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ERN eUROGEN

**European Reference Network for rare urogenital
diseases and complex conditions**

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1. ERN DEVELOPMENT PLAN

1.1. Background

The [European Reference Networks](#) (ERNs) were established in 2017 under Article 12 of the 2011 EC Directive on Patients' Rights in Cross-border Healthcare ([2011/24/EU](#)) in the field of rare or low-prevalence complex diseases. There are 24 virtual networks involving healthcare providers (HCPs) across the EU, each focusing on a specific medical domain of rare diseases or complex conditions. One of these is the **European Reference Network on Rare Urogenital Diseases and Complex Conditions** (hereinafter referred to by its acronym, [ERN eUROGEN](#)).

The establishment of the ERN initiative in 2017, followed by the integration of Affiliated Partners in 2019, and the enlargement with new members in 2022 (after the EC call in 2019) has been an unprecedented move in improving the healthcare management of patients suffering from rare diseases and complex conditions throughout Europe. More than 1600 specialised expert teams from almost 400 health Care Providers (HCP) in 26 EU member states have been officially recognised as rare disease expert centres. This was reached through the expansion in 2022, with 620 additional expert centers who were added as part of the second call for ERN membership.

Healthcare providers of an EU member state that are not represented by full members in an ERN can apply for an ERN partnership ("Affiliated Partners") as associated national centres ("associated national centres") or national coordination hubs ("national coordination hubs"). Affiliated Partners are smaller entities, usually with a lower degree of specialisation. Rare diseases or complex conditions are diseases or conditions with a particularly low prevalence; [the EU considers diseases to be rare](#) when they affect not more than 5 per 10,000 persons in the EU. The 24 ERNs facilitate knowledge sharing and care coordination and cure innovations, thereby establishing new ways to reduce negative outcomes for patients suffering from rare diseases while improving and innovating the quality of care provided by expert healthcare professionals and their teams, and subsequently diminishing the cumulative cost for society.

1.2. ERN eUROGEN

ERN eUROGEN's mission is to deliver faster specialist evaluation and more equitable access to high-quality diagnoses, treatment, and care for patients with rare urogenital diseases and complex conditions who need highly specialised assessment and surgery. The network is training the next generation of urologists and surgeons, increasing skill levels, and improving patient outcomes. A priority is transferring knowledge and training to those Member States with less expertise, thereby increasing the quality of surgical outcomes across the EU. Training, educational, and research activities are developed together with patients and ERN Patient Advocacy Group (ePAG) Advocates related to the relevant rare diseases or complex conditions.

Specific development targets or actions for each work package have been identified in this plan as priorities for action. This plan will be shared with the network Strategic Board for comments, input and approval.

1.3. WP1 Coordination

ERN eUROGEN now includes 56 Healthcare Providers (HCPs) and their urogenital specialists, multi-disciplinary teams (MDT), urology and surgical departments from 20 EU Member States (MS) as Members and Affiliated Partners (Associated National Centres and National Coordination Hubs). Each year the HCPs deliver the expert care needed for around 6,000 patients diagnosed under the rare urological disease codes included within the network. In 2023 (when the first aggregated results are expected to be made public), ERN monitoring data will provide an update on patient and surgical procedure numbers.

Within ERN eUROGEN, rare urogenital diseases and complex conditions are structured into three Workstreams (WS) based on age, functional disorder, or malignancy: (WS1) rare congenital uro-recto-genital anomalies, (WS2) functional urogenital conditions requiring highly specific surgery and (WS3) rare urogenital tumours. These three WS are further subdivided into 16 different Expertise Areas (EAs), currently covering 114 specific areas of expertise.

(Note: ERN eUROGEN prefers to refer to Expertise Areas (EAs) rather than disease areas, to respect the EU's principles of equality, diversity, and inclusiveness (as we do in all our activities), because we provide expertise relating to complex cases involving differences in sex development (DSDs) (EA 1.1) and surgery for transgender patients (EA 2.7). These areas involve the identities of individuals and are not diseases or disorders, so it would be disrespectful to the patients involved to refer to their requirements as such.)

Expansion of the network's Expertise Areas (EAs)

In 2019, ERN eUROGEN expanded the number of EAs covered by the network to include complex adult urogenital reconstructive surgery, surgery for transgender patients, and rare renal tumour surgery. In 2022, in response to recommendations from Orphanet who performed a gap analysis of the diseases covered by the ERNs and specific requests from patient organisations, ERN eUROGEN will aim to expand its EA coverage again to include male infertility, paediatric renal transplantation in urology (for improved urological care and cross-ERN collaborations with ERN TransplantChild and ERKNet), and paediatric oncological urology and rare bladder tumor surgery. An additional patient organisation dealing with male infertility (the Klinefelter's Syndrome Association) has joined the ERN eUROGEN ePAG and has already begun to attend relevant network meetings. The new EA can only officially be added to the scope of the network once they have been approved by the Board of Member States for ERNs (BoMS).

Specific development action:

- Add new EAs: male infertility, paediatric renal transplantation in urology and paediatric oncological urology and rare bladder tumour surgery. This will expand the number of patients with those rare diseases and complex conditions who can access the help of the ERN. It will also enable collaboration amongst expert clinicians working on these EAs.

Expansion of the network's geographical coverage

Since its launch, ERN eUROGEN has enlarged in its geographical coverage (in terms of the number of Members and Affiliated Partners, and thereby number of EU Member States covered, as well as the number of Supporting Partners, and Associate/Supporting Patient Partners participating in the network) and in its EA coverage, thereby increasing its accessibility and added value to European healthcare professionals seeking advice and innovating care for their patients. Although coverage of EU countries could be improved, ultimately membership and applications do not depend on the network, but rather on EC calls for applications and designations by the Board of Member States for ERNs (BoMS) and national ministries of health. However, further expansion of geographical coverage is expected in due course when additional Affiliated Partners are appointed by the BoMS in those Member States where the ERN does not yet have a member.

Specific development action:

- ERN eUROGEN aims to expand its geographical coverage to include all EU Member States. Currently, it covers 20 MS. Therefore, it will be a priority to integrate additional Affiliated partners as soon as information on official designation is received from the BoMS should they decide to designate further Affiliated Partners to work with ERN eUROGEN.

Integration of new members into the network and stimulating engagement and cohesion

A solid foundation of trust has been built and maintained, with an open and welcoming culture for all clinicians and patients seeking advice. Since the network's launch in 2017, we have developed a robust governance and organisational structure involving vertical and horizontal aspects that provide top-down and bottom-up guidance on strategy and activities. This structure is robust and effective, and we will continue to maintain and consolidate it as well as improving it by updating our network information, Governance Statutes and related policies where necessary. The network has already developed comprehensive protocols and policies relating to: responsibilities, tasks and actions for Members and Affiliated Partners; changes in HCP representatives, the HCP Network Coordinator and HCP Network Coordinator Representative; integration of Affiliated Partners; non-compliance and termination of HCPs; personal conflicts of interest; data privacy; requirements for supporting partnership for organisations and individual experts; memorandums of understanding for global collaboration; and rules of engagement for Associate/Supporting Patient Partners, the ePAG, the ePAG Chair, and ePAG Advocates (see the Annexes of our Governance Statutes).

ERN eUROGEN uses a Performance Dashboard developed by the ERN eUROGEN Lead IT & Data Performance Analyst in 2018 to monitor the activity of the Workstreams and HCP members. This involves the collection of general network information on MS, Member and Affiliated Partner HCPs, the ePAG, and Supporting Partners, numbers of patients and surgical procedures performed in the HCPs, CPMS panels, webinars, publications, presentations, Registry recruitment and observational studies, guidelines and Clinical Decision Support Tools (CDSTs), training activities and communication/dissemination activities and HCP activity. The performance dashboard is shared at all regular network meetings and is a standing agenda item for discussion to promote engagement with the network's activities.

Specific development targets:

- 100% of new members (29 HCPs in 2022) integrated and participating in network activities.
- Active participation in network activities (monitored using Performance Dashboard) - Monitoring information received from 90% of HCPs
- 100% HCPs sign Governance Statutes, agreeing to tasks, actions, and responsibilities document, and therefore to a minimum level of activity.
- Increase the number of patient organisations (PO) in the ERN, either as ePAG members or as individual patient experts.

1.4. WP2 Dissemination

Results and relevant insights from ERN eUROGEN are already communicated and disseminated through the ERN eUROGEN website, e-newsletters, YouTube channel, and social media platforms (Facebook, Instagram, LinkedIn, and X (former Twitter)). Information is already communicated and disseminated to the 18,000 members of the European Association of Urology (EAU) via their magazine European Urology Today (EUT) and their social media platforms, as well as the members of our other Supporting Partners (ESPU, EUPSA, ARM-Net, and ESSIC). Network members have presented network-related results and information at academic, scientific, and educational meetings and published network-related results and information in peer-reviewed academic and scientific publications, as well as in the wider media. ERN eUROGEN has had a presence at the annual EAU congress on a regular basis (usually attended in-person by 14,000 of its 18,000 members although in 2020 and 2021 the meeting was virtual due to COVID-19), progressing from being mentioned in the opening ceremony, to having a stand in the exhibition centre to demonstrate CPMS and answer questions, to having a Special Session of lectures dedicated to rare and complex urology. The Special Session has also been previewed pre-meeting and reported post-meeting in EUT, including coverage in the onsite congress editions that are provided to all delegates on entering the congress centre. The above demonstrates the collaboration the network already has with the major scientific societies in our medical field, and we will continue to build on this solid foundation. An ERN eUROGEN Update overview lecture is presented at the European Society for Paediatric Urology annual congress involving around 700 paediatric urology experts and nurses.

1.5. WP3 Evaluation

ERN eUROGEN has had a leading role in the ERN monitoring process since the group was created. The ERN eUROGEN HCP Network Coordinator Representative is the Co-chair of the ERN Monitoring Working Group and the ERN eUROGEN Lead IT & Data Performance Analyst has developed an innovative Performance Dashboard for monthly data reporting. Extensive input has been provided relating to the development of AMEQUIS in the former period (interviews, attendance at stakeholder meetings by the ERN eUROGEN HCP Network Coordinator Representative, Programme Manager and Lead IT & Data Performance Analyst, written feedback sent on AMEQUIS proposals from ERN eUROGEN, and input given on cross-ERN feedback). The AMEQUIS group's recommendations became available in early 2022 with the evaluation of the ERNs and their member HCPs taking place later in the year. The evaluation activities of the network will be further developed under this proposal by the creation of a Quality Improvement Group which will develop an Evaluation Plan and Report for the network which will be presented to the Strategic Board for agreement or further development.

Specific development action:

- Set up the Quality Improvement Group which will develop an Evaluation Plan and Report for the network.
- Survey the network's HCPs to gain insight into further improvement actions.

1.6. WP4 CPMS

Rare urogenital diseases and complex conditions are often so uncommon that specialists have never seen a specific case before. Since the launch of the network, a high degree of trust and collaboration has been fostered through regular monthly CPMS discussions. The network has published a 2022 paper: Cross-Border Video Consultation Tool for Rare Urology: ERN eUROGEN's Clinical Patient Management System. ERN eUROGEN's CPMS panel discussions usually involve a group of three or more experts. Experts from our network often include their trainees in CPMS discussions and many ask them to upload cases on their behalf; this has received very positive feedback. Many of the paediatric urological surgeons have noted the value of discussing extremely complex urological and surgical cases (some needing to be performed on very small infants) particularly those with additional legal or ethical issues (e.g., differences in sex development). In addition, ERN eUROGEN has piloted cross-ERN CPMS panel discussions where the expertise from more than one ERN is needed. Extensive input relating to the development of the new CPMS has already been provided and this will continue.

Specific development targets:

- Increase use of CPMS by the network's HCPs
- Provide input into the development of the new CPMS

1.7. WP5 Other digital activities

The lack of (long-term) evidence on treatments and interventions at present does not facilitate decisions on which treatment is most suitable for each patient. Due to the low numbers of affected individuals, the creation of a European-wide network has been very effective in terms of bringing together experts with the best knowledge to help other clinicians treat patients with rare urogenital diseases and complex conditions. The ERN eUROGEN registry went live in January 2022 and is collecting standardised, long-term data from HCPs on patients living with rare urogenital diseases or complex conditions. The registry has the capacity, at a European level, to track long-term outcomes into adulthood for the first time. Given that most of these conditions are detected in infancy but final outcomes are evaluated post-puberty, the full impact of the registry will be achieved after 15-25 years for new patients treated within the operational period of the ERN. Moreover, the efficacy of the treatments is being evaluated, resulting in improvements in quality of care over time and over the lifespan of the affected individuals. By pooling data and effort at a European level we can reach the economies of scale and patient numbers required for needed research. Currently, 4 observational studies are running, who collect with informed consent of the patient the common data elements and first snapshot information at European scale for specific diseases with a specific pilot study of each workstream.

Specific development targets:

- Increase the number of patients entered into the ERN eUROGEN registry over time.
- Increase the number of observational studies over time.

Clinical Practice Guidelines (CPGs) and Clinical Decision Support Tools (CDSTs) are in progress, working with the consortium appointed by the EC to facilitate ERN Guidelines development. We have appointed an ERN eUROGEN Guidelines Expert Panel and established two Working Groups, one to adapt/endorse a pre-existing CPG on anorectal malformations and another to create a CDST on posterior urethral valves. The CPG is well underway, overseen by the agency appointed to ERN eUROGEN by the EC's ERN Guidelines Consortium. If enough time is left from development of the CPG, we hope to progress the CDST. If not, we will either apply for further support in this call (as some of the other ERNs are not progressing guidelines at all) or apply for the next call. The Guidelines Expert Panel is already carrying out a scanning and evaluation exercise with input from the whole network relating to topics for future CPGs and CDSTs. All work is being done in collaboration with our ePAG's and Supporting Partners to ensure quality and avoid duplication of work. Once produced, as well as facilitating best practice and changing how services are delivered in all HCPs across Europe, these guidelines will enhance existing and new e-learning modules.

Specific development targets:

- Increase the number of clinical guidelines and CDSTs developed by the network's experts, where possible in collaboration with the scientific societies to avoid duplication of effort.

1.8. WP6 Training and Education

ERN eUROGEN is already promoting best practice to and enhancing the training and education of urologists, surgeons, and related healthcare professionals. The ERN Exchange Programme is designed to spread knowledge across the network and to stimulate collaboration between healthcare professionals in European Reference Networks (ERNs).

Highly specialised training activities for urologists and surgeons will be developed. Highly specialised surgeries will be recorded using a special camera in the Operating Room and will be shared with the network. The Coordination Team will work with DG SANTE to ensure the ERN Academy will fit the needs of the surgical ERNs – it should be able to safely store highly specialised surgeries for access by healthcare professionals.

The ERN eUROGEN educational webinar programme has already proved very successful, and in 2022 the frequency of webinars has increased to averaging weekly (about 40 times a year).

A contract has been signed with the publisher Elsevier to produce a book on rare and complex urology, with introductory chapters from the HCP Network Coordinator Representative, Coordination Team, EC, founding Supporting Partner the European Association of Urology, and our ePAG's, followed by clinical chapters for each Expertise Area authored by the Expertise Area Coordinator (EAC) together with two other experts and reviewed by an ePAG Advocate. Now the new Members have joined we will be able to fill the vacant EAC positions and begin commissioning chapters.

Specific development targets:

- Increase the quality of the webinar programme and number of views of webinars on the YouTube platform (please also see WP2 dissemination) and
- Obtain specific CME accreditation for a pilot series of webinars.

This ERN eUROGEN Development Plan will be regularly updated Including Information on the Development actions and progress toward meeting the development targets that have been identified as priorities for action in this plan.