cdisc

2023
US
INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER

**ADaM Discussion Topics:
PARQUAL, ADPL, and NADIR**

Presented by Sandra Minjoe, Senior Principal Clinical Data Standards Consultant
Clinical Data Science - ICON Operational Delivery

Meet the Speaker

Sandra Minjoe

Title: Senior Principal Clinical Data Standards Consultant

Organization: Clinical Data Science - ICON Operational Delivery

Sandra Minjoe has been part of the CDISC ADaM team since 2001, proposed structures that became ADSL and OCCDS, is a former ADaM Team Lead, and continues to work on sub-teams. She focuses on the fundamental principles of traceability and analysis-readiness. Sandra consults on ADaM standard implementation.

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.*
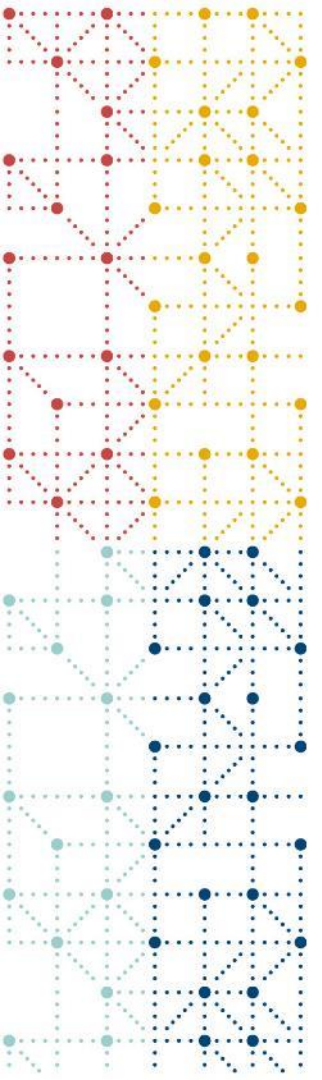
cdisc

Agenda

1. PARQUAL
2. ADPL
3. NADIR

There has been some discussion on these topics at CDISC ADaM team meetings

None of this content is in any official CDISC ADaM document

This presentation is informational, not meant to depict a current or future standard

PARQUAL

PARQUAL History

ADaMIG states: "PARAM must include all descriptive and qualifying information relevant to the analysis purpose of the parameter"

PARQUAL Current Status

- Currently a violation of BDS to use PARQUAL

- Some CDISC TAUGs contain PARQUAL in their examples
- ADaM Oncology Team will include it in their examples document

PARQUAL Example: Prostate Cancer TAUG

- **Use of the PARQUAL Variable:** Some ADaM examples make use of PARQUAL, a proposed variable with restricted defined usage currently under consideration by the CDISC ADaM team. Note, however, that this variable is incompatible with the current ADaMIG, which states, "PARAM must include all descriptive and qualifying information relevant to the analysis purpose of the parameter."

This is an example of an ADTTE dataset for time-to-event variables.

adtte.xpt

Row	STUDYID	USUBJID	TRTP	PARAM	PARQUAL	PARAMCD	AVAL	CNSR	ADT	EVNTDESC
1	ABC-123	ABC-123-001	A	Progression-free survival (months)	INDEPENDENT REVIEW	PFS	10.8090349075975	0	15OCT2014	Radiographic PD
2	ABC-123	ABC-123-001	A	Progression-free survival (months)	INVESTIGATOR REVIEW	PFS	15.8090349075975	0	20OCT2014	Radiographic PD
3	ABC-123	ABC-123-002	A	Progression-free survival (months)	INDEPENDENT REVIEW	PFS	3.81108829568789	0	07APR2014	Radiographic PD
4	ABC-123	ABC-123-002	A	Progression-free survival (months)	INVESTIGATOR REVIEW	PFS	3.81108829568789	1	07APR2014	No PD or Death

What to Expect in the Future

ADaM v3.0 (tentative release 2024-2025) is working to address this

- Current thought is to include a pair of variables

PARQUAL	PARQTYPE (tentative name)
Parameter Qualifier	Parameter Qualifier Type
Contains the qualifying text needed to fully describe PARAM	Is one of the allowed types of qualifications
Not subject to CDISC CT	Uses CDISC Non-Extensible CT
Must be used with variable PARQTYPE	Must be one of the CDISC CTs

- Allows PARQUAL to be used in certain specific situations
  - Conformance rules will be included to prevent misuse
  - Allows for future growth, by ADaM team approving other use cases through CT updates

cdisc

Possible Example Update for PARQUAL/PARQTYPE

This is an example of an ADTTE dataset for time-to-event variables.

adtte.xpt

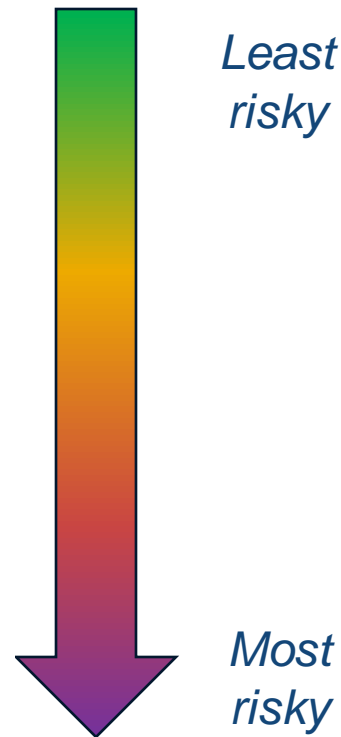| Row	STUDYID	USUBJID	TRTP	PARAM	PARQUAL	PARAMCD	AVAL	CNSR	ADT	EVNTDESC
1	ABC-123	ABC-123-001	A	Progression-free survival (months)	INDEPENDENT REVIEW	PFS	10.8090349075975	0	15OCT2014	Radiographic PD
2	ABC-123	ABC-123-001	A	Progression-free survival (months)	INVESTIGATOR REVIEW	PFS	15.8090349075975	0	20OCT2014	Radiographic PD
3	ABC-123	ABC-123-002	A	Progression-free survival (months)	INDEPENDENT REVIEW	PFS	3.81108829568789	0	07APR2014	Radiographic PD
4	ABC-123	ABC-123-002	A	Progression-free survival (months)	INVESTIGATOR REVIEW	PFS	3.81108829568789	1	07APR2014	No PD or Death

Would need to add variable **PARQTYPE*** with value of "**ASSESSOR**"* to all records where PARQUAL is either "INDEPENDENT REIVEW" or "INVESTIGATOR REVIEW"
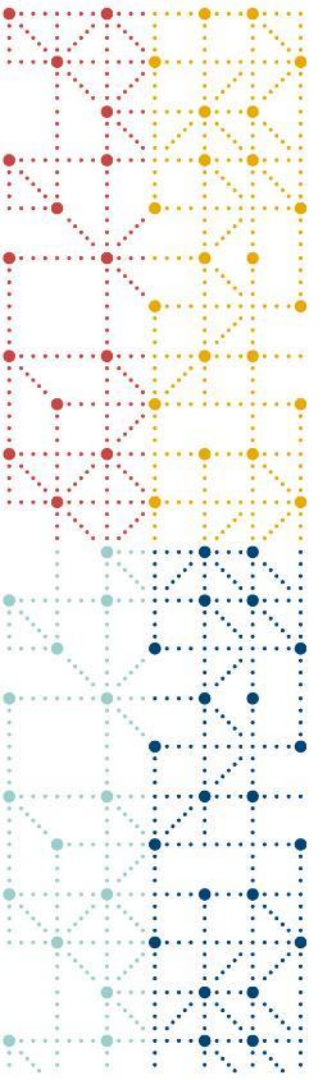
* tentative

cdisc

What Are Your Current Options Regarding PARQUAL?

Do not use PARQUAL

- Put all qualifying information into PARAM
- Create separate datasets for each "qualifier"

Least risky

Most risky

cdisc

ADPL

ADPL Introduction

How to handle when a subject participates in a study more than once?

- Screen failure then retry (sometimes more than once)
- Multiple enrollments within the same study
- Integration datasets, where the same subject participated in multiple studies

ADSL is structured as one record per USUBJID

- Conformance rules check for this

Structuring ADSL as one record per USUBJID <u>per participation</u> breaks conformance rules

- Any tools that depend on the one record per USUBJID structure will probably not work
- Some reviewers are adamant about the one record per USUBJID rule

Proposal for Multiple Participations in SDTM

SDTM Proposal
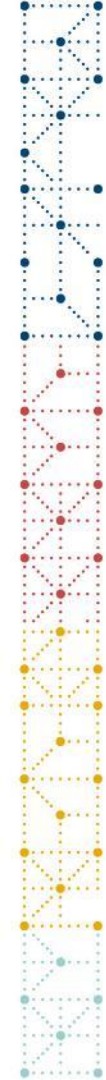*(out for public review in 2022)*

- DC structured as one record per subject participation (**SUBJID**)
- DM continues to be one record per unique person (**USUBJID**)

- Sponsor identifies which participation is "primary" (to put in DM)

- SUBJID is added to any SDTM domain where needed

cdisc

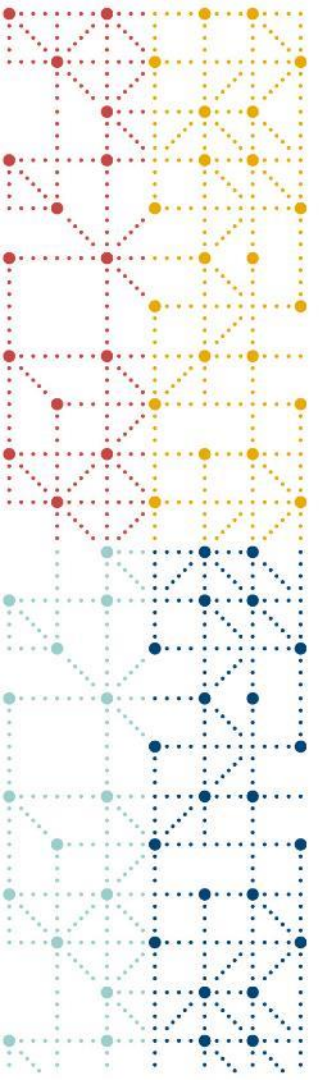# Proposal for Multiple Participations in ADaM

ADaM Team Discussion

- Create ADPL (Participation-Level Analysis Dataset)
  - Structure as one record per subject participation (**SUBJID**)
- ADSL continues to be one record per unique person (**USUBJID**)
- Add a standard dataset structure for ADPL

cdisc

What Can You Do Now?

NADIR

Nadir and BDS

What is Nadir?

- Lowest value of the parameter

Common Nadir variables needed for analysis

- Change from Nadir
- Percent Change from Nadir

cdisc

Solutions for Nadir Analysis

Compliant(ish) BDS Solution 1

- Treat Nadir as another "baseline"
  - Use BASETYPE = 'Nadir'
- Essentially doubles the size of the dataset
- Makes review confusing

cdisc

Solutions for Nadir Analysis

Non-Compliant BDS Solution

- Add variables for
  - Nadir
  - Change from Nadir
  - Percent Change from Nadir

cdisc

What to Expect in the Future

ADaM v3.0 (tentative release 2024-2025) is planning to add Nadir and other similar variables to BDS
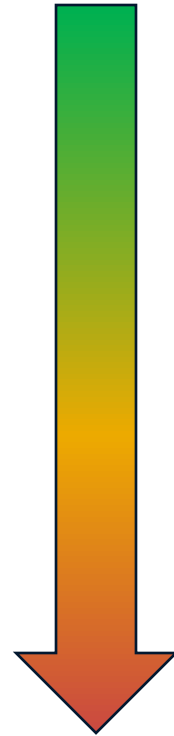
cdisc

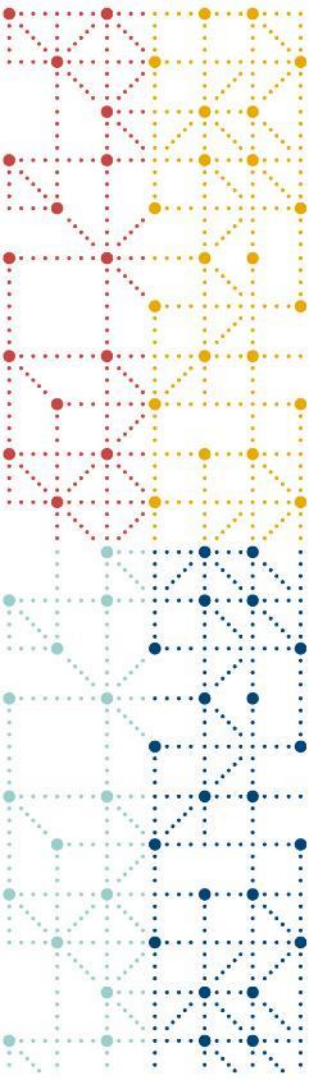# What Are Your Current Options Regarding Nadir?

Add Nadir variables, but don't call it BDS

- Pro: ADaM-compliant
- Con: can't take advantage of any tools that depend on BDS structure
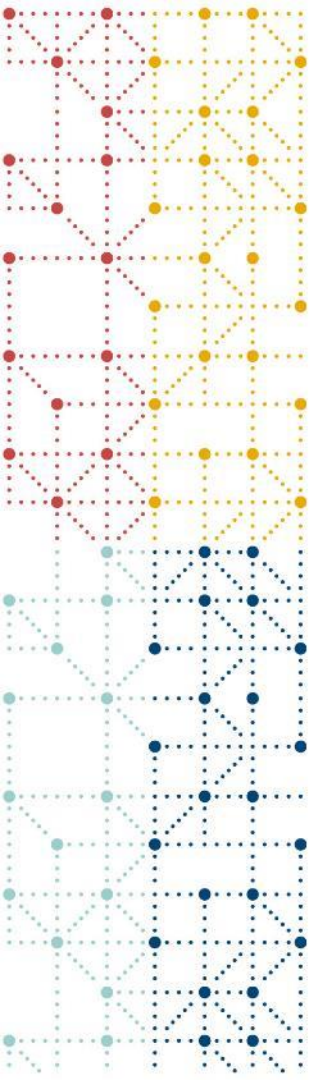
Most compliant

Least compliant

cdisc

Summary

1. PARQUAL
2. ADPL
3. NADIR

Consider using only for situations the ADaM team is planning to allow.

Legal now do this, just call the structure ADAM OTHER.

Consider adding variables. Decide whether to call it BDS or ADAM OTHER.

Thank You!