



Call for Proposals for

MULTINATIONAL RESEARCH PROJECTS ON TRANSLATIONAL BIOMARKERS IN BRAIN DISORDERS

Submission deadline for pre-proposals: 11 March 2019, 14:00 CET

Electronic proposal submission



For further information, please visit us on the web

<http://www.neuron-eranet.eu>

or contact

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1. Purpose

Maintenance, improvement and restoration of human health are of fundamental importance and worldwide priority. In Europe, one out of every four citizens experience a neurological or psychiatric condition, leading to a serious economic and social burden due to long-term disability and mortality. Neuroscience research and its translation into diagnostic and therapeutic outcomes are of fundamental importance to improve health in our society.

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 aim of the ERA-NET NEURON is to coordinate and optimise research efforts and funding programmes of its partner countries in the field of disease related neuroscience.

Under the umbrella of NEURON, a joint transnational call (JTC2019) is launched in the field of biomarkers in disorders of the brain. For the afflicted patients a correct diagnosis and individualized treatment without severe side effects are of crucial importance.

Despite impressive improvement on our knowledge of brain function, valid and reliable biomarkers for clinical and research use in the field of brain diseases are still urgently needed. Brain diseases biomarkers candidates are continuously identified and published by academic research groups. However, the rigorous validation of those promising candidates as research or clinical tools is seriously hindered by the frequent use of poorly standardised practices.

The following funding organizations have agreed to fund the present joint call for multinational research projects. The call will be conducted simultaneously by the funding organizations in their respective countries and coordinated centrally by the Joint Call Secretariat.

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| • Fonds de la Recherche Scientifique (FNRS) | Belgium |
| • Research Foundation – Flanders (FWO) | Belgium |
| • Fonds de recherche du Québec - Santé (FRQS) (Québec) | Canada |
| • Canadian Institutes of Health Research – Institute of Neurosciences, Mental Health and Addiction (CIHR-INMHA) | Canada |
| • Academy of Finland (AKA) | Finland |
| • French National Research Agency (ANR) | France |
| • Federal Ministry of Education and Research (BMBF) | Germany |
| • General Secretariat for Research and Technology (GSRT) | Greece |
| • Ministry of Health (MOH) | Italy |
| • State Education Development Agency (VIAA) | Latvia |
| • The Research Council of Norway (RCN) | Norway |
| • National Centre for Research and Development (NCBR) | Poland |
| • Executive Agency for Higher Education, Research, Development & Innovation Funding (UEFISCDI) | Romania |
| • Slovak Academy of Sciences (SAS) | Slovakia |
| • National Institute of Health Carlos III (ISCIII) | Spain |
| • Swiss National Science Foundation (SNSF) | Switzerland |
| • The Scientific and Technological Research Council of Turkey (TUBITAK) | Turkey |

2. Aim of the call

The aim of the call is to facilitate multinational, collaborative research projects that will address the unmet medical need for valid and reliable biomarkers for the diagnosis, patient stratification, prognosis, monitoring and prediction of treatment response and side effects in neurological and psychiatric diseases.

The NEURON funding organizations particularly wish to promote multi-disciplinary work and translational research proposals that combine basic and clinical approaches. In the context of the present call, the inclusion of psychiatrists and/or neurologists in the postulating consortia is highly encouraged, along with fundamental neuroscientists. The consortia are expected to 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 addressing the discovery and validation of biomarkers to be used as bio signatures of the pathophysiology associated to specific neurological and psychiatric diseases.
- b) Clinical research on clinically relevant biomarkers for the diagnosis, patient stratification, prognosis or monitoring or prediction of treatment response and side effects for specific neurological and psychiatric diseases.

Proposals may include hypothesis-driven studies on a variety of biomarkers, e.g. structural, functional, molecular, genetic biomarkers. Digital, behavioral or cognitive biomarkers are eligible only in combination with other bio signatures. In all cases, a clear pathophysiological correlate and studies on human participants or tissue should be included in the proposal. Clinical studies are eligible up to the point of proof of concept¹.

To address an important translational gap in the biomarker validation process, proposals are encouraged to perform retrospective **validation** for pre-identified candidates using high quality data samples such as highly stratified patients populations and rigorous analytical methods. Moreover, the combination of at least two types of biomarkers is required for biomarkers' validation studies.

Research consortia must demonstrate relevant expertise and range of skills required to conduct the study, including rigorous study design; alternatively, appropriate collaborations should be in place upon submission. Readily access to high quality biological materials- i.e. data sets, cohorts, animal models; high quality facilities and the latest analytical technologies- should be established. In this context, it is highly encouraged to get in contact with relevant European infrastructures early in the planning of the projects; in particular EATRIS-ERIC (focused on translational medicine),

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

BBMRI-ERIC (focused on biobanking) and ELIXIR (focused on data sharing). Specific contact details can be found in Annex I for each of these infrastructures.

The development of new technologies is excluded from this call unless appropriately justified by the absence of an alternative validated technology. Animal models or cell models used in the project should already be established and validated. The development of new animal or cell models is excluded from the scope of the call.

Research on neurodegenerative disorders that are addressed by the EU Joint Programme - Neurodegenerative Disease Research (JPND) is excluded from the present call².

The ERA-NET NEURON seeks to strengthen patient engagement in research. Applicants are expected to include patients, where appropriate, in their research process. Meaningful patient engagement can occur at the level of research planning, conducting research or research result dissemination. Patient representatives will participate in the review of selected proposals and provide feedback on patient engagement aspects.

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 research institutes, hospitals, as well as in commercial companies, particularly small and medium-size 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 organizations and will therefore differ. Please note that, for some funding organizations, 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 agencies (see contact details below). It is advised to read carefully all national annexes regarding eligibility and funding by the respective funding agencies.

Only transnational projects will be funded. Each consortium submitting a proposal must be comprised of a minimum of three research teams eligible for funding by organizations listed in this call text (see above). The eligible research teams must be from at least three different countries. The total number of research groups in a consortium is limited to five, including partners participating by own expenses. No more than two research groups can be from the same country.

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 ERA-NET NEURON strives to strengthen the European Research Area by including as many partner countries as possible in its funding scheme. Therefore, consortia including partners from countries that are to date underrepresented in this funding scheme (Latvia, Romania and Slovakia) may increase the total number of partners to six.

Research groups not eligible to their national funding organizations or from countries which are not involved in this call may participate in projects only if their participation clearly provides an added value to the consortium and if they present evidence on secured budget for their part in the project. Such research groups are not considered in the minimum number of three research groups mentioned above. In any case, the total number of research groups in one consortium must not exceed five, or six if one of the underrepresented countries listed above is comprised.

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

A single application must be submitted by the consortium coordinator to NEURON Joint Call Secretariat. The individual research groups will be funded by the NEURON funding organization(s) of their respective countries. Eligibility criteria are the matter of individual partner funding organizations.

Inclusion of a partner in a proposal who is not eligible for funding according to the specific regulations of their respective funding organisation may result in the rejection of the entire proposal without further review. Therefore, applicants are strongly advised to follow the instructions contained in the country-specific eligibility tables which are published on the NEURON website and to contact their national/regional funding organization to confirm eligibility before submitting an application.

Only projects that fulfil the legal and ethical international/EU (including ethical standards and guidelines in Horizon 2020) as well as national and institutional standards will be funded. Ethical approval and/or a positive vote must be obtained from the relevant national or local ethics committee(s) prior to the start of the project. All procedures involving human beings should conform to the Helsinki Declaration. Additional national regulations and requirements may apply.

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 one spokesperson, the coordinator.

Pre-proposals must be submitted in electronic format no later than **11 March, 2019** (14:00:00 CET) via the [electronic submission](#) system. All fields must be completed using **DIN-A4; font: Arial, 10pt; single-spaced, page limits.**

The information given in the pre-proposal is binding. Thus, any fundamental changes between the pre- and 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 their respective funding agencies with detailed justifications and will only be allowed in exceptional cases by the Call Steering Committee, before passing to evaluation stage.

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

3.3 Further information

For further details, please refer to the respective submission forms available through the NEURON web site. If you need additional information, please contact the Joint Call Secretariat, or the representative of your funding organization (see Annex I for contact details).

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; number of participating countries; inclusion of all necessary information in English). The Joint Call Secretariat will also forward the proposals to the national/regional funding organizations, which will perform a formal and eligibility check of 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., E-RARE, JPND, EuroNanoMed, ERA-PerMed and others) and national calls. Applicants shall avoid applying for 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 joint 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 carry out the evaluation according to specific evaluation 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

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

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. Based on the scores in the written reviews a ranking list will be established. Preferably, each pre-proposal will be reviewed by at least three reviewers. By mid-May 2019, the coordinators of the selected proposals will be invited by the Joint Call Secretariat to submit a full proposal before **27th June 2019** (14:00 CET).

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 of the fundable proposals based on scientific assessment. Based on this ranking list the Call Steering Committee will determine the projects to be funded, taking into account the national budgets available. Based on these recommendations, final

decisions will be made by the funding organizations and will be subject to budgetary considerations.

5. Funding procedure / Responsibilities / Reporting requirements

5.1 Funding procedure

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

Funding is expected to start **early in 2020**. Projects can be funded for a period of three years. Neutral-cost extensions can be granted for individual research groups according to respective funding organizations' regulations.

Funding will be administered according to the terms and conditions of the responsible funding organizations, taking into account all other applicable regulations and legal requirements.

5.2 Responsibilities

Within a joint proposal, each consortium coordinator will be the contact person for the relevant national/regional funding organization. The coordinators of funded projects together with the respective funding organizations shall make every effort to seek a common start date for all research groups in the consortium.

After the evaluation and selection procedures are completed, each consortium selected to be funded 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 which might be detrimental to the completion of the project. All consortia are strongly encouraged to sign the CA before the official project start date; within six months after the start of the project the DMP must be sent to the Joint Call Secretariat NEURON and the CA must be signed.

5.3 Reporting Requirements

On behalf of the research consortium, the project 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, group leaders may be required to submit reports separately to their national funding organization. In that case, reporting guidance will be forwarded by the relevant funding organization, as applicable.

Annual reports must be submitted by April, 30, starting in 2021. Final reports must be submitted six months after the end of the project at the latest. 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 will suffice. However, instead of submitting the final report within the usual six month period, the final report will be required within four months of project completion.

It is the task of the coordinators to determine a formal end date for project completion. This is required, as partners may be granted extensions of different duration. Coordinators will be informed about this procedure by the Joint Call Secretariat and will receive the report template in due course.

The coordinators will be asked to present a progress report during an intermediate status symposium. The attendance is obligatory for all coordinators and Principal Investigators (PIs). Early-career scientists working on the projects are welcome to join the intermediate symposium together with the PIs. Accordingly, travel expenses to attend the symposium should be considered in the proposal budget plans. Failure to comply with this requirement may result in administrative and/or financial [...]sanctions according to the rules of each funding agency.

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 organizations.

Annex I. Contact details

Please note that country specific requirements might apply to this call. **Compliance with the national/regional regulations specified in the country specific information is mandatory. We strongly advise you to contact your national/regional representative prior to submitting a pre-proposal:**

Country (Region)	Contact person(s)	Funding organizations contact Details
Belgium (French Speaking Community)	Dr Florence Quist Joël Groeneveld	Fonds de la Recherche Scientifique-FNRS (F.R.S.-FNRS) rue d'Egmont 5 1000 Bruxelles Tél. +32 (0)2 504 93 51 Florence.quist@frs-fnrs.be Joel.groeneveld@frs-fnrs.be <u>+32 (0)2 504 92 70</u>
Belgium (Flanders)	Dr Alain Deleener Toon Monbaliu	Research Foundation Flanders (FWO) Egmontstraat 5 1000 Brussel <u>www.fwo.be</u> <u>eranet@fwo.be</u> +32 2 550 15 70
Canada	Ms. Melody Sajedi	Canadian Institutes of Health Research (CIHR) Melody.sajedi@cihr-irsc.gc.ca 613-960-9475 www.cihr-irsc.gc.ca
Canada (Québec)	Mr. Maxime Beaudoin	Fonds de recherche du Québec-Santé (FRQS) Maxime.Beaudoin@frq.gouv.qc.ca 1+ 514-873-2114 #1369 <u>www.frqs.gouv.qc.ca</u>
Finland	Dr Hannele Lahtinen Dr Sirpa Nuotio	Academy of Finland (AKA) hannele.lahtinen@aka.fi +358 29 533 5055 sirpa.nuotio@aka.fi +358 29 533 5082
France	Dr Sheyla Mejia-Gervacio	French National Research Agency (ANR) Health & Biology Department NeuronCalls@agencerecherche.fr +33 178 09 80 14
Germany	Dr Anna Gossen	Project Management Agency (DLR-PT) – Health, on behalf of the Federal Ministry of Education and Research (BMBF) Anna.Gossen@dlr.de +49 228 3821 1684 <u>www.gesundheitsforschung-bmbf.de</u>
Greece	Georgia Kostopoulou	General Secretariat for Research and Technology (GSRT) g.kostopoulou@gsrt.gr +302131300100 <u>http://www.gsrt.gr/central.aspx?slid=11914281108913231488743</u>
Italy	Dr Gaetano Guglielmi	Ministero della Salute <u>g.guglielmi@sanita.it</u> <u>http://www.salute.gov.it/portale/home.html</u>

Latvia	Dr Uldis Berkis	State Education Development Agency (VIAA) www.viaa.gov.lv Uldis.Berkis@viaa.gov.lv Office: +371-67785406 Mobile: +371-29472349
Norway	Dr Alexandra Bjørk-Skaflestad	The Research Council of Norway (RCN) alb@rcn.no Tel.: +47 22 03 72 24
Poland	Dr Marcin Chmielewski	National Centre for Research and Development (NCBR) Department for International Cooperation marcin.chmielewski@ncbr.gov.pl phone: + 48 22 39 07 109 fax.: +48 22 20 13 408 www.ncbir.pl
Romania	Mrs. Mihaela Manole	Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI) Mihaela.manole@uefiscdi.ro Tel: +4 021 30 23 863
Slovakia	Dr Jan Barancik Mrs. Katarina Bibova	Slovak Academy of Sciences (SAS) Department for International Cooperation barancik@up.upsav.sk +421 2 5751 0137 bibova@up.upsav.sk +421 2 5751 0136 www.sav.sk
Spain	Mrs. Maria Druet	National Institute of Health Carlos III (ISCIII) SG de Programas Internacionales de Investigación y Relaciones Institucionales phone: +34 91 822 2530 mdruet@isciii.es
Switzerland	Dr Claudia Ellenrieder	Swiss National Science Foundation (SNSF) Division Biology and Medicine claudia.ellenrieder@snf.ch Tel: +41 31 308 22 22
Turkey	Dr. Recep Emrah Çevik	Health Sciences Research Support Group (SBAG) TÜBİTAK +90-312-298-1214 emrah.cevik@tubitak.gov.tr

EUROPEAN INFRASTRUCTURE - ESFRI

ESFRI	Contact Details
BBMRI	Petr Holub petr.holub@bbmri-eric.eu
EATRIS	Florence Bietrix florencebietrix@eatris.eu
ELIXIR	Serena Scollen serena.scollen@elixir-europe.org Andrew Smith andrew.smith@elixir-europe.org

Annex II. Anticipated amount of funding provided by each partner

The intended contribution by each participating funding organization to be used for the joint trans-national call for research projects is listed below.

Partner Country	Funding organization	Anticipated amount of funding (for 3 years)	Anticipated number of fundable research groups
Belgium	Fonds de la Recherche Scientifique (FNRS)	€200.000	1
Belgium	Research Foundation – Flanders (FWO)	200 000 €	1
Canada	Canadian Institutes of Health Research (CIHR)	\$450,000 CAD (€320,000)	2
Canada (Québec)	Fonds de recherche du Québec - Santé (FRQS)	\$CAD450,000 (€320,000)	2
Finland	Academy of Finland (AKA)	600 000 €	2
France	French National Research Agency (ANR)	€1 800 000	~6-7
Germany	Federal Ministry of Education and Research (BMBF)	3.000.000 €	About 10
Greece	General Secretariat for Research and Technology (GSRT)	1.000.000 €	About 4-5
Latvia	State Education Development Agency (VIAA)	€420.000	2
Italy	Ministry of Health (MOH)	€1.500.000	About 6
Norway	The Research Council of Norway (RCN)	€500.000	1-2
Poland	National Centre for Research and Development (NCBR)	600 000€ Up to 200 000€ per project, regardless of the number of Polish research groups in the project consortium.	1-3
Romania	Executive Agency for Higher Education, Research, Development & Innovation Funding (UEFISCDI)	€400.000	1-2
Slovakia	Slovak Academy of Sciences (SAS)	€120.000	1
Spain	National Institute of Health Carlos III (ISCIII)	250.000€	2-3
Switzerland	Swiss National Science Foundation (SNSF)	1.2 million Swiss francs (~1.058 million €)	3-4
Turkey	The Scientific and Technological Research Council of Turkey	150.000 €	1-2

Annex III. Call Timetable

Pre-proposal stage (I)

December, 2018	Preliminary Announcement of the Joint Transnational Call
January 9, 2019	Publication of the Joint Transnational Call
March 11, 2019	Deadline (submission of pre-proposals) 14:00 CET
mid-May, 2019	Formal invitation to submit a full proposal

Full proposal stage (II)

June 27, 2019	Deadline (submission of full proposals) 14:00 CET
July, 2019	Formal/Eligibility check of full proposals
October-November, 2019	Final funding decision by the CSC and start of national administrative procedures
Early in 2020	Start of funding