



## Frequently Asked Questions

### 1) What is ERK-Reg?

The ERKnet Registry, also known as ERK-Reg, is a secure web-based application which has two major aims: (i) to identify contemporaneous cohorts of patients with rare renal disorders for clinical research across national borders, and (ii) to monitor treatment performance and patient outcomes in the participating centers. Moreover, the registry allows to integrate detailed disease-specific registries as extensions to the core database.

### 2) Who can see the data I enter in the registry? Are my data visible to the investigators of other Centers?

Access of authorized users to the registry is controlled by assignment of a secure, individualized password. A hierarchical access authorization system is implemented with super-administrator, administrator, sub-administrator (ERN thematic workpackage lead, Affiliated Registry lead), and center user levels.

The data entered will only be visible to the investigators of the Center and will not be shared with other users of the registry, except in aggregated format for benchmarking purposes. Sub-administrators are authorized download data excerpts from patients with the disease(s) of their interest.

### 3) Where are the data stored?

The data are stored on a commercial server in Germany, inaccessible to non-authorized personnel or entities. Regular back-ups are made. These back-ups are kept in a secured location. They guarantee the protection of (identifiable) data and the security of all information.

### 4) For how long will data be kept in the ERK-Reg database?

The data will be kept in the database for at least 15 years. Data will not be destroyed without permission of the user.

### 5) Can I download the data of my center?

The lead investigator of the center is authorized to download at any time all data of the patients tagged as participating in the Registry/Affiliated Registry and use these data without restrictions for analytical purposes.

### 6) Which browser is best to use ERK-Reg?

To maximise your experience with ERK-Reg, users are highly advised to use modern web-browsers. Recent versions of Google Chrome, Mozilla Firefox and Safari provide the best user experience. Microsoft Edge and Internet Explorer (11.0) support ERK-Reg.





## 7) How can I request access to ERK-Reg?

To be able to start, the first requirement for the user is to request a login. For this purpose, please send an e-mail request to the help desk member responsible for your country.

*Germany, UK* : Tanja Wlodkowski ([tanja.wlodkowski@med.uni-heidelberg.de](mailto:tanja.wlodkowski@med.uni-heidelberg.de))

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## 8) How can I log in?

The application can be accessed through web-browsers. For best experience, make sure you are using a supported browser. ERK-Reg is supported to its full potentials on **Google Chrome, Mozilla Firefox and Safari**, preferably latest version. You can access the registry by the ERKNet page webpage by clicking on <https://www.erknet.org>

When you have an ERK-Reg login account (which can be used to access multiple ERKNet services), **enter username and the password provided** by the help desk member and click on the button "Login" .

## 9) Is patient consent mandatory for enrolling patients in the ERK-Reg?

Yes, all patients must give at least a consent for data use in ERN registries and databases that will be recorded by ticking a checkbox indicating the minimum has been collected. The consent forms can be downloaded by clicking the "Download" and "Consent Forms" button located on the left side of the menu.

## 10) How can I enrol a patient into ERK-Reg?

In order to enrol a new patient from your centre, please click on "Data entry ".

## 11) How do I know the ID code of my patient?

The patient ID is automatically generated by the system after saving the data. You can see the patient-ID on the left of the menu. We recommend to generate a local Excel document with the Name, Surname, date of birth, date of informed consent, together with the ERK-Reg patient ID. This key document should only be stored on a save hospital server and only be shared among the local users of the registry.





## 12) Do all ERK-Reg patients have to be registered in the sub-registries?

No, only patients with a rare kidney disease for which a sub-registry has been established can be entered into these affiliated registries by selecting the corresponding sub-registry in the basic data form. The Alport sub-registry is currently only available for Italian centres. Consent for registration in the affiliated registries must be indicated in the informed consent (see figure 17 of the ERK-Reg User Guide).

## 13) How can I choose the “primary renal diagnosis”?

Before registering a patient, we recommend to check the “Renal Orphacode list” (available in Downloads menu). The list contains all the kidney diseases in the registry in order to clarify the user which diseases can be entered and which not.

In the data entry menu the “Primary renal diagnosis” can be chosen through 4 different search bars:

- “*Select diagnosis*”: the search is made along the Orphanet diagnosis tree, choosing in hierarchical order the disease groups down to the entity of choice.
- “*Diagnosis by gene*”: Type in the search bar the name of the mutated gene that caused the disease. The disease(s) associated with the gene will pop up.
- “*Enter ORPHA code*”: Type the Orphanet disease code in the search bar.
- “*Search diagnosis name*”: Enter at least the first 4 letters of the disease name into the search bar.

## 14) What should I do when the renal diagnosis of a patient has not been established yet?

If the kidney diagnosis has not been established, mark "no" in the respective field of the basic entry menu. You can come back and change this entry and add additional information at any time once the renal diagnosis has been established.

## 15) How do I know when the diagnosis was confirmed?

This depends on the type of disease: sometimes it requires a genetic test or a kidney biopsy result, in other cases the physician in charge is able to make a diagnosis based on ultrasound or on clinical grounds.

## 16) How do I choose the date of the “initial visit”?

The date of the initial visit of a registry patient may coincide with the date of the signature of the informed consent but cannot be more than one month prior to the date of the informed consent.





## 17) How do I know when the next visit is due?

The date of the next visit to be documented is indicated in the patient dashboard.

## 18) Why is "next visit due" highlighted in different colors?

The statement "next visit due" can be highlighted in different colors depending on the status of the registration. Green means that the patient has been correctly saved in the system. Yellow means that the patient has been saved correctly but needs to be updated or has missing data. Red means that the initial visit of the patient has not been entered yet.

## 19) What "ID number" should I indicate in the informed consent?

This space must be completed with the automatically generated system patient ID once the patient has been successfully registered.

## 20) How can I contact the IT support?

In case you have any technical difficulty logging into the ERK-Reg or using any of its functions, please contact the support team via email [tanja.wlodkowski@med.uni-heidelberg.de](mailto:tanja.wlodkowski@med.uni-heidelberg.de). Please send your feedback, suggestions, or complaints to the support team.

