

# Outcomes of Intravitreal Anti-VEGF Therapy for Diabetic Macular Edema in Routine Clinical Practice

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## Disclosures

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- Regeneron - Investigator, consultant
- Genentech - investigator, speaker
- Allergan - consultant

# Dosing Approaches in Clinical Trials are Varied

## Quarterly

- PIER<sup>8</sup>
- SAILOR<sup>9</sup>
- EXCITE<sup>10</sup>

## PRN<sup>11,12</sup>

- HARBOR<sup>3</sup>
- CATT<sup>4</sup>
- RESOLVE<sup>13</sup>
- RESTORE<sup>14</sup>
- Protocol I<sup>15</sup>
- Protocol T<sup>16</sup>

## Treat-and-Extend<sup>11,12</sup>

- LUCAS<sup>17</sup>
- TREX<sup>18</sup>

## Monthly

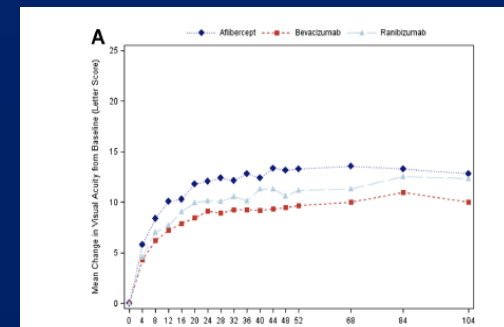
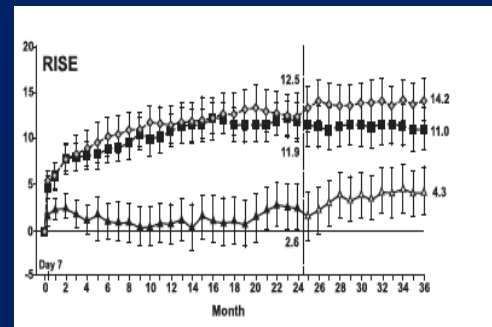
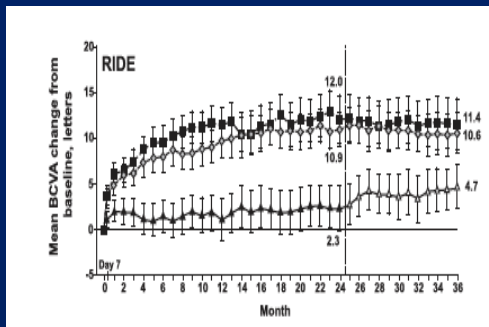
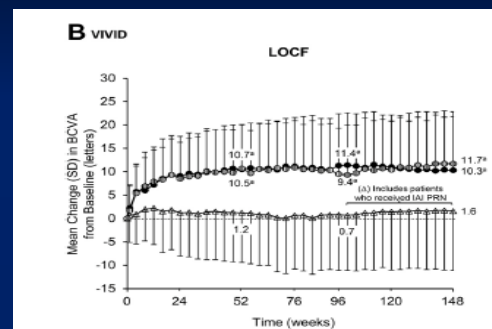
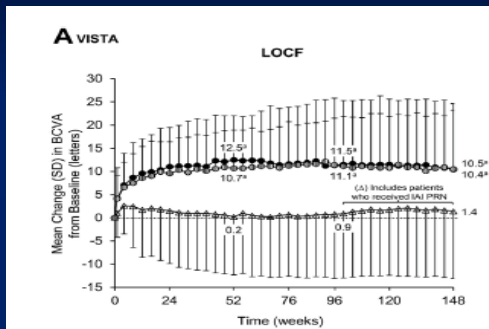
- ANCHOR<sup>1</sup>
- MARINA<sup>2</sup>
- HARBOR<sup>3</sup>
- CATT<sup>4</sup>
- RISE/RIDE<sup>5</sup>
- VIEW 1/2<sup>6</sup>
- VISTA/VIVID<sup>7</sup>

## Bimonthly

- VIEW 1/2<sup>6</sup>
- VISTA/VIVID<sup>7</sup>

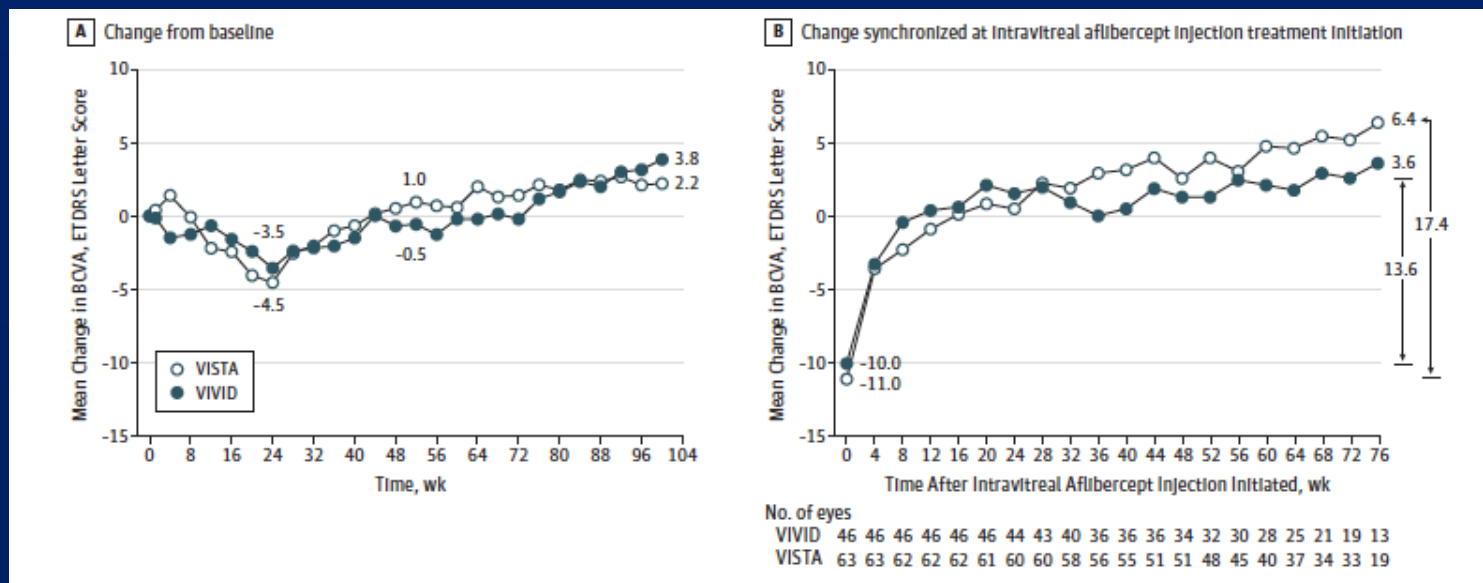
1. Brown DM et al. *N Engl J Med.* 2006;355(14):1432-1444. 2. Rosenfeld PJ et al. *N Engl J Med.* 2006;355(14):1419-1431. 3. CATT Research Group. *N Engl J Med.* 2011;364(20):1897-1908. 4. Heier JS et al. *Ophthalmology.* 2012;119(12):2537-2548. 5. Nguyen QD et al. *Ophthalmology.* 2012;119(4):789-801. 6. Busbee BG et al. *Ophthalmology.* 2013;120(5):1046-1056. 7. Korobelnik J-F et al. *Ophthalmology.* 2014;121(11):2247-2254. 8. Wyckoff C et al. *Ophthalmology.* 2015;122(12):2514-2522. 9. Regillo CD et al. *Am J Ophthalmol.* 2008;145(2):239-248.e5. 10. Schmidt-Erfurth U et al. *Ophthalmology.* 2011;118(5):831-839. 11. Freund KB et al. *Retina.* 2015;35(8):1489-1506. 12. Mantel I. *Transl Vis Sci Technol.* 2015;4(3):6. 13. Boyer DS et al. *Ophthalmology.* 2009; 116(9):1731-1739. 14. Massin P et al. *Diabetes Care.* 2010;33(11):2399-2405. 15. Diabetic Retinopathy Clinical Research Network. *Ophthalmology.* 2010;117(6):1064-1077. 16. Mitchell P et al. *Ophthalmology.* 2011;118(4):615-625. 17. Diabetic Retinopathy Clinical Research Network. *N Engl J Med.* 2015;372(13):1193-1203. 18. Berg K et al. *Ophthalmology.* 2015;122(1):146-152.

# Frequent Monitoring and Consistent Treatment Resulted in Optimal Outcomes in Clinical Trials for DME



# Limited Vision Improvement when Initial Treatment Approach was not Optimized in Patients with DME

- Final vision was limited in patients who were treated with intravitreal aflibercept following vision loss with initial laser treatment



# **Analysis of Outcomes in Routine Clinical Practice**

# Study Design

- **Objective**

- To evaluate visual acuity outcomes following treatment of DME 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 –
  - *Diabetic macular edema*
- Anti-VEGF treatment naïve eyes
  - 1<sup>st</sup> anti-VEGF injection between January 1<sup>st</sup>, 2012 and April 30<sup>th</sup>, 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* = 155,240

1<sup>st</sup> anti-VEGF between 01/01/12 – 04/30/15  
*n* = 16,207

VA reading on index date  
*n* = 13,016

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

VA reading at month 12  
*n* = 3,674

VA reading in all 4 quarters  
*n* = 3,032

Gender identified  
*n* = 3,028



# Baseline Characteristics

	Total (n=3028)	≤6 injections (n=1303)	≥7 injections (n=1725)
Mean age, years	62	61	63
Female, %	46%	47%	44%
Mean VA, letters	71	71	70
Median VA, letters	76	77	76
VA subgroups			
≥20/40	27%	29%	25%
<20/40 – 20/100	51%	50%	51%
<20/100 – 20/200	11%	11%	12%
<20/200	11%	10%	12%

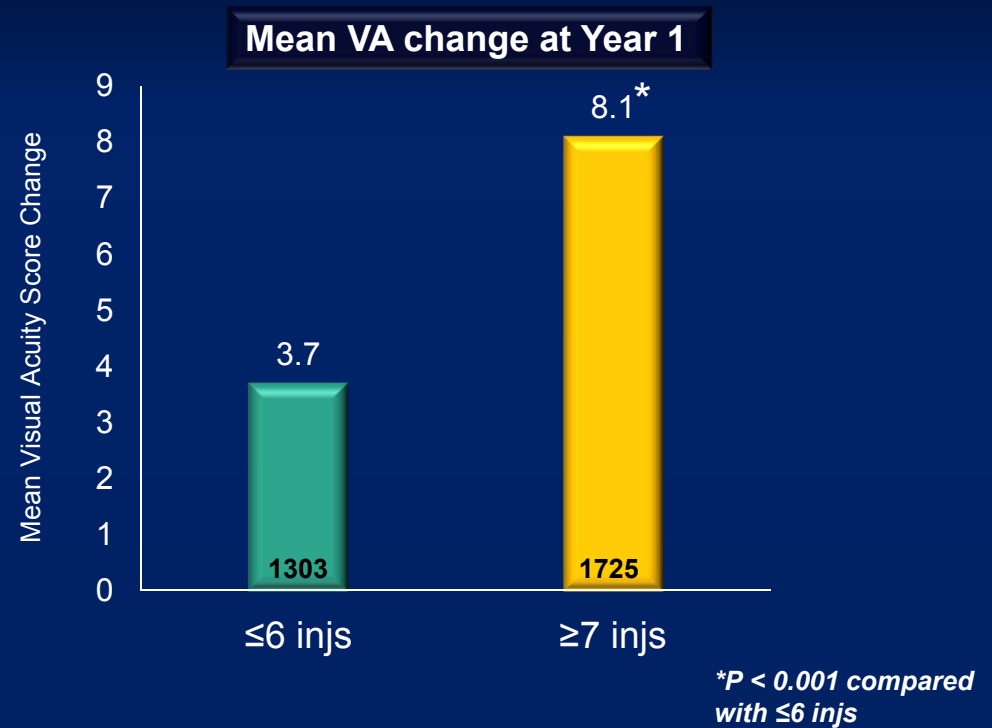
Patients included in Year 1 analysis

# Mean Visual Acuity Change By Injection Subgroups (Year 1)

Subgroup	Mean BSL VA
≤6 injs (n=1303)	71
≥7 injs (n=1725)	70

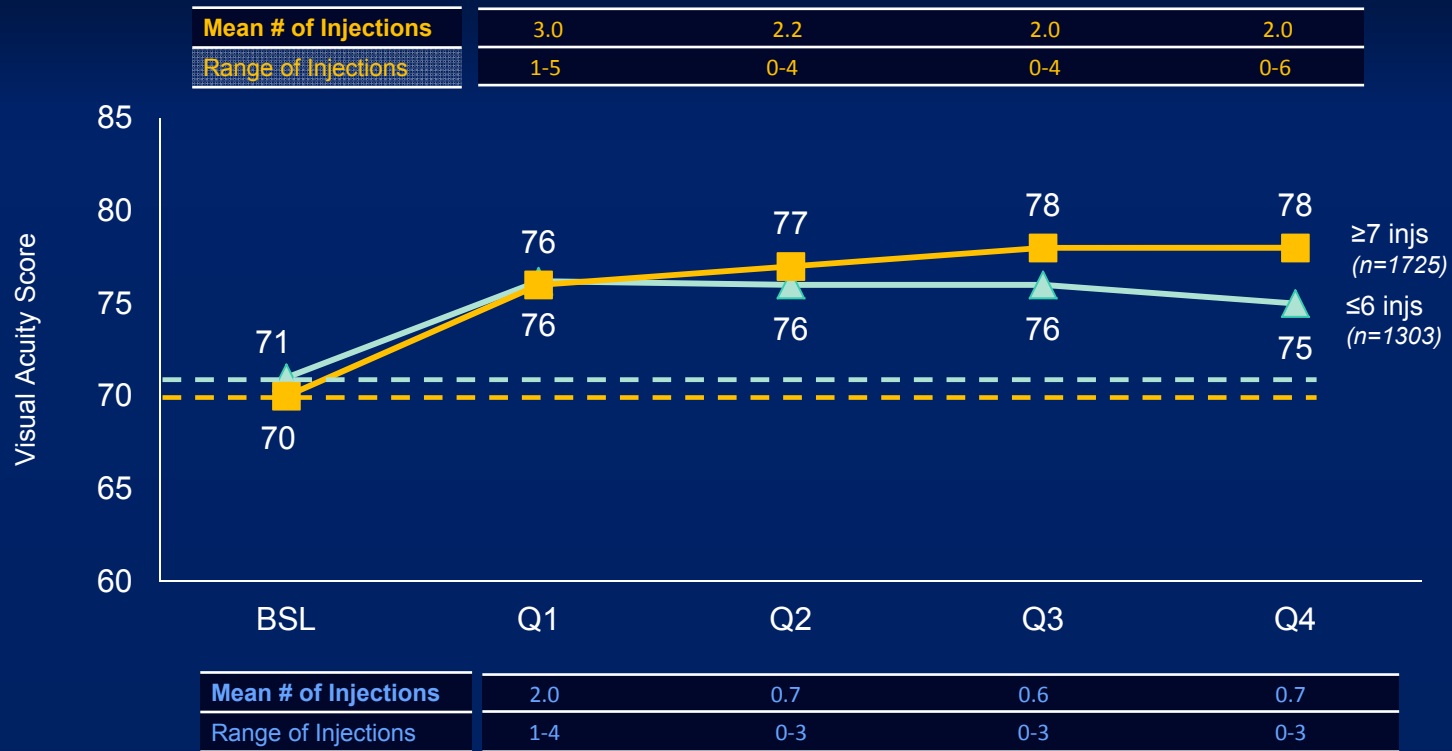
  

Subgroup	Mean Number of Injections
≤6 injs (n=1303)	4.0
≥7 injs (n=1725)	9.1



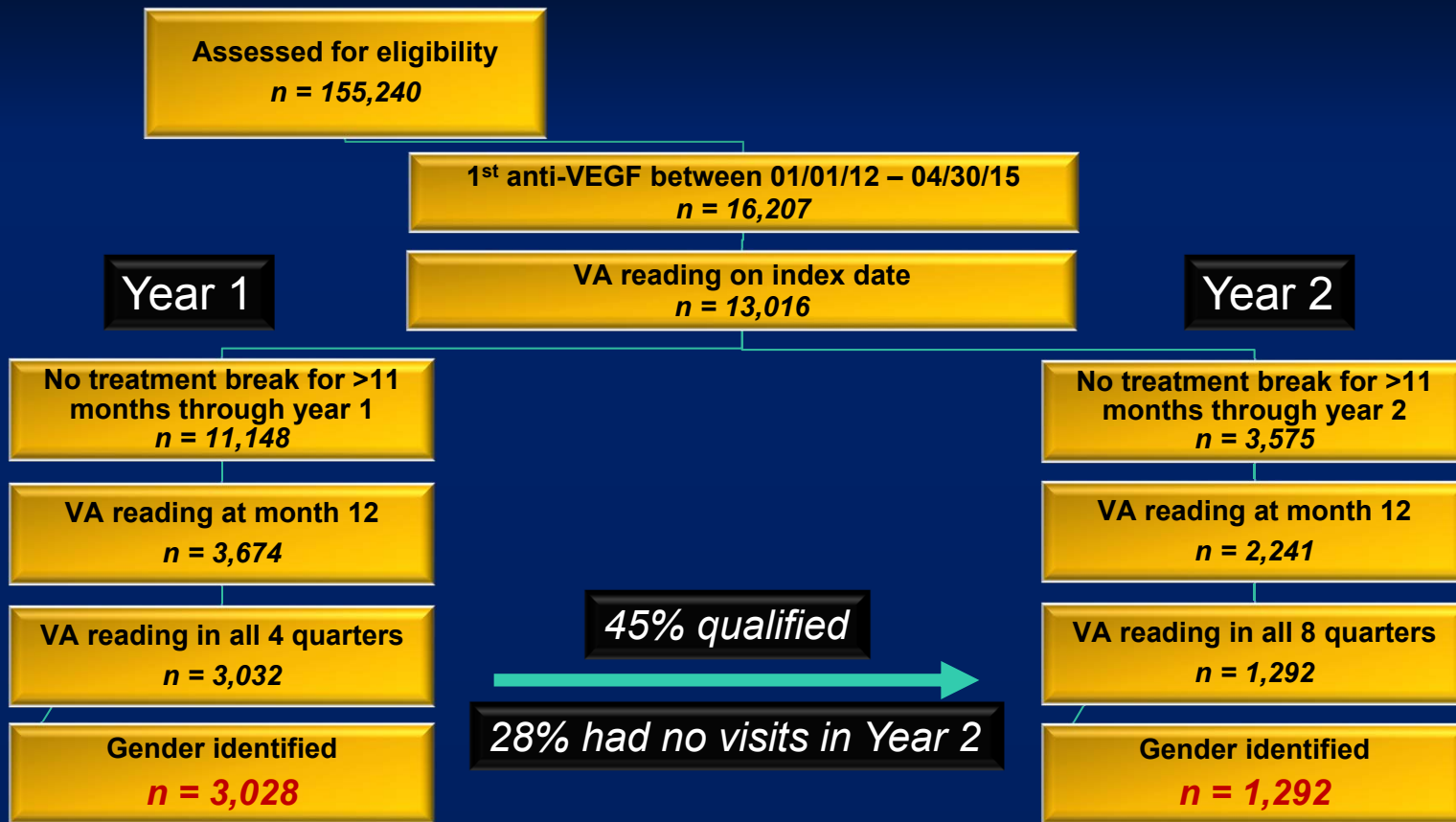
Visual acuity is reported in visual acuity score (VAS)

# Mean Visual Acuity by Injection Subgroups (Year 1)



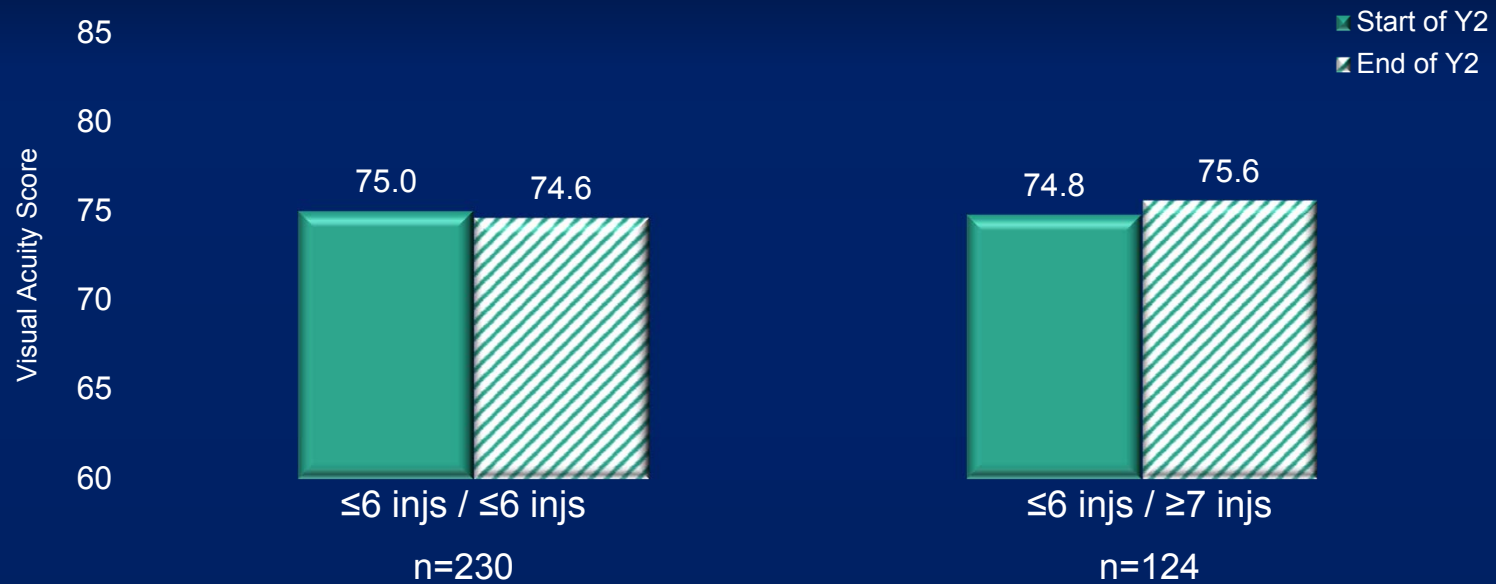
# Patient Selection

## Year 2



# Mean Visual Acuity by Injection Subgroups (Year 2)

## Patients Receiving $\leq 6$ injections in Year 1

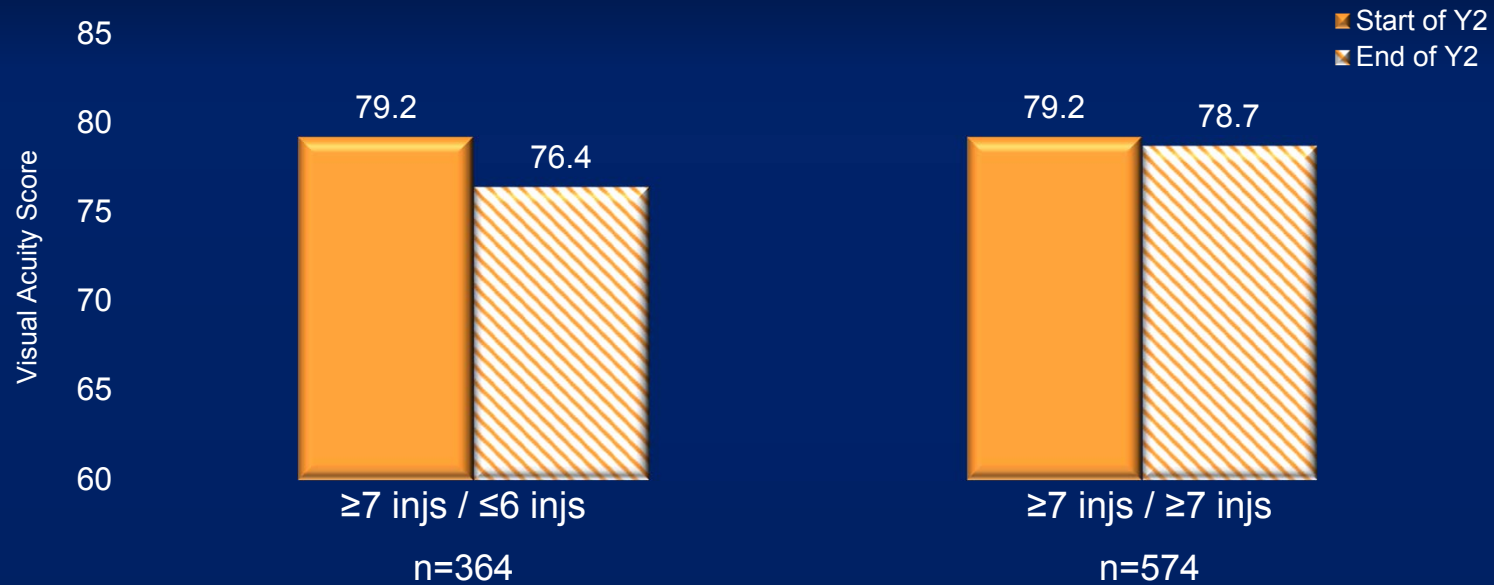


### Mean number of injections

Year 1	4.6	4.9
Year 2	4.3	8.2

# Mean Visual Acuity by Injection Subgroups (Year 2)

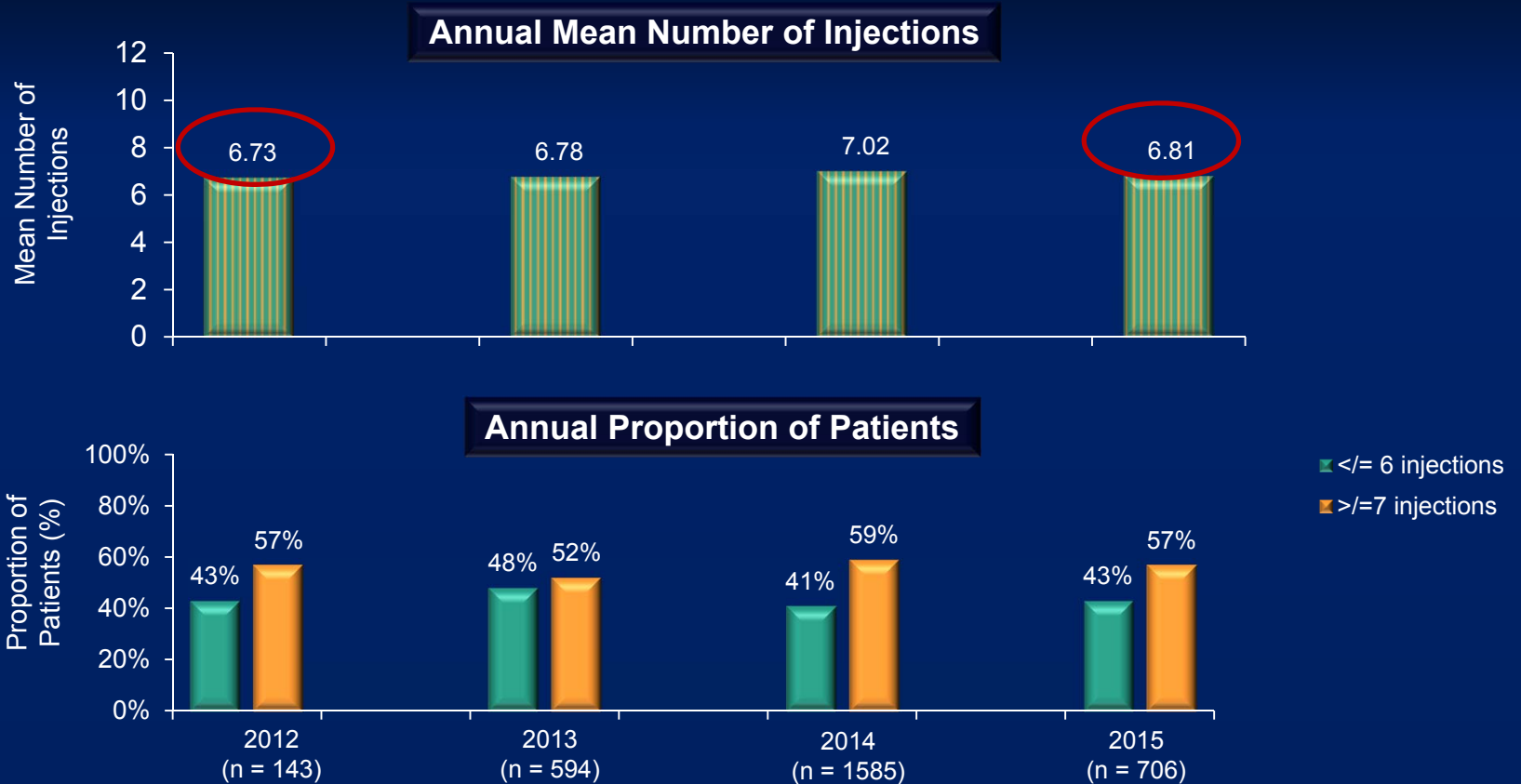
## *Patients Receiving $\geq 7$ injections in Year 1*



### *Mean number of injections*

Year 1	8.8	9.7
Year 2	4.7	9.0

# 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 DME
- Patients with DME were more likely to receive more frequent injections ( $\geq 7$ ) rather than fewer injections ( $\leq 6$ ) during the first year of treatment
  - A substantial proportion (43%) of DME patients received  $\leq 6$  injections during their first year of treatment



*Thank You*

**Back-Up**

# Overview of Trials

## *Diabetic Macular Edema*

Trial	Treatment Groups	Mean Change in BCVA at Year 2
RISE	RBZ 0.3mg monthly	+14.3
	sham	+5.1
RIDE	RBZ 0.3mg monthly	+13.1
	sham	+4.5
VISTA	IAI 2mg monthly	+12.5
	IAI 2mg bi-monthly*	+10.7
	laser	+0.2
VIVID	IAI 2mg monthly	+10.5
	IAI 2mg bi-monthly*	+10.7
	laser	+1.2
Protocol T	IAI 2mg PRN	+13
	RBZ 0.3mg PRN	+11
	BVZ 1.25mg PRN	+10

RBZ=ranibizumab, IAI=intravitreal aflibercept injection, BVZ=bevacizumab  
 \*following 5 initial monthly doses