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GCDMP

REVIEW ARTICLE

Good Clinical Data Management Practices

Keywords: Clinical Data Management; Research Data Management; Data Curation

"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.

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

(Contd.)

Publication Date	Comments
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 theClinical Data Manager.
October 2010	Data Acquisition chapter revised for content, style, grammar and clarity andrenamed Design and Development of Data Collection Instruments.
April 2011	Metrics for Clinical Trials revised for content, style, grammar and clarity andrenamed 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 importantin clinical research data management Database Closure revised for content, style, grammar, and clarity with databaseclosure sample flowchart and sample checklist added. Glossary revised with the addition of approximately seventy-five (75) terms.

Executive Summary

The Society for Clinical Data Management (SCDM) is a non-profit professional organization founded to advance the discipline of clinical data management (CDM). The SCDM is organized exclusively for educational and scientific purposes. The mission of the SCDM, promoting clinical data management excellence, includes promotion of standards of good practice within clinical data management. In alignment with this part of the mission, the SCDM Board of Trustees established a committee to determine standards for Good Clinical Data Management Practices (GCDMP) in 1998. The committee charter reads as follows:

> The review and approval of new pharmaceuticals by federal regulatory agencies is contingent upon a trust that the clinical trials data presented are of sufficient integrity to ensure confidence in the results and conclusions presented by the sponsor company. Important to obtaining that trust is adherence to quality standards and practices. To this same goal, companies must assure that all staff involved in the clinical development program are trained and qualified to perform those tasks for which they are responsible.
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> The discipline of Clinical Data Management 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. Independent of how individual companies perform these tasks within their company each company is obligated to ensure that the individuals performing these tasks follow Good Clinical Practices. However, currently prior to SCDM and this committee, there were no published good clinical practice guidelines specific to the discipline of Clinical Data Management. As the organization representing Clinical Data Management professionals in North America, SCDM is in a position to develop, maintain and publish GCDMP guidelines that define and promote current industry procedures and best practices.

One of the objectives of the committee is to develop, publish, and recommend use of guidelines for Good Clinical Data Management Practices. In addition to this stated objective of the GCDMP committee, it has been our continuing goal to obtain as much input and participation as possible from the SCDM members and other users to further develop GCDMP guidelines.

Over three years have passed since the September 2003 edition of the GCDMP was completed. During that time, the GCDMP Committee focused on the stability and future of the GCDMP and established a lifetime maintenance plan (LMP) to document the processes that guide changes. In an effort to keep the GCDMP current in a changing industry, this plan defines a formal process and timeline for review by the committee; the SCDM Board of Trustees; the international community, which is currently represented by the International Network of Clinical Data Management Associations (INCDMA); and the users. Four working subcommittees are defined in the LMP to assist in the maintenance of the GCDMP and the LMP itself.

In addition to planning for, writing, and putting in place the LMP, the GCDMP committee finalized a new chapter ("Metrics for Clinical Trials") and revised five chapters. These updated chapters will be released when the review process has been completed.

The GCDMP is provided as a special service to the SCDM membership. The primary recipients include professionals involved in the pharmaceutical, biotechnology, and medical device clinical data management. It will provide assistance to data managers in their implementation of high quality data management processes and in their quest to become Certified Clinical Data Managers (CCDM). It will also provide management with a guide for planning training and education for new clinical data management staff.

Acknowledgements

As the committee chairperson, I would like to acknowledge the expertise, dedication and hard work of the document authors. The following individuals have contributed to one or more versions of the

GCDMP: Susan Bornstein, Letitia Bowen, Sally Cassells, Anthony J. Costello, Wendy Cuthbert, Bernadette Farrell, Kaye Fendt, Lisa Freeman, Volker Freiman, Imogene Grimes, Marysasser Hedrick Holloway, Brenda Hoeper, Susan Howard, Becky Kush, Angel Lazarov, Terrence Loding, Meredith Nahm, Armelde Pitre, Don Rosen, Barbara Tardiff, Lisa Taylor, and Beth Wilson. In addition, Sasha Zucker provided his knowledge and skills as technical editor, for which we are most grateful. While I spearheaded the effort to update the Lifetime Maintenance Plan, Susan Howard led the Review and Update subcommittee, which dedicated its efforts to reviewing existing chapters and incorporating feedback from users. I would also like to acknowledge the GCDMP Full Committee, which has provided insight and expertise during the review of the new and revised chapters. Kaye Fendt—who initially took the idea of this committee to the Board of Trustees and to interested members of SCDM and who served as Board and FDA Liaison in its early years—has continued to lend her expertise to this committee as an innovator, an author, an editor, a supporter, and a motivator. Susan Bornstein led the committee during its formation and coordinated the creation of the CDM Task List, which served as the basis for the organization of this document. Meredith Nahm chaired the committee through 2001, served as Board Liaison through 2004, and has continued to contribute to the review process. Anthony Costello, who is currently Chair of the Board of Trustees and served as Board Liaison through 2006, continues to bring driven energy and focus on exposure and training of the document to the committee.

Special acknowledgements are extended to the users who offered helpful comments and feedback, the SCDM Board of Trustees, and the INCDMA members who participated in the review process. Without their continued interest and support, the GCDMP would not exist or be current.

Administrative help (which includes providing the technical expertise needed Copyright 2013 Society For Clinical Data Management to post the document and the Lifetime Maintenance Plan) was provided by SCDM's management organization, including Kim Breitbach and Monica Drake.

We are most grateful to all of you for your contributions and dedication.

Carol Garvey, GCDMP Committee Chair

Linda Talley, Board of Trustees Liaison

Introduction

The purpose of this document is to provide guidance on accepted practices for the many areas of CDM that are not covered by existing regulations and guidance documents. The intent is to remain consistent with regulatory practices in related areas of clinical research and to apply the concepts contained in those regulations and associated guidance documents to CDM. It is also the intent of the GCDMP to provide practical suggestions and proven means of meeting the guidelines recommended in the GCDMP. The GCDMP is written to serve the needs of multiple audiences including: data managers, data processors, statisticians, site personnel, clinical professionals, compliance auditors, regulatory affairs personnel, and all clinical research professionals making decisions regarding or using clinical trial data.

The GCDMP addresses the CDM areas of responsibility in 20 chapters. Each chapter includes two sections titled Minimum Standards and Best Practices respectively. These sections summarize the main recommendations of the chapter in bulleted form. For an executive summary or an overview of a chapter, read the chapter's abstract, Minimum Standards, and Best Practices. The Minimum Standards ensure that data are complete, reliable, and processed correctly, otherwise known as data integrity. The Best Practices offer higher efficiency, quality, and function and lower risk in addition to assuring data integrity. The body of each chapter provides the rationale, technical details, and, often, discussion of alternate or common practices.

References are provided at the end of each chapter to guide the reader to additional resources. Each chapter also contains recommended standard operating procedures (SOPs). Whether the SOPs are departmental or institutional in nature, it is the data manager's responsibility to ensure that all data management concerns are addressed.

In the absence of CDM regulatory standards, it is important for experienced, professional data managers to provide thought leadership on accepted data quality levels, on practical methods of achieving them, and on the implications of new technology on the CDM tasks. Data management tasks Copyright 2013 Society For Clinical Data Management are often technical and specialized. As the industry utilizes new technologies, it is therefore crucial that data management professionals take an active and forward-thinking role in setting appropriate expectations and standards for data quality, methodology for quantifying data quality, and auditing practices to ensure data quality.

The presence of acceptable quality standards becomes even more important as the industry undertakes larger trials where manual processes are no longer effective. New technologies often require not only retooling the data management process but also reforming the data management process to take advantage of the efficiencies offered by new technologies.

The GCDMP is a living document. In 2023, the GCDMP Chapters were separated and published as stand-alone chapters. This summary from the GCDMP 2013 Version includes those who participated in some fashion toward the GCDMP itself. As GCDMP Chapters are updated, they will be made available in the Journal for the Society of Clinical Data Management (JSCDM). This summary is being published to preserve the history of this important document to the SCDM Community.

Competing Interests

The author has no competing interests to declare.

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