Risk based approaches to monitoring of vaccine clinical trials – A quality driven and cost-effective model

Abby Abraham
Algorithm Inc., India

Clinical development of vaccines and drugs contributes to major costs of Bio-pharma R&D and is limiting the rate of innovation globally. A significant cost driver in clinical development of vaccines is clinical monitoring and management of clinical trials. In order to achieve the objective of clinical trial monitoring viz., protecting rights and safety of subjects, ensuring scientific integrity and compliance to ICH-GCP and regulatory guidelines, conventional monitoring involves frequent and on-site rigorous visit to sites that ends-up being cost intensive. The outcome of such monitoring is dependent on human competence, skill set & experience which are laden with subjective decisions, inconsistent quality and inefficient execution. This paradox of high costs not necessarily translating into assured quality is not sustainable and needs to be addressed. The session will describe a new model that uses risk based approaches to implement and monitor vaccine studies optimally. The key areas that will be covered are concept of risk based monitoring (RBM) and regulatory views, how risk based approaches to monitoring can be executed, resources required for implementing risk based monitoring and expected cost benefits of adopting such an approach especially in large vaccine clinical trials.

Biography
Abby Abraham has completed his M Pharm from Birla Institute of Technology and Sciences (BITS, Pilani) in 1998 and subsequently healthcare management from Symbiosis Institute, Pune. He is currently Co-founder and Vice-President of Clinical solutions of Algorithm Inc., an organization that specialize clinical research analytics. Prior to his new venture, he has worked in senior leadership roles within global clinical research organizations. He is also a co-founder and board member of a healthcare technology firm based out of Singapore.

abbyabraham2405@gmail.com