By-Laws of
ERN CRANIO

ARTICLE I
Name, Purpose, Scope

Section 1. The full name of the European Reference Network (ERN) is: The ERN for rare and/or complex Craniofacial Anomalies and Ear, Nose and Throat (ENT) disorders (ERN CRANIO).

Section 2. **The ERN CRANIO purpose:**

ERN CRANIO aims to pool together disease-specific expertise, knowledge and resources from across Europe.

A. to foster leadership and advances in the field of rare and/or complex craniofacial anomalies and ENT disorders.
B. to provide a forum for the exchange of knowledge pertaining to the practice of the above.
C. to stimulate high-quality care, research, education and training in aspects related to the diagnosis and treatment of rare and/or complex craniofacial anomalies and ENT disorders.
D. to acknowledge those who contribute to the care of rare and/complex craniofacial anomalies and ENT disorders in Europe.

Section 3. ERN CRANIO covers a range of rare and/or complex craniofacial anomalies and ENT disorders (Annex A).

ARTICLE II
Membership

Section 1. There are four types of involvement in ERN CRANIO:

- Full membership
- Affiliated partnership
- Patient representation
- Supporting partnership

Section 2. **Full membership**

ERN CRANIO full members are required to meet a general and network-specific criterion and obtain endorsement from their national health authority as an expert centre for disease(s) covered by ERN CRANIO (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).

A. Membership terms

- Commitment to ERN CRANIO's purpose and scope
- Compliance with the legal and operational criteria as set out by the European Commission
- Commitment to upholding terms outlined in membership network agreement
- Attendance at ERN CRANIO annual meetings and relevant network meetings
- Active contribution to relevant network activities
- Provision of data in line with ERN Monitoring Framework (mandatory European Commission requirement)

B. Membership rights:

- Each member hospital is licensed to use the ERN (CRANIO) logo for ERN CRANIO purposes
- Member hospital representatives are authorised to use the ERN-IT platform (European Collaborative Platform and Clinical Patient Management System) as supported by the European Commission.
- Each member hospital shall have one appointed representative (with one single vote) in the ERN CRANIO board. The representative may also appoint a proxy.

C. Expansion of disease areas

- Member hospitals may apply to expand their disease coverage for relevant ERN CRANIO diagnoses
- Member hospitals can apply for expansion of disease areas following the ERN protocol for managing disease areas within current ERN healthcare providers (HCPs)

Section 3. Affiliated partnership

There are two types of affiliated partnership:

- Associated National Centre[1]
- National Coordination Hub[2]

A. Affiliated partnership terms

- Commitment to ERN CRANIO's purpose and scope
- Compliance with the legal and operational criteria as set out by the European Commission
- Commitment to upholding terms agreed upon in bilateral agreement
- Attendance at ERN CRANIO annual meetings and relevant network meetings
- Active contribution to relevant network activities
- Provision of data in line with ERN Monitoring Framework (mandatory European Commission requirement)

B. Affiliated partnership rights

- Each affiliated partner is licensed to use the generic ERN logo for ERN CRANIO purposes.
- Affiliated partner representatives are authorised to use the ERN-IT platform (European Collaborative Platform and Clinical Patient Management System) as supported by the European Commission.

1 For definitions of Affiliated Partners see the Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU and the Board Statement of 10 October 2017: https://ec.europa.eu/health/sites/health/files/ern/docs/boms_affiliated_partners_en.pdf

An **Associated National Centre** is a healthcare provider with at least some special expertise matching the global thematic domain of a given reference network that concentrates primarily on the provision of healthcare directly related to the activities and services of this specific network, including any type of diagnostic contribution supporting this provision of healthcare.

2 A **National Coordination Hub** is a healthcare provider that can link the national healthcare system to a number or all European Reference Networks. National Coordination Hubs function as interfaces between the national healthcare system and those Networks where a given Member State is neither represented by a full member nor by an Associated National Centre. National Coordination Hubs do not need any specific medical expertise.

Section 4. Patient representation

There are two different levels of patient representation within ERN CRANIO:

- ERN CRANIO European Patient Advocacy Group (ePAG): comprised of Associate Partner patient organisations and their representatives [ePAG advocates- also known as patient representatives] (See Annex B)
- Supporting Partners (See Section 5.1)

A: Associate Partners

I. Requirements:

Patient organisations that meet the following resquirements may apply and be invited by the ERN Coordinator in agreement with the ePAG lead, on behalf of the ePAG, to join ERN CRANIO as an Associate Partner.

- The organisation is legally registered and operates 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 that belongs to the scope of ERN CRANIO. This registration requirement can be waived in exceptional cases, due to the particularity of patient-driven organisations and of rare diseases, as well as for historical or contextual reasons.
- Has a governing board made up of a majority of patients or of family members of patients. This requirement can be waived in exceptional cases, due to the particularity of patient-driven organisations and of rare diseases, as well as for historical or contextual reasons.
- Is financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies).
- Holds non-profit status.
- Has proven activities such as patient support and/or advocacy activities and/or research.

In exceptional cases, the above-mentioned requirements may be waived by the ERN Coordinator in agreement with the ePAG Lead, on behalf of the ePAG. Any such waiver is subject to notification to and formal endorsement by the ERN CRANIO Board following a vote.

As part of the application process, these patient organisations will formally endorse an ePAG advocate to be active in ERN CRANIO working groups. S/he will represent the voice and interests of all patients that fall under the scope of the ERN, beyond their own disease. More information on Associate Partner/ePAG advocates and the rules of engagement can be found in Annex B. If the application is successful, ERN CRANIO and the patient organisation will sign an Associate Partnership Bilateral agreement (see Annex C). Once this agreement is signed, the designated patient representative will be able to join ERN CRANIO and the European Patient Advocacy Group (ePAG) as an ePAG advocate.

II. Rights:

- Each Associate Partner is licensed to use the generic ERN logo for ERN CRANIO purposes.
- 1 ePAG advocate per workstream (1. Craniofacial 2. Cleft lip/palate & Orodental and 3. ENT) shall be part of the ERN CRANIO board (with 1 collective vote on behalf of all ERN CRANIO ePAG advocates)

Section 5. Supporting Partnership

In addition to ERN Full Members and Affiliated Partners, ERN CRANIO also involves supporting partners.

I. Patients as supporting Partners

The following patient organisations with no designated ePAG advocate in the ERN, as well as individual patients and family members or social-media patient support groups willing to

collaborate with ERN CRANIO may apply and be invited by the ERN coordinator in agreement with the ePAG lead, on behalf of the ePAG, to join ERN CRANIO as a Supporting Partner.

- Patient organisations registered in Europe representing patients and families living with a rare disease that belongs to the scope of ERN CRANIO that do not have a formal designated representative in the ePAG. These patient organisations represent an important component of the ePAG accountability and proper functioning. They may be willing to collaborate on specific tasks (e.g., respond to surveys), help to disseminate information about the ERN across their wider patient community, be consulted occasionally for feedback, and be kept informed on the development of the ERN activities.
- Patient organisations registered and operating outside of Europe representing patients and families living with a rare disease that belongs to the scope of ERN CRANIO may be invited to collaborate with the ERN and the ePAG on specific tasks and projects.
- Individual patients or family members may be invited to collaborate with the ERN and the ePAG on specific tasks or projects.
- Social media-based patient support groups representing patients and families living with a rare disease that belongs to the scope of the ERN CRANIO may be invited to collaborate with the ERN and the ePAG by signing up to receive and disseminate relevant information and/or materials.

Supporting Partners and their contact points do not form part of the ERN CRANIO ePAG group. More information on Supporting Partners can be found in Annex D.

II. Individual Experts and Organisations

Within ERN CRANIO the term Supporting Partner is also used as a generic term to "define healthcare providers, medical societies, and any other entity or individual 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. When using the term Supporting Partner it shall be clear that it refers to a collaboration with entities and individuals which are neither Full Members nor Affiliated Partners".

More information on Supporting Partners can be found in Annex E.

ARTICLE III
Administration

Section 1. Administration Bodies

The bodies of ERN CRANIO are:

A. ERN CRANIO Board

I. Board members shall be made up of the official member hospital representatives (1 per centre) and an ePAG advocate.

II. The Board shall be involved in operational and strategic decision making

III. If deemed appropriate for decision making, a board vote will be held. Decisions will be made on the basis of a simple majority vote.

B. ERN CRANIO workstreams and disease-specific working groups

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I. There are three workstreams within ERN CRANIO 1. Craniofacial 2. Cleft lip/palate and orodental and 3. ENT disorders (See Annex A)

II. Workstream 1 (Craniofacial) is comprised of three working groups: Craniosynostosis, other craniofacial anomalies and facial anomalies. Workstream 2 (Cleft Lip/Palate & Orodental) is comprised of two working groups: Cleft lip/palate and Orodental (See Annex A)

III. Workstreams/working groups are made up of clinicians from ERN CRANIO member and affiliated partner hospitals and ePAG advocates.

C. ERN CRANIO Committees:

Member centres, affiliated partners and ePAG advocates contribute to network activities based on their expertise and experience and may be active in one of the following committees (/working) groups:

- Scientific Committee
- ERN CRANIO assessment committee for 'disease expansion' and assessment of new member applications
- Steering group for clinical guideline development
- Consensus group on core outcome sets
- Cross disease working groups (Radiology, subnetwork of psychologists, subnetwork of nurse specialists)

Section 2. Roles and Responsibilities

A. The ERN CRANIO coordinator

- shall preside at annual network meetings and chair board meetings
- shall represent the ERN CRANIO network at meetings with the European Commission
- shall install ERN CRANIO working groups/committees and appoint chairpersons
- shall coordinate ERN-related grant applications
- shall administer technical and financial reports as requested upon by the European Commission
- shall oversee all ERN CRANIO activities

B. The ERN CRANIO vice-coordinator

- shall assist the ERN coordinator in network coordination tasks
- shall be called upon to deputise for the ERN coordinator in case of absence

C. ERN CRANIO board members:

- Shall preside at ERN CRANIO board meetings (at least x 1 per year) or appoint a proxy
- Disseminate relevant ERN CRANIO information to relevant persons within their hospital / ePAG group
- Represent their hospital/ePAG group within ERN CRANIO and if required, vote on an ERN CRANIO-related aspect on behalf of their member hospital / ePAG group

D. Workstream leads:

- Maintain an overview of tasks ongoing within their workstream
- Provide strategic and operational support to ERN CRANIO coordination team and ERN CRANIO board

E. Disease-specific working group leads:

- Shall plan and lead at least two working group meetings per year planned in advance
- Shall present progress reports (to be presented to ERN CRANIO board every 12 months)
- Shall support analysis of ERN CRANIO monitoring data relevant to diseases covered by their group (to be presented to the ERN CRANIO board every 12 months)

F: (in the case of) Committee leads

- Shall plan and lead at least two group meetings per year planned in advance
- Shall present progress reports (to be presented to ERN CRANIO board every 12 months)

G: Eligibility, review and continuity of leads

- Workstream leads, disease-specific working group leads and committee leads shall be active participants within ERN CRANIO and affiliated with a Full Member healthcare provider of the network.
- Leads are expected to demonstrate active engagement in ERN CRANIO activities, including the corresponding activities within their respective workstream, working group or committee, such as participation in network projects, the ERN CRANIO Registry, guideline development, educational activities, or other collaborative initiatives.

- Leads shall have relevant expertise and prior involvement in ERN CRANIO activities, as well as the capacity to coordinate, guide and actively drive the work of the respective group.
- Leads may be periodically reviewed by the ERN CRANIO Coordination Team to ensure continued active engagement, effective leadership and alignment with the objectives of the network.
- In the event that a lead retires from professional practice, steps down from their professional role, or is otherwise no longer in a position to actively contribute to the activities of the group, the individual shall step down from the lead role to allow for the appointment of new leadership and to ensure continuity of active coordination within the network.
- The appointment of new leads is subject to approval by the ERN CRANIO Board. Candidates may be proposed by the ERN CRANIO Coordination Team or through a call for candidates within the relevant group. All candidates shall be presented to the Board with a recommendation from the relevant working group and an advisory opinion from the Coordination Team. Based on these inputs, the Board shall make the final decision through a voting procedure, as outlined in Section 1 (ERN CRANIO Board) of this document.

H. Coordinator and Vice-Coordinator

- The Coordinator role is assigned to Erasmus MC as the coordinating healthcare provider (HCP) and legal entity for ERN CRANIO. This is necessary to ensure compliance with existing legal agreements and to safeguard the continuity, stability, and proper functioning of ERN CRANIO, regardless of any changes in personnel. ERN CRANIO itself does not constitute a legal entity, as it functions as a collaborative network of healthcare providers rather than an independent legal structure; therefore, all agreements are established with Erasmus MC as the contracting party. This includes, for example, the ERN CRANIO registry, service and data processing agreements with Molgenis as the service provider, data sharing agreements, and the broader technical and organisational infrastructure underpinning the network. Any change in the legal coordinating centre would invalidate these agreements, with significant consequences, including the termination of contracts, the inability to maintain or use established infrastructures, and the discontinuation and mandatory deletion of data.
- In the event that the Coordinator steps down or a new ERN CRANIO Coordinator needs to be appointed, the Vice-Coordinator shall assume the role on an interim basis to ensure continuity.
- Appointment of a new Coordinator shall, where possible, take place towards the end of a grant period, through a Board voting procedure, with the Board selecting the individual candidate, while the Coordinator role itself remains with Erasmus MC as the legal coordinating centre.
- The incoming Coordinator shall retain the existing project management team to ensure operational, financial, and administrative continuity.

All administration bodies are assisted by the ERN CRANIO project management team to provide support and track progress.

ARTICLE V
Meetings

Section 1. Annual meeting

An ERN CRANIO annual meeting shall be held at a time and place designated by the ERN CRANIO coordinator. The meeting shall be organised as a face-to-face meeting or virtual meeting. ERN CRANIO member representatives, affiliated partner representatives and ePAG advocates shall be invited to attend. The agenda shall be forwarded to attendees in advance of the meeting.

Section 2. Disease-specific working group and Committee meetings

At least two working group/committee meetings will take place per year. The agenda will be forwarded to attendees in advance of the meeting.

Section 3. Quorum

At least 50% of members and ePAG advocates eligible to vote in the ERN CRANIO board constitute a quorum for decision-making. Decisions are to be made based on simple majority vote. The by-laws may be amended by 2/3 majority vote.

Section 4. Board meeting

An ERN CRANIO Board meeting shall take place at least once a year and shall be organised as a face-to-face meeting or virtual meeting.

ARTICLE VI
Finances

Section 1. ERN CRANIO is funded by the European Commission and the sole beneficiary is the coordinating centre. The ERN coordinating centre is responsible for budget management in accordance with terms specified in the Grant Agreement.

Section 2. Representatives of ERN CRANIO member hospitals, affiliated partner hospitals, associate partner patient organisations (and their ePAG advocates) and supporting partners shall not be remunerated for their contribution to ERN CRANIO activities, unless otherwise specified in the Grant Agreement.

Section 3. As standard, it is expected that ERN CRANIO members and affiliated partners finance their own travel costs to ERN CRANIO meetings. ERN CRANIO is not liable to provide members/partners with reimbursement for meeting cancellations outside the network's control. ERN CRANIO ePAG advocates may have their travel costs reimbursed.

ARTICLE VII
Termination of membership

Section 1. Termination of membership

I. Non compliance

ERN CRANIO shall adopt the ERN CRANIO non-compliance policy for Termination of membership **(currently in development).** The Board is authorised to apply this procedure if deemed necessary.

If ERN CRANIO is informed that one of the HCPs within its network no longer complies with the legal and/or operational criteria as defined by the European Commission or has failed to commit to any of the other terms for membership, the ERN non-compliance policy for HCP membership will apply. The procedure shall also apply in any of the following conditions:

- Suspension or revocation of license to practice medicine
- Unauthorised use of the ERN (CRANIO) logo on publications, symposia, advertisements, or in any other manner
- Unethical or unprofessional conduct prejudicial to ERN CRANIO's reputation and purpose

II. Resignations

Should an ERN CRANIO member wish to voluntarily terminate its membership, the ERN CRANIO Coordinator, the European Commission, and their member of the ERN Board of Member States should be informed in writing.

Section 2. Termination of Affiliated Partnership

I. Non compliance

An Affiliated Partner may lose its partnership for one of the following reasons:

- If the Member State of establishment withdraws the official national designation letter
- If the Affiliated Partner is unable to fulfil essential parts of its bilateral cooperation

agreement with the Network
- If a full member from the same Member State joins the Network
- Suspension or revocation of license to practice medicine
- Unauthorised use of the ERN logo on publications, symposia, advertisements,or in any other manner
- Unethical or unprofessional conduct prejudicial to ERN CRANIO's reputation and purpose

The Board is authorised to terminate Affiliated Partnership following the steps outlined in the Rules for Termination of Affiliated Partnership.

II. Resignations

Should an Affiliated Partner wish to voluntarily terminate its partnership, the steps outlined in the Rules for Termination of Affiliated Partnership should be followed.

Section 3. Termination of Patient Representation

The mandate of an ePAG advocate shall terminate in any of the following cases:

1. The ePAG advocate sends a notice of resignation to the ERN CRANIO ePAG, the ERN Coordinator and to EURORDIS.
2. The patient organisation withdraws the endorsement given to the ePAG advocate.
3. If the associate partner is unable to fulfil essential parts of its bilateral cooperation agreement.
4. The ePAG advocate does not respond to emails, attend meetings or does not contact the ePAG group in a period of 3 months.
5. Unauthorised use of the ERN logo on publications, symposia, advertisements, or in any other manner.
6. Unethical or unprofessional conduct of the designated ePAG advocate in the ERN prejudicial to ERN CRANIO reputation and purpose.

An Evaluation Committee composed of the ERN CRANIO coordinator, ePAG lead, a EURORDIS representative and an ERN CRANIO project manager will examine the case and establish if there are reasons for termination based on the causes listed above. The Evaluation Committee can seek advice from clinicians, ePAG advocates and project managers involved in other ERNs.

In the circumstances referred to in points 3, 4, 5 and 6 above, before any decision is made to remove someone from being an ePAG advocate:

- the ePAG advocate as well as his/her endorsing Patient Organisation must be informed of the reasons why it is proposed to remove them (this includes an opportunity for open discussion), and
- at least one month should be allowed for mediation and any concerns raised to be addressed.

The Evaluation Committee shall inform the Associate Partner, the ERN board, and the ePAG of the reasons for this decision. The loss of Associated Partnership shall lead to the automatic loss of any of the rights and responsibilities associated with participation in the network.

At any time, ePAG advocates can send a notice of temporary suspension to the ERN CRANIO ePAG, the ERN Coordinator and to EURORDIS, in case he or she would like to voluntarily step down for a period of time.

I. Supporting Partners

If a Supporting Partner wishes to terminate his/her collaboration, in case of Conflict of Interest (CoI) or difference of directions, the legal representative of the organisation or, alternatively, the contact person should write to the ERN Coordinator explaining the reasons for the termination. The termination will be reviewed by the ERN CRANIO Coordinator and project management team and then a letter will be sent to the Supporting Partner to end the collaboration.

If ERN CRANIO wishes to terminate the collaboration due to CoI, difference of directions or other reasons,

a letter will be sent by the ERN CRANIO Coordinating Team with an explanation, after an additional consultation has been offered before, to exchange the views, discuss the change in collaboration and future options.

ARTICLE IX
Amendments

Section 1. All proposed amendments to the by-laws must be signed by three voting members and submitted in writing to the ERN CRANIO coordinator at least four months prior to the next annual meeting.

Section 2. The ERN CRANIO coordinator must notify the voting members by electronic mail of the proposed amendment in advance of the next annual meeting.

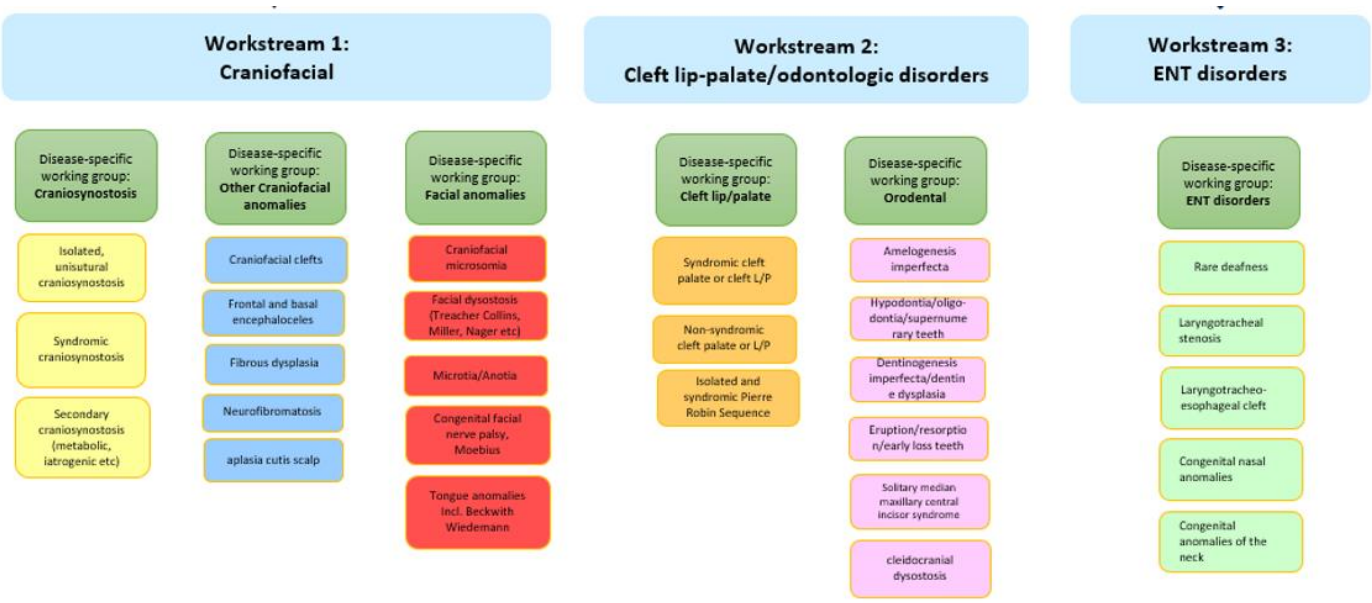
Section 3. The by-laws may be amended by a two-thirds affirmative vote of the voting members by secret ballot at the annual meeting. The secret ballot shall take place via electronic mail in the absence of a face- to-face annual meeting.

Section 4. Nothing in these by-laws removes the right of the ERN CRANIO coordinator to amend the contents of this document to comply with relevant directives or guidance from the European Commission.

European Reference Network
for rare or low prevalence complex diseases

Network
Craniofacial anomalies and ear, nose and throat disorders (ERN CRANIO)

Annex A: ERN CRANIO diseases



Annex B:

ERN CRANIO
Rules for Associate Partner representatives (ePAG advocates)

1. Introduction

According to the European Commission Expert Group (EUCERD) patients and patient representatives should play an active role in the decision and opinion making process of the European Reference Networks (ERNs) and be involved in structural and clinical network activities. The Expert Group recommended that ERNs demonstrate meaningful patient involvement, patient-centeredness and empowerment through recognition of the role of patients, as experts by experience and co-producers of knowledge, in the ERNs' structural and clinical activities and therefore demonstrate meeting the legal requirements in the Delegated Acts.

These rules for patient engagement aim to facilitate the effective involvement of patient representatives in the activities of ERN CRANIO. They are based on the governance framework developed by EURORDIS for patient engagement in the ERNs and contain specific provisions to adapt them to the governance structure of ERN CRANIO.

The position of ePAG advocate is a voluntary position and does not involve any financial compensation. Travel and accommodation expenses for meetings will be reimbursed according to the ERN CRANIO policy on reimbursement for travel expenses.

2. Role of ERN CRANIO European Patient Advocacy Group (ePAG)

The ERN CRANIO European Patient Advocacy Group (ePAG) is comprised of patient advocates that represent and are endorsed by a patient organisation following the process outlined in these terms.

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. To achieve this goal, the ePAG role is to:

- Represent the voice and interests of patients and families within ERN CRANIO
- Ensure a patient-centric approach in the collaborative activities of ERN CRANIO in the areas of care, education and training, knowledge sharing and research.
- Support the identification of ERN CRANIO strategic priorities.
- Provide input on ethical issues.
- Support the Network in the dissemination of its activities and information to the wider patient community to ensure transparency.

3. Role of ERN CRANIO ePAG advocates

ePAG advocates are patient representatives that are active in the ERN governance structure. The ePAG advocates role is to:

- Work in partnership with other patient advocates, clinicians and researchers involved in ERN CRANIO
- Champion the diversity of views of the ERN patient community, and not just to represent their own disease area nor their own experience;
- Support the ERN to disseminate information, primarily to the patient community, but as appropriate to other communities (e.g. healthcare providers, health authorities, clinicians and medical professionals and their professional bodies)
- Contribute, where needed, to the development of patient information, clinical practice guidelines, other clinical decision support tools and referral pathways;
- Contribute to the development of research priorities and ensure the needs of patients and families area taken into consideration;
- Contribute to other ERN CRANIO collaborative activities where patient involvement is required, as appropriate.
- Provide input on ethical issues, and balance patient and clinical needs appropriately;
- Scout for or make recommendations for new patient organizations to cover under-represented disease groups or patients from other EU countries.

The ERN CRANIO ePAG has a lead ('ePAG lead') whose role is to coordinate the group. The ERN CRANIO ePAG appoints 3 ePAG advocates to officially represent their workstream within the ERN CRANIO board (1 per workstream). However, this does not preclude the involvement of additional ePAG advocates. It does also not preclude patient organisations registered in Europe (without a designated ePAG advocate), patient organisations registered outside Europe, individual patients and family members and social media-based support groups collaborating with ERN CRANIO as 'Supporting Partners'.

4. Responsibilities of ERN CRANIO ePAG advocates

All ePAG advocates will be required to:

- Participate in ERN CRANIO working groups (depending on interests, expertise and availability).
- Participate regularly in the majority of the ePAG calls, and send apologies in advance if unable to attend.
- Report regularly in the ePAG calls and meetings on the progress of the work and projects in which they are directly involved in ERN CRANIO. If unable to attend, the update should be sent by email ahead of the meeting or call.

- Participate in ERN CRANIO annual meetings (and relevant network meetings), where possible. Travel and accommodation expenses will be reimbursed subject to the ERN budgetary rules.
- Contribute to identify and develop the ePAG annual objectives and work programme.
- Contribute to the overall strategy and mission of the ERN in all its aspects.
- Contribute to the assessment of new applications for membership of the ePAG.
- Respect the confidential nature of the discussions when it is made clear that this is a requirement by the person who is chairing a call or meeting.
- Comply with the ERN CRANIO conflict of interest policy (when available)
- Adhere to the decisions of the ERN governance bodies, as far as concerned and contribute to the reporting activity, if requested in the ERN CRANIO monitoring procedures.
- Adhere to the terms of the mediation agreement in the case of a mediation process described in the EURORDIS ePAG Constitution and Rules of Procedure.

The ePAG lead has the following additional responsibilities:

- Keeping up to date on ERN CRANIO EURORDIS and ePAG activities
- Sharing important news and updating the ePAG on ERN CRANIO activities as appropriate.
- Consulting with the ePAG on relevant issues and feeding back information to the ERN CRANIO coordination team
- Attending EURORDIS ePAG steering committee meetings.

Up to three ePAG advocates will represent their workstream (x 1 per workstream) in the ERN CRANIO board (with 1 collective vote on behalf of the ePAG group).

All ePAG advocates also commit to adhering to the following set of **core values**:

- Respecting the mission of the ERN CRANIO and its governance structure;
- Listening to the opinions and requests of others;
- Showing solidarity, mutual respect and support;
- Adhering to the principles of equity and social justice;
- Conducting themselves with professionalism in engaging with the clinical, research leads and fellow patient advocates;

5. ePAG advocates substitutes

ePAG advocates may nominate a substitute from his/ her own patient organisation to attend specific ERN or ePAG meetings if adequately briefed beforehand on the topic area. The ERN Coordinator or the ePAG lead shall validate the participation of such substitutes in the ERN or ePAG meetings, respectively. Substitutes must comply with the ERN CRANIO conflict of interest policy (when available) and with the core principles lay down in Section 4 when attending ERN or ePAG meetings.

6. Skills and experience for ePAG advocates

Required skills and experience:

1. Have knowledge of, or experience of living with, one of the rare and complex conditions included in the scope of the ERN;
2. Willingness and motivation to get involved, contribute actively to the discussions and work of the ePAG and the ERN working groups;
3. Ability to work effectively, constructively with other patient representatives and clinicians from different EU countries;
4. Ability to represent the interests of all represented diseases that are under the scope of the ERN, beyond their own disease.
5. Ability to bring independent judgement from a patient representative perspective;
6. Have an awareness of, and commitment to, equality, diversity and inclusiveness;
7. High level of organisation and self-motivation;
8. Understand the need for confidentiality;
9. Able to communicate in English to be able to follow and contribute to meetings.
10. Have computer skills and equipment to communicate through email, webinars, and videoconferences.
11. Have knowledge, or is willing to acquire knowledge, on the rare disease policy environment.

It is desirable to have experience working in a committee setting with clinicians and patient representatives.

8. Time Commitment

ePAG advocates will be required to attend ePAG calls approximately every two months that may take place during working hours. They will also need to attend the calls of the ERN working groups in which they decide to be involved, as well as the ERN annual meeting, that is usually at least a full day meeting. Attendance to the annual meeting will be subject to the ERN budget availability. In addition, they will need to dedicate time to review and read documents if necessary, ahead of the meetings and calls. Depending on ERN project and activities, this may imply a commitment of 2 days per month or 5 in the case of ePAG leads.

9. Benefits of becoming an ePAG advocate

ePAG advocates role and position in the ERNs give these representatives the possibility to:

1. Work closely with clinicians, researchers, and other patient representatives to transform healthcare services and accelerate research to improve the health outcomes of people living with a rare disease in Europe.
2. Participate firsthand in the development of the ERN objectives and infrastructure to ensure that it remains driven by patients' needs.
3. Increase their international exposure and expand their international network, specifically across Europe.

4. Improve their understanding of healthcare models across Europe and European Reference Networks.
5. Further develop soft skills such as communication, public speaking, conflict resolution, etc. acquired through trainings such as the ones provided by EURORDIS through its Open Academy, EUPATI and others, and through active participation in the ePAG.
6. Share and learn from other ePAG advocates and build their own capacities as patient representatives, broadening knowledge both within their own field of rare diseases and beyond.
7. Each Associate Partner is licensed to use the generic ERN logo for ERN CRANIO purposes.

10. How to apply

Patient organisations may contact the ERN project management team to express their interest in engaging as Associate Partners and designating an ePAG advocate. EURORDIS should be made aware of all expressions of interest to kick-start the application process. EURORDIS ePAG managers will send the prospective applicant an application package composed of: application form (https://form.jotform.com/eurordisforms/epag-application), ERN CRANIO By-laws, these ERN CRANIO Rules for patient engagement, endorsement letter template and ERN Conflict of Interest policy (when available).

As part of the evaluation form the following documents will be uploaded:

1. Endorsement letter signed by the legal representative of the patient organisation
2. Statutes of the patient organisation;
3. List of Board of Directors, indicating for each person if they are a patient or family member of a patient
4. Most recent Annual Report, including financial statement.

11. Assessment of Applications

Once received, the applications are processed as follows:

1. EURORDIS ePAG manager shares the application and accompanying documents with the ERN CRANIO ePAG lead and project management team.
2. The ERN project management team will review the information pertaining to the patient organisation to ensure that the requirements for patient organisations described in the ERN bylaws are met.
3. The application is reviewed and discussed by the ePAG. Applicants will be assessed against the required skills and experience outlined in Section 7. Selection will be made on the basis of the content of the application form and accompanying documents.
4. The ERN project management team and ePAG lead may request further information or arrange an informal call with the prospective applicant to get additional information on his or her skills, experience and motivation.

5. Priority will be given to prospective applicants that represent a country or a disease not currently represented in the ERN CRANIO ePAG.
6. Approval of new ePAG advocates is through agreement in the ePAG and in consultation with the ERN Coordinator.
7. All applications will receive a successful or unsuccessful notification.
8. In case of a successful application, the ERN Coordination team will send the patient organisation an Associate Partnership Bilateral Agreement. Once the agreement is received and signed by the ERN Coordinator and the Patient Organisation, the ePAG advocate will be able to join the ERN and ePAG meetings.

12. Induction for new ePAG advocates

The ERN CRANIO ePAG will request that all new ePAG advocates complete an interactive online induction session delivered by EURORDIS on a quarterly basis. This webinar lasts an hour and a half and will provide some background information to the European Reference Networks and European Patient Advocacy Groups and the work that they do.

In addition, new ePAG advocates will also receive an induction on the work of ERN CRANIO delivered by one of the seasoned ePAG advocates.

13. Duration and renewal of ePAG advocates mandate

The mandate of ePAG advocates expires at end of each five-year funding period of the ERNs. The mandate of ePAG advocates appointed for a given 5-year period may be renewed by another 5-years by reconfirming their willingness and presenting a new letter of endorsement signed by their patient organisation. ePAG advocates who joined in the last year of any 5-year ERN period, will not be required to renew their mandate.

Appointment of the ePAG Lead is for a period of 2 years and their mandate may be renewed with the agreement of the ERN CRANIO ePAG and in consultation with the ERN Coordinator.

14. Termination of role of ePAG advocates and voluntary suspension

The mandate of an ePAG advocate shall terminate in any of the following cases:

1. The ePAG advocate sends a notice of resignation to the ERN CRANIO ePAG, the ERN Coordinator and to EURORDIS.
2. The Patient Organisation withdraws the endorsement given to the ePAG advocate.
3. If the Associate partner is unable to fulfil essential parts of its bilateral cooperation agreement.
4. The ePAG advocate does not respond to emails, attend meetings or does not contact the ePAG group in a period of 3 months.
5. Unauthorized use of the ERN logo on publications, symposia, advertisements, or in any other manner.
6. Unethical or unprofessional conduct of the designated ePAG advocate in the ERN prejudicial to ERN CRANIO reputation and purpose.

An Evaluation Committee composed of the ERN CRANIO coordinator, ePAG lead, a EURORDIS representative and an ERN CRANIO project manager will examine the case and establish if there are reasons for termination based on the causes listed above. The Evaluation Committee can seek advice from clinicians, ePAG advocates and project managers involved in other ERNs.

In the circumstances referred to in points 3, 4, 5 and 6 above, before any decision is made to remove someone from being an ePAG advocate:

- the ePAG advocate as well as his/her endorsing Patient Organisation must be informed of the reasons why it is proposed to remove them (this includes an opportunity for open discussion), and
- at least one month should be allowed for mediation and any concerns raised to be addressed.

The Evaluation Committee shall inform the Associate Partner, the ERN board, and the ePAG of the reasons for this decision. The loss of Associated Partnership shall lead to the automatic loss of any of the rights and responsibilities associated with participation in the Network.

At any time, ePAG advocates can send a notice of temporary suspension to the ERN CRANIO ePAG, the ERN Coordinator and to EURORDIS, in case he or she would like to voluntarily step down for a period of time.

15. Amendment of the Terms of Reference

The ePAG on annual basis will make the necessary amendments to ensure they remain fit for purpose.

16. Authority of the ERN CRANIO Board

Nothing in this document removes the rights of the ERN CRANIO Coordinator and/or network Board to interpret and/or amend its content in the best interest of the Network or to comply with relevant directives or guidance from the European Commission.

Annex C: Associate Partnership Bilateral agreement

[insert ERN Logo]

ASSOCIATE PARTNER COLLABORATION AGREEMENT

Between the European Reference Network (ERN) for [insert ERN scope] (inset name of ERN) and [insert name of Patient Organisation]

[Insert date]

MISSION STATEMENT

[insert ERN mission statement]

[Insert name of Patient Organisation]
Hereby consents to become an Associate Partner of [Insert name of ERN] and accepts all the terms outlined in the ERN CRANIO By-laws as well as the terms for Associate partners included as an Annex.

[Insert name of Patient Organisation] acknowledges that the position of ePAG advocate is a voluntary position and does not involve any financial compensation. Travel and accommodation expenses will be reimbursed according to the [insert name of ERN] policy on reimbursement for travel expenses.

[Insert name of ERN]

Officially recognises [insert name of Patient Organisation] as an Associate Partner and affirms its commitment to work in collaboration with [insert name of Patient Organisation] and its representative for the benefit of patients living with [insert ERN disease area] under the leadership of [insert name of ERN Coordinator] and [insert name of Coordinating Centre] in [insert name of country where the ERN Coordinating centre is located].

[Name of ERN Coordinator]
Hereby certifies that the ERN has accepted the accession of [Insert name of Patient Organisation] as an Associate Partner.

Two originals of this Partnership Agreement have been duly signed by the undersigned authorized representatives.

Signature (Associate Partner):	**Signature insert name of ERN:**
[NAME]	Insert name of ERN Coordinator
[ROLE]	[Insert name of ERN] Coordinator
Date:	Date:

European Reference Networks

[insert ERN Logo]
Insert ERN website url

https://ec.europa.eu/health/ern_en

Co-funded by the European Union

Annex D: Patient and family groups or individuals as Supporting partners

The following groups/individuals may apply and be invited by the ERN Coordinator and ePAG lead in agreement with the ePAG to join as Supporting Partners:

1. Patient organisations registered in Europe representing patients and families living with a rare disease that belongs to the scope of ERN CRANIO that do not have a formal designated representative in the ePAG.

   These patient organisations represent an important component of the ePAG accountability and proper functioning. They may be willing to collaborate on specific tasks (e.g., respond to surveys), help to disseminate information about the ERN across their wider patient community, be consulted occasionally for feedback, and be kept informed on the development of the ERN activities.

   Patient organisations that are invited to collaborate as Supporting Partners should indicate a contact person who will act as the liaison between the patient organisation and the ePAG and ERN. Such individuals will not be formally involved in ERN CRANIO as ePAG advocates.
2. Patient organisations registered and operating outside of Europe representing patients and families living with a rare disease that belongs to the scope of ERN CRANIO, may be invited to collaborate with the ERN and the ePAG on specific tasks and projects. Patient organisations that are invited to collaborate as Supporting Partners should indicate a contact person who will act as the liaison between the patient organisation and the ePAG and ERN. Such individuals will not be formally involved in ERN CRANIO as ePAG advocates.
3. Individual patients or family members may be invited to collaborate with the ERN and the ePAG on specific tasks or projects. Such individuals are not formally involved in ERN CRANIO as ePAG advocates.
4. Social media-based patient support groups representing patients and families living with a rare disease that belongs to the scope of the ERN CRANIO may be invited to collaborate with the ERN and the ePAG by signing up to receive and disseminate relevant information and/or materials.

Application process

1.Patient organisations, individual patients, family members and social media-based patient support groups may contact the ERN project management team to express their interest in engaging as a Supporting partner.

2.The ERN project management team will request a motivation letter and the CV of the contact person who will act as a liaison with the Network, the individual patient or family member or the social media-based support group. The application will be considered by the ERN CRANIO coordinator, ePAG lead and ERN CRANIO project manager who will approve the collaboration with the Supporting Partner, or seek advice from the ERN Board when approval is unclear.

3. The ERN project management team will notify EURORDIS what patient organisations, social media-based support groups and/or individual patients or family members join the Network as Supporting Partners.

Obligations of patient and family groups or individuals as Supporting partners:

1. Collaborate with the ERN on areas of common strategic interest.
2. Help raise awareness about ERN CRANIO and contribute to disseminate information/surveys etc
3. Convey their opinions and input being respectful to the viewpoints and opinions of others and ensure criticism is constructive. An open and collaborative debate where all individuals can feel respected and valued is a core principle.
4. At the request of the ERN coordinator, consider attending the ERN CRANIO annual meetings (with no financial compensation) with no voting rights but an advisory status and informative role.
5. At the request of the ERN CRANIO Coordinator, consider participating in the development of specific collaborative activities, such as disease area clinical practice guidelines or other clinical decision support tools; ERN registry-related activities; training and education, awareness raising and communication or ERN research activities.
6. At the request of the ERN CRANIO ePAG, consider collaborating on specific tasks and projects to support the day-to-day work of the ePAG.
7. Attend at least an annual review meeting with ERN CRANIO, concerning the collaboration aspects, expectations and future directions.

Termination of patient and family groups or individuals as Supporting partners:

If a Supporting Partner wishes to terminate his/her collaboration, in case of Conflict of Interest (CoI) or difference of directions, the legal representative of the organisation or, alternatively, the individual should write to the ERN Coordinator explaining the reasons for the termination. The termination will be reviewed by the ERN CRANIO Coordinator and project management team and then a letter will be sent to the Supporting Partner to end the collaboration.

If ERN CRANIO wishes to terminate the collaboration due to CoI, difference of directions or other reasons, a letter will be sent by the ERN CRANIO Coordinating Team with an explanation, after an additional consultation has been offered before, to exchange the views, discuss the change in collaboration and future options.

ANNEX E ERN CRANIO Supporting Partner Agreement: Organisations

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Agreement between the European Reference Network (ERN) for rare and/or complex craniofacial anomalies and ear, nose and throat (ENT) disorders and [INSERT]

[INSERT] is officially recognised by ERN CRANIO as a Supporting Partner and ERN CRANIO affirms its commitment to work in collaboration with [INSERT] [and their representative(s)] for the benefit of patients living with rare and/or complex craniofacial anomalies and ear, nose and throat (ENT) disorders under the leadership of Prof. dr. Irene M.J. Mathijssen and Erasmus MC, Rotterdam in The Netherlands.

Terms of collaboration between ERN CRANIO and [INSERT]:

- ERN CRANIO and [INSERT] agree to work in collaboration, where possible, on areas of common strategic interest.
- In conveying their opinions and input, ERN CRANIO and [INSERT] will be respectful of the viewpoints and opinions of others and ensure criticism is constructive, to ensure maintenance of the very high standards of professionalism that ERN CRANIO adheres to. An open and collaborative debate where all individuals can feel respected and valued is a core principle.
- [INSERT] accepts the Governance Statutes and the ERN CRANIO by-laws
- One or more representatives of [INSERT] and ERN CRANIO should meet (virtually or face-to-face) at least once a year concerning collaboration, expectations, and future directions.
- A presentation can be given by a [INSERT] representative at the annual ERN CRANIO annual meeting to describe recent developments, expectations, and future directions.
- A presentation can be given at the annual [INSERT] meeting by the ERN CRANIO HCP Network Coordinator Representative or his Sub-Representative to give an update on ERN CRANIO activities.
- ERN CRANIO and [INSERT] will disseminate relevant information from each other through their communication channels.
- If [INSERT] wishes to terminate the partnership with ERN CRANIO, due to Conflict of Interests (COI), a difference in direction, or other reasons, they should write to the ERN CRANIO HCP Network Coordinator Representative explaining the reasons for the termination. The ERN Coordination Team will review this and then send a letter to [INSERT] to end the partnership.
- If ERN CRANIO wishes to terminate the partnership with [INSERT] due to COI, the difference in direction, or other reasons, after an additional consultation has been offered

to exchange views, discuss changes in collaboration, and future options, the ERN CRANIO Coordination Team will send a letter to [INSERT] to end the partnership.

Signed:	**Signed:**
[NAME]	Prof. dr. Irene M.J. Mathijssen
[ORGANISATION]	ERN CRANIO HCP Network Coordinator Representative
Date:	Date: