January 2016

KWF Programme Research & Implementation Instructions & Guidelines Project Proposal

Form for a project proposal for:

- Research Project
- Young Investigator Grant
- Unique High Risk Project

During the first call for proposals (January 8 - April 4, 2016) it will not be possible to submit a project proposal for infrastructure, consortia and implementation; KWF is still working on these types of funding.

During the first call for proposals (January 8 - April 4, 2016) companies can only be involved as a co-funder, not as one of the participants in the project team. If companies are involved as co-funder, specific arrangements will be agreed upon after granting funding of the project proposal.

KWF Kankerbestrijding can not be held accountable for the content of this document. This document serves solely as instruction and guideline to support you with drafting your project proposal. Only after you received (in duplicate) a message of KWF Kankerbestrijding that you have been granted funding for your project proposal (Toekenningsbesluit) and one copy signed by you as agreement has been received by KWF Kankerbestrijding, the following conditions apply to the Project leader, the Institute and the execution of the Project: the Funding Conditions KWF Kankerbestrijding 2016 (Financieringsvoorwaarden KWF Kankerbestrijding 2016) including the Financial Regulations KWF Kankerbestrijding 2016 (Financieel Reglement KWF Kankerbestrijding 2016) and the Audit protocol KWF Kankerbestrijding 2016 (Controleprotocol KWF Kankerbestrijding 2016) and possible additional conditions included in the Toekenningsbesluit.

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TAB 1 Project details

Project title

Please provide a clear title, preferably short and covering the content of the proposal.

Contact details Project Leader

Contact details of the Project Leader are automatically inserted from your profile. Please make sure your profile is up to date. These contact details include: Name Project Leader, Institute and Department. Address, Postal code, City, Phone number (secretary/general number), E-mail address Project Leader, Direct phone number Project Leader, Curriculum Vitae Project Leader, including Experience, Training/Education, Professional experience, relevant honours and awards, top 4 publications and ORCID ID.

Project Duration

Please provide the duration of the work plan of the project proposal in months. Follow up of clinical trials should not be included in the project duration.

Key words

Provide five key words representing the content of your proposal, such as tumour type, methodology, field of work. If your research is specifically focused on pediatric or geriatric oncology, please enter this as a key word. KWF supports the inclusion of elderly with cancer in clinical trials, especially in clinical trials concerning tumor types or quality of life aspects in which the elderly are over-represented.

Scientific Abstract (max 400 words)

Please summarise your proposal, preferably on the basis of the following subjects: Description of the problem, the envisioned solution/research direction, aim/hypothesis, plan of investigation and expected outcome. A problem can range from a specific lack of knowledge that prevents progression in a certain research field, to a specific problem that (a subset of) cancer patients or people at risk of developing cancer are facing.

If your proposal concerns basic research, the problem can be interpreted as a specific lack of knowledge in a research area (e.g. unsolved questions about the onset and progression of cancer), and the results of this proposal and research direction could contribute to the current scientific state of the art. The proposed solution would be specific research designed to obtain answers that will promote progress in the research field defined in the problem.

If your proposal works towards a solution for a defined (medical) "problem" or "need" (translational or clinical research), please describe the problem as well as the solution you are developing as clearly as possible. These problems can, for example, be medical, psychosocial or technological. The solution for example could be novel screening methodologies, diagnostics, therapies, and interventions that help prevent cancer, cure cancer or improve quality of life.

Should the project be eligible for funding, both the English and the Dutch summary will be published in the international research database of the International Cancer Research Partnership (www.icrpartnership.org), as well as on the KWF website. You are advised to make sure this text does not contain any confidential details that might infringe the intellectual property rights of your research. You should also refrain from including any

other sensitive information that should not be published. KWF will use these summaries for communication purposes (e.g., to inform the public/donors about KWF funded research).

Please note that any references included in the "Scientific Abstract" should also be listed under "References" in the proposal form.

Relevance to KWF's mission

This section is used by the KWF internal review committee, the external scientific reviewers and specific experts to determine the relevance of your project proposal in relation to the goals set out in KWF's mission statement. You can further substantiate the relevance of your proposal under the headings Problem, Solution/Research Direction and Aims in the "Project Proposal" section.

KWF has three mission goals: we want fewer people to get cancer, more people to cure from cancer, and patients to have a better quality of life during and after the disease. Please indicate which mission goal(s) your research will contribute to. You can select multiple options. If your proposal concerns basic research, it might be hard to specify the mission goal(s) your research will contribute to. In that case, please indicate "Basic Research". Please specify in addition how the results of this project will contribute to the overall KWF mission and the selected mission goals (less cancer, more cure, a better quality of life).

KWF project classification system (ICRP and modality coding)

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

To provide a more detailed picture of its portfolio of (early) translational and (early) clinical research, KWF also employs a system of classification specifically designed for this type of research. This "modality coding", used in addition to the ICRP classification, is based on the information presented in the report "Transforming Translation", by the Translational Research Working Group (TRWG) of the National Cancer Institute, and the report "Investment in early translational cancer research 2005-2007", by the Canadian Cancer Research Alliance (CCRA). The following modalities are used:

I. Biomarkers
II. Imaging (scanning techniques)
III. Agents (medicines)
IV. Immune response modifiers (therapeutics affecting the immune system)
V. Interventive devices (techniques of intervention)
VI. Lifestyle and exposure
VII. Quality of Life/Quality of Care

Under the ICR Partnership rules and the modality coding norms, KWF can use different codes for the eventual classification of the project as compared to the codes specified by the Project Leader.

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ICRP details

As coding instructions for the CSO code(s) we ask you to decide what the main aim or 'centre of gravity' is of the project proposal. Please apply the CSO codes that reflect the overall nature of the project and that are achievable within the lifetime of the project (no more than 2 CSO codes are allowed per project proposal). Coding should not include potential or future applications of the research findings. Please visit https://www.icrpartnership.org/CSO.cfm for more detailed information.

Common Scientific Outline	
1. Biology - Research included in this category looks at the biology of how cancer starts and progresses as well as normal biology relevant to these processes.	
1.1	Normal Functioning
1.2	Cancer Initiation: Alterations in Chromosomes
1.3	Cancer Initiation: Oncogenes and Tumor Suppressor Genes
1.4	Cancer Progression and Metastasis
1.5	Resources and Infrastructure related to biology
2. Etiology - Research included in this category aims to identify the causes or origins of cancer - genetic, environmental, and lifestyle, and the interactions between these factors.	
2.1	Exogenous Factors in the Origin and Cause of Cancer
2.2	Endogenous Factors in the Origin and Cause of Cancer
2.3	Interactions of Genes and/or Genetic Polymorphisms with Exogenous and/or Endogenous Factors
2.4	Resources and Infrastructure Related to Etiology
3. Prevention - Research included in this category looks at identifying individual and population-based primary prevention interventions, which reduce cancer risk by reducing exposure to cancer risks and increasing protective factors.	
3.1	Interventions to Prevent Cancer: Personal Behaviors (Non-Dietary) that Affect Cancer Risk
3.2	Dietary Interventions to Reduce Cancer Risk and Nutritional Science in Cancer Prevention
3.3	Chemoprevention and other medical interventions
3.4	Vaccines
3.5	Complementary and Alternative Prevention Approaches
3.6	Resources and Infrastructure Related to Prevention
4. Early Detection, Diagnosis, and Prognosis - Research included in this category focuses on identifying and testing cancer markers, imaging and other methods that are helpful in detecting and/or diagnosing cancer as well as predicting the outcome or chance of recurrence or to support treatment decision making in stratified/personalised medicine.	
4.1	Technology Development and/or Marker Discovery
4.2	Technology and/or Marker Evaluation with Respect to Fundamental Parameters of Method
4.3	Technology and/or Marker Testing in a Clinical Setting
4.4	Resources and Infrastructure Related to Detection, Diagnosis or Prognosis
5. Treatment - Research included in this category focuses on identifying and testing treatments administered locally (such as radiotherapy and surgery) and systemically (treatments like chemotherapy which are administered throughout the body) as well as non-traditional (complementary/alternative) treatments (such as supplements, herbs). Research into the prevention of recurrence and treatment of metastases are also included here.	
5.1	Localized Therapies - Discovery and Development
5.2	Localized Therapies - Clinical Applications
5.3	Systemic Therapies - Discovery and Development
5.4	Systemic Therapies - Clinical Applications
5.5	Combinations of Localized and Systemic Therapies
5.6	Complementary and Alternative Treatment Approaches
5.7	Resources and Infrastructure Related to Treatment and the Prevention of Recurrence

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

6.1	Patient Care and Survivorship Issues
6.2	Surveillance
6.3	Population-based Behavioral Factors
6.4	Health Services, Economic and Health Policy Analyses
6.5	Education and Communication Research
6.6	End-of-Life Care
6.7	Research on Ethics and Confidentiality
6.9	Resources and Infrastructure Related to Cancer Control, Survivorship, and Outcomes Research

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

Disease Site Codes		
Name	Code	Notes
Adrenocortical Cancer	0	
Anal Cancer	103	
Bladder Cancer	3	
Blood Cancer	67	Use this code for Blood Cancers other than: Hodgkin's Disease (24), Leukemia / Leukaemia (27), Myeloma (30), Non-Hodgkin's Lymphoma (35).
Bone Cancer	4	Includes Osteosarcoma, Malignant Fibrous Histiocytoma, Ewing's sarcoma and all other bone/cartilaginous tumors.
Brain Tumor	6	Includes Chordoma
Breast Cancer	7	
Cardiotoxicity / Heart Cancer	8	
Cervical Cancer	9	
Colon and Rectal Cancer	64	
Ear Cancer	10	
Endometrial Cancer	11	
Esophageal / Oesophageal Cancer	12	
Eye Cancer	13	Not including Retinoblastoma (45)
Gallbladder Cancer	14	
Gastrointestinal Tract	15	Use this code for GI cancers other than: Colon and Rectal (64), Esophageal / Oesophageal (12), Gallbladder (14), Liver (23), Pancreatic (37), Small Intestine (50), Stomach (51).
Genital System, Female	17	Use this code for genital system, female cancers other than: Cervical (9), Endometrial (11), Ovarian (66), Vaginal (57), Vulva (101).
Genital System, Male	19	Use this code for genital system, male cancers other than: Penile (39), Prostate (42), Testicular (52) cancers.
Head and Neck Cancer	21	Use this code for head and neck cancers other than: Laryngeal (26), Nasal Cavity and Paranasal Sinus (31), Oral Cavity and Lip (36), Parathyroid (38), Pharyngeal (61), Salivary Gland (63), and Thyroid (54) cancers.
Heart Cancer / Cardiotoxicity	8	

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

Modality details

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

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 • Cryoablation • Hyperthermia • Photodynamic therapy (PDT) • Surgery • Other • Supporting tool (e.g. reproducible assays, imaging methods for image guided therapy)
Lifestyle and exposure	• Prevention • Therapy (lifestyle interventions to improve cancer treatment, or as part of the 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, behavioural and/or imaging assays to measure effect of lifestyle alteration)
Quality of life/care	• Side effects of treatment • Quality of life of patients and survivors • (Quality of) care	• Direct/short term side effects • Long term side effects • Quality of life • Social/occupational participation • Psychological care/intervention • Somatic intervention • Needs/care use • Care service/improvement • Self management • Cost effectiveness • Other • Supporting tool (e.g. measurement instruments for quality of life, registries of quality of care)

Related proposals and granted funding

Please indicate whether this proposal is an updated version of a project proposal that was previously rejected by KWF. If this project proposal is an updated version of a previously rejected proposal, please indicate the project code(s) of the previous proposal(s).

In case of resubmission after a B or C advice, KWF always assumes the project proposal has been modified based on the reviewer reports. In the case of resubmission after a D advice, KWF assumes the project proposal has been rewritten and the assessment committee's feedback has been addressed in the new proposal. Please indicate what changes were implemented to improve the proposal and how the comments by the reviewers and the assessment committee have been addressed.

Specify the KWF-funded projects and their project code(s) that are part of the same research line/same development track. Related proposals are proposals addressing the same development track or proposals which were explorative to the development track. The development track is defined as the total set of steps a finding should go through in order to be applied in practice, thus becoming available to patients, care-givers and other end-users.

TAB 2. Dutch summary: Patient Advisory Committee (PACO)

This section is dedicated to the assessment of relevance and feasibility for the patient/public by the Patient Advisory Committee (PACO). Collaboration with cancer patients and their loved ones is central to KWF's new approach, as formulated in the new policy vision statement. They are the primary parties benefiting from KWF's activities and they have first-hand experience of undergoing cancer treatments and living with cancer. These experiences form valuable and essential input when fighting cancer and establishing the relevance of KWF's activities. KWF believes that expressly involving patients in the process contributes to the realisation of our mission.

Through the KWF Patient Advisory Committee (PACO), project proposals are evaluated from the patients' perspective (except for basic research and early translational research (credentialing)). PACO members are (former) cancer patients with a wide spread of indications and stages of the disease and higher education qualifications or experience. The patients who join the PACO get specialised training in the assessment of the relevance of project proposals, as well as the patient-related aspects of those proposals (i.e., patient involvement in set-up and performance of the research, patient factsheets, inclusion and exclusion criteria, burden for participating patients). PACO members will not assess the scientific quality or technical feasibility of project proposals. Although PACO members are trained, not all members have a background in a specific area of medical expertise or knowledge about research methodologies. It is therefore of the utmost importance to write in Dutch and avoid using specific medical or scientific terminology in the Dutch summary. PACO will assess the proposal and formulate advice from the patients' perspective. This advice will be included in the assessment of the proposal, alongside the peer review reports. Members of PACO will join the assessment committee meeting to ensure that PACO's arguments are interpreted correctly, and will substantiate arguments and discuss the project proposals where necessary. If an interview is part of the review phase of a project proposal, a PACO member will also be present.

Project title in Dutch

Geef een korte, bondige en heldere titel die de inhoud van het project omschrijft.

Samenvatting projectplan (max 800 woorden)

Het is niet de bedoeling om uw wetenschappelijke Engelse samenvatting te vertalen. Beschrijf uw onderzoek helder, leesbaar en in begrijpelijke taal. Gebruik korte, eenvoudige zinnen en schrijf in de actieve vorm. Vermijd acroniemen, afkortingen en medisch-wetenschappelijke termen of leg deze meteen uit. Vat uw aanvraag samen in een doorlopende tekst met eventueel tussenkopjes, bij voorkeur aan de hand van de volgende onderwerpen:

- Het probleem waar u in dit onderzoek aan gaat werken
    - Voor welke groep mensen is deze ontwikkeling van belang, wat is de omvang van deze groep en wat is hun situatie nu?
    - Wat is de huidige prognose van deze groep mensen qua levensduur en kwaliteit van leven, ernst van de aandoening (o.a. symptomen, lasten somatisch/psychosociaal)?
- De beoogde oplossing voor het probleem/de onderzoeksrichting
    - Welke oplossing heeft u voor ogen?
    - Hoe draagt deze oplossing/onderzoeksrichting bij aan de missiedoelen van KWF, minder kanker, meer genezing en een betere kwaliteit van leven? (bijvoorbeeld

preventie, diagnostiek/vroege ontdekking, genezing/overlevingskans, minder invasieve/belastende behandeling, (kwaliteit van) uitkomstmaten van klinisch onderzoek, kwaliteit van leven, kwaliteit van zorg en/of wetenschappelijke ontwikkeling)?
    - De verwachte toegevoegde waarde van uw oplossing/onderzoeksrichting ten opzichte van de huidige situatie voor: a. dagelijkse praktijk, b. (andere) experimentele therapieën/interventies, c. de zorg, d. toekomstige patiënten e. preventie van kanker of f. wetenschappelijke ontwikkeling?
    - Hoe draagt dit onderzoeksvoorstel bij aan deze oplossing?
    - Relevante onderzoeksresultaten (in klinische ervaring en literatuur) die deze oplossing/onderzoeksrichting onderbouwen.
- De studieopzet en te doorlopen stappen in het onderzoek.
    - Illustratie van de studieopzet in een overzichtelijk en begrijpelijk schema (incl. follow-up).
    - Wordt er samengewerkt/afgestemd met andere instellingen die verwant onderzoek doen?
    - Wat maakt dit onderzoek bijzonder of uniek?
    - Welke uitkomsten verwacht u?
    - Hoe worden de uitkomsten teruggekoppeld naar eindgebruikers?
    - Hoe vindt disseminatie naar de belangrijke doelgroepen plaats?
    - Welke vervolgstappen zijn nodig om het resultaat van dit onderzoek en de beoogde oplossing te implementeren?

Deelnemers (max 250 woorden)

Met deelnemers worden participanten/proefpersonen in een studie bedoeld. Dit betreft vaak klinische studies/onderzoeken. Indien uw aanvraag een klinische studie betreft waarbij deelnemers zijn betrokken, beschrijf dan:

1. De te doorlopen stappen voor de deelnemers inclusief nazorg/ follow-up periode;
2. De belasting (tijd, fysiek, psychisch, sociaal, bijwerkingen);
3. De mogelijke benefit (hoeveel baat hebben de deelnemers bij deelname);
4. Welke vergelijking van experimentele arm t.o.v. controlearm vindt plaats;
5. Wat zijn de risico's en ethische aspecten (veiligheid, keuzevrijheid, privacy) verbonden aan deelname;
6. De inclusie: wat is het aantal te includeren deelnemers, inclusie- en exclusiecriteria, kans op drop-outs, haalbaarheid inclusie, wervingsstrategie.

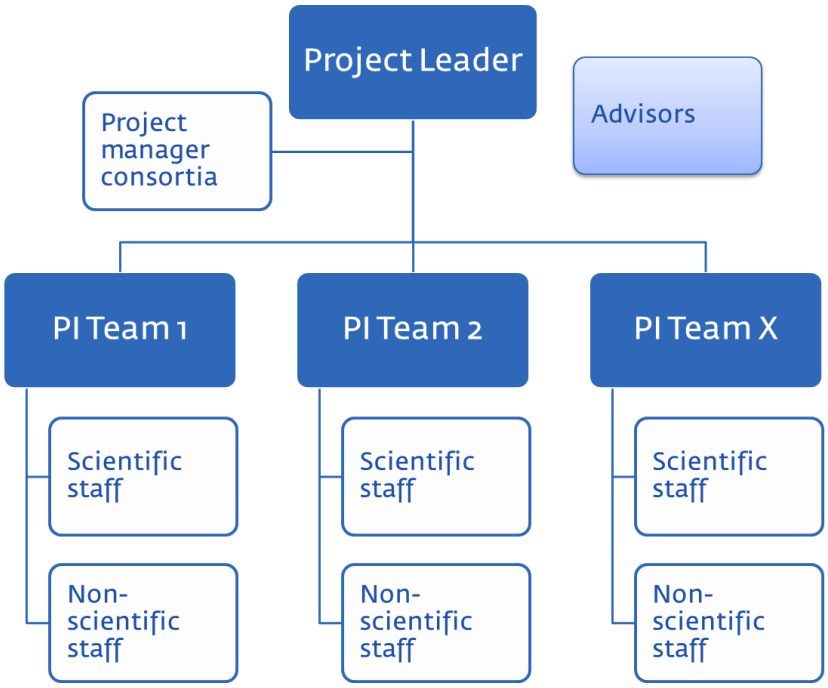
Patiëntenparticipatie (max 100 woorden)

KWF Kankerbestrijding vindt het belangrijk dat patiënten in een vroeg stadium betrokken worden bij wetenschappelijk kankeronderzoek, zodat aangesloten kan worden bij de wensen van patiënten. Zijn zij bijvoorbeeld betrokken geweest bij de onderzoeksvraagstelling? Hebben ze een rol in het vertalen van opbrengsten naar concrete acties? Wat is de meerwaarde van de opbrengst van het onderzoek voor patiënten? (het betreft hier niet de deelnemers die deelnemen aan een studie als 'participant/proefpersoon'). Geef aan of patiënten en/of patiëntenorganisaties betrokken zijn voorafgaand aan/tijdens/na de studie. Beschrijf bij de toelichting patiëntenparticipatie op welk moment en op welke manier patiënten/patiëntenorganisaties zijn betrokken en wat er met de input wordt gedaan of motiveer waarom patiënten(organisaties) niet zijn betrokken.

TAB 3. Parties involved in the project

Project team and collaboration

KWF employs a fixed organisational structure for projects and Consortia. This structure is shown in the diagram below. Please indicate which parties are involved in the execution or support of the work plan. The form has to be completed for each team/party involved in the project. To be able to assess the feasibility of the total project, we recommend that you include all the parties and staff involved.



If a company is involved in a different way than as a service provider, please submit a project proposal for a Consortium. A company cannot be included as a team (member) or co-funder in a proposal for a research project. However, as an exception, during the first call for proposals (January 8 - April 4, 2016), companies are allowed as a co-funder.

Project Leader

Each project has one Project Leader. The Project Leader (PL) is the exclusive/single point of contact for KWF. (S)he is responsible for the scientific management and coordination of the project as a whole and all required reports. In addition to his/her obligations as a participant, the Project Leader must ensure that the research team(s) comply with the terms and conditions of the research grant. The Project Leader should hold a PhD at the start of the project.

- If a project proposal is submitted before the PhD is obtained, the graduation date should be known and specified here. The project cannot start until the Project Leader has obtained the PhD.
- If the PhD graduation is delayed, KWF has to be notified, and an official request for an extension of the final start date can be submitted, which will be assessed in accordance with the regular procedure for request for extension.

A project team will consist of one or more research teams depending on how many teams are required to execute the work plan. The various research teams can be employed both inside and outside the Project Leader's institute.

Principal Investigator and team members

If the work plan is executed by multiple research teams, each research team has to be represented and managed by a Principal Investigator affiliated to the relevant group. A Principal Investigator (PI) can manage a maximum of one team. The Principal Investigator is responsible for the daily scientific management of the part of the project (usually a defined work package) his/her research team is involved in. The Project Leader has final accountability towards KWF. The Project Leader can also fulfil the role of Principal Investigator. In the case of a Young Investigator Grant, the Project Leader is the Principal Investigator.

Please select a Principal Investigator for each research team and select the project staff involved with the execution of the project. Every person that is registered in KWF GMS has a specific PIN that can be found at his/her profile page. This PIN number can be used to connect PI's to your project proposal. Please acquire the PI specific PIN (e.g. by e-mail) and use it to synchronize the contact details of a PI to the team. All PI's must be registered in KWF GMS and update their profile before the project proposal can be signed and submitted. PI's on the project are able to make changes to the project proposal. By providing their PIN the PI's assign rights to the Project Leader to submit the proposal on their behalf. With providing their PIN the PI's agree to execute and take responsibility for their part of the work plan. Please use the available fields to fill in the other team members. There are two types of project staff:

1. Scientific staff: includes PhD students and PhD/MDs who actively contribute to the research.
2. Non-scientific staff: includes, for example, technicians, research nurses, data managers.

List the staff members who will be funded by KWF as well as the staff members who will be funded by own contribution or co-funding. If a candidate for a vacancy has not been found yet, you can enter "vacancy". Please indicate for each staff member:

1. Their name;
2. Their function. For scientific staff, whether it concerns a Doctor/Researcher in Training, scientific staff/post-doc or physician-researcher. For non-scientific staff: whether the role requires Medium-Level Vocational Education, Higher Vocational Education or an academic degree;
3. The work package(s) they are involved in;
4. The FTE ratio allocated to this project.
5. E-mail
6. PI of the team the staff member belongs to

If the Project Leader will also act as the Principal Investigator or is a member of the project staff, please include the Project Leader in one of the teams. All project staff employed during the first year of the project should be registered in our system before the start of the project. Principal Investigators have to be registered in our system before submission.

Adding a foreign research team to the project is allowed. If an international researcher or research team is involved, it should be justified why this contributes to the execution of the

work plan, and why the research involved cannot be performed in the Netherlands. The centre of gravity for the execution of the work plan should always be located in the Netherlands. In case of foreign research teams, an international researcher can act as the Principal Investigator for the foreign team. The foreign activities in a Dutch project are eligible for funding. However, an international researcher employed at a foreign institute cannot be Project Leader, because international institutes are not eligible for KWF funding.

Service providers

Part of the research may be conducted by service providers. Service providers are parties that have an active role in the execution of the work plan, but do not benefit from the project results, apart from receiving payment for their services. For example: pathology labs, bio banks, trial monitors and data management, etc. The expertise provided in man hours should not already be available at the research institute(s) and should be used specifically for the project. A company cannot be included as a team (member) or co-funder in a proposal for a Research Project (with the exception that co-funding is allowed in the first call for proposals 2016). This is only allowed in Consortium Project proposals. In case a company is involved in a different way than as a service provider, please submit a Consortium proposal. If service providers are involved in the execution of the project, please provide the following information: Name of the organisation/company, contact person, expertise of organisation/contact person (why is this service provider included in the project?). Also indicate which work package the service provider will be involved in.
A trial manager can be entered as personnel in a project team.
All data management activities have to be coordinated by a data centre. Only data centres that are accredited by KWF, are accepted. These can be found on https://www.kwf.nl/onderzoek/zoekeensubsidie/datamanagement/Pages/datacentra-trialbureaus.aspx.

Advisors/Advocates

To ensure the proposal meets the needs of the field and the (end-)users of the development, and that choices made during the execution of the project remain focussed on the final goal or end product, KWF places a great deal of importance on involving the right advisors/advocates in the project. These advisors/advocates should be consulted regularly concerning all important decisions during the project. Advisors can be leading scientists in the field who support the project or other experts with specific (scientific) expertise that is not available within the research teams, such as regulatory affairs, intellectual property rights, clinical trials, etc. Advisors can also be professional healthcare providers or other end users, for example patients or patient associations who bring the perspective of those affected by cancer to the work plan. Advisors are not paid for their services. If any advisors/advocates are involved with the execution or support of the project, please provide the following information: name of the organisation/company, contact person, contact details (e-mail address), expertise of organisation/contact person (why is this advisor/advocate included in the project?). Each advisor/advocate must provide a letter of support that specifically details their contribution to this project. These letters can be uploaded as an attachment to the project proposal form. The letter of support should satisfy the following requirements:

- The letter must be printed with the correct address.
- The letter must be addressed to the Project Leader.
- The letter must be written in English.
- The letter must explicitly state that the contributing party has read the proposal.

- The letter must be signed by the advisor.
- The letter should specify the agreement made with the advisor in terms of advisory role in the project and why this fits within the project proposal/planning.

Co-funders

If the project involves co-funding, please specify the name of the institute/organisation and the name of the contact person. If a company is involved as a co-funder, please submit a Consortium Project proposal. A company cannot be included as a team (member) or co-funder in a proposal for a Research Project (with the exception for co-funding in the first call for proposals 2016).

A letter of support is obligatory if co-funding is provided for the project, including confirmation of the co-funding to be provided. The letter of support should be uploaded as an attachment to the project proposal and satisfy the following requirements:

- The letter must be printed with the correct address and on the headed notepaper of the co-funder.
- The letter must be addressed to the Project Leader.
- The letter must be written in English.
- The letter must explicitly state that the contributing party has read the proposal.
- The letter must explicitly state that the contributing party has agreed to the KWF Grant Conditions and the Intellectual Property arrangements stated in such.
- The letter must be signed by an authorised signatory.
- The letter should contain a brief description of the contributing party and the core activities/business of that party (type of organisation, size, which service, products, etc.).
- The letter should contain an explanation as to why this project, research direction or development is important to the contributing party. How does this solution fit within their strategy?
- The letter should specify what the contributing party will contribute (incl. funding for the cost of both man hours (number and/or rate applied) and material resources (numbers, cost price, rate, percentage that can be attributed to the project, etc.)) and why this fits within the project proposal/planning.

Project organogram

Please upload an organogram that shows the governance of the project team with research team(s) and the execution of the work plan. If your project team involves more than two research teams, please describe the quality of the collaboration between the research teams and the added value of the collaboration compared to the individual team(s). Include the frequency of project meetings, the decision-making process, roles and responsibilities.

TAB 4. Project proposal

This part of the project proposal form describes your actual project proposal/work plan. Use this section to describe and substantiate the activities covered by your request for funding.

Relevance

Problem description (unmet need): Substantiate the scientific value and (medical) need of your project by describing the problem you intend to solve. In this context, the problem can be a specific lack of knowledge in a research area, but where possible you should indicate the (medical) needs that will be fulfilled when your project or development plan is completed successfully. Be as specific as possible and substantiate the size of the problem (e.g., target population, (patient) burden, under-/overtreatment, costs, etc.).

Description of envisioned solution/research direction (max 400 words): Describe the solution you envisage to solve this problem (e.g., new diagnostic test, (preventive) therapy, screening modality, etc.). If the problem is a specific lack of knowledge, a description of how the results of this project will contribute to the current scientific state of the art and what type of spin-off/future activities you expect to evolve from this proposal, will suffice (e.g., a new platform technology, specific knowledge that will help the field forward, novel targets for prevention, diagnosis or therapy, etc.).

Aim (max 300 words): Please describe the goals of this project proposal, divided into main goals and secondary objectives or research questions. The achievement of the goals should be feasible within the duration of the proposed project. Formulate these goals within the perspective of the problem and the proposed solution.

Background

Summary of literature (max 600 words): Please provide a concise summary of the relevant literature details. Clearly distinguish the results of your own research from that of other research groups, and what gaps in the research field the project seeks to fill. Only referencing survey articles will not be sufficient. Please note that references listed under “Preliminary results” should also be listed under “References”!

Preliminary results of own research (max 600 words): Please specify the results of preliminary research (including any pilot studies) performed by you or the research team(s) that directly led to the current project proposal. Please also indicate the extent to which the preliminary research has already been turned into publications (including "in press" and "submitted") and abstracts. Reports on and conclusions from preliminary research will play a significant role in the project's assessment by reviewers. Please note that references listed under “Preliminary results” should also be listed under “References”!

Plan of Investigation

Synopsis of work packages and cohesion (max 200 words): Use this section to provide an overview of your overall work plan and activities. Include how the activities are divided across the work packages and how the work packages are interconnected.

Description of work packages: Please describe how the work plan is divided into various work packages. A work package is a unit of coherent work/activities that is clearly distinguishable from other work packages and has scheduled start and completion dates

with interim milestones (if applicable). The teams executing the work packages should be equipped with the required expertise.

Work packages can be created using the dedicated 'create work package' button. Upon pressing this button a new window will open in which you can provide the requested details of the work package. Multiple work packages can be created this way. Your input can be saved using the 'save draft' button. 'Validate and save' checks whether you filled out all required fields. For each work package specify the start and end in months relative to the start date of the project, the work package's objective(s) and contribution to the overall aim, a description of the work (methods and techniques), and the Principal Investigator who will be responsible for performing the activities. A detailed planning covering the entire duration of the project can be given in the project planning field.

KWF's monitoring and evaluation of progression of the project is based on milestones. For each work package, determine significant milestones that could be used to measure the success of the proposed research. For each work package, formulate at least one milestone. Milestones should not be confused with the specific deliverables of the project. Milestones can be determined as a point in time, within or at the end of a work package, that indicates the completion of a major activity or project requirement (or a set thereof). Milestones serve as progress markers (flags): make them SMART (Specific, Measurable, Acceptable, Realistic, Time bound), describe when the milestone is expected to be reached, and formulate the criteria for when a milestone is considered to be successfully met.

If an (early) clinical study is part of the work plan, please clearly describe the purpose, design, and patient recruitment plan, including inclusion and statistical substantiation. Use the format of a trial synopsis for this. Additionally, where relevant, a power calculation should be included in the statistics section of work plan. If available, upload the clinical trial protocol. However, it is not required to submit a detailed protocol as part of the project proposal. KWF will indicate whether and, if so, when a complete protocol should be provided. Please keep in mind that, during their review phase, reviewers will largely focus on the work plan. If the study is not a clinical study, but still involves patients and/or healthy subjects, it should be clearly indicated what numbers are needed to answer the research question, including statistical substantiation. It should also be indicated how and when inclusion/recruitment will occur and at which institutes. In addition, it should be demonstrated that accrual of the proposed number of patients and/or healthy subjects is feasible within the duration of the project.

It is also important to address the expected burden, side-effects and effects on quality of life for patients as early as possible in the development of interventions, diagnostic tests and care. If applicable, please include in the work plan the possible burden, side-effects and effects on quality of life for patients you might expect and describe how you will minimize the negative effects.

For clinical studies you are required to include the delivery of a final report that includes an implementation plan as a final milestone. The final report and implementation plan formats will be made available at the end of the project. In case of a clinical study the work packages could be structured as below:

- WP1: Preparatory work
- WP2: Performing the trial (Inclusion)
- WPx: Side study/studies

- WPx: Data management and analysis
- WPx: Implementation
- WPx: Follow-up

If an international internship is requested, this section must include a description of the capacity building and relevance of this international internship to the proposal's objectives. A description of the necessity of the internship for the execution of the work plan and a description of the host team's expertise has to be included as well.

Please note that references listed under "Description of work packages" should also be listed under "References"!

Statistics

Use this section to statistically substantiate the methodology/study design, including power calculations. Please also include a statistical analysis strategy. If applicable, describe how you will approach data management and sharing, quality control, bio-informatics, data accessibility, or any other specific data analysis methods.

Experiments involving human subjects, animals or recombinant DNA (genetically modified organisms)

If the work plan employs humans, animals or genetic modified organisms, please describe the amount and type of animal/organism required for the execution of the work plan.

Please notice that the guidelines for the use of these materials are as follows.

Human testing: if research involves patients and/or healthy people, or if material from patients is used, written permission must be obtained from the Medical Ethics Committee. KWF hereby gives notice that it is the responsibility of the Project Leader and the institute to ensure that the research adheres to the legal regulations applicable to the further use of bodily material and data, and to ensure that a project does not start before the Project Leader/the institute has obtained the proper declarations and permits.

Animal testing: use of laboratory animals and animal testing should only take place in accordance with the applicable legal regulations. Under Article 11 of the Experiments on Animals Act, only lab animals that are specifically bred for this purpose may be used. Finally, all animal testing research should be submitted to your institute's relevant animal ethics committee. KWF hereby gives notice that it is the responsibility of the Project Leader and the institute to ensure that the research adheres to the legal regulations applicable to the use of test animals, and to ensure that a project does not start before the Project Leader/the institute has obtained the written approval ("projectvergunning") of the Animal Ethics Committee (called the Centrale Commissie Dierproeven or CCD in Dutch).

DNA: if your project proposal includes recombinant DNA research, KWF hereby gives notice that the Project Leader and the institute must have all the required permits, licenses and facilities. Recombinant DNA research should be registered with the committee established for this purpose.

TAB 5. Feasibility Research Progress

Dissemination plan (max 400 words)

Dissemination: Please describe how you will ensure that the knowledge/skills/techniques that result from this project will be transferred to other parties that could benefit, if applicable including patients and society. How will you disseminate the knowledge obtained and how will you ensure the continuation of the research/development?

Intellectual Property (IP) strategy: the protection of intellectual property rights can be considered as a means to ascertain commercial value and thereby as an incentive for investors or third parties to provide further funding and/or commence widespread implementation. In many cases, solid protection of intellectual property rights is essential for inventions to reach the patient (e.g., agents or biomarkers). Please note that this does not only include patents. Many other types of protection can be considered (trade secrets, copyrights, trademarks, registered designs, etc.). In other cases, widespread dissemination of knowledge and awareness could be a strategy to acquire the funding required for implementation. Please use this section to describe whether you:

- have already secured related protection of intellectual property rights.
- have already considered the protection of intellectual property rights, and how and when you will do so, or explain why not.
- will involve the Technology Transfer Office (TTO) of your institute, or explain why you decided not to.
- are aware of conflicting intellectual property rights (freedom to operate) or published data preventing the protection of intellectual property rights (prior art).
- have made arrangements to protect intellectual property rights within your collaboration (if applicable).
- are aware of any existing contracts (including material transfer agreements, licenses, cooperation agreements) with third parties in relation to the subject of the research.

Development Plan (only applicable for project proposals in the development track)

This part of the proposal describes the steps towards implementation upon a successful outcome of the work plan. This entails the feasibility that your invention, product and/or services will actually become available to the patient and/or the public. Please consult your Technology Transfer Office (TTO) if you need guidance in providing information for this part of your proposal. In addition, you can also contact KWF for further information.

Background why KWF requires a development plan:
KWF intends to streamline the process from discovery towards implementation of the end product in terms of translation into public health or clinical practices and/or industrial applications. This requires alignment between all research activities in the current proposal and the requirements of the end product/the envisaged solution. We therefore ask Project Leaders to describe the steps that need to be taken after successful completion of the current proposal before the end product/solution can be implemented: the development plan. Designing this development plan in a very early phase of research will help to identify risks that threaten implementation, as well as the opportunities that could accelerate or even enrich the application of the end product. KWF is aware of the fact that not everything is clear in the early stages of research. Therefore, the evaluation of this section is tailored to the research phase. The closer a proposal is to implementation, the more details will need to

be included in this section and the more stringent the assessment will be. Using the following two examples we try to explain the reason why we ask you to describe the development plain.

Example A: Immune therapy

Suppose you are working on an autologous T cell based adoptive immune therapy. Your proposal comprises the validation of your specific T cell modification strategy in preclinical in vitro models and in vivo in xenograph models. At that stage, you should already be aware of the regulatory and the developmental hurdles your novel therapy is facing with regard to autologous immune enhancement therapies. For instance, you should not only address potential efficacy, but also evaluate whether your models provides relevant information on on-target and off-target toxicity, potential immunogenicity of your product, and on "pharmacokinetics" including in-vivo survival and proliferation in humans. If your model does not provide this information you should already develop a strategy for further testing. You should be looking for ways to create your protocols in such a way that they can be standardised and up-scaled to Good Manufacturing Practice (GMP) standards. Only then will your novel therapy be able to move on to preclinical preparations and further toxicology testing, once your validations in animal models are successful. If you only start thinking about these issues after you have finished preclinical and animal testing, it might be that you have to repeat certain parts of the validation due to changes in the protocol or preparation of your product, thereby decelerating progress towards the clinic. In addition, you should be aware of the high cost of clinical trials and the difficulty in getting them funded. KWF does not have the budget available to fully support all aspects of clinical trials. To allow further development you could consider several options:
Option 1: Possibly you can make your protocols patentable, for example by patenting the specific components of your strategy or T cell product. This way, commercial investors or perhaps pharmaceutical companies can be attracted to co-fund your clinical trials. In particular this may be most relevant in diseases with higher incidence rates and, therefore, larger market potential. This would be more interesting from an investor's perspective, resulting in more funding possibilities for your development. Furthermore, the accessibility of samples and subjects would be high.
Option 2: It could well be that there is no way to patent your immune therapy. Then, large scale clinical studies allowing evaluation of limited improvement in patients are difficult to perform and finance. In that case, your strategy could be more appropriate for smaller indications in patients with limited treatment options. This could result, for example, in easier access to study subjects, funding from orphan disease programmes and/or more lenient regulations towards market approval (e.g., conditional approvals and orphan designation). Furthermore, it could result in a higher chance of showing significant improvements in survival in smaller clinical trials, thereby reducing the required funding. Once proven in a low incidence indication, it might then be possible to extend the treatment to higher incidence indications.

This example shows how future steps can influence the way you should set up your research at this early stage, and what type of expertise should be involved. In this example, it would be advisable to consult a regulatory expert, and a clinical researcher with phase 1/2 clinical trial experience when drafting your study design. In option 1, it would be wise to also consult with your Technology Transfer Office (TTO) to discuss the Intellectual Property strategy and how to attract investors at later stages of development. In option 2, it would be wise to consult with clinicians treating the specific target indication, to discuss what evidence they

need and what requirements they would have before using your novel treatment in an experimental setting for patients who have no other treatment options.

Example B: Sleeping disorder as a consequence of treatment

Suppose you have discovered that sleeping disorders as a consequence of chemotherapy show high similarity to sleeping disorders as a consequence of post-traumatic stress syndrome, which can be treated by hypnosis therapy. You are planning to study whether hypnosis also works in chemotherapy-related sleeping disorders and what type of hypnosis therapy is most effective. Your development plan should contain the following steps:

1. Current proposal: first evaluation whether hypnosis therapy is effective, optimisation of this treatment and creating a standardised treatment protocol.
2. Evaluation of proposed treatment protocol in a randomised controlled trial setting.
3. Incorporate the treatment in standards and guidelines, create awareness among specialists and secure reimbursement.

In this example, it is probably feasible to fund these studies by public funding from KWF and government agencies. Regulatory issues are not to be expected. The biggest challenge will be obtaining reimbursement from health insurance companies. It would therefore be wise to assess what type of evidence for cost-effectiveness (e.g., Health Technology Assessment (HTA)) is required for health insurance companies to reimburse this type of treatment. By already taking the cost-benefit ratio into account in the initial design of the treatment protocols, one can reduce the risk of downstream failure. For example, if the initial study shows that 30 treatments of more than 1 hour are required with only 20% responders, while there are over 40,000 patients facing this problem, you should consult with the responsible stakeholders about whether it would be feasible to obtain reimbursement for this type of treatment at this cost level. If this is not feasible, the next step would be to further optimize the treatment, rather than moving on to the randomized controlled trial.

Development plan; steps towards implementation (max 400 words)

Use this section to briefly describe the major steps in the development plan and the specific hurdles that need to be overcome. Please indicate for each step:

- The major risks (these risks can be further addressed in the section below);
- The required expertise and who you envisage could perform this step.

Regulatory risks and/or opportunities

If applicable, please describe how you expect to obtain required regulatory approvals from regulatory authorities (e.g., CCD, METC, WBO/VWS, RIVM, IGZ, CBG, EMEA, FDA) and minimize the regulatory risks involved in the development plan at the earliest stage of your proposal. What relevant parties are/will be involved to prevent the regulatory risks in the development plan? Other ethical/legal issues are, for example, informed consent, data protection, privacy issues and material transfer obligations.

Production risks and/or opportunities

If applicable, please describe how you will manage, for example, production, quality control, storage and stock management, Good Manufacturing Practice (GMP) conditions, clinical grade production, scalability, etc. Are you dependent on specific suppliers and are they capable of producing the required amounts at acceptable prices? Are production and storage scales tailored to the demand for and stability of the product in later stages of the development plan? Is the pharmacy department of your institute or other experts involved, and are the necessary authorisations available?

Market position

Please describe the position of your development plan compared to competing developments and/or current alternatives. How does your development plan fit current market trends (e.g., novel therapies becoming available, increased availability of next-generation sequencing, changes in reimbursement strategies, renewal of guidelines)? Could your development become obsolete due to current developments?

Describe the demands your end product has to fulfil and how you will ensure that it will optimally fulfil those requirements in terms of:

- Cost-effectiveness (Health Technology Assessment) and pricing: will costs be reduced or will your end product result in increased costs that can be justified by the benefits?
- Clinical interest, clinical requirements, guidelines and standards: have healthcare providers expressed an interest and do you have an indication of minimum requirements?
- Market potential and willingness to invest: have commercial investors or the industry shown an interest in the end product?
- Reimbursement: have health insurance companies shown an interest?

The most effective way of aligning your development plan with (market) demands is to involve the major stakeholders as advisors in your project/development plan. Letters of support or intent from those stakeholders could substantiate the feasibility of your development plan.

Other risks and/or opportunities

Use this field to further substantiate the feasibility of your development plan if specific risks or opportunities could not be addressed in the sections above.

TAB 6. Budget

This section allows you to specify the budget for your project. Please provide specific information about the use of the requested funds, and specify any co-funding (or own funding) from other sources supporting the project (if applicable).

Fundable costs

Staff – salary

A minimum of 0.5 FTE/year of scientific staff should be attached to the project and actively involved in the project (staffing is reviewed by the KWF Internal Review Committee).

When calculating salaries, KWF uses the fixed salary scales for 'CAO Nederlandse Universiteiten' for the maximum fundable amount for the various roles:

Degree	CAO-NU salary scale
Scientific Staff- PhD-student	Specific PhD-student scale
Scientific Staff – senior (PhD/MD etc) (1)	11.0
Non-Scientific Staff – MBO	7.5
Non-Scientific Staff – HBO	9.3
Non-Scientific Staff – Academic (2)	11.2

(1) Scientific staff: includes PhD students and PhD/MDs who actively contribute to the research. The same salary scales are used for PhDs/Scientific Staff and for researchers with a medical degree/medical specialists. This is because researchers with a medical degree/medical specialists, when working on the project, are not employed as doctors but as researchers. The same salary scales will be used when calculating the cost or in kind contribution of scientific and non-scientific staff involved in collaborations with non-academic parties. Any staff costs beyond these scales will be payable by the participants and are not considered as co-funding. The salary for project staff is calculated using the fixed salary scales for 'CAO Nederlandse Universiteiten' from the year the proposal was granted. These rates are not adjusted over the course of the project. The CAO-NU calculations include indexing.

(2) Non-scientific staff: includes, for example, technicians, research nurses, data managers, trial managers. Non-Scientific Staff-"Academic" includes everybody with a university education who is not a researcher. In case of clinical trials you can also choose to budget data management and trial management activities as service providers.

You should distinguish between the staff you are requesting funding for and staff who will be funded by co-funding or own contribution or other funds.

Staff – personal budget

Scientific staff are assigned an annual personal budget of € 1,500 per FTE. This can be used, amongst other things, to cover travel expenses (including congress expenses), publication costs and thesis/dissertation printing costs. This is a standard amount that cannot be increased.

Open access

In 2013 KWF implemented a new policy to improve the accessibility of the results of research funded by KWF. Making publications more visible and easier to find through open access

publishing and archiving will enhance the research's impact. An additional advantage of open access archiving is that publications will remain available over a longer period. KWF requires Project Leaders of accepted projects to archive articles in an online repository of their choice within twelve months after publication. As of 2013, in addition to the title of the publication and the name of the journal it was published in, progress reports and final reports should also specify whether the article was an open access publication and detail the repository the article was or will be archived in.

KWF will make € 6,000 available for each project as a contribution to the cost of open access publications. This allowance should be budgeted/requested at the time of submission of the project proposal. No additional funds can be requested for open access publication during the course of the project.

Materials

Consumables: general consumables used specifically for the execution of the project, including project-specific:

- Non-reusable, routine items specific to the research (such as chemicals, enzymes, antibodies, molecular biology kits and reagents, glassware, plastics, dyes, radioisotopes, tissue culture costs)
- Licences (animal/software)
- Stationery, postage, courier costs, etc.
- Fees, including patient fees (if applicable) for clinical research

Per FTE of scientific staff, KWF will assign a maximum of € 8,000 annually for lab work and a maximum of € 2,000 annually for desk research. Consumables do not need to be specified.

Specified materials: if the amount required to cover the cost of materials needed for the execution of the project is larger than the amount made available for consumables, then these costs need to be specified. For example:

- Essential materials acquired and used for the execution of the project
- More expensive reagents
- Use of facilities and services of other departments – excluding staff departments – within the project team (services provided to each other), e.g. specific analyses, laboratory services, bio-informatics or statistics, bio-bank, imaging and pathology costs, quality of life registration
- Approvals of Medical Ethical Committee(s)
- Mice/lab animals

Devices: in exceptional cases, use of a specific device can be part of the project. The necessity of the device for the execution of the project (the project cannot be executed without this device) has to be reviewed by the KWF Internal Review Committee. Use of existing expensive equipment will be reviewed by the KWF Internal Review Committee for each proposal (whether the device is essential and indispensable for the execution of the project at hand and whether these costs, calculated in detail: the internal using price times duration for the project can be funded within the proposal).

Service providers

Costs incurred by service providers are costs for activities performed by a parties outside the project team, that do not benefit from the development, and that perform the activities

purely as a service. Data management and trial management services can be budgeted as service providers. Companies can be listed as service providers in a project, provided they are essential for the execution of the project, they do not benefit from the development, and they do not take on a shared risk (a Consortium is not necessarily required in such cases).

- The budget for service providing costs should be listed separately in the proposal's financial projections. The amount should be substantiated with the price quotations of the service provider. For staff financed by third parties, KWF will apply the same fixed rates as used for project members (salary scales for 'CAO Nederlandse Universiteiten').
- The Project Leader's institute will be responsible for performing the research as described in the proposal. Actual costs should be substantiated by quotes and invoices from service providers.
- There is no set maximum for service providing party costs as a proportion of the total project budget; the Internal Review Committee will assess whether each service provider has added value and whether the quoted amount is reasonable.
- Medical Ethical Committee (in Dutch: Medisch Ethische Toetsingscommissie, or METC) costs will be reimbursed (as part of project proposals in the pre-clinical or clinical research phases).
- Costs for the Animal Ethics Committee (in Dutch: Centrale Commissie Dierproeven, or CCD) and Genetically Modified Organisms (in Dutch: genetisch gemodificeerde organismen, or GGO) certificates will not be reimbursed.

International internship

An international internship for capacity building can be requested for scientific staff for a minimum of one month and a maximum of two years, but no longer than half the duration of the project. The international internship must take place at a single institute. It can be used to bring foreign knowledge and skills required for the execution of the project to the Netherlands. The international internship should start in the first half of the project; it should be possible to employ the knowledge and skills acquired abroad in the Netherlands within the duration of the project. After the conclusion of the international internship, there should still be sufficient time to implement the knowledge and skills (to be assessed by the Internal Review Committee). Staff will remain employed at the Dutch institute for the duration of the international internship. It is the responsibility of the Dutch institute to arrange financing for the internship. Funding can be requested for the travel (economy class) and accommodation expenses of the relevant researcher. Rates are automatically calculated based on the List of Rates for international travel and accommodation 2015-2016 in attachment 1. Please select the location closest to the destination.

Work-visits and exchanges of less than 1 month in international collaborations cannot be charged as an international internship for capacity building. The personal budget is a contribution towards travel expenses for conferences and work-visits.

Co-funding/own contribution

Because KWF places a great deal of importance on the involvement of (end) users to ensure an alignment between your research and user demands, we also expect others who might benefit from the results of this project, or who believe in this project/development and/or share our sense of urgency, to contribute to the project. The research institutes involved are responsible for financing the necessary cost of overhead, infrastructure and the supervision of project members form their direct government funding. On top of that, parties involved in the research teams that execute the proposal can provide an in cash or in kind

contribution to the project activities. This type of contribution to the project activities from within the project teams is referred to as own contribution. We urge you to indicate any own contribution in the budget sheet to further substantiate the commitment of the participating organisations.

Co-funders are all parties, in addition to the participating institutes/organisations hosting the Principal Investigators, that offer a cash or in-kind contribution to the project based on the expected outcome. In-kind contributions include paid staff and/or material resources contributed by parties. This should be clarified in the description and planning/phasing of the research.

KWF will accept staff input and material contributions as in-kind co-funding/own funding on the condition that they are an integral part of the project. When capitalizing (calculating the value of) co-funding/own funding in kind (man hours), use the fixed salary scales for 'CAO Nederlandse Universiteiten' for personal costs. Co-funding/own contribution can only consist of eligible costs as defined by KWF (also in the case of co-funding by companies). Non-eligible costs cannot be attributed as co-funding. The time spent in man hours should be verifiable and therefore logged.

Pledges of material resources should be charged at cost price. Commercial rates will not be accepted. For pledges of equipment, please take any previous depreciation and the intensity of use into account. Pledges in the form of supplies or services will only be allowed if the service can be itemised as an identifiable new endeavour. The service should not already be available at the research institute(s) performing the research. Applicants may wish to claim services already supplied (such as a database, software or plant lines) as in-kind co-funding.

The pre-financed amount of co-funding by each party can be indicated in the budget sheet. The following items do not count as co-funding:

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

Non-fundable costs

Any costs that are standard of care are non-fundable. General laboratory facilities should be provided by the institute, and costs stemming from this will not be reimbursed. This includes: indirect costs, overhead costs, office expenses, staff members at knowledge institutes, indirect personal costs, laboratory set-ups, declarations by accountants and employers, declarations of intent, knowledge transfer patents, etc. Network-meetings or other networking activities are also non-fundable. Neither can these costs be included in the calculations of co-funding for a specific project proposal.

TAB 7. References

Please list all references mentioned in the sections "Scientific Abstract", "Project Proposal" and "Development Plan". Make sure to include: authors, title, journal (official abbreviation), edition, year, first and last page. You can use as many characters as needed. The total number of references should preferably not exceed 50. Please keep in mind that all authors should be listed. **Use of the affix "et al." is not allowed.**

TAB 8. Reviewers

International reviewers

The list should include at least five international experts in the field of research of your project proposal. In this context, it is important that the Project Leader (and, if applicable, the Principal Investigators) is/are not involved in any collaborations with these experts. The list should include the names and institute employing the experts, as well as their e-mail addresses and fields of expertise.

National reviewers

The list should include at least two national experts in the field of research of your project proposal. In this context, it is important that the Project Leader (and, if applicable, the Principal Investigators) is/are not involved in any collaborations with these experts. The list should include the names and institute employing the experts, as well as their e-mail addresses and fields of expertise.

Persons excluded from reviewing

This list may contain up to three experts within your project proposal's field of research who are to be excluded from reviewing the proposal. In case of large clinical trial groups you would like to exclude, please indicate the name and details of the group. Please note that this information is not compulsory. KWF will consider these suggestions as it sees fit.

Acknowledgements

Please read the acknowledgements carefully, tick the boxes if you agree and submit your proposal.

- By signing, the Project Leader declares that he/she has final responsibility for the project's execution and is accountable for the project's content. The Project Leader also has final responsibility for the execution of collaborating partners' activities.
- By signing, the Project Leader declares that he/she subscribes to KWF's funding conditions and codes of conduct.
- By signing, the Project Leader declares that the information supplied in the project proposal and profile is truthful, and that he/she will immediately report to KWF any changes that may be relevant to the assessment/acceptance of the project proposal.
- By signing, the Project Leader declares that he/she has informed all PI's and participating parties of the project about the content of the project proposal before submitting the project proposal.

TAB 9. Personal Motivation

If you are submitting a project proposal for a Young Investigator Grant, please describe your personal motivation for applying for a Young Investigator Grant by answering the following questions:

1. Why are you submitting a project proposal for a Young Investigator Grant? What does this Young Investigator Grant mean to you?
2. Why are you the right person to receive a Young Investigator Grant?
3. In what position and role do you see yourself in the future (in 5 to 10 years)?

Submission

After submission by the Project leader, the project proposal is sent for sign-off to the director of the institute and financial contact person. The status of the project proposal changes to pending sign-off. If they both approve the project proposal, it is automatically submitted to KWF. If the director or the financial contact person does not approve the proposal, it is sent back to the Project Leader for adjustments. If the director or the financial contact person does not approve the project proposal in time and the project proposal is submitted after the deadline, the proposal will not be taken into consideration. Please make sure there is sufficient time between submission by the Project leader and the submission deadline for the director or the financial contact person to approve the project proposal.

With their signature, the director and financial contact person representing the institute of the Project leader:

- declare that the institute is accountable for the project's finances and vouches for the execution of the project in terms of content and finance, and that they are authorized to legally bind the institute in this way.
- declare that they subscribe to KWF's funding conditions and codes of conduct.
- declare that the information supplied in the project proposal and profiles is truthful, and that they will immediately report to KWF any changes that may be relevant to the assessment/acceptance of the project proposal.

Attachment 1: List of Rates for international travel and accommodation 2015-2016

These costs are valid for 2015-2016

Destination	Distance (km) to Amsterdam	Travel costs (€)	Accomodation costs (per month)
Australia			
Melbourne	*> 10.000*	2500	1728
Canberra	*> 10.000*	2500	1728
Sydney	*> 10.000*	2500	1728
Australia-other			1284
Canada			
Ottawa	*5.000 – 10.000*	2000	1991
Banff	*5.000 – 10.000*	2000	1498
Calgary	*5.000 – 10.000*	2000	1646
Edmonton	*5.000 – 10.000*	2000	1498
Halifax	*2.500 – 5.000*	1500	1909
Montreal	*5.000 – 10.000*	2000	2057
Toronto	*5.000 – 10.000*	2000	1860
Vancouver	*5.000 – 10.000*	2000	1959
Canada-other			1498
Germany			
Berlin	*500 – 1.000*	500	1909
Bonn	*< 500*	250	1432
Frankfurt	*< 500*	250	1547
Hamburg	*< 500*	250	1679
Keulen	*500 – 1.000*	500	1547
München	*500 – 1.000*	500	1547
Germany-other			1547
France			
Paris	*< 500*	250	2205
France-other			1564
UK			
London	*< 500*	250	2288
UK-other			1794
USA			
Boston	*5.000 – 10.000*	2000	1498
Chicago	*5.000 – 10.000*	2000	1383
Honolulu	*> 10.000*	2500	1267
Los Angeles	*5.000 – 10.000*	2000	1350
Miami	*5.000 – 10.000*	2000	1218
New York	*5.000 – 10.000*	2000	2057
Philadelphia	*5.000 – 10.000*	2000	1383
San Francisco	*5.000 – 10.000*	2000	1564

Washington D.C.	*5.000 – 10.000*	2000	1860
USA-other			1119
Destination	**Distance (km) to Amsterdam**	**Travel costs (€)**	**Accommodation costs (per month)**
Sweden			
Stockholm	*1.000 – 1.500*	750	2057
Göteborg	*5.000 – 10.000*	2000	1580
Malmö	*500 – 1.000*	500	1580
Sweden-other			1580
Spain			
Barcelona	*1.000 – 1.500*	750	1333
Madrid	*1.500 – 2.500*	1000	1399
San Sebastian	*1.000 – 1.500*	750	1432
Valencia	*1.000 – 1.500*	750	1218
Spain-other			1169
Italy			
Florence	*1.000 – 1.500*	750	1317
Rome	*1.000 – 1.500*	750	1794
Milan	*500 – 1.000*	500	1975
Italy-other			1251
Austria			
Vienna	*5.000 – 10.000*	2000	1876
Austria-other			1876
Norway			
Stockholm	*1.000 – 1.500*	750	2008
Norway-other			2008
Belgium			
Brussels	*< 500*	250	1843
Belgium-other			1843
other countries*			