





Funding call 2021

Characterization of preneoplastic lesions and stratification of their evolving risks

The ITMO Cancer of the French Alliance for Life Sciences and Health (AVIESAN) in collaboration with INCa 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/Prénéoplasie.asp

Deadline: 10/12/2020, 5pm

Contact: cancerinserm.preneoplasie@inserm.fr

CONTENTS

1.	C	Conte	xt and objectives of the FUNDING CALL
2.	S	Соре	of the FUNDING CALL4
3.	C	Criteri	ia for eligibility and project evaluation5
	3.1	E	ligibility Criteria5
	3.2	E	valuation Criteria5
4.	C	Calend	dar of the FUNDING CALL7
5.	A	Admin	nistrative and financial rules7
	5.1	P	reliminary article - Definitions:7
	5.2	S	cope7
	5.3	C	ontents 8
	5.4	N	Nanaging Bodies8
	5.5	C	oordinator9
	5.6	P	roject Duration9
	5.7	G	Granting Act9
	5.8	G	irant Allocated
	5.9	S	cientific and financial reports13
	5.10	0 0	Other undertakings on the part of the Coordinator and the Managing Body 14
	5.13	1 0	Organizer - assigned accountant14
	5.12	2 T	echnical and financial supervision14
	5.13	3 P	ublications – communication 14
	5.14	4 Ir	ntellectual property & consortium agreement15
	5.1	5 C	onfidentiality
	5.10	6 P	rotection of personal data15
	5.17	7 S	ettlement of disputes
	5.18	8 D	Pate of implementation of these Rules16
6.	S	Submi	ission procedure
	6.1	Α	pplication file
	6.2	E	lectronic submission procedure
7.	P	Public	ation of the results
0		Conta	ctc 17

1. CONTEXT AND OBJECTIVES OF THE FUNDING CALL

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. This requires understanding the biology of the pre-tumor 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.

The Multi-Organism Institute (ITMO) Cancer of Aviesan Alliance (National Alliance for Life Sciences and Health) in collaboration with the National Institute of cancer (INCa) wish to support the development of research in this field by launching a funding call allowing the characterization of pre-neoplasia and a better stratification of their evolutionary risks.

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

This call for projects is part of a more global approach by ITMO Cancer of Aviesan and INCa, which results in the establishment of a national think tank on pre-neoplasias, bringing together researchers from different disciplines, and a collaboration with the American National Cancer Institute (NCI) on this subject. The teams of the selected projects will be called upon to join this initiative.

The Cancer ITMO of Aviesan in collaboration with INCa implements the research component of this funding call. Inserm implements the operational component of this funding call.

2. SCOPE OF THE FUNDING CALL

This funding call is open to all disciplines including fundamental to translation research that, **in collaboration with clinicians**, allows 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 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 pathologists 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 researcher from a public body, a higher education institution or a health facility. He must be involved at least 30% of his 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, 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 or DGOS via another call for projects.

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

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.

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 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 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, planning review document production, holding follow up meetings and formatting results.

Methodology and feasibility:

- Methodological and technical relevance,
- Project environment (human resources, host structure),
- Quality of the coordination in the consortium (meetings, communication, reports...)
- Credibility of the project's calendar and of the financing requested.

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. It must be taken into account that an excessively quoted budget may not be favoured during the final round of ranking.

4. CALENDAR OF THE FUNDING CALL

Date of publication of the funding call	September 22 nd 2020
Opening of project submission site	October 22 nd 2020
Deadline for submitting application files online	December 10 th 2020, 5pm
Tentative meeting date for the evaluation committee	Mid of April 2021
Tentative date for publishing the results	End of April 2021

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>Research Charity</u>: a private body subject to the Law of 1901 devoting at least 50% of its main activity to research.

<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>Project Coordinator</u>: the person responsible for the scientific conduct of the Project as designated in the Granting Act.

<u>Research body</u>: This term refers to all entities such as public sector research institutions (EPST, EPIC, etc.), institutions of higher learning (universities, etc.), research foundations, health care establishments, and any other body involved in the research field.

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

<u>Project</u>: research project addressed in the scientist's Application File and selected by funding call for funding.

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.

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 includes:

- A scientific file,
- The Project's budget broken down in the financial appendices. The financial annexe should be uploaded as an Excel document <u>AND</u> as a signed and stamped PDF version.
- The CVs of the Project Coordinator and the Director(s) of any associated team(s) (all in a single file)
 which respect the template provided on the EVA3 website,
- The Administrative Form to be filled in online
- The bank statement of each Managing body.

<u>For research charities</u>, the following complementary documents should be appended to the Application File:

- Previous year's accounts together with forecasts and a financial plan, all following Inserm models.
- Updated status



All incomplete projects will be considered administratively ineligible.

5.4 Managing Bodies

Teams belong to the following bodies:

- Public-sector research institutions (EPST, EPIC, etc.),
- Institutions of higher learning (universities, etc.),
- Research foundations,
- Public-sector health care establishments,
- Other bodies involved in the research field.

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.

The funding of charities (<u>as defined in the 1901 Law</u>) not classified as **Research Charities** is not allowed. Management via a charity is only possible if it justifies research activity (minima 50%).

Similarly, Inserm will check the capacity of charities to finance the part of the cost, which is self-financed. In the course of the selection process, Inserm may check that any partner charities in the Research Project are in a position to finance the part of the cost of the research not covered by the Inserm grant.

When administrative and financial files are being finalized, charities allocated a grant may be asked for further information.

If the Project involves different teams associated with different 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 involved¹, 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 compiling the required reports and their transmission to Inserm.

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

The Coordinator must:

- Be a <u>statutory employee</u> of a public-sector research body, a public institution of higher learning or a public health care institution,
- Devote at least 30% of his/her time to the Project.

5.6 **Project Duration**

The Managing Body and the Coordinator undertake that the Project will be completed within the time frame stipulated in the Granting Act notwithstanding possible modifications.

The request for extension must be sent in writing by the Coordinator **within 6 months** of the end of the Granting Act.

Duration of the Project corresponds to that in which expenses must be assumed and paid.

The Project must begin before December 1st 2021.

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,

¹ Refer to eligibility criteria

- Duration of the Granting Act,
- Partners involved in the Project and the Coordinator,
- 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 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 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,
 - Appendix 1: summary of the Project as stipulated in the Application File,
 - Appendix 2: budget of the Project,
 - Appendix 3: model of the financial justification.
- The Rules

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 modification of the Project in the framework of the Tender for Projects 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, prolongation of the duration of the Project, agreed to on an exceptional basis, is notified by a simple letter sent to the grant's Coordinator or Managing Body.

Any prolongation cannot exceed 12 months. A request must be sent at least 6 months before the end of the project to cancer.preneoplasie@inserm.fr. It must include a signed scientific argument on an official letter head explaining the reasons for an extension.

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 or DGOS, 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 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 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 month of Inserm sending the E-mail, no grant will be attributed.

The grant attributed cannot be less than 25,000 € per team participating in the Project 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. Payment of the balance of 20% will be made after validation of the final reports mentioned on paragraph 5.9.

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 (§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 agreement.

At the end of the Project, any unspent moneys are to be reimbursed to Inserm within 30 days

5.8.6 Eligible expenditure

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

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 equipments, a scientific justification is required.

In the context of this Funding Call, expenditure on equipment is only funded <u>up to a maximum of 50,000</u> € per partner team.

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. An attestation signed by the HRD of the Managing Body must be provided.

The financing of doctoral contracts is not allowed.

Staff costs allocated to administrative functions are not eligible.

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

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 only bear on execution of a small part of the Project and 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,
- Project-related travelling expenses for scientists,
- Intellectual property expenses for patents and licenses resulting from execution of the Project,
- Publication expenses
- 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 and does not need financial justification.

5.8.6.5 VAT

For partners 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 expenses ticket. Budget can only be transferred for staff costs with the agreement of Inserm that is subjected to a scientific argument.

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 agreement together with the name of the co-financer and the sum of the co-financing, including funding obtained from INCa or DGOS.

In case the funding is from other funding call of INCa or DGOS, 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 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
- A Mid-Term Report half way through the Project 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 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.

Charities send an interim financial report on the anniversary date of the Granting Act.

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

Financial reports are signed by the Coordinator together with a financial manager in such a way as to represent the Managing Body. They are to be sent to Inserm by the grant's Managing Body.

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

At the end of the Project, any remaining sum will be paid back to Inserm by the Managing Body within 30 days.

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/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 and INCa (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 two 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 and INCa on funds administered by Inserm"

Any publications are to be sent to Inserm and ITMO Cancer of Aviesan 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—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 INCa) 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 grant agreement or the Rules,
- The information was already known to Inserm on the date of signing of the agreement,
- 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, 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 <u>Date of implementation of these Rules</u>

These Rules come into force on the date of their publication.

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 necessary.

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. 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 applicant's file is composed of 5 elements:

- The scientific file (download the template to be used),
- The financial annexes (download the Excel file to be used and upload an Excel version AND a signed and stamped PDF version),
- CVs of PI and Co-PI (together in a single file) using the template provided,
- Administrative forms (you have to fill it online on EVA3 in your personal space)
- Bank details (Relevé d'Identité Bancaire).



All incomplete projects will be considered administratively ineligible.

6.2 Electronic submission procedure

Site Web: https://eva3-accueil.inserm.fr/sites/eva/appels-a-projets/pca/Pages/Pré-néoplasie.aspx

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 by uploading (scientific file (pdf), financial annexes (Excel
 and pdf), CV of the project coordinator and heads of the participating groups (pdf) and bank
 details (RIB)).
- Charities must add the following supplementary documents:
 - The balance sheet of the closed fiscal year
 - The up-to-date statuses

Submission deadline: December 10th 2020, 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 the EVA3 website of Inserm, the ITMO Cancer of Aviesan and INCa websites. They may be the subject of a main list containing the financed projects and of a complementary list containing not selected projects for financing at first instance. The potential financing of these complementary projects will depend on any budgetary supplements brought by balances due to cancellations or postponements of 2021 Cancer Programs.

For these projects, the abstract (in French) will be published later, and each applicant 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 EVA3 application.