

Joint Transnational Call Investigator-Initiated Clinical Studies
(JTC IICS) 2027

**“Multi-national Investigator-Initiated Clinical Studies in Cardiovascular,
Autoimmune, Metabolic, and Non-Communicable Respiratory Diseases,
including Underrepresented Populations” (IICS4all 2027)**

GUIDELINE FOR APPLICANTS

DEADLINES

January 14th, 2027 (12:00 CET) - SUBMISSION OF PRE-PROPOSALS

June 14th, 2027 (12:00 CEST) - SUBMISSION OF INVITED FULL PROPOSALS

Link to the electronic proposal submission:

<https://ptoutline.eu/app/IICS4all>

The submission system will be open by October 27th, 2026

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 information	3
Eligibility.....	3
Composition of the consortium	8
Example of consortium sizes	11
Smallest consortia	11
Larger consortia.....	12
Funding mechanism.....	13
Example of a requested budget for a consortium:	22
Duration and start date of the IICS	23
ANNEX 1: RESOURCES AND USEFUL LINKS	26
ANNEX 2: ERA4Health Responsible Research and Innovation (RRI) Guidelines	27

General information

This call uses a two-step submission procedure (pre-proposals and full proposals) including a rebuttal stage and the assessment of the study feasibility.

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

All proposals must be written in English and submitted exclusively by using the electronic PT-Outline submission system before January 14th, 2027 for the pre-proposals and before the June 14th, 2027 for the invited full proposals.

Use of generative artificial intelligence tools

When considering the use of generative artificial intelligence (AI) tools for the preparation of the proposal, it is essential to exercise caution and careful consideration. Further information on the EC recommendations can be found here on this [website](#).

Applicants are reminded that they

- must be fully **transparent** towards the granting authority and disclose which AI tools were used and how they were utilized;
- must exercise **caution and careful consideration** while using generative AI tools;
- must **review and validate** thoroughly any AI-generated content to ensure its appropriateness and accuracy, as well as its compliance with intellectual property regulations;
- **remain fully responsible** for the content of the proposal (including the parts produced by AI tools).

Specifically, applicants are required to:

- **verify the accuracy, validity, and appropriateness** of the content and any citations generated by the AI tool and correct any errors or inconsistencies.
- provide a **list of sources** used to generate content and citations, including those generated by the AI tool. **Double-check citations** to ensure they are accurate and properly referenced.
- be **conscious of the potential for plagiarism** where the AI tool may have reproduced substantial text from other sources. Check the original sources to be sure you are not plagiarising someone else's work.
- **acknowledge the limitations of the AI tool** in the proposal preparation, including the potential for bias, errors, and gaps in knowledge.

Eligibility

Before being included in a consortium, all Principal Investigators should self-assure that her/his institution/organisation is eligible for funding by one of the funding organisations participating in the call. All specific funding rules from each participating funding organisation are available in the Annex I of the call text.

The following table provides an overview of the eligible partners and specific requirements per funding organisation/country. Please note that Breakthrough T1D is able to fund partners from different countries, also from countries not participating in the call, as long as the study topic is type 1 diabetes in alignment with the [Breakthrough T1D Research Strategy](#).

Table 1: Eligibility of partners for each participating funding organisation

Country	Funding Organisation	Eligibility of Partners
Austria	FWF	Austrian research institutions must be registered in the FWF's Research Institution Portal before the submission of the pre-proposal. The proposed research must be carried out in Austria under the auspices of the Austrian lead research institution.
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 <u>sponsor</u>, it must have successfully completed a KCE Trials sponsor capacity assessment. - If the partner acts as <u>BCC</u>, it must, depending on the tasks it is committed to conduct, demonstrate sufficient operational support from a Belgian 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 <u>Sponsor</u>: a signed sponsor letter of commitment. ➢ If the Belgian partner is the <u>BCC</u>: 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 (Calls).
Czech Republic	MZCR/AZVCR	IMPORTANT: The Czech applicant can only participate as a project partner, not as a coordinator under this call. Research Organisations, Enterprises, Patient Organisations. All eligibility rules and criteria can be found on the Czech Health Research website (ERA4Health Výzva 2027 – AZV ČR). It is strongly recommended to contact the responsible person at the Czech Health Research Council (prior to submission regarding the eligibility criteria). • Conditions for PO funding – Patients 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. • Eligibility criteria for the Principal Investigator - the PI must hold a Ph.D. degree (for more information, please refer to the national document "<i>Podmínky pro zapojení českého uchazeče do výzvy</i>", available on the AZV CR website). MZCR/AZVCR sets a criterion for the maximum workload, which must not exceed 1.00 FTE within a single submitted project. There is no minimum workload requirement for the PI in relation to European Partnerships (EP) in health-care area imposed by the national funding authority (MZCR). However, the allocated FTE must correspond to the actual workload required for the project. Within the EP, the assigned FTE is subject to verification by the institution or organisation employing the PI. Therefore, the provisions of Act No. 262/2006 Coll., the Labour Code, must be respected. AZV CR does not impose any additional FTE-related restrictions within the framework of the EP. • Definition of ECR - A natural person engaged in research who, in the year of submission of the Project proposal to the call for proposals, has received their Ph.D. academic title or its equivalent in the past 8 years, or has obtained it no later than the date of conclusion of the Contract/issuance of the Project Decision. If the

		Proposer has been on maternity or parental leave, has suffered a long-term illness, or has interrupted his/her scientific career for similar objective reasons, the time limit of 8 years from the award of the academic degree of Ph.D. or its equivalent is increased by this period. These facts (award of the degree, parental leave, etc.) shall be documented by the Applicant by means of a Sworn Statement.
Egypt	ASRT	• Eligible applicants are Egyptian legal entities established in Egypt, including public or private universities, research institutes, university hospitals and other healthcare or research institutions, non-profit organisations, SMEs and enterprises, provided that they can perform the proposed work and sign a national grant/contract with ASRT. • Participation of a private for-profit entity must be duly justified. A commercial enterprise or other for-profit organisation may not act as the clinical study coordinator. • All central ERA4Health eligibility and clinical-study requirements apply. Each Egyptian partner must have the expertise and institutional capacity required for its role; an Egyptian coordinator and/or sponsor must demonstrate capacity for multi-country study oversight, ethics, regulatory compliance and Good Clinical Practice. • At the time of national contracting, the Egyptian PI may not hold more than two ongoing ASRT-funded projects as PI or coordinator.
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 specified above 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. The projects must be clearly defined in terms of subject, time frame, and budget; they must not have been started [yet]. For specific conditions see also link to German version of the call below.
Ireland	HRB	Lead Applicants (Principal Investigators) based in Ireland must be from a recognised HRB Host Institution in the Republic of Ireland. The Lead Applicant must: • Hold a post (permanent or a contract that covers the duration of the award) in a HRB recognised Host Institution in the Republic of Ireland (the "Host Institution") as an independent investigator. For clinicians, an adjunct position in a HRB recognised Host Institution is acceptable (an accompanying letter of support is required in these cases, as well as in the case of contract positions). OR • Be an individual who will be recognised by the Host Institution upon receipt of an award as an independent investigator who will have a dedicated office and research space for the duration of award, for which they will be fully responsible. The Lead Applicant does not necessarily need to be employed by the Host Institution at the time of the application submission (an accompanying letter of support is required in these cases). Partners classed as 'Enterprise' cannot be in receipt of HRB funding. Additional eligibility requirements will apply for applicants. Please see the IICS4All scheme page on HRB's website for detailed guidance relating to eligibility for applicants based in Ireland (https://www.hrb.ie/funding-scheme/era4health-partnership-2027/).

Israel	CSO-MOH	Researchers will only be able to participate as partners in consortia , not as a coordinating investigator. Coordinators 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	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). Please note: All applicants, including the recruiting sites, must be located in Lombardy and their activities must take place exclusively in the Lombardy region. 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 (Regulation 651/2014) together with financial reporting requirements, in this case it is state aid. Two previous statements with sworn auditor's approval should be provided and they must reflect the correspondence to the regulation as well as prove the evidence of previous scientific activity and presence of capacity. <i>Enterprises not having closed two annual financial periods are not eligible.</i> Enterprises in difficulty are not eligible Sites can only take part if subcontracted by an eligible participant
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	The following entities are eligible to apply: Research organisations¹ . Entities must be established as a legal person² and must conduct its R&D or any other activity on the territory of the Republic of Poland, confirmed by an entry into the relevant register³. ¹Research organisation - an entity defined in Article 2(83) of Commission Regulation (EU) No 651/2014, and in Article 37(1) of the Act of 30 April 2010 on the National Centre for Research and Development (Polish Journal of Laws 2024, item 1170 as amended), in conjunction with Article 7(1)(1, 2, 4, 5, 6, 6a, 6b, 6c, 8) Act of 20 July 2018 of the Law on Higher Education and Science (Polish Journal of Laws 2024, item 1571 as amended); ²Legal person - an entity other than a natural person that has the legal capacity to hold and to exercise legal rights and obligations within a certain legal system, such as to enter into contracts, sue and be sued. ³if applicable. Does not apply to legal persons that are not obliged to register in a relevant Polish official register according to Polish law (e.g. KRS).
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	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. • Research institutions (e.g. the Slovak Academy of Sciences and its institutes) • Academic sector (e.g. universities and higher education institutions) • Non-governmental non-profit organizations • Cluster organizations • Private sector entities (entrepreneurial/business sector) Public administration bodies, including local and regional government authorities, are eligible to participate; however, they are not eligible to receive funding and therefore cannot have a budget allocated to them.
Spain	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
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	CPSEJA	Eligibility criteria are established in Orden de 10 de agosto de 2023 : • Eligible organisation must be Andalusian Non-profit entities registered as Agents of the Andalusian Knowledge System (Registro de Agentes Andaluces del Conocimiento) with research and innovation activity in Biomedicine and Health Sciences, ie: Research managing foundations of the Andalusian Public Health System. • Principal investigators must be linked through a civil servant, statutory or labour relationship with the applicant or performing centre. For Health Research Institutes (Institutos de Investigación Sanitaria, IIS), the link may be with any of the public or private law entities that are part of the IIS provided that the entity meets all the specific requirements determined in each action, and, in any case, be personnel assigned to the IIS. • More than one partner from Andalusia may participate in the same project • A PI can only participate in one application per call. • For receiving regional funding, the final funding decision issued by the corresponding program's decision-making body must be accredited. The duration of the projects shall be determined by the corresponding JTC. In any case, this period shall be stated in the award resolution.
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 at the SRC website. No funding of industrial partners. The applicant may not have an ongoing ERA4Health grant, or any other project grant concerning the same project concept, funded by the Swedish Research Council, at the start of the grant period. All Swedish project leaders participating in the call for support from the Swedish Research Council must also submit a parallel application according to the Swedish Research Council's instructions. The application form and instructions how to submit the parallel application can be reached from the call text at the SRC website. Parallel application is a mandatory eligibility criterion. Failure to submit the parallel application to the Swedish Research Council before the deadline of the SRC call will result in the Swedish partner being declared ineligible.
Türkiye	TÜSEB	Eligible applicants include universities, public and private hospitals, research institutes, and other healthcare and research organisations established in Türkiye that meet TÜSEB national funding requirements and have the scientific, legal, and operational

		capacity to conduct the proposed clinical study. Applicants must also comply with the general eligibility requirements of the ERA4Health IICS4all call. The Principal Investigator must have the relevant scientific qualifications and research experience and comply with applicable TÜSEB national eligibility criteria. For clinical trials subject to Turkish regulations requiring a medically qualified responsible investigator, this investigator must be a medical doctor or dentist with the specialist or doctoral qualifications required for the relevant clinical trial. Clinical studies must be conducted at eligible research sites, including university hospitals, public and private hospitals, research institutes, and other authorised healthcare and research facilities, with appropriate clinical infrastructure, qualified personnel, and necessary equipment.
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. 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 needs to appoint a **Coordinating Investigator** who will be the unique contact point of the ERA4Health Joint Call Secretariat during the application process.

Usually, the institution that hosts the Coordinating Investigator acts as the **Sponsor** of the study. The following conditions apply for Sponsors:

- Only a single sponsor per consortium is allowed
- A PI of one proposal cannot act as a sponsor representative of another proposal
- The sponsor can only be located in one of the participating countries of a consortium.
- The sponsor cannot be a collaborator of the consortium (i.e. self-funded partner)

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

Depending on the funding organisation there are two different possibilities to include national partners (see table 2 and Annex I of the call text for the possibility offered by each funding organisations):

- i. For funding organisations that restrict funding to a **single partner per country/region**: Only one national partner may join the consortium. This partner may allocate budget to other eligible national recruiting sites through subcontracting or collaboration agreements (these sites are considered 'associated partners'). If patient recruitment underperforms, initial recruiting sites may be replaced by additional ones, subject to the national/regional regulations of the respective funding agency
- ii. For funding organisations that fund **multiple partners per country/region**: A maximum of 3 (three) eligible partners from that country/region may join the consortium. They will be funded individually and manage separate budgets They collectively count as one country toward the consortium's maximum country limit.

The table below shows the requirement by each funding organisation participating in the call.

Table 2: Number of funded partners for each participating funding organisation

Country	Funding organisation	Funds one partner or several partners per consortium	If one partner is funded this type of agreement/contract needs to be established
Austria	FWF	One or several (national) partners per consortium can be funded.	Funding may be requested for project-specific work at the associated research partner's institution (if already registered in the FWF's Research Institution Portal). Associated research partners are researchers working on a project-specific basis at other Austrian research institutions (associated research institutions) and who are making a significant scientific/scholarly contribution to the project. Please refer to section 1.5 of the FWF Application Guidelines for more details. Otherwise, via subcontracting.
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 responsible for the appropriate distribution of funds to Belgian recruiting sites and associated partners.	The lead applicant must establish a consortium/collaboration agreement or site contracts with all involved partners.
Czech Republic	MZCR/AZVCR	Only one Czech partner per proposal will be granted.	This organisation will establish a collaboration with other Czech recruitment sites via subcontracting or a collaboration agreement.
Egypt	ASRT	Only one Egyptian organisation will be funded per proposal	This organisation will establish collaboration agreements with other additional national recruiting sites
France	Fr-MoH	Only one organisation will be granted funding and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement	The physical leader must be contractually linked to a healthcare institution specified above 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.
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.
Ireland	HRB	HRB will contract with a single Host Institution (Lead Applicant). Additional national recruiting sites (Associated Partners) are permitted to join the consortium. The HRB does not have a limit on the number of Associated Partners that will act as clinical study sites.	The Lead Applicant will be responsible for appropriate distribution of funds to the Associated Partner(s) /sub-contractors via appropriate agreements (collaboration and/or consortium agreements, sub-contract).
Israel	CSO-MOH	Only one Israeli partner may act as the lead applicant per proposal. This lead applicant will be the sole recipient of CSO-MOH funding.	A procurement agreement will be signed with the Ministry of Health
Italy	FRRB	Maximum 1 partner	

Latvia	LCS	Maximum 2 partners per proposal which must be completely independent on any organizational, personnel, funding, ownership aspect. Therefore it is highly advisable to have one partner per proposal, otherwise full demarcation firewall must be installed. Each partner requesting funding from LCS must be eligible Latvian beneficiary and conclude a funding contract with LCS. LCS is not funding anything else. LCS will fund only Latvian beneficiaries. All operations occur via a bank in Latvia.	Sites shall be subcontracted in full accordance with procurement law and the decisions of the beneficiary's procurement commission will be audited.
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	Funding will be awarded to one institution only.	Funding will be awarded to one institution only, which will act as coordinating institution responsible for establishing subcontracting or collaboration agreements with other recruitment sites.
Poland	NCBR	Only one organisation will be granted.	The funded 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 is authorised.	No subcontracting is 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
Spain	ISCIII	Only one eligible partner will be granted	This organisation will establish collaboration agreements with other additional national recruiting sites
Spain	CSPEJA	One or several partners per consortium can be funded	
Sweden	SRC	Only one eligible partner will be granted	This organisation will establish collaboration agreements with other additional national recruiting sites in Sweden.
Türkiye	TÜSEB	Up to two eligible Turkish partners per consortium may receive individual funding	Not applicable to the multiple-partner funding model adopted by TÜSEB.

		from TÜSEB, subject to national eligibility requirements and available funding.	
UK	DHSC-NIHR	NIHR issues research contracts to one lead UK contractor organisation within the consortium who will need to establish agreements with other eligible partners/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. Public and Patient organisations may be partners to this call but are not eligible to act as the UK lead contracting organisation.
Global organisation	BT1D	Only one partner	Should funding be approved, BT1D would establish a Memorandum of Understanding (MoU) directly with the academic partner to formalize the collaboration and funding arrangements. Patient association may be partners to this call but would not receive direct financial support from BT1D.

A consortium can include a maximum of 3 self-funded collaborators. Those collaborators can be patient organisations, enterprises or other entities with different roles, e.g. drug provider..

The following conditions apply for Collaborators:

- Clear added value for the IICS should be demonstrated in the proposal.
- Secure their own funding for participation with clear evidence in the proposal.
- A letter of commitment of the Collaborator(s) needs to be included as an annex to the pre-proposal / full proposal.
- A Collaborator cannot be a work package leader.
- A Collaborator cannot be a recruitment site for the study.
- A Collaborator cannot be the sponsor of the study.
- In the case that the Collaborator is a private for-profit entity, it is required that the consortia duly justify this involvement in the proposal and that there is no commercial purpose for this collaboration.

Example of consortium sizes

Smallest consortia

Consortium 1: each of the involved funding organisations restrict funding to 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 organisations fund 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

Partner D from country 3

Partner E from country 3 (*since additional recruiting sites are additional partners for this country, there can be 3 partners from country 3: C, D, and E*)

Larger consortia

Consortium 1: each of the involved funding organisations restrict funding to a single partner per country/ region 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*)

In this case, 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 underrepresented countries that allow an additional partner*

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

Collaborator 1

Collaborator 2

Collaborator 3

Consortium 2: in this case, one of the funding organisations will 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 additional recruiting sites are additional partners for this country, 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*)

In this case, 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 underrepresented countries that allow an additional partner*

Partner J from country 7 (*Supported by additional recruitment sites*), belonging to the list of underrepresented 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, e.g. if more funding organisations are involved in the consortium that fund multiple partners per country/region.

Funding mechanism

This funding mechanism demands special attention from the applicants. The clinical study tasks are composed of two different types of costs:

- a) Investigational costs covered by each national/regional funder:** 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).
 - Each project partner must oversee the budgeting of their planned tasks. The requested funds and the eligible costs are the following for the funding organisations participating to the call (see below table).

Table 3: Grant amounts and eligibility of costs for each participating funding organisation

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 per project submitted to the FWF is €450.000. Projects requesting funding above this upper limit will not be eligible.	The budget specified in the national submission must correspond to this consortium partner’s budget submitted to the EP and be calculated on the basis of the applicable FWF personnel cost rates at the time of submission in both the pre-proposal and full proposal stages. 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 (see section 2.3 of the FWF Application Guidelines). The FWF does not finance the infrastructure or basic equipment of research institutions. To ensure consistency, project costs should be calculated on elane (FWF) prior to inclusion in the consortium proposal.
Belgium	KCE	KCE will provide funding up to: -a maximum of 800.000 € for projects where the Belgian partner acts as sponsor of the trial. This amount includes both	Eligible Costs: All project-specific costs are eligible for funding, provided they are justified, and related tasks are well described in the budget template. The general budgeting principles outlined in the KCE Trials budget tool and guidance will be followed. Applicants are encouraged to use the KCE Trials budget tool as an aid to build their budget. KCE Trials will perform a check of submitted budgets against this tool. These costs include:

		sponsor-related costs and sites costs within Belgium. -a maximum of 400.000 € per project where the Belgian partner acts as Belgian Coordinating Center of the trial. This amount includes costs for sponsor-delegated tasks to BCC, where applicable, and site costs within Belgium. It is not anticipated that coordination fees will exceed site fees.	- Personnel and non-personnel costs essential to the execution of the project - Costs not covered by the infrastructure of the Belgian partner institution Ineligible costs include: - Costs already included in the tasks allocated to ECRIN or its subcontractor or another partner (cross-cutting tasks). - Costs solely related to other countries (e.g. buying, labeling and distributing drugs in other countries. Tasks can be organized by a single country but other countries should contribute pro-rata to the costs). - Costs related to translational research and exploratory endpoints (e.g. biobanking..). 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. If there are medical interventions, imaging, laboratory analysis or (day)hospitalisations that are not performed and reimbursed in the usual way (standard of care), the corresponding INAMI-RIZIV nomenclature number should be mentioned and the corresponding rate applied. 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).
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 (ERA4Health Výzva 2027 – AZV ČR). It is recommended to contact the responsible person at the Czech Health Research Council prior to submission regarding the eligibility criteria.
Egypt	ASRT	Maximum ASRT contribution to the Egyptian participation in one clinical study consortium: • Up to EUR 100,000 where the Egyptian participant(s) participate as partner(s). • Up to EUR 130,000 where an eligible Egyptian legal entity acts as the clinical study coordinator.	Eligible cost categories 1. Personnel: PI, researchers, clinicians, data managers, technical and support staff assigned to the project. Time records are required. Personnel costs are capped at 25% of the ASRT-requested contribution for each Egyptian applicant. 2. Consumables and project materials: laboratory consumables, kits, study materials and small supplies required for the approved activities. 3. Other direct clinical-study costs essential to achieve the objectives, such as sample processing, storage and shipment; access to specialised facilities, databases and software; patient and public involvement; data curation and repositories; regulatory or ethics-related fees; study insurance; monitoring; data management; biostatistical support; publication and intellectual-property costs; and external services that are not core scientific tasks. Such costs must be specifically justified. 4. Equipment: eligible only where directly required for the study and fully justified in relation to the proposed activities. 5. Travel and subsistence: in accordance with the applicable rules of the Ministry of Higher Education and Scientific Research and the host institution; economy class only; travel must directly serve the work plan, including justified consortium and ERA4Health meetings.

			6. Meetings and events: reasonable organisational costs for scientific meetings, workshops and consortium meetings directly linked to the study. 7. Patient and Public Involvement (PPI) and FAIR data-management costs: eligible where relevant, including patient or user engagement, data curation and use of appropriate repositories. 8. Indirect costs (overheads): 5% of eligible direct costs. Not eligible or capped - Activities primarily supporting teaching programmes, stand-alone website launches, or the design or development of original teaching tools are collectively capped at 15% of the Egyptian applicant's requested budget. Research communication and dissemination remain eligible where directly linked to the study. - Costs related to activities with a direct commercial purpose, and costs not necessary for the approved clinical study are not eligible.
France	Fr-MoH	<u>Funding Scenarios</u> - 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 results. <u>Important Note:</u> These two funding scenarios are mutually exclusive. The French Ministry of Health does not allow double funding for the same activities.	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.
Germany	BMFTR/ DLR	Up to 600.000 € for regular German partners; up to 800.000 € 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	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").

		intended sample size and the structure of the consortium and is not restricted.	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.
Ireland	HRB	Up to a maximum of €650,000 per project, including overhead contribution of 30% of Total Direct Modified Costs	Eligible costs include: • Salary related costs (including pension contributions) • Direct running costs, including travel, patient-related costs and costs to support the intervention study • Patient and Public Involvement (PPI) costs • Small equipment costs (€10,000) • FAIR data management costs, data stewardship costs • Open access costs • Dissemination and knowledge exchange costs. • Sub-contracting (for services/providers to be funded via sub-contracting at a national level. These costs should account for no more than 20% of the national budget) • Overheads (30% of Total Direct Modified Costs). Ineligible costs include: • Salary/benefits costs of academic staff within research institutions that are already in receipt of salary • Buy-out of academic/clinical time • Costs associated with a PhD/MSc (e.g. fees, stipend) Full details on eligible costs are available on the IICS4All scheme page on the HRB website https://www.hrb.ie/funding-scheme/era4health-partnership-2027/
Israel	CSO-MOH	Up to 140,000 €	Materials and consumables; Travel and hosting (up to 5%); No salaries for applicants; No heavy equipment, Institutional overhead 10%.
Italy	FRRB	Up to EUR 500.000,00 per project	
Latvia	LCS	Maximum funding allowed: 100.000 EUR per year per Latvian partner = grant of 0.4M for a 4-year project	• Personnel costs incl. taxes; • Consumables, animals; • Subcontracts (up to 25% of direct costs), needs detailed justification, includes external services, project core activities cannot be subcontracted; • Equipment (only depreciation costs during project the share directly attributable to project tasks); • Replaceable and fully consumable during project elements of equipment; • Travels (according to travel plan); • Indirect costs (up to 25% of direct costs excluding subcontracting) Costs covered by healthcare system are not eligible to be charged to projects
Lithuania	LMT	Maximum 500.000€ per project	All costs referred to as investigational costs in the Call text are eligible. These include: • site costs, such as personnel costs, clinical procedure costs, site services, and remuneration for patients or participants; • country-level site management costs, including site selection and coordination at the national level; and • clinical study management costs at the national or regional level, such as monitoring and insurance costs. Additional cross-cutting trial management costs may also be eligible if some of the sponsor's tasks are delegated to the Lithuanian team. Only costs incurred during the project period and directly related to the project are eligible. Eligible cost categories include personnel, consumables, subcontracting, equipment and

			instruments, other direct costs, costs related to the dissemination of results, data management and analysis, and overheads of up to 20% of direct costs. More details about eligibility of costs: https://www.e-tar.lt/portal/lt/legalAct/Oa8bead0577611e9975f9c35aedfe438/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 550 000 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	The maximum funding per grant awarded to a Polish partner is 700,000 EUR .	The eligible costs shall be the following: 1. personnel costs 2. consumables 3. equipment 4. travel 5. other direct costs 6. subcontracting – used exclusively for the research activity; this cost category shall not exceed 70% of all eligible costs of a project 7. additional overheads – incurred indirectly as a result of the research project. These costs are counted by multiplying direct costs (excluding subcontracting [6]) by 25%. It means $7 = (1+2+3+4+5)*25\%$ For research organizations, Industrial/Applied Research and Experimental Development are eligible for funding at an intensity of 100%. Please note that Fundamental/Basic research is entirely ineligible for funding. As part of the project implementation, key tasks related to coordination, management and dissemination are eligible for funding. For more details on eligible costs, applicants are advised to check cost eligibility guide (przewodnik kwalifikowalności kosztów) in the call announcement on NCBR webpage.
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 is 300 000 EUR per Slovak partner, or 400 000 EUR if a Slovak partner acts as the project coordinator or if there are two Slovak partners participating in a single project. These amounts may be further	Only direct costs that are essential to the project implementation and are directly related to its activities and timeline are eligible. No indirect costs/overheads will be funded. All costs must be fully utilized and accounted for by the end of 2029. Eligible costs: 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;

		increased by up to 15 000 EUR if a Slovak partner submits a patent, trademark, or design application, and/or publishes project results in an internationally indexed (peer-reviewed) scientific journal (e.g., WoS/Scopus). The minimum funding amount per Slovak project partner is 100 00 EUR.	- 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. General eligibility rule: All expenditures incurred by Slovak project participants must comply with: - Programme Slovakia, specifically Priority 1P1 Science, Research and Innovation, Specific objective RSO1.1: Development and enhancement of research and innovation capacities and the uptake of advanced technologies, Measure 1.1.3: Support for international cooperation in the field of research, development and innovation; - The provisions of the State Aid Scheme to Support Partnerships in the Field of Research, Development and Innovation under the Programme Slovakia; - Strategy for Financing the ERDF, ESF+, CF, FST, and ENRAF 2021–2027. Slovak applicants are advised to thoroughly familiarize themselves with the Guide for Applicants in European Co-funded Partnerships and Guide to Eligibility of Expenses under the Programme Slovakia, as the planned co-financing will be provided through this programme. It is further recommended that at least 30% of the Slovak applicant's total budget be dedicated to the actual performance of research activities. Important notice: All Slovak entities must have their contractual financial matters settled with CVTI SR by the end of 2029.
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) Equipment is not eligible
Spain	ISCIH	-Max. 1.000.000,00 € per project (if coordinator) - Max. 600.000,00 € per project (if not coordinator) (Including overheads)	
Spain	CSPEJA	Up to 125.000€ per partner or 250.000€ per coordinator (including 21% indirect costs)	a) Goods and services: consumables, bibliographic material, equipment rentals, software licenses and external services. b) Personnel costs: specifically hired for the project, including salaries, employer Social Security contributions, legally established compensation and other duly justified expenses derived. c) Travel, accommodation and subsistence according to the maximum amounts of compensation for service established in Decree 54/1989, of March 21, on compensation for service of the Junta de Andalucía, exclusively for people who are part of the research group or hired under the funded project. Exceptionally, any expense outside these amounts, or for people other than those listed before, must be authorised by the granting body. 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% f) Subcontracting costs: cannot exceed 50% of the funding and need prior authorization from the granting body. Nor Scientific aspects nor the management of the project should be subcontracted.
Sweden	SRC	Max 5 000 000 SEK (about 460 000 €) per project, including overheads. Use the conversion rate 1 € = 10.81 SEK.	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	EUR 300,000 per clinical study partner, subject to the overall TÜSEB funding commitment of EUR 600,000 and available funds.	Eligible costs may include personnel costs, consumables/materials, equipment, subcontracting, and other direct costs, subject to TÜSEB national funding rules. Travel costs, publication costs, and overheads are not eligible for funding. The eligibility and applicable limits of each cost category will be assessed in accordance with TÜSEB rules and the national funding agreement.
UK	DHSC-NIHR	Up to £1,000,000 (or approximately €1,150,000) for a project. Applicants must justify that the budget requested is appropriate and proportionate to the outlined research plans and ensures value for money. For conversion to GBP, please use your institution's standard exchange rate; NIHR does not mandate a fixed exchange rate, and total costs must be within the max funding threshold per award.	Eligible costs Costs for research and recruitment in the UK aligned to the most relevant NIHR domestic programme for this call and which meets NIHR finance requirements. In brief this means including only eligible UK investigational costs (staff time, study procedures, site services, participant expenses, and justified subcontracting), excluding NHS Support Costs, Treatment Costs and Excess Treatment Costs, and ensuring all costs are proportionate, deliverable and represent value for money. UK organisations are funded by NIHR for their UK-incurred costs only, and these are treated under NIHR domestic funding rules. UK HEIs are funded at 80% FEC, which may include indirect and estate costs in line with standard FEC methodology. UK NHS organisations are funded at 100% of eligible direct costs only. UK partners are not considered "international applicants" solely because the consortium is led or sponsored by a non-UK organisation. International costing rules (i.e. 100% direct costs only, no overheads) apply only where a UK applicant is requesting funding for activity undertaken outside the UK. Further information about costs can be found in the following publication Attributing the costs of health and social care research (AcoRD) N.B. NHS support costs and excess treatment costs are not supported through the NIHR research award funding. These are the responsibility of the NHS and should be funded through normal commissioning arrangements. 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.
Global organisation	BT1D	a maximum of 500.000 € per project	Direct Costs are defined as those costs falling within the following Breakthrough T1D budget categories: Salaries & Wages, Stipends, Supplies, Other Costs, Equipment and Travel. Salaries & Wages includes wages earned by an employee, and may include benefits, including insurance and retirement plans. Breakthrough T1D requires the Grantee Institution to have

			administrative and financial controls in place to allocate and track salaries and wages in realtime across a Breakthrough T1D-funded project. • Fringe benefits in the form of employer contributions or expenses for social security, employee insurance, workers' compensation insurance, tuition or remission of tuition for individual employees are allowable, provided such benefits are granted in accordance with established educational institutional policies, and are distributed to all institutional activities on an equitable basis. Tuition benefits for family members other than the employee are unallowable. Any deductions other than the listed above are not allowable. Car insurance that is not a standard institutional benefit offered to all employees of comparable rank is unallowable. • Stipends are applied for Breakthrough T1D Postdoctoral and Advanced Postdoctoral Fellowships in place of Salary & Wages. Stipend levels are determined based on the fellow's years of postdoctoral experience. • Supplies are general purpose consumable items that are used on a regular basis and have a shorter life span in use than equipment and machines. • Other costs might include items that are not consumable but are needed on a regular basis, such as animal purchases and maintenance charges. Other costs should also include the cost of making publications completely open access, whenever possible (see 5.8). • Salary and fringe for a statistician or other staff responsible for cleaning and entering data into the public repository, to comply with Breakthrough T1D's Data Sharing requirement (see 5.9), may be included as Direct Costs. • Research Allowances are provided for Postdoctoral Fellowships only in the amount of USD\$5,500 per year. These can be used towards travel to scientific meetings, journal subscriptions, books, health insurance costs, etc. • Travel may include any domestic and/or international journeys by an employee related to the project and is limited to USD\$2,000 per year on a grant unless otherwise approved by Breakthrough T1D. Indirect costs are limited to 10% of direct costs. The Grantee Institution may request indirect costs less than 10%. Equipment, subcontract, contractual, and fee-for service costs are not eligible for inclusion in calculating indirect costs. In instances where there is a subcontract, the Subcontract Institution may also budget up to 10% of their direct costs to indirect costs. The Grantee Institution may not incur any indirect costs off the subcontract costs.
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b) 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.

- An additional budget of a maximum up to 15% of the total budget requested to the national/regional funders can be requested for **covering the conduct of cross-cutting management activities** (i.e. clinical study management activities at consortium level) such as trial authorisations, Investigational Medicinal Product (IMP) or medical device purchase, labelling and distribution, safety and data management under the responsibility of the sponsor through collaboration with ECRIN (www.ecriin.org). This additional budget will be directly allocated to ECRIN to perform cross-cutting trial management activities.
- To request this additional budget in the pre-proposal, the consortium should 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). ECRIN provides services for multinational clinical trials with single sponsors. To guarantee that the collaboration is well established and with enough time, the consortium must **inform ECRIN representatives (Eucos)** as soon as possible and before this **deadline: 30th of November 2026** that they are preparing an application.

- To establish this contact with ECRIN, the consortium must contact the Euco (European Correspondent) from the country to which the Coordinating Investigator/sponsor is located (contact details of Euco can be found at: <https://ecrin.org/ecrin-staff> selecting the sponsor country) or in the case of Coordinating Investigator/sponsor from non-ECRIN member countries, the consortium must contact ECRIN Core Team contact point (<https://ecrin.org/contacts/sareema-javaid>).
- Once the collaboration between ECRIN and the applicants has been agreed, it will be formalized through a **written letter signed by ECRIN** representatives that must be **included as Annex of the pre-proposal** application. The letter will describe the agreed service provision for the additional budget.
- 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) to ensure full coverage of these cross-cutting management needs (the type of activities eligible for funding will vary between the respective funding organisation, please see Annex I).
- If applicants do not request the additional funding for cross-cutting management activities, they should clearly outline how these types of cross-cutting activities will be supported/funded in the study.

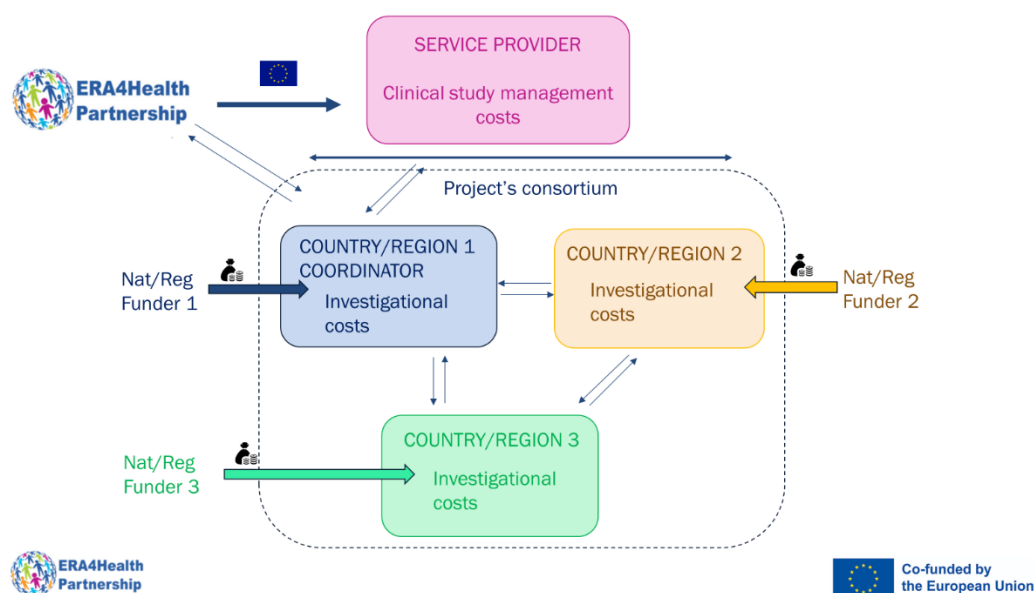


Figure 1: Funding mechanism. Plain arrows show the transfer of money and the two parallel arrows the exchange of information. The service provider costs of the crosscutting trial management activities performed by ECRIN will be requested as described in the example below.

Example of the requested budget for one consortium

In this example, the Partners from three different countries compose the consortium. The funders of two countries are funding one unique Partner whereas the funder of the third country will fund multiple partners (see consortium 2 from the examples of smallest consortia above).

The requested amount for each partner is the following:

Partners	Total requested budget €	Total cost of the project €
Partner A (Coordinating Investigator) requested funding to country 1	801 534	1 000 364 (198 830 provided in kind)
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 (76 632 provided in kind)
Partner E requested funding to country 3	260 380	260 380
Total for the consortium	2 181 659	2 457 121

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 optional 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, if ECRIN is selected as service provider of the cross-cutting activities. In this example: $15\% * 2\,181\,659 = 327\,249\text{ €}$.

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 pre-proposal).

Total requested budget for all partners (in €)	2 181 659 €
Budget available for Management costs (i.e. 15% of the sum mentioned above, in €)	327 249 €

Service Provider (please state if ECRIN or which entity subcontracted by ECRIN)	Costs (in €) (the total amount needs to be lower than 15% of the total requested budget, including indirect costs)	Justification
ECRIN	213 594	management, regulatory submission, data management and statistics, safety
xxx	113 655 €	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 funded project

The maximum funding duration is **48 months**.

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

Table 4: Information on study duration for each participating funding organisation

Country	Funding organisation	Duration of the funded project	Starting date	Possibility for potential extension
Austria	FWF	As specified by the EP ERA4Health.	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.
Egypt	ASRT	Up to 48 months	The exact contractual start and end dates will be defined in the ASRT grant agreement in accordance with the final call arrangements.	Potential extensions are exceptional and subject to prior written approval by ASRT. Any request must be submitted before the contractual end date and supported by a clear scientific, operational and financial justification. Approval of an extension does not entail an automatic increase in ASRT funding.
Czech Republic	MZCR/AZVCR	36 months All projects will be funded under the Programme for the Support of Applied Health Research for the Years 2024–2030 and <u>must therefore start on 1</u>	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

		<u>January 2028 and be completed no later than 31 December 2030, as the programme itself ends at the end of that year.</u>		itself comes to an end. Applicants are therefore strongly advised to start their projects on 1 January 2028 at the latest.
France	Fr-MoH	48 months		A one-year extension may be requested. No additional funding will be granted.
Germany	BMFTR/DLR	48 months	March 2028 (the earliest)	Cost neutral runtime extensions can only be granted in exceptional cases.
Ireland	HRB	48 months	Not specified	12-month no cost extension (NCE) permissible in line with HRB Policy on No-Cost Extensions.
Israel	CSO-MOH	Up to 4 years	Not specified	no option to extend
Italy	FRRB	Up to 48 months		
Latvia	LCS	Up to 48 months	Must start at common project start date. Consortium agreement in 6 months	Until End of 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.	,
Norway	RCN/ HSØRHF	Max 48 months	From January 2028	A cost-neutral extension based on a written request with justification and an agreement within the whole project consortium may be considered.
Poland	NCBR	Up to 48 months	Not specified	The Polish participant must notify the NCBR about the project extension and submit a formal request to amend the national contract.
Romania	UEFISCDI	48 months, max. until December 2030	Not specified	Cost neutral runtime extensions can only be granted until December 2030
Slovakia	CVTI SR	48 months; Important notice: All Slovak entities must have their contractual financial matters settled with CVTI SR by the end of 2029.	Not specified	
Spain	DS-CAT	48 months	Established in the national grant resolution (from January 2028)	Potentially cost-neutral extensions could be provided, according to national regulation

Spain	ISCIII	48 months	Established in the national grant resolution (probably beginning of 2028)	Potentially cost neutral extensions could be provided, according to national regulation.
Spain	CSPEJA	The duration of the projects shall be determined by the corresponding JTC.	Not specified	The maximum extension is limited to half of the initial duration of the project.
Sweden	SRC	36 months, with additional 12 months availability period	January 2028	No-cost extensions may be requested according to the terms and conditions of the grant from the SRC
Türkiye	TÜSEB	48 months	January to May 2028 (subject to national procedures)	No-cost extensions may be considered only in accordance with ERA4Health procedures and TÜSEB national rules. Extensions are not automatic and require prior approval by the relevant bodies/funder.
UK	DHSC-NIHR	Up to 48 months	1st of the Month (approx 6 months after outcome notification)	No-cost extensions may be requested and considered on a case-by-case basis where well justified.
Global organisation	BT1D	Up to 36 months	March 2028 the latest	Grants are eligible to request No Cost Extensions

ANNEX 1: RESOURCES AND 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 multi-country Investigator-initiated clinical studies

[D15.2 Mapping of organisations providing support to multi-country IICS](#)
[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>

ANNEX 2: Responsible innovation Journey Guide

Core idea

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

[The RRI journey guide](#) sets out a Responsible Innovation Journey for health research and innovation, organised by the maturity of a project rather than by administrative milestone. This guide encompasses these RRI themes in a health science setting:

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

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

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

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

The Responsible Innovation Journey related to proposal writing

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

Phase 1 – Project idea

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

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

Questions

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

Responsible approach

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

Ways to put this into practice

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

Possible approaches

- A consortium compares a new health technology with non-technological alternatives and identifies patient groups that may be excluded by cost, access or usability barriers.
- A project using sensitive data checks early whether open-science ambitions can be balanced with confidentiality, privacy and security obligations.
- A project involving animals, humans or environmental exposure identifies possible harm early and adapts the research design before the full proposal is developed.
- A project team invites patient representatives, health professionals or community actors to discuss whether the project's problem definition matches lived experience and practical needs.
- A consortium developing a diagnostic asks at the idea stage whether the test could realistically be manufactured, priced and distributed in the settings where the disease burden is highest and adjusts its partner composition accordingly.

- A team invites an industrial actor/investor and a policy actor alongside clinicians to its first framing workshop, on the grounds that uptake will depend on decisions no research partner controls.

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

Phase 2 – Proposal development

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

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

It divides the guiding questions into these advice points:

1. Define the purpose, need and expected value of the project
2. Identify relevant people, groups and expertise early
3. Design research methods and safeguards together
4. Anticipate consequences, risks and alternative futures
5. Address safety, sustainability and responsible implementation
6. Build reflection, learning and responsiveness into the work plan
7. Show how responsibility strengthens excellence, impact and implementation

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

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

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

Here is a main guide for phase 2:

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

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

Questions

- How are ethical safeguards, data practices, stakeholder involvement and scientific methods designed together?

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

Responsible approach

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

Ways to put this into practice

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

Possible approaches

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

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

Phase 3 – Proposal submission

Key question: Is responsibility convincingly addressed?

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

Questions

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

Responsible approach

- Make a structured internal read-through of the draft against the Phase 2 questions.
- Organise a review by an RRI or ethics advisor before submission.
- Do a budget check confirming that responsibility work has named people, person-months and money attached to it.
- Use precise, project-specific language and avoid generic statements.
- Show how activities will influence research choices, not only run in parallel to the science.
- Make the link between ethical safeguards, societal readiness and expected impact explicit.
- Demonstrate that the project has the capacity and flexibility to respond to new concerns.

Ways to put this into practice

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

Possible approaches

- A proposal states who leads RRI work, how it is resourced with a defined share of effort in the person-month table and which work packages can change in response to stakeholder or ethics input.
- A clinical or data-intensive project explains how consent, privacy, incidental findings, access rules and OS ambitions will be handled together.
- A high-novelty project includes decision gates where safety, sustainability or societal-readiness evidence must be reviewed before further development.
- Including a deliverable that reports stakeholder input and the changes it produced, rather than only that engagement took place.
- State **where in the proposal** each responsibility element sits — objectives, methods, work plan, impact section — so that evaluators do not have to search for it.

- Be explicit about openness: what will be published, which data will be shared, under what licence, and where confidentiality, personal-data protection or research security genuinely requires restriction.
- Show that the claimed societal benefit has a plausible route to the people who need it, including affordability, regulatory approval and health-system adoption.

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

Funding checkpoint – Quality assessment

Key question: Can this project proceed responsibly?

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

Questions

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

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