

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.

We ask for your understanding here, as your data make an essential contribution to cancer research and effective cancer treatments.

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 (including benign brain tumours since 2013). This makes it possible to detect noticeable clusters and assists the local health authorities in local research. It also helps facilities which treat cancer to better plan for future needs. The data collected by the EKN supports the evaluation and improvement of preventive and early detection measures (such as mammography screening) as well as accredited scientific research (e.g. aetiology).

As a clinical-based registry, the **KKN** was newly established at the end of 2017 to collect data on the diagnosis, progression and treatment of cancer and benign brain tumours, to analyse the data and report this back to the doctors and dentists who treat you. They can view and use the saved data on your disease via the reporting portal, e.g. if your case is to be discussed at a tumour board conference. The KKN also provides reporting doctors with analyses of quality assurance evaluations in relation to treatments.

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 cancer registries at state level, 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*) of 25 September 2017
- Act on the Clinical Cancer Registry Lower Saxony (*Gesetz über das Klinische Krebsregister Niedersachsen; GKKN*) of 25 September 2017 (see also ordinances pursuant to section 30 GKKN)
- Act on the Epidemiological Cancer Registry Lower Saxony (*Gesetz über das Epidemiologische Krebsregister Niedersachsen; GEKN*) of 7 December 2012.

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 according to their respective responsibilities.

Certain skin tumours and 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.

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 GKKN, 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 GKKN, identity data 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.

5. What happens with the data that have 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 centre (EKN and/or KKN) 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

CLARIUS.LEGAL Rechtsanwaltsaktiengesellschaft
Neuer Wall 77, 20354 Hamburg
Telephone: 040 257660-900
dsb@clarius.legal

Data Protection Officer at the EKN

Niedersächsisches Landesgesundheitsamt
Roesebeckstraße 4-6, 30449 Hannover
Telephone: 0511 4505-0
datenschutz@nlga.niedersachsen.de

Competent supervisory authority pursuant to article 77 General Data Protection Regulation/ GDPR (DSGVO)

State Data Protection Commissioner of Lower Saxony
Postfach 2 21, 30002 Hannover
poststelle@lfd.niedersachsen.de
www.lfd.niedersachsen.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 **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. If the restoration of your personal data is permitted, a cancer registry may contact you for study purposes or to examine a regional concentration.

However, you can also file an **objection**. While the objection applies to both cancer registries, the consequences differ: By law, the decryption of your personal data at the KKN is permitted only to securely associate the reports with a given data subject, to provide you with information and correct the identity data, and for billing statutory medical funds. At the EKN, it is generally no longer possible to decrypt your personal data after an objection has been filed. Should you object to the processing of your data, the KKN or EKN shall not contact you any further, e.g. in relation to studies or to examine a regional concentration (cluster analysis). Medical data on your disease will be saved in any event to allow the cancer registries to fulfil their basic responsibilities.

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, which you can send by post to the registries together with the front and back of your ID.

Last but not least, you have the **right of access to your data**. You can ask at any time whether and 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 you. 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, but also with aftercare examinations which do not lead to a change of treatment or which confirm that you are tumour-free. The KKN requires these particulars as well, as such data on the progression of your disease are important for assessing the quality of the treatment. 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 all legal grounds, 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 to them pursuant to the Federal Cancer Registry Data Act (*Bundeskrebsregisterdatengesetz*). 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 made available online.

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

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

Contact details

KKN with trust and registration centre

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Dr. med. Tonia Brand (Registration centre)
PD Dr. med. Sven Meyer (Trust centre)
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Telephone: 0511 277897-0
info@kk-n.de

EKN Trust centre

Dr. med. Claudia Jopp
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Telephone: 0511 4505-0
vertrauensstelle.ekn@nlga.niedersachsen.de

EKN Registration centre

Joachim Kieschke, MPH
OFFIS CARE GmbH
Industriestr. 9, 26121 Oldenburg
Telephone: 0441 361056-0
registerstelle@krebsregister-niedersachsen.de

Lower Saxon Ministry for Social Affairs, Health and Equality

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Publisher

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Sutelstraße 2, 30659 Hannover

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 3 January 2020) 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 Trust centre | 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

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

KKN Trust centre | 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

Declaration of consent

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