Continuous Monitoring of ERNs

ERN Continuous Monitoring and Quality Improvement System (ERN CMQIS)

ERN indicators – HCP form

November 2025

Version 9.1

ERN Continuous Monitoring Working Group

Version	Date	Comments
7.3	21.09.2020	Revision of indicators 3.1, 4.1, 4.2, 5.1, 5.2, 6.1, 7.1 Data collection of October 2020 (reporting period: Jan-Jun 2020)
7.3.1	14.10.2020	Summary of changes. Work in progress
7.4	24.02.2021	Editorial review Data collection of March 2021 (reporting period: Jan-Dec 2020)
7.4.1	01.03.2021	Work in progress Table of contents, minor rewordings,
7.4.2	08.07.2021	Work in progress Revision of indicator 5.1 by Monitoring Working Group
7.4.3	15.07.2021	Work in progress Further revision of indicator 5.1
7.5	07.09.2021	Editorial review Data collection of October 2021 (reporting period: Jan-Jun 2021)
7.5.1	15.09.2021	Corrected typo on indicator 1.3, discovered during the Monitoring Webinar of Oct 2021 Data collection of October 2021 (Jan-Jun 2021) and of March 2022 (Jan-Dec 2021)
7.5.2	9.06.2022	Work in Progress Data collection of 2023 (data of 2022 - reporting period: Jan-Dec 2022)
8.0	15.06.2023	New section (Introduction and Context) and KPIs for the ERN Direct Grants 2023-27. Overall revision of names and definitions.
8.0.1	22.06.2023	Work in progress. Adding more definitions for the Grant related KPIs Preparation for the data collection of 2024.
8.1	30.11.2023	Editorial review. Added glossary, legal references and minor revisions of definitions. Data collection of 2024 (reporting period: Jan-Dec 2023)
9.0.1	13.2.2025	Work-in-progress. Full restructuring of the document. Revision of definitions, clarifications and examples by the Monitoring Working Group.
9.1	3.11.2025	Editorial review. Data collection of 2026 (data of 2025) – HCP form

Versioning convention (X.Y.Z):

- X: main version number - advances on every major revision of the document (new indicators, new sections, etc.)
- Y: sub-version number - advances on minor revisions of the document (updates in the names or definitions of indicators, significant editorial change, etc.)
- Z: minor sub-version number - for work-in-progress versions of the document. Not to be officially released.

Contents

Introduction

The European Union's healthcare systems strive to deliver high-quality, cost-effective care. This goal is particularly challenging when addressing rare or low-prevalence complex diseases, which affect the daily lives of an estimated 30 million EU citizens. To overcome this inherent difficulty, the European Commission launched the European Reference Networks (ERNs) policy initiative [1, art. 12], [2], [3]. ERNs are networks of healthcare providers (HCPs) across Europe. Their primary purpose is to facilitate the cross-border sharing of knowledge on rare and complex diseases or conditions among healthcare professionals. Currently, there are 24 established networks covering various rare disease areas.

Evolution of Indicators

At the initiative's inception, the Board of Member States approved a core set of 16 indicators, which were used from 2017 to 2023. In September 2023, with the launch of multi-year direct grants for ERNs, several Key Performance Indicators (KPIs) were added to assess the fulfilment of grant obligations, bringing the total number of indicators to 24.

Data collection exercises

In the initial years of the initiative, there were two data collection exercises annually: one in October (covering January to June) and one in March of the following year (covering July to December). Since 2024, the process has been streamlined - the October data collection has been discontinued and the March collection has been split into two phases, both covering activities from January to December of the previous year:

- Phase 1 (January to February): Dedicated to Healthcare Providers (HCPs).
- Phase 2 (March): Dedicated to each ERN as a whole.

Data Collection Platform

To simplify the reporting process, a dedicated data collection platform was developed. This platform has been gradually adapted to accommodate the evolution of the data collection requirements. The platform is currently accessible to HCPs during the months of January and February of each year and to the ERNs in the month of March of each year.

Guidance Scope

This document provides an extract from the official data collection guidelines. It offers specific guidance for Phase 1 (HCPs) of the exercise, focusing on the two relevant indicators: New Patients and Use of Orphacodes.

For these two indicators, this document provides the official name, the approved definition, and includes answers to frequently received questions.

Legal references

1. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. Available here (original text) and here (consolidated).
2. Commission Implementing Decision 2014/287/EU, of 10 March 2014, setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks. Available here.
3. Commission Implementing Decision (EU) 2019/1269, of 26 July 2019, amending the Implementing Decision 2014/287/EU. Available here.

Glossary

To avoid confusion and guarantee a uniform interpretation, the following abbreviations and definitions apply:

HCP	Healthcare provider. Legally speaking HCP refers to any institution or professional that provides healthcare services but in the ERN context this concept is only applicable to hospitals.
HP	Healthcare professional. Any person accredited to provide healthcare services (clinicians, nurses, etc.).
ERN	European Reference Network. Network of HCPs that cooperate to share knowledge and advance the state of the art in one or more specific thematic areas. ERNs are composed of members and affiliated partners. All are requested to participate in the yearly data collections.
CC	Clinical centre. In the context of the ERNs it is a virtual entity that corresponds to the association of one ERN to one or more units/departments/services of one HCP.

Indicator 2.1 (KPI 6) - Number of new patients

Official name:
Number of new patients referred to the Health Care Providers of the ERN, with the diagnosis of a disease or condition that falls within the scope of the ERN

Official definition:
The number of patients attending the ERNs' Health Care Providers for the first time during the reporting period, with a confirmed diagnosis of a disease or condition falling within the scope of the ERN, whatever their age and sex. Includes visits to outpatient's clinics, hospital discharges and emergencies, coming from national and international referrals.

Expected answer:
A number.

Questions and answers:

- What is a new patient? New patients are those that have attended or been referred to the healthcare provider, within the specified timeframe and having a confirmed diagnosis of a rare disease. These patients should not have been previously included in the patient information system of the healthcare provider. It refers to the aggregated number of new patients, regardless of age and sex.
- What about undiagnosed conditions? Patients who have not obtained a diagnosis yet should not be taken into account.
- Is more better? No. In several instances, the number of new patients seen each year for some rare diseases will be very low. The intention of this data collection process is to establish a baseline for each healthcare provider, rather than comparing numbers between ERNs.
- What about recurrent patients? 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. In any case, patients that have been previously included in the patient information system of the healthcare provide shall not be counted.

Indicator 5.5 (KPI 16) - Use of Orphacodes

Official name:
Use of Orphacodes to code/classify patient cases

Official definition:
Acknowledgement that a clinical centre uses orphacodes to code/classify patient cases in the local medical record system, regardless of using other types of coding (e.g. for reimbursements) Applicable to ERNs for which the use of orphacodes is a relevant goal; otherwise, not applicable.

Expected answer
Yes/No/Not Applicable

Questions and answers: