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FRANCE 2030

Call for proposals

"UNIVERSITY HOSPITAL HEALTH RESEARCH (RHU)"

Closing date: 13/04/2023 at 11:00 am (CEST)

Consultation page for the call for proposals: http://anr.fr/RHU-2023

Summary

This call for proposals meets the objectives set out in the university hospital health research project. It aims to fund innovative and large-scale health research projects. The projects are expected to be translational. Therefore, they must offer major potential for rapid transfer to health care, industrial production, or the implementation of public policies. They must be coordinated by university hospital teams within a healthcare institution (University Hospitals, Cancer Treatment Centres, etc.) and include one or more enterprises with a view to developing healthcare solutions (medical devices, therapeutic products, diagnostic tools, etc.). Where relevant, the proposed projects may involve one or more local authorities. Proposals may be attached to projects funded under the France 2030 plan, but they must show a significant scientific or medical gain, thematic coherence and new ambition justifying such funding. In all cases, the university hospital health research project is intended to support research projects and not structures.

Keywords

Translational health research, clinical research, patient cohorts, personalised medicine, health technology, therapeutic, diagnostic, public-private partnerships, technology transfer, use, medicine, advanced therapy medicinal product, biotherapies, antibiotic resistance, medical devices, biomarkers, technology platforms, bioinformatics, pathophysiology, systems biology, etc.

Important dates

Closing date of the call for proposals

The submission dossier must be electronically submitted, including the documents signed by the legal representative of each partner before:

13 April 2023 at 11:00 am (CEST)

at:
https://france2030.agencerecherche.fr/RHU-V6/

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Please read carefully and thoroughly this document and the instructions available on the submission website:

https://france2030.agencerecherche.fr/RHU-V6

For any question regarding the AAP: RHU@agencerecherche.fr

Summary

1. Background and objectives of the call for proposals

1.1. Background

a. General background

The *university hospital health research* project is supporting a significant restructuring of heath research teams. Under the first Investments for the Future Programme (included in the France 2030 plan) in 2011-2012, this effort resulted in the "University Hospital Institutes" call, which selected 6 A-rated projects (IHU)[1], 6 B-rated projects (PHUB) and two Oncology Research University Hospitals (PHUC)[2]. Within the framework of the PIA3, a new IHU call for proposals helped fund 1 IHUA and 3 IHUB projects. The most recent IHU 3 call for proposals closed on 07 November 2023. These projects actively involve fundamental research, translational health research, clinical research, training, care and valorization in a specific thematic area (cardiology, neuroscience, metabolism, rare diseases, infectious diseases, health technology, oncology, haematology, immunology, transplantation, etc.). This structuring effort has been topped up by the creation of new entities recognised under a tripartite agreement between a University Hospital Center (CHU), a university and INSERM (French National Institute for Health and Medical Research) or any other institution who is a member of the AVIESAN alliance: University Hospital Departments (DHU) and University Hospital Federations (FHU), which today extends throughout France. The first two RHU waves were only intended for DHU/FHU project coordinators. The third, fourth and fifth waves, like this one, were opened to any university hospital team.

Through this sixth RHU call for proposals, the French State furthers its contribution to the structuring of health research teams. Indeed, the RHU project aims to create an ecosystem, by encouraging innovation and supporting university hospital health research, to establish a sustainable and fruitful partnership between academic and industrial teams. It also aims to promote innovation transfer into standard medical practice. Previous editions of the RHU call for proposals confirmed that French research can foster large-scale translational research projects of top quality, actively involving from research to care activities, with the support of industrial partners.

The candidates applying to this sixth RHU call for proposals must provide recognised expertise in pre-clinical research, pathophysiology, creation and study of cellular or animal model-based systems, or additional research methods (organoid, in silico systems, etc.), identification and validation of therapeutic targets and biomarkers. High-level skills are also required to establish and exploit well-documented and highly stratified patient cohorts associated with biological resource centres and readily available for clinical trials. Projects must be coordinated by teams known for their excellent methodological approaches and conducting clinical trials. They must be provided with hospital structures specifically intended for research and have easy access to high-performance technology platforms for biology and/or medical imaging to ensure the production of quality data backed by standardised procedures. In addition, they will also require information systems ensuring that the data collected is traceable and interoperable between the various participating centres. Finally, they will provide a single window for industrial partners to ensure the rapid transfer of scientific innovations to care practices.

1.2. Objectives of the call for proposals

The *university hospital health research* project aims to support translational health research or clinical research projects, which may rely on fundamental research in biology, epidemiology,

[1] http://www.agence-nationale-recherche.fr/investissementsdavenir/documents/ihu-selection-2010.pdf
[2] http://www.agence-nationale-recherche.fr/investissementsdavenir/documents/2011/phuc-selection-2011.pdf

social sciences or health economics, and extend them to improve patient care, understanding of diseases, more effective and better-tolerated treatments, or improving the performance of care systems.

The projects presented may cover the development of medical devices, biomarkers for therapeutic or diagnostic purposes, biology and technology platforms, bioinformatics or systems biology, software or connected objects. Projects in personalised medicine and innovative therapies, incorporating the use of connected health objects for the general public, or offering to experiment new therapeutic care-taking protocols or procedures, may be submitted.

The proposed research must seek a socio-economic impact, notably through the improvement of medical practices or healthcare systems, or lower healthcare costs. Projects must include an objective to use and/or transfer technology and attract a significant number of projects from private partnerships. Proposals must show a partnership-based research dynamic in health and social sciences, and thus better integrate research, education and healthcare around significant health challenges.

Large-scale research projects with major potential for transfer to industry and/or society are expected. Selected projects may benefit from €4 to 10 million funding and a 5-year completion date. Only new original projects with no prior ANR funding will be considered. The leadership provided by University Hospitals aims to ensure that health research is structured around themes of excellence and that structures are decompartmentalised (public institutions/private enterprises/local authorities). The inclusion of enterprises and, where relevant, local authorities, will ensure that the projects supported provide an economic and social return. Applicants should demonstrate, locally, regionally, nationally and internationally, the strategic and structuring role they play in their university hospital environment and medical field. They must demonstrate their ability to conduct and sustain innovative and high-quality research that meets the best global standards. The attractiveness and dynamic of the projects submitted will be assessed, especially their overall cost, which must be more than three times the amount of aid applied for.

2. Projects expected

2.1. Scope

In all cases, the call aims to support research projects and not structures. Projects must be coordinated by a university hospital team. They may involve other relevant academic partners as long as they show scientific consistency and gain. The same applies to projects capitalising on other achievements from previous Investments for the Future Programmes and France 2030.

Projects must involve at least one enterprise with a view to developing healthcare solutions (medical devices, therapeutic products or prophylaxis, diagnostic tools, etc.). Where relevant, the projects may also involve one or more local authorities.

Recipients of previous RHU call for proposals may submit new projects. However, project coordinators must be released from any duties as Scientific and Technical Project Manager of a previous RHU project at the closing date of this call (AAP).

Applicants must include a translational research dynamic in each project: from bench to beside and bedside to bench. They must prove the existence of carefully phenotyped active patient files or cohorts, supported by biological resource centres, and consistent with the theme proposed and scientific project. Thus, clinicians and researchers will take part in all project activities.

Applicants must provide a critical mass of researchers and clinicians, and core resources, equipment and skills compatible with the ambitious nature of the project submitted. The purpose is to fund realistic projects over the duration of the contract.

2.2. Partners

The proposed projects must be partnership-based and involve at least one University Hospital Center or a healthcare institution, a research institution (university, research institution, etc. see definitions in §6.2) and an enterprise. Projects may be limited to a primary site or alternatively associated with satellite sites but must be scientifically and medically consistent.

Projects may involve foreign partners (in and outside Europe), but foreign partners will not receive ANR funding.

Only one partner, the Coordinating Institution identified in the project, will sign the agreement with the ANR. This leading institution will be in charge of managing funding and will sign, when appropriate pay-out contracts with its Partner Institutions.

2.3. Project missions and characteristics

In terms of research, the projects submitted must be able to intricately connect fundamental and clinical research, and therefore:

- develop research questions arising from care and explore their fundamental aspects,
- generate results to support the main hypothesis,
- confirm pre-clinical proofs of concept and perform their clinical assessment,
- extract new preventive, diagnostic or therapeutic strategies,
- ensure their medical, social and economic assessment,
- build partnerships with the private sector,
- create a consortium consisting of researchers able to attract funding from national, European or international research institutions,
- contribute to the research training for health professionals,
- promote the dissemination of discoveries and innovative practices to professionals, patients and the public.

2.4. Specific provisions

During the selection process, the ANR will ensure that partner enterprises are financially sound.

The benefit for patients, medical and socio-economic impacts, as well as ethical issues and concerns regarding the social acceptance of the proposed research will be considered.

3. Review of projects submitted

3.1. Selection process

Projects will be selected by an international and independent panel consisting of international peer reviewers (mostly foreign members or working abroad in scientific, medical and technological fields, and leading figures from the economic and industrial world), who collectively have proven experience in research, training, translational and clinical research, and care system assessment.

The main stages of the selection process are as follows:

- the ANR reviews the admissibility of the project, under the criteria listed in §3.2,
- the panel reviews the eligibility of the project, under the criteria listed in §3.3,
- the panel evaluates the project after having sought, if appropriate, external peer reviews[3] and, if it deems relevant, pre-selecting and auditioning pre-selected project coordinators,

[3] The panel appoints external peer reviewers responsible for delivering a written opinion on the projects.

- submission of a report provided by the panel to the French Education, Research and Innovation Ecosystems Committee (CEERI), including: i) a set of grades from A to E (or equivalent) for each project, under the criteria described in §3.4; ii) a reasoned list of projects that the panel does not consider for funding due to insufficient quality on at least one of the criteria or to its overall perception; iii) a reasoned list of projects that the panel is possibly considering for funding and, where relevant, subject to changes to be listed as recommendations,
- based on the report from the international panel, CEERI i) proposes to the French General Secretariat for Investment to appoint recipients and the corresponding amounts: the final decision rests with the Prime Minister; ii) asks the President and CEO of the ANR to sign ANR/recipient agreements specifying the mutual obligations of the parties; iii) ensures the payment of all or part of the grants under the provisions set out in the agreements, and after decision from the Prime Minister.

Persons taking part in the evaluation of the project, particularly the panel and peer reviewers called upon, must comply with the ANR's Code of Ethics and Scientific Integrity[4]. The ANR will ensure that privacy is respected and that there are no ties or conflicts of interests. If there is a duly noted breach, the ANR reserves the right to take any action it deems necessary to remedy the situation. The ANR's Code of Ethics and Scientific Integrity is available on its website. The operational and organisational arrangements of the international panel are specified in documents available on the ANR's website.

The composition of the evaluation panel will be posted on the call for proposals publication website upon completion of the selection process.

3.2. Acceptability criteria

IMPORTANT

The dossiers that do not meet the acceptability criteria will not be submitted to the panel and will in no way be eligible for funding.

1) The submission dossier must be filed in full on the ANR submission website before the call for proposals closing date and time. In addition, the financial and administrative document and commitment letters, signed and scanned, must be filed on the ANR submission website at the time and date indicated in page 3.
2) The scientific document must be under unprotected PDF format and not exceed 40 pages (minimum font size: 11). Any project whose scientific document exceeds 40 pages will automatically be deemed ineligible.

   The scientific document must be accompanied by:

   a) an appendix describing the preliminary data and publications supporting the proof of concept on which the project is based. 5 pages maximum (minimum font size: 11),

   b) an appendix focusing exclusively on the methodology of the pre-clinical and clinical trials proposed in the project and required for scientific assessment. Each clinical trial planned in the project must be described over one page maximum, all compiled in a single appendix (minimum font size: 11),

   c) an appendix describing the sharing principles regarding the project impacts (intellectual property, skills, turnover, etc.) between partners, over 3 pages maximum (minimum font-size: 11).
3) The project must not last more than 60 months.
4) The amount of aid applied for must be between €4 and 10 million.

[4] https://anr.fr/en/anrs-role-in-research/commitments/scientific-integrity/

5) The project must exert a significant funding leverage effect. The overall project cost must be at least three times higher than the amount of funding granted.
6) This call for proposals is only intended for partnership-based research projects. Therefore, the project must involve at least a partner from each of the following categories (see definitions in §6.2):
   - Research institution (university, national institution, etc.),
   - Healthcare institution,
   - Enterprise.
7) The Coordinating institution must be a University Hospital Center or research institution (university, national institution, scientific research foundation, etc.) (see definitions in §6.2).
8) The Scientific Project Manager must belong to a university hospital team. The ANR reserves the right to request all the documents it deems appropriate to confirm that this admissibility criterion is effectively fulfilled.
9) An entity may propose and coordinate several projects. Recipients of previous RHU call for proposals may submit new projects. A Scientific and Technical Project Manager of a project funded under a previous wave may submit a new project if the funded project is completed by the closing date of this AAP.

3.3. Eligibility criteria

IMPORTANT

After review by the panel, the dossiers that do not meet the eligibility criteria will in no way be eligible for funding.

1) The project must fall within the scope of the call for proposals described in §2.
2) Project proposals must not be deemed by the panel as infringing an intellectual property right, which qualifies as counterfeiting within the meaning of intellectual property.

3.4. Evaluation criteria

IMPORTANT

The dossiers that meet the admissibility and eligibility criteria will be evaluated according to the following criteria.

External peer reviewers and members of the panel are called upon to review project proposals according to the evaluation criteria below. To help them in their evaluation, assessment elements are suggested for each criterion, without being neither restrictive nor required.

1) Relevance of the proposal to the objectives of the call for proposals
2) Innovative nature of the proposal
   - the project will be based on original research focusing on scientific, technological and medical innovations,
   - the project will aim to extend existing research in order to lead to innovations in the handling or the treatment of the pathology(ies) involved.
3) Preliminary data
   - preliminary data, published by the coordinating project team, will support a proof of concept on which the project is based (see appendix on preliminary data in §3.2).
4) Scientific and technical quality
   - positioning with respect to the state-of-the-art or innovation,
   - structuring the project, thorough definition of the final results (deliverables), identification of milestones,
   - identifying risk stages and project proposals to remove barriers as well as possible alternative methods,

- quality of the methodology and specific description of the hypotheses and tools used in pre-clinical experiments and clinical trials (methodological appendix).

5) Overall impact of the project
   - prospects for medical and/or public health use,
   - prospects for industrial and/or technological use, economic and commercial potential, business plan, integration into industrial activity, credibility of the valorization announced,
   - if relevant, approach to environmental impact issues.
6) Quality of the consortium
   - scientific quality, experience in conducting multi-partner projects, and involvement of the scientific and technical project manager,
   - level of scientific excellence (or expertise) and relevance of the choice of partner teams,
   - quality of the coordination and governance plan (project management with regard to its functional, technical, organisational, time and funding aspects),
   - involvement of the partner enterprise(s),
   - implementation and definition of the role played by an external Scientific Advisory Board (SAB),
7) Involvement in ongoing PIA and/or France 2030 projects, Matching project and resources
   - realistic timetable,
   - adjustment of the resources used to conduct the project,
   - adjustment and justification of the amount of aid applied for,
   - adjustment of coordinating costs,
   - justification of resourcing regarding permanent staff,
   - justification of resourcing regarding non-permanent staff (internship, thesis, post-docs),
   - assessment of the amount of investments and equipment purchases,
   - assessment of other financial items (missions, subcontracting, consumables, etc.).

3.5. Important recommendations

It is recommended to register as soon as possible, and to regularly visit the programme's dedicated website listed on the first page of this document. It will include updated information and links to reference documents and the submission website.

The following recommendations are intended as guidance to prepare project proposals under this call for proposals.

The panel may consider the relevance of any deviation, which must be justified, from the recommendations.

ENTERPRISE INVOLVMENT

Within the framework of this call for proposals, applicants are invited to submit projects in which enterprises are strongly involved. In that spirit, their financial implication should be significant and comply with the community framework regarding the support for research, development, and innovation. To be allocated, the funding requested by partner enterprises must show an incentive effect (see definition in § 6.4).

Partner enterprises, especially VSEs/SMEs, must pay special attention to their genuine ability in funding their contributions to the project. Overly optimistic or unrealistic perspectives may hinder the whole project. The ANR may subsequently decide not to fund the project or to stop it.

FOREIGN PARTNERS

French subsidiaries of foreign enterprises are eligible for funding, provided that their R&D is carried out in France. Foreign teams (public or private) may be involved (without funding) in the projects. However, this requires a true and significant return for the French health sector, particularly for enterprises. In addition, the foreign partner must provide its own funding.

INNOVATION AND INTELLECTUAL PROPERTY

Special attention will be paid to the originality and innovative nature of the project. The aspects of intellectual property must be specified and clearly described. The chosen protection strategy must be explicit and appropriate to the product, technology or service.

REGULATORY AND ETHICAL CONSIDERATIONS

Special attention will be paid to the quality of the assessment conducted on regulatory and ethical issues associated with the projects, as well as concerns regarding the social acceptance of the research proposed. The dossier must include a description of the regulatory framework, the constraints and requirements related to the project, possible product and deliverables targeted. Whenever applicable, it will be essential to explain the procedures to be carried out and authorisations to get, the applicable regulatory framework, and good practices (in laboratory, etc.) to be respected. Each procedure must be scheduled in the corresponding workpackage and the global planning of the project.

4. General provisions for funding

4.1. Funding

The project will be funded by a grant allocated, under the France 2030 plan, by the French State to the ANR.

FUNDING METHOD

The funding allocated will be provided in the form of a non-refundable grant, under the provisions of the regulations regarding the conditions of allocation of funding for call for proposals on university hospital research, available on the call for proposals website.

The grants will be allocated to the Coordinating institution (see definition in §6.1). These grants may be transferred to Partner institutions, under the terms and conditions set out in the regulations regarding the conditions of allocating of funding for call for proposals on university hospital research, available on the call for proposals website.

The payment of a pre-funding instalment immediately following the publication of the results will give a quick start to the projects. The pre-funding agreement will be effective until the final grant agreement is signed with the Coordinating institution having gathered all supporting documents, but may not exceed 12 months. Pre-funding may not exceed 10% of the amount allocated by decision of the French Prime Minister.

REQUIREMENTS FOR FUNDING OF TEMPORARY STAFF

Under this programme, temporary staff (interns, doctoral students, post-docs, fixed-term contracts, temping, etc.) may be assigned to the project. Except in specific cases, throughout the project, the corresponding contribution (person/months) funded by the ANR must not exceed 50% of the total contribution (person/months) to the project.

4.2. Consortium agreements

Under the auspices of the Coordinating institution, partner institutions must enter into an agreement specifying:

- the distribution of tasks, human and financial resources, and deliverables,

- the sharing of intellectual property rights on the results generated under this project,
- the regime for publication/dissemination of results,
- the exploitation of the results.

This agreement will help determine the existence of any indirect financial support included in the calculation of the maximum aid rate approved by the Community Framework for research, development and innovation (hereinafter referred to as "the Framework").

The absence of indirect financial support is assumed if at least one of the following conditions is met:

- the recipient subject to the Framework bears the overall costs of the project,
- if the results cannot be protected by an intellectual property right, the recipient research institution may widely disseminate these results,
- if the results can be protected by an intellectual property right, the recipient research institution retains its ownership,
- the recipient subject to the Framework exploiting a result developed by a recipient research institution pays to this institution fees equivalent to market conditions.

The Coordinating institution will provide a copy of this agreement to the ANR, as well as a certificate, signed by partner institutions, confirming its compliance with the provisions of the Framework and with the agreement(s) specifying the terms and conditions of implementation and funding of the project. Forwarding must be carried out within 12 months from the date of signature of the pre-funding agreement.

Therefore, the certificate must either confirm that the agreement meets one of the aforementioned conditions, or that all intellectual property rights to the results and the rights to access these results are awarded to various partner institutions and accurately reflect their respective interest, the level of involvement in the research and their financial and other contributions to the project.

4.3. Other provisions

Funding a project does not release participating partner units to comply with the requirements of the regulation, ethical rules and code of conduct applicable to their field of activity.

On behalf of all partner institutions, the coordinating institution undertakes to keep the ANR informed of any change, between the submission of the project and the list of selected projects being published, likely to adjust the content, partnership and timetable to conduct the project.

4.4. Open Science

As part of the ANR's contribution to the promotion and implementation of Open Science, and in line with the French National Plan for Open Science (NPOS) and International Plan S, recipients of the France 2030 grant undertake to ensure immediate open access to peer-reviewed scientific publications and to adopt, for research data, a FAIR (Findable, Accessible, Interoperable, Reusable) approach in line with the "as open as possible and as closed as necessary" principle. Thus, all scientific publications from projects funded within the framework of this plan will be available in open access, under the Creative Commons CC-BY license or equivalent, using one of the three following methods:

- publication in a natively open access journal,
- publication in a subscription journal that is part of a transformative agreement or transformative journal[5],

[5] Definition of a transformative agreement or transformative journal : https://www.coalition-s.org/faq-theme/publication-fees-costs-prices-business-models/

- publication in a subscription journal. The publisher's version or the manuscript accepted for publication will be deposited in the Open archive HAL by its authors, under a CC-BY license implementing the Rights Retention Strategy (RRS), according to the terms specified in the Special Conditions of the Funding Decision or Agreement.

Furthermore, the Coordinating Institution undertakes to ensure that the full version of these scientific publications (version approved for publication or publisher's version) is deposited in the national Open archive HAL, no later than the time of publication, and to mention the ANR reference of the research project from which they result.

The ANR encourages the deposit of pre-prints in open platforms or archives, and to privilege permanent or unique login details (e.g., DOI or HAL Id). In addition, the ANR recommends that priority be given to publications in natively open access journals or books[6].

Finally, the Coordinating Institution agrees to provide, within 6 months after the start of the project, a first version of the Data Management Plan (DMP), under the terms and conditions set out in the Grant Agreement.

5. Terms of submission

5.1. Content of the submission dossier

The submission dossier shall include all the elements required for the scientific and technical evaluation of the project. It must be deposited before the closing of the call for proposals, whose date and time are listed in page 3.

IMPORTANT

No additional element will be accepted after the closing for the submission of the call for proposals, whose date and time are listed in page 3.

The documents are to be deposited on the submission website whose address is listed in page 3. To access this service, opening an account first is required (username and password). It is recommended to register as soon as possible to obtain those elements.

The full submission dossier consists of the following documents, fully completed:

- the "administrative and financial document" and "commitment letters from the Coordinating institution and Partner institutions", available on the online submission website,
- the "scientific document" describing the scientific, technical and clinical aspects of the project, and the teaching and exploitation objectives to be achieved. The scientific document must include three appendices: one focusing exclusively on the methodology of the pre-clinical and clinical trials proposed in the project, required for scientific assessment; one on preliminary data and one on intellectual property.

The elements of the submission dossier (administrative and financial document, model for commitment letters and model for scientific document) will be available on the publication page of this call for proposals (see the URL on page 1).

5.2. Submission procedure

The documents of this submission dossier are to be sent by the Scientific and Technical Project Manager:

[6] The DOAJ website (https://doaj.org/) lists peer-reviewed open access scientific journals. The same applies to the DOAB website (https://www.doabooks.org/) but with monographs.

1) Only in ELECTRONIC FORMAT (administrative and financial document, scientific document and its three appendices):

- before the closing dates listed in page 3 of this call for proposals,
- on the submission website, as recommended in §5.1.

Prior registration on the submission website is required to submit a project.

Only the electronic version of the submission documents available on the submission website when this call for proposals closes will be sent to peer reviewers and panel members for evaluation.

2) The SIGNED VERSION IN SCANNED FORMAT ("administrative and financial document" and commitment letters) must:

- be signed by the Scientific and Technical Project Manager, the legal representative of the Coordinating institution, and all partner institutions,
- be deposited on the online submission website before the deadline listed in page 3 of this call for proposals, as evidenced by the submission date and time.

NB: The signed version will be used to certify that the partner institutions of the project have approved its submission.

An ACKOWLEDGEMENT OF RECEIPT, in electronic format, will be sent to the Scientific and Technical Project Manager once the online submission has been approved and the documents signed.

5.3. Submission advice

It is strongly advised to:

1) open an account on the submission website at the earliest,
2) not wait until the deadline for submission of projects to enter data online and upload files (please note that the submission deadline must be respected),
3) check that the documents submitted in the dedicated areas under the headings "submission documents" and "signed documents" are complete and consistent with the expected elements. The submission dossier and filing of signed documents can only be approved by the Scientific and Technical Project Manager if all documents have been uploaded,
4) regularly consult the programme's dedicated website at the address listed in page 1, which includes up-to-date information on its operation,
5) contact, if necessary, the correspondents by email at the address listed in page 3 of this document.

6. Lexicon

6.1. Definitions relating to the project organisation

Coordinating institution: endowed with legal personality, it is the preferred contact of the ANR for administrative matters. It is responsible for setting up and formalising the collaboration between the Partner Institutions, producing the project's deliverables, holding progress meetings and communicating the results. It relies on a Scientific and Technical Project Manager. It signs the Grant Agreement with the ANR and receives the funding allocated to the project.

Scientific and Technical Project Manager: he/she ensures the scientific, clinical, and technical coordination of the project on behalf of the Coordinating Institution. He/she is the physical person in charge of the scientific and technical aspects of the coordinating structure. He/she is the preferred contact of the ANR.

Partner: research unit of a research institution or enterprise involved in the project. Each partner unit appoints a scientific and technical correspondent, who is the preferred contact

of the Scientific and Technical Project Manager.

Partner institution: research or healthcare institution in charge of a partner unit, research or healthcare institution allocating resources to the partner unit or enterprise responsible for the partner unit. If required, it benefits, by virtue of a transfer agreement, from a share of the funding allocated to the Coordinating Institution by the ANR for carrying out an assignment or mission within the framework of the project.

6.2. Definitions relating to the structures

Enterprise: the term "enterprise" includes small, medium-sized, and large enterprises (SMEs). The definition of small and medium-sized enterprises (SMEs) is that of Regulation (EC) No. 70/2001 of the European Commission of 12 January 2001, set out in European Commission Recommendation 2003/361/EC of 6 May 2003 regarding the definition of micro, small and medium-sized enterprises, and any other community texts. Under Community Law, any entity pursuing an economic activity, regardless of their legal form, can be considered as an enterprise. An economic activity is any activity consisting of supplying goods and/or services in a given market.

Research institution: the term "research institution" must be understood under the definition provided in 2.2 d) of the Framework. An entity, such as a university or research institute, regardless of its legal status (body governed by public of private law) or funding method, whose primary goal is to conduct fundamental research, industrial research, or experimental development and disseminate their results by way of teaching, publication, or technology transfer. All profits must be reinvested in these activities, the dissemination of their results or teaching. Enterprises that can exert influence upon such an entity, for instance in their capacity as shareholders or members, shall enjoy no preferential access to the research capacities of such an institution or to the research results generated.

Territorial authorities: endowed with legal personality of public law, separate from the State, and benefiting as such from legal and patrimonial autonomy. They are also referred to as "local authorities". Both expressions are equally used in everyday language. For instance, the following are designated as territorial authorities: municipalities, departments including the 5 French overseas departments (Dom), regions including the 5 French overseas regions, local and regional bodies with special status, and overseas authorities (Com).

Healthcare institutions: structures ensuring the diagnostic, monitoring and treatment of patients, injured people, and pregnant women. They provide in-patient, out-patient and home-based care. They are committed to coordinating health care with health professionals practising in town and medico-social institutions and services. They contribute to the implementation of the public health policy and vigilance mechanisms intended to ensure public health security. Within their institution, they conduct a reflection on ethics in line with patient reception and care-taking (article L6111-1 *et seq.* of the French Code of Public Health).

6.3. Definitions relating to various research categories

These definitions are included in the Community Framework for State aid for research, development and innovation.

Fundamental research: means experimental or theoretical work undertaken primarily to acquire new knowledge on the underlying foundations of phenomena and observable facts, without any foreseen direct or practical application of use.

Industrial research: means planned research or critical investigations aimed at acquiring new knowledge and skills to develop new products, processes, or services or for bringing about a significant improvement in existing products, processes, or services. It includes the creation of component parts of complex systems required for industrial research, particularly for generic technology validation, but excludes prototypes as defined in the definition of experimental development below.

Experimental development: means acquiring, combining, shaping, and using existing scientific, technological, business, and other relevant knowledge and skills for the purpose of producing plans and arrangements or designs for new, altered, or improved products, processes, or services. These may also include, for instance, other activities aiming at the conceptual

definition, planning and documentation of new products, processes, or services. These activities may include producing drafts, drawings, plans and other documentation, provided that they are not intended for commercial use.

The creation of commercially viable prototypes and pilot projects involves experimental development when the prototype is necessarily the final commercial product and when it is too expensive to produce for demonstration and validation purposes only. In case of a subsequent commercial use of demonstration or pilot projects, any revenue generated from such use must be deducted from eligible costs.

The experimental production and testing of products, processes and services are also eligible for funding, provided that they cannot be used or transformed for use in industrial or commercial applications.

Experimental development does not include routine or periodic changes made to products, production lines, manufacturing processes, existing services, and other operations in progress, even if such changes may represent improvements.

6.4. Other definitions

Incentive effect: To have an incentive effect means, according to Community provisions, that the aid must induce changes in the recipient's behaviour, leading to increased R&D activities: it must significantly impact the increase of size, scope, budget, or rhythm of its R&D activities. The assessment of the incentive effect will be based on a comparison of the situation with and without aid, from answers to a questionnaire sent to the enterprise. Several indicators may be used in this respect: total cost of the project, R&D staff assigned to the project, scope of the project, level of risk, increase in the activities' level of risk, increase in R&D expenditure within the enterprise.

GOUVERNEMENT

Contacts

Information about the administrative process (compiling the application, online procedures, aid rate) may be obtained from the ANR at:

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