

Switch from Protease Inhibitor to Raltegravir  
**SPIRAL Trial**

# Switch from Protease Inhibitor to Raltegravir SPIRAL Trial: Study Design

## Study Design: SPIRAL

- **Background:** Randomized, open-label trial evaluating switch from a ritonavir-boosted protease inhibitor to raltegravir in persons with HIV.
- **Inclusion Criteria (n = 273)**
  - Age  $\geq 18$  years
  - HIV RNA  $< 50$  copies/mL for  $\geq 6$  months
  - No prior raltegravir treatment
- **Treatment Arms\***
  - Raltegravir 400 mg BID + background therapy
  - Ritonavir-boosted protease inhibitor + background therapy

*Switch Arm*  
**Raltegravir 400 mg BID**  
(n = 139)

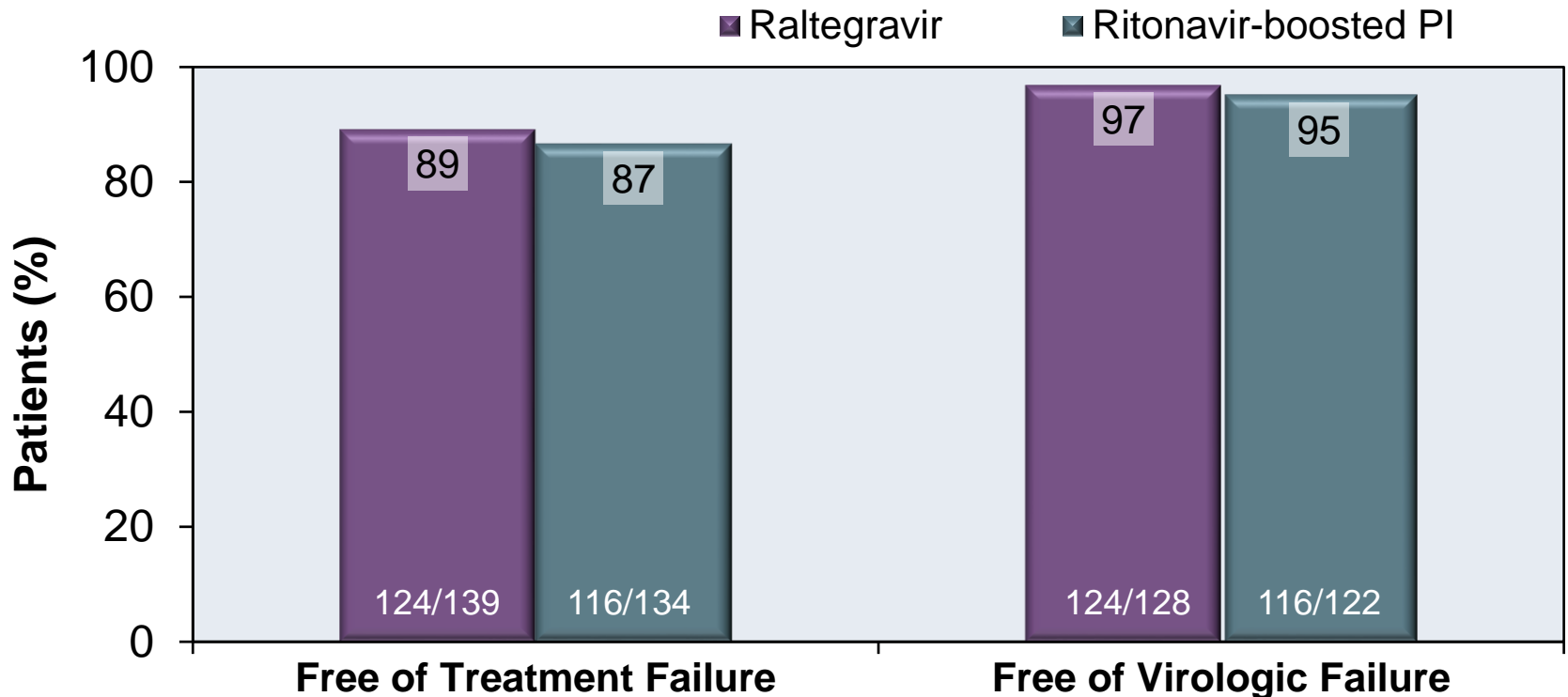
*Continuation Arm*  
**Ritonavir-boosted PI**  
(n = 134)

\*Background therapy in both groups included at least 2 additional ARVs

Source: Martinez E, et al. AIDS. 2010;24:1697-1707.

# Switch from Protease Inhibitor to Raltegravir SPIRAL Trial: Results

Week 48: Free of Treatment Failure and Virologic Failure



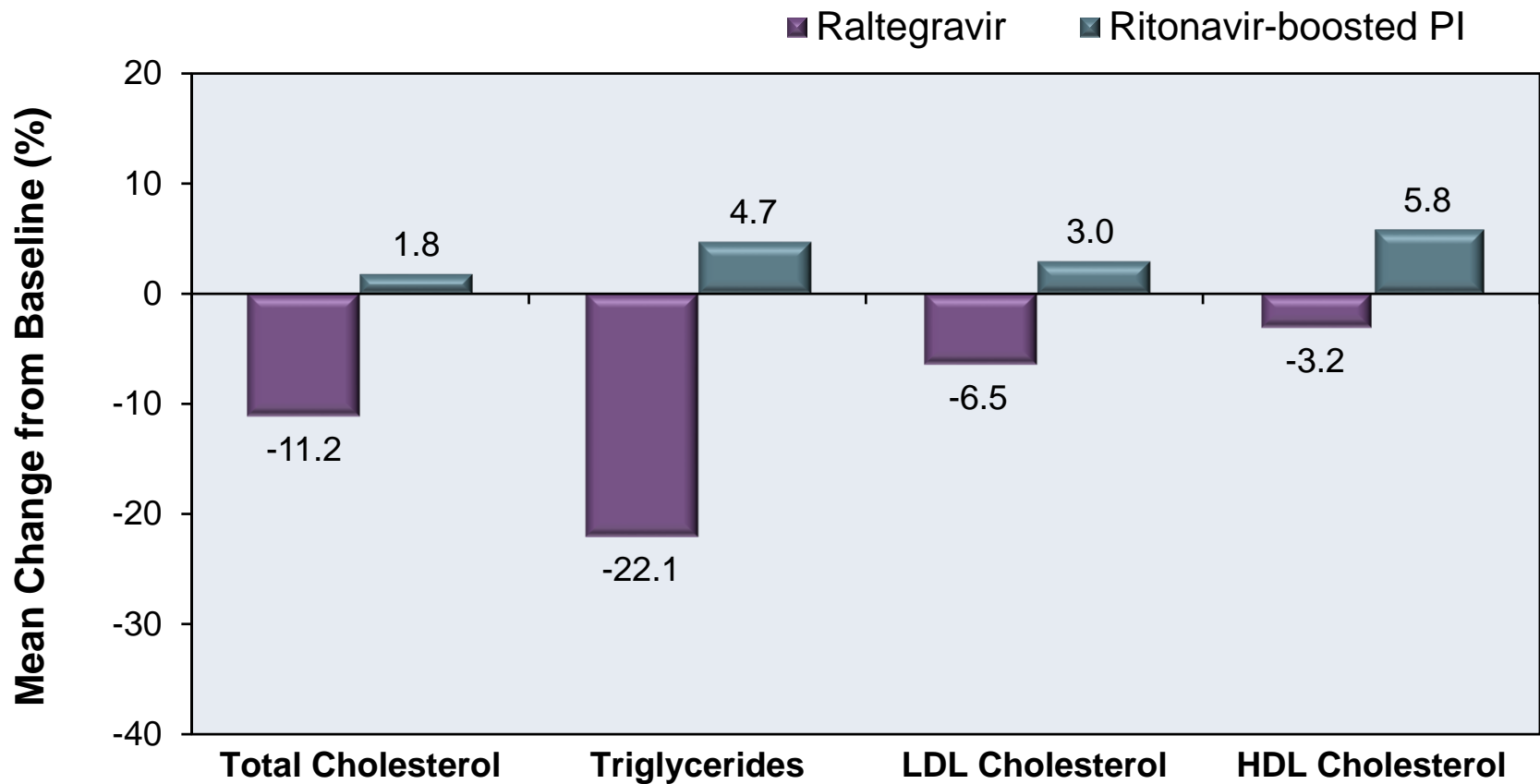
\*Treatment failure: virologic failure, withdrawal of consent, discontinuation, loss to follow-up, progression to AIDS, or death.

Source: Martinez E, et al. AIDS. 2010;24:1697-1707.

# Switch from Protease Inhibitor to Raltegravir

## SPIRAL: Result

Week 48: Analysis of Lipids



Source: Martinez E, et al. AIDS. 2010;24:1697-1707.

# Switch from Protease Inhibitor to Raltegravir SPIRAL Trial: Conclusions

**Conclusion:** “In patients with sustained virological suppression on ritonavir-boosted protease inhibitor-based therapy, switching from ritonavir-boosted protease inhibitor to raltegravir demonstrated noninferior efficacy and resulted in a better lipid profile at 48 weeks than continuing ritonavir-boosted protease inhibitor.”

# Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

*The content in this presentation 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.*

