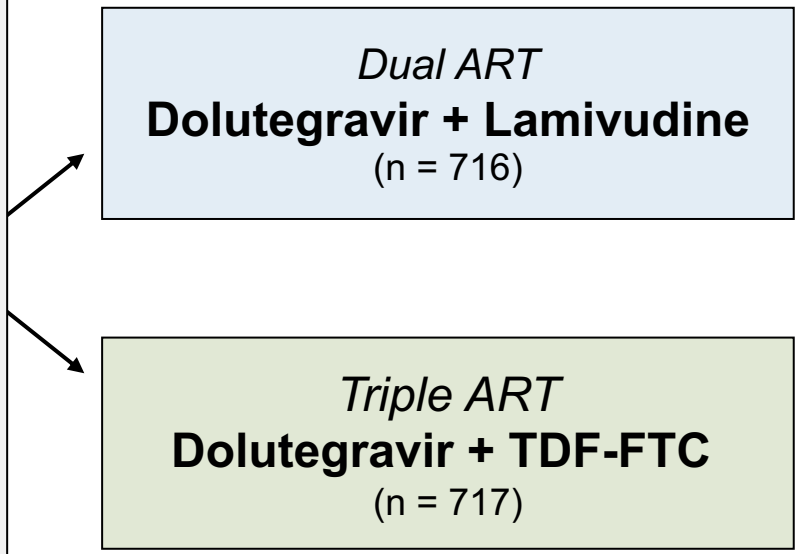
DTG + 3TC versus DTG + TDF-FTC as Initial ART

GEMINI 1 and GEMINI 2: Week 48 Data

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and GEMINI 2: Background

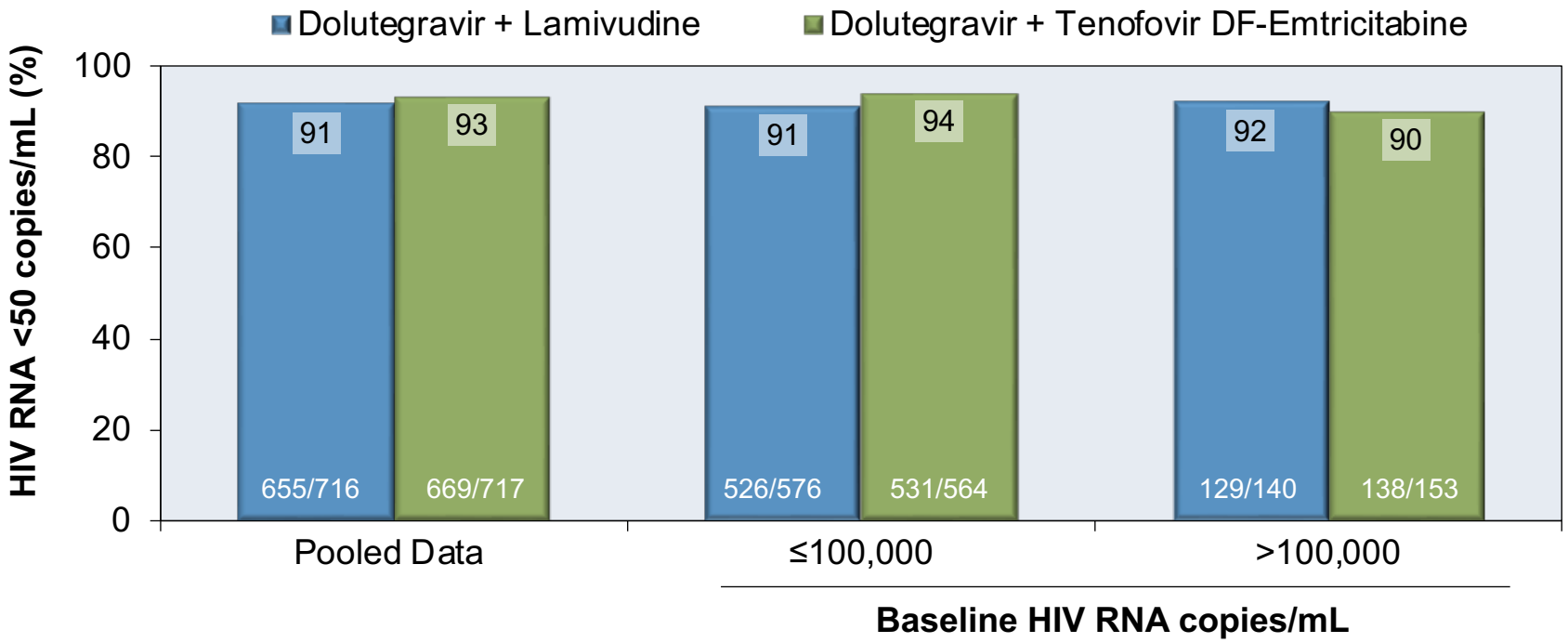
- **Background**
  - Two double-blind, multinational, noninferiority, randomized, controlled trials that compared initial ART of dolutegravir plus lamivudine (DTG + 3TC) versus dolutegravir plus tenofovir-DF-emtricitabine (DTG + TDF-FTC)
- **Enrollment Criteria**
  - Treatment-naïve adults
  - HIV RNA 1,000-500,000 copies/mL
  - No NRTI, INSTI, or major PI mutations
  - No chronic HBV
  - Not pregnant or breastfeeding



Source: Cahn P, et al. Lancet. 2019;393:143-55.

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and GEMINI 2: Results by Baseline HIV RNA Level

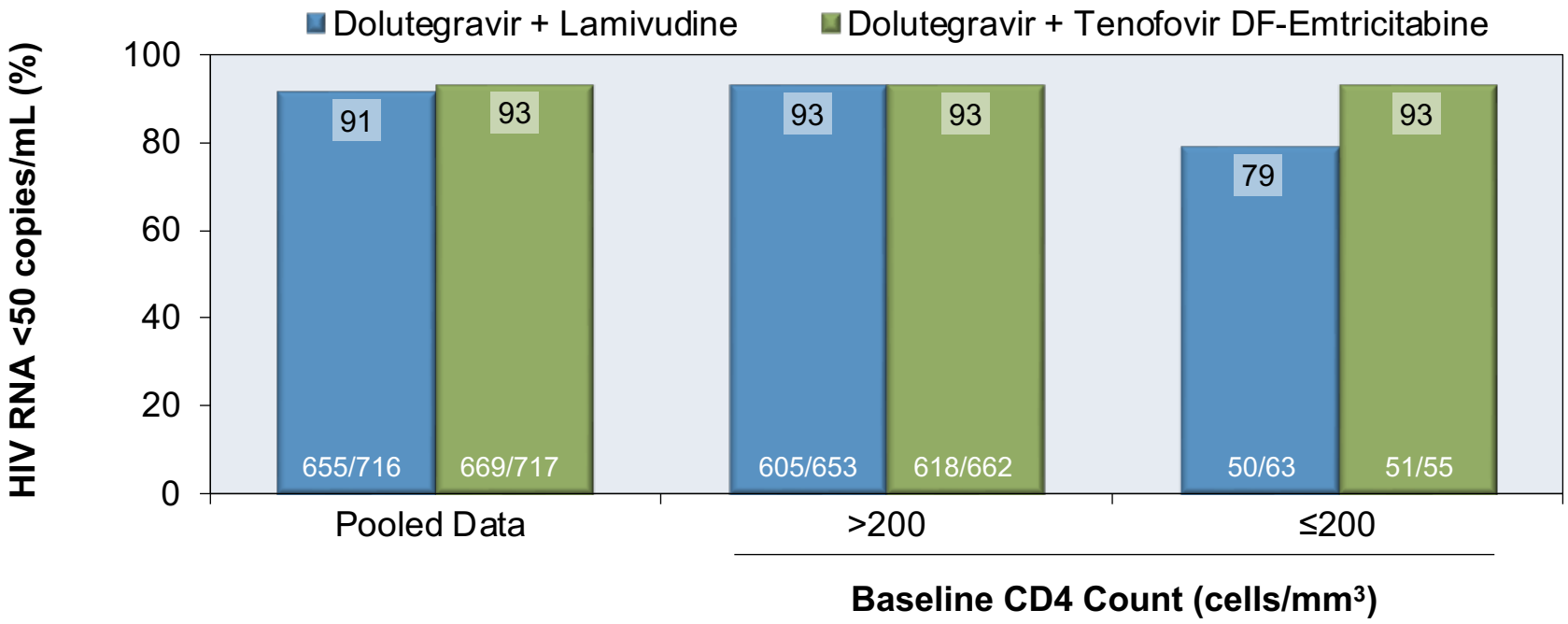
Week 48 Virologic Response (Intention-to-Treat Analysis)



Source: Cahn P, et al. Lancet. 2019;393:143-55.

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and GEMINI 2: Results by Baseline HIV CD4 Cell Count

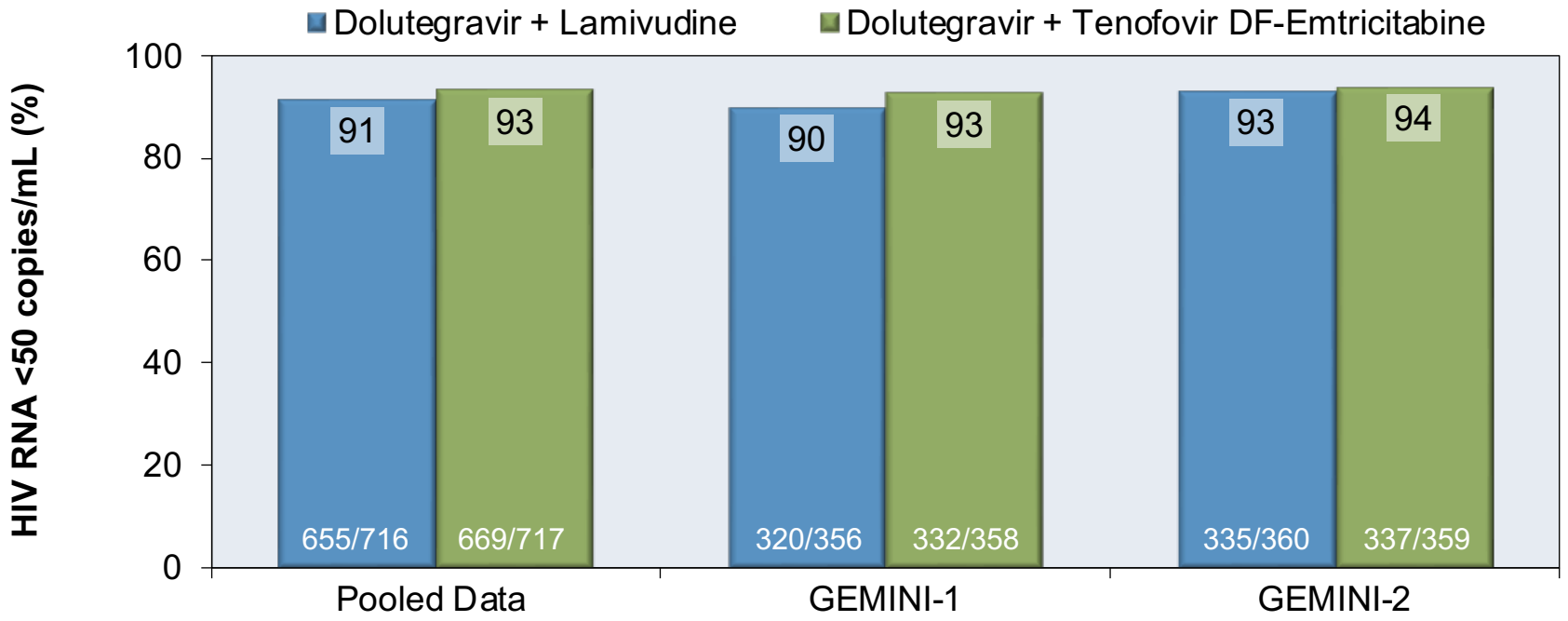
Week 48 Virologic Response (Intention-to-Treat Analysis)



Source: Cahn P, et al. Lancet. 2019;393:143-55.

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Results

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



Source: Cahn P, et al. Lancet. 2019;393:143-55

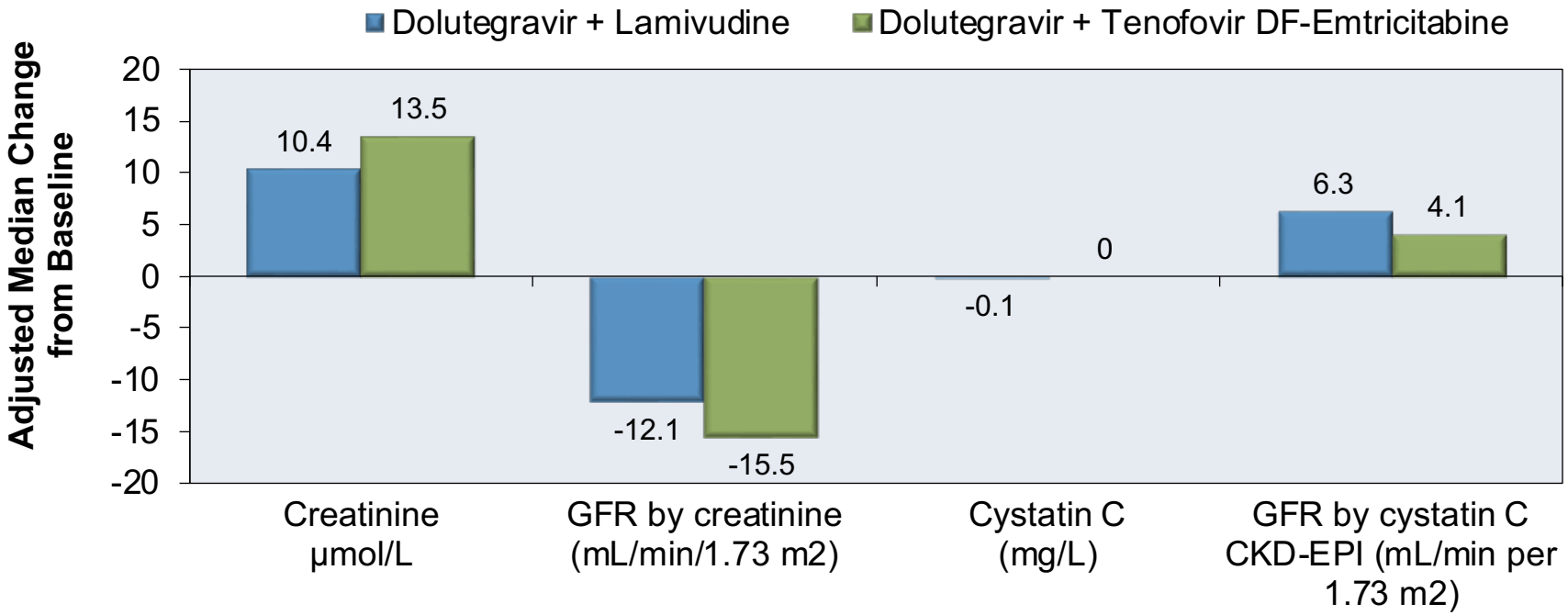
DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Baseline Characteristics

GEMINI 1 and 2 Baseline Characteristics		
Characteristic	**DTG + 3TC** (n = 716)	**DTG + TDF-FTC** (n = 717)
Age, years, median (IQR)	32 (26-40)	33 (26-42)
Female, n (%)	113 (16)	98 (14)
White, n (%)	480 (67)	497 (69)
Black or African American, n (%)	99 (14)	76 (11)
CD4 cell count, mean (SD)	462 (219.2)	461.3 (213.1)
CD4 count ≤200 cells/mm^3, n (%)	63 (9)	55 (8)
HIV RNA (log_{10} copies/mL)	4.42 (0.66)	4.45 (0.65)
≤100,000 copies/mL, n (%)	576 (80)	564(79)
>100,000 copies/mL, n (%)	140 (20)	153 (21)

Source: Cahn P, et al. Lancet. 2019;393:143-55.

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Results

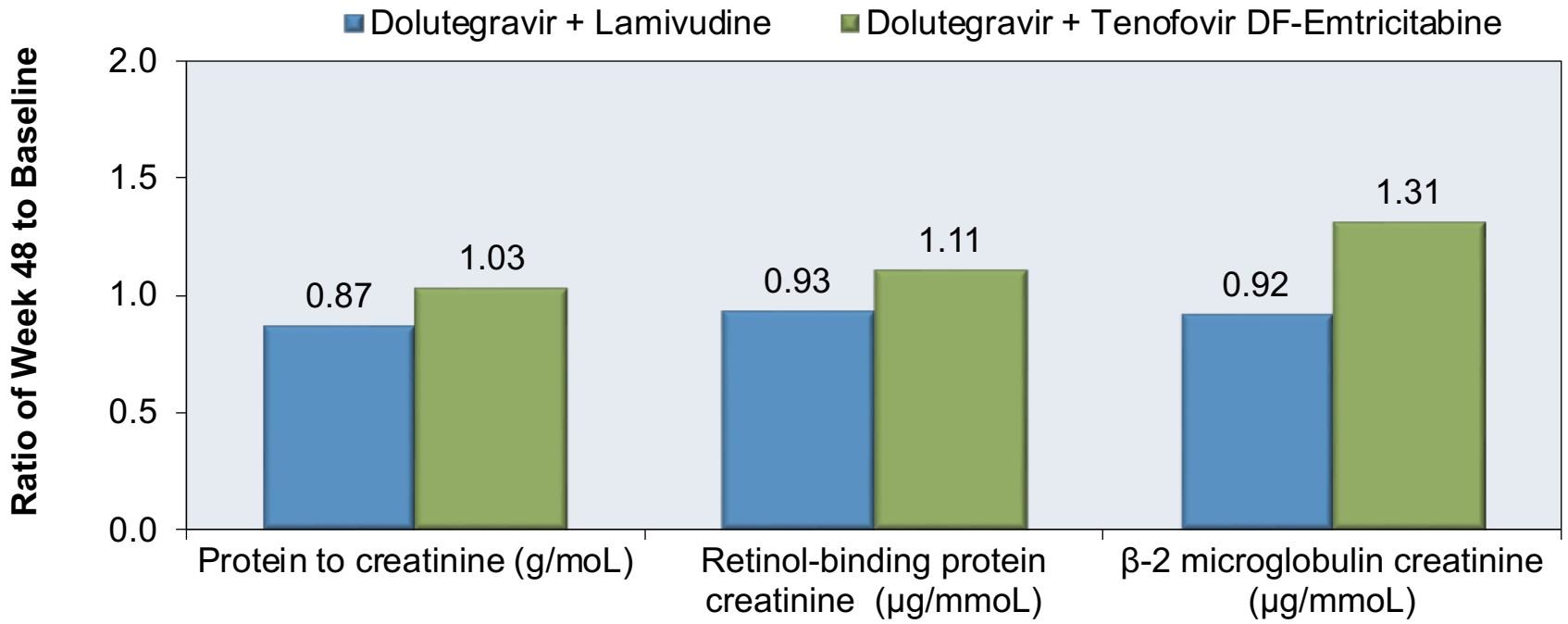
Week 48 Changes in Renal Function



Source: Cahn P, et al. Lancet. 2019;393:143-55.

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Results

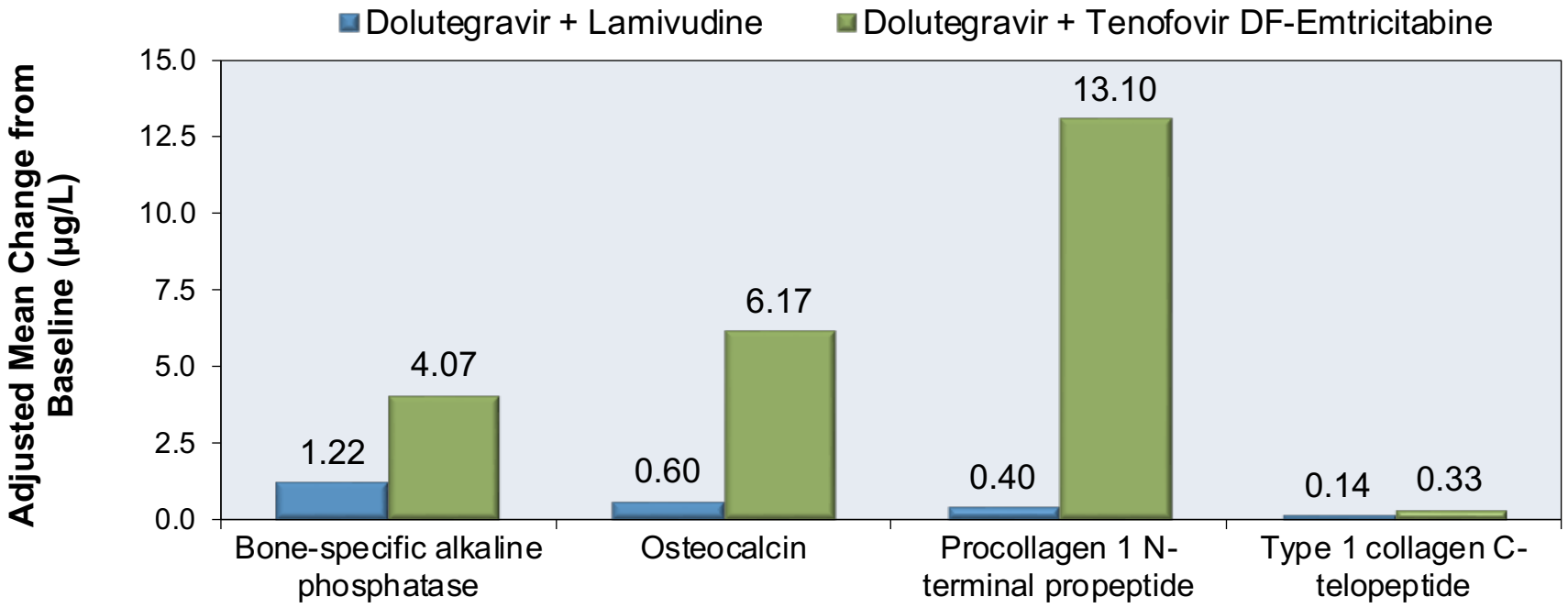
Week 48 Changes in Markers of Renal Proximal Tubulopathy



Source: Cahn P, et al. Lancet. 2019;393:143-55.

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Results

Week 48 Changes in Serum Bone Biomarkers



Source: Cahn P, et al. Lancet. 2019;393:143-55.

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Conclusions

Interpretation: “The non-inferior efficacy and similar tolerability profile of dolutegravir plus lamivudine to a guideline-recommended three-drug regimen at 48 weeks in ART-naive adults supports its use as initial therapy for patients with HIV-1 infection.”

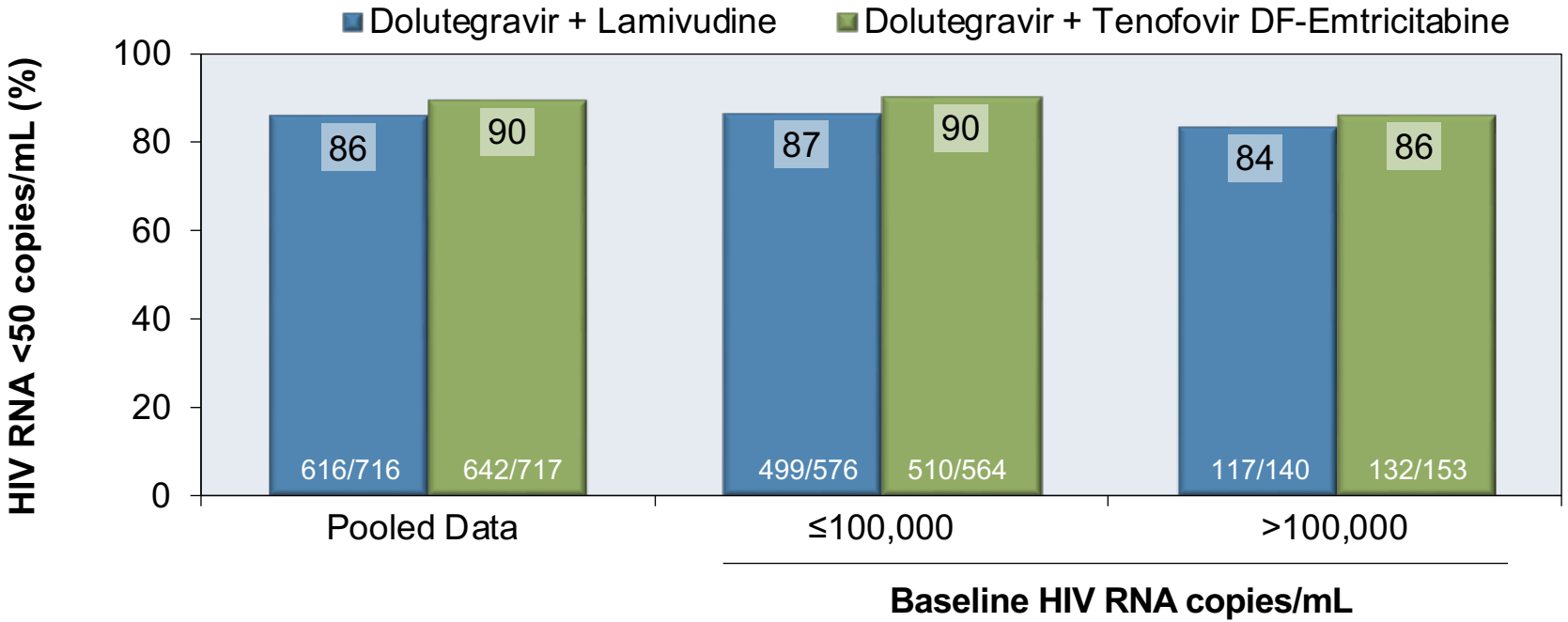
Source: Cahn P, et al. Lancet. 2019;393:143-55.

DTG + 3TC versus DTG + TDF-FTC as Initial ART

GEMINI 1 and GEMINI 2: Week 96 Data

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Results by Baseline HIV RNA Level

Week 96 Virologic Response (Intention-to-Treat Analysis)



Source: Cahn P, et al. J Acquir Immune Defic Syndrome. 2020;83:310-18.

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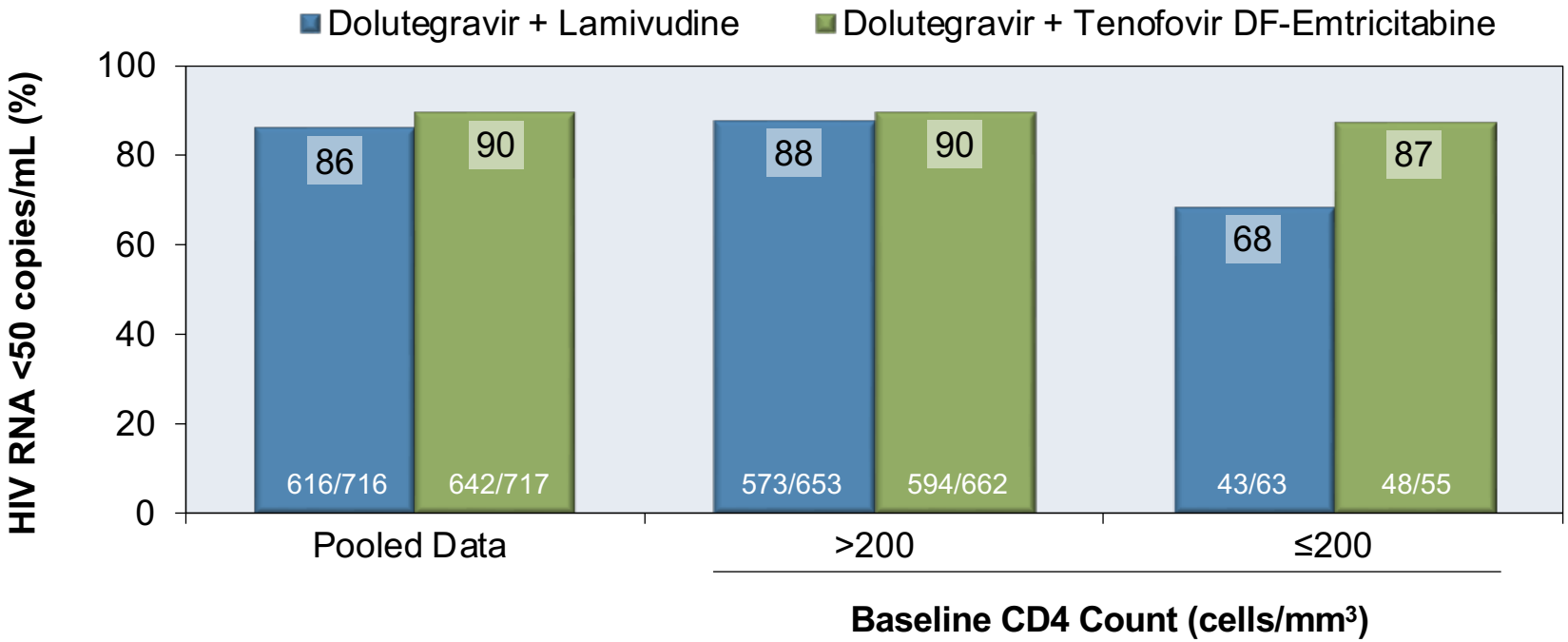
DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Results by Baseline CD4 Cell Count

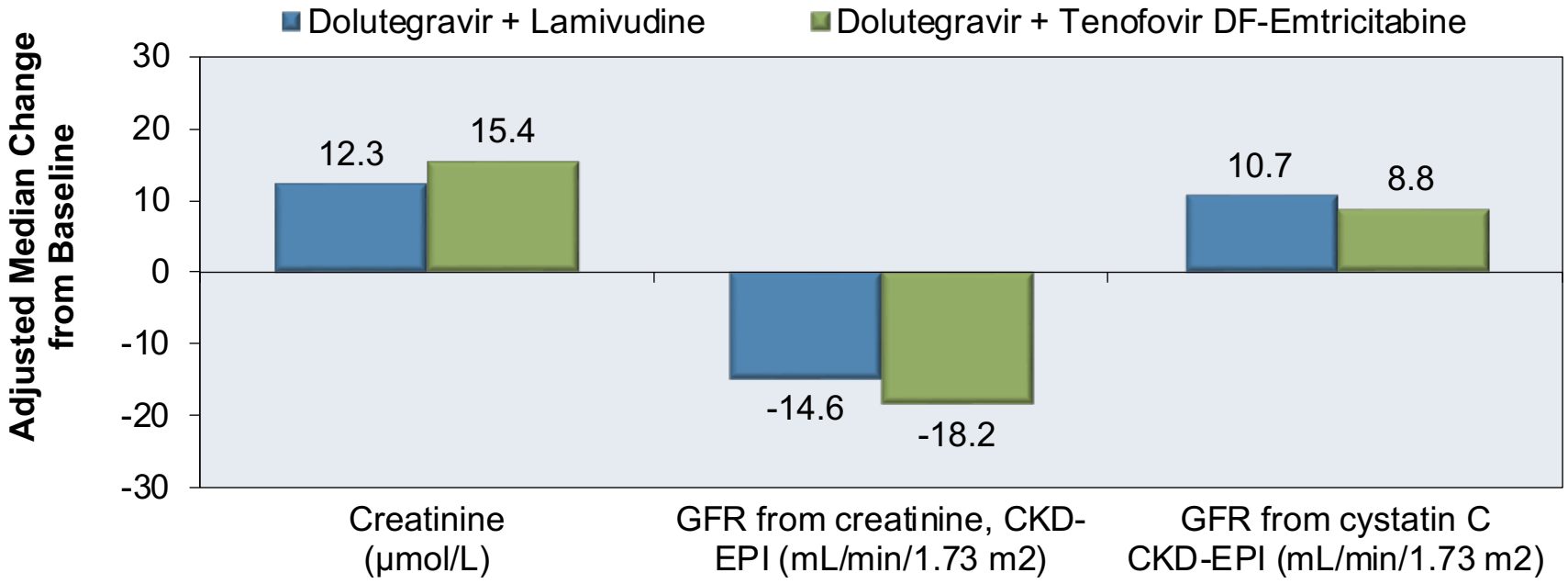
Week 96 Virologic Response (Intention-to-Treat Analysis)



Source: Cahn P, et al. J Acquir Immune Defic Syndrome. 2020;83:310-18.

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Results

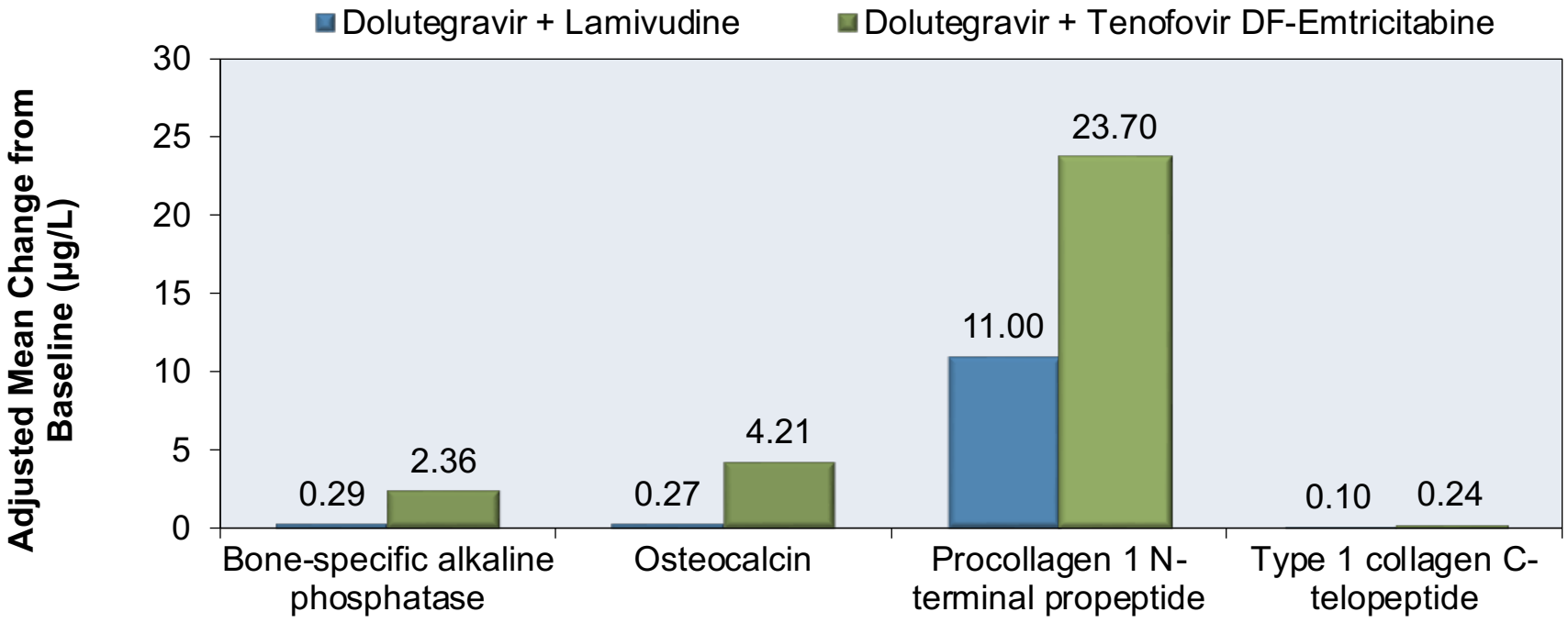
Week 96 Changes in Renal Function



Source: Cahn P, et al. J Acquir Immune Defic Syndrome. 2020;83:310-18.

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Results

Week 96 Changes in Serum Bone Biomarkers



Source: Cahn P, et al. J Acquir Immune Defic Syndrome. 2020;83:310-18.

DTG + 3TC versus DTG + TDF-FTC as Initial ART
GEMINI 1 and 2: Week 96 Conclusion

Conclusion: “Consistent with 48-week data, dolutegravir + lamivudine demonstrated long-term, non-inferior efficacy vs dolutegravir + tenofovir disoproxil fumarate/emtricitabine without increased risk of treatment emergent resistance, supporting its use in treatment-naive HIV-1–infected individuals.”

Source: Cahn P, et al. J Acquir Immune Defic Syndrome. 2020;83:310-18.

Acknowledgments

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AETC AIDS Education & Training Center Program

National HIV Curriculum

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