PRA Health Sciences

SLIP SHEET

Investigator-Initiated Trials Program Management

PRA Health Sciences' Strategic Solutions Division (SSD) understands the critical importance of Investigator-Initiated Trials (IIT) and the value they create in improving the treatment of disease, patient outcomes, healthcare quality, and the long term success of a product's commercialization life cycle.

Managing these studies can be especially demanding given the sponsor's additional competing clinical study needs. For this reason, having a dedicated solution that is seamlessly integrated into the organization can significantly improve management of these very important and complex studies.

Proven Experience & Expertise

As pioneers of the Embedded Solutions™ model, we have broad experience providing IIT solutions since 2011. When we work directly with researchers, we facilitate the long-term development of new therapeutic agents and help advance the clinical, medical, and scientific understanding of those therapies.

Our experience encompasses:

Three programs currently under management with the top **10 biopharmaceutical companies.**

More than 1400 IITs under management.

Management of existing IIT programs includes **2 programs for 5.5 years and 1 program for more than 2 years.**

Interventional studies; non-interventional studies (chart review, etiology, epidemiology, observational, PK, prospective, and tissue sample), registries, cooperative studies, and joint ventures.

SSD IIT Benefits

Seamless integration into the organization; our approach makes it easy and convenient for the client to manage these complex studies.

A scalable model that provides a customized solution based on the specific client need to match their corporate strategies.

Teams comprising client conversions as well as new recruits.

High client satisfaction, with teams remaining in place for more than 5 years.

Roles ranging from project managers, in-house clinical research associates, clinical trial assistants, payment/grants specialists, and contracts associates.

Other available services include medical writing, contracts management, drug safety, scientific engagement planning, scientific education, publication planning and management, and compliance.

A flexible management structure that includes options for line or functional management.

SSD teams assume responsibility for these tasks within their respective programs: concept development; proposal and protocol review; committee review; annual study review; performance management; budget and drug supply forecasting; contract and amendments; regulatory collection; coordination of INDSR distribution; collection of enrollment logs; payments; drug shipments; and tracking of study publications.

Teams knowledgeable in managing client and regulatory audits.

Next Steps

To learn more about PRA's options for IIT program management, please contact Rich Davis, Senior Director, Customer Strategy (DavisRich@prahs.com).