

ADaM programming made easy – Common ADaM templates and a SAS macro library

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Goal

Jumpstart ADaM programming in a structured and modular approach using:

- ADaM template programs for Basic Data Structure (BDS) and Occurrence Data Structure (OCCDS) datasets
- A library of data derivation and utility components

Motivation

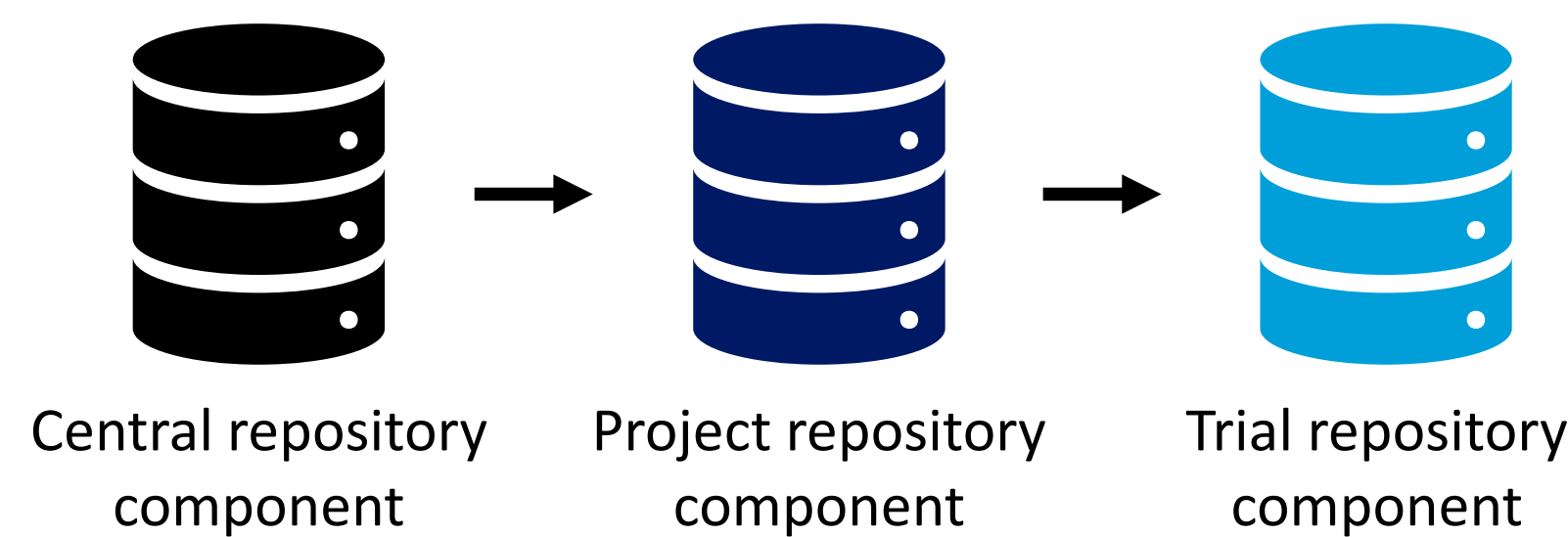
- Ease of use:
 - Saves time in development and maintenance
 - More time for trial specific needs
- Data readiness:
 - 80% of desired ADaM variables ready as soon as SDTM is ready
- Quality:
 - Same code used for the same derivations across different datasets, trials, and projects
 - Ensures good programming practice

Components

Our approach is built around a central repository of data derivation components. The components can be either macros or code snippets. They cover derivations like date/time imputation, retest rules, analysis flags, limit of quantification and screening observation carried forward.

The ADaM template programs are built using the data derivation components as building blocks. Each component can be replaced with another component according to project or trial specific requirements.

Figure 1 The data derivation component hierarchy



Data derivation components exist at three levels; company, project and trial level. Likewise, the templates exist at a company level, but are adapted to project needs within each project, which again form the basis or starting point for each trial.

Metadata

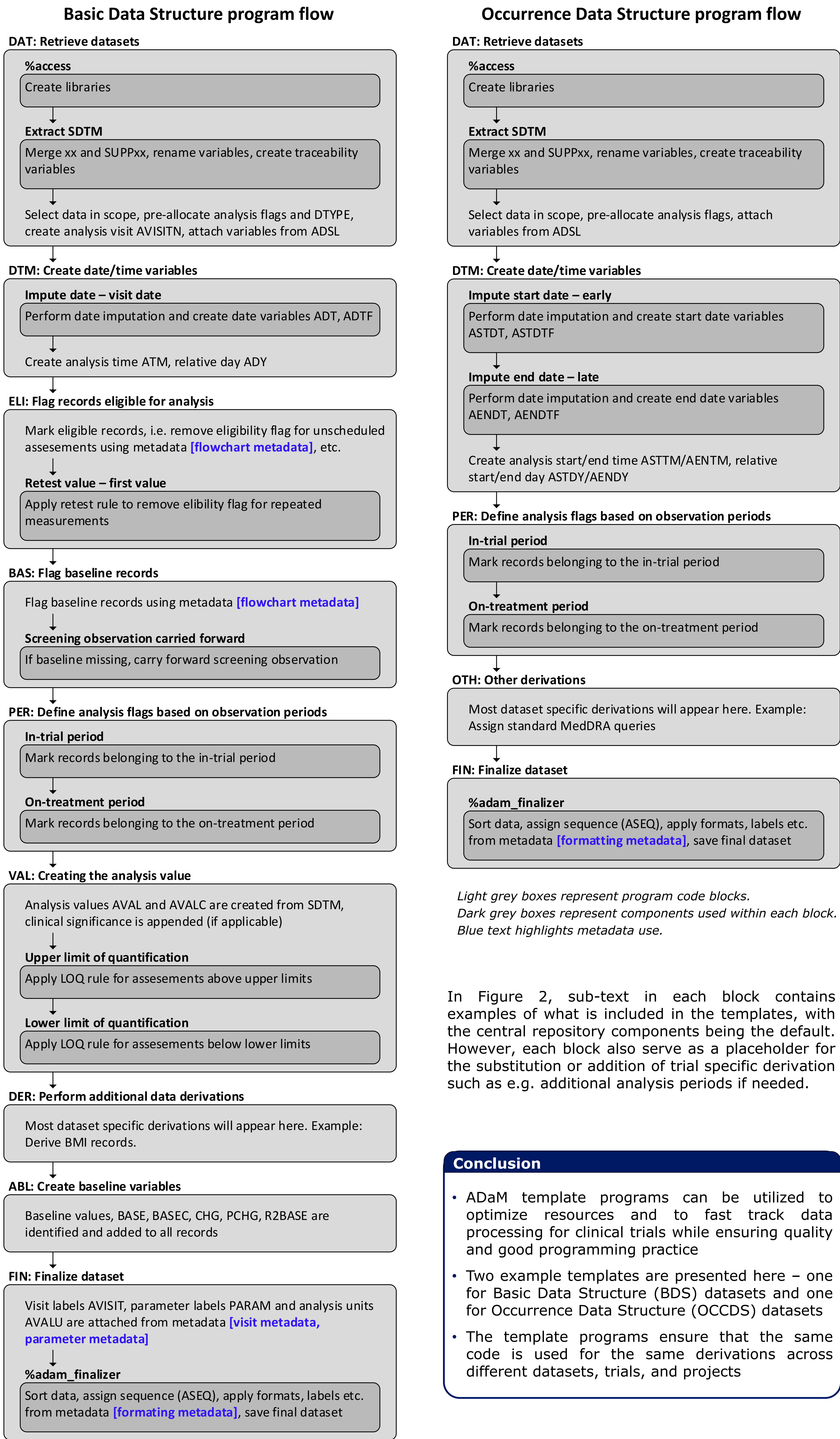
The ADaM template programs rely on metadata from several sources. Following are some of the key types of metadata:

- Visit metadata (Labels for each visit)
- Parameter metadata (Labels and units for each parameter code)
- Flowchart metadata (Planned assessments at each visit)
- Formatting metadata (Format, length, and label for each variable in final ADaM dataset)

ADaM template programs

The structure and program flow of the BDS/OCCDS templates are visualized in Figure 2. The functional steps have been grouped into code blocks for ease of readability, with the OCCDS flow having only a subset of the blocks of the BDS flow.

Figure 2 Program flow of the ADaM template programs



In Figure 2, sub-text in each block contains examples of what is included in the templates, with the central repository components being the default. However, each block also serve as a placeholder for the substitution or addition of trial specific derivation such as e.g. additional analysis periods if needed.

Conclusion

- ADaM template programs can be utilized to optimize resources and to fast track data processing for clinical trials while ensuring quality and good programming practice
- Two example templates are presented here – one for Basic Data Structure (BDS) datasets and one for Occurrence Data Structure (OCCDS) datasets
- The template programs ensure that the same code is used for the same derivations across different datasets, trials, and projects