

Patient-reported outcome (PRO) measures at 12 months in a real-world cohort of people living with HIV with a high prevalence of comorbidities receiving bictegrovir/emtricitabine/tenofovir alafenamide (B/F/TAF) in Europe, Canada, and Israel

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SUPPLEMENTARY INFORMATION

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Methods: PRO Measures

- **Adherence**
 - VAS adherence
 - A 10-cm VAS that assesses self-reported treatment adherence over the past 30 days
- **Physical/mental HRQoL: SF-36 questionnaire**
 - A generic 36-item questionnaire that assesses eight health domains (vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health)
 - SF-36 scale ranges from 0 to 100, where higher scores indicate better quality of life
 - Aggregated PCS/MCS scores are reported; summary scores are standardised to a mean of 50; scores >50 and <50 represent better than average and poorer than average function, respectively
- **Symptom burden: HIV-SI**
 - A 20-item questionnaire that assesses signs and symptoms associated with HIV with a recall period of the past 4 weeks
 - Symptoms dichotomised into bothersome or not bothersome (scores 2–4 or 0–1, respectively)
 - The “overall bothersome count” indicates the number of bothersome symptoms and ranges from 0 to 20
- **Treatment satisfaction: HIVTSQ**
 - A 10-item questionnaire regarding current treatment regimen to assess satisfaction with HIV-treatment at baseline (HIVTSQ score) and change in satisfaction during study follow-up (HIVTSQc score)
- **Health utilisation (physician visits)**
 - Number of participants with ≥1 physician visit due to HIV infection or other illness over the last 6 months

Methods: Analysis

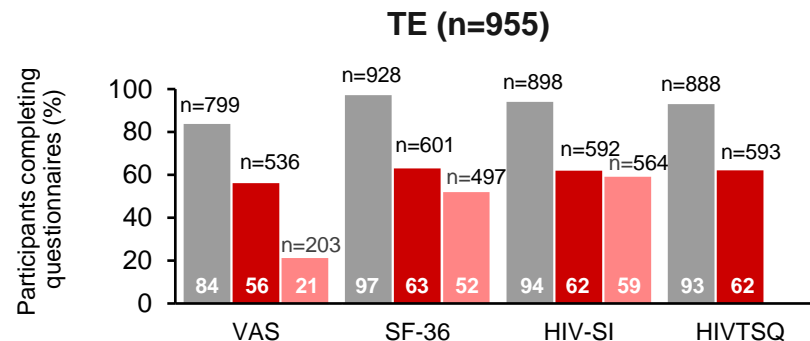
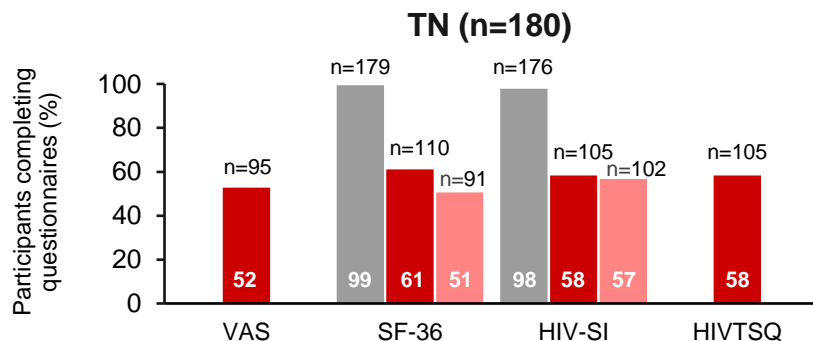
- **Adherence: VAS**
 - TE: analysis in participants with questionnaires completed at both baseline and 12 months
 - TN: analysis in participants with questionnaires completed at 12 months
 - VAS score represents how much (in %) of ART treatment the patient has received in the last 30 days
 - Factors associated with adherence ($\geq 95\%$) were assessed in a univariate analysis
- **Physical/mental HRQoL: SF-36 questionnaire**
 - TE/TN overall population: analysis in participants with questionnaires completed at both baseline and 12 months
 - TE/TN participants with/without neuropsychiatric disorders: baseline analysis of summary scores in participants with questionnaires completed at baseline, and 12-month analysis of summary scores in participants with questionnaires completed at 12 months; absolute change analysis and statistical testing in participants with questionnaires completed at both baseline and 12 months
- **Symptom burden: HIV-SI**
 - TE/TN: analysis in participants with questionnaires completed at both baseline and 12 months
- **Treatment satisfaction: HIVTSQ**
 - TE: baseline analysis in participants with questionnaires completed at baseline, and 12-month analysis in participants with questionnaires completed at 12 months
- **Health utilisation (physician visits)**
 - Assessed at 12 months
- **Subgroup analysis**
 - A sub-group analysis was performed for the SF-36, HIV-SI and HIVTSQ in those participants with a history of and/or ongoing neuropsychiatric symptoms at baseline

Study Participants and Questionnaire Completion

- Questionnaires were not available for approximately 40–50% of participants at M12. However, taking into account an overall completion rate of ~60%, the overall number of questionnaires analysed in this study was high (n=95–110 for TN participants and n=536–601 for TE participants, across all PRO measures at M12)

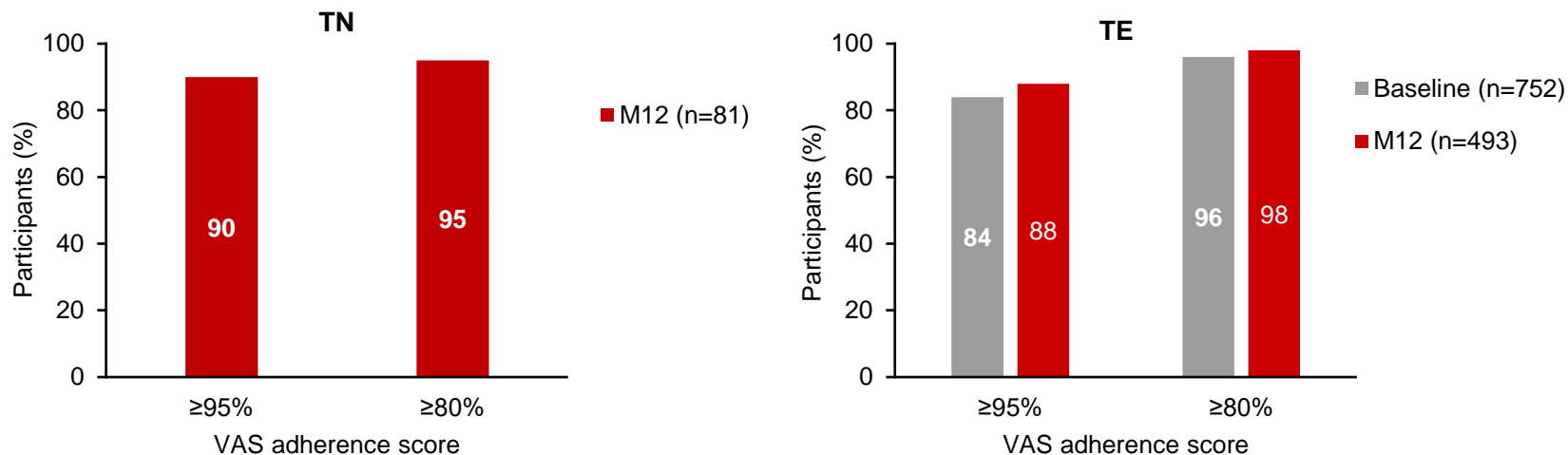
Completed questionnaires

■ Baseline ■ M12 ■ Baseline and M12



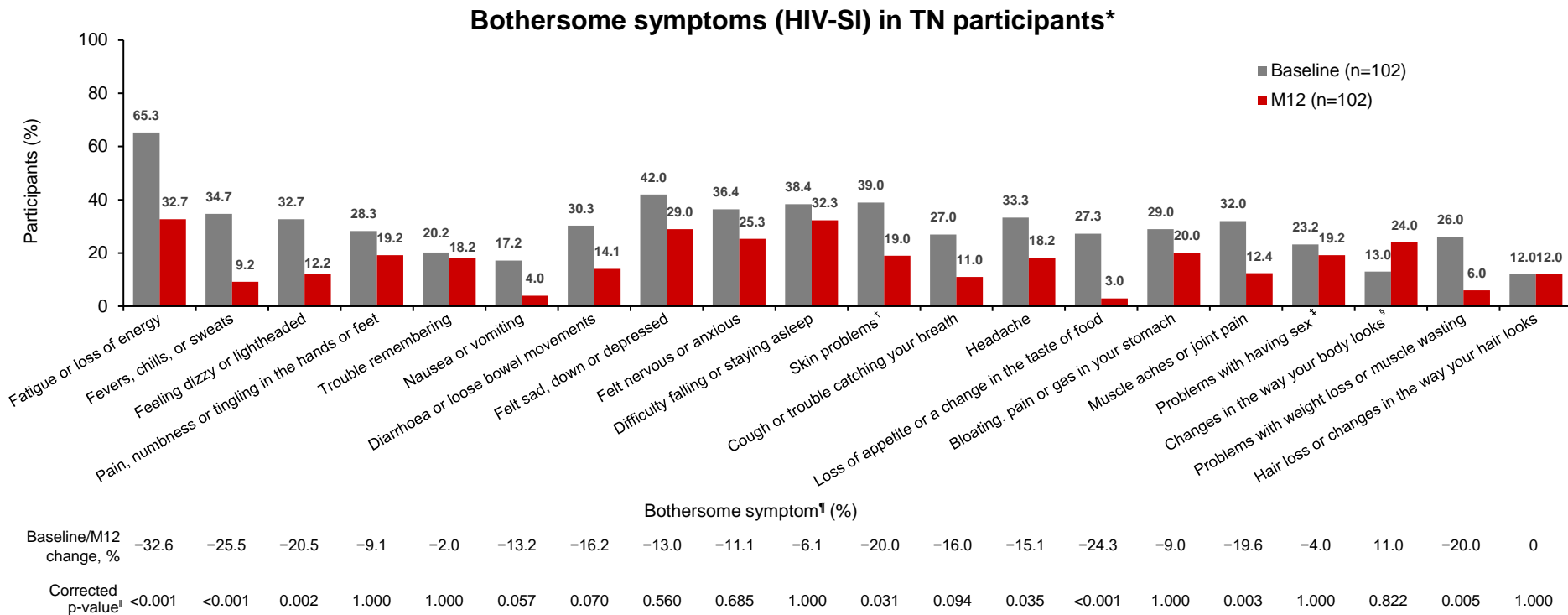
Adherence

VAS adherence scores at baseline and M12



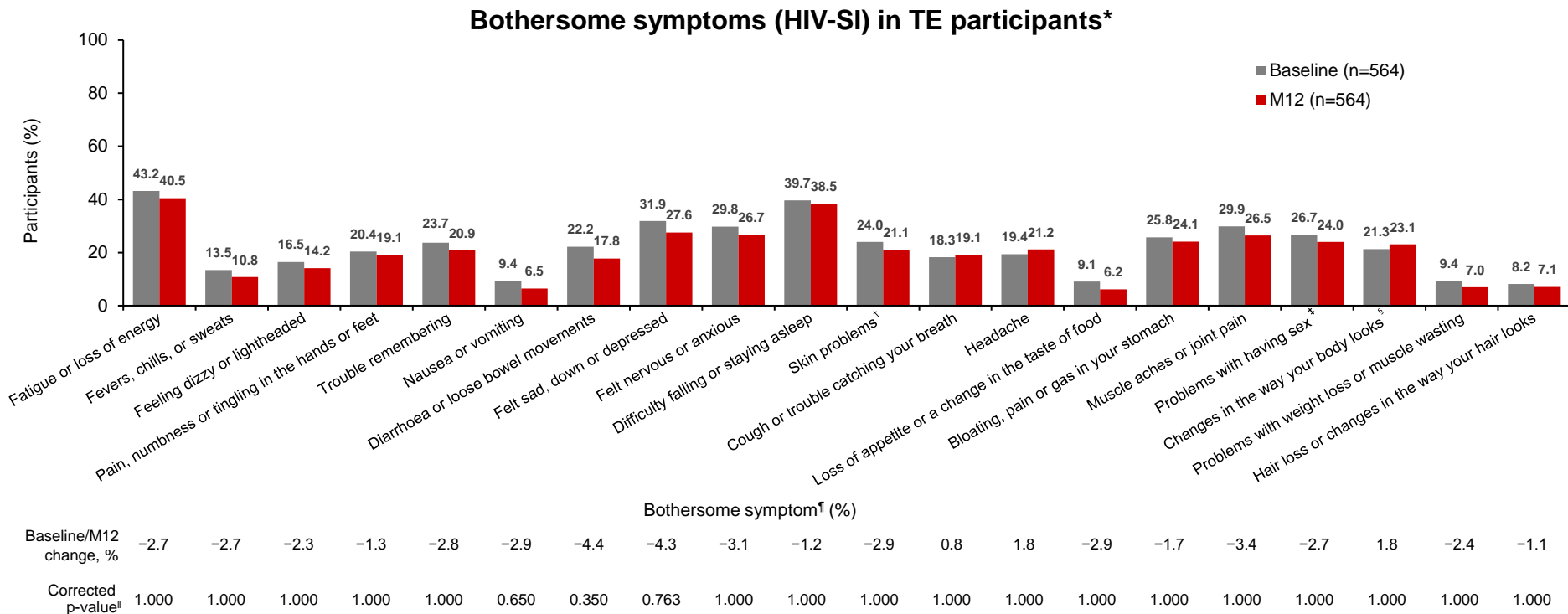
- In a univariate analysis, older age was associated with $\geq 95\%$ adherence at 12 months in TE participants: median age (Q1, Q3), 50 years (40, 57) vs 45 years (36, 55); $p=0.0069$

PROs: Bothersome Symptoms (HIV-SI) in TN Participants



*Analysis in participants with questionnaires completed at both baseline and M12; †such as rash, dryness, or itching; ‡such as loss of interest or lack of satisfaction; §such as fat deposits or weight gain; ¶Not bothersome: item score equal to "I do not have this symptom" or "I have had this symptom and it doesn't bother me", bothersome: item score equal to "I have had this symptom and it bothers me a little/it bothers me a lot"; ††McNemar: to account for multiple testing, Bonferroni correction has been applied. Corrected p-values have been obtained by multiplying the uncorrected p-values by 20, where 20 is the number of items of the health status questionnaire
HIV-SI, HIV Symptom Index; M, month; PRO, patient-reported outcome; TN, treatment-naïve

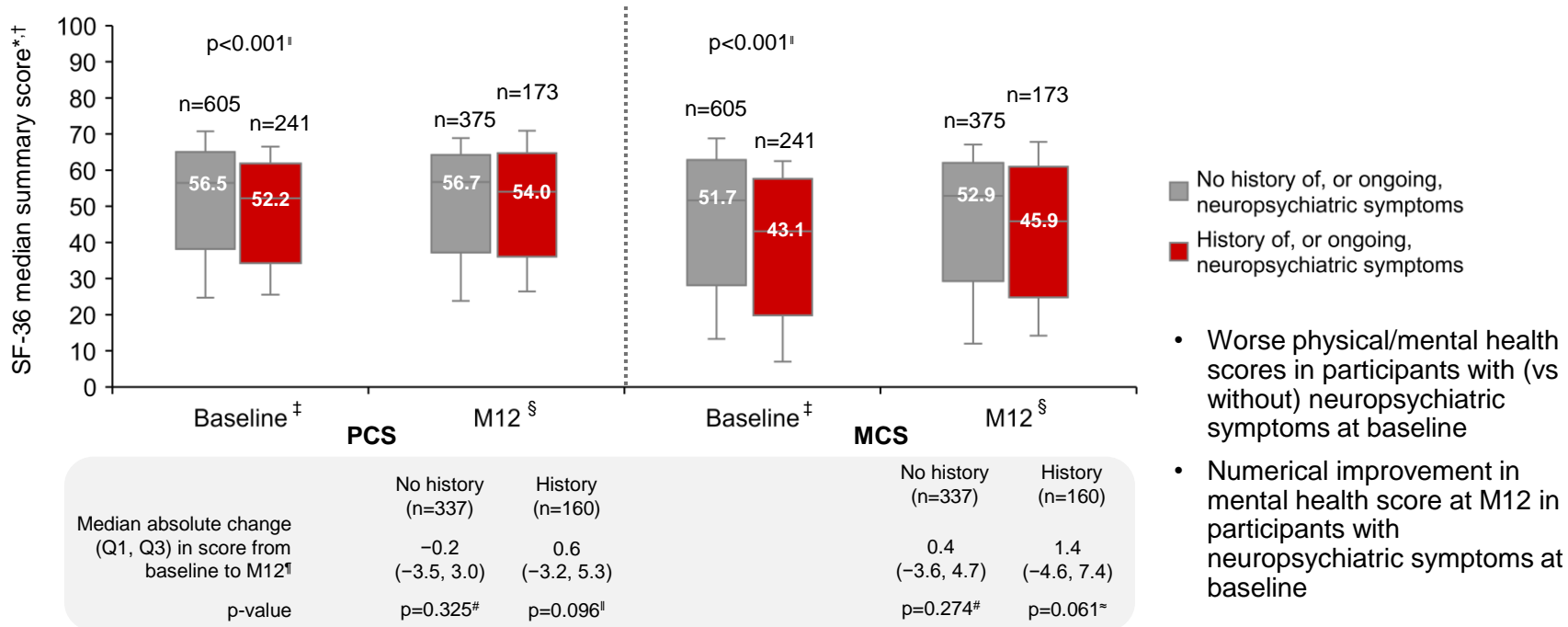
PROs: Bothersome Symptoms (HIV-SI) in TE Participants



*Analysis in participants with questionnaires completed at both baseline and M12; †such as rash, dryness, or itching; ‡such as loss of interest or lack of satisfaction; §such as fat deposits or weight gain; †Not bothersome: item score equal to "I do not have this symptom" or "I have had this symptom and it doesn't bother me", bothersome: item score equal to "I have had this symptom and it bothers me a little/it bothers me a lot"; †McNemar: to account for multiple testing, Bonferroni correction has been applied. Corrected p-values have been obtained by multiplying the uncorrected p-values by 20, where 20 is the number of items of the health status questionnaire
HIV-SI, HIV Symptom Index; M, month; PRO, patient-reported outcome; TE, treatment-experienced

SF-36: TE Participants with Neuropsychiatric Symptoms at Baseline

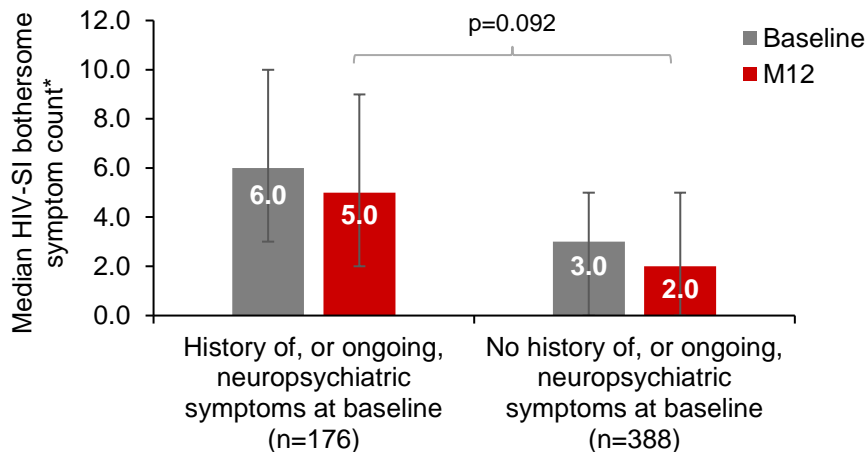
HRQoL SF-36 scores



*SF-36 scale ranges from 0 to 100, where higher scores indicate better quality of life; [‡]SF-36 summary scores are standardised to a mean of 50, with scores >50 and <50 representing better than average and poorer than average function, respectively; [‡]Analysis in participants with questionnaires completed at baseline; [§]Analysis in participants with questionnaires completed at M12; [¶]Absolute change and p-values in participants with questionnaires completed at both baseline and M12; ^{||}Wilcoxon signed-rank test; [#]Student t-test; [¶]Sign test
 HRQoL, health-related quality of life; M, month; MCS, mental component summary; PCS, physical component summary; Q, quartile; SF-36, 36-Item Short Form Health Survey; TE, treatment-experienced

HIV-SI: Overall Number of Bothersome Symptoms According to Presence of Neuropsychiatric Symptoms at Baseline (TE)

Overall bothersome symptom count* according to presence of neuropsychiatric symptoms at baseline (TE)[†]



- Significant reduction in bothersome symptoms at M12 in participants with neuropsychiatric symptoms at baseline

Change in count at M12

Mean (SD)

Median (Q1, Q3)

p-value

-0.8 (4.3)

-0.5 (-4.0, 2.0)

0.023[‡]

-0.2 (3.4)

0.0 (-2.0, 2.0)

0.527[§]

*The number of bothersome symptoms ranges from 0 to 20; [†]Analysis in participants with questionnaires completed at both baseline and M12 (error bars are IQR);

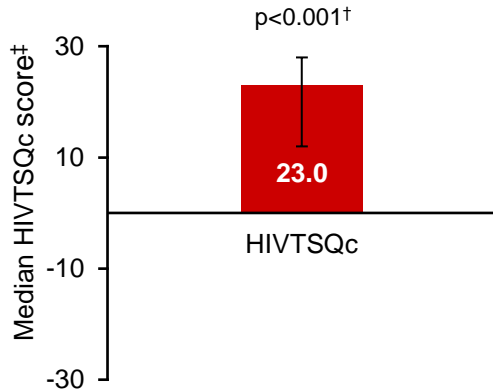
[‡]Student t-test; [§]Sign test

HIV-SI, HIV Symptom Index; IQR, interquartile range; M, month; PRO, patient-reported outcome; Q, quartile; SD, standard deviation; TE, treatment-experienced

HIVTSQ: HIV Treatment Satisfaction According to Presence of Neuropsychiatric Symptoms at Baseline

Treatment satisfaction in TE participants with history of, or ongoing, neuropsychiatric symptoms at baseline*

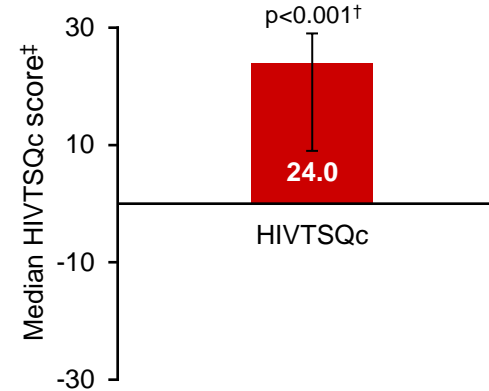
Change in score at M12 (n=185)



Median (Q1, Q3) HIVTSQ score[§] at baseline
54.0 (48.0, 59.0)
(n=250)

Treatment satisfaction in TE participants with no history of, or ongoing, neuropsychiatric symptoms at baseline*

Change in score at M12 (n=406)

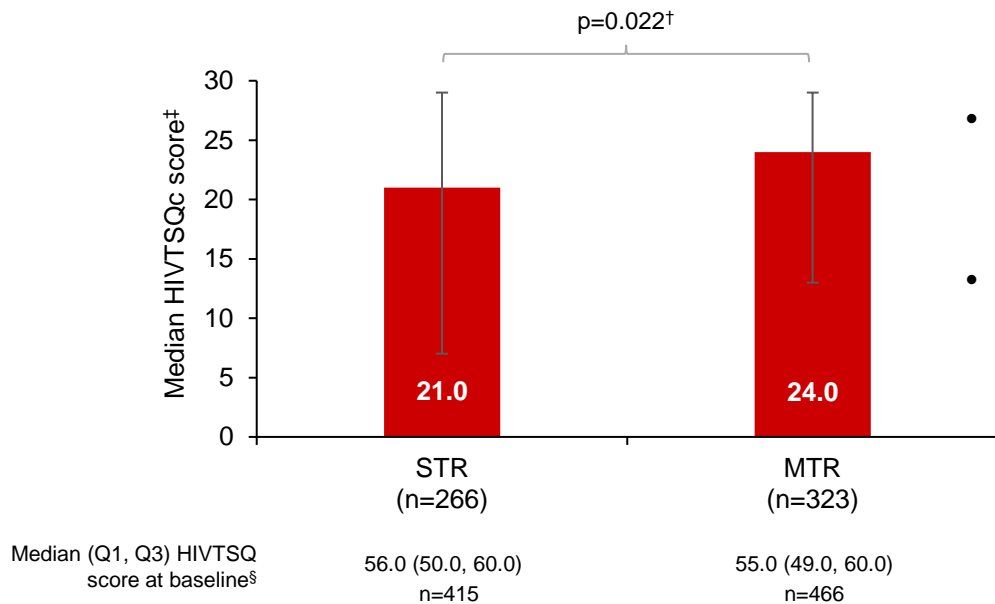


Median (Q1, Q3) HIVTSQ score[§] at baseline
56.0 (50.0, 60.0)
(n=636)

*Baseline analysis carried out in participants with questionnaires completed at baseline, and 12-month analysis carried out in participants with questionnaires completed at M12 (error bars are IQR); [†]Wilcoxon signed-rank test; [‡]HIVTSQc ranges from -30 to +30; [§]HIVTSQ score ranges from 0 to 60; higher total score indicates greater satisfaction with treatment HIVTSQ, HIV Treatment Satisfaction Questionnaire; HIVTSQc, HIV Treatment Satisfaction Questionnaire (change); IQR, interquartile range; PRO, patient-reported outcome; Q, quartile; TE, treatment-experienced

HIVTSQ: HIV Treatment Satisfaction (prior MTR vs STR)

Treatment satisfaction change at M12 in TE participants switching from either an STR or MTR to B/F/TAF*



- Participants switching to B/F/TAF from either an STR or MTR reported increased treatment satisfaction
- Participants switching from an MTR reported a somewhat greater increase in treatment satisfaction

*Baseline analysis carried out in participants with questionnaires completed at baseline, and 12-month analysis carried out in participants with questionnaires completed at M12 (error bars are IQR); [†]Wilcoxon signed-rank test; [‡]HIVTSQ_c ranges from -30 to +30; [§]HIVTSQ score ranges from 0 to 60; higher total score indicates greater satisfaction with treatment B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; HIVTSQ, HIV Treatment Satisfaction Questionnaire; HIVTSQ_c, HIV Treatment Satisfaction Questionnaire (change); IQR, interquartile range; M, month; MTR, multiple tablet regimen; STR, single tablet regimen; TE, treatment-experienced

Physician Visits Between M6 and M12

Participants with ≥ 1 physician visit	TN (n=100)	TE (n=543)
Due to HIV-infection	9%	10%
Due to other illness	37%	47%

- The majority of physician visits within the last 6 months were due to illnesses other than HIV-infection