



DEMYSTIFYING AMEQUIS

WEBINAR

15.06.2022

[EURORDIS.ORG](https://eurordis.org)



Agenda

Duration Total: 45 mins	Topics	Lead
5 mins	Introduction	Ines Hernando
5 mins	Overview of AMEQUIS	Matt Bolz-Johnson
5 mins	Part 1: Assessment	
5 mins	Part 2: Monitoring	
5 mins	Part 3: Evaluation	
5 Min	Part 4. Quality Improvement	
15 mins	Questions & Answers	All



Introduction

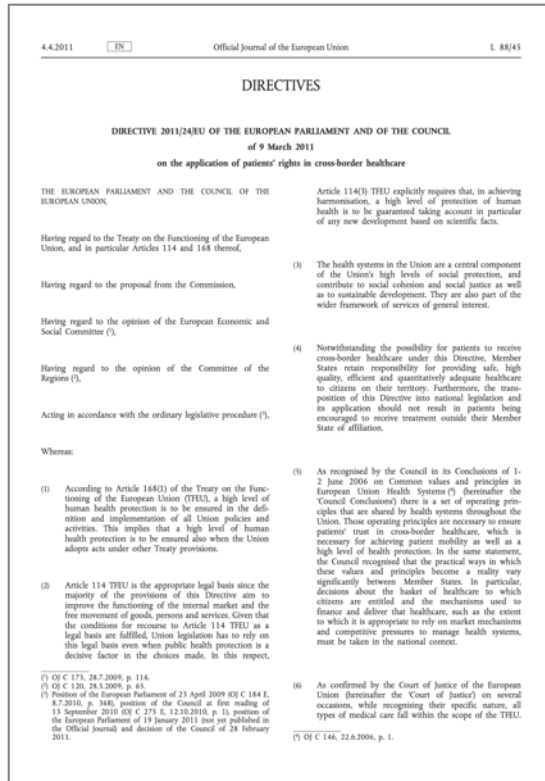
Ines Hernando



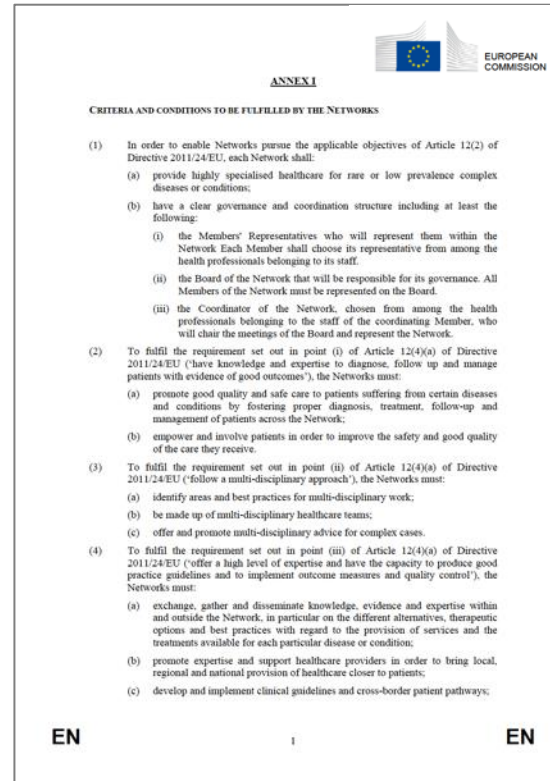
Overview for AMEQUIS

Matt Bolz-Johnson

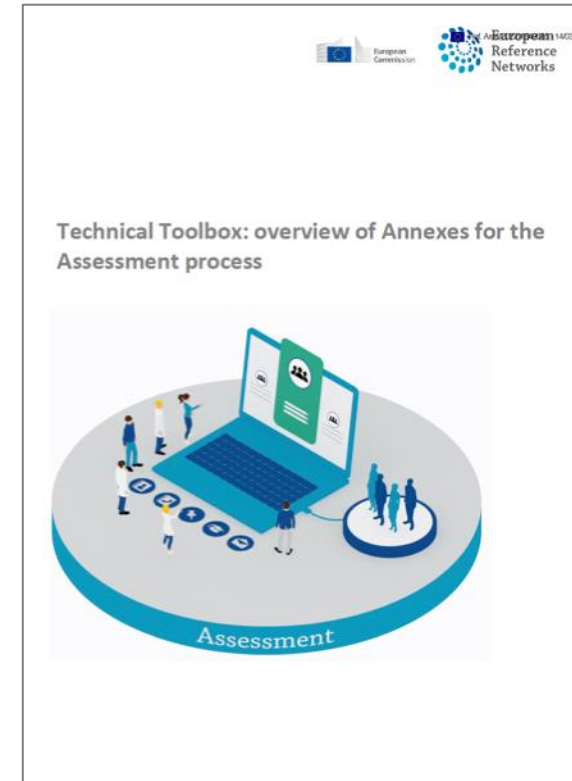
Core Reference Documents: Overview



Cross-border Healthcare Directive (2011/24/EU)



ERN Delegated Decision (2014/286/EU)



Application Form, Grant Agreements & Operational Criteria

Cross-border Healthcare Directive

ERNs' Objectives

European Reference Networks shall have **at least 3 of the following objectives:**

1. help realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems;
2. contribute to the pooling of knowledge regarding sickness prevention;
3. facilitate improvements in diagnosis & delivery of high-quality, accessible and cost-effective healthcare for patients with conditions requiring a particular concentration of expertise domains where expertise is rare;
4. maximise the cost-effective use of resources by concentrating them where appropriate;
5. reinforce research, epidemiological surveillance and provide training for health professionals;
6. facilitate mobility of expertise, develop, share and spread information, knowledge and best practice and foster developments of the diagnosis and treatment of rare diseases, within and outside the networks;
7. encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network;
8. help MS with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality.

“Quality Improvement” as a Learning System

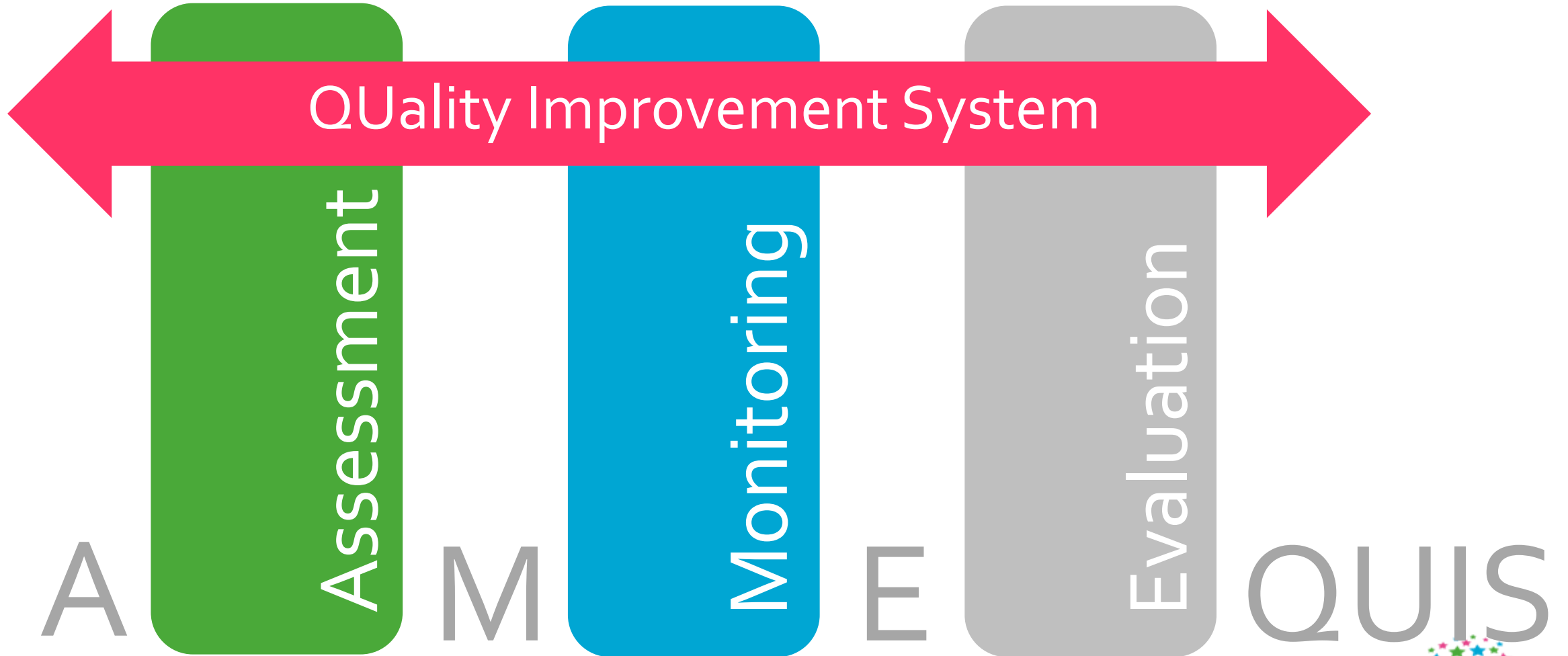
QI Guiding Principles:

1. Improvement Should be Continuous and Incremental (Process)
2. Everybody is responsible for Quality Improvement (Culture)
3. Goals & Metrics must be clear and aligned (Measures)
4. Respect for people is Indispensable (Partnerships)
5. Standards are necessary, but always changing (Standards)
6. Focus on patient experience across the care continuum. (Patient-Centred)

QI Approaches

- Plan-Do-Study-Act (PDSA) cycle
- Six Sigma
- Lean
- Donabedian (structure-process-outcome model)

Overview of AMEQUIS



'A' is for Assessment

Evidence-base

- Dynamic process to stimulate quality improvement, rather than a snapshot standalone activity¹.
- Promote improvements by applying standards and providing feedback².
- Strong association with improved quality, patient outcomes and reduce clinical variation³.
- Predictor of clinical and service performance⁴.
- All assessment methods have their strengths and limitations, multiple methods allows triangulation of evidence⁵.
- Patient involvement improves the relevance of the assessment to care⁶.

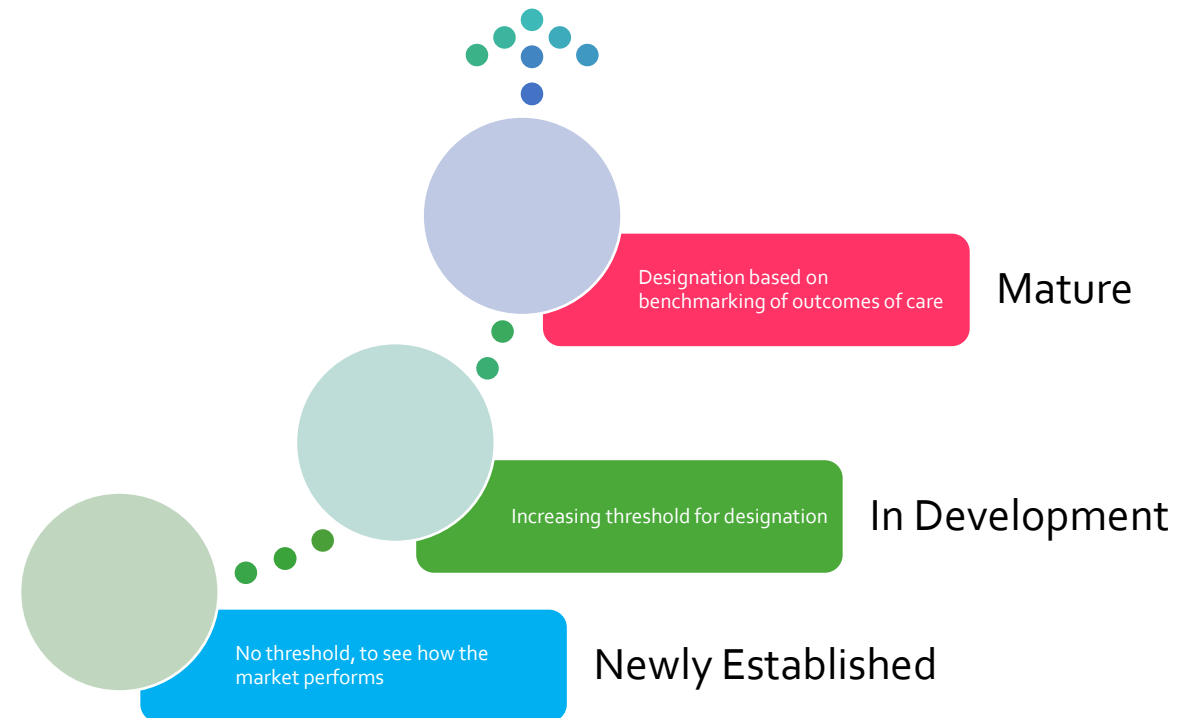
Assessment as a Dynamic Quality Improvement Framework

Clinicians and hospitals see accreditation as:

- A 'hurdle' to cross at a single point in time
- administrative burden with little value to their clinical services

However, [published evidence](#) positions it as:

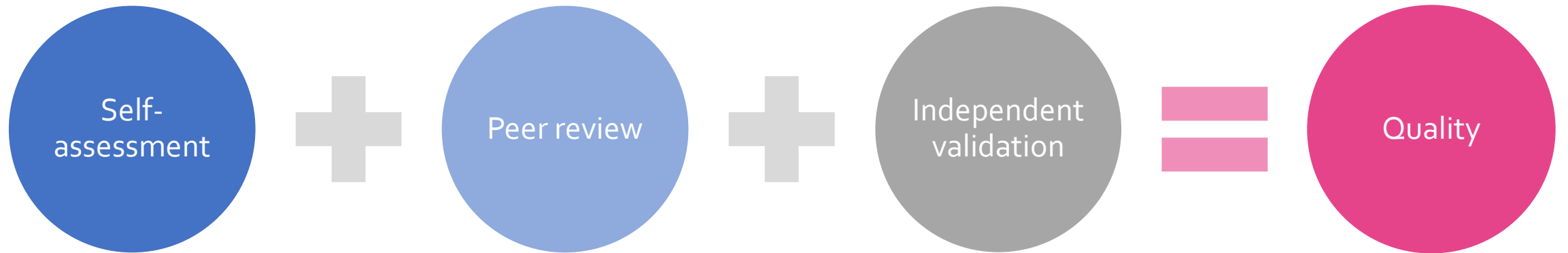
- 'continuous quality improvement schemes' which over time
- the threshold for endorsement is dynamic and increases, year on year
- requiring hospitals to continuously drive quality improvements to their services
- variability in the maturity of assessment



Summary of Assessment Methods Ability to Assess Structure, Processes and Outcomes

Location	Effort/ intensity	Structure	Processes	Outcomes	
Routine health system	Remote	+	+	+	+
Service specific	Remote	++	++	++	++
Service Based					
Visit	Local	++	+++	+++	+
Staff Interviews	Local	+++	+	+++	++
Patient Interviews	Local	+++	+	+++	++
Questionnaires					
Service Survey	Remote	+	++	++	+
Staff	Remote	+	++	++	+
Patient	Remote	+	+	+++	++
Case Review					
Medical Record Review	Local	+++	+	+++	+++
2nd Opinion	Remote	++	+	+	+++

Assessment Methodology – Mixed Model



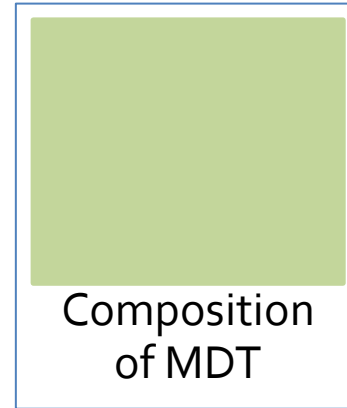
Effectiveness of technical assessment is dependent on using **multiple methods** to assess quality

- **Self-assessment** which is **peer reviewed** and with external validation optimise efficacy and improve the quality of the services
- **Documentation review** followed by a sample of on-site visit using a patient tracker system to validate self-assessment
- **Patient involvement in the process** of assessment improves the relevance of the assessment to patient care
- **Effectiveness of mix-model is dependent on the sampling methodology (!)**

TYPES OF OPERATIONAL CRITERIA TO ASSESS (NEW) NETWORKS & QUALITY AND EXPERTISE OF HCPS

Networks	Healthcare Providers
<p>GENERAL Criteria and Conditions to be fulfilled:</p> <ol style="list-style-type: none">1. Highly Specialised Healthcare2. Governance and Coordination3. Patient Care4. Multidisciplinary Approach5. Good Practice, Outcome Measures, and Quality Control6. Contribution to Research7. Continuous Education, Training, and Development8. Networking and Collaboration	<p>GENERAL Criteria and Conditions to be fulfilled:</p> <ol style="list-style-type: none">1. Patient Empowerment and Patient-Centred Care2. Organisation, Management, and Business Continuity3. Research, Education and Training4. Expertise, Information Systems, and e-Health Tools5. Quality and Safety
<p>Defined in the Network proposal, Fulfillment assessed for each applicant healthcare provider. Based on the evidence and consensus of the scientific, technical and professional community</p>	<p>SPECIFIC Criteria and Conditions to be fulfilled:</p> <ol style="list-style-type: none">1. Competence, Experience and Outcomes of Care2. Human Resources3. Organisation of Patient Care4. Facilities and Equipment

Specific Criteria for HCPs - Evidence



Competency & Expertise (examples):

- **No. of Interventions:** 50 bone sarcoma surgeries and 100 soft tissue surgeries per year
- **No. of Patients:** Caseload of 250 people with NF2
- **Treatment Outcome:** 5 positive diagnosis of Primary Ciliary Dyskinesia
- **Benchmarking Outcomes**

Operational Criteria & Core Measures

Networks

AREA	No. CRITERIA	No. MEASURES	No. Core MEASURES**
Establishment of an ERN	1	1 (*1)	-
Highly Specialised Healthcare	1	3	3
Governance & Coordination	1	7 (*2)	4
Patient Care	2	10	1
Multi-disciplinary Approach	1	3	1
Good Practice, Outcome Measures & Quality Control	4	8	6
Contribution to Research	1	4	1
Continuous Education & Training	1	3	1
Networking & Collaboration	1	3	2
Total	13	42	19

(*) This symbol is used to designate those measures identified as a minimum requisite for eligibility.

(**) This symbol is used to designate those measures that are considered “core measures”.

For the initial application, some of the measures have been designated as core measures. For these measures, Network Applicants must ensure that they are in compliance with these requirements by either having it in place or addressed within a detailed and well-defined implementation strategy within one year of the formal establishment of the Network.

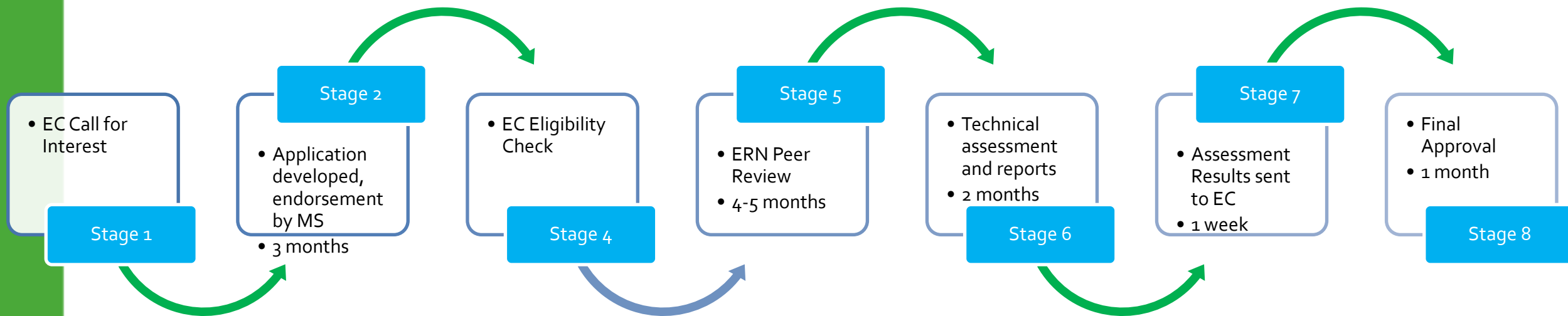
HCP Members

General Criteria	No. CRITERIA	No. MEASURES	No. Hospital MEASURES
Patient Empowerment & Patient Centred Care	7	15	5
Management & Business Continuity	6	10	1
Research, Education & Training	2	11	1
Expertise, Information Systems & eHealth Tools	4	5	-
Quality & Safety	3	9	1

Specific Criteria			
Competency, Experience & Outcomes of Care	2	4	-
Human Resources	1	4	-
Organisation of Patient Care	1	6	-
Facilities & Equipment	1	4	-
Total	27	68	8

Overview of Assessment Process for new HCPs

- National Endorsement
- Objectives of process
- 8-Stage Process that takes minimum 12 months
- Tools: HCP Members Operational Criteria, Check list



Threshold for Positive Assessment

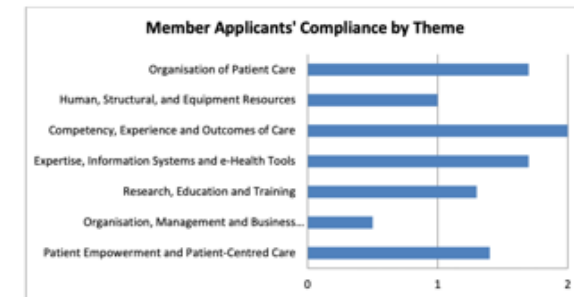
Positive Assessment for Networks:

- An **overall compliance rate of 50%** of the maximum score (previously 70%) must be achieved.
- At least **10 Healthcare Provider Applicants from 8 Member States** must receive a positive assessment

Positive Assessment for HCP Applicants:

- A minimum of **70% of the general operational criteria**
- A minimum of **80% of the specific criteria.**

Assessment Report



Assessment Report

Overall Compliance with Operational Criteria

Assessors evaluated the performance of the Healthcare Provider against the Operational Criteria for Healthcare Providers through the documentation review, virtual interviews and On-site Audits (if applicable). The following graph represents the overall distribution of the assessor ratings for the criteria for Healthcare Providers. Please see Appendix A for more information on the rating scale used by the assessors.



Overview by Themes

The Operational Criteria for the Healthcare Providers are grouped into the following seven themes:

- Patient Empowerment and Patient-Centred Care
- Organisation, Management, and Business Continuity
- Research, Education and Training
- Expertise, Information Systems, and e-Health Tools
- Competence, Experience and Outcomes of Care
- Human, Structural, and Equipment Resources
- Organisation of Patient Care

Each theme consists of one or more criteria with measurable elements in line with the Commission Delegated Decision on European Reference Networks (2014/286/EU). The following graph represents the Healthcare Provider's overall compliance with the Operational Criteria by theme.

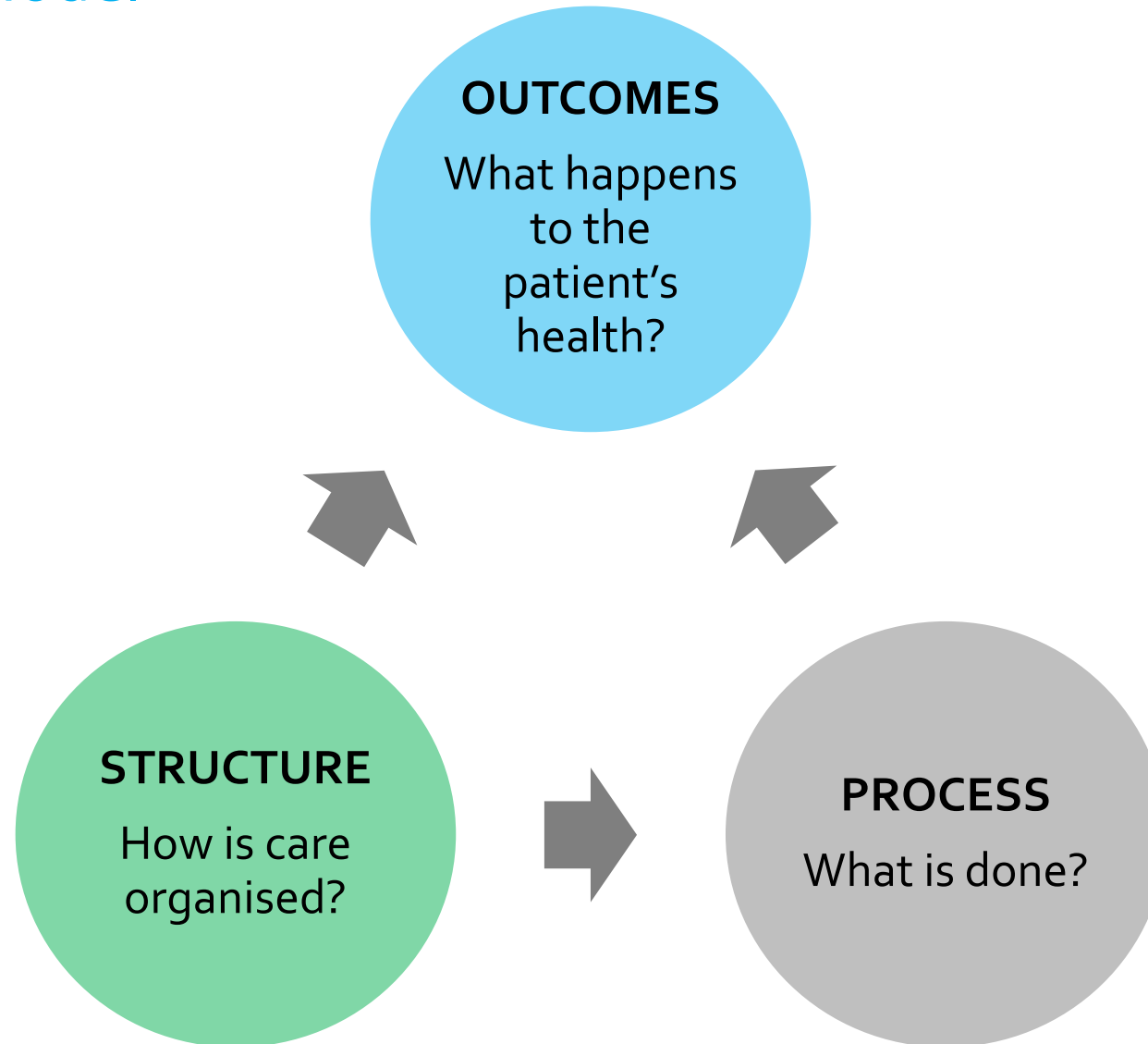
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'M' is for Monitoring

Evidence-base

- The **act of measuring alone** is viewed as a stimulus for quality improvement⁷.
- Provides an **opportunity to consider the results of monitoring, take timely action** and learn from experience along the lifecycle of the service⁸.
- Important to secure agreement on outcomes in advance rather than being imposed⁹.
- Indicators to raise the awareness of quality issues, alert stakeholders to specific areas and provide an opportunity to improve practice¹⁰.

Donabedian Model



ERN Monitoring Framework

HCP Members Continuous Monitoring

- All ERN HCP Members are assessed at point of enter to the ERNs by the EC IABs
- ERNs HCP Members report no. of new patients seen (specific criteria)

ERN 18 indicators

- No. MS, HCP Members & Affiliated Partners in the ERNs
- CPMS Panel Case Reviews
- No. of Clinical Practice Guidelines developed
- No. of Training Activities
- No. of Clinical Trials or Observational prospective studies; Peer-Reviewed Publications

Disease specific outcomes

- Celebrate the variation in practice across the EU28
- Simple disease specific outcomes measures
- Profiled against case-mix and benchmarked to identify emerging new best practice

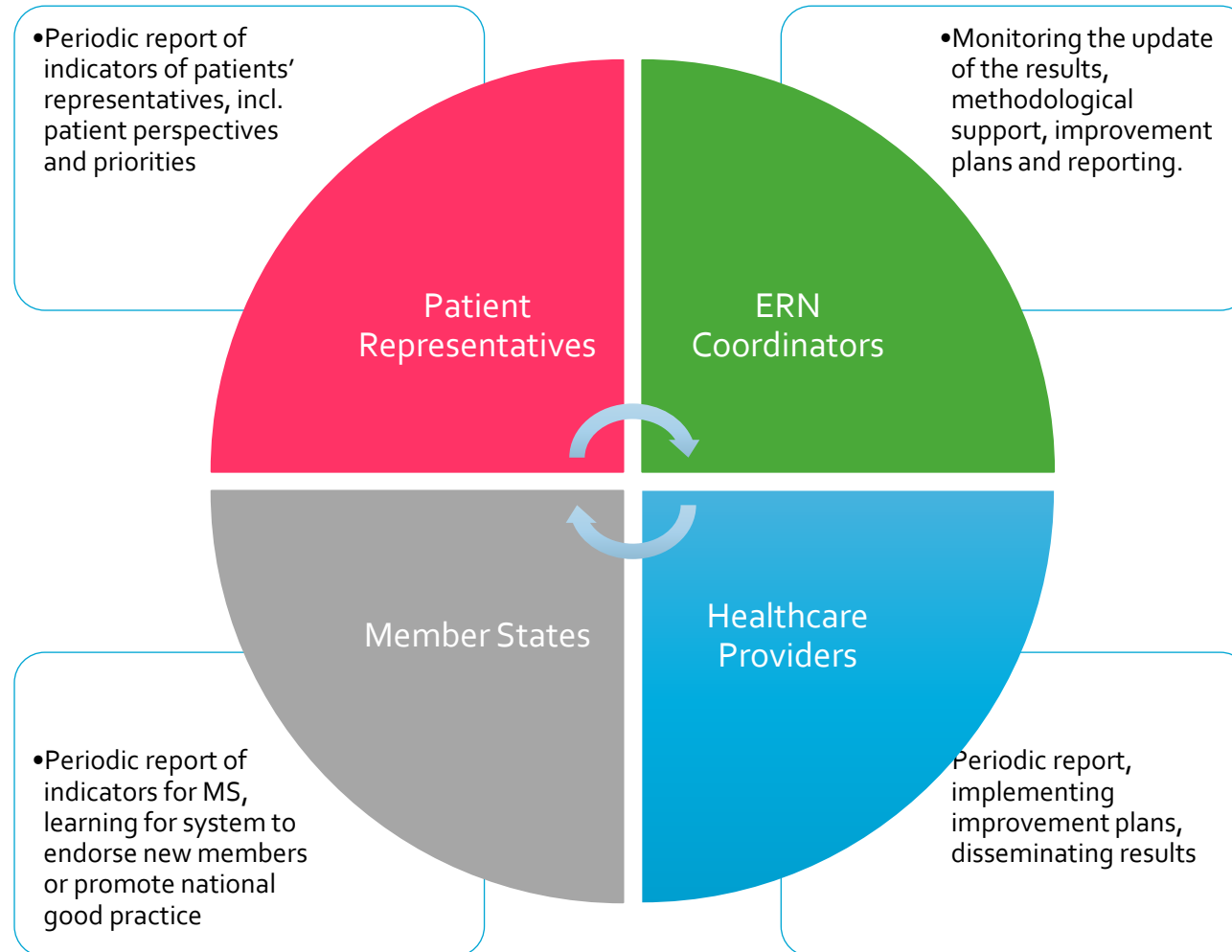
ERN Evaluation in first 5 yrs

- EC Implementation Decision requires each ERN to be evaluated before the end of their first 5 years.
- Evaluation framework has been developed under a tender in 2019/20.

Original ERN Continuous Monitoring - 18 Indicators

Domain	Indicators
Coverage & Membership	<ol style="list-style-type: none"> 1. No. MS represented in the ERN as full HCP Members – Structure (S) 2. No. of HCP Members - S 3. No. of Affiliated Partners (AP) represented in the ERN - S 4. No. of PO in the ERN Meetings – S
Expert Advice	<ol style="list-style-type: none"> 5. Total No. of New Patients referred to HCP Members – Process (P) 6. No. of Patients entered into CPMS (total volume) - P 7. No. of Panel Case Reviews - P 8. Delay to provide multidisciplinary clinical advice: Non-emergency cases - P
Patient Satisfaction	<ol style="list-style-type: none"> 9. Level of patient satisfaction – Outcomes (O)
Education Activities	<ol style="list-style-type: none"> 10. No. of Educational Webinars for healthcare professionals - P 11. No. of Formal Educational Activities for healthcare professionals - P
Research	<ol style="list-style-type: none"> 12. No. of Clinical Trials or Observational prospective studies within ERN - P 13. No. of Peer-Reviewed Publications in scientific journals – P
Clinical Guidelines	<ol style="list-style-type: none"> 14. No. of Clinical Practice Guidelines adopted – P 15. No. of new ERN Clinical Practice Guidelines - P 16. Health Care Provider Compliance to Clinical Guideline - P
Dissemination Knowledge	<ol style="list-style-type: none"> 17. No. of Congresses/Conferences/Meetings where ERN activities and results were presented - P 18. No. of individual ERN website hits – P

All Stakeholders Involved in Monitoring



Monitoring Domains

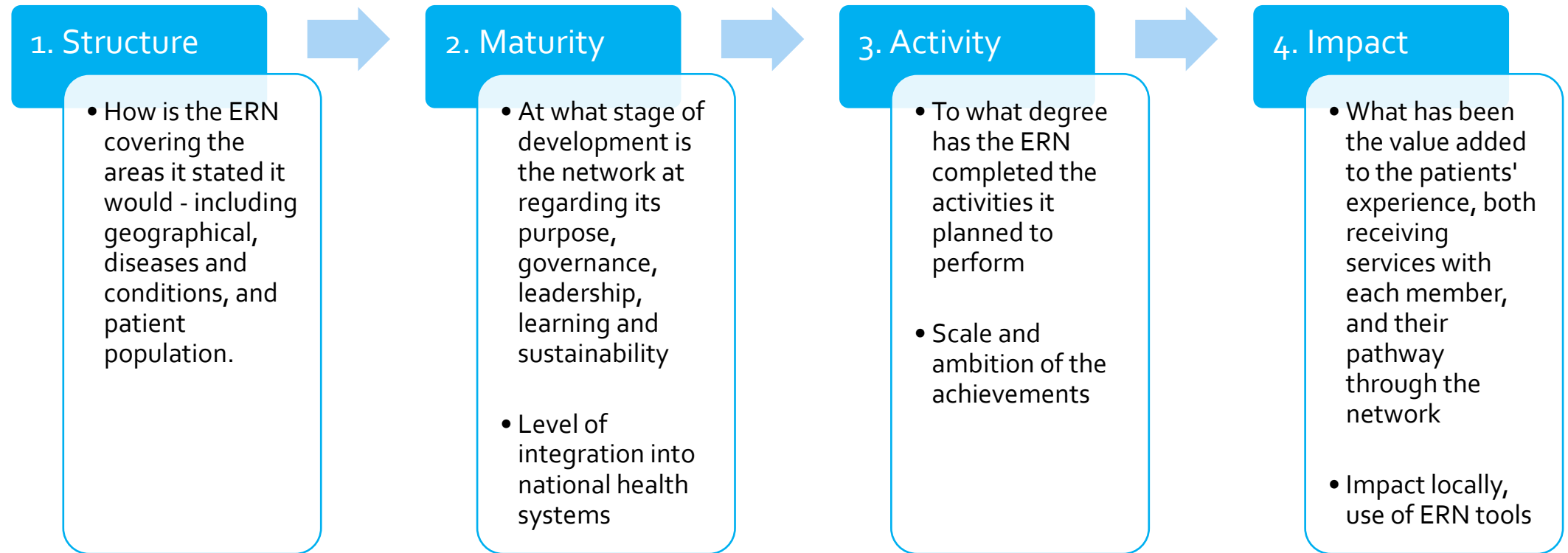
No.	Indicator Domains	No.	New Indicator Domains
4 (-)	Coverage & Membership	2 (-)	Organisation and coordination
4 (-)	Expert Advice	2 (4)	Patient Care
		2 (4)	Multidisciplinary approach and sharing of knowledge
1 (-)	Patient Satisfaction	4 (-)	Patient-Centred care
2 (-)	Education Activities	2 (-)	Professional's training
2 (-)	Research	3 (6)	Contribution to research & innovation
3 (-)	Clinical Guidelines	3 (-)	Clinical guidelines
1 (-)	Dissemination Knowledge	1 (-)	Dissemination & Communication
		1 (-)	Integration in the National System
Total:	18 (-)	Total	20 (27)

'E' is for Evaluation

Evidence-base

- Evaluation goes beyond simple judgement of achievement of objectives and standards. Evaluation outcomes need to stimulate improvement in quality across all stakeholder levels¹¹.
- Leverage data that has been collected under different contexts to evaluate added value¹².
- Motivates achievement of best practice credibility for current practice and future direction¹³.
- Patient experience and satisfaction of service quality is important enough that it is a predictor of survival¹⁴.

Evaluation Elements – EURORDIS approach



Reference:

- The Health Foundation, "Effective networks for improvement: Developing and managing effective networks to support quality improvement in healthcare", p.11.
- EURORDIS recommendations

Objectives of the Evaluation process of ERNs and HCPs

The general objective of the evaluation process is to verify and assess:

1. The accomplishment of the **objectives** set out in the Cross-border healthcare Directive
2. The fulfilment of the **criteria and conditions** set out in the Delegated Decision for ERNs and HCPs (2014/286/EU)
3. The **outcomes and performance** of the Network and the contribution of each Member
4. The achievement of the objectives and quality of the deliverables produced within the ERNs **Grant Agreements**

The evaluation of the individual Members of the Network should assess:

1. If the HCP continues to provide **specialised and quality care**
2. If the HCP team maintains the **necessary levels of activity and experience**
3. What has been the **contribution** of the HCP team to the Network
4. The **value of the ERN** for the HCP

Evaluation Criteria & Measurement Elements – proposed by the AMEQUIS Consortium

EVALUATION CRITERIA FOR NETWORKS			
AREA	No. CRITERIA	No. ME	No. core ME
Governance and coordination	4	15	10
Clinical care	3	9	5
Quality and patient safety	2	3	0
Patient centred care	3	6	3
Contribution to research	3	7	4
Education and training	2	6	4
Networking and dissemination	3	6	4
TOTAL	20	52	30

- The evaluation criteria is mainly based on [verifying to which extent the Networks and their Members meet quality requirements](#) related to the [achievement of the objectives](#) for which they were constituted.
- Quality requirements are formulated as criteria, which describe an “[enhanced practice](#)” which is both aspirational and achievable.
- The [measurable elements \(ME\)](#) are used to assess the aspect or level of performance under each criterion.

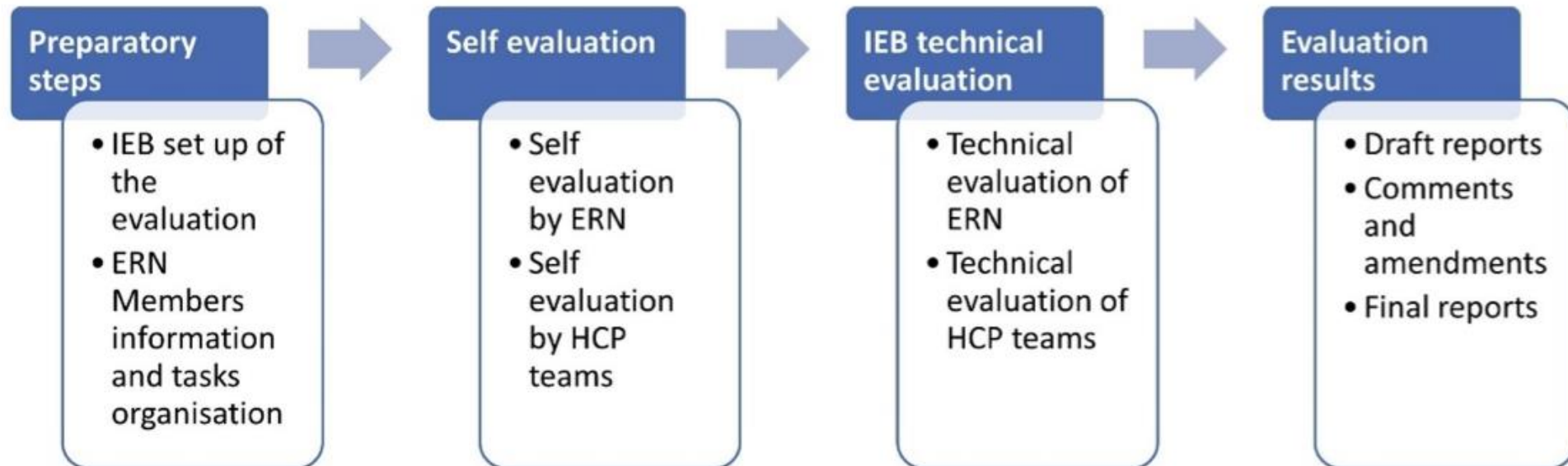
- Some measurable elements are considered “[core](#)” and should have been implemented at the time of evaluation.
- Remaining measurable elements are important areas as they can serve as an indicator of their [maturity status](#).
- The findings obtained to fulfilment of the criteria will serve to [draw conclusions about the performance of the Network & HCP Members](#) in the last 5 years

EVALUATION CRITERIA FOR HCP TEAMS			
AREA	No. CRITERIA	No. ME	No. core ME
Patient centred care	9	19	8
Organisation and management	5	10	4
Research, education, and training	2	11	6
Exchange of expertise, ICT, and eHealth	3	7	3
Quality and safety	2	9	2
Competence, experience, and outcomes of care	1	4	4
Human resources	2	4	2
TOTAL	24	64	29

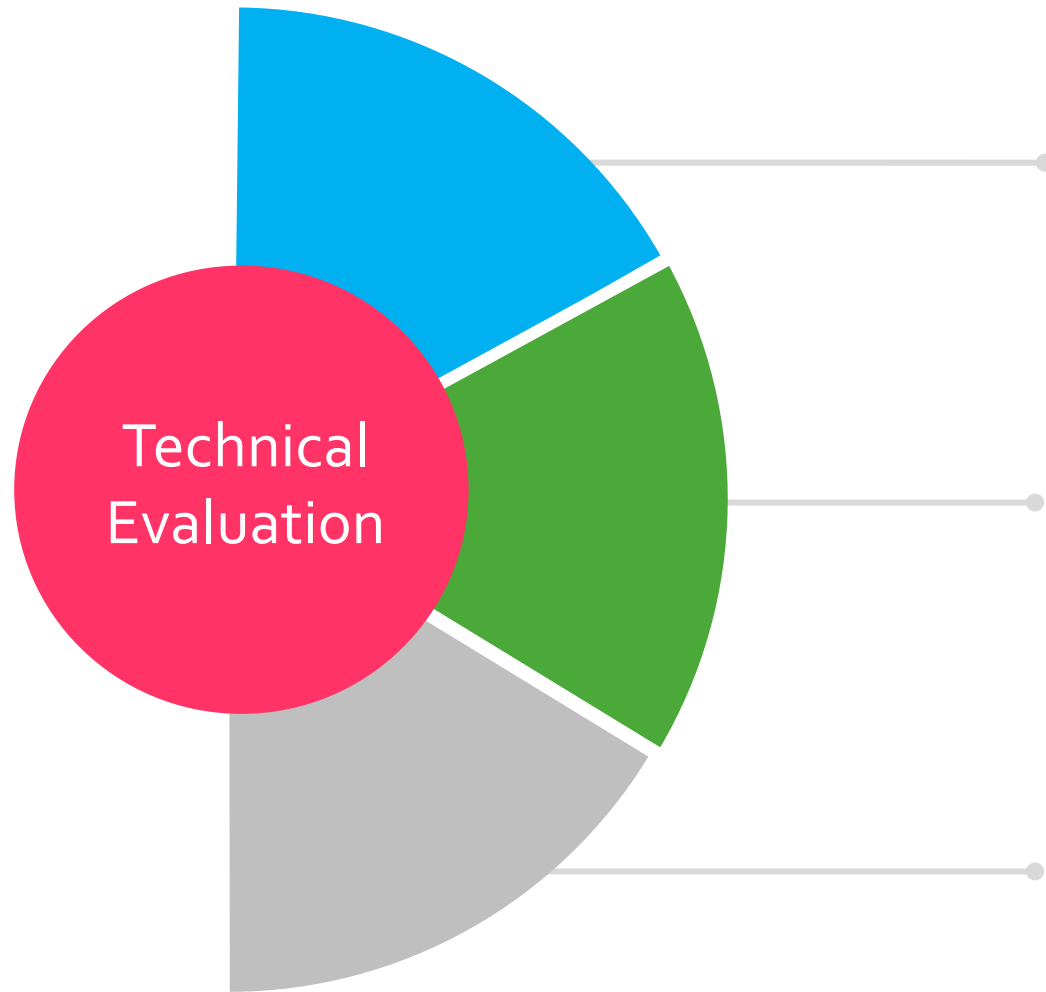
Timeline for the Evaluation Process

1. ERN Coordinators requests the EC to be evaluated and the EC appoints the Independent Evaluation Body.
2. The evaluation process may take between 10 to 12 months, from the appointment of the Independent Evaluation Body to the issuance of the final evaluation reports.

Phases of the evaluation process:



Technical Evaluation of the Networks



Online meeting with ERN and WPs Coordinators

- Conduct one or more interviews with the Network Coordinators & Coordinators of the EU Funded Project.

Self-Evaluation & Documentation Review

- Self-evaluation: Review each of the criteria and measurable elements, and justify level of compliance and providing corresponding evidence
- Documentation Review: Initial assessment application, monitoring indicators, grant reports, sample of deliverables and the self evaluation

Online meeting with patient representatives

- Level of participation in the different actions of the Networks including governance and strategic planning.

Evaluation Reports

Evaluation Report for Networks:

- Conclusions of the evaluation team
- Overall compliance with the operational criteria by the ERN and the HCPs
- Results of the Network in the measurable elements (MEs) from each area
- Detailed results of each criterion and areas for improvement
- Evaluation of the achievement of the objectives and quality of the deliverables produced within the ERNs Specific Grant Agreements.
- Summary of the evaluation results of the Members of the Network
- Outcome of the evaluation:
 - Scoring table of operational criteria for the ERN (including specific score of core MEs)
 - Qualitative assessment of the accomplishment of the objectives initially selected by the ERN
 - Result of the evaluation according to the [decision guidelines](#): satisfactory or needing improvement

Evaluation Report for HCPs:

- Conclusions of the evaluation team
- Overall compliance with the operational criteria
- Results of the HCP in the measurable elements from each area
- Detailed results of each criterion and areas for improvement
- Outcome of the evaluation (scoring table): indicating the specific score of core MEs and score of those MEs that identify HCP contribution to the mission of the Network
- Result (according to the [decision guidelines](#)): satisfactory or needing improvement.

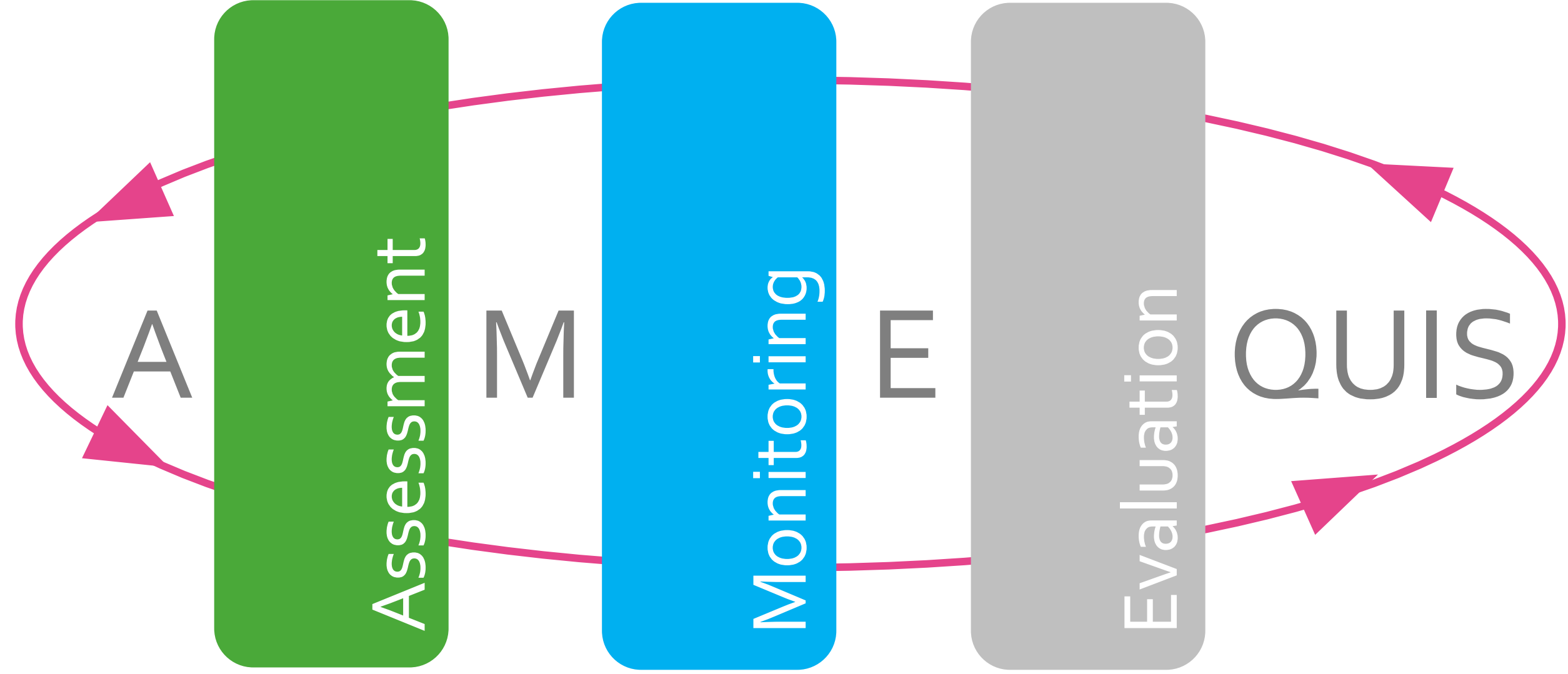
Outcome

- Not intended to obtain a “positive” or “negative” result
- Just “satisfactory” or “needs improvements”
- One year improvement plans

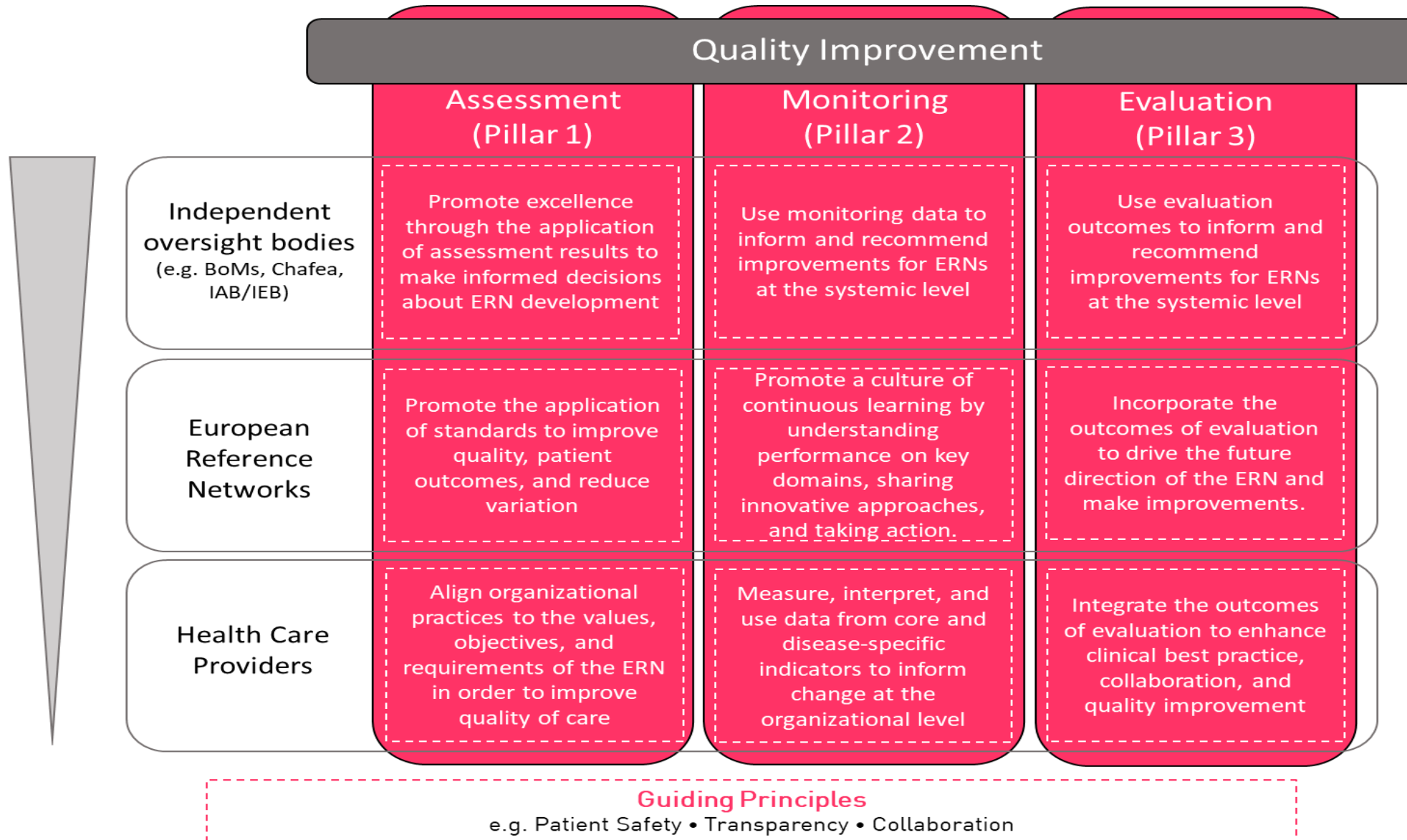
'QUIS' is for QUality Improvement System

Evidence-base

- A dynamic and responsive system that drives a **culture of continuous quality improvement and enhanced patient safety by leveraging the lessons and experiences** of ERN stakeholders.
- Assessment, monitoring and evaluation connected seamlessly to form a dynamic learning culture focused on quality improvement; and not conceptually standalone, static actions.
- The *AMEQUIS* model **promotes improvement through small, actionable cycles that, over time, assemble into a continuous thread of quality improvement** based on evidence, best-practice, and past-experience.

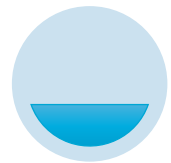


AMEQUIS System – EURORDIS approach



Objective #1: Facilitate mobility of expertise & help MS with insufficient number of patients to provide HSS

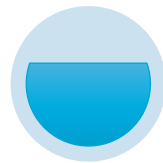
ERN Example



Assessment

Network Application Form:

- Rational for the Network
- Rarity of diseases and complexity

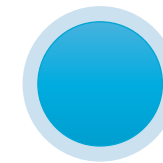


Monitoring

No. of Panel Case Reviews

No. of Patients entered into CPMS

MS represented in the ERN as **Affiliated Partners**



Evaluation

2.2.1 ERN has implemented a **process for offering advice** for complex patient cases

7.1.2 Collaboration strategies with Affiliated Partners

7.2.1 accessible information referrals

QUIS: Optimised the availability of expertise (and knowledge) that can be accessed locally to all

Objective #2: facilitate improvements in diagnosis & delivery of high-quality and accessible healthcare requiring a particular concentration of expertise

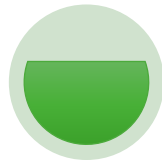
HCP Example



Assessment

Specialist Criteria:

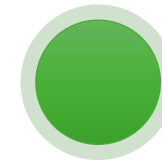
Number of Patients
- Caseload of 250 people with NF2



Monitoring

Total No. of New Patients:

Referred to HCP Members
Over 5 yrs.



Evaluation

7.1. The HCP has a team of trained professionals with the required competencies within the ERN's area of expertise.

QUIS: Increase in volume of cases leads to improved outcomes of care



Evidence-Base & References

Assessment

- Dynamic process to stimulate quality improvement, rather than a snapshot standalone activity¹.
- Promote improvements by applying standards and providing feedback².
- Strong association with improved quality, patient outcomes and reduce clinical variation³.
- Predictor of clinical and service performance⁴.
- All assessment methods have their strengths and limitations, multiple methods allows triangulation of evidence⁵.
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- Important to secure agreement on outcomes in advance rather than being imposed⁹.
- Indicators to raise the awareness of quality issues, alert stakeholders to specific areas and provide an opportunity to improve practice¹⁰.

Evaluation

- Evaluation goes beyond simple judgement of achievement of objectives and standards. Evaluation outcomes need to stimulate improvement in quality across all stakeholder levels¹¹.
- Leverage data that has been collected under different contexts to evaluate added value¹².
- Motivates achievement of best practice credibility for current practice and future direction¹³.
- Patient experience and satisfaction of service quality is important enough that it is a predictor of survival¹⁴.

Quality Improvement System

- A dynamic and responsive system that drives a culture of continuous quality improvement and enhanced patient safety by leveraging the lessons and experiences of ERN stakeholders.
- Assessment, monitoring and evaluation connected seamlessly to form a dynamic learning culture focused on quality improvement; and not conceptually standalone, static actions.
- The *AMEQUIS* model promotes improvement through small, actionable cycles that, over time, assemble into a continuous thread of quality improvement based on evidence, best-practice, and past-experience.

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