Data Management Plan (DMP) Development

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WANTED!

DATA MANAGEMENT PLAN

$$ MONEY $$

REWARD!

DMPs: Introduction

Why have a Data Management Plan?

A well-designed DMP provides a road map of how to handle data under any foreseeable circumstances and establishes processes for how to deal with unforeseen issues.

DMPs: Introduction

Why have a Data Management Plan?

- To translate the whats and hows of the study database into easily digestible language
- To document the processes used to promote consistent, efficient, and effective data management practices for each study
- To communicate and describe the information needed to create and maintain a high-quality database which will be ready for analysis
- To describe how data will be managed in order for it to be attributable, legible, contemporaneous, original, and accurate

DMPs: Introduction

Which studies should have a DMP?

> Every clinical study should have a data management plan to ensure and document adherence to good clinical data management practices for all phases of a study.
>
> *- Society for Clinical Data Management*

DMPs: Regulatory

The DMP is an auditable document often asked for by regulatory inspectors and should be written in a manner that is professional and of high quality.

DMPs: Regulatory

Minimum standards

- Complete a draft of the DMP prior to enrollment of the first subject
- Ensure the DMP supports compliance with applicable regulations and oversight agencies
- Identify and define the personnel and roles involved with decision making, data collection, data handling and data quality control
- Ensure data management processes are described and defined from study initiation until database closeout

DMPs: Creation and Maintenance

A detailed DMP should be based on:

- The protocol
- Work scope
- Contract
- Analysis plans
- Dataflows
- Case report forms (CRFs)
- Other supporting documents
- Data management standards and practices

DMPs: Creation and Maintenance

A DMP must be

- Uniquely identifiable
- Identifiable on each page (e.g. study name)
- And maintain version control

DMPs: Organization

Organization of a DMP

- Not all studies are the same, therefore the organization and structure of a DMP should vary to meet the needs
- Some sections may not be relevant to the study (e.g. MedDRA coding), but should be included with an explanation for why it isn't included
- For relevant sections, it is helpful to reference the group responsible for the task(s)

DMPs: Anatomy

The typical components

- Cover Page
- Introduction
- Study Overview
- Dictionary and Coding Management
- Case Report Form (CRF) Completion Guidelines (paper studies)
- Data Entry Guidelines (paper vs. EDC studies)
- Archival and Record Retention Process
- User Roles and Access Permissions
- Database Security

DMPs: Anatomy

The typical components, *cont.*

- SAE Data Reconciliation
- Processes for QA/QC
- Data Exports and Imports
- Data Audit Plan
- Quality Metrics
- Operational Reports (if applicable)
- Communications Plan
- Related SOPs
- Data Management Plan Approval

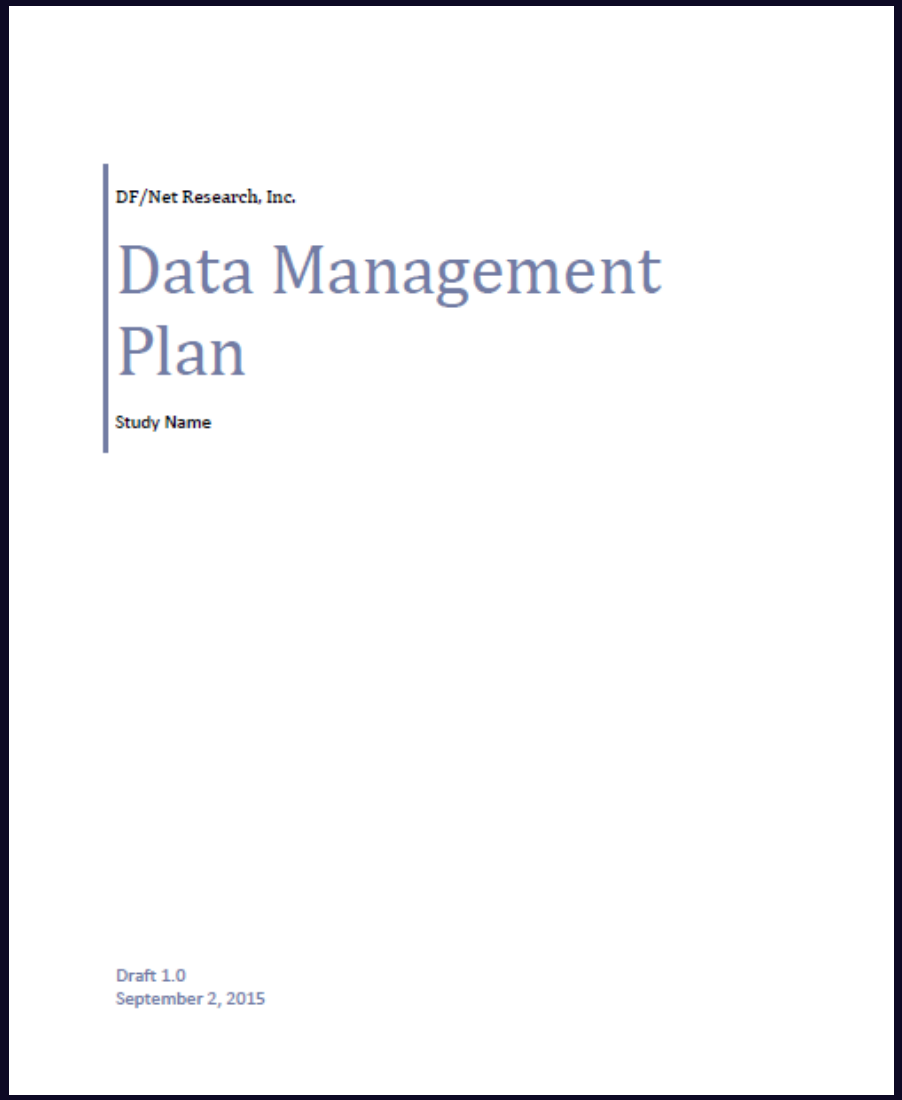
DMPs: Anatomy

The typical components, *cont.*

- Database Specifications
  - At DF/Net we often handle this part through several appendices:
    - Symbol translation
    - Visit map
    - Visit windows
    - Plate specifications

DMP: Anatomy, *cont.*

Cover Page



DF/Net Research, Inc.

Data Management Plan

Study Name

Draft 1.0
September 2, 2015

DMP: Anatomy, *cont.*

Introduction

- Describe what will be covered in this DMP
- State the goal of this DMP
  - Example: “The final data management endpoint is a study database that is fit for purpose (i.e., sufficiently supports conclusions and interpretations equivalent to those derived from error-free data), secure, and ready for statistical analysis.”

DMP: Anatomy, *cont.*

Study Overview

- Short synopsis of the protocol may include:
  - Visit schedule
  - Sample size
  - Study population

DMP: Anatomy, *cont.*

Dictionary and Coding Management

- Which medical coding dictionaries (e.g., MedDRA, WHO Drug) will be used
- Which version(s) of the dictionaries will be used
- How will dictionary updates be handled
- Description of how auto-coding and study-specific conventions will be managed

DMP: Anatomy, *cont.*

CRF Completion Guidelines (paper studies)

- Covers GCP expectations
- Study-specific instructions

DMP: Anatomy, *cont.*

Data Entry Guidelines

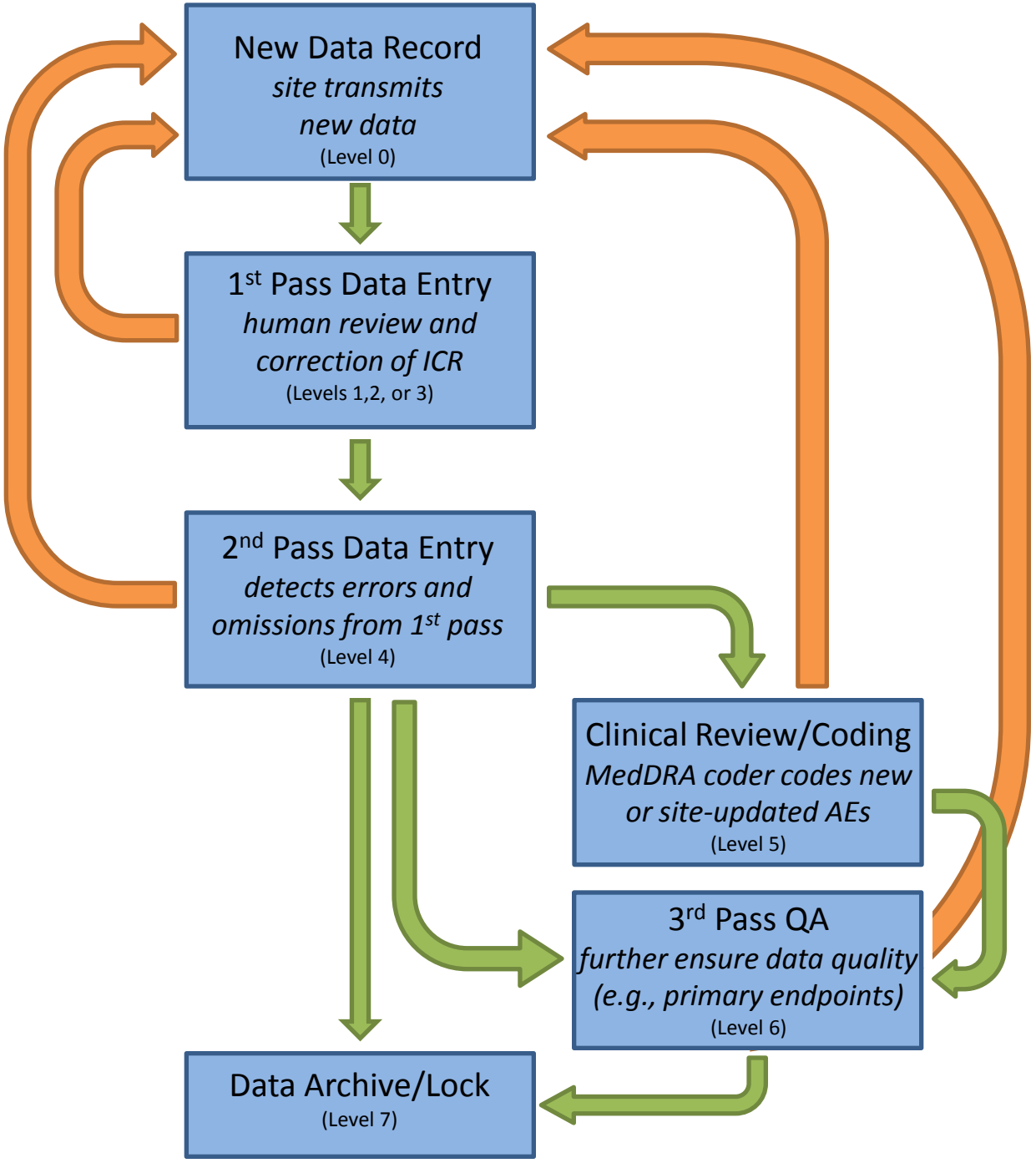
- Data entry priorities
- Text fields
- Handling missing data
- Dates
- Study-specific conventions

DMP: Anatomy, *cont.*

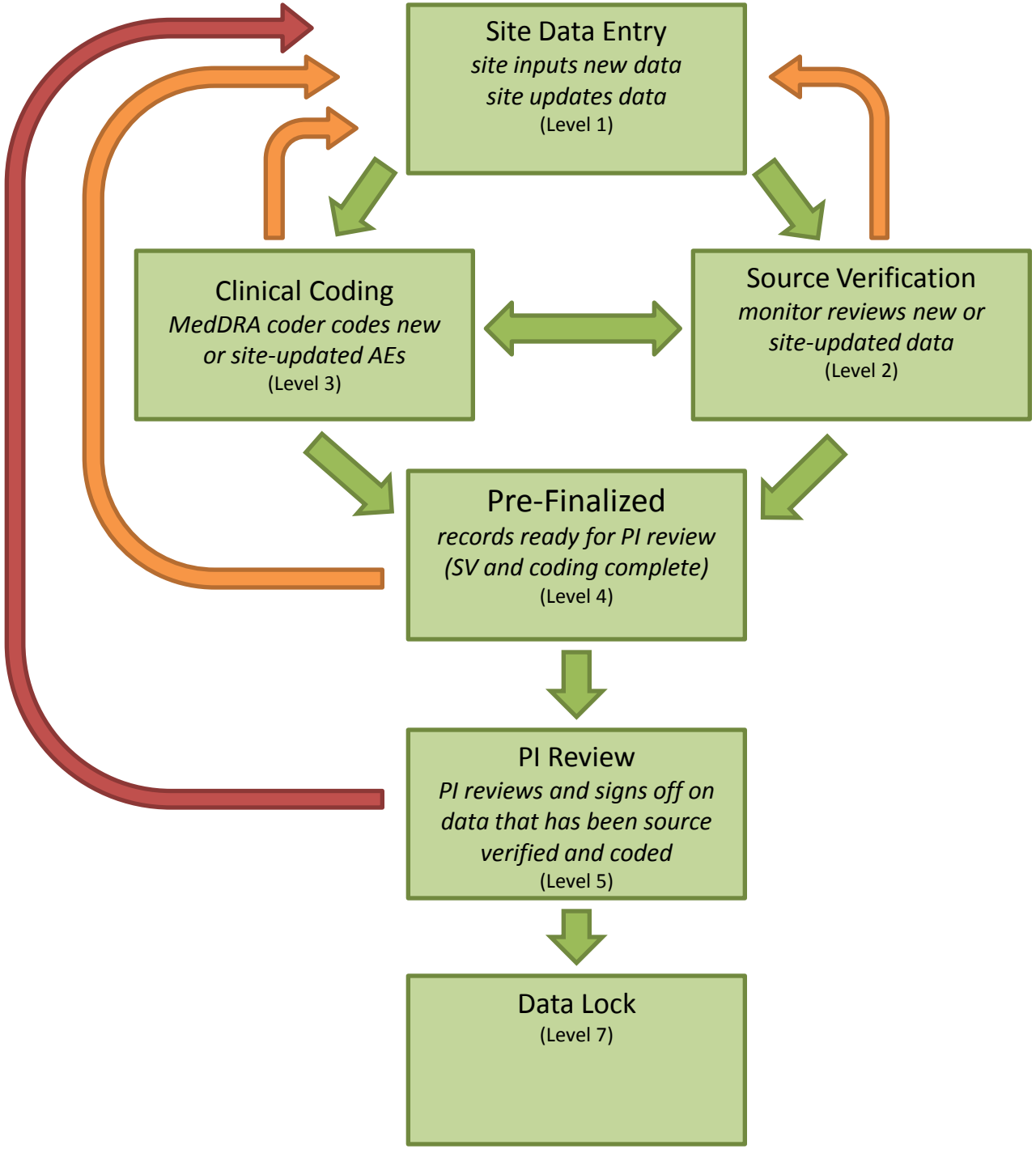
Data Validation and Workflow

- DataFax uses the term “validation” to refer to defined steps within the process of data entry and verification
- DataFax utilizes seven validation levels
- How these levels are used will vary depending on the type of study
  - Paper
  - EDC
  - Hybrid: paper and EDC combined

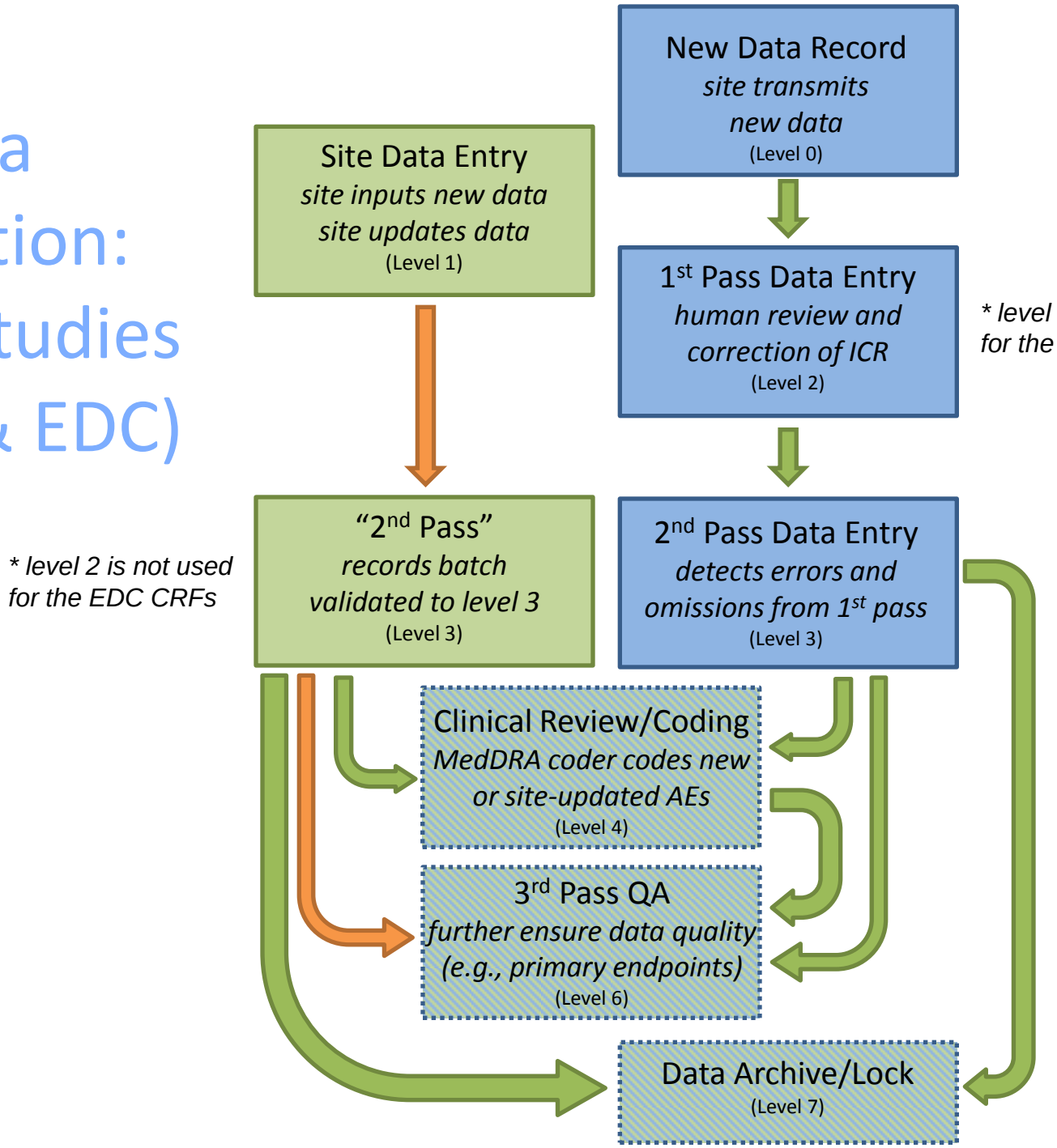
Data Validation: paper studies



Data Validation: EDC studies



Data Validation: hybrid studies (paper & EDC)



DMP: Anatomy, *cont.*

Archival and Record Retention Process

- Outline the procedures for archiving electronic records

DMP: Anatomy, *cont.*

User Roles and Access Permissions

- Role: examples include Site Data Entry, Principle Investigator, Monitor, Clinical Coder, Data Manager
- Access Permissions: view or edit data, access to all or selected sites, access to all or selected plates
- Affiliation: Data Management center, clinical research site, monitoring CRO, etc.

DMP: Anatomy, *cont.*

Database Security

- Describe how user roles and access will be handled
- Outline procedures for database backup

The details may be covered through referenced organizational SOPs

DMP: Anatomy, *cont.*

SAE/AE Reconciliation

- Describe how this will be handled for the study (e.g., which variables will be compared), if applicable

DMP: Anatomy, *cont.*

Process for Quality Assurance and Control

- Level of checks: specify the required level of checking to be performed. Depending on the type and regulatory importance of a study, different levels of checking may be implemented.
- Frequency of quality control checks: specify the frequency of QC checks in the DMP. According to ICH E6, “Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.”
- QC check documentation processes: define how QC checks are documented and how this documentation is maintained throughout the course of the study.

DMP: Anatomy, *cont.*

Data Export

- Include transfer method (e.g., web portal), file format, status of transferred data (.e.g., “clean” or “dirty”), and any specifications as they pertain to type of transfer (e.g., regular data transfer, DSMB meeting)

Data Import

- Include type of data (e.g., safety, laboratory, etc.), method, and frequency
- May be documented in an addendum to DMP or separate document, since often the details of data import are not known at the beginning of the study

DMP: Anatomy, *cont.*

Data Audit Plan

- Process and/or sampling to be used, including acceptable error rate
- Corrective action plan for discovered errors
- Frequency of quality assurance processes
- May also include critical variable review (e.g. primary endpoints and safety)

DMP: Anatomy, *cont.*

Quality Metrics

- Frequency
- Variables to be measured (e.g., query rate, time to enter data)

DMP: Anatomy, *cont.*

Communications Plan

- How will communication happen (e.g., telephone, email)
- Frequency
- Escalation process, if needed

DMP: Anatomy, *cont.*

Related SOPs

- List any SOPs which were referenced in the DMP
- These can be Administrative SOPs, System SOPs, Study SOPs, Statistical SOPs
- Recommended SOPs:
  - CRF Design and Development
  - Database Design and Testing
  - Data Management and Systems Roles and Responsibilities
  - Coding Dictionary Management
  - System Security
  - Change Control
  - Data Entry
  - Internal Data Handling
  - External Data Handling
  - Data Cleaning
  - SAE Data Reconciliation
  - Quality Control
  - Database Lock and Unlock

DMP: Anatomy, *cont.*

DMP Approval

- Have the study identifiers
- Name, date, and signature of approvers

It Isn’t As Bad As It May Seem

You do not need to cover every aspect in the DMP. Many sections can be handled by simply referring to your organization’s SOPs.

Discussion Topics

- How does your organization use DMPs?
- What are the challenges for your organization?
- What resources would be helpful?
- What questions do you have for us?

This presentation will be available to you here:
http://www.datafax.com/events/dfug-2015/