Chapter 6. Data Protection and Access to Data

6.1 JRC-EUROCAT Central Database Processing

1. EUROCAT is a European network of population-based registries for the epidemiological surveillance of congenital anomalies, which was established in 1979. Since 2015 the EUROCAT Central Registry is part of the European Platform on Rare Disease Registration, and is operated by the European Commission's Joint Research Centre, located in Ispra, Italy.

2. The EUROCAT Association is the association of member registries who, as a group, elect a president and a Steering Committee.

3. The standardised JRC-EUROCAT Central Database is held at the European Commission's Joint Research Centre (JRC), Health in Society Unit (JRC F1), Directorate F - Health, Consumer and Reference Materials – in Ispra, Italy. The database is updated twice a year. A description of the data (variables) held on each case can be found in Chapter 2.2.1 of this guide.

4. Full member registries biannually transmit a file containing records of individual cases, with standard data as described in Chapter 2.2.1 of this guide. Associate member registries transmit the numbers of cases by year and type of birth for an agreed list of congenital anomaly subgroups (see Chapter 2.2.5).

5. Data on cases with congenital anomalies are collected by registries at national/regional level, and processed in accordance with national legislation regulating their activities. Compliance with the obligations stemming from national legislation, including data protection legislation (e.g. with regard to purpose limitation, information to the data subjects the need of consent), lies with each registry. Registries are subject to supervision by the national Data Protection Authorities and subject to liability, administrative and criminal sanctions in case of breaches.

6. Many of the member registries use named records at local level for one or more of the following reasons:

- To link reports arriving from several sources, and so avoid duplicate registration;
- To allow the follow-up of cases to confirm the diagnosis and to study the outcome of malformed children;
- To trace the cases in order to conduct prospective or retrospective aetiological studies;
- To allow the delivery of information to the malformed children and their families.

All data on individuals affected by congenital anomalies are received and further processed by the JRC-EUROCAT Central Registry as pseudonymised data.

7. The JRC-EUROCAT Central Registry does not hold the names or addresses of cases. Instead, cases are identified for the purpose of communication with local registries by a unique identifier (a maximum of 11 characters long, consisting of either numbers, letters or both). Local codes are used for designating places of birth (e.g. hospital) and areas of residence (e.g. municipality). They do not include postcodes.

8. Collaboration Agreements are concluded between the registries and the JRC to frame the transfer of congenital anomaly data from a controller (each registry) to the JRC as recipient and new controller for further processing. In those Agreements, registries warrant and undertake full respect with their obligations under the General Data Protection Regulation (GDPR)[1] and declare their legal basis for the processing.

9. Processing of the data on congenital anomalies by the JRC-EUROCAT Central Registry is subject to obligations under the Regulation (EU) 2018/1725 (EUDPR)[2]. The processing has been described in detail and is

[1] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)

[2] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions,

available in the DPO's public register with the following Record reference: DPR-EC-01972 - European Platform on Rare Diseases Registration (https://ec.europa.eu/dpo-register/detail/DPR-EC-01972).

6.2 Release and publication of data

1. Only the Central Registry staff have the authority to release data from the JRC-EUROCAT Central Database, on approval of the JRC-EUROCAT Management Committee and of the registries (who are owners of their data). The Central Registry staff are responsible for correct procedures being followed in the event of data release.

2. Customised tables (according to user needs) indicating prevalence and prenatal detection rates derived from aggregate data of congenital anomalies in the member registries, are available on the website and are updated twice a year. In addition, a list of public health indicators based on EUROCAT data is periodically updated and published on the website. A full list of reports and peer-reviewed publications that use EUROCAT data is also available on the website. Registries confirm correctness of the data before every publication (e.g. on the website, in reports and in peer-reviewed publications).

3. Members of the Coding and Classification Committee and Management Committee can have access to individual case data in support of their tasks (e.g. review of coding and classification of anomalies, development of new coding tips, review of cases included in the clusters, etc.).

4. EUROCAT aims to encourage the use of its data for epidemiological surveillance and research whilst safeguarding the protection of complete confidentiality of the data and ensuring that existing knowledge is fully brought to bear on the interpretation of its data. Data requests for research or policy purposes are welcome and the JRC-EUROCAT Central Registry will endeavour to process requests in as timely a fashion as possible subject to resources. Enquiries should be addressed in the first instance to JRC-EUROCAT@ec.europa.eu. Information requests may concern (i) aggregate numbers of cases according to specified case characteristics where these are not available in EUROCAT publications or on the website or (ii) a request for a data file of individual records. See Requesting EUROCAT Data.

5. All requests for access to Central Registry data (both for aggregate number of cases and for individual cases) should be completed on the appropriate application form and sent by email to JRC-EUROCAT@ec.europa.eu. The data request will then be considered by the JRC-EUROCAT Management Committee. After approval from the JRC-EUROCAT Management Committee, written permission will be requested from registries for the use of their data.

6. Data will not be released until ethical approval, where necessary, has been obtained.

7. A data transfer agreement must be signed to indicate agreement with EUROCAT terms and conditions and to regulate the respective obligations of the Parties (i.e. the Central Registry and the person/institution requesting the data), in accordance with the GDPR and the EUDPR with regard to the processing of personal data transferred. See Requesting EUROCAT Data.

8. The JRC-EUROCAT Management Committee may recommend that one or two EUROCAT registry members and/or Central Registry staff collaborate in the proposed research, in order to advise on analysis and interpretation of EUROCAT data.

9. The formula for acknowledgement and/or authorship, is outlined in the EUROCAT Authorship guidelines.

10. A draft of any intended publication using EUROCAT data should be submitted to the JRC-EUROCAT Management Committee for comments. This will be advisory only, except where factual inaccuracies are seen. Approval for the paper should be sought from each contributing registry, and registries have a right to withdraw their data from an intended publication if they consider it to be factually inaccurate, in accordance with the EUROCAT Authorship guidelines.

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bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (Text with EEA relevance.)

11. The acceptance for publication of a manuscript based on EUROCAT data should be notified to the Central Registry as soon as possible. A copy of the subsequent publication should be sent to the Central Registry.

6.3 Guidelines on Security and Confidentiality for Staff Working in the JRC-EUROCAT Central Registry

The processing of personal data by the JRC-EUROCAT Central Registry is subject to Regulation (EU) 2018/1725 (Data Protection Regulation for the EU institutions, EUDPR).

1. In accordance with Art. 13 EUDPR, the JRC-EUROCAT Central Registry processing of personal data is subject to appropriate safeguards to ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation.

The following measures to safeguard the rights and freedoms of data subjects are implemented:

- **Pseudonymisation**
  Data on individuals affected by congenital anomalies are received and further processed by JRC as pseudonymised data. These data are linked to a code and not to a name of a specific person. The key of the pseudonymisation is held by the registries and is not exchanged with the JRC.

- **Data minimisation**
  The data transferred to by the registries to the JRC are well defined. All the variables, their format and coding are specified upfront and described in the EUROCAT Guide 1.5. Data on additional variables which the registry may collect are not transferred to the JRC.

- **Information to data subject on their rights**
  Privacy notices prepared by the JRC are provided to all the EUROCAT registries contributing their data. Registries are asked to make reference to these privacy notices in their privacy statements and make available the information to the data subjects. A link to the privacy notices prepared by the JRC is also available on the EUROCAT website.

2. In accordance with Art. 33 EUDPR, the JRC will implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk, taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for the rights and freedoms of natural persons.

The following technical and organisational measures are implemented:

- **Professional secrecy**
  JRC staff processing data on individuals affected by congenital anomalies are subject to a duty of professional secrecy.

- **Access limitation and staff awareness**
  Access to data on individuals affected by congenital anomalies within JRC is limited to selected staff having been formally authorised by the JRC management. JRC puts in place regular awareness-raising measures among authorised staff on their duties with regard to the level of security to be ensured.

3. The processing of data on individuals affected by congenital anomalies by JRC is subject to the requirements set out in Commission Decision COM (2017)/46[3] and its implementing rules on the security of communication and information systems in the European Commission. Compliance with these rules provide

[3] Commission Decision (EU, Euratom) 2017/46 of 10 January 2017 on the security of communication and information systems in the European Commission

appropriate safeguards in regard to personal data in full compliance with the data protection rules applicable to the Commission.

In particular, the following measures are adopted:

- Standard mandatory measures for access control and authentication, IT asset management, backups, business continuity, compliance, control against malicious code;
- Information security and risk management;
- Encryption, logging and monitoring of access, management of vulnerabilities from removable media, physical and environmental security, secure systems development, IT vulnerability and remediation management, web applications security standards;
- The system compliance is checked by a risk management process followed by the Local Informatics Security Officer (LISO).

4. The JRC has developed a data-submission portal to facilitate the data submission. Using the portal the registries benefit from high security and built-in mechanisms to manage participation in studies of their choice, and to track records of all transactions performed on the data to allow for transparency and accountability.

6.4 Data Protection

The JRC-EUROCAT Central Registry processes individual data concerning health, a special category of data that falls under Article 10 of Regulation (EU) 2018/1725. The health data include medical descriptions, medical diagnosis and tests results, medical classifications, and socio-demographic data (maternal education, socioeconomic status of mother and father, migrant status).

The processing of the data by the JRC-EUROCAT Central Registry has been notified to the European Commission Dara Protection Officer and is described in detail in the DPO record DPR-EC-01972, available in the register of the DPO at: https://ec.europa.eu/dpo-register/detail/DPR-EC-01972.