



European
Reference
Network

eUROGEN
Urogenital Diseases

Periodic Report

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

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1. DESCRIPTION OF THE ACTIVITIES CARRIED OUT BY THE BENEFICIARIES AND OVERVIEW OF THE PROGRESS

1.1. Description of the activities carried out during the reporting period in line with Annex 1 to the Grant Agreement

- Main activities carried out including methods and means

The ERN for rare and complex urogenital diseases and conditions (ERN eUROGEN) delivers faster specialist evaluation and more equitable access to high quality diagnosis, treatment, and care for patients with rare urogenital diseases and complex conditions who need highly specialised assessment and surgery. This has been conveyed to the public for awareness primarily through [our website](#).

ERN eUROGEN comprises three workstreams (WS). Focusing on clinical and surgical excellence, continuity of care is ensured from childhood throughout the patient's lifespan, encompassing the important and often neglected adolescent period of urogenital practice:

- Workstream 1 - Rare congenital uro-recto-genital anomalies
- Workstream 2 - Functional urogenital conditions requiring highly specialised surgery
- Workstream 3 - Rare urogenital tumours

ERN eUROGEN's priority has been to create faster and more equitable access to high quality diagnosis and treatment advice, using the Clinical Patient Management System (CPMS) which is the tool given to the ERNs by the European Commission (EC). With the full informed consent of the patient, CPMS has been used by medical professionals to review cases uploaded for advice on highly specialised surgery or for a second opinion. Evidence of this can be seen in the monthly CPMS user reports from DG SANTE which are published in the 'Plaza' section of the ERN Collaborative Platform (ECP).

Main activities in Year 3 (reporting period 1 June 2020 until 31 May 2021):

- To consolidate the operations of ERN eUROGEN. The network initially linked together 29 healthcare provider (HCP) members from 11 Member States (MS) with a functioning governance, accounting and coordination structure and put measures in place to evaluate its activities. As the Member States designated Affiliated Partners (APs) (Associated National Centers and National Coordination Hubs) in countries where the ERN had no full member, the geographical coverage of ERN eUROGEN expanded in 2019 to 45 HCPs in 16 EU countries and the network has been integrating these new AP members.
- To peer review the applications to ERN eUROGEN according to the network specific criteria with the input of the ePAGs following the EC's call for healthcare providers to join ERNs in September 2019.
- To aim to provide highly specialised multidisciplinary advice using CPMS for at least 96 patients with rare uro-recto-genital diseases or complex conditions (target number is monitored using the monthly DG SANTE ERN Status Reports).
- To actively collaborate with the Spanish consortium appointed by DG SANTE

to develop two new Clinical Practice Guidelines (CPGs) and five Clinical Decision Support Tools (CDSTs).

- To foster collaborative research and to facilitate clinical trials of new therapies.
- To continue to deliver an ERN eUROGEN educational webinar programme, in collaboration with other ERNs and Supporting Partners, where possible.
- To collaborate closely with other European Reference Networks and other European organisations e.g., scientific societies
- To carry out all of the above in equal partnership with patients, caregivers and lay organisations.
- To develop factsheets and protocols to ensure an equitable and consistent approach to different management processes such as the integration of new Affiliated Partners or taking steps to deal with the non-compliance of ERN eUROGEN's existing members.

ERN eUROGEN Registry

Within ERN eUROGEN, currently only very limited data is being gathered about disease progression, surgical procedures and treatment outcome. There are a few databases, but they are not standardized. In addition, they lack long-term follow up data on treatment outcome, which hinders improvement of treatments. Therefore, the ERN eUROGEN registry aims to collect individual data from patients suffering from rare urogenital diseases or complex conditions.

The ERN eUROGEN registry project consists of different phases. We have started with a pilot phase, the ERN eUROGEN Clinical Practice Snapshots. In this phase, part of the Common Data elements defined by the European Joint Research Centre platform on rare diseases will be collected. These are 16 data elements describing the general health status of the patients. In addition, information on diagnosis and treatment will be collected. This will be done with a disease-area specific dataset initially consisting of 6 clinical questions. A selection of all HCPs who are an expert center for a specific disease area have been asked to develop a protocol and when the platform is operational to fill out data on the last 30 new patients they have seen for that disease before the start of this year. This will help clinicians to get familiar with the registry and to test it and provide feedback. In addition, it will provide an overview of the numbers of patients treated at the different HCPs. With the information on the current clinical approaches used, the different approaches used among the different HCPs can be compared. So the answers on the questions will enable a snapshot of the current clinical practices in Europe to be performed. 5 of the disease areas for the Clinical Practice Snapshots were selected, which are 1.5, posterior urethral valves, 1.7, anorectal malformations, 1.8, paediatric kidney transplantations, 2.1, complicated & pelvic floor disorders: AMS800, and 3.3, adrenal tumors.

In the next phase of the ERN eUROGEN registry project, the expansion phase or the final ERN eUROGEN registry, ethical approval will be applied for at the ethical committees of all HCPs to start with the prospective inclusion of patients in the registry. After ethical approval, the collection of informed consent forms of patients and registration of patients who give consent can start. The data collected will entail the Common Data Elements, the disease area specific clinical questions, and additional patient-specific data items on, for example, follow-up. In addition, four existing rare urogenital disease-specific registries, AGORA, Saturn, Venus, and ARM-Net, will be integrated into the ERN eUROGEN registry. The aim of this final version of the ERN eUROGEN registry will be to identify contemporary cohorts of patients for clinical research across national borders. In addition, it will enable the treatment performance and patient outcomes to be monitored at the participating HCPs. This real life clinical information will be very valuable for research and evidence for the guidelines or clinical decision support tools.

The ERN eUROGEN registry project started in June 2020 and it will last 3 years. In the first year, a kick-off meeting was held with the Advisory Board and a platform provider was decided. The website, communication plan, protocol for Snapshot development, quality strategy, snapshots for the 5 pilot disease areas, protocol for performing the snapshots, and a survey about ethical, juridical and privacy issues concerning the snapshots were completed.

In the coming 2 years, more input from the HCPs involved will be needed, by filling out the survey about ethical, juridical and privacy issues concerning the snapshots, by entering clinical data on the last 30 new patients they treated for the 5 pilot disease areas into the snapshots, and by helping to develop the 6 clinical questions for the other disease areas and the patient-specific data items for all disease areas. In the meantime, the ERN Coordination Team coordinates all those actions and work on the protocol for the final ERN eUROGEN registry, the data transfer and data sharing agreements, and the integration plan for the already existing registries. The European Joint Program on rare diseases is working on generic informed consent forms that will be available in all European languages and could be used for all ERN registries in all HCPs.

In the coming period, again the HCPs will be needed to help obtain ethical and legal approval for implementing the final ERN eUROGEN registry. When those approvals are obtained, they will start data collection which means that patients will be asked to provide informed consent and if they do, their data will be entered in the ERN eUROGEN registry. In the meantime, the ERN Coordination Team again coordinates all these actions and integrate the existing registries in the ERN eUROGEN registry. In addition, the analyses of the snapshots will be coordinated.

ERN eUROGEN Educational Webinar Programme

See below for more information.

COVID-19

The ERNs were well placed to respond to the challenges posed by the COVID-19 pandemic as they have been operating virtual networks across Europe since 2017. Therefore physical meetings were replaced with virtual events very easily. A face-to-face Strategic Board meeting when the new members are integrated in 2022 will be very important for the trust and cohesion of the future network. Also, ideas for potential research and collaboration are more sparked and pursued following face-to-face meetings and this has been lacking during the COVID-19 pandemic.

- Coordination with other projects or activities at European, National and International level

COORDINATION WITH THE EC AND ALL OTHER ERNs

ERN Coordinators Group (ERN CG)

Since the COVID-19 pandemic prevented face to face meetings, the ERN CG has been held twice a year virtually. An internal meeting of the ERN CG took place before each ERN CG. The [reports of the meetings and meeting papers are on the ERN eUROGEN section of the ECP](#).

ERN Project Managers Group

The ERN Project Managers (PMs) held virtual meetings on 15 and 23 July 2020, with the kind support of DG SANTE. The [reports of the meetings and meeting papers are on the ERN eUROGEN section of the ECP](#).

ERN CG Working Groups

ERN eUROGEN, as one of 24 ERNs, plays an active role in the working groups set up by the ERN Coordinators to deal with key issues.

Monitoring Working Group

Prof Wout Feitz, was elected as the new co-chair, supported by the ERN eUROGEN Programme Manager and ERN eUROGEN Lead IT and Data Analyst. The group had four meetings in 2020, two in 2021 and two webinars in advance of the data collection exercise to explain any changes. Affiliated Partners were included in the data collection for the first time. The objective is not to compare ERNs as they are such a heterogeneous group, but to assess their overall performance. Some data will be made public soon and this is under discussion. Decisions still need to be taken on including new indicators in the future e.g., possibly the integration of new members and registries.

ERN eUROGEN developed an additional governance document on a fair and transparent process to remove an HCP from a network if it no longer has the required levels of expertise or if there are other issues which prevent active engagement with a network. This process has been shared with the Monitoring Working Group and many have developed a similar process. The activity of the HCPs is monitored using the ERN eUROGEN performance dashboard so that inactive members can be contacted and offered more support.

ERN eUROGEN developed a draft document for the ERN CG on the expansion of disease areas by ERNs. This was adapted by the ERN CG and the EC based on comments from the networks and a final version is expected to be approved by the Board of Member States for ERNs in the autumn 2022. ERN eUROGEN plans to add three new disease areas in 2022: Paediatric renal transplants, Male infertility and Paediatric oncological urology.

The network contributed actively to **other ERN CG Working Groups**, namely the **Knowledge Generation Working Group** (Prof Joergen Thorup, Serena Bartezzati, ePAG, Darren Shilhan and Michelle Battye) and the Research Working Group (Loes van der Zanden).

Cross-ERN Paediatric Anaesthesia Working Group

The Cross-ERN Paediatric Anaesthesia Working Group has been established. This is chaired by Prof. Ignacio Malagon, Radboudumc (NL) and is facilitated by ERN eUROGEN as it involves all disease areas in WS1. It has members from HCPs in the following ERNs: ERN CRANIO, Endo-ERN, ERN EYE, ERN LUNG, ERN-RND, ERN ERNICA, ERN eUROGEN, ERN GUARD-Heart, ERN PaedCan, ERN RARE LIVER, ERN TransplantChild, ERN VASCERN, as well as other experts on paediatric anaesthesia. At present there are no ePAGs in the group.

The group had its kick-off meeting via WebEx on 21 December 2020, following which a survey was sent out to all group participants to ask for suggestions relating to priorities. The results of this were discussed at a WebEx meeting on 25 May 2021 and a poll sent out to all group members to vote on the best suggestions for guidelines, clinical practice snapshots, and research projects. Once the results are in, the next steps will be progressed via email and video conferences, then reported in due course. The first steps will be a priority list of existing guidelines which could follow the endorsement process for the ERN Guidelines. The protocols have been shared with all involved.

Cross-ERN Surgical Research Working Group

A cross-ERN Surgical Research Working Group was formed in 2020 including representatives from 13 ERNs. ERN eUROGEN is a member. The WG has the following objectives: promote surgical research in the field of rare diseases; advance

surgical based research in the field; and to standardise data collection for surgical-based ERN registries and inform the development of clinical guidelines.

The first meeting was held virtually on 28 August 2020 and the following priorities for action were agreed:

- Organisation of support for the development of ERN research studies in the field of surgery and rare diseases. Support includes study design, methodology, data cleaning, management of data sets, interpretation of data bases, statistics support, cleaning, management of data sets, interpretation of data bases, statistics support.
- Focus on (long-term) outcomes, effectiveness of treatment (including implants/techniques/consequences of prophylactic surgery), cause of death and quality of life, standardising approaches across ERNs for the purpose of comparative quality of life, standardising approaches across ERNs for the purpose of comparative research and joint studies/cross-border research.
- Reaching out: to patient representatives/groups for discussions on surgical communication and expectation management (including aspects related to shared decision making); to industry for support in e.g., design of surgical tools, financial support).

COORDINATION WITH SPECIFIC OTHER ERNs

One of ERN eUROGEN's objectives is to develop links and connections with other ERNs, combining the efforts of experts when patients have multi-systemic rare diseases and complex conditions which require the input of more than one ERN. These cross-ERN collaborations that benefit from the input of two or more ERNs are active and progressing well. ERN eUROGEN has established links with several ERNs and the main activities over the last year are described below. For full details please see Deliverable 4 - Report on ERN eUROGEN Interactions with other ERNs.

All documents related to working with other ERNs are saved within [the ERN eUROGEN section of the ECP](#).

1) ERN ITHACA

ERN ITHACA brings together experts in rare congenital malformations and rare intellectual disability disorders. Cross-ERN interaction is a mandatory feature of ITHACA, as many patients with developmental disabilities also have interactions with specialists linked to other ERNs (patients with spina bifida are paradigmatic in this sense). Cross-ERN interactions are organised at two levels: between ERN coordination teams, for general cooperation (such as a joint evaluation of Orphanet summaries and HPO coding), or for a specific purpose (for instance, writing an expert consensus statement).

a) Dealing with a multisystemic disorder, spina bifida

Spina bifida (SB) fits mainly within the remit of both ERN ITHACA and ERN eUROGEN and is a disease area identified by both ERNs as being an area where collaboration, working with the patient organisations, would have considerable impact (e.g., producing care documents and guidelines). Therefore, a joint working group (WG) was set up. Andrea Manunta (ERN ITHACA) is Chair and Giovanni Mosiello (ERN eUROGEN Disease Area Coordinator for non-syndromic urogenital tract malformations) is co-Chair. The WG on SB interacts closely with patient organisations who are involved in all aspects of the work. The first meeting was held with the International Federation for Spina Bifida and Hydrocephalus on 12 August 2019. During this meeting it was decided that the group would collaborate on guidelines as well as the Orphanet coding and classification of the disease. After

consulting national guidelines, it was agreed to use the cross-ERN WG on spina bifida to issue an expert consensus statement on handling patients with this multisystemic disorder.

b) Collaboration with Orphanet

Orphanet requested support with the revision of the Orphacodes for Spinal Dysraphism as the current classification is mainly anatomical and incomplete. Additionally, more recent entities like limited dorsal myeloschisis (LDM) do not fit well in the present classification. Therefore, the need for a new classification is not only anatomical but also clinical and prognostic. The new classification will be validated by a multi-centre project which will analyse the next 100 cases of spinal dysraphism. The revision of the Orphacodes is ongoing: Orphacodes are used to insert data on BaMaRa (Banque Nationale de Données Maladies Rares) which in turn will serve to automatically fill in PIRAMIG and hence calculate the budget of the different French "centres de référence". A new test of a "simplified" new classification on 20-30 cases is planned in 2021, which will be validated by a European panel of experts.

c) Clinical guidelines

The WG on SB is developing the three new guidelines listed below, together with the patient organisation, the International Federation for Spina Bifida & Hydrocephalus (IFSBH) and their Secretary General, Sylvia Roozen. The literature searches have been completed, the guidelines groups established, and the work is expected to be finalised by the end of 2021.

- Paediatric Guidelines – coordinated by Giovanni Mosiello (ERN eUROGEN, IT) and Kate Abrahamsson (ERN eUROGEN, SE).
- Guidelines on Transition – coordinated by Dan Wood (UK) (to be replaced due to emigration to USA). It was decided to limit the work on transition to a single chapter which will be included in both pediatric and adult guidelines.
- Adult Guidelines – coordinated by Andrea Manunta (ITACHA, FR) and Benoit Peyronnet (ITACHA, FR, Centre de Référence Spina Bifida)

The methodology was reviewed by Cathy Yuan who is a Cochrane information specialist from McMaster University in Ontario. She also wrote the bibliographic search strategy for each chapter of the adult guidelines.

d) EJP-RD Research Training Workshop on spina bifida, 2021

The WG on SB, in collaboration with a third ERN, ERN ERKNet, also submitted a successful proposal to the European Joint Programme for Rare Diseases (EJP RD) for a research training workshop on future research on innovative diagnostic and interdisciplinary treatment - Giovanni Mosiello, MD, FEAPU, FEBPS, Department of Urology and Neuro-Urology Bambino Gesù Pediatric and Research Hospital, Rome, Italy and ERN eUROGEN, Andrea Manunta, MD, FRCS, FEBU, Department of Urology and Neuro-Urology, Centre Hospitalier Universitaire de Rennes, France (ITHACA with Alain Verloes).

The workshop will be arranged later in 2021 due to Covid travel restrictions and the wish for a face to face meeting, after this reporting period. The objective of the two day workshop is to train researchers and clinicians on: genetic neural tube defects, correlation with Orphacodes and post-natal outcomes; TRASCET: transamniotic stem cell therapy; prenatal diagnosis correlating fetal MRI and ultrasound with post-natal outcome; urinary markers on renal and bladder function; fetal surgery (different approaches), results on bladder function, etc; innovative urodynamic investigation on neurogenic bladder related to spina bifida; and long-term sequelae of continence treatment considering the specific spina

bifida patient. Patient representatives will be invited to participate along with junior and more experienced researchers.

The workshop will be aimed at researchers and the clinicians involved in spina bifida management: neurologists, neurosurgeons, obstetricians, neonatologists, urologists, pediatric urologists, fetal and pediatric surgeons, nephrologists, geneticists, epidemiologists, immunologists, etc.

The workshop will include presentations by the ERN experts and hands-on training sessions. At the end of the workshop all participants will have gained greater knowledge on new promising diagnostic procedures and new treatments, defining their feasibility, safety, and efficacy for spina bifida patients. The potential for a future cross-ERN multi-centre clinical trial will be explored. This would be based in Europe, using cross-ERN networks of highly specialised healthcare providers, according to EU rules, respecting all ethical and legal requirements and ensuring that all data is findable, accessible, interoperable, and reusable for all.

2) ERN ERNICA

The European Reference Network for Rare Inherited Congenital Anomalies (ERN ERNICA) covers rare inherited and congenital digestive disorders, including gastrointestinal disorders, which have in common early manifestation in life and the need for multidisciplinary care and long-term follow-up. At the instigation of the patient organisations, a cross-ERN Working Group on Anorectal malformations (ARMs) was formed in 2019. Regular meetings are held, and the following work has been delivered.

a) Collaboration with Orphanet

ERN eUROGEN clinicians and their ePAG Chair joined forces with the ARM Net consortium and the ERN ERNICA clinicians to update the classification system for ARMs. Several productive meetings were held which benefited from the input of the wide pool of experts and patient representatives. It was agreed with Orphanet that the "isolated" ARMs group will be renamed as "non-syndromic" and the low/intermediate/high subdivision of disorders will be removed and replaced with the Krickenbeck classification. As a secondary issue, some subtypes could potentially be included. After these amendments, the group code for "non-syndromic" ARM can be used for non-syndromic cases before ARM type is known, then when ARM type is known, the disorder code can be used. For syndromic cases, the syndrome disorder code can be used, and the non-syndromic disorder codes can be used as secondary codes.

The changes to the classification of ARMs were agreed by ERN eUROGEN, ERN ERNICA, the ARM Net consortium and the European Paediatric Surgeon's Association (EUPSA) in April 2021. On 12 June 2021, ERN eUROGEN was informed by Orphanet that all decisions validated in the framework of the collaboration between Orphanet and ERN eUROGEN on the classification of anorectal malformations had been implemented in the Orphanet database. The Krickenbeck classification is now reflected in the Non-syndromic ARM group, and the high/intermediate/low ARM entities are obsolete. The updates are already visible on the Orphanet website. A summary of the collaboration is [available on the ERN eUROGEN website](#).

The new ORPHAcodes and classification structure will be included in the next update of the Nomenclature pack (scheduled in July 2021), a set of computable files that was developed by Orphanet in the framework of the EU-funded RD-CODE project for the implementation of ORPHAcodes in health information systems.

The importance of this change for patients cannot be underestimated. In many countries, reimbursement for and access to services on the diagnosis of rare diseases is based on the Orphanet system. In the future, the changes will allow patients with ARMs to access specialised healthcare and services based on a more accurate clinical diagnosis of their rare condition.

The IT and Data Analyst and Clinical Data Specialist (funded by the CEF 2018 and CEF 2020 programmes) will lead the integration of the new coding into the network's monitoring information systems and patient number overviews for WS1 Disease Area 1.7.

b) Collaboration on surgical videos

Regular meetings were held including the ePAG representatives of both ERNs. Both ERN eUROGEN and ERN ERNICA deal with supra specialised paediatric urogenital surgeries. Both ERNs, with full informed consent from the patients, are filming such surgeries so that they can be used in education and training materials. A template agreement has been agreed between the Paediatric Surgery Departments of Erasmus MC and Radboud MC regarding the use of the surgical videos by both ERNs.

c) Joint webinar programme

The ARM webinar series covers all aspects of paediatric colorectal surgery, in particular (congenital) anorectal malformations (ARMs). They are joint presentations between ERNs eUROGEN and ERNICA and are supported by the European Paediatric Surgeons' Association (EUPSA). Seven webinars ran between July-20 and May-21.

A similar collaboration for webinars was established by ERN eUROGEN with our Supporting Partner, the European Society for Pediatric Urology (ESPU) for a webinar on Bladder Extrophy Surgical Care which was well attended and can be viewed on our website and ERN eUROGEN YouTube Channel.

3) ERKNET

a) Collaboration with Orphanet

It was identified that the disease descriptions of the following diseases should be updated/written by ERN eUROGEN experts and co-signed by ERN ERKNet. This work was paused during the COVID pandemic and other work was prioritized by Orphanet.

b) Obstructive uropathy

A publication is underway with the input of both ERNs on obstructive uropathy which is expected to be published later in 2021.

4) ENDO ERN

The European Reference Network on rare endocrine conditions (Endo-ERN) aims to improve access to high-quality healthcare for patients with hormonal disorders. Endocrine conditions are often complex and require a long period of care due to non-life-threatening chronic disease. There are cross-ERN discussions concerning ERN eUROGEN WS1 DA 1.1 Complex genital reconstructions (DSD) and WS3, DA 3.3 Adrenal tumours where patients need the Input of more than one ERN.

a) Disorders of sex development (DSD)

One of the disease areas covered by ERN eUROGEN is complex genital reconstructions which include disorders of sex development (DSD), a group of rare conditions

involving genes, hormones, and reproductive organs, including genitals. It means a person's sex development is different to most others. Many such cases need highly specialised surgeries. However, recent developments in some EU countries have seen legislation introduced to ban such very specific surgeries until legal informed consent can be given by the patient. The differing national approaches and approach of some patient organisations in the field make this a highly contentious and sensitive area. Different statements and policy documents have been shared (such as from our Supporting Partner, the European Society for Paediatric Urology) and placed on our website and/or ECP.

b) Joint CPMS cases

There have been two joint panels between ERN eUROGEN and ERN Endo-ERN in Feb-21 and Apr-21 where successful discussions were held in determining diagnosis and treatment.

Very specific ultra-rare cases have been discussed by experts representing medical and surgical fields from both ERNs to exchange case-specific knowledge and provide additional support for the decisions and advice of the treating physician (and multidisciplinary teams), the specific patients and the caretakers Involved. Additional CPMS panels between experts from Endo-ERN (medical therapy) and WS3.3 Adrenal tumours (surgical treatment) have been agreed in June 2021 in a coordinating meeting with the WS3 Leader of ERN eUROGEN and the Endo-ERN Coordinator. Meetings will be planned with support of the helpdesks (CEF).

5) ERN TRANSPLANT-CHILD

After a request from ERN TransplantChild, an investigation was performed within ERN eUROGEN to ascertain the number of HCPs Involved in pediatric kidney transplantations. This showed that 10 HCPs from the original 29 HCPs from 11 EU MS perform these procedures with their expert teams (as published in Oomen et al, Eur. Urol. 2021). A concept Clinical Practice Snapshot was developed and shared with other experts and finally approved upon in accordance with the ERN eUROGEN protocol for this. The finalized document will be used for the further development of this specific part of the ERN eUROGEN Practice Snapshots Evaluation and the ERN eUROGEN Registry.

6) ERN EURACAN

Upon request of our Supporting Partner, the European Association of Urology (EAU) and their Guidelines Office, experts from ERN eUROGEN take part in the multidisciplinary guideline group for our WS3, DA 3.1 Penile Cancer. This group combines experts from ERN eUROGEN, ERN EURACAN, the European Society for Medical Oncology (ESMO) and the EAU Guideline Office workgroup on penile cancer. In due time, the new guideline for penile cancer will go through the endorsement process for ERN Guidelines (ERN methodology provided in early 2021).

COORDINATION WITH EUROPEAN PROJECTS & ACTIVITIES

[The Joint Action on the EHDS](#)

ERN eUROGEN has been accepted as a stakeholder.

The European Joint Programme for Rare Diseases (EJP RD)

The EJP RD provides opportunities for ERN research related training (fellowships of up to six months) and research workshops. Unfortunately, the COVID-19 pandemic has delayed the implementation of these activities but ERN eUROGEN has made the following successful applications which will take place once European travel is possible again:

- Research Training Workshop on spina bifida, in collaboration with ITACHA, to be organised later in 2021 – please see above for full description
- two successful applicants to the EJP RD ERN research training fellowships

EUROCAT

At European level, ERN eUROGEN has regular discussions with EUROCAT (the European network of population-based registries for the epidemiological surveillance of congenital anomalies). EUROCAT is a member of ERN eUROGEN's Strategic Board and offers advice on registry development.

International Rare Cancer Initiative (IRIC)

A formal partnership has been established with ERN eUROGEN which includes jointly producing new research projects and helping to deliver current trial recruitment.

H-Care survey with EURORDIS

ERN eUROGEN, along with four other ERNs, is actively collaborating with EURORDIS on a project to capture patient satisfaction with ERN HCPs. ERN eUROGEN's Coordinator, Programme Manager and ePAG Representatives all contributed to this project. The report and recommendations became available in the summer 2020. The findings were widely disseminated through ERN eUROGEN's communication channels and through the ePAGs.

A proposal, led by EURORDIS with several ERNs, including ERN eUROGEN, has been submitted to the European Joint Programme for Rare Diseases to develop a validated scale to measure patient satisfaction at European level. It is currently under evaluation.

Rare 2030 Panel of Experts

The Rare 2030 Foresight Study was initiated by the European Parliament and co-funded by the European Commission Pilot Project and Preparatory Actions Programme. The [final report](#) of this two-year study with over 250 experts from across the rare disease community, has resulted in eight overarching recommendations to ensure that the future of 30 million people living with a rare disease is not left to luck or chance.

It sets out the need for a new European policy framework for rare diseases to:

- Guide the implementation of national plans for rare diseases with the same measurable objectives.
- Bring together a refreshed concerted strategy across research, digital, healthcare, social welfare complementing existing legislation
- Encourage continued investment in the field of rare diseases at both the European and national levels to ensure we do not lose momentum.
- The eight final recommendations covering diagnosis, treatment, care, research, data, and European and national infrastructures sets out the roadmap for the next decade of rare disease policies.

Prof Wout Feitz (ERN eUROGEN Coordinator), Michelle Battye (ERN eUROGEN Programme Manager) and Dalia Aminoff (ERN eUROGEN ePAG, ARM-Net) were all members of the Rare 2030 Panel of Experts. They attended several virtual meetings of the Rare 2030 "Panel of Experts", along with many other stakeholders to validate the trends and drivers that were identified, ranked, and prioritized throughout the year to define possible future trends important for rare diseases. They also contributing comments ensuring that highly specialised surgery was included, along with other important treatment options for patients with rare diseases and complex conditions.

World Health Organisation (WHO) Collaborative Global Network for Rare Diseases (CGN4RD)

Michelle Battye, ERN eUROGEN Programme Manager, is a member of the Panel of Experts.

COORDINATION WITH EUROPEAN SUPPORTING PARTNERS

ERN eUROGEN aims to collaborate as actively as possible with the major scientific societies. One of the strengths of the network is that it brings together paediatric and adult surgeons, facilitating highly specialised care of patients from birth to end of life. The strategic objectives of the scientific societies align with those of ERN eUROGEN, with such organisations able to work together in collaboration to focus on the rare and complex. Furthermore, the added communication and dissemination capabilities of the scientific societies are very important for spreading the message about the services offered by the ERNs to healthcare professionals, patients, and the public in general.

Supporting partner agreements have been signed with the following organisations ([more information on our website](#)):

- **European Association of Urology (EAU)**
- **European Society for Paediatric Urology (ESPU)**
- **Ano-Rectal Malformations Network (ARM Net)**
- **The International Society for the Study of BPS (ESSIC)**
- **The European Paediatric Surgeons' Association (EUPSA)**

To progress collaboration on areas of strategic interest, regular meetings take place with ERN eUROGEN and these Supporting Partners. [The minutes of the meetings are on the ERN eUROGEN section of the ECP.](#)

To intensify collaboration between the ePAGs of ERN eUROGEN and the EAU, one of eUROGEN's patient representatives (Serena Bartezzi) is now also a member of the EAU's ePAG. ERN eUROGEN welcomed three new patient representatives for penile cancer to our ePAG ([see all ePAG representatives on our website](#)) during early 2021. They are also members of the EAU guidelines panel on penile cancer, working on the development of new clinical guidelines.

Collaboration with EAU on EC public consultations

The creation of a European Health Data Space (EHDS) is one of the priorities of the EC 2019-2025. A common EHDS will promote better exchange and access to different types of health data. It will not only support healthcare delivery but also health research and health policymaking. The 24 ERN registries are likely to be building blocks of the EHDS and could be used as connection test cases. The EC held a public consultation on the EHDS and ERN eUROGEN worked with the European Association of Urology to develop a response. This joined up strategic approach will continue in the future.

The European Medicines Agency (EMA) has published its draft Guideline on Registry based studies. The new draft guidance aims to optimise the use of registry-based studies as a source of real-world evidence and address methodological, legal and operational aspects in the use of such studies to support regulatory decision-making. This has relevance for the 24 ERN registries including ERN eUROGEN's own registry. Therefore, the network worked with the European Association of Urology to deliver [a consultation response](#).

COORDINATION WITH ERN/EUROPEAN PATIENT ADVOCACY GROUPS (ePAGs)

Serena Bartezzati (Associazione Italiana Cistite Interstiziale) (IT) and Dalia Aminoff (Associazione Italiana Malformazioni Anorettali) (IT) delivered a report at our annual strategic meeting from the ePAGs. 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 ERN ERNICA for joint webinars with ePAG involvement, and supporting ERN eUROGEN at European conferences, workshops and meetings.

It is generally extremely difficult for parents and patients to talk about medical conditions affecting the genitourinary tract and sexual function. Therefore, it is more difficult for ERN eUROGEN to publicise patient stories. However, we have benefited from the enormous experience of the ePAG representatives in our disease areas. Patient representatives are active in the ERN eUROGEN educational webinar programme and have delivered the following four webinars with the network's clinical experts which are all available on our website:

- Pediatric Colorectal Surgery: An introduction to eUROGEN ARM Webinars - Ivo de Blaauw & Dalia Aminoff
- Bowel management for patients with anorectal malformations - June Rogers & Barbara Iacobelli
- Penile Cancer - ePAGs Rob Cornes, John Osborne, Kenny Manzie
- Hydrocolonic Sonography and self-management in patients with incontinence - tools to facilitate Bowel Management - Stefanie Märzheuser & Annette Lemli

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 and establishing a cross-ERN working group (WG) on transition, continuing to contribute to the cross-ERN WGs, continuing to raise awareness of ERNs and ePAGs at national and European level, and continuing involvement in guidelines development.

OTHER ACTIVITIES AT EUROPEAN, NATIONAL AND INTERNATIONAL LEVEL

Scientific Meetings

ERN eUROGEN participated in a total number of 5 meetings where 6 presentations have been given about the ERN to raise awareness about its activities. A full list of

presentations can be found in Annex 1. The COVID-19 pandemic resulted in an overall reduction in activity and all major scientific meetings took place online.

ERN Exchange programme

ERN eUROGEN participated in the discussions with ECORYS who coordinated and supports the ERN Mobility project on behalf of the EC. A protocol for ERN eUROGEN was developed and shared through the network. A call for candidates was launched through our newsletter communication channel and 8 responses were received and are currently further processed.

- Sponsorship

ERN eUROGEN does not receive Sponsorship.

- Project Coordination (WP 1)

The major objective of this work package is to ensure the overall effective project coordination, including organisation, management, communications and administration. The main areas of activity during this reporting period are listed below:

Coordination function of the network

Radboud University Medical centre (known as Radboudumc or RMU) in Nijmegen, the Netherlands is now the current Coordinator of ERN eUROGEN and Prof Wout Feitz is the Coordinator with legal effect from 1 April 2019. An amendment to the grant was agreed by HaDEA in May 2021 as the legal name of the coordinating institution changed after a de-merger of the Radboud University and Radboudumc.

Coordination team staff recruitment

Following the change of Coordinator from STH to Radboud University Medical Centre (RUMC), the initial plan was for the staff employed with a short term employment contract by STH (the Programme Manager and Lead IT and Data Performance Analyst posts) to be seconded to the new Coordinator (RUMC) complying with the terms of such arrangements as stipulated in the Grant Agreement. However, this posed some risks as identified by STH Human Resources and additional options were explored. The posts in question were transferred to RUMC, with effect from 1 February 2020 for the Programme Manager post and 5 November 2019 for the Lead IT and Data Performance Analyst post. The Coordination team visited RUMC 28-29 January 2020 to arrange all the practical issues with RUMC and to have meetings with Prof Feitz and other members of the Urology Department. The Business Support Manager postholder (Jen Tidman) is currently on secondment from her permanent post in STH to the Business Manager post until end of September 2021. Following that a contract will be arranged by RUMC.

Given the uncertainty with Brexit it was decided that the preferred option was for the Clinical Data Specialist post to be hosted by RUMC going forward. Prof Feitz then began recruitment procedures in RUMC and Erik Leijte (ERN eUROGEN Clinical Data Specialist) and Loes van der Zanden (ERN eUROGEN Registry Coordinator) were appointed to the Coordination Team with a start date of 1 July 2020. Erik Leijte left the team to continue his medical training in May 2021 and was replaced by Loes Oomen, who started with the team on 01/07/2021.

ERN eUROGEN has the following operational Coordination Team:

- **Coordinator (from 17 November 2018) and Workstream Leader 1 (2016 to date)** – Prof. Wout Feitz (RUMC including Radboudumc Amalia Children’s Hospital, one of the eight University Hospitals in The Netherlands).
- **Workstream Leader 2 (2016 to date)** – Prof. Margit Fisch is Fellow of the European Board of Urology (F.E.B.U.) and Fellow of the European Academy of Paediatric Urology (F.E.A.P.U.). Since 2008 she is Director and Chair of the Department of Urology and Pediatric Urology at the University Medical Center Hamburg-Eppendorf (UKE), Germany.
- **Workstream Leader 3 (April 2021 to date)** – Dr. Hans Langenhuijsen (RUMC including Radboudumc Amalia Children’s Hospital, one of the eight University Hospitals in The Netherlands). Post taken over from Prof. V. Sangar, Manchester, due to the UK exit from the EU and the change in leadership was carried out in consultation and with the agreement of all WS3 HCP experts.
- **Co-Chair of the ERNs representatives Working Group on Monitoring (2016 to date)** – Prof. Wout Feitz was unanimously appointed as Co-Chair in May 2021.
- **Programme Manager** (from 1 February 2020 with RUMC) – Michelle Battye is responsible for the management, reporting and operational aspects of the network.
- **Business Support Manager** (from 28 August 2018) – Jen Tidman is the administrative and communications lead for the network, supporting the operational running of the network and the coordination team, maintaining the ERN eUROGEN section of the ECP, as well as compiling the newsletter and running the network’s social media channels.
- **Lead IT and Data Performance Analyst** (CEF funded post - from 5 November 2019 with RUMC) – Darren Shilhan
- **Clinical Data Specialist** (CEF funded post – from 1 July 2021) – Loes Oomen
- **Registry Coordinator** (Registry grant funded post from 1 July 2020) – Loes van der Zanden

The CEF 2020 Grant Agreement was signed in July 2021 and funding will be sustained for the two posts until 31 December 2022. The ERNs are expecting a new call for proposals later in 2021 for direct grants which will run from 2022 until 2027 to ensure sustainability for the ERNs. It is expected that the funding for the previously CEF-funded posts will come from the next direct grant for the coordination and management of the ERN, as it is expected that CEF funding will be discontinued for the support of the ERN tasks and actions.

As the ERN eUROGEN direct grant came to an end on 31 May 2021, there was a certain degree of time urgency in order to arrange the contracts for the Coordination Team. DG SANTE provided Prof Feitz with a short letter in June 2021 to confirm the future funding for the network during a bridging period to bring it into the same timeline as the other 23 ERNs. This letter enabled the necessary arrangements to be made by RUMC for the ERN Coordination Team contracts. It is expected that the removal of the co-funding principle by the EC will reduce the administrative burden on the ERN coordinating HCPs.

Most HCPs involved in the network are major teaching centres and, therefore, the existing infrastructure can be used to deliver the objectives of ERN eUROGEN. Radboudumc has a dedicated EU grants office with several full-time staff who manage EC grants.

Governance

ERN eUROGEN has a network agreement which has been signed by all HCP representatives and copies of the signed agreements are saved [within the ERN](#)

[eUROGEN section of the ECP](#). ERN eUROGEN also developed an internal governance document which was enclosed with the Year 1 report. A protocol for dealing with noncompliance of HCPs was developed in 2019 and shared with the other 23 ERNs. DG SANTE adapted this document in 2020 and the ERNs were invited to provide comments. ERN eUROGEN, along with other ERNs, has developed and is implementing [our own internal non-compliance protocol](#).

The ERN eUROGEN governance documents will be reviewed by the end of 2021 with the input of the ePAGs to ensure they are up-to-date in time for the new members joining in early 2022.

Strategic Board Meeting

A Strategic Board Meeting is usually organised annually face to face. However, due to the COVID-19 pandemic, the ERN eUROGEN Strategic Board meetings were organised virtually, with attendees from the Coordination Team, Operational Board, Workstreams, Health Care Providers (HCPs) and ERN Patient Advocacy Group (ePAG), as well as the representatives from the Supporting Partner organisations and DG SANTE.

One virtual Strategic Board Meeting of the network was held during this reporting period and another shortly after: 12 June 2020 and 4 June 2021.

The 2020 programme included: updates on the 3-year plan and progress, monitoring and evaluation, CPMS, data collection and analysis, training and education, Supporting and Affiliated Partners, communications, registries and Cross ERN Actions; case studies, discussions and reports from the three workstreams; and presentations from the ePAG representatives.

The 2021 programme included: a status update, information on the management and enlargement of the network, an ePAG update, CPMS, guidelines, the ERN eUROGEN registry, the ERN Exchange programme, and the EURORDIS H-CARE proposal to the EJP RD.

The programmes, presentations, meeting reports etc., are all available [within the ERN eUROGEN section of the ECP](#).

Other meetings

As the webex tool was discontinued for regular meetings, ERN eUROGEN now uses GoToWebinar and GoToMeeting for all network meetings. Agendas and minutes are saved [within the ERN eUROGEN section of the ECP](#) so that all partners have access to all documents.

- ERN Coordinators Group meetings – the ERN eUROGEN Coordinator and Programme Manager attended virtually (due to COVID-19) for the internal CG meetings on 2 September 2020, 25 November 2020, and 10 March 2021, the full CG meetings on 10 June 2020, 27 November 2020, and 30 April 2021 and the CG brainstorming with the BoMS on 18 September 2020.
- ERN eUROGEN Coordination Team meetings – these increased in frequency to weekly (Thursdays at 13.30 CET) due to the increasing workload.
- Workstream Leads meeting – there is a bi-monthly meeting of the coordination team with the workstream leads on the first Tuesday of every other month at 18:00 CET.
- On the first Monday of each month, Workstream 1 has a meeting involving the workstream lead, Disease Area Coordinators (DACs), ePAG representatives, and at least one representative from each member HCP with disease area expertise in that workstream. This is usually followed by up to an hour of CPMS discussions. The disease areas, including new disease areas which were added prior to the call for new members in September 2019, can be found [on our](#)

[website](#). (Note: Experts from workstreams 1 and 2 discuss several patients' cases and give advice to the treating clinician via an outcome report which is automatically generated by CPMS. As workstream 2 experts deal with adult functional urogenital conditions that require highly specialised surgery, they often see the patients with congenital urogenital anomalies as they transition to adult care. Therefore, workstream 2 experts are often invited to join the workstream 1 CPMS meetings.)

- Workstream 2 quarterly meetings, involving the workstream lead, all Disease Area Coordinators (DACs), ePAG representatives, and at least one representative from each member HCP with disease area expertise in that workstream are held on the last Thursday of every quarter.
- Workstream 3 monthly meetings are held on the first Tuesday of each month involving the workstream lead, all Disease Area Coordinators (DACs), ePAG representatives, and at least one representative from each member HCP with disease area expertise in that workstream, usually followed by CPMS case discussions.
- European Association of Urology (EAU) Annual Congress – the main scientific congress in the field replaced face to face events with virtual events in 2020 and 2021. ERN eUROGEN usually has a Special Session on the ERN initiative during the EAU Congress. Unfortunately this could not take place in 2020 but there a [Special Session took place on 12 July 2021](#).
- ePAG meetings are held every two months with the ERN eUROGEN Coordinator and ERN eUROGEN Programme Manager and are chaired by EURORDIS.

- Financial management

Financial management and oversight have been provided by Radboudumc's Finance Department. Until the transfer of the grant to the new Coordinator, the finance team at STH were responsible for monitoring, reporting and overall management of the grant. This responsibility transferred to the new Coordinator, Radboudumc, with effect from 1 April 2019. Radboudumc has an EU grants team which includes project management and finance support. The team currently manages several EU grants and is very experienced in this area. The team managed the process of the grant transfer and coordination with the CEO of Radboudumc and this resulted in a smooth transfer with no operational problems identified.

EC Funding

Grant applications to the **Connecting European Facilities Fund** in 2017, 2018 and 2020 were successful and this ensured the continuation of the ERN eUROGEN Operational Helpdesk (2 posts). The CEF 2020 grant is expected to be signed in the summer 2021 and this means the two posts can be sustained until 31 December 2022. There are several benefits from funding posts held by an analyst and someone clinically trained. The clinical training is essential for customisation of the CPMS for ERN eUROGEN. There remains a need for greater awareness at national level and amongst healthcare professionals about the existence of the ERNs and how they can potentially help patients.

A grant application to set up a **registry for ERN eUROGEN** was submitted in autumn 2019 and was successful. Dr Loes van der Zanden joined the team to coordinate the registry for ERN eUROGEN and started on 1 July 2020. Please see research section below for more details.

1.2. Overview of the project results compared with the objectives of the action in line with the structure of Annex 1 to the Grant Agreement including summary of deliverables and milestones and a summary of project result. (No page limit per

work package but report shall be concise and readable. Any duplication should be avoided)

Reportable deliverables and milestones – Year 3

Deliverable No	Deliverable Title	Due date	Comments
D2	Spreadsheet on HCP activity published on ECP	36	Delivered and improved over the course of the project. The spreadsheet cannot be uploaded to the European Collaborative Platform but it can be sent upon request.
D4	Report on interactions with other ERNs	36	Delivered with final report
D8	Report on HCP activity published on ECP	36	Delivered with final report
D11	Final report including patient stories published on website and ECP	36	Delivered. Patient representatives are active in the ERN eUROGEN educational webinar programme and have delivered the following four webinars with the network's clinical experts which are all available on our website: <ul style="list-style-type: none"> - Pediatric Colorectal Surgery: An introduction to eUROGEN ARM Webinars - Ivo de Blaauw & Dalia Aminoff - Bowel management for patients with anorectal malformations - June Rogers & Barbara Iacobelli - Penile Cancer - ePAGs Rob Cornes, John Osborne, Kenny Manzie - Hydrocolonic Sonography and self-management in patients with incontinence - tools to facilitate Bowel Management - Stefanie Märzheuser & Annette Lemli
D14	Members of Guidelines group published on website	36	Delivered.
D15	Two new guidelines developed by clinicians and patients in areas where none currently exist	36	Not delivered due to circumstances outside the control of the network – COVID-19 pandemic delays. ERN methodology for guidelines became available to the ERNs January 2021 and training started in April 2021. This deliverable will be shifted to the next proposal. A small amount of the budget was used to fund translation of Dutch ARM guidelines - will follow the ERN adoption/adaption guidelines methodology. It is likely this work will start if agreed by the ERN eUROGEN Expert Panel on Guidelines which will hold the first meeting on 7 September.
D16	Final report on CPMS activity	36	Delivered with final report
D18	Report by trainee published on website/ECP	36	Not delivered due to circumstances outside the network's control. ERN Exchange programme start was delayed by COVID-19 pandemic travel restrictions. Exchange visits will take place as soon as HCPs open up again (expected Autumn 2021). The

			first call for applicants was launched in May 2021 and 8 applications have been approved by HaDEA.
D19	Papers published in scientific journals (at least 3 using eUROGEN logo)	36	Reported 3 in Y2. Delivered. All papers relating to ERN eUROGEN are on our website.
D21	Presentations saved on ECP	36	Yes Delivered.
D22	Short reports by trainees published on ECP website (staff from network's HCPs take up European School of Urology masterclasses)	36	It was not possible to organize this due to the impact of the COVID-19 pandemic

1.3. Project Results and Visibility

- Major results and key findings, their uptake and future potential use

The top priority for ERN eUROGEN is using the CPMS to conduct European MDT panel discussions to enhance learning on highly specialised surgery. It is a priority to offer advice to smaller population countries and thus fulfil the knowledge sharing objective of the ERN. For the network to be able to operate, it also remains a priority to have efficient coordination, communication, and management across the network. The results will form the basis of the activities going forward. **The network's top priority will be to upscale the use of the tools delivered by the EC.**

Enlargement of the network

ERN eUROGEN, as a highly specialised surgical network, comprised 29 healthcare providers (HCPs) in 11 Member States (MS) when it was originally set up. One of the major results has been the expansion of the network with Affiliated Partners (APs) - now including 12 Associated National Centres (ANCs) and 4 National Coordination Hubs (HUBs) that have been designated to work with ERN eUROGEN (1 ANC in Austria; 1 ANC in Latvia; 1 ANC in Croatia; 9 ANCs in Spain; HUBs in Malta, Hungary, Slovenia, and Luxembourg).

Integration of the Affiliated Partners

The 24 ERNs were required to develop a strategy to integrate the Affiliated Partners and it was agreed by the ERN Coordinators Group in June 2019 that a common approach would be beneficial. ERN eUROGEN drafted the template strategy document on behalf of the ERNs. ERN eUROGEN's strategy document and all the Bilateral agreements which specify which areas the Affiliated Partners want to work on with the ERNs are saved [within the ERN eUROGEN section of the ECP.](#)

The table below summarises the current position with the APs. Some are waiting to start their activities after they receive formal acceptance as a new member in accordance with the EU call 2019. The process of evaluating the expertise of the applicant HCPs has been delayed due to the COVID-19 pandemic.

	Member State	Center	Engaged in ERN eUROGEN Activities
Associated National	Austria (AT)	Krankenhaus der Barmherzigen Schwestern Linz	Yes
	Croatia (HR)	University Hospital Centre Sestre Milosrdnice, Zagreb	Yes

	Spain (ES)	Hospital Universitario 12 de Octubre, Barcelona	No
		Hospital Universitario Cruces, Barakaldo	No
		Hospital General Universitario Gregorio Marañón, Madrid	No
		Hospital Universitario La Paz, Madrid	Yes
		Marqués de Valdecilla University Hospital, Santander	No
		Hospital de la Santa Creu i Sant Pau y Fundació Puigvert, Barcelona	Yes
		Hospital Sant Joan de Déu, Barcelona	Yes
		Vall d'Hebron University Hospital, Barcelona	No
		Complex Public Hospital Virgen del Rocío Regional, Seville	No
		Latvia (LV)	Children's Clinical University Hospital, Riga
National Coordination Hubs (HUBs)	Hungary (HU)	Semmelweis University, Budapest	No
	Luxembourg (LU)	Centre Hospitalier de Luxembourg, Luxembourg City	No
	Malta (MT)	Mater Dei Hospital, Msida	Yes
	Slovenia (SI)	University Medical Center, Ljubljana	No

New call – September 2019

ERN eUROGEN received 31 applications to become members of the network. The call for new members to apply to the existing European Reference Networks was opened in 2019. ERN eUROGEN drafted the guidance document for the ERNs on how to conduct a peer review of the new applicants. The ERN eUROGEN evaluation team and the ePAG have been heavily involved in assessing the applicants and checking if they comply with the network specific criteria. This has taken a significant amount of time and detailed checking of every application form, including requests for further information and clarifications where the information provided on the forms was not clear. This work was completed on time. The new members are expected to join in early 2022 with the delays due to the pandemic.

Main results:

- Consolidating the network's coordination, management, and communication structures
- Expansion of the network and integrating the APs – encouraging them to join meetings and participate in network activities, including using CPMS
- Active external collaboration with other international and European organisations, scientific societies, other ERNs, and patient organisations
- Successful ERN eUROGEN registry grant application - the grant was signed and work began on 1 June 2020
- Using the Performance Management Dashboard to track the activity of the HCP members – regular discussion in monthly workstream management meetings
- Data collection, verification and reporting to the EC using the online tool
- Updating the website with new/additional information and uploading newly developed patient information (patient journeys on specific disease areas by the ePAG representatives) (ongoing). When the COVID-19 pandemic reached

Europe in March 2020, the website was updated to include [information for urology and rare diseases](#).

- [Monthly ERN eUROGEN newsletter](#) for more efficient communication with the network and other stakeholders (and to reduce volumes of email traffic)
- Educational webinar programme
- 40 of the most rare and complex urogenital patients reviewed using the CPMS from 1 June 2020 until 31 May 2021. Trainees of ERN eUROGEN experts and those from the team of the treating clinician can also participate in the panels as observers (and thereby CPMS also serves as an educational platform) and the feedback from them has been very positive. This facilitates rapid learning, secure exchange of information and knowledge transfer on surgery for rare urogenital diseases and complex conditions.
- Responded to requests for information from the Spanish consortium who will develop the methodology and training for ERNs on Clinical Practice Guidelines and Clinical Decision Support Tools.
- Agreement reached in ERN eUROGEN with ePAGs on topics for two new guidelines and five expert consensus recommendations in areas where there is less evidence available
- Discussion continuing on disease specific outcome indicators for Workstream 1 and a snapshot of current clinical practice pilot project is ongoing
- Scientific publications – knowledge sharing
- Development of the ERN Exchange programme protocol for ERN eUROGEN together with representatives from ECORYS and launch of a call for applicants in May 2021.

The most important ways ERN eUROGEN has provided EU added value are:

- Cross border knowledge transfer - networking expert surgeons together to allow for case discussion of rare urogenital diseases and complex conditions which leads to better surgical management of these rare and complex cases, therefore improving service delivery in ERN HCPs
- Improving education and training - opportunity for trainees to participate in case discussions and to watch highly specialised surgical videos uploaded to the CPMS
- Planning to develop an educational platform in 2021 (under development by DG SANTE – ERN Academy) where all network members can access educational and training materials and surgical videos
- Interaction with patient organisations involved at all levels of ERN eUROGEN in a way that has never been done before at European level – again patient input improves the quality of care and service delivery
- ERN eUROGEN ePAG member (Serena Bartezzati) became an official member of the EAU Patient Information Patient Advisory Group in 2020 to ensure strategic cooperation at European level between patient organisations
- ERN ePAG members of EAU guidelines panel on penile cancer
- HCP participation and integration of the APs will continue to be managed using the performance dashboard, which will be continually improved based on feedback - it is hoped more cases will be referred to ERN eUROGEN for advice from the smaller population countries
- Education eHealth program with specific Webinars and launch of ERN eUROGEN You Tube Channel.

- Target groups and added value

The target groups of ERN eUROGEN are:

- Healthcare providers (HCPs) and the healthcare professionals working in them (both ERN HCPs and HCPs outside the network)
- Patients and their parents or carers and patient organisations (at European and national level e.g., ARM-net)
- Scientific societies (e.g., EAU, ESPU, ESSIC, EUPSA)

- Researchers and academic and educational institutions
- Policy makers and health authorities (national health ministries, European regulators, health insurance companies)
- Industry
- General public

- Further use of the project results

The results will form the basis for activities during the bridging grant (June 2021 – February 2022). The focus will be on integrating the new members and upscaling the use of the tools provided by the EC (e.g., CPMS, the ERN eUROGEN registry, the ERN Exchange Programme etc)

- Major problems and lessons learned

Electronic Healthcare Records are still not interoperable with the clinical patient management system (CPMS) making it more time consuming to input the necessary patient information to CPMS. For example, CPMS users in some HCPs have reported problems uploading patient images in DICOM format. Learning how to use the IT tools, requests for web cameras and access to the Google Chrome web browser were all relatively minor issues, but which took considerable time for some members to be able to successfully connect to the CPMS. The time taken by different healthcare providers to complete the internal governance procedures and ethics approval to begin to use CPMS all took time, with delays experienced in some centres.

Workload volume for clinicians: it is quite time consuming in the current version of CPMS to upload all clinical data sets and medical imaging and ensuring that patient identifiable information is removed. Workaround methods have been used by ERN eUROGEN clinicians who have uploaded pdf files from PowerPoint presentations.

Currently the coordinating hospitals are investing a lot of staff member time to provide and complete all tasks requested. A more sustainable system and secure, fast, simple system with a short message option is needed for long term commitment and sustainability.

IT governance and approval from central and local data protection officers has taken more time and action than expected.

CPMS: ERN eUROGEN has provided numerous suggestions for changes and improvements to the CPMS, many of which have been implemented. It is hoped that the new "lighter" version of CPMS which will facilitate an even more rapid connection between healthcare professionals which will stimulate the use the system. CPMS has also been customised for ERN eUROGEN and it is hoped this will increase use. Feedback will be requested from the network.

- Future recommendations

- More engagement with the ERN Hospital Managers Network - support is needed for data entry at HCP level (uploading cases to CPMS and in future to the ERN eUROGEN registry)
- HCP CEOs should be aware of their responsibilities to support data collection and validation in their HCPs. It would be helpful if the CEOs of the HCPs could identify a lead contact point for data collection and communicate this to DG SANTE and the ERNs. The same contact point could sign off the validation of the patient and procedure data internally in the healthcare provider

- Development of a sustainability plan and financial reimbursement system for expert virtual consultations and time investment by ERN clinicians
- A financial reimbursement system for ePAG Representatives for time spent on ERN activities.
- Integration of ERN developments within National Rare Disease plans and Health Care Systems.
- An interaction system for meetings between the EC, HCP CEO Managers, Board of Member State representatives, ERN coordinators and health care financial system representatives
- Highly specialised surgeons face a particular challenge – training the next generation of surgeons, particularly at a time when medical leaders will retire. ERN eUROGEN would like to implement a highly specialised ERN surgical training programme (two years in more than one of the network's HCPs). In addition to gaining surgical skills, such fellows could upload cases to CPMS and the registry, and conduct ERN related research under the mentorship of the network's experts. HCPs currently do not have the capacity to fund these additional EU related activities. An ERN funded training post could also be beneficial to HCPs as they tackle the surgical backlog following the COVID-19 crisis.

- Dissemination activities during and after the project

Strategy

The [ERN eUROGEN Dissemination & Communication Strategy document](#) was finalised in October 2020 and sent out to network members with a dissemination package including an agenda/minutes template, presentation template, letterhead template, flyer and logos.

Scientific Meetings & Presentations

ERN eUROGEN participated in a total number of 5 meetings and gave 6 presentations about the ERN to raise awareness about its activities. There was a reduced number of presentations given during this reporting period due to the COVID-19 crisis and many meetings being cancelled, postponed, or decreased in scope. A full list of presentations can be found at Annex 1.

Scientific publications

The following publications have been published in the peer-reviewed literature during the current reporting period:

- Thomas A, Vanthoor J, Himmelreich U, Cawthorne C, Deroose CM, Gsell W, Spans L, Rizzotto L, Leucci E, Van Rompuy AS, Muneer A, Albersen M; European Reference Network for Rare Urogenital Diseases and Complex Conditions (eUROGEN). Establishment, Characterization, and Imaging of a First Platinum-resistant Penile Cancer Patient-derived Xenograft in Nude Mice: A eUROGEN Project. *Eur Urol.* 2020 Aug;78(2):294-296. doi: 10.1016/j.eururo.2020.05.033 [August 2020]
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Non-Scientific Publications

We have also been invited to produce articles for the European Association of Urology's monthly publication, [European Urology Today](#) which is sent out to all 15,000 of its members:

- "[ERN eUROGEN to double membership after new call for applicants](#)" p5 *European Urology Today* Vol. 32, No. 5, Oct/Dec 2020
- "[ERN eUROGEN: Late effects of Penile Cancer](#)" p6 *European Urology Today* Vol. 32, No. 5, Oct/Dec 2020
- "[The ERICA project: ERNs joining forces on research and innovation](#)" p6 *European Urology Today* Vol. 33, No. 1, Jan/Feb 2021
- "[ERN eUROGEN update](#)" p8 *European Urology Today* Vol. 33, No. 2, Mar/May 2021
- "[ERN eUROGEN: An update on rare and complex urology](#)" p28 *European Urology Today: EAU21 Congress Edition*

Book

We have signed a contract with the publisher Elsevier to produce an ERN eUROGEN book entitled "Rare and Complex Urology". Each of our disease areas will be covered by a chapter written by our Disease Area Coordinators with other co-authors from the network and ePAG. We have invited Enrique Terol to provide a foreword from the EC' as well as the Secretary General of the European Association of Urology to provide a foreword about the importance of the network in the field. The final author list and table of contents will be drawn up in early 2022 once the new members have joined the network. The deadline for manuscripts is August 2022 with a view to publication in December 2022.

Newsletters

The ERN eUROGEN e-newsletter is proving popular to keep the network and stakeholders updated with regular news, and it is hoped this reduces the volume of emails. 11 editions were issued during the reporting period and can be found [on our website](#). We use [MailChimp](#) to disseminate these, access to which is kindly provided by our supporting partner, the European Association of Urology. We have 188 subscribers to this mailing list. We also send out e-alerts about our webinar programme using MailChimp. We have 1,051 subscribers to this mailing list. The figure is higher for this list as registrants for the webinars are automatically added to the list unless they opt out, whereas all subscribers for our main newsletter have had to actively opt in.

Social Media

We have active social media profiles on [Facebook](#), [Instagram](#), [LinkedIn](#) and [Twitter](#). We also have a [YouTube](#) channel on which we publish recordings of our webinar series. As of 31/05/2021, the number of followers/subscribers for each of these channels was as follows:

- Facebook: 71
- Instagram: 219
- LinkedIn: 44
- Twitter: 673

- YouTube: 182

We use the graphic design platform [Canva](#) to make our communications look professional, eye-catching, and engaging.

- Project website

Website

ERN eUROGEN's website is fully operational: <http://eurogen-ern.eu>

A review of the website statistics show there were 24,593 page views in the period from 1 June 2020 until 31 May 2021 (this reporting period). Since it was launched the ERN eUROGEN website has received 64,383 hits.

The website is frequently reviewed and updated and contains a dedicated section for patients and parents/carers. A review of content took place in early 2020, learning lessons from the websites of other ERNs as how best to present information and enable access for visitors.

1.4. Overview of the evaluation activities and results

- Participant or partner feedback

Currently, the participants of the Strategic Board meetings have given positive feedback.

- Process, output, and outcome evaluation – Please use indicators specified in Annex 1 to the Grant Agreement)

Evaluation strategy

It was planned to evaluate each of the outcomes according to how they address the following six EU objectives in Article 12 of the 2011 EU Directive at the end of the three-year proposal. The ERN eUROGEN Coordinator, Workstream Leaders, Centre Manager and ePAG representatives will have an evaluation meeting organised by GoToMeeting, where all will discuss and score the outcomes against the six EU objectives. To assess the level of achievement, a questionnaire will also be sent to the network - all HCP members, APs and ePAG Representatives - to assess their view of the achievements of ERN eUROGEN. The results will be assimilated, and the results of the evaluation will be included in the final report.

- a) to help realise the potential of EU cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies.
- b) to facilitate improvements in diagnosis and delivery of high-quality, accessible, and cost-effective healthcare for patients with medical conditions requiring a particular concentration of expertise in medical domains where expertise is rare.
- c) to reinforce research, epidemiological surveillance/registries, and train health professionals.
- d) to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge, and best practice, and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks.
- e) to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network.
- f) to help those Member States with an insufficient number of patients with a particular medical condition, or lacking technology or expertise, to provide highly specialised services of high quality.

Each specific objective is numbered with a WP number and objective number according to the objectives in the work packages. The deliverables for these objectives are outlined above. The relevant EU objectives addressed are noted for each outcome (a-f). We will score each outcome according to whether it has addressed the priorities intended. Please see listed below the specific objectives with lines added to show how targets have been met during this reporting period (Y1).

Objective WP1.1	Set up and run an active, patient centred ERN
Process Indicator	The ERN has a functioning ePAG
Output Indicator	Regular meetings take place between the ePAG representatives and the Coordinator and Programme Manager (twice monthly meetings) supported by EURORDIS. ePAG representatives now join the monthly workstream meetings with the clinical experts. Additional ad hoc virtual meetings are organised as required. At least 2 ePAG representatives appointed in M1. At the end of M36 ERN eUROGEN is actively collaborating with nine patient organisations: https://eurogen-ern.eu/for-patients/patient-groups/
Outcome/impact	At least two lay/patient members are actively involved in WPs and Board. Number of patient representatives increased over the period of the grant. Two ePAG representatives have votes on the ERN eUROGEN Strategic Board. At end of M36, the ePAGs have: Provided vital input on updating the ARM Orphanet classification system with ERN eUROGEN and ERN ERNICA experts. developed common needs and patient journeys on Bladder Exstrophy, Interstitial cystitis and Anorectal malformations and they are available on the website: <ul style="list-style-type: none"> • https://eurogen-ern.eu/for-patients/patient-common-needs • https://eurogen-ern.eu/bladder-exstrophy/ • https://eurogen-ern.eu/ano-uro-rectal-malformations/ • https://eurogen-ern.eu/for-patients/workstream-2/interstitial-cystitis/
Outcome at Y3	ePAG functioning and expanded. In this period, the representation increased from seven members at the end of Y2 to nine members at the end of Y3. One representing a European umbrella patient organisation –ARM-Net. Two ePAG members on the ERN eUROGEN Strategic Board. One ePAG member appointed as official liaison with the EAU Patient Information Group. Regular twice-monthly meetings with EURORDIS and ERN eUROGEN Coordinator and Programme Manager. ePAG members attend workstream monthly meetings with clinical teams. Five ePAG members attended the annual Strategic Board meeting in June 2021 and a presentation was given to all participants. ePAG invited to draft terms of reference for ePAG engagement with the network and publish on the website, consider publication based on common needs; encourage ePAG participation in guidelines development; continue to present patient voices within network and other meetings and disseminate information to the patient community.
Objective WP1.2	Design and implement an ERN Dashboard and disseminate data
Process Indicator	Dashboard design and active data collection.
Output indicator	Dashboard available for inspection in M6, Regular

	analysis/dissemination of returned data
Outcome/impact	100% healthcare providers providing patient/procedure data by disease area.
Outcome at Y3	<p>The performance dashboard has been regularly updated to take account of additional data available to us, as well as being continuously improved based on feedback from the clinicians. It remains a regular item for discussion at the workstream monthly management meetings, identifying issues with engagement in a number of HCPs which the Coordination Team have taken steps to address. It is a very effective tool to manage engagement of the HCPs. It has been shared with the ERN Working Group on Monitoring who shared it as an example of best practice with the ERN Coordinators Group. (Four ERNs have an internal monitoring tool).</p> <p>Alongside this, almost all HCPs in the network are now providing data on both patient numbers (existing and new) and procedures in their HCPs by 6 month and at a full year timepoint for each disease area of expertise. Where there have been local issues, the Coordination Team has engaged with the HCP in question to identify the problem and gain assurances that the data will be provided in future data collections.</p> <p>The Coordination Team continue to develop methods to validate the data going forward, both within eUROGEN and for all ERNs via the Monitoring Working Group. An example of the former is the paper written by ERN eUROGEN which included an analysis of patient numbers provided by HCPs compared to those stated on their original application forms.</p>
Objective WP1.3	Establish formal interfaces with other networks
Process Indicator	Process for interactions with other networks established
Output Indicator	Contacts have been actively made with other networks. Target to have eUROGEN members on disease area or thematic groups of two other ERNs by M36.
Outcome/Impact	eUROGEN actively working with at least 2 other ERNs by M36
Outcome at Y3	<p>Achieved by Y1 and further intensified in Y2 and Y3.</p> <p>Working actively with five ERNs. Joint meetings held with ERN ERNICA and a series of special webinars with ARM-Net on ARMs to form part of the ERN eUROGEN webinar series are being delivered. Will work together to discuss relevant cases on CPMS that require the expertise of both ERNs. Worked actively with Orphanet on disease classification and coding of ARMs.</p> <p>Joint working group established with ERN ITHACA on spina bifida (plan to review guidelines and review the Orphanet disease area definitions and coding).</p> <p>Working with ERN ERKNET on reviewing the Orphanet disease area definitions and coding. Joint publication on the results of the collaboration is being written with expected publication in autumn 2021.</p> <p>Links established for joint working with ERN EndoERN and ERN EURACAN (joint panel discussion on CPMS which require the input of both ERNs to decide the optimal treatment for these patients).</p> <p>Working with ERN TransplantChild on paediatric renal transplants.</p>
Objective WP2.1	Establish clear dissemination channels using IT
Process indicator	ERN members and patient representatives are communicating with each other easily.
Output indicator	Functioning website with navigable links and using WebEx or

	teleconferencing by M6.
Outcome/Impact	Number of website hits. Number WebEx meetings or teleconferences
Outcome at Y3	Achieved. Newsletter has been improved based on feedback and the website is continually updated and new content added. Functioning newsletter and website. 24,593 page views of the website (1 June 2020 to 31 May 2021). Regular meetings take place for internal and external communication and dissemination using GoToMeeting after the EC discontinued support for WebEx. GoToWebinar is used for the ERN eUROGEN educational webinars.
Objective WP 2.2	Collate core list of patient information and resource needs
Process indicator	Patients have identified resources they need to access through the website.
Output indicator	Ability to access desired resources through the website or through links. Patient Information available on the website by M24
Outcome/Impact	Number of resources downloaded from the website
Outcome at Y3	Patient section on the website. ePAG representatives have provided patient information for inclusion on the ERN eUROGEN website.
Objective WP2.3	Disseminate outcomes of the ERN's activities
Process indicator	Experience of the ERN, its successes and limitations is being shared
Output indicator	Analysis of outcome measures of ERN shared via website/publication/presented
Outcome/Impact	At least one publication concerning the outcome data of the ERN by M36
Outcome at Y3	Too early – awaiting ERN eUROGEN registry to go live
Objective WP3.1	Identify robust outcome measures for ERN activities
Process indicator	Activities to decide on outcome measures are being undertaken
Output indicator	Scoping exercise with patients, parents and professionals undertaken
Outcome/Impact	List of outcome measures. Incorporation into monitoring dashboard
Outcome at Y3	Outcome measure agreed at eUROGEN's annual Strategic Board meeting in June 2019 for Workstreams 2 and 3. Further work ongoing to define outcome measures for Workstream 1 (more complex for paediatric area). Pilot project to collect a snapshot of current clinical practice is ongoing where data is being collected on the last 30 patients of each disease area in Workstream 1 for further analysis. Participation in EURORDIS Pilot H-Care project for the validation of questionnaire on patient experience of care has resulted in a new project application to EJP-RD for a specific questionnaire and validation in different languages.
Objective WP3.2	Ensure activities encompass a wide geography and range of HCPs
Process indicator	Activities are engaging participants from throughout the EU and often further
Output indicator	New and Affiliated Partners appointed by Board of Member States for ERNs by M24.
Outcome/Impact	Number of EU member states participating. Percentage classed as low population.
Outcome at Y3	Achieved as Member States have designated APs, ERN eUROGEN

	expanding geographical coverage to: Austria – 1; Latvia - 1; Spain – 9; Croatia – 1 and 4 national coordination hubs, Hungary, Luxembourg, Malta and Slovenia. Signed bilateral agreements with 15 out of 16 Affiliated Partners (the final partner sent a photo of their signed agreement and despite chasing have not provided a legally acceptable scan of the document. However, they have not applied for full membership and other HCPs from their country have, so their affiliated partnership will cease when the new members join.) Due to the UK's exit from the EU, UK HCPs no longer met the legal criteria for ERN membership from 1 January 2021.
Objective WP3.3	Demonstrate key ERN outcomes
Process indicator	Ongoing analysis of how ERN is performing and progress towards goals
Output indicator	Objective evidence of value of ERN or difficulties experienced via questionnaire to all HCPs and patient organisations, results available in M36.
Outcome/Impact	Proportion of deliverables met. Identification of good and poor outcomes
Outcome at Y3	Out of a total of 11 deliverables year 3, it was not possible to deliver 3 of them during the project time period due to circumstances outside the network's control (please see page 20 of this report for more details). They will be delivered in future proposals.
Objective WP4.1	Define rare disorders where guideline exists and those where one needed
Process indicator	Literature/database searches and patient/lay group consultation completed
Output indicator	Directory of existing guidelines and list of conditions with need for these by M24
Outcome/Impact	No. of existing guidelines identified. No. of guidelines needed ascertained
Outcome at Y3	Scoping work done to identify where guidelines exist and where there are knowledge gaps. To avoid duplication of effort, work related to guidelines will begin with the Spanish Consortium once they have defined the methodology to be used by the ERNs. ERN eUROGEN topics for CPGs and CDSTs was sent to the consortium in early 2020. ERN eUROGEN Expert panel on guidelines set up in May 2021 in accordance with the guidance from the Spanish consortium and members from the network volunteered for training. Coordination activities with our Supporting Partners EAU and their Guideline Office, ESPU and EUPSA have been undertaken to prevent duplication and participation in the ERN eUROGEN expert panel have been agreed upon.
Objective WP4.2	Determine which existing guidelines conform to AGREEII
Process indicator	Define process of evaluating guideline quality
Output indicator	Personnel have been trained to evaluate guidelines and are undertaking this
Outcome/Impact	Number of personnel trained. Number of guidelines evaluated.
Outcome Y3	14 ERN eUROGEN members volunteered for training (13 basic-intermediate and 1 advanced level) which was provided by the consortium during June/July 2021.
Objective WP4.3	Increase use of existing guidelines that are high quality
Process indicator	Target population for dissemination of high-quality guidelines ascertained
Output indicator	List and how to access made available on website or links

Outcome/Impact	Number of members of Working Group on guidelines that have been trained.
Outcome Y3	15 ERN eUROGEN members volunteered to do the guidelines training.
Objective WP 4.4	Achieve robust methodology for guideline development for a rare disease
Process indicator	Development of a formal process for high quality guideline development
Output indicator	Process has been piloted and found to be feasible and robust
Outcome/Impact	Number of new guidelines developed using this method
Outcome Y3	This has been delivered by the Spanish consortium for all 24 ERNs at the beginning of 2021 and has been distributed to all network HCPs contacts and our Supporting Partners by the coordinating team.
Objective WP 5.1	Use CPMS to review patients' cases
Process indicator	Work with all HCPs to ensure they can use CPMS effectively
Output indicator	CPMS has been used to jointly review cases
Outcome/Impact	At least 288 patients reviewed using CPMS by M36 (internal target set at beginning on ERN when there was no way of predicting how long it would take to connect to and train staff on CPMS).
Outcome at Y3	From 1 June 2020 until 31 May 2021 ERN eUROGEN conducted 40 panel reviews using CPMS, monitored using DG SANTE's CPMS monthly status reports and performance dashboard.
Objective WP 6.1	Collaborate to add value to research currently being undertaken
Process indicator	Research collaborations have been established
Output indicator	Directory of research studies compiled and published on website
Outcome/Impact	At least 70% of HCPs involved in collaborative research within the ERN by M36
Outcome Y3	eUROGEN HCPs members participating in research: AGORA research: an invitation to participate in a study on obstructive uropathy has been sent to all HCPs and currently protocols are being further developed. All 24 ERNs involved in successful CSA ERICA grant application Successful EC application to set up a registry EJP proposal to create a validate scale to measure patient satisfaction with care given in an ERN HCP submitted by EURORDIS (ERN eUROGEN non funded partner) The ERN eUROGEN Registry has been started, platform provider contracted and pilot data sheets developed. A draft for the ERN eUROGEN Research strategy has been developed and when the new members are joining the network in 2022 a process of further actions will be undertaken.
Objective WP 6.2	Establish research priorities for patients
Process indicator	Patients/lay groups are providing input to determine research priorities
Output indicator	Patient working group on research established and results of patient survey
Outcome/Impact	At least one research study involving ERN, where ideas are from patients, by M36
Outcome Y3	Research into interstitial cystitis has been strongly advocated by the ePAG. Prof. Margit Fisch is leading collaboration for ERN eUROGEN with a national network in Germany working on IC. Supporting Partner involvement has been arranged through ESSIC representation.
Objective WP 6.3	Provide the future workforce with knowledge and skills to lead research

Process indicator	Educational tools developed to offer training for research in the field
Output indicator	Rare urogenital disease research and training placements
Outcome/impact	At least three trainees undertaking training modules or placements. At least one publication by each trainee by M36
Outcome at Y3	Two successful ERN eUROGEN applications to EJP RD research fellowships. They were unfortunately delayed due to the pandemic.
Objective WP 6.4	Use combined knowledge to further new research
Process indicator	The ERN has led to initiation of new studies and research
Output indicator	New joint studies are actively ongoing or being developed
Outcome/Impact	At least one newly initiated joint study. At least three joint publications.
Outcome at Y3	Joint research proposal into penile cancer developed. However, due to high costs of consumables and materials research cannot be done without some industry funding. Awaiting guidance on collaboration with industry from BoMS. ERN eUROGEN registry grant application was successful; the grant has been signed and work began on 1 June 2020. The registry will be very important for research into the long-term outcomes of our patients. Plan for future - do everything possible to encourage HCPs to fill the registry
Objective WP 7.1	Collate and share current education/training information
Process indicator	Process for collection of diverse education/training initiatives
Output indicator	Directory of education and training resources compiled and made accessible
Outcome/impact	Number of education activities and training tools we can inform people about
Outcome at Y3	Webinar programme operational – 23 webinars delivered in total 17 (1 June 2020 to 31 May 2021) and available on our website and YouTube Channel (when applicable and allowed). Plan for future – develop educational material for upload to the ERN Academy - new IT platform under development by DG SANTE
Objective WP 7.2	Define unmet needs for parents/professionals and co-develop materials
Process indicator	A process for getting a complete picture of unmet needs is underway
Output indicator	Training needs stratified and priorities for development of new resources
Outcome/Impact	At least three new resources developed with patient involvement by M36
Outcome at Y3	Patient common needs and patient journeys developed and available on website: <ul style="list-style-type: none"> • https://eurogen-ern.eu/for-patients/patient-common-needs • https://eurogen-ern.eu/bladder-exstrophy/ • https://eurogen-ern.eu/ano-uro-rectal-malformations/ • https://eurogen-ern.eu/for-patients/workstream-2/interstitial-cystitis/
Objective WP 7.3	Provide rapid feedback on new clinical insights
Process indicator	Feedback of important learning points from high quality meetings/workshops
Output indicator	Presentations published on website or linked
Outcome/impact	At least 30 presentations published by M36. No. of website hits
Outcome at Y3	5 presentations given at 6 meetings describing the activities of

	ERN eUROGEN
Objective WP 7.5	Enhance education and training across the wider EU
Process Indicator	Education/training resources are being made accessible to a broad audience
Output indicator	Education/training resources published on website or uploaded to CPMS (e.g., complex surgeries)
Outcome/impact	At least six educational/training resources uploaded to website or CPMS. Number of website hits increasing over time.
Outcome Y3	Feedback given to DG Sante to request customisation of CPMS to allow highly specialised surgeries to be uploaded to CPMS for training and education purposes. Work completed and two highly specialised surgeries have been uploaded to CPMS. Funded by the CEF grant, purchase of a special macroscopic videoscopes allowed detailed urological videos to be made of rare and complex surgical cases. These were uploaded in short version in CPMS. Large video files are stored at HCP level and shared with other experts using different communication channels. Upload of large video files in CPMS is currently not yet possible and with help of the EU CPMS Helpdesk and the platform provider, solutions are currently being sought. This will probably require further adaptation of the current CPMS version with a special media/video server access for use within CPMS. Currently with the availability of an upgraded system (Storz Vitom 3D) it is possible to upload short High-Definition videos that are very useful for education and training purposes. Plan for future - to investigate if surgeries can be uploaded more easily to CPMS and to a new educational platform.

1.5. Overview of the dissemination activities

- Please comment on the Strength of the dissemination activities

The [ERN eUROGEN Dissemination & Communication Strategy document](#) provides a strong outline and plan for dissemination and communication and the dissemination package provided to our members enabled them to assist with dissemination and communication.

The fact that ERN eUROGEN has signed collaboration agreements with all the relevant major scientific societies in the field is a major advantage in disseminating information. The European Association of Urology, for example, has 15,000 members worldwide; they share our social media posts, have invited us to provide content for their bimonthly newsletter European Urology Today, and give us a Special Session at their annual congress. The network will continue to build on the excellent relationships with the scientific societies in areas of mutual interest.

- Please comment on the Weaknesses of the dissemination activities

Many members comment on the low awareness about the ERNs, but it is hard to see how to improve matters without the support of the EC – e.g., large scale campaigns targeted to national health ministries and national stakeholders.

Due to the COVID-19 pandemic the network was not able to give as many presentations as usual due to many meetings being cancelled, postponed, or decreased in scope.

- (if applicable) Update of the plan for dissemination of results

We will review our Dissemination & Communication Strategy document and update it as necessary. This will be helpful to share with the new members joining in 2022, as well as providing them with an updated dissemination package.

As the COVID-19 crisis recedes we are hopeful of being able to present at more meetings, especially face-to-face meetings where we can disseminate results relating to the network.

Over the next year we aim to increase our social media presence with more regular content and interaction with others.

1.6. Objectives

- List the specific objectives for the project and describe the activities carried out during the reporting period towards the achievement of each listed objective. Provide clear and measurable details.

WORK PACKAGE 1 (MANAGEMENT) OBJECTIVES:

Set up and run an active patient centred ERN

Patient representation in the ERN eUROGEN ePAG has increased during the final year of reporting from six to nine representatives. Virtual meetings are held every two months with the ERN eUROGEN Coordinator, Programme Manager and ePAGs, and supported by EURORDIS. ePAG representatives are also invited to join workstream meetings with the clinical leads. Six ePAG representatives attended the annual Strategic Board meeting in 2020 and five in 2021, with two having voting rights on the Board.

Design and implement a performance dashboard

This was designed and warmly welcomed by the network which finds it a very useful tool. It is under continuous development when feedback is received from network users. It is used to monitor the activity of the HCPs in using CPMS and report using monthly workstream meetings to the ERN eUROGEN Coordinator, the Workstream Leads and the Disease Area Coordinators. It has been shared with the Monitoring Working Group as an example of good practice.

Establish formal interactions with other ERNs

Formal interactions have taken place with five ERNs. Please see section 1 and also Deliverable 4 - report on interactions with other ERNs for more details.

WORK PACKAGE 2 (DISSEMINATION) OBJECTIVES

Establish clear dissemination channels using IT

Regular management, ePAG, network and workstream and disease area meetings take place using [GoToMeeting](#). All information is saved within the [ERN eUROGEN section of the ECP](#). Our [website](#) is active and regularly maintained. [E-newsletters](#) are sent monthly using [MailChimp](#) to keep all the members of the network and stakeholders informed of the latest developments (including e-alerts about upcoming webinars). We also provide [content for other media sources](#) as well as having a presence on [all relevant social media platforms](#). In addition, the ERN can access the dissemination channels of the [Supporting Partners](#) and [ePAGs](#).

Improve provision of resources to patients

The [patient information section](#) of the website has been improved and developed. Where useful patient information and resources have been identified, links have been placed on the ERN eUROGEN website.

Share experience of added value of ERNs

Members of the ERN network aim to give as many presentations as possible about the activities of the ERN at major scientific congresses and meetings. They present webinars on rare and complex urogenital surgery and aim to write scientific publications together.

WORK PACKAGE 3 OBJECTIVES (EVALUATION)**Identify which methodology to use and develop some robust outcome measures for ERN activities**

Disease specific outcome measures have been identified by Workstreams 2 and 3 and further work is ongoing for Workstream 1 where this is more complex.

Ensure activities encompass wide geography and range of HCPs

Effort was made to assimilate the APs into the network as quickly as possible. Providing training on CPMS and ensuring the AP clinicians are using CPMS to upload cases from their countries and participating in panel discussions is the top priority.

Demonstrate key ERN outcomes

Network activities have been disseminated through presentations at scientific meetings and congresses and through the website and e-newsletter (see above). A publication in European Urology which is the highest impact journal for the field of urology (IF >20) presents the readers with a clear current clinical overview and future expectations and is online currently available. (Oomen et al, Eur Urol, 2021).

WORK PACKAGE 4 OBJECTIVES (GUIDELINES)**Define disease areas where guidelines exist and those where needed and explore current use.**

This work has been completed.

Apply methodology for expert guidelines development

ERN methodology available in early 2021. Furthermore, many of our clinicians have participated in guidelines panels before at national and European level; therefore, the required expertise is within the network.

Determine which guidelines conform to AGREE II principles

This will be established in collaboration with the Spanish Organisation and we are waiting for the final timeline to be agreed upon.

WORK PACKAGE 5 OBJECTIVES (DIAGNOSIS AND ADVICE)**Use CPMS to review patients' cases**

The ERNs are connected through a dedicated IT platform called the Clinical Patient Management System (CPMS). Through this platform an ERN can convene 'virtual Consultations' 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.

This is ERN eUROGEN's top priority action. 40 cases were completed during the reporting period. It is very resource intensive as it requires continuous training and support to the HCP members of staff using CPMS. Also, many healthcare professionals are not yet aware of the existence of the ERN and so referral paths into the ERN from outside the network are not yet clear for some countries.

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).
- d. All WS1 CPMS video case discussions involved cross border experts and made showed a clear added value for all experts involved in the specific case discussed. A system to collect remaining clinical questions or subjects for further guideline development is currently missing.

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.

WORK PACKAGE 6 OBJECTIVES (RESEARCH)

Collaborate to add value to research

Establish research priorities of patients

Provide the future workforce with knowledge and skills to lead research

Use combined knowledge to further research

The ERN eUROGEN Registry is currently under development by the Coordination Team and Registry Coordinator as previously described.

A draft document on ERN eUROGEN Research was developed and shared including a priority setting of specific fields of urological/surgical research in relation to the patient impact.

After the expansion of the network, an additional analysis of the collaborative research opportunities will be further developed.

1.7. Description of the activities carried per WP

- Work Package 1 - Project Coordination

Describe the activities carried out in WP1 during the reporting period giving details of the work carried out by each beneficiary involved. Describe corresponding evaluation activities and results. Describe dissemination activities and their results.

Please see above (project coordination)

- Work Package 2 - Dissemination

Please see above (dissemination)

- Work Package 3 - Evaluation

Please see above (evaluation)

- Work Package 4 – Guidelines

The EC issued a call for tender in 2018 for an organisation or consortium to work with the ERNs to produce clinical guidelines to the same high standards and with methodological rigour. It was agreed by the Board of the Network at the ERN eUROGEN Strategic Board meeting in Noordwijk on 11- 12 June 2018 that, to avoid duplication of effort and resources, a logical approach would be for intensive work on guidelines to start only once the tender had been awarded. This has now happened, and the Spanish Consortium delivered the ERN methodology for developing clinical guidelines and Clinical Decision-Making Support Tools (CDSTs) on 28 January 2021.

During the monthly workstream and Disease Area Coordinators meetings, the network has reviewed the existing guidelines for the 16 disease areas covered by ERN eUROGEN to identify what currently exists and where there are gaps. The results of this work were discussed during the three-monthly meetings with the ePAG and at the annual Strategic Board meeting in June 2018. A prioritisation exercise was carried out including the views of the ePAG and two areas for new guidelines and five areas for the development of expert consensus recommendations were provisionally agreed upon. This work was presented in the report on guidelines (deliverable 4.1) which is saved [within the ERN eUROGEN section of the ECP](#) and published [on our website](#). This was shared with the Spanish consortium.

The disease areas that were agreed upon for guidelines work in 2018 were:

- Full clinical guidelines in areas where none currently exist:
- Anorectal malformations (ARMs) - a very small portion of the budget was used for a translation of a very recent Dutch Guideline for ARM patient care (about 150 pages), into English. This English version is currently being checked by clinicians and if agreed upon will be subjected to the ERN Guideline Endorsement process in accordance with the available protocol.
 - Vesicovaginal fistulae
 -
- Clinical Decision Support Tools (CDSTs) to elaborate more specifically on disease areas which are currently a part of the more comprehensive guideline:
 - Abdominopelvic Sarcomas
 - Melanoma effecting genitourinary tract
 - Cystinuria - collaboration with ERKNet

- Bladder Exstrophy
- Groin Dissection
- Complex genital reconstructions for Congenital Adrenal Hyperplasia (CAH)

Upon the request and following the guidance developed by the Spanish Consortium an [ERN eUROGEN Expert Group on guidelines was established](#) in May 2021. All Supporting Partners were asked to appoint a representative to be part of the Expert Group. A first meeting will be arranged of the Expert Panel on guidelines in Autumn 2021. A chair and co-chair will be appointed, a prioritisation exercise will be undertaken to check that the needs remain (i.e., do any revisions need to be made to the list above) and disease specific guidelines subgroups will be appointed (according to ERN methodology).

Members:

Name	Type of Member
Dalia Aminoff	EPAG Representative
Magdalena Fossum	HCP Representative & Disease Area Coordinator
Giovanni Mosiello	HCP Representative & Disease Area Coordinator
Ernest Leva	HCP Representative
Ana Frobe	AP Representative
Marijana Jazvic	AP Representative
Barbara Daniela Iacobelli	HCP Representative
Mariangela Mancini	HCP Representative & Disease Area Coordinator
Martin Lacher	HCP Representative
Jan-Hendrik Gosemann	HCP Representative
Karin Plass	Supporting Partner - EAU
Salvatore Cascio	Supporting Partner - EUPSA
Paola Midrio	Supporting Partner - EUPSA & ARMNet
Ramnath Subramaniam	Supporting Partner –ESPU
Aurore Bouty	Supporting Partner –ESPU
Mauro Cervigni	Supporting Partner –ESSIC
Wout Feitz	ERN / Ex Officio
Michelle Battye	ERN / Ex Officio
Jen Tidman	ERN / Ex Officio

The following members of ERN eUROGEN have volunteered to follow the ERN guidelines training which started in April 2021.

Training Level	Name
Advanced	Magdalena Fossum
Basic-Intermediate	Jan-Hendrik Gosemann
Basic-Intermediate	Martin Lacher
Basic-Intermediate	Marc Miserez
Basic-Intermediate	Gundela Holmdahl
Basic-Intermediate	ARM-Net TBC
Basic-Intermediate	Tabea Schröder

Basic-Intermediate	Anne-Françoise Spinoit
Basic-Intermediate	Giovanni Mosiello
Basic-Intermediate	Rien Nijman
Basic-Intermediate	Andrzej Gołębiowski
Basic-Intermediate	Antonio Di Cesare
Basic-Intermediate	Ernesto Leva
Basic-Intermediate	Ana Bujons Tur
Basic-Intermediate	Martin Promm
Basic-Intermediate	Mariangela Mancini
Basic-Intermediate	Marten Albersen
Basic-Intermediate	Ana Frobe
Basic-Intermediate	Marijana Jazvic
Advanced	Alberto Breda
Basic-Intermediate	Marija Miletić
Basic-Intermediate	Valerie Flaum

The Spanish consortium gave a presentation of the work and expected timeline during the ERN eUROGEN annual Strategic Board meeting on 4 June 2021 to facilitate the collaboration. ERN eUROGEN has indicated to the consortium it is ready to start work on guidelines and would like to among the first five ERNs with which it will begin work in 2021. However, our ERN was not listed in the first five group and guidelines work is scheduled to begin in summer 2022.

- Work Package 5 – Diagnosis and Advice (using CPMS)

Patients report a clear preference for highly specialised urogenital care and surgery to take place in a few centres of excellence by highly trained and experienced surgeons. This centralised approach is cost effective and provides the best possible outcomes. There is now reasonable evidence that promoting the care of rare conditions in centres of excellence, using multidisciplinary teams (MDTs) improves survival and quality of life and this is particularly pertinent for all of ERN eUROGEN's rare urogenital diseases and complex conditions. This was recently highlighted for penile and testis cancer and posterior urethral stricture disease as evidenced by recent literature and guidelines. The innovative approach offered by the CPMS allows expert advice to be sent to the treating clinician wherever the patient lives. This enables technology to drive service improvement and for data to be collected. As evidence and data is lacking in particular for Workstreams 1 and 2, this will be a strength of ERN eUROGEN, to collect information about these patients in a harmonised comparable way, which will lead to better clinical care and research outcomes. It is also very helpful for expert surgeons to discuss particular surgical approaches in rare and complex cases before the surgeries take place.

The ERN eUROGEN CPMS helpdesk is staffed by two posts funded by the Connecting European Facilities Fund grant: the Clinical Data Specialist and the Lead IT and Data Performance Analyst. It has been quite a challenge to connect and train the key members of staff in the network's 29 HCPs to be able to use CPMS effectively and this activity will be ongoing as it is fundamental to achieving the objectives of the ERN. It is expected that demands on the Helpdesk will increase as the enlargement of the ERNs takes place when the Member States designate APs and also when the new full members join in 2022 and ERNs expand their geographical coverage. At the time of writing this report, there are 12 Member States that do not have a member of eUROGEN, either full or AP in their country. ERN eUROGEN can provide

advice to clinicians in these countries via guest access to CPMS upon request. However, without a clear referral pathway at national level it may be more challenging for healthcare professionals working in those countries to connect with the network.

Providing expert advice using the CPMS on diagnosis or recommendations for surgical approaches in rare or highly complex cases is **the top priority** of ERN eUROGEN. Each Workstream Lead monitors the CPMS activities of their Disease Area Coordinators (DACs) using the performance dashboard. There were originally 16 Disease Areas covered by ERN eUROGEN. 3 new disease areas (adult urogenital reconstructive surgery; surgery for transgender patients and rare renal tumour surgery) were added in 2019. All surgical procedures performed by ERN eUROGEN are highly specialised procedures. There is an internal ERN target that each DAC should ensure one case is uploaded to CPMS from their disease areas every two months which would lead to a total of 288 cases by 36m. Obviously it takes considerable time, effort and resources to identify those staff in our HCPs who wish to use CPMS, arrange training, follow up with issues and to ensure all can actively participate in CPMS panel discussions on a patient's case. From 1 June 2020 until 31 May 2021 ERN eUROGEN conducted 40 panel reviews. This is less than expected, mainly due to the impact of the COVID-19 pandemic.

As familiarity with CPMS grows amongst our users, more CPMS dedicated training is delivered and more people start actively using the CPMS as the new members are integrated into the network. The modifications proposed by DG SANTE for the future CPMS, along with the CPMS app are promising developments which are expected to increase use of CPMS over time. With the inclusion of the APs, the numbers are expected to grow more rapidly in the future. ERN eUROGEN will need the designation by the Member States of APs in countries where there is no current member to happen before it can properly start to target help at some of the low population countries (mostly in central and eastern Europe) where it is considered that ERN expert advice might add the most value.

The Coordination Team requested a robust tool to help them performance manage the activities of the HCPs in the network. Therefore, the Lead IT and Data Performance Analyst has designed and developed a performance dashboard which can monitor the HCPs allowing their activities by workstream and by individual HCP. The tool is under constant review and is saved [within the ERN eUROGEN section of the ECP](#) so all members of our network can access and use it. It is regularly adapted to take into account feedback from the network and is used at the monthly management meetings.

- Work Package 6 - Research

ERN eUROGEN Patient Numbers & Procedures

Data is being collected on numbers of new patients and surgical procedures and this was analysed for better insight. The initial results formed [a publication which was included on the HaDEA website](#).

Registry

Please see above for summary of registry activity to date.

The 24 ERN registries are also expected to drive research activity and they will be interoperable with each other due to the use of a common dataset and with CPMS. The ERN registries will be used as pilots by the EC for the European Health Data Space (EHDS) and EMA for Real Life Data (DARWIN).

The European Rare Disease Research Coordination and Support Action consortium (ERICA)

This successful EC CSA application (involving all 24 ERNs) will aim to harness the research potential of the ERNs.

EJP RD

A proposal was submitted by EURORDIS and some ERNs to the EJP RD, including ERN eUROGEN as a non-funded partner. The outcome of the evaluation is not yet known.

Obstructive Uropathy

Some of the network's HCPs are participating in a research study on obstructive uropathy (AGORA).

- Work Package 7 – Teaching and Training ...

A list of high-quality meetings is published [on our website](#) which will be useful for healthcare professionals wanting to know more about rare urogenital diseases and complex conditions. (Deliverable 7.3).

ERN eUROGEN Educational Webinar Programme

Although this activity was not originally included in the direct grant proposal, after consultation with the ePAGs, the Coordination Team decided that delivering an ERN eUROGEN educational webinar programme would be a more useful activity for the network than a Directory of Education and Training resources. The Workstream Leads considered that the scientific societies offered excellent training and the ERN would try to align activities with those delivered by the scientific societies (e.g., EAU ESPU and EUPSA) which are well known amongst the urogenital scientific community. Therefore, the deliverable D17 was changed to "develop webinar programme" during the grant amendment to change the Coordinator of ERN eUROGEN.

The ERN eUROGEN educational webinar programme started in 2019 and 17 webinars were delivered by eUROGEN experts during this reporting period and a total of 23 since the programme began. Some of the webinars have been produced with the Supporting Partners of the ERN which fosters collaboration and reaches a wider potential audience and the webinars are disseminated through various networks and communication channels of our Supporting Partners. For example, ERN ERNICA, ERN eUROGEN and EUPSA are collaborating on an additional 25 webinars aimed at healthcare professionals and patients on anorectal malformations. A list of the webinars can be found [on our website](#). An evaluation form is sent after each event to all participants and feedback is acted on to continuously improve the webinars.

When the ERN Academy, the educational platform under development by DG SANTE for all 24 ERNs is available (expected 2021), ERN eUROGEN will upload all webinars and other education and training material there so it can be more easily accessed.

Live highly complex surgeries

Following a successful proposal to the Connecting European Facilities Fund, ERN eUROGEN has secured funding to purchase one specialist high resolution camera and rent a second one which can be used in operating rooms to video expert surgeons performing highly complex surgeries on patients with rare or very complex urogenital conditions, where the expertise is rare. As many of the HCPs in our networks are large teaching and referral centres at national and regional levels, the surgeons in the network do large volumes of these complex procedures. These videos have been used to test the current CPMS system and it was shown that additional technical support and developments are needed (video-server) in order to upload complex surgical procedures from the beginning to the end of the procedures

(length of about 4-6 hours). It is possible to upload short snapshots only at this moment. Additional educational informed consent is requested from parents/caretakers or patients to use the videos for specific educational purposes on surgical procedures.

The original intention was to upload the surgical videos to CPMS. However, with full informed consent from patients, videos will be securely uploaded to the new ERN Academy, possibly in a closed area, for training and educational purposes and where they can be viewed by all in the network. This is considered to be easier to implement than in CPMS. The Coordination Team has engaged with the EC's CPMS Helpdesk to ensure any modifications to CPMS to accommodate the uploading of very large files (surgical videos) were made. Very short surgical videos can now be viewed successfully on CPMS and a feature was added at the network's request, to allow the person viewing the videos to scroll through the video so they can quickly find the relevant part(s) (the videos can be several hours long in the future).

ERN eUROGEN Clinical Exchange Programme

This is a short-term exchange allowing clinicians in the network to visit HCPs in the network to transfer clinical knowledge over the course of 1-2 week(s), funded by the EC. ePAG representatives can also travel if relevant to the ERN. Currently 34 weeks of funding are available to the network. Our programme was launched in our April 2021 newsletter with a deadline of 17 May 2021 for the first applications. A total of 8 applications have been received and approved by the network and HaDEA. Planning for the visits is taking place so that they can be implemented once the COVID situation allows for travel once again. The main aim of the visits is knowledge exchange and fostering collaboration across borders. A second call for applications will be launched in September 2021.

1.8. Follow-up of recommendations and comments from previous review(s)

This is not applicable. ERN eUROGEN has not received any comments from previous reviews.

1.9. Deviations from Annex 1

Explain the reasons for deviations from Annex 1, the consequences and the proposed corrective actions

Explanations for tasks not fully implemented, critical objectives not fully achieved and/or not being on schedule. Explain also the impact on other tasks on the available resources and the planning

From internal performance monitoring and the data collection exercise for cross-ERN monitoring, it was identified that one HCP was not responding to requests or participating in CPMS. Therefore, the non-compliance process was implemented.

Use of resources in Annex 1 (Description of the Action), especially related to person-months per work package.

The person-months have been attributed broadly in line with the Grant Agreement and there are no major deviations to report.

1.10. Reasons for deviations from Annex 1

1.10.1. Implementation related deviations

- Explain the reasons for deviations from Annex 1, the consequences and the proposed corrective actions
- Explain **tasks not fully implemented**, critical objectives not fully achieved and/or not being on schedule. Explain also the impact on other tasks on the available resources and the planning.

ERN eUROGEN agreed an internal target that each Disease Area Coordinator should try to ensure one case is uploaded to CPMS every two months. 16 disease areas x 6 = 96 (annual target) x 3 = 288. 40 cases were reviewed by ERN eUROGEN during this reporting period. This is below what was expected due to the COVID-19 pandemic. A total number of 152 cases have been reviewed by ERN eUROGEN since CPMS went live.

It took considerably longer to solve IT issues and train HCP members than expected. Also, there were very low numbers of referrals into the ERN from outside the network as there is **very low awareness of the ERNs and what they can do**. This is still the case and remains the critical issue, in our view.

CPMS use is expected to increase as the ERN expands geographically with the integration of the new members in 2022. The Joint Action on integration of ERNs into Member States healthcare systems which is expected to be launched in 2022 is also expected to increase referrals to the ERNs. **Member States need to integrate the ERNs into their national healthcare systems and provide clear information about how patients can be referred to ERNs in the various countries.**

Some of the new APs have become active members of the network, attending meetings and participating in CPMS discussions. The same approach will be taken with the new members when they join in early 2022. It is hoped this will increase CPMS activity going forward.

- Explain **deviations of the use of resources** between actual and planned use of resources in Annex 1 (Description of the Action), especially related to person-months **per work package**.

There were no major deviations.

- Please describe changes to the original planning, their reasoning, which problems occurred and how did you solve them?

1.10.2. Unforeseen subcontracting

Specify in this section:

- a) the work (the tasks) performed by a subcontractor which may cover only a limited part of the action

There was no unforeseen subcontracting. A very small portion of the budget was used for a professional organisation, for the translation of a very recent Dutch Guideline for ARM patient care (about 150 pages), into English. This English version is currently being checked by clinical experts and if agreed upon can be subjected to the ERN Guideline Endorsement process in accordance with the available protocol.

b) explanation of the circumstances which caused the need for a subcontract, taking into account the specific characteristics of the action

Not applicable except the translation costs.

c) the confirmation that the subcontractor has been selected ensuring the best value for money or, if appropriate, the lowest price and avoiding any conflict of interests.

Not applicable except for the translation costs. A quick response and expertise in translating complex medical documents was required and a very reasonable price for the amount of work involved was offered, so approval was given.

2. FURTHER REMARKS

- Please state further remarks that you find noteworthy

None.

ANNEXES**Annex 1 – Presentations**

2020	Nov	Hans Langenhuijs en	NL-Radboud	adrenal surgery	Webinar for Dutch association of urological nurses, scrub nurses and nurse specialists
	02-Dec	Wout Feitz	NL-Radboud	ERN eUROGEN	Amalia Children's Academic Session, RUMC
	11-12 Dec	Erik Leijte	NL-Radboud	CPMS eUROGEN	Paediatric colorectal course
2021	15-Feb	Dalia Aminoff	ePAG	National sharing of good practices in ERNs	Italian event: National sharing of good practices in European Reference Networks
		Giovanni Mosiello	IT-Rome BG	National sharing of good practices in ERNs	
	17-Feb	Wout Feitz	NL-Radboud	COMPETITION OR COLLABORATION What is the best for The Future? > EU4Health	EPBU Meeting