KWF Guidelines 2024

Guidelines for the submission of a proposal in the KWF calls

Version 2.7
September 2024

Content

1. Introduction

This document contains the guidelines for the submission of a proposal for funding by KWF Kankerbestrijding (KWF). It provides practical information on the registration in the Grant Management System (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 proposal and the applicable fields in GMS. Lastly, it describes the reviewing process. Call specific criteria can be found in call specific addenda.

If your proposal has been granted for funding, you will receive a grant decision letter with the applicable conditions. These guidelines for submission do not cover the monitoring of your project by KWF nor the project closure procedure. Monitoring conditions are described in the Funding Terms & Conditions. These will be discussed with you by the Liaison during the kick-off of your project.

If you have procedural questions or questions concerning GMS, please contact our review and grants administration department:

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

Contact one of our science liaisons (via Contact information for researchers and applicants | Dutch Cancer Society (kwf.nl)) for more detailed information about applying for one of our grants.

1.1 Tips and tricks

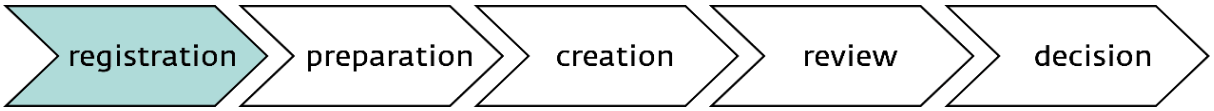
We advise you to read the entire guideline and pay extra attention to the following tips and tricks:

- When a call opens in GMS, a Word template for submitting your proposal will become available. The Word template can be downloaded from the GMS project proposal tab.
- Call-specific templates are subject to change, so please use the most recent version before uploading your final proposal. **Please register your organization, department and personal profile** as soon as possible and advise your fellow applicants and personnel to do the same. Please contact our review and grants administration department via www.kwf.nl/vraag as soon as the call opens, or **at the latest six weeks before the deadline** to approve the registration. Please respect our deadlines, the system CANNOT register a proposal if the organization is not approved by KWF!
- Registration of an organization entails amongst others a commercial register extract provided by the Chamber of Commerce (Kamer van Koophandel uittreksel), so start well in advance.
- Before creating a proposal, select the right type of funding and research phase. If you want to adjust the type of funding or research phase in GMS you have to create a new proposal (and discard the proposal that has been submitted in the wrong phase).
- Please check all eligibility conditions of your funding type (chapter 3 and call specific criteria). Any requests for exemption must be submitted to KWF **the latest six weeks before the deadline**.
- Text boxes in GMS do not support copying from external word processors. Importing formatted text into GMS is not supported. We therefore recommend to edit your text layout with the text editor in GMS. Before submitting, please check and verify the layout by clicking the print form - view button on the tab Project Details. Please note: not all special characters might be rendered correctly in the PDF and some information on the application form is not displayed in the PDF.
- As stated in the Word template, you are required to define certain milestones for the project. “Milestones” as defined by KWF are criteria for success that have been placed at critical points within the timeline of the project.
    - For proposals within the Exploration track, two to three milestones in total will be sufficient.
    - For proposals within the Development 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 instructions. Please note that you are required to submit your milestones through GMS after the proposal has been granted.
- If you enlist a service provider (see FV chapter 4.3 Ondersteunende partijen) or inclusion center (see FV chapter 7.2.3. Hoofcategorie 3: Cat. 3.5 Internal service provider / inclusion center) in a full proposal, it is obligatory to upload an official quotation in PDF format. The quotation needs to contain: company details or institution details of service provider (including logo), customer details of institution, quotation number, KWF project number + title, name of project leader, date of preparation, brief summary of requested work / supplied goods, hourly rate and/or breakdown of costs, total price (VAT may only be included for external service providers), validity period of the quotation) for the estimated costs (including taxes). In case of a pre-proposal it is not yet possible to upload a quotation.

- 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 for the actual regulations.
- KWF recommends you to contact your finance department for a budget check and to discuss if your 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 proposal or you can export your draft proposal from GMS to PDF.
- To generate a PDF file from the proposal, please ensure that the security settings of PDF documents are disabled (e.g. password-protection or any other encryption needs to be turned off).
- We strongly advise you to **validate** your proposal in GMS multiple times during the submission process, and start **at least four weeks before the call deadline**. After clicking the validate button, 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. Please note: after receiving a notification and altering faulty fields, new notifications can pop-up when validating again. Therefore, it is advised to start validating as soon as possible.
- 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.
- All proposals that do not meet the listed criteria on page length, margins, font size etc. are **not** eligible for funding. **Also note that proposals exceeding the maximum page length will be rejected automatically by GMS.**

- A Tipsheet with tips on the most common GMS-notifications you may encounter while validating your proposal can be found here: https://www.kwf.nl/onderzoek/programma-onderzoek-implementatie/downloads

2. Registration and approval



KWF uses GMS for its entire project management process, see www.gms.kwf.nl for more information regarding the registration of your project.

2.1. Registration of a department and/or organization

Your organization and department need to be registered in GMS to participate as a lead institute or participating organization in a proposal (see FinancieringsVoorwaarden Chapter 4.2 Project Partijen). During the registration process, you can either choose from existing organizations and departments (i.e. already registered by KWF) or you can create a new one.

N.B. All organizations need to be checked for eligibility (see 10.1). This needs to be done at least 6 weeks before the deadline.

2.2. Approval of a department or organization

The lead institute and all participating organizations have to be approved by KWF *before* you can submit the 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 review and grants administration department via www.kwf.nl/vraag **at least six weeks before the call deadline** since approval might take up to a week.

2.3. Requirements for a lead institute

Approval of a lead institute indicates that the organization is appropriate for performing the project. Appendix 1 gives an overview of the requirements that need to be met in order for an institute to qualify as a lead institute within the set of criteria maintained by KWF.

2.4. Approval of an organization

To approve an organization and/or a department, the following documents must be provided 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 contact person. The registration form includes a declaration from the director of the organization (whose name is on the register extract) stating that the delegated authority has the authority to sign. This registration form is available via the KWF review and grants administration department.

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

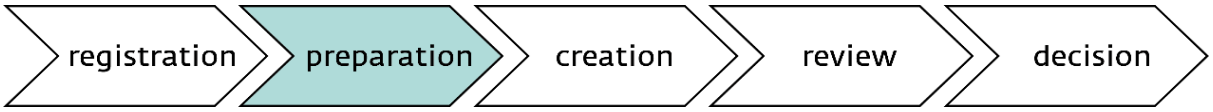
2.5. Registration of a personal profile

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. This can be used to link your account to 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, prevention).

3. Preparing a proposal



KWF offers various funding opportunities. Every year the calls Exploration and Development are opened. There are also various theme calls as well as the PPS (public private partnership) call you can apply for. Information on the various types of funding can be found on the website of KWF.
Please be aware that if you have submitted incorrectly to a wrong call, and switching is allowed by KWF, you may be asked to provide additional information on short notice.

3.1. Open calls

The open calls Exploration and Development are opened every year. The dates and constraints will be announced via Funding Opportunities | KWF

3.2. PPS (Public Private Partnerships)

At KWF, we see a great need for greater collaboration between public and private organizations, 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.

3.3. Theme calls

The scope of Theme calls and the funding types can vary per call, and only proposals within the scope of the specific theme call will be considered. The scope can be found in the call text on the website, see https://www.kwf.nl/onderzoek/financieringsinformatie.

3.4. Human measuring model

Please be aware that in principle all research must be executable in human measurement models, as determined by the Samenwerkende Gezondheidsfondsen (SGF, see https://www.gezondheidsfondsen.nl/themas/humane-meetmodellen/). If this is not the case, it is expected that applicants will try to find other, animal-free, methods to use. Only when there is no animal-free alternative method possible, and the use of animals is shown to be useful and necessary in the specific research, can the application be financed.

3.5. Funding types

After registration in GMS, you can select the type of funding you want to apply for (e.g. open call, theme call, PPS call). If applicable within the call, you can be requested to select a funding type and research phase.
KWF offers various funding types:

- Research projects
- Young Investigator Grants
- Unique High Risk projects
- Consortium projects
- Infrastructure initiatives
- Implementation Funding

For each funding type, the majority of the project work must be conducted in the Netherlands. Therefore, the project leader must be employed by a Dutch organization for the duration of the project. However, if a part of the project requires work abroad, this is permitted by KWF.
Depending on the call, specification collaboration with other organizations is 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 chapters. For the PPS and Theme calls the call specific information can be found on the KWF website.

3.5.1.Research project

The funding type Research project contains scientific projects that answer a hypothesis-driven research question. The duration of a Research project depends on your research question and budget.

Eligibility terms Research project:

- The Research project contains a hypothesis-driven research question and has a defined duration and 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 needs to be employed for a minimum of 0.5 FTE per year for the entire duration of the project.

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.

3.5.2.Young Investigator Grant

The funding type Young Investigator Grant (YIG) is for researchers who are in an early stage of their scientific career. The funding type is designed to give young talented researchers an 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 and 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 for a minimum of 0.5 FTE per year for the entire duration of the project.

- The project leader is eligible to submit a YIG 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, this **needs to be requested at least six weeks before the call deadline.**

3.5.3.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.

3.5.4.Consortium Project

The funding type Consortium project is a specific type of (research) project 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.

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.

3.5.5.Infrastructure initiatives

The funding type Infrastructure Initiatives was a previously existing funding type, aimed at the development of biobanks, databases, repositories, and research platforms to support oncological research. This funding type in itself is no longer available, as the current focus is on ensuring the sustainability of existing infrastructure initiatives. KWF aims to achieve this by enhancing their visibility and findability and to stimulate reuse of biobanks and databases. Nevertheless, KWF still wants to provide opportunities for initiatives that do not yet exist, especially when there is a great need from the field. Therefore, research proposals with infrastructural components may still be submitted and will fall under the research phase 'infrastructure' (See section 3.6.7). For more information, please contact the Science Liaison Infrastructure Initiatives.

3.5.6.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

3.6. Research phases in GMS

After choosing a funding type, you need to select a research phase. KWF identifies seven research phases. When you apply within an 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.

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 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 (modality) can be found in Appendix 3 or on our website. Please, also refer to our website for an up-to-date overview of the funding opportunities by modality.
There are differences in application form between research phases. **Submitting to the wrong call or wrong phase can influence the information you need to submit.**

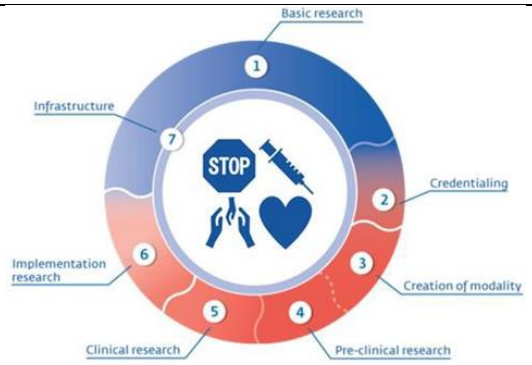
Exploration track Basic research Credentialing ***Development & Implementation track*** Creation of modality Preclinical research Clinical research Implementation research ***Infrastructure***	

Figure 1: Research phases

Please note that in the other calls such as theme calls is also necessary to classify the proposal in one of the phases described in this guideline.

3.6.1.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.

3.6.2.Credentialling 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.

3.6.3.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.

3.6.4.Preclinical 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).

3.6.5.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, combination of modalities or psychosocial treatment.
- changes to treatment regimens associated with existing methodologies (including population checks) in a patient population.

3.6.6.Implementation research 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 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?

3.6.7.Infrastructure phase

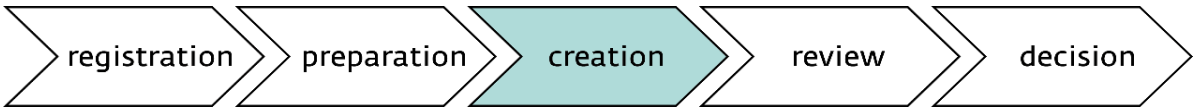
For Infrastructure initiatives, choose the research phase infrastructure. Cancer research infrastructures are fundamental facilities and systems that provide resources and services for the cancer research community. Infrastructures enable researchers to focus solely on conducting research and thereby 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.

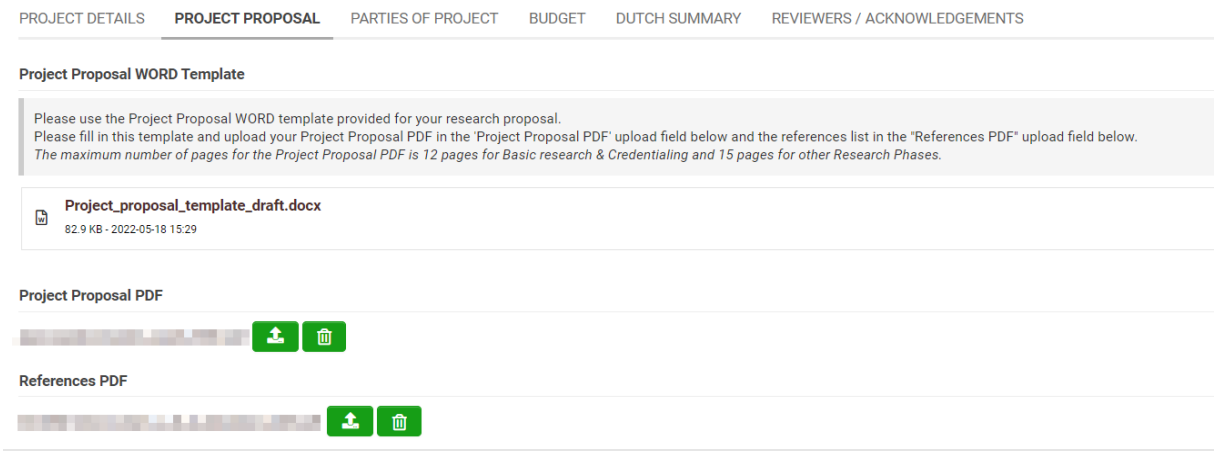
- Platforms: clinical trial platforms, early detection platforms, model organism platforms, and systems biology platforms.
- Data infrastructures: data repositories, computing systems, registries, catalogues, portals, tools that proactively promote, engage and/or are in transition to adopt well-curated and FAIR data, and communication networks.

4. Creating an application



After you have chosen the call, the funding type and research phase of your project in 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 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 excluding references. References can be uploaded in a separate PDF. **Please respect the following formatting constraints: Verdana, at least font size 9, margins (2.5 cm side and 2.5 cm top and bottom), single line spacing.**

After filling in the Word template please convert the 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 “proposal tab” in GMS. Do take care that the headers and footers of the references section are identical to the main document.

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

4.1. General instructions

- Unless indicated otherwise your proposal must be written in English, except for the “Dutch summary” tab.
- Proposals need to be submitted in PDF; the references can be uploaded as a separate PDF document.
- Fields marked with an asterisk (*) in GMS are mandatory. Some fields are conditionally mandatory. If one of these fields is missing, GMS indicates this if you validate your proposal.

- GMS does not support the import of texts that were priorly formatted, so please make sure to use plain text when copying from external word processors. To insert special characters, use the insert button in 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
- Proposal
- References
- Additional project information from the other tabs (a.o. parties of the project and & budget)
- Additional appendices

4.2. Application: Project Details for GMS

4.2.1.Title of the proposal

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

4.2.2.Duration

Choose the duration for the proposal in months. If your proposal lasts longer than 96 months, please contact KWF before submission.

4.2.3.Key words

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

4.2.4.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 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).

4.2.5.Modality classification

KWF 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 the KWF modality coding system.

Please classify your project proposal based on the KWF modality coding system. KWF can choose to change your classification of the project.

See Appendix 4 for more detailed instructions.

4.2.6.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 project will contribute to. If your proposal concerns basic research, you are requested to indicate this.
Describe how the results of this proposal will contribute to the selected main goal(s) in the field Relevance to KWF main goals.

4.2.7.Previous grants/awards

4.2.7.1. Previous rejected proposals

Please indicate whether this proposal is an updated version of a project which was previously rejected by KWF and specify the corresponding project number(s). 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 proposal in accordance with the feedback of the reviewers and review committee. Please indicate which changes you have implemented to improve the proposal and how the feedback of the reviewers and the review committee has been addressed.

4.2.7.2. Related proposals and previously granted funding

Specify the project number(s) of projects funded by KWF or other funders, which are related to the proposal.

4.2.7.3. Comparable grant proposal at other funding organizations

Please specify whether a comparable grant proposal, or any portions of the currently submitted proposal, have been or will be submitted to another funding organization. Additionally, clearly identify in the proposal the overlapping sections, including the budget, to facilitate necessary adjustments should funding be granted.

4.3. Application: General proposal template

In the proposal tab in GMS a call-specific proposal template is available for download. Use this document to describe your 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.

4.3.1.Page limit

A 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. **Please respect the following formatting constraints: Verdana, at least font size 9, margins (2.5 cm side and 2.5 cm top and bottom), single line spacing.** Additional information on the Work Packages, Milestones and GANTT charts

4.3.2.Description of the work packages

In the proposal work packages need to be described that relate to the GANTT chart (if possible). Work packages describe sub-projects for which certain achievements need to be obtained. These can be related to a date within the larger project when the achievements will be delivered (see below). 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.

For most projects deliverables can be measured in sub-projects within the larger project. 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).

4.3.3.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?

4.3.4.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). Please indicate your milestones within each work package. In order to be able to determine when a milestone is successfully met, distinct criteria for success must be formulated. Define a limited number of significant milestones that can be used to measure the progress of the project.
For proposals that fall within the exploration track, two to three milestones in total will suffice; for proposals within the development track, 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 proposal is accepted for funding you are required to add your milestones in GMS.**

4.3.5.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. For an example see figure 2.

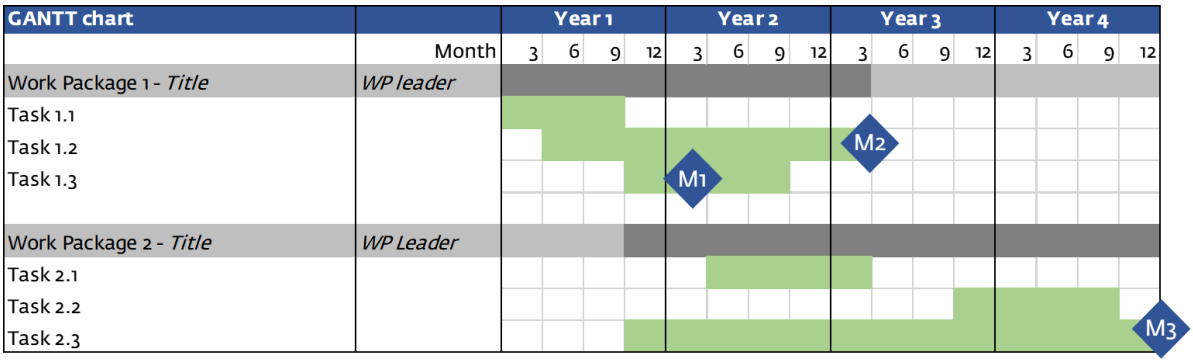


Figure 2: Example of a GANTT chart.

4.3.6.Statistics and data management

If the project includes methodology, please substantiate the methodology/study design. If applicable include power calculation, and include a statistical analysis strategy.

Also 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 of the data management expert.

In accordance with the funding conditions of KWF Kankerbestrijding 2022, 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 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 project 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 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 of 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 preserving 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, see for instance:
https://dmponline.dcc.ac.uk/help#PlanningHelp .

4.3.7.Development plan (not applicable for Exploration projects)

For KWF it is essential that obtained knowledge, skills and/or technology are made available for patients and/or 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 outcomes be used in practice? Are (technical) adjustments necessary to fit the outcomes into current standard (clinical) protocols? Can it be implemented in daily routine/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.

4.3.8.References

Please list your references. This section does not count for the total page length of the proposal and needs to be submitted as a separate PDF document. Just as the KWF proposal, the reference section is required to be in the **Verdana font, 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**.

4.3.9.Data management plan

If a Data Management Plan (DMP) is written according to your institute's policies, please attach the DMP

4.4. 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.

4.4.1.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 their contribution to the work plan in the corresponding work package(s).

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

- The role and responsibilities of the project leader are described in the Financieringsvoorwaarden in Chapter 4.2. This person is the holder of the grant, and the lead of the project. The project leader must be employed by a Dutch organization during the term of the project. Each project has one project leader, who also is 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.
- Support personnel (MBO, HBO or academic) refers to personnel that executes supporting tasks within the 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 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 the project 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 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 (see 4.5.1) to specify the agreement made with the advisor in terms of the advisory role in the project and how this contributes to the proposal/planning.

4.4.2.Register people of the project in GMS

You can add people to your proposal by linking them by PIN number or by adding them manually. By means of filling in Yes for people of the project for whom budget is needed, budget for FTE can be requested. Otherwise fill in 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).

4.4.3.PIN number to link principle investigators

Principal investigators with a personal profile in 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 proposal.
KWF therefore requests the project leader to ask for the other participants PIN number and use this to synchronize their contact details to the 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 person is linked to a proposal as principal investigator, he/she can make changes to the proposal.

4.4.4.Minimum of 0,5 FTE employment for scientific research

As described in the Financieringsvoorwaarden chapter 4.4 Personeel KWF requires a minimum of 0.5 FTE scientific employment per year for scientific research to gain enough momentum on a project to reach the objectives. 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.

➔ For PPS and Theme calls please also check the call requirements in the call text for the call specific conditions regarding employment.

4.4.5.No PIN number for support personnel and advisors

Support personnel, vacancies and advisors have no PIN number. You must fill out their name, organization and department in the table Support Staffing.

4.5. Parties of the project

Please complete the tab Parties of the project. If you have filled out the table Scientific Employment and table Support Staffing in the section Employment, GMS will fill out the lead institute and participating organizations automatically. A participating organization that 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 the Financieringsvoorwaarden chapter 4. Please be aware that each party has only one role in a project. Roles can switch per project/submission. Conditions for a project and each role are described in the FV.
In your proposal the added value of each of the separate organizations must be justified.

The definitions of the parties of the project are described in Chapter 4 of the Financieringsvoorwaarden.
Definitions parties of the project:

- The **lead institute** (Hoofd Organisatie) 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** (Deelnemende organisatie; 4.2.2.) 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 may 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** (see Cat. 3.5. Interne serviceverlenende partij / inclusiecentrum) 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. The quotation must be submitted in PDF format. The specification also needs to contain information on of the planned activities, divided by personnel costs and materials. Even more the quotation needs to contain: company details or institution details of service provider (including logo), customer details of institution, quotation number, KWF project number + title, name of project leader, date of preparation, brief summary of requested work / supplied goods, hourly rate and/or breakdown of costs, total price (NB: VAT may only be included for external service providers), validity period of the quotation.
- An **external service provider** (see 7.2.4. Hoofdcategorie 4: Externe Service verlenende partij / Inclusiecentrum) is an organization not within the lead or participating 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. The quotation must be submitted in PDF format. The specification also needs to contain information on of the planned activities, divided by personnel costs and materials. Even more the quotation needs to contain: company details or institution details of service provider (including logo), customer details of institution, quotation number, KWF project

number + title, name of project leader, date of preparation, brief summary of requested work / supplied goods, hourly rate and/or breakdown of costs, total price (VAT may only be included for external service providers), validity period of the quotation.

- An **internal inclusion center** (Cat. 3.5. Interne serviceverlenende partij / inclusiecentrum) is a department of the lead institute or participating organization that only includes patients in for instance 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 and contains at least the number of patients to be recruited, a date, logo and signature, specification of the planned activities, divided by personnel costs and materials.
- An **external inclusion center** is an organization outside the lead 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 to use its own generated data, information, samples, knowledge and inventions. A quotation for their services is obligatory and contains at least the number of patients to be recruited, a date, logo and signature, specification of the planned activities, divided by personnel costs and materials.
- **Co-funders** contribute by means of a financial and/or material donation for the execution of the project (co-funding) and does not receive 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.

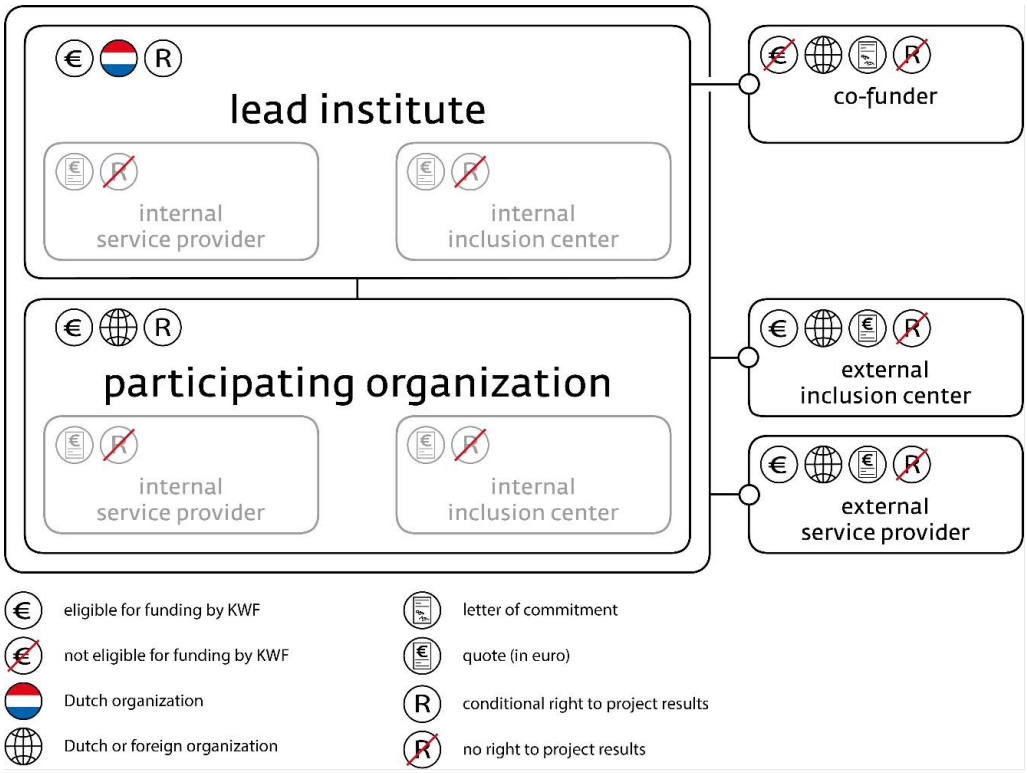


Figure 3: Schematic overview of organizations working on a project.*

* 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.

4.5.1.Letter of commitment

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 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 proposal/planning.
- The letter must give consent to 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.

NB: A letter of commitment regarding patient inclusion is not compulsory for mono-center studies.
NB: The letter of commitment for **patient organizations** needs to be uploaded in the tab Parties of the Project

4.5.2.Collaboration with and/or dependency on other project(s)

Please indicate if this proposal is part of a larger project with additional funding. If it is, describe the larger project in which the current proposal is embedded. Describe the ways in which the project plan and the larger project are dependent on each other in terms of organization (upload an organogram) and funding. Describe the relationships between the execution of the larger project and the execution, results and benefits of this proposal. Also, provide the exact amount of funding that is needed for the rest of the project and its funders in the co-funding section.

4.5.3.Existing Contracts and third party rights

In Figure 4 you can find the existing types of agreements. You need to fill in details on materials, data etc. that you received from a third party to be used in this project in this section. 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.

Figure 4: Types of agreements

4.5.4.Project leader details

The project leader's personal data will automatically be copied from the project leader's profile. This information includes: name, the institute and department the project leader is 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 proposal.

4.5.5. (Scientific) personnel details

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

4.6. Application: Budget

In the document Uitwerking Kostenposten you can find in the most detail what the various budget sub-categories entail. You can find this document on our webpage: Downloads Programma Onderzoek & Implementatie | KWF
In the GMS Budget tab you can request budget, needed for the duration of your project. This request is to be divided in several main categories and subcategories:

- personnel costs;
  - PhD Student
  - Medical Doctor
  - Senior Scientific
  - MBO
  - HBO
  - Academic
- additional personal budget
- materials;
  - Laboratory materials

    - Project specific materials – regular work
    - Other laboratorymaterials
    - Laboratory animals
    - Meetings and travel expenses
    - Internal service provider(s) and internal inclusion center(s)
    - Other
- external services / inclusion centra;
- publication- and accountants costs;
- patient participation.

By filling out the subcategories, GMS will automatically calculate the total amount of the requested budget at KWF, which will be shown in the summary requested budget.
Costs that will be paid from co-funding or by Own contribution (see 4.7.1) can be included in the corresponding items. Please do not include these costs in the subcategories requested at KWF. In 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 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-funding 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 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 proposal or you can export your draft proposal from GMS to PDF.

4.6.1.Personnel costs

See FV 7.2.1 Hoofdcategorie 1: Personeel.
This category includes the salary costs for scientific personnel involved in the actual execution of the project and support staff who contribute to the research project but are not directly involved in scientific tasks. The costs for scientific personnel relate to PhD students, postdocs, physician-researchers, and other scientific staff involved in conducting the research project. The costs for support staff may include, for example, laboratory technicians, data analysts, research assistants, (research) nurses, and other supporting staff.
Please specify the FTE of personnel which is requested for funding by KWF. The corresponding salaries will be calculated automatically. For scientific calls, 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 in the project. These are cumulative rates, including indexation and includes all legally required FTE-related surcharges and premiums, including the personal budget, disability insurance, and the transitional compensation. Any personnel costs exceeding these scales must be paid for by the lead institute or participating organization.
KWF will adjust the salary scales in case a CAO salary adjustment takes place after the opening of the call, but before the funding decision has been made**. Please bear in mind that salaries will not be adjusted during the course of the project**.

If applicable, call-specific instructions on this topic can be found in the call information text.

In case of changes in FTE of personnel during the conduction of the project, KWF needs to be contacted *before* these changes take place.

Degree	Scale
Scientific personnel Phd-student[1]	OiO scale
Senior scientific personnel[1]	11.2
Research support personnel[2]	7.5
Research support personnel[2]	9.3
Research support personnel[2]	11.2
MD project personnel[1]	10.4

[1] Scientific personnel: includes PhD students (Onderzoeker in Opleiding (OiO) scale). For MD's scale 10.4 is applicable.
[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.

It is possible to include an employee with a permanent appointment on the budget of the project. As a minimum requirement KWF needs a statement that the project employee actually performs work on the project.

A supervisor of the scientific staff (often the work package leader) may be put on the budget sheet for a maximum of 0.05 FTE (2 hours per week) (max. NFU salary scale NWP Academic 11.2).

For the Exploration and Development calls funding cannot be requested/awarded for a consultant. Check with the call-specific instructions for the other calls if a theme call or other type of call does allow for personal billed on payroll.

In the Grant offering letter, KWF asks the project manager to sign for the fact that the project officer is actually performing work on the project. No funding can be requested for an advisor.

4.6.2.Scientific personnel -additional personal budget

See FV 7.2.2 Hoofdcategorie 2: Aanvullend Persoonlijk 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.

4.6.3.Materials

See FV 7.2.3 Hoofdcategorie 3: Materiaal. This category includes the costs for various materials specifically needed for the execution of the project. Clearly explain how the amounts are calculated (Price * Quantity (P*Q)). Note: per subcategory 1 line item is available which can contain multiple cost which can be indicated in the description column, example:

Materials

Subcategory	Description	Year 1	Year 2	Year 3	Total
Laboratory materials	2 employments * 3 year * € 10.000 | 1 employment * 2 year * € 12.500	32,500.00	32,500.00	20,000.00	85,000.00
Other laboratory materials	750 samples NGS * € 200 | Large scale protein expression and purification 50k/year | Reagents for organoid cultures € 15.000 / 10 PDOs/year)	115,000.00	115,000.00	115,000.00	345,000.00
		147,500.00	147,500.00	135,000.00	430,000.00

4.6.3.1. Subcategory 3.1 – Laboratory materials and other research-related costs (including consumables, disposables, depreciation and maintenance of equipment, and dissemination costs):

This subcategory includes the costs for laboratory materials used in various experiments, such as reagents for cell and tissue culture, plastics, antibodies, enzymes, cytokines, chemicals, sequencing reagents, peptides, kits, tips, culture plates, transfection reagents, plasmids, and chromatography.
It also includes the costs for the use, depreciation, and maintenance of equipment and ICT (Information and Communication Technology) necessary for the project, such as mass spectrometry, single-cell sequencing, FACS, microscopy, software, licenses, biobank, and clinical data management.
This budget can also be used for intervention or questionnaire development, market research, literature studies, and the development and printing costs of flyers.
This subcategory includes a maximum of €12,500 per year, per FTE laboratory worker. This can be either scientific or supporting personnel. The filled-in number of FTE laboratory workers should be explained in the description;

- with an explanation of how many FTEs are working on the project as laboratory workers, even if the personnel costs of this laboratory worker are paid 'in kind' (from Own Contribution).
- why these employees are deployed in the laboratory and what tasks they will perform on the project.

If no laboratory materials are used in the project, a maximum of €6,250 per year (0.5 FTE at €12,500 per year) may be recorded for other research-related costs. This must be explained in the description. KWF finances a maximum amount for the costs within this subcategory. The actual costs may be recorded as unspecified in the financial accountability.

4.6.3.2. Subcategory 3.2 Other laboratory materials (project-specific large expenditures not fitting in Subcategory 3.2)

This subcategory includes larger expenditures for laboratory materials that exceed the unspecified category because they are very costly and project-specific, such as specific chemicals, sequencing costs, fluorescently labelled ligands, project-related costs for a biopsy, apheresis, or other patient materials.

4.6.3.3. Subcategory 3.3 – Laboratory animals

This subcategory includes costs related to laboratory animals used in experiments, such as the purchase, housing, interventions, and maintenance of mice and other animals. In principle, all research must be conducted using human measurement models, as required by the Samenwerkende Gezondheidsfondsen (SGF), see paragraph 3.3. If this is not feasible, applicants are expected to explore other animal-free methods. Only if no alternative methods are available, and the use of animals is proven necessary for the specific research, this category can be funded.

4.6.3.4. Subcategory 3.4 -Meetings and travel expenses

This subcategory includes travel and accommodation costs (in economy class) for data collection, audits, site visits, meetings with stakeholders, and internships abroad (excluding project team meetings).

4.6.3.4.1.1. International internships

Under category 2 Additional budget an international Internship can be applied for. This internship brings essential knowledge and skills required for the execution of the project to the Netherlands. Funding can be requested for scientific personnel to undertake an international internship 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).

4.6.3.5. Subcategory 3.5 - Internal service provider and internal inclusion center (recharge within the Main Organization or the Participating Organization):

This subcategory includes costs specifically necessary for the project and related to the use of facilities and services provided by internal service providers (such as trial office, animal facility, pharmacy, production facility, research MRI, lab tests, extra blood draws, project-specific declarations of the Central Committee on Animal Testing (CCD), the Medical Ethics Review Committee (METc), and the Central Committee on Medical Research (CCMO)) and internal inclusion centers (patient costs for patients participating in the research project, including insurance for these patients), where internal recharges are applied. Study medication is not reimbursed.
The recharged costs on the project will (in accordance with existing methodologies within the organization, based on economically acceptable standards and without profit) need to be allocated to the project through the usual approval procedures. This allocation should be the same for all projects, regardless of whether a grant has been awarded. KWF agrees to a recharge of overhead costs from the internal service provider/inclusion center if these are part of the standard recharging system. In this category, internal invoices generally do not contain VAT costs, with exceptions possibly for purchase costs or other clearly explained situations.
If it is not yet known how many inclusions will be conducted internally or externally, all costs (patient fees) can be recorded in **CATEGORY 4**.
The Main Organization can determine how to budget the costs for patient inclusions. If a fixed fee (P) per patient is chosen, the application must specify in advance how this fee is calculated, including the necessary expertise and activities (including Price * Quantity (P*Q)). During the audit, insight into the number of inclusions (Q) will be required after the project's duration.

4.6.3.6. Subcategory 3.6 – Other

This subcategory includes other costs that do not fit into the other categories. Specify which costs are included for what purposes. If possible, clearly explain how the amounts are calculated (Price * Quantity (P*Q)). In particular, clinical studies and other projects can account for costs in this subcategory.

For an oversight of what types of materials are fundable please check the call specific funding conditions (https://www.kwf.nl/onderzoek/programma-onderzoek-implementatie/downloads for the Terms and condition and the call specific information https://www.kwf.nl/en/forresearchers/funding). 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.

4.6.4.Services

See FV 7.2.4 Hoofdcategorie 4: Externe Service verlenende partij / Inclusiecentrum

This category includes costs that are specifically necessary for the project and related to the use of facilities and services provided by external service providers and external inclusion centers, such as trial management, scRNA-seq, project-specific declarations from the Central Committee on Animal Testing (CCD), the Medical Ethics Review Committee (METc), and the Central Committee on Medical Research (CCMO), patient costs for participation in the research project, including insurance for these patients, and other regulatory costs, consultancy, animation videos, and external development costs. HTA analyses are also included. VAT costs are charged in this category.

If it is not yet known how many inclusions will be conducted internally or externally, all costs (patient fees) can be recorded in this category. Clearly explain how the amounts are calculated (Price * Quantity (P*Q)). Study medication is not reimbursed.

The Lead Institute can determine how to budget the costs for patient inclusions. If a fixed fee (P) per patient is chosen, the application must specify in advance how this fee is structured, including the necessary expertise and activities (including Price * Quantity (P*Q)). During the audit, insight into the number of inclusions (Q) will be required after the project's duration.

Please be aware that the budget for service providers is limited to a maximum hourly fee. All budgets will be adjusted according to this fee.
This fee, as stated in the “KWF Tarievenbeleid” states the maximum hourly rate excluding VAT and includes all other costs (travel expenses, parking costs, travel hours, etc.) as they should be handled. If you would like to apply a higher hourly rate this should be substantiated with a motivation which should at all times be requested and approved well in advance by KWF. If a project is granted funding, KWF reimburses service provider fees up to the maximum hourly rate. The project budget will be adjusted accordingly.

The budget for fees paid to service providers and inclusion centers should be listed using a separate row in the budget tab. For each row, please specify whether it pertains to a service provider or an inclusion center and indicate the requested amount. The amount must be substantiated with quotations. Quotations must comply with legal requirements and need to contain: company details or institution details of service provider (including logo), customer details of institution, quotation number, KWF project number + title, name of project leader, date of preparation, brief summary of requested work / supplied goods, hourly rate and/or breakdown of costs, total price (VAT may only be included for external service providers), validity period of the quotation for the estimated costs. The quotation must be submitted in PDF*. 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.
*Screenshots from websites (for example to provide METC costs) and self-made excel sheets are not official and are not approved as a quotation by KWF

Example

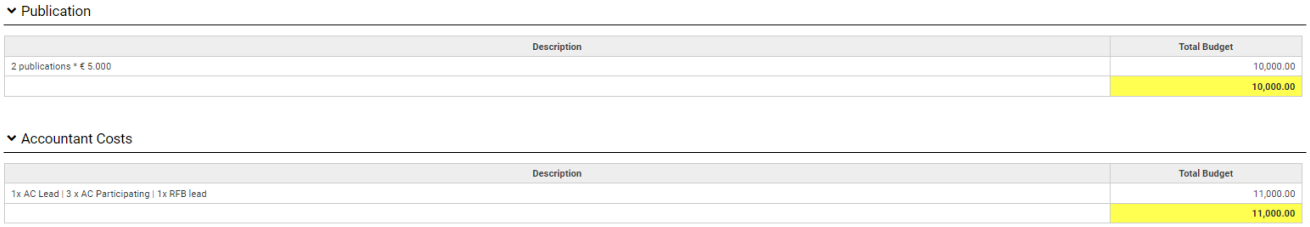
Services

Description	Year 1	Year 2	Year 3	Total
Services ABC (see Quote ABC.pdf)	10,000.00	11,000.00	12,000.00	33,000.00
Services DEF (see Quote DEF.pdf)	25,500.00	31,500.00	10,500.00	67,500.00
	35,500.00	42,500.00	22,500.00	100,500.00

4.6.5.Publication and accountant costs

The fifth category includes the costs for publication (such as open access, archiving in an online repository, etc., up to a maximum amount of €10,000) and auditing costs for an audit of the realized project expenditures (up to a maximum amount of €2,500 per audit statement requested by KWF, i.e., per Lead Organization and/or Participating Organization with costs above €125,000). If the Lead Organization must submit a Report of Factual Findings for accountability, it can include up to a maximum of €1,000 extra in the project budget. KWF finances a maximum amount for the costs that fall within this main category. The actual costs may be included as a lump sum in the financial reporting for research projects.

Example:



Publication

Description	Total Budget
2 publications * € 5.000	10,000.00
	10,000.00

Accountant Costs

Description	Total Budget
1x AC Lead | 3 x AC Participating | 1x RFB lead	11,000.00
	11,000.00

4.6.6.Patient participation

See FV 7.2.5. Hoofdcategorie 6: Patiëntenparticipatie

The costs for patients (representatives) who contribute to the project, through patient associations or other participation initiatives, as well as related costs for questionnaires, printing, etc. Clearly explain for each component which activities you are organizing, how often they will occur, how many patient representatives are involved, and what their roles are (for instance written input, dissemination of the project, etc.). Clearly explain how the amounts are calculated (Price * Quantity (P*Q)). More information of what is allowed, can be found in the “link uitwerking kostenposten per (sub)categorie”.

Patient participation prior to the project:

KWF reimburses a maximum amount of € 500 (per patient association/participation initiative) for patient involvement during the preparation of the funding application.

Patient participation during the project duration:

KWF reimburses travel costs within the Netherlands for patient participation (second-class public transport or a statutory mileage allowance).

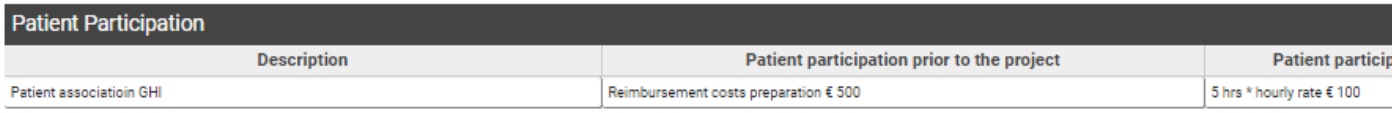
For simple contributions from patients, KWF reimburses gift vouchers/flowers up to a maximum of € 50 or a maximum hourly rate (see “KWF Rates Policy”). By simple contributions (experiential knowledge), KWF means sharing personal experiences through, for example, focus groups or by giving a presentation of their own story.

For substantial patient participation, KWF reimburses a maximum hourly rate (see “KWF Rates Policy”). By substantial patient participation, KWF means the representation of the collective patient perspective by a substantive partner.

Including a budget for providing input on follow-up steps is permitted, provided the input is given during the project's duration. KWF reimburses a maximum hourly rate for substantial contributions (see “KWF Rates Policy”).

Patient participation in dissemination of results:
Reimbursement for organizing symposia/conferences is only granted if there is patient participation and dissemination. If the symposium/conference covers topics beyond patient participation related to your project, only the part involving patient participation will be reimbursed. This explicitly excludes networking event. Patient participation and dissemination must be integral to the project's objectives and must be well substantiated. KWF reimburses up to a maximum amount of € 10,000 per project for this. This reimbursement covers the actual costs incurred. Costs incurred up to 6 months after the project's duration and before the audit is finalized are eligible for funding.

Example:



Patient Participation		
Description	Patient participation prior to the project	Patient particip
Patient associatioin GHI	Reimbursement costs preparation € 500	5 hrs * hourly rate € 100

4.7. 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 international internship , this budget is allocated in the first year of the term of the project. You can however spend these funds throughout the duration of the project.

4.7.1.Own contribution

See FV 7.3 Eigen Bijdrage & Cofinanciering. 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 lead institute and/or 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.

Be aware that **all** personal contributions must be accounted for by means of a signed board statement at the financial closure of a project. This requirement also applies to small contributions, such as 0.05 FTE.

4.7.2.Co-funders

See FV 7.3 Eigen Bijdrage & Cofinanciering. 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 institute(s) that is/are undertaking the project. 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 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 proposal (see https://www.kwf.nl/doneren/steun-met-een-grote-gift).

4.7.3.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, and if applicable add P (price)*Q (quantity);
- Describe the costs that will be covered by own contribution and co-funding;
- In case of no own contribution or co-funding, please justify.

4.7.4.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 personnel who performs educational tasks, patient care and administrative or not-project related managerial tasks (i.e. institute management, division management, etc.);
- 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 participants or project staff;
- Expenses for digital data carriers such as computers and iPads for general administrative purposes;
- Generic software;
- Study medication;
- Costs for purchase and depreciation for general laboratory equipment;
- Costs of setting up laboratories;
- Costs for housing and office supplies.

4.8. Application: Dutch summary

The Dutch summary is used for various purposes in and after the call. Thus, please ensure that you allocate sufficient time to drafting this section.

If a project is granted, the Dutch summary will be included in our public database (Onderzoeksdatabase | KWF Kankerbestrijding). In addition, the Dutch summary can be used for communication purposes to laymen. Therefore, the entire tab has to be filled out in Dutch. This information is read by our (potential) donors and by patients. Therefore please avoid the use of jargon, abbreviations and explain any technical terms. For more information on how to write a Dutch summary, please click: https://www.gezondheidsfondsen.nl/wordpress/wp-content/uploads/2019/10/SGF-A4-Handr_organisaties_2019.pdf

Even more, the tab Dutch summary will also be used by the patients advisory committee (PACO) for the assessment of the proposal. For the PACO this is the *only* information they will review, therefore be as concise and clear as possible.
The PACO reads the Dutch summary in order to review the relevance and feasibility of the proposal from a patient perspective and to assess patient involvement. PACO members review each project that is in one of the following phases: creation of modality, pre-clinal, clinical, implementation, and infrastructure. The PACO plays an active role in formulating the funding advice. For a correct assessment by the PACO, it is important that the Dutch summary is written in clear lay language.
Please bear in mind that if the summary is written poorly, this will result in a negative rating.

➔ KWF's funding partner Alpe d'HuZes also uses the Dutch summary as a basis for selecting the projects they wish to grant. A poor summary consequently diminishes your chance of selection by Alpe d'HuZes and as such could negatively influence your chance of funding.

The different parts of the Dutch summary are explained below.

Projects that are in the phases basic research or credentialing are not reviewed by the PACO and use a different format for the Dutch summary: only part 1 and 2 from the overview below are required for these projects.

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

2. Samenvatting projectplan (summary of project plan)
   Summarize your proposal in layman's terms and avoid using specialized medical or scientific terminology.

Please use the following subheadings:

A. Achtergrond en probleemstelling (Background and problem)
   - What is the background and the problem being the starting point of your 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?

B. (Onderzoeks)richting/voorgestelde oplossing (envisaged solution for the problem/the (research) direction)
   - What is your projects direction/ envisaged solution for the problem?

C. Relevantie (relevance)
   - In what way does your 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?

D. (Onderzoeks)vragen (research) question(s))
   - What are your (research) question(s)?

E. (Onderzoeks)opzet ((Study) design)
   - Describe the different stages of your study. A clear and comprehensible diagram ilustrating 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?

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

G. Omschrijving stappen nodig om resultaat te implementeren (follow up and implementation)
   - What steps are required to implement the findings of the project 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?

3. Toelichting deelnemers (patient/participant inclusion)
   If your 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 sample: the number of study participants, inclusion and exclusion criteria, chance of dropouts, feasibility of the envisaged sample and recruitment strategy.

4. 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 explain the reason.

   Answer the following questions, and include documents to support your answers:
- How and when are patients/patient organizations involved?
- What kind of input is provided? How will this input be used?
- Describe the role of patients and/or patient organizations before, during and after the project.
- Will they be involved in translating results into concrete actions?
- When and how will patient involvement take concrete shape?
- How will results of the project 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?

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 patients/patient organizations, you could contact the Dutch Federation for Cancer Patient Organizations (In Dutch Nederlandse Federatie van Kankerpatiëntenorganisaties, NFK). Their website www.nfk.nl provides direct links to the websites of the different cancer patient organizations.

For more information, visit the website https://www.kwf.nl/onderzoek/kwf-programma-onderzoek-implementatie/patientenparticipatie .

5. Reviewers

In the suggested reviewers section, please list at least 2 independent national experts and at least 5 international experts who are capable of reviewing your proposal.

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

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

Please do not enlist KWF employees or 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

5.1. National reviewers

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

5.2. International reviewers

Please 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.

5.3. 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 proposal.

5.4. Competing companies excluded from reviewing

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

6. Acknowledgement

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

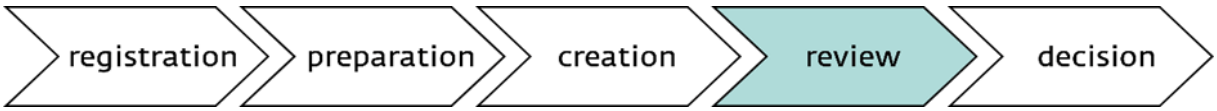
- General acknowledgements:
  - By signing, the project leader declares that the information supplied in the proposal and profile is truthful, and that he/she will immediately report to KWF in case of any changes that may be relevant to the development, assessment or acceptance of the proposal.
  - By signing, the project leader declares that he/she has informed all principal investigators and participating parties of the project on the content of the proposal before submitting the 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.

7. 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?

8. 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 proposals will be based on KWF's review criteria and executed by different assessors. All assessors are obliged to handle the proposal information faithfully, for example by respecting confidentiality and taking into account possible conflicts of interest.

8.1. Review criteria

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

- Relevance: the way in which, and the extent to which, the 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.
- Quality: the extent to which a 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.

➔ For other calls than Exploration and Development additional review criteria may be specified in the call text.

8.1.1. 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?

8.1.2. Review criteria for credentialling 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?

8.1.3.Review criteria for creation of modality 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?

8.1.4.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 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?

8.1.5.Review criteria for implementation research phase

Relevance:

- How and to what extent does the intended Implementation projects 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 project , 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?
- 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 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?

8.2. Review Process

8.2.1.Review process of the Open calls Exploration and Development

The review process of the open (Development and Exploration calls) 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 (both national and/or international)
- Board review
  - Review by individual board members
  - Interview with the project leader (not applicable for all funding types)
  - Board review meeting
- Prioritization meeting

The stages and substages will be explained in section 8.2.3.1 onwards.

8.2.2.Review procedure of the pre-proposal projects within theme calls

- Internal Review
  - Eligibility check
  - Scientific eligibility check (only applicable for scientific calls)
- Board review
  - Review by individual board members
  - Board review meeting

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

8.2.3.Review procedure of the full-proposal projects within theme-calls

- Internal Review
  - (Scientific) eligibility check
- External review (if applicable)
  - Patients' Advisory Committee (PACO)
  - Peer reviewers (national and/or international)
- Board review
  - Review by individual board members
  - If applicable interview with the project leader and project manager
  - Board review meeting
- Prioritization meeting

The stages and substages will be explained below.

8.2.3.1. Internal review

- Eligibility check

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

- Scientific eligibility check (only applicable for scientific calls)

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

- The proposal is scientifically eligible;
- it concurs with KWF's main goals;
- it contributes to existing knowledge about the causes, development and effects of cancer and cancer treatment;
- the proposal meets the minimum criteria. 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. Comparisons with competing projects can be made to determine which projects are the least likely to be fundable.

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

8.2.3.2. External review (if applicable)

8.2.3.2.1. Review by external peer reviewers

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

8.2.3.2.2. Review by the Patients' Advisory Commission (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. Therefore the PACO plays a role in the review process for all proposals in the following research phases: creation of modality, pre-clinal, clinical, implementation, or infrastructure. The PACO consists of members that are current or former cancer patients with a variety of indications and stages of the disease. PACO members use the Dutch summary to review the proposal from the patient perspective.

The advice issued by the PACO will be weighed in the review of the (full) proposal. 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 proposals when necessary. Depending on the call type if the review process involves an interview, a PACO member can also be present at the interview.

8.2.3.2.3. Review criteria for the PACO

- Relevance:
  - Does the objective of the 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 project acceptable, considering the envisaged results?
  - Has sufficient consideration been given to ethical aspects, the implementation of the results, and the realization of any necessary follow-up action?
  - Will (enough) patients be willing to participate in this project?

- Patient involvement:
  - To which extent are patients involved in the design of the proposal, the execution of the project and the dissemination of results?
  - How have/will their efforts been/be incorporated in the project?

- Quality:
  - Is the summary clearly written in layman's language and does it contain sufficient information to complete the PACO review?

8.2.3.3. Review by other experts/specialist

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

8.3. Board review

8.3.1.Review by individual committee members

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

8.3.2.Interview (if applicable)

In the open calls (Exploration and Development), specific theme calls and the PPS call assigned members of the review committee will review YIG, Consortium or call specific proposal types, and make a selection of proposals for which an interview needs to be scheduled. 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.

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.

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 (if applicable) 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 subsequent board review meeting.

8.4. Board review meeting

After finishing the above-described process, all proposals will be subjected to a final review during the board review meeting.
The aim of this meeting is to form a final recommendation and rating of the proposals, reflecting the opinion of the entire internal review subcommittee.
This final recommendation will be based on the external reviewers' reports (if applicable), the facts and reflections provided by KWF, the committee members' reviews, the advice from external experts and the PACO (if applicable), as well as the interview and the discussions during the board review meeting. **Funding depends on the available budget**.

Proposals will be rated on a scale from 1 (lowest) to 5 (highest). A score lower than 3 indicates that the proposal is not fundable in its current state. The score >= 3, however, will not automatically mean that the proposal is funded. **Funding depends on the budget that is available and the choices of KWF and its funding partners**.

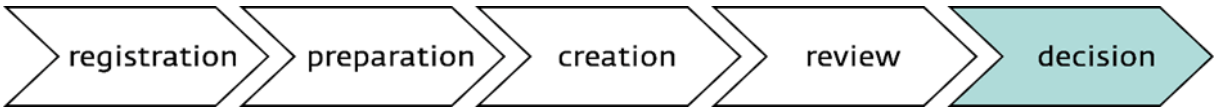
- 5: Excellent proposal, eligible for funding;
- 4: Good proposal, eligible for funding;
- 3: Sufficient proposal, eligible for funding;
- 2: Below average proposal, not eligible for funding;
- 1: Insufficient proposal, not eligible for funding.

8.5. Prioritization meeting

The aim of the prioritization meeting is to formulate a final funding recommendation to the board of KWF. The guiding principle for the recommendation will be the score the project obtained in combination with the impact the project is expected to have.
During this meeting funding partners of KWF choose proposals eligible for funding to fund on behalf of the funding partner as well.

Participants of the prioritization meeting are the chair(s) and vice-chair(s) of the respective review subcommittee, PACO members (if applicable), and if applicable the delegated persons of the funding partners. On behalf of KWF the secretary of the review committee and the manager/initiator of the funding initiative 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 the different perspectives. Furthermore, KWF input will also be taken into consideration.
The final recommendation of the proposals will be based on the comparison of all proposals that are eligible for funding.

9. Decision



After the prioritization meeting the board of directors of KWF and possible other funding partners make the final decision which projects are going to be funded.
This decision, including the substantiated final recommendation and the comments of the external reviewers and the PACO (if applicable), will be communicated to the project leader by means of a decision letter.

9.1. Funding granted

If funding for the 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 (if applicable), 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 (scientific) projects will be assigned to a specific KWF (science) liaison who has knowledge of the relevant research field. The (science) liaison will be the primary contact for the project leader and will contact the project leader 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.

9.1.1. Funding partners (Alpe d'HuZes)

A 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 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. It is not possible to indicate that you do not want to be funded by a funding partner.

Our current funding partner and their themes:

Alpe d'HuZes

- Theme "Ambitie: het stimuleren van jong talent (Bas Mulder Award)" will be matched with YIG's.
- Theme "Unieke kansen: 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. Also follow-up projects of Bas Mulder Laureats can be matched to this theme.

N.B.: Contact details from GMS will be provided to the Funding Partners' representative enabling the Funding Partners to contact the Funding Partners laureates once the funding decision has been announced.

9.1.2.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.

9.2. Funding rejected

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

In the rejection letter it is stated how the project leader can object against the rejection. The objection will be processed in accordance with the regulations for objections (see "Reglement Bezwaar & Beroep tegen Besluiten" via: Downloads Programma Onderzoek & Implementatie | KWF)

NB: If a resubmission is considered, please note that the guidelines for submission might have changed between the two financial initiatives, check the actual guidelines carefully.

9.3. Appeal Procedure

The project leader and the lead institute can object to KWF's decision. This must be done in concordance with the official decision letter and within the period stated in the GMS notification e-mail. Please use GMS or www.kwf.nl/vraag to submit your appeal.
After having received the appeal, KWF shall act in accordance to the Regulations for appeal.

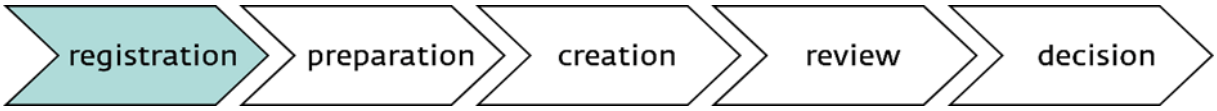
- If the objection is based on valid grounds, the decision and eventual granting of your project will be reconsidered. **Please note that even with a granted appeal, the decision whether or not to finance or to revise a decision always remains up to KWF. Even if your Objection or Appeal is found to be grounded.**
- If the objection is not grounded, the decision will not be changed.

The decision made by KWF is binding, and no further appeal is possible. When an objection is rejected on procedural grounds, it is possible to appeal against this decision.

The regulations for appeal, (in Dutch: Reglement Bezwaar & Beroep tegen Besluiten (project)financiering) are published on the KWF website, https://www.kwf.nl/onderzoek/programma-onderzoek-implementatie/downloads

10. Appendices

10.1. Appendix 1 Criteria for lead institute



The table below shows which types of organizations are eligible as lead institute in a scientific proposal. For theme calls and non-scientific calls special conditions may be applicable which will be stated in the call text and specifications.

Eligible as lead institute	Organization

Yes	• University
	• Medical center
	• Call specific invited centers
	• 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 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.

For scientific projects 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.

10.2. 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 XXX call, 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]

10.3. 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

10.4. Appendix 4 Information on KWF project classification, ICRP and modality coding

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

Research phase	**Modality**						
Basic research	Basic research						
Credentialing	Biomarkers	Imaging	Agents	Immune response modifiers	Interventive devices	Lifestyle	Quality of life/care
Creation of modality							
Preclinical development							
Clinical research							
Implementation research							
Infrastructure	Infrastructure						

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

10.4.1. Modality coding instructions

When deciding on the applicable coding for the modality please decide what the main aim or 'center of gravity' is of the proposal, and assign the modality that best matches the project. Coding should not include potential or future applications of the research findings.

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

10.5. Appendix 5 Version Management

Version	Date	Most important adjustments
2.7	September 2024	• Introduction of new funding conditions (FV 2025)
2.6	May 2024	• Updates
2.5	August 2023	• Adjustment to GMS • Adjustment to non-scientific projects
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