ERN eUROGEN registry
Protocol

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Sponsor	*ERN eUROGEN*
Subsidising party	*NA*
Independent expert (s)	*NA*
Laboratory sites	*NA*
Pharmacy	*NA*

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AB	Advisory Board
eCRF	Electronic Case Report Form
ERN	European Reference Network
HCP	Healthcare provider
PSC	Project Steering Committee

LIST OF ATTACHMENTS

1.0 Common Data Elements
1.2 Clinical Practice Snapshot - CBE
1.5 Clinical Practice Snapshot - PUV
1.7 Clinical Practice Snapshot - ARM
1.8 Clinical Practice Snapshot - KidTrans
2.1 Clinical Practice Snapshot - AMS800
3.2 Clinical Practice Snapshot - testicular cancer
3.3 Clinical Practice Snapshot - adrenal tumours
ICF ERN eUROGEN registry - adult patient
ICF ERN eUROGEN registry - parent_legal representative
ICF ERN eUROGEN registry - Dutch
PIF ERN eUROGEN registry - adult patient
PIF ERN eUROGEN registry - youngster
PIF ERN eUROGEN registry - parent_legal representative
PIF ERN eUROGEN registry - Dutch
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ERN eUROGEN Data Element Development Protocol
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ERN eUROGEN registry FAQ
ERN eUROGEN Data Access and Sharing Policy
F1 H-care survey
F2 SF-36 questionnaire
F3 PedsQL infant
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F5 PedsQL 5-7
F6 PedsQL 8-12
F7 PedsQL 8-12, patient
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F9 PedsQL 13-18, patient

SUMMARY

Rationale

European Reference Networks (ERNs) are virtual networks gathering doctors and researchers with high expertise in the fields of rare or low-prevalence and complex diseases. ERN eUROGEN is the ERN for rare urogenital diseases and complex conditions. Present registries in the field of rare urogenital diseases lack uniformity. ERN eUROGEN wants to facilitate knowledge sharing and better coordination of care through the continuous and comprehensive collection of relevant patient information. Therefore, a large population registry on rare urogenital diseases and complex conditions, the ERN eUROGEN registry, is a top priority.

Objectives

Harmonization and optimization of patient management across ERN eUROGEN.

Study design

Chart study.

Study population

All children and adults with a rare urogenital disease or a complex condition.

Main study parameters/endpoints

NA.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness

Participants will not benefit from inclusion, nor will it harm them. If permission has been given by the patient, they can be contacted if they are eligible for inclusion in a new study.

1. INTRODUCTION AND RATIONALE

European Reference Networks (ERNs) are virtual networks gathering doctors and researchers with high expertise in the fields of rare or low-prevalence and complex diseases. ERN eUROGEN is the ERN for rare urogenital diseases and complex conditions. Present registries in the field of rare urogenital diseases lack uniformity. Some European countries have their own national registry on rare diseases in general, but in the genito-urinary field only a few specific registries exist, most of which focus solely on a single condition. Given the disparate nature of these existing registries, the data collected is scattered and there is no uniformity, since most registries are started up by individual initiative or related to a clinical trial. The lack of consistent and complete data, together with issues of data ownership, impede the use of this material for scientific or clinical purposes. ERN eUROGEN wants to facilitate knowledge sharing and better coordination of care through the continuous and comprehensive collection of relevant patient information. Therefore, a large population registry on rare urogenital diseases and complex conditions, the ERN eUROGEN registry, is a top priority.

2. OBJECTIVES

The ERN eUROGEN registry has several objectives:

- The ERN eUROGEN registry will enable the identification of contemporary cohorts of patients with rare urogenital diseases for clinical research such as studies of diagnostic tools and prognostic biomarkers as well as interventional trials evaluating novel drugs and treatment protocols.
- The ERN eUROGEN registry will enable monitoring of diagnostic and treatment procedures at the healthcare providers (HCPs) which is very important because for most rare urogenital diseases and complex conditions no clear guidelines on these procedures are available.
- Finally, the ERN eUROGEN registry will enable research into the diagnosis, treatment and outcome or prognosis of rare urogenital diseases. It will help us to gain knowledge about the course of the disease and the effect of different treatments.

3. STUDY DESIGN

This is a prospective chart study. However, to ensure the inclusion of a considerable number of patients within a limited amount of time which enables us to get insight into the numbers of patients treated at the different HCPs and into differences in diagnostic and treatment procedures across Europe, the study also includes a retrospective part (see paragraph 8.3 for a description of the inclusion).

4. STUDY POPULATION

HCPs involved in ERN eUROGEN as a Full Member or Associated National Centre (see Annex 1) will implement the ERN eUROGEN registry at their site, but participation in the ERN eUROGEN registry is open to other HCPs, too.
The patients who will be asked for informed consent are all patients treated at an HCP at which implementation of the ERN eUROGEN registry was approved, for a rare urogenital disease or complex condition for which the HCP at which they are treated was recognised as a centre of expertise. Only patients who provided (or whose parents/legal representatives provided) informed consent will be included in the ERN eUROGEN registry. For more details, see paragraph 8.3.

5. TREATMENT OF SUBJECTS

Not applicable

6. INVESTIGATIONAL PRODUCT

Not applicable

7. NON-INVESTIGATIONAL PRODUCT

Not applicable

8. METHODS

8.1. Registry structure and contents

This registry will entail different elements:

- The Common Data Elements developed by the European Platform on Rare Diseases providing basic information about patient status, care pathway, disease history, clinical and genetic diagnosis, consent for reuse and recontacting, and availability of biological specimens (see attachment 1.0 Common Data Elements). These data elements will be collected from all patients suffering from a rare urogenital disease or complex condition treated at a HCP at which implementation of the ERN eUROGEN registry was approved.
- A Clinical Practice Snapshot containing 6 disease-specific questions about the clinical procedures performed. These Clinical Practice Snapshot questions were developed according to the "ERN eUROGEN Date Element Development Protocol" (see attachment) including consensus among at least three clinical experts in the field as well as at least one European Patient Advocacy Group (ePAG) representative. They were developed for some of the expertise areas (see attachment 1.2 Clinical Practice Snapshot - CBE, 1.5 Clinical Practice Snapshot - PUV, 1.7 Clinical Practice Snapshot - ARM, 1.8 Clinical Practice Snapshot - KidTrans, 2.1 Clinical Practice Snapshot - AMS800, 3.2 Clinical Practice Snapshot - testicular cancer and 3.3 Clinical Practice Snapshot - adrenal tumours), and will initially be collected only from patients suffering from diseases from these expertise areas. The Clinical Practice Snapshots will be developed for the other expertise areas later.
- Patient Reported Outcome Measure (PROM) questionnaires. These will be sent out via the Castor system and will be selected by experts in the field.
- Data elements on the follow-up of patients will be added to the registry in due time. The data elements to be collected and the timing of collecting them will be defined by experts in the field.

8.2. Roles and role assignment

In the ERN eUROGEN registry, different people have different roles:

- The Project Steering Committee (PSC) was involved in the setup of the ERN eUROGEN registry and will maintain oversight.
- The Advisory Board (AB) consists of three ERN eUROGEN representatives and two European Patient Advocacy Group (ePAG) representatives who gave advice during the setup of the ERN eUROGEN registry and who will continue this.
- The ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager are coordinating, managing and evaluating data processing in the ERN eUROGEN registry.
- The Principal Investigators are responsible for the local implementation of the ERN eUROGEN registry at their HCP. They are the contact persons for the PSC.
- The Data Managers perform the actual data entry in the ERN eUROGEN registry. This could be the same person as the Principal Investigator.
- The Scientific Researchers will perform the planned analyses of diagnostic and treatment procedures using the data from the ERN eUROGEN registry that were retrospectively collected. This could be the same person as the Principal Investigator and/or the Data Manager.
- Applicants are stakeholders who are interested in using data from the ERN eUROGEN registry. This could be a Principal Investigator, a Data Manager and/or a Scientific Researcher, or another stakeholder. Other stakeholders don't need to be affiliated to a ERN eUROGEN HCP.

The Principal Investigator will be assigned by the HCP and will:

- Make sure that the implementation of the ERN eUROGEN registry complies with the rules and regulations that pertain in their HCP.
  - This holds for the implementation of the ERN eUROGEN registry at large. The Principal Investigator ensures that they are familiar with the rules and regulations in their HCP and adheres to these.
  - This also holds for the actual inclusion of patient data in the ERN eUROGEN registry. There may be rules and regulations about who is allowed to see patients' medical files and to retrieve information for registries. The Principal Investigator will ensure these are adhered to.
- If the HCP of the Principal Investigator was acknowledged as a center of expertise for expertise area 1.2 bladder exstrophy/epispadias, 1.5 posterior urethral valves, 1.7 anorectal malformations, 1.8 pediatric kidney transplantations, 2.1 complicated pelvic floor disorders, 3.2 testicular cancer or 3.3 adrenal tumors (see Annex 1), the Principal Investigator will:
  - Make sure that the last 50/70 new patients for these expertise areas are asked for informed consent by sending them a postal invitation and a reply form (approach enough patients to register 30).

    - Make sure that responses are tracked.
    - Make sure that non-responders receive a reminder after four weeks.
- Implement a process in the HCP to make sure that all new patients presenting at the HCP with a rare urogenital disease or complex condition are asked for their informed consent to have their data entered in the ERN eUROGEN registry.
- Make sure that data of all patients who provided informed consent are entered in the ERN eUROGEN registry, and that no data of patients who did not provide informed consent are entered.
    - Assign the role of Data Manager to an individual with enough medical knowledge to fill out the electronic Case Record Forms (eCRFs) (e.g. medical students).
    - Inform the ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager of the names and e-mail addresses of persons who should obtain access to the ERN eUROGEN registry.
    - Inform the ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager when people should no longer have access to the ERN eUROGEN registry.
    - Instruct the Data Manager in such a way that they can fill out the eCRF properly.
    - Keep oversight of data entry by the Data Manager.
- Respond to data sharing requests and inform the ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager when data collected by the HCP cannot be used for a certain data sharing request.
- Inform other clinicians in the HCP about ERN eUROGEN, about the ERN eUROGEN registry and about research results.

The Data Manager will be assigned by the Principal Investigator and will:
- Enter data from patients who provided informed consent in the ERN eUROGEN registry.
- Respond to queries asked by the ERN eUROGEN registry Manager.

The Project Steering Committee (PSC) will:
- Keep track of the progress of data entry by the different HCPs.
- Assign (together with the AB) Scientific Researchers to perform the planned analyses of diagnostic and treatment procedures using the data collected retrospectively.
- Publish the names of the Scientific Researchers on the ERN eUROGEN website.
- Decide whether data from the ERN eUROGEN registry can be provided to Applicants by evaluating (together with the AB) application forms.

The ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager will:
- Analyse the data in the ERN eUROGEN registry at regular intervals for data consistency evaluations and to generate data reports.
- Inform the Principal Investigator and Data Manager of the HCPs about data inconsistencies via email or by adding queries to the ERN eUROGEN registry.
- Check whether the inconsistencies were resolved.
- Inform the Principal Investigators and Data Managers of the HCPs about patients who reached legal majority and who should be contacted for informed consent.
- Select patients who will receive online questionnaires via emails send out by Castor.
- Inform Principal Investigators of HCPs whose data were requested about the planned data sharing via e-mail.
- Publish approved data provisions on the ERN eUROGEN website.
- Draw up and sign Data Transfer Agreements for planned data sharing actions.
- Make data exports and share data for approved data sharing requests.
- Keep track of the progress of the projects of Scientific Researchers and Applicants.
- Forward research results of analyses of Scientific Researchers and Applicants to the contributing HCPs.
- Publish research results on the ERN eUROGEN website.
- Inform the AB about the progress of the ERN eUROGEN registry at regular intervals.

The Scientific Researchers will be selected by the PSC and AB and will:
- Perform the planned analyses using the data collected retrospectively in the ERN eUROGEN registry (data collected prospectively will be analysed by Applicants, see below).
- Inform the ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager about research results.
- Publish the results of the analyses in peer-reviewed scientific journals or, if this is not possible, make the research results public by other means.
- Destroy the data from the ERN eUROGEN registry five years after publication of the research results.

The Applicants will:

- Complete an application form to apply for data from the ERN eUROGEN registry. This can be data collected retro- and/or prospectively.
- Perform the planned research using the data provided.
- Inform the ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager about research results.
- Publish the results of the analyses in peer-reviewed scientific journals or, if this is not possible, make the research results public by other means.
- Destroy the data from the ERN eUROGEN registry five years after publication of the research results.

The Advisory Board (AB) will:

- Give advice on the ERN eUROGEN registry.
- Assign (together with the PSC) Scientific Researchers to perform the planned analyses of diagnostic and treatment procedures using the data collected retrospectively
- Decide whether data from the ERN eUROGEN registry collected pro- and/or retrospectively can be provided to Applicants by evaluating (together with the Project Leader and PSC) application forms.

8.3. Patient inclusion (see Annex 4 for a description of the local procedures)

Principal Investigators of HCPs involved in ERN eUROGEN as a Full Member or Associated National Centre will make sure that the implementation of the ERN eUROGEN registry complies with the rules and regulations that pertain in their HCP. This may mean that they need to apply for local approval of implementation of the ERN eUROGEN registry. Participation in the ERN eUROGEN registry is open to other HCPs, too. HCPs will start with retrospective inclusion if they are recognised as a centre of expertise for one or more of the five expertise areas for which the Clinical Practice Snapshots were initially developed (1.2 bladder exstrophy/epispadias, 1.5 posterior urethral valves, 1.7 anorectal malformations, 1.8 pediatric kidney transplantations, 2.1 complicated & pelvic floor disorders: AMS800, 3.2 testicular cancer and 3.3 adrenal tumors, see Annex 1). These HCPs will also start with the prospective inclusion of new patients for all expertise areas they are a recognised for as a centre of expertise (see Annex 2). Later, together with the Principal Investigators of the HCPs, we may decide to also ask the patients visiting the HCP for check-ups (see Annex 3).

Retrospective inclusion

- The Principal Investigator will make sure that the last 50/70 new patients per expertise area who visited the HCP before January 1st, 2022 will be identified using the local means that are available for this aim.
- The Principal Investigator will make sure that these patients are asked for their informed consent to have their data entered in the ERN eUROGEN registry.
    - The Principal Investigator (or the Data Manager or another person on behalf of the Principal Investigator) will send the specific Patient Information letter for retrospective inclusion and Informed Consent Forms via regular mail to the patient and/or their parents, depending on the age of the patient.
        - If the patient reached the age of legal majority, these should be:
            - one Patient Information Letter (attachment PIF ERN eUROGEN registry - adult patient),
            - two Informed Consent Forms for Patients (ICF ERN eUROGEN registry - adult patient).
        - If the patient did not yet reach the age of legal majority but can read and understand (~12):
            - one Youngster Information Letter (PIF ERN eUROGEN registry - youngster),
            - one Parent Information Letter (PIF ERN eUROGEN registry - parent_legal representative),
            - two Informed Consent Forms for Patients (ICF ERN eUROGEN registry - adult patient),
            - four Informed Consent Forms for parents/legal representatives (ICF ERN eUROGEN registry - parent_legal representative).
        - If the patient cannot read the patient information him- or herself, these should be:
            - one Parent Information Letter (PIF ERN eUROGEN registry - parent_legal representative),
            - four Informed Consent Forms for parents/legal representatives (ICF ERN eUROGEN registry - parent_legal representative).
    - After 4 weeks, a reminder with the same Patient Information and Informed Consent Form will be sent via regular mail to the non-responders.

- The Data Manager of the HCP will enter the data of patients who consented (which should be a minimal number of 30 patients per expertise area) to be included in the ERN eUROGEN registry according to the ERN eUROGEN registry Castor Manual. The Common data elements and the applicable Clinical Practice Snapshot can be filled in directly after ERN eUROGEN registry inclusion/obtaining the signed Informed Consent Form.
- The ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager will keep track of the different HCP's data entry progress and they will notify the Principal Investigators of HCPs that did not deliver their last 30 patients' data by the deadline.

Prospective inclusion

- The Principal Investigator will make sure that all new patients coming into their HCP with a rare urogenital disease or complex condition will be asked for their informed consent using the Informed Consent Forms developed by the Joint Research Centre to have their data entered in the ERN eUROGEN registry.
    - These should be two Informed Consent Forms for Patients if the patient is reached the age of legal majority (see attachment ICF ERN eUROGEN registry - adult patient).
    - These should be two Informed Consent Forms for Patients (ICF ERN eUROGEN registry - adult patient) and four Informed Consent Forms for parents/legal representatives (ICF ERN eUROGEN registry - parent_legal representative) if the patient is able to read and understand (~12 years of age) but did not yet reach the age of legal majority.
    - These should be four Informed Consent Forms for parents/legal representatives if the patient cannot read the patient information him- or herself (ICF ERN eUROGEN registry - parent_legal representative).
        - Numbers anticipated per HCP can be deduced from the ERN continuous monitoring system. Annex 2 shows the numbers of new patients per year per HCP. From our experience, we know that ~50% of patients provide Informed Consent, and therefore, we expect that the number of patients entered into the ERN eUROGEN registry will be ~50% of the total number of new patients per year per HCP. Later, we may decide to also ask the patients visiting the HCP for check-ups. Annex 3 shows the total numbers of patients per year per HCP (new patients + patients visiting for check-ups).
- The Data Manager of the HCP will enter the data of patients who consented to be included in the ERN eUROGEN registry according to the ERN eUROGEN registry Castor Manual. The Common data elements should be filled in upon ERN eUROGEN registry inclusion/obtaining signed Informed Consent Form, the Clinical Practice Snapshot 1 year after first contact with the HCP.
- The ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager will perform analyses on the amount of data entered by the different HCPs at regular intervals, and provide the HCPs with progress reports.

8.4. Patient withdrawal and data deletion requests (see Annex 4 for a description of local procedures)

Patients are allowed to withdraw informed consent without giving a reason. Patients also have the "right to be forgotten". This means that they can request their data to be deleted from the ERN eUROGEN registry. To withdraw informed consent or request the deletion of data:

- A patient (or parent/legal representative) needs to notify the treating physician.
    - The treating physician needs to make sure whether it is a withdrawal of informed consent, or whether the patient actually wishes to execute his right to be forgotten.
- The treating physician will notify the local Principal Investigator by email.
    - If a patient is younger than the legal majority, a withdrawal of consent or a request to delete data from one parent means that informed consent for the patient is withdrawn or the data needs to be deleted, independent of the opinion of the other parent.
    - If a patient reaches legal majority and provides informed consent, withdrawal of consent of parent(s) or their request to delete data has no influence anymore.
- The Principal Investigator will make sure that the request will be handled correctly.
- Withdrawal of informed consent means that the data cannot be used in new research projects.
    - The Principal Investigator will make sure that the answer on the first question in the Castor eCRF (Patient/parent(s)/legal representative(s) has/have given informed consent for the data being included in the ERN eUROGEN registry) will be changed into no.
    - The Principal Investigator will make sure that the record of the patient will be archived.
- Requests to delete data need to be handled within 30 days.

- If the request cannot be handled within the 30 days, the patient needs to be notified about this fact within 30 days with a good reason for the delay.
- The ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager needs to be notified about the Castor ID of patients who requested their data to be deleted.
- The ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager will send an e-mail to Castor with the request to delete the record from the Castor database and from the back-up.
- The ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager will notify the Principal Investigator when this request was handled.
- The Principal Investigator will make sure that the patient will be notified that the request was handled and that the personal data will be removed from the key file after sending this notification.
- The Principal Investigator will make sure that the patient will be deleted from the key file or from the pseudonymisation tool SPIDER when this is implemented.

9. SAFETY REPORTING

Not applicable

10. STATISTICAL ANALYSIS

Please see document "ERN eUROGEN Data Access and Sharing Policy" (see attachment).

11. ETHICAL CONSIDERATIONS

- The data will be extracted manually from the electronic medical files. The Data Managers performing these extractions will use targeted search strategies.
- Dates will be registered in the ERN eUROGEN registry. It is necessary to register the full date of birth in the ERN eUROGEN registry because most expertise areas concern congenital disorders or diagnoses in early life that need precise calculation of the ages at diagnosis, treatment, etc. in days.

12. ADMINISTRATIVE ASPECTS, MONITORING AND DATA SHARING

12.1. Handling and storage of data and documents

Pseudonymized data will be stored in the web-based registry. The pseudonymized name/number will be linked to hospital chart numbers and stored in a locked file in a separate location within the hospital (only accessible by the Principal Investigator and Data Manager from the HCP). When available and regarded as safe by the necessary committees, SPIDER will be used as the pseudonymization tool.
As the registry is designed to look at long term outcome, the data in the ERN eUROGEN registry will be stored for at least 25 years after collection. After 25 years, the need for keeping the stored data in this registry will be reviewed by the PSC in collaboration with the ethical committee of the Radboudumc every 10 years.

12.2. Monitoring and quality assurance

- A key instrument to optimize data quality in the ERN eUROGEN registry is the implementation of data plausibility checks.
- The ERN eUROGEN registry Coordinator and ERN eUROGEN registry Manager will keep track of the progress of data entry and provide progress reports at regular intervals. In addition, they will analyse the data in the ERN eUROGEN registry at regular intervals for detailed data consistency evaluations and asks queries about inconsistencies.
- The Principal Investigator or Data Manager adjusts the information according to the queries.

12.3. Data access

Data access will be provided to researchers, clinicians, and other persons who are interested after they go through a formal data request process involving approval of the process by the PSC and the Principal Investigators of the HCPs whose data it concerns. The exact process is described in the ERN eUROGEN Data Access and Sharing Policy (see attachment).

13.SIGNATURES

Signed for acknowledgement:

For **ERN eUROGEN registry PSC**

By: Prof. Dr. Peter Mulders
Project Leader

Date:_____

for **HCP <name of HCP>**

By: **……**
Principal Investigator

Date:_____

ANNEX 1: PRINICIPAL INVESTIGATOR - RETROSPECTIVE EXPERTISE AREA

Original Full Members	Prinipal Investigator	Retrospective inclusion for
BE - Ghent UZ	Anne-Françoise Spinoit	1.2
BE - Leuven UZ	Frank Van der Aa	1.2, 1.5, 1.7, 2.1, 3.2, 3.3
DE - Berlin Charité	Steven Warmann	1.7, 1.8
	Anja Lingnau	
DE - Bremen-Mitte Klinik	Eberhard Schmiedeke	1.7
DE - Hamburg-Eppendorf UK	Timothy Ludwig	1.5, 1.8, 2.1, 3.2
DE - Leipzig UK	Jan-Hendrik Gosemann	1.2, 1.7
DE - Munich LMUK	Oliver Muensterer	1.2, 1.7
DE - Regensburg UK	Martin Promm	1.2, 1.5
DK - Aarhus UH	Yazan Rawashdeh	1.2, 1.5, 1.7
DK - Copenhagen Rigshospitalet	Magdalena Fossum	1.2, 1.5, 1.7, 1.8
FR - Paris Necker	Célia Cretolle	1.2, 1.5, 1.7, 1.8, 2.1
IT - Rome Bambino Gesu	Barbara Daniela Iacobelli	1.2, 1.7, 1.8
IT - Rome Gemelli	Riccardo Bientinesi	2.1
IT - Milan Policlinico	Antonio di Cesare	1.2, 1.5, 1.7
IT - Padua AOU	Alessandro Morlacco	1.2, 1.7, 1.8, 2.1, 3.2
LT - Vilnius SK	Gilvydas Verkauskas	1.2, 1.5, 1.7, 1.8, 3.2, 3.3
NL - Nijmegen Radboudumc	Peter Mulders	1.2, 1.5, 1.7, 1.8, 2.1, 3.3
NL - Rotterdam Erasmus	Pim Sloots	1.2, 1.7, 3.2
PL - Gdansk MUG	Piotr Czauderna	1.2, 1.5, 1.7
PT - Porto IPO	Maria Mauricio	3.2
SE - Gothenburg Sahlgrenska	Sofia Sjöström	1.2, 1.5, 1.7
SE - Stockholm Karolinska	Gundela Holmdahl	1.2, 1.5, 1.7, 2.1
Associated National Centres that became Full Members		
AT - Linz Ordensklinikum	Bernhard Haid	1.2, 1.5
ES - Barakaldo Cruces	Beatriz Martinez Gonzalez	-
ES - Barcelona Fundació Puigvert	Anna Bujons Tur	1.2, 1.5, 1.7, 2.1, 3.2, 3.3
ES - Barcelona Sant Joan	Luis Garcia Aparicio	1.2, 1.5, 1.7
ES - Barcelona Vall d'Hebron	Romy Gander	1.2, 1.5, 1.8
	Carlos Gine	
ES - Madrid 12 de Octubre	José Medina-Polo	2.1
ES - Madrid La Paz	Pedro Lopez Pereira	1.2, 1.5, 1.7
ES - Santander Valdecilla	Jose Luis Gutierrez Baños	2.1, 3.2, 3.3
New Full Members		
BE - Antwerp	Stefan De Wachter	1.5, 1.7, 2.1, 3.2
FI - Helsinki	Seppo Taskinen	1.5, 1.7
NL - Amsterdam AvL	Oscar Brouwer	3.2
NL - Amsterdam AMC	Ernst van Heurn	1.7
NL - Groningen	Karin Ruitenbeek	1.7
NL - Utrecht	Laetitia de Kort	1.2, 1.5, 2.1, 3.2
SE - Lund	Pernilla Stenström	1.5, 1.7, 3.3
SE - Uppsala	Gisela Reinfeldt Engberg	1.2, 1.5
CZ - Prague Thomayer	Roman Zachoval	3.2
CZ - Prague University Hospital	Radim Kočvara	1.2, 1.5
DE - Dusseldorf	Peter Albers	3.2
DE - Mannheim	Raimund Stein	1.2, 1.5, 1.7
DE - Tubingen	Sara Brucker	1.2
DE - Ulm	Anne-Karoline Ebert	1.2, 1.5
DE - Aachen	Wim van Gemert	1.7
HR - Zagreb University Hospital	Tomislav Kuliš	3.2, 3.3
FR - Paris Robert-Debré	Alaa El Ghoneimi	1.2, 1.5
PL - Krakow	Rafal Chrzan	1.5, 1.7

IT - Bergamo	Lucia Migliazza	1.5, 1.7
IT - Bologna	Marcello Domini	1.5, 1.7
IT - Turin	Alessandro Giammo	-

Other participants

HR - Zagreb Sestre Milosrdnice	Ana Frobe	3.2, 3.3
LV - Riga BKUS	Valts Abols	1.2, 1.5, 1.7, 1.8
TR A2 - Ankara Bilkent City Hospital	…..	1.2, 1.7
DE H2 - Hannover Childrens's Hospital Auf der Bult	Barbara Ludwikowski	1.2, 1.5, 1.7, 2.1
TU MO - CHU Fattouma Bourguiba Monastir	Kechiche Nahla	1.2, 1.7, 3.2, 3.3
GR -	Michael Samarinas	

Withdrawn

BE - Liège CHU	David Waltregny	2.1

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IT TR - Treviso - Ospedale Ca' Foncello Treviso	Paola Midrio
IT PE - Pescara - Santo Spirito" Civil Hospital	Gabriele Lisi
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PT LI - Lisbon - Unidade Local de Saúde de São José	Filipa Jalles
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TR IZ - İzmir - University of Economics	Emre Divarci
UA DN - Dnepropetrovsk - Children's Hospital	Igor Makedonsky

Other ARM participants

CA MO - Montreal Children's Hospital	Lee Devlin Hill

ANNEX 2: NUMBER OF NEW PATIENTS PER YEAR PER HCP

	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	3.1	3.2	3.3	3.4	3.5	3.6
Original Full Members																						
BE06 - Ghent UZ		3												?	?	?						
BE10 - Leuven UZ		2	6	193	?	39	?		306	15	66	110	176				33	49	141	?		
BE03 - Liège CHU									172													
DE01 - Berlin Charité							104	?														
DE09 - Bremen-Mitte Klinik							19															
DE40 - Hamburg-Eppendorf UK					6	71		?	22	17	304	7	7	new	new	10		22				
DE10 - Leipzig UK	2	1	4	4			18															
DE03 - Munich LMUK	1	1	0	5			13															
DE19 - Regensburg UK		19		1	12	41																
DK01 - Aarhus UH	4	2		6	5	19	1															
DK02 - Copenhagen Rigshospitalet	15	2	3	4	4	14	9	?								?						
FR09 - Paris Necker	5	3			16		45	?	10													98
IT58 - Rome Bambino Gesu	5	2		36		20	28	?						2								
IT33 - Rome Gemelli									392	30	38	243	130									
IT34 - Milan Policlinico		new		new	new	new	26															
IT07 - Padua AOU	2	1		23		14	4	?	36	3	16	3	6	3			8	19		1		
LT01 - Vilnius SK	13	5		25	16	116	102	2										22	146	29	404	
NL09 - Nijmegen Radboudumc	13	11	229	199	15	204	36	?	414	197			13	?		?			210		new	
NL03 - Rotterdam Erasmus	new			new	new		31											new				
PL13 - Gdansk MUG	1	4	8	4	7	59	32							?							?	
PT08 - Porto IPO																		34				
SE02 - Gothenburg Sahlgrenska	8	1		14	3	132	16															
SE01 - Stockholm Karolinska	15	5		4	5	98	25		71	2	32											
Associated National Centres that became Full Members																						
AT08 - Linz Ordensklinikum	6	6	79	221	65	33																
ES11 - Barakaldo Cruces											25											
ES17- Barcelona Fundació Puigvert	9	11	21	68	9	10	11		121		95	22	3	12				13	33	36	115	
ES08 - Barcelona Sant Joan	4	4		26	8	11	27															
ES09 - Barcelona Vall d'Hebron	8			84	8	52		?														
ES10 - Madrid 12 de Octubre									9	2	10		5									
ES15 - Madrid La Paz	8	8		32	5	15	12					30	2									
ES70 - Santander Valdecilla									297		51							12	6		87	

	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	3.1	3.2	3.3	3.4	3.5	3.6
New Full Members																						
BE01 - Antwerp				28	6	16	new		22	40	40	50	4	35				new				
FI01 - Helsinki	3			9	3	9	31															
NL08 - Amsterdam AvL																	157	55				
NL01 - Amsterdam AMC							13															
NL02 - Groningen							12															
NL13 - Utrecht		6		114	5	5			116	new	66			41				new				
SE03 - Lund				39	13	6	17				27								4			
SE05 - Uppsala	7	9		1	10	69					30			17								
CZ07 - Prague Thomayer																		41				
CZ02 - Prague University Hospital		5			4	10																
DE37 - Dusseldorf																		82				
DE13 - Mannheim	new	25	13	96	?	30	new							new	new							
DE22 - Tubingen	13	242		80		38								new	new					new		new
DE36 - Ulm	3	new		7	7	12																
DE29 - Aachen							13															
HR01 - Zagreb University Hospital																		91	102			
FR10 - Paris Robert-Debré	44	9	39	63	9	31																
PL23 - Krakow	17			18	7	4	26															
IT05 - Bergamo				22	14	6	20															
IT11 - Bologna	6				5	82	8															
IT20 - Turin				10									50									
Other Participants																						
HR - Zagreb Sestre Milosrdnice																	4	15	0	2		
LV01 - Riga BKUS	4	0	0	6	0	42	23	1														
TR A2 - Ankara	x	x	x			x																
DE H2 - Hannover		x	x	x	x	x	x		x	x	x											
TU MO - Monastir		x					x										x	x	x	x	x	x

Numbers anticipated to be included in the ERN eUROGEN registry are ~50% of these numbers. Grey shading indicates expertise areas that were not officially approved yet, or that the HCP would like to withdraw from.

ANNEX 3: TOTAL NUMBER OF PATIENTS PER YEAR PER HCP

	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	3.1	3.2	3.3	3.4	3.5	3.6
Original Full Members																						
BE - Ghent UZ		15												?	?	?						
BE - Leuven UZ		8	10	610	?	79	?		641	26	171	216	247				84	298	321	59		
BE - Liège CHU									328													
DE - Berlin Charité							257	10														
DE - Bremen-Mitte Klinik							67															
DE - Hamburg-Eppendorf UK					16	103		11	302	520		?	?	new	new	10		?				
DE - Leipzig UK	44	4	26	59			103															
DE - Munich LMUK	2	4	3	21			56															
DE - Regensburg UK		211		20	55	158																
DK - Aarhus UH	12	7		38	13	47	3															
DK - Copenhagen Rigshospitalet	62	7	9	44	30	49	73	10								?						
FR - Paris Necker	22	56			80		170	13	27													120
IT - Rome Bambino Gesu	25	12		380		107	380	28						18								
IT - Rome Gemelli									512	45	49	288	217									
IT - Milan Policlinico		new		new	new	new	213															
IT - Padua AOU	20	25		137		216	101	16	300	58	186	52	89	53			51	137		7		
LT - Vilnius SK	80	16		56	21	279	65	10										81	344	51	1007	
NL - Nijmegen Radboudumc	25	64	535	785	67	459	116	9	1011	411			47	?		?			593		new	
NL - Rotterdam Erasmus	new			new	new		222											new				
PL - Gdansk MUG	2	7	28	9	14	84	45							?							?	
PT - Porto IPO																		?				
SE - Gothenburg Sahlgrenska	49	17		95	41	449	212															
SE - Stockholm Karolinska	67	22		42	45	229	106		219	6	85											
Associated National Centres that became Full Members																						
AT - Linz Ordensklinikum	17	33	151	511	236	101																
ES - Barakaldo Cruces											119											
ES - Barcelona Fundació Puigvert	44	132	128	395	67	74	71		1116		702	96	11	253				92	155	135	515	
ES - Barcelona Sant Joan	27	29		150	48	36	195															
ES - Barcelona Vall d'Hebron	43			452	23	114		?														
ES - Madrid 12 de Octubre									9	3	10		25									
ES - Madrid La Paz	28	96		246	22	35	75					45	2									
ES - Santander Valdecilla									1236		297							210	35		289	

	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	3.1	3.2	3.3	3.4	3.5	3.6
New Full Members																						
BE – Antwerp				149	50	64	new		62	215	215	250	11	270				new				
FI – Helsinki	16			105	53	48	116															
NL - Amsterdam AvL																	545	325				
NL - Amsterdam AMC							220															
NL - Groningen							250															
NL - Utrecht		36		425	37	32			465	new	192			203				new				
SE - Lund				113	17	56	102				48								4			
SE - Uppsala	69	39		45	30	137					40			56								
CZ - Prague Thomayer																		943				
CZ - Prague University Hospital		80			78	135																
DE - Dusseldorf																		340				
DE - Mannheim	new	39	20	167	?	50	new							new	new							
DE - Tubingen	30	311		185		56								new	new					new		new
DE - Ulm	37	new		34	17	20																
DE - Aachen							74															
HR - Zagreb University Hospital																		182	142			
FR - Paris Robert-Debré	298	67	77	263	95	225																
PL - Krakow	177			98	74	23	83															
IT - Bergamo				70	25	11	330															
IT - Bologna	14				18	150	85															
IT - Turin				200									80									
Other Participants																						
HR - Zagreb Sestre Milosrdnice																	11	62	0	4		
LV - Riga BKUS	7	2	0	76	3	66	94	4														
TR A2 - Ankara	x	x	x			x																
DE H2 - Hannover		x	x	x	x	x	x		x	x	x											
TU MO - Monastir		x					x										x	x	x	x	x	x

These are the new patients plus patients visiting for check-ups. Grey shading indicates expertise areas that were not officially approved yet, or that the HCP would like to withdraw from.

ANNEX 4: LOCAL PROCEDURES IN THE RADBOUDUMC

Retrospective inclusion

The treating physician, other member of the treatment team, or someone else on their behalf will perform the selection of patients for retrospective inclusion. Instructions:

1. Ask the medical registry department for the hospital number of the last 50/70 patients who came to the Radboudumc for the first time before January 1st, 2022 for posterior urethral valves, anorectal malformations, pediatric kidney transplantations, complicated & pelvic floor disorders: AMS800, testicular cancer and adrenal tumors (total number of 300 patients).
2. Ask your manager to request "PSG" access in de BI environment via **http://umcbiawebp01/radar_aanvraagformulier/**. Once you have access, send the list with patients numbers to informatievragen.bia@radboudumc.nl and request information on address, date of birth, patient status (death of alive) and if one had objected to be approached for research participation.
3. Create a PaNaMa file on the new study (contact the research super user of you department) and provide the basic information: Type project (clinical study, registry, etc), Title project, Acronym, Starting date of the project, End date of the project, department, whether Radboudumc is initiator of the project, the most important team members (head investigator and project coordinators) and the research institute.
4. Once the file has been created, log in to PaNAMA (PaNaMa | Inloggen (mibris.nl)) and make sure the study is registered in Epic (via 'algemeen', opnemen in epic). Make sure the study is in the execution phase.
5. Once you have received the details on the patients, register in Epic that these patients are informed and invited for the ERN eUROGEN registry (add the ERN eUROGEN registry for this patient in the tab Research Studies and change the status into "Wacht op informed consent").
6. Write the Radboudnumber on the Informed Consent Forms and (ask the treating physician to) sign them. Send the Informed Consent Forms together with the Patient Information Letter for retrospective inclusion via regular mail to the patient and/or their parents, depending on the age of the patient. Please note that there were different versions for the different ages, but that these were combined in one Dutch version.
    - These should be if the patient is 16 years of age or older:
        1. one Information Letter (see attachment PIF ERN eUROGEN registry - Dutch),
        2. two Informed Consent Forms (see attachment ICF ERN eUROGEN registry - Dutch).
    - These should be if the patient is 12 to 15 years of age:
        1. one Information Letter (see attachment PIF ERN eUROGEN registry - Dutch),
        2. one Youngster Information Letter (see attachment PIF ERN eUROGEN registry - youngster - Dutch),
        3. six Informed Consent Forms (see attachment ICF ERN eUROGEN registry - Dutch),
    - These should be if the patient is 11 years of age or younger:
        1. one Information Letter (see attachment PIF ERN eUROGEN registry - Dutch),
        2. four informed Consent Forms (see attachment ICF ERN eUROGEN registry - Dutch).
7. After four weeks, send a reminder with the same Patient Information Letter and Informed Consent Form via regular mail to the non-responders.
8. If the patient and/or the parents/legal representatives do not want to participate in the ERN eUROGEN registry, change the status for this patient in the Research Study tab in Epic for the ERN eUROGEN registry into "Niet geïnteresseerd".
9. If the patient and/or the parents/legal representatives do want to participate in the ERN eUROGEN registry, make sure that everyone who should sign the Informed Consent Form, signed it.
    - If not everyone did, collect the missing signatures by sending the patient and/or parents/legal representatives a letter or e-mail asking for the missing signatures.
        1. If the patient is 16 years of age or older, only a signature of the patient is needed.
        2. If the patient is 12 to 15 years of age, a signature of the patient and both parents is needed. If there is only 1 parent who signed, ask why the other parent did not sign. It is allowed to have only 1 signature if the other parent died or doesn't have parental authority.
        3. If the patient is 11years of age or younger, a signature of both parents is needed. If there is only 1 parent who signed, ask why the other parent did not sign. It is allowed to have only 1 signature if the other parent died or doesn't have parental authority.

The Data manager will add the patients who provided informed consent to the ERN eUROGEN registry. Instructions:

10. Change the status for this patient in the Research Study tab in Epic for the ERN eUROGEN registry into "Informed consent getekend". Fill out the date that informed consent was provided as start date.
11. Bring the Informed Consent Forms to the staff secretariat of the Department of Urology.
    - They will be stored in a locked cabinet at the Department of Urology.
12. Create a new record in Castor under the ERN eUROGEN registry for Institute Radboudumc (see ERN eUROGEN registry Castor Manual, see attachment).
13. Add the patient for who informed consent was obtained to the key file with his/her Radboudnumber, first and last name, date of birth, and Castor ID number.
    - There will be a key file for the ERN eUROGEN registry at \\Umcfs063\urodata$\eUROGEN\ERN eUROGEN registry\key file, which will only be accessible by the recruiting personnel for the ERN eUROGEN registry, for the Principal Investigator and for the Data Manager.

Prospective inclusion

In the Radboudumc, patients will be included at the outpatient clinic by the clinician who sees the patient. Instructions:

1. Inform the patient and/or the parents/legal representatives about participation in the ERN eUROGEN registry. Answer any questions they may have.
2. Register in Epic that the patient is informed and invited for the ERN eUROGEN registry (add the ERN eUROGEN registry for this patient in the tab Research Studies and change the status into "Wacht op informed consent").
3. Write the Radboudnumber on the Informed Consent Forms (see attachment ICF ERN eUROGEN registry - Dutch) and sign them. Hand them over to the patient and/or the parents/legal representatives and ask them to take time to read it carefully. Please note that there were different versions for the different ages, but that these were combined in one Dutch version.
    - These should be two Informed Consent Forms (for the patient) if the patient ≥ 16 years of age.
    - These should be six Informed Consent Forms (two for the patient and two per parent) if the patient is 12 to 15 years of age.
    - These should be four Informed Consent Forms (two per parent) if the patient ≤ 11 years of age.
4. Inform that if the patient and/or the parents/legal representatives agree to participate in the ERN eUROGEN registry, the patient and/or the parents/legal representatives should sign the Informed Consent Forms and bring one copy to their next appointment. They can keep the other copy for their own administration.
5. If the patient and/or the parents/legal representatives indicate not to participate, change the status for this patient in the Research Study tab in Epic for the ERN eUROGEN registry into "Niet geïnteresseerd".

At the second visit of the patient and/or parents/legal representatives, Informed Consent Forms will be collected and stored and participation will be indicated in Epic. Instructions:

6. If the patient and/or the parents/legal representatives do not want to participate in the ERN eUROGEN registry, change the status for this patient in the Research Study tab in Epic for the ERN eUROGEN registry into "Niet geïnteresseerd".
7. If the patient and/or the parents/legal representatives do want to participate in the ERN eUROGEN registry, make sure that everyone who should sign the Informed Consent Form, signed it.
    - If not everyone did, collect the missing signatures or give the Informed Consent Forms back to the patient and/or the parents/legal representatives and ask them to collect the missing signatures.
        1. If the patient is 16 years of age or older, only a signature of the patient is needed.
        2. If the patient is 12 to 15 years of age, a signature of the patient and both parents is needed. If there is only 1 parent who signed, ask why the other parent did not sign. It is allowed to have only 1 signature if the other parent died or doesn't have parental authority.
        3. If the patient is 11years of age or younger, a signature of both parents is needed. If there is only 1 parent who signed, ask why the other parent did not sign. It is allowed to have only 1 signature if the other parent died or doesn't have parental authority.
8. Change the status for this patient in the Research Study tab in Epic for the ERN eUROGEN registry into "Informed consent getekend". Fill out the date that informed consent was provided as start date.
9. Bring the Informed Consent Forms to the staff secretariat of the Department of Urology.
    - They will be stored in a locked cabinet at the Department of Urology.

10. Add the patient for who informed consent was obtained to the key file with his/her Radboudnumber, first and last name and date of birth. Do not fill out the Castor ID number yet.
    - There will be a key file for the ERN eUROGEN registry at \\Umcfs063\urodata$\eUROGEN\ERN eUROGEN registry\key file, which will only be accessible by the recruiting personnel for the ERN eUROGEN registry, for the Principal Investigator and for the Data Manager.

The Data Manager checks the key file regularly to see whether new patients can be added to the ERN eUROGEN registry. Instructions:

11. Check the key file for new patients indicated by the absence of a Castor ID number.
12. Create a new record in Castor under the ERN eUROGEN registry for Institute Radboudumc (see attachment ERN eUROGEN registry Castor Manual).
13. Add the Castor ID to the key file.
14. Fill in Castor according to the ERN eUROGEN registry Castor Manual, see attachment.
15. The Data Manager will also regularly check the diagnoses with the status hypothetical, so see whether a definitive diagnosis can be filled out.

Patient withdrawal and data deletion requests

The treating physician will inform the Principal Investigator when informed consent was withdrawn for a patient or when there is a data deletion request. The Principal Investigator or someone else on his behalf will handle these requests. Instructions:

- Withdrawal of informed consent means that the data cannot be used in new research projects.
    - Change the answer on the first question in the Castor eCRF (Patient/parent(s)/legal representative(s) has/have given informed consent for the data being included in the ERN eUROGEN registry) into no.
    - Archive the record of the patient.
    - Change the status for this patient in the Research Study tab in Epic for the ERN eUROGEN registry into “Informed Consent teruggetrokken”.
    - Find the actual paper Informed Consent Form and put a remark on it that the informed consent was withdrawn and the date of withdrawal.
- Requests to delete data need to be handled within 30 days.
    - Make sure with the treating physician when the request for data deletion was done.
        - If the request cannot be handled within the 30 days, notify the patient about this fact within 30 days with a good reason for the delay.
    - Send an e-mail to Castor with the Castor ID of the patients who requested their data to be deleted and ask them to delete the record from the Castor database and from the back-up.
    - Delete the ERN eUROGEN registry from the Research Study tab in Epic.
    - Find the actual paper Informed Consent Form and throw it away in the bin for confidential paper.
    - Notify the patient that the request was handled and that the personal data will be removed from the key file after sending this notification.
    - Delete the patient from the key file or from the pseudonymisation tool SPIDER when this is implemented.

http://eurogen-ern.eu/

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