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**GA²LEN/HAEi Angioedema Centers of Reference and Excellence (ACARE) Steering Committee (ASC) Charter**

**Version: 06/2023**

The ACARE program is a joint initiative by GA²LEN and HAE International (HAEi) for developing and accrediting an interactive network of centers of reference and excellence in angioedema. Angioedema is a common and debilitating condition and can be a challenge for both patients and treating physicians, especially when recurrent. ACAREs provide excellence in angioedema management, increase the knowledge of angioedema by research and education, and promote the awareness of angioedema by advocacy activities.

# ACARE Steering committee (ASC)

As a global and interactive network, all ACAREs have the same rights and responsibilities. The ACARE network is governed by the ACARE Steering Committee (ASC), which (1) oversees and coordinates the activities of the ACARE network, (2) reports to the GA²LEN executive committee, and (3) provides an annual update to the HAEi Board of Directors. The ASC has 5 members, which include the ACARE coordinator and deputy coordinator. In addition, a member of HAEi’s executive team will function as non-voting member and consultant. To ensure long-term continuity and alignment with other GA2LEN activities, one ASC position must be held by a member of the GA²LEN executive committee. This member is appointed by the GA2LEN executive committee. The ASC is supported by the ACARE office, in Berlin, Germany.

## Conflicts of Interest

The members of the ASC 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 ACARE. 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 disclosed as potential conflicts of interests.

## Confidential Information

All ASC 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 ASC members.

## Funding and reimbursement ASC members

ASC members will not receive honoraria or other fees for participating as a member or an author. If funding is available, reasonable travel reimbursement for attending ACARE meetings may be available.

# ACARE centers

## Application

Centers need to apply to become an ACARE. The application is received and confirmed by the ACARE office. The ACARE office informs the applicant center about the audit procedure and provides the documents needed for the audit. The applicant must send documentation to the ACARE office by e-mail that shows in how far the center meets the 32 ACARE criteria. The office checks this documentation and decides if the center is ready to be audited and informs it accordingly. Then the ACARE office looks for an appropriate auditor – the applicant center may suggest an auditor, but the ACARE office has final say and can appoint a different auditor. The ACARE office provides the auditor with the documentation needed for the audit (documentation and audit report template). After the applicant center has provided the needed documents and the ACARE office deems them complete, an audit date is set. Applicant centers will be added to the ACARE website when the date of the audit is set. If an ACARE applicant does not respond after 3 emails sent from the ACARE office, they will be removed from the applicant list again. If the applicant wants to pick up the process again after this, a new application must be submitted. Certification should take place no later than 5 months after application.

*Audit*ACARE audits are performed by ACARE heads and/or their deputies. Travel costs are not reimbursed unless this is cleared with the ACARE office before the audit. First ACARE audits should be performed on site. In special cases, audits by video conference are possible. For example, if the auditor has recently visited the applicant center in person or will visit at the next opportunity or the pandemic situation requires it. Videoconference audits need to be approved by the ACARE office before the audit. The auditor will receive a guideline for the online audit to be conducted.

Auditors report on their audit visit to the ACARE office, by sending the audit report and pictures taken together with a short summary (3 to 5 sentences) and their recommendation to certify the applicant center or not. The ACARE office obtains confirmation from all ASC members to follow the recommendation of the auditor. In case of different opinions, ASC members will seek consensus. After being successfully audited, centers receive a certificate valid for two years, after that there will be a re-audit. The second re-audit will take place after three years. After that the audit period will be every four years. Re-Audits can be conducted remotely. Providing documentation before each re-audit is mandatory for all ACAREs.

*ACARE projects -- Application and Procedure*

Scientific Projects run through the ACARE network must go through the following steps:

* The application form must be fully filled out and submitted via the ACARE office to the ACARE Steering Committee. Parameters such as scope, duration, aim, instruments, databases etc. must be fully formulated. If the application is accepted, a ACARE Steering Committee Project Advisor is assigned.
* The project must have an international Steering Committee, ideally with 3-7 members. It must be geographically diverse, and its members must have a strong interest in the project and work as project ambassadors in their region and within their scientific communities. The Steering Committee should have regular meetings at key junctures of the project.
* Project Leads must ensure that necessary ethics approvals are obtained.
* Project tools and documents must be developed.
* A pilot study (proof-of-concept) must be conducted at the ACARE centers of (some) steering Committee members.
* Depending on the project, further ethics approvals may have to be obtained from participating centers.
* If the tools and documents have been perfected (taking in learnings from the pilot study), a global rollout is the next step.
* After the deadline, data obtained should be analyzed and prepared for publication (see below for guidelines on publication).

The ACARE office will assist with the following points:

* Organizing meetings and streamlining communication
* Sending emails on behalf of the project lead
* Advertising the project via our website and social media
* Making project documents available via our website and/or member area
* Assisting with translations and scientific writing
* Giving the opportunity to present projects at ACARE sessions and possible future ACARE events.

# Guidelines for Authorship of publications arising from ACARE projects

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 ASC.

All authors of ACARE 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, all 3 of the following criteria must be fulfilled:

* Substantial contributions to design, acquisition of data, or analysis and interpretation of data
* Drafting the publication or revising it critically for important intellectual content, and
* 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 ASC 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.

# The ACARE network and GA2LEN

The ACARE program is part of the GA2LEN CORE (center of reference and excellence) initiative. The ACARE network will take full advantage of the experience and expertise of other GA2LEN networks including UCARE and ADCARE. The ACARE network is self-funded and meets its financial obligations through fundraising activities. The Network’s finances will be managed by the ACARE office with oversight and periodic reporting to the ASC.

# The ACARE network and HAEi

The ACARE network works with HAEi and receives support, including funding, from HAEi. In addition, the ASC works closely with HAEi Regional Patient Advocates, and provides HAEi leadership with regular, comprehensive updates on the activities of the ACARE network. These updates can take the form of written reports or meetings (online or in person).

# ACARE meetings

The ACARE network will hold ACARE sessions or meetings at affiliated meetings or conferences, such as the Bradykinin Symposium/ACARE Angioedema School, the Global Urticaria Forum (GUF), UCARE Conference or the HAEi Global Leadership Worskshop. In the long-term, a designated ACARE conference should be established.