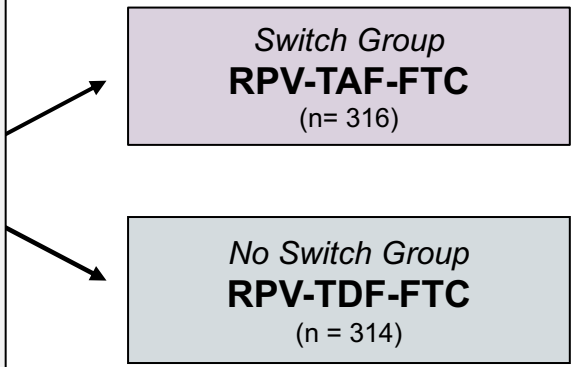
Switching to TAF from TDF, each with RPV and FTC

Study GS-366-1216

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)

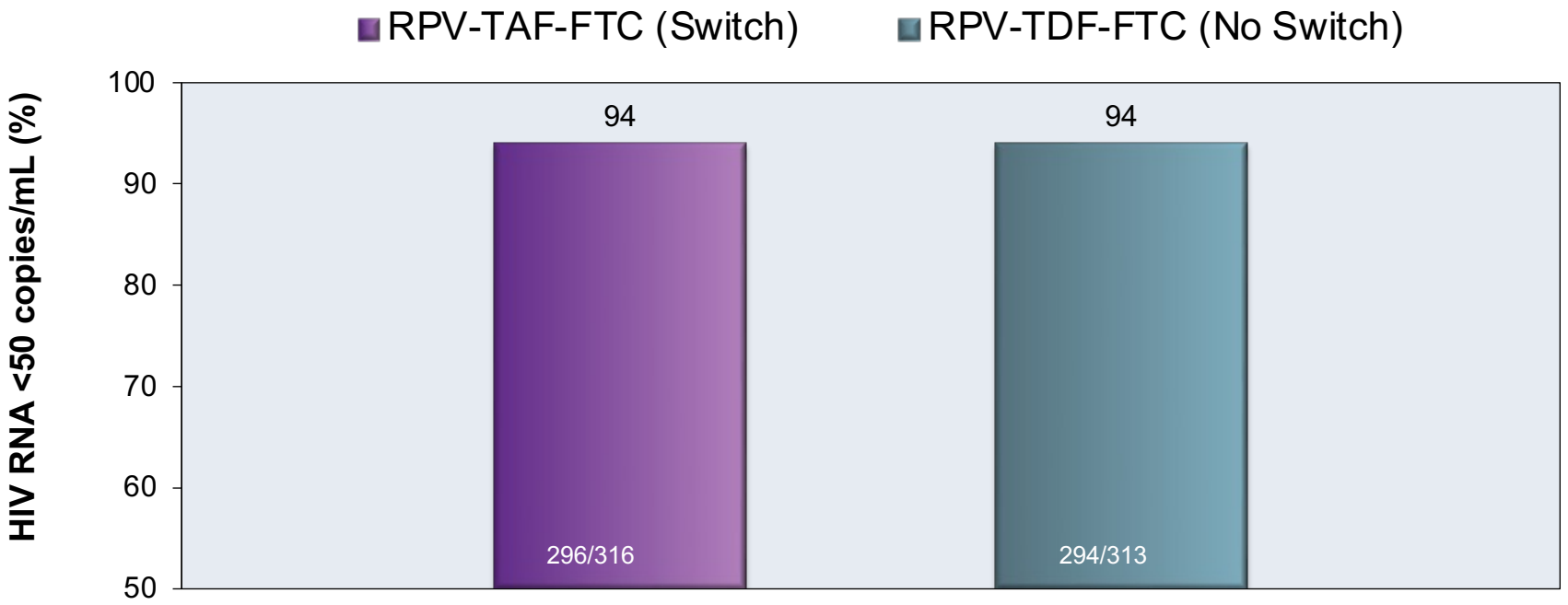


*__NOTE__: of 632 participants randomized, 2 were never treated (630 individuals treated)

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

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

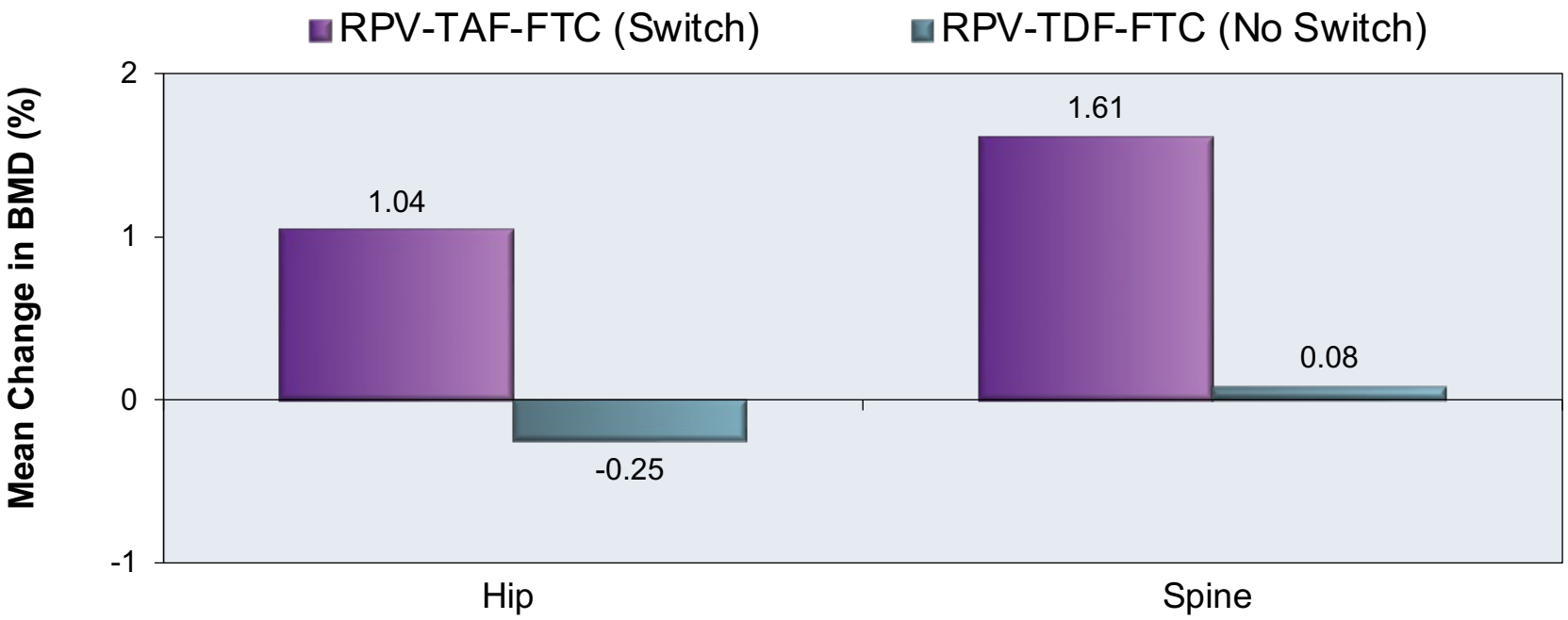
Week 48 Virologic Response (FDA Snapshot Analysis)



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

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

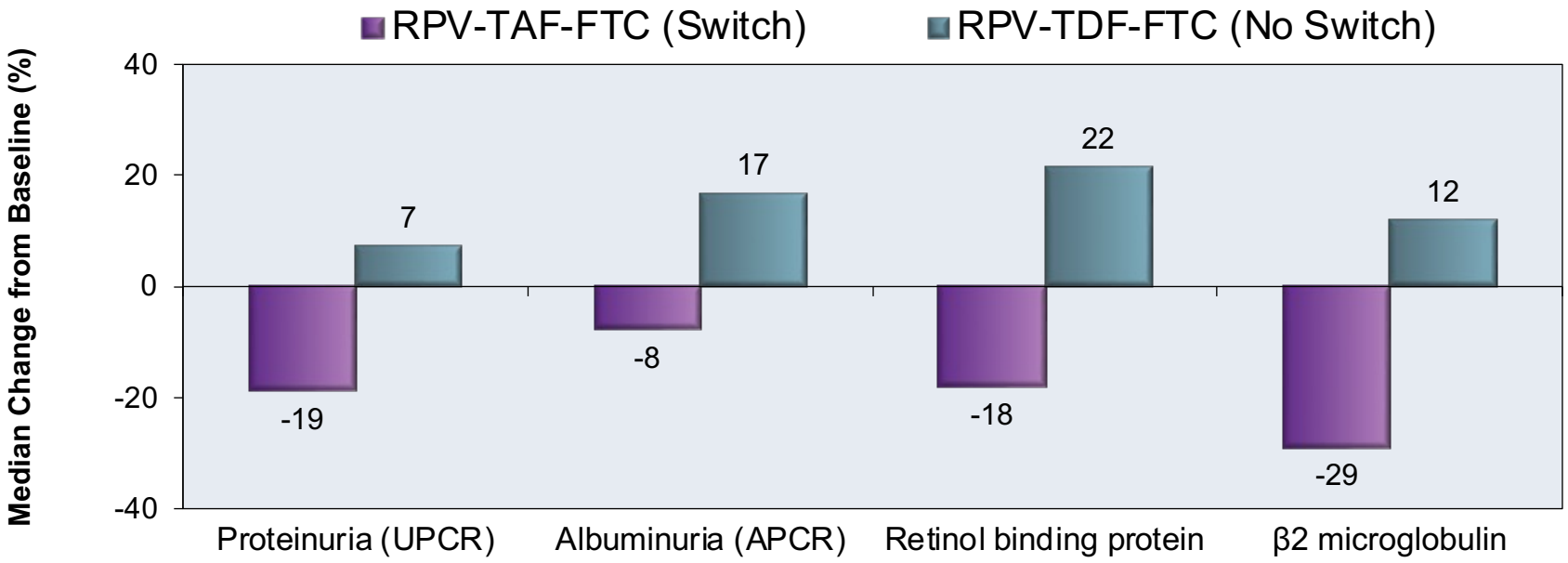
Week 48: Changes in Bone Mineral Density (BMD)



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

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

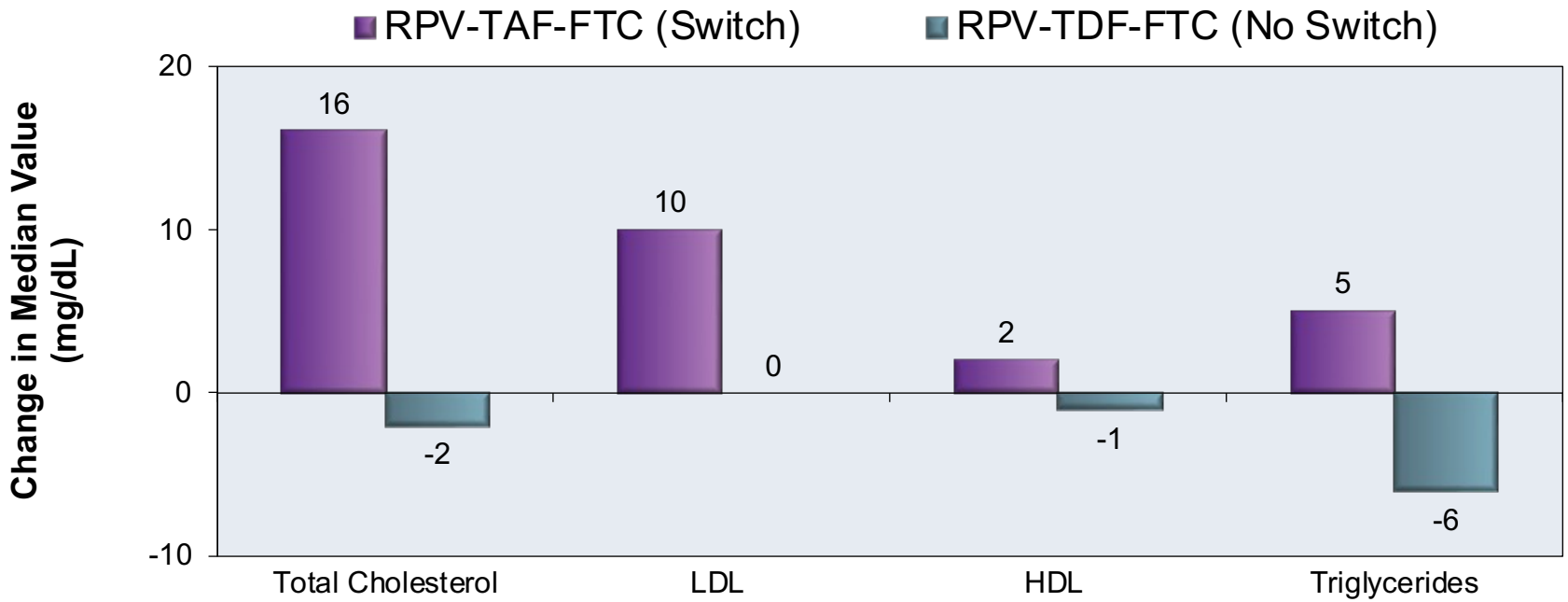
Week 48: Changes in Markers of Proximal Tubulopathy



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

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

Week 48: Change in Plasma Lipids from Baseline



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

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.”

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

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.

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National HIV Curriculum

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