

An ADaM Interim Dataset for Time-to-Event Analysis Needs

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ABSTRACT

The Clinical Data Interchange Standards Consortium (CDISC) Analysis Data Model (ADaM) Implementation Guide (IG) Version 1.0 and the appendix document titled “The ADaM Basic Data Structure for Time-to-Event Analyses” each provide guidance for how to set up a dataset for producing a Time-to-Event (TTE) analysis. In practice, a single TTE analysis dataset is often used for analysis of many different events and censoring times. In fact, this TTE analysis dataset is often one of the most complicated created for a study.

One of the biggest issues with TTE analyses is that there can be many different dates to consider for both the event and/or the censor. Some of these dates can be options for many different analyses – for example, date of death is the event in survival analysis, but can also be a censor date in time-to-response analysis. To make TTE analysis more clear, we’ve adopted the process of compiling an interim BDS (Basic Data Structure) dataset with all potential dates to be used in the TTE analyses. This paper explains our process and gives examples of how an interim dataset can be used to add traceability and understanding to a complex analysis.

INTRODUCTION

The following is an example of an ADaM TTE Analysis Dataset (ADTTE), where the event of interest is Progression Free Survival (PFS):

	USUBJID	PARAM	PARAMCD	AVAL	STARTDT	ADT	CNSR	EVNTDESC	CNSDTC
1	1001-0001	Progression Free Survival (days)	PFS	301	17MAR2007	11JAN2008	0	DISEASE PROGRESSION	
2	1001-0002	Progression Free Survival (days)	PFS	2556	21MAR2007	19MAR2014	3	COMPLETED STUDY	LAST ADEQUATE ASSESSMENT SHOWING NO PROGRESSION
3	1005-0023	Progression Free Survival (days)	PFS	1401	30JUN2007	30APR2011	0	DEATH	
4	1010-0007	Progression Free Survival (days)	PFS	1	10MAY2007	10MAY2007	1	NO BASELINE ASSESSMENT	RANDOMIZATION
5	1012-0010	Progression Free Survival (days)	PFS	405	25MAY2007	02JUL2008	2	NEW ANTI-CANCER THERAPY	LAST ADEQUATE ASSESSMENT PRIOR TO NEW ANTI-CANCER THERAPY
6	1015-0022	Progression Free Survival (days)	PFS	578	20JUN2007	17JAN2009	4	DISEASE PROGRESSION AFTER EXTENDED PERIOD OF INADEQUATE ASSESSMENT	LAST ADEQUATE ASSESSMENT PRIOR TO PERIOD OF INADEQUATE ASSESSMENT

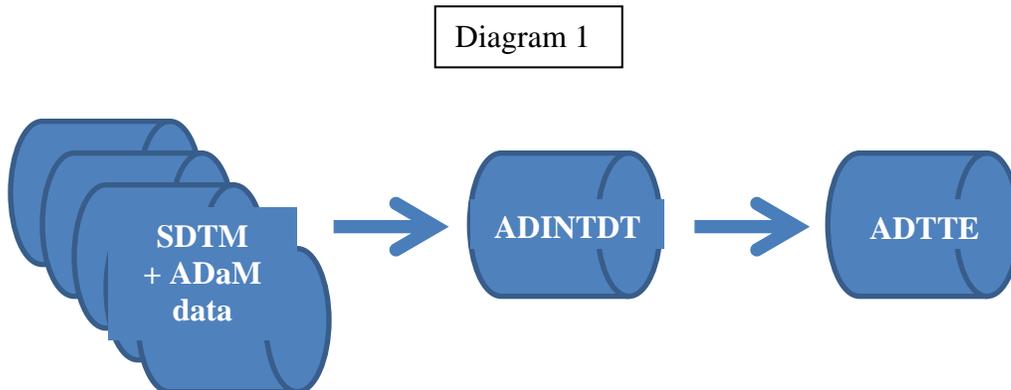
- AVAL is the elapsed time to the event of interest or censoring from the origin.
- PARAM describes the contents of AVAL, which is ‘Progression Free Survival (days)’.
- STARTDT is the date of origin from which AVAL is calculated. STARTDT can be the equivalent of the Randomization Date, Treatment Start Date, etc.
- ADT represents the analysis date for the event or censoring associated with AVAL.
- CNSR indicates an event or censoring. An event is indicated as CNSR=0. Censoring is indicated as CNSR>0. In this example, there are four reasons for censoring. If CNSR is not 0, then CNSR is an integer from 1 to 4, corresponding to each of the four reasons for censoring.
- The reasons for censoring are contained in CNSDTC. EVNTDESC indicates the event of interest or the event that warrants censoring. For example, Subject 1001-0001 had an event, so EVNTDESC is populated and CNSDTC is null. Subject 1012-0010, on the other hand, was censored. EVNTDESC indicates that the event that warranted censoring was the initiation of a new anti-cancer therapy. CNSDTC reveals that the exact point at which the subject was censored is the date of last adequate assessment prior to new anti-cancer therapy.

There are often many dates of interest that are used to derive ADT, such as the date of progression, date of death, date of last adequate assessment, date of new anti-cancer therapy, etc. These dates of interest can be added as variables in ADTTE. However, the structure would be horizontal and would not conform to the vertical structure of a BDS dataset. Additional information regarding the source and imputation level of each date of interest would require the number of variables to multiply even further, making ADTTE overly complicated.

INTERIM DATA TECHNIQUE

It is possible to create a dataset that consists of parameters of the form “Date of XYZ” that adheres to the BDS structure and contains all of the dates of interest for the TTE analyses. For the purposes of this paper, we’ll call this interim dataset ADINTDT (Interim Dataset of Dates used for ADTTE).

First, source datasets, which can be SDTM or ADaM, are used to derive the dates of interest. Then, ADINTDT stores these dates of interest and serves as input to ADTTE. The general process is illustrated in Diagram 1:



Consider the following rules for censoring from a hypothetical Statistical Analysis Plan (SAP):

1. Subjects will be considered to have had an event at the **date of progression** or the **date of death**, whichever comes first.
2. If the subject had no event, then the subject will be censored at the **date of last adequate assessment**. If the subject no adequate assessments, then the subject will be censored at the **date of randomization**.
3. If the subject had no event, but the subject initiated a new anti-cancer therapy, then the subject will be censored at the **date of last adequate assessment prior to new anti-cancer therapy**. If the subject had no adequate assessment prior to the new anti-cancer therapy, then the subject will be censored at the **date of randomization**.
4. If the subject had an event but initiated a new anti-cancer therapy and the **start date of new anti-cancer therapy** is prior to the event, then the subject will be censored at the **date of last adequate assessment prior to new anti-cancer therapy**. If the subject had no adequate assessment prior to new anti-cancer therapy, then the subject will be censored at the **date of randomization**.
5. If the subject had an event but the last adequate assessment prior to the event was more than 180 days prior to the event, then the subject will be censored at this **date of last adequate assessment prior to period of inadequate assessment**.

These rules may seem confusing. However, when preparing ADINTDT, the focus is strictly on the dates of interest, which have been highlighted in bold. The following is the ADINTDT dataset that stores these dates of interest:

	USUBJID	ASEQ	PARAMCD	PARAM	AVALC	ADT	ADTF	SRCDOM	SRCVAR	SRCSEQ
1	1001-0055	1	RANDDT	Date of Randomization	17MAR2007	17MAR2007		ADSL	RANDDT	.
2	1001-0055	2	LRSCDXDT	Date of Last Adequate Assessment Prior to Start of New Anti-Cancer Therapy	11JAN2008	11JAN2008		RS	RSDTC	21
3	1001-0055	3	LRSIADT	Date of Last Adequate Assessment Prior to Period of Inadequate Assessment	11JAN2008	11JAN2008		RS	RSDTC	32
4	1001-0055	4	NCTXSDT	Start Date of New Anti-Cancer Therapy	01MAR2008	01MAR2008	D	CM	CMSTDTC	52
5	1001-0055	5	LRSADT	Date of Last Adequate Assessment	21NOV2008	21NOV2008		RS	RSDTC	21
6	1001-0055	6	PROGDT	Date of Progression	21NOV2008	21NOV2008		RS	RSDTC	15
7	1001-0055	7	DTHDT	Date of Death	02JUL2009	02JUL2009		DM	DTHDTC	.

- The descriptions of the dates of interest that were highlighted in bold are contained in the values of PARAM.
- PARAMCD can be up to eight characters long, and should, ideally, contain values that are as intuitive as possible for reasons that will become apparent.
- The numeric values of the dates of interest are contained in ADT.
- ADTF is used to indicate the level of imputation according to ADaM Controlled Terminology, where ADTF='D' indicates that the day was imputed, ADTF='M' indicates that the month/day was imputed, and ADTF='Y' indicates that the year/month/day was imputed. If no imputation was done then ADTF is null.
- AVAL or AVALC must also be present to fulfill the ADaM requirement for a BDS dataset. In this example, the character version of the DATE9 format of ADT has been captured in AVALC.
- The source domain (or dataset), source sequence number, and source variable are contained in SRCDOM, SRCSEQ, and SRCVAR, respectively.
- The Analysis Sequence Number (ASEQ) is present so ADTTE can reference the appropriate record in this interim dataset, as will be demonstrated. ASEQ is a derived variable introduced in the ADTTE Appendix that should be included in the next version of the ADaMIG. In this example, ASEQ is derived by simply assigning the sequential value of the record number for a given subject.

PROCESS FOR CREATION AND APPLICATION OF ADINTDT

1. Create ADINTDT
 - a. Pre-process all source datasets from which the dates of interest will be obtained
 - b. Create one dataset for each individual date of interest
 - c. Set the datasets containing each individual date of interest together
2. Create ADTTE
 - a. Transpose ADINTDT
 - b. Apply the censoring rules in the SAP

Step 1. Create ADINTDT

Part A. Pre-process all source datasets from which the dates of interest will be obtained

The source datasets from which the dates of interest will later be derived are pre-processed to include key variables. The following DATA STEP pre-processes the LB domain:

```
data lb;
  set lb;
  length srcdom srcvar $8;
  format adt date9.;
  adt=input(lbdtc, yymmdd10.);
  srcdom='LB';
  srcvar='LBDTC';
  srcseq=lbseq;
run;
```

SRCDOM is set to "LB", SRCVAR is set to "LBDTC", SRCSEQ is set to LBSEQ, and ADT is set to the numeric version of LBDTC in DATE9 format. Any required imputation can also be performed in this DATA STEP and ADTF can be set to the appropriate value. This DATA STEP lends itself very well to being macrotized so that all of the source datasets can be pre-processed at the same time.

Part B. Create one dataset for each date of interest

For clarity and organization, we have found the creation of one dataset for each individual date of interest to be an important step in the creation of ADINTDT. Suppose the date of interest is **start date of new anti-cancer therapy**, where the earliest date from among the records with specific values of CM.CMCAT is to be selected:

```
proc sort data=cm(where=(cmcat='ANTI-CANCER')) out=nctxsdt;
  by usubjid adt adtf srcdom srcseq srcvar;
run;

data nctxsdt(keep=usubjid adt adtf srcdom srcseq srcvar);
  set nctxsdt;
  by usubjid adt adtf srcdom srcseq srcvar;
  if first.usubjid;
run;
```

Now, the dataset NCTXSDT will contain the appropriate date of interest. Only the necessary variables are kept: USUBJID, ADT, ADTF, SRCDOM, SRCSEQ, and SRCVAR.

Note that the dataset has been sorted first by USUBJID, then by ADT, and then by ADTF (Imputation Flag). This is to ensure that the date with the lowest level of imputation will be selected if the same date exists on multiple records, as illustrated:

	USUBJID	SRCDOM	SRCSEQ	CMSTDTC	ADT	ADTF
1	1012-0010	CM	19	2012-06-15	15JUN2012	
2	1012-0010	CM	17	2012-06	15JUN2012	D
3	1012-0010	CM	11	2012	15JUN2012	M
4	1012-0010	CM	7		15JUN2012	Y

← Lowest Level of Imputation

ADT=15JUN2012 on all four records. The record where SRCSEQ=19 would be selected because ADTF is null, indicating that no imputation was applied. A reviewer would be able to locate a complete date in the source data. Fortunately, the possible values of ADTF, per ADaM Controlled Terminology, correspond alphabetically to increasing levels of imputation (null, D, M, Y). If necessary, the word DESCENDING can be placed in front of ADTF in the BY statement to ensure that the date with the lowest level of imputation is selected.

If the same date with the lowest level of imputation exists across multiple domains, sequence numbers, or source variables, then arbitrary rules can be established to select a specific source (first alphabetically, last alphabetically, etc.). The ability to point the reviewer to a specific source that contains the date with the lowest level of imputation possible facilitates traceability.

All of the dates of interest will each have their own blocks of code where they will be derived and temporarily stored in their own datasets.

Part C. Set the datasets containing each individual date of interest together

```

data all;
  length param $200 paramcd $8;
  set nctxsdt(in=a) progdt(in=b) death(in=c) lrsadt(in=d);
  if a then do;
    param='Start Date of New Anti-Cancer Therapy';
    paramcd='NCTXSDT';
  end;
  else if b then do;
    param='Date of Progression';
    paramcd='PROGDT';
  end;
  else if c then do;
    param='Death Date';
    paramcd='DTHDT';
  end;
  else if d then do;
    param='Date of Last Adequate Assessment';
    paramcd='LRSADT';
  end;
run;

```

The DATA STEP in this example brings together all of the dates of interest. For illustration purposes only four parameters have been included. The datasets are set on top of each other to establish the vertical structure required for a BDS dataset. The IN operator is used to assign the values of PARAM and PARAMCD. As additional dates are added, more datasets may be stacked.

Step 2: Create ADTTE

Part A. Transpose ADINTDT

This part of the process is the pivotal step of the application of ADINTDT:

```

proc transpose data=adintdt out=dates(drop=_name_ _label_);
  by usubjid;
  var adt;
  id paramcd;
run;

```

The resulting dataset DATES is a horizontal structure:

	USUBJID	RANDDT	PROGDT	LRSADT	LRSDT	NCTXSDT	LRSIADT	DTHDT
1	1001-0001	17MAR2007	09JAN2008					
2	1001-0002	21MAR2007		19MAR2014				
3	1001-0055	17MAR2007	21NOV2008	21NOV2008	11JAN2008	01MAR2008	11JAN2008	02JUL2009
4	1005-0023	30JUN2007						30APR2011
5	1010-0007	10MAY2007						30OCT2007
6	1012-0010	25MAY2007		13AUG2008	17JUN2008	02JUL2008		
7	1015-0022	20JUN2007	13SEP2009				17JAN2009	22FEB2010

As illustrated, all of the dates of interest are now on a single observation for each subject. Each variable bears the name of the corresponding PARAMCD in ADINTDT. Remember that when describing the structure of ADINTDT the need for the value of PARAMCD to be as intuitive as possible was mentioned. Clearly, DTHDT contains the date of death, NCTXSDT contains the start date of new anti-cancer therapy, etc.

Part B. Apply the censoring rules in the SAP

The horizontal structure of the transposed dataset is programmatically optimal for applying the censoring rules through a series of IF-THEN-DO statements. The key variables ADT, AVAL, CNSR, CNSDTDSC and EVNTDESC are derived.

The resulting dataset is the ADTTE dataset previously illustrated, but with two additional variables:

	USUBJID	PARAM	PARAMCD	AVAL	STARTDT	ADT	CNSR	EVNTDESC	CNSDTDSC	SRCDOM	SRCSEQ
1	1001-0001	Progression Free Survival (days)	PFS	301	17MAR2007	11JAN2008	0	DISEASE PROGRESSION		ADINTDT	3
2	1001-0002	Progression Free Survival (days)	PFS	2566	21MAR2007	19MAR2014	3	COMPLETED STUDY	LAST ADEQUATE ASSESSMENT SHOWING NO PROGRESSION	ADINTDT	2
3	1005-0023	Progression Free Survival (days)	PFS	1401	30JUN2007	30APR2011	0	DEATH		ADINTDT	2
4	1010-0007	Progression Free Survival (days)	PFS	1	10MAY2007	10MAY2007	1	NO BASELINE ASSESSMENT	RANDOMIZATION	ADINTDT	1
5	1012-0010	Progression Free Survival (days)	PFS	405	25MAY2007	02JUL2008	2	NEW ANTI-CANCER THERAPY	LAST ADEQUATE ASSESSMENT PRIOR TO NEW ANTI-CANCER THERAPY	ADINTDT	4
6	1015-0022	Progression Free Survival (days)	PFS	578	20JUN2007	17JAN2009	4	DISEASE PROGRESSION AFTER EXTENDED PERIOD OF INADEQUATE ASSESSMENT	LAST ADEQUATE ASSESSMENT PRIOR TO PERIOD OF INADEQUATE ASSESSMENT	ADINTDT	5

SRCDOM and SRCSEQ have been added. SRCDOM='ADINTDT', the time to event predecessor dataset which is the focus of this paper. SRCSEQ contains the value of ASEQ on the record in ADINTDT from which ADTTE.ADT has been selected.

An important point to note is that ADINTDT.ASEQ is lost when ADINTDT is transposed. ADINTDT.ASEQ must be retrieved so that ADTTE.SRCSEQ can be set to the appropriate value. A merge between ADTTE and ADINTDT by ADT is not reliable because multiple parameters in ADINTDT may have the same value of ADT. A helpful tip to achieve a reliable merge is to create a temporary PARAMCD that can be used as a link between ADTTE and ADINTDT. The temporary PARAMCD can be conveniently created when the censoring rules are applied:

```

data censor;
  set dates;
  if not missing(dthdt) then do;
    cnsr=0;
    adt=dthdt;
    paramcd='DTHDT' ; * Temporary PARAMCD ;
  end;
  else if missing(dthdt) then do;
    cnsr=1;
    adt=lstalvdt;
    paramcd='LSTALVDT' ; * Temporary PARAMCD ;
  end;
run;

```

The above code applies the censoring rules of a typical overall survival analysis. If a subject died (DTHDT is not missing), then the subject had an event (CNSR=0), and the date is the Date of Death (ADT=DTHDT). If the subject did not die (DTHDT is missing), then the subject is censored (CNSR=1), and the date is the Last Known Alive Date (ADT=LSTALVDT). The ability to write code that clearly corresponds to a verbal description of the censoring rules is the main advantage of the horizontal structure of the transposed dataset.

Suppose the Date of Death for subject 1012-0010 is 11JAN2009, but the Last Known Alive Date for subject 1012-0010 is also 11JAN2009. The temporary PARAMCD for subject 1012-0010 will be set to "DTHDT" at the time ADT is set to DTHDT. Although the Date of Death and Last Known Alive Date are the same, the following merge can then bring in the appropriate value of ADINTDT.ASEQ to which ADTTE.SRCSEQ will be assigned:



After this merge, ADTTE.PARAMCD will be set to a different value that is appropriate to ADTTE, such as 'TTOVS' (Time to Overall Survival (days)). The value of 14 in ADINTDT.ASEQ is now captured in ADTTE.SRCSEQ.

USUBJID	PARAM	PARAMCD	AVAL	STARTDT	ADT	CNSR	EVNTDESC	SRCDOM	SRCSEQ
1012-0010	Time to Overall Survival (days)	TTOVS	598	25MAY2007	11JAN2009		0 DEATH	ADINTDT	14

BENEFITS

There are significant advantages to having a predecessor dataset, ADINTDT, with a vertical structure as opposed to a horizontal structure in ADTTE. The vertical structure of ADINTDT conforms to the ADaM Basic Data Structure. The statistician and/or reviewer can sort by the analysis dates to determine how the dates fall chronologically and in relation to one another. ADINTDT allows for data point traceability in addition to metadata traceability.

Data point traceability is implemented in a stepwise fashion. SRCSEQ in ADTTE points the reviewer to the record in ADINTDT from which ADTTE.ADT was selected. SRCDOM, SRCSEQ, and SRCVAR in ADINTDT will in turn point the reviewer to the precise source from which ADTTE.ADT was ultimately obtained. By using data point traceability, the location and existence of all dates can be systematically verified.

The metadata/specifications become dramatically simpler, as the derivations can be separated into individual components. Variables in ADaM datasets are often dependent on the associated parameters. For example, ADT may have one derivation for a particular value of PARAM, but ADT may have a different derivation for another value of PARAM. Herein lies the concept of parameter value level metadata, one of the main components of a standard Define.xml. ADINTDT provides a very good example of parameter value level metadata. The following is an excerpt of the parameter value level metadata section of a Define.xml file for a typical ADINTDT dataset:

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Source/Derivation/Comment
ADT	PARAMCD="RANDT" (Date of Randomization)	integer	date9.		ADSL.RANDT
ADT	PARAMCD="PROGDT" (Date of Progression)	integer	date9.		Earliest RS.RSDTC (converted to numeric) where RS.RSTESTCD="OVLRESP" and RS.RSSTRESC="PD"
ADT	PARAMCD="NCTXSDT" (Start Date of New Anti-Cancer Therapy)	integer	date9.		The earliest start date converted to numeric from the following records (after day imputation if necessary): CM.CMSTDTC where CM.CMCAT="ANTI-CANCER THERAPY" and CM.CMSTRF = "AFTER" or PR.PRSTDTC where PR.PRCAT="ANTI-CANCER THERAPY" and PR.PRSTRF = "AFTER". Use the following rules below for partial dates with Day missing (Only day missing is allowed in CRF): If partial date falls in the same month as the last dose of study treatment (TRTEDT), then assign to earlier of (date of last dose of study treatment+1, last day of month). If partial date falls in the same month as the subject's last assessment (RS.RSDTC) and the subject's last assessment is PD (RS.RSSTRESC="PD" and RS.RSTESTCD="OVLRESP"), then assign to earlier of (date of PD+1, last day of month). If both rules above apply, then assign to latest of the 2 dates. Otherwise, impute missing day to the first of the month.
ADT	PARAMCD="LRSCXTDT" (Date of Last Adequate Assessment Prior to Start of New Anti-Cancer Therapy)	integer	date9.		Get the latest RS.RSDTC (converted to numeric) where RS.RSTESTCD="OVLRESP" and RS.RSSTRESC in("CR" "PR" "SD" "PD") on or prior to ADINTDT.ADT where PARAMCD="NCTXSDT"
ADT	PARAMCD="LRSIADT" (Date of Last Adequate Assessment Prior to Period of Inadequate Assessment)	integer	date9.		Derive as follows: 1. Get the latest RS.RSDTC (converted to numeric) where RS.RSTESTCD="OVLRESP" (DATE1) and RS.RSSTRESC in("CR" "PR" "SD" "PD") on or prior to ADINTDT.ADT where PARAMCD in("PROGDT" "DTHDT") (DATE2) 2. Create a record if the assessment is more than 180 prior to the event (DATE2-DATE1+1 > 180)
ADT	PARAMCD="LRSADT" (Date of Last Adequate Response Assessment)	integer	date9.		Get the last RS.RSDTC (converted to numeric) where RS.RSTESTCD="OVLRESP" and RS.RSSTRESC in("CR" "PR" "SD" "PD")

The derivations of ADT are provided in separate rows for each parameter. The specifications for ADTTE can then simply reference these parameters when describing how the censoring rules are applied. Without ADINTDT, all of the derivations in the Define.xml shown above would have to be intermediate steps to the derivations in ADTTE. The application of ADINTDT provides the reviewer with a much clearer picture of how ADTTE is assembled.

Much simpler programming logic follows from the simplified specifications. Programming tasks can be neatly segregated into separate sections. The DATA STEP in Step 1 Part A is a straightforward way to pre-process all of the source datasets that are needed in the analysis. Step 1 Part B consists of individual pieces of code to create datasets that each contains one of the dates of interest. These pieces of code can be thought of as modules. When more dates are added to the analysis, more modules may be added. The datasets in the SET statement to bring all the dates together in Step 1 Part C can also be used to track and organize the addition of new parameters. The transpose of ADINTDT in Step 2 bridges the gap between the BDS and the horizontal structure that is conducive to implementing the censoring rules. The traceability of BDS is maintained while at the same time the programmatic benefit of a horizontal structure can be utilized.

Perhaps one of the biggest benefits is in the QC process. When the production and QC programmers have different results, the transposed dataset can be easily examined to determine who is selecting which date and why. ADINTDT is the common source from which all dates are selected. ADTTE and ADINTDT are separate datasets that will each undergo their own separate QC. If the value for a date of interest is updated in ADINTDT, then no change to the logic in ADTTE will be required.

CONCLUSION

The example presented in this paper lays out the framework for a basic TTE Analysis. This example can be expanded to more complex analyses. For example, a particular study may have a substantial number of dates under consideration to support various sensitivity and other analyses. Some events of interest might also consist of compound criteria derived in other ADaM datasets which can then be used as input to ADINTDT rather than the source data from SDTM. ADINTDT is a good repository to store a catalog of dates that often grows over the course of a project.

Think of TTE Analysis in terms of making cupcakes. ADINTDT is like gathering and mixing your ingredients. ADTTE is like pouring the batter into the cupcake tins and baking. The creation and application of ADINTDT using the steps described in this paper can make your TTE Analysis a piece of cake!

REFERENCES

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<http://www.cdisc.org/adam>
- **Analysis Data Model (ADaM) Implementation Guide version 1.0**
<http://www.cdisc.org/adam>
- **CDISC ADaM Basic Data Structure for Time-to-Event Analysis Version 1.0**
<http://www.cdisc.org/adam>

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