

## Funding call 2024

### Interdisciplinary approaches to oncogenic processes: Functional exploration of the microenvironment of cancers with poor prognosis

The ITMO Cancer of the French Alliance for Life Sciences and Health (AVIESAN) implements the  
research component of this funding call

Inserm implements the operational component of this funding call.

Online Submission: <https://eva3-accueil.inserm.fr/sites/eva/appels-a-projets/pca/Pages/MCMP.aspx>

Deadline: **8/02/2024, 5pm**

Contact: [cancerinserm.mcmp@inserm.fr](mailto:cancerinserm.mcmp@inserm.fr)

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## 1. CONTEXT AND OBJECTIVES OF THE FUNDING CALL

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While the importance of the tumor microenvironment has been known for decades, it's only recently that an integrative decryption of the role of the multiple components of the tumor ecosystem has become important. This decoding has been possible due to major technological advances – and is still in full swing – thus allowing a detailed analysis, in time and space, of the extracellular matrix, stromal cells, immune infiltrates, and vascular and neural networks around the tumor.

The microenvironment is a complex ecosystem, specific to the tissue and organ in which it is found. Interactions of the tumor cells - or in transformation - with this microenvironment are determinant in the evolution of tumor and metastatic processes. Without being exhaustive, and depending on the type of cancer, we can cite cellular stakeholders such as the stroma, fibroblasts, adipocytes, immune cells (myeloid and lymphoid - macrophages, dendritic cells, lymphocytes, granulocytes, etc.), epithelial cells, cells of the vascular system, nervous system, etc. Some of these cells organize themselves into structures such as lymphoid or create vascular or neural networks. All of these structures and cells secrete soluble factors (hormones, growth factors, chemokines, cytokines, enzymes, etc.) and emit micro vesicles (containing in particular microRNAs, transcription factors, enzymes, etc.). They can create physical barriers and control proliferation, cell anchoring and migration. Conversely, the tumor cell produces factors modulating its microenvironment to adapt it to its needs, making it co-evolve with its own progression. Bioavailability and distribution of microenvironmental factors depend on the extracellular matrix which, depending on its composition in macromolecules and fibrillar and structural proteins, allows the establishment of gradients of soluble molecules, reservoirs of transduction signals (by creating barriers to diffusion) and adhesion surfaces or protection zones. The extracellular matrix also has a role in determining the structural maintenance of the tumor and its spatial arrangement.

Dysplastic cells find in this environment sources of energy, oxygenation, nutrients and the signaling necessary for their own evolution. The pro or anti-tumor role of microenvironment is known for a long time.

Envisaging tumor cells in their **natural** microenvironment at **different stages of their progression** and functionally characterizing the **heterogeneity of all compartments of the microenvironment** depending on the **type of cancer with poor prognosis**, to date remains a challenge. Likewise, **the causal role of the microenvironment in the unfavorable prognosis of certain cancers should be explored**. It is hence necessary to capture this complexity, the evolution of the role and composition of the microenvironment in parallel with the evolution of the tumor, in a tissue-specific manner and depending on other perturbations based on patient's history: treatments, exposure to a risk factor, infectious comorbidities, infections and vaccine history, age, immune status, etc. At the same time, making sense of an immense amount of heterogeneous information requires the development, still ongoing, of processing and modeling algorithms (Note: it is the subject of another ITMO Cancer Aviesan call for projects, "MIC"). In essence, addressing the complexity of tumor microenvironment is therefore both interdisciplinary and, within the biology-health discipline, at the intersection of several sub-disciplines or specialties.

In this context, the Cancer Multi Thematic Organism Institute (ITMO) of the National Alliance for Life and Health Sciences (AVIESAN) wishes to continue its support for interdisciplinary research approaches in the field of cancer and to inscribe it as one of the objectives of the Ten-Year Cancer Control Strategy - to which it has actively contributed alongside the National Cancer Institute (INCa) - **by targeting cancers with a poor prognosis** from the outset. The general objective of this call for projects is therefore to finance **interdisciplinary or multi-intra-disciplinary** projects (involving several varied sub-disciplines of the same

discipline) allowing the **functional characterization of the microenvironment of cancers with poor prognosis**, listed under the eligibility criteria.

The aim is to better understand **the role of the tumor microenvironment in the development of cancers for which the treatment options are ineffective and are characterized by a standardized net survival rate at 5 years after diagnosis is less than 33%**. Four lines of research are proposed:

- The high definition spatio-temporal characterization of the microenvironment leading to a functional study
- The high definition decryption of cellular and local signaling networks
- The reprogramming of the tumor microenvironment
- The development of *in vitro* or *ex vivo* models reproducing the spatiotemporal evolution of the tumor/microenvironment couple.

**Target audience:**

A wide range of specialties are concerned: including mainly biochemistry, mechanobiology, cell biology, surgery, anatomopathology, infectiology, immunology, biology of the vascular and lymphatic systems, hematology, bioengineering, image analysis, profiling and spatial technologies, cancer biology, clinical, physics, biophysics, chemistry, mathematics.

The scientific programming of this call is taken care of by ITMO Cancer Aviesan and Inserm is entrusted with the management and the follow up of this call.

## **2. SCOPE OF THE FUNDING CALL**

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### **Eligibility Condition**

- The projects must address **solid or liquid tumors with a poor prognosis** with a standardized net survival rate **at 5 years after diagnosis is < 33%**.
- *Note 1:* The scientific justification for the classification as a 'cancer with a poor prognosis' as defined above must be included in the file (see § 5.3)
- *Note 2:* The use of patient samples is not a prerequisite

### **Eligible Fields**

- The high definition spatiotemporal characterization of the microenvironment leading to a functional study
  - Evolution of the microenvironment based on the tumour state and the perturbations induced
  - Comparative analysis of the microenvironment before and after treatment
  - Evolution of the microenvironment based on the age, tumour state and type
  - Spatiotemporal analysis of the physiochemical role of the extra cellular matrix in the tumour microenvironment
  - Tissue specific functional mapping of the secretome and the interactome of the tumour microenvironment

- Comparative studies of the tumour microenvironment
- Functional characterisation of the establishment of the metastatic niche
- The high definition decryption of cellular and local signaling networks
  - Fine functional characterization of the pro and anti-tumor cell population
  - Detailed characterization of the genetic and/or metabolic network presiding over the intercellular dialogue
  - Impacts of hematological, lymphatic, vascular and neural components on the tumor microenvironment
- Reprogramming of the tumor microenvironment
  - Molecular and cellular mechanisms at the origin of the inhibition of adaptive immunity
  - Comparison of tumor microenvironments of responder and non-responder patients
  - Coevolution of the microenvironment and the tumor
- Fine tuning of *in vitro* or *ex vivo* models reproducing the spatiotemporal evolution of the tumor-microenvironment coupling
  - Characterization of tissue and age specific patient multicellular 3D *ex-vivo* models
  - Development of sequential *in vitro/ex vivo* models of the tumor microenvironment at different times during the course of the disease
  - Comparison of the primary tumor microenvironment with that of the metastatic

#### Out of Scope criteria:

- Projects submitted to the PCSI and MIC 2024 calls are not eligible. The coordinator **must choose a single port of entry for 2024** for the projects in conformity to the eligible fields of these three calls
- Projects on:
  - Cancers not meeting the criteria for a poor prognosis (See §2)
  - Cancers that are not initially of poor prognosis **at the time of diagnosis**
  - Relapse or cancers in the metastatic stage
- Studies that are purely descriptive. **A functional analysis is required.**
- Clinical and therapeutic trials

### 3. CRITERIA FOR ELIGIBILITY AND PROJECT EVALUATION

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#### 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 must be composed of **at least 2 teams and a maximum of 4 teams** belonging **to different disciplines or sub-disciplines**.
- **Each team can submit only one application** (regardless of their status: as a project coordinator or a member of the consortium).
- **The same project cannot be submitted to the MIC or PCSI 2024 Calls**
- 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.
- Only academic partners operating in France within a structure under the supervision of a French organization (public research body, higher education institution, public health establishment, research foundation recognized as being of public utility, or French Comprehensive Cancer Centers (FCCC)) will be funded (for other cases, refer to paragraph 5.4).
- 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) but cannot be an association (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, DGOS and ANR<sup>1</sup> via another call for projects.

### 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 be evaluated.**

After publication of the list of selected projects, the composition of the evaluation committee is posted on the EVA3 website of Inserm. The opinions of the committee and experts are sent upon request of the Project Coordinator.

The Evaluation Committee assesses the scientific justification for the classification of the studied pathology as a "**cancer with a poor prognosis**" according to the definition mentioned in paragraph 2, the scientific quality, the synergy of the partnership, technical and financial feasibility, and the potential impact of the results.

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

**The criteria for evaluation are:**

***Scientific qualities***

- Scientific justification of the classification “cancer with a poor prognosis” (§2)
- Scientific excellence with regard to the state of art
- Relevance and originality of the project
- 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
- Organization of collaboration between candidate groups (governance), planning review document production, holding follow-up meetings and formatting results

***Methodology and feasibility***

- Methodological relevance and relevance of the technologies envisaged
- Human resources allocated to the project
- Technical resources: biological resource centers associated with clinical data, technological platforms, computer data processing centers, etc.
- Quality of coordination between candidate teams (planning of meetings, drafting of monitoring reports, communication, etc.)
- Adequacy and justification of the funding requested with regard to the objectives of the Project
- Adequacy and justification of the proposed schedule with regard to the objectives of the Project

***Innovation and development***

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

***Budget requested***

- The budget will be determined based on the Project. The adequacy of the estimated budget, indicated in the file, with the scope of the proposed Project will also be assessed by the Evaluation Committee, and the budget may be revised accordingly.

## 4. CALENDAR OF THE FUNDING CALL

Date of publication of the funding call	End of October 2023
Opening of project submission site	Nov 30 <sup>th</sup> 2023
Deadline for submitting application files online	February 8 <sup>th</sup> 2024, 5pm
Tentative meeting date for the evaluation committee	Beginning of July 2024
Tentative date for publishing the results <sup>2</sup>	End of July 2024

## 5. ADMINISTRATIVE AND FINANCIAL RULES

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### 5.1 Preliminary article - Definitions

Granting Act: 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".

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

Research Foundation: 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**.

Managing Body: 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.

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

Partner: A research team contributing to conduct of the Research Project.

Project: 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

These Rules apply to Managing Bodies allocated a grant by Inserm to conduct a Research Project, selected in a tender for projects launched by ITMO Cancer of Aviesan and managed by Inserm.

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<sup>2</sup> The results will be published on the EVA3 website of Inserm: <https://www.eva3.inserm.fr> and the Aviesan ITMO Cancer website.



### 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 latest WHO reference regarding the considered nosological subtype and the most recent reference providing the justification for the unfavorable prognosis as qualified in the eligibility criteria (§2)
- 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
- Reply to previous year's committee feedback in case of a resubmitted project
- Administrative authorizations for data usage, if applicable.



**All incomplete projects will be considered 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 **public-sector body or entity** must have their grant managed by their associated public body or one of the mixed administrators of their structure.

**The participation of industrial partners and/or foreign teams 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 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 statutory scientist 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 6 months before the end of the Project.

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.

**The Project must begin in the same year as the publication of the results, before 1<sup>st</sup> October 2024.**

## 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:

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<sup>3</sup> Refer to eligibility criteria

- 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 Article 5.9 of the current 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.mcmp@inserm.fr](mailto:cancerinserm.mcmp@inserm.fr). It must include a scientific 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 is aware, during the execution of the project, that it benefits from another funding from INCa, DGOS or ANR, irrespective of the operator of the said funding and who has not previously been validated by the ITMO Cancer of Aviesan, he reserves the right to request the reimbursement of all or part 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**

When the total sum granted is identical to that asked for in the Application File, it includes the budgetary appendix compiled by the Coordinator and signed when the application is submitted.

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 of Inserm.

In the event of refusal to compile a new financial appendix or failure to answer within one (1) month of Inserm sending the E-mail, no grant will be attributed.

The grant attributed cannot be less **than 25,000 € per participating team** in the Project, excluding management fees, and for its entire duration.

### **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 is paid on signing of the Granting Act and 30 days from the starting date of the Project. Payment of the balance of 20% will be made after validation of the final reports mentioned on paragraph **5.9 in proportion to the justified expenses**.

When the Managing Body is Inserm, credits corresponding to the grant are opened 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, 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

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 equipment, a scientific justification will be required. In addition, the computer equipment of staff recruited on fixed term contracts on the project is possible, if the purchase is indicated in the initial financial 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 up to a maximum of 50,000€ 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 men / month per year and per team**, (ex: for a 36-month project, the number of men / month is capped at 36).

**As a reminder: internship gratuity expenses are to be included in operations 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 fee is 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](mailto: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 this event, the Managing Body will tell Inserm about any co-financing agreed to subsequent to notification of the Granting Act together with the name of the co-financer and the sum of the co-financing, including funding obtained from INCa, DGOS or ANR (cf. § 5.8.1).

In case the funding is from other funding call of INCa, DGOS or ANR, Inserm, after consulting ITMO Cancer of Aviesan, 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 organised by ITMO Cancer of Aviesan (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 Director of Finance.

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 concert 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 moneys, 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 ITMO Cancer of Aviesan within the framework of the 2021-2030 Cancer Control Strategy, on funds administered by Inserm"**

Any publications are to be sent to Inserm ([cancerinserm.mcmp@inserm.fr](mailto:cancerinserm.mcmp@inserm.fr)) and ITMO Cancer of Aviesan ([secretariat.itmo-cancer@aviesan.fr](mailto:secretariat.itmo-cancer@aviesan.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 ITMO 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 ITMO Cancer



of Aviesan and 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 by ITMO Cancer Aviesan within the framework of Ten-Year cancer control Strategy (2021-2030).

## **6. SUBMISSION PROCEDURE**

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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 latest WHO reference regarding the considered nosological subtype and the most recent reference providing the justification for the unfavorable prognosis as qualified in the eligibility criteria (§2)
- 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
- Reply to previous year's committee feedback in case of a resubmitted project
- Administrative authorizations for data usage, if applicable.



**All incomplete projects will be considered administratively ineligible.**

## **6.2 Electronic submission procedure**

Web site: <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 Coordinator (surname, first name and e-mail), allowing the reception of a login and password giving access to a secure personal space on EVA3,
- The administrative section, online documents to be filled in your personal space,
- Submission of the required documents by uploading (cf. § 6.1)

**Submission deadline: 8<sup>th</sup> February 2024, 5pm**

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

## 7. PUBLICATION OF THE RESULTS

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The results will be published on the EVA3 website of Inserm and on the website of ITMO Cancer of Aviesan. They may be subject to a main list containing the funded projects and a supplementary list containing projects not selected for initial funding. The potential funding for these projects on the supplementary list will depend on any additional budgetary supplements provided by surpluses from programs of the same year.

For the funded projects, 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 of selected projects.

## 8. CONTACTS

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For further information, please contact:

- For scientific and technical aspects: [cancerinserm.mcmp@inserm.fr](mailto:cancerinserm.mcmp@inserm.fr)
- For financial aspects: [cancer.daf@inserm.fr](mailto:cancer.daf@inserm.fr)
- For problems relative to the electronic submission: [eva@inserm.fr](mailto:eva@inserm.fr)

Do not hesitate to consult the Candidate guide available on our EVA3 application.