PharmaSUG 2026 Paper DS-144

# Picking Up the Pieces:
# Implementation of (the forgotten) ADaM Naming Fragments

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## ABSTRACT

In working with ADaM standards, trying to build data sets and their variables can be a repetitive process that can become tedious as creating meaningful variable names within the 8-character limit. As opinions vary, even our own ideas can depend on the day-to-day, so it's good to be reminded that ADaM fragments exists and are required to help in the consistency of naming conventions and helping with regulatory review efficiency. Earlier versions or "client specifications" veer off path over time, so it is good from time to time to revisit the more common fragments as well as look at the less common fragments.

## INTRODUCTION

In the beginning of Analysis Data Model (ADaM) standards there existed a smaller set of core standards that were introduced for guidance to the industry. As time moved on, the need to expand those standards began to take place and without direct guidelines available for different needs of analysis, multiple efforts were made to fill in the gaps in the meantime. Because of the 8-character limit in naming conventions it becomes important to come up with naming conventions (i.e., fragments) to allow for consistency. Consistency is not only important for a company-wide set of standards, but industry wide as well.

Throughout the industry the specific prefix, suffix, etc. can all be determinative in variable naming conventions, however, just as a matter of opinion can differ the same can be said for naming fragments that are outside of any set of guidance documentation. However, similar to Study Data Tabulation Model (SDTM), within the ADaM standards there are pre-defined fragments. For example, just as the suffix --DTC is used in SDTM domains to represent the character date/time in ISO 8601 format, in ADaM standards, --DT is to be used to represent numeric dates. The use of these fragments allows the ease of implementation of standards regardless of the client and keeping consistency in data for the industry and regulatory review and efficiency.

Our goal was to bring together more commonly used conventions into one quick-reference document as a starting point to help implement a consistent approach in the naming process for any new variables or parameter codes that we may need to add to our data to assist or complete our analysis needs. We aim to not only to re-visit common ones but also bring forward some less common fragments to help avoid creating non-compliant variable names and/or analysis parameter codes. Just as earlier versions of ADaM standards can be forgotten or "client specifications" likely veering off path over time, throughout this whole process, creation and implementation of fragments should be focused on saving time and effort while being able to adhere compliance and submission reviews without worry.

## CDISC ADAM FRAGMENTS

Within the various ADaM standards documents, there are variable naming fragments. These fragments have specific meanings and are used within pre-defined ADaM variables and can also be used for creating sponsor-defined ADaM variables. Many of the fragments can be found within the ADaM Implementation Guide (ADaMIG). Others can be found within the Analysis Data Model (ADaM) Oncology Examples document.

### INDEXES

The first set of fragments we delve into are the indexes. These indexes have specific meanings. The use of these fragments should adhere to the following conventions defined in Table 1. The index in the variable name and in the variable label should be replaced with the corresponding number.

| Fragment | Description |
|---|---|
| xx | Refers to a specific period. Values are 01-99 (i.e., must be zero filled). |
| w | Refers to the index for the *w*th variable. Values are 1-9. |
| y | Refers to grouping or other categorization. Values are 1-99 (i.e., not zero filled). |
| zz | Refers to the index for the *zz*th variable. Values are 01-99 (i.e., must be zero filled). |

*Table 1: Indexes (CDISC, 2021)*

Indexes are seen in a number of pre-defined ADaM variables (refer to Table 2). However, they can also be used to create sponsor-defined variables as well as seen in Table 3 and Table 4.

In Table 2, notice that for PARCAT**y** and ANL**zz**FL, an additional descriptive text (in ***green***) is added to the label. For indexes **y** and **zz**, descriptive text can be added to the existing label as long as it remains within the 40-character limit.

| Pre-Defined Variables | | Substitution of Index with Correct Index Value | |
|---|---|---|---|
| **Variable** | **Label** | **Variable** | **Label** |
| TRT**xx**P | Planned Treatment for Period **xx** | TRT**01**P | Planned Treatment for Period **01** |
| APHASE**w** | Description of Phase **w** | APHASE**4** | Description of Phase **4** |
| PARCAT**y** | Parameter Category **y** | PARCAT**2** | Parameter Category **2 - *Method*** |
| ANL**zz**FL | Analysis Flag **zz** | ANL**55**FL | Analysis Flag **55 - *Steady State*** |

*Table 2: Examples of Indexes in Pre-Defined Variables*

Table 3 illustrates how pre-defined variables can be modified to create sponsor-defined variables based on the study needs. For example, if there are two enrollment periods, then index **xx** can be used to indicate the period that each enrollment corresponds. Or if there are two treatment phases to the study, then adding the PH (Phase) with the **w** index prior to the pre-defined variable TRCMP, can be created to capture the different compliances for each treatment phase. Or if we need to group the analysis duration, then appending GR (Group) with the **y** index to the pre-defined variable ADURN can be used to group the duration values.

| Combining Indexes with Pre-Defined Variables | | Substitution of Index with Correct Index Value | |
|---|---|---|---|
| **Variable** | **Label** | **Variable** | **Label** |
| ENRL**xx**DT | Date of Enrollment in Period **xx** | ENRL**01**DT | Date of Enrollment in Period **01** |
| PH**w**TRCMP | Phase **w** Treatment Compliance (%) | PH**2**TRCMP | Phase **2** Treatment Compliance (%) |
| ADURNGR**y** | Analysis Duration (N)-Group **y** | ADURNG**1** | Analysis Duration-Group **1** |

*Table 3: Examples of Indexes Combined with Pre-Defined Variables*

Table 4 demonstrates how to build sponsor-defined variables using the indexes. Notice that the same rules apply as the pre-defined variables and the pre-defined variables with indexes. For variables using the **y** and **zz** index, descriptive text (in ***green***) can be added to the end of the main portion of the label to add more meaning to the label. In addition, notice that multiple indexes can be used in the same variable as seen with the variable PH**w**SOCG**y**.

| Sponsor-Defined Variables | | Substitution of Index with Correct Index Value | |
|---|---|---|---|
| **Variable** | **Label** | **Variable** | **Label** |
| COHORT**xx** | Cohort in Period **xx** | COHORT**01** | Cohort in Period **01** |
| PH**w**THR | Phase **w** Therapy Type | PH**2**THR | Phase **2** Therapy Type |
| PH**w**SOCG**y** | Phase **w** Standard of Care Group **y** | PH**1**SOCG**3** | Phase **1** Standard of Care Group **3-*CHEMO*** |
| SMQ**zz**RID | SMQ **zz** Record Identifier | SMQ**05**RID | SMQ **05** Record Identifier-***Pancreatitis*** |

*Table 4: Examples of Indexes with Sponsor-Defined Variables*

## TIMING VARIABLES

Another group of fragments defined within the ADaMIG are timing variable fragments (Table 5). Most of the timing variable fragments are used for numeric values. Only the imputation variable fragments (DTF and TMF) are character.

| Fragment | Description | Label |
|---|---|---|
| *DT | Suffix used for numeric dates. | {Date} |
| *DTM | Suffix used for numeric datetimes. | {Datetime} |
| *TM | Suffix used for numeric times. | {Time} |
| *DY | Suffix used for relative day that does not include 0. | {Day} |
| *DTF | Suffix used for date imputation level indicator. | {Date Imputation Flag} |
| *TMF | Suffix used for time imputation level indicator. | {Time Imputation Flag} |
| *ADY | Suffix used for analysis relative day that does not include 0. | {Relative Day} |
| *SDT | Suffix used for numeric start dates. | {Start Date} |
| *STM | Suffix used for numeric start times. | {Start Time} |
| *SDTM | Suffix used for numeric start datetimes. | {Start Datetime} |
| *SDY | Suffix used for numeric relative start days that does not include 0. | {Relative Start Day} |
| *SDTF | Suffix used for start date imputation variables. | {Start Date Imputation Flag} |
| *STMF | Suffix used for start time imputation variables. | {Start Time Imputation Flag} |
| *EDT | Suffix used for numeric end dates. | {End Date} |
| *ETM | Suffix used for numeric end times. | {End Time} |
| *EDTM | Suffix used for numeric end datetimes. | {End Datetime} |
| *EDY | Suffix used for numeric relative end days that does not include 0. | {Relative End Day} |
| *EDTF | Suffix used for end date imputation variables. | {End Date Imputation Flag} |
| *ETMF | Suffix used for end time imputation variables. | {End Time Imputation Flag} |

*Table 5: Timing Variable Fragments (CDISC, 2021)*

Timing variable fragments are appended to a root value which match across all timing variables that represent a specific topic. In other words, if there is a datetime variable (DTM) in the data set and a corresponding date variable (DT) and a corresponding time variable (TM), the root value for all three must match. For example, in Table 6, the first two rows represent the thaw date and relative day of a specimen. There are only two variables, and both have the root 'THAW' and the root label 'Specimen Thaw'. The rest of the variables in the example pertain to the specimen spun date and time, thus they all have the root 'SPUN' with the root label 'Specimen Spun'.

| Variable | Label |
|---|---|
| **THAW**DT | **Specimen Thaw** Date |
| **THAW**DY | **Specimen Thaw** Relative Day |
| **SPUN**SDTM | **Specimen Spun** Start Datetime |
| **SPUN**SDT | **Specimen Spun** Start Date |
| **SPUN**STM | **Specimen Spun** Start Time |
| **SPUN**SDY | **Specimen Spun** Relative Start Day |
| **SPUN**SDTF | **Specimen Spun** Start Date Imputation Flag |
| **SPUN**STMF | **Specimen Spun** Start Time Imputation Flag |
| **SPUN**EDTM | **Specimen Spun** End Datetime |
| **SPUN**EDT | **Specimen Spun** End Date |
| **SPUN**ETM | **Specimen Spun** End Time |
| **SPUN**EDY | **Specimen Spun** Relative End Day |
| **SPUN**EDTF | **Specimen Spun** End Date Imputation Flag |
| **SPUN**ETMF | **Specimen Spun** End Time Imputation Flag |

*Table 6: Examples of Timing Variable Fragments*

Note that per section 3.1.5 in ADaMIG v1.3, the following fragments are required to be used when the concept applies for the indicated timing variable (CDISC, 2021).

- Numeric dates must use DT
- Numeric times must use TM
- Numeric datetimes must use DTM
- Imputation of dates must use DTF
- Imputation of times must use TMF
- Relative day based on numeric date must use DY

## OTHER VARIABLE FRAGMENTS

In addition to indexes and timing variable fragments, there are other fragments that are defined within the ADaMIG v1.3. As previously mentioned per section 3.1.5 of ADaMIG v1.3 there are specific fragments that are required to be used if the concept applies, the fragments in Table 7 are some additional fragments that are required to be used.

| Fragment | Description |
|---|---|
| GRy | Suffix used for grouping variables. Note that this can be abbreviated to Gy to fit within the 8-character limit. |
| FL | Suffix used for flag variables. Flag variables are variables that have a Y/null or Y/N/null. |

*Table 7: Required Variable Fragments (CDISC, 2021)*

The fragments in Table 8 are the recommended reserved fragments for creating variables within an ADaM data set. These fragments along with the indexes, timing variable fragments and SDTM fragments can be used to build sponsor-defined variables. Note that when the concept for an ADaM fragment conflicts with an SDTM fragment, the concept associated with the ADaM fragment takes precedence when used in an ADaM data set. (CDISC, 2021) Note that all the fragments in Table 8 are additional timing fragments except for U.

| Fragment | Description |
|---|---|
| BL | Fragment used for variables representing baseline. |
| CHG | Fragment used for variables representing change from baseline. |
| FU | Fragment used for variables representing follow-up. |
| OT | Fragment used for variables representing on-treatment. |
| RU | Fragment used for variables representing run-in. |
| SC | Fragment used for variables representing screening. |
| TA | Fragment used for variables representing taper. |
| TI | Fragment used for variables representing titer. |
| U | Fragment used for variables representing units. |
| WA | Fragment used for variables representing washout. |

*Table 8: Recommended Variable Fragments (CDISC, 2021)*

The order in which the fragments are used is dependent on what the variable represents.

- If the variable represents a value that is captured at a specific time point, then the recommended timing fragment is used as a suffix.
- If the variable represents a value that is captured at a specific time point within a specific period, then the period index precedes the timing variable suffix.
- If the variable represents a value that pertains to the timing of a timepoint, then the recommended timing fragment is used as a prefix.
- If the variable represents a value that pertains to the timing of a timepoint within a specific period, then the recommend timing fragment is used as a prefix with the period preceding the required timing fragment.
- If a variable represents a grouping, then the grouping fragment is used as a suffix. (CDISC, 2021)

Generally, the sponsor-defined portion comes prior to the fragments. Thus, you have sponsor-defined + period + recommended timing fragment + required timing fragment or sponsor-defined + period + recommended timing fragment + grouping fragment. Table 9 illustrates examples of variable names built with the various fragments.

| Variable | Label | Fragment Order |
|---|---|---|
| WTBL | Weight at Baseline | sponsor + recommended timing fragment |
| WT01BL | Weight at Period 01 Baseline | sponsor + period + recommended timing fragment |
| SCDT | Screening Date | recommended timing fragment + required timing fragment |
| RU01SDT | Run-in Period 01 Start Date | recommended timing fragment + period + required timing fragment |
| WTBLGR1 | Weight at Baseline Group 1 | sponsor + recommended timing fragment + grouping fragment |
| WT01BLG1 | Weight at Period 01 Baseline Group 1 | sponsor + period + recommended timing fragment + grouping fragment |

*Table 9: Examples of Recommended Fragments*

## ONCOLOGY EXAMPLES DOCUMENT V1.0

While a number of pre-defined fragments can be found in the ADaMIG, there are some additional fragments defined in supplemental documents. While these are not official standard fragments, it is recommended to use these fragments in naming subject-level variables, whenever the concept applies. Table 10 provides a list of the fragments found within the ADaM Data Model (ADaM) Oncology Examples document. Note that fragments found in supplemental documents may have a different concept that the pre-defined fragments in the ADaMIG, the definition and use in the ADaMIG takes precedence.

For example, in SDTM data sets status is represented with the suffix STAT, while in ADaM data sets that use the fragments in Table 10 for study-specific status is represented with the suffix STT. Thus, it is important to be mindful of fragments defined in the SDTM and SDTM Implementation Guide (SDTMIG) to avoid creating an ADaM variable with the same name as an SDTM data set variable.

| Fragment | Fragment Label | Notes |
|---|---|---|
| ACT | Anti-cancer Therapy | Position of the fragment depends on the purpose of the variable. |
| DX | Diagnosis | Position of the fragment depends on the purpose of the variable. |
| PD | Progressive Disease | Position of the fragment depends on the purpose of the variable. |
| MS | Metastasis | Position of the fragment depends on the purpose of the variable. |
| CHM | Chemotherapy | Position of the fragment depends on the purpose of the variable. |
| RAD | Radiotherapy | Position of the fragment depends on the purpose of the variable. |
| SRG | Surgery | Position of the fragment depends on the purpose of the variable. |
| *STAGE | Stage | Suffix used when describing study-specific stage of cancers. |
| *STT | Status | Suffix used when describing study-specific status, including substance use status |
| HISTOLG* | Histopathology | Prefix used to indicate study-specific histopathology |
| *STYP | Subtype | Suffix used for subtypes |
| DISF | Disease Finding | Position of the fragment depends on the purpose of the variable. |
| IMPTYP* | Immunophenotype | Prefix used to indicate immunophenotype |
| P | Prior | Position of the fragment depends on the purpose of the variable. |
| TS* | Time since | Prefix used to indicate time since |

*Table 10: Analysis Data Model (ADaM) Oncology Examples Fragments (CDISC, 2025)*

Table 11 illustrates some examples of how to implement the various fragments. Note in Table 10 there are fragments that include a *, the purpose is to designate when a fragment can only be a prefix or can only be a suffix. The ones with the preceding * indicate that the fragment should only be used as a suffix. The ones with the trailing * indicate the fragment should be used as a prefix. If there is no *, then the fragment can be used in any part of the variable. However, it is recommended to use the rules defined previously.

| Variable | Label |
|---|---|
| **PACTSDT** | **Prior Anti-cancer Therapy Start Date** |
| **PACTSDY** | **Prior Anti-cancer Therapy Relative Start Day** |
| O**STAGE** | Overall Cancer **Stage** |
| **MSSTAGE** | **Metastasis Stage** |
| N**STAGE** | Nodal Involvement **Stage** |
| T**STAGE** | Primary Tumor **Stage** |
| HER2**STT** | HER2 **Status** |
| **TSDX*** | **Time Since Diagnosis** (*) |

*Table 11: Examples of Using Oncology Example Fragments*
** represents the unit of measurement needed for analysis*

## CONCLUSION

ADaM-defined fragments help build variables and parameter codes. Implementing the use of existing fragments saves time and allows consistency in names not only within the company but also within the industry. Keeping in mind that fragments should be used according to intent defined in the CDISC notes. While there are fragments within the Oncology examples document these fragments can be used for other therapeutic areas, or in general, as needed.

## REFERENCES AND RECOMMENDED READINGS


CDISC. (2021, Nov 29). *Analysis Data Model Implementation Guide v1.3 (Final)*. Retrieved Feb 2026, from CDISC: https://www.cdisc.org/system/files/members/standard/foundational/ADaMIG_v1.3.pdf

CDISC. (2025, May 29). *Analysis Data Model (ADaM) Oncology Examples Version 1.0 (Provisional)*. Retrieved Feb 2026, from CDISC: https://www.cdisc.org/system/files/members/standard/foundational/ADaM%20Oncology%20Examples%20v1.0_Provisional.pdf


## CONTACT INFORMATION

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