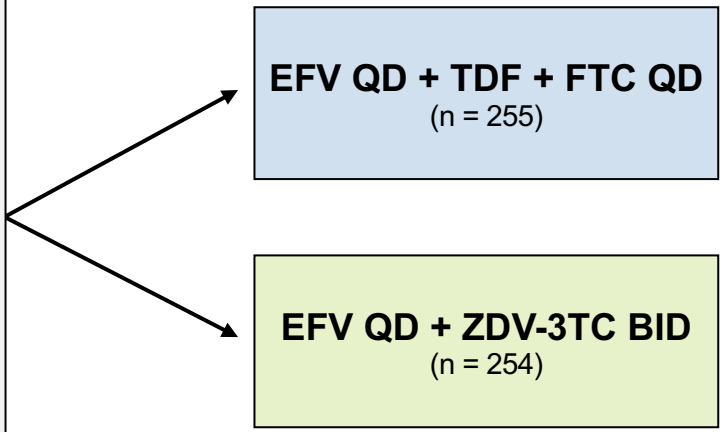
EFV + TDF + FTC versus EFV + ZDV-3TC

Study 934

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC
Study 934: Study Design

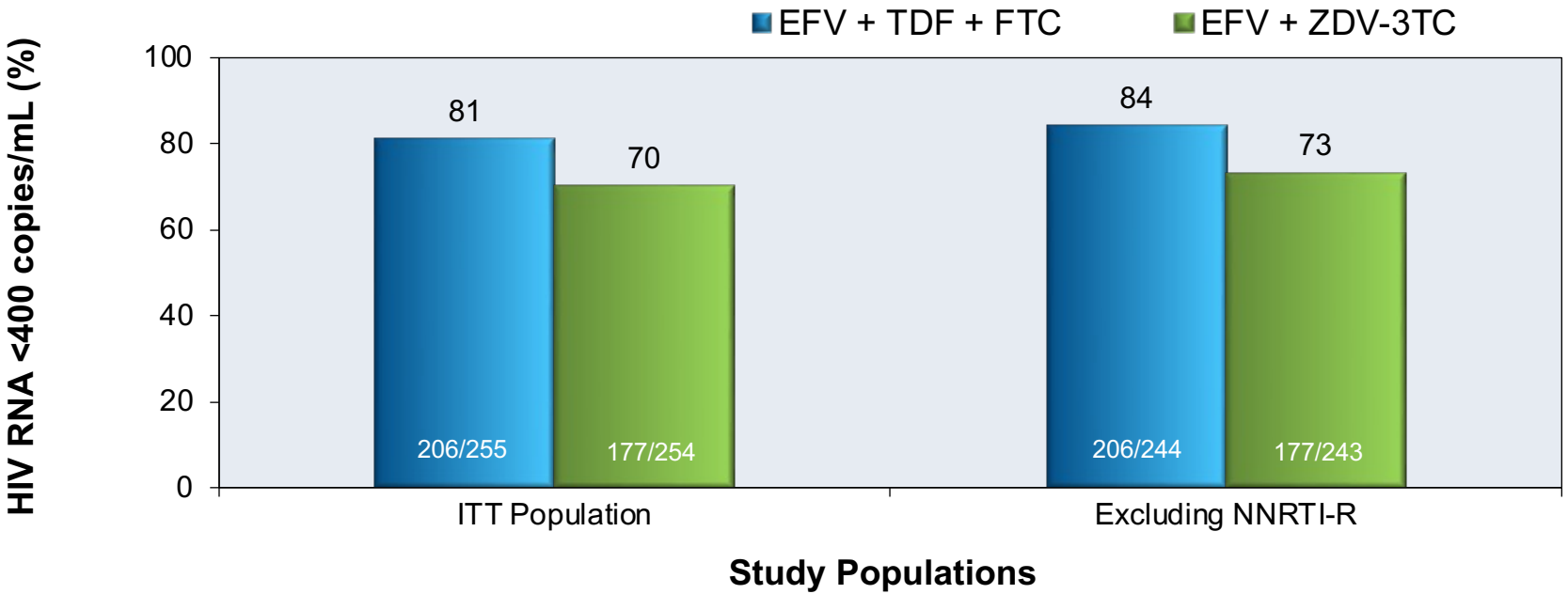
- **Background**: Randomized, open label phase 3 study comparing efavirenz plus either tenofovir DF and emtricitabine or fixed-dose zidovudine-lamivudine
- **Inclusion Criteria (n = 509)**
  - Antiretroviral-naïve adults
  - Age ≥18 years
  - HIV RNA ≥10,000 copies/mL
  - CD4 >50 cells/mm^3
  - No AIDS conditions in prior 30 days
- **Treatment Arms**
  - Efavirenz + tenofovir DF + emtricitabine
  - Efavirenz + zidovudine-lamivudine



Source: Gallant JE, et al. N Engl J Med. 2006;354:251-60.

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC Study 934: Results

Week 48: Virologic Response (<400 copies/mL)

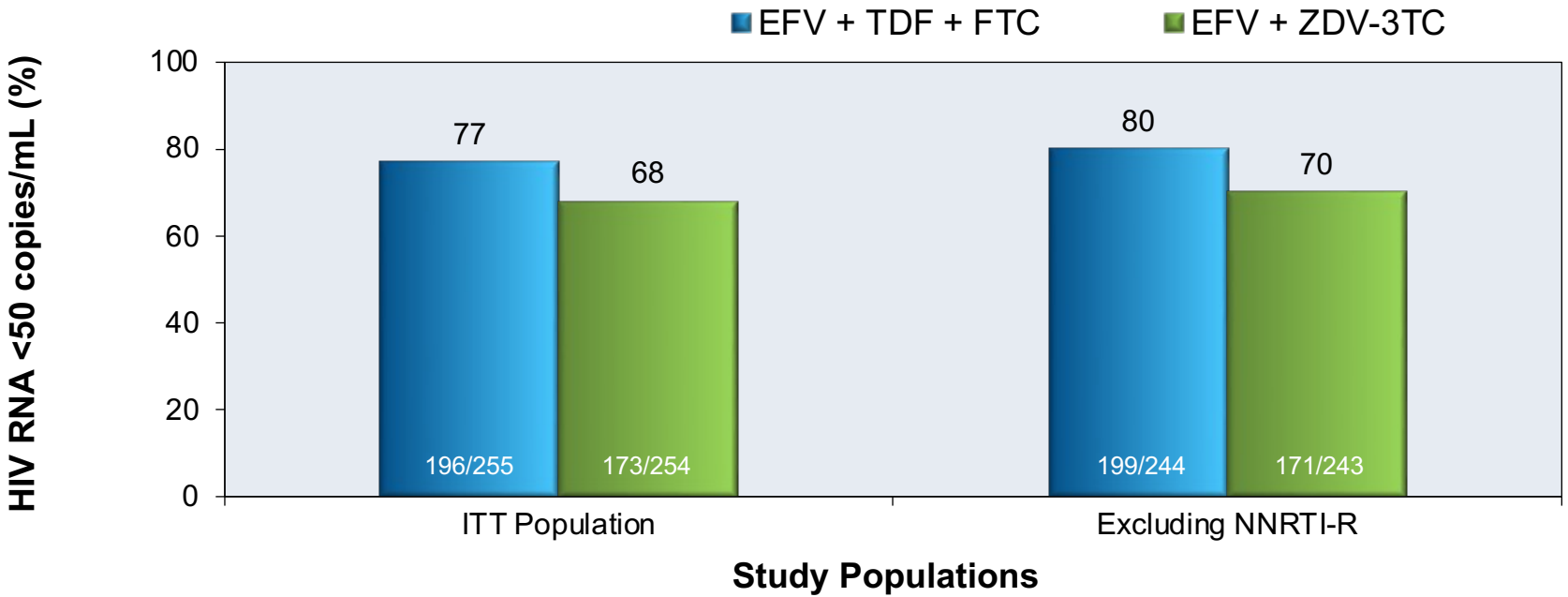


Abbreviations: ITT = Intention-to-Treat; NNRTI-R = Patients with baseline NNRTI mutations.

Source: Gallant JE, et al. N Engl J Med. 2006;354:251-60.

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC
Study 934: Results

Week 48: Virologic Response (<50 copies/mL)



Abbreviations: ITT = Intention-to-Treat; NNRTI-R = Patients with baseline NNRTI resistance mutations.

Source: Gallant JE, et al. N Engl J Med. 2006;354:251-60.

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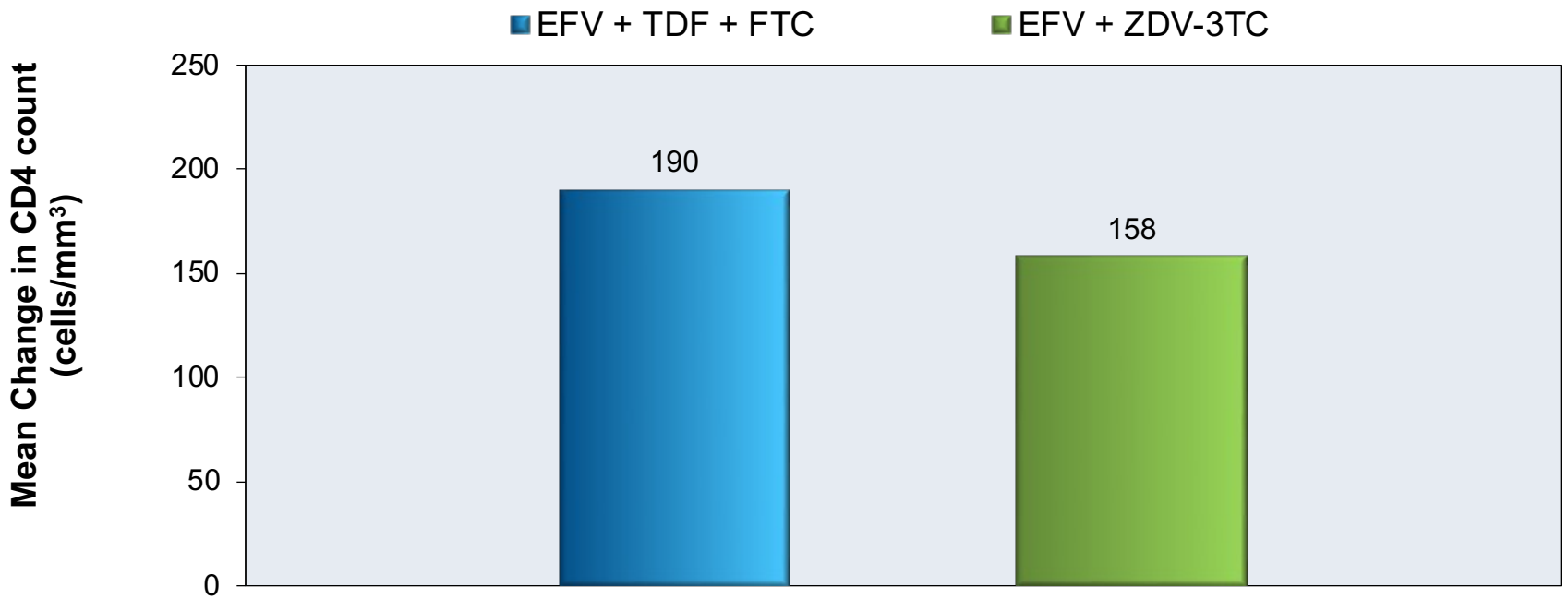
Study 934: Results

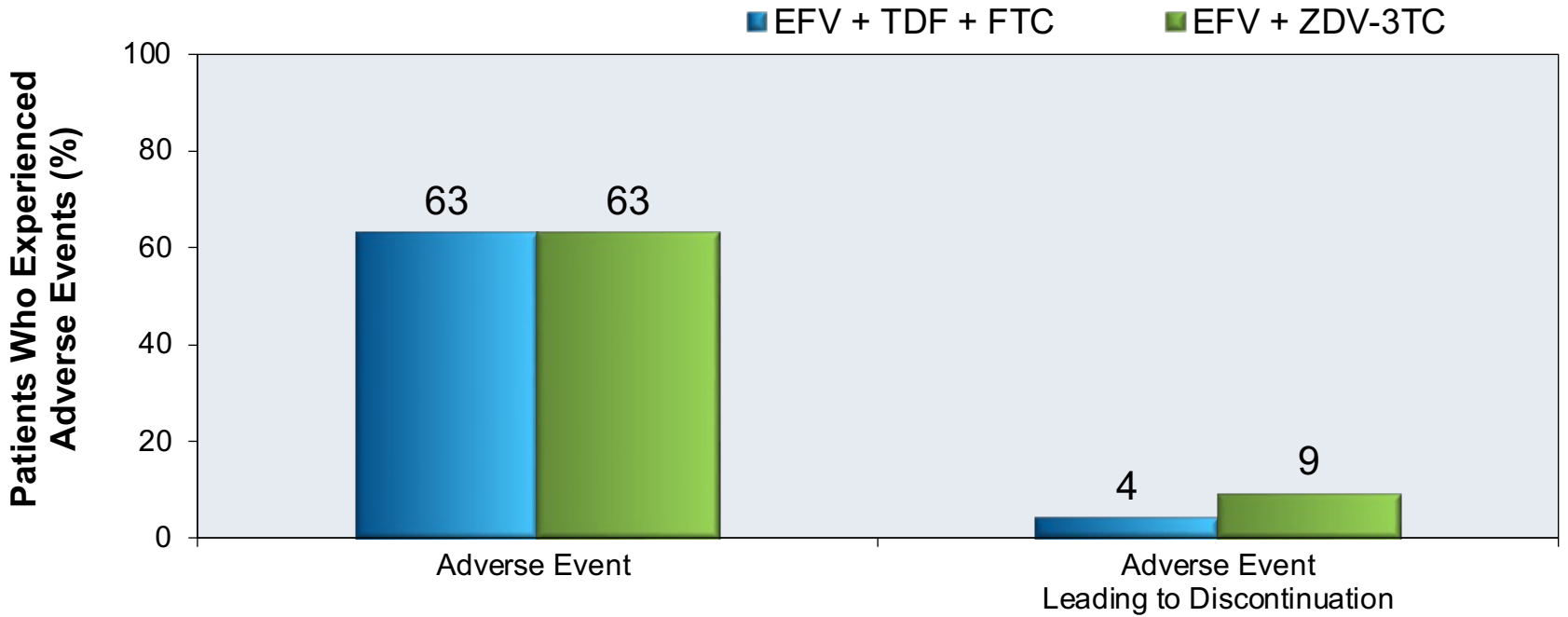
Week 48: Immunologic Response



Source: Gallant JE, et al. N Engl J Med. 2006;354:251-60.

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC Study 934: Results

Adverse Events Through 48 Weeks



Source: Gallant JE, et al. N Engl J Med. 2006;354:251-60.

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC
Study 934: Common Adverse Events

Treatment Emergent Adverse Events in ≥ 5% of Subjects in Either Arm		
	EFV + TDF + FTC (n = 257)	**EFV + ZVD-3TC** (n= 254)
Dizziness	8%	7%
Nausea	8%	6%
Diarrhea	7%	4%
Fatigue	7%	6%
Depression	4%	7%
Headache	5%	4%
Rash	5%	4%
Insomnia	4%	5%
Anemia	<1%	5%

Source: Gallant JE, et al. N Engl J Med. 2006;354:251-60

TDF+ FTC + Efavirenz versus ZDV-3TC+ Efavirenz
Study 934: Conclusions

Interpretation: “Through week 48, the combination of tenofovir DF and emtricitabine plus efavirenz fulfilled the criteria for noninferiority to a fixed dose of zidovudine and lamivudine plus efavirenz and proved superior in terms of virologic suppression, CD4 response, and adverse events resulting in discontinuation of the study drugs.”

Source: Gallant JE, et al. N Engl J Med. 2006;354:251-60.

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AETC AIDS Education & Training Center Program

National HIV Curriculum

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