

Raltegravir vs Darunavir/r vs Atazanavir/r  
**ARDENT (ACTG 5257) Trial**

# Raltegravir vs Darunavir/r vs Atazanavir/r ARDENT (ACTG 5257): Study Design

## Study Design: ARDENT (ACTG 5257)

- **Background:** Open-label, randomized, phase 3 trial evaluating virologic efficacy and tolerability of 3 NNRTI-sparing antiretroviral therapy regimens for persons with HIV.
- **Inclusion Criteria (n = 1809)**
  - Age ≥18 years
  - Antiretroviral-naïve
  - CD4 >200 cells/mm<sup>3</sup>
  - HIV RNA >1,000 copies/mL
  - No resistance to NRTIs or PIs
- **Treatment Arms**
  - ATZ 300 mg + RTV 100 mg + TDF-FTC
  - RAL 400 mg BID + TDF-FTC
  - DRV 800 mg + RTV 100 mg + TDF-FTC

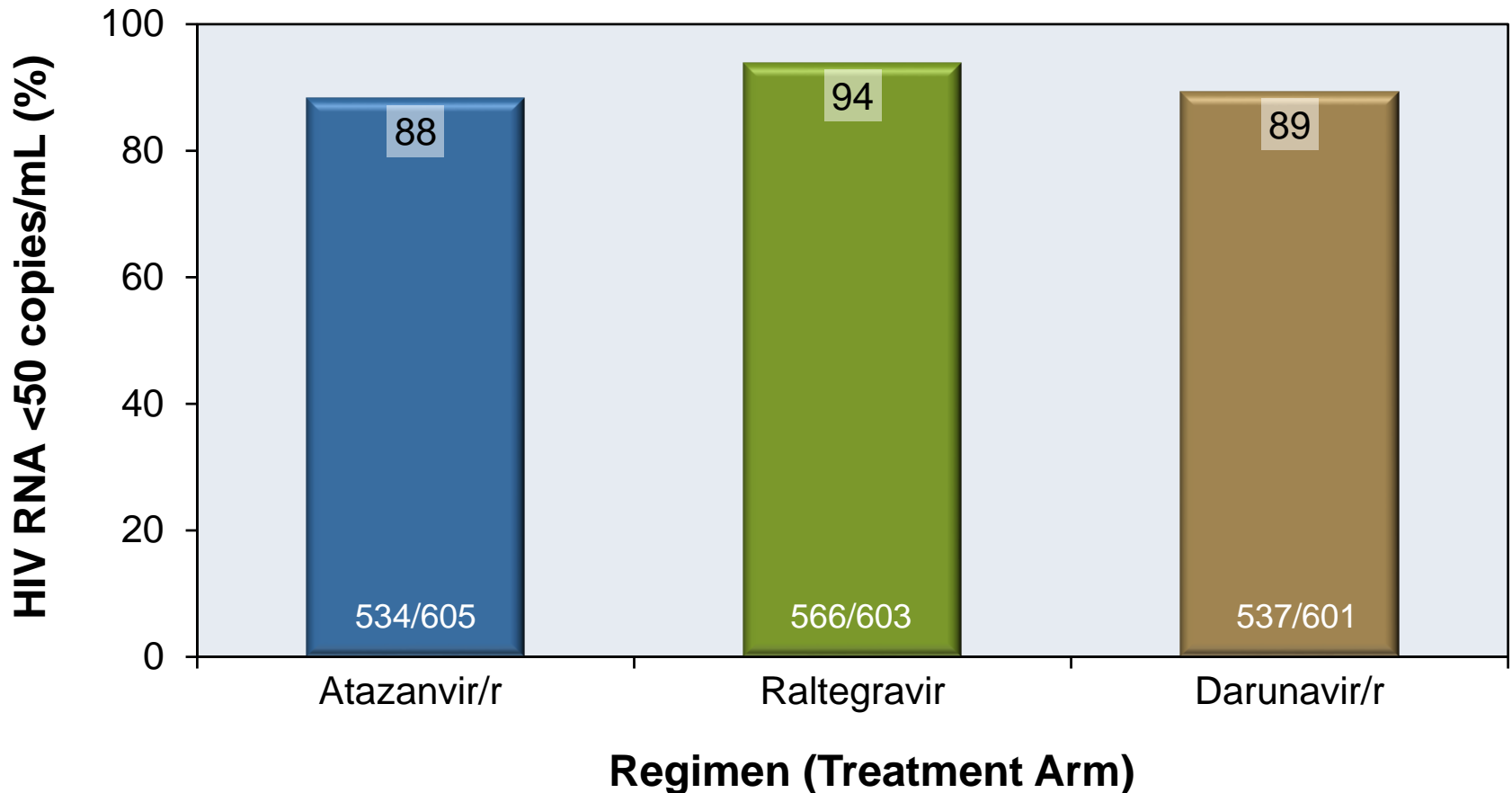
**Atazanavir 300 mg QD +  
RTV 100 mg QD + TDF-FTC QD**  
(n = 605)

**Raltegravir 400 mg BID +  
TDF-FTC QD**  
(n = 603)

**Darunavir 800 mg QD +  
RTV 100 mg QD + TDF-FTC QD**  
(n = 601)

# Raltegravir vs Darunavir/r vs Atazanavir/r ARDENT (ACTG 5257): Results

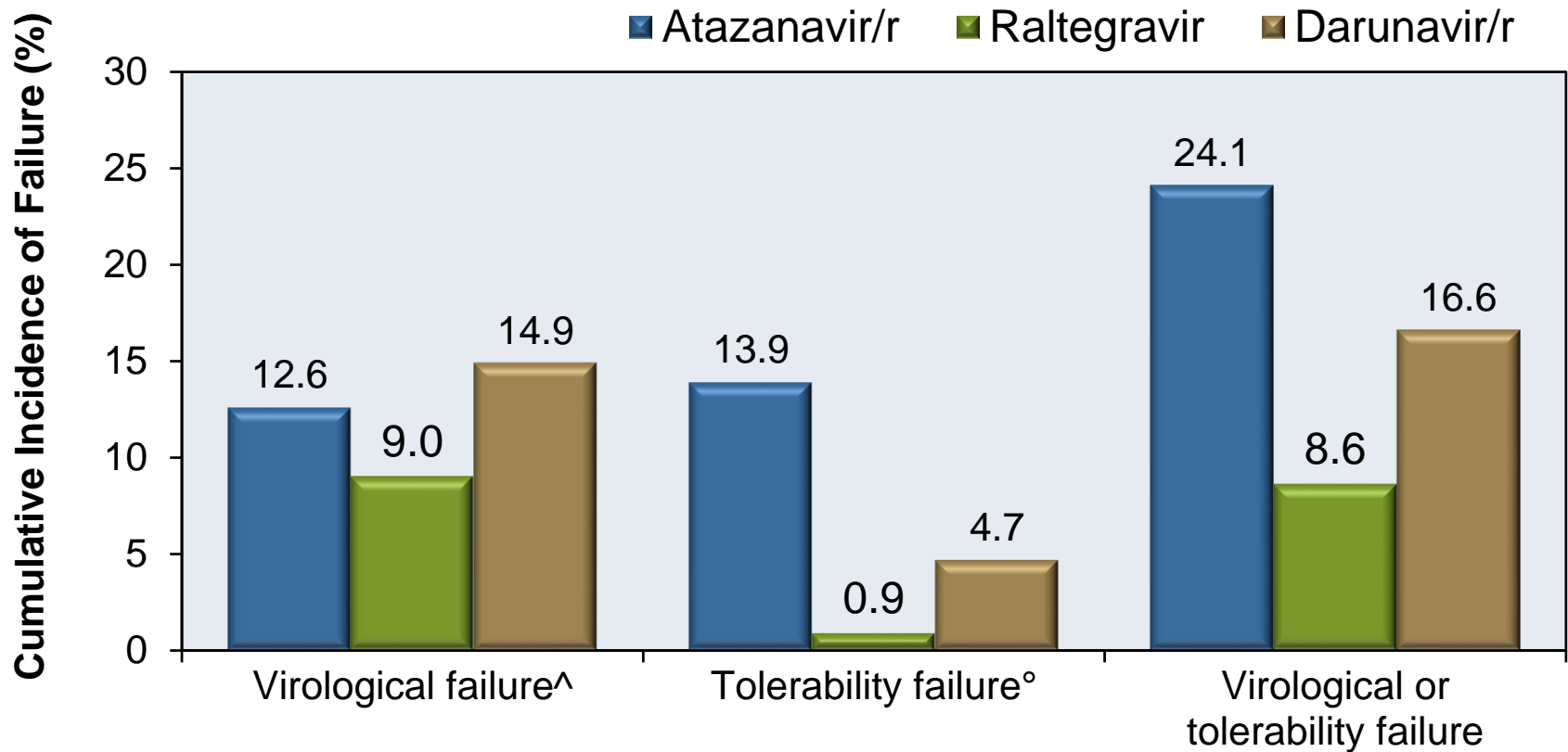
Week 96: Virologic Response (ITT analysis)



Source: Lennox JL, et al. Ann Intern Med. 2014;161:461-71.

# Raltegravir vs Darunavir/r vs Atazanavir/r ARDENT (ACTG 5257): Results

Week 96: Virologic and Tolerability Failures



<sup>^</sup>Virological failure: HIV RNA >1,000 copies/mL after 16 weeks or >200 copies/mL after 24 weeks

<sup>°</sup>Tolerability failure: discontinuation of raltegravir, darunavir/r, or atazanavir/r for toxicity

Source: Lennox JL, et al. *Ann Intern Med.* 2014;161:461-71.

# Raltegravir vs Darunavir/r vs Atazanavir/r ARDENT (ACTG 5257): Results

<b>Genotype Resistance Testing in ACTG 5257</b>			
<b>Variable</b>	<b>Atazanavir/r</b>	<b>Raltegravir</b>	<b>Darunavir/r</b>
Virologic failure (n)	95	85	115
Genotype testing complete	75	65	99
Any resistance	9	18	4
PI resistance	0	0	0
NRTI-only resistance	8	7	3
FTC	5	7	3
TDF	2	0	0
TDF and FTC	1	0	0
INSTI-only resistance	1	1	1
NRTI and INSTI resistance	0	10	0
RAL and FTC	0	7	0
RAL, TDF and FTC	0	3	0

Source: Lennox JL, et al. Ann Intern Med. 2014;161:461-71.

# Raltegravir vs Darunavir/r vs Atazanavir/r ARDENT (ACTG 5257): Conclusions

**Conclusion:** “Over 2 years, all 3 regimens attained high and equivalent rates of virologic control. Tolerability of regimens containing raltegravir or ritonavir-boosted darunavir was superior to that of the ritonavir-boosted atazanavir regimen.”

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