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Priority Programme

'Long-term Cancer Survivorship - Data Collection and Data Analysis' Applicants' Guidelines

Background

In Germany, there are currently around 5 million people living with or beyond cancer. The majority (~3.5 million) are long-term cancer survivors, i. e., having survived 5 years and more after diagnosis. These survivors are a heterogeneous group of individuals who have to deal with physical, psychological and social long-term and late effects of their disease and therapy and have different health needs. However, these needs of long-term cancer survivors, which can be specific and complex, are not yet adequately and systematically addressed.

Due to this situation the topic of long-term cancer survivorship was addressed in the so called 'National Cancer Plan' (Nationaler Krebsplan). The National Cancer Plan was launched in 2008 jointly by the Federal Ministry of Health (BMG), the German Cancer Aid, the German Cancer Society and the Working Group of German Tumor Centers. In 2018 an expert group within the National Cancer Plan has examined the complex care situation for long-term cancer survivors in Germany and has developed two recommendation papers for funding measures to close knowledge gaps as a prerequisite for a needs-based and target group-oriented further development and optimization of care for long-term survivors with and after cancer (more information on this is available on the BMG-website (link). Therefore, this call for applications by the German Cancer Aid results from the joint efforts in the National Cancer Plan.

Objectives

With the aim of improving the data basis for a follow-up care considering individual risk profiles and needs of long-term cancer survivors, German Cancer Aid has launched a funding priority programme 'Long-term Cancer Survivorship - Data Collection and Data Analysis'. The programme is budgeted at 3 million €.

The main topics of interest of this funding programme are:

- **Clinical epidemiological studies of long-term and late effects:**
- Survey and quantitative description of the risk for long-term and late effects of long-term survivors after cancer with a detailed analysis on the occurrence of physical and psychosocial long-term and late effects.
- Analysis of physical, psychological and social long-term and late effects with a particular focus on new therapy modes (e. g., immune and stem cell therapies), for which long-term and late effects are currently not well known. New insights with high clinical relevance should be preferably generated by ambi- and/or (ongoing) prospective cohorts.
- **Elaboration of evidence-based models of risk stratification regarding risk-modifying and needs-based services and development of screening measures:**
- Identification of risk factors and development of reliable and valid screening instruments regarding the development of late and long-term sequelae in long-term survivors.
- Development of evidence-based models for monitoring long-term and late effects of different groups of long-term survivors, including appropriate screening tools.

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Research proposals on the above-mentioned topics should take the bio-psycho-social model of the development and maintenance of disease and long-term consequences into account. It is therefore necessary to consider potential interactions at and between these three levels, moderator and mediator effects and the normal aging process. Lifestyle factors should be addressed as possible influencing factors in addition to clinical and sociodemographic factors in project plans.

Submitted applications are expected to take participatory approaches into account to ensure that the projects address relevant cancer survivors' needs.

Research questions should ideally be addressed by interdisciplinary collaborative working groups ('Verbundprojekte'). However, innovative relevant questions can also be investigated by single working groups or collaborative working groups in the same field of knowledge.

Funding will be granted for a period of 3 years.

Notes

Since the setup of a high-quality prospective long-term study requires a long study period, preferable - but not exclusive - candidates for study designs are:

- Clinical and population-based observational studies with long-term follow-up of (as far as possible) unselected survivor groups; in particular, cohorts that allow a differentiation between cancer survivors and cancer-free individuals as a control group.
- Studies with long-term follow-up of patients initially enrolled in clinical trials in order to link detailed treatment data with relevant outcomes (e. g., health-related quality of life, late and long-term effects).
- Projects including the analysis of secondary data e. g., with respect to the occurrence of other diseases, rehospitalization rates, as well as the utilization rates and (long-term) outcome of rehabilitation measures, etc.
- Systematic reviews on the aforementioned questions

In each case, the relevant specific methodological limitations, such as selection bias (i. e., Neyman bias, healthy volunteer bias) and confounding, are to be addressed. Adequate solutions to overcome these potential limitations should be provided. Projects are encouraged to use existing data (in order to minimize unnecessary data collection and documentation in duplicate) but legal restrictions with respect to data privacy and data availability should be scrutinized beforehand.

Application procedure

The procedure for application and evaluation consists of three steps:

1. Prospective applicants must submit a letter of intent to German Cancer Aid by March 23, 2023 (via e-Mail). Timely submission of a letter of intent is required for submission of a short proposal.
2. Short proposal must be submitted by April 21, 2023 (via e-Mail and postal delivery).
3. If the preliminary evaluation is favourable, full applications can be submitted to German Cancer Aid (via e-Mail and postal delivery). The according deadline will be announced in time.

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

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Please submit all required documents
- by e-mail (each time in one PDF document, not exceeding 8 MB) to foerderung@krebshilfe.de with subject: Priority Programme 'Long-term Cancer Survivorship - Data Collection and Data Analysis' and
- by post (short proposals and full applications) to the office of German Cancer Aid:

Stiftung Deutsche Krebshilfe
Abteilung Förderung
Buschstraße 32
53113 Bonn

Within two weeks of receipt of the documents by the Cancer Aid Office, the applicant/principal investigator will receive a written confirmation of receipt, together with a reference number. If you fail to receive confirmation of receipt, please send an e-mail to the Funding Department of German Cancer Aid (foerderung@krebshilfe.de), giving the full project title and your telephone number.

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 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.

If you have any questions, please contact:
Niklas M. Wiegand, 0228 / 72990-205, E-Mail: wiegand@krebshilfe.de

A. Guideline for Letter of Intent

You are requested to notify German Cancer Aid of your intent to submit an application. This notification must be provided no later than **March 23, 2023** (via e-Mail). German Cancer Aid office acknowledges receipt of every letter of intent by letter within two weeks.

A complete digital copy of the letter of intent must be sent as one pdf via e-mail to the following address: foerderung@krebshilfe.de (one PDF document, not exceeding 8 MB), subject: Priority Programme 'Long-term Cancer Survivorship - Data Collection and Data Analysis' - LOI.

The letter of intent must include:

1. Contact information
   Principal applicant:
   Full name, institution (in German), full address, phone and email-address.
   Information on all remaining applicants (if applicable):
   Full name, institution (in German), place
   Information on the collaborators (if applicable):
   Full name, institution (in German), place
2. Project title (not more than 160 characters each, including commas and spaces)
   in English
   in German
3. Key words
   e. g. target group(s), type(s) of long-term and late effects, study design, methodological approach.
4. Information on the processing of personal data:
   Please include and sign appendix 'Information on the processing of your personal data'
5. Signature(s)
   Place, date and signatures (digital or scan) of all applicants.

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.

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B. Guideline for Project Outlines

Project outlines must be submitted by **April 21, 2023** (via E-Mail and postal delivery).

A complete digital copy of the project outline (one PDF, not exceeding 8 MB) and the summary (in English and German, as one Word document) must be sent via e-mail to the following address: foerderung@krebshilfe.de, subject: Priority Programme 'Long-term Cancer Survivorship - Data Collection and Data Analysis' - LOI.

Please send an original unbound version of the project outline to:

Stiftung Deutsche Krebshilfe
Abteilung Förderung
Buschstraße 32
53113 Bonn

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 use the section numbers as below, with the corresponding titles.

1. General information

1.1 Project title in English and German
(not more than 160 characters each, including commas and spaces)

1.2 Requested Funding Period (in months)

1.3 Key words
E. g. study design, methods, target group, types of long-term and late effects.

1.4 Information on applicant(s), address Information in English
All applicants are expected to provide the following information:

- First name, surname, academic degree, date of birth
- Full name of the institution/organisation
- Postal address
- Telephone numbers, E-mail address
- Reference numbers of all previous applications to German Cancer Aid for project funding

Provide the full name of the institution/organisation of each applicant also in German.
Please inform us at once if you change your address.

Applications are not accepted from members of profit-making organisations or from persons not permitted to publish results in a generally accessible form.

If your application is submitted by several applicants, please indicate the principal investigator. German Cancer Aid will regard the principal investigator as the person assigned for corresponding with German Cancer Aid on behalf of all applicants.

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2. Project description (max. 8 pages)

2.1 Project Summary

2.1.1 Project summary in English (intelligible to all, e. g. scientists, patients, layperson)
Please give a short description of the whole project, including the aims and objectives. The summary is limited to 1 page.

2.1.2 Project summary in German
(German translation of the above)

2.2 Study synopsis (max. 1 page)

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

Principal Investigator	Name, Institution
Project title in English	(max. 160 characters)
Project title in German	(max. 160 characters)
Study Duration	Information on the duration of the study.
Objective(s)/Hypotheses	Which principal research questions are to be addressed? Specify clearly the primary hypotheses of the study.
Outcome(s)	• Primary endpoint(s) • Key secondary endpoint(s)
Study/Target population	• Key inclusion criteria • Key exclusion criteria
Sample size	Specify the sample size and its rationale.
Data collection	• Type of data • Main instruments/methods for data collection • Explanatory/main response variables
Study design	e. g. observational (case-control, cohort, ecological ...), analysis of secondary data.
Statistical analysis	• Main procedures/analytical tools • possible confounders/effect modifiers
Main benefit/output	Expected result in terms of main benefit for cancer patients
Concept of patient involvement	Please describe how involvement of patients will be implemented in the study.
Participating centres/collaborators	Brief list of all involved collaborators (name of institution, place)

2.3 Concise description of the proposed study (max. 3 pages)

Provide information on background, preliminary work, expected results/benefit, plan of investigation (study design, target population etc.).

2.4 Patient involvement (max. ½ page)

Please describe how involvement of patients will be implemented in the planning, conduction and exploitation of results of the study. Please note: Patient involvement is mandatory wherever feasible and constructive. Patient involvement can be implemented in different stages of the study and to a different extent. Please justify why your concept is adequate for the planned study.

2.5 Time schedule and milestones

Present a time-table/flow chart of the study. Set measurable milestones and describe them.

2.6 Financial summary (max. ½ page)

Rough estimate of the costs for the entire study (staff, consumables etc.).

2.7 Confirmation that the application has not been submitted to any other funding organisation

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.

3. Signatures and attachments

3.1 Signatures of all applicants

3.2 CVs and publications

Curriculum Vitae (max. 1 page of each applicant) and list of publications (max. 10 publications per person, max. 1 page).

3.3 Collaboration partners (if applicable)

List of all collaboration partners (name, institution, place) and a letter of intent from each collaboration partner (digital signatures are sufficient for project outlines).

Appendix: Information on the processing of personal data / Hinweise zur Verarbeitung Ihrer personenbezogenen Daten

Die Stiftung Deutsche Krebshilfe nimmt den Schutz Ihrer personenbezogenen Daten sehr ernst. Deshalb möchten wir Sie darüber informieren, welche personenbezogenen Daten wir nach der jeweiligen Zweckbestimmung erheben und verarbeiten werden.
Was versteht man unter personenbezogene Daten?
„Personenbezogene Daten sind alle Informationen, die sich auf eine identifizierte oder identifizierbare natürliche Person beziehen. Als identifizierbar wird eine natürliche Person angesehen, die direkt oder indirekt, insbesondere mittels Zuordnung zu einer Kennung wie einem Namen, zu einer Kennnummer, zu Standortdaten, zu einer Online-Kennung oder zu einem oder mehreren besonderen Merkmalen, die Ausdruck der physischen, physiologischen, genetischen, psychischen, wirtschaftlichen, kulturellen oder sozialen Identität dieser natürlichen Person sind, identifiziert werden kann.“ (DSGVO Artikel 4 – Begriffsbestimmungen 1.
Im Rahmen der Antragsbearbeitung verarbeiten wir Ihre Daten nach Artikel 5 und Artikel 6 Abs. 1 (a, f); Abs. 4 DSGVO. Dabei handelt es sich zum Beispiel um:

- Vorname, Name akademischer Grad, Geburtsdatum
- Vollständige Bezeichnung der Institution
- Postanschrift
- Telefon- und Faxnummer, E-Mail-Adresse usw.

Wir möchten Sie ausdrücklich darauf hinweisen, dass Ihre personenbezogenen Daten für wissenschaftliche und historische Forschungszwecke oder für statistische Zwecke gespeichert werden. Außerdem werden Ihre Unterlagen an externe Gutachter - ohne gespeichert zu werden - zur Prüfung weitergeleitet. Um eine mögliche Doppelförderung auszuschließen, behält sich die Stiftung Deutsche Krebshilfe das Recht vor, Anfragen an andere Fördereinrichtungen unter Angabe des Namens des Antragsstellers und des Projekttitels zu stellen. Weiterhin möchten wir Sie darüber informieren, dass wir über bewilligte Förderprojekte sowohl in unserem Jahresbericht als auch auf unserer Homepage Auskunft geben werden. Hierfür ist es wichtig, dass Sie uns am Ende dieses Merkblattes mit Ihrer Unterschrift auch Ihre Einwilligung bekunden. (DSGVO Art. 6 Abs. 1 und Abs. 4; BDSG § 49).
Wir möchten Sie ebenfalls auf Ihr Widerspruchsrecht hinweisen gemäß DSGVO Art. 21 Abs. 4 und Abs. 6.
Verantwortliche Stelle im Sinne des Datenschutzrechts ist die Stiftung Deutsche Krebshilfe,
Buschstr. 32, 53113 Bonn. Dort erreichen Sie auch unseren Datenschutzbeauftragten.
Weitere Informationen u. a. zu Ihren Rechten auf Auskunft, Berichtigungen und Beschwerden erhalten Sie unter www.krebshilfe.de/datenschutz.

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Ort, Datum Unterschrift der Antragssteller