National HIV Curriculum

Rilpivirine-Tenofovir alafenamide-Emtricitabine (*Odefsey*)

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Rilpivirine-Tenofovir Alafenamide-Emtricitabine

Rilpivirine-Tenofovir alafenamide-Emtricitabine

25 mg	25 mg	200 mg
NNRTI	NRTI	NRTI

Dose: 1 tablet once daily with a meal

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Rilpivirine-Tenofovir alafenamide-Emtricitabine

- **Indications**
  - Complete regimen for the treatment of HIV-1 for individuals who weigh at least 35 kg
  - Option for treatment-naïve individuals who have HIV RNA ≤100,000 copies/mL
  - Option to replace a stable regimen for individuals with HIV RNA <50 copies/mL for ≥6 months, with no history of treatment failure or resistance to the components
  - Acceptable for use during pregnancy if above criteria met, though HIV RNA should be measured every 1-2 months due to possible reduction in rilpivirine exposure
- **Contraindications**
  - Not recommended if creatinine clearance ≤30 mL/min
  - Contraindicated with proton pump inhibitors (PPIs) and with rifamycins
  - Dosing must be separated from H2 blockers and other antacids, or therapy modified
  - Caution advised if history of prolonged QT interval or taking meds that prolong the QT
- **Common Adverse Effects** (≥2%)
  - Headache, sleep disturbance

Rilpivirine-Tenofovir alafenamide-Emtricitabine Summary of Key Phase 3 Studies

- **Trials in in Treatment-Naïve Adults**
  - STUDY 1160: Switch to RPV-TAF-FTC from EFV-TDF-FTC
  - STUDY 1216: Switch to RPV-TAF-FTC from RPV-TDF-FTC

Abbreviations: RPV-TAF-FTC = rilpivirine-tenofovir alafenamide-emtricitabine; EFV-TDF-FTC = efavirenz-tenofovir DF-emtricitabine; RPV-TDF-FTC = rilpivirine-tenofovir DF-emtricitabine;

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Switch Studies in Adults with Virologic Suppression

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Switch to RPV-TAF-FTC from EFV-TDF-FTC

Study GS-366-1160

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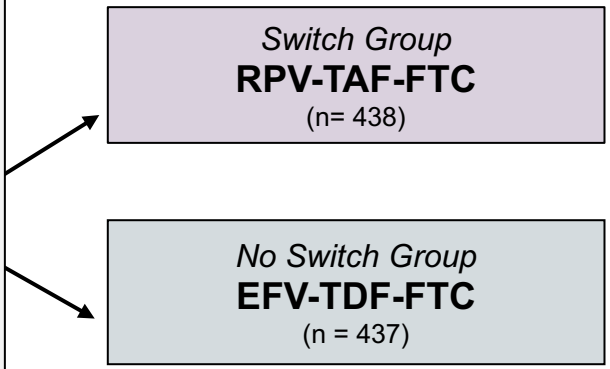
Switch to RPV-TAF-FTC from EFV-TDF-FTC
Study GS-366-1160: Design

- **Background**: Phase 3b, multinational, randomized, double-blind, placebo-controlled, noninferiority trial investigating the tolerability of switching to the single-tablet regimen rilpivirine-tenofovir alafenamide-emtricitabine (RPV-TAF-FTC)
- **Inclusion Criteria (n = 881 randomized)**
  - HIV-1-infected adults
  - HIV RNA <50 copies/mL for ≥6 months on EFV-TDF-FTC
  - Creatinine clearance at least 50 mL/min
  - No resistance to EFV, RPV, TDF, or FTC
- **Treatment Arms**
  - Switch to RPV-TAF-FTC (Switch group)
  - Remain on EFV-TDF-FTC (No switch group)



*__NOTE__: of 881 participants randomized, 6 were never treated (875 individuals treated)

Source: DeJesus E, et al. Lancet HIV. 2017;4:e205-e213.

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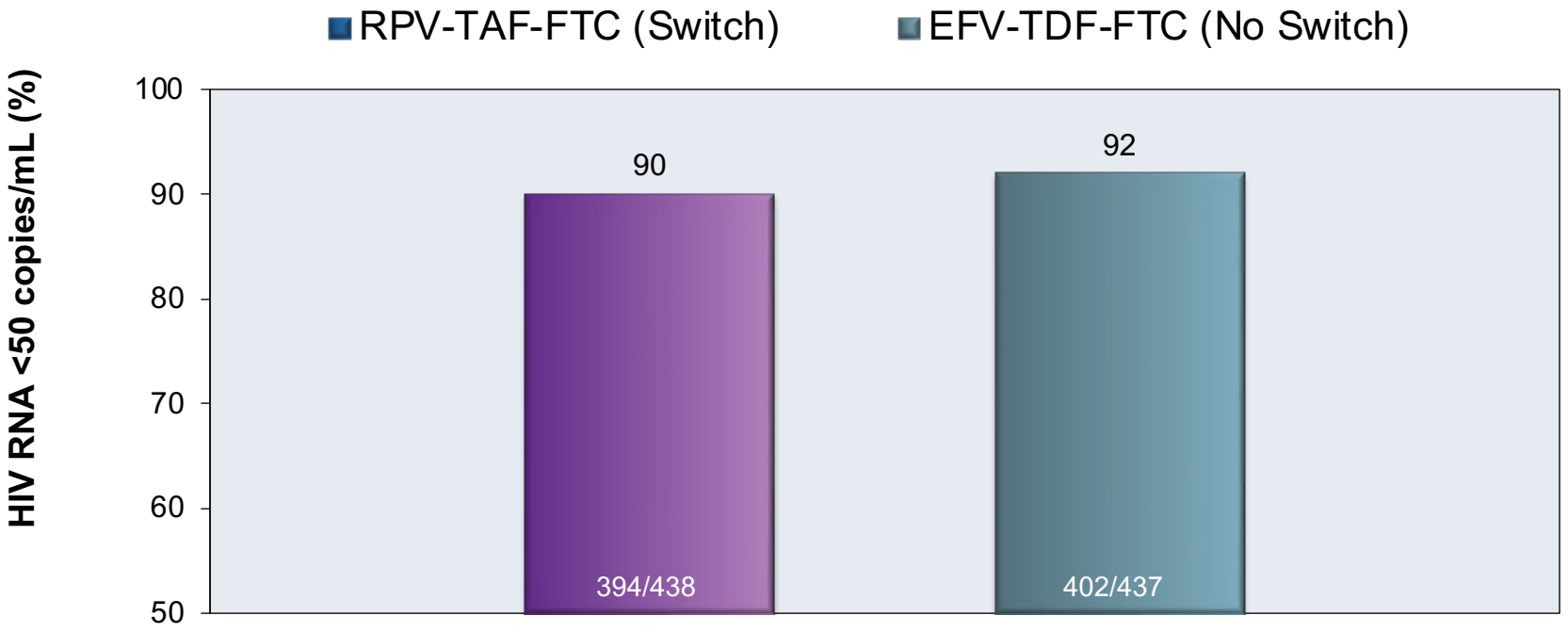
Switch to RPV-TAF-FTC from EFV-TDF-FTC
Study GS-366-1160: Results

Week 48 Virologic Response (FDA Snapshot Analysis)



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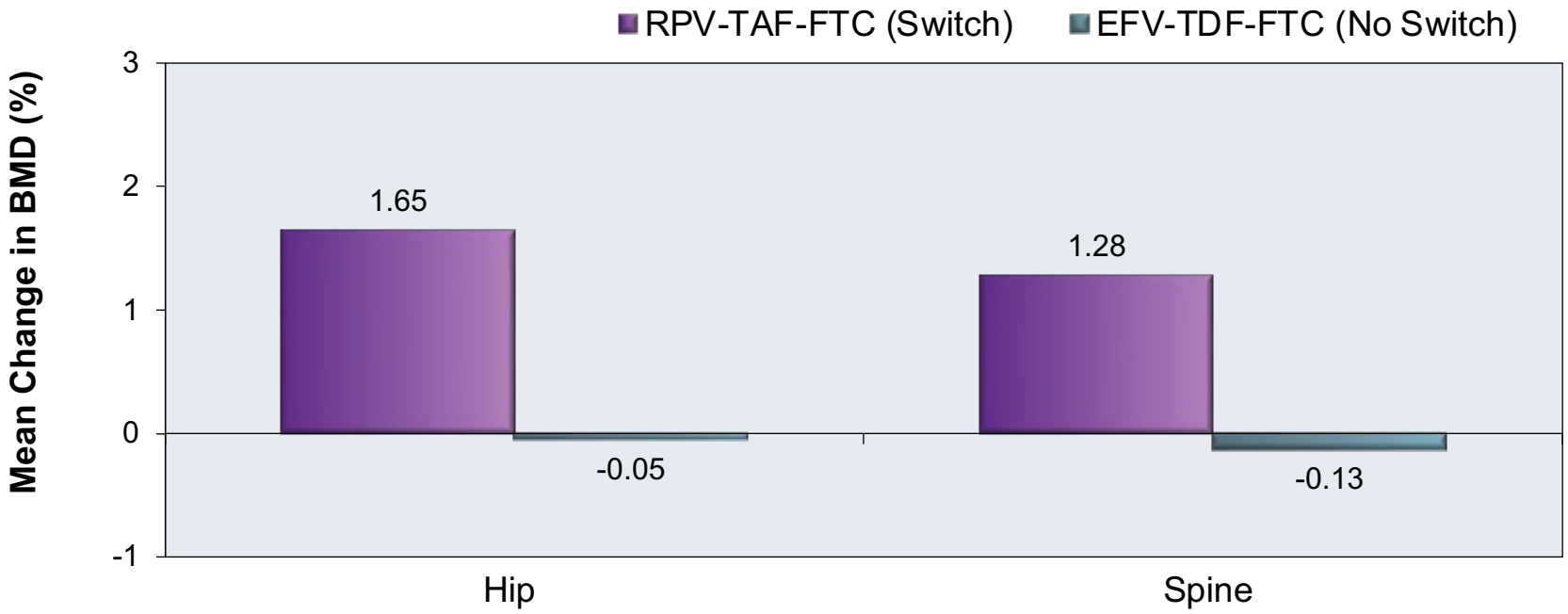
Switch to RPV-TAF-FTC from EFV-TDF-FTC
Study GS-366-1160: Results

Week 48: Changes in Bone Mineral Density (BMD)



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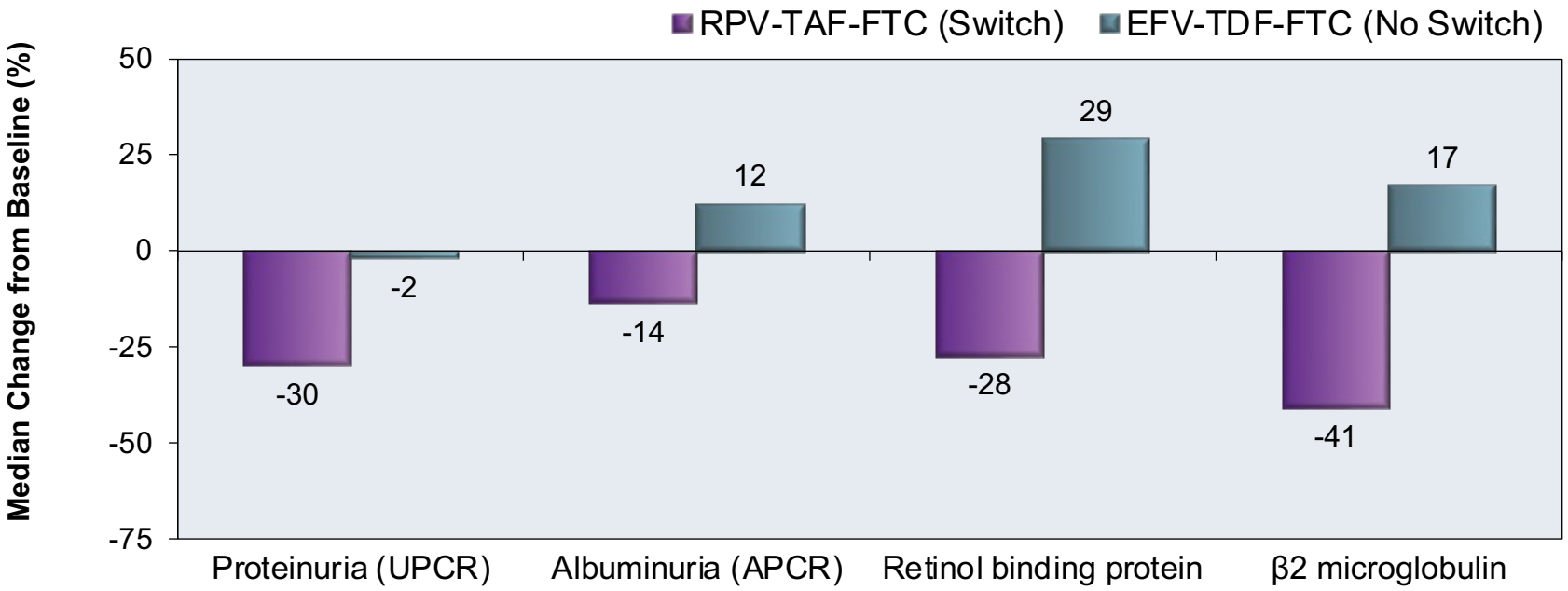
Switch to RPV-TAF-FTC from EFV-TDF-FTC
Study GS-366-1160: Results

Week 48: Changes in Markers of Proximal Tubulopathy



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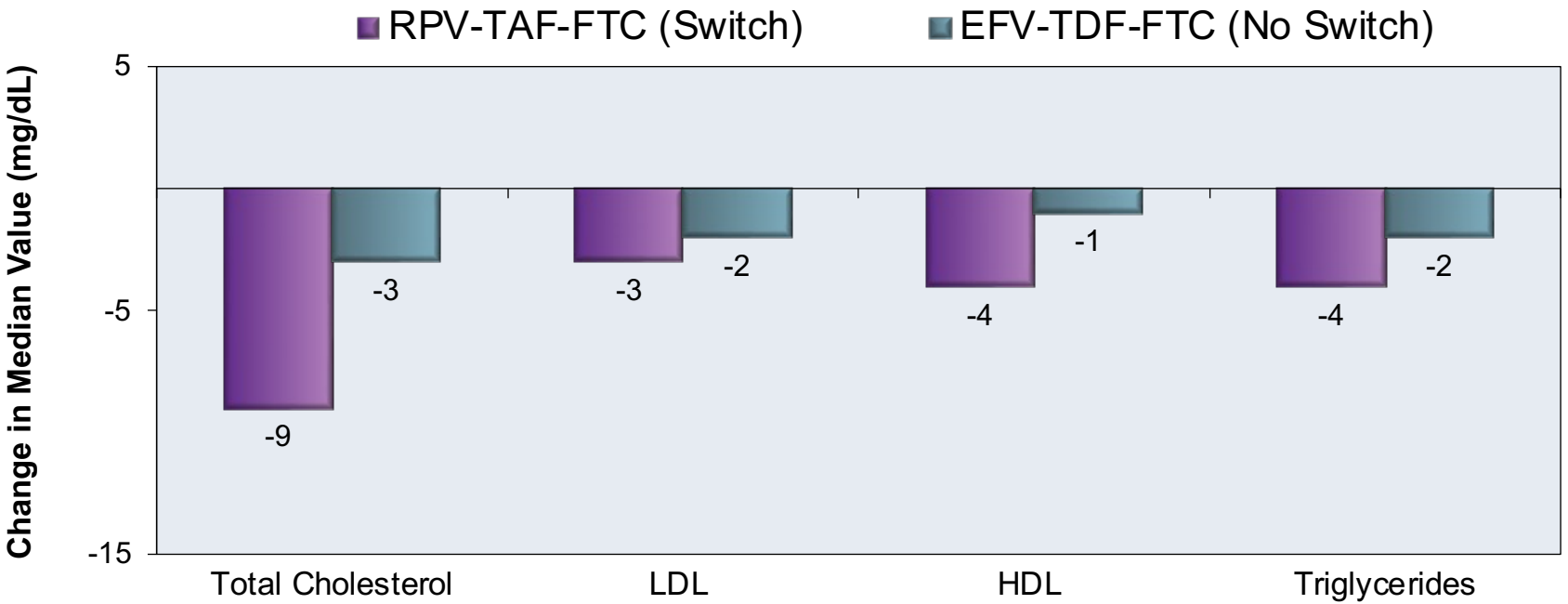
Switch to RPV-TAF-FTC from EFV-TDF-FTC
Study GS-366-1160: Results

Week 48: Change in Plasma Lipids from Baseline



Source: DeJesus E, et al. Lancet HIV. 2017;4:e205-e213.

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Switch to RPV-TAF-FTC from EFV-TDF-FTC
Study GS-366-1160: Conclusion

Interpretation: “Switching to rilpivirine, emtricitabine, and tenofovir alafenamide from efavirenz, emtricitabine, and tenofovir disoproxil fumarate was non-inferior in maintaining viral suppression and was well tolerated at 48 weeks. These findings support guidelines recommending tenofovir alafenamide-based regimens, including coformulation with rilpivirine and emtricitabine, as initial and ongoing treatment for HIV-1 infection.”

Source: DeJesus E, et al. Lancet HIV. 2017;4:e205-e213.

Switching to TAF from TDF, each with RPV and FTC

Study GS-366-1216

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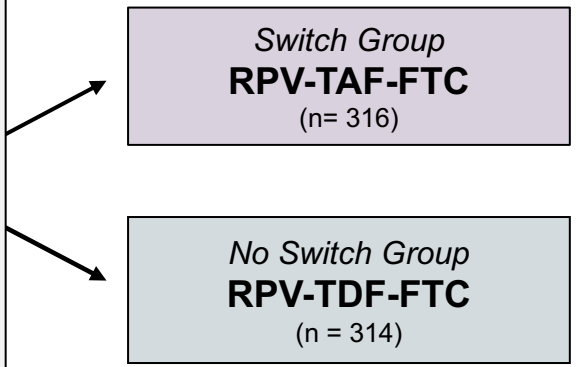
Switch from TDF to TAF, each with RPV and FTC
Study GS-366-1216: Design

- **Background**: Phase 3b, multinational, randomized, double-blind, placebo-controlled, noninferiority trial to investigate safety and tolerability of switching to the single-tablet regimen rilpivirine-tenofovir alafenamide-emtricitabine (RPV-TAF-FTC)
- **Inclusion Criteria** (n = 632 randomized)
  - HIV-1-infected adults
  - HIV RNA <50 copies/mL ≥6 months on RPV-TDF-FTC
  - Creatinine clearance at least 50 mL/min
  - No resistance to RPV, TDF, or FTC
- Treatment Arms
  - Switch to RPV-TAF-FTC (Switch group)
  - Remain on RPV-TDF-FTC (No switch group)



*__NOTE__: of 632 participants randomized, 2 were never treated (630 individuals treated)

Source: Orkin C et al. Lancet HIV. 2017;4:e195-e204.

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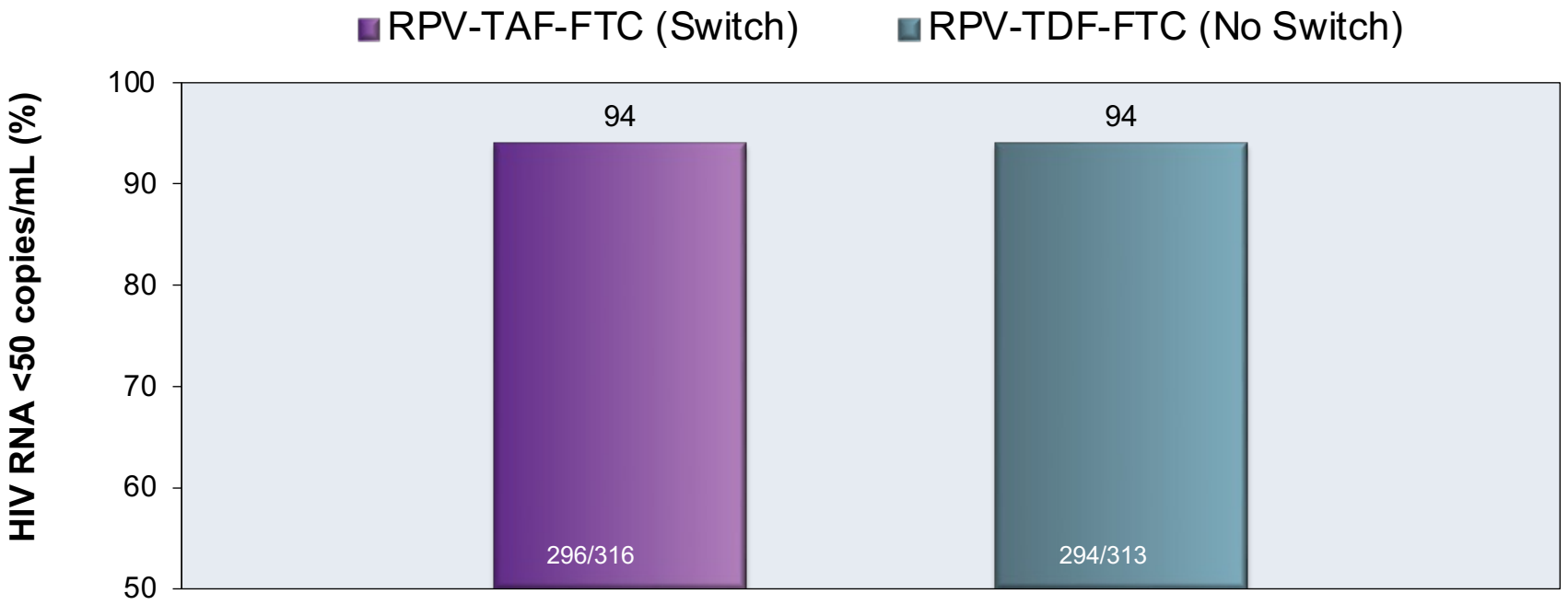
Switch to TAF from TDF, each with RPV and FTC
Study GS-366-1216: Design

Week 48 Virologic Response (FDA Snapshot Analysis)



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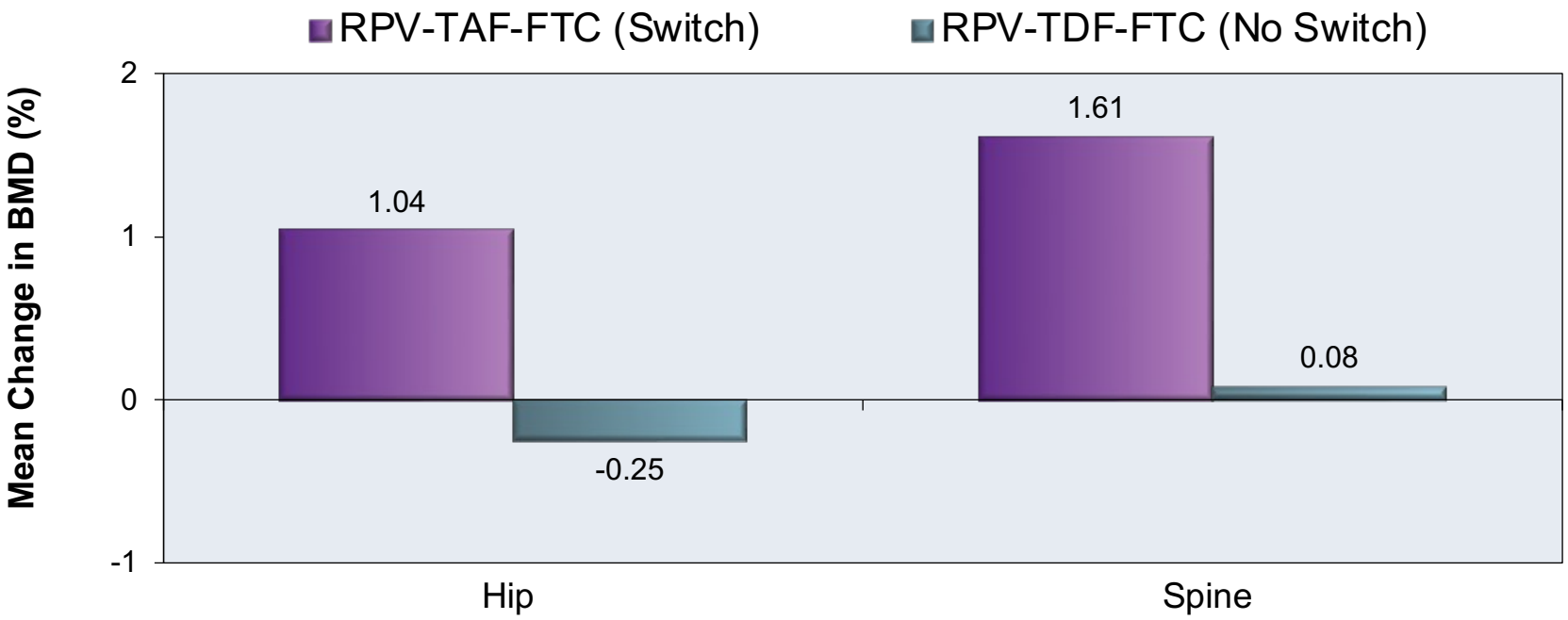
Switch to TAF from TDF, each with RPV and FTC
Study GS-366-1216: Results

Week 48: Changes in Bone Mineral Density (BMD)



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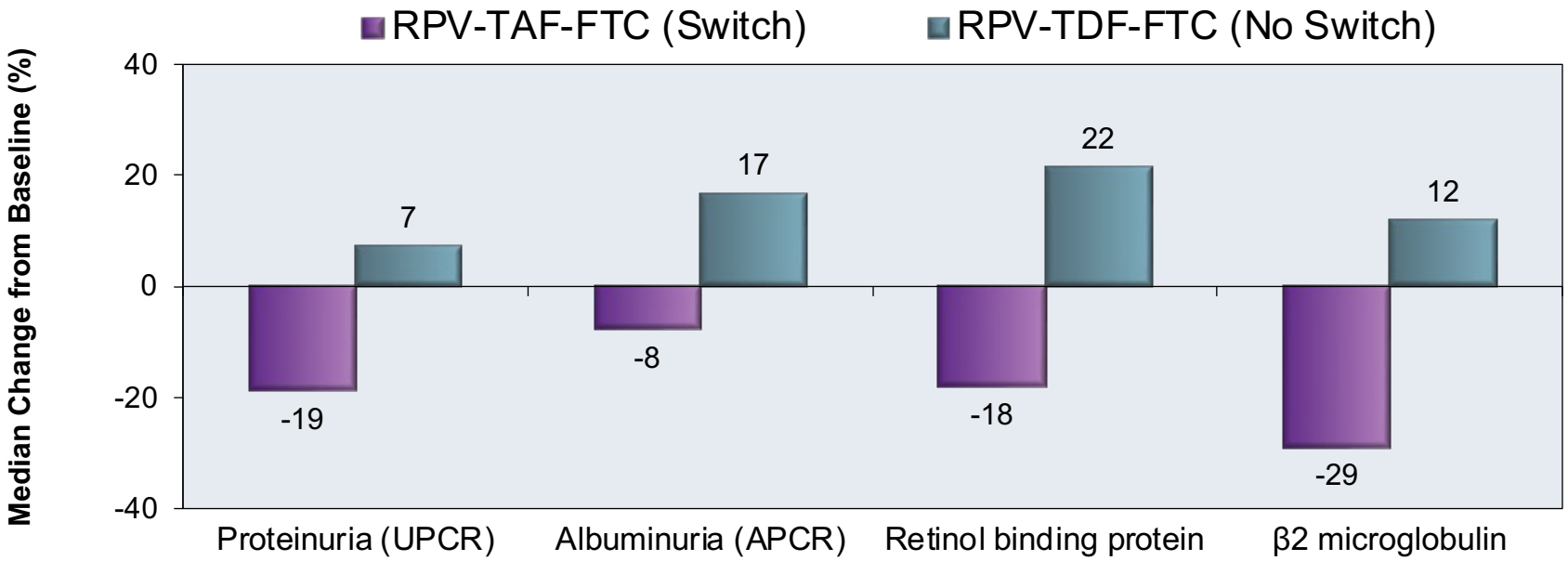

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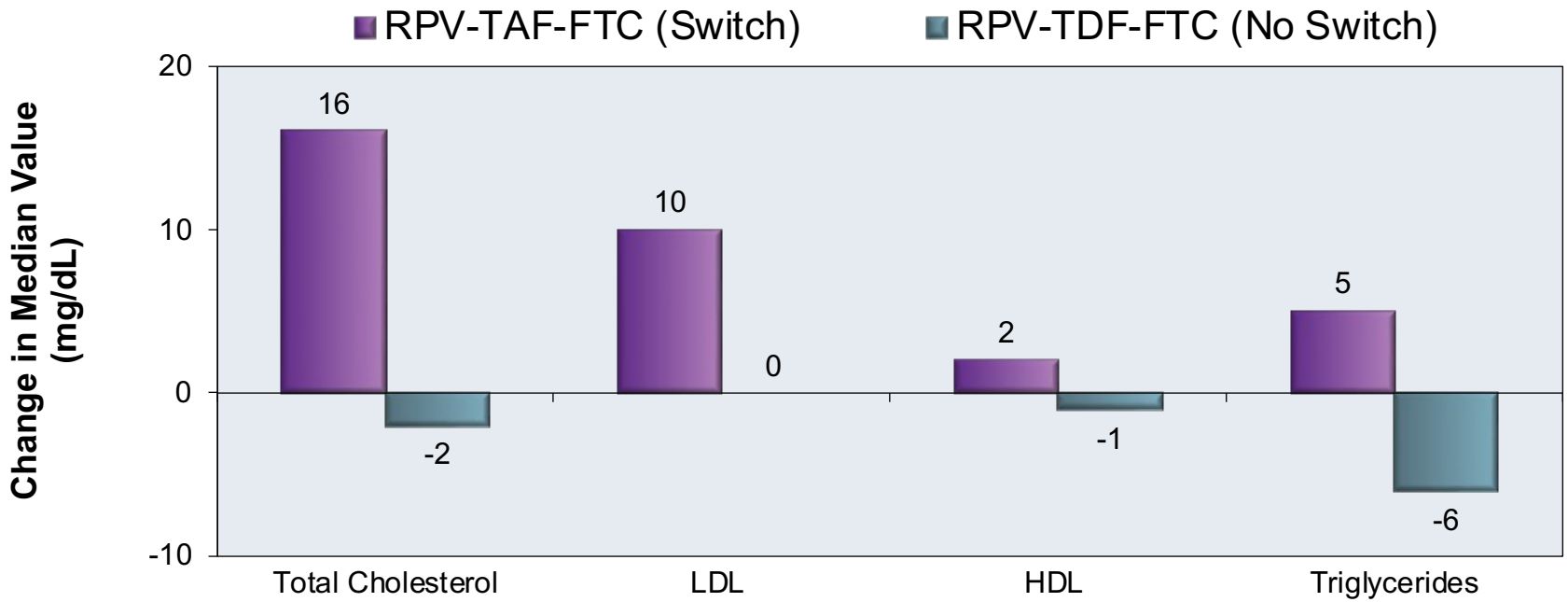

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National HIV Curriculum

Switch to TAF from TDF, each with RPV and FTC
Study GS-366-1216: Conclusions

Interpretation: “Switching to rilpivirine, emtricitabine, and tenofovir alafenamide was non-inferior to continuing rilpivirine, emtricitabine, tenofovir disoproxil fumarate in maintaining viral suppression and was well tolerated at 48 weeks. These findings support guidelines recommending tenofovir alafenamide-based regimens, including coformulation with rilpivirine and emtricitabine, as initial and ongoing treatment for HIV-1 infection.”

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Acknowledgments

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AETC AIDS Education & Training Center Program

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