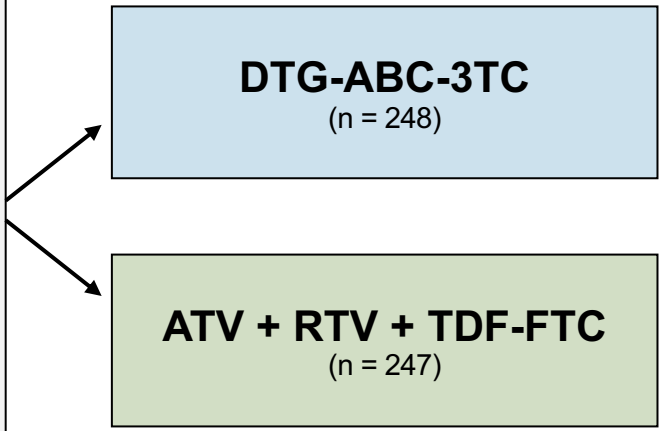
DTG-ABC-3TC versus ATV + RTV + TDF-FTC for Treatment-Naïve Women

ARIA

National HIV Curriculum

DTG-ABC-3TC vs. ATV +RTV + TDF-FTC for Treatment-Naïve Women
ARIA: Study Design

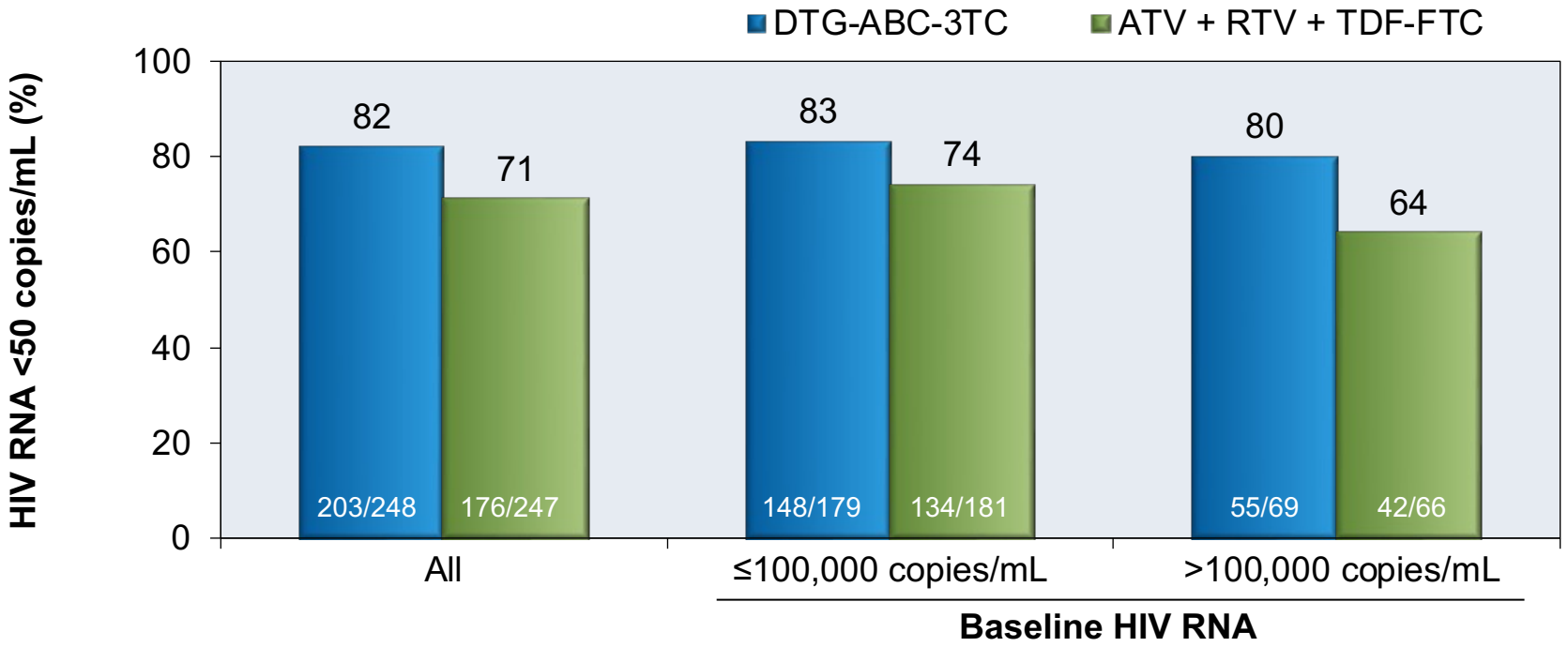
- **Background**: Phase 3b, randomized, open label, multicenter, active controlled, noninferiority trial in women
- **Inclusion Criteria** (n = 495 analyzed)
  - Age ≥18 years and assigned female sex at birth
  - HIV RNA ≥500 copies/mL
  - Received ≤10 days of ART prior to enrollment
  - HLA-B*5701 negative
  - Not pregnant
  - No hepatic impairment
  - Creatinine clearance ≥50 mL/min
  - No resistance to study drugs
- **Treatment Arms** (all meds given once daily)
  - Dolutegravir-abacavir-lamivudine (DTG-ABC-3TC)
  - Atazanavir (ATV) + ritonavir (RTV) + tenofovir DF-emtricitabine (TDF-FTC)



Source: Orrell C, et al. Lancet HIV. 2017;4:e536-46.

DTG-ABC-3TC vs. ATV +RTV + TDF-FTC for Treatment-Naïve Women ARIA: Results

Week 48 Virologic Response, by Baseline HIV RNA Level (Intention-to-Treat Analysis)



Source: Orrell C, et al. Lancet HIV. 2017;4:e536-46.

DTG-ABC-3TC vs. ATV +RTV + TDF-FTC for Treatment-Naïve Women ARIA: Results

Week 48 Snapshot Virologic Outcomes (Intention-to-Treat Analysis)

Snapshot Virologic Outcomes at 48 Weeks		
	DTG-ABC-3TC (n = 248)	**ATV + RTV + TDF-FTC** (n = 247)
Virologic success	82%	71%
Virologic failure	6%	14%
No virologic data	12%	15%

Source: Orrell C, et al. Lancet HIV. 2017;4:e536-46.

DTG-ABC-3TC vs. ATV +RTV + TDF-FTC for Treatment-Naïve Women ARIA: Results

Treatment Emergent Adverse Events (AEs)		
	DTG-ABC-3TC (n = 248)	**ATV + RTV + TDF-FTC** (n = 247)
Any AE	79%	80%
Drug-related AE	33%	49%
Psychiatric AE	14%	14%
Serious AE	5%	8%
Discontinuation due to AE	4%	7%

Source: Orrell C, et al. Lancet HIV. 2017;4:e536-46.

DTG-ABC-3TC vs. ATV +RTV + TDF-FTC for Treatment-Naïve Women ARIA: Results

Treatment Emergent Adverse Events (AEs)		
	DTG-ABC-3TC (n = 248)	**ATV + RTV + TDF-FTC** (n = 247)
Nausea	13%	14%
Diarrhea	5%	7%
Dyspepsia	2%	6%
Ocular icterus	0%	7%
Headache	2%	6%
Jaundice	0%	5%
Insomnia	4%	4%
Depression	2%	3%
Suicidal ideation	2%	1%

Source: Orrell C, et al. Lancet HIV. 2017;4:e536-46.

DTG-ABC-3TC vs. ATV +RTV + TDF-FTC for Treatment-Naïve Women
ARIA: Conclusions

Interpretation: “The non-inferior efficacy and similar safety profile of the dolutegravir combined regimen compared with the atazanavir regimen support the use of dolutegravir for HIV-1 infection in treatment-naive women.”

Source: Orrell C, et al. Lancet HIV. 2017;4:e536-46.

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