EPB140

Improvements in Patient-Reported Outcomes in Older Adults Aged ≥50 Years With HIV-1 After Switching to a 2-Drug Regimen of Fixed-Dose Combination DTG/3TC: 48-Week Results From the SALSA Study

Princy N. Kumar,[1] Laurent Hocqueloux,[2] Celia Jonsson-Oldenbüttel,[3] Miguel García Deltoro,[4] Amanda E. Clarke,[5] Simona Di Giambenedetto,[6] Po-Liang Lu,[7] Carlos Brites,[8] James Oyee,[9] Lee A. Evitt,[10] Lori A. Gordon,[11] Elizabeth Blair,[11] Brian Wynne,[11] Chinyere Okoli,[10] Jean van Wyk,[10] Julie Priest[11]

[1]Georgetown University Medical Center, Washington, DC, USA; [2]Centre Hospitalier Régional d'Orléans, Orléans, France; [3]MVZ München am Goetheplatz, Munich, Germany; [4]Consortium General University Hospital of Valencia, Valencia, Spain; [5]Royal Sussex County Hospital and Brighton & Sussex Medical School, Brighton, UK; [6]Fondazione Policlinico Universitario Agostino Gemelli IRCCS and Università Cattolica del Sacro Cuore, Rome, Italy; [7]Kaohsiung Medical University, Kaohsiung, Taiwan; [8]Universidade Federal da Bahia, Salvador, Brazil; [9]GSK, Brentford, UK; [10]ViiV Healthcare, Brentford, UK; [11]ViiV Healthcare, Durham, NC, USA

Key Takeaways

- **Patient-reported health outcomes in participants aged ≥50 years were evaluated 48 weeks after switching to DTG/3TC in the SALSA study**
- **Among older adults living with HIV (OALWH), switching to DTG/3TC resulted in greater treatment satisfaction early after switch compared with those continuing a 3- or 4-drug antiretroviral regimen and remained high through 48 weeks**

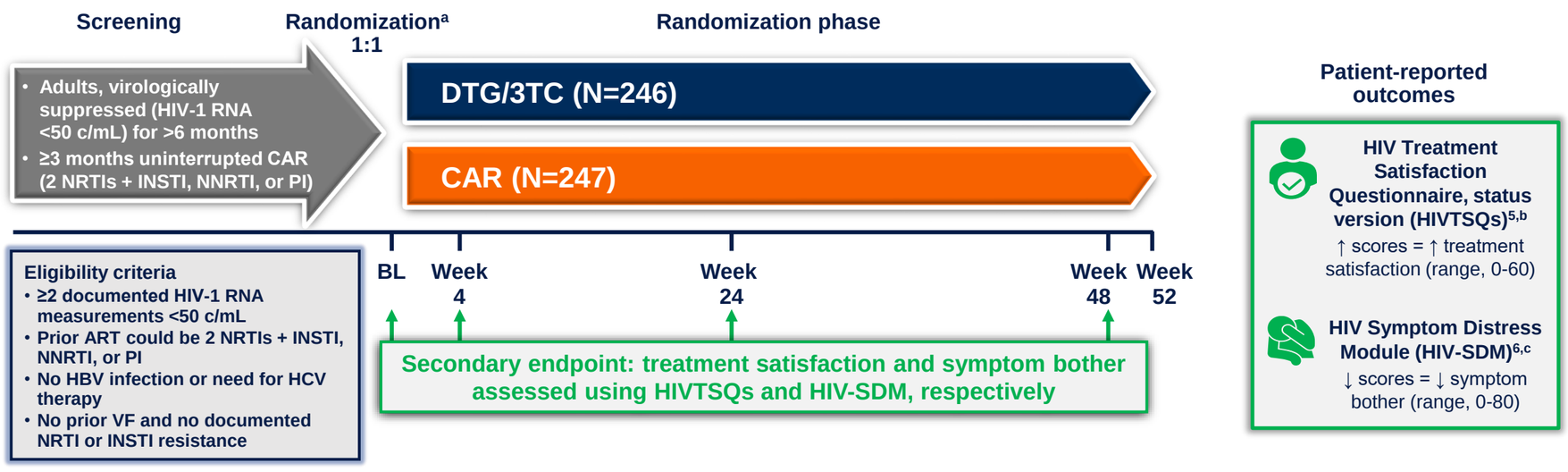
Introduction

- Due to significant improvements in HIV treatments and consequently longer life expectancies, OALWH are a growing and important population[1]
- Patient-reported outcomes provide insight into unmet needs beyond virologic suppression in OALWH[2]
- In the SALSA study (NCT04021290), switching to the 2-drug regimen DTG/3TC was non-inferior in maintaining virologic suppression at Week 48 compared with continuing a variety of 3- or 4-drug current antiretroviral regimens (CAR) in virologically suppressed adults, including OALWH[3]
  - Secondary analyses of patient-reported outcomes in SALSA demonstrated greater early improvements in treatment satisfaction and less symptom distress in participants switching to DTG/3TC vs those continuing CAR through 48 weeks of treatment[4]
- Here, we present a post hoc analysis of patient-reported outcomes through Week 48 in SALSA analyzed by age at baseline

Methods

- SALSA is a randomized, open-label study of virologically suppressed adults (HIV-1 RNA <50 c/mL) on a stable 3- or 4-drug regimen for ≥3 months who were randomly assigned to switch to DTG/3TC or continue CAR (Figure 1)
- A post hoc analysis of treatment satisfaction and symptom bother by age (≥50 and <50 years) using the HIV Treatment Satisfaction Questionnaire, status version (HIVTSQs) and HIV Symptom Distress Module (HIV-SDM), respectively, was performed at Weeks 4, 24, and 48
- Adjusted mean change from baseline to Week 48 for HIVTSQs and HIV-SDM were compared between treatment groups using mixed-model repeated-measures analyses adjusting for relevant baseline variables as specified in the respective figures below

Figure 1. Study Design



BL, baseline. [a]Stratified by BL third agent class (PI, INSTI, or NNRTI). [b]10-item, self-reported Likert scale (score of 0-6 per item). [c]20-item, self-reported Likert scale (score of 0-4 per item).

Results

Participants

- Of 493 participants, 39% were aged ≥50 years (Table)
  - Participants aged ≥50 years had greater concomitant medication use and more comorbidities at baseline; baseline characteristics were otherwise similar between age groups

Table. Demographics and Baseline Characteristics by Age and Overall

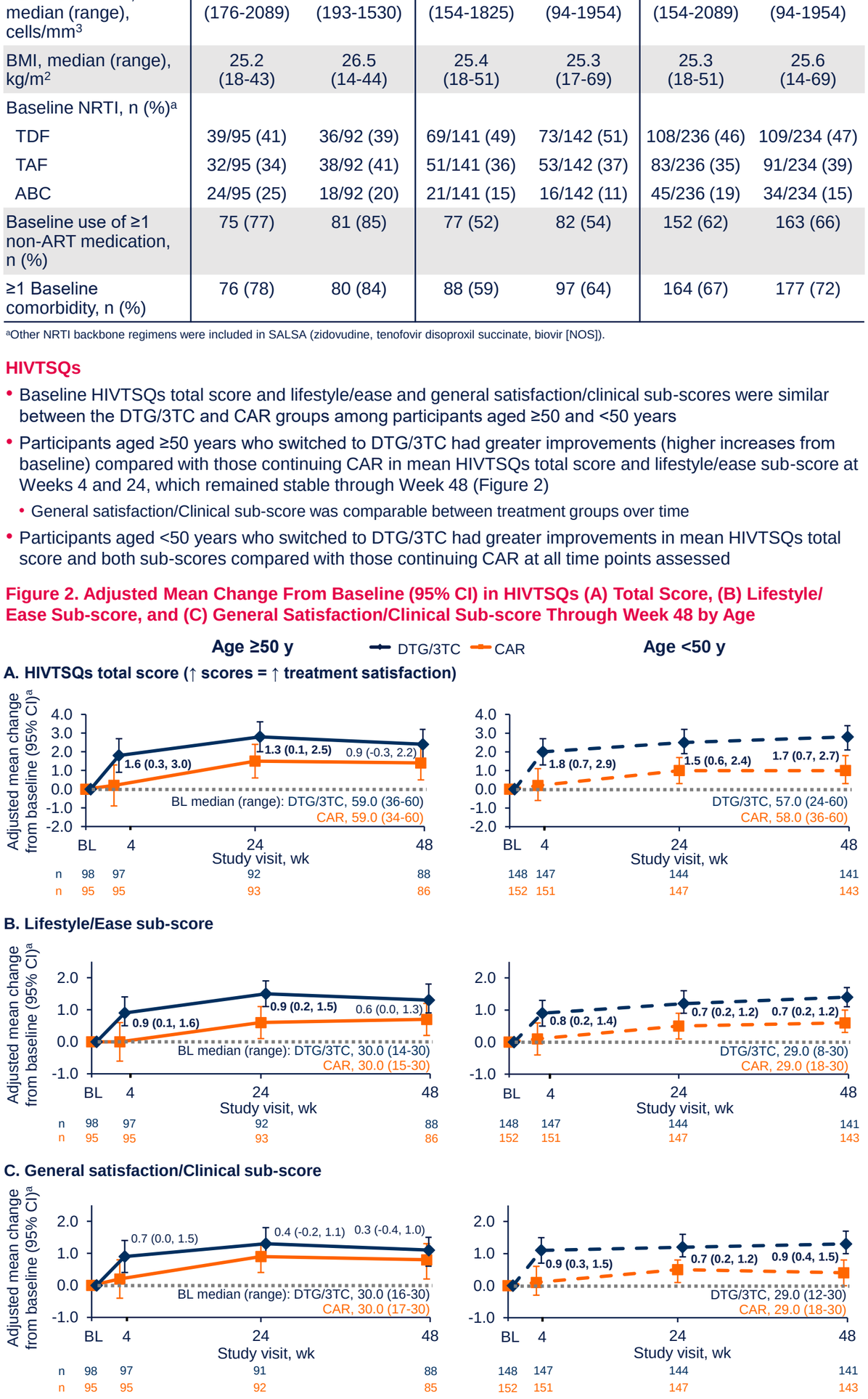
	Age ≥50 y		Age <50 y		Overall	
Parameter	**DTG/3TC (N=98)**	**CAR (N=95)**	**DTG/3TC (N=148)**	**CAR (N=152)**	**DTG/3TC (N=246)**	**CAR (N=247)**
Age, median (range), y	56 (50-74)	56 (50-83)	38 (22-49)	39 (23-49)	45 (22-74)	45 (23-83)
CD4+ cell count, median (range), cells/mm^3	690 (176-2089)	712 (193-1530)	666 (154-1825)	647 (94-1954)	675 (154-2089)	668 (94-1954)
BMI, median (range), kg/m^2	25.2 (18-43)	26.5 (14-44)	25.4 (18-51)	25.3 (17-69)	25.3 (18-51)	25.6 (14-69)
Baseline NRTI, n (%)[a]						
TDF	39/95 (41)	36/92 (39)	69/141 (49)	73/142 (51)	108/236 (46)	109/234 (47)
TAF	32/95 (34)	38/92 (41)	51/141 (36)	53/142 (37)	83/236 (35)	91/234 (39)
ABC	24/95 (25)	18/92 (20)	21/141 (15)	16/142 (11)	45/236 (19)	34/234 (15)
Baseline use of ≥1 non-ART medication, n (%)	75 (77)	81 (85)	77 (52)	82 (54)	152 (62)	163 (66)
≥1 Baseline comorbidity, n (%)	76 (78)	80 (84)	88 (59)	97 (64)	164 (67)	177 (72)

[a]Other NRTI backbone regimens were included in SALSA (zidovudine, tenofovir disoproxil succinate, biovir [NOS]).

HIVTSQs

- Baseline HIVTSQs total score and lifestyle/ease and general satisfaction/clinical sub-scores were similar between the DTG/3TC and CAR groups among participants aged ≥50 and <50 years
- Participants aged ≥50 years who switched to DTG/3TC had greater improvements (higher increases from baseline) compared with those continuing CAR in mean HIVTSQs total score and lifestyle/ease sub-score at Weeks 4 and 24, which remained stable through Week 48 (Figure 2)
  - General satisfaction/Clinical sub-score was comparable between treatment groups over time
- Participants aged <50 years who switched to DTG/3TC had greater improvements in mean HIVTSQs total score and both sub-scores compared with those continuing CAR at all time points assessed

Figure 2. Adjusted Mean Change From Baseline (95% CI) in HIVTSQs (A) Total Score, (B) Lifestyle/Ease Sub-score, and (C) General Satisfaction/Clinical Sub-score Through Week 48 by Age



Higher scores indicate improvement. Dotted lines indicate no change from BL. Median BL scores and adjusted difference between DTG/3TC and CAR are presented within each graph; bolded values indicate significance. The n for each study week is presented below each graph. BL, baseline. [a]Estimated mean change from BL at each visit in each group calculated using mixed-model repeated measures adjusting for treatment, visit, BL third agent class, race, sex, BL value, age, treatment-by-visit interaction, BL value-by-visit interaction, visit-by-age interaction, treatment-by-age interaction, and treatment-by-visit-by-age interaction, with visit as the repeated factor. The correlation matrix for within-participant errors was unstructured.

- From baseline to Week 48, the proportion reporting a score of 6/6 (very satisfied, controlled, convenient, and flexible) increased by ≥20% across 3 and 8 individual HIVTSQs items among participants aged ≥50 and <50 years, respectively, in the DTG/3TC group (Figure 3); in the CAR group, this was not achieved in participants aged ≥50 years and was achieved for 1 item in participants aged <50 years
- At Week 48, treatment satisfaction was high in both treatment groups, with most participants reporting they would be satisfied continuing their present treatment among those aged ≥50 years (DTG/3TC, 100%; CAR, 99%) and <50 years (DTG/3TC, 99%; CAR, 94%)

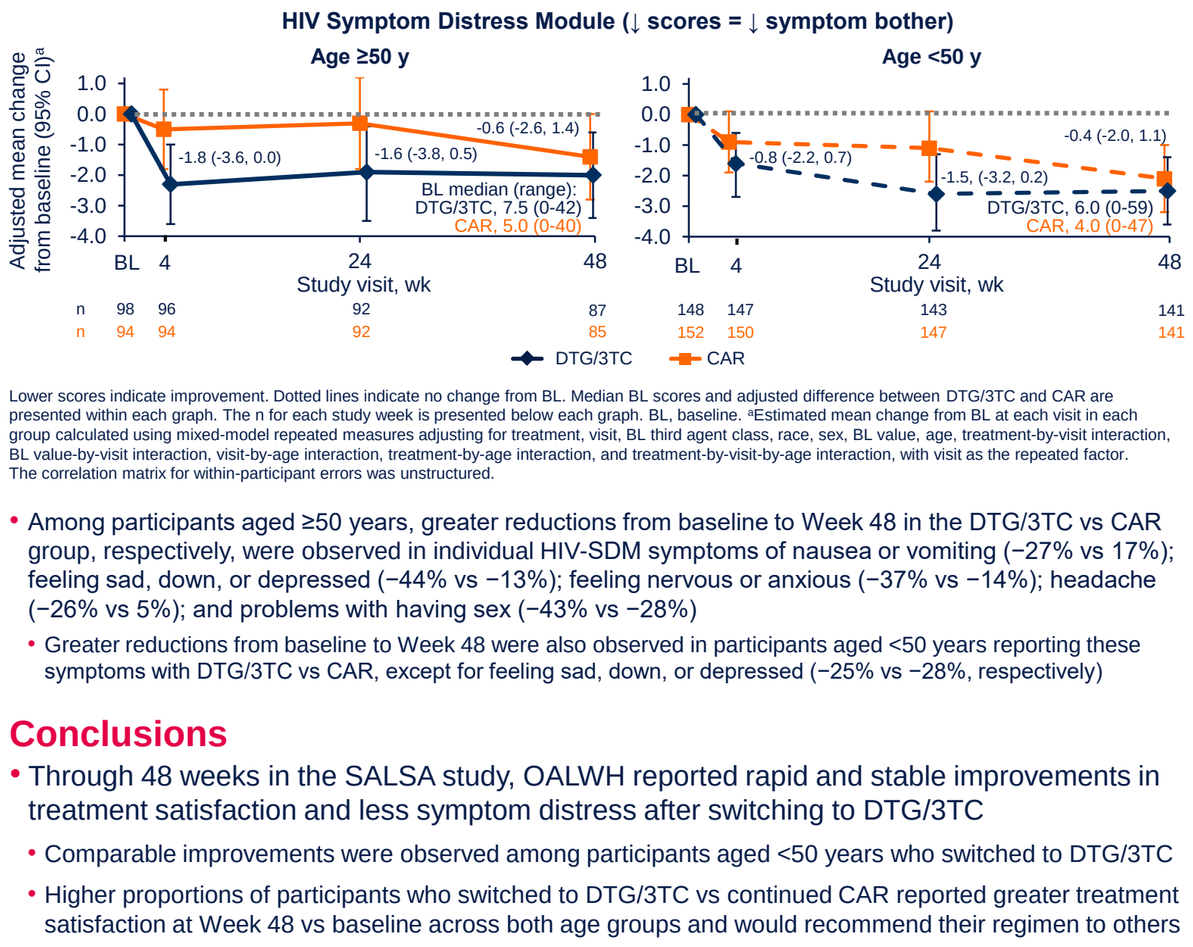
Figure 3. Percent Change From Baseline in Proportion of Participants With 6/6 Score by Each Individual HIVTSQs Item Through Week 48 by Age

Based on a Likert scale (0-6 for each answer); 6 = very satisfied, controlled, convenient, and flexible. Long and short dashed lines indicate 10% and 20% change from baseline, respectively.

HIV-SDM

- Baseline symptom bother scores were similar between treatment groups in both age groups
- Participants aged ≥50 years in the DTG/3TC group had numerical improvements in symptom bother score vs CAR at Weeks 4 and 24, which remained stable through Week 48 (Figure 4)
  - Participants aged <50 years in the DTG/3TC group had symptom bother scores comparable to CAR at Week 4 and numerical improvements vs CAR at Week 24, which remained stable through Week 48

Figure 4. Adjusted Mean Change From Baseline (95% CI) in HIV-SDM Through Week 48 by Age



Lower scores indicate improvement. Dotted lines indicate no change from BL. Median BL scores and adjusted difference between DTG/3TC and CAR are presented within each graph. The n for each study week is presented below each graph. BL, baseline. [a]Estimated mean change from BL at each visit in each group calculated using mixed-model repeated measures adjusting for treatment, visit, BL third agent class, race, sex, BL value, age, treatment-by-visit interaction, BL value-by-visit interaction, visit-by-age interaction, treatment-by-age interaction, and treatment-by-visit-by-age interaction, with visit as the repeated factor. The correlation matrix for within-participant errors was unstructured.

- Among participants aged ≥50 years, greater reductions from baseline to Week 48 in the DTG/3TC vs CAR group, respectively, were observed in individual HIV-SDM symptoms of nausea or vomiting (−27% vs 17%); feeling sad, down, or depressed (−44% vs −13%); feeling nervous or anxious (−37% vs −14%); headache (−26% vs 5%); and problems with having sex (−43% vs −28%)
  - Greater reductions from baseline to Week 48 were also observed in participants aged <50 years reporting these symptoms with DTG/3TC vs CAR, except for feeling sad, down, or depressed (−25% vs −28%, respectively)

Conclusions

- Through 48 weeks in the SALSA study, OALWH reported rapid and stable improvements in treatment satisfaction and less symptom distress after switching to DTG/3TC
  - Comparable improvements were observed among participants aged <50 years who switched to DTG/3TC
  - Higher proportions of participants who switched to DTG/3TC vs continued CAR reported greater treatment satisfaction at Week 48 vs baseline across both age groups and would recommend their regimen to others
- These findings support improved patient outcomes among OALWH after switching to DTG/3TC vs continuing CAR

Acknowledgments: This study was funded by ViiV Healthcare. We thank the study participants; their families and caregivers; investigators and site staff who participated in the study; and the ViiV Healthcare, GSK, and Pharmaceutical Product Development study team members. Editorial assistance and graphic design support for this poster were provided under the direction of the authors by MedThink SciCom and funded by ViiV Healthcare.

References: 1. Turrini et al. *PLoS One*. 2020;15:e0241833. **2.** Kall et al. *Lancet HIV*. 2020;7:e59-e68. **3.** Llibre et al. *Clin Infect Dis*. 2022 [Epub ahead of print]. **4.** Kumar et al. International Workshop on Long-term Complications of HIV and SARS-CoV-2 2021; Virtual. Poster ADRLH-36. **5.** Woodcock and Bradley. *Value Health*. 2006;9:320-333. **6.** Justice et al. *J Clin Epidemiol*. 2001;54(suppl 1):S77-S90.

Presenting author: Julie Priest; julie.l.priest@viivhealthcare.com

This content was acquired following an unsolicited medical information enquiry by a healthcare professional. Always consult the product information for your country, before prescribing a ViiV medicine. ViiV does not recommend the use of our medicines outside the terms of their licence. In some cases, the scientific Information requested and downloaded may relate to the use of our medicine(s) outside of their license.