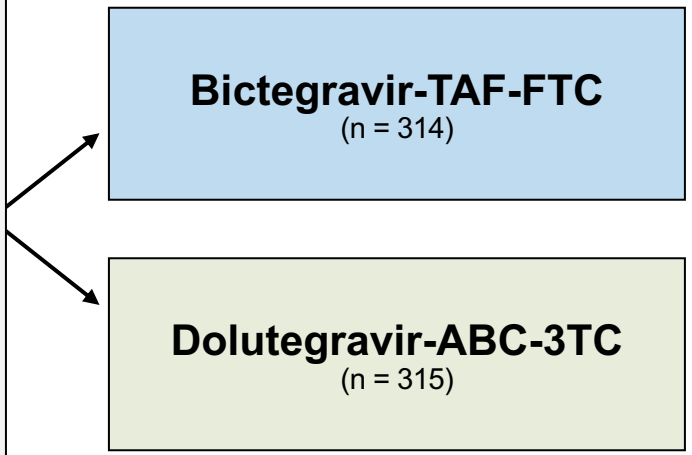
BIC-TAF-FTC vs. DTG-ABC-3TC as Initial Therapy

GS-380-1489: Week 48 Results

National HIV Curriculum

Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Design

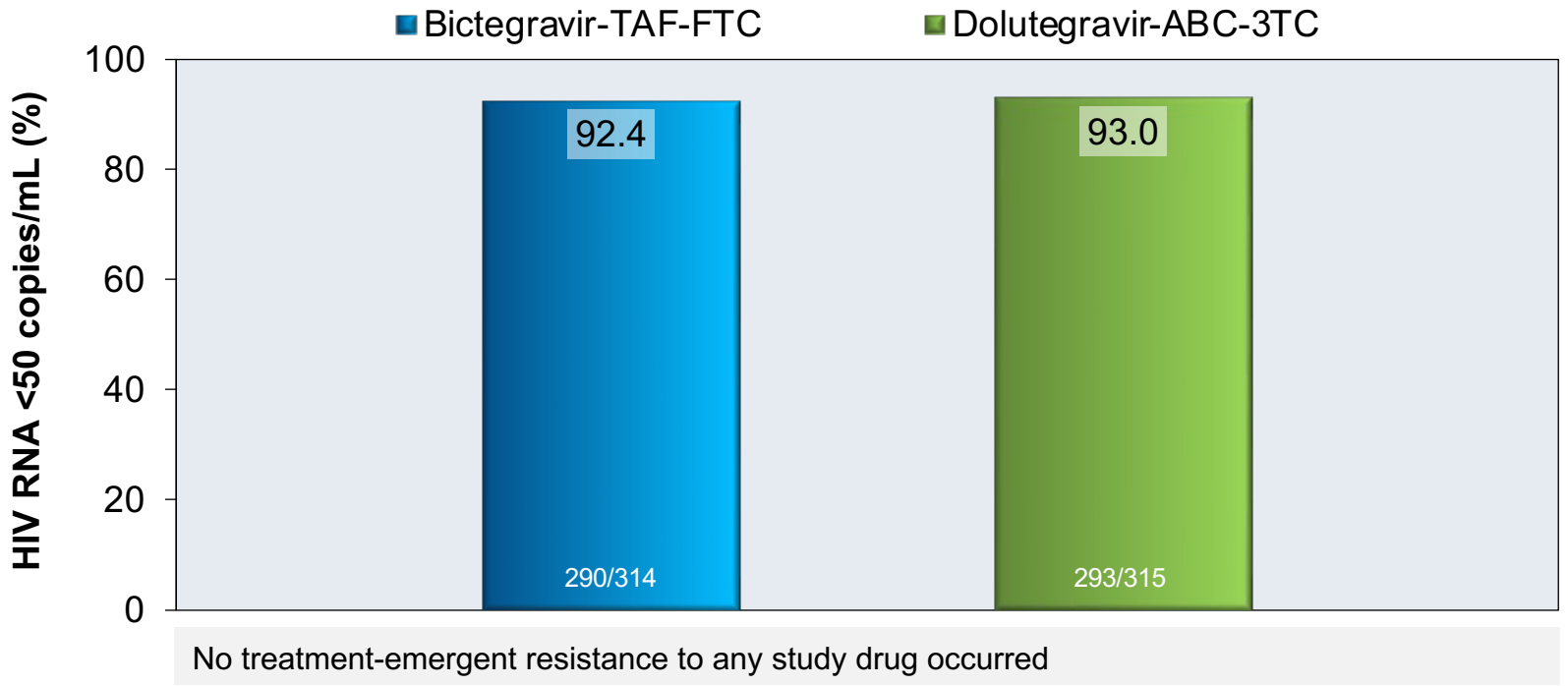
- **Design**
  - Randomized, double-blind, active-controlled, phase 3 study evaluating the efficacy and safety of bictegravir-tenofovir alafenamide-emtricitabine versus dolutegravir-abacavir-lamivudine for treatment-naïve adults with HIV
- **Including Criteria**
  - Age ≥18 years
  - Antiretroviral-naïve (or ≤10 days of treatment)
  - HIV RNA ≥500 copies/mL
  - eGFR ≥50 mL/min
  - HLA B*5701 negative
  - No chronic HBV infection



Source: Gallant J, et al. Lancet. 2017;390:2063-72.

Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Week 48 Results

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



No treatment-emergent resistance to any study drug occurred

Source: Gallant J, et al. Lancet. 2017;390:2063-72.

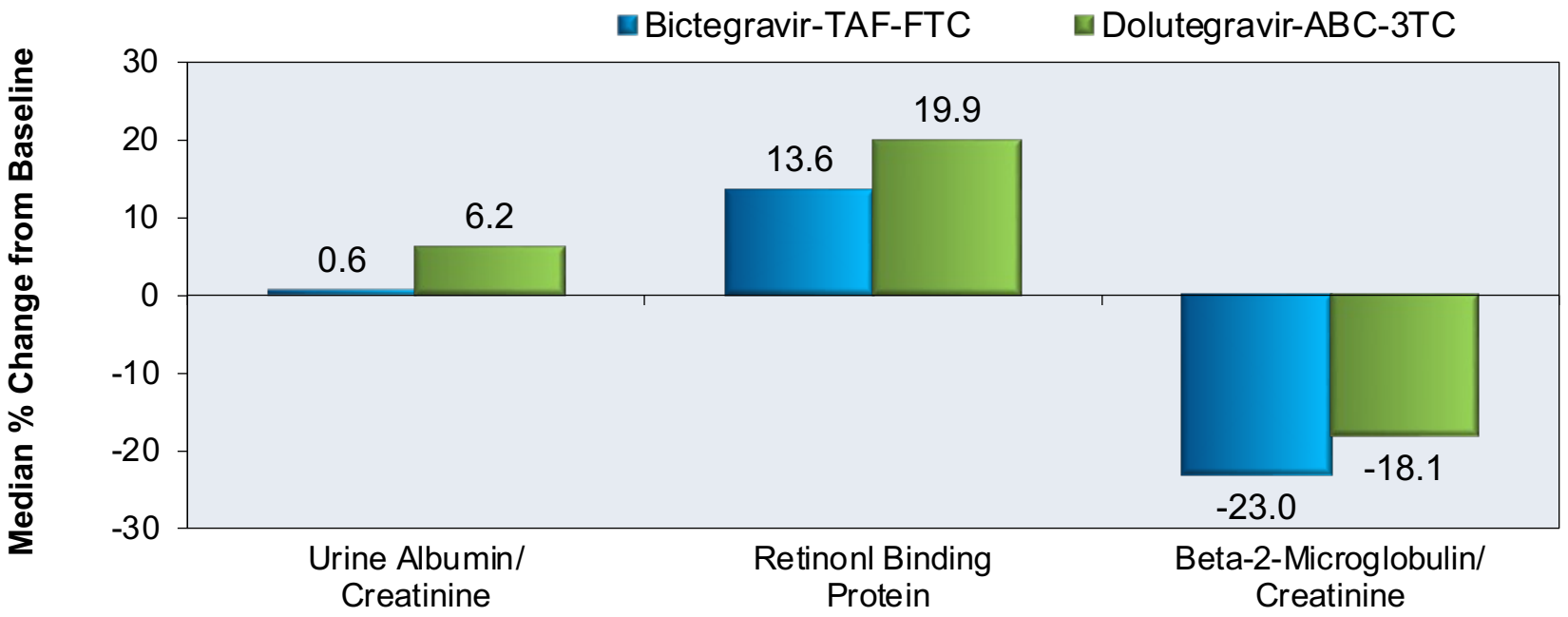
Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Adverse Effects

Treatment Emergent Adverse Events (AE's >5%) Through Week 48		
Adverse Effect	**BIC-TAF-FTC** (n = 314)	**DTG-ABC-3TC** (n = 315)
Diarrhea, %	13	13
Headache, %	11	14
Nausea, %	10	23
Fatigue, %	6	9
Arthralgia, %	4	6
Insomnia, %	4	6
Change in eGFR (mL/min)	-10.5	-10.8

Source: Gallant J, et al. Lancet. 2017;390:2063-72.

Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Adverse Effects

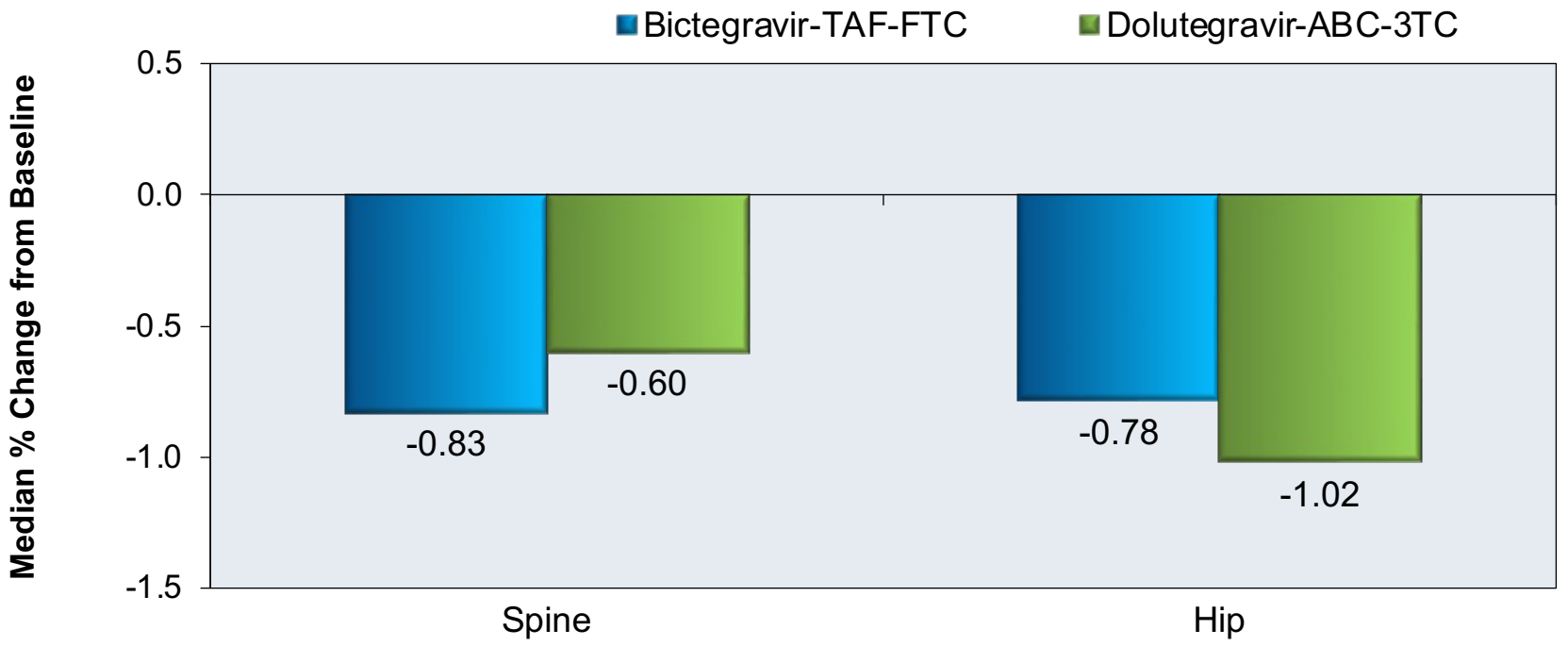
Change in Markers of Proximal Tubulopathy at 48 Weeks



Source: Gallant J, et al. Lancet. 2017;390:2063-72.

Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Adverse Effects

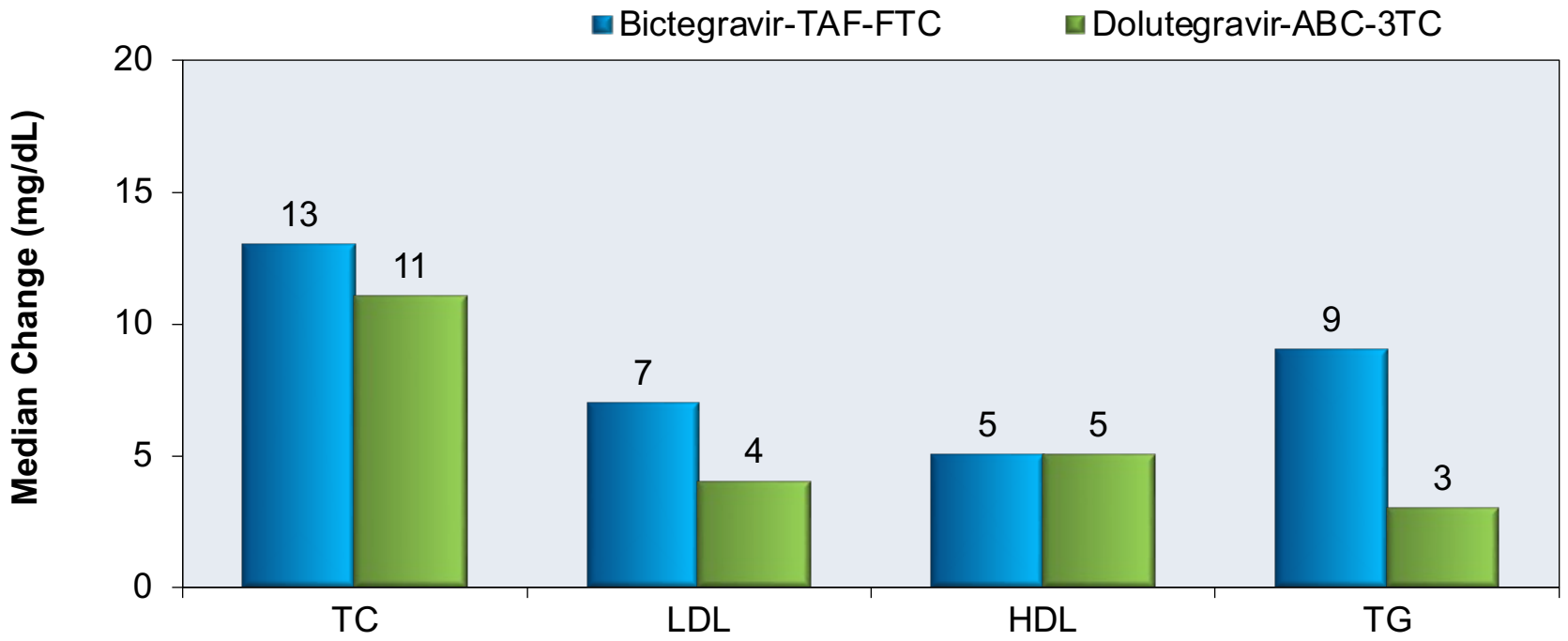
Change in Bone Mineral Density at 48 Weeks



Source: Gallant J, et al. Lancet. 2017;390:2063-72.

Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Results

Change in Lipids at 48 Weeks



Source: Gallant J, et al. Lancet. 2017;390:2063-72.

Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Conclusions

Interpretation: “At 48 weeks, coformulated bictegravir, emtricitabine, and tenofovir alafenamide achieved virological suppression in 92% of previously untreated adults and was non-inferior to coformulated dolutegravir, abacavir, and lamivudine, with no treatment-emergent resistance. Bictegravir, emtricitabine, and tenofovir alafenamide was safe and well tolerated with better gastrointestinal tolerability than dolutegravir, abacavir, and lamivudine. Because coformulated bictegravir, emtricitabine, and tenofovir alafenamide does not require HLA B*5701 testing and provides guideline-recommended treatment for individuals co-infected with HIV and hepatitis B, this regimen might lend itself to rapid or same-day initiation of therapy in the clinical setting.”

Source: Gallant J, et al. Lancet. 2017;390:2063-72.

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