



# **Funding call 2025**

Characterization of preneoplastic lesions and stratification of their evolving risks

Online Submission: https://eva3-accueil.inserm.fr

Deadline: 30/01/2025, 5pm

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#### 1. CONTEXT AND OBJECTIVES OF THE FUNDING CALL

This funding call from Inserm is firmly aligned with one of the key pillars of the 2021-2030 Decade-long Cancer Control Strategy: prevention.

Cancer diseases are multifactorial and extremely complex. Their genesis time is often estimated as several decades, necessary for the accumulation of deficient molecular and cellular processes. If the therapeutic advances against cancer are real, it is possible that the successes would be greater if we could intervene at the earliest stages of tumor development. The identification and characterization of pre-cancerous lesions is therefore a particularly important challenge to allow for the earliest possible therapeutic intervention in order to avoid the progression of cancers to stages that are difficult to be treated.

This requires understanding the biology of the pre-tumoral state and characterizing the factors that influence the transition to cancer or which, on the contrary, lead to the regression of the lesion. Therefore, it is necessary to distinguish lesions with high malignant potential from lesions that will not progress or which will disappear

This call for projects focuses on the study of pre-neoplastic, pediatric or adult lesions that are defined as lesions for which there is clear evidence of association with an increased risk of cancer, or with sharing molecular and phenotypic characteristics with an aggressive type of cancer. Therefore pre-neoplasias are pre-cancerous conditions defined at the cellular level.

The study of pre-neoplasia is largely hampered by the heterogeneity of the lesions, the slowness of their evolution and their small size. The improvement and development of new technologies (imaging; quantification; molecular single cell analysis; alternative experimental models such as organoids; the ability to analyze large-scale heterogeneous data and to establish models; etc.), makes it now possible to consider a more precise multidimensional characterization (study of the microenvironment, the microbiota, the exposome, the metabolome) and classification of pre-neoplasia based on the risk of their evolution into malignancy. Having met these prerequisites, it will be possible to move towards a precision prevention, an enlightened surveillance or an early treatment, adapted to the evolving risk of each lesion.

Inserm wish to continue their support for the development of research in this field. The general objective of the call resides in the characterization of pre-neoplasia and a better stratification of their evolutionary risks.

The goal is the spatial and temporal characterization of potentially malignant lesions, at the molecular, cellular, and tissular level. This will contribute to a better understanding and modelling of their evolution (pre-malignant to malignant transition, stabilization, regression) by characterizing the mechanisms inthe sequence of their formation and the factors involved in the emergence and evolution of the risk, in order to identify intervention targets and stratify the lesions according to their evolution risks.

#### 2. SCOPE OF THE FUNDING CALL

This funding call is open to all disciplines including fundamental to translational research that, **in collaboration with clinicians**, allowing the understanding of the progression of pre-neoplastic lesions to a tumor state or their regression. It will be about to demonstrate when, how and why lesions with malignant potential appear and evolve.

- The project should respond to one of the axes;
- The approaches can be pan-pre-neoplastic or organ-based;
- The choice of pre-lesion (s) must be justified with data from public health, access to samples and patients with sufficient monitoring, data on transformation risks and/or the existence of synergic collaborations;
- Studies requiring human samples should favor existing collections or cohorts that possess sufficient follow-up data, thus allowing to know the rate of progression to cancer. Moreover, the size of the cohorts, the number and the quality of available biological specimens and the quality of clinical annotations will be taken into account by the evaluation committee.

## The following fields are eligible:

#### Axis 1: Genesis of the pre-lesion

- Natural history of pre-neoplasia: longitudinal and spatial characterization
- Multi-scale spatio-temporal interactions with the ecosystem
- Molecular, genetic, epigenetic and metabolic mechanisms at the origin of the pre-lesion
- Retrospective data analysis, reverse trajectory

#### Axis 2: Transition from the pre-lesion to the tumor state

- Control mechanisms (regression, stability)
- Escape mechanisms (progression) of pre-lesions
- Molecular, genetic, epigenetic and metabolic mechanisms, immunosurveillance, dormancy, relation to the microenvironment, intrinsic and extrinsic factors, intercellular dialogues...
- Retrospective data analysis, reverse trajectory

## Axis 3: Risk assessment- Risk mapping - Therapeutic targets

- Modeling of transition from the potential malignant state to the cancerous state
- Identification of risk biomarkers, prediction of progression to malignancy or regression
- Identification of therapeutic targets
- Development of signatures for the stratification of pre-lesions, identification of risk parameters

## The following fields will be considered out of scope:

- Studies focusing exclusively on the identification of susceptible genes or predisposing factors
- Studies not relating to a pre-lesion
- Clinical trials
- The constitution of networks, cohorts, collection of biological or anatomo-clinical data, without any associated scientific question.

## 3. CRITERIA FOR ELIGIBILITY AND PROJECT EVALUATION

For each project submitted, a Scientific Coordinator of the project is identified.

In addition to his/her scientific and technical role, the Coordinator is responsible for setting up the modalities for collaboration between participating teams, **producing the required documents (reports and reports)**, holding meetings, advancing project and the communication of results. He / she ensures the deposit of the application file on behalf of the partners.

The participating teams also designate their recipient Managing Body (which may differ from the organization to which the Coordinator belongs). The managing body is contractually responsible for the implementation of the project and the proper execution of the aid granted, the transmission of all the scientific and financial reports provided for in the agreement.

## 3.1 Eligibility Criteria

To be considered eligible and qualify for submission to the Evaluation Committee, proposals must meet the following conditions:

- The project must meet the objectives of this funding call and fit into one of the fields identified in Section 2,
- The project must have a duration of 12 to 36 months ,
- The consortium executing the project must contain at least 2 teams and a maximum of 4 teams, including a team with clinician. The presence of anatomopathologists is strongly recommended,



- Each team can submit only one application (regardless of their status as a project coordinator or a member of the consortium),
- The Project Coordinator must be a statutory scientist from a French structure: public research body, higher education institution, public health establishment, research foundation recognized as being of public utility, or French comprehensive cancer centers (FCCC). He/She must be involved at least 30% of his/her research time in the project.
- The Managing Body of the Project Coordinator must be a public research organization, a public higher education institution, a public health institution or a recognized public utility research foundation or French comprehensive cancer centers (FCCC) <u>but cannot be an association</u>. See paragraph 5.4 for details
- The application file must be duly completed and include the required documents in accordance with the submission procedures in paragraph **6.1**.
- The project must not be funded by INCa, ANR or DGOS¹ via another call for projects.
- The project must take place in a lab affiliated to a French research organization located in France.
- The same project cannot be submitted to PCSI or MIC 2025 calls.

<sup>&</sup>lt;sup>1</sup> Consequently, when the same Project is selected via different calls, organized by Inserm, INCa, ANR or DGOS, the Project Coordinator will be invited to withdraw from one or more of the fundings received obtained. Similarity is established when the Projects in question describe identical main objectives, and involve mainly identical teams.

## 3.2 Evaluation Criteria

After verification of the eligibility criteria, the applications are submitted to a written evaluation by international experts, and by at least one reviewer of the evaluation committee whose members cannot be involved in the projects.

#### Projects that do not meet the eligibility criteria will not evaluated.

After publication of the list of selected projects, the composition of the evaluation committee is posted on SD-Cancer-PNP-Inserm Pro website of Inserm. The opinions of the committee and experts are sent on request of the Project Coordinator.

The submitted project should demonstrate the capacity of the consortium, depending on the case, to:

- Access to retrospective biological specimens or in the process of collection, pre-malignant specimens of high quality and well annotated;
- Access to pre-cancerous lesions with clear evidence of increased risk of progression to cancer
- Perform complete, longitudinal, multi-parametric and multi-dimensional characterizations of the composition and the architecture of human biological samples;
- Access to innovative technologies and instruments essential to the proposed project;
- Possess the IT expertise for data analysis when required.

The selection committee will appreciate the scientific quality, the synergy of the partnership, the technical and financial feasibility, and the potential impact of the results.

## The criteria for evaluation are:

#### Scientific qualities:

- Excellence beyond the state of the art
- Project relevance and originality
- Positioning of the project in the national and international context
- Clarity of the objectives

## Coordinator and participating teams:

- Skills of the coordinator in his/her discipline
- Complementarity and/or multi-disciplinarity of the various teams associated with the project
- Organisation of collaboration between candidate groups (governance), planning review document production, holding follow up meetings and formatting results.

## Methodology and feasibility:

- Methodological and technical relevance,
- Human resources allocated to the project,
- Technical resources: clinical data biological resource centers, technology platforms, data processing centers, etc
- Quality of the coordination in the consortium (meetings, communication, reports...)
- Credibility of the project's calendar and of the financing requested.
- Adequacy and justification of the budget requested with regard to the objectives of the project

 Adequacy and justification of the time planning proposed with regard to the objectives of the project

## Innovation and development:

- Innovative nature (strategy, concept, technology, etc.)
- Perspectives in terms of later developments, scientific, technical and medical impacts in patient care

## **Budget requested**

Budget will be determined based on the project. The adequacy of the proposed budget indicated by the applicant with the scope of the proposed project will be evaluated by the evaluation committee. The amount granted may be subjected to arbitration.

## 4. CALENDAR OF THE FUNDING CALL

Date of publication of the funding call	October end 2024
Opening of project submission site	26/11/2024
Deadline for submitting application files online	30/01/2025, 5pm
Tentative meeting date for the evaluation committee	Beginning of July 2025
Tentative date for publishing the results <sup>2</sup>	End of July 2025

## 5. ADMINISTRATIVE AND FINANCIAL RULES

## 5.1 Preliminary article - Definitions

<u>Granting Act:</u> Funding agreement or letter by which Inserm notifies the Managing Body of its rights and obligations with respect to conduct of the selected Project. The Granting Act takes the form of a notification letter if the body managing the grant is Inserm. These two instruments are hereafter referred to with the generic term "Granting Act".

<u>Project Coordinator</u>: The person (statutory scientist) responsible for the scientific implementation of the Project as designated in the Granting Act.

<u>Research Foundation</u>: Legal entity governed by private law, **recognized as being of public utility**, the object of which is mainly aimed at research activities and at least **50% of its main activity is devoted to research**.

<sup>&</sup>lt;sup>2</sup> The result will be published on: SD-Cancer-PNP-Inserm Pro et https://itcancer.inserm.fr/

<u>Managing Body</u>: Research body managing the grant to conduct the Research Project as submitted in the Application File. The Managing Body is contractually responsible for implementing the Contract and compiling all the scientific and financial reports stipulated in the Granting Act.

<u>Research organization</u>: Legal entity such as public research organizations (EPST, EPIC, etc.), higher education institutions (universities, schools), research foundations recognized as being of public utility, health establishments, FCCCs.

<u>Partner</u>: A research team contributing to conduct of the Research Project.

<u>Project</u>: Research project presented in the Coordinator's application file and selected during the Call for Projects with regard to its funding within the framework of the Ten-Year cancer control Strategy (2021-2030).

Rules: These financial rules with their appendices.

## 5.2 Scope

This Regulation applies to the Managing bodies managing an Inserm funding for the purpose of carrying out a Research Project selected under the Calls for Projects procedure launched by Inserm.

## 5.3 Contents

Funding is granted by Inserm after the Project has been selected on the basis of the Application File submitted by the Coordinator according to the criteria for eligibility and evaluation of the text of the corresponding tender for projects.

The Application File **must** include:

- The completed scientific file (template available on EVA3)
- The Project budget and its annual distribution, indicated in the financial annex (template available on EVA3, signed and stamped obligatorily) in Excel and PDF format
- The CVs of the Project Coordinator and Partners (compiled in a single file), respecting the template provided on the EVA3 website
- Recent Organizational Charts of Coordinator and Partner Units, indicating the Research teams involved in the project
- The administrative form to be completed online on the EVA3 website
- The Bank Identity Statement of each Managing Body
- Response to previous committee feedback in case of a resubmitted project
- Administrative authorizations for data usage if needed

Note: The templates for documents are available at: SD-Cancer-PNP-Inserm Pro



All incomplete projects will be deemed administratively ineligible.

#### **5.4 Managing Bodies**

Each participating team designates its Managing Body, recipient of funding (which may be different from that to which the Coordinator belongs). The Managing Body is contractually responsible for the implementation of the Project and the proper execution of the aid granted, the transmission of all the scientific and financial reports mentioned in the Granting Act.

The teams belong to one of the following managing bodies:

- Public-sector research institutions (EPST, EPIC, etc.),
- Institutions of higher learning (universities, etc.),
- Research foundations recognized as being of public utility,
- Public-sector health care establishments,
- French Comprehensive cancer centers (FCCC)

Public research teams affiliated with a <u>public-sector body or entity</u> must have their grant managed by their associated public body or one of the mixed administrators of their structure.

The participation of <u>industrial partners and/or foreign teams</u> is possible as long as they provide their own funding in the Project.

If the Project involves different teams associated with different managing bodies benefiting from part of the funds granted, each Managing Body will sign a separate agreement with Inserm.

## **5.5** Coordinator

If there are multiple teams involved<sup>3</sup>, a Project Coordinator must be appointed. Each associated team appoints a scientific leader.

In addition to his/her scientific and technical role, the Coordinator is responsible for organizing the collaboration between participating teams and meetings as well as monitoring progress and communicating results. The project Coordinator is responsible for establishing the required scientific reports and transmitting them to Inserm within the allocated time limit.

The Coordinator ensures the deposit of the application file on behalf of the research project partners.

In case of a change in the current Coordinator of the Granting Act, he/she must immediately notify Inserm of the planned modification.

#### The Coordinator must:

- Be a <u>statutory scientist</u> of a public-sector research body, a public institution of higher learning or a public health care institution, research foundation recognized as being of public utility or FCCC.
- Devote at least 30% of his/her researcher time to the Project.

## 5.6 **Project Duration**

The Managing Body and the Coordinator undertake that the Project will be carried out according to the duration notified in the Granting Act, including any possible modifications.

The request for extension must be sent in writing by the Coordinator on behalf of all the teams. It must be justified and formulated a maximum of <u>6 months before the end of the Project</u>.

The duration of the Research Project determines the eligibility period for expenses, which must be incurred and paid during the duration of the mentioned Project.

<sup>&</sup>lt;sup>3</sup> Refer to eligibility criteria of the call

The Project must begin in the same year as the publication of the results, before 1st November 2025.

## 5.7 **Granting Act**

## 5.7.1 Form of the Act

The Act takes the form of:

- Either a grant agreement signed by the Managing Body and Inserm,
- Or a notification letter sent to the beneficiaries if the Managing Body is Inserm.

## 5.7.2 Obligatory Information that must be mentioned in the Granting Act

The Granting Act is compiled by Inserm on the basis of information in the Application File and the text of the corresponding Tender for Projects.

It must include the following information:

- Title of the Project,
- Duration of the Project,
- Duration of the Granting Act,
- Partners involved in the Project and the Coordinator,
- A copy of the bank details (RIB) of the managing body, in case of non-Inserm,
- The total sum granted and how it is to be paid,
- The obligation to send Inserm the reports mentioned in Articles **5.9** of the Rules. How and when these are to be sent are stipulated in the Granting Act,
- Appendices to the Granting Act:
  - Appendix 1: summary of the Project as stipulated in the Application File,
  - Appendix 2: budget of the Project,
  - Appendix 3: model of the final financial justification.

## **5.7.3** Documents constituting the Granting Act

The documents that make up the Granting Act have the following order of precedence, especially in the event of conflicting provisions:

- The Granting Act and its appendices,
- The current regulations.

#### 5.7.4 Special provisions

Inserm and the Managing Body may include in the Granting Act special obligations and/or exemptions from the Rules that are justified either by specificities of the funded Project or by an agreement between Inserm and one or more of its partners.

## 5.7.5 Notification of the Granting Act

The Granting Act is notified by a letter from Inserm

## **5.7.6** *Modification of the Granting Act*

Inserm will compile and sign an additional clause for any modification of the provisions of the Granting Act.

However, extensions of the duration of the Project, granted on an exceptional basis based on the scientific justification from the Coordinator and a financial proof, are notified via a simple letter to the managing bodies taking care of the grant.

#### Any prolongation cannot exceed 12 months.

A written request must be sent at least 6 months before the end of the Project to cancerinserm.preneoplasie@inserm.fr. It must include a scientific and financial justification explaining the reasons for such an extension and must be signed by the Project Coordinator.

## 5.8 Grant Allocated

## 5.8.1 Co-financing by other public funders

If Inserm becomes aware during the project's execution that the project has received additional funding from INCa or DGOS, regardless of the funding operator, and this has not been previously validated by Inserm, it reserves the right to request partial or full reimbursement of the grant.

In addition, it is likely to trigger an audit of the project, the costs of which may be borne by the beneficiary if the conditions mentioned above are not fulfilled.

## 5.8.2 Calculation of the total sum

The amount of the allocated grant, when it matches the amount requested in the application, takes into account the budget appendix provided by the Project Coordinator during the application submission.

If the total sum granted by Inserm differs from that asked for in the Application File, Inserm sends the Coordinator an E-mail with the global total of the grant that it is intending to attribute to conduct the Project.

In this case, a new financial appendix is compiled, dated and signed by the legal representative of the Managing Body. Then the Coordinator must conduct the Research Project in line with the instructions from Inserm.

If the new financial appendix is not submitted, or there is no response within one month of Inserm's email, the grant will not be awarded.

The grant attributed cannot be less than 25,000 € per participating team in the Project (excluding management fees) and for its entire duration. At least two teams of the consortium should be requesting for funding.

#### 5.8.3 Value Added Tax

In the absence of counterpart to Inserm's financial support and applying the provisions of fiscal instruction BOI-TVA-CHAMP-10-10-60-40 20120912 from the Public Finances Directorate, the grant attributed by Inserm is not subject to VAT.

## 5.8.4 Payment of the subsidy

#### **5.8.4.1** *Schedule*

For Managing Bodies other than Inserm, 80% of the grant will be paid upon signing the Granting Act and within 30 days of the Project's start date. The remaining 20% will be paid after the final reports, as mentioned in paragraph 5.9, have been validated and **in proportion to the justified expenses**.

When the Managing Body is Inserm, credits corresponding to the grant are executed in annual blocks.

## 5.8.4.2 Suspension of the payment

If the project has not been started by the planned date of production of the first scientific report (§5.9.1), Inserm will notify the Managing Body of the breach in a registered letter with acknowledgement of reception. This letter will require the Managing Body to overcome the difficulties encountered within two months of reception of this letter.

If the deficient Managing Body has failed to remedy the problem by this deadline, cancellation is announced.

#### 5.8.5 Grant utilization

The Managing Body must use the grant paid by Inserm exclusively to conduct the Project stipulated in the Granting Act.

At the end of the Project, any unspent moneys is to be reimbursed to Inserm within 30 days from the date of the final financial statement.

## 5.8.6 Eligible expenditure

All expenditure must be directly related to the Project, strictly necessary for its conduct and duly justified.

Only expenses mandated during the duration of the Project are eligible.

## **5.8.6.1** Equipment and Informatics expenditures

The eligible expenditure on equipment is excluding office automation and furniture expenditure. Computers needed to operate experimental instruments or calculations are not considered office automation. For these equipments, a scientific justification is required.

In addition, the computer equipment for staff recruited **on fixed term contracts** (CDD) on the project is possible if the purchase is indicated in the **initial budget annex** and within the limit of **one computer per person recruited on the project for the duration of the project**.

In the context of this Funding Call, expenditure on equipment is only funded <u>up to a maximum of 50,000</u> € HT (excluding managing fees) per partner team for its entire duration.

#### **5.8.6.2 Staff Cost**

Only non-permanent staff costs are eligible.

For private law institutions, permanent staff costs are eligible when these personnel are assigned to the Project within the strict framework of its implementation, and subject to a certificate signed by the Director of Human Resources of the managing body certifying that the CDI is assigned to the Project and indicating the pro rata of time spent on the Project.

The financing of **doctoral contracts is not allowed**.

Staff costs allocated to administrative functions and vacation costs are not eligible.

The budget earmarked for the recruitment of staff cannot exceed 80% of the assistance requested, excluding management costs, per team and cannot exceed the limit of **12 persons / month per year and per team**, (eg for a 36-month project, the number of persons/ months is capped at 36).

Reminder: internship gratuity expenses are to be included in operation cost and not in personnel.

#### 5.8.6.3 Operating Cost

#### Services:

The Coordinator may sub-contract out part of the Inserm-funded work required for the Project to third-party service providers. However, these services must relate to the execution of a limited part of the Project, and when applicable, must comply with public-sector ordering regulations.

## **Consortium agreement:**

The cost of compiling a consortium agreement is eligible if the conditions stipulated in Article 5.14 of these rules are fulfilled.

The other operating costs that are eligible are:

- Consumables,
- Expenses incurred for the travel of researchers (mission) as part of and for the purposes of carrying out the research project,
- Intellectual property expenses for patents and licenses resulting from execution of the Project,
- The costs related to the publication of the results as well as any additional costs applied for the publication of the articles in open access,
- Internship bonus,
- Expenses justified by an in-house billing procedure.

#### **5.8.6.4** Management Costs

A fraction of general administrative costs generated by the Project may appear in the funded expenses. This fraction is limited to 8% of the Project's grant total cost of eligible expenses (this percentage of management fees may change by amendment to these financial regulations) and does not need financial justification. Management fees are calculated on the aid requested and not on the overall cost of the project.

#### 5.8.6.5 VAT

For Managing bodies who are not subject to VAT or only partly subjected, the unrecoverable part of VAT paid out on eligible expenses constitutes an eligible expense. However, an up-to-date certificate from the Public Finances General Directorate (DGFIP) should be provided in order to justify the non-recoverable part of VAT remaining payable by the Managing Body.

#### 5.8.7 Fungibility

The grant paid by Inserm is fungible under the operating costs. Budget can only be transferred to staff costs with the agreement of Inserm that is subjected to a scientific argument sent to cancer.daf@inserm.fr.

#### 5.8.8 Other provisions

If the amount of the grant paid by Inserm does not cover all expenses incurred in executing the Project, the Managing Body undertakes to complement the funding to ensure the Project's proper execution, either from its own resources or by means of one or more co-financing agreements.

In the latter case, the Managing Body will inform Inserm, in the event of co-financing obtained after the notification of the Grant allocated, the name of the co-funding body and the amount of co-funding obtained, including if the other funding body is INCa, ANR or DGOS.

In case, the funding is from other funding call of INCa, ANR or DGOS, Inserm, will study this request and may revise the amount initially allocated accordingly.

## 5.9 Scientific and financial reports

## 5.9.1 Interim and final scientific reports

The Coordinator is to issue reports as stipulated in the Granting Act.

They are to be sent:

- An interim report, six (6) months after the beginning of the Project (start date entered in the Granting Act)
- A Mid-Term Report for Projects lasting more than two years;
- A Final Report within four (4) months of completion of the Project.

## Failure to produce interim or final scientific reports will entail reimbursement of all sums paid by Inserm.

Scientific review of interim or final reports may lead Inserm to ask for complementary information and financial support may be suspended or terminated in the event of failure to adhere to the Project or use of the funds for some other project.

## 5.9.2 Final financial reports

Financial reports are compiled as stipulated in the Granting Act and the Rules. These present the expenses allowed throughout the duration of the Project.

Managing Bodies will issue a Final financial Report within four (4) months of completion of the Project.

The financial report is signed by the person authorized to certify the expenditure within the Managing Body.

#### **5.9.3** Others

Costs related to the certification of expenditure by an external auditor are eligible expenses.

The final scientific report, as well as the final financial proof, jointly referred to as the "Final Reports", guarantee the smooth running of the Project and compliance with the commitments of the Managing Body.

Consequently, failure to produce these documents referred to in these Articles **5.9.1** and **5.9.2** within the time limits may result in the reimbursement of the sum paid by Inserm.

They are to be sent at the same time to Inserm by the grant's Managing Body.

## 5.10 Other undertakings on the part of the Coordinator and the Managing Body

The Coordinator is obliged to tell Inserm about any substantial change to the Research Project vis-a-vis the contents of the Application File, of the Granting Act as well as about any difficulties encountered with conduct of the Project.

The Coordinator also undertakes to actively participate in operations to monitor the Project organized by IT Cancer (Institute thematic) (dissemination workshops, colloquia, etc.).

The Managing Body will inform Inserm of any change of address or bank details.

## 5.11 Organizer - assigned accountant

The organizer of grants and credit transfers is Inserm's Président Directeur Général or by proxy its Finance Director.

The assigned accountant for payments is Inserm's Head Accountant (Agent Comptable Principal).

## **5.12** Technical and financial supervision

At any point during the Project, Inserm reserves the right to organize site visits in concertation with the Managing Body and the Project Coordinator.

Use of the grant paid under the aegis of the Granting Act may, throughout the Project and for five years after its termination, be controlled or audited by Inserm or by an agent appointed by Inserm, by means of a document review or an on-site inspection.

The Managing Body will be expected to be able to justify allocation of funded staff members to the Project as well as all expenditure on the grant.

The Managing Body must be ready to provide all administrative, accounting and legal documents as well as receipts related to use of the grant.

Attention is drawn to the fact that, since this grant corresponds to public money, the funds may be audited by various state supervisory bodies.

## 5.13 Publications – communication

## **5.13.1** Publications

All publications resulting from the Research Project must mention this financial support in the following terms:

"With financial support from 2021-2030 Cancer Control Strategy, on funds administered by Inserm"

Any publications are to be sent to Inserm (cancerinserm.preneoplasie@inserm.fr and itcancer@inserm.fr) in a timely fashion (within five (5) days of publication).

## **5.13.2** Dissemination of the abstract

The Coordinator will authorize the dissemination of the abstracts (in both English and French) contained in the Application File. Before dissemination, the texts will be sent by E-mail to the Coordinator for validation of their contents. In the absence of any response within 45 days, the texts will be considered validated.

## 5.13.3 Impact analysis

The Coordinator undertakes to compile, on request, —for subsequent posting on the IT Cancer Web site—an impact analysis summarizing what the funded Project contributes to the fight against cancer.

## 5.14 Intellectual property & consortium agreement

As funder and issuer of tenders for projects and grants, Inserm does not acquire any intellectual property rights. All intellectual property rights related to work on the Project and its results accrue to the Managing Body. If there is more than one Managing Body, they will have to agree among themselves about the allocation of intellectual property rights.

Compiling a consortium agreement is highly advisable if:

- The overall total of the grant amounts to more than €250,000,
- More than three partners are involved in the Project.

It is obligatory if a private-sector Managing Body becomes a partner in the Project.

## 5.15 Confidentiality

Inserm undertakes to preserve the confidentiality of all information acquired in the course of execution of the project notably that contained in the Activity Report, hereafter referred to as the "Information". Inserm is not allowed to disclose anything at all in any form to any third party (apart from the Steering Committee for the 2021-2030 Ten-Year Cancer Control Strategy) without written permission from the Coordinator.

Nevertheless, Inserm will not be bound to secrecy for a specific point of information if it can prove that:

- The information is in the public domain without there having been infraction of the Granting Act or these Rules,
- The information was already known to Inserm on the date of signing of the Granting Act,
- The information becomes freely available from some other source which has the right to it.

## 5.16 Protection of personal data

Information of a personal nature collected in the Application File will be processed by computer to compile documents and help with the administrative and financial monitoring of Research Projects. In compliance with the Information Technology & Privacy Law of 6 January 1978 as amended in 2018 and in 2019, persons on whom data are collected have rights of access to, rectification of and deletion of information about themselves. These rights can be exercised by application to Inserm, Legal Affairs Department, 101 rue de Tolbiac - 75013 PARIS.

## 5.17 Settlement of disputes

For any conflict between Inserm and the Managing Body relating to interpretation or execution of the Granting Act, both parties undertake to bring their dispute to conciliators appointed by each of them (unless they can agree on a single conciliator) before recourse to any court.

The conciliator(s) will do all they can to settle the difficulties and bring the parties to amiable resolution within sixty (60) days of the date of their appointment.

In the absence of amicable resolution, the administrative judge will be convened to rule on the dispute related to application of the Granting Act.

## 5.18 Date of implementation of these Regulations

These Regulations come into force on the date of their publication. It applies to grants paid by Inserm for Projects selected in this Call for Projects programmed within the framework of Ten-Year cancer control Strategy (2021-2030).

## 6. SUBMISSION PROCEDURE

The submission of your application file includes **2 mandatory steps**:

- 1- Registration on the EVA3 website of Inserm
- 2- Submission of the application form online



Paper version is not required.

## 6.1 Application file

The application must include all elements that are required and needed for the scientific, technical and financial evaluation of the project. Applicants are recommended to produce a scientific and technical description of the project proposal in English as the evaluation is carried out by international experts. If the scientific and technical description is written in French, an English translation may be requested within a deadline compatible with the evaluation process milestones.

The Application File **must** include:

- The completed scientific file (template available on EVA3)
- The Project budget and its annual distribution, indicated in the financial annexe (template available on EVA3, signed and stamped obligatorily) in Excel and PDF format
- The CVs of the Project Coordinator and Partners (gathered in a single file), which respect the template provided on the EVA3 website
- Recent Organizational Charts of Coordinator and Partner Units, including the participating Research teams
- The administrative form to be completed online on the EVA3 website
- The Bank Identity Statement of each Managing Body
- Response to previous committee feedback in case of a resubmitted project
- Administrative authorizations for data usage if needed

**Note:** The templates for documents are available at: SD-Cancer-PNP-Inserm Pro



All incomplete projects will be considered administratively ineligible.

## 6.2 Electronic submission procedure

Site Web: https://www.eva3.inserm.fr

This submission procedure from the EVA3 website of Inserm will include:

- Creation of an account on EVA3/ Identification of the candidate (surname, forename and e-mail),
   allowing the reception of a login and password giving access to a secure personal space on EVA,
- The administrative section, online documents to be filled in your personal space,
- Submission of the required documents (cf. 6.1)

Submission deadline: 30/01/2025, 5pm

Applicants are strongly advised not to wait until the deadline to submit their project proposal.

Paper version of the application is not required.

## 7. PUBLICATION OF THE RESULTS

The list of projects financed will be published on SD-Cancer-PNP-Inserm Pro and IT Cancer website of Inserm. They may be the subject of a *main list* containing the financed projects and of a *complementary* list containing projects that were not retained for funding at the first instance. The potential financing of these complementary projects will depend on any budgetary balance available from the programs of the same year.

For the projects that are financed, the abstract (in French) will be published later, and each Coordinator will be contacted in order to confirm the content or provide a publishable version. Results will be communicated in writing to the Coordinators.

## 8. CONTACTS

For further information, please contact:

- For scientific and technical aspects: cancerinserm.preneoplasie@inserm.fr
- For administrative and financial aspects: cancer.daf@inserm.fr
- For problems relative to the electronic submission : eva@inserm.fr

Do not hesitate to consult the Candidate guide available on our SD-Cancer-PNP-Inserm Pro.