

## case study:

### **i3 RID APPLIES EXTENSIVE HIV EXPERIENCE TO TWO LATE-PHASE STUDIES**

**Challenge: Two late-phase HIV studies in treatment-naïve patients with multiple interim analyses.** A sponsor contracted full services for a pair of small open-label treatment studies (one Phase IV and one Phase IIIb) to evaluate the safety and efficacy of a three-drug treatment regimen for HIV. Each study included a primary analysis, multiple interim analyses, and a final analysis. The programming of datasets for each analysis was challenging because each included data only up to and including the specified visit week. Additionally, one of the studies included an extension because commercial product was not yet available.

**Solution: Category expertise and flexibility get the job done.** i3 RID provided full services for these two studies, from investigator selection and CRF design through final clinical study reports. Because of their extensive late phase experience in this category, i3 RID was able to streamline every aspect of the project. They developed close working relationships with the sites and the project manager, simplifying the gathering of data such as quality of life questionnaires and patient-completed medication adherence questionnaires. i3 also had flexibility to accommodate changes throughout the project, including an extension period necessitated by a lack of commercial product. i3 RID worked with sites to continue the study, developing new CRF pages by using existing CRF modules.

**Result: Studies successful; data presented at scientific conferences.** The 96-week studies were both completed successfully, and data from them has been presented at scientific conferences. Despite the small size of the studies, i3 RID applied the same level of focus and flexibility that they would have to a large, pivotal study — this commitment is one reason they're still working with the sponsor today.