



Measure 1

2013 CALL FOR PROPOSALS

Spontaneous tumor models in animals for translational research in oncology

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.

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

Deadline: November 15, 2012

Contact: plancancermodel@inserm.fr

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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 2009-2013. 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 in measure 1 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:

- The development of new research tools in the field of cancer (for example targeted monoclonal antibodies from a bank created in dogs)
- The development of new therapeutic approaches (for example tests of these monoclonal antibodies alone or in association with other molecules in dogs with spontaneous cancers)
- The 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
- The development of new technologies and the use of imaging coupled with antibodies.
- The 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 24 to 36 months. Projects will begin in 2013.

3.b. Eligible teams

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

- The teams shall belong to the following bodies:
 - Public research bodies (EPSTs (French Public Establishments for Scientific and Technological Research), EPICs (French Public Industrial and Commercial Establishments), etc.);
 - Higher education institutions (Universities, schools, etc.)
 - Research Foundations
 - Healthcare institutions
- The participation of foreign teams is possible as long as the latter provide their own financing in the project.
- Private veterinary clinics or industrial partners 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 spend **at least 30% of their time on the project**. Applications from early-stage investigators and women 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 eligibility and project 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 identified fields mentioned in point 2
- The project must have a duration that is compliant with the duration mentioned in point 3.a;
- The project coordinator must devote at least 30% of his/her time
- A calendar of key stages must be presented. This calendar will be a primary element for monitoring results.

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 from early-stage coordinators are welcome)
- Complementarity and/or multidisciplinary 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. General provisions for financing

Financing is awarded for the duration of the project (24 to 36 months).

The financing 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 INSERM grant can be used to finance:

- Equipment (< €50,000 exc. tax)
- Operations and various consumable items
- Missions
- Provisions of service
- Personnel costs for temporary staff and post-doctoral researchers; Management costs, for a maximum of 4% of the grant awarded by INSERM. (teams which are managed by Inserm will not include management costs)

Funding of PhD students is not allowed in this call for proposals. Budgetary items shall be fungible during the execution of the project, after approval obtained from INSERM.

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

6. Calendar of the call for proposals

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| Date of publication of the call for proposals: | | September, 2012 |
| Opening of project submission site: | | October 3, 2012 |
| Deadline for submitting application files | 1. Electronic submission of the complete application and 2. Paper copy (including 1 original) sent by the post to: | November 15, 2012 |
| Tentative meeting date for the evaluation committee: | | End-March 2013 |
| Tentative date for publishing the results: | | End-March 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),
- ✚ the administrative section, as a form to be completed on line
- ✚ 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 15, 2012

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
101, rue de Tolbiac
75013 Paris - France

Submission deadline: November 15, 2012 (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