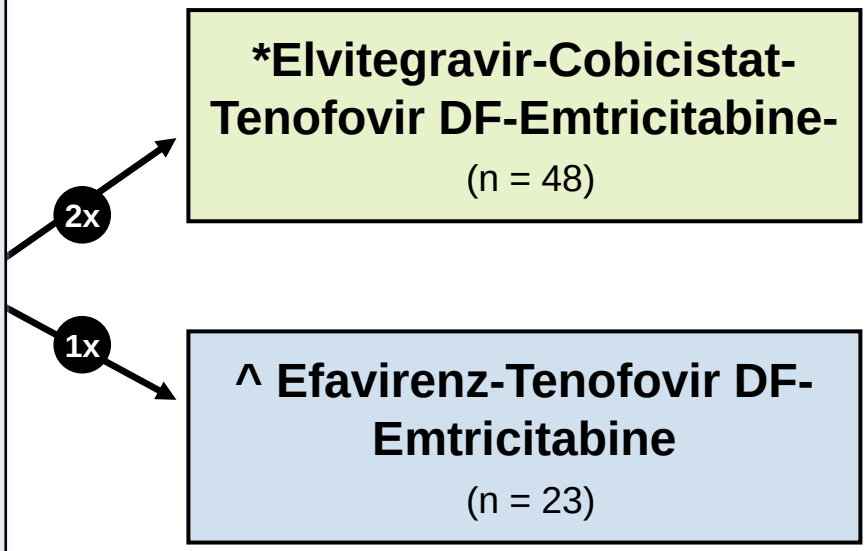
Elvitegravir in “Quad Pill” versus *Atripla*

Study 104

Elvitegravir-Cobicistat versus Efavirenz
Study 104: Design

Study Design: Study 104

- **Background**: Double-blind, double-dummy, randomized, phase 2a trial comparing EVG-COBI-TDF-FTC versus EFV-TDF-FTC
- **Inclusion Criteria (n = 71)**
  - Age ≥18 years
  - Antiretroviral naive
  - No baseline NRTI, NNRTI, or PI mutations
  - HIV RNA ≥5,000 copies/mL
  - CD4 >50 cells/mm^3
  - No AIDS condition in previous 30 days
  - eGFR ≥80 mL/min



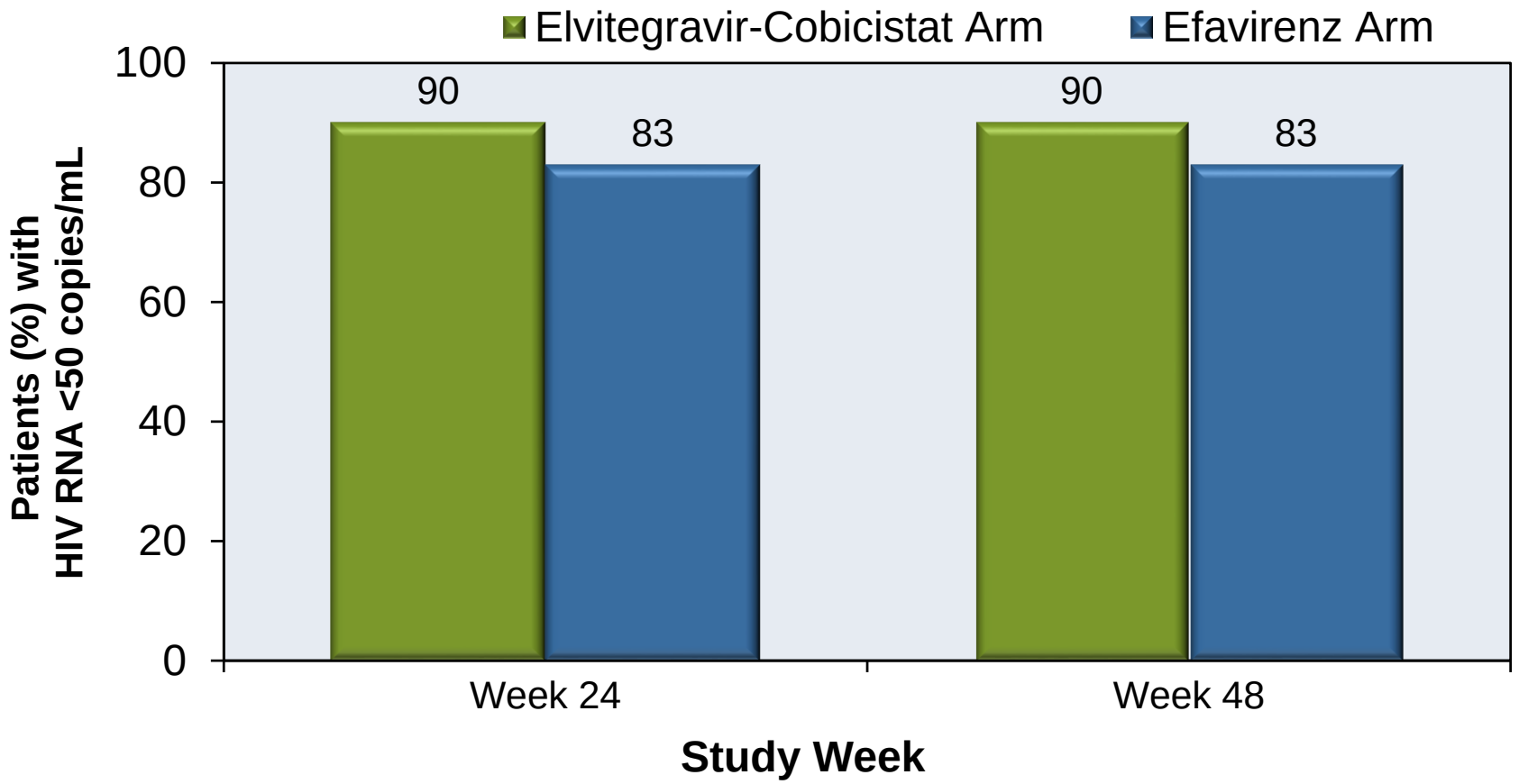
*Dosing: Tenofovir (300 mg); Emtricitabine (200 mg); Elvitegravir (150 mg); Cobicistat (150 mg)

^Dosing: Tenofovir (300 mg); Emtricitabine (200 mg); Efavirenz (600 mg)

Source: Cohen C, et al. AIDS. 2011;25:F7-12.

Elvitegravir-Cobicistat versus Efavirenz
Study 104: Results

Week 24 and 48: Virologic Response (ITT-TLOVR*)

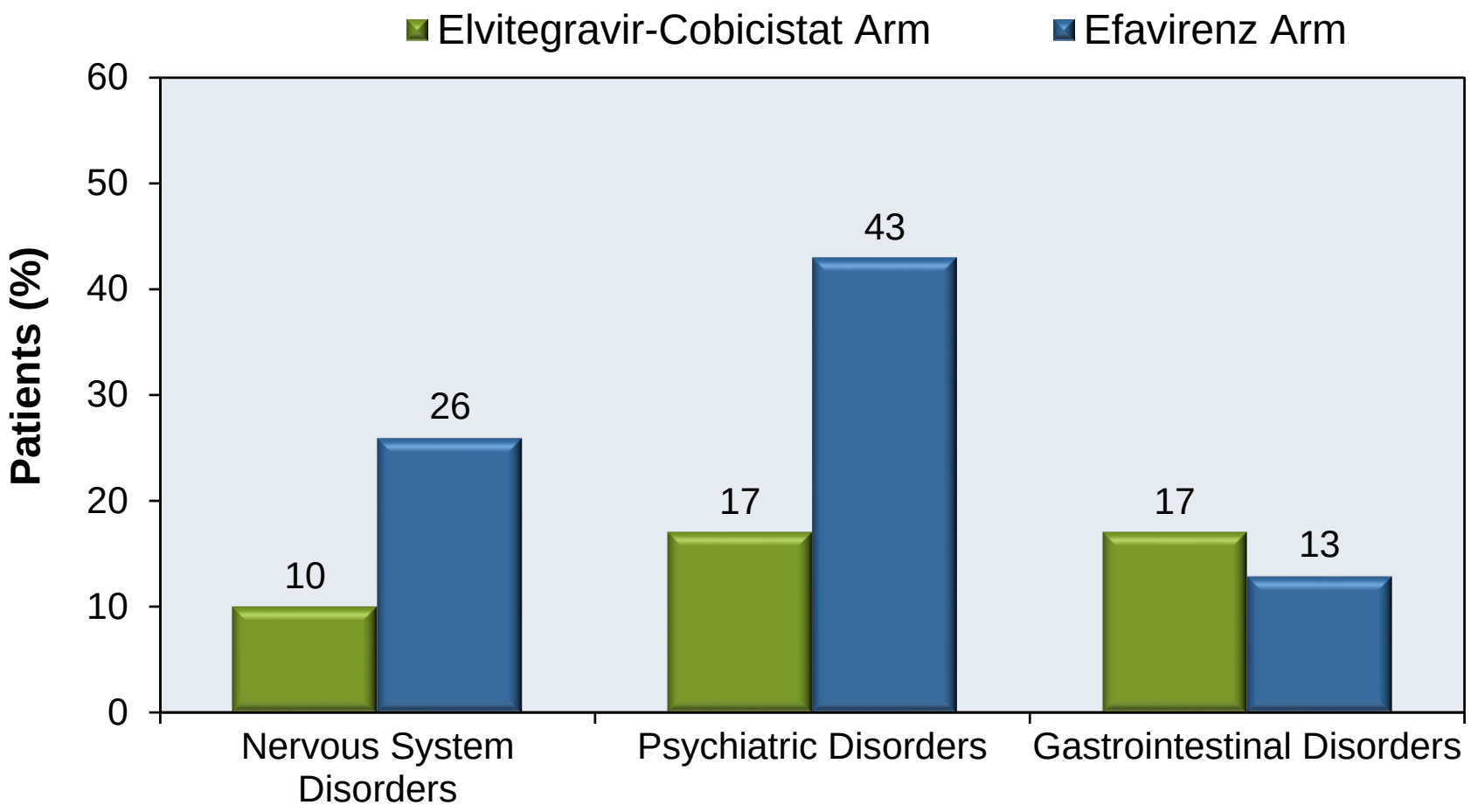


*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response

Source: Cohen C, et al. AIDS. 2011;25:F7-12.

"Quad" Pill versus *Atripla*
Adverse Effects

Drug-Related, Treatment-Emergent Adverse Effects

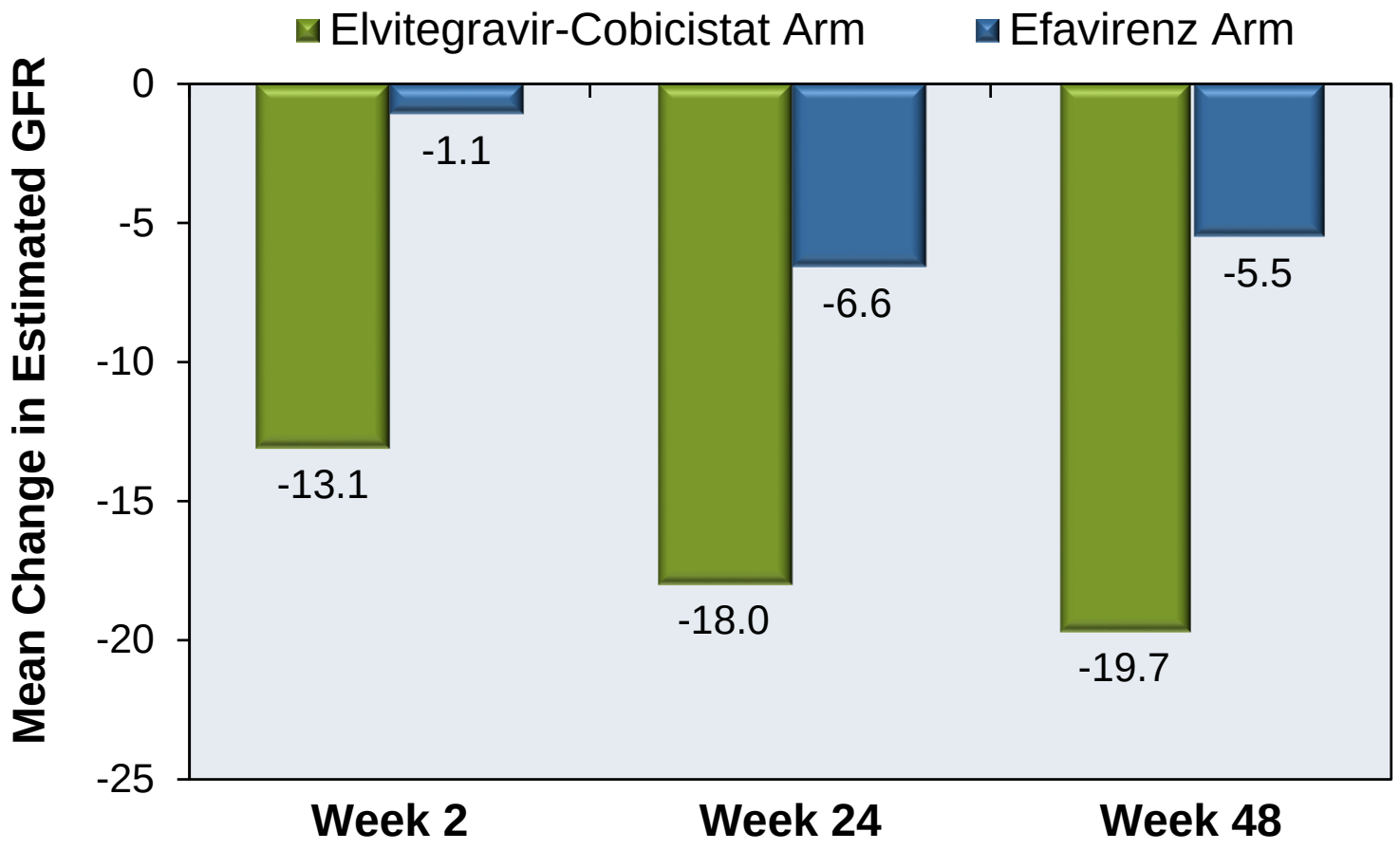


Source: Cohen C, et al. AIDS. 2011;25:F7-12.

National HIV Curriculum

"Quad" Pill versus *Atripla*
Adverse Effects

Change in Estimated Glomerular Filtration Rate (Cockcroft-Gault)



Source: Cohen C, et al. AIDS. 2011;25:F7-12.

Elvitegravir-Cobicistat versus Efavirenz
Study: Conclusions

Conclusions: “Once-daily elvitegravir/cobicistat/emtricitabine/tenofovir (EVG/COBI/FTC/TDF) achieved and maintained a high rate of virologic suppression with fewer central nervous system and psychiatric adverse events compared to a current standard-of-care regimen of efavirenz/emtricitabine/tenofovir (EFV/FTC/TDF).”

Source: Cohen C, et al. AIDS. 2011;25:F7-12.

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

The content in this presentation 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.

National HIV Curriculum

AETC AIDS Education & Training Center Program