Standardization in clinical trial data analysis and reporting

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Abstract

Human health is of utmost importance and for this reason the process of drug development has been a highly regulated process that takes about 10-15 years and could cost >800 million USD (for a single drug). Clinical trials form >60% of this cost and it is therefore imperative that the entire process be very efficient and cost-conservative without any compromise in its quality. Amongst the many ways of process improvement and cost control, clinical data standardization happens to be the most important. Over the past couple decades the clinical research industry, both sponsors and regulatory agencies have realized this and have attempted to work towards a common set of data standards with the goal of accelerating drug development by improving the data collection, analysis, and reporting process. The adoption of such standards has been a challenging task for the industry, however the birth of Clinical Data Interchange Standards Consortium (CDISC) has given a new direction to this goal. Today the CDISC Foundational Standards are increasingly being applied as the basis for supporting the standardization of clinical and nonclinical research process ranging from protocols through data collection, data analysis and reporting. In addition to CDISC, SAS which has always been a core component of clinical data processing and analysis, also adapted with PROC CDISC (early 2000s) and SAS Clinical Standards Toolkit and SAS Data Integration solutions that further support the needs within the industry for standardization. Herein, are discussed the brief history, evolution and the future of clinical data standards.

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Citation: Dr. Dhawal P Oswal, Standardization in clinical trial data analysis and reporting. Journal of Plastic Surgery and Case Studies.