CLINICAL DATA MANAGEMENT FOR PROJECT MANAGER: VENDOR SELECTION AND MANAGEMENT

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Introduction. The expert examination and approval of pharmaceuticals by national regulatory agencies is possible only in case when the clinical trials data presented are of sufficient integrity to ensure confidence in the results and conclusions presented by the sponsor company. Adherence to quality standards and practices, for instance Good Clinical Practice (GCP) is very important for obtaining that confidence.

Aim. This research examines the critical factors that a project manager need to look out for in the area of Clinical Data Management when undertaking a clinical trial project.

Materials and methods. In this work we used international and national regulations and guidelines, and a specifically developed questionnaire with a rating score as the analytical instrument to share the experience from internationally sponsored clinical trials and professional network.

Results and discussion. The purpose of this research is to present accepted practices and to demonstrate how to apply the concepts contained in existing regulations and associated guidance to Clinical Data Management as well as to provide practical suggestions and proven tools recommended by the clinical trials professionals when making decisions upon clinical trial data and its utilization. Commonly Clinical Data Management services are outsourced by the sponsoring companies to catch up with technology innovations and regulatory pressure for quality. Clinical trial projects are resource intensive and costly endeavors, and conducting them requires the establishment of a process in the execution of the project. Clinical Data Management constitutes a major part of the clinical trials conduct, and includes paper and electronic case report form (CRF) design, clinical trials database design and programming, data standards, system implementation, data acquisition, data integration into the clinical trials database, data review, validation, coding and database finalization. Each company involved in clinical trials conduct is obligated to ensure that the individuals performing tasks follow Good Clinical Practice.

Conclusions. Therefore, vendor management was examined, minimal standards and the best practices for the clinical trial project manager were provided constituting the essential theoretical part of our master’s thesis.