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Independent Evaluation Body

Network Evaluation Report

eUrogen

This report has been developed in the framework of the service contract signed between the consortium IDOM-ACSA as contractor and HADEA as contracting authority. The opinions expressed in this document are those of the contractor only and do not represent European Health and Digital Executive Agency official position.

Confidentiality Statement

The results of the evaluation of the eUrogen Network are documented in the attached report prepared by the Independent Evaluation Body (IEB).

This report is based on information obtained from the Network through the application form, self-evaluation form, results of the 18 monitoring indicators for ERNs, technical grant reports and supporting documentation. The IEB relies on the accuracy of this information to prepare the report.

This confidential report is intended for the Network, the European Commission, and the Board of Member States. Any alteration of this report is strictly prohibited.

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1. Introduction

The evaluation model for the European Reference Networks (ERNs) is a process that fosters a culture of quality improvement and offers a peer review evaluation of highly specialised healthcare providers. The evaluation process provides a standardised method for forming and evaluating ERNs under the regulatory framework of the Commission Delegated and Implementing Decisions of 10 March 2014 and amendment of the Implementing Decision of 19 July 2019. It includes a comprehensive evaluation of the Networks and their members through documentation review (the application forms, self-evaluation forms, results of the 18 monitoring indicators for ERNs, technical grant reports and supporting documentation), and the performing of online interviews with ERN coordinator teams and patient representatives as well as onsite audits in a sample of the HealthCare Providers (HCPs).

2. Evaluation Summary

eUrogen

Coordinating Member

Radboud University Medical Centre Nijmegen
Radboudumc route 633 Geert Groteplein 10 6500 HB Nijmegen (Netherlands)

Network Representatives

- Wout Feitz, *Network Coordinator*
- Jen Tidman, *Network Project Manager*
- Loes Oomen, *Network Project Manager*
- Loes van der Zanden, *Network Project Manager*
- Michelle Battye, *Network Project Manager*

Healthcare Providers

The Network is composed of the following Healthcare Providers

- Aarhus University Hospital (Denmark)
- Assistance Publique-Hôpitaux de Paris, Hôpital Necker-Enfants Malades (France)
- Charité Universitätsmedizin Berlin (Germany) (*)
- Copenhagen University Hospital, Rigshospitalet (Denmark) (*)
- Erasmus MC: University Medical Center Rotterdam (Netherlands) (*)
- Fondazione Policlinico Gemelli, IRCCs, Rome (Italy) (*)
- Foundation IRCCS CA'Granda Ospedale Maggiore polyclinic - Milan (Italy)
- Instituto Português de Oncologia do Porto (Portugal)
- Karolinska University Hospital (Sweden)
- Klinikum Bremen-Mitte (Germany)
- Klinikum der Universität München (Germany)
- Pediatric hospital Bambino Gesù, Rome (Italy)
- Radboud University Medical Centre Nijmegen (Netherlands)
- Sahlgrenska University Hospital (Sweden) (*)
- Universitätsklinikum Leipzig (Germany)
- Universitätsklinikum Hamburg-Eppendorf (Germany)
- Universitätsklinikum Regensburg (Germany)
- University Clinical Hospital of Medical University Gdansk (Poland)
- University Hospital Ghent (Belgium)
- University Hospital Leuven (Belgium)
- University Hospital Liège (Belgium)
- University Hospital of Padova (Italy)
- Vilnius University Hospital Santaros Klinikos (Lithuania)

(*) Selected for the onsite audit.

Virtual interview with Coordination Board date

06 March 2023

Board Members and task leaders interviewed

ASSISTANTS

- Wout Feitz: ERN eUROGEN HCP Network Coordinator Representative.
- Michelle Battye: ERN eUROGEN Programme Manager
- Jen Tidman: ERN eUROGEN Programme Manager
- Darren Shilhan: ERN eUROGEN Lead IT & Data Performance Analyst
- Loes Oomen: ERN eUROGEN Clinical Data Specialist
- Loes van der Zanden: ERN eUROGEN Registry Coordinator
- Lotte Boormans: ERN eUROGEN Registry Manager

Virtual interview with Patient Representatives date

03 April 2023

Patient Representatives interviewed

ASSISTANTS

- Claire Harkin: Klinefelter's Syndrome Association
- Steven Leusenkamp: Patiëntenvereniging voor Blaasextrophie Nederland
- Nicole Schwarzer: Selbsthilfeorganisation für Menschen mit Anorektalfehlbildungen (SoMA EV)
- Rob Cornes: Orchid UK

Evaluation Team

The following evaluation team completed the technical evaluation:

- Ms. Anna Sediva. Deputy for research, vice-head of the Department of Immunology. Motol University Hospital , Prague, Czech Republic. (Czech Republic) (*)
- Dr. Daniel Costa Pinto. Auditor and Project Manager. General-Directorate of Health. (Portugal)

(*) Team Leader.

3. Conclusions of the evaluation team

The evaluation team provided the following conclusions regarding the development and achievements of the Network.

Accomplishment of the objectives of the Network

ERN eUrogen credibly describes the achievement of the main goals, namely to help realize the potential of European cooperation regarding highly specialized healthcare, to facilitate improvements in diagnosis and the delivery of high-quality, accessible, and cost-effective healthcare, to reinforce research, epidemiological surveillance like registries and provide training for health professionals, 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, to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network.

The report provides an overview of the means developed by ERN for communication at the level of professionals and patients, which is the first time in history in the field of urogenital malformations.

The report also proves the achievement of milestones at the clinical level, the increase in the number of patients, the expansion of the spectrum of included clinical conditions, the maintenance of registers and the improvement of the level of education in the field. Overall, a shift at the ERN level is demonstrable. See also the material from the self-evaluation.

Development and achievements of the Network: Structure

ERN eUrogen is a major ERN covering the field of rare urogenital malformations. The broad spectrum of members includes, after the 2021 call, 30 new Full Members that joined ERN eUROGEN on 1st of January 2022, giving a total of 52 HCPs in 20 Member States (some of these new Full Members were previously Affiliated Partners), with a relatively small representation of Central and Eastern Europe. The network was conceived under the leadership of the UK, then the coordination was transferred to Radboud University. The structure of the network is very solid, it is led by a coordinator and his very strong technical support. The network has established 3 main work streams replicating clinical directions. In addition, it has 6 WPs interwoven through its structures. In addition to the coordinator, the network has an extensive committee of over 100 members. Despite this vastness, the network appears to be tightly controlled, but at the same time leaves space for all involved. The structure of the network is described in detail and is attached to the "self-assessment" documents. A number of patient organizations are involved in the network, their representatives are part of the management structures.

Development and achievements of the Network: Maturity

In the course of its existence, ERN eUrogen has demonstrated a shift in all aspects of its activity and has matured in its functioning. The shift is most marked by the expansion of the space of influence, which was mainly due to the accession of new members and their involvement in the functioning of the network. The ERN further improved the care of patients in its individual work streams. Patient registries document a significant increase, in some areas up to double the number of the patient pool. Cooperation with patients is also progressing very clearly. The coordination of the ERN has to be changed post-Brexit, but the new leadership has already been fully established, with processes in place to manage the function and monitor the network. Overall, the gradual increase in experience can also be seen in the self-assessment report and attached documents.

Development and achievements of the Network: Activity

ERN eUrogen is the architect and initiator of a number of activities on many different platforms. In line with the definition of the ERN network, it provides healthcare to its patients, in active cooperation with them and their organizations. In the professional part, the ERN pays attention to education at all levels of care. The ERN organizes the education of its members, collaborating professionals, but also patients and their families. It is very active in organizing events, 13 important events are placed on the network's website until the end of 2023 alone, including specific conferences and meetings of committee members as well as broad meetings of the membership base. The ERN network is uniquely active and uses all possibilities to move the field forward, including modern telemedicine and online resources.

Development and achievements of the Network: Impact

The impact of the establishment and operation of the network is difficult to assess, in the field there is practically no comparison with the period before the establishment of the network. Even thanks to its size and presence in most European countries, the impact has widely affected the field in Europe. The numbers of patients are significant, given the rarity of their diagnoses. Patients are fully included in decision-making, which is certainly a very important impact. The network itself also points to some weak points, the creation of common European guidelines is not progressing smoothly, and there is a certain imbalance even between the level of individual members and countries. The functioning of the network has been affected by Brexit and the COVID-19 pandemic. Overall, it can be concluded from the documented materials that the impact in the field of urogenital malformations, mediated by the numerous activities of the ERN network, is significant.

Strengths

The ERN eUrogen is particularly strong in the area of its governance, patient care, research and education and networking and dissemination. All mentioned points are well documented in the self-assessment form and were verified during online interview with the coordinator and ERN representatives.

Patient centred care

The care of patients is a clear priority of the network, as is expressed on many occasions in their extensive self-assessment form. The network established 3 working streams that concentrate on their major topics. In their patient-oriented task, the network cooperates closely with patient representatives and patient organizations. While still not ideal and with several gaps to be solved (such as lack of common guidelines, only marginal cooperation across 3 mentioned working streams etc.) the network represents a decisive force in the field of urogenital malformations in Europe.

Contribution to Research

Regarding its extent and the quality of individual members, there is no surprise to notice a high quality of research activities that concentrate in the network. The increasing number of patients with very rare diagnoses enables to perform unique research activities. Some of them, such as unique surgical procedures, are being applied in clinical practice.

Education and Training

The ERN is instrumental in initiating a range of activities and creating a number of opportunities for education and training for all participants within its structure and beyond. A list of activities can be found in their self-assessment reports and also in a clear form on their webpage.

Suggestions for improvement

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 imbalance between the level of countries and individual centers 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 centers. 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 centers.

Barriers

Several points representing a barrier to the efficient work of the network were mentioned by network representatives in their self-assessment form. They include the limited extra time that could be devoted to the work for the network which pays for almost all participating parts, mainly individual HCPs. To add to that, individual HCPs do not receive any extra funding for their work which creates a significant burden. General barriers, such as Brexit or COVID-19 pandemic were out of the hands of ERN but had to be dealt with for several years in an evaluation period. Finally, the administrative burden and the amount of bureaucracy connected with the network coordination and functioning is huge and steadily increasing, putting a real obstacle to the clinical work and care of patients.

Outstanding findings that can be useful to other Networks

The network presents outstanding work in the field of education, e-tools and telemedicine and in some specific surgical procedures.

4. Results overview

4.1. Overall compliance with the Operational Criteria for the Network

Based on the evaluation of compliance against the Operational Criteria for Networks, the following figure represents the overall distribution of the ratings for the Network. Please see Appendix A for more information on the rating scale used by the evaluation team.

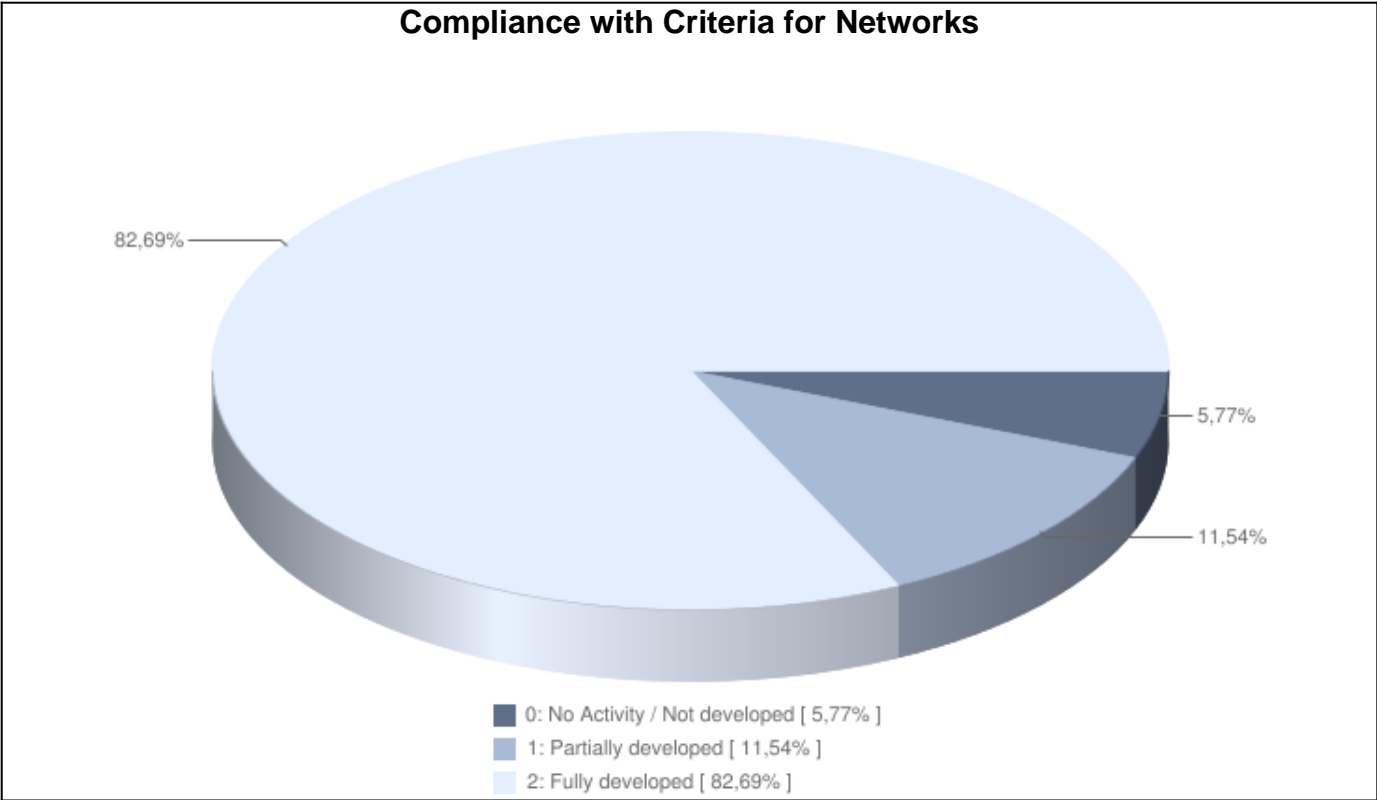


Figure 1

Measurable elements classified as Not Applicable (N/A) in the evaluation are not included in the calculations for the Figures results.

Legend
0: No Activity / Not Developed
1: Partially Developed
2: Fully Developed

Table 1

4.2. Overall compliance with Operational Criteria for Healthcare Providers

Compliance was also evaluated for each Healthcare Provider (HCP) team in the Network against the operational criteria for HCP teams. The following figure represents the distribution of the ratings against the criteria for each HCP team.

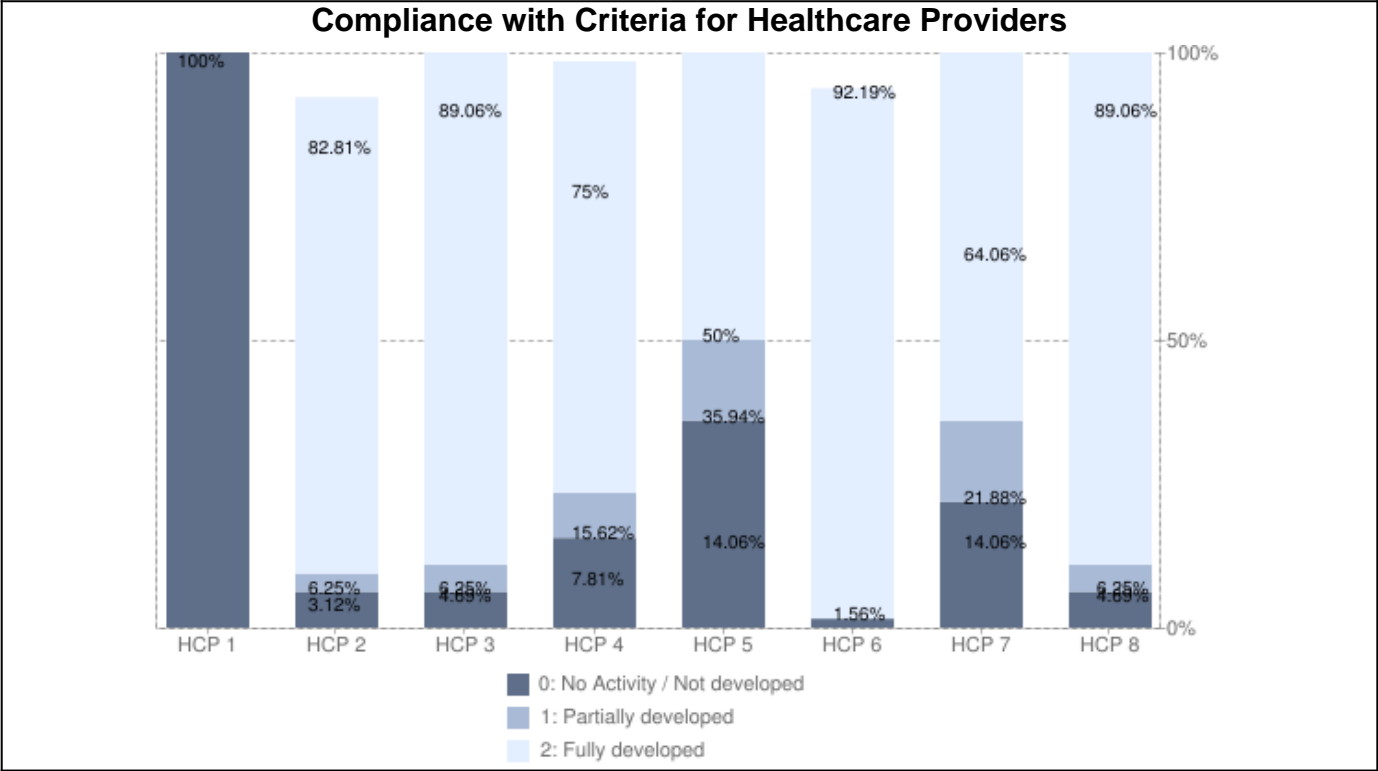


Figure 2

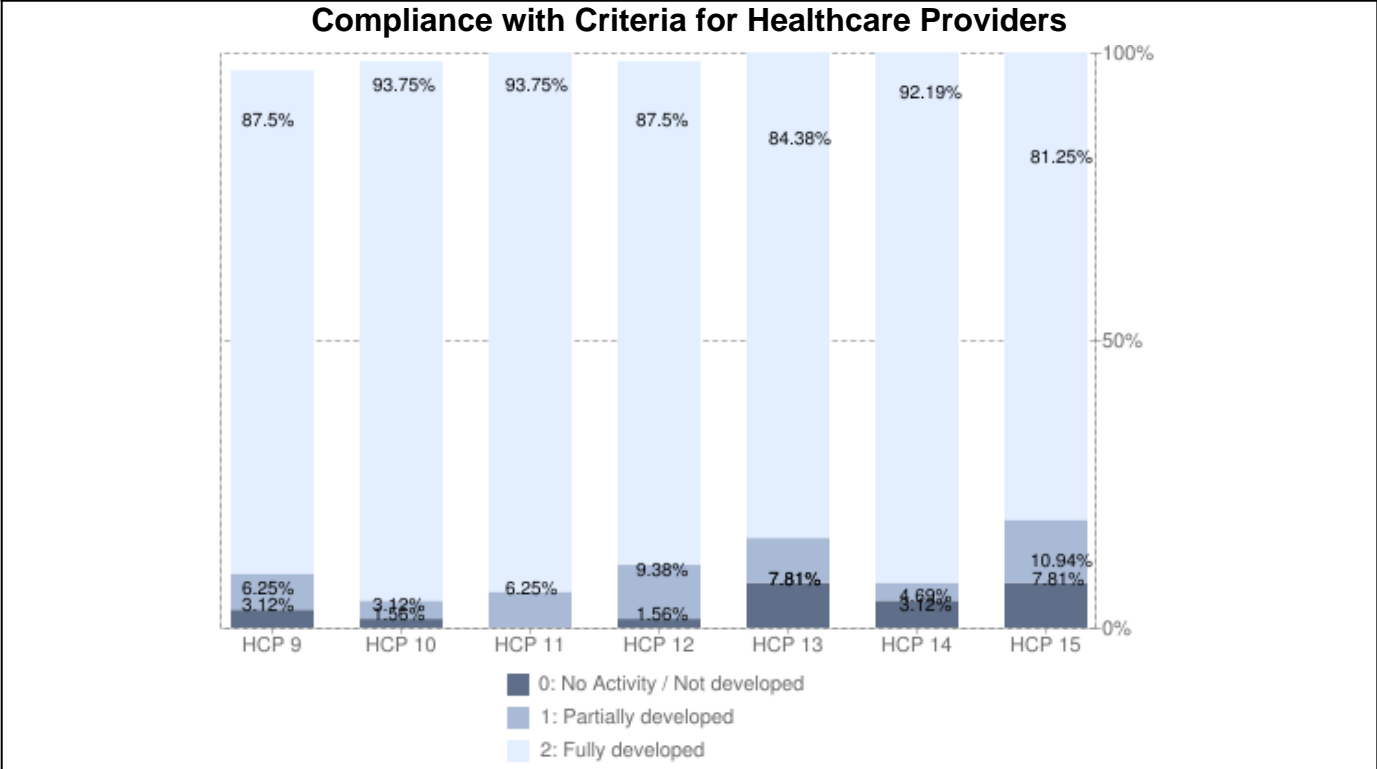


Figure 2

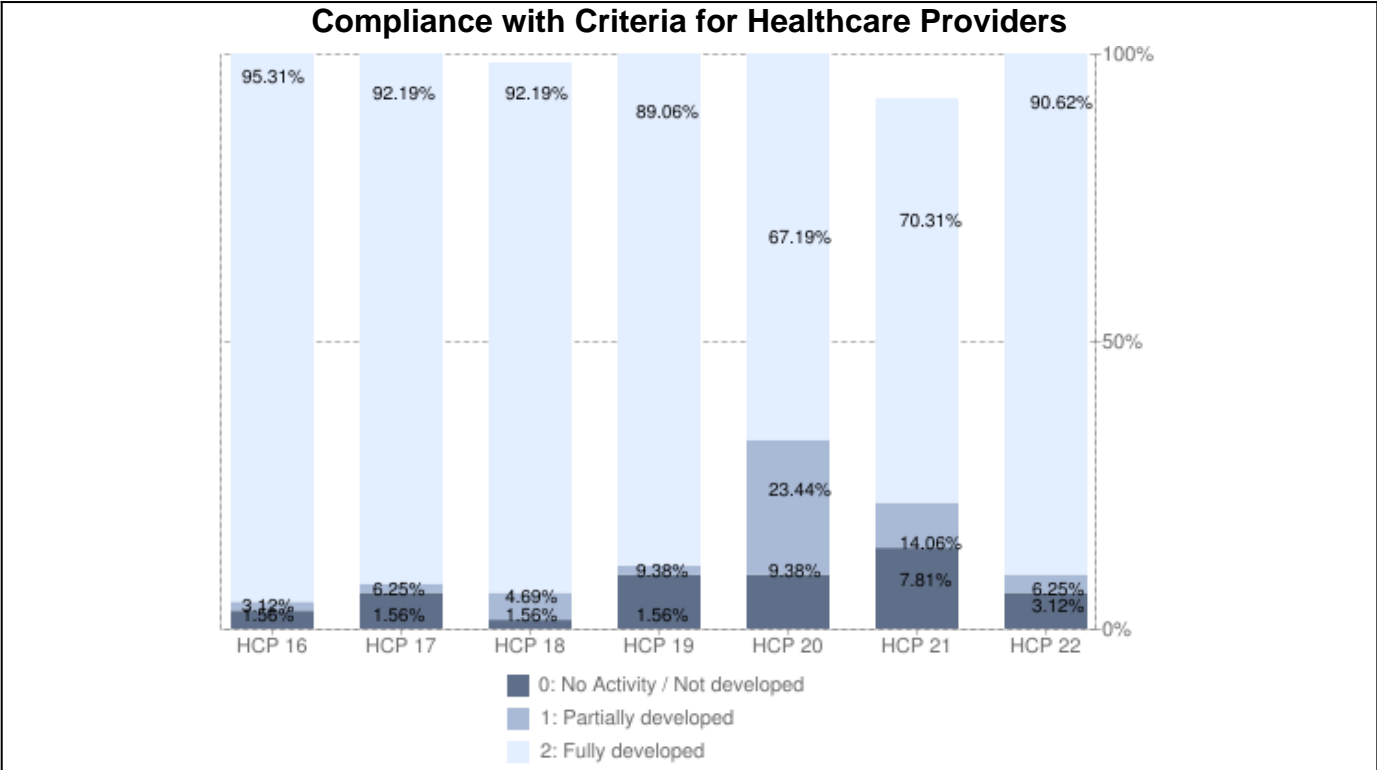


Figure 2

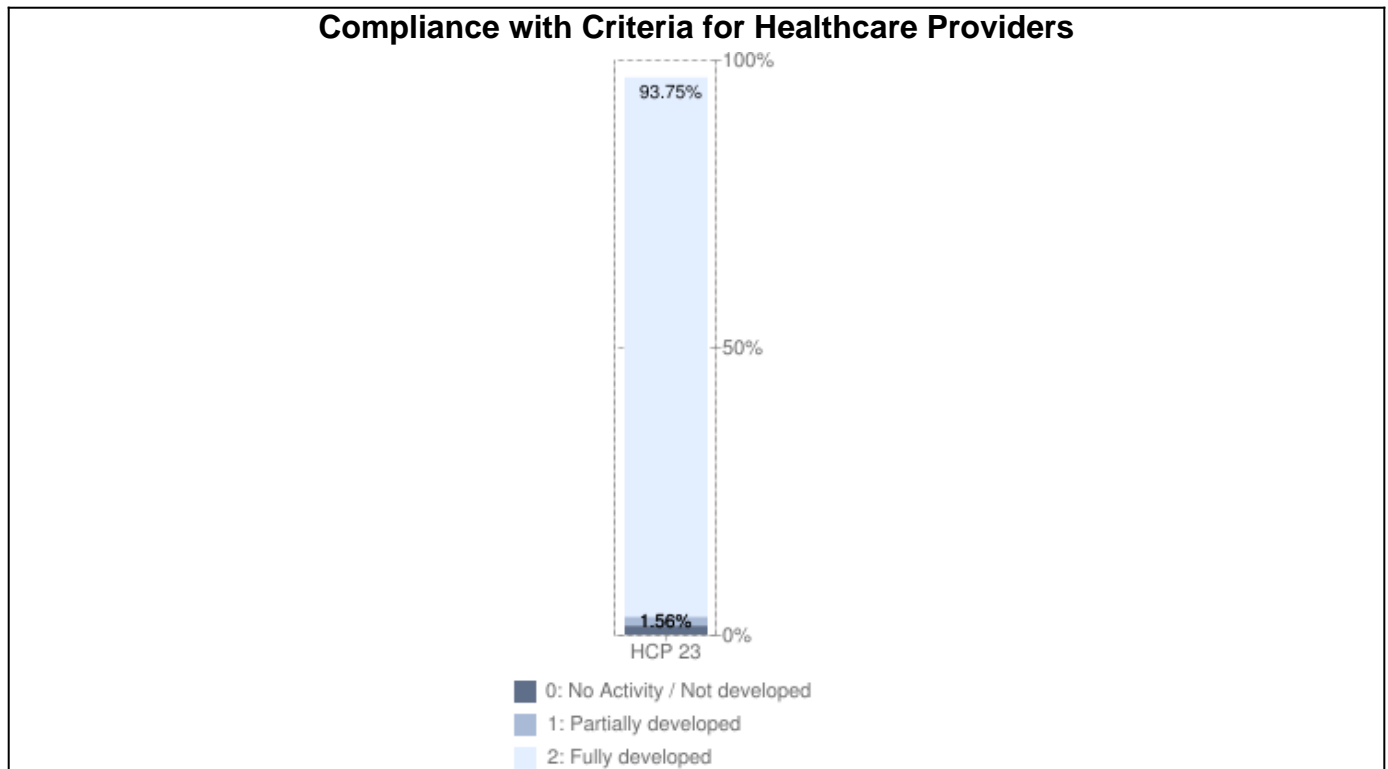


Figure 2

Measurable elements classified as Not Applicable (N/A) in the evaluation are not included in the calculations for the Figures results.

HCP	Healthcare Provider	0	1	2
1	University Hospital Liège	64	0	0
2	University Hospital Ghent	4	2	53
3	University Hospital Leuven	4	3	57
4	Charité Universitätsmedizin Berlin	10	5	48
5	Klinikum der Universität München	23	9	32
6	Klinikum Bremen-Mitte	1	0	59
7	Universitätsklinikum Leipzig	14	9	41
8	Universitätsklinikum Regensburg	4	3	57
9	Universitätsklinikum Hamburg-Eppendorf	2	4	56
10	Aarhus University Hospital	1	2	60
11	Copenhagen University Hospital, Rigshospitalet	0	4	60
12	Assistance Publique-Hôpitaux de Paris, Hôpital Necker-Enfants Malades	1	6	56
13	University Hospital of Padova	5	5	54
14	Fondazione Policlinico Gemelli, IRCCs, Rome	3	2	59
15	Foundation IRCCS CA'Granda Ospedale Maggiore polyclinic - Milan	5	7	52

16	Pediatric hospital Bambino Gesù, Rome	2	1	61
17	Vilnius University Hospital Santaros Klinikos	4	1	59
18	Erasmus MC: University Medical Center Rotterdam	1	3	59
19	Radboud University Medical Centre Nijmegen	6	1	57
20	Instituto Português de Oncologia do Porto	6	15	43
21	Karolinska University Hospital	9	5	45
22	Sahlgrenska University Hospital	4	2	58
23	University Clinical Hospital of Medical University Gdansk	1	1	60

Table 2

4.3. Overview by areas for the Network

The Operational Criteria for the Network are grouped into the following 7 thematic areas:

1. Governance and coordination
2. Clinical care
3. Quality and patient safety
4. Patient centred care
5. Contribution to Research
6. Education and Training
7. Networking and Dissemination

Each area consists of one or more criteria with measurable elements in line with the Commission Implementing Decision (2014/287/EU). The following figure represents the Network's average rating for each area (average of the score of all MEs in each area), with being 0 the lowest rate and 2 as the highest rate.

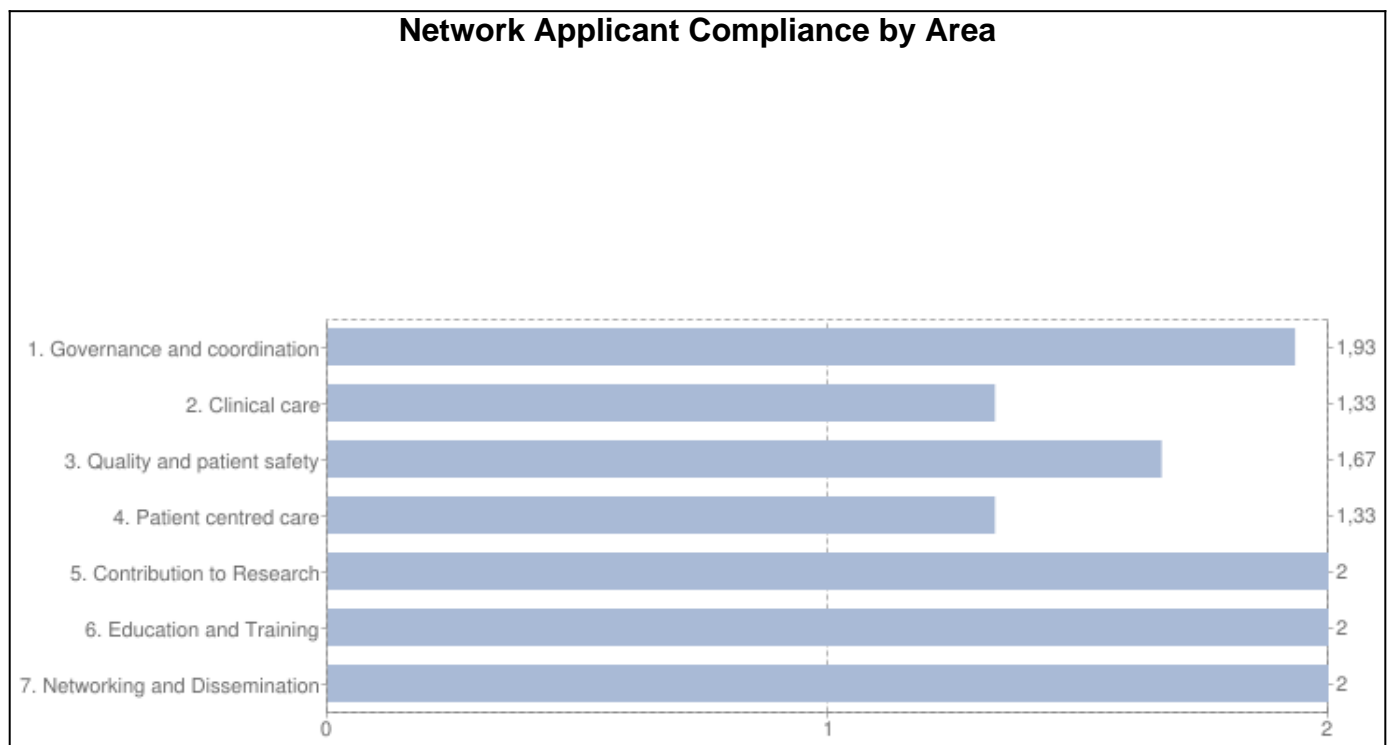


Figure 3

Some of the measurable elements are considered “core” and should have been accomplished or implemented at the time of the evaluation. The following figure compares the Network’s average rating for all the MEs in each area with the average rating obtained by the core MEs in the same area.

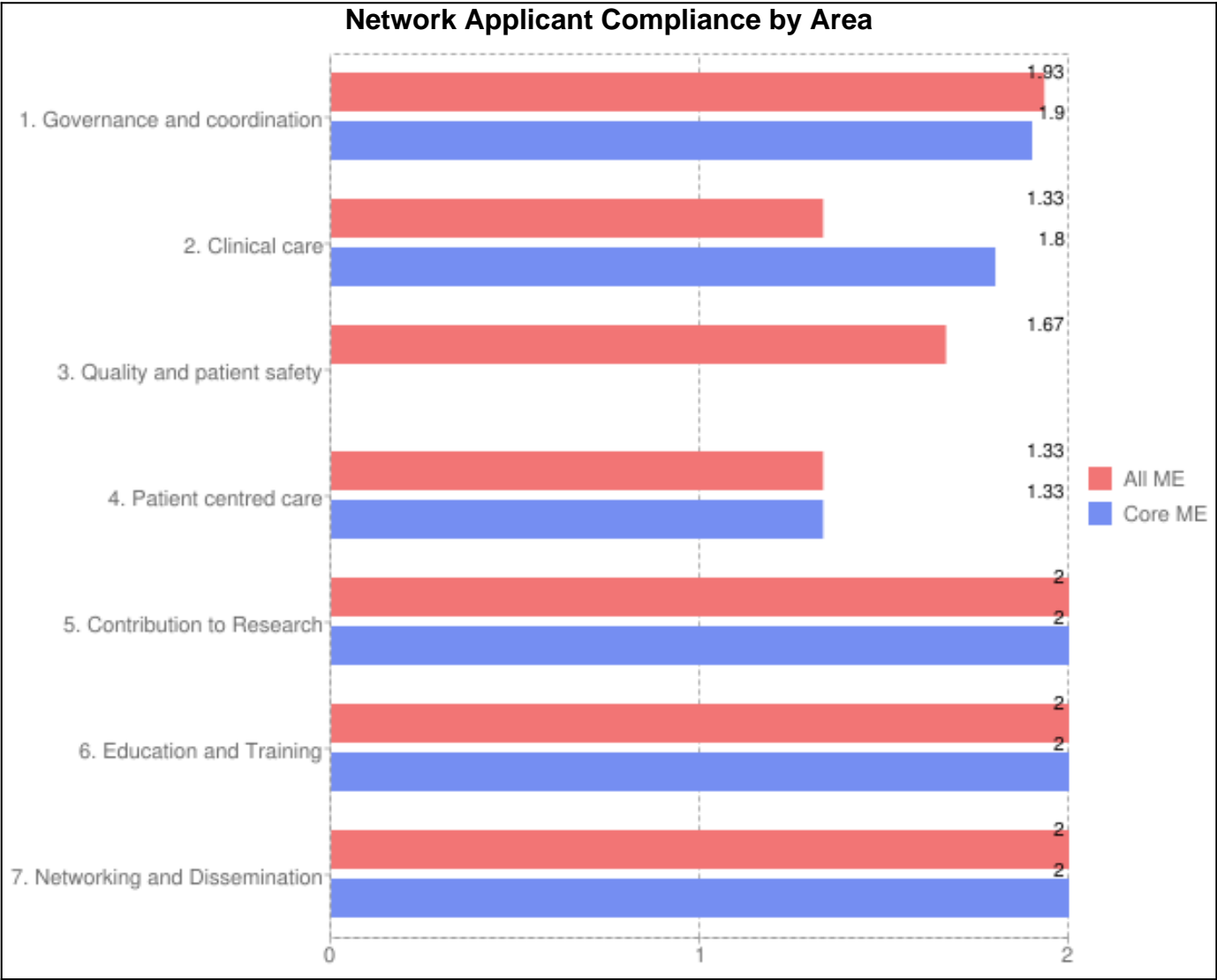



Figure 4











5. Detailed results for each area. Operational Criteria for the Network

The following tables show the Network's compliance with the ME in each area. Based on the evaluators' findings, strengths can be highlighted.

Core MEs are tagged with .




Two overall results are shown at the end of the table:

- Area average rating (all MEs in the area)
- Average core rating (only core MEs)

Governance and coordination		Evaluator's Rating
1.1.1 The structure and the implementation of the rules of procedure of the ERN's coordination board have facilitated the organization of tasks and the incorporation of new Members.		2
1.1.2 An efficient coordination structure to support the ERN is in place to assist the governing bodies in reporting, quality improvement, evaluation, meetings, and other activities.		2
1.1.3 Mechanisms to maintain or enhance the level of collaboration between the ERN members as well as its affiliates have been put into practice.		2
1.1.4 HCPs have been involved in specific ERN-related tasks, sharing responsibilities among all the Members of the ERN.		2
1.2.1 An ERN dashboard or similar has been implemented to monitor the activity, outcomes, and initiatives of the ERN and its Members.		2
1.2.2 There is an internal assessment of HCPs' participation.		2
1.2.3 HCP professionals' satisfaction with the performance of the ERN is periodically evaluated.		2
1.3.1 Patient representatives have been included in the governance framework of the ERN.		2
1.3.2 The Board has incorporated the opinion of patients and families when outlining strategies.		2
1.3.3 Patients and support groups are major stakeholders in ERN-related activities.		2
1.3.4 The ERN monitors and evaluates the involvement of patients in the activities of the ERN.		2
1.4.1 The ERN has identified goals, opportunities, and threats for the future.		1
<u>Evaluators observation:</u>		
<i>There is no SWOT analysis, but a credible statement of the network about their discussions about their future, including the implementation of new centers. Survey is out to map future needs.</i>		
1.4.2 The ERN has evaluated its own organisational and economic viability.		2
1.4.3 The ERN has developed a financial plan to meet its objectives including funding efforts and a		2

justified distribution of resources across members.



1.4.4 The ERN has ensured its connection with other existing networks, authorities, health systems, etc. for its long-term sustainability.	2
Average Rating	1,93
Core MEs Average Rating	1,9

Clinical care	Evaluator's Rating
<p>2.1.1 The ERN has developed or adapted (from other sources) and disseminated clinical guidelines and other types of clinical decision-making tools in collaboration with the HCPs.</p> <p><u>Evaluators observation:</u></p> <p><i>Guidelines are in preparation (although none have yet been completed). The point was discussed during the interview process, and the reasons and the readiness of the networks to proceed with this matter were credibly explained.</i></p>	 1
<p>2.1.2 The ERN has implemented guidelines and/or protocols to support transition and continuity of care from childhood, through adolescence, and into adulthood, where applicable.</p>	 2
<p>2.1.3 The ERN has developed recommendations for care pathways(2) based on the needs of patients, clinical evidence, and on the available organizational, professional, and technological resources. (2) A care pathway is a complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period. The aim of a care pathway is to enhance the quality of care across the continuum by improving risk-adjusted patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources. Defining characteristics of care pathways include: 1. An explicit statement of the goals and key elements of care based on evidence, best practice, and patients' expectations and their characteristics; 2. the facilitation of the communication among the team members and with patients and families; 3. the coordination of the care process by coordinating the roles and sequencing the activities of the multidisciplinary care team, patients and their relatives; 4. the documentation, monitoring, and evaluation of variances and outcomes; and 5. the identification of the appropriate resources</p>	 2
<p>2.1.4 The ERN has worked on recommendations for cross-border care pathways to ensure equality in the access to care within its area of expertise, according to the legislation applicable</p> <p><u>Evaluators observation:</u></p> <p><i>The network does not actively work on cross-border care, with an implication of future application of Joint Action on the integration of MS healthcare systems with the ERNs. If necessary, thought, such care is provided.</i></p>	0
<p>2.1.5 The ERN follows up the implementation of care pathways to encourage consistent use across its Members.</p> <p><u>Evaluators observation:</u></p> <p><i>Same as the previous criterion, the network believes that cross-border care pathways will be addressed by the Joint Action on the integration of MS healthcare systems with the ERNs.</i></p>	0
<p>2.1.6 Guidelines, care pathways, and protocols are rechecked and updated if needed at least every</p>	1


three years.

Evaluators observation:

New guidelines and their updates are in process, partially implemented. Existing guidelines are, however, in use.

2.2.1 The ERN has implemented a process for offering advice for complex patient cases provided by multidisciplinary healthcare teams.		2
2.3.1 The ERN promotes the use of technologies such as telemedicine, e-Health records, remote consultation, health information portals, electronic transfer of prescriptions, and multidisciplinary e-Meetings designed according to the needs and requirements of patients and families.		2
2.3.2 The ERN has implemented the CPMS to share clinical data, images, and additional information. If the ERN uses any other system, this should be compatible in all its centres and must meet national and European legal requirements.		2
Average Rating		1,33
Core MEs Average Rating		1,8


Quality and patient safety	Evaluator's Rating
3.1.1 The strategy includes specific objectives and recommended activities for their achievement.	2
3.2.1 The ERN has selected a pool of measures (indicators) to monitor clinical processes, performance or outcomes of care.	2
3.2.2 The indicators are periodically reported, and the information is used for collective reflection on outcomes to learn and improve.	1
<u>Evaluators observation:</u>	
<i>Indicators are in preparation, partially developed.</i>	
Average Rating	
1,67	
Core MEs Average Rating	
0	

Patient centred care	Evaluator's Rating
4.1.1 Educational resources for patients addressing disease management, coping skills and other practical skills, have been developed and disseminated.	 1
<u>Evaluators observation:</u>	
<i>Patient journeys are very comprehensive with detailed information and have been co-design with ePAGs. However, it has not been demonstrated specific indicators on patient education.</i>	

4.1.2 The ERN produces tailored information on patient safety standards and safety measures for patients and families to reduce or prevent errors. 0


Evaluators observation:

The ERN didn't evidence tailored information regarding patient safety measures to prevent or reduce errors.

4.2.1 The ERN collaborates with patient organisations to develop and implement care pathways, guidelines, protocols, and indicators.  1

Evaluators observation:

The ERN works with patients' organizations and ePAGs, as seen in the webpage, as well, they are called to contribute to publications, as an example, a chapter in a book about rare and complex urology diseases.

4.2.2 The ERN has undertaken initiatives to improve the safety and quality of care in collaboration with patient organizations.  2

4.3.1 The ERN has established a standardised common tool or methodology for measuring the patient and family experience. 2


4.3.2 The ERN periodically evaluates the needs and barriers to care experienced by patients and families and uses this information to implement actions to improve care. 2


Average Rating 1,33

Core MEs Average Rating 1,33

Contribution to Research


**Evaluator's
Rating**

5.1.1 Research gaps and opportunities have been identified and a research agenda has been developed.  2


5.1.2 The ERN has actively involved patients and other stakeholders in identifying research gaps and developing the agenda.  2

5.1.3 The ERN maintains ongoing technical oversight and discussions with HCPs to closely monitor and provide feedback on the research throughout the process. 2

5.1.4 The ERN implements actions to provide the future workforce with knowledge and skills to lead research. 2





5.2.1 The ERN fosters collaborative instrumental efforts (multicentre trials, participation in EU projects, etc.) amongst its Members, Affiliated Partners and relevant patient, professional and research organisations.  2





5.3.1 The ERN works to establish an EU wide solution for data sharing. 2

5.3.2 The ERN promotes the development of comprehensive registries and databases.  2

Average Rating 2

Core MEs Average Rating 2

Education and Training	Evaluator's Rating
6.1.1 The ERN has identified education, training, and professional development gaps within its area of expertise and defined priority areas for teaching and training.	 2
6.1.2 Plans have been implemented to address the priority areas for teaching and training in collaboration with Members, scientific societies, and other partners	 2
6.1.3 The plans have been evaluated and the areas of improvement identified have been addressed in the plans for the coming years.	2
6.1.4 ERN members periodically meet to review and share best practices, and discuss new evidence-based treatments, therapies, and healthcare technologies.	 2
6.2.1 Actions oriented to improve access to the educational resources available across Europe have been carried out.	 2
6.2.2 The participation of specialized healthcare professionals from Member States with insufficient number of patients or lacking technology or expertise has been facilitated and increasingly achieved.	2
Average Rating	2
Core MEs Average Rating	2

Networking and Dissemination	Evaluator's Rating
7.1.1 The ERN has enhanced the collaboration with other ERNs and HCPs to exchange and disseminate knowledge, best practices, clinical expertise, or other resources	 2
7.1.2 The ERN has developed collaboration strategies with Affiliated Partners from Member States with an insufficient number of patients or lacking technology or expertise to develop their skills	 2
7.1.3 The ERN has developed partnerships with other stakeholders of interest, such as scientific societies, centres of expertise, diagnostic laboratories, patient organisations, social care providers, industry, affiliated research groups or national healthcare authorities.	 2
7.2.1 The ERN provides accessible information highlighting sites and roadmaps for cross border expert advice and patients' referrals.	2
7.3.1 The ERN has defined and implemented a comprehensive communication and dissemination strategy.	 2
7.3.2 The ERN has developed actions to align information across target groups, i.e., defining audience, message, and methods to achieve the maximum level of inclusiveness of different groups.	2
Average Rating	2
Core MEs Average Rating	2

6. Evaluation of the achievement of the objectives and quality of the deliverables produced within the ERN's Specific Grant Agreements

The technical reports derived from these Specific Grant Agreements (SGAs) summarise the activities carried out by the Network in each work package as well as the deliverables produced during the 5 years in which the SGAs are established. The following table shows the findings regarding the review of the Grant Technical Reports of the Network:

The activities carried out by the different work packages in the last 5 years are clearly described

Comments:

The ERN eUrogen was provided 2 specific grant agreements, both are documented by SGA1 and SGA2 reports. Both grants are well organized in specified work packages and monitored by accomplished milestones and deliverables. The first SGA1 was mostly used for the establishment of the network and its organisation, setting the governmental structure and functioning of the network. Further, the topics included support of collaboration of centers and also collaboration with other ERNs as well as scientific societies,. The network used the support for the consolidation of the registry, for education, especially for their regular webinar program.

The ERN has evaluated the achievement of the objectives established in the initial strategic plan for the next 5 years

Comments:

The ERN has evaluated its achievement and improved and simplifies its approach, The second SGA2 is divided into 7 clearly defined WPs, management and organization, dissemination, WP3 is dedicated to evaluation (especially important with new members), then other WPs deal with virtual telemedicine (CPMS), creation of guidelines and education and training. The approach clearly reflects the maturity of the network and the efficiency of its management.

Expected deliverables have been produced in a timely manner

Comments:

Milestones and deliverables were produced as expected, with an exception of guidelines which showed up more complicated especially in their implementation. Another obstacle was caused by COVID pandemic and caused a limit to delivered reports of training.

Percentage (%) of deliverables produced from the initially planned

Comments:

20

The deliverables produced suit their original purposes

Comments:

The deliverables dedicated to the management, organization, education and training and also dissemination work very well and are reflected in an improvement of the process. The deliverables on guidelines are less efficient.

Total of deliverables produced from the initially planned

Comments:

80%

Observations of deliverables produced from the initially planned

Comments:

All deliverables led to the improvement of relevant areas in the second SGA2.

7. Summary of the evaluation of the Members of the Network

The Operational Criteria for the HCP teams are grouped into the following 7 thematic areas:

1. Patient centred care
2. Organisation and management
3. Research, education and training
4. Exchange of expertise, information systems and e-Health
5. Quality and safety
6. Competence, experience, and outcomes of care
7. Human resources

7.1. Average score of all the HCPs in each area

Each area consists of one or more criteria with measurable elements in line with the Commission Implementing Decision (2014/287/EU). The following figure represents the average rating of all the Healthcare Providers teams in each area.

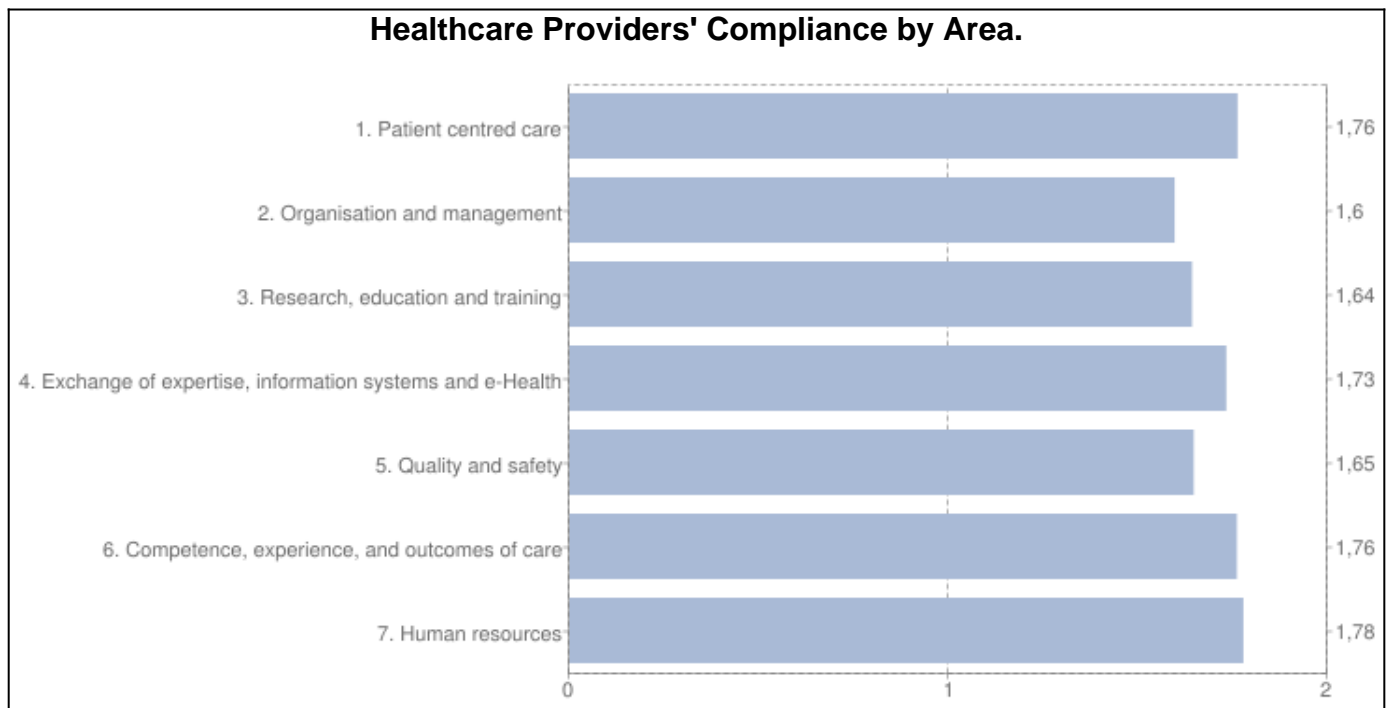




Figure 5

Legend
0: No Activity / Not Developed
1: Partially Developed
2: Fully Developed









Table 3



7.2. Average score of all the HCPs in each Measurable Element in each area







The following tables show the average rating of all the HCPs with the ME in each area. Core MEs are tagged  and those MEs that are related to specific contributions to the Network are tagged .

Three overall results are shown at the end of the table:














- Area average rating (all MEs in the area from all HCPs)
- Core MEs average rating (core MEs in the area from all HCPs)
- Contribution ME Average Rating (MEs contributing to the Network in the area from all HCPs)






Patient centred care	Evaluator	Rating
1.1.1 The HCP team provides patients and/or their families with written information about the facility, the organisation, and its specific area of expertise.		2
1.1.2 The HCP team gives patients and/or their families written information about their rights and responsibilities in a language they can understand		2
1.2.1 Patient and family educational needs are addressed in a defined process.		2
1.2.2 Education activities are recorded in the medical record.		2
1.3.1 The information about complaints, violation of the rights, and concern of the care and/or safety of patients and their families is periodically analysed and integrated into a continuous quality improvement process. An annual report is made on the complaints and the improvement actions carried out.		2
1.4.1 The HCP team routinely measures patient and family satisfaction using the ERN common tool.		2
1.5.1 The Informed Consent (IC) is documented in the patient's medical record, including the risks, benefits, and alternatives to the procedure to be performed, and must be understandable to patients.		2
1.5.2 The document to obtain IC for research must contain information on the risks, benefits, and alternatives to the procedure to be performed, and conflicts of interest (financial or non-financial).		2
1.5.3 The patients' medical records included in a clinical trial contain information about their participation in it.		2
1.6.1 The HCP team provides comprehensive diagnostic and treatment information.		2
1.6.2 Information is provided in the language of the different populations served.		2
1.6.3 The information necessary for the follow-up of the patient after the treatment is provided		2
1.6.4 The HCP team provides information on coordinating care with other levels of care.		2
1.6.5 The information provided to the patient and the family on the follow up and coordinating care with other levels of care is included in the clinical record.		2
1.6.6 Unanticipated outcomes and complications are disclosed to patients and their families as established in the HCP policy/procedure		2



1.7.1 In hospitalised patients with rare diseases or complex patients, pain is regularly identified with a standardised scale as established in the hospital's protocol.		2
1.8.1 Professionals encourage the participation of the patient and their family, based on their interests, in the care process and in decision-making.		2
1.9.1 The HCP team provides information on patients' associations and that can support the patient and their family.		2
1.9.2 The HCP team collaborates and carries out activities with patients' associations.		2
Area Average Rating		1,76
Core MEs Average Rating		1,82
Contribution MEs Average Rating		1,67




Organisation and management		Evaluator Rating
2.1.1 The HCP team establishes collaboration with affiliated centres in neighbouring countries for cross-border care or for training / dissemination of information for professionals and patients.		2
2.1.2 The HCP team establishes and maintains a set of policies and procedures addressing aspects for the management and health care services of cross border patients.		2
2.1.3 The HCP team shares information with patients and their families about any tariffs that may be in place for the reimbursement of care, as well as services provided and expected benefits.		2
2.2.1 When necessary, the HCP team has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.		2
2.2.2 The HCP team sends the receiving organization a written summary about the patient's clinical condition and the interventions carried out in the hospital from which he/she is referred. The process is recorded in the medical record.		2
2.3.1 Discharge reports contain at a minimum: diagnoses; significant physical findings; diagnostic, surgical and medical procedures performed; medication received at discharge; and follow-up instructions.		2
2.3.2 The HCP team provides clinicians post discharge with complete discharge summaries in English for all cross-border patients.		2
2.4.1 The HCP team collaborates in training or dissemination activities with centres which are not members of the ERN.	 	2
2.5.1 The HCP team shares patient information or participates in panels of complex cases through the CPMS with other members of the ERN.		1
2.5.2 The CPMS of each patient includes: a) physical needs b) social needs c) psychological needs d) treatment and care plan e) sign off completed		1
Area Average Rating		1,6







Core MEs Average Rating	1,64
Contribution MEs Average Rating	1,73

Research, education and training	Evaluator Rating
3.1.1 The HCP team has a defined set of objectives for its education and training activities aligned with the ERN.  	2
3.1.2 The HCP team regularly detects the training needs of the staff members.	2
3.1.3 Education and training activities are delivered to providers involved in the same chain of care within and outside the HCP's facility.	2
3.1.4 The HCP team participates in the training activities organised by the ERN.  	2
3.2.1 The HCP team leads and/or participates in research activities and clinical trials, at both national and international level, within the ERN's area of expertise.  	2
3.2.2 The HCP team ensures that records from research activities and clinical trials are safely stored.	2
3.2.3 The HCP team involves patients and / or their representatives in the most relevant aspects of the research process. 	2
3.2.4 The HCP team shares the results, in a timely manner, from its research activities and clinical trials through scientific publications.  	2
3.2.5 The results should be disseminated to patient associations in lay language. 	1
3.2.6 The HCP team provides patients' information for the registries or databases promoted by the ERN.  	1
3.2.7 The HCP team is contributing to disseminate the ERN activities. 	2
Area Average Rating	1,64
Core MEs Average Rating	1,64



Contribution MEs Average Rating		1,57
Exchange of expertise, information systems and e-Health		Evaluator Rating
4.1.1 The HCP team offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment.		2
4.2.1 The HCP team uses telemedicine and other e-health tools.		2
4.2.2 Professional telemedicine guidelines available are used to guarantee the homogeneity of its use.		2
4.2.3 The HCP team should identify inclusion and exclusion criteria for potential telehealth patients.		2
4.2.4 Patients and family members who access telehealth have the right to have their privacy guaranteed.		2
4.2.5 When surveying patient and family satisfaction, satisfaction with the services provided by telehealth should be included, when appropriate.		1
4.3.1 The HCP team uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s), agreed within the ERN.	 	2
Area Average Rating		1,73
Core MEs Average Rating		1,9
Contribution MEs Average Rating		1,8

Quality and safety		Evaluator Rating
5.1.1 The HCP team applies a strategy of quality and safety improvement, which includes specific objectives and recommended activities for the achievement of the objectives		2
5.1.2 The main objectives of the strategy on quality and safety improvement include: a) Hand hygiene b) Prevention and control of healthcare related infections c) Prevention of medication errors (completed medical orders, process of administration, identified high-risk medications) d) Ensure safe surgery (verification, time out and sign out) e) Unequivocal identification of patients		2
5.1.3 The quality and safety strategies are implemented, and the results obtained are evaluated.		2
5.1.4 There is a procedure in place to report, document, investigate, and learn from adverse events and complications.		2
5.1.5 The HCP team uses this information to make ongoing improvements.		2

5.1.6 All healthcare personnel are familiar with the system for reporting safety incidents and adverse events.		2
5.1.7 A procedure is implemented to provide information on adverse events with patient damage to patients and their families.		2
5.2.1 The HCP team adopts and implements clinical practice guidelines and decision-making tools developed or adapted by the ERN.	 	2
5.2.2 An annual evaluation on adequate compliance of the clinical practice guidelines is carried out using the indicators agreed in the ERN.		1
Area Average Rating		1,65
Core MEs Average Rating		1,66
Contribution MEs Average Rating		1,38

Competence, experience, and outcomes of care		Evaluator Rating
6.1.1 To maintain its competency and expertise, the HCP team serves the minimum/optimal number of patients per year as defined by the ERN based on professional/technical standards or recommendations.		2
6.1.2 To maintain its competency and expertise, the HCP team serves the minimum/optimal number of procedures per year as defined by the ERN based on professional/technical standards or recommendations.		2
6.1.3 The HCP team regularly collects, and monitors process and outcome indicators as established in the ERN.	 	2
6.1.4 The HCP team is actively involved in the activities organized for the development of the ERN.	 	2
Area Average Rating		1,76
Core MEs Average Rating		1,76
Contribution MEs Average Rating		1,7

Human resources	Evaluator
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		Rating
7.1.1 The HCP team identifies and documents the skills and professional qualifications required for the new staff in the multidisciplinary team performing activities critical to the quality of patient care.		2
7.1.2 There is a process to routinely assess staff skill to ensure adequate performance of specialized tasks.		2
7.2.1 There are regular structured meetings between multidisciplinary team members.		2
7.2.2 The decisions of the multidisciplinary clinical sessions on a given patient are recorded in their medical record.		2
Area Average Rating		1,78
Core MEs Average Rating		1,82
Contribution MEs Average Rating		0

7.3. Outcome of the evaluation for HCPs

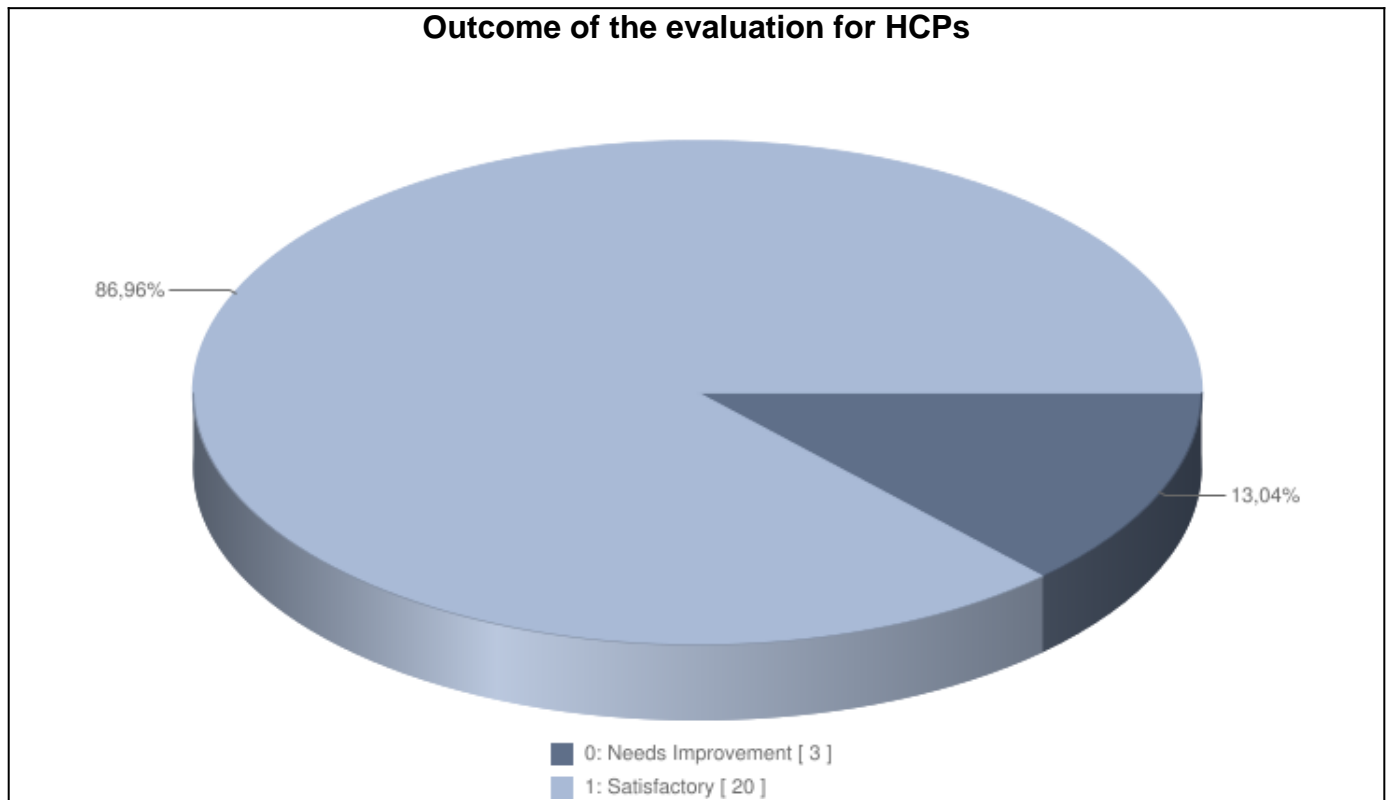


Figure 6

The following table provides a summary of the outcome of the evaluation for each Healthcare Provider.

HCP	Healthcare Provider	Outcome of the Evaluation
1	Aarhus University Hospital	SATISFACTORY
2	Assistance Publique-Hôpitaux de Paris, Hôpital Necker-Enfants Malades	SATISFACTORY
3	Charité Universitätsmedizin Berlin (*)	NEEDS IMPROVEMENT
4	Copenhagen University Hospital, Rigshospitalet (*)	SATISFACTORY
5	Erasmus MC: University Medical Center Rotterdam (*)	SATISFACTORY
6	Fondazione Policlinico Gemelli, IRCCs, Rome (*)	SATISFACTORY
7	Foundation IRCCS CA'Granda Ospedale Maggiore polyclinic - Milan	SATISFACTORY
8	Instituto Português de Oncologia do Porto	SATISFACTORY
9	Karolinska University Hospital	SATISFACTORY
10	Klinikum Bremen-Mitte	SATISFACTORY
11	Klinikum der Universität München	NEEDS IMPROVEMENT
12	Pediatric hospital Bambino Gesù, Rome	SATISFACTORY
13	Radboud University Medical Centre Nijmegen	SATISFACTORY
14	Sahlgrenska University Hospital (*)	SATISFACTORY

15	Universitätsklinikum Leipzig	SATISFACTORY
16	Universitätsklinikum Hamburg-Eppendorf	SATISFACTORY
17	Universitätsklinikum Regensburg	SATISFACTORY
18	University Clinical Hospital of Medical University Gdansk	SATISFACTORY
19	University Hospital Ghent	SATISFACTORY
20	University Hospital Leuven	SATISFACTORY
21	University Hospital Liège	NEEDS IMPROVEMENT
22	University Hospital of Padova	SATISFACTORY
23	Vilnius University Hospital Santaros Klinikos	SATISFACTORY

Table 4

(*) HCPs with onsite audit.

8. Outcome of the evaluation for the Network

The following table shows the total score for all MEs in each area as well as the total score for core MEs and of those MEs that identify HCP contribution to the mission of the Network.

Scoring Table			
Thematic Area	Total score	Total possible score	Percentage of total
Governance and coordination			
All MEs	29	30	96,67%
Core MEs	19	20	95%
Clinical care			
All MEs	12	18	66,67%
Core MEs	9	10	90%
Quality and patient safety			
All MEs	5	6	83,33%
Core MEs	0	0	0%
Patient centred care			
All MEs	8	12	66,67%
Core MEs	4	6	66,67%
Contribution to Research			
All MEs	14	14	100%
Core MEs	8	8	100%
Education and Training			
All MEs	12	12	100%
Core MEs	8	8	100%
Networking and Dissemination			
All MEs	12	12	100%
Core MEs	8	8	100%
Overall			
Grand Total	92	104	88,46%
Core Total	56	60	93,33%

Table 5

Considering all the information reviewed during the evaluation process, the level of accomplishment of the objectives that the ERN originally selected in the application for the initial assessment is the following:

Objectives set out in Article 12(2) of Directive 2011/24/EU	
<i>To help realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies</i>	<input type="checkbox"/> Excellent <input checked="" type="checkbox"/> Very good <input type="checkbox"/> Acceptable <input type="checkbox"/> Poor <input type="checkbox"/> Failing
<i>To facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare</i>	<input type="checkbox"/> Excellent <input checked="" type="checkbox"/> Very good <input type="checkbox"/> Acceptable <input type="checkbox"/> Poor <input type="checkbox"/> Failing
<i>To reinforce research, epidemiological surveillance like registries and provide training for health professionals</i>	<input checked="" type="checkbox"/> Excellent <input type="checkbox"/> Very good <input type="checkbox"/> Acceptable <input type="checkbox"/> Poor <input type="checkbox"/> Failing
<i>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</i>	<input type="checkbox"/> Excellent <input checked="" type="checkbox"/> Very good <input type="checkbox"/> Acceptable <input type="checkbox"/> Poor <input type="checkbox"/> Failing
<i>To encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network</i>	<input type="checkbox"/> Excellent <input type="checkbox"/> Very good <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Poor <input type="checkbox"/> Failing

The methodology has taken into account the overall score and the detailed findings of this report, and based on the decision guideline set out in Table 6, the result of the evaluation of this Network is:

- SATISFACTORY**
- NEEDS IMPROVEMENT**

The decision rules for the final outcome of the Network, based on the methodology, have been based on:

Decision guideline	
✓	Get a score of 1 or 2 in 90% of core ME (actual percentage: 100%)
✓	Get an average score at least 70% of the highest possible score in the group of core ME (actual percentage: 93%)

Table 6

Number of core MEs scored <1:0

Number of MEs scored as Not Applicable:0

9. Improvement Plan

Considering the final result of the evaluation with "Satisfactory", no improvement plan should be developed.

10. Next steps

The Network and Healthcare Providers are encouraged to follow up on the recommendations in this report, as appropriate.

The Board of Member States will issue the final approval for ERNs based on the evaluation results.

If you have any questions, please contact the IEB through the Communication Area of the project in ERN - Assessment Tool.

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Evaluation Coordinator

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15 September 2023

Appendix A: Rating Scale

The following rating scale is used by the evaluators to evaluate compliance with the operational criteria for the Networks and Healthcare Providers. The same rating scale is used by the applicant for the self-evaluations.

Rating	Guidelines
0: No Activity / Not Developed	<p>All Criteria: this rating is used when if then answer is “scarcely” or “none” to the specific measurable element and/or when there are no actions in place or there is insufficient evidence to support compliance.</p> <p><i>This rating may also be used when the practice is not developed by any of the Healthcare Providers of the Network (if applicable).</i></p> <ul style="list-style-type: none"> • <u>Considerations:</u> • Evidence of compliance is not appropriate for the purpose or not complete. • Actions have been described but they are not implemented. • When there are multiple requirements in one measurable element, less than 50% are present.
1: Partially developed	<p>All Criteria: this rating is used if the answer is “incomplete” or “partway” to the specific measurable element and/or when there are some actions in place or there is some evidence to support compliance</p> <p><i>This rating may also be used when the practice is not developed by any of the Healthcare Providers of the Network (if applicable).</i></p> <ul style="list-style-type: none"> • <u>Considerations:</u> • Evidence of compliance does not cover the whole period of time in which the requirement is applicable. • Not all actions required have been implemented. • When there are multiple requirements in one measurable element, at least half (50%) are present.
2: Fully developed	<p>All Criteria: this rating is used if the answer is “totally” or “completely” to the specific measurable element and/or when there is sufficient evidence to support compliance.</p> <p><i>This rating may also be used when the practice is not developed by any of the Healthcare Providers of the Network (if applicable).</i></p> <ul style="list-style-type: none"> • <u>Considerations:</u> • Evidence of compliance covers the whole period of time in which the requirement is applicable. • All actions required have been implemented or are underway. • When there are multiple requirements in one measurable element, all are present.

Table 7