

EU Joint Programme - Neurodegenerative Disease Research (JPND)

JPND Call for Proposals:

"Understanding the mechanisms of non-pharmacological interventions"

Submission deadline for pre-proposals:

March 1, 2022, 12:00h (noon) C.E.T.

For further information, please visit us on the web

http://www.jpnd.eu/

or contact the JPND Joint Call Secretariat:

Sabrina Voß Vera Mönter-Telgen

(+49) 228-3821 2111 or jpnd@dlr.de

1. INTRODUCTION

Neurodegenerative diseases are debilitating and largely untreatable conditions that are strongly linked with age. Worldwide, there are estimated to be 50 million people with Alzheimer's disease and related disorders, the most common group of neurodegenerative diseases. This figure is expected to double every 20 years as the population ages. The total direct and informal care costs of Alzheimer's, Parkinson's and related disorders are expected to surpass €350 billion per year across the European Union. Existing treatments for neurodegenerative diseases are limited in effect and mainly address the symptoms rather than the cause or the progressive course.

In this context, the EU Joint Programme - Neurodegenerative Disease Research (JPND) has been established to better coordinate research efforts across countries and disciplines to more rapidly find causes, develop cures and identify better ways to care for people with neurodegenerative diseases. To identify research priorities, the JPND Research and Innovation Strategy, published in 2019, provides a framework for future investment.

Several non-pharmacological interventions have been shown to be effective and accepted by the patients, e. g. from existing cohort data. Such interventions may include, among others, psychosocial interventions, neuromodulation, nutrition or exercise. Although neurodegenerative diseases are being recognized as multifactorial syndromes, there is little interaction between biomedical and psychosocial approaches. One rationale for integrating biomedical and psychosocial research is the discordance between neuropathology and cognitive functioning. However, there is yet little knowledge about the mechanisms of non-pharmacological interventions, e. g. on the molecular or cellular level.

For this reason, JPND launches this joint transnational call with the aim of improving the understanding of the mechanisms and biological substrates that underlie non-pharmacological interventions in order to tailor a holistic personalized treatment approach. The funding organisations that have agreed to fund this joint call for multinational research projects, with a view to adding value to their existing nationally funded activities, are listed below. The call will be conducted simultaneously by the funding organisations in their respective countries and coordinated centrally by the Joint Call Secretariat.

- Australia, National Health and Medical Research Council (NHMRC)
- Belgium, The Fund for Scientific Research (F.R.S.-FNRS)
- Belgium, The Research Foundation Flanders (FWO)
- Canada, Canadian Institutes of Health Research (CIHR)
- Czech Republic, Ministry of Education, Youth and Sports (MEYS)
- Denmark, Innovation Fund Denmark (IFD)
- Finland, Academy of Finland (AKA)
- France, French National Research Agency (ANR)
- Germany, Federal Ministry of Education and Research (BMBF)
- Hungary, National Research, Development and Innovation Office (NKFIH)
- Israel, Ministry of Health (CSO-MOH)
- Italy, Ministry of Health (IT-MOH)
- Latvia, State Education Development Agency (VIAA) / Latvian Council of Science (LZP)

- Luxembourg, National Research Fund (FNR)
- Netherlands, The Netherlands Organisation for Health Research and Dev. (ZonMw)*
- Norway, The Research Council of Norway (RCN)
- Poland, National Science Centre (NCN)
- Slovakia, Ministry of Education, Science, Research and Sport of the Slovak Republic
- Spain, National Institute of Health Carlos III (ISCIII)
- Switzerland, Swiss National Science Foundation (SNSF)
- Turkey, Scientific and Technological Research Council of Turkey (TUBITAK)

2. AIM OF THE CALL

The aim of the call is to establish a number of ambitious, innovative, multi-disciplinary and multi-national collaborative research projects that aim at understanding the biomedical, psychological and/or social mechanisms of non-pharmaceutical interventions in order to identify potential target sites for enhanced personalized interventions or a combination of pharmacological and non-pharmacological interventions. Proposals must focus on one or several of the following neurodegenerative diseases:

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

Proposals submitted under this call may include, but are not limited to, the following types of research:

- Determining biomolecular and/or physical underpinnings of effects of non-pharmacological interventions;
- Examining the mechanisms of effective non-pharmacological interventions on the molecular and cellular level by applying cutting-edge technologies;
- Identification of the mechanisms of non-pharmacological interventions within the brain, using brain imaging, electrophysiology and other equivalent state-of-the-art techniques;
- Identification of biological, psychological and social health markers and their associations to allow the identification of modifiable risk factors amenable to non-pharmacological interventions and better predict and monitor the effects of these interventions for future largescale clinical studies:
- Elaborating modified concepts of non-pharmacological interventions with enhanced efficacy based on a deeper understanding of the mechanisms;
- Identification of potential drug-target sites for a combination of pharmacological and nonpharmacological interventions;
- Finding (individual) factors that predict response to interventions.

^{*}final decision on participation is still pending.

Proposals must be hypothesis-driven and should have a strong focus on methodology. They should be based on mechanistic approaches rather than pure correlational research and focused on those interventions where there is solid and demonstrable indication of effectiveness. Special attention should be paid to the development of non-biased methods to control for potential 'placebo like' effects of non-pharmacological interventions. The potential of existing cohorts should be used as much as possible. However, gaining data on effectiveness and efficacy itself, e.g. by conducting clinical trials, is not within the scope of this call. Consortia should include researchers from social sciences, where needed.

Proposals should have novel, ambitious aims and ideas combined with well-structured work plans and clearly defined objectives deliverable within three years. If the proposals are complementary to research already funded or submitted to other funding initiatives, it should be clearly stated how JPND funding can supplement the ongoing research or applications. Each consortium should have the critical mass to achieve the identified scientific goals and the proposals should specify the benefit of working together. Applicants should demonstrate that they have the expertise and range of skills required to conduct the research project or that appropriate collaborations are in place. The value that will be added to ongoing national activities and the expected impact on future scientific use, medical application and well-being of people suffering from neurodegenerative diseases should be explicitly stated.

Proposals should consider the diversity and differentiation of the target group in terms of factors like sex, age, socioeconomic situation, level of education, migration and cultural background, and sexual orientation, where it is relevant for the implementation of the project. For assessing the well-being of people suffering from neurodegenerative diseases, quality of life measures should be used. Consortia should incorporate these factors when formulating their research hypotheses, aims and work plans.

Most patient-related research would be impossible without the active involvement of patients. Thus, JPND has determined that Patient and Public Involvement should be an integrated part of the implementation of its Research and Innovation Strategy. Proposals to be funded under this call will therefore need to adequately involve patients, carers and the public. Consortia are expected to make every effort to include approaches that involve these groups, where appropriate, at each stage of the research process including the preparation of the application (see the JPND website for further information). In the application, it must be described in which step of the research process patients, their relatives or carers will be involved, from where they will be recruited and which roles they would play. Appropriate justification must be given if such an approach is not taken.

Ethically appropriate access to and synergistic usage of resources, e.g. biomaterial, population and disease-specific cohorts as well as cutting-edge technical infrastructure is expected. To increase benefit, data, tools and resources being generated within the research projects should be made widely available to the public domain, considering national and international legal and ethical requirements. Access must be provided to other bona fide research groups. Consortia are strongly advised to define arrangements to deal with this issue across countries, while preserving integrity of study participants as early as at the submission of the preproposal.

Training of young researchers and mobility (e.g., exchanges of research assistants, students and postdoctoral researchers) within the consortia are encouraged if justified in terms of the training opportunities provided to the individual and the needs of the field, in the context of the proposed

workplan. Please note that there may be restrictions according to the specific regulations of each funder.

To have an impact at European and partner country levels, it is expected that all proposals will link activities across laboratories and clinics within JPND member countries. Proposals are encouraged to utilise expertise from areas outside of neurodegeneration research, which can bring innovation to the proposed research approach. The benefits of the multidisciplinary collaboration should be stated.

In preparation of your proposal we encourage you to use European Research Infrastructure Networks such as BBMRI (Biobanking and Biomolecular Resources Research Infrastructure), EATRIS (European infrastructure for translational medicine) or ECRIN (European Clinical Research Infrastructure Network) as valuable resources and platforms for knowledge exchange. Different platforms can be found via the European Strategy Forum for Research Infrastructures in Europe - ESFRI.

3. MANAGEMENT OF THE CALL

Below we outline the role of the three bodies that are responsible for the management of the call and the evaluation of proposals. Anyone who is a member of one of these bodies is not allowed to submit or participate in proposals within this call.

- The Call Steering Committee takes all decisions regarding the call procedures and operations. It is composed of representatives from each participating funding organisation. Based on the recommendations from the Peer Review Panel and budget considerations it will confirm the consortia being invited to submit full-proposals and decide on final funding decisions.
- The Joint Call Secretariat is led by DLR-PT, Health Division, Germany. It is responsible for the management of the call and it is a contact point for applicants and partner organisations. However, it is not the decision-making body of the call.
- The Peer Review Panel is composed of internationally recognised scientists related to the
 topics of the call as well as experts regarding the assessment of Public and Patient
 involvement. It is responsible for the scientific evaluation of proposals at both the pre- and fullproposal stage. The Peer Review Panel will rank the proposals according to the evaluation
 criteria and make funding recommendations to the Call Steering Committee.

4. ELIGIBILITY

Under this scheme, joint transnational research proposals can be funded for a period of up to three years. Proposals may be submitted by research groups working in universities or other higher education institutions, non-university public or private research organisations, hospitals and other health and social care settings, as well as commercial companies, in particular small and medium-size enterprises (SMEs). Collaborations with companies from outside the traditional medical sector (e.g. computing, artificial intelligence) are welcome. With regard to the research setting and collaborations with companies, specific regulations of individual funding organisations as well as the EU State aid regulations must be considered when creating the consortium.

Consortia may consist of partners who receive funding for research by funding organisations participating in this joint call ("regular funded partners") as well as non-funded external collaborators. Regular partners are represented by the leaders of individual research groups (typically a principal

investigator or a young academic group leader) within individual institutions. Each regular partner must verify their eligibility to request funding from one of the funding organisation(s) of their respective country participating in the call (see section one). If different research groups from the same institution request funding, these groups will be treated as separate regular partners under this call.

Each proposal must involve a minimum of three and a maximum of six regular partners, including the coordinator, from at least three different countries participating in this call (see section one). However, if the proposal involves at least one regular partner from an EU-13 country (i.e. Czech Republic, Hungary, Latvia, Poland, Slovakia) or from Turkey, the maximum number of regular partners is extended to seven. For reasons of transnational balance, no more than two regular partners from the same country are allowed to join a proposal.

In addition, external collaborators (e.g., research groups from countries not participating in this call or research groups that are from countries participating in this call but do not apply for funding) may participate in proposals. External collaborators must secure their own funding. They must state in the proposal if these funds are already secured or how they plan to obtain funding in advance of the project start date.

Whilst proposals are to be submitted jointly by regular partners from different countries, each regular partner will be funded by the corresponding funding organisation of their country participating in this call. In consequence, eligibility for funding is decided by the respective funding organisations and details of what may or may not be funded are subject to the specific regulations of these funding organisations and thus may vary. Please be aware that individual budget restrictions might apply for each country and/or funding organisation (see section 8).

Information on specific regulations (e.g., additional forms to be submitted before the submission deadline or details on eligible costs) is provided in the <u>specific information sheets</u>. Nevertheless, applicants are strongly advised to contact their corresponding funding organisation to enquire about their eligibility and to gain latest information. The inclusion of a regular partner that is not eligible for funding may result in the rejection of the entire proposal.

5. APPLICATION

There will be a two-stage procedure for applications: pre-proposals and full-proposals. The revision of the proposals between these stages will be accepted only in the circumstances indicated below. At both stages, one joint proposal document shall be prepared by the consortium and submitted by the coordinator. In addition, some funding organisations request additional information to be submitted before the proposal submission (see specific information sheets). In case of any questions concerning the proposal submission, please contact the Joint Call Secretariat.

5.1 Pre-proposal submission

Pre-proposals must be submitted by the coordinator in electronic format no later than 12:00h (noon) C.E.T. on March 1, 2022, via the JPND <u>electronic submission system</u>. No other means of submission will be accepted. A <u>pre-proposal template</u> is available at the JPND website. Adherence to this template is mandatory.

5.2 Revision of proposals

A revision of pre-proposal plans is allowed after the pre-proposal evaluation but only under certain conditions. Submission of a revised proposal is restricted to those consortia explicitly selected for the

full-proposal stage. The following modifications to pre-proposal plans are permitted in the preparation of a full-proposal:

- Adding or replacing regular partners. This should normally be restricted to one regular partner and the following cases:
 - Where a regular partner from the pre-proposal has been declared non-eligible.
 - Where the modification is derived and justified from the pre-proposal evaluation.
 - Where the aim is to include a regular partner from an EU-13 country (i.e. Czech Republic, Hungary, Latvia, Poland, Slovakia) or from Turkey or an underrepresented country (i.e. a country that will most likely not spend its entire budget), and where such inclusion can be scientifically justified. Further information on which countries are underrepresented will be provided prior to the full-proposal stage.
- Including or excluding external collaborators (no further restrictions).
- Changing the work plan and/or the budget of regular partners where it is either derived from the pre-proposal evaluation or the modification of the consortium (as outlined above). Changes need to be well justified in the full-proposal. Changes to the budget of individual regular partners require approval by the respective funding organisation.

Applicants are responsible for ensuring that any changes applied during the revision are in line with the eligibility criteria of the call (see section 4). Full-proposals that exceed the above conditions for revision or do not meet the eligibility criteria of the call may be rejected without further review. Therefore, applicants are strongly advised to consult the Joint Call Secretariat and/or the funding organisations involved in the full-proposal in advance of submission.

5.3 Full-proposal submission

Full-proposals will be accepted only from those consortia explicitly invited to submit them by the Joint Call Secretariat. Proposals must be submitted by the coordinator in electronic format no later than 12:00h (noon) C.E.S.T. on June 28, 2022, via the electronic submission system. No other means of submission will be accepted. The Joint Call Secretariat will provide a full-proposal template and further information to the coordinator. Adhering to this template is mandatory. Any changes applied during the revision should be described and justified in the full-proposal.

6. EVALUATION AND DECISION

Detailed information on the evaluation and decision-making process can be obtained from the accompanying call procedures document.

6.1 Evaluation criteria and scoring

The Peer Review Panel will carry out the evaluation of pre-proposals and full-proposals. The following evaluation criteria will be applied:

- Relevance to the aim of the call.
- Scientific quality including level of innovation, originality and feasibility.
- Transnational added value from working together as a research consortium, including planned scientific interaction, knowledge exchange and training.
- **International competitiveness** of participating research groups, including the demonstrated scientific expertise, and their appropriate combination.
- Deliverable outcomes in the short, medium and long-term, including risk assessment and management.

6.2 Evaluation and decision on pre-proposals

The Joint Call Secretariat will check the pre-proposals to ensure that these meet the call's formal conditions. In parallel, the involved funding organisations will perform eligibility assessments according to their specific criteria. Pre-proposals that do not meet the formal or specific eligibility criteria may be rejected.

Pre-proposals passing the formal and specific eligibility check will be evaluated by the Peer Review Panel. At least three panel members will be asked to assess each pre-proposal on a written basis. Based on these recommendations, the Call Steering Committee will make a final decision on full-proposal invitations.

The Joint Call Secretariat will inform each coordinator about the outcome of the pre-proposal evaluation and provide the written evaluations (with the evaluators remaining anonymous), the recommendation of the Peer Review Panel to improve the quality of project, the decision of the Call Steering Committee and information about any subsequent widening processes to encourage and facilitate the inclusion of the EU-13 or underrepresented countries. To increase the success rate of the selected consortia, the number of full-proposals to be invited will approximately match but not exceed a 3-fold oversubscription of the total budget available for the call.

6.3 Evaluation and decision on full-proposals

Full-proposals will be checked regarding formal and eligibility criteria and evaluated by the Peer Review Panel as described in section 6.2. The Peer Review Panel will make funding recommendations for each full-proposal and agree on a ranking order based on the scientific assessment according to the evaluation criteria. Based on these recommendations, and on the funds available, the Call Steering Committee will select the list of proposals for funding.

The Joint Call Secretariat will inform each coordinator about the outcome of the full-proposal evaluation, thereby providing the written evaluations (with the evaluators remaining anonymous), a summary of the panel discussion, the recommendation of the Peer Review Panel and the final

decision of the funding organisations as well as information on the possibility of adding partners due to the widening process.

7. FUNDING REGULATIONS, RESPONSIBILITIES AND REPORTING REQUIREMENTS

Funding decisions will be made by the relevant funding organisations and administered according to their terms and conditions, considering all other applicable regulations and legal frameworks.

A consortium agreement signed by all regular partners of the proposal is required within 6 months after the beginning of the project. It will specify as a minimum: decision-making authority, monitoring, reporting, intellectual property rights management and sharing, and handling of data and resources, as appropriate. Administrative and funding arrangements will be stated in the consortium agreement to be a bilateral responsibility between each regular partner and the relevant funding organisation.

Regular partners and external collaborators of a consortium (hereinafter referred to as the "partners") may as part of their activities individually or jointly with other partners collect or process Personal Data, as defined in Article 4(1) of Regulation (EU) 2016/679 of 27 April 2016 (General Data Protection Regulation, GDPR) or any applicable national data protection law. In such event, the partners shall individually or collectively with other partners be responsible for ensuring that the Personal Data is processed in accordance with GDPR or any applicable national data protection law and other applicable data protection legislation ("Data Privacy Legislation").

Each consortium must nominate a coordinator, who represents the consortium externally, acts as first point of contact and is responsible for its internal management in terms of formal responsibilities towards JPND (such as monitoring, reporting, intellectual property rights issues and sharing of data and resources). The coordinator will be required to submit a brief annual scientific progress report in January of each year and a final scientific progress report within three months from the end of the project to the Joint Call Secretariat. Those reports may be used internally for monitoring and evaluation purposes to assess the progress of the implementation of JPND's Research and Innovation Strategy. Each regular project partner will also be the contact person for the relevant funding organisations. It may be necessary for individual regular project partners to submit additional reports to their funding organisation, as required.

Funding recipients must ensure that all outcomes (publications, etc.) of transnational JPND projects and all other communications include a proper acknowledgement both of JPND and the respective funding organisations. For this purpose, a JPND dissemination strategy has been agreed to by all JPND member states. Adhering to the JPND dissemination guidelines is mandatory for researchers funded under the umbrella of JPND. From time to time consortia will be asked to work with the JPND Communications Manager and the funders on related communications (e.g., project summaries for the JPND website, blogs, tweets).

8. CONTACT DETAILS

Please note that country specific requirements might apply to this call. For further information please contact your national representative:

Country	Funding organisation, contact details
Australia	National Health and Medical Research Council (NHMRC)
	Adam Chapman
	+61 2 6217 9320
	International@nhmrc.gov.au
Belgium	Research Foundation - Flanders (FWO)
	Kristien Peeters (SBO)
	+32 25 50 15 95 or eranet@fwo.be
	Toon Monbaliu (FO)
	+32 25 50 15 70 or eranet@fwo.be
	The Fund for Scientific Research (F.R.SFNRS)
	Florence Quist
	+32 25 04 93 51 51 or international@frs-fnrs.be or florence.quist@frs-fnrs.be
Canada	Canadian Institutes of Health Research (CIHR)
	David Coffey
	david.coffey@cihr-irsc.gc.ca
Czech Republic	Ministry of Education, Youth and Sports (MSMT)
	Daniel Hanšpach
	+420 23 48 11 360 or Daniel.Hanspach@msmt.cz
Denmark	Innovation Fund Denmark (IFD)
	Martin Kyvsgaard
	+45 61905081 or martin.kyvsgaard@innofond.dk
Finland	Academy of Finland (AKA)
	Päivi Kolu
	+358 29 53 35 028 or paivi.kolu@aka.fi
France	French National Research Agency (ANR)
	Sheyla Meija-Gervacio
	+33 178 09 80 14 or sheyla.mejia@agencerecherche.fr
Germany	Federal Ministry of Education and Research, supported by DLR-PT
	Sabrina Voß, Vera Mönter-Telgen
	+49 228 38 21 2111 or jpnd@dlr.de
Hungary	National Research, Development and Innovation Office (NKFIH)
	Klara Horvath
	+36 18 96 37 48 or klara.horvath@nkfih.gov.hu
Israel	Ministry of Health (CSO-MOH)
	Irit Allon
	+972 25 08 21 67 or irit.allon@moh.health.gov.il
	Ministry of Health (MOH-IT)
Italy	Giselda Scalera

	research.EU.dgric@sanita.it Maria Josefina Ruiz Alvarez +39 06 59 94 32 14 Maria Grazia Mancini +39 06 59 94 32 15
Latvia	State Education Development Agency (VIAA) Maija Bundule +371 67 78 54 23 or Maija.Bundule@viaa.gov.lv Uldis Berkis +371 29 47 23 49 or Uldis.Berkis@viaa.gov.lv From 01.01.2022: Latvian Council of Science will take over the ERA-NETs from VIAA Arnis Kokorevics +371 29 473 753 or arnis.kokorevics@lzp.gov.lv
Luxembourg	National Research Fund (FNR) Sean Sapcariu +352 26 19 25 33 or sean.sapcariu@fnr.lu
Netherlands	Netherlands Organisation for Health Research and Development (ZonMw) Marjolein Scholten +31 70 34 95 335 or Scholten@zonmw.nl
Norway	Research Council of Norway (RCN) Alexandra Bjørk- Skaflestad +47 22 03 72 24 or alb@forskningsradet.no
Poland	National Science Centre (NCN) Alicja Dyląg +48 532 086 494 or alicja.dylag@ncn.gov.pl Jadwiga Spyrka jadwiga.spyrka@ncn.gov.pl
Slovakia	Ministry of Education, Science, Research and Sport of the Slovak Republic (MESR) Ms. Lubica Pitlova +4212 59374741 or lubica.pitlova@minedu.sk
Spain	National Institute of Health Carlos III (ISCIII) Candida Sanchez Barco +34 9182 22063 or cbarco@isciii.es
Switzerland	Swiss National Science Foundation (SNSF) Francis Parlange +41 31 308 23 85 or francis.parlange@snf.ch Carolin von Schoultz +41 31 308 23 25 or carolin.vonschoultz@snf.ch
Turkey	Scientific and Technological Research Council of Turkey (TÜBİTAK) Gaye Cetinkaya Campari +90 31 22 98 17 91 or gaye.cetinkaya@tubitak.gov.tr or jpnd@tubitak.gov.tr