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GCDMP

REVIEW ARTICLE

CDM Presentation at Investigator Meetings

Clinical data management professionals serve an important role at investigator meetings, especially when the trial is large, complex or multisite. This chapter covers the procedures clinical data management professionals should follow when preparing a presentation for such meetings, including presenting examples of case report forms, discussing various types of error- checks, reviewing the role of the data manager, and emphasizing the proper use of data clarification forms.

Keywords: Clinical Data Management; Investigator Meetings; Good Clinical Practice

Introduction

The investigator meeting provides an early opportunity for data managers to be in contact with site personnel for a clinical trial. It is often a joint effort among the project manager, the clinical team leader, the statistician, and the clinical data management (CDM) lead to describe procedures for preparing, conducting, and managing multicenter investigational trials. A CDM presence at this meeting should provide a well-rounded overview of the data collection strategies for a given study.

Scope

This task commences when the study team takes on the responsibility for preparing and conducting the meeting and ends when the required meeting documentation has been distributed following the meeting.

Minimum Standards

- The data manager should prepare their assigned presentation and materials for the meeting.
- Materials should include sample case report forms (CRFs), CRF completion guidelines, data queries and self-evident corrections.
- The data manager should prepare a visual presentation on the overall data collection process, including non-CRF data such as laboratory, ECG and imaging data.
- Role-based guidance should be provided for all project team members involved in the data cleaning process.
- Training on CRF and query completion should be documented.
- The data manager should present an overview of data collection processes in the study for adverse events (AEs) and serious adverse events (SAEs). In some organizations, the SAE collection process may be presented by a representative from a safety or pharmacovigilance group.
- Provide a presentation on the coding of AEs and concomitant medications.
- If self-evident corrections can be made for the study, the process should be addressed in the presentation, including site sign-off and examples of where this will be utilized.

Best Practices

- Avoid use of acronyms. If you must use an acronym, spell it out in the first instance and then use the acronym in subsequent references.
- Provide a copy of the presentation for all participants.
- Record the session (audio or video) for use in subsequent training as appropriate.
- Allow sufficient time at investigator meetings to answer CRF-related questions.
- Facilitate a breakout session where CRF completion exercises are performed and evaluated for common errors.
- If studies were completed in a previous indication with similar CRFs, provide targeted training based on discrepancy metrics per data panel or
- field. Also provide training for edit procedures to address the most common failures.
- Provide, or support the preparation of, materials that are best suited for the type of meeting that will occur. For example, slides and flowcharts are appropriate for presentations or Web-cast meetings. Other presentation methods are more appropriate for self-study. It is best to consult with experts to determine the most appropriate method for presenting information.

Procedures

The purpose of a CDM presentation is to familiarize site investigators and staff with case report forms, the electronic data capture (EDC) system and equipment if applicable, and clinical data management procedures such as CRF completion guidelines, data collection, and the query process. At minimum, the data manager should present the CRF completion guidelines and query workflow process at the investigator meeting.

In the past, investigator meetings were face-to-face meetings. Now, many companies are conducting investigator meetings via the Web, or preparing self-paced

training modules to complete online or via CD. Some programs can track the amount of time a user was online, as well as the assessment score achieved on an e-learning module. Data management should ideally be included in investigator meetings because of the expertise in data collection and integration methodologies, as well as its ability to inform the investigative and clinical staff of the most effective and efficient measures to take to enhance data quality and timeliness.

CRF presentations should use completed CRFs as examples. It is valuable to present a CRF packet containing all unique CRFs completed as if they contained actual patient data. This would allow attendees to see proper data recording for various requirements of all CRF pages. Every effort should be made to have final, approved CRFs prior to the investigator's meeting.

However, if a CRF is not finalized prior to the meeting, the study team should be reminded to plan sufficient time for CRF changes to be made before the start of the study. Another strategy would be to incorporate into the final draft any study coordinator or investigator data collection feedback provided at the meeting. Valuable feedback on the reality of treatment may drastically reduce the discrepancy load and reduce queries to the sites.

The presenter should demonstrate consistency checks between pages, and should point out potential spots for errors. Some of the cross checks that can be discussed include, but are not limited to:

- Compare current medical history to any concomitant medications. For example, if a subject has hypertension and is taking medication, it should be appropriate to show that they are taking an antihypertensive.
- Compare medical history to physical examination. For example, if a subject has a history of bronchitis, the physical exam may show bronchitis.
- Compare termination page to AE page. For example, if a subject withdrew from the study due to an AE, an AE should be indicated on the AE page and the action taken should be discontinuation from study.
- Compare AE where a medication was administered to the concomitant medication page to ensure medication has been documented with the appropriate indication, which should be noted in the AE.
- Provide an example where efficacy and safety data show a logical progression. For example, compare baseline vital signs with subsequent vital signs.
- Make certain investigational product accountability corresponds with dosing regimens outlined in the protocol, as well as drug return logs in patient packets.
- Check that visit dates are in range with visit windows specified in the protocol.
- Compare subject history and physical examination to basic eligibility criteria.

The CDM presenter should use the opportunity to explain the data manager's role in the overall scheme of the trial, including but not limited to the following:

- Establish project standards for handling partial, missing or incomplete data, as well as illegible text entries.
- Ensure that *Good Clinical Data Management Practices*' guidelines are followed by providing examples that indicate the proper mechanism for making corrections to the CRF.
- Review the amount of time CDM needs to complete milestones and meet timelines.
- Review the process of providing performance feedback to sites, perhaps in the form of trend reports for the data query process.
- The CDM presenter should use this opportunity to carefully review the data query process in a step-by-step manner, including but not limited to the following:
- Familiarize participants with various reports that organize data queries by data item or file names. Educate participants on problem areas of CRFs, or common mistakes made during the data query process.
- Demonstrate to site personnel how to address data issues before the monitoring visit in order to achieve best monitoring efficiency.
- Ensure site staff understand that the cleaner data are to start with, the quicker database lock can occur. The sites need to remain available to answer queries and questions at least until database lock.
- Explain any status reports site staff may receive that are based on data in the database. Some examples include outstanding CRF reports, outstanding data query reports, or outstanding lab samples.
- Explain the relevance of reports and any related workflow information. For example, if sites are paid for CRFs entered as of the 25th of each month, provide the site with the send-by or submit date that will assure data will be entered and included in the report run on the 25th.
- Describe the procedures for clarifying CRF questions or issues.
- For EDC studies, allow sites the opportunity to either participate in hands- on entry or to see a live demonstration of key points from the study and the EDC system.

Recommended Standard Operating Procedures

- Data collection and handling procedures
- Handling of standard clarifications or obvious data corrections

Competing Interests

The author has no competing interests to declare.

Chapter Revision History

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May 2007	Revised for style, grammar, and clarity. Substance of chapter content unchanged.
July 2008	Revised for content, style, grammar, and clarity.

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