Vikram Kukkadi, Pharmaceut Reg Affairs 2014, 3:3
http://dx.doi.org/10.4172/2167-7689.S1.016

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Pharmaceutical Regulatory Affairs
September 08-10, 2014 DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA

Efficiency in the context of data quality: The role of design and technology

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For CDM, the over-arching performance goal has always been about having a plan and competencies to ensure emergence of integrity-assured, analysis-ready data from the conduct of a clinical trial. The advent and increasing uptake of adaptive trials means that plans have to also ensure that the integrity-assured, analysis-ready data is ready and available at more or perhaps all stages of a clinical trial progression. The nature of the protocol and therapeutic area are primary sources of relative complexity in a clinical trial and determine its work-intensity. Within this context, the presentation will explore the key role design competency and modeling can play in achieving above normal efficiencies and continuous improvement. Using practical examples, we demonstrate how designs that take into account the competencies and capabilities of human/technical infrastructure with the goals of reducing possibility of error and elimination of unnecessary repetition are likely to induce performance that strongly correlates to and results in quality data. The role of technology in inducing quality and efficiency will be discussed. Efficacy vs. safety data aspects of CDM will be explored with an emphasis on coding, coding quality and efficiency as it relates to AEs and SAEs. Good KPI designs that encourage a culture continuous improvement and efficiency will be discussed and contrasted with designs that run the risk of driving counter-productive expediency.

Biography

Vikram Kukkadi is a qualified physician and diabetologist with more than 10 years of experience in clinical research and drug development in both Pharma and CRO with hands-on experience in medical monitoring and pharmacovigilance in a variety of therapeutic areas including Cardiology, Oncology, Immunology and Internal Medicine. He has broad experience in both safety monitoring and pharmacovigilance procedures through providing medical and safety review for thousands of AEs and safety reports both in major clinical trials and in post-marketing safety surveillance. He has completed his Post Graduation in Diabetology from Annamalai Univ., Madras, India and his Medical Doctor Degree (MD) from Rajiv Gandhi University, Bangalore, India. He is currently associated with Quintiles as Assoc. Director and in the past has worked for prestigious organizations like Abbott Vascular, Accenture, Max Neeman Clinical Research and Indegene Lifesystems.

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