European Reference Networks

European
Reference
Network
for rare or low prevalence
complex diseases

Network
Urogenital Diseases
(ERN eUROGEN)

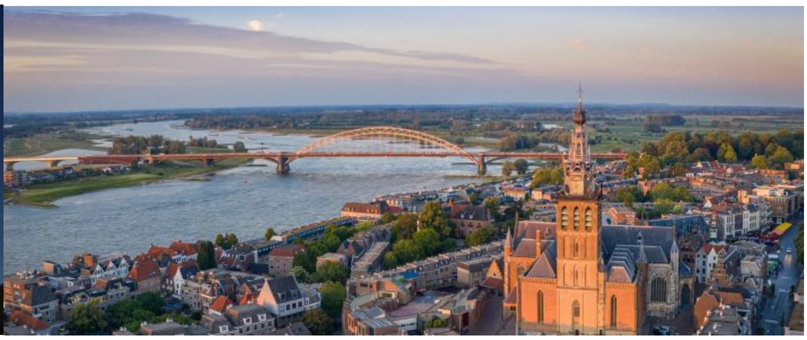
Report of ERN eUROGEN Strategic Board Meeting

13-14.09.2022, Van der Valk Hotel Nijmegen-Lent, NL

BACKGROUND

Following the covid-19 pandemic and two years of online meetings, the ERN eUROGEN Coordination Team was keen to hold a face-to-face version of the annual Strategic Board meeting rather than an online or hybrid event. A poll was sent out to determine whether people would attend a face-to-face meeting and, if so, what the best dates for this would be, with the result that an in-person meeting was held from 13-14 September 2022.

This year the meeting could not be allied with a European Association of Urology (Supporting Partner) meeting, so it was decided to hold this in Nijmegen, The Netherlands, in the same city as Radboudumc (the ERN eUROGEN HCP Network Coordinator). The venue was the Van der Valk Hotel Nijmegen-Lent.



The agenda was drafted and sent out to all full member and affiliated partner healthcare providers (HCPs), European Patient Advocacy Group (ePAG) advocates, and Supporting Partners (organisations and individual experts), according to the ERN eUROGEN Governance Statutes, with the request that attendees register for the meeting, book their travel and accommodation (to be reimbursed according to the ERN eUROGEN Expenses Factsheet), and submit any items for voting and discussion by 1 September 2022.

A live stream component was requested as some members could not attend in person due to clinical and other commitments. This was provided (via GoToMeeting and the support of the audio-visual and IT team of Moos + Spike) so that people could watch and participate remotely.

DAY 1 – 13 SEPTEMBER

Coordination (Work Package 1)

Strategy, Actions & Expectations – Wout Feitz, ERN eUROGEN HCP Network Coordinator Representative

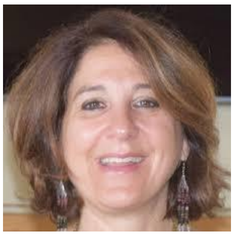
Link to presentation.

In his presentation, Wout gave the background to the ERNs and their current status, outlined the current EU4Health Programme (2021-2027), the enlargement of the networks, and the 24 ERNs and the way they collaborate on cross-ERN actions. He explained that ERN eUROGEN organises activities according to six work packages (WP1 Coordination, WP2 Dissemination & Collaboration, WP3 Evaluation, WP4 CPMS, WP5 Other Digital Activities, and WP6 Training & Education) which help with coordination and reporting to the EC. He also briefly discussed structure, communications, collaboration, Supporting Partners, the ePAG, global strategy, research, CPMS, guidelines, the registry, webinars, and the exchange programme (all covered in more depth elsewhere in the programme).

Management & Grant Actions of the Network – Michelle Battye, ERN eUROGEN Programme Manager

Link to presentation. Link to the 18-month bridging grant agreement.

In her presentation, Michelle explained the background and history of funding and the budgets currently available to the ERNs through the EU4Health Programme (2021-2027), specifically €52.7m from 2022-2023. ERN eUROGEN has just signed a grant agreement for a bridging grant, giving us 100% EC funding of €1.1m for 18 months. Michelle then outlined ERN eUROGEN's strategic objectives and deliverables in the grant agreement. She emphasised that the Coordination Team are happy to help and welcomes suggestions from members for items requiring funding, which can be included in the next EC grant proposal.



European Patient Advocacy Group (ePAG) Update – Dalia Aminoff, ePAG Chair (Associazione Italiana per le Malformazioni Anorettali) and Claire Harkin, ePAG Advocate (Klinefelter's Syndrome Association)

Link to presentation. Link to ePAG information.

Dalia introduced the members of the ePAG, and then Claire explained their role and relationship with EURORDIS, which ensures meaningful patient engagement in the ERNs.

Claire then gave an update on the ePAG's activities over the last 12 months, including ePAG gap analysis and recruitment of new ePAG advocates, which involves a balance of covering the Expertise Areas in ERN eUROGEN without overexpanding the group, so it is no longer manageable. The ePAG Terms of Reference have been updated, together with the ERN eUROGEN Coordination Team, defining the role of the ePAG and ePAG Advocates and the support provided to them by ERN eUROGEN. They have also worked with EURORDIS on the ePAG Steering Committee and given input on AMEQUIS. The ePAG were invited to provide a chapter for the ERN eUROGEN book on rare and complex urology (to be published by Elsevier) and have provided their first draft to the Coordination Team. An ePAG Taskforce on Compensation was set up, and a survey was sent out, from which a report will be drafted.

Future activities include:

1. Continue work on developing ERN eUROGEN patient journeys (e.g., the ones on anorectal malformation and penile cancer): next Klinefelter Syndrome.

2. Advocate for improvements in the transition pathway (and a cross-ERN working group (WG) on transition): the creation of a dedicated ePAG WG.
3. Continue contributing to the cross-ERN WG for multi-system conditions: a webinar with ERN ERNICA & ERN eUROGEN on anorectal malformation (ARM) and Hirschsprung's Disease.
4. Continue to raise awareness of ERNs and ePAGs at the national and European levels (dissemination of the information about the ERN and ePAG at the national level + cooperation with the Italian ePAG group).
5. Guidelines update: involvement in the ERN eUROGEN Guidelines Expert Panel and continuing to work on forming the European Association of Urology penile cancer guidelines.
6. Development of thresholds to support the ERN eUROGEN registry.
7. Contribute to fostering research through active involvement in the European Rare Disease Research Coordination and Support Action (ERICA) consortium – Nicole Schwarzer is involved in this WG to promote the inclusion of PROMs and PREMs in the different registries.

Breakout Meetings: Workstream Actions and Improvements

The three Workstream Leads (Margit Fisch was unable to attend, so appointed Tim Ludwig as her representative) were asked to lead breakout meetings covering the actions and improvements relating to WS1: rare congenital uro-recto-genital anomalies, WS2: functional urogenital conditions requiring highly specialised surgery, and WS3: rare urogenital tumours.

- **WS1 – Wout Feitz, Workstream 1 Lead**

  Link to presentation.

- **WS2 – Tim Ludwig (representing Margit Fisch, Workstream 2 Lead)**

  Link to presentation.

- **WS3 – Hans Langenhuijsen, Workstream 3 Lead**

  No presentation – a roundtable discussion was held.

Supporting Partners: Organisations & Individual Experts

The process for agreement of Supporting Partners is outlined in the ERN eUROGEN Governance Statutes.

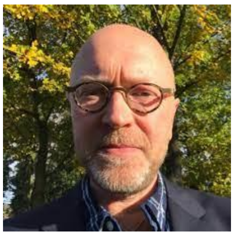
Our Supporting Partners (Individual Experts) are individual clinicians whose HCPs are not part of the network, including those who are not in the EC/EEA (e.g., those who had to leave the ERN following Brexit), who can provide specific expertise that is relevant to and of value to the network.

Our Supporting Partners (Organisations) are ARM-Net, the European Association of Urology (EAU), the European Society for Paediatric Urology (ESPU), the European Paediatric Surgeon's Association (EUPSA), and the International Society for the Study of Bladder Pain Syndrome (ESSIC). Wout Feitz noted that we can choose which Supporting Partner agreements to renew or discontinue. We are currently liaising with the International Continence Society (ICS) about a potential future Supporting Partnership.

Wout noted that members could let the ERN eUROGEN Coordination Team know about other organisations that might be appropriate for ERN eUROGEN to consider Supporting Partnerships. The ERN eUROGEN Coordination Team also welcomes any comments on the process for, and agreements with, Supporting Partners.

Global Strategy

ERN eUROGEN has a Global Strategy (and global collaboration strategy document) and, in terms of Collaborative Partners, has Memorandums of Understanding (MoUs) with CureForU and the Murdoch Children's Research Institute, which is working on an MoU relating to a Global Penile Cancer Collaboration, and is involved with Rare Diseases International and their global work.



Global Network for Rare Diseases – Matt Bolz-Johnson, Rare Diseases International

Link to presentation.

Matt worked for EURORDIS and was instrumental in the application to form ERN eUROGEN. Matt now works for a sister organisation to EURORDIS, Rare Diseases International (RDI), a global alliance working to ensure more significant equity for all Persons Living with a Rare Disease (PLWRD) and their families across all countries and all rare diseases. RDI brings together national and regional rare disease patient organisations, international federations for specific diseases, and multi-stakeholder groups.

In 2019, RDI co-organised a policy event at the United Nations NGO Committee for Rare Diseases, and the UN included RDs in the political declaration on Universal Health Coverage. Also, in 2019, RDI and WHO signed MoU for future collaboration and in 2022, the UN Resolution was passed on tackling the challenges of PLWRD & their families.

A Collaborative Global Network for Rare Diseases (CGN4RD) has been set up. It is in the pilot phase to increase access to specialist experts through regional and global hubs, not to duplicate the work of the ERNs but to enhance them. Michelle Battye, ERN eUROGEN Programme Manager, was on the Panel of Experts advising on the network's development and has been involved in their events championing RDI's work to the UN and WHO. Matt emphasised that Michelle has been very active in positioning the work of ERN eUROGEN as an innovator and leader in the global space.

Working groups provide access to specialist advice, share information, and jointly coordinate activities, and have initially been established according to the most relevant RD disease clusters, with a needs-led dimension (grouping by common needs to build common strategies and action) and a clinical-led dimension (grouping to access a panel of experts for specialist advice and opinion). So, of interest to ERN eUROGEN, Matt noted that, for example, anorectal malformations could be included as a disease cluster.

Matt congratulated ERN eUROGEN on their other global collaborative activities, particularly with CureForU.

Dissemination & Collaboration (Work Package 2)

H-Care Developments & Future Proposal – Jessie Dubief, EURORDIS

Link to presentation.

In her presentation, Jessie explained that the H-CARE project aims to develop a feedback mechanism to measure the healthcare experience of people living with RDs through the development and validation of Patient Reported Experience Measures (PREMs) for RD patients and carers. A pilot survey was conducted in 2020 (Step 1), where patients and carers were asked to rate their healthcare when they were treated in a hospital unit that was part of an ERN and in a hospital unit that was not part of an ERN. This survey used the PACIC-S scale developed by the MacColl Center for Healthcare Innovation and validated for common chronic disease patients and which is now included in the ERN eUROGEN registry as a proof of concept. In 2022 and 2023, using a literature review (Step 2) and focus groups with patients and carers (Step 3), EURORDIS, the ERNs and scientists will develop a theoretical model of the high-quality healthcare experience for RDs based on patients' needs. This will be followed by focus groups (Step 3), questionnaire design and administration (Step 4), and PREM finalisation (Step 5). Finally, in 2026, PLWRD should have access to scales measuring their healthcare experience and a feedback mechanism (Step 6), ensuring robust, comparable, and independent data collection across RDs and countries. This measurement could be used to assess the patient-centricity of the ERNs as part of AMEQUIS.

EJP RD: Research Workshop Reports & Action Plans

The European Joint Programme on Rare Diseases issues periodic calls for Research Training Workshops (current call open until 1 October 2022) and its Networking Support Scheme (current call open until 1 December 2022). The applications are easy to complete, and you can access the successful applications through the links below.

Report on Spina Bifida Workshop I and Action Plan for Spina Bifida Workshop II – Giovanni Mosiello, Expertise Area Coordinator (EAC) for EA 1.4 Non-Syndromic Urogenital Tract Malformation and Chair of the Cross-ERN Working Group on Spina Bifida (Spinal Dysraphism)

Link to presentation. Link to successful application.

Giovanni successfully applied for EJP RD funding for a research training workshop held in Rennes, FR, from 31 March - 1 April 2022, co-organised by ERN eUROGEN and ERN ITHACA. The workshop comprised two days of activities, the first with all participants and the second in small groups, to brainstorm new directions for research and amendments to Orphanet classification (see the report in the April 2022 edition of our newsletter). A follow-up meeting will be held in Rome, IT, from 19-21 October 2022, again co-organised by ERN eUROGEN and ERN ITHACA, to validate the amendments to the Orphanet classification discussed at the first workshop. Giovanni then successfully applied for funding for a second research training workshop, which will be held in June 2023, co-organised by ERN eUROGEN, ERN ITHACA and ERN ERKNet.

Action Plan for Psychology in Rare Diseases Workshop – Rosanne Smits, Post Doc Researcher, Radboudumc

Link to presentation. Link to successful application.

Rosanne previously presented a webinar for ERN eUROGEN on "Common Challenges in Uncommon Conditions". While there are 6,000-8,000 rare diseases, 30 million people in Europe live with one, so it is not rare to have a rare disease. One of the Rare 2030 recommendations is to reduce the level of psychological vulnerability of PLWRD and their families by one-third. Rosanne and her supervisor Chris Verhaak have been researching how to do this, and she has also been successful in applying for EJP RD funding for a research training workshop to further this aim, to be held in May/June/July 2023 (TBD). The workshop goals will be to learn about psychology and quality of life in RD and to define future research agendas for rare diseases. There will be a focus on patient experiences, their psychosocial needs, interventions for patients and families, networking opportunities, and the first meeting of the RARE TOGETHER consortium. The workshop output will be a consensus statement for future directions of psychosocial support in RD for publication in a scientific journal.

Strategic Research & Innovation Agenda – Wout Feitz, ERN eUROGEN HCP Network Coordinator Representative

Link to presentation.

In his presentation, Wout outlined the EU ERN Vision 2030, the recommendations from Rare 2030 and priorities from EURORDIS, ERN RND & MetabERN relating to research for RDs, and the funding available from the EC for research, through the EU4Health programme and the EJP RD (which the ERNs were only included in towards the end as it was already being established). The European Rare Disease Research Coordination and Support Action (ERICA) is a cross-ERN research consortium with a Strategic Research and Innovation Agenda. In the future, there will be Horizon Europe RD Partnerships (2024-2031) with €300-500m funding and Clinical Research Networks.

Another funding source will be industry, and the cross-ERN Working Group on Legal and Ethical Issues has been discussing how ERNs can interact with industry. ERN eUROGEN has been emphasising the importance of including medical and surgical device manufacturers in addition to pharmaceutical companies, as our patients need research on urological permanent/temporary implants, disposables, surgical instrument registries, etc.

ERN eUROGEN cannot fund research but can develop a model for it and provide non-financial support. Now, the focus for ERN eUROGEN is the registry, as this will be most useful to the network's research activities. The goal is to have 500,000 patients (with informed consent) included by 2025. Research could also cover new urological surgical reconstructive procedures and models, ATMPs, surgical decision-making (patients and caregivers), psychological processes and the burden of therapy, clinical and epidemiological data, biobank materials, basic science on regenerative medicine, genetic diagnosis, and prognosis. We have proposed a sub-working group focusing on surgical specialities to the cross-ERN Working Group on Research.

Evaluation (Work Package 3)

ERN Monitoring, Our ''Numbers'' impact, & Evaluation of the ERNs – Darren Shilhan, ERN eUROGEN Lead IT & Data Performance Analyst

Link to presentation. Link to Darren's website/newsletter article on AMEQUIS. Link to the official AMEQUIS documents.

In his presentation, Darren outlined the current situation, including ERN Core Indicators and annual data collection between January and March for the previous year (managed and validated by the ERN eUROGEN Coordination Team). He noted that one of the current issues is the significant discrepancies in the number of counted activities between ERNs which means we need to look at the definitions again. There may also be changes due to AMEQUIS, and ERN eUROGEN will be moving from Excel-based data collection to using Castor for the next full collection in Jan-Mar 2023. An online collection form will eventually be developed (2024?), so HCPs can input their data directly to the Commission.

ERN eUROGEN has nine years of data (for its original members), we can easily monitor what is happening at the network, workstream, Expertise Area (EA) and HCP levels, and we have published a Clinical Overview of ERN eUROGEN in European Urology. We are collecting data for EA 1.7 ARMs broken down according to the Krickenbeck classification to inform the threshold review (deadline 30 September 2022). A separate exercise was started on Friday to collect missing data from new members, thereby helping us to build a fuller data series from 2016 onwards for the entire network (deadline 18 November 2022). We will then collect data for 2022 between Jan and Mar 2023 (including the broader measures mentioned earlier).

The ERN eUROGEN Coordination Team has been working with the ePAG to develop a protocol relating to Network Specific Criteria (thresholds) as some EAs do not have a threshold, and those that do were set in 2017. Where EA Coordinators are appointed, they will be leading the work. Otherwise, we shall try to find experts within that EA.

The ERN eUROGEN Performance Report is usually sent out monthly with an update on much of the countable activity across the network (including CPMS, monitoring indicators, social media, and network information). A new section is an Annual Schedule which shows tasks within work packages across the forthcoming years. It is also possible to view Monthly Activities. A proposed section is HCP Assessment showing what each HCP is doing (or not!) to contribute to the network (providing monitoring data, attending workstream meetings, uploading CPMS panels/contributing expertise to them, delivering webinars, and registry involvement) which can be summarised and RAG-rated. The question is whether HCPs are happy for this to be available to the whole network or should it be restricted to the Coordination Team and the HCP representatives.

The Assessment, Monitoring, Evaluation, and Quality Improvement System (AMEQUIS) will review the KPIs used for continuous monitoring, ensuring they are relevant and appropriate. Proposals have been submitted, and changes will probably be made from 2023. The evaluation of the ERNs is to be done every five years, and the first evaluation is due in 2022. It was due to start on 1 September 2022, but we are awaiting confirmation as to the exact timeline and details of the appointment of the Independent Evaluation Body (IEB), who will undertake the evaluation. The process will likely take 10-12 months with evaluation at both the Coordination Team and HCP levels and a Patient Representative virtual interview. Only the original members of the network who joined in 2017 are included (23 HCPs following Brexit). The ERN eUROGEN Coordination Team will support the HCPs as far as possible in providing the required information.

DAY 2 – 14 SEPTEMBER

CPMS Activities (Work Package 4)

CPMS Pilot payments, Helpdesk, & Future CPMS – Darren Shilhan, ERN eUROGEN Lead IT & Data Performance Analyst

Link to presentation. Link to CPMS paper.

In his presentation, Darren reported that 179 ERN eUROGEN panels had been created in CPMS since November 2017. However, there were only 20 in the last year compared to 42 in the previous year, and we have not had >4 panels added in one month since March 2021. Nevertheless, there has been a 40% increase in ERN eUROGEN users with an enabled CPMS account. It is unclear why there are more users but fewer panels; do HCPs not have panels to upload? Is there not enough time to upload them? Is it too difficult to upload them?

The CPMS Helpdesk (Darren and Loes Oomen, ERN eUROGEN Clinical Data Specialist) can support using the system. The website has guides on EU login and CPMS setup, how to upload a panel, and how to join panels and meetings. They have also developed a panel creation protocol for medical specialists in training, so trainees can be made CPMS users and upload panels on behalf of their supervisors. The Helpdesk can invite panel members (from within and without the ERN), arrange meetings (finding the optimum day/time, calendar invites, reminders etc.) and close panels, but they cannot create panels or sign-off panels. They are working on creating Expertise Area groups to make it easy to invite experts relating to cases. They produce a CPMS newsletter three or four times a year and liaise with other helpdesks every month. They may be able to get minor changes implemented quickly; otherwise, they can suggest them for the new version of CPMS (scheduled for release at the end of 2023).

The CPMS reimbursement pilot began in March 2022, with €200 per video panel discussion from a total budget of €100,000 (i.e., 500 panels). This reimbursement is paid to the employing HCPs, not individuals, and the amount earned by a participating HCP varies from meeting to meeting. As an example, a panel was scheduled with eight reps from five member HCPs and one guest HCP – at the meeting, six reps attended representing four member HCPs and the guest HCP, and the €200 was shared equally amongst the member HCPs only – with the four receiving €50 each. Only the first video meeting for a panel qualifies for payment (i.e., where a case discussion takes place). Reimbursement is paid in a one-off payment at the end of the grant period. To date, 10 video panels have qualified for reimbursement, so we do not expect to utilise the whole available budget. The EC will consider extending the scheme at the end of the grant period and whether greater reimbursement may be offered in the future.

Other Digital Activities (Work Package 5)

Registry Pilot Payments, Update, & CASTOR Developments – Loes van der Zanden, ERN eUROGEN Registry Coordinator & Lotte Boormans, ERN eUROGEN Registry Manager.

Link to presentation.

In the presentation, Loes explained that as the Registry Coordinator, she mainly deals with legal and ethical issues, while as the Registry Manager, Lotte primarily deals with Castor.

The ERN eUROGEN registry is ready to be used, although the team is expanding the data elements to be collected. It is a centralised registry built using Castor. The registry team has developed a Data Sharing Agreement (to be signed), a Data Access and Sharing Policy which explains how data is handled, a protocol, a manual, patient information and informed consent forms, and a data protection impact assessment (DPIA). 54 ERN eUROGEN HCPs received these documents (reminder sent in June). and were asked to arrange legal/ethical approval and begin with retrospective inclusion, followed by prospective inclusion.

The EC evaluates all ERNs, and one of the major evaluation points is the status of the registry. At present, five HCPs are working on retrospective inclusion, four HCPs have legal OR ethical approval and are working on the other, and 45 HCPs are working on legal and ethical approval. Five HCPs have not responded to the reminder, and 12 HCPs have not responded at all. The deliverables that we gave to the EC were that 50% of HCPs would have entered their retrospective patients by August 2022, and 80% of HCPs would have entered their retrospective patients by November 2022, so we are behind schedule. Loes encouraged members to put pressure on their legal/ethical departments, mentioning that the registry is an important task that must be completed to stay a member of ERN eUROGEN. All issues can be forwarded to her as she has much experience and can have an online meeting with the HCP's legal/ethical department if that would be helpful.

Loes asked members to start preparing the retrospective inclusion of patients, even if approval has not been granted yet, by identifying patients, obtaining addresses, and drafting letters. Loes and Lotte demonstrated how this was done at Radboudumc. Lotte then gave a live demonstration of CASTOR data entry, focusing on retrospective data collection.

As with CPMS, there is a pilot for reimbursement for registry data input, with €10 paid per patient registered in CASTOR before 15 June 2023 (total budget available €100,000, i.e., 10,000 patients). Loes suggested tracking how much time it takes to collect the data as an amendment could be proposed to increase the amount paid.

The registry team is already working on further developing the registry, including tracking clinical information about the follow-up of patients, parent-reported questionnaires for patients in WS1, and patient-reported questionnaires for the other workstreams. The team are also creating clinical practice snapshots for the other Expertise Areas in ERN eUROGEN and on the SPIDER pseudonymisation tool, which was developed by the Joint Research Centre of the EC. Radboudumc's Privacy Officer is currently evaluating the tool. There will be SPIDER training sessions, but in the meantime, you can use your own pseudonymisation methods. The registry team will inform you when this changes.

Guidelines: Overview, Support, & Timeline – Michelle Battye, ERN eUROGEN Programme Manager

Link to presentation. Link to guidelines factsheet. Link to guidelines methodological handbooks.

In her presentation, Michelle explained that in 2018 the EC issued a call for tender for an organisation or consortium to work with the European Reference Networks (ERNs) to produce Clinical Practice Guidelines (CPGs) and Clinical Decision Support Tools (CDSTs) to the same high standards and with methodological rigour. This was won by a Spanish consortium led by Fundacion Progreso y Salud, who delivered the ERN methodological handbooks on 28 January 2021. The consortium ran guidelines training, and many ERN eUROGEN members participated in this.

In Spring 2021, the ERN eUROGEN Guidelines Expert Panel was established; representatives from full member/affiliated partner HCPs and ePAGs were invited to apply to join, and all Supporting Partners were asked to appoint a representative. All members had to submit a Disclosure of Interest before joining. This panel (led by a chair and co-chair) review, validate, and modify the list of potential CPGs and CDSTs and appoint disease-specific subgroups to work on the CPGs and CDSTs (according to the ERN methodology). On 14 June 2022, Ramnath Subramaniam was appointed as Co-Chair of the panel; Wout Feitz remains Chair at present.

Regarding current activities and support, at the ERN eUROGEN Guidelines Expert Panel kick-off meeting (7 September 2021), it was decided to progress a Clinical Practice Guideline (CPG) on Anorectal Malformation (ARM), translating and endorsing an existing Dutch guideline. A subgroup was formed with Jan Gösemann and Martin Lacher as Chair and Co-Chair, and work started with the Spanish agency, IACS. This paused when support finished, but work is due to resume with another round of support beginning on 27 October 2022. At the ERN eUROGEN Guidelines Expert Panel kick-off meeting (7 September 2021), it was also decided to progress a Clinical Decision Support Tool (CDST) on posterior urethral valves (PUV). A subgroup was formed with Magdalena Fossum and Yazan Rawashdeh as Chair and Co-Chair. Unfortunately, the Consortium and Agency cannot provide simultaneous support for this. In June 2022, it was noted that a French PUV guideline is being developed, which we could potentially translate and endorse as a CPG, as per the CPG on ARM. The ERN eUROGEN Coordination Team are in discussion with the subgroup chairs about how to proceed.

ERN eUROGEN is also involved in joint work on guidelines. With ERN ITHACA, there is a joint working group on spina bifida and its urological aspects (with the EAU Guidelines Office and International Federation for Spina Bifida and Hydrocephalus). Giovanni Mosiello & Kate Abrahamsson are leading a CPG on Paediatric Spina Bifida (a Memorandum of Understanding is in progress). As seen in his presentation, with funding from the EJP RD, Giovanni arranged a Research Workshop on Spina Bifida in Rennes, FR, where discussion on the guideline was progressed, and GM has been successful in his application to the EJP RD for a second workshop, to be held in June 2023. With ERN ERKNet, joint consensus papers have been published on cystinuria and foetal lower urinary tract obstruction. In the future, we will collaborate on a CPG for congenital solitary functioning kidney (Memorandum of Understanding in progress) and a consensus paper on urological and nephrological aspects of PUV (once the ERN eUROGEN CDST is complete). With ERN ERNICA, we are collaborating regarding anorectal malformation and Hirschsprung's Disease. All workstreams also collaborate (or will do so) with Supporting and Collaborative Partners to ensure there is no duplication of work: so, WS1 with EAU, ESPU, EUPSA, and potentially DGU (CPG on Bladder Exstrophy), WS2 with EAU (CPG on vesicovaginal fistulae) and ESSIC, and WS3 with EAU, CAU and the GSRGT.

Proposed topics for future CDSTs are abdominopelvic sarcomas, melanoma affecting the genitourinary tract, groin dissection, and complex genital reconstructions for Congenital Adrenal Hyperplasia (CAH), and a recommendation on best practice or a review from a group of experts on non-syndromic urogenital tract malformation.

The next steps are for the ARM subgroup to progress endorsement of the CPG, the PUV subgroup to progress the development of the CDST, to continue collaborative working, and for the ERN eUROGEN Guidelines Expert Panel to develop and execute a survey to members and supporting partners on who is active on which CPGs and CDSTs, and to identify gaps and support needed for the remainder of the EU4Health Programme (2021-2027).

Training & Education (Work Package 6)

ERN eUROGEN Webinar Programme & ERN Academy – Darren Shilhan ERN eUROGEN Lead IT & Data Performance Analyst

Link to presentation. Link to upcoming webinars.

In his presentation, Darren outlined the ERN eUROGEN webinar programme where we have (usually) weekly webinars on Wednesdays at 18:00 CET, giving approximately 40 webinars a year covering all Workstreams and aiming to cover all Expertise Areas (EAs). All full members are expected to deliver a webinar every 18 months, and where appropriate, we collaborate with other ERNs. All past and upcoming webinar information is on the website, and (nearly) all videos are on the ERN eUROGEN YouTube channel.

We have run 49 webinars, with over 6,000 registrations and almost 3,000 live attendees. There have been over 1,000 subsequent views on GoToWebinar and nearly 8,000 on YouTube. More webinars have focused on WS1 (66%), reflecting that

60% of all expertise areas covered in eUROGEN are in WS1. We have also delivered cross-workstream webinars. Twenty-one full-member HCPs have neither delivered a webinar in the previous 18 months nor scheduled one in the next 18 months. We'll be contacting all those HCPs to help support them in changing this.

We are happy to vary the format: half (25/49) of our webinars have been delivered by a single presenter, but 16 have been given by two presenters and eight by three presenters or more (five of which have been in the last six months), and panel discussions are also welcome. It is possible to include polls and video clips, and you can pre-record your presentation.

We are currently running an annual survey of the webinar programme (deadline 30 September 2022). So far, there is a >90% positive response to the quality of the webinars, and the vast majority also rate the length of the webinars as good. Two speakers for a webinar are the most popular option. We'll keep the starting time as 18:00 CET, though we could move it an hour back or forward if required. A few people are interested in certification/CMEs for webinars, but only a small number, and there are cost implications, so the ERN eUROGEN Coordination Team does not plan this in the near future.

The ERN Academy will be the EC's (Moodle-based) platform for online education used by all ERNs. The pilot phase is running at present (until December 2022), although we still don't have access to the platform. When we do, ERN eUROGEN is planning to utilise a surgical video from an operation in Radboud, which will help test the uploading of huge videos (circa 25 GB in some instances). The EC is keen that it is not simply a dumping ground for webinars, etc., but that the material is interactive with a lesson-based structure. If you have ideas, please let Darren or Loes Oomen (ERN eUROGEN Clinical Data Specialist) know, as they can help develop material before the system is up and running. They'll update you with more details as they get them.

ERN Exchange Programme – Jen Tidman, ERN eUROGEN Business Support Manager

Link to presentation. Link to the online tool.

In her presentation, Jen highlighted that the goal of the ERN Exchange Programme is "sharing expertise, experiences, and highly specialised knowledge between all ERN professionals under the scope and framework of the 24 ERNs, to strengthen clinical and organisational expertise and share best practices in the field of healthcare." The aim is for a horizontal approach of shared experiences rather than a vertical teacher-apprentice approach (i.e., knowledge exchanges, not training visits). These are supposed to be clinical/organisational exchanges, so they are not meant for research (though this may be a secondary effect of the exchange programme).

A total of 1080 exchange packages were available at the programme's start. According to the network size, ERNs were assigned 34, 44 or 55 packages, but unused packages are being reallocated to those using them on a first-come-first-served basis. ERN eUROGEN was allocated 34 packages and (as of 7 September 2022) has used 39.

Timeframe: applications should be received by 31 December 2022 and visits taken by 31 January 2023.

Duration: there is no minimum duration for visits (although each package is for five days, and a whole package will be "used" for even a one-day visit), and the maximum duration is six weeks.

Funding: Each package provides compensation for five working days, including travel and per diems (€200) for each night spent at the location of the visit for subsistence costs: accommodation, food, and local transport. Weekend stays are compensated with the full amount of per diem, i.e., €200 per night, provided that the programme cannot be conducted otherwise. This could also include a group event/workshop with programme activities on a weekend. The maximum per diems = 40 (i.e., 6 x working weeks, including the weekends in-between but not either side). Costs incurred by hosting HCPs are NOT included.

Ecorys: the agency facilitating the visits for HaDEA (the funding body of the EC), where account managers assist ERNs with needs, design and operationalisation of the programme and provide visitors with personalised logistical support. They also collect data and report to the EC for monitoring and learning purposes and run weekly Q&A sessions for ERN professionals who are interested in participating in the Exchange Programme.

Eligibility: Individuals or groups of health professionals (e.g., medical doctors, nurses, physiotherapists, laboratory staff) from all disciplines related to the relevant expertise area of the ERN, working in ERN full member or affiliated partner healthcare providers are eligible to make visits. Project managers and ERN patient representatives can also make visits, provided the objective of the visit is relevant. The hosting centres must also be full members or affiliated partners of the ERNs, but exchange visits from/to (members of) other ERNs are allowed (e.g., for us, visits to ERN ERKNet, ERN ERNICA, ERN ITHACA, or ERN EndoERN may be helpful). Linked visits (e.g., going from home HCP to one host, to another host, then home) are possible. Sadly, visits from/to HCPs outside the ERNs and outside the EU27 + Norway are NOT foreseen.

Clinical exchange examples: These have been used to enhance clinical skills, gain more specialised knowledge on rare diseases, see more patients with rare diseases than possible in their own hospital, contribute to the treatment of complex cases, and meet in person with ERN colleagues. These visits have strengthened ERNs by increasing compliance with treatment guidelines, improving diagnosis and care, increasing the incorporation of patient perspectives in treatment decisions, and diminishing disparities in knowledge and expertise among hospitals in the ERN.

Group exchange examples: These could be groups participating in a clinical exchange, groups of new members/affiliated partners being integrated into ERN activities, or groups meeting to work on, e.g., guidelines/registries/patient pathways.

Positive feedback: Received from everyone who has taken part in an exchange through ERN eUROGEN: *"It was a great opportunity", "We could share our experience", "It was interesting to finally meet people who I know from virtual conversations", "I was able to observe a wide array of complex surgeries", "I will take what I've learned back with me to improve my clinical practice. This has been an important step in my Urological training". "Successful, far beyond our expectations", "allowed us to exchange knowledge to a depth we never reach in our everyday clinical life", "this group visit provided great added value for all participants from both clinics."*

Application process: The process is straightforward.

1. The potential visitor completes Online Tool & emails the ERN Coordination Team.
2. The ERN contacts potential host representatives to see if they are willing to host and if mutually convenient dates can be found.
3. If a visit is possible, the ERN sends basic visit details to Ecorys, who contact HaDEA for pre-approval.
4. In the meantime, the visitor and host representative co-complete a Mobility Agreement (MA) and send it to the ERN for sign-off by the Coordinator.
5. Once pre-approval is given, the ERN sends the completed MA to Ecorys, who contact HaDEA for final approval.
6. Once final approval is given, logistical arrangements are progressed.

Mobility Agreement: The MA is very easy to complete, with basic details being taken for the participant, their HCP, the host HCP and representative, then information on the duration, a detailed programme (objectives, planned activities, and expected results) and then signatures from the participant, host, and ERN.

Logistics: When the MA is shared with Ecorys >2 months before the proposed exchange date, Ecorys will organise and manage travel arrangements for the participant(s), including the provision of tickets and travel insurance. When the MA is shared with Ecorys <2 months before the proposed exchange date, the participant(s) must arrange their own travel tickets. They will be reimbursed up to €300 for return air travel, up to €200 for return train travel, and up to €300 for car travel. In all cases, visitors must book their accommodation and cover other costs from the daily allowance compensation.

Receipt of funding: During the visit, as soon as Ecorys receives a written confirmation from the hosting institution representative that the participant has arrived at the hosting institution, Ecorys will order the transfer of the daily allowance. The participant will receive an email to inform them that the daily allowance is on its way. This will generally happen on the first day of the visit. Should questions arise, Ecorys will be ready to support the participant via email. When the Mobility Agreement is shared last minute with Ecorys, it can take a bit longer to transfer the daily allowance.

Evaluation: Ecorys will send an evaluation form to the visitor and host after the visit. After filling in the evaluation form, the visitor will receive a certificate stating the duration and activities performed, the Attestation of Attendance.

Summarising her presentation, Jen emphasised that the ERN Exchange Programme is a fantastic opportunity, so she asked everyone to make their colleagues aware. It's a case of "use it or lose it" regarding the remaining packages and the renewal of the programme beyond January 2023, which will depend on its success now. To finish she showed a video about the programme. Since the meeting, Ecorys has released another video about the programme.

ERN eUROGEN Book on Rare & Complex Urology (Elsevier) – Jen Tidman, ERN eUROGEN Business Support Manager

Link to presentation. Link to book contributor pack.

In her presentation, Jen gave the background to the book, nothing that an agreement was signed on 29 January 2021 between Prof. Wout Feitz, ERN eUROGEN HCP Network Coordinator Representative, Radboudumc and Elsevier.

Table of Contents: The book will have introductory chapters (an introduction from Wout Feitz, ERN eUROGEN HCP Network Coordinator Representative and then chapters about the development of the ERN from the EAU and the EC), followed by overview chapters (on patient care numbers, ePAG, cross-ERN/EU/global collaboration, the registry, and guidelines), and then clinical chapters on each of the ERN's Expertise Areas (EAs). The full table of contents is in the ERN eUROGEN Book Factsheet in the Contributor Pack.

Protocol: The protocol for the book is that

1. Expertise Area Coordinators (EAC) will be the lead authors for the clinical chapters. They should write and review their draft chapters with **at least two other experts** from their expertise area; **where there is a vice-EAC, they should be one of the experts**.
2. Each chapter should therefore be written by a **minimum of three experts**, and these should be **from different ERN eUROGEN HCPs**. Therefore, where the EAC **and** vice-EAC are from the **same** HCP, this means there will need to be at least four experts involved.
3. Each chapter should be peer-reviewed and agreed upon by **at least one ePAG Advocate**.
4. Once written/peer-reviewed, the chapter and a completed sign-off template should be sent to Wout Feitz and the Editorial Team.
5. The Editorial Team will review the chapter and ensure it meets agreed standards, asking for clarification where required.
6. Once the chapter is agreed upon, Editorial Team will ask the lead author to submit it to Elsevier via EMSS.

Where there are no EACs/vice-EACs, Jen has asked Darren for expert contacts relating to the EA for CPMS panels and has asked them if they would be willing to collaborate on a chapter, even if they are not willing to take on an EAC/vice-EAC role.

Content: This is up to the lead and co-authors; whatever is logical/realistic, noting limitations on time/words/figures. Chapters should be written in UK English (Jen can help with proofreading/copyediting) using the Vancouver referencing system.

Word count: For the complete book, this is 120,000 words, so with 30 chapters, each should be approximately 4,000 words, although some introductory chapters will be shorter, so leeway for other chapters to be longer if required.

Abstract & Keywords: Some authors were confused about why they were being asked for these, but Elsevier explained these are required to help readers find the book & individual chapters in online searches. They are nonprint items included in the online version of the chapters, not in the printed book.

Figures & Tables: Many authors have asked about these, and if authors produce new figures, the Elsevier production team may be able to redraw the images to be suitable for publication at little/no cost (a sample would be required to check this). Alternatively, Elsevier also offers formal illustration services, but there is a cost for this. Currently, the ERN eUROGEN Coordination Team has not set a limit for the number of figures and tables, preferring authors to use the amount necessary to make their chapters clear/helpful but asking them to bear in mind the budget limitations and keep numbers reasonable. The Coordination Team reserves the right to ask contributors to reduce the number of figures.

Contributor pack: Jen has made a contributor pack with an ERN eUROGEN factsheet and all documentation from Elsevier about chapter format, permissions, etc.

Timeline/Deadline: At present, the Coordination Team is asking for the first drafts of chapters by 31 October 2022 to allow time for review/revision, with a final deadline of 31 December 2022 for complete book submission. This may need to be negotiated with the publisher.

Summary & Strategic Board Actions:

Overall Q&A and Discussion

No questions were sent to the ERN eUROGEN Coordination Team before the meeting, either before or after the 1 September 2022 deadline set in the circulated agenda. Questions arising from the meeting itself and the presentations given were discussed and answered when asked.

Strategic Board Discussion & Voting

The ERN eUROGEN Governance Statutes state that minor decisions require a majority from members present or represented at the Strategic Board meeting. However, the Strategic Board may only legitimately pass resolutions if at least one-third of its members are present or represented. Major decisions require a qualified two-thirds majority. When these conditions are not met, or decisions are urgent, then voting will be organised by email with a two-week deadline for response to ensure all members can respond.

For the ERN eUROGEN Strategic Board Meeting 2022, no items for discussion and voting were submitted by members to the ERN eUROGEN Coordination Team before the meeting, either before or after the 1 September 2022 deadline. The Coordination

Team had identified some items for discussion and final approval, but these had already been circulated by email with a two-week deadline:

- **ERN eUROGEN Governance Statutes**

  Link to statutes (v.2022-03-02). These were sent to the new full members when they joined the network in January 2022 and subsequently sent to the original full members and affiliated partners, ePAG Advocates, and Supporting Partners (Individual Experts), for all to review and sign the agreement at the top of the first page. No complaints or amendments have been lodged with the ERN eUROGEN Coordination Team to date, and 29/57 agreements have been returned. The Coordination Team is chasing those who have not yet returned agreements but, without comment to the contrary, assumes that the ERN eUROGEN Governance Statutes are agreed upon in principle.
- **ERN eUROGEN Protocol on Network-Specific Criteria (Thresholds)**

  Link to network-specific criteria protocol (v.1.3, 2022-09-23). A version of the ERN eUROGEN Protocol on Network-Specific Criteria (Thresholds) had already been sent out to the whole network with a two-week response deadline. Darren Shilhan has been amending the document based on the comments received and is now preparing the document for final sign-off.
- **ERN eUROGEN Factsheet on Global Strategy**

  Link to global strategy (v.2022-06-22). The ERN eUROGEN Factsheet on Global Strategy had already been sent out to the whole network with a two-week response deadline. No comments were received, so the current version was already considered final.

If any additional questions or important suggestions arise after reviewing the above-mentioned documents using the links In this report, please contact the Coordination Team directly, who will then take appropriate action. If no reply is received within the normal two-week consultation period, the Coordination Team will presume agreement with the current versions.

Summary of Meeting – Wout Feitz, ERN eUROGEN HCP Network Coordinator Representative

Wout thanked everyone for their attendance and wished them a safe journey home. He hoped that the opportunity to meet in person was helpful and that relationships had been made and developed. He emphasised that the ERN eUROGEN Coordination Team are here to help and support everyone so just let us know. The Coordination Team will send a poll for dates for the 2023 meeting.

IN-PERSON ATTENDEES

Chair:

Wout Feitz

Coordination Team:

Darren Shilhan

Jen Tidman

Loes van der Zanden

Lotte Boormans

Michelle Battye

Member Representatives:

Aart Klijn

Alaa El Ghoneimi

Alexandre Serra

Antonio Di Cesare

Arnout Alberts

Barbara Dobrowolska-Glazar

Ernest van Heurn

Franziska Vauth

Gilvydas Verkauskas

Giovanni Mosiello

Hans Langenhuijsen

Ivo de Blaauw

Jørgen Thorup

Laetitia de Kort

Magnus Anderberg

Mark Schneider

Mateja Vinkšel

Michel Wyndaele

Nathalie Botto

Paul Broens

Pernilla Stenström

Pim Sloots

Raimund Stein

Ramon Gorter

Richard Meijer

Rosanne Smits

Seppo Taskinen

Simona Nappo

Steffi Mayer

Tahlita Zuiverloon

Tim Ludwig

Tomislav Kuliš

Verena Ellerkamp

Yazan Rawashdeh

Yue Che

ePAG Advocates:

Claire Harkin

Dalia Aminoff

Loredana Nasta

Serena Bartezzati

Supporting Partner Representatives:

Katja Wolffenbuttel (ESPU)

External Speaker:

Jessie Dubief (EURORDIS)

ONLINE ATTENDEES

Member Representatives:

Alessandro Morlacco

Anne-Francoise Spinoit

Carol Fenech

Gundela Holmdahl

José Medina Polo

Kate Abrahamsson

Lena Mesch

Lucia Migliazza

Mariangela Mancini

Paola Midrio

Pietro Bagolan

Tomislav Kulis

Vincenzo Davide Catania

External Speaker:

Matt Bolz-Johnson (RDI)