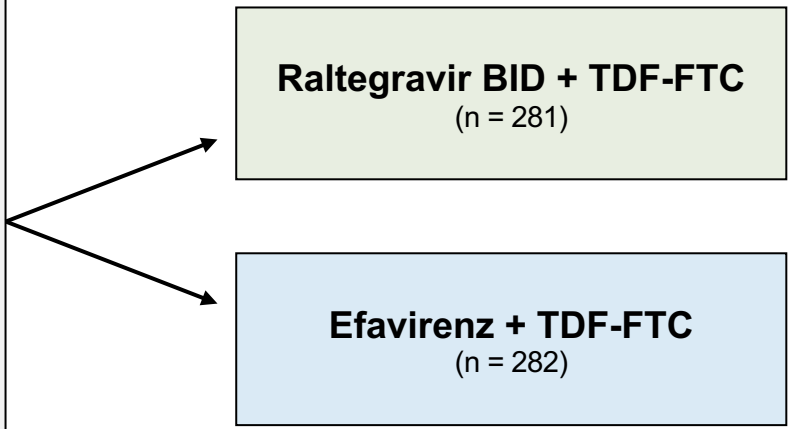
Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC

STARTMRK Trial

Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC
STARTMRK: Study Design

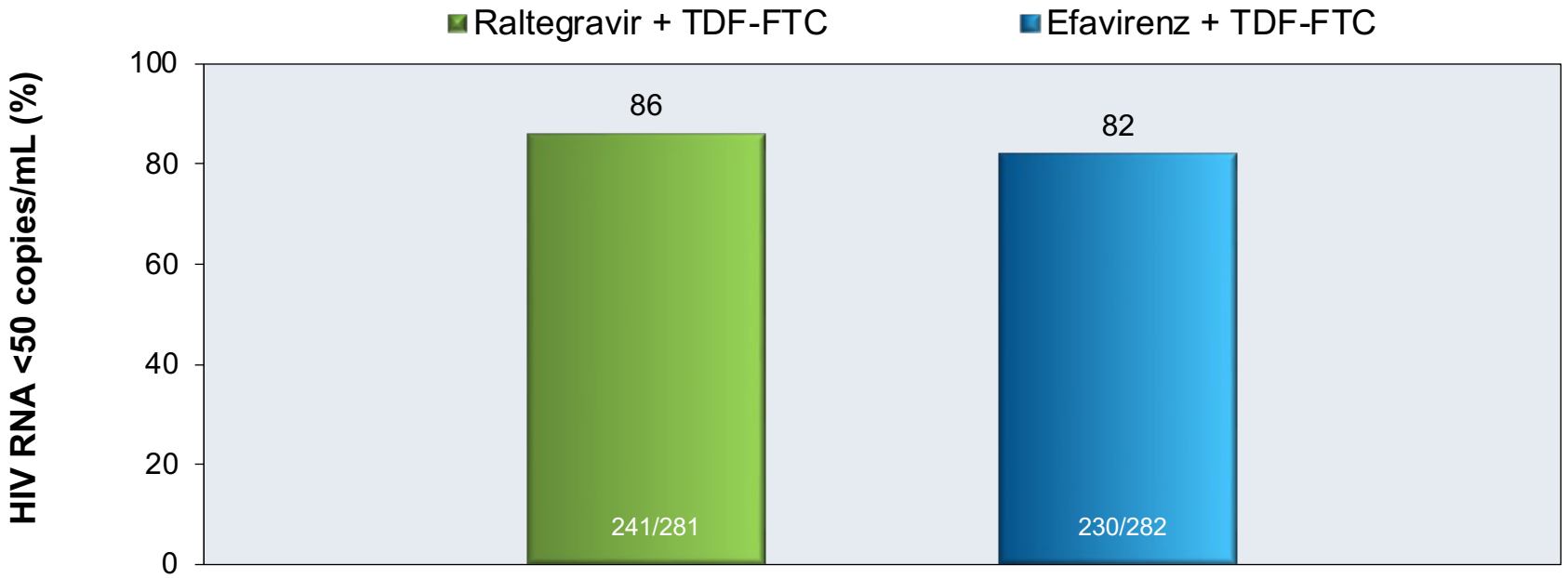
- **Background:** Randomized, double-blind, phase 3 study comparing the safety and efficacy of raltegravir versus efavirenz, each in combination with tenofovir DF and emtricitabine
- **Inclusion Criteria (n = 569)**
  - Antiretroviral-naïve patients
  - Age ≥18 years
  - HIV RNA ≥5000 copies/mL
  - No resistance to EFV, TDF, or FTC
- **Treatment Arms**
  - Raltegravir + TDF-FTC
  - Efavirenz + TDF-FTC



Source: Lennox JL, et al. Lancet. 2009;374:796-806.

Raltegravir + TDF-FTC versus Efavirenz + TDF- FTC
STARTMRK: Results

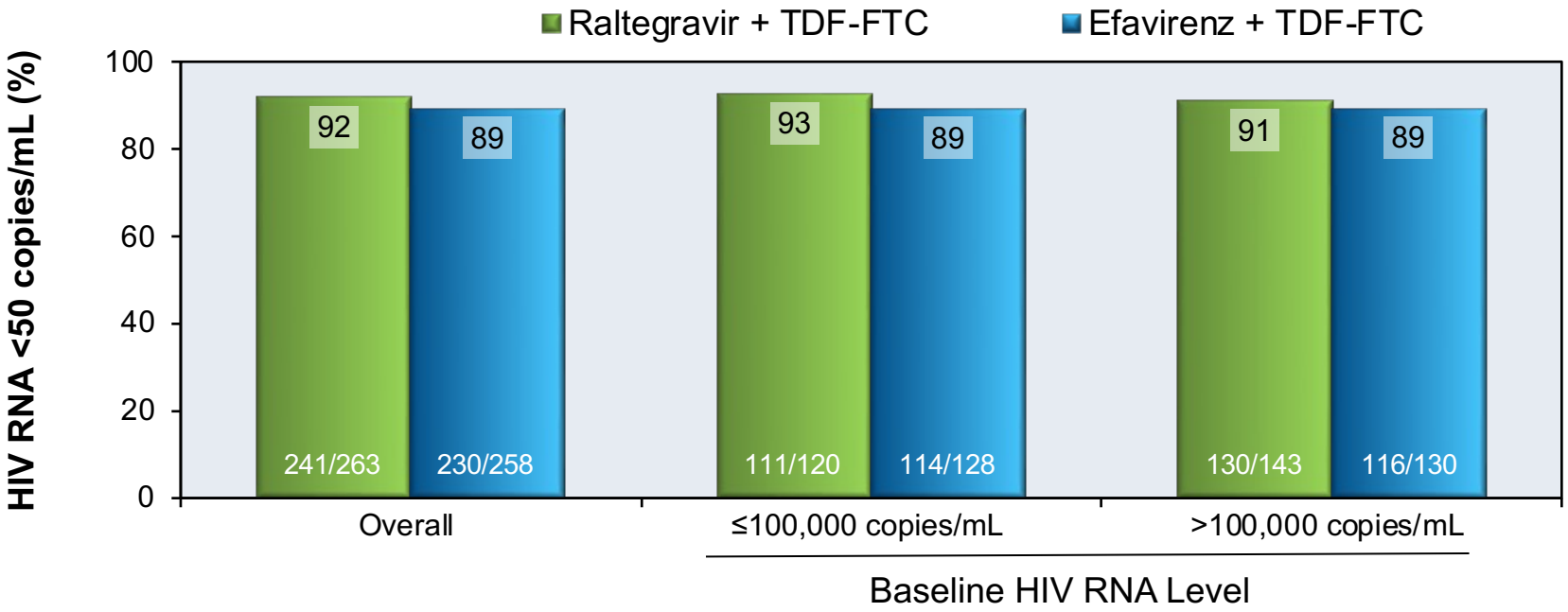
Week 48: Virologic Response (Primary Analysis, Missing=Failure)



Source: Lennox JL, et al. Lancet. 2009;374:796-806.

Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC
STARTMRK: Results

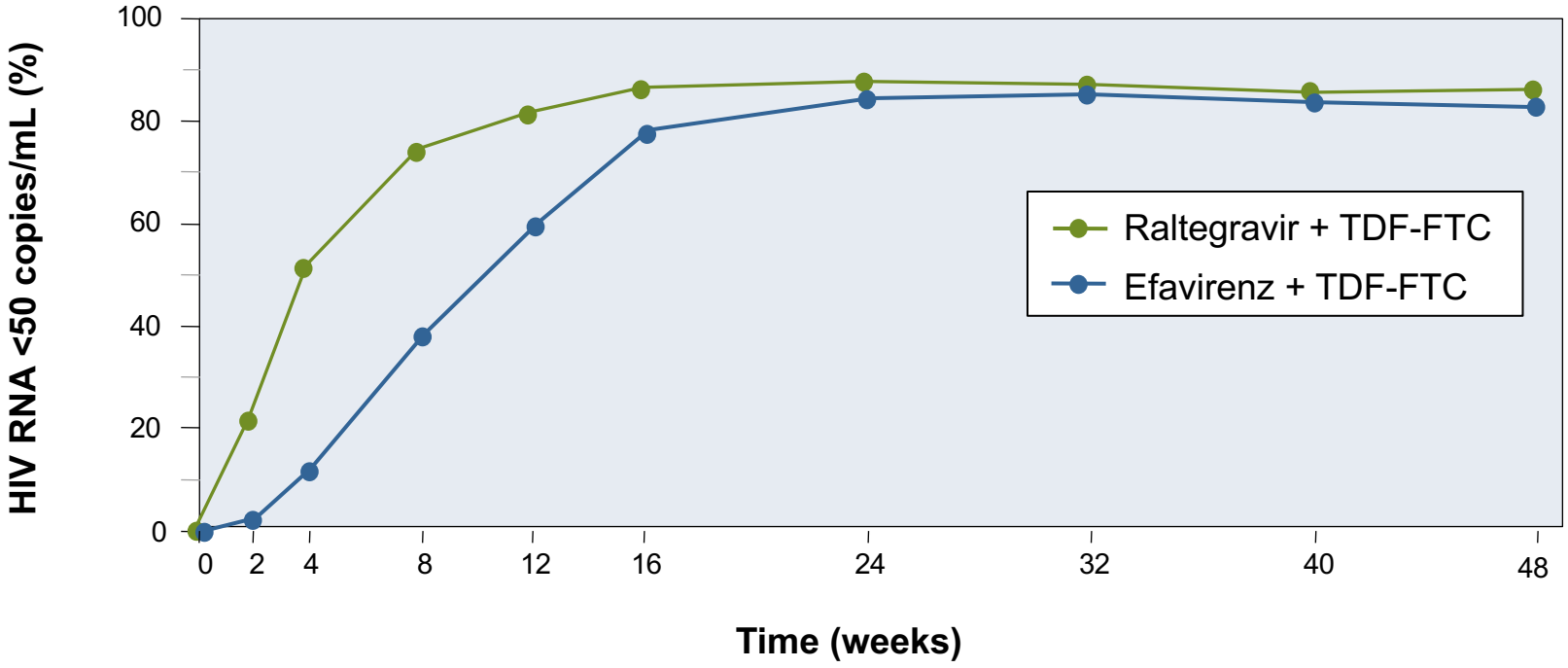
Week 48 Virologic Response (Observed-Failure Method)



Source: Lennox JL, et al. Lancet. 2009;374:796-806.

Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC
STARTMRK: Results

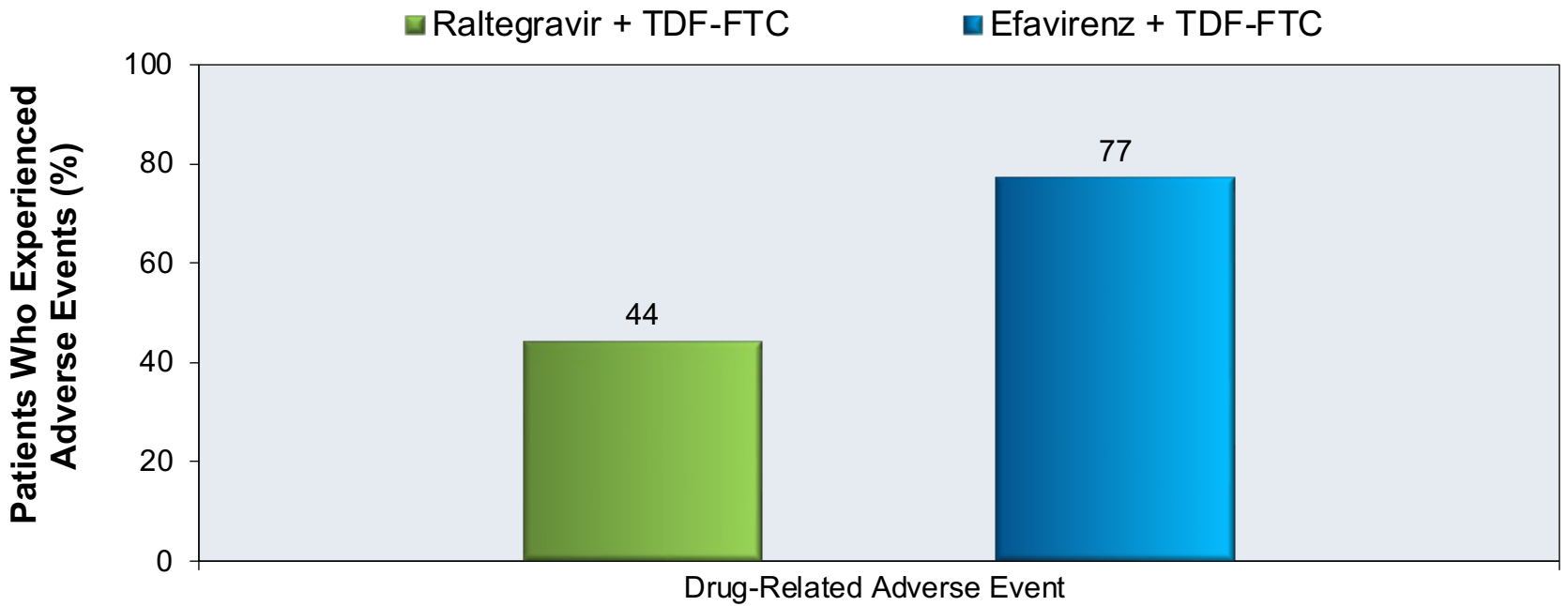
Week 48 Virologic Response



Source: Lennox JL, et al. Lancet. 2009;374:796-806.

Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC
STARTMRK: Results

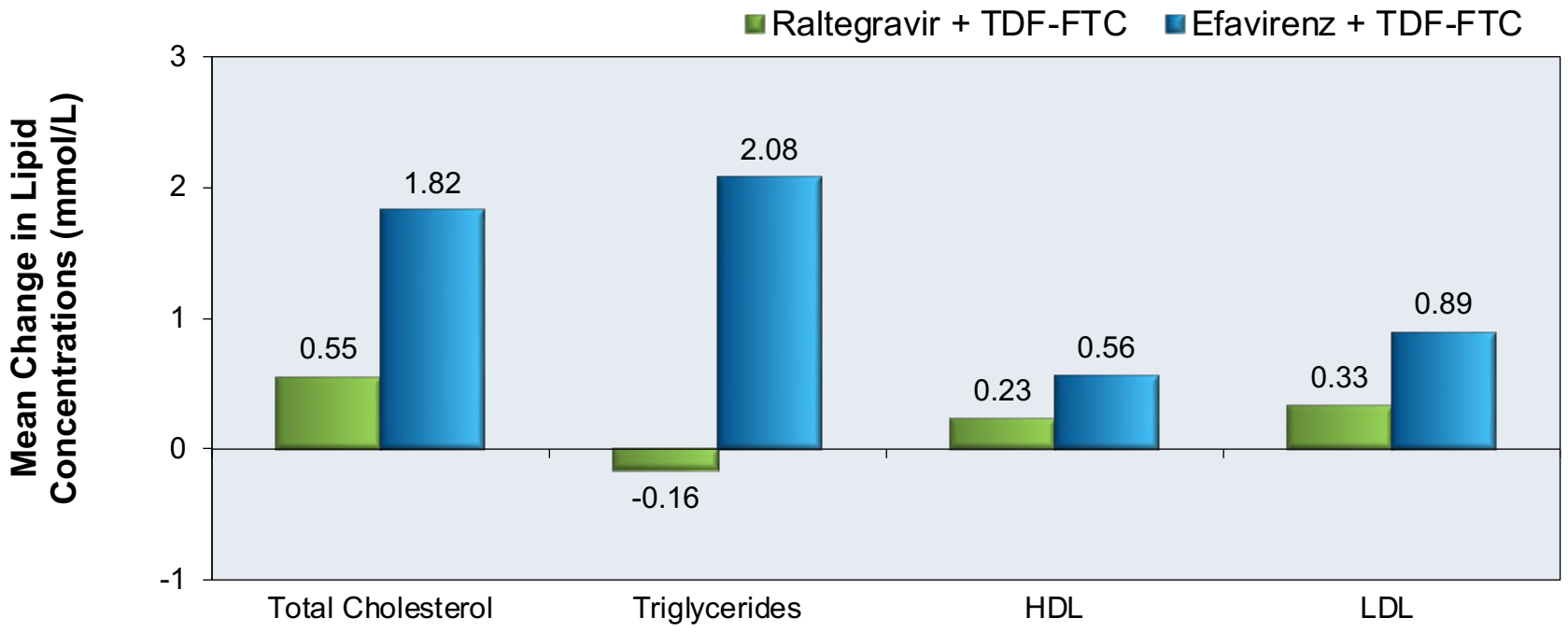
Adverse Events through 48 Weeks



Source: Lennox JL, et al. Lancet. 2009;374:796-806.

Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC
STARTMRK: Results

Week 48: Changes in Lipid Concentrations from Baseline



Source: Lennox JL, et al. Lancet. 2009;374:796-806.

Raltegravir + TDF-FTC versus Efavirenz + TDF-FTC
STARTMRK: Common Adverse Events

Treatment Emergent Adverse Events in >10% of Subjects in Either Arm		
	RAL + TDF-FTC (n = 281)	**EFV + TDF-FTC** (n= 282)
Dizziness	6%	34%
Headache	9%	14%
Abnormal dreams	7%	13%
Immune Reconstitution Inflammatory Syndrome	6%	4%

Source: Lennox JL, et al. Lancet. 2009;374:796-806.

Raltegravir + TDF-FTC vs. Efavirenz + TDF-FTC
STARTMRK: Conclusions

Interpretation: “Raltegravir-based combination treatment had rapid and potent antiretroviral activity, which was non-inferior to that of efavirenz at week 48. Raltegravir is a well tolerated alternative to efavirenz as part of a combination regimen against HIV-1 in treatment-naive patients.”

Source: Lennox JL, et al. Lancet. 2009;374:796-806.

Acknowledgments

The **National HIV Curriculum** is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,021,448 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

AETC AIDS Education & Training Center Program

National HIV Curriculum

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