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Technical Note

Standardize Operating procedure for Clinical Data Management (CDM), exploring the possibility under Indian Regulations

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ABSTRACT
With the advent of modifications in Indian regulations for clinical trials, there is the need to have standardization of individual clinical data management steps. This will not only have cost saving by mitigation of risk by avoiding data corruption but will help to evolve the Indian regulation towards globalization. This report shares the authors view based on experiences drawn by implementation of clinical trial data management procedures in an Indian biopharmaceutical company on vaccine trails.

Keywords: CDM, Indian Regulations

INTRODUCTION

As true with all the industries, every piece of information requires to be correctly documented and managed. It entails different set of skills to accomplish the task. Equally obvious, is the case of Indian clinical research industry, where certain skills-set and expertise is needed to carry out management of study data. These skills can be best acquired by having hands on practice. Broadly these skills may remain same, but the stepwise procedures adopted to do the task differ from one organization to another or the difference in the task may be based on therapeutic area under consideration.

Regulations for Indian clinical research industry are going through the dynamic flux and are evolving confidently to match with the standards of its counter parts in rest of the developed nations. It could be acknowledged that some of the recent norms are much more stringent in our county than those outside. But a big lacuna still exists in the form of 'dedicated guidelines' to establish and scan CDM processes for different therapeutic area.

Browsing through literature reveals that there are various methods which could be deployed for management of data from clinical studies. This diversity in the procedure may also reflect the want of 'standardization' and 'harmonization' for the field. One of the reasons for current scenario may be attributed to the shift of focus of Indian regulators more towards clinical trial operations, safety data management and Pharmacovigilance than for CDM. Also, the Indian Pharmaceutical Industry lacks the drive to create Indian forums which can work together to achieve the common goal.

CDM IN THE PAST

In the past, Indian companies have relied solely on manual skills to manage the data. Excel spread sheets were the only preferred tool for the task. This method required continuous investment of hours of hard work for achieving desired quality standards for clinical trial data.

ANALYZING PUBLISHED CDM PROCEDURES PRACTICE CURRENTLY

Although CDM professionals should generally follow standard practices to perform these tasks, one should realize that the phase and therapeutic area of a study can lead to the differences in tasks and how each task should be performed. [1] Based on our experience from data management of vaccine trails, we have identified following steps to manage clinical trial data for paper studies.

Once the trial design protocol gets finalized in the organization, the procurement of approvals by regulatory authority and ethical committee occurs, this is followed by the process of site selection. Subsequent to patient recruitment, study conduct starts at the site by the investigator. Data, 'the clinical information gathered from each patient enrolled in study' is the most valuable information and its handling and its management is the most critical step of a clinical study. CDM group keeps the database ready so that the clinical information collected at the site could be entered into the database.

Data is validated as per the protocol requirements and reviewed thoroughly. Any discrepancy identified in the data, is sent to the site in the data clarification form (DCF) for corrections. Only valid resolutions obtained from the site in response to the queries, are updated in the database. Once there are no discrepancies and database is clean, database is locked to prevent any unauthorized access.

Analysis ready data is sent to the biostatistician for future processing. Biostatistician creates the data tables and listings; this becomes the part of clinical trial study report.

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Once the report is finalized internally, same is submitted to the regulatory authorities for product related approvals. Study data may be published as applicable.

While each study scenario is unique and has to be approached as such, there are several elements in defining strategy and team structure in global CDM that can be applied universally.[2]

Regulatory requirements have advanced the necessity of CDM as science. Therefore the processes used to support the clinical data must be clearly defined and documented.[3]

Over the last decade the clinical research industry has attempted to work toward a common data standards with the goal of accelerating the drug development process by improving the data collection, transformation, analysis and submission.[4]

With advent of new genre of vaccine biopharmaceutical products, bio-similars, the CDM task need to be streamlined and the guidelines need to be implemented in an effective manner so as to achieve process standardization. These steps and procedures are to be made separately for vaccine trials. This is because the vaccine studies are different from other studies, as they are usually done on healthy subjects.

The global face of drug development demands that both government and industry, in India, should pay more attention to internationally acceptable technical standards and common conformance criterias for evaluation, supporting the idea of 'One Operating Procedure for Clinical Data Management (CDM)'.

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