

The Chronic Urticaria Registry – CURE

International Steering Committee (ISC) Charter

Introduction

The Chronic Urticaria Registry (CURE) is an open-ended patient registry for chronic urticaria that collects quality, real-world data, providing us with further understanding of chronic urticaria and its treatment. CURE is an urticaria network e.V. (UNEV) project, endorsed by the urticaria taskforces of the European Academy of Allergy and Clinical Immunology (EAACI) and the Global Asthma and Allergy European Network (GA²LEN) as well as the World Allergy Organization (WAO) and the European Academy of Dermatology and Venereology (EADV).

International Steering Committee Role and Responsibilities

The international Steering Committee (ISC) is the decision-making body in CURE and is established to:

- Identify scientifically and/or clinically relevant publications (manuscripts, abstracts, posters) generated from the CURE database and develop those publications.
- Coordinate all data exploration, analyses and peer-reviewed manuscripts, abstracts and other scientific publications generated from the CURE database.
- Facilitate dissemination of the results in timely and appropriate format.
- Discuss and make recommendations for future data exploration and analyses/types of data to be collected
- Decide on the addition of variables to the registry as suggested by the CURE-partners
- Decide on the acceptance of new CURE-partners / cooperations with CURE-partners

Structure of the CURE ISC

The CURE ISC is comprised of CURE Investigators. The total number of ISC members should not exceed twenty.

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

- 1 principal (coordinating) investigator, 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)

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 Committee members are present and two thirds of the votes are in favour of a proposal.

Potential new ISC members need to apply for membership. For becoming a member, a two third majority vote of the ISC is required.

Meeting frequency:

The ISC will meet twice a year. Members who are not able to attend a meeting can be represented by another investigator from another site or a co-investigator of his/her site from her/his Country or Region.

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 and two thirds of the votes are in favour of a proposal. At least the chair or co-chair and the principal investigator must be present for a valid vote to be cast.
- ISC members who are not able to attend a meeting in person will be invited to vote either through videoconferencing (e.g. Skype), through their delegate or by post/email. If they do not respond to the invitation within a certain timeframe (specified in the letter of invitation to vote), a decision may be taken by the chair and co-chair.

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 30 baseline data sets and corresponding follow up data sets (number is subject to annual review by ISC).
- The proposals will be handled by the CURE principal investigator and (if practicable within the constraints of the database) 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, the following general rules for co-authorship of the CURE centres apply: 1) if equal or more than 50 baseline data sets and corresponding follow up data sets were entered, the respective centre is automatically asked for co-authorship (one co-author). 2) if equal or more than 100 baseline data sets and corresponding follow up data sets were entered, the respective centre is automatically asked for co-authorship (two co-authors possible). For being part of the author team the criteria of authorship (as set forth in ANNEX 2) have to be met. All other centres, not involved with a co-author, need to be mentioned (acknowledged) in the publication.
- CURE Investigators may request information (raw data) from the database for their own study centres for their own use. Requests that may be of general interest should be forwarded to the CURE ISC through the principal investigator (Annex 1).
- CURE Investigators may request information about all data in her/his Country/Region. Such requests should be forwarded to the CURE ISC through the principal investigator. The responses of the CURE ISC will be forwarded to the investigators by the corresponding National/Regional ISC member.

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

The funding and reimbursement of ISC members is specified in Annex 3.

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.

Confidential Information

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 the urticaria network e.V.

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. UNEV owns the CURE data.

UNEV retains 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.

Annex 1

Request for Analysis

Date:

Requesting investigator:

Name:	
Affiliation:	
Address:	
E-mail:	
Tel:	
Fax:	

Working title:

Description of Project and requested analysis:

AIM:	
HYPOTHESIS OF INTEREST:	
POPULATION(S) OF INTEREST: <i>(e.g. all patients/ children/ adults/treated/untreated)</i>	1.
	2.
	3.
GROUPS OF INTEREST: <i>(e.g. sex, age groups 0-50, >50 etc)</i>	

The analysis should be based on data from:

- All countries*
- Selected countries**

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- Selected Country**
- Selected clinic(s)**

.....

Data needed by (DD/MM/YYYY):.....

(Normally at least 3 months are needed for answering a request)

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

*** Analysis of National data has to be approved by the National member of the CURE ISC (where applicable), and selected clinics before the request is executed.*

Purpose:

- Manuscript
- Oral presentation
- Abstract
- Other

Result will be presented at:.....

By.....

- Submitted to (state target journal).....

First author:

Co-authors

.....

- Other reason for request.....
-

Note also the following regulations:

The CURE ISC must always approve manuscripts before they are submitted to the journal publisher if it is based on International data. At least one member of the ISC must be involved as a coauthor. CURE and supporting partners must be acknowledged. The CURE National ISC Member and the Investigators in the participating clinics must additionally approve manuscripts based on data from one country.

In case of any questions please contact: karsten.weller@charite.

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:

All country/regional publication development will be under the supervision of the corresponding National/Regional member of the CURE ISC (if not available by an appointed member of the ISC). The respective member or the ISC will determine if and how the results of regional CURE analyses and data summaries should be published.

A copy of any publication for a country/regional publication 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.

Site publication:

Each participating investigator/study site is free to use and publish their own data, and also has the right to veto pooling of their data for scientific publications (apart from regular descriptive data summaries, which cannot be vetoed).

A standardised Request for Analyses form for CURE Investigators to request specific analyses from data set is available from the CURE principal investigator.

A copy of any publication for an individual investigator/study site 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 and presentations of the individual site results shall appropriately reference the multi-site study registry publication, if any, or the fact that the individual site registry results are a subset of data resulting from a larger multi-site study registry.

Publication development process:

CURE follows Good Publication Practice 2 (GPP2) guidelines (www.gpp-guidelines.org). Members of the International Steering Committee may become authors, but membership of the committee does not automatically confer authorship (BMJ 2009;339:b4330; doi: 10.1136/bmj.b4330.)

UNEV can facilitate professional writing and editorial assistance from a third party which can, under the direction of the ISC, assist with;

- the drafting or editing of publications (manuscript, abstract, poster)
- drawing figures and graphs,
- performing literature searches,
- manuscript submission

Guidelines for Authorship of publications arising from CURE

Authorship is attributed according to the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.icmje.org/>). Authorship selection for each publication activity of national or international data (manuscripts, abstracts, posters) is to be agreed by all members of the ISC.

All authors of CURE publications will be required to provide full disclosures of their financial interests in line with the international Good Publications Practice 2 (GPP2) guidelines for reporting medical research.

To be listed as an author, you must meet all 3 of the following criteria:

- Substantial contributions to design, acquisition of data, or analysis and interpretation of data
- Drafting the publication or revising it critically for important intellectual content
- Final approval of the version to be published

Positions of administrative leadership, contributing patients to the study and collecting and preparing data for analysis, however important to the research, are not by themselves criteria for authorship. The ISC will determine prior to the initiation of the publication which author should take the lead for writing and managing each publication or presentation (i.e. lead author). One author should take overall responsibility for the integrity of a study and its report.

Annex 3

Funding and reimbursement 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 can be reimbursed, depending on the funding obtained for CURE.