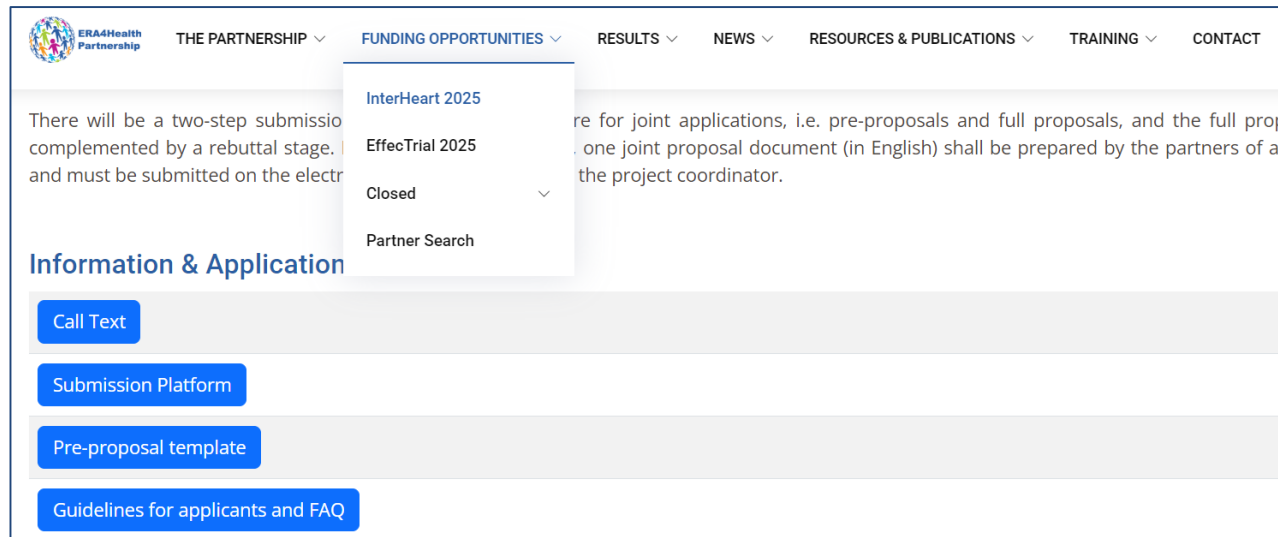
Password:

Login

[Forgot your password?](#)

# Conclusion

- Carefully read the call documents: <https://era4health.eu/calls/interheart2025.php>



The screenshot shows the ERA4Health website navigation menu. The 'FUNDING OPPORTUNITIES' dropdown is open, displaying the following options: InterHeart 2025, EffecTrial 2025, Closed, and Partner Search. Below the menu, there is a section titled 'Information & Application' with four blue buttons: 'Call Text', 'Submission Platform', 'Pre-proposal template', and 'Guidelines for applicants and FAQ'. The background text of the website is partially visible, mentioning a two-step submission process and joint applications.

- Reach out if you have any doubts

# Next webinar



THE PARTNERSHIP ▾

FUNDING OPPORTUNITIES ▾

RESULTS ▾

NEWS ▾

RESOURCES & PUBLICATIONS ▾

TRAINING ▾

CONTACT



News Detail

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ERA4Health  
Partnership

ERA4Health 2025  
3rd webinar

**Daniel J. Drucker, M.D.**

Senior Investigator, Mt. Sinai Hospital,  
Lunenfeld Tanenbaum Research Institute,  
Professor of Medicine,  
University of Toronto



**Mechanisms linking GLP-1 to  
reduction of cardiovascular disease  
and associated comorbidities**

**Jan 29 at 14:00-15 :00 CET**

**Mechanisms linking GLP-1 to reduction of cardiovascular  
disease and associated comorbidities**

## Upcoming Events



2025-01-29 *Featured*  
**Mechanisms linking GLP-1 to  
reduction of cardiovascular disease  
and associated comorbidities**

## Latest News



**InterHeart Infoday webinar**  
*Pub.Date 2025-01-08*



**Mechanisms linking GLP-1 to  
reduction of cardiovascular disease  
and associated comorbidities**  
*Pub.Date 2025-01-01*



**Now available the recording and  
presentations of the EffacTrial Call**



# Principles of Responsible Research and Innovation

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Dr Ellen-Marie Forsberg, NORSUS

January 14th, 2025



Co-funded by  
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)

The screenshot shows the EPSRC website header with the logo and navigation menu. The main content area features a breadcrumb trail: Home / Research / Framework for Responsible Innovation. A large blue arrow points to the left-hand navigation menu, which includes: Research, Framework for Responsible Innovation, Anticipate, reflect, engage and act (AREA), Support, Expectations, and Acknowledgements and resources. The main heading is 'Framework for Responsible Innovation'. Below it, a paragraph states: '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.' This is followed by an 'Introduction' section with a paragraph: '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.' A final paragraph states: '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' An image of a glowing blue network structure is visible on the right side of the page.

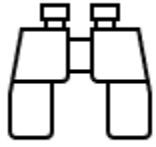
# The InterHeart call has RRI requirements

- **Proposals should be aligned with 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 p17-22).**



# **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.



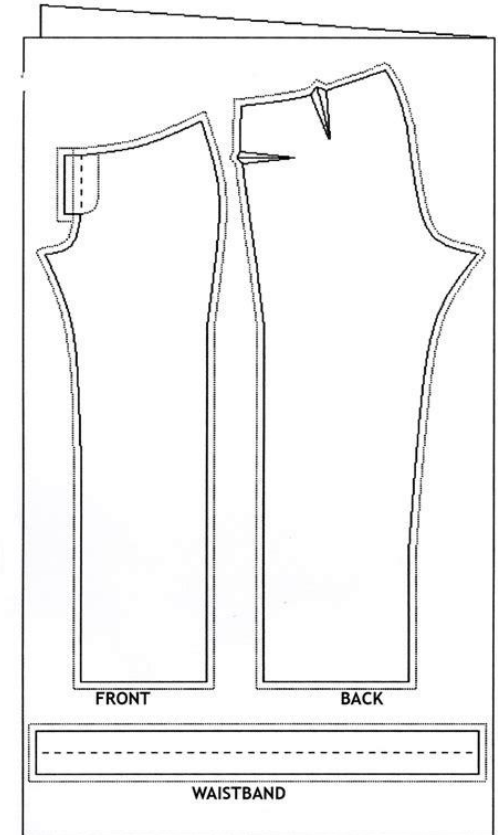
**Reflection.** Are there opportunities for you and your team to pause and 'take stock' about what you're doing? Would everyone agree with your goals and the decisions you've taken so far? Reflection is about making sure there is space and time to collectively ask hard questions about a project's foundations.



**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 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) satisfies 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 considered the **environmental, social, ethical or** **governance** impacts of your project? More detailed advice is given in the RRI guidelines
4. Have you considered the **ethical** implications of your project? For example
5. Have you considered the **diversity** of your project team and 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?

# 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](http://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).



# InterHeart Evaluation criteria

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Dr Martine Batoux

**anr**<sup>©</sup>  
agence nationale  
de la recherche

# Evaluation criteria

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1. Excellence

2. Impact

3. Quality and efficiency of the implementation

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# 1. Excellence

# 1. Excellence



# 186965 par alphaspirt

## 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

Gaps identified by our experts others topics may accepted if relevant and within the scope of the call

- Research that responds to gaps in the field:  
e.g. to understand temporal sequence in multi-organ failure, sex-specific differences in organ cross-talk, the characterization of molecular pathways between heart and other organs, reversibility of organ damage and the elaboration of predictive tools to harness drug-induced cardiotoxicity.

The need for digital disease modeling:

- to integrate of multi-scale data (physiological, biological and socioeconomical parameters...),
- a better interoperability between different modeling platforms,
- a better integration of molecular to clinical scale data and validation protocols for digital models and digital twins.



# 1. Excellence

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- Quality of the project consortium: international competitiveness of participants in the field(s), previous work and specific expertise of the participants, multidisciplinary nature of the consortium, 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 including expertise in different disciplines
  - Gender balance

# 1. Excellence

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- 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 (citizens/patients center approaches/bedside to bench approach)



Solution in clinical setting

Results of the proposal

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## 2. Impact

# 2. Impact

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- 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  
The same for animal experiments, possibility to use existing data and animal material from biobanks

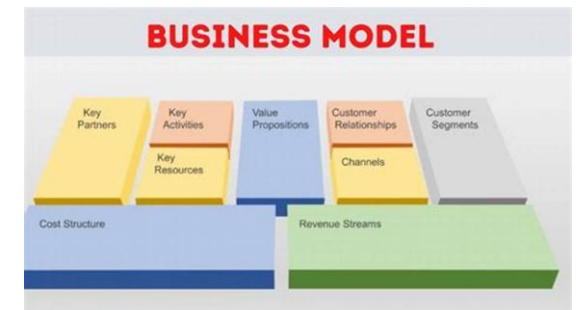
- Complementary of the consortium : avoid redundancy of expertise

# 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.

In case of proposals with high TRL :

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



## 2. Impact

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- 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 (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.

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



# 3. Quality and efficiency of the implementation plan

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

**Be ambitious but not overambitious!**

- Clarity on the unmet medical need (approach bedside, bench, bedside), the main idea and - technology readiness levels, contribution to solution for patients
- Convince the reviewers with preliminary results
  - Basic/in-vitro for low-TRL projects
  - In-vivo/in-human for high-TRL projects

# 3. Quality and efficiency of the implementation plan

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- b) Coherence and effectiveness of the work plan (including appropriateness of the allocation of tasks, resources and timeframe).
- 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)
  - A clear and informative Gantt chart or Pert

# 3. Quality and efficiency of the implementation plan

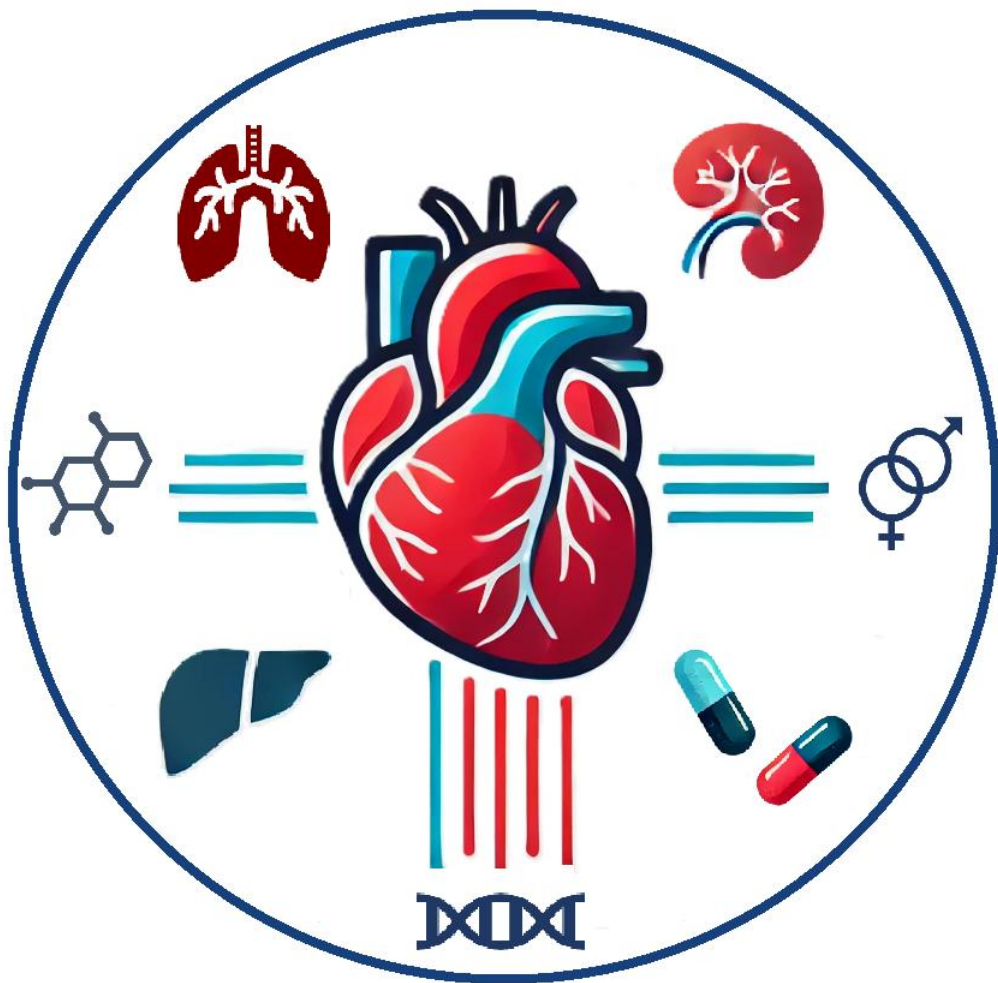
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- c) Use of existing biobanks and existing cohorts (when applicable/appropriate).

Otherwise it must be very well justified!

# 3. Quality and efficiency of the implementation plan

- d) Appropriateness of the management structures and procedures including risk, innovation management and RRI and ethical considerations.
- e) Adequacy of the budget
- f) Sustainability of the research capacities initiated by the project (e.g. FAIR data management, Open Science practices). Quality of Intellectual Property management.
  - Appropriate distribution of resources in relation to project activities, partner's responsibilities and time frame
  - Co-funding always necessary/desirable (salaries from Institution, partial coverage of consumables, intramural funding, .... )
  - Co-funding from Industrial Partners always desirable
  - If new data generated or new biological material (animal and human) plan to share it in databases or biobanks
  - Risk assessment (pitfalls and mitigations)



# Thank you

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# Q&A Session

