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**Patient information**

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**Participation in the disease registry for chronic urticaria**

**(Chronic Urticaria Registry - CURE)**

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Dear Madam or Sir,

Your are suffering from chronic urticaria. Although this disorder is highly frequent, the exact epidemiologiy (e.g. frequency, duration, course of disease), underlying causes, comorbities, trigger factors, treatment response, costs and impact of disease are still ill-defined. The aim of this registry, the chronic urticaria registry (CURE), is to close this gap. It collects data on the above mentioned areas from patients in multiple countries including European and Non-European nations. The available data is analyzed scientifically in regular intervals.

You are eligible for this registry and your treating physician would like to include you in this project. Please read the following information carefully and, in case of any remaining questions, please do not hesitate to ask your treating physician.

**Should you have any questions directed to the coordinating investigators of this study, please contact: PD Dr. med. Karsten Weller, Phone +49-30-450-518438, Email: karsten.weller@charite.de**

Aims of the chronic urticaria registry

The aim of this registry is to improve the knowledge on chronic urticariaregarding, among other things, its epidemiology (e.g. frequency, duration, course of disease), underlying causes, comorbities, trigger factors, treatment response, costs and impact of disease as well as to globally improve the understanding of chronic urticaria and its subforms. The results of the registry will be published and should help to improve the medical care for future patients.

Participation in the registry

Prerequisite for your participation is that you are informed thoroughly about the aims and nature of this registry with this patient information form and that you have dated and signed the written informed consent for this study.

If you consent to this study, data on your medical history such as onset of your chronic urticaria, comorbidities, medication, suspected causes, diagnostic measures (and their results), treatments (including their efficacy and tolerability) will be documented through a basic registry entry. After this basic entry, follow up entries will be done around every 6 months, which will record additional data on your disease, including the course and on additional diagnostic and therapeutic procedures.

This registry will not affect the management and treatment of your disease in any way. It is a purely observational (non-interventional) study. Accordingly, you will not be treated differently with regard to the usual medical routine when participating in this registry. Only the additional entry of your medical relevant data into the registry is different from the routine management.

Duration of participation

The course of your disease can be documented in and followed by the registry as long as your treating physician supports this and as long you agree to participate. The chronic urticaria registry is designed as an open ended registry, therefore, there is currently no defined ending date for the registry.

Risks of participation

Participation in this study is not linked to any risk or disadvantage for you. The same applies to a refusal to participate. There are no medical procedures associated with this registry, it just observes and documents your chronic urticaria and its real life routine management prospectively.

Conditions that lead to a withdrawal from/termination of the registry

* Withdrawal of the dated and signed written informed consent
* Termination of your participation by your treating physician
* Termination of the registry

Potential individual benefit for participants and future affected individuals

You will have no direct individual benefit from participating in this registry. However, new insights into chronic urticaria are expected from the results of this registry. This will help to improve the understanding of chronic urticaria in general and may also serve to improve the future care for affected patients.

Data analyses

All your data, relevant to the registry, will be entered pseudonymized into the registry, stored in the registry data bank, electronically processed, and later analyzed. Since all of your data in will be pseudonymized, it will not be possible to identify you by your registry data. Only your treating physician and his employees will be able to link your person to your pseudonymzed registry data, but they are not allowed to transfer this confidential information to anyone. The data processing in the registry will be performed according to and adhering to the current and relevant data protection laws. In addition, the registry will be performed in accordance with Good Clinical Practice (GCP). Your data will only be used for analyses serving the aims of this registry and to improve the knowledge on chronic urticaria. Your identity remains secret at any time.

Data storage time

All data captured in the registry data bank will be stored for at least 10 years.

Voluntariness of participation

It is your free decision to take part in this registry study or not. In any case, your decision will neither have any disadvantage for you nor will it have any impact on your further medical treatment. You can withdraw your signed written informed consent at any time without any negative consequences and without having to provide any reasons for this step. In this case, no further data on your case will be entered into the registry. In addition, you can disagree to a further processing of your data and you can require a deletion of your data.

Insurance

There is no patient insurance for this registry, because no interventions are linked to this registry.

Is there any honorarium for participation?

You will not receive any honorarium for taking part in this registry. Your participation does not go along with any extra time or extra costs for you, because the registry just documents what is performed in your case during routine medical care.

Financial funding of the registry

The study is partially financed by: the Urticaria Network e.V. (UNEV), Charitéplatz 1, 10117 Berlin, Germany, a non-profit organization aiming to promote research on urticaria (hives), and to improve patient care as well as by the European Academy of Dermatology and Venereology (EADV), via S. Balestra 22B, CH-6900 Lugano, Switzerland. The acquisition of funding from various other sources is planned. This includes pharmaceutical companies and other stakeholders.

In addition, the registry is non-financially supported by the urticaria task forces of the European Academy of Allergy and Clinical Immunology (EAACI) and the Global Allergy and Asthma European Network (GA²LEN) as well as by the World Allergy Organization (WAO).

Confidentiality of the registry data and data protection

By dating and signing the written informed consent of this study, you declare that your treating physician and his employees are allowed to enter your diseaserelevant data into the chronic urticaria registry (CURE) and that this data can be analyzed scientifically together with data from other urticaria affected patients.

Your physician and his employees will transfer your data online into the registry data bank, which is hosted by the Urtikaria Network e.V. (UNEV), Charitéplatz 1, 10117 Berlin, Germany. The registry is based on the eCRF system secuTrial, which is a FDA/GCP compliant software.

The entered and transferred data will be pseudonymized, i.e. no personal data such as name, initials, date of birth, address, etc. will be recorded in the registry. Accordingly, only the entering physician and his employees will be able to reconstruct which actual patient belongs to which registry record. The recording physicians are asked to put a note in your original patient chart, documenting participation in the registry. Only your treating physician and his coworkers have access to your original patient chart. The only exception are national health authorities. If they want to check the registry, it is possible that their representatives could request access to the registry data, to, for example, compare it with the data in the original patient chart (the source data).

All data captured in the registry data bank will be stored for at least 10 years.

Right to ask questions

You have the right to ask questions to your treating physician and his employees regarding every aspect of this registry at any time.