Continuous Monitoring of ERNs

ERN Continuous Monitoring and Quality Improvement System (ERN CMQS)

Update, clarifications and examples to the set of the 18 ERN core indicators

Version V7.3

ERN Continuous Monitoring Working Group
of the ERN Coordinators Group & the Board of Member States
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Table I: ERNs intervention areas' and specific objectives
1. **General organisation and coordination** Objective: To ensure that ERNs are operational and successfully carry out their organisational activities 2. **Patient Care** Objective: To improve access to clinical advice, diagnosis, treatment and follow-up of patients within the ERNs. Geographical and disease coverage 3. **Multidisciplinary approach and sharing of knowledge within the ERN** Objective: To optimise patient outcomes by combining skills of healthcare professionals involved and resources used 4. **Education and Training** Objective: To increase capacity of professionals to recognize and manage cases of rare or low prevalence complex diseases and conditions within the scope of the ERN 5. **Contribution to research and innovation** Objective: To reinforce clinical research in the field rare diseases and complex conditions by collecting data and carrying out collaborative research activities 6. **Clinical guidelines** Objective: To ensure that all patients referred to ERNs have access to high quality healthcare services 7. **Communication and dissemination within the scope of the ERN activities** Objective: To guarantee that knowledge and expertise is spread outside the ERN so that more people can benefit from the ERN activities.

Table II: ERN basic set of 18 Indicators		
1. **General organisation and coordination**		
1.1	Within an ERN, the number of Member States with Health Care Providers as full members or affiliated partners **Source:** DG SANTE (ERN Service Directory)	**Definition:** Within a particular ERN, the total number of Member States within the EEA covered by Directive 24/201 with at least one Health Care Provider participating as full member or affiliated partner within that ERN.
1.2	Number of Health Care Providers represented as full members in the ERN **Source:** DG SANTE (ERN Service Directory)	**Definition:** The total number of full members within the ERN.
1.3	Number of affiliated partners represented in the ERN **Source:** DG SANTE (ERN Service Directory)	**Definition:** The total number of affiliated partners within the ERN.
1.4	Number of patient organisations represented in the ERNs **Source:** ERN data collection **Evidence:** A list of the patient associations involved in an ERN published on the ERN Website	**Definition:** The total number of patient associations represented by one or more persons actively involved in the ERN. Patients may work within an ERN in many different ways to capture their voices and their needs.

1. **Patient Care**	
2.1	Total number of new patients referred to the Health Care Providers participating in the ERN with the diagnosis of a disease or condition that falls within the scope of the ERN.
	Definition: The total number of new patients attending the ERNs' Health Care Providers for the first time, whatever their age, within the specified timeframe, including visits to outpatient's clinics, hospital discharges and emergencies, coming from both national and international referrals whose disease or condition falls within the codes listed[1].
	Source: ERN data collection
2.2	Number of patients entered into CPMS (total volume)
	Definition: The total number of unique patients entered into CPMS within the specified timeframe for that ERN.
	Source: CPMS

1 The disease should be preferably confirmed at the moment of the data inclusion by using, in principle, the same codes as those specified in the ERNs disease-area breakdowns. Depending on the particularities of some diseases, patients still under diagnosis process could be included as referred patients.

	2. **Multidisciplinary approach and sharing of knowledge within the ERN**
3.1	Number of panels reviewed by the ERN for which an outcome report is produced within the specified timeframe.
	Definition: The total number of panels that have been reviewed by at least two experts and for which an outcome report is produced within the specified timeframe.
	Source: CPMS
3.2	Time taken to provide multidisciplinary clinical advice between referral to ERN and multidisciplinary clinical advice. 3.2a - non-urgent cases: days (median) 3.2b - urgent cases: days (median)
	Definition : For the panels that have produced an outcome report in the specified timeframe, the days (expressed by the median) for the time period specified between the date of start of the panel in CPMS[2] and the date of issue of multidisciplinary clinical advice (outcome report)[3] not the date of the closure of the panel, where at least two experts have participated.
	Source: CPMS
	3. **Education and Training**
4.1	Number of education/training activities not accruing higher education credits aimed at healthcare professionals delivered by the coordination teams or HCP members of the ERN
	Definition: The total number of unique education/training activities **not accruing higher education credits** (online or physical) aimed at healthcare professionals and/or patients, created and delivered by the ERN coordination team, HCP members, Affiliated Partners, or ePAGs/Patient Organisations/Representatives of the ERN within the specified time period.
	Source: ERN data collection **Evidence:** A list of the the education/training activities that in general are not accruing higher education credits including presential, online courses, educational webinars[4], and/or shorter videos delivered by an ERN and published on the ERN website/media channel.
4.2	Number of formal educational activities (i.e. those accruing higher educational credits) aimed at healthcare professionals delivered by the coordination teams, HCP members, Affiliated Partners, or ePAGs/Patient Organisations/Representatives of the ERN within the specified time period.
	Definition: The total number of unique formal educational activities (i.e. those accruing higher educational credits) certified by a formal educational body. Training activities can be physical or online.
	Source: ERN data collection **Evidence:** A list of the unique educational activities (presential or online: webinars, online

2 The time point measured automatically by CPMS will be the time from the start of the panel in CPMS until the production of the outcome report.

3 CPMS outcome report created and sent to the treating clinician i.e. the clinician who is responsible for treating the patient in the Member State where the patient lives.

4 Webinar is a seminar conducted over the internet

	courses etc) organised by an ERN published on the ERN Website.

	4. **Contribution to research and innovation**
5.1	This indicator is split into two subindicators: 5.1.a Number of Clinical Trials (involving ERN members in at least two Member States) 5.1.b Number of Observational prospective studies (involving ERN members in at least two Member States)
	Definition: The total number of unique (either ongoing or finalized) Clinical Trials or Observational Prospective Studies (including both academic and Industry driven studies) within the specified time period that involve ERN members from two different Member States, acknowledging the ERN.
	Source: ERN data collection **Evidence:** a) A list of the unique ongoing Clinical Trials, acknowledging the ERN, registered in a recognized clinical trials registry like the ClinicalTrials.gov and published on the ERN Website. b) A list of the unique ongoing Observational Prospective Studies, acknowledging the ERN, and published on the ERN Website.
5.2	Number of accepted peer-reviewed publications in scientific journals regarding disease-groups within the ERN and which acknowledge the ERN.
	Definition: The total number of unique peer-review publications that have been accepted in scientific journals regarding disease-groups within the ERN and within the specified time period. Publications should be PubMed accredited scientific journals and involve as major contributors at least two Health Care Providers from two different Member States within the ERN, and which include an explicit acknowledgement of the ERN such as **"This work is generated within the European Reference Network for …" or "This work is supported by the European Reference Network for…."**
	Source: ERN data collection **Evidence:** A list of unique publications in an ERN for the specified time period published on the ERN Website. The list could be provided following any of the recognized Science Citation Indexes like Google Scholar, ORCID, Web of Science, Scopus etc

	5. **Clinical guidelines**
6.1	Number of Clinical Practice Guidelines and other types of Clinical Decision Making Tools, **adopted** for diseases within the scope of the ERN.
	Definition: The number of Clinical Practice Guidelines (CPG)[5] and other types of Clinical Decision Making Tools[6], such as clinical consensus recommendations for disease areas within the scope of the ERN not developed by the ERN, that were formally[7] agreed and adopted by the ERN Board in the specified time period, and are publically available (e.g. on the website).
	Source: ERN data collection **Evidence:** A list of Clinical Practice Guidelines and other types of Clinical Decision Making Tools not developed by the ERN, **adopted** within an ERN in the specified time period, published in the ERN Website.
6.2	This indicator is split into two sub indicators, for diseases within the scope of the ERN: 6.2.a Number of new Clinical Practice Guidelines **written** by the ERN in the specified time period. 6.2.b Number of other types of new Clinical Decision Making Tools (clinical consensus statements or consensus recommendations), **written** by the ERN in the specified time period.
	Definition: The number of Clinical Practice Guidelines (CPG) and Clinical Decision Support Tools (CDST: clinical consensus statements or consensus recommendations), developed by the ERN, shall involve at least two Health Care Providers from two different Member States within the ERN, acknowledging the ERN, for diseases within the scope of the ERN where no guidelines existed previously, according to evidence based recognized methodology. The new CPGs or CDST should be developed by the ERN during the specified time frame.
	Source: ERN data collection **Evidence:** A list of Clinical Practice Guidelines and other types of Clinical Decision Making Tools, written by an ERN in the specified time period, published in the ERN Website and using the ERN logo.

5 Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Clinical Practice Guidelines We Can Trust. Robin Graham, Michelle Mancher, Dianne Miller Wolman, Sheldon Greenfield, and Earl Steinberg, Editors; Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Institute of Medicine 2011).

6 A clinical consensus statement is the end product developed by an independent panel of (at least 3) subject matter experts convened specifically to perform a systematic review of the available literature, for the purpose of understanding a clinically relevant issue or surgical procedure. It offers specific recommendations on a topic. Compared to Clinical Practice Guidelines and Clinical Practice Recommendations, Clinical Consensus Statements undergo a less rigorous peer review process.

7 The documentation of the adoption should include the ERN logo.

	6. **Communication and dissemination within the scope of the ERN activities**	
7.1	Number of congresses/ conferences/ meetings at which the ERN activities and results were presented	**Definition:** Within the specified time period, the total number of congresses/ conferences/ meetings at which the ERN activities and results were presented via a dedicated slot in the programme/agenda, acknowledging the Network.
7.2	Number of individual ERN website hits	**Definition:** The total number of page views including both the homepage of the website and the "child" pages.

	7. **Complex and long-term indicators which need further development**	
8.1	Level of patient satisfaction	To be developed
8.3	Health Care Provider Compliance to Clinical Guidelines	To be developed

Clarifications and examples

Indicator 1.4 - Number of patient organisations represented in the ERNs

To have a clearer idea of the participation of patients in the ERN, the following types of involvement should be, where possible, counted and reported in the comments box of the monitoring data collection IT tool.

Examples of the types of active participation in an ERN network (and therefore should be counted towards the total number) are:
Number of Patient associations represented:

1) as voting members of the Board of the Network (please count the patient associations represented that are entitled to vote in the decision-making bodies governing the ERN);
2) as Leader (or co-Leader) of specific activities of the ERN project (please count the patient associations represented and involved in working groups, work packages, tasks, etc. as Leader or co-Leader);
3) as members of the panel involved in the production of clinical practice guidelines (please count the number of patient associations represented during the process of creation of new clinical practice guidelines or adaptation - both as adaptation to the countries and adaptation in lay versions - of existing clinical practice guidelines);
4) as co-designer of activities related to the Network project (please count the number of patient associations represented and involved in the main activities of the ERN, such as co-design of surveys, training and education, website contents, dissemination materials, etc.).
5) that are actively involved in translation of ERN documents, evaluation of patient information, and other ERN documents, including proposing changes (to ensure they are suitable for patients or parents)

Participation of patient associations in other type of meetings directly related with the work of a given network (ePAGs meeting, sectorial or thematic patient associations meetings, etc.) should also be counted.

- To clarify that this indicator does not aim to count the number of meetings, nor the type of meeting in which patient representatives are participating.

- Such active involvement would include their participation in advisory groups, committees, and any other bodies within the organization of the network.

- This participation would normally be reflected in the membership and their attendance at the meetings (physical and virtual) of that body.

- In the case of umbrella organizations (for example, EURORDIS) please count each of the umbrella organizations once and count only once the other individual associations represented (whether that be European, national or regional). For example: a patient

representative that belongs both to EURORDIS and to a national association of disease X will be counted as 2 patients associations.

- With regards to umbrella organisations, please indicate in the comment box the name of each umbrella organisation represented and the type of coverage they have (e.g national, european or multidisease coverage).

- Patients associations represented by more than one person or in different advisory groups or committees or any other bodies of the ERN will be counted just once.

Indicator 2.1 – Total number of new patients referred to the Health Care Providers participating in the ERN with the diagnosis of a disease / condition that fall within the scope of the ERN

- New patients are those that have attended or been referred to the healthcare provider, within the specified timeframe and having a certified diagnosis of rare disease. These patients should not have been previously included in the patient information system of the healthcare provider.

- Patients who have not obtained yet a diagnosis should not be taken into account.
- In a number of instances, the number of new patients seen each year for some rare diseases will be very low. However, it is the intention of this data collection process to establish a baseline for each healthcare provider, rather than comparing numbers between ERNs.

- There are important differences between the ERNs on the type of contact with the healthcare provider. Some ERNs are mainly having outpatient visits while others are mainly focusing on hospital discharges. Recurrent patients shall be counted once. These clarifications should be noted, as far as is possible, in the comments box of the monitoring data collection IT tool.

- It would be important to consider the aggregated number of patients at the 31 of December of the previous year of the reported period.

Indicator 4.1 - Number of education/training activities not accruing higher education credits aimed at healthcare professionals delivered by the coordination teams or HCP members of the ERN

- Education/training activities not accruing higher educational credits that are delivered by an ERN within the specified timeframe and are publically available (eg on websites or ERN educational platforms) should be counted.

- If an educational activity with the same content is delivered 3 times in one year, this should be counted as 1.
- Educational activities should feature the ERN logo.

Indicator 4.2 - Number of formal educational activities (i.e. those accruing higher educational credits) aimed at healthcare professionals organised by the ERN

- The body shall have recognized capacity (at regional, national, EU, or International level) to issue educational credits.

- The credits should be aimed at healthcare professionals member or non-members of the Networks organised (including co-organisation or with important contribution) by the coordinating healthcare provider of the ERN or by one or more healthcare providers of the ERN.

- The activity should acknowledge the ERN participation (including the logo of the ERN) within the specified time period.

- Accredited digital educational activities should be included, including accredited Webinars and eLearning courses.

- **Example** (ReCONNET experience):

  An ERN highly involved in the scientific organizing committee in a CME course of one of the diseases covered by the network with a relevant contribution of their HCP as trainers.

  A request of a formal endorsement was submitted to the decision-making body of the ERN that approved the request enabling the organizer to acknowledge the ERN and to add the ERN logo to the materials of the course.

Only after ensuring that all the requested criteria were met, the network included this course as formal education activity of the ERN)

Indicator 5.1 - Number of a.Clinical Trials and b.Observational prospective studies (**involving ERN members in at least two Member States**).

- this indicator is asking for the number of trials or observational prospective studies that a) Involve healthcare providers within an ERN and b) includes an acknowledgement of the ERN.

- These qualifying criteria can be presented together or in different documents.

- Providing a reference for each study in the comment box could be very useful: https://clinicaltrials.gov/ct2/home

https://www.crd.york.ac.uk/prospero/

- Transversal studies such as genotype/phenotype correlation studies such can be counted as clinical trials (as clinical data are used on a group of patients within the ERN) as long as they acknowledge the ERN participation (including logo of the ERN) within the specified time period.

- The clarification of possibilities and limits regarding the cooperation with Industry is not a concluded process. The statement of ERN Board of Member States has been recently updated – 25th June 2019. This is impacting on the involvement of healthcare providers as ERN members in Industry driven studies, because ERNs do not have a clear view about how this kind of collaboration can be run – at the moment.
- For this reason, many HCPs have not acknowledged the ERN in the study, and have therefore not counted Industry driven studies in the collection of data.

Examples which should be counted:
1) See clinicaltrials.gov where the study clearly acknowledges an ERN (ERN-NMD) in the study description:
https://clinicaltrials.gov/ct2/show/NCT03857880?id=NCT02971683+OR+NCT03189875+OR+NCT02419365+OR+NCT03857880&rank=1&load=cart

2) See clinicaltrials.gov where the study involves more than two HCPs of ERN (ERN ReCONNET) but there is no clear acknowledgment of ERN; in this case a document with a clear statement of participation of the ERN will be made available as annex:
https://clinicaltrials.gov/ct2/show/study/NCT03189875?id=NCT02971683+OR+NCT03189875+OR+NCT02419365+OR+NCT03857880&rank=2&show_locs=Y&load=cart#locn

Indicator 5.2 - Number of accepted peer-reviewed publications in scientific journals regarding disease-groups within the ERN and which acknowledge the ERN.

For counting purposes, ERNs should only be counting those publications that include an explicit acknowledgment or reference the ERN's involvement such as **"This work is generated within the European Reference Network for …" or "This work is supported by the ERN for ….".** If the support is not financial, "(not financially)" can be added in brackets after the word "supporting" for additional clarification. This could be the case, for example, for ERNs that are involved in the Solve-RD or other similar European projects where ERN clinicians have been involved in publications but no ERN funding has been used.

The acknowledgment for collaboration can be included in the acknowledgement section and could follow this example:
"This research is supported (not financially) by the European Reference Network on Genetic Tumour Risk Syndromes (ERN GENTURIS)—Project ID No 739547.
ERN GENTURIS is partly co-funded by the European Union within the framework of the Third Health Programme "ERN-2016—Framework Partnership Agreement 2017–2021".

The figure captured here should be clearly linked to the ERN and its activities.

Example (ReCONNET)

- 12 peer-reviewed publications about the results of ERN ReCONNET activities on clinical practice guidelines carried out during the first 18 months had been published at the end of 2018.

  These publications are included in the supplement "ERN ReCONNET Supplement on the state of the art on CPGs in rCTDs". It was officially published after a peer-review process of each single article. The Supplement is already available in the RMD Open website (https://rmdopen.bmj.com/content/4/Suppl_1).

  Each publication has a different Pubmed ID code.
  After consulting the Communication experts within the ERN policy team within the EC, each publication reports the acknowledgment statement regarding the EU funding and the n. 24 ERNs.

Moreover, the ERN logo is included – in each publication.

Indicator 6.1 - Number of Clinical Practice Guidelines and other types of Clinical Decision Making Tools, adopted for diseases within the scope of the ERN.

- "The ERN has adopted the CPG or Clinical Decision Making Tools" means that the tools are publically available and all the healthcare providers within a network are following the guidance.

- The adaptation of the CPGs already existing appears a very crucial added value of the ERNs, since the adaptation may increase the application of CPGs by healthcare professionals. The adaptation of CPGs can be done by means of the ADAPTE methodology that guarantees the production of defined priorities to be followed across Member States.

- The Clinical Practice Guidelines (CPG) and other Clinical Decision Support Tools (CDST) based on consensus techniques to be counted shall be those adopted on the measured timeframe by the ERN (eg agreed by the ERN Board), not when they are published.

- The adoption of CPGs within an ERN could be defined, for example by means of an official endorsement of the Board of the ERN.

Indicator 6.2 – Number of a. new Clinical Practice Guidelines and b. other types of new Clinical Decision Making Tools (clinical consensus statements or consensus recommendations), written by the ERN in the specified time period.

- ERNs have very different scenarios with reference to the number of diseases covered and also to the number of already existing CPGs.

- It is important to underline that for some diseases, many CPGs are already available, for other rare diseases there are no CPGs available at the moment as there is insufficient evidence to produce new CPGs.

- The differentiation between evidence based Clinical Practice Guidelines (CPG) and other Clinical Decision Support Tools (CDST) based on consensus techniques (mainly expert or consensus recommendations) is important when identifying the elements to count. Currently the main criteria to distinguish CPG from Consensus recommendations shall be the standard definition of CPG.

- The Clinical Practice Guidelines (CPG) and other Clinical Decision Support Tools (CDST) based on consensus techniques to be counted shall be those written on the measured timeframe by the ERN (eg agreed by the ERN Board).

- Measuring only the new CPGs produced by the ERN is probably not sufficient to monitor the improvement of the access of patients to high and quality health care services. CDST production shall be considered crucial

- In many cases the role of ERNs would be to collect the evidence that will represent the baseline for the creation of CPGs. This will be done also through the ERN Registries.

- Another important element that should be considered in measuring the equal access to good quality health care is the adaptation of CPGs in the different Member States.

  example, for those diseases that already have published CPGs, ReCONNET is performing an adaptation of the guidelines in the different contexts by means of the ADAPTE methodology.

- Additional elements could be considered in the future as sub-indicators for 6.2 in order to capture relevant activities of ERNs related to the improvement and harmonization of care across Europe, not limiting to the creation of new CPGs, but also including adaptation, generation of new evidence, new clinical tools for monitoring the diseases, etc.

Indicator 7.1 - Number of congresses/ conferences/ meetings at which the ERN activities and results were presented

- The aim of this indicator is to capture the dissemination activities of the ERNs.
- The presentations must feature the ERN logo.
- Please do not consider presentations where the ERN is just mentioned.
- The ERN and its activities should be the focus of the presentations.

Indicator 7.2 - Number of individual ERN website hits

- There are different tools available that could help avoiding to count the machine-visits and include only actual page visits

  Example: Please use the google analytics tool for the counting, where “page visits” is a specified variable:

  https://analytics.google.com/analytics/web/