



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

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



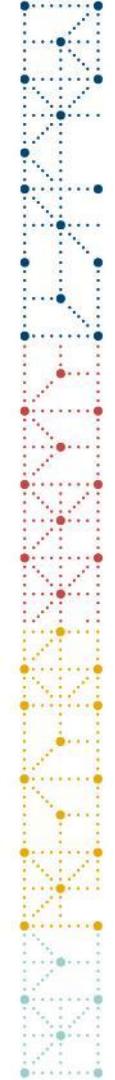
Meet the Speaker

Amanda Johnson

Title: Associate Principal Scientist, Stat Programming

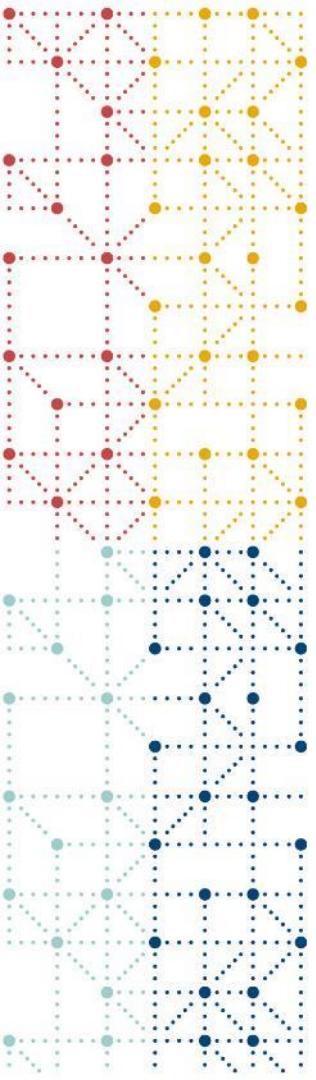
Organization: Merck & Co., Inc.

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.



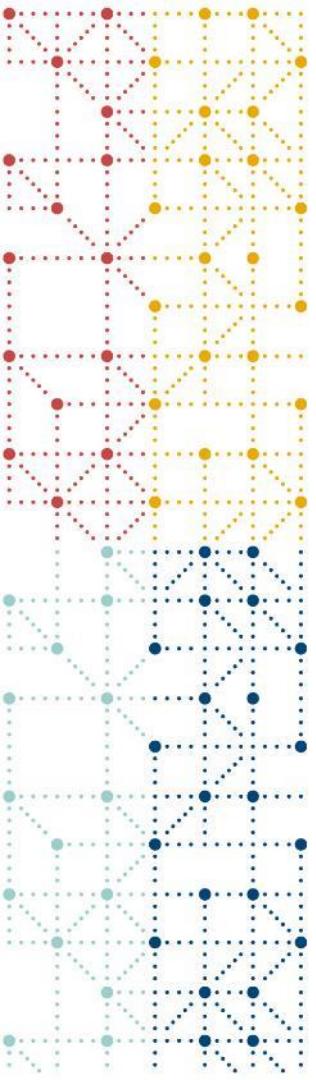
Disclaimer and Disclosures

- *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.*



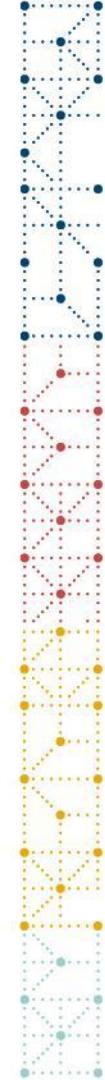
Agenda

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

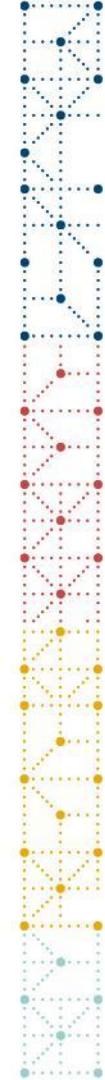
- **How can you tell which to do, and why does it matter?**

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

4	IMPLEMENTATION ISSUES, STANDARD SOLUTIONS, AND EXAMPLES.....	51
4.1	EXAMPLES OF TREATMENT VARIABLES FOR COMMON TRIAL DESIGNS	51
4.2	CREATION OF DERIVED COLUMNS VERSUS CREATION OF DERIVED ROWS	53
4.2.1	Rules for the Creation of Rows and Columns	54
4.2.1.1	Rule 1: A parameter-invariant function of AVAL and BASE on the same row that does not involve a transform of BASE should be added as a new column.....	54
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.....	55

© 2021 Clinical Data Interchange Standards Consortium, Inc. All rights reserved
2021-11-29

Page 2

CDISC Analysis Data Model Implementation Guide (1.3 Final)

4.2.1.3	Rule 3: A function of one or more rows within the same parameter for the purpose of creating an analysis timepoint should be added as a new row for the same parameter.....	56
4.2.1.4	Rule 4: A function of multiple rows within a parameter should be added as a new parameter.....	60
4.2.1.5	Rule 5: A function of more than one parameter should be added as a new parameter.....	61
4.2.1.6	Rule 6: When there is more than one definition of baseline, each additional definition of baseline requires the creation of its own set of rows.....	62

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 0.063575927	

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



	SUBID	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 Ant 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	0.018044287
4	000008	0002	2	2022-05-24	1	1	2	1	URINE		2 Ant 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 Ant 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 Ant Rec from 0 to 24 Hour (mg) - Imputed	8	0	0.0037057405
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 Ant Rec from 0 to 24 Hour (mg) - Imputed	8	0	0.0037057405
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.

SUBID	SITEID	ASEQ	VSSSEQ	TRTA	VSGRPID	VSDTC	ADT	ATM	ADTM	ADY	VISIT	VSTPTNUM	ATPTN	PARAM	PARAMCD	PARAMN	PARCAT1	VSP05	VSTREC	AVAL	AVALC	ABLFL	BASE	BASEC	BASETYPE	CHG	DTYPE				
1	0004-000001	0004	1	6	P0-SEM1	2024-04-23T08:29:43	2024-04-23	0:29:43	23APR2024 08:29:43	-18	SCREENING	Screening	Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECLINING	125	125		126	126	Y	126	126	PERIOD 1, PREDOSE	MEDIAN				
2	0004-000001	0004	2	7	B	P1/D1/H1-75-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-RECLINING	126												
3	0004-000001	0004	3	15	B	P1/D1/H1-75-SEM5	2024-05-11T05:45:04			2024-05-11	5:45:04	11MAV2024 05:45:04	1 PERIOD 1 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECLINING	114										
4	0004-000001	0004	4	18	B	P1/D1/H1-75-SEM1	2024-05-11T05:46:23			2024-05-11	5:46:23	11MAV2024 05:46:23	1 PERIOD 1 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECLINING	126										
5	0004-000001	0004	5	21	B	P1/D1/H1-75-SEM1	2024-05-11T05:47:41			2024-05-11	5:47:41	11MAV2024 05:47:41	1 PERIOD 1 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECLINING	130										
6	0004-000001	0004	6	62	A	P2/D1/H1-75-SEM5	2024-05-25T05:47:19			2024-05-25	5:47:19	25MAV2024 05:47:19	15 PERIOD 2 DAY 1	Baseline	-1.75	Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECLINING	125				125	125	Y	125	125	PERIOD 2, PREDOSE	MEDIAN
7	0004-000001	0004	7	63	A	P2/D1/H1-75-SEM5	2024-05-25T05:47:19			2024-05-25	5:47:19	25MAV2024 05:47:19	15 PERIOD 2 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECLINING	125										
8	0004-000001	0004	8	66	A	P2/D1/H1-75-SEM1	2024-05-25T05:48:44			2024-05-25	5:48:44	25MAV2024 05:48:44	15 PERIOD 2 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECLINING	124										
9	0004-000001	0004	9	69	A	P2/D1/H1-75-SEM1	2024-05-25T05:49:48			2024-05-25	5:49:48	25MAV2024 05:49:48	15 PERIOD 2 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECLINING	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	VISSEQ	TRTA	VSGRPID	VSDTC	ADT	ATM	ADTM	ADY	VISIT	VSTPTNUM	APTIN	PARAM	PARAMCD	PARAMN	PARCAT1	VSPOS	VSTRES	AVAL	AVALC	ABLFL	BASE	BASEC	BASETYPE	CHG	DTYPE	
1	0004-00001	0004	1	6	P0-SEMI	2024-04-23T08:29:43	2024-04-23	8:29:43	23APR2024	08:29:43	-18 SCREENING	Screening		Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLINER	125	125								
2	0004-00001	0004	2	15	P1/D1/H-1.75-SEMS	2024-05-11T05:04:04	2024-05-11	5:04:04	11MAY2024	05:04:04	1 PERIOD 1 DAY 1	Baseline	-1.75	Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLINER	126	126	Y							MEDIAN
3	0004-00001	0004	3	15 B	P1/D1/H-1.75-SEMS	2024-05-11T05:04:04	2024-05-11	5:04:04	11MAY2024	05:04:04	1 PERIOD 1 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLINER	114	114								
4	0004-00001	0004	4	18 B	P1/D1/H-1.75-SEMS	2024-05-11T05:46:23	2024-05-11	5:46:23	11MAY2024	05:46:23	1 PERIOD 1 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLINER	126	126								
5	0004-00001	0004	5	21 B	P1/D1/H-1.75-SEMS	2024-05-11T05:47:41	2024-05-11	5:47:41	11MAY2024	05:47:41	1 PERIOD 1 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLINER	130	130								
6	0004-00001	0004	6	53 A	P2/D1/H-1.75-SEMS	2024-05-25T05:47:19	2024-05-25	5:47:19	25MAY2024	05:47:19	15 PERIOD 2 DAY 1	Baseline	-1.75	Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLINER	125	125	Y							MEDIAN
7	0004-00001	0004	7	63 A	P2/D1/H-1.75-SEMS	2024-05-25T05:47:19	2024-05-25	5:47:19	25MAY2024	05:47:19	15 PERIOD 2 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLINER	125	125								
8	0004-00001	0004	8	66 A	P2/D1/H-1.75-SEMS	2024-05-25T05:48:44	2024-05-25	5:48:44	25MAY2024	05:48:44	15 PERIOD 2 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLINER	124	124								
9	0004-00001	0004	9	69 A	P2/D1/H-1.75-SEMS	2024-05-25T05:49:48	2024-05-25	5:49:48	25MAY2024	05:49:48	15 PERIOD 2 DAY 1	Day 1	-1.75	Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLINER	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.

ASEQ	ESEQ	TRTA	EGDTc	ADT	VISITNUM	AVSTN	EGTPNUM	ATM	PARAMC	EGSTRESC	AVAL	AVALC	AVALU	ABFL	BASE	BASEC	BASETYPE	CHG	DTYPE	ANLDFL	TRTSIG
1	2	B	2024-05-11T08:30:32	2024-05-11	1	1	EGHRMN	65	65	bedta fren	Y	73.7	73.7						BA		
2	3	8 B	2024-05-11T08:30:32	2024-05-11	3	2	EGHRMN	73.7	73.7	bedta fren	Y	75	75						BA		
3	4	15 B	2024-05-11T08:30:54	2024-05-11	3	3	EGHRMN	74	?	bedta fren	Y	74	74						BA		
4	5	23 B	2024-05-11T08:34:53	2024-05-11	3	3	EGHRMN	72	?	bedta fren	Y	72	72						BA		
5	6	29 B	2024-05-11T08:22:16	2024-05-11	3	3	EGHRMN	63	63	bedta fren	Y	73.7	73.7	PERIOD 1, PREDOSE	-10.7	Y			BA		
6	7	36 B	2024-05-12T08:19:20	2024-05-12	4	4	EGHRMN	71	71	bedta fren	Y	73.7	73.7	PERIOD 1, PREDOSE	-2.7	Y			BA		
7	8	43 B	2024-05-12T08:19:53	2024-05-13	5	5	EGHRMN	67	?	bedta fren	Y	73.7	73.7	PERIOD 1, PREDOSE	-6.7	Y			BA		
8	9	A	2024-05-12T08:19:26	2024-05-13	5	2	EGHRMN	64.7	64.7	bedta fren	Y	64.7	64.7	PERIOD 2, PREDOSE	AVERAGE	Y			BA		
9	10	50 A	2024-05-12T08:39:26	2024-05-13	7	3	EGHRMN	69	69	bedta fren	Y	69	69						BA		
10	11	57 A	2024-05-12T08:40:29	2024-05-13	7	3	EGHRMN	63	63	bedta fren	Y	63	63						BA		
11	12	64 A	2024-05-12T08:41:31	2024-05-13	7	3	EGHRMN	62	62	bedta fren	Y	62	62						BA		
12	13	71 A	2024-05-12T08:41:44	2024-05-13	7	3	EGHRMN	62	62	bedta fren	Y	64.7	64.7	PERIOD 2, PREDOSE	-2.7	Y			BA		
13	14	78 A	2024-05-12T08:31:39	2024-05-13	8	4	EGHRMN	65	65	bedta fren	Y	65	65	PERIOD 2, PREDOSE	0.3	Y			BA		
14	15	85 A	2024-05-12T08:15:02	2024-05-13	9	5	EGHRMN	70	70	bedta fren	Y	64.7	64.7	PERIOD 2, PREDOSE	5.3	Y			BA		
15	16	7	2024-05-12T08:15:13	2024-05-13	1	1	PRAG	900	900	ma	Y	900	900						BA		
16	17	B	2024-05-12T08:35:32	2024-05-13	3	2	PRAG	813.3	813.3	ma	Y	813.3	813.3	PERIOD 1, PREDOSE	AVERAGE	Y			BA		
17	18	14 B	2024-05-11T08:30:32	2024-05-11	3	3	PRAG	800	800	ma	Y	813.3	813.3	PERIOD 1, PREDOSE					BA		
18	19	21 B	2024-05-11T08:31:54	2024-05-11	3	3	PRAG	810	810	ma	Y	810	810						BA		
19	20	28 B	2024-05-11T08:34:53	2024-05-11	3	3	PRAG	820	820	ma	Y	820	820						BA		
20	21	35 B	2024-05-11T08:35:06	2024-05-11	3	3	PRAG	850	850	ma	Y	850	850	PERIOD 1, PREDOSE	136.7	Y			BA		
21	22	42 B	2024-05-12T08:19:20	2024-05-12	4	4	PRAG	840	840	ma	Y	840	840	PERIOD 1, PREDOSE	26.7	Y			BA		
22	23	49 B	2024-05-12T08:15:53	2024-05-13	5	5	PRAG	900	900	ma	Y	900	900	PERIOD 1, PREDOSE	86.7	Y			BA		
23	24	56 A	2024-05-12T08:15:26	2024-05-13	7	3	PRAG	933.3	933.3	ma	Y	933.3	933.3	PERIOD 2, PREDOSE	AVERAGE	Y			BA		
24	25	56 A	2024-05-12T08:35:26	2024-05-13	7	3	PRAG	870	870	ma	Y	870	870						BA		
25	26	63 A	2024-05-12T08:40:29	2024-05-13	7	3	PRAG	960	960	ma	Y	960	960						BA		
26	27	70 A	2024-05-12T08:41:31	2024-05-13	7	3	PRAG	970	970	ma	Y	970	970						BA		
27	28	77 A	2024-05-12T08:41:44	2024-05-13	7	3	PRAG	970	970	ma	Y	970	970	PERIOD 2, PREDOSE	36.7	Y			BA		
28	29	84 A	2024-05-12T08:31:39	2024-05-13	8	4	PRAG	890	890	ma	Y	890	890	PERIOD 2, PREDOSE	-3.3	Y			BA		
29	30	91 A	2024-05-12T08:15:02	2024-05-13	9	5	PRAG	860	860	ma	Y	860	860	PERIOD 2, PREDOSE	-73.3	Y			BA		
30	31	3	2024-04-12T08:26.33	2024-04-23	1	1	PRAG	166	166	ma	Y	166	166						BA		
31	32	8 B	2024-04-12T08:30:32	2024-04-23	2	PRAG	168	168	ma	Y	168	168						BA			
32	33	10 B	2024-04-12T08:30:32	2024-04-23	3	3	PRAG	168	168	ma	Y	168	168						BA		
33	34	17 B	2024-04-11T08:31:54	2024-04-23	3	3	PRAG	168	168	ma	Y	168	168						BA		
34	35	24 B	2024-04-11T08:34:53	2024-04-23	3	3	PRAG	168	168	ma	Y	168	168						BA		
35	36	31 B	2024-04-11T08:22:16	2024-04-23	4	4	PRAG	168	168	ma	Y	168	168						BA		
36	37	38 B	2024-04-11T08:22:16	2024-04-23	4	4	PRAG	168	168	ma	Y	168	168						BA		
37	38	45 B	2024-04-11T08:15:53	2024-04-23	5	5	PRAG	168	168	ma	Y	168	168	PERIOD 1, PREDOSE	0	Y			BA		
38	39	A	2024-05-10T08:39:26	2024-05-25	7	2	PRAG	170	170	ma	Y	170	170	PERIOD 2, PREDOSE	-2	Y			BA		
39	40	52 A	2024-05-10T08:39:26	2024-05-25	7	3	PRAG	172	172	ma	Y	172	172	PERIOD 2, PREDOSE	0	Y			BA		
40	41	59 A	2024-05-10T08:20:29	2024-05-25	7	3	PRAG	170	170	ma	Y	170	170	PERIOD 2, PREDOSE	-0.7	Y			BA		
41	42	66 A	2024-05-10T08:41:31	2024-05-25	7	3	PRAG	170	170	ma	Y	170	170	PERIOD 2, PREDOSE	-2.7	Y			BA		
42	43	73 A	2024-05-10T08:21:44	2024-05-25	7	3	PRAG	170	170	ma	Y	170	170	PERIOD 2, PREDOSE	-0.7	Y			BA		
43	44	80 A	2024-05-10T08:31:39	2024-05-26	8	4	PRAG	168	168	ma	Y	168	168	PERIOD 2, PREDOSE	-0.7	Y			BA		
44	45	87 A	2024-05-10T08:15:02	2024-05-27	9	5	PRAG	170	170	ma	Y	170	170	PERIOD 2, PREDOSE	-0.7	Y			BA		

Solution– remove EGDT and EGSTRESC

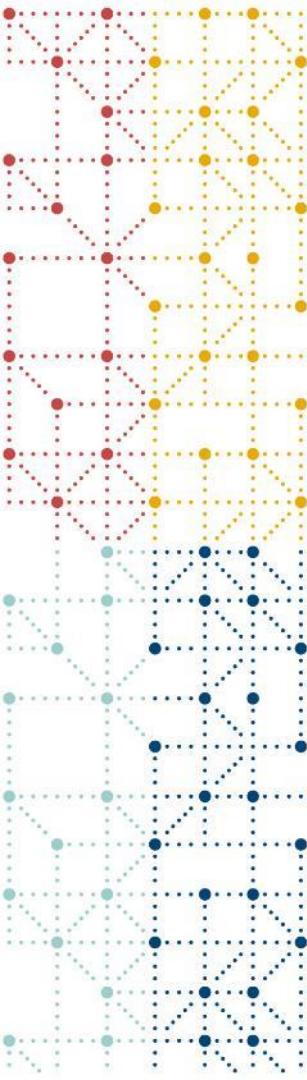
	ASEQ	EGSEQ	TRTA	EGDT	ADT	VISITNUM	AVISITN	EGTPNUM	ATPTN	PARAMCD	EGSTRESC	AVAL	AVALC	AVALU	ABFL	BASE	BASEC	BASETYPE	CHG	DTYPE	ANL0FL	TRTSEQP
1	1	1		2024-05-27T08:26:13	2024-05-27	1	1			EGHRM	65	65	65	beats/min		73.7	73.7	PERIOD 1, PREDOSE		AVERAGE	Y	BA
2	2	2	B		2024-05-27	3	2			EGHRM	75	75	75	beats/min		73.7	73.7	PERIOD 1, PREDOSE		AVERAGE	Y	BA
3	3	3	B	2024-05-11T05:36:32	2024-05-11	3	3	-2		EGHRM	75	75	75	beats/min		73.7	73.7	PERIOD 1, PREDOSE		AVERAGE	Y	BA
4	4	4	B	2024-05-11T05:31:54	2024-05-11	3	3	-198		EGHRM	74	74	74	beats/min		73.7	73.7	PERIOD 1, PREDOSE		AVERAGE	Y	BA
5	5	5	B	2024-05-11T05:34:53	2024-05-11	3	3	-197		EGHRM	72	72	72	beats/min		73.7	73.7	PERIOD 1, PREDOSE		AVERAGE	Y	BA
6	6	6	B	2024-05-11T08:22:16	2024-05-11	3	3	0.85		EGHRM	63	63	63	beats/min		73.7	73.7	PERIOD 1, PREDOSE	-10.7	Y	BA	
7	7	7	B	2024-05-12T07:19:28	2024-05-12	4	4	23.75		EGHRM	71	71	71	beats/min		73.7	73.7	PERIOD 1, PREDOSE	-2.7	Y	BA	
8	8	8	B	2024-05-13T07:15:53	2024-05-13	5	5	47.75		EGHRM	67	67	67	beats/min		73.7	73.7	PERIOD 1, PREDOSE	-4.7	Y	BA	
9	9	A		2024-05-25T05:39:26	2024-05-25	7	2			EGHRM	64.7	64.7	64.7	beats/min		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		EGHRM	69	69	69	beats/min		64.7	64.7	PERIOD 2, PREDOSE		AVERAGE	Y	BA
11	11	57	A	2024-05-25T05:40:29	2024-05-25	7	3	-198		EGHRM	63	63	63	beats/min		64.7	64.7	PERIOD 2, PREDOSE		AVERAGE	Y	BA
12	12	64	A	2024-05-25T05:41:31	2024-05-25	7	3	-197		EGHRM	62	62	62	beats/min		64.7	64.7	PERIOD 2, PREDOSE	0.3	Y	BA	
13	13	71	A	2024-05-25T08:21:44	2024-05-25	7	3	0.85		EGHRM	62	62	62	beats/min		64.7	64.7	PERIOD 2, PREDOSE	5.3	Y	BA	
14	14	78	A	2024-05-26T07:31:39	2024-05-26	8	4	23.75		EGHRM	65	65	65	beats/min		64.7	64.7	PERIOD 2, PREDOSE		AVERAGE	Y	BA
15	15	85	B	2024-05-27T07:15:02	2024-05-27	9	5	47.75		EGHRM	70	70	70	beats/min		64.7	64.7	PERIOD 2, PREDOSE		AVERAGE	Y	BA
16	16	92	A	2024-05-27T07:33:33	2024-05-27	1	1			PRAG	930	930	930	ms								BA
17	17	B		2024-05-27T07:33:33	2024-05-27	1	1			PRAG	8113	8113	8113	ms								BA
18	18	11	B	2024-05-11T05:30:32	2024-05-11	3	2			PRAG	813.3	813.3	813.3	ms								BA
19	19	18	B	2024-05-11T05:31:54	2024-05-11	3	3	-2		PRAG	800	800	800	ms								BA
20	20	25	B	2024-05-11T05:34:53	2024-05-11	3	3	-198		PRAG	910	910	910	ms								BA
21	21	35	B	2024-05-11T08:22:16	2024-05-11	3	3	-197		PRAG	830	830	830	ms								BA
22	22	42	B	2024-05-12T07:19:28	2024-05-12	4	4	23.75		PRAG	840	840	840	ms								BA
23	23	49	B	2024-05-13T07:15:53	2024-05-13	5	5	47.75		PRAG	900	900	900	ms								BA
24	24	A		2024-05-25T05:39:26	2024-05-25	7	2			PRAG	933.3	933.3	933.3	ms								BA
25	25	56	A	2024-05-25T05:39:26	2024-05-25	7	3	-2		PRAG	870	870	870	ms								BA
26	26	63	A	2024-05-25T05:40:29	2024-05-25	7	3	-198		PRAG	960	960	960	ms								BA
27	27	70	A	2024-05-25T05:41:31	2024-05-25	7	3	-197		PRAG	970	970	970	ms								BA
28	28	77	A	2024-05-25T08:21:44	2024-05-25	7	3	0.85		PRAG	970	970	970	ms								BA
29	29	84	A	2024-05-26T07:31:39	2024-05-26	8	4	23.75		PRAG	930	930	930	ms								BA
30	30	91	A	2024-05-27T07:15:02	2024-05-27	9	5	47.75		PRAG	860	860	860	ms								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		168	168	PERIOD 1, PREDOSE		AVERAGE	Y	BA
33	33	10	B	2024-05-11T05:30:32	2024-05-11	3	3	-2		PRAG	168	168	168	ms								BA
34	34	17	B	2024-05-11T05:31:54	2024-05-11	3	3	-198		PRAG	168	168	168	ms								BA
35	35	24	B	2024-05-11T05:34:53	2024-05-11	3	3	-197		PRAG	168	168	168	ms								BA
36	36	31	B	2024-05-11T08:22:16	2024-05-11	3	3	0.85		PRAG	168	168	168	ms								BA
37	37	38	B	2024-05-12T07:19:28	2024-05-12	4	4	23.75		PRAG	166	166	166	ms								BA
38	38	45	B	2024-05-13T07:15:53	2024-05-13	5	5	47.75		PRAG	168	168	168	ms								BA
39	39	A		2024-05-25T05:39:26	2024-05-25	7	2			PRAG	170.7	170.7	170.7	ms								BA
40	40	52	A	2024-05-25T05:39:26	2024-05-25	7	3	-2		PRAG	172	172	172	ms								BA
41	41	59	A	2024-05-25T05:40:29	2024-05-25	7	3	-198		PRAG	170	170	170	ms								BA
42	42	66	A	2024-05-25T05:41:31	2024-05-25	7	3	-197		PRAG	170	170	170	ms								BA
43	43	73	A	2024-05-25T08:21:44	2024-05-25	7	3	0.85		PRAG	170	170	170	ms								BA
44	44	80	A	2024-05-26T07:31:39	2024-05-26	8	4	23.75		PRAG	168	168	168	ms								BA
45	45	87	A	2024-05-27T07:15:02	2024-05-27	9	5	47.75		PRAG	170	170	170	ms								BA

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



#ClearDataClearImpact

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

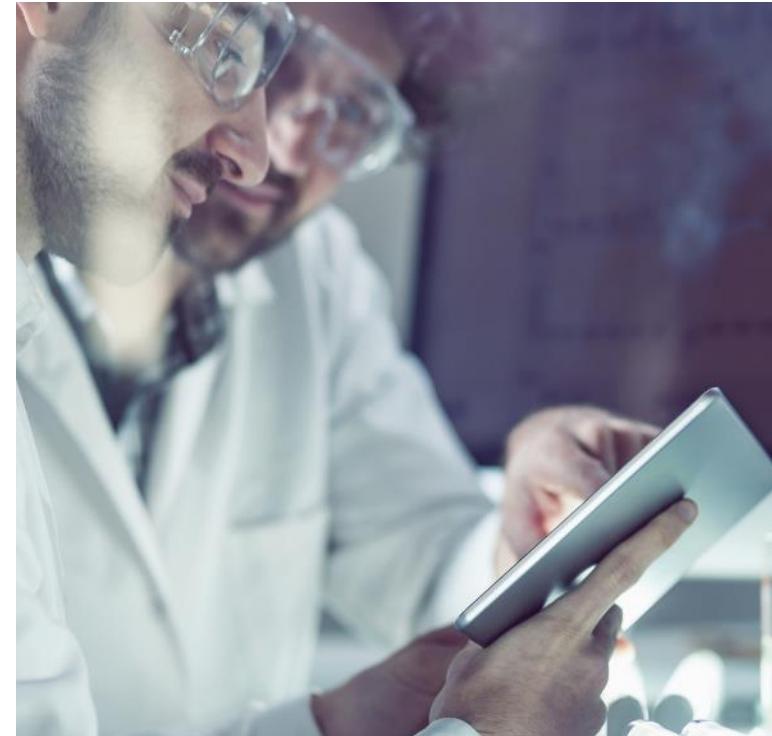


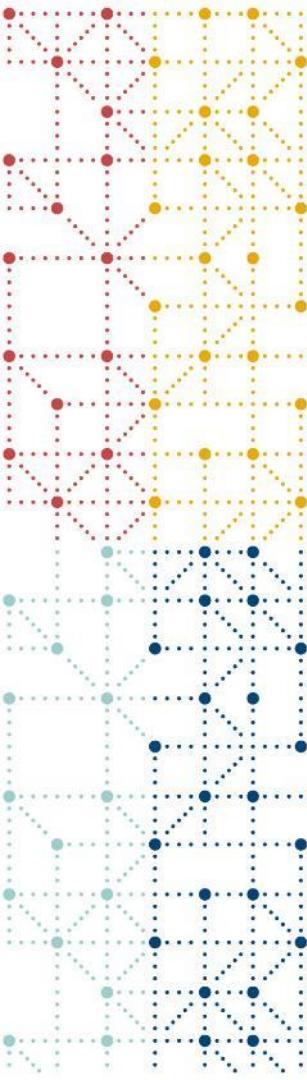
Key Takeaways

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.



A vertical decorative graphic on the left side of the slide. It consists of a grid of small, semi-transparent colored dots (red, yellow, green, blue) connected by thin lines, forming a pattern that resembles a stylized DNA helix or a complex network.

Thank You!

