YOUR PARTNER IN CLINICAL OPERATIONS

A well-designed clinical protocol is the foundation of a clinical trial, but the optimal execution of that protocol ensures overall trial success. BBA's Clinical Operations team works collaboratively with study investigators and sponsors to ensure patient safety, trial data integrity and protocol compliance are maintained throughout the trial. Our clinical monitors work closely with data management, safety, and other functional groups to proactively identify and address issues that arise during the conduct of trial.

SITE CAPABILITIES:

- Site study tool development
- IRB and Ethics Committee management
- Site regulatory document management
- Patient recruitment and retention
- eCRF completion, query resolution and data cleanliness

SITE MANAGEMENT

The BBA Clinical Operations team understands that investigator relationships are central to effective site management. Developing collaborative relationships with sites ensures Sponsor trials are executed seamlessly. BBA's Clinical Operations team develops a strong working relationship with each site to ensure proper conduct of the trial in accordance with the protocol, GCP and applicable regulations.

WE PARTNER WITH OUR SPONSORS TO DEVELOP THE MOST APPROPRIATE CLINICAL MONITORING STRATEGIES INCLUDING:

CLINICAL MONITORING

BBA's Clinical Research Associates (CRAs) have on average 10+ years of experience in monitoring all types of trials, from early feasibility proof of concept studies, pivotal and post-market. Our CRAs are located throughout the Americas and Europe, reducing expense and time. They have strong relationships with existing sites and work closely with Sponsors, site personnel and investigators to ensure effective and complete site qualification, site training and initiation, interim visits and site audits. BBA site monitoring visits incorporate a range of activities, to assess the current status of a clinical trial.

We strive to ensure our Sponsors understand patient disposition, trial enrollment, data integrity, investigator performance and protocol adherence. This is accomplished by, including review of source and regulatory documentation, detection and reporting of adverse events, protocol deviations, and resolution of outstanding queries. These monitoring strategies provide flexibility in ensuring data quality while balancing cost and timeline implications. Our efficient monitoring models and their associated metrics provide robust signal detection, enabling Sponsors to make more timely informed decisions.

CONNECT WITH BBA AT: info@bbacro.com or follow us on Linkedin or Twitter today.