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EUROCAT Association Constitution
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1. Name

The EUROCAT Association of **E**uropean **R**egistries of **C**ongenital **A**nomalies

2. Characteristics

The EUROCAT Association 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 birth defects.

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, 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

4. Membership

- General:

    Membership is open to any European registry of congenital anomalies provided delivery of data to the JRC -EUROCAT Central Registry.

    Registries are represented by registry leaders. A registry leader can be replaced by his/her representative.

➤ Qualifications:

Candidate 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
- Transmission of data to the JRC- EUROCAT Central Registry for analysis
- Emphasis on high data quality, confidentiality and safety

➤ Obligations:
- There are four types of active EUROCAT membership: Full members, Associate members, Affiliate members and World Affiliate members (cfr. Document membership criteria for EUROCAT).
- Full and Associate Members should send data on a regular basis to the Central Registry. They should take part in the Annual Meeting as well as in other joint activities. They should continue to fulfil the membership qualifications for EUROCAT.
- If a member does not fulfil the qualifications to be a Full (by sending individual data) or an Associate member (by sending aggregate data), the member can be eligible to become an Affiliate member. 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).
- World Affiliate Registries are non-European registries that benefit from close liaison with the EUROCAT Network (e.g. guidance on setting up a registry and on coding and classification). World Affiliates do not transmit data to EUROCAT, but do participate in meetings and may be asked to participate in specific projects.

➤ Admission procedures:
- 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 of the SC at least 2 weeks before a JEMC meeting. A majority vote of the JEMC members is required for admission.

5. The EUROCAT JRC Central Registry

Responsibilities and role of the JRC:

➤ 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

a) Participates to and supports the coordinating activities of EUROCAT
b) Organises meetings of the JRC-EUROCAT Management Committee, Coding and Classification Committee, other committees and working groups
c) Organises the annual Registry Leader's Meeting
d) Organises scientific symposia, workshops
e) Offers support for dissemination activities: newsletters, leaflets
f) Supports the organisation of trainings
g) Ensures to give visibility to the Registries
h) Disseminates the output of data analysis whilst ensuring anonymity of the Registries
i) 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

j) Promotes the registration of congenital anomalies across Europe

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.

6. JRC-EUROCAT Management Committee (JEMC)

At the Registry Leaders Meeting (RLM) the EUROCAT Association (EA) elects four members of the JEMC by secret vote for a period of four years. The mandate can be prolonged for one year in exceptional circumstances. All elected members must be registry leaders. The EA elects a President among the current elected members of the JEMC. The JEMC should propose a candidate. The President is elected for 2 years and may be re-elected for 2 more years. For the other JEMC members no consecutive re-election is possible. Every year, at least one member should resign in order to ensure turnover of members. If in a year, none of the members concludes the 4 year period, the longest serving member (the President excluded) resigns. An elected member who does not attend three consecutive meetings will be replaced.

The EUROCAT Association elects also a project leader for the period of three years with the possibility of re-election.

Members of the **JEMC**:

The **JEMC** consists of:
➢ Two representatives of the JRC Central Registry
➢ Four registry leaders elected by EA
➢ Project leader elected by EA
➢ President of the Coding Committee
➢ Representative of the former Central Registry

JEMC may also include:
➢ Leaders of the current projects linked to specific funding contracts
➢ Invited consultants/experts

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 Central Registry including data transmission

d) Facilitates the discussion between the Registries and the JRC 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 Central Registry for the activities listed in Article 2.1.a)

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.

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.

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

Functions of the President of the Coding Committee:

Chair of the coding and classification committee

Assist JRC in any coding queries and questions

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

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 Central Registry. The agenda will be sent to the JEMC members by the JRC Central Registry at least 2 weeks before the meeting.

7. 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 JEMC and needs to be ratified by a majority vote by members.

9. Official language

The official language of the EUROCAT Association is English.

10. 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.

11. Changes to these statutes

Changes to the statutes are prepared by the registry leaders elected in the JEMC and approved by a two-thirds majority vote of the members at the RLM or in a postal ballot.

12. 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.