

Fraternité





Emerging Infectious Diseases Priority Research Programme and Equipment (PEPR MIE) Call for proposals 2024

This call for proposals is open until 10/06/2024 at 11:59 p.m. (Paris time).

It can be consulted at:

https://anrs.fr/en/funding/all-calls-for-proposals/call-for-proposals-2024-emerging-infectious-diseases-pepr/

CALL FOR PROPOSALS 04/04/2024

Summary

In order to prepare France for a new major health crisis, the government launched in 2021 the Emerging Infectious Diseases and Nuclear, Radiological, Biological and Chemical (NRBC) threats acceleration strategy (referred to throughout this document as the acceleration strategy), which is included in the Health Innovation 2030 component of the France 2030 investment plan.

This acceleration strategy must enable the State to understand, prevent and control the phenomena of emergence or re-emergence of infectious diseases in order to limit their impacts, and also to combat other NRBC threats.

The acceleration strategy combines anticipation, mobilisation and coordination of a scientific, technical, organisational and industrial nature, enabling the construction of long-term sovereign capacities in conjunction with the European Union and other international partners.

It incorporates the integrated and unifying One Health approach that aims to address the issue of zoonoses through aspects relating to the health of people, animals and ecosystems. This concept recognises that the health of humans, domestic and wild animals, plants and the environment in general (including ecosystems) is closely linked and interdependent. Multiple sectors, disciplines and communities at different levels of society are mobilised to work together to combat infectious threats to humans.

As part of the research component supported by the acceleration strategy, two complementary Priority Research Programmes and Equipment (PEPRs) have been implemented to bring together, facilitate and structure the scientific communities concerned around emerging infectious disease research priorities through a decompartmentalised approach between human, animal and environmental health: PEPR PREZODE (Preventing Zoonotic Diseases Emergence) and PEPR MIE (*Maladies Infectieuses Emergentes* (Emerging Infectious Diseases)).

PEPR PREZODE is coordinated by the French National Research Institute for Sustainable Development (IRD), the Agricultural Research and Cooperation Organisation Working for the Sustainable Development of Tropical and Mediterranean Regions (CIRAD) and the National Research Institute for Agriculture, Food and Environment (INRAE), and is operated by the National Research Agency (ANR). Its objective is to reinforce knowledge production and the development of relevant tools to define innovative strategies for risk reduction and the early detection of emergences. It supports upstream research projects as well as infrastructures and the purchasing of equipment within the framework of this PEPR.

The objectives of PEPR MIE, coordinated and operated by Inserm through ANRS Emerging Infectious Diseases (ANRS EID), are to effectively prevent and control emerging and re-emerging infectious diseases on the individual and collective levels. It supports basic research, R&D, Humanities and Social Sciences and Public Health projects, infrastructure and the purchasing of equipment through calls for expressions of interest, as well as Chairs.

The PEPR call for proposals has three parts:

- Part 1 Accelerate the acquisition of knowledge on emerging infectious diseases
- Part 2 Organise and develop new treatments, vaccines and other means of prevention, diagnosis and surveillance for emerging infectious diseases
- Part 3 Enable public policy and society to deal with epidemic crises

A first call for proposals was launched in 2023. Following evaluation by an international panel of experts, 11 of the 37 eligible research projects have been selected to receive a total of around €22 million in funding. Each project is led by an interdisciplinary consortium of four to 20 teams with complementary areas of expertise, and fulfils at least one of the priority themes defined in the three scientific parts of the PEPR MIE.

This 2024 call for proposals builds on that of 2023. In order to take developments in knowledge and French research capacities into account and in order to further encourage interdisciplinarity, the priority themes within each part have been redefined, extended or updated. In addition, in order to focus research efforts and the resources provided as part of the 2024 call for proposals, its scope has been restricted, based on the list of priority pathogens established previously, to three groups of diseases presenting a high risk of health crisis in France: arboviruses, viral haemorrhagic fevers and respiratory viruses.

The 2024 call for proposals has an indicative budget of €13 million.

Key words

Emerging and re-emerging infectious diseases; health crises, crisis management; epidemic preparedness; epidemiology; public health; biological mechanisms; host-pathogen interactions; physiopathogenesis; immune response; biomarkers; risk factors; transmission; species barrier; climate change; One Health; surveillance, detection and modelling tools; health innovation and technologies; treatments, vaccines, diagnostic and screening tests; preclinical research; anti-infective molecules or biomolecules; new therapeutic strategies; humanities and social sciences; crisis management; public action processes; production and dissemination of scientific information; role of the media, social media, fake news; prevention strategies; vaccine hesitancy, and other barrier measures; social and regional health inequalities; vulnerable populations; impact of health measures, proof of concept, risk management.

Key dates

Closure of the call for proposals

The application elements must be submitted in electronic form and imperatively before:

10 June 2024 at 11:59 p.m. (Paris time)

on the platform: https://apogee.anrs.fr/

The persons authorised to represent the project's Coordinating Institution and Partner Institutions must sign a letter of commitment confirming the contributions (financial, human, premises, etc.) for the duration of the project.

ANRS EID contacts

Programme leaders: Yazdan Yazdanpanah and Hervé Raoul

Please be sure to thoroughly read this document and the instructions available on the application submission platform.

For any questions regarding the call for proposals: aap@anrs.fr

For any technical questions regarding the application submission platform: apogee@anrs.fr

France 2030 ______ 8 April 2024

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1. Background and objectives of the call for proposals

1.1. Background

In order to prepare France for a new major health crisis, the government launched in 2021 the Emerging Infectious Diseases and Nuclear, Radiological, Biological and Chemical (NRBC) threats acceleration strategy (referred to throughout this document as the acceleration strategy)¹, which is included in the Health Innovation 2030 component of the France 2030 investment plan.

This acceleration strategy must enable the State to understand, prevent and control the phenomena of emergence or re-emergence of infectious diseases in order to limit their impacts, and also to combat other NRBC threats. It combines mobilisation and coordination of a scientific, technical, organisational and industrial nature, and integrates the One Health² approach, taking into account the links between the health of humans, animals and ecosystems.

The acceleration strategy also includes humanities and social science approaches to evaluate the acceptability of certain communication and training measures and schemes.

Finally, it must ensure that it remains in step with advances in the various scientific or strategic sectors at international level and that it coordinates its work with that of the European Health Emergency Preparedness and Response Authority (HERA)³ to which it contributes.

In order to address these challenges, this acceleration strategy is funding two PEPRs: PREZODE⁴ (Preventing Zoonotic Disease Emergence) and MIE⁵ (*Maladies Infectieuses Emergentes* (Emerging Infectious Diseases)), with the objectives of reinforcing understanding, prevention and preparedness for the emergence and re-emergence of infectious diseases. These PEPRs form part of a continuum ranging from the pre-emergence of zoonotic pathogens to their emergence and spread within human populations.

PEPR MIE was set up to support research in better understanding, preventing and controlling emerging and re-emerging infectious diseases by promoting interdisciplinary and multi-institutional relationships and by promoting the One Health approach. It is also about streamlining collaborations between the various players and reinforcing the structuring of collective actions.

PEPR MIE is coordinated by Inserm through ANRS Emerging Infectious Diseases (ANRS EID) and

is divided into three types of research activities:

- Calls for proposals, which comprise three thematic parts whose priority areas of research are specified in §2.1. These
 calls will be used to fund projects in the fields of basic research, R&D (TRL⁶ 1 to 3), and the humanities and social
 sciences, while promoting interdisciplinarity.
- Calls for expressions of interest for the funding of research equipment and infrastructures.
- Calls for applications for Chairs.

1.2. General objective of the PEPR MIE calls for proposals

The PEPR MIE calls for proposals represent an unprecedented window for research into emerging infectious diseases by providing significant financial resources to form ambitious interdisciplinary consortia. These calls are part of a process of preparing for future health crises. Emergency funding for research in times of crisis will be covered by other financial instruments.

The PEPR MIE calls for proposals are all closely linked with those of PREZODE.

- In PREZODE, projects must be situated in the context of global changes and anthropogenic modifications in the environment, with the aim of preventing zoonotic emergences in order to reduce their number and detect such events as early as possible. In 2024, the PREZODE call for proposals will focus on Work Package 3 'Epidemiological surveillance and early warning systems', for approaches focused on wildlife, the environment and inter-species transmission upstream of human transmission.
- Those targeted by PEPR MIE focus on the biology of emerging, re-emerging or zoonotic pathogens (particularly molecular and cellular mechanisms) or on a human-centred approach. They may take into account the role of anthropogenic changes in the environment, but will in this case be situated not upstream of the emergence but at human

¹ https://www.gouvernement.fr/maladies-infectieuses-emergentes-menaces-nucleaires-radiologiques-biologiques-et-chimiques

² https://www.who.int/fr/news/item/01-12-2021-tripartite-and-unep-support-ohhlep-s-definition-of-one-health

https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/health-emergency-preparedness-and-response-authority_en

⁵ https://anrs.fr/en/who-are-we/strategy/emerging-infectious-diseases-pepr/

https://ncai.nhlbi.nih.gov/resources/techreadylevels

transmission and dissemination level.

Given that some projects may find themselves at the interface of both PEPRs, close coordination between the programmes will ensure good research project synergy. This coordination is provided by a Joint Directory Board (JDB) of representatives of the two PEPRs. The JDB ensures optimal links between the two programmes from the application eligibility stage to the implementation and follow-up of funded projects. As such, any projects at the interface of the two PEPRs must be submitted to just one of them, with the possibility to consult the coordinators of both programmes⁷ and receive an opinion from the JDB. These projects will be evaluated and funded under a single PEPR.

The PEPR MIE calls for proposals will also be strongly linked to the other acceleration strategy measures supporting prematuration and maturation (Measures 3 to 68), in order to accelerate the utilisation of the findings of the research projects supported by PEPR MIE, promote the development of innovative and industrialisable countermeasures, and validate them in accordance with French and international standards.

For some specific themes, a link may be established with projects funded as part of the Digital Health⁹ or Biological Therapies and Bioproduction of Innovative Therapies¹⁰ acceleration strategies.

The projects targeted by the PEPR calls for proposals are intended to complement those supported by other funding instruments, particularly at ANR. As such, they may follow on from them as part of an enlargement of the consortia, with reinforcement of the interdisciplinary aspect, or to incorporate a One Health approach. Projects or parts of projects funded by other agencies, particularly via the ANR general call for proposals or by foundations, may constitute a building block of projects submitted to the PEPR call for proposals, but these building blocks will not receive PEPR funding. In this case, the co-funding envisaged for the proposed projects must be made explicit.

1.3. Role of the PEPR coordinators

The PEPR MIE coordinator – Inserm via ANRS EID – in cooperation with the various PEPR MIE governing bodies¹¹, is responsible for preparing the text that describes the objectives, scientific scope and themes of the calls for proposals, the call for expressions of interest and the calls for applications for the Chairs, as well as the organisation of the scientific evaluation. It ensures the consistency and complementarity of these calls and of the projects proposed for funding with PEPR MIE objectives on the one hand and with the entire acceleration strategy on the other.

The programme coordinator can support the project leaders who wish to submit a project, either with a view to explaining the call and referring them to the most appropriate window, or in conjunction with the scientific facilitation groups set up by ANRS EID¹². Project leaders are strongly encouraged to contact ANRS EID as soon as possible to verify whether their envisaged project theme and construction fall within the scope of the call for proposals.

The projects submitted will be evaluated by an independent international Evaluation Committee, formed in conjunction with that of PREZODE, and incorporating all the disciplines necessary for a One Health perspective. The evaluation procedure is described in point §3 of this document.

At the end of this evaluation phase, and following discussion within the PREZODE MIE JDB, ANRS EID will submit to the French General Secretariat for Investment (SGPI) the list of projects recommended for funding and the amount of funding that could be definitively allocated to them.

Finally, ANRS EID, in conjunction with the party coordinating the acceleration strategy, will follow up the funded projects in terms of scientific advances, value-creation and dissemination actions, human resources and equipment aspects, and will facilitate the resolution of the difficulties encountered throughout the duration of the projects.

2. Themes of the call and projects expected

2.1. Themes

The 2024 call for proposals concerns the three thematic parts of PEPR MIE whose priority research areas are detailed in this document.

Part 1 – Accelerate the acquisition of knowledge on emerging infectious diseases

 $^{^7\,\}text{PEPR}$ MIE contact: $\underline{aap@\,anrs.fr}$ PEPR PREZODE contact: $\underline{pilotes-pepr-prezode@\,ird.fr}$

⁸ https://www.enseignementsup-recherche.gouv.fr/sites/default/files/2022-07/dossier-de-presse---france-2030-investir-pour-mieux-r-pondre-aux-maladies-mergentes-infectieuses-gouvernement--19105.pdf

 $^{{\}color{blue}9~\underline{https://www.entreprises.gouv.fr/fr/strategies-d-acceleration/strategie-d-acceleration-sante-numerique}$

 $^{{\}color{blue} {^{10}} \, \underline{^{https://www.entreprises.gouv.fr/fr/industrie/biotherapies-et-bioproduction-de-therapies-innovantes}}$

 $[\]frac{11}{\text{https://anrs.fr/wp-content/uploads/2023/02/pepr-emerging-infectious-diseases-juillet-2022.pdf}}$

¹² https://anrs.fr/en/scientific-research/scientific-animation-groups/

- Part 2 Organise and develop new treatments, vaccines and other means of prevention, diagnosis and surveillance for emerging infectious diseases
- Part 3 Enable public policy and society to deal with epidemic crises

Based on the list of priority pathogens established for the 2023 call for proposals, the 2024 call envisages a closer approach to three categories of emerging or re-emerging infectious diseases that present a high risk of health crisis in France: arboviruses, viral haemorrhagic fevers and respiratory viruses.

Examples of themes in each section are provided for information purposes only. The list is not exhaustive and any other innovative approach fulfilling the scientific orientations of the various parts may be submitted.

Projects addressing one or more priority areas within different parts are also encouraged, but these projects must be submitted in response to one part, which is considered the main part.

In order to ensure the production of knowledge covering a broad thematic field and to avoid duplicates, researchers wishing to submit a research project to this call for proposals are asked to familiarise themselves with the winning projects of the PEPR MIE¹³ and PEPR PREZODE 2023 calls for proposals and are encouraged to submit research on subjects not covered or that are complementary to those previously funded.

Project leaders who applied to the 2023 call for proposals but were unsuccessful may apply to the PEPR MIE 2024 call, taking into account the comments and recommendations issued by the Evaluation Committee, as well as the scientific scope and themes of this year's call.

The PEPR MIE 2024 call for proposals covers aspects complementary to those targeted by the PREZODE PEPR WP3 'Epidemiological surveillance and early warning systems' and for which a call for proposals will also be launched in 2024. It is strongly recommended to submit projects with a human health approach to PEPR MIE, and those with an approach centred on animals, the environment and inter-species transmission upstream of inter-human transmission to PEPR PREZODE.

The call for proposals targets large-scale research projects of a duration of 2 to 3 years, and for a minimum funding request of €1 million for Parts 1 and 2. No minimum funding amount is applied for research projects submitted under Part 3.

The 2024 call for proposals has an indicative budget of €13 million.

PART 1 – Accelerate the acquisition of knowledge on emerging infectious diseases

The objective of Part 1 is to accelerate the acquisition of knowledge on emerging and re-emerging infectious diseases in a coordinated and integrative manner.

It aims to study, in a non-crisis period, the concepts described below and related to priority infectious diseases, and their pathogens, targeted in this call in a human-centred approach. This fundamental knowledge will be valuable in taking effective action in the event of a crisis.

Two priority research areas are targeted:

Area 1: Prevent and limit emergences

- Define the biological mechanisms linked to emergences for the different classes of pathogens in humans: study of molecular and cellular mechanisms subjacent to infection; structural studies; pathogen cycles; persistence; resistance; evolution; adaptation; molecular and cellular mechanisms responsible for transition to humans; modes of transmission; vector competence and capacity.
- Characterise microbial communities: metagenomic studies of environmental and host biodiversity; applications to surveillance and diagnosis; phylogenetic approaches.
- Develop surveillance and modelling methods and tools, including epidemic dissemination, and build
 indicators for the rapid detection of biological threats and the monitoring of epidemic dynamics using an
 approach centred on interhuman transmission and the impact of countermeasures in humans: approaches using
 computational biology, modelling, biophysics, including bioaerosols, and the use of artificial intelligence.
- Understand and characterise human-animal-environment interactions including economic and geopolitical social dynamics, environmental factors (air pollution, chemical exposome, etc.) and climate factors promoting the dissemination of emerging infectious diseases in humans.

Area 2: Understand the molecular and cellular mechanisms related to infections and contributing to the development of prophylactic and therapeutic countermeasures for emerging and re-emerging infectious diseases

- Study of the natural history of the pathogen, host biology.
- Development of in vitro or in vivo models (organs-on-chips, organoids, animal models and others) for a better
 understanding of infection mechanisms and host/vector/pathogen interactions.
- Study of pathogenesis, innate and adaptive immune response, mucosal immunity.

 $^{^{13}\ \}underline{\text{https://anrs.fr/en/all-news/announcement-winners-call-for-proposals-pepr-mie-2023/2}}$

- Study of risk factors or protective factors against infection and disease severity: genetic factors and host susceptibility (sensitivity/receptivity), human-to-human transmission, epigenetic factors, age, comorbidities, co-infections, cross-immunity, environmental factors.
- Early markers of infection and biomarkers predictive of clinical outcome.
- Evolution of antigenic determinants characterisation of epitopes; identification of therapeutic and vaccine targets.

PART 2 – Organise and develop new treatments, vaccines and other means of prevention and diagnosis for emerging infectious diseases

This second part aims to prepare, in the medium- and long term and in a non-crisis period, innovative treatment or prevention technologies, new vaccines and diagnostic- or screening tools, in human and animal health, and to accelerate their proof of concept, development and potential deployment for an emerging event.

The innovative nature of the proposed research must be highlighted (TRL¹⁴ 1 to 3). Where applicable, industrial application and transfer to industry at the end of the project will be sought, consistent with the acceleration strategy. Projects should adopt an approach centred around obtaining proof of concept for the targeted tool. Collaboration with industrial partners is encouraged, however they will not be eligible for funding under this call for proposals. From an industrial development perspective, the definition of the development phases, the risk analysis and the contingency plan, as well as information on the strategy for creating value from the findings with a view to industrial transfer are expected.

This part is closely linked with the acceleration strategy pre-maturation and maturation measures (Measures 3 and 4¹⁵), and in particular with the CATRIEM consortium¹⁶, which will support innovative projects with a view to industrial transfer (proof of concept), facilitate the link with product-oriented technology transfer structures to help anticipate regulatory aspects, improve synergies between academic research and industry expectations, and promote a de-risked approach to future development in France.

Three priority research areas are targeted:

Area 1: Treatments

- Development of anti-infective agents: identification of molecules active against pre-identified targets; improvement of the understanding of their mechanisms of action; development of new chemical libraries and expansion of the therapeutic chemical space; virtual screening of chemical libraries or molecular screening and modelling and optimisation of pre-identified molecules.
- Development of biological therapies: mono- and polyclonal antibodies, immunotherapies, phages.
- Development of new anti-infectious therapeutic strategies targeting the host: new chemical entities (NCEs);
 development of strategies that induce/activate anti-infectious immunity and modulators of immune recognition or targeting epigenetic mechanisms, metabolism, microbiota, new biomimetic vectors; broad-spectrum therapeutic or prophylactic agents with novel mechanisms of action.
- Development of preclinical models (in vitro, ex vivo, in vivo) to evaluate the activity of therapeutic candidates.
- Definition of therapeutic strategies taking into account the evaluation of the risk of emergence of resistance to new anti-infective agents (therapeutic combination).

Area 2: Prevention tools – vaccines and other tools

- Development of new technologies and preclinical models to evaluate candidate vaccines.
- Development of vaccines, particularly in relation to the findings resulting from Part 1, for vaccination in humans or animals against pathogens transmissible to humans: study of the structural bases of antigens and associated complexes inducing a protective response; design and development of immunogens.
- Characterisation of the early responses induced by different types of vaccines that modulate and predict the protective response and its durability.
- Study and reduction of vaccine adverse effects: reactogenicity; ADE; impact on memory B repertoire; autoimmunity.
- Development of vaccine platforms (existing or new) and formulation (vaccine vector, adjuvant, targeting); new strategies for broad-spectrum vaccine design; new routes of administration.
- Development of innovative vector control methods and assessment of the risks of their use on ecosystems (adverse
 effects on non-target populations).

¹⁴ https://ncai.nhlbi.nih.gov/resources/techreadylevels

^{15/}https://www.enseignementsup-recherche.gouv.fr/sites/default/files/2022-07/dossier-de-presse---france-2030-investir-pour-mieux-r-pondre-aux-maladies-mergentes-infectieuses-gouvernement--19105.pdf

¹⁶ https://www.inserm-transfert.fr/chercheurs/le-consortium-catriem/

- Development of technologies for disinfection or decontamination of skin, surfaces, air, etc.
- Development of innovative protective equipment for healthcare professionals or the population.

Area 3: Diagnosis and detection

- Development of diagnostic and screening tests: less costly diagnostic solutions; self-tests; portable devices, point-of-care tests; multiplex/pan-pathogenic and/or no-a priori tests; syndromic approaches; presymptomatic early tests; disruptive technologies.
- Development of strain discrimination and fine characterisation technologies.
- Development of tools, particularly digital, that can inform the sharing of diagnostic and screening information and for the diagnosis and monitoring of the dynamics of human-to-human transmission.

PART 3 – Enable public policy and society to deal with epidemic crises

In the face of epidemic crisis situations, particularly emergences for which knowledge is limited or non-existent, research in the humanities and social sciences, epidemiology and public health is essential to inform the decisions and processes involved, evaluate the effectiveness and efficiency of countermeasures, measure their impacts and model the dynamics of epidemics in humans, particularly according to the different crisis scenarios.

Given the diversity of themes to explore, all disciplines in the humanities and social sciences, epidemiology, modelling and public health can be mobilised. Alongside research based on qualitative and/or quantitative, observational or interventional approaches, it is expected that long-term mechanisms will be initiated (or adjusted, for existing ones) enabling a proactive response to the emergence of an infectious disease. These mechanisms may be observational cohorts, panels or repeated surveys, in the general population or in special populations, whether or not linked to existing health data or surveys/cohorts. Research involving comparative approaches or the creation of international programmes, essential in this field, with a view to co-funding for foreign partners, is also expected.

Three priority research areas are targeted:

Area 1: Anticipation, crisis management and public action processes

- Study of public decision-making processes, modes of citizen and citizen-representative involvement, functioning of democratic institutions in times of crisis (including health democracy).
- Analysis of the legitimacy, effectiveness and adaptability of public and private bodies in the face of a health crisis, in relation to both decision-making processes and the challenges of coordination between institutions, bodies and players at different spatial levels of intervention (from supranational to local).
- Evaluation of the effectiveness, efficiency, acceptability, economic consequences and cost of epidemic control measures (in the general population or in specific populations, living environments, professional spaces, etc.).

Area 2: Knowledge, expertise, communication

- Evaluation of the production and dissemination of scientific information, whether between scientific expert bodies and political/governmental decision-makers as part of the public policy-making process (issue of knowledge transfer/brokerage) or between political decision-makers and the population.
- Analysis of the role of the media, including social media, in building trust, attitudes towards science, and issues regarding conspiracy theories and fake news.
- Improved understanding of population attitudes towards prevention measures (vaccines, barrier measures, etc.) to anticipate potential hesitancy or reticence during a crisis and adapt prevention strategies and their associated messages.

Area 3: Effects of crises

- Evaluation of the impact of health measures on the different daily life areas of the population: exposure to infection and transmission, healthcare consumption, personal and family life, mental health, employment and financial resources, living, working and school conditions, mobility and, at macroeconomic level, employment, poverty and human capital. This research must incorporate questions regarding the determinants of social and territorial health inequalities, both individual and structural factors, as well as in the infection exposure-prevention-screening-treatment continuum.
- Study of knowledge, perceptions, attitudes and practices in screening, vaccines and treatments, in the general population and in different subgroups (by sex, generation, social class, origin, etc.).
- Analysis of the levers and obstacles to actual access to protection and therapeutic innovation by particularly vulnerable populations.

2.2. Main characteristics of the projects expected

The research projects submitted to this call for proposals must enable better preparedness for the risk of epidemics or pandemics, including bioterrorism agents and the development of a faster and more effective anticipation and response capacity (detection, prevention, treatment).

The expected projects should be multipartner and interdisciplinary where possible. Projects comprising at least 1 or 2 domain(s) and 3 disciplines according to the European Research Council (ERC) guidelines will be considered interdisciplinary¹⁷. The involvement of civil society, and in particular patient and user organisations, is encouraged.

The proposed projects should fall within the priority areas of research described above, and apply to the categories of emerging and re-emerging infectious diseases presenting a high risk of health crisis in France: arboviruses, viral haemorrhagic fevers, and respiratory viruses. Approaches by virus, family of viruses, or syndromic aspects are possible. To meet the objective of preparedness for future epidemics, particular attention will be paid to projects proposing cross-cutting approaches to questions common to several viruses, families of viruses, or emerging and re-emerging diseases, including their co-infections.

Projects in France's overseas territories are also encouraged due to their specific epidemiological characteristics (particularly the prevalence of infectious diseases), as well as, for certain regions, their territorial characteristics (climate, biodiversity, insularity, isolated territories, low medical demographics, population diversity, high levels of mobility/migration, etc.).

In the case of research projects requiring the opinion of the ethics bodies concerned (ethics committee or committee for the protection of human subjects (CPP)), or requiring competent-authority authorisation (French medicines agency (ANSM)), or which are subject to compliance with the European General Data Protection Regulation (GDPR) with a French data protection authority (CNIL) opinion – these authorisations must be sent to ANRS EID before research begins. It is recommended to anticipate these aspects when drafting the project.

In the case of studies on a pathogenic microorganism, the findings obtained must be evaluated for their potential dual nature (favouring malicious actions) by competent authorities before publication

2.3. Partners

The projects must be collaborative (at least three research teams belonging to different units).

An explanation must be given of how the partners complement each other, and this will form part of the selection criteria. The participation of several disciplinary competences is necessary, particularly in the context of a One Health approach. The contribution of each partner must be specified and how the interdisciplinary approach is an added value when it comes to achieving the project objectives.

The beneficiaries of the funding are French higher education and/or research institutions or groups of these institutions, as well as French private institutions contributing to higher education and research public service missions falling under Article L. 732-1 of the French Education Code¹⁸.

Collaborations with private partners are encouraged with a view to subsequent value creation from the project findings towards industrial transfer. However, companies will not receive funding under this call for proposals.

Similarly, the proposed projects may be incorporated into international programmes, but only the French partners will be eligible for PEPR MIE funding.

3. Examination of the proposals

3.1. Selection procedure

The admissible projects (see §3.2 for the admissibility criteria) will be evaluated by an independent international Evaluation Committee incorporating all the disciplines necessary for optimal evaluation. However, ANRS EID may call upon experts external to the Evaluation Committee on specific subjects and for one-off evaluations when a specific area of expertise is not covered by the members.

The composition of the Evaluation Committee will be posted on the ANRS EID website at the end of the selection procedure. The composition of the Committee for the evaluation of projects submitted to the 2023 call for proposals can be consulted on

¹⁷ https://erc.europa.eu/sites/default/files/document/file/ERC_Panel_structure_2021_2022.pdf

¹⁸ https://www.enseignementsup-recherche.gouv.fr/fr/la-qualification-d-etablissement-d-enseignement-superieur-prive-d-interet-general-eespig-46277

the ANRS EID website¹⁹.

Following its work, the Evaluation Committee will provide ANRS EID with a report including:

- the scores given to the projects evaluated according to the criteria stated in §3.3.
- a list of the projects it recommends for funding due to their quality, evaluated based on the criteria stated in §3.3 as well as a rationale justifying their position on this list. An opinion on the amount of funding will also be provided.
- a list of the projects that the Committee does not recommend for funding due to quality considered insufficient for at least one of the criteria stated in §3.3 as well as a rationale justifying their position on this list.

ANRS EID will propose to the SGPI the projects that could be funded and the amount that could definitively be allocated to them.

The French Prime Minister, following the opinions of the SGPI and the Ministerial Health Steering Committee (CPM Santé), will decide on the funding beneficiaries and the amounts allocated. Each project will be the subject of a contract between ANRS EID and the project's Coordinating Institution, setting out the reciprocal obligations of the parties.

The Evaluation Committee members and external experts consulted undertake to comply with the rules of professional ethics and scientific integrity established by ANRS EID. ANRS EID ensures strict compliance with the rules of confidentiality, the absence of any interests between the Committee members or external experts and the project leaders and partners, as well as the absence of conflicts of interest for the Committee members and external experts. In the event of a duly observed breach, ANRS EID reserves the right to take any remedial action it considers necessary.

3.2. Admissibility criteria

ANRS EID verifies that the various admissibility criteria are met.

- The application must be submitted in full on the Apogée platform before the date and time of closure of the call for proposals. The online form to complete for a research project has four main parts: the administrative and scientific information about the project partners, the scientific presentation of the project itself, the budget section and the appendices.
- The persons authorised to represent the Coordinating Institution, as well as all partner investigators participating in the project, must sign a letter of commitment confirming their commitment for the duration of the project.
- The scientific part of the application must imperatively follow the template available on Apogée²⁰ and on the page dedicated to the PEPR MIE 2024 call for proposals on the ANRS EID website.
- The project must respect the scope of the call for proposals, fall within the themes described in the three parts, and cover one or more of the infectious diseases listed as priorities: arboviruses, viral haemorrhagic fevers and respiratory viruses.
- The project must be collaborative (at least three research teams belonging to different units) and interdisciplinary.
- The project will be of 2 to 3 years' duration.
- The amount of funding requested must comply with the instructions given for each part.
- A given project coordinator may only lead one project and must contribute at least 30% FTE.
- The Coordinating Institution must be a higher education and/or research institution or a group of these institutions, possibly a private institution contributing to public service missions of higher education and research falling within the scope of Article L. 732-1 of the French Education Code (§2.3).
- The project partners may be higher education and/or research institutions or groups of these institutions, possibly private institutions contributing to public service missions of higher education and research, falling within the scope of Article L. 732-1 of the French Education Code, or non-beneficiary partners, such as companies, foreign teams or representatives of civil society, which in this case will not receive any funding for this participation (§2.3).
- Projects that would cause significant environmental harm (application of the DNSH Do No Significant Harm principle) within the meaning of Article 17 of the EU Taxonomy Regulation are excluded.

Applications that do not meet the admissibility criteria will not be passed on to the Evaluation Committee and will in no event receive funding.

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¹⁹ https://anrs.fr/en/who-are-we/bodies/

²⁰ https://apogee.anrs.fr/

Particularities of research grants

Research grants (for a thesis or post-doc) may be funded under this call for proposals. These requests must imperatively be associated with the projects submitted.

A single template has been put in place for all applications for research grant funding. It is available on the Apogée¹⁸ platform and on the ANRS EID website dedicated to this call for proposals. The grant request must be appended to the research project in a single .pdf file. The total amount of the grant must be included in the amount requested for the project.

The relevance of the grant applicant's role in the research project must be clearly set out and will be evaluated. For the eligibility criteria relating to the recruitment of grant recipients (doctoral and post-doctoral contracts), please refer to French Law no. 2020-1674 of 24 December 2020 on the programming of research for the years 2021 to 2030 and containing various provisions relating to research and higher education. ²¹

3.3. Evaluation criteria

The members of the Evaluation Committee and external experts are called upon to examine the project proposals according to the following three main categories of evaluation criteria.

1. Scientific excellence and ambition:

- Clarity of the objectives and research hypotheses.
- Innovative nature, ambition, originality, methodological or conceptual disruption of the project in relation to the state of the art.
- Relevance of the methodology.
- For research grants: quality of the applicant and relevance of their role in the project.
- If relevant, ability of the project to address research questions as part of an interdisciplinary and One Health approach.
- If relevant, ability of the project to propose a co-production with the various stakeholders, including the decision-makers and communities concerned, to foster community engagement and private sector involvement from the very start of the project.

2. Quality of the consortium, resources mobilised and governance:

- Competence, expertise and involvement of the project manager: ability to coordinate interdisciplinary and ambitious consortia, academic background, international recognition.
- Quality, relevance and complementarity of the scientific consortium with regard to the project objectives.
- Match between the human and financial resources mobilised (including those requested as part of the project), but also the capacities available within the teams (including regulatory) in relation to the objectives.
- Relevance of the schedule, management of scientific risks and alternative solutions, adequacy of the proposed milestones.
- Relevance and effectiveness of project governance (steering, organisation, facilitation, establishment of advisory committees, involvement of stakeholders if necessary, etc.).

3. Impacts of the project:

- Contribution of the project to the PEPR MIE and acceleration strategy objectives.
- Impact of the consortium on the structuring of the national research space.
- Impact on population health and implementation in public policies. The aspects of co-production of public policies with the various stakeholders will be taken into account.
- Economic, social and societal impacts, contribution to the development of solutions in response to the challenges
 of emerging and re-emerging infectious diseases.
- Strategy for dissemination (*in itinere* and *ex post*) and value creation from the findings. Ability of the project to respond to the challenges of open science, dissemination to citizens and transparency in the field of emerging and re-emerging infectious diseases.

²¹ https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000042738027

4. General provisions for funding

4.1. Funding

Calls funded under PEPR MIE are exceptional in nature and differ from the recurrent funding of university or research institutions.

The funding allocated represents additional resources intended for new actions, making it possible to launch innovative research projects and to fund, for example, the purchase of equipment as well as the costs of personnel specifically allocated to these projects and the associated operations.

The funding rules and eligible expenditure are specified in the PEPR Financial Regulation²². The financial support shall be provided in the form of funding disbursed by ANRS EID for the project's Coordinating Institution, according to the schedule set out in the contract on the project duration.

The participants in the funded project undertake to mention the support provided by France 2030 within the framework of the Emerging Infectious Diseases and Nuclear, Radiological, Biological and Chemical (NRBC) threats acceleration strategy and that provided by ANRS EID through PEPR MIE in communications relating to any findings resulting from it.

4.2. Consortium agreements

A consortium agreement, which may consist of a set of agreements between the Coordinating Institution and each individual Partner Institution, specifying the rights and obligations of each Partner Institution with regard to the implementation of the project, must be provided by the Coordinating Institution within 12 months from the date of signature of the funding allocation contract. In the event of multiple agreements, the Coordinating Institution shall guarantee the consistency (absence of contradictory clauses) of that set of agreements.

All Partner Institutions assigning resources to the project are signatories to this/these agreements even if they do not benefit from a share of the funding.

This agreement specifies, in particular, according to the types of projects funded:

- the modalities for creating value from the findings obtained at the end of the research, and for sharing their intellectual property.
- the distribution of the tasks, human and financial resources, and deliverables.
- the regime for the publication/dissemination of the findings.
- the governance, specifying in particular the name of the project manager for the Coordinating Institution.
- the value creation from the digital educational products and/or tools produced.

The Coordinating Institution shall send a copy of this agreement, as well as any amendments thereto, directly to ANRS EID.

This agreement will make it possible to evaluate the absence of indirect funding granted to the Companies through the intermediary of higher education and/or research institutions.

The absence of this document may lead to cessation of the project funding and application of the provisions of Article §6.6 of the Financial Regulation²¹ relating to the procedures for awarding PEPR funding (suspension and repayment of the funding).

It is not necessary to create a consortium agreement if there is already a framework contract containing the above provisions binding the Partner Institutions. A copy of this framework contract or a certificate must be sent before signing the funding allocation contract. On expiry of the said contract, if it is not renewed, the consortium agreement shall then be required.

4.3. Open science

As part of the contribution of ANRS EID to the promotion and implementation of open science²³, and in conjunction with the

²² https://anrs.fr/wp-content/uploads/2023/02/pepr-mie-reglement-financier-2023.pdf

 $^{^{23} \, \}underline{https://anrs.fr/fr/recherche/engagements-scientifiques/science-ouverte/} \\ \, \underline{https://predatoryreports.org/news/fr/french-institutions-launch-list-of-recommended-journals} \\$

French National Plan for Open Science (PNSO) and the international Plan S, the beneficiaries of France 2030 funding undertake to guarantee immediate free access to the peer-reviewed scientific publications and to adopt, for the research data, the FAIR (Findable, Accessible, Interoperable, Reusable) procedure in accordance with the principle of 'as open as possible and as closed as necessary'. As such, all scientific publications deriving from projects funded under the PEPRs will be made freely accessible under the Creative Commons CC-BY licence or equivalent, using one of the following three channels:

- publication in a natively open access journal.
- publication in a subscription journal that is part of a transformative agreement or in a transformative journal.
- publication in a subscription-based journal. The version of record or post-print shall be filed in the HAL open archive by the author(s) under the Creative Commons Licence (CC-BY) by implementing the Right Retention Strategy (RRS), in accordance with the procedures indicated in the specific conditions of the decision or funding contract.

In addition, the Coordinating Institution undertakes to ensure that the full text of these scientific publications (version of record or post-print) is filed in the national HAL open archive, at the latest at the time of publication, and to mention the ANRS EID reference of the research project from which they originated.

ANRS EID encourages the submission of pre-prints to open platforms or open archives and to favour permanent or unique identifiers (e.g. DOI or HAL Id). Furthermore, ANRS EID recommends giving preference to publication in natively open access journals or books.

Finally, the Coordinating Institution undertakes to provide a first version of the Data Management Plan (DMP) within 6 months of the start of the project in accordance with the terms indicated in the funding allocation contract.

4.4. State aid

Aid paid within the framework of this call for proposals is subject to European State aid regulations (Articles 107, 108 and 109 of the Treaty on the functioning of the European Union and derived texts), provided that it qualifies as State aid. This funding must therefore comply with the European rules relating to State aid and fall within the framework of Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty Text²⁴.

5. Submission procedures

5.1. Content of the application

The application must be written in English and include all elements necessary for the scientific and technical evaluation of the project. It must be submitted to the Apogée platform before the closure of the call for proposals.

The full application consists of the following elements:

- Administrative part: administrative and scientific information on the project partners, including the list of the
 most significant scientific publications of the last 5 years, publications devoted to the subject, and patents of the
 researchers/teams proposing the project.
- Scientific part: scientific presentation of the project, no more than 25 pages in length, which must <u>imperatively</u> respect the template available on the Apogée submission platform and on the PEPR MIE page of the ANRS EID website.
 - If applicable: requests for research grants must respect the template available on the ANRS EID website and the Apogée platform and must be attached to the project as a single .pdf file.
- **Budget part** comprising the total amount requested for the project, including research grants
- Appendices to be uploaded separately from the project document and research grants: appendices should only be used for supporting material, such as figures, tables, raw data and other information supporting the research project. The main text of the research project must be sufficiently precise and detailed to be understood without the appendices.
- Letter of commitment signed by the persons authorised to represent the project's Coordinating Institution and Partner Institutions, which will confirm the contributions (financial, human, premises, etc.) for the duration of the project, to be submitted as an appendix.

Project leaders associated with existing research (clinical trial, cohort or pathophysiological study) must contact the Scientific Advisory Board of said research prior to compiling their applications in order to obtain its approval. A letter from the Scientific

 $^{^{24} \}underline{\text{https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:en:PDF} \\$

Advisory Board should be enclosed with the application. The leaders of these projects are also asked to provide a brief recap of the existing research (objectives, study population, etc.) to which the project relates and to describe its progress (status of inclusions, follow-ups, etc.).

Documents to help with completing the forms as well as a guide for submitting research projects to the PEPR MIE 2024 Call for proposals are also available for project leaders. These documents can be consulted in the 'Reference documents' section of the Apogée submission platform.

No additional elements may be accepted after the closure of the call for proposals, whose date and time are given on page 4.

5.2. Submission procedure

The partners must submit the application documents before the closing date given on page 4 of this document and exclusively on the Apogée submission platform according to the recommendations in §5.3.

It is necessary to pre-register on Apogée in order to submit a project.

Only the electronic version of the application documents present on the Apogée submission platform at the closure of the call for proposals is taken into account for the evaluation.

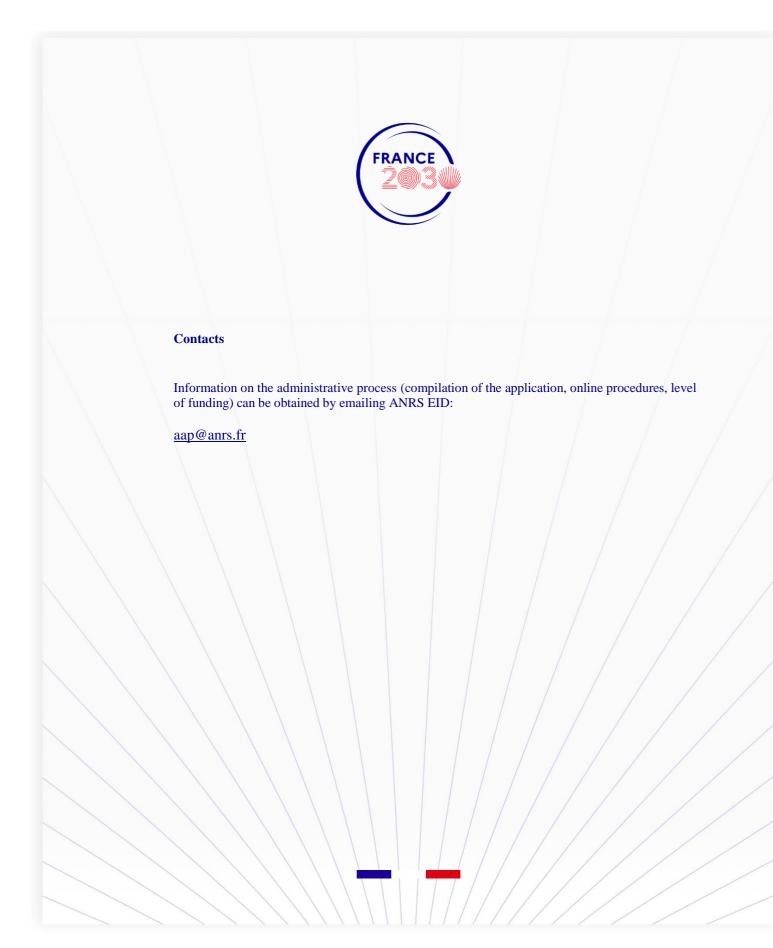
An acknowledgement of receipt, in electronic form, will be sent to the project manager when the documents are submitted.

5.3. Advice for submission

It is strongly recommended to:

- open an account on the Apogée submission platform as soon as possible.
- not leave it until the project submission deadline to enter the data online and upload the files (NB: it is imperative to respect the submission deadline).
- check that the documents submitted with the form are complete and correspond to the elements expected.
- regularly consult the Apogée submission platform as well as the PEPR MIE page on the ANRS EID website, which contains updated information on its progress.
- if needed, get in touch with the contacts by email at the address mentioned on page 4 of this document.





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