For this phase III, randomized, multicenter study of HIV-infected subjects, the null hypothesis (H_0) is that the proportion of subjects who have HIV-1 RNA below the lower limit of detection at 48 weeks when taking a drug candidate added to standard of care is the same as the proportion of subjects who have HIV-1 RNA below the lower limit of detection at 48 weeks when taking standard of care alone. From review of the available literature, the standard of care will have 80% of subjects with HIV-1 RNA below the lower limit of detection at 48 weeks. Based on the results of the recently completed phase II study, it is expected that this proportion will be 90% in subjects receiving the drug candidate added to standard of care. Based on these assumptions and using a *z*-test statistic, 325 subjects per group (650 total subjects) in the ITT analysis is sufficient to detect a 10% difference in the proportion of subjects with HIV-1 RNA below the lower limit of detection at 48 weeks with 95% power and a 5% type I error rate.