Supplemental Online Content

Berkowitz ST, Groth SL, Gangaputra S, Patel S. Racial/ethnic disparities in ophthalmology clinical trials resulting in US Food and Drug Administration drug approvals from 2000 to 2020. *JAMA Ophthalmol.* Published online April 22, 2021. doi:10.1001/jamaophthalmol.2021.0857

This supplemental material has been provided by the authors to give readers additional information about their work.

eMethods: Trends in EID over time with regression analysis:

Clinical Trials relative to NEI projections

For AMD trials, the trial year was statistically significantly correlated with a decrease in EID for white race (F (1, 3) = 8.31, p = .063, R^2(adj) 64.62%), with no significant correlation for other race (F(1, 3) = 8.29 p = .064, R^2(adj) 64.56%), black race (F(1, 3) = 2.93, p = .19, R^2(adj) 32.53%) or Hispanic or LatinX (F(1, 3) = 6.55, p = .08, R^2(adj) 58.13%).

For glaucoma trials, the trial year was statistically significantly correlated with an increase in EID for Hispanic or LatinX (F(1, 4) = 25.79, p = .007, R^2(adj) 83.22%), decrease in EID for white race (F(1, 4) = 15.26, p= .02, R^2(adj) 74.04%) with no significant correlation for other race (F(1, 4) = 0.55, p = .50, R^2(adj) -0.0979), or black race (F(1, 4) = 5.45, p = .08, R^2(adj) 47.08).

Clinical Trials relative to literature (5-Category race data)

For AMD trials, the trial year was statistically significantly correlated with an increase in EID for Asian race (F(1, 3) = 12.06, p= .04, R^2(adj) 73.44%) with no significant correlation for other race (F(1, 3) = 1.88, p= .26, R^2(adj) 18.02%), black (F(1, 3) = 2.43, p = .22, R^2(adj) 26.32%), white (F(1, 3) = 8.27, p = .06, R^2(adj) 64.51%), or Hispanic or LatinX (F(1, 3) = 6.60, p=.08, R^2(adj) 58.35%).

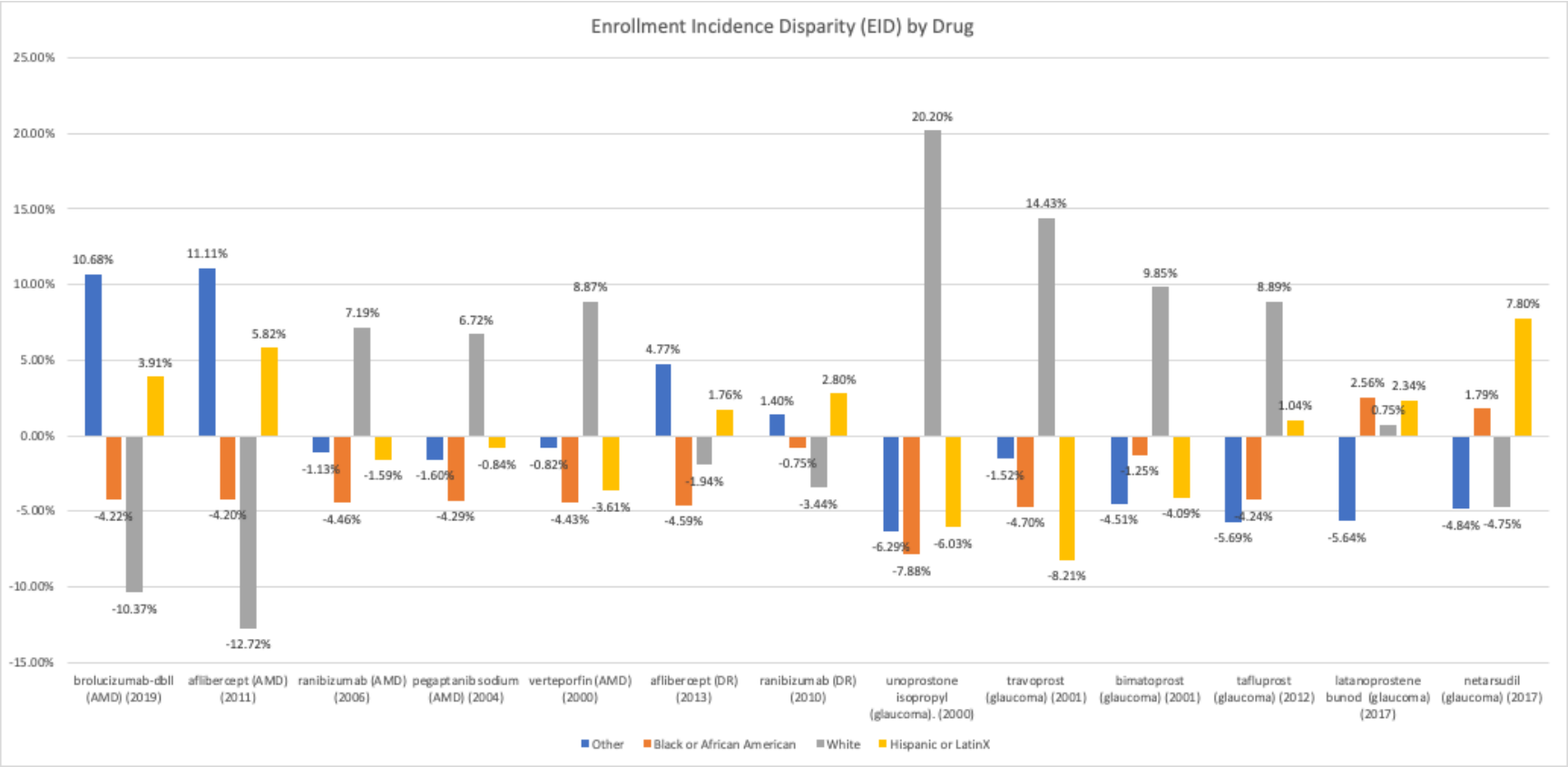
For OAG trials, the trial year was statistically significantly correlated with increase in EID for Hispanic or LatinX (F(1, 4) = 26.10, p= .007 R^2(adj) 83.39%) with an decrease in EID for white (F(1, 4) = 15.60, p = .02, R^2(adj) 74.49%), with no significant correlation for other race (F(1, 4) = 0.83, p= .41, R^2(adj) - 3.51%), Asian (F(1, 4) = 0.08, p= .80 R^2(adj) – 22.63%), or black (F(1, 4) = 5.51, p= .08, R^2(adj) 47.45%).

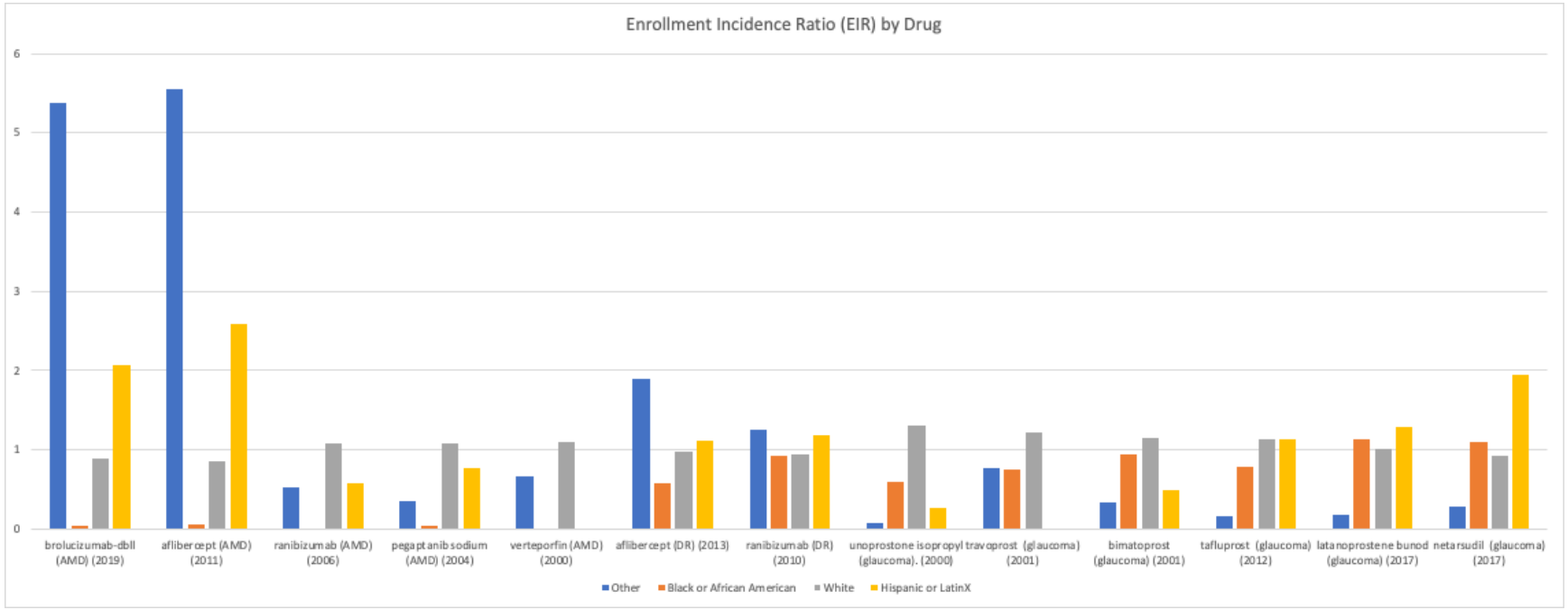
eTable: Comparison of racial/ethnic composition of trials leading to drug approval with the expected trial demographic distribution in the US based on published 5-Category Race/ethnic prevalence data

	5-Category Race [a]	
	Pearson's	P-value
brolucizumab-dbll (AMD)	247.774	<.001
aflibercept (AMD)	326.415	<.001
ranibizumab (AMD)	220.011	<.001
pegaptanib sodium (AMD)	185.060	<.001
verteporfin (AMD)	145.228	<.001
unoprostone isopropyl (glaucoma).	2.37E+02	<.001
travoprost (glaucoma)	541.759	<.001
bimatoprost (glaucoma)	107.566	<.001
tafluprost (glaucoma)	117.086	<.001
latanoprostene bunod (glaucoma)	34.665	<.001
netarsudil (glaucoma)	42.1577	<.001

[a] Pearson's coefficient calculated as the difference between trial composition and the expected composition based on published prevalence (Stein et al. 2011, Vanderbeek et al. 2011) and US Census data

eFigure 1: Enrollment Incidence Disparity (EID) and Enrollment Incidence Ratio (EIR) for each pharmaceutical agent relative to expected NEI prevalence rates.





eFigure 2: Enrollment Incidence Disparity (EID) and Enrollment Incidence Ratio (EIR) for each pharmaceutical agent relative to expected prevalence from Stein et al. 2011, Vanderbeek et al. 2011, and US Census data