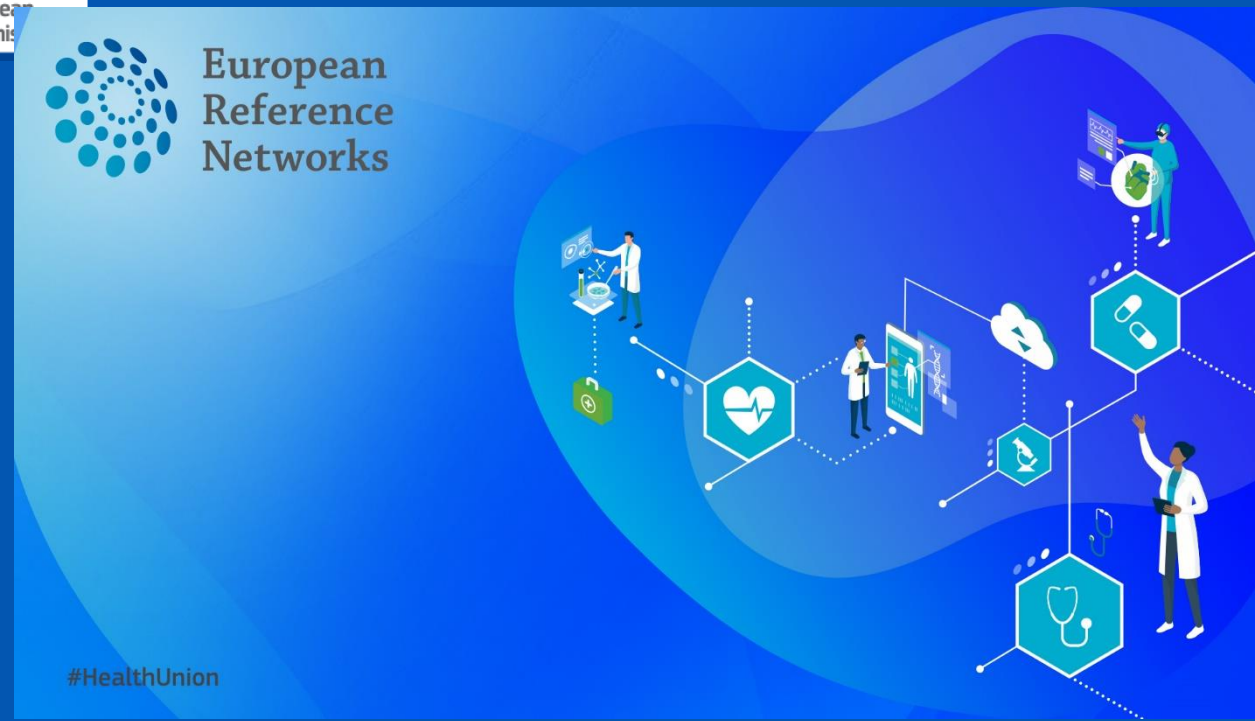




European Reference Networks and their evaluation

Conference on Rare Diseases,
Bilbao, 11 October 2023



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The European Reference Networks for Rare Diseases

24 Networks of healthcare providers **improving quality, and safety and access to highly specialised healthcare**

Patients affected by rare or low prevalence and complex diseases

Added value at EU level

Multidisciplinary approach
(different specialities/areas of knowledge)

Need of cooperation:

- Scarcity knowledge
- Need education
- Complexity / high cost
- Effectiveness in the use of resources

"The knowledge travels, not the patient"

24 European Reference Networks for Rare Diseases

[Endo-ERN](#): European Reference Network on endocrine conditions.

[ERKNet](#): European Reference Network on kidney diseases.

[ERN BOND](#): European Reference Network on bone disorders.

[ERN CRANIO](#): European Reference Network on craniofacial anomalies and ENT disorders.

[ERN EpiCARE](#): European Reference Network on epilepsies.

[ERN EURACAN](#): European Reference Network on adult cancers (solid tumours).

[ERN EuroBloodNet](#): European Reference Network on haematological diseases.

[ERN eUROGEN](#): European Reference Network on urogenital diseases and conditions.

[ERN EURO-NMD](#): European Reference Network on neuromuscular diseases.

[ERN EYE](#): European Reference Network on eye diseases.

[ERN GENTURIS](#): European Reference Network on genetic tumour risk syndromes.

[ERN GUARD-HEART](#): European Reference Network on diseases of the heart.

[ERNICA](#): European Reference Network on inherited and congenital anomalies.

[ERN ITHACA](#): European Reference Network on congenital malformations and rare intellectual disability.

[ERN LUNG](#): European Reference Network on respiratory diseases.

[ERN PaedCan](#): European Reference Network on paediatric cancer (haemato-oncology).

[ERN RARE-LIVER](#): European Reference Network on hepatological diseases.

[ERN ReCONNET](#): European Reference Network on connective tissue and musculoskeletal diseases.

[ERN RITA](#): European Reference Network on immunodeficiency, autoinflammatory and autoimmune diseases.

[ERN-RND](#): European Reference Network on neurological diseases.

[ERN Skin](#): European Reference Network on skin disorders.

[ERN TRANSPLANT-CHILD](#): European Reference Network on transplantation in children.

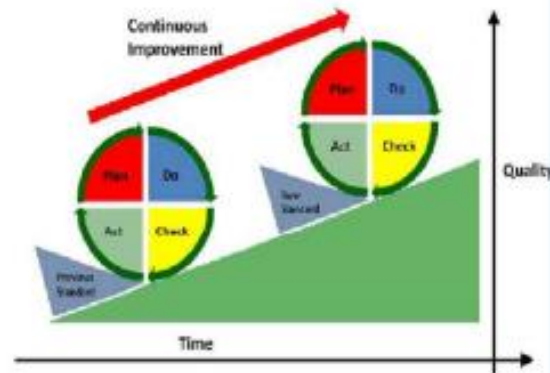
[MetabERN](#): European Reference Network on hereditary metabolic disorders.

[VASCERN](#): European Reference Network on multisystemic vascular diseases.

Current ERNs External Evaluation

AMEQUIS

- Assessment
- Monitoring
- Evaluation
- Quality
- Improvement
- System



Initial assessment of networks (Delegated Decision 2014/286/EU)

Continuous monitoring of performance of ERNs and their members (18 common indicators (structure, process and outcomes) agreed by ERNs)

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

- After 5 years of membership
- 24 ERNs and 840 members
- Process and methodology based on specific legislation (Implementing Decision 2014/287/EU as amended)
- Evaluation Manual and Toolbox available online
- Evaluation results: Reports, Feedback, amendments and improvements

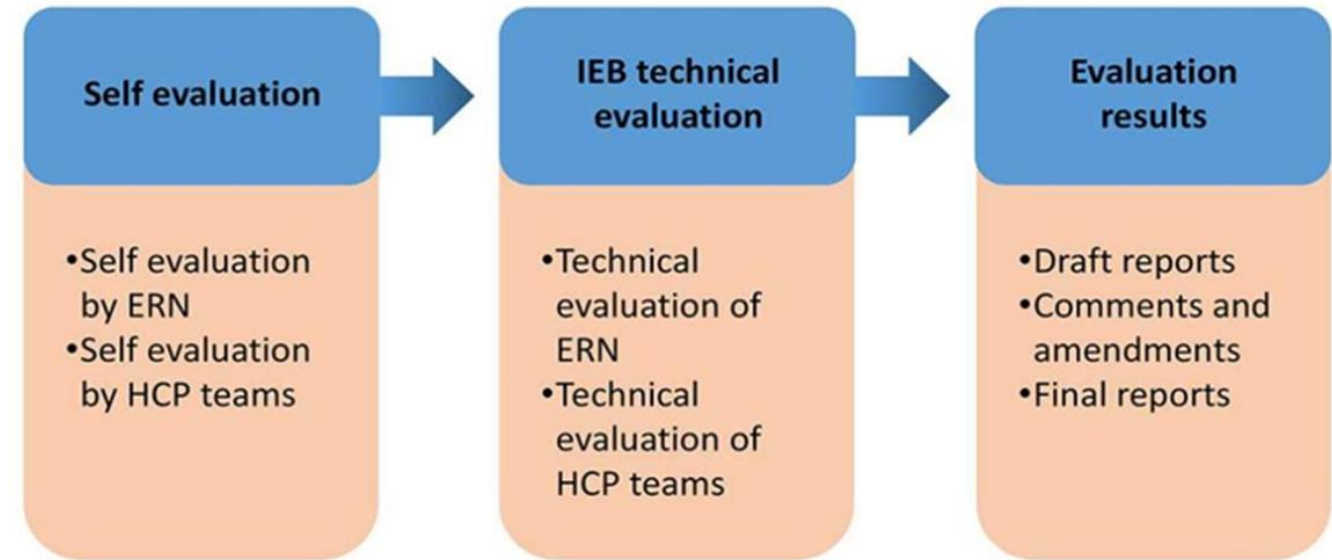
Current ERNs External Evaluation

Objectives:

- To identify best Practises in the development of the Networks
- To identify the areas for improvement

Criteria:

- European Reference Networks: 7 areas, 20 operational criteria with 52 measurable elements
- Healthcare Providers: 24 operational criteria with 64 measurable elements



IEB (Independent Evaluation Body); ERN (European Reference Network for Rare Diseases); HCP (Health Care Provider)

Preliminary evaluation results

- All 24 ERNs have achieved satisfactory results.
- 87% HCP units out of 840 are evaluated satisfactory
- 10% of evaluated HCP units have received a preliminary “needs improvement” result and were invited to submit the improvement plan.
- Results will be published in the EU website [Evaluation of the European Reference Networks](https://european-council.europa.eu/media/eu-website/evaluation-of-the-european-reference-networks) (europa.eu)

Next steps:

- The results of the evaluation process will be presented to Board of Member States during the plenary meeting on 24th October 2023.
- Board of Member States will decide whether to grant one year implementation period followed by re-evaluation to those members that submitted the improvement plan.
- Board of Member States will decide on termination for those Members that do not fulfill the evaluation criteria.
- 626 members which joined the ERN system in 2022 will be evaluated latest in 2027

More information on ERNs...



...can be found on the EC website:

https://health.ec.europa.eu/european-reference-networks_en

Information and recent news

- Available materials

[Video](#)

Thank you for your attention!

Any questions?



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EU action on rare diseases



Research activities

More than 2.9 billion funded
from the Commission
New Partnership on Rare
Diseases



24 European Reference Networks

1669 healthcare providers
– 395 hospitals



Pharmaceutical legislation

New legislative
proposal - Orphan
drugs



EU Platform RD Registries

More than 50 000
rare diseases
patients



European Health Data space

New legislative proposal