Call for proposals 2027 – JTC10

Nano and advanced technologies for developing Diagnostic tools to improve the detection and the clinical management of non-communicable diseases

NanoDiagNCD



Guidelines for applicants and Frequently Asked Questions

DEADLINES

19 January, 2027 (12:00, CET) - SUBMISSION OF PRE-PROPOSALS

9 June 2027 (12:00, CEST) - SUBMISSION OF INVITED FULL-PROPOSALS

Link to electronic proposal submission

https://ptoutline.eu/app/E4H-NANODIAGNCD

For further information, please visit us on the website: https://era4health.eu/

or contact the Joint Call Secretariat (JCS):

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These guidelines are a summary of the call rules and are not exhaustive. If you intend to participate to this call, it is strongly recommended to carefully read the call text.

GENERAL

This call uses a two-step submission procedure (pre-proposals and full proposals), including a rebuttal stage.
All proposals must be written in English and submitted exclusively by using the PT-Outline electronic submission system (https://ptoutline.eu/app/E4H-NANODIAGNCD), and this before January 19st, 2027 for the pre-proposals and before the June 9th, 2027 for the full proposals.
The project duration is 36 months.

ELIGIBILITY

Before participating to a consortium, principal investigators (PI) should self-assure that their organisation is eligible for funding by one of the funding organisations participating in the call. The funding rules of each funding organisation participating to the call are available in the Annex I of the call text.
After the deadline, the funding organisations will review the composition of the consortia to make sure that each partner applying to get funding from them is following the national/ regional funding rules. Only pre-proposals from consortia that have been deemed eligible will be sent to the reviewers for scientific evaluation. The scientific evaluation will be coordinated by the joint call secretariat on behalf of all participating funding organisations.

The table below shows a summary of the eligibility criteria of each funding organization participating to the call, in case of doubt refer to the annex I of the call text and contact your national contact point:

Country	**Funding organisation**	**Eligibility of Partners**
Belgium	F.R.S.-FNRS	All eligibility rules and criteria can be found in the PINT-MULTI Regulations. It is **strongly advised** to contact the F.R.S.-FNRS prior to submission regarding the eligibility criteria. Please note that the F.R.S.-FNRS only funds Basic research (low Technology Readiness Level) carried out in a research institution from the "Fédération Wallonie-Bruxelles". The F.R.S.-FNRS will not fund industrial partners or any activity related to the private sector. Nevertheless, partners funded by the F.R.S.-FNRS can be in a consortium where there are also partners from the private sector. Clinical research is eligible for funding by the F.R.S.-FNRS under the condition that the funded research is oriented towards the understanding of fundamental mechanisms, excluding clinical trials with purely therapeutic or industrial goals.
Egypt	ASRT	• Eligible applicants: Egyptian legal entities established in Egypt, including public or private research-performing organisations (universities, research institutes, university hospitals), and other legal entities (e.g., non-profits, SMEs, enterprises) able to carry out the work and sign a national grant/contract with ASRT. • PI load: The Egyptian PI may not hold >2 ongoing ASRT-funded projects as PI or coordinator at the time of contracting.

France	ANR	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 at actual costs 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. Note that companies in difficulty are excluded from ANR subventions (More details here: ANR-RF-Fiche-EED-2021.pdf).
Hungary	NKFIH	Institution of higher education, Other budgetary research institution, Other budgetary institution (outside education or research), Enterprise-based research organisation, Enterprise (non-research type), Non-profit research organisation, Other non-profit organisation (outside research), HUN-REN Hungarian Research Network.
Israel	CSO-MOH	Position in a university, research center or hospital. Research authority must approve position prior to submission. **Prior to submission, researchers will submit to CSO-MOH an abstract approved by their research authority including budget distribution. No submission of abstract can result in declaration of the consortium as ineligible.** **If the application involves human or animal experiments, bioethics approvals must be submitted with the application.**
Italy	IT MOH	Only IRCCS (Istituti di Ricovero e Cura a Carattere Scientifico) researchers are eligible to apply. **Not fundable:** Universities, other research Institutes, companies. Simultaneous PI participation in different 2026 JTCs funded by the Ministry of Health is not allowed. Italian PAOs can be funded as a sub-contractor of an IRCCS if they fulfil the eligibility criteria of the EC. The maximum amount eligible for a sub-contract is **≤10% of the total budget** (from the IRCCS Budget). Italian PAOs can still participate in Consortia as "Collaborators" with their own funds. **It is mandatory that the applicants fill out and return to the IT-MoH, a pre-submission eligibility check form through their IRCCS, using WFR System-> ER communication code, before submitting their proposal to the Joint Call Secretariat.** **The pre-eligibility form can be downloaded here:** https://www.salute.gov.it/imgs/C_17_pagineAree_4441_0_file.pdf
Latvia	LCS	Only the following **legal persons** are eligible: 1) Research institutions registered in the Latvian Registry of Scientific Institutions, e.g. - Research Institutes - Universities And must have the status of Research and knowledge dissemination organization (Regulation EC 651/2014) 2) Business enterprises entered into the Latvian Commercial registry as companies, assumed they are eligible to do the specific research and have specific capacity and resources to do the research in Latvia and have their main activity in Latvia. Limitations of EU legislation apply (Regulation 651/2014) together with financial reporting requirements, in this case it is state aid. Two previous statements with sworn auditor's approval should be provided and they must reflect the correspondence to the regulation as well

		as prove the evidence of previous scientific activity and presence of capacity. Enterprises having not closed two annual financial periods are not eligible.
Lithuania	LMT	Eligible for funding institutions are Lithuanian research and higher education institutions that are included in the Register of Education and Research institutions, public healthcare institutions, academy of science mentioned in the state Law on Science and Studies, other state public institutions such as National libraries, archives, museums. Beneficiary institution (grant holder) manages the state budget funds allocated to the project following the rules stated in the legal acts, as well as representing the project partners (if applicable 'project partner' means public or private legal entity that, together with the eligible institution, created the conditions for project implementation). Principal investigator (PI) must hold a PhD degree.
Norway	RCN	Norwegian universities, university colleges, hospitals, research institutes, public sector, user organisations, NGOs, SME and other private industry. The Research Council cannot award support to an enterprise that is defined as an "undertaking in difficulty" under the state aid rules (see the "Definition of 'undertaking in difficulty" on our website). "Enkeltpersonforetak", that is Norwegian companies with sole proprietorship, cannot participate as coordinator. Technology Transfer Offices (TTOs) are not eligible partners in this call.
Poland	NCBR	Following entities are eligible to apply: • Enterprises[1] - Micro, Small, Medium and Large; • Research organisations[2]; • Groups of entities composed of at least two enterprises, • Groups of entities composed of at least one research organisation and at least one enterprise, • Group of entities composed of at least two research organisations.
Romania	UEFISCDI	Eligible entities for funding are universities, public institutions, R&D national institutions, joint-stock companies, SME's and Large companies, NGOs (associations, foundations, etc.), others.
Slovakia	SAS	Only research Institutes of the Slovak Academy of Sciences are eligible organisations for funding by SAS (up to 100%). 1. The Slovak principal investigator must have a job contract for more than 50% working hours in the SAS organization for which the project proposal or participation in the project proposal is submitted. 2. Other researchers, except for doctoral students, must have a working relationship with the SAS organization. 3. Each researcher of the Slovak partner research team of a project consortium (other than the Slovak Principal Investigator) must have a job contract with or a fellowship with the Slovak Principal Investigator, lasting until the end of the project or beyond.
Slovakia	SCSTI	Legal entities established in the Slovak Republic, such as public or private research and academic institutions, higher education institutions, SMEs, public sector entities, and other relevant organizations actively involved in research, development, and innovation.

[1] defined in Annex I to Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty (hereinafter referred to as "Commission Regulation (EU) No 651/2014");
[2] Defined in Commission Regulation (EU) No 651/2014;

		· Research institutions (e.g. the Slovak Academy of Sciences and its institutes) · Academic sector (e.g. universities and higher education institutions) · Non-governmental non-profit organizations · Cluster organizations · Private sector entities (entrepreneurial/business sector) Public administration bodies, including local and regional government authorities, are eligible to participate; however, they are not eligible to receive funding and therefore cannot have a budget allocated to them.
Spain	AEI	The AEI will fund non-profit research organizations (such as universities, research centres, technological centres and other private non-profit institutions performing RDI activities in Spain). They must have been previously beneficiaries of any of the AEI calls, and they must ensure contractual relationship with the Principal Investigator (PI) during the whole duration of the project. IMPORTANT: Spanish legal entities which are part of mixed centres will be considered as a unique beneficiary, and thus the maximum funding should not exceed the limits per proposal established above. PIs must be eligible according to the PCI general requirements 4Sep26 of the corresponding PCI call (read PCI2026_1 call as an example) and read carefully the "General Conditions Trans Calls 2026" in Oportunidades de Colaboración
Spain	CPSEJA	• Eligible organisation must be Andalusian Non-profit entities registered as Agents of the Andalusian Knowledge System (Registro de Agentes Andaluces del Conocimiento) with research and innovation activity in Biomedicine and Health Sciences, ie: Research managing foundations of the Andalusian Public Health System. • Investigators must be linked through a civil servant, statutory or labour relationship with the applicant or performing centre. For Health Research Institutes (Institutos de Investigación Sanitaria, IIS), the link may be with any of the public or private law entities that are part of the IIS provided that the entity meets all the specific requirements determined in each action, and, in any case, be personnel assigned to the IIS.
Spain	FICYT/ SEKUENS	**Non-profit entities, not engaged in economic activity,** with research and innovation activity in **Biomedicine and Health Sciences**, such as: • University of Oviedo • Hospitals and primary health care centers of the Asturias Health System • Accredited Health Research Institutes located in Asturias, or the foundation in charge of managing the research of these Institutes • Public or Private Research and Technology Organisations located in Asturias
Spain	ISCIII	A maximum of **one partner** requesting funding from ISCIII may participate in the same project proposal. **ELIGIBLE INSTITUTIONS:** • **Accredited Health Research Institutes (Institutos de Investigación Sanitaria acreditados, IIS).** Accredited according to the RD 279/2016 (These institutions may manage research via a foundation regulated

		according to the Spanish Act 50/ 2002, of December 26th). See the list of IIS in this **link**. • Hospitals, primary health care or public health administration of the Spanish **National Health System (SNS).** These institutions may manage research via a foundation regulated in accordance to the Spanish Act 50/2002, of December 26th (a copy of the foundation's statutes may be submitted). • **CIBER:** team members applying to the call must be from at least two groups belonging to CIBER in two different home institutions and one of these two should be a hospital, primary health care or public health administration of the Spanish National Health System (SNS) or Accredited Health Research Institutes (Institutos de Investigación Sanitaria acreditados, IIS). Please contact Cristina Rodríguez (cristina.rodriguez@ciberisciii.es) for more information related to CIBER's eligibility. • Applicants not related with the National Health System from non-profit research organizations such as universities, OPIs, technological centres and other private non-profit institutions performing RDI activities in Spain **need to apply for funding to the Agencia Estatal de Investigación (AEI)**, following their eligibility criteria. It is highly recommended to this type of members to integrate in their consortium other Spanish clinical partner (IIS/SNS/CIBER) eligible for funding by ISCIII. **NOT eligible institutions:** - Those declared by **AES 2027** as ineligible to receive funds by ISCIII.
Taiwan	NSTC	All research institutes, universities, hospitals, public organisations in Taiwan endorsed by the National Science and Technology Council (NSTC) as eligible institutions.
The Netherlands	NWO	**National main applicants** To be eligible to submit a proposal, researchers must be employed for an indefinite period (with the associated employment contract) or have a tenure track agreement at any of the following research organisations: • universities and universities of applied sciences, as described in Section 1.8, subsection 1 of the Dutch Higher Education and Research Act, or universities referred to in the Policy Rules for Universities in the Kingdom of the Netherlands; • university medical centres, as described in Article 1.13, paragraph 1 of the Higher Education and Scientific Research Act; • KNAW institutes and NWO institutes; • TO2 institutions[3]; • Netherlands Cancer Institute; • Max Planck Institute for Psycholinguistics in Nijmegen; • Naturalis Biodiversity Center; • Advanced Research Centre for NanoLithography (ARCNL); • Princess Máxima Center Researchers employed at a university of applied sciences and researchers employed at a TO2 institute may also submit as a national main applicant if

[3] The TO2 Institutions are Deltares, NLR, TNO, WUR and MARIN.

		they have at least a salaried position for a limited period of time. **National co-applicants** All requirements regarding the employment contract described under ´National main applicant', also apply to national co-applicants. National co-applicants must be affiliated with a research organisation either: 1. eligible as a national main applicant (see above), or; 2. with other research organisations as described in Article 1.1, paragraph 4 of the NWO Grant Rules 2024 that comply with the following cumulative conditions. The organisation must: • be established in the Netherlands; • be a foundation, organisation or legal entity established and governed by public law (in Dutch: publiekrechtelijke rechtspersoon) (all other legal forms, including private and public limited companies, are excluded); • have as its primary goal the independent conduct of its own fundamental research, industrial research or experimental development or with widely disseminating the results of those activities through teaching, publications or knowledge transfer; be able to state that the organisation keeps separate accounts regarding economic/non-economic activities and that undertakings with decisive influence on the organisation do not enjoy preferential access to the organisation's results.
Türkiye	TUBITAK	For further information about application rules and procedures, please refer to the related TUBITAK website. **Participants from Türkiye should also submit their proposals to TUBITAK electronically via (https://uidb-pbs.tubitak.gov.tr/) for the pre-proposal phase.**

COMPOSITION OF THE CONSORTIUM

Each consortium must have a coordinator, they will be the unique contact point of the Joint Call Secretariat during the application process.

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

- A minimum of 3 (three) eligible and a maximum of 5 eligible partners from at least 3 different countries participating in the call. In addition, at least 2 (two) eligible partners must be from different **EU Member States or Horizon Europe Associated Countries** participating in the call. The countries that are participating to the call and are not EU member states or Horizon Europe associated countries are Taiwan and Egypt.
- The maximum number of eligible partners can be increased up to 6 (six) or 7 (seven) if they include 1 or 2 partners, respectively, from the following participating countries: Lithuania, Slovakia (applying to SAS or SCSTI), Taïwan and Türkiye.
- No more than 2 eligible partners from the same country participating in the call will be accepted within one consortium (may be subject to national regulations).
- A maximum of 2 collaborators (self-funded) per consortium.

Each application must include partners applying for funding from at least two of the three categories A, B and C (see below).

- **A. Academia –** research teams working in public and private universities, other higher education institutions or research institutes.
- **B. Clinical/public health sector –** research teams working in hospitals/public health and/or other health care settings and health organisations, including primary health care.
- **C. Enterprises –** private companies of all sizes involved in health research and innovation.

FUNDING MECHANISMS

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

The table shows **the maximum funding per grant awarded** to a project or a project partner:

Country	**Funding organisation**	**Maximum funding per grant** awarded per project and/or per partner
Belgium	F.R.S.-FNRS	300 000 € for a total period of three years.
Egypt	ASRT	Up to EUR 100,000 (when participating as partner) Up to EUR 130,000 (when the Egyptian entity is the consortium coordinator/lead) Funding is per Egyptian legal entity; multi-beneficiary participation from Egypt shares the national cap.
France	ANR	250 000€ for a partner, 330 000€ for a partner taking the coordination. If there are two French partners in one project, the maximum amount per project is 450 000 €.
Hungary	NKFIH	200 000€
Israel	CSO-MOH	Up to 140,000 €; additional 20,000 € for coordination
Italy	IT MOH	400 000€ per project

Latvia	LCS	300 000 Euros per partner, not exceeding 100 000 EUR per year
Lithuania	LMT	150 000€ for a partner, 200 000€ for a partner taking the coordination or for two partners in a consortium, 250 000€ for a partner and a coordinator
Norway	RCN	For a single partner role, the funding can be up to 380 000 EUR. If the Norwegian participant has a coordinator role, the funding can be up to 420.000 EUR. If the project has more than one Norwegian partner, the maximum total RCN funding is up to 450.000 EUR.
Poland	NCBR	400 000€ per project
Romania	UEFISCDI	200 000€ for a partner, 250 000€ for a partner taking the coordination
Slovakia	SAS	120 000€ per project
Slovakia	SCSTI	300 000€ for a partner, 400 000€ for a partner taking the coordination or in case there are two Slovak partners in one project. These amounts may be further increased by up to 15 000 EUR if a Slovak partner submits a patent, trademark, or design application, and/or publishes project results in an internationally indexed (peer-reviewed) scientific journal
Spain	AEI	**Maximum funding per project** / CD (€)* / CI (25%) (€)* / TOTAL (€)* One AEI applicant (partner) / 140.000 / 35.000 / 175.000 One AEI applicant – (coordinator) / 220.000 / 55.000 / 275.000 One coordinator and one applicant- (balanced budgets) / 260.000 / 65.000 / 325.000 Additional funding for substantial experimental tasks (per project) / 30.000 / 7.500 / 37.500
Spain	CPSEJA	125 000€ for a partner, 250 000€ for a partner taking the coordination
Spain	FICYT/ SEKUENS	150 000€ per project
Spain	ISCIII	200 000€ for a partner, 275 000€ for a partner taking the coordination
Taiwan	NSTC	270 000€ (90 000 € per year)
The Netherlands	NWO	400 000€
Türkiye	TUBITAK	Up to 200 000 Euros per project, max. 100 000 Euros for public institutions and max. 200 000 Euros for private companies with 60% funding of the eligible costs for large companies and 75% funding of the eligible costs for SMEs

WHO TO CONTACT AND FOR WHAT PURPOSE:

National and regional contacts should be contacted for all questions regarding: the national and regional eligibility of the partners, the eligibility of the costs, and the eventual submission of required national and regional documents in addition to the proposal submitted by the coordinator on Pt-outline.

The funding organisations requiring submission of additional national/regional documents are: AEI, F.R.S.- FNRS, FICYT/ SEKUENS, CSO-MOH, It-MoH, ISCIII, and TUBITAK.

All other questions should be addressed to the joint call secretariat (NanoDiagNCD@agencerecherche.fr).

National/regional contact persons:

Country	**Funding organisation**	**Email address for all national/regional questions**

Belgium	F.R.S.-FNRS	international@frs-fnrs.be
Egypt	ASRT	innov@sti.sci.eg / engasmaa2005@gmail.com / radwan.amro@gmail.com
France	ANR	ERA4HealthCall@agencerecherche.fr
Hungary	NKFIH	zsuzsanna.kurti@nkfih.gov.hu
Israel	CSO-MOH	irit.allon@moh.health.gov.il / netta.koren@moh.health.gov.il
Italy	IT MOH	int-dgric@sanita.it/ g.papagni@sanita.it
Latvia	LCS	Uldis.Berkis@lzp.gov.lv
Lithuania	LMT	zivile.ruzele@lmt.lt
Norway	RCN	Login custom - Forskningsrådet Kontakt
Poland	NCBR	era4health@ncbr.gov.pl
Romania	UEFISCDI	mihaela.manole@uefiscdi.ro / nicoleta.dumitrache@uefiscdi.ro
Slovakia	SAS	katarina.bibova@urad.sav.sk
Slovakia	SCSTI	marek.babusiak@cvtisr.sk / libusa.dadova@cvtisr.sk
Spain	AEI	Era4Health@aei.gob.es
Spain	CPSEJA	ep.fps@juntadeandalucia.es
Spain	FICYT/ SEKUENS	maria.gonzalez@ficyt.es/ anae@sekuens.es
Spain	ISCIII	anagarcia@isciii.es
Taiwan	NSTC	cmtom@nstc.gov.tw
The Netherlands	NWO	ERA4Health@nwo.nl
Türkiye	TUBITAK	sukran.alpdemir@tubitak.gov.tr

ERA4HEALTH RESPONSIBLE INNOVATION JOURNEY GUIDE:

Responsible innovation is **not a single activity**, but a **continuous journey** that evolves with the maturity, direction and potential impact of research and innovation activities.

The Responsible Innovation Journey Guide compiles four sets of ideas that complement each other:

- **Responsible Research and Innovation (RRI) ->** RRI drives research and innovation towards socially desirable outcomes in a process of co-creation and co-design with all relevant knowledge actors, including citizens. It is based on the co-responsibility of knowledge actors for long term sustainability goals and aligns research and innovation with fundamental ethical values.
- **Research ethics ->** Responsible Conduct of Research (RCR) is dealing with the ethically grounded and professionally accountable conduct of research across all stages of the research lifecycle. It includes the design, performance, documentation, analysis, reporting, review, and dissemination of research in accordance with principles of honesty, rigor, transparency, objectivity, accountability, respect for participants and subjects, responsible data stewardship, fair attribution of credit, and social responsibility. This understanding follows the broader research integrity literature, which views RCR not merely as the avoidance of misconduct, but as adherence to the ethical norms and professional standards that sustain trustworthy science.
- **Societal Readiness (SR) ->** SR describes how the needs and concerns of relevant actors, institutions and systems are considered and included in social and technological innovation, with the aspiration that greater inclusion of needs and concerns enhances the readiness of innovations for eventual adoption.
- **Open science (OS) ->** Open Science establishes the value of 'openness' in research by enabling knowledge and data sharing among researchers. It implies not only 'openness'

towards knowledge and data sources but also 'openness' to knowledge producing actors, including citizens (citizen science).

These four sets sit within the broader European framing of **Open and Responsible Research and Innovation (ORRI)**, which treats openness and responsibility as a single agenda spanning anticipation, inclusion, ethical integrity, open science, equitable access and institutional learning. Where this guide says RRI, it means responsibility in that broad sense: a property of the innovation ecosystem — academia, government, business and industry, and civil society — and not of the research team alone.

The Responsible Innovation Journey Guide helps, via appropriate questions, ways to put this into practice and possible approaches, project teams and programme actors to integrate these sets of ideas with the R&I processes in a coherent, proportional and phase-appropriate way. **This Responsible Innovation Journey Guide is intended as a framework for thinking and dialogue. It is intended to be adaptable to user's specific contexts and risks. It is not a one-size-fits-all prescription.** This lifecycle-based framework creates a bridge between ethics, governance and impact in a shared language for applicants and evaluators.

Responsibility in health innovation is a **shared commitment across the quadruple helix**: academia generates knowledge, government funds and regulates, industry develops and distributes, and civil society articulates what is needed and what is acceptable. Few health innovations reach patients through any one of these actors alone. The questions in this guide therefore concern the relationships between them — who sets the agenda, who is consulted, who carries the risk, who gains access — as much as the internal conduct of a project.

The guide encompass these RRI themes in a health science setting:
Responsible Conduct of Research (RCR) – as ethics in design and continuous oversight
Sustainability and circularity – environmental, social, economic and long-term responsibility
Research security –dual use and geopolitical risks, protection against misuse
Social science and humanities (SSH) integration – reflexive capacity, interdisciplinarity and societal insight
Equity, access and inclusive innovation – who benefits, who is left out, and whether results will reach the people whose need is greatest
Openness, engagement and science literacy – open science, public engagement and an informed citizenry as conditions for trust and uptake.

The listed questions and points therefore provide overall ideas and advice but cannot give a recipe that all potential applicants may use. However, by using this journey guide and appropriately integrating the results of doing so, you will have taken an important step toward more deeply engaging with and considering the tensions and meaningful societal benefits associated with health research and innovation.

So what should you do?

In ERA4Health, the commitment to ethics and RRI is clear and fixed in the programme, but there is an openness about the issues addressed and the specific ways to practise responsibility – these must be adapted to each project. Your approach to Responsible Innovation should be proportionate to the nature and maturity of your proposal. Disruptive, ground-breaking or high-Technology Readiness Level (TRL) research is likely to require more substantive engagement, while for exploratory research, the

Responsible Innovation components may themselves be exploratory, helping to tease out potential visions, goals and future uses of the project.

The full guideline presents the Responsible Innovation Journey where phases depend on project status – from mindset and idea to impact and legacy. *It guides you on what you should actually do and holds as starting points to help you identify the most relevant dimensions for your project. The questions will direct you to different perspectives relevant to health research and innovation projects. Many can be explored through practical approaches and methods, with examples (possible approaches) provided below. These options are illustrative rather than exhaustive or mandatory and should be selected in proportion to the project's maturity, novelty, risk and expected impact.*

Please be aware that these options neither represent a complete list of examples, nor the mandated approaches by ERA4Health. The full guide is not presented in this call, but you will find it on this ERA4Health RRI webpage: https://era4health.eu/publications/rri.php

The mindset

The main mindset in RRI and RCR is not seeing them solely as matters of compliance ('taking care of'), but contemplation ('caring for'). **This also applies to the development and use of artificial intelligence (AI) in research and innovation**. Where AI is used, researchers should reflect not only on what the technology can do, but also on why and for whose benefit it is being used, how it may affect people and society, and where meaningful human agency, judgement and oversight need to be maintained. This reflects the EU's human-centred approach to trustworthy AI.

The following points will provide a good mindset and foundation for how to develop the responsible innovation approach in your proposal, making your response able to:

1. Treat responsible innovation as an integrated part of the project, involving as many project members as possible. Do not think of it 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. It is a theme requiring recurring attention in the lifecycle of your project.

2. Develop the scientific and "responsible 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. Where AI is developed or used, these conversations should include reflection on human agency and oversight, transparency and explainability, data and privacy, potential bias and discrimination, accountability, and possible societal and environmental consequences.

3. Integrating responsible research and innovation into projects will require the acquisition of new knowledge, expertise and skills. Where relevant, this may include combining scientific and technical expertise with expertise in ethics, social sciences and humanities, law, stakeholder engagement, and responsible and human-centred AI.

4. The ethics-related questions included are based on the norms of RCR and support reflection on RCR throughout the whole journey. They have a broad scope and will not be equally relevant in all projects. Projects developing or using AI should explicitly consider whether AI introduces additional ethical or societal questions, including effects on human autonomy and decision-making, transparency, fairness, privacy, accountability, and the distribution of benefits and risks, including the environment.

For projects involving AI, a useful European reference is the European Commission's Ethics Guidelines for Trustworthy AI. The associated Assessment List for Trustworthy Artificial Intelligence (ALTAI) can also be used as a practical reflection tool.

All applicants must also carry out a research ethics self-assessment in line with Horizon Europe procedures (https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf). Please note that the full ethics self-assessment will be required at the stage of submitting a full proposal for this call.

In some research areas, there are also national laws and international conventions and agreements that researchers and research managers must follow, for example on the processing of personal data. Central documents are Declaration of Helsinki, European Code of Conduct for Research Integrity and CIOMS Guidelines.

Both medical, health and animal research are regulated by law, and require prior approval. Assessments of such assumptions are in addition to the research ethics self-evaluation. The questions represent reminders of the most important norms of research ethics. However, other norms of research ethics may also be relevant to your project, and you are responsible for checking this.

The Responsible Innovation Journey related to proposal writing

The phases below are designed to complement each other. Each phase has the same structure and avoids repeating questions, approaches, ways to put this into practice or possible approaches. The level of activity should remain proportionate to the project's maturity, novelty, risk and expected impact.

Phase 1 – Project idea

Key question: Why should we do this, why now, and for whom?

Purpose: Clarify whether the idea has a responsible, meaningful and legitimate starting point before the project direction becomes fixed.

Questions

- What health-related, societal or environmental need does the idea address, and why is it important now?
- Who may benefit, who may be left out, and who could face new burdens, harms or risks?
- Which assumptions, values, interests or alternative framings should be tested before the idea is developed further?
- Could the idea create ethical, legal, environmental, security or dual-use concerns that should affect whether or how it proceeds?

Responsible approach

- Start with purpose and direction, not only scientific feasibility.
- Identify affected groups and missing perspectives early.
- Determine uncertainties, values, possible harms and security sensitivities before the proposal is locked.
- Decide whether ethics, SSH, regulatory, sustainability or stakeholder expertise is needed already at this stage.

Ways to put this into practice

- A short problem-framing workshop with project partners and selected stakeholders.
- A preliminary benefit-risk, harm and dual-use screening.
- Stakeholder and affected-groups mapping, including groups that may be excluded.
- A short comparison of alternative approaches to the same challenge.
- An early ethics and integrity check, including research culture, independence, openness and possible regulatory requirements.
- A simple decision log documenting why the project idea should proceed, change direction or stop.
- A short horizon-scanning or scenario exercise to surface plausible future uses, misuses and side effects of the intended results.
- A check of whether the intended benefit can reach its users through existing market and health-system pathways, or whether a deliberate access strategy is needed.

Possible approaches

- A consortium compares a new health technology with non-technological alternatives and identifies patient groups that may be excluded by cost, access or usability barriers.
- A project using sensitive data checks early whether open-science ambitions can be balanced with confidentiality, privacy and security obligations.
- A project involving animals, humans or environmental exposure identifies possible harm early and adapts the research design before the full proposal is developed.
- A project team invites patient representatives, health professionals or community actors to discuss whether the project's problem definition matches lived experience and practical needs.
- A consortium developing a diagnostic asks at the idea stage whether the test could realistically be manufactured, priced and distributed in the settings where the disease burden is highest and adjusts its partner composition accordingly.
- A team invites an industrial actor/investor and a policy actor alongside clinicians to its first framing workshop, on the grounds that uptake will depend on decisions no research partner controls.

Outcome: A responsible starting point with clear awareness of purpose, affected groups, assumptions, possible harms and conditions for proceeding.

Phase 2 – Proposal development

Key question: How will we do this responsibly and on solid ethical grounds?

In Annex 2 of the full Responsible Innovation Journey Guide, you can find a more detailed version of guiding to this phase 2 -" Proposal development". Below is a summarised oversight of this longer guide and the areas it covers is presented.

It divides the guiding questions into these advice points:

1. Define the purpose, need and expected value of the project
2. Identify relevant people, groups and expertise early
3. Design research methods and safeguards together
4. Anticipate consequences, risks and alternative futures

5. Address safety, sustainability and responsible implementation
6. Build reflection, learning and responsiveness into the work plan
7. Show how responsibility strengthens excellence, impact and implementation

And the possible ways to put this into practice and possible approaches are divided into these areas:

- Stakeholder and public involvement
- Ethical, legal and social considerations in research design
- Reflection, learning and adaptive project management
- Data stewardship and Open Science
- Safety, implementation and societal uptake
- Sustainability and environmental responsibility
- Fair collaboration and responsible research culture
- Monitoring, indicators and responsible metrics
- Public engagement, science communication and science literacy

Quick self-check: For each area above, identify what is already addressed, what still needs strengthening, and what is not relevant to your project, with a brief justification. The aim is not to maximise a score, but to identify the actions that are most relevant and proportionate to the project.

Here is a main guide for phase 2:
Key question: How will we do this responsibly and on solid ethical grounds?

Purpose: Translate responsibility into concrete choices in the scientific design, work plan, governance, resources and expected impact.

Questions

- How are ethical safeguards, data practices, stakeholder involvement and scientific methods designed together?
- What expertise, roles, budget and decision points are needed for RRI, ethics, SSH, sustainability, Open Science and research security?
- How will the project handle bias, vulnerable groups, animal welfare, international collaboration, regulatory requirements and conflicts of interest where relevant?
- How can stakeholder input, ethical reflection or new knowledge realistically change the project during implementation?

Responsible approach

- Move from general commitments to project-specific activities, responsibilities and resources.
- Make inclusion purposeful and proportionate: who is involved, why, when and with what influence.
- Clarify differences of opinion among stakeholders and how to advance the state of art of science and innovation by being mutually responsive to those opinions.
- Build flexibility into milestones and governance so learning can shape the project.
- Balance openness, FAIR data and transparency with confidentiality, privacy, safety and security needs.

Ways to put this into practice

- Co-design, focus groups, advisory boards or living labs where stakeholder knowledge can shape design.

- Ethics-by-design, data governance review, research integrity review or independent ethical monitoring.
- Foresight, scenario work, stage-gate review or philosopher-in-the-lab/embedded SSH collaboration from relevant fields.
- Regulatory road mapping, safety-by-design or safe-and-sustainable-by-design assessment.
- Open science and data management plan based on “as open as possible, as closed as necessary”.
- Publish reports, data and deliverables in open science infrastructures
- Employ open notebooks for swift knowledge and data sharing among project partners and beyond
- Do a consortium governance review, include equality/diversity/inclusion in plans and collaboration agreement.

Possible approaches

- Stakeholder representatives are included in governance with a clear mandate and documentation of how their input will be used.
- An embedded SSH or ethics task helps adjust research questions, interpretation and communication, rather than only supporting dissemination.
- A data-driven project reviews dataset for bias and sets rules for secure sharing, access control and reporting of negative or null results.
- A materials or technology project compares design options through safety, environmental and circularity criteria before protocols are finalised.
- Employ a publicly funded and controlled platform (e.g. Zenodo) as open science infrastructure to openly share data and knowledge

Outcome: A proposal where responsibility is integrated into design, methods, safeguards, stakeholder involvement, governance, resources and implementation planning.

Phase 3 – Proposal submission

Key question: Is responsibility convincingly addressed?

Purpose: Present the responsible-innovation approach clearly enough for evaluators to understand its relevance, credibility and feasibility.

Questions

- Does the proposal show how responsibility strengthens excellence, impact and implementation?
- Are RRI and ethics addressed as substantive project work, not only as compliance text or box-ticking?
- Are responsibilities, resources, milestones, deliverables and decision points visible and proportionate to the project’s maturity and risk?
- Does the ethics self-evaluation cover the relevant legal, ethical, data, security and participant-related issues?

Responsible approach

- Make a structured internal read-through of the draft against the Phase 2 questions.
- Organise a review by an RRI or ethics advisor before submission.

- Do a budget check confirming that responsibility work has named people, person-months and money attached to it.
- Use precise, project-specific language and avoid generic statements.
- Show how activities will influence research choices, not only run in parallel to the science.
- Make the link between ethical safeguards, societal readiness and expected impact explicit.
- Demonstrate that the project has the capacity and flexibility to respond to new concerns.

Ways to put this into practice

- Proposal cross-check against ethics self-evaluation and relevant legal/regulatory requirements.
- RRI activity table linking objectives, tasks, responsibilities, timing, budget and deliverables.
- Risk and responsiveness matrix showing triggers for adaptation or escalation.
- Data, Open Science and confidentiality/security statement.
- Stakeholder involvement plan showing influence, documentation and feedback loops.

Possible approaches

- A proposal states who leads RRI work, how it is resourced with a defined share of effort in the person-month table and which work packages can change in response to stakeholder or ethics input.
- A clinical or data-intensive project explains how consent, privacy, incidental findings, access rules and OS ambitions will be handled together.
- A high-novelty project includes decision gates where safety, sustainability or societal-readiness evidence must be reviewed before further development.
- Including a deliverable that reports stakeholder input and the changes it produced, rather than only that engagement took place.
- State **where in the proposal** each responsibility element sits — objectives, methods, work plan, impact section — so that evaluators do not have to search for it.
- Be explicit about openness: what will be published, which data will be shared, under what licence, and where confidentiality, personal-data protection or research security genuinely requires restriction.
- Show that the claimed societal benefit has a plausible route to the people who need it, including affordability, regulatory approval and health-system adoption.

Outcome: Transparent accountability: evaluators can see what will be done, by whom, with what resources and how it can affect the project.

Funding checkpoint – Quality assessment

Key question: Can this project proceed responsibly?

Purpose: This is a programme-level intervention point into the Responsible Innovation Journey and an evaluation / quality assessment. It assesses whether the proposal's responsible innovation approach is credible, proportionate and embedded across excellence, impact and implementation.

Questions

The kinds of questions the RRI Advisers/reviewers can ask regarding the stated commitments included in the proposal/project are about qualities such as:

- **Specificity:** is this appropriately tailored to this project?
- **Proportionality**: does the approach fit maturity, risk and context?
- **Integration:** can responsibility influence the science rather than merely accompany it?
- **Capacity:** are expertise, resources, responsibilities and time credible?
- **Responsiveness:** are there genuine opportunities to change course?
- **Learning and impact:** is there a credible account of how experience, stakeholder knowledge and effects will be captured and used?

FREQUENTLY ASKED QUESTIONS:

Composition of the consortium and eligibility of the partners

- **My consortium has two partners from the same country but applying to different funding organisations, can we have another partner from the same country?**

No, the rule is a maximum of two partners from the same country, it does not matter what organisation they are applying to.

- **Can Postdoctoral fellows be principal investigators?**

This will depend on the funding organisation involved, you need to contact the national contact person (see annex I of the call text). You will very likely need a letter from the institution stating that the PI will stay at the institution during the whole duration of the project.

- **Can non-tenure personal be principal investigator?**

This will depend on the funding organisation involved, you need to contact the national contact person (see annex I of the call text). You will very likely need a letter from the institution stating that the PI will stay at the institution during the whole duration of the projects.

- **Can Co-PI represent a partner?**

No, a single PI must represent the partner.

- **Can collaborators be eligible for funding but not want to apply as partners anyway?**

Yes, collaborators are self-funded partners. Even if the organisation of a collaborator is eligible for funding, it is not mandatory for them to request a budget.

- **There are two partners from the same country in my consortium, can my collaborator come from that country as well?**

Yes, the collaborator does not count for the country rule.

Proposal

- **Can I apply only to the second step of the call?**

No, your consortium must apply to the first step, i.e. submit a pre-proposal, to apply to this call. The application on the second step is made only upon invitation, which is based on the eligibility and the scientific evaluation results of your pre-proposal.

- **Do I need to follow the format of the pre-proposal template?**

Absolutely, you must keep the format as it is. All fields must be completed using "Arial font, size 11" characters; paper format: A4 with all margins minimum 1.27 cm.

- **Can additional figures be inserted?**

You can only add figures in the work plan, and you must still respect the maximal length for the section.

- **Can I add several CV for one partner?**

No, you must only add the CV of the PI who represent the partner respecting the format in the template.

- **Can supporting letters be added?**

No, extra material including letters of support are not allowed.

- **Who must sign the pre-proposal and the proposal, the Principal Investigator or the administrative representative of the partner?**

The principal investigator must sign the pre-proposal and proposal.

- **Do the collaborators need to fill the budget table?**

No, collaborators do not need to fill the budget table

- **What does *in kind* mean?**

In kind means the funds you are bringing in the project but for which you are not requesting any funding from a participating funding organisation.

Electronic submission platform PT-outline

- **What is the link to the submission platform?**
  https://ptoutline.eu/app/E4H-NANODIAGNCD

- **I do not have an account on PT-outline. How do I create one?**

When you are on the home page. On the right of the tab “login”, you have a tab “sign up” where you can enter your email address to receive a password.

- **Does the data of the collaborators need to be inserted on the submission platform?**

Yes, there is a specific tab on the platform for collaborators

- **How do I add more partners on PT-Outline?**

You need to first save the first partner (by clicking save at the bottom of the page), then a button “add a new partner” will appear on top of the page. Use the same process on the collaborator tab.