

ERN eUROGEN
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Dear Members of the EAU National Societies,

We are writing to update you about recent developments of the European Reference Network (ERN) for are urogenital diseases and complex conditions (ERN eUROGEN).

As you may know, ERN eUROGEN was launched by the EAU in 2017 and the two organisations collaborate actively on areas of strategic interest. Please find enclosed an Update Report which we hope will give you a concise summary of recent activities and developments.

The main aim of ERN eUROGEN is to provide, upon request, free advice to healthcare professionals in the EU or EEA on patients with a rare urogenital disease or complex condition requiring highly specialised surgery.

ERN eUROGEN welcomes contact from clinicians in the national societies and we are grateful if you could pass this information onto your urological colleagues at national level, for their information. Please feel free to get in touch via our website <https://eurogen-ern.eu/>

We would be very happy to hear from you.

Yours sincerely,
Kind regards,



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Update for EAU National Societies on ERN eUROGEN activities – January 2021

EXECUTIVE SUMMARY

24 European Reference Networks (ERNs) facilitate discussion on rare diseases and complex conditions requiring highly specialised treatment and concentrated knowledge and resources. ERN eUROGEN is the ERN for rare uro-rectal-genital diseases and complex conditions and covers three workstreams dealing with different disease areas: workstream 1 - rare congenital uro-recto-genital anomalies (paediatric); workstream 2 - functional urogenital conditions requiring highly specialised surgery (adults); and workstream 3 - rare urogenital cancers. ERN eUROGEN currently has 39 healthcare provider members and following the call for new members in 2019, 30 new providers will be joining the network in 2021. More information about ERN eUROGEN can be found here: eurogen-ern.eu

Using an IT platform called the Clinical Patient Management System (CPMS) ERNs hold ‘virtual’ advisory boards/multi-disciplinary team meetings of medical specialists using telemedicine tools to review a patient’s condition for diagnosis or treatment. Healthcare providers not in the network but in an EU or EEA Member State can refer their rare disease or complex patients into the network for review and advice.

The ERNs are also developing Clinical Guidelines and Clinical Decision Support Tools (needed in areas where the evidence is lacking), patient registries to collect individual data from patients in all member healthcare provider centres, educational and training initiatives, research, and collaboration with patient groups and academic/professional societies.

ERN eUROGEN welcomes any enquires from healthcare professionals regarding rare uro-recto-genital diseases or complex conditions. Please contact: eurogen@uroweb.org

1. INTRODUCTION

Health systems in the EU aim to provide high-quality, cost-effective care. This is particularly difficult, however, in cases of rare or low-prevalence complex diseases which affect the daily lives of around 30 million EU citizens.

European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and complex conditions that require highly specialised treatment and concentrated knowledge and resources. Expertise in rare diseases or complex conditions is fragmented across Europe.

24 ERNs in a variety of medical disciplines were formally approved and accredited by the European Commission and the Board of Member States for ERNs (representatives from the health Ministries of all EU Member States who oversee the governance of the ERNs at European level) in March 2017. ERNs are an innovative new form of cooperation at European level between healthcare providers with expertise in rare diseases or highly specialised healthcare for complex conditions.

ERN eUROGEN is the ERN for rare uro-rectal-genital diseases and conditions, and currently consists of 23 full members from 10 countries and 12 Associated National Centres from 4 countries, as well as 4 Coordination Hubs based in a further 4 countries. The UK withdrawal from the European Union took effect on 31 January 2020 with the transition period ending on 31 December 2020. This sadly meant 6 UK healthcare providers ceased to be part of the network. However, collaboration will continue as far as possible with UK-based clinicians as individual experts in areas such as research and education.

The ERNs are not a time limited project, rather they are an EU initiative which is a new form of interaction based on the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare between healthcare providers and Member States at a scale never attempted before, supported and funded by the European Commission, to improve care for patients with rare diseases and complex conditions. More information about the ERNs can be found here: https://ec.europa.eu/health/ern/work_en and about ERN eUROGEN here: <https://eurogen-ern.eu/>

17 of the 24 ERNs include highly specialised surgery and in the summer 2020 they formed a new cross ERN Working Group on Surgical Research to collectively work on surgical related issues.

Collaboration Agreements have been signed with the following Supporting Partners:

- The European Association of Urology (EAU) – which started ERN eUROGEN
- The Ano-Rectal Malformations Consortium (ARM Net)
- The European Society for Pediatric Urology (ESPU)
- The European Paediatric Surgeons Association (EUPSA)
- International Society for the Study of Bladder Pain Syndrome (ESSIC)
- European Society for Paediatric Anaesthesia (ESPA) (in progress)

2. UPDATE ON ACTIVITIES

2.1. Enlargement of the ERNs

The EC launched a process for Affiliated Partners and a call for applications for new members to join existing ERNs in September 2019. The new member applicant healthcare providers are currently being assessed by the ERNs. 31 healthcare providers applied to join ERN eUROGEN which currently has 39 healthcare provider members. The ERN assessment is the first phase in this evaluation process and next will follow an assessment by the Independent Assessment Body and finally the Board of Member States representatives for ERNs (government representatives from the Ministries of health in the Member States which has a governance function for the ERNs) to approve members.

The ERN assessment was suspended temporarily in April 2020 due to the COVID-19 pandemic. The assessment reopened on 1 September and the ERN eUROGEN network has collated the results of the assessments, which have now all been uploaded to the online portal set up by the EC. As a result of this unavoidable delay, it is expected the new members will join around June 2021.

As required by the legislation, countries where the ERN has no full member have also been appointing Affiliated Partners to work with ERNs, in order to expand the geographical coverage of the ERNs. These healthcare providers are usually located in Member States with smaller populations that benefit the most from the knowledge transfer from interacting with the high volume healthcare providers and expert clinicians in the networks.

- Objective: increase geographical coverage of all 24 ERNs to all EU countries

2.2. Future funding of ERNs

Discussions are currently taking place with the EC and the Coordinators of the 24 ERNs, who meet regularly with the EC as the ERN Coordinators Group. ERNs are arguing for more funding as the size of most networks is expected to double. The Member States, the EC and the European Parliament are in the legislative and administrative phase where the budget division for the priorities funded by the EU4Health programme are being negotiated.

3. IMPROVING CARE FOR PATIENTS WITH A RARE UROGENITAL DISEASE OR COMPLEX CONDITION

The ERNs are connected through a dedicated IT platform called the Clinical Patient Management System (CPMS). Through this platform an ERN can convene 'virtual' advisory boards/multi-disciplinary team meetings of medical specialists using telemedicine tools to review a patient's condition for diagnosis or treatment. This allows health professionals who would previously have handled rare and complex cases in isolation to consult their peers and seek a second opinion from a panel of experts. A central feature of these tools is interoperability. Thanks to technology, geographical distance does not need to be a barrier to working in dispersed teams. The ERNs use the CPMS to securely share medical information and high-resolution images (e.g. MRI and CT scans) of rare and complex conditions in accordance with the latest EU privacy and data protection regulations. These technologies can also be used as a repository of cases, helping to build a large bank of data for further research.

The CPMS has proved to be an incredibly useful tool that has improved patient care, even within the short time frame of existence for some ERNs. In the arena of rare urogenital cancers the following are examples:

- a. Teams have learnt from ERN eUROGEN's panel of European experts and helped deliver care in a UK man with a complex groin cancer which had spread from the penis. It was treated using multi-modality therapy: Complex surgery, reconstruction, chemotherapy and radiotherapy. In some circumstances this patient may have had no treatment at all.
- b. A UK patient with a rare skin cancer of the penis and scrotum was advised by the ERN eUROGEN panel of European experts to have ongoing excision of large areas of his genitals in place of creams or no treatment. This patient continues to survive and is clear of cancer.
- c. A Greek patient with testis cancer was advised to proceed immediately with surgery over further chemotherapy (possible life saving intervention).

It has been very interesting to see how ERNs are incubators for the development of digital services for the provision of virtual healthcare and were well placed to deal with the COVID-19 pandemic, with clinical experts able to consult each other quickly and easily using the CPMS for the most challenging patients. This is likely to accelerate as the COVID-19 situation has significantly speeded up the implementation of eHealth solutions, which the ERNs have been using since 2017.

3.1. How to refer a patient to CPMS



ERNs are now fully operational to provide highly specialised advice from a group of multi-disciplinary experts which is given freely in order to achieve the knowledge sharing objective of the ERNs. It is the knowledge which travels and not the patient.

Please follow the steps below to contact ERN eUROGEN to seek advice (free) on a rare or complex patient.

- the healthcare provider must be located in an EU or EEA Member State
- the patient must have a rare uro-recto-genital disease or complex condition that falls within the scope of our ERN – you can find a list of the disease areas covered here: <http://eurogen-ern.eu/about-us/organisational-structure>

- you should ask advice also from your national contact point on the Board of Member States for ERNs about the referral process into the ERNs - their contact details can be found here: https://ec.europa.eu/health/sites/health/files/ern/docs/ern_board_members_en.pdf
- **if you have a rare or complex uro-recto-genital case that you would like to refer to ERN eUROGEN, please use this email: eurogen@uroweb.org**
- if your referral is accepted by eUROGEN, you must be willing to obtain full informed consent from the patient to share their data using CPMS, then we can grant you a guest user account for a short time period to access the system
- you must be willing to invest some time to upload the patients' medical information, including any relevant imaging into CPMS in order for their case to be discussed by our panel of experts
- you will receive an ERN Outcome Report document from our panel of experts with highly specialised advice on diagnosis or treatment of the patient concerned, based upon the latest current available scientific knowledge
- you understand that eUROGEN can only provide expert highly specialised multi-disciplinary advice - all legal liability and responsibility for the patient rests, as it has always done, with the clinician and healthcare provider treating the patient where the patient lives.

4. CLINICAL GUIDELINES AND CLINICAL DECISION-MAKING SUPPORT TOOLS (CDSTS)

The EC issued a tender of €4m to support the development of ERN Clinical Guidelines and Clinical Decision Support Tools (needed in areas where the evidence is lacking). A Spanish consortium won the tender and they are currently working on the methodology that the ERNs should use. They will also review all of the guidelines produced to date by the ERNs to check for a consistently high level of scientific rigour.

- Objective: to foster as much collaboration with all scientific societies and patient organisations as possible in this area, with ERN eUROGEN focussing on the rare and complex, with ideally the ERN logo to be used where possible
- ERN methodology has been developed now by the Spanish consortium. The release of this has been delayed now until the end of February 2021. ERN eUROGEN will discuss with all relevant organisations.

5. ERN REGISTRIES (ALL 24 ERNS WILL HAVE REGISTRIES)

Five ERNs received grants (>€200,000 each) to set up registries in 2017. The ERN for rare kidney diseases (ERN ERKNet) has a registry which has been operational for 3 years now and has over 3000 patients. The other nineteen received grants in 2019, including ERN eUROGEN.

The ERN eUROGEN registry is currently being developed, supported by a grant from the EC of €200,000. The aim of this registry is to collect individual data from patients suffering from rare urogenital (uro-recto-genital) diseases or complex conditions. Currently, very limited data is being gathered about disease progression, surgical procedures and treatment outcome, and the few existing databases are not standardized, fragmenting and scattering the information. Moreover, there is a lack of long-term follow up of the treatment outcome into adolescence and adulthood, which hinders improvement of treatments over time.

ERN eUROGEN will launch a core registry containing the 16 Joint Research Centre (JRC) core elements plus several urogenital specific data elements. Together, they will form the pilot phase of the registry where clinicians from all our healthcare providers will be asked to register their last 30 rare and complex cases in an anonymous way. This pilot phase will allow users to understand how to use the registry and to perform a clinical snapshot of the current practices, i.e., to compare the clinical management of these cases among the expert centres across Europe. All 24 ERNs will use the core data set, thus ensuring interoperability between the registries.

In addition, the plan is to integrate four existing rare urogenital disease-specific registries into the ERN eUROGEN registry by assessing interoperability and data elements to be imported. We will also prepare the next expansion

phase of the registry by collecting the informed consent forms of patients, incorporating suggestions of the users from the pilot phase and enlarging the data set of the ERN eUROGEN registry.

The final ERN eUROGEN registry for more than 120 rare urogenital diseases will benefit patients and their families who go through a diagnosis odyssey, clinicians who will learn about rare and complex conditions and get new insights into the best treatment options, and scientists who are looking for patient cohorts for future research and clinical trials.

- The ERN eUROGEN registry is being designed to be interoperable with two of the EAU's registries: SATURN (Prospective European registry for patients undergoing surgery for male stress urinary incontinence) and VENUS (Prospective Registry for Patients Undergoing Artificial Urinary Sphincter) in order to foster collaborative research efforts.
- The ERN eUROGEN registry is being designed to be interoperable with the AGORA registry, which is a local data and biobank including patients and controls (>15,000 patients).
- The ERN eUROGEN registry will be connected with the ARM Net registry to connect with patients with anorectal malformations (>3,000 patients).
- Objective: collaborate actively on research using the registries. The ERN eUROGEN registry will provide the evidence, in time, for the clinical guidelines and CDSTs.

6. EDUCATION AND TRAINING

The ERN eUROGEN educational webinar programme started in 2019 and details can be found on the website here: <https://eurogen-ern.eu/what-we-do/education-training/>

Topics for the programme are shared regularly with the ESU to avoid duplication and so, if there is a topic of joint interest, webinars can be delivered jointly.

6.1. ERN Educational platform

ERN eUROGEN will be developing an educational platform in 2021 and this will be part of the EC's plan to develop an ERN Academy, where all educational and training materials developed by the ERNs will be available.

6.2. ERN Education and Training Strategy

The ERN Knowledge Generation Working Group is developing an ERN Education and Training Strategy for the 24 ERNs. ERN eUROGEN is contributing to this as it is considered important to address how to train the next generation of supra specialised surgeons, especially given the medical workforce challenges faced by many Member States.

6.3. ERN Mobility Programme

The ERN clinical fellowship exchange programme was planned to start in March 2021, however, this is now likely to be delayed due to COVID-19 restrictions. This is a short term exchange between clinicians to transfer clinical knowledge (1 week) funded by the EC.

6.4. European Joint Programme for Rare Diseases

The European Joint Programme for Rare Diseases also funds ERN **research training** activities. For example, it funds ERN research workshops up to €25,000 and ERN research fellowship exchanges (2 to 6 weeks). More information can be found here: <https://www.ejprarediseases.org/index.php/training-and-empowerment/ern-trainings-copy/>

- Objective: knowledge transfer from the ERNs to other clinicians across the EU and between the ERNs

7. RESEARCH

A proposal for EC funding that was submitted by all 24 ERNs with the aim at stimulating research activities (the ERICA proposal) was successful and the grant agreement is currently under preparation.

The registries are also expected to drive research activity as they become operational.

- Objective: stimulate as much research activity as possible. Open to collaboration with Supporting Partners.

8. MONITORING/DATA COLLECTION

ERN eUROGEN plays an active role in the cross ERN working groups set up by the ERN Coordinators to deal with key issues.

ERNs collect data twice a year on their numbers of patients and surgical procedures, along with other key performance indicators. The results of the data collection were presented to the ERN Coordinators Group and the Board of Member States representatives for ERNs in November 2020. It showed that since collection began in 2013, healthcare providers in the ERNs are currently treating some 1.5 million patients with rare diseases and complex conditions. More data is expected to be released soon by the EC.

- Pooling this real time clinical data at this scale at European level will be valuable for improving patient outcomes and for future research.

9. COLLABORATION WITH PATIENT ORGANISATIONS AND REPRESENTATIVES

Working together with patient organisations and representatives is a fundamental principle of the ERNs and they are included in all ERN eUROGEN activities and have two seats on the Network Strategic Board.

It is not always easy to find patient organisations and representatives in this medical area. Information on collaborators with the ERN can be found here: <https://eurogen-ern.eu/for-patients/patient-groups>

However, ERN eUROGEN has a European Patient Advocacy Group (ePAG) and works very actively with eight patient organisations.

- Objective: keep patient organisations at the heart of the ERN and fully integrate them into all areas of work
- encourage ERN eUROGEN patient organisations and representatives to join EAU patient initiatives so they can make connections and links
- Work with EURORDIS to increase the engagement with patients in the uro-recto-genital/urological area
- Patient representatives will be trained on how to be involved in developing the ERN clinical guidelines and CDSTs and will be involved in their production

10. COMMUNICATION & DISSEMINATION

ERN eUROGEN has a Communication & Dissemination (C&D) Strategy Plan in order to meet the expectations and needs of the program.

- **Communication** covers the whole of a program, including results, and starts at the outset of the program. It is directed towards multiple audiences, within and also beyond the program's own community, including all stakeholders

- media and general public. The aim is to inform and engage with society to show how it can benefit from clinical care, education and training, research and new innovations and to highlight the impact on health care for rare and complex diseases.
- **Dissemination** covers program results only and happens only once results are available. It is directed towards specialist audiences, groups that may use the results in their own work, including peer groups, industry, professional organizations and policymakers. The aim is to enable the take up and use of results and make a significant impact on health care.

The C&D tools which are being used (or will be used) are:

- Websites – [EC website](#), [Network website](#), and [ERN Collaborative Platform \(ECP\)](#)
- Newsletters – [EC e-newsletter](#), and [Network e-newsletter](#).
- Social media – [Facebook](#), [Instagram](#), [LinkedIn](#), [Twitter](#), and [YouTube](#).
- A smartphone app (under development)
- Promotional materials, e.g. a flyer, posters, banners, logos, videos and a dissemination package for members.
- [Media](#) and [scientific publications](#), scientific abstracts/presentations for academic meetings, press releases, advertisements, interviews, TV/radio coverage, patient stories.
- Events – [ERN eUROGEN Strategic Board Meeting](#), [ERN eUROGEN Webinars](#), [European Association of Urology Annual Congress](#) and other scientific congresses, [Rare Disease Day](#), [Urology Week](#), policy events and European Commission events.

CONCLUSION

ERN eUROGEN warmly welcomes any enquires from healthcare professionals seeking advice on a rare uro-recto-genital disease or complex condition that requires highly specialised healthcare. Please contact ERN eUROGEN here: eurogen@uroweb.org



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