

## case study:

### **i3 RESPIRATORY AND INFECTIOUS DISEASE COMPLETES DEMANDING ASTHMA STUDY**

**Challenge: Enroll a unique population in a compressed timeframe.** Pediatric asthma studies can be difficult, requiring key timing of enrollment, knowledge of the regulatory and ethical issues with pediatric populations, and an understanding of the disease category. In one recent study, the sponsor launched the trial very late during summer vacation, missing part of the prime time to enroll pediatric patients. Despite the timeframe, i3 Respiratory and Infectious Disease tackled the study and saw it through.

**Solution: Smart site identification, fast enrollment, close management.** Early on, i3 recognized that proper site selection was key to success. A large number of candidate sites were identified through the i3 Investigator Network Database, and from the list of candidates, sites underwent an intensive screening process.

Patient enrollment occurred rapidly and was supported by a responsive i3 team. i3 aggressively addressed protocol questions and issues surrounding patient enrollment. The team tracked enrollment on a daily basis and through use of i3's clinical trial management system, provided expected versus actual enrollment figures, and kept all sites and the study sponsor abreast of enrollment activity. Through monitoring of key study parameters — and the availability of comprehensive study reports — i3 had the tools required to help the sponsor complete the study.

**Results: Database locked a month ahead of schedule.** Through extensive experience in the disease category, the i3 team was able to quickly identify the potential challenges and develop effective solutions to meet them — and lock the study database one month early.

The study also experienced a very low rate of data queries, due in large part to well-designed CRFs, clear and comprehensive guidelines, and a capable and experienced monitoring team. Clean data allowed an acceleration of data management timelines, which contributed to faster database lock and ultimately, greatly exceeded sponsor expectations.