

ABC-3TC + LPV-RTV versus TDF-FTC + LPV-RTV  
**HEAT Trial**

# ABC-3TC + LPV-RTV versus TDF-FTC + LPV-RTV in Treatment Naïve HEAT: Study Design

## Study Design: HEAT

- **Background:** Randomized, double-blind, placebo-matched phase IV study comparing the efficacy, safety, and tolerability of abacavir-lamivudine versus tenofovir DF-emtricitabine in combination with lopinavir-ritonavir in treatment-naïve patients with HIV infection
- **Inclusion Criteria (n = 688)**
  - Age  $\geq 18$
  - Antiretroviral-naïve
  - HIV RNA  $\geq 1000$  copies/mL
  - No CD4 criteria, no HLA-B\*5701 screening done
- **Treatment Arms**
  - Abacavir-lamivudine + lopinavir-ritonavir BID
  - Tenofovir DF-emtricitabine + lopinavir-ritonavir BID

**ABC-3TC + LPV-RTV**  
(n = 343)

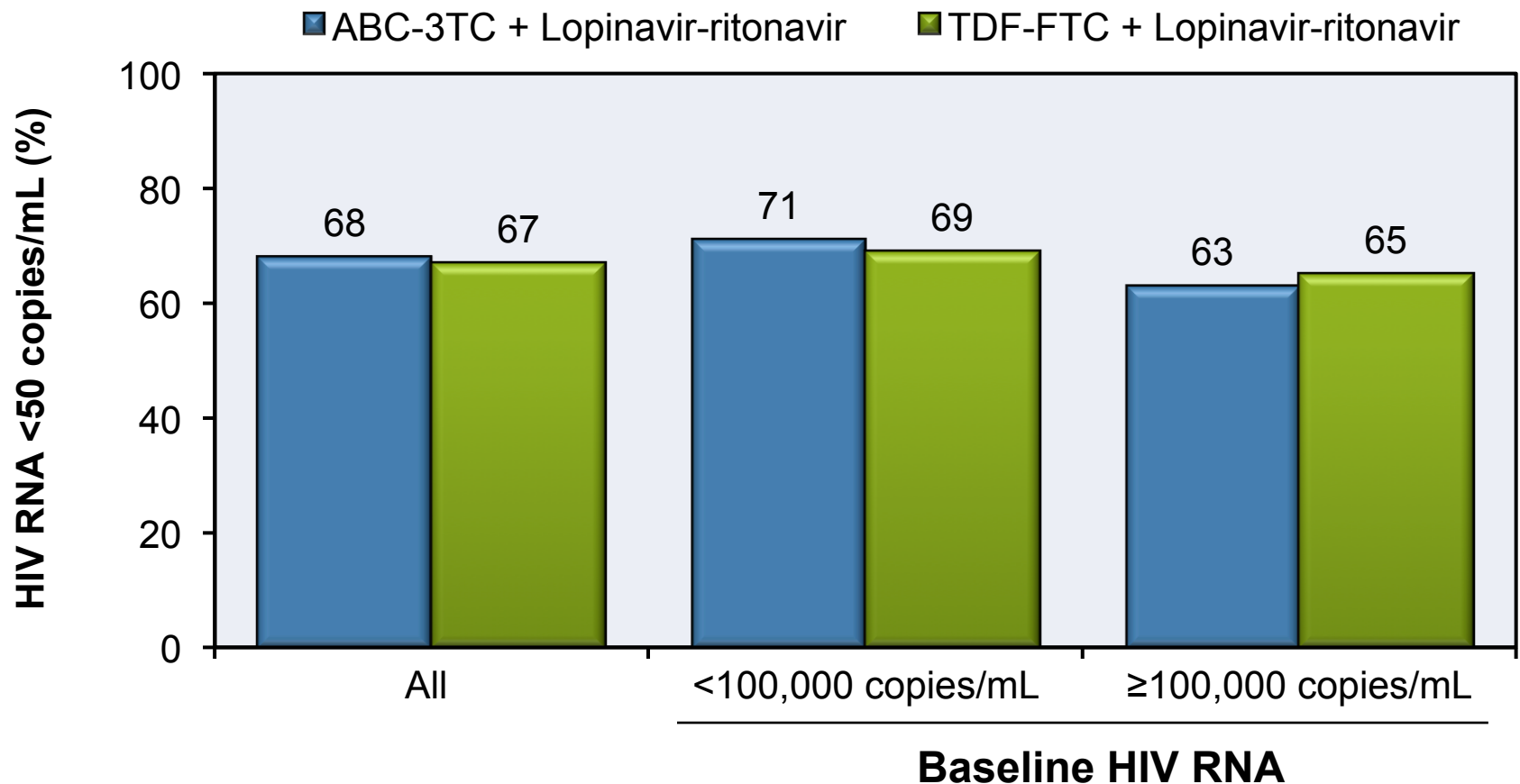
**TDF-FTC + LPV-RTV**  
(n = 345)

HEAT = HIV study with Epizicom And Truvada

Source: Smith KY, et al. AIDS. 2009;23(12):1547-56.

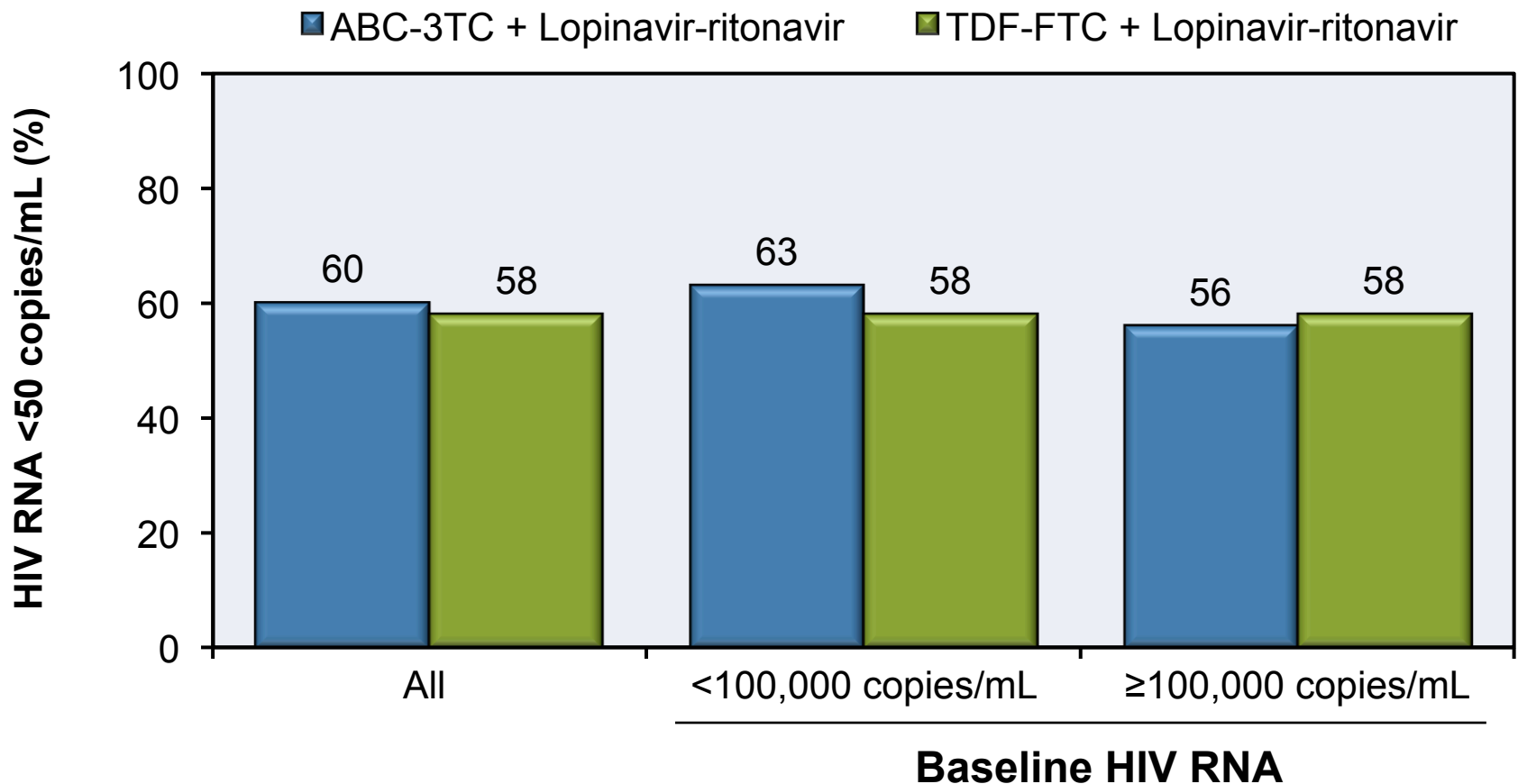
# ABC-3TC + LPV-RTV versus TDF-FTC + LPV-RTV in Treatment Naïve HEAT: Results

Week 48: Virologic Response (ITT, Missing=Failure)



# ABC-3TC + LPV-RTV versus TDF-FTC + LPV-RTV in Treatment Naïve HEAT: Results

Week 96: Virologic Response (ITT, Missing=Failure)



# ABC-3TC + LPV-RTV versus TDF-FTC + LPV-RTV in Treatment Naïve HEAT: Results

## Most Common Drug-Related Adverse Events (in at least 5% of patients and all serious adverse events reported by investigators)

Adverse Event	ABC-3TC + LPV/r (n = 343)	TDF-FTC + LPV/r (n = 345)
Any drug-related grade 2-3 AEs	50%	46%
Any drug-related grade 3-4 AEs	15%	15%
Serious drug-related AEs	5%	3%

## ABC-3TC vs. TDF-FTC, with Lopinavir-RTV in Treatment Naïve HEAT: Conclusion

**Conclusion:** “Both ABC/3TC and TDF/FTC provided comparable antiviral efficacy, safety, and tolerability when each was combined with lopinavir/ritonavir in treatment-naïve patients.”

# Acknowledgment

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*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*

