ERKReg
The European Rare Kidney Disease Registry

European Reference Networks

ERK-Reg User Guide

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1. Welcome to the ERKNet Registry

ERKnet Registry, 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.

The core registry made for ERKNet

The recent implementation of European Reference Networks for Rare Diseases (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 43,000 patients in 38 specialist centers. The Network members are committed to collaborating closely in order 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.

Clinical registries are indispensable instruments to provide demographic, genotype-phenotype and natural history information. The ERKNet centers 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 centers. This paradigm of a Web based registry with an immediate benefit to user centers 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.**

2. Getting Started

2.1. Access to ERK-Reg

Access to the ERKNet Registry (ERK-Reg) is strictly regulated to protect the data privacy rights of the patients. Only authenticated users can request access to use the ERK-Reg. The username and password are strictly personal and may be requested to be provided to the ERKNet Help Desk team member in charge of your country of origin. Accounts for co-workers can be created at the direct request of the Center Coordinator. ERKNet has member Healthcare Provider **centres** (HCP) and it is envisaged that the users of ERK-Reg are Health Professionals (HP) within these Healthcare Provider **centres** (HCPs).

2.2. Request Access to ERK-Reg

This document explains how to request access to **ERK-Reg.** To be able to start, the first requirement for the user is to request a login. On 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)
Belgium, The Netherlands: Ilse Rood (Ilse.Rood@radboudumc.nl)
Italy: Giulia Bassanese (giulia.bassanese@med.uni-heidelberg.de)
Poland, Czech Republic, Lithuania, Schweden: Magda Duklas (mduklas@gumed.edu.pl)
Spain, France: Victor Perez Beltan (victorpbeltran@gmail.com)
All the other Countries (affiliated partners):
Tanja Wlodkowski (tanja.wlodkowski@med.uni-heidelberg.de)
Giulia Bassanese (giulia.bassanese@med.uni-heidelberg.de)

2.3 Logging 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** and **Mozilla Firefox** preferably latest version.

You can access the registry by the ERKNet page webpage by cliking https://www.erknet.org

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

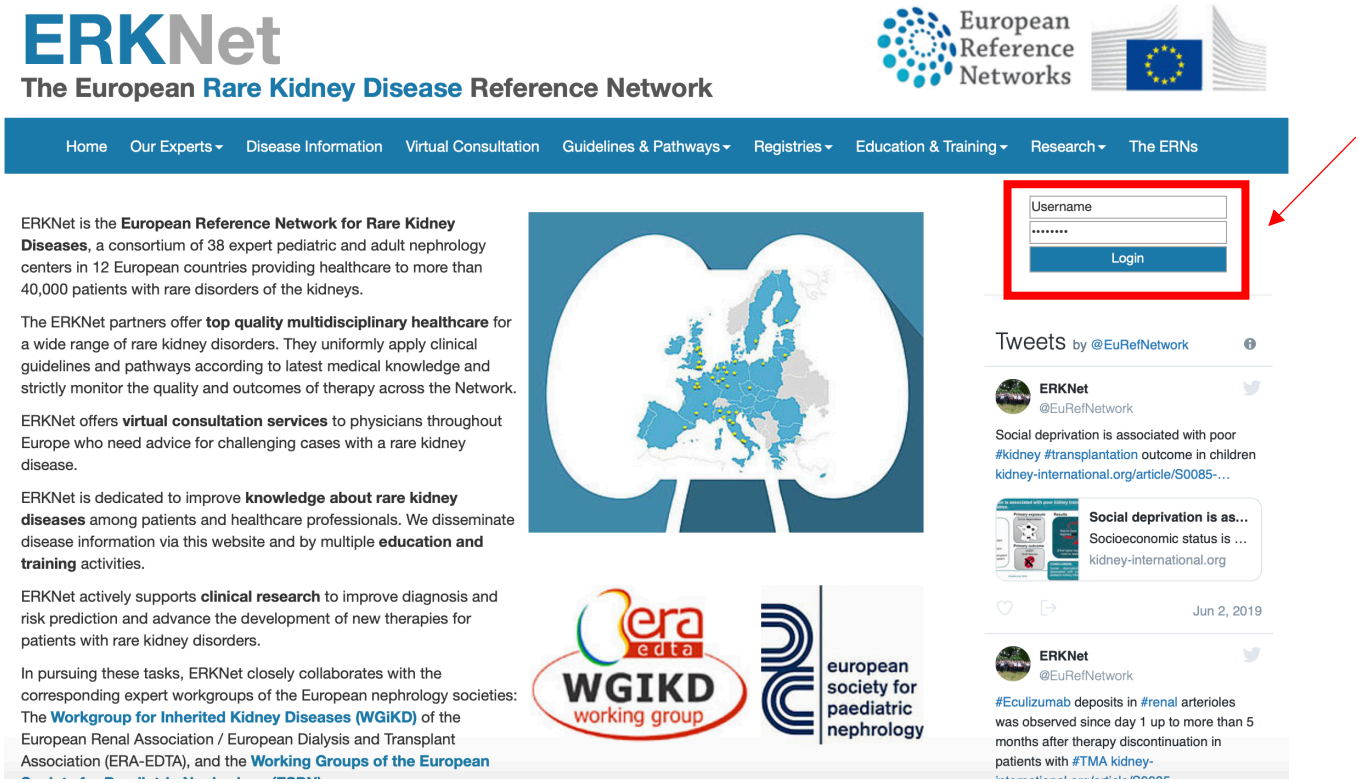


Figure 1: ERKNet home page

Once you have logged in, you can access the registry by clicking on "Registry" and choose "ERK-Reg" as showed in Figure 2.

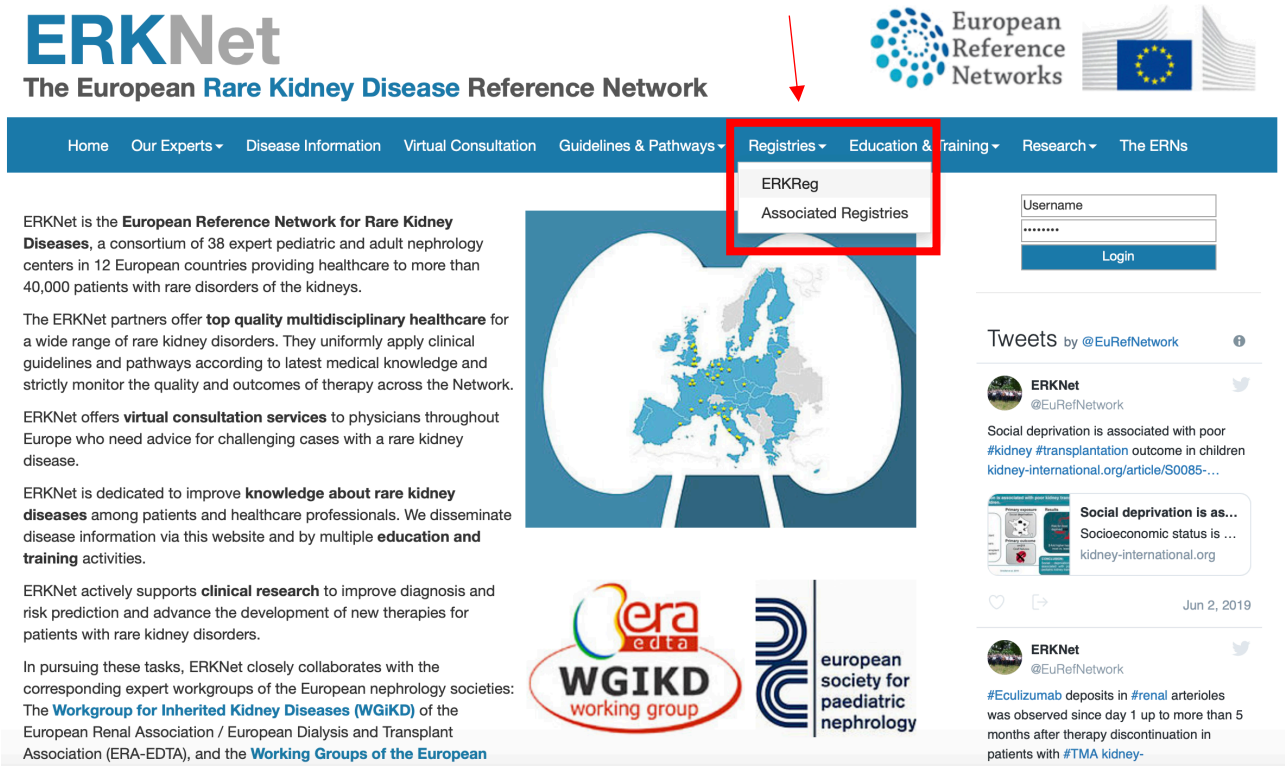


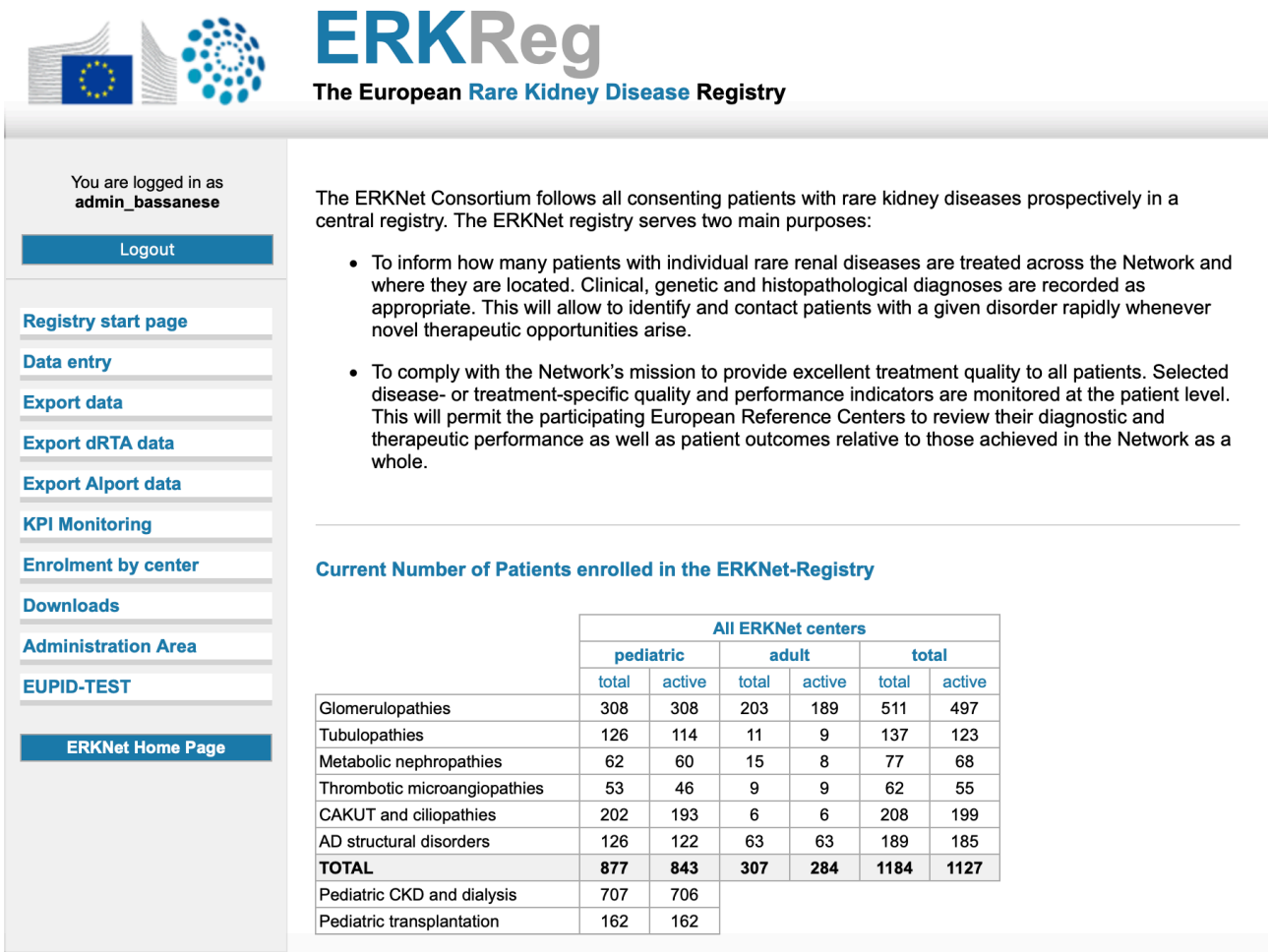
Figure 2: ERKNet home page

2.4. ERK-Reg Support Desk

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

3. Accessing ERK-Reg Applicatons

Successfully logging in to the Registry, it will direct the user to the **Registry start Page** as displayed below:



	All ERKNet centers					
	pediatric		adult		total	
	total	active	total	active	total	active
Glomerulopathies	308	308	203	189	511	497
Tubulopathies	126	114	11	9	137	123
Metabolic nephropathies	62	60	15	8	77	68
Thrombotic microangiopathies	53	46	9	9	62	55
CAKUT and ciliopathies	202	193	6	6	208	199
AD structural disorders	126	122	63	63	189	185
TOTAL	**877**	**843**	**307**	**284**	**1184**	**1127**
Pediatric CKD and dialysis	707	706				
Pediatric transplantation	162	162				

Figure 3: Registry start page

3.1. Accessing the ERK-Reg

Successfully logging in to the ERK-Reg, it will direct the user to the **Main Dashboard** Page as displayed below:

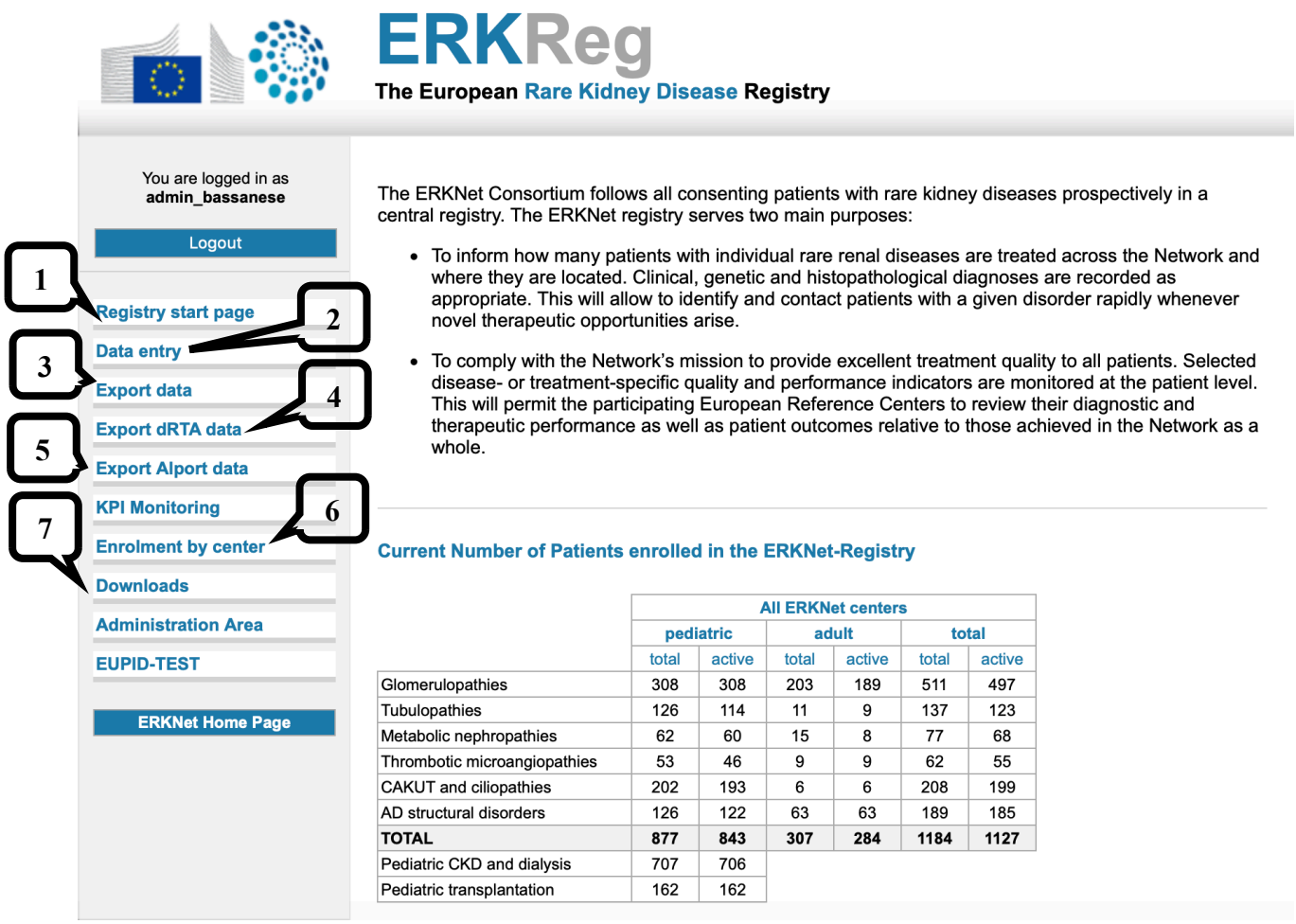


Figure 4: ERK-Reg main Dashboard page

1. Clicking here will always direct the Registry start page from anywhere in the system.

2. „Data entry“ will allow the user to access the page where to enter patients data.

3. Allow the user to export via Excel spreadsheet all the data relating to patients in his Centre entered in the Registry.

4. Enable the user to export via Excel spreadsheet all the data relating to patients in his Centre entered in the dRTA sub-registry.

5. Allow the user to export via Excel spreadsheet all the data relating to patients in his Centre entered in the Italian Alport sub-registry (only for Itaian ERKNet users).

6. By clicking here is available a statistic table with the updated number of patients enrolled in th eERKNet-Registry.

7. In „downloads“ is available the informed consents and all documentation about ERK-Reg i PDF.

4. Data entry

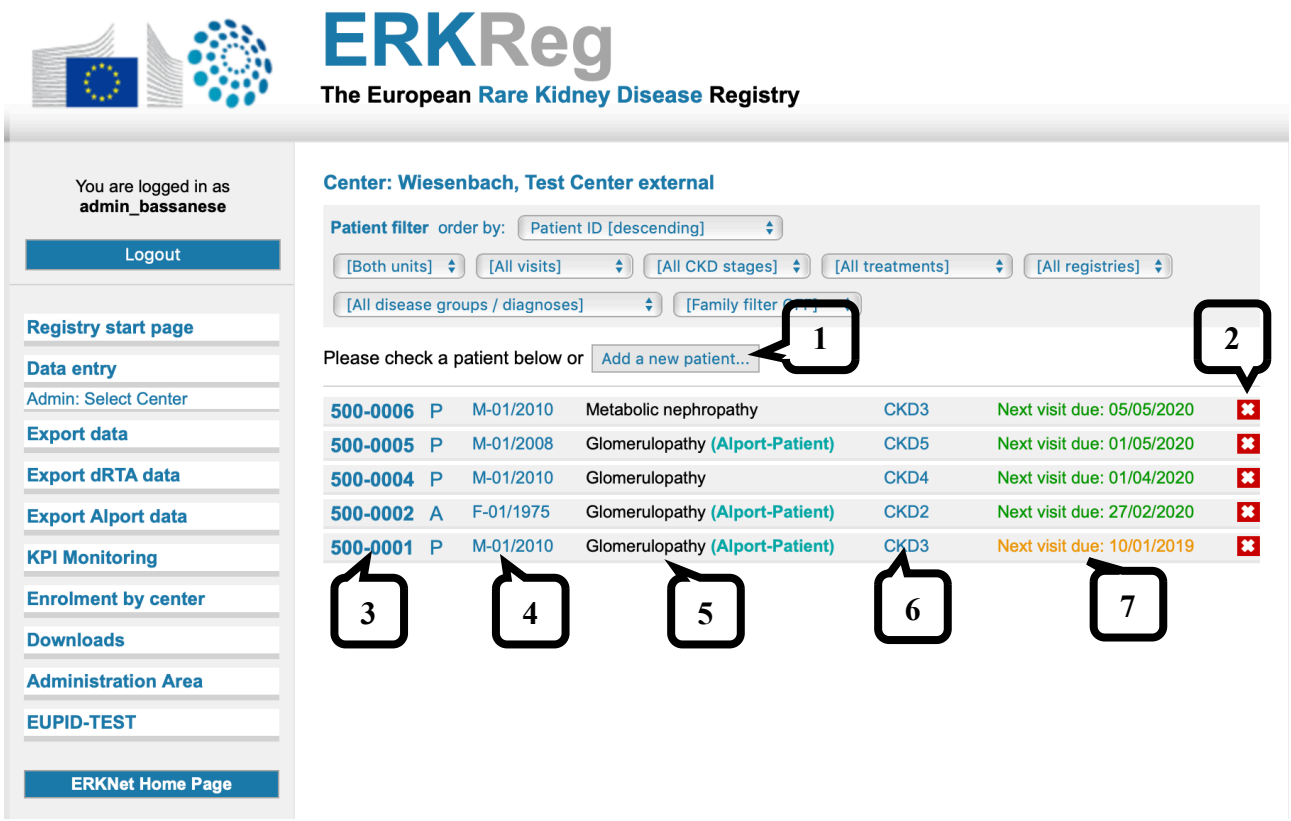


Figure 5: Data entry

By clicking on "data entry", the user can enter patient data in the registry.

1. The first step to follow in order to record the patient's data is to click on "**add a new patient**".
2. The “red cross” permit the user to delete the patient entry.
3. The “Patient code” is unique and is automatically generated by the system whenever a new patient is correctly registered in the registry. The patient code consists of 7 numbers: the first 3 numbers correspond to the centre code and are identical for all patients registered in the same ERKnet centre.
4. Indicates the sex and date of birth of the patient.
5. Indicates the group of rare kidney diseases related to the patient's pathology. This box also indicates whether the patient has been registered in subregistries.
6. Patient´s CKD stage

7. Alerts the user when the next update is due. The colour green indicates that the patient is correctly registered, yellow or red warning the user the patient data must be updated or completed.

4.1. Add a new patient

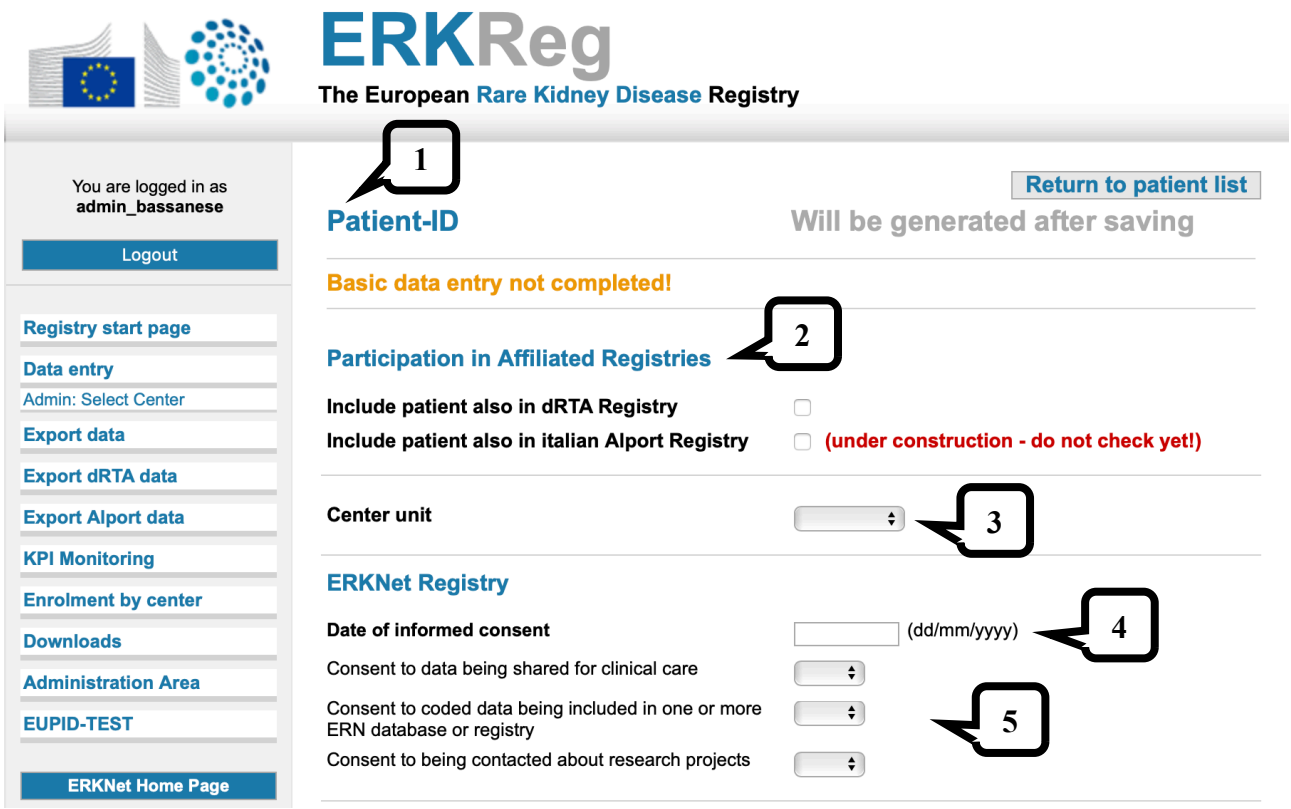


Figure 6: Data entry

1. Patient ID will be automatically generated by the System after saving. Produce a excel document in order to save the Name, Surname, date of birth, date of informed consent of the patient, personal Patient ID of the patient (generated after that all the data will be correctly saved).

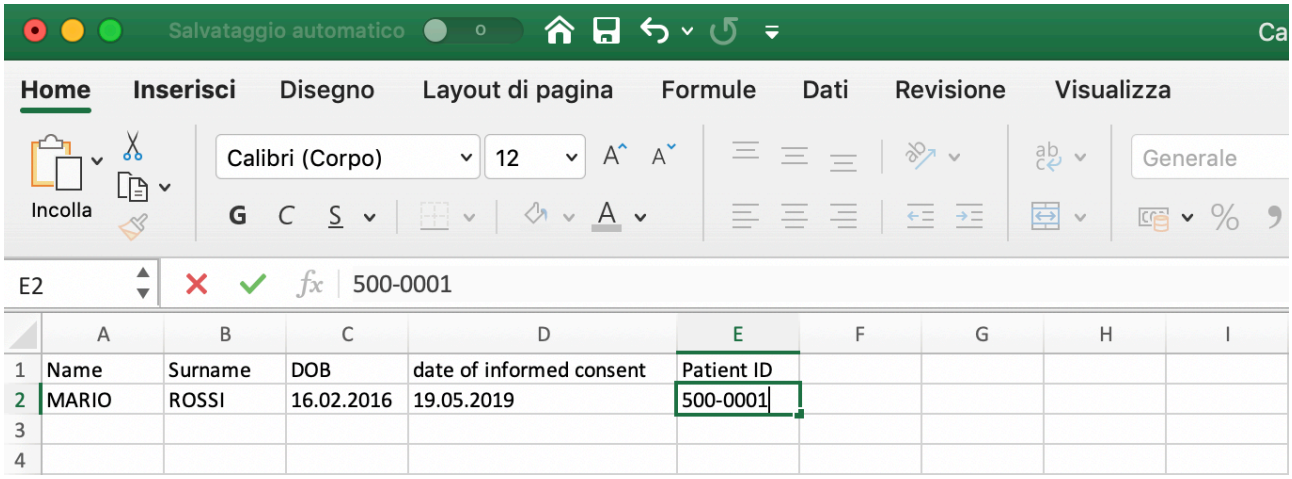


Figure 7: Example of Excel table with the data of patients

2. If the patient has a rare kidney disease for which a subregister has been established, select the corresponding subregister. The Alport sub-register is currently only available for Italian centres.
3. Indicate if your center is a pediatric or adult unit. If the centre is only pediatric or only for adult, the system will automatically select the correct choice.
4. Enter the date of informed consent. This is mandatory. **Is not permitted to register patients who have not signed the document.**
5. Insert the statements signed in the patient's consent, choosing between "yes" or "no". To be able to enter the patient in the register, all 3 statements must be "yes”.

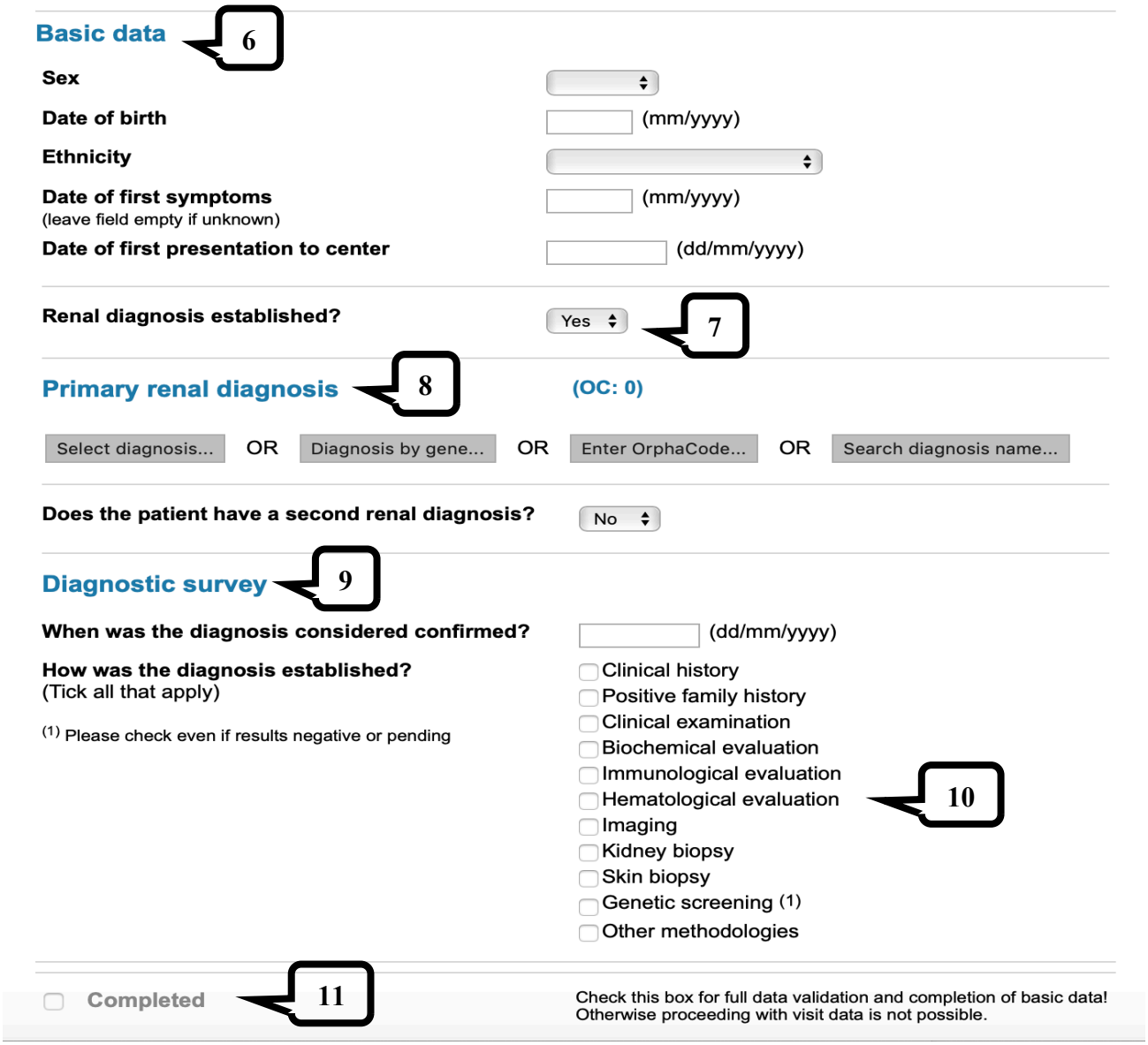


Figure 8: Data Entry

6. Fill the Basic data about the patient in.
7. If the kidney diagnosis has not been established, mark "no". The user can change the information at any time (even after saving the data).
8. “Primary renal diagnosis” can be chosen through 4 different search bars:
   - **“Select diagnosis”:** the search is made through Orphanet catalogue, choosing in hierarchical order the group of the disease up to the defined pathology.

- **“Diagnosis by gene**”: the search for rare kidney disease is done by typing in the search bar the name of the mutated gene that caused the disease.
- **“Enter ORPHA code”**: the search for rare kidney disease is done using the code Orphanet
- **“Search diagnosis name”**: the search is done by directly typing the name of the rare kidney disease into the search bar.

9. 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.
10. 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.
11. Once finished, click on "completed". Patient registration is now finished, the system will generate automatically a patient ID code (as showed below). Basic data entry is completed, you can enter the initial visit entry by clicking on “initial visit entry”.

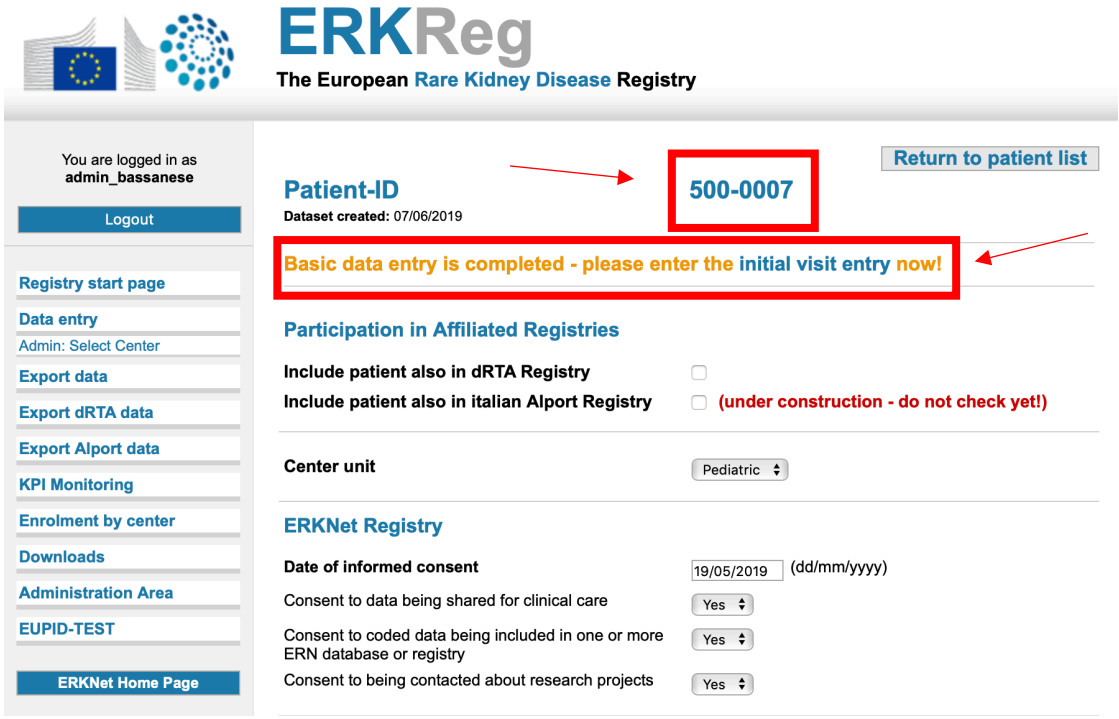


Figure 9: Data entry completed

5. Initial visit

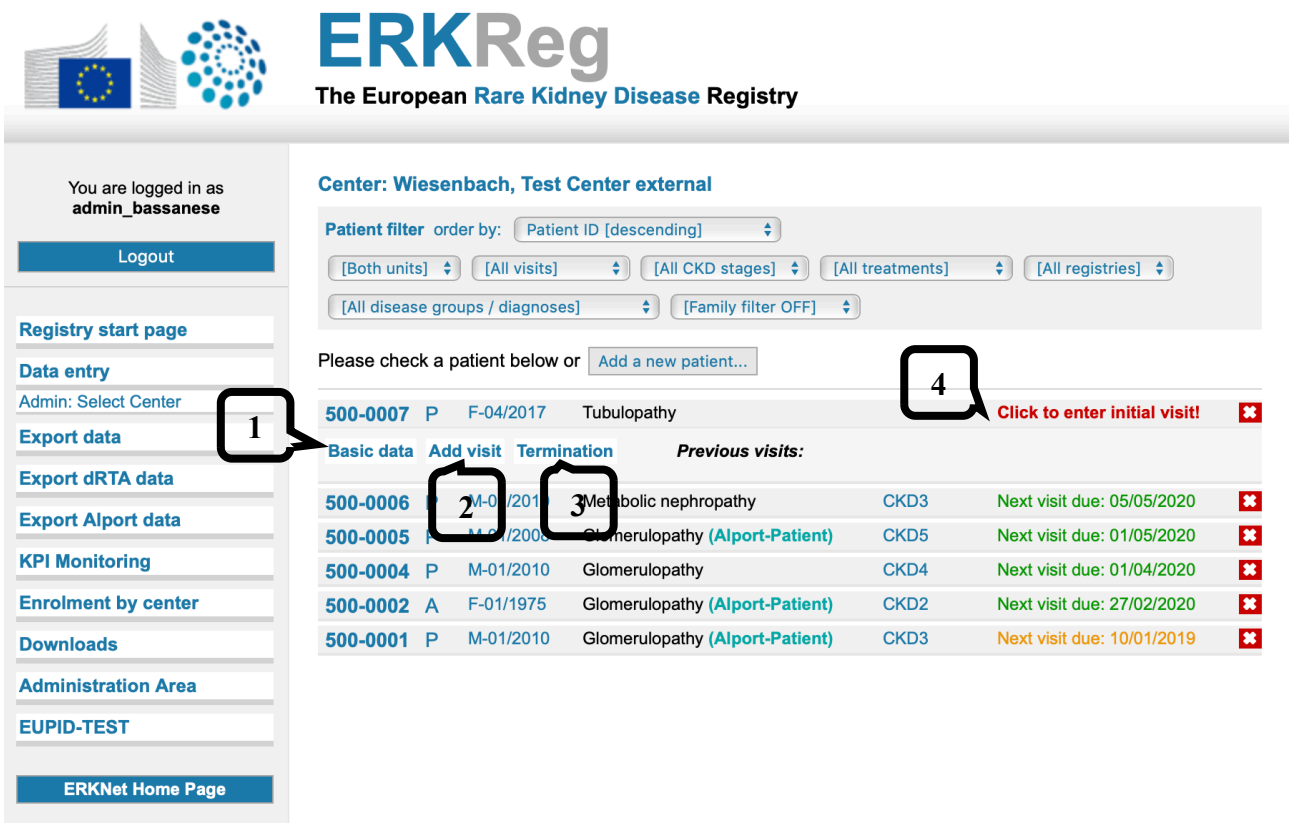


Figure 10: Data entry menu page

1. Click it for modyfing “basic data” and to come back to the previous screen
2. Click for enterying the initial visit
3. If the patient should dropp out from the registry because of his willing or in case of death
4. To enter the initial visit

5.1. Add the initial visit

The date of the initial visit may coincide with the date of the signature of the informed consent but cannot older than one month. (see figure 11 below)

Add the patient data as requested by the System. Additional specific questions will be automatically added by the system depending by the disease.

ERKReg
The European Rare Kidney Disease Registry

You are logged in as
admin_bassanese

Logout

Registry start page
Data entry
Admin: Select Center
Export data
Export dRTA data
Export Alport data
KPI Monitoring
Enrolment by center
Downloads
Administration Area
EUPID-TEST

ERKNet Home Page

Patient 500-0007 (F-04/2017)

Visit Date	19/05/2019 (dd/mm/yyyy)	Age at visit	2.1 y
Current treatment modality			

Anthropometric features

Height	cm	Height SDS	
Weight	kg	BMI	
		BMI SDS	
Blood pressure (mean of last 2-3 measurements if measured more than once in past 12 months)	/ mm Hg		

Biochemical features

Serum creatinine	mg/dl	or convert:	µmol/L
Estimated GFR			

Save Return to patient list

Figure 11: Initial visit

ERKReg
The European Rare Kidney Disease Registry

You are logged in as
admin_bassanese

Logout

Registry start page
Data entry
Admin: Select Center
Export data
Export dRTA data
Export Alport data
KPI Monitoring
Enrolment by center
Downloads
Administration Area
EUPID-TEST

ERKNet Home Page

Patient 500-0007 (F-04/2017)
Visit data created: 07/06/2019

Visit Date	19/05/2019 (dd/mm/yyyy)	Age at visit	
Current treatment modality	Conservative		

Saving successful!
Chiudi

Heig			-3.23
Weig			20.78
		BMI SDS	2.76
Blood pressure (mean of last 2-3 measurements if measured more than once in past 12 months)	90 / 60 mm Hg	BP SDS	0.66 / 1.41

Biochemical features

Serum creatinine	0.3 mg/dl	or convert:	µmol/L
Estimated GFR		**CKD1**	

Save Return to patient list

Delete visit:

Figure 12: Initial visit successfully saved

6. End of patient registration process

The patient was successfully saved as indicated in the green colour message “next visit due: 19/05/2019”. The user will add a new visit in the data suggested by the system.

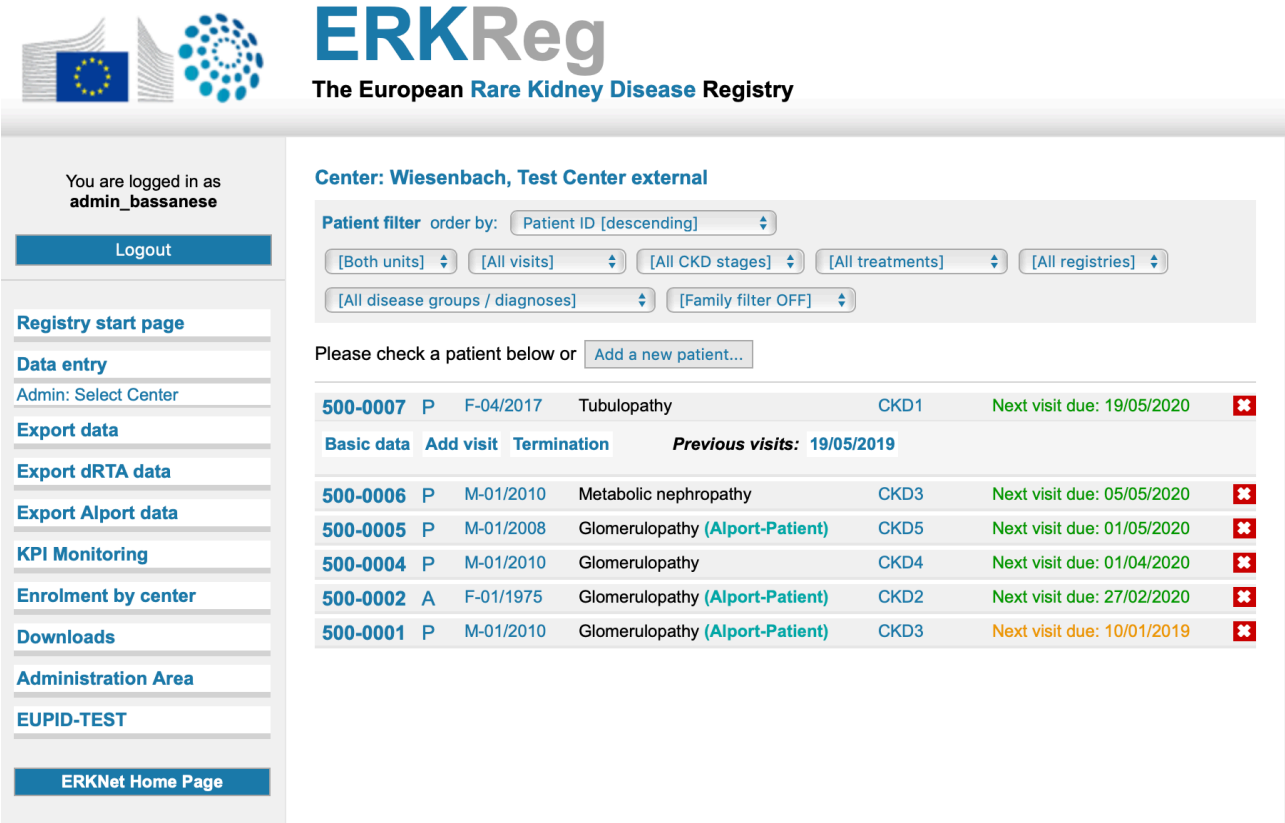


Figure 13: Data entry menu

7. Downloads

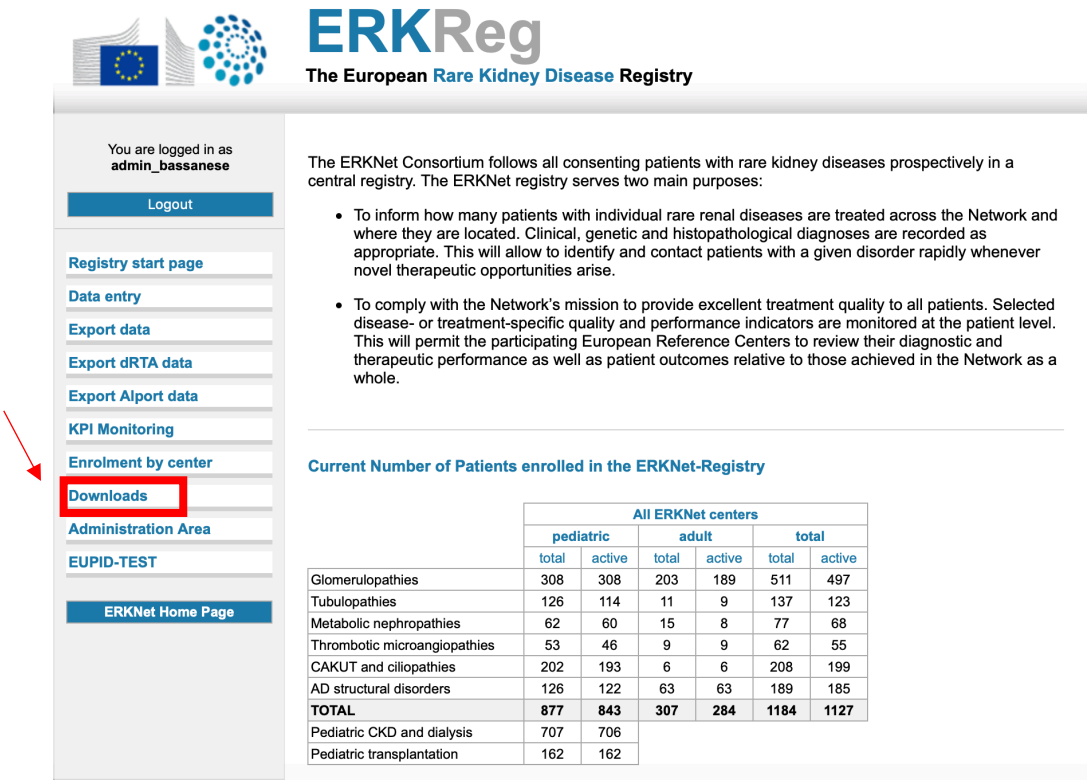


Figure 14: Registry start page

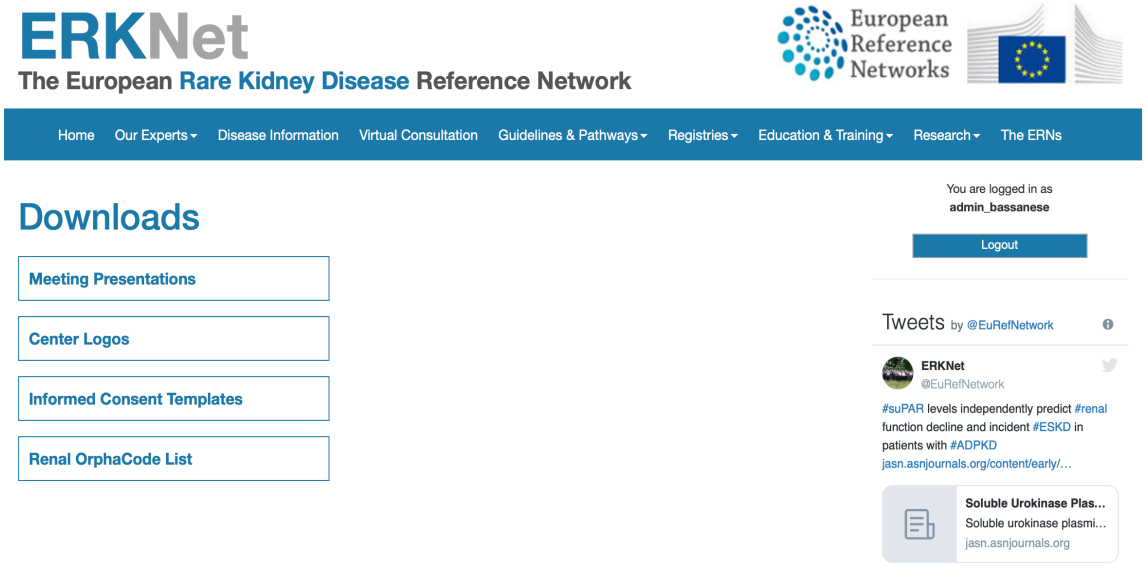


Figure 15: Downloads page

7.1. Informed consent template

In this section are available the informed consent in all the languages of the European Community.

THIS CONSENT FORM MAY BE USED FOR SHARING DATA WITH THE FOLLOWING ERN(S)
(To be completed by the health care professional signing below)
..... 1

PATIENT DETAILS
First Name: ..... Surname: .....
Date of Birth: D D M M Y Y Y Y ID number: 2
Please tick the box that applies:
I am the patient I am the parent/guardian of the patient I have power of attorney

I CONSENT to my de-identified data being shared in ERN(s) for my CARE
I understand that my data will be shared with healthcare professionals in the ERN (s) so that they may work together to support my care.
Signature Date
....

I DO NOT CONSENT to my data being shared in ERN(s) for my CARE
I understand that this means the ERN(s) cannot be consulted to support my care.
Signature Date
....

***I CONSENT** to my de-identified data being included in one or more ERN database or registry.*
Signature Date
....

***I DO NOT CONSENT** to my data being included in an ERN database or registry.*
Signature Date
....

***I WOULD LIKE TO BE CONTACTED** about research. I will decide if I consent to my data being used for a specific project if I am contacted.*
Signature Date
....

***I DO NOT WANT TO BE CONTACTED** about my data being used in research.*
Signature Date
....

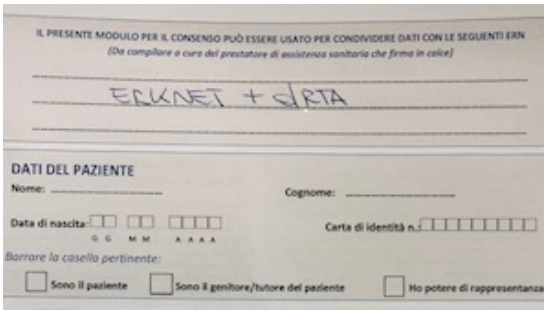
TREATING PHYSICIAN or PERSON AUTHORISED TO WITNESS CONSENT 3
Name ..... Position ..... Date .....

WHERE CAN I FIND MORE INFORMATION?
You can find more information about ERKNet at **www.erknet.org**
And general information about ERNs at **https://ec.europa.eu/health/ern_en**

This document is part of the project / joint action '777304 / ERK-REG' which has received funding from the European Union's Health Programme (2014-2020)

Figure 16: Informed consent template

1. Indicate the ERN name, in this case ERKNet and eventually sub-registries (dRTA)


IL PRESENTE MODULO PER IL CONSENSO PUÒ ESSERE USATO PER CONDIVIDERE DATI CON LE SEGUENTI ERN
(Da compilare a cura del prestatore di assistenza sanitaria che firma in calce)

ERKNET + SIRTA

DATI DEL PAZIENTE
Nome: _____ Cognome: _____
Data di nascita: GG MM AAAA Carta di identità n.:
Barrare la casella pertinente:
Sono il paziente
Sono il genitore/tutore del paziente
Ho potere di rappresentanza

Figure 17: Exemple

2. Complete with the Patient ID automatically generated by the system (once the patient is sucesfully registered – for more info see figure 6 and 11)
3. Complete with the name of the treating physiscian who has gathered the Consent.

7.2. Renal Orpha code list

The list contains all the kidney diseases in the registry and in order to clarify the user which diseases can be entered and which not, it must be consulted before starting the registration process.