ADaM Model for Time-to-Event Analysis Files

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1 INTRODUCTION

The Analysis Dataset Models (ADaM) Working Group has constructed several statistical analysis dataset models intended for submission to the FDA (CBER, CDER, and CDRH). These dataset models were selected based on different analysis techniques that have often been used in performing efficacy analyses. Note that these dataset models may also be effective in the presentation of safety or integrated summary data. However, for clarity and concreteness, we will limit the presentation of the example below to a primary or high-level secondary efficacy variable.

These statistical analysis data models represent consensus across a large number of reviewers experienced in regulatory submissions. While these examples are presented as models, it is recognized that these examples do not represent the only approach. While different data models/structures/approaches may be used, the CDISC submission metadata model must be followed. We cannot emphasize enough that early and effective cross-communication between regulatory reviewers and sponsors is requisite for mutual success.

All dataset models use the principles established by the CDISC metadata model (http://www.cdisc.org/pdf/CDISC_SDS_Model_1-1.PDF). All dataset models also follow the ADaM guidelines for the creation of analysis data files and the documentation of statistical analyses for submission to the FDA (http://www.cdisc.org/models/adam/ADaM_Guidelines_V1.pdf).

The current example deals with a type of analysis frequently used by industry statisticians: the time-to-event analysis. This example considers the occurrence of the first event only, but may not preclude the development of analysis files for analyzing recurrent event data through straightforward extensions. This example may be useful in clinical trials in a broad spectrum of therapeutic areas: oncology (e.g., time to disease progression), cardiovascular (e.g., time to death, myocardial infarction, or hospitalization), AIDS (e.g., time to virological suppression), anti-infectives (e.g., time to infection or anti-microbial medications), analgesics (e.g., time to perceptible pain relief), osteoporosis (e.g., time to fracture), etc.

Data Files and Corresponding Metadata

The event(s) of interest are followed longitudinally in a clinical trial. There may be more than one type of event being followed simultaneously, either to make up a compound event for one time-to-event variable or to derive at least two time-to-event variables.

Metadata for one source file and three analysis files are presented in the example below.

- *Source File contains collected data that are useful in the assessment of the occurrence or non-occurrence of the event of interest. In situations in which the occurrence or non-occurrence of this event is verified at regular intervals during the clinical trial, Source File augments the dataset containing results of these regular checks with flags for the analysis populations.*
- *Analysis File #1is an intermediate analysis file that contains ancillary information on the reasons for censoring. This file also contains additional information on the occurrence of each constituent event in cases in which the*

event of interest is actually a compound event (i.e., an event composed of at least two different types of constituent events).

- *Analysis Files #2 and #3 contain the time-to-event variables and corresponding censoring variables that relate directly to the primary and secondary efficacy variables. Analysis File #2 utilizes a structure wherein there is one record per subject per time-to-event variable. Analysis File #3 utilizes a structure wherein there is one record per subject (i.e., the different time-to-event variables for a subject are all contained in one record).*

Source File and Analysis File #1 may be viewed as intermediate files and may be useful to the FDA Statistical Reviewer to document the construction of Analysis Files #2 and #3. Typically, various complex calculations are required to obtain Analysis Files #2 and #3 from either Source File or Analysis File #1. Analysis Files #2 and #3 may be viewed as the ultimate analysis files, using two different data structures. The Sponsor could submit both structures or just the one preferred by the FDA Statistical Reviewer. Considerations when deciding which data structures may be appropriate are summarized in Guideline for the Creation of Analysis Files and Documentation of Statistical Analyses for Submission to the FDA.

The source file and all three analysis files contain a set of common variables. Some of these common variables are obtained from the set of core variables in the CDISC metadata model (http://www.cdisc.org/pdf/SubmissionMetadataModelV2.pdf); these appear in ***bold*** *(black color) in the examples. The other remaining common variables are specific to ADaM models; these appear in* ***bold*** *(green color) in the examples.*

Description of Current Example

The example below evaluates the efficacy of experimental drug B when combined with the existing standard drug A compared with drug A alone as measured by time to disease progression, time to treatment failure, and duration of survival. The following specification of the study objectives could be considered to be excerpts from the protocol.

The primary objective of this study is the following:

- To evaluate the efficacy of multiple administrations of drug B when combined with standard drug A compared with drug A alone in subjects with previously treated metastatic breast cancer, as measured by time to disease progression

The secondary objectives of this study are the following:

- To evaluate the efficacy of multiple administrations of drug B when combined with standard drug A compared with drug A alone in subjects with previously treated metastatic breast cancer, as measured by time to treatment failure and duration of survival
- (Other objectives like safety and pharmacokinetics)

Furthermore, the following details on the definition and statistical analysis of the efficacy endpoints could also be considered to be excerpts from the protocol.

Analysis of the Primary Efficacy Variable (Time to Disease Progression)

Time to disease progression, as determined by the Independent Review Facility (IRF), is defined as time from randomization to the date of IRF-documented disease progression or death on study, whichever occurs first. Time to disease progression for subjects who have discontinued from the study or who have not progressed at the time of analysis will be treated as censored at the date of the last tumor assessment. In cases in which the investigator determined that the subject had progressive disease and took the subject off therapy but there was no IRF assessment of progressive disease, time to disease progression will be treated as censored on the day of the last tumor assessment.

Formal hypothesis testing using the two-sided unstratified log-rank test will be performed at the two-sided 0.05 level to determine whether time to disease progression is prolonged for the Drug A + B group compared with the Drug A alone

group. The null and alternative hypotheses can be described in terms of hazard ratios as H_0: $_{A+B}/_{A}$ = 1 and H_A: $_{A+B}/_{A}$ 1, where $_{A+B}$ ($_{A}$) represents the hazard of disease progression for the Drug A+B (Drug A alone) group.

An estimate of the hazard ratio $_{A+B}/_{A}$ with 95% confidence intervals will be determined using a Cox regression model with an indicator variable for treatment group. Kaplan-Meier methodology will be used to estimate the time to disease progression curves (including the median) in each treatment group.

Analysis of the Secondary Efficacy Variables

a. Time to Treatment Failure

Time to treatment failure, as determined by the Independent Review Facility (IRF), is defined as time from randomization to the date of IRF-documented disease progression, death on study, start of non-protocol-specified anti-cancer therapy, or study discontinuation due to toxicity, whichever occurs first. Time to treatment failure for subjects who are still participating in the study without treatment failure at the time of analysis will be treated as censored at the date of the last tumor assessment. Time to treatment failure for subjects who have discontinued from the study for reasons other than toxicity and who did not experience treatment failure prior to study discontinuation will be treated as censored on the day of study discontinuation.

A formal comparison of treatment failure between the two treatment groups will be made using the unstratified log-rank test. The null and alternative hypotheses are H_0: $_{A+B}/_{A}$ = 1 and H_A: $_{A+B}/_{A}$ 1, where $_{A+B}$ ($_{A}$) represents the hazard of treatment failure for the Drug A+B (Drug A alone) group. An estimate of the hazard ratio with 95% confidence interval will be determined using a Cox regression model with an indicator variable for treatment group. Kaplan-Meier methodology will be used to estimate the time to treatment failure curves (including the median) in each treatment group.

b. Duration of Survival

Duration of survival is defined as the time from randomization to death from any cause. All reported deaths will be included, whether the death occurred during treatment or following treatment discontinuation. Subjects who have not died at the time of analysis will be treated as a censored observation on the date the subject was last known to be alive.

A formal comparison of duration of survival between the two treatment groups will be made using the unstratified log-rank test. The null and alternative hypotheses are H_0: $_{A+B}/_{A}$ = 1 and H_A: $_{A+B}/_{A}$ 1, where $_{A+B}$ ($_{A}$) represents the hazard of death for the Drug A+B (Drug A alone) group. An estimate of the hazard ratio with 95% confidence interval will be determined using a Cox regression model with an indicator variable for treatment group. Kaplan-Meier methodology will be used to estimate the survival curves (including the median) in each treatment group.

Tumor assessments are performed at Screening, during Weeks 6, 12, 18, and 24, and every 9 weeks thereafter until the investigator determines that the subject has progressive disease. Tumor assessments are also performed as clinically indicated when signs and symptoms suggest the development of disease progression.

Finally, the following section could be considered to be excerpts from the statistical analysis plan (SAP) submitted to the FDA.

The time to disease progression, time to treatment failure, and duration of survival endpoints will use the attached mock table and figure for presenting results. Appropriate adjustments (e.g., specification of subject groups) will be made when displaying the intent-to-treat and per-protocol analyses. Criteria for the per-protocol analysis are stated in the protocol.

Additional Technical Details Regarding the Current Example

In the current example, we make the assumption that all randomized subjects will be included in the intent-to-treat analysis. Hence, only one data flag (for indicating inclusion or exclusion of subjects in the per-protocol analysis) is incorporated in the source file and in the analysis files. Note that the protocol and/or the statistical analysis plan should provide specific details on the definitions of the criteria for the inclusion of subjects in (possibly several) analysis subgroups. We recommend that this issue be discussed with the FDA Statistical Reviewer before submission.

Similarly, the protocol and/or the statistical analysis plan should also provide specific details regarding other relevant statistical and technical issues such as adjudication of endpoints, methodological considerations when dealing with interval censored data, analytical concerns related to stratification, etc. As before, we recommend that these issues be discussed also with the FDA Statistical Reviewer before submission.

Finally, the current example focuses on the estimation and comparison of survival curves (e.g., Kaplan-Meier methodology, log-rank and Wilcoxon tests). Straightforward augmentation of the proposed analyses files to deal with life-table-type analyses may be handled as follows.

- *Suppose event rates for a fixed set of non-overlapping time intervals comprising the totality of the relevant time domain are specified in the protocol and/or statistical analysis plan. Then the following four variables for each interval may be added to the analysis files:*
    1. *Number of subjects at risk at the start of the interval,*
    2. *Number of subjects experiencing an event during the interval,*
    3. *Number of subjects censored during the interval, and*
    4. *Probability of not experiencing an event to the end of the interval.*

. *Suppose event rates at a fixed number of timepoints during the relevant time domain are specified in the protocol and/or statistical analysis plan. Then the following four variables for each timepoint may be added to the analysis files:*

1. *Number of subjects who have experienced an event by the timepoint,*
2. *Number of subjects known to have not experienced an event by the timepoint,*
3. *Number of subjects known to have not experienced an event at a time prior to the timepoint and lost to follow-up since, and*
4. *Probability of not experiencing an event by the timepoint.*

Note, therefore, that the number of additional variables rises proportionally (4-fold) as the number of time intervals or timepoints increases.

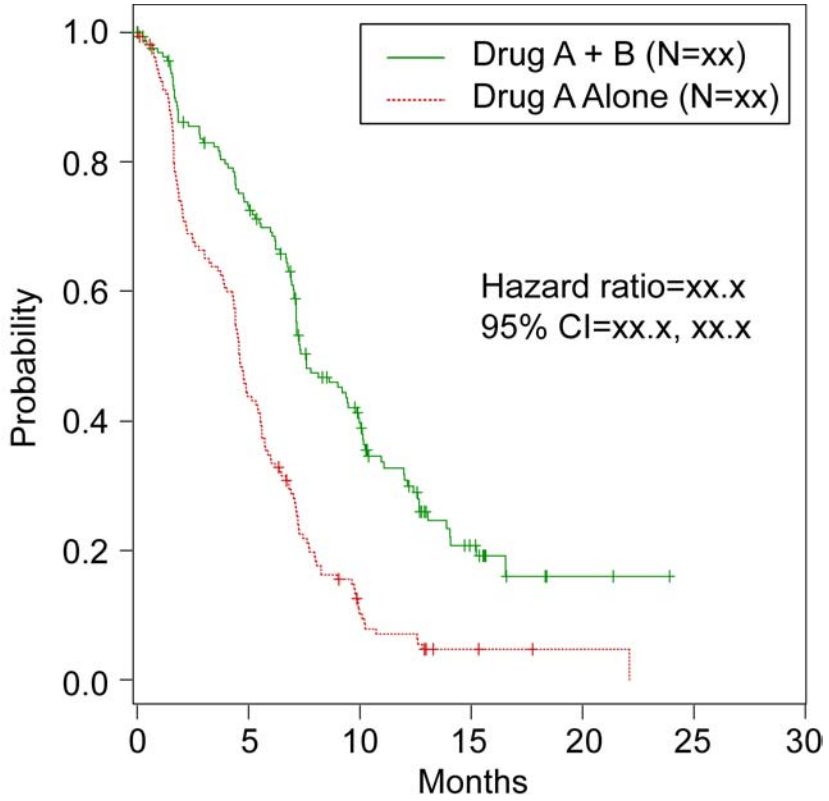
2 MOCK DISPLAY OF ANALYSIS RESULTS

Table 1
Time to Disease Progression
Patient Group: All Randomized Subjects

	Drug A Alone (N=xxx)	Drug A+B (N=xxx)
No. of Randomized Subjects	xxx	xxx
No. Of Subjects with Disease Progression	xxx	xxx
No. Of Subjects without Disease Progression (censored)	xxx	xxx
Percent Censored	xx.x	xx.x
Time to Disease Progression (days)		
Median	xx.xx	xx.xx
(95% c.i.)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
25 - 75 percentile	xx.xx – xx.xx	xx.xx – xx.xx
Minimum - Maximum	xx.xx – xx.xx	xx.x – xx.xx
Hazard Ratio (relative to Drug A Alone)		xx.xx
(95% c.i.)		(xx.xx, xx.xx)
P-value		
Logrank		0.xxxx
Wilcoxon		0.xxxx

Notes:
1. The data being summarized may contain censored observations (i.e., patients without disease progression contribute data until date of censoring).
2. N=xxx in column heading is number of randomized subjects.
3. Time to disease progression (median, percentiles, minimum, maximum) estimated from the Kaplan-Meier curves.
4. Hazard ratio estimated by Cox regression.
5. Refer to the protocol and/or statistical analysis plan regarding which of the logrank or Wilcoxon tests should be used and/or which one is the primary test.

Figure 1
Time to Disease Progression: Kaplan-Meier Curves
Patient Group: All Randomized Subjects



Notes:
1. The data being summarized may contain censored observations (i.e., patients without disease progression contribute data until date of censoring). These censored observations are indicated by "+"'s on the curves.
2. "Probability" on the vertical axis refers to Progression-Free Survival Rate.
3. Hazard ratio estimated by Cox regression.

3 SOURCE FILE

In situations in which the occurrence or non-occurrence of the event of interest is verified at regular intervals during the clinical trial, this source file augments the dataset containing results of these regular checks (referred to as the RESPONSE dataset in the following example) with a Per-Protocol analysis population flag. These regular checks on the occurrence or non-occurrence of the event may be direct assessments (e.g., disease progression or no disease progression) or may be part of a more thorough assessment (e.g., complete response, partial response, stable disease, or disease progression). This source file may be considered optional, and supplied only after negotiations with the FDA Statistical Reviewer. If it is not useful to the FDA Statistical Reviewer, it could be retained internally in the Sponsor's clinical database as an intermediate step to the final analysis datasets (Analysis Files #2 and #3).

Depending on the definition of the time-to-event endpoints, other source files may be required. In the current example, other relevant data such as the date of death, the start date of non-protocol-specified anti-cancer therapy, and the date of study discontinuation due to toxicity will also be obtained from other CRT's to construct Analysis Files #1, #2, and #3.

Finally, determining whether censoring has occurred at each visit may be useful intermediate information for some time-to-event variables. In the current example in which RESPONSE is one of the source files for the time to disease progression and time to treatment failure endpoints, censoring variables for each of these two endpoints at each visit are also presented. Note that no censoring variable for duration of survival (which does not use RESPONSE as a source file) is included.

Structure: 1 Record per Subject Visit

Variable Name	Variable Label	Type	Decodes/Format	Origin	Role	Comment
DRUGID	**Drug ID**	**Char**		**Sponsor Defined**	**Key**	**May be used by some Sponsors for Integrated Summary of Efficacy (ISE) or Reviewers for drug class analyses**
STUDYID	**Study ID**	**Char**		**Demo.STUDYID**	**Key**	
SITEID	**Center or Site ID**	**Char**		**Demo.SITEID**	**Key**	
INVID	**Investigator ID**	**Char**		**Demo.INVID**	**Key**	
USUBJID	**Unique Subject ID**	**Char**		**Sponsor Defined**	**Key**	**May be used for ISE.**
SUBJID	**Subject ID**	**Char**		**Demo.SUBJID**	**Key**	

[1] Some variables, such as SEX, will be represented in both numeric and decoded character formats. Here we have included both formats.
[2] Or independent detailed documentation of algorithm and programming assumptions.
[3] These variable names are Sponsor defined.
*Common variables found across all datasets appear in **bold** (from CDISC metadata model) or in **bold** (specific to ADaM models).*

S_PP[3]	Subject Per-Protocol Flag	Num	0 = No 1 = Yes	Derived	Selection	Link to Protocol Exceptions Listing
AGE	**Age in Years at Baseline**	**Num**		**Demo.AGE**	**Selection**	**Could use 2 variables Age and Age Units**
SEX[1]	**Sex**	**Char**	**M=Male F=Female**	**Demo.SEX**	**Selection**	
SEXCD[1]	**Sex Code**	**Num**	**1=Male 2=Female**	**Derived**	**Selection**	
RACE	**Race**	**Varies**		**Demo.RACE**	**Selection**	**Coding or Char/Num could depend on indication**
TRTCD[1]	**Treatment Code**	**Num**	**1=A 2=A+B**	**EXPOSE.TRTCD**	**Selection**	
TRTGRP[1]	**Treatment Group**	**Char**		**EXPOSE.TRTGRP**	**Selection**	
VISIT	**Visit Name**	**Char**		**From the RESPONSE dataset**	**Key**	**May be standardized for ISE.**
VISITNUM	**Visit Number**	**Num**		**From the RESPONSE dataset**	**Key**	
DMREFDT	**Subject Reference Date**	**Num**	**ISO 8601 YYYY-MM-DD**	**Demo.DMREFDT or Derived**		**Sponsor-defined date by which other dates will be referenced; may be defined as screen date, randomization date, date of first dose, etc.; reference dates for efficacy and safety may be different; if different from reference dates used in other datasets such as the Demographic domain, Sponsor should consider using a different variable name; (Link to protocol or analysis plan.)**[2]

[1] *Some variables, such as SEX, will be represented in both numeric and decoded character formats. Here we have included both formats.*

[2] *Or independent detailed documentation of algorithm and programming assumptions.*

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*Common variables found across all datasets appear in **bold** (from CDISC metadata model) or in **bold** (specific to ADaM models).*

RSPACTDT[3]	Actual Visit Date of Response Assessment	Num	ISO 8601 YYYY-MM-DD	From the RESPONSE dataset		
RSPACTDY[3]	Relative Study Day	Num		Derived: e.g., RESPONSE.RSPACTDT – Demo.DMREFDT + 1		(*Link to protocol or analysis plan.*)[2]
RSP[3]	Response	Num	1 = Complete Response 2 = Partial Response 3 = Stable Disease 4 = Progressive Disease 5 = Unable to Evaluate Response	From the RESPONSE dataset		
V_CNRTTP[3]	Censoring Indicator for Time to Disease Progression at Specific Visit	Num	0 = Not Censored 1 = Censored	Derived		(*Link to protocol or analysis plan.*)[2]
V_CNRTTF[3]	Censoring Indicator for Time to Treatment Failure at Specific Visit	Num	0 = Not Censored 1 = Censored	Derived		(*Link to protocol or analysis plan.*)[2]

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Common variables found across all datasets appear in ***bold*** *(from CDISC metadata model) or in* ***bold*** *(specific to ADaM models).*

PROC CONTENTS

-----Variables Ordered by Position-----					
#	**Variable**	**Type**	**Len**	**Format**	**Label**
1	DRUGID	Char	20	$20.	Drug ID
2	STUDYID	Char	20	$20.	Study ID
3	SITEID	Char	20	$20.	Center or Site ID
4	INVID	Char	20	$20.	Investigator ID
5	USUBJID	Char	20	$20.	Unique Subject ID
6	SUBJID	Char	20	$20.	Subject ID
7	S_PP	Num	8	3.	Evaluable for Efficacy (1=YES, 2=NO)
8	AGE	Num	8	8.	Age in Years at Baseline
9	SEX	Char	1	$1.	Sex
10	SEXCD	Num	8	1.	Sex Code
11	RACE	Char	40		Race
12	TRTCD	Num	8	8.	Treatment Code
13	TRTGRP	Char	20	$20.	Treatment Group

-----Variables Ordered by Position-----					
#	**Variable**	**Type**	**Len**	**Format**	**Label**
14	VISIT	Char	20	$20.	Visit Name
15	VISITNUM	Num	8	8.	Visit Number
16	DMREFDT	Num	8	YYMMDD10.	Subject Reference Date
17	RSPACTDT	Num	8	YYMMDD10.	Actual Visit Date of Response Assessment
18	RSPACTDY	Num	8	8.	Relative Study Day
19	RSP	Num	8	8.	Response
20	V_CNRTTP	Num	8	8.	Censor Time to Progression at this event
21	V_CNRTTF	Num	8	8.	Censor Time to Treat Fail at this event

PROC PRINT

Obs	DRUGID	STUDYID	SITEID	INVID	USUBJID	SUBJID	S_PP	AGE	SEX	SEXCD	RACE	TRTCD	TRTGRP
1	Study Drug B	Sample Study	2105	6401	6401-1001	1001	1	65	F	2	WHITE	1	Drug A
2	Study Drug B	Sample Study	2105	6401	6401-1001	1001	1	65	F	2	WHITE	1	Drug A
3	Study Drug B	Sample Study	2105	6401	6401-1001	1001	1	65	F	2	WHITE	1	Drug A
4	Study Drug B	Sample Study	2105	6401	6401-1003	1003	1	66	F	2	ASIAN OR PACIFIC ISLANDER	2	Drugs A + B
5	Study Drug B	Sample Study	2105	6401	6401-1004	1004	1	45	F	2	ASIAN OR PACIFIC ISLANDER	2	Drugs A + B

Obs	VISIT	VISITNUM	DMREFDT	RSPACTDT	RSPACTDY	RSP	V_CNRTTP	V_CNRTTF
1	Visit 1	1	1998-06-08	1998-07-28	51	2	1	1
2	Visit 2	2	1998-06-08	1998-10-02	117	2	1	1
3	Visit 3	3	1998-06-08	1999-01-06	213	4	0	0
4	Visit 1	1	1998-06-22	1998-07-01	10	4	0	0
5	Visit 1	1	1998-06-26	1998-08-13	49	3	1	1

4 ANALYSIS FILE #1 (INTERMEDIATE)

This analysis file contains additional information on the reasons for censoring. In cases in which the event of interest is actually a compound event (i.e., an event composed of at least two different types of constituent events), this analysis file also contains additional information on the occurrence of each constituent event. Therefore, this analysis file may be submitted if the FDA Statistical Reviewer would like additional detail on the censoring or on the constituent events. If it is not useful to the FDA Statistical Reviewer, it could be retained internally in the Sponsor's clinical database as an intermediate step to the final analysis datasets (Analysis Files #2 and #3).

Structure: 1 Record per Subject

Variable Name	Variable Label	Type	Decodes/Format	Origin	Role	Comment
DRUGID	**Drug ID**	**Char**		**Sponsor Defined**	**Key**	**May be used by some Sponsors for ISE or Reviewers for drug class analyses**
STUDYID	**Study ID**	**Char**		**Demo.STUDYID**	**Key**	
SITEID	**Center or Site ID**	**Char**		**Demo.SITEID**	**Key**	
INVID	**Investigator ID**	**Char**		**Demo.INVID**	**Key**	
USUBJID	**Unique Subject ID**	**Char**		**Sponsor Defined**	**Key**	**May be used for ISE.**
SUBJID	**Subject ID**	**Char**		**Demo.SUBJID**	**Key**	
AGE	**Age in Years at Baseline**	**Num**		**Demo.AGE**	**Selection**	**Could use 2 variables Age and Age Units**
SEX[1]	**Sex**	**Char**	**M=Male F=Female**	**Demo.SEX**	**Selection**	
SEXCD[1]	**Sex Code**	**Num**	**1=Male 2=Female**	**Derived**	**Selection**	
RACE	**Race**	**Varies**		**Demo.RACE**	**Selection**	**Coding or Char/Num could depend on indication**
TRTCD[1]	**Treatment Code**	**Num**	**1=A 2=A+B**	**EXPOSE.TRTCD**	**Selection**	
TRTGRP[1]	**Treatment Group**	**Char**		**EXPOSE.TRTGRP**	**Selection**	

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*Common variables found across all datasets appear in **bold** (from CDISC metadata model) or in **bold** (specific to ADaM models).*

VAR #1-K[2]	K variables representing analysis and subgroup covariables			Usually Derived	Selection	*(Link to protocol or analysis plan.)*[3]
S_PP[4]	Subject Per-Protocol Flag	Num	0 = No 1 = Yes	Derived	Selection	Link to Protocol Exceptions Listing
DMREFDT	**Subject Reference Date**	**Num**	**ISO 8601 YYYY-MM-DD**	**Demo.DMREFDT or Derived**		**Sponsor-defined date by which other dates will be referenced; may be defined as screen date, randomization date, date of first dose, etc.; reference dates for efficacy and safety may be different; if different from reference dates used in other datasets such as the Demographic domain, Sponsor should consider using a different variable name; (Link to protocol or analysis plan.)**[2]
EV1ACTDT[4]	Actual Date of Event Type 1 (Disease Progression)	Num	ISO 8601 YYYY-MM-DD	Usually Derived		*(Link to protocol or analysis plan.)*[3]
EV1ACTDY[4]	Relative Study Day of Event Type 1 (Disease Progression)	Num		Derived: e.g., EV1ACTDT – Demo.DMREFDT + 1		*(Link to protocol or analysis plan.)*[3]
EV1CNSR[4]	Censoring Indicator for Event Type 1 (Disease Progression)	Num	0 = Not Censored 1 = Censored	Derived		*(Link to protocol or analysis plan.)*[3]

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[2] *K covariates prespecified in protocol and/or statistical analysis plan.*
[3] *Or independent detailed documentation of algorithm and programming assumptions.*
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EV2ACTDT[4]	Actual Date of Event Type 2 (Death)	Num	ISO 8601 YYYY-MM-DD	Usually Derived		*(Link to protocol or analysis plan.)*[3]
EV2ACTDY[4]	Relative Study Day of Event Type 2 (Death)	Num		Derived: e.g., EV2ACTDT – Demo.DMREFDT + 1		*(Link to protocol or analysis plan.)*[3]
EV2CNSR[4]	Censoring Indicator for Event Type 2 (Death)	Num	0 = Not Censored 1 = Censored	Derived		*(Link to protocol or analysis plan.)*[3]
EV3ACTDT[4]	Actual Date of Event Type 3 (Onset of Other Anti-Cancer Therapy)	Num	ISO 8601 YYYY-MM-DD	Usually Derived		*(Link to protocol or analysis plan.)*[3]
EV3ACTDY[4]	Relative Study Day of Event Type 3 (Onset of Other Anti-Cancer Therapy)	Num		Derived: e.g., EV3ACTDT – Demo.DMREFDT + 1		*(Link to protocol or analysis plan.)*[3]
EV3CNSR[4]	Censoring Indicator for Event Type 3 (Onset of Other Anti-Cancer Therapy)	Num	0 = Not Censored 1 = Censored	Derived		*(Link to protocol or analysis plan.)*[3]
EV4ACTDT[4]	Actual Date of Event Type 4 (Discontinuation Due to Toxicity)	Num	ISO 8601 YYYY-MM-DD	Usually Derived		*(Link to protocol or analysis plan.)*[3]
EV4ACTDY[4]	Relative Study Day of Event Type 4 (Discontinuation Due to Toxicity)	Num		Derived: e.g., EV4ACTDT – Demo.DMREFDT + 1		*(Link to protocol or analysis plan.)*[3]
EV4CNSR[4]	Censoring Indicator for Event Type 4 (Discontinuation Due to Toxicity)	Num	0 = Not Censored 1 = Censored	Derived		*(Link to protocol or analysis plan.)*[3]
CNRDTTTP[4]	Censoring Date for Time to Disease Progression	Num	ISO 8601 YYYY-MM-DD	Derived		*(Link to protocol or analysis plan.)*[3]
CNRDYTTP[4]	Relative Study Day for Censoring for Time to Disease Progression	Num		Derived: e.g., CNRDTTTP – Demo.DMREFDT + 1		*(Link to protocol or analysis plan.)*[3]

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Common variables found across all datasets appear in ***bold*** *(from CDISC metadata model) or in* ***bold*** *(specific to ADaM models).*

CNRRTTP[4]	Reason for Censoring for Time to Disease Progression	Num	1 = Active, Without Disease Progression, at Time of Analysis 2 = Study Discontinuation 3 = Investigator Disease Progression	Derived		*(Link to protocol or analysis plan.)*[3]
TTPTRIG[4]	Triggering Constituent Event for Time to Disease Progression	Num	1 = Disease Progression 2 = Death	Derived		*(Link to protocol or analysis plan.)*[3]
CNRDTTTF[4]	Censoring Date for Time to Treatment Failure	Num	ISO 8601 YYYY-MM-DD	Derived		*(Link to protocol or analysis plan.)*[3]
CNRDYTTF[4]	Relative Study Day for Censoring for Time to Treatment Failure	Num		Derived: e.g., CNRDTTTF – Demo.DMREFDT + 1		*(Link to protocol or analysis plan.)*[3]
CNRRTTF[4]	Reason for Censoring for Time to Treatment Failure	Num	1 = Active, Without Treatment Failure, at Time of Analysis, 2 = Study Discontinuation For Reasons Other Than Toxicity	Derived		*(Link to protocol or analysis plan.)*[3]
TTFTRIG[4]	Triggering Constituent Event for Time to Treatment Failure	Num	1 = Disease Progression 2 = Death 3 = Non-protocol-specified anti-cancer therapy 4 = Discontinuation due to toxicity	Derived		*(Link to protocol or analysis plan.)*[3]

[1] *Some variables, such as SEX, will be represented in both numeric and decoded character formats. Here we have included both formats.*
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[3] *Or independent detailed documentation of algorithm and programming assumptions.*
[4] *These variable names are Sponsor defined.*
Common variables found across all datasets appear in ***bold*** *(from CDISC metadata model) or in* ***bold*** *(specific to ADaM models).*

CNRDTSRV[4]	Censoring Date for Duration of Survival	Num	ISO 8601 YYYY-MM-DD	Derived		*(Link to protocol or analysis plan.)*[3]
CNRDYSRV[4]	Relative Study Day for Censoring for Duration of Survival	Num		Derived: e.g., CNRDTSRV – Demo.DMREFDT + 1		*(Link to protocol or analysis plan.)*[3]
CNRRSRV[4]	Reason for Censoring for Duration of Survival	Num	1 = Alive at Time of Analysis 2 = Lost to Follow-up	Derived		*(Link to protocol or analysis plan.)*[3]
SURVTRIG[4]	Triggering Constituent Event for Duration of Survival	Num	2 = Death	Derived		*(Link to protocol or analysis plan.)*[3]

[1] *Some variables, such as SEX, will be represented in both numeric and decoded character formats. Here we have included both formats.*

[2] *K covariates prespecified in protocol and/or statistical analysis plan.*

[3] *Or independent detailed documentation of algorithm and programming assumptions.*

[4] *These variable names are Sponsor defined.*

Common variables found across all datasets appear in ***bold*** *(from CDISC metadata model) or in* ***bold*** *(specific to ADaM models).*

PROC CONTENTS

-----Variables Ordered by Position-----						
#	**Variable**	**Type**	**Len**	**Format**	**Informat**	**Label**
1	DRUGID	Char	20	$20.		Drug ID
2	STUDYID	Char	20	$20.		Study ID
3	SITEID	Char	20	$20.		Center or Site ID
4	INVID	Char	20	$20.		Investigator ID
5	USUBJID	Char	20	$20.		Unique Subject ID
6	SUBJID	Char	20	$20.		Subject ID
7	AGE	Num	8	8.		Age in Years at Baseline
8	SEX	Char	1	$1.		Sex
9	SEXCD	Num	8	1.		Sex Code
10	RACE	Char	40			Race
11	TRTCD	Num	8	8.		Treatment Code
12	TRTGRP	Char	20	$20.		Treatment Group
13	VAR1	Num	8	1.	BEST22.	Risk Factor #1: Baseline ECOG
14	VAR2	Num	8	12.4	BEST22.	Risk Factor #2: Baseline Albumin

-----Variables Ordered by Position-----						
#	**Variable**	**Type**	**Len**	**Format**	**Informat**	**Label**
15	VAR3	Num	8	8.2		Risk Factor #3: Primary Tumor Size (cm^2
16	VAR4	Char	3	$3.		Risk Factor #4: Prior Chemotherapy
17	S_PP	Num	8	3.		Evaluable for Efficacy (1=YES, 2=NO)
18	DMREFDT	Num	8	YYMMDD10.		Subject Reference Date
19	EV1ACTDT	Num	8	YYMMDD10.		Date of Disease Progression
20	EV1ACTDY	Num	8	8.		Study Day for Disease Progression
21	EV1CNSR	Num	8	8.		Censoring for Disease Progression
22	EV2ACTDT	Num	8	YYMMDD10.		Date of Death
23	EV2ACTDY	Num	8	8.		Study Day for Death
24	EV2CNSR	Num	8	8.		Censoring for Death
25	EV3ACTDT	Num	8	YYMMDD10.		Date of Excluded Therapy
26	EV3ACTDY	Num	8	8.		Study Day for Excluded Therapy
27	EV3CNSR	Num	8	8.		Censoring for Excluded Therapy
28	EV4ACTDT	Num	8	YYMMDD10.		Date of Study Disc due to Toxicity
29	EV4ACTDY	Num	8	8.		Study Day for Study Disc due to Toxicity
30	EV4CNSR	Num	8	8.		Censoring for Study Disc due to Toxicity

-----Variables Ordered by Position-----						
#	**Variable**	**Type**	**Len**	**Format**	**Informat**	**Label**
31	CNRDTTTP	Num	8	YYMMDD10.		Censored Date for Time to Progression
32	CNRDYTTP	Num	8			Censored Study Day for Time to Progressi
33	CNRRTTP	Num	8	PROGRFMT.		Reason for Censoring Time to Progression
34	TTPTRIG	Num	8	TRIGFMT.		Triggering Event for Time to Progression
35	CNRDTTTF	Num	8	YYMMDD10.		Censored Date for Time to Treat Fail
36	CNRDYTTF	Num	8			Censored Study Day for Time to Treatment
37	CNRRTTF	Num	8	FAILRFMT.		Reason for Censoring Time to Treat Fail
38	TTFTRIG	Num	8	TRIGFMT.		Triggering Event for Time to Treat Fail
39	CNRDTSRV	Num	8	YYMMDD10.		Censored Date for Survival
40	CNRDYSRV	Num	8			Censored Study Day for Survival
41	CNRRSRV	Num	8	SURVRFMT.		Reason for Censoring Survival
42	SURVTRIG	Num	8	TRIGFMT.		Triggering Event for Survival

PROC PRINT

Obs	DRUGID	STUDYID	SITEID	INVID	USUBJID	SUBJID	AGE	SEX	SEXCD	RACE
1	Study Drug B	Sample Study	2105	6401	6401-1001	1001	65	F	2	WHITE
2	Study Drug B	Sample Study	2105	6401	6401-1002	1002	51	F	2	BLACK
3	Study Drug B	Sample Study	2105	6401	6401-1003	1003	66	F	2	ASIAN OR PACIFIC ISLANDER
4	Study Drug B	Sample Study	2105	6401	6401-1004	1004	45	F	2	ASIAN OR PACIFIC ISLANDER
5	Study Drug B	Sample Study	2105	6401	6401-1005	1005	74	F	2	WHITE

Obs	TRTCD	TRTGRP	VAR1	VAR2	VAR3	VAR4	S_PP	DMREFDT	EV1ACTDT	EV1ACTDY	EV1CNSR
1	1	Drug A	1	4.0000	3.00	NO	1	1998-06-08	1999-01-06	213	0
2	2	Drugs A + B	0	.	72.00	NO	1	1998-06-15	.	.	1
3	2	Drugs A + B	2	2.8000	.	NO	1	1998-06-22	1998-07-01	10	0
4	2	Drugs A + B	1	4.2000	4.00	NO	1	1998-06-26	1999-06-23	363	0
5	2	Drugs A + B	1	2.5000	9.00	NO	1	1998-06-26	1998-07-15	20	0

Obs	EV2ACTDT	EV2ACTDY	EV2CNSR	EV3ACTDT	EV3ACTDY	EV3CNSR	EV4ACTDT	EV4ACTDY	EV4CNSR
1	.	.	1	.	.	1	.	.	1
2	1998-08-12	59	0	.	.	1	1998-08-12	59	0
3	1998-08-14	54	0	.	.	1	.	.	1
4	.	.	1	.	.	1	.	.	1
5	1998-10-18	115	0	.	.	1	.	.	1

Obs	CNRDTTTP	CNRDYTTP	CNRRTTP	TTPTRIG	CNRDTTTF	CNRDYTTF	CNRRTTF	TTFTRIG
1	.	.	.	1	.	.	.	1
2	.	.	.	2	.	.	.	2
3	.	.	.	1	.	.	.	1
4	.	.	.	1	.	.	.	1
5	.	.	.	1	.	.	.	1

Obs	CNRDTSRV	CNRDYSRV	CNRRSRV	SURVTRIG
1	1999-01-28	235	1	.
2	.	.	.	2
3	.	.	.	2
4	1999-09-15	447	1	.
5	.	.	.	2

5 ANALYSIS FILE #2

Analysis Files #2 and #3 may be viewed as the ultimate analysis files. Analysis File #2 utilizes a structure wherein there is one record per subject per time-to-event variable, whereas Analysis File #3 utilizes a structure wherein there is one record per subject (i.e., the different time-to-event variables for a subject are all contained in one record). Each of these analysis files contains the time-to-event variables and corresponding censor variables that relate directly to the primary and secondary efficacy variables. The Sponsor should consult with the FDA Statistical Reviewer for a preference between this structure and that of Analysis File #3 below -- the choice may be decided based on the considerations outlined in the ADaM document entitled "Evaluation Criteria for All Submission Dataset Structures." Should this structure be chosen, it is recommended that record placeholders be incorporated to indicate missing values of the time-to-event variables.

Note that typically, various complex calculations are required to obtain Analysis Files #2 and #3 from either Source File or Analysis File #1.

Structure: 1 Record per Subject per Time-to-Event Variable

Variable Name	Variable Label	Type	Decodes/Format	Origin	Role	Comment
DRUGID	**Drug ID**	**Char**		**Sponsor Defined**	**Key**	**May be used by some Sponsors for ISE or Reviewers for drug class analyses**
STUDYID	**Study ID**	**Char**		**Demo.STUDYID**	**Key**	
SITEID	**Center or Site ID**	**Char**		**Demo.SITEID**	**Key**	
INVID	**Investigator ID**	**Char**		**Demo.INVID**	**Key**	
USUBJID	**Unique Subject ID**	**Char**		**Sponsor Defined**	**Key**	**May be used for ISE.**
SUBJID	**Subject ID**	**Char**		**Demo.SUBJID**	**Key**	
AGE	**Age in Years at Baseline**	**Num**		**Demo.AGE**	**Selection**	**Could use 2 variables Age and Age Units**
SEX[1]	**Sex**	**Char**	**M=Male F=Female**	**Demo.SEX**	**Selection**	
SEXCD[1]	**Sex Code**	**Num**	**1=Male 2=Female**	**Derived**	**Selection**	

[1] *Some variables, such as SEX, will be represented in both numeric and decoded character formats. Here we have included both formats.*
[2] *K covariates prespecified in protocol or SAP*
[3] *Or independent detailed documentation of algorithm and programming assumptions.*
[4] *These variable names are Sponsor defined.*
Common variables found across all datasets appear in **bold** (from CDISC metadata model) or in **bold** (specific to ADaM models).

RACE	**Race**	**Varies**		**Demo.RACE**	**Selection**	**Coding or Char/Num could depend on indication**
TRTCD[1]	**Treatment Code**	**Num**	**1=A** **2=A+B**	**EXPOSE.TRTCD**	**Selection**	
TRTGRP[1]	**Treatment Group**	**Char**		**EXPOSE.TRTGRP**	**Selection**	
VAR #1-K[2]	K variables representing analysis and subgroup covariables			Usually Derived	Selection	*(Link to protocol or analysis plan.)*[3]
S_PP[4]	Subject Per-Protocol Flag	Num	0 = No 1 = Yes	Derived	Selection	Link to Protocol Exceptions Listing
TTEVAR[4]	Time-to-Event Variable	Char	Time to Disease Progression (days) Time to Treatment Failure (days) Duration of Survival (days)		Selection	
TTEVALUE[4]	Time-to-Event Value	Num		Derived		*(Link to protocol or analysis plan.)*[3]
TTECNSR[4]	Censoring Indicator for Time-to-Event Variable	Num	0 = Not Censored 1 = Censored	Derived		*(Link to protocol or analysis plan.)*[3]

[1] *Some variables, such as SEX, will be represented in both numeric and decoded character formats. Here we have included both formats.*
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[4] *These variable names are Sponsor defined.*
Common variables found across all datasets appear in ***bold*** *(from CDISC metadata model) or in* ***bold*** *(specific to ADaM models).*

PROC CONTENTS

-----Variables Ordered by Position-----						
#	**Variable**	**Type**	**Len**	**Format**	**Informat**	**Label**
1	DRUGID	Char	20	$20.		Drug ID
2	STUDYID	Char	20	$20.		Study ID
3	SITEID	Char	20	$20.		Center or Site ID
4	INVID	Char	20	$20.		Investigator ID
5	USUBJID	Char	20	$20.		Unique Subject ID
6	SUBJID	Char	20	$20.		Subject ID
7	AGE	Num	8	8.		Age in Years at Baseline
8	SEX	Char	1	$1.		Sex
9	SEXCD	Num	8	1.		Sex Code
10	RACE	Char	40			Race
11	TRTCD	Num	8	8.		Treatment Code
12	TRTGRP	Char	20	$20.		Treatment Group
13	VAR1	Num	8	1.	BEST22.	Risk Factor #1: Baseline ECOG
14	VAR2	Num	8	12.4	BEST22.	Risk Factor #2: Baseline Albumin

-----Variables Ordered by Position-----						
#	**Variable**	**Type**	**Len**	**Format**	**Informat**	**Label**
15	VAR3	Num	8	8.2		Risk Factor #3: Primary Tumor Size (cm^2
16	VAR4	Char	3	$3.		Risk Factor #4: Prior Chemotherapy
17	S_PP	Num	8	3.		Evaluable for Efficacy (1=YES, 2=NO)
18	TTEVAR	Char	40	$40.		Time to Event Variable
19	TTEVALUE	Num	8	8.		Time to Event Value
20	TTECNSR	Num	8	8.		Censoring Indicator for Time to Event

PROC PRINT

Obs	DRUGID	STUDYID	SITEID	INVID	USUBJID	SUBJID	AGE	SEX	SEXCD	RACE	TRTCD	TRTGRP
1	Study Drug B	Sample Study	2105	6401	6401-1001	1001	65	F	2	WHITE	1	Drug A
2	Study Drug B	Sample Study	2105	6401	6401-1001	1001	65	F	2	WHITE	1	Drug A
3	Study Drug B	Sample Study	2105	6401	6401-1001	1001	65	F	2	WHITE	1	Drug A
4	Study Drug B	Sample Study	2105	6401	6401-1002	1002	51	F	2	BLACK	2	Drugs A + B
5	Study Drug B	Sample Study	2105	6401	6401-1002	1002	51	F	2	BLACK	2	Drugs A + B

Obs	VAR1	VAR2	VAR3	VAR4	S_PP	TTEVAR	TTEVALUE	TTECNSR
1	1	4.0000	3.00	NO	1	Time to Disease Progression (days)	213	0
2	1	4.0000	3.00	NO	1	Time to Treatment Failure (days)	213	0
3	1	4.0000	3.00	NO	1	Duration of Survival (days)	235	1
4	0	.	72.00	NO	1	Time to Disease Progression (days)	59	0
5	0	.	72.00	NO	1	Time to Treatment Failure (days)	59	0

6 ANALYSIS FILE #3

Analysis Files #2 and #3 may be viewed as the ultimate analysis files. Analysis File #2 utilizes a structure wherein there is one record per subject per time-to-event variable, whereas Analysis File #3 utilizes a structure wherein there is one record per subject (i.e., the different time-to-event variables for a subject are all contained in one record). Each of these analysis files contains the time-to-event variables and corresponding censor variables that relate directly to the primary and secondary efficacy variables. The Sponsor should consult with the FDA Statistical Reviewer for a preference between this structure and that of Analysis File #2 above -- the choice may be decided based on the considerations outlined in the ADaM document entitled "Evaluation Criteria for All Submission Dataset Structures."

Note that typically, various complex calculations are required to obtain Analysis Files #2 and #3 from either Source File or Analysis File #1.

Structure: 1 Record per Subject

Contents of Dataset ANAL2

The CONTENTS Procedure

Data Set Name:	OUTDATA.ANAL2	**Observations:**	414
Member Type:	DATA	**Variables:**	20
Engine:	V8	**Indexes:**	0
Created:	7:01 Thursday, June 6, 2002	**Observation Length:**	296
Last Modified:	7:01 Thursday, June 6, 2002	**Deleted Observations:**	0
Protection:		**Compressed:**	NO
Data Set Type:		**Sorted:**	NO
Label:	Analysis File - 1 record/TTE variable		

-----Engine/Host Dependent Information-----	
Data Set Page Size:	24576
Number of Data Set Pages:	6
First Data Page:	1
Max Obs per Page:	82
Obs in First Data Page:	71
Number of Data Set Repairs:	0
File Name:	/onco/stdsoft/adam/tte/outdata/anal2.sas7bdat
Release Created:	8.0101M0

Variable Name	Variable Label	Type	Decodes/Format	Origin	Role	Comment
DRUGID	**Drug ID**	**Char**		**Sponsor Defined**	**Key**	**May be used by some Sponsors for ISE or Reviewers for drug class analyses**
STUDYID	**Study ID**	**Char**		**Demo.STUDYID**	**Key**	
SITEID	**Center or Site ID**	**Char**		**Demo.SITEID**	**Key**	
INVID	**Investigator ID**	**Char**		**Demo.INVID**	**Key**	
USUBJID	**Unique Subject ID**	**Char**		**Sponsor Defined**	**Key**	**May be used for ISE.**
SUBJID	**Subject ID**	**Char**		**Demo.SUBJID**	**Key**	
AGE	**Age in Years at Baseline**	**Num**		**Demo.AGE**	**Selection**	**Could use 2 variables Age and Age Units**
SEX[1]	**Sex**	**Char**	**M=Male F=Female**	**Demo.SEX**	**Selection**	
SEXCD[1]	**Sex Code**	**Num**	**1=Male 2=Female**	**Derived**	**Selection**	

[1] *Some variables, such as SEX, will be represented in both numeric and decoded character formats. Here we have included both formats.*
[2] *K covariates prespecified in protocol or SAP*
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[4] *These variable names are Sponsor defined.*
Common variables found across all datasets appear in **bold** (from CDISC metadata model) or in **bold** (specific to ADaM models).

RACE	**Race**	**Varies**		**Demo.RACE**	**Selection**	**Coding or Char/Num could depend on indication**
TRTCD[1]	**Treatment Code**	**Num**	**1=A** **2=A+B**	**EXPOSE.TRTCD**	**Selection**	
TRTGRP[1]	**Treatment Group**	**Char**		**EXPOSE.TRTGRP**	**Selection**	
VAR #1-K[2]	K variables representing analysis and subgroup covariables			Usually Derived	Selection	*(Link to protocol or analysis plan.)*[3]
S_PP[4]	Subject Per-Protocol Flag	Num	0 = No 1 = Yes	Derived	Selection	Link to Protocol Exceptions Listing
TTP[4]	Time to Disease Progression (days)	Num		Derived		*(Link to protocol or analysis plan.)*[3]
TTPCNSR[4]	Censoring Indicator for Time to Disease Progression	Num	0 = Not Censored 1 = Censored	Derived		*(Link to protocol or analysis plan.)*[3]
TTF[4]	Time to Treatment Failure (days)	Num		Derived		*(Link to protocol or analysis plan.)*[3]
TTFCNSR[4]	Censoring Indicator for Time to Treatment Failure	Num	0 = Not Censored 1 = Censored	Derived		*(Link to protocol or analysis plan.)*[3]
SURV[4]	Duration of Survival (days)	Num		Derived		*(Link to protocol or analysis plan.)*[3]
SURVCNSR[4]	Censoring Indicator for Duration of Survival	Num	0 = Not Censored 1 = Censored	Derived		*(Link to protocol or analysis plan.)*[3]

[1] Some variables, such as SEX, will be represented in both numeric and decoded character formats. Here we have included both formats.

[2] K covariates prespecified in protocol or SAP

[3] Or independent detailed documentation of algorithm and programming assumptions.

[4] These variable names are Sponsor defined.

*Common variables found across all datasets appear in **bold** (from CDISC metadata model) or in **bold** (specific to ADaM models).*

PROC CONTENTS

-----Variables Ordered by Position-----						
#	**Variable**	**Type**	**Len**	**Format**	**Informat**	**Label**
1	DRUGID	Char	20	$20.		Drug ID
2	STUDYID	Char	20	$20.		Study ID
3	SITEID	Char	20	$20.		Center or Site ID
4	INVID	Char	20	$20.		Investigator ID
5	USUBJID	Char	20	$20.		Unique Subject ID
6	SUBJID	Char	20	$20.		Subject ID
7	AGE	Num	8	8.		Age in Years at Baseline
8	SEX	Char	1	$1.		Sex
9	SEXCD	Num	8	1.		Sex Code
10	RACE	Char	40			Race
11	TRTCD	Num	8	8.		Treatment Code
12	TRTGRP	Char	20	$20.		Treatment Group
13	VAR1	Num	8	1.	BEST22.	Risk Factor #1: Baseline ECOG
14	VAR2	Num	8	12.4	BEST22.	Risk Factor #2: Baseline Albumin

-----Variables Ordered by Position-----						
#	**Variable**	**Type**	**Len**	**Format**	**Informat**	**Label**
15	VAR3	Num	8	8.2		Risk Factor #3: Primary Tumor Size (cm^2
16	VAR4	Char	3	$3.		Risk Factor #4: Prior Chemotherapy
17	S_PP	Num	8	3.		Evaluable for Efficacy (1=YES, 2=NO)
18	TTP	Num	8	8.		Time to Disease Progression (days)
19	TTPCNSR	Num	8	8.		Censoring Indicator for TTP
20	TTF	Num	8	8.		Time to Treatment Failure (days)
21	TTFCNSR	Num	8	8.		Censoring Indicator for TTF
22	SURV	Num	8	8.		Duration of Survival (days)
23	SURVCNSR	Num	8	8.		Censoring Indicator for Survival

PROC PRINT

Obs	DRUGID	STUDYID	SITEID	INVID	USUBJID	SUBJID	AGE	SEX	SEXCD	RACE	TRTCD	TRTGRP
1	Study Drug B	Sample Study	2105	6401	6401-1001	1001	65	F	2	WHITE	1	Drug A
2	Study Drug B	Sample Study	2105	6401	6401-1002	1002	51	F	2	BLACK	2	Drugs A + B
3	Study Drug B	Sample Study	2105	6401	6401-1003	1003	66	F	2	ASIAN OR PACIFIC ISLANDER	2	Drugs A + B
4	Study Drug B	Sample Study	2105	6401	6401-1004	1004	45	F	2	ASIAN OR PACIFIC ISLANDER	2	Drugs A + B
5	Study Drug B	Sample Study	2105	6401	6401-1005	1005	74	F	2	WHITE	2	Drugs A + B

Obs	VAR1	VAR2	VAR3	VAR4	S_PP	TTP	TTPCNSR	TTF	TTFCNSR	SURV	SURVCNSR
1	1	4.0000	3.00	NO	1	213	0	213	0	235	1
2	0	.	72.00	NO	1	59	0	59	0	59	0
3	2	2.8000	.	NO	1	10	0	10	0	54	0
4	1	4.2000	4.00	NO	1	363	0	363	0	447	1
5	1	2.5000	9.00	NO	1	20	0	20	0	115	0