

Priority programme 'German Pancreatic Cancer Alliance'

Guidelines for Letter of Intent / Project Outline

1 Introduction

Pancreatic cancer with its very unfavourable prognosis is still one of the most urgent unsolved problems in cancer research/cancer treatment. According to a group of experts appointed by Deutsche Krebshilfe, progress can only be achieved with a substantial, targeted and focussed initiative to promote research (basic research, translational research).

A core activity of the initiative is the creation of a comprehensive network of experts ('**German Pancreatic Cancer Alliance**'). This network will unite scientists from Germany and abroad with the aim to exchange research results and jointly develop strategies for tackling and answering the unresolved questions in the fight against pancreatic cancer. To this end, a coordinating centre financed by Deutsche Krebshilfe and an umbrella structure (research and data platform) is to be set up. This structure is intended to create a framework to unite current research results and information on experimental technologies in a targeted manner and provide it to all network partners. This could generate a constantly growing wealth of knowledge and experience with the aim to accelerate the acquisition of knowledge on pancreatic cancer and develop concepts for pioneering research strategies - also beyond the 'mainstream'.

The structure and governance of the research alliance - managed by a scientific/medical project coordinator - should be regulated in rules of procedure/statutes. If necessary, a separate legal form/support structure (gGmbH, e. V. or similar) should be created for the research alliance. The research alliance should be coordinated by an interdisciplinary and transdisciplinary steering committee that represents all necessary specialisations/disciplines. This body will support and advise the coordination centre. To anchor career development as an integral part of the alliance, young investigators should be part of this committee. The activities of the research alliance should be supported by an external, international Scientific Advisory Board (SAB).

A further key component of the Deutsche Krebshilfe initiative on pancreatic cancer is the funding of innovative, groundbreaking, interdisciplinary research networks.

To establish the research alliance, as a first step, three to five interdisciplinary collaborative scientific projects will be funded as part of a 5-year initiation phase of the programme. Once an international panel of experts has selected the collaborative projects for funding, the project leaders are expected to jointly develop a concept for the research platform and coordinating centre. This concept will be reviewed by the expert panel as well. An active participation in the research alliance is mandatory for all grantees.

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3 General Comments/Procedure

3.1 General Comments

Scientific collaborative projects/consortia

The consortium-application and the cooperation of the participating working groups must be seen as providing a clear added value/benefit in contrast to single project applications ('synergy effect'). It must be demonstrated for each sub-project of a collaborative project that it makes a significant contribution to the joint research objective. Similar scientific interests are not sufficient. The quality and originality of collaborative projects must meet the highest standards.

National and international collaborative projects are funded. One of the applicants located in Germany represents the collaborative group as lead applicant and is to be the only contact person for all correspondence and dealings with the Deutsche Krebshilfe. Scientific partners/working groups from abroad can be integrated in the consortia as cooperation partners or with individual sub-projects (one subproject from abroad per consortia). In general, the research work of the international partners should be financed by their home institution or by a responsible funding organisation abroad. However, if international project leaders do not have sufficient funding to conduct the project and are unable to obtain money from a funding organisation in their own country, funding of international project costs is possible. The prerequisite for this is

a) that the research institution of the international project leader must conduct independent research. Universities and publicly funded research institutes that do not impose restrictions on publishing are generally regarded as such. Commercial institutions abroad are not eligible for funding.

b) scientific excellence, convincing thematic integration into the overall concept and clear added value for the collaborative research area.

Deutsche Krebshilfe provides the funds to the grant recipient in Germany in accordance with its standard procedures. The recipient then forwards the funds allocated for the international project component to the international project leaders. Project leaders in Germany are solely responsible to the Deutsche Krebshilfe for project implementation according to plan and for the proper use of funds.

Clinical studies (Phase I/II)

If you plan to integrate non-commercial science-driven innovative cancer therapy studies ('Investigator Initiated Trials') please contact the office of Deutsche Krebshilfe (Dr. Matejka: 0228/72990202; matejka@krebshilfe.de). Note: funding of higher study-phases as I or II are not possible.

Pancreatic cancer database

As part of the 'German Pancreatic Cancer Alliance' research and patient data will be collected in a pancreatic cancer database, that will be established once the collaborative projects have been selected for funding. There will be additional information concerning the prerequisites for shared data use and exchange later. Make sure to comply with the standards of the Medical Informatics Initiative Germany (MII). Necessary commitments for sharing research and patient data need to be considered while planning the collaborative project.

Formal information on submitting an application

- Formally incomplete applications cannot be included in the review process.
- Project plans in whose results profit making organisations have a direct economic interest are excluded from funding.
- The call for proposals is aimed at university and non-university research institutions. Members of profit-making organisations or from persons not permitted to publish results in a generally accessible form are not eligible to apply.

Information on the processing of personal data

Information on the handling of your personal data can be found on our website at www.krebshilfe.de/datenschutz and on the corresponding form attached (see 7.3). The form - signed by all applicants - must be enclosed with the application documents. You can also find the form on our website (<https://www.krebshilfe.de/forschen/formulare-merkblaetter/antragstellen/>.)

Safety and other evidence for products and software solutions used (if applicable)

It must be ensured that all products and software solutions used in the project fulfil the legal specifications and requirements before they are used. If, for example, the application of medical device law comes into consideration, it must be clarified in advance with the competent authorities of the federal states and/or a notified body whether the product or software solution to be used qualifies as a medical device within the meaning of Article 2(1) of Regulation (EU) 217/45 (MDR). The corresponding proof of safety (e.g. CE conformity labelling if medical device law applies) should generally already be available when the application is submitted or a timetable should be provided for when this will be available. If digital health applications within the meaning of Section 33a SGB V are used, proof of provisional or permanent inclusion in the list of digital health applications in accordance with Section 139e SGB V must be enclosed.

Science communication and open access

Funding recipients are required to plan and present suitable measures for science communication in connection with their research process and research results. Collaborative partners should develop a joint strategy for science communication and coordinate it with the coordinating centre. Deutsche Krebshilfe encourages funding recipients to make their results publicly available via open access publication. Quality-assured or professionally recognised open access journals or open access platforms are suitable for this purpose.

3.2 Procedures

Review process and deadlines

The application/assessment procedure is a three-step process:

1. Applicants must inform the Deutsche Krebshilfe by **April 30th, 2024** that they plan to submit an application (Letter of Intent).
2. Project outlines must be submitted to Deutsche Krebshilfe by **June 14th, 2024** at the latest.
3. The submission deadline for full applications (with a favourable preliminary evaluation) will be announced.

Please submit all required documents by e-mail only to:
pankreas@krebshilfe.de

Other forms of submission (e.g. by post or fax) will not be accepted or included in the review process.

Within two weeks of receipt of the Letter of Intent and project outline respectively, the lead applicant will receive a written confirmation of receipt. If you fail to receive a confirmation of receipt, please send an e-mail to the Funding Department of the Deutsche Krebshilfe (pankreas@krebshilfe.de), giving the full project title and your telephone number.

The project outlines and applications submitted will be evaluated by an international committee of experts. For this reason, all project outlines and applications must be in English.

If you have any questions, please contact Dr. Matejka (0228/72990202; matejka@krebshilfe.de). It is recommended that you contact the office for advice and explanation.

Assessment criteria

The applications received will be assessed and reviewed according to the following criteria:

- Scientific quality (innovative research beyond the mainstream/realisation of visions; development and application of new technologies)
- Prior achievements and expertise of the applicants
- Coherence and synergies (integration of disciplines outside oncology as far as possible 'inter- and transdisciplinarity')
- Translational potential
- International visibility

4 Letter of Intent

The letter of Intent must be sent via e-mail to the following address:

pankreas@krebshilfe.de (one PDF document, not exceeding 8 MB), subject: FSP German Pancreatic Cancer Alliance - Letter of Intent.

Please note that this Letter of Intent is a prerequisite for submission of an application, i.e. project outlines will only be accepted from applicants who submitted a Letter of Intent earlier.

Letters of Intent are not reviewed but are merely used to prepare the review process.

The Letter of Intent must contain the information listed below. Address all points mentioned in the guidelines, repeating all section numbers / letters, as well as the complete section titles. Please use font size 11 (Arial) and single line spacing (see 7.1 for a template).

4.1 Applicants

The following information is needed for the **lead and all co-applicants**. Please give the name of the lead applicant, who is the speaker of the consortium and the contact person for correspondence with the Deutsche Krebshilfe first:

- First name, surname, academic degree
- Full name of the institution at which the coordinator works
- List of all co-applicants and the full name of their participating centres/institutions

Please inform us immediately of any changes to your contact details.

4.2 Project title (maximum 160 characters, including commas and spaces)

4.3 Key words

4.4 Information on the processing of personal data

Please include and sign form 7.3 'Information on the processing of your personal data'

4.5 Signature

The Letter of Intent needs to be signed by the lead applicant only.

No legal entitlement to funding can be derived from the submission of a Letter of Intent. Applicants have no legal claim to the return of a submitted Letter of Intent.

5 Project outline

The submission of a draft application is only possible if the intention to submit an application has been declared in due time.

The project outline 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.

The completed project outline should not exceed 12 pages (DIN A4 format, font size 11 (Arial)) excluding appendices (CVs, publication lists and third-party funding). Please adhere strictly to the specified page limits for each section.

The application documents must contain the information listed below. Address all points mentioned in the guidelines, repeating all section numbers / letters, as well as the complete section titles. Start the project outline with a table of contents and indicate the page numbers.

After reviewing and evaluating the project outlines, the expert committee selects the most promising concepts. The respective applicants are given the opportunity to further develop their concepts and submit a full application.

5.1 General information

5.1.1 Applicants

Deutsche Krebshilfe assumes that the funding for the positions of all applicants is secured until the end of the funding period applied for. The following information is required from all applicants (please name the lead applicant first):

- First name, surname, academic degree
- Full name of the institution
- Postal address
- Telephone number, e-mail address

Please inform us immediately of any changes to your contact details.

5.1.2 Project title

Please state the project title here in English and German (maximum 160 characters, including commas and spaces).

Please note that the project title in a full proposal, that may be submitted following a positive review of a project outline, can generally no longer be changed.

5.1.3 Requested Funding Period (maximum 5 years).

5.2 Project description

5.2.1 Hypothesis

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

5.2.2 Short summary and description of the planned collaborative project (not more than **2 pages**)
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**).

What is the particular innovation potential and long-term perspective of the collaborative project (taking into account the current state of research)? Explain why the question can only be answered through close cooperation between the working groups involved in the collaborative project ('necessity of cooperation between the working groups'): What contribution does each working group make to the overall objective of the consortium? What are the strengths of the individual working groups? How do they support/complement each other?

5.2.3 Project Summary (universally understandable, e. g. by patients, layperson) (**1 page**)
Please give a short description of the whole project, including the aims and objectives.

5.2.4 Graphic of Overall concept (1 page)

Graphic representation of the overall concept illustrating the interrelationship between all subprojects (by arrows). Include a graphical timeline below the graph of the overall concept (showing also the start- and endpoints of all subprojects).

5.2.5 Translational aspects (0.5 page)

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

5.2.6 Long-term research objective(s) of the planned collaborative project (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)?

5.2.7 Planned national and international collaborations

Please only specify those scientists or physicians with whom specific collaboration exists or will exist for this project. Use existing (infrastructure) structures / existing networks / cooperation partners in Germany and abroad and avoid the establishment of parallel structures.

Please include (as an appendix to the proposal) a written agreement of cooperation for each partner, which must state the content of the project-specific cooperation (see 7.2 for a template).

5.3 Tabular overview of the sub-projects (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

Note, that at least one junior research group leader must be involved with his/her own subproject.

Please use the following table:

| Subproject No. and title | Applicant (with academic degree) | Institution |
|--------------------------|----------------------------------|-------------|
| | | |
| | | |
| | | |
| | | |

5.4 Patient Involvement (0.5 page)

It is recommended to involve patient representatives at an early stage, e.g. in the conceptual design of the project and the definition of patient-relevant endpoints. Please describe how patient participation is to be implemented in the project and which roles and tasks the patient representatives will fulfil.

5.5 Consideration of gender aspects and diversity.

The relevance of sex and/or gender and diversity of the target groups for the programme must be examined. It must be explained how these aspects are appropriately addressed in the programme. If the aspects of diversity and/or sex/gender are not considered relevant for the programme, this must be (briefly) justified.

5.6 Data protection (if applicable)

Brief description of the data protection concept and appointment of a qualified internal or external data protection officer.

5.7 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, 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/services from the third parties will be needed.

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

| Subproject | Personnel | Consumables | Animal costs | Investments | Travel | 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 also note the following when filling out the table:

For reasons of principle, the Deutsche Krebshilfe does not fund overhead costs.

Funds for congress or convention trips cannot be requested separately. However, if a project is approved by the Deutsche Krebshilfe, 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.

5.8 References

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

5.9 Applicants' expertise

Presentation of the applicants' expertise in relation to the proposed project.

For each applicant:

- Current tabular CV (not more than **1 page**)
- Publication list of the **7** 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**). It is not possible to include works that are still in preparation or have only been submitted.
- Third-party funding - current and applied for - from all applicants, stating the project title in English (no acronyms), the (potential) third-party funding providers, the duration and the amount of financial support. Please differentiate the project you are applying for to Deutsche Krebshilfe from other third-party funding in terms of content and funding (both from projects already funded and from projects applied for) (**0.5 page**).

5.10 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 Deutsche Krebshilfe, I will not submit any equivalent or thematically similar application to any other funding organisation.

In order to exclude the possibility of double funding, the Deutsche Krebshilfe reserves the right to submit enquiries to other funding organisations, stating the names of the applicants, the project title and the summary.

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.

5.11 Appendices (if applicable)

- A confirmation from the management of the institution at which the project applied for funding is to be carried out, stating that it has been informed of the application and agrees to the project being carried out with the participation of the applicant (such a confirmation does not need to be submitted by the clinic or institute management if the applicant holds this position). If the project is to be carried out at several institutions, corresponding confirmations must be submitted by all clinic or institute management if necessary.
- Signed confirmations of cooperation (see 7.2)
- The 'Information on the processing of personal data' form signed by each applicant (see 7.3)

6 Full Application

The Deutsche Krebshilfe office will provide you with information on submitting a completed application later. The 'full application' must only be submitted after a positive evaluation of the project outline.

7 Forms

Status: March 2024

7.1 Template Letter of Intent

Stiftung Deutsche Krebshilfe
Abteilung Förderung
Buschstraße 32
53113 Bonn
pankreas@krebshilfe.de

Letter of Intent for the Priority programme 'German Pancreatic Cancer Alliance'

Ladies and Gentlemen,

With this letter, we are declaring our intention to submit an application for the priority programme 'German Pancreatic Cancer Alliance'.

1. Applicants

- a. First name, surname, academic degree
- b. Full name of the institution
- c. Postal address
- d. Telephone number, e-mail address

2. Project title

3. Key words

Yours sincerely

Place, date

Lead applicant

Attachment:

Form for the processing of personal data signed by all applicants.

7.2 Cooperation agreement

Priority programme 'German Pancreatic Cancer Alliance', Cooperation agreement for the project outline by XXX (lead applicant) with the title "XXX"

Ladies and Gentlemen,

I (we) hereby confirm the following cooperation for the above project outline:

1. name and professional address of cooperation partner
2. content of the cooperation/offered services of the cooperation partner/if applicable, division of tasks within the cooperation
3. duration of the cooperation

Yours sincerely

Place, date

Cooperation partner

7.3 Information on the processing of your personal data

The Deutsche Krebshilfe takes the protection of your personal data very seriously. Therefore, we would like to inform you which personal data we will collect and process according to the respective purpose.

What is meant by personal data?

“Personal data” is any information relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.” (GDPR Art. 4 – Definitions, 1).

When assessing your application, we process your data in accordance with Article 5 and Article 6(1) (points a, f); Article 6(4) GDPR. These are for example:

- First name, surname, academic degree, date of birth
- Full name of the institution
- Postal address
- Phone and fax numbers, e-mail address, etc.

We expressly would like to point out that your personal data will be stored for scientific and historical research purposes or for statistical purposes. In addition, your documents will be forwarded to external reviewers. In order to exclude the possibility of double funding, the Deutsche Krebshilfe reserves the right to submit requests to other funding organisations using the names of the applicants and the title of the project. We would also like to inform you that we will provide details of approved funding projects in our annual report as well as on our website. In this respect, it is important that you also give your consent by signing this leaflet at the bottom. (GDPR Art. 6(1) and 6(4); German Federal Data Protection Act – BDSG § 49).

We would also like to inform you of your right of objection in accordance with GDPR Art. 21(4) and 21(6).

The responsible body in accordance with data protection law is the Stiftung Deutsche Krebshilfe, Buschstr. 32, 53113 Bonn. You can also contact our Data Protection Officer there. For more information, including your rights to access, rectification and complaint please visit www.krebshilfe.de/datenschutz.

Place, date

Signature of all applicants