



2024 CDISC + TMF
US INTERCHANGE

PHOENIX/SCOTTSDALE

23-24 OCTOBER: CONFERENCE & EXPO | 21, 22, 25 OCTOBER: TRAININGS

ADaM Adventures in Oncology

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Team Lead – ADaM Oncology Methods Document



Meet the Speaker

Paul Slagle

Title: Sr Director Data Standards

Organization: IQVIA

Paul is the Senior Director of Data Standards at IQVIA where he manages a team responsible for the management and governance of End to End Data Standards. This includes the use of IQVIA Data Standards and Client specific Data Standards.

Paul started his career working in the food industry for 17 years and graduated to the pharmaceutical industry for 25 years. His background is in statistical programming starting as a SAS programmer for most of his career. Paul started applying CDISC standards in 2005 and has been implementing governance practices for the last 10 years.



Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*



Agenda

1. Background on Examples Document
2. Content of Version 1
3. Future Content

An Examples Document is NOT....

ADaM Model

ADaM IG

Therapeutic
Usage Guide

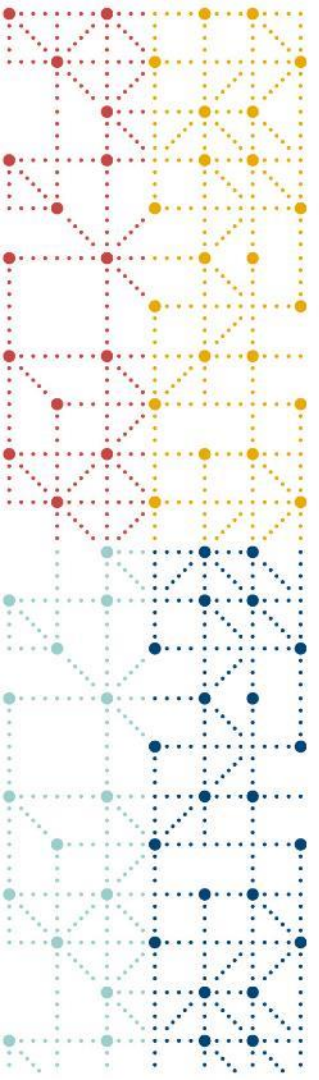
Regulatory
Document



The ADaM Oncology Examples Document IS

- An approach to applying ADaM Data Structures
- A collaboration of multiple pharma, biotech, and CRO experts
- Incorporation of FDA OOD/OCE Pilot Project Document
- Reviews by FDA representatives
- Almost 400 comments reviewed and addressed
- Years of development

Most Important: the Examples follow the use of CDISC ADaM rules in the application of standards to Oncology Clinical Trials



Current Example Document V1

Sections and Points of Consideration

Subject-Level Characteristics

- ADSL

- It's a lot about the **BASE line**

- A dataset called ADBASE is NOT REQUIRED

- A dataset called ADBASE is HELPFUL

- Why chose ADBASE over just adding to ADSL?

- Oncology Trials have a lot of baseline values

- Not all baseline values are used as categorical

- Flexibility is needed for analysis

- Governance is needed for usage

- Usability of ADSL should be considered



Cycle Reporting

- ADCYCLE Dataset
 - Allows for Cycle Visit windows
 - Can Capture
 - Actual Cycles
 - Planned Cycles
 - Missed Cycles
 - Useful for evaluating when actual versus planned visits deviate from protocol



Laboratory Results

- Detailed approach to Toxicity Grading
 - Bi-directional Grading
 - Shift from Baseline calculations



Study Drug Exposure

- ADEXP
 - Contains data from EX and EC domains
 - Is an OCD dataset
 - Provides Traceability for ADEXSUM
- ADEXSUM
 - Provides common parameters used in trials
 - Calculations which trace back to ADEXSUM



The PARQUAL Variable

- Background
 - In discussion since 2015 as a variable needed for ADaM
 - Originally to be included in ADaM ig 1.2
- Purpose
 - When a parameter is used with a common SDTM source and Analysis Algorithm but the collection source is different (ie Investigator versus IRB)
 - In all cases, parameter calculation must be the same except for the selection of SDTM rows being used.
- Example found in ADEXPSUM



Future Examples Document

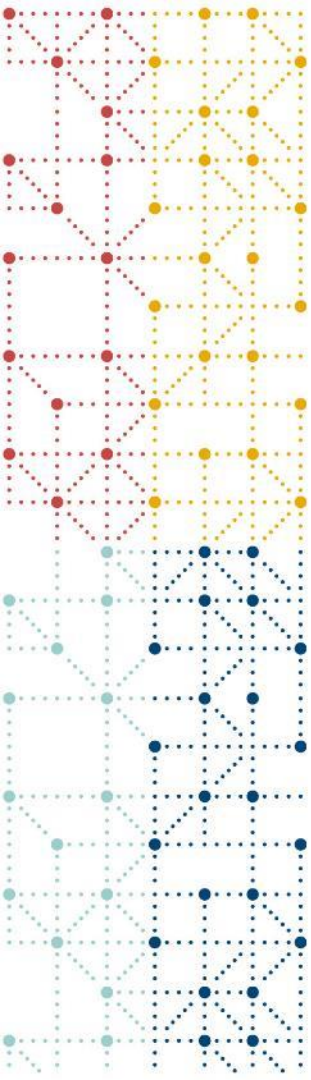
To be released after current Examples Document is published



Topics in Development

- Adverse Events
- Recist Based Efficacy
- Outcomes Based Efficacy
- Hematologic Analysis

- Others?



Thank You!

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