SCDM CCDA

CCDA Exam Study Guide

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CCDA EXAM STUDY GUIDE

This document is a study guide to help test takers prepare for the CCDA Exam by listing the chapters in the Good Clinical Data Management Practices (GCDMP©) Handbook that align with the core CCDA exam domains and associated tasks.

This guide also shows the domains and tasks that are regulated by the ICH GCP guidelines.

Please note this document is a supplemental study aid. It does not replace review of the GCDMP Handbook and ICH GCP guideline.

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1 CCDA Exam Domains and Tasks

Design Tasks

Tasks

1. Assist with implementing data standards
2. Assist in the design of the data collection forms
3. Read and interpret annotated forms
4. Assign in design of edit checks
5. Understand data transfer specifications
6. Create specifications for reports

Applicable GCDMP Chapters

GCDMP Chapter	1. Assist with implementing data standards	2. Assist in the design of the data collection forms	3. Read and interpret annotated forms	4. Assist in design of edit checks	5. Understand data transfer specifications	6. Create specifications for reports
Database Validation, Programming, and Standards	✓					
Design and Development of Data Collection Instruments	✓	✓				
Edit Check Design Principles		✓	✓	✓		
Electronic Data Capture—Concepts and Study Start-up				✓		
Laboratory Data Handling					✓	
Metrics for Clinical Trials						✓

Applicable ICH GCP Guidelines

There are no applicable ICH GCP guidelines for this domain.

Programming and Testing Tasks

Tasks

1. Build data visualizations
2. Test visualizations and reports
3. Executes UAT of EDC/eCOA study-specific configuration
4. Basic understanding of SQL and programming knowledge (R, Python, and Magro)
5. Understand the types of programming tools that are available for data review, data reporting, and data analysis
6. Runs simple import/export programs

Applicable GCDMP Chapters

GCDMP Chapter	1. Build data visualizations	2. Test visualizations and reports	3. Executes UAT of EDC/eCOA study-specific configuration	4. Basic understanding of SQL and programming knowledge (R, Python and	5. Understand the types of programming tools that are available for	6. Runs simple import/export programs
Database Validation, Programming, and Standards	✓	✓	✓	✓		
Design and Development of Data Collection Instruments					✓	✓
Edit Check Design Principles					✓	
Electronic Data Capture—Concepts and Study Start-up			✓			
Electronic Data Capture—Study Closeout			✓			
Reports and Metrics	✓	✓			✓	

Applicable ICH GCP Guidelines

There are no applicable ICH GCP guidelines for this domain.

Data Processing Tasks

Tasks

1. Collect study data (Paper Process) including local lab ranges
2. Enter data (Paper Process)
3. Write simple queries

Applicable GCDMP Chapters

GCDMP Chapter	1. Collect study data (Paper process) including local lab ranges	2. Enter data (Paper Process)	3. Write simple queries
Data Entry Processes	✓	✓	✓
Data Privacy	✓		
Design and Development of Data Collection Instruments	✓	✓	
Edit Check Design Principles	✓	✓	
Electronic Data Capture—Concepts and Study Start-up	✓		
Laboratory Data Handling	✓	✓	

Applicable ICH GCP Guidelines

There are no applicable ICH GCP guidelines for this domain.

Training Tasks

Tasks

1. Support creation of investigator site training materials
2. Demonstrate proficiency in Good Clinical Practice (GCP)
3. Understand Drug Development process
4. Understand and apply ALCOA+ principals
5. Understand data privacy laws
6. Understand randomization and study blinds
7. Understand primary and secondary endpoints including critical variables
8. Review and understand SOPs
9. Review and understand Protocol
10. Understanding the purpose of data standards
11. Understanding the purpose of coding dictionaries
12. Understand the data flow from initial entry through CSR
13. Awareness of different roles to maintain the blind
14. Understand TMF Reference Model and company-specific implementation
15. Awareness of study documentation completeness in TMF Data Management zone

Applicable GCDMP Chapters

GCDMP Chapter	2. Demonstrate proficiency in Good Clinical Practice (GCP)	3. Understand Drug Development process	4. Understand and apply ALCOA+ principals	5. Understand data privacy laws	8. Review and understand SOPs	9. Review and understand Protocol	10. Understanding the purpose of data standards	11. Understanding the purpose of coding dictionaries	12. Understand the data flow from initial entry through CSR	15. Awareness of study documentation completeness in TMF Data Management
Design and Development of Data Collection Instruments									✓	
Data Management Standards in Clinical Research							✓			
Data Privacy				✓					✓	
Electronic Data Capture—Concepts and Study Start-up			✓	✓	✓					
Laboratory Data Handling		✓								
Medical Coding Dictionary Management & Maintenance								✓		
Project Management for the Clinical Data Manager										✓
Vendor Selection and Management	✓									

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Applicable ICH GCP Guidelines

ICH GCP Topic	1. Support creation of investigator site training materials	2. Demonstrate proficiency in Good Clinical Practice (GCP)	3. Understand Drug Development process	4. Understand and apply ALCOA+ principals	6. Understand randomization and study blinds	7. Understand primary and secondary endpoints including critical variables	9. Review and understand Protocol	10. Understanding the purpose of data standards	13. Awareness of different roles to maintain the blind	14. Understand TMF Reference Model and company-specific implementation	15. Awareness of study documentation completeness in TMF Data Management
Appendix B. Clinical Trial Protocol and Protocol Amendment(s)							✓				
Confidentiality of Records		✓									
Data Governance - Investigator and Sponsor									✓		
Data Management Standards in Clinical Research								✓			
Data Privacy				✓							
Essential Documents for the Conduct of a Clinical Trial		✓									
Essential Records for the Conduct of a Clinical Trial										✓	✓
Ethics Committee	✓										
ICH GCP			✓	✓							
Investigator									✓	✓	
Investigator's Brochure	✓	✓									
Laboratory Data Handling					✓	✓					
Medical Coding Dictionary Management & Maintenance								✓			
Principles of ICH GCP							✓				
Sponsor		✓									
Training	✓										

ICH GCP Topic	Applicable ICH GCP Guideline
Confidentiality of Records	ICH E6(R2), Chapter 2 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with applicable regulatory requirement(s).
Data Governance - Investigator and Sponsor	ICH E6(R3), Chapter 4 [Draft]
Data Management Standards in Clinical Research*	M2 Electronic Standards, M2 EWG Electronic Standards for the Transfer of Regulatory Information
Data Privacy	ICH E6(R2), Chapter 2 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with applicable regulatory requirement(s).
Essential Documents for the Conduct of a Clinical Trial	ICH E6(R2), Chapter 8
Essential Records for the Conduct of a Clinical Trial	ICH E6(R3), Appendix C [Draft]
Ethics Committee	ICH E6(R2), Chapter 3
ICH GCP	ICH E6(R3), Chapter II [Draft]
Investigator	ICH E6(R2), Chapter 4
Investigator's Brochure	ICH E6(R2), Chapter 7
Laboratory Data Handling	ICH E6(R2) Chapter 8 Normal value(s)/range(s) for medical/laboratory/technical procedures(s) and/or test(s) included in the protocol to be located in the files of the investigator/institution and sponsor to document normal values and/or ranges of the tests. Updates to normal value(s)/range(s) for medical laboratory/technical procedures(s)/test(s) included in the protocol to be located in the files of the investigator/institution and sponsor to document normal values and ranges that are revised during the trial.
Medical Coding Dictionary Management & Maintenance*	M1 MedDRA Terminology (Multidisciplinary Guideline), MedDRA – Medical Dictionary for Regulatory Activities M1 PtC WG, MedDRA Points to Consider
Principles of ICH GCP	ICH E6(R3), Chapter II [Draft]
Sponsor	ICH E6(R2), Chapter 5
Training	ICH E6(R2), Chapter 2 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

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The ICH GCP Guidelines are available here:

- ICH_E6(R2) Guideline: ICH_E6(R2) Guideline
- ICH_E6(R3) Guideline: ICH_E6(R3) Guideline
- Index of ICH Guideline: Index-ICH Guidelines
- ICH Guidelines by Category: ICH Guidelines by Category
- Multidisciplinary Guidelines: Multidisciplinary Guidelines

Coordination & Management Tasks

Tasks

1. Assist with system and data management startup
2. Assist and report on data collection and processing
3. Assist with site data close-out
4. Assist with tasks required for database lock
5. Assist with implementation of new system
6. Supporting summary of data trends
7. Assists in creating study storyboards as part of inspection readiness
8. Assists in document retrieval during inspections

Applicable GCDMP Chapters

GCDMP Chapter	1. Assist with system and data management startup	2. Assist and report on data collection and processing	3. Assist with site data close-out	4. Assist with tasks required for database lock	5. Assist with implementation of new system	6. Supporting summary of data trends	7. Assists in creating study storyboards as part of inspection readiness	8. Assists in document retrieval during inspections
Data Privacy					✓			✓
Database Closure				✓		✓		
Database Validation, Programming, and Standards					✓			
Design and Development of Data Collection Instruments	✓	✓						
Edit Check Design Principles		✓						
Electronic Data Capture—Concepts and Study Start-up	✓		✓					✓
Electronic Data Capture—Study Closeout		✓	✓				✓	
Laboratory Data Handling		✓						
Medical Coding Dictionary Management & Maintenance					✓			
Project Management for the Clinical Data Manager	✓						✓	
Reports and Metrics						✓		
Serious Adverse Event Data Reconciliation			✓					

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Applicable ICH GCP Guidelines

There are no applicable ICH GCP guidelines for this domain.

Review Tasks

Tasks

1. Review protocols and study plans (e.g. data management plan, project management plan, safety management plan, site monitoring plan)
2. Review reports for inconsistencies in the data
3. Review work of peers
4. Identify data driven protocol deviations
5. Performs simple QC of study documentation content (e.g. version control)
6. Understand the different data types

Applicable GCDMP Chapters

GCDMP Chapter	1. Review protocols and study plans (e.g. data management plan, project management plan, safety management plan, site monitoring plan)	2. Review reports for inconsistencies in the data	3. Review work of peers	4. Identify data driven protocol deviations	5. Performs simple QC of study documentation content (e.g. version control)	6. Understand the different data types
Data Entry Processes	✓	✓				
Data Privacy				✓		
Database Closure	✓					
Design and Development of Data Collection Instruments	✓		✓		✓	✓
Edit Check Design Principles		✓				
Electronic Data Capture—Concepts and Study Start-up		✓				
Electronic Data Capture—Study Closeout	✓				✓	
Laboratory Data Handling	✓					✓
Measuring Data Quality		✓				
Project Management for the Clinical Data Manager	✓			✓		
Serious Adverse Event Data Reconciliation	✓	✓				

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Applicable ICH GCP Guidelines

There are no applicable ICH GCP guidelines for this domain.

2 GCDMP Chapters – Minimum Standards and Best Practices

Data Entry Processes

Minimum Standards

- Utilize written procedures describing data flow, data entry, data processing, and required quality level. Ensure enough specificity to reproduce the analysis database from source documentation.
- Ensure employees are appropriately trained (including ICH-specified documentation of having been trained) on systems, procedures, guidelines, working practices, and appropriate references (e.g., materials such as medical dictionaries, medical abbreviations, etc.) and that these documents are current and available to employees throughout the course of the study.
- Ensure all personnel involved with data entry or data management have the proper levels of access, grants and privileges.
- Maintain a list of individuals who are authorized to make data changes.
- Apply quality control to each stage of data entry processes to ensure data are reliable and processed correctly.

Best Practices

- Address the purpose, characteristics and complexity of each study in data entry training sessions, including, but not limited to a brief review of the protocol, scope of work, and identification of critical variables (usually privacy controlled subject identifiers, primary and secondary efficacy variables, and safety information).
- Verify in a test environment (before the data entry system is placed into active use) that entry fields function as planned (e.g., date fields only accept dates, drop-down lists contain appropriate values, skip patterns function properly). In some organizations, true test data pages may be entered for an entire case report form (CRF) packet, while other organizations may perform more focused testing. This is not to be considered a substitute for software validation or edit check testing.
- Provide comprehensive user training on CRF completion guidelines and data entry instructions.

- Provide sites, sponsors, vendors and study team members with timeline expectations for data receipt, data tracking, data entry, and turnaround times for data queries, file transfers and database deliverables.
- Establish thorough tracking mechanisms for the receipt of CRFs and other forms containing data to be entered. Tracking ensures control of the received records, identifies missing records and facilitates the archival of records at the end of the study.
- Establish database quality criteria, including a quality control plan that appropriately addresses primary efficacy and safety data.
- Monitor data entry functions while in active use to identify trends and ensure stable and desirable quality levels are consistent with study needs.
- Create and maintain comprehensive processes for change control.

Data Management Standards in Clinical Research

Minimum Standards

- Use the most current version of any standard, if appropriate.
- Use standards required by regulatory agencies in the country where the study is conducted.
- Do not modify published standards.

Best Practices

- Use accepted standards whenever possible, and strive for interoperability.
- Use all standards recommended by regulatory agencies in the locale of the study.
- Review implementation guidelines for any standard having associated guidelines documents.

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Data Privacy

Minimum Standards

- Use the most current version of any standard, if appropriate.
- Use standards required by regulatory agencies in the country where the study is conducted.
- Do not modify published standards.

Best Practices

- Use accepted standards whenever possible, and strive for interoperability.
- Use all standards recommended by regulatory agencies in the locale of the study.
- Review implementation guidelines for any standard having associated guidelines documents.

Database Closure

Minimum Standards

- Establish clearly documented procedures defining all steps of database lock, database closure, and unlocking and relocking the database after database closure.
- Clearly define all roles with respective responsibilities involved with database lock and closure procedures.
- Prior to database lock (interim, soft, or final) or database closure, ensure documentation of all defined tasks or criteria has been completed.
- At final database lock, ensure all team members are notified and access that allows database changes is removed and documented.

Best Practices

- Clearly define all terms relating to interim lock, soft lock, final lock, database unlock and final database closure.
- Develop and utilize a database closure checklist.
- Maintain documentation and approval or acknowledgement documents requiring signatures of all responsible parties involved in database lock, unlock and closure procedures.
- Where indicated, plan an interim or soft lock with a statistical analysis and data review prior to the final lock. This review may identify potential data errors, preventing the need to unlock the database after the final lock.

Database Validation, Programming, and Standards

Minimum Standards

- Generate a validation plan defining the testing methodology, scope, problem reporting and resolution, test data, acceptance criterion and members of the validation team.
- Ensure the CDMS meets user/functional and regulatory requirements and continues to meet these requirements through the course of its use.
- Implement the CDMS carefully, testing according to specifications, documenting all testing and issues, and ensuring objective evidence of testing is generated.
- Define processes for handling change control issues, with a clear determination of when revalidation will be required due to changes.
- Document all validation details prior to implementation in a summary document (e.g., validation report), including all applicable review and approval signatures.
- Ensure documentation remains complete and current.
- Ensure that only qualified staff develop, maintain and use the system.
- Approval of validation plan and documented results from an appropriate level of independent quality resource(s).

Best Practices

- Identify all intended user requirements of study-specific programming.
- Use organization standards, as available, to prepare study-specific programming.
- Use organization standards to document programs.
- Use code libraries wherever possible.
- Confirm that study-specific programming applications perform as intended based on the user requirements (data management plan requirements, CRF requirements, database specifications, edit check specifications, validation plan, etc.).
- Document performance during validation.
- Ensure documentation remains complete and current for live use, and is indexed for ready retrieval when it is retired or archived.
- Confirm accuracy, reliability, performance, consistency of processing and the ability to identify invalid or altered records. Confirm through testing and document.
- Ensure the system has an appropriate traceability matrix linking test cases to requirements.
- Confirm that the study-specific application has been configured properly.

Design and Development of Data Collection Instruments

Minimum Standards

- Design CRFs to collect the data specified by the protocol.
- Document the process for CRF design, development, approval, and version control.
- Document training of clinical site personnel on the protocol, CRF completion instructions and data submittal procedures prior to subject enrollment.
- Verify CRFs based on rating instruments created by an independent source (e.g. Health Status Questionnaire, Beck Depression Inventory, etc.), have been properly licensed for use and follow prescribed formatting or copyright requirements.
- Ensure CRFs are available at the clinical site prior to enrollment of subjects.

Best Practices

- Establish and maintain a library of standard forms and associated edit checks (CRFs, CRF completion guidelines, subject diaries, etc.).
- Use a multidisciplinary team to provide input into the CRF design and review processes. Data entry personnel, biostatisticians, the internal study team, and clinical operations personnel may be able to provide valuable perspectives to help optimize CRFs.
- Design CRFs with safety and efficacy endpoints in mind. Consult the protocol, study biostatistician(s) or review the statistical analysis plan (SAP) (if available) to ensure all key endpoints are collected.
- Keep the CRF's questions, prompts, and instructions clear, concise and conformant to CDISC CDASH standards, where possible.
- Design the CRF to follow the data flow from the perspective of the person completing it, taking into account the flow of study procedures.
- Whenever possible, avoid referential and redundant data points within the CRF. If redundant data collection is used to assess data validity, the measurements should be obtained through independent means.
- Use carbonless copy paper (NCR) paper or other means to ensure exact replicas of paper collection tools.

Edit Check Design Principles

Minimum Standards

- Finalize protocol and complete initial database specifications prior to designing edit checks.
- Specify edit checks based on parameters of case report form (CRF) pages and safety and efficacy parameters from the protocol.
- Specify edit checks for all primary study endpoints and safety data.
- If applicable, specify edit checks with external data (e.g., laboratory data) for reconciliation purposes.
- Ensure all edit checks are programmed, validated, and documented in accordance with established standard operating procedures.
- Ensure all edit checks specification documents are appropriately version controlled.
- Provide training to relevant personnel on the impact of edit checks on their individual roles in entering and managing clinical data.

Best Practices

- Where appropriate, specify edit checks to compare study inclusion and exclusion criteria and any data (that are collected in CRF pages) that could be indicative of protocol violations.
- Design edit check specifications so redundant output does not occur when edit checks are run.
- Review edit checks with appropriate clinical and statistical personnel to ensure edit checks meet study needs and help identify inconsistencies in study endpoints.
- Specify edit checks for all study endpoints and all data supporting safety data and study endpoints.
- Develop a library of standard CRFs and edit checks based on standards used, such as CDASH or company-specific standards.
- Perform a quality control review of edit check design and specifications prior to performing user acceptance testing (UAT) of edit checks.
- Evaluate the effectiveness of edit checks once in active use, and modify, delete or create new edit checks accordingly.

Electronic Data Capture—Concepts and Study Start-up

Minimum Standards

- Ensure compliance with 21 CFR 11 and consistency with the Food and Drug Administration's (FDA) Guidance for Industry: Computerized Systems Used in Clinical Trials.
- Stated quality standards should support the utilization of automated data capture, management and archiving.
- Ensure requirements are defined for data transfers and integration with other systems.
- Software systems validation should be scheduled and completed prior to EDC study implementation.
- Ensure user acceptance testing (UAT) is completed prior to implementation and deployment to sites.
- Verify training is provided for all users of the EDC systems and that all training is documented and minimum competencies are met.
- Verify access to data is limited to authorized individuals.
- Determine roles and responsibilities in data review and query management.
- Software technical support should be provided to users and a toll free phone number should be available for the help desk.
- Ensure sites have access and control of data up to database lock.

Best Practices

- Use business process analysts (possibly external, for objectivity) to establish EDC-specific workflow processes and identify required transitions from current processes.
- Do not apply paper study processes to studies using EDC.
- Identify stakeholders in current processes, as well as additional stakeholders required for new EDC processes.
- Plan studies to avoid "last minute" system modifications that introduce errors and complexity to study-specific CRFs.
- Develop CRFs or data collection tools with teams of individuals from monitoring, data management, statistics, regulatory affairs, and medical, ensuring adequate attention to the collection of safety data.
- Ensure systems are user-friendly and flexible for data entry.
- Ensure EDC systems do not restrict answers site staff can provide in a way that introduces bias into the clinical study.

- Ensure adequate edit check procedures and query management tools are built into EDC software.
- Before the start of a study, conditions (e.g., SDV completed, all queries resolved) for locking forms and/or casebooks should be set according to a set of criteria, such as, all SDV complete, all data review complete, no outstanding queries or missing data exist.
- When coding in an EDC environment it is recommended not to display coded terms back to the site user.
- Ensure data can be traced from the time of original input through the reporting and analysis files via easily accessible audit trails.
- Ensure ease and quality of all data transfers by testing data transfers prior to deployment of EDC systems.
- Ensure your EDC system integrates as needed with other databases by testing integrations with your EDC system prior to initiating any trials using the system.
- Ensure processes are defined to integrate laboratory and other non-CRF data with data obtained from the CRF.
- Ensure all user acceptance tests are documented.
- Ensure change control procedures include complete documentation.
- Ensure all documentation for use by site staff is adequately reviewed before being provided to site staff.
- If 24 x 7 x 365 support is not available, the help desk should cover the work days/times of all regions included in the study.
- The help desk should support the minimum number of languages needed to communicate with all users and all languages, including local dialects.
- Develop and follow standard operating procedures (SOPs) for electronic data capture, data validation, and data archiving.
- Assess current SOPs for potential impact created by EDC workflow processes and update SOPs as necessary.
- Include SOP modification time in project plans for EDC implementation.
- Assume that both the new workflow and SOPs will be in transition for some period of time as the staff interact with the EDC system following any modification of SOPs.
- Verify all users have documented training prior to being granted access to the system.

- Create a training environment in which users can practice, and create training cases as examples that are pertinent to the study.
- Provide a “Train the Trainer” program for clinical research associates (CRAs), data managers or others to be able to provide training to sites.
- Provide training customized to each user’s role. A study coordinator may need in-depth training of most system functions, while users with read only access may need minimal instructions.
- Document all training for trial master files as well as site files.
- Integrate metrics on process and cost/benefit into the EDC process to enable better EDC versus non-EDC comparisons and comparisons across EDC technologies.
- CRF specifications should be finalized prior to finalization of edit check specifications, although development of both should be performed concurrently

Electronic Data Capture—Study Closeout

Minimum Standards

- Ensure completion of all required source document verification and data review.
- Ensure all investigator signatures (principal and sub) are in place at closeout.
- Ensure the procedures established for locking fields or forms in a CRF have been followed, including those with open queries or unreviewed and/or unverified status.
- Perform a final review of data listings to identify and resolve any remaining data discrepancies that may generate queries.
- Perform a final review of query status for both open and answered queries through reports and task summaries.
- Ensure defined procedures have been followed for locking the database, and for unlocking the database if necessary.
- Ensure defined processes have been followed for restricting user access once the database is locked, and for revoking access to the production database.
- Ensure adherence to definitions of the audit plan and post audit data transfer process, as well as identifying audit team members well before study closeout.
- Define specifications for formatting subject profiles, as well as a process for generating and reviewing subject profiles.
- Ensure investigative sites have access to their CRF data after study completion. Once they have received the appropriate media for this data, their access to corresponding data in the EDC system can be revoked.
- Ensure any hardware provided to sites is retrieved according to organization standard operating procedures (SOPs).
- Determine requirements for creating additional media to represent the study database if needed.

Best Practices

- Use business process analysts (possibly external, for objectivity) to establish EDC-specific workflow processes and identify required transitions from current processes.
- Implement a verification procedure to ensure data received or extracted from the database matches data entered in CRFs, especially in cases where additional output programming is conducted. This practice confirms integrity of the data being released for statistical analysis.

- Review and refine the source data verification timeline with monitors and clinical operations after the last subject visit occurs and data entry is completed, (In some cases these processes can also be performed prior to the last subject visit).
- Ensure all medical coding activities have occurred as required.
- Use an incremental form or casebook lock strategy to reduce the amount of data review and locking needed upon study completion.
- Ensure all tasks documented in the data management plan are complete, and coordinate with clinical operations personnel to ensure all site monitoring activities are complete prior to database lock.
- Use an established checklist of tasks to be completed prior to database lock in order to meet database lock timelines.
- In preparation to meet database lock deliverables, adjust timelines as needed for all queries to be answered by sites.
- Use an established communication plan between the clinical team, site staff, statisticians, and data management. This communication plan should ensure all data reviews are completed and queries are answered in time to meet database lock deliverables.
- Create a calendar of vacations or out of offices for all team personnel to ensure proper resources are available for study close out activities.
- Review current regulatory standards and guidelines for how data should be presented in the subject profile (e.g., headers, footers, and margins).
- Determine the appropriate media to use for reporting of subject profile data.

Laboratory Data Handling

Minimum Standards

- Maintain standard operating procedures (SOPs) for all processes relating to lab data collection, transfer, and validation of data loading and data feasibility.
- Identify labs involved with a study as early in study setup as possible.
- Use standardized names for lab tests and units.
- Ensure reference ranges are defined prior to first data receipt when using a central lab.
- Where possible, ensure reference ranges are defined prior to first data receipt when using a local lab.
- Ensure updates to reference ranges are obtained and implemented in a timely fashion.
- Document all data transfer specifications thoroughly when using labs transferring data electronically.
- Determine software/hardware required to access data prior to a test transfer and ensure the format of the data medium is compatible.

Best Practices

- Use accepted standards such as those from Clinical Data Interchange Standards Consortium (CDISC) when possible.
- Define all lab data standards prior to beginning data collection.
- Ensure reference ranges are defined for population subgroups (e.g., ethnicity) that differ significantly from other defined groups or subgroups.
- Implement a standard process to collect and archive reference range data.
- Use a standard method of data review for local lab data and reconciliation of central lab data.
- Develop a data transfer agreement for electronic transfers and perform quality control of the test transfer.
- Document and confirm all lab variables prior to signing off on data transfer specifications.
- Implement a conversion factor table to standardize conversion of conventional units to the International System of Units (SI).
- Define edit checks for inclusion/exclusion criteria based on lab data and route to appropriate team members to review.
- Use standardized units so that performing edit checks on converted data produces a more consistent review of results.

- Send requests for central lab data corrections using a formalized process, for example, on a correction log sent to the lab vendor to update and return after correcting and resubmitting the lab data file.
- Implement a system to manage data collected outside protocol parameters.

Measuring Data Quality

Minimum Standards

- Use statistically appropriate inspection sample sizes for decision making.
- Document the method and frequency of data quality assessments in the study's data management/quality plan.
- Perform at least one quality assessment of the study data prior to final lock.
- Document data quality findings and corrective actions, if needed.
- Determine acceptable error rates for primary and secondary safety and efficacy (also known as "critical") variables.

Best Practices

- Use quantitative methods to measure data quality.
- NOTE: Quantitative methods for measuring data quality involve classifying the data, counting the data, and constructing statistical models to help explain database quality, database errors, and patterns of errors. Database errors, or "findings", can be generalized to the entire data set, and direct comparisons can be made between the sample and the whole data population as long as valid sampling and significance techniques are used. Quantitative methods help differentiate between data errors that might be pervasive in the data set and errors that are merely random occurrences.
- Compare trial data and processes in the beginning, middle, and end stages of the trial.
- Work with clinical operations to predefine criteria to trigger site comparisons based on monitoring reports.
- Perform quality control on 100% of key safety and efficacy (critical) variables.
- Monitor aggregate data by site to detect sites whose data differ significantly so that appropriate corrective actions can be taken.
- Perform quality control prior to release of data used for decision making.

Medical Coding Dictionary Management & Maintenance

Minimum Standards

- Select dictionaries that meet project and regulatory requirements.
- Follow established security procedures for dictionary installation and maintenance.
- Ensure user licenses are obtained and kept up to date for any dictionaries and applications used.
- Ensure all sponsor personnel and vendors who will use the dictionaries hold the appropriate licenses. If a vendor has access to the dictionary application, ensure the application license covers vendor access.
- Implement an audit trail for all changes/updates to the dictionaries or synonym listings and support tables associated with the dictionaries.
- Do not modify published commercially available coding dictionaries. If a commercially published dictionary has been modified, then do not refer to it by its commercially available product name.
- Specify the dictionary name and dictionary versions used during coding on all study reports and integrated summaries.
- Store all utilized versions of dictionaries for future reference.

Best Practices

- Select a coding tool to facilitate consistent dictionary use.
- Include the version(s) of utilized dictionaries in metadata.
- Ensure all levels and versions of dictionaries used for coding can be accessed by data management and other dictionary users.
- Establish a process for evaluating term or categorization changes in a dictionary and its effect on previously coded data when moving to a different version.
- Ensure the capability to recode to different versions of a dictionary. For example, this may be needed to allow integrated study analyses to be reported using the same version.
- Ensure individuals who code data have training and professional background appropriate to the dictionary and the version for which they are coding. Training must be completed and documented before coding with the dictionary or version.
- Educate individuals involved in recording, monitoring, reviewing, analyzing and reporting coded data on the functionality and capabilities of the coding dictionaries used.

- Submit requested dictionary changes to the organizations responsible for maintaining the dictionaries using the appropriate approved process of submitting changes.
- Ensure change control processes are in place for all dictionaries, whether commercially available or custom.

Project Management for the Clinical Data Manager

Minimum Standards

- Identify all data management study team members, stakeholders, and respective alternates wherever possible and as early in study setup as possible. Ensure information is documented and updated regularly, with documentation centrally located or otherwise easily accessible to the study team regardless of their physical location. Clearly identify the individual(s) responsible for information updates. For an example of what should be included in a project plan, see Appendix A: Sample Project Plan Template.
- Identify, define, and document all study-specific processes. Any planned study-specific deviations from organizational SOPs and the rationale for the deviations should be brought to the attention of quality assurance personnel and logged for discussion during future SOP review cycles.
- Ensure clear, comprehensive, and technically feasible timelines with dependencies that are created and documented such that all personnel are in agreement and can access timelines relative to their scheduled tasks. This may take the form of Gantt charts (derived from a project plan).
- Monitor, track and document projected costs and timelines against actual expenditures and deliveries (e.g., comparison of percentage of work completed to the percentage of budget spent).
- Identify potential risks to the project or study. Develop early warning signals and response strategies for each identified risk (e.g., risk mitigation plan). Review and adjust study-specific contingencies in accordance with study life cycle.
- Create and propose to the project team a communication plan, which, upon approval, shall be adhered to by all study personnel and stakeholders. The plan should be specific and easy to follow based on individual end user needs. The plan should identify a schedule for routine communications, the means by which these communications will be conducted, and how communications will be documented and archived.
- Common elements may include issue categories and associated severity codes, severity-based time/resource/cost impact, escalation rules, and resolution plans. For an example of what should be included in a communication plan, see Appendix B: Sample Communication Plan Template.
- Assure a thorough assessment has been made of CDM team members' familiarity with clinical study processes, disciplines, or functional lines.
- **Ensure appropriate project- or study-specific training is delivered, maintained and documented for all study personnel performing CDM tasks.**

- Ensure adequate and compliant electronic, virtual, and physical resources will be available for intake and archival of final accepted CDM deliverables. This may involve working with personnel from different departments, including information technology (IT), legal, and regulatory operations, as well as external vendors.

Best Practices

- Create a responsibility matrix that describes activities to be conducted during the course of the study.
- Conduct regular meetings with the study team (may be conducted via Web or telephone conferences). During these meetings, track progress and upcoming milestones, and discuss corrective actions if needed.
- Continually assess project processes and modify processes as needed to function more efficiently. Ensure all process changes are communicated, documented, and version controlled. File this documentation within the study master file in effort to establish a clear audit trail.

Serious Adverse Event Data Reconciliation

Minimum Standards

- Create entry and edit instructions, including deletion and change control procedures.
- Standardize the capture of SAE data elements in both the clinical database and the safety database.
- Conduct the reconciliation of event terms so they are at least similar if not exactly the same.

Best Practices

- Establish the time intervals in the project where reconciliation will be performed and in particular the mechanisms to cover interim analyses or safety data reporting. Often SAEs continue to be reported after a clinical trial has concluded. Some companies collect information in a single database and some companies collect information in two separate databases: a safety database and a clinical database. It is important to establish a cutoff point after which no SAEs will be added to the clinical database, even if the safety data or safety database is updated.
- Identify the data items to be reconciled. This may include, but not be limited to the following:
    - Protocol
    - Investigator
    - Subject identification
    - Randomization number
    - Initials
    - Date of Birth
    - Gender
    - Race
    - Event number
    - Diagnosis
    - Verbatim
    - Coded or preferred term
    - Onset date
    - Resolution date
    - Date of death
    - Outcome
    - Severity
    - Causality assessment
    - Action taken with study drug

  Sometimes data items are used from other modules for further reconciliation or clarification.
- From the demography module, items used may include but not be limited to the following:
    - Subject identification
    - Weight

    - Date of birth
    - Gender
    - Race
- From the discontinuation module, items used may include but not be limited to the following:
    - Subject identification
    - Primary reason for discontinuation being an event
    - Cause of hospitalization
    - Cause of death listed on the death certificate
    - Autopsy result
- From the concomitant medications module, items used may include but not be limited to the following:
    - Subject identification
    - Medication name
    - Start date
    - Stop date or ongoing
    - Indication
- When possible, customize database fields used in reconciliation to be programmatically compared without compromising the integrity of the software or databases. Even programmatic reconciliation of fewer than 100 events can be cost effective in both time and quality. The process can be validated once and run as frequently as data and time allow.
- When initiating the reconciliation process, clinical data management should confirm that all data to be included in the reconciliation have been entered and validated. Clinical data management should also confirm that any data clarifications have been returned and applied to the clinical database, and that the coding of AE verbatim terms against the common dictionary has been completed.
- Clinical data management, safety leads, and clinical operations should establish a mutually agreeable turnaround time for researching, retrieving, and correcting any discrepancies found during or since the last reconciliation period.
- Read-write access to either database (but not both) is granted to personnel trained in data entry for the purpose of and whose responsibilities include data entry, data modification, or data validation. Read-only access is granted to personnel related to reconciliation, but who are not directly responsible for those tasks related to data modification. System administration rights are limited to personnel responsible for database configuration.

Vendor Selection and Management

Minimum Standards

- Document the sponsor's process and support functions that are needed to evaluate the use of vendor services.
- Evaluate and qualify (e.g., capacity, qualifications, experience, regulatory compliance, company stability, etc.) vendors prior to contracting for their services or products.
- Obtain a confidentiality agreement with the vendor prior to exchange of proprietary information.
- Create a contacts list that is centrally accessible to study team members.
- Determine and document whether the sponsor's or vendor's standard operating procedures (SOPs) (or a combination of procedures) are to be followed.
- Clearly define expectations, deliverables and responsibilities. Both the sponsor and the vendor must participate in establishing definitions of their roles.
- Conduct ongoing management of vendor activities. Communicate and assess the vendor's performance throughout the study.

Best Practices

- Where feasible, evaluate from a CDM perspective the risk of utilizing or not utilizing vendor services related to the conduct and outcome of the study.
- Maintain an internally approved vendor list with regular evaluations (e.g., preferred vendor list or prequalified vendor list).
- Establish a cross-functional vendor auditing program based on established services, which should include plans to re-audit the vendor within a stated amount of time, if applicable.
- Oversee vendors by utilizing subject matter experts within a centralized organizational team to provide input into the processes of vendor evaluation, vendor audits, and issue resolution and escalation.
- Define and document a detailed statement of work and project plans that detail who is responsible for each task; who is responsible for reviewing and approving various documents; details of project reporting; or a checklist of tools, processes, and services to be performed by the sponsor and vendor at each phase of the study.
- Define and document detailed sponsor/vendor communication plans that clearly address the expected communication tools and frequency, as well as establish who is responsible for communications and how to escalate issues when deemed necessary.

- Identify other possible vendors or options as part of a contingency plan in case the vendor relationship is deemed unsatisfactory at any point during the course of the study.
- Establish a collaborative relationship based on partnership, trust and coownership of the project.
- If the vendor is providing services that involve computerized systems, ensure system support documentation is in place, such as a service level agreement (SLA), that describes in detail how much time it will take the vendor to respond to support inquiries, how long it will take to get a database back online in case of a system failure, and other details related to supporting the sponsor's business requirements.

Vendor Selection and Management (Released 2021)

Minimum Standards

- Sponsors should assess a vendor's Quality Management System and deem it appropriate prior to receiving goods or services toward a clinical study.
- Decisions made in the course of such an assessment may be risk-based.
- Sponsors should assess potential impact of contracted work on human subject protection and reliability of trial results.
- Sponsor responsibilities delegated to a vendor should be documented in writing.
- Sponsors should establish a vendor-auditing program including plans to and criteria for re-audit.
- Sponsors who contract goods or services toward a clinical study should provide adequate oversight.

Best Practices

- Obtain a confidentiality agreement with the vendor prior to exchange of proprietary information.
- Document the sponsor's process and support functions needed to evaluate the use of vendor services.
- Evaluate and qualify, e.g., by capacity, capability, qualifications, experience, regulatory compliance, company stability, vendors prior to contracting for their services or products.
- Create a contacts list that is centrally accessible to study team members.
- Determine and document whether the sponsor's, the vendor's, or a combination thereof standard operating procedures (SOPs) are to be followed.
- Clearly define expectations, deliverables, and responsibilities.
- Conduct ongoing management of vendor activities by communicating and assessing the vendor's performance throughout the study.
- Review data transfer agreement for all the third party vendors.
- Where feasible, evaluate from a CDM perspective the risk of utilizing or not utilizing vendor services related to the conduct and outcome of the study.
- Maintain an internally approved vendor list (Template available in Appendix A) with regular evaluations (e.g., preferred vendor list or prequalified vendor list). This may be risk-based.
- The vendor-auditing program should be cross-functional based on contracted services.

- Processes for vendor evaluation, vendor audits, issue resolution, and escalation should be informed by cross-functional subject matter experts within a centralized organizational team. Use a subject matter consultant if your organization lacks this expertise in-house.
- Define and document a detailed statement of work and project plans that delineate each task, role or person responsible, task timing and dependencies, related documentation, role or person responsible for reviewing and approving related documentation or other task results, and reporting related to the task.
- Define and document detailed sponsor/vendor communication plans that clearly address the expected communication tools and frequency, as well as establish who is responsible for communications and how to escalate issues when deemed necessary.
- In high risk situations, identify other possible vendors or options as part of a contingency plan in case the vendor relationship is deemed unsatisfactory at any point during the course of the study.
- Establish a collaborative relationship based on partnership, trust, and coownership of the project.
- Hold frequent one-on-one meetings or teleconferences with the vendor lead to share concerns, provide mutual feedback, plan for success, and ensure activities are on track without any red flags.
- If the vendor is providing services that involve computerized systems, ensure system support documentation is in place. For example, establish a service level agreement (SLA), that describes in detail how much time it will take the vendor to respond to support inquiries, how long it will take to get a database back online in case of a system failure, and other details related to supporting the sponsor's business requirements.
- Study teams should engage early to begin a study-level sourcing strategy and vendor identification.
- SLAs should be defined for vendors with whom your organization works frequently.

CCDA Study Guide Updates

Date	Notes
V1 - 26 July 2024	New version - no changes.

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