FavoR

2018-12-17

Question 1

Count the number of subjects respectively in each treatment arm.(dm.sas7bdat)

ARM	No_of_Patients
GDC-0449	98
Placebo	101

Question 2

You can include R code in the document as follows:In dm.sas7bdat, generate baseline age variable (DM.RFSTDTC - DM.BRTHDTC + 1, Subject Reference Start Date/Time minus Date/Time of Birth plus 1) for each subject and make a corresponding boxplot group by sex.

Box Plot of Test Results:Safety-Evaluable Patients
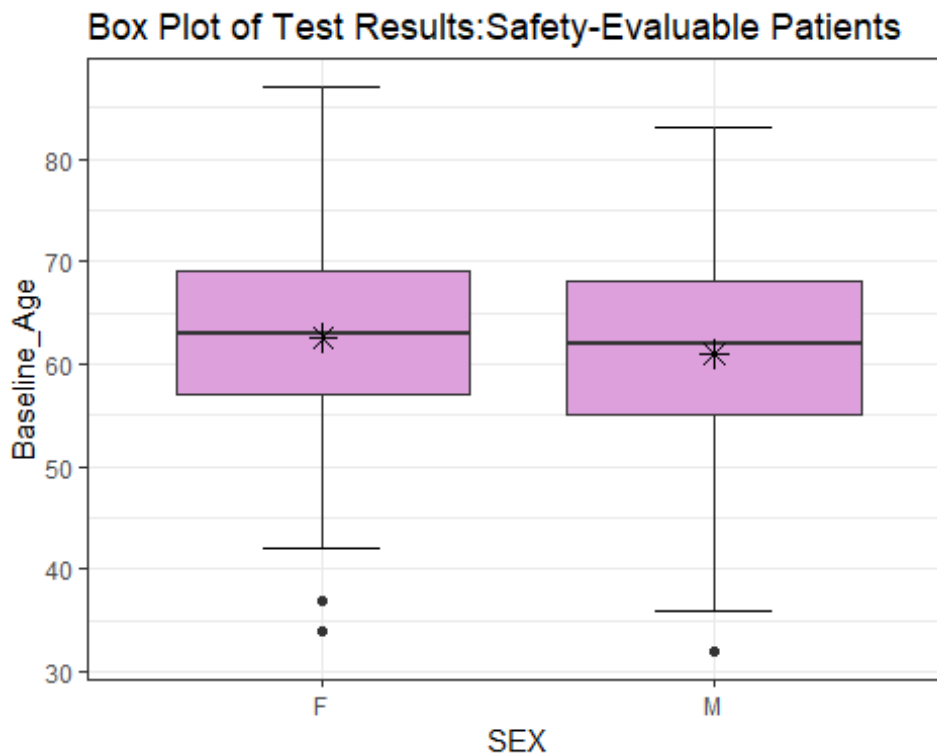
Question 3

How many subject had "Fatigue" (AE.AEDECOD, 'Dictionary-Derived Term') Adverse Event in this Study ?

Number of Fatigue Adverse Event

ARM	Fatigue_in_Patients
GDC-0449	70
Placebo	74

Question 4

What is the duration (day as unit) for each subject who had 'Cough' Adverse Event (AE.AEDECOD, 'Dictionary-Derived Term')? In additional, is there any subject who had recurrent 'Cough' events?

Listing of AE duration: Cough Patients

USUBJID	AEDECOD	AE_Duration_Days	AESTDTC	AEENDTC
SHH4429G-S19914-16102	Cough	6	2009-02-17	2009-02-23
SHH4429G-S19914-16102	Cough	8	2008-11-15	2008-11-23
SHH4429G-S19916-15950	Cough	6	2008-08-05	2008-08-11
SHH4429G-S19916-15950	Cough	NA	2008-10-27	
SHH4429G-S19916-15951	Cough	3	2008-06-20	2008-06-23
SHH4429G-S19917-15551	Cough	136	2010-01-04	2010-05-20

Listing of Cough Recurrent

USUBJID	AEDECOD	AE_Duration_Days	AESTDTC	AEENDTC
SHH4429G-S19914-16102	Cough	6	2009-02-17	2009-02-23
SHH4429G-S19914-16102	Cough	8	2008-11-15	2008-11-23
SHH4429G-S19916-15950	Cough	6	2008-08-05	2008-08-11
SHH4429G-S19916-15950	Cough	NA	2008-10-27	
SHH4429G-S20395-	Cough	78	2009-01-	2009-04-

| | | | 30 | 18 |
| SHH4429G-S20395-15401 | Cough | 8 | 2009-04-18 | 2009-04-26 |

Question 5

What adverse events leaded to drug withdrawn or drug interrupted (AE.AEACN)? Calculate the duration(day as unit) for those Adverse Events respectively. Is there any difference in the these kinds of AE duration between treatment arms? Hint: Boxplot; statistical tests

Listing Of AE duration: Drug Withdrawn or Interupted Patients

USUBJID	AEDECOD	AE_Duration_Days	AEACN	ARM
SHH4429G-S19914-16101	Delusion	NA	DRUG WITHDRAWN	Placebo
SHH4429G-S19914-16101	Hallucination	NA	DRUG WITHDRAWN	Placebo
SHH4429G-S19914-16101	Leukopenia	7 days	DRUG INTERRUPTED	Placebo
SHH4429G-S19914-16101	Lymphopenia	7 days	DRUG INTERRUPTED	Placebo
SHH4429G-S19914-16101	Neutropenia	7 days	DRUG INTERRUPTED	Placebo
SHH4429G-S19914-16101	Catheter Site Infection	13 days	DRUG INTERRUPTED	Placebo

```
## Don't know how to automatically pick scale for object of type difftime. Defaulting to continuous.
```

Box Plot of Safety-Evaluable Patientd
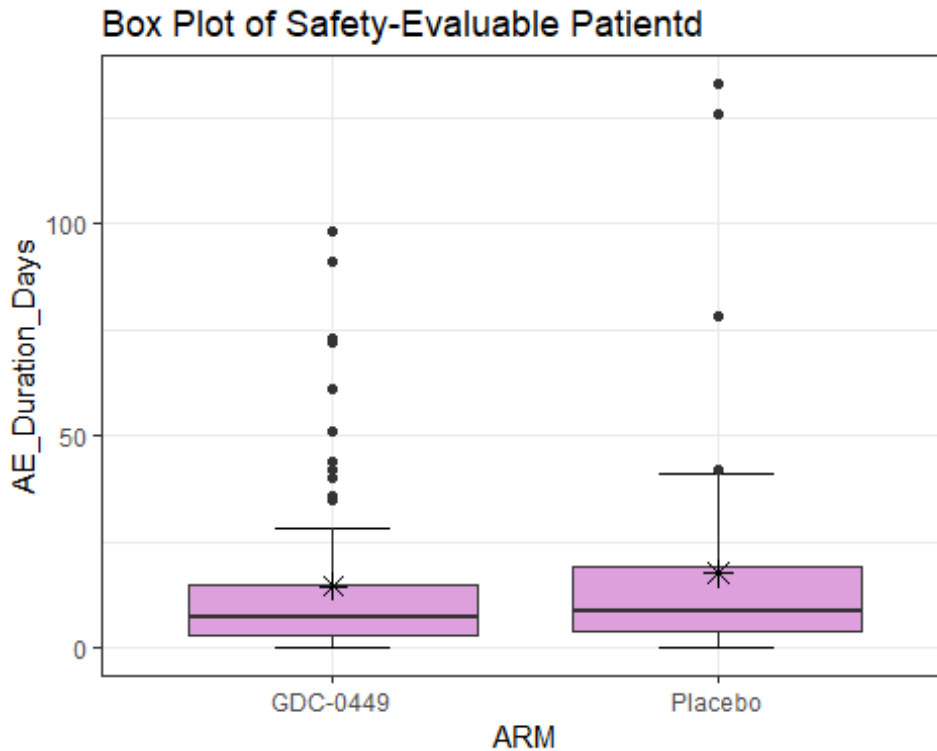
Question 6

Merge ae.sas7bdat and dm.sas7bdat by patient ID, find out how many subjects had at least one adverse event in each treatment arm respectively.

*Patient Disposition: Patient who had at least on Adverse Event*

ARM	No_of_Patients
GDC-0449	98
Placebo	101

Question 7

In dm.sas7bdat, Calculate study durations of each subject (DM.RFENDTC - DM.RFSTDTC + 1). Use graphs to demonstrate if the following assumptions exist:

```
     Is there any potential difference of durations between female and
 male?
     Is there any relationship between durations and ages?
```

Box Plot of Safety-Evaluable Patients

Shift Study Duration to Age Safety-Evaluable Patients
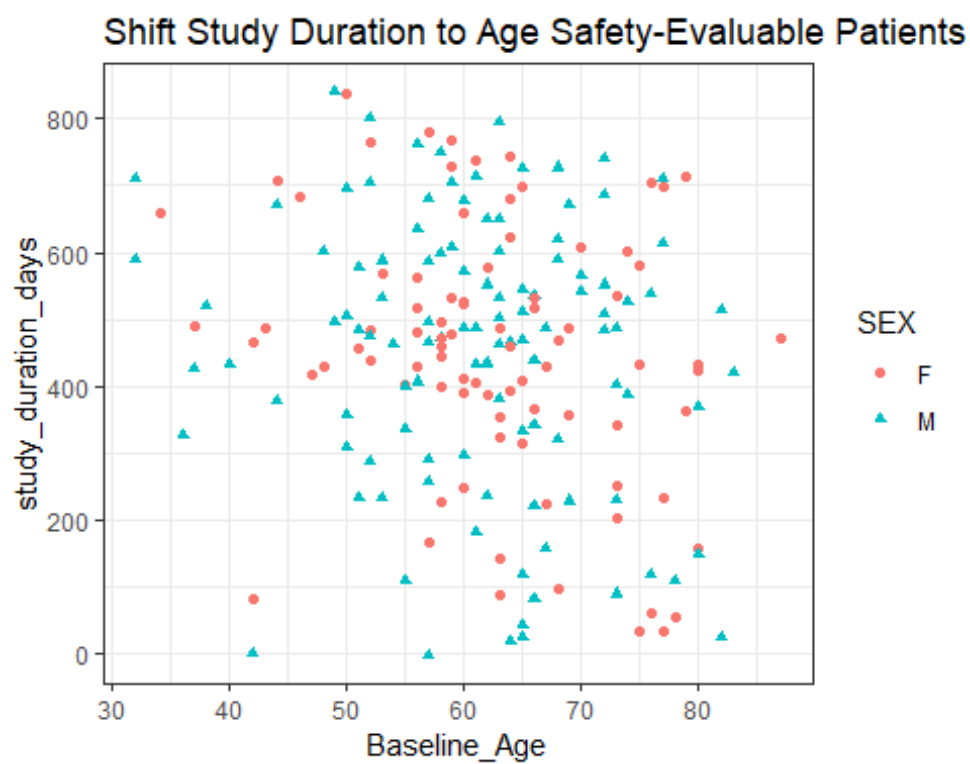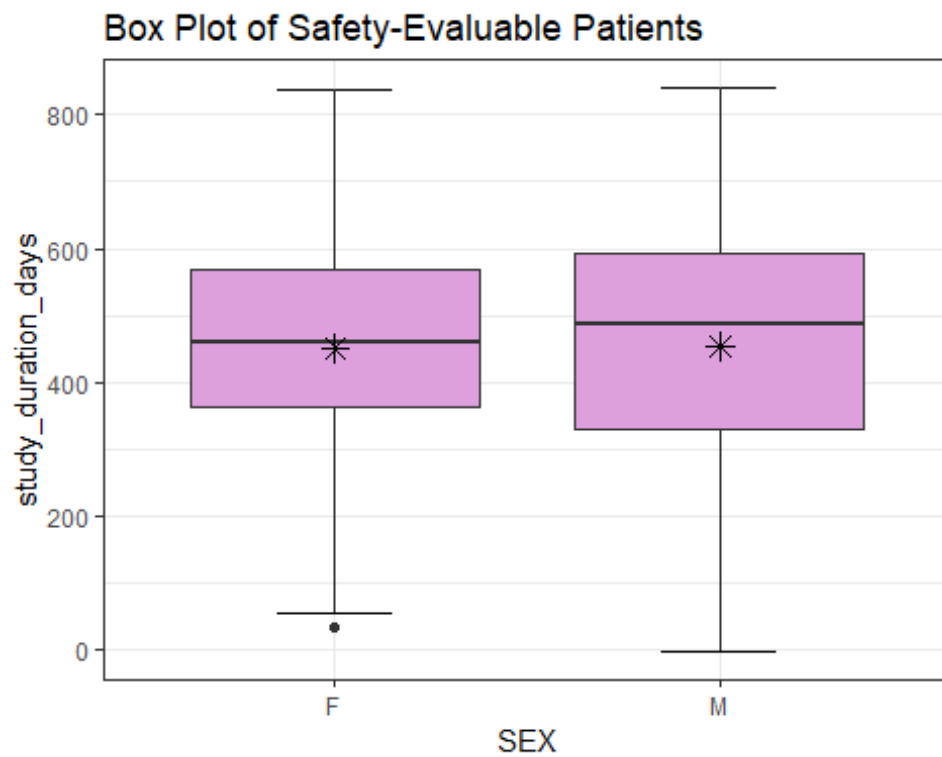
Question 8

In ex.sas7bdat, calculate duration of exposure per subject per treatment and be careful about the DataType. If the time part is missing, you may think about the following imputation rules.

```
If time is completely missing, impute time with 23:59:59
If partially missing, impute with 23 for missing hours, 59 for missing
minutes, 59 for missing seconds.
```

Listing of exposure per subject per treatment

USUBJID	EXTRT	EXTPTREF	Explosure_Duration_Hours
SHH4429G-S19914-16100	5-FLUOROURACIL	VISIT 1	23.85
SHH4429G-S19914-16100	5-FLUOROURACIL	VISIT 2	46.50
SHH4429G-S19914-16100	5-FLUOROURACIL	VISIT 3	23.92
SHH4429G-S19914-16100	5-FLUOROURACIL	VISIT 4	48.00
SHH4429G-S19914-16100	5-FLUOROURACIL	VISIT 5	46.17
SHH4429G-S19914-16100	5-FLUOROURACIL	VISIT 9	45.67

Question 9

In tr.sas7bdat dataset, plot the graph of percentage of change from baseline of sum diametera of tumor lesion for each subject over timeb.

```
a The sum diameter of tumor lesion is calculated by the sum of Longest
Diameter and Perpendicular Diameter for all target lesions.

b Use relavent study day and it is defined as Tumor Identification date
 minus first treatment date plus one (  TR.TRDTC - EX.EXSTDC + 1 ).
```

Percentage of Change from Baseline of Sum Diamete

Thank you.