Call for projects 2016

Tertiary prevention in oncology: Developing a prevention strategy for patients with cancer

With support of the French Institute for Public Health Research

Notice of call for projects

1- Context

The latest estimates of cancer prevalence indicate that by 2008, three million people in France had already had one cancer in their lifetime. The increase in the number of people living with a cancer diagnosis, during or after treatment – an increase that may be explained by the increasing number of cancers diagnosed each year and by the improvement in the associated survival rates - has unveiled new issues. The development of a tertiary prevention strategy, targeting avoidable risk factors in patients, is thus essential to improve their chance of survival, their quality of life during and after treatment and, generally speaking, their short-, medium- and long-term health. The persistence of avoidable risk factors (smoking, alcohol, obesity, sedentary lifestyle, etc.) in cancer patients is likely to not only speed the tumorigenesis process (recurrent or second cancer) but also exacerbate the treatment-induced toxicities and increase the risk of other illnesses, such as cardiovascular diseases, occurring.

Of all the tertiary prevention measures, the 2014-2019 Cancer Plan recognises systematic support for stopping smoking for patients who smoke as a measure which must be considered as separate from cancer treatment and include the involvement of all health professionals in supporting their patient. There exists a causal link between smoking in cancer patients and worsening health, an increase in mortality (overall and specific), a risk of second primary cancers occurring and a decrease in physical and psychological quality of life. However, according to a French study

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carried out on a patient cohort, nearly two thirds of patients who smoke continue to do so two years after their diagnosis despite undergoing medical treatment for their cancer.\(^3\)

Nutritional support for patients should also be promoted as a preventative measure. Indeed, the American Cancer Society has published nutritional recommendations aiming to improve cancer patients’ health. A study carried out in the United States on over 9,000 people who had had cancer, nevertheless showed that few patients followed these recommendations, while a previous study showed that a low-calorie diet was linked to a reduction in the risk of breast cancer recurring.\(^4,5\) Excess body weight is also linked to a greater risk of second primary cancer after breast cancer, as well as an increased risk of cancer recurring.\(^6,7\) In the light of recent scientific data, nutritional support for cancer patients, focusing primarily on issues of patient malnutrition, has led to the issues of excess body weight or obesity being considered. Changes to nutritional information, including messages about reducing alcohol consumption, and physical exercise, are possible measures that could complement nutritional support work. Indeed, physical activity during and after treatment improves quality of life and reduces fatigue in cancer patients, with no side effects. Available epidemiological studies also highlight the link between physical activity and increased survival rates (overall and specific) and a decreased risk of recurrence.\(^8,9\)

Thus, developing a strategy for preventing exposure to avoidable risk factors (smoking, alcohol, sedentary lifestyle, excess weight) and ensuring patients comply better with prevention advice are new challenges for personalised care in oncology in order to improve quality of life and health of cancer patients and reduce the risk of morbidity and mortality in the long term.

Against this backdrop, the ARC Foundation, the France National Cancer Institute (INCa) and the French Institute for Public Health Research (IReSP) have collaborated to implement one of the measures of the 2014-2019 Cancer Plan: “Promote observation and research dedicated to preventing risks of second cancer”. Following an international scientific symposium dedicated to this measure, the ARC Foundation and the INCa, with the support of the IReSP, are continuing their commitment to research on cancer prevention through this call for projects: “Tertiary prevention in oncology: Developing a prevention strategy for cancer patients”. The partners of the call for projects therefore wish to enlist French research teams, in collaboration with players on the ground, for original, ambitious and innovative projects on complex issues regarding behavioural risk factors and their prevention in cancer patients.

2. Aims

The aim of this call for projects is to support innovative research on the prevention of behavioural risk factors (smoking, alcohol, sedentary lifestyle, excess weight) in patients with cancer in order to

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\(^3\) Blanchard CM et al. Cancer survivors’ adherence to lifestyle behavior recommendations and associations with health-related quality of life: results from the American Cancer Society’s SCS-II. J Clin Oncol. 2008 May 1;26(13):2198-204.
generate new knowledge (prevalence, determining factors, effects on patients’ health, etc.) and/or carry out interventions to reduce exposure to these factors.

3- Scope of the call for projects

The projects expected as part of this call for projects must fall within at least one of the following three priority areas:

**Priority Area 1: The health of people who have had cancer and the expected benefits of tertiary prevention strategies**

Epidemiological studies from France and abroad have helped estimate the risk of second cancer and associate this risk with several behavioural risk factors (smoking, alcohol consumption and excess weight)\(^{11,12}\). Beyond the risk of second cancer, the current data still has several shortcomings regarding the overall state of health of patients some time after diagnosis (prevalence of co-morbidities, care needed, etc.). Furthermore, studies investigating the presence of behavioural risk factors at the time of diagnosis - with or without follow-up - and more particularly the impact on patients’ health of changes to these factors are still rare.

Projects within this priority area should notably focus on:

- Studying the health of patients with cancer some time after diagnosis (overall state of health, prevalence of co-morbidities, care needed, etc.) and the impact of behavioural change on state of health;
- Better understanding the expected benefits from different prevention strategies implemented in patients;
- Documenting the prevalence of behavioural risk factors and changes to exposure to these factors before and after diagnosis, as well as factors determining changes to risky behaviour.

As regards the means to be used, the projects proposed should be based on:

- cohorts, or
- existing medico-economic databases, or
- clinical trials including an ancillary study studying behavioural risk factors during treatment.

**Priority Area 2: Barriers and facilitators to behaviour change in cancer patients**

Falling ill, in particular with cancer, can be a real disruption to a patient’s daily life and can lead to their deciding to change certain risk behaviours. Indeed, a French study shows that nearly 70% of patients asked would be willing to change their behaviour (diet, alcohol consumption or smoking) to increase their life expectancy by a few years\(^{3}\). British and American studies also show such behaviour changes and consider a cancer diagnosis as an opportune moment in a person’s life for changing risky behaviour, known as a “teachable moment”)\(^{13}\).

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\(^{12}\) Identifie et prévenir les risques de second cancer primitif chez l’adulte, collection Etat des lieux et des connaissances, INCa, décembre 2013.

Health professionals and oncologists in particular play a key role in heightening patients’ awareness of prevention advice\(^4\). It seems, however, that health professionals are reticent or unable to give prevention advice in particular to certain populations of patients (poor prognosis, fragile mental health, elderly, etc.)\(^1\).

Projects within this priority area may focus on:
- Observation of barriers developed by patients and/or health professionals to implementing a prevention strategy as part of treatment following a cancer diagnosis;
- Acquisition of data on starting and/or continuing changes of behavioural risks in patients with cancer, some time after diagnosis;
- Identification of barriers and facilitators for certain types of patients who need specific strategies (presence of comorbidities or anxio-depressive disorders, patients who had pediatric cancer, those with a high genetic risk of developing cancer, etc.); The issue of the relationship between prevention and risky behaviour in different populations may be examined;
- Dialogue between health professionals and patients regarding prevention and behaviour change;
- Use of engaging communication methods in delivery of prevention advice;
- Training of healthcare staff in supporting patients in behaviour change;
- Identification of favourable means (when, who, how, etc.) of delivering prevention advice.

**Priority Area 3: How can patients’ behaviour be changed and how can this be maintained over time?**

This priority area is dedicated to intervention research projects in population health. This inclusion of prevention strategies in treatment courses is an important issue that requires the involvement of healthcare professionals and patients’ commitment to lead to change clinical practices.

Intervention research is defined as the use of scientific methods to produce knowledge on interventions, in the form of policies and programs, which are used or not in the healthcare industry and could have an impact on the health at a population level\(^15\). Within the context of tertiary prevention in oncology, the challenge is to increase the overall efficiency of patient treatment through the inclusion of interventions in order to prevent comorbidities, risk of recurrence and second cancers.

Encouraging partnerships between research stakeholders and players on the ground (healthcare professionals, patient associations, networks, care homes, etc.) is a key issue in this priority area in order to facilitate the implementation of interventions in the right spheres and to increase the chances of success and continuation in the future.

Proposals for intervention research projects should notably focus on:
- Suggesting interventions helping to break down the barriers to behavioural change developed by patients and/or health professionals (see priority area 2) or implementing positive behavioural change mechanisms already identified in the literature, by involving health professionals and/or promoting patients’ involvement in interventions (acceptability, adhesion, feasibility) to change their behaviours;


- Testing and evaluating several methods for innovative intervention and care in the same project (if relevant) by conveying the intervention’s logical model and its effects (adhesion, efficiency, etc.);
- Evaluating the relevance and transferability of therapeutic patient education (ETP) in order to better involve and support patients in managing their illness, within the context of behaviour change.

Interventions will be evaluated in terms of impact: change of professionals’ clinical practices, behavioural changes for patients, and/or in fine changes to patients’ health (overall state of health, prevalence of co-morbidities, re-occurrence, toxicity of treatments in medium or long term, etc.); but also in terms of the mechanisms which explain these results (process evaluation).

Projects wishing to test measures or interventions with a proven impact on other pathologies, which would be applicable in cancer patients, may also be submitted.

The evaluation committee will pay close attention to the transferability criteria proposed in the research protocol.

Feasibility studies may be proposed for Priority Area 3 only.
These studies must be on an innovative issue relevant to the scope of this call for projects and must help promote the implementation of interventions and study their feasibility (recruitment, acceptability, relevance of research question, partnerships, etc.), by working notably on the success indicators before carrying out the intervention.
This funding must allow researchers, notably young research fellows, interested by intervention research to build a project with the aim of it being submitted the following year to ARC Foundation or INCa calls for projects.
The duration and sum authorised for feasibility studies are set out in the “Funding Arrangements” section.

N.B.: The priority areas are described separately in this document. However, one project may cover two project areas with the aim, for example, of making the most of an intervention to collect other data (analysis of patient/doctor relationship during the implementation of an intervention, collection of biological samples during an intervention, epidemiological study linked to a clinical trial, etc.).

Transversal aspects:
The issue of inequalities, be they social, cultural, economic or geographical, is a cross-cutting theme for all priority areas. Work on equality in tertiary prevention, as a project aim, may concern whole projects or feasibility studies. Finally, the research approach used will be as multi-disciplinary as possible.

The following are excluded from the scope of this call for projects:
- Constitution of cohorts or biological collections;
- Projects on preservation of fertility in cancer patients;
- Projects concerning patients’ adhesion to treatments (observance).
4- **General recommendations**

Specific attention will be accorded to projects which propose:

- An integrated approach, involving a variety of caregiver profiles (oncologists, nurses, coordinating nurses, occupational doctors, family doctors, etc.);
- A multi-disciplinary approach, involving teams from different fields. The projects may be underpinned by the following disciplines: epidemiology, biology, clinical medicine, public health, occupational health, human and social sciences, political sciences, economic sciences, anthropology, law, sociology, psychology, etc.
- Involvement of one or more patient associations in the implementation and monitoring of the project.

The inclusion of bio-statisticians and/or methodologists in the projects is strongly recommended and will be specifically evaluated during the project assessment.

The evaluation committee will pay close attention to the originality and innovativeness of the research questions.

5- **Presentation of partners of call for projects**

**France National Cancer Institute (INCa)**

France National Cancer Institute (INCa) is the preeminent health and science agency in charge of cancer control. Created under the Public Health Act of 9 August 2004, it is attached to both Ministries of Health and Research.

INCa is a public interest group (GIP) which brings together State representatives, large NGOs, health insurance funds, research organisations and hospital federations. These stakeholders share a common goal of reducing the incidence of avoidable cancers and the number of cancer deaths, improving the quality of life of people with cancer during and after their illness, and reducing inequalities related to cancer.

Within this context, the INCa provides integrated undertakings in all dimensions (health, scientific, social and economic) and areas of intervention (prevention, screening, care and research) associated with malignant pathologies. The INCa works at the interface with patients, their friends and families, the healthcare system users, the general public, healthcare professionals, researchers, experts and decision-makers to catalyse progress.

INCa’s priorities:

- coordination of cancer control actions;
- initiating and supporting research projects and medical, technological and managerial innovation;
- monitoring screening, care and research organization;
- disseminating nationwide information on cancer that is reliable and succinct;
- producing and assessing data throughout every field of cancerology;
- improving knowledge on cancer risk factors and proper behaviour.

**The ARC Foundation for Cancer Research**

The ARC association, created half a century ago, now The ARC Foundation for Cancer Research is the main French non-profit donor-supported organization entirely dedicated to cancer research, recognised as a major stakeholder steering, structuring and fostering cancer research in France.
The ARC Foundation’s scope covers all the fields of oncology: basic science and clinical research, epidemiology, social sciences. Combining both discipline and creativity, and with the involvement of the best researchers and clinicians, the ARC Foundation identifies, selects and implements the most innovative and promising research projects. All its actions are motivated by excellence and innovation, which are both a rule and a requirement to its dynamism.

A major milestone has been achieved in cancer research, thus moving the scientific concepts to a new paradigm. In this context, taking into account this real paradigm shift, the ARC Foundation wishes to increase further the impact of its investments to cancer research.

Its main objective is to design and expand new concepts, new tools, new technologies and new therapies in order to always benefit both more directly and more rapidly to the patients. These innovations will cover all fields, from prevention and early diagnosis to patient care and treatments.

Each year, the ARC Foundation devoted nearly €30 million to cancer research. Without the benefit of public subsidies, its actions rely on the generosity of its donors and testators.

### 6- Eligibility criteria

Eligibility criteria
- Complete applications must be submitted online by the deadlines, to: [http://gap.recherche-cancer.net](http://gap.recherche-cancer.net).
- Unless specifically indicated, the application must be written in English.
- The project must fall within the field of this call for projects.
- The application must be submitted in the name of a single project leader, who is to be the coordinator recognised by the participating teams and who undertakes to be fully engaged in setting up and following up the project (at least 30% of his/her research time).
- The project leader must hold a full, permanent post in a hospital, university or research establishment in France; failing this, the project leader must hold a temporary post covering the relevant grant period.
- A single researcher or research team can only propose one project under this call for projects, but may be associated with several projects.
- At least one person involved in each team is to devote most of his/her working time to the project.
- All of the teams involved in the submission must belong to one of the following bodies:
  - Public research body (university, public science and technology research establishment or industrial and commercial establishment etc.);
  - Non-profit organisation (association, foundation etc.);
  - Public or non-profit private health establishment (CHU, CH, CRICC, health cooperation groups, care homes, health centres, etc.).
- The therapeutic patient education (ETP) programmes must prove that they have obtained authorisation from the Agence Régionale de Santé (Regional Health Agency); if this has not been obtained, the authorisation request must be ongoing and must be received before 22 November 2016 (see “Submission Procedures” section).
- Foreign partners may participate as long as they provide their own funding for the project.

**Applications not meeting the eligibility criteria will not be considered.**
7- **Expertise criteria**

**Project expertise will take place as follows:** the ARC Foundation and the INCa will be supported by an ad hoc international committee whose members, recognised for their expertise, will select the submitted proposals. In view of the committee’s expertise, the partners’ decisional bodies will vote for the projects funding.

**Expertise criteria**

- Scientific quality, relevance and innovativeness of the project.
- Clarity of objectives.
- Quality of the methodology and statistical approach (where relevant).
- Competence of the applicant; Complementary nature of the various teams involved in the project and the scientific added value of the project as organised (where relevant).
- Respect of ethical rules and regulatory aspects.
- How the project is positioned in the national and international context.
- Perspective of application or scientific, social or public health impact.
- Credibility of the timetable for achieving the results over the funding period.
- Supervision and training of young researchers (where relevant).
- Appropriateness of funding requested.

Any application package will be examined in accordance with the confidentiality agreement and conflict of interests procedure set up by the ARC Foundation and the INCa.

8- **Funding procedures**

Funding is granted for a period of 12, 24, 36 or 48 months. The maximum amount that can be applied for is €1,000,000.

**For feasibility studies only:**
Funding is granted for a period of 12 months. The maximum amount that can be applied for is €30,000.

**Expense types:**
- Operating (this includes software licences and fees and acquisition work in the field: travel costs involved in investigations etc.);
- Equipment;
- Subsistence costs;
- Recruitment of post-doctorate researchers, PhD students, engineers, technicians, clinical research associates, investigators or other professionals for a period not exceeding the grant period.

There are no restrictions on how the budget is allocated, particularly how much is set aside for funding personnel. Apart from exceptional circumstances (evidence must be provided), incidental expenses must not exceed 8% of the total. **This call for projects does not cover the management costs of the fund managing body.**
9. Timetable of the call for projects

Launch of call for projects: 7 July 2016
Return of complete packages: 22 September 2016, midday
Examination of project by an international ad-hoc committee: November 2016
Notification of results: December 2016

10. Submission procedures

The complete application package, including all items required for scientific and technical assessment of the project, must be put together in accordance with this notice and submitted online at:

http://gap.recherche-cancer.net
no later than 22 September 2016, midday.

Until the package has been validated, the applicant may revisit it as many times as desired, up to the closing date of the call for projects (22 September 2016).

The application package will be admissible only when validated by the applicant.
When the online package is validated the computer system will generate an acknowledgement of receipt and send it to the applicant.

N.B.: once validated, the package can no longer be amended.

However, the applicant will be able to supplement the package until 22 November 2016 but only by adding the following documents:

- Attachments: Signatures of the participating team leaders and/or persons in charge of the research facilities involved.
  N.B.: the application is admissible only if the required attachments have been uploaded.
- Appendices:
  • Evolving publications: publications that have been accepted or given a favourable review (attach letter from publisher and acknowledgement of receipt);
  • Change in administrative situation: concurrent funding obtained from another body;
  • Authorisation of a therapeutic patient education (ETP) programme: copy of authorisation signed by Director of Agence Régionale de Santé (Regional Health Agency).

For any further information:
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