



A Metadata Driven Approach to Streamline AE Groupings

David WANG



Agenda



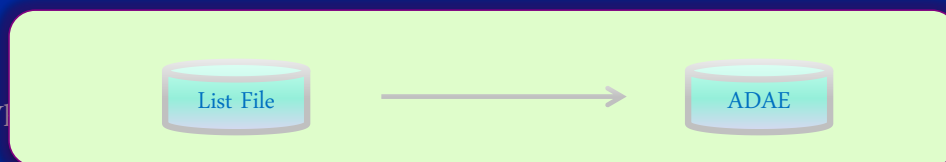
- Background: a case study
 - MedDRA baskets
- Metadata Driven Approach
 - Description and Purpose
 - Specification
 - Example
- Process
- Benefit

Background: a case study



- In your study, there is a table mockup with the title **Adverse Events of Special Interest: Rituximab Infections**. You probably need to do the following preparation.
 1. Request for the list of terminology
 2. Program your **ADAE** code to load the list and to define grouping variables in ADAE.

- With this approach, you can load the list across studies within your project:



- MedDRA baskets are groupings of preferred terms into medical concepts to enable analyses based on these groupings. Baskets are commonly used to represent syndromes or conditions characterized by a cluster of signs, symptoms, and test results or therapeutic procedures falling across many different SOCs. There are four types of baskets:
 - **SMQs**: Standardized MedDRA queries supplied from MedDRA MSSO (Maintenance and Support Services Organization).

(Below are company customized)

 - **Standard Adverse Event Group Terms (AEGTs)**: created by Drug Safety.
 - **Product-Specific AEGTs**: project / product specific baskets created by Drug Safety.
 - **Study-Specific AEGTs**.
- These definitions get maintained and updated periodically (twice a year).

The Metadata Driven Approach

Roche



ADAG Description and Purpose



PURPOSE:

- Intermediate data set for **Medical Concept flags** to be created in the ADaM ADAE dataset.
- Contains the **full list of AE terms** within an AE grouping and **details of the variable** to be created in ADAE

DESCRIPTION:

- One record per dictionary term and code included in a grouping definition
- ADAG **must be created before ADAE** if adverse event groupings are required.
- Metadata driven** – a user-defined data set describes the groupings required.

ADAG – Specification & Example

Roche

VARIABLE NAME	VARIABLE LABEL	VARIABLE TYPE	DISPLAY FORMAT
GRPVAR	Name of grouping flag	Char	8
GRPLBL	Label of grouping flag variable	Char	40
SRCVAR	Variable on which grouping is based	Char	8
GRPTYPE	Grouping definition type	Char	6
REFID	Grouping definition identifier	Char	9
REFNAME	Grouping definition name	Char	200
REFDICT	Grouping definition dictionary and version	Char	12
REFTERM	Grouping definition clause dictionary term	Char	100

GRP1FL

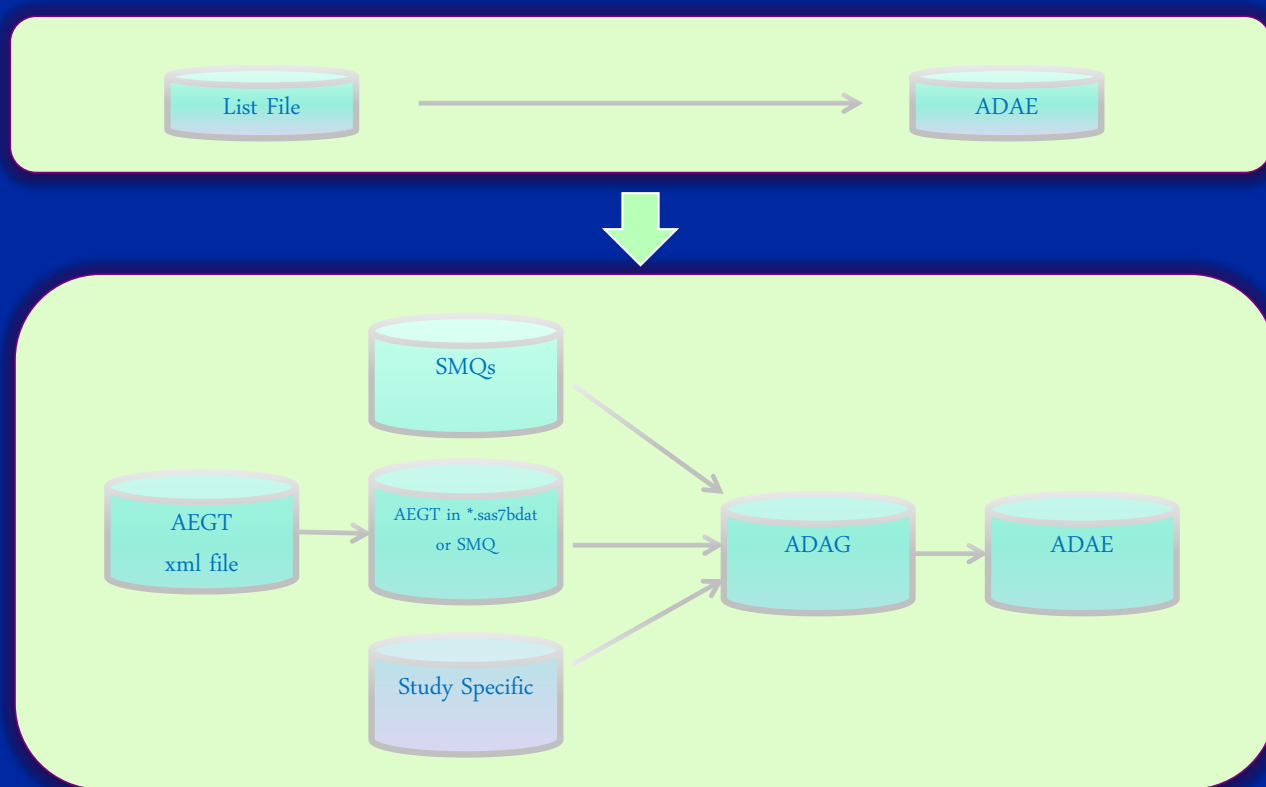
	Name of Grouping Flag Variable	Label of Grouping Flag Variable	Variable on which Grouping is Based	Grouping Definition Type	Grouping Definition Name	Grouping Def. Dictionary and Version	Grouping Def. Clause Dictionary Term
33	Grp1	SMQ - Asthma/Bronchospasm	aedecod	SMQ	sw-Asthma/bronchos (SMQ)	MedDRA v14.0	BRONCHIAL HYPERREACTIVITY
34	Grp1	SMQ - Asthma/Bronchospasm	aedecod	SMQ	sw-Asthma/bronchos (SMQ)	MedDRA v14.0	REACTIVE AIRWAYS DYSFUNCTION SYNDROME
35	Grp1	SMQ - Asthma/Bronchospasm	aedecod	SMQ	sw-Asthma/bronchos (SMQ)	MedDRA v14.0	OCCUPATIONAL ASTHMA
36	Grp1	SMQ - Asthma/Bronchospasm	aedecod	SMQ	sw-Asthma/bronchos (SMQ)	MedDRA v14.0	PULMONARY SENSITISATION
37	Grp2	AEGT Rituximab Infections	aedecod	AEGT	Rituximab-Specific	MedDRA v14.0	ABDOMINAL WALL ABSCESS
38	Grp2	AEGT Rituximab Infections	aedecod	AEGT	Rituximab-Specific	MedDRA v14.0	ABORTION INFECTED
39	Grp2	AEGT Rituximab Infections	aedecod	AEGT	Rituximab-Specific	MedDRA v14.0	ABSCESS
40	Grp2	AEGT Rituximab Infections	aedecod	AEGT	Rituximab-Specific	MedDRA v14.0	ABSCESS BACTERIAL
41	Grp2	AEGT Rituximab Infections	aedecod	AEGT	Rituximab-Specific	MedDRA v14.0	ABSCESS INTestinal
42	Grp2	AEGT Rituximab Infections	aedecod	AEGT	Rituximab-Specific	MedDRA v14.0	ABSCESS OF EXTERNAL AUDITORY MEATUS
43	Grp2	AEGT Rituximab Infections	aedecod	AEGT	Rituximab-Specific	MedDRA v14.0	ABSCESS OF EYELID

Example: ADAE



Subject Identifier for the Study	Reported Term for the Adverse Event	Body System or Organ Class	SMQ - Asthma/Bronchospasm	AEGT Rituximab Infections
16100	ANEMIA	Blood And Lymphatic System Disorders		
16100	INSOMNIA	Psychiatric Disorders		
16100	NAUSEA	Gastrointestinal Disorders		
16100	VOMITING	Gastrointestinal Disorders		
16100	CONSTIPATION	Gastrointestinal Disorders		
16100	DIARRHEA	Gastrointestinal Disorders		Y
16100	NAUSEA	Gastrointestinal Disorders		
16100	VOMITING	Gastrointestinal Disorders		
16100	HYPOKALEMIA	Metabolism And Nutrition Disorders		
16100	LEUKOPENIA	Blood And Lymphatic System Disorders		
16100	NEUTROPENIA	Blood And Lymphatic System Disorders		

Process



Benefit

Roche

- Streamlined
- Traceable and transparent
- Flexible to cope with:
 - most coding systems
 - different versions if needed
 - combination of various level of groups
 - E.G. a few SOC's with a few PTs
- Ensure consistency across studies and projects



Q & A



Doing now what patients need next