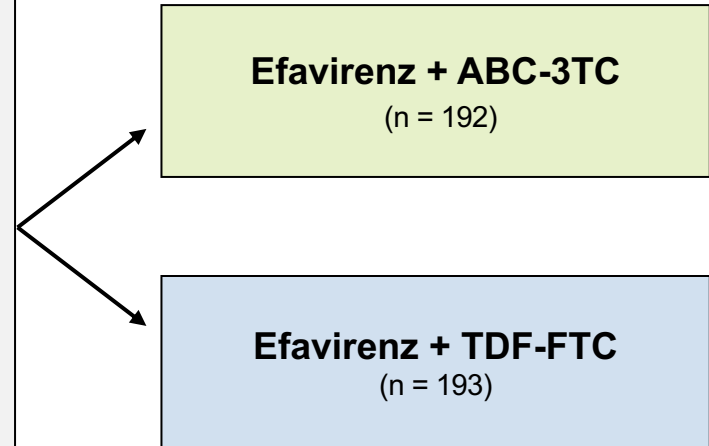


EFV + ABC-3TC versus EFV + TDF-FTC  
**ASSERT Trial**

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

## ASSERT: Study Design

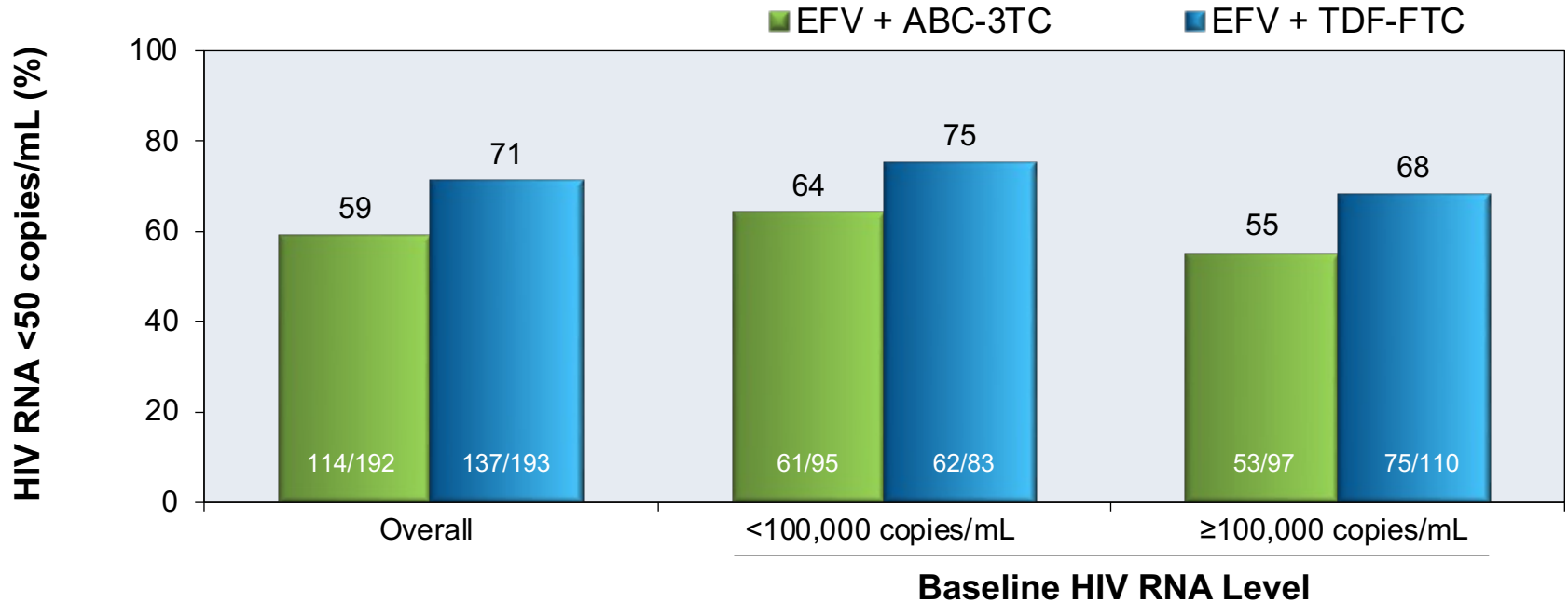
- **Background:** Randomized, open label, phase 3 study comparing tenofovir DF-emtricitabine plus efavirenz with zidovudine-lamivudine plus efavirenz in antiretroviral-naïve adults with HIV
- **Inclusion Criteria (n = 385)**
  - Antiretroviral-naïve adults
  - Age  $\geq 18$  years
  - HIV RNA  $\geq 1,000$  copies/mL
  - HLA-B\*5701 negative
  - CrCl  $\geq 50$  mL/min
  - No AIDS-defining condition or HBV infection
- **Treatment Arms**
  - Efavirenz + abacavir-lamivudine
  - Efavirenz + tenofovir DF-emtricitabine



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

## ASSERT: Results

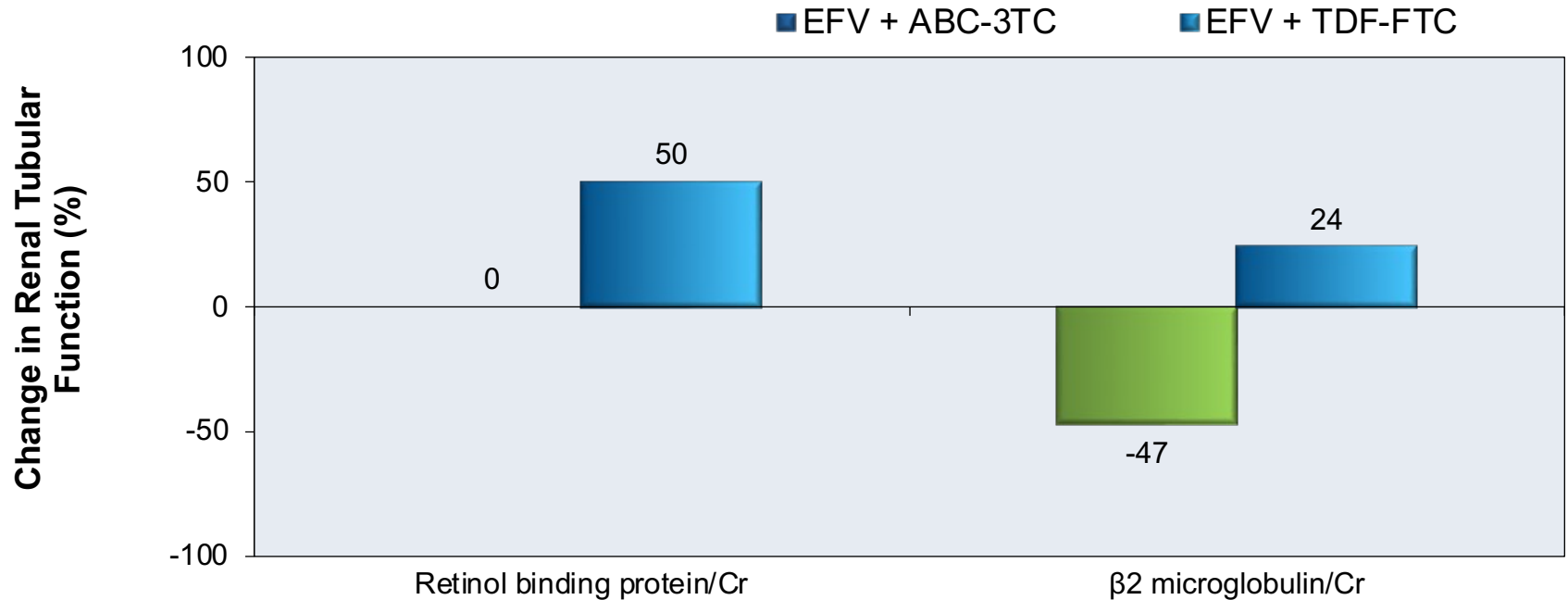
Week 48 Virologic Response (Intent-to-Treat Analysis)



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

## ASSERT: Renal Biomarkers

Week 48: Changes in Markers of Renal Tubular Function from Baseline



# Efavirenz + ABC-3TC vs. Efavirenz + TDF-FTC

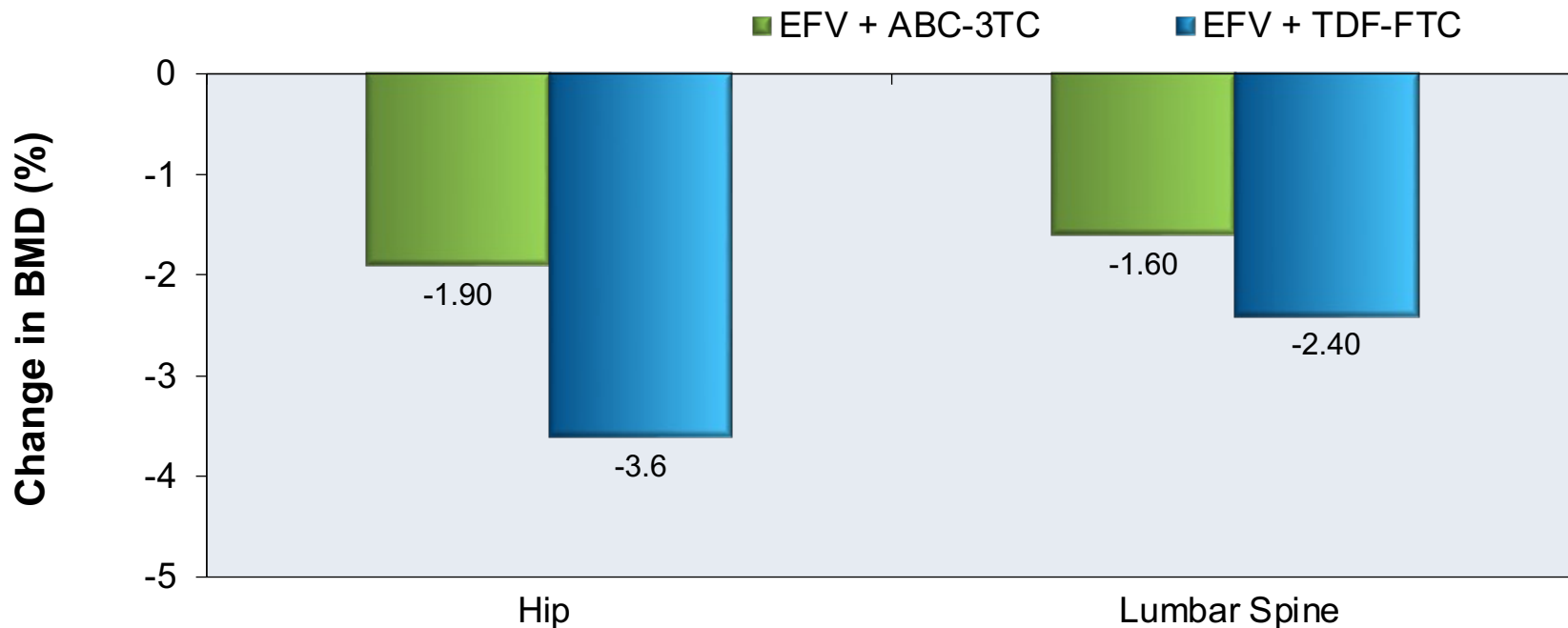
## ASSERT: Conclusions

**Interpretation:** “The study showed no difference in estimated glomerular filtration rate between the arms, however, increases in markers of tubular dysfunction were observed in the tenofovir/emtricitabine arm, the long-term consequence of which is unclear. A significant difference in efficacy favoring tenofovir/emtricitabine was observed.”

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

## ASSERT: Bone Effects

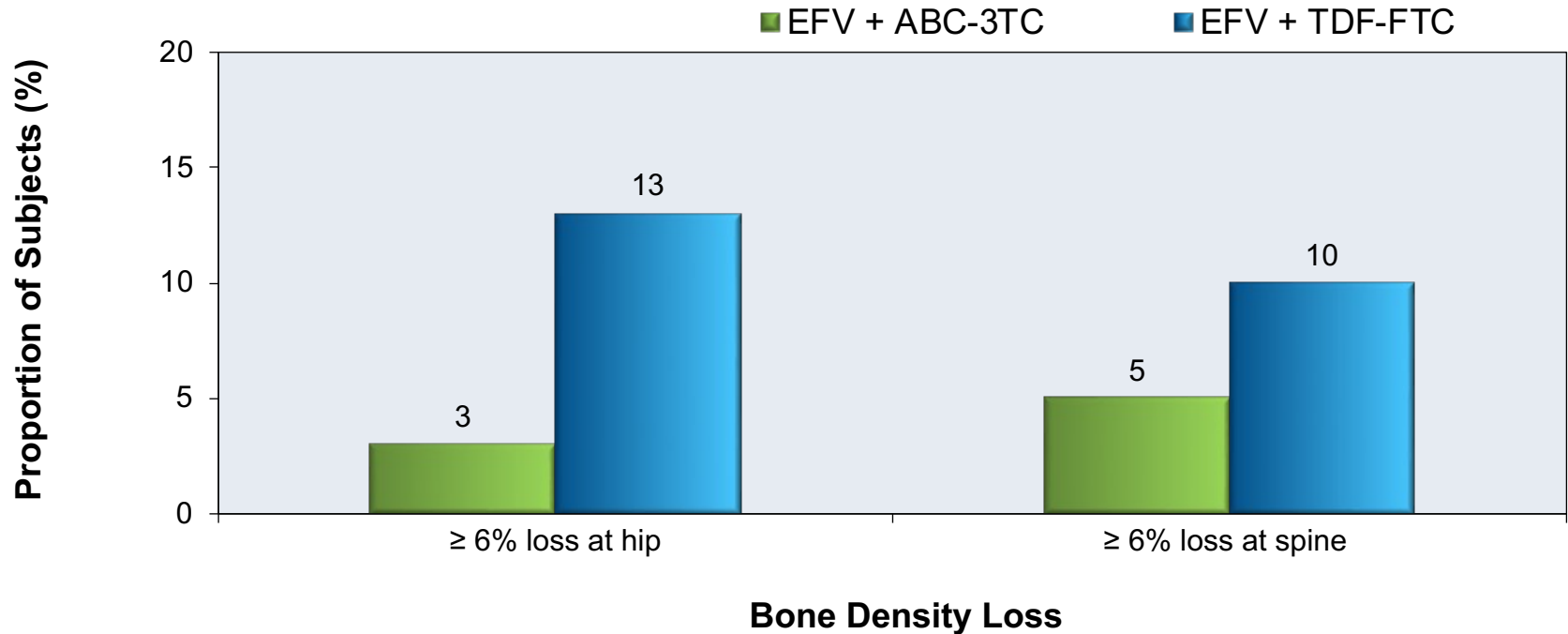
Week 48: Changes in Spine and Hip Bone Mineral Density from Baseline



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

## ASSERT: Bone Effects

Week 48: Proportion of Subjects with Decrease in BMD from Baseline



# Acknowledgments

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