



ERN eUROGEN: Transition Protocol & Procedures for Coordinating HCP, Coordinator & Workstream Leads

V 2024-05-08

CONTENTS

Table of Contents

1. Background	1
2. ERN eUROGEN Governance Statutes	2
3. Transition of The Coordinating HCP	2
4. Transition of The Coordinator	3
5. Additional Procedures for Transition of The Coordinator	4
6. Financial Issues	4
7. Transition of Workstream Leads	5
Appendix A: EC ERN Procedures - April 2024	6

1. BACKGROUND

- 1.1. The European Reference Network named the "European Reference Network for Rare Urogenital Diseases and Complex Conditions" (hereinafter referred to by its acronym, ERN eUROGEN) was established in 2017 in response to the European Commission (EC) call for the setup of European Reference Networks (ERNs), published within the framework of the Third Programme of the Union's action in the field of health.
- 1.2. According to Article 12 of the EC Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, ERN eUROGEN operates on a non-profit basis to facilitate access to the best available expert clinical advice and to address the needs of all patients (and their families) affected by rare urogenital diseases and complex conditions in EU countries. Therefore, ERN eUROGEN has the character of a non-profit organisation of social utility without a legal entity.
- 1.3. The ERN eUROGEN Coordinating HCP is responsible for managing ERN eUROGEN's EC grants and arranging the employment contracts of the Coordination Team in accordance with the governance documents, EC Grant requirements and job descriptions.
- 1.4. For the first two years of its operation since 2017, ERN eUROGEN's Coordinating HCP was Sheffield Teaching Hospitals NHS Foundation Trust in the UK, and the Coordinator was Prof Christopher Chapple. From April 2019, due to the UK's withdrawal from the EU and after approval by ERN eUROGEN's Strategic Board, Full Members and Affiliated Partners, ERN eUROGEN's Coordinating HCP has been Radboudumc in The Netherlands. Prof Wout Feitz has been the Coordinator and the Workstream 1 Lead during this period.
- 1.5. During this first transition and change of ERN eUROGEN Coordinating HCP, a transition protocol was unnecessary as both the new Coordinating HCP and Coordinator were identified in the risk planning of the first grant application in 2016.



- 1.6. However, the retirement plans of the current Coordinator on 8 May 2024 have now led to the development of this transition protocol to ensure a smooth and professional transfer of duties and to ensure the business continuity of the ERN eUROGEN network.

2. ERN EUROGEN GOVERNANCE STATUTES

- 2.1. ERN eUROGEN has a comprehensive set of Governance Statutes ([available here](#)) that are signed by all healthcare providers (HCPs) to facilitate the professional management of the network. The first version of the ERN eUROGEN Governance Statutes was adopted by ERN eUROGEN's original Full Members in 2018 and the Affiliated Partners who joined in 2019. The Governance Statutes were then updated for presentation to the whole network, including those Full Members who joined the network in 2022. The Governance Statutes will be refreshed again in 2024 for presentation to and voting by the Strategic Board at the 2024 annual Strategic Board meeting, followed by the re-signature of the Governance Statutes by all Full Members and Affiliated Partners.
- 2.2. Section 3 of the Governance Statutes (2022 version) concerns the ERN's organisational structure. Article 17 concerns the Coordinating HCP (formerly known as the HCP Network Coordinator) (i.e., the **institution**), and Article 18 concerns the Coordinator (HCP Network Coordinator Representative) (i.e., the **person**).

3. TRANSITION OF THE COORDINATING HCP

- 3.1. Article 17 within the ERN eUROGEN Governance Statutes (2022 version) concerns the Coordinating HCP (formerly known as the HCP Network Coordinator) (i.e., the **institution**, e.g., Sheffield Teaching Hospitals NHS Foundation Trust or Radboudumc).

Article 17 - HCP Network Coordinator

The HCP Network Coordinator is the legal coordinator of ERN eUROGEN. The HCP Network Coordinator representative is elected for a five-year mandate, renewable for additional terms upon approval of the Strategic Board. The Coordinating HCP appoints a representative substitute person to have the best cover for the sustainability of the network activities.

Should it be necessary to change the HCP Network Coordinator, the Coordination Team should be notified in writing. They will then arrange the process to nominate a new HCP Network Coordinator, by emailing the network to ask for volunteer HCPs that have the full support of their CEO. The option(s) will then be voted on by the Strategic Board, with the elected HCP Network Coordinator requiring a two-thirds majority vote, in accordance with Article 19 of these Statutes.

The new HCP Network Coordinator and the outgoing HCP Network Coordinator must arrange a transition protocol for a smooth transition of all actions, grants, contracts, reporting and financial information, and related aspects, and the new coordinator must also take over and continue the contracts in place for all existing management staff. This should be managed at senior level, supported by HCP Human Resource departments. This is to guarantee the seamless continuation of operations.

When there is a transfer of the HCP Network Coordinator ⁽¹⁾:

1. The ERN must send an email to inform the ERN Secretariat (sante-ern@ec.europa.eu), copying the corresponding national representative of the BoMs. This email should include, in attachment, a letter signed on behalf of the Board of the Network and by the CEOs - or his/her representative – of both previous and new coordinating HCPs, in line with Article 16(2) ⁽²⁾ of the Commission Implementing Decision 2014/287/EU ⁽³⁾. This letter should include the following information:
 - confirmation of the change of the existing coordinating HCP;

⁽¹⁾ A transfer of a coordinating HCP to another HCP is limited to the HCPs that are already members within the concerned Network, as approved by the Board of Member States.

⁽²⁾ 'For the purpose of publishing the list referred to in paragraph 1(b), any change in the Member acting as Coordinator of a Network or in the person nominated as Coordinator of a Network shall be communicated to the Commission by the Board of the Network.'

⁽³⁾ 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 Text with EEA relevance

- information regarding the new coordinating HCP:
 - contact details of the CEO and of the data protection officer;
 - contact details of the new coordinator;
 - agreement by the Board of the Network and the CEOs - or his/her representative, both existing and new coordinating HCPs of the change in coordinating HCP.
2. The ERN secretariat acknowledges receipt, registers the email and the letter and updates the information regarding the change in the coordinating HCP in the ERN directories and distribution list(s), and in the ERN search tool ⁽⁴⁾ as regards the new coordinating HCP.
 3. The ERN Secretariat informs the Co-Chair of the BoMS and the Co-Chairs of the CG of the change in the coordinating HCP.

4. TRANSITION OF THE COORDINATOR

4.1. Article 18 within the ERN eUROGEN Governance Statutes (2022 version) concerns the Coordinator (formerly known as the HCP Network Coordinator Representative) (i.e., the **person** within the institution, e.g., Prof Christopher Chapple or Prof Wout Feitz).

Article 18 - HCP Network Coordinator Representative

The HCP Network Coordinator's Chief Executive Officer (CEO) appoints a Representative and Sub-Representative based on their proven ability to coordinate and lead a network, as well as their medically relevant activities in the field.

Assisted by the other Administrative Bodies, the HCP Network Coordinator Representative supports and facilitates coordination both within and outside the network. The HCP Network Coordinator Representative chairs the meetings of the Strategic Board and the Operational Board and represents the network at EC and external meetings. They are elected for a five-year mandate, renewable for a second term upon approval of the Strategic Board. The HCP Network Coordinator Representative has the deciding vote on the Strategic Board in the case of a draw.

The HCP Network Coordinator Representative oversees the successful management and control of work, in particular:

- coordinating the work of all the WS, EAs, and Working Groups,
- identifying, tracking, managing, and resolving programme and project issues and risks,
- proactively disseminating and communicating programme and project information to all stakeholders, supported by the Coordination Team,
- managing the overall work plans to ensure work is assigned and deliverables are completed on time and within budget.

When there is a change in HCP Network Coordinator Representative within the same HCP Coordinator:

1. The ERN must send an email to inform the ERN Secretariat (sante-ern@ec.europa.eu), copying the corresponding national representative of the Board of Member States (BoMS). This email should include, in attachment, a letter signed on behalf of the Strategic Board and by the Chief Executive Officer (CEO) - or his/her representative - of the HCP to which the existing coordinator Representative belongs, in line with Article 16(2) ⁽⁵⁾ of the Commission Implementing Decision 2014/287/EU ⁽⁶⁾. This letter must include the following information:
 - confirmation of the change regarding the existing coordinator Representative;
 - contact details regarding the new coordinator Representative;
 - agreement by the Board of the Network and the CEO - or his/her representative - of the HCP of the change in coordinating person.

⁽⁴⁾ webgate.ec.europa.eu/ernsd/cgi-bin/ern_public.cgi?npage=ern_portal.html#!/

⁽⁵⁾ 'For the purpose of publishing the list referred to in paragraph 1(b), any change in the Member acting as Coordinator of a Network or in the person nominated as Coordinator of a Network shall be communicated to the Commission by the Board of the Network.'

⁽⁶⁾ 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 Text with EEA relevance.

2. The ERN secretariat acknowledges receipt, registers the email and the letter, and updates the information regarding the coordination change in the ERN directories and distribution list(s).
3. The ERN Secretariat informs the Co-Chair of the BoMS and the Co-Chairs of the Coordinators Group (CG) of the change in the Coordinator Representative.

5. ADDITIONAL PROCEDURES FOR TRANSITION OF THE COORDINATOR

- 5.1. The Coordinator can be changed internally within the Coordinating HCP, should this become necessary, for example, due to retirement, ill health, or any other circumstances where the Coordinating HCP considers a change of leadership necessary. If it is necessary to change the Sub-Coordinator, the same processes as described in this document for change of Coordinator will be followed. If it is necessary to change the ERN Programme Manager, candidates with a similar level of professional experience will be sought.
- 5.2. If a change of Coordinator is initiated, the CEO or person with responsibility for the ERNs within the Coordinating HCP will write to the ERN eUROGEN Programme Manager to inform them of the proposed changes so that the correct network Governance Statutes can be followed in a timely manner, i.e., the Strategic Board of the network will be advised of the proposed changes by email and all members of the Strategic Board will be given a two-week period to approve the changes or send comments. Following usual network arrangements, if no reply is received within the two-week period, approval will be assumed, and this will be made clear in the email correspondence.
- 5.3. Any newly selected Coordinator must have a recognised international clinical profile and have made a significant contribution to research and teaching activities. The person's CV should be broadly comparable with those of the other ERN Coordinators.
- 5.4. The CV will be shared with the network Strategic Board, the European Commission, and the Board of Member States for ERNs (BoMS). For comparison, a sample of CVs for other ERN Coordinators can be [accessed here](#).
- 5.5. If comments are received from the network Strategic Board regarding the change in the Coordinator, they will be addressed by the current Coordinating HCP, Coordinator, and Programme Manager as far as possible. Additional advice will be sought if needed.
- 5.6. If the network Strategic Board receives new proposals for other candidates for the position of Coordinator, which may involve changing the ERN's Coordinating HCP, a vote of the network Strategic Board may become necessary following all the existing ERN eUROGEN Governance Statutes.
- 5.7. Once the network Strategic Board agrees on a new Coordinator, the ERN Programme Manager will follow the processes outlined in Article 18 of the Governance Statutes (see Section 4 above) and by the European Commission in their document of April 2024, "European Reference Networks: Procedures," (included as Appendix A to this protocol), to officially inform the relevant stakeholders of the changes.
- 5.8. To ensure a smooth transition and maintain business continuity, the outgoing Coordinator will transfer all their ERN-related files and documents to the incoming Coordinator upon their approval by the network Strategic Board.
- 5.9. To further facilitate a smooth transition, the outgoing Coordinator will remain in contact with ERN eUROGEN for a minimum of one year to provide strategic advice or share knowledge on previous historical developments, where needed. This may include attendance at meetings if this is considered to be of strategic importance, and reimbursement of specific costs will take place in agreement with the ERN Programme Manager and in accordance with the budget.

6. FINANCIAL ISSUES

- 6.1. The Coordinating HCP will arrange a meeting with the Financial Officer responsible for the financial issues of the grant to resolve any outstanding issues and ensure a smooth transition to the new Coordinator.
- 6.2. The Financial Officer will develop a new internal Radboudumc ERN eUROGEN budget, including the budget available for the Coordinator, the Sub-Coordinator, and Workstream Lead positions.
- 6.3. Around 10% of the total ERN budget should be transferred to the HCPs within the network, and the budget should be arranged accordingly.

- 6.4. Some budget (the suggested amount is around €10,000) should be included to allow the outgoing Coordinator to attend relevant meetings to ensure the smooth transition to any new appointees in an appropriate way. This will be included as a new budget line in the internal Radboudumc ERN eUROGEN budget.
- 6.5. Other EC grants which are related to ERN activity will also be discussed with the Coordinator, the Financial Officer and the Programme Manager, and handed over to the incoming Coordinator.

7. TRANSITION OF WORKSTREAM LEADS

- 7.1. Should it be necessary to change a Workstream Lead, the Workstreams being internal groups to ERN eUROGEN, for example, due to retirement, ill health, or any other reason, the current Workstream Lead should, if possible, notify the Coordinator and the Coordination Team in writing at least two months before the change is due to take effect.
- 7.2. The Coordination Team will then arrange the process of nominating a new Workstream Lead by emailing the network to ask for volunteer HCPs with the full support of their CEO.
- 7.3. Applications for the position of Workstream Lead should include a CV to demonstrate the required high profile. The option(s) will then be voted on by the HCP Representatives and Sub-Representatives within the relevant Workstream, with the elected Workstream Lead requiring the majority of votes.
- 7.4. The outgoing Workstream Lead will aim to facilitate as smooth a transition as possible with the incoming Workstream Lead and will transfer all their ERN-related files and documents to the incoming Workstream Lead, upon their approval by the network Strategic Board.
- 7.5. Again, to facilitate a smooth transition, the outgoing Workstream Lead will remain in contact with ERN eUROGEN for at least six months to provide strategic advice or share knowledge on previous historical developments, where needed. This may include attendance at meetings if this is considered to be of strategic importance.

Background

In their activity, European Reference Networks (ERNs) may have changes that occur within their Networks. This can include changes in the Coordinator of a Network, changes in the coordinating Healthcare Provider (HCP) of a Network and voluntary withdrawals of HCPs within a Network.

Purpose

This document outlines the procedures to be followed as relates to changes within an ERN. It comprises the following procedures:

1. Changes in an ERN's coordination:
 - a. Case A: change in coordinator within the same coordinating HCP of an ERN
 - b. Case B: transfer of the coordinating HCP
 - c. Case C: change of the coordinating HCP ⁽⁷⁾
2. Voluntary withdrawal of an HCP from an ERN
3. Change of an HCP member within an ERN ⁽⁸⁾

These procedures provide a clear and homogenous approach for the ERNs and the Commission for implementation in case of changes within the Networks. Additional procedures can be elaborated and included in case required.

For any clarifications, contact the ERN Secretariat, sante-ern@ec.europa.eu.

ANNEX 1

CHANGE IN AN ERN's COORDINATION

CASE A

Change in Coordinator within the same coordinating HCP of an ERN

2. An ERN affected by a **change in the Coordinator** must send an email to inform the ERN Secretariat (sante-ern@ec.europa.eu), copying the corresponding national representative of the Board of Member States (BoMs). This email should include, in attachment, a letter signed on behalf of the Board of the Network and by the Chief Executive Officer (CEO) - or his/her representative - of the HCP to which the existing coordinator belongs, in line with Article 16(2) ⁽⁹⁾ of the Commission Implementing Decision 2014/287/EU ⁽¹⁰⁾. This letter must include the following information:
 - confirmation of the change regarding the existing coordinator;
 - contact details regarding the new coordinator;
 - agreement by the Board of the Network and the CEO - or his/her representative - of the HCP of the change in coordinating person.
4. The ERN secretariat acknowledges receipt, registers the email and the letter, and updates the information regarding the coordination change in the ERN directories and distribution list(s).

⁽⁷⁾ This refers to national changes – such as institutional mergers – that may impact the name and structure of the coordinating HCP.

⁽⁸⁾ This refers to national changes – such as institutional mergers – that may impact the name and structure of an HCP within an ERN.

⁽⁹⁾ 'For the purpose of publishing the list referred to in paragraph 1(b), any change in the Member acting as Coordinator of a Network or in the person nominated as Coordinator of a Network shall be communicated to the Commission by the Board of the Network.'

⁽¹⁰⁾ 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 Text with EEA relevance.

5. The ERN Secretariat informs the Co-Chair of the BoMS and the Co-Chairs of the Coordinators Group (CG) of the change in the coordinator.

CASE B

Transfer of the coordinating HCP of an ERN

3. An ERN affected by a **transfer of the coordinating HCP** ⁽¹¹⁾ must send an email to inform the ERN Secretariat (sante-ern@ec.europa.eu), copying the corresponding national representative of the BoMs. This email should include, in attachment, a letter signed on behalf of the Board of the Network and by the CEOs - or his/her representatives – of both current and future coordinating HCPs, in line with Article 16(2) ⁽¹²⁾ of the Commission Implementing Decision 2014/287/EU ⁽¹³⁾. This letter should include the following information:
 - confirmation of the change of the current coordinating HCP;
 - information regarding the future coordinating HCP:
 - contact details of the CEO and of the data protection officer;
 - contact details of the future coordinator;
 - agreement by the Board of the Network and the CEOs - or his/her representatives - of both current and future coordinating HCPs of the change in coordinating HCP.
4. The ERN secretariat acknowledges receipt, registers the email and the letter and updates the information regarding the change in the coordinating HCP in the ERN directories and distribution list(s), and in the ERN search tool ⁽¹⁴⁾ as regards the new coordinating HCP.
5. The ERN secretariat informs the Co-Chair of the BoMS and the Co-Chairs of the CG of the change in the coordinating HCP.

CASE C

Change in the coordinating HCP

1. An ERN affected by a **change in the coordinating HCP** must send an email to inform the corresponding national representative of the BoMs, with the ERN secretariat (sante-ern@ec.europa.eu) in copy. This email should include, in attachment, a letter signed on behalf of the Board of the Network and by the CEO - or his/her representative - of the HCP to which the existing coordinator belongs, in line with Article 16(2) ⁽¹⁵⁾ of the Commission Implementing Decision 2014/287/EU ⁽¹⁶⁾. This letter must include the following information:
 - confirmation of the change regarding the coordinating HCP and the reason for the change;
 - information regarding the change of the coordinating HCP:
 - name of the coordinating HCP;

⁽¹¹⁾ A transfer of a coordinating HCP to another HCP is limited to the HCPs that are already members within the concerned Network, as approved by the Board of Member States.

⁽¹²⁾ 'For the purpose of publishing the list referred to in paragraph 1(b), any change in the Member acting as Coordinator of a Network or in the person nominated as Coordinator of a Network shall be communicated to the Commission by the Board of the Network.'

⁽¹³⁾ 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 Text with EEA relevance

⁽¹⁴⁾ webgate.ec.europa.eu/ernsd/cgi-bin/ern_public.cgi?npage=ern_portal.html#!/

⁽¹⁵⁾ 'For the purpose of publishing the list referred to in paragraph 1(b), any change in the Member acting as Coordinator of a Network or in the person nominated as Coordinator of a Network shall be communicated to the Commission by the Board of the Network.'

⁽¹⁶⁾ 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 Text with EEA relevance.

- contact details of the CEO or his/her representative and of the data protection officer;
 - contact details of the coordinator;
 - agreement by the Board of the Network and the CEO or his/her representative of the coordinating HCP of the change in the coordinating HCP.
6. The corresponding national representative of the BoMs must reply via email acknowledging receipt. This email should include, in attachment, a letter signed on behalf of the representative of the BoMs, which confirms that the capacities and expertise of the coordinating HCP are maintained in line with the last evaluation process.
 7. The ERN secretariat acknowledges receipt, registers the emails and the letters, and updates the information regarding the change in the coordinating HCP in the ERN directories and distribution list(s).
 8. The ERN Secretariat informs the Co-Chair of the BoMS and the Co-Chairs of the CG of the change in the coordinating HCP.