

Priority Program: 'Translational Oncology'

Applicants' Guidelines for Project Outlines

Introduction

The major goal of German Cancer Aid's funding program for the development of 'Interdisciplinary Oncology Centers of Excellence' ('Onkologische Spitzenzentren', CCC) in Germany is to continuously improve the treatment and care of cancer patients. Conducting interdisciplinary research programs that encompass both basic science as well as the essential translation of scientific findings into clinical practice is therefore an essential task of 'Interdisciplinary Oncology Centers of Excellence'. Patients can then rapidly benefit from new scientific progress. The following program for 'Translational Oncology' is another step in reaching this goal.

With the goal of further supporting collaborative translational cancer research projects at 'Interdisciplinary Oncology Centers of Excellence' and Comprehensive Cancer Centers, the German Cancer Aid has decided to launch a 12th call for applications within the funding program 'Translational Oncology'. Applications may be submitted for a collaborative scientific project ('Verbundprojekt'; CP), a combination of a collaborative scientific project and a clinical trial (Phase I/II; CPT) or an innovative clinical trial (Phase I/II; T). The projects/clinical trial (CP, CPT and T) must be performed at least at 3 sites (separate cities) and necessitate close collaboration between several research groups. At least one research group must be located at an 'Interdisciplinary Oncology Center of Excellence' (CCC) funded by the German Cancer Aid. The maximal budget for this call for all funded projects is in total 7 million Euros.

General Comments/Procedure:

Eligibility

Researchers in Germany who have completed their academic training (a doctorate as a rule) are eligible to apply within the Translational Oncology program.

As a general rule the following persons cannot be lead- or co-applicants of a proposal:

- persons working at a profit-making organization*; particularly, if the profit-making organization is a subcontractor in the application,
- persons not permitted to publish results in a generally accessible form,
- persons or organizations situated in a foreign country.

* As a rule, persons working at an institution/a hospital/a clinic which is organized as 'GmbH' are not eligible as applicants. If you are not sure, if a person is eligible as applicant, please contact the office of German Cancer Aid before sending a LOI or project outline.

The application and evaluation procedure takes place in three steps:

1. Applicants must inform the German Cancer Aid by **December 19, 2024, 17:00 (per email)** that they plan to submit an application (Letter of Intent).
2. Project outlines must be submitted no later than **February 04, 2025, 13:00 (per email)**.
3. If the preliminary evaluation is favorable, full applications must be submitted by **July 02, 2025, 13:00**.

Project outlines must be submitted no later than February 04, 2025, 13:00 (per email) at foerderung@krebshilfe.de.

All other required documents must be sent with the post to the offices of the Deutsche Krebshilfe at the following address:

Stiftung Deutsche Krebshilfe
Abteilung Förderung
Buschstraße 32
53113 Bonn

Within two weeks of receipt of the letters of intent, project outlines and full applications by the German Cancer Aid, the lead applicant will receive a written confirmation of receipt. If you fail to receive confirmation of receipt, please send an email to the Funding Department of the German Cancer Aid (foerderung@krebshilfe.de), giving the full project title and your telephone number.

If you have any questions, please contact:

Dr. Matthias Serwe, 0228 / 729 90-223, email: serwe@krebshilfe.de

Kim Tiede, 0228 / 729 90-217, email: tiede@krebshilfe.de

Marina Stockem, 0228 / 729 90-215, email: stockem@krebshilfe.de

A. General Guidelines for all Project Outlines

Before sending a project outline please read carefully 'What to consider before applying' (see 'Guidelines for Letter of Intent')!

Please submit **one** PDF-Version (one document) of your project outline by e-mail (foerderung@krebshilfe.de).

The project outlines must be written in English. If your cover letter contains relevant information for the reviewers, please **write it in English** and include it to your PDF-Version.

Please follow the correct guideline for your project. There are three separate guidelines:

Guideline for a Collaborative Project (CP; **p. 4**)

Guideline for a Combination of a Collaborative Project and Clinical Trial (Phase I/II) (CPT; **p. 8**)

Guideline for a Clinical Trial (Phase I/II) (T; **p. 13**)

Important:

Clinical trials in the sense of this priority program are exclusively **interventional** clinical trials. An application for a non-interventional clinical trial, e. g. diagnostic and observational clinical trial, are eligible but has to be applied as a subproject of a Collaborative Project (CP).

Important: To simplify the evaluation process:

- start the application with a **title page and include:**
 - Name of lead applicant (only one person possible)
 - Institution of lead applicant
 - Title of the applied project (max. 160 characters)
 - Type of application (CP, CPT or T)
- include a table of contents and page numbers
- address all points mentioned in the guidelines, repeating all section numbers/letters, as well as the complete section titles
- use 'Verdana', font size 10 and 1.2 line spacing.

Terms to be used in the application:

For consistency in the review process, only use the following terms for participating persons:

Lead applicant*

Co-Applicant*

Co-operation Partner** Co-operation partners **do not** receive any funding.

*Co-applicants (as well as the lead applicant) cannot be employed in a foreign country, as no funding from the German Cancer Aid is to be used outside of Germany. Companies or persons mainly working at companies/profit-making organizations are not allowed as (co-)applicants.

* As a rule, persons working at an institution/a hospital/a clinic which is organized as 'GmbH' are not eligible as applicants. If you are not sure, if a person is eligible as applicant, please contact the office of German Cancer Aid before sending a LOI or project outline.

**Persons from foreign countries can participate as co-operation partners but can not receive funding.

If companies offer material, we need a MTA (Material Transfer Agreement) for the full proposal. In the MTA it must clearly state that all rights to the results/findings of the project/trial belong to the applicant. For further information on participation of companies, please see Appendix 4. **If a company is involved in the project, please comment on all points in Appendix 4.**

Please note:

The German Cancer Aid reserves the right to refuse and send back incomplete applications or applications, which have not been prepared according to the guidelines. Therefore, we urge you to address all points in the guidelines. **Please adhere strictly to the given page limits for each section.**

Please check your application completely before submitting. Your application will not be screened for completeness upon receipt and will be given to the reviewers as is even if information is missing or incorrect.

Project Outline for Collaborative Projects (CP):

The completed project outline is **not to exceed 10 pages** (excluding Appendices - CVs, Publication lists and third-party funding). Please adhere strictly to all given page limits for each section.

1. General Information

1.1 Project title (**not more than 160 characters**, including commas and spaces).

1.2 **Lead applicant** (one person)

- First name, surname, academic degree
- Full name of the institution/department where the lead applicant works and the project will be performed
- Postal address
- Telephone and fax number, e-mail address

1.3 **Requested Funding Period** (in months)

1.4 **Hypothesis**

Please describe clearly and concisely (in 2 - 3 sentences) the hypothesis to be tested in this project.

1.5 **Short summary and description** of the planned collaborative project (not more than **2 pages - see below**)

Description of the overall concept and the main focal points of the project (**1 page**). Each subproject can here be very briefly described (**1 page for all subprojects**).

If a non-interventional clinical trial is to be a part of the applied project, please adhere mainly to the guideline for clinical trials (page 13 et seq. point 1 of this guideline; study synopsis). The application will be accepted if longer due to these additional pages.

1.6 **Graphic of Overall Concept** (1 page)

1.6.1 Graphic representation of the overall concept illustrating the interrelationship between all subprojects (by arrows).

1.6.2 Include a graphical timeline below the graph of the overall concept (showing also the start- and endpoints of all subprojects and for the clinical trial also start- and endpoints of all periods/phases of the trial, e.g. start-up-, recruiting-, treatment-, follow-up-phase).

1.7 **Reapplications** (0.5 page)

If your collaborative project was already submitted in an earlier call and you are resubmitting your project, please explain what you have changed since the previous submission. Please add all reviewers' comments and criticisms which were communicated to you before the hearings and respond to these criticisms/comments. If this does not apply to your application, please write 'N.A.'

1.8 Translational aspects of the proposed project
(not more than **0.5 page**)

What are the expected translational aspects of the project? How will scientific findings be translated into clinical practice?

1.9 Long-term research objective(s) of the planned collaborative project
(not more than 0.5 page)

What are the special potential innovation and the long-term perspective for the project (bearing in mind the current status of the research)?

1.10 Status of the planned collaboration in national and international competition
(not more than **2 pages**)

- What are the important national and international developments (or lack of developments) in this area of research?
- How does the planned collaboration fit into the present research landscape? To what extent does it go beyond the current status of this research?
- How does it differ from present research collaborations working on similar themes?

2. Tabular overview of subprojects (1-2 pages)

For each subproject, please give the following:

- Number and title of the subproject
For each applicant:
- First name, surname, academic degree
- Full name of the institution and department where the applicant works*

Please use the following table:

Subproject Nr. and Title	Applicants (with academic degree)	Institution*

*If an applicant has more than one affiliation, please list all affiliations and mark those where the project will be performed.

3. Overview Financial plan (1 page)

Tabular overview of the estimated **total amount** of funding for each subproject and the total amount for the complete funding period. Please note that all contracts/agreements with third parties (e.g for sequencing by companies, licenses for computer programs, software, orders to core-facilities etc.) **go under the rubric 'Other'** and **not 'Consumables'**. Study related examinations e.g. MRI must also be listed under 'Other'.

If you are asked to submit a full proposal, cost estimates for these items and for investments from the third parties will be needed! **Please specify the investments, which you are applying for.**

Please use the following table **in landscape** format:

Subproject	Personnel*	Consumables	Animal Costs	Investments	Travel (For consortium meetings)	Other	Total
Total							

*For personnel costs, please give the title of the position(s) (e.g. Technician, Scientific Assistant, PhD Student, physician) and the salary grade in accordance with the collective agreement for federal state public employees (TV-L). Please use the personnel rates from German Cancer Aid, see **Appendix 1**.

If a requested personnel position is intended to be a part of more than one subproject (part-time position at different subprojects) please mark this personnel position (e. g. with an asterisk) and explain the total amount (time and requested funding) applied for this position and at which applicant's institution it should be located.

Please also note the following when filling out the table:

For reasons of principle, the German Cancer Aid **does not fund overhead costs**.

Funds for **congress or convention trips** cannot be requested separately. However, if a project is approved by the German Cancer Aid, there is a possibility to re-allocate funds. Each subproject may re-allocate up to € 1,000 (cost-neutral) per year for project-related congress attendances with active participation (talk or poster).

Funds for **publication costs** also **cannot** be requested separately. Again, each subproject has the possibility to re-allocate funds, if funding is approved. Up to € 750 per year can be re-allocated for each subproject. The financing of abstracts or reprints is excluded.

4. References

Citation list no longer than **0.5 page**.

5. Appendices: CVs, publication lists and third-party funding for all applicants

For each applicant:

- Current tabular CV (not more than **1 page**)
- Publication list of the **5** most important publications from the last 5 years in chronological order. All authors must be given for the citations in the publication lists. The abbreviation 'et al.' does not suffice. (**0.5 page**)
- Third party funding - current and applied for - of all applicants, giving for each the project title in English (no acronyms), the (potential) source of funds, the duration (exact start and end date of the project in months) and the amount of the financial support. In case of a potential overlap with the current application, please give a short explanation (two sentences) how the projects differ from each other. (**0.5 page**)

6. Confirmation that the application has not been submitted to any other funding organisation together with all signatures of the applicants.

Confirmation using the following declaration:

No equivalent or thematically similar application has been submitted to any other funding organisation or has already been processed and advocated by any other funding organisation. During the processing of this application by the German Cancer Aid, I will not submit any equivalent or thematically similar application to any other funding organisation.



Place, date, and signatures of all subproject applicants. You may use electronic signatures. Please have **all signatures on 1 - 2 pages** starting with the confirmation above. Do not submit the signatures on separate pages.

Project Outline for a combination of a collaborative project and a clinical trial (Phase I/II; CPT)

Important:

Clinical trials in the sense of this priority program are exclusively interventional clinical trials. An application for a non-interventional clinical trial, e. g. diagnostic and observational clinical trial, are eligible but has to be applied as a subproject of a Collaborative Project (CP).

The completed project outline is not to exceed 15 pages (excluding Appendices - CVs, Publication lists and third-party funding). Please adhere strictly to all given page limits for each section.

If you plan to apply funding for a clinical trial, you have to involve an expert in bioinformatics or statistics to verify the case numbers (if this person will not be an applicant the verification must be proven by a signed document).

1. General Information

1.1 **Project title (not more than 160 characters, including commas and spaces).**

1.2 **Lead applicant** (one person)

- First name, surname, academic degree
- Full name of the institution/department where the lead applicant works and the project will be performed
- Postal address
- Telephone and fax number, email address

1.3 **Requested funding period** (in months)

1.4 **Hypothesis**

Please describe clearly and concisely (in 2 - 3 sentences) the hypothesis to be tested in this project.

1.5 **Short summary and description** of the planned collaborative project with a clinical trial (not more than 2 pages - see below)

Description of the overall concept and the main focal points of the project (1 page). Each subproject can here be very briefly described (1 page). **Please include the clinical trial as one subproject.**

1.6 **Study Synopsis of the clinical trial (1 - 3 pages)**

Give a synopsis of your planned clinical trial, **using this tabular form:**

Lead Applicant/Co-applicants of the clinical trial	Name, address, telephone, fax, e-mail If there are multiple applicants*, the principal investigator/coordinating investigator of the trial will assume responsibility for conducting the clinical trial and should be listed first. *If an applicant has more than one affiliation, please list all affiliations and mark those where the project will be performed.
Participating Centers	Name the participating centers involved in the trial

Title of study	(maximum 160 characters, including commas and spaces)
Condition	The medical condition being studied
Objective(s)/Hypotheses	Which principal research questions are to be addressed? Clearly specify the primary hypotheses of the trial that determine sample size calculation.
Intervention(s)	Description of the experimental and the control treatments or interventions, as well as dose and mode of application. For diagnostic tests or procedures, the index test and the reference procedure (gold standard) should be described. Experimental intervention / index test: Control intervention / reference test: Follow-up per patient: Duration of intervention per patient: Number of doses:
Key inclusion, exclusion and withdrawal criteria	Key inclusion criteria: Key exclusion criteria: Key withdrawal criteria:
Conditions for discontinuing the trial	Explain what criteria will be used to determine if the trial should be discontinued.
Outcome(s)	Primary efficacy endpoint: Key secondary endpoint(s): Assessment of safety:
Study design	e. g. Phase I or II or I/II, basket, umbrella, randomized/non-randomized, type of masking (single, double, observer blind), type of controls (active/placebo), parallel group/crossover, prognostic, diagnostic (Note: funding of higher study-phases as I or II are not possible)
Statistical analysis	Efficacy / test accuracy: Description of the primary efficacy / test accuracy analysis and population: Safety: Secondary endpoints:
Trial Drug(s)*	Name the trial drug(s) and how it will be obtained and financed (e.g. name of the pharmaceutical company, over the counter - pharmacy of the university hospital). See also Appendix 4.
Total Patient Numbers	To be assessed for eligibility (n = ...) To be allocated to trial (n = ...) To be analyzed (n = ...)
Study duration (in month) (Give information for <u>all</u> periods listed! <u>The sum of the duration of each period must add up to the total duration of the entire trial (see also 1.7.1)</u>	Set-up period: Recruitment period: First patient in; to last patient out: Treatment period: Follow-up per patient: Total duration of the entire trial: (if total study duration is longer than the requested funding period, please explain why and how it will be financed)
Requested Funding Period	in months (if this period is shorter or longer than the trial duration or the requested funding period for the whole project, please ex-

plain and justify)

***Please be aware, that should the drug(s) come from a pharmaceutical company, an MTA (Material Transfer Agreement) will be needed for the full proposal (please see p. 3). The trial cannot be co-financed by a pharmaceutical company (please see Appendix 4).**

1.7 **Graphic of Overall Concept (1 page)**

1.7.1 Graphic representation of the overall concept illustrating the interrelationship between all subprojects (by arrows).

1.7.2 Include a graphical timeline below the graph of the overall concept (showing also the start- and endpoints of all subprojects and of all periods/phases of the trial, e.g. start-up-, recruiting-, treatment-, follow-up-phase).

1.8 **Reapplications (0.5 page)**

If the project was already submitted in an earlier call and are resubmitted now in a revised form, please explain what you have changed since the previous submission. Please add all reviewers' comments and criticisms which were communicated before the hearings and respond to these criticisms/comments. If this does not apply to the application, please write 'N.A.'

1.9 **Translational aspects** of the proposed study (not more than **0.5 pages**)

What are the expected translational aspects of the project? How will scientific findings be translated into clinical practice?

1.10 **Long-term research objective(s)** of the planned collaborative project with a clinical trial (not more than **0.5 pages**)

What are the special potential innovation and the long-term perspective for the project (bearing in mind the current status of the research)?

1.11 **Status of the planned collaboration in national and international competition** (not more than **2 pages**)

- What are the important national and international developments (or lack of developments) in this area of research?
- How does the planned collaboration fit into the present research landscape? To what extent does it go beyond the current status of this research?
- How does it differ from present research collaborations working on similar themes?

2. **Tabular overview of subprojects (1 - 2 pages)**

List the clinical trial as one of the subprojects. For each subproject, please give the following:

- Number and title of the subproject
For each applicant:
- First name, surname, academic degree
- Full name of the institution and department where the applicant works

Please use the following table:

Subproject Nr. and Title	Applicants (with academic degree)	Institution*

*If an applicant has more than one affiliation, please list all affiliations and mark those where the project will be performed.

3. Overview Financial plan (1 page) - Use Appendix 2

Tabular overview of the estimated **total amount** of funding for each subproject and the total amount for the complete funding period. Please note that all contracts/agreements with third parties (e.g. for sequencing, analyses, licenses for computer programs and software, etc.) **go under the rubric 'Other'** and **not 'Consumables'**. Study related examinations e.g. MRI must also be listed under 'Other'.

If a consortium is asked to submit a full proposal, cost estimates for these items and for investments from the third parties will be needed. **Please specify the investments, which you are applying for.**

Please use the table: **Appendix 2 in landscape format.**

Please also note the following when filling out the table:

For reasons of principle, the German Cancer Aid **does not fund overhead costs.**

Funds for **congress or convention trips cannot** be requested separately. However, if a project is approved by the German Cancer Aid, there is a possibility to re-allocate funds. Each subproject may re-allocate up to € 1,000 (cost-neutral) per year for project-related congress attendances with active participation (talk or poster).

Funds for **publication costs** also **cannot** be requested separately. Again, each subproject has the possibility to re-allocate funds, if funding is approved. Up to € 750 per year can be re-allocated for each subproject. The financing of abstracts or reprints is excluded.

4. References

Citation list no longer than **0.5 page.**

5. Appendices: CVs, publication lists and third-party funding for all applicants

For each applicant:

- Current tabular CV (**1 page**)
- Publication list of the 5 most important publications from the last 5 years. All authors must be given for the citations in the publication lists. The abbreviation 'et al.' does not suffice. (**0.5 page**)
- Third party funding - current and applied for - of all applicants, giving for each the project title in English (no acronyms), the (potential) source of funds, the duration (exact start and end date of the project in months) and the amount of the financial support. In case of a potential overlap with the current application, please give a short explanation (two sentences) how the projects differ from each other. (**0.5 page**)

6. Confirmation that the application has not been submitted to any other funding organisation together with all signatures of the applicants.



Confirmation using the following declaration:

No equivalent or thematically similar application has been submitted to any other funding organisation or has already been processed and advocated by any other funding organisation. During the processing of this application by the German Cancer Aid, I will not submit any equivalent or thematically similar application to any other funding organisation.

Place, date, and signatures of all subproject applicants. You may use electronic signatures. Please have **all signatures on 1 - 2 pages** starting with the confirmation above. Do not submit the signatures on separate pages.

Project Outline for clinical studies (Phase I/II; T)

Important:

Clinical trials in the sense of this priority program are exclusively **interventional clinical trials**. An application for a non-interventional clinical trial, e. g. diagnostic and observational clinical trial, are eligible but has to be applied as a subproject of a Collaborative Project (CP).

The completed project outline is not to exceed 10 pages (excluding Appendices - CVs, Publication lists and third-party funding). Please adhere strictly to all given page limits for each section.

If you plan to apply funding for a clinical trial, you have to involve an expert in bioinformatics or statistics to verify the case numbers (if this person will not be an applicant the verification must be proven by a signed document).

An application can be made to the German Cancer Aid for a research grant for performing non-commercial science-driven cancer therapy studies ('Investigator Initiated Trials'). Please note the following:

- If a study is supported by the German Cancer Aid, the only permissible form of support from industrial partners is the free provision of the test substance. The project management must disclose financial support for the study to the German Cancer Aid in the application and at any time during the course of the study. Written agreements with industrial partners must be attached to the application documents. The project management must have exclusive ownership of all data. The design, conduct, recording and reporting of the clinical trial has to be under the control of the project management.
- Outlines and applications for funding study projects cannot be included in the evaluation procedure if recruitment has started before application or is to be started during the application procedure.
- The outlines **must** be written according to the following template:

1. Study Synopsis (1-3 pages)

Give a synopsis of your planned study, **using this tabular form**:

Lead Applicant (one person) Co-applicants	Name, address, telephone, fax, e-mail If there are multiple applicants*, the principal investigator/coordinating investigator of the trial will assume responsibility for conducting the clinical trial and should be listed first . *If an applicant has more than one affiliation, please list all affiliations and mark those where the project will be performed.
Participating Centers	Name the participating centers involved in your trial
Title of study	(maximum 160 characters, including commas and spaces)
Condition	The medical condition being studied
Objective(s)/Hypotheses	Which principal research questions are to be addressed? Clearly specify the primary hypotheses of the trial that determine sample size calculation.
Intervention(s)	Description of the experimental and the control treatments or interventions, as well as dose and mode of application. For diagnos-

	<p>tic tests or procedures, the index test and the reference procedure (gold standard) should be described.</p> <p>Experimental intervention / index test:</p> <p>Control intervention / reference test:</p> <p>Follow-up per patient:</p> <p>Duration of intervention per patient:</p> <p>Number of doses:</p>
Key inclusion, exclusion and withdrawal criteria	<p>Key inclusion criteria:</p> <p>Key exclusion criteria:</p> <p>Key withdrawal criteria:</p>
Conditions for discontinuing the trial	<p>Explain what criteria will be used to determine if the trial should be discontinued.</p>
Outcome(s)	<p>Primary efficacy endpoint:</p> <p>Key secondary endpoint(s):</p> <p>Assessment of safety:</p>
Study design	<p>e. g. Phase I or II or I/II, basket, umbrella, randomized/non-randomized, type of masking (single, double, observer blind), type of controls (active/placebo), parallel group/crossover, prognostic, diagnostic</p>
Statistical analysis	<p>Efficacy / test accuracy:</p> <p>Description of the primary efficacy / test accuracy analysis and population:</p> <p>Safety:</p> <p>Secondary endpoints:</p>
Trial Drug(s)*	<p>Name the trial drug(s) and how it will be obtained and financed (e.g. name of the pharmaceutical company, over the counter - pharmacy of a university hospital). See also Appendix 4.</p>
Total Patient Numbers	<p>To be assessed for eligibility (n = ...)</p> <p>To be allocated to trial (n = ...)</p> <p>To be analyzed (n = ...)</p>
Study duration (in month) (Give information for <u>all</u> periods listed! <u>The sum of the duration of each period must add up to the total duration of the entire trial.</u>)	<p>Set-up period:</p> <p>Recruitment period:</p> <p>First patient in to last patient out:</p> <p>Treatment period:</p> <p>Follow-up per patient:</p> <p>Total duration of the entire trial: (if total study duration is longer than requested funding period, please explain why and how it will be financed)</p>
Requested Funding Period	<p>in months (if this period is shorter or longer than the trial duration or the requested funding period for the whole project, please explain and justify)</p>

*Please be aware, that should the drug(s) come from a pharmaceutical company, an MTA (Material Transfer Agreement) will be needed for the full proposal (please see p. 3). The trial cannot be co-financed by a pharmaceutical company (please see Appendix 4).



1.1 Reapplications (0.5 page)

If your collaborative project was already submitted in an earlier call and you are resubmitting your project, please explain what you have changed since the previous submission. Please add all reviewers' comments and criticisms which were communicated to you before the hearings and respond to these criticisms/comments. If this does not apply to your application, please write 'N.A.'

1.2 Intervention scheme/trial flow/Clinical trial schedule/Timeline (1 page)

1.2.1 Schematic diagram (flow chart)

Describe the intervention scheme and give a schematic diagram (flow chart) of design, procedures and stages (trial schedule, clinical follow-up plan).

1.2.2 Include a graphical timeline below the graph of the schematic diagram (showing also the start- and endpoints of all periods of the trial e.g. start-up-, recruiting-, treatment-, follow-up-phase).

1.3 Frequency and scope of study visits (0.5 page)

What is the proposed frequency and scope of study visits and, if applicable, the duration of post-trial follow-up? Please also give a table with time points of visits and procedures per time-point. Specify items to be recorded CRF per procedure.

2. The medical problem (0.5 page)

- Which medical problem is to be addressed?
- What is the novel aspect of the proposed trial?
- Which principal research questions are to be addressed? Bring them into order indicating major and minor motivations / starting hypotheses of the investigation planned.

2.1 Evidence (0.5 page)

Set your trial into perspective. This section should give the detailed background of the starting hypotheses and the feasibility of the trial.

- Which trials have been conducted either by you or by others? What is the relevance of their results? Give references to any relevant systematic review(s) and/or (your own) pilot studies, feasibility studies, relevant previous/ongoing trials, case reports/series. State what your study adds to the overall evidence, in the context of previous work. Include a description of how you searched for evidence (databases, search terms, limits) and how you assessed its quality - i.e., how you selected and how you combined the evidence. If any relevant evidence is not included, the project will not be funded.

2.2 The need for a trial (0.5 page)

- How significant is the trial in terms of its potential impact on relieving the burden of disease and/or improving human health?
- What impact will the results have on clinical practice?
- How will the individual patient benefit from the trial? Describe any potential commercial interest of a company in the results of the trial or explain why no such interest exists. If a company has direct commercial interest in the results of the trial, funding of the project could be rejected (please see Appendix 4).



2.3 Feasibility of recruitment (0.5 page)

What is the evidence that the intended recruitment rate is attainable (e.g. pilot study)? Describe the data you used to assess the potential for recruiting the required number of suitable subjects.

3. Statistical analysis (0.5 page)

- What is the proposed strategy of statistical analysis?
- What is the strategy for analyzing the primary outcome? If interim analyses are planned, please specify.
- Are there any subgroup analyses?

4. Ethical considerations (0.5 page)

Briefly discuss the acceptability of the risk incurred by the individual participant versus the potential benefit for the participant/population concerned.

5. Overview Financial plan (1 page) - Use Appendix 3

Tabular overview of the estimated **total amount** of funding for each subproject and the total amount for the complete funding period. Please note that all contracts/agreements with third parties (e.g. for sequencing, analyses, licenses for computer programs and software, etc.) **go under the rubric 'Other'** and **not 'Consumables'**. Study related examinations e.g. MRI must also be listed under 'Other'.

If you are asked to submit a full proposal, cost estimates for these items and for investments from the third parties will be needed. **Please specify the investments, which you are applying for.**

Please use the table: **Appendix 3** in **landscape format**.

Please also note the following when filling out the table:

For reasons of principle, the German Cancer Aid **does not fund overhead costs**.

Funds for **congress or convention trips cannot** be requested separately. However, if a clinical trial is approved by the German Cancer Aid, there is a possibility to re-allocate funds. The clinical trial may re-allocate up to € 1,000 (cost-neutral) per year for project-related congress attendances with active participation (talk or poster).

Funds for **publication costs** also **cannot** be requested separately. Again, clinical trial has the possibility to re-allocate funds, if funding is approved. Up to € 750 per year can be re-allocated. The financing of abstracts or reprints is excluded.

6. References

Citation list no longer than **0.5 page**.

7. Appendices: CVs, publication lists and third-party funding of all applicants

For each applicant:

- Current tabular CV (**1 page**)
- Publication list of the 5 most important publications from the last 5 years. All authors must be given for the citations in the publication lists. The abbreviation 'et al.' does not suffice. (**0.5 page**)
- Third party funding - current and applied for - of all applicants, giving for each the project title in English (no acronyms), the (potential) source of funds, the duration (exact start and

end date of the project in months) and the amount of the financial support. In case of a potential overlap with the current application, please give a short explanation (two sentences) how the projects differ from each other. **(0.5 page)**

- 8. Confirmation** that the application has not been submitted to any other funding organisation together with all signatures of the applicants.

Confirmation using the following declaration:

No equivalent or thematically similar application has been submitted to any other funding organisation or has already been processed and advocated by any other funding organisation. During the processing of this application by the German Cancer Aid, I will not submit any equivalent or thematically similar application to any other funding organisation.

Place, date, and signatures of all subproject applicants. You may use electronic signatures. Please have all signatures on 1 - 2 pages starting with the confirmation above. Do not submit the signatures on separate pages.

Additional Comments

- No legal claim for funding can be derived from the submission of an application. The applicant has no claim that a submitted application should be returned.
- The German Cancer Aid retains the right to check for duplicate funding by providing other external funding sources with the applicant's information (name, theme and objective of the project).
- The acceptance of a research grant obligates the funding recipient to comply with the rules of Good Scientific Practice. The rules of Good Scientific Practice are described in detail in the user guidelines for research funds from the German Research Foundation (DFG pre-prints 2.01 and 2.02). In the event of scientific misbehavior, sanctions can be concluded. In particular, scientific misbehavior is present when false information is provided deliberately or with gross negligence in a context of considerable scientific importance, or the intellectual property of others is violated or their research work is impaired. The circumstances of the individual case are always decisive.

Contact

Your contacts are:

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Appendix 1: Personnel Rates of German Cancer Aid 2024

Vergütungsgruppe nach TV-L	Ab 2024 p.a.
E 1	38.200,00 €
E 2	45.900,00 €
E 3	48.700,00 €
E 4	50.300,00 €
E 5	52.300,00 €
E 6	54.300,00 €
E 7	55.800,00 €
E 8	58.600,00 €
E 9	62.800,00 €
E 10	74.700,00 €
E 11	78.800,00 €
E 12	85.300,00 €
Doktorand/in (E 13, 65 %)	58.175,00 €
E 13	89.500,00 €
E 14	96.200,00 €
E 15	105.900,00 €
E 15Ü	127.000,00 €
Professuren	
W2	109.200,00 €
W3	120.600,00 €

Ärzte	Ab 2024 p.a.
Ä1/1-6	102.300,00 €
Ä2/1-6	136.300,00 €
Ä3/1-3	158.100,00 €
Ä4/1-3	185.900,00 €
Hilfskraftstellen	Stundenlohn
Stud. HK *	15,00 € / Stunde
Wiss. HK *	21,00 € / Stunde

* Für Hilfskräfte werden die Anzahl der Stunden pro Woche auf den Monat mit 4 Wochen und auf das Jahr mit 12 Monaten berechnet.

Appendix 2: Overview Financial Plan: Combination of a Collaborative Project and a Clinical Trial (Phase I/II)

Subproject	Personnel*	Consumables	Animal Costs	Investments	Travel	Other			Total
Subproject 1									
Subproject 2									
	Personnel*	Documentation	Monitoring**	Pharmacovigilance	Patient Insurance	Other	Trial Drug	Fees (Ethic committees and Federal Authorities)	
Subproject X Clinical Trial									
Total									

Note:

*For **personnel costs**, please give the title of the position(s) (e.g. Technician, Scientific Assistant, PhD Student, physician) and the salary grade in accordance with the collective agreement for federal state public employees (TV-L) - **Appendix 1**.

If a requested personnel position is intended to be a part of more than one subproject (part-time position at different subprojects) please mark this personnel position (e. g. with an asterisk) and explain the total amount (time and requested funding) applied for this position and at which applicant's institution it should be located.

****Monitoring costs** should **include** travel costs. If the monitoring costs are calculated by case numbers, the required personnel for monitoring can be included under monitoring costs. If this is the case, please give a short explanation for this and mention the estimated money calculated per case (1-2 sentences).

Appendix 3: Overview Financial Plan: Clinical Trial (Phase I/II)

	Personnel*	Documentation	Monitoring**	Pharmacovigilance	Patient Insurance	Other	Trial Drug	Fees (Ethic committees and Federal Authorities)	Total
Clinical Trial									
Total									

Note:

*For **personnel costs**, please give the title of the position(s) (e.g. Technician, Scientific Assistant, PhD Student, physician) and the salary grade in accordance with the collective agreement for federal state public employees (TV-L) - **Appendix 1**.

If a requested personnel position is intended to be a part of more than one subproject (part-time position at different subprojects) please mark this personnel position (e. g. with an asterisk) and explain the total amount (time and requested funding) applied for this position and at which applicant's institution it should be located.

****Monitoring costs** should **include** travel costs. If the monitoring costs are calculated by case numbers, the required personnel for monitoring can be included under monitoring costs. If this is the case, please give a short explanation for this and mention the estimated money calculated per case (1-2 sentences).

Appendix 4: Co-operation with Industries

Conditions, which must be fulfilled, when the execution of the clinical trial or research project is essentially dependent on a substance or service produced and provided by a company:

1. Studies, which are the focus and interest of the industry (e.g. pharmaceutical industry, manufacturers of medical products), are excluded from funding. Please explain or let the company explain why the clinical trial is not in the focus or interest of the company. An appropriate letter from the company with a statement regarding this would be beneficial.
2. It must be clearly shown that the study project could not be executed without the support of the German Cancer Aid (sole financing by company not possible).
3. During the entire study period, the study management must be prepared to reveal the complete project financing to the German Cancer Aid at any time (transparency).
4. Industrial partners are not allowed to influence the study design or execution (no contract research). Nor are they to influence the evaluation and publication of the study results (publication rights).
5. The study management must have data sovereignty and exploitation rights of the results.

Please note: Written agreements with industrial partners (e.g. Material Transfer Agreement) must be attached to full applications **not** to project outlines.