PRA Health Sciences

CASE STUDY

Investigator-initiated Trials Program Management

Linking Strategy and Implementation

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PROGRAM DESCRIPTION

A large biopharma with shared full-time equivalents (FTEs) and contractors

Study Duration
6 years and ongoing

No. of Trials (Overall)
1,200+

Average Years of Staff Experience
14.5

Situation

A large biopharma company needed to change the operating model for their investigator-initiated trials (IIT), in part because of a merger.

Challenges

The client did not have dedicated resources for their IIT program. Frequent contractor turnover was resulting in high training costs and contributing to quality concerns.

Solutions

PRA's Strategic Solutions Division (SSD) established an Embedded Solutions™ IIT program management structure leading to a seamless, quality-based operating model. This included creating and updating process flows, the supported research operations manual, and governance and relationship management plans. The scalability of the program accommodates changes in IIT funding, strategy, and trial numbers.

SSD provided highly experienced project managers, in-house clinical research associates, and clinical trial associates with an average of 14.5 years of clinical trial experience. Employees were carefully selected to align with the client's corporate culture, and they worked with therapeutically-aligned client medical directors, product directors, medical science liaisons, and project managers.

Results

Over the course of managing 1200 trials in the 6-year relationship (currently 454 trials, including 90 multi-center trials and more than 25 molecules), registries, interventional/non-interventional trials (chart review, etiologic, epidemiology, observational, pharmacokinetics (PK), prospective, and tissue samples), cooperative trials (including National Cancer Institute, Radiation Therapy Oncology Group, Gynecologic Oncology Group, Eastern Cooperative Oncology Group, and SWOG), and scientific collaboration trials, PRA achieved:

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