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## 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

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.