

ADTTE: Through a Beginner’s eye... under 1 minute!

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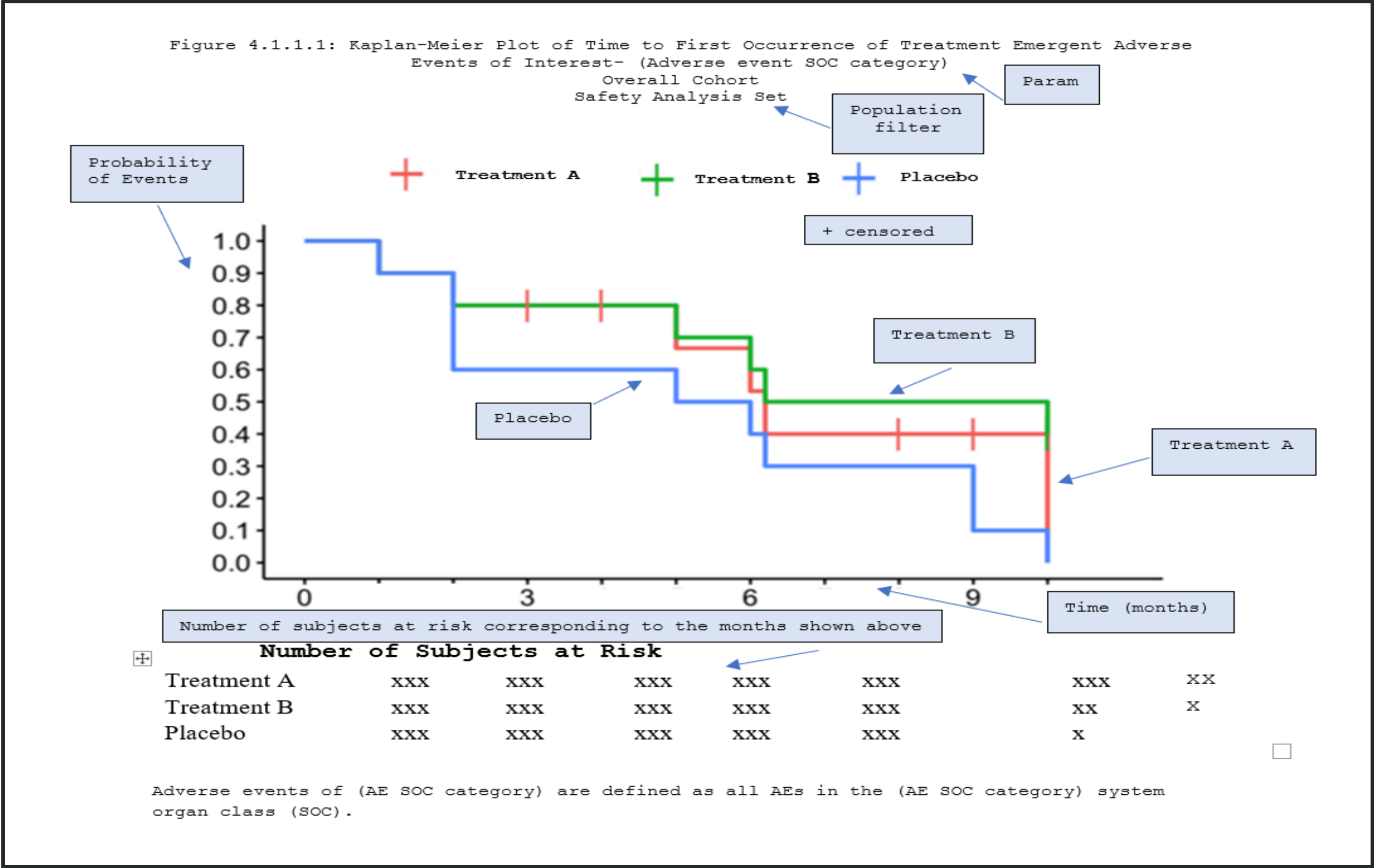
How to Prepare

Structure is key

Dataset Name	Dataset Description	Dataset Location	Dataset Structure	Key Variables of Dataset	Class of Dataset
ADTTE	Data for the Time to Event Analyses	adtte.xpt	one record per subject per parameter	USUBJID, PARAMCD	BDS

First step in preparing is to know the structure of ADTTE .It belongs to the class BDS and has a horizontal way of anylzing the variables than the vertical structure of analyzing in BDS. we will look at it when we get to our programing steps.

The END GAME :Build the Basics



Yes,keep endpoint in mind and build the basic requirements. Here we have an annotated Kaplan-Meier plot. Let’s decode this plot by understanding

- What is the **PARAM** here and the subject **population**
- Here our PARAM is the first occurrence of any adverse event from the given Adverse event SOC category
- X axis is AVAL.That’s the time from a defined starting point (the date of randomization or an intervention) to the time until the first occurrence of AE in months **AVAL =(ADT-STARTDT + 1)**
- Y axis ,which is the Probability of events taken from a variable **Survival** derived from the procedure PROC LIFETEST.
- For Censoring we use the variable Censor which again a PROC LIFETEST result derived from the ADTTE variable **CNSR** .
- **Treatments**.Here we have 3 treatments. A,B and Placebo.

Annotated PROC LIFETEST procedure

```
proc lifetest data=adtte plots=survival(atrisk=0,3,6 to &max_time. by 6);
    time aval*cnsr(1);
    strata trta / notest;
    ods output Survivalplot=survival;
run;
```

Hope this poster gave you an overview of ADTTE and how it is presented in KM plot . That’s 1 minute! Happy learning !!!

The Progammig LOGIC FLOW

Let’s build a programing logic flow by looking at the requirement list:

- **Treatment (TRTA):**This will be the Treatment subject has taken. In our case ,this variable comes from ADSL.
 - Create each PARAM dataset separately :
- Subjects with events + Subjects with no events = PARAM
- **Events :**As per KM plot ,events are our Adverse events from the SOC category lets say **Infections**. Now that you have all the AEs ,lets sort it by usubjid param trta asdt and take the first.trta. Now we have **infections_event**
 - **No events:**Take the rest of the subjects which didn’t have an event from ADSL.lets call it **infections_noevent** and combine it to the events dataset using set statement.This will be your PARAM
 - **Aval :** This is the time to occurance of an event .

Analysis Date ADT + 1 = AVAL

- **Analysis date (ADT):**ADT is the date of the Event. In our case ,this is the first occurrence of the AE .Hence AE start date. There are studies where we will have mutple dates to choose ADT from. This could be occurrence of an AE, a subjects death etc.In that case you might need to present Source domain (SRCDOM) and Source variable (SOCVAR) .Bringing all different dates and its source in can make our variables list huge and hard to process them in ADTTE with its horizontal structure.Hence it is recommended to build an intermediate dataset in BDS structure and set all dates of interest together.When you have found your first occurrence of the event ,transpose it to get your ADTTE dataset to add your additional variables like CNSR.
- **Startdate (STARTDT):**Start date is usually the day when the subject started treatment or date of randomization.In our case this is the start date per treatment .
- **Censor (CNSR):**If your subject has the event then mark this value as 0 which means they are **not censored** .If no event mark it as 1 ,which means they are **censored**. When you have multiple conditions for censoring you might have CNSR values >0 .eg;1,2,3...etc.

Now that we’ve created all the required variables and our ADTTE is ready... Lets see an example of how our varibales feeds into an annotated PROC LIFETEST procedure and the Kaplan Meier plot generated using PROC SGPLOT

Kaplan Meier plot

