



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.

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

Chaired by Name Surname (EMA)

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## 11:00 Joining and technical checks

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## 11:30 Welcome and opening speeches

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*Chair: TBC*

**Ways of working for virtual meeting** 5 min  
*Jane Moseley (EMA)*

**Opening statement from Chair of CHMP** 5 min  
*Bruno Sepodes (INFARMED-PT)*

**Opening statement from Patients Perspective** 5 min  
*Name Surname*

**Opening statement from Industry perspective** 5 min  
*Name Surname*

**Opening statement from Academic/health care professional Perspective** 5 min  
*Name Surname*

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## 00:00 Session 1: Potential primary visual functional endpoints for GA pivotal trials: microperimetry, reading speed

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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-SE)*

*Elina Rantala (FIMEA-FI)*

*Muzaffer Özalp (MPA-SE)*

<b>Presentation on microperimetry</b>	<b>20 min</b>
<i>Name Surname</i>	
<b>Presentation on reading speed</b>	<b>10 min</b>
<i>Name Surname</i>	
<b>Panel discussion</b>	<b>25 min</b>
<i>Additional panellists:</i>	
<i>Name Surname</i>	
<i>Name Surname</i>	
<i>Name Surname</i>	

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**00:00 Coffee break**

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**00:00 Session 2: Potential primary visual functional endpoints for GA pivotal trials (visual acuity-based, and contrast-based outcomes). Enrichment and Extrapolation**

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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-IE)*

*Hemme Hijma (MEB-NL)*

**Vision scientist presentations:**

<b>Presentation on best corrected visual acuity, low luminance visual acuity, low luminance deficit</b>	<b>20 min</b>
<i>Name Surname</i>	
<b>Presentation on Contrast sensitivity</b>	<b>10 min</b>
<i>Name Surname</i>	
<b>Panel discussion</b>	<b>25 min</b>

Additional panellists:

Name Surname

Name Surname

Name Surname

**00:00 Lunch**

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**00:00 Session 3: Imaging endpoints, current methods, relationship with histology and retinal function**

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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)*

*Jane Moseley (EMA)*

**Brief outline of principles for validation of a surrogate endpoint options for qualification advice** **10 min**  
*Name Surname (EMRN)*

**Vision scientist presentations:**

**GA Imaging** **20 min**  
*Name Surname*

**GA Histology / imaging overlays– overview and uncertainties** **10 min**  
*Name Surname*

**Overview of structure function relationship** **15 min**  
*Name Surname*

**Panel discussion** **25 min**

*Additional panellists:*

*Name Surname*

*Name Surname*

*Name Surname*

**00:00**      **Coffee break**

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

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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

*Chair:*

*Jane Moseley (EMA)*

*Johanna Wernsperger (AGES – AT)*

**Vision scientist presentations:**

**Presentation on PROs, QoL, Safety outcomes in GA** **15 min**

*Name Surname*

**Panel discussion** **25 min**

*Additional panellists:*

*Name Surname*

*Name Surname*

*Name Surname*

**00:00**      **Session 5: Emerging functional vision endpoints/forward look**

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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 – NL)*

*Tanya Moutray (HPRA – IE)*

**Vision scientist presentation** **15 min**

*Name Surname*

**Panel discussion**

**25 min**

Additional panellists:

*Name Surname*

*Name Surname*

*Name Surname*

**00:00**

**Q&A**

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**00:00**

**Closing remarks**

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**Wrap up**

**10 min**

*Name Surname (EMRN)*

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