Más de 35 años innovando para mejorar el futuro de las PVIH

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HIV management goals have expanded to meet the evolving needs of people with HIV[1,2]

Ongoing challenges include:

- Socioeconomic vulnerability[2]
- Migration of people[3]
- Stigma[1,3]

Emerging challenges include:

- Ageing[1,2]
- Frailty[2]
- Multimorbidity[1]

Improved treatment options:[4]

- Advances in ART, long-acting formulations, improved tolerability and safety profiles vs. older regimens

Improved models of care:[1,3]

- Holistic, integrated and person-centred approaches

ART: antiretroviral therapy

1. Antela A, *et al. J Antimicrob Chemother* 2021; 76:2501–2518. 2. DHHS. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf (Last accessed: Mar 2025).
3. UNAIDS. Prevailing against pandemics. Available at: https://aidstargets2025.unaids.org/assets/images/prevailing-against-pandemics_en.pdf (Last accessed: Mar 2025).
4. Taramasso L, *et al. Pharmacol Res* 2023; 196:106898.

Low toxicity is one of the important characteristics of ART for people with HIV and HIV specialists[1]

Proportion of people with HIV (n=502) and HIV specialists (n=101) reporting ART characteristics as quite important or very important[1,a]

ART characteristic	Proportion of people with HIV	Proportion of HIV specialists
Efficacy	**97%**	**100%**
Low toxicity	**96%**	**100%**
Simplicity and convenience	93%	97%
Use in aging population	93%	97%
Effective use in all people with HIV	93%	90%
High barrier to resistance	92%	97%

This list is not exhaustive

For HIV specialists, low toxicity and efficacy had equal top importance[1]

For people with HIV, low toxicity was the second most important characteristic after efficacy[1]

AEs can lead to nonadherence or ART discontinuation[2,3]

Minimising AEs and their effect on an individual could be expected to improve clinical outcomes[3-5]

[a] *Ex post facto* cross-sectional surveys in 18 sites in Spain (July–November 2020); the top 5 characteristics are shown for each group (for people with HIV: efficacy, low toxicity, simplicity / convenience, use in aging population and effective use in all people with HIV; for HIV specialists: efficacy, low toxicity, simplicity / convenience, use in aging population and high barrier to resistance)
AE: adverse event

1. Galindo Puerto MJ, *et al. HIV Med* 2024; 25:565–576. 2. DHHS. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf (Last accessed: Mar 2025).
3. Al-Dakkak I, *et al. AIDS Care* 2013; 25:400–414. 4. Antela A, *et al. J Antimicrob Chemother* 2021; 76:2501–2518. 5. Taramasso L, *et al. Pharmacol Res* 2023; 196:106898.

Multinational, observational, cross-sectional survey (global)

Survey on the Treatment Experiences and Satisfaction of PWH Across Diverse Settings

N=2532

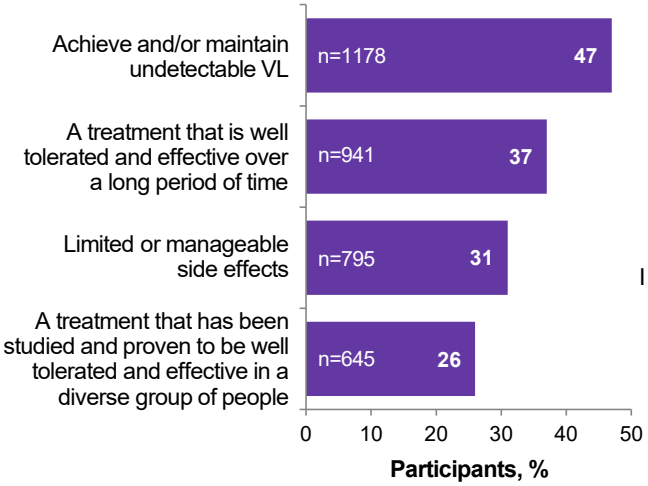
PWH aged ≥18 years with a self-reported diagnosis of HIV across 11 countries

Outcomes

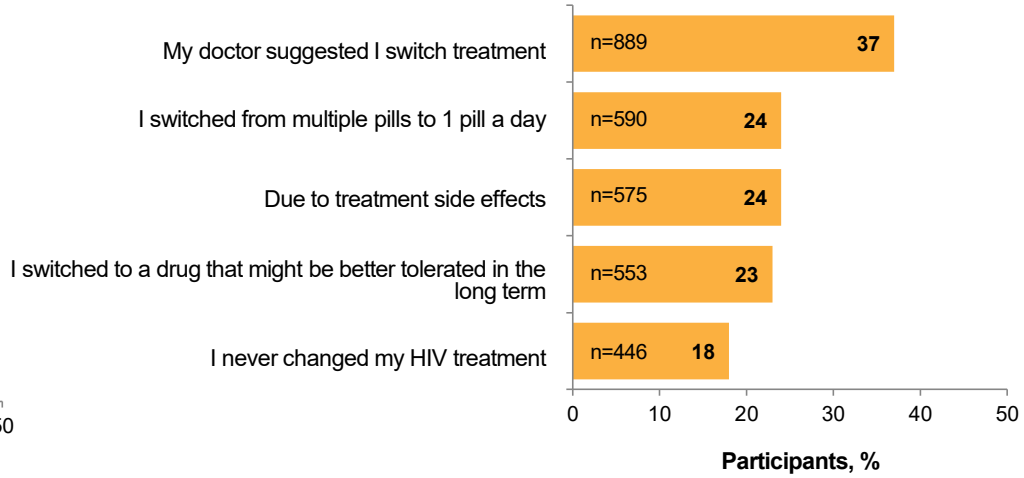
Perspectives of PWH on treatment initiation, treatment persistence, and preferences for and satisfaction with HIV treatment options

May 2024–May 2025

Most Important Features for Treatment Persistence (Reported by ≥25% of Participants) (n=2532)[a,b]



Reasons for Last Actual Treatment Switch (Reported by ≥15% of Participants) (n=2424)[b]



Treatment effectiveness, reduced side effects and long-term safety were top considerations for remaining on or switching ART; physician suggestion was the most common reason for switching ART

[a]Participants were asked to rank their top 3 treatment features among 13 possible responses that would be most important to motivate them to stay on treatment long term or be most important in switching HIV treatment. [b]Participants could have selected multiple response; therefore, percentages may not sum 100%.

Guillaume X, et al. IAS 2025, Poster THPED077

B/F/TAF is a Preferred Treatment to Help a Broad Range of Clinically Appropriate PWH Achieve Long-term Treatment Success

Forgiveness

Reduced dosing frequency[31]

HIV Coinfection

HIV/HBV: ALLIANCE: OLE Week 48[29]
HIV/TB: No association of NP AEs with B/F/TAF[30]

Renal Safety

Renal pooled analysis in TN/VS PWH[27]
Post–renal transplant[28]

Barrier to Resistance

Aquitaine[24,25] and Haiti[26]: B/F/TAF in PWH with resistance

>4,400 participants and up to 5 years of follow-up in clinical trial programs[9,10,a]

0 cases of treatment-emergent resistance in Phase 3 trial participants receiving B/F/TAF[10]

>137,000 participants in Phase 4, real-world research programmes[10,b]

>5.1 million patent-years of exposure to B/F/TAF globally[10,b]

Metabolic Neutrality

Weight and CV safety[17-19]

Late Presenters

LAPTOP: B/F/TAF in late presenters[20]

Aging With HIV

Switch in PWH ≥60 years[21]

Women and Pregnancy

Canada Pregnancy Registry[22]

PWH Unable to Swallow Pills

Crushed/dissolved B/F/TAF[23]

NP, neuropsychiatric; OLE, open-label extension; TN, treatment-naïve; VS, virologically suppressed
For footnotes and references, refer to slide notes

U.S. Retrospective Cohort Study (RWE)

Treatment Persistence Among Treatment-Experienced People With HIV Switching to INSTI-Based ART Regimens

‡

N=29,348

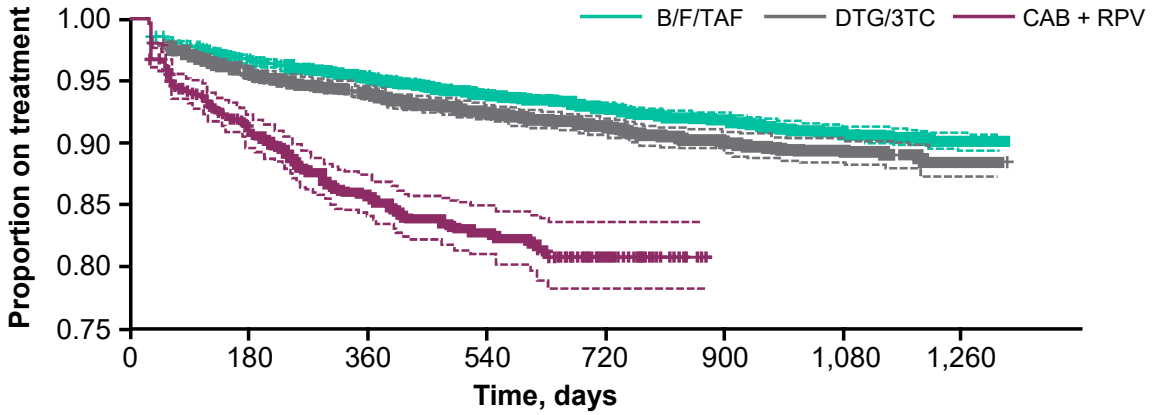
Adults with HIV with a history of ≥1 ARV with a newer INSTI-based regimen[a] and were receiving an ARV regimen for ≥6 months

Outcomes

Factors associated with treatment switch, persistence of INSTI-based regimens by age, insurance, and comorbidities

January 2018–August 2023

Time to treatment switch for the 3 most common regimens (overall population)



B/F/TAF	17,917	16,014	13,344	10,682	8,006	5,622	3,348	980
DTG/3TC	8,034	7,085	5,515	3,988	2,666	1,432	578	148
CAB + RPV	2,186	1,706	931	282	72	0	0	0

People with HIV treated with B/F/TAF had a reduced likelihood of subsequent treatment switch compared with individuals receiving DTG/3TC and CAB+RPV IM

[a] CAB+RPV, DTG/3TC/ABC, B/F/TAF, DTG/3TC, DTG/F/TDF, or DTG/F/TAF

ARV: antiretroviral; INSTI: integrase strand transfer inhibitor; RWE: real-world evidence

Chuo CY, *et al. J Med Econ* 2025; 28:1241–1251.

Retrospective claims database analysis (US)

ART Persistence Among TE PWH With Low Adherence and Mental Health/Substance Use Disorders

14,826 TE PWH restarting or switching ART during the study period[a]
(5310 with MHD/SUD, 4090 with PDC <85%)

Outcomes

- Proportion of PWH with MHD/SUD and PWH with low adherence (PDC <85%)
- Persistence at 1 year in these groups by regimen

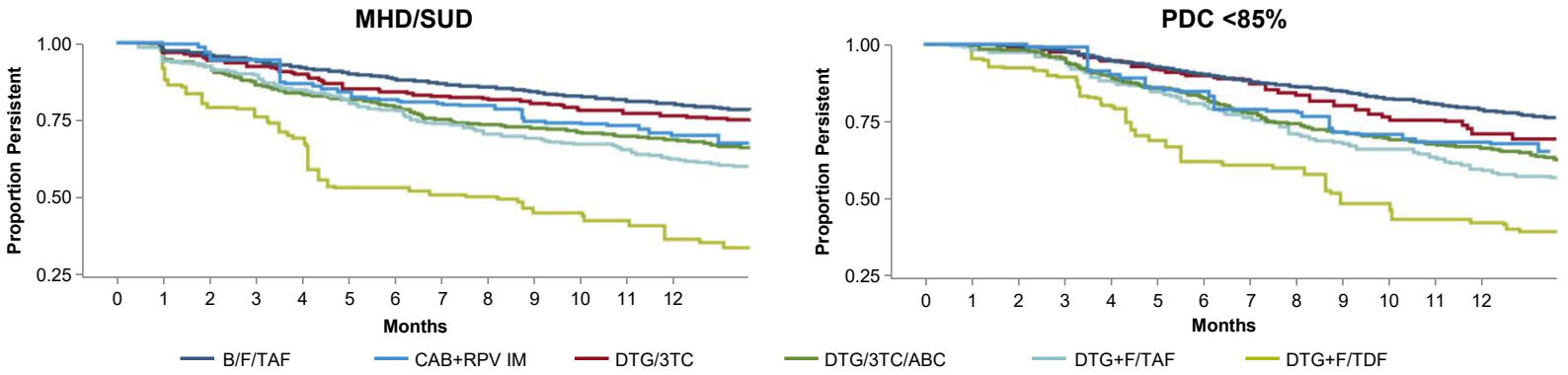
January 2017–February 2024

ART Regimens Used

n	MHD/SUD (n=5310)	PDC <85% (n=4090)
B/F/TAF	3178	2323
CAB+RPV IM	217	145
DTG/3TC	674	366
DTG/3TC/ABC	680	739
DTG+F/TAF	477	436
DTG+F/TDF	84	81

Persistence was defined as the time to the earliest of ART discontinuation (gap in all ART ≥90 days), ART switch or add on, death

Weighted Kaplan-Meier Curves – Persistence



- **36%** (5310/14,826) of TE PWH had **MHD/SUD**
- Among these, **persistence at 1 year** was **significantly higher for B/F/TAF (80%) versus DTG/ABC/3TC (69%), DTG+F/TAF (62%) and DTG+F/TDF (37%) (*P*<0.001)**

- **28%** (4090/14,826) of TE PWH had **PDC <85%**
- Among these, **PWH on B/F/TAF** were **significantly more likely to be persistent at 1 year (79%) versus DTG/ABC/3TG (66%), DTG+F/TAF (59%) and DTG+F/TDF (42%) (*P*<0.001)**

PWH with MHD/SUD or low adherence who switched to or restarted B/F/TAF were more likely to stay on their treatment at 1 year compared to those receiving other commonly prescribed ART

Study limitations: There were difficulties in capturing adherence data for injectable therapy using medical claims due to variations in days supplied (i.e., 30 vs. 60 days); in addition, virologic suppression rates and reasons for switching or discontinuing ART were not reported. [a]With or without a gap in therapy. MHD/SUD, mental health or substance use disorders; PDC, proportion of days covered; TE, treatment-experienced

Mordi U, et al. EACS 2025, Poster MeP05.4

‡

B/F/TAF in Special Populations

LAPTOP: Open-label, multicenter, noninferior, controlled trial (Europe)

INSTI Versus PI-Based Therapy for PWH With Advanced Disease

N=442

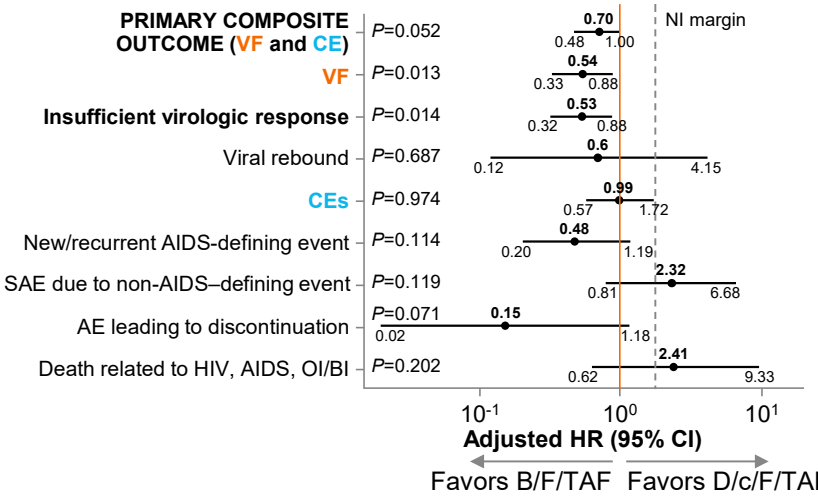
TN PWH with advanced disease and:
- AIDS/any CD4 count
- or severe bacterial infection/CD4 <200/µL
- or any or no symptoms/CD4 <100/µL
- or serious opportunistic infection currently under treatment

Week 0 → Week 48
- B/F/TAF QD (n=220)
- D/c/F/TAF QD (n=222)

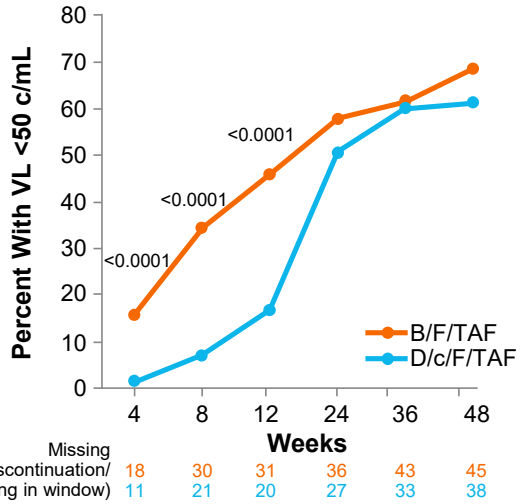
Outcomes

- Time to failure, as the first occurrence of any of a composite of specified VF[a] or CEs plus the individual components evaluated by Kaplan-Meier and Cox regression analyses[b]

Primary Composite Endpoint and Components



Individuals With VL <50 c/mL (%)



Drug-Related Safety Events

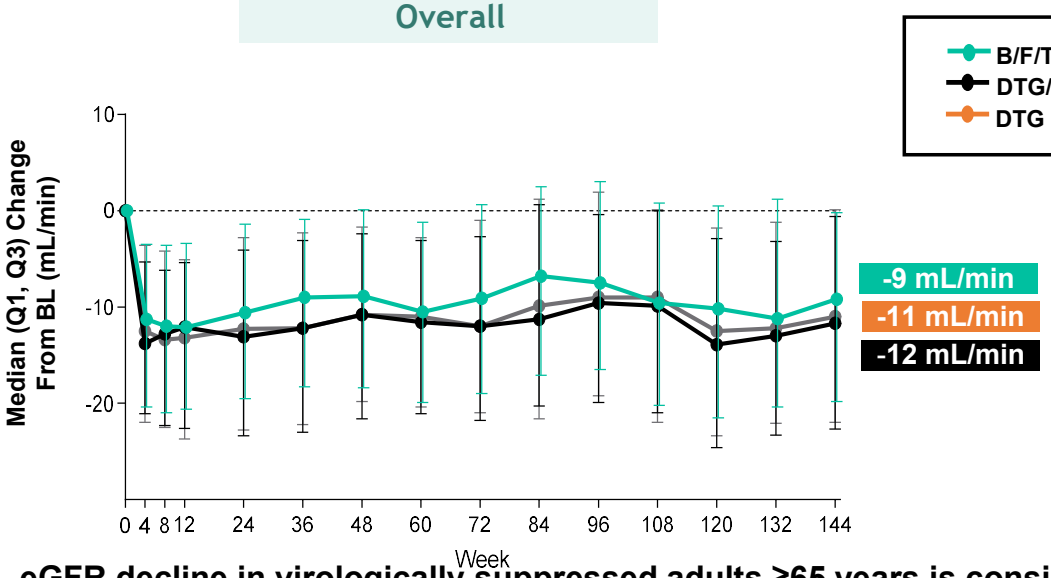
	B/F/TAF (n=220)	D/c/F/TAF (n=222)	Adjusted IRR	*P* value
Any Grade ≥2 AE				
N events	435	548		
Incidence rate per 100 PY	220.5	264.7	0.82 (0.73–0.93)	0.0024
Drug-related Grade ≥2 AEs				
N events	27	45		
Incidence rate per 100 PY	13.7	21.7	0.61 (0.38–0.98)	0.0431

In people with advanced HIV disease B/F/TAF was non-inferior to D/c/F/TAF in terms of composite outcomes, had a better virologic response at week 48, and fewer overall adverse events

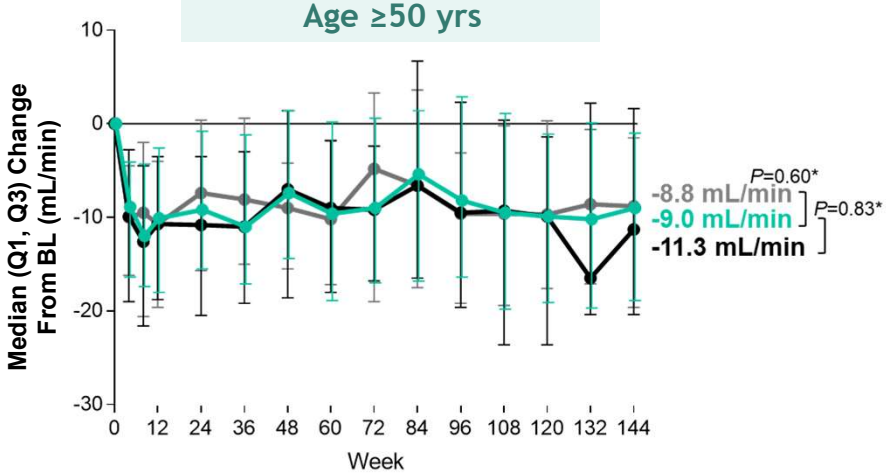
[a]Insufficient virologic response was defined as HIV-1 RNA reduction <1 $\log_{10}$ c/mL at Week 12 or VL >50 HIV-1 RNA c/mL at Week 48. [b]NI margin of 1.606 in the HR
BI, bacterial infection; CE, clinical event; NI, noninferiority; OI, opportunistic infection; PY, person-years; TN, treatment-naïve; VF, virologic failure; VL, viral load
Behrens GMN, et al. CROI 2025, Poster 0658; Lancet Infect Dis 2025; https://doi.org/10.1016/S1473-3099(25)00681-4

BFTAF and older adults: eGFR Change by Visit

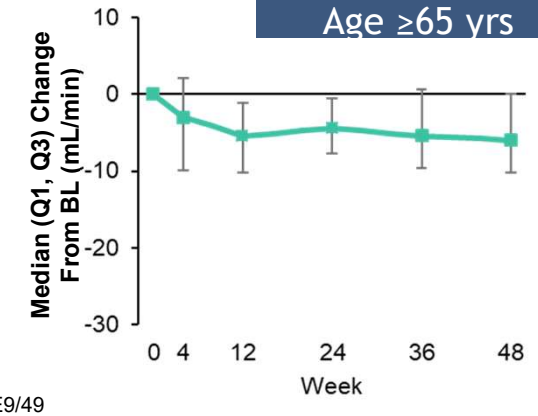
Pooled 1489 & 14901
Overall



Pooled 1489 & 14902
Age ≥50 yrs



Study 44493
Age ≥65 yrs



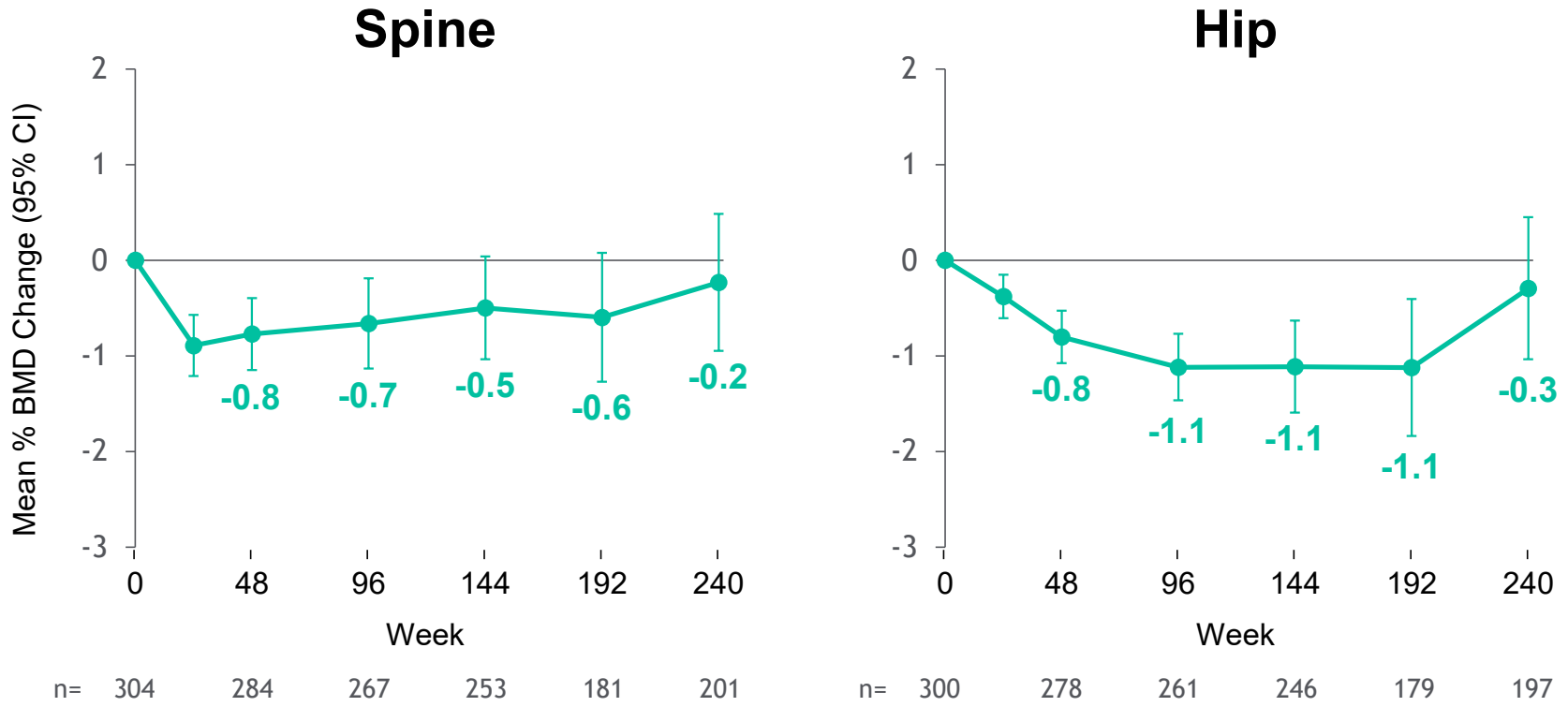
-6 mL/min*

- **eGFR decline in virologically suppressed adults ≥65 years is consistent with known inhibition of OCT2 creatinine transporter**
- **Changes from baseline in eGFR were comparable between B/F/TAF and DTG/ABC/3TC in ART-naïve adults**
  - **No statistically significant difference between B/F/TAF and comparators in adults ≥50 years**

*Data on File
eGFR, estimated glomerular filtration rate; OCT-2, organic cation transporter-2

1. Orkin C, et al. EACS 2019. Basel, Switzerland. PE3/14
2. Mills A, et al. CROI 2020. Boston, MA. 477
3. Maggiolo F, et al. EACS 2019. Basel, Switzerland. PE9/49

Spine and Hip BMD Changes Through Week 240 with BFTAF



*Includes only participants initially randomized to B/F/TAF; bone mineral density (BMD) measured by dual-energy x-ray absorptiometry in Study 1489 only. CI, confidence interval.

Wohl D.A, et al. B/F/TAF Five-Year Outcomes in Treatment-Naïve Adults. Póster 494 presentado en el Virtual CROI 2022, 12-16 de febrero de 2022.

There was no increased risk of MACE associated with INSTI use in REPRIEVE[1]

N=5162

PWH on stable non-INSTI based regimens[a] with low to moderate CVD risk

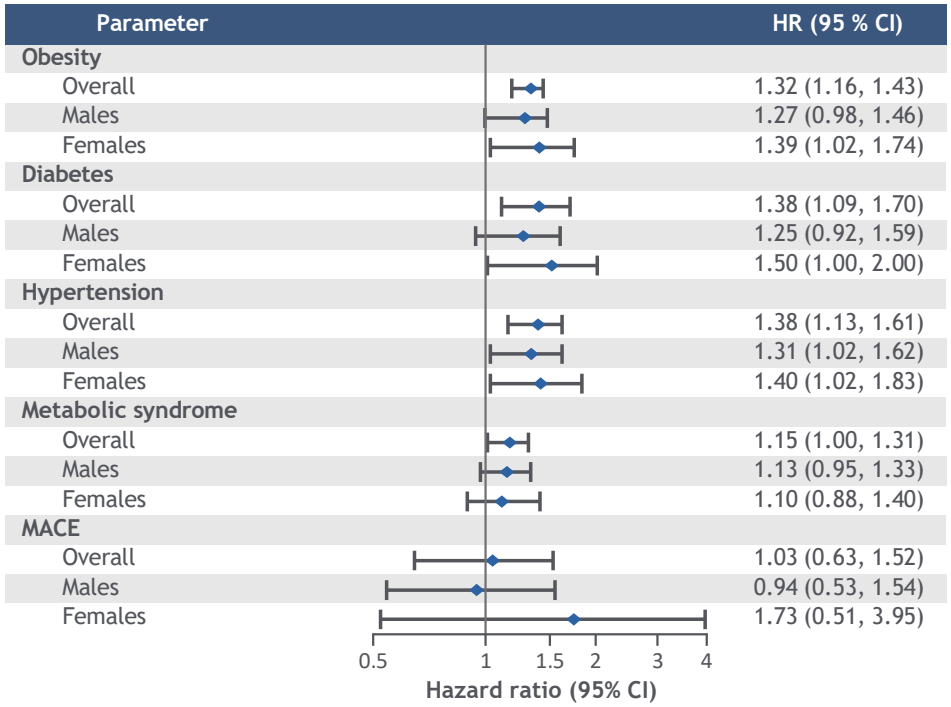
Switch to INSTI (n=2708)

Stay on non-INSTI (n=2454)

Emulated series of trials with IPTW adjusting for cofounders
- 82% switched to DTG

Outcomes

Incident obesity, diabetes, hypertension, metabolic syndrome and MACE



Former and current use of ABC was previously associated with higher MACE incidence compared with no ABC use in REPRIEVE[2]

In this most recent analysis, switching to an INSTI did not have an impact on cardiovascular risk (MACE)[1]

Modest increased risk of some outcomes (HR ranges from 1.15 - 1.38):[1]

- Obesity
- Hypertension
- Diabetes
- Metabolic syndrome

70% of participants were on EFV/FTC/TDF prior to switch[3]

IPTW: inverse probability of treatment weights

1. Kileel EM. CROI 2025 (Abstract 838; poster presentation). 2. Fichtenbaum CJ, *et al.* AIDS 2024 (Abstract OAB3406LB; oral presentation). 3. Data on file

Fasting lipids through Week 240 in treatment-naive people with HIV receiving B/F/TAF[a]

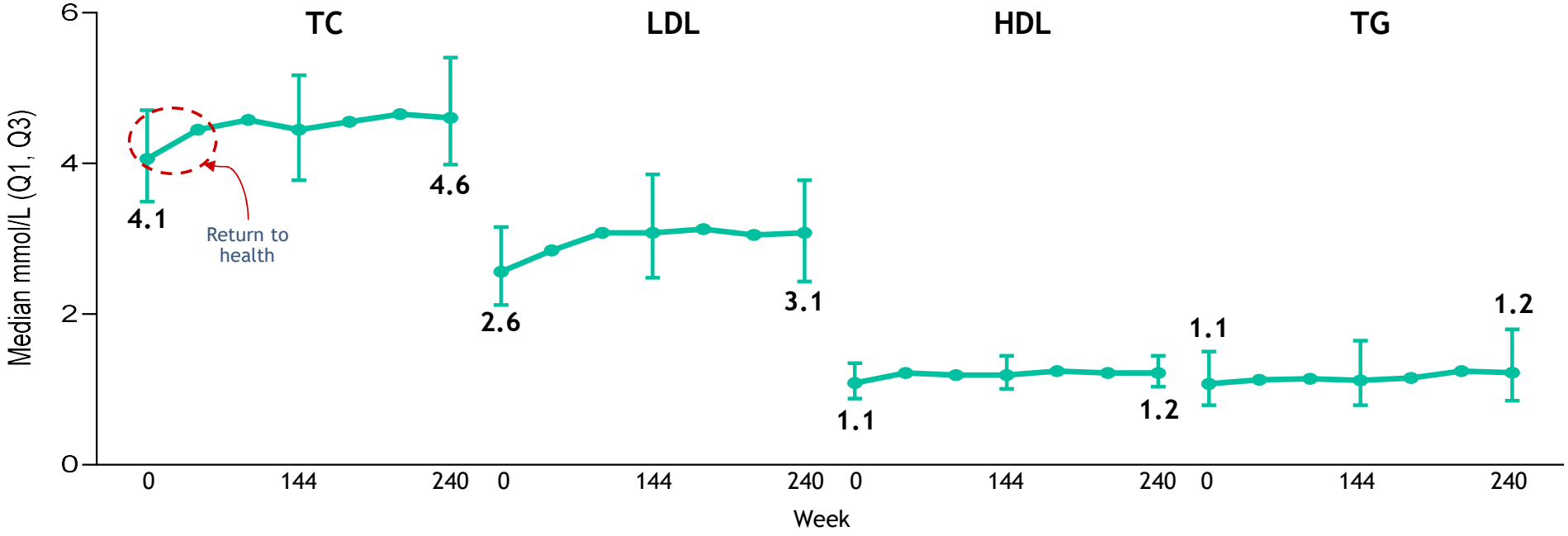
N=634

Study 1489, B/F/TAF (n=314)

Study 1490, B/F/TAF (n=320)

Outcomes

Assess 5-year outcomes including long-term safety after 144 weeks of blinded treatment plus 96 weeks in OLE



Small changes in lipids were observed among participants randomised to B/F/TAF over 5 years

[a] Includes only participants initially randomised to B/F/TAF
HDL, high-density lipoprotein; TC, total cholesterol; TG, triglycerides.
Sax P et al. AIDS 2022, Montreal, Poster EPB150.

Updated EACS and DHHS guideline recommendations for specific populations

	EACS 2025 Guidelines[1]	DHHS 2025 Guidelines[2-4]
Pregnancy	▪ B/F/TAF is a **recommended regimen** for treatment in ART-naïve pregnant women (updated from 'alternative')	▪ B/F/TAF is **recommended as a preferred regimen** for HIV during pregnancy (updated from 'alternative')
Weight management in PWH	▪ Switching ART with the goal of reducing excess body weight has **limited or no benefits**	▪ Specific antiretrovirals **should not be selected** to prevent or reduce weight gain
Post-exposure prophylaxis (PEP)	▪ B/F/TAF is a **preferred regimen** for PEP	▪ No update since last edition. 2025 CDC guidance: – B/F/TAF **OR** – DTG + [TAF or TDF] + [FTC or 3TC]

Improved forgiveness[1] is introduced as a new rationale for switching ART, highlighting the importance of regimens with a higher barrier to resistance in persons with reduced adherence

1. EACS. Guidelines v13.0. Available at: https://eacs-prod.sanfordguide.com/ (Last accessed: Oct 2025). 2. DHHS. Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States, Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/perinatal-hiv/guidelines-perinatal.pdf (Last accessed: Oct 2025). 3. DHHS. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf (Last accessed: Oct 2025).
4. CDC. Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV — CDC Recommendations, United States, 2025. Available at: https://www.cdc.gov/mmwr/volumes/74/rr/rr7401a1.htm (Last accessed: Oct 2025).

NEURO-INSTI (SCOLTA project): Retrospective analysis of multicenter observational study (Italy)

‡

Neuropsychiatric AEs Among PWH Starting a New INSTI-Based Regimen

N=2922

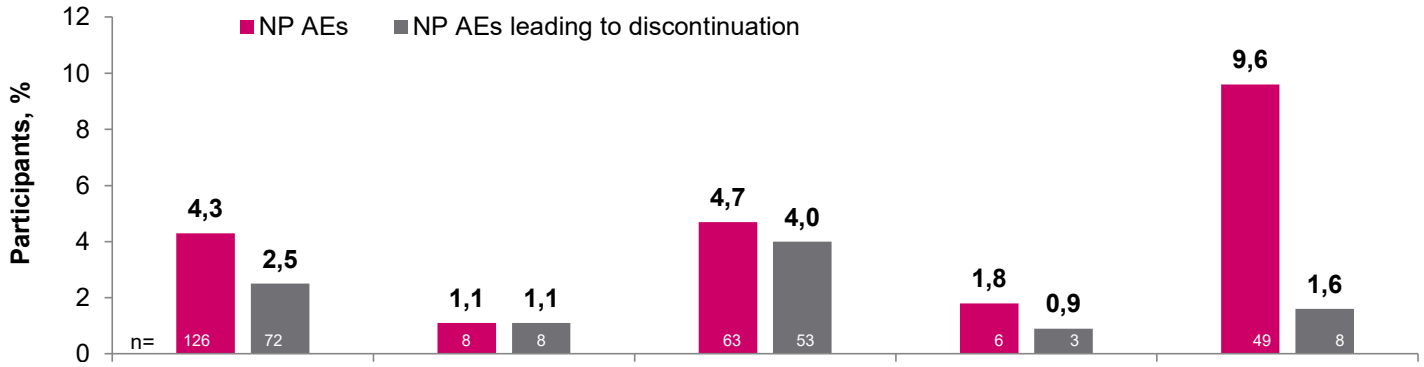
PWH starting a new INSTI

Outcomes

Incidence rates of NP AEs and related discontinuations

2007 onwards

NP AEs and NP AEs Leading to Discontinuation According to Treatment



	Total (N=2922)	B/F/TAF (n=735)	DTG (n=1339)	EVG/COBI (n=338)	RAL (n=510)
	Adjusted incidence rate per 1000 PYFU (95% CI):				
NP AEs	**15.9 (13.4, 19.0)**	**7.6 (3.4, 17.3)**	**25.4 (16.5, 39.0)**	**15.1 (6.1, 37.5)**	**60.5 (36.1, 101.4)**
NP AEs leading to Discontinuation	9.1 (7.2, 11.5)	13.4 (6.2, 29.0)	18.2 (13.3, 24.8)	8.2 (2.5, 26.5)	14.3 (6.6, 31.1)

Compared to DTG – BIC reduced the HR by ↓ 73% to CNS/NP AEs.

B/F/TAF was associated with a low rate of treatment discontinuation due to NP AEs in a real-life setting, consistent with findings from clinical trials

A multivariate generalized linear model was used to calculate adjusted incidence rate based on selected baseline variables; observation was truncated at the first occurrence of NP AEs regardless of discontinuation. NP, neuropsychiatric; PYFU, person-years of follow-up; SCOLTA, Surveillance Cohort Long-Term Toxicity Antiretrovirals

Squillace N, et al. AIDS 2024, Poster TUPEB082 NEURO-INSTI study Squillace et al. BMC Infectious Diseases , MAY 2025 25:763

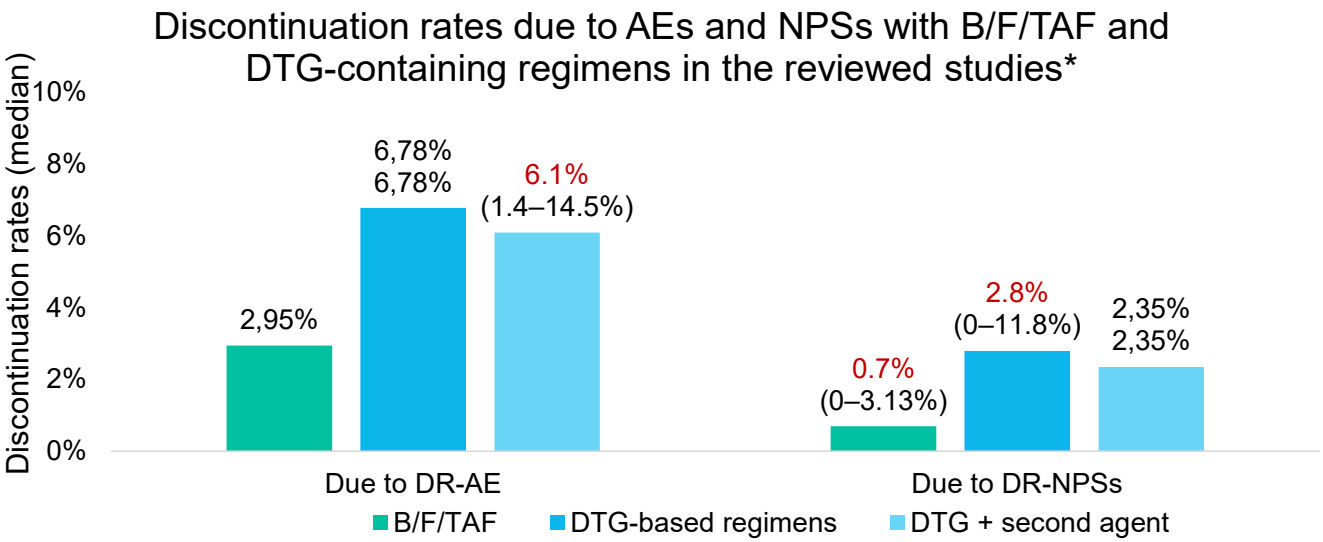
Discontinuations due to drug-related neuropsychiatric symptoms are an important clinical consideration

SLR of 90 studies*

Studies reporting data on treatment discontinuation due to drug-related AEs and NPSs (2013-2022)

Outcomes[1]

Rates of discontinuation on B/F/TAF and DTG-based regimens



Discontinuation rates for B/F/TAF and DTG-based regimens ranged from 0% to 3.1% and 0% to 11.8%, respectively

Discontinuations with either regimen increased with longer follow-up

Discontinuation due to DR-NPSs in PWH who are on B/F/TAF were observed to be numerically lower than those on DTG-based regimens

*65/90 (72.2%) provided details on the rate of discontinuation due to DR-NPSs
DR: drug-related; NPS: neuropsychiatric symptom; SLR: systematic literature review
Pérez-Valero I, *et al. Expert Rev Anti-Infect Ther* 2023; 21:655–665.

What is the effect of reducing number of ARV agents on drug-related AEs?

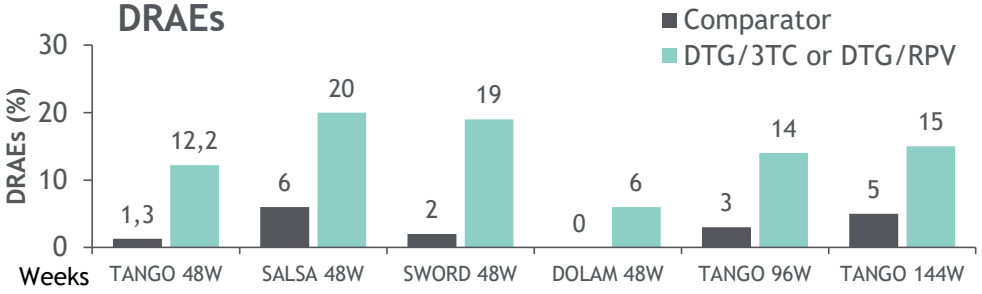
SLR of 9 studies

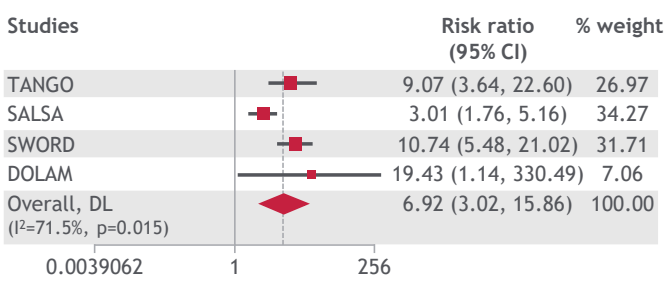
SATISFACTION study: Participants from TANGO, SALSA, SWORD and DOLAM

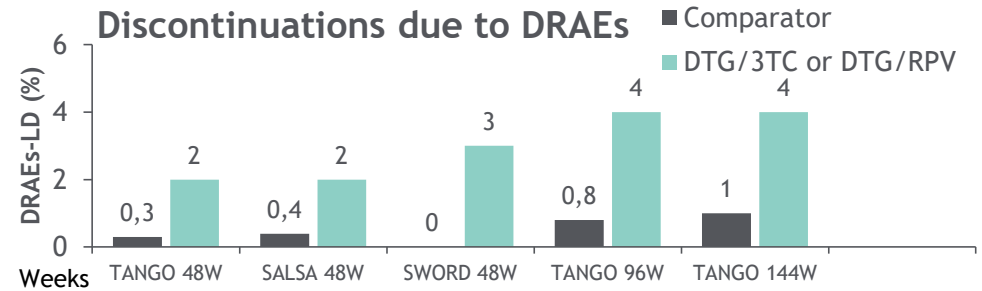
Outcomes[1]

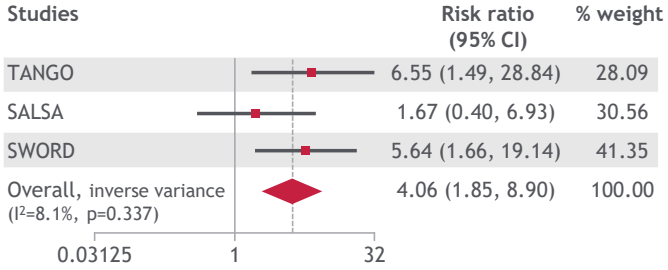
Proportion of DRAEs and DRAEs-LD in PWH who switched to DTG/3TC or DTG/RPV compared to staying on their baseline regimen

Mar 2014









PWH who switched vs. maintained regimen:

- % of DRAEs and DRAEs-LD was numerically higher in PWH who switched
- PWH who switched had a significantly higher RR of developing DRAEs (RR = 6.92; p = 0.000) and DRAEs-LD (RR = 4.06; p = 0.000)

In this meta-analysis of randomised control trials, switching to DTG/3TC or DTG/RPV from various ART regimens resulted in significantly more DRAEs and DRAEs leading to discontinuation

DL: DerSimonian-Laird estimate of tau; LD: leading to discontinuation; RR: relative risk; SLR: systematic literature review; W: weeks

Antela A, *et al.* IDWeek 2024 (Abstract 539; poster presentation).

Helping to End the HIV Epidemic

Focused on Person-Centered Innovation

Treatment + Prevention

Gilead is pioneering long-acting therapies that require less frequent dosing to provide the best options to complement once-daily orals and reach more people

Cure

Discovering a cure for HIV is highly aspirational. Gilead has the most comprehensive cure development program and is advancing with speed and conviction

Advancing Health Equity and Access Around the Globe

Increasing awareness, reducing stigma and disparities in care, and supporting local communities will enable today's therapies to have a larger impact

All Grounded in Partnerships and Collaborations

HIV VISION

End the Epidemic for Everyone, Everywhere