

Background

Analysis results play a crucial role in the drug development process, providing essential information for regulatory submission and decision-making. However, the current state of analysis results reporting is suboptimal, with limited standardization, lack of automation, and poor traceability.

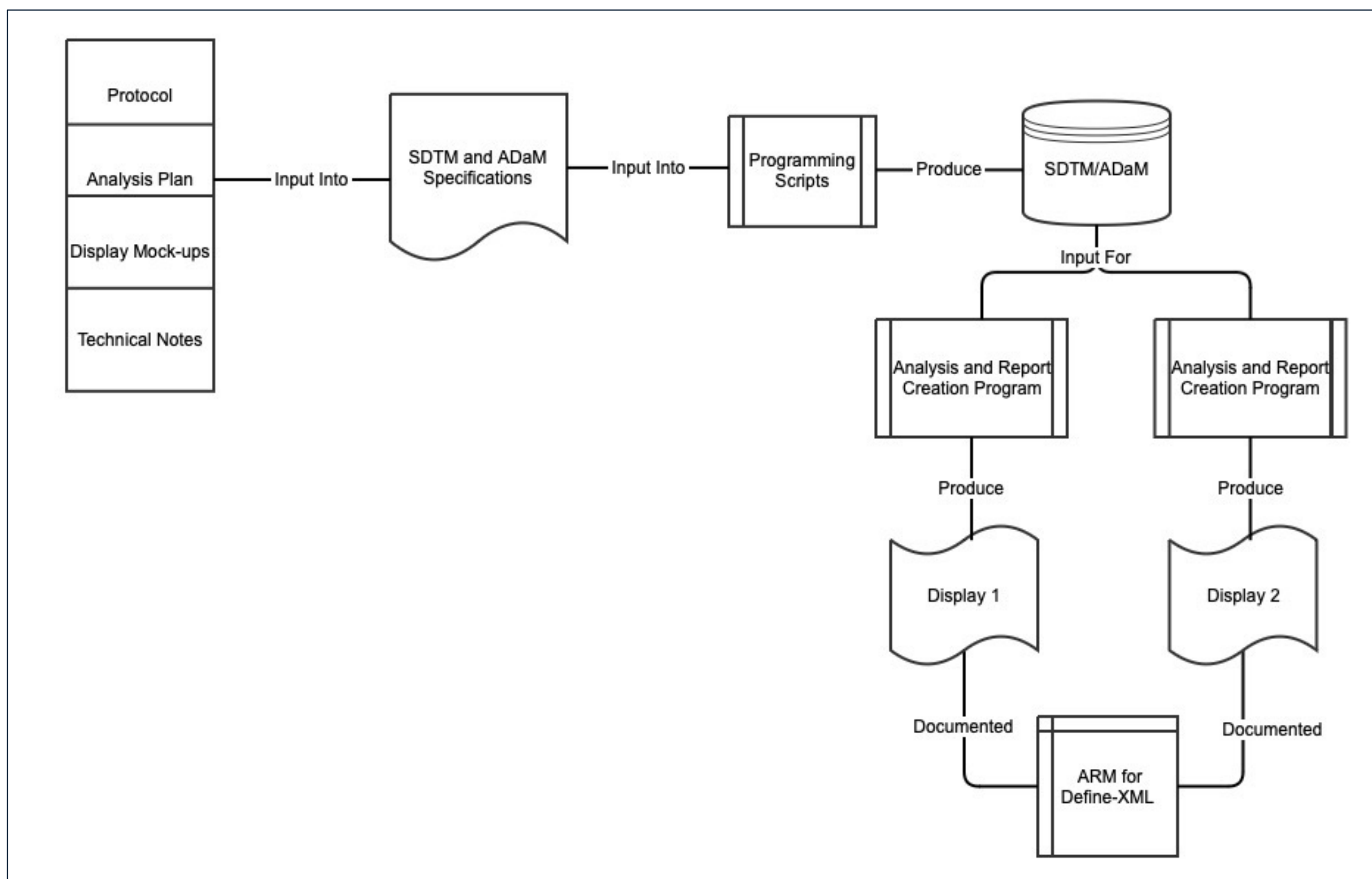


Figure 1. Example of Current Workflow

Analysis Results Standard

CDISC has developed an Analysis Results Standard (ARS) to represent analysis results and associated metadata.

Key Objectives

- Leverage analysis results metadata to drive the automation of results
- Support storage, access, processing, traceability and reproducibility of results

Key Results

- Logical Model that describes analysis results and associated metadata
- User Guide to illustrate and exercise model with common safety displays

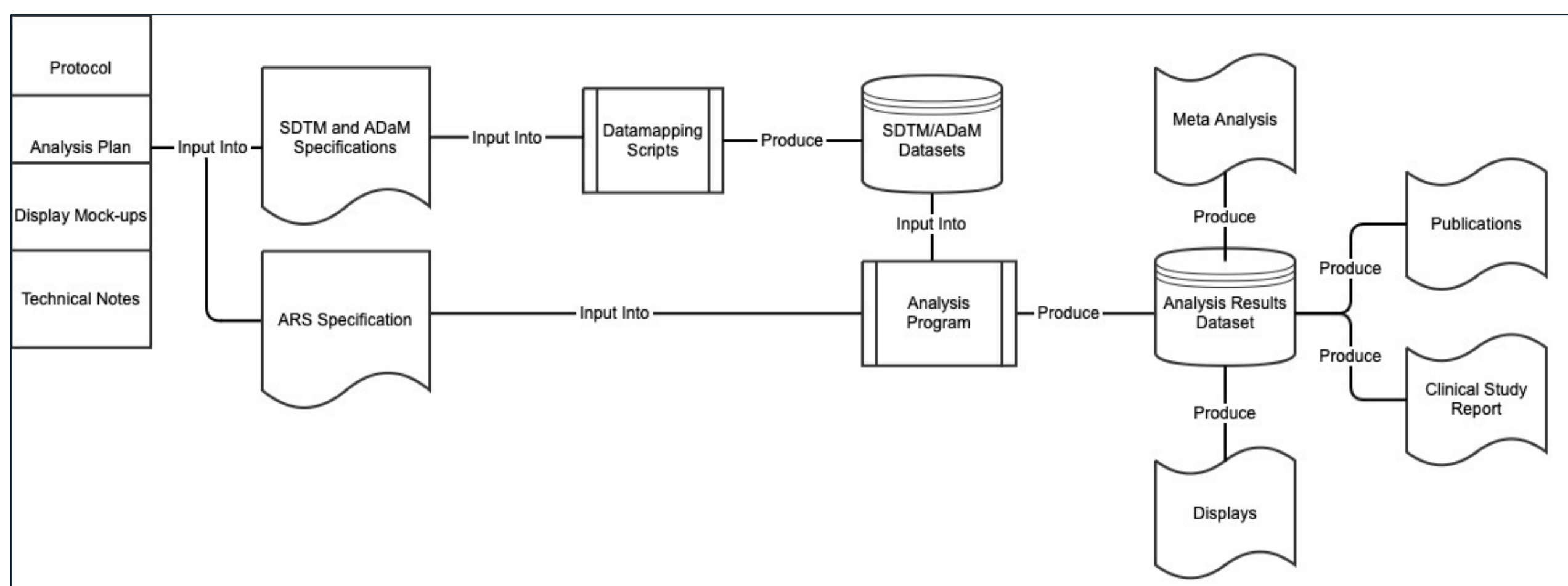
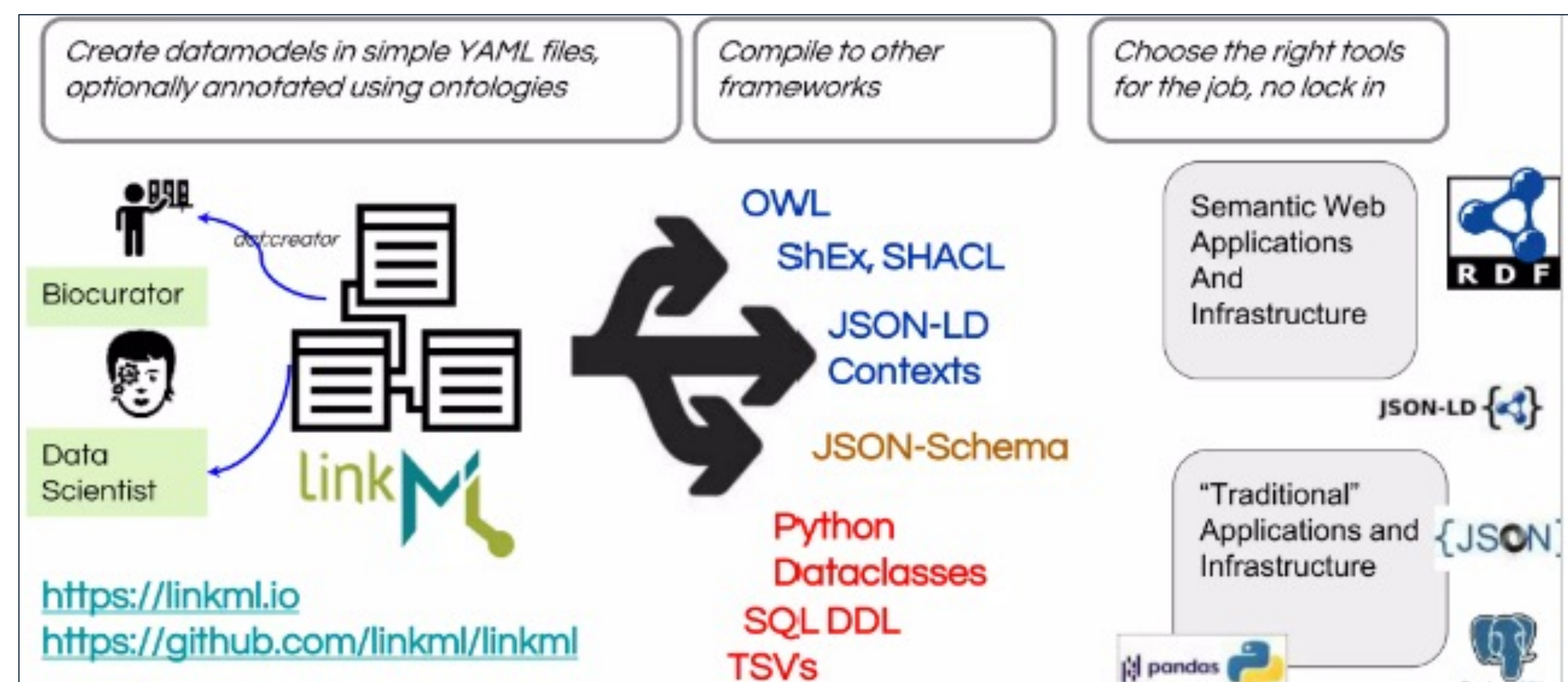


Figure 2: Example of Potential Future Workflow

Analysis Results Logical Model

- A logical data model establishes the structure of data components and the relationships between them
- Designed to accurately represent complexity of all components
- It is independent of the physical database design
- The ARS Logical Model was developed using LinkML which is a general-purpose modeling language that can be used with linked data, JSON, and other formalisms



ARS Logical Model Components

- **Reporting Event:** A set of analyses and outputs created to meet a specific reporting requirement, such as a CSR or interim analysis
- **Analysis Set:** The subject populations defined for the reporting event
- **Data Subset:** A subset of data identified by selection criteria for inclusion in the analysis
- **Analysis Grouping:** A subdivision of the subject population based on a defined factor (e.g., subjects whose treatment is Drug A, subjects whose gender is male)
- **Analysis Method:** A set of one or more statistical operations
- **Result:** The result of an analysis method operation performed on a subdivision of subjects or data records
- **Analysis:** A set of operations (Analysis Method) performed on a specified analysis variable for any specified subset of data records (Data Subset) for a given subject population (Analysis Set) which may be subdivided by 1 or more factors (Analysis Grouping)

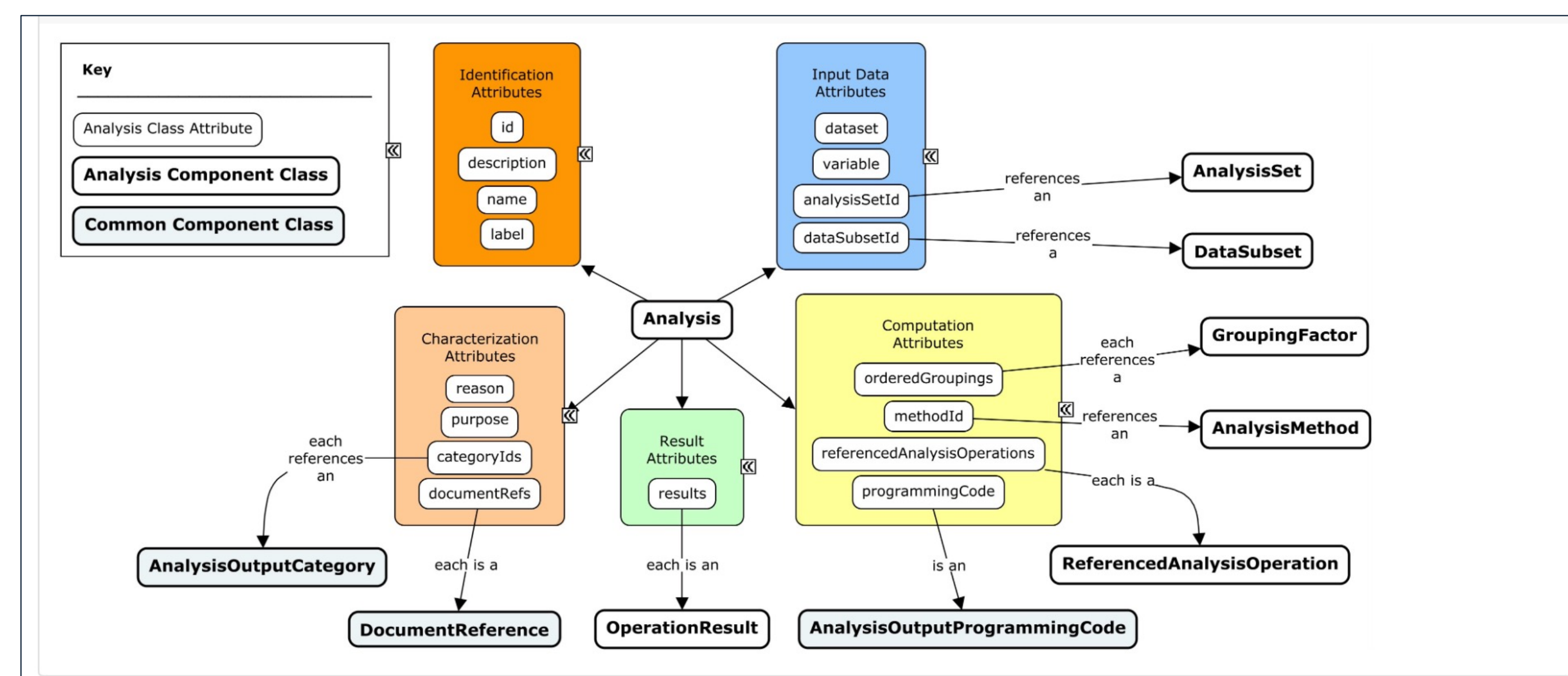


Figure 3. Analysis Class Attributes and Associated Component Classes

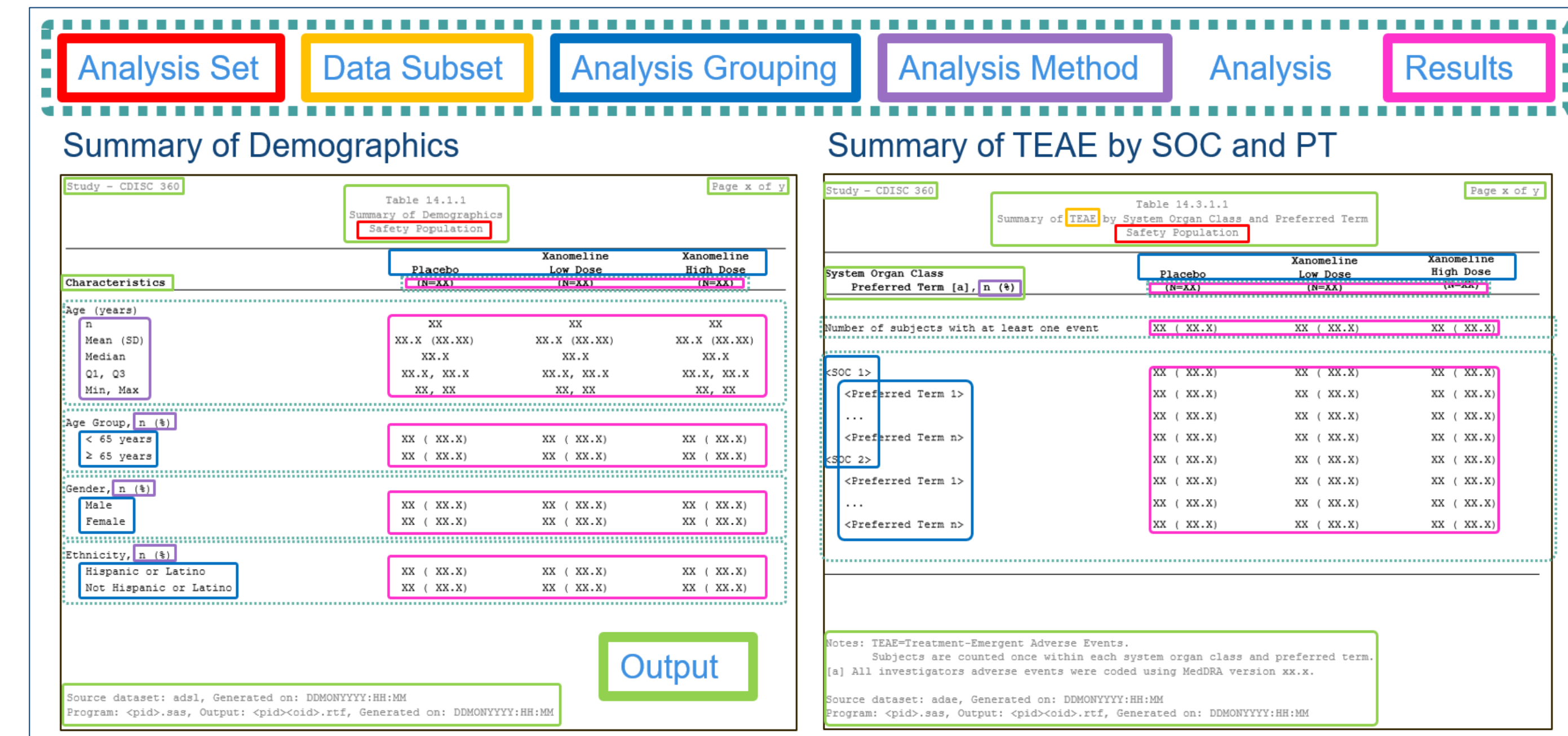
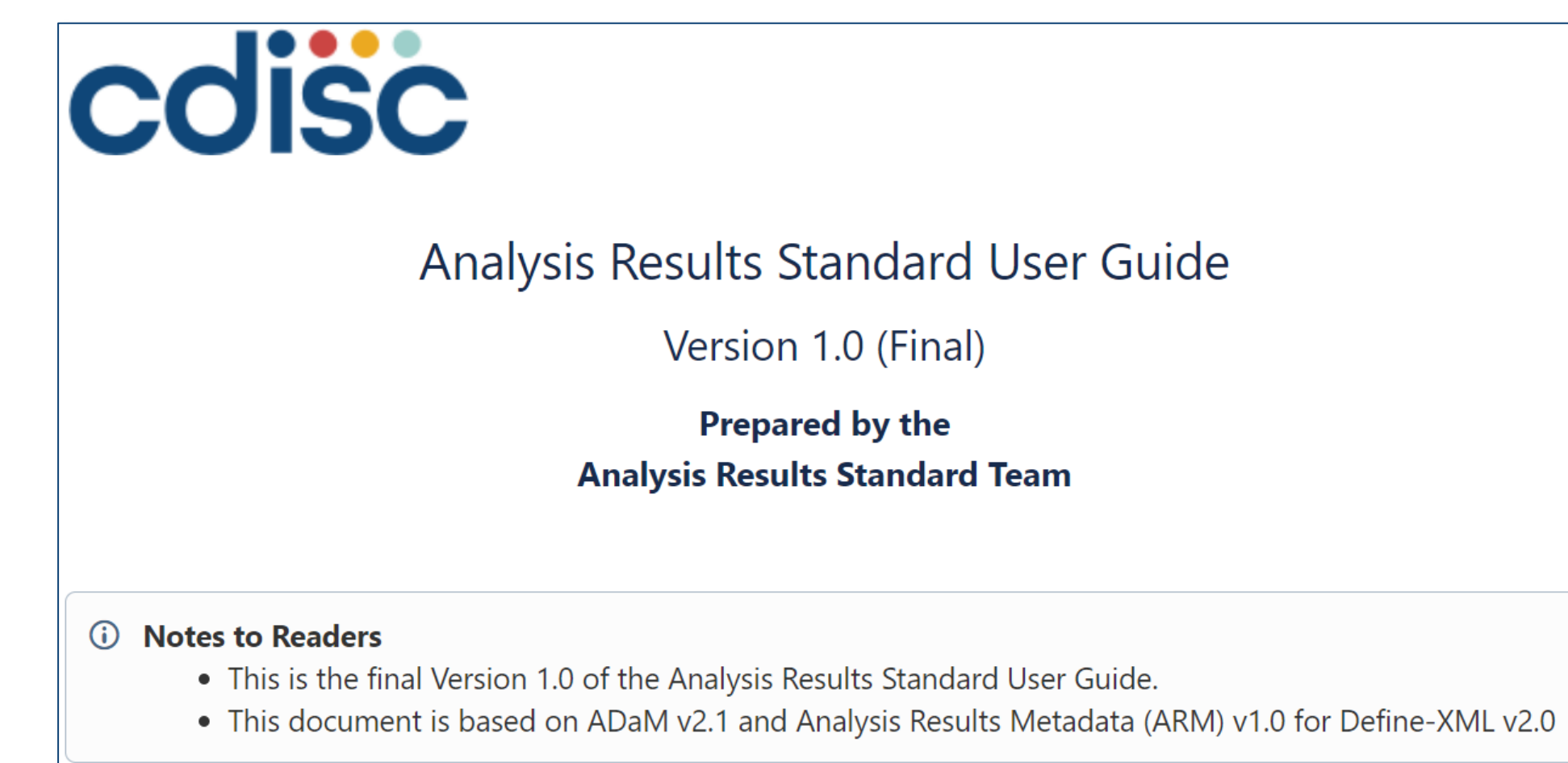


Figure 4. Example Safety Displays Showing ARS Components

ARS User Guide

The ARS User Guide (ARS-UG) is intended to be used in conjunction with the ARS Model documentation. The UG provides expanded information about the purpose and use of each of the components of the Model, as well as implementation examples.



Example Reporting Events

- Common Safety Displays
 - Summary of Demographics
 - Overall Summary of Treatment-Emergent Adverse Events
 - Summary of TEAE by System Organ Class and Preferred Term
 - Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs
 - Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs <Vertical Layout>
- FDA Standard Safety Tables and Figures
 - Table 2: Baseline Demographic and Clinical Characteristics, Safety Population