

Outcomes of Anti-VEGF Therapy for Neovascular Age-Related Macular Degeneration in Routine Clinical Practice

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Saturday, July 21, 2018

Disclosures

- Consulting: Regeneron, Genentech, Allergan, Visunex, Valeant, Spark
- Research funding: Regeneron, Genentech

Dosing Approaches in Clinical Trials are Varied

Quarterly

- PIER⁸
- SAILOR⁹
- EXCITE¹⁰

PRN^{11,12}

- HARBOR³
- CATT⁴
- RESOLVE¹³
- RESTORE¹⁴
- Protocol I¹⁵
- Protocol T¹⁶

Treat-and-Extend^{11,12}

- LUCAS¹⁷
- TREX¹⁸

Monthly

- ANCHOR¹
- MARINA²
- HARBOR³
- CATT⁴
- RISE/RIDE⁵
- VIEW 1/2⁶
- VISTA/VIVID⁷

Bimonthly

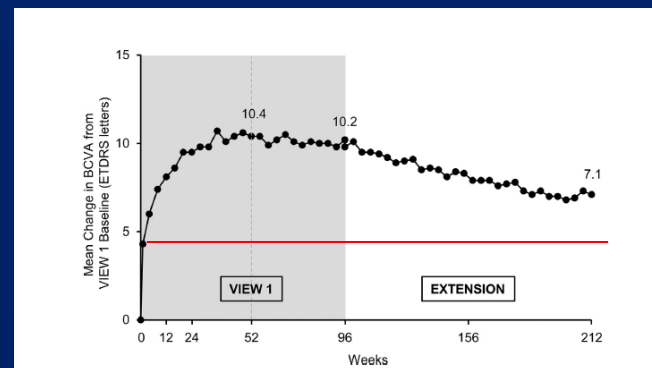
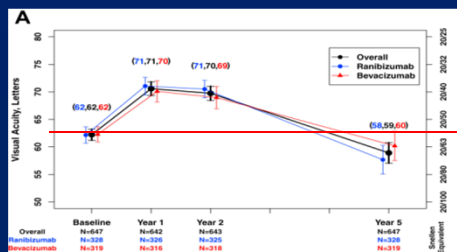
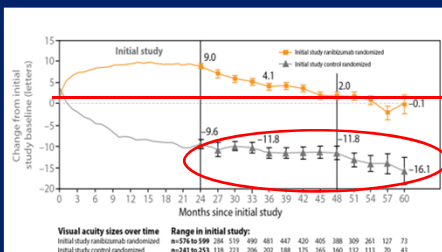
- VIEW 1/2⁶
- VISTA/VIVID⁷

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Long-term Trials in AMD Demonstrated that

Deviation from Vision Stable During Results and Decline of Visual Acuity Over Time

And Vision Could Largely be Maintained When Patients with Wet AMD Were Treated Consistently



HORIZON	
Dosing Regimen in Extension Phase	PRN
Mean Number of Injections	
Year 3	2.2**
Year 4	2.0**

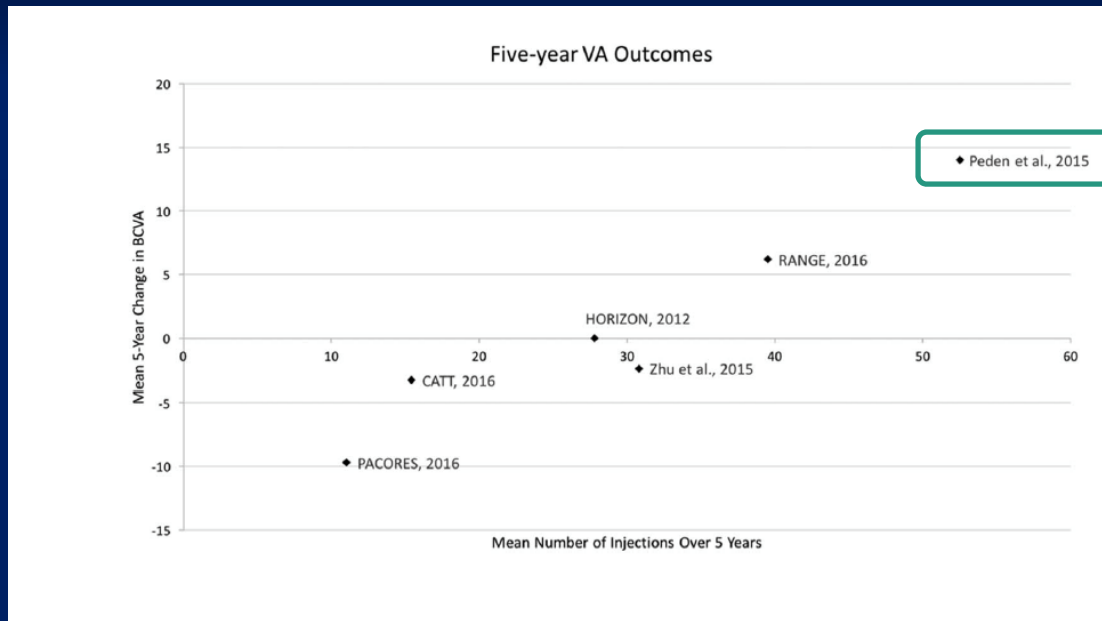
CATT	
Dosing Regimen in Extension Phase	Investigator Determined
Mean Number of Injections	
Year 3	4.8
Year 4	4.5
Year 5	4.0

VIEW 1 Extension	
Dosing Regimen in Extension Phase	Modified Quarterly*
Mean Number of Injections	
Year 3	6.0
Year 4	5.5

**Calculated from the cumulative injection total

All patients received IAI 2 mg on a modified quarterly dosing schedule until the amendment in June 2012 mandated q8 dosing
*Mandatory dosing at least every 12 weeks, up to monthly injections possible

Five Year Visual Acuity Outcomes vs Injection Frequency in wAMD



Fixed q4/q8 weeks (10.5 injs/year)

“The body of evidence to date regarding long-term anti-VEGF treatment indicates a variable course at greater than 36 months follow-up and seems to be dependent on the treatment protocol. Consistent dosing with fluid-free interval is suggested to maintain VA gains in patients with exudative age-related macular degeneration.”

Analysis of Outcomes in Routine Clinical Practice

Study Design

- **Objective**

- To evaluate visual acuity outcomes following treatment neovascular AMD with intravitreal anti-VEGF agents in routine clinical practice through 2 years

- **Methods**

- Electronic medical record data* collected from 251 Retina Specialists for patients with –
 - *Neovascular age-related macular degeneration*
- Anti-VEGF treatment naïve eyes
 - 1st anti-VEGF injection between January 1st, 2012 and April 30th, 2015
- Two subgroups evaluated –
 - *Group 1: ≤6 injections/year*
 - *Group 2: ≥7 injections/year*

*Source: Vestrum Database

Patient Selection

Year 1

Assessed for eligibility
n = 213,824

1st anti-VEGF between 01/01/12 – 04/30/15
n = 26,943

VA reading on index date
n = 22,638

No treatment break for >11
months through year 1
n = 21,148

VA reading at month 12
n = 9,248

VA reading in all 4 quarters
n = 8,131

Gender identified
n = 8,127

Baseline Characteristics

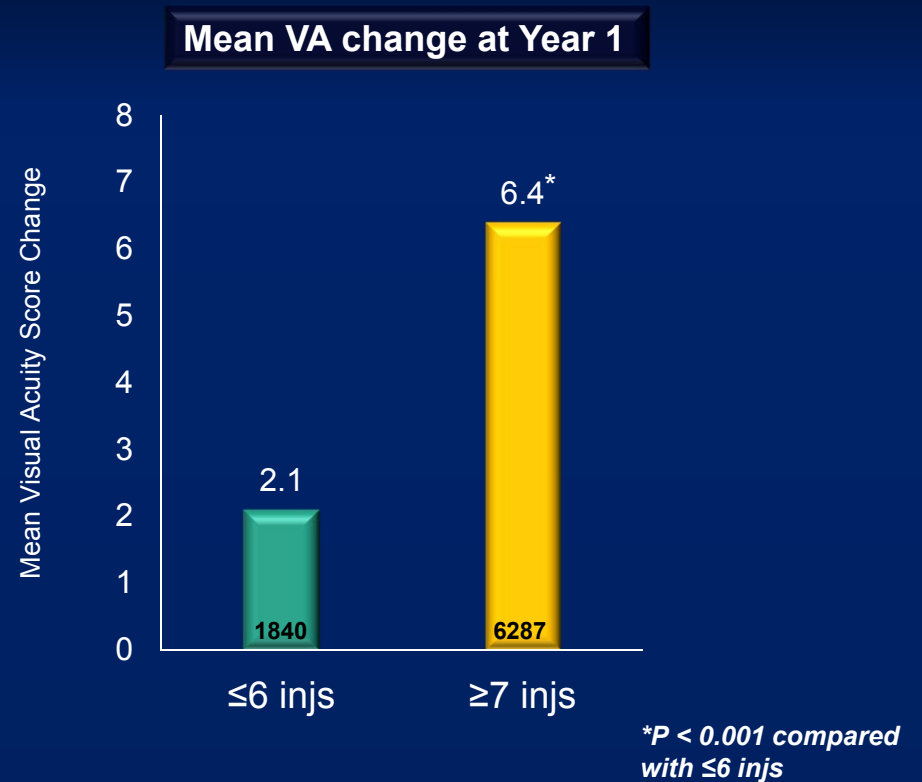
	Total (n=8127)	≤6 injections (n=1840)	≥7 injections (n=6287)
Mean Age, years	80	80	80
Female, %	64%	63%	65%
Mean VA, letters	65	61	66
Median VA, letters	74	72	74
VA Subgroups			
≥20/40	22%	23%	21%
<20/40 – 20/100	47%	39%	49%
<20/100 – 20/200	15%	13%	15%
<20/200	17%	24%	15%

Patients included in Year 1 analysis

Mean Visual Acuity Change By Injection Subgroups (Year 1)

Subgroup	Mean BSL VA
≤6 injs (n=1840)	61
≥7 injs (n=6287)	66

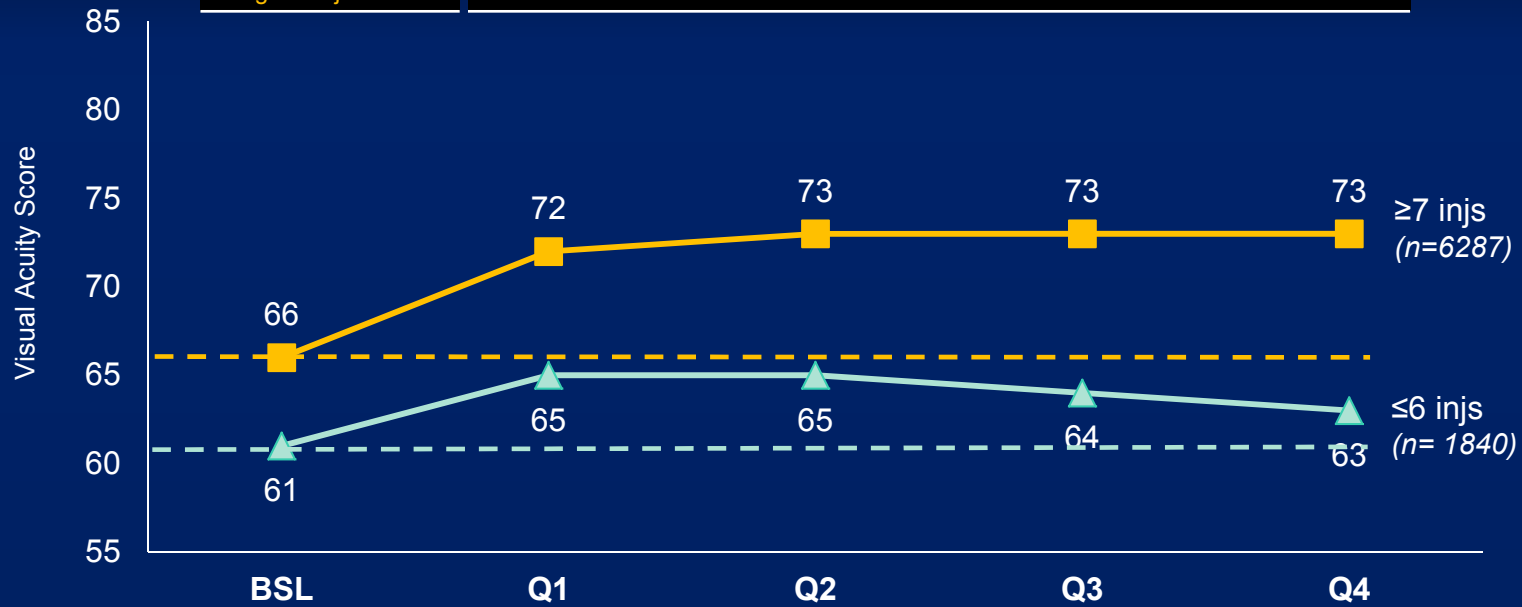
Subgroup	Mean Number of Injections
≤6 injs (n=1840)	4.5
≥7 injs (n=6287)	9.1



Visual acuity is reported in visual acuity score (VAS)

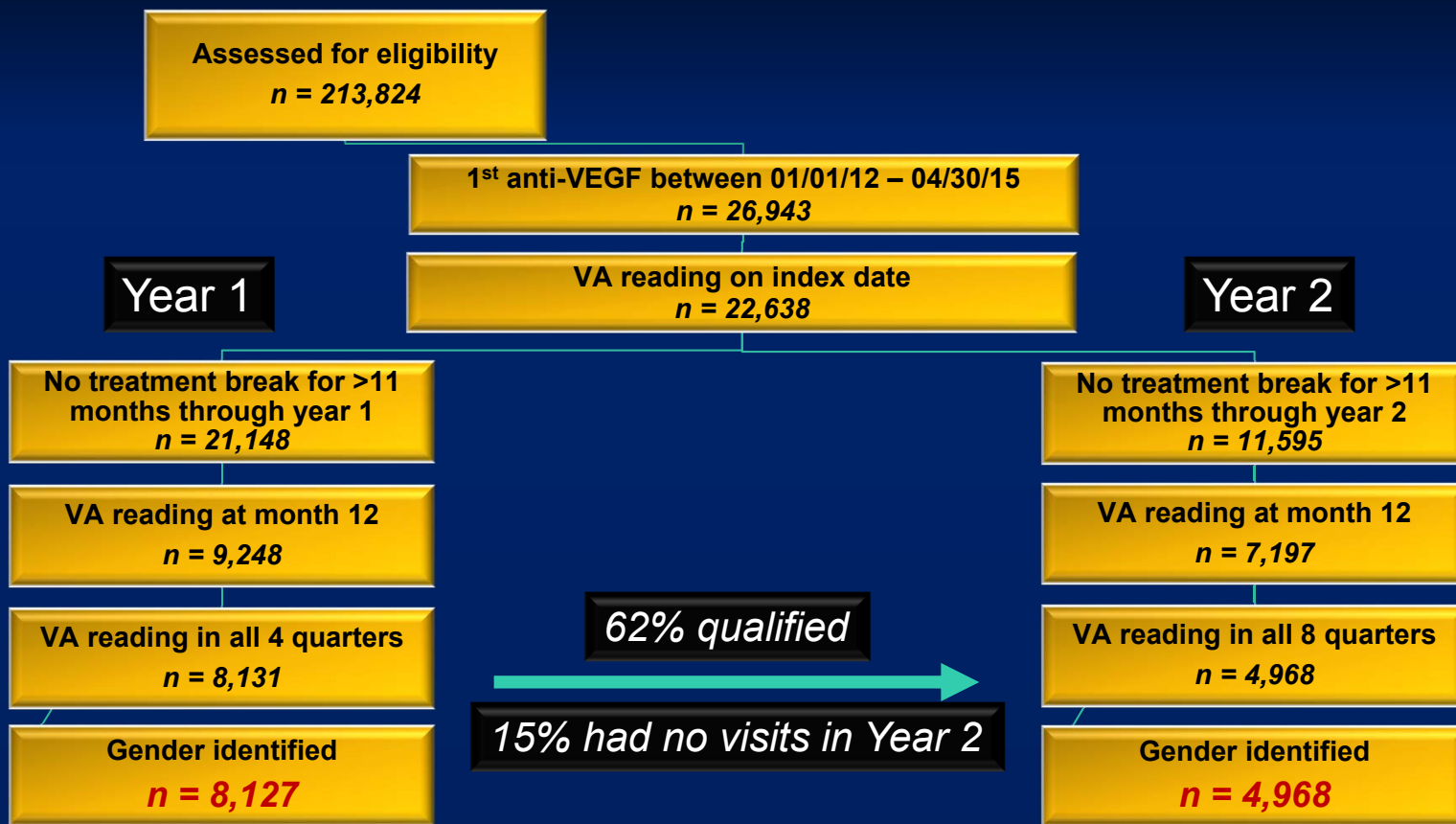
Mean Visual Acuity by Injection Subgroups (Year 1)

Mean # of Injections	3.1	2.1	1.9	2.0
Range of Injections	1-6	0-5	0-6	0-6



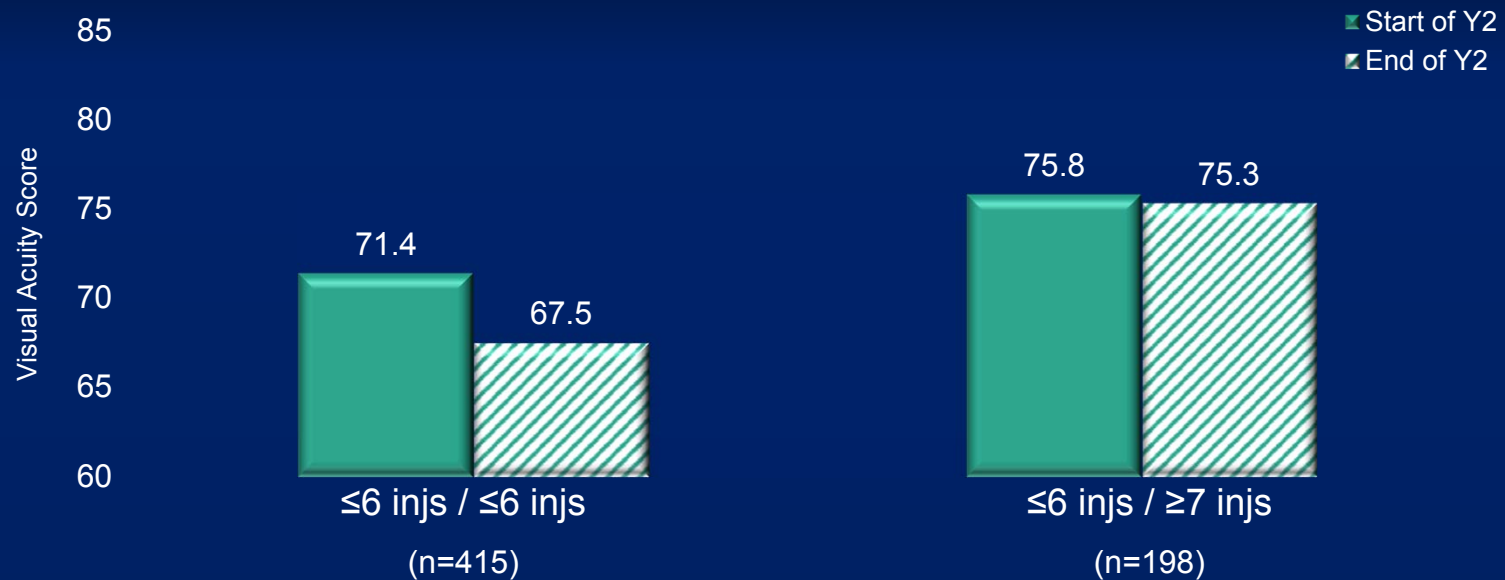
Mean # of Injections	2.4	0.8	0.6	0.7
Range of Injections	1-5	0-3	0-3	0-4

Patient Selection Year 2



Mean Visual Acuity by Injection Subgroups (Year 2)

Patients Receiving ≤ 6 injections in Year 1

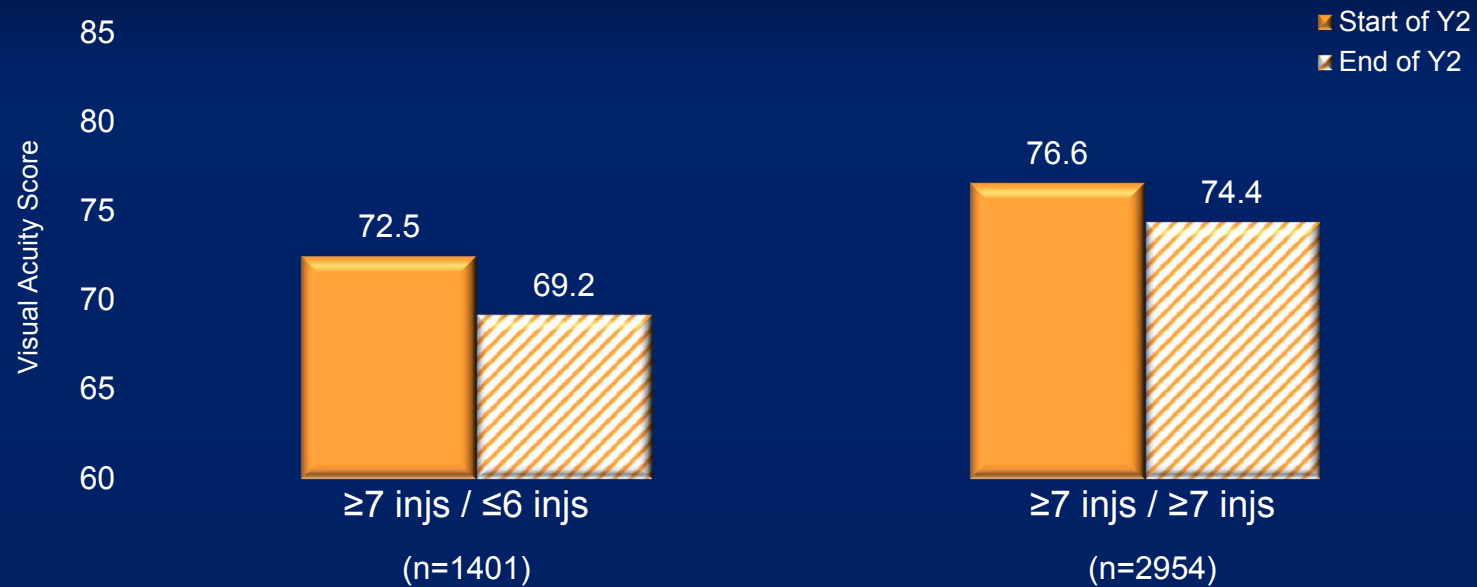


Mean number of injections

Year 1	5.2	5.3
Year 2	4.4	8.2

Mean Visual Acuity by Injection Subgroups (Year 2)

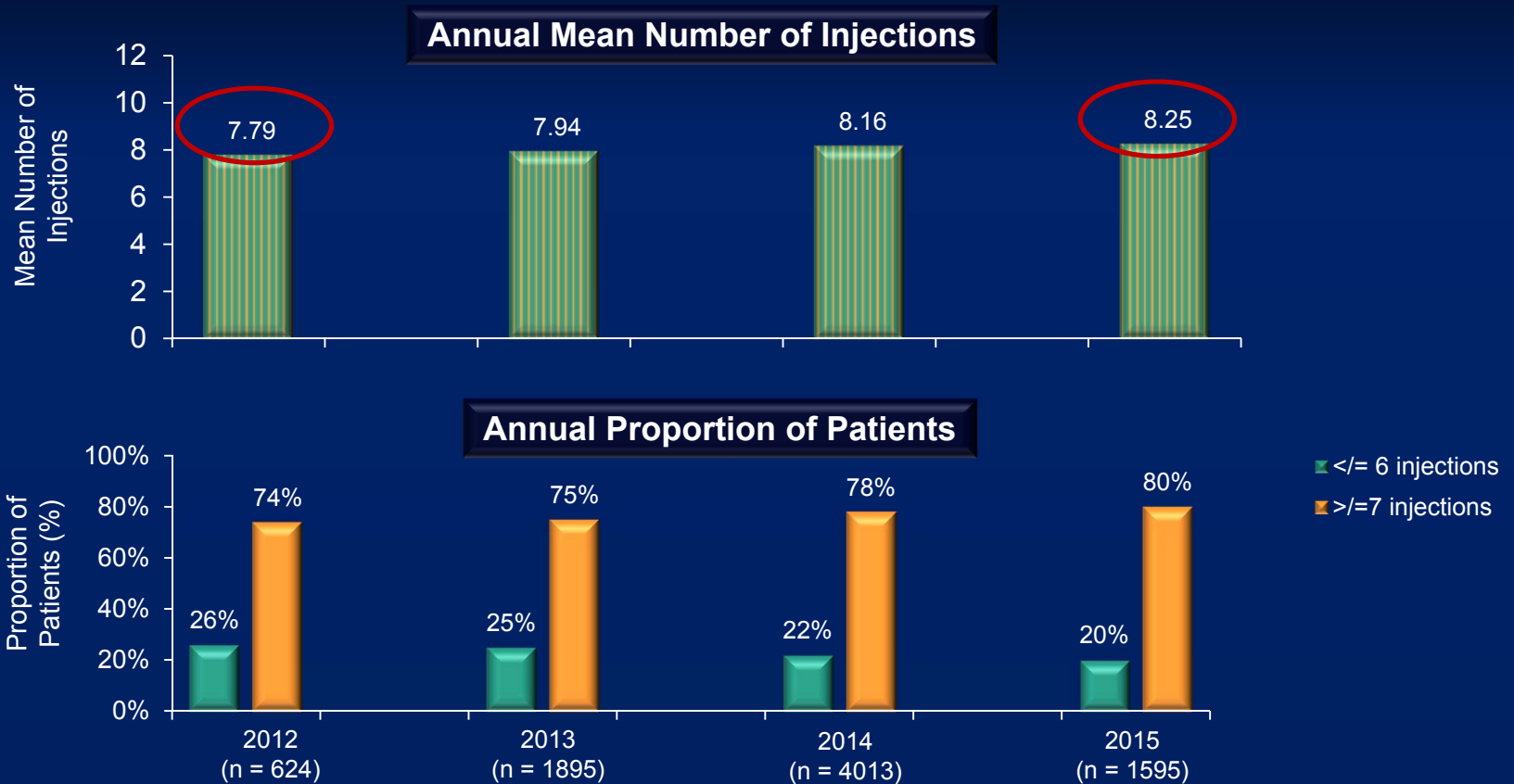
Patients Receiving ≥ 7 injections in Year 1



Mean number of injections

Year 1	8.5	9.7
Year 2	5.0	9.1

Change Over Time in Injection Frequency During Year 1 of Treatment



Summary

- Consistent with results of clinical trials, in routine clinical practice, maintenance of visual gains was associated with more frequent anti-VEGF injections in patients with neovascular AMD
- Patients with neovascular AMD were more likely to receive more frequent injections (≥ 7) rather than fewer injections (≤ 6) during the first year of treatment
 - Annually, a trend towards more injections during the first year of treatment was observed in the neovascular AMD cohort

Thank You

Back-Up

Overview of Trials

Neovascular Age-related Macular Degeneration

Trial	Treatment Groups	Mean Change in BCVA at Year 1	Long-Term Follow-up	Mean Change in BCVA (As compared to enrollment in original study)
MARINA	RBZ 0.5mg monthly	+7.2	HORIZON** (PRN) Annual: 2.0 -2.2 injs	Year 2: +9.0
	sham	-10.4		Year 3: +4.0
ANCHOR	RBZ 0.5mg monthly	+11.3		Year 4: +2.0
	PDT	-9.6		Year 5: -0.1
VIEW 1	IAI 2mg monthly	+10.9	VIEW 1 Extension (Modified Quarterly/ Bimonthly) Annual: 5.5-6 injs	Week 96: +10.2
	IAI 2mg bi-monthly*	+7.9		Week 212: + 7.1
	RBZ 0.5mg monthly	+8.1		
CATT	RBZ 0.5mg monthly	+8.5	Extension (Variable) Annual: 4.0-4.8 injs	Year 2: +8 [#]
	RBZ 0.5mg PRN	+6.8		
	BVZ 1.25mg monthly	+8.0		
	BVZ 1.25mg PRN	+5.9		Year 5: -11 [#]

RBZ=ranibizumab, IAI=intravitreal aflibercept injection, BVZ=bevacizumab

*following 3 initial monthly doses

** Also Included patients from the FOCUS study

[#]Calculated mean change