When applying, cancer registry data can be requested to answer specific clearly defined scientific oncology-related questions in areas such as prevention, patient care and causative research as well as health reporting. This application form can be used to request cancer registry data from one federal state, multiple federal states or all federal states. The requirements for the transmission of data are based on the applicable regulations in each federal state. For any questions regarding the application process, please contact the relevant cancer registry.

1. **Information about the applicant**

You may submit the data use application on behalf of an institution or as a private individual. The applicant is responsible for ensuring proper data processing, data security and compliance with data protection regulations. The applicant will be the recipient of transmitted data and responsible for data storage.

If you are applying on behalf of an institution, please designate the project manager or an authorized signatory of the data-holding institution as the applicant.

Additionally, a contact person at the institution can also be named for any questions regarding your data use application.

Please note that, depending on the federal state`s regulations, not all types of data may be available to private persons.

# **Persons involved**

Cooperation partners include other institutions/individuals essential for conducting the research project. Please specify if any cooperation partners will be involved in data processing tasks, such as storing, adapting, or modifying the transmitted data. The data processing cooperation partners will be named in the data use agreement and are thereby also obliged to comply with the regulations on data security and data protection.

# **Project description**

* 1. **Merging the requested data with other datasets**

If it is planned to merge the cancer registry data with data from other institutions (record linkage), please specify along with the data source to be linked. Please describe the linkage methodology in detail under section 3.6.

* 1. **Planned project duration**

Please provide the planned start and end dates of the project. The project duration should include the time period for preparing and submitting publications.

* 1. **– 3.5: Scientific background, research question and project aims, own previous work and publications**

To evaluate whether the requested data is suitable for answering the research question, please provide a brief description of the scientific background. Formulate a clearly defined scientific question or a hypothesis that you intend to investigate.

Include references to any of your previous work related to this research question. In the case of previously published work, a citation is sufficient.

Please limit each section to a maximum of 400 words.

* 1. **Study design and methodology**

Please describe the study design and methodology, including the statistical analysis and, if applicable an estimate of the sample size required to answer the research question. If a combination of the cancer registry data with other data sources (record linkage) is planned (see 3.1), please describe the methodology for this data linkage here (max. 400 words).

* 1. **Project financing**

Please indicate the funding/support for your project. This information will help to determine whether the project is publicly or privately funded.

1. **Specification of the requested data set**
	1. **Type of data requested**

When applying, a distinction is made between anonymized, pseudonymized or personally identifiable data. Below you will find detailed information about the types of data you can request and the documents that may need to be attached to the application. Additional documents and justifications (e. g. if pseudonymized data is requested instead of anonymized data) may be required if the provided information is insufficient for verification. Please note that the classification into one of the following categories may change after assessment by the cancer registry and that not every cancer registry is authorized to provide every type of data.

The possibility of support with the recruitment of study participants and the provision of aggregated analyses is regulated on a country-specific basis. For more information, please contact the cancer registries.

**Data definitions**

***Anonymized data***

Data is considered anonymized if the data subject cannot, or can no longer, be identified based on the data itself and cannot be identified by association with an identifier or by using additional information. The European Union's General Data Protection Regulation (GDPR), as a legal basis, does not explicitly address the anonymization of personal data. Sentence 5 of Recital 26 of the GDPR simply states that data protection principles do not apply to anonymous data, meaning no further rules need to be followed.

***Pseudonymized data***

In the case of pseudonymized data, the personal data is processed in such a way that it can no longer be linked to a specific data subject without the use of additional information, provided that this additional information is kept separately and protected by technical and organizational measures to ensure that the personal data cannot be associated with an identified or identifiable natural person. (see also Art. 4 GDPR No. 5).

***Personally identifiable data***

Personally identifiable data, as defined in the application, refers to data that includes both medical information and identity information, such as name, address, and date of birth in plain text. The requirements for transmitting personally identifiable data are based on the applicable state laws of the respective cancer registries. Before transmitting the data, consent from the patients must be obtained through the reporting institution or the cancer registry. Any costs arising from this process may be the responsibility of the applicant.

***Cohort matching***

External cohorts can be matched with cancer registry data using pseudonyms or identity data.

In pseudonymized matching, external cohorts and cancer registry data are matched using pseudonyms or control numbers. These are generated from individual or combined personal characteristics and do not allow any identifications of individual persons.

For cohort matching with identity data, personally identifiable characteristics (e.g. first name, surname, date of birth) are used. After the matching process, the data are sent to the applicant, who can then link the retrieved information to the personally identifiable data (e.g. via a communication number). The consent of the study participants is generally required for this type of matching.

In general, when applying for cancer registry data, additional documents can affect the processing time of the request. These include an ethics vote, a data protection concept and a study protocol. The following documents are always required when applying for personally identifiable data and for cohort matching with identity data:

* A sample consent form (in some cancer registries, copies/samples of signed consent forms),
* Study participant information,
* a credible assurance or statement confirming that the consent of the study participants has been obtained (individual proof may be requested on a random basis).
	1. **Inclusion and Exclusion Criteria**

Describe as precisely as possible the desired sample which will be used for answering the research question. Specify the inclusion criteria.

Under ‘Other’, please include any additional details about the requested data (e. g., including only new cases or including recurrences).

***Place of residence or location of treatment***

Please specify whether the requested variables pertain to affected persons residing in the federal state covered by the cancer registry or to all treated cases in the catchment area of the cancer registry.

***Clinical or epidemiological counting***

There are differences between epidemiological and clinical counting methods with regard to paired organs, early stage and later invasive tumors of the same organ (e. g. bladder), and tumors of the bowel organs and skin. Epidemiological counting provides a broader, population-based perspective and helps to understand cancer trends and risks, while clinical counting is more specific to individual disease progression and treatment information. In the clinical counting method, cancers are recorded as assessed by physicians, considering medical information, and reported to the cancer registry. In the epidemiological counting of cancers of paired organs, only the first cancer is recorded if they belong to the same histological group. For example, in the clinical count, each breast cancer case (right side, left side, multiple tumors on one side) is considered and recorded separately. Epidemiological data combine breast cancers of the same histological type.

The current guidelines for counting and recording diagnoses in population-based and clinical cancer registries can be found at:

* International Agency for Research on Cancer, World Health Organization, International Association of Cancer Registries, European Network of Cancer Registries: International Rules for Multiple Primary Cancers. IARC, Lyon 2004.
<http://www.iacr.com.fr/images/doc/MPrules_july2004.pdf>
* GKV-Spitzenverband: Empfehlungen des Paritätischen Gremiums. GKV-Spitzenverband, Klinische Krebsregister nach SGB V § 65c. Stand: 03.03.2022.
<https://www.gkv-spitzenverband.de/media/dokumente/krankenversicherung_1/qualitaetssicherung_2/klinische_krebsregister/Diagnoseliste_ICD-10_ab_2023_final.pdf>
* Plattform § 65c: Paarige Organe, Stand: 09.03.2023
[https://plattform65c.atlassian.net/wiki/spaces/UMK/pages/15533189/Paarige+Organe](https://plattform65c.atlassian.net/wiki/spaces/UMK/pages/15533189/Paarige%2BOrgane)

***Exclusion criteria***

Please also specify any exclusion criteria (e. g. exclusion of cases known only from the death certificates (so-called DCO cases) or cases for which only pathology- reported data is available).

* 1. **Specification of required variables**

***Appendix 1, Specification of Variables***, contains the defined oncological basis dataset (oBDS) and the organ-specific modules. Please select the required variables and provide a brief justification for each selected variable group (keywords), explaining their relevance to the project. In the interest of data minimization, please limit the variables to those essential for answering the research questions. You may add comments to the requested variables (e.g. age or age group instead of date of birth and date of diagnosis; calculation of time between diagnosis and first surgery or year of diagnosis instead of the full date of diagnosis; vital status; date of the last registration office comparison). If you require calculated variables, please coordinate this with the respective cancer registries.

Please note that not all variables from oBDS 3.0 are available over time. Cancer registries reserve the right not to release variables for which data quality cannot be guaranteed.

1. **Ethical and data protection aspects**
	1. **Has this project received a positive ethics vote?**

Please specify the ethics committee(s) that have positively assessed your project.

* 1. **Measures for ensuring data security and data protection**

Please select the technical and organisational measures implemented at the applicant's institution or by the applicant to ensure data security and data protection. The information provided will be used to assess whether and how cancer registry data can be provided, ensuring compliance with data protection and data security regulations.

1. **Other**
	1. **Use of the results**

Please describe how you plan to use the research results (e. g. publication in a scientific journal, conference paper, dissertation, etc.).

* 1. **Further comments from the applicant**

This section allows you to provide additional comments and highlight any special aspects not yet addressed in the application.

**Notes**

* The approval for data delivery is the responsibility of the relevant authorities of the federal states. There is no automatic right to transmission.
* Please note that the approval procedures and the data provision may take several weeks.
* The provision of data may be subject to a fee, in accordance with the applicable fee regulations of the federal states.