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Effective eCRF designing – Data management approach

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An effective eCRF design is always a key to the successful outcome of a clinical trial. The main objective is to offer improved data quality, online discrepancy management, faster database lock and at the same to time preserve and maintain quality and integrity of the data. eCRF design should be standardized to address the needs of all user roles enrolled within the clinical trials. Data should be organized in a format that facilitates and simplifies data analysis for submission. Review of the primary and secondary study end points as well as well-planned study design and safety/efficacy outcomes will assist the process of effective eCRF designing. Use of CDISC standards variables will also enhance the process of effective eCRF building. Effective measures taken while conducting eCRF design as well as post production changes (changes deployed on production environment of the eCRF design) will result in reduced query generations and improved data integrity. This presentation will also describe the methods of CRF designing in clinical research and discusses the challenges encountered in this process.

Biography

Mohsin Shaikh has completed his MD from MS University, Gujarat and Post-graduate studies from AAPS Toronto. He is a lead Clinical Data Manager at Axiom Real-Time Metrics, a premier clinical data management service organization providing expert solutions into the EDC/DM/IWRS sector. He has published more than 15 papers in reputed journals and has been serving as an Editorial Board Member of repute. He is an international medical graduate with more than eight years of experience in clinical research industry mainly in clinical data management.

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Page 48