DOR-TDF-3TC vs. EFV-TDF-FTC as Initial Therapy

DRIVE AHEAD

National HIV Curriculum

Doravirine-TDF-3TC versus Efavirenz-TDF-FTC as Initial Therapy
DRIVE AHEAD: Design

- **Design**
  - Randomized, double-blind, phase 3 study comparing fixed dose doravirine-tenofovir DF-lamivudine with fixed dose efavirenz-tenofovir DF-emtricitabine as initial antiretroviral therapy
- **Inclusion Criteria**
  - Antiretroviral-naïve
  - Age ≥18 years
  - HIV RNA ≥1,000 copies/mL
  - No resistance to any study drug
- **Regimens**
  - Doravirine-TDF-3TC (100/300/300 mg) daily
  - Efavirenz-TDF-FTC (600/300/200 mg) daily

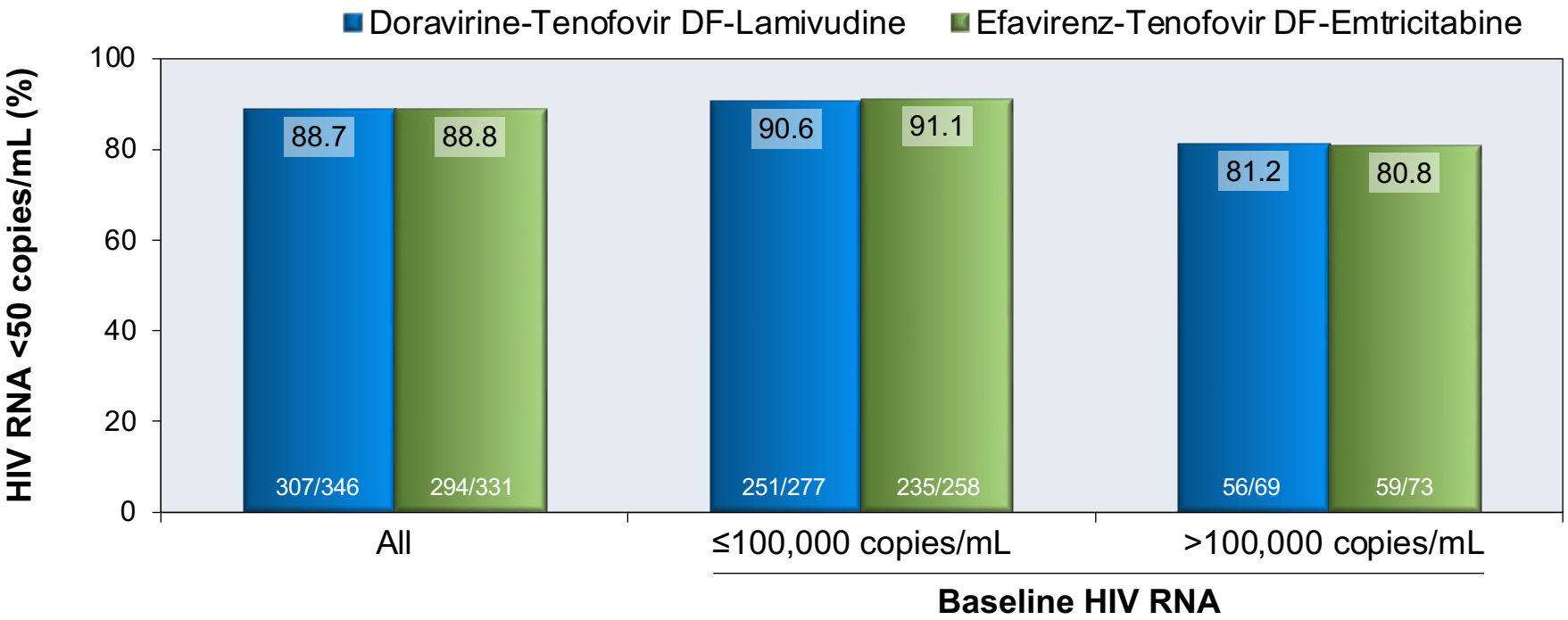
Doravirine-TDF-3TC
(n = 364)

Efavirenz-TDF-FTC
(n = 364)

Source: Orkin C, et al. Clin Infect Dis. 2019;68:535-44.

Doravirine-TDF-3TC versus Efavirenz-TDF-FTC as Initial Therapy
DRIVE AHEAD: 48 Week Results

Week 48 Virologic Response (Observed Failure)



Source: Orkin C, et al. Clin Infect Dis. 2019;68:535-44.

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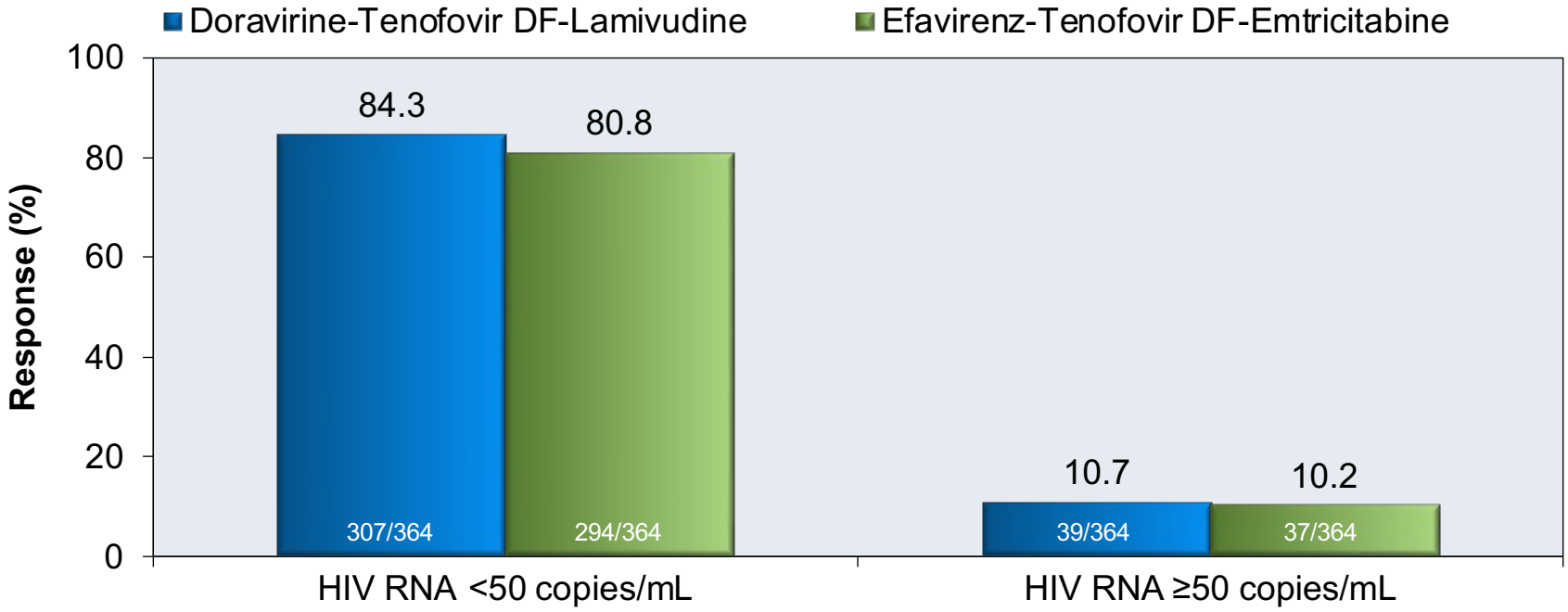
Doravirine-TDF-3TC versus Efavirenz-TDF-FTC as Initial Therapy
DRIVE AHEAD: Results

Week 48 Virologic Response (FDA Snapshot: All missing data = Failure)



Source: Orkin C, et al. Clin Infect Dis. 2019:68:535-44.

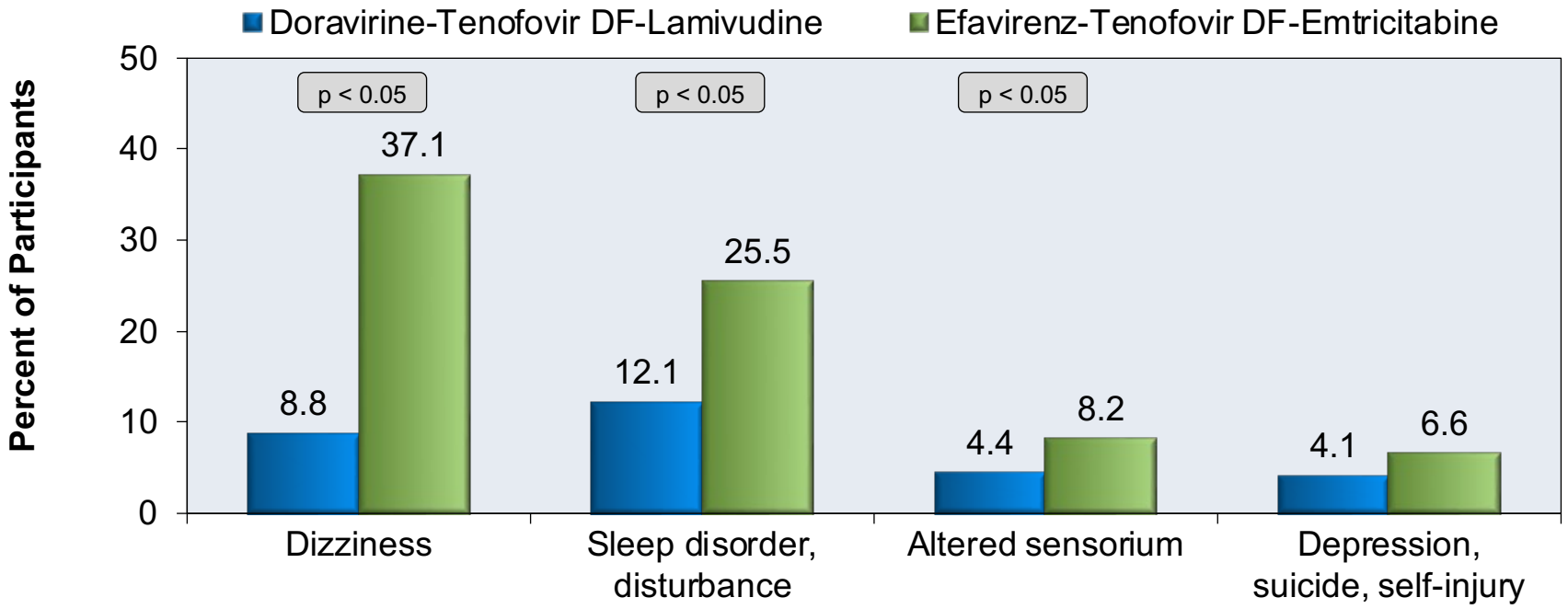
Doravirine-TDF-3TC versus Efavirenz-TDF-FTC as Initial Therapy
DRIVE AHEAD: Adverse Effects

Treatment Emergent Adverse Events in DRIVE AHEAD Through Week 48		
Adverse Effects	**DOR/TDF/3TC** (n = 364)	**EFV/TDF/FTC** (n = 364)
Drug-related AE's, %	31	63
Discontinued due to drug-related AE, %	3	7
Headache, %	13	12
Diarrhea, %	11	13
Nausea, %	8	11
Vomiting, %	4	7
Abnormal Dreams, %	5	12
Rash, %	5	12

Source: Orkin C, et al. Clin Infect Dis. 2019:68:535-44.

Doravirine-TDF-3TC versus Efavirenz-TDF-FTC as Initial Therapy
DRIVE AHEAD: Adverse Effects

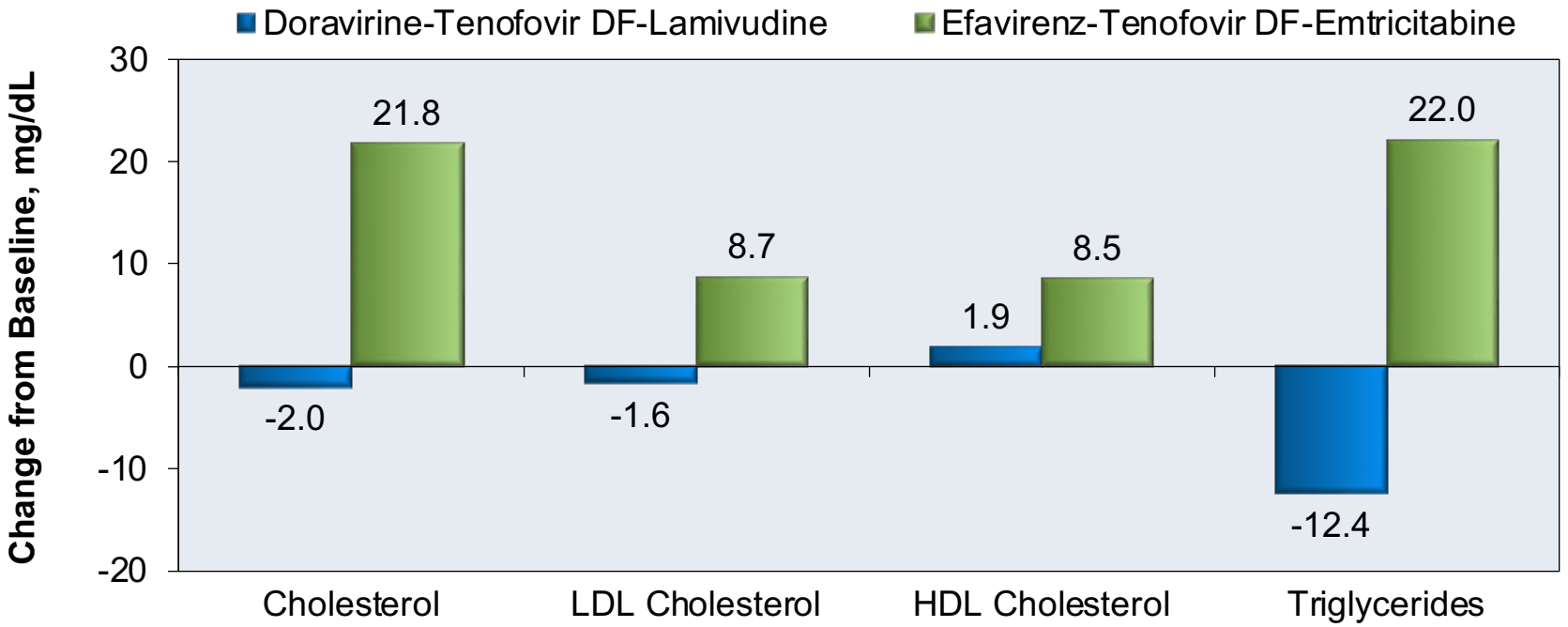
Proportion with Pre-Defined Neuropsychiatric Side Effects at Week 48



Source: Orkin C, et al. Clin Infect Dis. 2019:68:535-44.

Doravirine-TDF-3TC versus Efavirenz-TDF-FTC as Initial Therapy
DRIVE AHEAD: Adverse Effects

Change in Baseline Fasting Lipids at Week 48



Source: Orkin C, et al. Clin Infect Dis. 2019:68:535-44.

National HIV Curriculum

DOR-TDF-3TC vs. EFV-TDF-FTC as Initial Therapy
DRIVE AHEAD: Summary

Conclusions: “In HIV-1 treatment-naive adults, doravirine/lamivudine/tenofovir DF demonstrated non-inferior efficacy to efavirenz/emtricitabine/tenofovir DF at week 48 and was well tolerated, with significantly fewer neuropsychiatric events and minimal changes in LDL-C and non-HDL-C compared with efavirenz/emtricitabine/tenofovir DF.”

Source: Orkin C, et al. Clin Infect Dis. 2019:68:535-44.

Acknowledgments

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AETC AIDS Education & Training Center Program

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