PRA Health Sciences

FACT SHEET

PRA Site Support Services

PRA Health Sciences recognizes that the world of clinical development is complex and dynamic. To address this, we've created a solution designed specifically to help alleviate the administrative burden & complexities at sponsor-lead investigator sites. PRA is proactive and always looking to the future, providing on-site support services that deliver administrative support, resulting in stronger site performance across single and multiple center trials.

Optimizing Investigator Site Performance

PRA experience over recent years, particularly with more complex studies and oncology trials, has shown that the majority of studies are concentrated at the most experienced sites recruiting high volumes of patients. These sites routinely experience a tremendous administrative strain, leading to greater pressures in keeping the focus on patient recruitment and care, as well as the complete oversight of the study. PRA is able to ease this strain by deploying highly skilled healthcare professionals to manage the administrative components of your trials, thereby enabling site personnel to focus on strategic and core aspects of the clinical trial.

PRA has extensive experience in providing tailored solutions to both naïve and experienced Investigator sites. Our established **Naïve Site Training Program** has allowed us to leverage acquired site knowledge to launch world-class on-site support services, benefiting complex and high volume patient trials, including oncology trials.

PRA Site Support Services are performed by professionals that are fully trained in GCP and applicable therapeutic areas, as well as the Oncology University Program. PRA professionals are graduates in health sciences related fields, with high IT systems knowledge and experience. Our services support single trial investigator sites through to a full solution for multiple sites and trials.

Site Readiness as Pandemic Restrictions Ease Around the World

During the pandemic, where research centers have stopped monitoring visits and are carrying out only essential trial activities, support services to centers are deemed necessary in the resumption of trial activities, assisting them in administrative activities, plus managing the backlog so that they can receive monitors and return to routine at the earliest.

- Well trained research sites are able to deliver greater quality, reducing and optimizing the monitoring days on-site.
- Reduction of the administrative burden enables site personnel to focus on strategic trial activities.
- Enables investigators to provide a greater focus on the patient assessments and trial inclusion, leading to conducting more trials with minimal impact on recruitment, data quality, or responsiveness to sponsor.
- Helping to enhance the recruitment potential.
- PRA serves as a bond between research sites and sponsor, creating rapid and successful communications.

Site Support Services delivered by Clinical Study Specialists:

During pre-screening and screening phases:

Supports submission process of the protocol and other documents to the Ethics Committees (ECs) for approval

Works with investigators and study coordinators to create tools that support flow of regulatory and study documents

Supports the design of recruitment strategies with administrative assistance

During a trial:

Supports patient visit scheduling

Facilitates the submission of applicable trial documents to ethical and regulatory entities

Supports on- and off-site monitoring visits

Assists in the completion of CRF and query resolution

Aids in submitting Serious Adverse Events and follow-up

Assists in auditing activities as necessary

Supports documentation of receipt and return of IMP

Assists in completion and archiving of regulatory folders and binders

Supports meeting management and coordination

At closure and follow up:

Supports scheduling of follow-up visits

Assists in the resolution of any open action items to the site(s)

Completion of queries and CRF in order to achieve the DBL in the expected timeline

Support Study Closure Visits

PRA Site Support Services enable Sponsors to operate clinical trials more efficiently across study sites, improving the Patient site experience, thereby helping investigators meet recruitment targets.

Next Steps

For further information: SiteSupportServices@prahs.com. Also, please contact us for more information on PRA's Naïve Site Training Program or Oncology University Training.