The Chronic Urticaria Registry – CURE

International Steering Committee (ISC) Charter

Introduction

The Chronic Urticaria Registry (CURE) is a registry for chronic urticaria and urticarial vasculitis that collects quality, real-world data, providing us with further understanding of chronic urticaria, urticarial vasculitis and its treatment. CURE is a project, managed by urticaria network (UNEV).

CURE governance and bodies

CURE is academia-driven, international, and peer-governed. Its bodies include the CURE International Steering Committee (ISC) and the CURE Coordinating Office.

International Steering Committee

The ISC is the decision-making body in CURE and is established to:

- Decide on the addition and/or changes of variables to the registry
- Oversee the scientific integrity and output of CURE
- Oversee and promote the dissemination of CURE results
- Advise on publication proposals by CURE investigators
- Develop scientifically and/or clinically relevant publications (manuscripts, abstracts, posters) based on the CURE database including generation of ideas and coordination of data exploration and analyses.
- Discuss and make recommendations for future data exploration and analyses/types of data to be collected
- Work with the CURE Office to promote and continuously improve CURE
- Recruit and help CURE investigators
- Obtain endorsements of CURE by regional, national, and international societies
- Help to obtain funding and support for CURE
- Present CURE data at regional, national, and international meetings and congresses
- Decide on and invite new CURE ISC members
- Decide on the acceptance of new CURE-partners / co-operations

The CURE ISC is comprised of CURE Investigators. The structure of the ISC will be as follows:

- 1 chair and 1 co-chair (must be from different countries), nominated and voted on by the ISC
- Up to 3 principal (coordinating) investigators, nominated by ISC
- Up to 1 member per country/region participating in CURE
- The period of office for ISC members, the chair, the co-chair, and the principal investigator is 2 years (with an option of renewal as agreed by the ISC)

Selection Criteria and Requirements to be met to become an ISC member

1. Clinical Expertise in Urticaria: Active involvement in clinical practice with chronic urticaria or urticarial vasculitis patients.

2. Research Experience in Urticaria: Published research in urticaria, urticarial vasculitis and/or closely related fields.
3. Project Involvement: Active member of the CURE project who included, at least, 50 chronic urticaria patients or 20 urticarial vasculitis patients at the moment of application.

ISC members should have/follow

1. Global Perspective: Ability to contribute an international viewpoint on chronic urticaria.
2. Collaboration: Strong teamwork and collaboration skills.
3. Commitment: Willingness to dedicate time and effort to the steering committee's activities.
4. Ethical Standards: High ethical standards and commitment to patient confidentiality.

A potential candidate should provide (cureoffice@urtikaria.net) a motivation letter, short CV, publication list and the number of patients included in the CURE from their center (separately baseline and follow-up).

For becoming a member, a two third majority vote of the ISC is required.

Meeting frequency

The ISC will meet (in person/virtually) at least once a year. Another co-investigator from their center in their country or region can represent members who are unable to attend a meeting.

Processes for Decision-Making and Voting by the ISC

Processes for ISC decision-making and voting will be as follows:

- Decisions can be made and voting can take place only if at least two thirds of the ISC members are present.
- Decisions can be made only if at least two thirds of the votes are in favor of a proposal.
- At least the chair or co-chair and one principal investigator must be present for a valid vote to be cast.
- Votings on urgent topics can also be made outside of ISC meetings by post/email.

Renewal and change of the ISC

The renewal of the ISC will occur every 2 years. Decisions can be made and voting can take place only if at least two thirds of the ISC members are present and two thirds of the votes are in favor of a proposal.

The CURE Coordinating Office

The CURE Coordinating Office assists the CURE ISC. Its responsibilities include:

- Preparation of ISC and other project related meetings

- Management of the CURE website and social media activities
- Publicizing CURE activities and outcomes
- Preparing and sending out CURE newsletters and communication
- Management of data entry and query
- Processing of CURE investigator applications and collaboration agreements
- Processing of CURE manuscript proposals
- Processing of cooperation agreements with sponsors
- Collection and documentation of required documents for participation, e.g. ethics approvals
- Communication with and coordination of the legal support
- Communication with partners and supporters
- Organization and secure transmission of raw data for CURE centers who ask for their own data for their own use

Processes for Data Analyses and Interpretation

Reports containing descriptive information, as well as analyses of CURE patient data, will be provided for information to CURE investigators and eligible partners at regular intervals. In addition to these regular descriptive data summaries, the capability exists to conduct specific analyses of scientific or clinical interest on the CURE database.

- Specific analyses of CURE data can be proposed by any investigator participating in CURE who has entered at least 50 baseline data sets and corresponding follow up data sets (number is subject to annual review by ISC, Annex 1).
- The proposal should be sent to the CURE Office (cureoffice@urtikaria.net) and if all formal criteria are fulfilled, the proposal will put forward for consideration by the ISC.
- The analyses will be overseen by the ISC or by an appointed investigator(s) and carried out by an ISC member or an appointed investigator(s) / biostatistician(s).
- It is the responsibility of the ISC to approve the use of global data for publications and to collectively agree on the interpretation of data analyses, where relevant.
- If a publication results from data analyses of global data of patients with chronic urticaria, the following general rules for co-authorship of the CURE centers apply:
    - The number of co-authorships for each center is based on the number of data sets and whether the ICMJE criteria are met. Furthermore, the data sets must fulfill the specific requirements of the analysis (e.g. pertaining to adult participants, individuals with CSU, or other specified conditions). Co-authorship will be granted exclusively based on the quality and completeness of the data utilized in the analysis, rather than the total number of data entries submitted.
    - According to the specific requirements of the analysis, if 50 or more baseline data sets and/or corresponding follow up data sets were entered, the respective center is automatically asked for co-authorship (one co-author). The number of additional co-authors also depends on the number of entered patients (see table below):

Number of data sets entered	Number of Co-Authorships
100	2

200	3
400	4
800	5
1,600	6

- If exclusively baseline data sets are utilized for the analysis, the identical co-authorship criteria are upheld, with the caveat that only baseline data sets numbering ≥50 are considered, excluding follow-up data sets. In other words, the quantity of follow-up data sets included by these centers doesn't impact the analysis for this publication, as follow-up data sets are disregarded.
- If both baseline data sets and follow up data sets are utilized for the analysis, then the centers must include both ≥50 baseline and follow up data sets in order to be asked for co-authorship.
- Head of the respective center takes the responsibility to discuss the co-authorship within his/her team and get back to the CURE Coordinating Office with response who should be included as a co-author.
- The ISC members will be asked whether they would be interested to contribute to a CURE manuscript and become co-authors (ICMJE criteria must be fulfilled!) but won't be automatically included as co-authors of the manuscript.
- If an ISC member agrees to be a co-author, they can also be qualified for an additional authorship based on the number of data entries included. In this case, an additional author from the ISC member CURE center can be included on their behalf.

- If a publication results from data analyses of global data of urticarial vasculitis patients, the following rules for co-authorship of the CURE centers apply:

  - The number of co-authorships allocated to each center is based on the number of data sets provided and compliance with the ICMJE criteria. Furthermore, the data sets must fulfill the specific requirements of the analysis (e.g., pertaining to adult participants, individuals with specific symptoms, or other specified conditions). Co-authorship will be granted exclusively based on the quality and completeness of the data utilized in the analysis, rather than the total number of data entries submitted.
  - According to the specific requirements of the analysis, if 10 or more baseline data sets and/or corresponding follow up data sets were entered the respective center is automatically asked for co-authorship (1 co-author). The number of additional co-authors also depends on the number of entered patients (see table below):

Number of data sets entered	Number of Co-Authorships
20	2
40	3
80	4
160	5
320	6

- If exclusively baseline data sets from patients with urticarial vasculitis are utilized for the analysis, the same co-authorship criteria apply. However, only ≥10 baseline data sets are considered, while follow-up data sets are disregarded. Consequently, the number of follow-up data sets included by these centers has no bearing on the analysis for this publication, as they are not factored into it.
- If both baseline data sets and follow up data sets of patients with urticarial vasculitis are utilized for the analysis, then the centers have to include both ≥10 baseline and follow up data sets in order to be asked for co-authorship.
- Head of the respective center takes the responsibility to discuss the co-authorship within his/her team and get back to the CURE Coordinating Office with response who should be included as a co-author.
- The ISC members will be asked whether they would be interested to contribute to a CURE manuscript and become co-authors (ICMJE criteria must be fulfilled!) but won't be automatically included as co-authors of the manuscript.
- If an ISC member agrees to be a coauthor, they can also be qualified for an additional authorship based on the number of data entries included. In this case, an additional author from the ISC member's CURE center can be included on their behalf.

- For being part of the author team, the criteria of authorship (as set forth in Annex 2) have to be met. All other centers, not involved with a co-author but whose data will be considered in analyses, should be acknowledged and listed (each CURE publication should be accompanied by a table that provides information on which CURE centers' data were used) in the publication.
- CURE Investigators may request information (raw data) from the database for their own study centers for their own use (Annex 2). Requests that may be of general interest should be forwarded to the CURE ISC through the principal investigator.
- Sponsors and financial supporters of analyses may be eligible for up to two co-authorships, provided they meet the ICMJE criteria and depending on the nature and extent of their involvement. This inclusion ensures that their contribution to the research is appropriately acknowledged and recognized in the publication process.

The details of the scientific publication activities including global publication, development process and guidelines for authorship are specified in Annex 2.

Joint analysis of the CURE data and data from other data sources (e.g. CARE and/or CRUSE data) is intended in the future. A clarification of the authorship criteria for this particular situation will be provided in a future revision of the Charter or in a separate document.

The funding and reimbursement of ISC members

ISC members will not be rewarded with honoraria or other fees for participating as a member or an author. Reasonable travel expenses, however, to attend CURE meetings or to present CURE-based analyses at international conferences and congresses can be reimbursed, depending on the funding obtained for CURE and the involvement of the ISC member.

Declaration of Conflicts of Interest

The members of the ISC should not undertake any other activity which could affect their independent judgment in the performance of their duties, or which conflicts with (or could

reasonably give the appearance of conflicting with) the interests of CURE. This does not preclude membership on advisory boards of pharmaceutical companies, receiving honoraria for lectures or consulting, membership on the executive boards of other disease registries or other scientific committees, but such activities should be included in the regular descriptive CURE data summaries as potential conflicts of interests.

Confidentiality

All ISC members shall be aware that the information they receive may be of confidential nature, and that they may not make use of, or disclose, such confidential information for any other purpose than for performing their duties as ISC members.

Role of UCARE and UNEV

CURE is the preferred registry of UCARE*. All UCAREs are encouraged to contribute to disease registries. Participation in CURE does not require UCARE membership. The UCARE network and steering committee support CURE. UCARE activities and meetings disseminate CURE results.

UNEV has developed and maintains the CURE database. UNEV has the right and the obligation to use the information in the database in relation to the authorities. Participation of investigators and centers in CURE requires completion of a collaboration agreement with UNEV (available from the CURE Coordinating Office and website).

UNEV and UCARE retain the right to evaluate data within CURE and may perform any such evaluations with the approval of the ISC. UNEV has overall responsibility for all statistical work on CURE National and International data.

**The Urticaria Centers of Reference and Excellence (UCARE) program, an initiative by the Global Allergy and Asthma Excellence Network aims to enhance understanding of urticaria through research, advocacy, and by accrediting a global network of specialized centers. These centers focus on providing excellence in urticaria management, promoting research, and raising awareness about the condition. A close collaboration exists between UNEV gGmbH, the host of CURE, and Global Allergy and Asthma Excellence Network, the organization behind UCARE. This partnership facilitates the integration of clinical excellence and comprehensive data collection, aiming to improve patient care and advance research in the field of urticaria.*

Role of CURE partners

CURE aims to partner with regional, national and international medical and scientific societies and networks, patient organizations, industry and other stakeholders, including other urticaria, angioedema and urticarial vasculitis registers to promote CURE participation and dissemination of results. CURE is funded via donations, collaboration, and sponsoring by partners. The terms and conditions of financial support by partners are detailed in the Partner Collaboration Agreement, available from the CURE Coordinating Office.

Data privacy

The patient data on which the CURE analyses are based are exclusively and without exception pseudonymized data. Conclusions about the

person of the respective patient can only be drawn by the respective attending physicians and their staff. However, these persons are legally prohibited from disclosing this data to unauthorized persons. In addition, UNEV is responsible for complying with the relevant data protection requirements within the framework of the collaboration agreements, particularly those relating to the lawfulness of data processing. The registry is designed to conclude its activities once it has fulfilled its purpose, ensuring that the data collection and processing are limited to what is necessary to achieve its research and healthcare objectives.

Liability

UNEV does not guarantee whether analyses suggested by CURE investigators/centers are carried out.

In all other respects, UNEV shall only be liable for intentional and grossly negligent acts of its agents. The liability for damages caused by negligence is limited to the amount of the damages that are foreseeable and typical for the type of business in question. In the event of data loss, UNEV shall only be liable for the damage that would have occurred even if the respective contractual partner (CURE investigators/centers) had properly backed up the data. No liability is accepted for loss of profit, indirect damage, and consequential damage.

Annex 1 – Proposal for CURE Data Analysis

Date		
Requesting investigator (please complete the boxes below)		
Name		
Affiliation		
Address		
E-Mail		
Tel.		
Working title		
Description of project and requested analysis		
Aim		
Hypothesis of interest		
Population(s) of interest (e.g. all patients/children/ adults/treated/untreated)	1	
	2	
	3	
Groups of interest (e.g. sex, age groups 0-50, >50 etc.)	1	
	2	
	3	

The analysis should be based on data from

☐ All CURE countries*	☐ Selected CURE countries* please enter all selected countries here	☐ My CURE patients

*Analysis of data has to be approved by the CURE ISC

Data needed by (DD/MM/YYYY) (normally at least 3 months are needed for answering a request)	

Purpose

☐ Manuscript ☐ Other, please specify

Authors	
Intended authors	

Note also the following regulations
The CURE ISC must always approve manuscripts before they are submitted to the journal publisher. CURE and supporting partners must be acknowledged. The authorship criteria are defined in the CURE Charta.

In case of any questions please contact: cureoffice@urtikaria.net

Annex 2 – Scientific Publication Activities

Global publications

The International Steering Committee (ISC) will develop and maintain the overall CURE Publication Plan based on available CURE data:

- The overall CURE Publication Plan is based on an evaluation of the available data within the CURE database, expected timelines for further data to accrue/analyses to become available, assessments of the current scientific literature.
- The ISC is responsible to identify scientifically and/or clinically relevant publications (manuscripts, abstracts, posters) generated from the CURE database and develop those publications.
- The ISC will have oversight of all concepts and proposals for publications to ensure scientific accuracy and appropriateness.
- International summaries and analyses of CURE data must not be published by the National/Regional Boards or disclosed to any outside entities without the agreement of the ISC.
- The CURE Publication Plan will be shared with all investigators regularly (intended is on an annual basis).
- Copies of published CURE manuscripts may be made available to the CURE investigators by the ISC.

Country/Regional publications (data analyses of more than one CURE center)

All country/regional publication development should be under the supervision of the corresponding National/Regional member of the CURE ISC (if not available by an appointed member of the ISC).

A copy of any publication for a country/regional publication using CURE data should be sent to the ISC prior to submission at least twenty-one (21) days prior to submitting an abstract, manuscript or other document for publication or presentation.

All country/regional publications/presentations shall appropriately acknowledge that the publication/presentation benefitted from the work of CURE, reference relevant previous CURE publications, and state that the country/regional results are derived from a subset CURE data.

Publications by individual CURE investigators/centers

Each CURE investigator/center is free to use, define their authorship criteria and publish their own data and has the right to veto pooling of their data for scientific publications (apart from regular descriptive data summaries, which cannot be vetoed). A data cut can be requested by the project manager / CURE investigator.

A copy of any publication for a CURE investigator/center using CURE data should be sent to the ISC prior to submission at least twenty-one (21) days prior to submitting an abstract, manuscript or other document for publication or presentation.

All publications/presentations of individual CURE investigator/center results shall appropriately acknowledge that the publication/presentation benefitted from the work of the UCARE network and CURE, reference relevant previous CURE publications, and state that the individual CURE investigator/center results are derived from a subset CURE data.

Procedures for Global Publications

1.	Preparation of Publication draft (manuscript/abstract/poster/presentation: After approval of analyses by the ISC, the analyses are performed, and the first publication/presentation/poster draft is prepared by core author team. The core author team should include, at a minimum, one or two lead authors, one member of the International Steering Committee (ISC), and, where applicable, the investigator who conceived the idea for the analysis. The core author team may also choose to involve a medical writer as needed. The roles of lead author and investigator may be held by the same individual. The ISC will determine prior to the initiation of the publication which author(s) should take the lead for writing and managing each publication or presentation (i.e. lead author(s)). The lead author(s) should take the overall responsibility for the integrity of the work.
2.	Submission of Publication draft: The publication draft shall be submitted to the CURE Coordinating Office (cureoffice@urtikaria.net) then.
3.	Notification of Involved Parties: The CURE Coordinating Office will then contact the whole ISC and all CURE investigators/CURE centers whose data were used in the analyses for the creation of the publication draft, provided they have entered the minimum defined number of patient data into the CURE database.
4.	Request for Feedback/Input/ Confirmation of Co-Authorship: The contacted ISC members and CURE investigators/CURE centers will be asked by the CURE Coordinating Office to provide feedback/input and confirm their co-authorship within a specified deadline. If the CURE Coordinating Office does not receive a response within the deadline, it will be assumed that there is no interest in co-authorship of the respective publication draft.
5.	Additional Co-Author Proposals: If a CURE center meets the criteria for more than one co-author, the program manager of the respective CURE center may propose additional colleagues from their center as co-authors. These additional co-authors will also receive the publication draft and will be asked to confirm their co-authorship and provide feedback/input within a specified deadline.
6.	Compilation of Final Feedback: Once all co-authors have provided their feedback on the publication draft, the CURE Coordinating Office will forward this feedback to the core author team, who will then create a final version of the publication.
7.	Final Approval:

	The final version of the publication will be provided to all co-authors for their final approval.	
8.	Submission: Once approved, the publication draft is ready for submission to journals/ congresses/events, as intended, a task which will be handled by the CURE Coordinating Office. The submitted material will be shared with all co-authors. Open access publication can be considered depending on the funding obtained for CURE.	
9.	Notification of Publication Status: The publication status (feedback regarding its acceptance or rejection) will be provided to all co-authors.	
10.	Published: All co-authors will be informed as soon as the publication is available.	Acceptance and identify a presenter: All co-authors will be informed by the CURE Coordinating Office if the abstract has been accepted as an oral presentation or poster. The presentation/poster shall be presented by one member of the core author team (ideally the lead author). A CURE presentation template will be provided to the presenter by the CURE Coordinating Office. The final presentation/poster will be sent to all co-authors prior the congress/event. Financial support for the abstract submission fee and meeting registration fee can be considered depending on the funding obtained for CURE.

Guidelines for Authorship of publications arising from CURE

Members of the ISC as well as the investigators of the CURE centers who meet the CURE authorship criteria may become authors, but both does not automatically confer authorship. In order to become a co-author the ICMJE criteria must also be met.

UCARE and UNEV can facilitate professional writing and editorial assistance from a third party which can, under the direction of the core author team, assist with:

- The drafting or editing of publications (manuscript, abstract, poster)
- Drawing figures and graphs
- Performing literature searches
- Manuscript submission

To be an author of a CURE publication/abstract, all 3 of the following criteria must be met:

- Substantial contributions to design, acquisition of data, or analysis and interpretation of data

- Drafting the publication/abstract or revising it critically for important intellectual content
- Final approval of the version to be published

Positions of administrative leadership, however important to the research, are not by themselves criteria for authorship.

All authors of CURE publications will be required to provide full disclosures of their financial interests in line with the international Good Publications Practice 2022 guidelines for reporting medical research.