ERA4Health Partnership

Co-funded by the European Union

Joint Transnational Call Investigator-Initiated Clinical Studies

(JTC IICS) 2026

"Multi-country Investigator-Initiated Clinical Trials in Cardiovascular, Autoimmune and Metabolic diseases"

(Trials4Health)

Guideline for applicants

DEADLINES

January 27 th, 2026 (16:00, CET) - SUBMISSION OF PRE-PROPOSALS

June 17th, 2026 (16:00, CEST) - SUBMISSION OF INVITED FULL PROPOSALS

Link to the electronic proposal submission:

Link

The submission system will be open by November 13th, 2025

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

or contact the Joint Call Secretariat (JCS):

Institute of Health Carlos III, Spain

Astrid Valencia Quiñónez

+34 918 222 227

Trials4Health@isciii.es

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 27th, 2026 for the pre-proposals and before the June 17th, 2026 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 table below shows the eligibility of partners for each funding organization participating to the call:

Country	Funding Organisation	Eligibility of Partners
Austria	FWF	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.
Belgium	KCE	To be considered eligible, the Belgian partner, whether acting as Sponsor or Belgian Coordinating Center (BCC), must be a Belgian non-profit institution or research organisation with proven expertise in conducting non-commercial multicentre clinical trials. Specifically: - If the partner acts as sponsor, it must have successfully completed a KCE Trials sponsor capacity assessment. - If the partner acts as BCC, it must, depending on the tasks it is committed to conduct, demonstrate sufficient operational support from a clinical trial centre (CTC) or equivalent. Regardless of the role (Sponsor or BCC), the Belgian partner must: - Agree in writing to the KCE Trials terms and conditions (as implemented in the KCE Trials contract templates) and submit the following documentation to KCE Trials by the ERA4Health call deadline. ➢ If the Belgian partner is the Sponsor: a signed sponsor letter of commitment. ➢ If the Belgian partner is the BCC: two signed letters of commitment (one by the BCC, one by the international sponsor), confirming acceptance of the KCE Trials terms and conditions. ➢ If there is an entity offering additional funding and/or in-kind support to the trial in Belgium, a signed letter of commitment from such party at the time of the application.

		- Declare no conflicts of interest, in accordance with the *General principles for the declaration of interests by applicants and the management of (potential) conflicts of interest in KCE-funded clinical trials*. All those documents have to be submitted using the KCE Trials templates, which can be found on the KCE Trials ERA4Health dedicated webpage (CallsHYPERLINK "https://kce.fgov.be/en/kce-trials/calls").
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). Conditions for PO funding – Patient organisations can receive direct funding if they take an active role in the project's research activities. This means they must contribute to specific research objectives (for example, by being involved in one or more work packages) and these types of research activities must be clearly described in their statutes.
France	Fr-MoH	Eligible institutions: French ministry of Health (Fr MoH) funds French healthcare institutions defined by public health regulation articles L.611-1 and further, L.6141-1 and further, L6161-1 and further (établissements de santé), L6133-1 to 8 (groupements de coopération sanitaire), L6323-3 (maisons de santé) and L6323-1 (centres de santé) of the Code de la Santé Publique. A partner must be composed of a physical leader and of a health care institution, which manages the financing. The physical leader must be contractually linked to a healthcare institution and get its approval to be part of the project. For example, leaders can be private health professionals if they have a binding agreement with a French healthcare institution. Minimum funding per awarded to a partner: 10 000 € Fr MoH will avoid double funding and will not finance projects or parts of projects that have been funded through other calls.
Germany	BMFTR/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.
Italy	IT MOH	Only IRCCS (Istituti di Ricovero e Cura a Carattere Scientifico) researchers are eligible to apply. Universities, other research Institutes, companies are excluded from funding.
Italy	FRRB	Eligible institutions 1. Public or Private Italian IRCCS (Scientific Institutes for Health Research, Hospitalization and Health Care) 2. Public Health Care Providers (ASST) 3. Agenzie di Tutela della Salute (ATS) 4. Azienda Regionale Emergenza Urgenza (AREU) 5. Universities - only in partnership with one of the organizations above (1,2,3,4) located in Lombardy and requesting funding to FRRB 6. Research Institutes - only in in partnership with one of the organizations above (1,2,3,4) located in Lombardy and requesting funding to FRRB. Please note: All applicants must be located in Lombardy and

		their activities should take place in Lombardy. Enterprises and for-profit Organisations are NOT eligible
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 (R651/2014) together with financial reporting requirements, in this case this is state aid. Two previous statements with sworn auditor's approval should be provided and they must reflect the correspondence to the regulation as well as prove the evidence of previous scientific activity and presence of capacity. Enterprises not having closed two annual financial periods (years) 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, university hospitals. (Further details in Annex I)
Norway	RCN/ HSØRHF	Approved Norwegian research organizations, hospitals or a private, non-profit hospitals eligible for the regional health authorities' research funds.
Poland	NCBR	Following entities are eligible to apply: **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)
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	CVTI SR	CVTI SR can fund only Principal Investigator (PI), not a Coordinating Investigator in this call. 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. (Further information in Annex I)
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)
Spain	DS-CAT	Foundations managing research activities of both SISCAT and Public health centres who carry out research activity in Catalonia, including accredited Health Research Institutes and CERCA institutions
Sweden	SRC	The applicant must be an individual researcher holding a PhD. Only researchers at an administrating organisation approved by the Swedish Research Council may apply. Please refer to general applicant eligibility requirements found here. The applicant may not have any other project grant concerning the same project concept, funded by the Swedish Reseach Council, at the start of the grant period. No funding of industrial partners. (Further information in Annex I).
Türkiye	TÜSEB	Within the scope of this call: Higher education institutions covered by the Higher Education Law, Training and research hospitals, Public institutions and organizations, Capital companies (private organizations) established in Turkey that create added value at the firm level and hold a trade registry certificate, regardless of sector or size. Only researchers in Turkey will be funded.
UK	DHSC-NIHR	Academic Higher Education institutions/ Research Institutes, NHS bodies and providers of services, local authorities, industry, charities, social care organisations in England, Scotland, Wales and Northern Ireland (check individual NIHR programme remits)
Global organisation	BT1D	Applicants must hold an MD, DMD, DVM, PhD, or equivalent, and have a faculty position (or equivalent) at a college, university, medical school, company, or other research facility. Applications may be submitted by non-profit, public, or private organizations such as colleges, universities, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. For this specific call, funding eligibility is restricted to institutions based in European countries under the scope of EU Clinical Trial Regulation. Clinical projects must be aligned with the Breakthrough T1D Research Strategy. Approval from the Breakthrough T1D Board of Directors is required for the commitment of Breakthrough T1D funds.

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): IT-MOH, CSCJA, CVTI SR, LCS and FRRB. For FWF and UEFISCDI 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 table below 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	The Austrian subprojects must have a thematic focus on clinical/translational research with patient-oriented approaches, whereby the elucidation of disease mechanisms is desirable and cooperation between clinicians and basic researchers should be intensified. All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners are authorised. If the following option is intended, please contact the FWF office: Only one organisation will be granted and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement.	
Belgium	KCE	Single lead applicant: Only one Belgian partner may act as the lead applicant per proposal. This lead applicant will be the sole recipient of KCE funding and is	The lead applicant must establish a consortium/collaboration agreement or site contracts with all involved partners. (Further information in Annex I)

		responsible for the appropriate distribution of funds to Belgian recruiting sites and associated partners.	
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	Only one organisation will be granted	This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement.
Germany	BMFTR/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.
Italy	IT MOH	Simultaneous PI participation in different 2026 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. The maximum amount eligible for a subcontract is < **10% of the total budget** (from the IRCCS Budget). Italian PAOs can still participate in Consortia as "Collaborators" with their own funds.	
Italy	FRRB	Maximum two partners from Lombardy per project. CROs deemed necessary for the conduct of clinical trials may be engaged as subcontractors by the beneficiary. Italian PAOs are not eligible for funding. They can still participate in Consortia as "Collaborators" with their own funds.	
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 / HSØRHF	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.
Romania	UEFISCDI	For UEFISCDI, 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 UEFISCDI NCP for a detailed clarification which approach would be the most appropriate for your proposal.	
Slovakia	CVTI SR	All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners are allowed.	
Spain	ISCIII	Only one eligible partner will be granted	This organisation will establish collaboration agreements with other additional national recruiting sites
Spain	CSCJA	A maximum of 1 coordinator or 2 partners per proposal are allowed.	
Spain	DS-CAT	Only one organisation will be granted	This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement
Sweden	SRC	Only one organisation will be granted	This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement.

Türkiye	TÜSEB	Only one institution or organization located in Turkey can be granted and receive funding from TÜSEB.	This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement
UK	DHSC-NIHR	NIHR issues research contracts to lead UK contractor organisation within the consortium who will need to establish agreements with other eligible collaborators or recruitment sites via collaboration or subcontracting agreements. The contracting organisation must be able to meet these NIHR contract terms without amendments in any way. (Further information in Annex I).	This organisation will establish agreements with other eligible collaborators or recruitment sites via collaboration or subcontracting agreements.
Global organisation	BT1D	Only one organisation will be granted	This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement

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 remuneration), 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	The FWF generally does not have any minimum limit. The maximum limit is 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 research institution must provide the necessary infrastructure. Personnel costs for administrative tasks cannot be funded by the FWF. The current FWF Personnel Costs and Salary Rates 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.
Belgium	KCE	KCE will provide funding up to: - a maximum of 1.000.000 € for projects where the Belgian partner acts as sponsor of the trial. This amount includes both sponsor-related costs and sites costs within Belgium. - a maximum of 500.000 € per project where the Belgian partner acts as Belgian Coordinating Center of the trial. This amount includes costs for sponsor-delegated tasks to BCC and site costs within Belgium.	Eligible Costs: All project-specific costs are eligible for funding, provided they are justified and related tasks are well described in the budget template. These costs include: - Personnel and non-personnel costs essential to the execution of the project - Costs not covered by the infrastructure of the Belgian partner institution Note: Sponsors eligible costs might be covered but KCE will not cover costs already included in the tasks allocated to ECRIN or its subcontractor, (cross-cutting tasks). Overhead policy: KCE permits a maximum overhead rate of 17% on costs not delivered by third-party providers (e.g. subcontractors, drug or equipment purchase). Overhead on site costs must be fully transferred to the sites (and detailed in the "Overhead" section of the requested budget template). Site fees Sites should be compensated for their study related work. Those costs should be mentioned in the "subcontracting" section of the requested ERA4Health budget template. VAT on site costs should be taken into account, if applicable.
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	Funding Scenarios - Case 1: A maximum of €500,000 per project may be granted. - Case 2: A maximum of €300,000 may be granted if the clinical study is already funded by the French Ministry of Health through a national call for proposals (notably PHRC-N). In this case, eligible costs are strictly limited to cross-cutting activities at the European level, provided they are not already covered by ECRIN. These activities may include: Data management, Comparative analyses between countries, Dissemination of	Funds are reserved for the exclusive use of French healthcare institutions involved in the project. Transfer for part of these funds to other French structures, organisations or physical or legal person may be allowed provided they are not eligible for funding by another financing body of the partnership. The healthcare institution would also have to demonstrate that they do not have the necessary skills. If so, public tenders rules including call of bides applies. Investment expenses giving rise to depreciation are not eligible. Management costs up to 10% of personal expenses are eligible.

		results. Important Note: These two funding scenarios are mutually exclusive. The French Ministry of Health does not allow double funding for the same activities.	
Germany	BMFTR/ DLR	Up to 500.000 € for regular German partners; up to 750.000 € for German partners in the role of the sponsor (overhead costs included). Only one German partner per consortium is allowed. The applicants (PI) are not allowed to participate in more than one research proposal. The number of recruitment sites in Germany depends on the intended sample size and the structure of the consortium and is not restricted.	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 BMFTR regulations. Funding rates for universities, university hospitals and non-university research institutes can be up to 100% of their costs.
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)
Italy	FRRB	Maximum/ Minimum funding per grant awarded to a clinical study partner: 750,000.00€	Direct costs: • Personnel (for public IRCCS and ASST, ATS, AREU, Universities and Research Centres). The specific details will be set out in the reporting manual, to be issued by FRRB in due time. • Consumables: reagents/animal purchase, etc.. • Equipment (eligible amortization rate). • Travel: max 10% of the total direct costs (overheads and subcontracting costs excluded) • Publications (only Open Access): max 5% of the total direct costs (overheads and subcontracting costs excluded). • Other direct costs: please insert under this category any other costs, including those related to patient involvement (insurance, etc.). •Subcontracting: max 30% of the total direct costs (overheads costs excluded).

			• Overheads: 20% flat rate calculated on direct costs (subcontracting costs excluded from this calculation). FRRB will require the submission of a financial audit certificate together with the final financial report. This cost, to be included under the "Subcontracting" category will be eligible up to a maximum of € 8.000. Only costs generated over the lifetime of the project will be considered eligible.
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). (Further details in Annex I)
Lithuania	LMT	Maximum 500.000€ per project	All costs mentioned in the Call text as Investigational costs are eligible: site costs (personnel, clinical procedure, site services, patient/participant remuneration), 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). More details about eligibility of costs: https://www.e-tar.lt/portal/lt/legalAct/0a8bead0577611e9975f9c35aedfe438/asr
Norway	RCN/ HSØRHF	For a single project, the maximum grant awarded can be up to 450 000 EUR. If the participant has a coordinator role, the maximum grant can be raised up to 500 000 EUR.	Payroll expenses, consumables and operating costs, networking/study meetings and expenses relating to user involvement and dissemination. PhD fellowships are not eligible within the national funding. For postdoctoral fellowships, duration of the support is limited to a minimum of three years and a maximum of four years. Any overhead costs may be 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)
Romania	UEFISCDI	Funding rates vary in accordance with state aid legislation. For more information: https://uefiscdi.gov.ro/parteneriate-si-misiuni-europene 250.000 euro for all Romanian partners in case a Romanian institution is the Coordinator; 200.000 for all Romanian partners in case a Romanian institution is not the Coordinator.	a. Staff costs; b. Logistics expenses - Capital expenditure; - Expenditure on stocks - supplies and inventory items; - Expenditure on services performed by third parties cannot exceed 25 % of the funding from the public budget. The subcontracted parts should not be core/substantial parts of the project work; c. Travel expenses; d. Overhead (indirect costs) is calculated as a percentage of direct costs: staff costs, logistics costs (excluding capital costs and cost for subcontracting) and travel expenses. Indirect costs will not exceed 25% of direct costs.
Slovakia	CVTI SR	The maximum funding amount requested by all Slovak partners in each international project is 400 000 EUR. The minimum funding amount is 100 000 EUR per project.	• Personnel costs (salaries of researchers, technicians and other support staff employed by the beneficiary, to the extent that they are directly involved in the project, salaries of project management personnel and other essential positions necessary for the implementation and coordination of the project; • Costs of instruments and equipment; • Costs for contract research, technical knowledge and patents purchased or licensed from external sources under market conditions as well as costs for consultancy and equivalent services used exclusively for the project. (Further information in Annex I)
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, that can be justified as necessary to carry out the proposed activities. • Overheads, according to AES 2026 (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)
Spain	DS-CAT	- Max. 400.000,00 € per project (if coordinator) - Max. 300.000,00 € per project (if not coordinator) (Including overheads)	Personnel costs Consumables Core facilities Travel Other (direct costs). It is compulsory to include the cost of a financial audit certificate up to a maximum of € 2,000 Overhead (Flat rate 21% calculated on direct costs)
Sweden	SRC	Maximum 5 700 000 SEK (approximately 500 000 €), minimum 3 420 000 SEK (approximately 300 000 €)	The project grant may be used to fund all types of project-related costs, such as salaries (including your own salary, however no more than corresponding to the person's activity level in the project), running costs (such as consumables, travel including stays at research facilities, publication costs and minor equipment), premises and depreciation costs. The project grant may also be used to cover costs for patient advocacy organisations (PAO) part in the project. The costs that can be covered are the same as the above mentioned. Grants may not be used for scholarships. If a doctoral student participates, project funds may not be paid out as salary during teaching or other departmental duties.
Türkiye	TÜSEB	Maximum €300,000 per clinical study partner. Support will be provided for 2 projects.	- Personnel expenses (researchers, project personnel, scholarship holders) - Consumable expenses - Travel expenses - Service purchases - Machinery and Equipment Expenses - Information Systems Purchases TÜSEB national rules and budget guides apply.
UK	DHSC-NIHR	Max €1,500,00 for a project. Applicants must justify that the budget requested is appropriate and proportionate to the outlined research plans and ensures value for money.	In Scope: Costs for research and recruitment in the UK aligned to the most relevant NIHR domestic programme for this call and which meet NIHR finance requirements Out of scope: ●NIHR does not fund research involving animals or animal tissue. ●See NIHR finance guidance for applicants. This includes costs for Research training, mobility and academic career development for early career researchers is a key priority for NIHR in supporting the next generation of research leaders. (Further information in Annex I)
Global organisation	BT1D	Max: € 800.000	Direct Costs are defined as those costs falling within the following Breakthrough T1D budget categories: Salaries& Wages, Stipends, Supplies, Other Costs, Equipment and Travel. Indirect costs are limited to 10% of direct costs. (Further information 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 trial 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 with 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 pre-proposal template that they wish that ECRIN (or an entity subcontracted by ECRIN) acts as service provider for those cross-cutting activities and include the written letter signed by ECRIN representatives as Annex of the pre-proposal application. If this additional budget is requested in the proposal, the consortium shall closely collaborate with ECRIN during the pre-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).
- Applicants shall be aware that this additional budget, allocated for cross-cutting management activities, may not be sufficient to cover all such activities required for conducting the clinical trial. Therefore, it may be necessary to request additional funding from national/regional funding organisation(s) (subject to the eligibility of such costs for specific funding organisations that can be found in Annex I) to ensure full coverage of these cross-cutting management needs.

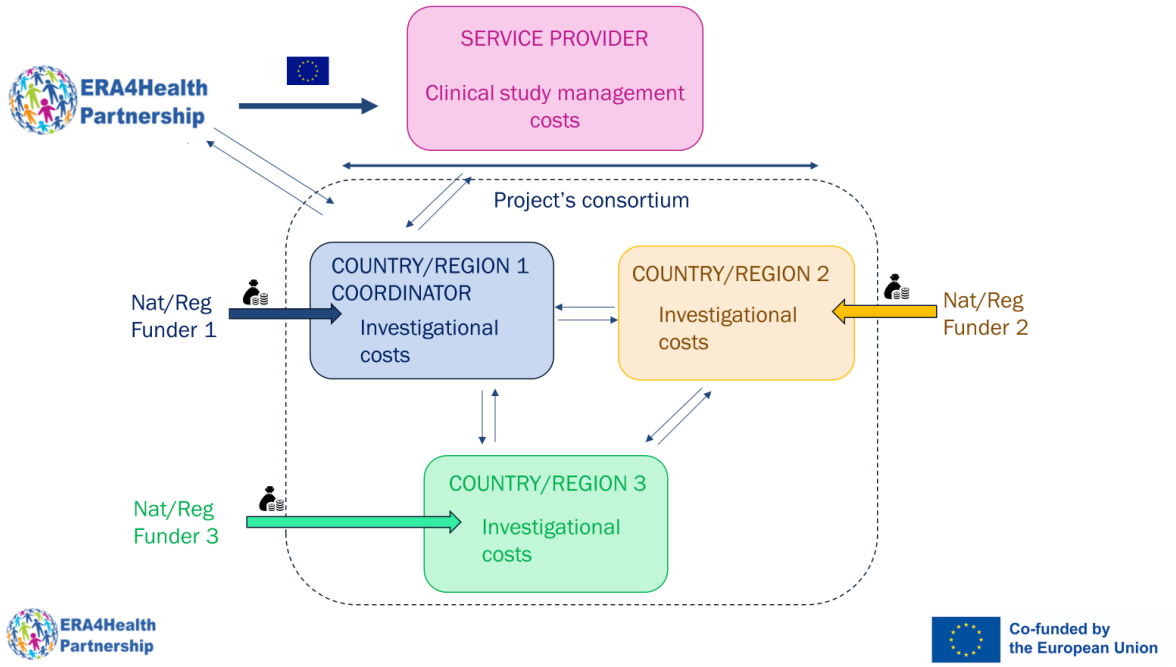


Figure 1: funding mechanisms. Plain arrows show the transfer of money and the two parallel arrows the exchange of information. The service provider costs of the crosscutting trial management activities performed by ECRIN will be requested as described in the example below.

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 partner 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 to the budget requested by the three different funding organisations, an **additional 15% of the total budget requested** 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 with 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 the clinical studies will be 48 months.

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

Country	Funding organisation	Duration of the IICS	Starting date	Possibility for potential extension
Austria	FWF	48 months	The FWF expects the start of the project within six months from the date 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.
Belgium	KCE	48 months	KCE expects that the clinical trial will be submitted to the competent national Ethics Committee and/or national competent authority within six months following the official ERA4Health approval notification. If submission is delayed beyond this six-month window, an extension of up to 12 months may be accepted, but only if a clear and justified explanation is provided. Failure to comply with this timeline may result in the withdrawal of funding approval.	Under exceptional circumstances, a cost-neutral extension is possible and must be applied for and accepted by KCE and all other project funders before the official end date of the project in accordance with ERA4Health call conditions.
Czech Republic	MZCR /AZVCR	48 months Duration of the clinical study is 48 months. However, all projects funded under the Programme for the Support of Applied Health Research for the period 2024-2030 must be completed no later	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.	Under this call, project extensions are not possible, as all projects funded through the Programme for the Support of Applied Health Research for the period 2024-2030 must be completed **by the end of 2030,** when the Programme

		than **31 December 2030**, as the Programme itself concludes at the end of that year.		itself comes to an end. Applicants are therefore strongly advised to start their projects on 1 January 2027 at the latest.
France	Fr-MoH	48 months	First semester of 2027.	A one-year extension may be requested. No additional funding will be granted.
Germany	BMFTR/DLR	48 months	March 2027 (the earliest)	Cost neutral runtime extensions can only be granted in exceptional cases.
Italy	IT MOH	48 months	Not specified	Max 1 year extension
Italy	FRRB	48 months	Not specified	Maximum 12 months
Latvia	LCS	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 and not beyond of the planned final calendar year.
Lithuania	LMT	48 Months	It must be in 2027, preferably no later than the common start date of the study agreed upon by the consortium partners.	During the implementation of the project, the reasoned amendments of the agreement may be initiated, including extensions. Amendments to the agreement shall be made in accordance with the procedures and within the time limits specified in the agreement.
Norway	RCN/ HSØRHF	48 months	From January 2027	A cost-neutral extension based on a request with justification and an agreement in the whole project consortium may be considered.
Poland	NCBR	48 months	Not specified	Not specified
Romania	UEFISCDI	48 months, max. until December 2030	Not specified	Cost neutral runtime extensions can only be granted until December 2030
Slovakia	CVTI SR	Important notice: All Slovak entities must have their contractual financial matters settled with CVTI SR **by the end of 2029.**	Based on the agreement between partners.	N/A

Spain	ISCIII	48 months	Established in the national grant resolution (probably beginning of 2027)	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.
Spain	DS-CAT	48 months	Established in the national grant resolution (from January 2027)	Potentially cost-neutral extensions could be provided, according to national regulation
Sweden	SRC	Project period plus an availability period of one additional year.	January 1st, 2027	The Swedish project leader must submit an application for an extension in the Swedish application system Prisma, in according to the instructions on the SRC website.
Türkiye	TÜSEB	48 months	The project must be started within 3 months at the latest after the signing of the fund agreement.	Upon justified request, an extension of up to 24 months is possible with TÜSEB approval; no additional budget will be provided.
UK	DHSC-NIHR	48 months	1st of the Month (approx 6 months after outcome notification)	No-cost and cost extensions may be requested and considered on a case by case basis where well justified.
Global organisation	BT1D	48 months	Max at three months after notification	Grants are eligible to request No Cost Extensions

APPENDIX
RESOURCES, USEFUL LINKS

1. Study design

- ERA4Health Training "Management of multinational clinical studies".
  https://era4health.eu/training/detalletraining.php?conexion=1

- IICS Recommended Training
  https://era4health.eu/training/iicsrectraininglist.php

- 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 Patient Forum

https://www.eu-patient.eu/Members/

- 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://era4health.eu/results/docs/D131.pdf

REMEDi4ALL - Repurposing of medicines 4ALL

REPO4EU – Euro-Global Platform for drug repurposing

5. Clinical Site Agreement Template (ERA4Health supporting material)

https://era4health.eu/results/docs/D167.pdf

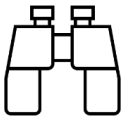
ERA4Health Responsible Research and Innovation (RRI) Guidelines

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?

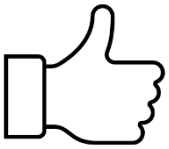
ERA4Health's approach to RRI is focused on improving the quality of research and innovation by keeping the broader context of your work visible. It encourages you to embed methodologies and processes to consider four important dimensions related to research and innovation:



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 of 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 studies, 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 studies 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 advice 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.