Real-world effectiveness and safety of aflibercept 8 mg in the treatment of neovascular age-related macular degeneration and diabetic macular edema: Design of the SPECTRUM study

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Disclosures

- **Clare Bailey:** Received honoraria from Alimera Sciences, Apellis, Bayer, and Roche; has served on advisory boards for Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche; **CL:** Receives honoraria from Apellis, Bayer, Biogen, and Novartis; **PL:** Consultant for Aerie Pharmaceuticals, Allergan, Annexon, Apellis, Bausch + Lomb, Bayer, Biogen, Boehringer Ingelheim, Eyepoint Pharmaceuticals, Genentech, I-Care, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche; **MRM:** Consulting fees from AbbVie, Allergan, Apellis, Aviceda Therapeutics, Bayer, Boehringer Ingelheim, Dandelion, Eyepoint, Gensight, Iveric Bio, Isarna Therapeutics, Kubota, Lumithera, Novartis, Ocuterra, Oculis, Ocular Therapeutix, RetinAI, Roche, and Zeiss; **HO:** Consultant for AbbVie, Bayer, Novartis, and Roche; **TM:** Employee of Bayer AG; **HA, XZ, and ZH:** Employees of Bayer Consumer Care AG; **VC:** Receives grants from Bayer, Novartis, Roche; serves on advisory boards of Alcon, Roche, Bayer, Novartis, Apellis, and Boehringer Ingelheim
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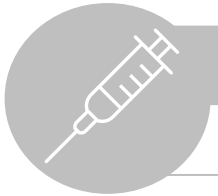
SPECTRUM overview

Prospective real-world study in 18 countries

North America, Europe, the Middle East, and Asia Pacific

Two indications, four patient cohorts

Treatment-naïve **nAMD** and previously treated **nAMD**
Treatment-naïve **DME** and previously treated **DME**



Treated with intravitreal aflibercept 8 mg

Per routine clinical practice

Data collection from medical records for up to 24 months per patient

Feb 2024 to Sep 2027

nAMD, neovascular age-related macular degeneration; DME, diabetic macular edema

SPECTRUM inclusion criteria

	Population	Diagnosis	Treatment
nAMD cohorts	Aged ≥ 50 years	A diagnosis of nAMD	Patients across all cohorts had to have been prescribed aflibercept 8 mg as part of routine clinical practice
DME cohorts	Aged ≥ 18 years with type 1 or type 2 diabetes mellitus	A diagnosis of DME	

All patients were categorized as being either:

Treatment-naïve
Never been exposed to any medical treatment for nAMD/DME

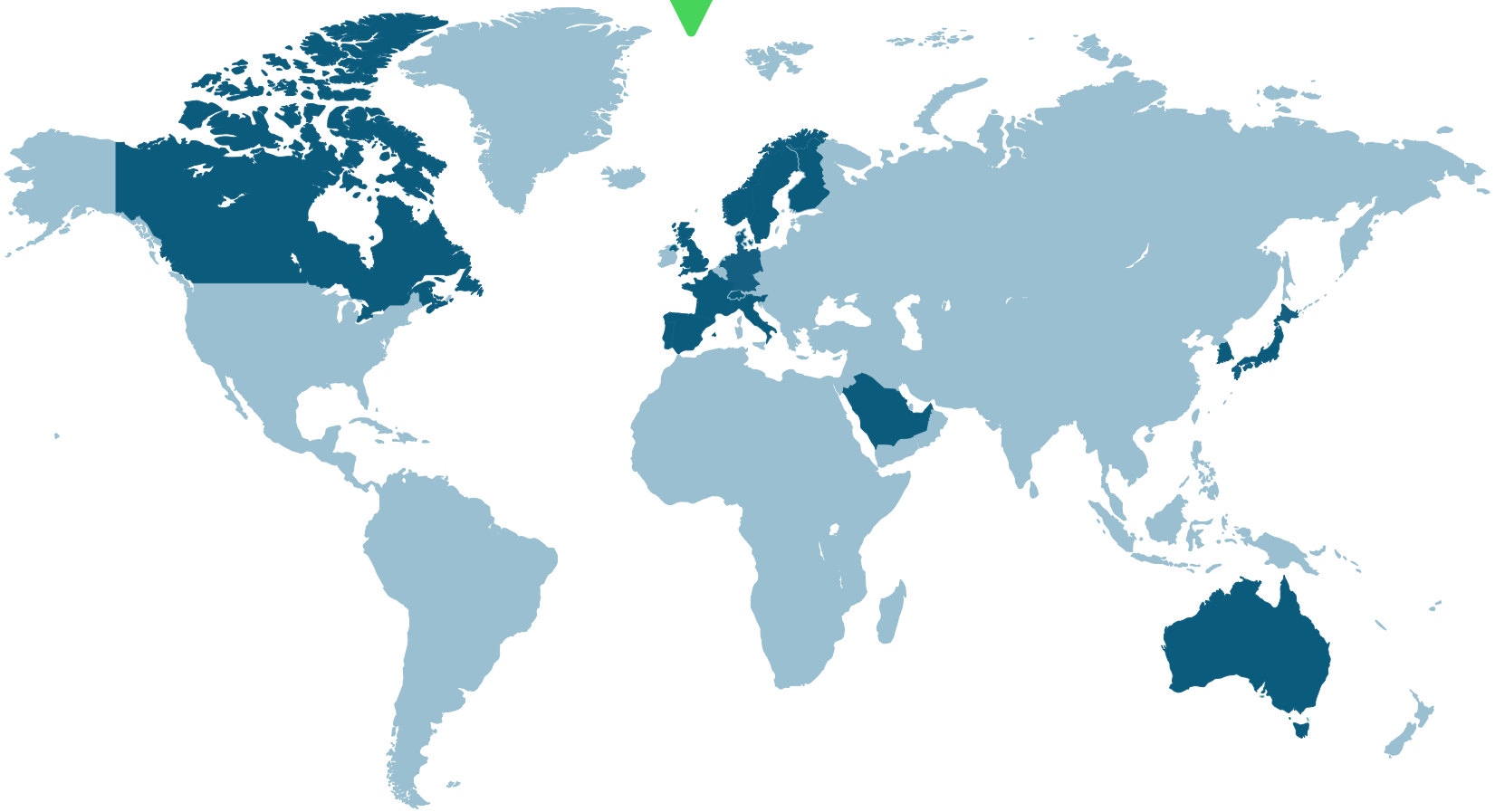
Previously treated
Received prior treatment, including other anti-VEGFs, up to prespecified timepoints before study start

anti-VEGF, anti-vascular endothelial growth factor

SPECTRUM enrollment

SPECTRUM is a **country** and **global cohort** study planned in **18 countries**

To date, **1048** patients enrolled



It is expected that a minimum of ~2500 patients will be enrolled

It is planned that each **participating country/country cluster** will contribute ~100 patients to 1 or more of the 4 cohorts

SPECTRUM endpoints

Primary endpoint:

Change in BCVA from BL to Month 12

Secondary endpoints include:

Change in BCVA from BL to Weeks 4 and 8, and Months 6 and 24

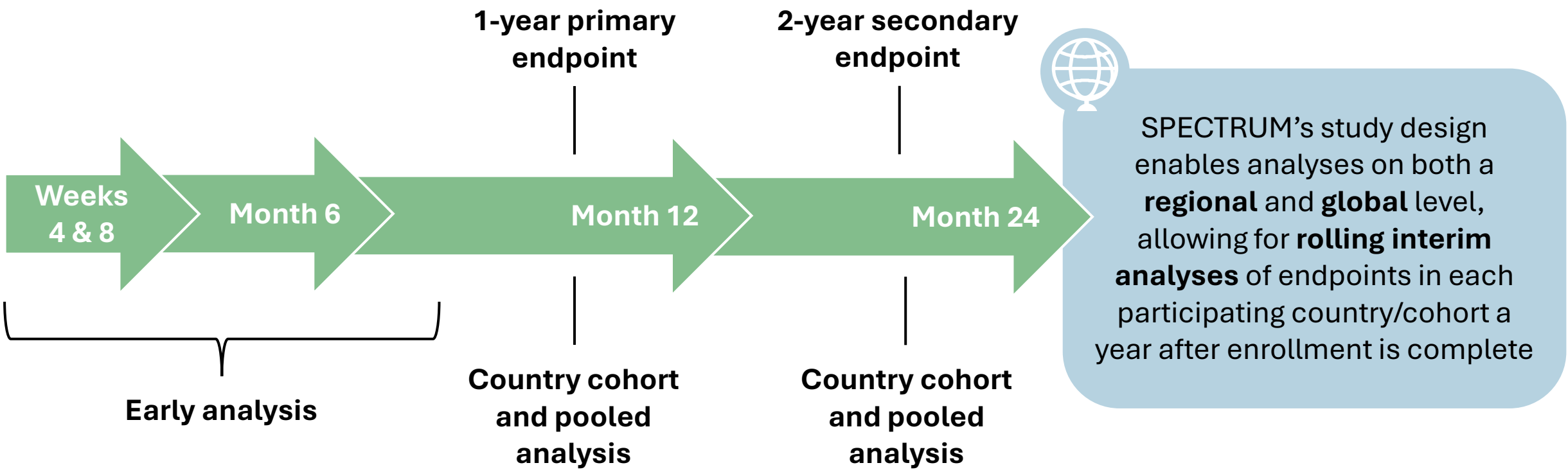
Change in CRT from BL to Weeks 4 and 8, and Months 6, 12, and 24

Number of aflibercept 8 mg injections from BL to Months 6, 12, and 24

Number of adverse events and **serious adverse events**

BCVA, best-corrected visual acuity; BL, baseline; CRT, central retinal thickness

SPECTRUM timeline and analyses



SPECTRUM's study design enables analyses on both a **regional** and **global** level, allowing for **rolling interim analyses** of endpoints in each participating country/cohort a year after enrollment is complete

All analyses will be of an exploratory and descriptive nature

Conclusions

As the **first global real-world study on aflibercept 8 mg**, SPECTRUM will generate a **wealth of long-term data** on the real-world **effectiveness and safety** of **aflibercept 8 mg** in **nAMD** and **DME** across geographically and clinically **diverse patient populations**

The design of SPECTRUM allows **rolling interim analyses** of endpoints in each participating country/cohort 1 year following completion of enrollment

To date, **1048 patients** have been enrolled, with the **first set of evaluations** underway