european surveillance of congenital anomalies

Terms and conditions for the use of EUROCAT Data
Version 27.03.2019

Terms and conditions

1. The Lead Investigator(s) will be responsible for obtaining approval (if required) from a formally constituted and recognised Ethics Committee before any data will be released from the JRC-EUROCAT Central Registry for the study.
2. It is implied that registries that have given permission for their data to be used in the proposed study will ensure that the data provided is as complete and correct as possible, that any deficiencies are communicated to the Lead Investigator(s), and that reasonable queries about individual cases in the dataset are answered.
3. Once permission has been granted registries shall not contribute their data to any other multicenter study with the same objectives (unless notified to the Lead Investigator).
4. Data released is to be used for the stated research only and any significant deviation from the research protocol must be agreed by the JRC-EUROCAT Management Committee.
5. Any corrections to data should be reported immediately to the JRC-EUROCAT Central Registry (JRC-EUROCAT@ec.europa.eu).
6. It is the responsibility of the Lead Investigator(s) to apply for funds to carry out the proposed study.
7. All data released from the JRC-EUROCAT Central Registry should be treated as strictly confidential and stored securely to protect against illegal usage and theft.
8. No-one must attempt to discover the identity of any registered person within the JRC-EUROCAT Central Registry data or attempt to make contact with them or their families. Any reports of the findings of the defined research project will make no reference to individuals or make any statements which would allow individuals to be identified.
9. Data released from the JRC-EUROCAT Central Registry will not be divulged to a third party.
10. Data released from the JRC-EUROCAT Central Registry will be stored on a computer, use of which will be password protected and restricted to named personnel.
11. On completion of the analysis the Lead Investigator's institution archives the dataset (in particular if revisions have been made to the dataset released from Central Registry) for maximum 10 years from the release date of the data. The data will then be returned to the Central Registry or destroyed.

12. The JRC-EUROCAT Management Committee requests a short (no more than 2 A4 pages) progress report once a year during the course of the study. Any change in contact address or personnel undertaking the research should be notified to the Administrator at Central Registry (JRC-EUROCAT@ec.eurocat.eu).
13. Resulting publication from the data released should credit that the data come from EUROCAT and the EUROCAT authorship guidelines must be followed.
14. Publication of small numbers should be discussed with each registry.
15. The JRC-EUROCAT Management Committee can withdraw the approval for use of data if the stated terms and conditions are not followed. Any disputes regarding the use of EUROCAT data will be considered by Management Committee. Unsettled disputes will be referred to the legal advisors of the parties concerned.

Guidance for data use

1. Researchers are advised to FIRST find out the proportion of missing data (per registry/ per year). For a registry to be included in any study using EUROCAT data, the key variable of interest must be complete for at least 80% of cases in the registry e.g. if a study is investigating maternal age then each registry must know maternal age for 80% of cases. Missing Frequency Rates per Variable can be accessed on the EUROCAT website.
2. As well as referring to EUROCAT Guide 1.4 the researcher may also refer to the EUROCAT Data Manual when analysing the data as it provides further historical information on the data held in the database (available by contacting JRC-EUROCAT@ec.europa.eu). This includes important registry-specific information such as changes in coding, coding methods and changes in variables collected over time.
3. Before contacting registries with dataset queries Lead Investigators are advised to fully consult the above to documents in addition to the following documents available on the EUROCAT website:
    a. the Prevalence Data Tables where users can specify years, registries and congenital anomalies (CA) of interest (these tables indicate prevalence rates of CA and are updated twice a year),
    b. EUROCAT Members & Registry Descriptions,
    c. Data Quality Indicator Tables,
    d. the full publications list using EUROCAT data.