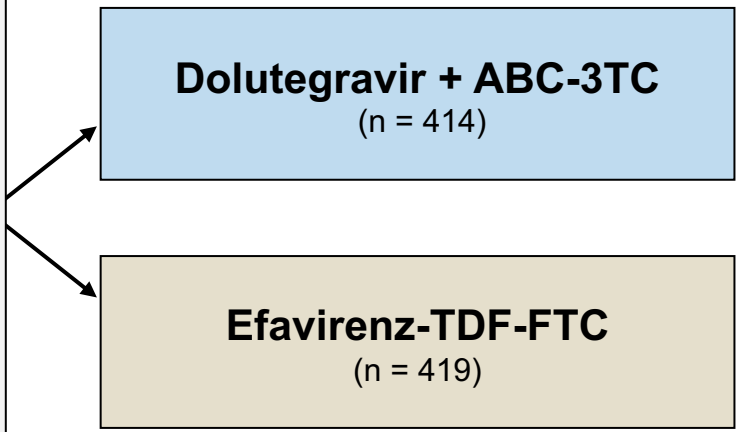
Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC

# SINGLE Study

# Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC SINGLE Study: Design

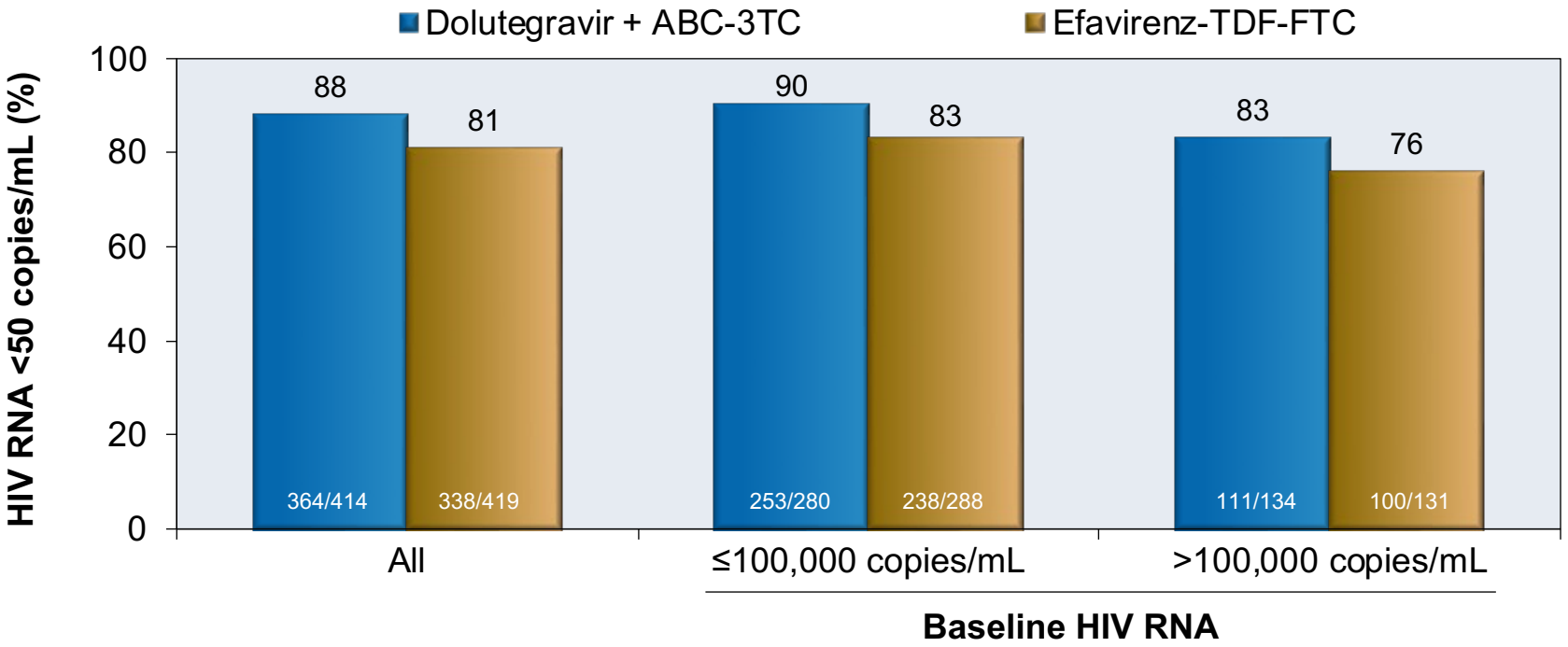
- **Background**:
  - Randomized, double-blind study, phase 3 trial comparing dolutegravir + abacavir-lamivudine with efavirenz-tenofovir DF-emtricitabine
- **Inclusion Criteria (n = 833)**
  - Antiretroviral-naïve adults
  - Age ≥18 years
  - HIV RNA ≥1,000 copies/mL
  - No active CDC AIDS-defining condition
- **Treatment Arms**
  - Dolutegravir (QD) + Abacavir-Lamivudine
  - Efavirenz-Tenofovir DF-Emtricitabine




Source: Walmsley SL, et al. N Engl J Med. 2013;369;1807-18.

# Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC SINGLE Study: Results

## Week 48 Virologic Response (Intention-to-Treat Analysis)

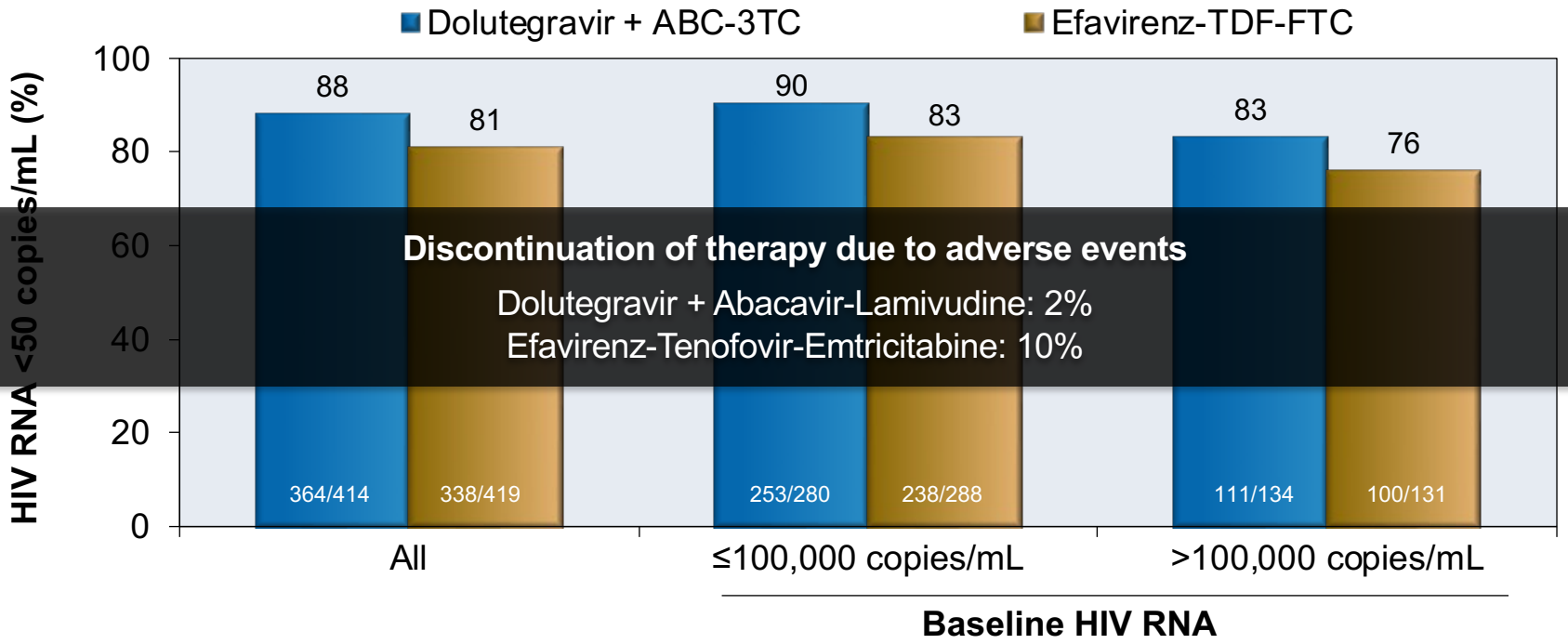



Source: Walmsley SL, et al. N Engl J Med. 2013;369;1807-18.

National HIV Curriculum

# Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC SINGLE Study: Results

## Week 48 Virologic Response (Intention-to-Treat Analysis)



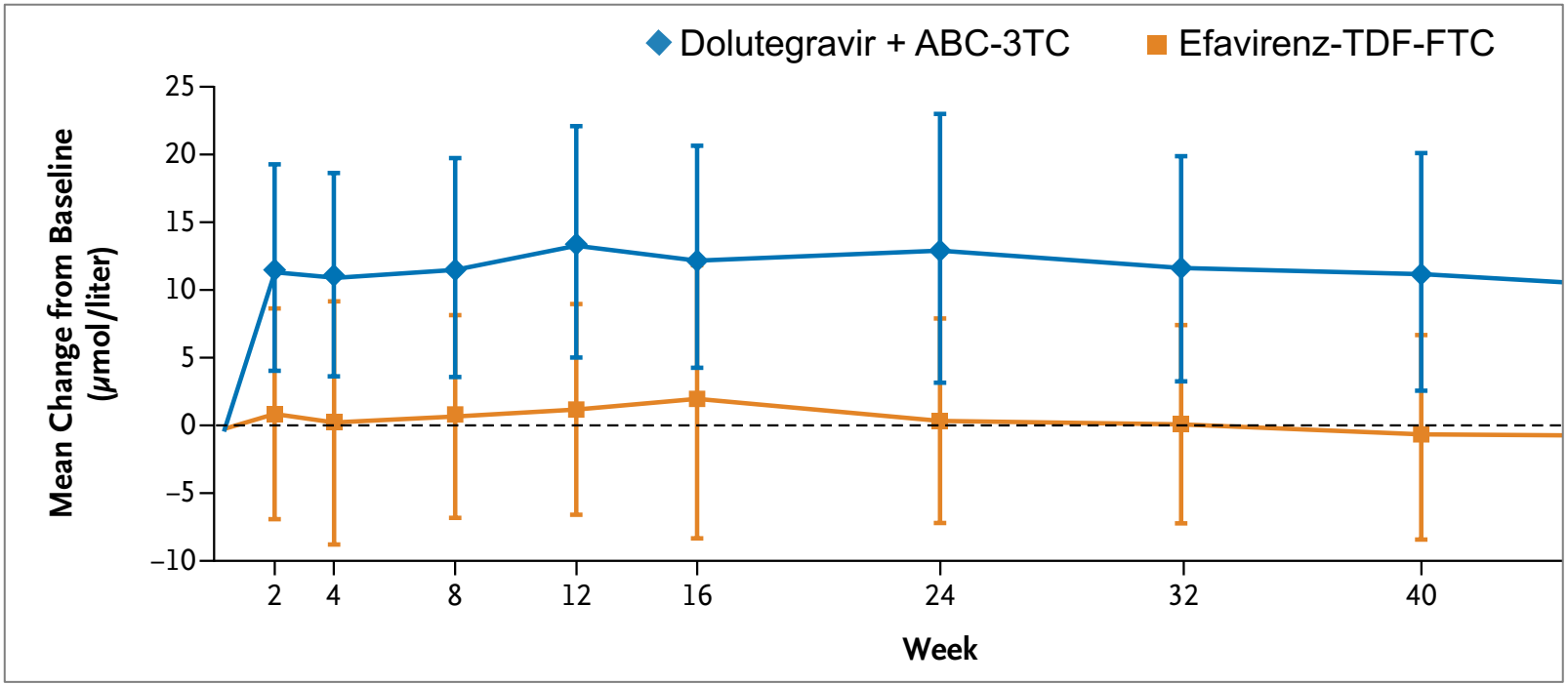

**Discontinuation of therapy due to adverse events**

Dolutegravir + Abacavir-Lamivudine: 2%
Efavirenz-Tenofovir-Emtricitabine: 10%

Source: Walmsley SL, et al. N Engl J Med. 2013;369;1807-18.

# Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC SINGLE Study: Results

## Mean Change from Baseline in Serum Creatinine Levels




Source: Walmsley SL, et al. N Engl J Med. 2013;369;1807-18.



National HIV Curriculum

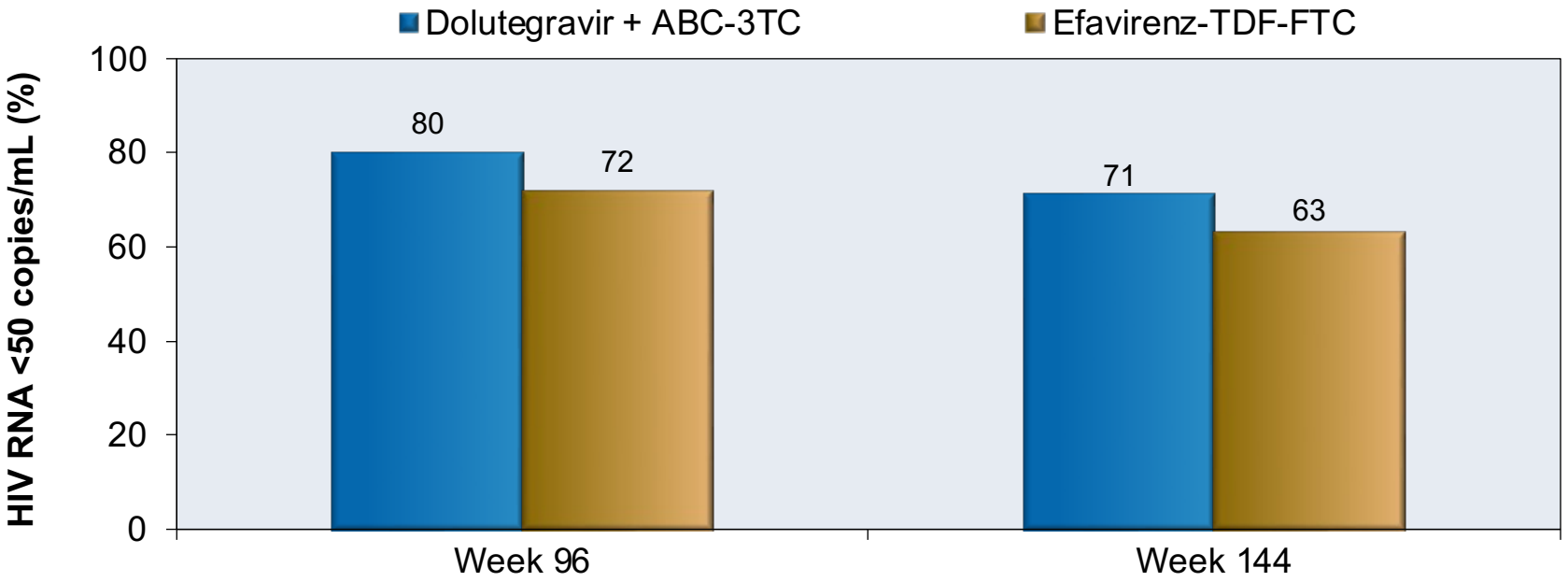
# Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC SINGLE Study: Conclusions

Conclusions: “Dolutegravir plus abacavir-lamivudine had a better safety profile and was more effective through 48 weeks than the regimen with efavirenz-tenofovir DF-emtricitabine.”

Source: Walmsley SL, et al. N Engl J Med. 2013;369;1807-18.

# Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC SINGLE Study: Results

## Week 96 and Week 144 Virologic Response (Intention-to-Treat Analysis)




Source: Walmsley SL, et al. J Acquir Immune Defic Syndr. 2015;70:515-19.

# Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC SINGLE Study: Results

| Treatment Emergent Adverse Events (AEs >5%) | DTG-ABC-3TC (n = 414) | | EFV-TDF-FTC (n = 419) | |
|---|---|---|---|---|
| | Week 96 | Week 144 | Week 96 | Week 144 |
| Any, % | 44 | +1 | 67 | +1.2 |
| Dizziness, % | 7 | +0 | 33 | +0.2 |
| Abnormal dreams, % | 7 | +0 | 16 | +0.2 |
| Nausea, % | 11 | +0.2 | 12 | +0 |
| Insomnia, % | 10 | +0 | 6 | +0.7 |
| Diarrhea, % | 6 | +0 | 8 | +0 |
| Fatigue, % | 7 | +0 | 7 | +0 |
| Headache, % | 6 | +0 | 7 | +0 |
| Rash, % | <1 | +0 | 8 | +0 |

Source: Walmsley SL, et al. J Acquir Immune Defic Syndr. 2015;70:515-19.

# 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

IDEA INFECTIOUS DISEASES EDUCATION & ASSESSMENT