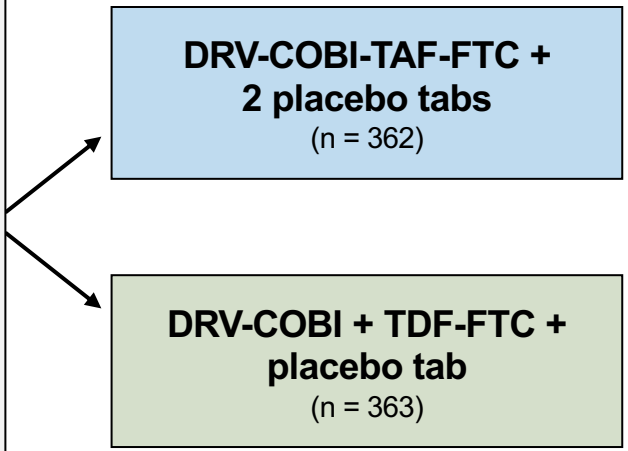
DRV-COBI-TAF-FTC vs DRV-COBI + TDF-FTC

AMBER

DRV-COBI-TAF-FTC vs DRV-COBI + TDF-FTC as Initial ART
AMBER: Design

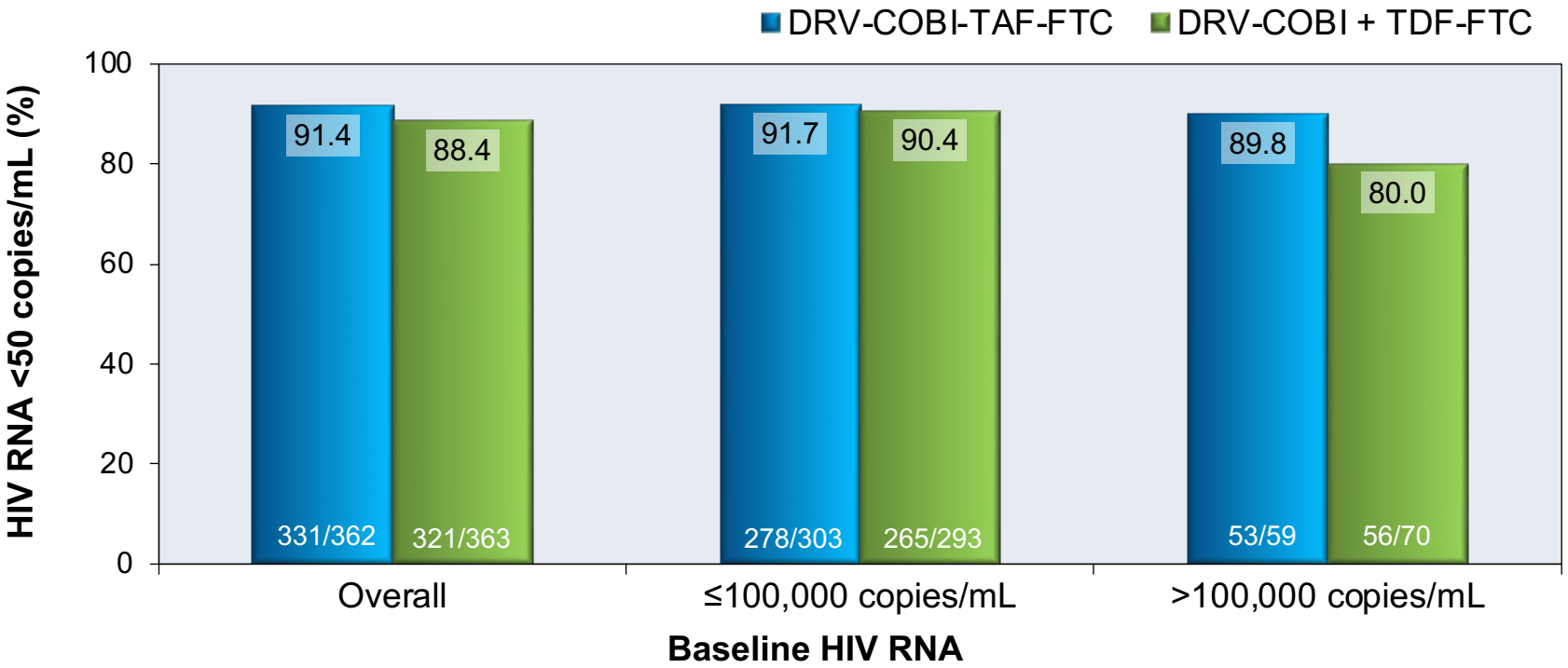
- **Background**: Randomized, double-blind, active-controlled, international, phase 3 study evaluating the efficacy and safety of the single-tablet regimen DRV-COBI-TAF-FTC compared with DRV-COBI + TDF-FTC for treatment-naïve individuals
- **Inclusion Criteria (n = 725)**
  - Age ≥18 years
  - Antiretroviral naïve
  - CD4 count >50 cells/mm^3
  - HIV RNA ≥1,000 copies/mL
  - eGFR ≥70 mL/min
  - Genotypic sensitivity to DRV, TDF, and FTC
  - No hepatitis B or C
  - Not pregnant
  - No AIDS-defining condition within 30 days



Source: Eron JJ, et al. AIDS. 2018;32:1431-42.

DRV-COBI-TAF-FTC vs DRV-COBI + TDF-FTC as Initial ART
AMBER: Results

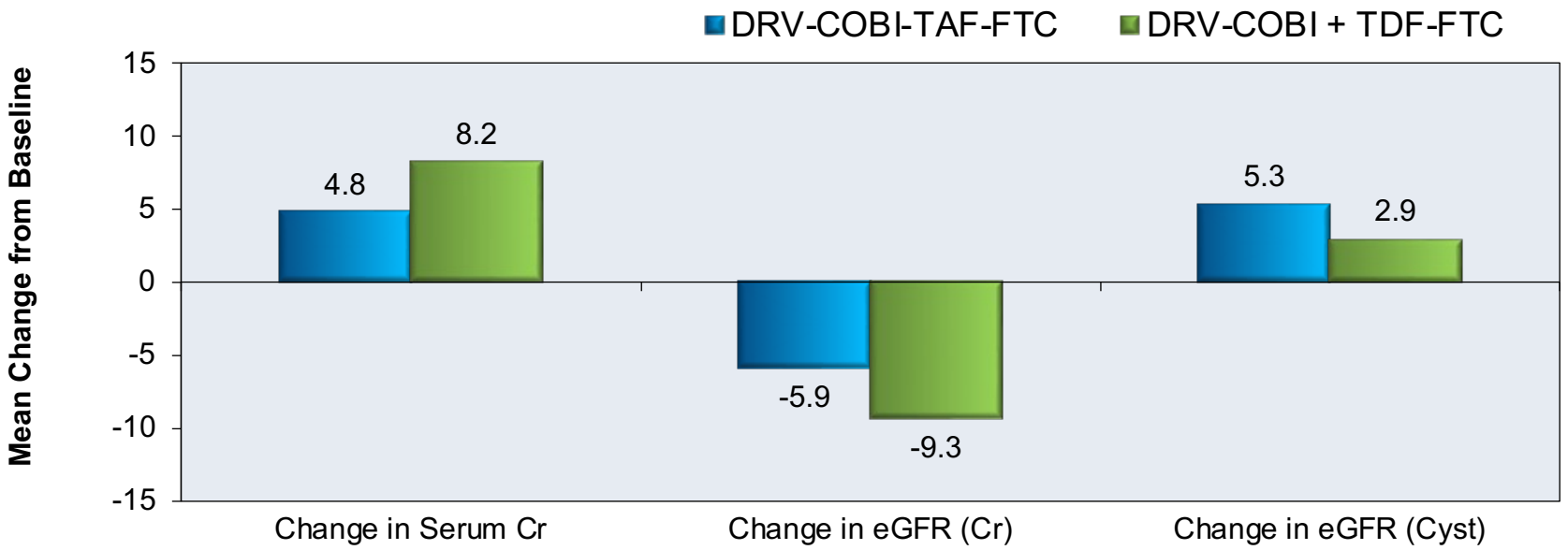
Week 48: Virologic Response by FDA Snapshot Analysis, ITT



Source: Eron JJ, et al. AIDS. 2018;32:1431-42.

DRV-COBI-TAF-FTC vs DRV-COBI + TDF-FTC as Initial ART
AMBER: Results

Week 48: Change in Serum Creatinine and Estimated GFR



Abbreviations: Cr = creatinine (measured in µmol/L); eGFR = estimated glomerular filtration rate (measured in mL/min/1.73m^2, calculated using CKD-EPI); Cyst = cystatin C

Source: Eron JJ, et al. AIDS. 2018;32:1431-42.

DRV-COBI-TAF-FTC vs DRV-COBI + TDF-FTC as Initial ART
AMBER: Results

Week 48: Change in Urinary Markers of Tubular Dysfunction

Mean Change in Markers of Proximal Tubulopathy at Week 48

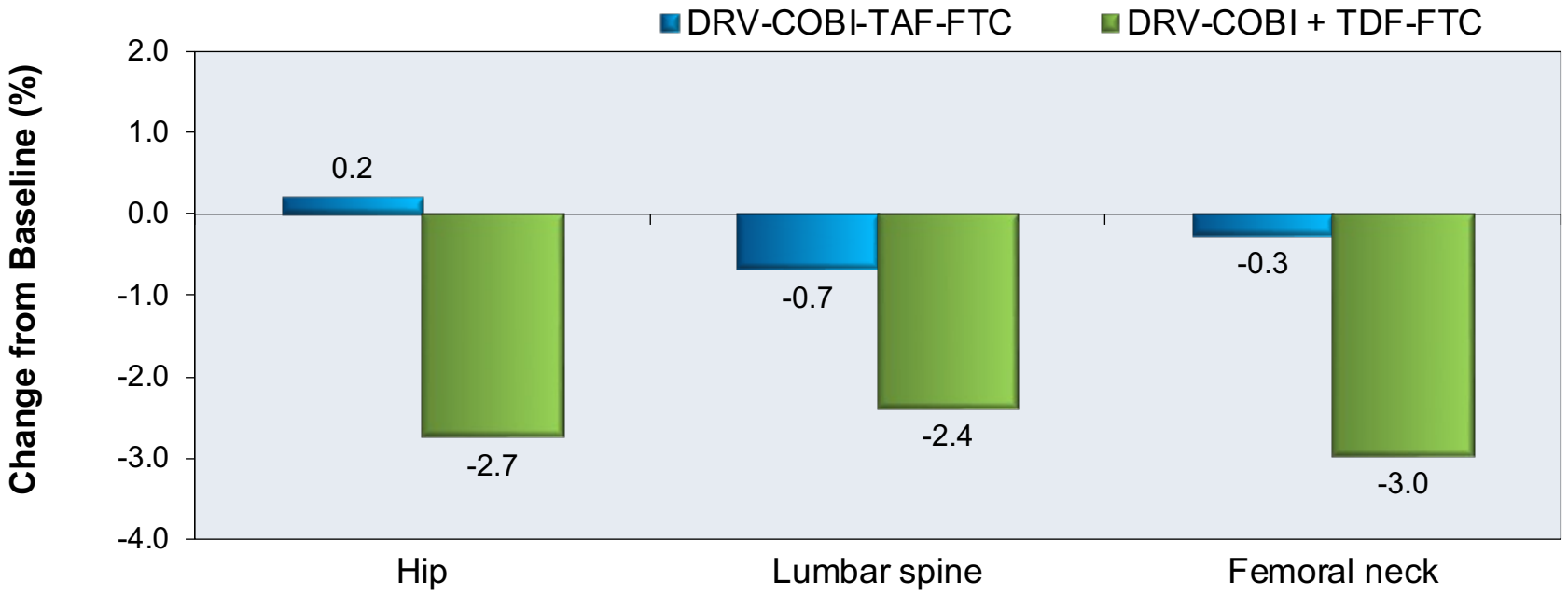
	DRV-COBI-TAF-FTC (n = 362)	DRV-COBI + TDF-FTC (n = 363)
UPCR (mg/g)	-22.42	-10.34
UACR (mg/g)	-2.45	-0.58
RBP:Cr (µg/g)	16.84	401.12
β2M:Cr (µg/g)	-100.58	837.63

UPCR = urine protein to creatinine ratio; UACR = urine albumin to creatinine ratio
RBP:Cr = retinol binding protein to creatinine ratio; β2M:Cr = beta-2-microglobulin to creatinine ratio

Source: Eron JJ, et al. AIDS. 2018;32:1431-42.

DRV-COBI-TAF-FTC vs DRV-COBI + TDF-FTC as Initial ART
AMBER: Results

Week 48: Percentage Change in Bone Mineral Density*



*This is from a bone mineral density substudy (n = 113 participants in TAF arm, 99 in control arm)

Source: Eron JJ, et al. AIDS. 2018;32:1431-42.

DRV-COBI-TAF-FTC vs DRV-COBI + TDF-FTC as Initial ART
AMBER: Results

Median Change in Fasting Lipid Parameters at Week 48

	DRV-COBI-TAF-FTC (n = 362)	DRV-COBI + TDF-FTC (n = 363)
TC (mg/dL)	28.6	10.4
LDL (mg/dL)	17.4	5.0
HDL (mg/dL)	4.3	1.5
TC:HDL ratio	0.2	0.08
Triglycerides (mg/dL)	23.9	14.2

TC = total cholesterol; LDL = low density lipoprotein; HDL = high density lipoprotein

Source: Eron JJ, et al. AIDS. 2018;32:1431-42.

DRV-COBI-TAF-FTC vs DRV-COBI + TDF-FTC as Initial ART
AMBER: Results

Conclusions: “Darunavir-cobicistat-emtricitabine-tenofovir alafenamide achieved a high virologic suppression rate (91.4%) and was noninferior to darunavir-cobicistat with emtricitabine-tenofovir DF. Darunavir-cobicistat-emtricitabine-tenofovir alafenamide also demonstrated the bone and renal safety advantages of tenofovir alafenamide in combination with darunavir-cobicistat.”

Source: Eron JJ, et al. AIDS. 2018;32:1431-42.

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.

AETC AIDS Education & Training Center Program

National HIV Curriculum

IDEA Infectious Diseases Education & Assessment