

Update for ERN Network Board on ERN eUROGEN activities – 2 October 2020

1. INTRODUCTION

ERN eUROGEN was approved by the Board of Member States for ERN representatives in 2017. ERN eUROGEN currently consists of 29 full members from 11 countries, 12 Associated National Centres from 4 countries, and 4 Coordination Hubs based in a further four countries.

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 by the European Commission, to improve care for patients with rare and complex diseases. 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)

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)

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 43 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 mostly been uploaded to the online portal set up by the EC. Once this is done, those healthcare providers whose applications need amending will have one month in which to resubmit their applications for approval. 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.

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.

Possible areas for collaboration for example with Supporting Partner organisations:

- Joint activities, e.g. lobbying the European Parliament and Health Programme Committee Members to ensure funding for joint strategic priorities. Joint lobbying activities as well as including patient organisations, will have the most impact.

2.3. 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.

2.4. 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 CDSTs (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. Prof Feitz has had several discussions with EAU and ESPU members and the position is that ERN eUROGEN experts are not constrained in any way by their membership of ERN eUROGEN to collaborate with any of the Supporting Partners. Duplication of work and effort should be avoided. ERN eUROGEN has identified the areas where it will develop guidelines and these were shared early with the EAU to avoid duplication. Once the ERN methodology is available (expected soon) ERN eUROGEN will share this widely and further discussions can take place. Unlike most other ERNs, ERN eUROGEN has not started any guidelines work yet as it was thought prudent to wait until the methodology is available.

- Objective: to foster as much collaboration as possible in this area, with ERN eUROGEN focussing on the rare and complex, with ideally the ERN logo to be used where possible
- EAU application (Karin Plass) to the ERN Advisory Body (supported by EAU and ERN eUROGEN) on clinical guidelines currently being set up by the Spanish consortium. Aim to develop the best possible methodology for the ERNs, given the low level of evidence in many areas. Results expected in October.
- ERN methodology has been developed now by the Spanish consortium and is with the EC for comment. Expected to be released to the ERN by mid-November. ERN eUROGEN will discuss with all relevant organisations.

2.5. 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 43 Health Care 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 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 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 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 Pax).
- The eUROGEN registry will be connected with the ARM Net registry to connect with patients with anorectal malformations
- Objective: collaborate actively on research using the registries. The ERN eUROGEN registry will provide the evidence, in time, for the clinical guidelines and CDSTs.

2.6. Education and Training

The ERN eUROGEN educational webinar programme started in 2019. 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. ERN eUROGEN will be developing an educational platform in 2022.

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.

The ERN clinical fellowship exchange programme will start in 2021. This is a short term exchange between clinicians to transfer clinical knowledge (2 – 6 weeks).

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).

- EAU disseminates information about ERN eUROGEN webinar programme and promotes via social media. This is very effective and we hope it can continue.
- ERN eUROGEN has been in touch with the EAU Education Section to offer to provide information about the ERNs when useful. It was considered that this might be interesting for young urologists to understand the ERN developments at European level
- ERN eUROGEN would like to collaborate with all Supporting Partners on joint education and training initiatives

2.7. Research

A proposal for EC funding has been submitted by all 24 ERNs with the aim at stimulating research activities (the ERICA proposal – details can be provided upon request).

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.

2.8. 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. **Prof Chris Chapple is the current co-chair of the Monitoring Working Group**, supported by the ERN eUROGEN Centre Manager and ERN eUROGEN Lead IT and Data Analyst. It has been agreed by the group that Prof Chapple will continue as long as possible and only step down when the UK actually leaves the EU.

The results of the data collection will be presented to the ERN Coordinators Group and the Board of Member States representatives for ERNs in November 2020. It is likely to show that healthcare providers in the ERNs are currently treating some 1.5 million patients with rare diseases and complex conditions. Pooling this real time clinical data at this scale at European level will be valuable for improving patient outcomes and for future research.

2.9. 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 Strategic Board.

It is not always easy to find patient organisations and representatives in this medical area. However, ERN eUROGEN has a European Patient Advocacy Group (ePAG) and works very actively with seven patient organisations.

- Objective: 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

2.10. Communication & Dissemination

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

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

3. SUMMARY

ERN eUROGEN welcomes any suggestions for future areas of joint working and the network is very much looking forward to continuing the excellent collaborations. Please feel free to share this report, request meetings, reports or any other information that may be helpful.



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