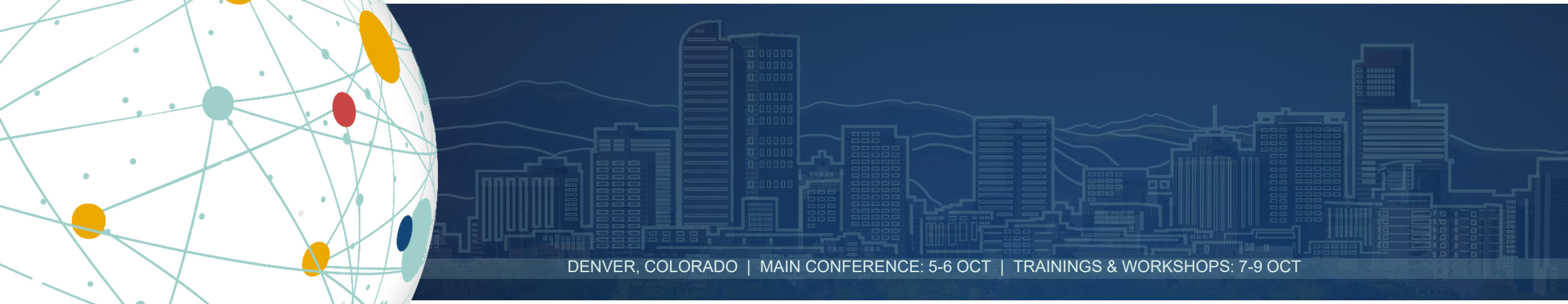


2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



ADaM 3.0 Update Part 3: New Content

Sandra Minjoe & Alyssa Wittle
Monday, October 5, 2026

Section 3
Track A

ADaM 3.0
Update Part 3:
New Content

Speakers



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ICON plc



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Atorus Research

Section 3
Track A

ADaM 3.0
Update Part 3:
New Content

Agenda

1. ADaM+IG v3 Overview
2. PARQUAL and Analysis Topic
3. Other New Variables and Conformance Rules

ADaM+IG v3 Overview

Recap of ADaM 3.0 Update Parts 1 & 2

ADaM+IG v3 Overview

- ADaM+IG v3 includes content from:
  - ADaM (model document)
  - ADaMIG
  - OCCDS IG
  - ADaMIG-NCA
  - ADaMIG-popPK
  - *Antidrug Antibody (if completed)*

- Note: rules are already consolidated into one document

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- ADaM+IG v3 does not include:
  - ADaM Statistical Examples
  - ADaM BDS for TTE
  - ADaM Traceability Examples
  - ADaM Oncology Examples
  - ADaM Metadata Submissions Guideline
  - ARM for Define-XML v2.0
  - ADaMIG for Medical Devices
  - *Lengthy examples from the list on the left*

cdisc®

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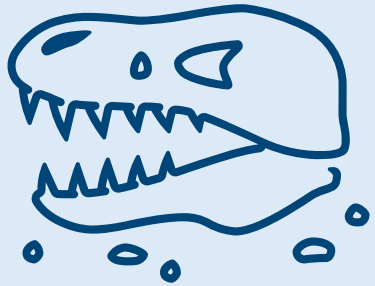
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* This content is part of the “Informative Documents” remit

PARQUAL and Analysis Topic

PARQUAL in BDS: History



What you may have seen:

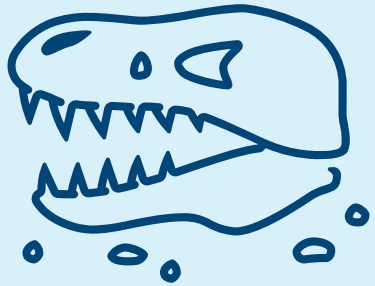
- PARQUAL is included in some Examples (including TAUGs) as “provisional”
- Was part of draft ADaM IG v1.2, but not in the final version (October, 2019)
- Included in some FDA documents

What’s been going on in the ADaM team

- Biggest concern was about misuse of PARQUAL
  - By those not understanding the difference between SDTM and ADaM
  - By those looking for ways around the BDS requirements
- Another concern about the use of “QUAL” in the variable name and label
  - ADaM doesn’t have “qualifiers”
  - PARQUAL is simply a piece of the Analysis Parameter

BDS

PARQUAL in BDS: History



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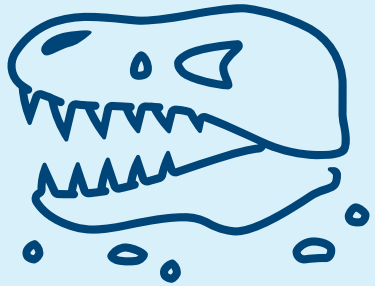
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Not seen in the 7 years since the release of ADaMIG v1.2

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New BDS Variable: PARAMXT (Parameter Extension)

PARAMXT variable is defined as the extension of the description of the analysis parameter

PARAMXT essentially replaces what we'd been calling PARQUAL

BDS

New BDS Variable: PARAMXT (Parameter Extension)

When **PARAMXT** is used, then the combination of **PARAM** and **PARAMXT** must include all descriptive and qualifying information to sufficiently and unambiguously describe the contents of AVAL and/or AVALC as needed for the planned analysis

When **PARAMXT** is <u>not</u> used, then **PARAM** alone must include all descriptive and qualifying information to sufficiently and unambiguously describe the contents of AVAL and/or AVALC as needed for the planned analysis

New Concept: Analysis Topic

Analysis Topic is the complete and unambiguous description of what is being analyzed in the planned analyses.

- In many cases, the parameter alone is sufficient to describe the analysis value, so the analysis topic = PARAM
- When parameter extension is used in addition to parameter, the analysis topic is the combination of the PARAM and PARAMXT

Analysis Topic is not a variable in the dataset

- Simply a concise way to describe what is being analyzed, even if that content is spread across multiple variables

Analysis Topic Example

Analysis Topic in a Single Variable

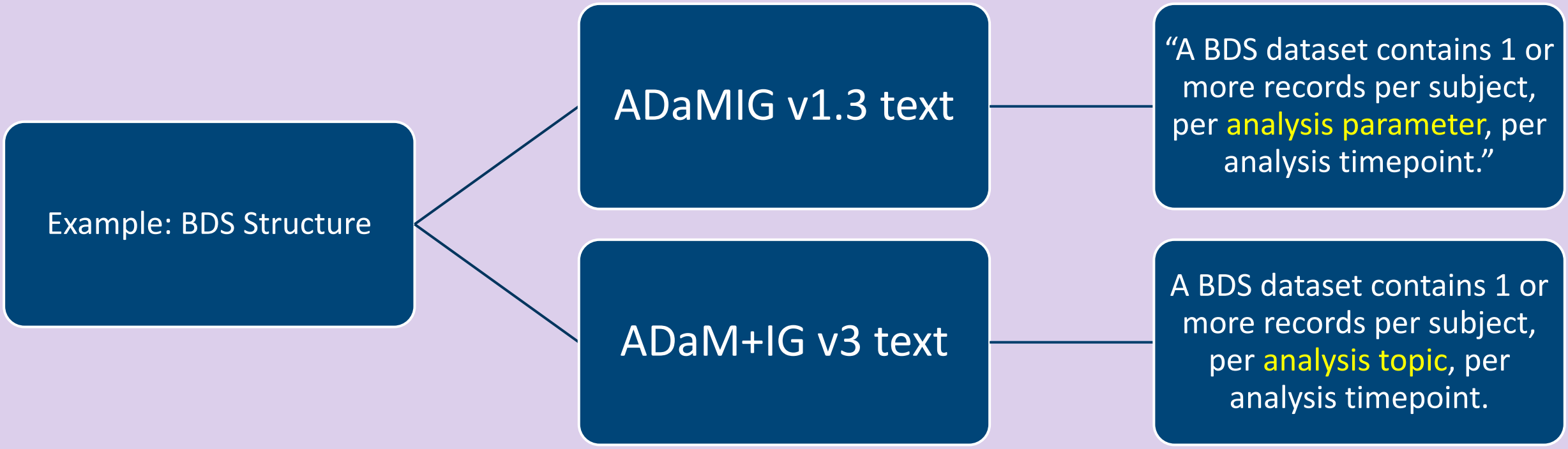
PARAM
Progression-free Survival (months) - Investigator
Progression-free Survival (months) – Independent Reviewer

OR

Analysis Topic in Two Variables

PARAM	PARAMXT
Progression-free Survival (months)	Investigator
Progression-free Survival (months)	Independent Reviewer

New Concept: Analysis Topic



Other New Variables & Rules (to date)

BDS

New BDS Variable: PARAMU

Issues

- Units are sometimes required in their own variable, such as in PK tools
- There are some cases where units do not appear on the output row (maybe instead in the output title) and it would be easier to not have them in the parameter

AVALU: already exists in some documents

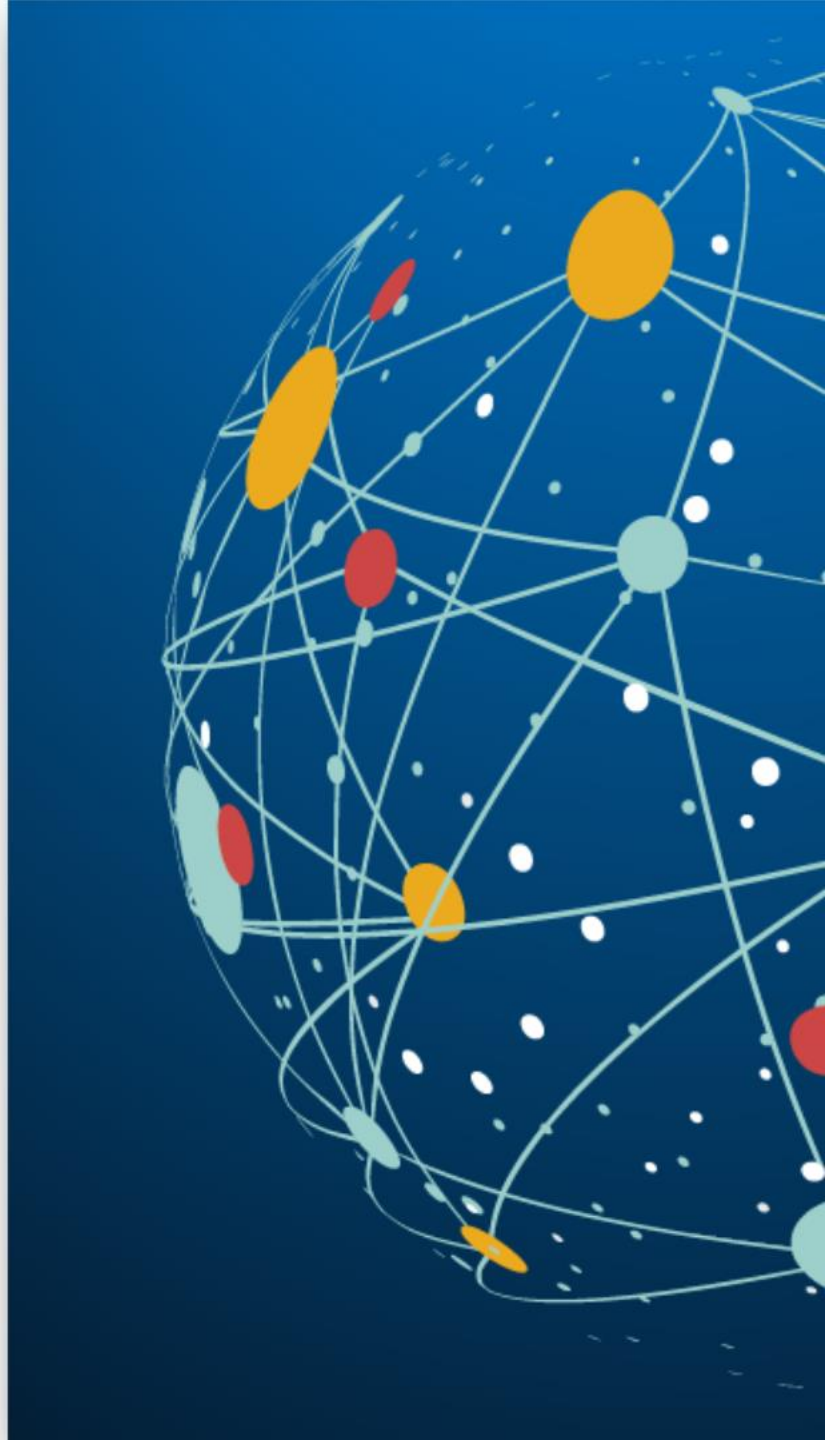
- AVALU doesn't convey that the units must be the same across the parameter
- For analysis, it doesn't make sense for records of the same parameter to use different units

New Conformance Rules

- Rules for **PARAMU**
  - Can’t be used without variable PARAM

- Rule for **PARAMXT**
  - Can’t be used without variable PARAM
  - Can’t contain just units alone

NOTE:
Both variables have already been reviewed and OK’d by US FDA standards representatives



BDS

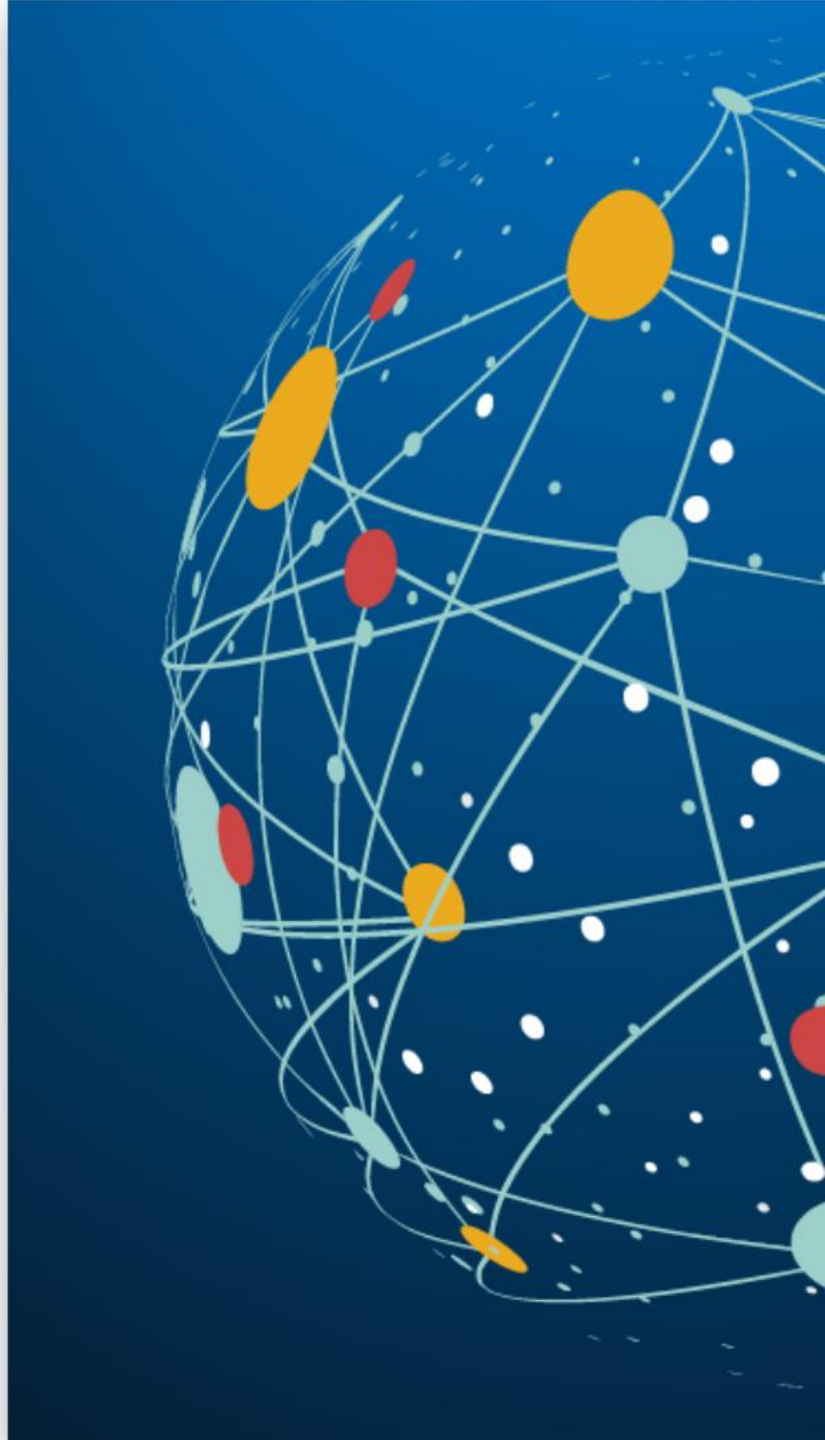
New BDS Variables: Ratios

- **R2ANRLO**: Ratio to Analysis Normal Range Low
  - Derived from AVAL and ANRLO
- **R2ANRHI** : Ratio to Analysis Normal Range High
  - Derived from AVAL and ANRHI

- *Note: these variables are similar to existing R2AyLO and R2AyHI*

New Conformance Rules

- Rule for **R2ANRLO**
  - Can’t be used without variables AVAL and ANRLO
- Rule for **R2ANRHI**
  - Can’t be used without variables AVAL and ANRHI



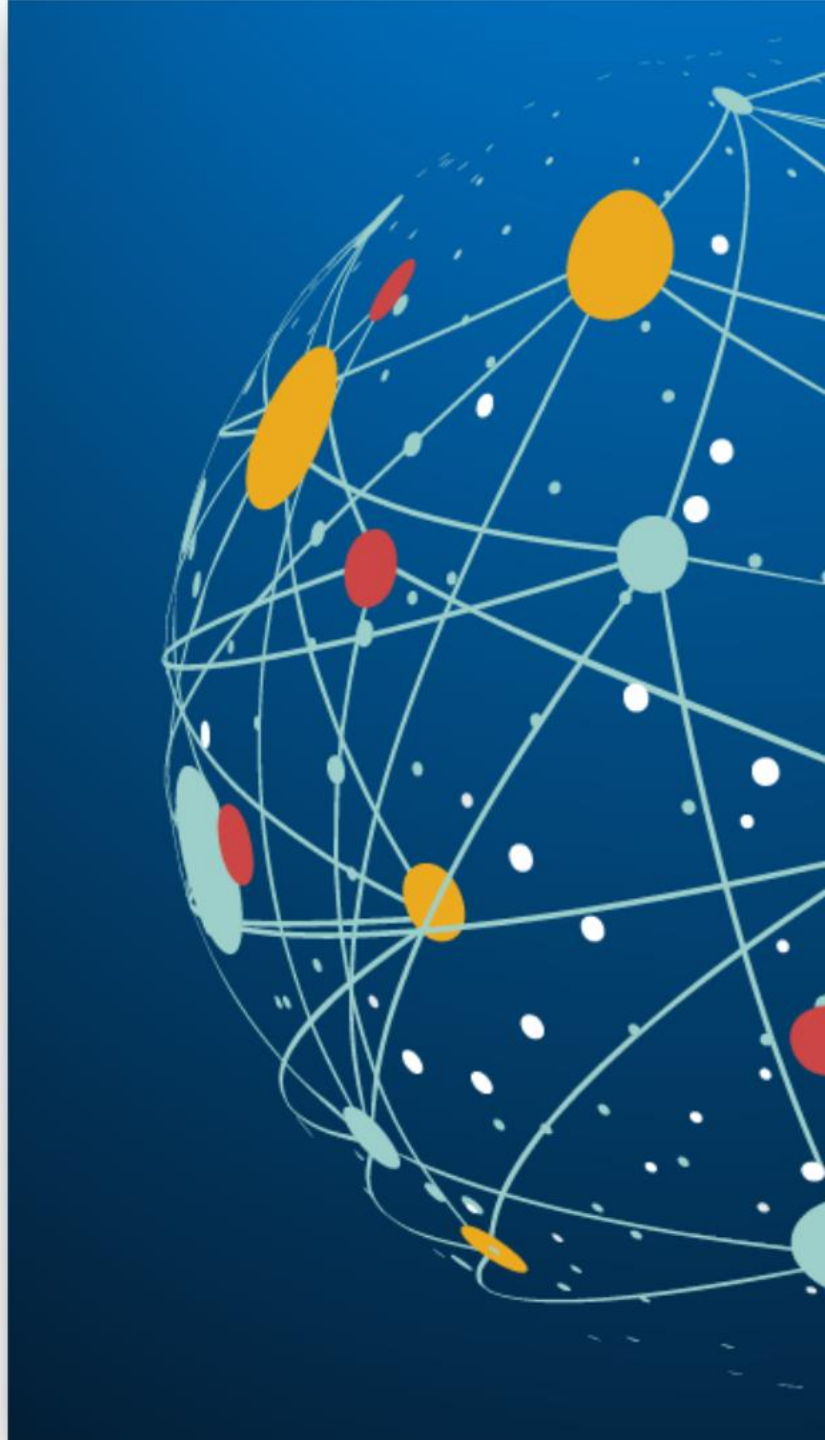
BDS

New BDS Variable: Toxicity Description

- **ATOXDSC**: Analysis Toxicity Description
  - Used to describe the toxicity when not using high and low direction variables
- *Similar to ATOXDSCL, ATOXDSCH*

New Conformance Rule

- Rule for **ATOXDSC**
  - Can’t be used without variable ATOXGR



BDS

New BDS Variables: Nadir analysis

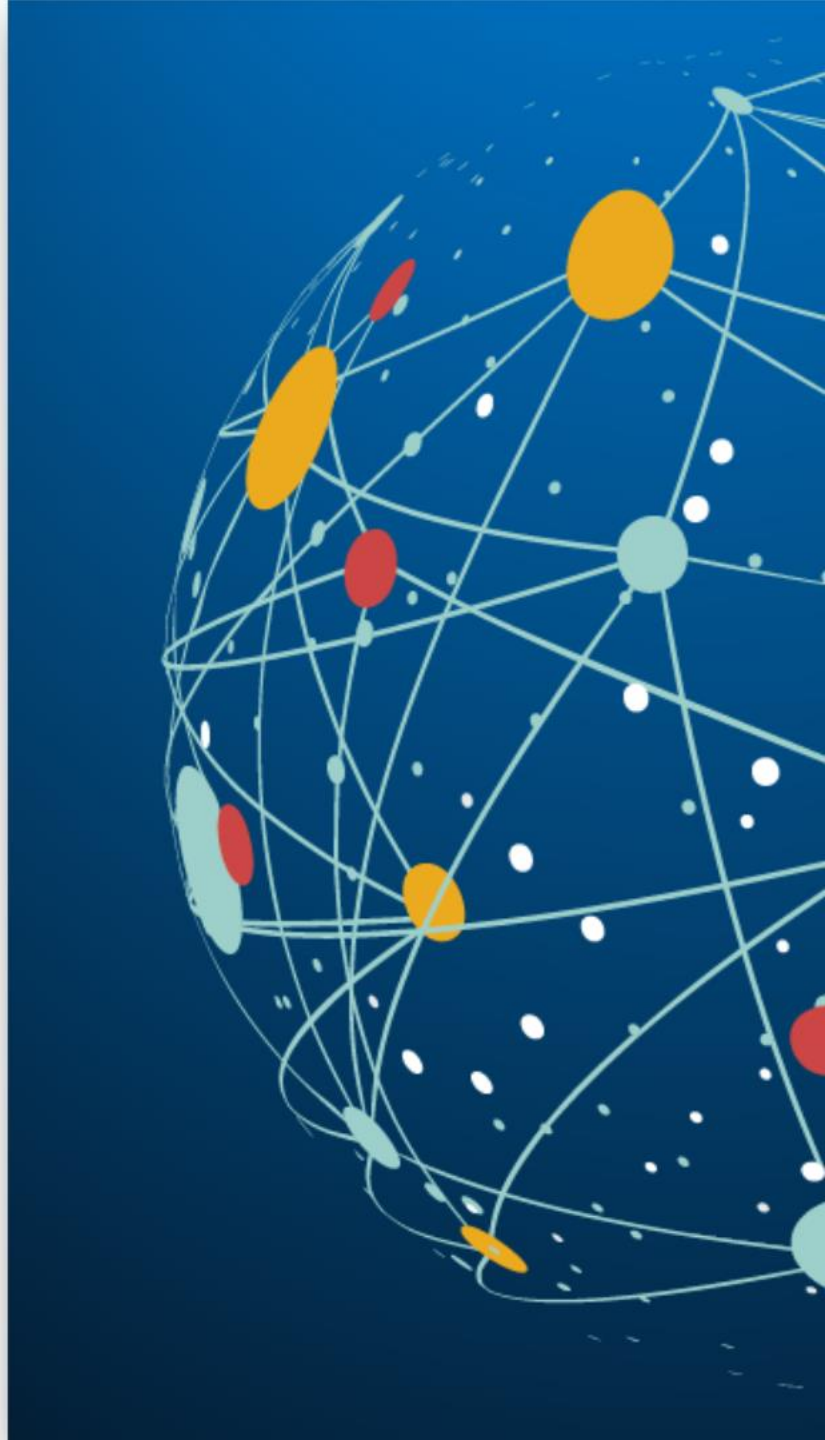
- **NADR**: Nadir Value (lowest value prior to this point in time)
- **NADRCHG**: Change from Nadir Value
- **NADRPCHG**: Percent Change from Nadir Value
- **NADRFL**: Nadir Record Flag
  - Note: allows for multiple records with NADRFL = 'Y' for subject and param

- Note: All variables are permissible.

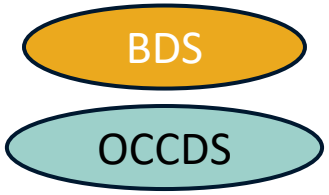
New Conformance Rules

- Rules for **NADR** and **NADRFL**
  - If NADR and NADRFL are present in the dataset and NADR is non-null for at least one record for a subject for that analysis topic, then the value of NADR must equal the value of AVAL on a record flagged by NADRFL for that subject and analysis topic
  - NADRFL can’t be used without variable NADR

- Rules for **NADRCHG**, **NADRPCHG**
  - If present, must be populated for all chronologically post-NADR records when AVAL and NADR are non-missing



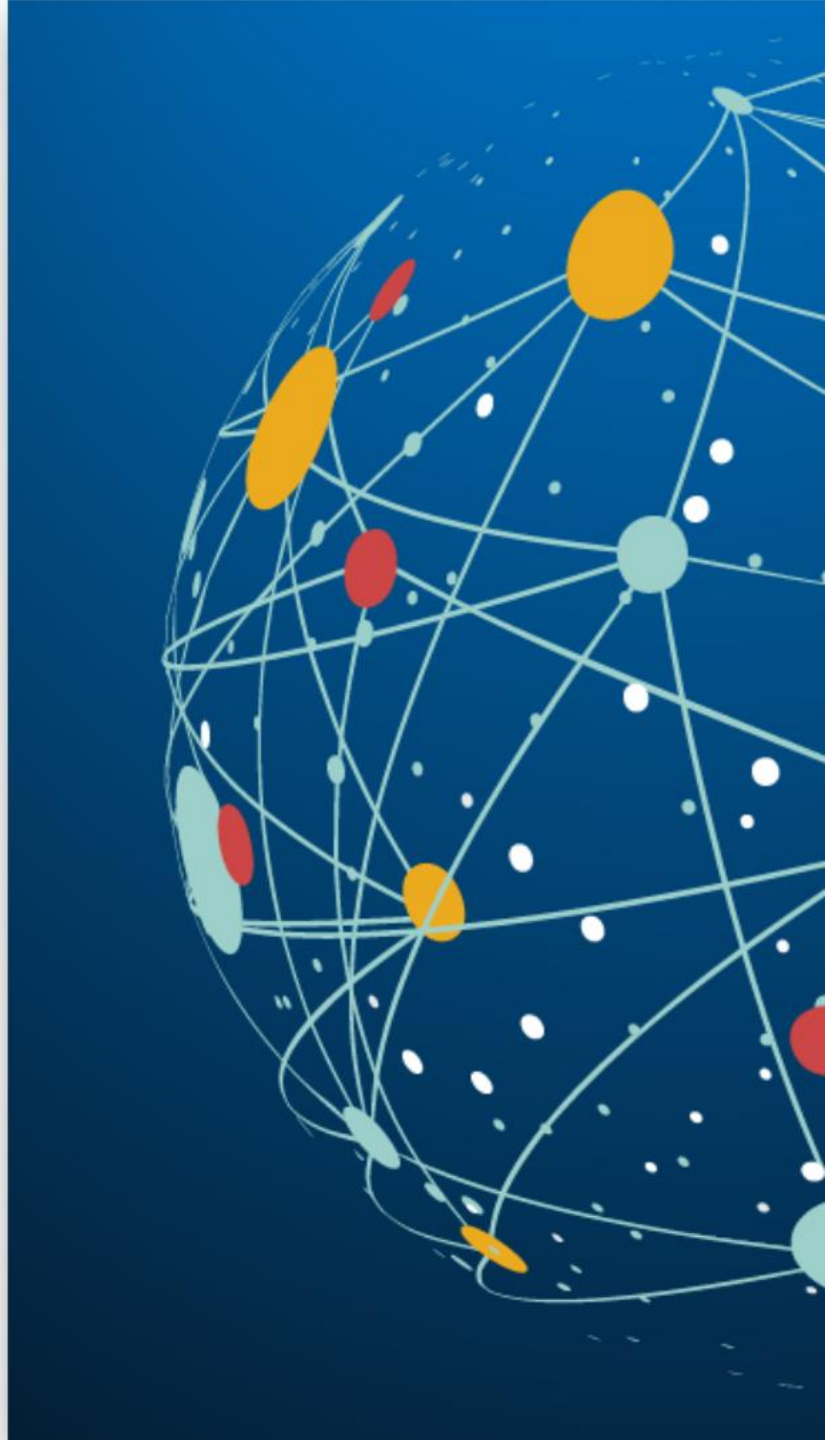
New Timing Variables: Days from an alternate Anchor Date (applies to BDS and OCCDS)



AyDY: Analysis Day using an alternate anchor date	**ASTyDY**: Analysis Start Day using an alternate anchor date	**AENyDY**: Analysis End Day using an alternate anchor date
• Derived from ADT and the alternate anchor date	• Derived from ASTDT and the alternate anchor date	• Derived from AENDT and the alternate anchor date

New Conformance Rules

- Rule for **AyDY**
  - Can’t be used without variable ADT
- Rule for **ASTyDY**
  - Can’t be used without variable ASTDT
- Rule for **AENyDY**
  - Can’t be used without variable AENDT



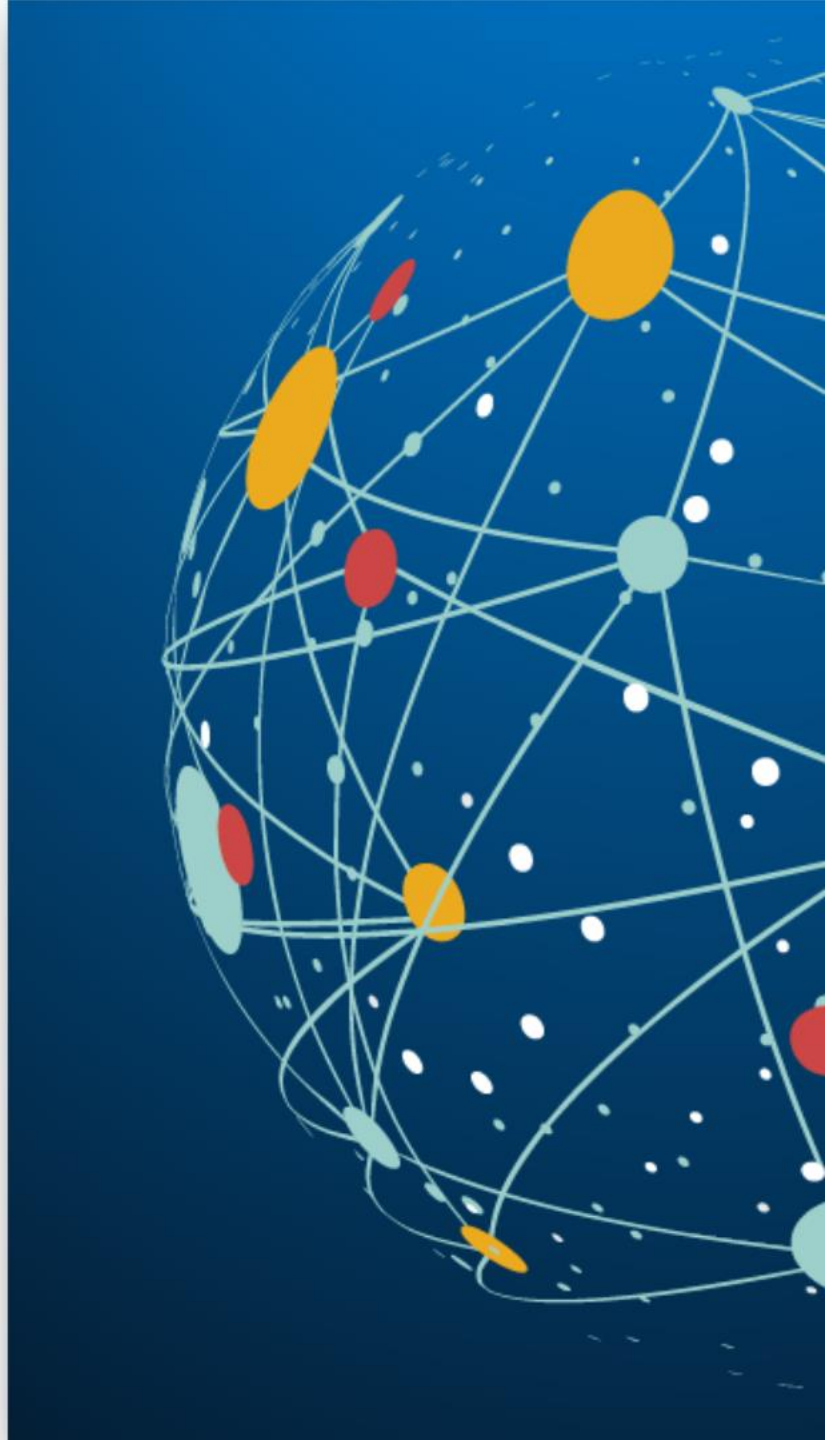
ADSL

New ADSL Variable: Age Units

- **AAGEU**: Analysis Age Units
  - Used when AAGE is in different units than AGE

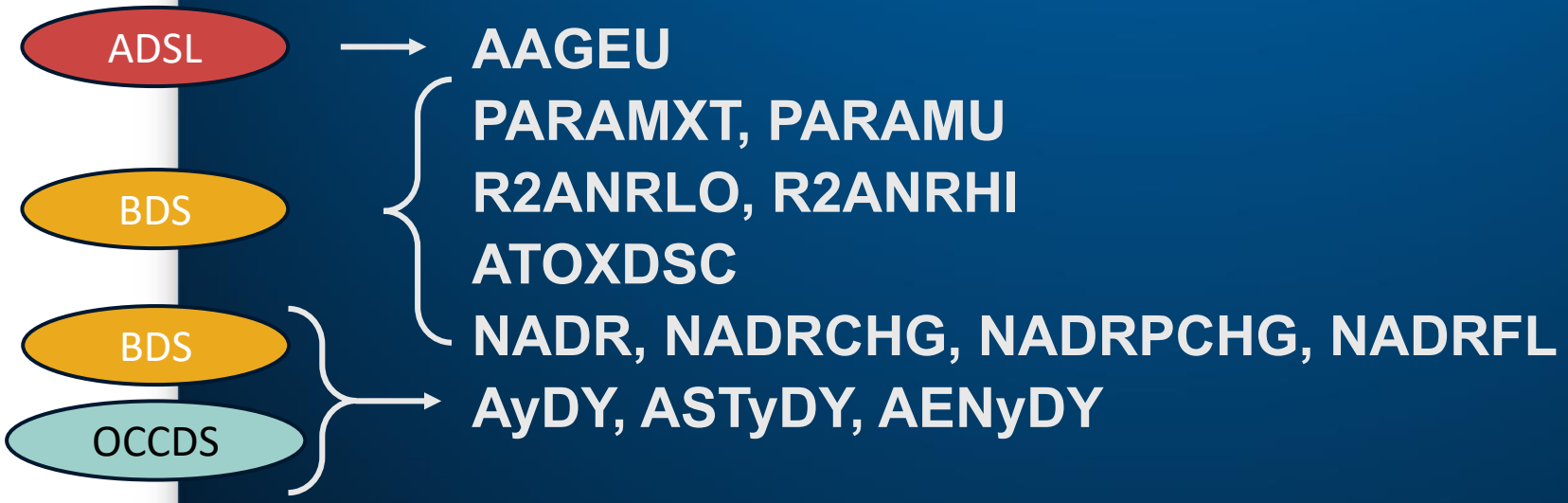
New Conformance Rule

- Rule for **AAGEU**
  - Can’t be used without variable AAGE



Summary

New Variables and their Conformance Rules, to date



Also described “Analysis Topic”

Either PARAM or PARAM + PARAMXT

Thank You!



Backup Slides

Nadir Variables Example

AVISIT	AVAL	NADRFL	NADR	NADRCHG	NADRPCHG
BASELINE	25	Y			
WEEK 1	26		25	1	3.8%
WEEK 2	24	Y	24	0	0%
WEEK 3	27		24	3	12.5%

Notice:

Baseline low value is copied as Nadir until a new lower value is seen