

Web based statistical approaches for risk monitoring of sponsor clinical development programs

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At EmpiriStat we consider monitoring both a process and implementation of statistical reporting and people “on the ground” delivered through a risk-based prioritization approach. Many pharmaceutical companies (and often led that way to think by CROs) have interpreted FDA’s guidance that they need 100% auditing by monitors every 6-8 weeks during their study. This is completely not true, and EmpiriStat was pleased to see the release of FDA’s Draft Guidance “Guidance for Industry Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring” released in August 2011, in which this thought was disputed.

EmpiriStat works with the Sponsor on a tailored approach for their particular clinical development program, their sites and trials based on identified and perceived risks. We know and understand the FDA’s current risk based approach for monitoring of sites and sponsors upon their NDA submission, and have used this knowledge as well as our statistical prowess, for creating and implementing risk based approaches during the Sponsor’s IND phase of trial implementation. We know that no one single approach to monitoring is appropriate or necessary for every clinical trial. But we work with each Sponsor and design a statistical monitoring plan that is tailored to the specific human subject protection and data integrity risks of the trial. To provide an integrated monitoring plan and to track metrics across all of the Sponsor’s study, we automate those processes through a web-based system. Through a mix of statistical processes and integrated technology, regulatory GCP compliance can be easily tracked on a Sponsor level, therapeutic level, site level and even a detailed investigator level.

Our approach to risk based prioritization monitoring is based on principles of statistics, statistical modeling, good data management, site management and training, and clinical monitoring. We identify the critical data and processes that should be monitored based on the study protocol, knowledge and information about the site, and risk assessment; all adhering to the new guidance from the FDA. This information deals with the complexity of the protocol procedures, the study design, types of study endpoints, the study population, where the study is taking place, the site and its staff (experience, previous studies, competing studies), safety parameters, how the data are being collected and stored, as well as how much data are being collected. Our risk-based approach saves several hundreds of thousands of dollars per study for our clients and potentially could save millions across the clinical development program.

Biography

Nicole C. Close is a clinical trialist, epidemiologist and Biostatistician. As a Board Member of the Society for Clinical Trials (SCT) and a member of the Regulatory Sub-committee of the International Society for Clinical Biostatistics, She is a leader in her field with over 17 years of experience. She is the Lead Statistician contractor for the US Food and Drug Administration’s (FDA) “Development of Advanced Engineering Methods for Risk-Based Prioritization for Clinical Development and Pharmacovigilance Inspections Project.” On this project she works with the Directors of each FDA Division for identifying the key clinical elements from all Sponsor drug and therapeutic applications filed under IND and NDA status. She has been the Lead Statistician on over 23 open INDs at a previous place of employment with the Department of Defense (USAMRMC) and has provided regulatory strategy and the statistical summaries (integrated summary of safety and integrated summary of efficacy) for multiple NDA submissions to the FDA for various clients. She has also been called to be a statistical reviewer for the NHLBI on Coordinating Center Contract reviews, and a six time statistical panel reviewer for the Department of Defense’s (DoD) Congressionally Directed Medical Research Programs (CDMRP) in wound care (diabetes related issues), Rehabilitation medicine, and Post Traumatic Stress Disorder and Traumatic Brain Injury, reading and evaluating over 265 research applications and providing detailed statistical reviews via written and oral communication on these panels.

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