

case study:

i3 RID HANDLES VACCINE MEGA TRIAL FROM START TO FINISH

Challenge: Managing a complex vaccine mega trial in a pediatric population — and many variables along the way.

A sponsor engaged i3 Respiratory and Infectious Disease to help with a large Phase III global pediatric vaccine trial for an acute gastrointestinal illness from the protocol implementation phase through data-base lock and study completion. The study involved:

- Approximately **36,000** subjects
- **170 sites** in the US and Caribbean
- **Sites assigned to four different cohorts** based on safety and efficacy parameters and procedures, and could switch from one cohort to another

Not only was working with the sites a challenge, but i3 also had to engage with several different vendors and another CRO. The complexity of the trial and the sheer number of organizations involved created a need for constant management of change: changes to monitoring plans, changes in data management responsibilities and case report form flow, and many others.

Solution: Leadership, communication, flexibility.

The leadership of the i3 team — from study champions and directors to regional CRAs and call center staff — helped maintain consistency across sites and functions to manage the complexity of the different arms of the study.

- **Clear and consistent communication with study sites** — through teleconferences, a monthly newsletter, and mass fax notifications — helped the site staff feel like valued team members and streamlined the flow of important information.
- **A cross-functional project management team** with representatives from both i3 and the sponsor communicated frequently, reviewing custom metric reports to assess key study objectives.
- **i3 and the sponsor developed a rolling close-out plan** to shut down certain sites, while simultaneously recruiting and opening new ones.

Result: Massive trial approaching critical milestone. The 31-member i3 team, working closely with the sponsor, has been instrumental in managing this trial to study completion. Enrollment is completed and the study is now approaching the last patient out. More than 3,000 monitoring visits were performed and approximately 1.8 million CRFs have been submitted for data entry within the project-defined timeframes.