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Unique eCRF – A wave of the clinical trial future

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Unique eCRF is an electronic platform which maintains and integrates clinical trial subject's lifetime health care and financial records. Unique eCRF could route authorized person to a private and secure environment to confidentially access, manage and share the health information of a subject. Unique e-CRF has potential of integrating various domains of clinical trial to a unifocal point like data capture, data cleaning, and data mining hence significantly contribute in trial management. Unique eCRF helps both in reducing risk and improving efficiency throughout a study by eliminating the need for data reconciliation and the expenses of managing separate systems. Thus, it also contributes in huge saving of a pharmaceutical company in terms of cost and time. Unique eCRF make clinical trial more transparent by allowing real time data asses to all involved parties (clinical trial manager, investigator, sponsor, licensee, regulatory auditors, etc.) simultaneously. The other potential advantages include integrated patient's health and financial data, audit trial capabilities, identifying eligible patients for clinical trials from patient's records, trial randomisation, agile data transfer, follow patient outcomes, in creating patient registries, monitoring adverse drug reactions and pharmacovigilance reporting. The auto-alerts and correction feature of eCRF will improvise data collection, faster database lock and hence a smart way for data management and quick statistical analysis. However, unique eCRF should be featured in compliance with 21 CFR part 11 requirements which impose extra pressure and a challenge in its design. In addition, the initial cost of adopting this model is quiet heavy.

Biography

Supreet Kaur Gill, BDS is a Bachelor of Dental Surgery from Adesh Institute of Dental Sciences and Research, Bathinda under Baba Farid University of Health Sciences, Faridkot, India). At present she is pursuing her post-graduation in Clinical Research (MSc clinical research from University Centre of Excellence in Research, Baba Farid University of Health sciences, Faridkot, India). One of her paper is to be published in *Asian Journal of Pharmaceutical Sciences and Clinical Research*. She wants to pursue her career in dental product industry as clinical research associate.

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