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U.S. FOOD & DRUG ADMINISTRATION

The Data Management Plan – Pulling It All Together

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FDA GCP Workshop

Data Integrity in Global Clinical Trials

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Small Business and Industry Assistance
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DISCLAIMER

The views and opinions presented represent those of the speaker and should not be considered to represent advice or guidance on behalf of the Food and Drug Administration.

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OBJECTIVES

At the conclusion of this activity, participants will be able to:

- Describe what is a Data Management Plan
- Give examples of what should be included in a Data Management Plan
- Recognize what is needed to carry out a successful Data Management Plan

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Why is a Plan Needed?

Subject → Investigator → Sponsor

Confidential information

Confidential information

Confidential information

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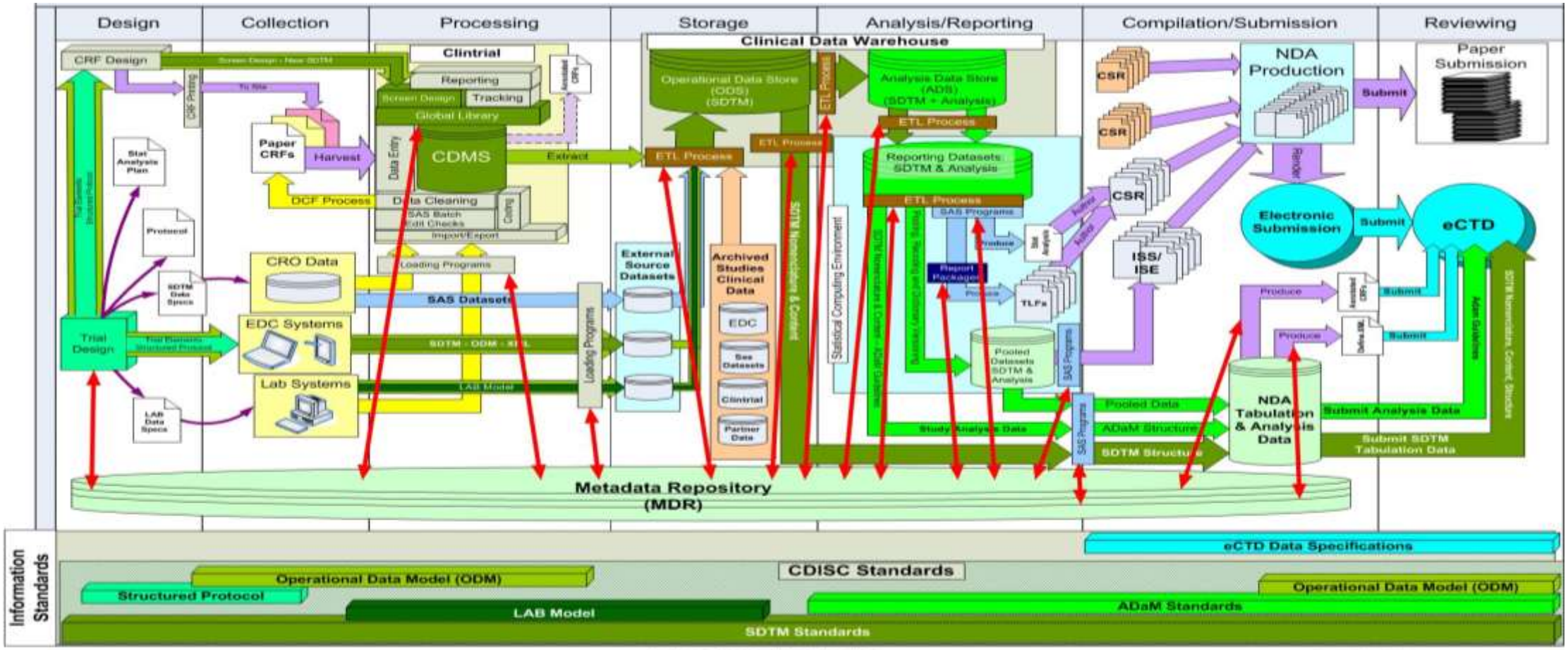
Reality



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! Spoiler Alert !

- The FDA Code of Federal Regulations contains no mention of a clinical data management plan
  - Part 11 has criteria for electronic records, electronic signatures, and handwritten signatures
- "Data management plan" is mentioned in the FDA Guidance *Electronic Source Data in Clinical Investigations*

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Examples

- Concerning CRFs: *Sponsors should describe (e.g., **in a data management plan**) the electronic prompts, flags, and data quality checks that are designed to address, for example, data inconsistencies, missing data, and entries out of range.*
- *The sponsor should have a list (e.g., **in a data management plan**) of the individuals with authorized access to the eCRF.*
- Concerning masking: *Data exempt from review should be listed (e.g., **in a data management plan**).*

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What is a Data Management Plan?

- **A roadmap** to achieving reliable, high-quality and statistically sound data more efficiently and effectively
- **A living document** throughout the life cycle of a study
  - Includes how the document will be reviewed, approved, and finalized; how it will be modified if needed during the project; and links to SOPs in place governing its use and modifications. *It does not stand alone.*

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Pieces to Tie Together

- Case report form (CRF) designing
- Data entry
  - A CRF tracking system is essential to ensure the required CRFs are collected
- Data extraction
  - (e.g., recording devices, electronic health records)
- Data validation
  - Specifications are often documented in a standalone Data Validation Plan

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More Pieces to Tie Together

- External data (e.g., labs from off-site, imaging, etc.)
- Quality assurance/quality control
  - Includes audit and monitoring activities
- Discrepancy management
- Generated reports (standard and custom)
- Medical coding
  - Adverse events, medications
- Reconciliation with the Safety database

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And More Pieces

- Data security
  - Restricted access, data back-up, etc.
- Database locking
  - Describe any soft lock and distinguish from hard lock in terms of user access and write privileges
- Database unlocking
- Data export (scope, frequency, and format)
- Data archiving

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How to Begin

- Review the project/protocol
  - Should have one data management plan per study
- Hire a knowledgeable team
  - Decide who will ensure that the data management plan is carried out
- Ensure a good support network
- Ensure comprehensive training is in place
  - investigator site staff, contract staff, sponsor staff

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Preparation Review

- How will the data be created?
  - e.g. interview data, questionnaires, imaging, experimental measurements, etc.
- How and in what format will the data be captured?
  - e.g., excel spread sheets, paper, electronic case report forms, mobile devices, etc.
  - Set up Standard Data Transfer Specifications for non-CRF data

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Review – 2

- How much data will be collected, how often, how long?
  - What tools or software will be required to read or view the data?
- How will metadata be created, captured, and managed? Is everyone using CDISC metadata standards?
  - date/time stamp, user ID, instrument ID, audit trails, etc.
- How will folders and files be named and organized?

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Review – 3

- How will everyone understand the data?
  - e.g., data dictionaries, codebooks, questionnaires
- What will be the data validation process?
  - at the investigator site, contractor site, sponsor site
- How will the data be stored?
  - short-term, long-term, back-up, destroyed
  - will the data need to be converted to more stable file formats
- How will the data be secured?

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Review – 4

- Will the data be shared? How will the data be shared?
  - –what is needed to prepare the data for preservation or data sharing, transfer to investigators; are there ethical/privacy issues, etc.
- What are the quality assurance and quality control mechanisms <u>at each stage</u> of data handling?

In Addition

- Include all roles and responsibilities with contact information
- Include a communication plan
- Include a data flow diagram
- Document deviations from the plan

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Pitfalls

- Poor case report form design
- Not addressing missing data before it goes missing
- Not involving appropriate staff
- External data loading error
- Site/monitoring issues

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Key Take Away Message

- Your Data Management Plan is a living document
  - Understand good data management practices before you begin
  - Involve all appropriate staff in the writing and review of your plan as it is created
  - Be prepared for changes as they *will* happen.

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Challenge Questions

1. Should a company strive to use the same Data Management Plan for all studies? **NO**
2. Your Data Management Plan should include which of the following:
   a. All data exempt from review (masked data)
   b. All of the individuals with authorized access to the eCRF
   c. Links to SOPs in place governing its use and modifications
   d. B & C
   e. All of the above

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Resources

- Title 21 FDA Code of Federal Regulations Part 11

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11

- Guidance for Industry: Computerized Systems Used in Clinical Investigations

https://www.fda.gov/iceci/enforcementactions/bioresearchmonitoring/ucm135196.htm

- Guidance for Industry: Part 11: Electronic Records, Electronic Signatures-- Scope and Application

https://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm

- Guidance for Industry: Electronic Source Data in Clinical Investigations

https://www.fda.gov/downloads/drugs/guidances/ucm328691.pdf

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Resources

- NIH NIDCR Clinical Data Management Plan Template

www.nidcr.nih.gov/sites/default/files/2018-03/clinical-data-management-plan-template.docx

- Guidelines for Effective Data Management Plans

https://www.icpsr.umich.edu/icpsrweb/content/datamanagement/dmp/index.html

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Resources

- Society for Clinical Data Management Good Clinical Data Management Practices

https://www.scdm.org/publications/gcdmp/

- USGS Data Management Website

https://www2.usgs.gov/datamanagement/

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