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Clinical data management: An overview

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Management of data of clinical trials on clinical database is known as clinical data management. It is one of the most critical aspects of clinical research. It consists of three phases i.e. start up, conduct and close out. Conduct is the most important phase and comprises of 90 percent of data management activity. Startup phase comprises of activity like designing of electronic CRF, validation of CRF, designing of edit checks, UAT of edit checks and programming of edit checks for query management. However conduct phase comprises of activities like discrepancy management, vendor data Reconciliation, solving programmed listings and data validation. It should be noted that conduct phase occupies more than 90% activity of data management. Discrepancy management alone contains more than 98% of conduct activity. On the other hand close out is the ultimate phase of data management and consist of locking & freezing of data and database and archival of entire documentation of clinical trial. There are various tools which are being used in data management activity out of which Informed, medidata Rave and oracle clinical are the most popular one. Clinical data managers are supported by several other teams like medical coding, SAS programmers, EDC study testers etc. Medical coders contribute in coding medical history and adverse events through WHODD and medra Dictionary respectively. SAS programmer helps data managers to program edit checks in clinical database so that appropriate query fired after entering discrepant data. However ECD study tester performs user acceptance test of clinical database for its appropriate functioning.

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