Future Development of EUROCAT

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FUTURE DEVELOPMENT OF EUROCAT

EUROCAT is a network of population-based congenital anomaly (CA) registries covering at present approximately 1.7 million births in Europe. EUROCAT has been in existence since 1979. The registries joined into the EUROCAT Association, a voluntary, non-profit organisation with the purpose to maintain a network of population based congenital anomaly registries in Europe for surveillance, research and prevention of congenital anomalies. A central database of individual anonymised records is a basic achievement and the core principle of all activities of the network.

1. OBJECTIVES

The general aim of EUROCAT is the epidemiologic surveillance of congenital anomalies to support the reduction of the public health burden of congenital anomalies. Reduction of the public health burden encompasses (i) promotion of health, (ii) reduction of teratogenic risks preconceptionally and in early pregnancy, (iii) high quality diagnostics, treatment and counselling prenatally and postnatally and (iv) minimising inequalities in the experience of prevention and care.

The **objectives** of EUROCAT are:

- To provide essential epidemiologic information on CA in Europe
- To facilitate early warning of new teratogenic exposures
- To evaluate health services (primary prevention, prenatal diagnosis, screening and treatment)
- To act as an information and resource centre for the population, health professionals and policy makers regarding clusters, exposures and risk factors of concern
- To provide a ready collaborative network and infrastructure for research related to causes and prevention of CA and treatment and care of affected children
- To act as catalyst for the setting up of new registries in Europe collecting comparable, standardised data
- Setting quality standards and quality assurance of data in registries of CA

2. MEMBERSHIP

The membership is open to any population based registry of congenital anomalies that adhere to the EUROCAT Membership Criteria. Registries are represented by registry leaders (RL) or his/her representative. There are four types of membership: full, associate, affiliate and world affiliate. Full members send anonymized individual case data on a full range of

congenital anomalies diagnosed among live births, fetal deaths from 20 weeks' gestation, and terminations of pregnancy following prenatal diagnosis. Associate members transmit aggregate data per anomaly subgroup, year and type of birth. Affiliate members have an active interest in congenital anomaly surveillance, and are working toward, but don't conform to the requirements for full or associate membership. World affiliates are Non-European registries with an active interest in CA surveillance. For full details of membership criteria, see http://www.eurocat-network.eu/content/EUROCAT-Membership-Rules.pdf

3. The EUROCAT Central Registry

A Central Registry co-ordinates the network, manages the central database, and carries out core surveillance activities. The main activities are:

3.1. Maintenance of a centralised, uniformly coded database of congenital anomalies
3.2. Ensuring the security of data transmission and storage
3.3. Data management and Surveillance - quality assurance including validation, routine monitoring and analysis, regular updates of the central database, update of DQI, Statistical Monitoring Report (core surveillance that includes prevalence tables and investigation of trends and clusters), additional reports, publications and other required outputs
3.4. Liaison with local registries, technical support to registries, including training sessions during RLM
3.5. Organisation of annual Registry Leaders Meeting
3.6. Liaison with other organisations/stakeholders with interest in CA

The member registries who collect data remain the data owners. Any other access and use of data is under the responsibility and control of the **Steering Committee (SC)**. Publications, reports and transfer of data to the public part of the EUROCAT Website need approval and permission by the data owners.

4. Steering Committee (SC)

SC of the EUROCAT Association consists of six elected members, including the President and the Director of the Central Registry. The election of the SC is regulated by the EUROCAT Association Constitution. The main functions of the SC are:

4.1. Decide on EUROCAT general policy
4.2. Decide on EUROCAT activities (changes to be introduced in the database or in the procedures, meetings, workshops, contact with other stakeholders, new projects, etc)
4.3. Regulation of all affaires and issues concerning registry members and Central Registry
4.4. Appoint the Central Registry and Director of the Central Registry

4.5. Organisation and scientific governance of the biannual European Symposium on congenital anomalies
4.6. Decide on applications for EUROCAT membership
4.7. Decide on applications for studies regarding protocol, data and authorship
4.8. Establish all regulations concerning EUROCAT activities (e.g. documents regulating terms and conditions for the release of data, terms and conditions for membership etc)
4.9. Plan the future of the EUROCAT Association

5. EUROCAT Programme Management Committee (EPMC)

EPMC consists of the members of SC plus members of the Central Registry included in the current studies/projects, project manager and leaders of the working packages linked to specific funding contracts, and invited consultants. EPMC meets to discuss and resolve topics concerning individual projects (e.g. FP7, Joint Action)

6. FUTURE PLAN AND ORGANISATION OF EUROCAT

This document describes the future plan for organisation and activities of the EUROCAT network taking into consideration new developments in the organisation of Rare Disease activities at the European level, particularly with regard to the establishment of Platform for Rare Diseases and its management by the Joint Research Centre (JRC) ISPRA.

From 1 January 2015, EUROCAT activities are to be transferred to the JRC, as part of the Rare Diseases Platform. This transfer needs to be managed carefully in order to: i) maintain the current level of recognised excellence of the existing network, ii) allow EUROCAT to resume its full activities as soon as possible, and iii) to allow the network to develop in new directions. This is also a chance for EUROCAT network to explore all the possibilities and advantages that could provide his new position at the JRC. To make the transition as successful as possible and to enable the EUROCAT to continue soon with his full activities, it is necessary to define:

6.1. Elements necessary for timely and successful transition to the JRC

6.1.1. A roadmap document ***Transfer of the EUROCAT database and coordinating activities to the JRC*** presented and discussed at the 29th EUROCAT Registry Leaders' Meeting on 26th -27th June 2014 in Belfast The document included the time frame, milestones and procurement in the transition period for:

- Maintenance of Database and Surveillance activities

- Exploring the possibility that ECD data assistant manager (RG) continues working for 6 months/ 1 year in parallel with the JRC statistician responsible for ECD
- Exploring the possibility that the epidemiologist (ML) continues working for 6 months/ 1 year providing education in epidemiological surveillance and data interpretation (producing yearly Statistical Monitoring Report, tables and other core outputs)
- Preparing the framework for a contract with the IT company and securing further software developments

- Supporting of routine core clinical, scientific and dissemination activities
  - 3 meetings of the EUROCAT Management Committee + 3 teleconferences/year
  - 3 meetings of the Coding and Classification Committee/year
  - 1 workshop of the Registry Advisory service/year and regular support for new/affiliate members
  - Creation of the promotional leaflet, 2 newsletters/year and 2 EUROCAT Communication e-mails/month
  - 1 Registry Leaders Meeting/year
  - Biannual scientific symposium *"European symposium on congenital anomalies"* (2016)
- Activities for adding value and further integration of the EUROCAT data in the larger health information systems as a part of JRC

6.1.2. Preparation of the *Memorandum of Understanding* and a contract template for obtaining registry permission for data transmission that will also address data protection and ownership issues. The contract should include the requirement of annual approval and evaluation of the JRC activities by the EUROCAT Association and the possibility that the data can be withdrawn/withheld

6.1.3. Signing of the *Memorandum of Understanding* by the authorised persons in the local registries as a formal approval of the transfer to JRC

6.2. New organisation of EUROCAT at the JRC

6.2.1. New governance of the network. The project will be managed by EUROCAT Management Committee (EMC). The EMC will consist of two JRC representatives and the EUROCAT Scientific Committee (ESC) which will include a scientific leader, six elected members and project leaders of any projects undertaken. The election of the SC and scientific leader will be regulated by the amendment of EUROCAT Constitution as at present there is no rules regarding the election of the scientific leader.

The activities of EMC will be those listed under 4.1-4.9 of this document.
The activities of the scientific leader will be as follows:

- Leads EMC meetings and RLM
- Directs and guides the activities/goals set by EMC
- Co-ordinates and supervises the EUROCAT scientific activities
- Represents the EUROCAT Association whenever necessary

6.2.2. Activities of the JRC Central Registry

6.2.2.1. Management and governance of the EUROCAT Central database
6.2.2.2. Routine surveillance and epidemiologic data analysis
6.2.2.3. Maintenance of the website including further improvements, especially making it more accessible for a lay audience and translation to different languages
6.2.2.4. Clinical and scientific activities and development (epidemiological analysis of data, clinical interpretation of surveillance results)
6.2.2.5. Maintenance of the activities of the:
- EUROCAT Management Committee - organisation of the meetings (3/year)
- Coding & Classification committee - organisation of the meetings (3/year)
- Registry Advisory Service - workshops for new/affiliate members (1/year)

6.2.2.6. Organisation of annual RLM Meetings
6.2.2.7. Yearly report on project development at the Registry Leaders Meeting
6.2.2.8. Liaison with local registries, technical support, including training sessions for RL and staff during RLM
6.2.2.9. Organisation of the d biannual EUROCAT Symposium (European Symposium on Congenital Anomalies)
6.2.2.10. Liaison and reporting with external stakeholders
6.2.2.11. Promotional leaflet, two EUROCAT Newsletters per year and two EUROCAT Communication e-mails per month that will include new development activities
6.2.2.12. Ethical and Data security issues
6.2.2.13. Administrative help
6.2.2.14. Financial procurement and management

6.3. Strategic goals and future activities or the EUROCAT network

6.3.1. Definition of the position of EUROCAT at the Rare Disease Platform exploring the possibilities of using the existing facilities, skill and expertise (e.g. linkage to environmental pollution databases maintained at JRC, or using JRC facilities for the economic assessment the cost of CA and the savings to be made from prevention activities)
6.3.2. Outlining priority areas for further research, taking into account the interests

of various stakeholders (e.g. medical professionals, industry, patients, policy and governments)

- Improvement of the data collection and presentation on the website/reports (new variables e.g. cell free fetal DNA tests, microarray and next generation sequencing (NGS) results, surgery and outcome, environmental pollutants, new DQI, new tables/maps etc)
- Considering collecting biologic samples (DNA)
- Developing at local registries the methods to allow for use of other data sources, e.g. electronic healthcare databases, birth and death registries
- Explore the possibility of linkage of local registries with other registries of CA e.g. congenital hypothyroidism, Down syndrome, rare CA registries in their countries

6.3.3. Expanding the network by recruiting new registries in EU

6.3.4. Links with other partners e.g. for policy and advocacy particularly in relation to CA prevention, for relevance to clinical practice (e.g. prenatal screening, medical genetics etc), for genetic research, pharmacovigilance, envirovigilance.

- link with the EUROMediCAT database for pharmacovigilance, in particular post-marketing surveillance of orphan medicinal products
- link with the WHO, using Collaborating Centre status of the University of Ulster for disseminating EUROCAT surveillance results, and expansion of global interest, e.g. through a web-based education/training course to support extension of methodology and standards to other parts of the world or developing simpler version of the EDMP for a web-based module for the use in developing countries

6.3.5. Integration of information on CA collected by EUROCAT into common European resource platform on RD to be of further used in the study of aetiology, epidemiology, and the evaluation of diagnostic, preventative and therapeutic interventions. Networking with other infrastructures related to CA and Rare Disease Community, exploring ways to use/give data for joint research projects (e.g. H2020, E-Rare, IRDiRC -International Rare Diseases Research Consortium, RD- Connect, ECRIN -ERIC -European Clinical Research Infrastructures Network)

6.3.6. Preparation of the project proposals

6.3.7. Preparation of scientific/technical and strategic design reports/ recommendations