

prolonged ARV use and reduce the risk of virologic failure. Support for these recommendations includes data demonstrating that adherence is inversely related to the number of daily doses, ARV regimens with reduced dosing frequency have higher levels of adherence and patient satisfaction increases with regimens with fewer pills and reduced dosing frequency.<sup>13</sup>

This chapter reviews available data demonstrating the clinical benefits of STRs in the treatment of HIV disease. Large clinical trials and retrospective analyses have shown the advantages of STRs over other treatment regimens, including greater adherence and persistence, better health outcomes, improved patient preference and quality of life and reduced healthcare resource utilization. Ongoing and planned trials designed to further evaluate current and future STRs and their potential benefits in the successful management of HIV patients are also summarized.

## 14.2 Adherence

Adherence to antiretroviral therapy (ART), defined as the extent to which a patient complies with their prescribed treatment regimen in terms of dose, frequency and timing of administration, is essential for long-term treatment success in HIV-infected individuals.<sup>16</sup> High adherence rates are critical to achieve virological suppression and to minimize the emergence of drug resistance mutations, resulting in positive clinical outcomes. Patients with suboptimal adherence to ART are at increased risk for reduced treatment response and more rapid disease progression.<sup>13,17</sup> Studies from HIV and other disease areas have shown that medication adherence is inversely related to the number of daily doses and the number of pills per dose.<sup>3,4,6,18–20</sup> Results from numerous clinical trials and cohort studies have demonstrated that STRs are associated with higher adherence compared with multiple-pill ART regimens.

### 14.2.1 Clinical Trials

Improved adherence with the EFV/FTC/TDF STR was demonstrated in Study 934, a prospective, randomized, open-label, 144-week, non-inferiority study comparing the safety and efficacy of FTC/TDF + EFV (FTC/TDF fixed-dose combination tablets were used from week 96 to 144) *versus* zidovudine/lamivudine (AZT/3TC) twice daily + EFV once daily in ARV-naive patients. After week 144, patients could switch their ARV regimen to EFV/FTC/TDF STR. A total of 160 patients in the FTC/TDF + EFV arm and 126 patients in the AZT/3TC + EFV arm switched to EFV/FTC/TDF STR. In an *ad hoc* analysis through 240 weeks of follow-up, mean adherence rates by pill count were improved when patients had smaller daily pill burdens of one pill (97.9%;  $p=0.0005$ ) or two pills (97.0%;  $p=0.0262$ ) daily *versus* three pills daily (95.6%).<sup>21</sup>

Switching to an STR significantly improved adherence in the ADONE (ADherence to ONE pill) study. This was a prospective, open-label, comparative, multicenter, non-inferiority, 6-month simplification study in