YOUR PARTNER IN SAFETY AND PHARMACOVIGILANCE

SAFETY MANAGEMENT AND STUDY OVERSIGHT

Through our Safety Management Group, BBA offers sponsors guidance in the establishment and management of Clinical Events Committees (CECs) and Data Monitoring Committees (DMCs). We use our extensive experience and network of qualified experts in relevant therapeutic areas to assemble CEC and DMC committees best suited for unbiased, independent, thorough, and targeted reviews of study endpoint and safety data. We coordinate all committee activities, ensure no potential conflicts of interest, and support committee members so they focus on enhancing study data quality and integrity and ensuring patient safety.

A PROVEN APPROACH

We start by carefully analyzing the clinical study protocol and developing an understanding of the product under investigation. Based on our expertise, we can recommend a committee composed of multidisciplinary specialists who understand the product, technology, and event outcomes.

OUR CAPABILITIES INCLUDE:

01 Member selection and qualification

02 Charter development

03 Committee oversight, meeting, and workflow management, including payments and ongoing assessment of committee independence

CLINICAL EVENTS COMMITTEES

By standardizing reporting of outcomes across large, multicenter studies with complex endpoints, CECs are critical to the integrity of clinical study data. Our CECs are comprised of physician experts with relevant therapeutic experience and medical knowledge of the product under investigation. BBA offers clients the necessary expertise for successful implementation of endpoint adjudication services for studies. Our Safety Oversight Group can manage the process from beginning to end or to work with clients to develop a select list of services.

DATA MONITORING COMMITTEES

Since subject safety is paramount DMCs and DSMBs play a crucial role during clinical studies. DMCs are independent panels of expert physicians and biostatisticians who review clinical study data continuously to ensure patient safety and study integrity with scientific rigor. BBA partners with sponsors to ensure the successful implementation of DMCs. Then the Data Analytics team can provide study data and reporting on the findings.

SAFETY SIGNAL DETECTION AND SUSAR REPORTING

For studies of investigational drugs, biologics, or combination products, BBA provides customized patient profiles and case report form listings that allow early detection of trends and clusters to best protect study subjects and support decisions, when necessary, to change dosing regimens, inclusion criteria, or other protocol parameters. We organize safety trend review meetings at appropriate frequencies. We also manage serious adverse event cases to ensure each has an accurate, concise, but thorough narrative and that suspected unexpected serious adverse reactions are reported to regulatory agencies within the required timeframes.

BBA DELIVERS

01 Customized patient profiles and case report forms allowing for early detection of trends and clusters

02 Data to support decisions, to change dosing regimens, inclusion criteria, or other protocol parameters.

03 Safety trend review meetings at appropriate frequencies

04 Management of serious adverse event cases by reporting events within the required time frames and providing thorough narratives to regulatory agencies