



# ERKReg

The European **Rare Kidney Disease** Registry

# ERKNet

## Disclosure

I have no actual or potential conflict of interest in relation to this presentation

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*On behalf of Prof. Franz Schaefer*



## Network-wide single core registry for all rare kidney disease in pediatric and adult patients

### Objectives:

- Continuous and comprehensive collection of relevant patient information
- Identify currently patient cohorts for clinical research
- Performance assessment, benchmarking: Disease-specific key quality and outcome indicators

The ERKReg website interface includes a navigation menu with the following items: Registry start page, Data entry, Export data, Export dRTA data, Statistics & Benchmarking, Enrolment by center, Downloads, Administration Area, and ERKNet Home Page. The user is logged in as admin\_wlodkowski.

The ERKNet Consortium follows all consenting patients with rare kidney diseases prospectively in a central registry. The ERKNet registry serves two main purposes:

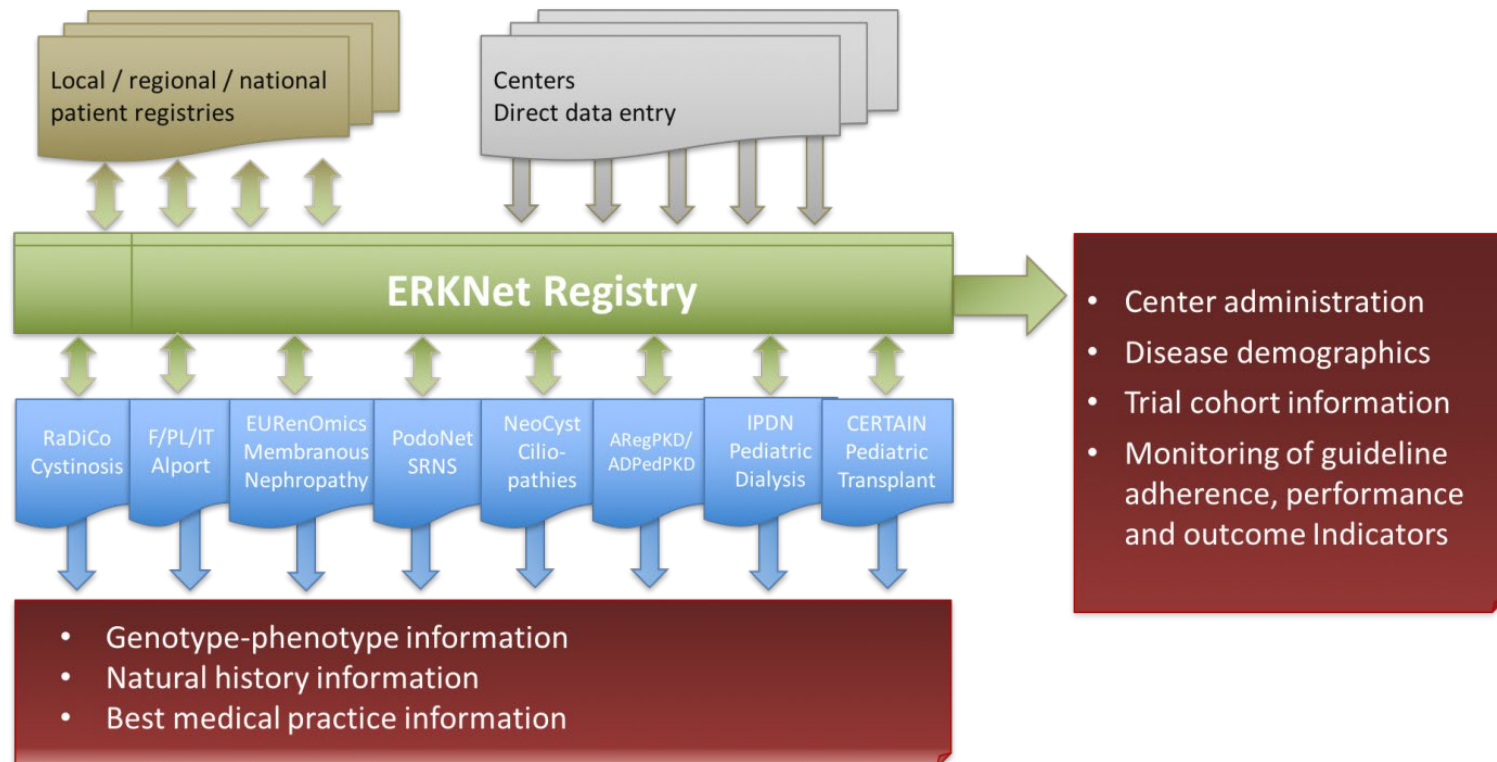
- To inform how many patients with individual rare renal diseases are treated across the Network and where they are located. Clinical, genetic and histopathological diagnoses are recorded as appropriate. This will allow to identify and contact patients with a given disorder rapidly whenever novel therapeutic opportunities arise.
- To comply with the Network's mission to provide excellent treatment quality to all patients. Selected disease- or treatment-specific quality and performance indicators are monitored at the patient level. This will permit the participating European Reference Centers to review their diagnostic and therapeutic performance as well as patient outcomes relative to those achieved in the Network as a whole.

Current Number of Patients enrolled in the ERKNet-Registry

	Your center				All ERKNet centers			
	total	active	total	active	total	active	total	active
Glomerulopathies	4	0	---	---	5	1	0	0
Tubulopathies	1	0	---	---	3	1	0	0
Metabolic nephropathies	2	2	---	---	3	3	0	0
Thrombotic microangiopathies	1	0	---	---	1	0	0	0
CAKUT and cilopathies	14	3	---	---	14	3	0	0
AD structural disorders	7	1	---	---	8	2	0	0
<b>TOTAL</b>	<b>29</b>	<b>6</b>	<b>---</b>	<b>---</b>	<b>34</b>	<b>10</b>	<b>0</b>	<b>0</b>
Pediatric CKD and dialysis	6	6	---	---	10	10	0	0
Pediatric transplantation	0	0	---	---	0	0	34	10

Open to all European nephrology centers interested in rare diseases

- Core registry to obtain basic information (and disease specific performance information) from all RD patients in all ERN centers
- External links to existing disease specific registries
- Integration of new disease specific registries (first use case: ESPN distal RTA Registry)





ERKReg collects **two datasets**:

(1) A **common data set (CDS)** including

- the JRC minimum data set, ensuring full inter-operability with other RD registries
- essential information relevant to all patients with rare kidney diseases.

(2) A **Disease-specific data set**. 40 key performance and outcome indicators (**KPI**) were defined by the thematic workgroups in a Delphi consensus-building process following structured review of existing clinical guidelines

## Incentive for ERN centers: Efficient Quality Monitoring and Outcomes Benchmarking

You are logged in as  
**admin\_schaefer**

Logout

**Registry start page**

**Data entry**

**Statistics & Benchmarking**

General

Glomerulopathies

**Tubulopathies & metabolic nephropathies**

Thrombotic microangiopathies

Structural kidney disorders

CAKUT, Ciliopathies & OUP

Pediatric CKD

Pediatric Dialysis

Pediatric Transplantation

**Enrolment by center**

**Downloads**

**Administration Area**

ERKNet Home Page

### Statistics & Benchmarking: Tubulopathies & metabolic nephropathies

	Pediatric patients		Adult patients	
	Your center	All ERKNet centers	Your center	All ERKNet centers
% children (<16y) with normal length/height SDS	66.7 % (2/3)	66.7 % (2/3)	---	---
% patients with hereditary nephropathy with genetic confirmation	50.0 % (2/4)	50.0 % (2/4)	---	0.0 % (0/0)
% patients with renal tubular acidosis maintaining normal serum bicarbonate	50.0 % (1/2)	50.0 % (1/2)	---	0.0 % (0/0)
% cystinosis patients with documented cystein level in therapeutic range	50.0 % (1/2)	50.0 % (1/2)	---	0.0 % (0/0)
% cystinuria patients free of new stones in past 12 months	0.0 % (0/0)	0.0 % (0/0)	---	0.0 % (0/0)

# HCP Local Ethics Approval



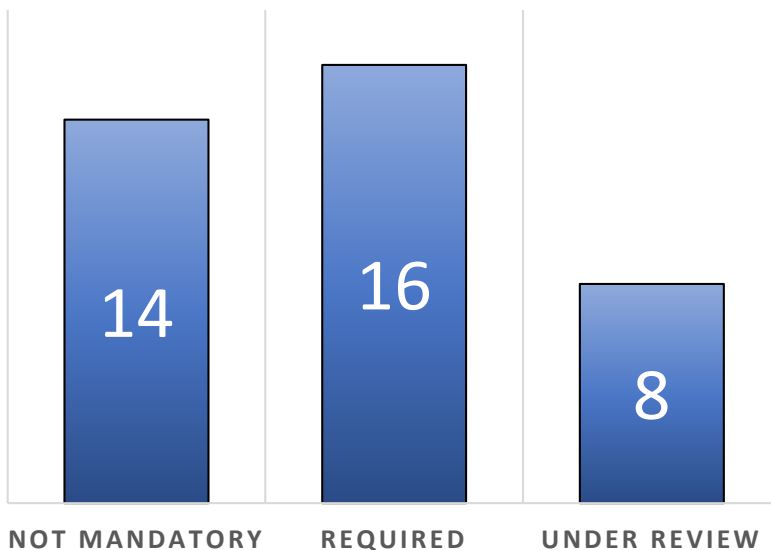
# ERKReg

The European Rare Kidney Disease Registry

September 2018:

All ERKNet centers were asked to clarify whether formal ethics approval is required to use ERN IC forms for use in clinical registry

## STATUS NOV 2018



**PATIENT CONSENT FORM FOR DATA SHARING**  
in  
**EUROPEAN REFERENCE NETWORKS** FOR RARE DISEASES  
for  
**PATIENT CARE and COORDINATION OF RARE DISEASE RESEARCH**

**WHAT ARE THE EUROPEAN REFERENCE NETWORKS AND HOW CAN THEY HELP ME?**

- European Reference Networks (ERNs) are networks of health-care professionals working in rare diseases across Europe. They are established by Directive 2011/226/EU on the application of patients' rights in cross-border healthcare.
- ERNs exist to allow healthcare professionals to work together to support patients with rare conditions or other conditions which need highly specialised therapeutic procedures.
- With your consent, and in accordance with national and European data protection legislation, your data may be referred to the ERN(s) for specialist care. Your doctor will be notified so that the healthcare professional nearest to you can help your doctor develop the ERN plan for your care plan.
- In order for the ERN to advise on your care, data collected about you in this hospital and other hospitals, some of which may be in other European countries. Your doctor will inform you about which countries are relevant to your condition.
- Your care will remain the responsibility of the healthcare professionals who care for you.
- Data about you will not be shared with other ERNs unless you consent. Your doctor will ensure you to the best of their ability.

**PATIENT DATA SHARED FOR CARE WILL BE IDENTIFIED**

- If you and your doctors agree that it would be good to ask for support from one or more ERNs, this consent form will be used to ensure that your data is shared with the healthcare professionals who will support your care.

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

**PATIENT DETAILS**

First Name: \_\_\_\_\_ Surname: \_\_\_\_\_  
Date of birth: \_\_\_\_\_ ID number: \_\_\_\_\_  
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 (s) so that I can be supported in my care.  
Signature \_\_\_\_\_ Date \_\_\_\_\_

**I CONSENT to my de-identified data being included in one or more 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 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 DO NOT CONSENT to my data being included in an ERN database or registry.**  
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**  
Name: \_\_\_\_\_ Position: \_\_\_\_\_ Date: \_\_\_\_\_

**WHERE CAN I FIND MORE INFORMATION?**  
You can also find more information about ERNs at [https://ec.europa.eu/health/ern\\_en](https://ec.europa.eu/health/ern_en)

GDPR-conforming informed consent forms designed by the EU Commission for ERN patients



- Regional contact for different European regions
- Provides technical, administrative and practical help for both CPMS and ERKNet Registry
- Regular on-site visits (1 to 2/year) by a tutor to help updating patient entries

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