eurocat

european surveillance of congenital anomalies

EUROCAT Authorship Guidelines

Version 27.03.2019

Reporting EUROCAT Data

If data acquired from EUROCAT registries is to be reported in any form of publication or official document, EUROCAT follows the guidance of the International Committee of Medical Journal Editors (ICMJE, www.icmje.org). The ICMJE currently recommend the following criteria for authorship as part of what is commonly referred to as the "Vancouver Guidelines" (a set of principles drawn up by the ICMJE to give guidance to authors and medical journals in the presentation of medical research and the criteria for authorship of articles). The criteria facilitate clear distinction between those that can be included as contributing authors and other forms of contributors who cannot be considered authors.

- An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study. An author must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors ability and integrity.
- Authorship credit should be based on: 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

1. The first author (usually the lead-investigator), the other lead 2-4 authors (as applicable), and the final listed author will be those who have had a substantial contribution in drafting the manuscript. Each other registry (not yet represented in authorship) who has contributed data that has been incorporated in the manuscript will be represented by one author (who need not be the Registry Leader). That author must take responsibility for the accuracy and valid interpretation of the data supplied from their registry, as well as fulfilling the other authorship criteria in the ICMJE guidelines (see above). These authors will be listed alphabetically between the lead and final authors. It is the responsibility of each author to verify that they comply with the ICMJE "Vancouver" guidelines. A JRC-EUROCAT Central Registry staff member should be included as author and must also fulfil the ICMJE guidelines. Discretion on authorship must be used when there are no cases reported in the study period by the participating registry.

   There may be urgent public health issues which require rapid response where registries will be asked for permission to use their data but not the permission to publish. The Management Committee will take responsibility for the publication.

   Journals may now also request that one or more authors, referred to as "guarantors", be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article. This will usually be the first or last author, and should be indicated to JRC-EUROCAT Management Committee for approval.

2. Where a journal refuses a long list of authors, the alphabetic listing may be replaced by "and a JRC-EUROCAT Working Group". All members of the JRC-EUROCAT Working Group will then also be considered authors. The National Library of Medicine (NLM) indexes the group name AND the names of the individuals the group has identified as being directly responsible for the manuscript during the submission process.
   This results in the members of the "JRC-EUROCAT Working Group" being assigned the same individual credit as if they were listed individually in the author byline (http://www.nlm.nih.gov/pubs/factsheets/authorship.html).

3. To ensure efficiency and transparency in drafting and agreeing manuscripts for journal submission across the EUROCAT network, all authors must follow the protocol described below in Figure 1.
   - The first or corresponding author will distribute drafts to co-authors (the JRC-EUROCAT Central Registry assistance can be sought for the administration of this task).
   - All registry designated co-authors must read and comment on all drafts distributed within the required deadlines and express their concerns at the earliest possible stage. It is the responsibility of each registry's contributing author(s) to check drafts within the allocated timeframe in order to determine if data needs to be withdrawn. The lead author should define after which point in time the data cannot be withdrawn.

- Any registry no longer agreeing to participate can withdraw (data and authorship) at stage 4 of the process (See Figure 1), if they reply within the designated deadline. Lack of reply will be interpreted as approval to include the data in the paper.
- The main authors will revise the manuscript in light of co-authors comments.
- A **final draft** should be distributed to participating registries for approval. Lack of reply within the designated deadline may lead to the author's name being moved to the acknowledgements section. This does not necessitate removal of that registry's data. The data may still be removed at the author's discretion.
- Main authors will revise the manuscript in light of co-author comments and distribute the **final revised draft** to the JRC-EUROCAT Management Committee for final comments, particularly in relation to authorship and references to EUROCAT, acknowledgements etc.
- The assigned corresponding author will submit the paper and let all co-authors know that the submission has occurred, sending them the submitted version.
- All authors will sign copyright transfers, conflicts of interest, authorship declaration and other forms as requested by corresponding author. Lack of reply will result in an author's name being moved to the acknowledgments section.
- Following editorial response the main authors will be responsible for making the necessary revisions and resubmitting the manuscript to the same or a different journal.
- The JRC-EUROCAT Central Registry and all contributing authors will be kept informed by the corresponding author of progress up to publication.
- It is the responsibility of each contributing author to update the corresponding author if their contact details change. If the necessary contact cannot be established at a stage before completion of the publication process, that author may be excluded from authorship and placed in the acknowledgment section.

4. To ensure accuracy, efficiency and transparency in all JRC-EUROCAT documentation, all other documents not submitted for peer review (including documents on websites or technical documents that are EC deliverables, encoded in the Administrative Arrangement with DG SANTE and in the JRC's Work programme relating to JRC-EUROCAT) must be circulated to the JRC-EUROCAT Management Committee at least 10 days before submission to allow time for the members to make comments. Such comments must be responded to. If the Management Committee do not provide comments within the timeframe, submission should not be delayed.

5. The corresponding author or guarantor may draft a press release in advance of publication and agrees this with all co-authors, who may translate it into other languages.

6. For external authors (i.e. authors who are not members of EUROCAT), each paper must have one EUROCAT member as a main author (within the first 2-4 authors or listed as the final author) and one member from each Registry that has contributed data must be included (as

above). At least one JRC-EUROCAT Central Registry staff member should be included as author if he/she fulfils the ICMJE guidelines. All external authors must also fully meet the EUROCAT criteria for authorship in accordance with the ICMJE guidelines and follow the protocol described in Fig 1. External authors who uniquely use data published on the EUROCAT website may do this without co-authorship with EUROCAT members as long as they reference correctly the EUROCAT website (see Referencing EUROCAT below).

7. Internal authors who uniquely use data published on the EUROCAT website are still subject to "Terms and Conditions" regarding reporting their progress annually and the authorship selection.

8. Conference abstracts relating to a paper which is in progress or published can be authored by the main authors and a "JRC-EUROCAT Working Group". Members of the JRC-EUROCAT Working Group should be determined as above, should be sent the abstract and details of the presentation before the conference, and should be acknowledged on one of the presentation slides. If the paper related to the abstract has not yet reached first draft stage, the JRC-EUROCAT Working Group authors should be given the chance to withdraw their data and authorship from the presentation.

9. Papers by EUROCAT members which have not required a request for EUROCAT data or are not research papers using data already available on the website, such as methodology papers and reviews of EUROCAT results, should submit their authorship plan to the JRC-EUROCAT Management Committee for approval. Authorship should include all substantial intellectual contributions to the subject of the paper.

10. Core surveillance activities specified in the Collaboration Agreement will be carried out without requesting specific permission from member registries beforehand, but approval will always be sought before publication (no reply taken as approval). These core activities are website tables, statistical monitoring, and response to exposure incidents. Epidemiological papers relating to trends identified in current statistical monitoring will also be carried out without specific registry permission, but will join the protocol described in Fig 1. at Stage 3.

11. The JRC-EUROCAT Management Committee is the final arbiter of all queries regarding authorship.

Acknowledging JRC-EUROCAT

12. If JRC-EUROCAT Central Registry has provided data but is not included in the authorship, the following statement must be included in the acknowledgments section:

"We thank JRC-EUROCAT Central Registry, European Commission, Joint Research Centre (JRC), Ispra, Italy, *for the data management and extraction of cases included in the study."*

13. The following statement should be included to acknowledge all the funders of individual registries:

"EUROCAT registries are funded as fully described in the EUROCAT 'Members & Registry Descriptions'. The responsibility for the interpretation of data and/or information supplied is the authors' alone."

The paper by Kinsner-Ovaskainen et al. (2018) and the Member Registry Descriptions on the EUROCAT website should be cited and referenced in addition to providing the above statement (see Referencing section below).

14. The following statement should also be included:

"We thank the many people throughout Europe involved in providing and processing information, including affected families, clinicians, health professionals, medical record clerks, and registry staff."

Referencing

15. Citing and Referencing the following paper describing the organisation of the JRC-EUROCAT Central Registry and the Member Registry Descriptions on the JRC-EUROCAT website:

Kinsner-Ovaskainen A., Lanzoni M., Garne E., Loane M., Morris J., Neville A., Nicholl C., Rankin J., Rissmann A., Tucker D., Martin S. (2018) A sustainable solution for the activities of the European network for surveillance of congenital anomalies: EUROCAT as part of the EU Platform on Rare Diseases Registration. Eur J Med Genet. 61(9):513-517.

EUROCAT 'Members & Registry Descriptions' (2019), [Online], available: https://eu-rd-platform.jrc.ec.europa.eu/eurocat/member-registries/eurocat-members [Accessed Date]

16. If JRC-EUROCAT Central Registry has provided data, the EUROCAT Guide 1.5 (Instructions for the Registration of Congenital Anomalies) must be included as a citation and reference, as it provides a full explanation of EUROCAT data. The date of extraction of the data must be stated.

EUROCAT (2021). EUROCAT Guide 1.5. Instructions for the registration and surveillance of congenital anomalies [Online], available: https://eu-rd-platform.jrc.ec.europa.eu/eurocat/data-collection/guidelines-for-data-registration [Accessed Date].

The author overseeing the submission will assume responsibility of ensuring the accuracy of the URL at any given time.

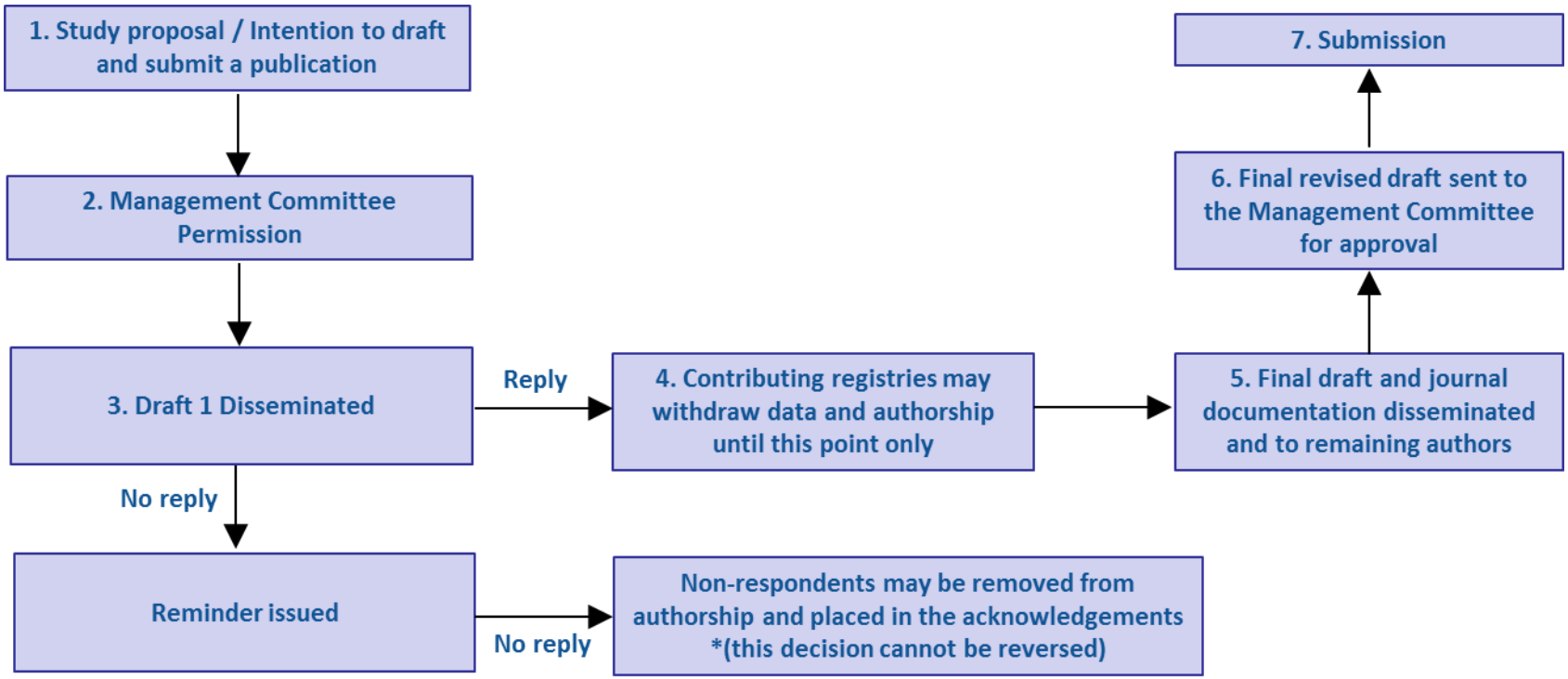

Fig. 1. Scheme of the process of preparation and submission of manuscript based on EUROCAT data.

** This does not necessitate removal of that registry's data. It is the responsibility of each registry contributing author's to check drafts within the allocated timeframe in order to determine if data needs to be withdrawn. The data may still be withdrawn at the main author's discretion.*