**Appel à projets national**

**en cancérologie** 2021- 2022

**PHRC-K**

**Programme Hospitalier de Recherche Clinique en Cancérologie**

**Lettre d’intention – Letter of intent**

DATE LIMITE DE SOUMISSION de la lettre d'intention : **23 septembre 2021– 18h00**

**Document à soumettre en ligne (télécharger) dans la rubrique "Descriptif du projet"**

**La lettre d’intention est à rédiger en anglais pour permettre l'évaluation internationale**

<https://www.e-cancer.fr/Institut-national-du-cancer/Appels-a-projets/Appels-a-projets-en-cours/PHRCK2022>

|  |  |
| --- | --- |
| n° du dossier :  Veuillez indiquer le n° de dossier attribué par le portail PROJETS (Menu "Dépôt de projets") |  |
| **Acronym (15 characters max without any space):** |  |
| **Titre du projet :** |  |
| **Project title***:* |  |
| **Research domain**  **-Organ, tumor location:**  **-Others:** |  |
| **Keywords**  **-Coordinator domain:**  **-Required reviewer’s field of expertise:** |  |

# GENERAL INFORMATION

|  |  |
| --- | --- |
| **First name and name of coordinator** |  |
| **Specialty** |  |
| **Service ou département - Unit or department** |  |
| **Name and address of the hospital** |  |
| **Phone number** |  |
| **E-mail** |  |
| **Physician, dental practitioner / Biologist / Nurse, other healthcare professional:** |  |

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| **Previous grants from DGOS (List with: year, ref number, status)** |  |

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| **Institution in charge of budget management** |  |
| **Approximate level of funding required (K euros):** |  |

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| --- | --- |
| **First name and name of the methodologist** |  |
| **Name and addressof the hospital** |  |
| **Phone number** |  |
| **E-mail** |  |
| **First name and name of the economist**  **(if any)** |  |
| **Name and address of the establishment** |  |
| **Phone number** |  |
| **E-mail** |  |

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| **Organization in charge of project management** |  |
| **Organization responsible for quality assurance** |  |
| **Organization in charge of data management and statistics** |  |

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| **Anticipated number of recruiting centers (NC)** |  |
| **Anticipated number of scheduled patients** |  |

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|  | | **Co-investigators (1 à n)** | | | | | | | |
| N° | Name | | Firstname | Town | Country | Hospital | E-mail | Tel | Specialty |
| 1 |  | |  |  |  |  |  |  |  |
| 2 |  | |  |  |  |  |  |  |  |
| 3 |  | |  |  |  |  |  |  |  |
| 4 |  | |  |  |  |  |  |  |  |
| 5 |  | |  |  |  |  |  |  |  |

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| **References** |
| *Main scientific publications (5 maximum) justifying the project*  - 1  - 2  - 3  - 4  - 5 |

# RESEARCH PROJECT

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| **Rationale (Context and hypothesis, max 320 words)** |
|  |
| **Originality and innovative aspects (max 160 words)** |
|  |
| **Focus of research** |
| Health technology (tick and provide details):  Drugs □ Devices □  Procedures and organizational systems used in health care (including Health services*[[1]](#footnote-1)*) □  If relevant: date of CE mark / market authorization  **Details :** |
| **Keywords (5):** |
|  |
| **Main objective (max 48 words)** |
|  |
| **Tick one:** |
| Hypothesis description □ Feasibility □ Tolerance □ Efficacy □ Safety □  Efficiency □ Budget impact □ Organization of care □ |
| **Tick one:** |
| Etiology □ Causality[[2]](#footnote-2)□ Diagnosis □ Prognosis □  Therapeutics (impact on clinically meaningful endpoint[[3]](#footnote-3) ) □  Therapeutics (impact on intermediate endpoint[[4]](#footnote-4) ) □  Compliance □ Standard clinical practice □ Research methodology □  Qualitative Research □ Other □ |

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| **Secondary objectives (max 160 words)** |
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| **Primary endpoint (in relation with the main objective)** |
|  |
| **Secondary endpoints (in relation with the secondary objectives)** |
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| **Study population** |
| **Main inclusion and exclusion criteria** |

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| **Design (tick + max 320 words)** |
| Meta-analysis □  Randomized clinical trial □ if yes : Open label □ Single blind □ Double blind□  Systematic review □ Pragmatic study □  Quasi-experimental studies (non randomized cohorts …) □ Prospective cohort study □  Case-control study □ Cross-sectional study □  Retrospective cohort □ Administrative / hospital inpatient database research □  Modelling □ Case series □ Qualitative studies□ Other □  **Please give details:** |

|  |  |
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| **If health-economics analysis (tick + max 320 words) :** | |
| Cost-utility analysis □ Cost-effectiveness analysis □ Cost-benefit analysis □  Budget impact analysis□ Cost-minimization analysis □ Cost-consequence analysis□  Cost of illness analysis □ Other □  **Please give details:** | |
| **Technology Readiness Level:**  *(https://www.medicalcountermeasures.gov/federal-initiatives/guidance/integrated-trls.aspx)* |  |
|  | |
| **In the case of a drug trial:** | |
| **Phase: I □ phase: II □ phase: I/II □ phase: III □ phase: IV □** | |
| **If comparison groups :** | |
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| **Experimental group (max 48 words)** |
|  |
| **Control group (max 48 words)** |
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# INCLUSIONS

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| **Duration of participation of each patient (days/months/years):** |
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| **Anticipated duration of recruitment (DUR) (in months):** |
|  |
| **Planned number of patients/observations to be recruited (NP) (3 digits + Justification of sample size max 80 words):** |
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| **Number of patients / observations to be recruited / month / centre ((NP/DUR)/NC) (2 digits + Justification if more than 2 patients/month/center)** |
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| **Expected number of eligible patients in the centres** | | | | | | |
| N° | Name | Surname | Town | Country | Expected recruitment/month | Total |
| 1 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |

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| **Participation of a research network (max 32 words)** |
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| **Participation of structures coordinated by INCa or DGOS (ministry of health): biobanks (tumorothèques) clinical-biological databases (CBC), centres for data analysis (CTD), molecular genetic platforms, etc…** |
|  |
| **Industrial participation (max 64 words)[[5]](#footnote-5)** |
|  |
| **Others aspects to ensure the feasibility of the project (max 64 words)** |
|  |
| **Expected patient or public health benefit (max 320 words)** |
|  |

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| **In case of a previous submission, mention the additional aspects relevant to the recommendations of the scientific committee (Experts comments and corresponding answers, max 320 words)** |
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1. http://htaglossary.net [↑](#footnote-ref-1)
2. Studies designed to determine the causes of a disease, the risk of being exposed to a drug, a pollutant etc [↑](#footnote-ref-2)
3. Example: reduction of myocardial infarction incidence, of mortality [↑](#footnote-ref-3)
4. Example: reduction of serum cholesterol, improvement of a pain scale [↑](#footnote-ref-4)
5. If necessary, justify that out of labelled health technologies are not sponsored by the industrial owner [↑](#footnote-ref-5)