



Call for research projects: Long-term consequences of treatments in pediatric oncology (CTCP)

Presentation and guidelines

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A. Context and objectives

Each year, approximately **2,300 children and adolescents (aged 0 to 17)** are diagnosed with **cancer** in France. Nearly 500 children die from cancer annually, making it the leading cause of disease-related death in children over the age of one. While research advances have significantly improved overall survival rates—now exceeding 80% at five years—progress remains uneven across different cancer types. Additionally, the treatment pathway for newly diagnosed children does not always lead to complete and lasting remission. Managing pediatric cancer requires long-term follow-up to ensure sustained remission and detect potential relapses. It is also essential to address the **possible long-term effects of treatments**, as improved survival rates over time increase the number of patients at risk of experiencing late side effects. Today, **two-thirds of children who survive cancer will develop treatment-related complications**, including chronic illnesses, secondary cancers, or fertility issues.

While significant funding is dedicated to developing new, effective treatments that improve long-term survival in children, it is equally crucial to allocate resources to **studying the longterm side effects of these treatments**. Understanding their impact over **time** and on the **quality of life** of survivors is essential. This long-term toxicity assessment must be multidimensional, taking into account chronic side effects, the risk of secondary cancers, and associated conditions. Given that these patients have overcome cancer at an early age, they are likely to experience an extended life trajectory, marked by critical phases of **physiological**, **cognitive, and emotional development**.

Beyond **identifying the long-term consequences of cancer treatments**, the challenge lies in developing **new tools and strategies** to mitigate, manage (through close monitoring or dedicated treatments), or even prevent them. Continuous improvements in dose adjustments based on observed toxicity, as well as the development of individualized predictive scores, already help guide treatment decisions and enhance patient education. Future research should also **investigate the role of genetic factors** in long-term sequelae, **unravel the mechanisms underlying the accelerated aging** observed in survivors and their link to prior treatments, and design as well as evaluate interventions—such as promoting physical activity—to **reduce late effects**. The development of effective screening strategies to support early diagnosis and prevention of sequelae is strongly encouraged.

At both the European and national levels, several key strategies are currently being implemented to address these challenges. Europe's Beating Cancer plan and EU Mission: Cancer promote research that not only aims to increase cancer patients' survival but also seeks to enhance their long-term quality of life by reducing social barriers and discrimination, as well as minimizing the long-term side effects of treatments without compromising their effectiveness.

« Limiter les séquelles et améliorer la qualité de vie » (i.e. « Limiting after-effects and improving quality of life") is one of the four key pillars of the **Stratégie décennale de lutte contre les cancers 2021-2030** (Ten-year cancer strategy 2021-2030). As part of this effort, the Institut national du cancer (INCa, French National Cancer Institute) has launched several multidisciplinary and multi-thematic research calls under this theme (Action II.2), with the

overarching goal of optimizing therapeutic efficacy while minimizing adverse effects, particularly toxicity and the risk of secondary cancers.

In 2022, an additional budget allocated through the French annual "Loi de finance" was used to strengthen a research fund dedicated to childhood, adolescent, and young adult cancers. As part of this initiative, the French Ministry of Higher Education and Research entrusted Inserm with the implementation of studies based on existing population registries and pediatric cohorts, focusing on the long-term effects of treatments and the health of individuals treated for cancer during childhood. Inserm is therefore launching a call for research projects on "Long-term Consequences of Treatments in Pediatric Oncology."

B. Scope of the call and support modalities

1. Thematic scope

The call for projects targets **multidisciplinary research projects** exploring the long-term health consequences of treatments received by pediatric cancer survivors. The primary objective is to **enhance the understanding of risks associated with these treatments**. **Innovative research projects** addressing various aspects of these issues are strongly encouraged, aiming to deepen knowledge on the long-term effects of pediatric cancer treatments, associated risk factors, and potential interventions to improve survivors' quality of life.

From a medical perspective, long-term follow-up falls within the scope of **clinical epidemiology**, which should be assessed at the **population level** to avoid the selection biases inherent to clinical research. The goal is not only to identify risks but also to **understand their determinants and risk factors**, enabling the identification of patient groups who may benefit from prevention or screening strategies. This approach ensures clinically relevant findings that are directly applicable to **pediatric oncology practices** and contribute to optimizing treatments for children with cancer.

Eligible projects may focus on **commonly used pediatric oncology treatments**, such as **chemotherapy, surgery, or radiotherapy**, but may also consider other types of therapies.

Applicants are encouraged to investigate scientific questions related to physical, reproductive, psychological, or socio-economic health, with the overarching aim of informing clinical practices and public health policies.

2. Disciplinary fields and collaborative aspect

Projects may be **collaborative**, involving **multiple disciplines** relevant to pediatric cancer research. This can include fields such as epidemiology, hematology, radiology, fundamental biology, translational research, as well as the social sciences (sociology, health economics, psychology, etc.). These collaborations will provide complementary perspectives to better address the complex challenges of these diseases.

3. Support modalities

a. Conditions of participation

This call for research projects is intended for teams that have **already established their own datasets**, derived from cohorts or population registers. The creation of new databases **is not eligible** for this call.

The objective of this call is to encourage collaboration among French research teams involved in the field of pediatric cancers. As such, all coordinating teams within the framework of this call **must participate in a network**, managed in collaboration with the Inserm thematic public health institute, to develop a joint initiative.

b. Duration and amount of the allocated grant

Projects of **up to 36 months** are eligible. Funding for each project will range from a minimum of $\leq 50,000$ to a maximum of $\leq 400,000$, within the limits of the program's total available budget.

C. Admissibility and eligibility criteria

- 1. Admissibility and administrative eligibility
- a. Admissibility

To be admissible, projects must:

- Be submitted exclusively under the name and contact details of the project coordinator
- Be submitted before the application deadline
- Comply with the funding conditions outlined above
- Be written in English
- Be complete
- Be signed

b. Administrative eligibility

To be administratively eligible, projects must meet the administrative and financial conditions of the call, as described below. It is particularly emphasized that:

- The scientific coordinator of the project must be eligible (see "i. Administrative eligibility of the scientific coordinator")
- The entities receiving the funds must be eligible
- The number of teams is **limited to 5** (including the coordinator's team), whether requesting funding or not.
 - i. Administrative eligibility of the scientific coordinator

The project coordinating team will be team number 1, and its managing institution must be eligible for this status (see « iii. Administrative eligibility of the affiliated organizations »).

For each submitted project, a scientific coordinator is designated. This individual is a physical person, primarily responsible for the scientific execution of the project and serves as the point of contact with Inserm. **Only one** scientific coordinator is designated as the reference for the submitted project. It is the responsibility of the project coordinator, and only the project coordinator, to submit the application on their behalf.

The scientific coordinator must dedicate at least 20% of their research time to the project. The scientific coordinator of the project must reside in France or be affiliated with a research team in France, hold a PhD¹ and be actively engaged in research. They must not be a member of the Scientific Evaluation Committee (CSE) of the call for research projects.

In addition, the scientific coordinator must be:

- Either a permanent staff member (civil servant or on a permanent contract)
- Or on a fixed-term contract, **if the contract covers the entire duration of the project** with one of the eligible structures
- Or provide, at the time of application submission, a **written promise of employment** from the employer covering the entire duration of the project

A doctoral student, an emeritus researcher, or a retired individual cannot be the project coordinator.

ii. Administrative eligibility of the partner teams

The number of partner teams participating in the project, whether requesting funding or not, is **limited to 5**. There is no limit to the number of individuals involved in each team. Each partner team in the project must appoint a scientific leader. **The managing institution of the team must be eligible for this status** (see "iii. Administrative eligibility of the affiliated organizations").

iii. Administrative eligibility of the affiliated organizations

For each submitted project, the participating teams must designate their respective **managing institution**, whether it is a recipient of funding or not. The managing institution is contractually responsible for the implementation of the project, the proper use of the allocated funds, and the submission of the scientific and financial reports specified in the Grant Agreement.

The **teams must belong** to one of the following French organizations:

- Public institutions with a research mission (EPST, EPIC, etc.)
- Higher education institutions (universities, schools)
- Publicly recognized foundations of public utility
- Public healthcare institutions
- Cancer research centers (CLCC)
- Associations (including patient associations)

¹ Les titulaires d'un diplôme d'état de docteur en médecine ou en pharmacie ayant une activité de recherche et résidant en France peuvent aussi être coordonnateurs.

Note #1

In any case, public research teams affiliated with a public organization or a public entity must have their grant managed by their affiliated public organization or one of their structure's overseeing bodies.

Note #2

Eligible private entities may receive financial support only up to 80% of its allocated budget within the project.

Note #3

Foreign teams can participate in the project as partner teams, provided they secure their own funding.

Note #4 - Distinction between partner team and service provider

- **Partner team:** Involved in the design and development of the research, it can receive and "manage" the project funds more easily. However, it must ensure the achievement of the set objectives, or it may be required to partially or fully reimburse the funds received in case of non-compliance.
- Service provider: Engaged for a specific, one-time task that must be justified in the application and the budgetary appendix. The managing institution must comply with public procurement rules, if applicable. The service provider is not responsible for achieving the overall project objectives but is required to deliver the specific service with a result-based obligation.

2. Scientific eligibility

To be scientifically eligible, projects must meet the following conditions:

- The project must align with the **thematic scope** of this call for research projects
- The project must be based on <u>existing population registers or cohorts in France</u>, following individuals diagnosed with pediatric cancer, and **not on the creation of new databases**
- The projects must be **coordinated by teams that have developed these population registers or cohorts**. Other research teams, whether or not involved in these registers or cohorts, may be associated to strengthen the multidisciplinary approach and promote collaboration
- The coordinating teams commit to participating in the consortium that Inserm will develop around pediatric cancer epidemiology for a period of 5 years from the establishment of the agreement
- The project must not fall under any exclusion criteria.

D. Submission modalities

1. Schedule

Launch of the call for projects	March 31, 2025
Opening of the EVA3 submission platform	Tuesday, April 1, 2025, at 10:00 AM
Application deadline	Wednesday, May 28, 2025, at 12:00 PM

Project selection	Fall 2025
Announcement of results	December 2025

2. Submission procedure and required documents

The entire application file must be submitted on the EVA platform **before the indicated deadline and in the requested formats.**

If you already have an account, please log in at the following address: <u>https://www.eva3.inserm.fr</u>

If you need to create a new account, click on the following link: <u>https://eva3-accueil.inserm.fr/</u>

For more information, please refer to this guide (in French): <u>Guide to create an account on the</u> <u>EVA3 platform</u>

The entire application must be written in English. All documents must be submitted in PDF format, except for the budgetary appendix, which may be in Excel format.

The different steps for applying are as follows:

- **Read the text of the call**. The application must comply with all the rules to be eligible.
- Complete the various sections of the application:
 - Fill out the online form on the EVA3 platform.
 - Complete the application file according to the provided template and upload it in PDF format on the EVA3 platform, along with all necessary supporting documents (see "3. Additional Documents"). The annexes must be included in this document and should not be submitted as separate files.
 - **Complete the budgetary appendix and upload it in Excel format** on the EVA3 platform. All tabs must be filled out. The appendix must be signed by the legal representatives of the managing organizations of the teams requesting funding.
- Validate the project submission (with all documents).

Warning: Please ensure that you click the "validate" button to finalize the submission process (otherwise, your application will remain in "draft" on the platform). **You should receive a confirmation email upon validation.**

Note: The research consortium must ensure that all partner teams involved in the project, **whether requesting funding or not**, and their composition, are accurately included in both the application file and the budgetary appendix.

3. Additional documents

Additional supporting documents may include:

⇒ For **associations** requesting funding:

- Articles of association
- o Income statement for the last closed financial year
- Organizational chart
- Bank certificate of financial capacity (dated within the last three months)
- o Justification of their interest in participating in the research
- Any **regulatory approvals** already obtained.

4. Contact

For any **scientific or administrative** inquiries, please contact: <u>aap-ctcp.isp@inserm.fr</u>

For **technical aspects** related to the **EVA platform**, please contact: <u>eva@inserm.fr</u>

E. Selection and evaluation procedures

1. Selection steps

The project selection procedure takes place in several stages, based on complete application files:

- Stage 1: Examination of admissibility and administrative eligibility. All application files are reviewed according to admissibility and administrative eligibility criteria, as defined in section « C. Admissibility and Eligibility Criteria ».
- **Stage 2: Examination of scientific eligibility.** Admissible and administratively eligible projects are reviewed by the CSE to validate their scientific eligibility in accordance with the scope of the call for research projects.
- **Stage 3: Scientific evaluation of projects.** Admissible and eligible projects will be evaluated based on scientific criteria, as outlined below. The scientific members of the CSE will then collectively decide which projects are recommended for funding.

A **two-phase evaluation** will be conducted to assess the scientific quality of the projects and establish a ranking based on **scientific criteria** (evaluation grid followed by the CSE). The composition of the CSE is **confidential** until the publication of the results. These independent experts are selected for their scientific excellence, in compliance with ethical and deontological rules (notably through the signing of a confidentiality and non-conflict of interest declaration by each expert).

2. Evaluation criteria

Projects will be assessed according to the following criteria:

• Principal investigator and partner teams:

• Quality of the teams involved (skills, experience, complementary, etc.)

• Scientific quality:

- Clarity of objectives
- Originality and scientific or public health relevance
- Coherence with the targeted theme
- o Excellence relative to the state of science
- Position of the project within the national and international context
- Methodology, degree of maturity and feasibility:
 - Methodological quality and relevance of the planned technologies and methods
 - Appropriateness and justification of the proposed schedule in relation to the project's objectives
 - Feasibility of the research (access to data, project task completion, detailed program, deliverables, compliance with ethical rules and regulatory requirements, status of authorization requests, declaration of access to databases or cohorts, etc.)
 - Technical, financial and legal-administrative feasibility (budget alignment with the request, compatibility of funding obtained through the call with other funding the unit is or will be receiving)
- Impact of the project:
 - Scale of the project
 - Scientific, technical, and societal impacts, while contributing to the understanding of treatment consequences and the assessment of the health of patients treated during childhood

F. Administrative and financial rules

1. Scientific coordinator and partner teams responsibilities

As the principal project leader, the coordinator will be designated in the Grant Agreement if the project is funded. In addition to their scientific and technical role, the coordinator will be **responsible for establishing the collaboration arrangements** between the participating teams.

Regarding the commitment letters, they will be signed after the project is selected for funding. Only **the coordinator's team** will need to sign the letter, which must include the signatures (possibly electronic) of the project coordinator, the director of the affiliated laboratory or structure (or the director of their organization), and the legal representative of the managing organization.

2. Budgetary and financial rules

a. Recommendations for the budgetary appendix

It is strongly recommended to prepare the budgetary appendix with the managing institution.

The budgetary appendix, in Excel format, includes several sheets:

1. **Notice**: Details the different expense categories to be filled in the following sheets. It is recommended to review this section before entering any data.

- 2. **« Equipe » Sheets (from "A Equipe 1" to "E Equipe 5"):** All teams, including those not requesting funding, must fill out their respective sheet.
- 3. **« K Répartition annuelle » Sheet:** The requested funding must be distributed by year for the duration of the project. This distribution is done on a calendar year basis.
- 4. **« L Fiche de synthèse » Sheet:** This is **automatically** filled out based on the data entered in the other sheets.

When completing the budgetary appendix, make sure to:

- Read the notice carefully
- Identify the coordinator's team as Team 1
- Number the teams consistently between the budgetary appendix (Excel) and the application form (Word).

b. General measures for funding

The funding granted under this call may cover all or part of the project's budget. **Each team must ensure, in collaboration with its managing organization, the coherence of the financial structure before submitting the application.** Project participants agree to comply with the allocation rules by signing the letters of commitment.

Costs charged to the project **must be directly related to its implementation and must not include any profit margin**. Co-funding of projects is allowed, but the funding provided here cannot cover expenses already covered by other sources of funding. Only expenses incurred between the project start date and its end date are eligible.

Eligible expenses include:

- Equipment expenses: Equipment necessary for the project, excluding office equipment, is eligible. Computers used for experimental instruments are considered as equipment.
- **Personnel expenses:** Expenses for non-permanent staff and, **under certain conditions**, for permanent staff assigned to the project are eligible.
- **Operating expenses**: Eligible expenses include consumables, travel, publication fees, internship stipends, and service fees (within the limits defined in the budgetary appendix).
- Management fees: The managing organization may charge overhead fees, as outlined in the budgetary appendix, up to 13% of eligible expenses, calculated excluding overhead costs.

Budget reallocation between expense categories is allowed. However, transferring funds to personnel expenses can only be done after submitting a scientific justification to <u>aap-ctcp.isp@inserm.fr</u> and is subject to prior approval by Inserm.

c. Conditions for personnel costs

Requests for personnel funding **cannot exceed 85%** of the total project amount. **Support and administrative roles**, except for scientific profiles such as grant officers or lab managers, are not eligible.

Funding for interns, master's students, doctoral students, and post-doctoral researchers is possible, subject to the conditions specified in the budgetary appendix.

A French team cannot fund fixed-term contracts (post-doctoral researchers, doctoral students, etc.) or interns working in laboratories abroad, **unless the stay abroad does not exceed one-third of the total project duration**.

d. Payment of the grant

Inserm will be r**esponsible** for the implementation of the Grant Agreement, the disbursement of the grant, as well as the administrative and financial monitoring of the projects.

The grant is paid by Inserm to the managing organization of the scientific coordinator. If multiple partner teams are funded, transfer agreements will need to be established between the managing organization of the coordinator and the managing organizations of the partner teams receiving funding.

The project start date, **determined by the coordinators**, must be set **within eight months following the announcement** of the call for projects results. This date must also be after the establishment of the Grant Agreement.

Finally, by the end of the award agreement, any unused funds must be reimbursed by the coordinator to Inserm.

Any modification of the budgetary appendix after the notification of funding or the signing of the agreement **must be requested via email to Inserm.**

G. Project monitoring and valorization1. Publications and communication

As the principal project coordinator, the coordinator will be responsible for producing and submitting the required documents for project monitoring and communication of results. The coordinator must provide several scientific and financial reports, including:

- An initial report (6 months after the start of the funding)
- A mid-term report, for projects lasting more than 20 months
- A final report at the end of the project.

These reports will include:

- A scientific section detailing the progress of the project and the results obtained
- A financial section summarizing the expenses incurred
- A list of publications and other dissemination actions associated with the project

All documents to be submitted, along with their submission deadlines, will be specified in the Grant Agreement.

The project partners commit to acknowledging the support of Inserm and its supervising authority, the Ministry of Higher Education and Research, in all publications and communications related to the project, as follows:

"This study was supported by a grant from Inserm and the French Ministry of Higher Education and Research in the context of "Conséquences à long terme des traitements en cancérologie pédiatrique" call operated by Inserm (CTCP, 2025, [registration number])".

They must inform **Inserm – ISP of the publications** and send them by email (<u>aap-ctcp.isp@inserm.fr</u>) within two weeks of their publication, even after the end of the funding agreement, and register the studies and results according to the procedures outlined in the funding agreement.

2. Intellectual property

Inserm does not claim ownership rights over the results generated within the framework of supported projects. The results of these projects belong, in accordance with applicable regulations, either to the researchers who generated them, their employing institutions, or the supervisory institutions of the research teams involved.

Inserm fully allows the scientific coordinators to publish, in compliance with the relevant rules, the knowledge produced within the framework of the funded projects.

3. Confidentiality and data protection

Project leaders commit to complying with obligations related to the protection of personal data in accordance with the General Data Protection Regulation (GDPR). They must designate a Data Protection Officer (DPO) if necessary and implement appropriate measures to ensure the compliance of data processing collected within the scope of the project. Project leaders must also provide a **Data Management Plan** within 6 months following the project start date.

4. Open science

In the context of implementing the 2nd National Open Science Plan, the beneficiary organization of the grant and the project coordinator commit, in the event of funding, to prioritize the deposit of scientific articles resulting from the funded research projects in openaccess journals. If this is not feasible, the beneficiary and the project teams involved are required to submit the articles in a public open archive, such as HAL. <u>Article 30 of the French</u> <u>Digital Republic Law</u> establishes the following maximum embargo periods:

- 6 months for publications in the fields of science, technology, and medicine (STM)
- 12 months for publications in the fields of humanities and social sciences

Dissemination may occur immediately or within a shorter embargo period than those specified above, provided the publisher permits.