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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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Definition, aims, and implementation of GA²LEN/HAEi Angioedema Centers of Reference and Excellence

To the Editor,

GA²LEN, the Global Allergy and Asthma European Network, and HAE international (HAEi), the global umbrella organization for the world's hereditary angioedema (HAE) patient groups, have launched their joint ACARE (Angioedema Center of Reference and Excellence) program, within GA²LEN's center of reference and excellence (CORE) initiative. Angioedema is a common, heterogeneous, often debilitating and chronic condition and is frequently a challenge for physicians and affected patients, especially patients suffering from recurrent attacks. Additionally, it can be a challenge for some patients to understand the underlying etiology of their angioedema (Table 1). GA²LEN's CORE networks, such as UCARE for urticaria and ADCARE for atopic dermatitis, help to improve the management of difficult-to-treat conditions. Here, we describe the aims, requirements, provisions, application process, audit, and accreditation

protocol for GA²LEN/HAEi ACAREs. ACAREs aim to provide excellence in angioedema management, increase the knowledge of angioedema through research and education, and promote advocacy activities that raise angioedema awareness. To become a certified ACARE, angioedema centers must fulfill 32 requirements, defined by specific provisions that will be assessed during an audit visit. The ACARE program will result in a strong network of angioedema specialists, promote angioedema research and awareness, and harmonize and improve angioedema management globally. ACAREs will expand access to modern angioedema medicines in countries where they are available and help to bring them to countries where they are not.¹

This document summarizes the aims of GA²LEN/HAEi Angioedema Centers of Reference and Excellence (ACAREs) and elaborates the requirements that ACAREs must fulfill to become

TABLE 1 Classification of angioedema



Bradykinin-mediated angioedema				Mast cell mediator-mediated angioedema		Unknown mediator
C1-INH deficiency/defect		C1-INH normal		IgE mediated	Non-IgE mediated	
Inherited	Acquired	Inherited	Acquired			
HAE-1 HAE-2	AAE-C1-INH	HAE nC1-INH (HAE-FXII, HAE-ANGPTI, HAE-PLG, HAE-KNG1, HAE-UNK)	AE due to medication that interferes with BK degradation, eg ACEi	Angioedema with or without wheals in patients with urticaria Anaphylaxis	Angioedema with or without wheals in patients with urticaria	Idiopathic AE

Abbreviations: AAE-C1-INH, acquired angioedema due to C1-inhibitor deficiency; ACEI-AE, angiotensin-converting enzyme inhibitor-induced angioedema; BK, bradykinin; HAE nC1-INH, hereditary angioedema with normal C1-inhibitor levels, either due to a mutation in factor XII (F12), angiotensin-converting enzyme 1 (ACE1), plasminogen (PLG), kininogen-1 (KNG1), or unknown (UNK) (HAE-FXII, HAE-ANGPTI, HAE-PLG, HAE-KNG1, HAE-UNK); HAE-1, hereditary angioedema due to C1-inhibitor deficiency; HAE-2, hereditary angioedema due to C1-inhibitor dysfunction.

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(A)

Audit Date: _____ **Head of the Center:** _____
Audited Center: _____
Auditor: _____ **Deputy Auditor:** _____
Last audit: _____

Introduction / Not up					
Requirement	Description	Subscribed	No/Yes	Yes	Yes
1. Provision of services	Center needs to be a hospital or affiliated with a hospital with a specific service for the condition and a specific service for the condition.	Existence of a specific service or affiliation with a hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Information about the service	Center needs to have a specific service for the condition and a specific service for the condition. Information about the service should be available to patients and the general public.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Open to children and adults	Center needs to be able to provide care for children and adults.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Have multidisciplinary with specific angioedema team	Center needs to have a multidisciplinary team with specific angioedema team.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Multidisciplinary approach	Center needs to have a multidisciplinary approach to the management of patients.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Accessibility and visibility	Center needs to be accessible and visible to patients and the general public.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Communication skills	Center needs to have good communication skills.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Quality management	Center needs to have a quality management system.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Structure documentation	Center needs to have a structure documentation.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Clinical evidence regarding your management	Center needs to have clinical evidence regarding your management.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Assessment of current practice and needs	Center needs to have an assessment of current practice and needs.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Involvement	Center needs to have involvement.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Active participation of research funding and support for educational activities and education	Center needs to have active participation of research funding and support for educational activities and education.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(B)

Management					
Requirement	Description	Subscribed	No/Yes	Yes	Yes
14. Support of the ACARE network	Center needs to support the ACARE network.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Research and innovation	Center needs to have research and innovation.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Knowledge and use of evidence	Center needs to have knowledge and use of evidence.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Knowledge and use of differential diagnosis algorithm	Center needs to have knowledge and use of differential diagnosis algorithm.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Individualized assessment and monitoring of disease severity, impact and control of disease	Center needs to have individualized assessment and monitoring of disease severity, impact and control of disease.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Identification of comorbidities and addressing issues	Center needs to have identification of comorbidities and addressing issues.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Family concerns and caregiver therapy	Center needs to have family concerns and caregiver therapy.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Knowledge and use of therapeutic approaches	Center needs to have knowledge and use of therapeutic approaches.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Counseling	Center needs to have counseling.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Research					
Requirement	Description	Subscribed	No/Yes	Yes	Yes
23. Scientific excellence	Center needs to have scientific excellence.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Scientific activity	Center needs to have scientific activity.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Scientific productivity	Center needs to have scientific productivity.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Chronology	Center needs to have chronology.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Participation in projects	Center needs to have participation in projects.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Education					
Requirement	Description	Subscribed	No/Yes	Yes	Yes
28. Educational activities	Center needs to have educational activities.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Assessory					
Requirement	Description	Subscribed	No/Yes	Yes	Yes
29. Increase awareness of angioedema	Center needs to have increase awareness of angioedema.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Interaction with and support of patient organizations	Center needs to have interaction with and support of patient organizations.	Existence of a specific service or affiliation with a hospital. Existence of a specific service for the condition. Information about the service should be available to patients and the general public.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Audit result: All requirements fulfilled, no areas with a need for further improvement, center should be certified
 All requirements fulfilled, some areas require further improvement, center should be certified Area with a need for further improvement: _____
 Most requirements fulfilled, center should be certified after providing documentation that the following requirements are fulfilled _____
 no audit in _____ months _____

Comments: _____





The GALEN ACARE office hereby certifies that the Department and Center Name and/or Name of Head of Center, City/Country has been externally audited and fulfills the GALEN HAEi quality criteria as a GALEN HAEi Angioedema Center of Reference and Excellence (GALEN HAEi ACARE).

Date: 10/27/2019 Valid until: 10/27/2021




FIGURE 1 A and B, Audit checklist for GA²LEN/HAEi Angioedema Center of Reference and Excellence (ACARE) certification (A) and certificate awarded to GA²LEN/HAEi ACAREs upon a successful audit (B). A, The list shows and explains the requirements for becoming a G^{A2}LEN/HAEi ACARE and the deliverables that are reviewed during the audit process. B, The certificate is awarded for 2 y and requires successful re-audit to be extended

certified. It also provides (see Appendix S1) background information on GA²LEN and HAEi, including HAEi member organizations and regional patient advocates, on why we need an Angioedema Center of Reference and Excellence (ACARE) program and network, and on the accreditation and certification process, governance and funding, and on the interaction with other GA²LEN networks of centers of reference and excellence. The protocols, aims, requirements, and provisions related to becoming a certified ACARE are based on (a) the experience of the GA²LEN UCARE network and (b) input from angioedema patients, general practitioners, and angioedema specialists.

What are the aims of GA²LEN/HAEi ACAREs? The aims of ACAREs are to set the global standard for excellence in comprehensive angioedema care through research, education, advocacy, and interaction among ACAREs. By serving as referral centers for the diagnosis and management of patients with angioedema, ACAREs will complement the local healthcare system. ACAREs aim to increase knowledge and awareness of angioedema.

What are the requirements for GA²LEN/HAEi ACAREs? ACAREs are required to demonstrate excellence in the management of angioedema, research activities, efforts in education, and advocacy activity. ACAREs need to fulfill 32 requirements, which are explained in the audit checklist (Figure 1A). This checklist includes specific deliverables for each requirement. For example, the requirement to know and follow international guidelines and consensus documents for angioedema (Requirement #16) entails that physicians and other ACARE healthcare professionals have read and understood the current versions of these guidelines and consensus documents and that their recommendations are implemented in their center.

These guidelines and consensus documents include, for example, the international WAO/EAACI guideline for HAE, the EAACI/GA²LEN/EDF/WAO guideline for urticaria, the International/Canadian hereditary angioedema guideline,²⁻⁵ the international consensus on the diagnosis and management of pediatric patients with hereditary angioedema with C1 inhibitor deficiency, the international consensus on the use of genetics in the management of HAE,⁶ and the international consensus and practical guidelines on the gynecologic and obstetric management of female patients with hereditary angioedema caused by C1 inhibitor deficiency.⁷ The deliverables for this requirement are that (a) current guideline and consensus document versions are present (paper or electronic version) at the center, (b) ACARE staff can answer questions on the recommendations these documents provide, and (c) ACARE physicians can show, upon request, by use of a patient file, that patient

management decisions are based on guideline recommendations (Figure 1B).

This publication marks our intent to start the implementation of the GA²LEN/HAEi ACARE initiative. Specialty centers for angioedema have started to apply to become ACAREs, and audits and certifications are ongoing (Figure 1B). We expect that most GA²LEN UCARE centers and many angioedema specialty centers will become ACAREs in the near future. We predict and hope that by 2022, GA²LEN/HAEi ACAREs will be established in every continent. This will result in a strong global network of angioedema specialists, promote angioedema research, and harmonize and improve angioedema management worldwide. GA²LEN and HAEi will measure the impact of ACAREs over time and document and report the benefits of this initiative. ACARE network activities and a current list of ACAREs are posted on the network's website (www.acare-network.com).

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CONFLICT OF INTEREST











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Marcus Maurer¹ 
 Werner Aberer²
 Rosana Agondi³
 Mona Al-Ahmad⁴ 
 Maryam Ali Al-Nest⁵ 
 Ignacio Ansotegui⁶
 Rand Arnaout⁷
 Luisa Karla Arruda⁸ 
 Riccardo Asero⁹ 
 Emel Aygören-Pürsün¹⁰
 Aleena Banerji¹¹
 Andrea Bauer¹²
 Moshe Ben-Shoshan¹³
 Alejandro Berardi¹⁴
 Jonathan A. Bernstein¹⁵ 
 Stephen Betschel¹⁶
 Carsten Bindslev-Jensen¹⁷
 Mojca Bizjak¹⁸ 
 Isabelle Boccon-Gibod¹⁹
 Konrad Bork²⁰ 
 Laurence Bouillet¹⁹ 
 Henrik Balle Boysen²¹
 Nicholas Brodzski²²
 Sigurd Broesby-Olsen¹⁷ 
 Paula Busse²³

Thomas Buttgerit¹
 Anette Bygum²⁴ 
 Teresa Caballero²⁵
 Régis A. Campos^{26,27}
 Mauro Cancian²⁸
 Ivan Chérrez-Ojeda^{29,30} 
 Danny M. Cohn³¹
 Célia Costa³²
 Timothy Craig³³
 Paulo Ricardo Criado^{34,35,36}
 Roberta F. Criado³⁷
 Dorottya Csuka³⁸
 Joachim Dissemond³⁹
 Aurélie Du-Thanh⁴⁰
 Luis Felipe Ensina⁴¹
 Ragıp Ertaş⁴²
 José E. Fabiani⁴³
 Claudio Fantini⁴⁴
 Henriette Farkas³⁸ 
 Silvia Mariel Ferrucci⁴⁵
 Ignasi Figueras-Nart⁴⁶
 Natalia L. Fili⁴⁷ 
 Daria Fomina^{48,49}
 Atsushi Fukunaga⁵⁰ 
 Asli Gelincik⁵¹ 
 Ana Giménez-Arnau⁵² 
 Kiran Godse⁵³
 Mark Gompels⁵⁴
 Margarida Gonçalves⁵⁵
 Maia Gotua⁵⁶ 
 Richard Gower⁵⁷
 Anete S. Grumach⁵⁸
 Guillermo Guidos-Fogelbach⁵⁹
 Michihiro Hide⁶⁰
 Natalia Ilina⁶¹
 Naoko Inomata⁶²
 Thilo Jakob⁶³
 Dario O. Josviack⁶⁴
 Hye-Ryun Kang⁶⁵ 
 Allen Kaplan⁶⁶ 
 Alicja Kasperska-Zajac⁶⁷ 
 Constance Katelaris⁶⁸
 Aharon Kessel⁶⁹
 Andreas Kleinheinz⁷⁰
 Emek Kocatürk⁷¹
 Mitja Košnik¹⁸ 
 Dorota Krasowska⁷²
 Kanokvalai Kulthanan⁷³
 M. Sendhil Kumaran⁷⁴
 José Ignacio Larco Sousa⁷⁵
 Hilary J. Longhurst^{76,77,78}
 William Lumry⁷⁹
 Andrew MacGinnitie⁸⁰ 

- Markus Magerl¹
 Michael P. Makris⁸¹
 Alejandro Malbrán⁸²
 Alexander Marsland⁸³
 Inmaculada Martinez-Saguer⁸⁴
 Iris V. Medina⁸⁵
 Raisa Meshkova⁸⁶
 Martin Metz¹ 
 Iman Nasr⁸⁷ 
 Jan Nicolay⁸⁸
 Chikako Nishigori⁸⁹
 Isao Ohsawa⁹⁰
 Kemal Özyurt⁹¹
 Nikolaos G. Papadopoulos⁹² 
 Claudio A. S. Parisi⁹³
 Jonathan Grant Peter⁹⁴
 Wolfgang Pfützner⁹⁵ 
 Todor Popov⁹⁶
 Nieves Prior⁹⁷
 German D. Ramon⁹⁸
 Adam Reich⁹⁹
 Avner Reshef¹⁰⁰ 
 Marc A. Riedl¹⁰¹ 
 Bruce Ritchie¹⁰²
 Heike Röckmann-Helmbach¹⁰³
 Michael Rudenko¹⁰⁴
 Andaç Salman¹⁰⁵ 
 Mario Sanchez-Borges¹⁰⁶ 
 Peter Schmid-Grendelmeier¹⁰⁷ 
 Faradiba S. Serpa¹⁰⁸
 Esther Serra-Baldrich¹⁰⁹
 Farrukh R. Sheikh¹¹⁰
 William Smith¹¹¹
 Angèle Soria¹¹² 
 Petra Staubach¹¹³
 Urs C. Steiner¹¹⁴
 Marcin Stobiecki¹¹⁵
 Gordon Sussman¹¹⁶ 
 Anna Tagka¹¹⁷ 
 Simon Francis Thomsen¹¹⁸ 
 Regina Treudler¹¹⁹
 Solange Valle¹²⁰
 Martijn van Doorn¹²¹
 Lilian Varga³⁸ 
 Daniel O. Vázquez¹²² 
 Nicola Wagner¹²³
 Liangchun Wang¹²⁴ 
 Christina Weber-Chrysochoou¹⁰⁷
 Young-Min Ye¹²⁵ 
 Anna Zalewska-Janowska¹²⁶
 Andrea Zanichelli¹²⁷
 Zuotao Zhao^{128,129} 
 Yuxiang Zhi¹³⁰ 
- Torsten Zuberbier¹³¹ 
 Ricardo D. Zwiener¹³²
 Anthony Castaldo¹³³
- ¹Department of Dermatology and Allergy, Dermatological Allergology, Allergie-Centrum-Charité, Charité—Universitätsmedizin Berlin, Berlin, Germany
²Department of Dermatology, Medical University of Graz, Graz, Austria
³University of São Paulo, São Paulo, Brazil
⁴Microbiology Department, Faculty of Medicine, Kuwait University, Safat, Kuwait
⁵Allergy and Immunology Section, Department of Medicine, Hamad General Hospital, Doha, Qatar
⁶Department of Allergy and Immunology, Hospital Quiron Bizkaia, Bizkaia, Spain
⁷King Faisal Specialist Hospital & Research Center, Al Faisal University, Riyadh, Saudi Arabia
⁸Ribeirão Preto Medical School, University of São Paulo, São Paulo, Brazil
⁹Ambulatorio di Allergologia, Clinica San Carlo, Paderno Dugnano (MI), Italy
¹⁰Center for Children and Adolescents, University Hospital Frankfurt, Frankfurt, Germany
¹¹Division of Rheumatology, Allergy and Immunology, Massachusetts General Hospital, Boston, MA, USA
¹²Department of Dermatology, University Allergy Center, University Hospital Carl Gustav Carus, Technical University, Dresden, Germany
¹³Division of Allergy, Immunology and Dermatology, Department of Pediatrics, McGill University Health Center, Montreal, QC, Canada
¹⁴Instituto de Asma, Alergia y Enfermedades Respiratorias, Corrientes, Argentina
¹⁵Allergy Section, Division of Immunology, Department of Internal Medicine, Partner Bernstein Allergy Group, Partner Bernstein Clinical Research Center, University of Cincinnati, Cincinnati, OH, USA
¹⁶Division of Clinical Immunology and Allergy, St. Michael's Hospital, University of Toronto, Toronto, ON, Canada
¹⁷Department of Dermatology and Allergy Center, Odense University Hospital, Odense, Denmark
¹⁸Division of Allergy, University Clinic of Respiratory and Allergic Diseases Golnik, Golnik, Slovenia
¹⁹Clinical Immunology/Internal Medicine Department, National Reference Center for Angioedema, Grenoble University Hospital, Grenoble, France
²⁰Department of Dermatology, Johannes Gutenberg University Mainz, Mainz, Germany
²¹HAE International (HAEi), Horsens, Denmark
²²Skåne University Hospital, Lund University, Lund, Sweden
²³Division of Clinical Immunology, Icahn School at Mount Sinai,

- New York, NY, USA
- ²⁴HAE Centre, Odense University Hospital, Odense, Denmark
- ²⁵Allergy Department, Hospital Universitario La Paz, IdiPaz, CIBERER U754, Madrid, Spain
- ²⁶Universidade Federal da Bahia, Salvador, Brazil
- ²⁷Serviço de Imunologia, Hospital das Clínicas Professor Edgard Santos, Salvador, Brazil
- ²⁸Department of Systems Medicine, University Hospital of Padua, Padua, Italy
- ²⁹School of Medicine, Universidad de Especialidades Espíritu Santo, Samborondón, Ecuador
- ³⁰RespiraLab, Research, Guayaquil, Ecuador
- ³¹Department of Vascular Medicine, Amsterdam UMC, University of Amsterdam, Amsterdam, The Netherlands
- ³²Immunoallergology Department, Hospital de Santa Maria, Centro Hospitalar Universitário de Lisboa Norte (CHLN), EPE, Lisbon, Portugal
- ³³Department of Medicine and Pediatrics, Penn State University, Hershey, PA, USA
- ³⁴Faculdade de Medicina do ABC, Santo André, Brazil
- ³⁵Alergoskin Alergia e Dermatologia SS Ltda, Santo André, Brazil
- ³⁶UCARE Center, São Paulo, Brazil
- ³⁷Faculdade de Medicina do ABC (FMABC), Santo André, Brazil
- ³⁸3rd Department of Internal Medicine, Hungarian Angioedema Reference Center, Semmelweis University, Budapest, Hungary
- ³⁹Department of Dermatology, Venereology and Allergology, University of Essen, Essen, Germany
- ⁴⁰Service de Dermatologie-allergologie, CHU Montpellier, Montpellier Cedex 5, France
- ⁴¹Division of Allergy, Clinical Immunology and Rheumatology, Department of Pediatrics, Federal University of São Paulo, São Paulo, Brazil
- ⁴²Department of Dermatology, Kayseri City Education and Research Hospital, Kayseri, Turkey
- ⁴³Private Practice, Lomas de Zamora, Argentina
- ⁴⁴Servicio de Alergia e Inmunología—Hospital Alende y Clínica Colón, Mar del Plata, Argentina
- ⁴⁵Ambulatorio di Dermatologia Allergologica e Professionale, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milano (MI), Italy
- ⁴⁶The Dermatology Department of the Hospital de Bellvitge, Universitat de Barcelona, Barcelona, Spain
- ⁴⁷Unidad Alergia e Inmunología Clínica, Hospital Público Materno Infantil, Salta, Argentina
- ⁴⁸Center of Allergy and Immunology, City Clinical Hospital No. 52, Moscow Ministry of Healthcare, Moscow, Russian Federation
- ⁴⁹Department of Allergology and Clinical Immunology, I.M. Sechenov First Moscow State Medical University, Moscow, Russian Federation
- ⁵⁰Division of Dermatology, Graduate School of Medicine, Kobe University, Kobe, Japan
- ⁵¹Division of Immunology and Allergic Diseases, Department of Internal Medicine, Istanbul Faculty of Medicine, Istanbul University, Istanbul, Turkey
- ⁵²Department of Dermatology, Hospital del Mar, IMIM, Universitat Autònoma, Barcelona, Spain
- ⁵³Department of Dermatology, D Y. Patil University School of Medicine, Mumbai, India
- ⁵⁴Department of Immunology, North Bristol NHS Trust, Southmead Hospital, Bristol, UK
- ⁵⁵Clinica de Dermatologia, Centro Hospitalar Universitário Coimbra, Coimbra, Portugal
- ⁵⁶Center of Allergy and Immunology, Tbilisi, Georgia
- ⁵⁷Marycliff Clinical Research, Spokane, WA, USA
- ⁵⁸Clinical Immunology, Medical School, University Center Health ABC, Santo Andre, Brazil
- ⁵⁹National School of Medicine, Instituto Politécnico Nacional, Mexico City, Mexico
- ⁶⁰Department of Dermatology, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan
- ⁶¹NRC Institute of Immunology FMBA, Moscow, Russia
- ⁶²Department of Environmental Immuno-Dermatology, Yokohama City University Graduate School of Medicine, Yokohama, Japan
- ⁶³Department of Dermatology and Allergy, University Medical Center Giessen (UKGM), Justus-Liebig-University Giessen, Giessen, Germany
- ⁶⁴Instituto de Medicina Respiratoria—Rafaela, Santa Fe, Argentina
- ⁶⁵Institute of Allergy and Clinical Immunology, Seoul National University Medical Research Center, Seoul, Korea
- ⁶⁶Medical University of South Carolina, Charleston, SC, USA
- ⁶⁷European Center for Diagnosis and Treatment of Urticaria, Zabrze, Poland
- ⁶⁸Immunology & Allergy Unit, Department of Medicine, Campbelltown Hospital, Campbelltown, NSW, Australia
- ⁶⁹Division of Allergy & Clinical Immunology, Rappaport Faculty of Medicine, Bnai Zion Medical Center, Technion, Haifa, Israel
- ⁷⁰Clinic for Dermatology, Elbe Kliniken Buxtehude, Buxtehude, Germany
- ⁷¹Department of Dermatology, School of Medicine, Koç University, Koc, Turkey
- ⁷²Department of Dermatology, Venerology and Pediatric Dermatology, Medical University of Lublin, Lublin, Poland
- ⁷³Department of Dermatology, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand
- ⁷⁴Department of Dermatology, Postgraduate Institute of Medical Education and Research, Chandigarh, India
- ⁷⁵Clinica San Felipe, Lima, Peru
- ⁷⁶Department of Immunology, Addenbrookes Hospital Cambridge University NHS Foundation Trust, Cambridge, UK
- ⁷⁷UCLH, London, UK
- ⁷⁸Addenbrooke's Hospital Cambridge and University College Hospital, London, UK
- ⁷⁹Allergy/Immunology Division, Department of Internal Medicine, University of Texas Southwestern Medical School,

Dallas, TX, USA

- ⁸⁰Division of Immunology, Department of Pediatrics, Boston Children's Hospital, Harvard Medical School, Boston, MA, USA
- ⁸¹Allergy Unit "D. Kalogeromitros", 2nd Department of Dermatology and Venereology, University Hospital "Attikon", National and Kapodistrian University of Athens, Athens, Greece
- ⁸²Unidad de Alergia, Asma e Inmunología Clínica, Buenos Aires, Argentina
- ⁸³Department of Dermatology, The Urticaria Clinic, Salford Royal Foundation Trust, University of Manchester, Manchester, UK
- ⁸⁴Hemophilia Centre Rhine Main (HZRM), Moerfelden-Walldorf, Germany
- ⁸⁵Allergy and Clinical Immunology Department, Centro Médico Vitae, de Julio, Argentina
- ⁸⁶Department of Clinical Immunology and Allergology, Smolensk State Medical University, Smolensk, Russian Federation
- ⁸⁷Adult Immunology and Allergy Unit, Department of Medicine, Royal Hospital, Muscat, Oman
- ⁸⁸Klinik für Dermatologie, Universitätsklinikum Mannheim, Mannheim, Germany
- ⁸⁹Division of Dermatology, Kobe University Graduate School of Medicine, Kobe, Japan
- ⁹⁰Department of Internal Medicine, Saiyu Soka Hospital, Soka, Japan
- ⁹¹Department of Dermatology, Faculty of Medicine, Kırşehir Ahi Evran University, Kırşehir, Turkey
- ⁹²Allergy Unit, 2nd Pediatric Clinic, National and Kapodistrian University of Athens, Athens, Greece
- ⁹³Adults and Pediatrics Allergy Unit, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina
- ⁹⁴Department of Medicine, University of Cape Town, Cape Town, South Africa
- ⁹⁵Department of Dermatology and Allergology, Allergy Center Hessen, University Clinic Marburg, Marburg, Germany
- ⁹⁶University Hospital Sv. Ivan Rilski, Sofia, Bulgaria
- ⁹⁷Allergy Department, Hospital Universitario Severo Ochoa, Madrid, Spain
- ⁹⁸Instituto de Alergia e Inmunología del Sur, Buenos Aires, Argentina
- ⁹⁹Department of Dermatology, University of Rzeszow, Rzeszów, Poland
- ¹⁰⁰Angioedema Center, Barzilai Medical Center, Ashkelon, Israel
- ¹⁰¹Department of Medicine, University of California—San Diego, La Jolla, CA, USA
- ¹⁰²Departments of Medicine and Medical Oncology, University of Alberta, Edmonton, AB, Canada
- ¹⁰³Department of Dermatology and Allergology, University Medical Center Utrecht, Utrecht, The Netherlands
- ¹⁰⁴London Allergy and Immunology Centre, London, UK
- ¹⁰⁵Dermatology Department, Marmara University School of Medicine, Pendik Research and Training Hospital, Istanbul, Turkey
- ¹⁰⁶Allergy and Clinical Immunology Department, Centro Medico Docente La Trinidad, Caracas, Venezuela
- ¹⁰⁷Allergy Unit, Department of Dermatology, University Hospital of Zürich, Zürich, Switzerland
- ¹⁰⁸Hospital Santa Casa de Misericórdia de Vitória, Espírito Santo, Brazil
- ¹⁰⁹Dermatology Department, Hospital Sant Pau, Barcelona, Spain
- ¹¹⁰Department of Medicine, King Faisal Specialist Hospital & Research Center, Riyadh, Saudi Arabia
- ¹¹¹Clinical Immunology and Allergy, Royal Adelaide Hospital, Adelaide, SA, Australia
- ¹¹²Service de Dermatologie et Allergologie, Hopital Tenon, APHP, Sorbonne Université, Paris, France
- ¹¹³Department of Dermatology, University Medical Center, Mainz, Germany
- ¹¹⁴Department of Clinical Immunology, University Hospital Zurich, Zurich, Switzerland
- ¹¹⁵Department of Environmental Allergology, Jagiellonian University Medical College Kraków, HAE Center, University Hospital, Kraków, Poland
- ¹¹⁶Division of Allergy and Immunology, University of Toronto, Toronto, ON, Canada
- ¹¹⁷First Department of Dermatology and Venereology, National and Kapodistrian University of Athens, "A. Syggros" Hospital, Referral Center of Occupational Dermatological Diseases, Athens, Greece
- ¹¹⁸Department of Dermatology, Bispebjerg Hospital, Copenhagen, Denmark
- ¹¹⁹Department of Dermatology, Venereology and Allergology and Leipzig Interdisciplinary Center of Allergology—Comprehensive Allergy Center, UMC Leipzig, Leipzig, Germany
- ¹²⁰Federal University of Rio de Janeiro, Rio de Janeiro, Brazil
- ¹²¹Department of Dermatology, Erasmus MC, Rotterdam, The Netherlands
- ¹²²Clínica Privada Monte Grande, Buenos Aires, Argentina
- ¹²³Department of Dermatology, University of Erlangen, Erlangen, Germany
- ¹²⁴Dermatology Department of Sun Yat-sen Memorial Hospital, Guangzhou, China
- ¹²⁵Department of Allergy and Clinical Immunology, Ajou University School of Medicine, Suwon, Korea
- ¹²⁶Chair of Clinical Immunology and Rheumatology, Department of Psychodermatology, Medical University of Lodz, Lodz, Poland
- ¹²⁷Department of Biomedical and Clinical Sciences, Luigi Sacco Hospital, University of Milan, Milan, Italy
- ¹²⁸Department of Dermatology and Venereology, First Hospital, Peking University, Beijing, China
- ¹²⁹Beijing Key Laboratory of Molecular Diagnosis on Dermatoses, Beijing, China
- ¹³⁰Department of Allergy, Peking Union Medical College

Hospital &, Chinese Academy of Medical Sciences, Beijing, China

¹³¹Department of Dermatology and Allergy, Allergie-Centrum-Charité, Charité—Universitätsmedizin Berlin, Berlin, Germany

¹³²Servicio de Alergia e Inmunología, Hospital Universitario Austral, Buenos Aires, Argentina

¹³³HAE International (HAEi), Fairfax City, VA, USA

Correspondence

Marcus Maurer, Department of Dermatology and Allergy, Allergie-Centrum-Charité, Dermatological Allergology, Charité—Universitätsmedizin Berlin, Charitéplatz 1, D-10117 Berlin, Germany.

Email: marcus.maurer@charite.de

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ORCID

Marcus Maurer  <https://orcid.org/0000-0002-4121-481X>
 Mona Al-Ahmad  <https://orcid.org/0000-0003-3720-7032>
 Maryam Ali Al-Nesf  <https://orcid.org/0000-0001-9354-0214>
 Luisa Karla Arruda  <https://orcid.org/0000-0002-7505-210X>
 Riccardo Asero  <https://orcid.org/0000-0002-8277-1700>
 Jonathan A. Bernstein  <https://orcid.org/0000-0002-3476-1196>
 Mojca Bizjak  <https://orcid.org/0000-0003-2595-468X>
 Konrad Bork  <https://orcid.org/0000-0002-6084-4577>
 Laurence Bouillet  <https://orcid.org/0000-0001-8245-4767>
 Sigurd Broesby-Olsen  <https://orcid.org/0000-0002-1558-8471>
 Anette Bygum  <https://orcid.org/0000-0002-3004-0180>
 Ivan Cherez-Ojeda  <https://orcid.org/0000-0002-1610-239X>
 Henriette Farkas  <https://orcid.org/0000-0003-2929-1721>
 Natalia L. Fili  <https://orcid.org/0000-0003-0327-3963>
 Atsushi Fukunaga  <https://orcid.org/0000-0003-2026-8154>
 Asli Gelincik  <https://orcid.org/0000-0002-3524-9952>
 Ana Giménez-Arnau  <https://orcid.org/0000-0001-9548-5423>
 Maia Gotua  <https://orcid.org/0000-0003-2497-4128>
 Hye-Ryun Kang  <https://orcid.org/0000-0002-2317-4201>
 Allen Kaplan  <https://orcid.org/0000-0002-6566-4743>
 Alicja Kasperska-Zajac  <https://orcid.org/0000-0002-2000-0070>
 Mitja Košnik  <https://orcid.org/0000-0002-4701-7374>
 Andrew MacGinnitie  <https://orcid.org/0000-0002-9451-3733>
 Martin Metz  <https://orcid.org/0000-0002-4070-9976>
 Iman Nasr  <https://orcid.org/0000-0003-0346-9675>
 Nikolaos G. Papadopoulos  <https://orcid.org/0000-0002-4448-3468>

Wolfgang Pfützner  <https://orcid.org/0000-0002-8721-724X>
 Avner Reshef  <https://orcid.org/0000-0002-3324-7072>
 Marc A. Riedl  <https://orcid.org/0000-0003-3460-1544>
 Andaç Salman  <https://orcid.org/0000-0002-6407-926X>
 Mario Sanchez-Borges  <https://orcid.org/0000-0002-9308-6418>
 Peter Schmid-Grendelmeier  <https://orcid.org/0000-0003-3215-3370>
 Angèle Soria  <https://orcid.org/0000-0002-8726-6658>
 Gordon Sussman  <https://orcid.org/0000-0002-2202-2513>
 Anna Tagka  <https://orcid.org/0000-0003-3307-6522>
 Simon Francis Thomsen  <https://orcid.org/0000-0002-4838-300X>
 Lilian Varga  <https://orcid.org/0000-0002-5484-364X>
 Daniel O. Vázquez  <https://orcid.org/0000-0001-9864-0783>
 Liangchun Wang  <https://orcid.org/0000-0002-5169-2751>
 Young-Min Ye  <https://orcid.org/0000-0002-7517-1715>
 Zuotao Zhao  <https://orcid.org/0000-0002-9595-6050>
 Yuxiang Zhi  <https://orcid.org/0000-0001-7539-6650>
 Torsten Zuberbier  <https://orcid.org/0000-0002-1466-8875>

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.