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.