

JPco-fuND-2 Call for Proposals:

"Multinational research projects on Personalised Medicine for Neurodegenerative Diseases"

Submission deadline for pre-proposals:

March 12 2019, 15:00h C.E.T.

For further information, please visit us on the web

http://www.jpnd.eu/

or contact the JPND Joint Call Secretariat:

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1. INTRODUCTION

Neurodegenerative diseases are debilitating and largely untreatable conditions that are strongly linked with age. Worldwide, there are estimated to be 47 million people suffering from Alzheimer's disease and related disorders, the most common class 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 in the range of €105-160 billion per year across the European Union and about US\$ one trillion worldwide. 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) was established in order 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 disease. The JPND Research and Innovation Strategy, published in 2012 and refreshed in 2018, identifies research priorities and provides a framework for future investment.

Neurodegenerative diseases are characterised by a large variability in their origins, mechanisms and clinical expression. When searching for a medical solution, e.g. a treatment or an optimised approach for care, this large variability constitutes a major hurdle if not controlled. Indeed a treatment addressing one disease pathway may not be useful for all patients experiencing the relevant symptoms. Thus, one of the greatest challenges for treating neurodegenerative diseases is the deciphering of this variability.

According to the Horizon 2020 advisory group, Personalised Medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging and lifestyle data) for tailoring the right (individual) therapeutic strategy, for determining the predisposition to disease and/or for delivering timely and targeted prevention. Although approaches that focus on tailoring to individuals are also included under this call, the research field related to neurodegenerative diseases may not be at the stage where there can be realistic personalised approaches according to the above definition. Instead, the field is at the stage of Precision Medicine. A workshop conducted by JPND in 2017 defined Precision medicine as relating to stratification of subgroups of populations for diagnosis, treatment or prevention, which may result in the targeting of specific elements responsible for pathology in a given individual at a particular point in time. This includes the use of tools for stratification based on risk of disease, or response to treatment, using

diagnostic tests or techniques. It is an emerging approach for disease prevention, diagnosis and treatment that takes into account individual variability in genes, biological/molecular characteristics together with environmental and lifestyle factors. The concept provides the opportunity to better understand the complex mechanisms underlying a disease and seeks to apply optimally targeted and timed therapies to the precise molecular causes in well-defined or stratified patient populations. Thus, the call text will use the terminology of Precision Medicine.

With a view to promoting research aimed at changing the trajectory of these debilitating diseases through the development of Precision Medicine approaches, this joint transnational co-funded call is launched in partnership with the European Commission under the ERA-NET Co-fund scheme. Under Horizon 2020, the European Commission is scaling up the implementation of the JPND research strategy by providing additional funding to 'top up' the funding that is being made available through national/regional funding organisations. The goal of the partners is to maximise the number of high quality transnational scientific projects that can be funded through this call. These projects must demonstrate clear scientific added value from working across national borders.

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 Research Foundation Flanders (FWO)
- Belgium, The Fund for Scientific Research (FRS-FNRS)
- Canada, Canadian Institutes of Health Research (CIHR)
- Czech Republic, Ministry of Education, Youth and Sports (MEYS)
- Denmark, Innovation Fund Denmark (IFD)
- Denmark, VELUX Foundation (VELUX)
- 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)
- Ireland, Health Research Board (HRB)
- Israel, Ministry of Health (CSO-MOH)
- Italy, Ministry of Health (IT-MOH)
- Italy, Ministry of Education, Universities and Research (MIUR)
- Latvia, State Education Development Agency (VIAA)
- Luxembourg, National Research Fund (FNR)
- Netherlands, The Netherlands Organisation for Health Research and Development (ZonMw)
- Norway, The Research Council of Norway (RCN)

- Poland, National Science Centre (NCN)
- Portugal, Foundation for Science and Technology (FCT)
- Portugal, Regional Fund for Science and Technology of the Azores (FRCT)
- Romania, Ministry of Research and Innovation (MCI)
- Slovenia, Ministry of Education, Science and Sport (MIZS)
- Spain, National Institute of Health Carlos III (ISCIII)
- Sweden, Swedish Research Council (SRC)
- Turkey, Scientific and Technological Research Council of Turkey (TUBITAK)
- United Kingdom, United Kingdom Research and Innovation Medical Research Council (UKRI MRC)
- * Final decision on participation pending

2. AIM OF THE CALL

The aim of the call is to establish a number of ambitious, innovative, multi-national and multi-disciplinary collaborative research projects that will add value to the respective research areas.

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 adequately to 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. Reasons must be given if such an approach is not taken.

Proposals can apply when focussing 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 will have to include one or several of the research areas listed below:

Diagnosis, by integrating the validation and harmonised use of biomarkers, deep analysis of data from noninvasive imaging (with associated development of interoperable methodologies and protocols), high throughput "omics" approaches and big data analyses, recognising the critical importance of promoting reproducibility through data standardisation and quality control of data and biomarker stability at all stages of work. Where appropriate,

studies should include head to head comparisons and benchmarking of assays/methods. This will prepare the ground for pooling and sharing of data as well as cross-initiative data exchange, e.g. by establishing guidelines for data access and management or by establishing or refining core common formats and requirements for data. This will allow a better classification and segregation of disease diagnoses for more targeted care and will open up new insights for future clinical studies.

- Prevention, through the identification of predictive, translatable biomarkers to study the efficacy of novel treatments and to stratify populations for preventive interventions. Biomarkers that integrate real-life measures based on digital technology and that permit the stratification of risk by gender or ethnicity are welcomed. This approach will allow the assessment of the impact of co-morbidities (vascular disease, inflammation, and metabolic disorders), the appreciation of cross-disease commonalities, and the identification of people who would benefit from preventive strategies and treatments. Integrating digital technologies within research on neurodegenerative diseases, establishing better connections between long term observational cohorts and clinical trials as well as an enhanced understanding and modelling of healthy ageing are crucial. For this, also existing longitudinal cohort studies (e.g. studies set up initially for cardiovascular or metabolic research purposes) that have data sets that are relevant for the study of neurodegenerative disease should be made use of. The aim is to postpone the onset and slow the progression of these diseases, thus reducing de facto their prevalence and population impact.
- Care, based upon an evidence-based approach to social and health care systems, addressing all aspects of these chronic diseases including any comorbidity, spanning care provision, diagnostic disclosure, palliative care and health economic studies to guide improved care in a more efficient way. Through enhancing understanding of the large variability in the origins, mechanisms and clinical expression at the patient level, Precision Medicine opens up new and important opportunities for optimising care outcomes. Maximising these opportunities will require the introduction of new medical models that successfully incorporate molecular profiling, medical imaging, lifestyle data and other data. Better use of real world data and establishing common standards for the content and quality of this data type is urgently needed, as well as improved approaches towards including patients and other members of the public and health & social care elements. The communication gap between the neurodegenerative research community and healthcare providers as well as with patients, needs to be bridged.

Proposals should have novel, ambitious aims and ideas combined with well-structured work plans and clearly defined objectives deliverable within three years. Where proposals are complementary to work funded or applied for under other initiatives, this should be indicated, so that it is clear how any work supported by JPND will add value. Each consortium should have the critical mass to achieve the identified scientific goals and the proposals should specify the added value 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 medical as well as health and social care for people suffering from neurodegenerative diseases should be explicitly stated.

Ethically appropriate access to and synergistic usage of resources, e.g. data from patients and health care providers or existing population and disease-specific cohorts and registries, is expected. To increase added value, data, tools and resources being generated within the research projects should be made widely available in the public domain, taking into account 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 subjects.

Proposals should address socio-economic factors, gender-related research questions and comorbidities, where appropriate. Consortia should incorporate these factors when formulating their research hypotheses, aims and work plans. Cross-cultural issues and diversity, should be taken into account, particularly when developing and implementing instruments and intervention strategies.

Training of young researchers and mobility (e.g., exchanges of research assistants or for students and postdoctoral researchers to learn new techniques) within the consortia are encouraged for inclusion within proposals, where this can be specifically justified in terms of the training opportunities provided to the individual and the needs of the field. Please note that there may be restrictions according to national regulations.

To have an impact at European and partner country levels, it is expected that all proposals will link activities across laboratories/clinics/care settings within JPND member countries. Proposals are encouraged to import expertise from areas outside of neurodegeneration research, e. g. from primary care or for incorporating computational approaches, which can bring innovation to the approach to be pursued. Proposals should make clear what added value will be provided by this type of multidisciplinary collaboration.

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 (www.esfri.eu).

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 will not be allowed to submit or participate in proposals within this call.

- The Joint Call Secretariat is led by DLR-PT, Health Research, Germany. The Joint Call Secretariat is responsible for the management of the call and is a point of contact for both applicants and partner organisations.
- The Call Steering Committee is composed of representatives from each participating funding organisation. All decisions concerning the call procedures will be taken by the Call Steering Committee. Based on scientific recommendations from the Peer Review Panel and budget considerations it will confirm the list of consortia that will be invited to submit full proposals

and also confirm final funding recommendations to the national/regional funding organisations.

• The Peer Review Panel is composed of internationally recognised scientific experts from different fields of research related to the topics of the call. The Peer Review Panel is responsible for the scientific evaluation of proposals at both the pre- and full proposal 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 institutes, hospitals and other health and social care settings, as well as commercial companies, in particular small and medium-size enterprises (SMEs). Also collaborations with companies from outside the traditional healthcare sector (e.g. computing, artificial intelligence) are welcomed. With regard to the research setting and collaborations with companies, specific regulations of individual funding organisations must be taken into account 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 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 that are participating in this call (see section one). However, if the proposal involves at least one regular partner from an underrepresented European country (Czech Republic, Hungary, Latvia, Poland, Romania, Slovenia, Turkey), the maximum number of regular partners is extended to seven partners. 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 that are 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, if not, how they plan to obtain funding in advance of the project start.

Whilst proposals are to be submitted jointly by research groups from different countries, individual regular partners 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 will 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 specific information sheets. Nevertheless, applicants are strongly advised to contact their corresponding funding organisation to confirm 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 without further review.

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 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 are requesting 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 15:00h C.E.T. on March 12th, 2019, via the JPND electronic submission system. No other means of submission will be accepted. A pre-proposal template is available at the JPND website. Adhering 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 underrepresented European country (Czech Republic, Hungary, Latvia, Poland, Romania, Slovenia, Turkey), and where such inclusion can be scientifically justified.
- 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). Any
 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 15:00h C.E.S.T. on June 25th, 2019, 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

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:

Excellence

including the level of innovation and originality of the proposal along with novel methodology, international competitiveness of participating research groups in the field(s) of the proposal (expertise relevant for the field, expertise of the research groups) and their appropriate mix; quality of collaborative interaction between the groups for the proposed work, level of training/knowledge exchange between research organisations, and added value, on both scientific and transnational levels, of the research consortium.

Impact

deliverable outcomes in the short, medium and long term and likely impact - potential of the expected results for future clinical and other health relevant applications

Quality and efficiency of the implementation

including feasibility of the project such as adequacy of project work plan, time schedule, availability of well characterised patient groups or samples, quality and linkages of data within and between countries, budgetary and other resources.

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 check for compliance with their funding regulations. Pre-proposals not meeting the formal or eligibility criteria will be rejected.

Pre-proposals passing the formal and 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 and the decision of the Call Steering Committee.

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 available funds, the Call Steering Committee will propose a package of awards for a final decision by the respective funding organisations, subject to budgetary considerations. The joint selection list of projects to be funded will be submitted to the EC together with other relevant information.

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.

7. FUNDING REGULATIONS, RESPONSIBILITIES AND REPORTING REQUIREMENTS

Funding decisions will be made on a national basis by the relevant funding organisations and administered according to their terms and conditions, taking into account all other applicable regulations and legal frameworks, including the legislation of the European Commission.

A consortium agreement signed by all regular partners of the proposal is a requirement for the liberation of funds. It will specify as a minimum: decision making, monitoring, reporting, intellectual property rights management and sharing 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.

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 internally be used for monitoring and evaluation purposes to assess the progress of the implementation of JPNDs' Research and Innovation Strategy. Each group leader individually will also be the contact person for the relevant funding organisations. It may be necessary for group leaders to submit additional reports to their funding organisation, if 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. BUDGET RESTRICTIONS

Country	Funding organisation	Budget limit *
Australia	National Health and Medical Research Council	none
Belgium	Research Foundation Flanders	350.000 €
	The Fund for Scientific Research	200.000 €
Canada	Canadian Institutes of Health Research	none
Czech Republic	Ministry of Education, Youth and Sports	none
Denmark	Innovation Fund Denmark	500.000€
	VELUX Foundations	none
Finland	Academy of Finland	600.000 €
France	French National Research Agency	200 000 € per partner 250 000 € per coordinator
Germany	Federal Ministry of Education and Research	600.000€
Hungary	National Research, Development and Innovation Office	none
Ireland	Health Research Board	none
Israel	Ministry of Health	140.000 € per project 200.000 € per coordinator
	Ministry of Health	250.000 €
Italy	Ministry of Education, Universities and Research	150.000 €
Latvia	State Education Development Agency	210.000 €
Luxembourg	National Research Fund	500.000€
Netherlands	Netherlands Organisation for Health Research and Dev.	none
Norway	Research Council of Norway	700.000 €
Poland	National Science Centre	none
Portugal	Foundation for Science and Technology	100.000 € (partner) 200.000 € (coordinator)
	Regional Fund for Science and Technology of the Azores	100.000€
Romania	Ministry of Research and Innovation	200.000 € (per partner) 250.000 € (coordinator)
Slovenia	Ministry of Education, Science and Sport	210.000€
Spain	National Institute of Health Carlos III	100.000 € (per partner) 175.000 € (coordinator)
Sweden	Swedish Research Council	Minimum 1,2 M SEK; maximum 4,5 M SEK
Turkey	Scientific and Technological Research Council of Turkey	720.000 TL (+ overhead)
United Kingdom	United Kingdom Research and Innovation Medical Research Council	none

^{*}If not specified otherwise: The indicated budget limit relates to the whole proposal. If more than one group requests budget from the same funding organisation, the total amount of budget requested by these groups must not exceed the indicated limit. For further national requirements please see the country specific information sheets.

9. CONTACT DETAILS

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

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