

ePAG glossary of terms

European Reference Network (ERN): a group of highly specialised healthcare providers that have been awarded with the membership of a given Network. Networks focus on rare or low prevalence and complex disease(s), condition(s) or highly specialised intervention(s) as regulated by article 12 of the Directive 2011/24/EU on patients' rights in cross-border healthcare¹.

Board of Member States (BoMs): a governing body consisting of representatives from Member States across EU Member States and European Economic Area responsible for the formal designation of European Reference Networks as provided in the Commission Implementing Decision 2014/287/EU². The Board of Member States (BoMS) has the responsibility of approving European Reference Networks (ERNs).

Patient Organisations (PO): Non-profit organisations that are legally registered and operating in [Europe](#) (48 countries as defined by EURORDIS based on definitions by the EU, the Council of Europe and the WHO-Europe), representing patients and families living with a rare disease, has a governing board made up of a majority patients or of family members of patients, is financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies) and has proven activities such as patient support and/or advocacy activities and/or research. Individual ERNs may waive some of these requirements in exceptional cases, due to the particularity of patient-driven organisations and of rare diseases, as well as for historical or contextual reasons.

Patient partnership: a mutual relationship between persons living with a rare disease and other stakeholders where input from people living with a rare disease or caring for someone with a rare disease routinely and formally informs policy reflections and decisions. Patient partnership implies going beyond empowerment and engagement but considering people living with a rare disease and their advocates as equal partners and actors in policy and programme design and evaluation. For the purposes of this governance framework the terms “patient involvement” and “patient partnership” are used interchangeably.

ERNs Associate Partner - Patient Organisation: Patient Organisation registered and operating in [Europe](#) that has been invited to partner with an ERN, complies with the requirements established by the ERN and has gone through the Network’s application process to designate a patient representative to be involved in the ERN activities as an ePAG advocate. An Associate Partner agreement is signed between the ERN and the Patient Organisation to establish the terms of this collaboration.

ERN Supporting Partner - Patients: Patient Organisation with a national, European or international remit with no designated patient representative in the ERN, individual patients and family members or social-media patient support groups that have been invited to collaborate with an ERN. A Supporting Partner Agreement is signed between the ERN and the Patient Organisation, individual or support group to establish the terms of this collaboration.

¹ OJ L 88, 4.4.2011, p. 45, 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

² OJ L 174, 17.5.2014, p. 79, 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

ePAG Advocate: A patient representative to a specific European Reference Network who has been endorsed by an ERN Associate Partner-Patient Organisation to be active in the ERN governance structure including its working groups. For the purpose of this framework, the terms ePAG advocate, patient representative and patient advocate are used interchangeably.

European Patient Advocacy Group (ePAG): A patient group, specific to each European Reference Network, composed by patient advocates that have been endorsed by a Patient Organisation established by EURORDIS to optimise patient involvement in the ERNs' decisions and activities. Some ERNs have formally recognised these groups as part of their governance structure. The overarching objective of the ePAG is to ensure that the needs of people living with rare and complex conditions covered by the ERN are included in its strategic and operational delivery.

ePAG Steering Committee: Transversal working set up and managed by EURORDIS composed by ePAG Advocates from the 24 ePAGs sitting in the ERNs Boards or Executive Committees to provide strategic advice, share experience and knowledge from the 24 ERNs.

ePAG Transversal Topic Based Groups: Transversal peer learning working groups set up and managed by EURORDIS composed by ePAG Advocates dedicated to a specific topic, e.g.: clinical practice guidelines and clinical decision support tools, communication and dissemination, research and registries, training and education, monitoring and evaluation.

ERN Coordinator: the person appointed as the Coordinator of the Network by the Member of a European Reference Network chosen as the coordinating Member as referred to in recital 3 and Article 4 of Delegated Decision 2014/286/EU.

ERN Project Managers: the persons in charge of coordinating the Networks' collaborative activities, financial and technical reporting, monitoring and evaluation.

Board of the ERN: the coordination body for each Network responsible for its governance, as foreseen in the Commission Delegated Decision 2014/286/EU³ (Annex I)³. All members of the Network must be represented on the Board.

ERN Core Networks (or sub-thematic networks): ERNs are thematic networks covering a number of rare or complex diseases and/or highly specialised interventions or surgery, as defined in their ERN application scope. Each ERN is structured differently to reflect the needs and grouping of their rare diseases into a number of 'Core Networks', also known as Disease Specific Networks or Sub-Thematic Working Groups, (e.g.: ERN-Lung has 9 core networks including Cystic Fibrosis, Pulmonary Hypertension, etc). Each one of these networks have a clinical committee or board of experts in that specific field to coordinate and lead the ERN activities specific to this disease area.

ERNs Coordinators Group: a working group that brings together the Coordinators of the 24 ERNs to discuss common technical matters.

ERN Transversal Working Groups: Transversal working groups set up by the ERN Coordinators, sometimes jointly with the ERNs BoMs, to discuss on topics and activities that are cross-cutting all 24 ERNs e.g.: clinical practice guidelines and clinical decision support tools, legal and ethics, research, training and education, integration of ERNs into national health systems, monitoring and evaluation.

³ OJ L 174, 17.5.2014, p. 71, Commission Delegated Decision 2014/286/EU of 10 March 2014, setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

ERN Healthcare Provider (HCP) Member: a centre of medical expertise / excellence or specialist team treating rare and complex diseases, who has been endorsed by their Member State as an expert centre, is in compliance with the criteria and conditions laid down in Article 5 of the Commission Delegated Decision (2014/286/EU) and has been awarded with the membership of a given network.

ERN Affiliated Partner: Member States with no Member of a given Network may decide to designate healthcare providers with a special link to a given ERN, following a transparent and explicit procedure. Those providers might be designated as Associated National Centres focusing on the provision of healthcare, Collaborative National Centres focusing in the production of knowledge and tools to improve the quality of care or a National Coordination Hub who connects their national healthcare system with ERNs, coordinating information and referrals.

ERN Supporting Partner: healthcare providers, medical societies, and any other entity or individual experts which, without having a commercial relation with the ERNs and their Full Members or Affiliated Partners, or with the European Commission, contribute in different ways to the work of the networks.

EUCERD: European Union Committee of Experts on Rare Diseases established to support EU policy on rare diseases, and specifically provide policy guidance on the effective implementation of the 2008 EU Commission Communication on Rare Diseases and the 2009 Council (of the European Union) Recommendation on action in the field of rare diseases. In 2013 it was replaced by the European Commission Expert Group on Rare Diseases (CEG –RED) whose mandate terminated in 2016. The EUCERD and CEG-RD brought together representatives from: the 28 EU Member States, Iceland, Norway, Switzerland, the EU Commission, the Committee for Orphan Medicinal Products of the EMA, industry, academia, eight individual experts as well as eight patient advocates.