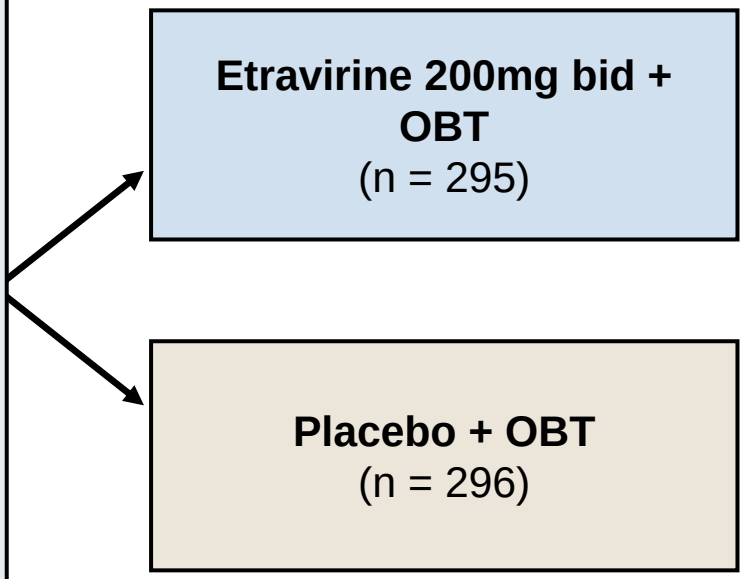
Etravirine in Treatment Experienced

DUET-2 (TMC125-C216)

Etravirine in Treatment Experienced
DUET-2: Study Design

Study Design: DUET-2

- **Background**: Randomized, controlled, double-blind, placebo-controlled phase 3 trial evaluating the long-term efficacy, tolerability, and safety of etravirine in treatment-experienced adults with HIV
- **Inclusion Criteria (n = 591)**
  - Age ≥18 years
  - On stable ARV regimen for ≥8 weeks
  - HIV RNA >5000 copies/mL
  - ≥3 primary PI mutations
  - ≥1 NNRTI resistance-associated mutation
- **Treatment Arms**
  - Etravirine 200 mg BID + OBT*
  - Placebo + OBT*

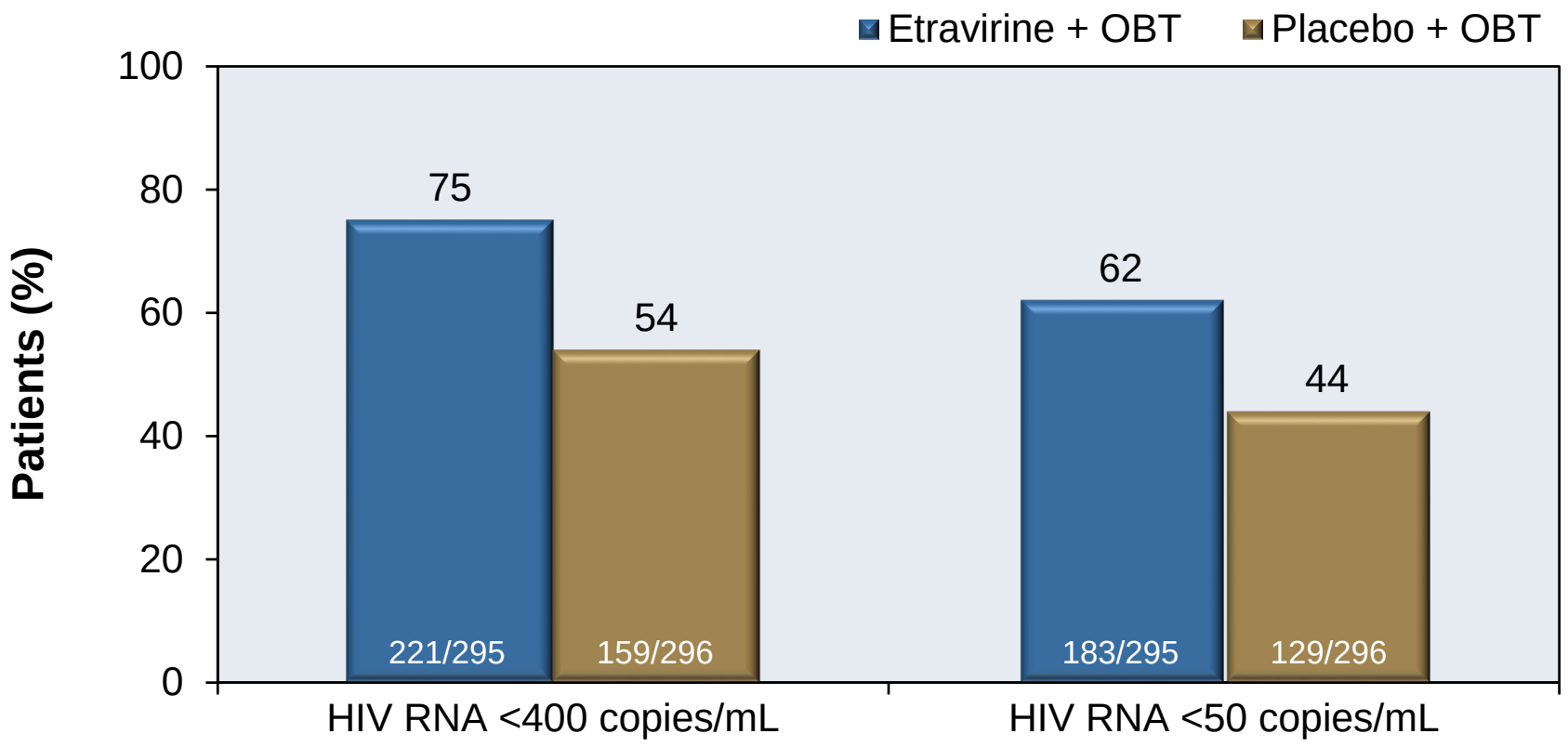


*OBT = NRTIs, Darunavir/r, +/- Enfuvirtide

Source: Lazzarin A, et al. Lancet. 2007;370:39-48.

Etravirine in Treatment Experienced
DUET-2: Results

Week 24: Virologic Response (ITT-TLOVR*)



*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.

Source: Lazzarin A, et al. Lancet. 2007;370:39-48.

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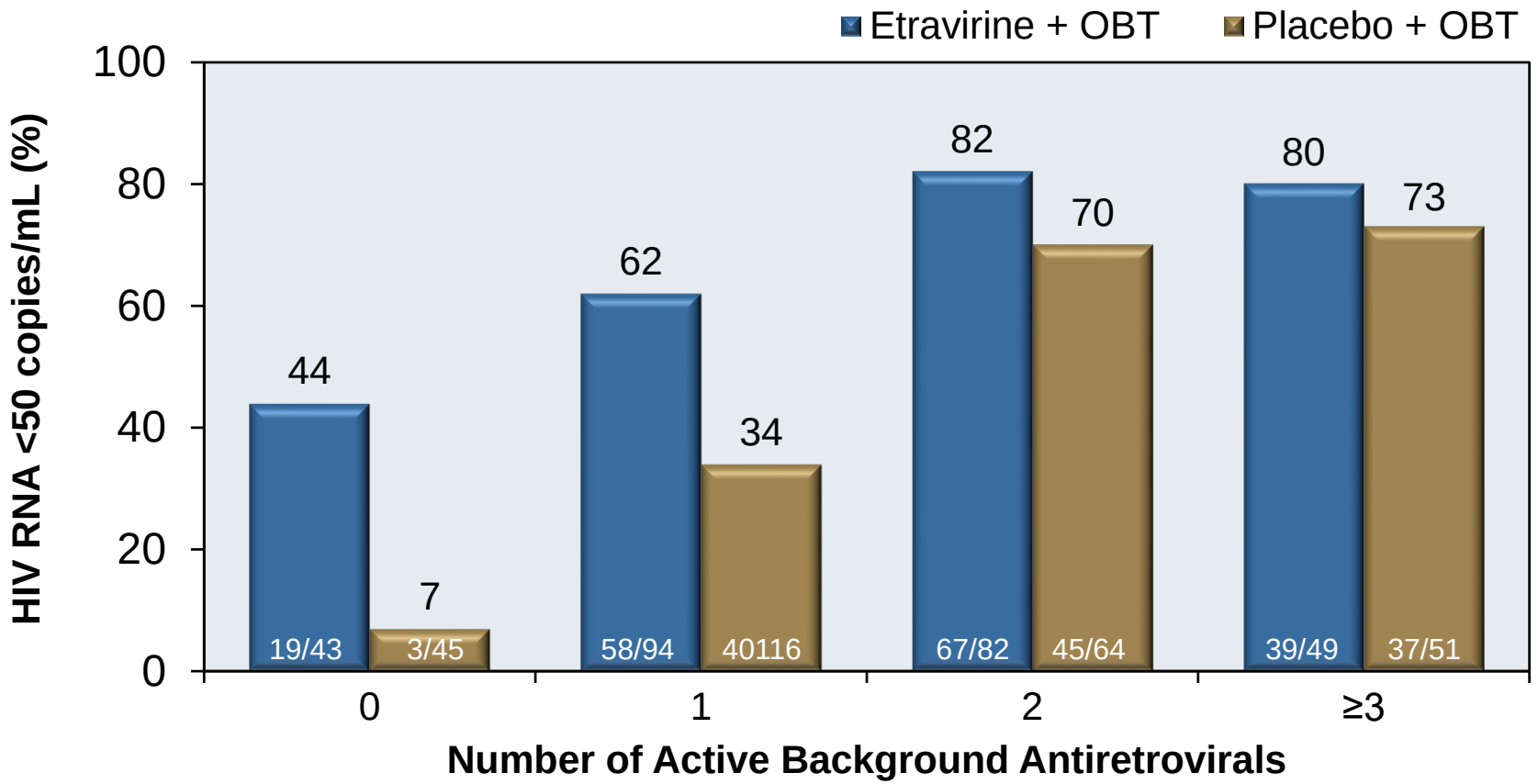
DUET-2: Results

Week 24: Virologic Response (ITT-TLOVR*)



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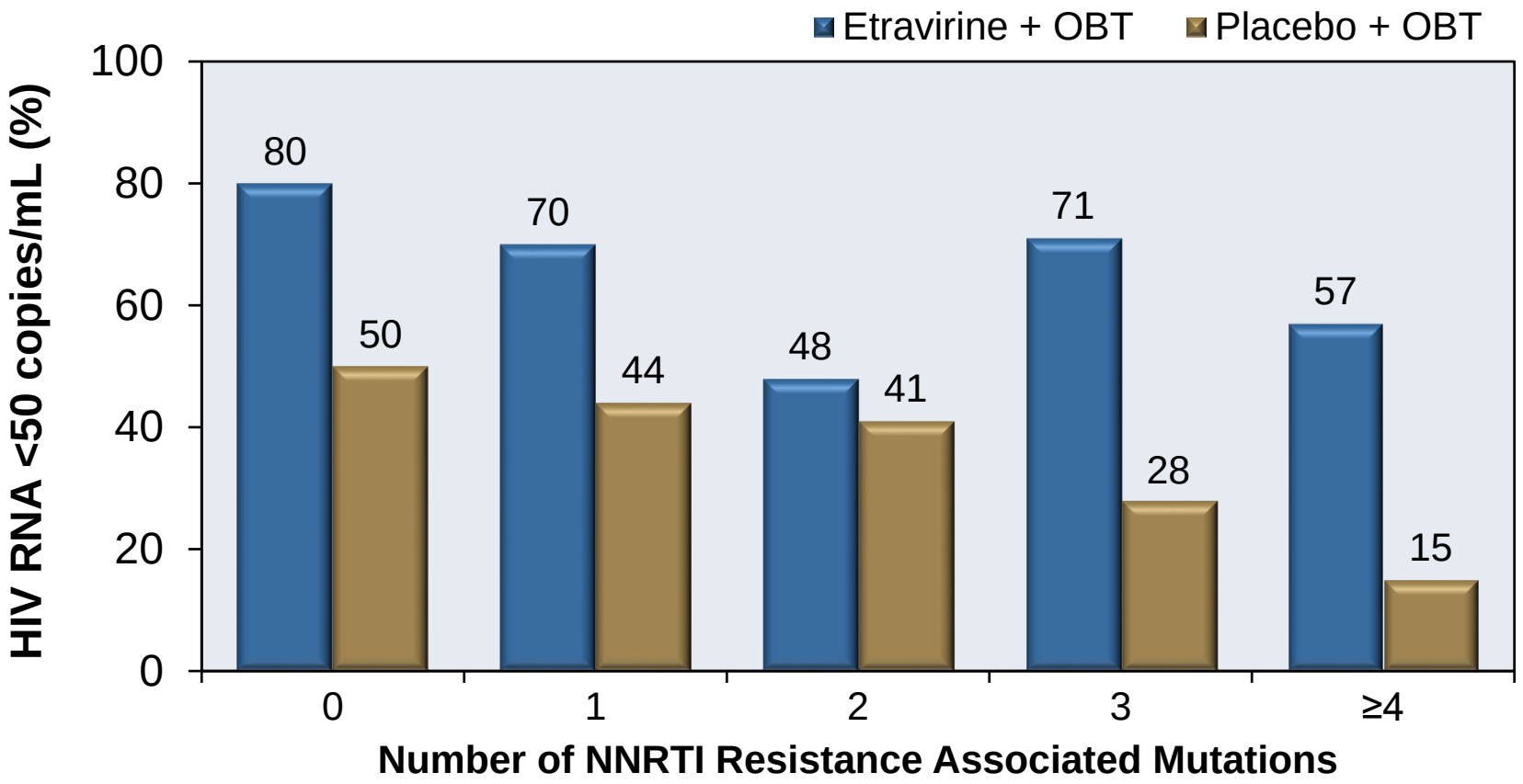
Etravirine in Treatment Experienced
DUET-2: Results

Week 24: Virologic Response (ITT-TLOVR*) in Patients Re-using or Not Using Enfuvirtide



*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.

Source: Lazzarin A, et al. Lancet. 2007;370:39-48.

DUET-2: Conclusions

Interpretation: “In treatment-experienced patients, treatment with TMC125 (etravirine) led to better virological suppression at week 24 than did placebo. The safety and tolerability profile of TMC125 (etravirine) was generally comparable with placebo.”

Source: Lazzarin A, et al. Lancet. 2007;370:39-48.

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.

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