

A Review of Software for Data Management, Design and Analysis of Clinical Trials

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Abstract

In clinical trials, subjects are usually entered one at a time, and their responses to treatment monitored sequentially. Regular monitoring of trial progress in the early stages is crucial for accurate reporting of the final results. This paper discusses in detail the principles of quality data management in clinical trials, with specific reference to three clinical data management systems namely, CLINTRIAL, ORACLE CLINICAL and MACRO. All three systems have the essential features for monitoring and processing quality clinical trials data. In terms of functionality, there appears to be no significant advantage of one system over the other. However, to reap the full benefits of sophisticated systems such as these, a good support network and comprehensive training programmes are essential since their day-to-day use demands a high level of technical competence. Basic considerations pertinent to the success of a clinical trial involve not only logistics and data management. Issues relating to the study design are also of primary concern. In this respect, we briefly describe some sample size packages, NQUERY, PEST, POWER, POWER AND PRECISION and SAMPSIZE. Finally, a brief comparison is made with regards to some distinct features of three commonly used statistical packages, namely SPSS, SAS and STATA.

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