1

Since this is a very extensive Appendix, the format and content has not been edited by ActaDV.

Appendix S1

This appendix has been provided by the authors to give readers additional information about their work.

METHODS

In order to establish treatment targets for AD, we conducted a consensus-building study among dermatologists with significant clinical and research expertise in AD, nurses and patient representatives through the Delphi method. In a pre-Delphi exercise, based on a systematic literature review the available evidence for key questions relating to disease assessment, patient characteristics, and treatment pathways in moderate-to-severe AD in adults was reviewed, discussed and summarised by key opinion leaders from Europe, Canada, and Australia.

Thereafter, based on a systematic assessment of their publication record, expertise in treating AD, participation in clinical trials on AD, and/or participation in comparable consensus activities such as HOME (13), and TREAT (S1) or AD guideline development, experts from across Europe (MdB-W, TB, MD, JH, GG, AP, M-A R, J-F S, SW), Canada (RB, C-HH), Australia (PF, SS) and Japan (NK) were selected for a Steering Committee. All members of the Steering Committee declared potential conflicts of interest. Via two live meetings and one teleconference the Steering Committee; (1) developed a core set of candidate-Delphi statements that could inform a treat-to-target approach to be examined in an eDelphi; (2) appointed an independent methodology expert to guide the eDelphi process (C.A); (3) established the principles of consensus rating and criteria used to determine agreement; and (4) agreed on criteria for the composition of an international extended panel for the eDelphi process. An overview of our approach is shown below in Fig. S1

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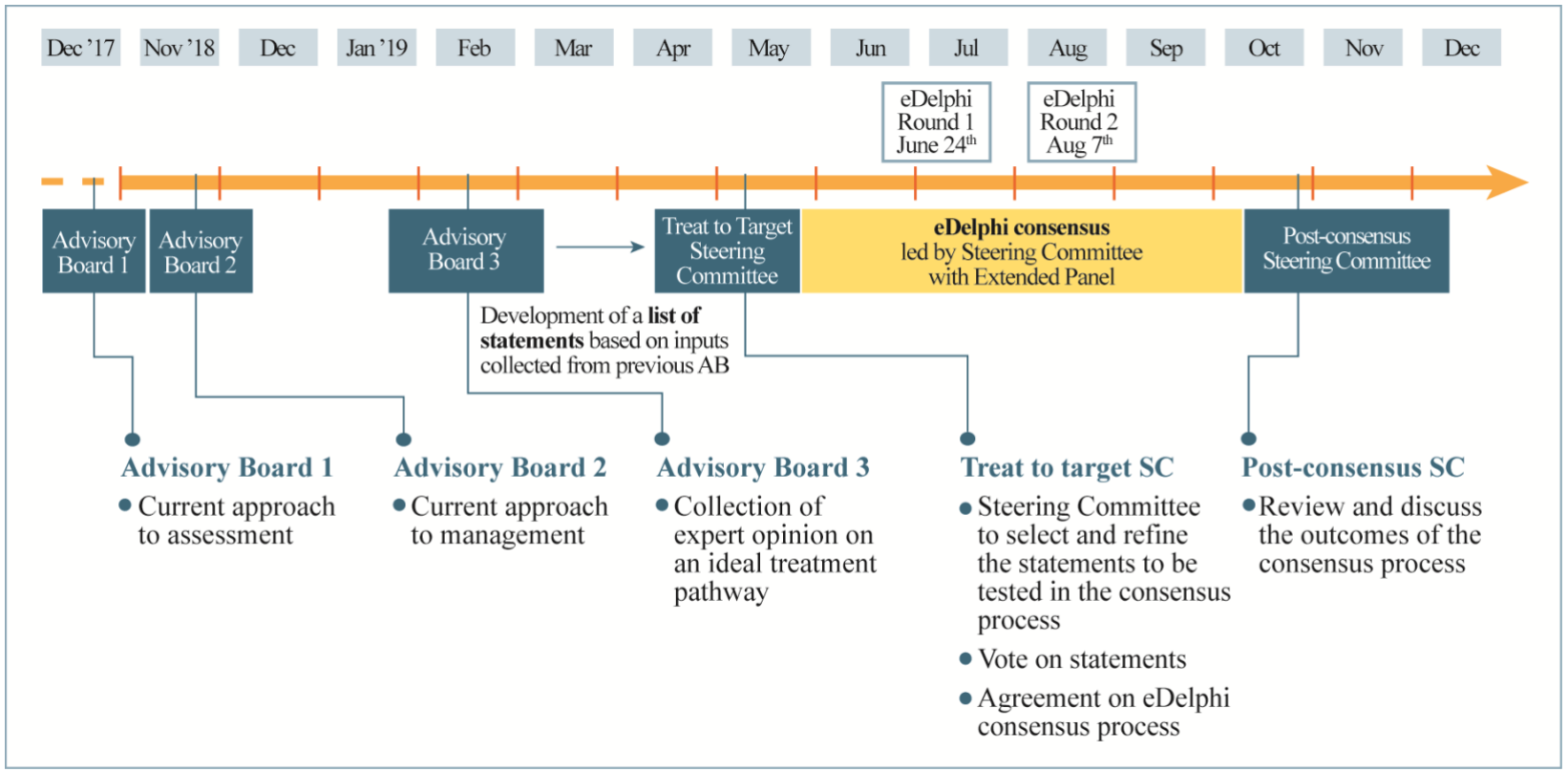
Figure S1. Treat-to-Target consensus process and timeline



2

3

eDelphi survey questionnaire development

Questionnaire development was informed by outputs from previous pre-Delphi meetings. A list of statements was drafted by the Steering Committee, falling within three broad areas pertinent to a treat-to-target approach: Guiding Principles, Decision Making, and Outcome Thresholds.

The document proposed a multidimensional assessment approach, including a range of physician-reported and patient-reported outcome measures to provide flexibility and ensure clinical utility. This approach reflects the fact that no single outcome assessment tool can capture the entire benefit of a treatment (S2), along with the awareness that both physician assessments of clinical signs and patient-oriented assessments are important (S2, S3), with the caveat that outcome assessment be made using validated instruments. The recommended instruments were agreed and ratified by vote at a Steering Committee meeting. The Patient self-reported Global Assessment of disease severity (PtGA), rated on a 5-point scale (clear, mild, moderate, severe, or very severe, [0-4]) was chosen as a principal instrument for a more holistic assessment of disease severity, beyond and independently from objective measures of specific disease domains. The Eczema Area and Severity Index (EASI) was selected for assessment of clinical signs by physicians. The SCORing Atopic Dermatitis (SCORAD) instrument, which provides a combined assessment of clinical signs and symptoms, was also included (S4).The Dermatology Life Quality Index (DLQI) was included for QoL assessment. The Patient-Oriented Eczema Measure (POEM) was also chosen for symptom assessment, in line with the Harmonising Outcome Measures for Eczema (HOME) initiative (S5, S6). The Peak Pruritus Numerical Rating Scale (NRS) was chosen for assessment of itch; the Steering Committee considered carefully whether average or peak outcomes would provide the best measure for itch. Although average intensity may be more in line with everyday clinical practice, and more likely to capture the overall impact of treatment on a patient's life, it was recognised that this approach has not been validated; in contrast, Peak Pruritis NRS has been validated (S7), and has been used in a number of recent clinical trials in AD (S8). For each instrument, a threshold was proposed for two assessment time-points; the initial threshold to be attained at 3 months, and the second to be attained at 6 months. These 3- and 6-month time-frames were proposed on the basis that they represent an appropriate treatment period for assessing therapeutic response, and align with typical consultation schedule patterns.

All statements in the draft document were reviewed, revised, and ratified for inclusion in the eDelphi survey questionnaire at a full meeting of the Steering Committee.

4

eDelphi participants and recruitment

Panel participants were selected to provide representation of key stakeholder groups in accordance with established principles (S9). Three broad categories were identified; physicians, specialist nurses with experience in the management of patients with moderate-to-severe AD, and patients/patient association representatives. Candidate physicians (comprising dermatologists, allergists, immunologists, and pediatric dermatologists) were identified on the basis of recommendations by Steering Committee members, and had to fulfil at least one of the following criteria: extensive clinical experience as the primary treating physician in the management of moderate-to severe AD requiring systemic therapy; a strong publication profile and/or involvement in guideline and recommendation task forces; past or current involvement in clinical studies in AD. This is in keeping with criteria used in similar consensus exercises in AD (S10–S13), and also in other disease areas where treatment goals/treat-to-target consensus has been developed, such as psoriasis, rheumatoid arthritis, and juvenile idiopathic arthritis (S14–S18).

In line with one of this project's overarching aims (the development of treatment goals applicable to a broad, global audience of physicians, other HCPs and patients) and in keeping with other similar initiatives, panellists were recruited from a wide range of countries and geographical locations (S11, S12, S16-S18). Patient representatives were recruited from recognised support groups (with the caveat that, ideally, they would have a working understanding of the principles and terminology employed in the eDelphi process, including the instruments used to evaluate treatment objectives and outcomes).

Eligible candidates were invited directly by the Steering Committee by email, explaining the project's aim and methodology and requesting their agreement to participate. Final selection was influenced by the need to achieve a balanced and pragmatic geographical spread. In addition, in part due to recruitment limitations in selecting appropriate nurses and patient representatives, but also with the aim of generating a core dataset that would have the greatest value and acceptance by and for dermatologists, it was agreed that the majority of panellists would be physicians. Following agreement to participate, to avoid any potential influence on subsequent participant responses in the eDelphi, no other communication or educational activities with panel participants occurred prior to formal participation in the eDelphi process.

The final extended panel comprised 87 participants; the 14 members of the Steering Committee (all physicians), 60 additional physicians, 3 nurses, and 10 patient representatives. The panel included members from 28 different countries, representing most of mainland Europe, Australia, Japan, and Canada (see Table S1 below).

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eDelphi process and definition of consensus

The eDelphi questionnaire consisted of core statements accompanied by supporting information; all panel participants received identical questionnaires. Participants were asked to rate each of the statements using a 9-point Likert scale ranging from 1= 'strongly disagree' to 9 = 'strongly agree'. For each statement, participants could add a comment explaining their vote (addition of comments was mandatory for statements rated <5). Consensus on any given statement required 75% or more of all participants to rate their level of agreement as 7, 8, or 9 (a "consensus in" approach). Applying this rule across all participants rather than to each individual stakeholder groups reduced the risk that a lower level of agreement in the smaller stakeholder group could exert undue influence on the overall result.

For round 1 of the eDelphi, the statements were rated by participants, and results and feedback gathered for analysis. Those statements which met the criteria were considered to be agreed and were not available for voting in subsequent eDelphi rounds. Those statements that failed to reach agreement were reviewed and revised by Steering Committee members, after considering the voting scores and comments, and then submitted for a new eDelphi voting round (see Table S2 below). In each subsequent voting round, participants were able to view the voting results and anonymised comments for the previous eDelphi round. Participant consent was on the basis of initial agreement to participate, and subsequent registration and completion of the initial or subsequent eDelphi rounds. Consent to list participants in the acknowledgments section of this publication was confirmed during manuscript development. In line with similar externally supported consensus projects, the project sponsor was not present during the Steering Committee discussions on statement development, and had no involvement in the conduct of the eDelphi and subsequent consensus process.

Questionnaire distribution, data entry and collection of respondent ratings and feedback, was performed on a dedicated, password-protected, online platform (www.t2tconsensus.com). This platform was independently managed by a medical communications agency (IntraMed, Milan, Italy). All participant responses were anonymised (using unique respondent identification numbers), although their stakeholder category was recorded; participant anonymity was maintained throughout the eDelphi process and subsequent discussions.

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Table S1. eDelphi panel participants

Country	Physicians (n=74)		Nurses (n=3)	Patients/patient associations (n=10)
	Steering Committee (n=14)	Invited (n=60)		
Australia	2	3	1	1
Austria		1		
Belgium		2		
Bulgaria		1		
Canada	2	3		1
Czech Republic	1	1		
Denmark	1	4		
Estonia		1		
Finland		2		
France	1	2		
Germany	2	6		1
Greece		1		
Hungary		1		
Ireland		2		
Israel		2		
Italy	1	4		1
Japan	1	4		1
Lithuania		1		
Netherlands	1	3	1	2
Norway		1		
Poland		3		
Portugal		1		1
Romania		1		
Slovakia		2		
Spain	1	4		1
Sweden		1		
Switzerland		1		
UK	1	2	1	1

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Table S2. Revisions made prior to eDelphi round 2

	eDelphi round 1		eDelphi round 2		
Item	**Original statement**	**Agreement (%)***	**Revised statement†**	**Explanatory notes**	**Agreement (%)***
Decision framework					
6	There should be an acceptable/minimal target, to be reached by 3 months	70.2%	There should be an ***initial acceptable*** target, to be reached by 3 months ***at the latest***	Only systemic therapies are considered.	86.5%
8	If target outcomes are achieved for at least one specific disease domain (signs, symptoms, quality of life), and for patient global, treatment should be continued	57.8%	If target outcomes are achieved *for patient global plus* at least one specific disease domain (signs, symptoms, quality of life), ***treatment continuation should be considered***	Only systemic therapies are considered. Other therapies such as topical corticosteroids are at the discretion of the prescribing physician. The criteria require that at least two treatment goals are met: patient global, plus one of the three disease domains. Targets that include at least two, or all three, of the disease domains may also be imposed at the discretion of the treating physician. The requirement for a satisfactory Patient Global response aims to ensure that the assessment is clinically relevant. "Patient Global" is an umbrella term indicating any assessment that captures global patient well-being and satisfaction, for example the Patient Global Assessment (PtGA).	75.0%

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				Treatment continuation is always contingent on acceptable safety/tolerability (see Statement 5).	
Outcome thresholds					
11a	For EASI, the treatment target at 3 months is EASI 50	64.9%	For EASI, the ***initial acceptable*** treatment target is ***at least*** EASI 50	The initial acceptable treatment target is to be reached by 3 months at the latest (see Statement 6) EASI 50 indicates that the visible skin signs of atopic dermatitis have reduced by 50%, since initiation of the systemic treatment. This target considers only signs. It forms only part of the overall treatment target, which incorporates signs, symptoms, quality of life, and patient global (see Statement 6).	80.8%
12a	For SCORAD, the treatment target at 3 months is SCORAD 50	63.1%	For SCORAD, ***the initial acceptable*** treatment target is ***at least*** SCORAD 50	The initial acceptable treatment target is to be reached by 3 months at the latest (see Statement 6). SCORAD provides a combined assessment of skin signs, itch, and sleep disturbance. SCORAD 50 indicates that this score has reduced by 50%, since initiation of the systemic treatment.	82.7%
12b	For SCORAD, the treatment target at 6 months is SCORAD 75 or SCORAD ≤24	70.2%	For SCORAD, the ***optimal*** treatment target at 6 months is SCORAD 75 or SCORAD ≤24	SCORAD provides a combined assessment of skin signs, itch, and sleep disturbance. SCORAD 75 indicates that this score has reduced by 75%, since initiation of the systemic treatment. SCORAD ≤24 indicates mild atopic dermatitis.	90.4%

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13a	For Peak Pruritus NRS (0–10), the treatment target at 3 months is a reduction of 3 points	71.9%	For Peak Pruritus NRS (0–10), the ***initial*** acceptable treatment target is a reduction of **at least** 3 points	The initial acceptable treatment target is to be reached by 3 months at the latest (see Statement 6) A 3-point reduction in peak pruritus NRS is the minimal clinically important difference (MCID), and would likely be perceived as an improvement by a patient. This target is just one part of the overall treatment target, which incorporates signs, symptoms, quality of life, and patient global (see Statement 8). The requirement for a satisfactory Patient Global response aims to ensure that the overall assessment is clinically relevant, and should capture cases where initially high itch scores are reduced by no more than three points.	78.8%
14a	For DLQI, the treatment target at 3 months is a reduction of 4 points	68.4%	For DLQI, the ***initial acceptable*** treatment target is a reduction of ***at least*** 4 points	The initial acceptable treatment target is to be reached by 3 months at the latest (see Statement 6) The Dermatology Life Quality index (DLQI) is a patient administered questionnaire that measures the impact of skin disease on quality of life. A 4-point reduction in DLQI is the minimal clinically important difference (MCID), and would likely be perceived as an improvement by a patient.	82.7%

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				This target is just one part of the overall treatment target, which incorporates signs, symptoms, quality of life, and patient global (see Statement 8). The requirement for a satisfactory Patient Global response aims to ensure that the overall assessment is clinically relevant.	
14b	For DLQI, the treatment target at 6 months is an absolute score ≤5	70.2%	For DLQI, the ***optimal*** treatment target at 6 months is an absolute score ≤5	The Dermatology Life Quality index (DLQI) is a patient administered questionnaire that measures the impact of skin disease on quality of life. A DLQI score ≤5 indicates "small effect or no effect on the patient's life". This target is just one part of the overall treatment target, which incorporates signs, symptoms, quality of life, and patient global (see Statement 8). The requirement for a satisfactory Patient Global response aims to ensure that the overall assessment is clinically relevant.	80.8%
15a	For PtGA (0–4), the treatment target at 3 months is a reduction of 1 point	70.2%	For PtGA (0–4), the ***initial acceptable*** treatment target is a reduction of ***at least*** 1 point	The initial acceptable treatment target is to be reached by 3 months at the latest (see Statement 6). A patient global assessment (PtGA) is a patient administered tool that records the impact of disease.	84.6%

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				The designation "0–4" indicates a 5-point scale, with 0 indicating no impact, and higher scores indicating increasing impact.	
16a	For POEM, the treatment target at 3 months is a reduction of 4 points	70.2%	For POEM, the ***initial acceptable*** treatment target is a reduction of **at least** 4 points	The initial acceptable treatment target is to be reached by 3 months at the latest (see Statement 6). POEM is a patient administered assessment that measures severity of atopic dermatitis. A 4-point reduction in POEM is the minimal clinically important difference (MCID), and would likely be perceived as an improvement by a patient.	88.5%
16b	For POEM, the treatment target at 6 months is an absolute score ≤7	71.9%	For POEM, the ***optimal*** treatment target at 6 months is an absolute score ≤7	POEM is a patient-administered assessment that measures severity of atopic dermatitis. A POEM score ≤7 indicates "mild disease (3–7)" or "clear/almost clear (0–2)"	88.5%

†Revisions highlighted in bold italics.

*Agreement % presented for rounds 1 and 2 represent percentage of overall participants who responded (which includes physicians, nurses and patients/patient association representatives).

DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; Peak Pruritus NRS, Peak Pruritis Numerical Rating Scale; POEM, Patient Oriented Eczema Measure; Pt GA, Patient Global Assessment; SCORAD, SCORing Atopic Dermatitis.

Table S3. Complete Listing of eDelphi participants

SURNAME, forename	Affiliation and country
AGNER, Tove	Department of Dermatology, Bispebjerg Hospital, Copenhagen, Denmark
AMERIO, Paolo	Department of Dermatology and Venereology, University G.d'Annunzio, Chieti-Pescara, Italy
ARENTS, Bernd	Past-president | Volunteer Medical Affairs & Health Care Dutch Association for People with Atopic Dermatitis (VMCE), The Netherlands
ARMARIO HITA, José Carlos	Department of Dermatology, Hospital Universitario de Puerto Real, University of Cádiz, Cádiz, Spain
BEWLEY, Anthony	Barts Health NHS Trust, London, UK
BIEBER, Thomas	Department of Dermatology and Allergy, University Hospital of Bonn, Bonn, Germany
BRADLEY, Maria	Department of Dermatology, Karolinska University Hospital, Stockholm, Sweden
BRUNNER, Patrick	Department of Dermatology, Medical University of Vienna, Vienna, Austria
BUCHVALD, Dušan	Dept. Paediatric Dermatovenereology, Comenius University; Faculty of Medicine, National Institute of Children's Diseases, Bratislava, Slovakia
BYLAITĖ-BUČINSKIENĖ, Matilda	Vilnius University, Faculty of Medicine, Centre of Dermatovenereology; Clinic of Infectious diseases and Dermatovenereology; Innovative dermatology Center, Vilnius, Lithuania
CAMILO, Joana	Founding President of ADERMAP - Associação Dermatite Atópica Portugal, Portugal
CHAN, Anthony	Canada
CHIRICOZZI, Andrea	Institute of Dermatology, Catholic University; Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy
COSTANZO, Antonio	Dermatology Unit, IRCCS Humanitas Clinical and Research Center, Rozzano (Milan), Italy
COTO-SEGURA, Pablo	Dermatology Division, Hospital Alvarez Buylla-Mieres, Mieres, Spain
DARLENSKI, Razvigor	Department of Dermatology and Venereology, Acibadem City Clinic Tokuda Hospital, Sofia, Bulgaria; Department of Dermatology and Venereology, Trakia University, Stara Zagora, Bulgaria
DE GROOT, Jette	National Expertise Center for Eczema, UMC Utrecht, Utrecht, The Netherlands
FURUE, Masutaka	Department of Dermatology, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan
GÁSPÁR, Krisztián	Department of Dermatology, Faculty of Medicine, University of Debrecen, Debrecen, Hungary
GOODERHAM, Melinda	SKiN Centre for Dermatology, Peterborough, Ontario, Canada
GUTERMUTH, Jan	Department of Dermatology, Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel, Brussels, Belgium
HARRISON-MULLAN, Charlotte	Skin & Cancer Foundation Inc., Carlton, Australia
HERRÁEZ, Lys	Hospital Universitario 12 de Octubre, Madrid, Spain

HODAK, Emmilia	Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel; Department of Dermatology, Rabin Medical Center, Petah Tikva, Israel
IKEGAMI, Yuko	Director and peer counselor of Allergy Tomono Kai - AltogetherEczema, Japan
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JACKSON, Carina	St. John's Institute of Dermatology, Guy's and St. Thomas's NHS Foundation Trust, London, UK
JAMES, Christopher	Australia
KATAOKA, Yoko	Department of Dermatology, Osaka Habikino Medical Center, Osaka, Japan
KATELARIS, Connie	Western Sydney University & Campbelltown Hospital, Sydney, Australia
KLINGO, Külli	Department of Dermatology and Venerology, University of Tartu; Estonia Clinic of Dermatology, Tartu University Hospital, Tartu, Estonia
KORHONEN, Laura	Department of Dermatology, Tampere University Hospital, Tampere, Finland
LAPEERE, Hilde	Department of Dermatology, Ghent University Hospital, Ghent, Belgium
LINSLEY, Simon	United Kingdom
LØVOLD BERENTS, Teresa	Department of Dermatology/Regional Centre for Asthma, Allergy and Hypersensitivity, Oslo University Hospital -Rikshospitalet, Oslo, Norway
MURPHY, Michelle	Department of Medicine, University College Cork, Cork, Ireland
NOSBAUM, Audrey	Department of Clinical Immunology and Allergy, Lyon-Sud University Hospital, Pierre-Benite Cx, France. CIRI – Centre International de Recherche en Infectiologie, Univ. Lyon, Université Claude Bernard Lyon 1, Inserm, CNRS, ENS Lyon, Lyon, France
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PICOZZA, Mario	President of ANDeA (Associazione Nazionale Dermatite Atopica), Italy
PLAZA, Mercedes	Spain
RAMOT, Yuval	Department of Dermatology, Hadassah Medical Center, Hebrew University of Jerusalem, The Faculty of Medicine, Jerusalem, Israel
RUBEL, Diana	Woden Dermatology, Phillip, ACT, Australia
RUDNICKA, Lidia	Department of Dermatology, Medical University of Warsaw, Poland

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SMITH, Saxon	Northern Clinical School, Sydney Medical School, University of Sydney, Sydney, Australia
STAUMONT-SALLE, Delphine	Service de Dermatologie, Hôpital Claude Huriez – CHRU, Lille, France
SZEPIETOWSKI, Jacek	Department of Dermatology, Venereology and Allergology Wroclaw Medical University, Wroclaw, Poland
TAMS, Michael	Germany
TORRES, Tiago	Department of Dermatology, Centro Hospitalar Universitário do Porto; Instituto de Ciências Biomédicas Abel Salazar, University of Porto; Instituto Médico de Estudos Imunológicos, Porto, Portugal
URBANCEK, Slavor	Department of Dermatology, Slovak Medical University, F. D. Roosevelt Hospital Banska Bystrica, Slovakia
VAKIRLIS, Efstratios	Department of Dermatology, Aristotle University of Thessaloniki, Greece
VAN DER VEEN, Dirk	Member of the VMCE board, The Netherlands
VESTERGAARD, Christian	Department of Dermatology, Aarhus University Hospital, Aarhus, Denmark
WERFEL, Thomas	Department of Dermatology, Allergology and Venereology, Hannover Medical School, Hannover, Germany
WOLLENBERG, Andreas	Department of Dermatology and Allergy, Ludwig-Maximilian University, Munich, Germany
WORM, Margitta	Division of Allergy and Immunology, Klinik für Dermatologie, Venerologie und Allergologie, Charité-Universitätsmedizin Berlin, Berlin, Germany

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