EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Regulatory Network workshop on Geographic Atrophy endpoints

29 April 2026, 11:30 – 19:00 (CEST)
Virtual meeting / EMA, Amsterdam

Geographic atrophy (GA) is a slowly progressing and seriously debilitating condition with a high prevalence and unmet medical need. GA has a major impact on patients/families from a health and quality of life perspective. To support a Centralised marketing authorisation for a medicinal product in GA, it is necessary to show a clinically relevant treatment benefit of the medicinal product to patients, like on visual function. Alternative primary endpoints to demonstrate efficacy of the medicinal product, e.g. based retinal imaging, must be able to robustly predict that there is a clinically relevant treatment benefit of the medicinal product to patients in a reasonable period following treatment.

Therefore, there is a need to discuss the state of the art on functional endpoints for GA and retinal imaging with stakeholders in order to facilitate medicinal product development for GA, and thus address the unmet need for many EU patients with GA. Relevant stakeholders include patients and carers, healthcare professionals, academics and industry concerned with the development of medicinal products for GA.

The aims of the workshop are:

- To communicate the principles/regulatory expectations for endpoints to support the risk benefit assessment of medicinal products, to identify gaps in research and to encourage further necessary work on endpoints to meet regulatory expectations.
- To allow public presentation of: the state of the art on candidate functional endpoints in GA, an overview of how structural changes and retinal function inter-relate, and the translatability of endpoints into patient benefit.
- To encourage wider discussion from stakeholders into identified discussion points.

European Medicines Regulatory Network (EMRN) workshop on Geographic Atrophy endpoints

11:00 Joining and technical checks

11:30 Welcome and opening speeches

Chair: Michael Berntgen (European Medicines Agency (EMA))

Welcome & ways of virtual working **5 min**

Opening statement from Chair of CHMP **5 min**
Bruno Sepodes (INFARMED, Portugal)

Opening statement from Patients Perspective **5 min**
Avril Daly (Retina International)

Opening statement from Industry perspective **5 min**
Fabio Baschiera (Industry)

Opening statement from Academic/health care professional Perspective **5 min**
Frank Holz (University Hospital Bonn)

Comments from floor 10-15 mins

12:10 Session 1: Potential primary visual functional endpoints for GA pivotal trials: microperimetry, reading speed

In this session; we will discuss;

- What are the most promising microperimetry outcomes (parameters)?
- What is the most promising reading speed parameters?
- The minimal clinically important differences (MCID) of these functional endpoints in the GA population.
- Establishing surrogacy of such endpoints for patient benefit.
- Additional aspects such as timing of primary analysis, impact of stage/location of disease.
- Gaps in knowledge.

Chairs:

Laila Eriksson (MPA, Sweden)

Elina Rantala (FIMEA, Finland)

Muzaffer Özalp (MPA, Sweden)

Primer on human macular neuroanatomy **5 min**
Christine Curcio (University of Alabama at Birmingham)

Presentation on microperimetry **20 min**
Maximilian Pfau (University Hospital Bonn)

Presentation on reading speed **10 min**
Maximilian Pfau (University Hospital Bonn)

Panel discussion **25 min**
Additional panellists:

Nabin Paudel (Retina International)
Anat Loewenstein (Tel Aviv Medical Center)
Karl Csaky (Retina Foundation)
Zhichao Wu (The University of Melbourne)
Andrew Want (Industry)

13:15 Coffee break

13:35 Session 2: Potential primary visual functional endpoints for GA pivotal trials (visual acuity-based, and contrast-based outcomes). Enrichment and Extrapolation

In this session; we will discuss

- The feasibility and importance of Visual acuity-based, contrast acuity-based outcomes in GA development programs.
- The minimal clinically important differences (MCID) for these outcomes in GA populations.
- The most appropriate time for assessment and impact of stage/location and progression pattern of disease on trial design.
- Enrichment with fast-progressors; feasibility of extrapolation of results in fast-progressors to the broad GA-population.
- Use of contrast sensitivity functions; potential specific parameters, and endpoint position.
- Relationship between endpoints, any potential for composite endpoints.

Chairs:

Agnieszka Przybyszewska (HPRA, Ireland)

Hemme Hijma (MEB, Netherlands)

Vision scientist presentations:

Presentation on best corrected visual acuity, low luminance visual acuity, low luminance deficit **20 min**
Rufino Silva (Coimbra University Hospital)

Presentation on Contrast sensitivity **10 min**
Karl Csaky (Retina Foundation)

Panel discussion **25 min**
Additional panellists:

Franz Badura (Retina International)
Robyn Guymer (Centre for Eye Research Australia)
Janet Sunness (Greater Baltimore Medical Center)
Nida Sen (Industry)
Stela Vujosevic (University of Milan, Eye Clinic IRCCS MultiMedica, Milan)
Leopold Schmetterer (Singapore Eye Research Institute and Medical University of Vienna)

14:35 Lunch

15:15 Re-start

Chair: Christian Gartner (AGES, Austria)

Welcome back

Session 3: Imaging endpoints, current methods, relationship with histology and retinal function

In this session: we will discuss

- Established and emerging imaging endpoints, timing of assessment.
- When can imaging endpoints be useful in GA drug development?
- What are the gaps currently in the validation status for imaging endpoints for use as a surrogate for primary endpoint?
- How to progress validation of retinal imaging endpoints as a surrogate primary endpoint?
- How to establish clinical relevance of a difference in imaging? Potential use of prespecified subgroups.
- What combinations of anatomical and functional might be a relevant package for a pivotal clinical trial in GA?

Chairs:

Tanya Moutray (HPRA, Ireland)

Jane Moseley (EMA)

Brief outline of principles for validation of a surrogate endpoint options for qualification advice **10 min**
Elisabeth Wischnitzki (AGES, Austria)

Vision scientist presentations:

GA Imaging **20 min**
Ursula Schmidt-Erfurth (Medical University Vienna)

GA Histology / imaging overlays– overview and uncertainties **10 min**
Christine Curcio (University of Alabama at Birmingham)

Overview of structure function relationship **15 min**
Sobha Sivaprasad (Moorfields Eye Hospital NHS Trust, London)

Panel discussion **25 min**
Additional panellists:

Maria Vittoria Cicinelli (Vita-Salute San Raffaele University, Milan)
Avril Daly (Retina International)
Seema Garg (Industry)
Frank Holz (University Hospital Bonn)
Laura Sararols (OMIQ Institute, General University Hospital of Catalonia)
Jordi Monés (Barcelona Macula Foundation: Research for Vision- Macula Institute, Teknon Medical Center Barcelona)

16:40 Coffee break

17:00 Session 4: Patient reported outcomes (PRO), quality of life (QoL) measures, safety outcomes

In this session: we will discuss

- What issues are most significant to patients for benefits and risks of treatment.
- Which GA specific PRO has most experience/validation in GA?
- NEI VFQ-25; validity for use in GA?
- How can GA PRO data be best used to support GA drug development?
- Use of FRI index, alone or with reading speed be used to support the clinical relevance of a change in lesion progression?
- Reflection on measuring safety assessments/outcomes and treatment burden.

Chairs:

Jane Moseley (EMA)

Johanna Wernsperger (AGES, Austria)

Vision scientist presentations:

Presentation on PROs, QoL, Safety outcomes in GA **15 min**
Jan Terheyden (University Hospital Bonn)

Panel discussion **25 min**
Additional panellists:

Alba Perez (Federation of Associations of Hereditary Retinal Dystrophies (FARPE))
Francisco Lopez (Industry)
Robert Finger (University Hospital Mannheim)
Nicole Eter (University Hospital Münster)
Emily Chew (National Eye Institute, Bethesda)

17:45 Session 5: Emerging functional vision endpoints/forward look

In this session: we will:

- Reflect/supplement the content presented in this session.
- Consider what key regulatory challenges exist for use of AI for image analysis in ophthalmologic clinical trials?

Chairs:

Hemme Hijma (MEB, Netherlands)

Tanya Moutray (HPRA, Ireland)

Vision scientist presentation **15 min**
Marion Munk (Gutblick Practice Group, Switzerland and Inselspital, University Hospital Bern)

Panel discussion **15 min**
Additional panellists:

Inga Britt (The Norwegian Association of the Blind and Partially Sighted)
Silvia Specker (Industry)
Thomas Aleman (Scheie Eye Institute, University of Pennsylvania)
Adnan Tufail (Moorfields Eye Hospital NHS Trust, London)
Ursula Schmidt-Erfurth (Medical University Vienna)
Giuseppe Querques (University of Modena and Reggio Emilia UNIMORE)

18:15 Closing remarks

Wrap up **10 min**
Christian Gartner (AGES, Austria)

About the speakers

0 - Welcome and opening

Michael Berntgen

Chair – European Medicines Agency

Michael Berntgen is Head of the Scientific Evidence Generation Department at the European Medicines Agency (EMA), Amsterdam. This department aims to support the development of medicines to ensure generation of robust and relevant scientific evidence, also in collaboration with other stakeholders (e.g. patients, HTAs). Activities include the provision of scientific advice and methodology qualification, support to medicines for the paediatric population and for orphan diseases, as well as provision of expertise and support in translational sciences. Furthermore, the department manages the PRIME scheme and facilitates collaboration with downstream decision-makers (HTA bodies and payers), to foster timely access to medicines.

Michael is a pharmacist by training and holds a PhD as well as a Master of Regulatory Affairs. From 1999 to 2006, Michael worked in various positions in regulatory affairs in the pharmaceutical industry in Germany and in the UK. In 2006 he joined the German national competent authority BfArM as Scientific Administrator in the Scientific Advice unit. Following this assignment, he moved to the European Medicines Agency in 2007 where he initially took up a position as Scientific Administrator in the Therapeutic Group "Anti-infectives" of the Safety and Efficacy sector, followed in September 2009 by the assignment as Head of Rheumatology, Respiratory, Gastroenterology and Immunology in this sector. From September 2013 he was heading the Scientific and Regulatory Management Department and from September 2016 the Product Development Scientific Support Department. In March 2020, he took over the current position as Head of the Scientific Evidence Generation Department.

Bruno Sepodes

Speaker - INFARMED

Full Professor of Pharmacological Sciences (Universidade de Lisboa, Portugal). Bruno joined the COMP in 2008 as a member nominated by the EC under EMA recommendation, and between 2012 and 2018 was the Chair of the COMP. After joining the CHMP in 2012, he became Vice-Chair of this Committee in 2018 and, in 2024, Bruno was elected Chair of the CHMP. In 2022, Bruno became Co-Chair of the ETF. Since 2019, Bruno is member of the ICH Assembly representing EC Europe.

Avril Daly

Panellist - *Retina International*

Avril Daly is CEO of Retina International since 2016, she was previously CEO of Fighting Blindness Ireland for eight years. Avril held roles in Public Affairs and Media Relations, representing patients living with retinal degenerations and rare diseases for 25 years. Her focus is patient centricity in decision making working on policies that impact health innovation from bench to bedside. She is the current volunteer president of EURORDIS (Rare Disease Europe) and is a Board member of Rare Disease Ireland. Avril holds a BBS and MA in Strategic Planning.

Summary Disclosure of conflicts of interest: Retina International recieves funding support for specific patient led programmes from patient organisations and industry including: Amgen, Boehringer Ingelhiem, F. Hoffman la Roche, Johson &Johnson, Outlook Pharmaceuticals

Fabio Baschieri

Speaker - Industry

Dr. Fabio Baschiera is the Head of Clinical Development for Eye Health at Boehringer Ingelheim and one of the Founders of the BRIDGE Study Group. In recent years, Dr Baschiera served as Global Clinical Leader for Ophthalmology at Bayer leading the development of new therapeutics for Diabetic Retinal Diseases, Inherited Retinal Diseases, and clinical submissions for Eylea 8mg. Additionally, Dr Baschiera led the development of emodepside, in River Blindness and other Neglected Diseases, a partnering effort with Swiss TPH, Drug for Neglected Disease Initiative (DNDi), and the Gates Foundation. Previously, Dr. Baschiera served as VP Clinical Development at Oculis SA and held portfolio leadership positions at Novartis Ophthalmology as well as Clinical Science positions in Cardiovascular. He joined the industry after his experience at the Division of Pharmacology and Chemotherapy, University Hospital in Pisa. Dr. Baschiera's obtained PharmD, then a magna cum laude license in Applied Pharmacology and a PhD in Medical Physiopathology and Pharmacology both at the Faculty of Medicine in Pisa, Pisa, Italy.

Summary Disclosure of conflicts of interest: Employee of Boehringer Ingelheim, Retained shares from: Novartis AG, Sandoz, Alcon, Bayer AG.

Frank Holz

Speaker - University Hospital Bonn

Frank G. Holz is Professor and Chairman of the Department of Ophthalmology at the University of Bonn, Germany. His main research interests include the pathogenesis, biomarkers and new therapies for macular and retinal diseases. He has a keen interest in innovative retinal imaging technologies and image analysis strategies. He was a scholar of the German National Academic Foundation (Studienstiftung des Deutschen Volkes), trained at the University of Heidelberg and the University of Chicago/Pritzker School of Medicine, and passed a clnical research fellowhip at Moorfields Eye Hospital, London, He founded the GRADE Reading Center Bonn and is coordinator of the MACUSTAR study on development of structural, functional and PRO endpoints in intermediate AMD. He is a Board Member of the German Ophthalmological Society (DOG), Member of the Academia Ophthalmologica Internationalis (AOI), the Macula Society, and Editor-in-Chief of Der Ophthalmologe. He has received numerous awards including the Pro Retina Macular Degeneration Research Award, the Leonhard-Klein Award for Ocular Surgery, the Alcon Research Institute (ARI) Award, the Senior Achievement Award of the AAO and the Jules Gonin Award. He published more than 800 articles in peer-reviewed journals, and is a member of the German National Academy of Sciences Leopoldina.

Summary Disclosure of conflicts of interest: Acucela (C, F), Alcon (C), Alexion (C), Alnylam (C), Alzheon (C), Apellis (C, F), Bayer (C, F), Boehringer-Ingelheim (C), Galimedix (C), Genentech/Roche (C, F), EyePoint (C), Grayburg Vision (C), Heidelberg Engineering (C), Astellas (C, F), Lin Bioscience (C), Janssen (C), Novartis (C, F), Oculis (C), Oxurion (C), Okuvision (C), Science (C), Stealth Biotherapeutics (C), Zeiss (C, F), Allergan (F), Belite Bio (F), Bioeq (F), Centervue (F), Geuder (F), NightStarx (F), Optos (F), Sanofi (C), Stada (C), 4D Molecular Therapeutics (C), Eyepoint (C), Merck (C), Ocular Therapeutix (C), RetinaAI (C), GRADE Reading Center (O)

1 – Session

Laila Eriksson

Chair - MPA

Laila Eriksson is an ophthalmologist with a dedicated career in medical retina. Served as Associate Senior Consultant at St. Erik's Eye Hospital in Stockholm before transitioning to Clinical Assessor at the Swedish Medical Products Agency. Holding an MBChB degree and the European Board of Ophthalmology Diploma.

Elina Rantala

Chair - FIMEA

Elina Rantala, MD, PhD, is a Senior Medical Officer at the Finnish Medicines Agency (Fimea), where she works primarily on marketing authorisation and scientific advice for ophthalmology and oncology products. She is a specialist in ophthalmology with a subspecialty in ophthalmic surgery and holds an Executive MBA from Switzerland. She is also a deputy member of the Expert Group of the Pharmaceuticals Pricing Board in Finland. In addition to her regulatory role, she has clinical experience in ophthalmology and academic experience from the University of Helsinki, with research focusing on metastatic uveal melanoma.

Muzaffer Özalp

Chair - MPA

Clinical Assessor at the Swedish Medical Products Agency,

Ophthalmology products 12/2019-present,

Pain relief/Anaesthesia products 10/2015-01/2020

Specialist in Family Medicine (SE) 2011

(additional clinical training in General Practice, Dermatology, Ophthalmology and ENT in Sweden 2009-2011. Clinical Experience in General Practice and Care of the Elderly in Sweden 2011-2015)

Consultant in General Practice (UK) 2006

(PRHO and General Practice training in the UK 2011-2007, experience as GP in the UK 2007-2009)

Licensed Physician (DE; UK; SE) 2001

(Medicine studies at Hamburg University)

Licensed Pharmacist (DE) 1995

(Pharmacy studies at Marburg and Hamburg University)

Christine Curcio

Speaker - University of Alabama at Birmingham

Christine A. Curcio PhD, a neuroscientist by training, has made seminal contributions to the anatomic and molecular pathobiology of age-related macular degeneration (AMD), which degrades central vision in aged adults worldwide. Using tools of digital histology, her lab has made major discoveries in human aged and AMD eyes. These include hallmarks such as early loss of parafoveal rod photoreceptors, gliosis, and RPE transdifferentiation, as well as the composition, ultrastructure, and imaging correlates of characteristic extracellular deposits and neovascularization morphologies. Her microscopy studies support multiple clinical diagnostic techniques for ophthalmology, including optical coherence tomography, fundus autofluorescence, adaptive optics, and rod-mediated dark adaptation. Over four decades, she has amassed 317 PubMed entries, >40,156 citations, and an H-index of 99. Awards include: 2002 (inaugural) Roger H. Johnson Prize for Macular Degeneration research, 2014 Ludwig von Sallmann Prize (International Society for Eye Research, 2020 Research to Prevent Blindness – David F. Weeks Award, 2022 Lawrence A. Yannuzzi Lectureship of the International Retinal Imaging Society, 2022 Laureate of the Future Vision Foundation, and the 2025 Award of Merit in Retina Research (Retina Society), and (jointly with Cynthia Owsley) the 2025 Proctor Medal from the Association of Research in Vision and Ophthalmology.

Summary Disclosure of conflicts of interest: Financial Support: Heidelberg Engineering, Hoffman LaRoche. Consultant/ Contractor: Genentech/ Hoffman LaRoche, Astellas, Boehringer Ingelheim, Character Biosciences, Osanni, Annexon, Mobius, Ripple, Sanofi, Merck, Ikarovec, Espansione, Topcon, Precision Ocular Network

Maximilian Pfau

Speaker - University Hospital Bonn

Professor Maximilian Pfau is an internationally recognized clinician-scientist and Full Professor of Medical Retina and Inherited Retinal Diseases at the University of Bonn. He specializes in advanced visual function assessment and the analysis of retinal microstructure using optical coherence tomography. His work integrates cutting-edge psychophysics, high-resolution retinal imaging, and artificial intelligence to develop sensitive outcome measures for clinical trials and precision medicine.

He is a leading expert in fundus-tracked visual field testing (microperimetry), with a strong focus on quantifying localized retinal function and linking it to structural biomarkers. His research further advances reading performance metrics, including reading speed and acuity, establishing clinically meaningful endpoints for macular diseases. Complementing this, he develops deep-learning-based analyses of retinal imaging data.

Prof. Pfau has led multiple investigator-initiated and industry-funded studies, contributed as subject matter expert to regulatory discussions with the FDA, and held leadership roles in international clinical trials.

Summary Disclosure of conflicts of interest: iCare: Funding of clinical studies. Apellis: Funding for post-hoc analyses. Roche: Former employee, ongoing research projects

Nabin Paudel

Panellist - Retina International

Dr Nabin Paudel is a vision scientist and optometrist, currently serving as Director of Research, Patient Evidence and Programmes at Retina International, a patient-driven umbrella organisation that represents charities, foundations and groups funding research into inherited and age-related retinal diseases and/or supporting people living with these conditions. Dr Paudel has ten years of experience in clinical and patient-evidence research across ophthalmology and optometry. Over the past four years at Retina International, Dr Paudel has led several high-impact projects that quantify the societal burden of retinal diseases, identify outcomes and endpoints that matter most to patients, and illuminate impacts that extend beyond vision loss. He also leads a bench-to-bedside educational course for patient leaders and early-career researchers/clinicians, building a cohort of informed patients/early career researchers/clinicians equipped to contribute confidently to decision-making forums such as regulatory meetings, health technology assessments, and clinical trial steering groups.

Anat Loewenstein

Panellist - Tel Aviv Medical Center

Vice President for Ambulatory Services and Head of the Retina, Department of Ophthalmology, Tel Aviv Medical Center.

Sidney Fox Chair of Ophthalmology at Tel Aviv University, Member of the Executive Committee of Board of the European Society of Retina Specialists (Euretina).

Global leader in developing and implementing innovative ophthalmic technologies, including early detection of macular degeneration and home-based OCT monitoring.

Serves as Chief Editor of Case Reports in Ophthalmology and as Associate Editor for the European Journal of Ophthalmology, Investigative Ophthalmology & Visual Science (IOVS), and Ophthalmologica.

Summary Disclosure of conflicts of interest: Consultant for: 4DMT, Abbvie, Adverum, Astellas, Aviceda, Bayer, Boeringer Ingelheim, Eyepoint, Ocular Therapeutix, Oculis, Ocuphire, Roche, Voiant

Board Member of: Beyeonics, NotalVision, Revenio

Karl Csaky

Panellist – Retina Foundation

Dr. Csaky is the T. Boone Pickens Director of the Clinical Center of Innovation for Age- Related Macular Degeneration (AMD) and Chief Strategy Officer of the Retina Foundation of the Southwest in Dallas, Texas. His main areas of interest are clinical research into AMD and ocular drug delivery. Dr. Csaky has been involved in over 50 phase 1, 2 and 3 clinical trials in retina treatment and is studying vision function assessments including novel approaches to microperimetry and contrast sensitivity in subjects with various stage of AMD. Dr. Csaky has led several meetings with the FDA and NEI on evaluating novel endpoints for retinal diseases. Dr. Csaky is a member of the Macula Society, Retina Society, and American Academy of Ophthalmology, ARVO, AOS and the American Society of Retinal Specialists. He finished a retina fellowship at the Wilmer Eye Institute, Johns Hopkins University and a postdoctoral fellowship at the National Cancer Institute. Dr. Csaky completed an internship in medicine at Duke University, ophthalmology residency at Washington University, and was a Fulbright Scholar at the Essen Eye Clinic, Essen, Germany. He received his combined MD/PhD degree from the University of Louisville. Dr. Csaky has over 150 peer-reviewed publications and book chapters.

Summary Disclosure of conflicts of interest: Abbvie (Consultant), Adverum Biotechnologies (Data and Safety Monitoring), Annexon Biosciences (Consultant, Grant Support), Boehringer Ingelheim (Consultant, Grant Support), EyeBio (Consultant), F. Hoffman-La Roche AG (Consultant, Grant Support), Genentech, Inc. (Consultant, Grant Support), Heidelberg Engineering, Inc. (Consultant), Johnson & Johnson Health Care Systems Inc. (Consultant, Grant Support), Life Sciences (Consultant), Merck (Consultant), Novartis (Consultant, Grant Support), PYC Biotherapeutics (Data and Safety Monitoring), Ray Therapeutics (Data and Safety Monitoring), Regeneron Pharmaceuticals, Inc. (Consultant, Grant Support), Vinci Pharmaceuticals (Consultant, Stock Options)

Zhichao Wu

Panellist – The University of Melbourne

Zhichao (Zhi) Wu is a Principal Research Fellow and the Head of Clinical Biomarkers Research at the Centre for Eye Research Australia (CERA), and an Associate Professor at the Department of Surgery (Ophthalmology), University of Melbourne. His work focusses on establishing novel clinical biomarkers for eye diseases like age-related macular degeneration using state-of-the-art imaging and functional assessment techniques, to be used in clinical trials to expedite the discovery of new treatments.

Andrew Want

Panellist – Industry

Andrew Want, MBBS, PhD, FRCOphth, is Senior Medical Director, Global Medical Lead at Astellas Pharma Europe Ltd., working on therapies for geographic atrophy including avacincaptad pegol (Izervay).

He is an ophthalmologist by training, based in the UK. He completed his PhD in Vision Sciences investigating the role of neuroprotective factors on retinal ganglion cells. As well as clinical ophthalmology, Andrew previously worked as a research physician across a variety of clinical trials and medical specialties.

Summary Disclosure of conflicts of interest: Employee of Astellas Pharma Europe Ltd.

2 – Session

Agnieszka Przybyszewska

Chair - HPRA

Agnieszka Przybyszewska holds an M.D. and Ph.D. in Medicine from the Medical University of Łódź, Poland, as well as an M.Sc. in Molecular Medicine and a Postgraduate Diploma in Pharmaceutical Medicine from Trinity College Dublin. She is trained and qualified in Internal Medicine.

She joined the Health Products Regulatory Authority (HPRA) in 2009 and currently serves as a Senior Medical Officer in the Human Products Authorisation and Registration Department. Her work focuses on the clinical assessment of medicinal products in marketing authorisation applications and clinical trials. Agnieszka is an active member of the EMA Scientific Advice Working Party and the Working Party on Immunology and Inflammatory Diseases. She has extensive experience as a clinical assessor for numerous medicinal products across a wide range of therapeutic areas, including ophthalmology.

Hemme Hijma

Chair – CBG-MEB

Hemme Hijma, PhD is a board-certified clinical pharmacologist and works as clinical assessor at the Medicines Evaluation Board (CBG-MEB), the Netherlands. His focus is on scientific advice and marketing authorization applications for ophthalmologic and analgesic medicinal products. Previously worked in clinical drug development in which he advanced the use of mechanism-based methodologies and biomarkers, across therapeutic areas.

Summary Disclosure of conflicts of interest: Current: Guest appointment at Centre for Human Drug Research (CHDR; the Netherlands)

Rufino Silva

Speaker - Coimbra Hospital and University Centre

Rufino Silva, MD, PhD, is a senior ophthalmologist at the Coimbra Hospital and University Centre with over three decades of dedicated clinical and academic

experience in retinal diseases. He serves as Full Professor of Ophthalmology at the Faculty of Medicine of the University of Coimbra and is Director of the Department of Ophthalmology at the Coimbra Local Health Unit.

He is a former President of the Portuguese Ophthalmological Society (2021–2022) and has an extensive track record in translational and clinical research, having acted as Principal Investigator in 57 national and international projects. His research is primarily focused on age-related macular degeneration, with particular emphasis on epidemiology, risk factors, genetics, and metabolomics.

Professor Silva has authored or co-authored more than 250 peer-reviewed scientific publications, as well as 6 books and 35 book chapters. His work has achieved an h-index of 45, reflecting sustained scientific impact in the field of ophthalmology.

Karl Csaky

Speaker – Retina Foundation

Dr. Csaky is the T. Boone Pickens Director of the Clinical Center of Innovation for Age- Related Macular Degeneration (AMD) and Chief Strategy Officer of the Retina Foundation of the Southwest in Dallas, Texas. His main areas of interest are clinical research into AMD and ocular drug delivery. Dr. Csaky has been involved in over 50 phase 1, 2 and 3 clinical trials in retina treatment and is studying vision function assessments including novel approaches to microperimetry and contrast sensitivity in subjects with various stage of AMD. Dr. Csaky has led several meetings with the FDA and NEI on evaluating novel endpoints for retinal diseases. Dr. Csaky is a member of the Macula Society, Retina Society, and American Academy of Ophthalmology, ARVO, AOS and the American Society of Retinal Specialists. He finished a retina fellowship at the Wilmer Eye Institute, Johns Hopkins University and a postdoctoral fellowship at the National Cancer Institute. Dr. Csaky completed an internship in medicine at Duke University, ophthalmology residency at Washington University, and was a Fulbright Scholar at the Essen Eye Clinic, Essen, Germany. He received his combined MD/PhD degree from the University of Louisville. Dr. Csaky has over 150 peer-reviewed publications and book chapters.

Summary Disclosure of conflicts of interest: Abbvie (Consultant), Adverum Biotechnologies (Data and Safety Monitoring), Annexon Biosciences (Consultant, Grant Support), Boehringer Ingelheim (Consultant, Grant Support), EyeBio (Consultant), F. Hoffman-La Roche AG (Consultant, Grant Support), Genentech, Inc. (Consultant, Grant Support), Heidelberg Engineering, Inc. (Consultant), Johnson & Johnson Health Care Systems Inc. (Consultant, Grant Support), Life Sciences (Consultant), Merck (Consultant), Novartis (Consultant, Grant Support), PYC Biotherapeutics (Data and Safety Monitoring), Ray Therapeutics (Data and Safety Monitoring), Regeneron Pharmaceuticals, Inc. (Consultant, Grant Support), Vinci Pharmaceuticals (Consultant, Stock Options)

Franz Badura

Panellist - Retina International

I'm a trumpet player, music school director and networker for improved vision for patients. Since my youth I have been committed to supporting people with visual impairments - also because of my own story. At the age of 15, the first effects of my RP (Retinitis Pigmentosa) began to appear, leading to an ever-expanding involvement and network in the field of retinal disease research. From 1990 until 2023 I was engaged on a voluntary basis for the patient organization PRO RETINA Germany e.V. and its research foundation. From 2012 to 2020 I led PRO

RETINA Germany as its chairman. Since 2019 until end of 2023, I have been working as lobbyist and head of the Berlin office of PRO RETINA. In 2020 I was also elected Chair of the Board of Directors of the international umbrella organization Retina International, founded in 1978. Since January 2024, I am working part-time for the German Ophthalmic Society which represents the medical and scientific community in Ophthalmology.

In addition to my commitment to research and health policy in the field of retinal diseases, I am involved in politics and have been a city council member in my hometown Amberg since 2008 and its deputy mayor since 2020.

Robyn Guymer

Panellist - Centre for Eye Research Australia

Robyn Guymer is Professor of Ophthalmology at Melbourne University, and a deputy director of the Centre for Eye Research Australia. She is also a senior retinal specialist at the Royal Victorian Eye and Ear Hospital in Melbourne. She is a clinician scientist who leads a team of researchers primarily investigating Age related macular degeneration (AMD) and has co-authored over 450 peer reviewed papers. She is currently investigating new strategies for treating early stages of AMD and is working to identify novel imaging and functional biomarkers and surrogate endpoints to improve the feasibility of conducting early intervention trials. She has been a principal investigator in many industry sponsored trials, serves on several pharmaceutical advisory boards and is a member of several international working groups on macular diseases. She is an inaugural fellow of the Australian Academy of Health and Medical Sciences. In June 2018 she was awarded the Member of the Order of Australia for significant service to medicine in the field of ophthalmology, particularly age related macular degeneration as a clinician, academic and researcher.

Summary Disclosure of conflicts of interest: Advisory boards

Alnylam, Astellas, Apellis, Bayer, Belite Bio,Complement therapeutics, Boehringer Ingelheim Pharmaceuticals, Character Bioscience, Ocular therapeutix, Roche/Genentech, Vioant, BioJIVA

Janet Sunness

Panellist - Greater Baltimore Medical Center

Dr. Janet Sunness is a world expert on geographic atrophy. She conducted an NIH-funded natural history study of GA at Wilmer, which has served as the basis for designing most clinical trials for this condition. Her study included both visual function measures and measures of GA lesion size and progression. The low luminance visual acuity measure now routinely used was developed and used as part of her study. She has received awards from the Macula Society and from Envision for her research on GA and low vision. She is the author of 37 papers on GA. She was the chair of the Data Safety and Monitoring Board for the Lineage OpRegen trial of stem-cell derived RPE cells for GA.

She is Medical Director of the Hoover Low Vision Rehabilitation Services of the Greater Baltimore Medical Center. She practices medical retina, low vision rehabilitation, and clinical electrophysiology and visual function testing (including microperimetry). She is thus able to provide comprehensive evaluation and treatment of patients with GA.

Nida Sen

Panellist - Industry

H. Nida Sen, MD, MHS is the Head of Ophthalmology Strategy and Development at Sanofi and Professor of Ophthalmology at George Washington University. A board-certified retina specialist with nearly two decades of experience, Dr. Sen is internationally recognized as a leading expert in ophthalmology, shaping the field through her research and as a clinician, trialist, educator, and industry advisor. Prior to her roles in industry, Dr. Sen was a Lasker Clinical Research Scholar, NIH Distinguished Scholar and Investigator at the National Eye Institute of the National Institutes of Health (NIH) in Bethesda, MD for over a decade. At NIH, she built a clinical and translational research program in retinal inflammatory diseases, serving as Head of the Translational Ocular Immunology Laboratory, Head of the Uveitis Clinic, and director of the Clinical Fellowship training program. She led clinical trials from Phase 0 through Phase IV, pioneered biomarker-driven patient stratification and novel endpoint development and served as Principal Investigator and Steering Committee Member on multiple landmark Phase III trials. She advised many companies on drug development. Dr. Sen has held key leadership positions in major ophthalmology organizations, serving on important committees of the American Academy of Ophthalmology (AAO), Association for Research in Vision and Ophthalmology (ARVO) and the

American Society of Retina Specialists (ASRS). Recognized as a global thought leader, she has delivered visiting professorships at premier academic institutions, given numerous invited talks, and mentored many ophthalmologists who became leaders in the field. She served as President of the American Uveitis Society (AUS) and has been recognized with the Senior Achievement and Secretariat Awards of the AAO and Gold Fellows award of ARVO. She has authored over 200 peer-reviewed publications in leading journals, edited multiple textbooks, and received numerous research awards. Dr. Sen continues to see patients in clinical practice.

Summary Disclosure of conflicts of interest: Employee of Sanofi

Stela Vujosevic

Panellist - University of Milan, Eye Clinic IRCCS MultiMedica, Milan

Retina specialist, Head of Ophthalmology Unit-Medical Retina at San Giuseppe Hospital, MultiMedica Group in Milan and assoc/Professor of Ophthalmology at the University of Milan, already qualified as Full Professor in 2020.

Her MD, PhD and Ophthalmology training were performed at the University of Padova, Italy. Medical Retina Fellowship and Reading Centre fellowship were performed at the Moorfields Eye Hospital, London, UK.

She has an extensive global research network collaborations and has been dedicated in increasing and disseminating worldwide the knowledge on imaging biomarkers, structure-function correlations, quality of life and patient reported outcome measures and AI application in retinal diseases and retinal trials. She has been actively involved in training and mentoring young ophthalmologists both in Italy and overseas. She is currently participating in several global working groups and consortiums with the goal to develop and validate novel clinical endpoints and to build global foundation models. She has been participating in numerous clinical trials and research projects, both Italian and international in the role of Principal Investigator.

Gold fellow of the ARVO and the fellow of the EBO; elected member of Diabetic Retinopathy

Expert Committee of the EVICRnet, Macula Society, Co-chair of the Imaging Subspecialty Section of the

EURETINA, Vice-president of the EAsDEC, scientific committee member of the SISO.

Major awards include:

- "The Power List 2022", the Top 100 most influential ophthalmologists in the world by the Ophthalmologist;

- TOP LIST of excellent Women in European Vision Research and Ophthalmology 2021 by the European Vision Institute;

- and Women's Leadership Development in ARVO Program and Gold fellow.

Prof Vujosevic serves as the Associate Editor of the AJO Case Reports, and the EBM of the IOVS, JAMA Ophthalmology, RETINA and the Acta Ophthalmologica, and has more than 155 published papers and 8 book chapters.

Leopold Schmetterer

Panellist - Singapore Eye Research Institute and Medical University of Vienna

Professor Leopold Schmetterer has graduated from the Technical University of Vienna. In 1989 he finished his PhD. He is Scientific Director and Head of Ocular Imaging at Singapore Eye Research Institute, Professor of Ophthalmology at National University of Singapore, and Professor of Biomedical Engineering at the Nanyang Technological University. Since 03/2020 he holds a named Professorship (SNEC/SERI Professorship in Ophthalmic Engineering & Technology) at Nanyang Technological University. Until 08/2016 he was chairing the Ophthalmic Pharmacology at the Department of Clinical Pharmacology at the Medical University of Vienna. In addition, he had an affiliation with the Center of Medical Physics and Biomedical Engineering. Dr. Schmetterer held a post doc position at the Institute de Recherche en Ophthalmologie in Sion and was a guest Professor at École polytechnique fédérale de Lausanne and Institute of Molecular and Clinical Ophthalmology in Basel. His research interests include a wide array of sub-specialities in ophthalmology including imaging, glaucoma, medical retina and dry eye syndrome. He is involved in many international societies including European Association for Vision and Eye Research (EVER: president 2012 and president of the EVER foundation 2014-2016), Association for Research in Vision and Ophthalmology (ARVO: program committee member 2009-2011 and member of the board of trustees since 2018, Vice-president 2025). Professor Schmetterer has published more than 585 research articles, has an h-index of 94 and is in the Editorial Board of multiple journals including Progress in Retinal and Eye Research. He has published in journals such as Lancet Digital Health, Nature Biomedical Engineering, Nature Communications, JAMA Netw Open, NPJ Digitial Medicine, IEEE Transactions on Medical Imaging, Progress in Retinal and Eye Research, Diabetes Care, Diabetes, Diabetologia, Neurology, Alzheimer's Dementia, Alzheimer's Research & Therapy, Ophthalmology and JAMA Ophthalmology.

Second half

Christian Gartner

Chair - AGES

Christian Gartner has been a member of the Committee for Medicinal Products for Human Use (CHMP) since 2019, where he presently covers the role of being Alternate Member for Austria. Before entering this role he has been Co-opted member of the CHMP for Biostatistics and clinical trial methodology. In his seven years of CHMP membership Christian Gartner has taken over a large number of Rapporteurships for Marketing Authorization Applications in a range of therapeutic areas, including in the area of ophthalmology.

Christian Gartner has now been working as regulator at the Austrian Agency for Health and Food Safety (AGES) for almost 20 years. In this time he has been a relevant contributor to the European Regulatory Network (EMRN) in several working parties, including the EMA Scientific Advice Working Party (SAWP), where he has served until joining the CHMP.

3 – Session

Tanya Moutray

Chair - HPRA

- Tanya Moutray is a Senior Medical Officer at the Health Product Regulation Authority (HPRA), Ireland. Her work as an expert ophthalmology scientific adviser focuses on the clinical assessment of medicinal products in marketing authorisation applications and clinical trials.

- UK and Ireland registered Consultant Ophthalmologist, fellowship trained retinal specialist with over 20 years clinical experience. She is a Fellow of Royal College of Ophthalmologists, London and Member of European Society of Retinal Specialists.

- Sub Deanery Lead for Ophthalmology (Queen's University, Belfast and Ulster of University, Belfast). She is actively involved in training and mentoring young doctors as an educational supervisor.

- Awarded MD and MSc Medical Education from Queen's University Belfast. She completed a Cochrane Ireland research fellowship and has publications in the area of retinal imaging, AMD, and Diabetic eye disease. She has previously participated in clinical trials and research projects in the role of Principal Investigator. She sits on national committee advocating for the visually impaired.

Jane Moseley

Chair – European Medicines Agency

- Responsible for administration of Scientific Advice, Protocol Assistance and qualification procedures at EMA since 2009.

- Professional background in ophthalmology, epidemiology and regulatory including clinical assessor at the MHRA for pharmacovigilance, clinical trials, and licensing. Currently registered with the General Medical Council, UK.

- Education: Medical degree Trinity College, Dublin, Masters in Epidemiology at the London School of Hygiene and Tropical Medicine and Diploma in pharmaceutical medicine, granted fellowship of the

Royal college of ophthalmologists in UK, the Royal college of surgeons/ophthalmology in Ireland, membership of the faculty of pharmaceutical medicine UK.

Elisabeth Wischnitzki

Speaker - AGES

Elisabeth Wischnitzki is a member of the Scientific Advice Working Party and the Modelling and Simulations Operational Expert Group. She acted as Coordinator and was involved as peer reviewer and assessor in a large number of Scientific Advice and Qualification procedures including also indications and endpoints in the area of ophthalmology.

She has a background in Bioinformatics and Biomarker Development and is working at the Austrian Agency for Health and Food Safety (AGES) for almost 10 years. In her role as senior expert she is also involved in the clinical assessment of pharmacology, efficacy and safety in marketing authorization procedures.

Ursula Schmidt-Erfurth

Speaker - Medical University Vienna

Ursula Schmidt-Erfurth, MD, is Professor of Ophthalmology at the Medical University of Vienna, Austria. Her clinical expertise includes surgical and medical retina. Her scientific research focuses on innovative techniques in retinal imaging with a focus on artificial intelligence (AI) and the translational introduction of novel diagnostic and therapeutic strategies in retinal disease. She founded the Vienna Reading Center and the Ophthalmic Image Analysis group (OPTIMA), an interdisciplinary team of computer scientists and retina experts. She holds several patents for the development of novel imaging analysis methods and has published more than 600 scientific peer-reviewed papers. She is a full member of the Austrian Academy of Sciences, the ethics board of the Federation of European Academies of Medicine (FEAM), the Macula Society, Retina Society, ASRS and the Club Gonin et al.

Summary Disclosure of conflicts of interest: AbbVie, ADARx, Alcon, Alkeus, Apellis, Astellas, Aviceda, Bayer, Complement Therapeutics, Genentech, Heidelberg Engineering, Kodiak, Medscape, RetInSight, Roche, Topcon

Christine Curcio

Speaker - The University of Alabama

Christine A. Curcio PhD, a neuroscientist by training, has made seminal contributions to the anatomic and molecular pathobiology of age-related macular degeneration (AMD), which degrades central vision in aged adults worldwide. Using tools of digital histology, her lab has made major discoveries in human aged and AMD eyes. These include hallmarks such as early loss of parafoveal rod photoreceptors, gliosis, and RPE transdifferentiation, as well as the composition, ultrastructure, and imaging correlates of characteristic extracellular deposits and neovascularization morphologies. Her microscopy studies support multiple clinical diagnostic techniques for ophthalmology, including optical coherence tomography, fundus autofluorescence, adaptive optics, and rod-mediated dark adaptation. Over four decades, she has amassed 317 PubMed entries, >40,156 citations, and an H-

index of 99. Awards include: 2002 (inaugural) Roger H. Johnson Prize for Macular Degeneration research, 2014 Ludwig von Sallmann Prize (International Society for Eye Research, 2020 Research to Prevent Blindness – David F. Weeks Award, 2022 Lawrence A. Yannuzzi Lectureship of the International Retinal Imaging Society, 2022 Laureate of the Future Vision Foundation, and the 2025 Award of Merit in Retina Research (Retina Society), and (jointly with Cynthia Owsley) the 2025 Proctor Medal from the Association of Research in Vision and Ophthalmology.

Summary Disclosure of conflicts of interest: Financial Support: Heidelberg Engineering, Hoffman LaRoche; Consultant/ Contractor: Genentech/ Hoffman LaRoche, Astellas, Boehringer Ingelheim, Character Biosciences, Osanni, Annexon, Mobius, Ripple, Sanofi, Merck, Ikarovec, Espansione, Topcon, Precision Ocular Network

Sobha Sivaprasad

Speaker - Moorfields Eye Hospital NHS Trust, London

Professor Sobha Sivaprasad is a Medical Retina Consultant Ophthalmologist at Moorfields Eye Hospital NHS Foundation Trust and a Professor in Retinal Clinical Research at University College London. She is the Director of Moorfields Clinical Research Facility and the Vascular Theme Lead for Moorfields Biomedical Research Centre. Professor Sivaprasad has published over 600 peer-reviewed publications. Her main research interests are clinical trials, imaging and risk prediction in AMD and retinal vascular diseases. She has successfully completed many multicentre clinical trials in the UK and has received about £15M in grant funding for her research. She is a member of various research collaborations such as BRIDGE Consortium; R.E.T.I.N.A collaboration and the Wellcome funded PINNACLE Consortium investigating clinical endpoints for intermediate AMD. She is a NIHR Senior Investigator. She was the Chair of the RCOphth AMD Commissioning Guidance, RCOphth Retinal Vein Occlusion Guidelines and the Chair of the RCOphth Scientific Committee from 2021 to 2025. She was also the Editor in Chief of EYE from 2018-2025.

Summary Disclosure of conflicts of interest: I have received fees as advisory board member from AbbVie, Adverum, Alimera Sciences, Amgen, Apellis, Astellas, Bayer, Biogen, Boehringer Ingelheim, Clearside bio, Novartis, EyeBiotech, Eyepoint Pharmaceuticals, Eyexora, 4DMT, Janssen Pharmaceuticals, Kodiak Sciences, Merit, NanOptima, Nova Nordisk, Optos, Ocular Therapeutix, Kriya Therapeutics, OcuTerra, Roche, Sanofi, Stealth Biotherapeutics, Surrozen.

I have received honoraria/travel reimbursement from Bayer, Boehringer Ingleheim and Roche.

Maria Vittoria Cicinelli

Panellist - Università Vita-Salute San Raffaele, Milano

Maria Vittoria Cicinelli, MD, FEBO, is an Assistant Professor at Università Vita-Salute San Raffaele, Milano (Italy), a position she has held since 2021.

She completed her residency training in Ophthalmology at Università Vita-Salute San Raffaele, Milano (Italy). Her primary areas of expertise are Medical Retina and Uveitis. She completed a fellowship in Medical Retina and Uveitis at Northwestern University (Chicago, Illinois).

Dr. Cicinelli was the 2020 recipient of the ICO Allergan Fellowship, a prestigious research grant supporting international ophthalmologists. In 2023, she was awarded the Macula Society Research Grant and the American Academy of Ophthalmology Secretariat Award.

With an h-index of 41 and over 13,000 citations, Dr. Cicinelli has contributed to more than 250 peer-reviewed articles indexed in Pubmed. She is the editor of the book "Ultra Widefield Imaging of the Retina" (1st Edition, March 2025, ISBN: 9780443290855). Dr. Cicinelli earned the National Scientific Qualification for Associate Professor in July 2020. She currently serves as editor-in-chief of the American Journal of Ophthalmology International and as an associate editor for several indexed journals. She has also played an active role in mentoring and training residents and medical students at Università Vita-Salute San Raffaele.

Avril Daly

Panellist - *Retina International*

Avril Daly is CEO of Retina International since 2016, she was previously CEO of Fighting Blindness Ireland for eight years. Avril held roles in Public Affairs and Media Relations, representing patients living with retinal degenerations and rare diseases for 25 years. Her focus is patient centricity in decision making working on policies that impact health innovation from bench to bedside. She is the current volunteer president of EURORDIS (Rare Disease Europe) and is a Board member of Rare Disease Ireland. Avril holds a BBS and MA in Strategic Planning.

Summary Disclosure of conflicts of interest: Retina International recieves funding support for specific patient led programmes from patient organisations and industry including: Amgen, Boehringer Ingelhiem, F. Hoffman la Roche, Johson &Johnson, Outlook Pharmaceuticals

Seema Garg

Panellist - Industry

Seema Garg, MD, PhD is an Executive Medical Director in Ophthalmology Clinical Development at Johnson & Johnson Innovative Medicine. She is a retinal physician with expertise in the clinical development of therapies for retinal diseases, including geographic atrophy, age-related macular degeneration and diabetic retinopathy.

Dr. Garg has led and contributed to multiple global clinical programs mainly in late-phase development, including the design and evaluation of functional, structural, and patient-reported endpoints in retinal disease. Her work emphasizes the integration of retinal imaging, visual function measures, and patient-relevant outcomes.

Dr. Garg collaborates with academic investigators, regulators, and patient representatives on topics related to endpoint development, validation, and trial design in ophthalmology. She has contributed to scientific and regulatory discussions addressing structure–function relationships, surrogate endpoint considerations, and outcome measure interpretation in geographic atrophy.

Dr. Garg completed her Ph.D. In Biomedical Engineering (with an Imaging focus) followed by her MD and Ophthalmology residency at Duke University (Durham, NC, USA). She completed her retina fellowship at Northwestern University (Chicago, USA). She was an Associate Professor on the clinical/research faculty at the University of North Carolina at Chapel Hill (USA), as well as a site PI for the DRCR Network for 15 years.

Summary Disclosure of conflicts of interest: Employee of Johnson & Johnson Innovative Medicine.

Frank Holz

Panellist - University Hospital Bonn

Frank G. Holz is Professor and Chairman of the Department of Ophthalmology at the University of Bonn, Germany. His main research interests include the pathogenesis, biomarkers and new therapies for macular and retinal diseases. He has a keen interest in innovative retinal imaging technologies and image analysis strategies. He was a scholar of the German National Academic Foundation (Studienstiftung des Deutschen Volkes), trained at the University of Heidelberg and the University of Chicago/Pritzker School of Medicine, and passed a clnical research fellowhip at Moorfields Eye Hospital, London, He founded the GRADE Reading Center Bonn and is coordinator of the MACUSTAR study on development of structural, functional and PRO endpoints in intermediate AMD. He is a Board Member of the German Ophthalmological Society (DOG), Member of the Academia Ophthalmologica Internationalis (AOI), the Macula Society, and Editor-in-Chief of Der Ophthalmologe. He has received numerous awards including the Pro Retina Macular Degeneration Research Award, the Leonhard-Klein Award for Ocular Surgery, the Alcon Research Institute (ARI) Award, the Senior Achievement Award of the AAO and the Jules Gonin Award. He published more than 800 articles in peer-reviewed journals, and is a member of the German National Academy of Sciences Leopoldina.

Summary Disclosure of conflicts of interest: Acucela (C, F), Alcon (C), Alexion (C), Alnylam (C), Alzheon (C), Apellis (C, F), Bayer (C, F), Boehringer-Ingelheim (C), Galimedix (C), Genentech/Roche (C, F), EyePoint (C), Grayburg Vision (C), Heidelberg Engineering (C), Astellas (C, F), Lin Bioscience (C), Janssen (C), Novartis (C, F), Oculis (C), Oxurion (C), Okuvision (C), Science (C), Stealth Biotherapeutics (C), Zeiss (C, F), Allergan (F), Belite Bio (F), Bioeq (F), Centervue (F), Geuder (F), NightStarx (F), Optos (F), Sanofi (C), Stada (C), 4D Molecular Therapeutics (C), Eyepoint (C), Merck (C), Ocular Therapeutix (C), RetinaAI (C), GRADE Reading Center (O)

Laura Sararols

Panellist - Institut OMIQ, Hospital General Universitari de Catalunya

I am a retina specialist working in Barcelona, I do Medical Retina and VitreoRetinal Surgery and have been working as a retinologist for nearly 30 years. My passion for clinical research started around 25 years ago and have been involved over 25 clinical trials for DME, exudative AMD and in the last 10 years also Geographic AMD. My combined clinical and research work gives me a practical approach for interpretation of trial results and complementary tests as I see patients daily and follow them for a long time, allowing to understand better the implications of retinal diseases in the patients life and quality of life.

Jordi Monés

Panellist - Barcelona Macula Foundation: Research for Vision-Institut de la Màcula, Centro Médico Teknon Barcelona

Jordi Monés is Director of Institut de la Màcula, Director of the Barcelona Macula Foundation, and Adjunct Professor at John A Moran Eye Center, University of Utah Health, USA.

He earned his degree and PhD cum laude in Medicine and Surgery at the Universitat de Barcelona, Spain. He specialized in Ophthalmology at the Centro de Oftalmología Barraquer, Universitat Autònoma de Barcelona, from 1986-1989. He completed his Research Retina Fellowship at the Massachusetts Eye and Ear Infirmary at Harvard University, Boston, the USA, in 1990 and 1991, and a Clinical Retina Fellowship at the Hospital San José at the Monterrey Institute of Technology and Higher Education, Mexico, in 1992.

Since 2007, he has been the Director of the Institut de la Màcula in Barcelona (accredited site of the network of excellence in research, the European Vision Institute) within the Centro Medico Teknon Hospital campus. He is also the Medical Director and one of the founder governors of the Barcelona Macula Foundation: Research for Vision since 2011, whose mission is to fight blindness, supporting and conducting research in retinal diseases that currently have no treatment. He has been an Adjunct Professor at John A Moran Eye Center, University of Utah Health, since February 2023.

His particular research fields are the pathophysiology, imaging, endpoints, biomarkers, clinical trial design, and emerging therapies for AMD, with a specific interest both in the end-stage atrophic and the intermediate form, as well as for retinal dystrophies, regenerative medicine, stem cells, microbiome, and gene therapy.

For the past 20 years, he has been the Principal Investigator in most of the international multicentre clinical trials for treating AMD or conducting phase I–IV and Investigator-driven clinical trials. He is currently participating in or designing clinical trials for exudative AMD, intermediate AMD, atrophic AMD, Stargardt's disease and Retinitis pigmentosa (RP).

He has worked in regenerative stem-cell therapy in a large animal model, creating a mini-pig model of well-defined atrophy mimicking GA in humans and evaluating the safety of implanting human RPE-derived iPSC cells. Dr. Monés also contributed to the new formulation of retinal progenitor stell cells used by ReNeuron in its Phase II clinical trial in humans. He also participated in the ReNeuron Phase II extension clinical trial, implanting embryonic retinal progenitors in a patient with RP for the first time in Europe.

In 2005, he envisioned encouraging the US biotech Ophthotech to use a drug, that at that time was intended for exudative AMD in combination with anti-VEGF therapy, in patients with atrophic AMD. This led to the conduction of a Phase I trial, and at the Institut de la Màcula, anti-complement therapy was intravitreally administered for the first time in human patients. This was the pioneer seed for the drug currently named avacincaptad pegol, which, after almost 20 years, has shown significant results in preventing the progression of geographic atrophy and visual loss, and it is one of the first and only two drugs approved by the FDA for this condition.

He recently found and described retinal restoration/regeneration cases in patients with geographic atrophy after subretinal implantation of RPE-derived embryonic stem cells (Lineage Cell Therapeutics).

Dr Monés, as adjunct Prof. at University of Utah and as scientific advisor of Perceive Biotherapeutics, is currently contributing to the development of a gene therapy for atrophic and intermediate AMD.

He is a member of various research groups, such as the CAM Study Group, and a scientific advisor or member of the Steering Committees of several other pharma and related clinical trials (PerceiveBio,

Iveric, Apellis, Novartis, Roche, Kodiak, Genentech, Allegro, EyeBio, Annexon, Aviceda, Nanoscope, Panther Pharmaceuticals) and biotech companies, such as the CellCure/Lineage and ReNeuron in the stem cell regenerative therapy field. He has recently participated as principal investigator in four major projects funded by the European Union's Horizon 2020 Programme: the EYERISK, the LITE, the PRO4VIP, and the ADVANCE CAT Consortiums.

He has published over 100 articles in scientific journals and specialist books and has given over 500 presentations, conferences, or talks at international congresses and meetings. He is a member of 12 scientific societies. Prof Monés is one of the 5 European specialists and one of the 40 international specialists that belong to the 4 major retina societies: Macula Society, Retina Society, Club Jules Gonin, and American Society of Retina Specialists.

4 – Session

Johanna Wernsperger

Chair - AGES

Dr. Johanna Wernsperger is a Senior Clinical Assessor at the Austrian Medicines and Medical Devices Agency (AGES), where she has worked since 2007. She is an EMA expert involved in national, decentralised and centralised regulatory procedures and Scientific Advice and a vet by training. She has been an Austrian (alternate) delegate to the EMA Paediatric Committee (PDCO) since 2017.

Jane Moseley

Chair – European Medicines Agency

- Responsible for administration of Scientific Advice, Protocol Assistance and qualification procedures at EMA since 2009.
- Professional background in ophthalmology, epidemiology and regulatory including clinical assessor at the MHRA for pharmacovigilance, clinical trials, and licensing. Currently registered with the General Medical Council, UK.
- Education: Medical degree Trinity College, Dublin, Masters in Epidemiology at the London School of Hygiene and Tropical Medicine and Diploma in pharmaceutical medicine, granted fellowship of the Royal college of ophthalmologists in UK, the Royal college of surgeons/ophthalmology in Ireland, membership of the faculty of pharmaceutical medicine UK.

Jan Terheyden

Speaker - University Hospital Bonn

Dr Jan H. Terheyden is an ophthalmologist-researcher based at the Department of Ophthalmology, University Hospital Bonn, Germany. His work focuses on the integration of the patient perspective into clinical research and care in chronic conditions of the retina. His research emphasizes the importance of capturing patients' subjective experience of visual impairment, complementing traditional clinical endpoints such as visual acuity and those based on retinal imaging.

Dr Terheyden has contributed to the development and validation of patient-reported outcome instruments tailored to age-related macular degeneration (AMD) in collaborative projects involving academia, healthcare providers, and industry, supporting their use in both clinical trials and real-world

settings. His work highlights how functional vision and vision-related quality of life can be systematically assessed to better inform benefit-risk evaluation and patient-centered decision-making in drug regulation, reimbursement and clinical contexts.

Through journal publications, international initiatives and work with patient organizations, Dr Terheyden supports the integration of the patient perspective into ophthalmology, advocating for more holistic outcome frameworks in AMD research and therapeutic development. He has received international awards for this work and is an active member of initiatives aligning PROM data with regulatory expectations, including their potential role in supporting labeling claims and health technology assessments.

Summary Disclosure of conflicts of interest: Bayer, Okko: Consulting. Novartis, Bayer, Roche: Grant funding. Bayer, Novartis: Speaker fees

Alba Perez

Panellist - Federation of Associations of Hereditary Retinal Dystrophies (FARPE)

She is a physicist and currently a biotechnology project manager. She holds a PhD in data analysis with a strong research background. In 2024, she co-founded the FARPE (Federation of Associations for Hereditary Retinal Dystrophies) Young Group in Spain and serves as Spain's representative at Retina International.

Francisco Lopez

Panellist - Industry

Francisco J. López, MD, PhD, is an accomplished physician and neuroendocrinologist who currently serves as the Head of the Retina Section within AbbVie Eye Care Clinical Development. Since joining Allergan (now part of AbbVie) in July 2015 as Senior Medical Director in Ophthalmology, he has played key roles in advancing therapies for retinal diseases. Dr. López oversees major clinical programs such as ABBV-RGX-314 (Sura-Vec) for neovascular age-related macular degeneration (nAMD) and diabetic eye diseases, ABBV-6628 for Geographic Atrophy, and the Ozurdex programs. He has also contributed to pioneering gene therapy and in vivo gene editing research— notably leading the first in vivo genome editing program for Leber congenital amaurosis type 10 (LCA10). In prior roles, Dr. López served in medical and scientific leadership at GlaxoSmithKline, Corning Life Sciences, Bausch & Lomb, Ligand Pharmaceuticals, and Wyeth-Ayerst Research. In addition to his clinical and research expertise, he is actively involved in business development for retinal therapies and helps direct the Eye Care Development Fellowship with USC. Dr. López has published over 125 peer-reviewed articles and is an inventor on several patents.

Summary Disclosure of conflicts of interest: Employment at Abbvie

Robert Finger

Panellist - Universitätsklinikum Mannheim

Professor Finger is director of the Department of Ophthalmology Mannheim, chair of Ophthalmology at the Medical Faculty Mannheim, Heidelberg University, and an internationally recognized clinician-scientist with extensive expertise in retinal diseases, particularly age-related macular degeneration (AMD). His research focus is

two-fold: Epidemiology and health services research as well as clinical research. The former includes the running of population-based, clinical and registry cohorts as well as the use of secondary data (such as health claim data), the latter both methods development related to clinical trial endpoints and outcomes research as well as the actual implementation of clinical trials. From 2018 to 2022, he led the European Eye Epidemiology Consortium and is currently Co-PI of the European Registry for Uveitis (TOFU) and the European public-private partnership MACUSTAR on intermediate age-related macular degeneration.
He is an Editor/Reviewer for a number of research journals in the field, has voer 300 peer-reviewed publications in scientific journals and is Co-Lead for Health Research and Epidemiology at the German Ophthalmological Society (DOG).

Summary Disclosure of conflicts of interest: Consulting fees: Alimera , Caterna, Apellis, Novartis, Astellas, ODOS, Bayer, ProGenerika, Biogen, Stada Pharm, Böhringer-Ingelheim, Roche

Payment for expert testimony: Roche

Participation on a Data Safety Monitoring Board or Advisory Board: Stada Pharm, Roche, Opthea

Nicole Eter

Panellist - University Hospital Münster

Professor Nicole Eter completed her specialist training in 1999 and worked as a senior physician in the Department of Ophthalmology at the University Hospital in Bonn. She obtained her habilitation in 2002 and became Professor of Ophthalmology in 2007. In 2010, Professor Eter was appointed Department Chair and Medical Director of the Department of Ophthalmology at the University of Münster. Her core competence lies in vitreoretinal surgery and medical retina, besides covering the entire range of ophthalmic surgical procedures.

She was President of the German Society of Ophthalmology 2017/2018 and is currently Chair of the Association of Ophthalmological Chairholders. She is also currently president oft he European Society of Retina Specialist (EURETINA). Her research focuses on age-related macular degeneration, anti-angiogenic therapies, molecular imaging and nanotechnology in ophthalmology. In 2018, she founded the German Registery for health care research in Ophthalmology (OREGIS). Prof. Eter serves as member of editorial boards and reviewer for several scientific journals, and has written more than 350 articles in peer-reviewed journals and 6 book chapters. She has also given more than 600 scientific presentations.

Summary Disclosure of conflicts of interest: Grants/Contracts: Novartis, Bayer

Consulting: Novartis, Bayer, Roche, Apellis, Allergan, Alcon, Ocular Therapeutics, Outlook Therapeutics, Advanz Pharma, Medscape WebMD

Honoraria: Novartis, Bayer, Roche, Apellis, Allergan, Advanz, Boehringer, Medscape WebMD

Emily Chew

Panellist - National Eye Institute/National Institutes of Health

Emily Chew is an ophthalmologist specializing in medical retina. She is an NIH Distinguished Investigator and the director of the Division of Epidemiology and Clinical Applications at the National Eye Institute/National Institutes of Health. As the chief of the Clinical Trials Branch, she has conducted several epidemiologic and randomized clinical trials in age-related macular degeneration and rare retinal diseases. She serves on boards of the family of the American Academy of Ophthalmology journals and Retina as well as the inaugural editor-in-chief of Ophthalmology Science.

5 – Session

Hemme Hijma

Chair - MEB

Hemme Hijma, PhD is a board-certified clinical pharmacologist. He works as clinical assessor at the Medicines Evaluation Board (CBG-MEB), the Netherlands, with an emphasis on scientific advice and marketing authorization applications for ophthalmologic and analgesic medicinal products. Previously held a senior role in clinical research focusing on mechanism-based methodologies and biomarkers for drug development across therapeutic areas.

Summary Disclosure of conflicts of interest: Current: Guest appointment at Centre for Human Drug Research (CHDR; the Netherlands)

Tanya Moutray

Chair - HPRA

Tanya Moutray is a Senior Medical Officer at the Health Product Regulation Authority (HPRA), Ireland. Her work as an expert ophthalmology scientific adviser focuses on the clinical assessment of medicinal products in marketing authorisation applications and clinical trials.

UK and Ireland registered Consultant Ophthalmologist, fellowship trained retinal specialist with over 20 years clinical experience. She is a Fellow of Royal College of Ophthalmologists, London and Member of European Society of Retinal Specialists.

Sub Deanery Lead for Ophthalmology (Queen's University, Belfast and Ulster of University, Belfast).

She is actively involved in training and mentoring young doctors as an educational supervisor.

Awarded MD and MSc Medical Education from Queen's University Belfast. She completed a Cochrane Ireland research fellowship and has publications in the area of retinal imaging, AMD, and Diabetic eye disease. She has previously participated in clinical trials and research projects in the role of Principal Investigator. She sits on national committee advocating for the visually impaired.

Marion Munk

Speaker - Gutblick Practice Group, Switzerland and Inselspital, Univ Hospital Bern

Prof. Marion R. Munk is a trained MD, PhD, Uveitis and Medical Retina specialist. She is Chief Scientific Officer and Head of Research at Augenarzt-Praxisgemeinschaft Gutblick AG, Professor at Inselspital, Univ Hospital Bern and adjunct professor at the Northwestern University, Chicago, USA, Director of Eyegnos Consulting and Chief Medical Officer at Isarna Therapeutics. Marion is author of > 270 scientific articles. Her major research interests cover image processing, image analyses, artificial intelligence, macular diseases and uveitis. She is Research chair at the International retinal Imaging Society (InTRIS), member of the Editorial Board of IOVS, Acta Ophthalmologica, Ocular Inflammation and Infection, Ophthalmologica, BMC Ophthalmology and EyeNet and is providing peer-review for a long list of scientific journals within Ophthalmology. She has been recognized on The Ophthalmologist Power List 2026 as one of the 50 global leaders advancing the field of ophthalmology.

Summary Disclosure of conflicts of interest: Consultant for Allergan/Abbvie, Alcon, Alimera, Amgen, Apellis, Astellas, Aviceda Therapeutics, Bayer, Böhringer-Ingelheim, Dandelion, Eyegnos consulting, Eyepoint, Gensight Therapeutics, Isarna Therapeutics, Iveric Bio, Kubota, Lumithera, Novartis, Oculis, Ocuterra, OD-OS, ORA, RetinAI, Roche, Sandoz, Sitala, Zeiss, ONL therapeutics, Ocular Therapeutics, Evolve Medical Education, UBS analytics, J&J, 4DMT

Inga Britt

Panellist - The Norwegian Association of the Blind and Partially Sighted

I currently serve as Research Director at the Norwegian Association of the Blind and Partially Sighted, where I have worked for the past eight years. Prior to this, I was an Associate Professor at the Department of Optometry and Visual Sciences at the University of South-Eastern Norway, where I spent 22 years. My professional experience also includes senior leadership roles as Chief Executive Officer, Clinical Director in private healthcare services, and Municipal Director of Health.

I hold a Dr.philos. in Ocular Neuroanatomy from the University of Oslo, an M.Phil. in Visual Sciences from City University UK, and a Diploma in Optometry from Kongsberg College of Engineering. I have also completed studies in Leadership and Public Administration at The Arctic University of Norway. I have contributed to numerous research projects, including studies on a range of ocular diseases.

Advocacy

In my role at the Norwegian Association of the Blind and Partially Sighted, I represent the perspectives of different patient groups. Furthermore, I bring over 40 years of experience in the field of visual functions and eye health.

Summary Disclosure of conflicts of interest: I hold board positions with the Norwegian Brain Council and Headache Norway, and have contributed to the Global Retina Patient Community Council.

Silvia Specker

Panellist - Industry

Silvia Specker is a Global Regulatory Strategist at Bayer AG in Berlin where she develops regulatory strategies to facilitate the transition of novel Ophthalmology products from the laboratory to patients. She believes multistakeholder discussions are critical to develop and evaluate new clinical endpoints in ophthalmology clinical trials. Together with Bayer clinical experts, she founded the BRIDGE Study Group (Building Research Innovations and Developing Global Endpoints) in 2024 to further ophthalmologic endpoint development.

Silvia joined Bayer in 2008 and has held various roles in Regulatory Affairs across multiple therapeutic areas. She holds a degree in pharmacy and earned a PhD with a focus on molecular biology. In addition, Silvia holds a Master's degree in Drug Regulatory Affairs from the University of Bonn.

Through her work, Silvia aims to contribute to advancements in regulatory strategies and clinical practices within the field of ophthalmology, ensuring that new developments meet the necessary regulatory standards. Her background and ongoing efforts reflect her commitment to improving patient outcomes through effective regulatory frameworks.

Summary Disclosure of conflicts of interest: I would like to disclose any potential conflicts of interest related to my participation in this workshop.

I am currently employed by Bayer AG as Global Regulatory Strategist, where I am involved in my regulatory role in drug development, registration and maintenance of pharmaceutical licenses among others for ophthalmology products.

My role at Bayer includes responsibilities that may intersect with the topics discussed at this workshop, particularly in relation to Geographic Atrophy.

I have not received any additional funding or compensation from external organizations in relation to this workshop.

I hold stock options in Bayer AG.

I am committed to transparency and integrity in my contributions to this workshop, and I will ensure that my involvement is in the best interest of the participants and the objectives of the EMA.

Thomas Aleman

Panellist - Scheie Eye Institute, University of Pennsylvania

Dr. Aleman is an ophthalmologist, board-certified, fellowship-trained medical retina and retinal degeneration specialist. His expertise is in detailed phenotyping of patients and animal models with retinal disease, to contribute to a better understanding of mechanisms of disease with the primary goal of transitioning treatments from the bench, to clinical trials, and ultimately to the clinic. Together with Dr. Artur V. Cideciyan, he co-directs the Center for for Hereditary Retinal Degenerations (CHRD) at the Scheie Eye Institute at the Perelman School of Medicine, University of Pennsylvania. The CHRD oversights the Retinal Degeneration Clinics Clinics and Retinal Structure and Function Laboratories at Scheie Eye Institute, the Perelman Center for Advanced Medicine, and The Children's Hospital of Philadelphia, evaluating patients ranging in age from infancy to late geriatric. He was part of all the pre-clinical trial and trial research that led to landmark trials for Leber congenital amaurosis (LCA) associated with mutations in *RPE65*, which led to the first FDA approved treatment for a genetic retinal disease. Since, this group have confirmed effective genetic treatments for *CEP290*-, *GUCY2D*-, and *LCA5* forms of this devastating conditions,

including the first ever use of gene editing in children with a genetic retinal degeneration. He is actively engaged in numerous active or prospective clinical trials for inherited retinal degenerations, including macular dystrophies. He has contributed hundreds of high impact articles and book chapters.

Adnan Tufail

Panellist - Moorfields Eye Hospital NHS Trust, London

Professor Tufail is a consultant ophthalmologist at Moorfields Eye Hospital and Professor of Ophthalmology at University College London (UCL). He has extensive experience in age-related macular degeneration (AMD) clinical trials and endpoint development. As a member of the MACUSTAR leadership team, he is leading the development and validation of structural, functional and patient-reported composite endpoints for intermediate AMD.

He has previously conducted measurement-precision studies, including work on ETDRS visual acuity, contrast sensitivity and optical coherence tomography (OCT) thickness repeatability. In addition, he contributed to the development of novel microperimetry endpoints, including perilesional and responding sensitivity, which outperform conventional functional endpoints. He has published key analyses demonstrating that geographic atrophy (GA) lesion growth is a poor predictor of decline in visual function, and has led a genome-wide association study (GWAS) distinguishing reticular pseudodrusen from drusen to support patient stratification. He has also contributed to publications on the reliability of retinal-pathology quantification in AMD, with implications for trial design and machine-learning applications, as well as on deep-learning quantification of retinal features in early and late AMD. Pioneering causal inference in ophthalmology, he applied target trial emulation using electronic health records to contextualise single-arm neovascular AMD trials with real-world data. He has been involved in AMD clinical trials across all stages. His current research focuses on translational therapies for intermediate and atrophic AMD.

Summary Disclosure of conflicts of interest: Consultant: 4DMT, Adverum, Annexon, Apellis, Aviceda, Bayer, Boehringer Ingleheim, Cellio (S), Iveric, Janssen, Nanoscope, Novartis, Oculogics (S), OcuTerra, Ocular Therapeutix, Regenxbio,, Roche/ Genentech

Ursula Schmidt-Erfurth

Panellist - Medical University Vienna

Ursula Schmidt-Erfurth, MD, is Professor of Ophthalmology at the Medical University of Vienna, Austria. Her clinical expertise includes surgical and medical retina. Her scientific research focuses on innovative techniques in retinal imaging with a focus on artificial intelligence (AI) and the translational introduction of novel diagnostic and therapeutic strategies in retinal disease. She founded the Vienna Reading Center and the Ophthalmic Image Analysis group (OPTIMA), an interdisciplinary team of computer scientists and retina experts. She holds several patents for the development of novel imaging analysis methods and has published more than 600 scientific peer-reviewed papers. She is a full member of the Austrian Academy of Sciences, the ethics board of the Federation of European Academies of Medicine (FEAM), the Macula Society, Retina Society, ASRS and the Club Gonin et al.

Summary Disclosure of conflicts of interest: AbbVie, ADARx, Alcon, Alkeus, Apellis, Astellas, Aviceda, Bayer, Complement Therapeutics, Genentech, Heidelberg Engineering, Kodiak, Medscape, RetInSight, Roche, Topcon

Giuseppe Querques

Panellist - University of Modena and Reggio Emilia UNIMORE

Giuseppe Querques, MD, PhD, is Full Professor at University of Modena and Reggio Emilia UNIMORE and Chairman of Ophthalmology Unit at University Policlinic of Modena, Italy.

His main research interests are in medical retina and ophthalmic surgery. Dr Querques has contributed to >700 peer-reviewed articles and >20 books and book chapters as editor/author, published mainly in the areas of medical retina (AMD, retinal vascular diseases, hereditary retinal diseases, ophthalmic genetics).

Dr Querques was a board member of the European Association of Retinal Specialists (EURETINA) and is currently a board member of the International Retinal Imaging Society (IntRIS), the Asia Pacific Retinal Imaging Society (APRIS), and the Italian Retina Society (SIR). He is a member of the Retina Society, Club Jules Gonin and the Macula Society, among others, and received the AAO Achievement Award and the Macula Society (Young Investigator Award).

Dr Querques serves currently as editor-in-chief/associate editor/editorial board member of Expert Review of Ophthalmology, Ophthalmologica, Ophthalmology and Therapy, Asia Pacific Journal of Ophthalmology, Nature Scientific Reports, Retinal Cases & Brief Reports, BMC Ophthalmology, and American Journal of Ophthalmology Case Reports.

Summary Disclosure of conflicts of interest: Abbvie: Consultant/Advisor, Alcon: Consultant/Advisor, Apellis : Consultant/Advisor, Baush & Lomb: Consultant, Bayer: Consultant/Advisor, Boehringer Ingelheim: Advisor, EyePoint: Consultant/Advisor, iCARE-CenterVue: Consultant/Advisor, Heidelberg Engineering: Consultant/Advisor, Lumithera: Advisor, Novartis: Consultant/Advisor, Roche: Consultant/Advisor, Sandoz: Consultant/Advisor, Thea: Consultant, Zeiss: Consultant/Advisor

6 - Closing remarks

Christian Gartner

Chair - AGES

Christian Gartner has been a member of the Committee for Medicinal Products for Human Use (CHMP) since 2019, where he presently covers the role of being Alternate Member for Austria. Before entering this role he has been Co-opted member of the CHMP for Biostatistics and clinical trial methodology. In his seven years of CHMP membership Christian Gartner has taken over a large number of Rapporteurships for Marketing Authorization Applications in a range of therapeutic areas, including in the area of ophthalmology.

Christian Gartner has now been working as regulator at the Austrian Agency for Health and Food Safety (AGES) for almost 20 years. In this time he has been a relevant contributor to the European Regulatory Network (EMRN) in several working parties, including the EMA Scientific Advice Working Party (SAWP), where he has served until joining the CHMP.