ERA4Health Partnership

Co-funded by the European Union

Joint Transnational Call Investigator-Initiated Clinical Studies (JTC IICS) 2025

"Fostering Pragmatic Comparative-Effectiveness Trials in Non-communicable Diseases"

(EffecTrial)

Guideline for applicants

DEADLINES

January 28th, 2025 (16:00, CET) - SUBMISSION OF PRE-PROPOSALS

June 17th, 2025 (16:00, CEST) - SUBMISSION OF INVITED FULL PROPOSALS

Link to the electronic proposal submission will be published here:

https://era4health.eu/calls/effectrial2025.php

The submission system will be open by November 28th, 2024 (*to be confirmed)*

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

or contact the Joint Call Secretariat (JCS):

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Content

General

This call uses a two-step submission procedure (pre-proposals and full proposals), including a rebuttal stage and an online interview.

All proposals must be written in English and submitted exclusively by using the PT-Outline electronic submission system, and this before January 28th, 2025 for the pre-proposals and before the June 17th, 2025 for the full proposals.

It is recommended to carefully read the call text and the guidelines for applicants prior to starting an application.

Eligibility

Before being included in a consortium, all Principal Investigators should self-assure that her/his organisation is eligible for funding by one of the funding organisations participating in the call. All funding rules from a specific funding organisation are available in the Annex I of the call text. Here we will present the Eligible Partners for the different funding organisations to have an overview of country for a specific rule.

The below table shows the eligibility of partners for each funding organization participating to the call:

Country	Funding Organisation	Eligibility of Partners
Austria	FWF	The proposed research must be carried out in Austria under the auspices of the Austrian lead research institution The principal investigator must be employed at the Austrian research institution applying for funding at the time the project is scheduled to begin. All Austrian research institutions are eligible to apply if they are registered in the FWF's research institution portal. Applications are to be submitted by the research institution where the project is to be carried out. Neither a specific academic degree nor Austrian citizenship is required to act as principal investigator. The principal investigator must, however, have appropriate scientific qualifications (see section 1.4) and sufficient time resources to carry out the proposed research. The research institution must provide the necessary infrastructure. Please refer to the general FWF Application Guidelines and the respective Application and project number limit
Czech Republic	MZCR /AZVCR	Research Organisations, Enterprises. All eligibility rules and criteria can be found on the Czech Health Research website (AZV ČR – Agentura pro zdravotnický výzkum České republiky (azvcr.cz). It is **recommended** to contact the responsible person at the Czech Health Research Council (prior to submission regarding the eligibility criteria).
France	Fr-MoH	To be confirmed
Germany	BMBF/DLR	Eligible applicants are researchers or research groups from German universities, German university hospitals and German non-university research institutes. Enterprises in the commercial sector are only eligible to apply in exceptional cases if they are also a

		healthcare organisation. For specific conditions see also link to German version of the call below. Only consortia whose research question includes at least the use of one nutrition and/or lifestyle interventions are eligible for funding from BMBF/DLR-PT. The comparison of e.g. two pharmacological interventions cannot be funded by BMBF/DLR-PT. Please note that dietary supplements in pharmacological doses are not considered a nutrition intervention. Prior the submitting of the proposal, it is **highly recommended** to get in touch with the national contact persons to clarify the specific requirements of this call.
Ireland	HRB	Lead Applicants (Principal Investigators) based in Ireland must be from a recognised HRB Host Institution in the Republic of Ireland (Policy on Approval of HRB Host Institutions). Partners classed as 'Enterprise' cannot be in receipt of HRB funding. Please see HRB's dedicated scheme page on HRB's funding page for Guidance and FAQ specific to eligibility for applicants based in Ireland.
Israel	CSO-MOH	Researchers will only be able to participate as partners in consortia. Sponsors will be considered and approved only in exceptional cases where funding is secured from other sources. Position in a university, research center or hospital. Research authority must approve position prior to submission. PI should hold a Ph.D., M.D., D.M.D., D. Sc or equivalent degree and employed by an eligible institution. Research will not be funded simultaneously by CSO-MOH on more than one grant (Era-NET or national). Researchers can not apply for more than one grant from any ERA-NET funded by CSO-MOH or submit more than one proposal for any programme.
Italy	IT MOH	Only IRCCS (Istituti di Ricovero e Cura a Carattere Scientifico) researchers are eligible to apply. (Further details in Annex I)
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. (Further details in Annex I)
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, university hospitals. (Further details in Annex I)
Norway	RCN	Principal investigators must come from an approved Norwegian research organization. User/patient organizations may participate under the umbrella of the principal investigator (with a collaboration agreement or subcontracting).

Poland	NCBR	Research organization (research and knowledge-dissemination organisations). Entities must be established as a legal person and must conduct its business, R&D or any other activity on the territory of the Republic of Poland, confirmed by an entry into the relevant register. (Further details in Annex I)
Slovakia	SAS	Only research Institutes of the Slovak Academy of Sciences are eligible organisations for funding by SAS (up to 100%). **SAS can fund only Principal Investigator (PI), not a Coordinating Investigator** in this call.
Spain	ISCIII	Eligible Institutions : - Accredited Health Research Institutes - Hospitals, primary health care or public health administration of the Spanish National Health System (SNS). - CIBER - Monographic public R&D Centres, exclusively working in the field of the priority medical areas included in the call Principal Investigators (PI) shall mandatory have PhD degree. Principal Investigators (PI) can only participate in one project proposal per call. (Further details about eligibility of partners and eligibility of PIs in Annex I)
Spain	CSCJA	Eligible organisation must be Andalusian Non-profit entities registered as Agents of the Andalusian Knowledge System with research and innovation activity in Biomedicine and Health Sciences. (Further details and eligibility of PIs in Annex I)

Composition of the consortium

Each consortium should have a coordinator, and he/she will be the unique contact point of the ERA4Health Joint Call Secretariat during the application process.

The maximum size of the consortium is detailed in the Call Text and examples are given below.

The consortium should include only one main partner/organisation eligible by each national/regional funding organisation. Then this partner/organisation will coordinate additional recruiting sites at national/regional level via subcontracting or collaboration agreements (see table for the possibility offered by each funding organisation). These additional recruiting sites do not receive funding directly from the funding organization, but from the main partner. In case of issues regarding the patient/participant recruitment during the runtime of the clinical study, these additional recruiting sites could be substituted by different ones if it is possible under the national/regional regulations of the respective national funding agency for that specific partner. This could allow flexibility in opening/closing the recruitment sites during the clinical study.

An **exception** exists for the following funder(s): CSO-MOH, IT-MOH, LCS and CSCJA,. For FWF both options are possible.

In this case, the consortium can include a maximum of 3 national/regional partners eligible by each of those funding organisation(s) (Check Annex I for specific national/regional regulation). The funding organisations will fund the 2 or max. 3 national/regional partners directly and there will be no subcontracting or collaboration agreements between them.

The below table shows the requirement by each funding organization participating to the call:

Country	Funding organisation	Funds one partner or several partners per consortium	If one partner is funded this type of agreement/contract need to be established
Austria	FWF	For the FWF, both options are theoretically possible: - All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners are authorised. - Or only one organisation will be granted and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement. Please contact the FWF office for a detailed clarification which approach would be the most appropriate for your proposal.	
Czech Republic	MZCR /AZVCR	Only one organisation will be granted	This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement
France	Fr-MoH	To be confirmed	
Germany	BMBF/DLR	Only one German partner per proposal will be granted	This organisation will establish a collaboration with other German recruitment sites via case payments based on collaboration agreements.
Ireland	HRB	HRB will contract with a single Host Institution (Lead Applicant).	Additional national recruiting sites (associate partners) are permitted to join the consortium. The Lead Applicant will be responsible for appropriate distribution of funds to the associated partner(s) via collaboration and/or consortium agreements.
Israel	CSO-MOH	All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners are authorised.	
Italy	IT MOH	Simultaneous PI participation in different 2025 JTCs funded by the Ministry of Health is not allowed.	

		No more than two Italian PIs (Principal Investigators) are eligible to apply for the same project. Italian PAOs can be funded as a sub-contractor of an IRCCS if they fulfil the eligibility criteria of the EC.	
Latvia	LCS	Maximum 2 funded Latvian partners per proposal allowed, they must be fully independent on legal, financial and personnel basis.	
Lithuania	LMT	Only one organisation will be granted	This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement.
Norway	RCN	Only one organisation will be granted	This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement.
Poland	NCBR	Only one organisation will be granted	This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement.
Slovakia	SAS	Only one organisation will be granted	This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement.
Spain	ISCIII	Only one eligible partner will be granted	Collaboration agreements with other additional national recruiting sites
Spain	CSCJA	All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners are authorised.	

The consortium can have a maximum of 3 self-funded collaborators. Those collaborators can be patient organisations, enterprises or other entities with different roles, e.g. drug provider, an important stakeholder to implement the outcomes of the clinical study at its term.

Example of consortia:

Smallest consortia:

Consortium 1: the funding organisations involved are funding each one a single partner, who will establish collaboration agreements with additional national recruitment sites.

Partner A from country 1 *(Supported by additional recruitment sites)*

Partner B from country 2 *(Supported by additional recruitment sites)*

Partner C from country 3 *(Supported by additional recruitment sites)*

Consortium 2: in this case one of the funding organisation should grant several partners within the same consortium:

Partner A from country 1 *(Supported by additional recruitment sites)*

Partner B from country 2 *(Supported by additional recruitment sites)*

Partner C from country 3 (*no possibility to be supported by additional recruitment sites, since the funding organization does not allow* the establishment of a collaboration agreement with other national recruitment sites, additional recruiting sites will be added as additional partner for this country)

Partner D from country 3 (*no possibility to be supported by additional recruitment sites, since the funding organization does not allow the establishment of a collaboration agreement with other national recruitment sites, additional recruiting sites will be added as additional partner for this country)*

Partner E from country 3 (*no possibility to be supported by additional recruitment sites, since the funding organization does not allow the establishment of a collaboration agreement with other national recruitment sites, additional recruiting sites will be added as additional partner for this country)*

Larger consortia:

Consortium 1: the funding organisations involved are funding each one a single partner, who will establish collaboration agreements with additional national recruitment sites.

Partner A from country 1 *(Supported by additional recruitment sites)*

Partner B from country 2 *(Supported by additional recruitment sites)*

Partner C from country 3 *(Supported by additional recruitment sites)*

Partner D from funder X in country 4 *(Supported by additional recruitment sites)*

Partner E from funder Z in country 4 *(Supported by additional recruitment sites), here the partner D and partner E are eligible by different funding organisations from country 4; it can be regional and national funding organisations.*

Partner F from country 5 *(Supported by additional recruitment sites)*

Partner G from country 6 *(Supported by additional recruitment sites), belonging to the list of countries that allow an additional partner*

Partner H from country 7 *(Supported by additional recruitment sites), belonging to the list of countries that allow an additional partner*

Collaborator 1

Collaborator 2

Collaborator 3

Consortium 2: in this case, one of the funding organisation should grant several partners within the same consortium:

Partner A from country 1 *(Supported by additional recruitment sites)*

Partner B from country 2 *(Supported by additional recruitment sites)*

Partner C from country 3 *(Supported by additional recruitment sites)*

Partner D from country 4

Partner E from country 4

Partner F from country 4 *(Since the funding organisation of country 4 does not allow the establishment of collaboration agreements with other national recruiting sites, there can be 3 partners from country 4: D, E, and F)*

Partner G from funder X in country 5 *(Supported by additional recruitment sites)*

Partner H from funder Z in country 5 *(Supported by additional recruitment sites), here the partner G and partner H are eligible by different funding organisations from country 5; it can be a regional and a national funding organisations*

Partner I from country 6 *(Supported by additional recruitment sites), belonging to the list of countries that allow an additional partner*

Partner J from country 7 *(Supported by additional recruitment sites), belonging to the list of countries that allow an additional partner*

Collaborator 1

Collaborator 2

Collaborator 3

These are examples of potential large consortia, but the consortia could be even larger. In the last example, in case that funders from country 1, 2 and 3 do not allow the establishment of collaboration agreements with other national recruiting sites, there could exist up to 3 maximum partners from each of those countries (1, 2 and 3) in the same consortia.

Funding mechanism

This funding mechanism is a pilot scheme and demands special attention from the applicants.

The clinical study tasks are composed of two different types of costs:

- **Investigational costs** covered by each country/region: site costs (personnel, clinical procedure, site services, patient/participant renumeration), country management sites (site selection and coordination at the country level), and clinical study management costs at national or regional level (e.g. monitoring and insurance).

  The investigational costs should be requested to the national/regional funding organisations by only one eligible partner or a maximum of 3 partners in the same region/country according to the mode of funding of the specific funding organisation (see section “composition of the consortium” above). The requested funds and the eligible costs are the following for the funding organisations participating to the call (see below table).

Country	Funding organisation	Maximum/ Minimum funding per grant awarded to a clinical study partner	Eligibility of costs, types and their caps
Austria	FWF	Austrian participations are expected not to exceed the average range of an FWF stand-alone Project (typically € 300.000 to €450.000).	Project-specific costs are eligible for funding. These include personnel and non-personnel costs that are needed to carry out the project and that are not included in the infrastructure provided by the research institution. The FWF does not finance the infrastructure or basic equipment of research institutions. The current FWF Personnel Costs and Salary Rates scale indicates the salaries that may be requested. The FWF grants an annual salary adjustment to compensate for inflation, which is applied automatically to all contracts of employment in Principal Investigator projects that are valid when the adjustment takes effect. Please refer to the FWF Application Guidelines
Czech Republic	MZCR /AZVCR	The maximum funding per grant awarded to a clinical study partner is 250,000 EUR.	All eligibility of costs, types and their caps can be found on the Czech Health Research website (AZV ČR – Agentura pro zdravotnický výzkum České republiky (azvcr.cz)). It is **recommended** to contact the responsible person at the Czech Health Research Council prior to submission regarding the eligibility criteria.
France	Fr-MoH	To be confirmed	To be confirmed
Germany	BMBF/DLR	Up to 350.000 € for regular German partners; up to 500.000 € for German partners in the role of the sponsor (overhead costs included).	The following costs are eligible for funding (details see German version of the call): - Personnel (e.g. project management, clinical project management, coordination and quality assurance); - case payments; - patient and target group involvement; - materials; - Fees and Insurance; - Travel & networking costs; - Communication, Dissemination and Publication costs; - Overhead costs ("Projektpauschale"). Overheads are eligible according to standard BMBF regulations. Funding rates for universities, university hospitals and non-university research institutes can be up to 100% of their costs.
Ireland	HRB	To be confirmed	Funding available is inclusive of overheads and pension contributions • Salary related costs • Direct running costs, including patient-related costs and costs to support interventional studies • Patient and Public Involvement (PPI) costs • Small equipment costs (€10,000) • Travel • FAIR data management costs • Dissemination and knowledge exchange costs

			For more information please see HRB's guidance on the dedicated scheme page on HRB's funding page.
Israel	CSO-MOH	Up to 160,000 €	Materials and consumables; Travel and hosting (up to 5%); No salaries for applicants; No heavy equipment, Institutional overhead 10%.
Italy	IT MOH	Max. € 650.000 per project	Direct Costs: •Personnel (only temporary contracts or permanent contracts for the amount of hours dedicated to the project, < 60%); •Consumables/Supplies; •Animals/Model costs; •Equipment (only on leasing or rent); •Travel (< 30%); •Dissemination activities (< 1%); •Publication costs: < 2%; open access < 5%; •Patients recruitment costs; •IT Services and Data Bases; •Coordination costs Indirect Costs: • Overhead (< 10%, included in the total) (Further details in Annex I)
Latvia	LCS	Maximum funding for a funded partner is 100.000 EUR per year	• Personnel costs incl. taxes; • Consumables; • Subcontracts (up to 25% of direct costs), needs detailed justification, includes all external services, project core activities cannot be subcontracted; • Equipment (only depreciation costs during project directly attributable to project tasks); • Replaceable and fully consumable during project elements of equipment (e.g. electrodes); • Travels (according to travel plan); Indirect costs (up to 25% of direct costs excluding subcontracting). For pragmatic clinical trials the healthcare costs must be carried by the national healthcare system. LCS funding is not allowed to create additional demand in the healthcare system, nor to cover standard healthcare costs, nor to reduce waiting lines. The funding for LCS is for the research going outside of the normal healthcare services provided in the case of a specific ailment. LCS is not funding postmarket activities. LCS is not funding any activity beyond experimental development. (Further details in Annex I)
Lithuania	LMT	Maximum 500.000€ per project	Investigational costs are eligible: site costs (personnel, clinical procedure, site services, patient/participant renumeration), country management sites (site selection and coordination at the country level), and clinical study management costs at national or regional level (e.g. monitoring and insurance). Additional cross-cutting trial management costs can also be eligible if some of the

			sponsor's tasks are delegated to Lithuanian team. Only costs generated during the lifetime of the project, related to the project, are eligible. Eligible cost types: personnel, consumables, subcontracting, equipment and instruments, other direct costs, costs for dissemination of results, data handling and analysis, overheads (up to 20 % from direct costs). (Further details in Annex I)
Norway	RCN	Within a single project, the maximum funding can be up to 300 000 EUR. If the participant has a coordinator role, the maximum funding can be up to 450 000 EUR.	Payroll expenses, consumables, operating expenses, network measures. PhD fellowships are not eligible within the RCN funding. For postdoctoral fellowships, duration of the support is limited to a minimum of three years and a maximum of four years. The overhead cost is included in the rates for personnel. For funded projects, the contractual budget will be in NOK using the exchange rate (European Central Bank) from the pre-proposal deadline.
Poland	NCBR	Maximum 500 000 €	1. personnel costs 2. consumables 3. equipment 4. travel 5. other direct costs 6. subcontracting - this cost type cannot account for more than 70% of all eligible costs of a project 7. additional overheads incurred indirectly as a result of the research project; that costs are exactly 25% of eligible project costs (Further details in Annex I)
Slovakia	SAS	Max. 240.000€	Total eligible costs = Direct costs + Indirect costs (DC + IC) • Direct costs (DC): Personnel (max. 15% of DC for the Project Partner) • Consumables and Travel costs • Indirect costs (IC, Overheads): max. 20 % of DC. https://oms.sav.sk/wp-content/uploads/Financne-pravidla-na-udelovanie-grantov-SAV-na-medzinarodne-vyskumne-projekty-platne-na-vyzvy-zverejnene-od-1.12.2023.pdf
Spain	ISCIII	- Max. 1.000.000,00 € per project (if coordinator) - Max. 750.000,00 € per project (if not coordinator) (Including overheads)	• Personnel costs (see Annex I for details). • Other eligible costs: Current costs, small scientific equipment, disposable materials, travelling expenses, complementary expenses (use of central and general research support services of the beneficiary entity), publication and dissemination of results, costs of external service providers directly involved in the development of the clinical study, specific clinical studies related costs (e.g. administrative fees for civil responsibility insurance, taxes for regulatory approvals, clinical study monitoring costs) and other

			costs as included in "Líneas Estratégicas de Investigación en Salud" 2025, that can be justified as necessary to carry out the proposed activities. • Overheads, according to "Líneas Estratégicas de Investigación en Salud" 2025 (25%). • Double funding of the same concept is not allowed. (Further details in Annex I)
Spain	CSCJA	-Max 125.000€ (if not coordinator) -Max. 250.000€ if coordinator (including 21% indirect costs)	a. Goods and services. b. Personnel costs c.Travel, accommodation and subsistence d. Registration fees for congresses or conferences for the presentation and dissemination of the results. Publication costs e.Other expenses duly justified and necessary for carrying out the project. f. Indirect costs 21% g. Subcontracting costs (Further details in Annex I)

Each project partner must oversee the budgeting of their planned tasks.

- **Cross-cutting trial management costs** for the whole consortium: Intervention/study drug, trial authorization, data collection and management, statistical analysis, safety, study design and protocol development, and the overall management activities.
- To facilitate the multinational trial management tasks, ERA4Health offers trials management services performed by ECRIN (or by an entity directly subcontracted by ECRIN, in the case that ECRIN cannot provide these services). Only if this option is used, a top-up budget, up to 15% of the budget requested to national/regional funders, will be directly allocated to ECRIN to perform cross-cutting trial management activities.
- The management costs associated to these cross-cutting activities should indeed be requested in a different way so that the whole consortium can benefit from these funds, since those costs concern all the partners involved. In addition, this system will reduce the administrative burden for the coordinator. To benefit from this additional budget (up to 15%), the consortium should indicate in the proposal template that they wish that ECRIN (or an entity subcontracted by ECRIN) acts as service provider for those cross-cutting activities. If this additional budget is requested in the proposal, the consortium shall closely collaborate with ECRIN during the full proposal phase to define the details of the service provision (either directly performed by ECRIN or by an entity subcontracted by ECRIN, in the case that ECRIN cannot provide these services).

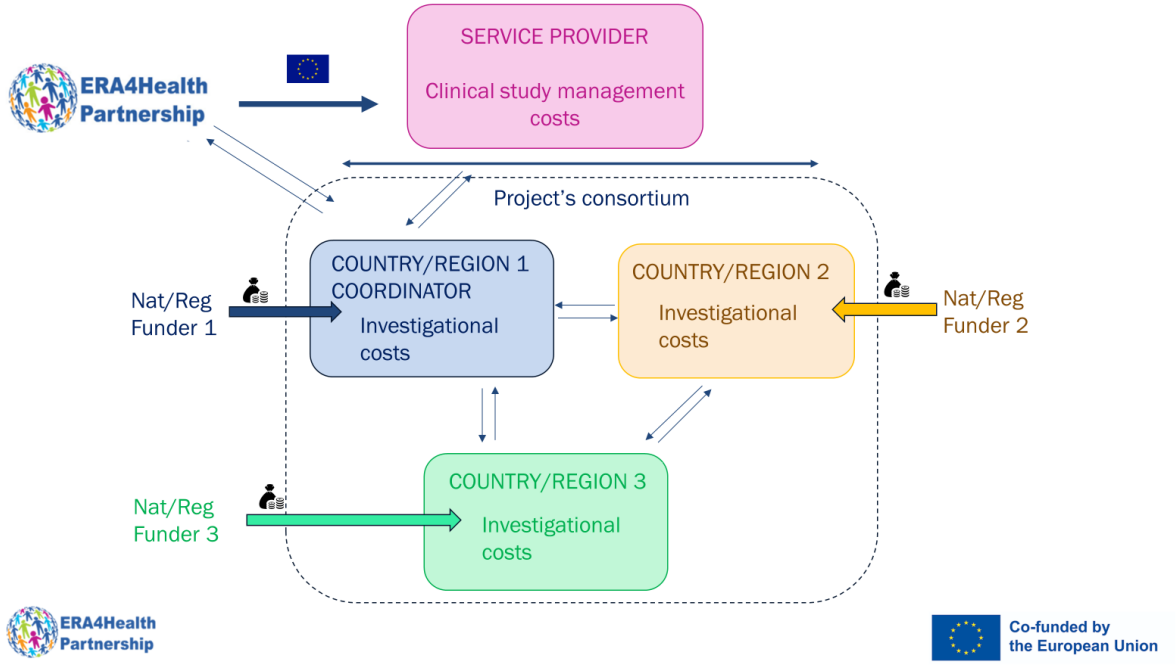


Figure 1: funding mechanisms. Plain arrows show the transfer of money and the two parallel arrows the exchange of information. The service provider costs of the crosscutting trial management activities performed by ECRIN will be requested as described in the example below.

Example of a requested budget for a consortium:

In this example, the partners from three different countries composed the consortium. The funders of two countries are funding one unique partners whereas the funder of the third country will fund multiple partners.

The requested amount for each partner is the following one:

Partners	**Total requested budget €**	**Total cost of the project €**
Partner A (Coordinator) requested funding to country 1	1 201 534	1 400 364
Partner B requested funding to country 2	645 945	645 945
Partner C requested funding to country 3	320 000	320 000
Partner D requested funding to country 3	153 800	230 432
Partner E requested funding to country 3	260 380	260 380
Total for the consortium	2 581 659	2 857 121

Such a table is not requested in the proposal, it is just used as an example for the explanation of the budget. The total costs include the requested budget to the funding organisations and the in-kind contribution of the different partners.

In addition of the budget requested to the three different funding organisations, **additional 15% of the total requested budget** by the whole consortium can be requested for the management costs required for the whole consortium only if ECRIN is selected as service provider of the cross-cutting activities. In this example: 15% * 2 581 659 = 387 248 €

In the example, the consortium decides in close collaboration which ECRIN which services will be provided directly by ECRIN and which other entity (xxx) can be subcontracted by ECRIN to act as service provider as displayed in the below table (requested in the full proposal).

Service Provider	Amount (<15% of total requested budget)	Justification
ECRIN	213 594 €	management, regulatory submission, data management and statistics, safety
xxx	173 654 €	Monitoring

ATTENTION: The cost requested for hiring ECRIN (or an entity directly subcontracted by ECRIN) as service provider for the research consortia should not overlap with the costs requested to the different national/regional funding organisations.

Duration and start date of the IICS

The duration of an IICS will be up to 48 months.

The starting date of the IICS can be different from one funding organisation to the other one. The below table summarise the conditions for the different funding organisations.

Country	Funding organisation	Duration of the IICS	Starting date	Possibility for potential extension
Austria	FWF	A maximum of 48 months.	The FWF expects the start of the project within six months from the date of of approval notification. Any further delays of up to 12 months after notification must be justified, otherwise the funding approval may be rescinded.	A cost-neutral extension of up to 12 months is possible and must be applied for at the FWF before the official end date of the project.
Czech Republic	MZCR /AZVCR	48 months	In line with the start date of the project as stated in the "Contract" or "Decision" on the provision of support or the issuance of a decision.	An optional cost-neutral extension of 1 year if needed
France	Fr-MoH	To be confirmed	To be confirmed	To be confirmed
Germany	BMBF/DLR	Up to 48 months	April 2026 (the earliest)	Cost neutral runtime extensions can only be granted in exceptional cases.
Ireland	HRB	48 months	Jan - May 2026	12-month no cost extension (NCE) permissible
Israel	CSO-MOH	Up to 48 months	Not specified	See national guidelines
Italy	IT MOH	Up to 48 months	Not specified	Max 1 year
Latvia	LCS	Up to 48 months	Application for the state aid must be submitted **before** the start of the project which is stated in the consortium agreement	Extensions can be without funding only
Lithuania	LMT	48 Months	It must be in 2026, no later than the common start date of the study agreed upon by the consortium partners.	Reasoned amendments to the agreement, including extensions shall be made in accordance with the procedures and within the time limits specified in the agreement.
Norway	RCN	Max 48 months	From January 2026	A cost-neutral extension based on a request with justification and an

				agreement in the whole project consortium may be considered.
Poland	NCBR	Up to 48 months	Not specified	Not specified
Slovakia	SAS	48 months	Based on the agreement in the consortium in the consortium agreement (CA)	If necessary, the possibility of a cost-neutral extension based on a request with justification and an agreement in the whole project consortium.
Spain	ISCIII	48 months	Established in the national grant resolution (probably beginning of 2026)	Potentially cost-neutral extensions could be provided, according to national regulation.
Spain	CSCJA	The duration of the projects shall be determined by the corresponding Call. In any case, this period shall be stated in the award resolution:	The starting date will be stated in the award resolution.	The maximum extension is limited to half of the initial duration of the project.

APPENDIX
RESOURCES, USEFUL LINKS

1. Study design

- SPIRIT STATEMENT (Standard Protocol Items)
  https://pubmed.ncbi.nlm.nih.gov/23295957/
- SPIRIT PRO Extension for inclusion of patient-reported outcomes in clinical trials protocols
  https://jamanetwork.com/journals/jama/article-abstract/2671472
- ICH General considerations for clinical studies E8
  https://database.ich.org/sites/default/files/E8_Guideline.pdf
- ICH General principles for planning and design of multi-regional clinical trials
  https://database.ich.org/sites/default/files/E17EWG_Step4_2017_1116.pdf
- COMET: Core outcome measures in effectiveness trials
  https://www.comet-initiative.org/
- COSMIN: Database of systematic reviews of outcome measurement instruments
  https://database.cosmin.nl/

2. Patient engagement

- EUPATI CONNECT

https://connect.eupati.eu/

- European YPAG Network

https://eypagnet.eu/services/

3. Reporting

- CONSORT statement

https://legacyfileshare.elsevier.com/promis_misc/CONSORT-2010-Checklist.pdf

https://jamanetwork.com/journals/jama/fullarticle/2799401

4. Organizations supporting multicountry Investigator-initiated clinical studies

https://www.era4health.eu/wp-content/uploads/2024/04/D131.pdf

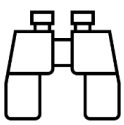
ERA4Health Responsible Research and Innovation (RRI) Guidelines

What is RRI and why do we need it?

Health research and innovation is crucial for maintaining and improving European public health. In this context, it is easy to acknowledge that science is not separate from society but part of it, which confers an important social responsibility on science. It is important, therefore, that funders, researchers and other key groups involved in the development of science, technology and innovation think about: (i) the potential directions of research being taken; (ii) who might benefit from new research and inventions and who might not; and (iii) how consideration of the potential social, environmental and ethical issues can be considered throughout the science and innovation process. Responsible research and innovation (RRI) are not about adjudicating what is 'good 'or 'bad', 'positive 'or 'negative', or 'responsible 'or 'irresponsible'. Instead, RRI offers techniques, tools and frameworks to think about questions of social responsibility and ensure scientists, funders and technologists don't lose sight of the context in which they do science, technology and innovation.
RRI is closely related to other cross-cutting issues, and actions can be taken that address both RRI and other important values, such as public/user engagement, open science or ethical assessments.

What is ERA4Health's approach to RRI?

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



Anticipation. What might the future desirable and undesirable effects of your work be? Who will benefit from it, and who might not? Can decisions be made now

to encourage the good, while minimising the bad effects? This isn't about exhaustive prediction but about building a sense of preparedness for the future.

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

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

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

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

How should you include RRI in your study?

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

This means that ***the commitment*** to RRI is clear and fixed in the programme, but there is an openness about the issues addressed and the specific ways to practise responsibility – these must be adapted to each study. In general, your approach to RRI should be proportionate to your proposal – disruptive,

ground-breaking or high-TRL (Technology Readiness Level) work is likely to require a more substantive engagement with RRI. If the research is exploratory then RRI components can also be exploratory – teasing out the potential visions, goals and end uses of a study. Overall, the goal is to demonstrate that you have engaged and seriously considered the tensions and meaningful societal benefits associated with health research and innovation.

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

1. Treat **RRI as an integrated part of the study** involving as many study 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 study's RRI aspects** as early as possible, and for the work plan to be specific to the study. 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 study 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 study, ideally RRI needs to be coordinated and should have a lead.

But what should you actually do?

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

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

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

1. **Who will benefit from your study**, who will not, and who may experience new risks? Are those answers acceptable to you?

    a. Does your study address a specific health-related or societal problem or need?
    b. Will your innovation be affordable and accessible? If not, is that a problem?
    c. Does your framing of the problem fit with other people's understanding of it? Can you access these alternative framings?
    d. How does your approach to the health challenge compare to others approaches?
    e. What is the most appropriate form of intellectual property (IP) for your study goals and affordability aspirations? Do classical IP strategies deliver the broadest benefit? Can new strategies (e.g. Open Material Transfer Agreements) be adopted at certain points of the research process?
    f. How could commercial or non-commercial organisations benefit from your research?

g. Are there foreseeable risks that you can mitigate now? For instance, what are the potential risks of data being released? How can you take care to ensure these data are interpreted appropriately?

2. Have you identified and involved **relevant stakeholders, and have you considered public engagement activities**? Are there opportunities for stakeholders and the public to contribute to your work? Stakeholders are people or organisations with a vested interest in the study (both positive and negative), who may also contribute knowledge to it. They could be patients, minorities and marginalised groups, health system users, special interest groups, health professionals, companies, nonprofits, or advocacy organisations. A number of different considerations for stakeholder engagement are important:

a. **Think about the methodology you will use**. For instance, 'co-design' and 'knowledge co-production' methodologies are good at generating trust and allowing stakeholders, including the public, to contribute their knowledge to the problem your study is trying to address.
b. **Think also about the appropriate timing** of different stakeholders' inclusion: certain kinds of knowledge may be more useful early on, whereas other knowledge may be useful later.
c. It will likely be valuable (but not obligatory) to **include expertise beyond the medical and health science**s – such as lawyers, social scientists or philosophers – to provide anticipatory and reflective methodologies or to address key challenges. Approach them early in your study design.
d. Think about **how best to formalise and include stakeholder knowledge** in your study. Are they best placed as scientific collaborators, as members of an advisory board, or as consultants to deliver only specific tasks? Check if your approach is in line with the national/regional funding rules before designing your proposal.

3. **Have you created good deliberative spaces** for your study team, partners and aforementioned stakeholders, including the public, to anticipate and reflect on the broader social, political, ethical or environmental context of your research? If not, RRI experts in Science and Technology Studies, medical sociology, bioethics and science communication may be able to help you with this in study design and implementation. A number of different approaches are possible, e.g.:

a. Focusing on your day-to-day research work ("philosopher in the lab approach").
b. Using foresight and critical futures methodologies.
c. Utilising a diverse advisory board.
d. Trans-disciplinary reflection at consortium meetings.
e. Using stage-gate approaches where explicit decisions about technological choices are taken.

4. Have you reflected on/considered adapting **your choice of research methods** regarding, for example:

a. Ethical issues in the study (including ethical considerations in the design of participatory science and possibly broader than the "ethics self-assessment")?
b. The use of data in your study – where does it come from, how will it be used and where will it go? How will ethical use be ensured?
c. In vivo/in vitro experiments and need for use of animals in experiments?
d. Use of new approaches such as "Safe(r) by Design"?

e. Your ability to increase the likelihood of translation by outlining e.g. strategies of scientific rigour, and strategies to reduce bias, inclusion of sex/gender as a biological variable in study design?

f. Open Science (such as open data, open code, open protocol or other low barrier data sharing practices) and other publication practices (including report all results, also negative or so-called null results)?

g. And are there ways that your study can advance common practices on these issues?

5. Have you engaged with important aspects of **your research environment** such as:
   a. gender, ethnicity and intersectional equality, diversity and inclusivity?
   b. career progression and precarity?
   c. equity between partners in your research consortium?

6. Have you shown how the study (and product) satisfy requirements for **patient and production safety** and efficiency? Will there be clear benefits for the patient by, for example by:

   a. listening to/satisfying user needs and safety concerns, or involving them in design;

   b. involving regulatory affairs professionals (toxicity tests, etc.),

   c. communicating with regulatory entities as early as possible (the Food and Drug Administration (FDA) or the European Medicines Agency (pharmaceuticals and medical devices), etc.

7. Have you considered and evaluated **environmental impacts and sustainable solutions**, in line with the **Do No Significant Harm principle**[10], by including, for example:
   a. lifecycle analysis (LCA)?
   b. ecotoxicology studies?
   c. safer- sustainable-, or recyclable-by-design methodologies?

How does ERA4Health support and evaluate RRI?

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

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

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

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

- General RRI aspects
- Involvement of stakeholders and the public

- Ethical considerations (in your ethics self-assessment)

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

Relating to Excellence

- Is the RRI approach proportionate to the content of the scientific proposal?
- Does RRI extend across the lifespan of the study? (e.g. as a sub-study, 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 study's scientific trajectories?
- Does the RRI work help align the study's research better to the needs and values of society?

Relating to Implementation

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

Web resources for including RRI in your project

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

https://infieri.online/en/home/#section-what-is-rih provides a particular framework to approach RRI in health researchhttps://thinkingtool.eu/ The Societal Readiness Thinking Tool guides you through the steps of including RRI in a project.

Tools for public engagement: https://www.publicengagement.ac.uk/resources and http://actioncatalogue.eu/

Responsible Innovation-UKRI and RRI as a method (the Research Council of Norway) explains also RRI and the value it adds.

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

ERA4HEALTH's approach to RRI builds on previous frameworks published by the UK and Norway, the European Commission and funding programmes such as M-ERA.NET3, ERA CoBioTech and EuroNanoMed3.