

Use of ADaM metadata in ADaM dataset creation programs

Marleen Nijs

Statistical Programming, Janssen R&D

Agenda

- **Introduction**
- **Analysis planning**
 - **Create ADaM metadata**
- **ADaM dataset creation**
 - **Read and update/complete metadata**
 - **Metadata/data checks**
- **ADaM eSub package**
- **Overview/Recap**

Introduction

To meet ADaM principles, the ADaM datasets must be accompanied by metadata. Metadata created upfront (as part of study planning) can serve multiple purposes:

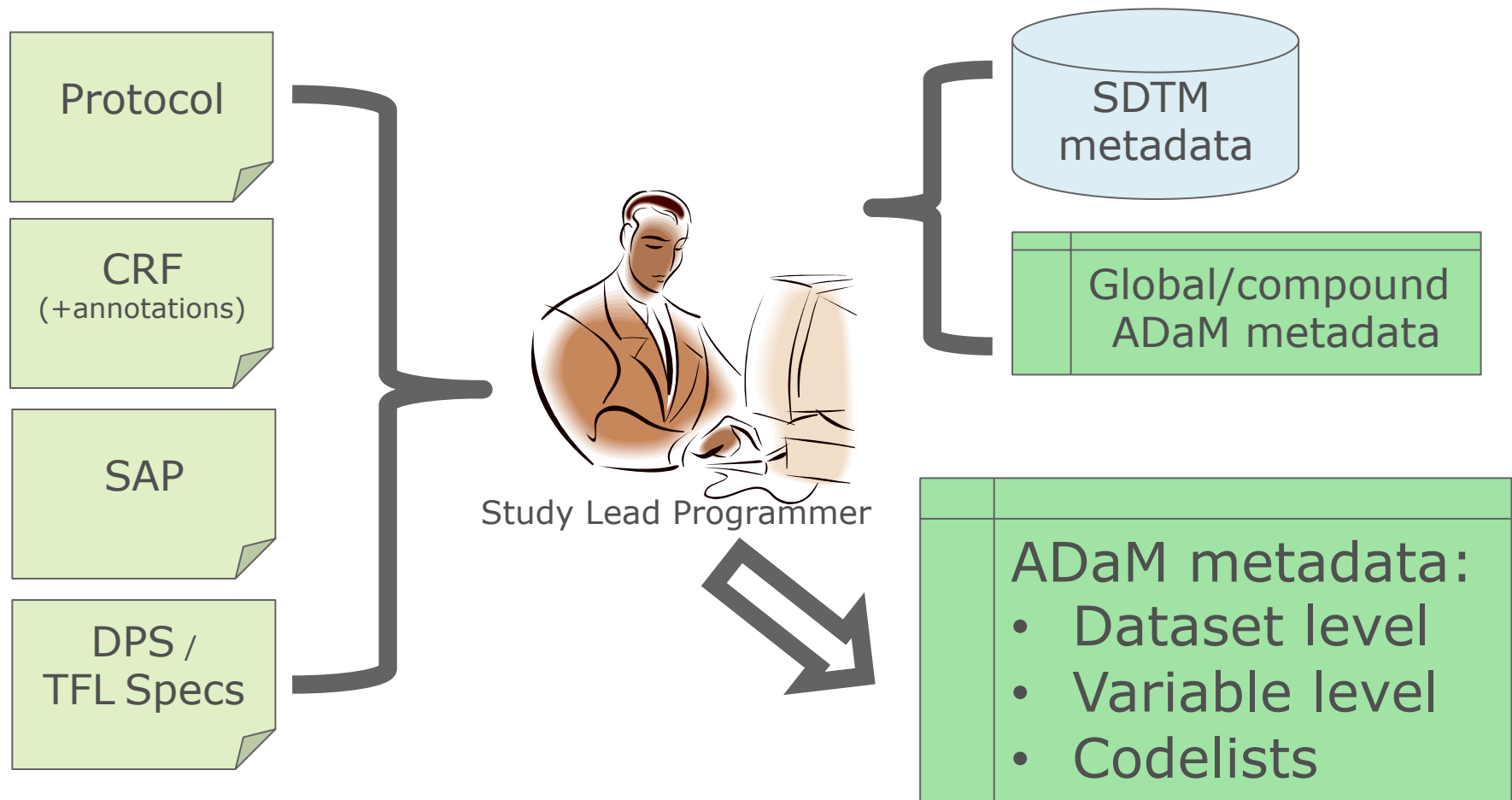
- Be a reference when creating ADaM datasets, as the metadata contains details on derivation rules;
- Hold the variable attributes which can be applied to the datasets;
- Be used to compare with the data to ensure consistency, e.g. check whether all ADaM variables are available in the metadata, check whether codelists match with data;
- Be used in eSub at time of submission.

Creating metadata before any programming is done, and finalizing it during programming, will speed up the creation of define.xml at time of submission.

Analysis Planning

Create ADaM metadata

Analysis planning: Create ADaM metadata



ADaM metadata: Dataset level

- Dataset **Label**
- **Key** Variables
- **Class** of dataset: ADSL, BDS, ADAE, OTHER
- **Documentation** Notes (**submission-ready**)
 - Description of source data, processing steps, and analysis decisions pertaining to the dataset
- **Additional Notes** for Programmer (Not intended for submission)
 - Notes from Lead programmer to Programming team with additional detail on usage or definition.

ADaM metadata: Variable level

- **Attributes:** label, type, length, format
- **Parameter Identifier** (Value level metadata)
 - Identifies which variables have metadata that vary depending on PARAM/PARAMCD in BDS ADaM datasets
- **Variable order**
- **Codelist/Controlled Terms**
 - Codelist name if variable has a discrete set of values or populated via coding dictionary
 - CODELST content described in Codelist metadata

ADaM metadata: Variable level (cont'd)

- **Source/Derivation**
 - Describes source of data or derivation
 - Should be **submission-ready**
- **Additional Notes** for Programmer (Not intended for submission)
 - Notes from Lead programmer to Programming team with additional detail on usage or definition
 - Used in conjunction with 'Source/Derivation'

ADaM metadata: Codelists

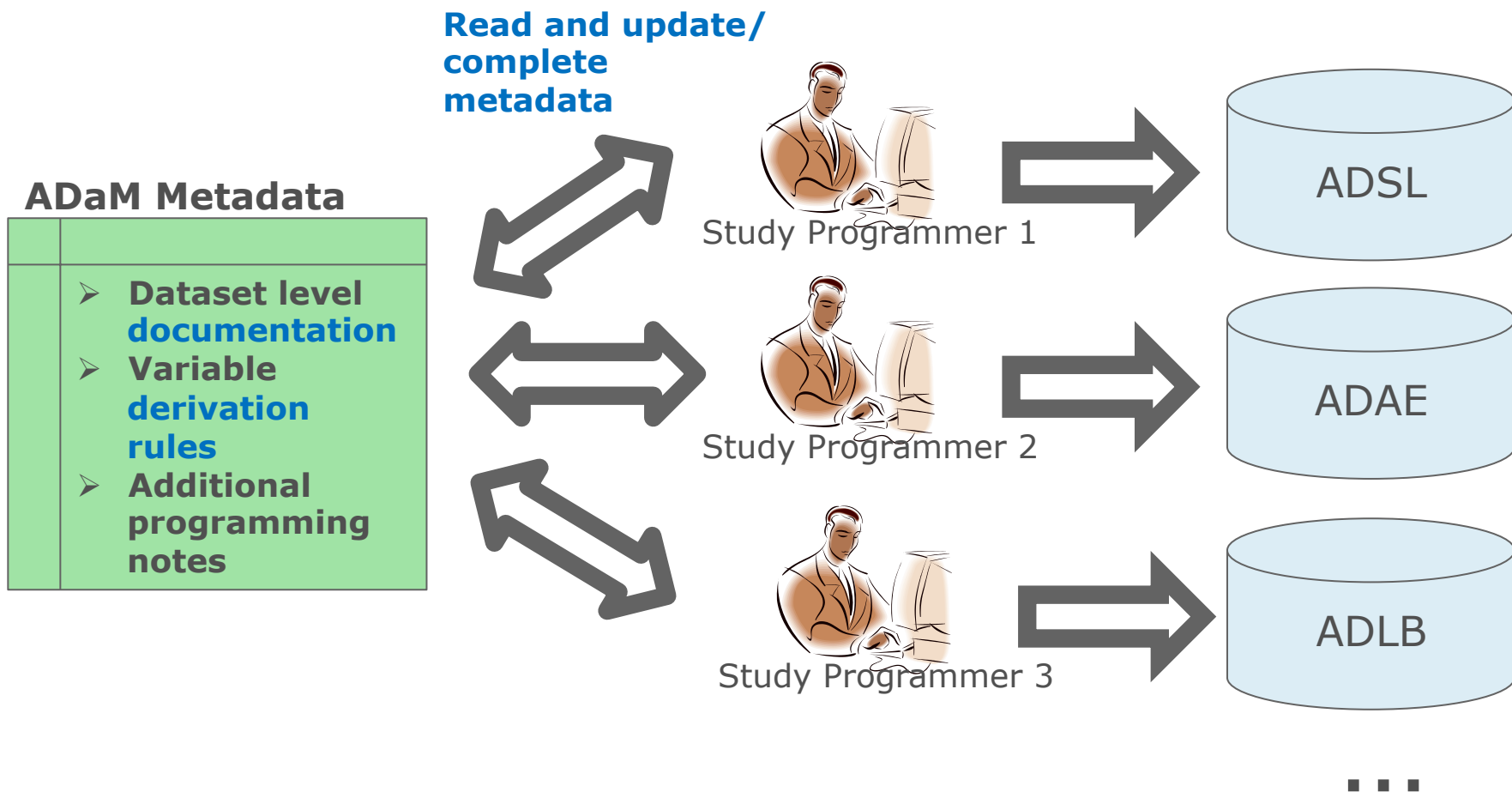
- Code List **Name**
- Code **Value**
- Code **Decode**
 - Decode or descriptive text associated with code value

ADaM Dataset Creation

Read and update/complete metadata

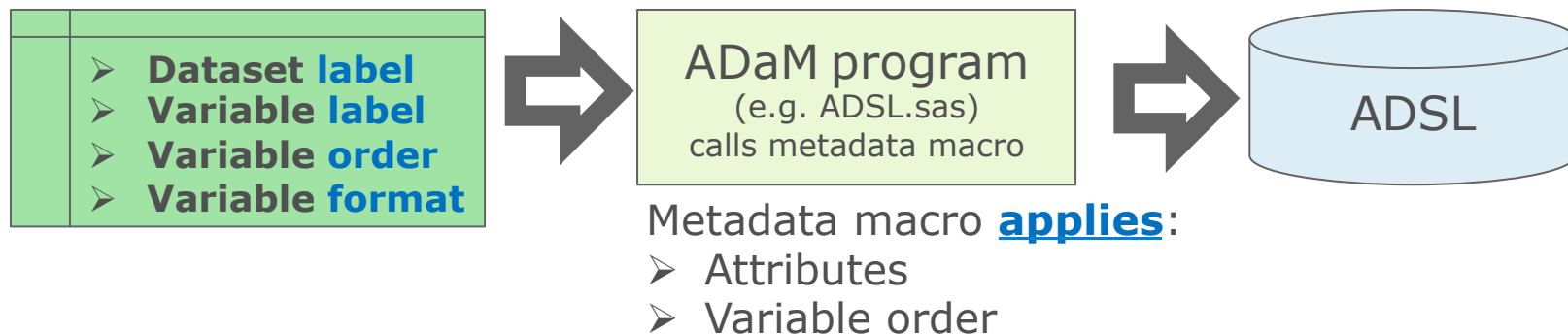
Metadata/data checks

ADaM Dataset Creation – Based on metadata

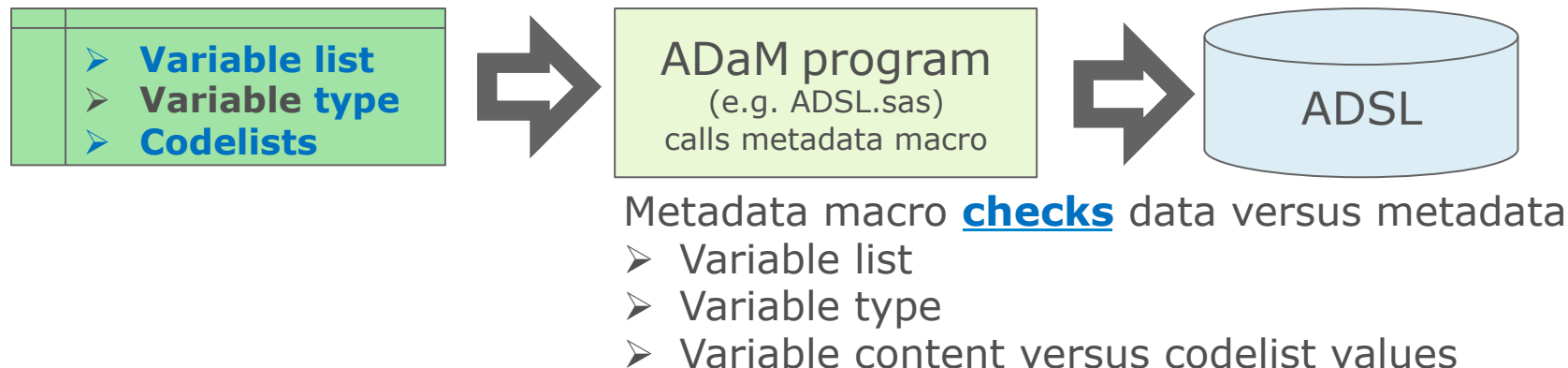


ADaM Dataset Creation – Metadata macro

ADaM Metadata



ADaM Metadata



ADaM metadata macro

- Performs data/metadata **checks**, e.g.
 - Dataset/Variable **name**: max. 8 characters
 - **Label**: not blank and max 40 characters
 - Variable **type**: non-missing and content per CDISC guidelines
 - Decimal digits filled if variable type is float
 - Derivation rules not blank for derived variables
 - ...

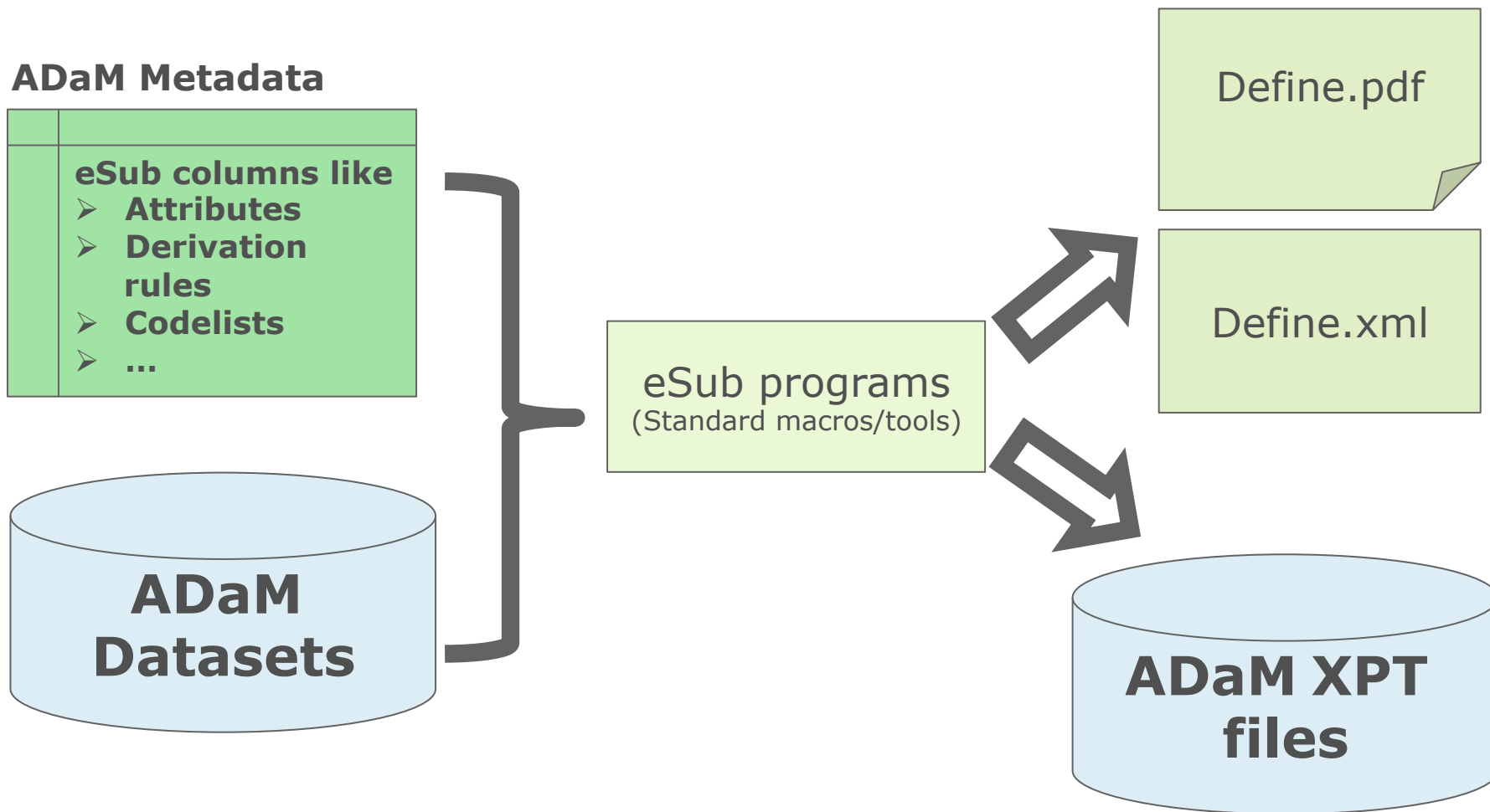


Submission-Ready ADaM data +
metadata

ADaM eSub Package

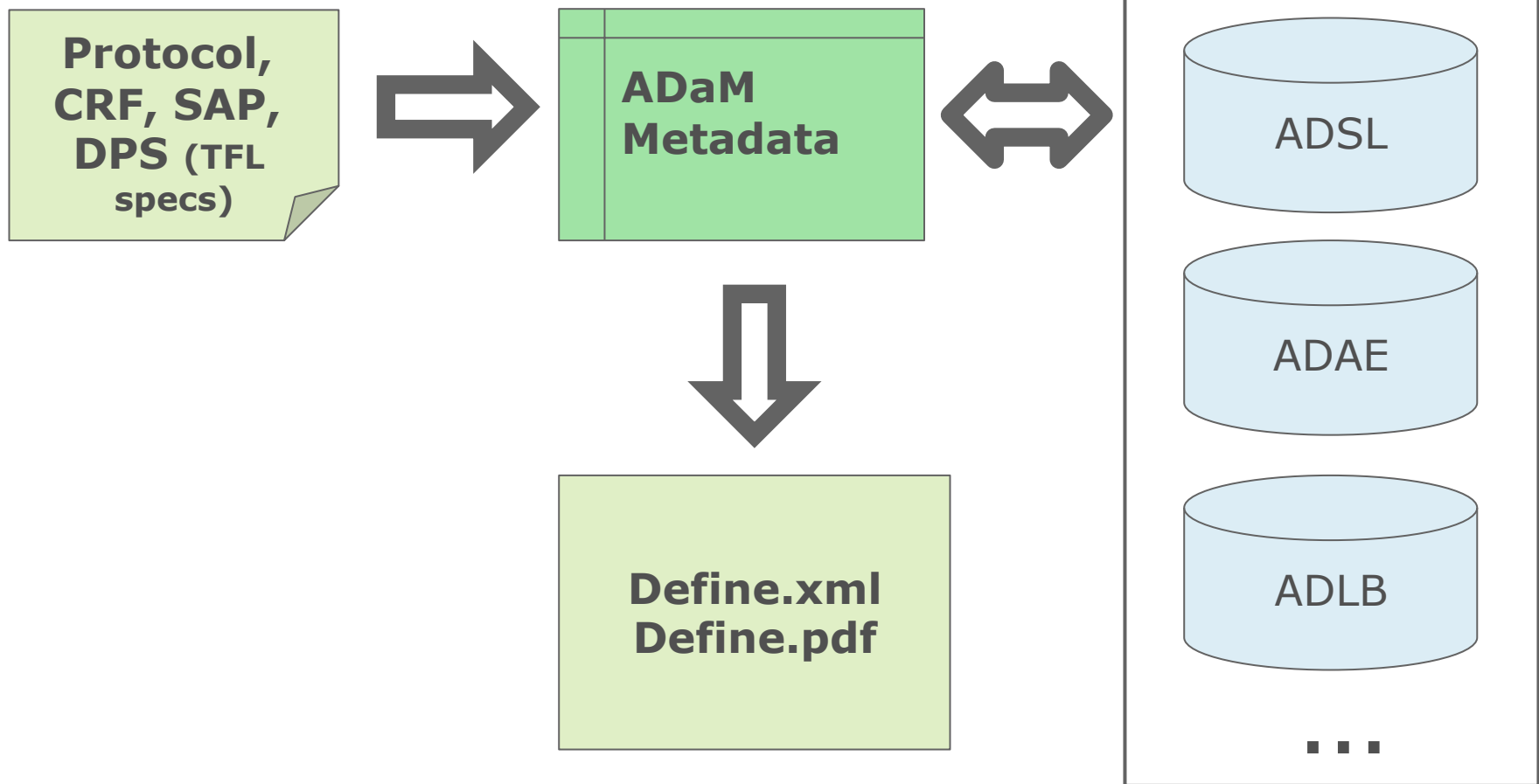
**Based on submission ready data +
metadata**

Create eSub package



Overview / Recap

Process overview



ADaM metadata tips

- **Metadata requirements (for this process):**
 - Include all columns required for **define**.
 - Include **additional detail** for internal communication and documentation.
- **Helpful:**
 - Create and maintain global and compound templates/standards.

