

# PATIENT-REPORTED OUTCOMES AFTER SWITCHING TO A 2-DRUG REGIMEN OF FIXED-DOSE COMBINATION DOLUTEGRAVIR/LAMIVUDINE: 48-WEEK RESULTS FROM THE SALSA STUDY



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# Introduction and Overall Results

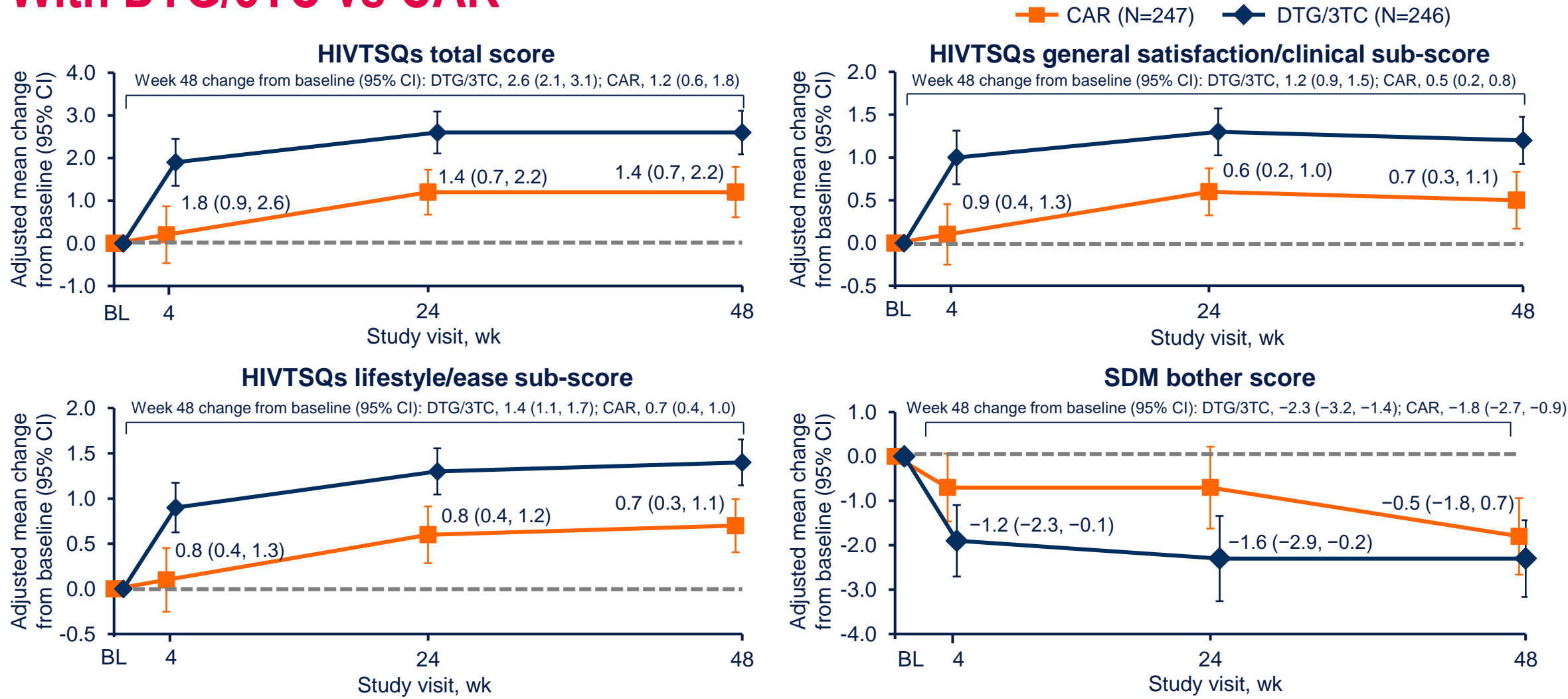
- Patient-reported outcomes can help optimize HIV clinical care by providing insights into key measures of treatment success beyond virologic efficacy (eg, health-related quality of life)<sup>1</sup>
- In the open-label SALSA study, switching to DTG/3TC was non-inferior to continuing current 3-/4-drug regimen (CAR) in maintaining virologic suppression at Week 48, with no confirmed virologic withdrawals and good safety<sup>2</sup>
- **Here we present secondary analyses of patient-reported health outcomes through Week 48 of SALSA**

Population <sup>2</sup>	Methods	Overall findings
<p><b>Of participants switching to DTG/3TC (n=246) or continuing CAR (n=247)</b></p> <ul style="list-style-type: none"> <li>• 39% were women</li> <li>• 39% were aged ≥50 years</li> <li>• 19% were African American or of African heritage, and 14% were Asian</li> <li>• Median duration of ART before Day 1 of the study was between 5 and 6 years</li> </ul>	<p> <b>HIV Treatment Satisfaction Questionnaire, status version (HIVTSQs)<sup>a</sup></b></p> <p>↑ scores = ↑ treatment satisfaction (range, 0-60)</p> <hr/> <p> <b>Symptom Distress Module (SDM)<sup>b</sup></b></p> <p>↓ scores = ↓ symptom bother (range, 0-80)</p>	<p>The DTG/3TC group had rapid and stable improvements compared with CAR in</p> <ul style="list-style-type: none"> <li>✓ <b>HIVTSQs total score</b></li> <li>✓ <b>Lifestyle/Ease sub-score</b></li> <li>✓ <b>General satisfaction/Clinical sub-score</b></li> </ul> <hr/> <p><b>Improved SDM score</b> with DTG/3TC compared with CAR was <b>observed as soon as Week 4</b> and was stable through Week 24 and similar at Week 48</p>

<sup>a</sup>10-item self-reported scale (Likert 0-6). <sup>b</sup>20-item self-reported measure (Likert 0-4).

1. Kall et al. *Lancet HIV*. 2020;7:e59-e68. 2. Llibre et al. *Clin Infect Dis*. 2022 [Epub ahead of print].

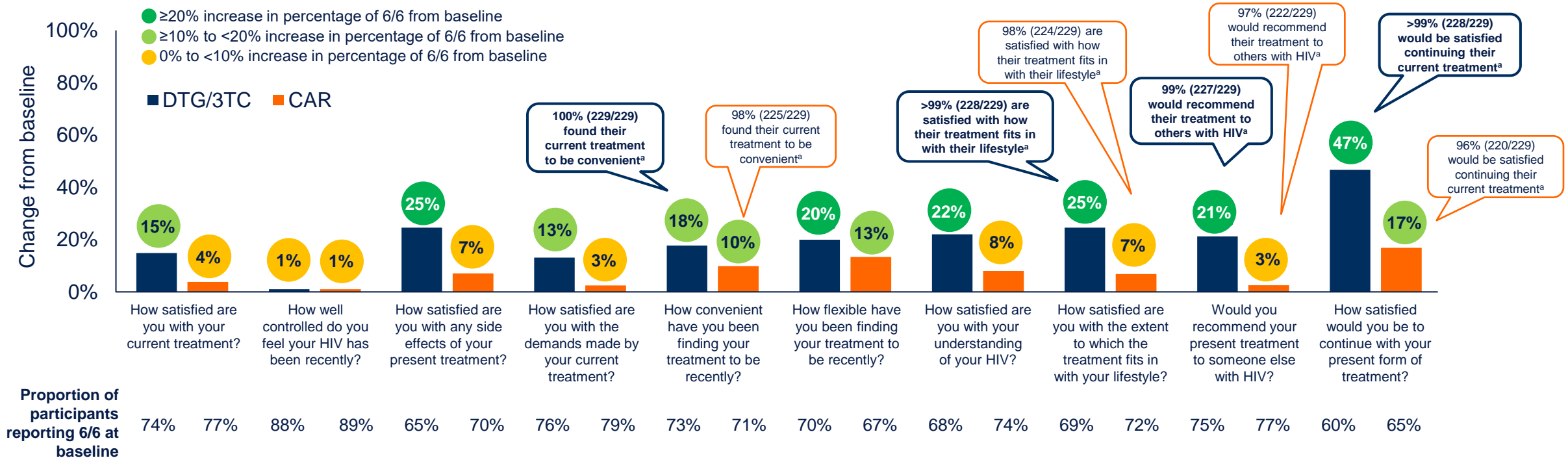
# Improvements in HIVTSQs and SDM Bother Score Were Demonstrated With DTG/3TC vs CAR



Adjusted treatment difference (95% CI) is displayed in the middle for each post-baseline study visit. Dashed line represents no change from baseline. Adjusted mean is the estimated mean change from baseline at each visit in each group calculated from mixed-model repeated measures adjusting for treatment, visit, baseline third agent class, age (continuous), sex, race, baseline value (continuous), treatment-by-visit interaction, and baseline value-by-visit interaction, with visit as the repeated factor.

# HIVTSQs Scores Demonstrated Significant Improvements in Patient Satisfaction With Use of the 2DR DTG/3TC vs 3/4DRs

Percent change from baseline in proportion of participants with 6/6 score by each HIVTSQs individual item through Week 48



<sup>a</sup>Based on a rating of 4, 5, or 6 on the Likert scale (0-6 for each answer) at Week 48. 0 = very dissatisfied, poorly controlled, inconvenient, and inflexible; 3 = neutral response; 6 = very satisfied, controlled, convenient, and flexible. Based on a rating of 5 or 6 on the Likert scale at Week 48: convenience: DTG/3TC, 99% (226/229); CAR, 92% (210/229); fit with lifestyle: DTG/3TC, 97% (222/229); CAR, 93% (213/229); recommend treatment to others: DTG/3TC, 98% (224/229); CAR, 95% (217/229); satisfied continuing present treatment: DTG/3TC, 97% (223/229); CAR, 92% (211/229).

# SDM Scores Showed Reduction in Symptom Distress With DTG/3TC

## Proportion of participants with each type of symptom

≥25% reduction in symptom distress from baseline  
 >0% to <25% reduction in symptom distress from baseline  
 0% to <25% increase in symptom distress from baseline



	Individuals reporting symptoms, %	Baseline		Relative percentage change from baseline to Week 48 <sup>b</sup>	
		DTG/3TC (N=246)	CAR (N=247)	DTG/3TC (N=246)	CAR (N=247)
<b>Metabolism and nutrition<sup>a</sup></b>	Appetite loss/Changed taste of food	11%	9%	-45%	-11%
<b>Nervous system<sup>a</sup></b>	Feeling dizzy/light-headed	20%	17%	-35%	-6%
	Headache	26%	22%	-31%	-9%
	Trouble remembering	27%	25%	-11%	-4%
<b>Gastrointestinal<sup>a</sup></b>	Bloating, pain, or gas in stomach	29%	22%	-14%	14%
	Nausea or vomiting	11%	9%	-36%	-22%
	Diarrhea or loose bowel movements	18%	19%	-22%	-11%
<b>Musculoskeletal and connective tissue<sup>a</sup></b>	Pain/Numbness/Tingling in hands/feet	26%	25%	-35%	-8%
	Muscle aches/Joint pain	33%	31%	-33%	-10%
<b>General disorders and administration site conditions<sup>a</sup></b>	Fever, chills, sweats	14%	13%	-50%	-23%
	Fatigue/Loss of energy	40%	38%	-25%	-13%
<b>Investigations<sup>a</sup></b>	Problems with weight loss/wasting	11%	11%	-45%	-18%
	Change in body appearance	27%	24%	4%	-8%
<b>Reproductive system and breast<sup>a</sup></b>	Problems with having sex	25%	21%	-44%	-19%
<b>Psychiatric<sup>a</sup></b>	Felt nervous/anxious	39%	28%	-38%	-14%
	Felt sad, down, or depressed	31%	28%	-32%	-21%
	Difficulty falling/staying asleep	41%	38%	-12%	-18%
<b>Skin and subcutaneous tissue<sup>a</sup></b>	Hair loss/Change in hair appearance	16%	14%	-13%	-21%
	Skin problems, eg, rash, dryness	25%	25%	-4%	-12%
<b>Respiratory, thoracic, and mediastinal<sup>a</sup></b>	Cough or trouble catching breath	17%	20%	-47%	-40%

## Conclusions

- Participants switching to DTG/3TC in the open-label SALSA study reported greater early improvements in treatment satisfaction and less symptom distress vs continuing CAR as early as 4 weeks after switch and were stable through 1 year of treatment
- These findings further support greater patient satisfaction with use of the 2DR DTG/3TC vs 3/4DRs in ART-experienced PWH, complementing data showing improvements in patient satisfaction and reduction in symptom distress when switching to DTG/3TC in clinical practice<sup>1</sup>

<sup>a</sup>System organ class categorization not included in the SDM. <sup>b</sup>Relative percentage change between the absolute percentage points reported at baseline to Week 48.

1. Scholten et al. EACS 2021; Virtual and London, UK. Poster PE2/52.

Data included in this presentation have previously been presented in full at 23rd International Workshop on Long-term Complications of HIV and SARS-CoV-2; December 6-9, 2021; Virtual; Poster ADRLH-36.