Guidelines 2021

guidelines for the submission of a project proposal

KWF Programme Research & Implementation

Version 2.2
August 2021

Version management

Version	Date	Most important adjustments
2.2	August 2021	• Correction of web address GMS • Correction of salary scales
2.1	January 2021	• Deletion of Pink Ribbon as funding partner • Typo corrections
2.0	1st October 2019	• Total revision (New Funding Conditions)
1.9	23rd Januari 2019	• Scope Infrastructure initiatives
1.8	19th December 2018	• Reformulations with regard to parties involved in the project; • Merge with guidelines for implementation projects and Infrastructure initiatives.
1.7	1st April 2018	• Overall general adjustments
1.6	1st October 2017	• Overall general adjustments; • Removed funding, review and operating; • Translated Dutch summary tab; • Added research activities per research phase ; • Added funding partners; • Added inclusion center in a clinical trial; • Updated travel and accommodation costs and ICRP instructions.
1.0	June 2016	• Initial document

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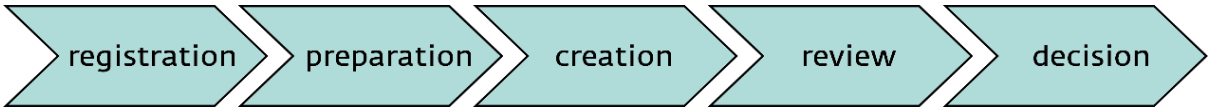
1. Introduction

This document explicates the guidelines for the submission of a project proposal within the KWF Kankerbestrijding (KWF) programme Research & Implementation (in Dutch: Programma Onderzoek en Implementatie, PO&I). It provides practical information on the registration in the Grant Management System (KWF GMS, see https://gms.kwf.nl/). It explains the different funding types, conditions and research phases under which you can submit. Furthermore, it guides you through the actual submission of a project proposal form and the applicable fields in KWF GMS. Lastly, it describes the reviewing process and explains the criteria that are used to review a project proposal.



After your project proposal has been granted for funding, you will receive a grant decision letter with the applicable conditions. These guidelines do not cover the monitoring of your project by KWF neither the project closure.

If you have any procedural questions or questions concerning KWF GMS, please contact our scientific review and grants administration department.

Phone: +31 (0)20 5700450
E-mail: bestedingen@kwf.nl
Website: www.kwf.nl/poi

See www.kwf.nl/onderzoek/poi/Pages/Contact if you have questions regarding the content of your project proposal, please contact the programme coordinator.

2. Tips and tricks

We advise you to read the entire guideline and pay extra attention to the following tips and tricks.

2.1 If you intend to involve patients or a patient organization during your study, please make sure you contact them in time. See chapter 5.

2.2 If you have not already done so, please register your organization, department and personal profile as soon as possible and advise your fellow principal investigators and scientific personnel to do the same. Please contact our scientific review and grants administration department at least six weeks before the call deadline to approve the registration. See chapter 3.

2.3 Before creating a project proposal, select the right type of funding and research phase. See chapter 4. If you want to adjust the type of funding or research phase in KWF GMS you have to create a new project proposal.

2.4 Please check all eligibility conditions of your funding type in chapter 4. Any requests for exemption must be submitted to KWF at the latest six weeks before the call deadline.

2.5 KWF GMS does not support copying from external word processors since importing formatted text into KWF GMS is not supported. We therefore recommend to edit your text layout with the text editor in KWF GMS. Before submitting, please check and verify the layout by clicking the print form - view button on the tab project details. Disclaimer: not all special characters might be rendered correctly in the PDF and some information on the application form is not displayed in the PDF.

2.6 Restrict the number of your work packages. In general, one to three work packages will suffice. This also applies for complex research proposals.

2.7 Milestones are defined as critical points in time to ascertain that sufficient and successful progress has been made in your project. For project proposals within the exploration track, two to three milestones in total will be sufficient. For project proposals within the development and implementation track, three to six milestones in total will suffice.

2.8 If you enlist a service provider or inclusion center, it is obligatory to upload a quotation for the estimated costs (including taxes).

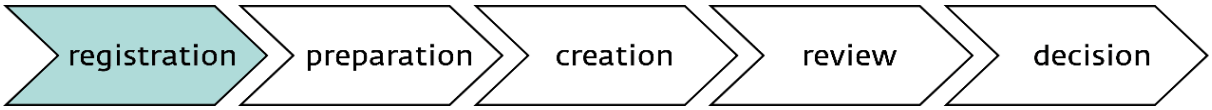
2.9 In case of collaboration with other organizations, or in case of co-funding, please be aware that Value Added Tax, VAT (in Dutch: BTW) may be charged. Contact your organization's finance department or Technology Transfer Office, TTO, for the actual regulations.

2.10 KWF recommends to request your finance department to check if the budget of your project proposal is filled out correctly and in accordance with the guidelines and funding conditions. To this end, the financial contact person can view and edit the project proposal or you can export your draft project proposal from GMS to PDF.

2.11 To generate a PDF file from the project proposal, please ensure that the security settings of PDF documents are disabled (e.g. password-protection or any other encryption).

2.12 We strongly advise you to validate your project proposal in KWF GMS at least two days before the call deadline. After clicking the validate button, all obligatory fields will automatically be checked for completeness. A timely validation of your proposal will allow you to correct unexpected errors/issues while being able to continue writing on your proposal. When the deadline has passed, projects that have not been submitted properly will automatically be recorded as missed deadline and will not be taken into consideration.

3. Registration and approval in KWF GMS



KWF uses KWF GMS for the whole process of submission (registration, preparation and creation), review, decision, monitoring and closing of projects, see www.gms.kwf.nl. This chapter provides information on the registration in KWF GMS.

3.1 Registration of a department and/or organization

To participate as a lead institute or participating organization in a project proposal, your organization and department need to be registered in KWF GMS. During the registration process, you can choose from existing organizations and departments (i.e. already registered by KWF) or you can create a new one.

All organizations will be checked for eligibility, see chapter 3.2.

3.2 Approval of a department and/or organization

The lead institute and all participating organizations have to be approved by KWF before you can submit the project proposal. A red notification bar on the application form indicates that your department has not been approved yet. Please click the validation button to check the approval status of the participating departments. For approval, contact KWF's scientific review and grants administration, at least six weeks before the call deadline.

Requirements for a lead institute:

Approval of a lead institute indicates that the organization is appropriate for performing scientific research and that the organization is equipped with the required infrastructure. Appendix 1 gives an overview of types of organizations which are eligible as lead institute.

Approval of an organization:

To approve an organization and/or a department, the following documents have to be presented to KWF:

- A recent (no older than two months) commercial register extract, issued by the Chamber of Commerce (in Dutch: uittreksel Kamer van Koophandel). In case the organization is already approved but approval is requested for a new department of this organization, this register extract is only required when the director of the organization has changed.
- A registration form, describing details of the organization, the department, the director of the organization, payment details and contact details of the delegated authority at the department level and the financial person. The registration form includes a declaration from the director of the organization (whose name is on the register extract of the Chamber of Commerce) stating that the delegated authority has the authority to sign. This registration form is available at KWF scientific review and grants administration department.

KWF reserves the right to reject a project proposal if the organization does not satisfy the approval requirements or the requested documents are not provided on time.

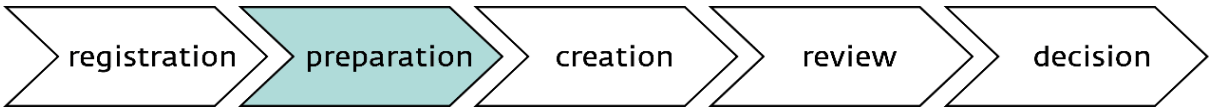
3.3 Registration of a personal profile

After choosing an organization and department, you will be asked to fill out a personal profile in GMS. This profile contains your contact details, CV and other information which is relevant for the review and monitoring process, such as specific expertise and experience. After having created a personal profile, you will receive a PIN number, which is accessible via your personal profile. It can be used to link your account to project proposals.

The following distinction has been made between expertise and experience:

- Expertise refers to your competencies in terms of specialisation, qualifications, position (e.g. biologist, pathologist, epidemiologist, psychologist, surgeon).
- Experience refers to your competencies in terms of the field of oncology and/or research in which you have worked or are working (e.g. type of tumors, techniques, methods, models, project management).

4. Preparing a project proposal



After registration in KWF GMS, you will be requested to select the funding type and research phase. Based on your choices, a project proposal form will open in which you can draft your project proposal.

Chapter 4.1 describes the different funding types and their terms for eligibility and these terms are binding. It also provides you a guideline to select the best funding type for your research.

Chapter 4.2 describes the several research phases.

4.1 Funding types

KWF offers five funding types:

- Research project
- Young Investigator Grant
- Unique High Risk project
- Consortium project
- Infrastructure initiatives

For each funding type, the greater part of the work on the project must be performed in the Netherlands. Therefore, during the term of the project the project leader is to be employed by a Dutch organization. When it is required for the project, parts of the work plan can be performed abroad.

For all funding types it is allowed to collaborate with other organizations to address the research question. If the collaboration has a complex nature, e.g. because of participation of private parties, a collaboration agreement may be required.

Conditions and guidelines for each funding type are described in the next five chapters.

In case you have a valid reason, e.g. for a follow up of a clinical trial, you may deviate from the eligibility condition of at least one scientific researcher to be employed on the project with a minimum of 0.5 FTE per year during the term of the project. This valid reason must be substantiated in the section people of the project. KWF assesses whether the reason is valid.

4.1.1 Research project

The funding type Research project aims at scientific projects which address a research question. The duration of a Research project is generally up to four years, but depends on your research question, as is the budget.

Eligibility terms Research project:

- The Research project is hypothesis-driven and has a defined duration and defined final analyses in which the hypothesis is confirmed or rejected.
- The project leader holds a PhD degree at the start of the project.
- At least one scientific researcher is to be employed on the project with a minimum of 0.5 FTE per year during the term of the project.

4.1.2 Young Investigator Grant

The funding type Young Investigator Grant (YIG) is for researchers who are in an early stage of their scientific career and offers talented young researchers the opportunity to initiate an independent oncological research line. The young researcher must be capable of leading the project and executing the project independently.

The suggested duration of a YIG project is four years, with 1.0 FTE scientific and 1.0 FTE non-scientific personnel per year.

Eligibility terms YIG:

- The YIG is hypothesis-driven and has a defined duration and defined final analyses in which the hypothesis is confirmed or rejected.
- The project leader has to initiate an independent line of research.
- The project leader holds a PhD degree at the start of the project.
- The project leader needs to be employed on the project for a minimum of 0.5 FTE per year during the term of the project.
- The project leader is eligible to submit a YIG project proposal if the call deadline is within five years after obtaining his/her PhD degree. Possible exceptions are:
    - An extension with the time spent on study/training to become a clinical/medical doctor after obtaining a PhD;
    - An extension with a maximum of two years in case of any valid reason, e.g. in case of maternity leave. This valid reason must be substantiated with official documents at the latest six weeks before the call deadline. If KWF considers the reason to be valid, an extension will only be granted for the upcoming call.

Exceptions are only possible after written approval by KWF.

4.1.3 Unique High Risk project

The funding type Unique High Risk project (UHR) provides the possibility to perform short-term preparatory work to determine whether a not yet fully crystallised idea offers viable opportunities. This type of funding is to validate innovative ideas, to realise preliminary work and is meant for non-existing lines of research on a mostly theoretical basis, but with high potential for breakthroughs in science. Therefore the project leader is an experienced scientist in the specific area to ensure pilot experiments will be undertaken efficiently.

The guideline for the duration of a UHR project is one to one and a half years. Six months after the starting date the project will be evaluated to ascertain that sufficient and successful progress has been made in the project and funding can be continued.

Eligibility terms UHR:

- The project leader holds a PhD degree at the start of the project.

4.1.4 Consortium project

The funding type Consortium project is for Research projects in which expertise from different organizations is required to address a complex research question. A project performed by four or more organizations (this does not include service providers, inclusion centers and co-funders) is always considered to be a Consortium project. Because of the complexity of a Consortium project, a project manager must be appointed to coordinate the project. In general, the duration of a Consortium project may last up to six years.

Eligibility terms Consortium project:

- The Consortium project is hypothesis-driven and has a defined duration and defined final analyses in which the hypothesis is confirmed or rejected.
- The project leader holds a PhD degree at the start of the project.
- At least one scientific researcher is employed on the project at a minimum of 0.5 FTE employment per year during the term of the project.
- A project manager is appointed.
- A collaboration agreement, signed by the lead institute and all participating organizations, is required before starting the project.

4.1.5 Infrastructure initiatives

The funding type Infrastructure initiatives facilitates existing or new Infrastructure initiatives that support and enable oncological research. KWF expects that the Infrastructure initiative is able to anticipate on its continuity and thereby to be implemented in a self-sustainable manner. So, the (financial) support provided by KWF is of temporary nature and KWF is not responsible for the continuity of this infrastructure. There is no guideline for the duration and budget of an Infrastructure initiative. The review process of Infrastructure initiative includes a two-stage process. When the pre-proposal has been positively reviewed and selected, you will be invited to submit a full proposal.

The scope of Infrastructure initiatives can vary per call, and only project proposals within the scope will be considered. The scope can be found in the call text on the website, see https://www.kwf.nl/onderzoek/poi/Pages/Infrastructurele-initiatieven

Examples of Infrastructure initiatives are:

- Facilities and platforms: biobanks, clinical trial platforms, early detection platforms, omics facilities, model organism platforms, imaging facilities and systems biology platforms.
- Data infrastructures: data repositories/archives/catalogues/portals/tools that proactively promote, engage and/or are in transition to adopt well-curated and FAIR (Findable, Accessible, Interoperable and Reusable) data.

Characteristics of Infrastructure initiative are:

- Value to oncology by fostering, enabling and supporting oncological research. Clear description of one or more research questions/Research projects which will be enabled by the Infrastructure initiative.
- Nationwide need and a broad support from the scientific community.
- Services and resources are available and accessible on a national scale.
- Collaboration within the oncology research area with existing Infrastructure initiatives, at both national and international scale.
- Transition to adopt the FAIR data policy (e.g. FAIRification of existent data and preparation phase to integrate single data resources/collections into overarching initiatives).

Collaboration between Infrastructure initiatives is encouraged. Therefore, if complementary Infrastructure initiatives are submitted in the pre-proposal stage, KWF can invite the project leaders to submit a merged full proposal. In this case, please be aware that:

- Only one project leader can submit the full proposal.
- Both project leaders have to sign a statement in which they accept to merge the preproposals to one full proposal. The signed statement has to be forwarded to KWF, see a template in appendix 2.
- Only after receiving the signed statement of acceptance, KWF will activate the full proposal submission form.

Eligibility terms Infrastructure initiative:

- A project manager is appointed.

4.2 Research phases

After choosing a funding type, you need to select a research phase. KWF identifies seven research phases, divided in two tracks.
The exploration track focuses on finding solutions to address knowledge gaps, obtaining new scientific knowledge and identifying first leads and targets.
The development and implementation track focuses on the development and implementation of leads and targets in the area of prevention, diagnosis, treatment and coping with cancer. The focus is on problems relevant to patients or the general public in a healthcare or practical setting.

In case a project proposal contains activities that apply to several research phases, please choose the earliest research phase of the project. If an interventive prospective clinical study is part of the project, always choose the research phase clinical research.

The research phases are explained below and shown in figure 1. Research activities and examples per research phase can be found in appendix 3.

Exploration track

- Basic research
- Credentialing

Development and Implementation track

- Creation of modality
- Preclinical research
- Clinical research
- Implementation research
- Infrastructure

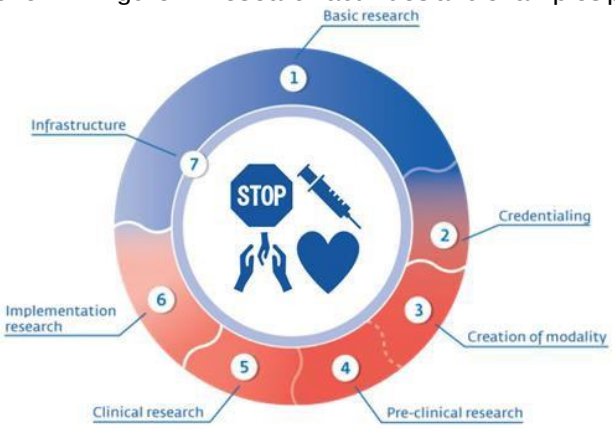


Figure 1: Research phases

4.2.1 Basic research

The goal of basic research is to obtain essential insight into the origin and progression of cancer and its (psychosocial) effects, as well as basic principles underlying the prevention and treatment of cancer and relevant technological developments. Basic research does not focus directly on the possible application of this knowledge.

4.2.2 Credentialing

Credentialing (or collecting credentials, evidence, confirmation) aims at identifying factors, targets and leads that could influence or improve prevention, diagnostics, treatment and quality of life. Examples are the discovery of drugs or biomarkers and compound or drug screening. Observational and population studies are also part of credentialing, including cross-sectional research, retrospective and/or prospective cohort studies and case-control studies. The credentialing phase includes a first step towards validating the identified factors, targets or leads.

4.2.3 Creation of modality

The goal of creation of modality research is the extensive characterisation and further development of new inventions/modalities until there is sufficient (*in vitro* and *in vivo*) evidence from model systems or retrospective data and sample sets, to start preparing for human evaluation.

The development of psychosocial interventions is included in this research phase. Human participation in the development of inventions/modalities is possible in this phase when it is not meant for a validation in a human setting. Starting from this research phase, concrete solutions for specific problems and needs (including unmet medical needs) are developed and validated.

4.2.4 Preclinical research

The goal of preclinical research is the completion of all stages required to start the clinical/human evaluation of a new invention/modality in subjects, such as:

- the development of GMP/clinical-grade production, toxicity testing, pilot or technical testing, successful IND/IMPD/CE submission and regulatory/ethical aspects;
- prospective analyses of the clinical feasibility of an invention or modality without performing the actual intervention (e.g. prospective biomarker studies without changing the actual treatment).

4.2.5 Clinical research

The goal of clinical research is to realize prospective clinical research, such as:

- a prospective clinical evaluation of a new invention/modality or assay/tool using a limited number of subjects;
- establishing the effectiveness of a new invention, dosage, off-label usage, combinations of modalities or psychosocial treatment;
- changes to treatment regimens associated with existing methodologies (including population checks) in a patient population.

4.2.6 Implementation research

Implementation research encompasses scientific studies on methods to promote the delivery and enhance the adoption of evidence-based interventions in (clinical) practice aligning with the main goals of KWF. A project proposal must have a research focus, including a scientific research question. Eligible projects focus on any aspect of Implementation research, including the factors affecting implementation, the process of implementation and the results of implementation. This also includes how to introduce potential solutions into a (health) system or how to promote their large scale use and sustainability. The purpose is to understand what, why, and how evidence based interventions/new methods work in “real world” settings, and to test approaches in order to improve them. Implementation projects require an optimal alignment between the current Research project and the envisioned end product and its users. Possible research questions can be:

- What are barriers and/or success factors in the implementation of an (evidence-based) innovation/new method?
- Which implementation strategies are effective and which are not?
- Why does an implementation strategy work in one healthcare practice and not in another?
- What are the unintended and unexpected effects of the implementation?
- To what extent has an innovation/new method been implemented and adopted in the organization?
- How can the result of the implementation be sustained?

4.2.7 Infrastructure

For Infrastructure initiatives, choose the research phase infrastructure.

5. Creating a project proposal

After having chosen the funding type and research phase in KWF GMS, an application form (draft version) with a project number will be created.

The project proposal consists of several sections and tabs. Please find below a detailed comment on all tabs.

General instructions:

- Your project proposal must be written in English, except for the Dutch summary tab.
- Fields which are marked (*) in KWF GMS are mandatory. Some fields are conditionally mandatory. If one of these fields is missing, KWF GMS indicates this by validation of your project proposal.
- KWF GMS does not support importing formatted text, so please make sure to use plain text when copying from external word processors. To insert special characters, use the insert button in KWF GMS.
- For Infrastructure initiatives: the fields requested in the pre-proposal submission form will be supplemented with extra fields in the full proposal submission form. The specific fields of the pre-proposal can still be edited in the full-proposal submission form.

5.1 Project details

5.1.1 Title of the project

Please choose a clear title, covering the contents of the project proposal.

5.1.2 Project duration

Choose the duration for the project proposal in months. When your project will last longer than 96 months, please contact KWF before submission.

5.1.3 Keywords

Keywords (maximum of five) are requested to represent the content of your project proposal, such as tumor type, methodology or field of work. If your Research project is specifically focused on paediatric or geriatric oncology, enter this as a keyword.

5.1.4 Scientific abstract

Summarise your proposal, preferably based on the following structure:

- description of the problem;
- envisioned solution/research direction;
- aim/hypothesis;
- plan of investigation;
- expected outcome.

If funding for the project is granted, the scientific abstract can be published in the international research database of the International Cancer Research Partnership. It is obligatory to ensure this text does not contain any confidential details that might reveal sensitive information or infringe the intellectual property rights of your research. KWF will use these summaries for communication purposes (e.g. to inform the public/donors about KWF-funded research).

For Infrastructure initiatives pre-proposal: summarise your proposal using the following topics:

- aim;
- preliminary activities;
- the need for the Infrastructure initiative;
- examples of oncological research lines/projects that the infrastructure will enable;
- financial self-sustainability;
- work plan.

5.1.5 Main goals

KWF has defined four main goals:

- We prevent cancer wherever we can;
- We stimulate better treatment for every type of cancer ;
- We aim for a better quality of life for (former) patients and their loved ones;
- We ensure that high quality palliative care is available for all patients.

Please indicate which main goal(s) your research will contribute to. If your proposal concerns basic research, you are requested to indicate this.
Describe how the results of this project proposal will contribute to the selected main goal(s).

5.1.6 Previous rejected project proposals

Please indicate whether this project proposal is an updated version of a project which was previously rejected by KWF and specify the corresponding project codes.
When resubmitting, you are advised to modify the project proposal in accordance with the feedback of the reviewers and review committee. Please indicate which changes you have implemented to improve the project proposal and how the feedback of the reviewers and the review committee has been addressed.

For Infrastructure initiatives - pre-proposal:
Please explicate whether the Research project(s)/research lines have been submitted to KWF earlier and indicate the corresponding project codes.

5.1.7 Related proposals and previously granted funding

Specify the project codes of projects, funded by KWF or other funders, which are related to the project proposal.

5.2 Classification

KWF is a member of the International Cancer Research Partnership (ICRP). The ICRP partners have adopted a common method of classification, the Common Scientific Outline (CSO) and Disease Site Code (DSC), which provide a simple overview of national and international cancer research.
KWF also employs a system of classification specifically designed for translational and clinical research to have a more detailed overview of its own portfolio, which is called modality coding.

You are to classify your project proposal based on the ICRP and modality coding system. KWF can choose to change your classification of the project.

Please be aware of the following specific aspects of the modality coding:

- If the project proposal concerns basic research, select basic research as the primary modality. Only code a secondary modality if the research goals of this second modality are actually to be achieved during the term of the current project proposal;
- For Infrastructure initiatives, the primary modality is fixed to infrastructure and the corresponding application and type are fixed to not applicable.

See appendix 4 for more detailed instructions.

5.3 Dutch summary

The tab Dutch summary will be used by the patients advisory committee (PACO) for assessing the project proposal. If the project is granted, the Dutch summary can be used for communication purposes to laymen. Therefore the entire tab has to be filled out in Dutch.
The PACO reads the Dutch summary in order to review the relevance and feasibility of the project proposal from patient perspective and to assess patient involvement. PACO members are part of the development and implementation review committee and play an active role in formulating the funding advice. The PACO is not involved in the assessment of the exploration track.

5.3.1 Project titel (project title)

Choose a clear Dutch title which describes the content of the project.

5.3.2 Samenvatting projectplan (summary of project plan)

Summarise your project proposal in layman's terms and avoid using specialised medical or scientific terminology. Although PACO members are trained in reading project proposals, not all members have a background of medical expertise or knowledge of specific research methodologies.
For more information on how to write a Dutch summary, please click:
https://www.gezondheidsfondsen.nl/wordpress/wp-content/uploads/2019/07/SGF-A4-Handr_onderzoekers.pdf

Please use clear subheadings, as shown below.

For development and implementation projects:
Background

- Problem: identification of the problem being the starting point of your project proposal;
- Objective: the envisaged solution for the problem/the research direction. In what way does your research proposal contribute to this solution?

Relevance

- Target population: for whom and in what way is this development significant, what is the size of this group of (ex)patients, and what is their current situation? What is the current prognosis for this group in terms of life expectancy, quality of life and the seriousness of their condition (including symptoms, somatic complaints and psychosocial burden)?
- Patient needs: does the objective of the study correspond to the needs of the target population?
- Contribution to the KWF main goals: How does this solution/research direction contribute to KWF's main goals? For example by prevention, diagnostics/early detection, recovery/survival rate, less invasive/stressful treatment, impact on outcomes of clinical research, quality of life, quality of health care provided and/or scientific development.
- Added value related to the field of oncology: describe the expected added value of your solution/research direction to:
  - everyday practice;
  - other therapies/interventions (including experimental treatment methods);
  - the health care sector;
  - future patients;
  - cancer prevention;
  - scientific development.
- Scientific foundation: the relevant research findings (in clinical experience and literature) which substantiate this solution/research direction.

Study design

- Study design: describes the different research stages.
- A clear and comprehensible diagram Illustrating of the study design (including follow-up). This can be attached as PDF file.
- Partnerships: whilst researching, will you be collaborating or coordinating with other parties?
- Dissemination of results: how will the results be disseminated to end users as well as participating patients?
- Follow-up: what steps are required to implement the findings of the research and the envisaged solution, and how does this project anticipate on it?

For Infrastructure initiatives:

Background

- Problem: describe what support the Infrastructure initiative offers to tackle which problem.
- Objective: the envisaged solution for the problem. Describe the scientific need for this Infrastructure initiative and how it will enable and facilitate the scientific research.
- Contribution to the KWF main goals: how will this Infrastructure initiative enable scientific research that contributes to KWF's main goals?

Relevance

- The expected added value of the Infrastructure initiative in view of the current situation in the following areas:
  - everyday practice;
  - other therapies/interventions (including experimental treatment methods);
  - health care;
  - future patients;
  - cancer prevention;
  - scientific development.

Study design

- Work plan: the different stages for the set-up of the Infrastructure initiative.
- A clear and comprehensible diagram illustrating the study design (including follow-up). This can be attached as PDF file.
- Collaborations: will the Infrastructure initiative collaborate with other initiatives?
- Dissemination of results: how are results disseminated to end users as well as to participating citizens?
- Follow-up: which follow-up steps can be anticipated to ensure the financial self-sustainability of the Infrastructure initiative?

5.3.3 Toelichting deelnemers (patient inclusion)

If your project proposal includes human subjects, please describe:

- All steps the study participants will experience during the project, including the follow-up period. We advise you to attach a PDF file including a diagram showing these steps.
- The imposition on the study participants (in terms of time, physical, psychological and social impact and potential side effects) and how they will be supported.
- The possible benefits (what will study participants gain from participating?).
- The planned comparisons between the experimental arm and the control arm.
- The risks and ethical aspects (freedom of choice, privacy) associated with participation.
- The research sample: the number of study participants, inclusion and exclusion criteria, chance of dropouts, feasibility of the envisaged research sample and recruitment strategy.

5.3.4 Toelichting patiëntenbetrokkenheid (patient involvement)

Patient involvement is a process that includes patients or their informal caregivers as stakeholders, advisors and shared decision makers, in research, policy, or quality of care. Please note this is not patient inclusion, which refers to persons who are included in a clinical trial.
KWF believes it is important to involve patients and/or patient organizations to enable them to address their needs in all stages. Please describe how patients and/or patient organizations are actively participating in the design, planning, development and execution of your study, as well as dissemination of results. If patients or patient organizations are not participating, please explicate the reason.
Answer the following questions, and include documents to support your answers:

- How and when are patients/patient organizations involved?
- What kind of input is provided? What will this input be used for?
- Describe the role of patients and/or patient organizations during and after the study? Will they be involved in translating results into concrete actions?
- When and how will patient involvement take concrete shape?
- How will results of the study be communicated to the patients and/or patient organizations ?
- How will patients and/or patient organizations be involved in the dissemination of results?
- For Infrastructure initiatives: In what way will patients be involved in data ownership, privacy, ethical and societal issues?

For more information, see the website www.kwf.nl/patientenparticipatie.

In order to establish a meaningful involvement of patients or patient organizations, they should be contacted at the latest 6 weeks prior to the call deadline. In your search for participating patients, you could contact the Dutch Federation for Cancer Patient Organizations (In Dutch Nederlandse Federatie van Kankerpatiëntenorganisaties, NFK). Their website www.nfk.nl provides direct links to the websites of the different cancer patient organizations.

For more detailed information on patients/patient representatives involvement during the different stages of research, please click www.participatiekompas.nl/kickstarter.

5.4 Parties of the project

In KWF GMS, tab parties of the project an overview is requested of

- all people who actively work on the project;
- all organizations involved in executing.

5.4.1 People of the project

You must register the principal investigators and scientific personnel in the table people of the project. If a position is vacant, you can enter vacancy. Adding a foreign researcher as a principal investigator or scientific personnel is permitted. Please justify in the corresponding work package(s) their contribution to the work plan.

Persons who can contribute to the project, people of the project:

- The **project leader** being the holder of the grant, is the lead researcher of the project and takes direct responsibility for completion of a funded project. The project leader must be employed by a Dutch organization during the term of the project. The project leader is responsible for the scientific management and coordination of the whole project and the submission of all required reports on behalf of the lead institute. In addition to his/her obligations as a participant, the project leader must ensure that the project team complies with the terms and conditions of the research grant. Each project has one project leader, who also is also the exclusive contact for KWF. Please note that the project leader cannot take the role of project manager.
- The **principal investigator** is responsible for the daily scientific management of a specific part of the project, usually defined in (a) work package(s). A project can have multiple principal investigators.

- **Scientific personnel** are researchers such as PhD students, postdoctoral researchers, medical doctors or trainee doctors who execute the research activities.
- **Research support personnel** (MBO, HBO or academic) refers to personnel that executes non-scientific supporting tasks within the Research project, such as technicians, research nurses, data managers and trial managers. These personnel costs can be added to the budget according to their level of education: MBO (vocational education); HBO (Bachelor's degree) and academic (Master's degree).
  An example of research support personnel is a **project manager**, who supports the project leader to ensure that the project will be completed on time and within budget, with a specific focus on facilitating collaboration between the different organizations in a complex project. The project manager's main goal is to ensure that the project's objectives are met to the highest possible standards and to ensure everyone completes their required tasks. The project manager does not have a scientific/research role in the project and is not involved in the project at a content level. Examples of possible tasks: organizing and taking minutes of meetings, contacting stakeholders and external parties, taking care of contracts and payments, logistics of the samples, and monitoring of the progress. A project manager is obligatory for Consortium projects and Infrastructure initiatives and recommended for multi-center clinical studies.
- **Advisors** support with expertise which is not available in the project team. Their advice on the progress of the project is focussed on the final goal or product. KWF encourages involving the right advisors and (patient-) advocates both before and during the project. This is to ensure that the project proposal meets the needs of the field and the end users of the modality/invention being developed. Advisors are not involved in the implementation of the work plan. An advisor sends a letter of commitment to specify the agreement made with the advisor in terms of the advisory role in the project and how this contributes to the project proposal/planning.

5.4.2 Register people of the project in KWF GMS

You can add people to your project proposal by linking them by PIN number or by adding manually. For all people of the project, fill out in which work package(s) they are involved and if budget for FTE is requested by filling out yes or no:

- By clicking yes you state that personnel costs will be requested for funding by KWF. The requested data on FTE/salary must also be processed in the budget tab.
- By clicking no you state that personnel costs will be funded by own contribution. In that case funding for this employee is already provided for by their organization and you must indicate FTE own contribution (average/project).

5.4.2.1 PIN number to link principle investigators and scientific personnel

Principal investigators with a personal profile in KWF GMS have a unique PIN number that can be found on their profile page. The project leader must use this PIN number to link principal investigators and known scientific personnel to the project proposal**.**
KWF therefore request the project leader to ask for the other participants PIN number and use this to synchronise their contact details to the project proposal. Before providing their PIN number the principal investigator or scientific personnel must ensure their profile is up-to-date. By providing their PIN number, the participants authorise the project leader to submit the proposal on their behalf, as well as agreeing to undertake, and assume responsibility for, their part of the work plan. When a researcher is linked to a project proposal as principal investigator, he/she can make changes to the project proposal.

5.4.2.2 Minimum of 0.5 FTE employment

For Research projects, YIG and Consortium projects: please state if you have at least one scientific researcher employed on the project at a minimum of 0.5 FTE employment per year during the term of the project. If you do not meet this eligibility condition, please justify.

5.4.2.3 No PIN number for research support personnel and advisors

Research support personnel, vacancies and advisors have no PIN number. You must fill out their name, organization and department.

5.4.3 Project leader details

The project leader's personnel data will automatically be copied from his/her profile. This information includes: name, the institute and department he/she registered and CV, including obtained degrees, education/training, professional experience and relevant honours and awards. Please ensure this profile is up–to-date. The project leader's four most relevant publications can be added manually to the project proposal.

5.4.4 Principal investigator details

After the PIN number and last name have been added, the profile data of the principal investigator is automatically copied into the project proposal. This data includes: the name of the principal investigator and CV, including obtained degrees, education/training, professional experience and relevant honours and awards. The principal investigator's four most relevant publications can be added manually to the project proposal.

5.4.5 Scientific personnel details

After the PIN number and last name have been added, the profile data of the scientific personnel is automatically copied into the project proposal. This data includes: the name(s) and CV, including obtained degrees, education/training, professional experience and relevant honours and awards.

5.4.6 Parties of the project

Please complete the table parties of the project. If you have filled out the people of the project, KWF GMS will fill out the lead institute and participating organizations automatically. A participating organization who does not request budget for FTE but does request other funding, must be indicated here. Finally, the service providers, inclusion centers and co-funders must be added. For definitions of the parties please read below. Figure 2 shows schematically all criteria for the parties involved.

Conditions:

- The project must resort under one lead institute.
- The lead institute is permitted to cooperate with one or more parties.
- Each party has only one role in a project. The party acts either as:
  - lead institute
  - participating organization;
  - service provider;
  - inclusion center;
  - co-funder.

  Roles can switch per project and are not fixed between projects.
- The right on intellectual property on the project results depend on the role of the organization in the project. A project result is defined as: all information, samples, knowledge and inventions arising from the project. This result may possibly be protected by means of right on intellectual property.
- The added value of each of the separate organizations must be justified.
- Data management can be performed by the lead institute, a participating organization or service provider. The project leader and the lead institute are responsible for safeguarding of data management.

Definitions parties of the project:

- The **lead institute** is a Dutch organization that carries the final substantive and financial responsibility for the project and the dissemination and exploitation of the project results. The lead institute is also employer of the project leader, the sole recipient of the funding and point of contact for KWF, the participating organizations and other stakeholders. Appendix 1 gives an overview of types of organizations which are eligible as lead institute.

- A **participating organization** is an organization that carries substantive and financial responsibility for a part of the project, the dissemination and/or exploitation of the results. A foreign participating organization can perform parts of the work plan, when the project leader deems this necessary. The necessity must be justified in the description of collaboration.
  A participating organization whose owners benefit from the net income or earnings of the organization, cannot receive funding from KWF, unless all of the net income or earnings are used for the stated purpose of the organization to increase the social impact and/or public good. These specific participating organizations must confirm their contribution in a letter of commitment. The letter must comply with the guidelines as stated below.
- An **internal service provider** is a department of the lead institute or participating organization that provides a necessary service for the work plan, such as data management, animal facilities, pathology review and MRI scans. An internal service provider does not benefit from the project results and has no right to the project results. A quotation for their services is obligatory.
- An **external service provider** is an organization that provides a necessary service for the work plan, such as data management, animal facilities, pathology review and MRI scans. An external service provider does not benefit from the project results and has no right to the project results. A quotation for their services is obligatory.
- An **internal inclusion center** is a department of the lead institute or participating organization that only includes patients for clinical studies and has no active research role in the project. It has no right to the project results, an exception to this is that an inclusion center retains the right to information, samples, knowledge and inventions on its own generated data.A quotation for their services is obligatory.
- An **external inclusion center** is an organization that only includes patients for clinical studies and has no active research role in the project. It has no right to the project results, . It has no right to the project results, an exception to this is that an inclusion center retains the right to information, samples, knowledge and inventions on its own generated data. A quotation for their services is obligatory.
- **Co-funders** contribute in the form of a financial and/or material donation for the execution of the project (co-funding). A co-project, unless agreed in a separate agreement with the lead institute and participating organization. This agreement should be in line with the articles of the funding conditions on dissemination and exploitation of the results of the project. A letter of commitment from the co-funder is obligatory.
- For Infrastructure Initiatives full proposal: **User groups**: user groups of the Infrastructure initiative must justify their support and commitment for using the Infrastructure initiative, by describing which kind of scientific research will be performed. Letters of commitment from the Infrastructure initiative user groups are obligatory.

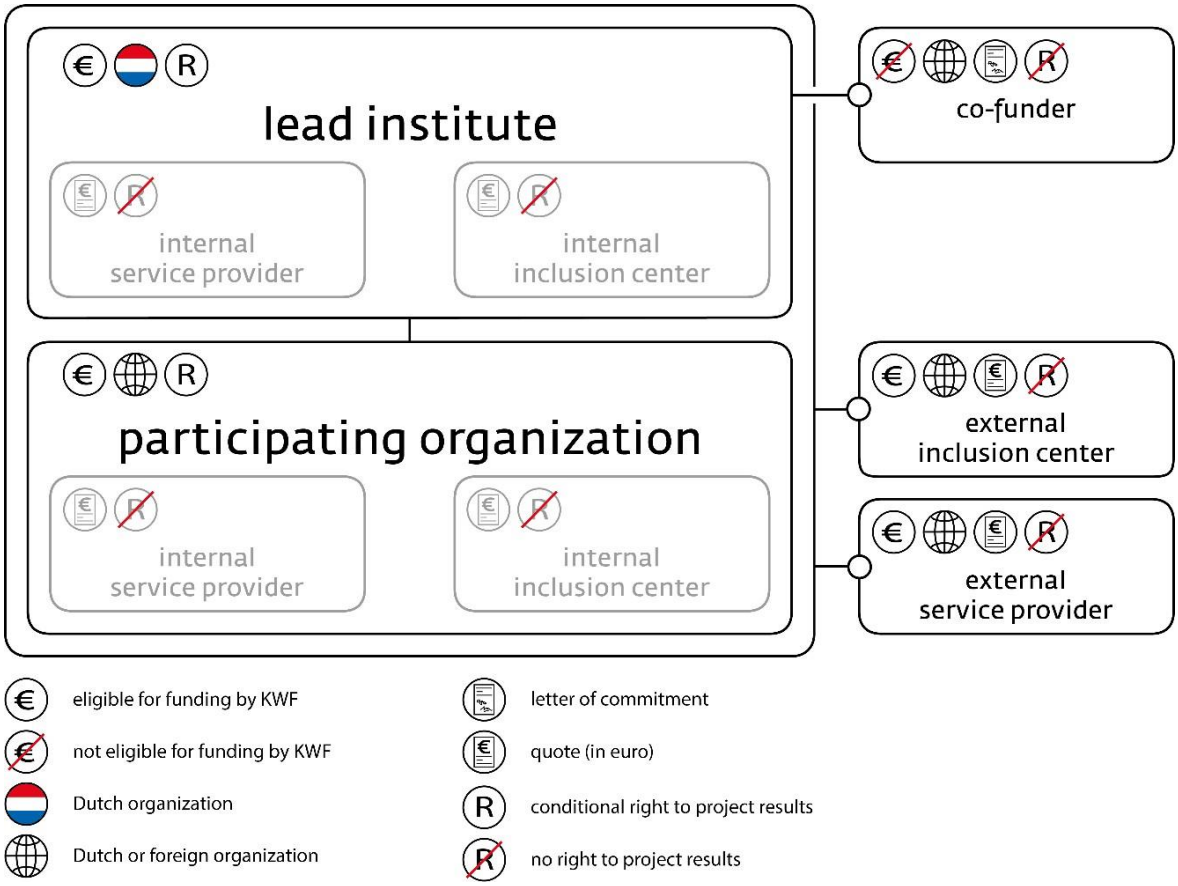


Figure 2: Schematic overview of organizations working on a project.*

* An exception to the right of project results is that an inclusion center retains the right to information, samples, knowledge and inventions on its own generated data.

Letter of commitment:
In a letter of commitment the organization specifies the contribution they will make to the project, e.g. in-cash contribution, costs of man-hours, material resources and number of patients to be included, etcetera. The letter includes how their contribution fits within the project proposal/planning.
You can upload the letter as attachment (PDF file) to the project proposal form. The PDF file name must clearly indicate the subject of the letter. Letters of commitment are compulsory for: participating organizations who receive no funding from KWF, co-funders, advisors and user groups (Infrastructure initiatives). The letter must comply with the following terms:

- The letter must be printed on headed stationery and must be addressed to the project leader. It must show the correct address of the organization.
- The letter must specify the contribution made by the organization. E.g. in-cash contribution, the cost of man-hours (number and/or rate applied), material resources (numbers, cost prices, rates, percentages that can be attributed to the project, etc.), number of patients to be included and how their contribution fits within the project proposal/planning.
- The letter must give consent for KWF to publish the organization's name as participating organization, inclusion center or co-funder of the project.
- The letter must be signed by an authorised person from the committing organization.

- A letter of commitment by user groups of Infrastructure initiatives should demonstrate their support and commitment to use the Infrastructure initiative, by describing which kind of scientific research will be performed in the Infrastructure initiative.

5.4.7 Collaboration

5.4.7.1 Upload organogram

Please provide a schematic representation (in PDF format) of the parties of the project and the people working on the project (project leader and principal investigators), including the work packages for which they are responsible. Figure 2 could form the basis for the organogram.

5.4.7.2 Description of collaboration

When applicable, please describe the role of the collaborating organizations in the project and their synergy, based on their specific expertise and including the knowledge exchange and decision-making process within the collaboration.

5.4.7.3 Project embedding

Please indicate if this project proposal is part of a larger project with additional funding. If it is, describe the larger project in which the current project proposal is embedded. Describe the ways in which the project plan and the larger project are dependent upon each other in terms of organization and funding. Describe the relationships between the execution of the larger project and the execution, results and benefits of this project proposal.

5.5 Project proposal

In the tab project proposal you have to describe your actual project proposal/work plan. Use this section to describe and substantiate the activities that cover your request for funding. Please note that the references which are in this tab must also be listed under the references tab.

5.5.1 Relevance

5.5.1.1 Problem and research direction or solution

Please describe the problem you intend to solve and specify the needs that will be fulfilled when your project or development plan has been successfully completed. Make sure to be as specific as possible and substantiate the size of the problem (e.g. target population, burden on the patient, under-or overtreatment, costs, etc.). Describe the solution you envisage (e.g. new diagnostic test, therapy or preventive therapy, screening modality, etc.). When the problem involves a specific lack of knowledge, it suffices to describe how the results of the project will contribute to the current state-of-the-art research and what type of spin-off/future activities you expect it to generate (e.g. a new platform technology, specific knowledge that will help the field move forward, new targets for prevention, diagnosis or therapy, etc.).

5.5.1.2 Aim/hypothesis

Please describe the goals of this project proposal, divided into main goals and secondary objectives or research questions; and/or specify the hypothesis that you will test.

5.5.2 Background

5.5.2.1 Summary of literature

Please provide a concise summary of the relevant literature. Clearly distinguish between the results of your own research and those of other research groups and what gaps in the research field the proposal seeks to fill.

5.5.2.2 Preliminary results of own research

Please specify the results of preliminary research (including pilot studies) undertaken by you or the research team that led to the current project proposal. Refer to the preliminary research that has already been/or is in the process of being published and abstracts.

5.5.2.3 Supporting documentation

If applicable, upload supporting figures of (preliminary) work.

When applying for a clinical research proposal please note that it is not obligatory to attach the Patient information form, PIF, to the project proposal (clinical supporting documentation section of the tab). If the PIF is not yet available during submitting the project proposal, please upload a statement on when the document will be available.

5.5.3 Plan of investigation

5.5.3.1 Synopsis of work packages and their interconnection

Please explain how the activities of your overall work plan are divided across the work packages and how the work packages are interconnected.

5.5.3.2 GANTT chart

You are advised to add a GANTT chart, showing the duration of the work packages, the major activities included in these work packages and the time frame in order to reach the milestones.

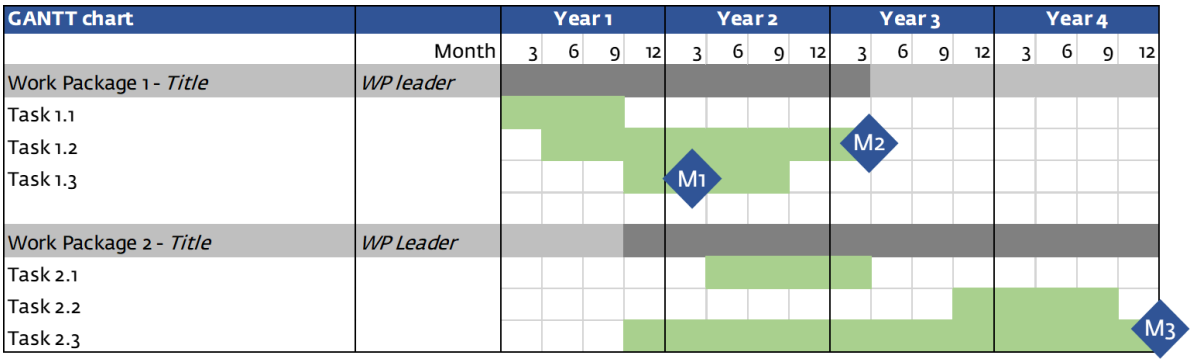


Figure 3: Example of a GANTT chart.

5.5.3.3 Creating a work package

Restrict the number of work packages to a minimum. For straightforward projects and even for more complex projects, one to three work packages will suffice.

5.5.3.4 Description of work packages

A work package consists of a unit of coherent work/activities and is clearly distinguishable from other work packages. A scheduled start and completion date with interim milestones (if applicable) are defined, as well as at least one milestone to conclude the work package (obligatory).

Required fields for each work package are:

- specification of the work package number;
- starting month and duration of the work package;
- principal investigator who will be responsible for the completion of the work package;
- objective(s) of the work package and significance to the overall project aim;
- description of the work (methods and techniques);
- statistics utilised in this work package and any supporting documentation if applicable.

If applicable, please include in the work plan the possible burden, side effects and effects on quality of life for patients and describe how you will minimise the negative effects. KWF advices to address this as early as possible during the development of interventions, diagnostics tests and care.

If the project proposal includes an internship abroad, describe in the work package the internship's contribution to capacity-building and its relevance to the proposal's objectives. Explain why the internship is necessary for the implementation of the work plan and include a description of the available expertise at the host institute.

5.5.3.5 Work packages for clinical studies

KWF recommends to describe at least the following aspects of the clinical study in separate work packages:

WP1: Undertaking the trial (including selection of research sample)

Please describe in a work package the organizational structure of the trial and the sample selection strategy, including the following information:

- How is the research organised?
- Necessary research sample (the number of required trial subjects) and statistical validation.
- Is the study single-center/multi-center? When multi-center, KWF recommends to appoint a project manager.
- Will the study be undertaken at a national or international level?
- A list of the participating hospitals/inclusion centers.

WP2: Data management and analysis

KWF recommends to include the description of execution and organization of data management as extra separate work packages in the work plan (handling and storage of data and documents and monitoring and quality assurance):

- How will the central data management be organized? Is a CRF being used? What are the qualifications of the staff?
- What database will be used and how will the data be stored?
- How is the local data management organised? Who collects the data and what are the qualifications of the staff?
- How will the monitoring be organised and to what extent? Does the local monitoring comply with the Netherlands Federation of University Medical Centers (in Dutch: Nederlandse Federatie van Universitair Medische Centra, or NFU) guidelines? What are the qualifications of the staff?
- Deployment of personnel, registered at the Netherlands Association of Oncology Data Managers (applies to local and central data management and to monitoring).
- How is the trial management organised? Will there be any trial management agencies involved? If so, please specify the agreements.
- Does the organization or trial management agency have a quality guarantee or any certification? If so, please attach the relevant documents.

WP3: Follow-up

When the follow-up of the clinical trial is required to address the hypothesis, this must be described in a separate work package. The follow-up work package describes:

- Motive for follow-up. What are the end points? Which questions are important?
- Duration of follow-up, frequency of follow-up (yearly frequency, timeline of agreements in protocol) and required time per visit.
- Expected drop-out rate.
- Will the patients be invited for follow-up (or regular care/registration) as part of the study?

5.5.3.6 Milestones

Milestones are the starting point for monitoring a project. They are critical points in time, set to ascertain that sufficient and successful progress has been made in the project. Do not confuse with specific deliverables of the project such as publications.

A milestone can be defined as a point in time, either during or at the end of a work package, that marks the completion of a major activity or project requirement (or set of activities). Since milestones serve as markers of progress, please describe them SMART (Specific, Measurable, Acceptable, Realistic, Time-Bound). In order to be able to determine when a milestone is successfully met, distinct criteria must be formulated.

Define a limited number of significant milestones that can be used to measure the progress of the project. For project proposals that fall within the exploration track, two to three milestones in total will suffice; for project proposals within the development track, an average of three to six milestones in total will suffice. It is obligatory to formulate at least one milestone per work package.

5.5.3.7 Statistics

Please substantiate the methodology/study design, including power calculations, and include a statistical analysis strategy. If applicable, describe how you will approach data management and -sharing, quality control, bioinformatics, data accessibility, or any other specific data analysis methods you intend to use.

5.5.4 Experiments including human subject, animals or recombinant DNA

If the work plan includes human subjects (= patients, healthy people or material/tissue from patients), animals or genetically modified organisms, please describe the intended numbers and the type of animals/organisms required for the implementation of the work plan.
Please note, that it is the responsibility of the project leader and the lead institute to ensure that the research complies with the legal regulations applicable to the use of human subjects, animals or recombinant DNA.

5.5.5 Dissemination plan

Describe how you will ensure that the knowledge/skills/technology resulting from this project will be transferred to potential users that could benefit from this, e.g. scientists, clinicians, healthcare professionals, patients and policymakers. Describe your actions to disseminate the obtained knowledge, such as publications, presentations, education, media, training etc.

5.5.6 Intellectual property strategy

All projects will yield results, information, samples, knowledge and inventions. For further development to the benefit of public and patients it may be necessary to protect the results. Please describe your strategy to protect these as they arise, e.g. patents, trade secrets, copyrights, trademarks, registered designs. If you are electing not to protect the knowledge/skills/technology resulting from the project, please motivate your decision. Describe any relevant existing intellectual property needed for the execution of the project as well. Also, specify if and how the Technology Transfer Offices (TTOs) of the participating organizations are involved in the project.

5.5.7 Infrastructure Initiatives

5.5.7.1 Pre-proposal

For Infrastructure initiatives pre-proposal, fill out the following fields. Please note that these fields are editable during full proposal submission.

- Relevance
- Aim: define the aim of the Infrastructure initiative by describing which oncological Research projects will be enabled by this infrastructure, and conclude by providing at least three concrete examples of Research projects.
- Preliminary activities: motivate why you and the proposed team are the best suited to carry out the work plan and indicate the preliminary activities that have been undertaken.
- Plan of investigation
- Work plan: draft a general description of the work plan that is to be executed, using the following structure:
    - initiation;
    - consolidation;
    - full independence.

- Feasibility
- Financial self-sustainability plan: describe how you foresee to achieve long-term financial self-sustainability, indicating concrete measures (e.g. catalogue of services, service price, user numbers, etc) for the proposed Infrastructure initiative, after KWF (financial) support has stopped.

5.5.7.2 Full proposal

For Infrastructure initiatives full-proposal, fill out in the following fields

- Relevance
- National accessibility: describe how the resources and services, enabled by the Infrastructure initiative, will be accessible at a national level.
- Timely nature of the Infrastructure initiative: justify why the current moment is the most appropriate to set/implement/further develop the Infrastructure initiative.
- Merged submission: when different complementary pre-proposals are merged into one full proposal form, please describe how the overlap in the activities of the merged Infrastructure initiatives will be tackled.
- Quality
- Plan of Investigation
- Synopsis of work packages and cohesion: please use this section to provide an overview of your overall work plan and activities. Include how the activities will be divided across the work packages, how the work packages are interconnected and the added value of each work package.
- GANTT chart: provide a GANTT chart showing the duration of the work packages, major activities therein and the required timeframe for reaching the milestones.
- Description of work packages: provide a concise and concrete description of each work package. State the work package number, the name of the work package leader, the starting and closing dates of the work package and the objective of the work package. Please specify the contribution of the objective of each work package to the overall aim of the Infrastructure initiative and conclude by indicating the milestones and results of each work package.
- Milestones: are critical points in time, set to ascertain that sufficient and successful progress has been made in the Infrastructure initiative. It is obligatory to formulate at least one milestone per work package; a total of three to six milestones will suffice.
- Feasibility
- Financial self-sustainability: describe which arrangements you have planned to ensure long term financial self-sustainability (such as potential and contact with other (co-)funders, development of a business model, by e.g. indicating the contribution of different funders, the cost modalities being developed: fee-for-service, full-cost/recovery-cost/pay-per-view/pay-per-computing, etc).
- Continuity of the Infrastructure initiative: estimate the number of users of the Infrastructure initiative, and explain the intended measures to maintain and/or increase this number.
- Risk analysis: provide a SWOT analysis including strengths, weaknesses, opportunities and threats of the Infrastructure initiative. Include also the planned arrangements to overcome/mitigate the weaknesses and threats of the Infrastructure initiative.
- Dissemination plan: describe how you will ensure that the information, samples, knowledge and inventions, that are enabled by this Infrastructure initiative, will be transferred to the potential users (e.g. scientists, researchers, clinicians, care professionals, patients, policy makers). What are your actions to raise awareness of the Infrastructure initiative?
- Technology transfer involvement: specify how the TTOs of the participating organizations are involved in the project. If a collaboration between the Infrastructure initiative and a commercial partner is foreseen, please describe how your TTO is involved. If applicable, provide specific examples(s) of the potential opportunities for valorisation.

5.5.7.3 FAIR Data

In accordance with the funding conditions of KWF Kankerbestrijding 2020, the lead institute is required to work according to the FAIR data principles (Findable, Accessible, Interoperable and Reusable). In order to further stimulate the FAIRification of data and tools, a data management plan is requested.

For Infrastructure initiatives:

Please fill out the data management plan as complete and accurate as possible. Indicate which steps will be taken during the course of the Infrastructure initiative to ensure that data and tools are FAIR. Be aware that the data management plan is a dynamic document. As such, and in case funding is granted, further developments and adjustments will be allowed during the course of the Infrastructure initiative. The developments of the data management plan will be monitored by KWF. For assistance on creating a data management plan, click https://dmponline.dcc.ac.uk/help#PlanningHelp

Data management plan

- General features: indicate if you created the data management plan with the assistance of a data management expert. If so, please state the name, organization/department, phone number and email address.
- Characteristics of the data collection: describe the characteristics of the collected data (e.g. data type; is the data new, existent or coupled data; will the collected data be coupled to patient data). If you are going to reuse/combine data sets, please describe whether you have the data owner's permission to use/combine the data. Describe the envisaged end product (e.g. raw data, computed data, software, semantics and/or ontologies). Indicate if an estimation of the size of the data collection can be given (e.g. number of participants or subjects in the collection and if so, its size in GB/TB) and indicate the storage capacity to save and back up the available data during the course of the Infrastructure initiative.
- Legislation (including privacy): when the research, enabled by the Infrastructure initiative, involves human subjects please include if informed patient consent is available for data collection. And describe also whether there is need to anonymize/pseudonymize the data.
- Findable data: describe how the data can be found (e.g. search engine, archive, catalogue) and which metadata scheme will be used to describe the data collection (e.g. which metadata and which persistent and unique finders (DOI) will be used).
- Accessible data: state whether the data collection will be accessible for further research and verification. Also indicate if the data is:
  - openly available;
  - only partially available;
  - under embargo.

  If applicable, please describe the restricting access conditions to access the data collection.
- Interoperable data: describe which data standards will be used and which metadata standards will enable further data coupling to other data collections. If the research, which is enabled by the Infrastructure initiative, involves human subjects please describe the privacy protection measures associated with the reuse of the data and potential combination with other data sets.
- Reusable data: include how you will ensure the sufficient quality of the data and associated documentation so it can be reused by others (e.g. replication package) and which selection criteria will be used to ensure that the data is preserved and reused. Please estimate the size of the data collection (in GB/TB) that is to be preserved in an archive/repository and which archive/repository will be used to ensure long term use of the data? Once the project is closed, how long will you recommend to preserve the selected data for archiving? Did you make an estimation of the costs for data preparation for archiving and is this estimation provided for in the current project budget?

5.6 Budget

In this tab you can request budget, needed for the duration of your project. This request is to be divided in several subcategories:

- personnel costs;
- materials;
- services;
- open access;
- internship abroad.

By filling out the subcategories, KWF GMS will automatically calculate the total amount of the requested budget, which will be shown in the summary requested budget.
Costs that will be paid from co-funding or by own contribution can be included in the corresponding items. In the preclinical and clinical research phases, KWF expects co-funding by other organizations or by means of own contribution from the participating organizations to be part of the project proposal.

Based on the input of the requested budget, own contribution and co-funding, the summary budget table, will be filled out automatically. Please specify and justify in detail in the budget description. This applies for requested budget, co-finance and own contribution. Costs that are eligible for funding by KWF can be requested, or listed as own contribution or co-funding. Poorly defined costs and non-eligible costs will not be funded by KWF.

KWF recommends to request your finance department to check if the budget of your project proposal is filled out correctly and in accordance with the guidelines and funding conditions. To this end, the financial contact person can view and edit the project proposal or you can export your draft project proposal from GMS to PDF. If you do not know who has access to KWF GMS, please contact KWF scientific review and grants administration department.

5.6.1 Personnel costs

Please specify in this section the FTE of personnel which is requested for funding by KWF. The corresponding salaries will be calculated automatically. Calculations are made with reference to the salary scales based on the Collective Labour Agreement for Dutch University Medical Centers (in Dutch: CAO Nederlandse Federatie Universiteiten, NFU: https://www.nwo.nl/en/salary-tables), applicable at the date of opening of the call to determine the maximum fundable amount for the various roles that are involved at the project. These are cumulative rates, including indexation. The salary scales will be updated before issuing the decision letter, but will not be adjusted during the course of the project. Any personnel costs exceeding these scales must be paid for by the lead institute or participating organization.

Degree
Scientific personnel – PhD-student[1]
Scientific personnel – senior (PhD/MD etc.)[1]
Research support personnel – MBO[2]
Research support personnel – HBO[2]
Research support personnel – Academic[2]

[1] Scientific personnel: includes PhD students (PhD-student scale) and PhD/MDs (senior scientific staff) who actively contribute to the research. The same salary scales are used for PhDs/scientific personnel and for researchers with a medical degree. This is because specialists/ researchers with a medical degree are not employed on the project in a role of medical doctor, but of researcher. Please note: funding of scientific personnel with (partial or full) structural financing cannot be applied for.

[2] Research support personnel: includes non-scientific staff that provides support with no scientific role, for example technicians, research nurses, data managers and project managers. For a project manager, funding can be requested for up to a maximum of 1.0 FTE per year.

5.6.1.1 Scientific personnel – additional personal budget

Scientific personnel receiving salary from funding by KWF, are granted an annual additional personal budget of € 750.- per FTE. This standard and fixed amount will be added automatically. The additional personal budget can be used for attending conferences and associated travel expenses, publications and printing a thesis.

5.6.2 Materials

All material costs must be specified per year in detail using a separate row for each type of product. This can be further justified in more detail in the budget description. Materials must be specifically required for the execution of the project, this includes:

- Project-specific software and licences;
- Unspecified consumables for standard laboratory work and routine procedures, e.g. chemicals, enzymes, molecular biology kits and reagents, glassware, plastics, dyes, radioisotopes, tissue cultures, stationery, postage and courier costs. Per FTE scientific and supporting personnel requested for funding by KWF to perform laboratory work, per year €12.500 can be applied for as unspecified consumables;
- Extra consumables required for executing the research needs to be properly justified and specified in the budget description;
- Relevant literature, surveys and market research;
- Purchase of and accommodation for laboratory animals;
- Use of a specific device if it is essential for executing the project and if the device is not already available;
- Travel and accommodation costs for data collection, site visits, stakeholder or focus group meetings. Travel and accommodation costs for meetings of the project team are **not eligible** for funding;
- Costs made for patient involvement, to enable executing and evaluate the project;
- Audit fees up to a maximum of € 2,500.- per project.

5.6.3 Services

The budget for fees paid to service providers and inclusion centers, should be listed using a separate row in the budget tab. Indicate per row whether it concerns a service provider or an inclusion center and state the requested amount. The amount must be substantiated with quotations, which can be uploaded as PDF file. Please ensure that the uploaded quotation matches the description and amount in the budget tab. There is no set maximum for these costs as a proportion of the total project budget; the internal review committee will assess whether each service provider and inclusion center has added value and whether the quoted price is fair.

- Examples of services provided by services providers are specific analyses, laboratory services, bioinformatics or statistics, biobanks, imaging and pathology costs, quality-of-life registration;
- The costs for requesting a permit at the Centrale Commissie Dierproeven (CCD), the Medisch Ethische Toetsingscommissie (METC) or Centrale Commissie Medisch Onderzoek (CCMO) can be applied for if these permits are required to execute the proposed research. This is only applicable for the research and experiments which will be executed on the research proposal;
- The quotations for an inclusion center must specify the costs of patient inclusion. The number of patients to be included and the fee per patient needs to be specified.

5.6.4 Open access

Please indicate the budget requested for open-access publication during the project. A maximum of € 10,000.- can be applied for.

5.6.5 Internships abroad

Internships abroad can bring essential knowledge and skills, which are required for the execution of the project, to the Netherlands. Funding can be requested for scientific personnel to undertake an internship abroad for capacity-building purposes, with a minimum of one month and a maximum of two years, but no longer than fifty percent of the duration of the project. The internship must take place at a single institute, however you can apply for multiple internships during one project. In that case the total time spent on the different internships abroad may not exceed the maximum duration. Staff will remain employed at the Dutch institute for the duration of the internship. Funding can be requested for travelling (return trip, economy class) and accommodation expenses incurred by the relevant researcher(s).

5.6.6 Requested budget – summary

Based on the previously provided input, the requested budget summary will automatically be filled out. When funding is requested for open access or an internship abroad, this budget is allocated in the first year of the term of the Research project.

5.6.7 Own contribution

The lead institute and participating organizations can provide personnel, materials or cash contributions to project activities. This type of contribution to the project activities is referred to as own contribution.
Please indicate the capital contribution for material costs made by the participating organizations. This only refers to eligible expenses. The amount stated here must be specified in the budget description section.

Contributions being made in terms of personnel should also be indicated in the tab parties of the project. These contributions are summed automatically in the budget tab and must be specified in the budget description in order to further substantiate the commitment of the participating organizations.

5.6.8 Co-funders

Please describe any co-funding that exists for this project. This refers to contributions to the project, in cash or materials, made by non-participating organizations. Please note this only refers to eligible expenses.

Co-funding in the form of material resources must be calculated at cost price. Commercial retail rates will not be accepted. For co-funding of equipment, please take any previous depreciation and the intensity of use into account. Co-funding in the form of supplies or services will only be permitted if the service can be specified as an identifiably new endeavour. The service is not permitted to already be available within the research institute(s) that is /are undertaking the research. Applicants may wish to list services that have already been supplied (such as a database, software, or plant lines) as co-funding. The pre-financed amount of co-funding from each party can be added to the total co-funding amount in the budget sheet and be specified in the budget description.

The following items do not fall within co-funding:

- Discounts on (commercial) rates for materials, equipment and/or services;
- Costs relating to overhead, supervision, and consultancy;
- Funding that has not yet been secured, for example from project proposals that are still under consideration by KWF or other funding organizations;
- KWF funding secured through other projects;
- Funding by private persons, associations, foundations, or funds that are not registered as a Public Benefit Organization (in Dutch: ‘Algemeen Nut Beogende Instelling’, or ANBI). This type of funding can be arranged through donations at KWF with specific earmarking for this project proposal.

5.6.9 Budget description

In the budget description you must justify the requested budget, own contribution and co-funding.

- Briefly describe the tasks of the requested personnel;
- Motivate and justify your budget request;
- Describe the costs that will be covered by own contribution and co-funding;
- In case of no own contribution or co-funding, please justify.

5.6.10 Non eligible costs

Costs that are not eligible for funding are infrastructural costs at company level and costs for materials and personnel that are not related to the project, for example:

- Salary of scientific personnel, such as an academic or a medical doctor with structural funding , as from 'de eerste geldstroom' ;
- Salary of personnel who performs educational tasks, patient care and administrative or managerial tasks;
- Indirect overhead costs;
- Expenses for organizing project team meetings;
- Expenses for employer's and intention declarations;
- Expenses for application, maintenance, licensing and transfer of patents and results;
- Gifts for patients or project staff:
- Expenses for digital data carriers such as computers and iPads for general administrative purposes;
- Generic software;
- Costs for purchase and depreciation for general laboratory equipment;
- Costs of setting up laboratories;
- Costs for housing and office supplies.

5.7 Development plan

The tab development plan is applicable for project proposals in the development and implementation track. Most likely, your project will not be the endpoint of a development. This section focuses on the steps to achieve implementation into practise after having successfully completed the project. It includes the relevant stages, stakeholders, feasibility and risks. KWF considers it essential that the knowledge, skills and technology resulting from a project, are to be further developed for the benefit of patients and the general public. Therefore it is important that the steps, following after completion of the project, are to be taken into consideration at an early stage. Please consult your TTO if you need guidance in providing information on this part of your proposal.

5.7.1 Development plan

Please describe the necessary steps after completing the project, in order to come to the implementation of the application/intervention you developed. Include the necessary parties and people and expected timeline. To support your development plan, a schematic representation of the development plan can be uploaded.

5.7.2 Opportunities and risks

Please describe the risks and opportunities you are likely to face after finishing the project and the actions you will take to prepare for this and ensure your project stands the best possible chance of arriving at implementation (e.g. specific expertise provided by external advisors, companies involved in the project, data handling in accordance with the required formats for regulatory authorities). In addition, consider aspects such as reimbursement, user adoption, regulatory issues, incorporation in guidelines, manufacturing issues and future funding. This section specifically focuses on the steps that need to be taken after closing the project. Opportunities and risks during the term of the project should be described in the project proposal tab.

5.7.3 References

Please list all references mentioned in the scientific abstract, project proposal and development plan sections. Make sure to include: authors, title, journal (official abbreviation), edition, year, first and last page. Preferably, the total number of references does not exceed fifty. Listing all authors will help KWF finding suitable external reviewers, therefor use of 'et al.' is not allowed.

Please use the reference format used by the Journal of Biochemistry, as illustrated below: first author surname, first author initial, second author surname, second author initial, [etc], year published, title, publication, title volume number, pages used. If the Journal of Biochemistry is not available in your reference software, please use the Harvard referencing style.

5.8 Reviewers/Acknowledgements

Enlist in the suggested reviewers section national and international experts, capable of reviewing your proposal.

Please do not include reviewers with a conflicts of interest. KWF refers to a conflict of interest if a reviewer:

- Is currently working in the same department or lab or did so during the past five years;
- Published a co-publication during the past five years,
- Is a former colleague or (co-)promotor;
- Has any collaborations that might influence the review.

Please do not enlist members of the KWF internal review committee as reviewers. For an overview you can read:

- Internal review committee Exploration, see https://www.kwf.nl/over-kwf/Pages/KWF-Adviesraad.aspx#exp
- Internal review committee Development, see https://www.kwf.nl/over-kwf/Pages/KWF-Adviesraad.aspx#op

5.8.1 National reviewers

The list should include at least two national experts in the field of research of your project. In this context, it is important that the project leader and principal investigators have no conflict of interest with these experts. The list must show the names, institutes employing the experts and their email addresses.

5.8.2 International reviewers

The list should include at least five international experts in the field of research of your project. In this context, it is important that the project leader and principal investigators have no conflict of interest with these experts. The list must show the names, institutes employing the experts and their email addresses.

5.8.3 Those excluded from reviewing

If desired, you can list a maximum of three experts or clinical study groups you wish to exclude from reviewing the project proposal.

5.8.4 Competing companies excluded from reviewing

To review the feasibility of the project, KWF might send project proposals, resorting under the development track, to business experts who are employed by companies in the life sciences sector. If you wish to exclude competing companies from reviewing your project proposal, please list them in this section.

5.8.5 Acknowledgments

Please read the acknowledgments carefully, tick the box(es) to agree and submit your project proposal.

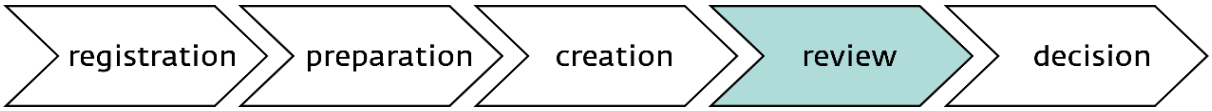
- General acknowledgements:
  - By signing, the project leader declares that the information supplied in the project proposal and profile is truthful, and that he/she will immediately report to KWF in case of any changes that may be relevant to the development, assessment or acceptance of the project proposal.
  - By signing, the project leader declares that he/she has informed all principal investigators and participating parties of the project on the content of the project proposal before submitting the project proposal.
- For Infrastructure initiatives (pre-proposal): Data sharing acknowledgements:
  - By signing, the project leader declares that he/she agrees with sharing the contact information, which includes the name, the email address and the keywords, with other project leader(s) in case of the pre-proposal being selected for merged full proposal submission.

5.9 Personal motivation (YIG only)

Please describe your personal motivation for applying for a YIG by answering the following questions:

- Why are you submitting a project proposal for a YIG?
- What does this YIG mean to you and in what way will the YIG help your scientific career to move forward?
- Why are you the right person to receive a YIG?
- What future position and role do you hope to be in, in five to ten years?

6. Review



KWF funds and facilitates high-quality projects that contribute to the realisation of KWF's main goals and the development of scientific knowledge of oncology. Therefore, the reviewing of the project proposals will be based on KWF's review criteria and executed by different assessors. All assessors are obliged to handle the project proposal information faithfully, for example by respecting confidentiality and taking into account possible conflicts of interest.

6.1 Review criteria

KWF uses three review criteria: relevance for KWF's main goals, scientific quality and feasibility.

- Relevance: the way in which, and the extent to which, the project proposal contributes to KWF's main goals, or contributes to increase the knowledge of the causes, the development and effects of cancer and cancer treatment.
- Scientific quality: the extent to which a project proposal satisfies all the scientific requirements to achieve the objective that has been set.
- Feasibility: the extent to which the necessary resources are available, and all the preconditions have been satisfied, to achieve the objective that has been set.

The three review criteria will be defined in more specific details for each research phase.

6.1.1 Review criteria for basic research

Relevance:

- In what way, and to what extent, does this research contribute to increasing knowledge of the causes, the development and effects of cancer and cancer treatment?

Scientific quality:

- Is there adequate theoretical and/or empirical substantiation?
- Can the hypothesis be tested and will it lead to the objective that has been set?
- Is the hypothesis innovative and/or does it contribute to progress in the field?
- Methodology: is the research design suitable for testing the hypothesis?

Feasibility:

- Is the required expertise to successfully complete this project available in the project team?
- Is the composition of the project team and advisors (including personal contributions) logical?
- Is the Research project feasible in terms of the proposed costs, available infrastructure, milestones and proposed time frame?

6.1.2 Review criteria for credentialing research

Relevance:

- In what way, and to what extent, does this research contribute to achieving the main goals of KWF?
- To what extent does it provide added value compared with the current state of science?

Scientific quality:

- Is there adequate theoretical and/or empirical substantiation?
- Can the hypothesis be tested and will it lead to the objective that has been set?
- Is the hypothesis innovative and/or does it contribute to progress in the field?
- Methodology: is the research design suitable for testing the hypothesis?

Feasibility:

- Is the required expertise to successfully complete this project available in the project team?
- Is the composition of the project team and advisors (including personal contributions) logical?
- Is the Research project feasible in terms of the proposed milestones, costs, available infrastructure and proposed time frame?

6.1.3 Review criteria for creation of modality research

Relevance:

- In what way, and to what extent, will the envisaged findings contribute to or provide a solution for an unmet (medical) need in scope of less cancer, more cure, and a better quality of life for patients?
- What impact will the solution have on the problem?
- In what way, and to what extent, does the obtained knowledge provide added value in comparison with the current scientific state?

Scientific quality:

- Is there adequate theoretical and/or empirical substantiation?
- Does the study fit within the development and implementation track, to completely or partially solve or prevent the problem?
- Can the hypothesis be tested and will it lead to the objective that has been set?
- Methodology: is the research design suitable for testing the hypothesis?

Feasibility:
- Is the required expertise to successfully complete this project available in the project team?
- Is the composition of the project team and advisors (including personal contributions) logical?
- Is the Research project feasible in terms of the proposed milestones, costs, available infrastructure and proposed time frame?

Feasibility development plan:
- Is the development and implementation track realistic?
- Will the proposed solution become available for patients/target population in due time?

6.1.4 Review criteria for preclinical research

Relevance:
- In what way, and to what extent, does the envisaged solution contribute to an unmet (medical) need in scope of less cancer, more cure, and a better quality of life for patients?
- In what way, and to what extent, does the knowledge that is generated offer added value compared to the current scientific state of art?
- What is the impact of the solution on the problem?
- What is the added value compared with international developments?
- Are there developments in the field that render this approach obsolete?

Scientific quality:
- Is there adequate theoretical and/or empirical substantiation?
- Does the study fit within the development and implementation track, to completely or partially solve or prevent the problem?
- Will this project pave the way to proceed to the following phase in the development and implementation track?
- Methodology: are the steps, which are proposed in the study design, adequate?

Feasibility:
- Is the required expertise to successfully complete this project available in the project team?
- Is the composition of the project team and advisors (including personal contributions) logical?
- Is the Research project feasible in terms of the proposed milestones, costs, available infrastructure and proposed time frame?
- Is the necessary study population available for the follow-up phase?

Feasibility development plan:
- Is the development and implementation track realistic?
- Will the proposed solution become available for patients/target population in due time?

6.1.5 Review criteria for clinical research

Relevance:
- In what way, and to what extent, does the envisaged solution contribute to an unmet (medical) need in scope of less cancer, more cure, and a better quality of life for patients?
- In what way, and to what extent, does the knowledge that is generated offer added value?
- What is the added value in the context of developments in the field?
- Are there developments in the field that render this approach obsolete?

Scientific quality:
- Is there adequate theoretical and/or empirical substantiation?
- Does the study fit within the development and implementation track, to completely or partially solve or prevent the problem?
- Can the hypothesis be tested and will it lead to the objective that has been set?
- Methodology: is the clinical study design adequate?

Feasibility:

- Is the required expertise and experience to successfully complete this project available in the project team?
- Is the composition of the project team and advisors (including personal contributions) logical?
- Is the Research project feasible in terms of the proposed milestones, costs, available infrastructure and proposed time frame?
- Is the necessary study population available and willing to take part in the research study and is the predicted rate of inclusion realistic and feasible? Do the potential benefits proportionate to the burden on the patients/persons involved in this research study?
- Is the plan for the selection of the research sample properly substantiated and realistic?

Feasibility development plan:

- Is the development and implementation track realistic? Will the proposed solution become available for patients/target population in due time?

6.1.6 Review criteria for Implementation research

Relevance:

- How and to what extent does the intended Implementation research contribute to the main goals of KWF?
- In what way, and to what extent, does the knowledge that is generated offer added value?
- To what extend does the project work facilitate and aid in the national accessibility of the actual application? (Scale, size, timing)
- Is the studied innovation/new method the best option for (future) implementation and this related research, or are other innovations/new methods more suitable (in terms of quality improvement or cost efficiency)?

Scientific quality:

- Is this innovation/ new method sufficiently validated and ready for Implementation research?
- Is there adequate scientific, practical and organizational substantiation for this Implementation research?
- Can the hypothesis be tested and will it lead to the objective that has been set?
- Methodology: is the (real world) study design adequate?
- Will the proposed implementation strategy and project plan facilitate future (national) implementation of the innovation/new method?

Feasibility:

- Is the required expertise, ownership and experience to successfully complete this project available in the project team?
- Is the composition of the project team and advisors (including personal contributions) logical?
- Are all relevant stakeholders involved?
- Is the Research project feasible in terms of the proposed milestones, costs, available infrastructure and proposed time frame?
- Is actual implementation and national accessibility of the innovation / new method facilitated and/or stimulated given the chosen strategies, involved stakeholders, proposed costs, infrastructure, and given the proposed schedule and milestones?
- If applicable, is there reimbursement by health insurer? Or is there attention for this aspect?
- If applicable, to what extent is future adoption of the innovation/new method by the executing party/parties realistic and expected?

6.1.7 Review criteria for Infrastructure initiatives

The Infrastructure initiatives will be subjected to a review process according to the review criteria below. Please note that some of the review criteria will only be applicable for full proposal.

(Scientific) quality:

- Is/are the applicant(s) the most appropriate party(ies) to be executing this initiative?
- Is the expertise within the project team available to carry out the work plan?
- To what extent is the work plan the most appropriate and realistic plan to reach the proposed aim in view of the milestones and time frame?

Relevance:

- Is KWF the most appropriate party to contribute to the proposed Infrastructure initiative?
- Is the research, enabled by this Infrastructure initiative, the most suitable and appropriate?
- Are the services/resources, provided by the Infrastructure initiative, nationally accessible?
- Is there national support and (inter)national integration of the initiative?
- Does the Infrastructure initiative tackle the fragmentation problem (e.g. resources & collections, data & tools, regulation, etc.) and thus of added value?
- For merged submissions only: are the complementary aspects of the Infrastructure initiatives well tackled?

Feasibility:

- Is the financial self-sustainability of the Infrastructure initiative anticipated, realistic and concretely described?
- Is the continuity of the Infrastructure initiative well planned and ensured?
- Is the information provided in the SWOT analysis sufficient?
- Are the transfer of knowledge measures sufficiently described and appropriate to reach the external stakeholders (research community, patients, general public) and is/are the technology transfer officers involved in a feasible way?

6.2 Review process

The review process takes six to eight months and consists of the following stages and sub-stages:

- Internal Review
  - Eligibility check
  - KWF internal analysis
  - Scientific eligibility check
- External review
  - Patients' Advisory Committee (PACO)
  - Peer reviewers
- Board review
  - Review by individual board members
  - Interview with the project leader (not applicable for all funding types)
  - Board review meeting
- Prioritisation meeting

For Infrastructure initiatives:

- The Infrastructure initiatives review procedure consists of a two-stage process: a pre-proposal and full proposal review.
- Both pre- and full proposals will be reviewed by KWF and the internal review committee Infrastructure initiatives.
- The internal review committee Infrastructure initiatives will be composed of members of the internal review committees and (inter)national experts in different areas.

The review procedure of pre-proposal projects:

- Internal Review
  - Eligibility check
  - Scientific eligibility check
- Board review
  - Review by individual board members
  - Board review meeting

Please note: Invitation to submit a full proposal does not guarantee funding.

Review procedure of full proposal projects:

- Internal Review
  - KWF internal analysis
- External review
  - Patients' Advisory Committee (PACO)
  - Peer reviewers
- Board review
  - Review by individual board members
  - Interview with the project leader and project manager
  - Board review meeting
- Prioritisation meeting

The stages and substages will be explained below.

6.2.1 Internal Review

6.2.1.1 Eligibility check

During the internal review, KWF performs an eligibility check. Project proposals are checked for errors and it is verified whether the project proposal has been submitted in accordance with the eligibility terms. If the project proposal passes these preliminary checks, it proceeds to the next stage of the review process.

6.2.1.2 Scientific eligibility check

Subsequently, three members of the internal review committee with the appropriate expertise to assess the proposal will determine whether:

- The project proposal is scientifically eligible;
- does it concur with KWF's main goals;
- does it contribute to existing knowledge about the causes, development and effects of cancer and cancer treatment?
- does the project proposal meet the minimum criteria? And is it sufficiently developed? This means the proposed research is cancer-related, sufficient preliminary research has been undertaken to support the hypothesis, the proposal is sufficiently developed, the proposal is well written and the proposed research is ethical.

If the project proposal passes the scientific eligibility check, it proceeds to the next stage of the review process and will be sent to external reviewers.

6.2.2 External review

6.2.2.1 Review by external peer reviewers

During the external review, the project proposal is reviewed by external scientific experts in accordance with the review criteria. The reviewers may also add recommendations for possible improvement. Preferably minimum of three national or international external reviewers, with the appropriate assessment expertise will review the project proposal in accordance with KWF's review criteria.

6.2.2.2 Review by the Patients' Advisory Committee (PACO)

Patients are the primary group to benefit from KWF's activities, and they have first-hand experience of undergoing cancer treatments and living with cancer. These experiences are valuable and essential input in establishing the relevance of KWF's activities and therefore the Patients' Advisory Committee (PACO) is involved in the review process for all project proposals in the development and implementation track. The PACO consists of members that are current or former cancer patients with a variety of indications and stages of the disease and have higher-education qualifications or experience. PACO members use the Dutch summary to review the project proposal from the patient perspective on relevance, feasibility and patient involvement.

The advice issued by the PACO will be included in the review of the project proposal along with the external peer review reports. Members of the PACO will attend the board review meeting to ensure that PACO arguments are interpreted correctly, explaining them in greater detail and discussing the project proposals when necessary. If the review process involves an interview, a PACO member will also be present at the interview.

Review criteria for the PACO:
Relevance:

- Does the objective of the project proposal match the needs/wishes of cancer patients or the general public?
- Does the envisaged result offer sufficient added value compared to the current status quo?

Feasibility:

- Is the burden placed upon participants in the study acceptable, considering the envisaged results?
- Has sufficient consideration been given to ethical aspects, the implementation of the results, or the realisation of any necessary follow-up action?
- Will (enough) patients be willing to participate in this study?

Patient involvement:

- To which extent are patients involved in the design of the project proposal, the execution of the study and the dissemination of results?
- Have patients, patient organizations or patient representatives actively been participating in the design and execution of the study?
- How have their efforts been incorporated in the study?

6.2.2.3 Review by other experts/specialists

In addition to consulting scientific reviewers and patients, expertise from other experts or specialists will sometimes be required to review project proposals. These experts/specialists can include entrepreneurs, statisticians, implementation experts, caregivers, pharmacists, end users, or other relevant parties in the field of oncology. When a development plan is applicable, these experts or specialists will review its feasibility within the project proposal from a specific expert angle, such as business, statistics, or health care.

6.2.3 Board review

To enable comparison, project proposals will be categorised for review. This selection will be based on the research phase. The review committee consist of two subcommittees, the exploration review committee and the development and implementation review committee.

The exploration review committee consists of approximately 30 members. The development and implementation review committee consists of approximately 40 members and includes additionally two appointed representatives from the PACO. Together, these members cover a wide range of expertise in oncology.

6.2.3.1 Review by individual committee members

To each project proposal three members of the internal review committee will be assigned to and they shall receive all external reviewer reports. KWF will also provide a summary of all the information related to the project proposal and specific points which need to be addressed in the review process. Based on the external reviewer reports and considering the input from various experts, the three committee members will independently provide an objective review of the project proposal's relevance, scientific quality and feasibility.

6.2.3.2 Interview

Three assigned members of the review committee will review YIG and Consortium project proposals, and make a selection of project proposals that have been most favourably reviewed.

- For YIG projects, the interview will assess the opportunity to initiate an independent oncological research line and the capability of taking the responsibilities of a project leader.
- For Consortium projects, the interview will assess the collaboration in the project and how the project is executed by the participating organizations of the Consortium project.

In order to be able to make their final selection, the review committees may at any point decide to initiate interviews for all funding types.

The project leaders will be invited for the interview approximately one week before the interview. A delegation of the internal review committee, a PACO member (in the development track) and the secretary of the internal review committee will be present during the interviews. The assessors form their opinion during the interview, which will be input for the board review meeting.

6.2.3.3 Board review meeting

After finishing the above described process, all project proposals will be submitted to a final review during the board review meeting.
The aim of this meeting is to form an final recommendation and rating of the project proposals, which reflects the opinion of the entire internal review subcommittee.
This final recommendation will be based on the reviewers' reports, the facts and reflections provided by KWF, the three committee members' reviews, the advice from the PACO, the interview and the discussions during the board review meeting.

Method of rating the project proposals:

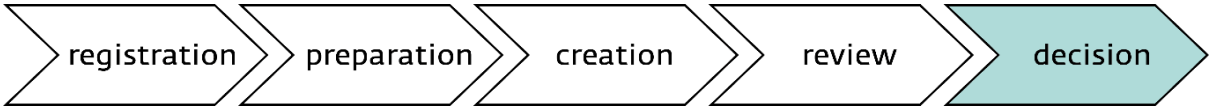
- A: excellent project proposals, eligible for funding;
- B: project proposals eligible for funding;
- C: project proposals not eligible for funding.

6.2.4 Prioritisation meeting

The aim of the prioritisation meeting is to formulate a final recommendation to the board of KWF for granting funding to the selected project proposals from both tracks. The guiding principle for the recommendation will be the impact the project is expected to have. Besides, funding partners of KWF may choose project proposals eligible for funding to fund on behalf of the funding partner.

Participants of the prioritisation meeting are the chairs and vice-chairs of both review subcommittees, PACO members, the chairman of the KWF board of advisors and the delegated persons of the funding partners. On behalf of KWF the secretaries of the review subcommittees and the manager Research will attend.
The input for the prioritisation meeting will be the recommendation and rating of the board review meeting, including a summary and arguments from different perspectives. Furthermore, KWF input at policy level is to be taken into consideration.
The final recommendation of the project proposals will be based on the comparison of all project proposals that are eligible for funding. Taking into account that A-rated project proposals will be given precedence over those with a B-rating. The board of directors of KWF are the final decision makers. This decision, including the substantiated final recommendation and the comments of the external reviewers and the PACO, will be communicated to the project leader.

7. Decision



After the review process the project leader will receive a decision letter.

7.1 Funding granted

If funding for the project proposal is granted, the project leader will receive a grant decision letter, including an attachment informing him/her on the approved budget, the justification of the board review, the comments from the external reviewers and the PACO, and the terms and conditions. The terms and conditions consist of the KWF Funding conditions and the KWF Audit protocol and will be applicable as from the signature date of the funding contract.

Funded projects will be assigned to a specific KWF programme coordinator who has knowledge of the relevant research field. The programme coordinator will be the primary contact for the project leader, and will contact him/her to arrange a personal start up meeting. In this meeting, arrangements will be made regarding the monitoring of the project, collaboration between the research group and KWF, and interim meetings and communications. Expected milestones and designated go/no-go milestones will be discussed.

7.1.1 Funding Partners

A project proposal eligible for funding can be selected by a funding partner*. Selected projects may receive specific funding conditions upon granting the funding.

*A funding partner is a fundraising party with a long term partnership agreement with KWF. The funds raised by the funding partners are spent through KWF Programme Research and Implementation. The preferred funding themes are being set out in the partnership agreement. In the prioritising meeting, projects are matched and selected by funding partners. Projects that best match the funding themes are being funded by the funding partner.

Current funding partners and their themes:

7.1.1.1 Alpe d'HuZes

- Theme "*Ambitie: het stimuleren van jong talent (Bas Mulder Award)*" will be matched with YIG's.
- Theme "*Nieuwe Ontwikkelingen: het creëren van extra kansen voor baanbrekende onderzoeksideeën*" will be matched with UHR projects.
- Theme "*Hermannetje: de kennisbenutting van onderzoeksresultaten te versnellen, middels 'een extra duwtje'*" will be matched with specific (pre-)clinical Research projects.

7.1.2 PPP allowance (PPS-toeslag)

Innovative research and development realised by public private partnerships, PPP (in Dutch: publiek private samenwerking, PPS) is supported by the Top Sector Life Sciences & Health. Depending on the regulations of the Ministry of Economic Affairs, KWF may use the option to finance projects partly by using PPP allowance, and thus effectively increase the number of projects that can be funded. For projects that are partially funded with PPP allowance, additional funding conditions, including reporting criteria, might apply. When this occurs, KWF will inform the project leader. KWF will maximise their efforts to minimise the additional funding conditions.

7.2 Funding rejected

When funding of the project proposal is rejected, the project leader will receive a decision letter with the justification of the board review and the comments of the external reviewers and the PACO attached.

7.2.1 Rejection with a B-rating

Rejected project proposals with a B-rating are projects of good quality, feasibility, and relevance. They will not be funded because of insufficient budget. During the prioritisation meeting other project proposals were considered to be more suitable for funding. Rejected B-rated project proposals can be resubmitted in a future call and again follow the full review procedure. When the project proposal is resubmitted, it is advised to amend in accordance with the comments of the reviewers and the advice of the KWF internal review committee. Also further improvements on the project proposal are allowed.

If a resubmission is considered, please note that the guidelines for submission might have changed, check the actual guidelines carefully.

7.2.2 Rejection with a C-rating

Project proposals of insufficient quality, relevance and/or feasibility will be rejected with a C-rating. Depending on the comments of the review committee, the project leader can be encouraged or discouraged to resubmitting the project proposal in an amended form. If a project proposal is resubmitted, it will not be treated differently from the other new project proposals. When the project proposal is being resubmitted, it must be amended in accordance with the comments of the reviewers and the advice of the KWF internal review committee.

If a resubmission is considered, please note that the guidelines for submission might have changed, check the actual guidelines carefully.

7.3 Appeal procedure

The project leader and the lead institute can object against KWF's decision to reject a project proposal in the scientific eligibility check phase or if rejected with a C-rating. This must be done within fourteen days upon receipt of the decision letter. Please note that appeal against the decision of KWF to reject a proposal with a B-rating is not allowed.
After having received the appeal, KWF shall consult the internal review committee and aims to decide and respond within four weeks.

- If the objection is based on valid grounds, the decision and eventual granting of your project will be reconsidered.
- If the objection is not valid, the decision will not be changed.

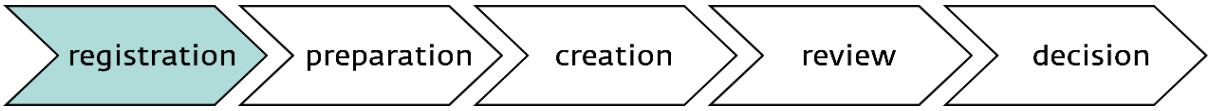
The decision made by KWF is binding, no further appeal is possible. Except when an objection is rejected on procedural grounds, it is possible to appeal against this decision. The KWF Board of directors will handle this appeal.

The regulations for appeal, (in Dutch: reglement bezwaren tegen besluiten op aanvragen van wetenschappelijke onderzoeksprojecten KWF Kankerbestrijding) are published on the KWF website, see https://www.kwf.nl/onderzoek/poi/Pages/default.aspx

Attachments:

- Appendix 1 Criteria for a lead institute
- Appendix 2 Statement of acceptance to merge projects
- Appendix 3 Research activities per research phase
- Appendix 4 KWF project classification, ICRP and modality coding

Appendix 1 Criteria for a lead institute



The table below shows which types of organizations are eligible as lead institute in a project proposal.

Eligible as lead institute	Organization

Yes	• University
	• Medical center
	• Research institute, for example:
	  ○ A NWO institute
	  ○ A KNAW institute
	  ○ Netherlands Cancer Institute
	  ○ Princess Máxima Center

Upon approval	• Peripheral hospitals, including:
	  ○ hospitals affiliated with the Association of Top Clinical Teaching Hospitals (in Dutch: Samenwerkende Topklinische Ziekenhuizen, STZ)
	• Organizations*, for example:
	  ○ Universities of applied sciences
	  ○ So-called Public Benefit Organizations (in Dutch: Algemeen Nut Beogende Instelling, or ANBI)
	  ○ Data management centers

No	• Organizations*, for example:
	  ○ SMEs (small to medium enterprise)
	  ○ Large companies
	• Foreign organizations

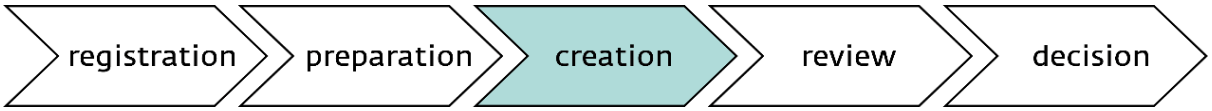
* Organizations whose owners benefit from the net income or earnings of the organization, cannot act as lead institute, unless all of the net income or earnings are used for the stated purpose of the organization to increase the social impact and/or public good.

Organizations that are listed as upon approval in the table above may request to act as a lead institute. Please forward this request to KWF scientific review and grants administration department at least six weeks before the call deadline. KWF will take this request under consideration and will inform the project leader on the outcome.

Criteria for a lead institute are:
The organization:

- Has to undertake independent scientific research as a main objective;
- has relevant knowledge, expertise, and facilities to perform high quality scientific research. E.g. expertise of both the project leader and the department, publications and meetings with scientists on a regular basis, PhD students.
- grants researchers the freedom to publish in international scientific journals;
- has a repository or has access to a repository;
- has a mandate on the obtained data;
- receives a proportion of its basic funding from public funds.

Appendix 2 Statement of acceptance to merge projects



I, [Name project leader (PL)], project leader of the pre-proposal [Title of pre-proposal], [Name lead institute] submitted under the Infrastructure initiatives, hereby declare that I will be project leader of the merged proposal [Title merged proposal] and that [Name of organization] will act as lead institute.

The project leaders of the pre-proposal(s):

[Title pre-proposal 1], [Name PL 1], [lead institute 1]
[Title pre-proposal 2], [Name PL 2], [lead institute 2]
[Title pre-proposal 3], [Name PL 3], [lead institute 3]

Agreed with and accepted the merging of the above mentioned pre-proposals and with my nomination as project leader of the merged full proposal [Title Full proposal]

[Signature PL]

[Name PL]

[Signature PL pre-proposal 1]

[Name PL pre-proposal 1]

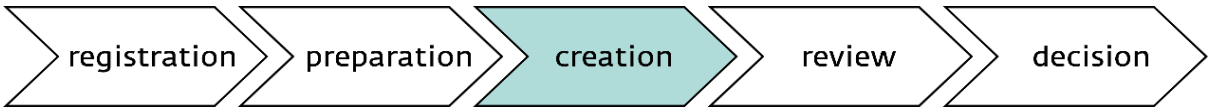
[Signature PL pre-proposal 2]

[Name PL pre-proposal 2]

[Signature PL pre-proposal 3]

[Name PL pre-proposal 3]

Appendix 3 Research activities per research phase



In these tables you find the research activities for each research phase. The tables are divided in research areas, so called modalities. The modalities are explained in appendix 4.

I. BIOMARKERS	
Research phase	Research activities
Credentialing	• Discovering molecular biomarker with clinical potential • Validating biomarker (confirming sensitivity/specificity expected for clinical utility) • Assessing feasibility of development of protocol/reagent/device
Creation of modality	• Defining patient subset with biomarker using small number of specimens in single laboratory • Validating assay and correlation of biomarker with outcomes retrospectively across large numbers of specimens in different labs
Preclinical development	• Developing/refining clinical grade biomarker assay protocol/ reagent/device • Validating in prospective human study the correlation of biomarker with outcome
Clinical research	• Studying in humans the utility of biomarker to direct therapy or chemoprevention or to predict outcome/risk
Implementation research	• Scientific studies on methods to promote the delivery, and enhance the adoption of biomarkers for patients/end users within diagnostic tests and/or treatments on several locations

II. IMAGING	
Research phase	Research activities
Credentialing	• Discovering imaging biomarker with clinical potential • Validating biomarker (confirming sensitivity/specificity expected for clinical utility) • Assessing feasibility of developing agent or technique
Creation of modality	• Developing new imaging platform • Developing new technique/imaging agent • If technique, optimising acquisition and analytic parameters in preclinical or phase 0 setting • If imaging agent, performing radiolabelling dosimetry
Preclinical development	• Testing/refining imaging performance, pharmacokinetics/ pharmacodynamics (PK/PD), toxicology etc. in preclinical setting • Establishing good manufacturing practice (GMP) production for agent as necessary • Testing/refining imaging performance, PK/PD, toxicology etc. in phase I/II setting • Establishing GMP for platform as necessary • Optimising platform available for clinical testing
Clinical research	• Conducting phase II/III trials for specific clinical utilities
Implementation research	• Scientific studies on methods to promote the delivery, and enhance the adoption of imaging techniques within diagnostic tests and/or treatments of patients/end users on several locations

III. AGENTS	
Research phase	Research activities
Credentialing	• Discovering target with clinical potential • Validating target (convincing empirical basis for attributing clinical potential) • Assessing feasibility of developing agent against the target
Creation of modality	• Assessing impact of perturbing target using experimental system • Identifying candidate agents and screen for binding and influence on activity • Selecting lead candidate
Preclinical development	• Conducting preliminary toxicology screening • Conducting process development/pilot manufacturing • Verifying activity/PK in pilot product • Implementing Good Laboratory Practice (GLP)/GMP • Verifying activity/pharmacokinetics (PK)/stability/quality control in GLP/GMP product • Performing definitive toxicology screening • Completing Investigational New Drug (IND) submission
Clinical research	• Conducting phase I clinical trial(s) • Conducting phase II clinical trial(s) • Conducting phase III clinical trial(s)
Implementation research	• Scientific studies on methods to promote the delivery, and enhance the adoption of agents within (preventive) treatments of patients/end users on several locations

IV. IMMUNE RESPONSE MODIFIERS	
Research phase	Research activities
Credentialing	• Discovering antigen or other immune modifier with clinical potential in specific cancer(s) • Validating immune modifier (convincing empirical basis for attributing clinical potential) • Assessing feasibility of identifying/developing the immune response modifier
Creation of modality	• Characterising and/or modify antigens • Identifying or developing delivery vehicle (vector, cell, etc.) • Identifying or developing immune modulator (adjuvant, cytokine, chemokine, etc.) • Developing immune response modifier • Measuring response to immune response modifier and refining antigen(s), delivery vehicle, immune modulator, as necessary • Refining immune response modifier and/or immunisation strategy • Identifying lead immune response modifier candidate
Preclinical development	• Conducting process development/pilot manufacturing • Verifying activity in pilot product • Implementing GMP/GLP • Verifying activity in GMP product • Conducting toxicology screening • Completing IND submission
Clinical research	• Conducting phase I clinical trial(s) • Conducting phase II clinical trial(s) • Conducting phase III clinical trial(s)
Implementation research	• Scientific studies on methods to promote the delivery, and enhance the adoption of immune response modifiers within (preventive) treatments of patients/end users on several locations

V. INTERVENTIVE DEVICES	
Research phase	Research activities
Credentialing	• Identifying technology innovation or innovative application of existing technology • Validating technology (convincing empirical basis for attributing clinical potential) • Assessing feasibility of developing the technology
Creation of modality	• Analysing utility of technology in laboratory • Building/refining prototype device • Testing prototype on phantoms and/or animals • Defining usage protocol for humans
Preclinical development	• Building/refining clinical-grade device • Testing clinical-grade device on phantoms and/or animals • Conducting phase 0 tests on humans • Preparing regulatory submission
Clinical research	• Conducting phase I trials (proof of principle) • Conducting phase II clinical trial(s) • Conducting phase III clinical trial(s)
Implementation research	• Scientific studies on methods to promote the delivery, and enhance the adoption of interventive devices within (preventive) treatments of patients/end users on several locations

VI. LIFESTYLE AND EXPOSURE	
Research phase	Research activities
Credentialing	• Identifying and validating correlation between behaviour and exposure and disease (empirical basis for attributing causal effect consistent across diverse populations/study designs) • Identifying specific lifestyle alteration that would mitigate the risk factor
Creation of modality	• Specifying lifestyle alteration and developing lifestyle alteration intervention • Evaluating effect in relevant animal model
Preclinical development	• Conducting pilot study to evaluate effects among healthy individuals
Clinical research	• Conducting pilot study to assess efficacy of lifestyle alteration in the study population • Refining specification of lifestyle alteration • Conducting study of efficacy in larger, more diverse population
Implementation research	• Scientific studies on methods to promote the delivery, and enhance the adoption of interventions to improve quality of life and/or quality of care for patients/end users and survivors on several locations

VII. QUALITY OF LIFE / QUALITY OF CARE	
Research phase	Research activities
Credentialing	• Identifying and validating factors that influence quality of life • Gaining insight in and validating mechanisms underlying factors that influence quality of life or (variation in) quality of care • Identifying specific alteration that would mitigate the negative impact on quality of life or quality of care • Identifying and validating factors resulting in negative side effects of interventions
Creation of modality	• Developing interventions to improve quality of life or quality of care • Developing/adapting intervention to reduce/avoid side effects • Developing tools measuring or supporting quality of life or quality of care • Specifying variations in patient needs
Preclinical development	• Technical testing of interventions • Conducting pilot study on healthy individuals
Clinical research	• Conducting pilot study in study population to assess efficacy of interventions to improve quality of life • Conducting pilot study in study population to assess efficacy of interventions to improve quality of care • Conducting study of efficacy in larger, more diverse population
Implementation research	• Scientific studies on methods to promote the delivery, and enhance the adoption of interventions to improve quality of life and/or quality of care for patients/end users and survivors on several locations

Appendix 4 KWF project classification, ICRP and modality coding

KWF joined the International Cancer Research Partnership (ICRP) in 2009. This partnership brings together a large number of international organizations funding cancer research, including the American Cancer Society, the US National Cancer Institute and Cancer Research UK. The ICRPs mission is to increase the benefits cancer patients receive from the results of cancer research through global collaboration and strategic coordination of research. The ICRP has adopted a common method of classification – the Common Scientific Outline - (CSO) and Disease Site Codes - (DSC) – which provides a simple and easy overview of national and international cancer research. This overview can be used to improve the coordination and organization of the efforts by various stakeholders.

To provide a more detailed picture of its portfolio of (early) translational and (early) clinical research, KWF also employs a system of classification specifically designed for this type of research. This 'modality coding', used in addition to the ICRP classification, is based on a classification system developed by the US National Cancer Institute and the Canadian Cancer Research Alliance. The following modalities are used:

<table>
<tr><th>Research phase</th><th colspan="7">Modality</th></tr>
<tr><td>Basic research</td><td colspan="7">Basic research</td></tr>
<tr><td>Credentialing</td><td rowspan="5">Biomarkers</td><td rowspan="5">Imaging</td><td rowspan="5">Agents</td><td rowspan="5">Immune response modifiers</td><td rowspan="5">Interventive devices</td><td rowspan="5">Lifestyle</td><td rowspan="5">Quality of life/care</td></tr>
<tr><td>Creation of modality</td></tr>
<tr><td>Preclinical development</td></tr>
<tr><td>Clinical research</td></tr>
<tr><td>Implementation research</td></tr>
<tr><td>Infrastructure</td><td colspan="7">Infrastructure</td></tr>
</table>

Following the ICRP rules and the modality coding norms, KWF can choose to change your classification of the project.

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4a. ICRP coding instructions

As coding instructions for the CSO code(s) we ask you to decide what the main aim or 'center of gravity' is of the project proposal. Please apply the CSO codes that reflect the overall nature of the project and that are achievable within the lifetime of the project (no more than two CSO codes are allowed per project proposal). Coding should not include potential or future applications of the research findings.

For more detailed information on the CSO codes please click:
https://www.icrpartnership.org/sites/default/files/cso/ICRP_Coding_Guidelines.pdf

Common Scientific Outline (CSO)

1. Biology - Research included in this category looks at the biology of how cancer starts and progresses as well as normal biology relevant to these processes.

1.1 Normal Functioning

Examples of science that would fit:

- Developmental biology (from conception to adulthood) and the biology of aging
- Normal functioning of genes, including their identification and expression, and the normal function of gene products, such as hormones and growth factors
- Normal formation of the extracellular matrix
- Normal cell-to-cell interactions
- Normal functioning of apoptotic pathways
- Characterization of pluripotent progenitor cells (e.g. normal stem cells)

1.2 Cancer Initiation: Alterations in Chromosomes

Examples of science that would fit:

- Abnormal chromosome number
- Aberration in chromosomes and genes (e.g. in chronic myelogenous leukemia)
- Damage to chromosomes and mutation in genes
- Failures in DNA repair
- Aberrant gene expression
- Epigenetics
- Genes and proteins involved in aberrant cell cycles

1.3 Cancer Initiation: Oncogenes and Tumor Suppressor Genes

Examples of science that would fit:

- Genes and signals involved in growth stimulation or repression, including oncogenes (Ras, etc.), and tumor suppressor genes (p53, etc.)
- Effects of hormones and growth factors and their receptors such as estrogens, androgens, TGF-beta, GM-CSF, etc.
- Research into the biology of stem cell tumor initiation

1.4 Cancer Progression and Metastasis

Examples of science that would fit:

- Latency, promotion, and regression
- Expansion of malignant cells
- Interaction of malignant cells with the immune system or extracellular matrix
- Cell mobility, including detachment, motility, and migration in the circulation
- Invasion
- Malignant cells in the circulation, including penetration of the vascular system and extravasation
- Systemic and cellular effects of malignancy
- Tumor angiogenesis and growth of metastases
- Role of hormone or growth factor dependence/independence in cancer progression
- Research into cancer stem cells supporting or maintaining cancer progression
- Interaction of immune system and microbiome in cancer progression

1.5 Resources and Infrastructure related to biology

Examples of science that would fit:

- Informatics and informatics networks
- Specimen resources
- Epidemiological resources pertaining to biology
- Reagents, chemical standards
- Development and characterization of new model systems for biology, distribution of models to scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Guidance note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer-term research-based training, such as Ph.D. or post-doctoral fellowships.

2. Etiology - Research included in this category aims to identify the causes or origins of cancer - genetic, environmental, and lifestyle, and the interactions between these factors.

2.1 Exogenous Factors in the Origin and Cause of Cancer

Examples of science that would fit:

- Research into the role of lifestyle factors such as smoking, chewing tobacco, alcohol consumption, parity, diet, sunbathing, and exercise in the origin and cause of cancer or increasing the risk of cancer
- Research into the social determinants of cancer such as crime, housing dilapidation (poor housing), neighbourhood level socioeconomic status and services and their relationship to cancer incidence and mortality etc.
- Studies on the effect(s) of nutrients or nutritional status on cancer incidence
- Development, characterization, validation, and use of dietary/nutritional assessment instruments in epidemiological studies and to evaluate cancer risk
- Environmental and occupational exposures such as radiation, second-hand smoke/e-cigarettes, radon, asbestos, organic vapors, pesticides, and other chemical or physical agents
- Infectious agents associated with cancer etiology, including viruses (Human Papilloma Virus-HPV, etc.) and bacteria (helicobacter pylori, etc.)
- Viral oncogenes and viral regulatory genes associated with cancer causation
- Contextual factors contributing to cancer incidence (e.g. race/ethnicity, socioeconomic status, neighbourhood factors, community factors, built environment).

2.2 Endogenous Factors in the Origin and Cause of Cancer

Examples of science that would fit:

- Free radicals such as superoxide and hydroxide radicals
- Identification /confirmation of genes suspected of being mechanistically involved in familial cancer syndromes; for example, BRCA1, Ataxia Telangiectasia, and APC
- Identification/confirmation of genes suspected or known to be involved in 'sporadic'cancer events; for example, polymorphisms and/or mutations that may affect carcinogen metabolism (e.g. CYP, NAT, glutathione transferase, etc.)
- Investigating a role for stem cells in the etiology of tumors

2.3 Interactions of Genes and/or Genetic Polymorphisms with Exogenous and/or Endogenous Factors

Examples of science that would fit:

- Gene-environment interactions, including research into the role of the microbiome
- Interactions of genes with lifestyle factors, environmental, and/or occupational exposures such as variations in carcinogen metabolism associated with genetic polymorphisms
- Interactions of genes and endogenous factors such as DNA repair deficiencies and endogenous DNA damaging agents such as oxygen radicals or exogenous radiation exposure

2.4 Resources and Infrastructure Related to Etiology

Examples of science that would fit:

- Informatics and informatics networks; for example, patient databanks
- Specimen resources (serum, tissue, etc.)
- Reagents and chemical standards
- Epidemiological resources pertaining to etiology
- Statistical methodology or biostatistical methods
- Centers, consortia, and/or networks
- Development, characterization and validation of new model systems for etiology, distribution of models to the scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer term research based training, such as Ph.D. or post-doctoral fellowships.

3. Prevention - Research included in this category looks at identifying individual and population-based primary prevention interventions, which reduce cancer risk by reducing exposure to cancer risks and increasing protective factors.

3.1 Interventions to Prevent Cancer: Personal Behaviors (Non-Dietary) that Affect Cancer Risk

Examples of science that would fit:

- Research on determinants of personal behaviors, such as physical activity, sun exposure, alcohol and tobacco use, known to affect cancer risk and interventions (including educational and behavioral interventions, such as e-cigarettes, directed at individuals as well as population-based interventions including social marketing campaigns, environmental supports, and regulatory, policy and legislative changes) to change determinants or to target health inequalities.
- Directed education to specified populations of patients, health care providers, and at-risk groups about cancer risk and prevention and relevant interventions with the intent of promoting increased awareness and behavioural change. This includes communication of lifestyle models that reduce cancer risk, such as communicating smoking and tobacco cessation interventions, genetic counselling, or targeting/addressing health inequalities.

3.2 Dietary Interventions to Reduce Cancer Risk and Nutritional Science in Cancer Prevention

Examples of science that would fit:

- Quantification of nutrients, micronutrients, and purified nutritional compounds in cancer prevention studies
- Development, characterization, validation, and use of dietary/nutritional assessment instruments to evaluate cancer prevention interventions
- Research on determinants of dietary behavior and interventions to change diet (including educational and behavioral interventions directed at individuals as well as population-based interventions including social marketing campaigns, environmental supports, and regulatory and legislative changes)
- Education of patients, health care providers, at-risk populations, and the general population about cancer risk and diet
- Communicating cancer risk of diet to underserved populations, at-risk populations, and the general public
- Communication of nutritional interventions that reduce cancer risk
- Nutritional manipulation of the microbiome for cancer prevention

3.3 Chemoprevention and other medical interventions

Examples of science that would fit:

- Chemopreventive agents and their discovery, mechanism of action, development, testing in model systems, and clinical testing
- Other (non-vaccine) preventive measures such as prophylactic surgery (e.g. mastectomy, oophorectomy, prostatectomy etc.), use of antibiotics, immune modulators/stimulators or other biological agents.
- Manipulation of the microbiome for cancer prevention (e.g., fecal transplant)

3.4 Vaccines

Examples of science that would fit:

- Vaccines for prevention, their discovery, mechanism of action, development, testing in model systems, and clinical testing (e.g. HPV vaccines)

3.5 Complementary and Alternative Prevention Approaches

Examples of science that would fit:

- Discovery, development, and testing of complementary/alternative medicine (CAM) approaches or other primary prevention interventions that are not widely used in conventional medicine or are being applied in different ways as compared to conventional medical uses
- Mind and body medicine (e.g. meditation, acupuncture, hypnotherapy), manipulative and body-based practices (e.g. spinal manipulation, massage therapy), and other practices (e.g. light therapy, traditional healing) used as a preventive measure.

3.6 Resources and Infrastructure Related to Prevention

Examples of science that would fit:

- Informatics and informatics networks; for example, patient databanks
- Specimen resources (serum, tissue, etc.)
- Epidemiological resources pertaining to prevention
- Clinical trials infrastructure
- Statistical methodology or biostatistical methods
- Centers, consortia, and/or networks
- Development and characterization of new model systems for prevention, distribution of models to scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer term research based training, such as Ph.D. or post-doctoral fellowships.

4. Early Detection, Diagnosis and Prognosis - Research included in this category focuses on identifying and testing cancer markers, imaging and other methods that are helpful in detecting and/or diagnosing cancer as well as predicting the outcome or chance of recurrence or to support treatment decision making in stratified/personalised medicine.

4.1 Technology Development and/or Marker Discovery

Examples of science that would fit:

- Discovery or identification and characterization of markers (e.g. proteins, genes, epigenetic, microbiomic), and/or technologies (such as fluorescence, nanotechnology, etc.) that are potential candidates for use in cancer detection, staging, diagnosis, theranostics and/or prognosis
- Use of proteomics, genomics, expression assays, or other technologies in the discovery or identification of markers
- Defining molecular signatures of cancer cells, including cancer stem cells (e.g. for the purposes of diagnosis/prognosis/theranostic and to enable treatment decision planning in personalized/stratified/precision medicine)

4.2 Technology and/or Marker Evaluation with Respect to Fundamental Parameters of Method

Examples of science that would fit:

- Development, refinement, and preliminary evaluation (e.g. animal trials, preclinical, and Phase I human trials) of identified markers or technologies such as genetic/protein biomarkers (prospective or retrospective) or imaging methods (optical probes, PET, MRI, etc.)
- Preliminary evaluation with respect to laboratory sensitivity, laboratory specificity, reproducibility, and accuracy
- Research into mechanisms assessing tumor response to therapy at a molecular or cellular level

4.3 Technology and/or Marker Testing in a Clinical Setting

Examples of science that would fit:

- Evaluation of clinical sensitivity, clinical specificity, and predictive value (Phase II or III clinical trials), including theranostics and prediction of late/adverse events
- Quality assurance and quality control
- Inter- and intra-laboratory reproducibility
- Testing of the method with respect to effects on morbidity and/or mortality
- Study of screening methods, including compliance, acceptability to potential screenees, and receiver-operator characteristics. Includes education, communication (e.g. genetic counselling and advice on screening behavior based on cancer risk factors), behavioral and complementary/alternative approaches to improve compliance, acceptability or to reduce anxiety/discomfort, and evaluation of new methods to improve screening in healthcare settings.
- Research into improvements in techniques to assess clinical response to therapy

4.4 Resources and Infrastructure Related to Detection, Diagnosis or Prognosis

Examples of science that would fit:

- Informatics and informatics networks; for example, patient databanks
- Specimen resources (serum, tissue, images, etc.)
- Clinical trials infrastructure
- Epidemiological resources pertaining to risk assessment, detection, diagnosis, or prognosis
- Statistical methodology or biostatistical methods
- Centers, consortia, and/or networks
- Development, characterization and validation of new model systems for detection, diagnosis or prognosis, distribution of models to the scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer term research based training, such as Ph.D. or post-doctoral fellowships.

5. Treatment - Research included in this category focuses on identifying and testing treatments administered locally (such as radiotherapy and surgery) and systemically (treatments like chemotherapy which are administered throughout the body) as well as non-traditional (complementary/alternative) treatments (such as supplements, herbs). Research into the prevention of recurrence and treatment of metastases are also included here.

5.1 Localized Therapies - Discovery and Development

Examples of science that would fit:

- Discovery and development of treatments administered locally that target the organ and/or neighboring tissue directly, including but not limited to surgical interventions, cryotherapy, local/regional hyperthermia, high-intensity, focused ultrasound, radiotherapy, and brachytherapy
- Therapies with a component administered systemically but that act locally (e.g. photodynamic therapy, radioimmunotherapy, radiosensitizers and theranostics)
- Development of methods of localized drug delivery of systemic therapies e.g. Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC), direct intratumoral polymers/gels/nanoparticles/microsomes etc.
- Research into the development of localized therapies to prevent recurrence
- Identifying mechanisms of action of existing localized therapies and targets, including cancer stem cells.

5.2 Localized Therapies - Clinical Applications

Examples of science that would fit:

- Clinical testing and application of treatments administered locally that target the organ and/or neighboring tissue directly, including but not limited to surgical interventions, cryotherapy, local/regional hyperthermia, radiotherapy, and brachytherapy.
- Clinical testing and application of therapies with a component administered systemically but that act locally (e.g. photodynamic therapy, radiosensitizers and theranostics, Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC), direct intratumoral polymers/gels/nanoparticles/microsomes etc.)
- Phase I, II, or III clinical trials of promising therapies that are administered locally
- Side effects, toxicity, and pharmacodynamics
- Clinical testing of localized therapies to prevent recurrence and prevent and treat metastases

5.3 Systemic Therapies - Discovery and Development

Examples of science that would fit:

- Discovery and development of treatments administered systemically such as cytotoxic or hormonal agents, novel systemic therapies such as immunologically directed therapies (treatment vaccines, antibodies , antibiotics, theranostics or other biologics), gene therapy, angiogenesis inhibitors, apoptosis inhibitors, whole body hyperthermia, bone marrow/stem cell transplantation, differentiating agents, adjuvant and neo-adjuvant treatments, systemically-delivered nanoparticles/microsomes, cell-based therapies, manipulation of the microbiome etc.
- Identifying mechanisms of action of existing cancer drugs and novel drug targets, including cancer stem cells for the purposes of treatment/identifying drug targets
- Drug discovery and development, including drug metabolism, pharmacokinetics, pharmacodynamics, combinatorial chemical synthesis, drug screening, development of high-throughput assays, and testing in model systems, including that which may aid treatment planning in stratified/personalised medicine
- Investigating the molecular mechanisms of drug resistance (including the role of cancer stem cells) and pre-clinical evaluation of therapies to circumvent resistance
- Development of methods of drug delivery
- Research into the development of systemic therapies to prevent recurrence

5.4 Systemic Therapies - Clinical Applications

Examples of science that would fit:

- Clinical testing and application of treatments administered systemically such as cytotoxic or hormonal agents, novel systemic therapies such as immunologically directed therapies (treatment vaccines, antibodies, antibiotics, theranostics or other biologics), gene therapy, angiogenesis inhibitors, apoptosis inhibitors, whole body hyperthermia, bone marrow/stem cell transplantation, differentiating agents, adjuvant and neo-adjuvant treatments, systemically-delivered nanoparticles/microsomes, cell-based therapies, manipulation of the microbiome etc.
- Phase I, II, or III clinical trials of promising therapies administered systemically
- Side effects, toxicity, and pharmacodynamics
- Clinical testing of systemic therapies to prevent recurrence and prevent and treat metastases

5.5 Combinations of Localized and Systemic Therapies

Examples of science that would fit:

- Development and testing of combined local and systemic approaches to treatment (e.g. radiotherapy and chemotherapy, or surgery and chemotherapy)
- Clinical application of combined approaches to treatment such as systemic cytotoxic therapy and radiation therapy
- Development and clinical application of combined localized and systemic therapies to prevent recurrence and prevent and treat metastases

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5.6 Complementary and Alternative Treatment Approaches

Examples of science that would fit:

- Discovery, development, and clinical application of complementary/alternative medicine (CAM) treatment approaches such as diet, herbs, supplements, natural substances, or other interventions that are not widely used in conventional medicine or are being applied in different ways as compared to conventional medical uses
- Complementary/alternative or non-pharmaceutical approaches to prevent recurrence and prevent and treat metastases

5.7 Resources and Infrastructure Related to Treatment and the Prevention of Recurrence

Examples of science that would fit:

- Informatics and informatics networks; for example, clinical trials networks and databanks
- Mathematical and computer simulations
- Specimen resources (serum, tissue, etc.)
- Clinical trial groups
- Clinical treatment trials infrastructure
- Epidemiological resources pertaining to treatment
- Statistical methodology or biostatistical methods
- Drugs and reagents for distribution and drug screening infrastructures
- Centers, consortia, and/or networks
- Development and characterization of new model systems for treatment, distribution of models to scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Reviews/meta-analyses of clinical effectiveness of therapeutics/treatments
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer term research based training, such as Ph.D. or post-doctoral fellowships.

6. Cancer Control, Survivorship and Outcomes Research - Research included in this category includes a broad range of areas: patient care and pain management; tracking cancer cases in the population; beliefs and attitudes that affect behavior regarding cancer control; ethics; education and communication approaches for patients, family/caregivers, and health care professionals; supportive and end-of-life care; and health care delivery in terms of quality and cost effectiveness.

6.1 Patient Care and Survivorship Issues

Examples of science that would fit:

- Research into patient centred outcomes
- Quality of life
- Pain management
- Psychological impacts of cancer survivorship
- Rehabilitation, including reconstruction and replacement
- Economic sequelae, including research on employment, return to work, and vocational/educational impacts on survivors and their families/caregivers
- Reproductive issues
- Long-term issues (morbidity, health status, social and psychological pathways)
- Symptom management, including nausea, vomiting, lymphedema, neuropathies, etc.
- Prevention and management of long-term treatment-related toxicities and sequelae, including symptom management (e.g. physical activity or other interventions), prevention of mucosities, prevention of cardiotoxicities, opportunistic infections, cachexia etc.
- Psychological, educational or complementary/alternative (e.g. hypnotherapy, relaxation, transcendental meditation, imagery, spiritual healing, massage, biofeedback, herbs, spinal manipulation, yoga, acupuncture) interventions/approaches to promote behaviors that lessen treatment-related morbidity and promote psychological adjustment to the diagnosis of cancer and to treatment effects
- Burdens of cancer on family members/caregivers and interventions to assist family members/caregivers
- Educational interventions to promote self-care and symptom management
- Research into peer support, self-help, and other support groups
- Behavioral factors in treatment compliance

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6.2 Surveillance

Examples of science that would fit:

- Epidemiology and end results reporting (e.g. SEER)
- Registries that track incidence, morbidity, co-morbidities/symptoms, long-term effects and/or mortality related to cancer
- Surveillance, measurement, evaluation or tracking of established cancer risk factors in populations such as diet, body weight, physical activity, sun exposure, and tobacco use, including method development
- Analysis of variations in established cancer risk factor exposure in populations by demographic, geographic, economic, or other factors
- Trends in use of interventional strategies in populations (e.g. geographic variation)

6.3 Population-based Behavioral Factors

Examples of science that would fit:

- Research into populations' attitudes and belief systems (including cultural beliefs) and their influence on behaviors related to cancer control, outcomes and treatment. For example, how populations' beliefs can affect compliance/interaction with all aspects of the health care/service provision
- Research into the psychological effects of genetic counselling
- Research into behavioral barriers to improving cancer care/survivorship clinical trial enrolment

6.4 Health Services, Economic and Health Policy Analyses

Examples of science that would fit:

- Development and testing of health service delivery methods
- Interventions to increase the quality of health care delivery
- Impact of organizational, social, and cultural factors on access to care and quality of care, including studies on variations or inequalities in access among racial, ethnic, geographical or socio-economic groups
- Studies of providers such as geographical or care-setting variations in outcomes
- Effect of reimbursement and/or insurance on cancer control, outcomes, and survivorship support
- Health services research, including health policy and practice and development of guidelines/best practice for healthcare delivery across the diagnostic/preventive/treatment spectrum
- Analysis of health service provision, including the interaction of primary and secondary care
- Analyses of the cost effectiveness of methods used in cancer prevention, detection, diagnosis, prognosis, treatment, and survivor care/support
- Ethical, legal or social implications of research/health service delivery (e.g. genetic counselling)
- Research into systemic or operational barriers to trial enrolment

6.5 Education and Communication Research

Examples of science that would fit:

- Development of generic health provider-patient communication tools and methods (e.g. telemedicine/health)
- Tailoring educational approaches or communication to different populations (e.g. social, racial, geographical, or linguistic groups)
- Research into new educational and communication methods and approaches, including special approaches and considerations for underserved and at-risk populations
- Research on new methods and strategies to disseminate cancer information/innovation to healthcare providers (e.g. web-based information, telemedicine, smartphone apps, etc.) and the effectiveness of these approaches
- Research on new communication processes and/or media and information technologies within the health care system and the effectiveness of these approaches
- Media studies focused on the nature and ways in which information on cancer and cancer research findings are communicated to the general public
- Education, information, and assessment systems for the general public, primary care professionals, or policy makers
- Research into barriers to successful health communication

6.6 End-of-Life Care

Examples of science that would fit:

- Hospice/end-of-life patient care focused on managing pain and other symptoms (e.g. respiratory distress, delirium, cachexia) and the provision of psychological, social, spiritual and practical support through either conventional or complementary/alternative interventions/approaches throughout the last phase of life and into bereavement
- Quality of life and quality of death for terminally-ill patients
- Provision of psychological, social, spiritual and practical support to families/caregivers through either conventional or complementary/alternative interventions/approaches
- Research into the delivery of hospice care

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6.7 Research on Ethics and Confidentiality

Examples of science that would fit:

- Informed consent modeling/framing and development
- Quality of Institutional Review Boards (IRBs)
- Protecting patient confidentiality and privacy
- Research on publication bias within the cancer research field

6.9 Resources and Infrastructure Related to Cancer Control, Survivorship, and Outcomes Research

Examples of science that would fit:

- Informatics and informatics networks
- Clinical trial groups related to cancer control, survivorship, and outcomes research
- Epidemiological resources pertaining to cancer control, survivorship, and outcomes research
- Statistical methodology or biostatistical methods pertaining to cancer control, survivorship and outcomes research
- Surveillance infrastructures
- Centers, consortia, and/or networks pertaining to cancer control, survivorship and outcomes research
- Development and characterization of new model systems for cancer control, outcomes or survivorship, distribution of models to scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Psychosocial, economic, political and health services research frameworks and models
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer-term research-based training, such as Ph.D. or post-doctoral fellowships.

Concerning the **Disease Site Codes (DSCs)**, please indicate which Disease Site Code(s) is/are applicable to the research described in the project proposal (no more than 12 DSCs are allowed per project proposal). If the research does not focus on a particular type of cancer, please use the 'not site-specific' category (code 2).

Disease Site Codes (DSC)		
Name	**Code**	**Notes**
Adrenocortical Cancer	0	
Anal Cancer	103	
Bladder Cancer	3	
Blood Cancer	67	Use this code for Blood Cancers other than: Hodgkin's Disease (24), Leukemia/Leukaemia (27), Myeloma (30), Non-Hodgkin's Lymphoma (35).
Bone Cancer	4	Includes Osteosarcoma, Malignant Fibrous Histiocytoma, Ewing's sarcoma and all other bone/cartilaginous tumors.
Brain Tumor	6	Includes Chordoma
Breast Cancer	7	
Cardiotoxicity/Heart Cancer	8	
Cervical Cancer	9	
Colon and Rectal Cancer	64	
Ear Cancer	10	
Endometrial Cancer	11	
Esophageal/Oesophageal Cancer	12	
Eye Cancer	13	Includes uveal (eye) melanoma Not including Retinoblastoma (45)
Gallbladder Cancer	14	
Gastrointestinal Tract	15	Use this code for GI cancers other than: Colon and Rectal (64), Esophageal/Oesophageal (12) , Gallbladder (14), Liver (23), Pancreatic (37), Small Intestine (50), Stomach (51).
Genital System, Female	17	Use this code for genital system, female cancers other than: Cervical (9), Endometrial (11), Ovarian (66), Vaginal (57), Vulva (101).

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Genital System, Male	19	Use this code for genital system, male cancers other than: Penile (39), Prostate (42), Testicular (52) cancers.
Head and Neck Cancer	21	Use this code for head and neck cancers other than: Laryngeal (26), Nasal Cavity and Paranasal Sinus (31), Oral Cavity and Lip (36), Parathyroid (38), Pharyngeal (61), Salivary Gland (63), and Thyroid (54) cancers.
Heart Cancer/Cardiotoxicity	8	
Hodgkin's Disease	24	
Kaposi's Sarcoma	46	
Kidney Cancer	25	Includes Kidney cancer and Wilm's tumor
Laryngeal Cancer	26	
Leukemia/Leukaemia	27	Including ALL, AML, CLL, CML & Hairy Cell Leukaemia, Myelodysplastic Syndrome and Myeloproliferative disorders
Liver Cancer	23	Including Bile Duct
Lung Cancer	28	Including Mesothelioma
Melanoma	29	
Myeloma	30	Including Multiple Myeloma
Nasal Cavity and Paranasal Sinus Cancer	31	
Nervous System	33	Use this for nervous system cancers other than: Brain (6), Eye (16), Neuroblastoma (32), Pituitary (40), Primary CNS Lymphoma (104) and Retinoblastoma (45).
Neuroblastoma	32	
Non-Hodgkin's Lymphoma	35	
Not Site-Specific Cancer	2	Includes fundamental research (fluids, secretions, milk lymph, blood components, cell lines and cell fractions, etc.) and research that applies to all types of cancer.
Oesophageal/Esophageal Cancer	12	
Oral Cavity and Lip Cancer	36	
Ovarian Cancer	66	
Pancreatic Cancer	37	
Parathyroid Cancer	38	
Penile Cancer	39	
Pharyngeal Cancer	61	
Pituitary Tumor	40	
Primary CNS Lymphoma	104	
Primary of Unknown Origin	102	
Prostate Cancer	42	
Respiratory System	43	Use this code for respiratory cancers other than: Lung (28), Nasal Cavity & Paranasal Sinus (31) cancers.
Retinoblastoma	45	
Salivary Gland Cancer	63	
Sarcoma (soft tissue)	105	Includes Fibrosarcoma, Rhabdomyosarcoma, Leiomyosarcoma, Liposarcoma, Muscle and other Soft Tissue Sarcoma (but not Ewing's Sarcoma or other bone/cartilaginous tumors (4) of Kaposi's Sarcoma (46)).
Skin Cancer (non-melanoma)	49	
Small Intestine Cancer	50	
Stomach Cancer	51	
Testicular Cancer	52	
Thymoma, Malignant	53	
Thyroid Cancer	54	
Urinary System	55	Use this code for urinary cancers other than: Bladder (3), Kidney or Wilm's tumor (25).
Vaginal Cancer	57	
Vulva Cancer	101	

4b. Modality coding instructions

When deciding on the applicable coding for modality, applications, and type of research, please decide what the main aim or 'center of gravity' is of the project proposal, and assign the modalities, applications and types that best match the project. No more than two modalities may be assigned to each project proposal. An unlimited number of applications and types can be assigned to each project proposal. If more than two modalities will apply to the research, choose the two most important and characteristic aspects of the study. Coding should not include potential or future applications of the research findings.

We ask you to pay attention to a few specific aspects of the modality coding:

- If the project proposal concerns basic research, code basic research as the primary modality. Only code a secondary modality if the research aims concerning this modality are actually achieved during the term of the current proposal.
- For Infrastructure initiatives, the primary modality is fixed to infrastructure and the corresponding application and type are fixed to not applicable.
- Research into image guided therapy, using imaging to improve or complement a therapy, should be coded to the relevant treatment modality plus type supporting tool.
- (Clinical) research with quality of life as a secondary endpoint should **not** be coded to the modality quality of life/care.

MODALITY CLASSIFICATION		
Modality	**Application**	**Type**
Biomarkers	• Risk assessment/predisposition/ susceptibility • (Early) detection/screening • Diagnosis/staging • Prognosis • Prediction/patient selection • Response assessment	• Single gene, molecule or protein • Profile: molecular, cellular • Histological characteristics • Physiological characteristics • Other • Supporting tool (device/test to develop or measure a biomarker)
Imaging	• Risk assessment/predisposition/ susceptibility • (Early) detection/screening • Diagnosis/staging • Prognosis • Prediction/patient selection • Response assessment	• X-ray/Computed tomography (CT) • Magnetic Resonance Imaging (MRI) • Nuclear Imaging (PET and SPECT) • Ultrasound • Spectroscopy • Light (e.g. endoscopy) • Infrared (e.g. near- infrared fluorescence) • Other • Supporting tool (e.g. contrast, imaging enhancers)
Agents	• Prevention • Therapy	• Small molecules • Nucleic acids (DNA, RNA, antisense oligonucleotides) • Proteins/peptides (e.g. recombinant proteins, therapeutic enzymes) • Hormones • Microorganisms (virus, bacteria) • (Multidrug) resistance • Agent not yet known • Other • Supporting tool (e.g. cell culture systems, mouse models, carriers)

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Immune response modifiers	• Prevention • Therapy	• (Monoclonal) antibodies • Cytokines (e.g. growth factors, interleukins, chemokines, interferons) • Other immunostimulants/immunosuppressors • Vaccines • (Adoptive) immune cells • Transplantation • Other • Supporting tool (e.g. cell culture systems, mouse models, delivery expression vector)
Interventive devices	• Prevention • Therapy • Non-invasive • Minimally invasive • Invasive	• Radiation therapy (incl. radionuclides) • Cryoablation • Hyperthermia • Photodynamic therapy (PDT) • Surgery • Active surveillance • Other • Supporting tool (e.g. reproducible assays, imaging methods for image guided therapy, carriers)
Lifestyle and exposure	• Prevention • Therapy (as part of or to improve cancer treatment)	• Tobacco • Physical activity • Alcohol • Diet and nutrition • Herbs and botanicals • Social and cultural environment • Gene/environment interactions • Exogenous hormones • Adverse exposure to infectious agents and contaminants in the air, water and soil • Solar radiation • (Hazardous) occupational exposure • Adherence to screening/treatment • Other • Supporting tool (e.g. identification of target population, biochemical, behavioral and/or imaging assays to measure effect of lifestyle alteration)
Quality of life/care	• Physical (side) effects of treatment/cancer • Cognitive (side) effects of treatment/cancer • Psychological (side) effects of treatment/cancer • Social (side) effects of treatment/cancer • Unspecified Quality of Life • Quality of Care	• Tissue damage (e.g. cardiovascular (side) effects) • Changes in body composition/weight and physical fitness • Mouth and throat problems • Nausea and vomiting • Hormonal (side) effects • Sexual (side) effects • Pain • Secondary malignancies • Concentration and learning problems • Memory issues • Fatigue and sleep • Psychological distress • Fear of recurrence • Societal participation • Relations and family • Needs/care use • Care service/improvement • Communication and decision making • Other