

20th EUROPEAN AIDS CONFERENCE

15–18 October 2025 | Paris, France



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RO3.8.LB

Virological non-inferiority
and lower weight gain with

DTG/3TC versus

BIC/FTC/TAF:

96-week final results from the

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inferiority trial



Declaration of interest

Received research grant/served as Principal Investigator, Consultant, and Lecturer for Gilead Sciences, Janssen, MSD, and ViiV Healthcare.

PASO DOBLE

Phase IV, open-label, multicentre, randomised clinical trial^{1,2}

Screening

- / HIV-1 RNA <50 c/mL for ≥24 weeks
- / Current ART with >1 pill/day, cobi booster, EFV or TDF
- / No prior VF or known/suspected resistance
- / No prior DTG or BIC
- / No chronic hepatitis B

The two-arm switch design reduces any potential bias introduced when switching only one arm³⁻⁷

30 sites
across
Spain

Collaborative study between
Fundación SEIMC-GESIDA
and ViiV Healthcare



Switch
hypotheses

1. DTG/3TC will be non-inferior to BIC/FTC/TAF
2. BIC/FTC/TAF will lead to greater weight gain than DTG/3TC

Randomised 1:1

Stratified by BL TAF use
and sex at birth

DTG/3TC (n=277)

BIC/FTC/TAF (n=276)

BL Week 6 Week 24 Week 48 Week 96

Primary endpoint: Participants with plasma HIV-1 RNA ≥50 c/mL (FDA Snapshot; non-inferiority margin 4%)

Key secondary endpoint: Weight change (study was powered to assess differences)

Other secondary endpoints include efficacy, safety, tolerability, immune recovery, metabolic parameters, kidney function, blood pressure, body and bone composition, PROs, and genotypic resistance analysis in case of VF, allowing for a comprehensive comparison of the regimens



Four sub-studies:
click for more info >>

 Omics



Senescence



Fat biopsies



Liver
steatosis

1. Ryan P, et al. Lancet HIV 2025;12:e473–84

2. PASO DOBLE. Available at: <https://clinicaltrials.gov/ct2/show/NCT04884139>. Accessed October 2025

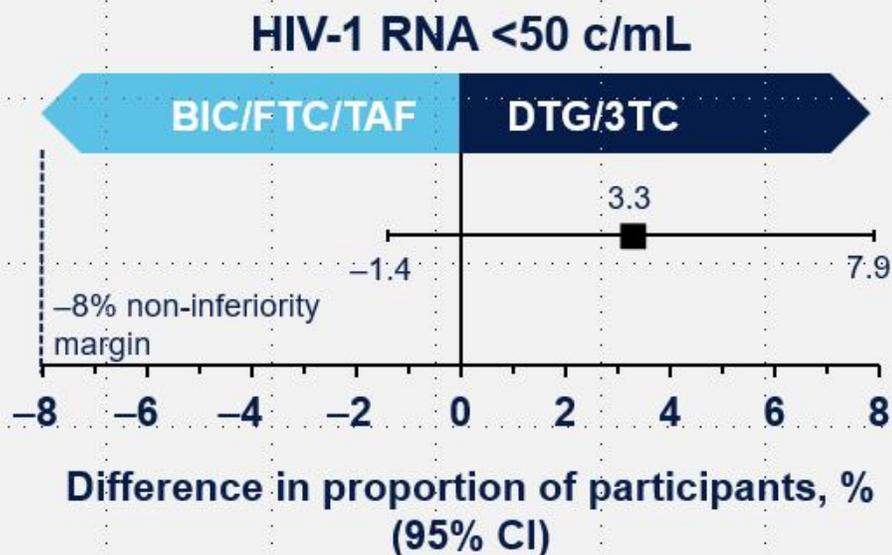
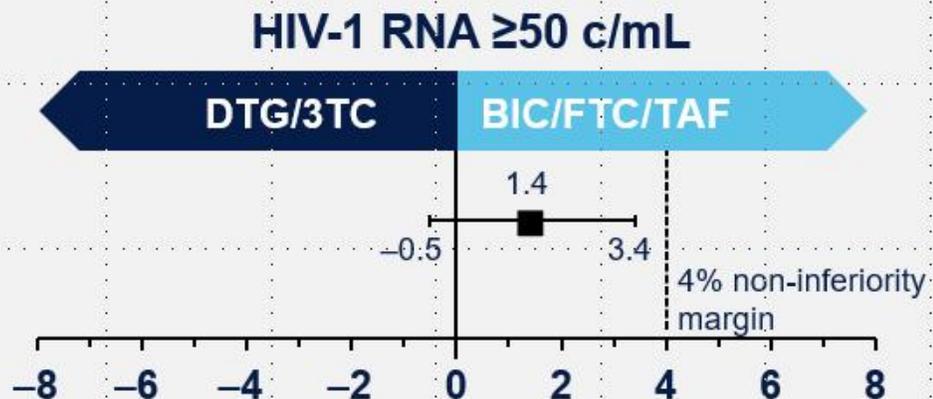
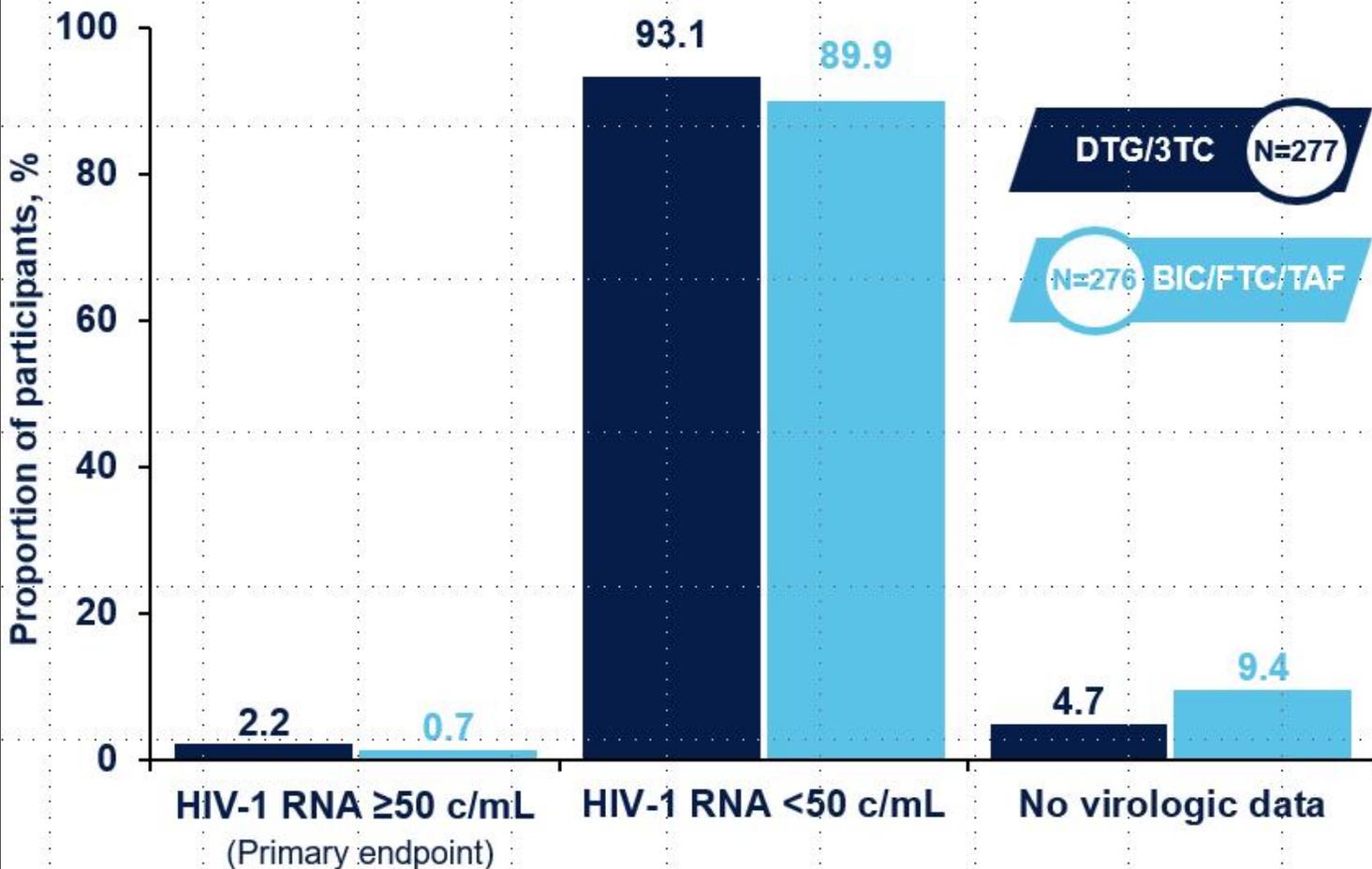


Baseline characteristics

Parameter, n (%) or median (IQR)	DTG/3TC N=277	BIC/FTC/TAF N=276
Age, years	50 (41–57)	51 (39–58)
Female sex at birth	74 (26.7)	73 (26.4)
Ethnicity*	Caucasian	201 (72.6)
	Latinx	66 (23.8)
	Black	4 (1.4)
Total time on ART, years	11.7 (7.2–19.3)	11.1 (7.0–19.2)
Time with HIV RNA <50 c/mL, months	103.4 (43.0–170.2)	97.7 (41.5–163.3)
Duration of previous ART regimen, months	66.2 (43.5–97.0)	62.8 (41.1–88.7)
CD4 ⁺ T-cell count, cells/mm ³	712 (516–918)	684 (473–859)
CD4 ⁺ T-cell count <350 cells/mm ³	26 (9.4)	24 (8.7)
CD4 ⁺ T-cell count nadir, cells/mm ³	293 (144–472)	302 (159–476)
BMI, kg/m ²	25.1 (22.3–28.5)	24.8 (22.2–28.2)
Overweight/obese (BMI >25 kg/m ²)	143 (51.8)	134 (48.6)

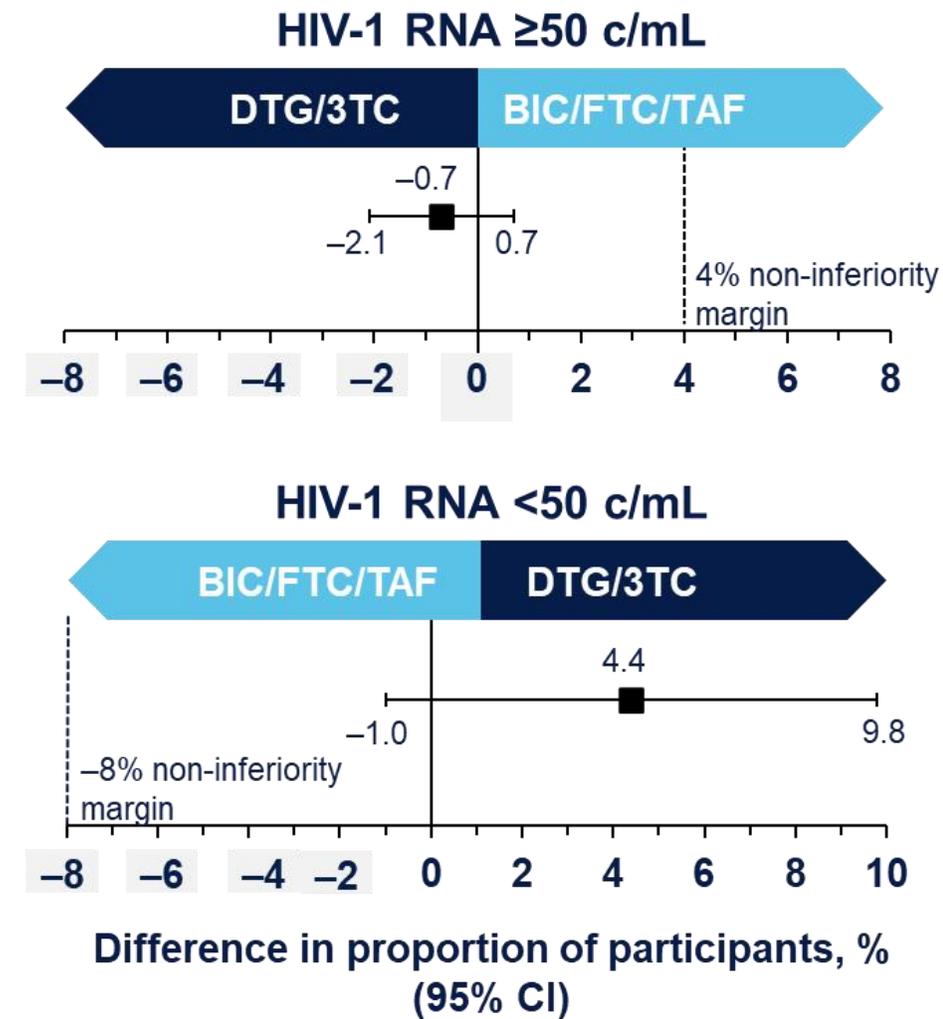
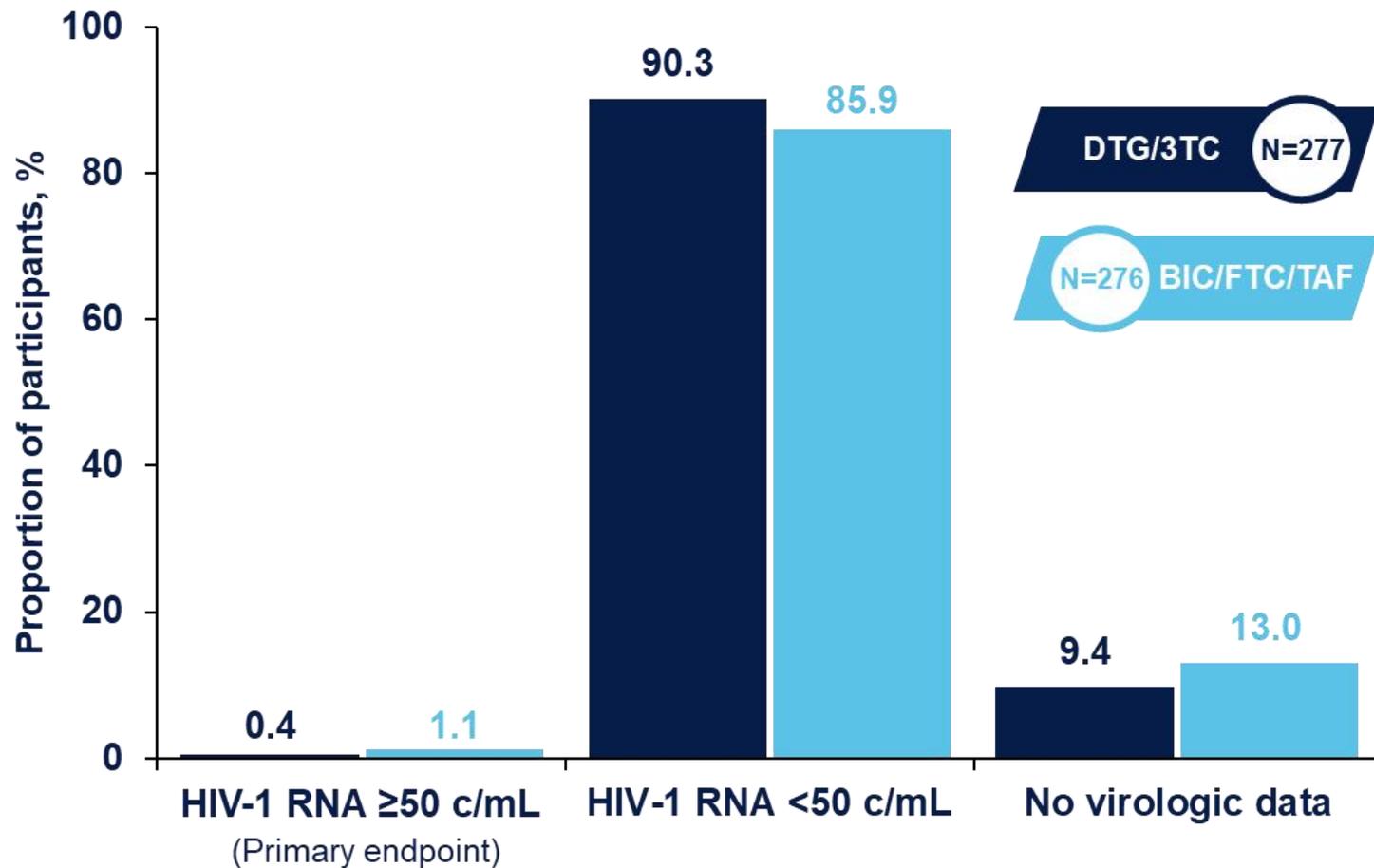


Snapshot outcomes at Week 48 (ITT-E population)





Snapshot outcomes at Week 96 (ITT-E population)





DTG/3TC

N=277

N=276

BIC/FTC/TAF

Confirmed virologic failure*
through Week 96

0

3

Emergent resistance
through Week 96

0

0

*Confirmed virologic failure was defined as HIV-1 RNA ≥ 50 c/mL followed by a second consecutive HIV-1 RNA assessment ≥ 200 c/mL

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Participants with AEs at Week 96, n (%)	DTG/3TC N=277	BIC/FTC/TAF N=276	p-value
Any AE	239 (86.3)	243 (88.0)	0.536
Grade 3–4 AEs	13 (4.7)	18 (6.5)	0.350
SAE	23 (8.3)	30 (10.9)	0.305
Drug-related AEs	21 (7.6)	37 (13.4)	0.025
AEs leading to withdrawal	2 (0.7)	4 (1.4)	0.409

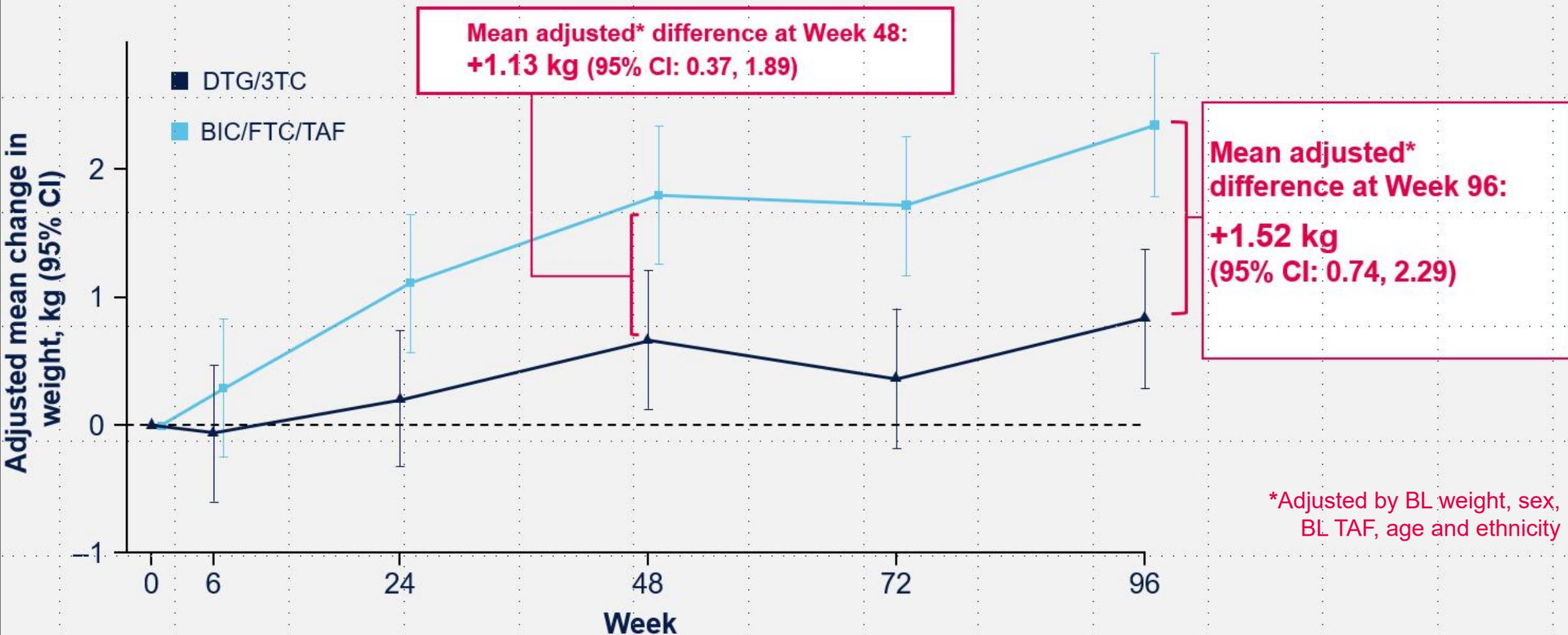
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Adjusted mean change in weight from BL through Week 96



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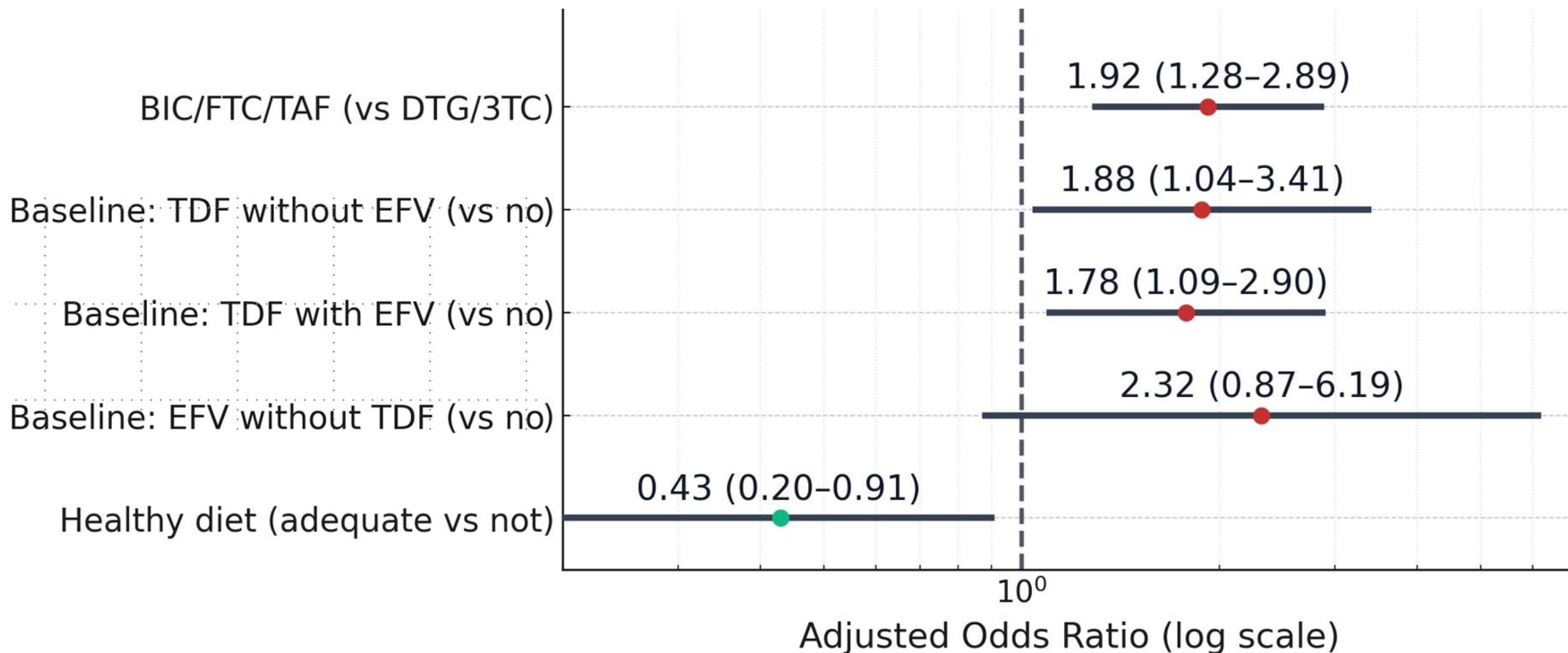
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Proportion of participants with weight gain >5% through 96 weeks



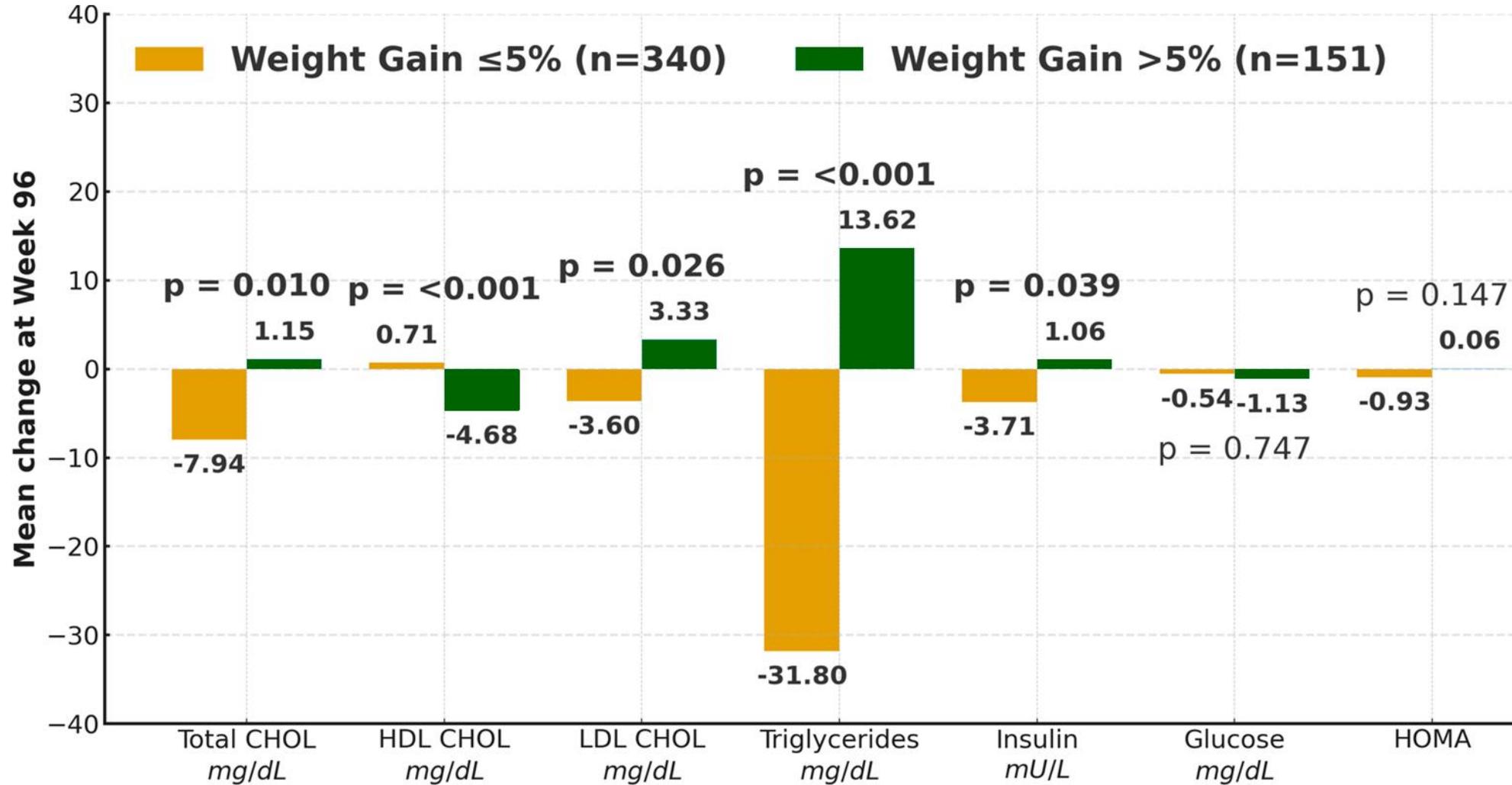


Independent Factors Associated with >5% Weight Gain





Absolute Mean Changes in Metabolic Parameters at Week 96 According to Weight Gain ($\leq 5\%$ vs $> 5\%$)





CONCLUSIONS

- ✓ **Efficacy:** Non-inferiority of DTG/3TC vs BIC/FTC/TAF maintained.
- 🧬 **CVF/Resistance:** Few CVF cases (DTG/3TC 0; BIC/FTC/TAF 3), no RAMs.
- ⌘ **Safety:** Good safety profile with both; more DRAEs with BIC/FTC/TAF.
- 🤝 **Tolerability:** Low discontinuation rates with both regimens.
- ⚖️ **Weight:** Greater weight gain with BIC/FTC/TAF; a >5% increase was independently associated with this regimen and with a worse metabolic profile.

When used as a switch regimen, DTG/3TC maintained virological efficacy and offered a better metabolic profile compared with BIC/FTC/TAF

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HU Son Llàtzer
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HU Puerta de Hierro
HU La Paz
HU Infanta Leonor
HU Alcorcón

10. Málaga

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11. Murcia

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HUC Valladolid

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Thank you

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[*x.com/Esteban09090*](https://x.com/Esteban09090)