EUROCAT Association Constitution

1. Name

   The EUROCAT Association of European Registries of Congenital Anomalies

2. Characteristics

   The EUROCAT Association (EA) is a voluntary, non-profit organisation.

3. Objectives and Functions

   The purpose of the EUROCAT Association is to maintain a network of population-based congenital anomaly registries in Europe for surveillance, research and prevention of congenital anomalies.

4. Types of Registry membership

   The EUROCAT Association recognises four types of registry membership. These are:

   - **Full member registries**. Full member registries should be population-based rather than hospital based. Full member registries submit detailed case by case data that are appropriately pseudonymised to meet the legal requirements of the host country. Data should be sent at least once a year.
   - **Associate member registries**. Associate member registries should aim to be population-based rather than hospital based. Associated registries submit aggregate data. Data should be sent at least once a year.
   - **Affiliate member registries**. New registries are welcome to apply to EUROCAT as affiliate members. Before registries can become Full or Associate members, they must meet the standards required by EUROCAT (see appendix A). Data are submitted to EUROCAT for quality assurance purposes but normally will not be included for publication. Failure to maintain standards can result in Full or Associate registries being relegated to Affiliate Registry membership status until standards are raised.
   - **World affiliate Registries**. These are non-European registries that benefit from close liaison with the EUROCAT Network (e.g. guidance on setting up a registry and help with coding and classification). World affiliates do not transmit data to EUROCAT but do participate in Registry Leaders' meetings and may be asked to participate in specific projects.

5. Membership of the EUROCAT Association (EA)
   - Membership is open to anyone associated with a European registry of congenital anomalies (Registry leader and staff members)
   - Non-JRC appointed committee members (Project leader, President of the Coding Committee, Representative of the former Central Registry) are automatically members of the EA.
   - Other people can attend EA meetings only by invitation from the EA committee.

6. EUROCAT Association Meeting

   At the EUROCAT Association meeting, normally held annually at the annual Registry Leaders' Meeting, an election will be held to elect an EA committee.

- Four members may be elected for a term of 4 years. By rotation it is expected that one existing committee member will resign each year. This ensures both rotation and continuity of leadership.
- The resigning member may seek re-election and serve another 4 years. In exceptional circumstances, agreed at the annual meeting, a 4 year term may be extended for 1 year.
- Those elected will sit on the JRC-EUROCAT Management Committee (JEMC).

7. Voting and voting rights of the EUROCAT Association
   - Voting will be conducted by secret ballot, organised by the President of the EUROCAT Association and assisted by other committee members.
   - Voting rights are restricted to leaders of full and associated registries who are in good standing:
       i. A registry that has failed to submit data for over 2 years is no longer of good standing and loses the right to vote.
       ii. A registry whose prevalence rate has fallen below 200 per 10,000 total births for over 2 years with no remedial action being taken is no longer of good standing and loses the right to vote.
   - Affiliate registries, World affiliate registries and Past members can attend EUROCAT Association Meetings and voice opinions on matters discussed but as they do not submit quality approved data, they do not have a right to vote on any issues.
   - Only one person from each eligible registry can exercise a vote. If a registry leader is unable to vote, he / she can nominate another member of staff from that registry in his / her place.
   - The quorum for an annual meeting should be 50% of the voting membership registries (Full or Associate registries) present either in person or online.
   - The EA also elects a project leader for a period of three years with the possibility of re-election.

The appointment of the President of the coding committee and the Representative of the former Central Registry are approved by the EA.

Extraordinary meetings of the EA may be called as necessary by the EA committee or by the decision of 50% of voting member registries independently of the committee.

10. The EUROCAT Association Committee

   The EA committee consists of:

   Four registry members elected by EA

   Project leader elected by EA

   President of the Coding Committee - (nominated by JEMC and approved by the EA)

   Representative of the former Central Registry - (nominated by JEMC and approved by the EA)

   From among its members the EA committee will elect a President from one of the four registry leaders.

   The President is elected for 2 years and may be re-elected for 2 more years

   The EA Committee role is to represent the best interests of all the registries collectively.

The EA Committee join with staff of the JRC-EUROCAT Central Registry to form the JRC-EUROCAT Management Committee (JEMC). (See Appendix B for the roles & responsibilities of the JEMC). (See Appendix C see for the role & responsibilities of the JRC-EUROCAT Central Registry)

An elected member who does not attend three consecutive meetings of the JEMC will be replaced.

11.   The Role of President
    a. To call & lead meetings of the EA committee
    b. To lead meetings of the JEMC
    c. To liaise with staff members of the JRC
    d. To encourage the development and growth of the registry network
    e. To be the public representative of EUROCAT

12. Voting and Mail Ballot

Any election or decision in the EUROCAT Association by the members may be made either by (secret) voting during a meeting, or by mail ballot if no meeting takes place. In elections when no alternative candidate is proposed, voting is not mandatory.

13. Changes to these statutes are prepared by the EA committee and approved by a two-thirds majority vote of the members at the RLM or in a postal ballot.

14. Dissolution of the EUROCAT Association.

The dissolution of the EUROCAT Association requires a two-third majority at two successive votes of the members at a RLM or in a postal ballot, separated in time by at least one year. In case of dissolution, the property will go to an organisation suggested by the JEMC and approved by a majority of the members. All data will be returned to the respective member registries

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Appendix A

EUROCAT Membership

Qualifications:

- Candidates for full or associated membership can be any European registry of congenital anomalies fulfilling the following qualifications:
- Covering of a geographically defined population
- Registration of congenital anomalies aimed at monitoring of live births, stillbirths and terminations of pregnancy following prenatal diagnosis
- Use of multiple sources of ascertainment
- Registration of uniformly coded standard data on fetus-child, diagnoses and risk factors using EUROCAT Guide 1.5
- Transmission of data to the JRC-EUROCAT Central Registry for analysis
- Emphasis on high data quality, confidentiality and safety

Particular requirements:

- Candidates are required to submit a detailed description of their registry in a Registry Description Questionnaire.
- Decision on membership will be made by the JRC-EUROCAT Management Committee (JEMC). The application shall be circulated to all members at least 2 weeks before a JEMC meeting. A majority vote of the JEMC members is required for admission.
- Prevalence should meet a minimum rate of 200 per 10,000 total births

Registries failing to meet these requirements upon application will be accepted as affiliate members with a view of raising their standards and aiming in the longer term to become either full or associate members.

Members who have closed their activities are considered as Past members. They will, on request, have their data returned from the Central Registry unless this is not in conflict with contract(s) signed for designated period(s), (e.g. a Joint Action).

Specific objectives of EUROCAT are:

- Maintenance of a Central Database at the JRC-EUROCAT Central Registry, for:
  - Provision of baseline rates of congenital anomalies
  - Detection and investigation of changes in the frequency of congenital anomalies, including temporal trends and clusters
  - Assessment of the impact of known or suspected new environmental teratogens
  - Evaluation of health services (prevention, prenatal diagnosis, screening, and treatment)
  - Research on causes and consequences of congenital anomalies
  - Setting quality standards for malformation registries
- Quality assurance of data
- Promotion of research by sub-projects or other collaborative studies
- Provision and distribution of information, to members and the community at large
- Exchange of experience between the European EUROCAT Association member registries
- Training of member registries' staff and clerks

Data Ownership:

The member registries, who are the data providers, are and remain the data owners. Any other access and use of data are under the control and the responsibility of the JRC EUROCAT Management Committee. Publications, reports and transfer to the public EUROCAT Website require permission and approval by the data owners.

Appendix B

JRC-EUROCAT Management Committee (JEMC)

1. Members of the JEMC:

The JEMC consists of:

Two representatives of the JRC-EUROCAT Central Registry

Four registry members elected by EA

Project leader elected by EA

President of the Coding Committee - (nominated by JEMC and approved by the EA)

Representative of the former Central Registry - (nominated by JEMC and approved by the EA)

2. JEMC may also include:

Leaders of the current projects linked to specific funding contracts

Invited consultants/experts

3. Functions of the JEMC:

a) Prepares and takes decisions on the JRC-EUROCAT activities

b) Decide on membership issues including applications for membership.

c) Supervises the security and confidentiality of data held at the JRC-EUROCAT Central Registry including data transmission

d) Facilitates the discussion between the Registries and the JRC-EUROCAT Central Registry concerning the execution of the planned activities.

e) Supervises and supports the organisation of the annual Registry Leader's Meeting

f) Decides on applications for additional meetings, workshops and working groups

g) Decide on applications for studies regarding protocol, data and authorship

h) Establish policies and adopts documents related to the Management Committee and the JRC Central Registry

i) Supports and collaborates with the Central Registry

j) All other matters related to the activities of EUROCAT

JEMC decisions, particularly those that involve all EUROCAT members or important aspects of the EUROCAT Association, will be communicated to Registry Leaders by EUROCAT Communication Bulletins and/or at the RLM. Any decisions can be discussed at the RLM. If any disagreements remain unresolved, the final decision to approve/disapprove the JEMC decision will be made through voting (simple majority rule). In the event of a tight vote, the President has the casting vote.

4. Functions of the President:
   - Convene and lead EA meetings.
   - Takes over the EUROCAT association management in the case of the disagreement with the Central Registry or the inability of the JEMC to convene
   - Represent the EUROCAT association whenever necessary.

5. Functions of the Project leader:
   - Identifying new research topics and funding possibilities
   - Submitting of new project proposals
   - Co-ordination and supervision of the EUROCAT scientific activities

6. Functions of the President of the Coding Committee:
   - Chair of the coding and classification committee
   - Assist JRC in any coding queries and questions

7. Functions of the Representative of Ulster:
   - Scientific interpretation of surveillance data and identifying issues of interest
   - Help JRC CR staff in producing yearly Statistical Monitoring Report which is to be published on the EUROCAT website

8. Meetings of the JEMC:

At least two JEMC meetings are to be held each year. The JEMC can arrange additional meetings. These can be telephone conferences. The meetings are chaired by the JRC-EUROCAT Central Registry. The agenda will be sent to the JEMC members by the JRC-EUROCAT Central Registry at least 2 weeks before the meeting.

9. Resources

The resources comprise EU funding or other contracts concluded and all other public or private financial support. There is no membership fee except in times of funding gap. The decision to institute a membership fee will be made by EA committee and needs to be ratified by a majority vote by members.

10. Official language

The official language of the EUROCAT Association is English.

Appendix C

The JRC-EUROCAT Central Registry

Although independent from the EUROCAT Association, the JRC-EUROCAT Central Registry is crucial for the operation of the network. Members of the JRC-EUROCAT Central Registry do not have voting rights at EUROCAT Association meetings and are not normally permitted to attend. However, in exceptional circumstances, representatives may attend by invitation of the EA committee.

Responsibilities and role of the JRC:

a) Operates the JRC-EUROCAT Central Registry. The role of the Central Registry is:

- To maintain and further developed a centralised database of congenital anomalies according to established coding methodologies.
- To coordinate and operate data collected from the Registries
- To ensure data security/safe including the process of data transmission
- To manage data including data checking, standardisation, quality assessment, validation, statistical analysis for further dissemination
- To manage the website - administration, maintenance, updates, development
- To communicate with the Registries on data-related issues and results of the monitoring
- To offer support to individual registries for the implementation of EUROCAT procedures
- To produce and disseminate to the Registries the monthly "Communication"
- To maintain and establish relations with other organisations
- To process and evaluate new applications for membership and requests for data use

b) Participates to and supports the coordinating activities of EUROCAT

c) Organises meetings of the JRC-EUROCAT Management Committee, Coding and Classification Committee, other committees and working groups

d) Organises the annual Registry Leader's Meeting

e) Organises scientific symposia, workshops

f) Offers support for dissemination activities: newsletters, leaflets

g) Supports the organisation of trainings

h) Ensures to give visibility to the Registries

i) Disseminates the output of data analysis whilst ensuring anonymity of the Registries

j) Supports actions aimed at adding value to the EUROCAT data by: integration into larger health information systems, links to other databases (e.g. environmental data), dissemination of public health indicators to policy makers for decision on primary/secondary prevention

k) Promotes the registration of congenital anomalies across Europe.