Not registered

Project overview

Project title

--

Publishable project title

--

Acronym

--

Use of Publishable project title and Acronym

I am informed that in case of funding, the "Publishable project title" and "Acronym" may be used by the INTER-LOCAL partners in actions aimed at the general public, donors, subscribers to the various communication media and I expressly agree to this use.

--

Study population

Select one or several from the list:

Pediatric (0-14)

No

Teenager (15-17)

No

Young adult (18-30)

No

Adult

No

Elderly-Geriatric

No

Not relevant

No

Cancer type of study

Specify cancer type of study

--

Countries and centers involved

How many countries and centers are involved? Shortly list the centres and countries (eg: University Hospital X - Sweden)

--

Scientific abstract

Keywords – Min: 3 ; Max:5 ; 50cc max per keyword

--

Scientific abstract

--

Project Leader

Please provide information about the Project Leader, who must be exclusively located in Belgium, the Netherlands, Spain, Sweden or Norway. If the project is selected, he/she will be the national contact point for the project follow-up and will be responsible for the funds granted at his/her national level.

Birthdate

--

First name

--

Last name

--

Mr/mrs

--

Title (Dr/Pr/Other)

--

E-mail

--

Phone number

--

Other phone

--

Nationality

--

Second nationality

--

ORCID ID number

--

Reference country

--

Research expertise

Please describe briefly your research expertise demonstrating the competence to carry out this project.

--

Institution

Reference country

--

Company identity number (if applicable)

--

Research Institution Name

Laboratory Name

--

Address

--

Postal code

--

City

--

National Coordinator

Please provide information about the National Coordinator Leader, who must be exclusively located in Belgium, the Netherlands, Spain, Sweden or Norway. Each of these countries may appoint only one National Coordinator.

Birthdate

--

First name

--

Last name

--

Mr/Mrs

--

Title (Dr/Pr/Other)

--

E-mail

--

Phone number

--

Other phone

--

Research Institution Name

--

Laboratory Name

--

Address

--

Postal code

--

City

--

Nationality

--

Reference country

--

Sponsor/Promotor

Sponsor/Promotor of the Study Name

--

Patient organisations

Are patient organisations involved?

Yes

Please describe the patient organisations involved and elaborate on their role.

--

Please provide a letter of commitment

Other participating parties

Indicate whether there are other participating parties involved and, if so, elaborate in the follow-up questions.

External inclusion centres

Are external inclusion centres (i.e. centres from outside Belgium, the Netherlands, Spain, Sweden or Norway) involved in the project?

Yes

Please elaborate External Inclusion Centers (outside the 5 funding countries)

--

Industrial parties

Have IP agreements already been made?

Yes

Please describe the for-profit parties involved and elaborate on the role and relation with the company. Describe if there is commitment from the company to support the study, and what kind of support (e.g. in-kind, financial, supply of study drugs). Is there commitment (yes/no) from the company to support further development in case of positive study results? Are IP agreements already been made?

Enter description

--

Please provide a letter of commitment

Co-funders

Are there any co-funders involved?

Yes

Please list the co-funders involved

--

Please provide a letter of commitment

Other parties

Are other parties involved?

Yes

Please describe the name and role of other parties involved

--

Please provide a letter of commitment

Collaboration

Briefly describe the nature and experience of the collaboration between the Project Leader, the National Coordinators and the participating parties, including the added value of any proposed multidisciplinary or public-private collaboration.

--

Adherence to scope, aim and topic of this call

Proposals need to cover at least all four criteria to be eligible for application

1. Rare and/or hard-to-treat cancer

Rare cancers: the cancer type must be rare, defined as having an annual incidence (number of initial diagnoses) of fewer than 6 cases per 100,000 individuals in the European region, based on the most recent and reliable epidemiological data or registry sources. This classification is based solely on the cancer type itself and is independent of the stage at initial diagnosis. Rare cancer in both adult and paediatric populations are accepted.
Hard-to-treat cancers: the cancer type must be classified as hard-to-treat by a 5-year survival rate below 25% (from the time of initial diagnosis and independent from the stage at the time of initial diagnosis), based on peer-reviewed scientific evidence published in high-impact journals. Please provide a description and/or literature evidence if necessary in the bibliography section.

Please elaborate

--

2. Phase II/III clinical trial with a patient-relevant primary endpoint

Phase II and/or phase III clinical trial, or comparable (including single arm phase II trial) with a patient-relevant primary endpoint (e.g. improvement of quality-of-life and/or survival while at least maintaining quality of life). The trials should be confirmatory or pivotal trials and should be close to patient impact, implementation, registration, market authorisation and/or change of treatment guidelines.

Please elaborate

--

3. Collaboration of at least 3 consortium partners

International collaboration of at least 3 consortium partners from Belgium, the Netherlands, Spain, Sweden or Norway.

Please list the consortium partners and shortly describe the collaboration

--

4. Type of intervention

Type of intervention: surgery and/or radiotherapy, and/or combined therapies.

Please elaborate

--

Background and Relevance

Please elaborate on the study background and relevance.
- Scientific background, previous research and evidence supporting the objective of the trial (i.e. state of the art),
- Unmet patient need; based on the target population, current standard of care, current life expectancy and potential impact on survival and/or quality of life of patients

Enter study background and relevance

--

References

--

References/Bibliography

Study synopsis

- Describe the trial design (including statistics, methodology)
- A schematic representation of the design and treatment arms, a flowchart and/or visit overview must be included

Study phase/type

--

Patient population with main eligibility criteria

--

Local therapy (surgery and/or radiotherapy)?

--

Objective

--

Primary endpoint

--

Secondary endpoints

--

Study design – Methodology, set up, arms, visits, procedures.

--

Sample size and sample size calculation

--

Number of sites, countries

--

Statistical Analysis Plan

--

Schematic representation

Please provide a schematic representation of the study design and treatment arm

Workplan

Enter a Global Workplan. Describe the work packages needed to execute the trial, including Responsible parties and success indicators.

--

Milestones

EC/CA submissions

Estimated timeline - fill in preliminary dates

--

Duration (months)

0

EC/CA approvals

Estimated timeline - fill in preliminary dates

--

Duration (months)

0

Clinical Trial Agreements signed

Estimated timeline - fill in preliminary dates

--

Duration (months)

0

First Patient Enrolled

Estimated timeline - fill in preliminary dates

--

Duration (months)

0

Last Patient Enrolled

Estimated timeline - fill in preliminary dates

--

Duration (months)

0

Data collection Complete

Estimated timeline - fill in preliminary dates

--

Duration (months)

0

Analysis & Reporting

Estimated timeline - fill in preliminary dates

--

Duration (months)

0

Please upload a GANTT chart

Recruitment plan

Describe the estimated number of enrolled patients per country (or site). Please provide the exact actual number of eligible patients treated per year per country (or site). Numbers may be derived directly from the clinic/national registry/etc.

--

Enrolment projection graph

Please provide a realistic enrolment projection graph.

Development strategy

It is not obliged to have these regulatory steps completed at the time of the application; applicants may describe the current status and future plans on these topics. However, the better elaborated and the further in progress, the higher the developmental potential.

Therapy description

Please provide information about the study therapy(s)

--

Combined therapies

Please provide information if drug therapy is involved in the study in combination with the surgery or radiotherapy main treatment. What is the active substance? Is it the standard of care for this type of cancer and stage? Please elaborate:

--

Implementation and Regulatory Engagement plan and Dissemination Plan

Applicants are requested to provide a clear and realistic plan for the implementation of the trial results into routine clinical practice across multiple European countries, assuming the trial demonstrates positive outcomes. Applicants should demonstrate awareness of the regulatory and implementation landscape relevant to their intervention and describe how they will ensure alignment with these requirements throughout the project lifecycle. This plan should include:

- A description of the anticipated pathway to clinical adoption, including integration into clinical guidelines and healthcare systems, potential reimbursement, intellectual property strategy and professional training.
- Identification of the key oversight bodies involved in this process, such as:
  - Competent Authorities
  - Regulatory Authorities
  - Professional and Scientific Societies
  - Accreditation or Certification Bodies
- Evidence of early consultation or engagement with these bodies, or a plan to do so during the project. If available, description of previous consultations.
- Consideration of country-specific requirements that may affect the uptake of the intervention (e.g. reimbursement, training, infrastructure).

  A plan to disseminate project data and results is required. Projects are expected to contribute to reproducible science and have a plan to disseminate their data and results
  - Sharing of results in public databases, particularly after initial publication;
  - Publication of data in addition to the results adhering to FAIR principles (https://www.gofair.org/);
  - Publication of results in open-access journals.

Enter Implementation and Regulatory Engagement plan and Dissemination Plan

--

Project request

Project duration (months)

--

0 EUR

Complementary funding resources

Are there complementary funding resources contributing to the project?

--

Budget specification

Attach a file with detailed costs per year etc. You must use the template found in the guidelines. More information is available at www.kwf.nl.

Total project cost

	Value (EUR)
Total project cost Value missing	0

Patient Advocacy Committee Application Form

1. This section of the pre-proposal application must be completed in layman's language, so that non-scientists, people without scientific/medical background, can read and assess the preproposal. Using layman's language not only ensures that the patient advocacy committee (PAC) gets a clear and structured representation of your project, but also gives the PAC an idea of the way the researcher communicates with patients. Please note that the PAC will only evaluate this application form. They do not have any insight into the scientific application form, nor any appendices or references attached to the scientific application form.

2. When writing a project application, it is important that all evaluation criteria are filled in and interpreted correctly. If certain criteria require additional clarification, please do not hesitate to contact us.

3. The concrete guidelines for drawing up a patient-oriented project (application), which meets the requirements of the PAC, can be found in the Guidelines for Applicants. You must use the form found in the guidelines.

4. If you would like more information about this application and/or the PAC, you can always contact the contact person of your local funding organization.