

Traceability in the ADaM Standard

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ABSTRACT

Traceability is one of the fundamentals of the ADaM Standard. However, there is not currently a traceability appendix to aid in implementation. Traceability is key to a truly ADaM-compliant submission. Having a clear path from SDTM to ADaM, within ADaM, and from ADaM to statistical analyses are all necessary components of ADaM datasets. This paper presents basic and advanced traceability techniques that can be useful for both reviewers and programmers. It also poses questions about difficult analyses for traceability such as occurrence and time-to-event analyses.

INTRODUCTION

Having a clear path from raw datasets to analysis datasets and output is vital for programmers, QCers and reviewers. The Analysis Data Model (ADaM) has built-in variables to allow programmatic connections from Study Data Tabulation Model (SDTM) datasets to ADaM datasets, within ADaM datasets and from ADaM datasets to analyses. In addition to data point traceability, metadata can enhance these connections. A basic understanding of the SDTM and ADaM models is assumed for readers of this paper.

SDTM TO ADAM

The first important connection for ADaM is SDTM since it is the source data for ADaM. The first ADaM dataset developed for a study will be the subject-level analysis dataset (ADSL). ADSL will draw data from many different SDTM domains. One example is Demographics (DM) which will provide Age, Sex and Race. These variables will fall under “same name, same meaning, same values” as mentioned in the ADaM Implementation Guide (ADaMIG). Added traceability for these variables is not needed as they are a direct copy from SDTM. Another source for ADSL will be Exposure (EX) which will be the source for all treatment dates. Since these variables are usually derived, specific metadata descriptions of the derivation are necessary. These practices mentioned are basic and are not ADaM-specific. There are specific ADaM variables for the SDTM to ADaM connections to other ADaM datasets. This includes the basic data structure (BDS) for analyses of ECG, labs and vital signs and occurrence analyses for adverse events, concomitant medications and medical history.

USE OF DATAPOINT TRACEABILITY VARIABLES (--SEQ AND SRCDOM/SRCSEQ/SRCVAR)

Some of our analyses are quite simple. One example might be a vital signs analysis over several visits. Our SDTM.VS.VISIT variable might always equal our ADaM.ADVS.AVISIT variable. We might have the same number of records in both datasets. VS.VSSTRESN might always equal ADVS.AVAL. One could argue that a programmatic connection could be made simply through the visit variables previously mentioned. However, the above example is a simple case that won't always occur. Keeping the VS.VSSEQ variable in our ADVS dataset is a basic and important traceability practice. It allows for a programmatic connection and also frees the ADVS dataset to keep only variables needed for analysis. A reviewer or QCer can easily add additional variables to the dataset from SDTM.VS. Our ADaM dataset doesn't need to keep all SDTM variables because of this simple connection using the --SEQ variable.

The simple one SDTM dataset to one ADaM dataset is the best use of the --SEQ variable for traceability. When connecting multiple SDTM datasets to one ADaM dataset, keeping the --SEQ variables from each dataset is not the intended implementation. If we had scores from both SDTM.QS and SDTM.FA

USUBJID	AVAL	QSSEQ	FASEQ
XYZ-1001	8	10	
XYZ-1001	4	11	
XYZ-1001	7		2

Table 1. --SEQ Example 1

One could argue that there is no issue with the above implementation. It doesn't break any of the ADaM compliance checks so there would be no OpenCDISC warning or error from this data. Ideally, the use of --SEQ variable as a traceability variable is best used when there is only a one-to-one connection from SDTM to ADaM. In time-to-event analyses there will often be multiple datasets as the source. When a reviewer sees the SRC variables they should be able to infer that multiple datasets are being used as a source. This also means that the SRC variables should not be used when there is only one source dataset. This intended use of the --SEQ and SRC variables is not expressly written in current the ADaMIG but it is a common practice and the best use for traceability.

USUBJID	AVAL	SRCDOM	SRCSEQ	SRCVAR
XYZ-1001	8	QS	10	QSSTRESN
XYZ-1001	4	QS	11	QSSTRESN
XYZ-1001	7	FA	2	FASTRESN

Table 2. --SEQ Example 2

WHEN TO KEEP SDTM VARIABLES FOR TRACEABILITY

In the previous section, it was mentioned that the traceability variables to provide connections from dataset to dataset allow the ADaM dataset to keep less variables. However, there are several instances when keeping other SDTM variables allow for traceability as well. One basic principle is that when a variable used for analysis is changed in ADaM from SDTM it is good practice to keep the original SDTM variable in ADaM. One example would be if we changed an analysis value

USUBJID	LBSTRESC	AVAL
XYZ-1001	6	6
XYZ-1001	<3	2.99
XYZ-1001	4	4

Table 3. LBSTRESC Example

In this analysis, the SDTM collected value of <3 was imputed to be 2.99 to allow its use in analysis. Keeping the LBSTRESC variable provides direct connection to the original collected value. If we were to always keep LBSTRESC in our dataset even when there was no imputation then this potentially valuable piece of information would be lost. In addition to keeping LBSTRESC, the metadata for AVAL could explicitly explain this imputation. A separate variable could also be used to indicate the imputation. Consider using the DTYPE variable to indicate such an imputation. The use of the DTYPE variable has different interpretations because of the CDISC notes phrasing which says, "DTYPE is used...when the value of AVAL or AVALC (and thus the entire record) has been imputed, derived, or copied from other record(s)." One interpretation is that the words "from other record(s)" apply to all cases of "imputed, derived, or copied." The interpretation in this paper is that "from other record(s)" applies to the word "copied" and therefore DTYPE can and should be used whenever AVAL is imputed or derived.

Other examples of when keeping SDTM variables are useful for traceability are:

- When mapping multiple VISIT to one AVISIT.

USUBJID	VISIT	AVISIT
XYZ-1001	Screening	Baseline
XYZ-1001	Day 1	Baseline
XYZ-1001	Week 1	Week 1

Table 4. VISIT Example

In this analysis, Screening and Day 1 are both mapped to an analysis visit of Baseline.

- When creating new rows within a parameter

USUBJID	VSSEQ	VISIT	AVISIT	AVAL	DTYPE
XYZ-1001	4	Day 1	Day 1	122	
XYZ-1001	5	Day 2	Day 2	131	
XYZ-1001	5	Day 2	Day 3	131	LOCF
XYZ-1001	6	Day 7	Day 7	119	

Table 5. DTYPE Example

In this analysis, missing visits are resolved with the last observation carried forward (LOCF) imputation method. Both the VSSEQ and VISIT values are also carried forward to the derived Day 3 record. While the VSSEQ value provides traceability back to SDTM, the VISIT variable allows for an easier understanding of where the LOCF AVAL originated. An alternative implementation would be to leave the VSSEQ and VISIT variables blank. However, the traceability for the above implementation is arguably more helpful for review and QC.

Keeping the SDTM variables --TEST or --TESTCD in ADaM is not quite as useful. The relationship between the SDTM --TEST value and the ADaM PARAM is more constant. Systolic blood pressure is always going to be systolic blood pressure. The PARAM variable does add other variables such as location, position and unit. However, the

SDTM versions of these variables should be constant from SDTM to ADaM so keeping them in ADaM adds little value.

The above examples for traceability from SDTM to ADaM do not apply in all cases and do not cover all possible traceability techniques. This section used fairly straightforward SDTM to ADaM examples. The techniques could be applied to an integrated analysis with several studies of SDTM datasets but different techniques might better serve that more complicated analysis.

ADAM TO ADAM

While ADaM datasets could arguably be considered more complicated than SDTM datasets, some of the previously discussed techniques can still be applied. There are also ADaM-specific variables which we can use to aid traceability within ADaM.

PARAMTYP

The CDISC Notes for PARAMTYP are “Indicator of whether the parameter is derived as a function of one or more other parameters.” This applies whether the derivation occurs within one ADaM dataset or across datasets. Using this variable is a very simple yet crucial way to provide traceability. It draws attention to the parameter and indicates to the reviewer that there is not a simple SDTM to ADaM origin.

ASEQ

Much like the --SEQ variable, the ASEQ variable can be used to provide traceability. This variable was first mentioned in the supplemental document for time to event but it can be used in any BDS dataset and will be discussed in a future update to the ADaMIG. There is no reason why this variable can't be used in occurrence datasets. However, including the ASEQ variable when your ADaM dataset only has one SDTM source might not be very useful. It is possible ASEQ will just equal --SEQ or will simply provide an additional variable that has a unique value.

USUBJID	VSSEQ	ASEQ
XYZ-1001	4	4
XYZ-1001	5	5
XYZ-1001	6	6
XYZ-1001	7	7

Table 6. ASEQ Example 1

USUBJID	VSSEQ	ASEQ
XYZ-1001	4	1
XYZ-1001	5	2
XYZ-1001	6	3
XYZ-1001	7	4

Table 7. ASEQ Example 2

For both cases, the ASEQ variable does not add any value so there is no reason to add this into the dataset.

If we look back at Table 2, where we have multiple SDTM sources, this could be a case where ASEQ is useful. If we're using this data as the source for other ADaM data then having ASEQ can be useful for traceability.

USUBJID	ASEQ	AVAL	SRCDOM	SRCSEQ	SRCVAR	PARAMTYP
XYZ-1001	1	8	QS	10	QSSTRESN	
XYZ-1001	2	4	QS	11	QSSTRESN	
XYZ-1001	3	7	FA	2	FASTRESN	
XYZ-1001	4	16	ADXX	1	AVAL	DERIVED
XYZ-1001	5	8	ADXX	2	AVAL	DERIVED
XYZ-1001	6	14	ADXX	3	AVAL	DERIVED

Table 8. ASEQ Example 3

We've taken the data from Table 2 and added ASEQ. We've called this dataset ADXX and updated the SRCDOM, SRCSEQ and SRCVAR variables respectively. We've also included the PARAMTYP variable to call further attention to the derived data where we've simply taken AVAL and doubled it. In this case, the direct source of AVAL for the derived records is the previous AVAL so updating the SRC variables illustrates the true path of the data. The ASEQ

variable was a needed tool to help the traceability of the SRC variables. Note that while the ADaMIG specifies that SRCDOM is for SDTM domains, the time to event supplement mentions that ADaM datasets can be used for this variable.

TIME TO EVENT

Time to event analysis is a special case where traceability becomes vital. These parameters will always be derived and are not direct copies from a SDTM domain like vital signs.

SRCVAR

As mentioned above, the time to event supplement indicated ADaM datasets can be used in the SRCDOM variable. The SRCVAR variable's CDISC notes were also updated to be "The name of the column (in the domain or dataset identified by SRCDOM) that relates to the analysis variable." The notable change here is that the text "AVAL and AVALC" in the ADaMIG were replaced with "analysis variable." For time to event analysis the fundamental variables are ADT and STARTDT. AVAL is a derivation of these two variables. A typical derivation would be ADT – STARTDT + 1. For this reason AVAL is not the central variable to trace. This means SRCVAR becomes more important. In an analysis for time to first AE of specific system organ class we could have the following.

USUBJID	STARTDT	ADT	AVAL	SRCDOM	SRCSEQ	SRCVAR
XYZ-1001	01FEB2013	22FEB2013	22	AE	8	AESTDTC

Table 9. SRCVAR Example 1

If we were using ADAE as our source we might have the following instead.

USUBJID	STARTDT	ADT	AVAL	SRCDOM	SRCSEQ	SRCVAR
XYZ-1001	01FEB2013	22FEB2013	22	ADAE	8	ASTDT

Table 10. SRCVAR Example 2

In a previous ASEQ example, it was stated that when ASEQ equals --SEQ it is usually not useful for ASEQ to be added. The above example could be considered an exception by some. However, as long as the SRC link is being used consistently in a dataset a reviewer can still understand the link being made. An additional way to ensure the path is understood is through metadata which can explain that the AESEQ variable is being used as the link for ADAE.

STARTDT

Metadata is probably the most common way where traceability for STARTDT will be shown. If the analysis starts from a single known date that is kept in ADSL such as randomization or first study drug exposure then metadata should simply state the origin is ADSL.RANDDT or ADSL.TRTSDT. In a duration of response analysis in oncology where STARTDT would be the first date a subject shows signs of a response to treatment, this might not be a variable kept in ADSL. In this type of situation it might be ideal to have additional variables to show data point traceability to the response date. ADaM does not currently have any variables for such traceability but custom variables could be created. An obvious naming convention would be STSRCDOM, STSRCSEQ and STSRCVAR where ST represents STARTDT. Because the source for the STARTDT variable is often a single variable, this situation might be very uncommon but having a common practice like this can be useful for traceability. Any analysis being done could be considered vital to a study so having the ability to create a clear path for all types of analyses is important.

ANALYSIS FLAGS

All traceability connections are essential whether they are from SDTM to ADaM, within ADaM or from ADaM to analysis. The final path, ADaM to analysis, is very important and can easily be overlooked because some analyses could be considered simple and obvious. The key principle of ADaM being discussed in this document is that the datasets are traceable from a data point and metadata standpoint. Another key principle is that the datasets are "analysis-ready." One can argue that this is simply another form of traceability. When talking about "analysis-ready", the ADaMIG states, "Analysis datasets should have a structure and content that allow statistical analyses to be performed with minimal programming." The ADAE and ADTTE supplements expand on this and state, "...it should contain all of the variables needed for the specific analysis, so that the analysis can be replicated by performing the actual statistical test without first having to manipulate data." One assumption that can be made is that no derivations are being done in table and figure programs. This seems fairly obvious from the definitions provided and is not something likely to be debated. Another assumption that might be made is that the path from ADaM to the table and figure analysis should be provided. This is where "analysis-ready" is a subset of traceability. Flags can be used to define the specific records used in analysis.

ANLZZFL

The most basic way the ANLZZFL flag can be used is to indicate the exact records used in analysis. The table below expands on the Table 4 example.

USUBJID	VISIT	AVISIT	ANL01FL
XYZ-1001	Screening	Baseline	
XYZ-1001	Day 1	Baseline	Y
XYZ-1001	Week 1	Week 1	Y
XYZ-1001	Week 4	Week 4	Y
XYZ-1001	Week 12/ET	Week 12/ET	Y

Table 11. ANLZZFL Example 1

There are two records for AVISIT = "Baseline" and the analysis needs to pick one. ANL01FL indicates which record is being used. If there was also a change from baseline analysis, there might be an additional flag created.

USUBJID	VISIT	AVISIT	ANL01FL	ANL02FL
XYZ-1001	Screening	Baseline		
XYZ-1001	Day 1	Baseline	Y	
XYZ-1001	Week 1	Week 1	Y	Y
XYZ-1001	Week 4	Week 4	Y	Y
XYZ-1001	Week 12/ET	Week 12/ET	Y	Y

Table 12. ANLZZFL Example 2

Simply having the above variables is not quite enough to create good traceability. Metadata would need to indicate the derivation of these variables. It would also be helpful to indicate where and why these variables were created. The label for the ANLZZFL variable is "Analysis Record Flag zz" where the zz represents the flag number. However, additional text is allowed at the end of a label with zz at the end. This extra space could be used to indicate the specific table or figure number where the flag is used (e.g. "Analysis Record Flag 02 Table 12"). If a blank space is left after zz in the label, there are 16 other spaces that can be used. Putting table numbers into labels might not be the most practical practice. Over the course of a study, flags can change and table numbers can change. It's very possible this information could be incorrect when done in the real world. It might be easier to simply place a simple explanation of how the flag is used (e.g. "Analysis Record Flag 02 Chg from Base").

AUC Derivation

The blank space in a label can also be used in ADaM to ADaM traceability. An example of this is for area under the curve (AUC) derivation. Matching a derived AUC can be very difficult when many records are used. Starting points, ending points and records used or not used can easily be different when two programmers are independently deriving an AUC. Specifically indicating the records used in the derivation can help isolate these issues and provide reviewers with a better understanding of the derivation. In this example there is an ADaM dataset, ADPAIN, which used to derive the ADAUC records.

USUBJID	ADTM	TIME	AVAL	ANL01FL	ANL02FL	ANL03FL	ANL04FL
XYZ-1001	09FEB2013:10:35:00	0	10	Y	Y		
XYZ-1001	09FEB2013:11:35:00	1	7	Y	Y		
XYZ-1001	09FEB2013:13:35:00	3	6	Y	Y		
XYZ-1001	09FEB2013:15:35:00	5	4	Y	Y		
XYZ-1001	09FEB2013:17:35:00	7	2	Y	Y		
XYZ-1001	09FEB2013:21:35:00	11	3	Y	Y		
XYZ-1001	10FEB2013:08:00:00	21.4166	4	Y	Y		
XYZ-1001	10FEB2013:12:00:00	25.4166	4	Y		Y	

USUBJID	ADTM	TIME	AVAL	ANL01FL	ANL02FL	ANL03FL	ANL04FL
XYZ-1001	10FEB2013:16:00:00	29.4166	4	Y		Y	
XYZ-1001	10FEB2013:20:00:00	33.4166	4	Y		Y	
XYZ-1001	11FEB2013:08:00:00	45.4166	1	Y		Y	
XYZ-1001	11FEB2013:12:00:00	49.4166	1	Y			Y
XYZ-1001	11FEB2013:16:00:00	53.4166	1	Y			Y
XYZ-1001	11FEB2013:20:00:00	57.4166	2	Y			Y
XYZ-1001	12FEB2013:08:00:00	61.4166	1	Y			Y
XYZ-1001	12FEB2013:12:00:00	73.4166	2				

Table 13. ANLzzFL Example 3 - ADPAIN

USUBJID	PARAMCD	AVAL	PARAMTYP
XYZ-1001	AUC072	2.7941176471	DERIVED
XYZ-1001	AUC024	3.920233463	DERIVED
XYZ-1001	AUC2448	3.1	DERIVED
XYZ-1001	AUC4872	1.4	DERIVED

Table 14. ANLzzFL Example 3 – ADAUC

A reviewer can more easily trace from ADPAIN to ADAUC with the addition of the four ANLzzFL flags. In addition, as previously mentioned, the labels for the four flags can help with traceability. An example of a label could be “Analysis Record Flag 02 ADAUC.AUC024” where the label includes the specific dataset and parameter value created through the flag. Since ADaM variable labels only have 40 characters, if your ADaM dataset had 8 characters and the parameter being created also had 8 characters, this exact method could not be used since there are only 16 available characters and the period symbol is being used to split the dataset and parameter names. Another benefit of the analysis flags is that it would allow a macro to be created to derive the AUC. This would simplify the ADPAIN to ADAUC transition. We should note that in this example the standard trapezoidal method was used and the area is standardized over (divided by) the interval where the records occur.

OCCURRENCE ANALYSIS

Occurrence analysis is unique in that there is not usually a specific record being analyzed like a BDS dataset. The analysis is not based on a specific visit for every subject. The analysis is usually indicating what occurred. In adverse events, the analysis indicates the subject incidence of specific events so subjects having more than one event are counted only once for each level in the summary. On a dataset level this means it does not make a difference which specific event we are using for our summary. As long as we are using the correct subset of events such as treatment emergent AEs or concomitant medications, the analysis will be the same. This often means that analysis datasets do not indicate the specific event being analyzed. The ADAE supplement indicates there should be a flag for treatment emergent events and a future standard for occurrence analyses will require a similar flag for medications but occurrence flags are not required. Because the nature of occurrence analysis is analyzing records that are simply part of the dataset many agree with this model and would only include occurrence flags if they were needed for another analysis like time to adverse event with special interest, such as neurological event. Having code in the table program which determines incidence by selecting only one unique record in the table program breaks the “analysis-ready” philosophy of ADaM and does not provide good traceability.

If a reviewer were to recreate any of our analyses they would also have to have their own code to select unique records. This might not cause any issues for simple analyses but for more complex analyses this might be problematic. One purpose of ADaM and CDISC in general is standardization and the use of these flags would more easily allow for standard programs.

For a simple adverse event analysis, the dataset would have three flags. Unfortunately, the names of the flag variables do not make the derivation of the flag self-evident. AOCCFL, AOCCSFL and AOCCPFL are the standard ADAE flag variables for “1st Occurrence of Any AE Flag,” “1st Occurrence of SOC Flag” and “1st Occurrence of Preferred Term Flag.”

AESEQ	AEBODSYS	AEDECOD	ASEV	AREL	TRTEMFL	AOCCFL	AOCCSFL	AOCCPFL
1	Eye disorders	Eye pain	Mild	Not Related	Y	Y	Y	Y
2	Gastrointestinal disorders	Diarrhoea	Severe	Not Related	Y		Y	Y
3	Gastrointestinal disorders	Nausea	Moderate	Not Related	Y			Y
4	Nervous system disorders	Headache	Mild	Related	Y		Y	Y
5	Nervous system disorders	Headache	Moderate	Related	Y			

Table 15. Occurrence Example 1

The records in the dataset are for one subject and it can be assumed the dataset was sorted by AEBODSYS, AEDECOD and date of the event. The analysis flags flag one record for the subject overall, one record per unique system organ class and one record per unique preferred term. The dataset itself becomes more useful because a separate program is not required to create the unique records. Including analysis flags for occurrence allows for simple code in the table program for basic analysis:

```
proc freq data=adam.adae noprint;
  where TRTEMFL = 'Y';
  tables TRT01PN * AOCCFL / out=any (where=(AOCCFL='Y'));
  tables TRT01PN * AEBODSYS * AOCCSFL / out=soc (where=(AOCCSFL='Y'));
  tables TRT01PN * AEBODSYS * AEDECOD * AOCCPFL / out=pt (where=(AOCCPFL='Y'));
run;
```

A more complex analysis can also benefit when we include the flags. In this case the analysis being done is by relationship to study drug and severity of event. To determine the unique records to be used at the subject, system organ class and preferred term level, the sorting algorithm first looked at the closest relationship to study drug and then the severity of the event. The ADAE supplement does not have a flag for combined relationship and severity analysis. Instead we have to use the AOCCzzFL flag where for our example, AOCC01FL will represent the subject level, AOCC02FL represents the system organ class level and AOCC03FL represents the preferred term level. Again, the flag names do not help explain where they are going to be used but they do follow the ADAE supplement. Good metadata is vital to explain where these flags are used.

AESEQ	AEBODSYS	AEDECOD	ASEV	AREL	TRTEMFL	AOCC01FL	AOCC02FL	AOCC03FL
1	Eye disorders	Eye pain	Mild	Not Related	Y		Y	Y
2	Gastrointestinal disorders	Diarrhoea	Severe	Not Related	Y		Y	Y
3	Gastrointestinal disorders	Nausea	Moderate	Not Related	Y			Y
4	Nervous system disorders	Headache	Mild	Related	Y			
5	Nervous system disorders	Headache	Moderate	Related	Y	Y	Y	Y

Table 16. Occurrence Example 2

Because the last event is related to study drug and has moderate severity, this will be the record we analyze at the subject level. As long as the sorting algorithm is clear in metadata, reviewers and QCers should be able to easily recreate the above dataset. This sorting is very important because when creating the flags we need to include enough variables to ensure unique records. Including the AESEQ variable at the end of a sort would help ensure the flags are created properly. If a unique sorting algorithm is not used then QCers will face difficulty re-creating the flags exactly. Just like the simple analysis, the occurrence flags also allow for simple code in more complex analyses:

```
proc freq data=adam.adae noprint;
  where TRTEMFL = 'Y';
  tables TRT01PN * AOCC01FL * AREL * ASEV / out=any (where=(AOCC01FL='Y'));
run;
```

```
tables TRT01PN * AOCC02FL * AREL * ASEV * AEBODSYS / out=soc  
(where=(AOCC02FL='Y')) ;  
  
tables TRT01PN * AOCC03FL * AREL * ASEV * AEBODSYS * AEDECOD / out=pt  
(where=(AOCC03FL='Y')) ;  
run;
```

For sorting and/or transposing purposes in our table output, using or including numeric equivalents of AREL and ASEV is recommended but the above code works with our example.

Admittedly, if we have several types of occurrence analyses in one dataset there could be a large number of flags included in the dataset. A visual look at the metadata might be overwhelming but additional documents can be used to simplify the dataset and provide an overall explanation of the flags. The addition of these types of flags adds traceability from the ADaM dataset to the output. The specific records being used allow for easier reviewer and the path from ADaM to analysis is clear instead of being hidden in a separate program.

CONCLUSION

The freedom of ADaM is both a strength and a weakness of the model. Analysis cannot be held down by a strict model like SDTM because every analysis has unique components. What is needed is a set of tools used in a standard way depending on the conditions. A major part of this approach assumes that traceability will always be part of the datasets created no matter the situation. Being able to find the way back to where we started, knowing where we are and knowing where we're going are the key parts of the path of traceability.

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