Good Clinical Data Management Practices

Published October 2013

"The need for Good Clinical Data Management Practices is not new. In the early 1970s, the Public Health Service recognized this need through a contract to a major research university for training of research data managers. However, the need continues, the need changes over time, and the need for good clinical data management practices has become even more important as biopharmaceutical and medical device industry and regulatory bodies rely more and more heavily on the evaluation of electronically transmitted clinical trials data for critical data-based decision making."

Thus, the Society for Clinical Data Management provides the *Good Clinical Data Management Practices* to the SCDM membership.

This document constitutes neither consensus nor endorsement by regulatory agencies, pharmaceutical or biotech companies, contract research organizations or the academic community, but rather reflects the current views of SCDM membership. Additionally, none of the recommendations contained herein supersede regulations or regulatory guidelines, which should always be consulted prospectively to assure compliance. The document should not be considered an exhaustive list of topics.

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GCDMP Revision History

Publication Date	Comments
September 2000	Initial publication of the GCDMP with the following chapters: Assuring Data Quality; Data Acquisition; Data Entry and Data Processing; Data Storage; Database Closure; Database Validation, Programming and Standards; Laboratory and Other External Data; Measuring Data Quality; Safety Data Management and Reporting; Vendor Management; Glossary.
January 2002	The following chapters added to the GCDMP: CDM Presentation at Investigator Meetings; CRF Printing and Vendor Selection; Preparation and Preservation of CRF Completion Guidelines; Serious Adverse Event Data Reconciliation; Training. Data Entry and Data Processing chapter revised.
September 2003	The following chapters added to the GCDMP: Clinical Data Archiving; Data Privacy; Dictionary Management; Electronic Data Capture Principles.
October 2005	Metrics chapter revised.
May 2007	All chapters revised for consistency of style, grammar, and clarity. Substance of chapter content unchanged.
July 2008	All chapters revised with new headers, footers and pagination. The following chapters were revised for content, style, grammar and clarity: Serious Adverse Event Data Reconciliation; CRF Completion Guidelines; Clinical Data Archiving, CDM Presentation at Investigator Meetings, Vendor Management..
September 2008	The following chapters added to the GCDMP: Electronic Data Capture—Concepts and Study Start-up; Electronic Data Capture—Study Conduct; Electronic Data Capture—Study Closeout. Measuring Data Quality chapter revised for content, style, grammar and clarity.
December 2008	The following chapter added to the GCDMP: Data Management Plan.
March 2009	Database Validation, Programming and Standards chapter revised for content, style, grammar and clarity.
April 2009	Data Privacy chapter revised for content, style, grammar and clarity.
May 2009	Dictionary Management chapter revised for content, style, grammar and clarity and renamed Medical Coding Dictionary Management and Maintenance.
July 2009	The following chapters added to the GCDMP: Patient-Reported Outcomes; Data Management Standards in Clinical Research.
October 2009	The following chapter added to the GCDMP: Laboratory Data Handling. Data Entry and Data Processing chapter revised for content, style, grammar and clarity and renamed Data Entry Processes Laboratory and Other External Data chapter renamed External Data Transfers
December 2009	The following chapter added to the GCDMP: Edit Check Design Principles.
March 2010	Vendor Management chapter revised for content, style, grammar and clarity and renamed Vendor Selection and Management.

June 2010	The following chapter added to the GCDMP: Project Management for the Clinical Data Manager.
October 2010	Data Acquisition chapter revised for content, style, grammar and clarity and renamed Design and Development of Data Collection Instruments.
April 2011	Metrics for Clinical Trials revised for content, style, grammar and clarity and renamed Metrics in Clinical Data Management.
October 2013	Assuring Data Quality revised for content, style, grammar, and clarity. Added more explicit description of quality management system components important in clinical research data management Database Closure revised for content, style, grammar, and clarity with database closure sample flowchart and sample checklist added. Glossary revised with the addition of approximately seventy-five (75) terms.

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