
# *Derived Parameters: Best Practices to Ensure Clear Sightlines to Traceable Data*

Presented by Amanda Johnson, Merck & Co., Inc., Associate Principal Scientist, Stat Programming

# Meet the Speaker

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I’ve been involved with everything from raw data extraction to CDISC SDTM and ADaM programming, TFL development, Define.xml development, Global Data Standards support (ADaM focus). Lately I have been supporting regulatory submissions to different authorities as a standards quality submissions consultant. I have a particular interest in analytics and love to learn.

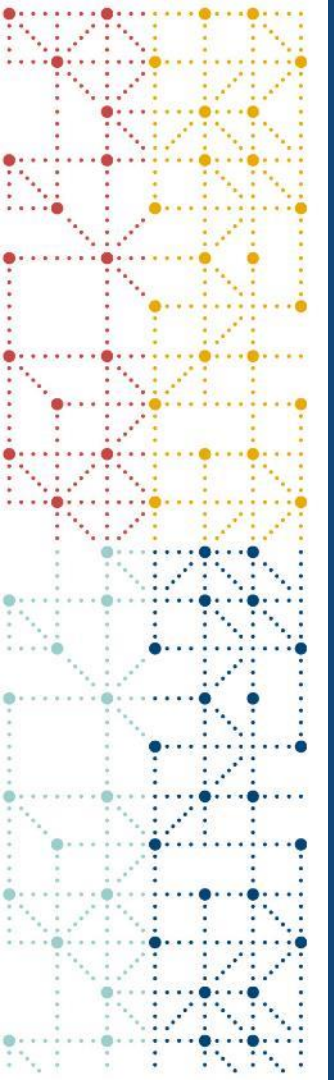
# Disclaimer and Disclosures

- *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.*

- *The author(s) have no real or apparent conflicts of interest to report.*

# Agenda

1. When to Derive a Parameter or add a Variable
2. ADaM IG Rules – Uncovering the Details
3. Examples of Implementation Struggles + Solutions
4. Key Takeaways



# Deriving a Parameter vs. Adding a Variable

Which one is the right choice for me?

# Deriving a parameter vs. adding a variable

## How can you tell which to do, and why does it matter?

Back in 2016 the FDA Business and Validation Rules required CDISC compliance for all submissions. Yet, many people are unsure of what it means to be CDISC compliant.

What is the definition?

It varies from person to person; however, most people would point to the following as evidence that they are being CDISC compliant:

- Pinnacle 21 fitness scores
- Internal checklists
- FDA compliance lists

# Deriving a parameter vs. adding a variable, Cont.

**Yet we often discuss in the ADaM team that neither is enough to make your study *truly* compliant.**

**To us, being *truly compliant* is a multi-tiered approach:**

- Did you follow the guidelines from CDISC?
- When looking at ADaM, have you kept to the fundamental principles?
- Are the ADaM rules for deriving a parameter versus adding a variable violated?

We know these are things which come with experience, so we'd like to share and clarify one of our favorite topics – when, why and how to derive a parameter

# Sightline: CDISC ADaM IG Rules

Currently, we have 6 rules in ADaM which are unique.

These rules go into detail on when to derive a column (variable) versus a row (analysis parameter).

Recently, it has become very evident to me that these rules may be misunderstood. Furthermore, the examples in the ADaMIG are limited in scope.

We are going to explore these rules and their implications further.

# Sightline: CDISC ADaM IG Rules

# Sightline: CDISC ADaM IG Rules

**Rule 1 –** covers when to add a new variable, such as CHG.

**Rule 2 –** Covers situations when AVAL, BASE or CHG would be altered for analysis purposes, which warrants a new parameter.

**Let's take a shot at Rule 2 and try to understand it a bit more.**

**4.2.1.2 Rule 2: A transformation of AVAL that does not meet the conditions of Rule 1 should be added as a new parameter, and AVAL should contain the transformed value.**

If the intention is to redefine AVAL, BASE, CHG, etc. in terms of a transform of AVAL, then a new parameter must be added in which PARAM describes the transform. ***The creation of a new parameter results, by definition, in the creation of a new set of rows.***

For example, as described in the discussion of Rule 1, in a change from baseline analysis of the logarithm of weight, AVAL should contain the log of weight, BASE should contain the baseline value of the log of weight, and CHG should contain the difference between the two. PARAM should contain a description of the transformed data contained in AVAL, e.g., "Log10 (Weight (kg))". In this way the ADaM standard accommodates an analysis of transformed data in the standard columns without creating a multiplicity of new special-purpose columns.

# Sightline: CDISC ADaM IG Rule #2

**Rule 2 –** ‘If the intention is to redefine AVAL, BASE, CHG, etc. in terms of a transform of AVAL, then a new parameter must be added in which PARAM describes the transform. *The creation of a new parameter results, by definition, in the creation of a new set of rows.’* CDISC ADaM IG v1.3, Section 4.2.1.2, page 55

What does it mean to redefine AVAL? Some may say this is up to interpretation, but common options are:

1) Impute AVAL for analysis needs
2) Perform an algorithmic transformation of the analysis value

Let’s take a look of an example…

# Example 1 Covert Introduction: A New Parameter?

**Study Dilemma #1:** The value of AVAL is 0 for specific parameters, which does not contribute to our analysis. We cannot model using 0, so we need to impute.

- This study needed to impute values for certain parameters, so their solution was to add AVAL1.
  - PS: Our friendly industry checker won't complain.

Fact: In BDS, we need results in AVAL (or BASE, CHG) only.

- Here we see the situation where AVAL doesn't equal AVAL1

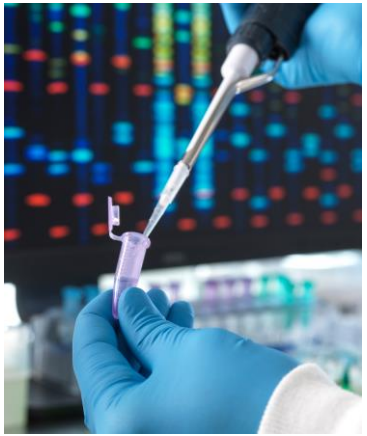
| | SUBJID | SITENUM | TRT01AN | TRTSDT | STRATARN | PERIOD | TRTAN | DAY | PPSPEC | PPCATN | PARAMCD | PARAM | PARAMN | PPSTRESC | AVAL | AVAL1 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 000103 | 0001 | 2 | 2022-09-23 | 1 | 1 | 2 | 1 | URINE | 2 | RCAMINT | Amt Rec from 0 to 24 Hour (mg) | 8 | 0 | 0 | 0.001263174 |
| 2 | 000103 | 0001 | 2 | 2022-09-23 | 1 | 1 | 2 | 1 | URINE | 2 | RCPCINT | Pct Rec from 0 to 24 Hour (%) | 9 | 0 | 0 | 0.01263174 |
| 3 | 000103 | 0001 | 2 | 2022-09-23 | 1 | 1 | 2 | 1 | URINE | 2 | RENALCL | Renal CL (L/h) | 10 | 0 | 0 | 0.0180442897 |
| 4 | 000008 | 0002 | 2 | 2022-05-24 | 1 | 1 | 2 | 1 | URINE | 2 | RCAMINT | Amt Rec from 0 to 24 Hour (mg) | 8 | 0 | 0 | 0.001263174 |
| 5 | 000008 | 0002 | 2 | 2022-05-24 | 1 | 1 | 2 | 1 | URINE | 2 | RCPCINT | Pct Rec from 0 to 24 Hour (%) | 9 | 0 | 0 | 0.01263174 |
| 6 | 000008 | 0002 | 2 | 2022-05-24 | 1 | 1 | 2 | 1 | URINE | 2 | RENALCL | Renal CL (L/h) | 10 | 0 | 0 | 0.010953321 |
| 7 | 000104 | 0002 | 2 | 2022-08-30 | 1 | 1 | 2 | 1 | URINE | 2 | RCAMINT | Amt Rec from 0 to 24 Hour (mg) | 8 | 0 | 0 | 0.001263174 |
| 8 | 000104 | 0002 | 2 | 2022-08-30 | 1 | 1 | 2 | 1 | URINE | 2 | RCPCINT | Pct Rec from 0 to 24 Hour (%) | 9 | 0 | 0 | 0.01263174 |
| 9 | 000104 | 0002 | 2 | 2022-08-30 | 1 | 1 | 2 | 1 | URINE | 2 | RENALCL | Renal CL (L/h) | 10 | 0 | 0 | 0.0313148939 |
| 10 | 000016 | 0002 | 2 | 2022-12-14 | 2 | 1 | 2 | 1 | URINE | 2 | RCAMINT | Amt Rec from 0 to 24 Hour (mg) | 8 | 0 | 0 | 0.0037057405 |
| 11 | 000016 | 0002 | 2 | 2022-12-14 | 2 | 1 | 2 | 1 | URINE | 2 | RCPCINT | Pct Rec from 0 to 24 Hour (%) | 9 | 0 | 0 | 0.037057405 |
| 12 | 000016 | 0002 | 2 | 2022-12-14 | 2 | 1 | 2 | 1 | URINE | 2 | RENALCL | Renal CL (L/h) | 10 | 0 | 0 | 0.2112417732 |
| 13 | 000014 | 0002 | 2 | 2023-02-01 | 2 | 1 | 2 | 1 | URINE | 2 | RCAMINT | Amt Rec from 0 to 24 Hour (mg) | 8 | 0 | 0 | 0.0037057405 |
| 14 | 000014 | 0002 | 2 | 2023-02-01 | 2 | 1 | 2 | 1 | URINE | 2 | RCPCINT | Pct Rec from 0 to 24 Hour (%) | 9 | 0 | 0 | 0.037057405 |
| 15 | 000014 | 0002 | 2 | 2023-02-01 | 2 | 1 | 2 | 1 | URINE | 2 | RENALCL | Renal CL (L/h) | 10 | 0 | 0 | 0.063575925 |

# Zooming in #1 – A new parameter in disguise

**Solution: Add a *new parameter* to explain this**

**Situation:** If analysis cannot run based on 0, and there is an agreed upon algorithm, then there should be new parameters added.

These new parameters should unambiguously describe the analysis result (AVAL) which is clearly done in a new parameter.



The suggested approach: use AVAL, not AVAL1.

- AVAL1 might potentially confuse a reviewer
- While you could document in the ADRG, it would be better to fix.
- CDISC didn't design AVALy… but maybe we need to address it.
  - ✓ Food for thought as we develop ADaM v3

| | SUBJID | SITENUM | TRT01AN | TRTSDT | STRATARN | PERIOD | TRTAN | DAY | PPSPEC | PPCATN | PARAM | PARAMN | | PPSTRESC | AVAL |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 000103 | 0001 | 2 | 2022-09-23 | 1 | 1 | 2 | 1 | URINE | 2 | Amt Rec from 0 to 24 Hour (mg) - Imputed | 8 | 0 | | 0.001263174 |
| 2 | 000103 | 0001 | 2 | 2022-09-23 | 1 | 1 | 2 | 1 | URINE | 2 | Pct Rec from 0 to 24 Hour (%) - Imputed | 9 | 0 | | 0.01263174 |
| 3 | 000103 | 0001 | 2 | 2022-09-23 | 1 | 1 | 2 | 1 | URINE | 2 | Renal CL (L/h) - Imputed | 10 | 0 | | 0.0180442897 |
| 4 | 000008 | 0002 | 2 | 2022-05-24 | 1 | 1 | 2 | 1 | URINE | 2 | Amt Rec from 0 to 24 Hour (mg) - Imputed | 8 | 0 | | 0.001263174 |
| 5 | 000008 | 0002 | 2 | 2022-05-24 | 1 | 1 | 2 | 1 | URINE | 2 | Pct Rec from 0 to 24 Hour (%) - Imputed | 9 | 0 | | 0.01263174 |
| 6 | 000008 | 0002 | 2 | 2022-05-24 | 1 | 1 | 2 | 1 | URINE | 2 | Renal CL (L/h) - Imputed | 10 | 0 | | 0.010953321 |
| 7 | 000104 | 0002 | 2 | 2022-08-30 | 1 | 1 | 2 | 1 | URINE | 2 | Amt Rec from 0 to 24 Hour (mg) - Imputed | 8 | 0 | | 0.001263174 |
| 8 | 000104 | 0002 | 2 | 2022-08-30 | 1 | 1 | 2 | 1 | URINE | 2 | Pct Rec from 0 to 24 Hour (%) - Imputed | 9 | 0 | | 0.01263174 |
| 9 | 000104 | 0002 | 2 | 2022-08-30 | 1 | 1 | 2 | 1 | URINE | 2 | Renal CL (L/h) - Imputed | 10 | 0 | | 0.0313148939 |
| 10 | 000016 | 0002 | 2 | 2022-12-14 | 2 | 1 | 2 | 1 | URINE | 2 | Amt Rec from 0 to 24 Hour (mg) - Imputed | 8 | 0 | | 0.003705740 |
| 11 | 000016 | 0002 | 2 | 2022-12-14 | 2 | 1 | 2 | 1 | URINE | 2 | Pct Rec from 0 to 24 Hour (%) - Imputed | 9 | 0 | | 0.037057405 |
| 12 | 000016 | 0002 | 2 | 2022-12-14 | 2 | 1 | 2 | 1 | URINE | 2 | Renal CL (L/h) - Imputed | 10 | 0 | | 0.2112417732 |
| 13 | 000014 | 0002 | 2 | 2023-02-01 | 2 | 1 | 2 | 1 | URINE | 2 | Amt Rec from 0 to 24 Hour (mg) - Imputed | 8 | 0 | | 0.003705740 |
| 14 | 000014 | 0002 | 2 | 2023-02-01 | 2 | 1 | 2 | 1 | URINE | 2 | Pct Rec from 0 to 24 Hour (%) - Imputed | 9 | 0 | | 0.037057405 |
| 15 | 000014 | 0002 | 2 | 2023-02-01 | 2 | 1 | 2 | 1 | URINE | 2 | Renal CL (L/h) - Imputed | 10 | 0 | | 0.063575926 |

# When adding a new row in BDS, what should VSDTC be?

## Please consider this next example:

When adding a record and *correctly following* Rule #2, you should consider all the source variables that are coming directly from SDTM, because this is your **traceability element.**

**Fact: Traceability is a crucial element of CDISC and therefore compliance.**

| | SUBJID | SITEID | ASEQ | VSSEQ | TRTA | VSGRPID | VSDTC | ADT | ATM | ADTM | ADY | AVISIT | VSTPTNUM | ATPTN | PARAM | PARAMCD | PARAMN | PARCAT1 | VSPOS | VSSTRESC | AVAL | AVALC | ABLFL | BASE | BASEC | BASETYPE | CHG | DTYPE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 0004-000001 | 0004 | 1 | 6 | | P0/SEM1 | 2024-04-23T08:29:43 | 2024-04-23 | 8:29:43 | 23APR2024:08:29:43 | -18 | SCREENING | Screening | | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 125 | 125 | 125 | | | | | | |
| 2 | 0004-000001 | 0004 | 2 | 8 | B | P1/D1/H-1.75/SEM5 | 2024-05-11T05:45:04 | 2024-05-11 | | | 1 | PERIOD 1 DAY 1 | Baseline | -1.75 | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 126 | 126 | 126 | Y | 126 | 126 | PERIOD 1, PREDOSE | | MEDIAN |
| 3 | 0004-000001 | 0004 | 3 | 15 | B | P1/D1/H-1.75/SEM5 | 2024-05-11T05:45:04 | 2024-05-11 | 5:45:04 | 11MAY2024:05:45:04 | 1 | PERIOD 1 DAY 1 | Day 1 | -1.75 | -2 Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 114 | 114 | 114 | | | | | | |
| 4 | 0004-000001 | 0004 | 4 | 18 | B | P1/D1/H-1.75/SEM1 | 2024-05-11T05:46:23 | 2024-05-11 | 5:46:23 | 11MAY2024:05:46:23 | 1 | PERIOD 1 DAY 1 | Day 1 | -1.75 | -2 Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 126 | 126 | 126 | | | | | | |
| 5 | 0004-000001 | 0004 | 5 | 21 | B | P1/D1/H-1.75/SEM1 | 2024-05-11T05:47:41 | 2024-05-11 | 5:47:41 | 11MAY2024:05:47:41 | 1 | PERIOD 1 DAY 1 | Day 1 | -1.75 | -2 Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 130 | 130 | 130 | | | | | | |
| 6 | 0004-000001 | 0004 | 6 | . | A | P2/D1/H-1.75/SEM5 | 2024-05-25T05:47:19 | 2024-05-25 | | | 15 | PERIOD 2 DAY 1 | Baseline | -1.75 | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 125 | 125 | 125 | Y | 125 | 125 | PERIOD 2, PREDOSE | | MEDIAN |
| 7 | 0004-000001 | 0004 | 7 | 63 | A | P2/D1/H-1.75/SEM5 | 2024-05-25T05:47:19 | 2024-05-25 | 5:47:19 | 25MAY2024:05:47:19 | 15 | PERIOD 2 DAY 1 | Day 1 | -1.75 | -2 Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 125 | 125 | 125 | | | | | | |
| 8 | 0004-000001 | 0004 | 8 | 66 | A | P2/D1/H-1.75/SEM1 | 2024-05-25T05:48:44 | 2024-05-25 | 5:48:44 | 25MAY2024:05:48:44 | 15 | PERIOD 2 DAY 1 | Day 1 | -1.75 | -2 Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 124 | 124 | 124 | | | | | | |
| 9 | 0004-000001 | 0004 | 9 | 69 | A | P2/D1/H-1.75/SEM1 | 2024-05-25T05:49:48 | 2024-05-25 | 5:49:48 | 25MAY2024:05:49:48 | 15 | PERIOD 2 DAY 1 | Day 1 | -1.75 | -2 Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 133 | 133 | 133 | | | | | | |

# Example 2 – Adding a new row in BDS, how can you say what VSDTC should be?

- **However, when looking at CDISC ADaM IG v1.3, we noticed that there are not any date/time variables in the examples that would help to illustrate this point.**

**Fact: Date of collection in this case is not optimal to populate.**

Without any xxDTC references in the rules section, it might be unclear to a reader what to do in regard to source variable population.

**Solution:**

- **Remove VSGRPID and VSDTC.**

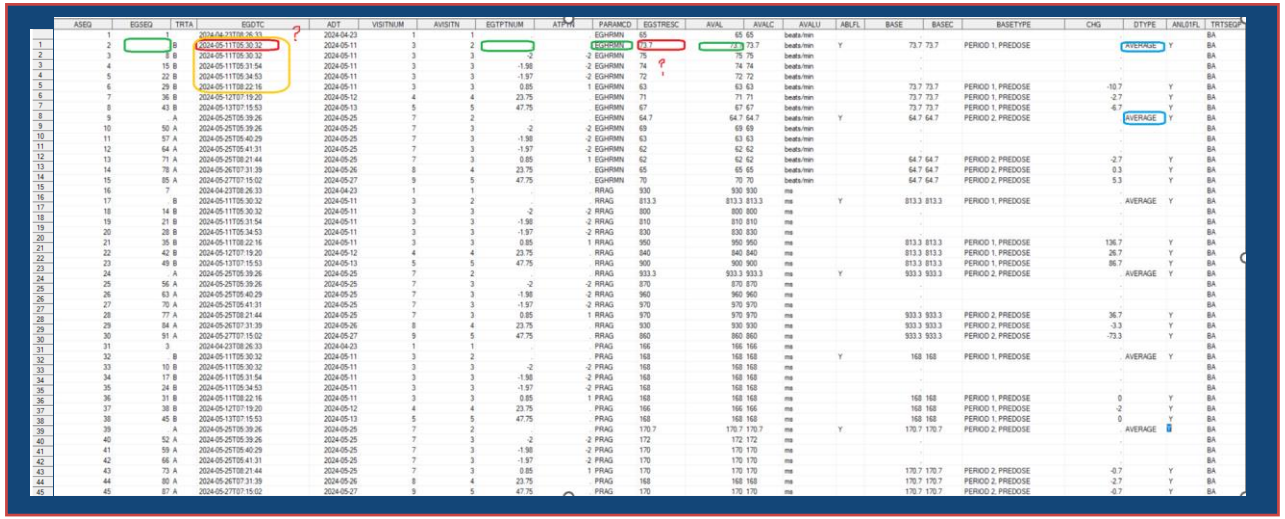
| | SUBJID | SITEID | ASEQ | VSSEQ | TRTA | VSGRPID | VSDTC | ADT | ATM | ADTM | ADY | AVISIT | AVISIT | VSTPTNUM | ATPTN | PARAM | PARAMCD | PARAMN | PARCAT1 | VSPOS | VSSTRESC | AVAL | AVALC | ABLFL | BASE | BASEC | BASETYPE | CHG | DTYPE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 0004-000001 | 0004 | 1 | 1 | | P0/SEM1 | 2024-04-23T08:29:43 | 2024-04-23 | 8:29:43 | 23APR2024:08:29:43 | -18 | SCREENING | Screening | | | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 125 | 125 | 125 | | | | | | |
| 2 | 0004-000001 | 0004 | 2 | | B | [redacted] | | 2024-05-11 | | | 1 | PERIOD 1 DAY 1 | Baseline | -1.75 | | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 126 | 126 | 126 | Y | 126 | 126 | PERIOD 1, PREDOSE | | MEDIAN |
| 3 | 0004-000001 | 0004 | 3 | 15 | B | P1/D1/H-1.75/SEM5 | 2024-05-11T05:45:04 | 2024-05-11 | 5:45:04 | 11MAY2024:05:45:04 | 1 | PERIOD 1 DAY 1 | Day 1 | -1.75 | -2 | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 114 | 114 | 114 | | | | | | |
| 4 | 0004-000001 | 0004 | 4 | 18 | B | P1/D1/H-1.75/SEM1 | 2024-05-11T05:46:23 | 2024-05-11 | 5:46:23 | 11MAY2024:05:46:23 | 1 | PERIOD 1 DAY 1 | Day 1 | -1.75 | -2 | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 126 | 126 | 126 | | | | | | |
| 5 | 0004-000001 | 0004 | 5 | 21 | B | P1/D1/H-1.75/SEM1 | 2024-05-11T05:47:41 | 2024-05-11 | 5:47:41 | 11MAY2024:05:47:41 | 1 | PERIOD 1 DAY 1 | Day 1 | -1.75 | -2 | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 130 | 130 | 130 | | | | | | |
| 6 | 0004-000001 | 0004 | 6 | | A | [redacted] | | 2024-05-25 | | | 15 | PERIOD 2 DAY 1 | Baseline | -1.75 | | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 125 | 125 | 125 | Y | 125 | 125 | PERIOD 2, PREDOSE | | MEDIAN |
| 7 | 0004-000001 | 0004 | 7 | 63 | A | P2/D1/H-1.75/SEM5 | 2024-05-25T05:47:19 | 2024-05-25 | 5:47:19 | 25MAY2024:05:47:19 | 15 | PERIOD 2 DAY 1 | Day 1 | -1.75 | -2 | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 125 | 125 | 125 | | | | | | |
| 8 | 0004-000001 | 0004 | 8 | 66 | A | P2/D1/H-1.75/SEM1 | 2024-05-25T05:48:44 | 2024-05-25 | 5:48:44 | 25MAY2024:05:48:44 | 15 | PERIOD 2 DAY 1 | Day 1 | -1.75 | -2 | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 124 | 124 | 124 | | | | | | |
| 9 | 0004-000001 | 0004 | 9 | 69 | A | P2/D1/H-1.75/SEM1 | 2024-05-25T05:49:48 | 2024-05-25 | 5:49:48 | 25MAY2024:05:49:48 | 15 | PERIOD 2 DAY 1 | Day 1 | -1.75 | -2 | Systolic Blood Pressure (mmHg) | SYSBP | 1 | STANDARD | SEMI-RECUMBENT | 133 | 133 | 133 | | | | | | |

# Example 3: A Similar Dilemma What EGDTC should be?

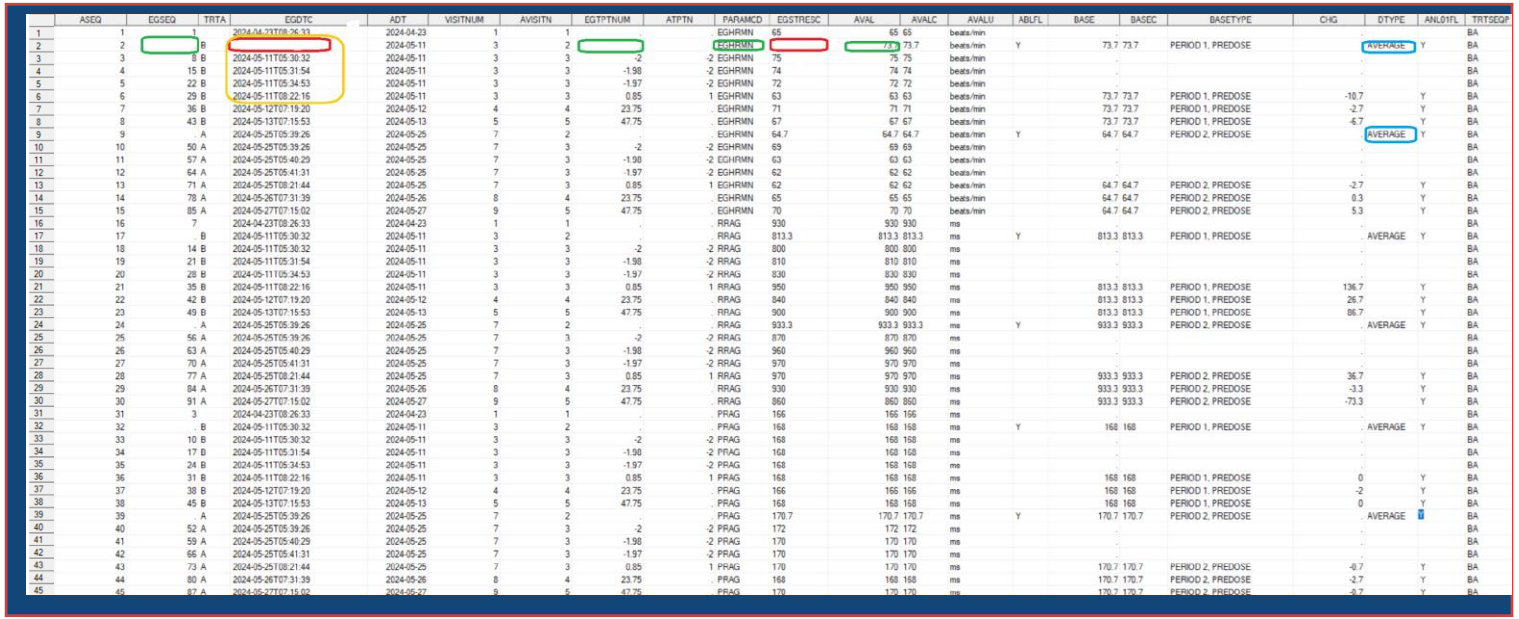
## Lastly, let's look at this situation:

When adding a record, we need to consider the source records from SDTM EG *completely.*

EGSTRESC & EGDTC should be null, since we cannot definitively say that the 'AVERAGE' record was derived from one date with a single result.



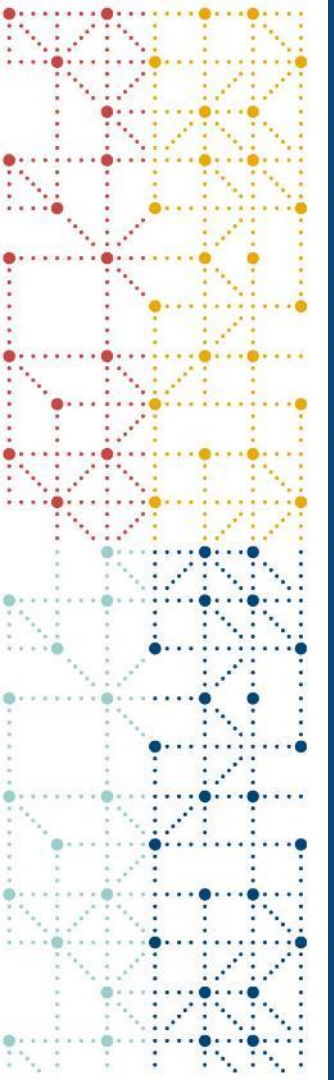
# Solution– remove EGDTC and EGSTRESC



| | ASEQ | EGSEQ | TRTA | EGDTC | ADT | VISITNUM | AVISITN | EGTPTNUM | ATPTN | PARAMCD | EGSTRESC | AVAL | AVALC | AVALU | ABLFL | BASE | BASEC | BASETYPE | CHG | DTYPE | ANL01FL | TRTSEQP |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 | 1 | | 2024-04-23T08:26:33 | 2024-04-23 | 1 | 1 | | | EGHRMN | 65 | 65 | 65 | beats/min | | | | | | | | BA |
| 2 | 2 | | B | 2024-05-11T05:30:32 | 2024-05-11 | 3 | 2 | | | EGHRMN | | 73.7 | 73.7 | beats/min | Y | 73.7 | 73.7 | PERIOD 1, PREDOSE | | AVERAGE | Y | BA |
| 3 | 3 | 8 | B | 2024-05-11T05:30:32 | 2024-05-11 | 3 | 3 | -2 | -2 | EGHRMN | 75 | 75 | 75 | beats/min | | | | | | | | BA |
| 4 | 4 | 15 | B | 2024-05-11T05:31:54 | 2024-05-11 | 3 | 3 | -1.98 | -2 | EGHRMN | 74 | 74 | 74 | beats/min | | | | | | | | BA |
| 5 | 5 | 22 | B | 2024-05-11T05:34:53 | 2024-05-11 | 3 | 3 | -1.97 | -2 | EGHRMN | 72 | 72 | 72 | beats/min | | | | | | | | BA |
| 6 | 6 | 29 | B | 2024-05-11T08:22:16 | 2024-05-11 | 3 | 3 | 0.85 | 1 | EGHRMN | 63 | 63 | 63 | beats/min | | 73.7 | 73.7 | PERIOD 1, PREDOSE | -10.7 | | Y | BA |
| 7 | 7 | 36 | B | 2024-05-12T07:19:20 | 2024-05-12 | 4 | 4 | 23.75 | | EGHRMN | 71 | 71 | 71 | beats/min | | 73.7 | 73.7 | PERIOD 1, PREDOSE | -2.7 | | Y | BA |
| 8 | 8 | 43 | B | 2024-05-13T07:15:53 | 2024-05-13 | 5 | 5 | 47.75 | | EGHRMN | 67 | 67 | 67 | beats/min | | 73.7 | 73.7 | PERIOD 1, PREDOSE | -6.7 | | Y | BA |
| 9 | 9 | | A | 2024-05-25T05:39:26 | 2024-05-25 | 7 | 2 | | | EGHRMN | 64.7 | 64.7 | 64.7 | beats/min | Y | 64.7 | 64.7 | PERIOD 2, PREDOSE | | AVERAGE | Y | BA |
| 10 | 10 | 50 | A | 2024-05-25T05:39:26 | 2024-05-25 | 7 | 3 | -2 | -2 | EGHRMN | 69 | 69 | 69 | beats/min | | | | | | | | BA |
| 11 | 11 | 57 | A | 2024-05-25T05:40:29 | 2024-05-25 | 7 | 3 | -1.98 | -2 | EGHRMN | 63 | 63 | 63 | beats/min | | | | | | | | BA |
| 12 | 12 | 64 | A | 2024-05-25T05:41:31 | 2024-05-25 | 7 | 3 | -1.97 | -2 | EGHRMN | 62 | 62 | 62 | beats/min | | | | | | | | BA |
| 13 | 13 | 71 | A | 2024-05-25T08:21:44 | 2024-05-25 | 7 | 3 | 0.85 | 1 | EGHRMN | 62 | 62 | 62 | beats/min | | 64.7 | 64.7 | PERIOD 2, PREDOSE | -2.7 | | Y | BA |
| 14 | 14 | 78 | A | 2024-05-26T07:31:39 | 2024-05-26 | 8 | 4 | 23.75 | | EGHRMN | 65 | 65 | 65 | beats/min | | 64.7 | 64.7 | PERIOD 2, PREDOSE | 0.3 | | Y | BA |
| 15 | 15 | 85 | A | 2024-05-27T07:15:02 | 2024-05-27 | 9 | 5 | 47.75 | | EGHRMN | 70 | 70 | 70 | beats/min | | 64.7 | 64.7 | PERIOD 2, PREDOSE | 5.3 | | Y | BA |
| 16 | 16 | 7 | | 2024-04-23T08:26:33 | 2024-04-23 | 1 | 1 | | | RRAG | 930 | 930 | 930 | ms | | | | | | | | BA |
| 17 | 17 | | B | 2024-05-11T05:30:32 | 2024-05-11 | 3 | 2 | | | RRAG | 813.3 | 813.3 | 813.3 | ms | Y | 813.3 | 813.3 | PERIOD 1, PREDOSE | | AVERAGE | Y | BA |
| 18 | 18 | 14 | B | 2024-05-11T05:30:32 | 2024-05-11 | 3 | 3 | -2 | -2 | RRAG | 800 | 800 | 800 | ms | | | | | | | | BA |
| 19 | 19 | 21 | B | 2024-05-11T05:31:54 | 2024-05-11 | 3 | 3 | -1.98 | -2 | RRAG | 810 | 810 | 810 | ms | | | | | | | | BA |
| 20 | 20 | 28 | B | 2024-05-11T05:34:53 | 2024-05-11 | 3 | 3 | -1.97 | -2 | RRAG | 830 | 830 | 830 | ms | | | | | | | | BA |
| 21 | 21 | 35 | B | 2024-05-11T08:22:16 | 2024-05-11 | 3 | 3 | 0.85 | 1 | RRAG | 950 | 950 | 950 | ms | | 813.3 | 813.3 | PERIOD 1, PREDOSE | 136.7 | | Y | BA |
| 22 | 22 | 42 | B | 2024-05-12T07:19:20 | 2024-05-12 | 4 | 4 | 23.75 | | RRAG | 840 | 840 | 840 | ms | | 813.3 | 813.3 | PERIOD 1, PREDOSE | 26.7 | | Y | BA |
| 23 | 23 | 49 | B | 2024-05-13T07:15:53 | 2024-05-13 | 5 | 5 | 47.75 | | RRAG | 900 | 900 | 900 | ms | | 813.3 | 813.3 | PERIOD 1, PREDOSE | 86.7 | | Y | BA |
| 24 | 24 | | A | 2024-05-25T05:39:26 | 2024-05-25 | 7 | 2 | | | RRAG | 933.3 | 933.3 | 933.3 | ms | Y | 933.3 | 933.3 | PERIOD 2, PREDOSE | | AVERAGE | Y | BA |
| 25 | 25 | 56 | A | 2024-05-25T05:39:26 | 2024-05-25 | 7 | 3 | -2 | -2 | RRAG | 870 | 870 | 870 | ms | | | | | | | | BA |
| 26 | 26 | 63 | A | 2024-05-25T05:40:29 | 2024-05-25 | 7 | 3 | -1.98 | -2 | RRAG | 960 | 960 | 960 | ms | | | | | | | | BA |
| 27 | 27 | 70 | A | 2024-05-25T05:41:31 | 2024-05-25 | 7 | 3 | -1.97 | -2 | RRAG | 970 | 970 | 970 | ms | | | | | | | | BA |
| 28 | 28 | 77 | A | 2024-05-25T08:21:44 | 2024-05-25 | 7 | 3 | 0.85 | 1 | RRAG | 970 | 970 | 970 | ms | | 933.3 | 933.3 | PERIOD 2, PREDOSE | 36.7 | | Y | BA |
| 29 | 29 | 84 | A | 2024-05-26T07:31:39 | 2024-05-26 | 8 | 4 | 23.75 | | RRAG | 930 | 930 | 930 | ms | | 933.3 | 933.3 | PERIOD 2, PREDOSE | -3.3 | | Y | BA |
| 30 | 30 | 91 | A | 2024-05-27T07:15:02 | 2024-05-27 | 9 | 5 | 47.75 | | RRAG | 860 | 860 | 860 | ms | | 933.3 | 933.3 | PERIOD 2, PREDOSE | -73.3 | | Y | BA |
| 31 | 31 | 3 | | 2024-04-23T08:26:33 | 2024-04-23 | 1 | 1 | | | PRAG | 166 | 166 | 166 | ms | | | | | | | | BA |
| 32 | 32 | | B | 2024-05-11T05:30:32 | 2024-05-11 | 3 | 2 | | | PRAG | 168 | 168 | 168 | ms | Y | 168 | 168 | PERIOD 1, PREDOSE | | AVERAGE | Y | BA |
| 33 | 33 | 10 | B | 2024-05-11T05:30:32 | 2024-05-11 | 3 | 3 | -2 | -2 | PRAG | 168 | 168 | 168 | ms | | | | | | | | BA |
| 34 | 34 | 17 | B | 2024-05-11T05:31:54 | 2024-05-11 | 3 | 3 | -1.98 | -2 | PRAG | 168 | 168 | 168 | ms | | | | | | | | BA |
| 35 | 35 | 24 | B | 2024-05-11T05:34:53 | 2024-05-11 | 3 | 3 | -1.97 | -2 | PRAG | 168 | 168 | 168 | ms | | | | | | | | BA |
| 36 | 36 | 31 | B | 2024-05-11T08:22:16 | 2024-05-11 | 3 | 3 | 0.85 | 1 | PRAG | 168 | 168 | 168 | ms | | 168 | 168 | PERIOD 1, PREDOSE | 0 | | Y | BA |
| 37 | 37 | 38 | B | 2024-05-12T07:19:20 | 2024-05-12 | 4 | 4 | 23.75 | | PRAG | 166 | 166 | 166 | ms | | 168 | 168 | PERIOD 1, PREDOSE | -2 | | Y | BA |
| 38 | 38 | 45 | B | 2024-05-13T07:15:53 | 2024-05-13 | 5 | 5 | 47.75 | | PRAG | 168 | 168 | 168 | ms | | 168 | 168 | PERIOD 1, PREDOSE | 0 | | Y | BA |
| 39 | 39 | | A | 2024-05-25T05:39:26 | 2024-05-25 | 7 | 2 | | | PRAG | 170.7 | 170.7 | 170.7 | ms | Y | 170.7 | 170.7 | PERIOD 2, PREDOSE | | AVERAGE | Y | BA |
| 40 | 40 | 52 | A | 2024-05-25T05:39:26 | 2024-05-25 | 7 | 3 | -2 | -2 | PRAG | 172 | 172 | 172 | ms | | | | | | | | BA |
| 41 | 41 | 59 | A | 2024-05-25T05:40:29 | 2024-05-25 | 7 | 3 | -1.98 | -2 | PRAG | 170 | 170 | 170 | ms | | | | | | | | BA |
| 42 | 42 | 66 | A | 2024-05-25T05:41:31 | 2024-05-25 | 7 | 3 | -1.97 | -2 | PRAG | 170 | 170 | 170 | ms | | | | | | | | BA |
| 43 | 43 | 73 | A | 2024-05-25T08:21:44 | 2024-05-25 | 7 | 3 | 0.85 | 1 | PRAG | 170 | 170 | 170 | ms | | 170.7 | 170.7 | PERIOD 2, PREDOSE | -0.7 | | Y | BA |
| 44 | 44 | 80 | A | 2024-05-26T07:31:39 | 2024-05-26 | 8 | 4 | 23.75 | | PRAG | 168 | 168 | 168 | ms | | 170.7 | 170.7 | PERIOD 2, PREDOSE | -2.7 | | Y | BA |
| 45 | 45 | 87 | A | 2024-05-27T07:15:02 | 2024-05-27 | 9 | 5 | 47.75 | | PRAG | 170 | 170 | 170 | ms | | 170.7 | 170.7 | PERIOD 2, PREDOSE | -0.7 | | Y | BA |

Since we are creating an *average* record, we know that time differs across the reference records.

It would be hard to identify one time here, and it would be hard to point to a single SDTM result.



# Key Takeaways

# Even though we may run into complicated situations, there is always a compliant solution

**I hope that this discussion helped you consider different ways to derive records, and how to populate the values to best show traceability.**

- If there is a concept that is unclear, I encourage CDISC participation through volunteering.
- Helping to create standards is fun!
- Please consider joining an CDISC team that grabs your attention, standards thrive on different ideas.

# Thank You!