AETC AIDS Education & Training Center Program Mountain West

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AIDS Clinical Conference
The Future of ART: Two-Drug Oral and Injectable Therapy

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Disclaimer

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Disclosures

I have no financial disclosures or conflict of interest.

I will mention investigational therapies.

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Learning Objectives

1. Review the latest guidelines for which antiretroviral regimen to start and various options for switching therapy
2. Explain the newest data and developments in long-acting antiretroviral therapy and evolutions in our understanding of who may benefit from this therapy
3. Describe novel antiretroviral therapy that is in development and likely coming in the near future – all two-drug options!

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The Latest Antiretroviral Guidelines & Treatment Innovations

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Case

- 55-year-old man with new diagnosis of HIV in setting of low platelet count. Genotype result available and shows no resistance mutations.
- Ready to start ART. CD4 count 112 (8%), HIV RNA 460,000 copies/mL. No hepatitis B. Very worried about potential side effects.
- Which option would you recommend?

A) Bictegravir/TAF/FTC

B) Dolutegravir plus TAF/FTC

C) Dolutegravir/lamivudine

D) Darunavir/cobicistat/TAF/FTC

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IAS-USA Guidelines: December 2024 Update
Recommended Initial ART Regimens

For Most People with HIV (Listed in Alphabetical Order)*

- Bictegravir/TAF/FTC
- Dolutegravir + TAF/FTC or TDF/FTC (or TDF/3TC)
- Dolutegravir/3TC
  Only if HIV RNA <500,000 copies/mL, no 3TC resistance, and no HBV

*If acquired HIV with prior integrase inhibitor exposure (such as cabotegravir PrEP) or another reason to suspect integrase resistance, add integrase genotype to baseline resistance testing and start a boosted darunavir-anchored regimen while awaiting result.

Source: Gandhi RT, et al. JAMA. 2025:333(7):609-628.

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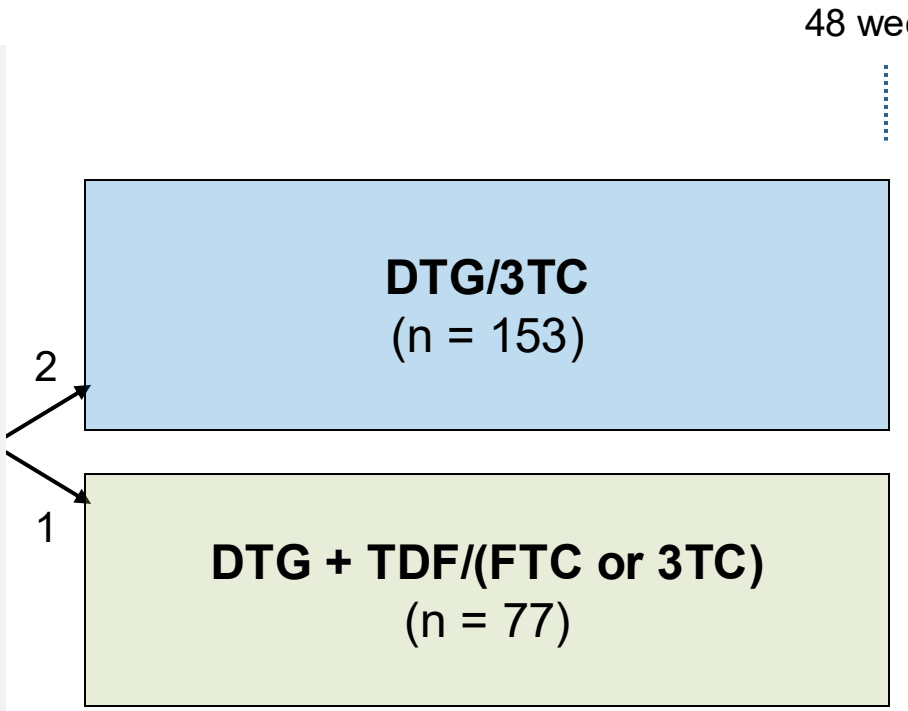
DOLCE: Dolutegravir/Lamivudine (DTG/3TC) for Treatment-Naïve Individuals with CD4 count ≤200 cells/mL

- **Design**
  - Phase 4, randomized, open-label study conducted at 11 sites in Argentina and Brazil
- **Eligibility Criteria**
  - Age ≥18 years old
  - Antiretroviral naïve
  - CD4 count ≤200 cells/mL
  - Plasma HIV RNA ≥1,000 copies/mL
  - Not pregnant
  - No hepatitis B
  - No major resistance mutations to DTG, 3TC, or TDF
  - No liver or kidney disease



Source: Figueroa MI, et al. Clin Infect Dis. 2025 Aug 28: ciaf415.

DOLCE: Dolutegravir/Lamivudine (DTG/3TC) for Treatment-Naïve Individuals with CD4 count ≤200 cells/mL

DOLCE Study: Select Participant Baseline Characteristics		
Characteristic	**DTG/3TC** (n = 153)	**DTG + TDF/FTC (or TDF/3TC)** (n = 77)
CD4 count, cells/mL, median (IQR)	109 (49,177)	128 (59,200)
CD4%, median (IQR)	8 (4,12)	10 (4,13)
CD4 count ≤100 cells/mL, n (%)	69 (45.4%)	29 (39.2%)
HIV RNA, copies/mL, median (IQR)	180,000 (57,300, 468,700)	137,100 (43,900, 419,600)
HIV RNA ≥100,000 copies/mL, n (%)	94 (61.4%)	47 (61.0%)
HIV RNA ≥500,000 copies/mL, n (%)	35 (22.9%)	18 (23.4%)
HIV RNA >1,000,000 copies/mL, n (%)	16 (10.5%)	7 (9.1%)

Source: Figueroa MI, et al. Clin Infect Dis. 2025 Aug 28:ciaf415.

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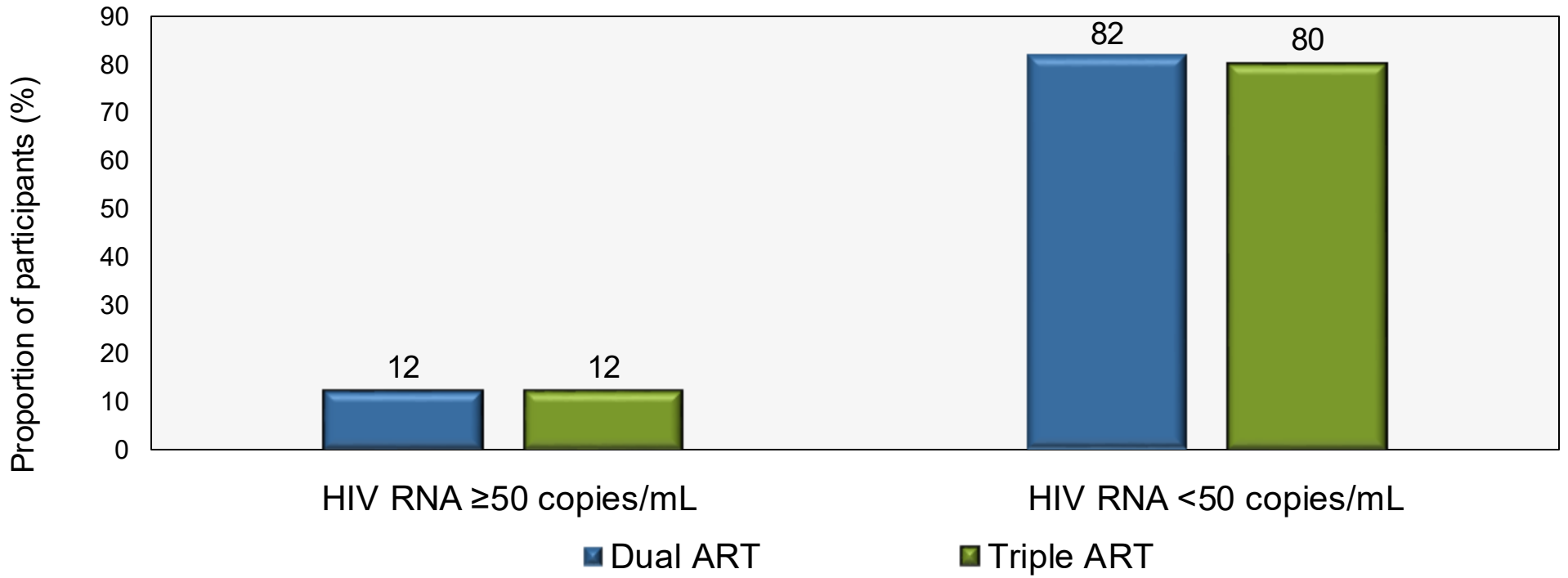
DOLCE: Dolutegravir/Lamivudine (DTG/3TC) for Treatment-Naïve Individuals with CD4 count ≤200 cells/mL

Virologic efficacy results at 48 weeks (intention-to-treat)



Efficacy consistent for participants with baseline HIV RNA ≥500,000 or ≥1 million copies/mL
No emergent drug resistance in either arm

Source: Figueroa MI, et al. Clin Infect Dis. 2025 Aug 28:ciaf415.

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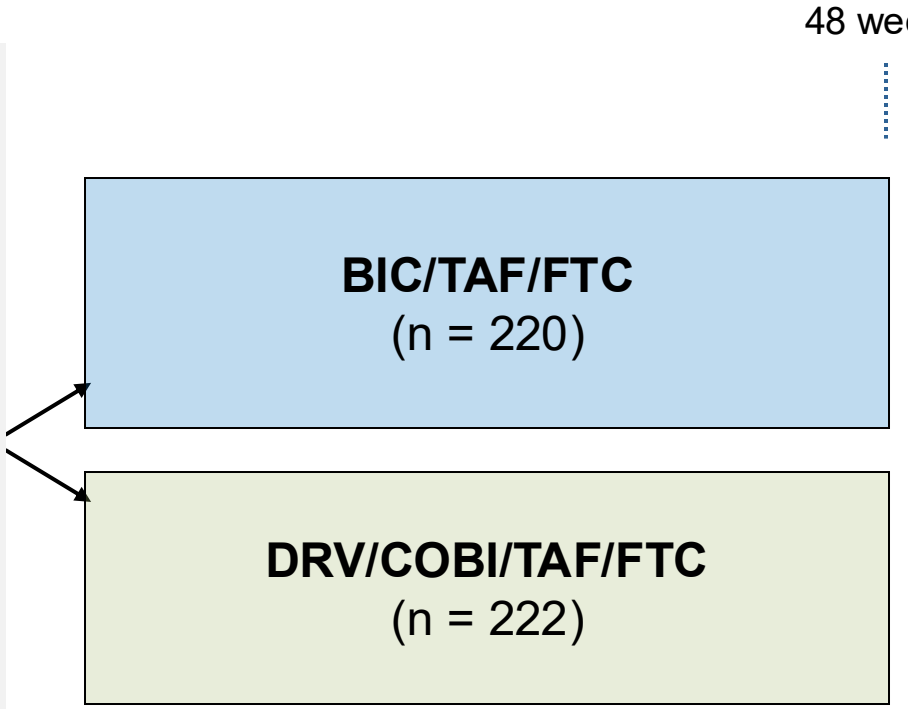
LAPTOP: Integrase vs. Protease Inhibitor-Based ART for Treatment-Naïve Individuals with Advanced HIV

- **Design**
  - Multicenter, open-label, noninferiority study conducted across 7 European countries
- **Eligibility Criteria**
  - Age ≥18 years old
  - Antiretroviral naïve
  - Plasma HIV RNA ≥1,000 copies/mL and at least one of the following: AIDS diagnosis, severe bacterial infection with CD4 count <200 cells/mL, CD4 count <100 cells/mL, or current OI treatment
  - Not pregnant
  - No hepatitis B
  - No major resistance mutations to DTG, 3TC, or TDF
  - No liver or kidney disease

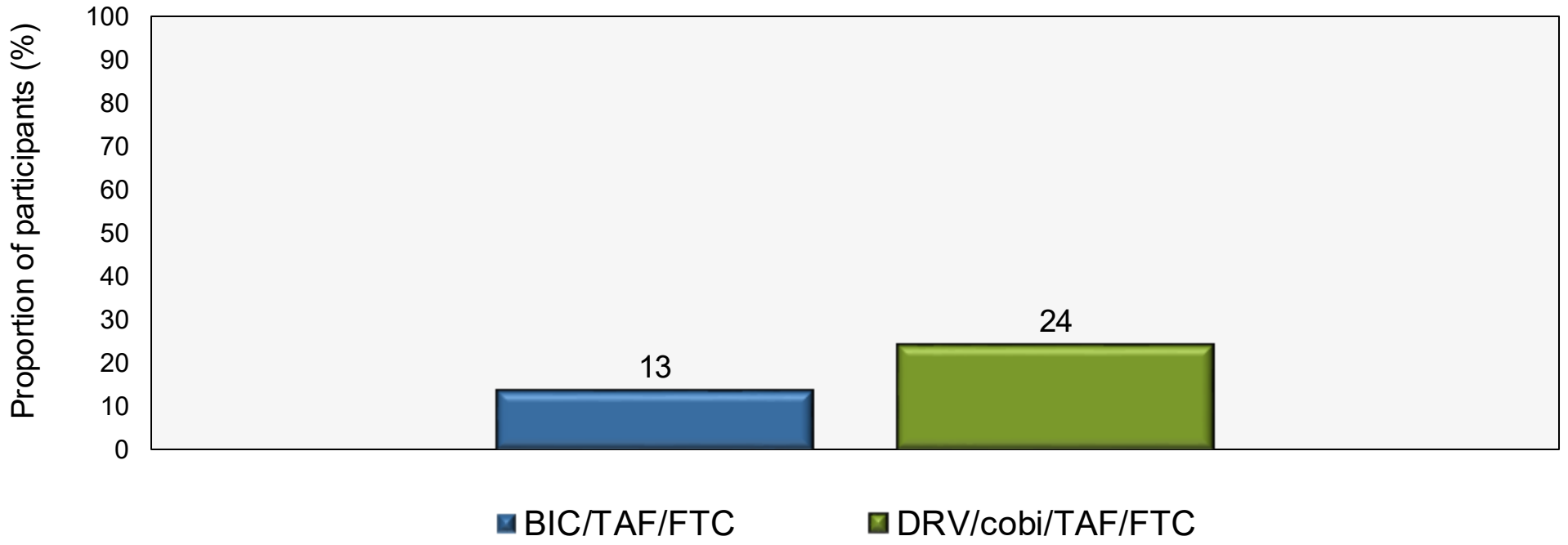


Snapshot of baseline characteristics:
Median CD4 count 41 (IQR 17-79);
197 (44.6%) had HIV RNA >500,000 copies/mL

Source: Behrens G, et al. CROI 2025. Abstract 658.

LAPTOP: Integrate vs. Protease Inhibitor-Based ART for Treatment-Naïve Individuals with Advanced HIV

Virologic failure at week 48 (intention-to-treat)



BIC/TAF/FTC non-inferior to DRV/cobi/TAF/FTC for composite outcome of virologic and clinical events (p=0.052)
Rates of virological failure significantly lower with BIC/TAF/FTC (p=0.013)

Source: Behrens G, et al. CROI 2025. Abstract 658.

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Now on to switching ART…

Poll

- 55-year-old woman from outside the US has long term suppressed viral loads on dolutegravir + doravirine + TAF/FTC. She asks about a simpler option.
- Past drug resistance: M184V, 3 thymidine analog mutations (TAMs), and K103N
- No hep B coinfection. Returns to her home country regularly, about 1 month at a time.
- Which one of the following would you recommend?

A) Switch to bictegravir/TAF/FTC

B) Switch to injectable cabotegravir/rilpivirine

C) Switch to dolutegravir/3TC

D) Switch to dolutegravir/rilpivirine

E) Wait for new daily oral pills (e.g., doravirine/islatravir or lenacapavir/bictegravir)

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Two-Drug Antiretroviral Therapy is the Future: Expanded Use of a Current Option Plus New Options Coming Soon…

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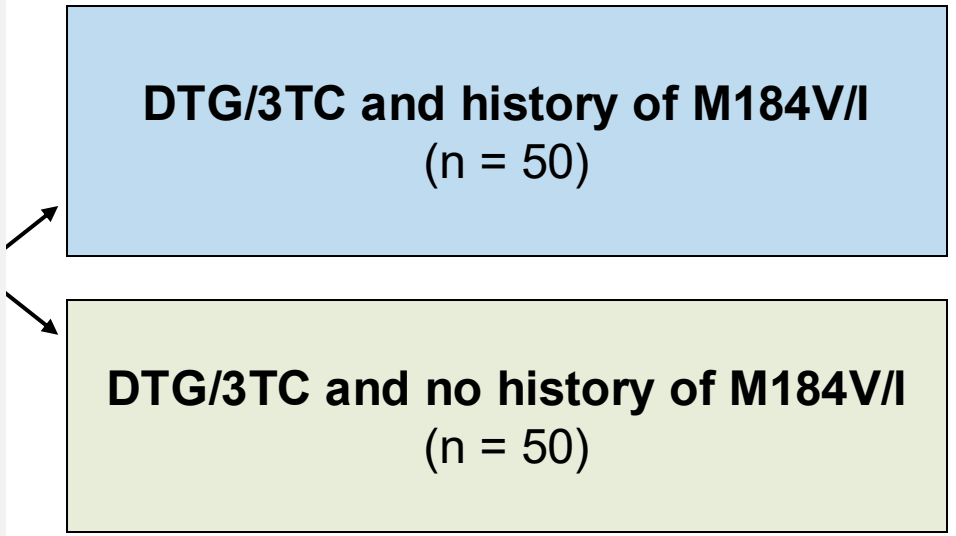
SOLAR3D:
Switch to DTG/3TC with Prior Virologic Failure and M184V/I Mutation

- **Design**
  - Prospective, open-label, comparative study
- **Eligibility Criteria**
  - Adults with HIV RNA <50 copies/mL for ≥6 months on any stable 2-/3-/4-drug ART
  - All with prior virologic failure and at least 2 prior ART regimens
  - No exclusion for CD4 count, INSTI experience, past NRTI resistance, M184V/I or K65R on baseline proviral genotype
- **Primary endpoint:**
  - Proportion of participants with HIV RNA >50 copies/mL at 144 weeks



At baseline: median ART duration 22.3 years, median 7 previous ART regimens, median duration viral suppression 11.8 years

Source: Blick G, et al. IAS 2024. Abstract SS0403LB.

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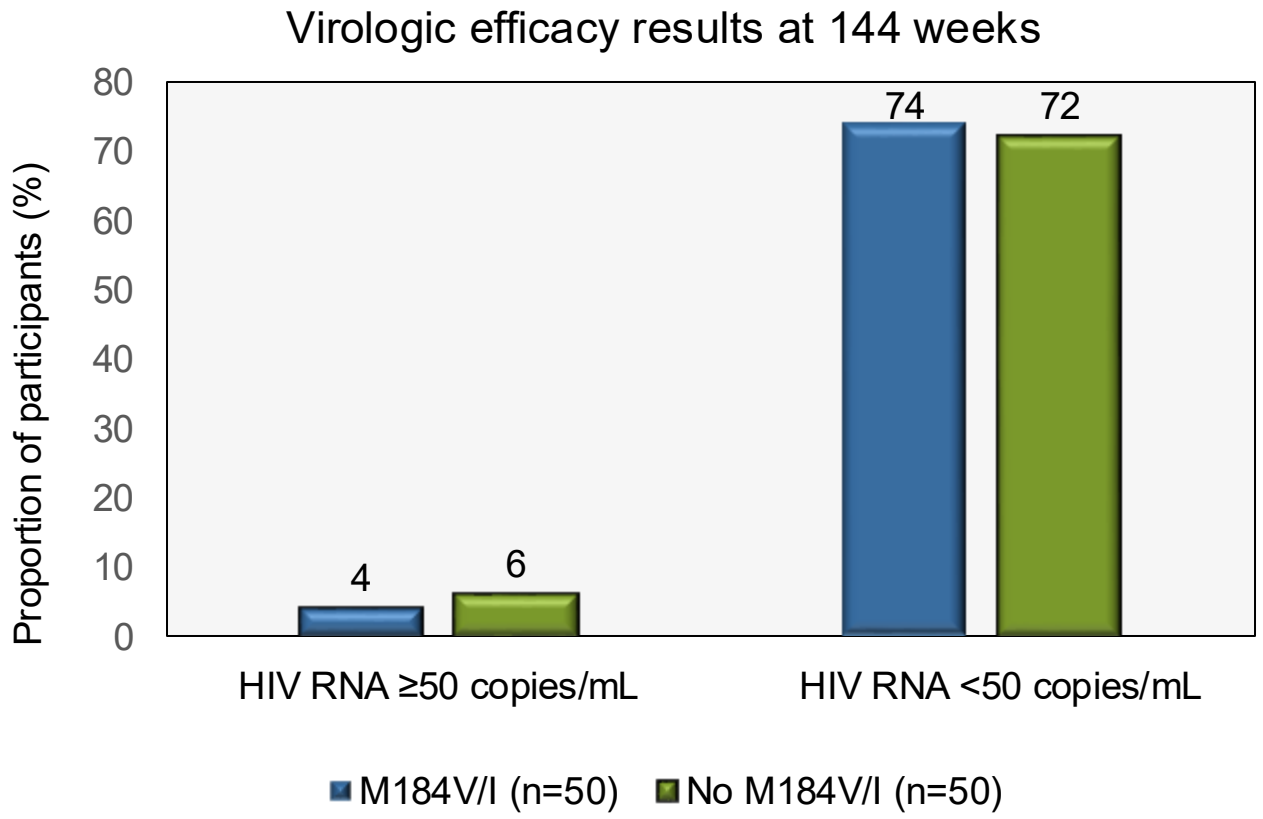
SOLAR3D:
Switch to DTG/3TC with Prior Virologic Failure and M184V/I Mutation



	M184V/I on Historical Genotype (n = 50)	No M184V/I on Historical Genotype (n = 50)
Proviral genotype	41 (82)	29 (58)
M184V/I present	15 (37)	0
M184V/I absent	26 (63)	29 (100)
All reported as: n (%)		

No difference in rate of virologic suppression, confirmed virologic failures (0 with M184V/I, 1 with no M184V/I due to missed doses), incidence of viral blips

Source: Blick G, et al. IAS 2024. Abstract SS0403LB.

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Long-Acting Injectable Cabotegravir/Rilpivirine (LAI CAB/RPV) Updates

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Counseling About Long-Acting Injectable Cabotegravir/Rilpivirine Suppressed Viral Load

- Benefits:
  - Non-daily therapy (injections every 1 or 2 months)
  - Reduced stigma, avoid risks of keeping meds at home
  - Improvements in pill burden, pill fatigue
  - HIV treatment compartmentalized in the clinic
- Concerns:
  - Coming to clinic every 1 or 2 months
  - Injection site reactions, pain
  - Risk of virologic failure despite doing everything right (1-2%)
  - Many individuals prefer daily oral therapy with fewer visits

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Considerations for Long-Acting Injectable Cabotegravir/Rilpivirine Viremia

- Systematic review: cumulative of probability VL suppression: 87% (79-95%)
  - Questions: dosing frequency, VL monitoring frequency, therapeutic drug monitoring
- HHS guidelines:
  - Data limited; recommended on case-by-case basis for select individuals with persistent VF despite intensive adherence support and no resistance to CAB or RPV
- CROWN study:
  - Phase 3b, open-label, multicenter, superiority study of LAI CAB/RPV every 2 months vs. oral ART for individuals with viremia and barriers to taking oral ART

Sources:
Systematic review & meta-analysis: Bardo B, et al. HIV Med. 2025 July;26(7):993-1003.
HHS guidelines: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv (Sept. 2024)
CROWN study: https://www.clinicaltrials.gov/study/NCT06694805

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Is Bictegravir/TAF/FTC Effective After Virologic Failure on Cabotegravir/Rilpivirine?

- **Design**
  - Case series, description of 5 patients, single center
- **Key clinical data**
  - Virologic failure on every 2-month IM CAB/RPV
  - No known pre-existing rilpivirine or integrase resistance
  - All switched to LAI CAB/RPV for convenience (not due to adherence challenges)
  - All received injections within target dates, except for one (traveled abroad for 3 months; took 2 months of locally-obtained ART as bridge)
  - All found to have significant integrase and rilpivirine resistance mutations at virologic failure
  - All achieved virologic re-suppression on bictegravir/TAF/FTC

	INSTI Resistance	NNRTI Resistance
1	148R	101E
2	74I, 138E/K, 140A/G, 148K/Q/R, 230R/S	138G, 230L
3	138K, 148R	181C, 221Y
4	138K, 148K	90I, 103N
5	118R	98G, 101E, 181C, 190A

Source: Pierre G, et al. AIDS. May 2025;39(6):777-779.

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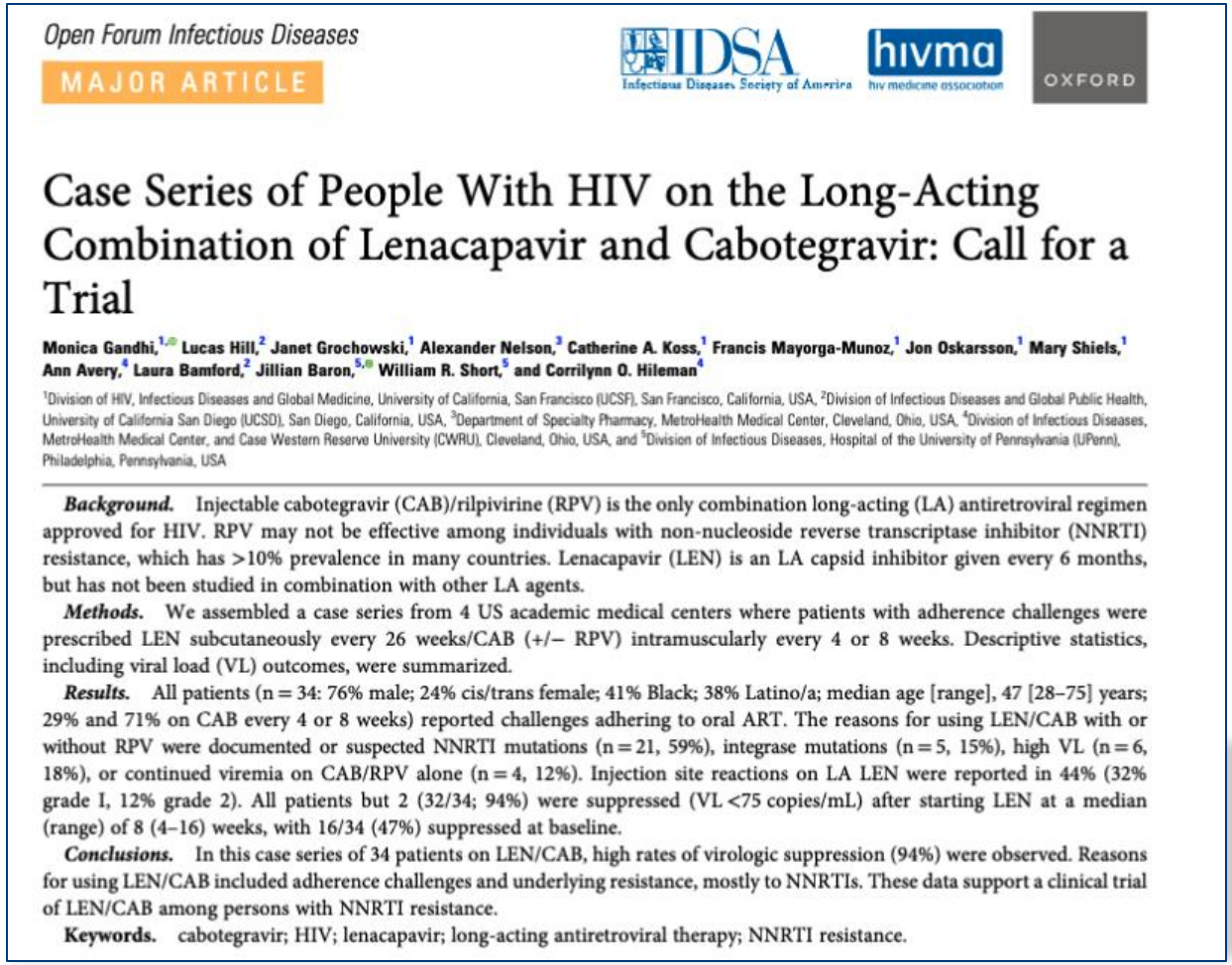
Lenacapavir + Cabotegravir +/- Rilpivirine Case Series & Call for a Trial

- N = 34
- 53% detectable viral load (300's-1.2 million)
- Reasons:
  - 21 NNRTI resistance
  - 5 minor INSTI resistance
  - 6 high viral load
  - 4 viremia on CAB/RPV
  - 1 BMI >40 kg/m^2
  - 1 IM RPV adverse reaction
- 32/34 suppressed (<75 copies) at median 8 weeks (range 4-16)



Open Forum Infectious Diseases

MAJOR ARTICLE

Case Series of People With HIV on the Long-Acting Combination of Lenacapavir and Cabotegravir: Call for a Trial

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Background. Injectable cabotegravir (CAB)/rilpivirine (RPV) is the only combination long-acting (LA) antiretroviral regimen approved for HIV. RPV may not be effective among individuals with non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance, which has >10% prevalence in many countries. Lenacapavir (LEN) is an LA capsid inhibitor given every 6 months, but has not been studied in combination with other LA agents.

Methods. We assembled a case series from 4 US academic medical centers where patients with adherence challenges were prescribed LEN subcutaneously every 26 weeks/CAB (+/− RPV) intramuscularly every 4 or 8 weeks. Descriptive statistics, including viral load (VL) outcomes, were summarized.

Results. All patients (n = 34: 76% male; 24% cis/trans female; 41% Black; 38% Latino/a; median age [range], 47 [28–75] years; 29% and 71% on CAB every 4 or 8 weeks) reported challenges adhering to oral ART. The reasons for using LEN/CAB with or without RPV were documented or suspected NNRTI mutations (n = 21, 59%), integrase mutations (n = 5, 15%), high VL (n = 6, 18%), or continued viremia on CAB/RPV alone (n = 4, 12%). Injection site reactions on LA LEN were reported in 44% (32% grade I, 12% grade 2). All patients but 2 (32/34; 94%) were suppressed (VL <75 copies/mL) after starting LEN at a median (range) of 8 (4–16) weeks, with 16/34 (47%) suppressed at baseline.

Conclusions. In this case series of 34 patients on LEN/CAB, high rates of virologic suppression (94%) were observed. Reasons for using LEN/CAB included adherence challenges and underlying resistance, mostly to NNRTIs. These data support a clinical trial of LEN/CAB among persons with NNRTI resistance.

Keywords. cabotegravir; HIV; lenacapavir; long-acting antiretroviral therapy; NNRTI resistance.

Source: Gandhi M, et al. Open Forum Infect Dis. 2024 Apr 16;11(4):ofae125.

Upcoming Trials of Long-Acting Injectable ART

- A5431 (PALACE): People with Active viremia treated with Lenacapavir And long-acting Cabotegravir for Effectiveness
  - Single-arm, proof of concept study
  - Assess efficacy for ART-experienced individuals with known NNRTI resistance, viremia, and adherence challenges

- A5433 (LANCET): Phase 3b, randomized, multicenter, open-label trial to evaluate LA lenacapavir plus Cabotegravir for PWH with virologic failure on TLD
  - Randomization 1:1 to LA LEN+CAB vs. oral TLD with enhanced adherence counseling (or switch to PI regimen)
  - Low- and middle-income countries

Information courtesy of Dr. Rachel Bender-Ignacio

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Barriers to Injectable ART

Factors That Create Obstacles to Injectable ART Access
Prior auth/appeals, different for each insurance, labor intensive
Medical rather than pharmacy benefit (risky buy-and-bill strategy)
Challenges coordinating specialty pharmacy/dispenser
Not on ADAP formulary, patient co-pay issues, difficulty accessing manufacturer patient assistance
Need for admin support (injection tracking, reimbursement, inventory), plus staff for injection visits
Storage/refrigeration requirements
Need for buy-in among clinic leadership
Clinical expertise for eligibility determination

Sources: Hack J, Open Forum Infect Dis. 2025;12(4):ofaf192.
Cooper SE, et al. Clin Infect Dis. 2022;75(S4):S541-8.

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Which New 2-Drug ART Options Are in the Pipeline: Quite a Few!

HIV ART Pipeline
With Estimated Year of Approval

2026

- Doravirine/islatravir PO daily
- Bictegravir/lenacapavir PO daily

2027

- Islatravir/lenacapavir PO weekly
- Cabotegravir ultra long-acting (ULA) IM + rilpivirine IM every 4 months

2028+

- GS1720 + GS4182 PO weekly (?)
- ISL/ULO PO weekly
- ISL/INSTI PO weekly
- GS3107 + INSTI PO monthly
- GS1614 + LEN SC every 3 months
- LEN + INSTI SC every 6 months
- CAB-ULA + bNAB IM every 6 months
- VH4524184 + X SC every 6 months
- VH4011499 + X SC every 6 months
- LEN SC + bNAbs every 6 months

Sources: Adapted from a talk by Dr. Raj Gandhi at IAS 2025 Conference.

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Future Trends:
Two-Drug ART, and Avoidance of NRTIs…

Doravirine/Islatravir (DOR/ISL) Oral Daily
Summary of Key Phase 3 Studies

- **Completed trials using higher dose ISL**
  - ILLUMINATE SWITCH A: switch to DOR/ISL vs. continue standard oral ART
  - ILLUMINATE SWITCH B: switch to DOR/ISL vs. continue oral BIC/TAF/FTC
  - ILLUMINATE NAÏVE: DOR/ISL vs. BIC/TAF/FTC for treatment-naïve
  - ILLUMINATE HTE: DOR/ISL plus OBR in heavily-treatment-experienced
- **Ongoing trials using lower dose ISL**
  - 051: switch to DOR/ISL vs. continue standard oral ART
  - 052: switch to DOR/ISL vs. continue oral BIC/TAF/FTC
  - 053: DOR/ISL vs. BIC/TAF/FTC for treatment-naïve
  - 054: open-label with lower dose ISL for participants of higher-dose ISL trials

Abbreviations: DOR = doravirine, ISL = islatravir, BIC = bictegravir, TAF = tenofovir alafenamide, FTC = emtricitabine, OBR = optimized background regimen, HTE = heavily treatment experienced

NDA submitted to FDA for switch indication - Decision by April 28, 2026

Source: clinicaltrials.gov

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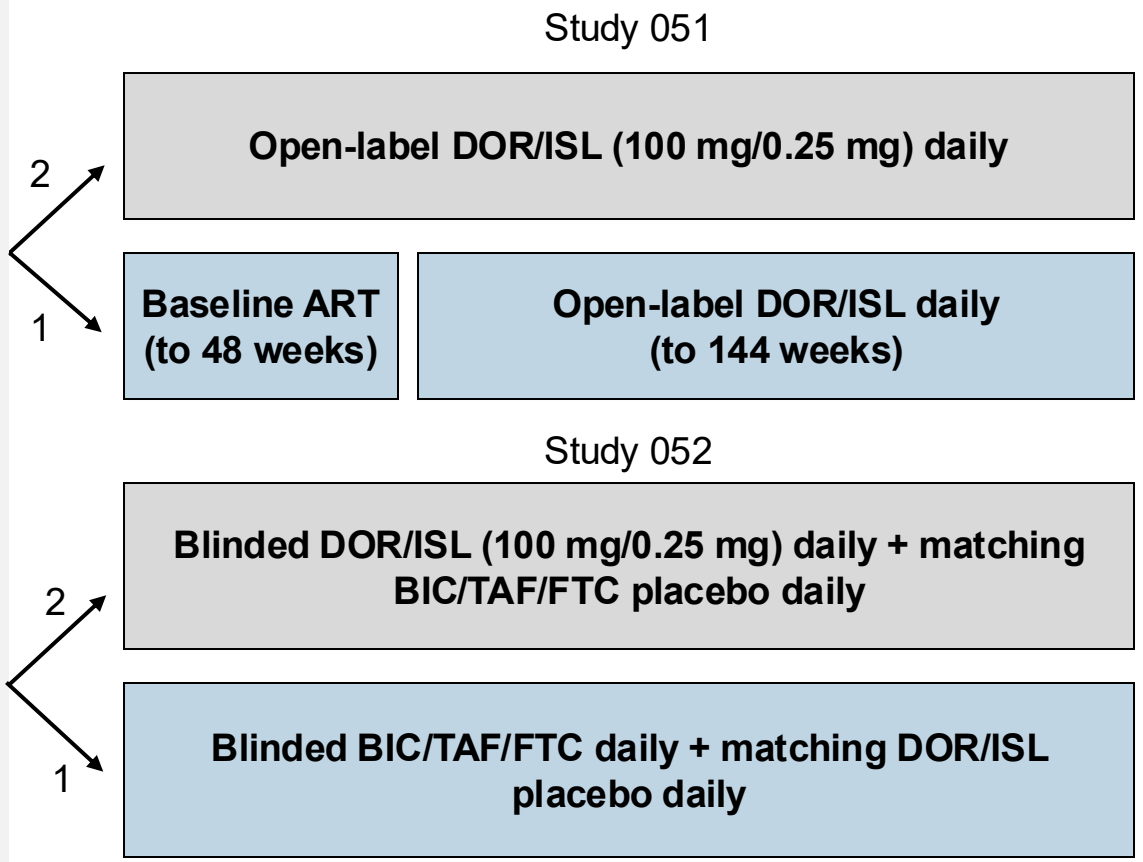
Doravirine/Islatravir Oral Daily
Results of Two Phase 3 Switch Trials (051, 052)

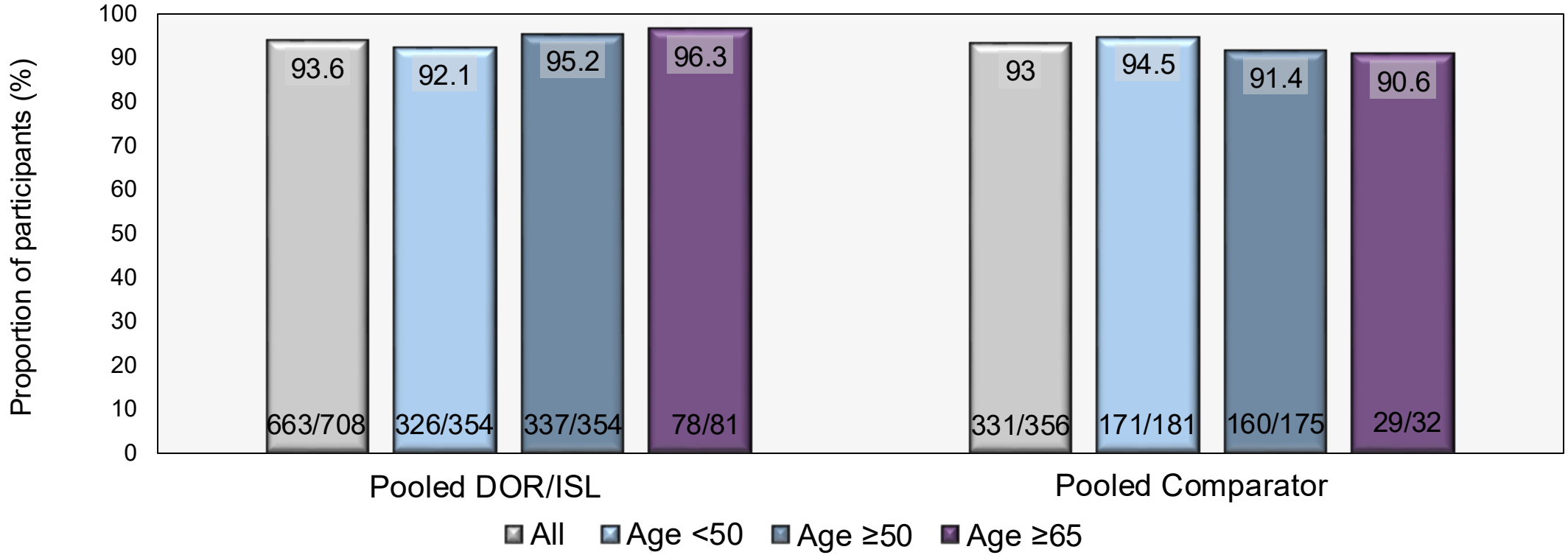
- **Background**: two phase 3, randomized, active controlled, non-inferiority trials
- **Inclusion Criteria**
  - Adults with HIV RNA <50 copies/mL for ≥3 months
  - Taking stable oral 2- or 3-drug ART (P051, open-label) or BIC/TAF/FTC (P052, double-blind)
  - CD4 count ≥50 cells/mL, total lymphocyte count ≥650 cells/mL
  - No history of treatment failure on any regimen
  - No resistance to doravirine
  - No hepatitis B
- **Subgroups defined by age at study entry**
  - <50, ≥50, or ≥65 years old
- **Primary Outcome:**
  - Virologic efficacy at 48 weeks



Source: Tebas P, et al. ID Week 2025.

Doravirine/Islatravir Oral Daily
Results of Two Phase 3 Switch Trials (051, 052)

Virologic efficacy (HIV RNA <50 copies/mL) at 48 weeks



Additional data:

- CROI 2025: primary data from 051 and 052; ID Week & IAS 2025: 054 (rollover study) data
- Efficacy with archived NNRTI resistance or M184V/I, several metabolic studies

Source: Source: Tebas P, et al. ID Week 2025.

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Which individuals will benefit most from a switch to doravirine/islatravir?
Please answer in chat box…

Oral Lenacapavir (LEN) Phase 3 Studies

- **Daily oral bictegravir/lenacapavir (BIC/LEN) studies**
  - ARTISTRY1: switch to BIC/LEN vs. continue complex ART regimen
  - ARTISTRY2: switch to BIC/LEN vs. continue BIC/TAF/FTC

- **Weekly oral islatravir/lenacapavir (ISL/LEN) studies**
  - ISLEND1: switch to weekly oral ISL/LEN vs. continue BIC/TAF/FTC
  - ISLEND2: switch to weekly oral ISL/LEN vs. continue standard of care ART

Abbreviations: BIC = bictegravir, LEN = lenacapavir, TAF = tenofovir alafenamide, FTC = emtricitabine, ISL = islatravir

Source: clinicaltrials.gov

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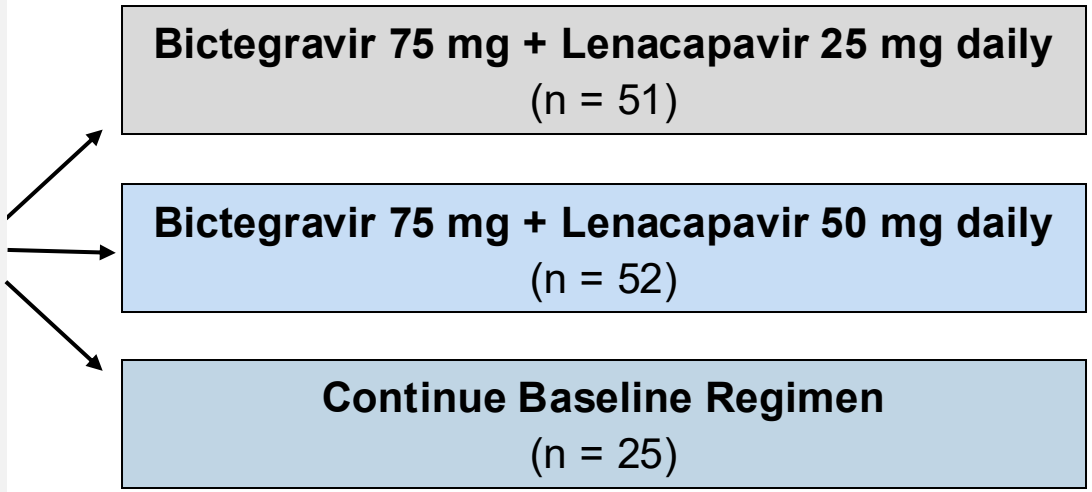
ARTISTRY-1: Switch to Daily Oral BIC + Daily Oral LEN for PWH Taking Complex ART Regimens

- **Background**: Phase 2/3, open-label, randomized trial
- **Inclusion Criteria**
  - Adults with HIV RNA <50 copies/mL for ≥6 months while taking a complex ART regimen*
  - No prior lenacapavir exposure or bictegravir resistance
  - No hepatitis B
  - eGFR above 15 mL/min
- **Participants:**
  - Median age 60, 79% male, 41.4% taking ART twice daily, 27.3% taking ≥5 pills per day, 72% taking a PI, resistance in INSTI/NNRTI/NRTI/PI classes: 0%/52%/64%/36%
- **Primary Outcome:**
  - Virologic efficacy at 48 weeks



*Complex ART regimen: boosted PI or NNRTI + ≥1 other ARV from a class other than NRTI, or a combination requiring ≥2 pills daily or ≥once-daily dosing, or regimen with a parenteral ARV

Source: Mounzer K, et al. Open Forum Infectious Diseases. November 2025. 12(11):ofaf615.

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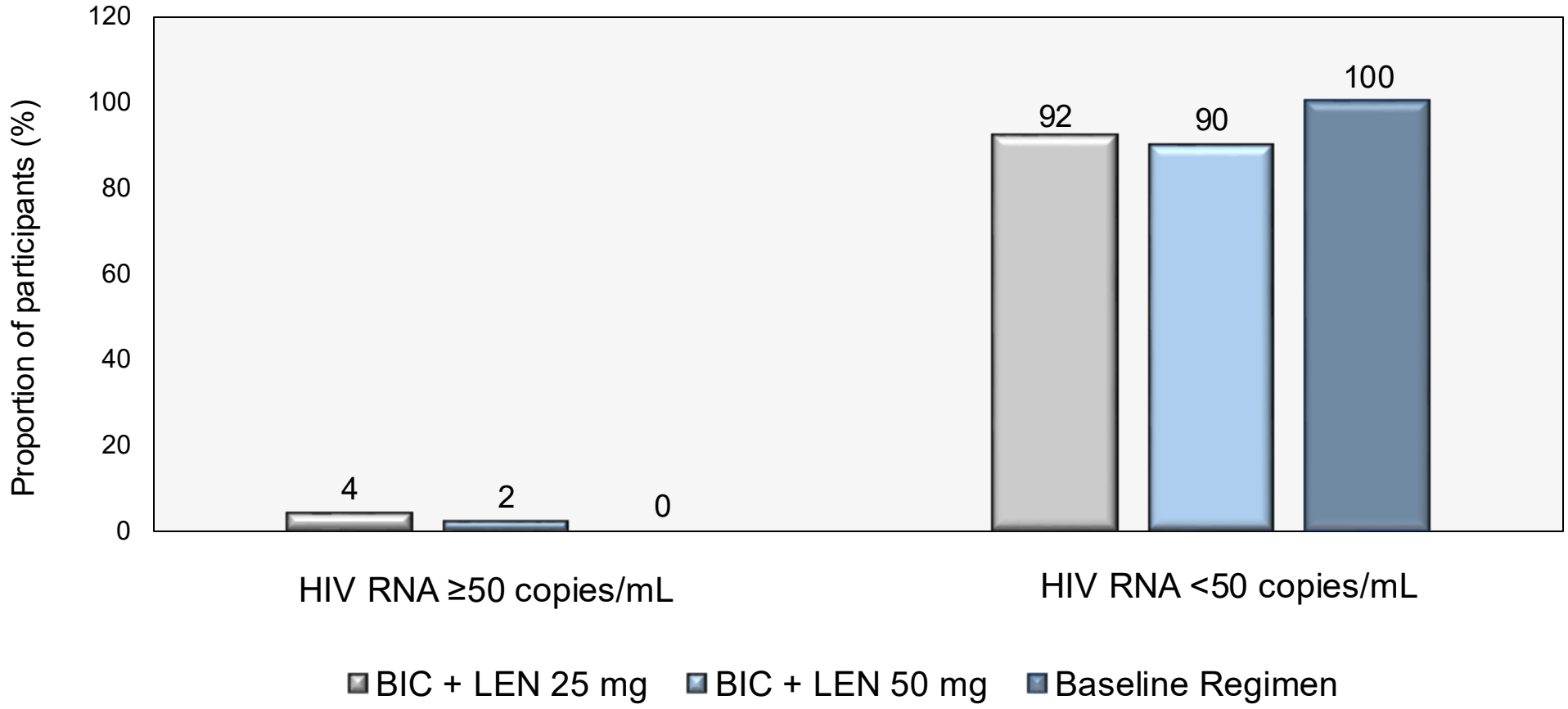
ARTISTRY-1: Switch to Daily Oral BIC + Daily Oral LEN for PWH Taking Complex ART Regimens

Virologic efficacy results at 48 weeks



Source: Mounzer K, et al. Open Forum Infectious Diseases. November 2025. 12(11):ofaf615.

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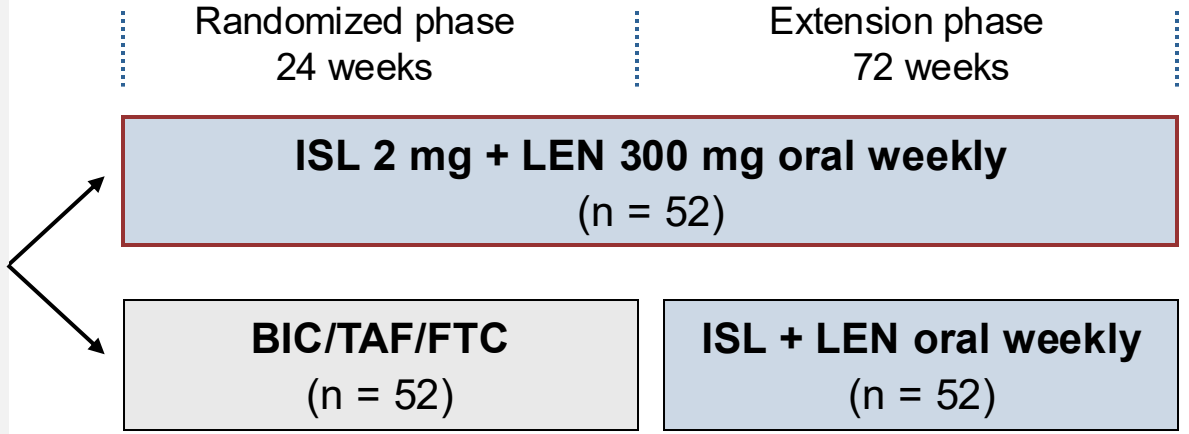
ISLEND-1: Switch to Weekly Oral ISL+LEN After Virologic Suppression on BIC/TAF/FTC

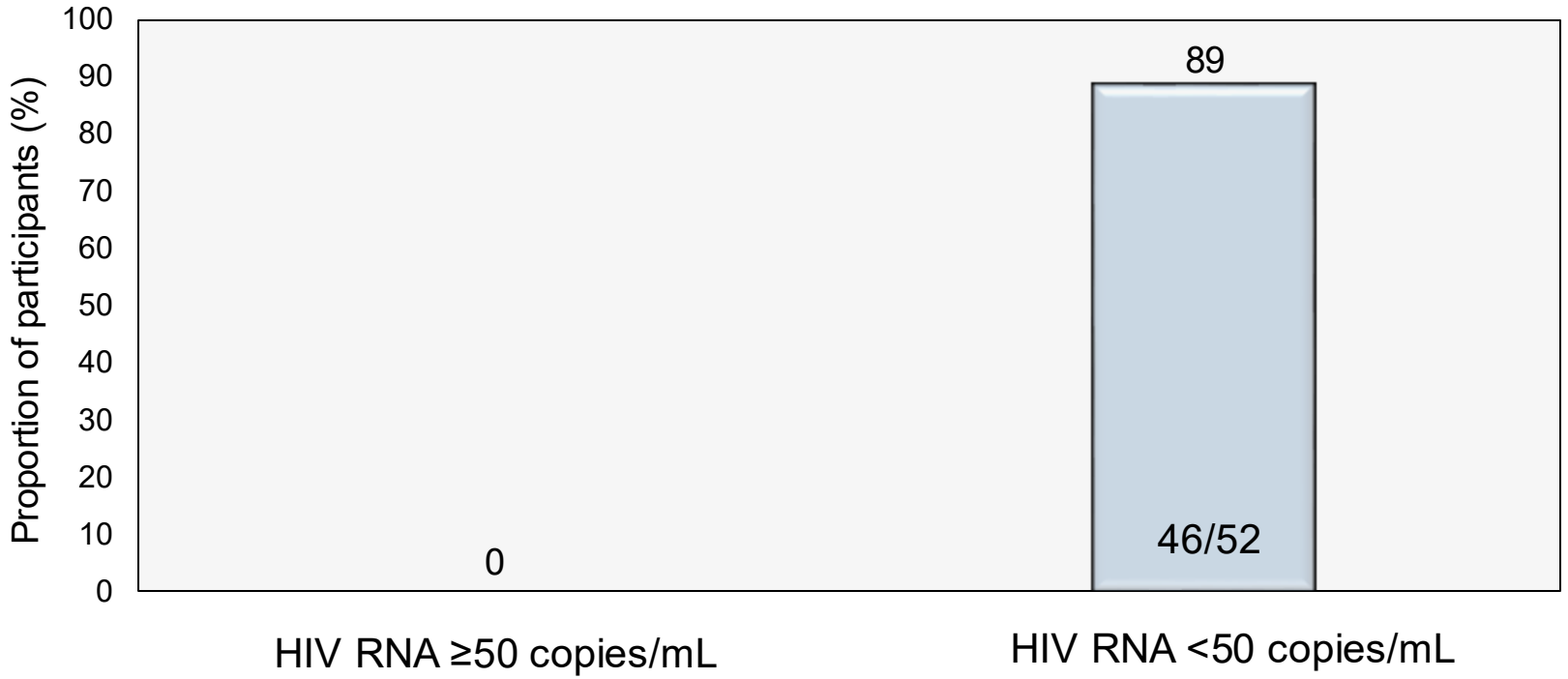
- **Background**: Phase 2, open label, randomized trial
- **Inclusion Criteria**
  - Adults with HIV RNA <50 copies/mL for ≥6 months while taking BIC/TAF/FTC
  - No history of virologic failure
  - CD4 count ≥350 cells/mL
  - Lymphocyte count ≥0.9x10^3 cells/mL
  - No hepatitis B
- **Primary endpoint:**
  - Proportion of participants with HIV RNA ≥50 copies/mL at 24 weeks
- **Secondary endpoint:**
  - Proportion of participants with HIV RNA ≥50 copies/mL at 96 weeks



Source: Colson A, et al. EACS 2025. Abstract PS15.5.LB.

ISLEND-1: Switch to Weekly Oral ISL+LEN After Virologic Suppression on BIC/TAF/FTC

Virologic efficacy results at 96 weeks



- Well tolerated – no treatment-related grade 3 or serious adverse events
- No clinically significant changes in lymphocytes or CD4 T-cell count
- Body weight and BMI remained stable

Source: Colson A, et al. EACS 2025. Abstract PS15.5.LB.

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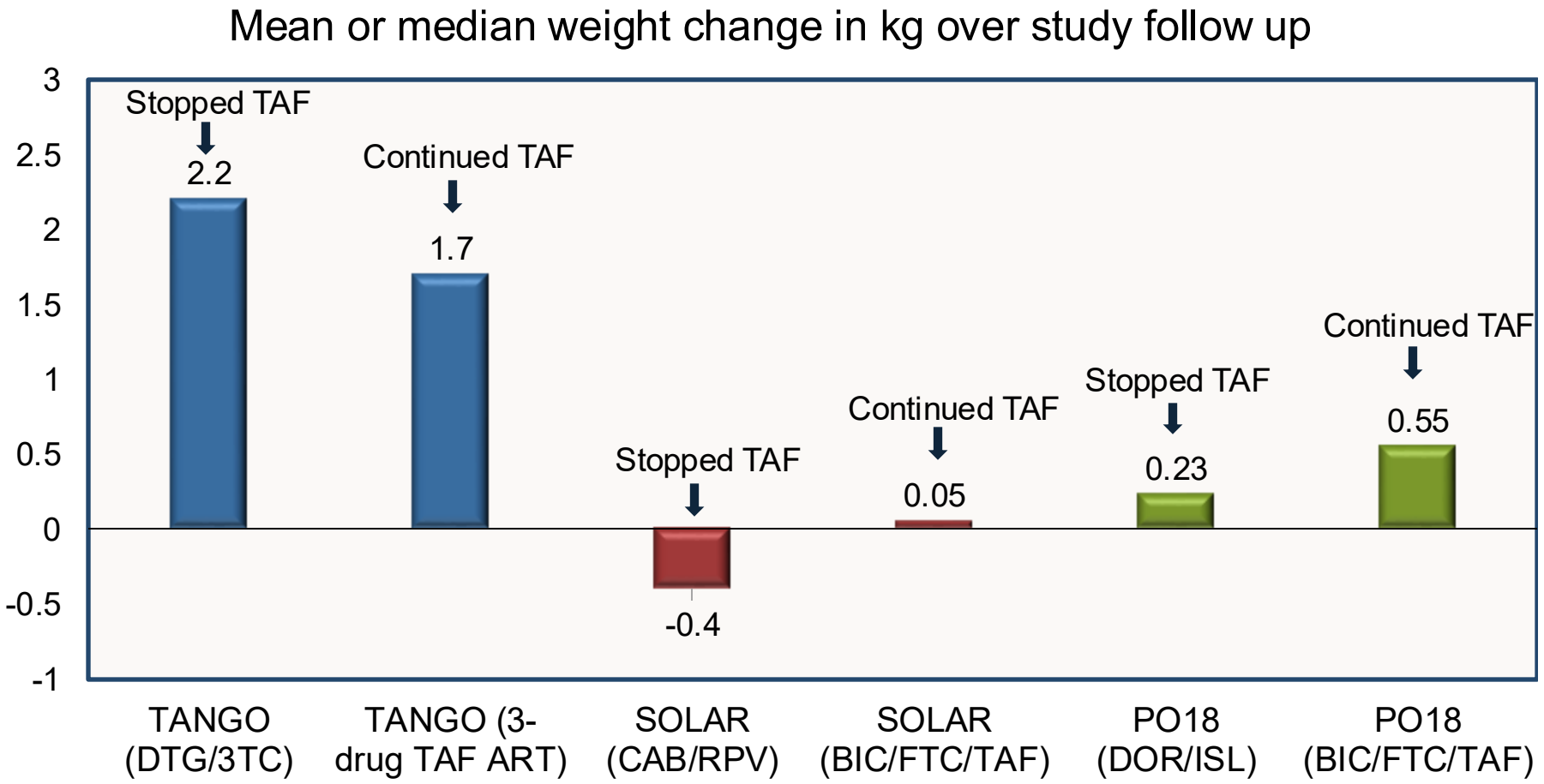
Is Weight Gain a Reason to Switch ART (to 3-Drug or 2-Drug ART)? My answer is no…

ART Switch:
Stopping TAF Does Not Lead to Weight Loss



Recreated from: Wohl DA, et al. Clin Infect Dis. 2024 (Oct 15);79(4):999-1005.

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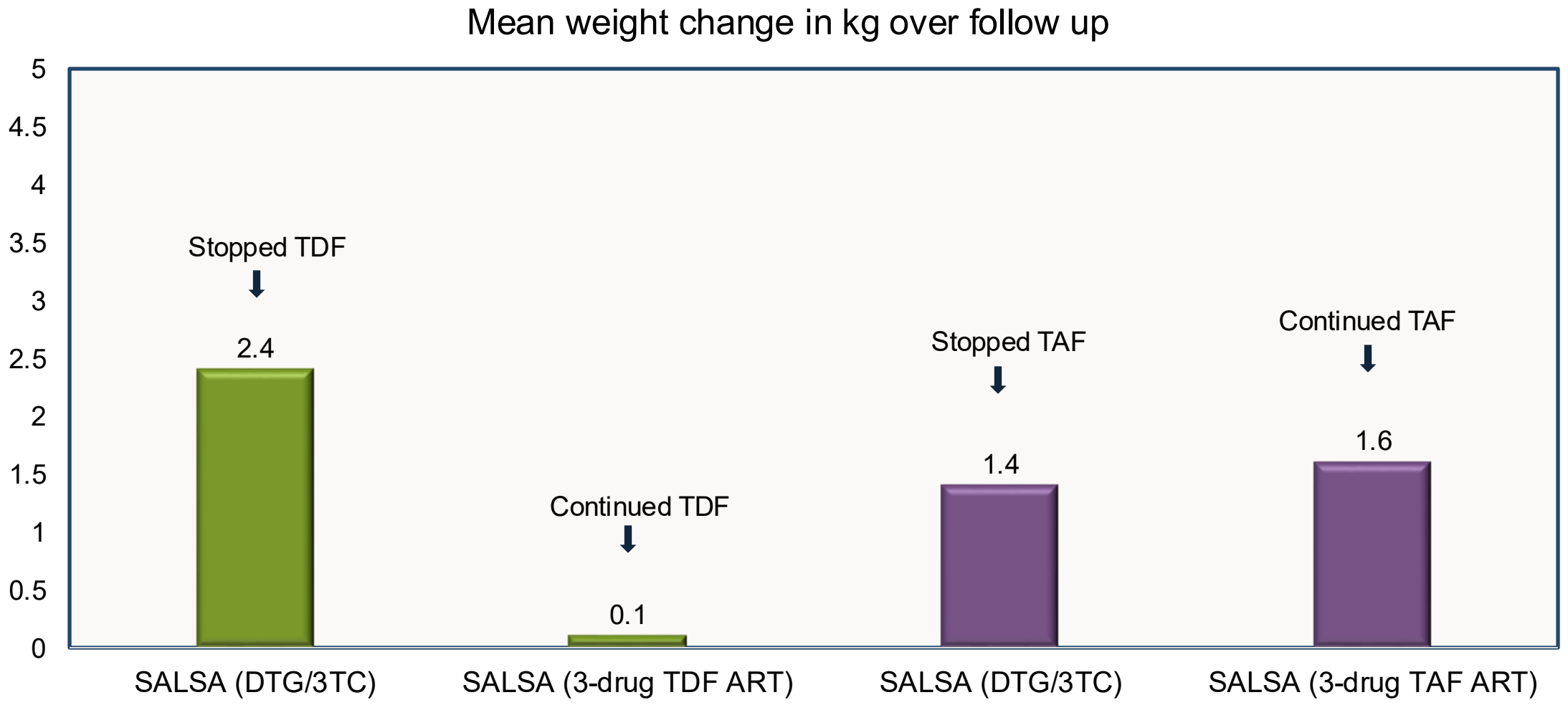
ART Switch:
Stopping TDF Leads to Weight Gain



Recreated from: Wohl DA, et al. Clin Infect Dis. 2024 (Oct 15);79(4):999-1005.

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HHS Guideline Updates on Metabolic Complications
Weight Gain

- ART initiation should not be delayed due to concerns for weight gain **(AIII)** and ART should not be interrupted or discontinued due to weight gain **(AIII)**
- Specific ARVs should not be selected to prevent or reduce weight gain **(AII)**
- Providers should include weight monitoring and counseling on strategies for weight control as part of care for PWH

Source: HHS Antiretroviral Guidelines for Adults and Adolescents. Updated September 25, 2025. clinicalinfo.hiv.gov

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So, is 2-drug ART better than 3-drug ART? Should this be the future? Would love to hear your thoughts…
(Please answer in chat box)

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Conclusions

- The future of ART seems to be 2-drug therapy, with new options coming soon
- Is 2-drug ART better than 3-drug ART? Theoretical benefit to avoiding NRTIs, but have yet to see convincing data
- Remember *hepatitis B*! Will become even more important to consider
- Potential for weekly 2-drug regimens, followed by other new non-daily options
- Hopefully future will include an array of accessible, effective, well-tolerated ARVs

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Questions, Comments, Complaints

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