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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 PASO-DOBLE (GeSIDA 11720) randomised, multicentre, open-label, non-inferiority trial

Esteban Martinez
Senior Consultant & Associate Professor
Hospital Clínic & University of Barcelona

Declaration of interest

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

PASO DOBLE

The two-arm switch design reduces any potential bias introduced when switching only one arm[3–7]

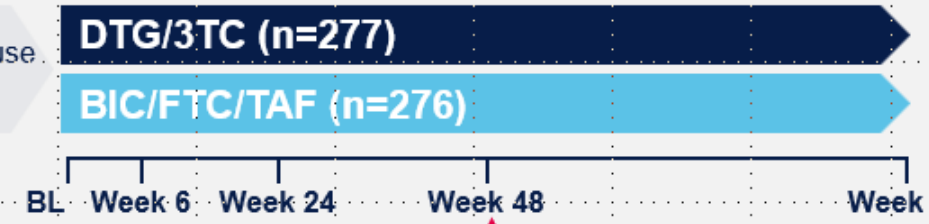
30 sites across Spain — Collaborative study between **Fundación SEIMC-GESIDA** and ViiV Healthcare

Phase IV, open-label, multicentre, randomised clinical trial[1,2]

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

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

Randomised 1:1
Stratified by BL TAF use and sex at birth



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

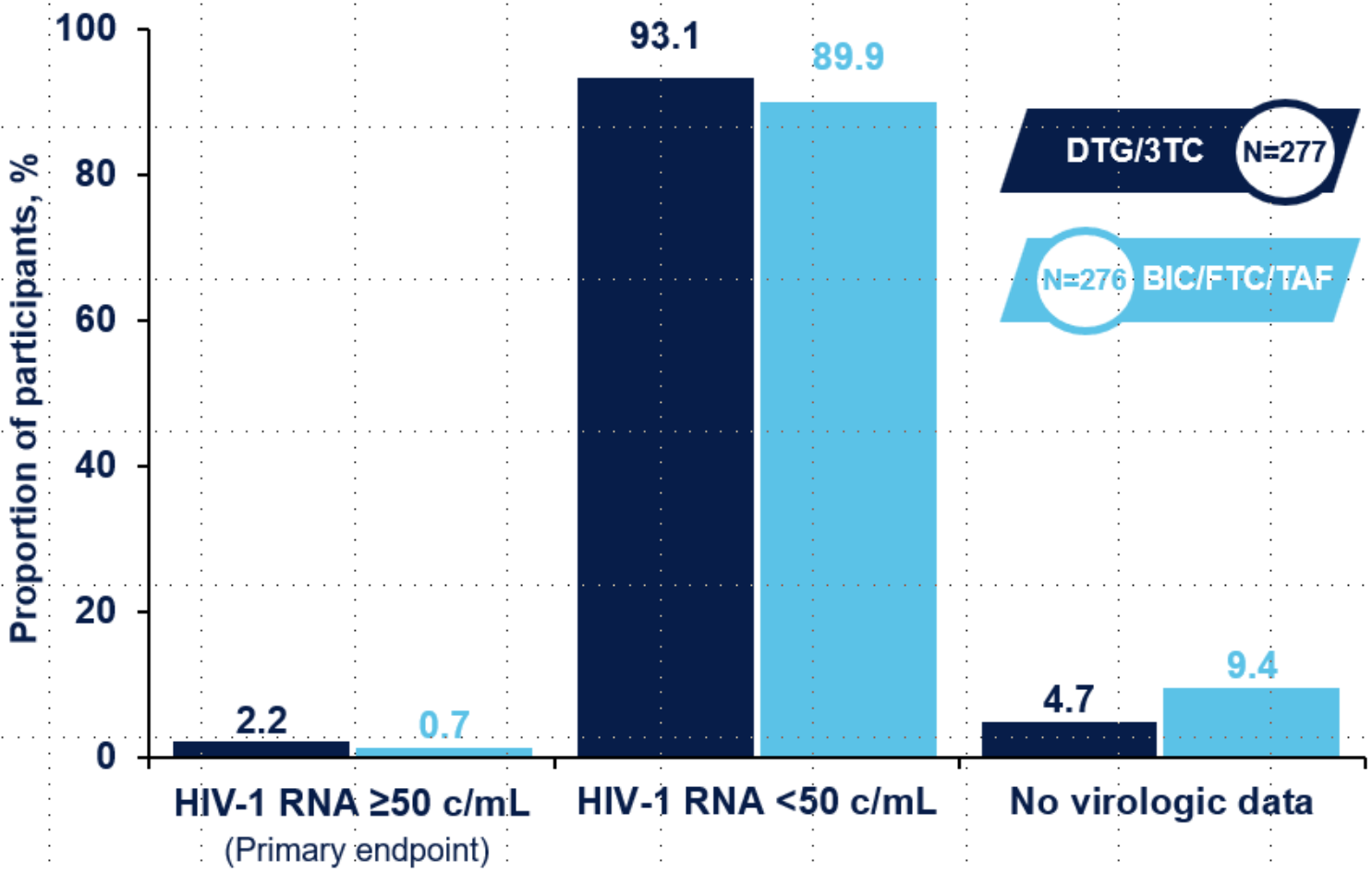
1. Ryan P, et al. Lancet HIV 2025;12:e473–84
2. PASO DOBLE. Available at: https://clinicaltrials.gov/ct2/show/NCT04884139. Accessed October 2025

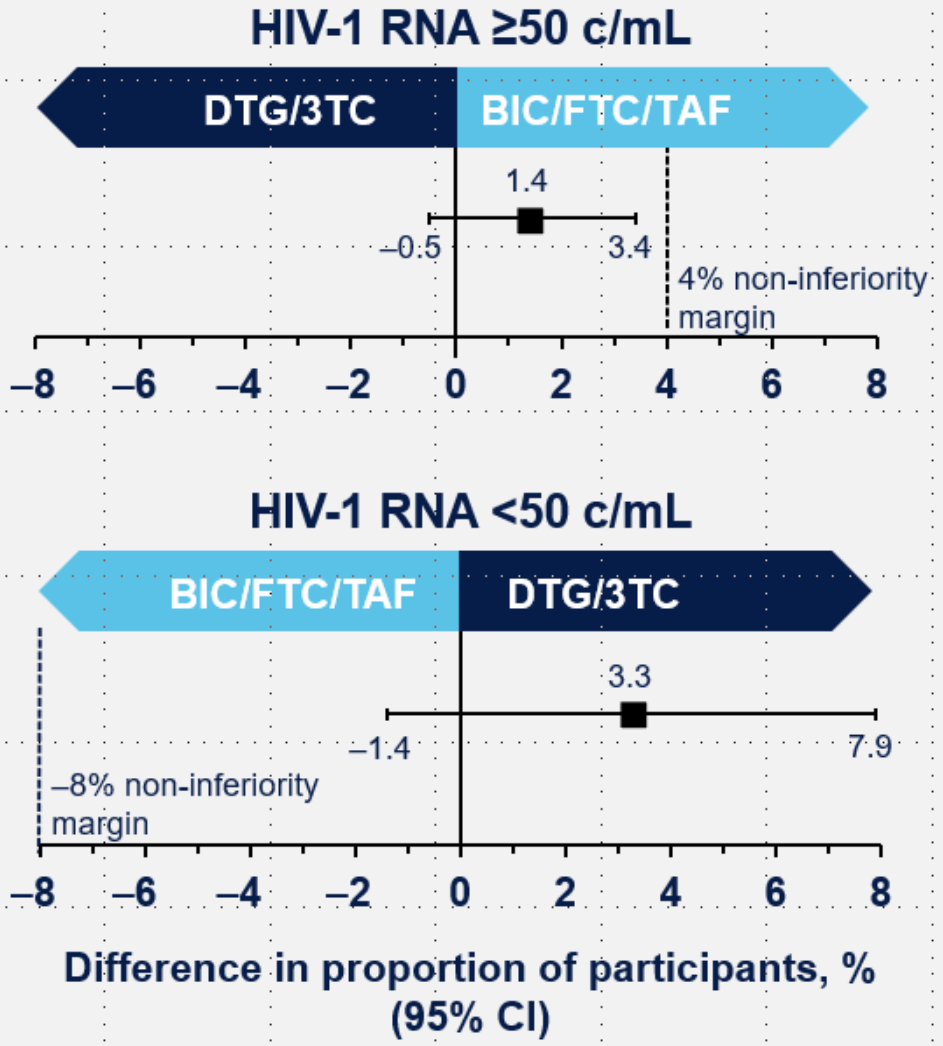
Baseline characteristics

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)	201 (72.8)
	Latinx	66 (23.8)	67 (24.3)
	Black	4 (1.4)	5 (1.8)
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)

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

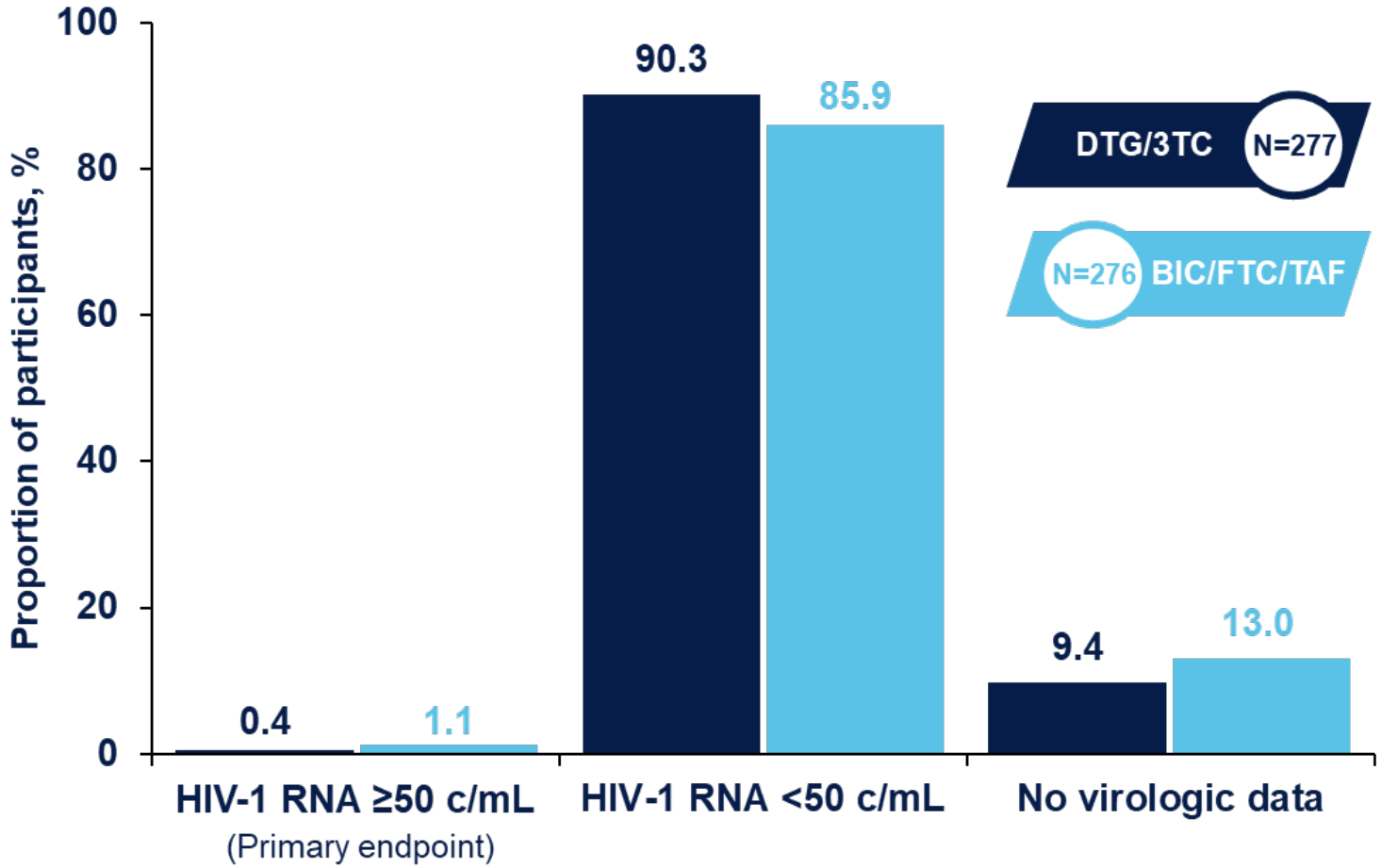
Snapshot outcomes at Week 48 (ITT-E population)



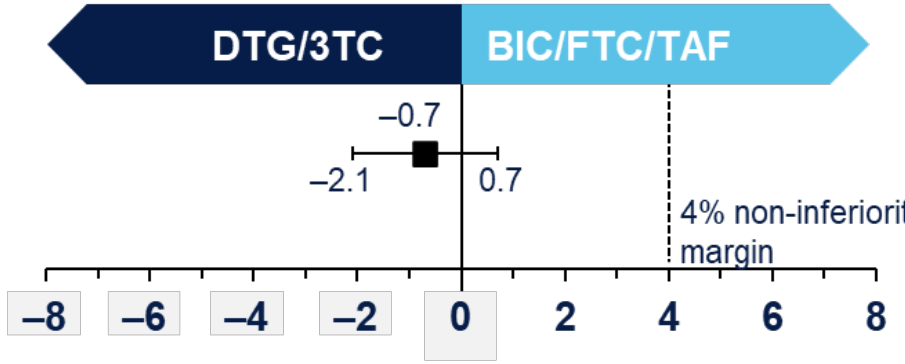


Ryan P, et al. Lancet HIV 2025;12:e473–84

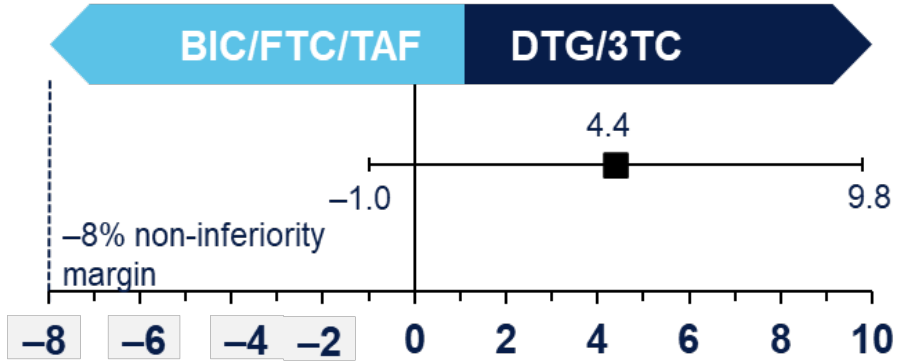
Snapshot outcomes at Week 96 (ITT-E population)



HIV-1 RNA ≥50 c/mL



HIV-1 RNA <50 c/mL



Difference in proportion of participants, % (95% CI)

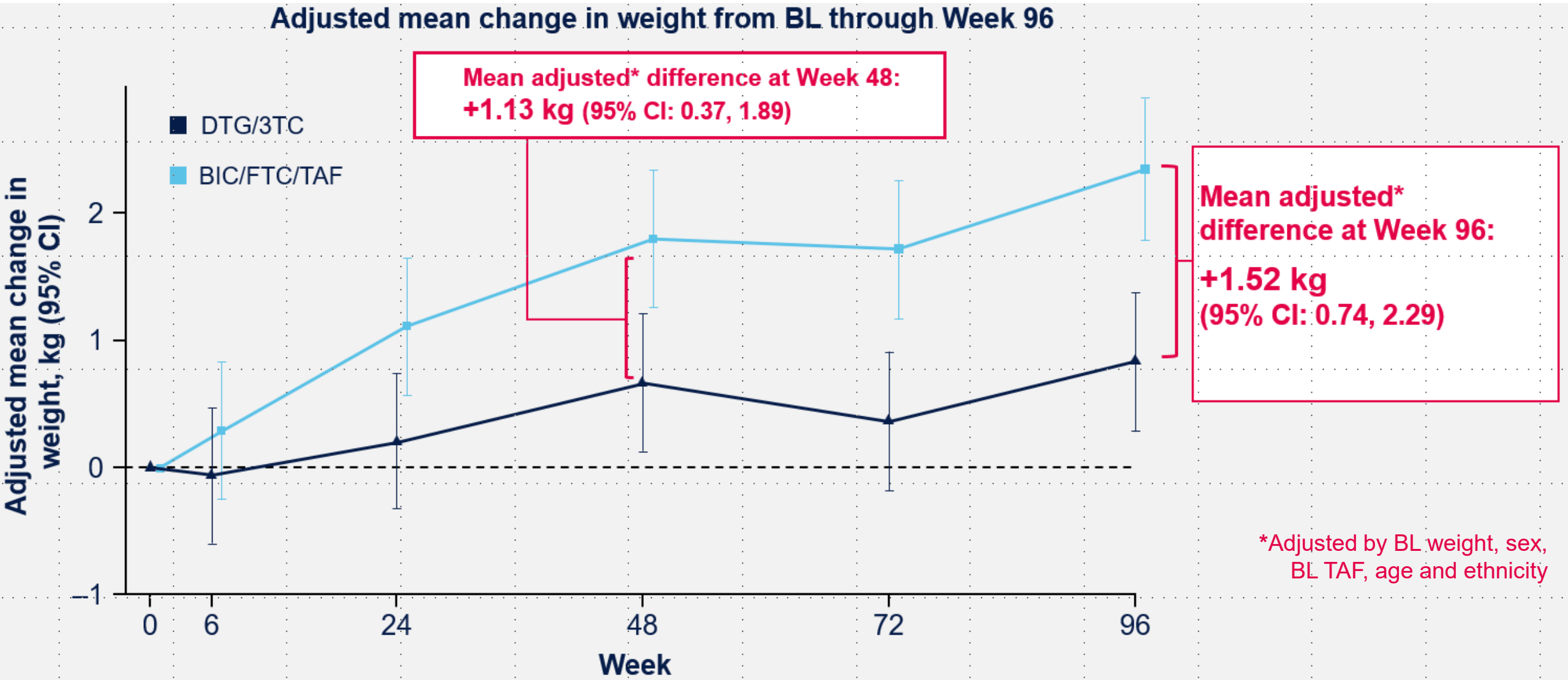
Aaaa bbbb

	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

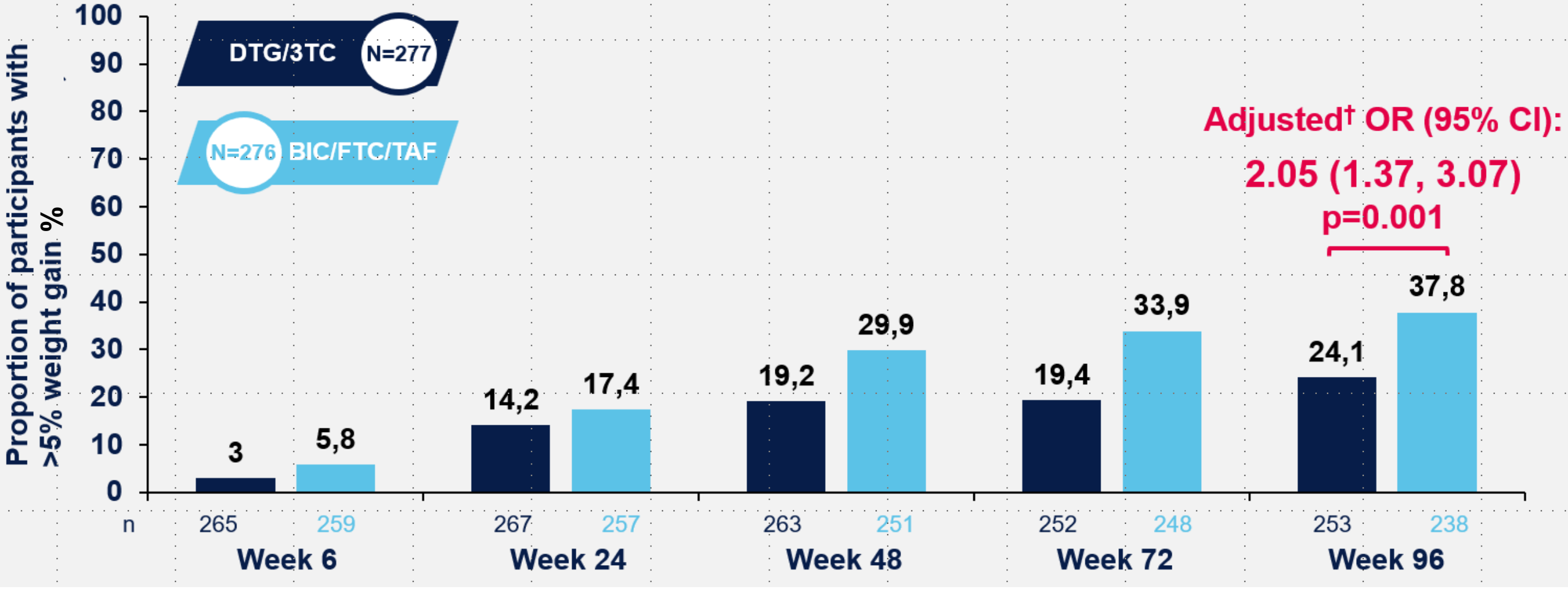
Participants with AEs at Week 96, n (%)	DTG/3TC N=277	BIC/FTC/TAF N=276	p-value
Any AE	239 (86.3)	243 (88.0)	0.536
Grade 3–4 AEs	13 (4.7)	18 (6.5)	0.350
SAE	23 (8.3)	30 (10.9)	0.305
Drug-related AEs	21 (7.6)	37 (13.4)	0.025
AEs leading to withdrawal	2 (0.7)	4 (1.4)	0.409

Adjusted mean change in weight from BL through Week 96

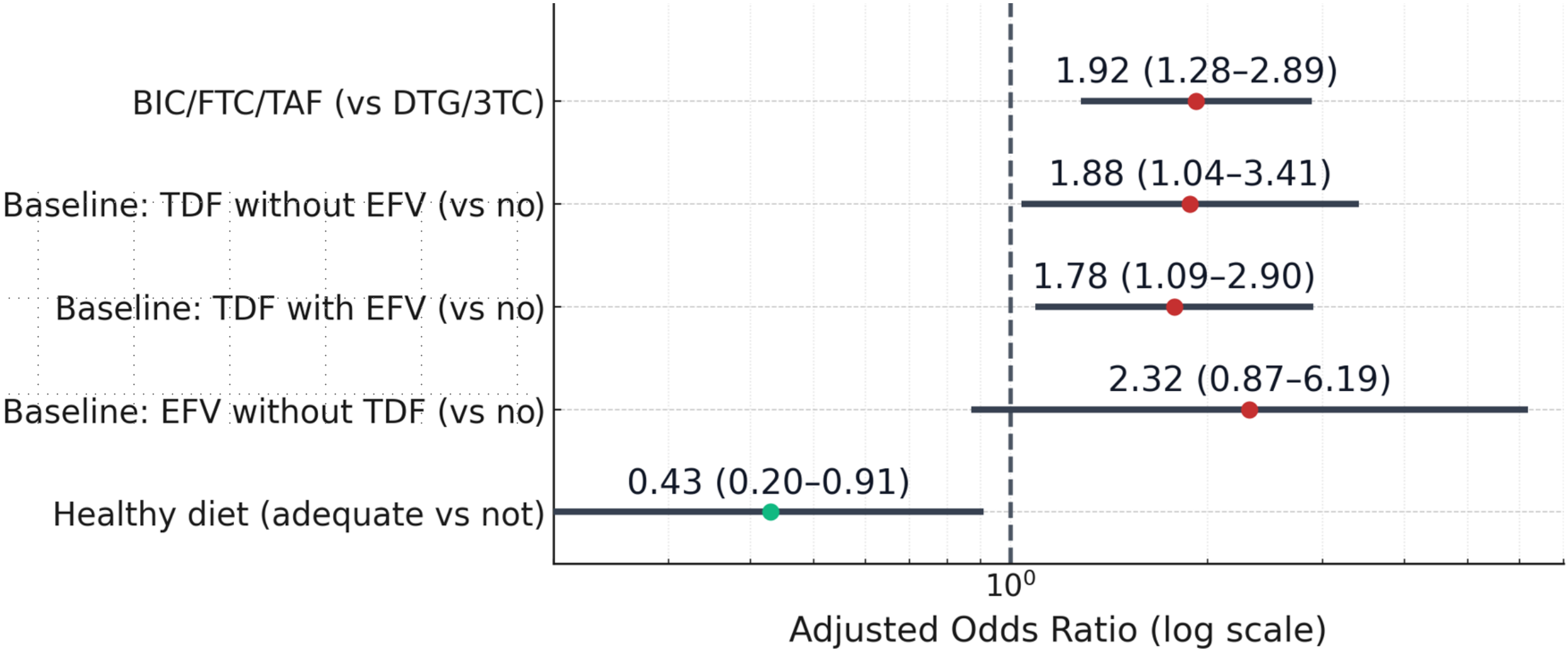


*Adjusted by BL weight, sex, BL TAF, age and ethnicity

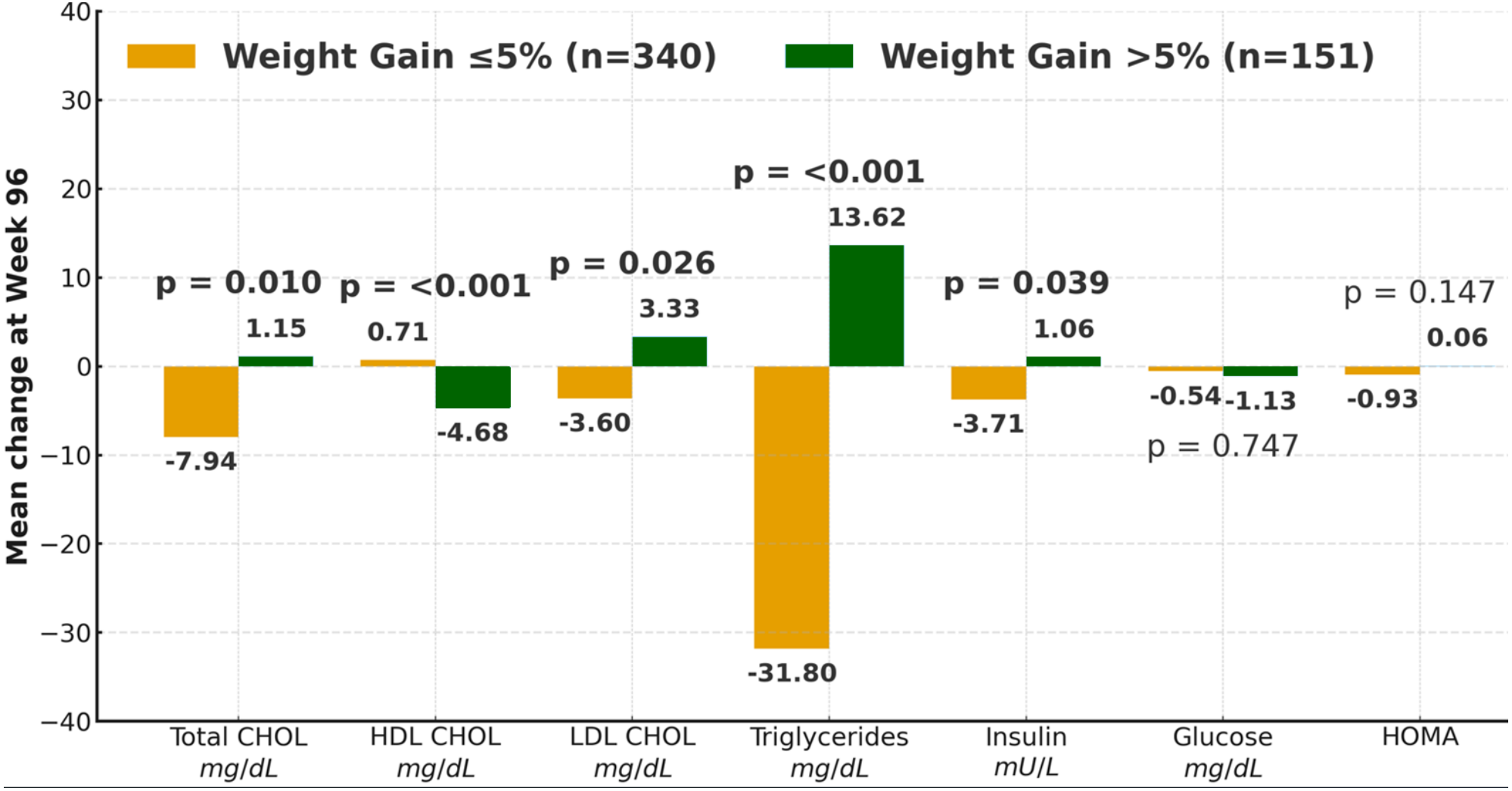
Proportion of participants with weight gain >5% through 96 weeks



Independent Factors Associated with >5% Weight Gain



Absolute Mean Changes in Metabolic Parameters at Week 96 According to Weight Gain (≤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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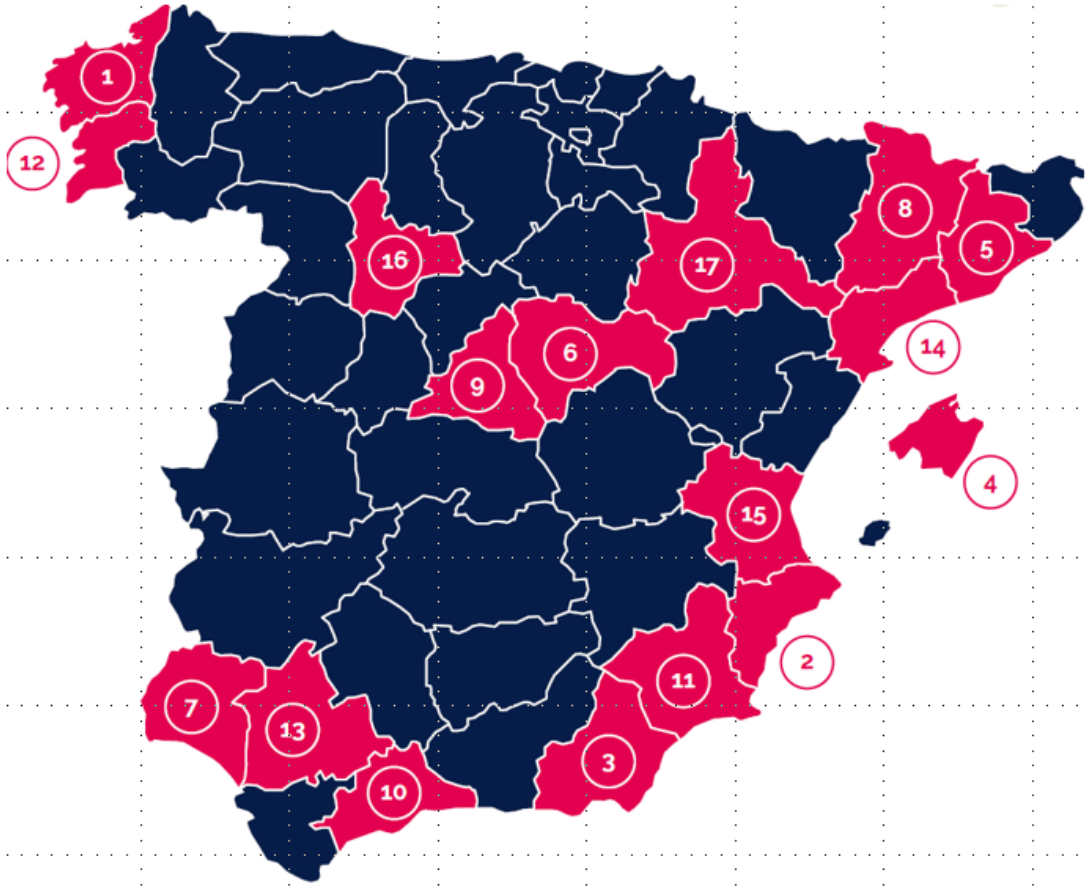

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Esteban Martinez
estebanm@clinic.cat
x.com/Esteban09090

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