

Call for Proposals for Multinational and Translational Research Projects in the ERA-NET NEURON on

"BIDIRECTIONAL BRAIN-BODY INTERACTIONS"

Submission deadline for pre-proposals: 8th March 2024, 14:00 CET

Electronic proposal submission

For further information, visit our website:

http://www.neuron-eranet.eu

or contact the

NEURON Joint Call Secretariat:

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1. Purpose

Maintenance, improvement, and restoration of human brain health are of fundamental importance and a worldwide priority. It has become increasingly evident that bidirectional communication between the central nervous system and the body has significant implications for maintaining both homeostatic and brain function. Abnormalities in brain—body interaction linked to genetic, environmental or lifestyle factors encompass a wide range of conditions affecting millions worldwide. Dysregulation of the brain-body axis can potentially contribute to or exacerbate various neurological and psychiatric disorders. The estimated prevalence can vary significantly depending on factors such as geographic location, population demographics, and advancements in medical diagnosis.

The study of bidirectional interactions between the central nervous system and the body is an emerging field of research that holds the potential to enhance our understanding of often overlooked pathophysiological processes involved in common neurological and psychiatric disorders. Expanding our current knowledge in this area is crucial as it serves as the initial step towards the development of therapeutic and preventive approaches aimed at preserving and improving brain health on a global scale.

The 'Network of European Funding for Neuroscience Research' (NEURON) has been established under the ERA-NET scheme of the European Commission (www.neuron-eranet.eu). The ERA-NET NEURON aims to coordinate and optimize research efforts and funding programmes of its partner countries/regions in the field of mental, neurological, and sensory disorders. Under the umbrella of NEURON, a joint transnational call (JTC 2024) in the field of bidirectional brain-body interactions is now launched. The current call will cover multiple areas in which brain-body interaction appears to be centrally implicated in the genesis or progression of common neurological and psychiatric disorders.

The following funding organisations have agreed to fund the joint call for multinational research projects in this scientific area. The call will be conducted simultaneously by the respective national and regional funding organisations and coordinated centrally by the Joint Call Secretariat.

Fonds de la Recherche Scientifique-FNRS (F.R.S.-FNRS) Belgium* Ministry of Science and Education (MSE) Croatia French National Research Agency (ANR) France Federal Ministry of Education and Research (BMBF) Germany German Research Foundation (DFG) Germany National Research, Development, and Innovation Office (NKFIH) Hungary[†] Chief Scientist Office, Ministry of Health (CSO-MOH) Israel* Italian Ministry of Health (IT MoH) Italy Latvian Council of Science (LZP) Latvia Research Council of Lithuania (LMT) Lithuania The Research Council of Norway (RCN) Norway National Centre for Research and Development (NCBR) Poland Executive Agency for Higher Education, Research, Development & Innovation Romania Funding (UEFISCDI) Slovakia Slovak Academy of Sciences (SAS) Agencia Estatal de Investigación (AEI) Spain National Institute of Health Carlos III (ISCIII) Spain Swiss National Science Foundation (SNSF) Switzerland* National Science and Technology Council (NSTC) Taiwan The Scientific and Technological Research Council of Türkiye (TUBITAK) Türkiye*

2. Aim and scope of the call

The aim of the call is to facilitate multinational, collaborative research projects that will address critical translational and clinical questions to improve our knowledge concerning the role of bidirectional central nervous system-body interactions on the genesis and progression of neurological and psychiatric diseases. A better understanding of these interactions has the potential to uncover solutions to prevent and treat those disorders.

The central nervous system and other body compartments are highly interconnected. The central nervous system affects physiological functions through signals transmitted from the brain to the body and vice versa. Signals from peripheral organs to the brain could be derived from the immune system, metabolic processes, gut-brain axis and microbiome, among others. Dysregulation of the brain-body communication may cause severe brain disorders. The roles of the signals and their pathways for regulating brain functions are poorly understood. Consequently, the associated pathophysiological mechanisms leading to central nervous system disorders and their related co-morbidities are largely unknown.

^{*}Funding organisations with parallel national application procedures or extra requirements for submission. We strongly recommend contacting the respective funding organisation for further information (contacts, see Annex I).

†Pending on decision.

The present call aims to fund preclinical and clinical research up to proof-of-concept clinical studies¹ addressing the pathophysiology and therapeutic developments for neurological or psychiatric disorders associated with bidirectional brain-body interactions. Research areas may cover a broad range of aspects such as genetic, epigenetic, and molecular mechanisms of disease. They may include research on the role of the immune system, gut and microbiome, metabolic system, autonomic system, hormonal system in neurological or psychiatric disorders, without ruling out others, e.g. the role of body representation in the brain. The development of preventive, diagnostic and/or therapeutic approaches including pharmacological studies and technological developments based on pathophysiological mechanisms are within the scope of the call.

The ERA-NET NEURON funding organisations particularly wish to promote multi-disciplinary work and translational research proposals that combine basic and clinical approaches. The consortia should submit novel, ambitious ideas that can only be achieved by the complementary collaboration between partners.

Research proposals should cover at least one of the following areas:

- a) Fundamental research on the role of the bidirectional brain-body interaction on the pathogenesis and/or aetiology of neurological and psychiatric diseases. This may include the development of innovative or shared resources and technologies considered of relevance in the context of this call.
- b) Pre-clinical and clinical research to develop new strategies for prevention, diagnosis, therapy, and rehabilitation procedures for diseases in which alterations in brain-body communication constitutes a relevant process of the pathology.

The following research areas are excluded from this call:

- Neurodegenerative disorders that are addressed by the EU Joint Programme Neurodegenerative Disease Research (JPND)².
- Proposals focusing on neuro-oncology.
- Proposals dealing primarily with periphery organ functions (e.g. lung, sensory organs, liver, cardiovascular, etc.) without specifically focusing on the brain-body interaction aspect.
- Proposals focusing solely on technological developments in disregard of neurobiological mechanisms.

Applicants should demonstrate that they have the expertise and skills required to conduct the study, including already established external collaborations.

¹ Eligibility and funding requirements for clinical trials vary between the partner countries. Clarification may be obtained from the individual funding organisations

² Alzheimer's disease and other neurodegenerative dementias, Parkinson's disease (PD) and PD-related disorders, Prion disease, Motor neuron diseases, Huntington's disease, Spinocerebellar ataxia, Spinal muscular atrophy

The translational value for human disease must be addressed explicitly in the proposals. If used, the choice of the animal model must be justified in the context of human pathology. The development of new transgenic animal models is outside the scope of the current call. The use of existing transgenic models and the usage of infrastructures offering access to existing models is encouraged. The consideration of sex differences in the studies is mandatory.

Clinical studies are eligible up to the point of proof of concept³. Multimodal and multicenter clinical studies are highly encouraged. The proposals should consider the cultural, societal background and general individual diversity of patients if relevant. ERA-NET NEURON will not fund the establishment of large cohorts, but the use of existing cohorts, biobanks/brain banks and exploitation of existing datasets is encouraged. Appropriate access to relevant, well-characterized patient populations or suitable biomaterial collections must be demonstrated. The proposal should describe plans to make data available for the research and clinical communities. It is recommended that the appropriate European infrastructures are contacted early in the planning of the projects; the following are potentially of interest for the applicants to this call: EBRAINS (focused on data and tools for brain-related research), INFRAFRONTIER (focused on modelling of human diseases) with the European Mouse Mutant Archive (EMMA), ECRIN (focused in clinical research), EATRIS-ERIC (focused on translational medicine), BBMRI-ERIC (focused on biobanking), and ELIXIR (focused on data sharing).

The ERA-NET NEURON seeks to strengthen patient engagement in research. All applications should include a description of expected outcomes with potential relevance for patients. Applicants are expected to engage patients, their care givers or patient organisations as appropriate in the research. Meaningful patient engagement can occur at the level of research planning, conducting research or disseminating research results. Patient representatives will assess patient engagement aspects, the feasibility, and the relevance of the full proposals from a patient perspective.

3. Application

3.1 Eligibility

Joint transnational research proposals may be submitted by research teams working in universities (or other higher education institutions), non-university public or private research organisations, hospitals or foundations, and commercial companies, particularly small and medium-sized enterprises. The eligibility of the afore-mentioned institutions, together with details of eligible costs (e.g. personnel, material, consumables, travel money, investments), are subject to the administrative requirements of individual funding organisations and will therefore differ. Please note that, for some funding organisations, commercial companies are not eligible or are only eligible under certain conditions (e.g. only in partnership with academic institutions in the consortium). Clarification should be obtained from the individual funding organisations (see contact details below). It is strongly recommended to carefully read

³ Eligibility and funding requirements for clinical trials vary between the partner countries. Clarification may be obtained from the individual funding organisations.

the funder-specific regulations regarding eligibility and funding and to contact the respective funding organisations, since additional national/regional procedures might be mandatory.

Only transnational projects will be funded. Each consortium submitting a proposal must comprise a minimum of three research partners eligible for funding by organisations listed in this call text (see above). Involvement of promising early career researchers (ECRs)⁴ as consortium partners is highly encouraged and will be part of the evaluation criteria (see section 4). The eligible research partners must be from at least three different participating countries. The total number of research partners in a consortium is limited to five, including partners participating with their own expenses. No more than two consortium partners can be from the same country. Attention should be paid to respect gender balance among the partners of a consortium.

The ERA-NET NEURON strives to strengthen a global Brain Research Area by including as many partner countries as possible in its funding scheme. Therefore, consortia including at least one partner from countries that are to date underrepresented in this funding scheme (Croatia, Hungary, Latvia, Lithuania, Romania, Slovakia, Taiwan and Türkiye) may increase the total number of partners to six.

Applicant partners who are not eligible for funding from their national/regional funding organisations or from countries/regions that are not involved in this call, may participate in consortia only if a) their participation clearly provides an added value to the consortium, and b) they have secured a budget for their part in the project. Such potential partners are not considered in the minimum number of three research partners mentioned above. In any case, the total number of research partners in one consortium must not exceed five, or six, if partners from the underrepresented countries (listed above) are included.

Each consortium should have the critical mass to achieve ambitious scientific goals and **should clearly demonstrate added value** from working together. Each consortium must nominate a coordinator who represents the consortium externally and is responsible for its internal management (e.g. the application procedure, coordination of consortium agreement drafting, Data Management Plan, reporting). The consortium coordinator must be eligible for funding from one of the organisations listed in this call text.

A single proposal must be submitted by the consortium coordinator to the NEURON Joint Call Secretariat. The individual research partners in a consortium will be funded by the respective national/regional NEURON funding organisation(s). Eligibility criteria are the matter of individual partner funding organisations and additional national/regional regulations and requirements may apply.

The inclusion of a research partner that is not eligible for funding according to the specific regulations of its respective funding organisation may result in the rejection of the entire proposal without further review. Therefore, applicants are strongly advised to follow the instructions in the funder-specific regulations section, published on the NEURON website and to contact their

⁴ 2-7 years of experience since completion of PhD or medical specialization diploma at the date of the launch of this call and a scientific track record showing great promise. Allowed extensions 18 months maternity leave for each child born, duration of paternity leave for each child born, duration of long-term illness or national service, duration of clinical training with a maximum of 4 years). Please check the funder specific regulations for the national/regional eligibility criteria that apply.

national/regional funding organisation to confirm eligibility rules before submitting a proposal.

Only projects that fulfil the legal and ethical international/EU regulations (including ethical standards and guidelines in Horizon EUROPE) as well as national and institutional regulations and standards will be funded. All proposed activities including those undertaken in countries outside the EU must comply with EU regulations (see Annex I of the full proposal template). Ethical approval(s) and/or a positive vote(s) must be obtained from the relevant national or local ethics committee(s) prior to the start of respective studies.⁵ The obtainment of ethical clearance will be queried by ERA-NET NEURON. All procedures involving human beings must conform to the Helsinki Declaration.

3.2 Submission of joint transnational proposals

There will be a **two-stage procedure** for joint applications: **pre-proposals** and **full proposals**. In both cases, one joint **proposal document** (in English) shall be prepared by the partners of a joint transnational proposal, and must be submitted to the Joint Call Secretariat by the coordinator.

Pre-proposals must be submitted in electronic format no later than 8th March, 2024 (14:00 CET) via the electronic submission system. All fields must be completed using DIN-A4; font: Arial, 10pt; single-spaced, page limits. Pre-proposals that do not meet the formal criteria will be rejected from the call process without further review.

NOTE: Full proposal submissions will be accepted only from those applicants **explicitly invited** by the Joint Call Secretariat.

The information given in the pre-proposal is binding. Thus, any fundamental changes between the preand full proposals stages concerning the composition of the consortia, objectives of the project or requested budget must be communicated to the Joint Call Secretariat and approved by the respective funding organisations with detailed justifications and will only be allowed in exceptional cases before passing to the evaluation stage.

3.3 Further information

For further details, please refer to the respective submission forms available through the NEURON website. If you need additional information, please contact the Joint Call Secretariat. Finally, national/regional organisations may set special requirements for their applicants. Applicants are therefore strongly advised to review the instructions contained in the funder-specific information published on the NEURON website and to contact their national/regional funding organisation for further information (see Annex I for contact details).

⁵ Requirements for ethical approvals may vary between the partner countries. Please refer to the funder-specific information or contact the individual funding organisations.

4. Evaluation and decision

The review process will be in two stages.

4.1 Formal check of pre- and full proposals

The Joint Call Secretariat will check the proposals to ensure that they meet the call's formal criteria (e.g. date of submission; the number of participating partners and countries/regions; inclusion of all necessary information according to the respective templates in English). The Joint Call Secretariat will provide online access to the proposals to the national/regional funding organisations, which will perform a formal eligibility check for compliance with their respective regulations.

The Joint Call Secretariat and national/regional funding organisations will perform cross-checks in parallel submissions to other joint transnational calls (e.g. EJP RD, JPND, ERA PerMed and others) and national calls. Applicants shall avoid applying for the same research activities to different calls. Double funding is not allowed.

Proposals not meeting the formal criteria described above will be rejected at this stage. Proposals passing this step will be forwarded to the Peer Review Panel for evaluation.

4.2 Peer-review of pre- and full proposals

The reviewers will assess if the projects are within the scope of the call and evaluate them using the following criteria:

1. Excellence

- Scientific quality of the approach and methodology
- Quality of the experimental design and data analysis
- Novelty of the scientific concept/hypotheses
- Competence and experience of participating research partners in the field(s) of the proposal (previous work in the field, specific technical expertise)

2. Impact

- Potential impact of the expected results on clinical and other health-related applications
- Added value of transnational collaboration
- Inclusion of early career researchers (ECRs)
- Potential impact for patients; patient involvement and ethical aspects

3. Quality and efficiency of the implementation

- Feasibility of the project
- Coherence and effectiveness of the work plan, including appropriateness of the allocation of tasks, resources, time frame and related risk analysis

- Quality and added value of collaborative and multi-disciplinary interactions within the consortium
- Appropriateness of the management structures and procedures

ERA-NET NEURON strives to fund reproducible and solid scientific outputs, our evaluation criteria value the methodological rigor of the experimental approaches proposed.

4.3 Decision

4.3.1 Pre-proposals

Eligible pre-proposals will be reviewed using the above-mentioned evaluation criteria via a written (remote) peer review process. Preferably, each pre-proposal will be reviewed by at least three reviewers. Based on the scores in the written reviews, a ranking list will be established. By mid-May 2024, the coordinators of the selected proposals will be invited by the Joint Call Secretariat to submit a full proposal before **28**th **June 2024** (14:00 CEST).

4.3.2 Full proposals

The international Peer Review Panel will evaluate the full proposals based on the above-mentioned evaluation criteria and establish a ranking list based on scientific assessment at the panel meeting. Additionally, expert patient reviewers will assess the patient-relevant aspects of the full proposals and an Ethics board will give recommendations on the ethical aspects of the full proposals. A short list of proposals will be identified as recommended for funding based on the ranking list. The Call Steering Committee will determine the projects to be funded, considering the national budgets' availability.

5. Funding procedure / Responsibilities / Reporting requirements

5.1 Funding procedure

Successful research groups will be funded directly by the respective funding organisations.

Funding is expected to start by early to mid-2025. Projects should be designed to be achievable during a maximum funding period of three years.

Funding will be administered according to the terms and conditions of the responsible funding organisations, considering all other applicable regulations and legal requirements.

5.2 Responsibilities

Within a joint proposal, each research partner will be the contact person for the respective national/regional funding organisation. The coordinators of funded projects together with the relevant

funding organisations shall make every effort to seek a common start date for all research groups in a consortium.

After the evaluation and selection procedures are completed, each funded consortium is required to draft a Consortium Agreement (CA) and a Data Management Plan (DMP). The CA will determine a common project start date, manage the delivery of project activities, finances and intellectual property rights (IPR), and avoid disputes that might be detrimental to the completion of the project. With the first annual report the coordinator must provide the DMP and the CA signed by all parties to the Joint Call Secretariat. Please note that some funding organisations may require the submission of a DMP, CA, and/or ethical approval at an earlier time point. Please read carefully the funder-specific information section.

5.3 Reporting Requirements

On behalf of the research consortium, the consortium coordinator will be required to submit to the Joint Call Secretariat annual scientific progress reports, as well as a final report at the end of the project. Additionally, the individual partners may be required to submit reports separately to their national/regional funding organisation. In the latter case, reporting guidance will be forwarded by the relevant funding organisation, as applicable.

Annual reports must be submitted by 30th April, starting in 2026. Final reports must be submitted at the latest six months after the end of the project. Annual reports do not need to be submitted if the project ends between January and March on the last year. In the latter case, the submission of a final report three months after the end of the project will suffice.

In exceptional cases, partners may be granted runtimes of different start and/or duration according to the national funders' decision. It is the task of the coordinators to determine, in agreement with the consortia, a formal end date for project completion; usually the latest end date of individual national contracts. Coordinators will be informed about this procedure by the Joint Call Secretariat and will receive the report templates in due course.

The coordinators will be asked to present a progress report during a Midterm symposium. Attendance is mandatory for all coordinators and project partners. Failure to comply with this requirement may result in administrative and/or financial sanctions according to the rules of each funding organisation. Students and postdoctoral researchers working on the projects are welcome to join the midterm symposium. Accordingly, travel expenses to attend the symposium should be included in the proposal budget plans.

Funding recipients must ensure that all outcomes (publications, etc.) of transnational NEURON projects include a proper acknowledgement of ERA-NET NEURON and the respective funding partner organisations. All the publications resulting from funded projects must be published in adherence to the EC Open Science Policy and specific rules of the funding agencies.

5.4 General data protection regulation

Applicants are informed that their personal data submitted in their application to the call are processed in accordance with article 6.1 (e) and (c) of the General Data Protection Regulation (GDPR) (2016/679)⁶, and for the purposes of:

- processing and evaluating the application where processing shall be lawful only if and to the
 extent that processing is necessary for the performance of a task carried out in the public
 interest or in the exercise of official authority vested in the controller;
- · administering any subsequent funding award;
- managing the funding organisations relationship with them;
- analyzing and evaluating the call;
- providing aggregate data to national and European surveys and analyses on the funded projects.

The Call Steering Committee may share applicant's data with third parties (some of which may be based outside the European Economic Area) in relation to the above activities including evaluators, auditors and the European Commission (or its agencies).

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⁶ Last name, first name of the researchers, date of birth, professional contact information, degree(s), position (current and previous), fields of activity, place of work, organisation, address(es), curriculum vitae, ORCID number, name and reference of projects, pre-proposals, project proposals (scientific document, administrative and financial appendix).

Annex I. Contact details

Please note that <u>funder-specific requirements</u> might apply to this call. <u>Compliance with the national/regional regulations specified in the funder-specific information is <u>mandatory</u>. A parallel national/regional application or additional requirements may be requested by certain funding organisations (see table page 3). We strongly advise you to contact your national/regional representative prior to submitting a pre-proposal:</u>

Country	Contact	
/region	person(s)	Funding organisations contact Details
Belgium	Dr Florence	Fonds de la Recherche Scientifique – FNRS (F.R.SFNRS)
(French-	Quist	International@frs-fnrs.be
Speaking	Dr Agnès	+32(0)2 504 93 51
Community)	Roba	+32(0)2 504 92 36
Croatia	Mateo A.	Ministry of Science and Education (MSE)
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France	Dr. Sheyla	French National Research Agency (ANR)
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	Provenzano	
Germany	Dr. Sophia	Federal Ministry of Education and Research (BMBF)
	Schach	Sophia.Schach@dlr.de
		+49 228 3821 1743
Germany	Dr. Anke Ley	German Research Foundation (DFG)
		anke.ley@dfg.de
		Tel. +49 (228) 885-3197
		<u>www.dfg.de</u>
Hungary	Dr. Klara	National Research, Development and Innovation Office (NKFIH)
	Horvath	klara.horvath@nkfih.gov.hu
		+36 1 896 3748
Israel	Dr. Liron	Chief Scientist Office - Ministry of Health (CSO-MOH)
	Even-	https://www.gov.il/he/departments/general/international_cooperations
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		972-2-508-2168
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Annex II. Anticipated amount of funding provided by each partner

The intended contribution by each participating funding organisation to be used for the joint transnational call for research projects is listed below.

Partner Country / Region	Funding organisation	Anticipated amount of funding (for 3 years)	Anticipated number of fundable research groups
Belgium	Fonds de la Recherche Scientifique-FNRS (F.R.SFNRS)	200.000€	1
Croatia	Ministry of Science and Education (MSE)	200.000€	1
France	French National Research Agency (ANR)	1.800.000€	6-7

Germany	Federal Ministry of Education and Research (BMBF)	3.000.000€	8-9
Germany	German Research Foundation (DFG)	1.200.000€	3
Hungary	National Research, Development and Innovation Office (NKFIH)	300.000€	2-3
Israel	Ministry of Health (CSO-MOH)	320.000€	2
Italy	Italian Ministry of Health (IT MoH)	1.500.000€	4
Latvia	Latvian Council of Science (LZP)	600.000€	2
Lithuania	Research Council of Lithuania (LMT)	300.000€	2
Norway	The Research Council of Norway (RCN)	500.000€	1-2
Poland	National Centre for Research and Development (NCBR)	1.200.000	1-4
Romania	Executive Agency for Higher Education, Research, Development & Innovation Funding (UEFISCDI)	500.000€	1-2
Slovakia	Slovak Academy of Sciences (SAS)	120.000€	1
Spain	Spanish State Research Agency (AEI)	800.000€	4
Spain	National Institute of Health Carlos III (ISCIII)	750.000€	3-4
Switzerland	Swiss National Science Foundation (SNSF)	~1.000.000€ (CHF 1.000.000)	3-4
Taiwan	National Science and Technology Council (NSTC)	810.000€	2-3
Türkiye	The Scientific and Technological Research Council of Türkiye (TUBITAK)	300.000€	2-3

Annex III. Call Timetable

Pre-proposal stage (I)

December 05, 2023	Preliminary Announcement of the Joint Transnational Call
January 08, 2024	Launch of the Joint Transnational Call
March 08, 2024	Deadline (submission of pre-proposals) 14:00 CET
May 24, 2024	Formal invitation to submit a full proposal

Full proposal stage (II)

June 28, 2024	Submission deadline of full proposals 14:00 CEST
September, 2024	Peer Review Panel meeting to assess the full proposals
October 2024	Final funding decision by the CSC and start of national administrative procedures
Early 2025	Start of funding