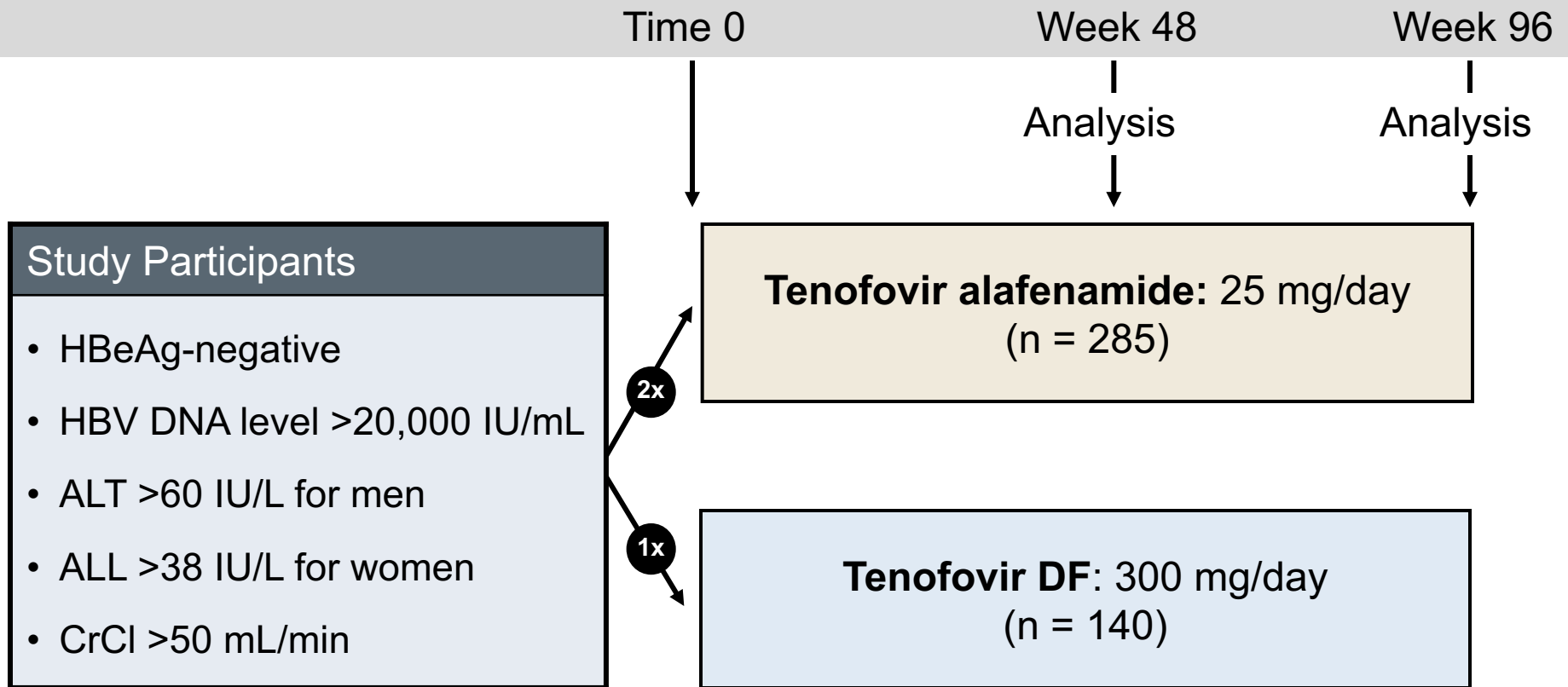


Tenofovir AF vs Tenofovir DF in HBeAg-Negative Study 108

Tenofovir AF vs Tenofovir DF for HBeAg-Negative Study 108: Design

- **Background**
 - Randomized double-blind placebo-controlled non-inferiority trial of tenofovir alafenamide (TAF) versus tenofovir disoproxil fumarate (TDF) in HBeAg-negative adults with chronic hepatitis B
- **Subjects (n = 426)**
 - Age ≥ 18 years
 - Chronic HBeAg-negative
 - HBV DNA level $> 20,000$ IU/mL
 - ALT > 60 IU/L in men, > 38 IU/L in women; ALT $< 10 \times$ ULN for both
- **Regimen**
 - Tenofovir AF: 25 mg once daily with matching placebo
 - Tenofovir DF: 300 mg once daily with matching placebo
- **Study End-Point**
 - HBV DNA level < 29 IU/mL at week 48

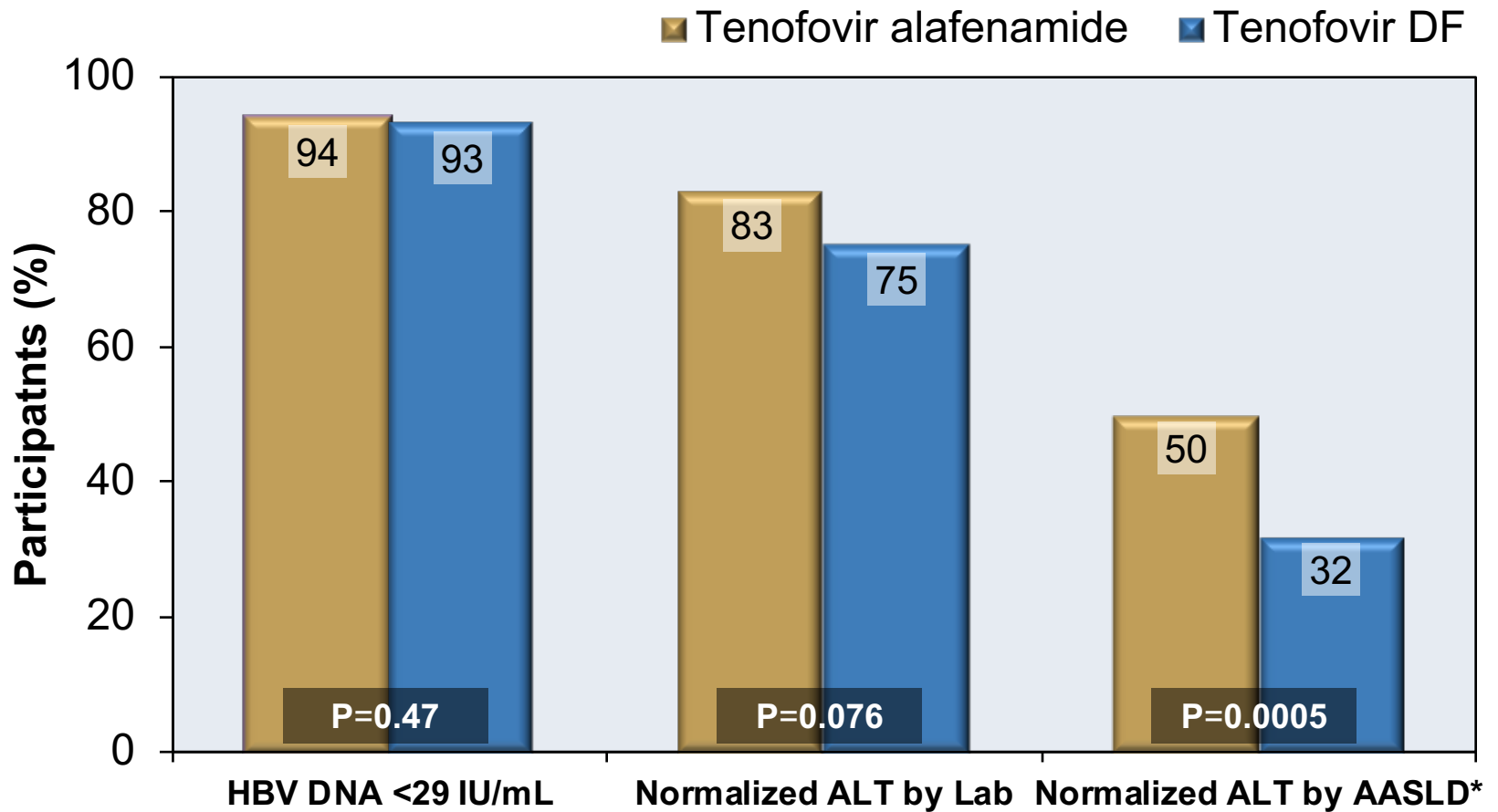
Tenofovir AF vs Tenofovir DF for HBeAg-Negative Study 108: Design



Tenofovir AF vs Tenofovir DF for HBeAg-Negative Study 108: Baseline Characteristics

| Baseline Characteristic | Tenofovir AF (n = 285) | Tenofovir DF (n = 140) |
|--|---------------------------|---------------------------|
| Age, mean (\pm SD), years | 45 (12) | 48 (10) |
| Male, no. (%) | 173 (61) | 86 (61) |
| Race, no. (%) | | |
| Asian | 205 (72) | 101 (72) |
| White | 71 (25) | 35 (25) |
| Black | 5 (2) | 3 (2) |
| Other | 4 (2) | 1 (1) |
| ALT > ULN by central lab, no. (%) | 236 (83) | 121 (86) |
| HBV DNA, log ₁₀ IU/mL (\pm SD) | 5.7 (1.3) | 5.8 (1.3) |
| FibroTest score \geq 0.75, no. (%) | 31/280 (11) | 20/139 (14) |
| Previous nucleos(t)ide therapy, no. (%) | 60 (21) | 31 (22) |
| Previous interferon therapy, no. (%) | 29 (10) | 19 (14) |

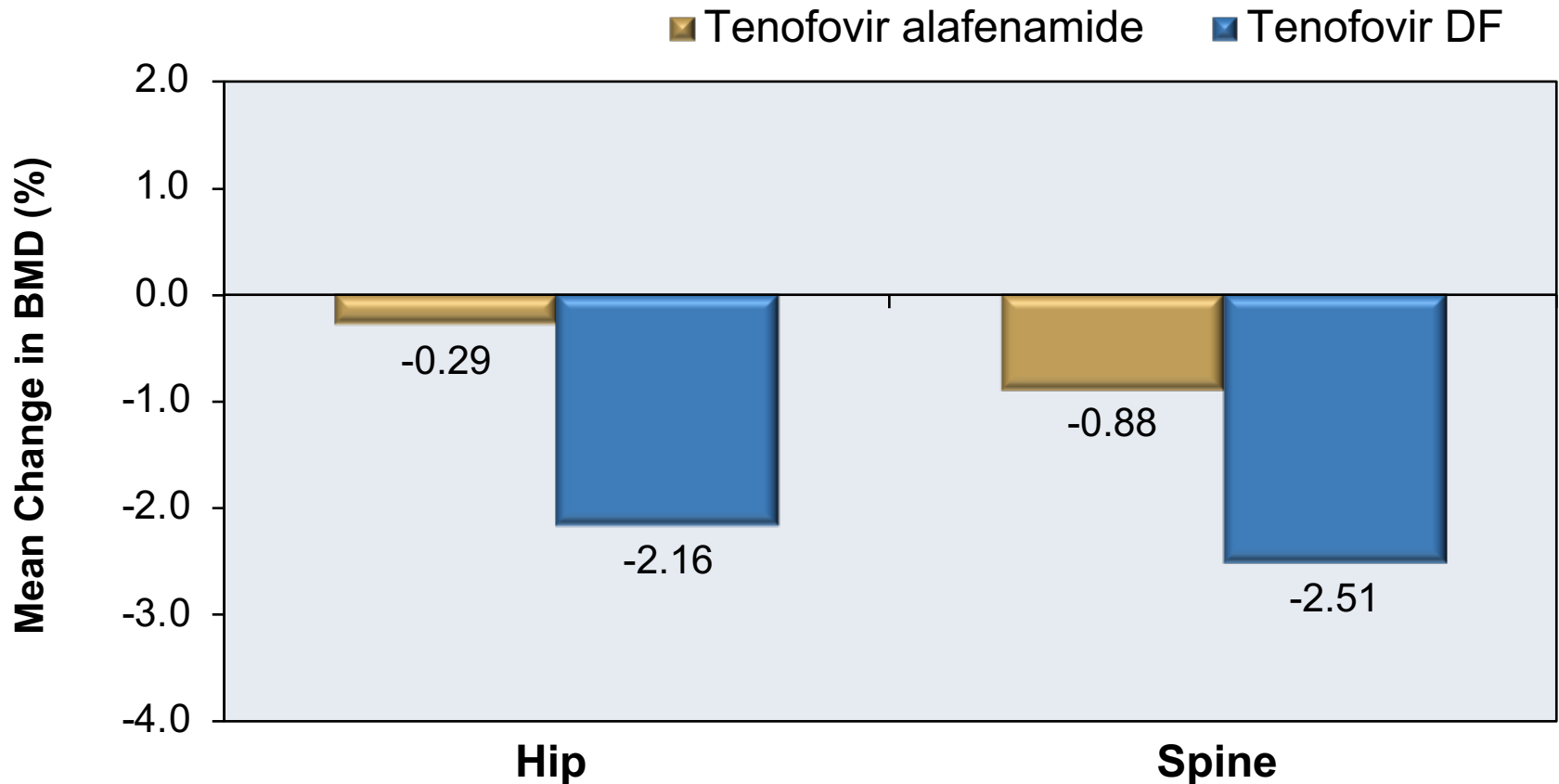
Tenofovir AF vs Tenofovir DF for HBeAg-Negative Study 108: Results at Week 48



*Using normal ranges of ≤ 30 U/L for men and ≤ 19 U/L for women

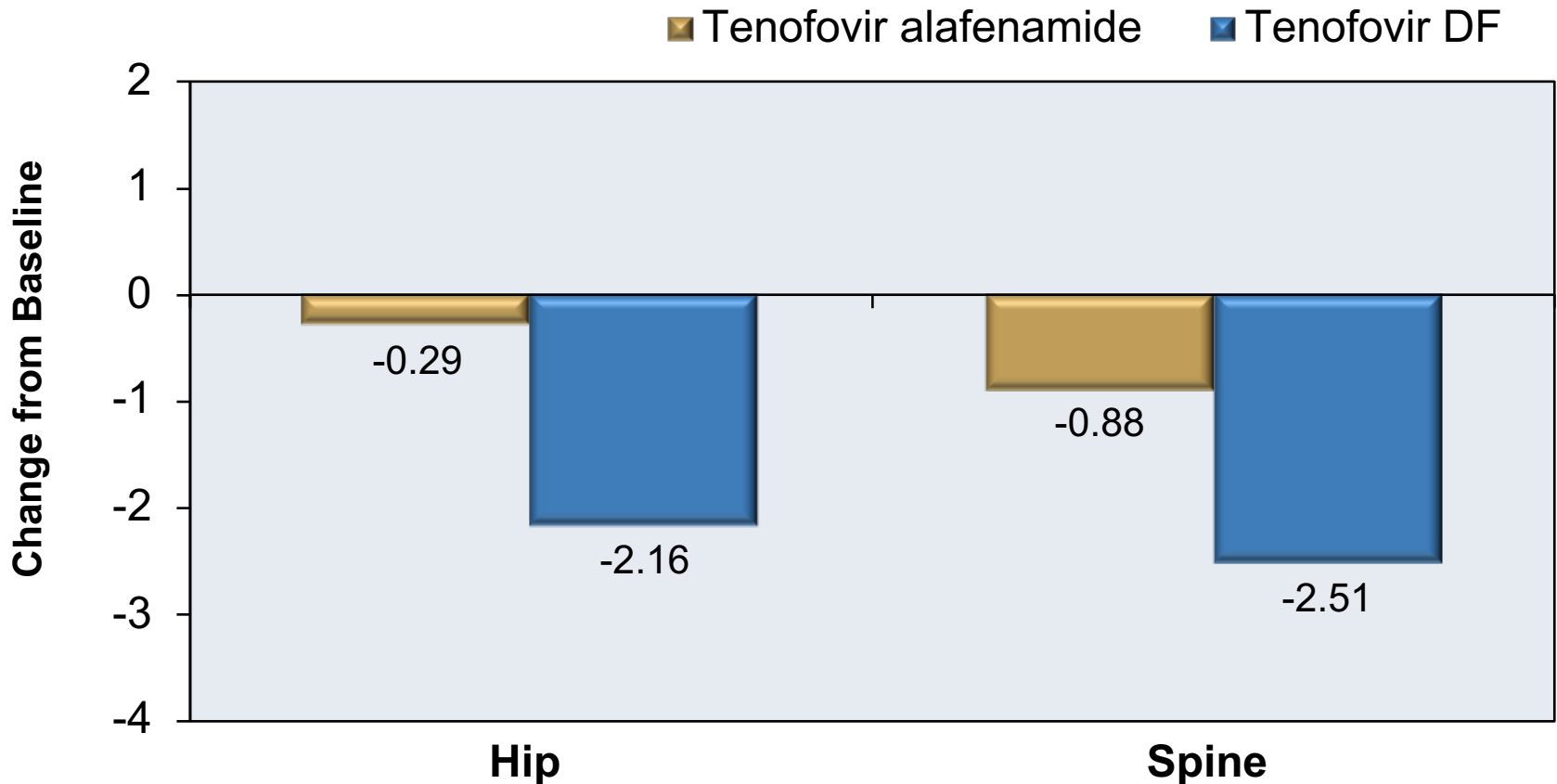
Tenofovir AF vs Tenofovir DF for HBeAg-Negative Study 108: Adverse Effects

Week 48 Changes in Bone Mineral Density (BMD)



Tenofovir AF vs Tenofovir DF for HBeAg-Negative Study 108: Adverse Effects

Week 48 Changes in Bone Mineral Density (BMD)



Tenofovir AF vs Tenofovir DF for HBeAg-Negative Study 108: Results

Interpretation: “In patients with HBeAg-negative chronic HBV, the efficacy of tenofovir alafenamide was non-inferior to that of tenofovir disoproxil fumarate, and had improved bone and renal effects. Longer term follow-up is needed to better understand the clinical impact of these changes.”