

The Geographic Atrophy Long-Term Outcomes Study (GALTOS): Preliminary Analysis of Patient Clinical Characteristics, Retrospective Natural History, and Patient Survey Results

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Introduction

- Geographic atrophy (GA) is an advanced form of age-related macular degeneration, characterized by progressive, irreversible loss of visual function¹
- More than 5 million people are affected by GA worldwide, with the incidence rate predicted to rise as the global population ages¹⁻³
- Significant vision loss caused by GA is associated with worse quality of life (QoL) and increased physical and mental health burdens^{1,4,5}
- There is limited research on the daily experiences of people living with GA^{3,4}

Purpose

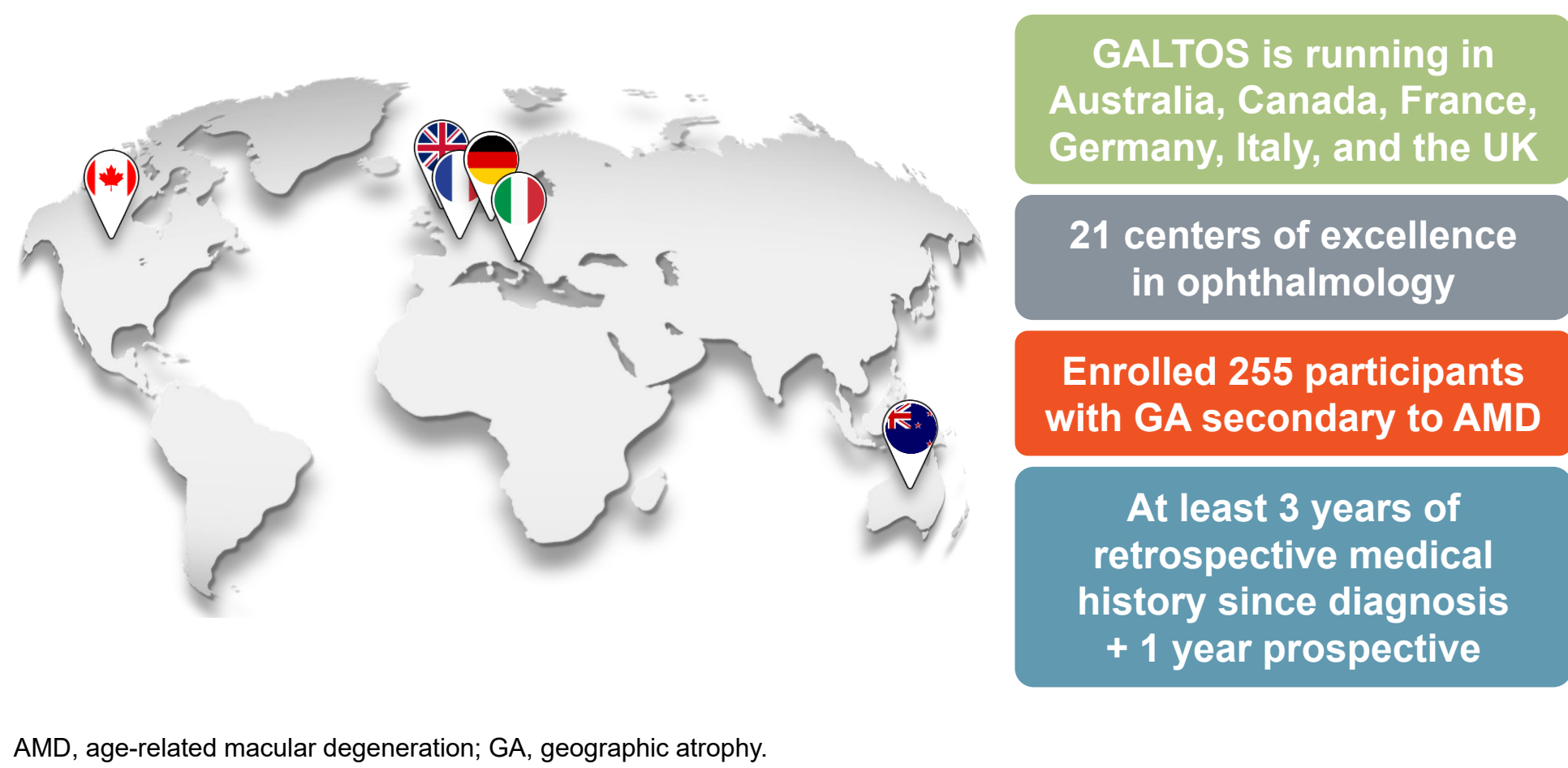
The primary objective of GALTOS is to characterize long-term clinical and functional outcomes of individuals with GA

- What are the demographic and clinical characteristics of people living with GA?
- What are the physical and mental health burdens of GA on people with the disease?

Methods

- GALTOS is an international, ambispective, observational study in individuals diagnosed with GA (**Figure 1**)
 - GA diagnosis between 3–10 years before index date (enrollment) (**Figure 2**)
 - Participants' charts were used to retrospectively collect data from initial diagnosis to enrollment
 - At enrollment and during the prospective 12-month period, participants responded to a survey specifically developed for GALTOS
 - The survey consisted of questions related to performance outcomes, assisted care, and financial impact of GA
- This is the second interim analysis of 255 participants enrolled in the study

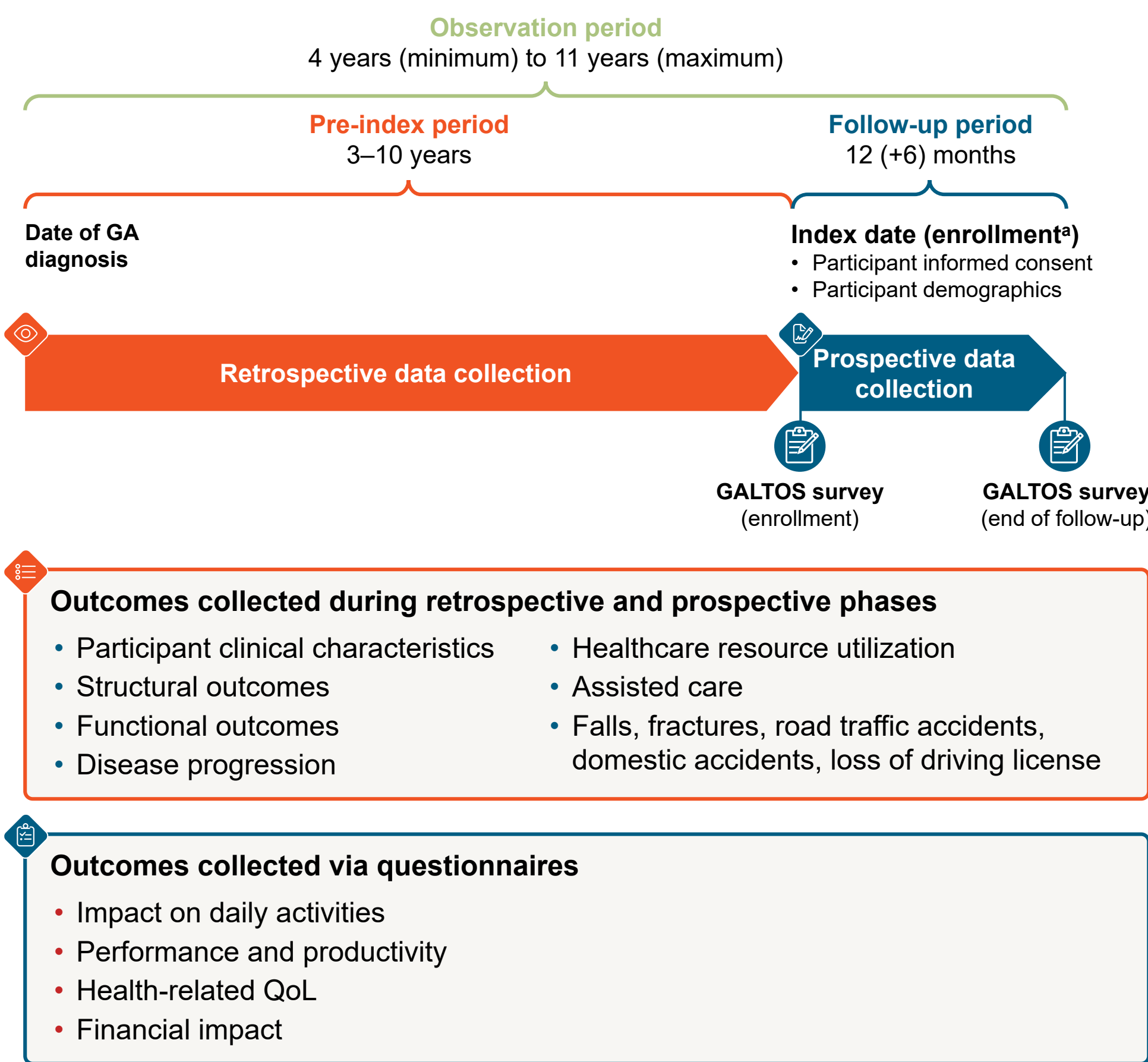
Figure 1. GALTOS: Multinational, Multicenter, Ambispective, Observational Study



AMD, age-related macular degeneration; GA, geographic atrophy.

Figure 2. GALTOS Study Design

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none">✓ Age ≥60 years at time of GA diagnosis✓ First diagnosed with GA in ≥1 eye between 3–10 years prior to index date✓ Bilateral GA or signs of AMD in fellow eye	<ul style="list-style-type: none">✗ GA due to causes other than AMD (eg, Stargardt disease)✗ GA with any concurrent intraocular condition requiring surgical or intravitreal intervention✗ First diagnosed with GA <3 years prior to index date



*Enrollment period: October 2022 to July 2023.
AMD, age-related macular degeneration; GA, geographic atrophy; QoL, quality of life.

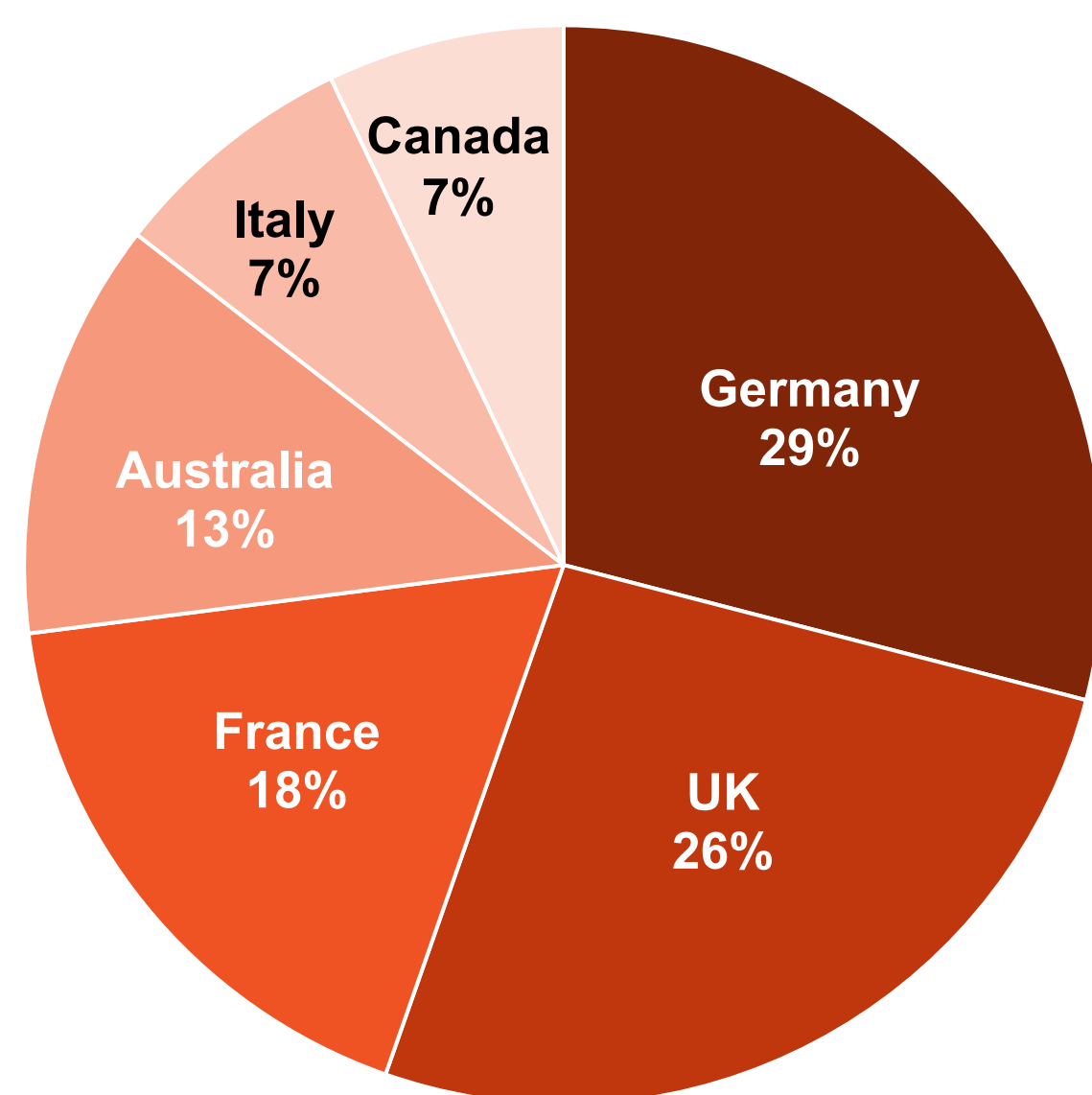
- Additional questionnaires used in the study were:
 - EuroQoL Five Dimension (EQ-5D) Questionnaire
 - Hospital Anxiety and Depression Scale (HADS)
 - 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25)
- Questionnaires were administered at index date and during follow-up

Statistics

- Descriptive statistics were used to summarize primary and secondary outcomes
- For the questionnaires, scores were calculated using the published formula for each instrument, and outcomes were reported with descriptive statistics

Results

- At the data cutoff (April 3, 2024), 255 participants constituted the full analysis set
 - 83 (33%) completed the study
 - 7 (3%) discontinued
 - 165 (65%) were ongoing



- The mean age (standard deviation [SD]) at index was 80.9 (7.2) years, and 62% of participants were female (**Table 1**)

Table 1. Participant Demographics and Disease Characteristics

Participants		n*
Age, mean (SD), years		254
Female, n (%)		254
Disease duration from first diagnosis of GA to enrollment, mean (SD), months		246
GA area at index date, mean (SD), mm ²		139
NL-BCVA at index date, mean (SD), ETDRS letters		376
Time from unilateral to bilateral GA, mean (SD), months		41
Bilateral disease at GA diagnosis, n (%)		246
Retired, n (%)		244
Living situation, n (%)	Live with a partner, child, or other relative	135 (56%)
	Live alone	240 (100 (42%))
	Live in an assisted living facility or retirement home	5 (2%)
Treated at a public institution, n (%)		248

*n=number of respondents.
ETDRS, Early Treatment Diabetic Retinopathy Study; GA, geographic atrophy; NL-BCVA, normal-luminance best-corrected visual acuity; SD, standard deviation.

- Most participants had past or ongoing ocular comorbidities and had received non-GA-related treatments (**Table 2**)

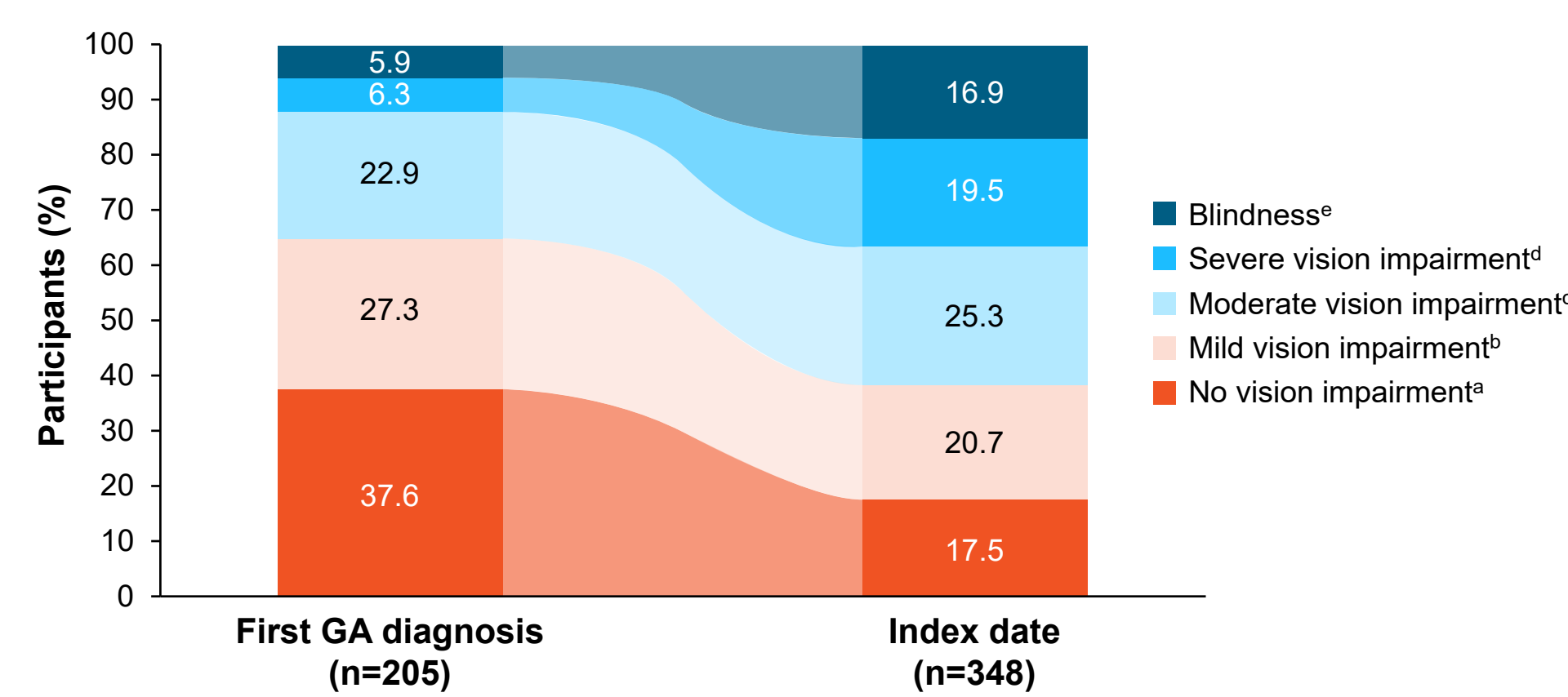
Table 2. Ocular Comorbidities and Treatments Received

Past or Ongoing Ophthalmic Comorbidities, n (%)	GA Eyes (N=463)
Any past or ongoing ocular medical conditions present	441 (95%)
Cataract ^a	101 (23%)
nAMD/MNV (CNV) ^a	55 (12%)
Ophthalmic Treatments Received, n (%)	GA Eyes (N=463)
Cataract surgery	230 (50%)
Intravitreal anti-VEGF	85 (18%)

^aSelect conditions; other past or ongoing conditions noted in >12% of participants were early/intermediate AMD, geographic atrophy, nuclear cataract, and other.
AMD, age-related macular degeneration; CNV, choroidal neovascularization; GA, geographic atrophy; MNV, macular neovascularization; nAMD, neovascular age-related macular degeneration; VEGF, vascular endothelial growth factor.

- Among participant eyes at the time of GA diagnosis:
 - 38% had no visual impairment
 - 6% had severe visual impairment, defined as <35 Early Treatment Diabetic Retinopathy Study (ETDRS) letters and ≥20 ETDRS letters
 - 6% had blindness, defined as <20 ETDRS letters
- In the time between initial GA diagnosis and the study index date, the proportion of participants with visual impairment increased (**Figure 3**)

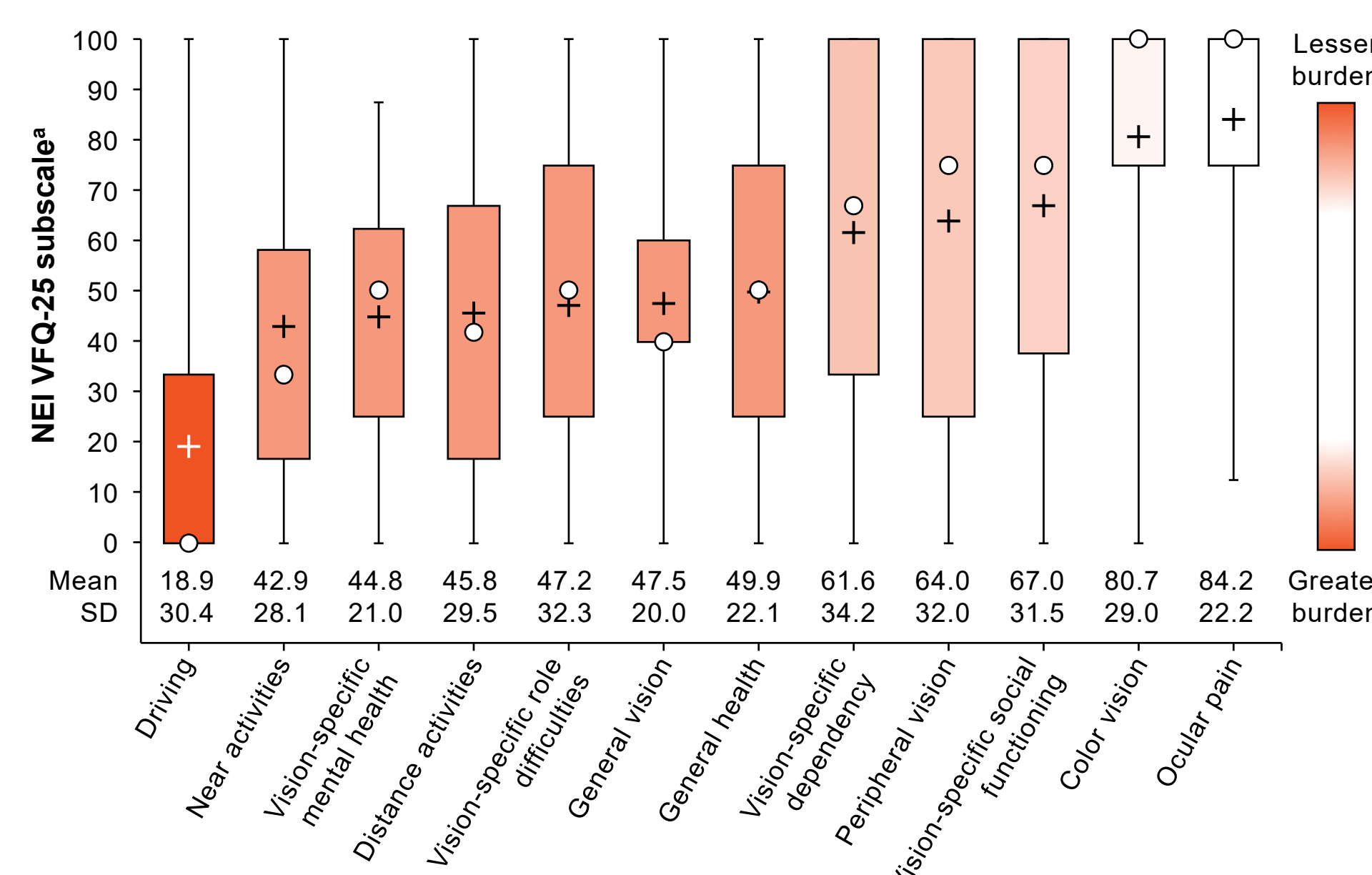
Figure 3. The Proportion of Participants With Severe Visual Impairment Increased Over Time



^aNo vision impairment: ≥70 ETDRS letters. ^bMild vision impairment: <70 ETDRS and ≥60 ETDRS letters. ^cModerate vision impairment: <60 ETDRS and ≥35 ETDRS letters. ^dSevere vision impairment: <35 ETDRS and ≥20 ETDRS letters. ^eBlindness: <20 ETDRS letters. ETDRS, Early Treatment Diabetic Retinopathy Study; GA, geographic atrophy.

- Participants reported low scores on NEI VFQ-25 for driving, mental health, near activities, and distance activities subscales (**Figure 4**)

Figure 4. Impact of GA on Daily Life: NEI VFQ-25 Subscale



In the graph above, the box represents the interquartile range, the circle inside the box is the median, the plus ("+") inside the box is the mean, and the whisker ends denote the minimum and maximum values. N=214 participants for all subscale scores except color vision (n=212) and peripheral vision (n=211).
*A score of 100 represents the best possible score, and 0 represents the worst possible score.
GA, geographic atrophy; NEI VFQ-25, National Eye Institute Visual Function Questionnaire-25; SD, standard deviation.

- Participants reported a wide variety of concerns and physical limitations due to their eyesight (**Table 3**)

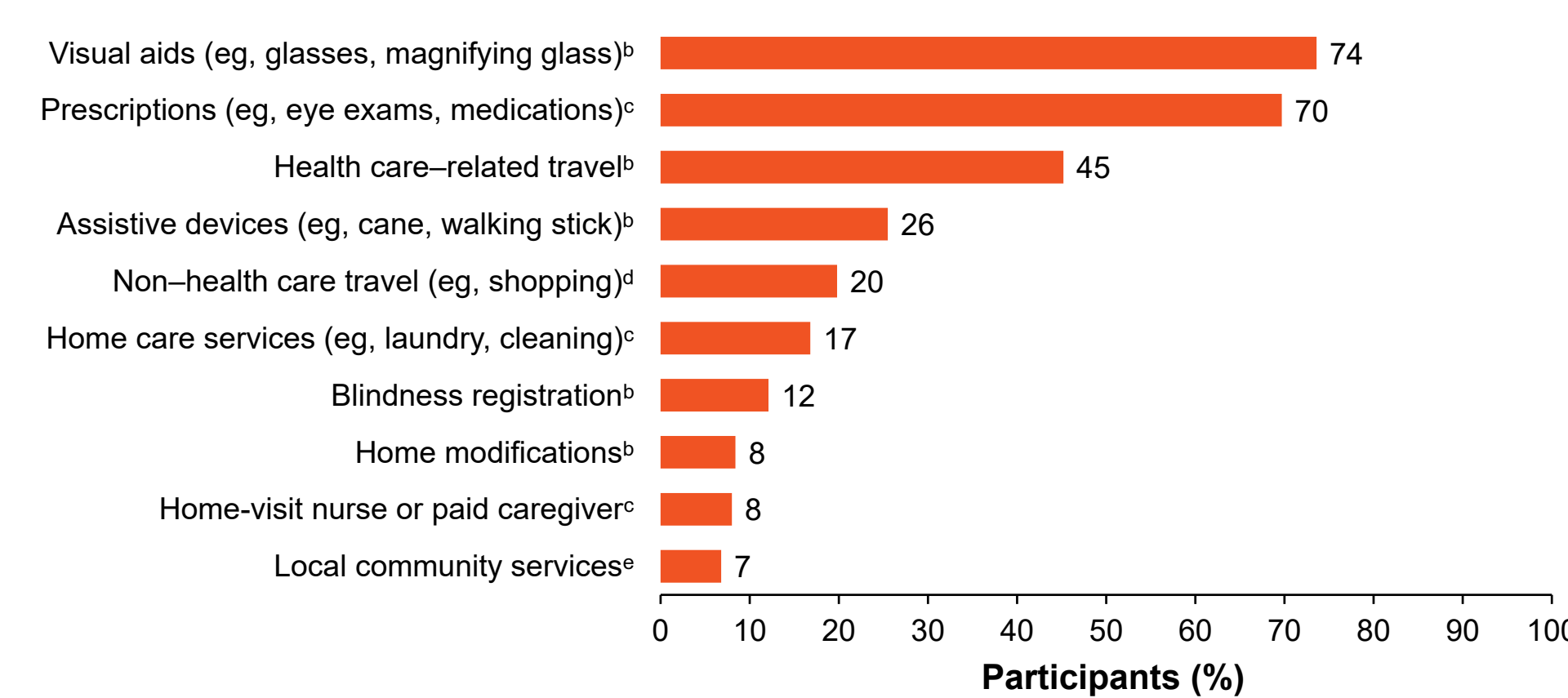
Table 3. Participants Experience Limitations Due to GA

Participants, n (%)		n=240
Falls	Concerned about falling due to eyesight	162 (68%)
	Experienced ≥1 serious fall since GA diagnosis	53 (22%)
	Experienced ≥1 non-serious fall since GA diagnosis	39 (16%)
Difficulty performing daily activities due to GA	Difficulty seeing in bright sunlight	198 (83%)
	Difficulty using electronic devices (eg, remote control, computer) ^a	174 (73%)
	Difficulty being mobile outside the home	142 (59%)
	Difficulty attending exercise classes or exercising at home	141 (59%)
	Difficulty socializing or attending community events	133 (55%)
	Difficulty preparing meals or hot drinks	112 (47%)
	Needing daily help from a caregiver ^b	62 (46%)

^an=239 respondents. ^bn=135 respondents.
GA, geographic atrophy.

- Most participants reported using supportive services due to living with GA (**Figure 5**)
 - Few participants utilize additional support such as assistive devices, paid caregivers, and home care services

Figure 5. Participants' Use of Supportive Care and Resources^a



^aData from GALTOS Patient Survey at index date. ^bn=239. ^cn=238. ^dn=237. ^en=236.

Study Limitations

- Information captured from medical records can be limited by coding errors or omissions, and the data are not intended for research
- As with any survey research, sampling bias and response bias may occur

Conclusions

- Blindness and severe visual impairment increased between the initial GA diagnosis and the study index date
- Patients with GA experienced severe limitations, including the need for daily help in nearly 50% of participants and having had at least one serious fall in more than 20% of participants
- Most participants used visual aids and prescriptions, but only a minority utilized support such as assistive devices, paid caregivers, and home care services
- GA impacts quality of life and the ongoing need for support and resources

References

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