ERN eUROGEN registry
Patient Reported Outcome Measure (PROM) Questionnaires Factsheet

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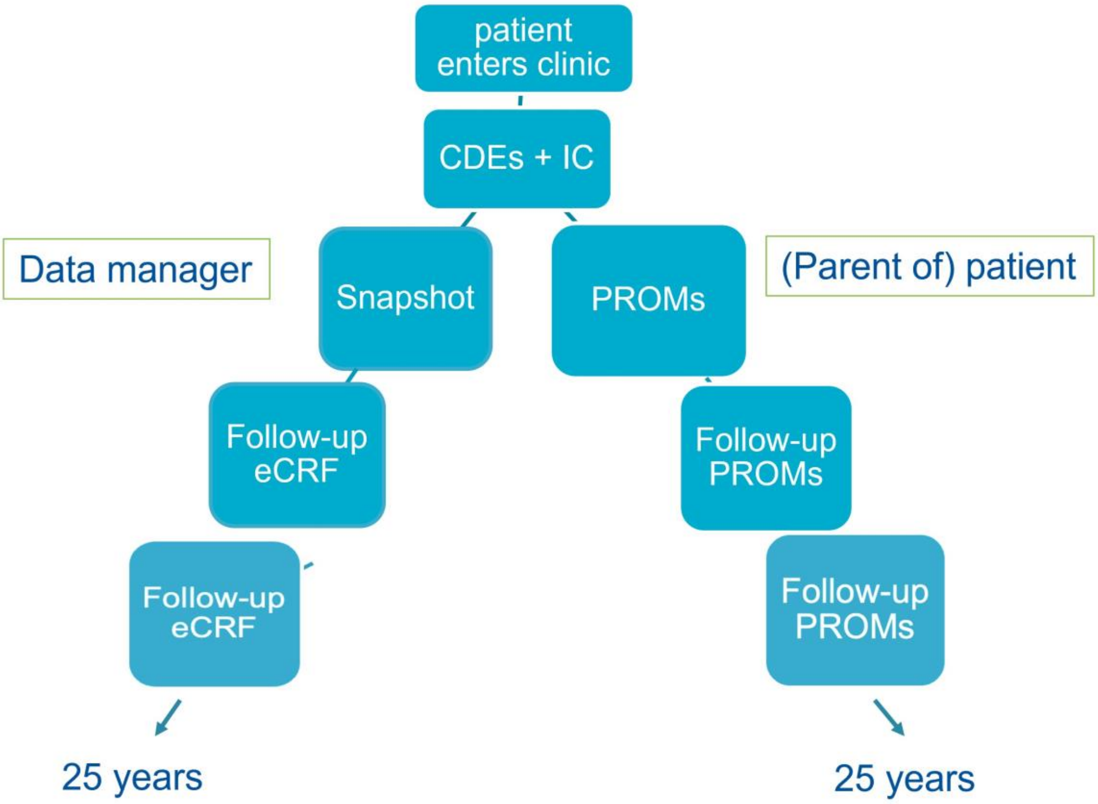
PROM QUESTIONNAIRES IN THE ERN EUROGEN REGISTRY

The picture below shows an overview of the data elements to be collected in the ERN eUROGEN registry. Patient Reported Outcome Measures (PROMs) are part of the data elements to be collected.

- We will select validated instruments as much as possible.
- To select the PROM instruments to include in the ERN eUROGEN registry, we use the PROMs Repository developed in Work Package 3 of the ERICA project (see WP3 Patient-Centred Research | ERICA (erica-rd.eu)) and PROQOLID (About PROQOLID - ePROVIDE™ (mapi-trust.org)).
- The PROM instruments should be available in as many languages as possible.
- The PROM instruments are implemented in Castor as surveys.
- ERN eUROGEN registry participants who consented to receiving questionnaires on the informed consent form (ICF) will receive a link to the Castor surveys that are applicable for them on the email address that they provided on the ICF.
    - These email addresses are entered into Castor by the Healthcare Provider (HCP) where the patient is treated.
    - The ERN eUROGEN registry Coordinator and Manager can select participants that should receive the link to a specific survey.
    - To keep the participants' identity hidden, the ERN eUROGEN registry Coordinator and Manager cannot see or change the email addresses of participants.
    - The survey response will be added to the participants' Castor record and is visible to the ERN eUROGEN registry team, while the Principal Investigator and Data managers of the HCPs don't have access to survey responses.



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STATUS OF THE USE OF PROM QUESTIONNAIRES

Status in February 2025

3 PROM questionnaires have been selected:

- To assess pediatric health-related quality of life, we will use the validated PedsQL questionnaires for patients from workstream 1 (rare congenital uro-recto-genital anomalies), as these are mainly children under the age of 18. The PedsQL questionnaires are directed at parents with different versions available for different age groups of children. For the age group of 8 to 18, there is a questionnaire for both the child and the parents. The PedsQL questionnaires are available in many languages and we are currently working on implementing them as Castor surveys in the ERN eUROGEN registry.
  - We performed a pilot by implementing one of the PedsQL surveys (the one for parents of 2-4 year old children in Dutch) as a Castor survey in the ERN eUROGEN registry and sending a link to this survey to the email addresses of parents of Radboudumc patients. In total, 41 parents received the invitation. After 3 weeks, a reminder was sent. In total, we got a response rate of 54%.
- To assess adult health-related quality of life, we will use the validated SF-36 (or RAND-36) questionnaire for patients from workstream 2 and 3 (functional urogenital disorders requiring complex surgery and rare urogenital tumors). The RAND-36 questionnaire is a widely known questionnaire that is available in many languages and we are currently working on implementing it as Castor survey in the ERN eUROGEN registry.
- To assess the patient experience of the quality and/or satisfaction of care, we will use the H-care survey. This survey was developed by EURORDIS by adapting the validated Patient Assessment of Care for Chronic Conditions Short Form (PACIC-S) to a questionnaire suitable for patients with rare diseases. Normally, the H-care survey is filled out in a special platform of EURORDIS, but we will implement the questionnaire as a Castor survey in the ERN eUROGEN registry. We are waiting for EURORDIS to provide us with the questionnaire in different languages. The H-care survey will be directed to parents for patients under the age of 12 and to the patients themselves for patients aged 12 and older.

Expertise Area	**Selected PROMs**		
	H-care survey: Satisfaction with care	**PedSQL: Quality of Life for children**	**SF-36 / RAND-36: Quality of Life for adults**
1.1 Complex genital reconstructions (DSDs)	In progress	Pilot performed	
1.2 Bladder exstrophy/epispadias	In progress	Pilot performed	
1.3 Rare urologic stone & kidney diseases	In progress	Pilot performed	
1.4 Non-syndromic urogenital tract malformation	In progress	Pilot performed	
1.5 Posterior urethral valve	In progress	Pilot performed	
1.6 Posterior hypospadias	In progress	Pilot performed	
1.7 Urorectal/anorectal malformations	In progress	Pilot performed	
2.1 Complex pelvic floor disorders: AMS800	In progress		In progress
2.1 Complex pelvic floor disorders: Fistula surgery	In progress		In progress
2.1 Complex pelvic floor disorders: ProACT	In progress		In progress
2.1 Complex pelvic floor disorders: Redo SUI OK	In progress		In progress
2.2 Rare diseases & conditions affecting female urethra	In progress		In progress
2.3 Urethral reconstruction in rare diseases & conditions	In progress		In progress
2.4 Rare retroperitoneal diseases & conditions	In progress		In progress
2.5 Interstitial cystitis	In progress		In progress
2.6 Adult urogenital reconstructive surgery	In progress		In progress
2.7 Surgery for transgender patients	In progress		In progress
3.1 Penile cancer	In progress		In progress
3.2 Testicular cancer	In progress		In progress
3.3 Adrenal tumors	In progress		In progress
3.4 Abdomino pelvic sarcoma	In progress		In progress
3.5 Rare renal tumour surgery	In progress		In progress

European
Reference
Networks

https://ec.europa.eu/health/ern_en

European
Reference
Network
for rare or low prevalence
complex diseases

Network
Urogenital Diseases
(ERN eUROGEN)

http://eurogen-ern.eu/

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ERN eUROGEN is one of the 24 European Reference Networks (ERNs) approved by the ERN Board of Member States. The ERNs are funded by the European Commission. For more information about the ERNs and the EU health strategy, please visit http://ec.europa.eu/health/ern_en