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Inserm
La science pour la santé
From science to health

Call for research projects

MESSIDORE 2025

Methodology for Innovative Clinical Trials, Devices, Tools and Research using Health Data and Biobanks

An Inserm call for project, funded by the French Ministry of labour, health, solidarities and families, and operated by IReSP

Strategic Program for Collaborative Health Research

Presentation and Regulations

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1. Context and objectives

Research conducted at Inserm (National Institute of Health and Medical Research*; Institut national de la santé et de la recherche médicale*) are driven by the continuum from bench to bedside. To fully realize its potential, research must be confronted with real-world use cases and its concrete application in healthcare pathways. Research is also inherently interdisciplinary and requires collaboration of a wide range of expertise.
Recognizing this major challenge and its significant impact on diagnostic, therapeutic and preventive interventions, whether in hospitals, outpatient care or the general population, Inserm has received support by its regulatory authorities, including funding from the French Directorate-General for Healthcare Provision (*DGOS*) of the French Ministry of labour, health, solidarities and families (*Ministère du travail, de la santé, des solidarités et des familles*). This support has enabled Inserm to implement a strategic collaborative health research program (PSRCS), as part of its 2021-2025 objectives, resources and performance agreement.

The MESSIDORE call represents a major initiative within this program. Operated for Inserm by the French Institute for Public Health Research (IReSP, *Institut pour la Recherche en Santé Publique*), it aims to bring unprecedented support to the health research continuum, foster a new collaborative model with healthcare professionals and strengthen French expertise in key scientific fields. These range from new trial methodologies through to the development of expertise in the use of health data and biobanks. This initiative provides coherence and resources to serve the entire national scientific community within the innovative fields of clinical research (including primary care) and population-based interventional studies (supported through the call for proposals *Services, Interventions, and Policies for Health* [1]). MESSIDORE strategically complements, rather than duplicates, other funding calls, particularly those led by the French Ministry of labour, health, solidarities and families[2].

2. Scope of the call for research projects

2. 1. Thematic scope

The thematic scope of this call is structured around two main areas:

Area 1 - Methodological Innovations in Clinical Research, Medical Devices, and Trials in Primary Care

This axis consists of three components:

[1] https://iresp.net/thematiques/programme-sip/

[2] Refer to https://sante.gouv.fr/systeme-de-sante/innovation-et-recherche/l-innovation-et-la-recherche-clinique/appels-a-projets/programmes-recherche

- To address emerging challenges in clinical research, this area will support studies aimed at demonstrating the value of novel methodological approaches that could later be implemented in clinical research projects.
- It will also support applied research and evaluation studies focused exclusively on the early development stages of medical devices. This includes research projects with a Technology Readiness Level[3] (TRL) ranging from 1 to 6b (inclusive)[4], including devices incorporating artificial intelligence techniques (*Software as Medical Devices* or SAMD). Projects with higher TRL (TRL levels 6c to 9) should be submitted to calls from the French Ministry of labour, health, solidarities and families, as well as to Bpifrance's dedicated medical device funding programs[5]. Additionally, health economics studies on medical devices are excluded from the scope of this call.
- Trials in primary care[6 ; 7], particularly those incorporating innovative, specific, and/or complex methodologies.

Area 2 - Studies using health data or based on biobanks

This focus area aims to support projects based on *existing databases or biobanks* - for which access protocols are clearly established - particularly if they involve multiple databases or biobanks and encourage data sharing and/or standardization, address the challenge of ensuring the reproducibility of scientific results, and/or contribute to the structuring and long-term sustainability of these databases and biobanks. Support will also be provided for the development of multimodal data processing tools and methodologies (omics data, imaging data, etc.), as well as innovative tools that promote data sharing and reuse.

For projects focusing on rare diseases: if the project is part of a consortium (European or international), it will be required to describe the consortium and specify what the submitted project will finance.

For projects requiring access to SNDS data: it will be crucial to outline the progress of the regulatory procedures when submitting the letter of intent (phase 1 of the call for projects) to confirm the feasibility of the project within the proposed timeline. An update will be possible at the time of the full project submission (phase 2).

Within each focus area, methodological and validation work on the themes of the area will be supported and encouraged.

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[3] https://horizoneuropencpportal.eu/sites/default/files/2022-12/trl-assessment-tool-guide-final.pdf

[4] See annex 1 in the following document: https://sante.gouv.fr/IMG/pdf/note-aap-2024_dgos-ri1.pdf

[5] https://www.bpifrance.fr/nos-appels-a-projets-concours

[6] Primary care encompasses the concepts of first contact, accessibility, coordination and continuity of care. It serves as the gateway to a system that provides local, integrated and continuous care, accessible to the entire population, while also coordinating and integrating services needed at other levels of care. While primary care is the patient's first point of contact with the healthcare system, it also plays a structuring role in shaping the patient's subsequent care pathway.

[7] Project leaders should be aware of the Resp-Ir call for projects, issued by the French Ministry of labour, health, solidarities and families and operated by the Inter-Regional Clinical Research and Innovation Groups (GIRCI), which serves as the main funding channel for these projects (https://sante.gouv.fr/IMG/pdf/note_information_respir_2023_174.pdf)

⚠ Projects that could be funded through other research funding programs, particularly those from the French Ministry of labour, health and solidarities and families, INCa, ANRS-EID and IReSP on addictions, **are not eligible**.

2. 2. Disciplinary fields

This program is intended for the entire national health research community. Projects must be collaborative, or even integrative, involving two or more disciplines of health research (epidemiology, clinical research, fundamental biology, biostatistics, technological research, social sciences).

2. 3. Collaborative aspect

One of the key objectives of the program is to bring together academic research teams, involving at least one Inserm-labelled team, and healthcare providers, involving a team from a healthcare institution[8].

This collaborative aspect[9] must be clearly presented and will be considered in the evaluation.

3. Support modalities

3. 1. Types of projects supported

Large-scale projects and/or those relying on existing research infrastructures and/or data, which can start quickly after the funding notification, will be prioritized, without excluding pilot projects[10].

3. 2. Amounts and eligible durations

Projects between **12 and 48 months** are eligible.
Funding amounts will range **from €100,000 to €1.2 million**, within the limits of the total budget available for the program.

3. 3. Schedule

The selection procedure is divided into two phases: a pre-selection based on letters of intent and a final selection based on full submissions for the pre-selected projects (see submission and selection procedures below: section 4 "Submission and Selection Procedure").

- Launch of the call for projects: **February 10, 2025**;

[8] Medical and pharmaceutical professions, healthcare auxiliaries, healthcare institutions, multidisciplinary health networks, preventive care structures ; refer to viepublique.fr for definitions and stakeholders within the French healthcare system – (https://www.vie-publique.fr/fiches/37853-definition-et-acteurs-du-systeme-de-sante-francais - only available in French).

[9] The project must involve at least one team under Inserm supervision, and one team affiliated with a healthcare institution. Clinical investigation centers (CICs), which are jointly supervised, may apply on their own.

[10] This involves supporting a small-scale preliminary study to determine feasibility, time, cost and risks before carrying out a similar project on a larger scale.

- Deadline for submission of letters of intent: **Friday, April 11, 2025, at noon (Paris time)**;
- Scientific evaluation and selection of letters of intent: Spring 2025;
- Notification of pre-selection results: by early July 2025;
- Deadline for submission of full proposals: **Monday, September 22, 2025, at noon (Paris time)**;
- Scientific evaluation of full proposals: Fall 2025;
- Final selection by the Committee: December 2025;
- Announcement of results: **by January 2026 at the latest**.

The letter of intent, followed by the full proposal, must be submitted on the EVA3 platform (see link below, section 4.2).

4. Submission and Selection Procedure

4. 1. Committees of the Selection Procedure

The selection procedure relies on two committees:

- The **Scientific Evaluation Committee** (SEC), which assesses the scientific quality of the projects and ranks them based on scientific criteria. A confidentiality and conflict-of-interest declaration is signed by each member. The composition of the SEC remains confidential until the results are published.

  The SEC relies on a **network of experts in the projects' fields**. These independent experts conduct scientific evaluations of one or more projects, are chosen for their scientific excellence and adhere to ethical and deontological standards (notably by signing a confidentiality and conflict-of-interest declaration).
- The **Strategic Oversight Committee**, which includes representatives from the Directorate-General for Healthcare Provision (DGOS) and Inserm, whose mission is to assess the overall progress of the program at key stages of the call.

4. 2. Submission procedure

The submission procedure is divided **into two phases**:

- **Phase 1: Letter of intent** evaluated by the SEC for the pre-selection phase
- **Phase 2: Full submission** for pre-selected projects, evaluated by external experts and the SEC during the final selection phase.

The template for the letter of intent to be completed is available on the IReSP website: https://iresp.net/appel_a_projets/appel-a-projets-messidore-2025-methodologie-des-essais-cliniques-innovants-dispositifs-outils-et-recherches-exploitant-les-donnees-de-sante-et-biobanques/

It must be submitted before the specified deadline, in the requested format, and uploaded after completing the online application form on the EVA 3 platform; creating an account is mandatory **for the principal investigator**: https://www.eva3.inserm.fr/login

4. 3. Selection criteria

4. 3. 1. Administrative eligibility criteria

To be administratively eligible, applications must meet the specific administrative requirements of the MESSIDORE call for projects (outlined below), as well as the general rules of IReSP (described in section 5 "Administrative and Financial Rules of the call" below).

Specifically for this call for projects, the following conditions must be met:

- The partnership must involve at least one Inserm-labelled team and healthcare providers, with a team affiliated with a healthcare institution (Clinical investigation centers (CICs) - which are jointly supervised - may apply on their own)
- The scientific description must be written in English
- The principal investigator of the project must reside in France, hold a doctoral degree or an equivalent professional thesis[11], and be actively engaged in research.

4. 3. 2. Scientific eligibility criteria

To be scientifically eligible, projects must meet the following conditions:

- The project must align with one or more focus areas of the MESSIDORE call.
- The project must not fall under any exclusion criteria.

The letter of intent (phase 1 of the call) must particularly justify the alignment of the project with the thematics of the call in the section dedicated to this purpose in the application form on the EVA3 platform, as well as explain why it is not eligible for the funding previously mentioned.

4. 3. 3. Scientific evaluation criteria

These criteria concern the following areas:

- Principal investigator and partner teams:
    - Quality and synergy of the partnership between researchers and on-the-ground practitioners, especially between academic staff and healthcare providers
    - Quality of the teams involved (skills, experience, complementary, etc.)
- Scientific quality:
    - Clarity of objectives
    - Scientific and public health relevance
      Coherence with the targeted themes
      Excellence relative to the state of science
    - Position of the project within the national and international context
- Methodology, degree of maturity, and feasibility:
    - Methodological quality and relevance of the planned technologies and methods

[11] Holders of a state-recognized degree in medicine, pharmacy, or dentistry, with a research activity and residing in France, may also serve as coordinators.

    - Appropriateness and justification of the proposed schedule in relation to the project's objectives
    - Feasibility of the research (access to data, project task completion, detailed program, deliverables, compliance with ethical rules and regulatory requirements, status of authorization requests, declaration of access to databases or cohorts, etc.)
    - Technical, financial and legal-administrative feasibility (budget alignment with the request, compatibility of funding obtained through the call with other funding the unit is or will be receiving)
- Impact of the project:
    - Scale of the project
- Scientific, technical, social and public health impact

The public health impact criterion will be given special consideration during the evaluation and final ranking by the SEC. If this criterion is deemed insufficient, projects aligned with thematic priorities of the French Ministry of labour, health, solidarities and families or French government public health plans may receive enhanced consideration. Currently, the thematic priorities include mental health and psychiatry, various types of health prevention, paediatrics and child health (including child psychiatry), and fertility.

5. Administrative and Financial Rules of the call

5. 1. Eligibility of applicant institutions and affiliated organizations

For each submitted project, the participating teams must designate their respective managing institution, whether it is a recipient of funding or not.
The managing institution is defined as the entity responsible for administering the grant for the execution of the research project as evaluated. It is legally accountable for implementing the contract, including the submission of all financial reports required under the grant agreement.
The managing institution of the principal investigator's team, referred to as the Host Institution, will be the sole entity to enter into a contractual agreement with Inserm. **It will be responsible for distributing the received funds to the managing institutions of the funded partner teams.**

The home institutions of the principal investigator and partner teams **must comply with the following conditions**:

Status of the host institutions of the coordinating team, funded partner teams, and non-funded partner teams

Legal status (based on registered statutes or founding documents)	Institution **eligible for funding** as the host of the **principal investigator**	Institution **eligible for funding** as the host of the **partner teams**	Institution **not requesting funding**

Public institutions			
Public institutions with a research mission: E.P.S.T. (Inserm, CNRS, INRA, etc.), EPSCP (universities, schools, etc.), some E.P.I.C. or EPA, and public health institutions (CH, CHU, etc.)	YES	YES	YES
Regional and local authorities, Regional Health Agencies (ARS)	NO	NO	YES
Private institutions **(see note #1)**			
Non-profit private healthcare institutions with a research mission	YES	YES	YES
Cancer research centers (CLCC)	YES	YES	YES
Public interest groups with a research mission	YES	YES	YES
Research foundations (with a research mission stated in their statutes)	YES	YES	YES
Publicly recognized foundations of public utility (Institut Pasteur, Institut Curie, etc.)	YES	YES	YES
Scientific cooperation foundations (IHU, etc.)	YES	YES	YES
Other foundations	NO	YES	YES
Research associations or health and social mission organizations **(see note #2)**	YES, **under conditions**	YES, **under conditions**	YES
International organizations applying on behalf of research teams based in France	YES	YES	YES
Pharmaceutical, medical device, or food company [12]	NO	NO	NO
Tobacco industry, gambling operators, and alcohol or cannabis supply chains	NO	NO	NO
Other commercial companies (SA, SAS, SARL, etc.) **(see note #3)**	NO	NO	YES

[12] For more information on the definition of pharmaceutical, medical devices, or food companies, please refer to the annex of this call.

Other institutions			
Foreign teams (from a private or public institution)	NO	NO	YES
Other private institutions or public organizations not listed above	*Managing institutions, whether coordinating or partner organizations, not listed here must submit an eligibility request **BEFORE** applying to: messidore@inserm.fr*		

NOTES

(1) For private institutions:

A private institution without a research mission, not involved in research, or not recognized as a public-interest organization cannot apply for funding.

At any stage of the selection process and during the final phase of project implementation, managing institutions may be asked to provide any additional supporting information required to assess their eligibility. The IReSP may declare a structure ineligible after reviewing the submitted documents and information.

An eligible private entity may receive financial support only up to 80% of its allocated budget within the project (i.e., the funding rate must not exceed 80% of the private entity's budget).

(2) For associations:

If the project is preselected, the association's financial health will be assessed at the time of the full proposal submission, notably through a positive income statement. As a private entity, the association must be able to cover at least 20% of the project expenses from its own funds.

(3) For companies:

The outsourcing of services is permitted but should cover only a limited portion of the research project and must be strictly justified (nature of outsourced expenses). These expenses cannot exceed 20% of the total requested funding.

5. 2. For projects preselected in phase 1

The rules described below will apply when preparing the full proposal:

- All necessary documents for Phase 2 ("full submission") — including the scientific proposal template, commitment letters, financial annex, and applicant guide — will be provided to each principal investigator upon notification of preselection.
- **It is strongly recommended to carefully read the guidelines in the applicant guide**, which will be made available to assist with preparing the full proposal and budget.
- The financial annex must be completed correctly, in accordance with the rules outlined in the annex of the applicant guide.
- The funding granted under this call may cover all or part of the project budget.

- Each team must consult its managing institution to ensure the financial setup is coherent before submitting the proposal. **If the project includes costs related to healthcare service provision, the healthcare provider must be a project partner and be listed among the designated partner teams in both the letter of intent and the full proposal.**
- **The minimum funding request is €100,000, and the maximum is €1.2 million.**
- The managing institution may apply **overhead costs** of up to **11% of the eligible expenses**, calculated excluding overhead costs.

6. Valorisation of Scientific Publications

All the scientific leaders involved in the project commit to acknowledging the support of Inserm, IReSP and its supervisory body, the French Ministry of labour, health, solidarities and families, in publications and communications concerning the project ("*This study was supported by a grant from Inserm and the French Ministry of labour, health, solidarities and families in the context of MESSIDORE call operated by IReSP (acronym of the call, year, registration number ; ex. : AAP-MESSIDORE-2025-XXXXX")*.

They must inform IReSP of the publications and send them by email (or a link to access them) within two weeks of their publication, even beyond the end of the funding agreement, and register the studies and results in accordance with the procedures outlined in the funding agreement, in line with Inserm and IReSP's commitments to open science, transparency and research integrity.

7. Contact

For any scientific or administrative inquiries, please contact:

- The MESSIDORE Team: messidore@inserm.fr

For technical aspects related to the EVA platform, please contact:

- The EVA3 technical team: eva@inserm.fr

8. Annex – Definition of pharmaceutical, medical device, and food companies

Note sur les industries pharmaceutiques, les industries de dispositifs médicaux, les industries alimentaires, les industries du tabac et les opérateurs de jeux

Annexe au Guide du candidat pour les candidatures aux appels à projets de l'IReSP

A jour du 25.06.2024

Dans son paragraphe 3.3 du Guide du Candidat, l'IReSP exclut du financement et du partenariat certains types d'entreprises, à savoir :

- Industries pharmaceutiques,
- Industries de dispositifs médicaux,
- Industries alimentaires,
- Industrie du tabac,
- Opérateurs de jeux.

Cette note a pour vocation de définir ces différents organismes afin de mieux guider les candidats des appels à projets.

Les indications du Guide du candidat et par extension de cette note ont une valeur règlementaire et peuvent donc être opposables aux candidats.

1. L’industrie

La définition de **l’industrie** est disponible sur le site du gouvernement : entreprise.gouv.fr :

« L'industrie rassemble les activités économiques dédiées à la conception, la fabrication et la vente de biens matériels. Elle fait intervenir de nombreux acteurs pour transformer des matières premières en biens de consommation. »

2. Les industries pharmaceutiques

Les industries pharmaceutiques sont donc un secteur économique qui regroupes des activités spécifiques liées aux médicaments. **Le médicament** est défini dans le **Code de la santé publique à l’article L5111-1** (dernière modification par Ordonnance n°2022-414, le 23 mars 2022) :

« I.-On entend par médicament à usage humain **toute substance ou composition présentée comme possédant des propriétés curatives ou préventives à l'égard des maladies humaines, ainsi que toute substance ou composition pouvant être utilisée chez l'homme ou pouvant lui être administrée, en vue d'établir un diagnostic médical ou de restaurer, corriger ou modifier ses fonctions physiologiques en exerçant une action pharmacologique, immunologique ou métabolique**.

Sont notamment considérés comme des médicaments les produits diététiques qui renferment dans leur composition des substances chimiques ou biologiques ne constituant pas elles-mêmes des aliments, mais dont la présence confère à ces produits, soit des propriétés spéciales recherchées en thérapeutique diététique, soit des propriétés de repas d'épreuve.

Les produits utilisés pour la désinfection des locaux et pour la prothèse dentaire ne sont pas considérés comme des médicaments.

II.-On entend par médicament vétérinaire tout médicament tel que défini par l'article L. 5141-2.

III.-Lorsque, eu égard à l'ensemble de ses caractéristiques, un produit est susceptible de répondre à la fois à la définition du médicament prévue au premier alinéa du I et au II et à celle d'autres catégories de produits régies par le droit européen ou national, il est, en cas de doute, considéré comme un médicament. »

3. Les industries de dispositifs médicaux

D’autres industries basent leurs activités sur **les dispositifs médicaux**, qui sont définit à l’article **L.5211-1 du Code de la santé publique** :

« II.-On entend par dispositif médical : **tout instrument, appareil, équipement, logiciel, implant, réactif, matière ou autre article, destiné par le fabricant à être utilisé, seul ou en association, chez l'homme pour l'une ou plusieurs des fins médicales mentionnées ci-après et dont l'action principale voulue dans ou sur le corps humain n'est pas obtenue par des moyens pharmacologiques ou immunologiques ni par métabolisme**, mais dont la fonction peut être assistée par de tels moyens :

1° Diagnostic, prévention, surveillance, prédiction, pronostic, traitement ou atténuation d'une maladie ;

2° Diagnostic, contrôle, traitement, atténuation d'une blessure ou d'un handicap ou compensation de ceux-ci ;

3° Investigation, remplacement ou modification d'une structure ou fonction anatomique ou d'un processus ou état physiologique ou pathologique ;

4° Communication d'informations au moyen d'un examen in vitro d'échantillons provenant du corps humain, y compris les dons d'organes, de sang et de tissus.

Sont réputés être des dispositifs médicaux :

- les dispositifs destinés à la maîtrise de la conception ou à l'assistance à celle-ci ;
- les produits spécifiquement destinés au nettoyage, à la désinfection ou à la stérilisation des dispositifs médicaux, de leurs accessoires et des groupes de produits n'ayant pas de destination médicale dont la liste figure à l'annexe XVI du règlement (UE) 2017/745 précité.

III.-On entend par accessoire de dispositif médical : tout article qui, sans être lui-même un dispositif médical, est destiné par son fabricant à être utilisé avec un dispositif médical donné, ou avec plusieurs d'entre eux, pour permettre une utilisation de ce dispositif médical conforme à sa destination, ou pour contribuer spécifiquement et directement à la fonction médicale du dispositif médical selon sa destination. »

4. Les industries alimentaires

Les industries alimentaires sont assimilées à **l'industrie agroalimentaire** (IAA), **définies et listées par l'INSEE** :

« Les industries agricoles et alimentaires (ou agro-alimentaires) correspondent au code EB de la NES, nomenclature de synthèse qui a disparu avec le passage à la NAF Rév. 2 :

- industrie des viandes ;
- industrie du lait ;
- industrie des boissons ;
- travail du grain, fabrication d'aliments pour animaux ;
- industries alimentaires diverses ;
- industrie du tabac. »

Pages internet sources :
https://www.insee.fr/fr/metadonnees/definition/c1426 et
https://www.insee.fr/fr/metadonnees/definition/c1900

5. Les industries du tabac

L'industrie du tabac englobe le secteur économique des « **produits du tabac** », définis dans la **Code de la santé publique à l'article L3512-1** :

« Sont considérés comme **produits du tabac les produits pouvant être consommés et composés, même partiellement, de tabac, qu'il soit ou non génétiquement modifié**.

Les produits du tabac comprennent les cigarettes, le tabac à rouler, le tabac à pipe, le tabac à pipe à eau, les cigares, les cigarillos, le tabac à mâcher, le tabac à priser, le tabac à chauffer et le tabac à usage oral.

Sont également des produits du tabac au sens du premier alinéa, les nouveaux produits du tabac qui sont les produits autres que ceux mentionnés au deuxième alinéa et qui sont mis sur le marché après le 19 mai 2014. »

Pour rappel (article L3512-4 du Code de la santé publique) : « La propagande ou la publicité, directe ou indirecte, en faveur du tabac, des produits du tabac, des ingrédients définis à l'article L. 3512-2, ainsi que toute distribution gratuite ou vente d'un produit du tabac à un prix inférieur à celui qui a été homologué conformément à l'article 572 du code général des impôts sont interdites. »

6. Les opérateurs de jeux

Les **opérateurs de jeu** sont directement définis dans la **Loi n° 2010-476 du 12 mai 2010** relative à l'ouverture à la concurrence et à la régulation du secteur des jeux d'argent et de hasard en ligne en son **article 10, 2°** :

« 2° Est un opérateur de jeux ou de paris en ligne **toute personne qui, de manière habituelle, propose au public des services de jeux ou de paris en ligne comportant des enjeux en valeur monétaire et dont les modalités sont définies par un règlement constitutif d'un contrat d'adhésion au jeu soumis à l'acceptation des joueurs** »