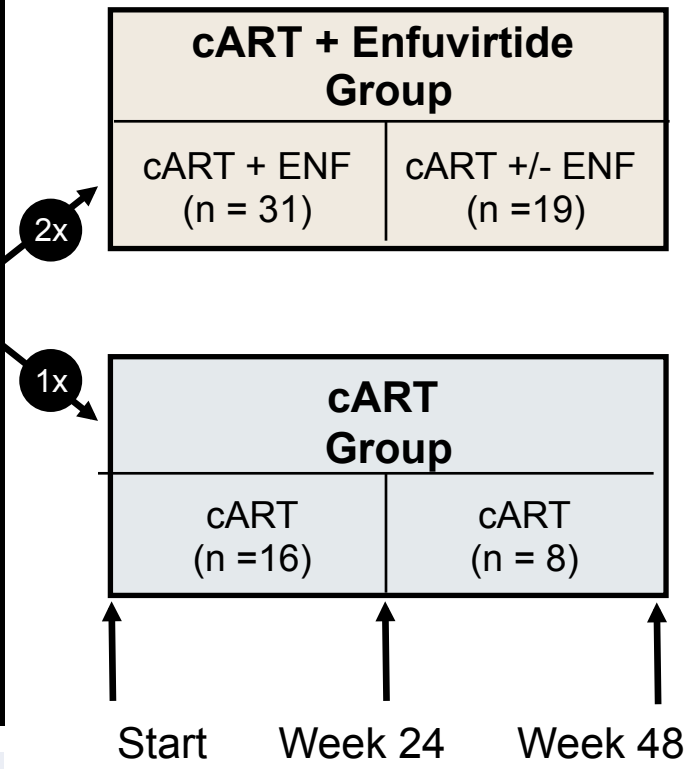
cART + Enfuvirtide versus cART Alone in Virologic Failure

INTENSE Study

cART + Enfuvirtide versus cART Alone in Virologic Failure
INTENSE: Study Design

Study Design: INTENSE

- **Background**: Open-label, randomized, phase IIIb/IV study patients comparing the efficacy and safety of enfuvirtide in combination with a new antiretroviral regimen with at least 2 active agents (cART) with cART alone in antiretroviral-experienced patients with virologic failure
- **Inclusion Criteria (n = 47)**
  - Age ≥18 years of age
  - HIV RNA ≥1000 copies/mL on current regimen
- **Treatment Arms**
  - cART* + ENF 90mg SC BID x 24 weeks, then 1:1 randomization to continue or discontinue ENF
  - cART alone



*cART= combination antirretroviral therapy
cART regimen of 3 to 5 active agents was selected based on treatment history and resistance data

Source: Clotet B, et al. J Antimicrob Chemother. 2008;62:1374-8.

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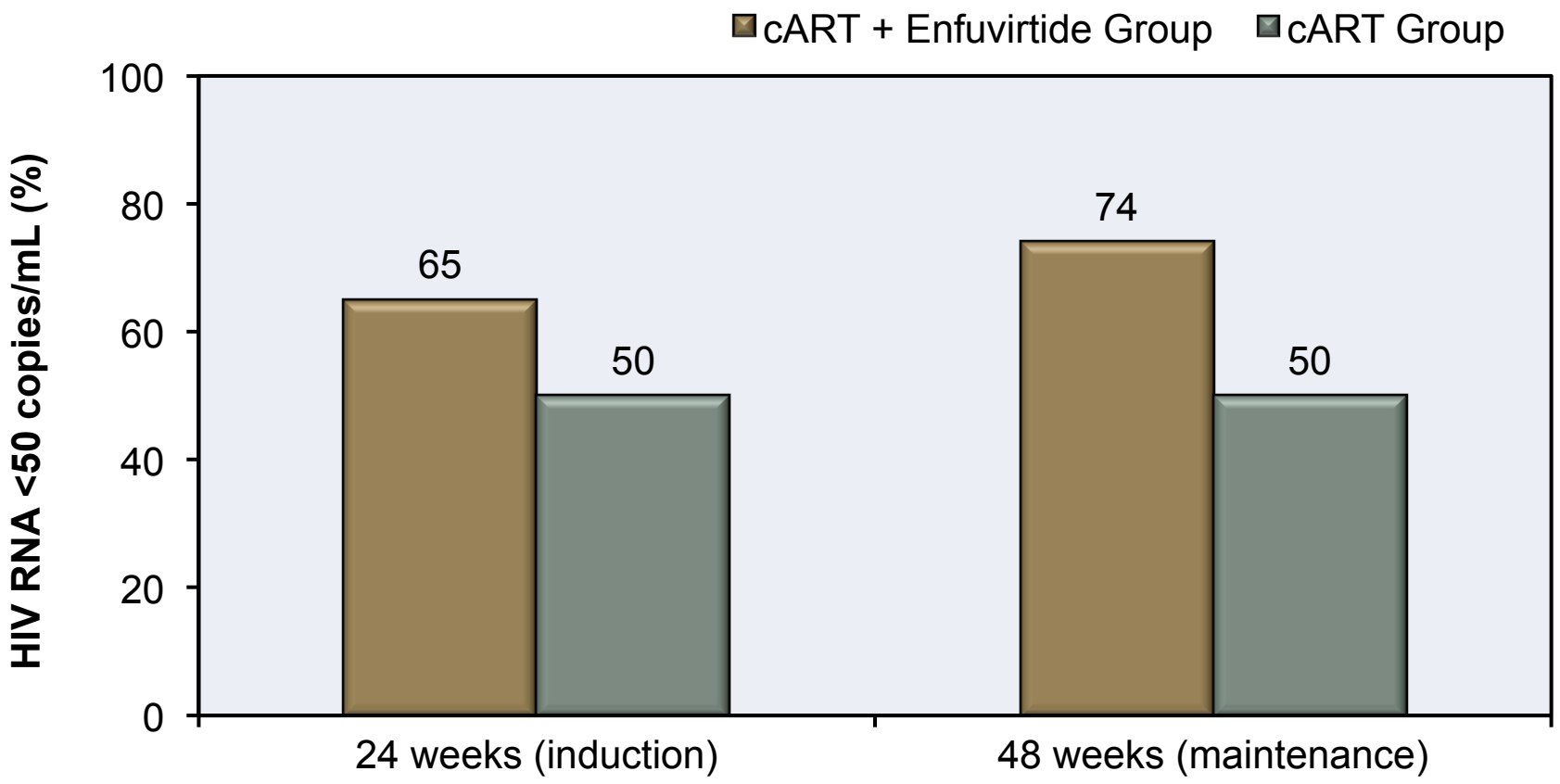
INTENSE: Result

Week 24 & 48*: Virologic Response (Intent-to-Treat)



*48 week data based on original cART + enfuvirtide arm, regardless of second randomization at 24 weeks

Source: Clotet B, et al. J Antimicrob Chemother. 2008;62:1374-8.

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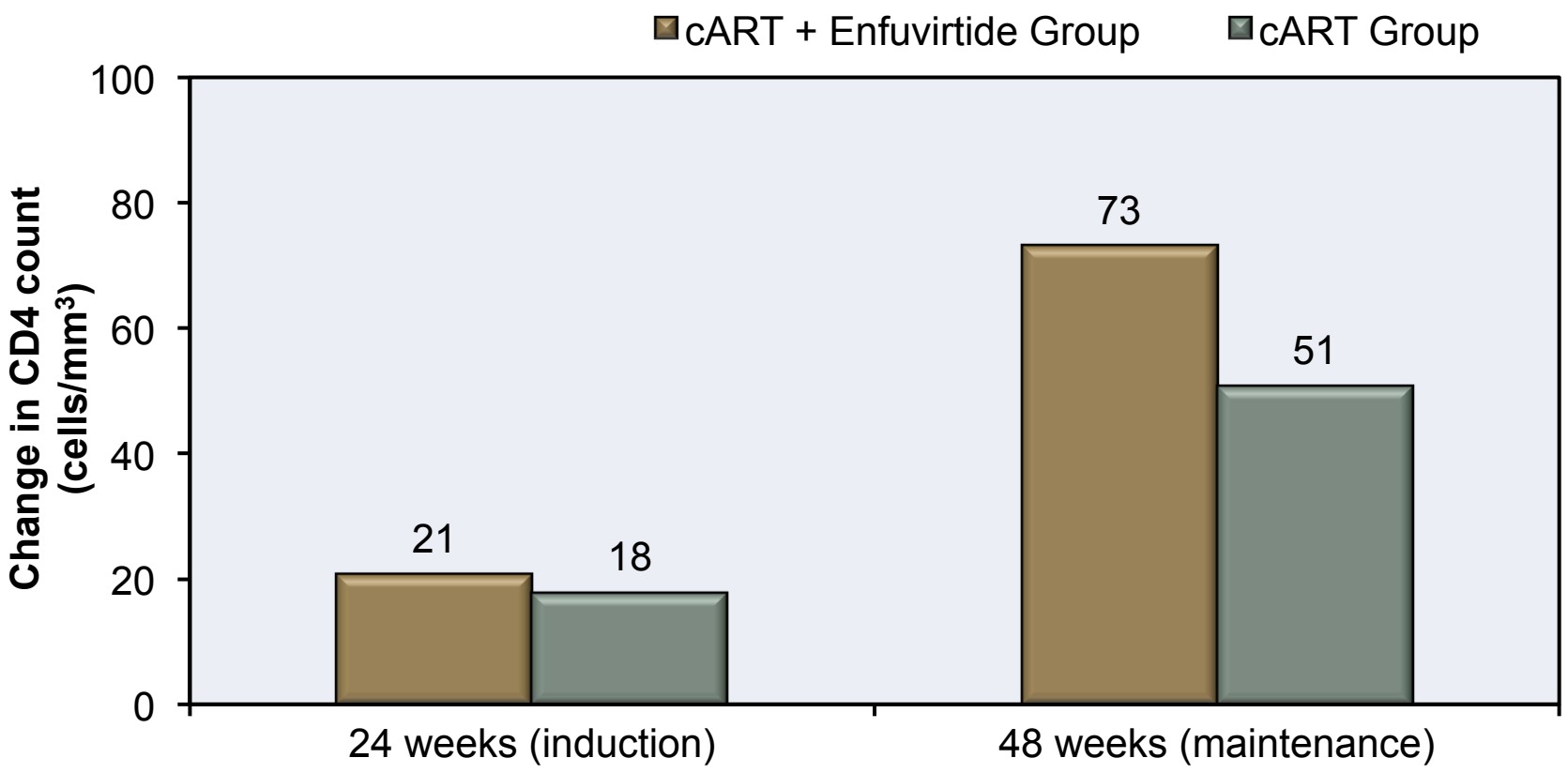
INTENSE: Result

Week 24 & 48*: Immunologic Response



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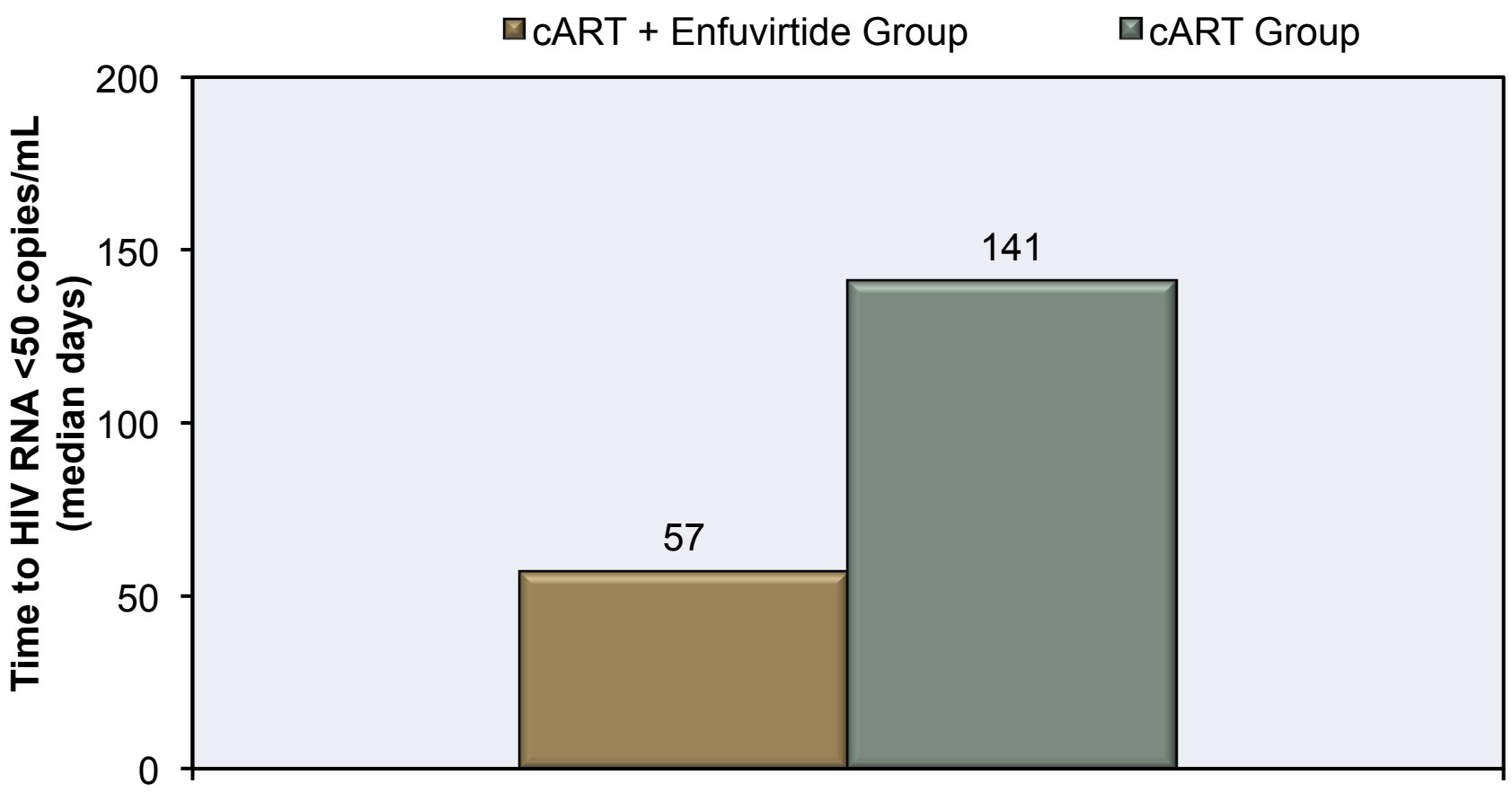
INTENSE: Result

Time to Achievement of Viral Suppression



Source: Clotet B, et al. J Antimicrob Chemother. 2008;62:1374-8.

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INTENSE: Conclusions

Conclusions: “Although limited by small participant numbers, these results suggest that treatment with enfuvirtide added to highly active antiretroviral therapy may be an option for many patients.”

Source: Clotet B, et al. J Antimicrob Chemother. 2008;62:1374-8.

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.

National HIV Curriculum

AETC AIDS Education & Training Center Program
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