PharmaNet/i3
Strategic Resourcing
INVENTIV HEALTH CLINICAL

Case Study

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Evolution of an Outsourced Monitoring Model

Scope of Program
- 175 studies
- 4,500 sites
- 11,000 patients
- 300 field employees

Services
- Site Management/Clinical Monitoring

All Phases and Therapeutic Areas

Outcome Highlights
- Standalone monitoring program
- Integrated management and operations infrastructure

Efficiency Highlights:
- Met 100% of 122 site selection deadlines
- Delivered nearly half of site selection deadlines 5.4 days early
- 50% site selection cycle time reduction

Situation

One of the world's largest pharmaceutical companies chose to outsource their clinical monitoring function completely. We were already the preferred provider of a mirrored model for clinical monitoring (our CRAs worked side-by-side with the sponsor's CRAs) when the client decided to outsource completely. The sponsor wanted to retain oversight responsibilities and eliminate the function in house.

Solution

To facilitate our expanded relationship, we invested in infrastructure to support the size of the organization and improve process efficiencies. We implemented dedicated training programs and site selection, metrics/reporting and quality management over a two year period to ensure the monitoring function was truly "free standing." Highlights of the enhancements made to the new outsourced managed model included:

- Dedicated team of 30 study start-up leads to speed the site selection process.
- Addition of the Lead CRA role to replace sponsor staff and help meet/exceed enrollment and recruitment deliverables.
- Program and individual CRA-level scorecards to measure performance, drive continuous improvement and report all performance metrics.
- A comprehensive oncology certification training program for monitors who had previously specialized in other therapeutic areas.
- Technology solutions for capacity planning and forecasting, centralized resourcing site-level and protocol-level databases.
- Dashboard views to manage timelines/deliverables and capture expenses
- A quality management process, including oversight, training, quality review and Corrective Action and Protective Action (CAPA) activities. A quality trend analysis workgroup identifies and tracks corrective actions, quality reviews or regulatory inspections and provides recommendations on a quarterly basis.

Outcome

We successfully transitioned the client to a standalone clinical monitoring program with nearly 300 field employees and an integrated management and operations infrastructure that were responsible for nearly 175 studies, 4,500 sites and more than 11,000 patients – nearly two thirds of the client's portfolio. In 2010, this dedicated team met 100 percent of the 122 site selection deadlines, with 48.4 percent delivered an average of 5.4 days early. The sponsor's personnel reported a 51 percent cycle time reduction for site selection based on data from 61 studies.

About PharmaNet/i3

PharmaNet/i3, the inVentiv Health clinical segment, is recognized as a leading provider of global product development services to pharmaceutical, biotechnology, generic drug, and medical device companies, offering therapeutically specialized capabilities for Phase I-IV product development, bioanalytical services, and staffing from a single clinical professional to an entire functional team. For intelligent solutions needed to accelerate high quality product development programs of all sizes around the world, ***PharmaNet/i3 works for you***.