KWF Guidelines 2022

Guidelines for the submission of a project proposal in the KWF calls

Version 2.4
June 2022

Version management

Version	Date	Most important adjustments
2.4	June 2022	• Adjustment to GMS update • New call types • Typo corrections
2.3	January 2022	• Adjustment to GMS update • Typo corrections
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 January 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). 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.

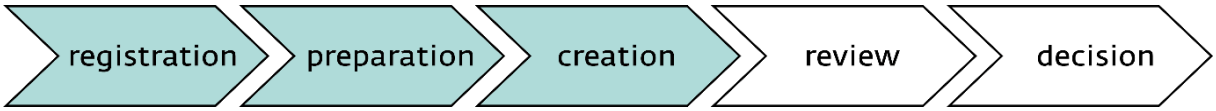
If your project proposal has been granted for funding, you will receive a grant decision letter with the applicable conditions. These guidelines do not cover the monitoring of your project by KWF nor the project closure procedure.

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

Phone:	+31 (0)20 5700 450
E-mail:	bestedingen@kwf.nl
Website:	https://www.kwf.nl/onderzoek

See www.kwf.nl/onderzoek/poi/Pages/Contact to select a programme coordinator who works in a matching topic so they can help you with more detailed information on how to apply for one of our grants.

1.1 Tips and tricks

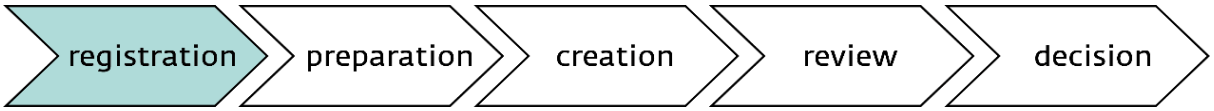


We advise you to read the entire guideline and pay extra attention to the following tips and tricks.

- Please note that substantial changes have been made to the application process; from the 14th of June onwards, KWF provides a Word template for submitting your project proposal. The Word template can be downloaded from the GMS project proposal tab. If you intend to involve patients or a patient organization during your study, please make sure you contact them in time. See chapter 5.
- 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 2). The system CANNOT register a proposal if the organization is not cleared by KWF in advance!
- Registration of an organization entails amongst others a Kamer van Koophandel Uittreksel, so start well in advance.
- Before creating a project proposal, select the right type of funding and research phase. See chapter 3. If you want to adjust the type of funding or research phase in KWF GMS you have to create a new project proposal.
- Please check all eligibility conditions of your funding type in chapter 3. Any requests for exemption must be submitted to KWF **at the latest six weeks before the call deadline**.
- The KWF GMS text boxes do 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.
- The Word template asks you to create milestones. 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 & Implementation track, three to six milestones in total will suffice.
    - For other calls such as the theme calls please pay close attention to the call specific instruction file. Please note that from the 14the of June onwards it is only required to submit your milestones in GMS when the project proposal has been approved.
- If you enlist a service provider or inclusion center, it is obligatory to upload a quotation for the estimated costs (including taxes).
- 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.
- KWF recommends you to contact your finance department for a budget check and to discuss with them if 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.

- 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).
- We strongly advise you to **validate** your project proposal in KWF GMS at least two weeks 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 status missed deadline and will not be taken into consideration.

2. 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.

2.1 Registration of a department and/or organization

For most calls your organization and department need to be registered in KWF GMS to participate as a lead institute or participating organization in a project proposal. 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.

2.2 Approval of a department and/or organization

For most call types 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**.

2.2.1 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.

2.2.2 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.

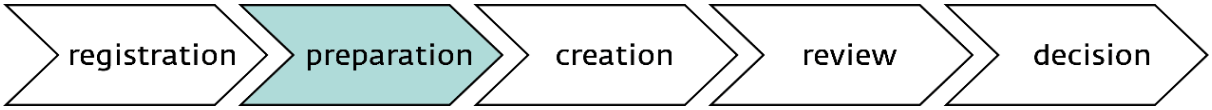
KWF reserves the right to reject a project proposal if the organization does not satisfy the approval requirements or the requested documents are not provided on time.

2.3 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 specialization, 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).

3. Preparing a project proposal



After registration in KWF GMS, you will be requested to select the funding type and research phase.

3.1 Funding types

KWF offers various funding types:

- Research projects
- Young Investigator Grants
- Unique High Risk projects
- Consortium projects
- Infrastructure initiatives
- Implementation Funding
- PPS (Public Private Partnerships)
- Theme calls (which could entail research projects, consortium projects)
- SGI projects

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 collaborations with other organizations to address the research question are allowed. 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 or in the case of the Theme calls in the Theme call specific information sheet found on the KWF website.

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.

3.1.1 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 consists of a hypothesis-driven research question and has a defined duration as well as 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 each year during the term of the project.

3.1.2 Young Investigator Grant

The funding type Young Investigator Grant (YIG) is for researchers who are in an early stage of their scientific career. It is aimed at offering 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 consists of a hypothesis-driven research question and has a defined duration as well as 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 each 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 parental 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. However, these **need to be requested at least six weeks before the call deadline.**

3.1.3. 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 crystallized idea offers viable opportunities. This type of funding is to validate innovative ideas, to realize 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.

3.1.4 Consortium project

The funding type Consortium project is for Research projects in which expertise from different organizations is required to address a complex hypothesis driven 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 aimed to answer a hypothesis-driven research question 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 each 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.

3.1.5 Infrastructure funding type

The funding type infrastructure aims to consolidate and expand Dutch national cancer research infrastructure. For the definition of infrastructure, please see section 3.2.6. KWF offers temporary funding for the design, preparation and implementation of existing or new infrastructures. Funding of infrastructures is temporary because KWF expects that the proposed infrastructure will be set up and implemented in a (financially) self-sustainable manner and that it will be available and accessible on a national scale. A nationwide need, broad support from the scientific community and a solid sustainability plan are therefore important aspects of the infrastructure proposal. Multidisciplinary, (Inter)national collaboration with (existing) infrastructures and between research groups is encouraged as well.

Eligibility terms:

- Only proposals within the criteria of the scope are eligible. The scope of infrastructure call can vary per call. The scope can be found in the call text on the website, see https://www.kwf.nl/onderzoek/poi/Pages/Infrastructurele-initiatieven
- An dedicated project manager must be appointed
- There is demonstrated nationwide need for the proposed infrastructure
- There is broad support from and/or collaboration with the oncological community and its stakeholders at large
- The proposed infrastructure collaborates, consolidates, or builds upon existing infrastructures as much as possible
- The proposed infrastructure will be findable and (inter)nationally available and accessible

Review process:
The review process of infrastructures includes a two-stage process. When the pre-proposal has been positively reviewed and selected, you will be invited to submit a full proposal. Collaboration between infrastructures is encouraged. If complementary infrastructures 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.

3.1.6 Implementation Funding

To create impact for the patient and public, it is essential that new innovations with proven benefits are made available on large scale. KWF aims to stimulate and facilitate the implementation of effective innovations by means of funding for implementation projects. In these projects the scale up of an innovation is central.

Eligibility terms for Implementation Funding

- Innovation is (almost) ready for practice
- Innovation is proven effective in research
- Stakeholders have a need for and support the innovation
- Scale up on national level is possible
- Use of the innovation is/will be structurally funded

3.1.7 PPS (Public Private Partnerships)

At KWF, we see a great need for greater collaboration between public and private organization, to create more impact of research findings for the oncology patient.
With the Health~Holland PPP allowance program for Public Private Partnerships (PPP), KWF and Health~Holland aim to stimulate innovative research projects that are necessary for the next step in translational research in oncology. This program is looking for innovative, translational, and multidisciplinary research focused on oncology in which knowledge institutes and private partners are collaborating. For more information see https://www.kwf.nl/onderzoek/financieringsinformatie.

Eligibility terms for Public Private Partnerships

- The research fits within the Knowledge and Innovation Agenda 2020-2023 of Health~Holland (https://www.health-holland.com/).
- The project is not funded otherwise.
- The consortium consists of at least one Dutch knowledge institute and at least one industrial partner.
- The project will be realized at joint cost and risk and all consortium partners will make a substantial contribution to the project, not only in cash or materially, but also in kind. In other words, the project should be a true collaborative effort.
- Maximum duration of the project is four years.
- The project can be defined as fundamental research, industrial research or experimental development. Or a combination thereof.

3.1.8 Theme calls

The scope of Theme calls 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/financieringsinformatie.

3.1.9 SGI projects (Speerpuntgedreven initiatieven)

Within KWF the work is focused on working groups aiming for progression in a certain area within cancer. These groups are called Spearheads (speerpunten). Each Spearhead can propose Spearhead Driven Initiatives (SpeerpuntGedreven Initiatieven, SGI). With these initiatives fall initiatives that offer opportunities for breakthroughs or acceleration within one or more KWF Spearheads. Where possible and appropriate, KWF aims for submission in the open calls that are assessed by the Exploration and Development & Implementation committees. However, due to their structure, some initiatives do not fit in the regular open call. For example, because in terms of recruitment proposition they do not fit in well with the regular call, because they are actively supported with input from FTE from a spearhead, or because it concerns an infrastructural initiative that falls outside the scope of the Infrastructure Call of that year.

3.2 Research phases

After choosing a funding type, you need to select a research phase. KWF identifies seven research phases. When you apply within the open call you have to take the research phase into account since this is the basis on which projects are divided between the two open call committees: Exploration and Development & Implementation.

The exploration track focuses on finding solutions to address knowledge gaps, obtaining new scientific knowledge and identifying first leads and targets.
The Development & 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 & Implementation track
Creation of modality
Preclinical research
Clinical research
Implementation research

Infrastructure

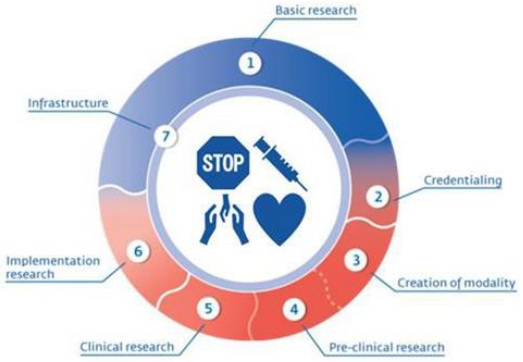


Figure 1: Research phases

However, in the other calls (such as theme calls, SGI etc.) it can sometimes also be possible to classify the proposal in one of the phases described in this guideline.

3.2.1 Basic research phase

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.

3.2.2 Credentialing phase

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 can also be part of the credentialing phase, as well as 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.

3.2.3 Creation of modality phase

The goal of creation of modality research is the extensive characterization 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.

3.2.3 Preclinical research phase

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).

3.2.4 Clinical research phase

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.

3.2.5 Implementation phase

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?

3.2.6 Infrastructure

For Infrastructure initiatives, choose the research phase infrastructure. Cancer research infrastructures are fundamental facilities and systems that provide resources and services for the cancer research community. Infrastructures enable researchers to focus solely on conducting research and thereby accelerate innovation and implementation of novel techniques, tools and treatments. Infrastructures add value to oncology by fostering and supporting cancer research. Infrastructures are sustainable and continuously accessible for use by the (inter)national research community and are independent of use for specific research questions.

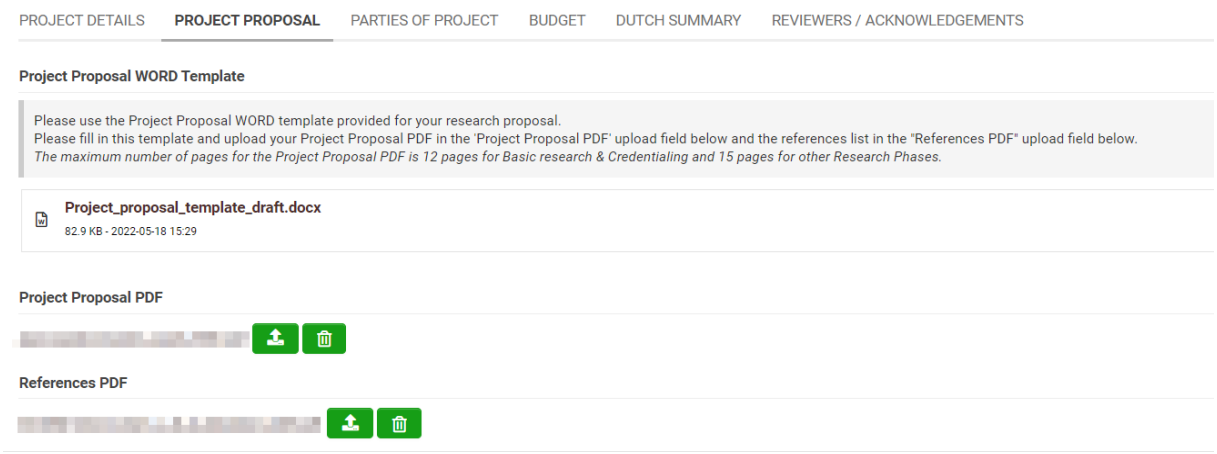
Examples of research infrastructures are:

- Facilities: biobanks, omics facilities, imaging facilities, animal modelling facilities, functional genomic screening facilities, cell and gene therapy facilities, etc.
- Platforms: clinical trial platforms, early detection platforms, model organism platforms, and systems biology platforms.
- Data infrastructures: data repositories, computing systems, registries, catalogues, portals, tools that proactively promote, engage and/or are in transition to adopt well-curated and FAIR data, and communication networks.

4. Creating an application

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 tab” (in bold in the figure below) shows you a button with which you can download a Word template.



In this Word template, detailed instructions on the contents of the project proposal are provided. The Word template varies per call type. The proposal should not exceed the number of pages that is indicated in the template, including figures but not including references. KWF project proposals are required to be in at least font size 9, with set margins (2.5 cm side and 2.5 cm top and bottom), and single line spacing.
After filling in the Word template please convert the project proposal into a PDF format in order to upload it. Please note that the references need to be provided in a separate PDF document for which a template can be found on the “project proposal tab” in GMS. Do take care that the headers and footers of the references section are identical to the main document.

All project proposals that do not meet the above criteria on page length, margins, font size etc. are **not** eligible for funding. Also note that project proposals exceeding the maximum page length will be rejected automatically by GMS.

General instructions

- Your project proposal must be written in English, except for the “Dutch summary” tab.
- Project proposals need to be submitted in PDF, the literature index can be uploaded as a separate document.

- Fields marked with an asterisk (*) in KWF GMS are mandatory. Some fields are conditionally mandatory. If one of these fields is missing, KWF GMS indicates this upon validation of your project proposal.
- KWF GMS fields do 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.

The final PDF that will be sent out to reviewers will be composed of:

- A front page containing the Project Details
- Project Proposal
- References
- Additional project information from the other tabs (a.o. parties of the project and & budget)
- Additional appendices

4.1 Application: Project details for GMS

4.1.1.1 Title of the project

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

4.1.1.2 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.

4.1.1.3 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 pediatric or geriatric oncology, enter this as a keyword.

4.1.1.4 Scientific abstract

Summarize 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 for instance 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 also use these summaries for communication purposes (e.g. to inform the public/donors about KWF-funded research).

For Infrastructure initiatives pre-proposal: summarize 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.

4.1.1.5 Modality

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 modality coding system. In the modality field the modalities you can choose from are Basic Research, Biomarkers, Imaging, Agents, Immune response modifiers, Interventive devices, Lifestyle and exposure, Quality of life / care. KWF can choose to change your modality classification of the project and will add a ICRP classification to your project proposal.

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.

4.1.1.5 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).

4.1.1.6 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. Please use the button Previous Rejected or Granted Proposal to use the selection menu. In case you cannot select your previous proposal then you can enter this manually.
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.

4.1.1.8 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. Application: General project proposal

In the project proposal tab in GMS a call-specific proposal template is available for download. Use this document to describe your project proposal and to substantiate the activities that cover your request for funding. As mentioned above, please note that in the definitive PDF version the references are to be uploaded in a separate template.
Page limit: A Project Proposal PDF (incl. figures and excl. references) for the Research Phases Basic research & Credentialing is limited to 12 pages. For all other Research Phases the limit is 15 pages. There is no page limit for the References PDF. The KWF project proposal is required to be in at least font size 9, with set margins (2.5 cm side and 2.5 cm top and bottom), and with single line spacing.

5.1 Additional information on the Work Packages, Milestones and Gantt chart

In all the project proposals work packages need to be described that relate to the GANTT chart. 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.

5.1.1 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).

Work packages for clinical studies – recommendations

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 organized?
- 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 organized? Who collects the data and what are the qualifications of the staff?
- How will the monitoring be organized 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 organized? 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

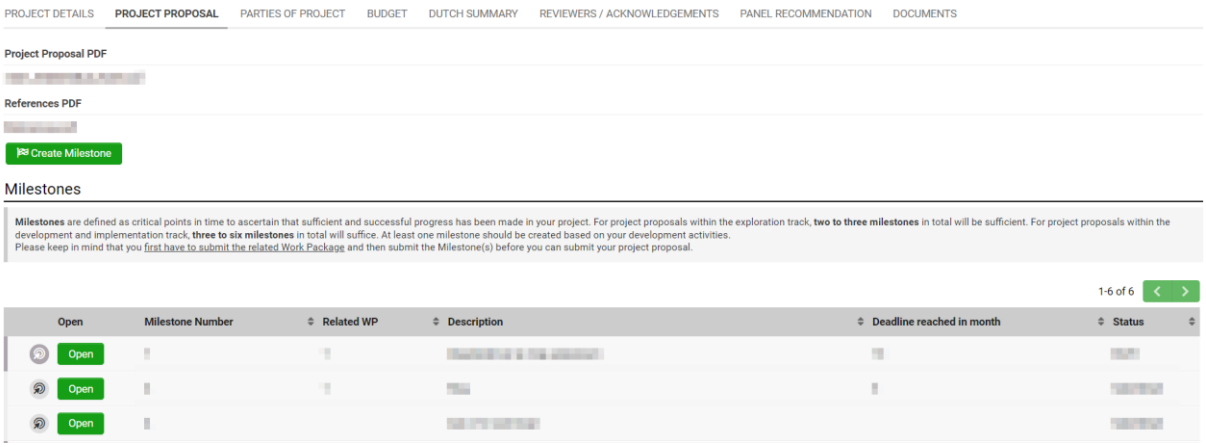
When the follow-up of the clinical trial is required to address the hypothesis, this must be described in a separate work package. The follow-up work package describes:

- 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?

5.1.2 Milestones

Within the work package please indicate your milestones. Milestones are defined as critical points in time to ascertain that sufficient and successful progress has been made in your project. Do not confuse these with specific deliverables of the project such as publications. 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 within the Development & Implementation call, two to three milestones in total will suffice; for project proposals within the development track within the Development & Implementation call, an average of three to

six milestones in total suffices. It is obligatory to formulate at least one milestone per work package. **Note: Only if the project proposal is accepted for funding you are required to complete your milestones in GMS:**



5.1.3 GANTT chart

Please provide a GANTT chart showing: the duration of the work packages, the major activities included in these work packages and the timeframe necessary to reach the milestones.

GANTT chart		Year 1				Year 2				Year 3				Year 4			
	Month	3	6	9	12	3	6	9	12	3	6	9	12	3	6	9	12
Work Package 1 - *Title*	*WP leader*																
Task 1.1																	
Task 1.2											M2						
Task 1.3						M1											
Work Package 2 - *Title*	*WP Leader*																
Task 2.1																	
Task 2.2																	
Task 2.3																M3	

Figure 3: Example of a GANTT chart.

5.2 Statistics and Data management

Please substantiate the methodology/study design, if applicable include power calculation, and include a statistical analysis strategy.

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. 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.

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).

General features

- If a Data Management Plan (DMP) is written according to your institute's policies, please attach the DMP.
- What are the characteristics of the collected or generated data? (e.g. raw data, clinical data, computed data, software, semantics and/or ontologies?)
- Will you be (re)using or coupling with existing data? If yes, which data and do you have the data owner' s permission to use the data?

Legislation

- What privacy policies and laws are applicable to your project and how will you comply to these privacy policies and laws?
- If the research involves human subjects:
  - is informed consent available?
  - how will you anonymize/pseudonymize the data?

Findability

- How will the generated or collected data be findable?
- Which metadata scheme or unique persistent identifiers will be used for the description of the data?

Accessibility

- Will the data be accessible for further research and verification? If yes, how can end users can access the data
- Will the data be openly available/or only partially available/or are the data(sets) under embargo?
- Which are the restricting access conditions to access the data collection?

Interoperability

- Which (meta)data standards will be used to enable further data coupling?
- What are the privacy protection measures associated with the reuse of the data and potential combination with other data sets?

Reusability

- How will you ensure that the data and associated documentation will be of sufficient quality and thus can be reused?
- Can you provide an estimation on the size of the data collection (in GB/TB) to be preserved in an archive/repository?
- Which archive/repository/cloud will be used to ensure long term use of the data?
- Once the project has ended which period will you recommend to preserve the selected data for archiving?
- Is there a cost estimation for preparation of the data for archiving?
- Is the cost estimation provided in the current project budget?

For assistance on creating a data management plan, click https://dmponline.dcc.ac.uk/help#PlanningHelp .

5.3 Development plan (not applicable for the Exploration call)

For KWF it is essential that obtained knowledge, skills and technology are made available for patients and the public. For a successful translation and implementation of research findings into practice, it is important to have insight into the following at an early stage during the development of the innovation:

- The development route from the initial idea towards the end point, at which it is used in clinical practice and the necessary steps to get there.
- The risks and opportunities that play a role in the development route.

Please describe which steps and actions are needed to realize implementation of the innovation/new method. Which actions will be taken during this project? And which after successful completion of this project? Please include the actions taken during this project in your plan of investigation. Describe the following topics:

- Applicability and wide availability in clinical practice: How will the invention be used in practice? Are (technical) adjustments necessary to fit the innovation into current standard clinical protocols? Can it be implemented in all hospitals/ at all care providers, or only in specialized centers? What actions are needed in this phase?
- IP strategy: What is your IP strategy to protect the knowledge / skills / technology obtained during this project (e.g. patents, trade secrets, copyrights, trademarks, registered designs)? Have you been in contact with your TTO? In case you decide not to protect the knowledge / skills / technology, please explain.
- Potential commercialization: What is the financial model of the development route and why? Fully in an academic setting/ co-development with a commercial partner/ initiating a start-up / licensing of a patent? Or is the financial model still undecided? Have you been in contact with your TTO, or other experts? What actions are needed in this phase?
- Legislation: Is the regulatory pathway that will apply for further development or implementation of your innovation clear? Think of Health Insurance Act (Zvw), DOT (DBCs on the way to Transparency), CE-marking requirements, Medical Device Regulation (MDR), In Vitro Diagnostics Regulation (IVDR) and privacy regulations (AVG). Which actions are needed in this phase?
- Reimbursement: Who will pay the costs of the invention when it is in clinical use? Patient/ Care Provider/ Municipality/ Health insurer/ Government. If it is unclear at this stage, describe the actions needed to select the right funder. Otherwise, describe what (evidence) is needed for the (potential) funder in order to cover the innovation in practice? What actions are needed in this phase?
- Stakeholders: Which stakeholders (i.e. end user, provider, referrer) need to be involved in the development route? How do you need to involve them (e.g. collaboration or co-creation)? What actions are needed in this phase?
- Risks and opportunities: Which risks and opportunities arise while taking the above mentioned steps? Please describe what actions are needed to mitigate them.

5.4 References

Please list your references. This section does not count for the total page length of the project proposal and needs to be submitted as a separate document. Just as the KWF project proposal the reference

section is required to be in at least font size 9, with set margins (2.5 cm side and 2.5 cm top and bottom), and with single line spacing.

6. Infrastructure Initiatives

6.1 Pre-proposal

For Infrastructure initiatives pre-proposals, an infrastructure pre-proposal template is available for download on the project proposal tab in GMS Use this document to describe your project and to 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. The Infrastructure pre-proposal contains the following elements:

- Relevance
- Aim: define the aim of the Infrastructure initiative by describing which oncological Research projects will be enabled by this infrastructure initiative 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
- References

6.2 Full proposal

For Infrastructure initiatives full-proposal, an infrastructure proposal template is available for download on the project proposal tab in GMS. The Infrastructure pre-proposal contains the following elements:

- 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 valorization.
- Data management plan: see section 5.2 above
- References

7. Implementation funding, PPS, theme call, and key area driven initiatives (themacalls and speerpunt gedreven initiatieven)

For implementation funding, PPS, theme calls, and SGI initiatives a proposal template is available for download on the project proposal tab in GMS. The template is based on the same elements as the regular project proposal template so please refer to section 5 for detailed instructions.

8. Application: Parties of the project

In the GMS Parties of the project tab an overview is requested of all people who actively work on the project and all organizations involved in executing.

8.1 Employments

You must register the principal investigators and scientific personnel in the table Scientific Employment. 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.
- A 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 focused 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.

8.1.1 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 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).

8.1.2 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 synchronize 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 authorize 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.

8.1.3 Minimum of 0.5 FTE employment

For most call types a 0,5 FTE employment is mandatory within the Research projects, YIG and Consortium project types. Please state that you have at least one scientific researcher employed on the project at a minimum of 0.5 FTE employment each year during the term of the project. If you do not meet this eligibility condition, please justify.

8.1.4 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 in the table Support Staffing.

8.2 Parties of the project

Please complete the table parties of the project. If you have filled out the table Scientific Employment and table Support Staffing in the section Employment, 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.

<u>Conditions:</u>

- 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 intellectual property rights of the project results depend on the role of the organization(s) 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 regulated by the lead institute, a participating organization or service provider. The project leader and the lead institute are responsible for the 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 the 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 a participating organization that provides a necessary service for the work plan, such as data management, animal facilities, pathology review or 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 or 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. This center has no right to the project results. An exception to this is that an inclusion center retains the right to its own generated data such as information, samples, knowledge and inventions. A quotation for their services is obligatory.
- An **external inclusion center** is an organization outside the leas institute or participating organization(s) that only includes patients for clinical studies and has no active research role in the project. This center has no right to the project results. An exception to this can be that an external inclusion center retains the right on its own generated data, information, samples, knowledge and inventions. 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). This co-funding should be 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.

8.3 Collaboration

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 on 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.

8.4 Existing Contracts and Third Party Rights

In this section you need to fill in details on any materials, data etc. that you received from a third party to be used in this project. If available you need to provide the third party contracts for instance Material or Data Transfer Agreements. If the project is part of an ongoing collaborative project please also provide a copy of the signed agreement. KWF also needs to know whether you have obligations to sponsors/co-funders. If this is applicable to your project please state this in this tab.

8.5 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 honors 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.

8.6 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 honors and awards. The principal investigator's four most relevant publications can be added manually to the project proposal.

8.7 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 honors and awards.

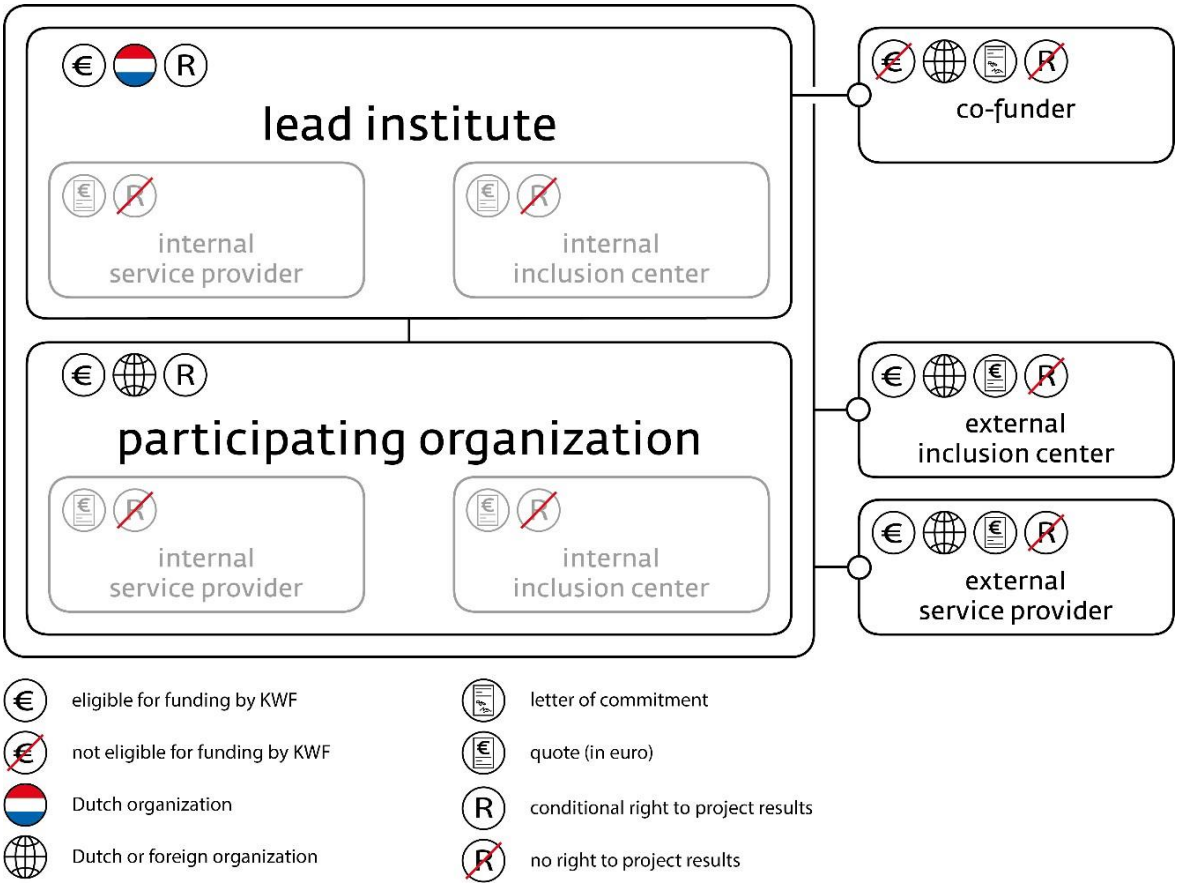


Figure 4: Schematic overview of organizations working on a project.*

* 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.

9. Letter of commitment

Letters of commitment are compulsory for co-funders and studies in which patients are included.
In the 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 or number of patients to be included, etcetera. The letter includes how the contribution fits within the project proposal/planning.
You can upload the letter as attachment (PDF file) in GMS. The PDF file name must clearly indicate the subject of the letter.
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 authorized 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.

10. Application: Budget

In the GMS Budget 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.

10.1 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.

10.2 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.

10.3. 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 licenses;
- 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.

10.4 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.

10.5 Open access

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

10.6 Internships abroad

Internships abroad can bring essential knowledge and skills 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).

10.7 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.

10.8 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.

10.9 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 endeavor. 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.

10.10 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.

10.11 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.

11. Application: Dutch summary

If the project is granted, the Dutch summary will be included in our public research database. In addition, it can be used for communication purposes to laymen. Therefore, the entire tab has to be filled out in Dutch. Please avoid the use of jargon, abbreviations and explain any technical terms that have to be included. 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

Depending on the call you are submitting your proposal to, there are different requirements for the Dutch Summary. Please read the instructions for the different calls below.

11.1 Dutch summary for Development, Infrastructure, Theme calls and SGI

The tab Dutch summary will be used by the patients advisory committee (PACO) for assessing the project proposal. 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 & Implementation review committee and play an active role in formulating the funding advice. Although PACO members are trained in reading project proposals, not all members have a background of medical expertise or knowledge of specific research methodologies therefore please refrain from translating a scientific abstract into the Dutch language.

- Project titel (project title)

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

- Samenvatting projectplan (summary of project plan)
  Summarize your project proposal in layman's terms and avoid using specialized 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.

Please use the following subheadings:

- Achtergrond en probleemstelling (Background and problem)

- What is the background and the problem being the starting point of your project proposal?
- **Infrastructure initiatives only**: Describe the scientific need for this Infrastructure initiative. How will enable and facilitate scientific research that contributes to KWF's main goals?

- Onderzoeksrichting/voorgestelde oplossing (envisaged solution for the problem/the research direction)
  - What is your research direction/ envisaged solution for the problem?

- Relevantie (relevance)
  - In what way does your research proposal contribute to your envisaged solution?
  - Describe the novelty and expected added value of your solution/research direction.
  - For whom and in what way is this development significant?
  - How does your envisioned solution/research direction impact society?
  - Does the objective of the study correspond to the needs of the target population?

- Onderzoeksvragen (research question(s))
  - What are your research question(s)?

- Onderzoeksopzet (Study design)
  - Describes the different stages of your study. A clear and comprehensible diagram Illustrating of the study design (including follow-up can be attached as PDF file.
  - **Infrastructure initiatives only**: Collaborations: will the Infrastructure initiative collaborate with other initiatives?

- Verwachte uitkomsten (expected outcomes)
  - What outcomes do you expect?
  - How will the results be disseminated to end users as well as participating patients/citizens?

- Omschrijving stappen nodig om resultaat te implementeren (follow up and implementation)
  - What steps are required to implement the findings of the research and the envisaged solution, and how does this project anticipate on it?
  - **Infrastructure initiatives only:** which follow-up steps can be anticipated to ensure the financial self-sustainability of the Infrastructure initiative?

- 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 risks and ethical aspects (freedom of choice, privacy) associated with participation.
  - 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 research sample: the number of study participants, inclusion and exclusion criteria, chance of dropouts, feasibility of the envisaged research sample and recruitment strategy.

- Toelichting patiëntenparticipatie (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.

  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.

  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? How will this input be used?
  - Describe the role of patients and/or patient organizations before, 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?
  - Infrastructure initiatives only: 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 .

11.2 Dutch summary for Exploration calls

This summary will amongst others be used on the website of KWF to give insight into how the money is spent that KWF collects. Therefore bear in mind that the content should be comprehensible for lay people.

- Project titel (project title)
  - Choose a clear Dutch title which describes the content of the project.
- Samenvatting projectplan (summary of project plan)
  - Summarise your project proposal in layman's terms and avoid using specialised medical or scientific terminology.

  Please use the following subheadings:
- Achtergrond en probleemstelling (Background and problem)
  - What is the background and the problem being the starting point of your project proposal?
- Voorgestelde oplossing/ doelstelling (envisaged solution for the problem/ aim)
  - What is your research direction/ envisaged solution for the problem?
- Onderzoeksvragen (research questions)
  - What are your research questions?

- Onderzoeksopzet (Study design)
    - Describe your study design.
- Verwachte uitkomst / relevantie (Expected outcome and relevance for patiënts)
    - In what way does your research proposal contribute to your envisaged solution?
    - Describe the novelty and expected added value of your solution/research direction.
    - For whom and in what way is this development significant?
    - How does your envisioned solution/research direction impact your target population?
- Vervolgstappen / implementatie (follow up / implementation)
    - What steps are required to implement the findings of the research and the envisaged solution, and how does this project anticipate on it?

12. Reviewers/Acknowledgements

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

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.

When possible please do not enlist members of the KWF internal review committee as reviewers. For an overview of the regular committees see the KWF website https://www.kwf.nl/onderzoek/kwf-programma-onderzoek-implementatie/beoordelingscommissies

12.1 National reviewers

The list should include at least two independent 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.

12.2 International reviewers

The list should include at least five independent 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.

12.3 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.

12.4 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.

13. Acknowledgments

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

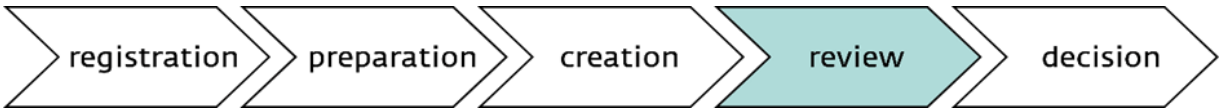
- General acknowledgements:
  - By signing, the project leader declares that the information supplied in the project proposal and profile is truthful, and that he/she will immediately report to KWF in case of any changes that may be relevant to the development, assessment or acceptance of the project 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.

14. Personal motivation (YIG only)

Please describe your personal motivation for a Young Investigator Grant (YIG) application by answering the following questions:

- 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?

15. Review



KWF funds and facilitates high-quality projects that contribute to the realization 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.

15.1 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.

15.1.1 Review criteria for basic research phase

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?

15.1.2 Review criteria for credentialing research phase

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?

15.1.3 Review criteria for creation of modality research phase

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 & 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?

15.1.4 Review criteria for preclinical research phase

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?

15.1.5 Review criteria for clinical research phase

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?

15.1.6 Review criteria for the implementation research phase

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?

15.1.7 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?

16. Review process

16.1 Review process of the Open calls

The review process of the open (Development & Implementation and Exploration) call takes approximately 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
- Prioritization meeting

16.1.1 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.

16.2 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.

16.3 Review procedure of full proposal projects

- Internal Review
  - Scientific eligibility check
- 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
- Prioritization meeting

The stages and substages will be explained below.

16.4 Internal Review

- 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.

- 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 driven research question, 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.

16.5 External review

16.5.1 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.

16.5.2 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 (creation of modality phase up to and including implementation phase). 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.

16.5.2.1 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 realization 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?

16.5.3 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.

16.6 Board review

To enable comparison, project proposals will be categorized 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.

16.6.1 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.

16.7 Interview

In the open call, the call for implementation funding and the PPS call assigned members of the review committee will review YIG, Consortium or call specific project proposals, and make a selection of project proposals for which an interview needs to be scheduled.
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.

16.8 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 a final recommendation and rating of the project proposals, reflecting the opinion of the entire internal review subcommittee.
This final recommendation will be based on the external reviewers' reports, the facts and reflections provided by KWF, the committee members' reviews, the advice from the PACO, the interview and the discussions during the board review meeting.

Method of rating the project proposals:

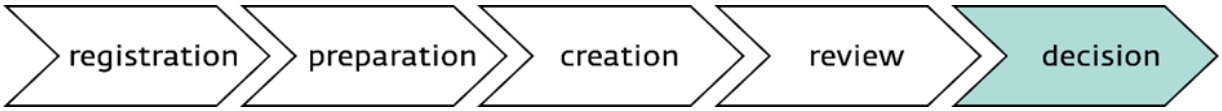
- A: excellent project proposals, eligible for funding;
- B: project proposals eligible for funding;
- C: project proposals not eligible for funding.

16.9 Prioritization meeting

The aim of the prioritization 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. During this meeting funding partners of KWF choose project proposals eligible for funding to fund on behalf of the funding partner.

Participants of the prioritization meeting are the chair(s) and vice-chair(s) of the respective 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 prioritization meeting will be the recommendation and rating of the board review meeting, including a summary and arguments from different perspectives. Furthermore, KWF input will also 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. Subsequently the board of directors of KWF make the final decision which projects are to be funded.
This decision, including the substantiated final recommendation and the comments of the external reviewers and the PACO, will be communicated to the project leader by means of a decision letter.

17. Decision



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

17.1 Funding granted

If funding for the project proposal is granted, the project leader will receive a grant decision letter, including attachments regarding 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.

17.1.1 Funding Partners

A project proposal eligible for funding can be selected by a funding partner. A funding partner is a fundraising party with a long-term partnership agreement with KWF. The funds raised by the funding partners are spent in the open calls of Exploration and Development & Implementation. The preferred funding themes are being set out in the partnership agreement. In the prioritizing meeting, projects are matched and selected by funding partners. Projects that best match the funding themes are being

funded by the funding partner. Selected projects may receive specific funding conditions upon granting the funding.

Current funding partners and their themes:

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.

17.1.2 PPP allowance (PPS-toeslag)

Innovative research and development realized 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 maximize their efforts to minimize the additional funding conditions.

17.2 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 attached the comments of the external reviewers and when applicable the PACO.

17.2.1 Rejection with a B-rating

Rejected project proposals with a B-rating are projects of good quality, feasibility, and relevance. They cannot be funded because of insufficient budget. During the prioritization meeting other project proposals were considered to be more suitable for funding. It is not possible to submit an appeal against a B-rejection. 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.

17.2.2 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, so check the actual guidelines carefully.

17.3 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.

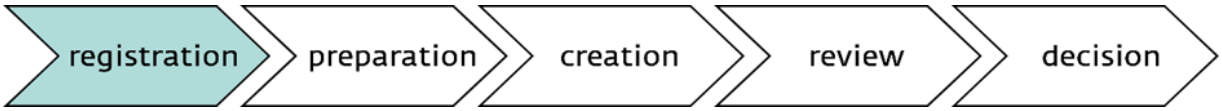
The decision made by KWF is binding, no further appeal is possible. Except when an objection is rejected on procedural grounds, it is possible to appeal against this decision. The KWF Board of directors will handle this appeal.

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

18. 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. For theme call special conditions may be applicable.

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:
	  o SMEs (small to medium enterprise)
	  o 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 • 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 • 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 • 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 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 Information on 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 an overview of national and international cancer research: https://www.icrpartnership.org/db_search 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
Creation of modality
Preclinical development
Clinical research
Implementation research</td><td>Biomarkers</td><td>Imaging</td><td>Agents</td><td>Immune response modifiers</td><td>Interventive devices</td><td>Lifestyle</td><td>Quality of life/care</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.

4a. 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)
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	• 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
	• Cognitive (side) effects of treatment/cancer	• Concentration and learning problems • Memory issues
	• Psychological (side) effects of treatment/cancer	• Fatigue and sleep • Psychological distress • Fear of recurrence
	• Social (side) effects of treatment/cancer	• Societal participation • Relations and family
	• Unspecified Quality of Life	
	• Quality of Care	• Needs/care use • Care service/improvement • Communication and decision making • Other