Deutsches Hämophilieregister

Information for Parents

valid as per 1 September 2023

A co-operation of

Deutsche Hämophiliegesellschaft e. V. (DHG; German Haemophilia Association)
Interessengemeinschaft Hämophiler e. V. (IGH; Interest Group of Haemophiliacs)
Gesellschaft für Thrombose- und Hämostaseforschung e. V. (GTH; Society for Thrombosis and Haemostasis Research)
Paul-Ehrlich-Institut (PEI; Federal Institute for Vaccines and Biomedicines)

Dear Sir or Madam, dear Parents,

Your child's doctor has provided you with this information for parents and informed you on the possility to participate in the **German Haemophilia Registry** (*Deutsches Hämophilieregister*/DHR).

This brochure serves to provide you with all the necessary information on the DHR. If there is anything you don't understand, please talk to your child's doctor. You can also visit our homepage www.pei.de/dhr) for further information on the DHR.

We would be very pleased if you supported us with the data on your child in providing medical care and researching your child's disorder in future.

Your DHR Team

Your renewed consent on the capture and transmission of your child's data is necessary for the transmission of the data from the previous software to the updated system, even if you already gave your consent on the single capture of your child's data in the DHR in the past. This is the case because of the adaptation and amendment of Sections 14, 21, and 21a of the German Transfusion Act (Transfusionsgesetz) from 2017 and 2019.

Who manages the DHR?

With the support from the Federal Ministry of Health (Bundesministerium für Gesundheit [BMG]), many people and institutions are working on making the German Haemophilia Registry (DHR) a successful registry to improve treatment of coagulation disorders and increase the quality of life of those affected.

On the one hand, these include the two German patient advocacy organisations as direct representatives of the patients' interests.

- Deutsche Hämophiliegesellschaft zur Bekämpfung von Blutungskrankheiten e. V. ([**DHG**], German Haemophilia Association for Combating Bleeding Disorders)

and

- Interessengemeinschaft Hämophiler e. V. ([**IGH**], Interest Group of Haemophiliacs).

and on the other hand

- the Gesellschaft für Thrombose- und Hämostaseforschung e. V. ([**GTH**], Society for Thrombosis and Haemostasis Research) in its function as specialist scientific organisation for medical doctors

and

- the Paul-Ehrlich-Institut (**PEI**) as the senior federal authority. The PEI is also the location for the DHR office.

What is the DHR?

The DHR is an online database for the storage and evaluation of pseudonymised data of patients with blood coagulation disorders.

The DHR serves

- to **support** the best **possible provision** of blood products for each patient.

  The data stored in the DHR can support your doctor in finding the best suited medicine for you.

- to capture the **supply situation with medicinal products** for the **treatment of coagulation disorders**.

  Every doctor who treats patients with coagulation disorders must report the number of patients cared for and the consumption of medicinal products for the specific therapy of coagulation disorders to the PEI annually. The PEI prepares and publishes an anonymised report on the supply situation based on the information captured.

- to **promote** scientific clinical **research** for better treatment of your rare disease.

Even though coagulation disorders have been known for a long time, there are still many open questions which among other things relate to concepts of prevention, care in operations, and the treatment of complications. Data from the DHR can help answer these questions. Only when we have consolidated the data on many patients will we gain information that goes beyond the experience of individual patients and doctors.

What will the changes to the law of 2017 and 2019 mean for you and your child?

Pursuant to Section 14 German Transfusion Act, patients or their legal representatives are obliged to document all use of medicines for the specific therapy of coagulation disorders (e.g. coagulation factors or monoclonal antibodies). Please agree upon the form of **documentation** with your child's doctor. He or she will depend on your documentation and is obliged to check your information regularly and to integrate it into his/her own documentation.

Is your child's participation in the dhr voluntary?

You are not obliged by law to allow your child to participate in the single data capture in the DHR. If you decide against your child's participation in the DHR, this will affect neither your child's treatment nor the relationship with your child's doctor.

If you decide against **single data capture** of your child's data, the doctor will still be obliged to comply with the reporting obligation, which serves to judge the supply situation for medicines for the treatment of coagulation disorders. He/she will do this by reporting a largely reduced data package anonymously in a **collective report** or **anonymised single report**. The collective report will be a summary of the data of all patients of the appropriate facility who did not agree to a single data capture. The same reduced data package will be reported in the anonymised single report as is the case for the collective report, however, the data will not have to be pooled from multiple patients.

The reporting obligation is thus met. This reduced data set, however, will not allow a more thorough research into your child's disorder.

Why it is important to give your consent to the single data capture?

Your decision to participate in the DHR will actively help to improve your own supply and treatment situation of your child and that of all other persons affected. Besides, your participation is important to us, because the data of each individual patient, in particular in rare diseases like yours, will help improve the basis of the data – after all, **no data means no research.**

However, **the protection of your child's data** and **your rights as a patient is all important to us**.

What are pseudonymised data?

Pseudonyms are aliases, which prevent an individual from being identified. The DHR works exclusively with pseudonymised data. This means that:

(1) The DHR will **not** capture **your child's name, complete date of birth** and **address.**

(2) Instead, a **pseudonym**, i.e. an alias, will be calculated from a patient number. This patient number is only used while the pseudonym is calculated and will not be stored. It consists of the number of your electronic health card or your health insurance number. It will not be possible to identify you by this alias: A backwards calculation of the patient number from the pseudonym is not be possible.

Why are the data pseudonymised not anonymised?

If the data were completely anonymised, it would not be possible to add additional data each year on a continuous basis. Only a pseudonym makes it possible for your doctor to reassign the data to be reported unambiguously each time to your child's existing data within the DHR. This is the only method of making **reliable statements** on the

number of the patients to be treated and the course of the disease, i.e. to achieve the aim pursued by the DHR, which is the creation of a major database with a high informational value.

Which of my child's data will be transmitted?

Your doctor will transmit profile data and medical data during the single data capture. The latter data consist of diagnostic and therapeutic data.

Profile data consist of sex, month and year of birth and the first two digits of the residential post code. The profile data are assigned to the pseudonym and are necessary to form patient groups. Patient groups are required, e.g. to analyse whether in treating younger people other things should be in the focus that in the treatment of older people.

Diagnostic data include the type of disorder, the degree of severity, and some laboratory values captured for diagnostic purposes as well as data on the medical history. Such data include the date of your child's diagnosis, if and when the first bleeding took place, and whether another person in your family has a coagulation disorder.

Therapeutic data can be reported to the DHR on a regular basis but must be reported at least once a year by your child's doctor. This for example includes the consumption of medicines for the treatment of coagulation disorders, the therapy regimen (prophylactic or on-demand treatment), the name of medicinal product, the number of days on which your child received this medicinal product, the number of bleeding events, whether your child developed an inhibitor, and whether this inhibitor was treated by means of an immune tolerance therapy.

What happens if the treatment options change or additional data have to be recorded?

The DHR was conceived completely afresh in August 2019, because the legal basis changed as a result of amendments to the Transfusion Act. Additional data to be captured refer to new treatment options. Now, data can be captured which take into account the current and future treatment options, e.g. treatment with monoclonal antibodies or data on gene therapy.

Such **adaptations** must be **authorised** each time by the **steering committee** of the DHR. The latter consists of two representatives each of the two patient advocacy organisations, two representatives of the professional organisation, and two representatives of the PEI.

The **patient advocacy organisations** will represent your child's interests as a patient also in this case and will ensure that only those data are captured which are required for the research, and are used for the benefit of the treatment.

How will the DHR protect your child's data?

To preserve your child's personal rights and to guarantee data protection, the concept of the DHR was submitted to the data protection representatives of the Federal German Government and the Länder (federal states) for verification and was accepted by them before it was established.

In the revision of 2019, the concept of the DHR was maintained and the amendments were again verified and accepted by the **federal data protection officers**. Since the DHR captures personal data, you have the right to submit a complaint to the data protection officer of the federal state of Hesse pursuant to General Data Protection Regulation (GDPR), Article 13 (2), letter d.

To protect the DHR from unauthorised access, the PEI has installed extensive protective mechanisms. For further details, please visit the website of the DHR.

How can your child participate in the DHR?

Talk to your child's doctor and ask to be included in the DHR. Because of the amendment to the transfusion Act in 2019, your child's doctor

is now obliged to inform you on the DHR and to perform the single registration when the patient's consent is available.

For your participation, we need your full consent for the use, evaluation, and retransmission of your child's personal medical data including the exemption of your doctor from his/her secrecy obligation, which exclusively refers to the transmission of your child's data to the DHR.

Minors who are old enough and can judge the significance and the implications of their participation in the DHR are required to sign as well. Whether a minor is able to do so has to be decided on a case-to-case basis.

You will find the English version of the **informed consent form** for download on our homepage (www.pei.de/dhr).

What is important if you change your child's doctor?

If you change your child's doctor, the new doctor will not be able to see the data on your child previously entered into the DHR. He/she will have to enter them from the beginning. For this reason, please ask your child's previous doctor to provide you with a printout of your child's master data (data which do not change in the course of time including type and severity of the disease, date of birth, date of first bleeding, etc.) to save your child's new doctor from requesting this data once again.

The registry will merge the data from the different facilities in the database. This is of major importance to ensure continuity of data capture and evaluation.

Who will transmit and edit your child's data?

Only the **participating doctors** and their members of staff who enter the data will have access to the DHR by means of **personal credentials** like user ID and password. Each doctor will be able to view only the patients at their own facility.

To assure the quality of the data including the identification of data entry errors or preparing the necessary reports required by law, the office of the DHR will be granted the right to view the medical data. In this context, **it is important to know** that, in doing so the DHR office will not be able to identify your child personally, since no identifying data will be recorded.

Who will decide on the transmission of data for research purposes?

If scientists and research institutes wish to evaluate data for the purpose of further research, they will be obliged to make a written application to the **Steering committee of the DHR**.

The application must include a detailed description of the study project, the data required, and guarantee data protection. The steering committee will decide whether to accept the application for the use of the data for the research and scientific purpose concerned.

The **research activities** must agree with the aims of the DHR or must be beneficial to them. If this is the case, the data requested by the DHR office will be exported from the DHR without transmitting the pseudonyms, will be verified, and released. The data will only be made available to the applicant after their release. Before the data are published, they will be reviewed again.

Data protection has top priority for us, also with regard to the handling of anonymous data.

Who is responsible for my child's data?

The **Paul-Ehrlich-Institut** is the competent authority for the data stored in the DHR as defined in the data protection laws. You can contact the Paul-Ehrlich-Institut whenever you have any questions concerning the DHR.

Paul-Ehrlich-Institut,
Office of the German Haemophilia Registry
Paul-Ehrlich-Strasse 51-59
63225 Langen, Germany
Phone: (+49) 6103 / 77 – 1860
E-Mail: dhr@pei.de

However, the PEI cannot give you any information on your child's personal data, since the DHR only

contains pseudonyms, which are not assigned to an individual. Only your child's doctor will be able to answer questions concerning your child's data. You have the right to obtain information on these data or to have errors in your child's data corrected.

How can you withdraw your consent?

If you, or your child, no longer wish to participate in the DHR, despite your signed informed consent, you can inform **your child's doctor on** your withdrawal **in writing** at any time. You do not have to state any reasons. Your withdrawal will not affect your child's treatment or your relationship with your child's doctor. No further personal data will be recorded. The data recorded on your child up to the time of your withdrawal will be anonymised entirely, i.e. the pseudonym will be deleted and replaced by a random number. This number is stored exclusively in the registry and cannot be communicated to anybody, not even your child's doctor. This will ascertain that the captured medical data, which are valuable for science and research, will be preserved.

Where can I find further information?

You will find further information including annual reports or the exact data sets of the single reports, collective reports, or anonymised single reports on the website of the DHR (www.pei.de/dhr).

We look forward to your participation in the DHR!

Information for Parents on the German Haemophilia Registry (*Deutsches Hämophilieregister*/DHR)

Issued by:

Office of the German Haemophilia Registry

Paul-Ehrlich-Institut

Paul-Ehrlich-Strasse 51 – 59

D-63225 Langen, Germany

Please contact: Dr Christine Keipert, Birgit Haschberger or Janina Hesse

English Version 3.0 (September, 2023)

Informed Consent for Parents

Please provide the treating doctor with the original, the copy is for the parents.

First and last name of the **legal representative(s)**

1. _____

2. _____

☐ The person under 1. is the only legal representative of the child indicated below

Address of the legal representative(s) _____

_____

First and last name of the **child** _____

Date of the child's birth _____ Age: _____

Address of the child (if different from the above) _____

_____

The doctor has informed me/us on the DHR according to § 21a paragraph 4 TFG.

Title, last name, first name of **doctor** _____

Address of doctor's practice/facility _____

(stamp) _____

We have been informed that our child's participation in the DHR is voluntary, and that we have the right to withdraw our consent at any time without stating any reasons. In the event that we withdraw our consent, our child's data stored in the DHR up to that moment will be anonymised and assigned to a random code number. No further data will be captured.

We were given the opportunity to ask questions. These were answered to our satisfaction and in their completeness. The scope and the course of our child's participation in the DHR have been made transparent to us. The following questions were discussed in addition to written information provided:

_____

_____

_____

We agree to my/our personal data being processed in the DHR, including evaluation and retransmission to the treating doctor.

No ☐ Yes ☐

With this informed consent, we also release our child's aforementioned treating doctor from his/her secrecy obligation to the extent that this is required for the participation in the DHR.

We have received the written parents' information about the DHR. We have been informed which personal and health data of our child will be communicated to the DHR and that both the parties participating in the DHR and representatives of science and research may receive, process, and use the pseudonymised data on our child. If data on our child are already stored in the old databank, we agree to these data being transmitted to the new DHR.

We understand that the data communicated to the DHR are health data, i.e. personal data of a particular category in the meaning of Art. 9 (1) GDPR (General Data Protection Regulation).

_____

City or town, date — Signature legal representative(s)

_____

City or town, date — Doctor's signature