Phase 3b randomized, open-label, multi-center, international, 48-week study to evaluate the safety and efficacy of switching from a regimen consisting of PI + RTV + two NRTIs to the FTC/RPV/TDF STR in virologically suppressed HIV-1 infected participants. Patients were randomized 2 : 1 to switch to FTC/RPV/TDF at baseline ($n = 317$) or maintain their current PI + RTV + two NRTIs regimen ($n = 159$) with a delayed switch to FTC/RPV/TDF at week 24. The primary endpoint was non-inferiority (12% margin) of FTC/RPV/TDF relative to PI + RTV + two NRTIs in maintaining plasma HIV-1 RNA <50 copies mL^{-1} at week 24. At week 24, 93.7% of patients who switched to FTC/RPV/TDF at baseline maintained HIV-1 RNA <50 copies mL^{-1} compared with 89.9% of patients who stayed on their PI + RTV + two NRTIs regimen (difference 3.8%, 95% CI –1.6 to 9.1). Non-inferiority was maintained regardless of viral load $\geq$ or $<100\,000$ HIV-1 RNA copies mL^{-1} prior to original ARV treatment initiation. Fewer patients who switched to FTC/RPV/TDF experienced virologic failure (0.9%) compared with the PI + RTV + two NRTIs arm (5.0%).[34]

Switching to the EFV/FTC/TDF STR was non-inferior to staying on a baseline regimen (SBR) in Study 073, a Phase 4 randomized, open-label, 48-week, non-inferiority study that evaluated switching to the EFV/FTC/TDF STR ($n = 203$) *versus* staying on a baseline regimen ($n = 97$). Patients were virologically suppressed (HIV-1 RNA <200 copies mL^{-1}) on a stable ARV regimen for $\geq$12 weeks with no history of virologic failure (VF). At baseline, patients were receiving an NNRTI [EFV or nevirapine (NVP)]- or a PI (most commonly ATV + RTV, lopinavir/RTV, fosempranavir + RTV or nelfinavir)-containing regimen most commonly with FTC/TDF, ABC/3TC, zidovudine (AZT)/3TC or TDF + 3TC. EFV/FTC/TDF was non-inferior to SBR for maintenance of virologic suppression through week 48 [HIV-1 RNA <200 copies mL^{-1} 89% *versus* 88% (treatment difference 1.1%; 95% CI –6.7 to 8.8%); HIV-1 RNA <50 copies mL^{-1} 87% *versus* 85% (treatment difference 2.6%; 95% CI –5.9 to 11.1%)]. Responses were similar for patients on prior NNRTI- and PI-based regimens.[35]

Switching to the STR EFV/FTC/TDF from the individual components given as a multi-pill regimen maintained virologic suppression in the ONCE study. This was a Phase 4 48-week, prospective, open-label, single-arm study in subjects stable on a first-line regimen of either TDF + FTC + EFV, FTC/TDF coformulation + EFV or TDF + 3TC + EFV for at least 24 weeks ($N = 115$). The primary endpoint was the proportion of subjects who maintained virologic suppression of HIV-1 RNA <50 copies mL^{-1} over 48 weeks. At week 48, 99.0% of subjects were virologically suppressed (HIV-1 RNA <50 copies mL^{-1}) with only one subject meeting the criteria for virologic failure (two consecutive HIV-1 RNA ≥ 50 copies mL^{-1} or one HIV-1 RNA ≥ 50 copies mL^{-1} followed by discontinuation from the study).[36]

Figure 14.7 illustrates efficacy results for the FTC/RPV/TDF and EFV/FTC/TDF STRs in virologically-suppressed patients who switched from other ARV regimens in Study 111, SPIRIT, Study 073 and ONCE.