2014 CALL FOR PROPOSALS

Spontaneous tumor models in animals for translational research in oncology

The Cancer ITMO of the French National Alliance for Life and Health Sciences (AVIESAN), in collaboration with the Institut National du Cancer (French National Cancer Institute) and Inserm, implements the research section of the cancer plan; the budget allocated to the various actions (call for proposals, call for applicants, support for cohorts, integrated platforms and research centers, etc.) is about €27M in 2014.

Electronic submission: https://www.eva2.inserm.fr/EVA/jsp/

Deadline: November 5th, 2013

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Increasing collaboration between veterinarians, researchers and clinicians for the transfer of cancer research results.

Supporting research and development projects for tools for assessing treatments of spontaneous cancers in animals in a medical perspective for diagnosing and treating cancer in humans.

1. **Context and objectives of the call for proposals**

Although the diagnosis and the treatment of cancers have greatly changed in the last few decades, it must be acknowledged that a good deal of progress is still indispensable in order to improve the therapeutic prognosis from a mortality standpoint as well as a morbidity standpoint. The development of new cancer diagnosis and treatment tools is at the core of the strategic orientations listed in the French Cancer Plan for 2014 - 2018. As such, developing experimental alternatives in animals at the various stages of clinical trials of new antineoplastic treatments in humans is one of the actions of the Cancer Plan. This call for proposals is organized by the Cancer TMOI of the French National Alliance for Life and Health Sciences (AVIESAN) jointly with the Institut National du Cancer (French National Cancer Institute). The operational management and follow-up have been entrusted to Inserm.

The validation and the development of new therapeutic concepts have limits when they are studied from mouse tumours or human tumours implanted in immunodeficient mice, in KO or transgenic mice or in other species. It is widely accepted that more relevant preclinical models are needed.

For example, certain spontaneous tumors in dogs have biological and clinical similarities with human tumors and these canine models seem to be a complementary alternative to existing models for validating new antineoplastic treatments. Over the last few years, decrypting the canine genome and the first experimental studies have opened the door to the development of translational research and the use of these animal models should increase in the future.

The general objective of this call for proposals is to develop collaboration between various disciplines and to incorporate spontaneous cancers developed in animals, in particular in dogs into the global studies of biology of cancer, diagnosis, prognosis and the treatment of neoplastic diseases. The projects must bring together veterinary and medical oncologists, pathologists, surgeons, geneticists and molecular and cellular biologists, but also methodologists and statisticians.

The types of cancers which will be given priority consideration are those that not only comprise a major concern in the animal population but which also have comparative value for clinical research in humans.

Innovative existing projects (relay financing), exploratory projects aimed at a future full application (start-up) or high-risk projects that may not be considered for funding through existing mechanisms will be eligible for this call for proposals. The spontaneous tumour models identified will also be able to be used in the medium and long term to develop various therapeutic and/or diagnostic approaches.

The proposed projects must fall clearly within the scope - even over the long term - of a medical application and entail multidisciplinary research. Whenever possible, interaction between veterinarians
and physicians will be encouraged with the purpose of establishing and strengthening comparative oncology in order to facilitate translational research in the field of cancer. Establishment of a new consortium will be considered with particular interest.

2. **Scope of the call for proposals**

This call for proposals covers not only new approaches in treating cancers in pets (dogs and cats in particular) which could be transferred to early phase clinical trials in humans (adults or children), the validation of the use of targeted treatment in pets, but also the development and/or optimization of new imaging techniques and new therapeutic tools suitable for these species of animal and the characterization of new biomarkers.

The following fields are clearly eligible:

- development of new research tools in the field of cancer (for example targeted monoclonal antibodies from a bank created in dogs),
- development of new therapeutic approaches (for example tests of these monoclonal antibodies alone or in association with other molecules in dogs with spontaneous cancers),
- development of resources and reagents, cell lines, tissue banks and the use of collections of samples in order to validate new classifications of tumors,
- Characterisation and pathophysiological studies on animal models and confirmation of their relevance to human diseases,
- development of new technologies and the use of imaging coupled with antibodies,
- development of preclinical and clinical studies in the investigation centers of the French national veterinary schools,
- Opportunities for clinical research in humans including a section of preclinical studies in animals.

The following projects are out of scope:

- Projects aimed at improving the diagnosis and therapies solely in animals,
- Cancer models induced in animals (eg. the mouse or any other genetically modified animal).

3. **Participation particulars**

3.a. **Duration of the projects**

The projects may have a duration of 12 to 36 months. Projects will begin in 2014.

3.b. **Eligible teams**

The projects shall associate at least two teams that belong to different disciplines, different research units and/or bodies.

- The teams shall belong to the following bodies:
  - Public research bodies (EPST (French Public Establishments for Scientific and Technological Research), EPIC (French Public Industrial and Commercial Establishment), etc.),
- Higher education institute (University, schools, etc.),
- Research foundations,
- Healthcare institutions,
- Other bodies that work in the area of research.

The participation of industrial partners and/or foreign teams is possible as long as the latter provide their own financing in the project.

3.c. Coordinator
For each project submitted, the participating teams shall designate a scientific coordinator for the project. In addition to his or her scientific and technical role, the coordinator is responsible for setting up the procedures for the collaboration between the participating teams, for the production of the required documents (reports and assessments), holding meetings, the progress and the communication of results.

The project coordinator must be:

- A permanent member of a public research organization or of a higher public education institute,
- involved at least 30% of their time in the project.

Applications from early-stage investigators are strongly encouraged.

3.d. Management body
For each project submitted, the participating teams shall designate their management body to receive the funding (which can be different from the body that the coordinator belongs to). The bank information (Relevé d'Identité Bancaire) will be included to the application file.

The management body is contractually liable to Inserm for implementing the contract, forwarding all of the financial and scientific reports provided for in the agreement.

For projects that involve several teams that belong to different bodies, and which benefit from a portion of the funds awarded, each management body shall sign an agreement concluded with Inserm.

4. Criteria for project eligibility and evaluation
After the eligibility criteria have been verified, the applications are submitted for a written evaluation by international experts and a representative from the assessment committee, the members of which cannot be involved in the projects. Projects which do not meet the eligibility criteria shown in point 4a will not be assessed.

After publication of the list of projects selected, the membership of the assessment committee will be posted on the EVA website of Inserm. The opinions of the committee and experts will be sent at the request of the project co-ordinator.

4.a. Criteria for eligibility
In order to be eligible, the projects must satisfy the following conditions:

- The application file must be duly completed and include the required documents, and comply with the submission procedures mentioned in point 7,
• The project must meet the objectives of this call for proposals and fall within one of the fields identified in point 2,
• The project must have a duration of 12 to 36 months,
• The consortium must combine at least two teams,
• The project coordinator must be, save for some exceptions, a permanent researcher of a public body or of a higher public education institute,
• The project coordinator must spend at least 30% of his/her time in the project,
• The management body of the project coordinator must not be an association.

4.b. Criteria for evaluation

Scientific qualities:
• Project relevance and originality,
• Relevance of the animal model used to human diseases,
• Positioning of the project in the national and international context,
• Clarity of the objectives.

Methodology and feasibility:
• Methodological relevance (involvement of methodologists/statisticians),
• Project environment (human resources, host structure),
• Credibility of the project's calendar and of the financing requested.

Coordinator and participating teams:
• Skills of the coordinator in his discipline; (Applications form early-stage coordinators are welcome),
• Complementarity and/or multidisciplinarity of the various teams associated with the project,
• Skills of the associated teams in their discipline.

Innovation and development:
• Innovative nature (strategy, concept, technology, etc.);
• Perspectives in terms of later developments.

5. Provisions for funding

5.a. General methods

Funding is awarded for the duration of the project (12 to 36 months). The amount requested must be duly justified and show the breakdown for the detailed portion allocated for operation, small pieces of equipment and grants for personnel.

The funding awarded to each project shall be provided in the form of a non-refundable grant within the framework of an agreement between Inserm and the management body designated in the application file.

Assistance of less than €25,000 will not be provided to a partner of a project.
The grant from Inserm can be used to fund:
- Equipment,
- Missions,
- Operations and various scientific consumable items,
- Provisions of service,
- Personnel costs for non-permanent personnel,
- Management costs, for a maximum of 4% of the grant awarded by Inserm (teams for which the management body is Inserm will not incorporate management costs).

Personnel costs for administrative support functions are not eligible.

**Funding of doctoral students is excluded in this call for proposals.** An annual call for applicants intended for training physicians, dentists, pharmacists and veterinarians via research on translational research projects is open to doctoral students (opening in December 2013 with taking up duty in the fall of 2014).

For private law establishments, personnel holding open-ended contracts assigned to the research project and for whom funding is requested in the strict framework of conducting the research project is authorized.

Budgetary items except for the "personnel" item shall be fungible during the execution of the project, after approval obtained from Inserm.

### 5.b. Methods for funding associations

Management via an association cannot be retained unless it can justify research activity. Funding for not-for-profit associations is not, save for some exceptions, authorized; public research teams that are attached to a public body or entity must have their grant managed by the public body they are attached to or by one of the joint authorities of their structure.

Associations in difficulty are not eligible for funding allocated within the framework of the Cancer Plan. Inserm will therefore ensure, for all of the projects selected and funded by the Institute and at the end of the selection process that any partner associations in the research project are not in this situation. Likewise, Inserm will make sure of the association's ability to fund the counterpart of the work remaining at their expense. Inserm will therefore ensure for all of the projects funded by Inserm at the end of the selection process any partner associations in the research project are able to fund the portion of the work that is not covered by the grant from Inserm.

Associations selected for funding can be called on, during the finalization phase of the administrative and financial aspects, to provide any additional items for assessment.

### 6. Calendar of the call for proposals

| Date of publication of the call for proposals: | September 2013 |
| Opening of project submission site: | October 4th, 2013 |
7. Submission procedure

7.a. Electronic submission procedure

Website: https://www.eva2.inserm.fr/EVA/jsp/AppelsOffres/CANCER/index_F.jsp

This submission procedure from the EVA website of INSERM will include:

- Identification of the candidate (surname, first name and e-mail),
- Administrative section, as a form to be completed online,
- Submission of the required documents by uploading (scientific dossier, financial appendices and CV of the project co-ordinator and heads of the participating groups).

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

Submission deadline: November 5th, 2013

7.b. Application

The application must include all of the 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 complete dossier is submitted in electronic format and in paper format.

Both formats are identical except for the signatures which are required only on the original paper version.

7.c. Paper format

Two copies of the application dossier including 1 original signed by the people responsible (management body + project scientific co-ordinator) sent to the following address:

Inserm – DESP
Plan Cancer – AAP « Tumeurs Spontannées »
101, rue de Tolbiac
75013 Paris - France

Submission deadline: November 5th, 2013 (submission date based on the postmark)
8. **Publication of the results**

The list of projects financed will be published on the EVA website of Inserm. For these projects, the abstract 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 and to the legal representatives of the management bodies.

9. **Contacts**

For further information, please contact:

- for scientific and technical aspects: plancancermodel@inserm.fr
- for administrative and financial aspects: plancancer.daf@inserm.fr

Please do not hesitate to refer to the application guide.