



EU Joint Programming Initiative
A Healthy Diet for a Healthy Life (JPI HDHL)

***Joint Action 2: Biomarkers in Nutrition and
Health (BioNH)***

Call for Submission of Proposals

Submission deadline 10th June 2014 5p.m CEST

<http://www.healthydietforhealthylife.eu/index.php/bionh>

Call Secretariat

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JPI HDHL BioNH Call for submission of Proposals

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1. Introduction

The Joint Programming Initiative is a European process, by which Member States engage on a variable geometry basis in defining, developing and implementing an agreed vision with common strategic research agenda (SRA) to address major societal challenges that no individual Member State is capable of handling independently. In the context of the JPI “A Healthy Diet for a Healthy Life” (JPI HDHL), trans-disciplinary expertise, knowledge, facilities and approaches ranging from blue sky research to large population studies and controlled trials are needed to investigate the relationship between diet, exercise and health. In addition, there is a need to examine the influence of genotypes, individual genetic and epigenetic differences, dietary patterns and life styles, including their interactions and changes over the time, on health and disease susceptibility and morbidity. The JPI HDHL entails a voluntary partnership between Member States and Associated Countries of the European Union and aims to bring major benefits to this sector by:

2. *Helping to coordinate research programmes across Europe and reducing duplication of efforts;*
3. *Making it easier to address common challenges, developing suitable solutions with the same objective concerning food, nutrition and active life policy in the international arena while taking into consideration cultural diversities among countries;*
4. *Promoting scientific excellence through joint activities with common funding and peer-review processes to minimise fragmentation of research activities and to use public resources more efficiently and effectively improving the accountability and transparency of public research programmes;*
5. *Supporting cross-border collaboration and facilitating data pooling and their collection in a uniform and standardised way;*
6. *Sharing expertise scattered across countries or throughout Europe as a whole promoting creation of a critical mass, cross-border mobility and training to facilitate timely dissemination and translation of research results to inform public health practice and policy;*
7. *Increase the scientific, technological and innovative impacts of public investments in research by strengthening the coordination with other related policies through greater programme visibility and promotion of cross-border policy learning.*

1.1. Joint Action 2: Biomarkers in Nutrition and Health (BioNH)

In pillar two of the [strategic research agenda](#) (SRA) that the Management Board (MB) of the JPI HDHL has adopted, the establishment of an initiative for biomarkers in nutrition and health has been identified as a joint activity to be developed over the period 2012–2014. This joint activity will define a research strategy and launch research activities that address the nutritional and health needs of consumers in addition to addressing the needs of industry. The following research challenge has been outlined in the SRA:

- Define and harmonise the methodology necessary to prove the nutritional effects in the development of foods.

A biomarker may be defined as *“a characteristic that is objectively measured and evaluated as an indicator of any exposure, biological process or state of a biological system.”* Several national and international authorities have presented general concepts for identification of biomarkers in disease. However, clear recommendations on biomarkers in nutrition and health are lacking.

Biomarkers are important as surrogate measures in studies on nutrition and health, in particular when dietary intake is difficult to monitor objectively, or the ultimate health effect cannot be measured due to length of time it takes to establish and be measurable. Any biomarker needs careful validation. The Institute of Medicine recommended basing the evaluation process for biomarkers on three steps:

- Technical (analytical) validation as described, e.g. in ISO17025 for performance, including accuracy, precision, repeatability and other technical performance measures.
- Biological validation showing that the surrogate measure is highly predictive of the targeted health or disease endpoint. Data demonstrating the effects of interventions on the biomarker and outcomes are essential for providing support for the proposed use of the biomarker.
- Utilisation step: determines whether the analytical and biological validation provide sufficient support for the proposed use of the biomarker.

Biomarkers in nutrition and health may be classified in several ways and one of the most common classifications defines the nature of the endpoint covered by the biomarker:

- Biomarkers of intake/exposure (diet, food, food component, ingredient, contaminant or nutrient) or nutritional status;
- Biomarkers of effect (altered biological response, health status or disease risk);
- Biomarkers of individual susceptibility and inter- (and intra-)individual variation (genetic or phenotypic).

These three classes are not mutually exclusive and a biomarker may belong to more than one class. To monitor key biological processes which are important to human nutrition and health, new biomarkers or biomarker patterns are necessary. The biomarkers are, in turn, required in the process of substantiating Article 14 health claims through evaluation by the [European Food Safety Authority \(EFSA\)](#).

2. Scope of the BioNH

The main objective of the **Biomarkers in Nutrition and Health (BioNH)** call is to support interdisciplinary research and innovative approaches for the validation of biomarkers and the investigation of intake/exposure and nutritional status of biomarkers within this scientific area. This is a key step in the implementation of the JPI HDHL SRA. **BioNH aims to *define and harmonise the methodology necessary to prove the nutritional effects in the development of foods.***

The intake of foods, food ingredients and food contaminants in a population is a major challenge and questionnaire technology may lead to biased results. Dietary patterns may be even more

complicated. Intake/ exposure biomarkers covering a broad number of foods and food components could provide a more objective measure of actual intake and status, and will be an important adjunct to classical dietary data. However, few foods are covered by validated intake/exposure biomarkers. One of the main applications of dietary biomarkers is to use them as a reference measurement to assess the validity and accuracy of dietary assessment methodologies. The most important dietary biomarkers for this application are:

- Recovery dietary biomarkers: based on the metabolic balance between intake and excretion over a fixed period of time;
- Predictive dietary biomarkers: to assess the degree of measurement errors in dietary assessment methods;
- Concentration and replacement dietary biomarkers: For comparison with estimated dietary intakes and estimated diet–disease risk associations.

The proposals could concern other dietary biomarkers in case they can assess the validity and accuracy of dietary assessment methodologies.

The joint action cannot stand alone and will require a close alignment with the joint actions “DEDIPAC” and the “ENPADASI” (<http://www.healthydietforhealthylife.eu/>). It is envisaged that appropriate horizontal initiatives will be put in place to allow for the rapid dissemination of knowledge between each of the actions at the end of 2014.

3. Participating Member States

The funding organisations that have agreed to fund this joint call for multinational research projects in this scientific area, with a view to adding value to their existing nationally funded activities, are listed below.

Country	Partner Contribution (€)
Austria	200.000
Belgium	400.000 ^a
Denmark	500.000
France	1.000.000
Germany	500.000
Ireland	500.000
Italy	300.000 + in-kind
Netherlands	500.000 + in-kind
Norway	500.000
Poland	250.000
Spain	300.000 (MINECO) + In-Kind (ISCIII)
Switzerland	500.000
Total	5.450.000 (+in Kind)

^aMax. 100.000 top-up funding: 10.000–25.000/existing FWO-funded project (4–10 projects). Research Foundation–Flanders (FWO) intends to integrate existing FWO projects into the consortia of the JPI Climate call through this top-up.

The call will be coordinated centrally by the Joint Action Secretariat (JAS), ZonMw. Contact details are:

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4. Eligibility Criteria

Joint transnational research proposals may be submitted by research groups working in universities (or other higher education institutions), non-university public research institutes, hospitals and other health care settings, as well as commercial companies, in particular small and medium-size enterprises. The eligibility of the afore-mentioned institutions, together with details of eligible costs (personnel, material, consumables, equipment, travel expenses, etc.), are subject to the individual administrative requirements of individual funding organisations and may therefore vary. Applicants will need to obtain clarification from the individual funding agencies (see National regulations in ANNEX 1 below).

Each proposal must involve a minimum of three research groups (Principal investigators) applying for funding. Only transnational projects will be funded: each consortium must involve groups from at least three different countries of the funding organisations participating in this call (see list above). Research groups from countries that are not partners in the JPI HDHL joint transnational call may participate in projects if they are able to secure their own funding. They must state clearly in the proposal if these funds are already secured or, if not, how they plan to obtain funding in advance of the project start. However, the majority of research groups in a consortium and the coordinator must be from countries participating in the call.

Each consortium should have the critical mass to achieve ambitious scientific goals and the proposals should **clearly demonstrate added value** from working together. The project coordinator will be responsible for its internal scientific management and will represent the consortium externally.

Consortia are strongly encouraged to contribute information on data, tools and bioresources generated by their research to the public domain where it should be made widely available. Access must be provided to other bona fide research groups, with the necessary arrangements in place.

Whilst applications will be submitted jointly by groups from different countries, individual research groups will be funded by the individual JPI HDHL funding organisation(s) respective of their country/region. Eligibility is the matter of individual partner organisations ([ANNEX 1](#)).

Please note: Inclusion of a non-eligible partner (i.e., an applicant applying for funding, although this partner cannot be funded by the funding agency in its country for administrative reasons according to country specific regulations) in a proposal may result in the rejection of the entire proposal without further review. Applicants are therefore strongly advised to contact their national/regional funding organisation and confirm eligibility (if any doubts) before participating in an application.

4.1. Financial and Legal Modalities

Projects can be funded for a period of up to three years. Single research groups will be funded according to national regulations. Eligible costs may vary according to the corresponding funding organisations regulations. Each group is subject to the rules and regulations of its respective national/regional funding organisation.

All project partners are advised to follow the “Quick guide for dissemination of the JPI research projects results”, elaborated in the framework of the JPI-HDHL. This document is available at the [JPI-HDHL website](#).

A project consortium agreement must be signed by all project partners in each project consortium before the commencement of the project. The project consortium agreement will specify at least decision making, monitoring, reporting, intellectual property rights (IPR) and sharing of data and resources as appropriate. The exact content of a consortium agreement will vary according to the nature and scope of the project in question. It is therefore recommended that each project partner spend adequate time assessing the construction of the agreement in order to work through and understand the implications of the terms chosen, as regards their particular participation in the project. Further guidance and model consortium agreements can be found at the [European IPR Helpdesk](#) and [DESCA](#) websites.

5. Application Procedure

The Call process will be carried out online on the [HDHL-JPI Submission Tool](#). A Proposal Template is available in ANNEX 2. The submission of an application to the Call shall be construed as consent by the applicant(s) to participate in the peer-review process.

5.1. Proposal Review Procedure and Criteria

1. Formal check of proposals:

The JAS will check the proposals to ensure that they meet the call’s formal conditions (date of submission; number of participating countries and groups; inclusion of all necessary information in English; adherence to the proposal template). Proposals not meeting the formal conditions will be rejected. However, in case of only minor formal problems, the applicants may resolve these issues within a time frame of 24 hours. The project coordinator will be contacted by the Next, the

proposals meeting the formal conditions will be checked by the national/regional funding organisations for compliance with their respective regulations. Proposals passing both these checks will be forwarded to peer-review.

2. Peer Review Stage 1 (Postal Review):

In accordance with the peer-review process used to evaluate proposals submitted to the JPI HDHL, all eligible proposals will be forwarded to international experts for evaluation. Each proposal will receive at least three reviews from peers with expertise in the substantive area of the proposed research.

3. Peer Review Stage 2 (Panel Review):

Panels of high-level independent researchers will be convened to assess the inputs of the postal peer reviews and the overall merit and priority of applications. In addition to briefing material, panel members will receive the original application and the anonymous postal reviews. Panels will be invited to rank proposals and to make recommendations for an application to be given consideration for funding by the Call Steering Committee (CSC). When ranking proposals, panel members will give due regard to applicant's career stage and budget requested.

5.2. Further Information

For further details, please refer to the submission form ("Proposal template") available online and in ANNEX 2 and the guidelines for the Electronic Submission system. If you need additional information, please contact the JAS or your national/regional funding organisations representative (see [ANNEX 1](#) for contact details).

6. Evaluation

Before the peer review evaluation the submitted proposals have to pass through an eligibility check for the coherence with both the general BioNH criteria and the specific national eligibility rules (stated in ANNEX 1).

The following criteria will be used for the peer review evaluation of proposals submitted:

- Scientific quality of the proposal and quality of the transnational project
 - Sound concept, and quality of objectives
 - Progress beyond the state-of-the-art
 - Quality and effectiveness of the scientific and technological methodology and associated work plan
 - Relevance to the concept of BioNH
- Quality and relevance of individual scientists and research groups
 - Quality of the consortium as a whole (including complementarity, balance) and added value achieved through transnational collaboration

- Quality and efficiency of the implementation and management of resources made available to the collaborative projects
 - Track record in leadership and research management
 - Appropriateness, quality and efficiency of the management structure and procedures, its organisation and coordination, including the management and sharing of data
 - Quality and relevant experience of the individual participants, including interdisciplinarity
 - Appropriate allocation and justification of the resources to be committed
 - Effective use of budget
 - Project feasibility and timeliness
- Potential impact
 - Achieve critical mass and ensure better use of limited resources in fields of mutual interests
 - Share good practices in implementing research programme, promote transnational collaborations and new knowledge generation and innovation
 - When possible, mobilise SMEs in the transnational projects to enhance innovation
 - Establish a network of research activities carried out at national and regional research programmes
 - Contribute to the advancement of knowledge and innovation approaches and socio-economic aspects of BioNH
 - Appropriateness of measures for spreading excellence through engagement with stakeholders and the public at large
 - Exploitation and dissemination of results and knowledge
 - Management of intellectual property

The proposals will be reviewed primarily for scientific excellence; however, it will be essential that the applications address each criterion fully. All applications will be graded A, B & C, and those proposals deemed fundable will be ranked by the Review Panel. Of note, only those applications with an A grade will be considered for funding by the CSC. All applicants will receive feedback on their proposals.

7. Project funding

Projects can be funded for a period of up to three years and according to funding organisations' regulations. Funding is expected to start in Q4 of 2014.

- The funding of a successful project is provided based on the virtual common pot scheme, meaning that each funding organisation will fund its own national partner(s) within the project (funding of project partners is provided by the participating national programmes according to National Regulations). However, some funding organisations may be able to fund foreign teams, e.g. via subcontracting. More information is available in the National Regulations (ANNEX 1).

- The budget for individual project proposals is not restricted; it must meet the project goals and must follow the national/organisational funding and not exceed the cash limits for each partner (see partner country contributions).
- The indicative total available budget amounts to € 5.5M.
- Successful consortia should negotiate and sign a Consortium Agreement before commencement of the project. This should address matters such as the regulation of intellectual property rights and actions to be taken in the event of unsatisfactory performance by one or more partners. In some countries, such an agreement might be required for release of the funds. Applicants have to obey national/organisational regulations regarding this issue.
- Project coordinators of a consortium having submitted an eligible proposal will be informed about the funding recommendation of the CSC regarding their proposal. Project coordinators are responsible to communicate this information to the project partners.
- After a positive funding recommendation, the project partners must directly contact their national/regional funder in order to start the contract negotiation and accomplish the remaining steps until the research project can start.

8. Responsibilities and Reporting Requirements

Each project must nominate a project coordinator, who represents the consortium externally and is responsible for all communications with the JPI HDHL (such as monitoring, reporting, intellectual property rights (IPR) issues and sharing of data and resources). Within a joint proposal, each group leader will be the contact person for the relevant national/regional funding organisation.

The project coordinator will be required to submit a brief annual scientific progress report on the joint project, on behalf of the project consortium, to the Secretariat in January of each year. The project coordinator will be required to submit a final scientific progress report on the joint project, on behalf of the project consortium, to the Secretariat within a period of 3 months after the project ends. It may also be necessary for group leaders and/or project participants to submit reports individually to their funding organisation if required by national/regional regulations.

To guarantee that all the selected projects/activities will effectively contribute the establishment of BioNH in the biomarkers field, the coordinators of the awarded projects must be available to participate in joint meetings in order to:

- exchange project results;
- develop a joint strategy to coordinate and facilitate integration of the planned activities across the different awarded projects into JPI HDHL BioNH;
- ensure that results arising are communicated promptly and regularly across the BioNH members and to the JAS, CSC and MB;
- monitor the progress of the activities and coordinate the exploitation of results;
- interface and build collaborations with the other JPI HDHL Joint Actions (ENPADASI and DEDIPAC) and relevant organisations within Europe and worldwide, providing the means to build and strengthen the research communities in the area of Biomarkers.

This activity will be facilitated by the JAS.

Funding recipients must ensure that all outcomes (publications, etc.) of transnational JPI HDHL projects include a proper acknowledgement of JPI HDHL and the respective funding partner organisations. Researchers funded under the umbrella of JPI HDHL are requested to adhere to the JPI HDHL dissemination guidelines, which are briefly outlined below.

- As a general principle, for any research project or activity supported under JPI HDHL, participants are encouraged to take appropriate measures to engage with the public and the media about the project and to highlight the financial support from the relevant funding organisation in the JPI HDHL initiative.
- When referencing JPI HDHL for the first time within a report, article or other document, please use 'EU Joint Programming Initiative – A Healthy Diet for a Healthy Life (JPI HDHL)', and not JPI HDHL. Please also include a link to the JPI HDHL website: <http://www.healthydietforhealthylife.eu/>
- JPI HDHL should be referenced and acknowledged appropriately on any scientific report or publication as part of a JPI HDHL-supported project. The acknowledgement should reference the support provided to the project by JPI HDHL and the appropriate national/regional funding organisations.
- JPI HDHL-supported projects should always display the JPI HDHL logo and the JPI HDHL acknowledgement on any project-specific promotional material including event programmes, invitations, press releases, reports, presentations and external websites.

9. Ethical Issues

Research supported by the JPI HDHL must respect fundamental ethical principles. Applicants must ensure that the proposed research **respects all national rules and procedures**. It is the responsibility of the applicant to identify if their proposed research requires ethical approval. Where ethical approval is required, applicants must inform their NCP and may be requested to provide further detail. Ethical approval must be obtained from the relevant national or local ethics committee prior to the start of the project.

10. Confidentiality

The JPI HDHL JAS takes all reasonable steps to ensure that information provided in the application is treated as confidential subject to submission to the members of its committees and merit review and to any obligations under law.

11. Acronyms

CSC	Call Steering Committee
JAS	Joint Action Secretariat
JPI	EU Joint Programming Initiative
HDHL	A Healthy Diet for a Healthy Life



JPI HDHL BioNH Call for submission of Proposals

JTC	Joint Transnational Call
MB	Management Board of JPI HDHL
PRP	Peer Review Panel
SAB	Scientific Advisory Board of JPI HDHL