

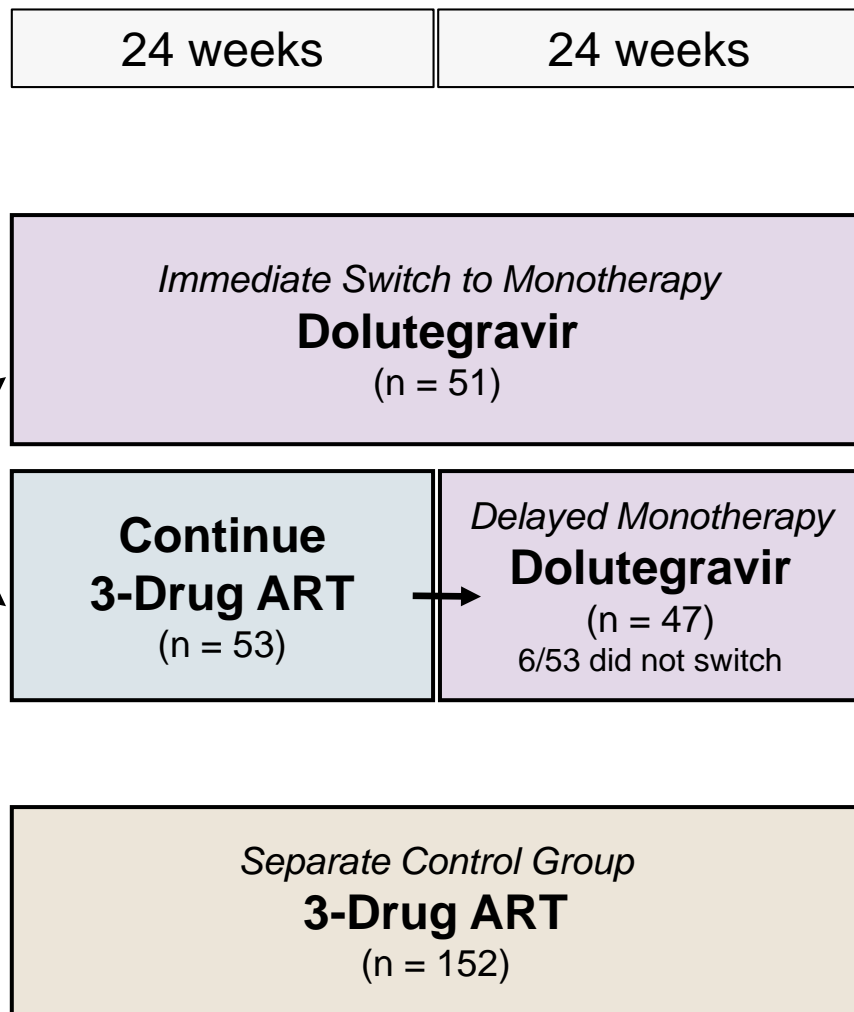
Dolutegravir as Maintenance Monotherapy  
**DOMONO**

# Dolutegravir as Maintenance Monotherapy

## DOMONO: Design

### Study Design: DOMONO

- **Background:** Randomized, open-label, phase 2, non-inferiority trial conducted at 2 centers in Netherlands to determine if dolutegravir monotherapy is noninferior to combination antiretroviral therapy in maintaining viral suppression.
- **Inclusion Criteria:**
  - Age  $\geq 18$  years old
  - On 3-drug ART
  - HIV RNA  $< 50$  copies/mL for  $\geq 6$  months
  - HIV RNA zenith  $< 100,000$  copies/mL
  - CD4 count nadir  $> 200$  cells/mm<sup>3</sup>
  - No baseline HIV drug resistance
  - No history of virologic failure
  - No HBV co-infection
- **Dolutegravir Regimen**
  - Dolutegravir 50 mg once daily



# Dolutegravir as Maintenance Monotherapy

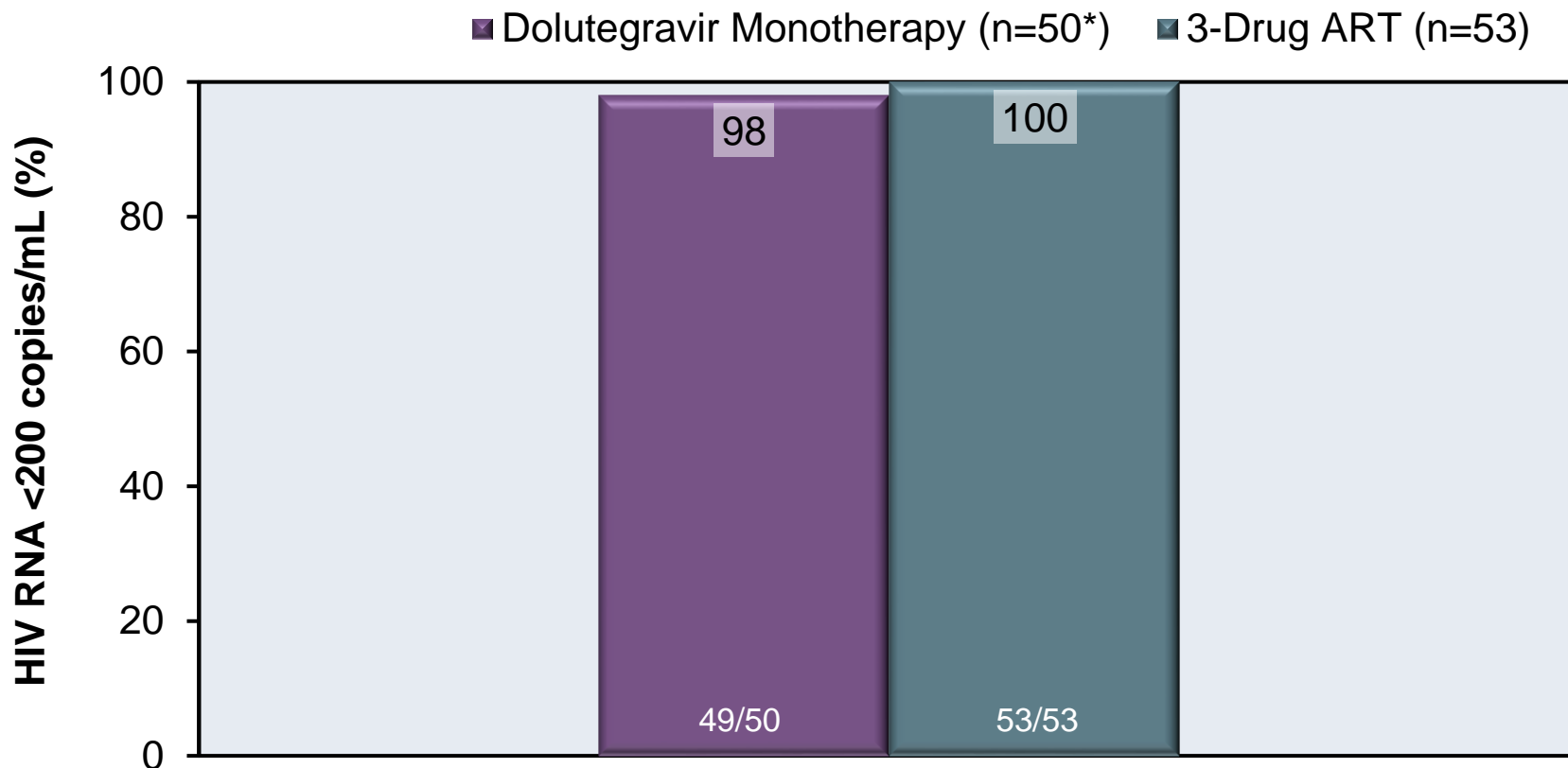
## DOMONO: Baseline Characteristics

Baseline Characteristic	Immediate Switch to DTG Monotherapy (n = 51)	Delayed Switch to DTG Monotherapy (n = 53)
Age (median, years)	46	45
Male, %	47	48
MSM, %	80	77
Caucasian ethnicity, %	86	79
On TDF before switch, %	86	85
On NNRTI + 2 NRTI's before switch, %	80	81
On PI + 2 NRTI's before switch, %	4	2
On INSTI + 2 NRTI's before switch, %	14	17
Receiving a STR before switch, %	63	77
Time on ART (median, months)	35	43
HIV RNA zenith (median, copies/mL)	29,300	44,877
CD4 T-cell nadir (median, cells/mm <sup>3</sup> )	320	380

Source: Wijting I, et al. *Lancet HIV*. 2017;4:e547-54.

# Dolutegravir as Maintenance Monotherapy DOMONO: 24-Week Results

## Week 24 Virologic Suppression

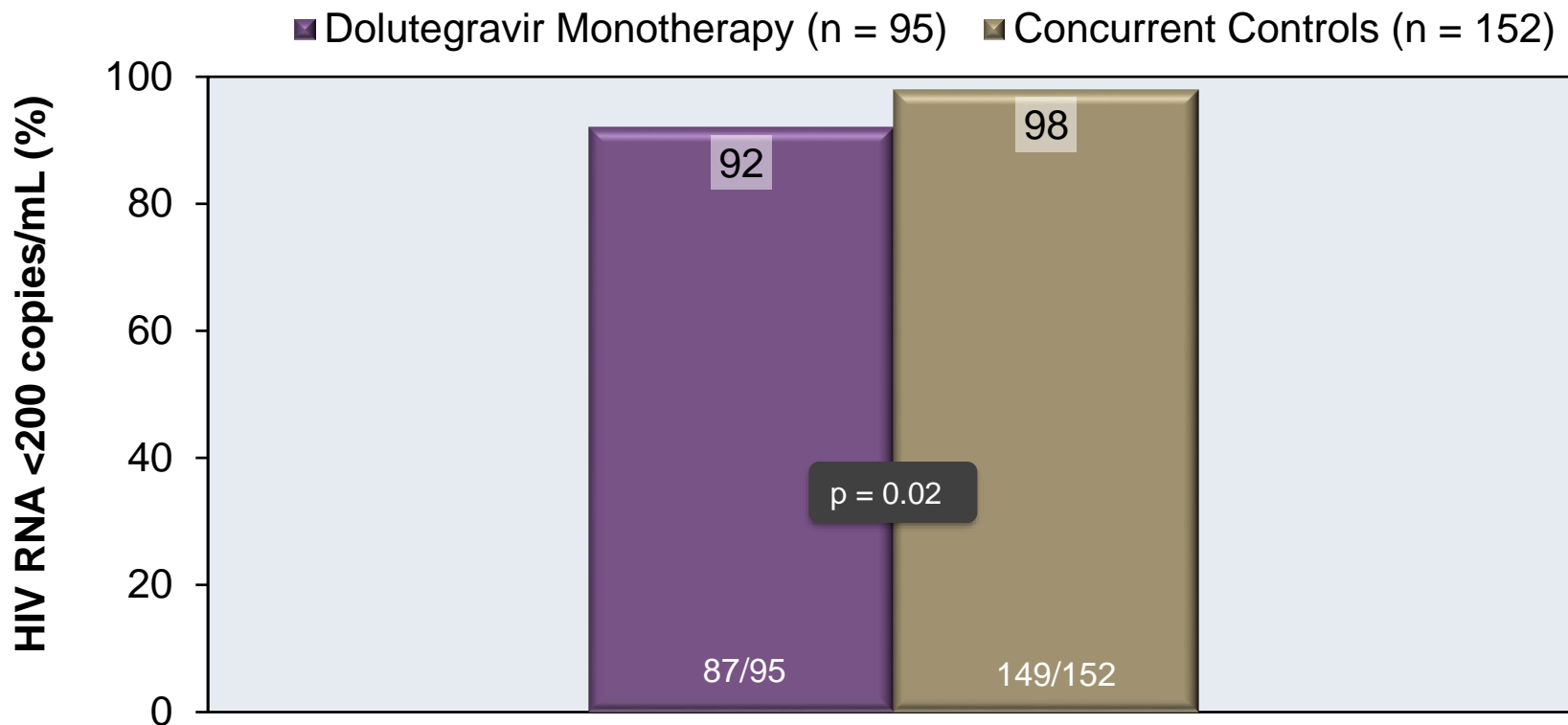


\*One of 51 participants in the immediate DTG switch arm discontinued treatment after 12 weeks because of disturbed sleep (HIV RNA <50 copies/mL at the time)

# Dolutegravir as Maintenance Monotherapy

## DOMONO: 48-Week Results

Week 48 Virologic Suppression (Entire Study Population)



- Study stopped early; 8 virologic failures in dolutegravir arm, 3 with INSTI resistance (N155H, R263K, S230R)
- RNA at failure 678-4,990 copies/mL with one exception (71,600 copies/mL); all reported >95% adherence and all suppressed with re-initiation of cART

Source: Wijting I, et al. *Lancet HIV*. 2017;4:e547-54.

# Dolutegravir as Maintenance Monotherapy

## DOMONO: Conclusion

**Interpretation:** “Dolutegravir monotherapy was non-inferior to combination ART at 24 weeks. However, virological failure continued to occur thereafter and led to dolutegravir resistance. Dolutegravir should not be used as maintenance monotherapy.”

# 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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