

## **RULES OF PROCEDURE OF THE EUROPEAN REFERENCE NETWORKS**

### **COORDINATORS GROUP**

**VERSION OF 15 March 2024**

The European Reference Networks Coordinators Group [Hereinafter 'ERN-CG'],

Having regard to 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<sup>1</sup> [Hereinafter 'cross-border healthcare Directive'], and in particular to Article 12,

Having regard to the 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<sup>2</sup>, and, in particular, Article 4 and Recital 3,

Having regard to the 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<sup>3</sup>,

Having regard to the Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU 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<sup>4</sup>,

Having regard to the Decision No 153/2014 of the EEA Joint Committee of 9 July 2014 amending Annex X to the EEA agreement which incorporated the cross-border healthcare Directive into the EEA Agreement<sup>5</sup>.

Has adopted the following rules of procedure:

#### *Article 1*

#### **The European Reference Networks Coordinators Group**

1. The ERN Coordinators Group brings together the Coordinators of the European Reference Networks [Hereinafter 'the Coordinators']. These Coordinators are approved by the ERNs Board of Member States [Hereinafter 'the Board'] during the initial ERN application procedure.

2. The ERN-CG shall focus its activities on strategic issues relevant to the European Reference Networks [Hereinafter 'ERNs'] implementation, functioning and governance and shall ensure the consistency and efficiency of the ERNs' actions, in particular with regard to those issues which are

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<sup>1</sup> 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 (*OJ L 88, 4.4.2011, p. 45*).

<sup>2</sup> 2014/286/EU: Commission Delegated Decision 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 (*OJ L 147, 17.5.2014, p. 71*).

<sup>3</sup> 2014/287/EU: Commission Implementing Decision 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 (*OJ L 147, 17.5.2014, p. 79*).

<sup>4</sup> Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU 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 (*OJ L 200, 29.7.2019, p. 35*).

<sup>5</sup> Decision of the EEA Joint Committee No 153/2014 of 9 July 2014 amending Annex X (Services in general) to the EEA Agreement (*OJ L 15, 22.1.2015, p. 78*).

common to all ERNs. When needed, it may also provide advice to the European Commission and the Member States in matters related to the ERNs.

#### *Article 2*

#### **Members of the ERN-CG**

1. The members of the ERN-CG are the persons appointed by the Board of the ERNs to act as the coordinator of each Network. Each ERN shall inform the Secretariat of the name of its Coordinator.
2. After the approval process for establishing an ERN has been completed, changes in the Coordinator or transfers of the Coordinating Healthcare Provider of an ERN may take place in line with the corresponding procedures relating to the changes or transfers to the coordination of an ERN and the governance statutes of the given network.

#### *Article 3*

#### **Chairs**

1. A Chair of the ERN-CG [Hereinafter 'the Chair'] shall be elected from among the Coordinators. An elected future Chair shall support and act as an alternate for the Chair replacing the Chair when needed.
2. The Chair and the future Chair shall be appointed for a period of one year, according to the procedures laid out in Article 8. The appointment shall take effect on the 1<sup>st</sup> day of the month following the election.
3. When the Chair's term expires, the future Chair will take the role of the Chair, and a new future Chair will be elected.
4. The Chair, once their term has expired, will serve for a period of one year, as past Chair and support the Chair and the future Chair in the management of the ERN-CG.
5. The ERN-CG meetings shall be co-chaired by the Chair and by a Commission representative [Hereinafter 'the Co-Chairs'].

#### *Article 4*

#### **Convening a meeting**

1. Meetings of the ERN-CG shall be convened by the Co-Chairs at least once a year, but preferably twice a year. ERN-CG meetings should be held back-to-back to ERN Board of Member States meetings to facilitate their collaboration and exchange of views.
2. The Member State Chair of the ERNs Board of Member States and other Board members may be invited to attend the ERN-CG meetings.
3. The Co-Chairs may also request the ERN-CG to convene for ad-hoc meetings. In such cases the delivery of the agenda and supporting documents may be closer to the meeting than the 10 working days envisaged for ordinary meetings.
4. The Coordinators are requested to participate in the meetings of the ERN-CG in person or virtually (online meetings). In case of absence, they shall designate an alternate and inform the Secretariat of their name within a reasonable time and no later than 5 working days before the meeting.

5. When needed, more than one representative per ERN can attend ERN-CG meetings, depending on the need of their presence and logistic conditions. Notably, ERNs' project or financial managers can be invited to attend the meetings when their presence is required.

6. The Coordinators shall communicate in writing to the Secretariat whether they (or their alternates) will be accompanied by other persons, the name and function of the persons and the reason for which their presence is required. The Secretariat must confirm the participation of additional representatives.

7. Preparatory or working meetings of the ERN Coordinators and of the ERN-CG working groups, may be arranged before or after the meeting of the ERN-CG.

8. Physical meetings of the ERN-CG shall be held on Commission premises unless otherwise decided by the Co-Chairs.

9. According to its rules, the Commission will cover the subsistence expenses of one representative per ERN for the ERN-CG meetings.

#### *Article 5*

#### **Secretariat**

The Commission shall support the effective functioning of the ERN-CG and of its Working Groups by providing secretarial support.

#### *Article 6*

#### **Agenda**

1. The Secretariat shall draw up the agenda after consulting the Co-Chairs and send it out to the members of the ERN-CG no later than 15 working days before the meeting.

2. The agenda shall be adopted by the ERN-CG at the start of the meeting.

#### *Article 7*

#### **Documentation to be sent to the members of the ERN-CG**

1. The Secretariat shall send the documents to be discussed by the ERN-CG no later than 10 working days before the date of the meeting.

2. CIRCA-BC will be the official repository of the ERN-CG documents. The ERNs coordinators will grant and supervise the accesses or termination of accesses to CIRCA-BC of representatives of the ERNs other than the coordinators.

#### *Article 8*

#### **Voting rules and decision-making process of the ERN-CG**

1. The ERN-CG shall decide by consensus, as far as possible. Consensus requires a quorum of two thirds of the Coordinators for both physical and virtual meetings. Abstentions shall not prevent the adoption of deliberations by consensus.

2. A vote shall be taken if any ERN-CG member so requests. Voting requires a quorum of two thirds of the Coordinators for both physical and virtual meetings. The outcome shall be decided by a majority of two thirds of the present Coordinators. In the case of a tied vote, the Chair holds the casting vote.

3. Each Coordinator or their alternate shall have one vote. In case of absence of the Coordinator and of their alternate, the vote shall be taken into account if a written voting mandate is provided to another Coordinator. These mandate letters should be communicated to the secretariat of the ERN-CG no later than 5 working days before the meeting.

4. It is highly advisable that the representation of each network is ensured during each ERN-CG meeting. If physical participation is not possible, at least virtual participation should be ensured during ERN-CG meetings. This is especially important for all cases where voting is scheduled on the agenda to reach the required quorum and have as many Coordinators as possible expressing their views.

#### *Article 9*

#### **Working Groups and Steering Group**

1. The ERN-CG may decide to set up working groups [Hereinafter 'WGs'] to carry out a specific task of interest or importance to the Coordinators or the Commission, defined when the WG is set up.
2. The ERN-CG may decide that the WG will be set up jointly by the ERN-CG, the Board of Member States and the Commission.
3. Each WG will be led by an elected WG Chair. The WGs Chair may be an ERN Coordinator, a Board of Member States representative, or a Commission representative.
4. Each WG shall finalise, no later than 4 weeks after its activation, a draft mandate describing the scope, goals, tasks, timeline and expected deliverables of the WGs. The ERN-CG shall approve the mandate of the WG. In the case of a joint WG, both the ERN-CG, the Board of the Member States and the Commission shall approve the mandate of the WG according to the decision-making rules set up in their respective Rules of Procedures.
5. The Chair of the WGs shall lead, organise, and supervise the work of the WGs based on their mandate. This might include organising web conferences or, when necessary, ad hoc meetings of the WGs.
6. Once the mandates of a WGs is fulfilled or when so decided by the ERN-CG, and, if relevant, the Board of Member States and the Commission, the WGs shall be terminated.
7. The Chairs of the WGs will constitute the Steering Group of the ERN-CG and will support the CG Chair in the management of the ERN-CG. The Steering Group may propose ERN-CG initiatives, based on the work done by the WGs. The Steering Group also helps to ensure a strategic overview of the WGs and avoid duplication of work across the WGs. The Steering Group may be convened on request of the CG Chair who supervises the work of the Steering Group.
8. The list of the WGs, including a description of their mandate will be published on the ERNs webpage of the Commission.
9. It is recommended that the WGs are aligned with the work package structure of the ERN grants, if any. This aims to ensure opportunities for harmonisation, collaboration and exchange of best practice across common areas of work.

10. WGs should convene at least twice a year. Any further meetings are voluntary, if the group so wishes, based on the needs and ongoing priorities.

*Article 10*

**Admission of third parties**

The Co-Chairs may invite, on an *ad-hoc* basis, experts from outside the ERN-CG with specific competence in a subject on the agenda to participate in the meeting of the ERN-CG.

*Article 11*

**Written procedure**

1. If necessary, the ERN-CG's opinions, conclusions, recommendations, or reports on a specific question may be delivered via a written procedure. To this end, upon request of the Co-Chairs, the Secretariat will send the ERN-CG members the document(s) on which the ERN-CG is being consulted and, where appropriate, sets a time limit for observations.

2. The Secretariat shall inform the ERN-CG of the outcome(s) of the written procedure.

3. However, if a simple majority of the ERN-CG members request that the question should be discussed at a meeting of the ERN-CG, the written procedure shall be terminated without result and the Secretariat shall convene a meeting of the ERN-CG as soon as possible.

*Article 12*

**Summary minutes of the meetings**

1. Summary minutes of the discussion on each point of the agenda and the opinions and decisions adopted by the ERN-CG shall be drafted by the Secretariat and sent to the ERN-CG members no later than 15 working days after the meeting.

2. The ERN-CG members shall send any comments they may have on the draft summary minutes to the Secretariat in writing within 10 working days of receiving these.

*Article 13*

**Attendance list and conflict of interest**

1. At each meeting, the Secretariat shall draw up an attendance list of participants at the ERN-CG meeting.

2. At the beginning of each meeting, either ERN-CG meetings or ERN-CG WGs meetings, any ERN-CG Member, as well as experts and representatives of third parties who have been invited to attend the meetings, shall inform the Co-Chairs of any conflict of interest with regard to a particular item on the agenda.

3. Conflict of interest is defined as any situation where an individual has an interest that may compromise or be reasonably perceived to compromise the individual's ability to act independently and in the public interest when participating in the ERN-CG meeting.

4. In the event of such a conflict of interest, the person concerned shall, at the request of the Co-Chairs, withdraw from the meeting whilst the relevant items of the agenda are being dealt with.

5. Conflicts of interest shall be reported in writing, e.g., in the summary minutes of the ERN-CG meeting.

6. Paragraphs 1, 2, 3 and 4 shall also apply to deliberations taken by the ERN-CG in written procedures.

#### *Article 14*

### **Correspondence**

1. Correspondence relating to the ERN-CG shall be addressed to the Secretariat, for the attention of the Co-Chairs.

2. Correspondence for ERN-CG shall be sent to the e-mail address or addresses which they provide for that purpose.

#### *Article 15*

### **Access to documents**

Requests for access to ERN-CG's documents shall be handled in accordance with Regulation (EC) No 1049/2001<sup>6</sup>. It is for the Commission to take a decision on requests for access to those documents pursuant to its Rules of Procedure as amended by Decision 2001/937/EC<sup>7</sup>.

#### *Article 16*

### **Confidentiality of deliberations**

1. The ERN-CG's deliberations shall be confidential.

2. The ERN-CG may, by a simple majority of its members, decide to open its deliberations to the public.

#### *Article 17*

### **Protection of personal data**

All collecting, processing, and publishing of personal data for the purposes of these rules of procedure shall be in accordance with relevant EU legislation where applicable Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies<sup>8</sup> and Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data<sup>9</sup>.

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<sup>6</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (*OJ L 145, 31.5.2001 p.43*).

<sup>7</sup> Commission Decision of 5 December 2001 amending its rules of procedure (notified under document number C(2001) 3714) (*OJ L 345, 29.12.2001, p. 94*).

<sup>8</sup> Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (*OJ L 295, 21.11.2018, p. 39*).

<sup>9</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (*OJ L 119, 4.5.2016, p. 1*).