



# ERKReg Quick User Guide v2

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*If you have technical difficulties or trouble with any of ERKRegs' services or if you want to share your feedback, suggestions, or complaints, please contact the ERKReg support team [erkreg@erknet.org](mailto:erkreg@erknet.org).*

## 1. Welcome to ERKNet

The implementation of European Reference Networks (ERNs) is an unprecedented move to improve the care of patients suffering from rare health disorders by transnational collaboration. ERKNet, the ERN for Rare Kidney Diseases, oversees more than 70,000 patients in 72 specialist centres. The network members are committed to collaborating closely to improve the health outcomes of their pediatric and adult patients with rare kidney disorders. Core objectives of the collaboration will be the implementation of clinical practice guidelines and the definition and prospective monitoring of core indicators of guideline conforming management, treatment quality and patient health outcomes.

### 1.2 The European Rare Kidney Disease Registry - ERKReg

#### *Background:*

Clinical registries are indispensable instruments to provide demographic, genotype-phenotype and natural history information. The ERKNet centres are currently active in more than 60 mostly disease specific registries, most of which are limited to regional or national patient coverage. While the existing registries are collecting important information, none of them is currently used in all ERKNet centres. This paradigm of a web-based registry with an immediate benefit to user centres can serve as a blueprint for a network wide registry in ERKNet that, interconnected with and complementary to the existing rare kidney disease registries, will have a clear patient-oriented focus on healthcare quality improvement.

In 2019, ERKNet established ERKReg, a web-based registry for all patients with rare kidney diseases.

The main objectives of this core registry are

- (i) to generate epidemiological information,
- (ii) to identify current patient cohort for clinical research,
- (iii) to explore diagnostic and therapeutic management practices and
- (iv) to monitor treatment performance and patient's outcomes.

The registry has a modular design that allows to integrate comprehensive disease-specific registries as extensions to the core database. The diagnosis (Orphacode) and diagnostic information (clinical, imaging, histopathological, biochemical, immunological, and genetic) are recorded. Anthropometric, kidney function, and disease-specific management and outcome items informing a set of 61 key performance indicators (KPIs) are obtained annually. Data quality is ensured by automated plausibility checks upon data entry and regular offline database checks prompting queries. Centre KPI statistics and benchmarking are calculated automatically.

Please find here the publication which describes the objectives and design of ERKReg:

[https://www.erknet.org/fileadmin/files/user\\_upload/13023\\_2021\\_Article\\_1872.pdf](https://www.erknet.org/fileadmin/files/user_upload/13023_2021_Article_1872.pdf)

## 2. Getting Started

### 2.1 How to request access to ERKReg

Access to ERKReg is strictly regulated to protect the data privacy rights of the patients. Only authenticated users can request access to use the registry.

If you want to access the registry, please get in touch with the ERKReg support team at [erkreg@erknet.org](mailto:erkreg@erknet.org). Please note that registry access can be only granted to HCP members with a duly signed data sharing agreement with Heidelberg University Hospital.

### 2.2 How to login

ERKReg can be accessed through web browsers. Make sure you are using the latest version of supported browsers (Google Chrome, Mozilla Firefox).

Go to the ERKReg webpage at [www.erkreg.org](http://www.erkreg.org) and enter your username and password.



Figure 1. ERKReg start homepage

## 2.3 Accessing ERKReg

Once you have successfully logged into your ERKReg account, you will be directed to the registry start webpage as shown below.

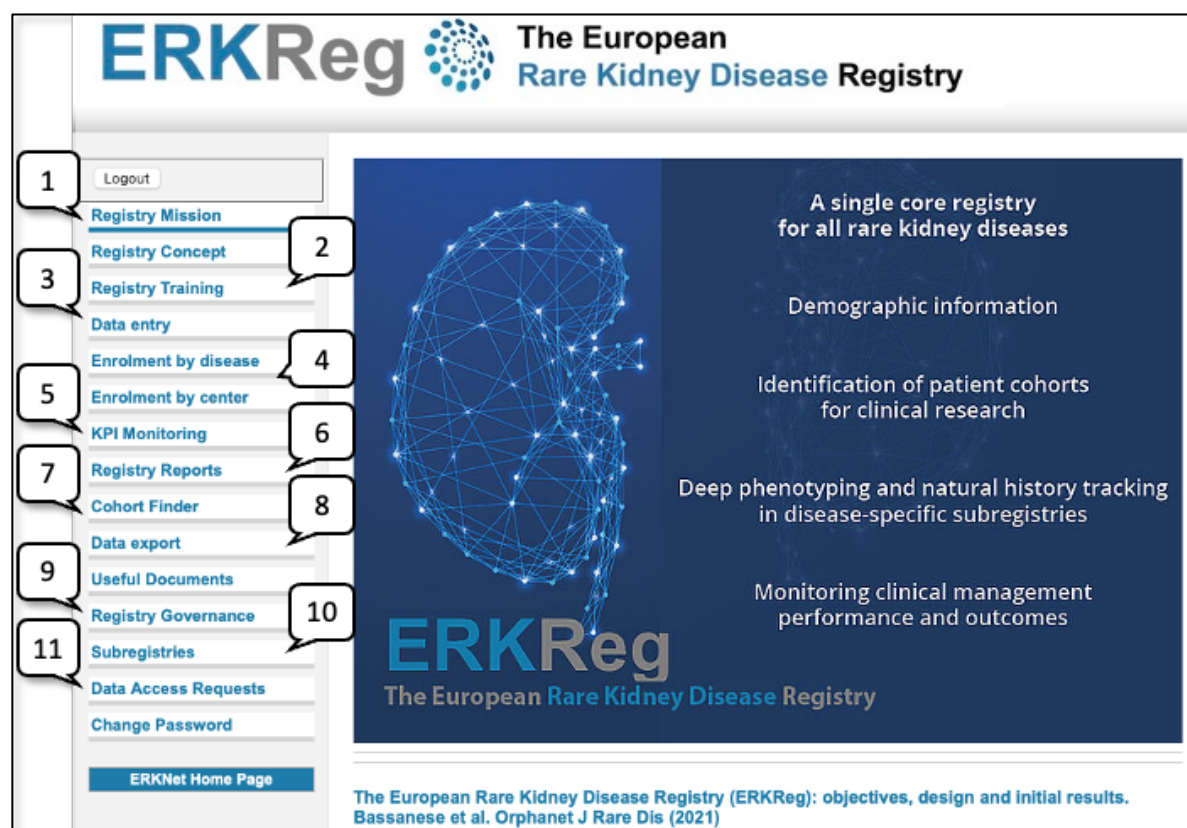
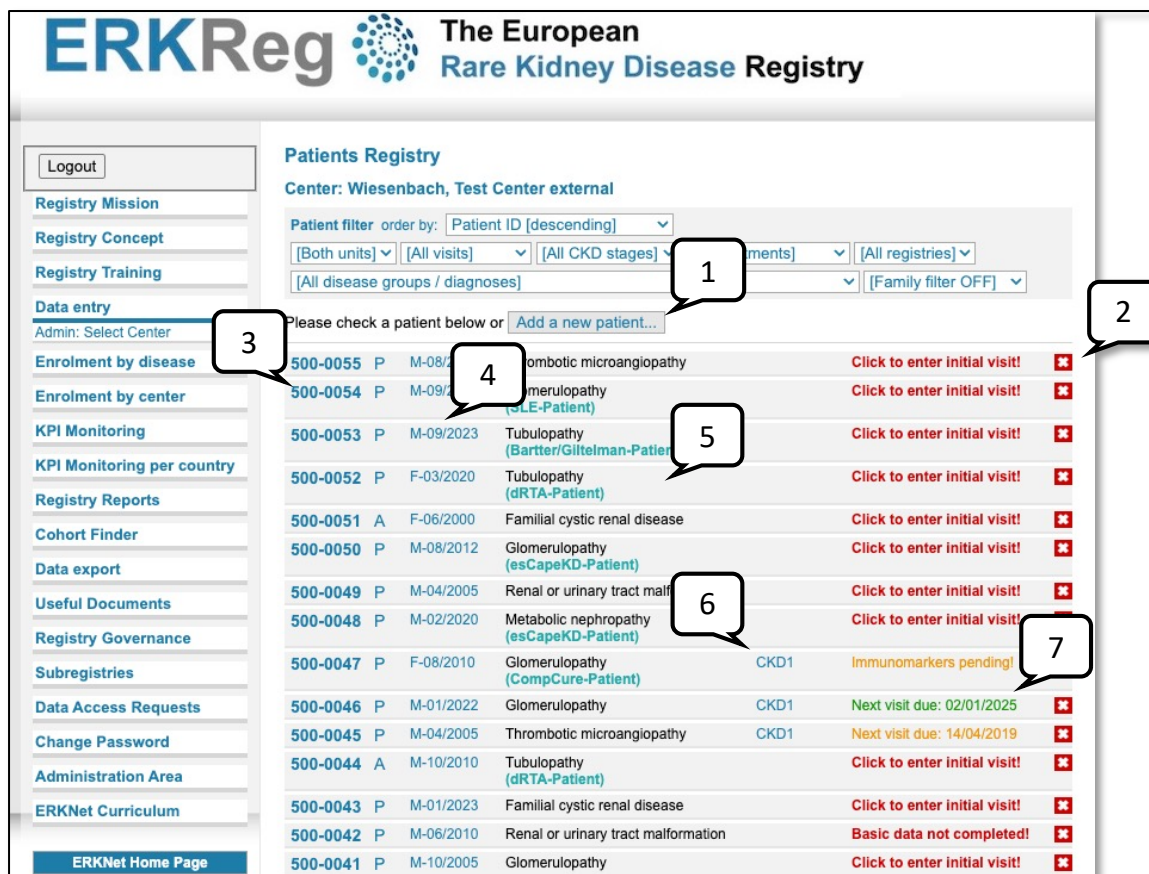


Figure 2. Registry main dashboard after successful login

1. “Registry Mission” - directs you to the landing page.
2. “Registry Training” – here you can find the next dates for basic and advanced ERKReg training courses.
3. “Data Entry” – here you enter your patients.
4. “Enrolment by disease and centre” – here you can see the current number of patients that are enrolled.
5. “KPI monitoring” – here you can find your own centre performance statistics and benchmarking on diagnostics and treatments.
6. “Registry Reports” – here you can find all past annual registry reports.
7. “Cohort Finder” – this tool allows you to identify patient cohorts by diagnosis, age, CKD status, treatment. This function is only accessible after having 50 patients enrolled.
8. “Data Export” – here you can download your patient list.
9. “Registry Governance” – here you can see the current ERKReg Board composition and ERKReg Support Team.
10. “Authorship Policy” – explains the authorship rules for ERKReg contributors.
11. “Subregistries” – here you find an overview of all existing subregistries, their governance and data element.
12. “Data Access Request” – provides information on the official rules and procedure for requesting data access.

## 3. Data Entry

### 3.1 Your patient list dashboard



The screenshot shows the ERKReg Patients Registry interface. The left sidebar contains navigation links: Logout, Registry Mission, Registry Concept, Registry Training, Data entry (highlighted), Admin: Select Center, Enrolment by disease, Enrolment by center, KPI Monitoring, KPI Monitoring per country, Registry Reports, Cohort Finder, Data export, Useful Documents, Registry Governance, Subregistries, Data Access Requests, Change Password, Administration Area, ERKNet Curriculum, and ERKNet Home Page. The main area is titled 'Patients Registry' and 'Center: Wiesenbach, Test Center external'. It features a 'Patient filter' section with dropdowns for 'order by: Patient ID [descending]', '[Both units]', '[All visits]', '[All CKD stages]', '[All registries]', '[All disease groups / diagnoses]', and '[Family filter OFF]'. Below the filters is a table of patients with columns for Patient ID, Sex, Date of Birth, Disease, CKD status, and Action. Numbered callouts point to specific elements: 1 points to the 'Add a new patient...' link; 2 points to the red cross icon in the action column; 3 points to the 'Admin: Select Center' link; 4 points to the Patient ID; 5 points to the Disease column; 6 points to the CKD status; and 7 points to the action column.

Patient ID	Sex	Date of Birth	Disease	CKD status	Action
500-0055	P	M-08/2005	Thrombotic microangiopathy		Click to enter initial visit! ✖
500-0054	P	M-09/2005	Glomerulopathy (SLE-Patient)		Click to enter initial visit! ✖
500-0053	P	M-09/2023	Tubulopathy (Barter/Gitelman-Patient)		Click to enter initial visit! ✖
500-0052	P	F-03/2020	Tubulopathy (dRTA-Patient)		Click to enter initial visit! ✖
500-0051	A	F-06/2000	Familial cystic renal disease		Click to enter initial visit! ✖
500-0050	P	M-08/2012	Glomerulopathy (esCapeKD-Patient)		Click to enter initial visit! ✖
500-0049	P	M-04/2005	Renal or urinary tract malformation		Click to enter initial visit! ✖
500-0048	P	M-02/2020	Metabolic nephropathy (esCapeKD-Patient)		Click to enter initial visit! ✖
500-0047	P	F-08/2010	Glomerulopathy (CompCure-Patient)	CKD1	Immunomarkers pending! ✖
500-0046	P	M-01/2022	Glomerulopathy	CKD1	Next visit due: 02/01/2025 ✖
500-0045	P	M-04/2005	Thrombotic microangiopathy	CKD1	Next visit due: 14/04/2019 ✖
500-0044	A	M-10/2010	Tubulopathy (dRTA-Patient)		Click to enter initial visit! ✖
500-0043	P	M-01/2023	Familial cystic renal disease		Click to enter initial visit! ✖
500-0042	P	M-06/2010	Renal or urinary tract malformation		Basic data not completed! ✖
500-0041	P	M-10/2005	Glomerulopathy		Click to enter initial visit! ✖

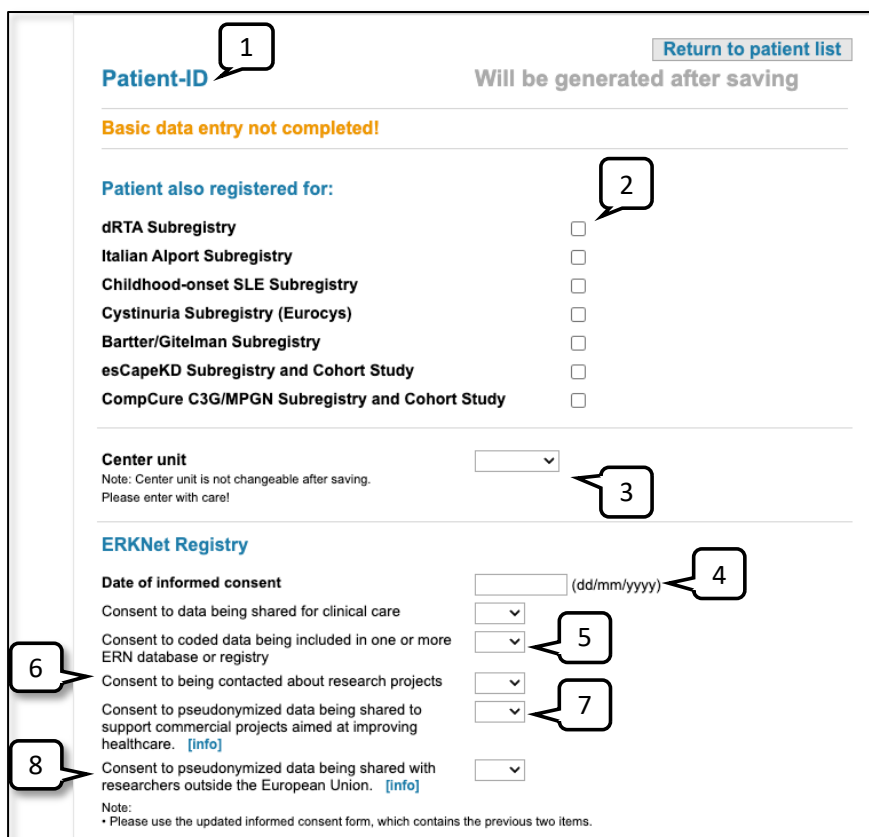
Figure 3. Data entry – patient list.

Here you can see the list of all patients that you have entered in ERKReg. You also have several filter options to go through your patient list easily.

1. Click on “add a new patient” to start a new patient record.
2. The red cross allows you to delete patient entries.
3. The patient-ID is unique and will be generated by the system upon saving the successfully the basic menu. The first three numbers correspond to you centre-ID and are identical for all your patients.
4. Indicates the sex and date of birth of your patient.
5. Indicates the thematic disease group related to your patients ‘diagnosis. This box also indicated whether the patient is also enrolled in a subregistry.
6. Indicates the patients current CKD status.
7. This box gives alerts once a visit is due. Red means that an initial visit has not been entered or a visit is already overdue. Yellow means that a next visit is due soon. Green means that the patient data is up to date.



## 3.2 Add a new patient – basic data



**Patient-ID** 1 Return to patient list  
Will be generated after saving

**Basic data entry not completed!**

**Patient also registered for:** 2

- dRTA Subregistry ☐
- Italian Alport Subregistry ☐
- Childhood-onset SLE Subregistry ☐
- Cystinuria Subregistry (Eurocys) ☐
- Barter/Gitelman Subregistry ☐
- esCapeKD Subregistry and Cohort Study ☐
- CompCure C3G/MPGN Subregistry and Cohort Study ☐

**Center unit** 3  
Note: Center unit is not changeable after saving.  
Please enter with care!

**ERKNet Registry**

**Date of informed consent** 4  
(dd/mm/yyyy)

Consent to data being shared for clinical care 5 ☐

Consent to coded data being included in one or more ERN database or registry 7 ☐

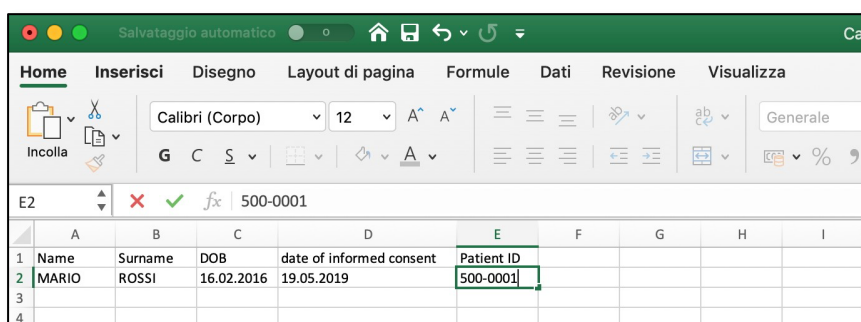
Consent to being contacted about research projects ☐

Consent to pseudonymized data being shared to support commercial projects aimed at improving healthcare. [\[Info\]](#) ☐

Consent to pseudonymized data being shared with researchers outside the European Union. [\[Info\]](#) ☐

**Note:**  
• Please use the updated informed consent form, which contains the previous two items.

Figure 4. Data entry - basic menu.



	A	B	C	D	E	F	G	H	I
1	Name	Surname	DOB	date of informed consent	Patient ID				
2	MARIO	ROSSI	16.02.2016	19.05.2019	500-0001				
3									
4									

Figure 5. Example for your internal documentation of enrolled patient.


1. The ERKReg patient-ID will be automatically generated by the system after saving. Create an excel file to document your patients name, surname, date of birth, date of informed consent **and** the ERKReg patient-ID. Keep this document for your own records. Only you will be able to re-identify your patient at a later stage (see figure 5).
2. If you want to add you patient also so an existing subregistry, select the corresponding box. After ticking the box more data element will appear.
3. Please choose whether you work at the pediatric or adult nephrology unit. HCPs with only one active unit will

be selected by default.


4. Please enter the date when the informed consent form (ICF) has been signed by the patient. This step is mandatory. It is not permitted to enter patients for which no signed ICF exists.

Please note that there are two versions of ICFs. Ensure that you are using the new form from 2021. However, some of you may use the old forms. Please see below the meaning of the consent options according to the different forms.

5. “Consent to coded data being included in one or more ERN database or registry”

Version 1	Version 2
 <p><b>I CONSENT</b> to my de-identified data being included in one or more ERN database or registry.</p> <p>Signature _____ Date _____</p>	<p><b>INFORMED CONSENT</b></p> <p>Patient First and Last Name: _____</p> <p>Date of Birth (dd/mm/yyyy): ____/____/____ ID number: _____</p> <p>I have read the information sheet about the <b>European Rare Kidney Disease Registry (ERKReg)</b>. I have been given the time and opportunity to ask questions about the objectives of the registry and the use of my data and that I have solved all my doubts with the medical doctor.</p> <p>I understand that my participation is voluntary and that I can withdraw the consent at any time without the need of justification and without affecting my future medical care.</p> <p>I approve that my data will be stored in the <b>ERKReg registry</b>, used for non-profit purposes and shared with approved users to improve the delivery of healthcare as described above.</p> <p>I consent to the processing of my pseudonymized data for the purposes described above.</p>

6. “Consent to being contacted about research project/clinical trials”.

Version 1	Version 2
 <p><b>I WOULD LIKE TO BE CONTACTED</b> about research. I will decide if I consent to my data being used for a specific project if I am contacted.</p> <p>Signature _____ Date _____</p>	<p><input type="checkbox"/> <input type="checkbox"/> <b>I WOULD LIKE TO BE CONTACTED</b> by my medical doctor about any research project and/or clinical study related to my condition.</p>

7. Consent to pseudonymized data being shared to support commercial projects aimed at improving healthcare”

Version 1	Version 2
<p><b>NOT EXISTING – USE VERSION 2</b></p> <p><b>Please use blank field</b></p>	<p><b>I CONSENT</b> that my pseudonymized data may also be used to support commercial projects aimed to improve healthcare.</p>

8. “Consent to pseudonymized data being shared with researchers outside the European Union”.



Version 1	Version 2
<p><b>NOT EXISTING – USE VERSION 2</b></p> <p><b>Please use blank field</b></p>	<p><b>I CONSENT</b> that my pseudonymized data <b>may be transferred to non-EU countries, in compliance with GDPR</b>, to support projects aimed to improve healthcare.</p>

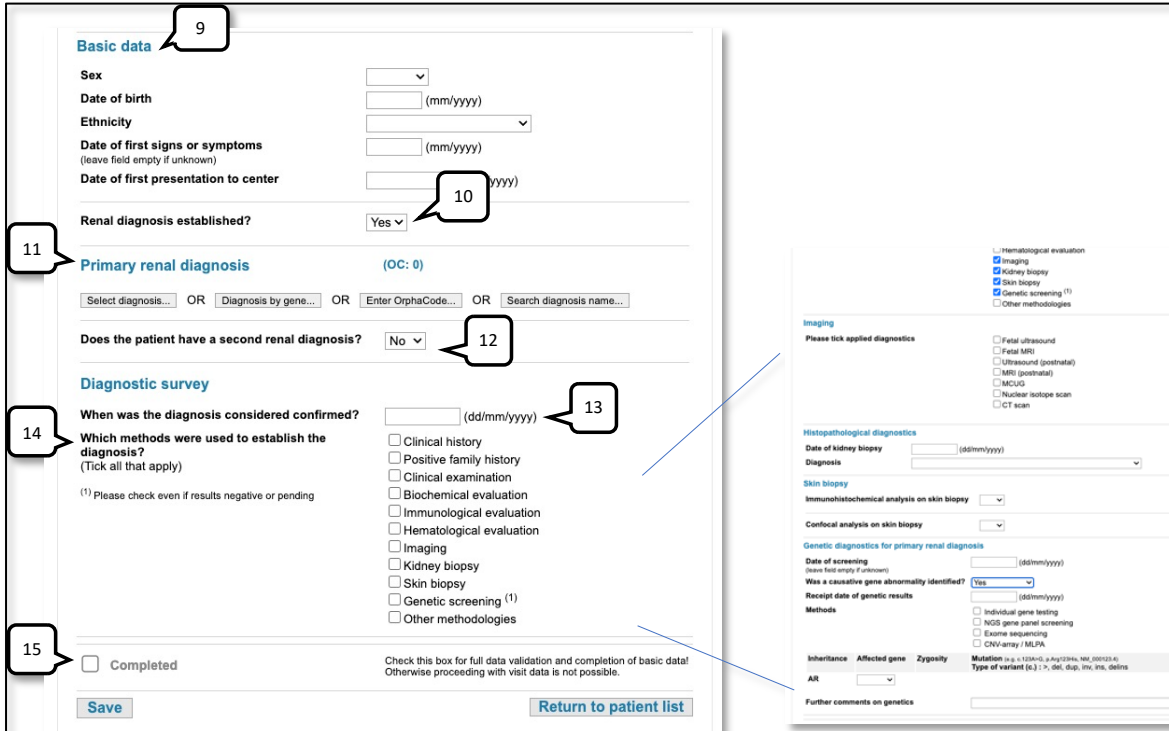


Figure 6. Data entry - basic menu.

9. Fill in basic information for your patient.
10. Indicate whether a renal diagnosis has been established. You may click “no” if you are still waiting for diagnostic results (e.g. genetic testing, histopathology). You can get back later to the patient record and continue.
11. Select the primary renal diagnosis.
  - a. **“Select diagnosis”**: the search is made through Orphanet catalogue, choosing in hierarchical order the group of the disease up to the defined pathology.
  - b. **“Diagnosis by gene”**: the search for rare kidney disease is done by typing in the name of the mutated gene that caused the disease.
  - c. **“Enter ORPHA code”**: the search for rare kidney disease is done using the orphacode.
  - d. **Search diagnosis name**: the search is done by directly typing the name of the rare kidney disease into the search bar.
12. If applicable, select the second renal diagnosis → [read the FAQ for more information](#).
13. Depending on the disease, the diagnosis can be confirmed at different times: sometimes it can be combined with genetics, in other cases such as cystinuria, the doctor is able to make a diagnosis almost immediately without the need for genetic testing.
14. Proceed by clicking on the clinical exams that enabled you to make a diagnosis. Additional specific questions will be automatically added by the system depending by the disease. → [Please read the FAQ sheet for detailed explanations](#).
15. Once finished, click on “completed”. Patient registration is now finished, the system will generate automatically

a patient ID code (see figure 7). Basic data entry is completed, you can enter the initial visit entry by clicking on “initial visit entry”. For some diseases, we are collecting the medication history, which you can enter in the medication database.

**Patient-ID**  
Dataset created: 12/02/2024

**500-0055**

[Return to patient list](#)

**Basic data entry is completed - please enter the initial visit entry now!**

**Please make sure to record the medication history in the "Medications" section!**

**Patient also registered for:**

dRTA Subregistry	<input type="checkbox"/>
Italian Alport Subregistry	<input type="checkbox"/>
Childhood-onset SLE Subregistry	<input type="checkbox"/>
Cystinuria Subregistry (Eurocys)	<input type="checkbox"/>
Bartter/Gitelman Subregistry	<input type="checkbox"/>
esCapeKD Subregistry and Cohort Study	<input type="checkbox"/>
CompCure C3G/MPGN Subregistry and Cohort Study	<input type="checkbox"/>

**Center unit** Pediatric ▾

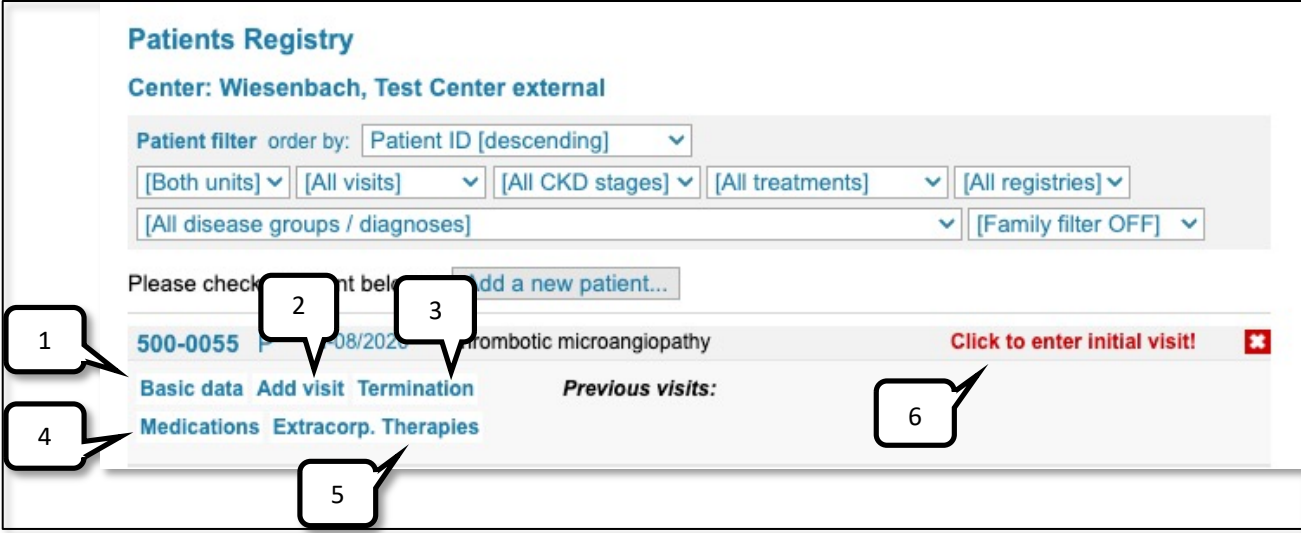
Note:

- If you wish to transfer the patient to your adult unit, please go to [termination entry](#) and select transition to adult unit.
- If you wish to transfer the patient to an other center, please contact the ERKReg administrators.

Figure 7. Completed data entry-basic menu

### 3.3 Add a new patient-initial visit

Click on one patient in your list and several options will appear.



The screenshot shows the 'Patients Registry' interface for 'Center: Wiesenbach, Test Center external'. It includes a 'Patient filter' section with dropdowns for 'order by: Patient ID [descending]', '[Both units]', '[All visits]', '[All CKD stages]', '[All treatments]', '[All registries]', '[All disease groups / diagnoses]', and '[Family filter OFF]'. Below the filters is a table of patients. The first patient row is highlighted with callouts: 1 points to the 'Basic data' link, 2 points to the 'Add visit' link, 3 points to the 'Termination' link, 4 points to the 'Medications' link, 5 points to the 'Extracorp. Therapies' link, and 6 points to the 'Click to enter initial visit!' button. The patient's ID is '500-0055', the date is '08/2023', and the diagnosis is 'thrombotic microangiopathy'.

Figure 8. Data entry-patient dashboard

1. Click it for modifying “basic data” and to come back to the previous screen.
2. Click for entering a new visit.
3. Click to terminate the patient and indicate the reasons (e.g. lof, death...).
4. For some diagnoses, you can record the mediation history.
5. For some diagnoses, you can record extracorporeal therapies
6. Here you are prompted to enter an initial or next visit.

Please see in figure 9 the data element that are being collected in the visit menu. Depending on the selected diagnoses and CKD stage conditional data elements will appear.

- The date of the initial visit may coincide with the date of the signature of the informed consent but cannot be older than six weeks.
  - Upon entering anthropometric features, some parameters are calculated automatically.
  - Upon entering serum creatinine, GFR and CKD stage are calculated automatically.
  - Other blood/urine parameters or key performance indicator measures are disease-specific.

**Patient**
500-0055 (M-08/2020)

Visit data created: 20/02/2024

Visit Date
20/02/2024 (dd/mm/yyyy)
Age at visit
3.5 y

Current treatment modality
Conservative

**Anthropometric features**

Height	100 cm	Height SDS	0.04
Weight	20 kg	BMI	20.0 kg/m <sup>2</sup>
		BMI SDS	3.09
Blood pressure (mean of last 2-3 measurements if measured more than once in past 12 months)	120 / 80 mm Hg	BP SDS	2.54 / 2.71

**Biochemical features**

Serum creatinine	1 mg/dl	or convert:	μmol/L
Estimated GFR	33 ml/min/1.73m <sup>2</sup>	CKD3	

Blood parameters

Serum bicarbonate	5 mmol/L	or convert:	mmol/l
Hemoglobin	4 g/dl	or convert:	mmol/l
Serum inorganic phosphorus	1 mmol/L	or convert:	mg/dl

Save

Return to patient list

Delete visit:

Do not forget to fill the medications, extracorporeal therapies, diet and adverse events, if applicable!

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Figure 9. Data entry-visit