Protocol of the EUROCAT network for the evaluation of applicant registries

EUROCAT is a network of population-based registries for the epidemiological surveillance of congenital anomalies in Europe. Currently, the registries cover about 25% of the European birth population. A complete list of EUROCAT members is published on the EUROCAT website.

The EUROCAT network aims to perform population-based, standardized, high-quality registration of congenital anomalies.

There are four types of EUROCAT membership:

- **Full Member Registries** transmit to the JRC-EUROCAT Central Registry case data on all congenital anomaly cases in their region.
- **Associate Member Registries** transmit to the JRC-EUROCAT Central Registry an aggregate file containing the total number of cases in each congenital anomaly subgroup by type and year of birth.
- **Affiliate Member Registries** do not transmit data to EUROCAT but participate in meetings and projects. New Members remain Affiliate Members until their first set of data have been published on the EUROCAT website at which time their membership status transfers to Full or Associate.
- **World Affiliate"** Registries are non-European registries that collaborate closely with the EUROCAT network.

The types of EUROCAT membership are described in detail in the document "EUROCAT Membership Criteria" that can be found on the EUROCAT website.

EUROCAT adopts an open approach to membership, enabling those registries that do not yet meet the criteria for full membership to participate in the activities of the network. In this way, by advancing the quality of data collection and coding, registries can gradually achieve full or associate membership.

The present document defines the procedures to be followed by the EUROCAT network and the Central Registry to evaluate new member registries. It also defines criteria to assess the quality of data from applicant registries and affiliate member registries. It has to be noted that membership will be evaluated based on the given criteria, but it is not expected that all of them are fulfilled. An overall evaluation of the quality of the applicant registry will be done.

1. Applying for EUROCAT membership: procedures to be followed by the applicant registry, the EUROCAT network and the Central Registry

1.1. The first step in applying for EUROCAT membership is to fill in the Membership application form, which can be found on the EUROCAT website. The Applicant Registry must complete the form and submit the document to the JRC-EUROCAT Central Registry at the following address: JRC-EUROCAT@ec.europa.eu. The Central Registry will acknowledge the receipt of the application within 10 working days of receiving the document.

1.2. The application will be assessed by the JRC-EUROCAT Management Committee. If the Management Committee have additional questions, they will inform the Central Registry. The Central Registry will contact the registry for additional information and clarification. If all issues are resolved satisfactorily, the registry will be informed of the Management Committee's decision to appoint the Applicant Registry as an **Affiliate EUROCAT member**.

1.3. Following Management Committee approval, the affiliate registry will be asked to provide a standard format Registry description that must be reviewed by the EUROCAT Registry Advisory Service (RAS) and approved by the Management Committee before being uploaded on the website.

1.4. The EUROCAT Data Management Software (DMS) and instructions will be sent to the registry in order for the new registry to apply all standard EUROCAT methodology based on the coding instructions described in detail in EUROCAT Guide 1.4 and Reference Documents (last updated version 07/10/2021).

1.5. To progress to associate or full member status, the affiliate registry must submit to the JRC-EUROCAT Central Registry congenital anomaly monitoring data for a minimum of **three** consecutive birth years if **< 20,000 births** per year or **two** consecutive years if **> 20,000 births** per year. Data must be submitted via the EUROCAT DMS. Aggregate data can be submitted if associate membership is being applied for, but individual case data is required for full member status. Data may be sent prospectively year by year, or data collected in the previous two or three years may be sent simultaneously.

1.6. The affiliate Registry has to sign the **Declaration** provided by the JRC that allows the JRC-EUROCAT Central Registry to manage the submitted data.

2. Evaluation of new potential members: Procedures and flowchart to be followed by the EUROCAT network and the Central Registry

Once the affiliate registry has sent data to the JRC-EUROCAT Central Registry, the data will be stored centrally using EUROCAT DMS (in a database separate from the EUROCAT Central Database).

The data quality will be evaluated by the EUROCAT Registry Advisory Service (RAS), composed of at least two members of the Coding and Classification Committee**.**

The Central Registry will create the following four documents using EUROCAT DMS:

- The A1 table with prevalence data for all EUROCAT subgroups by type of birth and by individual birth year
- Document with Q-codes and written text descriptions extracted from DMS
- Table with the proportion of missing data for each variable (see examples on EUROCAT website)
- Document with data quality indicators (DQI) for all two or three years submitted (see also section **3.5** of this document for details)

Each RAS member will evaluate the registry data separately and will then work together to develop a joint document analysing the quality of the data according to the set criteria.

A written evaluation will be provided to the Central Registry no later than two months after receipt of the documentation. Based on a RAS report, the Management Committee may decide to appoint the registry as a full or associate EUROCAT member or to continue with affiliate membership.

EUROCAT full membership will be evaluated based on the following:

- The data have to be population-based;
- All birth outcomes are included (livebirths, fetal deaths from gestational age of 20 weeks and terminations of pregnancy after prenatal diagnosis of fetal anomaly - TOPFA);
- Individual pseudonymised data are transmitted to the Central Registry through the EUROCAT Data Management Software (DMS);
- The recommended minimum number of births per year in the registry area is 10,000 births per year, but smaller registries may also apply for membership;
- Two or three years of individual data will be reviewed for quality before full membership is accepted (for details see section 3). [*Note: the registry has to cover an area with minimum 20,000 births/year if only two years of data are evaluated*].

EUROCAT associated membership will be evaluated in the same way, but the evaluation will be limited to the available aggregate data.

The entire evaluation process, including feedback from registries, usually takes between six months to one year to complete.

New members remain affiliate members until their first set of data has been published on the EUROCAT website at which time their membership status transfers to Full or Associate.

When the applicant Registry changes status from affiliate to full or associate member, the legal representative of the registry must sign the **Collaboration Agreement** with JRC that defines the Rules and Responsibilities of the JRC and the Registry related to data collection, data management and access rights. The registry also has to resubmit to the Central Registry the most updated dataset to be included in the EUROCAT Central Database and published on the EUROCAT website.

It should be noted that registries that are registering the full range of congenital anomalies, with an overall prevalence of all anomalies of at least 2% and very good data quality as reviewed by the RAS, will not have their data published on the website until they reach at least 20,000 births over one or more years.

The flowchart to be followed by the EUROCAT network and the Central Registry to evaluate the new potential members is presented in Figure 1.

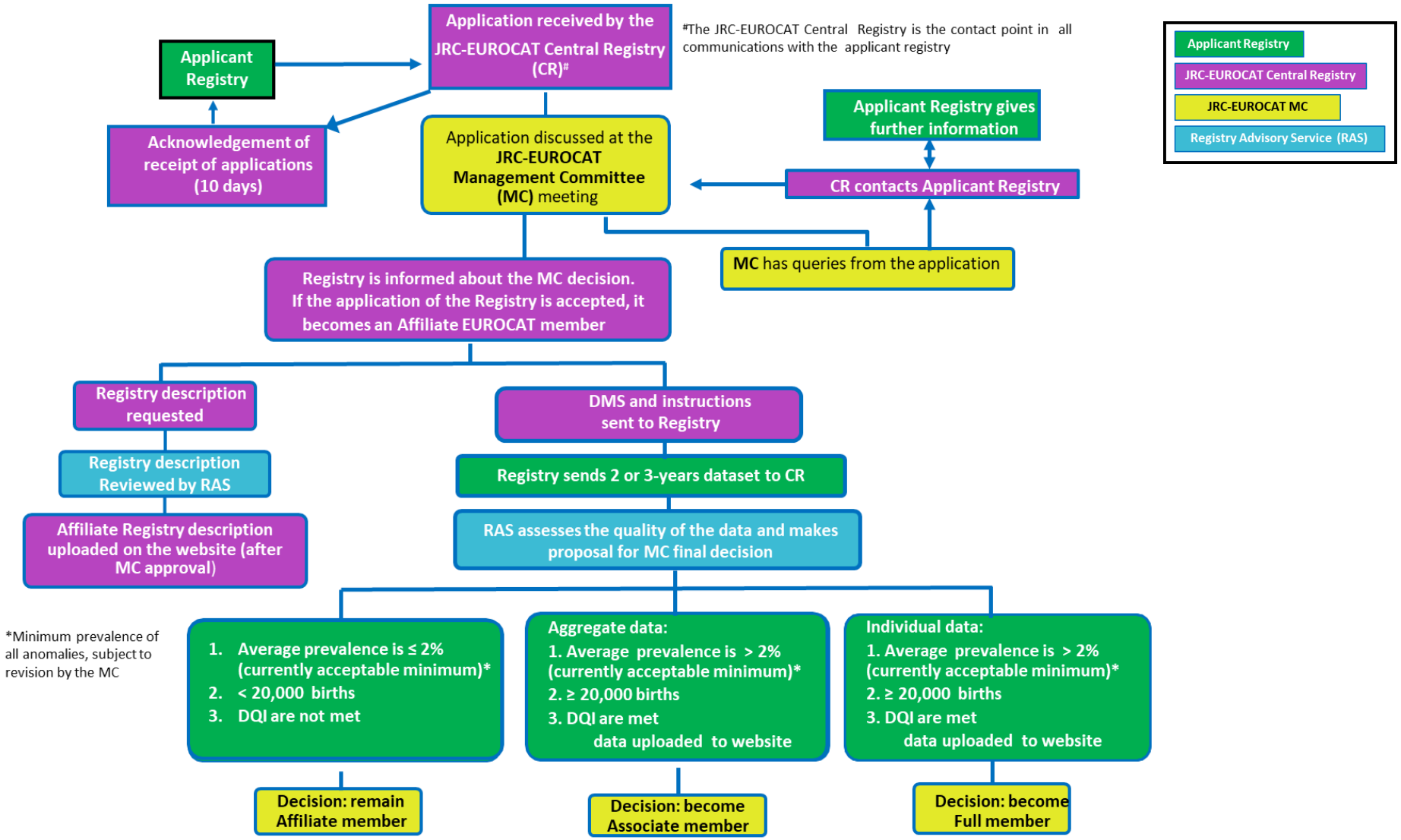

Figure 1. Flowchart for the EUROCAT membership application process

3. Criteria to assess the quality of data from new applicant registries and affiliate member registries

3.1. Registry description

- Description and coverage of the region
- Years of data collection
- Description of methods of data collection
- Sources of case ascertainment
- Coverage of congenital anomalies
- Registration of termination of pregnancies (TOPFA)
- Registration of late fetal deaths and stillbirths
- Duration of the follow-up of liveborn cases
- The type of profession and qualifications of the team members involved in registration and coding

3.2. Ascertainment: evaluated based on the A1 table created via EUROCAT DMS

- Total number of cases and denominator information
- Total congenital anomaly prevalence (>200 per 10,000 births expected) with 95% confidence interval
- Number of and proportion of live births, fetal deaths and TOPFA*
- Prevalence of congenital anomalies by EUROCAT subgroups of congenital anomalies (see **EUROCAT Guide 1.4**, Sections 2.2.1a and 2.2.1b)
- Prevalence of selected anomaly subgroups that are known to be overreported or underreported or serve as a representative of specific groups of anomalies that require expertise in diagnosis and recording

**Note: the proportion of livebirths, fetal deaths and TOPFA will depend on the local laws and screening programmes*

3.3. Accuracy of diagnosis: evaluated based on ICD10 codes for congenital anomalies (Q-codes) and the written text descriptions of the anomalies

- Use of specified Q-codes
- Written text description for each code, including bilaterality/unilaterality and severity if appropriate
- Correlation between Q-codes and written text description
- Cases of chromosomal with known karyotype

*Note: When preparing the data it is recommended to consult the **EUROCAT Guide 1.4**, Section 3.5 "Detailed Congenital Anomaly Coding Guidelines"*

3.4. Missing values

- The proportion of missing values in core variables will be evaluated (for the list of core variables see **EUROCAT Guide 1.4**, Sections 2.2.1a). The minimum proportion of known values for core variables is 90%.
- The birth type and birth year must be known for each case. It is expected that sex, birth weight, gestational age and when discovered is known for almost all cases.

3.5. Data evaluated based on calculated DQI: Completeness of information

- % genetic syndromes + microdeletions with syndrome text complete
- % malformation 1 text complete
- % livebirths with one-week survival known
- % livebirths with ASD, VSD, hydronephrosis, hypospadias or club foot with known data of surgery
- % TOPFA with civil registration known

Note: DQI from the applicant registry will be compared to the EUROCAT average.

3.6. Accuracy of coding

- Prevalence of selected exact 4-digit Q-BPA codes
- Prevalence of selected unspecified Q codes
- % of “other specified“ or “unspecified“ codes without text description
- Use of major codes for minor anomalies – list of examples to be sent to the registry

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