

Project name:
ERN eUROGEN

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

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ERN eUROGEN is a European Reference Network (ERN) approved by the ERN Board of Member States (BoMS). For more information about the ERNs and the EU health strategy, please [click here](#). The ERNs are funded by the European Union. The views and opinions expressed are those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor HaDEA can be held responsible for them.

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A. BACKGROUND

1. ERN eUROGEN took the decision not to implement a Quality Improvement Group (QIG) or associated improvement plan in M3, but instead waited until after the 5-year ERN evaluation had largely been completed. We believed that this would more clearly drive out the areas in need of improvement going forward.
2. Furthermore, much of our resource that would have been dedicated to enacting any plan was instead used to support our HCPs through the 5-year evaluation process itself from Month 7 of the grant period.
3. However, certain pieces of work to improve processes and deliverables, such as the webinar surveys detailed below, were taken forward across the period of the grant. We are now looking forward to implement further improvements via the QIG.

B. DEVELOPMENT OF THE GROUP

4. The ERN eUROGEN Quality Improvement Group was instituted on 4 July 2023 with the following membership:
 - Wout Feitz (ERN eUROGEN Coordinator)
 - Michelle Battye (ERN eUROGEN Programme Manager)
 - Jen Tidman (ERN eUROGEN Business Manager)
 - Darren Shilhan (ERN eUROGEN Performance & Data Manager)
 - Loes Oomen (ERN eUROGEN Clinical Data Specialist)
 - Dalia Aminoff (ERN EUROGEN ePAG Representative)

- Serena Bartezzi (ERN EUROGEN ePAG Representative)
 - Kate Tyler (ERN EUROGEN ePAG Representative)
5. The network is working to secure HCP representation on the group going forward but due to the high demands on time already made by ERN eUROGEN activities for our HCPs, there was a lack of volunteers to join another group.
 6. The group will meet 2-3 times per year, and a initial meeting was held at the recent Strategic Board Meeting, where the terms of reference for the group were signed off.

C. OVERVIEW OF EVIDENCE

7. Evaluation of the following areas have taken place over the grant period:
 - The ERN eUROGEN Webinar series
8. Additional evidence is also now available from the following sources:
 - The results of the 5-year evaluation from the Independent Evaluation Body (IEB)
 - HCP comments in the Self-Evaluation forms submitted for the 5-Year Evaluation
 - A network survey, including a SWOT analysis, carried out in August 2023

D. EVALUATION OF WEBINARS

9. Monitoring the quality of the webinars is done on a twofold basis. The first is via a regular questionnaire at the end of every session that is sent to all live attendees. The results of these, as shown in **Annex A**, demonstrate small improvements across most of our measures over time.
10. The only measure that does not show a year-on-year increase is that for the sound. This is probably due to the increased number of pre-recordings that were done in 2022. Where these were done by the individual themselves, the level of the audio could vary. We have now put procedures in place to ensure that low audio volumes are boosted before being used in a webinar session.
11. We also undertake an annual survey for our webinars, which is sent to all of those on our registration list. The most recent iteration of this was in November 2022.
12. The highlights of this report were that:
 - Over 90% of respondents rated the quality of the webinars as either good or very good.
 - 90% of respondents thought the length of the webinars (mean of 52 minutes) was good.
13. This survey will be run again in November 2023.

E. EVIDENCE FROM THE 5-YEAR EVALUATION

14. The initial version of the ERN eUROGEN Quality Improvement Plan (QuIP) has been developed from the sources described in Section A above.
15. The starting point for the plan was the 5-Year Evaluation and the results of the assessment for the Network from the IEB. This feedback can be found in **Annex B**. In summary, whilst ERN eUROGEN received a satisfactory rating overall, the recommendations for further improvement were:
 - The clinical guidelines that are still in preparation and marked the lowest of all evaluated elements.
 - The online interview with patient representatives revealed only marginal cooperation between three major working streams formed within the network.
 - Both the periodic report and the discussion with patient representatives show discrepancies between individual members and countries, which is reflected in an uneven level of care for patients. The situation is mostly influenced by national health care systems, but it might be an impulse for the ERN for further improvement.

- The evaluation report shows some gaps in cross-border care and different levels of care among all centres. While it is difficult to influence these facts on the level of the whole network, it leaves some space for improvement.
 - The ERN should create a pool of measures to monitor clinical processes, performance or outcomes of care among its members. Whilst in preparation, such indicators are not yet functioning and may help to balance the levels of participating centres.
16. Secondly, we have the comments provided during the evaluation in the HCP self-assessment forms, where they were asked to detail what aspects have hindered their participation in the Network or have prevented a more active participation. This feedback can be found in **Annex C**. In summary, the main issues were:
- Existing clinical, research, and education obligations prevent many clinicians from being able to support the network further.
 - Budget constraints also prevent the hiring of additional staff to deal with the administrative burden of being part of the network, particularly as there is no remuneration for any activities carried out for ERN eUROGEN.
 - Most of the monthly workstream web meetings were not attended because of the scheduled time overlapping with important clinical activities (although minutes of the meeting were regularly monitored).
 - It is very difficult to motivate staff and it is very difficult to prove working hours to the Hospital's administration.
 - Another major issue is a huge rise in administrative work after entering the ERNs (reports, monitoring, assessment, evaluation, National designation and ERN application procedures, etc.). Highly specialized experts are keen to engage in clinical work, research and education/training in which they are experts, but they are highly reluctant to undertake burdensome administrative and bureaucratic work that is not within their expertise. Moreover, there is a constant change of these procedures from both EU and national authorities' side that impose additional challenges and dissatisfaction.
 - There have been difficulties in the development of teaching materials for colleagues, in organizing meetings in the disease area, as well as in the setting up of studies and obtaining grants in this field.
 - When communicating things about the ERN, it is hard for us to understand the administrative language used.

F. EVIDENCE FROM NETWORK SURVEY

17. In addition to this, we have gathered feedback via a network-wide survey that was issued in August 2023. This asked respondents to score the progress and development of the network across a range of areas of its work, as well as including a SWOT analysis to gather their opinions regarding the **Strengths** and **Weaknesses** of the network, along with the **Opportunities** and **Threats** for it going forward. The full results and comments are provided in **Annex D**.
18. In summary, the survey results showed that our network members feel we need to do more work in the areas of:
- Building a European-wide infrastructure for rare urogenital diseases and complex conditions.
 - Usage of the Clinical Patient Management System
 - Working in partnership with patient representatives.
 - Publications (e.g. scientific papers, supplements, etc.)
 - Clinical Practice Guidelines and clinical decision-making tools.
 - The development of patient pathways
19. In terms of the network's strengths, they identified:
- Networking
 - Strong organization and communication among network members, and the linkage of professional expertise
 - A solid organization to raise awareness of rare diseases, support improvement of treatment of rare urological conditions, including discussing and standardizing approach strategies for rare diseases, and making the best possible care available to patients.
20. In terms of the network's weaknesses, they identified:
- Lack of time and financial resources
 - Too much bureaucracy and complexity; too slow; too many emails

- Some communication difficulties - there should be translation.
- Representation is unevenly distributed across countries (some have a broad representation, some very limited), and we have not yet achieved full EU coverage
- Different health care system between European nations
- Trying to invent the wheel

21. In terms of the opportunities, they identified:

- Guidelines development based on the eUROGEN Registry data
- Closer collaboration between centres
- Harmonisation of the treatment better results for the patients, objective evaluation of the outcomes
- Enhancing support at all levels of national institutions

22. In terms of threats or hindrances, they identified:

- Lack of financial support
- Limited time and manpower in HCPs
- Too many groups working together and losing the overview - growing too much will paralyse the network
- If representation is not broadened, the perspective may become too narrow and not applicable to all European countries
- Resistance to national implementation
- Too much information - rules and procedures are sometimes rather time consuming for a clinicians
- High effort, but little direct reward for participants
- The neglect of its members

23. The full responses can be found in **Annex D**.

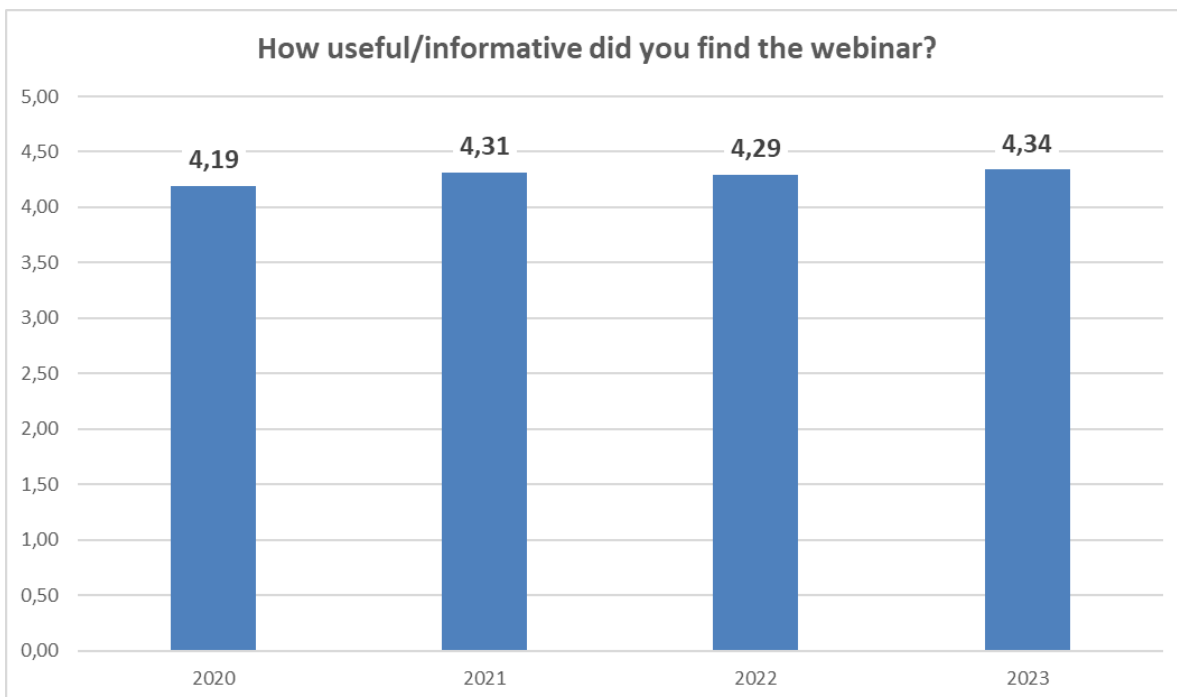
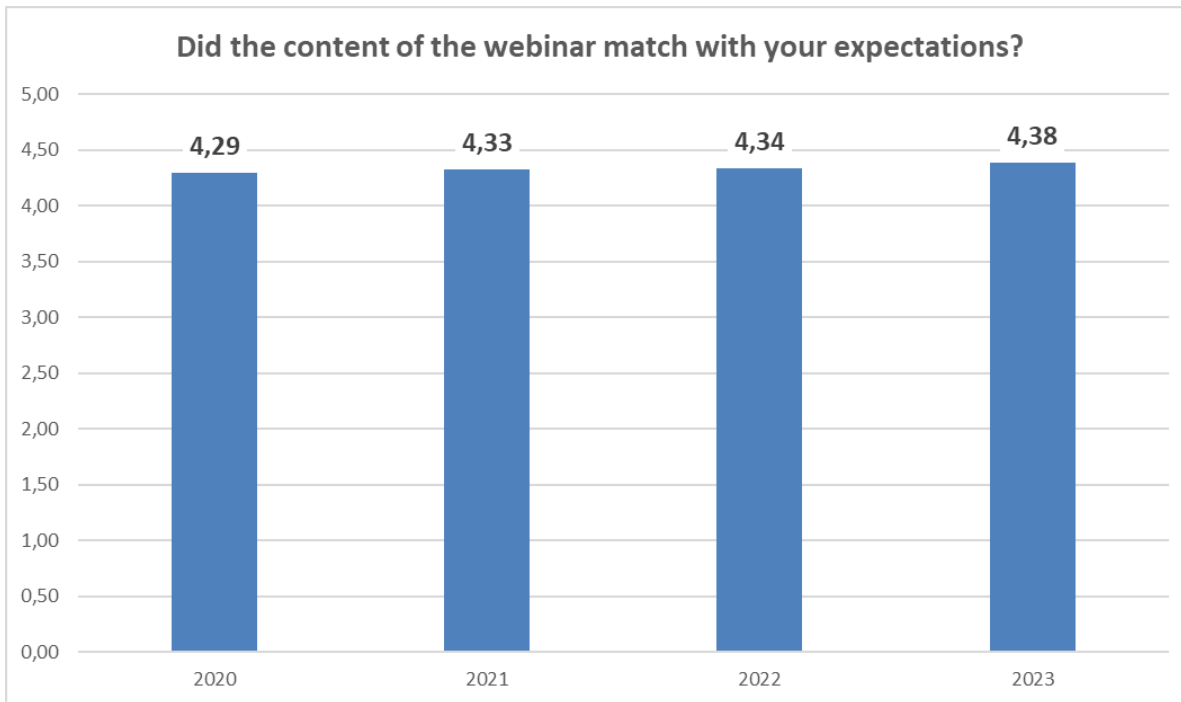
G. NEXT STEPS

24. The next step will be to hold a meeting of the group and pull together an action plan based on the findings detailed in sections D & E above and in the annexes. This will have a particular focus on improvements that can be made to the experience of clinicians working with the network, including how we can support them in terms of securing more resource for ERN work and how to ensure we are as efficient as possible with the processes we ask them to undertake.

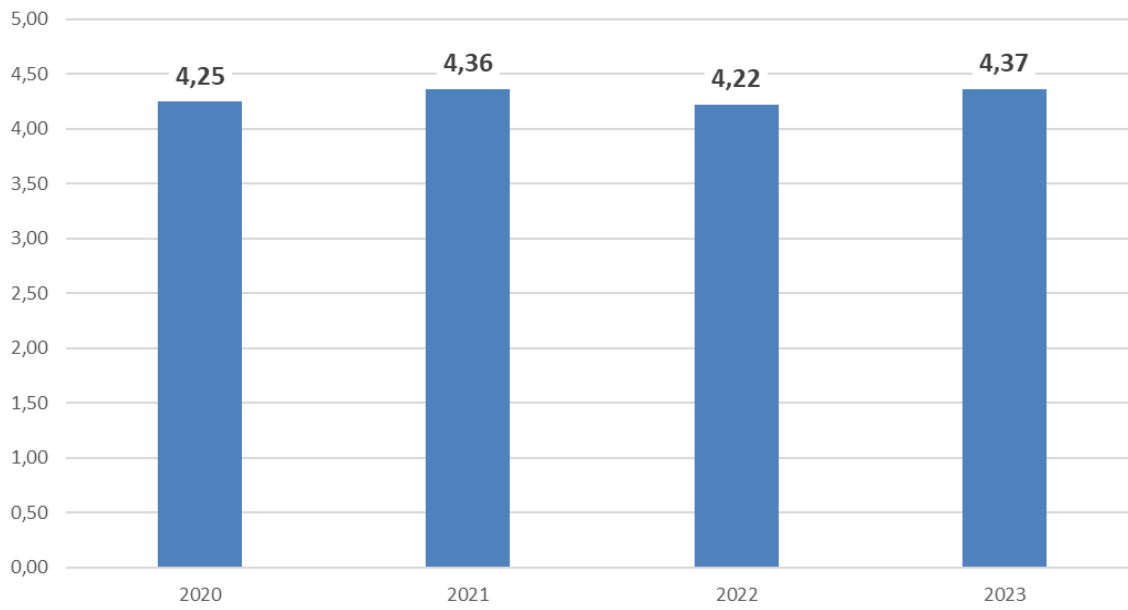
25. Furthermore, the group will monitor progress against the deliverables for WP3 in the new direct grant. These are shown in **Annex E**.

ANNEX A: WEBINAR EVALUATION RESULTS

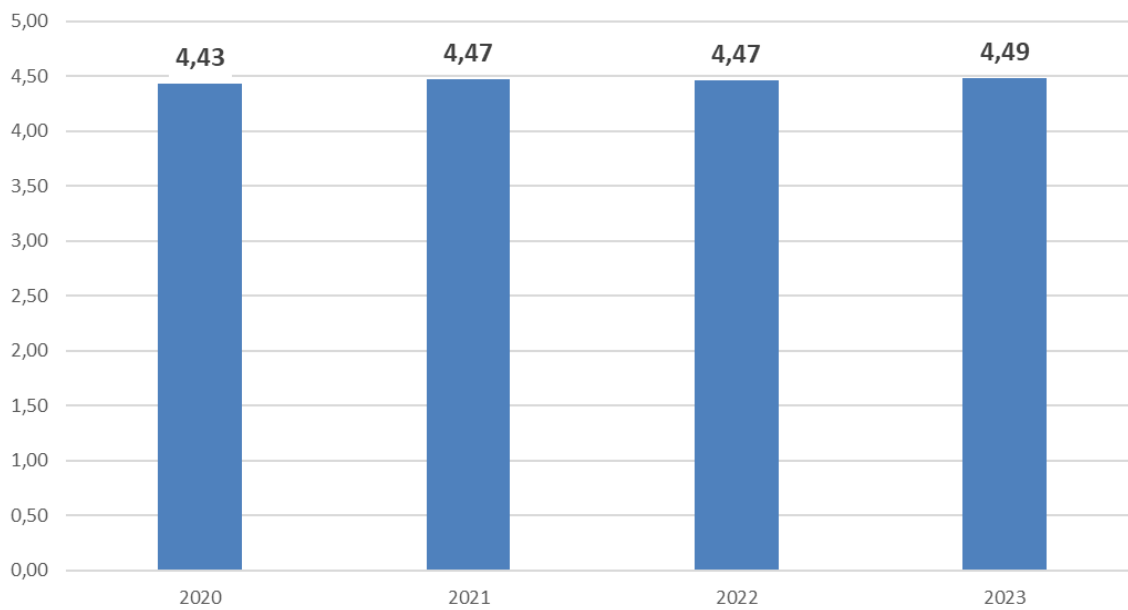
The graphs below show the average scores out of 5 for all responses gathered from live attendees in that year.



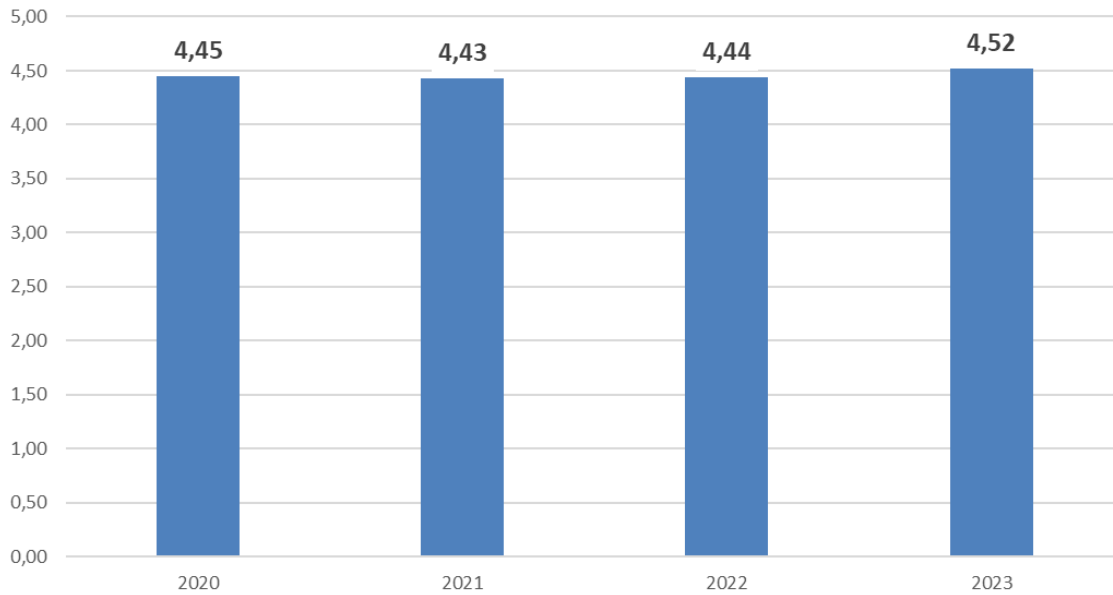
How was the sound?



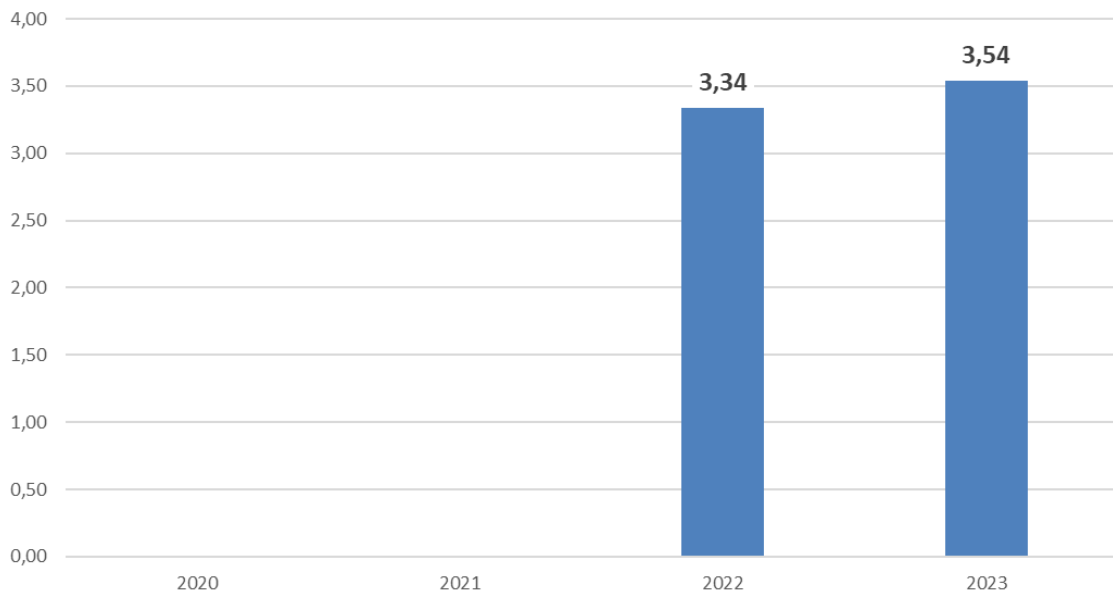
How clear were the slides?



Were the speakers clear and understandable in their presentations?



What did you think about the length of the webinar?



General

The network is continuously building its functional structure. The detailed evaluation revealed some areas for improvement, namely the common guidelines that are still in preparation and marked the lowest of all evaluated elements. Further, the online interview with patient representatives revealed only marginal cooperation between three major working streams formed within the network. Noticeable disbalance between the level of countries and individual centres also opens the space for improvement.

Governance and coordination

The periodic report and also a discussion with patient representatives show discrepancies between individual members and countries, which is reflected in an uneven level of care for patients. The situation is mostly influenced by national health care systems, but it might be an impulse for the ERN for further improvement.

Clinical care

The evaluation report shows some gaps in cross-border care and different levels of care among all centres. While it is difficult to influence these facts on the level of the whole network it leaves some space for improvement.

Quality and patient safety

The ERN should create a pool of measures to monitor clinical processes, performance or outcomes of care among its members. Such indicators are not yet functioning (are in preparation, however) and may help to balance the levels of participating centres.

ANNEX C: HCP SELF-ASSESSMENT RESPONSES ON BARRIERS TO WORKING WITH THE NETWORK

Mention what aspects have hindered your participation in the Network or have prevented a more active participation	
HCP	Comments
Ghent	<ul style="list-style-type: none"> The lack of financial support to hire staff or to reimburse time spent on the multiple ERN activities, CPMS and registries is a major concern for which we hope to obtain better solutions in the future.
Leuven	<ul style="list-style-type: none"> Clinical, research and education obligations in daily practice. Participation in the network involves a large amount of administration. This requires extra administrative personnel. Going through the ethical/legal procedures is (very) time consuming.
Berlin	<ul style="list-style-type: none"> Mrs. Prof Märzheuser, who was the main partner for the project, switched to the University of Rostock as chief of pediatric surgery on January 1st 2022. Due to this change, the team had to be completely reorganize.
Munich	<ul style="list-style-type: none"> Time, just doing the self-evaluation takes at least 10 hours. For a busy pediatric surgeon, taking that much time is difficult.
Leipzig	<ul style="list-style-type: none"> No study/registry assistant Staff shortage High caseload – clinical obligations
Regensburg	<ul style="list-style-type: none"> Staff shortage. At this point in time, the work in the ERN is still done during or after clinical working hours. This means that only a very limited number of hours is available, which prevents us from being more active in the ERN. Currently, there are considerations and discussions on how to solve this time problem without affecting the clinical work.
Hamburg	<ul style="list-style-type: none"> For our Workstream our Department represents a reference center. Therefore, there are little to now cases where we need advice and define our role more into spreading knowledge and giving advice. Due to limited numbers of Panels this is not on a regular base but we are working to encourage others to create panels. Actually, we focus our efforts to getting into the ERN registry. German law is strict to these issues. We already got the Ethic committees votum and are working with our legal department right now.
Aarhus	<ul style="list-style-type: none"> Busy daily clinical work is a hindrance HCPs are all clinical staff and only minimal time during working hours is set aside for ERN related work.
Copenhagen	<ul style="list-style-type: none"> Lack of Man-Power
Necker	<ul style="list-style-type: none"> We are very interested in participating in this European network, and personally, especially since I coordinate the MAREP network and the NeuroSphinx network in collaboration with Pr Sarnacki. However, without funding and time dedicated by our institution for this activity, it is very difficult to participate in all the meetings and other actions of eUROGEN unfortunately. As a national reference center, we have a very large care activity (our patients come from all over France, Europe and Africa). Without dedicated time, we cannot devote much time to this network. A reflection on this specific matter must be carried out by and with our institution.
Padova	<ul style="list-style-type: none"> One aspect deserving attention is the need of approval by the Ethical Committee to start an active use of eUROGEN database. Hopefully we will be able to complete this procedure in the next future.
Gemelli	<ul style="list-style-type: none"> Low interest of colleague on rare diseases (these cases are often more complex, resources to manage these patients are insufficient [e.g. costly devices], some treatments are not reimbursed by the national health services). Consequent difficulties to settle a multidisciplinary team on rare disease.
Milan	<ul style="list-style-type: none"> Our HCP participated as much as possible to the activities proposed by the network, including meetings, webinars (also as presenter), CPMS case discussion. No case from our HCP was discussed in the CPMS because all our complex cases were managed primarily among the our internal HCP multidisciplinary team (MDT). Unfortunately most of the monthly workstream web meetings last year were unattended because of the scheduled time overlapping with important clinical activities but minutes of the meeting were chased regularly.

	<ul style="list-style-type: none"> None of our HCP MDT members participated to inter-ERNs visit exchange program so far because of the logistic difficulties finding time to take off from our busy job. If the program can be extended to our trainees we are sure that this great opportunity won't be missed.
Bambino Gesù	<ul style="list-style-type: none"> COVID-19 pandemic significantly impacted on OPBG activities from March 2020 up to end 2021. In this framework OPBG also served as Regional Referral Center for COVID-19 pediatric patients ensuring treatments for more than 900-ish children who required hospitalization care. Absence of staff dedicated to data entry ERN in CPMS and registry.
Vilnius	<ul style="list-style-type: none"> There is no any remuneration for any activities carried for eUROGEN, and it is a major challenge: it is very difficult to motivate staff and it is very difficult to prove working hours to Hospital's administration. Another major issue is a huge rise in administrative work after entering ERNs (reports, monitoring, assessment, evaluation, National designation and ERN application procedures, etc.): highly specialized experts are keen to engage into clinical work, research and education/training and they are experts in this work, but they are highly reluctant to do burdensome administrative, bureaucratic work that is not their expertise; moreover, there is a constant change of these procedures from both EU and national authorities' side that impose additional challenges and dissatisfaction. 2020 and in part 2021 were very difficult because of pandemics: VUHSK was appointed as the main hospital in Lithuania for the coordination of COVID-19 pandemics and accrued the highest numbers of patients, especially complicated COVID-19 cases; many staff members were either directly (through facility and staff redistribution) or indirectly involved in the management of pandemics; together with the lock-down measures that were especially strict in 2020, these imposed major challenges for all the activities carried in rare disease reference centres, including Center of Rare Urogenital Diseases and Complex Conditions, that participates in eUROGEN. Additionally, participation in the eUROGEN registry was complicated because of bioethical requirements in Lithuania to obtain both parents signature on the ICF.
Erasmus	<ul style="list-style-type: none"> It is possible to participate in the CPMS as an expert and to share information in cases, in the webinars on expert subject, in the EUROGEN meetings, in the development of guidelines, in joining the registry. A lot of information and (administrative) time is being asked for participation in the ERN next to our clinical/research tasks. Minimal financial support for research, expected was the possibility to get access to more research funding for ERN members to conduct research together. Difficulties are experienced in the development of teaching materials for colleagues, in organizing meetings in the disease area, in set-up of studies and obtaining grants in this field.
Radboud	<ul style="list-style-type: none"> Radboudumc has participated in all ERN eUROGEN Network related aspects and is the Coordinating center for its members. Time limits of experts and support personel are of course a reason for the amount of activities undertaken or participated in and the Network has developed an activity and engagement tool for its members in 2022.
Porto	<ul style="list-style-type: none"> Time constrains of the human resources have hindered a more active participation in eUROGEN. Specific funding for human resources to the local HCPs by the European Union or the Portuguese Health Administration would greatly facilitate a more fruitful participation in the Network.
Karolinska	<ul style="list-style-type: none"> Too much ordinary work both clinically and administratively. When communicating things about the ERN it is hard for us to understand the administrative language used.
Sahlgrenska	<ul style="list-style-type: none"> Swedish law for enter data in the ERN registry, work load on clinical staff during the pandemic, in the initial stages there were technical difficulties with e.g. CPMS-system, resources to fully integrate the ERN work into the Swedish health care system.
Gdansk	<ul style="list-style-type: none"> A lack of a person responsible for CPMS management and patient enrollment in the system hindered our participation in Network Activities. We were used to consulting patients via The Hendren Project (https://www.hendrenproject.org/), and the AMEQUIS 5-Year ERN Evaluation allowed us to see the problem. We thus decided to take care of this problem and delegate a person to this task. We are a very busy Department, and we have concentrated for the last five years on performing surgeries, teaching at the undergraduate and postgraduate levels and trying to obtain funds that could allow us to expand. At last, this has effects, and Our team will hopefully grow.



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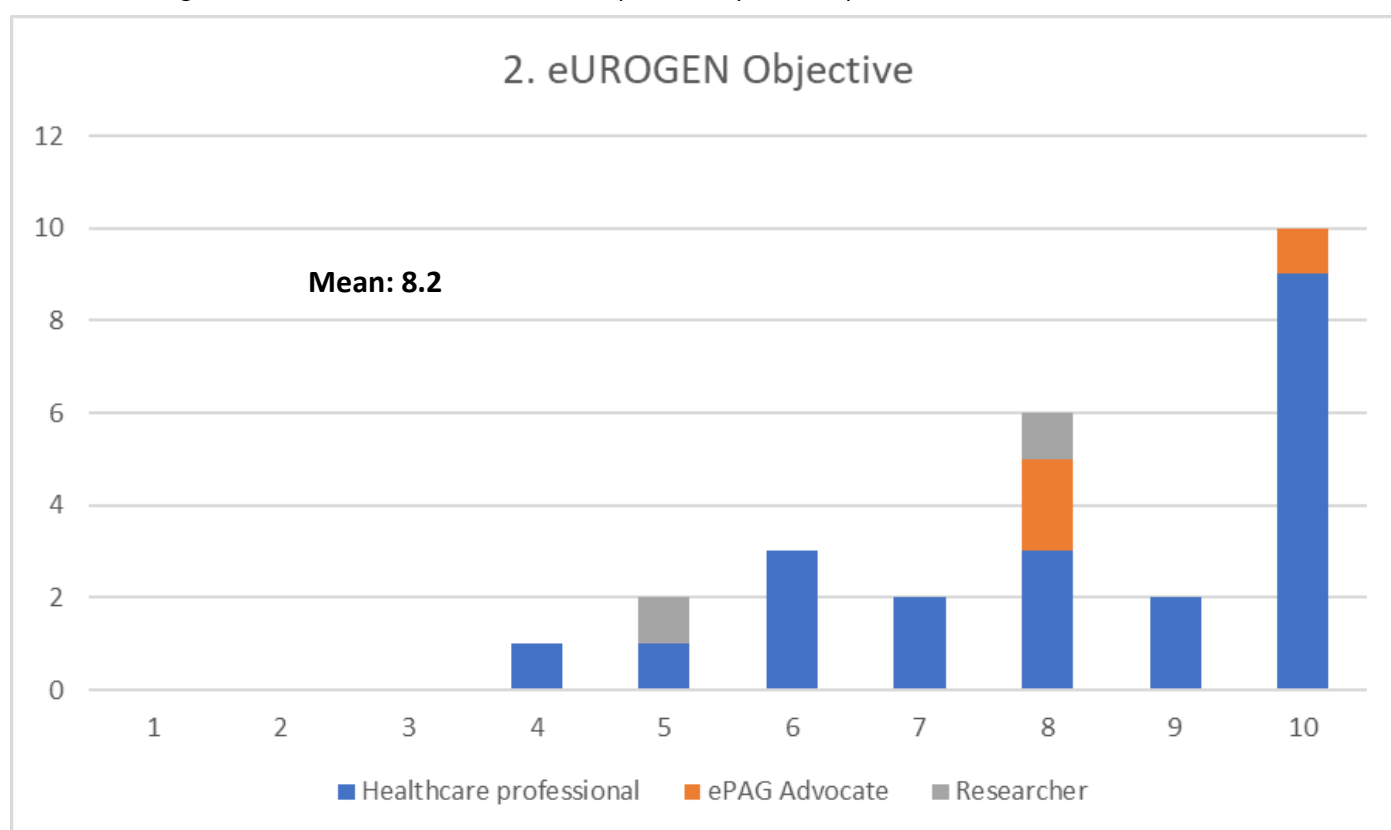
Network
Urogenital Diseases
(ERN eUROGEN)

ANNEX D: ERN EUROGEN QUALITY IMPROVEMENT SURVEY RESULTS & SWOT ANALYSIS (AUGUST 2023)

This survey was issued to the network in August 2023. We received 26 responses. The first part of the survey asks respondents to rate their agreement with the current network mission statement. Questions 3 to 12 then ask for their opinion of the network's achievement in terms of the activities and results delivered by ERN eUROGEN since 2017 for a number of different topics. Finally, in questions 13 to 16, the respondents were asked to provide what they considered to be the strengths and weaknesses of the network, as well as what opportunities and threats they saw on the horizon.

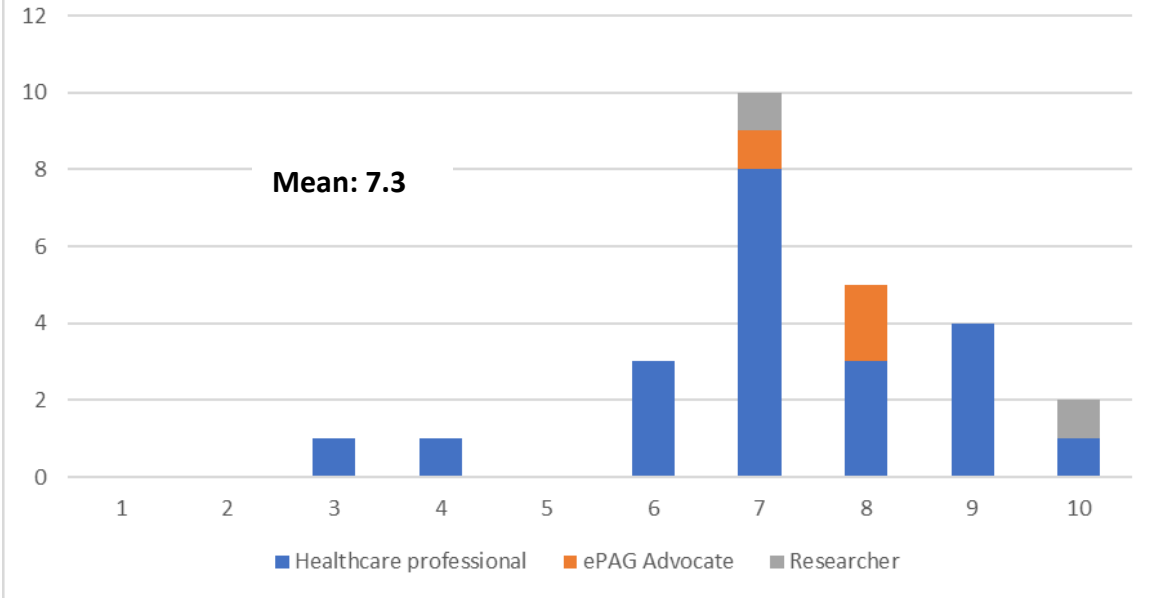
2. Please rate your agreement with the current mission of ERN eUROGEN, as stated above, taking into account the mandate of the ERNs provided by the European Commission (where 0 represents no agreement and 10 represents full agreement):

The mission of ERN eUROGEN is to develop a framework to provide faster specialist evaluation and more equitable access to high-quality diagnoses, treatment, and care for patients with rare urogenital diseases and complex conditions who need highly specialised assessment and surgery. Please rate your agreement with the current mission of ERN eUROGEN, as stated above, taking into account the mandate of the ERNs provided by the European Commission:

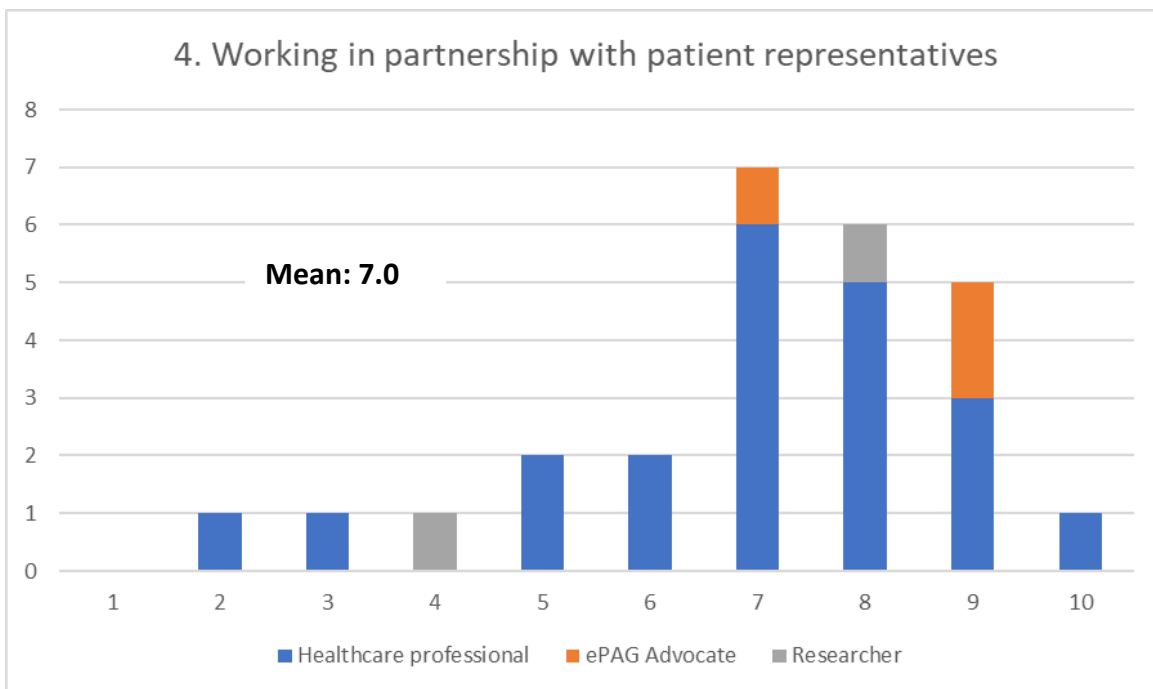


3. Building a European-wide infrastructure for rare urogenital diseases and complex conditions.

3. Building a European-wide infrastructure

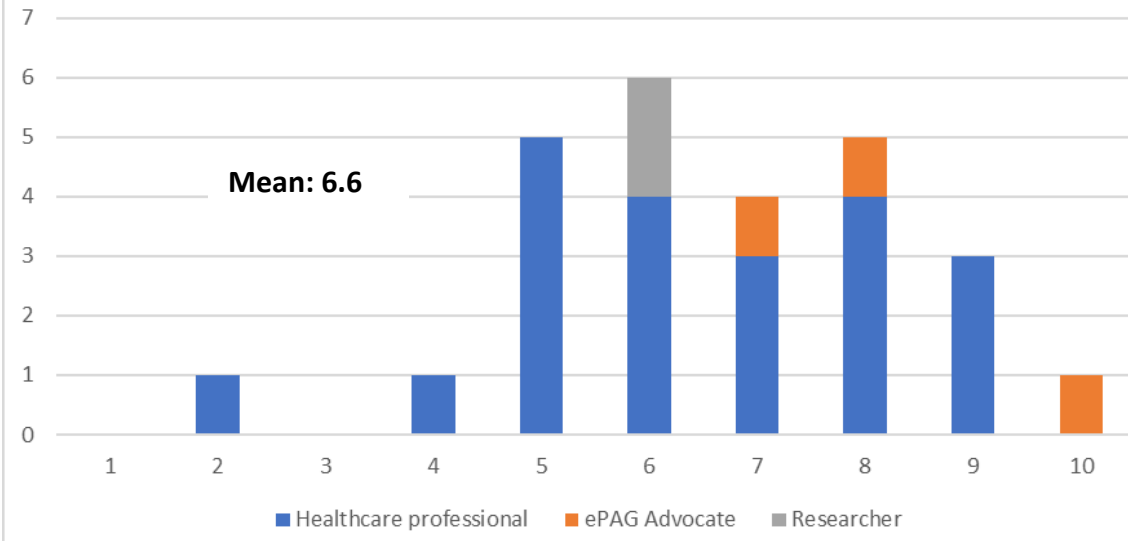


4. Working in partnership with patient representatives.

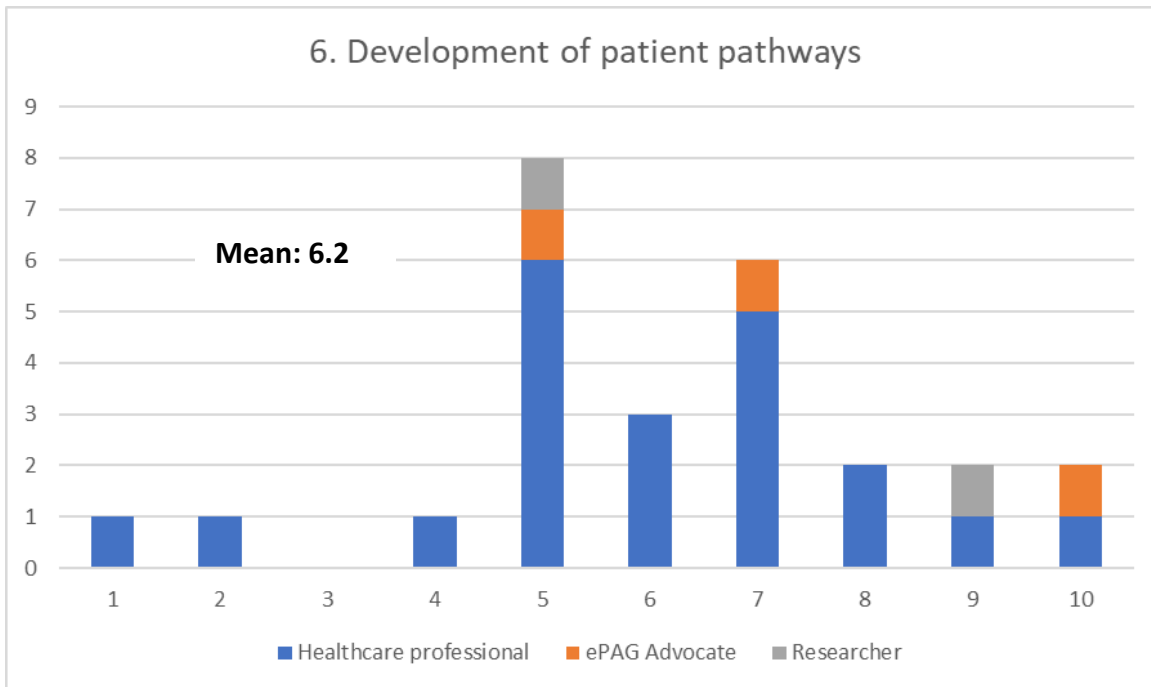


5. Clinical Practice Guidelines and clinical decision-making tools.

5. Clinical Practice Guidelines & clinical decision-making tools

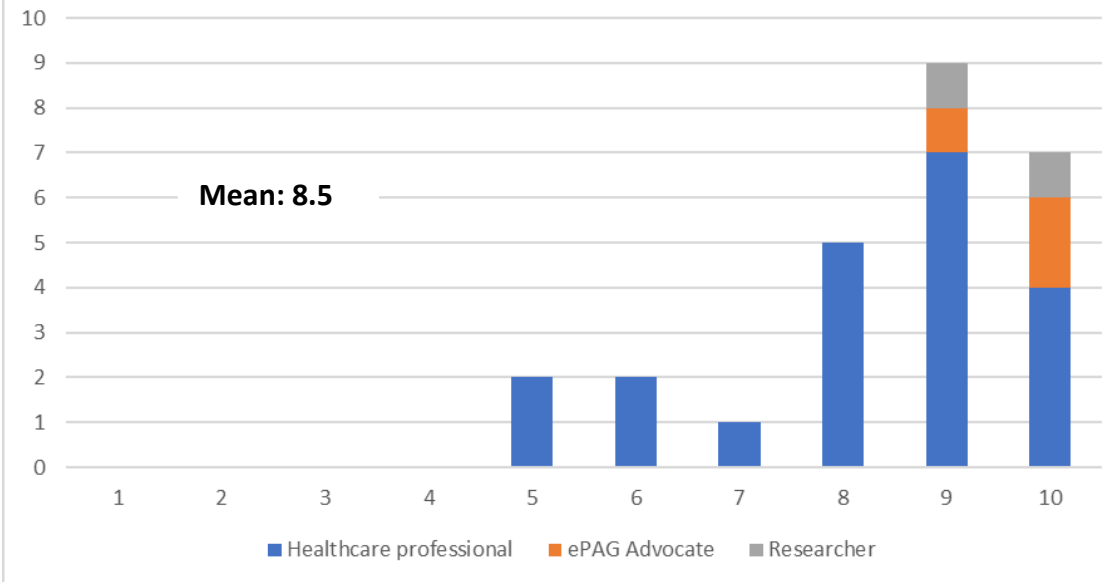


6. Development of patient pathways

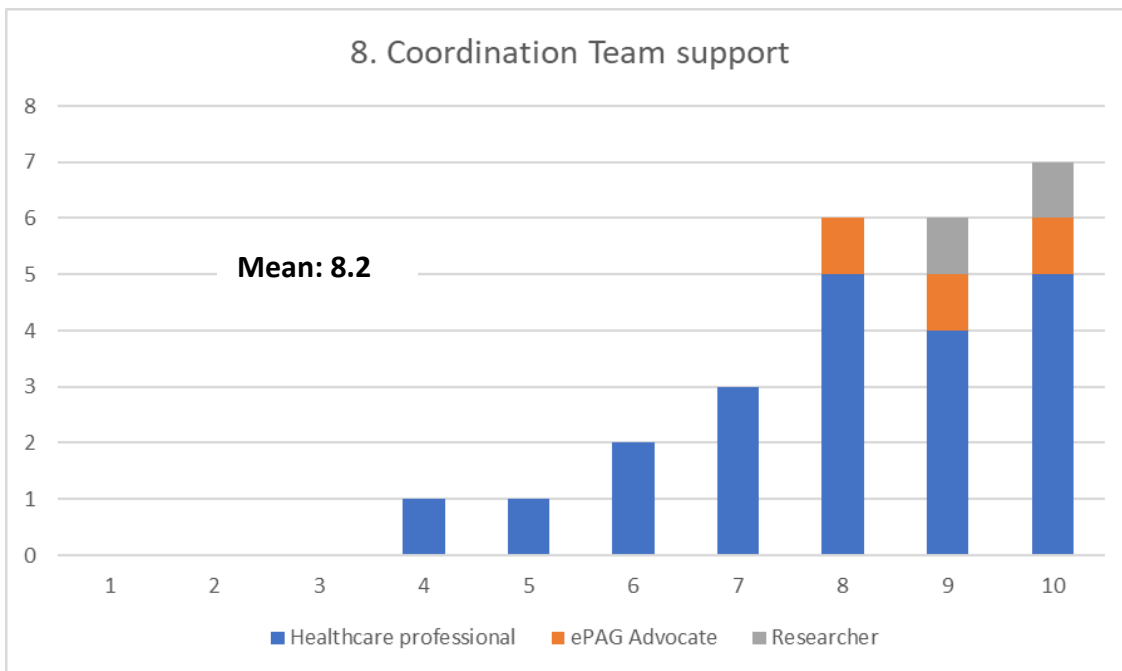


7. Educational and training activities (webinars, ERN Exchange Programme, etc.)

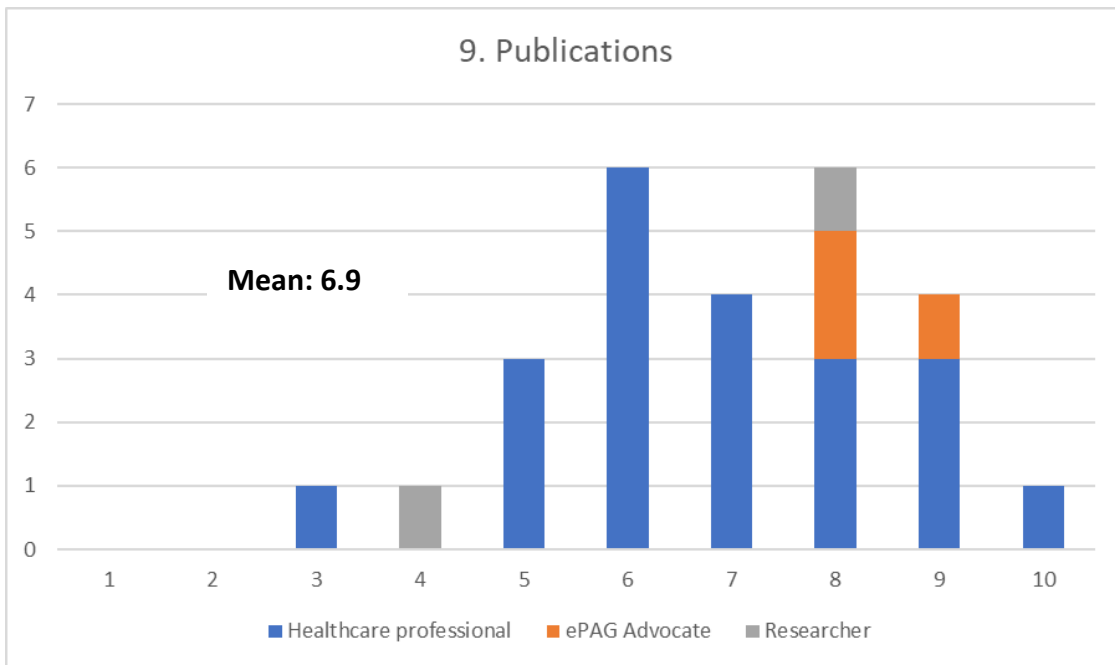
7. Educational and training activities



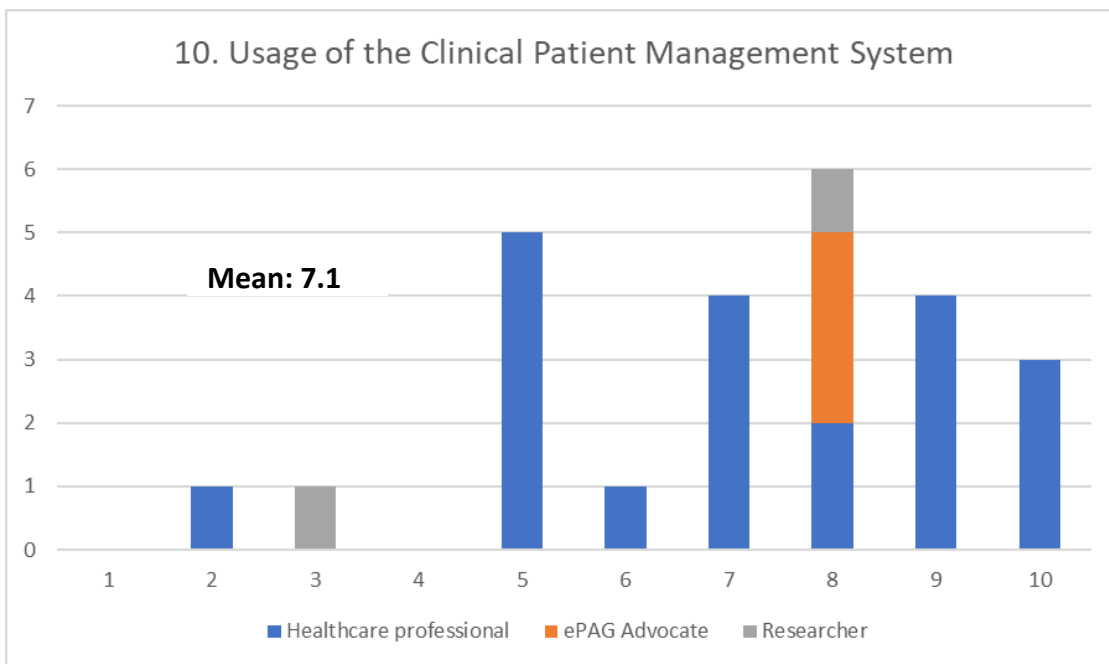
8. Provision of continuous support from the Coordination Team (e.g. ERN Monitoring, ERN Evaluation, etc.)



9. Publications (e.g. scientific papers, supplements, etc.)

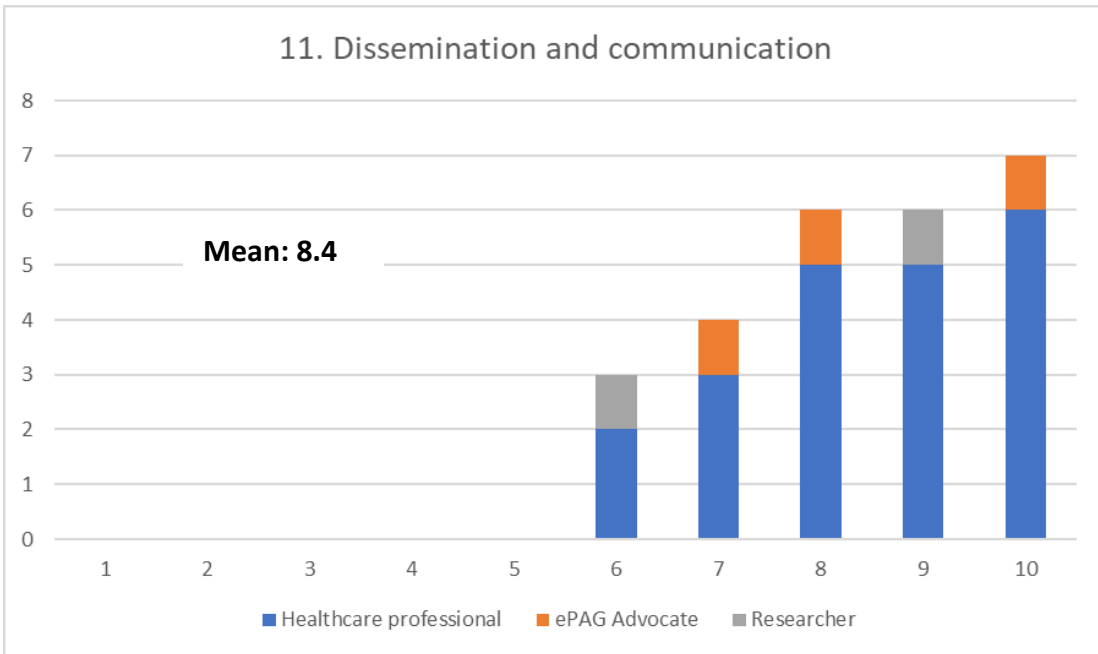


10. Usage of the Clinical Patient Management System

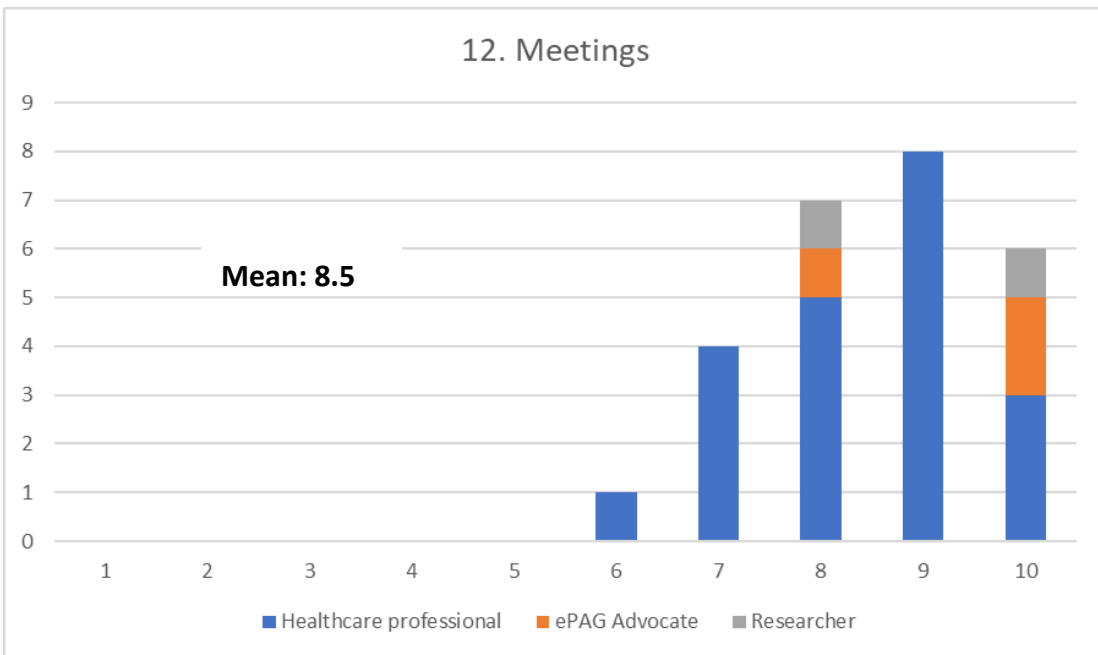


11. Dissemination and communication from ERN eUROGEN (e.g. website, newsletter, etc.)

11. Dissemination and communication



12. Organisation of regular meetings and similar (e.g. annual Strategic Board Meeting, monthly Workstream meetings, etc.)



13. In your opinion, what are the greatest strengths of the ERN eUROGEN network?

- Awareness for rare diseases especially in the field of urorectogenital malformations
- Strong organization, will of sharing experience
- Centrally coordinated activities help to reach our mission

- Identification of specialists
- Networking
- ACCESS TO NETWORKS WITH PROFESSIONALS
- A solid organization to support improvement of treatment of rare urological conditions
- Creating a network, bringing people together
- International communication about rare diseases
- The will to work together and to improve the medical outcome.
- Sharing information and platform across Europe
- Organization and communication among its members
- Possibility of discussing and standardizing approach strategies for rare diseases
- Friendly atmosphere and connectivity
- Linkage of professional expertise
- Networking and committees
- To make the best possible care available to patients and improve quality of assistance
- Resources management
- The coordination team! They manage to quickly bring together a gigantic project. Their enthusiasm spreads to HCP representatives making it a fruitful ERN
- Easy access education. Quick in contact with each other

14. And its greatest weaknesses?

- Sometimes to slow for the patients;
- Lack of time for dedicated clinicians and lack of funding for data management
- We really need more time to reach all HCPs for their help and support in reaching our mission
- Trying to invent the wheel
- Patient consultation system is rather complex
- Hard to navigate.
- The EU bureaucracy (which we fully understand is necessary to some extent)
- Many experts with similar expertise, a lot of administration, to many emails.
- Financial support for registration of patients
- Losing control of the many groups working together.
- Different health care system between European nations
- None
- "Need for available time for the team.
- Some communication difficulties. There should be translation."
- Not yet full EU coverage
- The lack of or low financial remuneration for participating centres, long and slow decision-making processes
- progress
- To wide system with to many subcategories, difficult to manage and develop
- Too many emails etc., it is not easy to stay up to date
- Wide range of diseases
- Representation is unevenly distributed across countries: some have a broad representation, some very limited to none. The goal should be to find representation in as many countries as possible (if the expertise is available)
- Representation. Variety regarding the number of patients / level of expertise.

15. What opportunities do you see for the network to embrace in the future?

- Set large databases for rare diseases, increase exchanges between clinicians
- Guidelines development based on amongst others also the eUROGEN Registry data
- Working with what is already available (guidelines, etc)
- Closer collaboration between centres
- A much closer contact between network members to the benefit of improved patient care
- Data projects, trials
- Harmonisation of the treatment better results for the patients, objective evaluation of the outcomes
- Better medical path and outcome for the patient. For the patient to know what options he has during recovery.

- Meeting organisation and publications
- Enhance support at all levels of national institutions
- Opportunity to better serve patients. Ability to create a European assistance and scientific team to fill in the gaps that compromise the success of some testicular cancer treatments.
- Continuation of current strategy
- Connect and making a large program for rare diseases
- Development is really unpredictable at present
- Guidelines, patient pathways, expanding the registry and publications
- Further development of intensive working together

16. And what hindrances are on the horizon that may become an issue for the network?

- Financial situation
- Too much information
- Rules and procedures are sometimes rather time consuming for a clinician.
- Shortness of financial support
- High effort, little direct reward for participants
- Time and manpower at the local healthcare providers
- Too many groups working together and losing the overview.
- The neglect of its members
- Lack of time to place cases in CPMS.
- None as far as can be overseen now
- Sustainability
- Growing to much will paralyse the network
- Resistance to national implementation
- If representation is not broadened, the perspective may become too narrow and not applicable to all European countries

17. Other comments:

- Availability of presenting/discussing real rare cases
- More support on registration/organisation for the patients
- Ability to communicate in multiple languages
- A combined research project based on the registry knowledge
- No, thanks. You are doing your best with the best intentions
- Financial support for national patient days must be possible
- Keep on going!

ANNEX E: 2023-2027 GRANT DELIVERABLES FOR WORK PACKAGE 3 - EVALUATION

No.	Deliverable	Due Date
D3.1	Evaluation Plan	M3
D3.2	Evaluation Report 1	M12
D3.3	Evaluation Report 2	M24
D3.4	Indicators Report 1	M12
D3.5	Indicators Report 2	M24
D3.6	Indicators Report 3	M36
D3.7	Indicators Report 4	M48