

European Reference Networks: Main achievements and ongoing initiatives

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European
Reference
Networks

DG SANTE - European Commission

European Reference Networks

https://ec.europa.eu/health/ern_en



24 European Reference Networks



ERN BOND	Bone Diseases
ERN CRANIO	Craniofacial anomalies and ENT disorders
Endo-ERN	Endocrine Conditions
ERN EpiCARE	Rare and Complex Epilepsies
ERKNet	Kidney Diseases
ERN GENTURIS	Genetic Tumour Risk Syndromes
ERN-EYE	Eye Diseases
ERNICA	inherited and congenital anomalies
ERN-LUNG	Respiratory Diseases
ERN-RND	Neurological Diseases
ERN-Skin	Skin Disorders
ERN EURACAN	Solid Adult Cancers

ERN EuroBloodNet	Onco-Hematological Diseases
ERN EUROGEN	Urogenital Diseases
ERN EURO-NMD	Neuromuscular Diseases
ERN GUARD-HEART	Diseases of the Heart
ERN ITHACA	Congenital Malformations and Intellectual Disability
MetabERN	Hereditary metabolic diseases
ERN PaedCan	Paediatric Cancer
ERN RARE-LIVER	Hepatological Diseases
ERN ReCONNET	Connective Tissue and Musculoskeletal Diseases
ERN RITA	Immunodeficiency, Auto-Inflammatory and Auto Immune Diseases
ERN TRANSPLANT-CHILD	Transplantation in Children
VASCERN	Multisystemic Vascular Diseases

ERN Ecosystem



- ✓ Virtual remote consultations and clinical data on patient cases
- ✓ Knowledge Generation
- ✓ Research on rare diseases
- ✓ Education & professional training

Key achievements so far

24 ERNs



25 Countries

Affiliated Partners

Call for new members

2017

2019-2021

Established structure

- ✓ Clear Legal Basis and Institutional framework
- ✓ Consolidated governance structure and networking capacity
- ✓ EU funding sources available
- ✓ Joint ownership (Member States authorities, patients, health professionals, hospitals, EU institutions)
- ✓ Strong political support (EU) and perceived as a good example of European cooperation
- ✓ 24 Networks started their clinical work with patients

Actions and outcomes

- ✓ Clinical cooperation, **patient cases** discussed virtually (CPMS)
- ✓ Knowledge Generation and development of **training, education and awareness** actions
- ✓ Development and implementation of **clinical practice guidelines**
- ✓ Important number of **scientific publications**
- ✓ Development of **research projects**
- ✓ Support for ERN patient **registries** as part of EHDS



ERNs: future activities

- Manage ERN enlargement and consolidate the ERN system for clinical collaboration (including IT infrastructure)
- Support ERN knowledge generation actions
- Support ERN research activities
- Integrate ERNs into national healthcare systems
- **Demonstrate the added value of the ERNs:
Evaluation and monitoring**



ERNs Evaluation and monitoring

- Evaluation of Cross-border Healthcare Directive (2011/24/EU), including legal provisions on ERNs and rare diseases cooperation (2021-2022)
- First periodic 5-year evaluation of performance of ERNs and their members (2022-2023)

I. Evaluation of CBHC Directive/ERNs (2021-22)

- Evaluation of the policy and legislation in accordance with “Better Regulation” principles
- 10 years after the adoption of the Directive
- The evaluation will assess:
 - How the Directive’s objective to facilitate access to safe and high quality cross-border healthcare in another Member State has been met?
 - To what extent is the Directive relevant for meeting patient needs in cross-border healthcare?
 - To what extent the Directive has promoted patient rights and cross-border cooperation between Member States for the benefit of EU citizens?
 - Approaches implemented by Member States in practice? How effectively these are working, what barriers patients still face seeking healthcare across borders?
 - **How the treatment and diagnosis of patients with rare and complex diseases have benefitted from the support of the ERNs?**

I. Evaluation of CBHC Directive/ERNs (2021-22)

Some evaluation questions related to ERNs:

- How effective is the directive in supporting the diagnosis and treatment of patients with rare and complex diseases through ERNs?
- How effective is the directive in facilitating knowledge sharing on rare and complex diseases among EU healthcare professionals via ERNs?
- What has been the impact of the directive on the research on rare and low prevalence and complex diseases through the ERNs?
- Are the ERNs as set out in the directive still relevant for meeting the needs of patients with rare and complex diseases?
- In what ways the ERNs established by the Directive provide an added value for patients with rare and complex diseases compared to the national solutions alone?

I. Evaluation of CBHC Directive/ERNs (2021-22)

Timelines:

- Evaluation started in January 2021 (Roadmap published for feedback)
- Open Public Consultation (4 May-27 July 2021):
<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Evaluation-of-patient-rights-in-cross-border-healthcare>
- Targeted Stakeholder consultations
- Final Evaluation report: 1st half of 2022

Next steps?

II. “AMEQUIS” for ERNs / First periodic 5-year ERN evaluation

1. “Assessment”

- Initial assessment of networks and healthcare providers wishing to join the ERN system
- Each network's and healthcare provider's application should be technically assessed according to the criteria set out in Delegated Decision 2014/286/EU

2. “Monitoring”

- Continuous monitoring of performance of ERNs and their members throughout the ERN lifecycle
- Initial basic set of 18 common indicators (structure, process and outcomes) agreed by ERNs (ERN monitoring system)

3. “Evaluation”

- Periodic evaluation of performance of the networks and their members, five years after their approval or last evaluation (Implementing Decision 2014/287/EU)

 **Intergrated Continuous Quality Improvement
System of ERNs**

II. First periodic 5-year evaluation of ERNs and their members

Timelines:

- AMEQUIS project: methodology, manual and procedure for the evaluation; to be completed in Q1 2022.
- Appointment of new Independent Assessment and Evaluation body: 1st half 2022
- Start of the ERN 5-year evaluation: 2nd half 2022
- Final evaluation reports on each network and each member: 2023



EU4HEALTH Programme:

- Adopted in March 2021 (Regulation (EU) 2021/552)
- €5.3 billion for actions with an EU added value, complementing EU countries' policies and pursuing one or several of EU4Health's objectives
- EU4Health will pave the way to a European Health Union by investing in health priorities, including Europe's Beating Cancer Plan actions and the European Reference Networks



- ERNs explicitly mentioned under the **specific objectives** of the Programme for 2021-2027
- Grants to the ERNs to be awarded without prior publication of calls for proposals (**direct grants**) and may be up to 100 % of the eligible costs (**no co-funding** requirement anymore)

Specific ERN actions in 2021 Annual Work Programme:

- Direct Operating Grant to ERN eUROGEN;
- Direct Grant to Orphanet: technical assistance and support for disease codification, knowledge and information sharing;
- Upgrade of the CPMS to a new enhanced modular version and maintenance of the current CPMS until the new one becomes available;
- Virtual ERN and EHDS Academy;
- Framework contract for independent assessment and evaluation bodies for ERNs;
- Service contract for ERN logistic, administrative and secretarial support;
- Analysis of options for administrative simplification for ERN coordination teams.

European Reference Networks 2017-2021/22:

Important achievements but also existing challenges

European Reference Networks beyond 2022

Need to turn the challenges into opportunities!



