



Similar Visual and Anatomic Outcomes with Fewer Injections with Aflibercept 8 mg Versus 2 mg by Baseline Age, Sex, and Race in Patients with Treatment-naïve Macular Edema Following Retinal Vein Occlusion: A Week 64 QUASAR Subgroup Analysis

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Disclosures

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QUASAR Study Design



A multicenter, randomized, double-masked, Phase 3 study in patients with treatment-naïve macular edema secondary to RVO
Randomly assigned at baseline 1 (2q4) : 1 (8q8/3) : 1 (8q8/5)

2q4

Aflibercept 2 mg initiated with 9 monthly injections, followed by T&E^a
n=301

8q8/3

Aflibercept 8 mg initiated with 3 monthly injections, followed by Q8 and T&E^a
n=293

8q8/5

Aflibercept 8 mg initiated with 5 monthly injections, followed by Q8 and T&E^a
n=298

Primary
endpoint

EOS
Key secondary
endpoint

	Day 1	W4	W8	W12	W16	W20	W24	W28	W32	W36	W40	W44	W48	W52	W56	W60	W64
2q4	X	X	X	X	X	X	X	X	X	T&E	T&E	T&E	T&E	T&E	T&E	T&E	
8q8/3	X	X	X	o	X	o ^b	X	o ^c	X	T&E	T&E	T&E	T&E	T&E	T&E	T&E	
8q8/5	X	X	X	X	X	o	X	o ^c	X	o ^c	X	T&E	T&E	T&E	T&E	T&E	

DRM for interval shortening

Dosing interval shortened by 4 weeks beginning at W16 for 8q8/3, W24 for 8q8/5, or W40 for 2q4 if both the following criteria were met at a dosing visit:

- BCVA loss of >5 letters from the reference visit, AND
- >50 µm increase in CRT from the reference visit^d

DRM for interval extension

Dosing interval extended by 4 weeks starting at W32 for 8q8/3 and 2q4 and at W40 for 8q8/5 if both the following criteria were met at a dosing visit:

- BCVA loss of <5 letters from the reference visit^d, AND
- CRT <320 µm Heidelberg/<300 µm Cirrus or Topcon SD-OCT

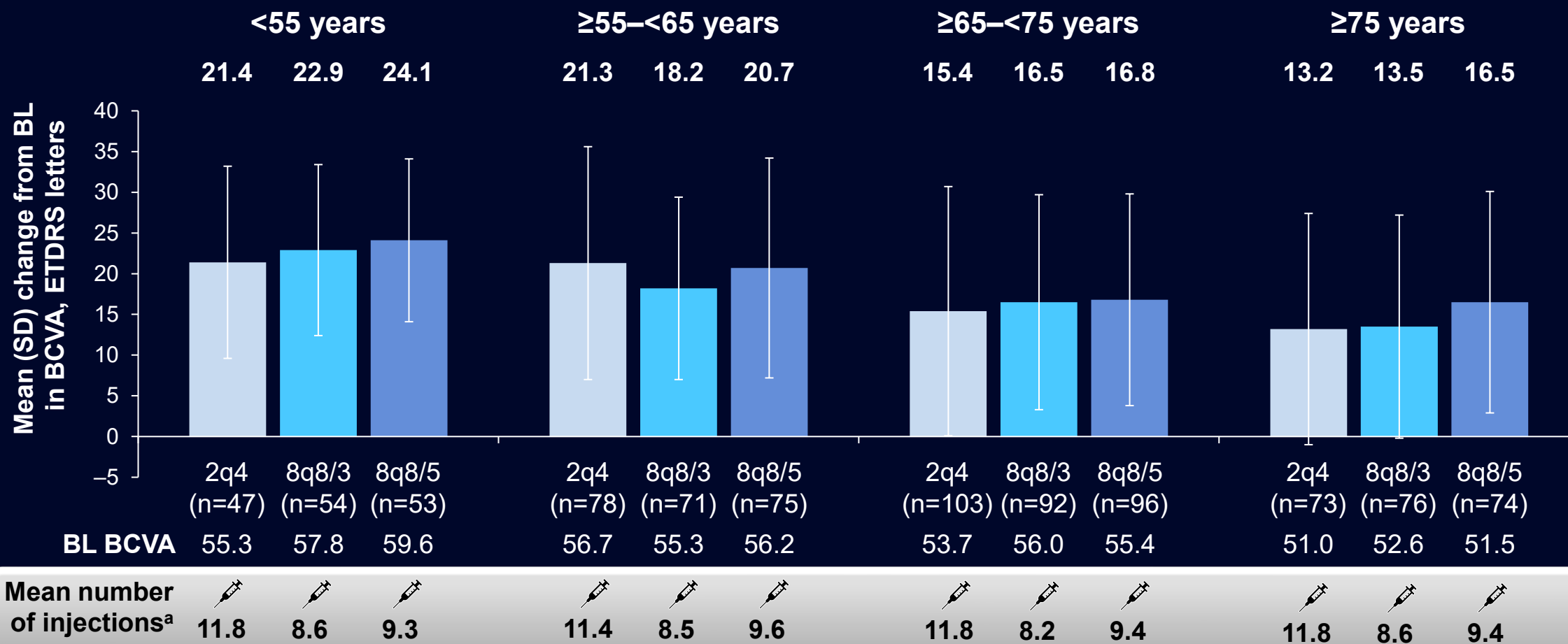
The primary efficacy endpoint was change from baseline in BCVA at W36, with a non-inferiority margin of 4 letters. Stippled boxes = initial treatment phase; X = active injection; o = sham injection.

Note: Table does not reflect all dosing options once a patient's dosing interval is shortened. ^aWith opportunity for extension per DRM. ^bActive injection for patients meeting DRM criteria at W16. ^cActive injection for patients meeting DRM criteria from W16 for 8q8/3 or W24 for 8q8/5. ^dReference is W12 for 8q8/3 and W20 for 8q8/5 and 2q4 (denoted by green boxes on table).

2q4, aflibercept 2 mg administered every 4 weeks; **8q8/3**, aflibercept 8 mg administered every 8 weeks, after 3 initial injections at 4-week intervals; **8q8/5**, aflibercept 8 mg administered every 8 weeks, after 5 initial injections at 4-week intervals; **BCVA**, best-corrected visual acuity; **CRT**, central subfield retinal thickness; **DRM**, dose-regimen modification; **EOS**, end of study; **Q8**, every 8 weeks;

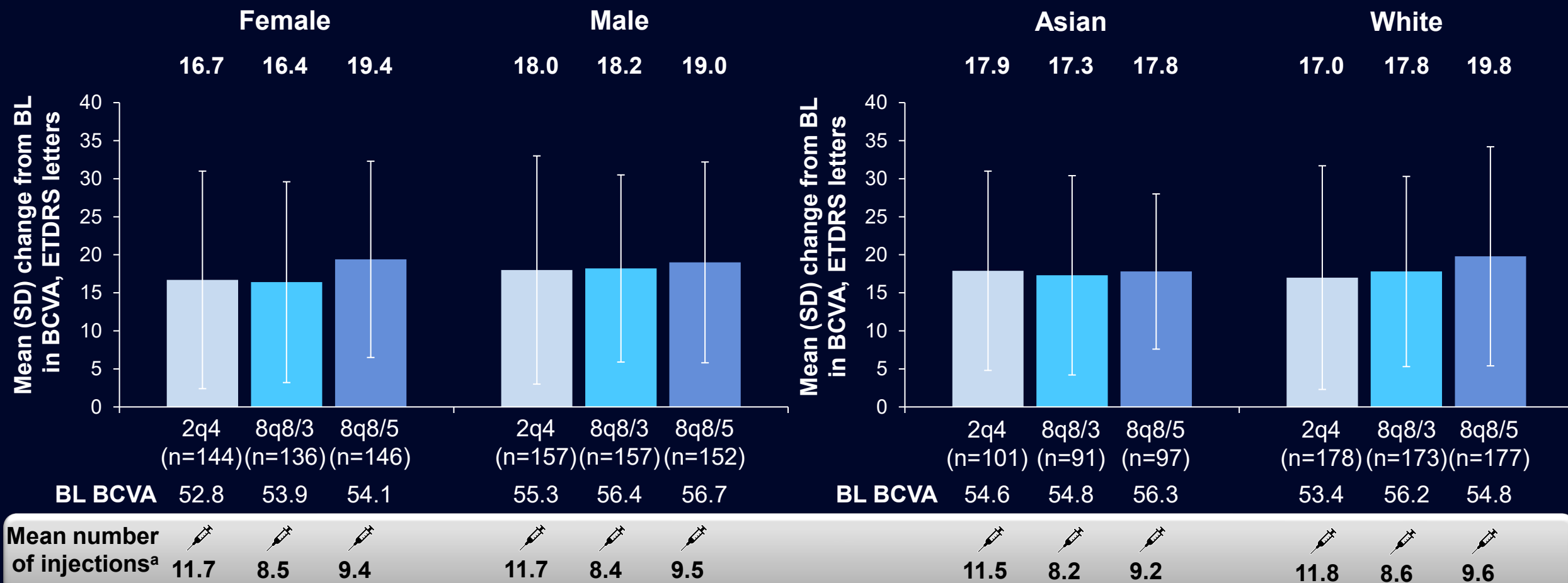
RVO, retinal vein occlusion; **SD-OCT**, spectral-domain optical coherence tomography; **T&E**, treat and extend; **W**, week.

Mean Change From BL in BCVA at W64 was Generally Comparable Across Treatment Groups by Age

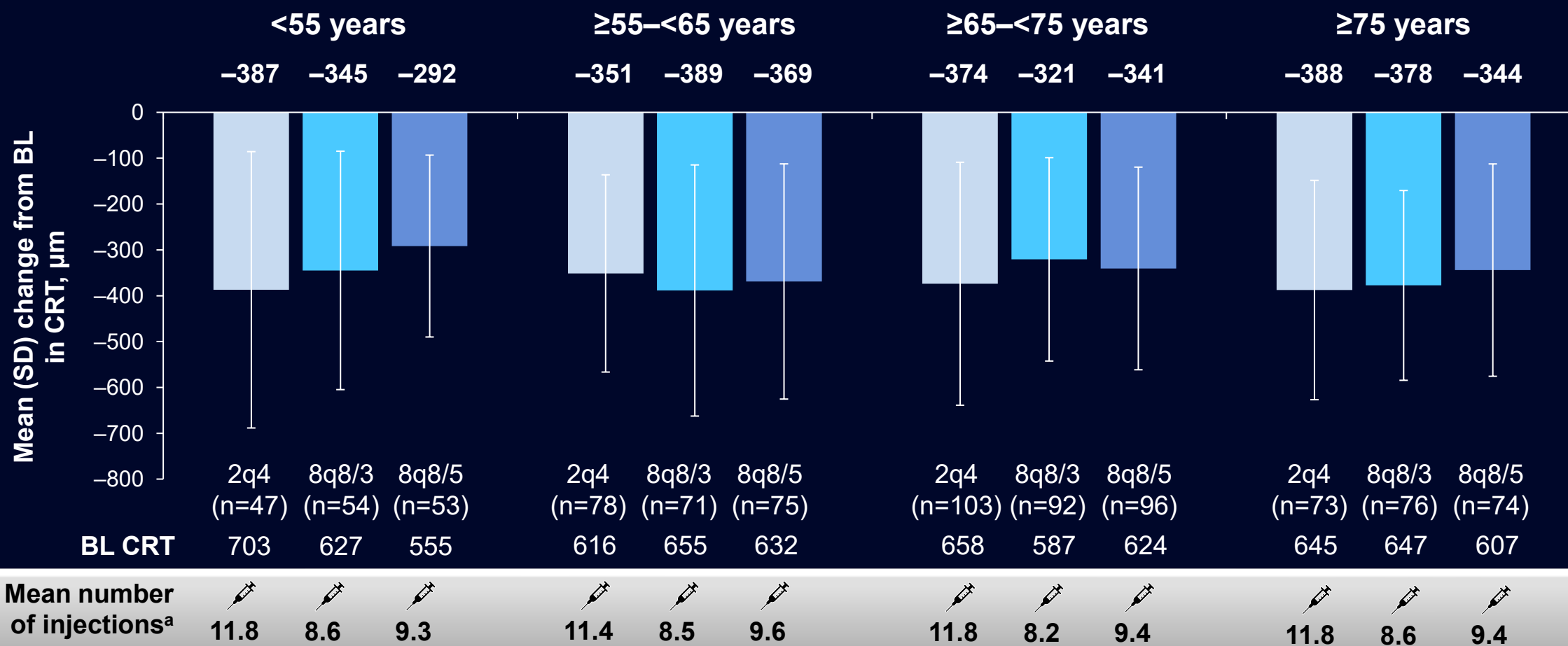


Full analysis set. Observed values (censoring data post intercurrent event). ^aSafety analysis set, only patients considered as completers for W64.
 BL, baseline; ETDRS, early treatment diabetic retinopathy study; SD, standard deviation.

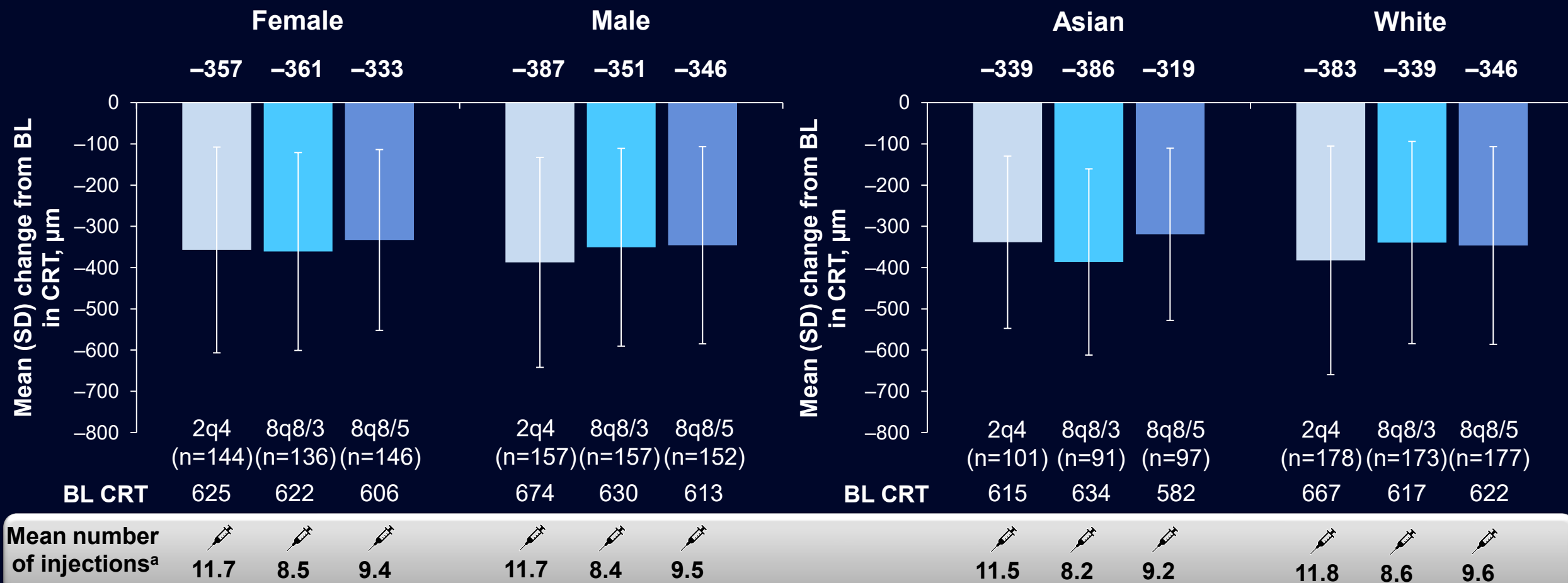
Mean Change From BL in BCVA at W64 was Similar Across Treatment Groups by Sex and Race



Mean Change From BL in CRT at W64 was Generally Comparable Across Treatment Groups by Age

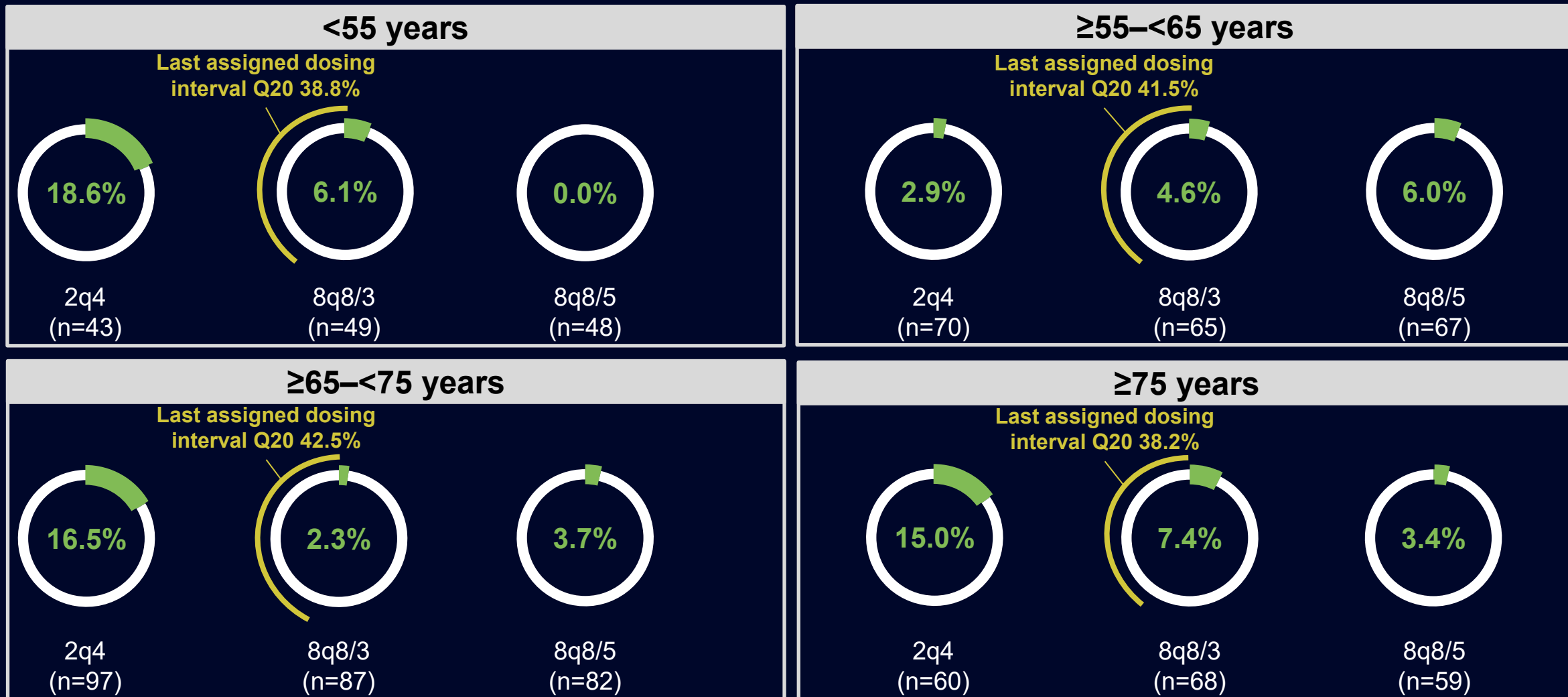


Mean Change From BL in CRT at W64 was Similar Across Treatment Groups by Sex and Race



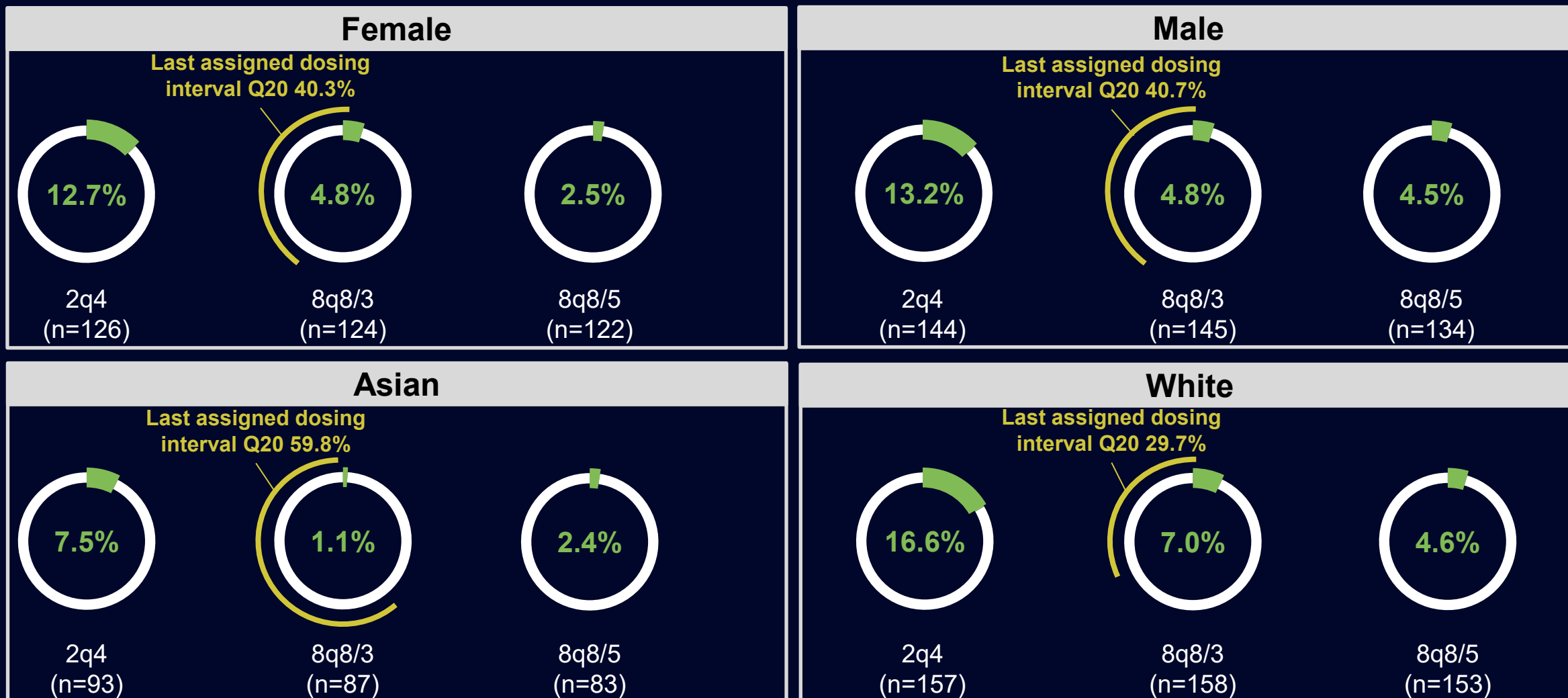
Generally, Fewer Patients Receiving Aflibercept 8 mg Versus 2 mg had a Last Completed Q4 Interval at W64 Regardless of Age Subgroup

Proportion of patients with last completed
Q4 interval at W64



At W64 Fewer Patients Receiving Aflibercept 8 mg Versus 2 mg had a Last Completed Q4 Interval Regardless of Sex and Race Subgroups

Proportion of patients with last completed Q4 interval at W64



Aflibercept 8 mg at Extended Dosing Intervals Achieved Sustained Disease Control with Fewer Injections versus Aflibercept 2 mg Regardless of Age, Sex or Race



- Across evaluable subgroups of BL age, sex, and race, visual and anatomic gains through W64 were **comparable with fewer injections of aflibercept 8 mg versus aflibercept 2 mg**
 - Aflibercept 8q8/3 and 8q8/5 groups achieved **similar clinically meaningful BCVA gains and robust reductions in CRT from BL**, with fewer injections than in the aflibercept 2q4 group at W36 and W64
 - At W64, **fewer patients receiving aflibercept 8 mg versus 2 mg** had a **last completed dosing interval of every 4 weeks while more had intervals of $\geq$ Q12**, regardless of BL age, sex and race subgroups