

INFORMATION FOR PATIENTS

about reporting to the Clinical Cancer Registry Lower Saxony (Klinisches Krebsregister Niedersachsen; KKN) and the Epidemiological Cancer Registry Lower Saxony (Epidemiologisches Krebsregister Niedersachsen; EKN)

Dear patient,

Cancer continues to be one of the most common diseases in Germany. Thanks to medical and technological progress, survival rates for many forms of cancer have improved significantly. Nevertheless, systematic documentation of the frequency, early detection, treatment and aftercare is still required to address the numerous unresolved questions about these issues.

The benefits of cancer registration depend to large degree on the completeness and quality of the data collected. For this reason, your doctor and dentist are required by law to report information on your disease to the state cancer registries if you are suffering from any form of cancer, an early stage of cancer or a benign brain tumour.

Your data is an important contribution to effective treatment and research into cancer. Thank you for your understanding.

1. Why do we have two state cancer registries?

The functions and objectives of the epidemiological and clinical cancer registries differ:

As a population-based cancer registry, since 2000 the **EKN** has been monitoring the occurrence and regional distribution of cancer in Lower Saxony over time. This makes it possible to detect noticeable clusters and assists the local health authorities in local research. The data collected by the EKN supports the evaluation and improvement of preventive and early detection measures as well as accredited scientific research.

As a hospital-based registry, the **KKN** has been collecting data on the diagnosis, progression and treatment of cancer via an electronic reporting portal since 2018 in order to analyse the data and report this back to the doctors and dentists who treat you. They can view the saved data on your disease via the reporting portal. The KKN also provides reporting doctors with analyses of quality assurance evaluations in relation to treatments and supports research projects.

2. What is the legal basis for this?

The Federal Act on the Early Detection of Cancer and Cancer Registries (*Krebsfrüherkennungs- und -registergesetz*; KFRG) of 9 April 2013 (section 65c of Book V of the German Social Code (*Sozialgesetzbuch V*

(SGB V)) requires the establishment of clinical state cancer registries, which are to be used for improving and developing treatments and to assess the benefits and side effects of certain treatments.

At the state level, the following legislation regulates the EKN and the KKN:

- Act for the Implementation of the Early Detection of Cancer and Cancer Registries in Lower Saxony (*Gesetz zur Umsetzung des Krebsfrüherkennungs- und -registergesetzes in Niedersachsen*)
- Act on the Clinical Cancer Registry Lower Saxony (*Gesetz über das Klinische Krebsregister Niedersachsen*; GKKN), see also ordinances pursuant to section 30 GKKN
- Act on the Epidemiological Cancer Registry Lower Saxony (*Gesetz über das Epidemiologische Krebsregister Niedersachsen*; GEKN).

The Lower Saxon Ministry for Social Affairs, Health and Equality exercises supervisory control over both cancer registries.

3. Which data are reported?

The extent of the data to be reported was uniformly defined on a nationwide level and includes:

1. Information on the reporting institution
2. Personal information
 - Name(s)
 - Gender
 - Address
 - Date of birth
 - Health insurance information
3. Medical information about the tumour, particularly
 - Diagnosis, histology, localisation and spread of the tumour
 - Date of diagnosis
 - Type of diagnosis
 - Type, start, duration, side effects and outcome of treatment
 - Disease progression
 - Vital status

Since 1 July 2018, reporting to both cancer registries is done electronically via a web-based reporting portal. The data are assigned and processed in a data collection point jointly operated by the EKN's trust

centre and the KKN's trust centre unit according to their respective responsibilities.

Data on malignant tumours and their early stages as well as benign brain tumours are saved in both cancer registries. Certain skin tumours as well as certain tumours of uncertain or unknown behaviour are analysed exclusively by the EKN.

Tumours in children and adolescents under the age of 18 continue to be recorded by the German Childhood Cancer Registry (*Deutsches Kinderkrebsregister*) in Mainz and by the EKN.

Reporting institutions and public health authorities will continue to send your data (e.g. relocation data) directly to the EKN; the EKN then forwards the data relevant to the KKN to that registry.

If the place of treatment and your place of residence fall in different catchment areas (different federal states), the cancer registries concerned mutually forward the reported data to each other in accordance with statutory requirements.

4. Purposes and legal basis of the data processing

Your personal data are required to process the data reported and for billing. Section 5 and 9 GKK, section 3 and 7 GEKN and section 65c(6) of Book V of the German Social Code (SGB V) are the principal legal bases.

Your medical data are saved permanently by the cancer registries. Pursuant to section 27 GKK, identity data in the KKN are saved for 50 years after the death of the person, or for an absolute maximum of 130 years after the birth of the data subject. Identity data is deleted from the EKN 75 years after death and no later than 130 years after birth in accordance with GEKN § 13.

5. What happens with the data that has been registered so far?

Data relating to you in connection with an earlier disease may already be stored in the EKN, or data from the aftercare programme may be on record in the ONkeyLINE database of the Association of the Statutory Health Insurance Physicians of Lower Saxony (*Kassenärztliche Vereinigung Niedersachsen*). In accordance with statutory provisions, these data, if detected in a report to the KKN, may be added to the data in the KKN.

6. How are your data protected?

In both cancer registries the data are processed strictly confidentially and in accordance with the latest technological and organisational standards. Additional protection of your data is ensured by separating the confidential and registration sections at the KKN and the confidential notification and registration units at the EKN.

After the reported data are processed at the joint data collection point, identity data (name, address, health insurance number) are always stored permanently in encrypted form. The medical data are stored in the registration section and/or in the registration unit using assigned pseudonyms. The data are used for quality assurance and research purposes exclusively in accordance with statutory requirements. If your personal data are required for special scientific studies, you will be asked in each case in advance to consent to the transmission.

Data Protection Officer at the KKN

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Märkische Straße 212-218, 44141 Dortmund
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dsb@datatree.ag

Data Protection Officer at the EKN

Niedersächsisches Landesgesundheitsamt
Telephone: 0511 4505-0
datenschutz@nlga.niedersachsen.de
OFFIS CARE GmbH
Telephone: 0441 361056-12
dsb.registerstelle@krebsregister-niedersachsen.de

Competent supervisory authority pursuant to article 77 GDPR

State Data Protection Commissioner of Lower Saxony
Postfach 2 21, 30002 Hannover
poststelle@lfd.niedersachsen.de
www.lfd.niedersachsen.de

Controller for data processing pursuant to Article 4(7) GDPR:

Klinisches Krebsregister Niedersachsen
Sutelstraße 2, 30659 Hannover
Telephone: 0511 277897-0
info@kk-n.de

7. Your rights

As the data subject, you have a

- right to information
- right to object
- right of access to data.

This means that you or the relevant guardian **must be informed** by the doctors or dentists treating you about the fact that your data is reported to the KKN and EKN, the content of the data reported and your right to object.

Your doctor or dentist is obliged to report all forms of cancer and benign brain tumours.

The encrypted personal data stored in both registries can be legally restored for certain purposes. In such cases, a cancer registry may contact you for study purposes or to examine a regional concentration. You can limit the data restored in this way by **objecting**. You cannot, however, object to data being submitted to the cancer registry, because there is a reporting obligation in this respect. If you object, you will not be contacted at a later stage by the KKN or EKN. Objections by adults

apply to both cancer registries. Objections by guardians or minors themselves (15 years and older) only apply to the EKN.

You can file your objection with any doctor or dentist directly during the conversation in which they inform you of the reporting obligation, or even later, and you can also revoke it again (only for the KKN). If you would like to file an objection with a cancer registry immediately, a form is available on the KKN and EKN websites. This also contains information about the implications of objecting.

Last but not least, you have the **right of access to your data**. You can ask at any time which entries relating to you are stored in one of the cancer registries.

You will be required to complete a form in full, sign it and submit it to one of the doctors or dentists treating your cancer. This doctor or dentist will submit the form and inform you about the feedback from the cancer registries. The form is available on the website of the registry concerned; access to the information is free of charge to you.

If it becomes apparent in the course of accessing the information that the data saved in the EKN and/or KKN are not correct, your doctor or dentist may trigger a **correction** of the data pursuant to article 16 GDPR.

8. When is your consent required additionally?

There are two special instances of data transmission for which your consent is required:

- for reporting authorisations and
- for reporting via a cooperating institution.

A reporting authorisation exists, for example, if your medical case was discussed at a tumour board conference. In this case there is no reporting obligation; the doctor or dentist treating you may transmit these data to the KKN with your written consent (see last page).

We would appreciate your support in this matter and ask for your consent.

Reporting via cooperating institutions present a particular form of collaboration between the reporting party and the data collection point. Only institutions experienced in the registration of cancer cases with certain medical or specialist facilities (e.g. tumour centres in major clinics) will receive this status upon request. Cooperating institutions may receive the information stored in the KKN, e.g. on the treatment success and vital status of the patients reported by them; this applies independently of a cause to be documented specifically. This information would otherwise have to be collected by the institutions through their own research, which would amount to a disproportionately high effort. If your doctor or dentist wishes to report your data through a cooperating institution, your separate consent is required for your data to be exchanged in this way.

9. Where can you obtain additional information?

For information on the KKN, including annual reports from 2019 and all legal bases, please see www.kk-n.de.

Information on the EKN, as well as the annual reports and interactive database, is available at: www.krebsregister-niedersachsen.de.

At the federal level, the EKN cooperates with the Robert Koch Institute (RKI) and transmits data there pursuant to the Federal Cancer Registry Data Act. The RKI issues the publication *Krebs in Deutschland (Cancer in Germany)* in collaboration with the Association of Population Based Cancer Registries in Germany (*Gesellschaft der epidemiologischen Krebsregister in Deutschland e.V.*; GEKID): www.gekid.de.

As envisaged by the KFRG, the KKN provides the Joint Federal Committee with anonymised data (transmitted by the clinical evaluation unit of the federal state) for the purpose of quality assurance.

The two state cancer registries annually publish a joint report, which is also available online.

Contact details

KKN with confidential and registration section

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Clinical Evaluation Unit of the Federal State of Lower Saxony

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EKN Trust centre

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EKN Registration unit

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registerstelle@krebsregister-niedersachsen.de

Lower Saxon Ministry for Social Affairs, Health and Equality

Postfach 141, 30001 Hannover
Telephone: 0511 120-0

Declaration of consent



reporting authorisation to transmit data pursuant to section 7 GKKN

My doctor or my dentist _____ informed me about the report to the state cancer registry on _____. I have received the patient information (version of 01 January 2021) as well as a copy of this declaration of consent.

Where reporting authorisation is required, consent is required for the transmission of the data. If I have any questions about the transmission or storage of these data, I can contact the Clinical Cancer Registry Lower Saxony (KKN):

KKN Trust centre unit | Sutelstraße 2, 30659 Hannover | 0511 277897-0 | info@kk-n.de

I consent to the transmission of data by my doctor or dentist to the KKN in accordance with the statutory reporting authorisation. I am aware that this consent is voluntary and that I can withdraw the consent at any time via my doctor or dentist or directly with the KKN.

Your personal data	
Title	
First name	
Surname	
Date of birth	

Place, date _____ Signature of patient _____

to the transmission of data via a cooperating institution pursuant to section 13 GKKN

My doctor or my dentist _____ informed me on _____ about the report to the state cancer registry via the cooperating institution _____. I have received the patient information (version of 01 January 2021) as well as a copy of this declaration of consent.

Consent is required for this purpose, as well as for the exchange of data between the Clinical Cancer Registry Lower Saxony (KKN) and the cooperating institution. If I have any questions or require access to the information, I can contact the KKN:

KKN Trust centre unit | Sutelstraße 2, 30659 Hannover | 0511 277897-0 | info@kk-n.de

I consent to the transmission of data by my doctor or dentist via a cooperating institution in accordance with the statutory basis.

Your personal data	
Title	
First name	
Surname	
Date of birth	

Place, date _____ Signature of patient _____

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