

# Report: ERN eUROGEN Strategic Board Meeting

Friday 4 June 2021, held via GoToMeeting



## 1. ATTEENDES

- Anne-Françoise Spinoit
- Anne-Laure Aslanian
- Antonio di Cesare
- Barbara Iacobelli
- Célia Crétolle
- Christiaan Groen
- Dalia Aminoff
- Darren Shilhan
- EAU Research Foundation
- Eberhard Schmiedeke
- Frank van der Aa
- Franziska Vauth
- Gilvydas Verkauskas
- Giovanni Mosiello
- Gundela Holmdahl
- Hans Langenhuijsen
- Hein Van Poppel
- Ivo De Blaauw
- Jan Gosemann
- Jen Tidman
- Joao De Sousa
- Jorgen Thorup
- José Medina Polo
- Kate Abrahamsson
- Kenneth Manzie
- Loes Oomen
- Loes Van Der Zanden
- Lourdes Gonzalez Bermudez
- Magdalena Fossum
- Mariangela Mancini
- Mateja Vinksel
- Mauro Cervigni
- Michelle Battyte
- Nicole Schwarzer
- Pim Sloots
- Piotr Czauderna
- Ramnath Subramaniam
- Rene Wijnen
- Sarah Collen (EAU)
- Serena Bartezzi
- Stefan Anzelewicz
- Tim Ludwig
- Vanessa Ritzel
- Vijay Sangar
- Wim Witjes
- **Wout Feitz (Chair)**
- Yazan Rawashdeh

## 2. INTRODUCTION

The ERN eUROGEN annual strategic board meeting was held on Friday 4 June 2021. In view of the continuing COVID-19 pandemic, this was once again held as a virtual rather than face-to-face meeting. All full member Healthcare Provider (HCP) representatives, Affiliated Partner (Associated National Centre and National Coordination Hub) representatives, ERN Patient Advocacy Group (ePAG) representatives and Supporting Partner representatives were invited to attend. The [agenda](#) was sent out in advance of the meeting.

## 3. SUMMARY OF PRESENTATIONS

### 3.1. ERN eUROGEN Status Update – Wout Feitz, ERN eUROGEN

#### [\(Link to presentation\)](#)

WF covered the development of the EC's [EU4Health programme](#) 2021-2021, and the ways in which this will strengthen national health systems, support the functioning of the ERNs, and lead to the digital transformation of health through the [European Health Data Space](#) (which will link to the ERN registries).

One indicator for the success of the ERNs are the number of hospitals involved in the ERN and of patients diagnosed and treated by members of the ERN networks. WF noted that ERN eUROGEN has published [a paper in European Urology giving a clinical overview of the network](#) and demonstrating the number of patients diagnosed and treated since the network's formation.

WF proceeded to give an overview of the EU, Board of Member States (BoMS), ERN Coordinators, ERN Working Groups, ERN Cross-Actions, and ERN Tasks.

ERN eUROGEN's Supporting Partners now include the [EAU](#), [ARM-Net](#), [ESSIC](#), [ESPU](#) and [EUPSA](#), and we have been developing a protocol for Individual Experts to be Supporting Partners.

Following Brexit, ERN eUROGEN is now formed from 39 healthcare providers (HCPs) from 18 Member States (MS) (previously 44 HCPs from 19 MS). Following the EC Call 2019 we are awaiting the Independent Assessment Board evaluation of 30 new applicants, which will lead to an expansion of the network in 2022.

ERN eUROGEN is also hoping to expand its disease area coverage, adding in paediatric kidney transplant surgery, male infertility and paediatric oncological urology. A decision from the BoMS is awaited.

In terms of the Clinical Patient Management System (CPMS) ERN eUROGEN has successfully been running panels. A new mobile CPMS app is in development by the EC.

ERN eUROGEN continues to Chair the ERN Monitoring Working Group. All ERNs reported their patient data in 2020, which showed an estimated patient population of 1.7 million (increasing), increasing participation of patient organisations, increasing engagement in research and educational activities, and around 1 million hits on ERN websites. From 2013-2019, ERN eUROGEN itself had a total of 122,040 patient contacts under chronic care in its (then) 29 members.

The ERN eUROGEN webinar programme has been continuing and all are available on our [YouTube](#) channel. From January 2021 the webinars will be twice monthly and later in the year may move to weekly.

The Consortium running the ERN Guidelines and Clinical Decision Support Tools has now sent out the protocols and begun running training. ERN eUROGEN has compiled a [factsheet](#) and formed an Expert Group to lead on developing new (or endorsing existing) guidelines and CDSTs. ERN eUROGEN is collaborating with the EAU, ESPU, EUPSA, ARM-Net, ESSIC and the ERN Study Group on Paediatric Anaesthesia.

The ERN Mobility Programme providing short term clinical exchanges is now up and running. This will allow trainees/fellows to gain expertise or carry out research as well as visits from MDT members, or experts to travel following requests through CPMS. The applications for the first call have been received and are in progress.

As ever, the ERN Patient Advocacy Group (ePAG) representatives have been very active, involved in meetings, protocols, all three workstreams, compiling common needs and developing patient journeys, the Rare 2030 foresight study, a survey on transition in ARM, and the EJP RD EURORDIS H CARE application.

ERN eUROGEN's research programme is under development, with the main focus being the development of the ERN eUROGEN Registry, which is about to enter its pilot phase. The network is also involved in the [European Rare Disease Research Coordination and Support Action consortium \(ERICA\)](#) together with the other 23 ERNs. Following a successful application to the European Joint Programme on Rare Diseases (EJP RD) ERN eUROGEN and ERN ITHACA will be running a workshop on spina bifida in 2021. ERN eUROGEN is also a co-applicant in three further bids to the EJP RD and the outcomes are awaited.

ERN eUROGEN has been advising the EC regarding their Provision of an Integrated Assessment, Monitoring, Evaluation and Quality Improvement System (AMEQUIS) for the ERNs, as well as contributing to the EU ERN Vision 2030.

In terms of communications and dissemination, as well as our website, social media platforms ([Twitter](#) - [LinkedIn](#) - [Facebook](#) - [Instagram](#)) and newsletters, we have signed a contract with Elsevier to produce an ERN eUROGEN book on rare and complex urology, which will publish in 2022, with chapters provided by expert network members.

In summary, as the ERNs move toward their 5-year anniversary in 2022, WF stated: “We have achieved progress in all areas and the future looks bright!”

## **3.2. Management & Enlargement of ERN eUROGEN – Michelle Battye, ERN eUROGEN**

[\(Link to presentation\)](#)

MB reiterated that ERN eUROGEN be enlarging after the call for new members once the Independent Assessment Body and Board of Member States for ERNs have approved the applications, with new HCPs joining in early 2022 (estimated). If all 30 applicants to ERN eUROGEN are approved, it will be comprised of 58 HCPs from 20 MS. When new Affiliated Partners are appointed (late 2022/2023) from MS with no full member, then the network will expand to 66+ HCPs from 28 MS. New members will be integrated with a welcome pack, an invitation to meetings, CPMS training and inclusion in all other ERN activities.

In terms of existing members, we are using our Performance Dashboard to monitor activity and participation and have a termination process for non-compliant HCPs (e.g. not providing data, not using CPMS). This involves a “step up process” with the coordination team writing to the HCP representative if one data collection missed, the coordinator writing to the HCP CEO if two are missed, etc.

Following an EU survey, new ERNs have been proposed for rare gynaecological and obstetric diseases, rare mental diseases, and rare infectious diseases, which will allow further cross-ERN action. Orphanet are carrying out analysis to identify gaps in ERN disease area coverage so that all RD patients should be able to find a “home” in the ERNs.

ERN eUROGEN expanded to include new disease areas in 2019 (adult urogenital reconstructive surgery, surgery for transgender patients, and rare renal tumour surgery) and these were included in the 2019 call for new members. We need to update the disease coverage of existing members and the BoMs is currently considering the protocol for managing disease areas within current HCPs as adding new disease areas to the network (as mentioned by WF).

## **3.3. ERN eUROGEN ePAG update – Serena Bartezzati & Dalia Aminoff**

[\(Link to presentation\)](#)

The presentation emphasised the challenges of the COVID-19 and the ways this had highlighted the importance of an integrated view of vulnerable communities, such as rare disease patients, who suffer most from health inequality within the welfare system. The need for evaluation of service performance, health pathways, interventions and outcomes has become evident. In many countries, national ePAGs have been working to raise awareness at national government level of the needs of rare disease patients and families supported by the experience and knowledge of the ERNs.

The ERN eUROGEN ePAG group is Dalia Aminoff, Nicole Schwarzer, Serena Bartezzati, Christiaan Groen, Robert Cornes, John Osborne and Kenneth Manzie.

In the last year they have been involved in: the EAU’s Patient Advisory Group, collaborating relating to guidelines, drafting a proposal for a training & education strategy, completing patient journeys for bladder exstrophy, interstitial cystitis, and anorectal malformations, developing common needs for rare and complex urogenital anorectal conditions, advising the EC regarding the AMEQUIS monitoring system in terms of what is important for HCPs to provide, proposing (and agreeing) a review of the thresholds for disease areas, revising the Orphanet coding system for anorectal malformations, advising on the ERN eUROGEN Registry, contributing to the Rare 2030 foresight study, facilitating a Supporting Partner agreement between ESSIC and ERN eUROGEN, linking ERN eUROGEN with ERNICA for joint webinars with ePAG involvement, and supporting ERN eUROGEN at European Conferences, Workshops and Meetings.

Future activities will include: writing a chapter for the ERN eUROGEN book, developing ePAG Terms of Reference (rules for patient engagement in ERNs), advocating for improvements to the transition pathway (from childhood to adulthood) and establishing a cross-ERN working group (WG) on transition, continuing to contribute to the cross-ERN WG for multi-system, continuing to raise awareness of ERNs and ePAGs at national and European level, and continuing involvement in guidelines development.

## **3.4. The New CPMS – Joao de Sousa, DG SANTE**

[\(Link to presentation\)](#)

It was acknowledged that at present the Clinical Patient Management System (CPMS) is complex and difficult to use, expensive and difficult to maintain. This is caused partly by a lack of user feedback and partly by it being a closed, monolithic desktop application. Conversely, something is required which is flexible and user-friendly, good value for money, and easy to maintain. This can be achieved by incorporating user feedback and making the system open source, modular and loosely-coupled. It is important for CPMS to be able to integrate into national health systems and have long-term sustainability, as well as user satisfaction.

With this in mind, the EC will be putting out a call for tenders for a new developer in Q3 of 2021, with software development taking place 2022 and the new CPMS being launched in Q1 of 2023. In the meantime they have signed a short term contract with the current contractor.

The aim is that the new CPMS will have clinical functions, management functions, a centralised database, and connections to electronic health records and the ERN registries. The system will have two-factor authentication, encryption, and in terms of privacy will be consent based, fully GDPR compliant and pursuant to DPIA recommendations. There will be both desktop and mobile interfaces which are multilingual, allowing panel discussions, secure instant messaging, a smooth workflow, and simplified data entry.

### **3.5. ERN Guidelines Update – Lourdes Gonzalez Bermudez, ERN Guidelines Consortium**

[\(Link to presentation\)](#)

The objectives of the Consortium are to provide assistance to the ERNs and their HCPs in the process of development, appraisal and implementation for clinical practice guidelines (CPGs) and clinical decision support tools (CDSTs) and to improve the capacity of the Networks in their task to produce and adhere to high quality CPGs and CDSTs.

In January 2020 the project officially kicked off (duration: 48 months) comprised of four work packages: Governance, Methodology, Training and Development.

In terms of governance, an advisory body (AB) was set up formed of EC officers, BoMS, ERN coordinators, ERN clinical experts, ERN patient representatives and representatives from recognised institutions. This group has given feedback on the methodological handbooks. The Consortium also asked the ERNs to constitute Expert Panels.

Regarding methodology, a literature review and EU Survey on methodology were carried out and delivered to the EC, identifying the methodologies and tools that are used and recognized at an international level for the development, appraisal and implementation of CPGs and CDSTs. Following this the Methodological Manual and Toolkit for the development, appraisal, adaptation and implementation of CPGs and CDSTs has been shared with the AB and the ERNs.

For training, a EU-Survey was conducted on training needs regarding CPGs and CDSTs as well as training style preferences among ERN health professionals. The training scheme and the plan were approved for two levels of training: advanced and basic-intermediate, with 35 hours of training to be carried out between 28th April 2021-4th July 2021.

An EU-Survey was carried out with the ERNs to define goals and planning for the development and appraisal of CPGs and CDSTs. Individual meetings were held with the ERNs to establish the current status of their CPGs/CDSTs, the methodology they are using, their list of disease priorities, what support they require, and their preferred timeline.

ERN eUROGEN has prioritised CPGs on anorectal malformations and vesicovaginal fistulae and CDSTs on abdominopelvic sarcomas, melanoma affecting the genitourinary tract, and groin node dissection. We requested support from one of the health agencies and a methodologist, and support for a systematic review. We have formed our expert panel and have participants in the training programme.

The Consortium (in agreement with the EC) will prioritise five ERNs to start working on the development of CPGs/CDSTs in June 2021, with a further five beginning work after the summer.

### **3.6. ERN eUROGEN Registry – Loes van der Zanden, ERN eUROGEN**

[\(Link to presentation\)](#)

The ERN eUROGEN Registry is led by WF, with LvdZ as Coordinator. Darren Shilhan and Wim Witjes form the steering committee, with the advisory board comprising of Jorgen Thorup, Kate Abrahamsson, Vijay Sangar, Dalia Aminoff and Nicole Schwarzer.

At present, there is currently limited data about disease progression, surgical procedures and treatment outcomes. The few existing databases are not standardized and lack long-term follow-up data. Therefore the aim of the ERN eUROGEN Registry is to set up a large patient registry collecting individual data from patients suffering from rare urogenital diseases or complex conditions.

The pilot phase is currently under way and involves ERN eUROGEN Clinical Practice Snapshots for five disease areas using common data elements (not all of them) and six disease-area-specific clinical questions. We asked HCPs to register their last 30

new patients seen before 1-1-2021 in order to get familiar with registry, test the registry and feedback, give us an overview of the numbers of patients and a snapshot of current clinical practices in the EU.

The expansion phase will create the final ERN eUROGEN registry, again with common data elements and six disease-area-specific clinical questions, and with additional patient-specific data items on e.g. follow-up, quality of life, PROMs. The plan is to integrate four existing registries (AGORA, Saturn, Venus, and ARM-Net), assessing their interoperability and the data elements to be imported. We will arrange ethical approval to start prospective inclusion of coded data of patients who consented to identify contemporary cohorts of patients for clinical research across national borders and to monitor treatment performance and patient outcomes in the participating HCPs.

Using the registry we will be able to gather data on disease demographics, study disease outcome and treatment efficacy into adulthood, and develop new guidelines for EU standard care.

### **3.7. ERN Exchange Programme – Michelle Battye, ERN eUROGEN**

[\(Link to presentation\)](#)

The EC's ERN Exchange Programme is being supported by Ecorys (a research & consultancy firm) who will help with start up, design and operationalisation, monitoring & learning during the programme, and personalised assistance in financial and travel arrangements for visiting professionals.

The main aim of the programme is to further consolidate and strengthen the ERNs and to enable collaboration and mutual exchange of expertise within ERNs. Other objectives are to improve disparities in specific knowledge or gaps in expertise by facilitating the arrival of high-level expertise in a considerable number of diseases to ERN HCPs, to increase the level of highly specialised knowledge in a field, to strengthen professional relationships with peer-to-peer dialogues, to encourage closer collaboration among HCPs and ultimately increase access to high-quality care for patients with rare diseases or complex conditions across Europe.

The exchange packages are for full members and affiliated partners, although ePAG representatives can also participate if there is a good justification. There is a maximum of 3-5 packages for one exchange visit, with one package covering a maximum of 5 days. A daily allowance is provided to cover subsistence, accommodation and travel insurance for the professional that travels, with the funding transferred 1 day after their arrival. Visitors can choose and book accommodation themselves no need to justify your expenses with receipts and Ecorys will arrange travel and provide a practical information kit. Financial compensation for HCPs and professionals hosting the visit and insurance for professional liabilities are not included.

ERN eUROGEN's programme was launched in March with a deadline of 17 May for the first call. We received 8 applications through [our online tool](#) and the successful applicants were informed in the first week of June. We are currently arranging individual meetings to discuss arrangements whilst being mindful of the ongoing COVID-19 pandemic.

MB asked HCP representatives present to be willing to host and to think about whether they or their trainees would like to participate in an exchange visit to transfer knowledge in the network. The next call for applicants is likely to be in September 2021.

### **3.8. EURORDIS H-Care Proposal – Jessie Dubief, EURORDIS**

[\(Link to presentation\)](#)

Unfortunately JD was unable to present at the meeting as originally planned, but provided her presentation afterwards.

In the H-CARE Pilot Survey (2019-2020) rare disease patients gave their healthcare experience a medium-low score, but had a better experience when they were treated by hospital units that are part of an ERN. Based on these findings the recommendations were to go beyond diagnosis and medical treatment, ensure access to multidisciplinary and networked healthcare, and to develop and validate a questionnaire to measure the healthcare experience of rare disease patients and caregivers.

The European Joint Programme on Rare Diseases (EJP RD) is running a joint transnational call (JTC) for applicants funded by national agencies from 15 EU countries (excluding the Netherlands, Czech Republic, Portugal and the Scandinavia countries), Canada, Israel and Turkey, and non-funded collaborators from any country.

EURORDIS is coordinating the proposal from a consortium of seven partners to develop two validated scales to measure the healthcare experience of patients and carers living with a rare disease. This will involve a literature review and focus groups to set up a model of high quality medical care for rare disease patients (taking into account their carers); question development, content validity and translation, followed by questionnaire dissemination in partner hospitals, online and in other HCPs; and a feasibility and sustainability study to define the conditions in which the validated scales could be used by patients, carers, healthcare professionals and hospital managers in order to improve clinical practice:

The other partners are Heidelberg University Hospital (Germany), SickKids, the hospital for Sick Children (Toronto, Canada), Katholieke Universiteit Leuven (Belgium), Bambino Gesù Children's Hospital (Roma, Italy), and Vilnius University Hospital

Santaros Klinikos (Lithuania). The collaborators are 11 ERNs (iERKNet, **eUROGEN**, Genturis, ENDO, Liver, EpiCare, ITHACA, ERNICA, EuroBloodNet, MetabERN, RITA and EYE) and ICON-PLC (specialised in PROM validation).

## 4. STRATEGIC BOARD VOTING AND DISCUSSION

### 4.1. Supporting Partner (Individual Expert) Agreement

[\(Link to agreement\)](#)

To date the Supporting Partners of ERN eUROGEN have been academic/scientific associations, societies or other organisations related to clinicians, patients, and conditions covered by the network. Brexit and the removal of UK HCPs from the ERNs prompted the idea that in some cases it may be helpful to be able to involve individuals with very specific expertise as a supporting partner, outside of a group – for example a clinician, a researcher, a patient, etc. Having checked the legality with the EC, a draft agreement document was drawn up. In April this was sent around the network with a two-week deadline for comment (otherwise agreement was assumed). Members were given another chance to comment at this meeting.

No comments were received and so now the agreement will be used with appropriate individual experts.

## 5. NEXT MEETING

ERN eUROGEN plan to hold another strategic board meeting in the first quarter of 2022 once the new full member Healthcare Providers join the network. The date and whether this will be a face-to-face or virtual meeting will be confirmed in due course.



European  
Reference  
Networks

[https://ec.europa.eu/health/ern\\_en](https://ec.europa.eu/health/ern_en)



European  
Reference  
Network  
for rare or low prevalence  
complex diseases  
Network  
Urogenital Diseases  
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