



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.

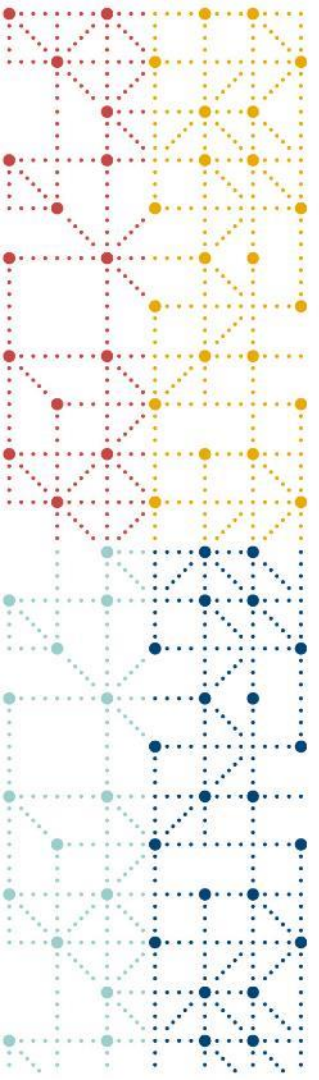
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Agenda

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

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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	0.001263174
2	000103	0001	2	2022-09-23	1	1	2	1	URINE			2	RCPCINT	Pct Rec from 0 to 24 Hour (%)	9	0	0.01263174
3	000103	0001	2	2022-09-23	1	1	2	1	URINE			2	RENALCL	Renal CL (L/h)	10	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	0.001263174
5	000008	0002	2	2022-05-24	1	1	2	1	URINE			2	RCPCINT	Pct Rec from 0 to 24 Hour (%)	9	0	0.01263174
6	000008	0002	2	2022-05-24	1	1	2	1	URINE			2	RENALCL	Renal CL (L/h)	10	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	0.001263174
8	000104	0002	2	2022-08-30	1	1	2	1	URINE			2	RCPCINT	Pct Rec from 0 to 24 Hour (%)	9	0	0.01263174
9	000104	0002	2	2022-08-30	1	1	2	1	URINE			2	RENALCL	Renal CL (L/h)	10	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	0.0037057405
11	000016	0002	2	2022-12-14	2	1	2	1	URINE			2	RCPCINT	Pct Rec from 0 to 24 Hour (%)	9	0	0.037057405
12	000016	0002	2	2022-12-14	2	1	2	1	URINE			2	RENALCL	Renal CL (L/h)	10	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	0.0037057405
14	000014	0002	2	2023-02-01	2	1	2	1	URINE			2	RCPCINT	Pct Rec from 0 to 24 Hour (%)	9	0	0.037057405
15	000014	0002	2	2023-02-01	2	1	2	1	URINE			2	RENALCL	Renal CL (L/h)	10	0	0.063575926

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		0.018042897
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		0.0037057405
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 Amt 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	VSRPID	VSDTC	ADT	ATM	ADTM	ADY	VISIT	AVISIT	VSTPTNUM	ATPTN	PARAM	PARAMCD	PARAMN	PARCAT1	VSPOS	VSTSTRES	AVAL	AVALC	ABLFL	BASE	BASEC	BASETYPE	CHG	DTTYPE		
1	0004-000001	0004	1	6	B	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-RECURRENT	125										
2	0004-000001	0004	2	6	B	P1/D1/H-1.75-SEMS	2024-05-11T05:43:04	2024-05-11		11MAY2024.05:45:04	1	PERIOD 1 DAY 1	Baseline			Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECURRENT	126		Y	126	126	PERIOD 1, PREDOSE					
3	0004-000001	0004	3	15	B	P1/D1/H-1.75-SEMS	2024-05-11T05:43:04	2024-05-11	5:45:04	11MAY2024.05:45:04	1	PERIOD 1 DAY 1	Day 1			Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECURRENT	114										
4	0004-000001	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			Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECURRENT	126										
5	0004-000001	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			Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECURRENT	130										
6	0004-000001	0004	6	21	A	P2/D1/H-1.75-SEMS	2024-05-25T05:47:19	2024-05-25		25MAY2024.05:47:19	15	PERIOD 2 DAY 1	Baseline			Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECURRENT	125		Y	125	125	PERIOD 2, PREDOSE					
7	0004-000001	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			Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECURRENT	125										
8	0004-000001	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			Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECURRENT	124										
9	0004-000001	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			Systolic Blood Pressure (mmHg)	SYSBP	1	STANDARD	SEMI-RECURRENT	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	VSEQ	TRTA	VSGRPID	VSDTC	ADT	ATM	ADTM	ADY	VISIT	AVISIT	VSTPTNUM	ATPTN	PARAM	PARAMCD	PARAMN	PARCAT1	VSPDS	VSTRESC	AVAL	AVALC	ABLFL	BASE	BASEC	BASETYPE	CHG	DTYPE		
1	0004-000001	0004	1		B	P0/SEM1	2024-04-23T08:29:43	2024-04-23	8:29:43	23APR2024:08:29:43	-18	SCREENING	Screening			-2: Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLIMBENT	125	125	125								
2	0004-000001	0004	2		B	P1/D1/H1.75/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)	SYSPB	1	STANDARD	SEMI-RECLIMBENT	126	126	126	Y	126	126	PERIOD 1, PREDOSE			MEDIAN		
3	0004-000001	0004	3		B	P1/D1/H1.75/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)	SYSPB	1	STANDARD	SEMI-RECLIMBENT	114	114	114									
4	0004-000001	0004	4		B	P1/D1/H1.75/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)	SYSPB	1	STANDARD	SEMI-RECLIMBENT	126	126	126									
5	0004-000001	0004	5		B	P1/D1/H1.75/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)	SYSPB	1	STANDARD	SEMI-RECLIMBENT	130	130	130									
6	0004-000001	0004	6		A	P2/D1/H1.75/SEM5	2024-05-25T05:47:19	2024-05-25	5:47:19	25MAY2024:05:47:19	15	PERIOD 2 DAY 1	Baseline			-1.75	-2: Systolic Blood Pressure (mmHg)	SYSPB	1	STANDARD	SEMI-RECLIMBENT	125	125	125	Y	125	125	PERIOD 2, PREDOSE			MEDIAN
7	0004-000001	0004	7		A	P2/D1/H1.75/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)	SYSPB	1	STANDARD	SEMI-RECLIMBENT	125	125	125									
8	0004-000001	0004	8		A	P2/D1/H1.75/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)	SYSPB	1	STANDARD	SEMI-RECLIMBENT	124	124	124									
9	0004-000001	0004	9		A	P2/D1/H1.75/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)	SYSPB	1	STANDARD	SEMI-RECLIMBENT	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.

ASSEQ	ESSEQ	TRITA	EGDTG	ADT	VISITNUM	ANVSTN	EGDTFNUM	ATP	PARAMC	EGSTRESC	AVAL	AVALC	AVALLU	ABLFL	BASE	BASEC	BASETYPE	CHG	DTYPE	ANLSTFL	TRTSEQ	
1	1	B	2024-05-11T05:30:32	2024-04-22	1	3	1	EGHRMN	65		65	65	beats/min									BA
2	2	B	2024-05-11T05:30:32	2024-05-11	3	3	2	EGHRMN	70.7		70.7	70.7	beats/min	Y	73.7	73.7	PERIOD 1, PREDOSE			AVERAGE	Y	BA
3	3	B	2024-05-11T05:30:32	2024-05-11	3	3	-2	EGHRMN	75		75	75	beats/min									BA
4	15	B	2024-05-11T05:31:54	2024-05-11	3	3	-1.98	EGHRMN	74		74	74	beats/min									BA
5	22	B	2024-05-11T05:34:53	2024-05-11	3	3	-1.97	EGHRMN	72		72	72	beats/min									BA
6	29	B	2024-05-11T05:32:18	2024-05-11	3	3	0.85	EGHRMN	63		63	63	beats/min		73.7	73.7	PERIOD 1, PREDOSE	-10.7		Y	BA	
7	36	B	2024-05-12T07:15:25	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	43	B	2024-05-13T07:15:53	2024-05-13	5	5	47.75	EGHRMN	67		67	67	beats/min	Y	73.7	73.7	PERIOD 1, PREDOSE	-6.7		Y	BA	
9	5	A	2024-05-25T05:39:26	2024-05-25	7	2	-2	EGHRMN	64.7		64.7	64.7	beats/min		64.7	64.7	PERIOD 2, PREDOSE			AVERAGE	Y	BA
10	50	A	2024-05-25T05:39:26	2024-05-25	7	2	-2	EGHRMN	69		69	69	beats/min									BA
11	57	A	2024-05-25T05:40:29	2024-05-25	7	3	-1.98	EGHRMN	63		63	63	beats/min									BA
12	64	A	2024-05-25T05:41:31	2024-05-25	7	3	-1.97	EGHRMN	62		62	62	beats/min									BA
13	71	A	2024-05-25T05:41:44	2024-05-25	7	3	0.85	EGHRMN	62		62	62	beats/min		64.7	64.7	PERIOD 2, PREDOSE	-2.7		Y	BA	
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	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	7		2024-04-23	2024-04-23	1	1		RRAG	930		930	930	me									BA
17	17	B	2024-05-11T05:30:32	2024-05-11	3	2		RRAG	813.3		813.3	813.3	me	Y	813.3	813.3	PERIOD 1, PREDOSE			AVERAGE	Y	BA
18	14	B	2024-05-11T05:30:32	2024-05-11	3	2	-2	RRAG	800		800	800	me									BA
19	21	B	2024-05-11T05:31:54	2024-05-11	3	2	-1.98	RRAG	810		810	810	me									BA
20	28	B	2024-05-11T05:34:53	2024-05-11	3	3	-1.97	RRAG	830		830	830	me									BA
21	35	B	2024-05-11T05:32:18	2024-05-11	3	3	0.85	RRAG	950		950	950	me		813.3	813.3	PERIOD 1, PREDOSE	136.7		Y	BA	
22	42	B	2024-05-12T07:15:25	2024-05-12	4	4	23.75	RRAG	840		840	840	me		813.3	813.3	PERIOD 1, PREDOSE	26.7		Y	BA	
23	49	B	2024-05-13T07:15:53	2024-05-13	5	5	47.75	RRAG	900		900	900	me		813.3	813.3	PERIOD 1, PREDOSE	86.7		Y	BA	
24	56	A	2024-05-25T05:39:26	2024-05-25	7	2	-2	RRAG	933.3		933.3	933.3	me	Y	933.3	933.3	PERIOD 1, PREDOSE			AVERAGE	Y	BA
25	63	A	2024-05-25T05:40:29	2024-05-25	7	3	-2	RRAG	970		970	970	me									BA
26	70	A	2024-05-25T05:41:31	2024-05-25	7	3	-1.98	RRAG	960		960	960	me									BA
27	77	A	2024-05-25T05:41:44	2024-05-25	7	3	-1.97	RRAG	970		970	970	me									BA
28	84	A	2024-05-26T07:31:39	2024-05-26	8	4	23.75	RRAG	930		930	930	me		933.3	933.3	PERIOD 2, PREDOSE	-3.3		Y	BA	
29	91	A	2024-05-27T07:15:02	2024-05-27	9	5	47.75	RRAG	860		860	860	me		933.3	933.3	PERIOD 2, PREDOSE	-73.3		Y	BA	
30	3		2024-04-23	2024-04-23	1	1		PRAG	166		166	166	me									BA
31	3	B	2024-05-11T05:30:32	2024-05-11	3	2		PRAG	168		168	168	me	Y	168	168	PERIOD 1, PREDOSE			AVERAGE	Y	BA
32	10	B	2024-05-11T05:30:32	2024-05-11	3	2	-2	PRAG	168		168	168	me									BA
33	17	B	2024-05-11T05:31:54	2024-05-11	3	2	-1.98	PRAG	168		168	168	me									BA
34	24	B	2024-05-11T05:34:53	2024-05-11	3	3	-1.97	PRAG	168		168	168	me									BA
35	31	B	2024-05-11T05:32:18	2024-05-11	3	3	0.85	PRAG	168		168	168	me		168	168	PERIOD 1, PREDOSE	0		Y	BA	
36	38	B	2024-05-12T07:15:25	2024-05-12	4	4	23.75	PRAG	166		166	166	me		168	168	PERIOD 1, PREDOSE	-2		Y	BA	
37	45	B	2024-05-13T07:15:53	2024-05-13	5	5	47.75	PRAG	168		168	168	me		168	168	PERIOD 1, PREDOSE	0		Y	BA	
38	52	A	2024-05-25T05:39:26	2024-05-25	7	2	-2	PRAG	170.7		170.7	170.7	me	Y	170.7	170.7	PERIOD 2, PREDOSE			AVERAGE	Y	BA
39	59	A	2024-05-25T05:40:29	2024-05-25	7	3	-1.98	PRAG	170		170	170	me									BA
40	66	A	2024-05-25T05:41:31	2024-05-25	7	3	-1.97	PRAG	170		170	170	me									BA
41	73	A	2024-05-26T07:31:44	2024-05-26	7	3	0.85	PRAG	170		170	170	me		170.7	170.7	PERIOD 2, PREDOSE	-0.7		Y	BA	
42	80	A	2024-05-26T07:31:39	2024-05-26	8	4	23.75	PRAG	168		168	168	me		170.7	170.7	PERIOD 2, PREDOSE	-2.7		Y	BA	
43	87	A	2024-05-27T07:15:02	2024-05-27	9	5	47.75	PRAG	170		170	170	me		170.7	170.7	PERIOD 2, PREDOSE	-0.7		Y	BA	

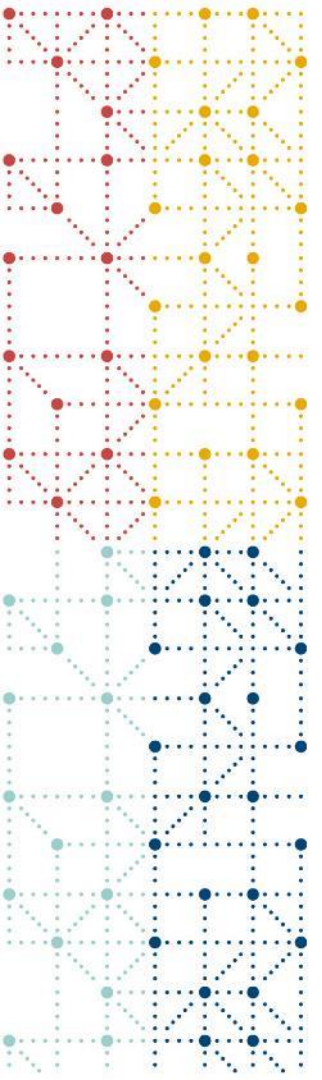
Solution— remove EGDTC and EGSTRESC

ASEQ	EGSEQ	TRITA	EGDTC	ADT	VISITNUM	AVISITN	EGTPNUM	ATPTN	PARAMCD	EGSTRESC	AVAL	AVALC	AVALU	ABLFL	BASE	BASEC	BASETYPE	CHG	DTYPE	ANLDTFL	TRTSEGP	
1	1	B	2024-04-23T08:36:33	2024-04-23	1	1	1	EGHRMN	65	EGDTC	65	65	65									BA
2	2	B	2024-05-11T05:30:32	2024-05-11	3	2	-2	EGHRMN	73	EGDTC	73	73	73	Y	73	73	PERIOD 1, PREDOSE		AVERAGE	Y	BA	
3	3	B	2024-05-11T05:30:32	2024-05-11	3	3	-2	EGHRMN	75	EGDTC	75	75	75									BA
4	4	B	2024-05-11T05:31:54	2024-05-11	3	3	-1.98	EGHRMN	74	EGDTC	74	74	74									BA
5	5	B	2024-05-11T05:34:53	2024-05-11	3	3	-1.97	EGHRMN	72	EGDTC	72	72	72									BA
6	6	B	2024-05-11T08:22:16	2024-05-11	3	3	0.85	EGHRMN	63	EGDTC	63	63	63		73	73	PERIOD 1, PREDOSE	-10.7	Y		BA	
7	7	B	2024-05-12T07:19:20	2024-05-12	4	4	23.75	EGHRMN	71	EGDTC	71	71	71		73	73	PERIOD 1, PREDOSE	-2.7	Y		BA	
8	8	B	2024-05-13T07:15:53	2024-05-13	5	5	47.75	EGHRMN	67	EGDTC	67	67	67		73	73	PERIOD 1, PREDOSE	-6.7	Y		BA	
9	9	A	2024-05-25T05:39:26	2024-05-25	7	2	-2	EGHRMN	64.7	EGDTC	64.7	64.7	64.7	Y	64.7	64.7	PERIOD 2, PREDOSE		AVERAGE	Y	BA	
10	10	A	2024-05-25T05:39:26	2024-05-25	7	3	-2	EGHRMN	69	EGDTC	69	69	69									BA
11	11	A	2024-05-25T05:40:29	2024-05-25	7	3	-1.98	EGHRMN	63	EGDTC	63	63	63									BA
12	12	A	2024-05-25T05:41:31	2024-05-25	7	3	-1.97	EGHRMN	62	EGDTC	62	62	62									BA
13	13	A	2024-05-25T08:21:44	2024-05-25	7	3	0.85	EGHRMN	62	EGDTC	62	62	62		64.7	64.7	PERIOD 2, PREDOSE	-2.7	Y		BA	
14	14	A	2024-05-26T07:31:39	2024-05-26	8	4	23.75	EGHRMN	65	EGDTC	65	65	65		64.7	64.7	PERIOD 2, PREDOSE	0.3	Y		BA	
15	15	A	2024-05-27T07:15:02	2024-05-27	9	5	47.75	EGHRMN	70	EGDTC	70	70	70		64.7	64.7	PERIOD 2, PREDOSE	5.3	Y		BA	
16	16	B	2024-04-23T08:36:33	2024-04-23	1	1		RRAG	930	EGDTC	930	930	ms									BA
17	17	B	2024-05-11T05:30:32	2024-05-11	3	2	-2	RRAG	813.3	EGDTC	813.3	813.3	ms	Y	813.3	813.3	PERIOD 1, PREDOSE		AVERAGE	Y	BA	
18	18	B	2024-05-11T05:30:32	2024-05-11	3	3	-2	RRAG	800	EGDTC	800	800	ms									BA
19	19	B	2024-05-11T05:31:54	2024-05-11	3	3	-1.98	RRAG	810	EGDTC	810	810	ms									BA
20	20	B	2024-05-11T05:34:53	2024-05-11	3	3	-1.97	RRAG	830	EGDTC	830	830	ms									BA
21	21	B	2024-05-11T08:22:16	2024-05-11	3	3	0.85	RRAG	950	EGDTC	950	950	ms		813.3	813.3	PERIOD 1, PREDOSE	136.7	Y		BA	
22	22	B	2024-05-12T07:19:20	2024-05-12	4	4	23.75	RRAG	940	EGDTC	940	940	ms		813.3	813.3	PERIOD 1, PREDOSE	26.7	Y		BA	
23	23	B	2024-05-13T07:15:53	2024-05-13	5	5	47.75	RRAG	900	EGDTC	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	-2	RRAG	933.3	EGDTC	933.3	933.3	ms	Y	933.3	933.3	PERIOD 2, PREDOSE		AVERAGE	Y	BA	
25	25	A	2024-05-25T05:39:26	2024-05-25	7	3	-2	RRAG	870	EGDTC	870	870	ms									BA
26	26	A	2024-05-25T05:40:29	2024-05-25	7	3	-1.98	RRAG	960	EGDTC	960	960	ms									BA
27	27	A	2024-05-25T05:41:31	2024-05-25	7	3	-1.97	RRAG	970	EGDTC	970	970	ms									BA
28	28	A	2024-05-25T08:21:44	2024-05-25	7	3	0.85	RRAG	970	EGDTC	970	970	ms		933.3	933.3	PERIOD 2, PREDOSE	36.7	Y		BA	
29	29	A	2024-05-26T07:31:39	2024-05-26	8	4	23.75	RRAG	930	EGDTC	930	930	ms		933.3	933.3	PERIOD 2, PREDOSE	-3.3	Y		BA	
30	30	A	2024-05-27T07:15:02	2024-05-27	9	5	47.75	RRAG	860	EGDTC	860	860	ms		933.3	933.3	PERIOD 2, PREDOSE	-73.3	Y		BA	
31	31	B	2024-04-23T08:36:33	2024-04-23	1	1		PRAG	168	EGDTC	168	168	ms									BA
32	32	B	2024-05-11T05:30:32	2024-05-11	3	2	-2	PRAG	168	EGDTC	168	168	ms	Y	168	168	PERIOD 1, PREDOSE		AVERAGE	Y	BA	
33	33	B	2024-05-11T05:30:32	2024-05-11	3	3	-2	PRAG	168	EGDTC	168	168	ms									BA
34	34	B	2024-05-11T05:31:54	2024-05-11	3	3	-1.98	PRAG	168	EGDTC	168	168	ms									BA
35	35	B	2024-05-11T05:34:53	2024-05-11	3	3	-1.97	PRAG	168	EGDTC	168	168	ms									BA
36	36	B	2024-05-11T08:22:16	2024-05-11	3	3	0.85	PRAG	168	EGDTC	168	168	ms		168	168	PERIOD 1, PREDOSE	0	Y		BA	
37	37	B	2024-05-12T07:19:20	2024-05-12	4	4	23.75	PRAG	166	EGDTC	166	166	ms		168	168	PERIOD 1, PREDOSE	-2	Y		BA	
38	38	B	2024-05-13T07:15:53	2024-05-13	5	5	47.75	PRAG	168	EGDTC	168	168	ms		168	168	PERIOD 1, PREDOSE	0	Y		BA	
39	39	A	2024-05-25T05:39:26	2024-05-25	7	2	-2	PRAG	170.7	EGDTC	170.7	170.7	ms	Y	170.7	170.7	PERIOD 2, PREDOSE		AVERAGE	Y	BA	
40	40	A	2024-05-25T05:39:26	2024-05-25	7	3	-2	PRAG	172	EGDTC	172	172	ms									BA
41	41	A	2024-05-25T05:40:29	2024-05-25	7	3	-1.98	PRAG	170	EGDTC	170	170	ms									BA
42	42	A	2024-05-25T05:41:31	2024-05-25	7	3	-1.97	PRAG	170	EGDTC	170	170	ms									BA
43	43	A	2024-05-25T08:21:44	2024-05-25	7	3	0.85	PRAG	170	EGDTC	170	170	ms		170.7	170.7	PERIOD 2, PREDOSE	-0.7	Y		BA	
44	44	A	2024-05-26T07:31:39	2024-05-26	8	4	23.75	PRAG	168	EGDTC	168	168	ms		170.7	170.7	PERIOD 2, PREDOSE	-2.7	Y		BA	
45	45	A	2024-05-27T07:15:02	2024-05-27	9	5	47.75	PRAG	170	EGDTC	170	170	ms		170.7	170.7	PERIOD 2, PREDOSE	-9.7	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.

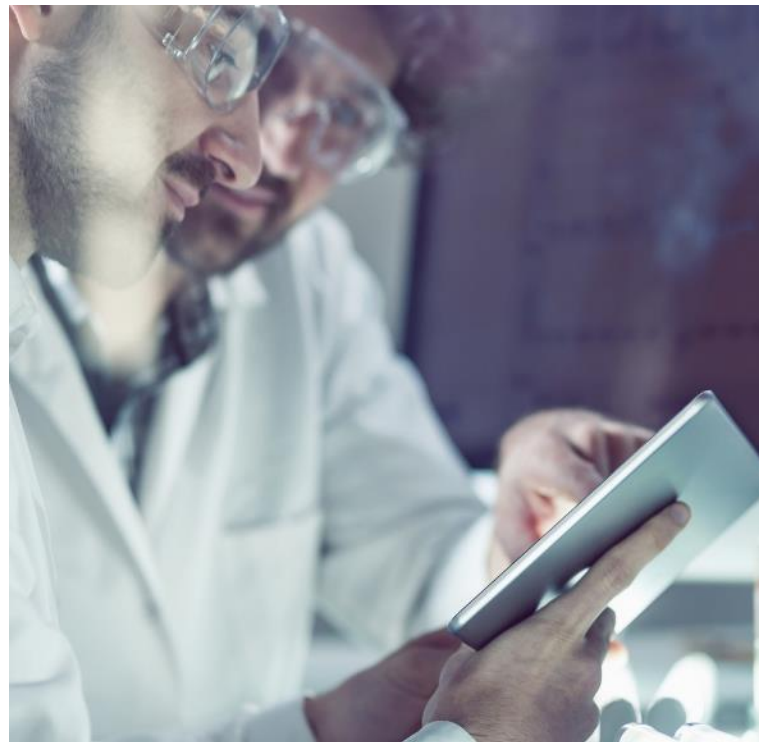


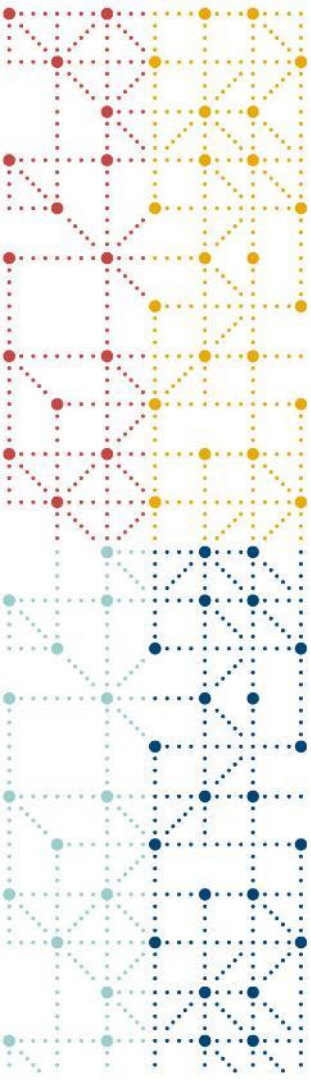
Key Takeaways

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!

