ADaM: Data Preparation, Reporting Programs and ADRG

Jianyong Tong
MSD R&D (China)

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Key Contents

- Components of Analysis Package
- Prepare Analysis ADaM Datasets
- Prepare programs
- Draft ADRG and Define.xml

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Background

1: FDA requires the sponsor to submit standardized study data using FDA-supported data standards

FDA Data Standards Catalog:

Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)
Clinical study datasets	Study Data Tabulation Model (SDTM)	XPT	Clinical Data Interchange Standards Consortium (CDISC)
Clinical study datasets	SDTM	XPT	CDISC
Clinical study datasets	SDTM	XPT	CDISC
Clinical study datasets	SDTM	XPT	CDISC
Clinical study datasets	SDTM	XPT	CDISC
Clinical study datasets	Analysis Data Model (ADaM)	XPT	CDISC

2: ADaM "provides a framework that enables analysis of the data, while at the same time allowing reviewers and other recipients of the data to have a clear understanding of the data's lineage from collection to analysis to results. ADaM is now the primary choice of Analysis datasets in most of the Pharmaceutical company and CROs.

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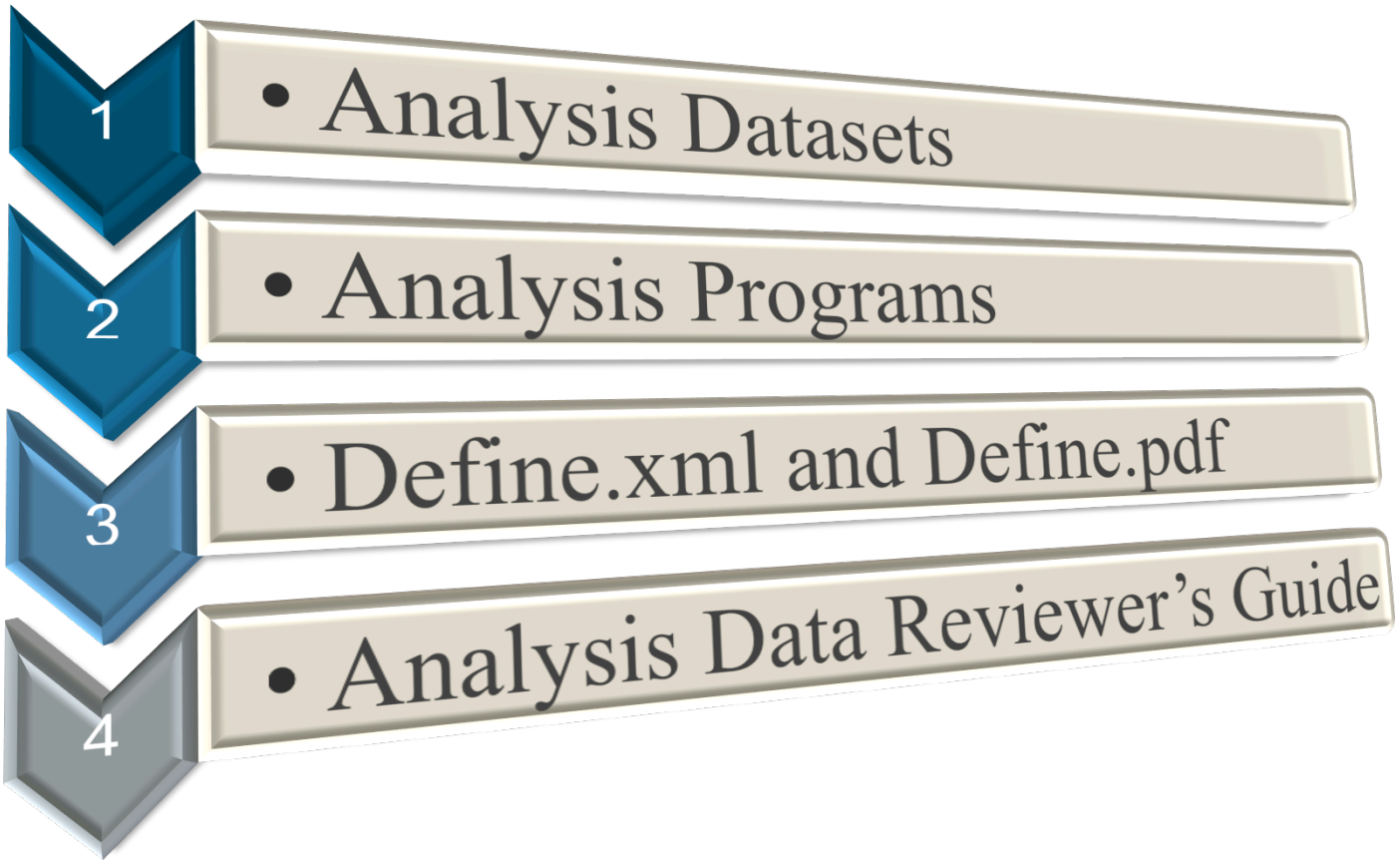
Components of Analysis Package

Comprised of four (4) components:



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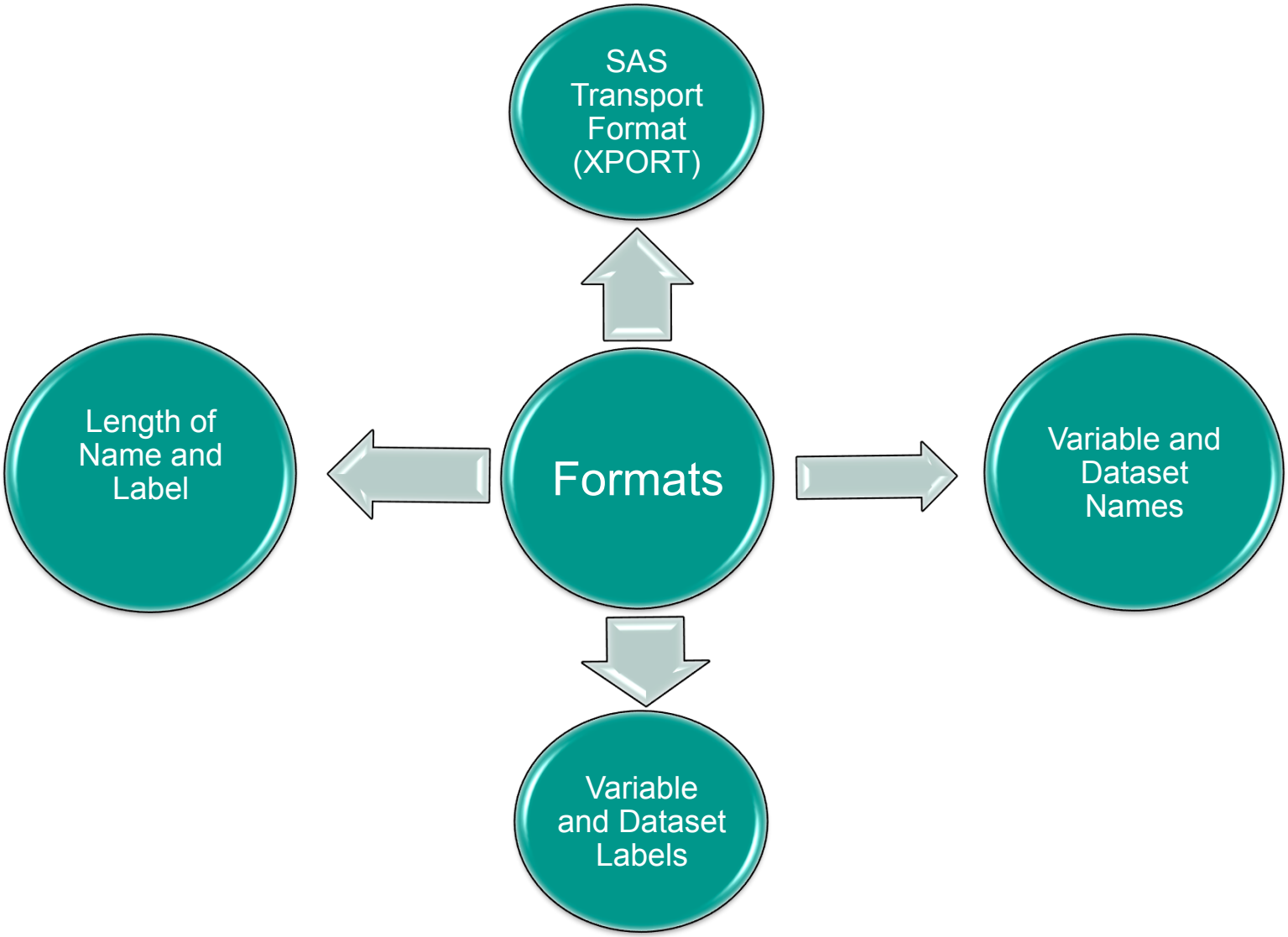
Prepare Analysis ADaM Datasets



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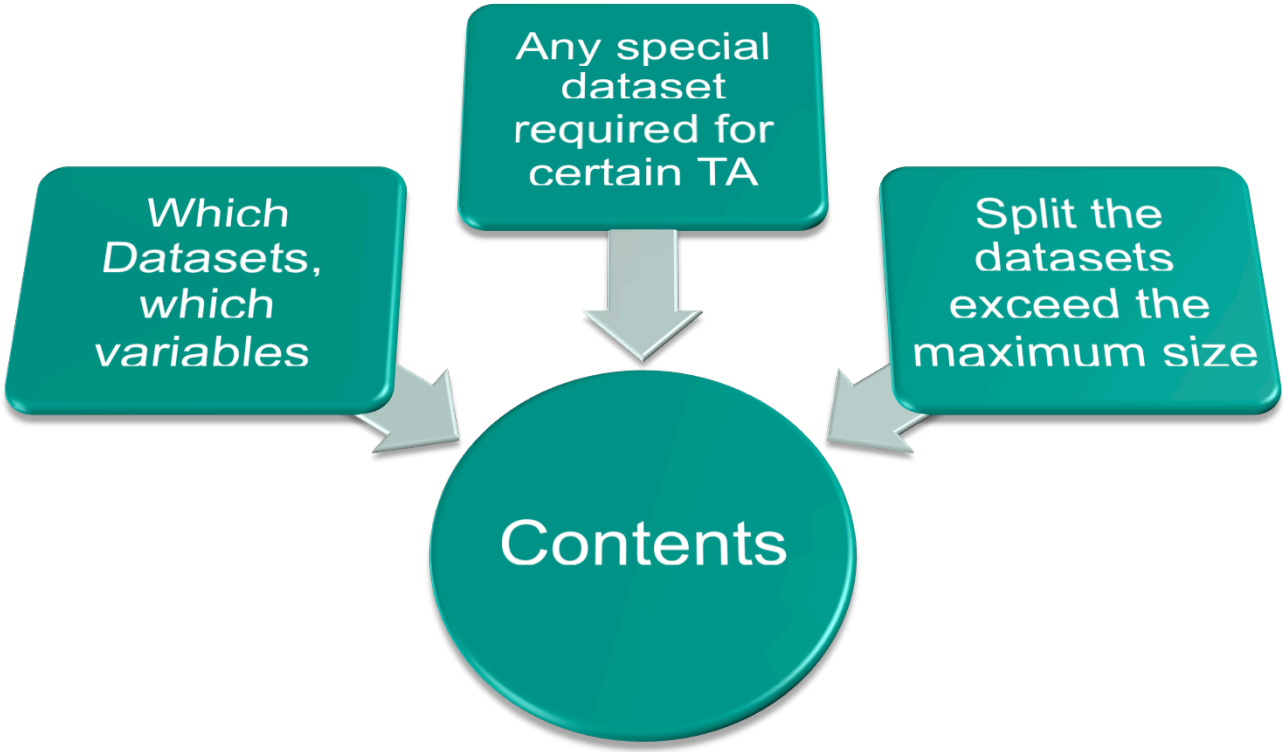
Prepare Analysis ADaM Datasets



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Prepare Analysis ADaM Datasets

Sponsors should validate their study data before submission using the most recently published validation rules

Pinnacle 21 Enterprise

Double programming, Independent validate

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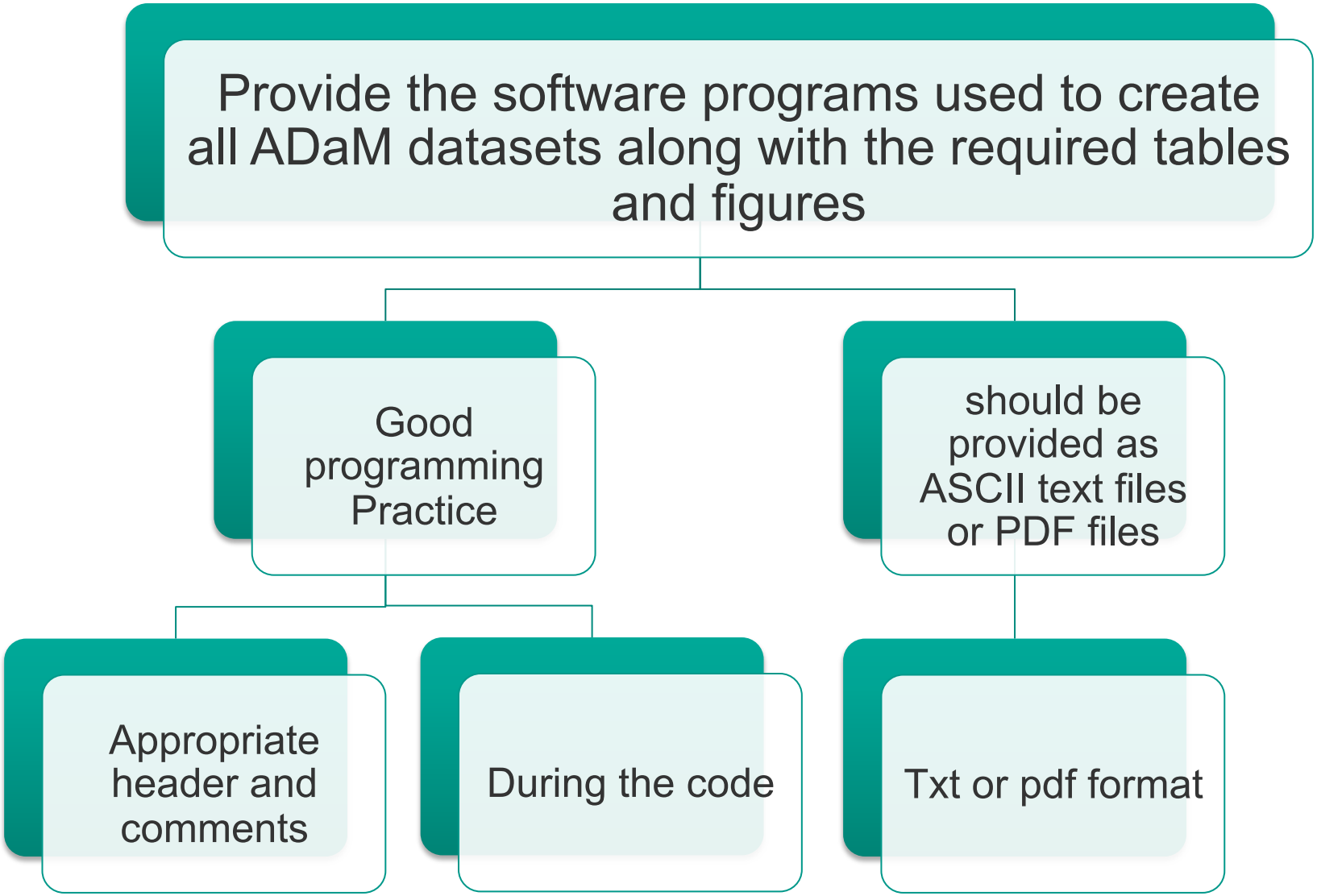

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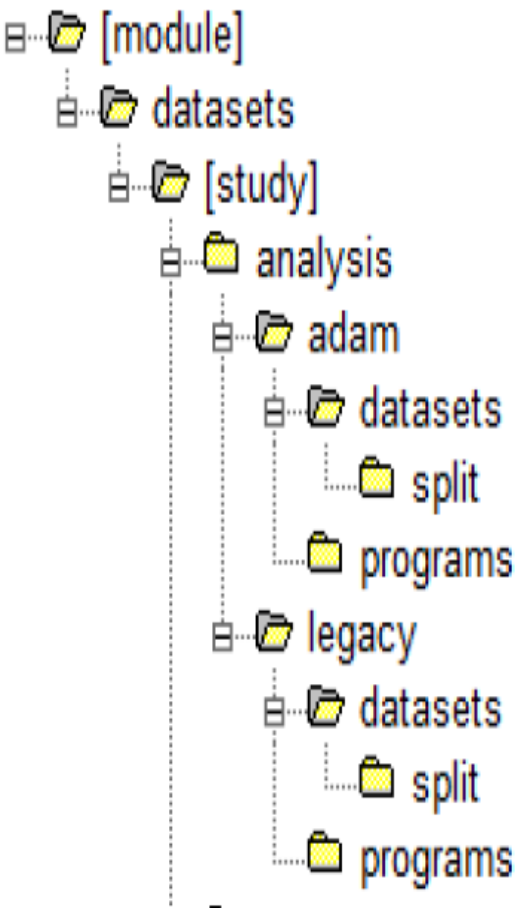
Prepare Programs



Folder Name	Folder Level	Description/Contents
[module]	1	Refers to the eCTD module in which study data is being submitted. Name this folder m4 for nonclinical data and m5 for clinical data. Do not place files at this level.
datasets	2	Resides within the module folder as the top-level folder for study data (nonclinical or clinical) being submitted for the specified module (m4 or m5). Do not place files at this level.
[study]	3	Name this folder with the study identifier or analysis type performed (e.g., study123, iss, ise). Do not place files at this level.
analysis	4	Contains folders for analysis datasets and software programs; arrange in designated level 6 subfolders. Do not place files at this level.
adam	5	Contains subfolders for ADaM datasets and corresponding software programs. Do not place files at this level.
datasets	6	Place ADaM datasets in this subfolder.
split	7	Place any split ADaM datasets in this subfolder.
programs	6	Place software programs for ADaM datasets, tables and figures in this subfolder.
legacy	5	Contains legacy formatted analysis datasets and corresponding software programs. Do not place files at this level.
datasets	6	Place legacy analysis datasets in this subfolder.
split	7	Place split legacy analysis datasets in this subfolder.
programs	6	Place software programs for legacy analysis datasets, tables and figures in this subfolder.

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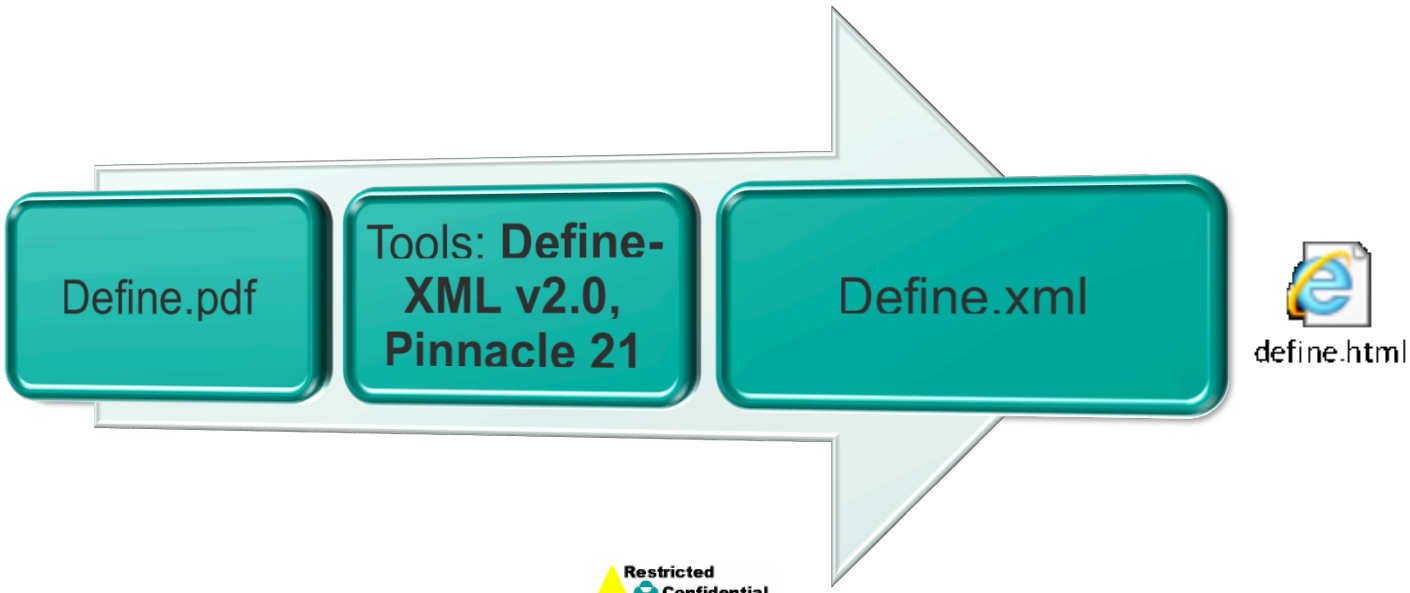
Define.pdf and Define.xml

Separate data definition files should be included for each type of electronic dataset submission, i.e., a define file for the SDTM datasets, and a define file for the ADaM datasets.

The data definition file should be submitted in XML format, In addition to the define.xml, a printable define.pdf should be provided if the define.xml cannot be printed.

Specific and detailed explanation to the analysis dataset you submitted



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Draft ADRG

The **Analysis Data Reviewer's Guide** (ADRG) provides FDA Reviewers with additional context for analysis datasets (AD) received as part of a regulatory submission.

The ADRG is intended to describe analysis data submitted for an individual study in the Module 5 clinical section of the eCTD.

A specific template for an Analysis Data Reviewer's Guide is not specified. However, an example of an Analysis Data Reviewer's Guide (template, completion guidelines and examples) can be found at http://www.phusewiki.org/wiki/index.php?title=Analysis_Data_Reviewer's_Guide

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Draft ADRG

The ADRG has 8 sections :

- Introduction
- Protocol Description
- Analysis Considerations Related to Multiple Analysis Datasets
- Analysis Data Creation and Processing Issues
- Analysis Dataset Descriptions
- Data Conformance Summary
- Submissions of Programs
- Appendix (optional)

Programmer	Statistician
Section 1.3, 1.4	Section 1.2, 1.4
	Section 2.1, 2.2
Section 3.2	Section 3.1, 3.3 to 3.6
Section 4.1	Section 4.2 to 4.4
Section 5.2	Section 5.1, 5.2
Section 6.1	Section 6.1
Section 7	Section 7
Section 8	

PhUSE Documents

ADRG CDISC pilot
oject sample 2014-0

ADRG_Completio
uidelines_2014-05-0

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Draft ADRG

- 2.2 Protocol Design in Relation to ADaM Concepts
- 4.2 Data Dependencies

- 4.1 Split Datasets
- 4.3 Intermediate Datasets

- bulleted questions intended to aid FDA Reviewers

Source data other then SDTM
Subjects need special analysis rules
Special variable convention

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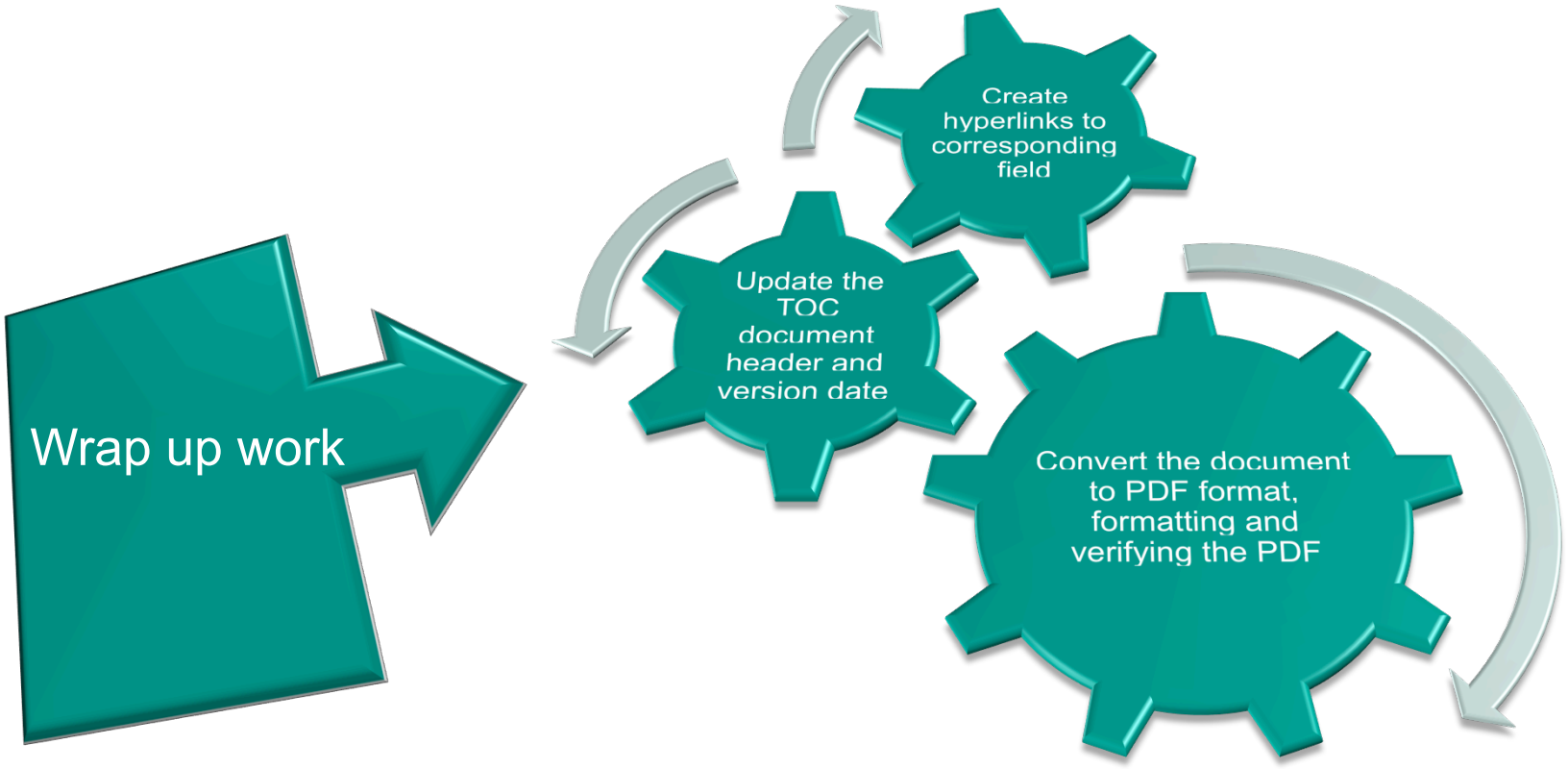
Draft ADRG



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Q & A

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Biostatistics and
Research Decision Sciences