



European Society
for Immunodeficiencies

ESID PUBLICATION GUIDELINES

Version 2.1 December 2022

Authors: Markus G. Seidel, Mikko R J Seppänen, Isabelle Meyts

Approved for the ESID Board: Fabio Candotti

The European Society for Immunodeficiencies (ESID) encourages the submission of research proposals from researchers interested in analysing the ESID Registry data. Publications in peer-reviewed journals represent one of the most important indicators of the scientific contribution of ESID to the field of inborn errors of immunity. Authorship on scientific manuscripts is therefore a key means of acknowledging the contribution of ESID and its members to retrospective registry studies and prospective clinical trials.

EUROPEAN SOCIETY FOR IMMUNODEFICIENCIES

Contents

1.	ESID scientific works and accordance with GCP guidelines.....	3
2.	Authorship guidelines	3
2.1	Authorship criteria	3
2.2	ESID attribution.....	4
2.3	Pharmaceutical company attribution	4
2.4	Representatives of participating ESID documenting centres/ national registries	5
2.5	Order of authors	5
2.6	Author obligations for ESID-R studies.....	5
3.	Writing committee	5
4.	Statisticians.....	7
5.	Approval for submission.....	7
6.	Specific circumstances and examples.....	7
6.1.	Publication of statistics without prior notice to documenting centers.....	7
6.2.	Patients for disease-specific studies identified through the ESID Registry	8
6.3.	Data from the ESID-R is evaluated, but usurp minor role in larger paper	8
6.4.	Data analysis restricted to patients from individual centres/national cohort analyses	8
6.5.	Studies performed by sponsors of the ESID Registry	9
7.	Final remark.....	9

1. ESID scientific works and accordance with GCP guidelines

Scientific journals require all submitted manuscripts to state that studies involving human subjects have undergone independent Institutional Review Board (IRB) approval. The principal investigator (PI) and the corresponding author of the research group that performs the study are responsible for the compliance of the study with Good Clinical / Scientific Practice (GCP) guidelines according to the current version and principles of the Declaration of Helsinki, ensuring that the scope and methodology of the study is covered by an appropriate IRB approval, patient information and informed consent and that the relevant data protection issues along with the General Data Protection Regulation (GDPR) are followed; ESID cannot be held liable for study-related regulatory issues.

For studies involving the ESID Registry (ESID-R), It remains the responsibility of the PI and the corresponding author of the research group to ensure that the current versions of the Documenting Center Agreement and the existing patient informed consent (different versions of which might be applicable within a multicenter study) as well as the PI's or research group's local IRB approval are valid and applicable to the proposed study project. This means that the responsible investigators need to evaluate and declare if their study is feasible within the regulatory framework of the regular ESID-R IRB approval or if it might require a separate, additional patient consent and IRB review/approval or an amendment from an ethics committee.

2. Authorship guidelines

These guidelines apply to all publications involving the use of the ESID-R. All authors need to adhere to these guidelines when preparing proposals, abstracts, manuscripts, or other forms of scientific communication. They resemble in part similar guidelines from other societies (e.g. the EBMT) and were adapted from them.

The recommendations of the International Committee of Medical Journal Editors (ICMJE) on defining the role of authors and contributors should be considered as the basis of ESID-R publication guidelines. In the event of any uncertainty or conflict, these recommendations provide the basis for their resolution.

2.1 Authorship criteria

Authorship of a study using the ESID-R as a resource is based on the following criteria. All co-authors listed on the title page must:

- Be ESID members or working in formal co-operation with an elected member of the ESID Board (does not apply to representatives of other societies or consortia within joint studies)
- Have made substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work

- Have had a substantial role in writing the work or revising it critically for important intellectual content
- Have approved the final version prior to journal submission
- Be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Many journals have guidelines limiting the number of authors allowed on a publication. Previous ESID-R publications have, therefore, also used the possibility to list collaborators with minor contributions (such as regular data acquisition and entry into the ESID-R not specifically and substantially involved in the present study design and analyses) at the end of the article, still searchable as authors in PubMed® and Web of Science®. An example for this wording would be mentioned after the last author on the title page: “...as for the ESID Registry Working Party and Collaborators [OR: “... (additional members of this working group who have contributed as authors to this manuscript are listed in the online version)]; For a complete list of ESID Registry Working Party collaborators, please see the Acknowledgment section at the end of the article.” In general, manuscripts should aim to incorporate as many authors as possible, if they have met the above eligibility criteria.

2.2 ESID attribution

ESID invests considerable financial and intellectual resources into keeping and improving ESID-R and in supporting the activities of its Working Parties (WPs).

To ensure recognition of the key scientific role of ESID in supporting studies using the ESID-R and works contributed by the ESID WPs, manuscripts published on behalf of ESID or use the ESID brand must include the following words in the title:

“...– an ESID Study”

Or

“...– an ESID xx[e.g., Registry] Working Party Study”

If the title is too long or does not meet the manuscript title guidelines of a given journal, an alternative is to add this phrase after the name of the last author, such as:

“...on behalf of ESID”

Or

“...on behalf of the ESID xx[e.g., Registry] Working Party”

For national studies and other specific circumstances, see below (chapter 6).

2.3 Pharmaceutical company attribution

In the case of non-interventional prospective studies and prospective clinical trials, a representative of the pharmaceutical company sponsoring the study may be considered for authorship, if their involvement meets the ICJME criteria.

2.4 Representatives of participating ESID documenting centres/ national registries

Representation should be as wide as possible, always taking into consideration specific journal author guidelines and the number of patients included in the analysis. If needed, a “List of collaborators under *Acknowledgements*” may be used as described above.

The authorship position of documenting/national center representatives will be based on the number of patients included in the study and the authorship criteria as defined in chapter 2.1, with emphasis on intellectual input in the present scientific study project and manuscript. Similar contributions or mentioning of coauthors under further collaborators will lead to a listing in alphabetical order.

2.5 Order of authors

First Author: Person who mainly conducted the study, performed analyses and drafted the figures, tables, and manuscript. Two (and rarely three) authors could share first authorship. Such an arrangement should be proposed by the PI and discussed with the ESID-R WP or other WP Chair as applicable (see below) and agreed upon beforehand.

Last Authors: Should include PI, possibly the WP Chair most involved in running the study and ESID-R WP Chair(s) as outlined in chapters 2.1 and 2.2. The respective order of last authors needs to be assessed and negotiated openly before, transparently and in mutual understanding, and reflect the authors’ relative contributions throughout the study.

2.6 Author obligations for ESID-R studies

As the ESID has a valid scientific and economic interest in the timely and successful publication of retrospective studies performed using ESID-R data and ESID resources, principle investigators (PIs) / first authors are obliged to complete manuscripts in a timely manner once the study has been completed and the statistical analysis have been performed.

If the PI fails to deliver a manuscript within a reasonable time frame (in general, six months after having received the results of the statistical analysis), the Registry WP, when applicable together with the relevant other WP Chair may transfer first authorship to another investigator or may complete the manuscript themselves. In case the PI is either of the above Chairs, she/he may be substituted by the ESID President in assessing potential acceptable causes of delay.

3. Writing committee

To ensure a timely realization of a study and carrying it into publication, all ESID-R studies or studies published on behalf of ESID require the formation of a writing committee (WC).

The composition of the WC and the roles and responsibilities should be defined before starting the study and should include the following:

- 1) Principal Investigator (PI) who originally proposed the study***
- 2) Registry WP Chair*, and when applicable, other (e.g., Inborn Errors, Clinical, Genetics) WP Chair(s)***
- 3) Study coordinator or main (junior) investigator, who typically performed experiments, collected and analyzed the data, would write the first draft of the manuscript and design the figures and tables#**
- 4) Study statistician / Registry information technology (IT) team member, as applicable**
- 5) If funding by ESID, applicable member of ESID Executive Board of Directors (e.g., President)***
- 6) Additional members of WPs, if they have made significant contributions that qualify for authorship**
- 7) Representatives of centers that will potentially contribute the largest number of patients to the study, based on the pre-study feasibility check, may be invited to join the WC**
- 8) Representatives from countries or study groups that wish to collaborate in a formal Joint Study, and who would lead local involvement (“National Coordinator”)**

*As shared senior authors, with the PI typically holding the last position (followed by “on behalf of...” as outlined above)

#As proposed first author(s)

Exact roles of ESID officials in the WC need to be assessed and negotiated openly, transparently and in mutual understanding. ESID officials may change during study execution, which would not automatically grant authorship. However, all ESID members qualifying as WC members who actively contributed to a study and its publication according to ICMJE criteria should be included in author list.

For joint studies with partner organizations (for instance, EBMT), authorship should fairly reflect the individual contributions of the participating organizations and should be discussed and agreed upon in advance.

Substantial deviations from these guidelines need to be agreed upon, explained, and declared in writing to the ESID-R WP Chair or ESID President before any submission. If these procedures are not adhered to, ESID claims the right to demand an author correction or retraction of published works.

Professional scientific English language editing is recommended for all manuscripts, especially those from non-native English speaking authors. ESID officials may assist in the identification of affordable editing services.

4. Statisticians

In general, ESID-R recommends the involvement of an experienced statistician when handling ESID-R data already at the initiation, design and proposal of a project, and during the conduction and analyses of a study with ESID-R data. The role of the statistician as a co-author should be decided upon as the study progresses and will depend on the amount of work involved.

5. Approval for submission

When a manuscript/meeting abstract draft is finalised, the corresponding author should e-mail the draft to the ESID-R WP Chair for approval in sufficient time before a deadline. The ESID-R Chair might involve the ESID-R Steering Committee for review.

6. Specific circumstances and examples

The regulations on the use of ESID-R data for studies and publications are defined in the current ESID-R Documenting Center Agreement, an update of which is planned to be implemented in 2023.

6.1. Publication of statistics without prior notice to documenting centers

Statistics on the following items are regularly published on the ESID Website and in the ESID Newsletters:

- Total number of patients
- Prevalence of PID per country
- Number of patients by main category
- Number of patients by center
- Number of living patients receiving Ig-replacement (intravenous, subcutaneous, intramuscular)
- Age distribution of living patients

The number of patients by disease (including genetic diagnosis) and country are currently not published on the website, but can be obtained from the registry team via queries to registry@esid.org or esid-registry@uniklinik-freiburg.de.

National registries may publish a similar set of data, e.g., on their websites or in newsletters. These data can be used in talks and publications without prior consent of the Documenting Centers or the ESID Registry Steering Committee using the following acknowledgement:

“Data from the ESID Registry (www.esid.org)”

6.2. Patients for disease-specific studies identified through the ESID Registry

Example: an investigator wishes to identify patients with XLA who have developed carcinomas.

Publication: Authorships are negotiated between the principal investigator, Registry WP Chair, and the contributing centers.

In the methods or in the acknowledgement section, the following statement must be included:

“Patients for this study were (in part) identified through the ESID Registry.”

6.3. Data from the ESID-R is evaluated, but usurp minor role in larger paper

Example 1: in the context of a review on CVID, an analysis of ESID-R data on the age distribution of CVID patients is performed and included.

Example 2: a study on mechanisms of carcinogenesis in radiosensitive immunodeficiencies uses ESID-R data to document the incidence of tumours in these patients in Fig. 1, but then goes on to address the question experimentally.

Publication: ESID Registry WP Chair and/or one member of the ESID Registry SC or IT Team, who has extracted the data and/or provided the statistical analysis, are listed among the authors as follows: “<Names>, for the ESID Registry Working Party”. Potential further ESID Board and/or ESID-R officials, who may qualify as authors according to chapter 2 should be negotiated between the investigator and ESID Registry WP Chair. As an affiliation note, the following statement is included:

“The ESID Registry is based on contributions by the following national registries (in alphabetical order): Austria, Belgium, Czech Republic, CEREDIH (France), Estonia, PID-NET (Germany), IPINET (Italy), the Netherlands, REDIP (Spain), and UKPIN (UK). Additional contributions are received from the following countries: Belarus, Croatia, Egypt, Greece, Hungary, Ireland, Israel. Lithuania, Poland, Portugal, Romania, Russia, Serbia, Switzerland, Slovakia, Slovenia, Sweden, Turkey, Ukraine” (to be updated accordingly).

6.4. Data analysis restricted to patients from individual centres/national cohort analyses

Procedure: Individual study centers are entitled to analyse ESID-R data from their patients and national registries are entitled to analyse Registry data from their nation without the need to involve the ESID officials or ESID-R Steering Committee in the publication process.

Publication: The following statement must be included in the methods or acknowledgement section:

"The ESID Registry was used for collecting data for this study."

If national studies need additional, significant help in programming and/or data analysis or strategical, study design or coordination issues, the respective Registry IT Team member(s) and/or Registry WP Chair or SC member(s) should be included in author list.

6.5. Studies performed by sponsors of the ESID Registry

Example: PPTA has internally analysed data on Ig replacement in CVID patients and now wishes to publish these.

Publication: The sponsor has the right to nominate authors. The ESID Registry WP Chair and the members of the ESID Registry IT team, who have extracted the data and/or provided the statistical analyses, are listed among the authors as follows: <Names>, on behalf of the ESID Registry Working Party. Representatives of all Documenting Centers providing such data should be listed in a contributors list under Acknowledgements (see chapter 2).

As an affiliation note, the following statement is included:

The ESID Registry is based on contributions by the following national registries: Austria, Belgium, Czech Republic, CEREDIH (France), Estonia, PID-NET (Germany), IPINET (Italy), the Netherlands, REDIP (Spain), and UKPIN (UK). Additional contributions are received from the following countries: Belarus, Croatia, Egypt, Greece, Hungary, Ireland, Israel, Lithuania, Poland, Portugal, Romania, Russia, Serbia, Switzerland, Slovakia, Slovenia, Sweden, Turkey, Ukraine" (to be updated accordingly).

7. Final remark

The ESID-R chairperson and members of the SC will always aim to assist in the project design and performance of studies involving ESID-R data until their publication. Please do not hesitate to contact us with further questions regarding the research and publications process, either personally or at registry@esid.org.