

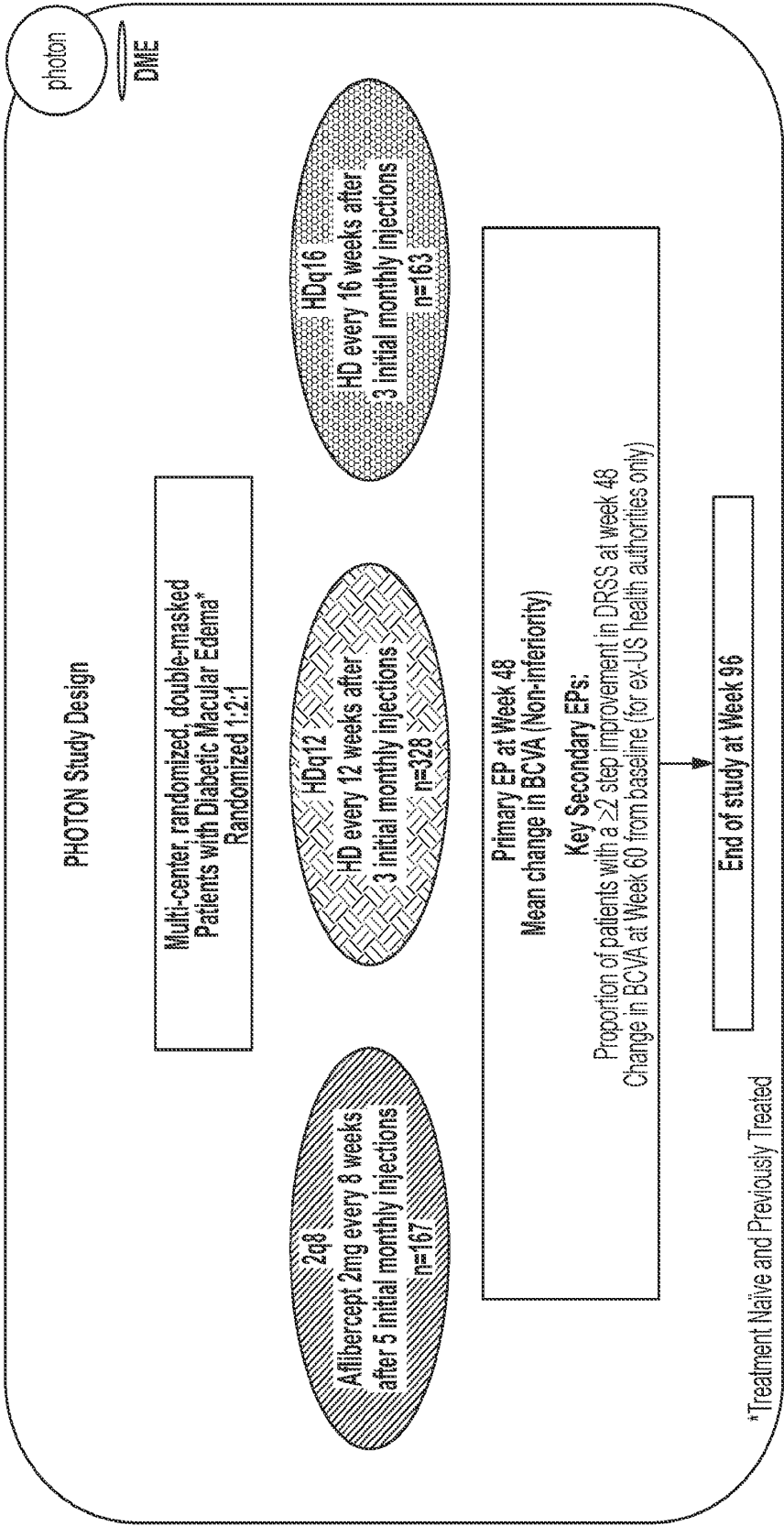


FIG. 1

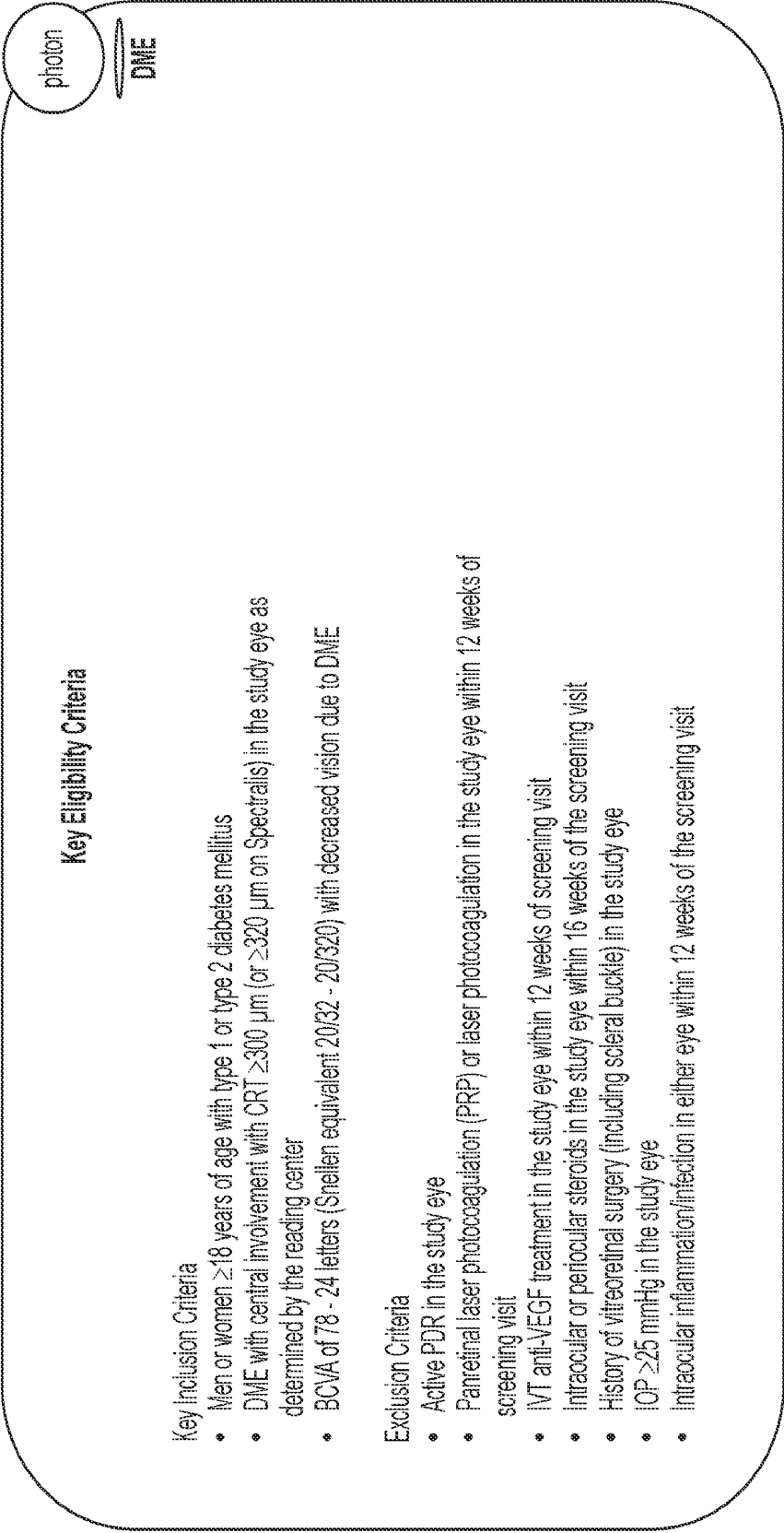
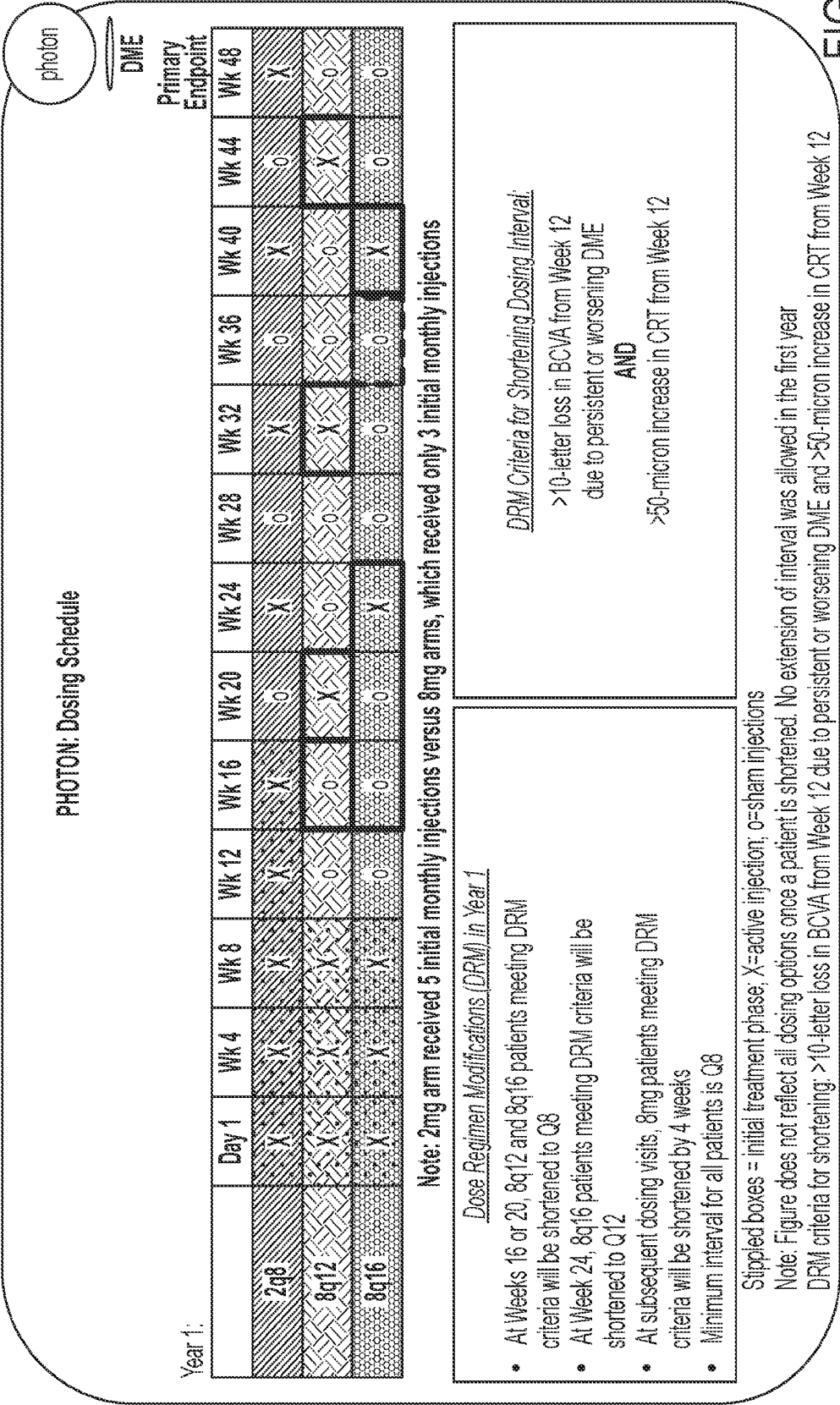


FIG. 2



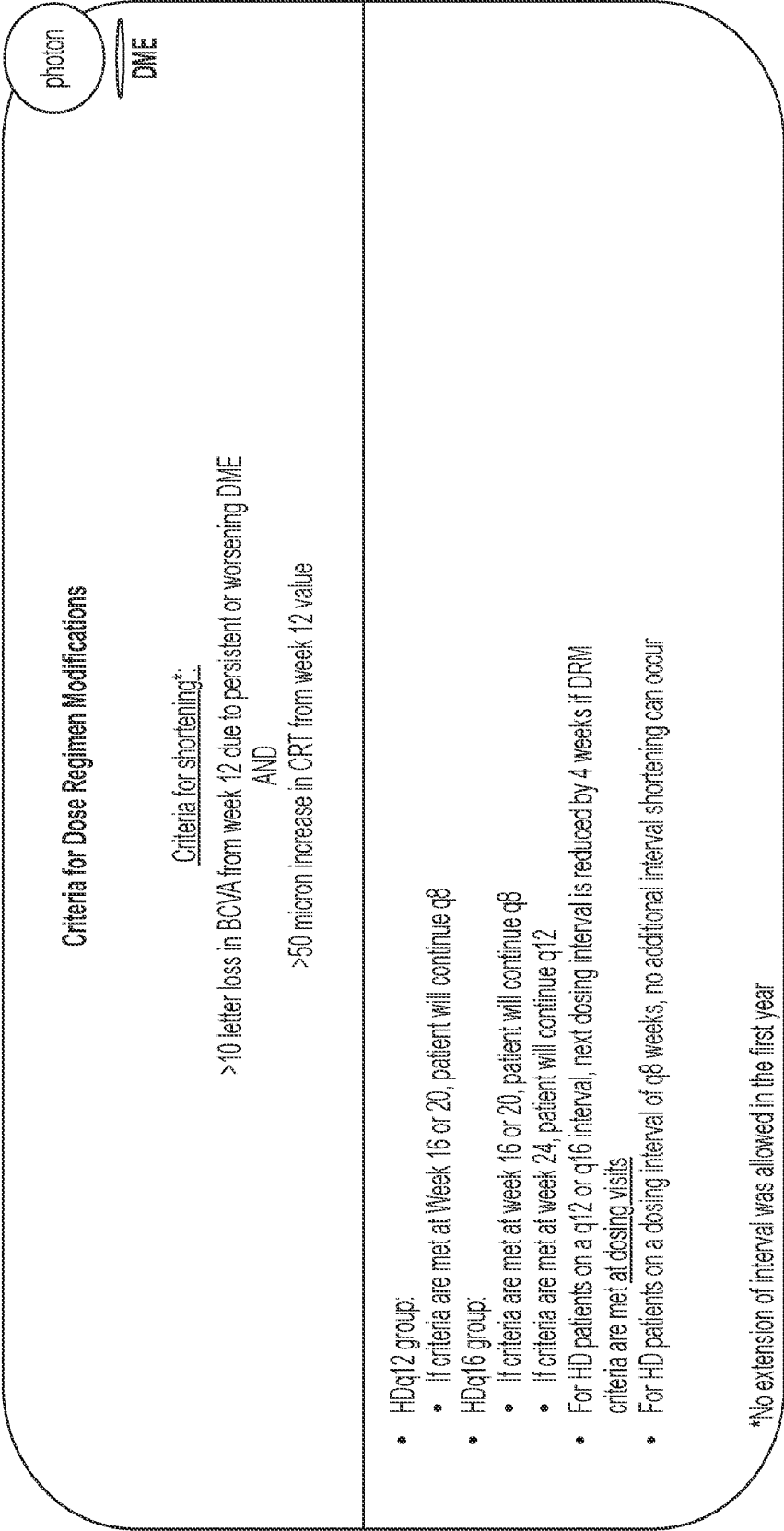


FIG. 4

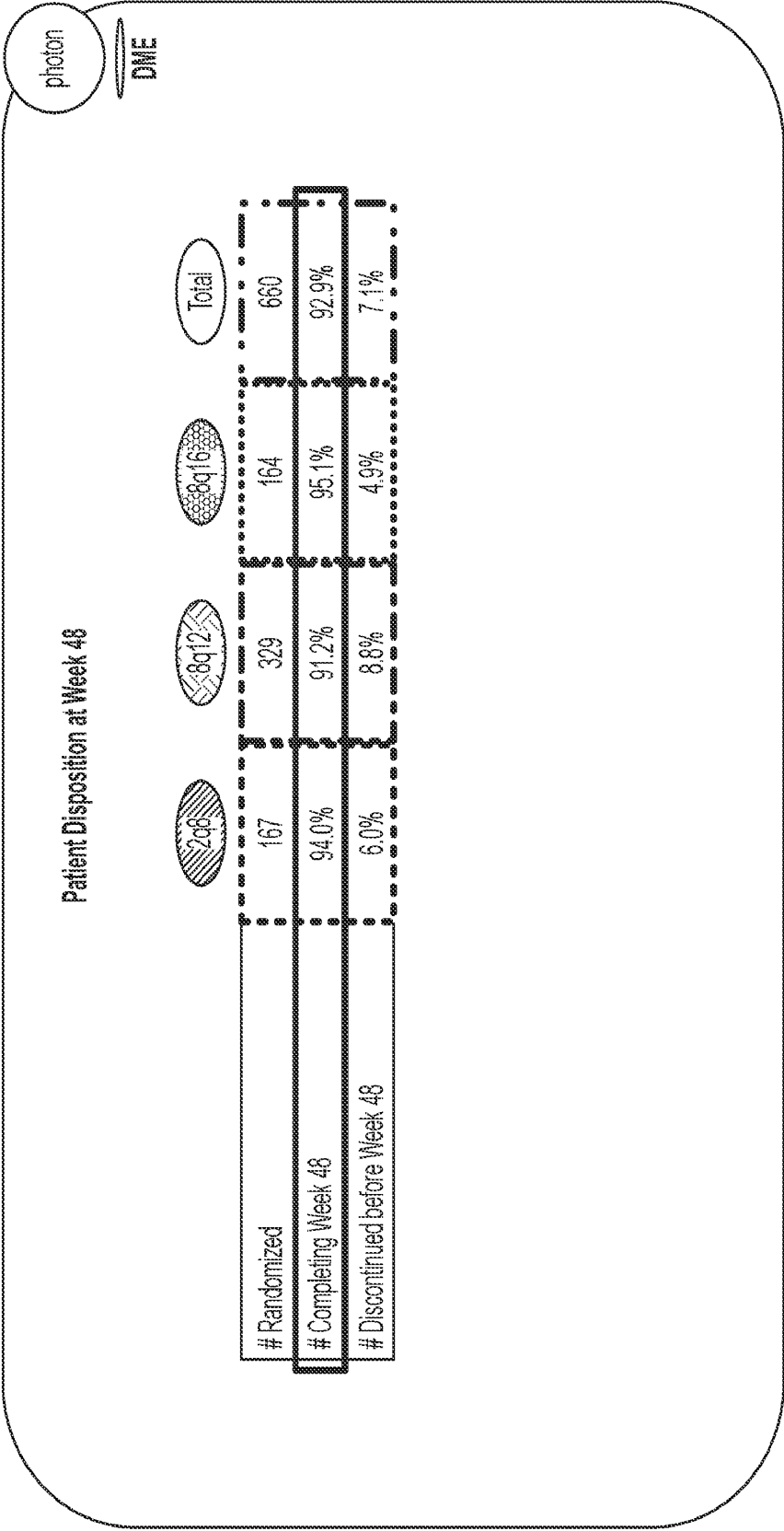


FIG. 5

photon

DME

Baseline Demographics

	2q8	Hdq12	Hdq16	Total
N (FAS/SAF)	167	328	163	658
Age (years (SD))	63.0 (9.78)	62.1 (11.13)	61.9 (9.50)	62.3 (10.41)
Women # (%)	75 (44.9%)	118 (36.0%)	64 (39.3%)	257 (39.1%)
Race # (%)				
White	112 (67.1%)	231 (70.4%)	128 (78.5%)	471 (71.6%)
Black or African American	18 (10.8%)	35 (10.7%)	9 (5.5%)	62 (9.4%)
Asian	30 (18.0%)	48 (14.6%)	23 (14.1%)	101 (15.3%)
Other	4 (2.4%)	10 (3.0%)	1 (0.6%)	15 (2.4%)
Not Reported	3 (1.8%)	4 (1.2%)	2 (1.2%)	9 (1.4%)
Hispanic or Latino	31 (18.6%)	54 (16.5%)	34 (20.9%)	119 (18.1%)
Duration of Diabetes (years (SD))	15.9 (10.04)	15.1 (9.96)	15.7 (10.67)	15.5 (10.15)
Hemoglobin A1C (%)	8.14 (1.482)	7.94 (1.546)	7.84 (1.502)	7.97 (1.521)
BMI (kg/m ²)	29.91 (6.525)	30.44 (6.156)	31.02 (6.123)	30.45 (6.247)

FIG. 6

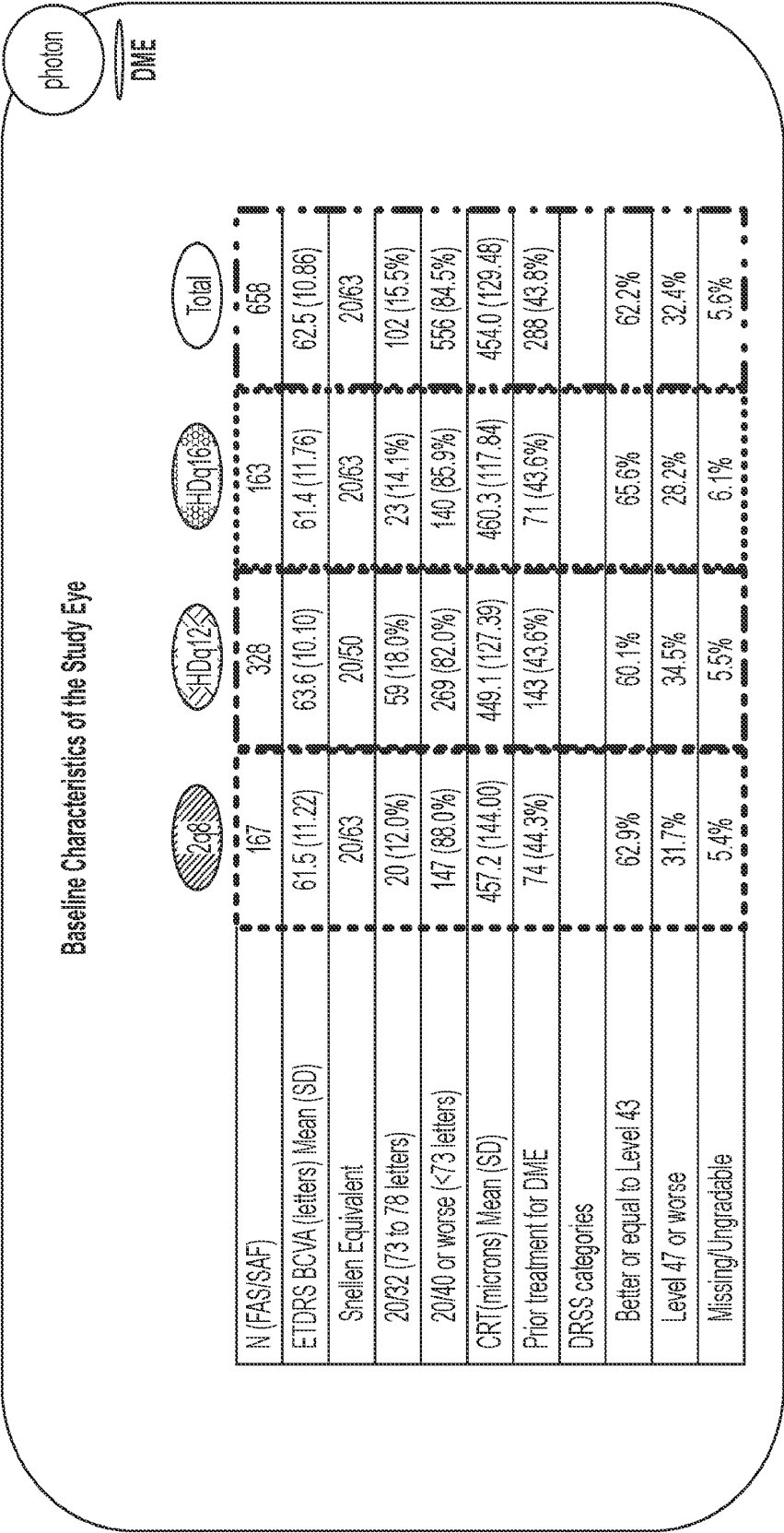


FIG. 7

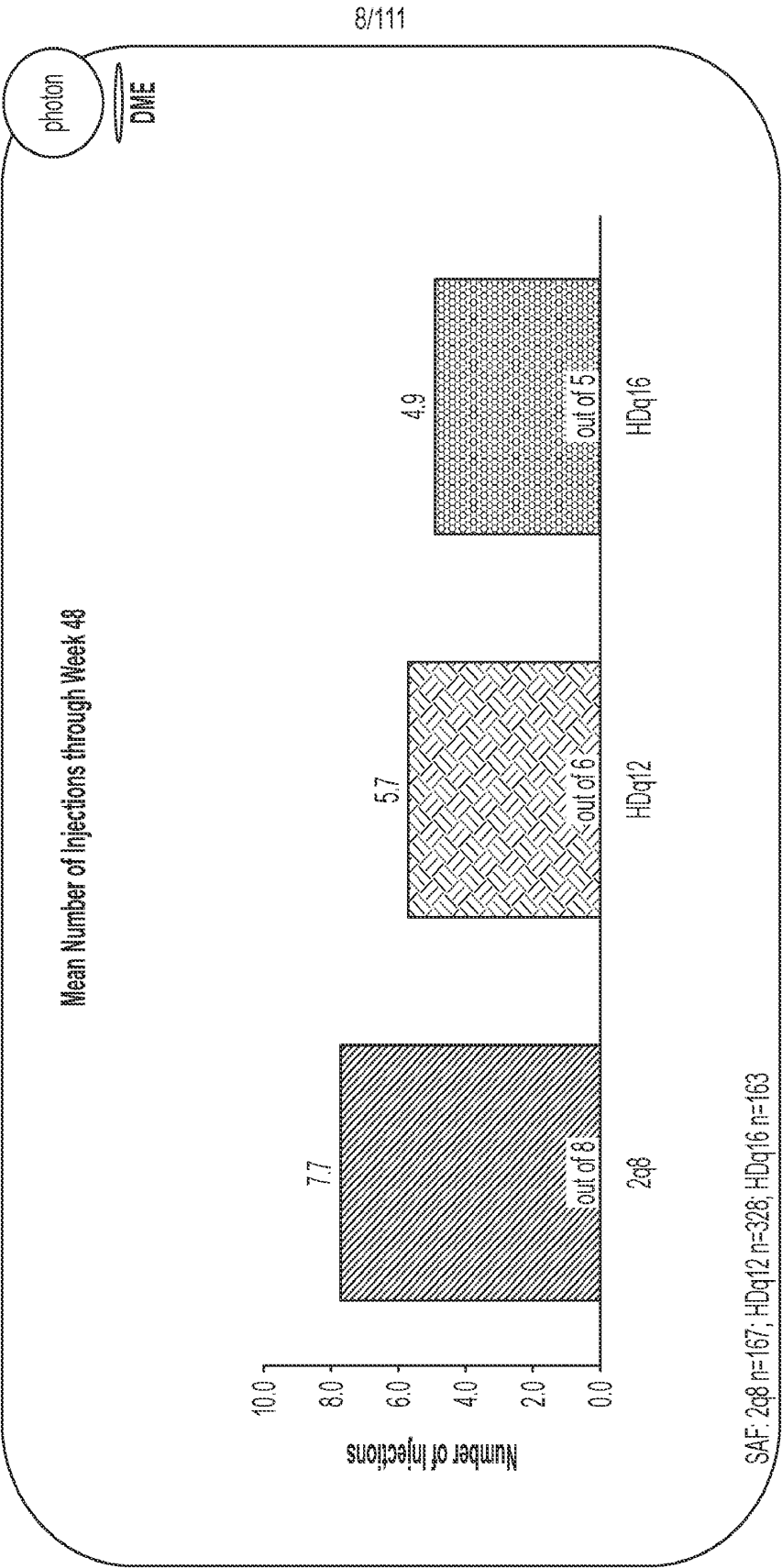


FIG. 8

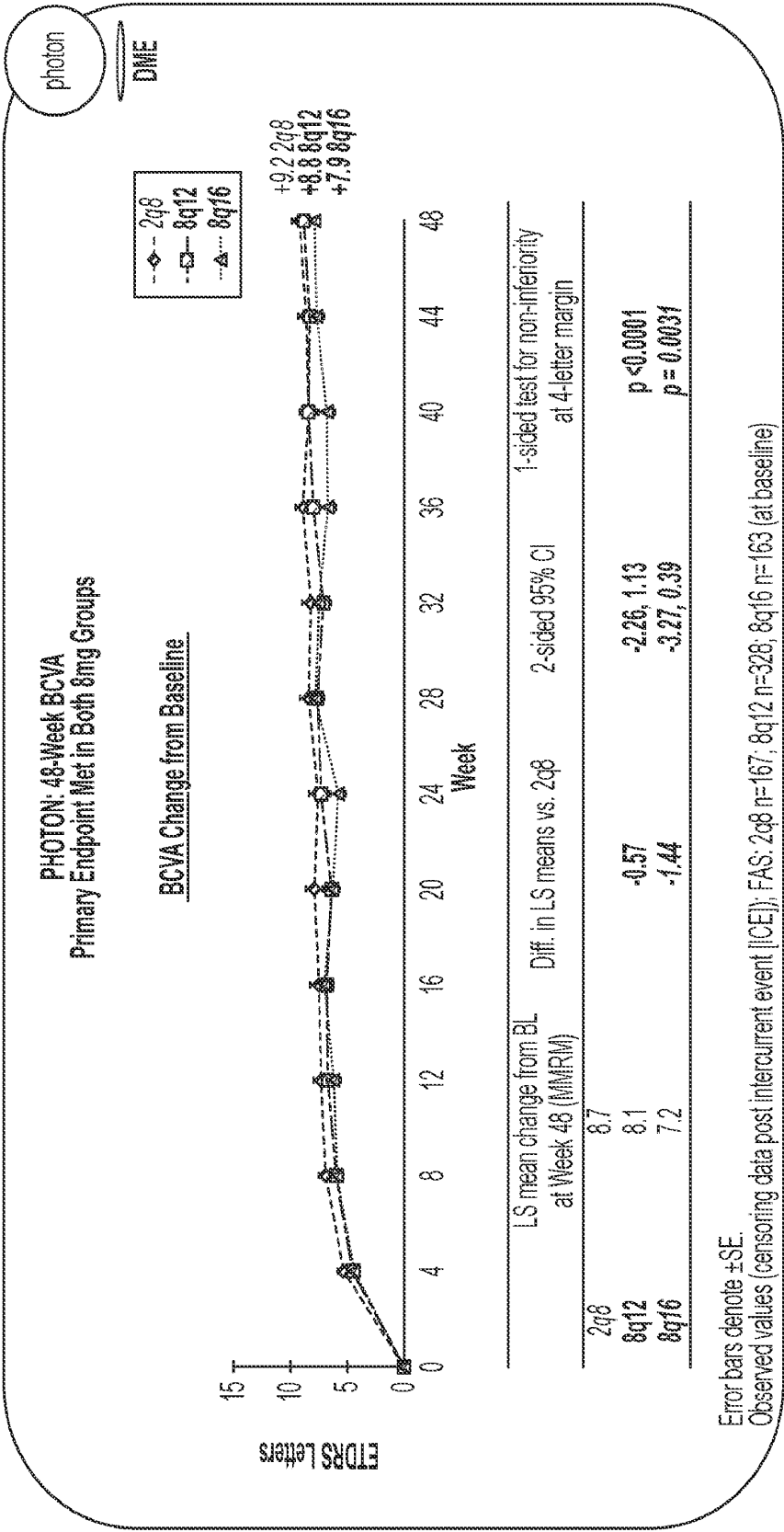


FIG. 9

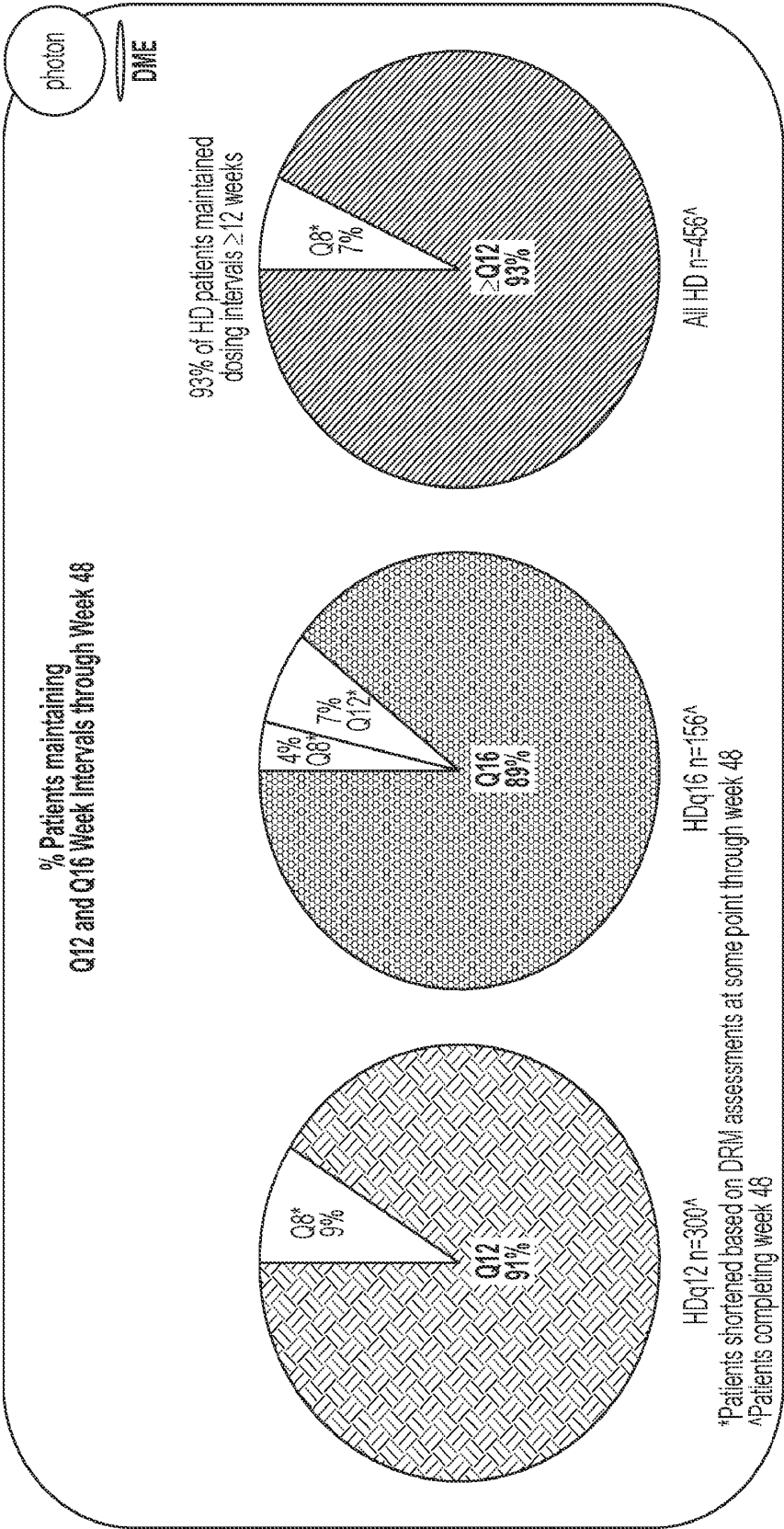


FIG. 10

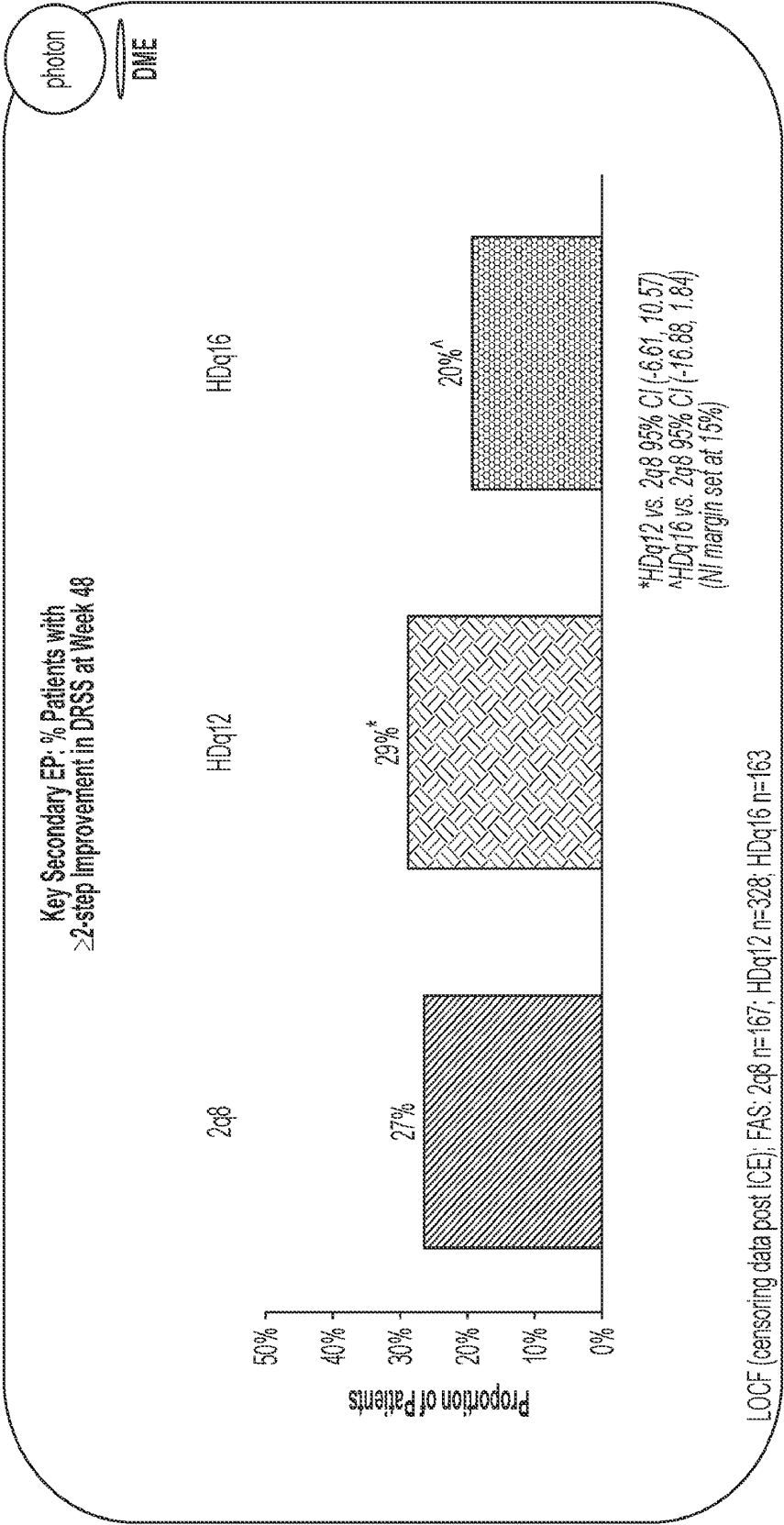


FIG. 11

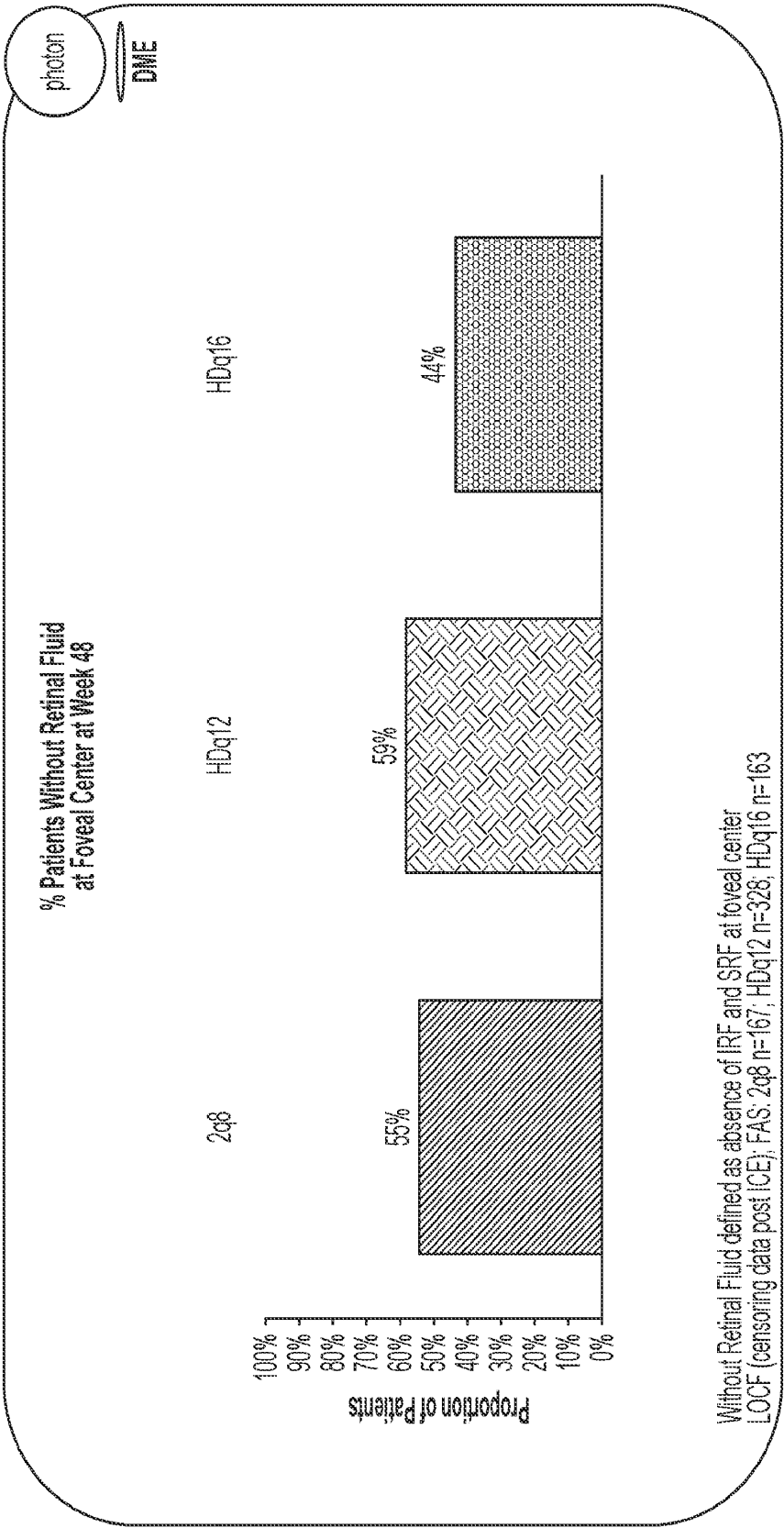


FIG. 12

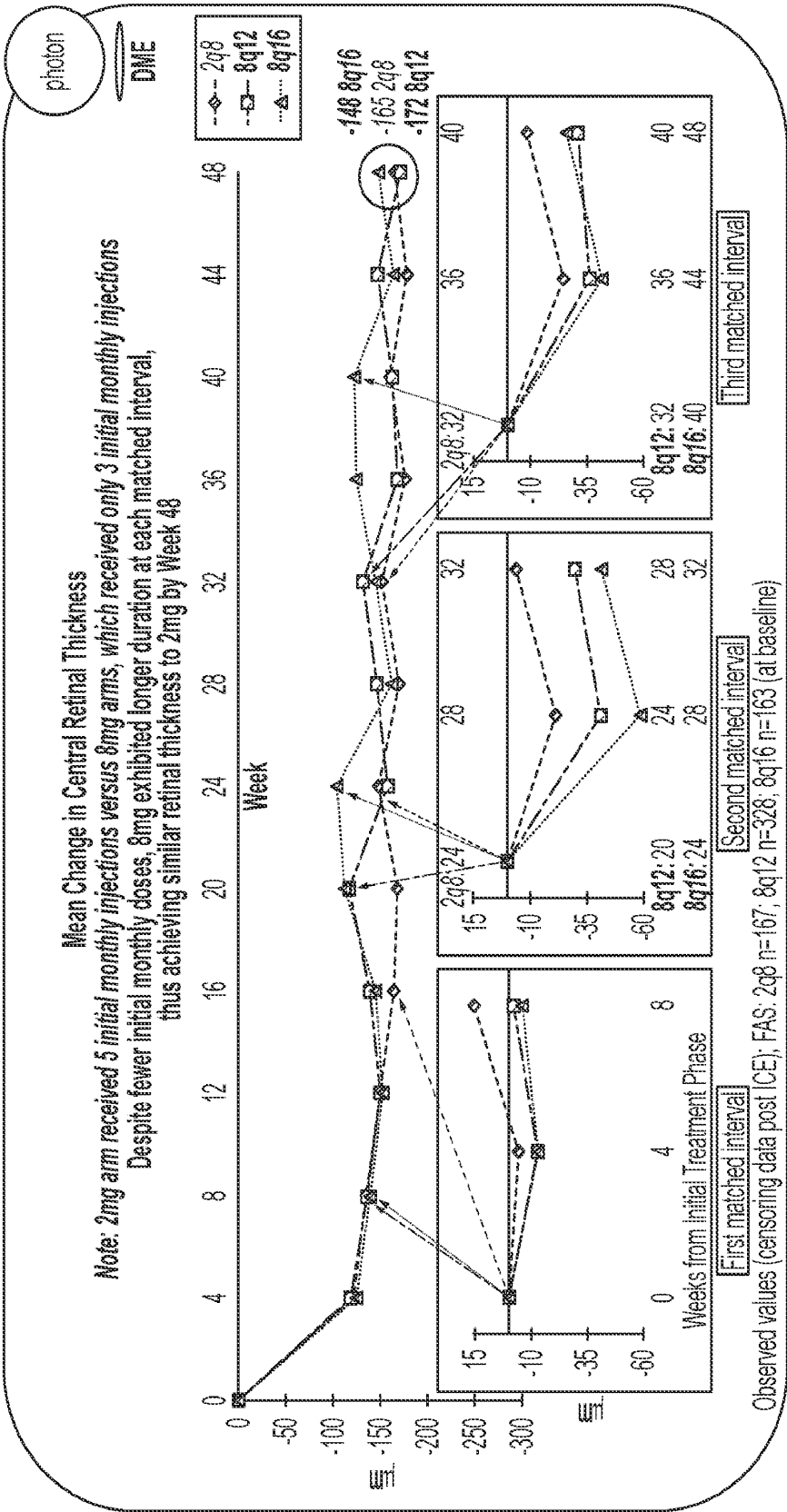


FIG. 13

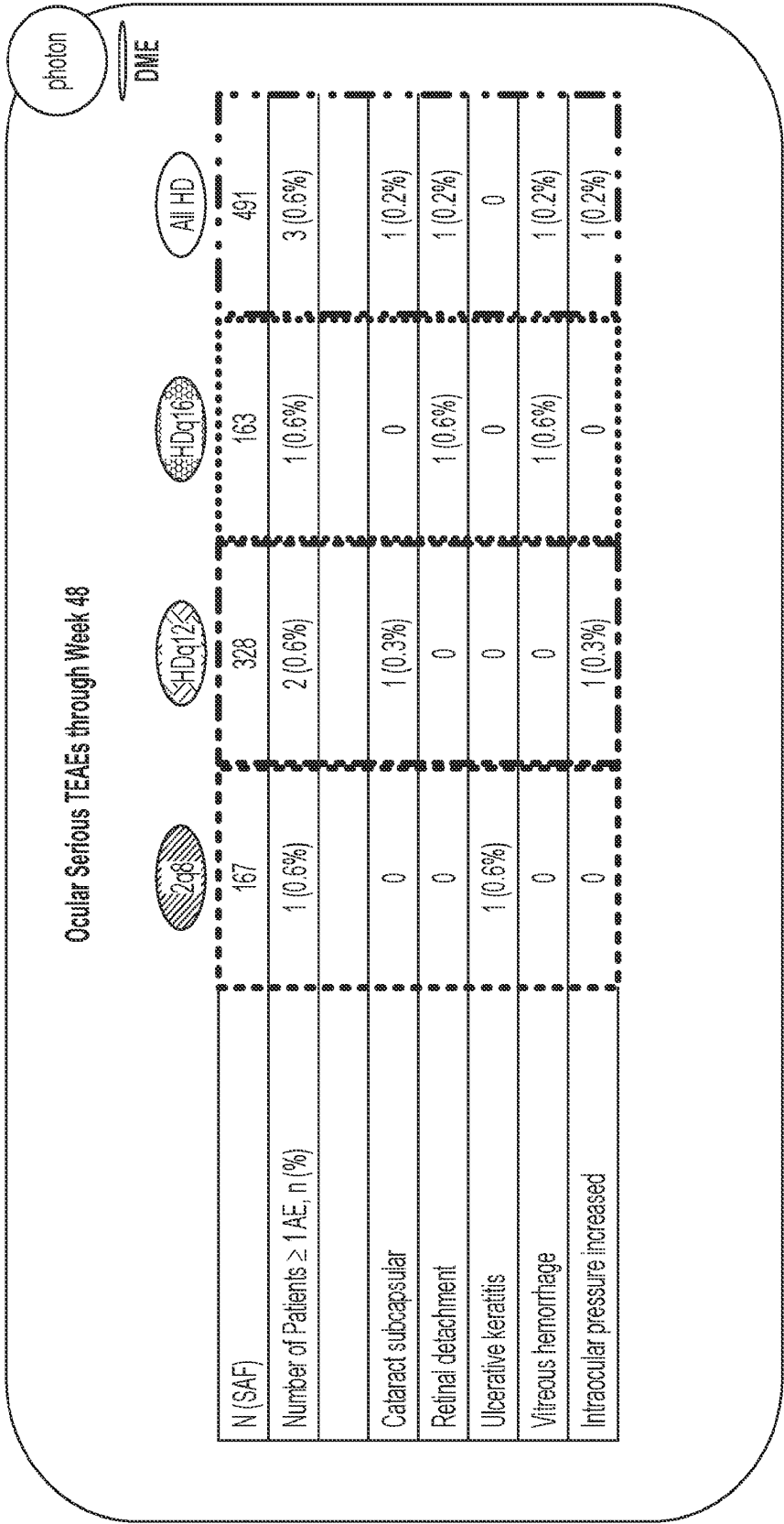




FIG. 14B

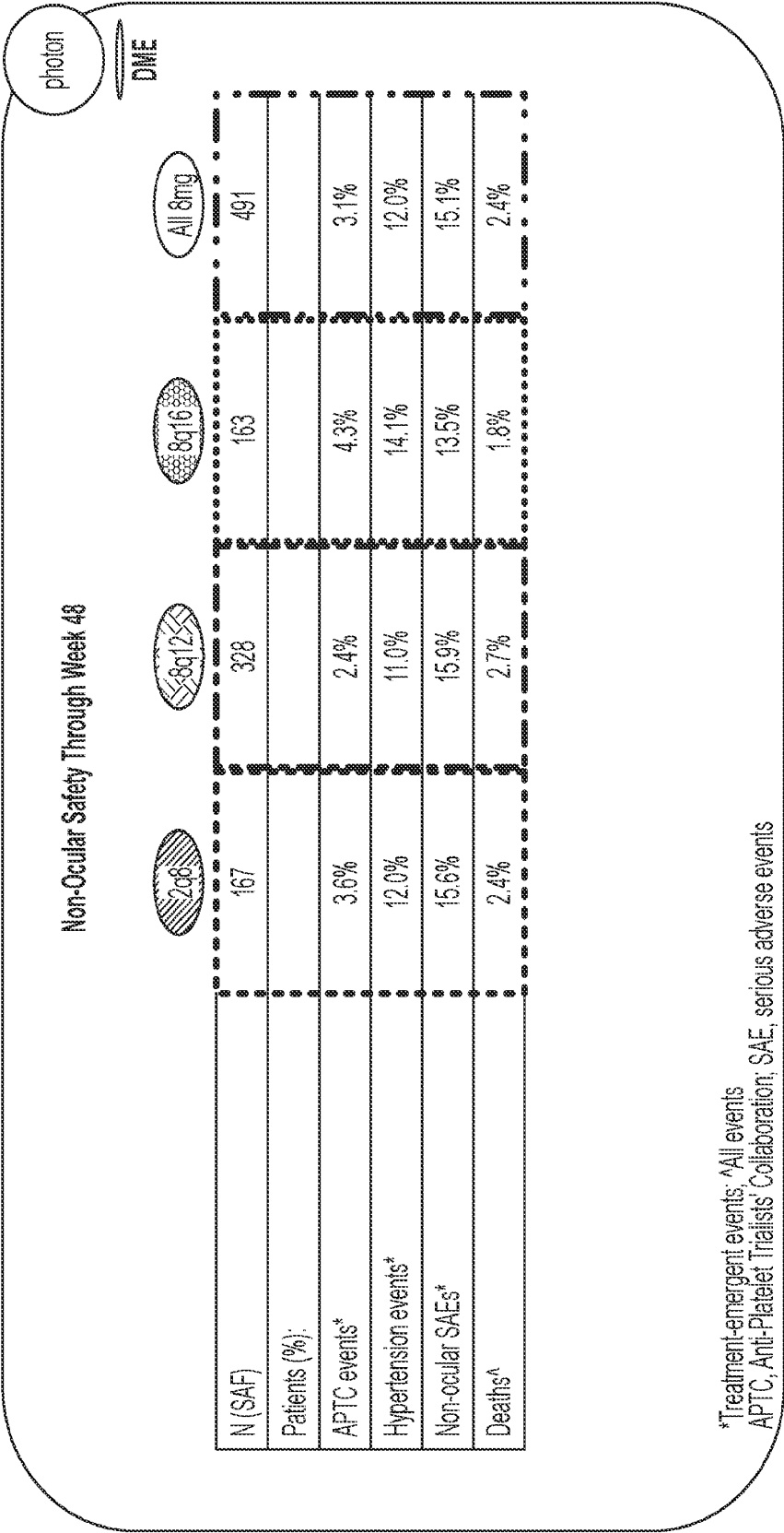


FIG. 14C

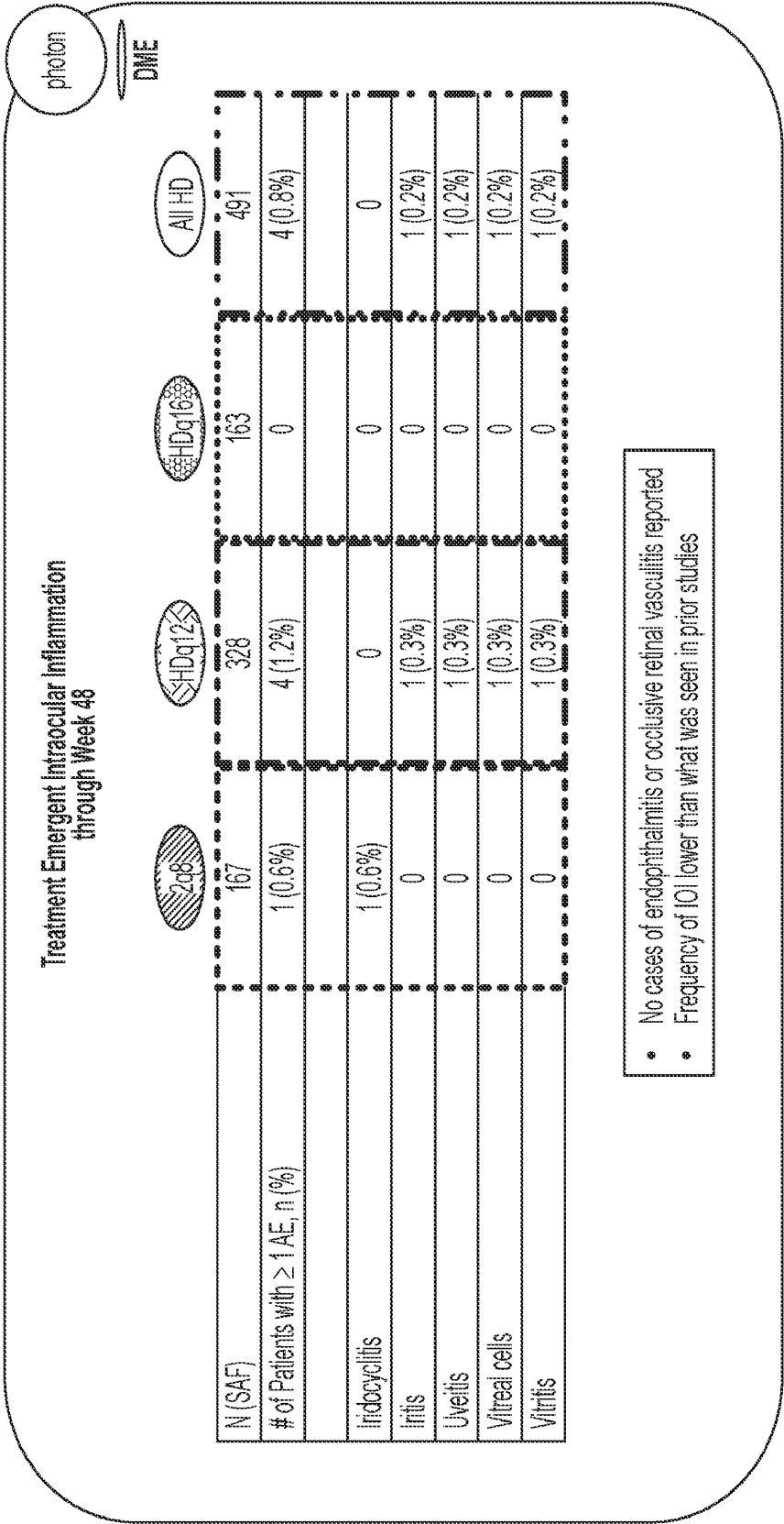


FIG. 15

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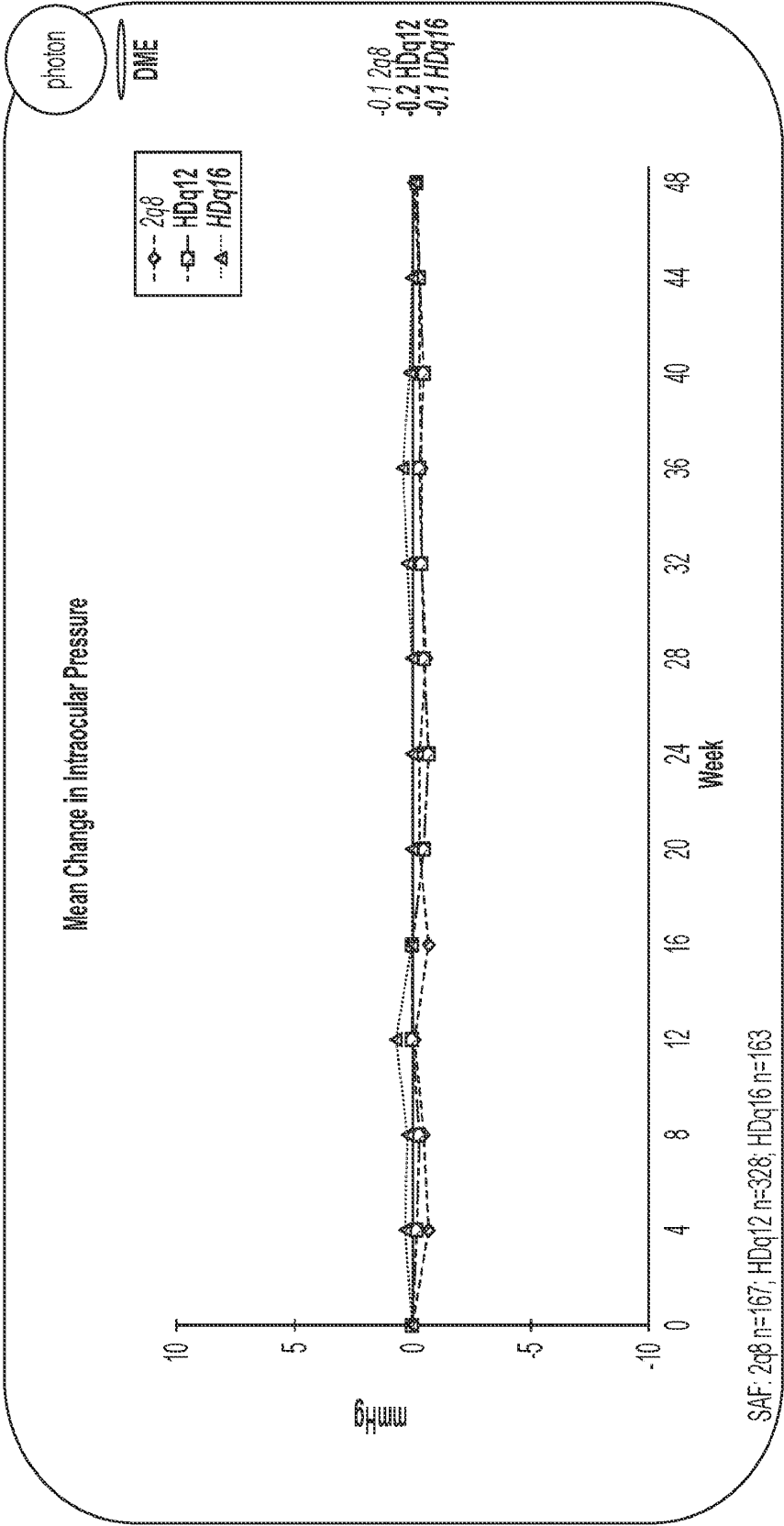
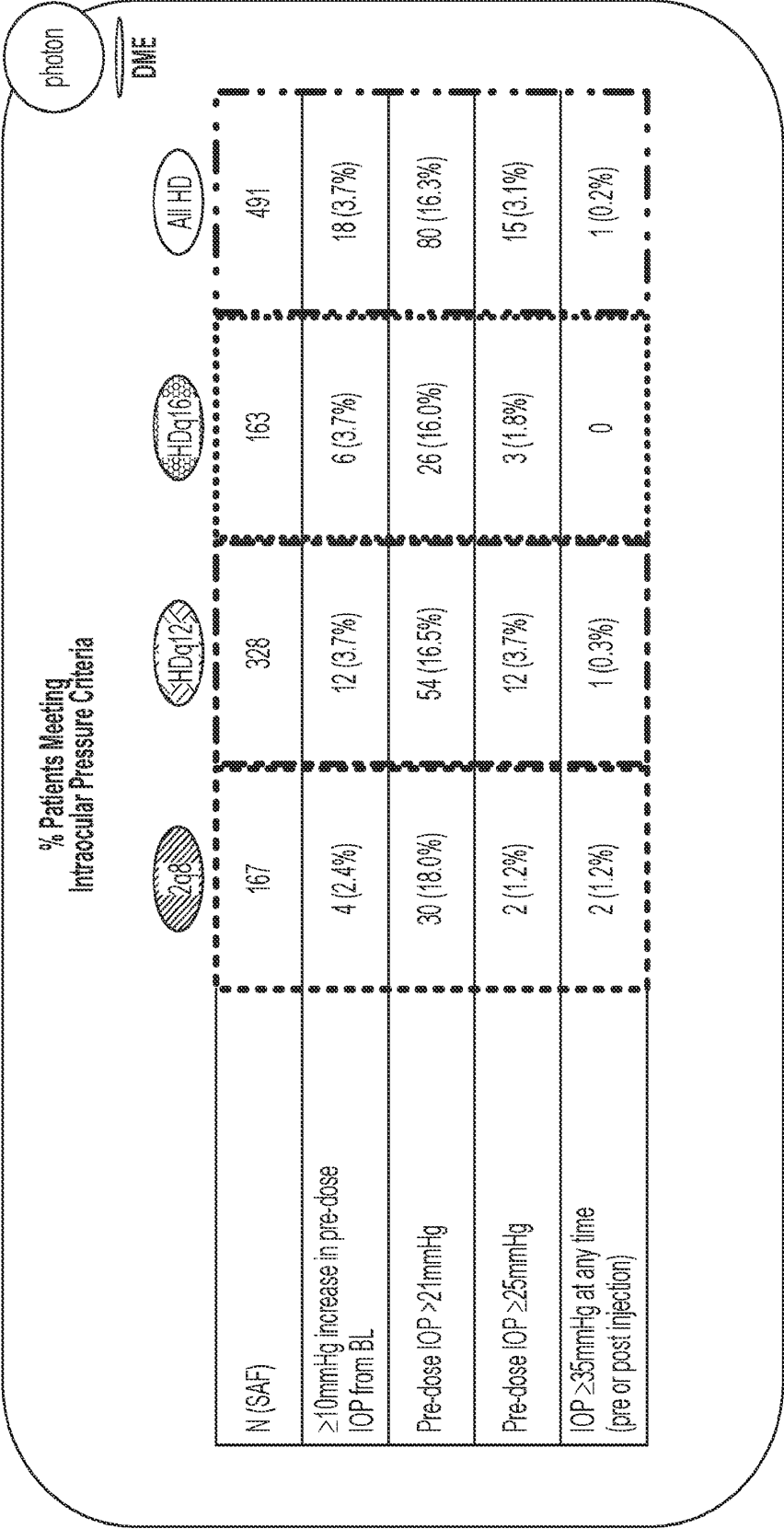


FIG. 16



Non-Ocular Serious TEAEs $\geq 1\%$ through Week 48					photon
	2q8	HDq12	HDq16	All HD	DME
N (SAF)	167	328	163	491	
Number of Patients ≥ 1 AE, n (%)	26 (15.6%)	52 (15.9%)	20 (12.3%)	72 (14.7%)	
Acute left ventricular failure	3 (1.8%)	1 (0.3%)	0	1 (0.2%)	
Acute myocardial infarction	2 (1.2%)	1 (0.3%)	1 (0.6%)	2 (0.4%)	
Cardiac arrest	2 (1.2%)	2 (0.6%)	0	2 (0.4%)	
Coronary artery disease	1 (0.6%)	1 (0.3%)	2 (1.2%)	3 (0.6%)	
Myocardial infarction	2 (1.2%)	3 (0.9%)	1 (0.6%)	4 (0.8%)	
COVID-19 pneumonia	2 (1.2%)	2 (0.6%)	0	2 (0.4%)	
Gangrene	2 (1.2%)	0	0	0	
Pneumonia	1 (0.6%)	4 (1.2%)	0	4 (0.8%)	
Hypotatraemia	2 (1.2%)	0	0	0	
Cerebrovascular accident	0	2 (0.6%)	3 (1.8%)	5 (1.0%)	
Acute kidney injury	0	4 (1.2%)	0	4 (0.8%)	
Acute respiratory failure	2 (1.2%)	1 (0.3%)	2 (1.2%)	3 (0.6%)	

FIG. 18



FIG. 19

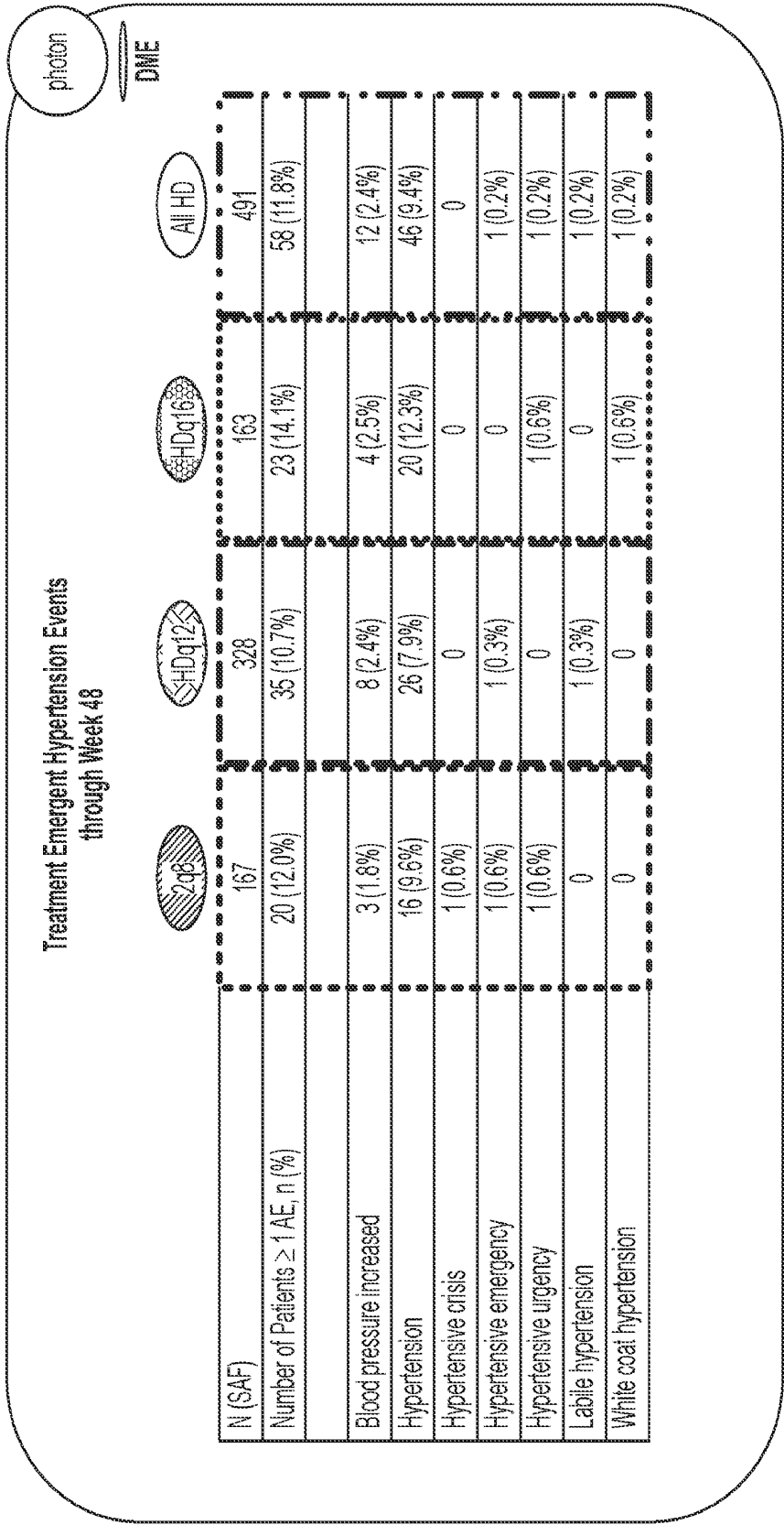


FIG. 20

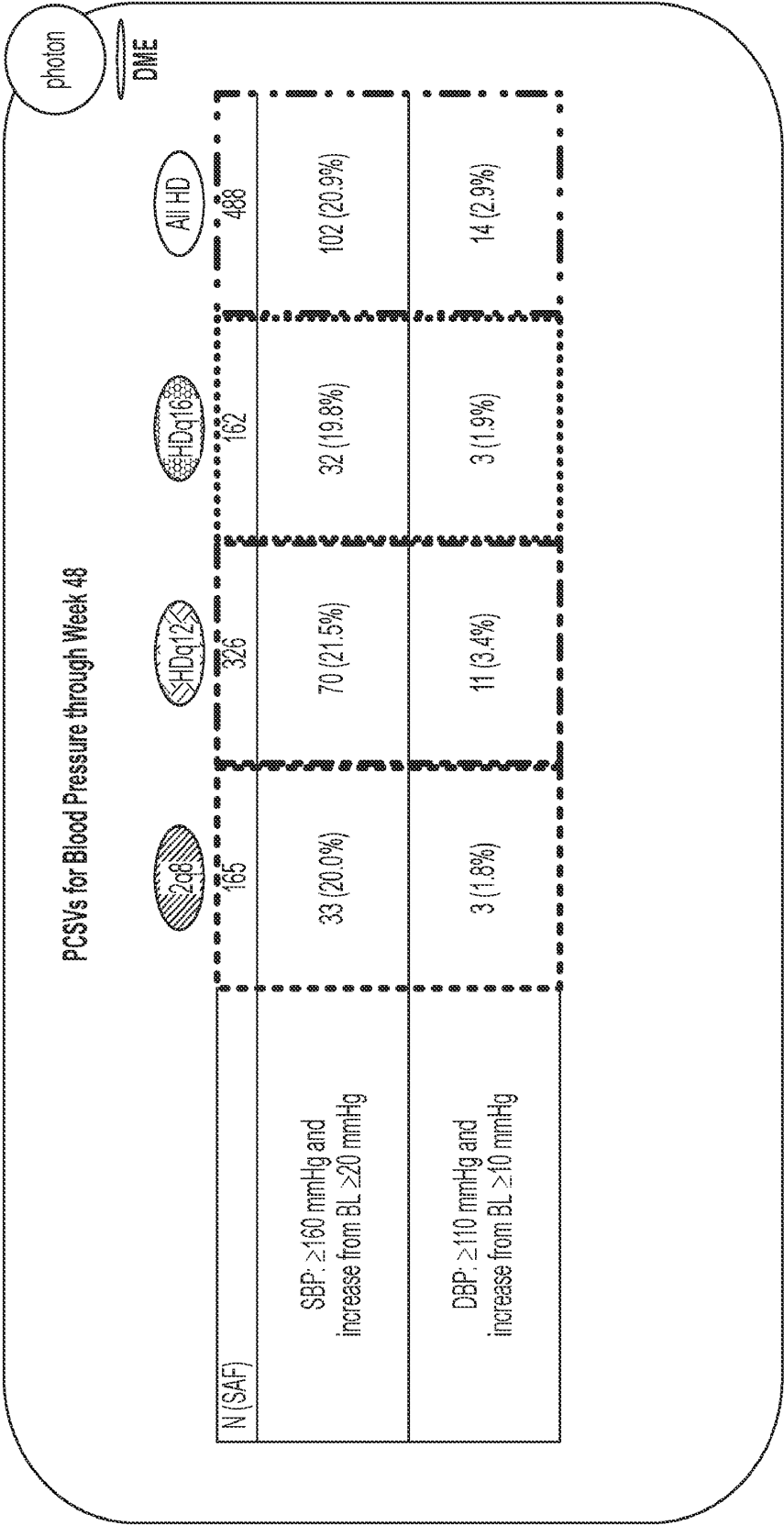


FIG. 21

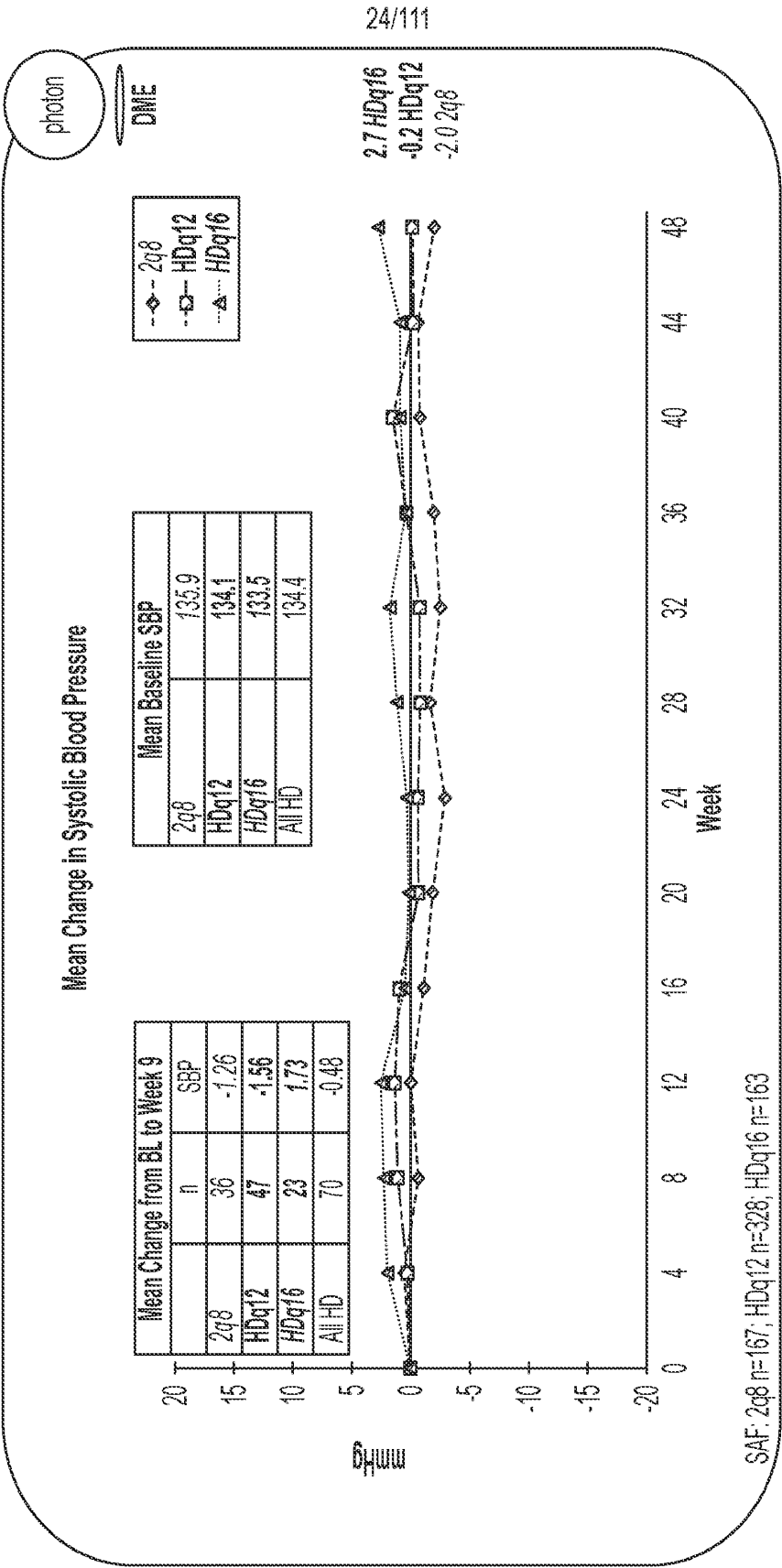


FIG. 22

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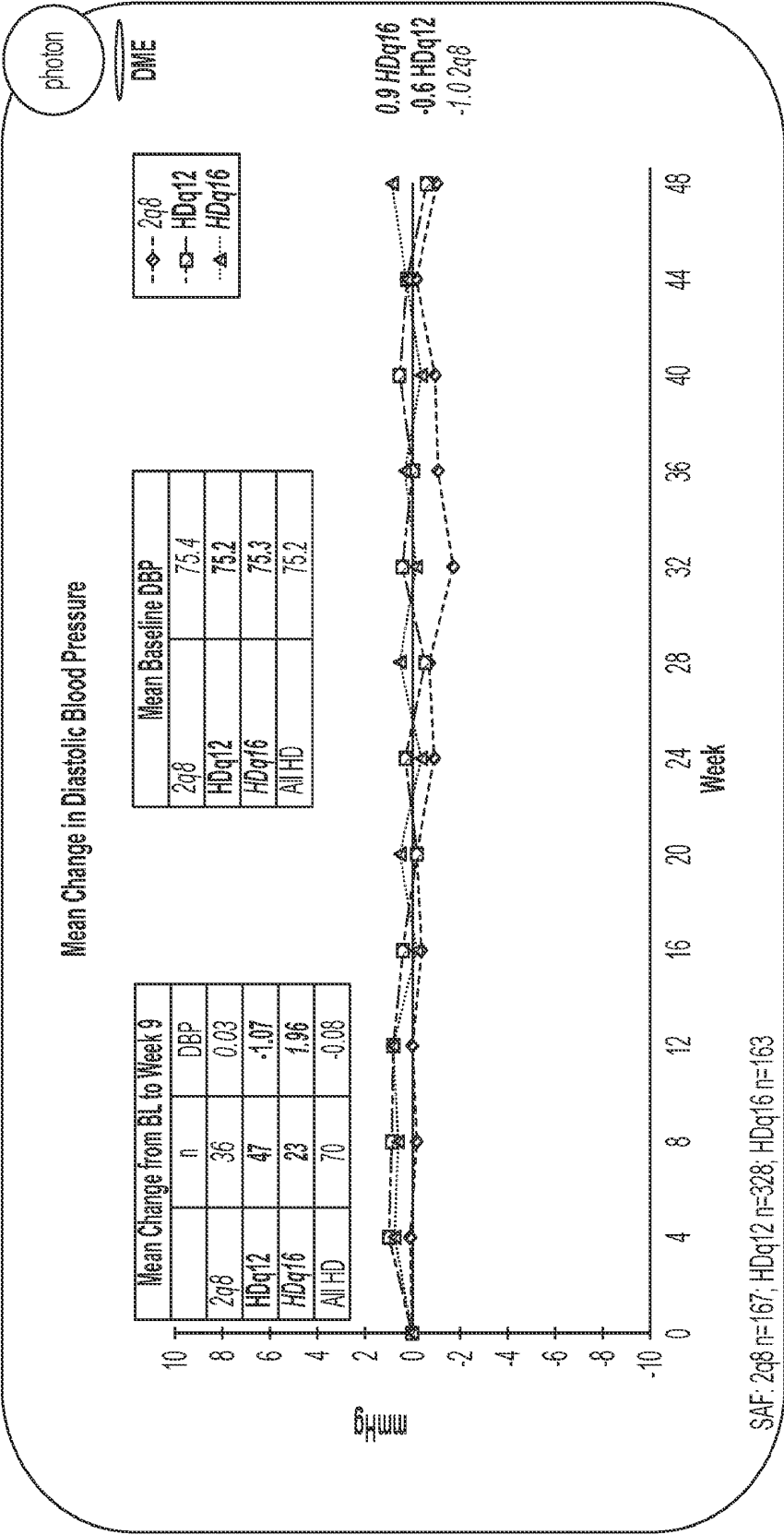


FIG. 23

photocopy

DEATHS THROUGH WEEK 48

DME

N (SAF)	167	328	163	491
Number of Deaths, n (%)	4 (2.4%)	9 (2.7%)	3 (1.8%)	12 (2.4%)
Cardiac arrest	2 (1.2%)	2 (0.6%)	0	2 (0.4%)
Cardio-respiratory arrest	0	0	1 (0.6%)	1 (0.2%)
Left ventricular failure	0	0	1 (0.6%)	1 (0.2%)
Myocardial infarction	1 (0.6%)	1 (0.3%)	0	1 (0.2%)
Death	0	2 (0.6%)	0	2 (0.4%)
Sudden death	0	0	1 (0.6%)	1 (0.2%)
COVID-19	0	1 (0.3%)	0	1 (0.2%)
Pneumonia	0	1 (0.3%)	0	1 (0.2%)
Diabetic metabolic decompensation	1 (0.6%)	0	0	0
Endometrial cancer	0	1 (0.3%)	0	1 (0.2%)
Acute kidney injury	0	1 (0.3%)	0	1 (0.2%)

FIG. 24

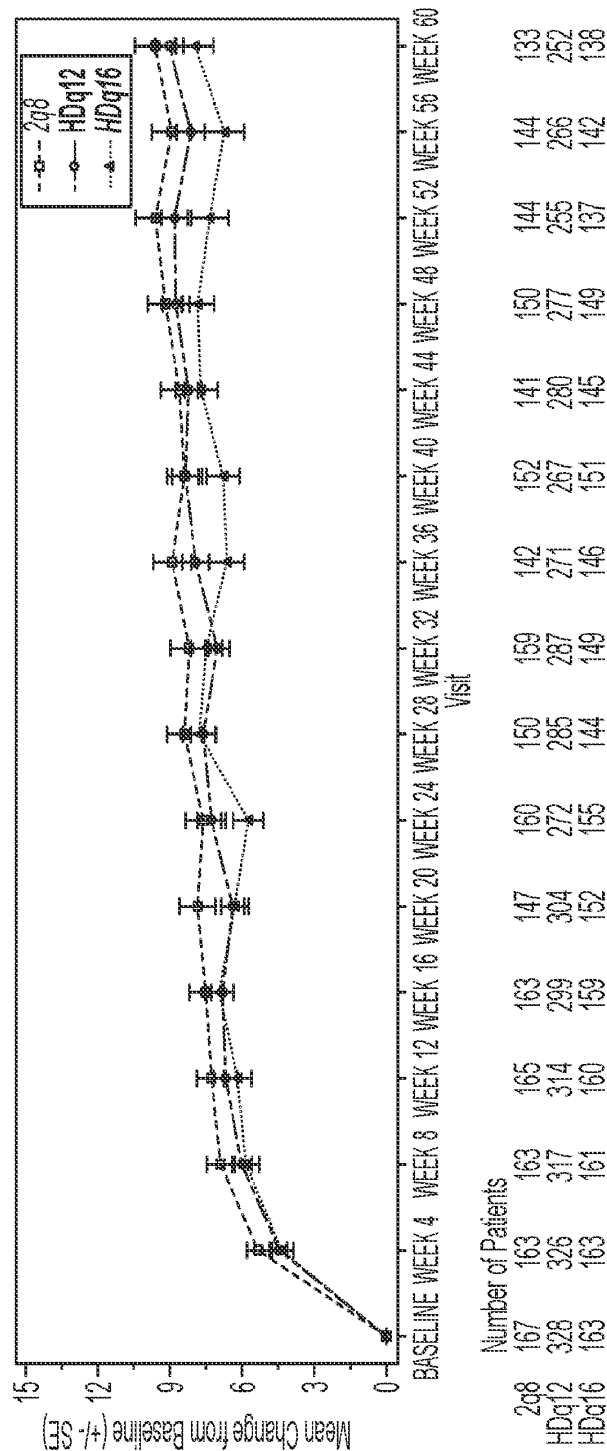
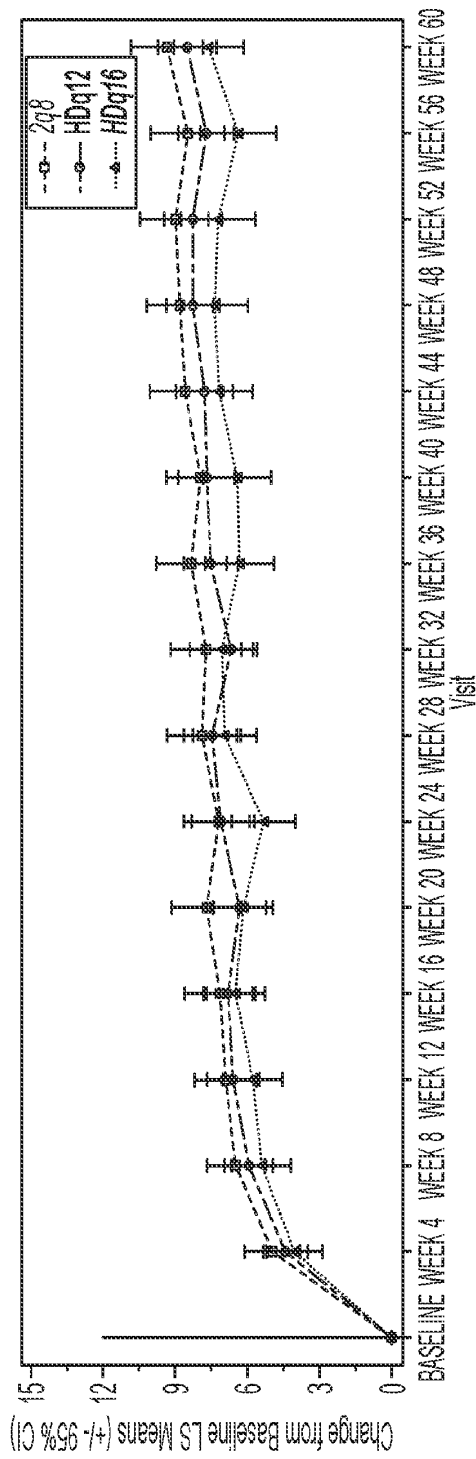


FIG. 25A



Abbreviations: 2q8: Afibercept 2 mg administered every 8 weeks after 5 initial injections at 4-week intervals; HDq12: High dose aflibercept 8 mg administered every 12 weeks after 3 initial injections at 4-week intervals; HDq16: High dose aflibercept 8 mg administered every 16 weeks after 3 initial injections at 4-week intervals.

BCVA=best-corrected visual activity; ETDRS=Early Treatment of Diabetic Retinopathy Study; HD=high dose; OC=observed cases; CI=confidence interval.

Least square mean (LSM) was generated from a mixed model for repeated measurements (MMRM) with baseline BCVA measurement as a covariate, treatment group and the stratification variables (geographic region [Japan vs. Rest of World]; baseline CRT (from reading center) [$<400\mu\text{m}$ vs. $\geq 400\mu\text{m}$]; prior treatment for DME (per EDC) [yes vs. no]) as fixed factors, and terms for the interaction between baseline and visit and the interaction between treatment and visit. A Kenward-Roger approximation was used for the denominator degrees of freedom. An unstructured covariance structure was used to model the within-subject error.

FIG. 25B

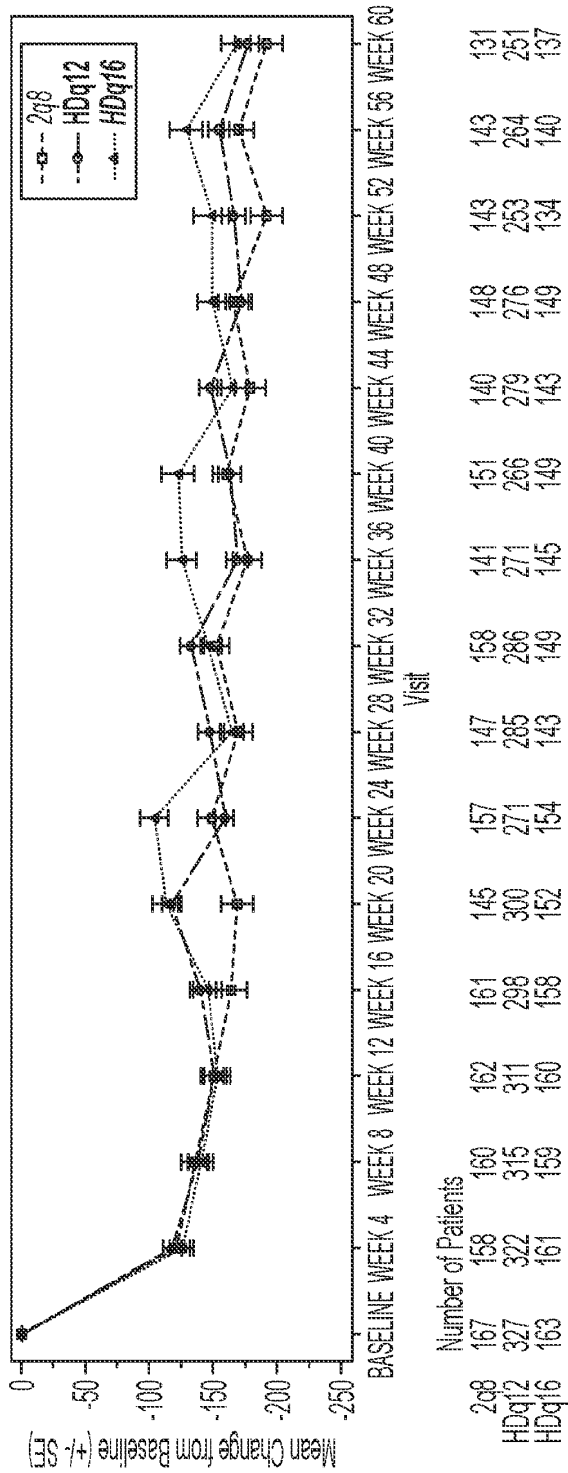
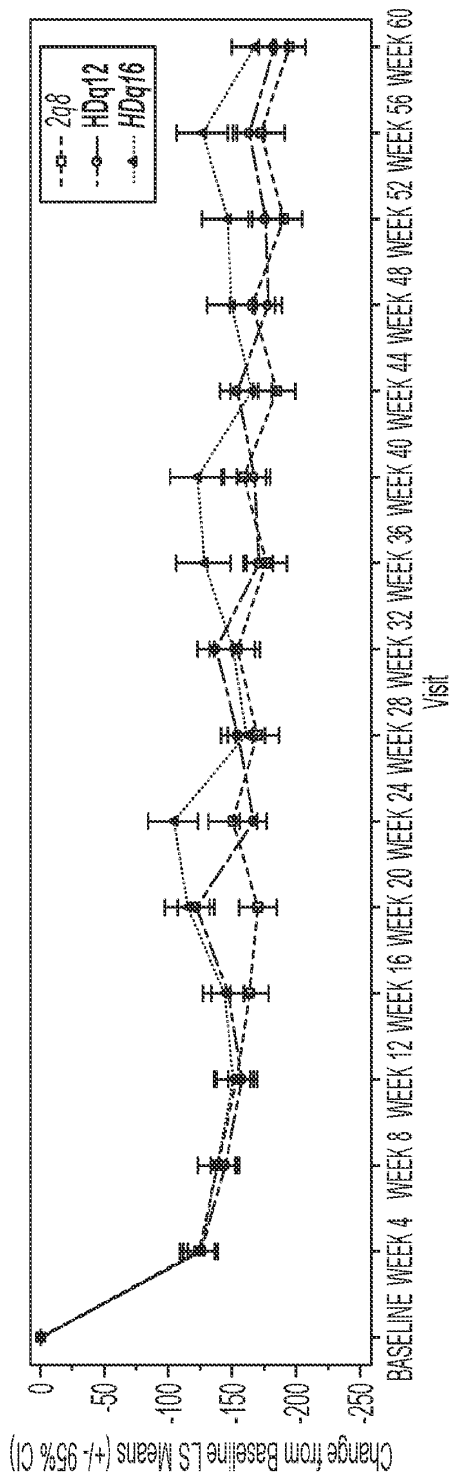


FIG. 26A



Abbreviations: 2q8: Aflibercept 2 mg administered every 8 weeks after 5 initial injections at 4-week intervals; HDq12: High dose aflibercept 8 mg administered every 12 weeks after 3 initial injections at 4-week intervals; HDq16: High dose aflibercept 8 mg administered every 16 weeks after 3 initial injections at 4-week intervals.

BCVA=best-corrected visual activity; CI=confidence interval; CRT=central retinal thickness; HD=high dose; LS=least square; OC=observed cases.

Least square mean (LSM) was generated from a mixed model for repeated measurements (MMRM) with baseline CRT measurement as a covariate, treatment group and the stratification variables (geographic region [Japan vs. Rest of World]; baseline CRT (from reading center) [$<400\mu\text{m}$ vs. $\geq 400\mu\text{m}$], prior treatment for DME (per EDC) [yes vs. no]) as fixed factors, and terms for the interaction between baseline and visit and the interaction between treatment and visit. A Kenward-Roger approximation was used for the denominator degrees of freedom. An unstructured covariance structure was used to model the within-subject error.

FIG. 26B

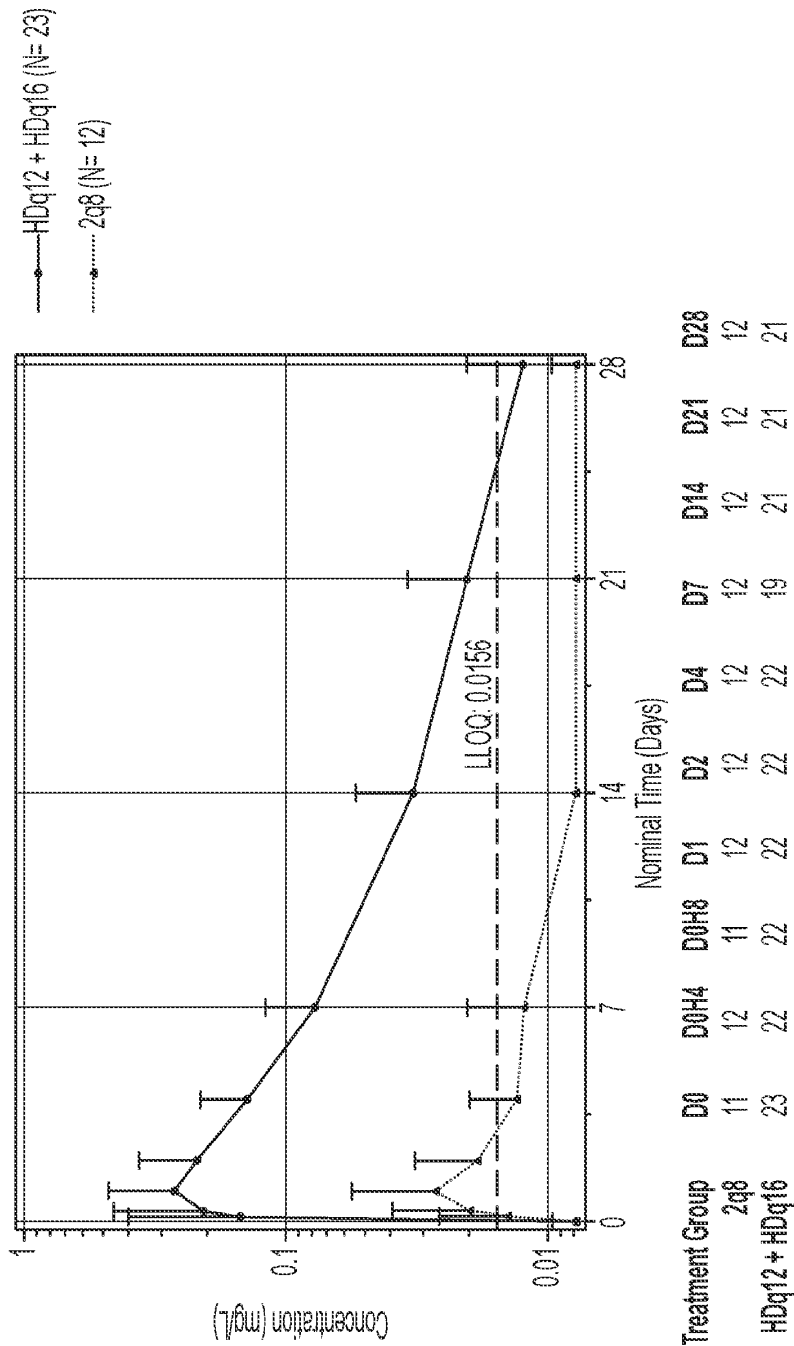


FIG. 27

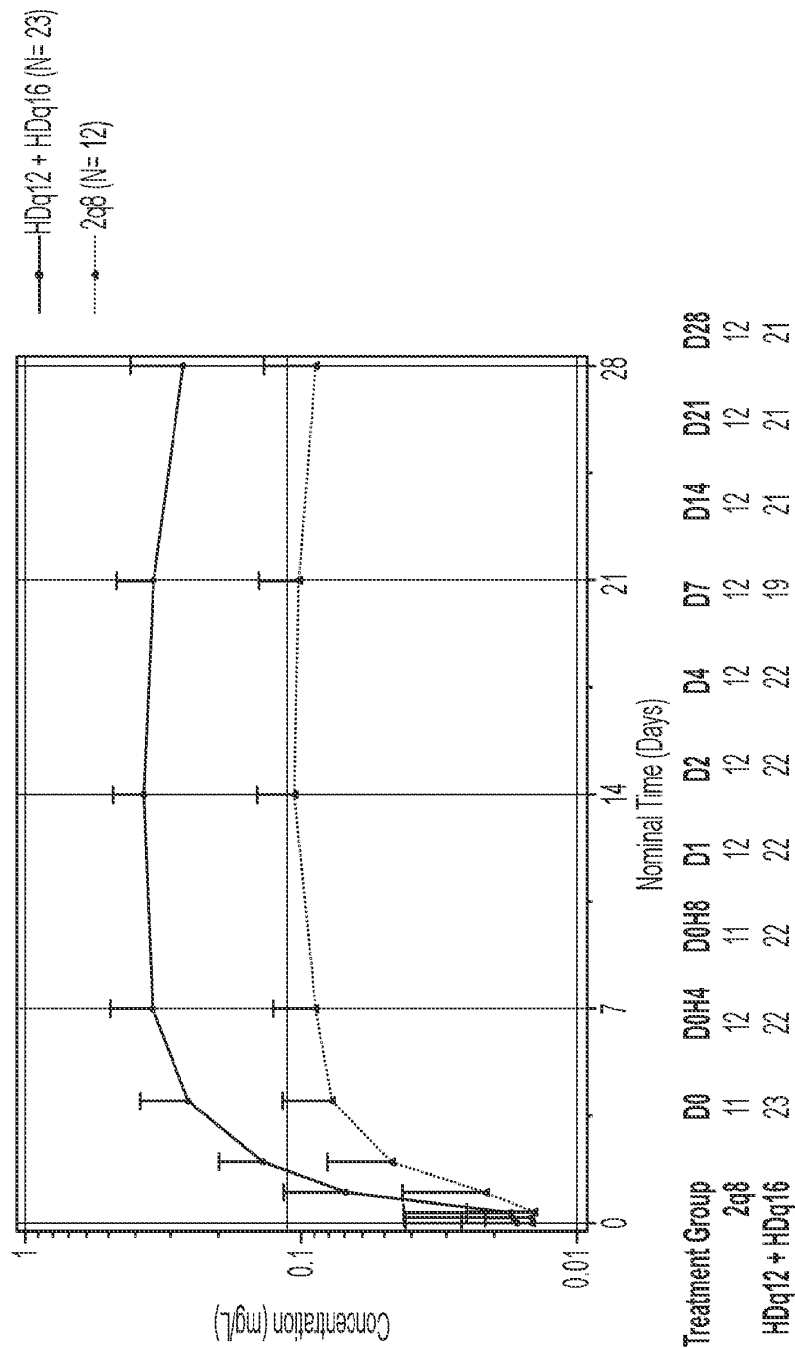


FIG. 28

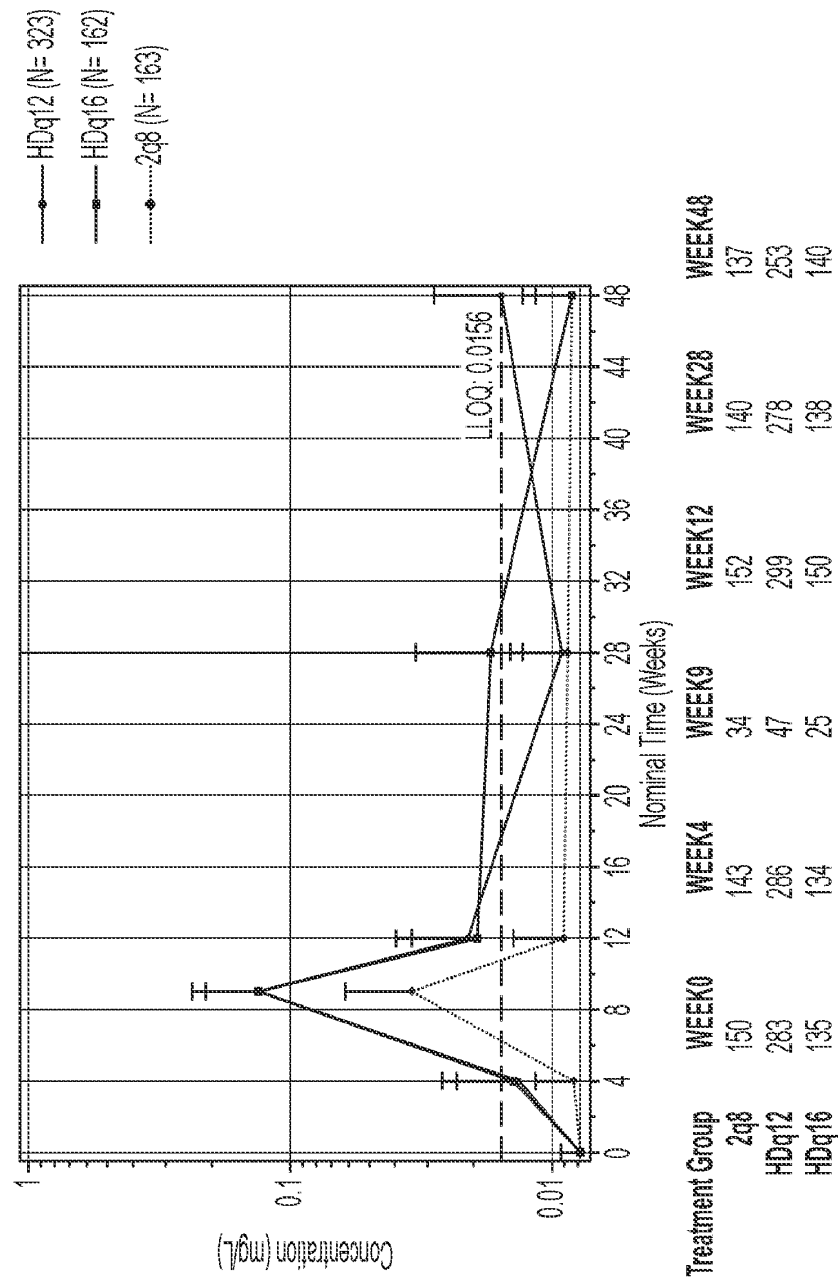


FIG. 29

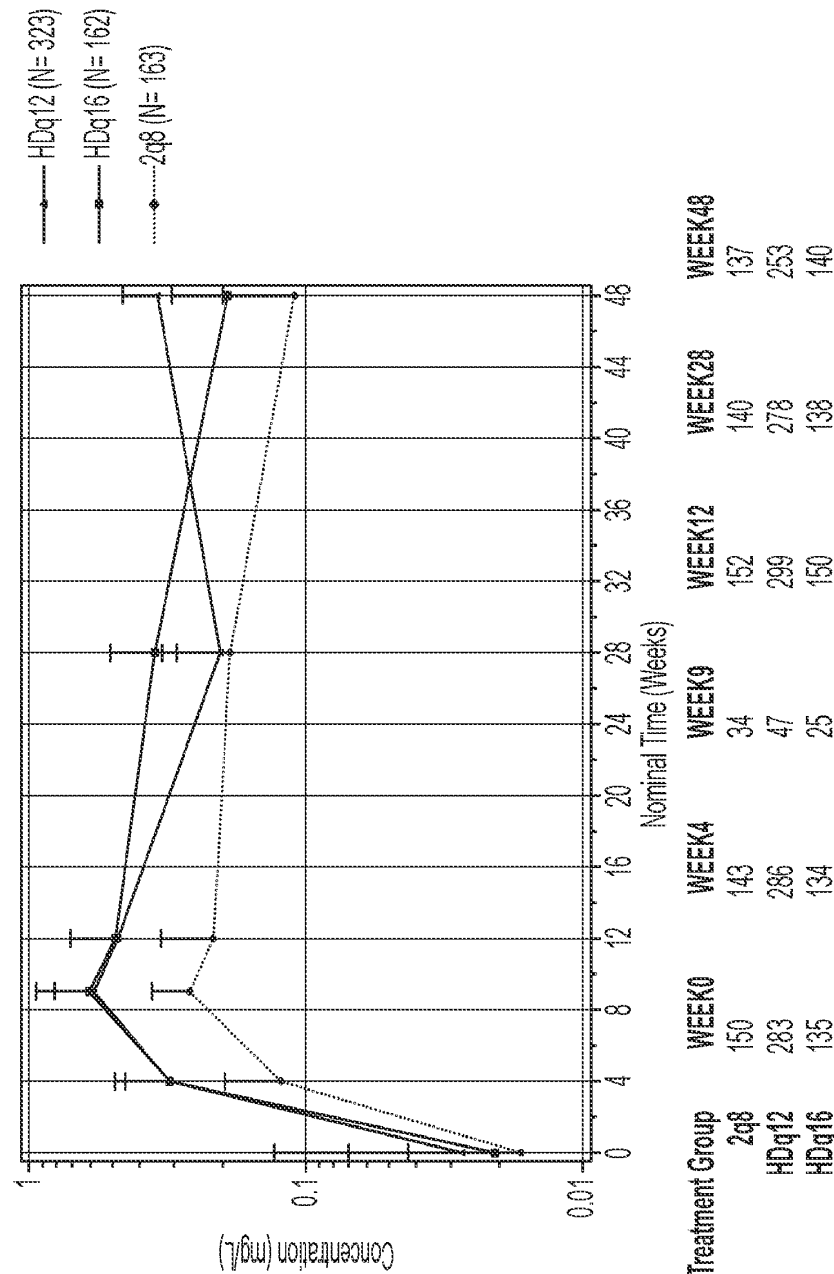


FIG. 30

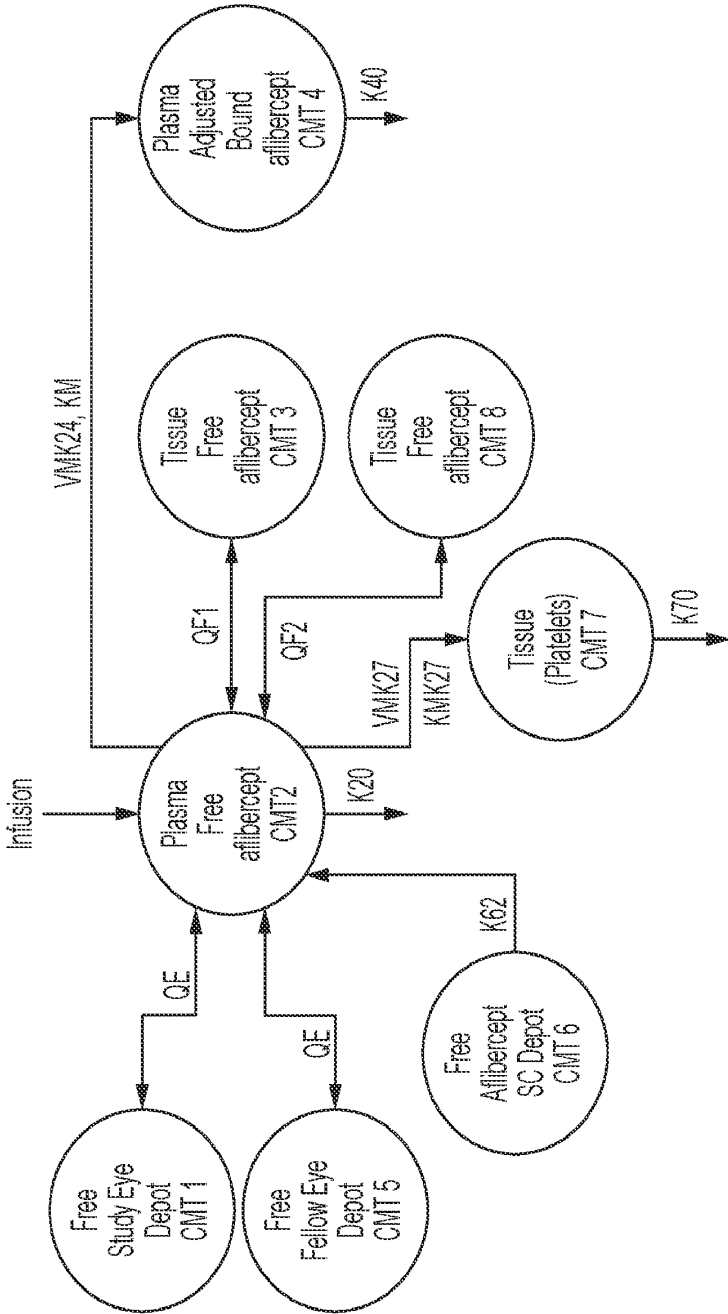


FIG. 31

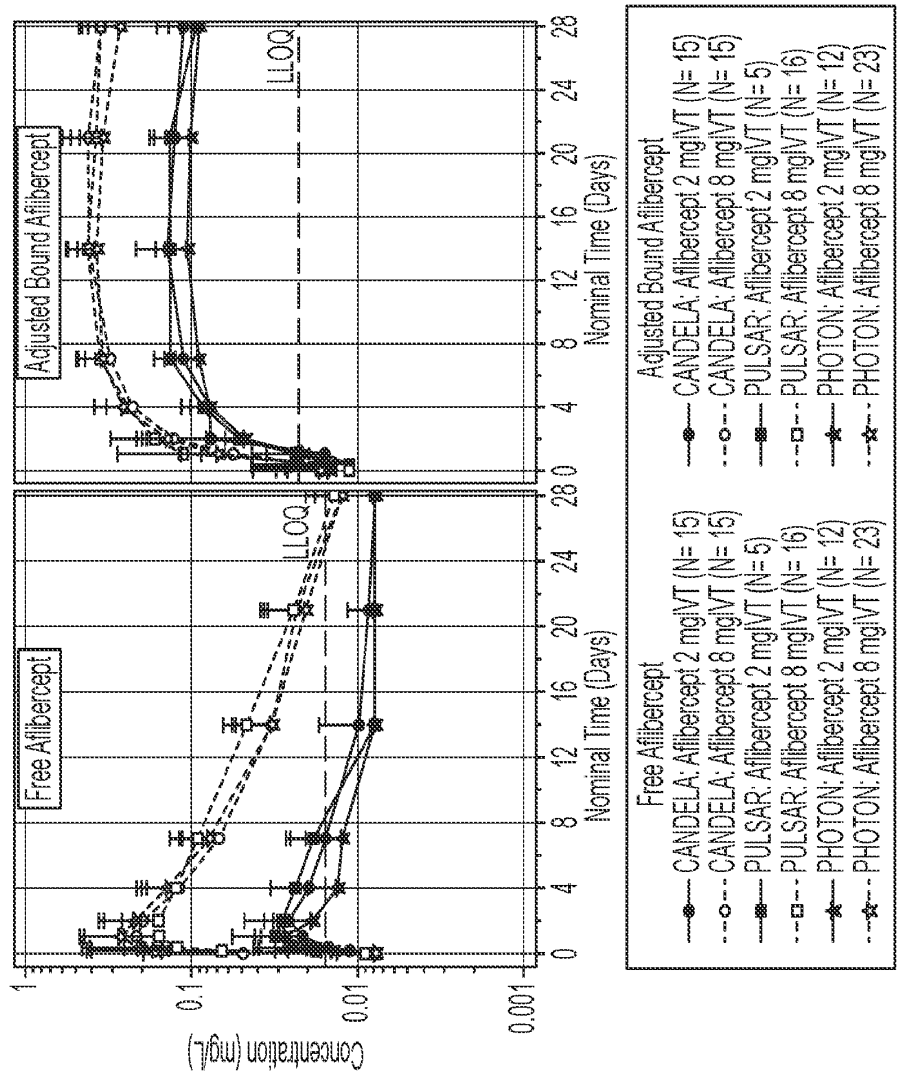


FIG. 32

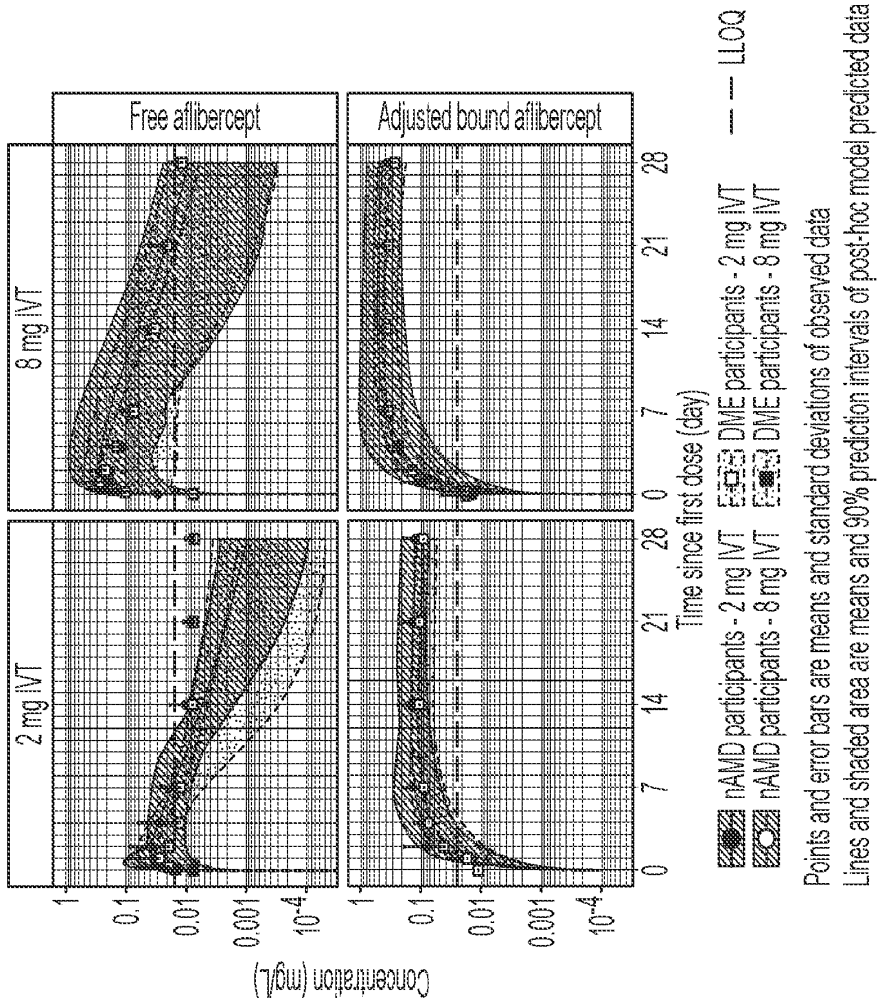


FIG. 33

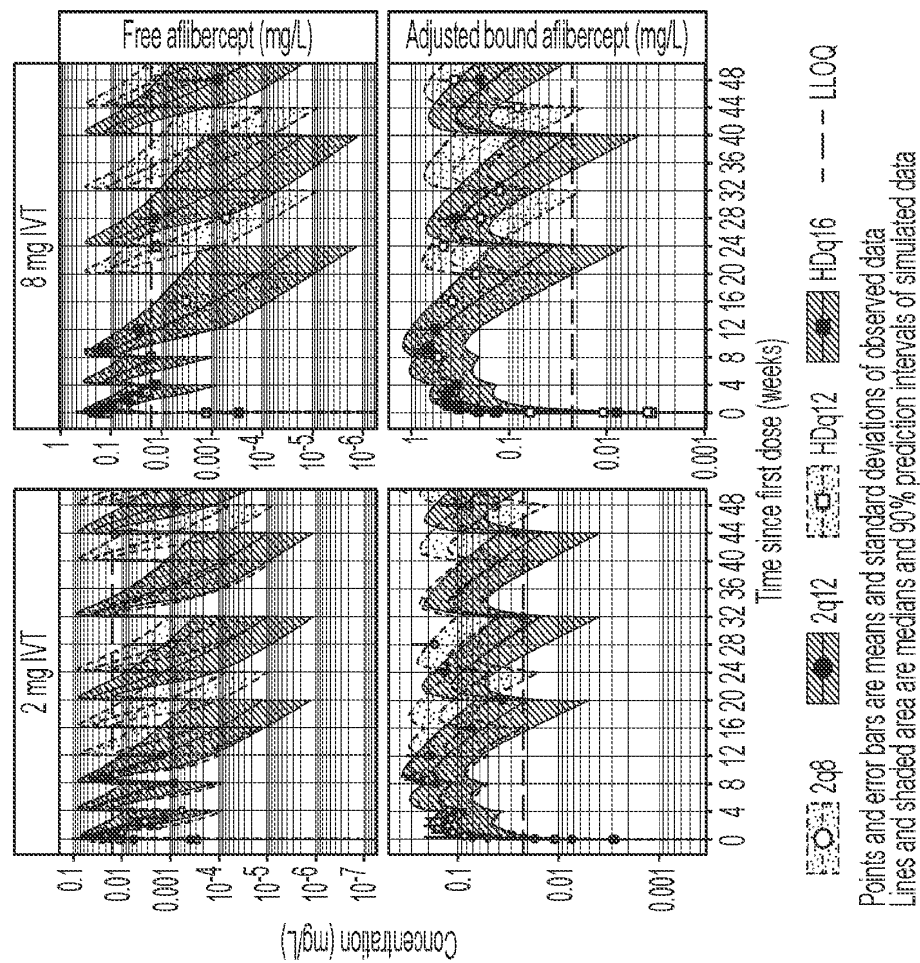


FIG. 34

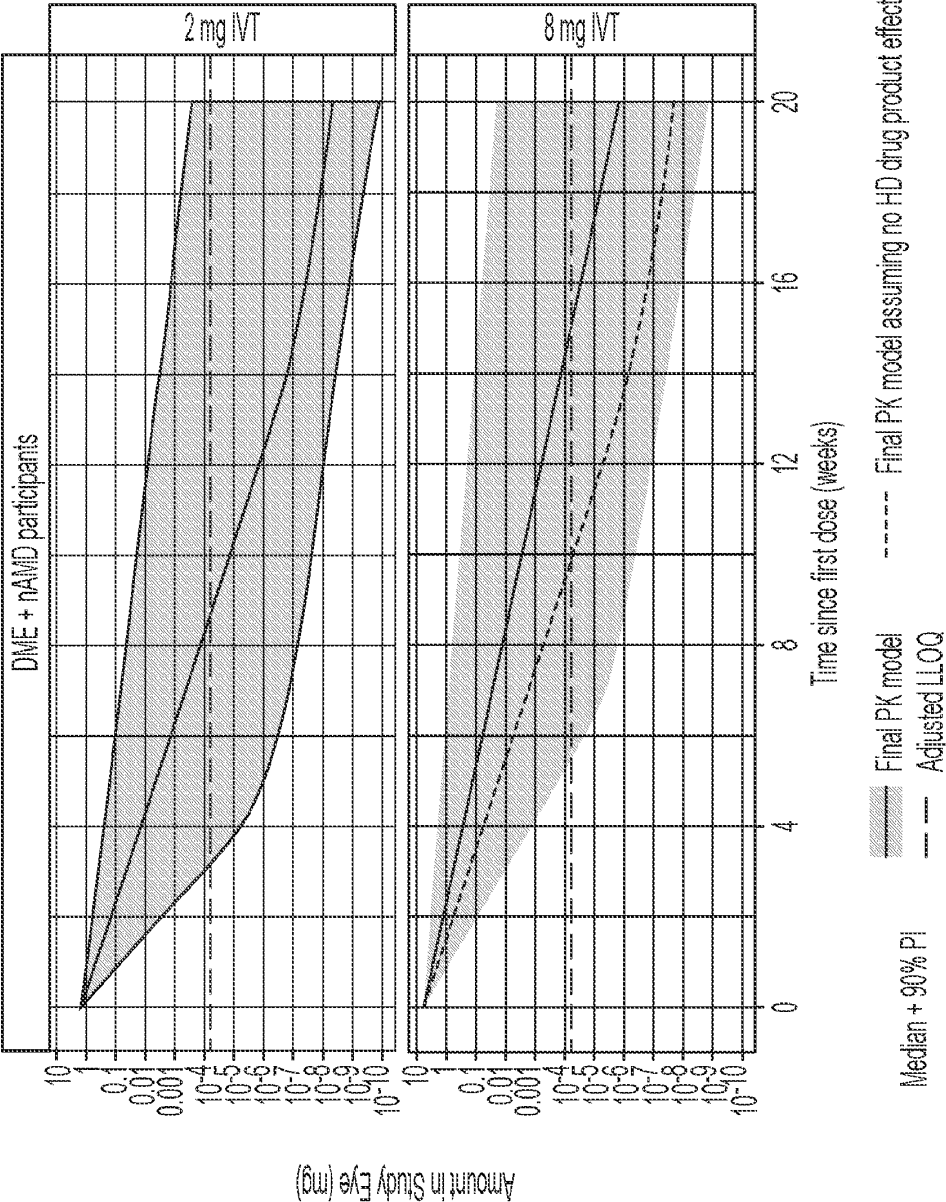


FIG. 35

Adjusted LLOQ = LLOQ of free aflibercept in plasma (0.0156 mg/L) x the assumed volume of the study eye (4 mL)

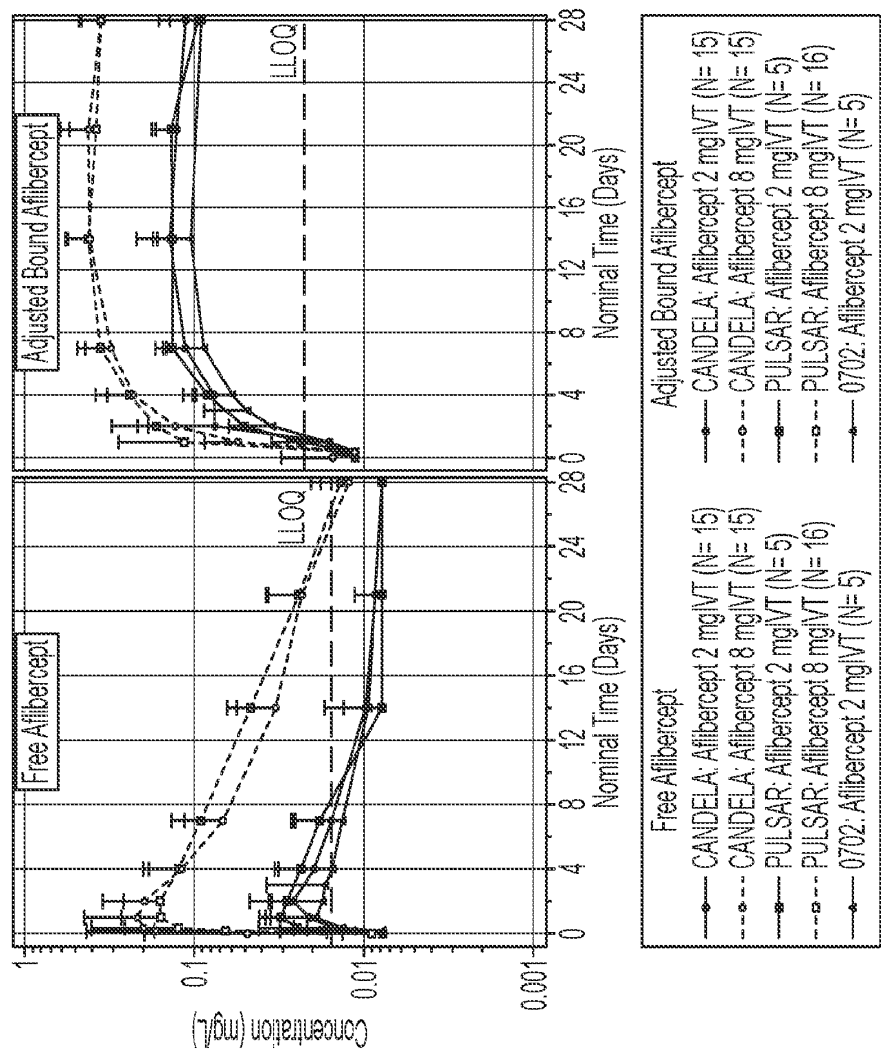


FIG. 36

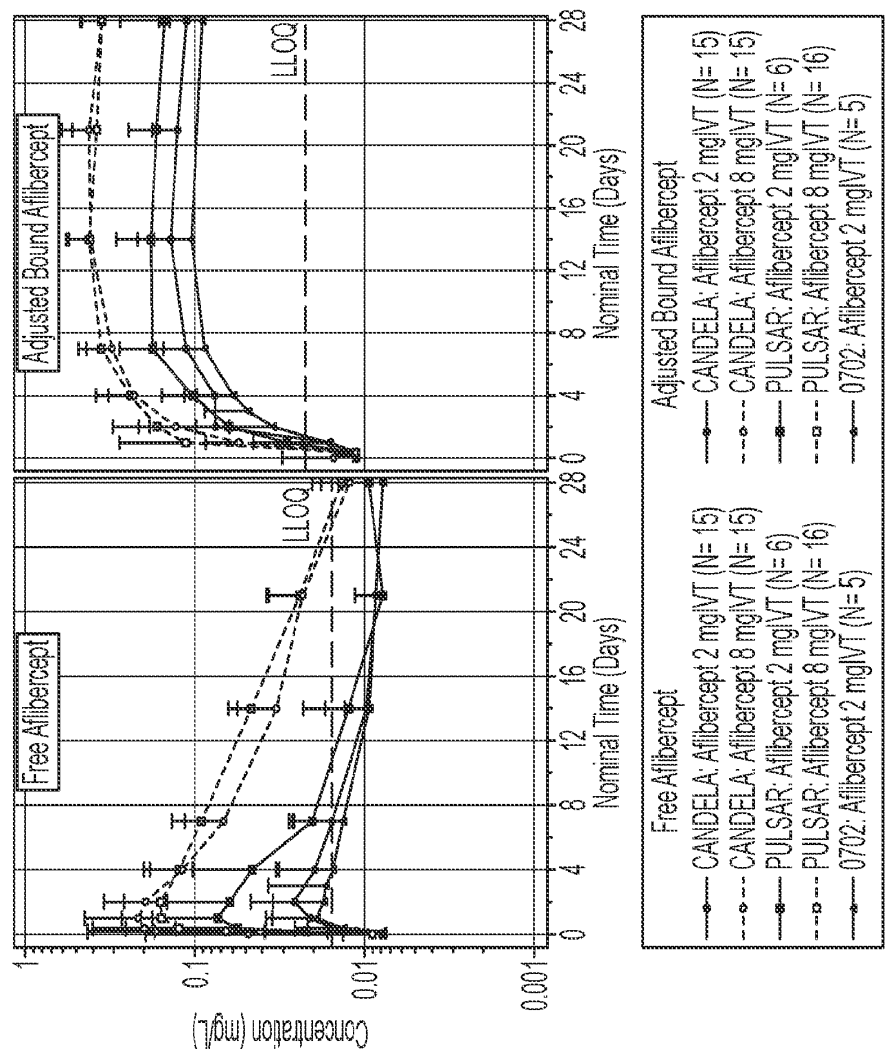


FIG. 37

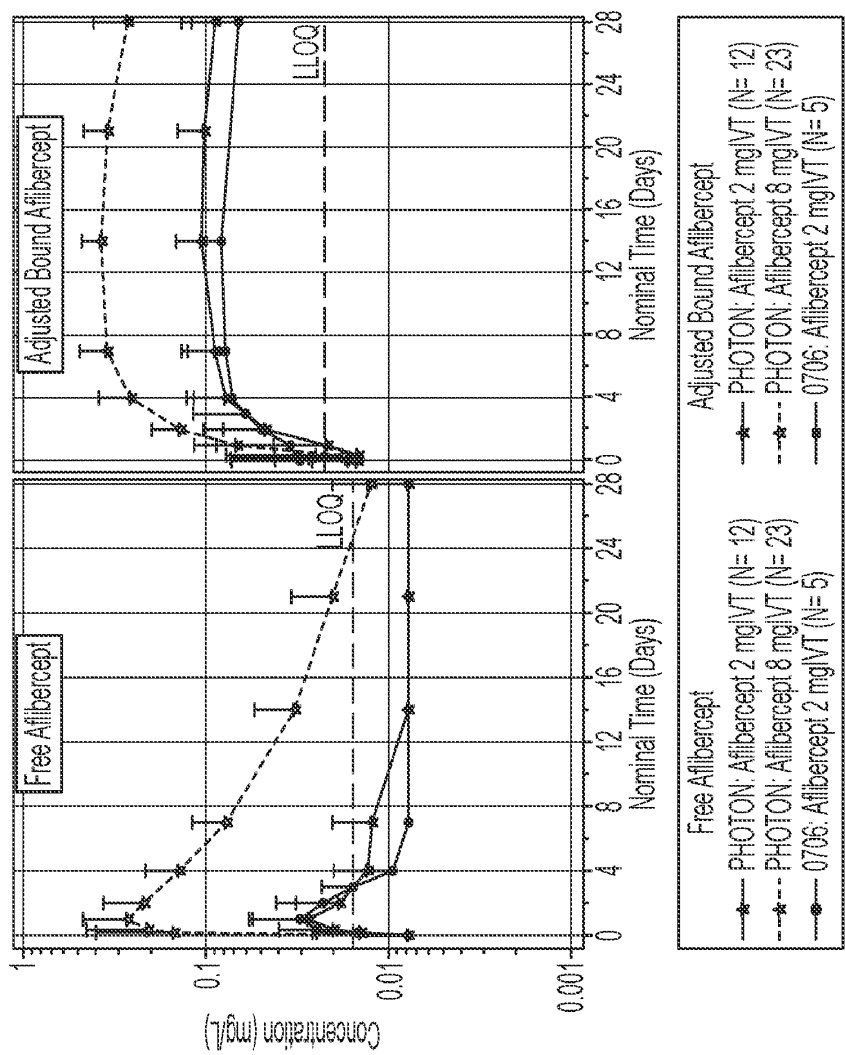


FIG. 38

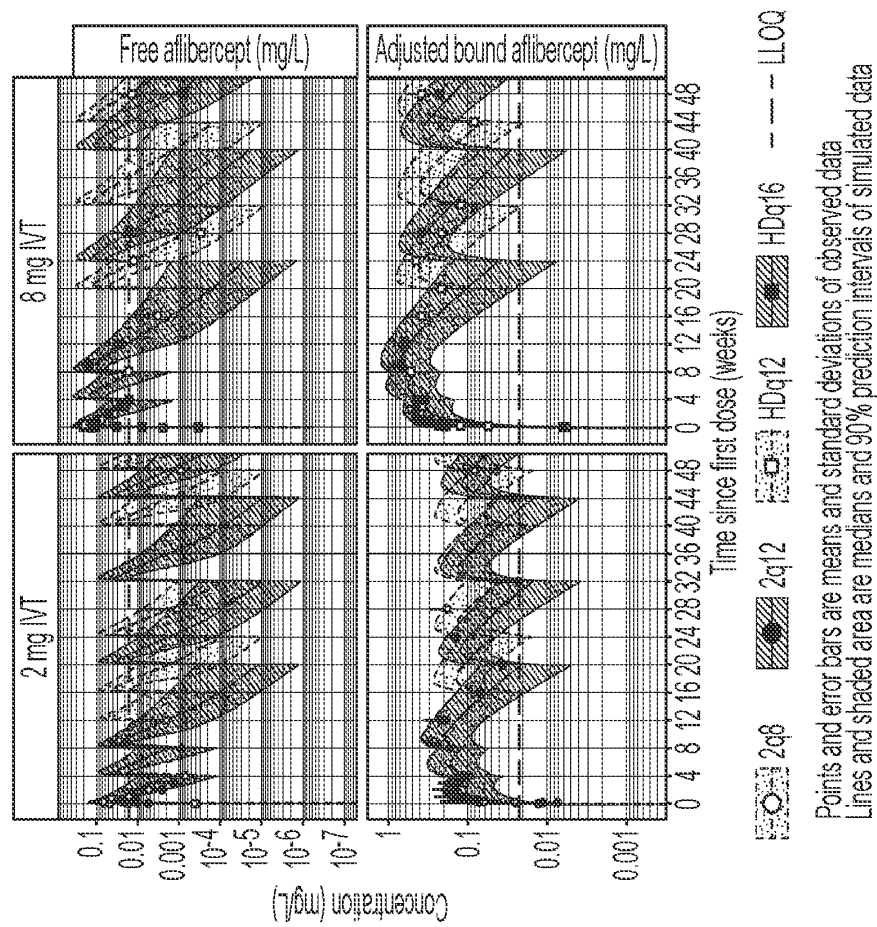
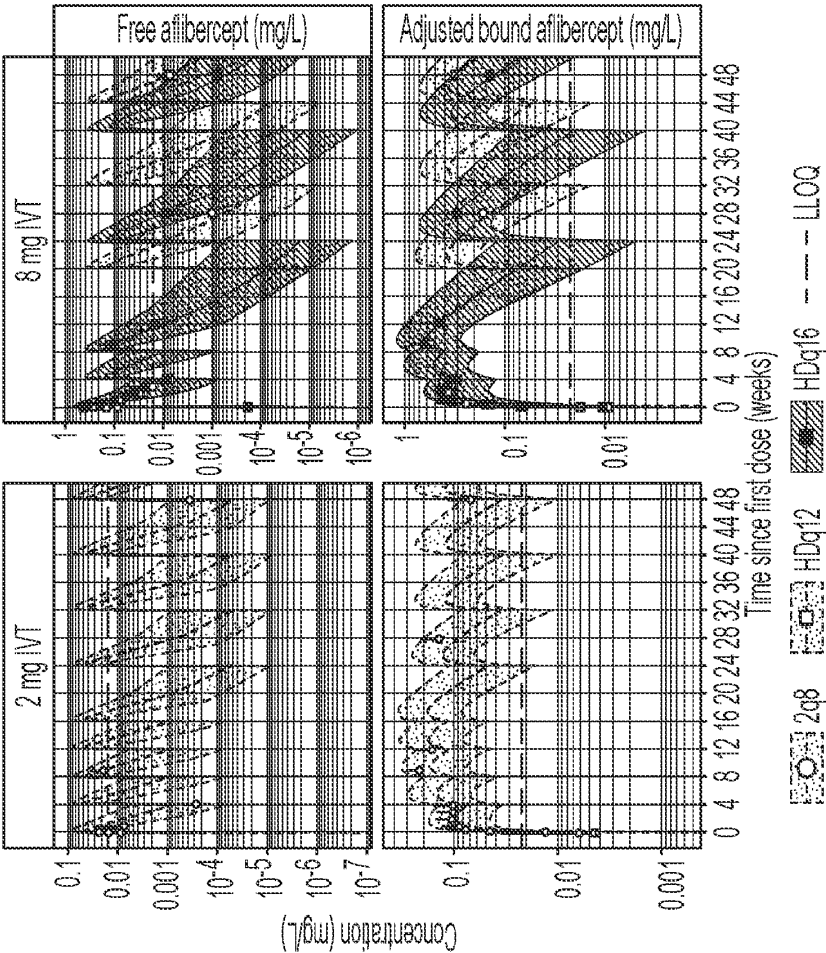


FIG. 39



Points and error bars are means and standard deviations of observed data
Lines and shaded area are medians and 90% prediction intervals of simulated data

FIG. 40

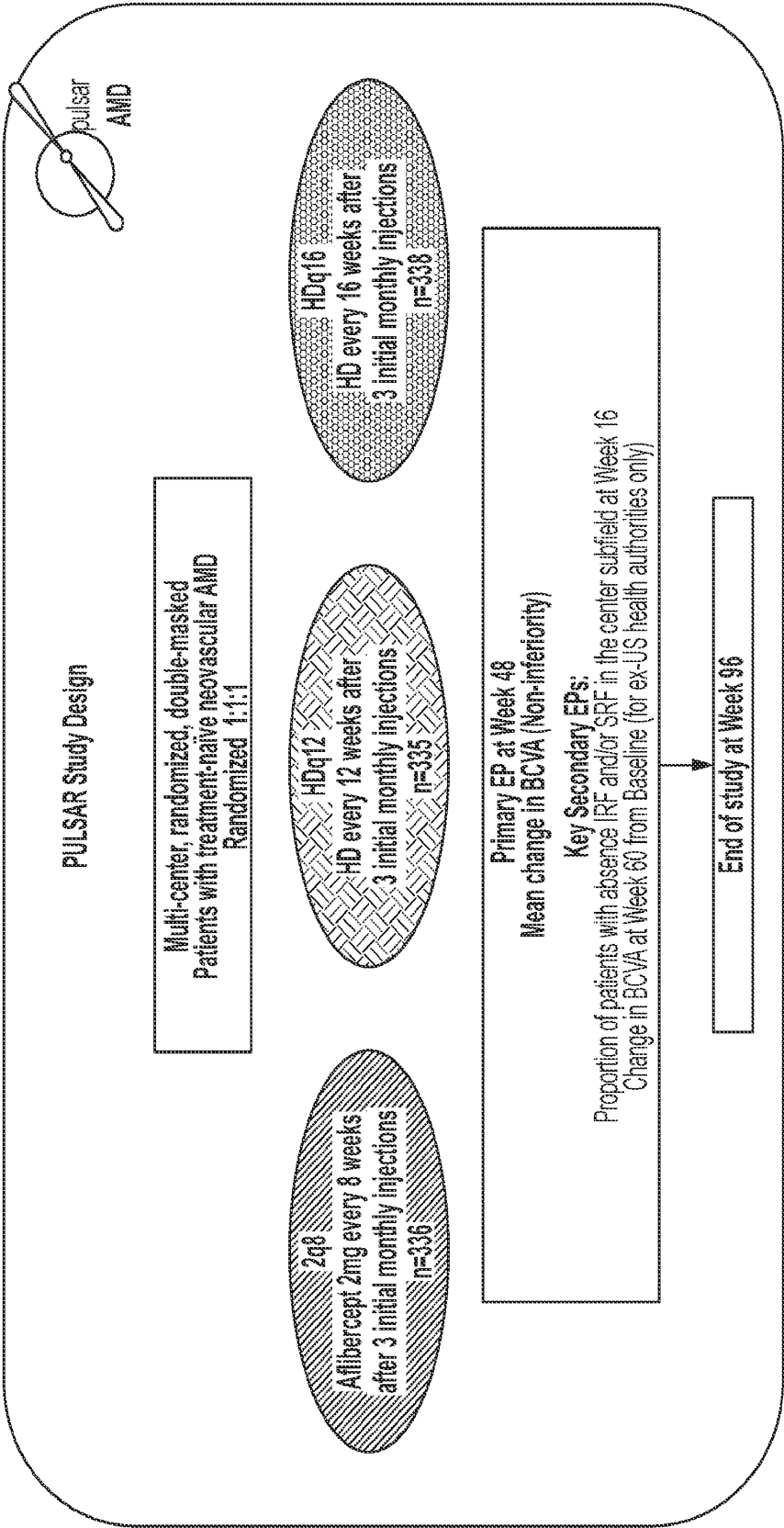
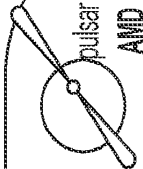


FIG. 41



Key Eligibility Criteria

Key Inclusion Criteria

- Men or women ≥50 years of age with treatment-naïve neovascular AMD (nAMD)
- Active subfoveal CNV, with a total area > 50% of the total lesion area in the study eye
- Presence of intraretinal and/or subretinal fluid in the central subfield on OCT
- BCVA of 78 - 24 letters (Snellen equivalent 20/32 - 20/320) with decreased vision due to nAMD

Exclusion Criteria

- Causes of CNV other than nAMD in the study eye
- History or clinical evidence of diabetic retinopathy, diabetic macular edema, or any retinal vascular disease other than nAMD in either eye
- Scar, fibrosis, atrophy or RPE tears/rips involving the central subfield in the study eye
- IOP ≥25 mmHg in the study eye despite glaucoma treatment
- Intraocular inflammation/infection in either eye within 12 weeks of the screening visit

FIG. 42

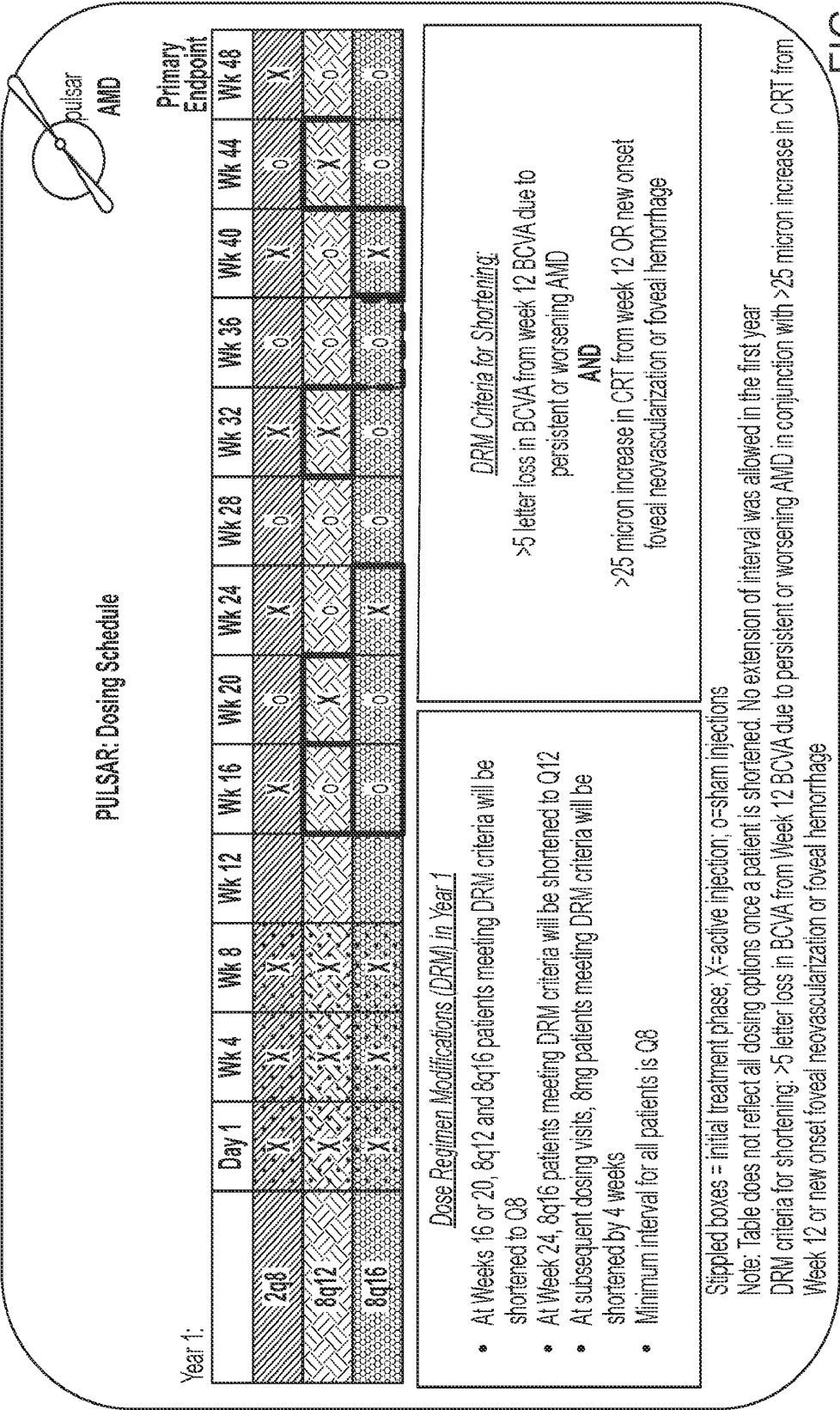


FIG. 43

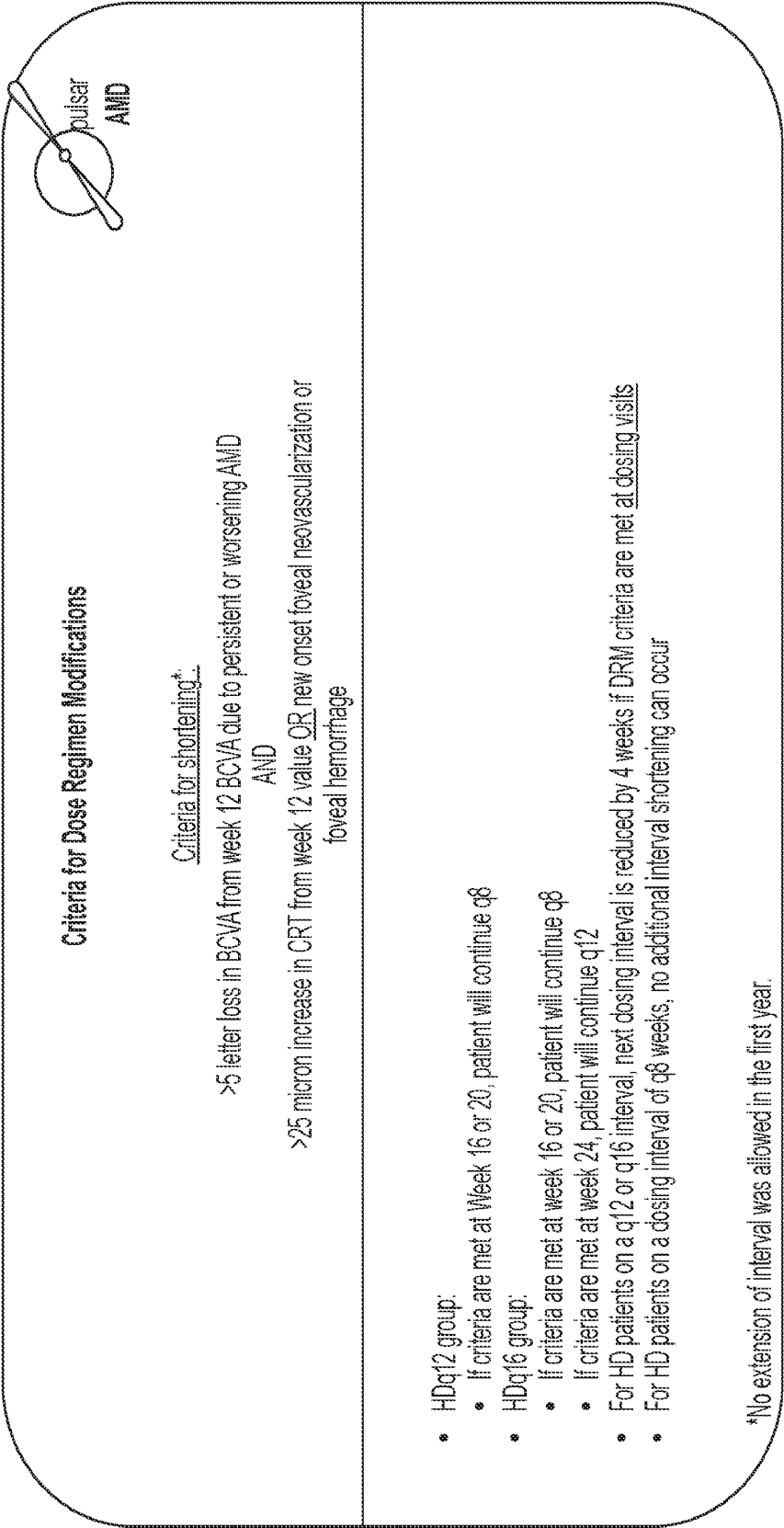


FIG. 44

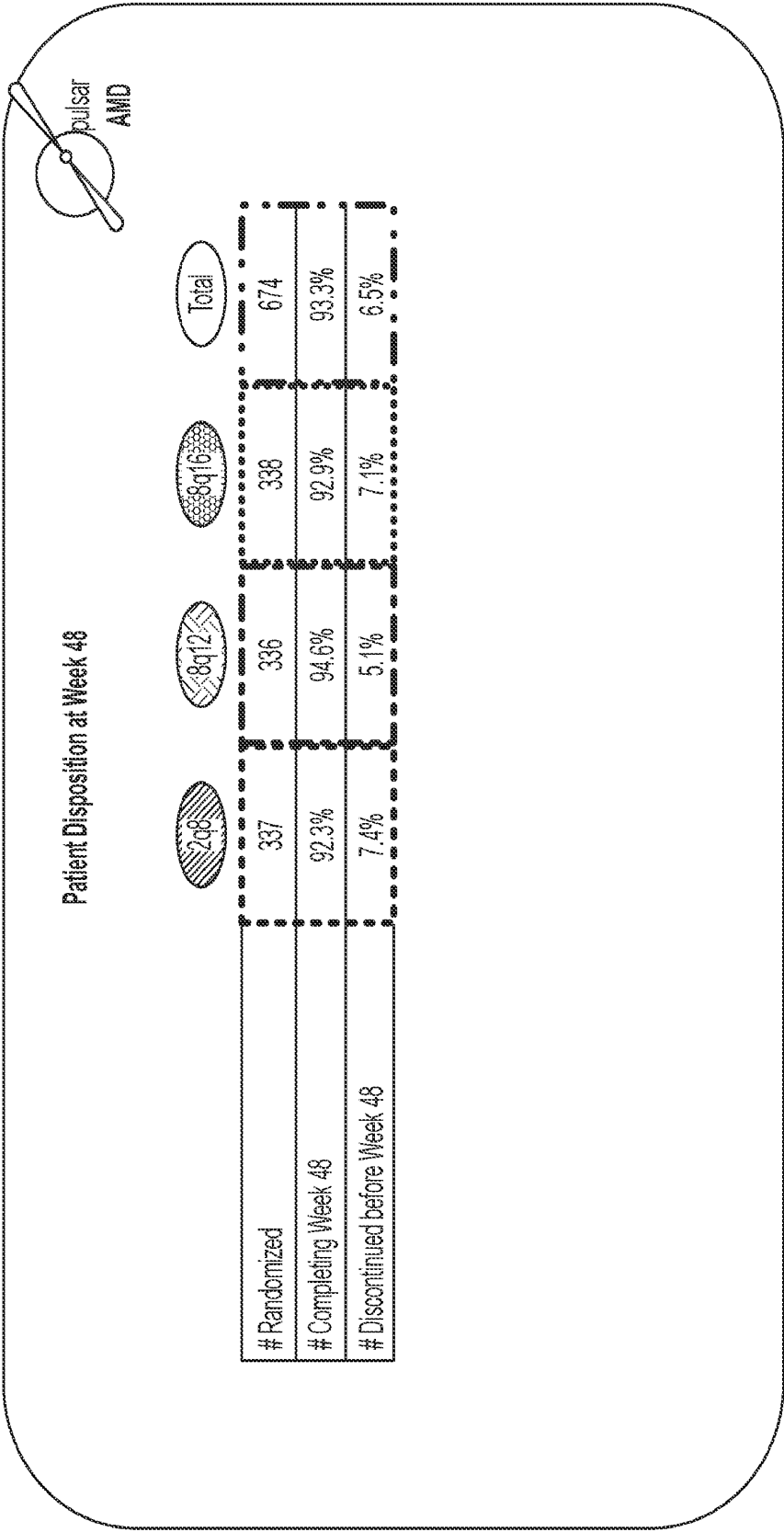


FIG. 45

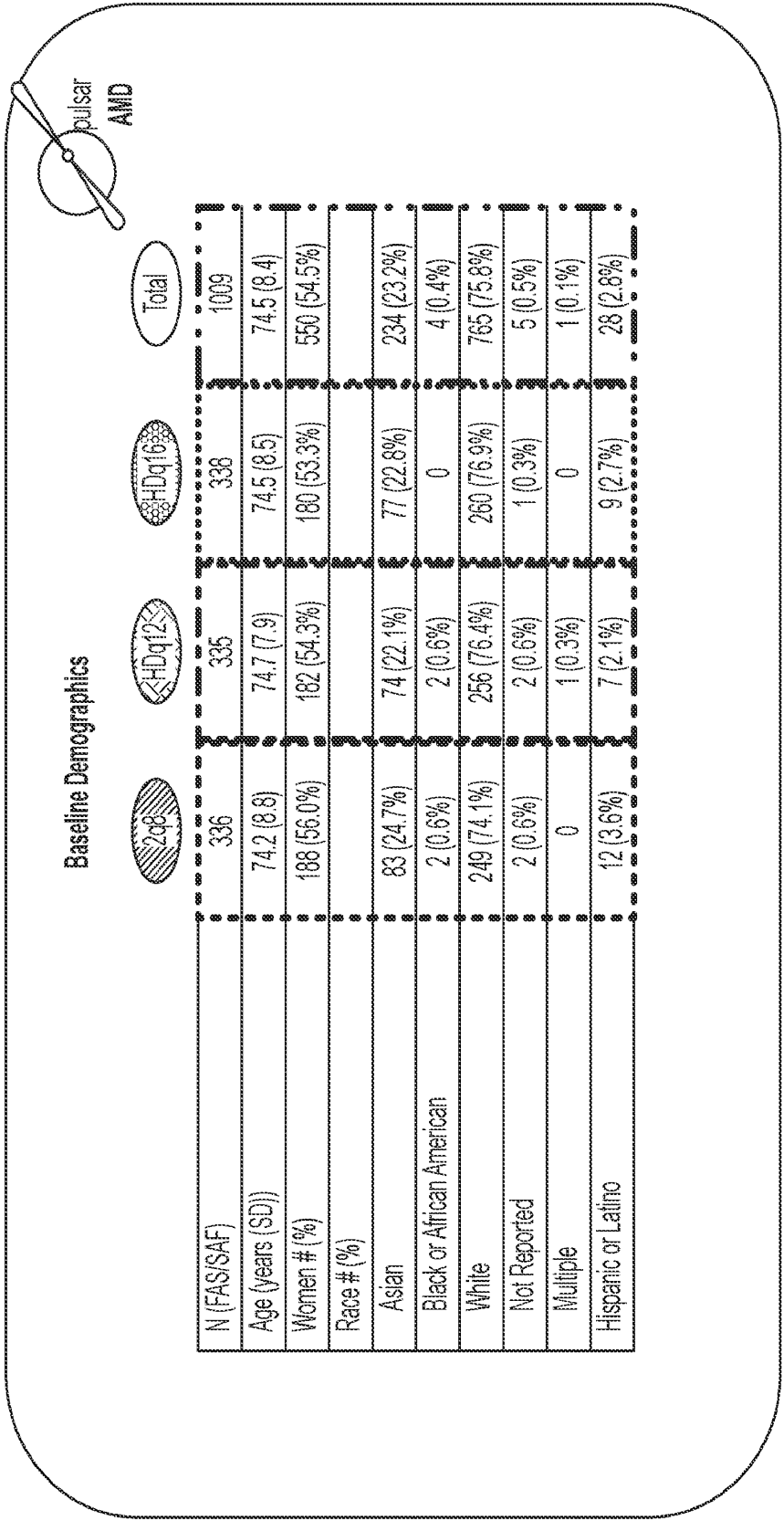


FIG. 46

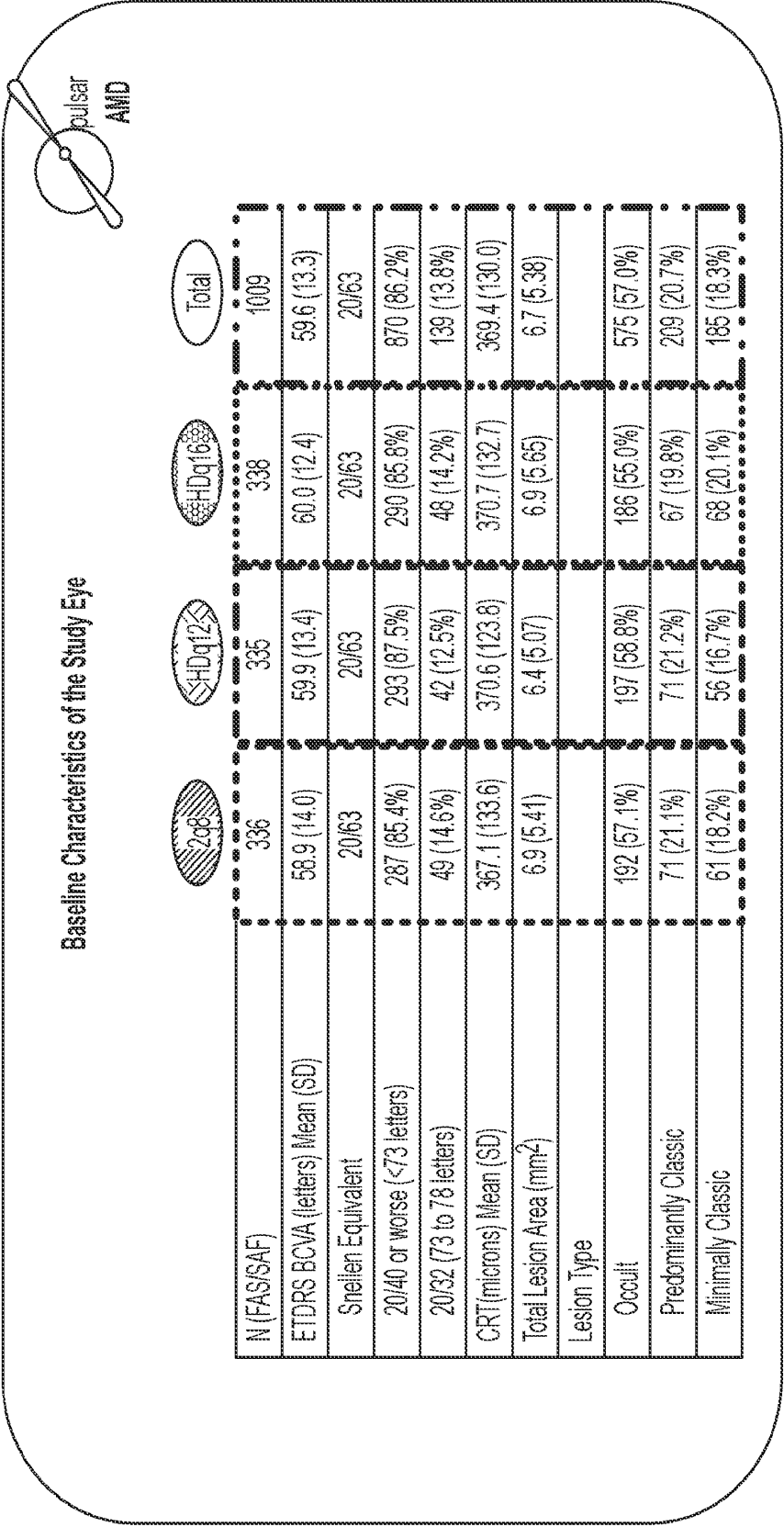


FIG. 47

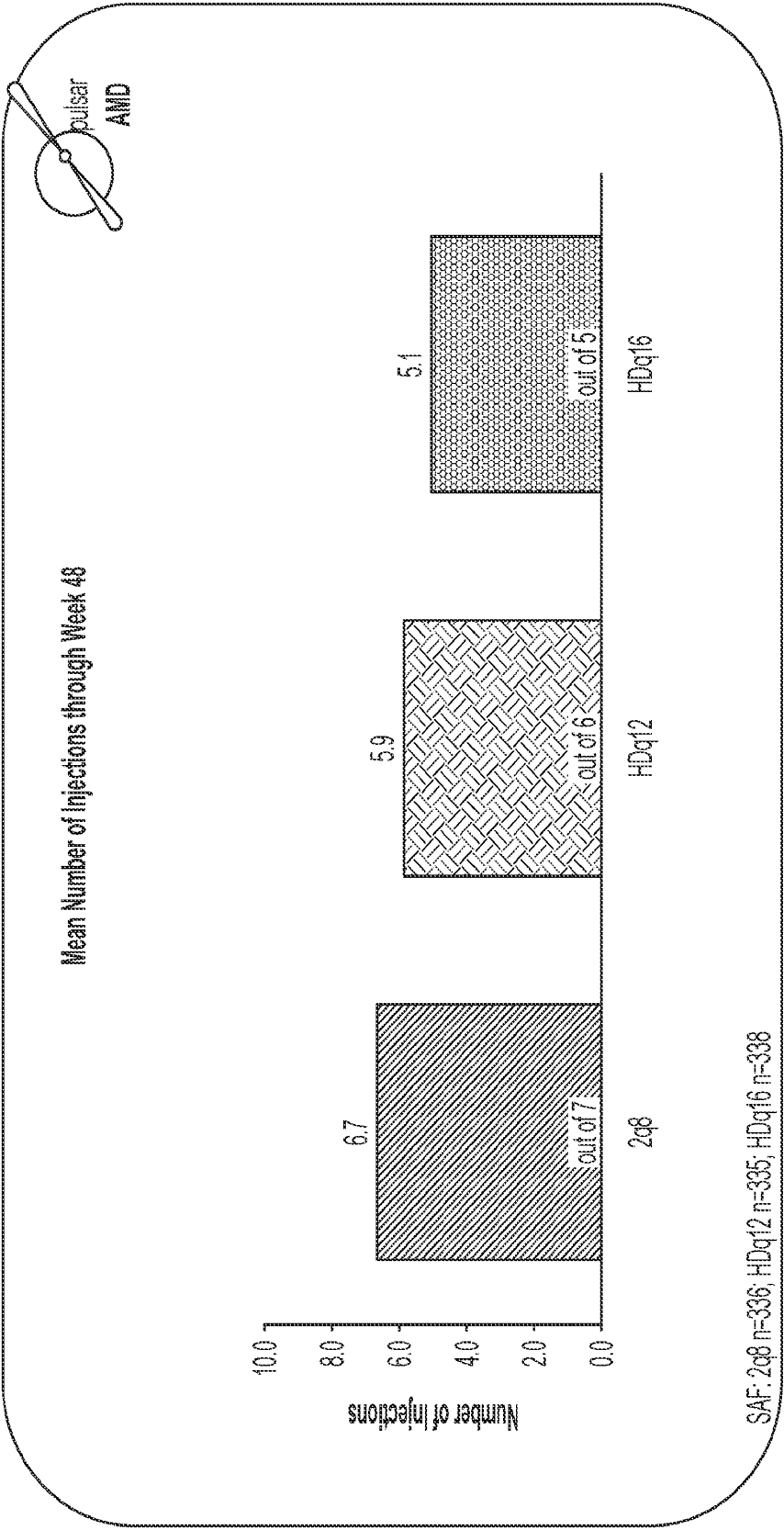


FIG. 48

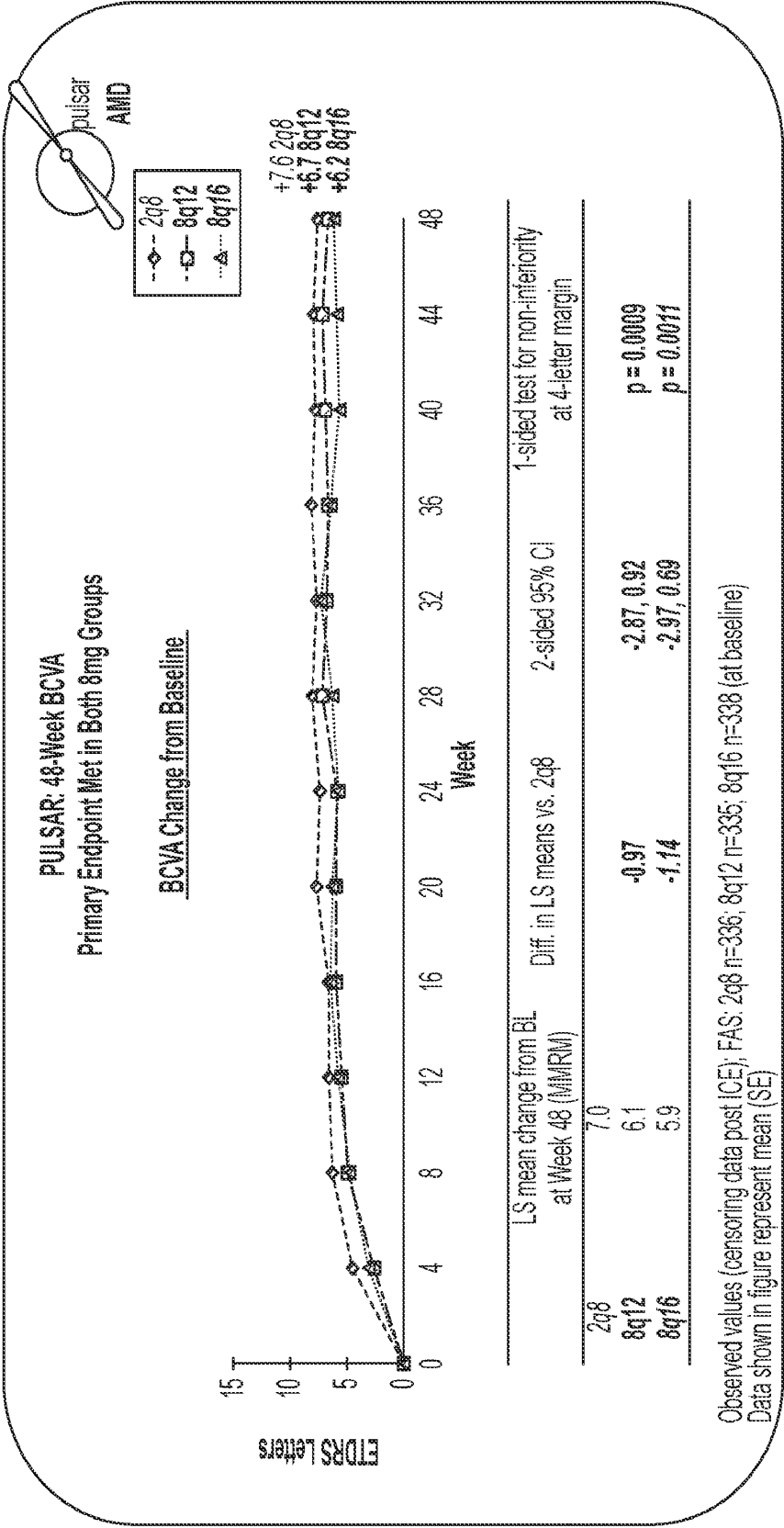


FIG. 49

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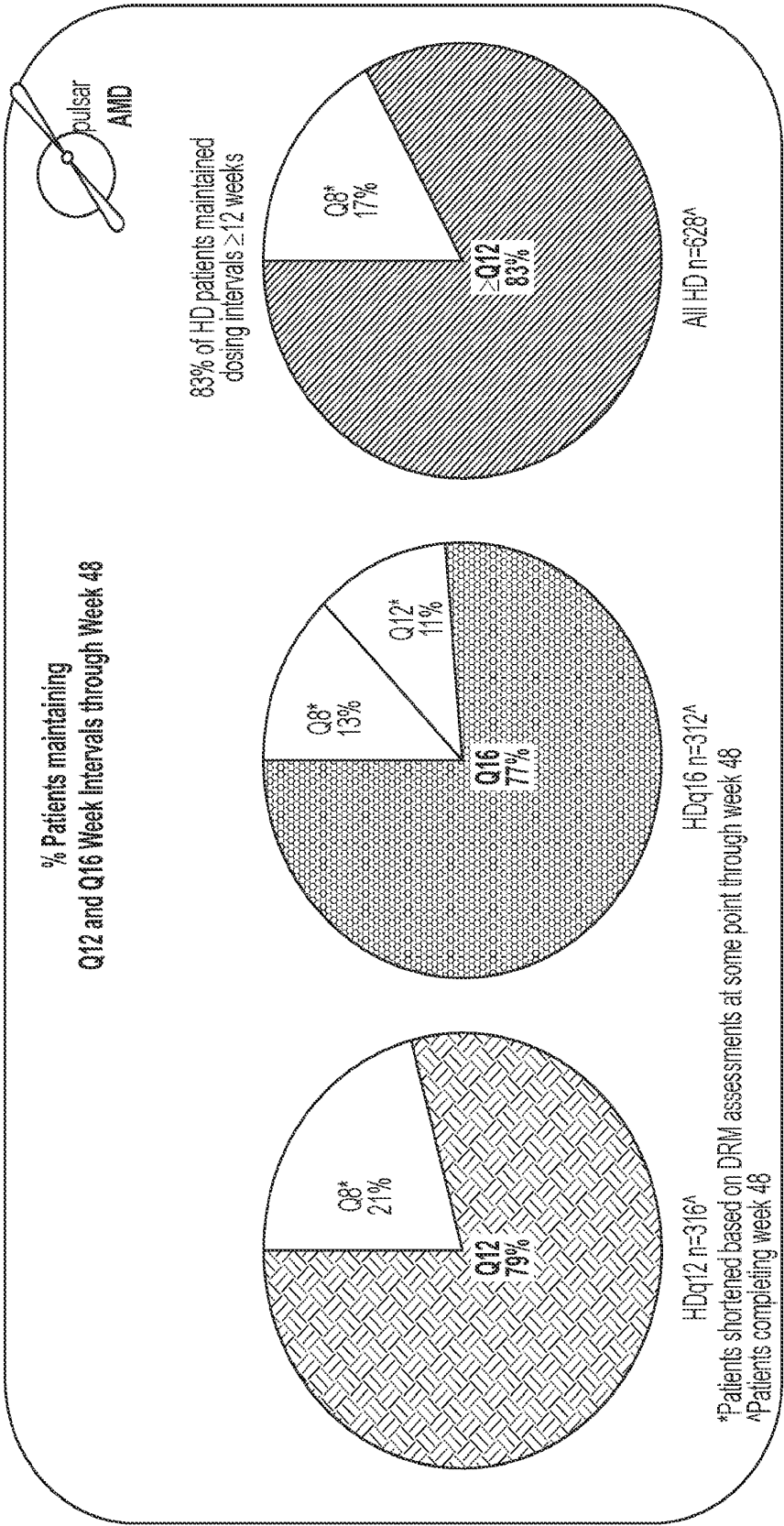
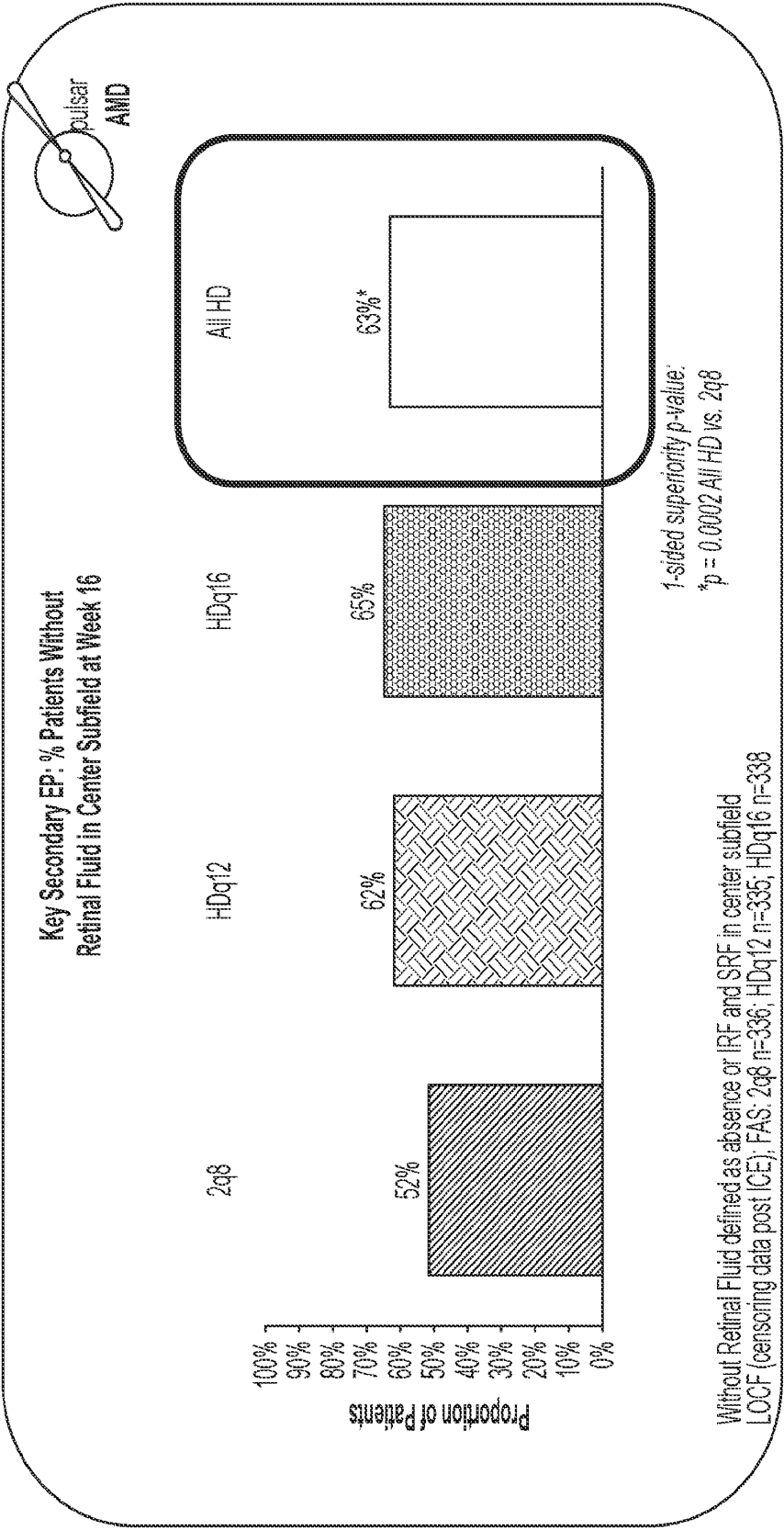


FIG. 50



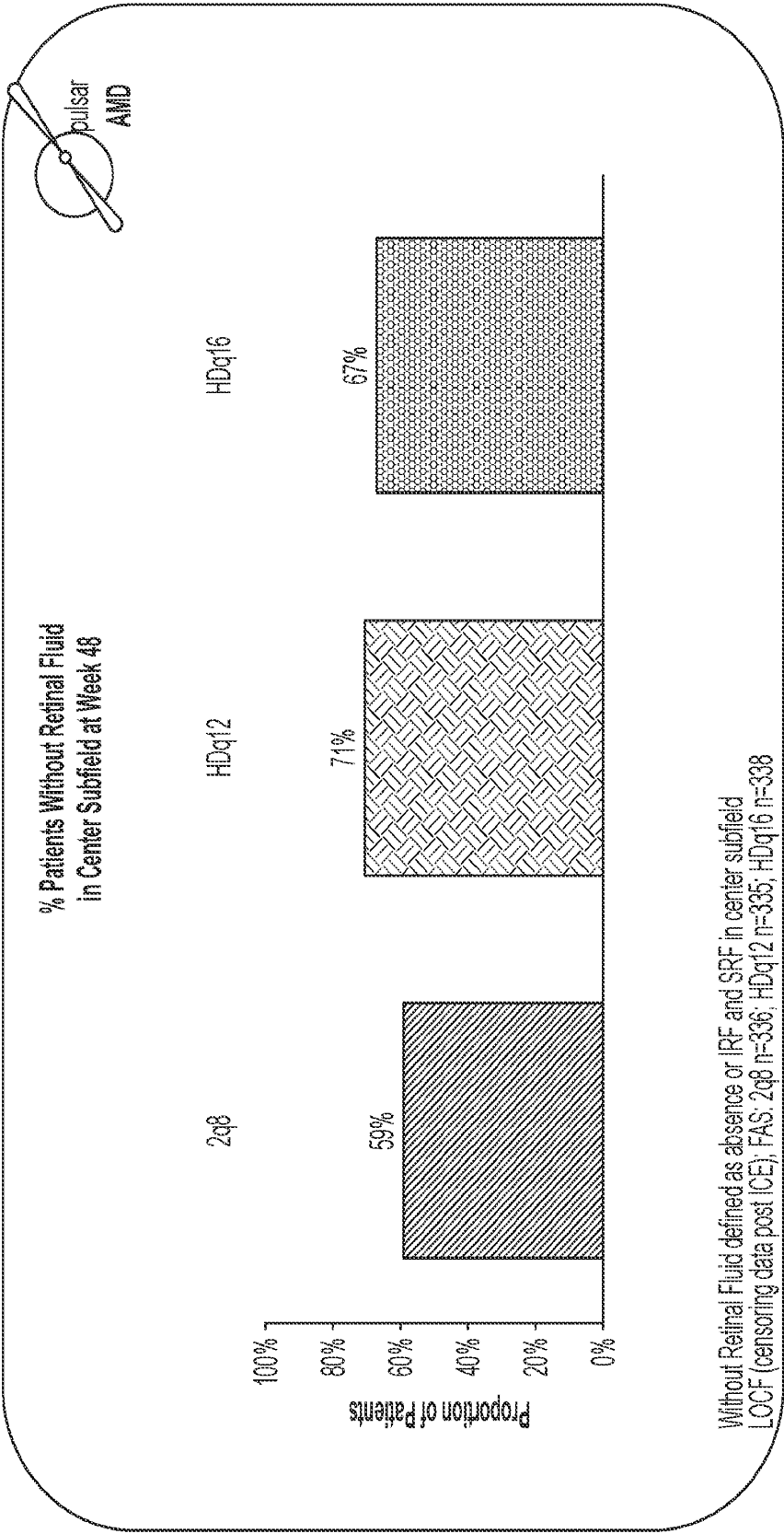


FIG. 52

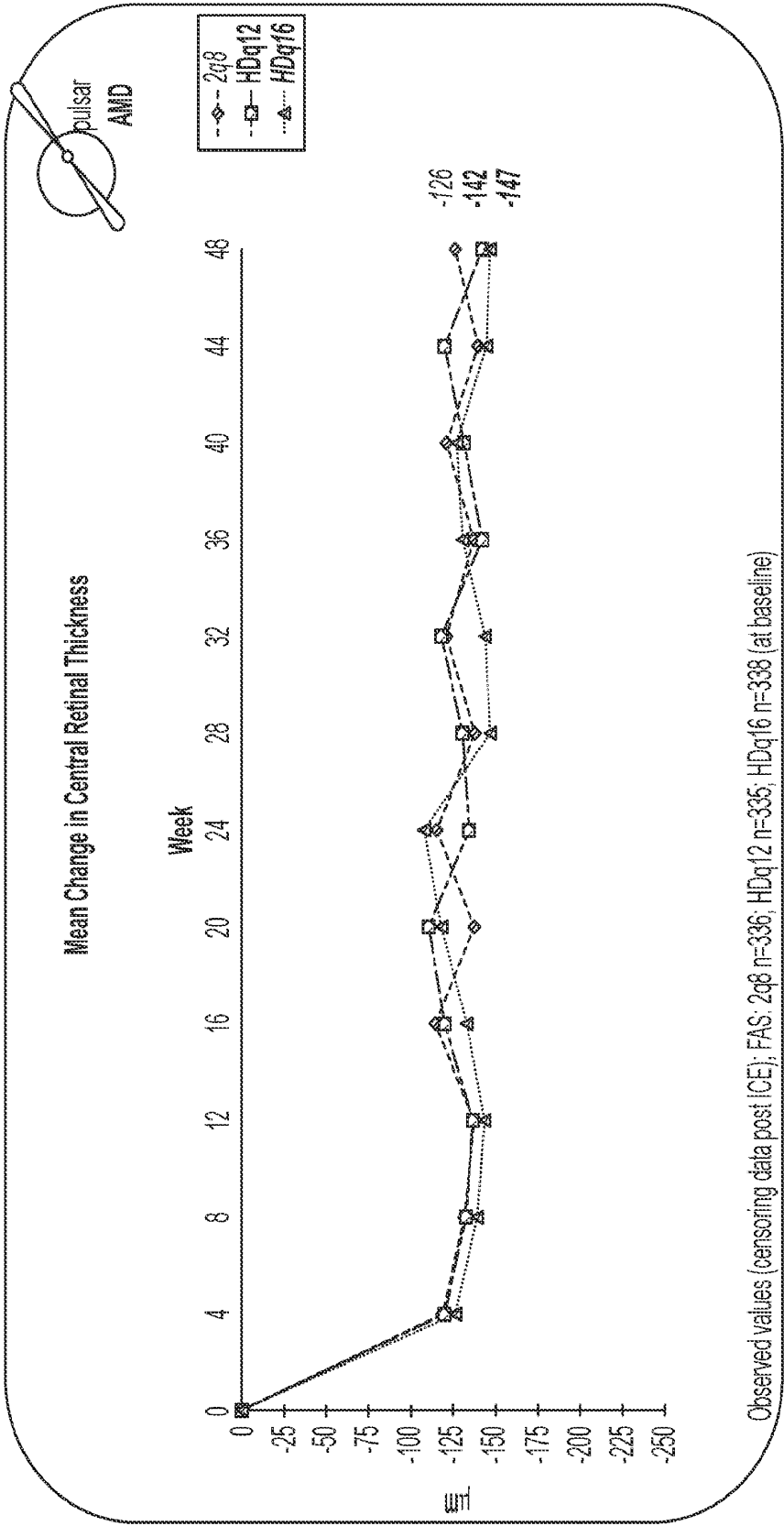


FIG. 53A

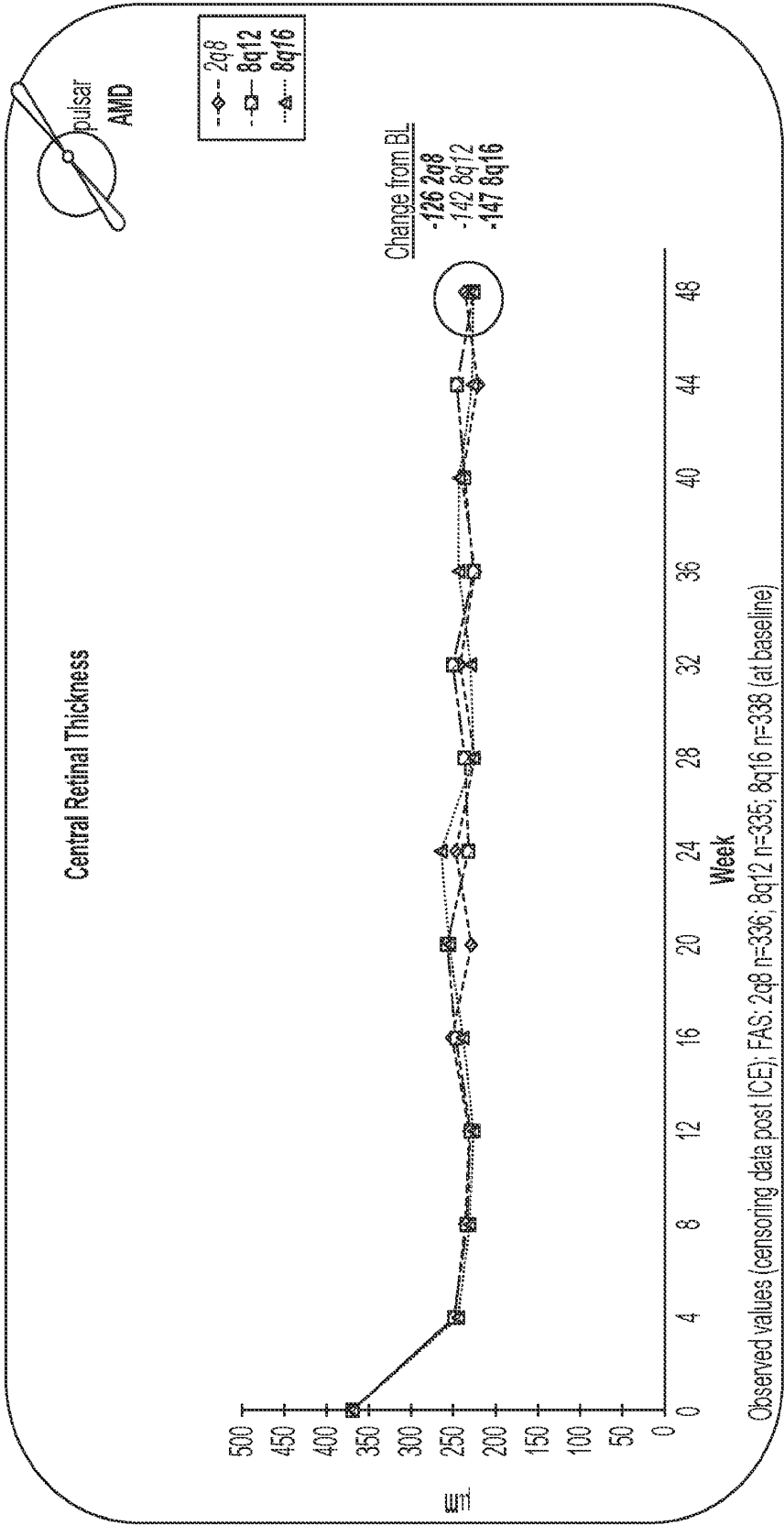


FIG. 53B

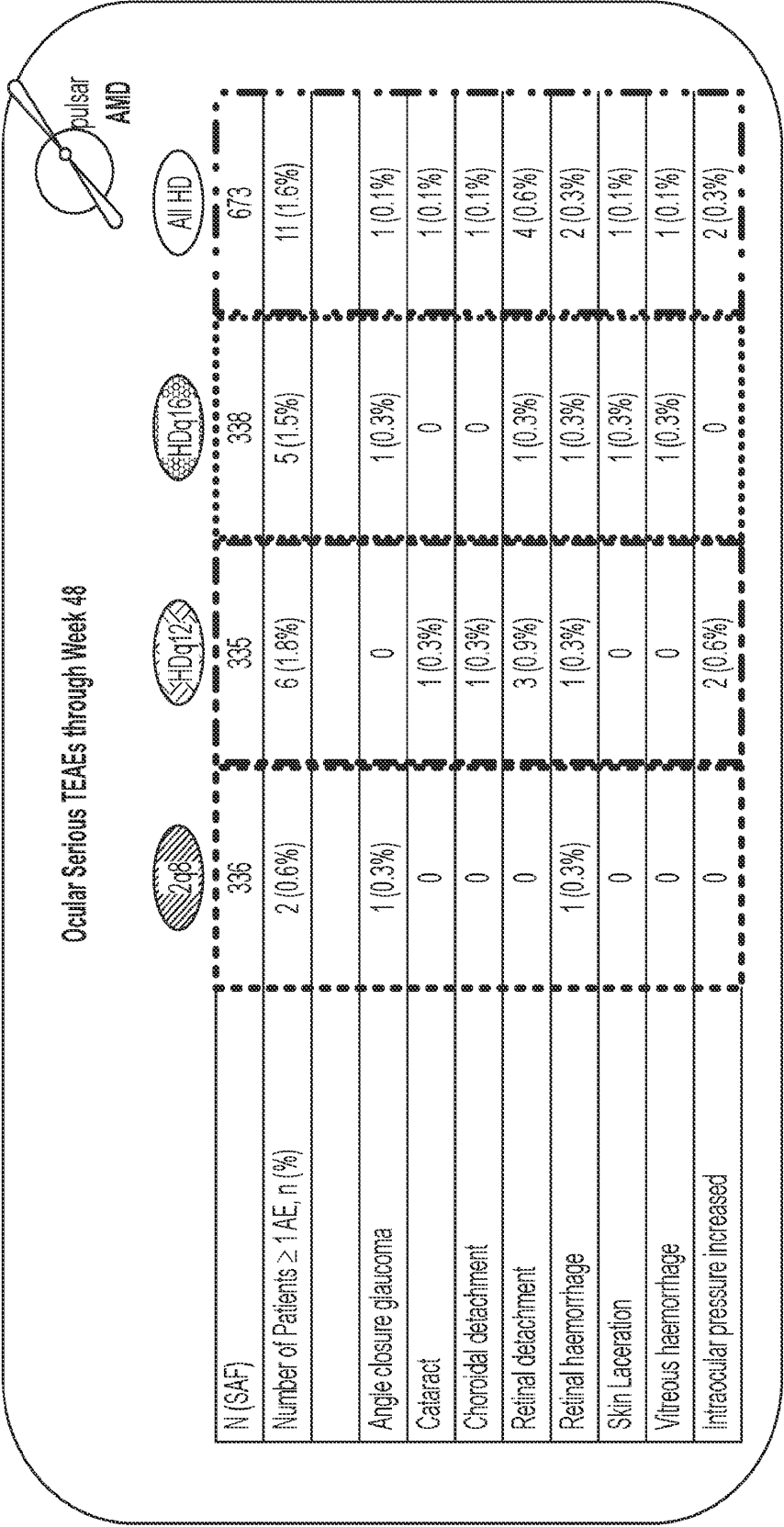


FIG. 54A

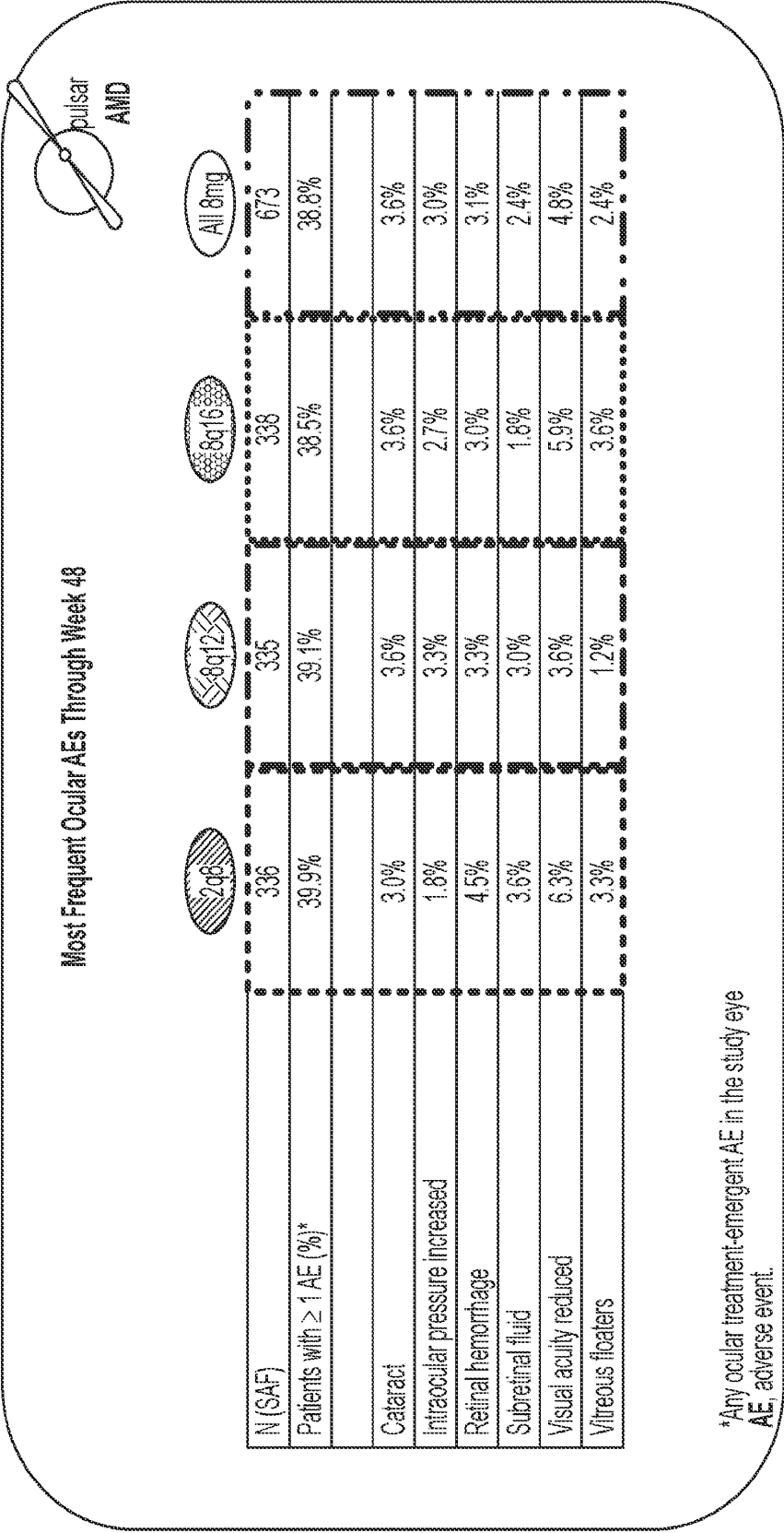


FIG. 54B

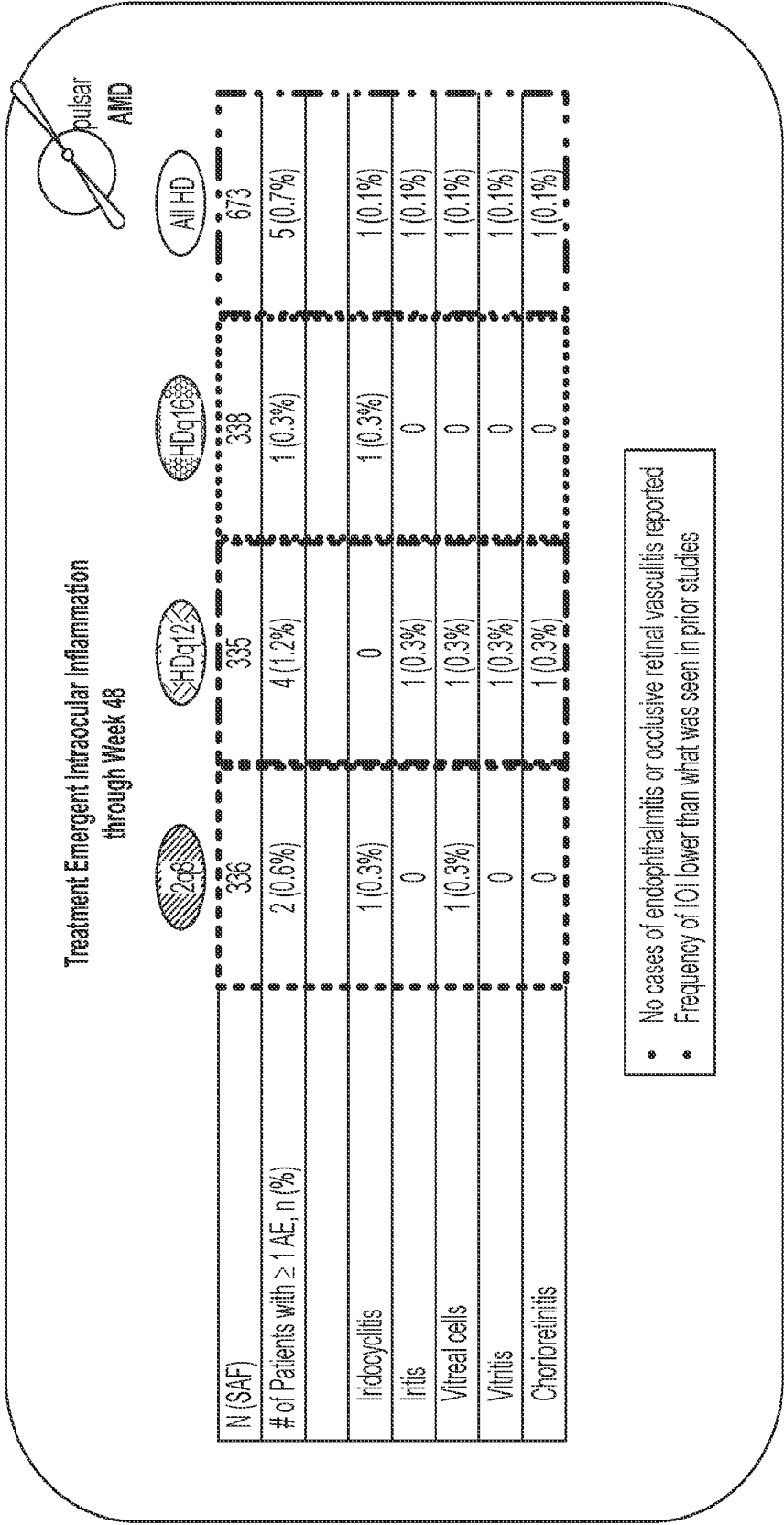


FIG. 55

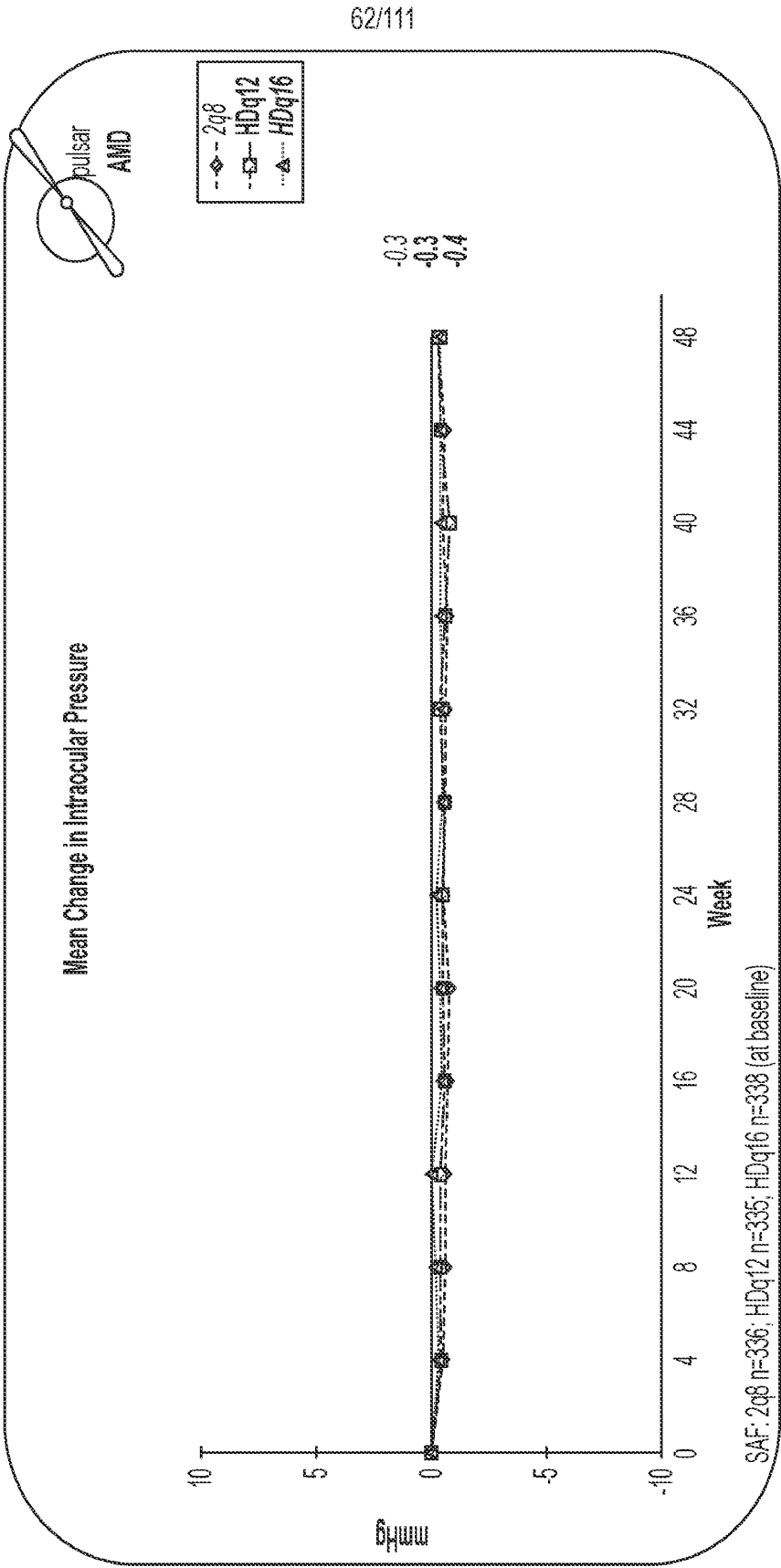


FIG. 56

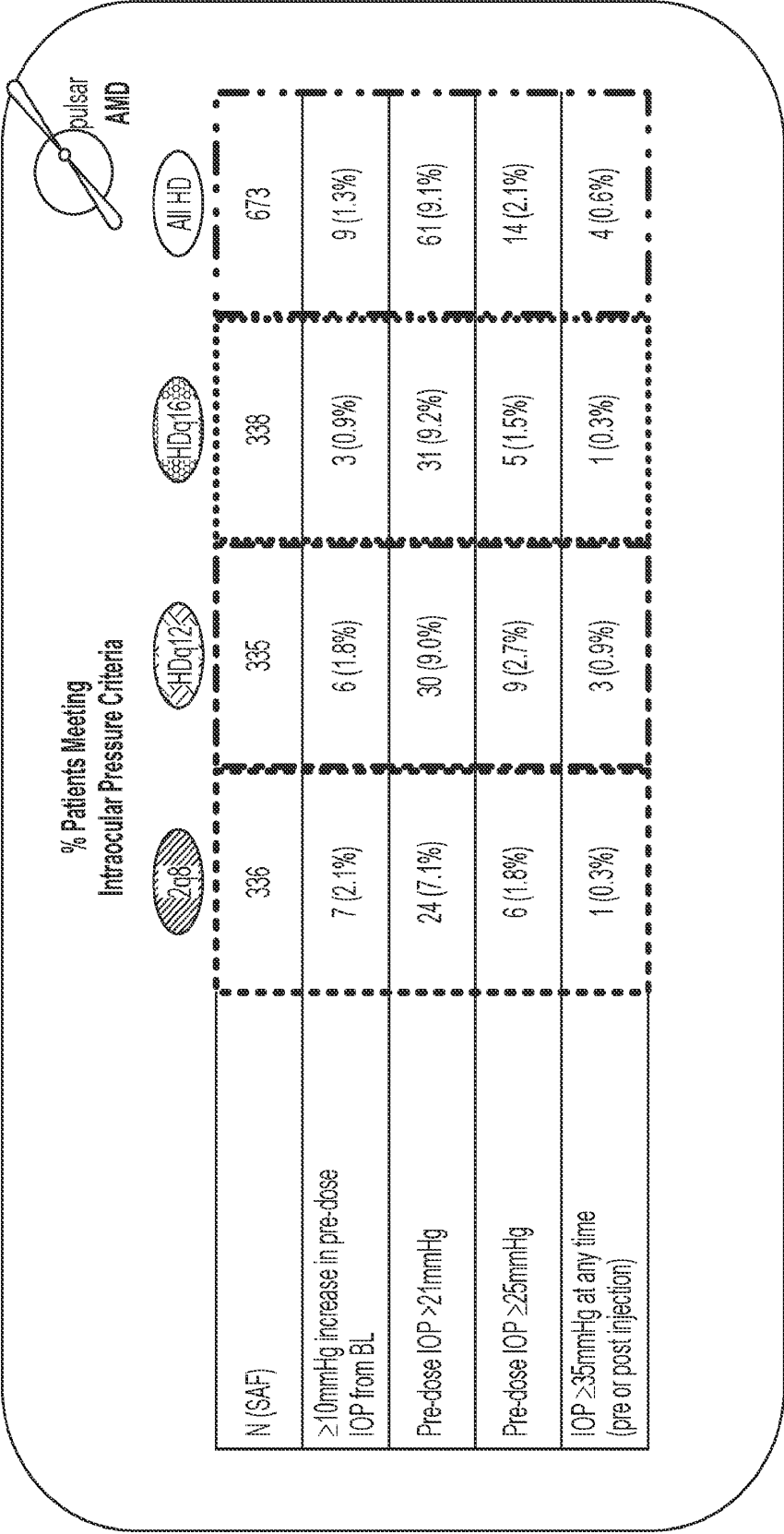


FIG. 57

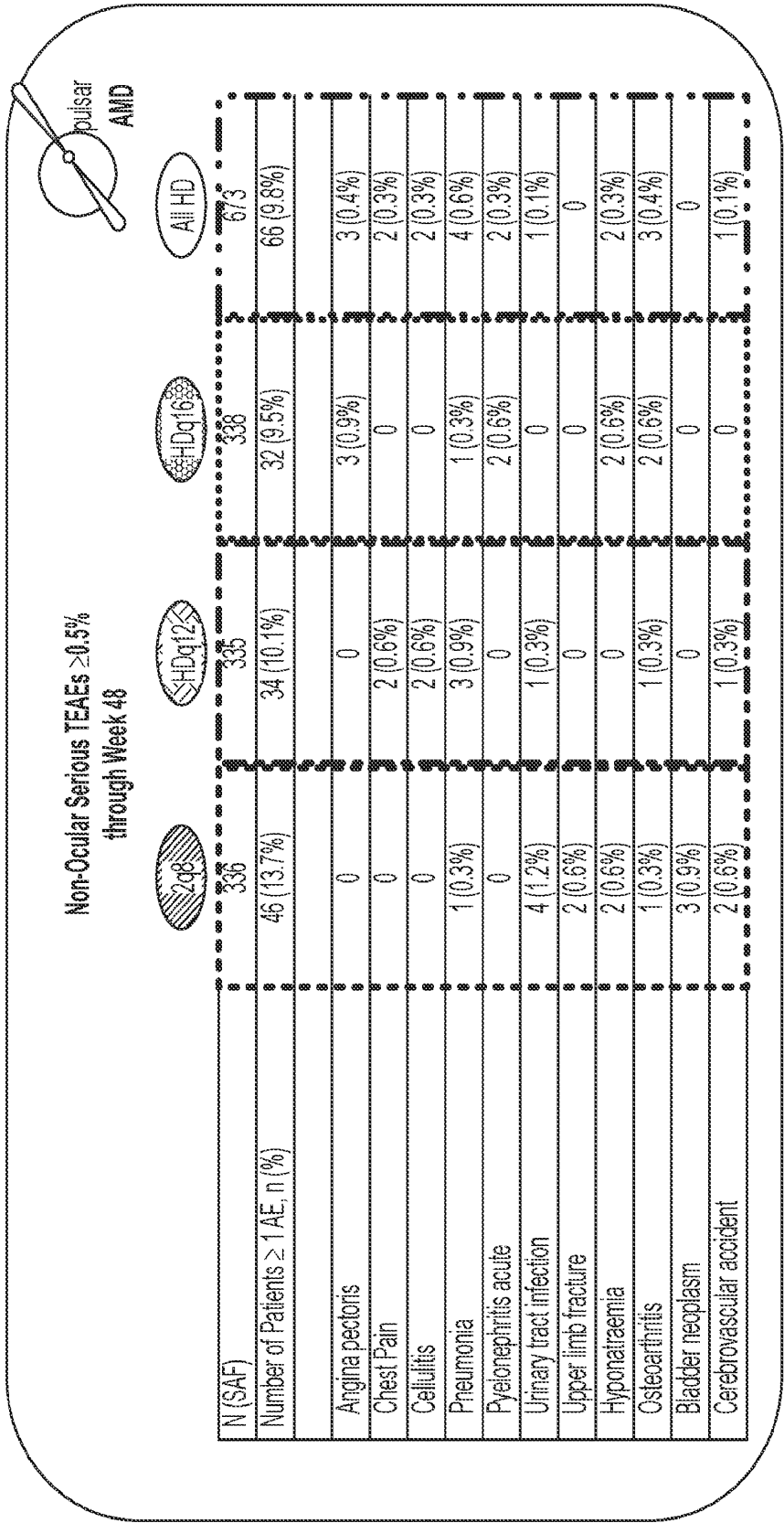


FIG. 58

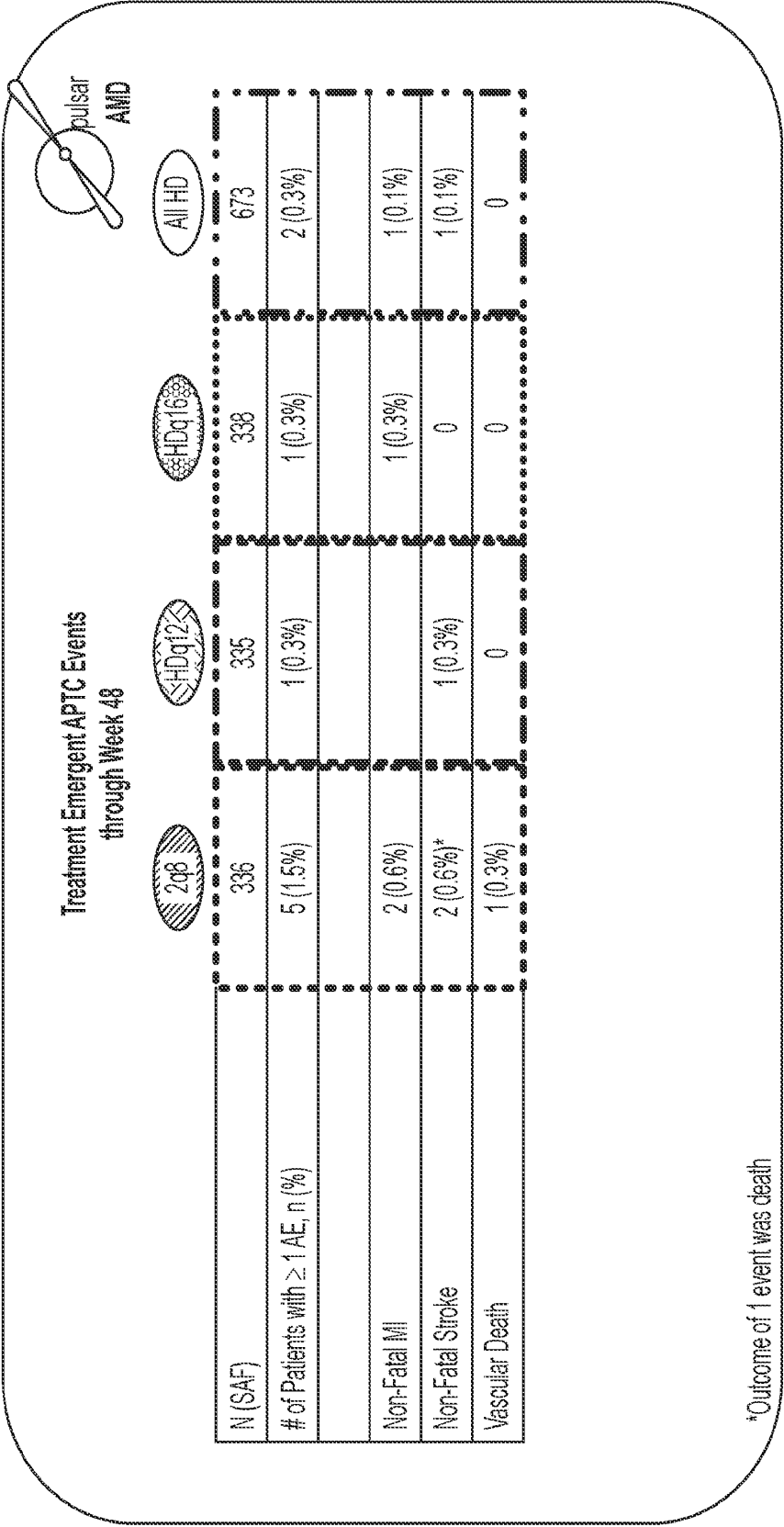


FIG. 59A

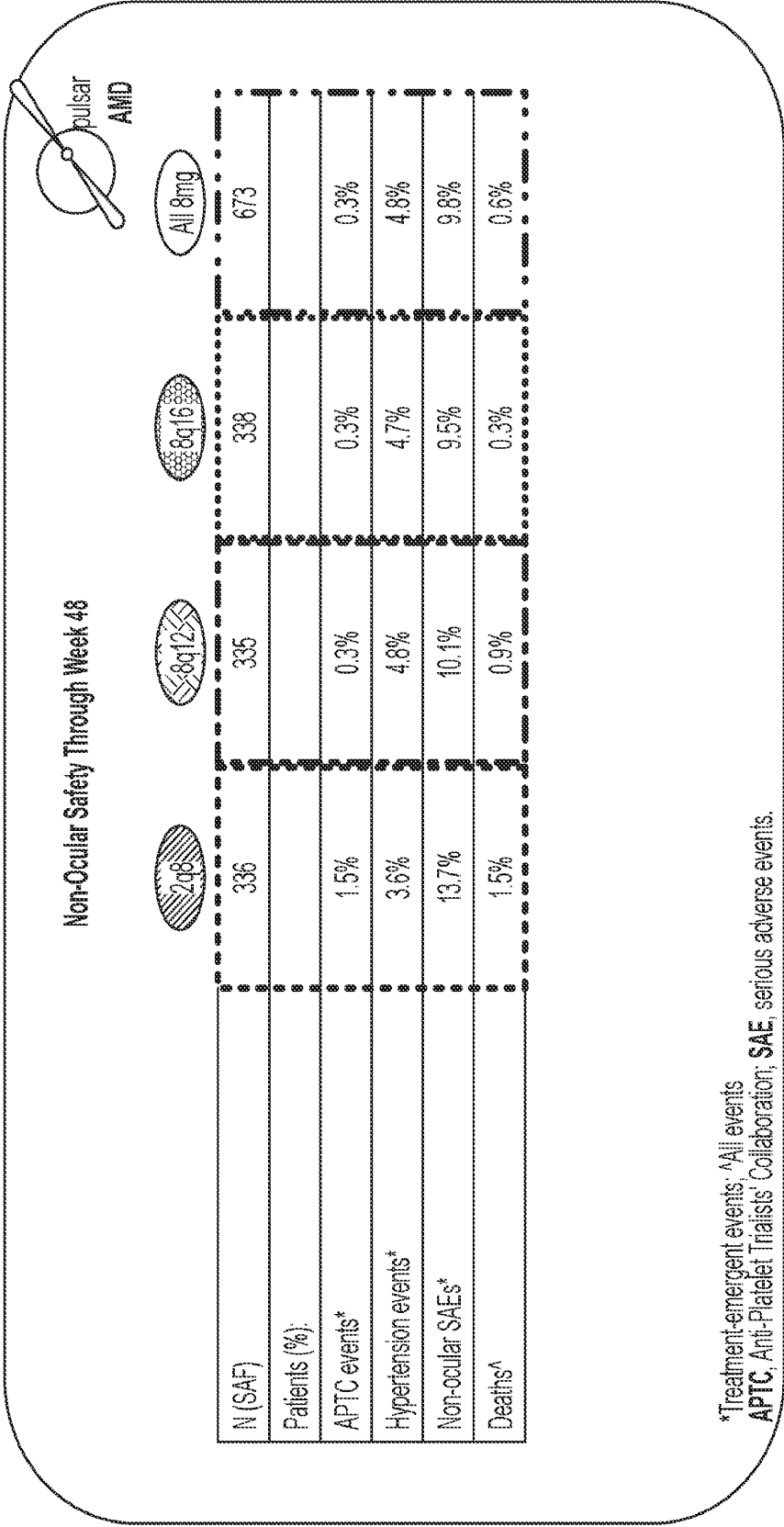


FIG. 59B

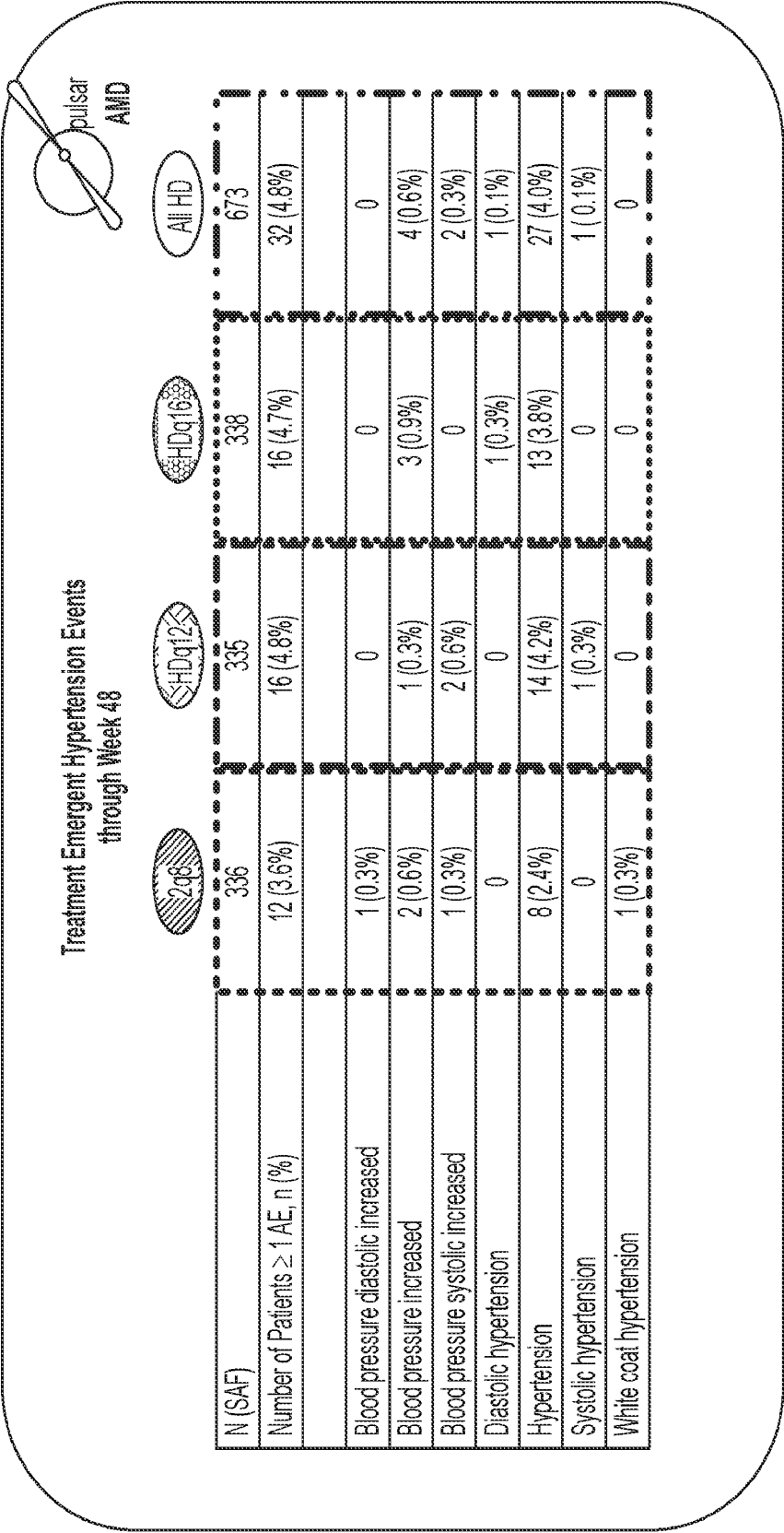


FIG. 60

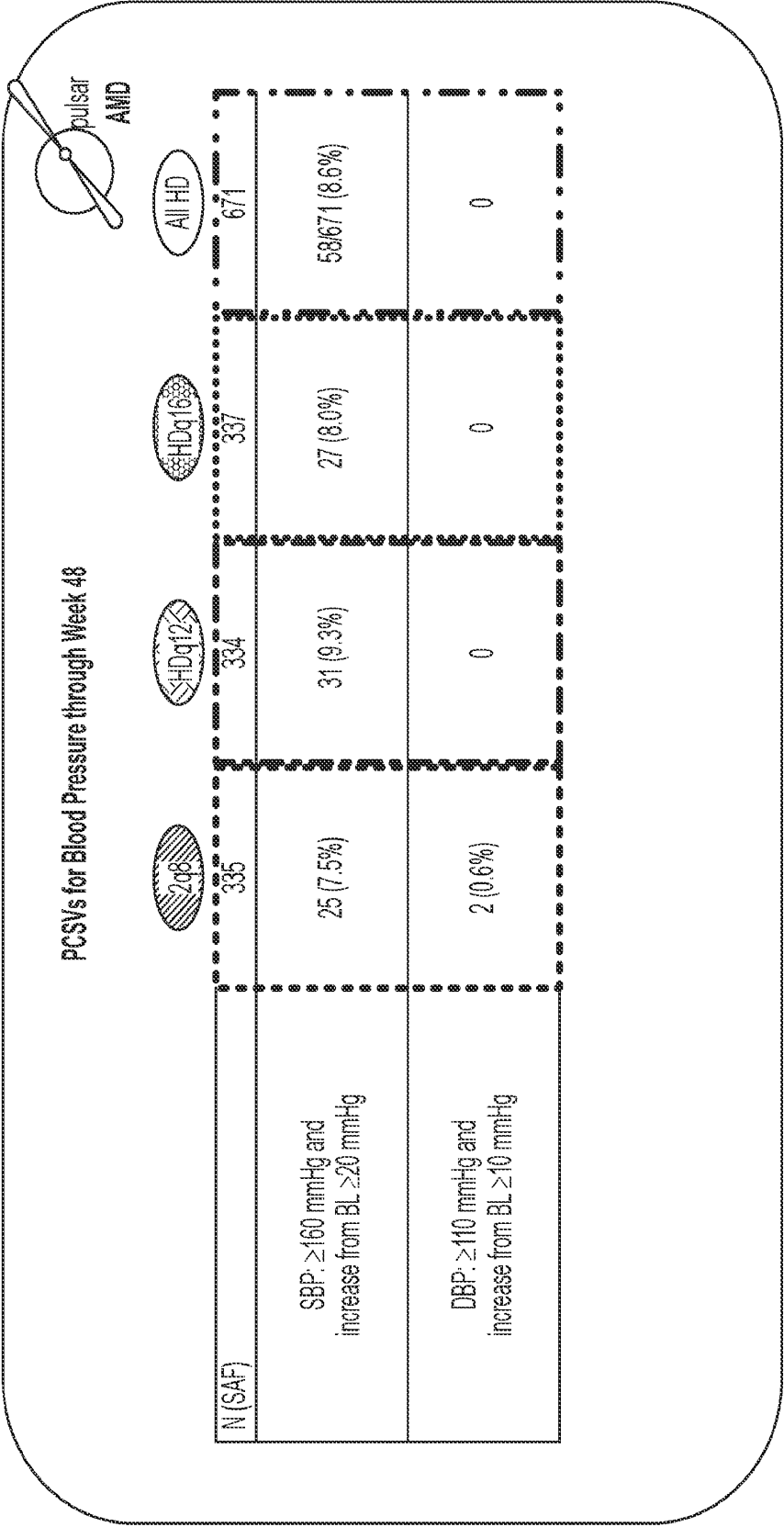


FIG. 61

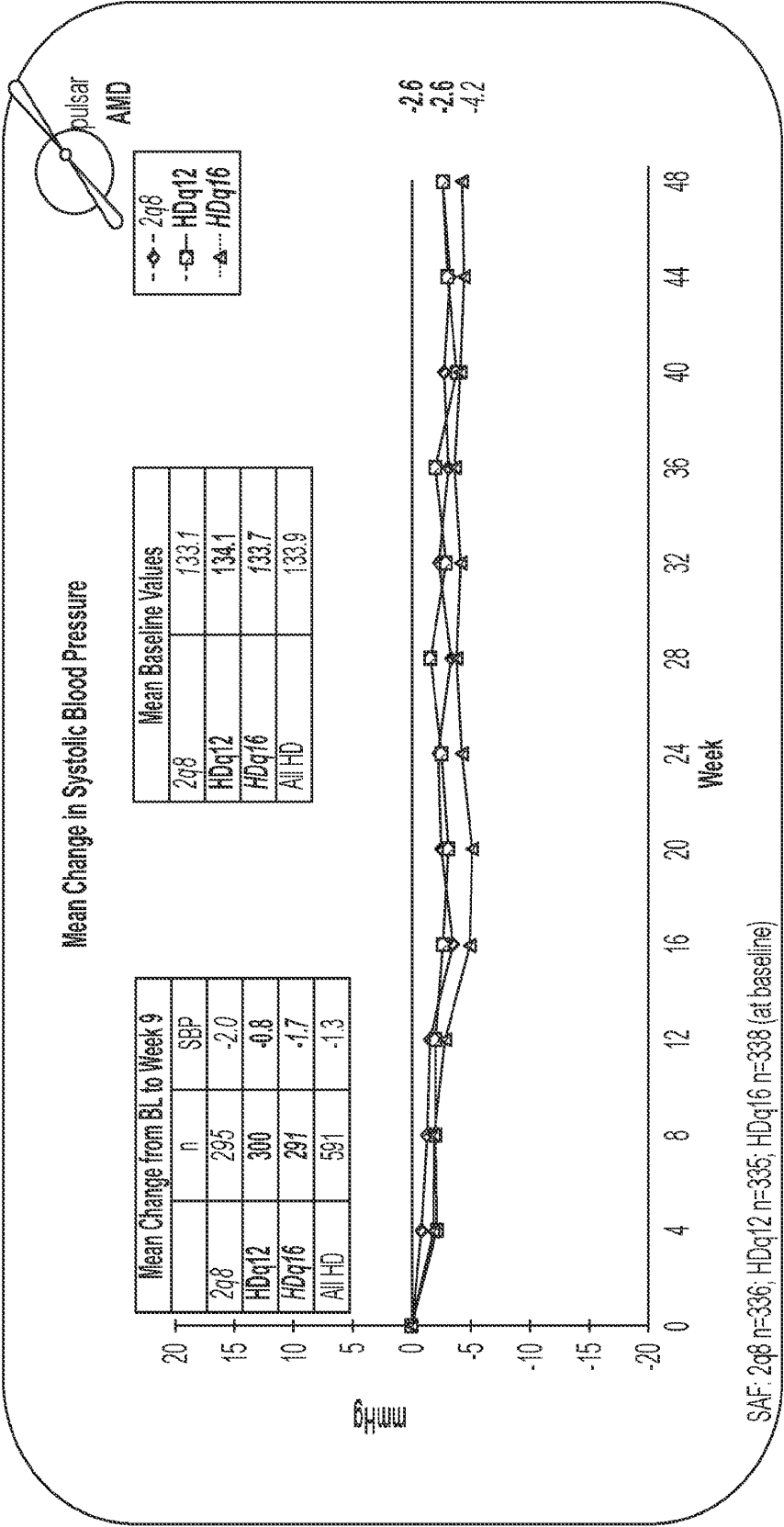
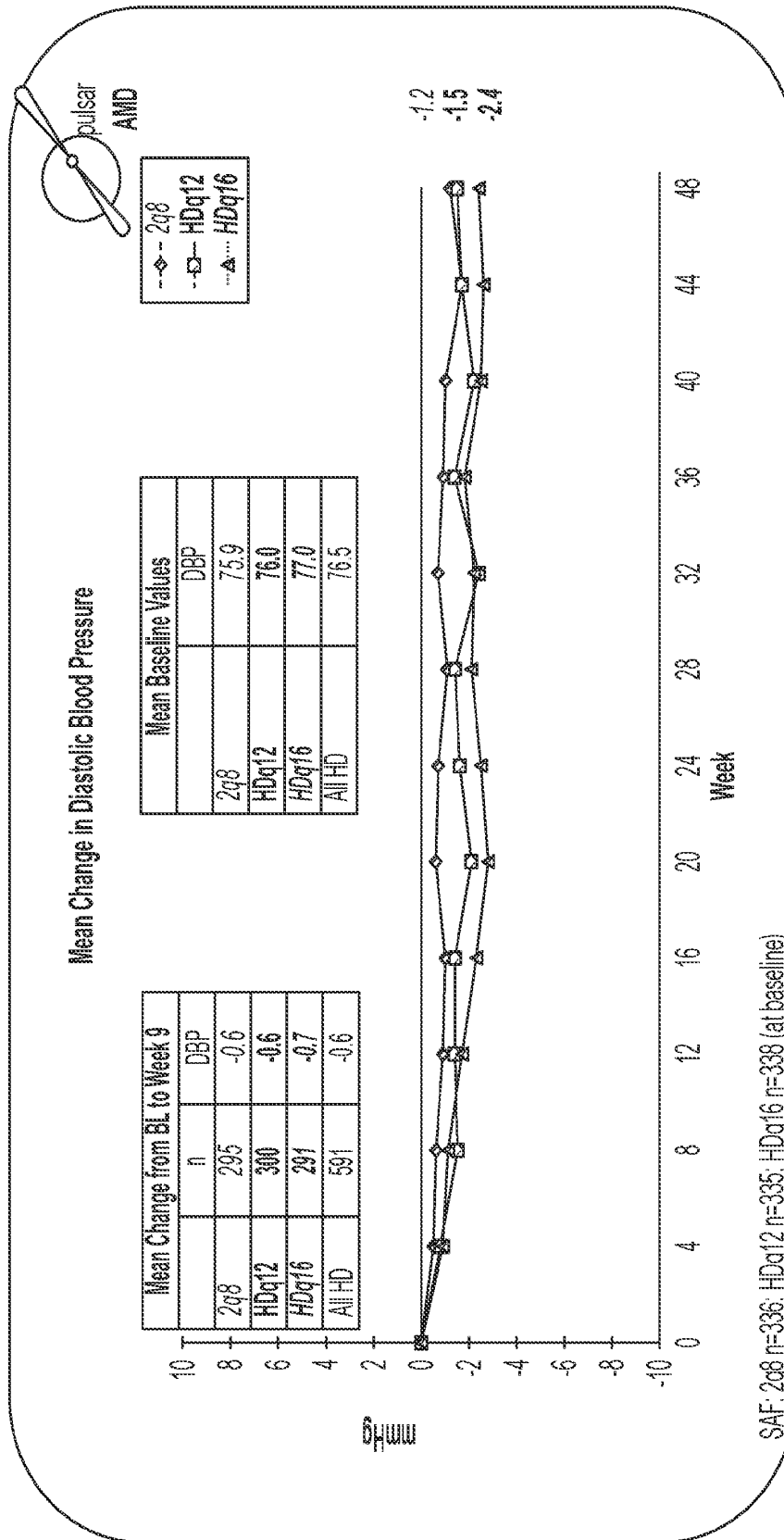


FIG. 62



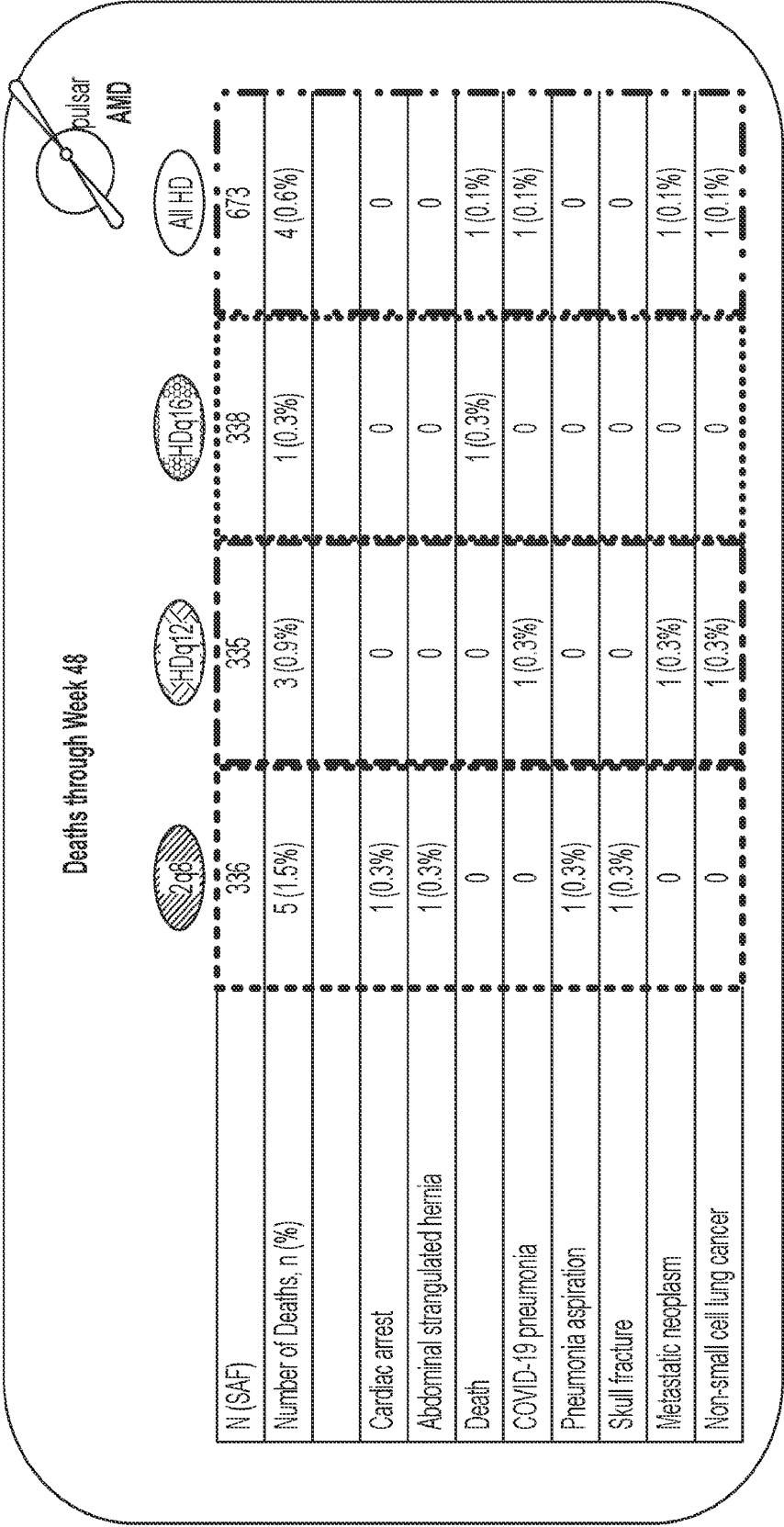


FIG. 64

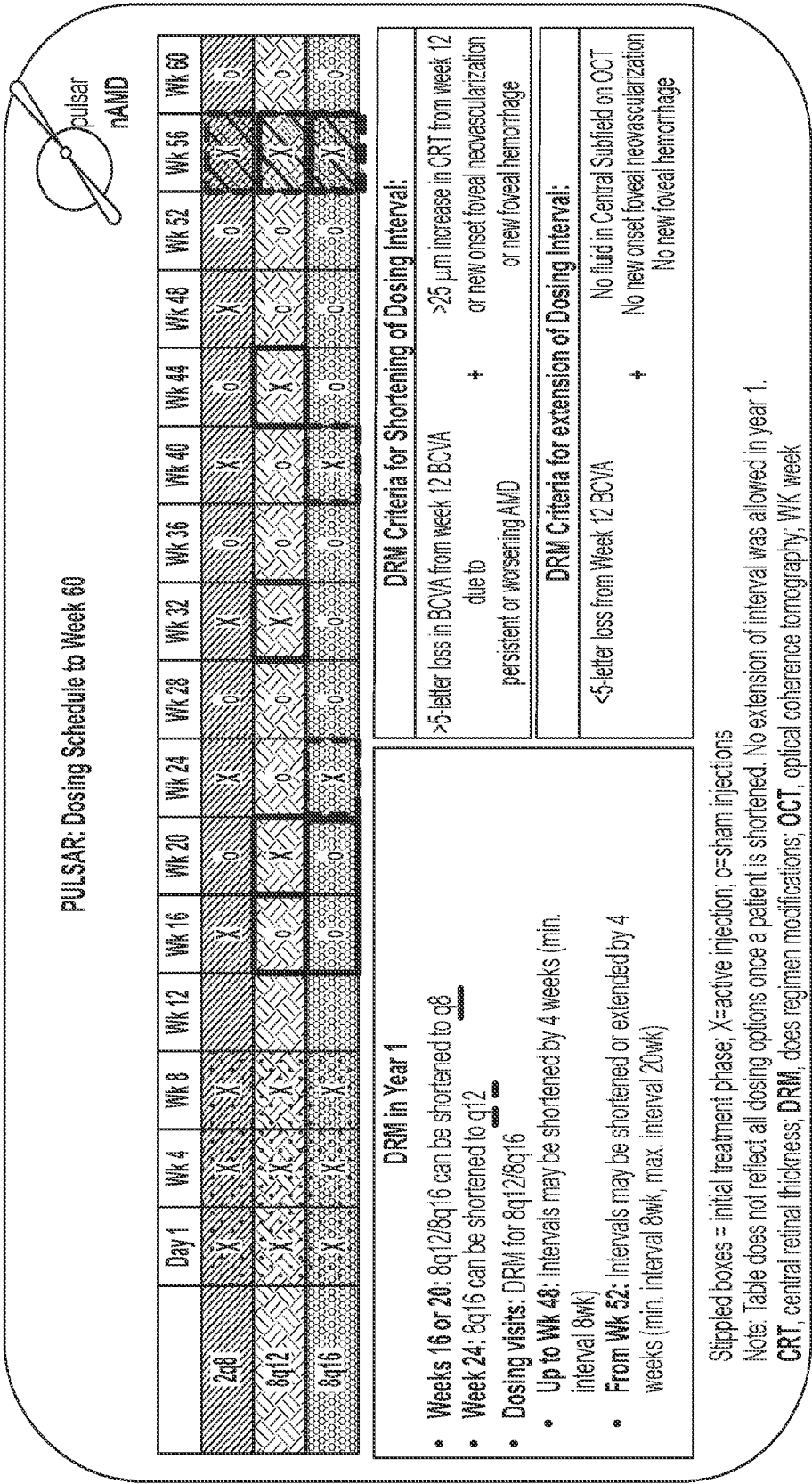
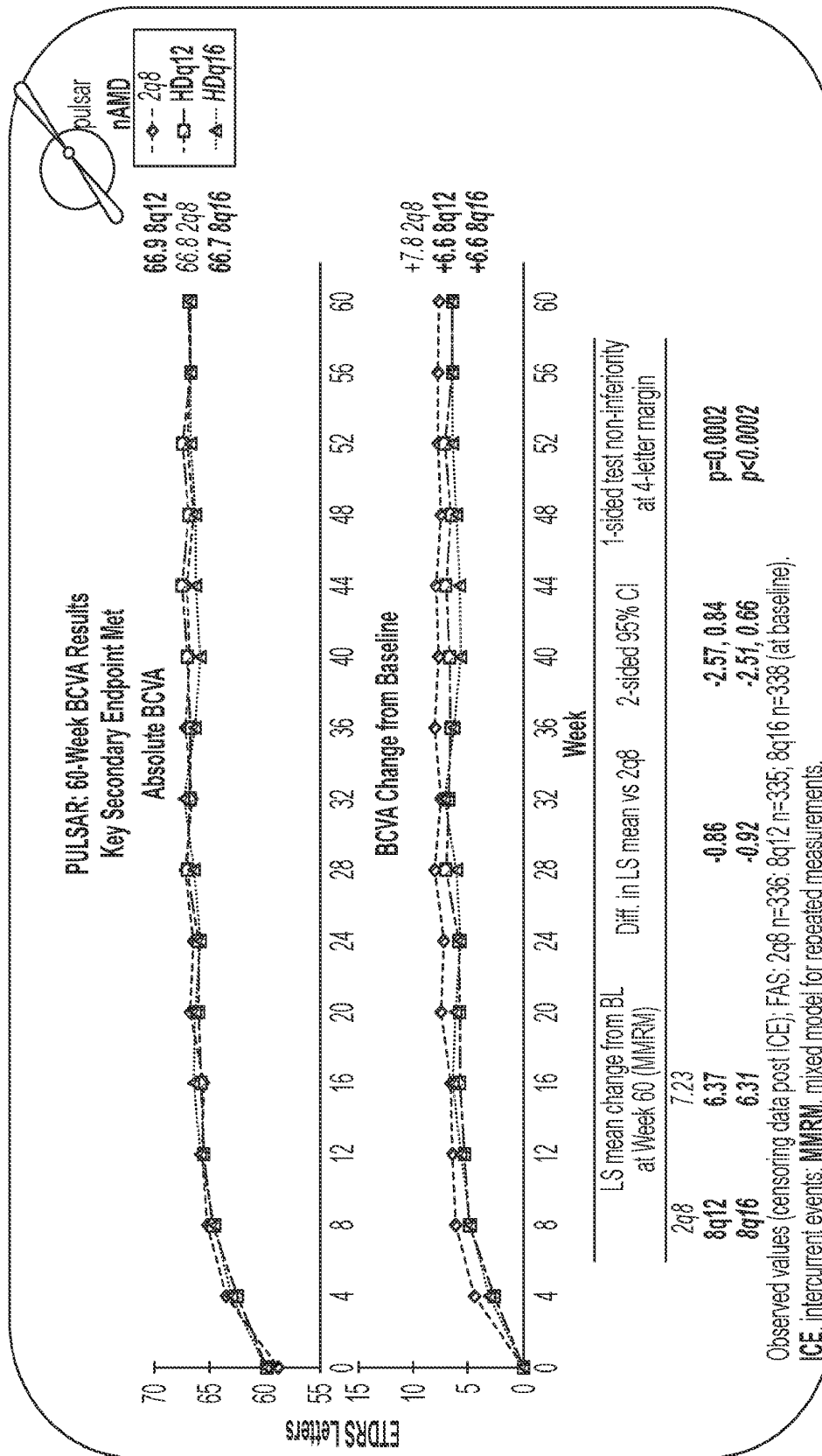


FIG. 65



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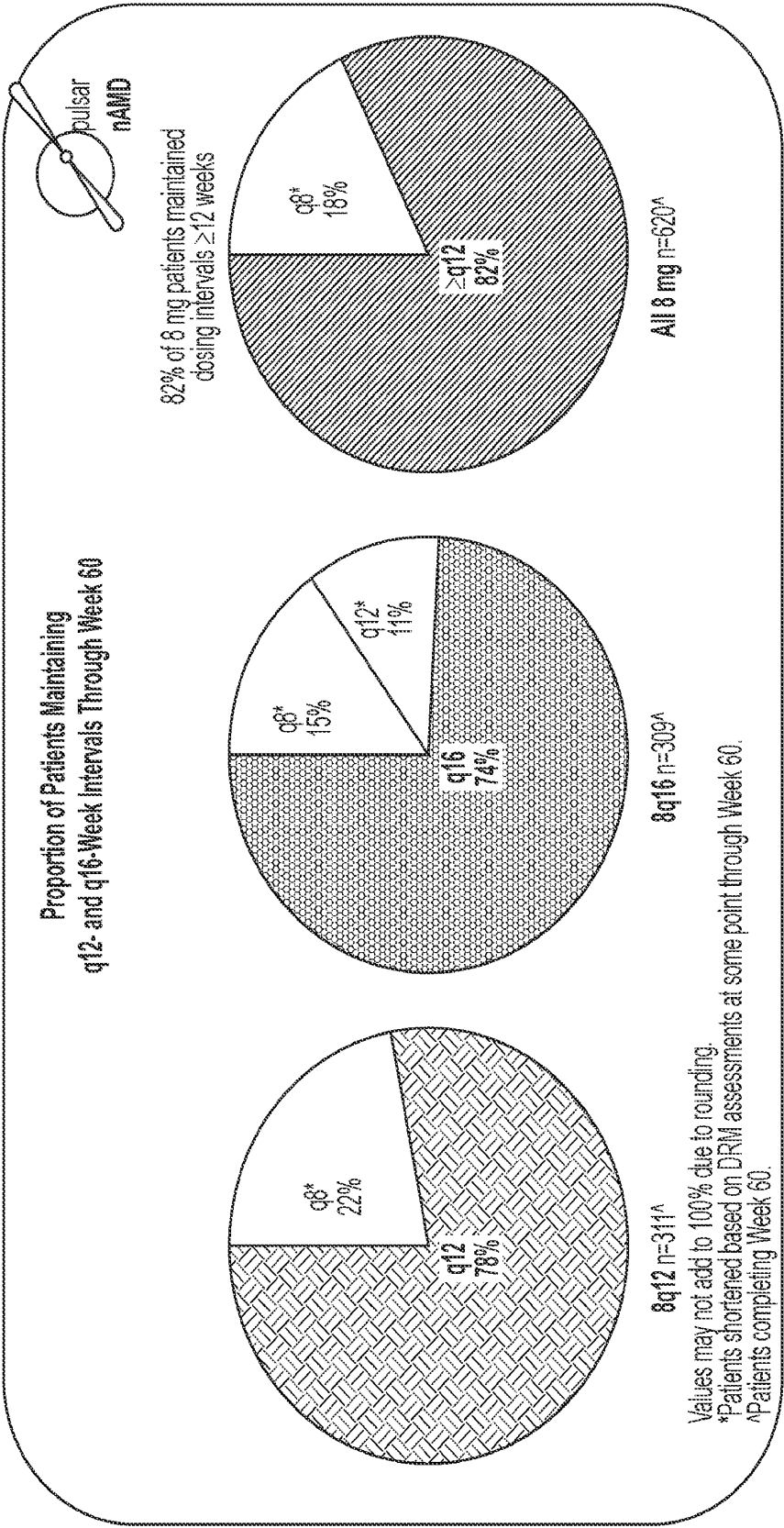


FIG. 67

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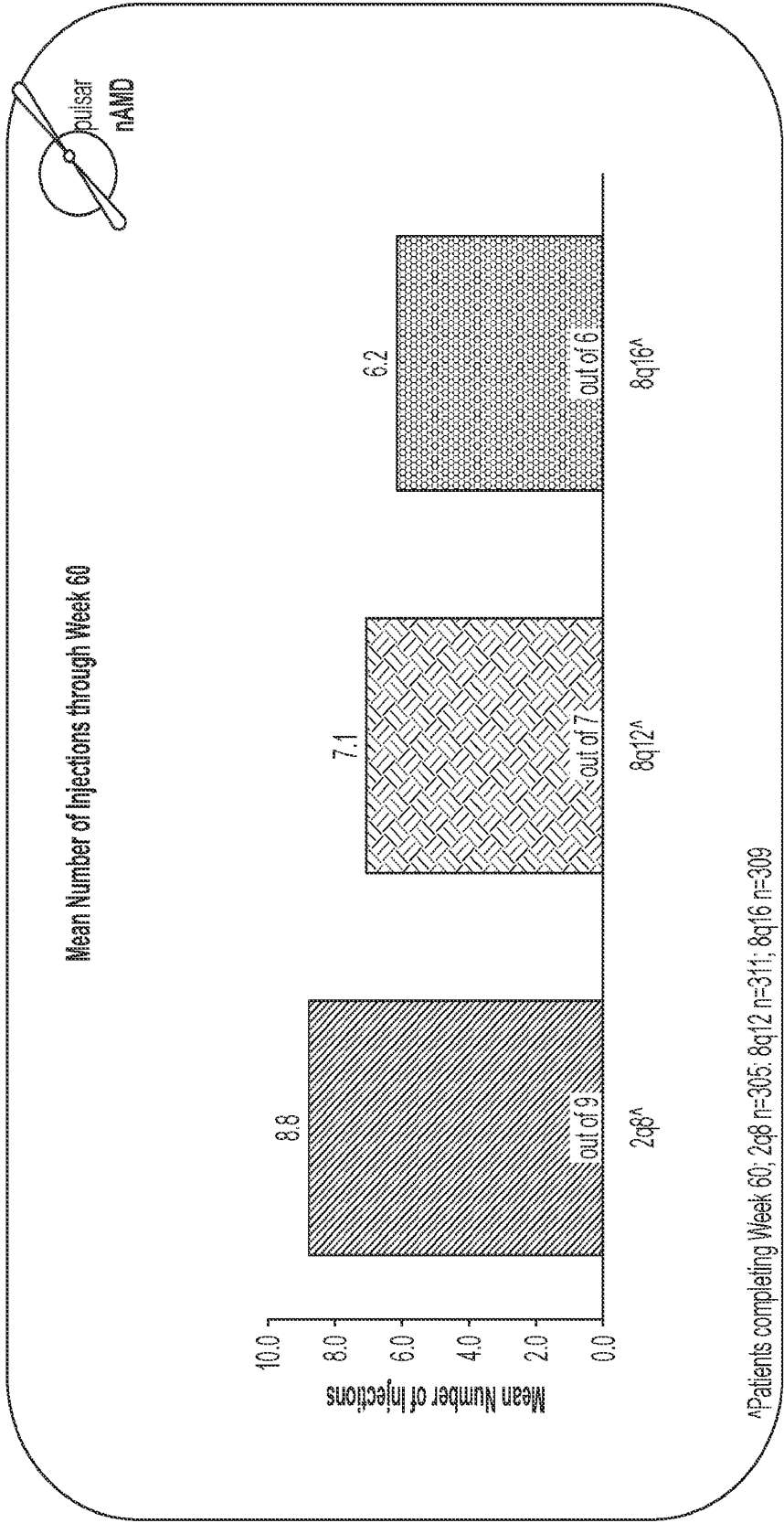


FIG. 68

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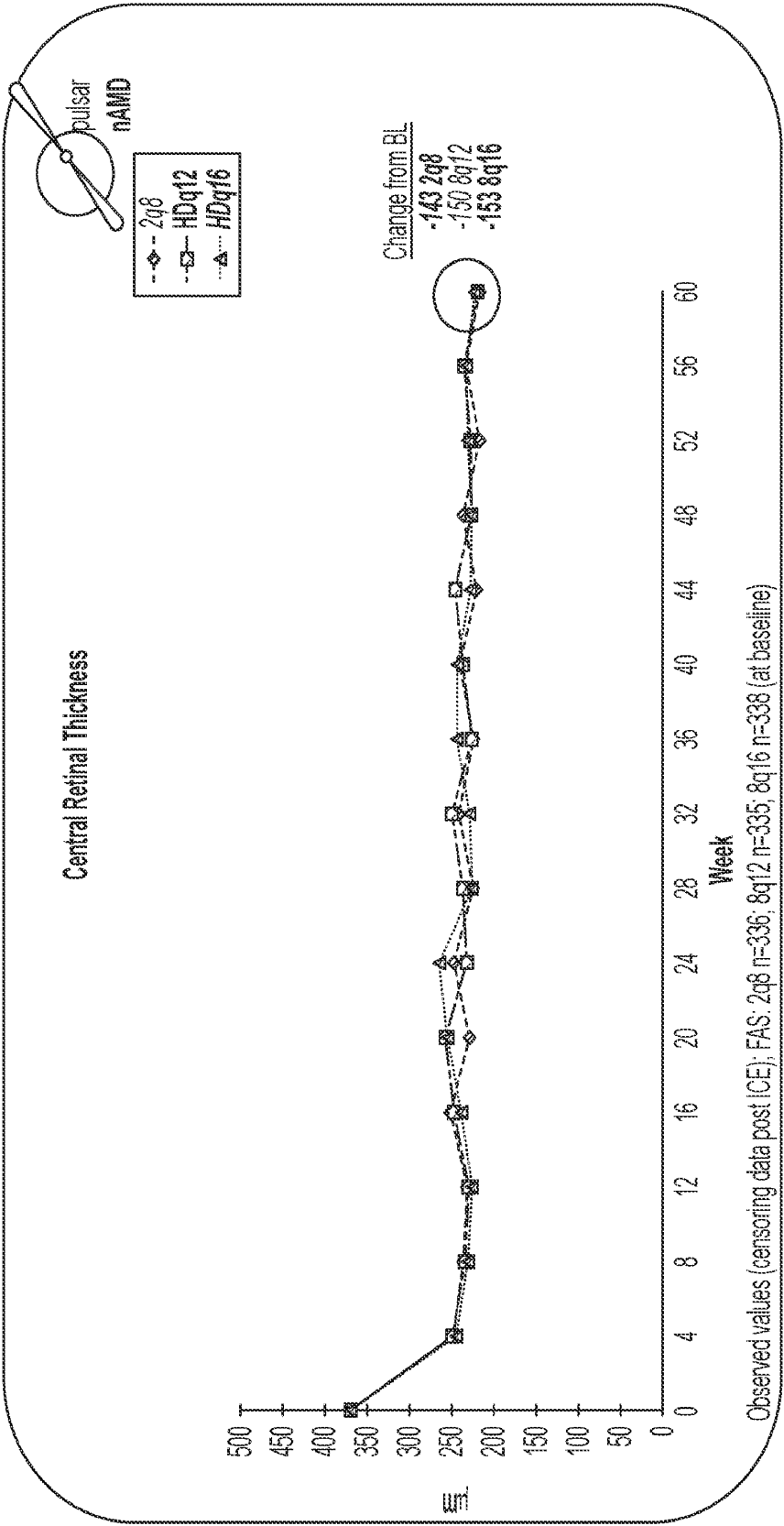


FIG. 69A

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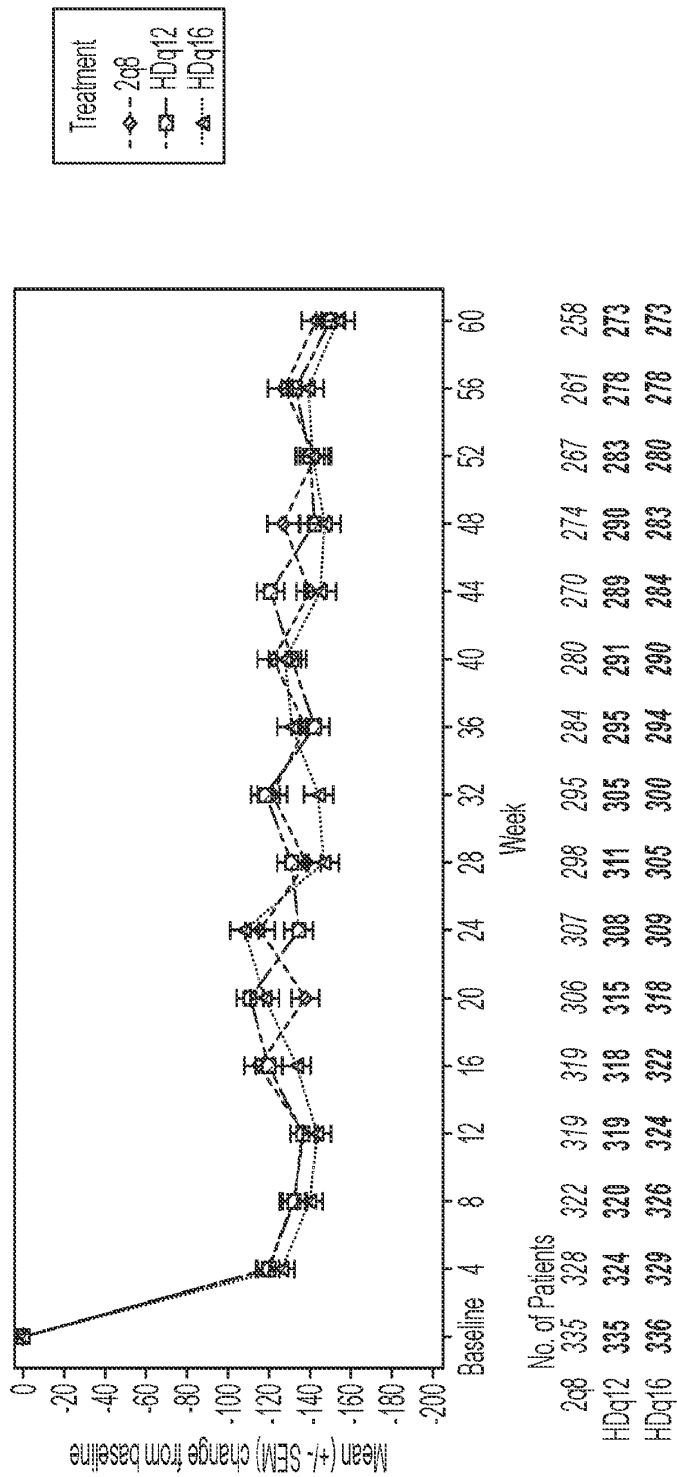


FIG. 69B

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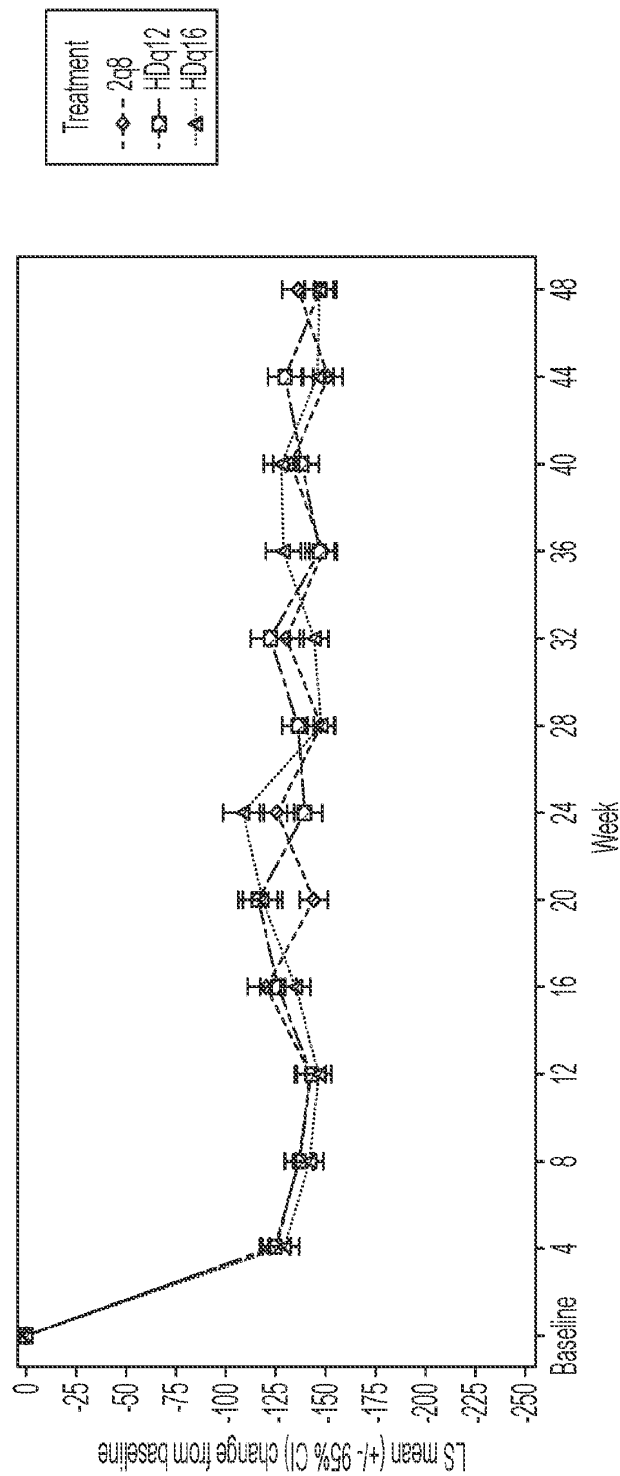


FIG. 69C

Ocular TEAEs $\geq 2\%$ through Week 60

				
N (SAF)	336	335	338	673
Number of Patients ≥ 1 AE, n (%)	152 (45.2%)	142 (42.4%)	143 (42.3%)	285 (42.3%)
Cataract	13 (3.9%)	16 (4.8%)	15 (4.4%)	31 (4.6%)
Conjunctival haemorrhage	6 (1.8%)	8 (2.4%)	6 (1.8%)	14 (2.1%)
Dry Eye	8 (2.4%)	7 (2.1%)	6 (1.8%)	13 (1.9%)
Macular oedema	8 (2.4%)	2 (0.6%)	8 (2.4%)	10 (1.5%)
Macular thickening	3 (0.9%)	8 (2.4%)	7 (2.1%)	15 (2.2%)
Neovascular AMD	2 (0.6%)	8 (2.4%)	7 (2.1%)	15 (2.2%)
Retinal haemorrhage	15 (4.5%)	12 (3.6%)	13 (3.8%)	25 (3.7%)
Subretinal fluid	12 (3.6%)	11 (3.3%)	8 (2.4%)	19 (2.8%)
Visual Acuity Reduced	21 (6.3%)	13 (3.9%)	20 (5.9%)	33 (4.9%)
Vitreous Detachment	5 (1.5%)	7 (2.1%)	10 (3.0%)	17 (2.5%)
Vitreous Floaters	13 (3.9%)	4 (1.2%)	14 (4.1%)	18 (2.7%)
Sensation of Foreign Body	7 (2.1%)	3 (0.9%)	4 (1.2%)	7 (1.0%)
Intraocular Pressure Increased	9 (2.7%)	11 (3.3%)	10 (3.0%)	21 (3.1%)
Conjunctivitis	5 (1.5%)	7 (2.1%)	3 (0.9%)	10 (1.5%)

FIG. 70A

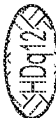
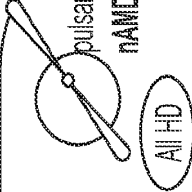
Ocular Serious TEAEs through Week 60				
				
N (SAF)	336	335	338	673
Number of Patients ≥ 1 AE, n (%)	4 (1.2%)	7 (2.1%)	7 (2.1%)	14 (2.1%)
Angle closure glaucoma	1 (0.3%)	0	1 (0.3%)	1 (0.1%)
Cataract	0	0	1 (0.3%)	1 (0.1%)
Dry age-related macular degeneration	0	1 (0.3%)	0	1 (0.1%)
Retinal detachment	1 (0.3%)	2 (0.6%)	1 (0.3%)	3 (0.4%)
Retinal haemorrhage	1 (0.3%)	2 (0.6%)	2 (0.6%)	4 (0.6%)
Skin Laceration	0	0	1 (0.3%)	1 (0.1%)
Vitreous haemorrhage	0	0	1 (0.3%)	1 (0.1%)
Intraocular pressure increased	0	2 (0.6%)	0	2 (0.3%)
Endophthalmitis	1 (0.3%)	0	0	0

FIG. 70B

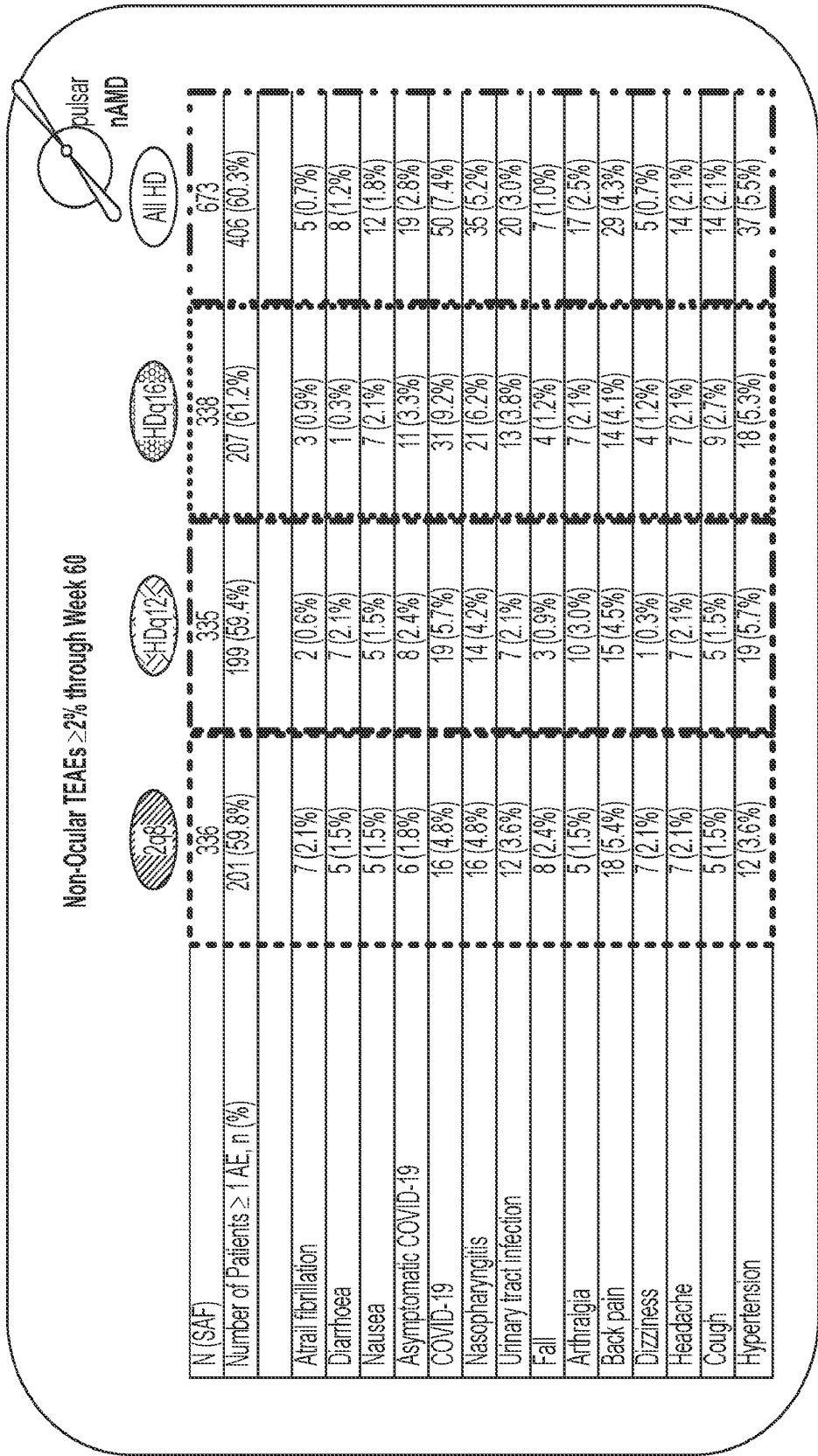


FIG. 70C

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Non-Ocular Serious TEAEs $\geq 0.5\%$ through Week 60

				
N (SAF)	336	336	338	673
Number of Patients ≥ 1 AE, n (%)	53 (15.8%)	41 (12.2%)	41 (12.1%)	82 (12.2%)
Angina pectoris	0	0	3 (0.9%)	3 (0.4%)
Cardiac failure congestive	0	2 (0.6%)	0	2 (0.3%)
Chest Pain	0	2 (0.6%)	1 (0.3%)	3 (0.4%)
Cellulitis	0	2 (0.6%)	0	2 (0.3%)
Pneumonia	1 (0.3%)	4 (1.2%)	2 (0.6%)	6 (0.9%)
Pyelonephritis acute	0	0	2 (0.6%)	2 (0.3%)
Urinary tract infection	4 (1.2%)	1 (0.3%)	0	1 (0.1%)
Pelvic fracture	2 (0.6%)	0	0	0
Rib fracture	2 (0.6%)	0	0	0
Upper limb fracture	2 (0.6%)	0	0	0
Hyponaemia	2 (0.6%)	0	2 (0.6%)	2 (0.3%)
Osteoarthritis	1 (0.3%)	1 (0.3%)	3 (0.9%)	4 (0.6%)
Bladder neoplasm	3 (0.9%)	0	0	0
Cerebral infarction	2 (0.6%)	0	0	0
Cerebrovascular accident	2 (0.6%)	1 (0.3%)	0	1 (0.1%)
Hypertension	1 (0.3%)	2 (0.6%)	0	2 (0.3%)

FIG. 70D

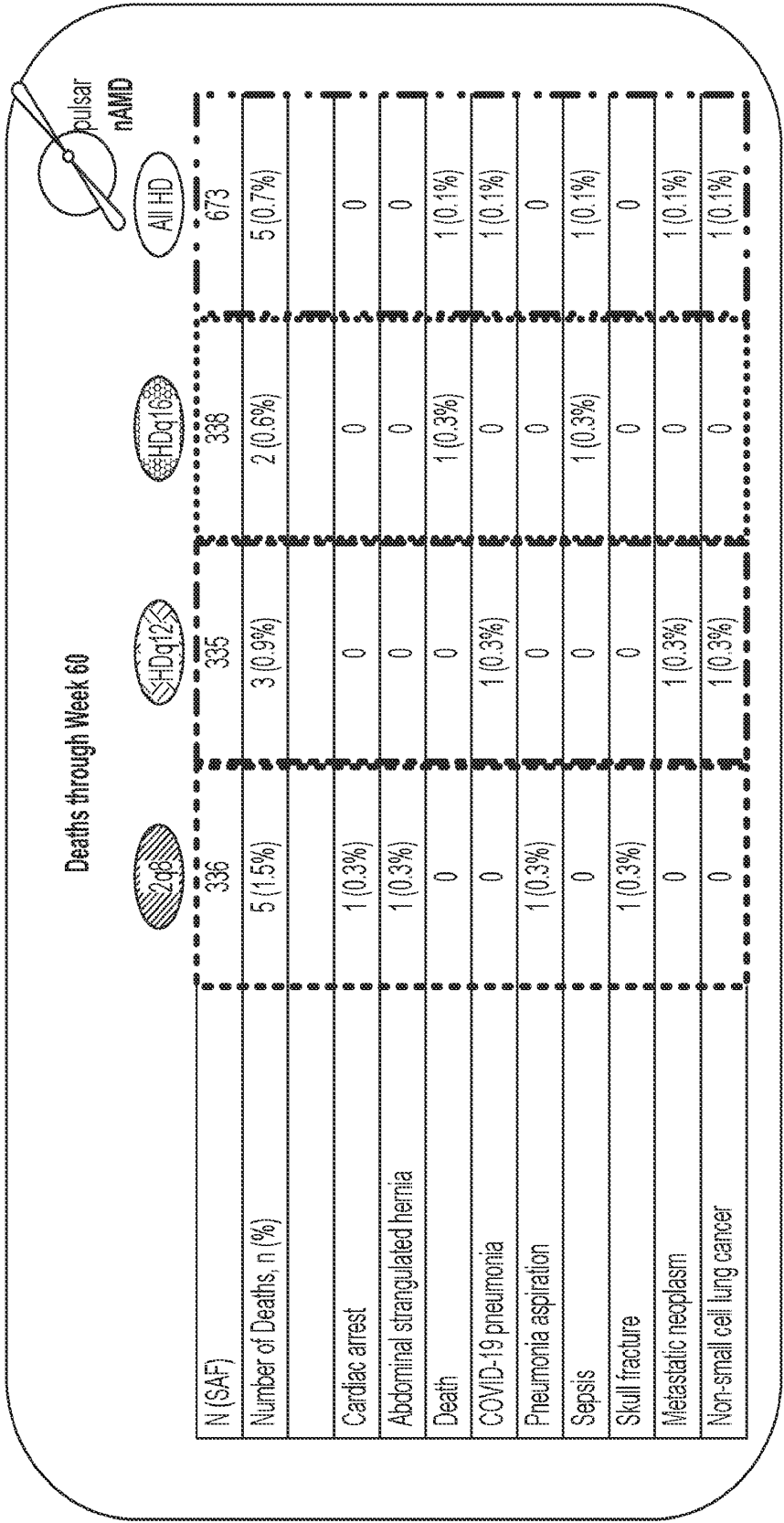


FIG. 70E

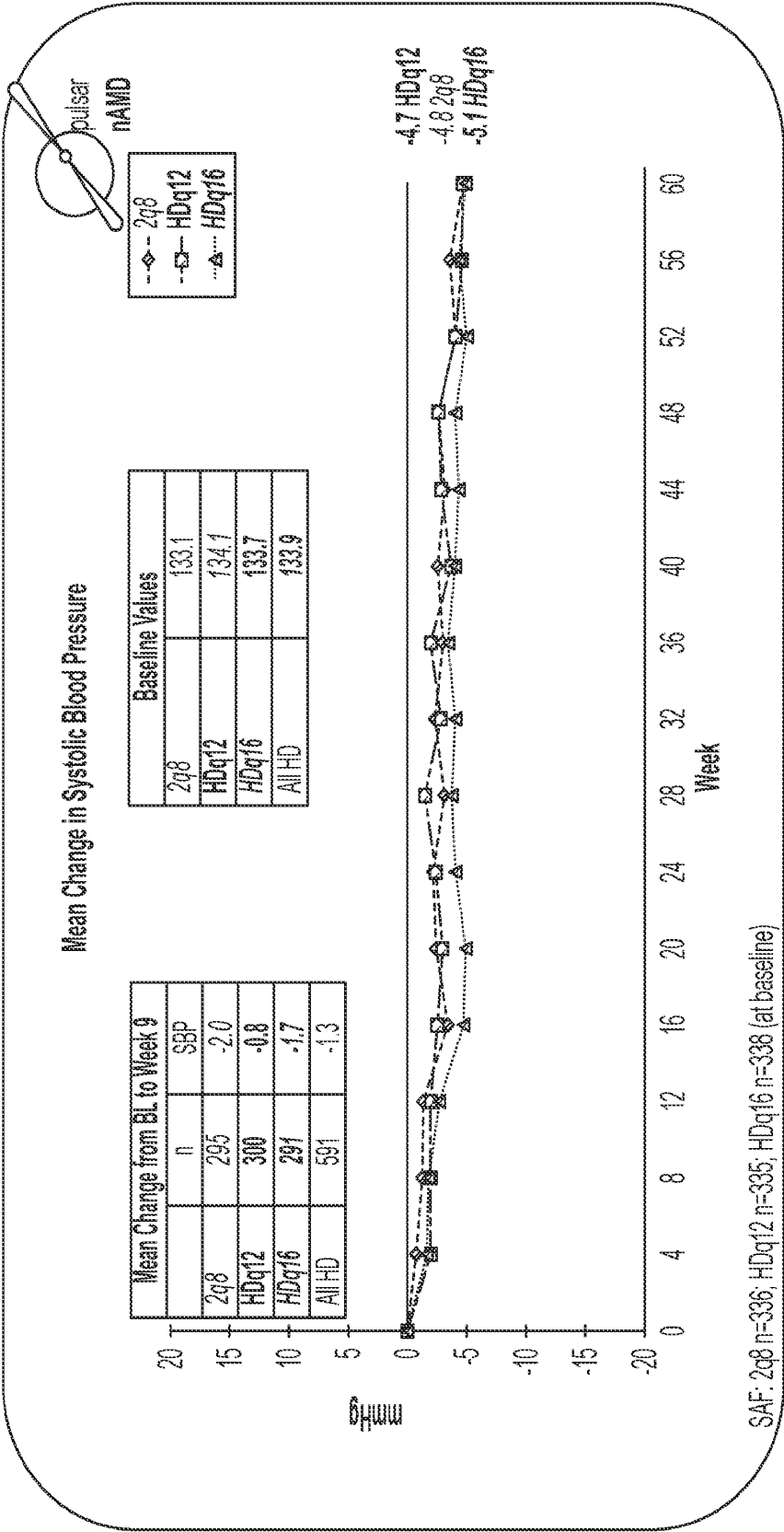


FIG. 70F

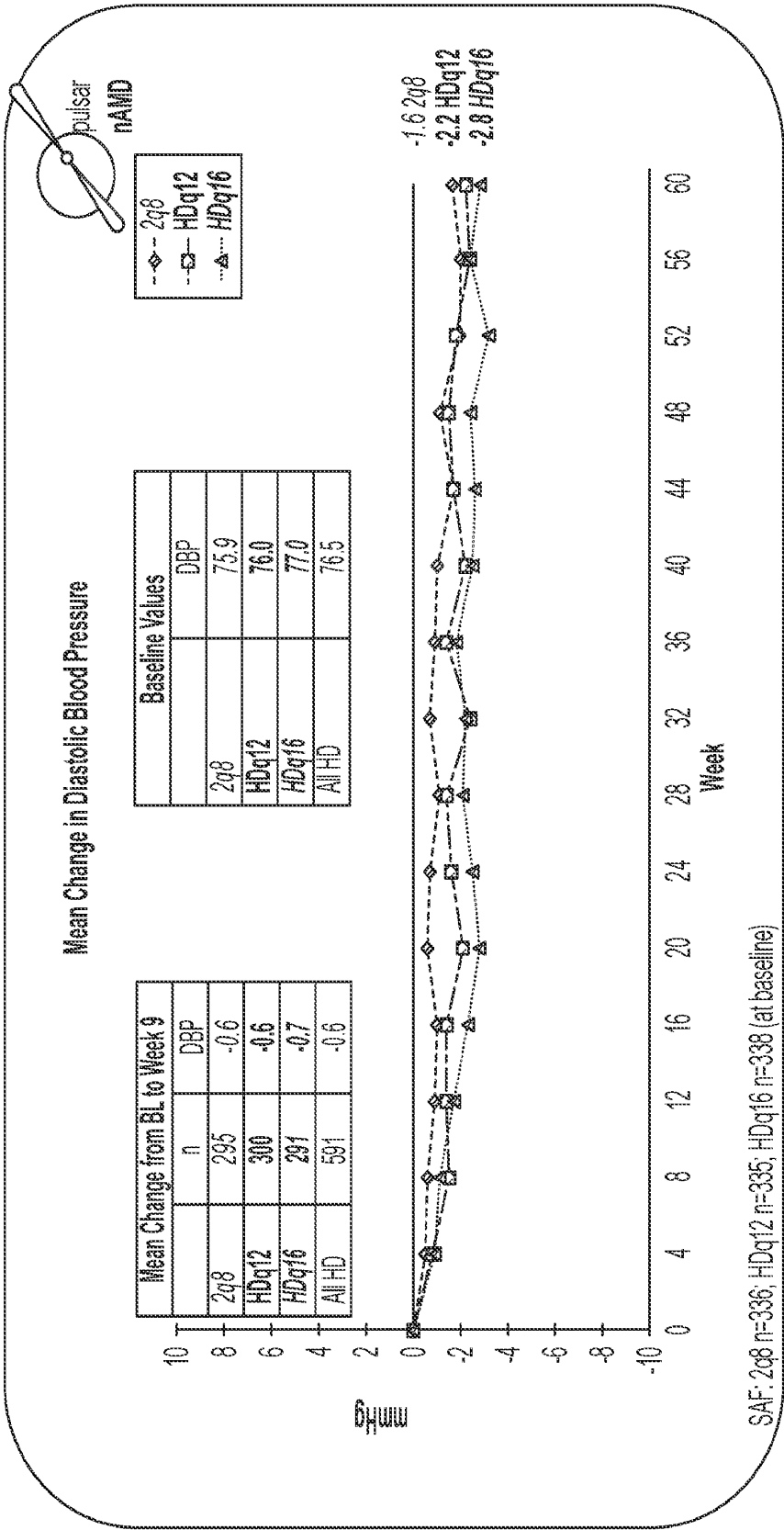


FIG. 70G

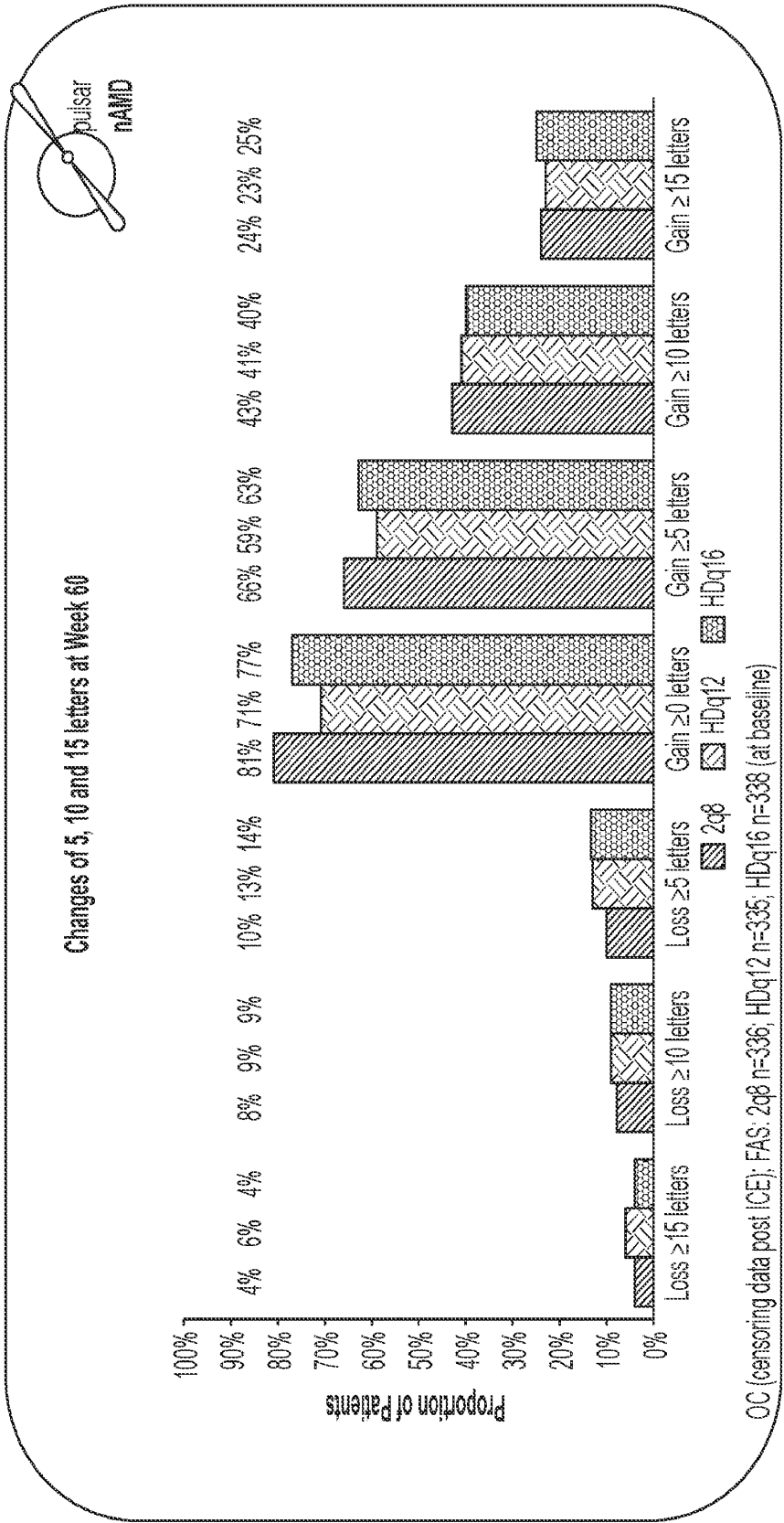


FIG. 71

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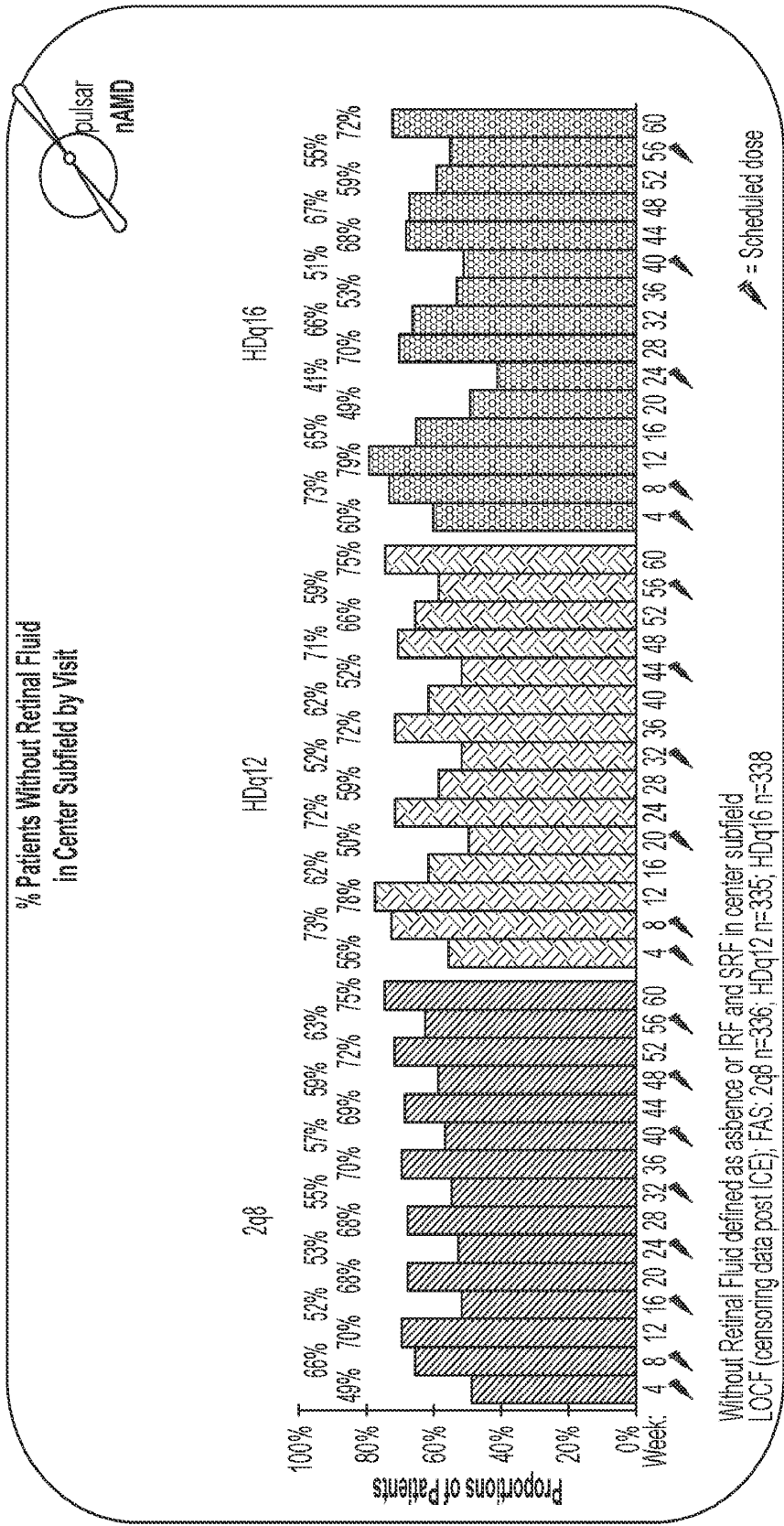


FIG. 72

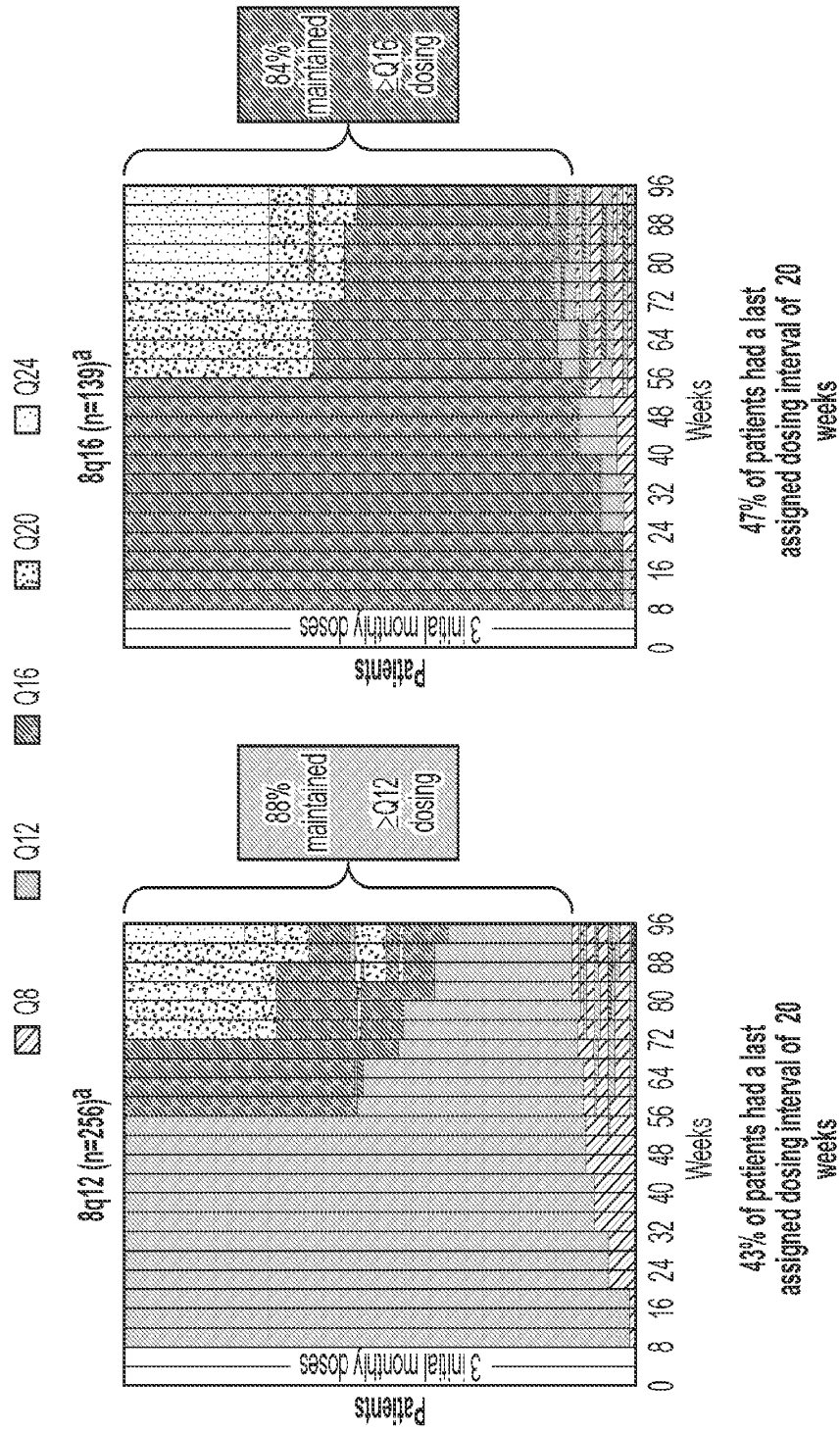


FIG. 73

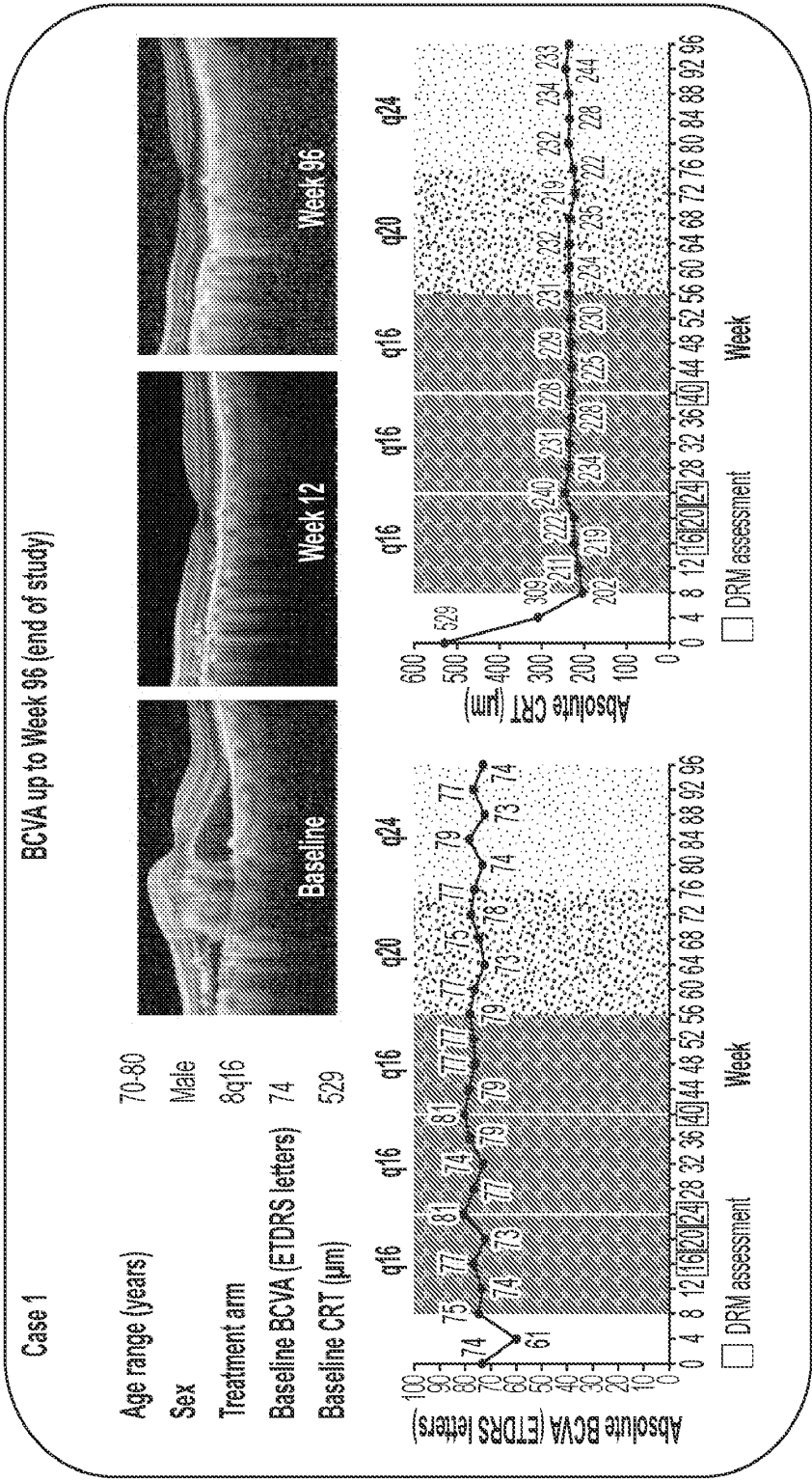


FIG. 74A

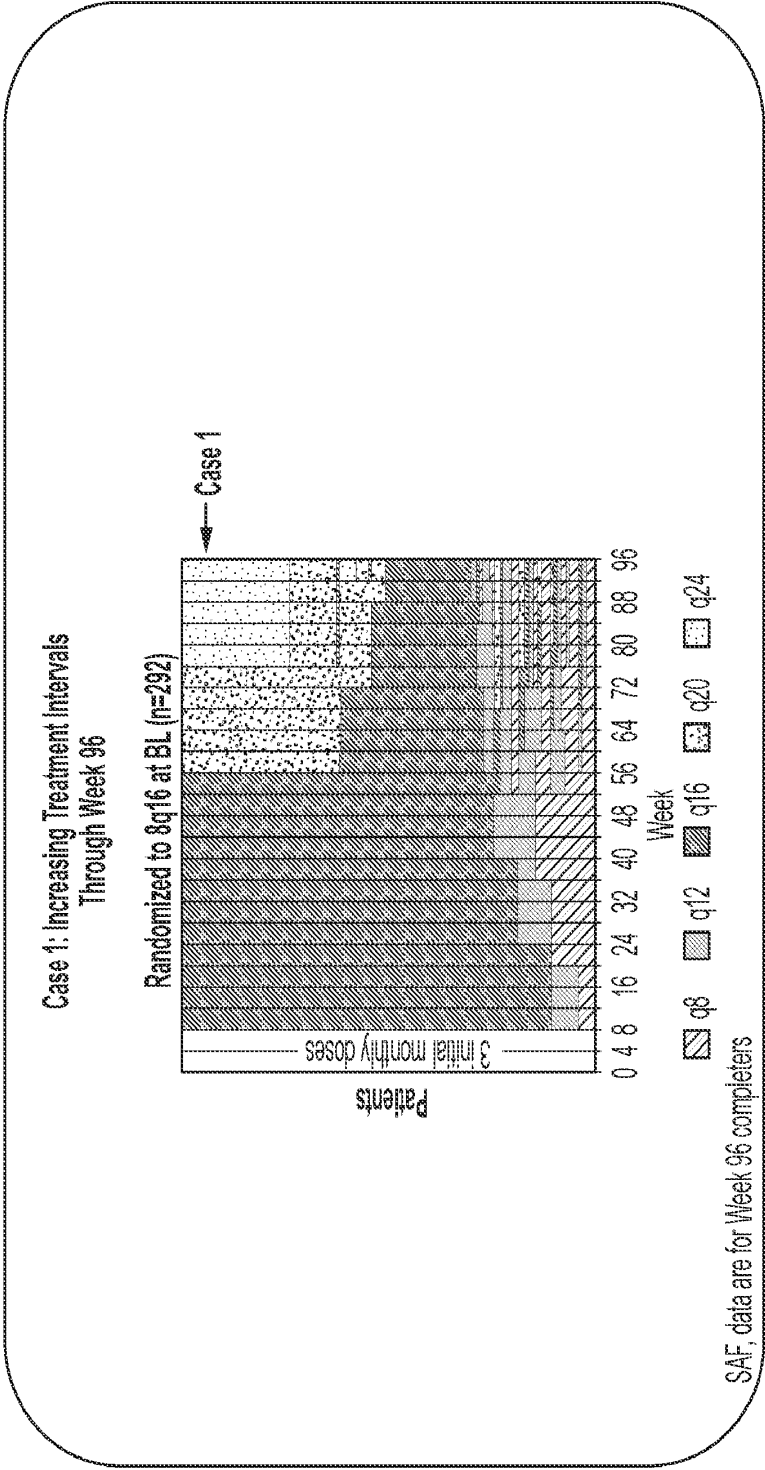


FIG. 74B

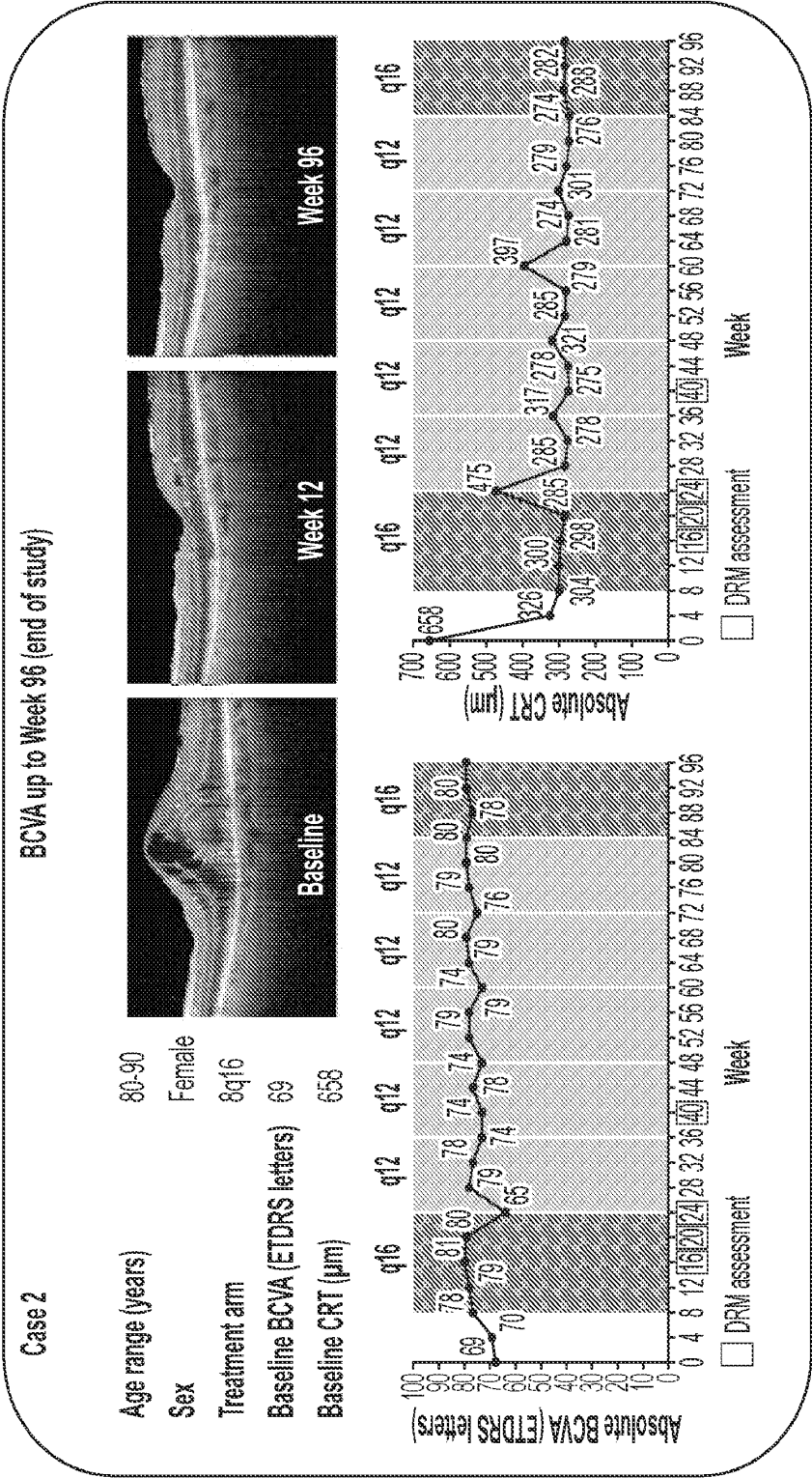


FIG. 75A

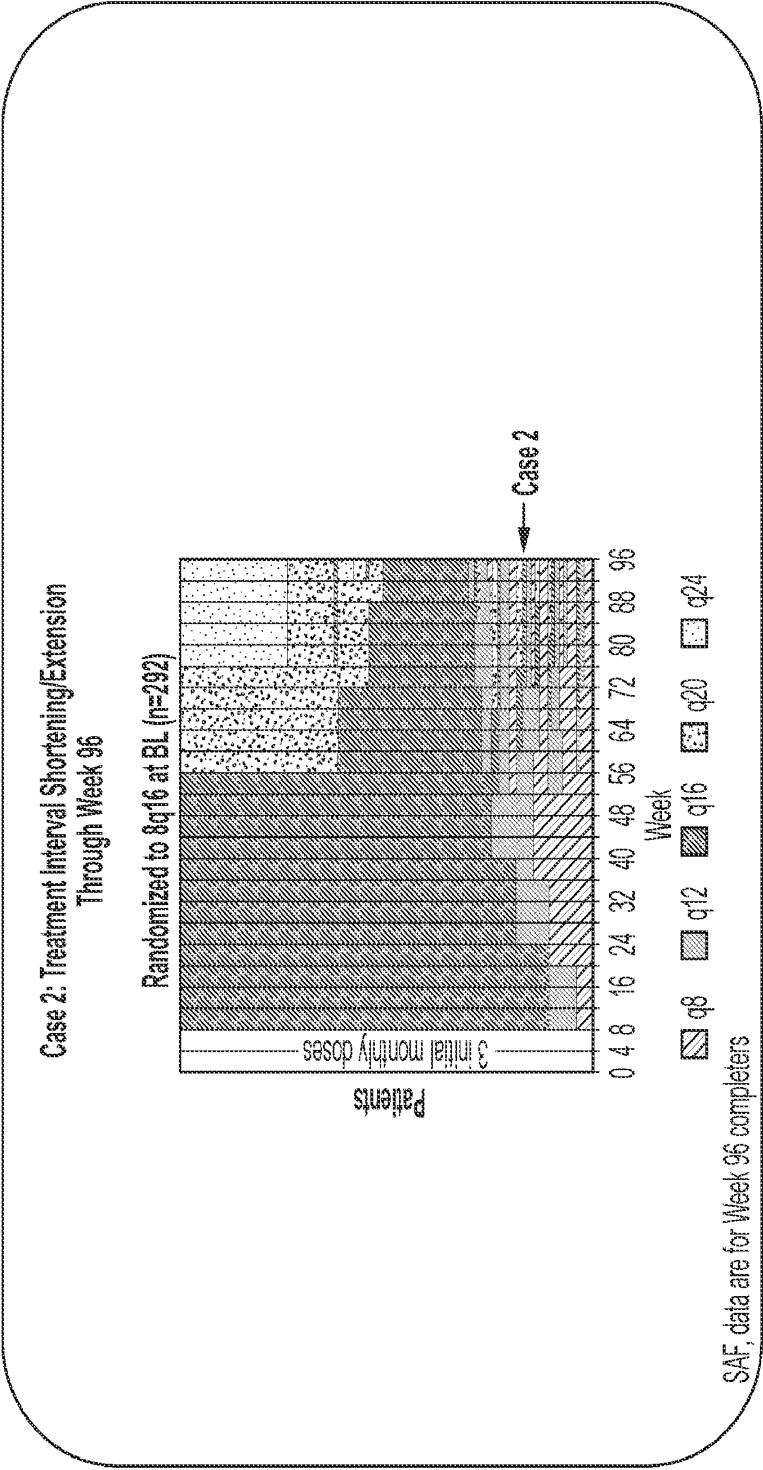
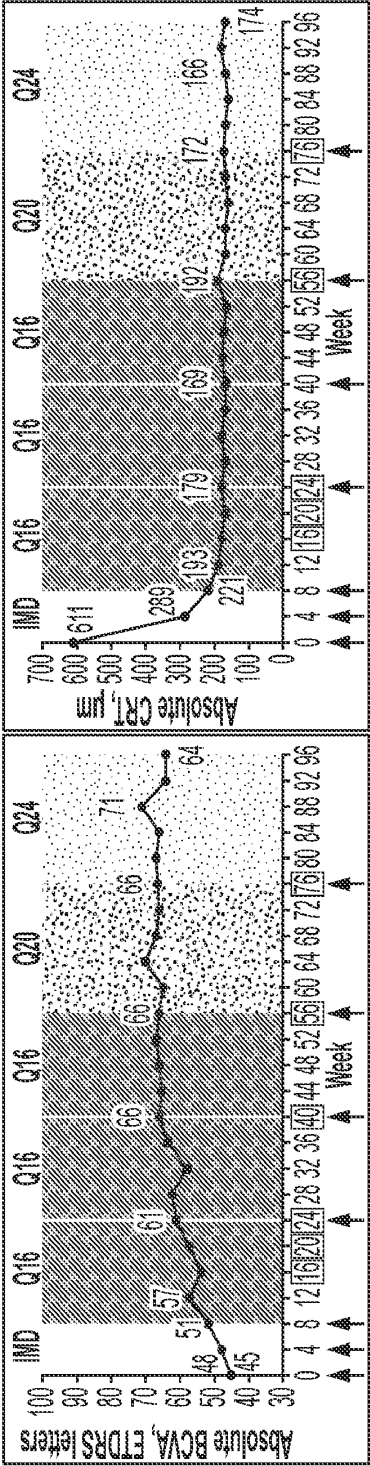
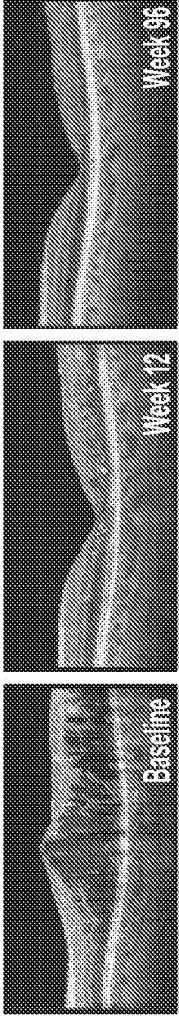


FIG. 75B

Case: Treatment-Naïve Patient Randomized to 8q16
Maintained Improvements in BCVA and CRT Through Week 96

Treatment arm	8q16
Age	55 years
Sex	Male
Race	White
Baseline BCVA	45 ETDRS letters
Baseline CRT	611 µm



▲ indicates active injection.
□ indicates timepoints at which patients were assessed for interval shortening (from baseline through Week 96) or extension (from Weeks 52 through 96) based on DRM criteria.

FIG. 76

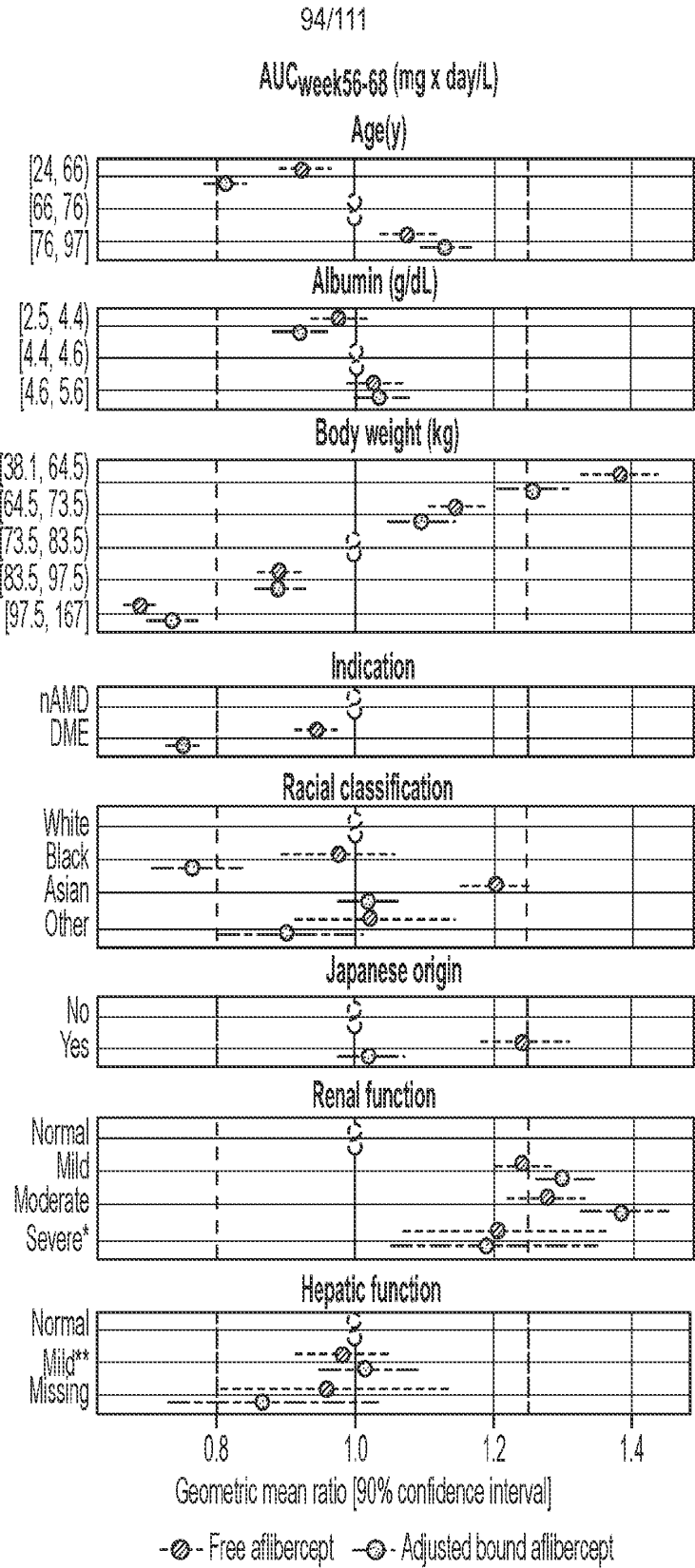


FIG. 77

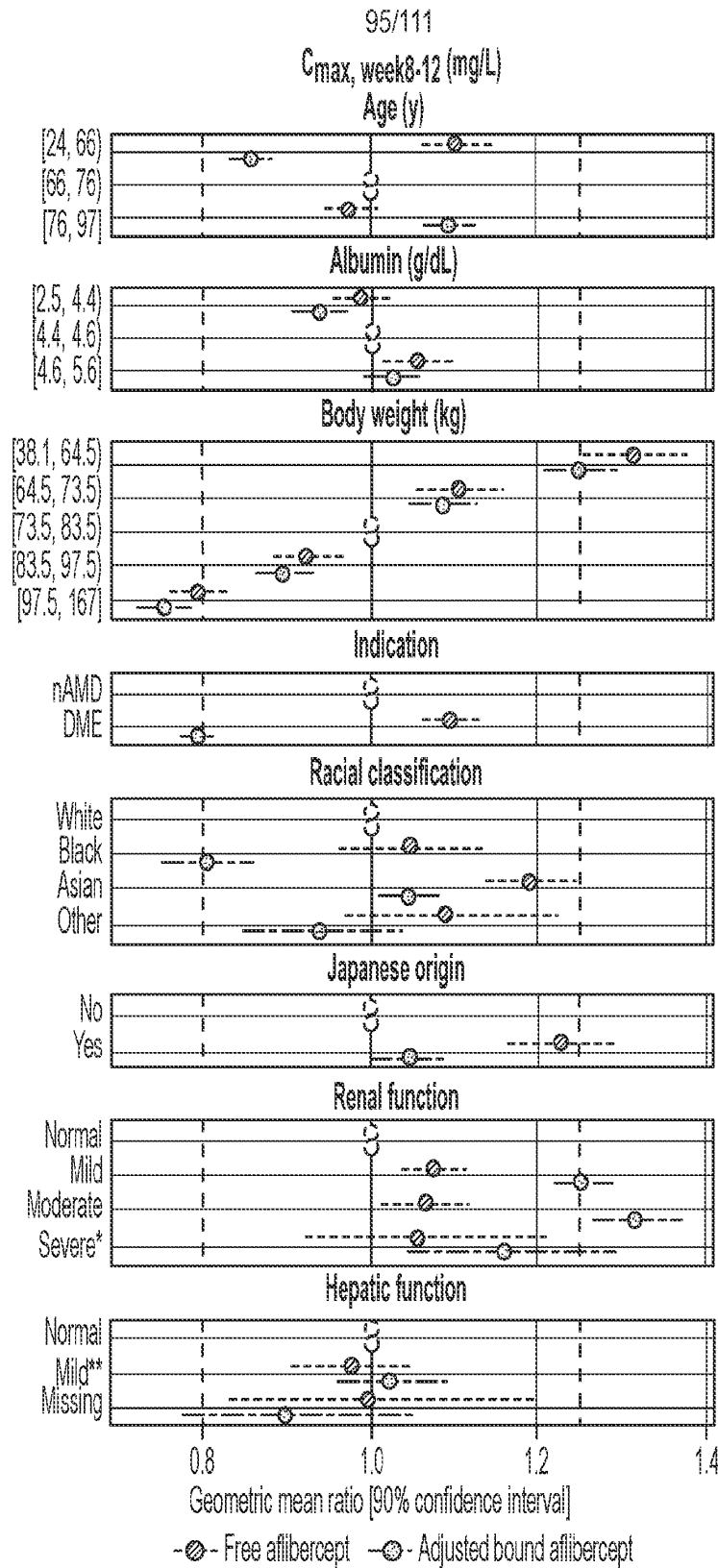


FIG. 77

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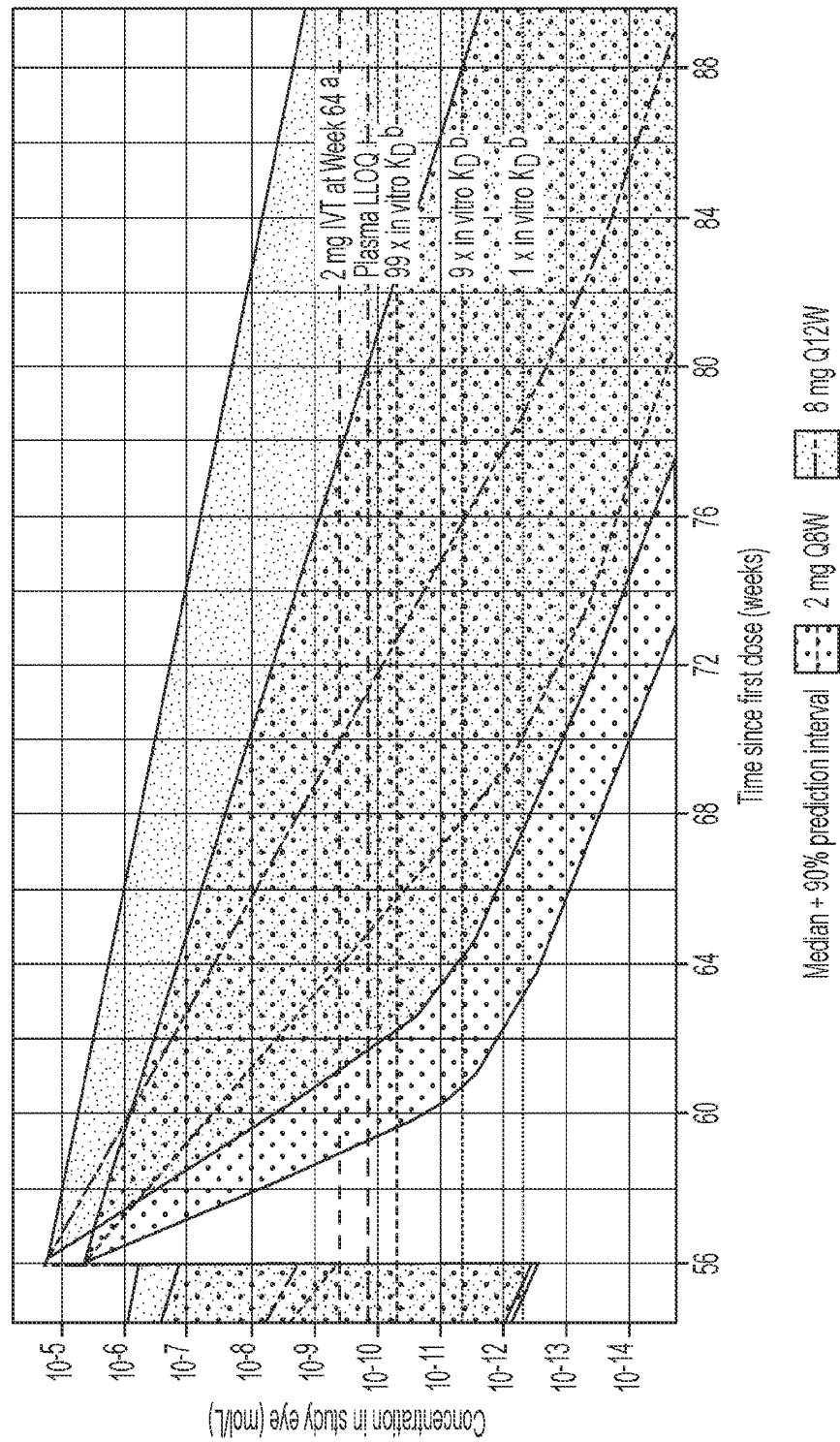
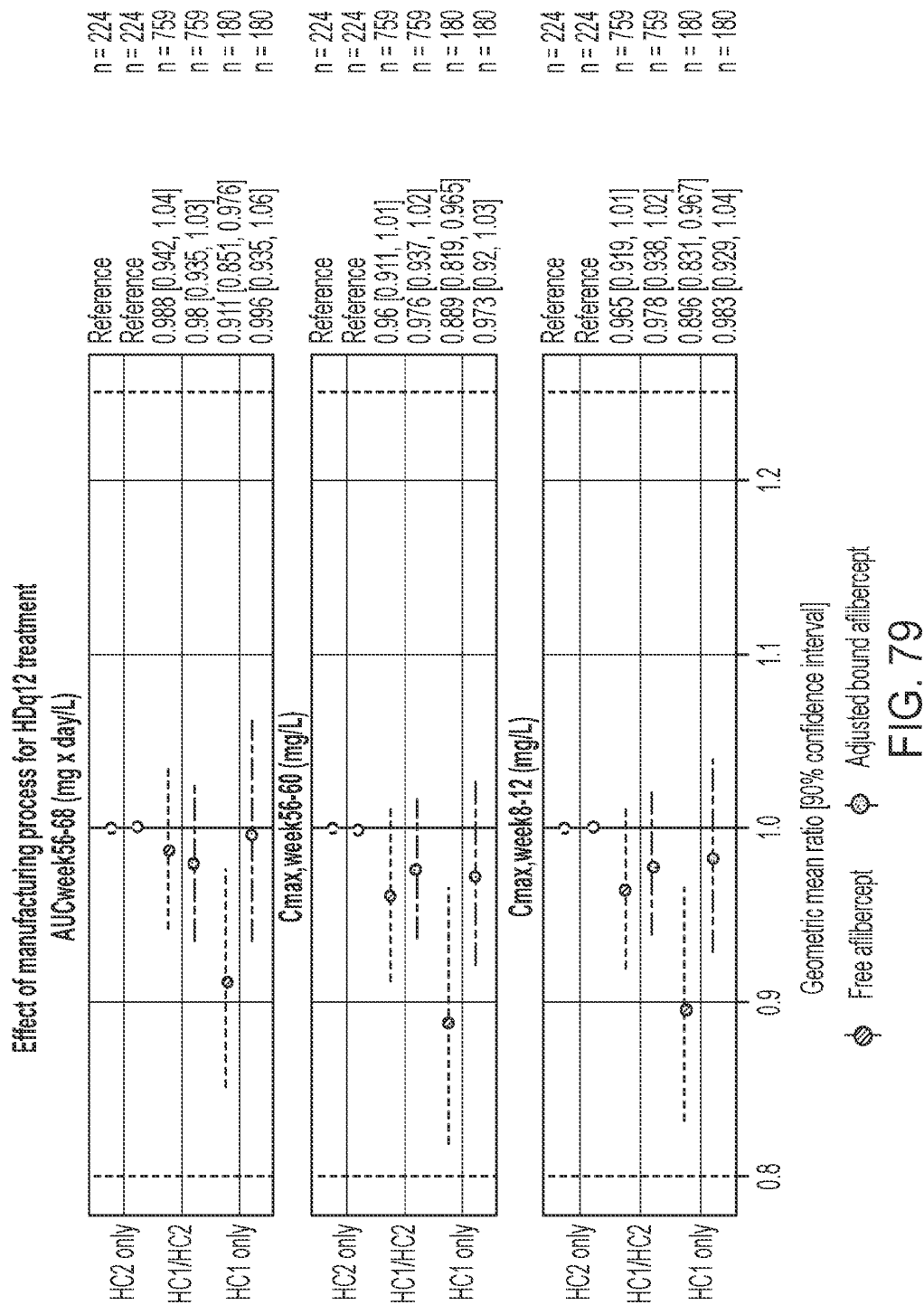
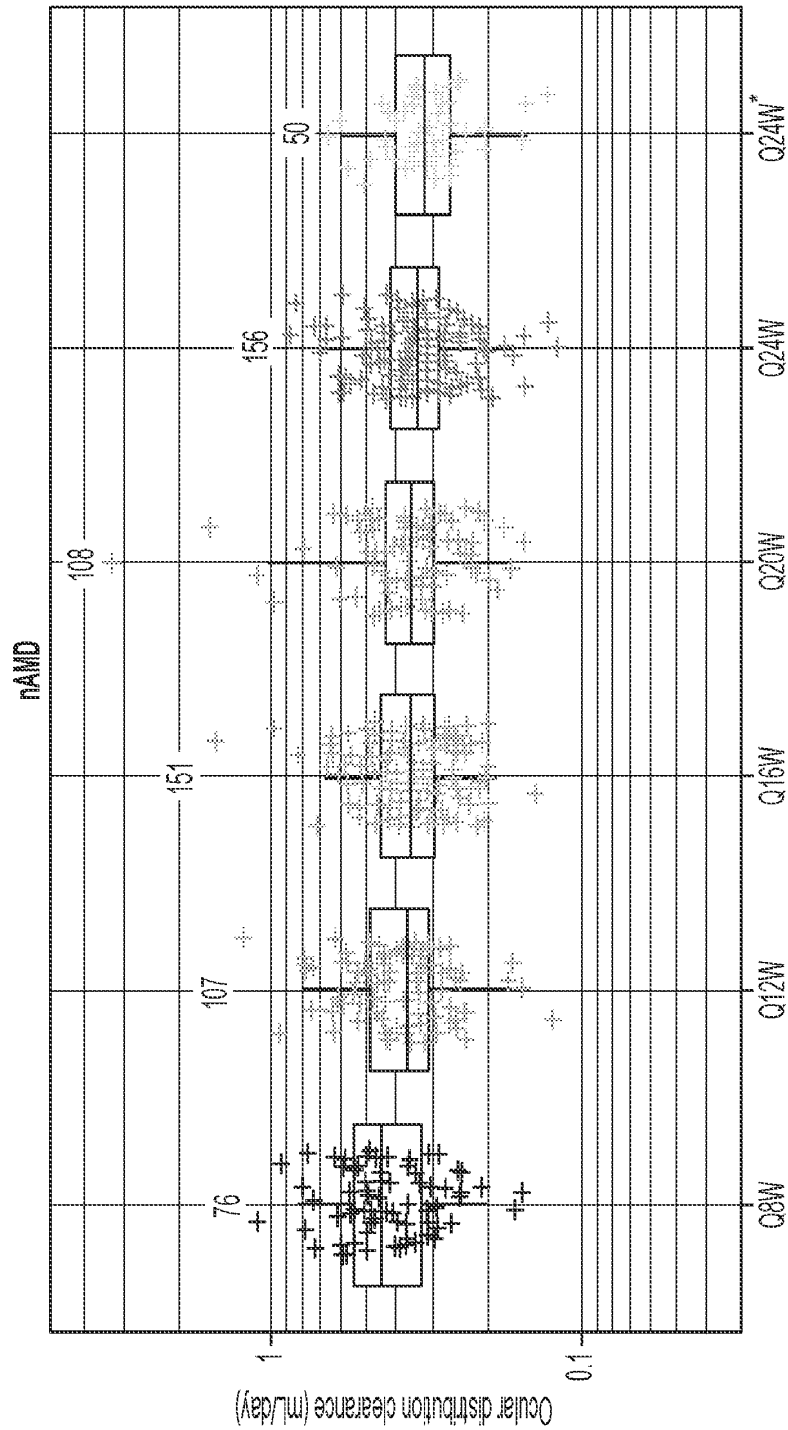


FIG. 78

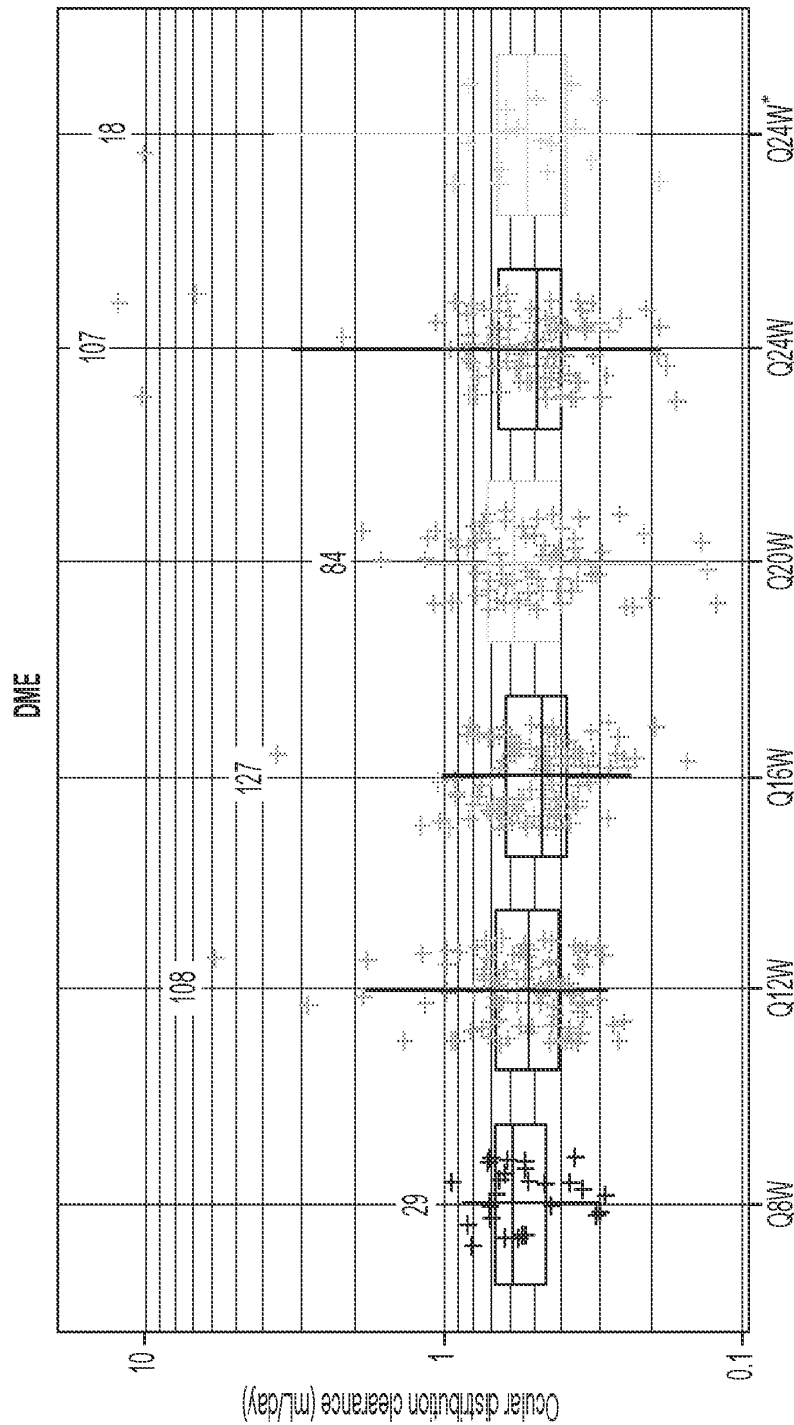
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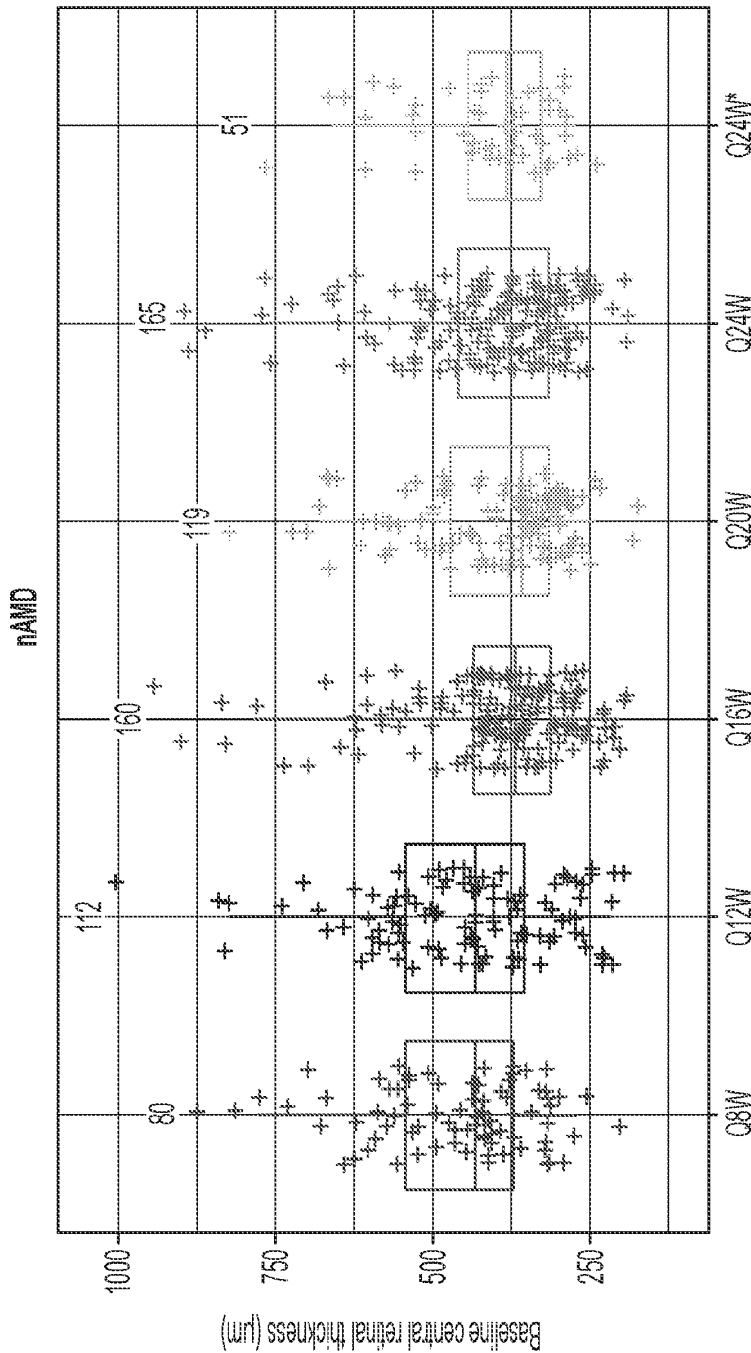
QxW = Every X weeks; nAMD = Neovascular age-related macular degeneration
Q24W* is a subset of the Q24W group and includes patients who were extended to and completed a 24-week interval without shortening.
The boxes and whiskers delimit the interquartile range and 95% confidence interval of the data, respectively. The lines inside the boxes represent the medians. The number of data points associated with each group is shown above each box.

FIG. 80



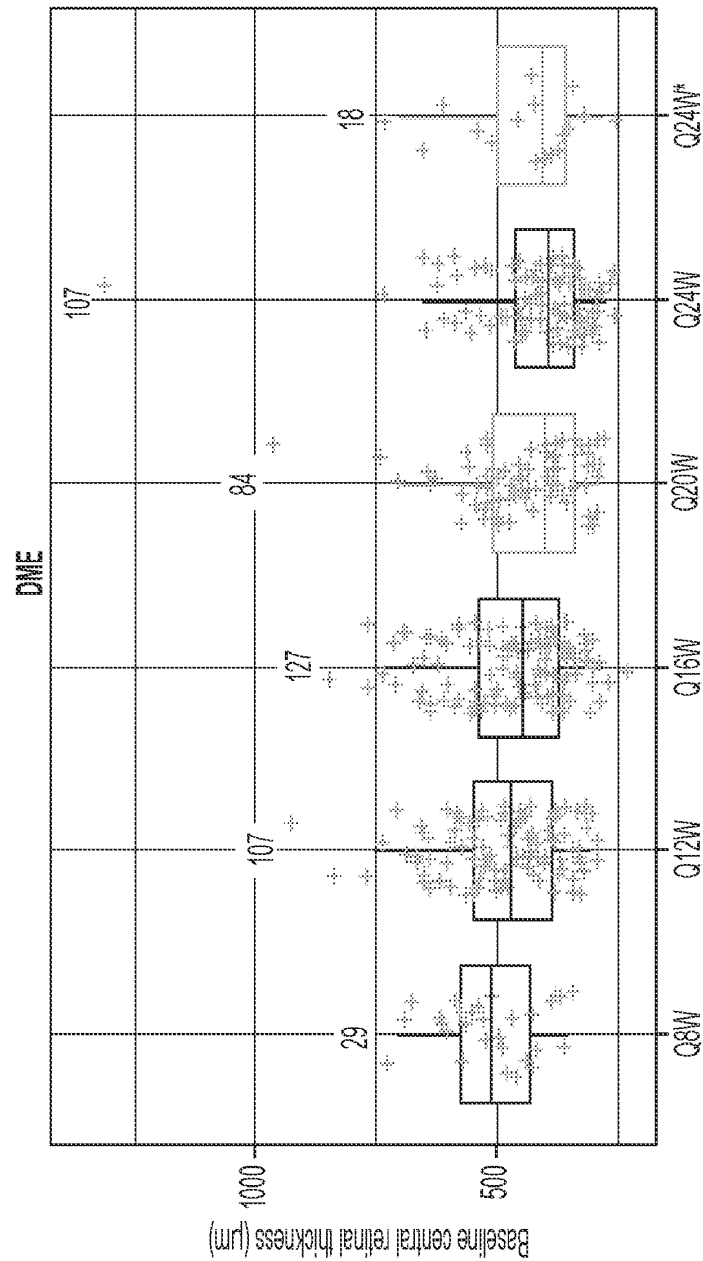
DME = Diabetic macular edema; QxW = Every X weeks
Q24W* is a subset of the Q24W group and includes patients who were extended to and completed a 24-week interval without shortening. The boxes and whiskers delimit the interquartile range and 95% confidence interval of the data, respectively. The lines inside the boxes represent the medians. The number of data points associated with each group is shown above each box.

FIG. 81



QxW = Every X weeks; nAMD = Neovascular age-related macular degeneration
Q24W* is a subset of the Q24W group and includes patients who were extended to and completed a 24-week interval without shortening. The boxes and whiskers delimit the interquartile range and 95% confidence interval of the data, respectively. The lines inside the boxes represent the medians. The number of data points associated with each group is shown above each box.

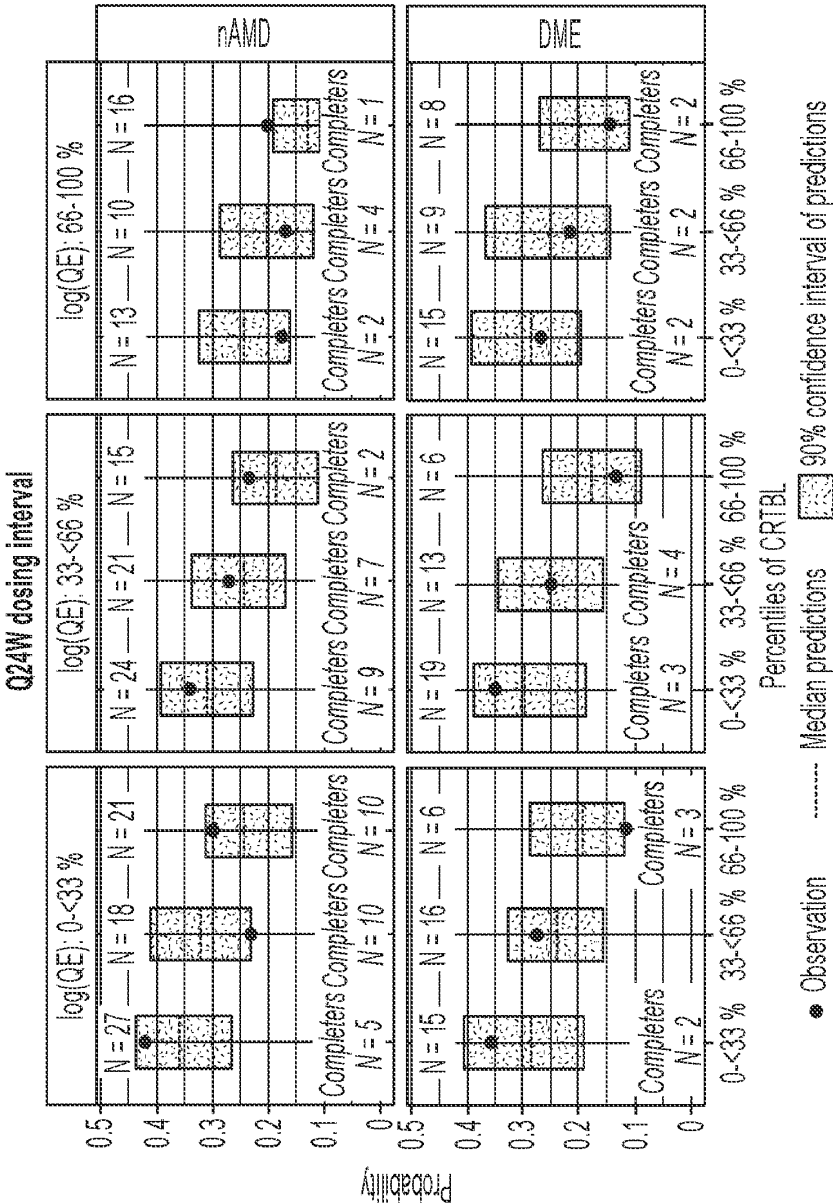
FIG. 82



DME=Diabetic macular edema; QxW = Every X weeks

Q24W* is a subset of the Q24W group and includes patients who were extended to and completed a 24-week interval without shortening. The boxes and whiskers delimit the interquartile range and 95% confidence interval of the data, respectively. The lines inside the boxes represent the medians. The number of data points associated with each group is shown above each box.

FIG. 83



CRTBL = Baseline central retinal thickness; DME = Diabetic macular edema; N = Number of patients; nAMD = Neovascular age-related macular degeneration; QE = Ocular distribution clearance; QxW = Every X weeks
Probabilities are calculated across assigned dosing intervals within a disease population, tertile of QE, and tertile of CRTBL.
Limits of QE and CRTBL tertiles are specific to the nAMD and DME populations.

FIG. 84

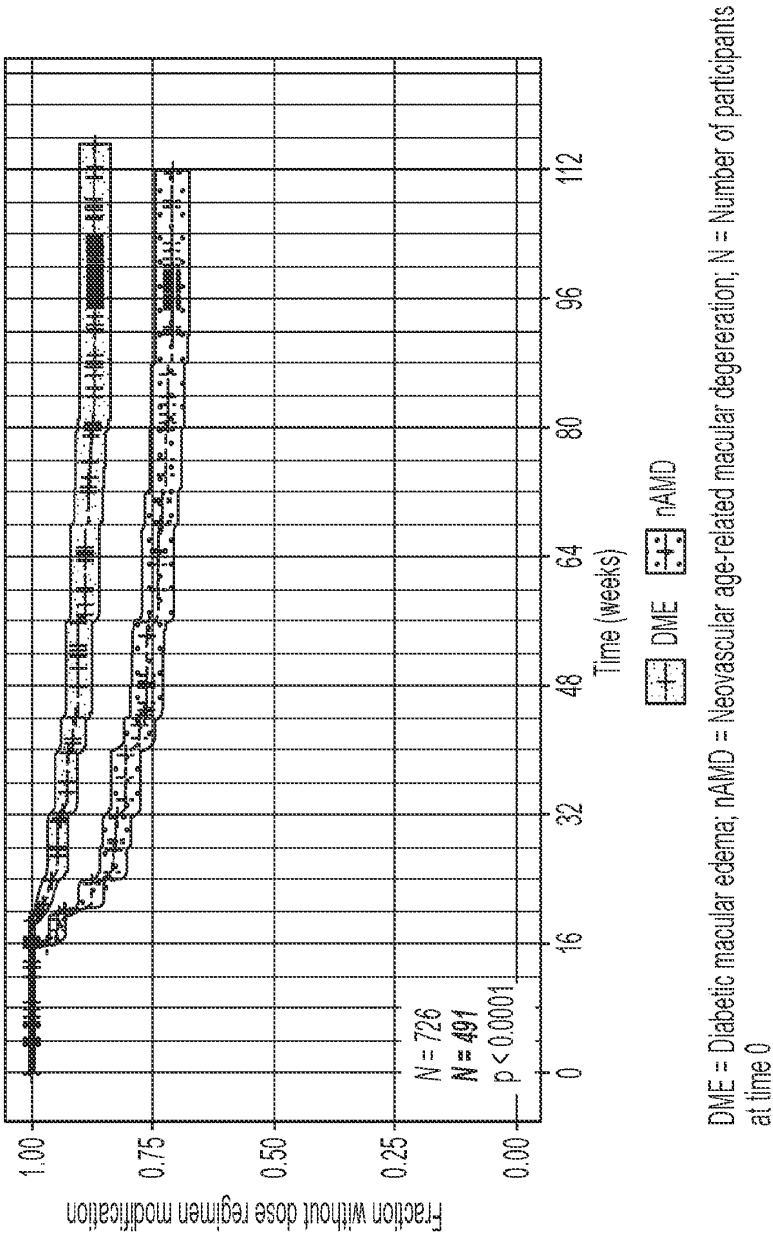
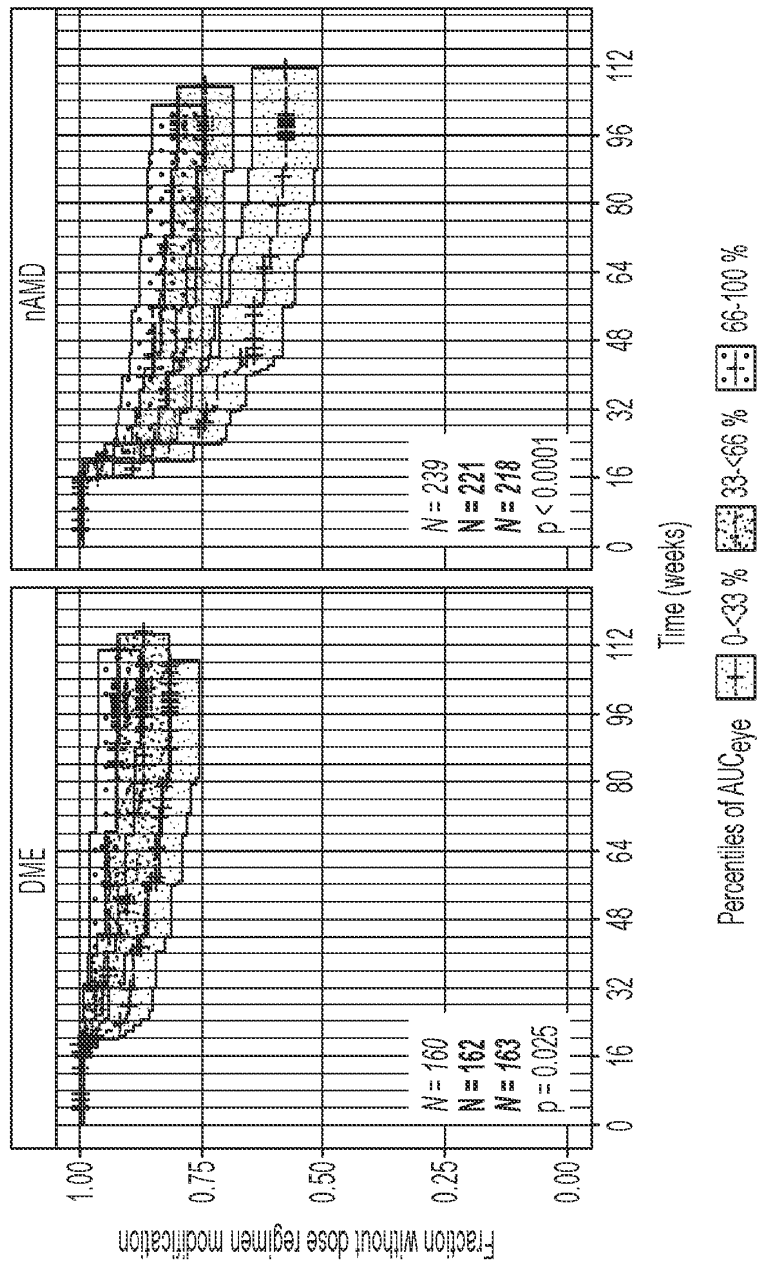
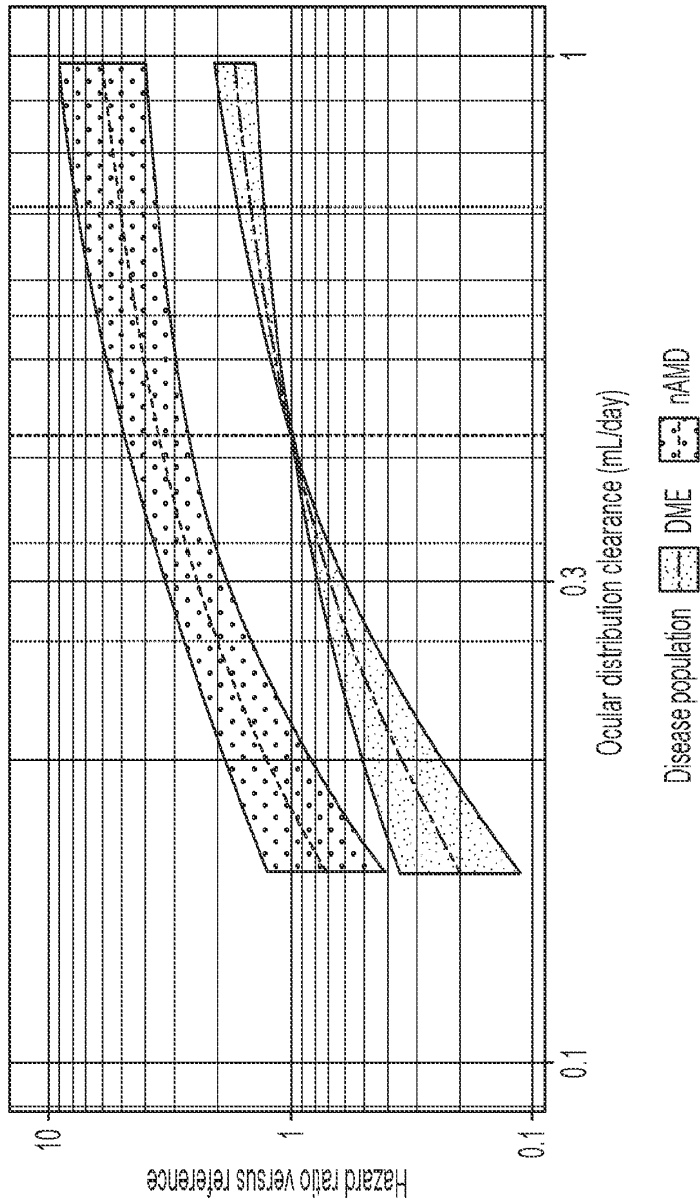


FIG. 85



AUCeye = Area under the curve of concentration in the eye; DME = Diabetic macular edema; nAMD = Neovascular age-related macular degeneration; N = Number of participants at time 0
Data from 6 DME and 48 nAMD patients with imputed ocular distribution clearance are not shown.

FIG. 86



DME = Diabetic macular edema; nAMD = Neovascular age-related macular degeneration
The colored lines and shaded areas represent the model-predicted hazard ratio and associated 95% prediction intervals.
The vertical dotted and dashed lines represent the 10th, 25th, 50th, 75th, and 90th percentiles of ocular distribution clearance. The reference for hazard ratio is a DME participant at the overall medians of ocular distribution clearance and baseline central retinal thickness.

FIG. 87

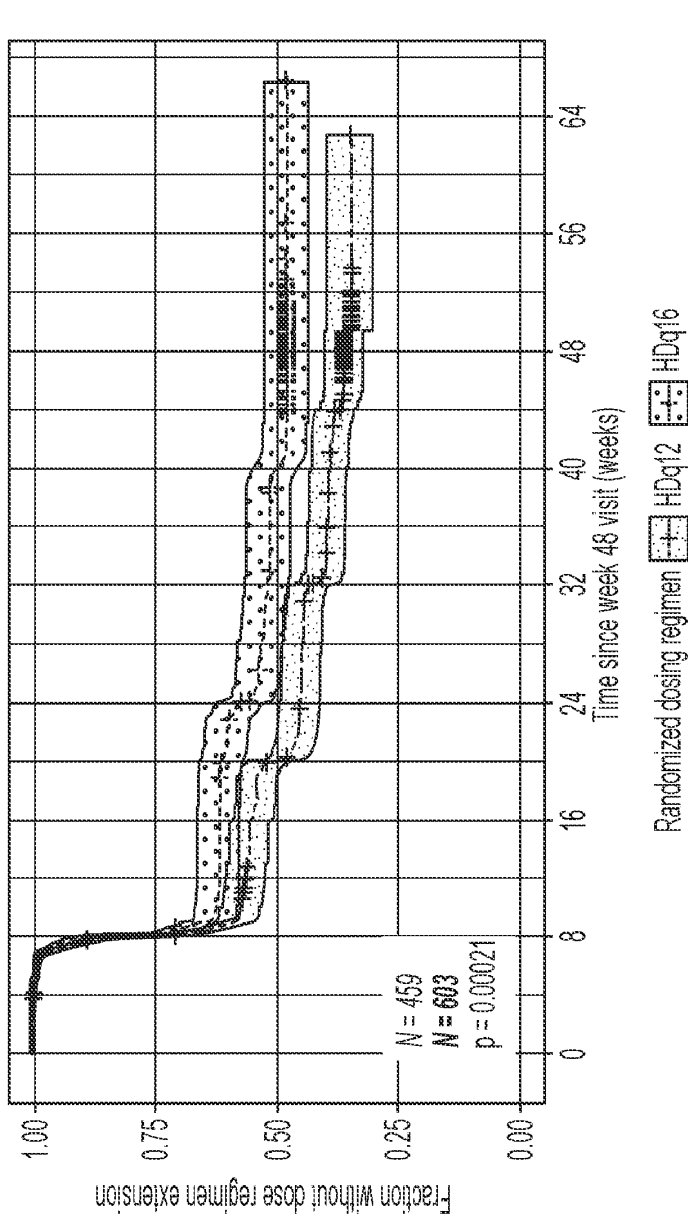
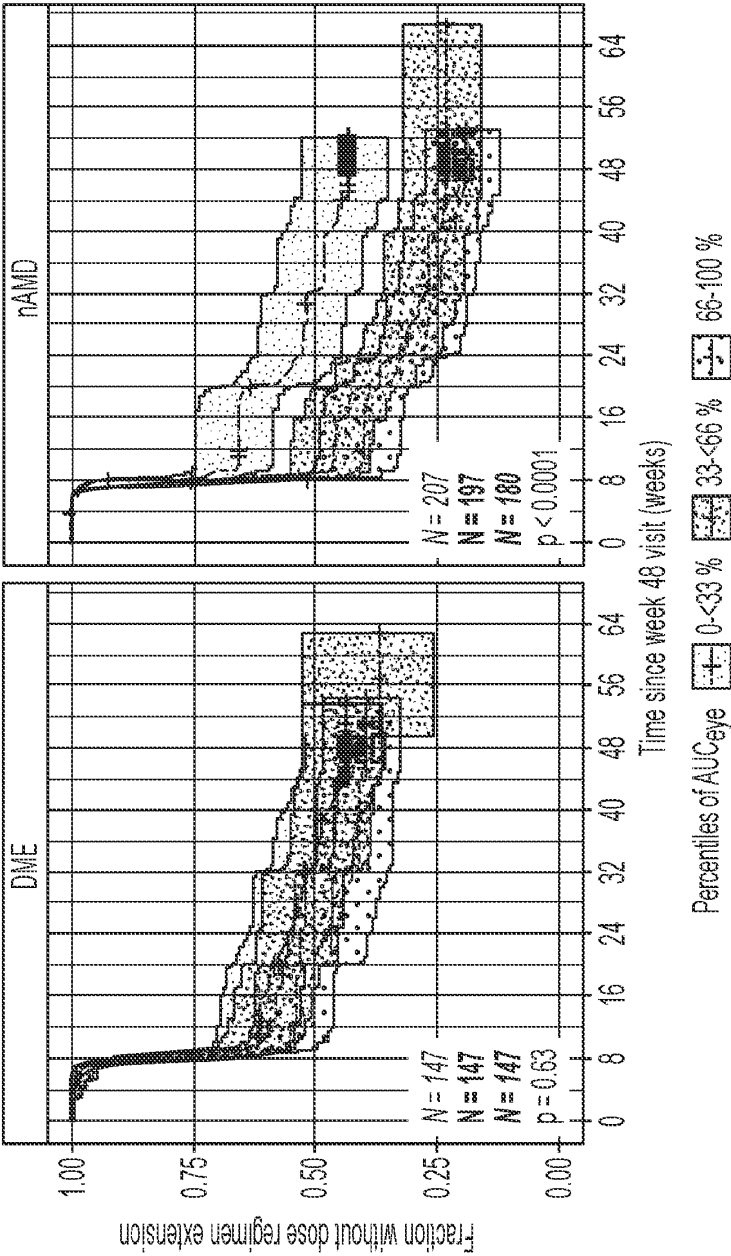
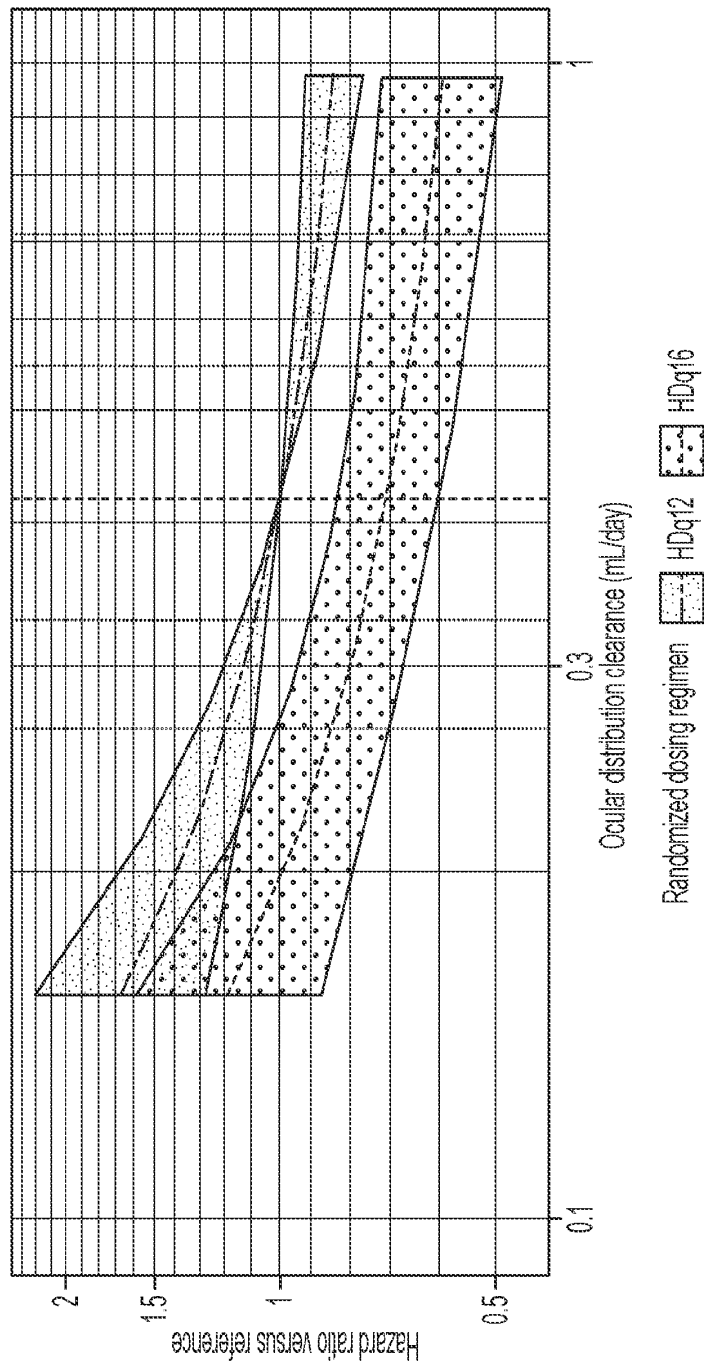


FIG. 88



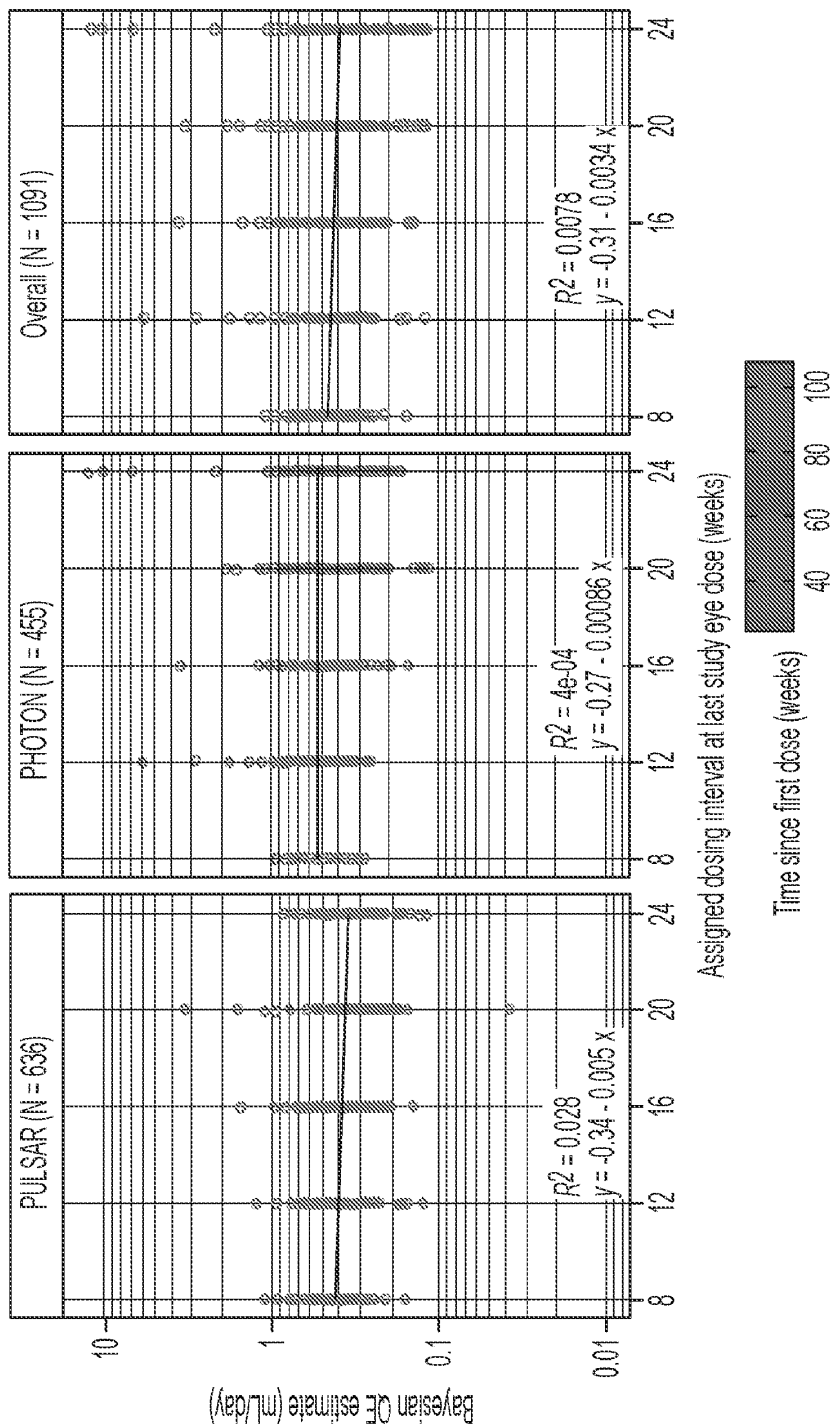
AUC_{eye} = area under the curve of concentration in the eye; DME = Diabetic macular edema; nAMD = Neovascular age-related macular degeneration; N = Number of participants at time 0
Data from 37 nAMD patients with imputed AUC_{eye} are not shown.

FIG. 89



HDqX = 8 mg aflibercept every X weeks following 3 initial monthly injections
The colored lines and shaded areas represent the model-predicted hazard ratio and associated 95% prediction intervals.
The vertical dotted and dashed lines represent the 10th, 25th, 50th, 75th, and 90th percentiles of ocular distribution clearance.
The reference for hazard ratio is a patient randomized to HDq12 and at the overall medians of ocular distribution clearance and baseline central retinal thickness.

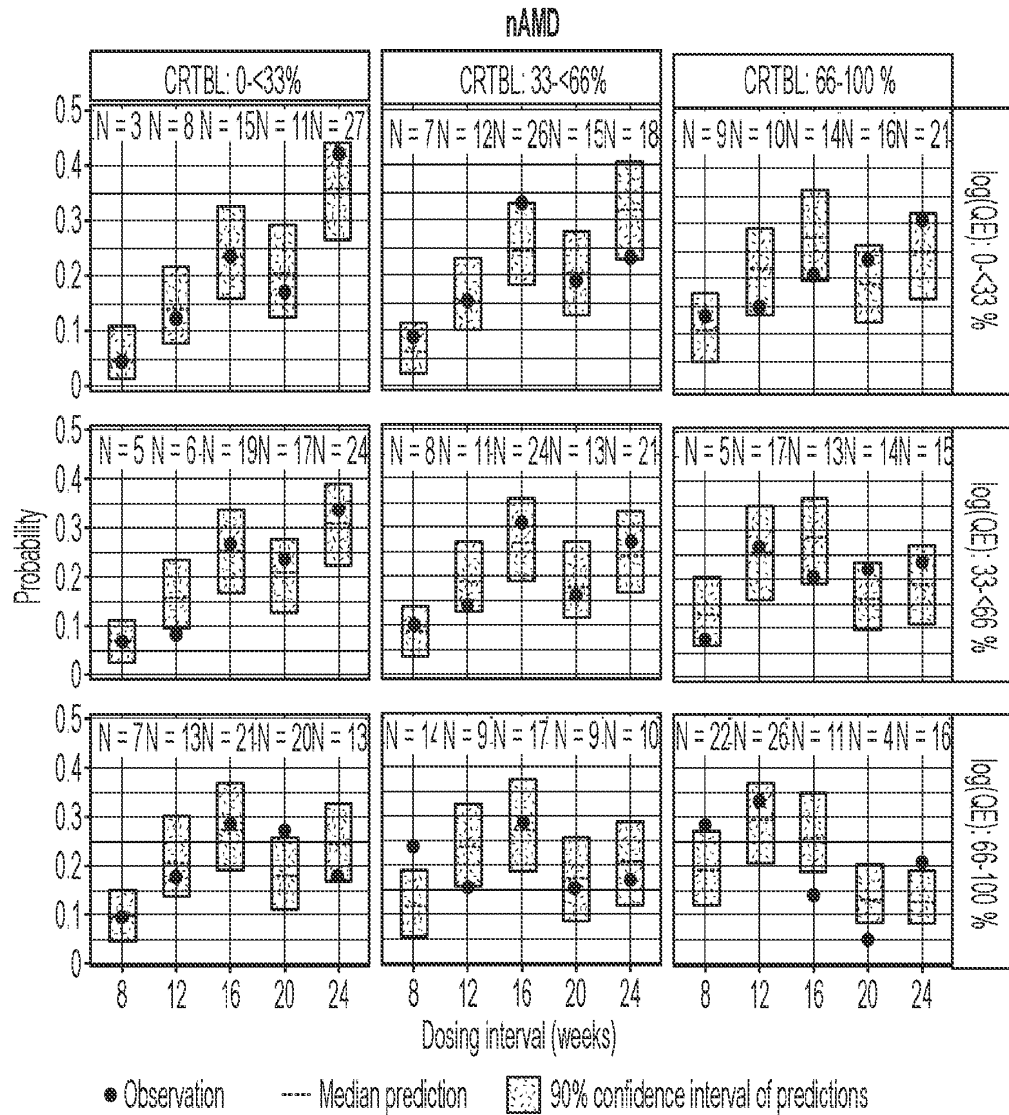
FIG. 90



QE = Ocular distribution clearance
The equation of the linear regression of the Y-axis versus X-axis variables are displayed along with the square of the Pearson's correlation coefficient (R²).

FIG. 91

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CRTBL = Baseline central retinal thickness; N = Number of patients; nAMD = Neovascular age-related macular degeneration; OE = Ocular distribution clearance
Limits of OE and CRTBL tertiles are specific to the nAMD population

FIG. 92

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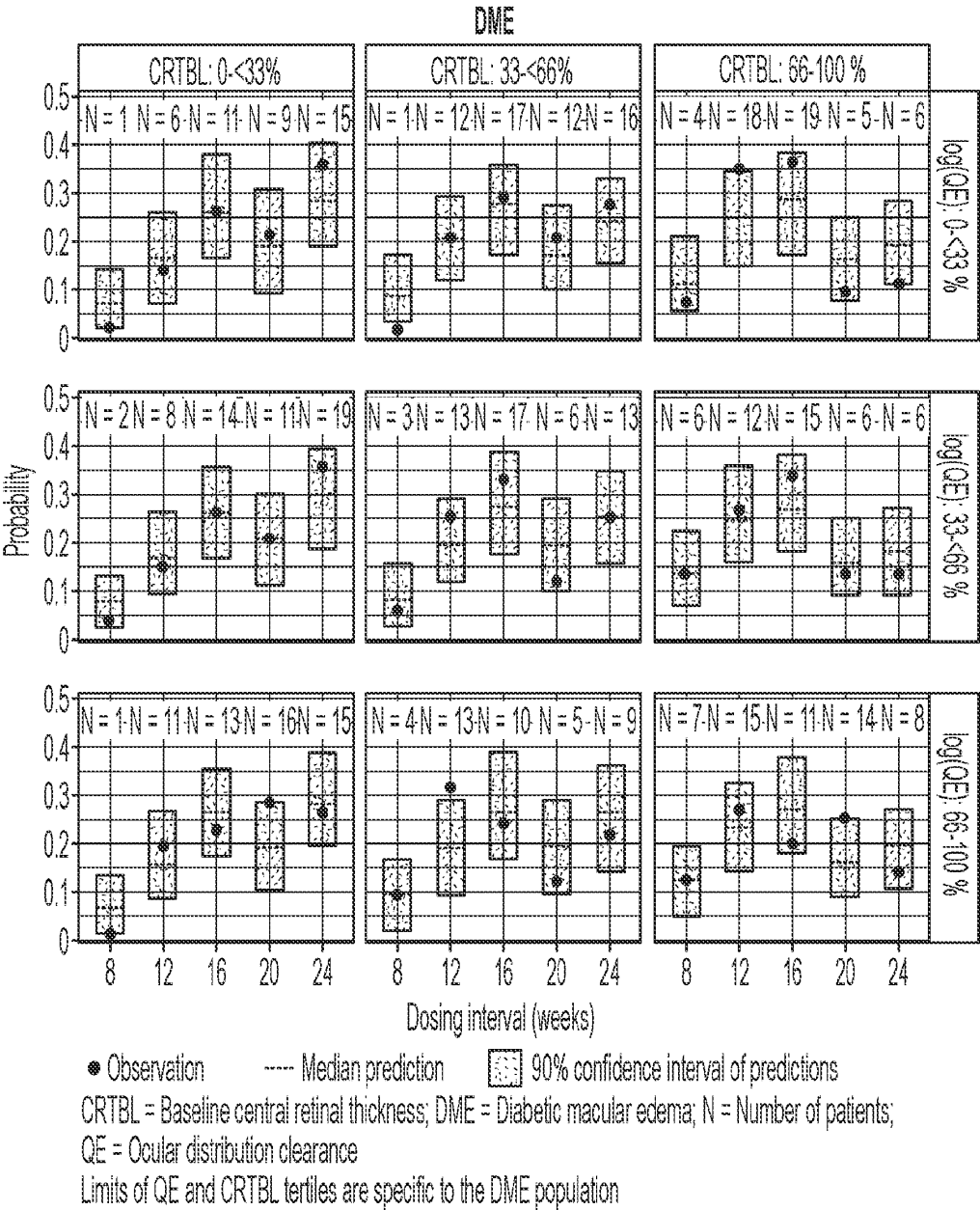


FIG. 93