**INTERPRETATIONS**

TASK 1 - DEMOGRAPHIC EXPLORATION

Table 1.1

The table gives the summary of Baseline grouping variables in “adsl” dataset. The variables are AGE, HEIGHTBL, WEIGHTBL, BMIBL (Continuous variables) and SEX, RACE, ETHINICITY (categorical variables). From this table we can find the count, mean, median, standard deviation and range for the continuous variables and count and mean for the categorical variables.

Figure 1.1

The given Sunburst chart explains the distribution of age groups in different treatment groups.

1. Majority of the study population belongs to the age group of 65 – 80(144).
2. Least number of subjects belong to the age group of <65 (33).
3. In the age group <65, count of Placebo is higher, in the group 65 – 80 Xanomeline high dose count is higher and in the age group > 80 ,the count of Placebo is higher.

Figure 1.2

The inverted pyramid chart shows the distribution of subjects gender-wise in different treatment groups.

1. The study population consists of 43.71% males and 56.29% females .
2. Majority subjects in placebo and Xanomeline Low dose are females while in Xanomeline High dose it is males.

Figure 1.3

The Histogram shows the BMI-Group wise distribution of the study population.

1. Range of BMI group is 13.7-40.1.
2. Majority of study population has BMI <25 which is the normal range for BMI.
3. Very less number of subjects have BMI >=30.

Figure 1.4

The stacked bar chart shows the discontinued reason-wise frequency of subjects taking 3 types of treatments. Here we have used the variable DCDECOD for the x-axis as it is the standard disposition term of the discontinuation reasons.

1. Major reason for discontinuation is adverse events and adverse events are more in Xanomeline Low dose.
2. Least important reason is lost to follow-up.
3. Number of discontinued subject counts is more in treatment with Xanomeline Low dose.
4. Major reason for placebo treated subjects to discontinue the treatment is Withdrawal by subjects.

Figure 1.5

The pie chart shows the distribution of total unique subject IDs according to their site id group.

1. There are 254 unique subject IDs.
2. Majority subjects are from the site id 701 (16.1%) and least are from site id 713 (3.5%).

Figure 1.6

The Boxplot shows the distribution of MMSE (Mini Mental State Examination) Total score by education level of subjects of treatment groups.

1. Interquartile range of MMSE of subjects is more in Xanomeline High dose.
2. Least ranges of MMSE are observed in subjects treated with Placebo.
3. Many outliers are also observed in MMSE.
4. Every treatment is not being given to the subjects with different education levels.

TASK 2- ADVERSE EVENTS OVERVIEW

Table 2.1

The table shows the summary of most prevalent adverse events grouped by treatments.

1. The most frequent adverse event is general disorders and administration site conditions with frequency of 108.
2. Average duration of this adverse event is highest under Xanomeline High dose.
3. The least prevalent among them is injury poisoning and procedural complications with th frequency of 14.

Figure 2.1

The bar charts 2.1.1 and 2.1.2 shows the frequency distribution of subjects in treatment –emergent and treatment non-emergent adverse events.

1. There are a total of 23 treatment emergent adverse events and 16 treatment non-emergent adverse events indicating majority of adverse events in the study population is caused from the treatment.
2. The variable AEBODYSYS is taken to be in x-axis which shows the system or body class getting affected from adverse event.
3. In Figure 2.1.1 the most reported adverse event which is treatment non-emergent is Skin and Subcutaneous tissue disorders for 10 subjects and least reported includes metabolism and nutrition disorders, immune system disorders, ear and labyrinth disorders, vascular disorders and renal and urinary disorders each of frequency of subjects as 1.
4. In treatment emergent adverse events the most reported is general disorders and administration site conditions for 211 subjects and least reported is Hepatobiliary disorders, social circumstances and immune system disorders for 1 subject each.

Figure 2.2

The cone chart shows the treatment wise duration of adverse events.

1. Average treatment duration is highest for Placebo.
2. Treatment with High dose is more efficient in reducing the average duration as compared to low dose.

Table 2.2

The table gives the count and percentage of subjects under different severity categories.

1. Majority of subjects are under moderate category.
2. Fatal cases are very few.
3. Causality is higher for probable cases
4. Majority of severity reasons are marked no for the subjects.

Figure 2.3

The stacked bar chart shows the treatment wise adverse events.

1. Fatal adverse events resulted from treatments is very less.
2. Number of adverse events recovered is greater in treatment with Xanomeline High Dose.
3. Number of adverse events cases is also greater in Xanomeline High Dose.
4. Least number of subjects recovered under placebo treatment.

Figure 2.4

The sunburst chart shows the distribution of different flags by adverse events’ severity – mild, moderate and severe.

1. There are 5 flags categorized under severity – AESHOP (Requires or prolongs hospitalization), AESLIFE(Is life threatening), AESCAN(Involves cancer), AESDTH(Results in death), AESDISAB(Persistent or significant disability).
2. There are mild, moderate and severe cases that require or prolong hospitalization.
3. There are only moderate and severe cases that is life threatening.
4. There are mild and severe cases that involve cancer.
5. Only severe cases involve death.
6. Only mild cases come under persistent or significant disability.
7. Majority of the mild, moderate and severe cases requires or prolongs hospitalization.

Figure 2.5

This visualization contains a bar graph, two scatter plots explaining about the lifecycle of hospitalized and serious adverse events.

1. In the bar graph we see that there are 28 hospitalized cases, 3 serious cases and 2 hospitalized and serious cases. The corresponding adverse events are syncope and Partial seizures with secondary visualization.
2. The 1st scatter plot shows the lifecycle of 3 subjects affected with syncope among which 1 subject got affected two times.
   1. In subjects 01-718-1049 there is no treatment end date.
   2. In 01-718-1170 and 01-718-1066 the adverse event starts after the treatment ends.
   3. The subject 01-718-1066 does not get recovered from the adverse event 2nd time.
   4. The duration between adverse event start date and treatment end date is very less.
3. In the scatter plot showing lifecycle of 1 subject(01-718-1371) affected with partial seizures with secondary generalization the adverse event occurs between the treatment . The treatment duration is longer but adverse event duration is very less.

TASK 3 – LABORATORY RESULTS OVERVIEW

Table 3.1

The table gives the summary statistics values like count, mean, median, standard deviation, and range of the parameters tested by the subjects.

1. There are a total of 15 parameters tested.
2. Parameters ANISO, MACROSY, MICROSY, POIKILO, POLYCHR show constant values.
3. The parameter PLAT has the maximum range.

Table 3.2

The tables shows the CHG and PCHG values of the parameters.

CHG and PCHG means tells about the average chage and percentage change across the observations.

1. Since we have good number of values in the CHG and PCHG, it give more reliable statistics.
2. There is a raise in the values for mean, median, standard deviation, and range in the week 6, 8, 12 for EOS.
3. There is a general trend of decreasing CHG and PCHG over time. Initially, both the mean changes and percentage changes are high, with substantial variability, but this variability decreases as time progressed.
4. There is fall in the mean CHG in week 20 for LYM.
5. Even though the mean CHG don't change much over time in MCH there are minor variations in the mean percent change (PCHG), with some weeks showing slight positive or negative shifts.
6. There’s a noticeable drop in CHG at Week 12 and Week 16, followed by some recovery in later weeks.
7. The standard deviation values suggest that the variability in PLAT levels is generally high throughout the study period, with the highest variability observed around Week 8.Weeks like Week 8 and Week 26 show substantial outliers in terms of the lower and upper ranges of percent change.

Figure 3.1

The Dot plot shows the relationship between analysis visits and analysis relative day of subjects.

1. Visits have been done from almost 100 days prior to the treatment.
2. There are unscheduled visits prior to and during the treatment but it gradually decreases as analysis duration increases.
3. The visit weeks of subjects are overlapping indicating that there is no sharp distinction between the days included in any visits of the subjects.

Figure 3.2

The horizontal bar chart is used to compare the number of subjects across different visit weeks in a study.

1. Largest number of subject visit is during Baseline week.
2. 46 subject visits are unscheduled and can be between any visits.
3. 109 subjects completed the last week 26 visit that is, the follow up week.
4. Out of 254 unique subjects IDs 247 subjects have taken the baseline visit and the rest 7 subjects have taken unscheduled visits before the start of analysis.

Figure 3.3

The Heatmap shows the count of subjects in different parameters marked according to reference range indicator. The variable used is PARAMCD.

1. Majority of subjects have remained normal pre and post treatment.
2. There has been an increase in the number of records in the high value in parameter ‘MCV’ (116 - 187),’RBC’ (90 - 132) and ‘HGB’(54 -96).
3. Frequency of subjects normal is largest in 12 parameters.
4. Number of subjects tested for parameters Anisocytes, Macrocytes and Polychromasia remained abnormal before and after the treatment.
5. There has been an increase in the number of records for 4 parameters i.e., BASO, HCT, MCHC, and PLAT.

Figure 3.4

The line plot tells about the average CHG and PHG IN treatment groups.

1. The parameter PLAT shows the highest range of values.
2. The PCHG of BASO is not shown as its value is infinity because its baseline value is 0.
3. Average PCHG value is marked highest for Xanomeline High dose under the parameter EOS.
4. Highest CHG value is also observed for Xanomeline High dose under the parameter PLAT.

TASK 4\_ BONUS TASK

Figure 4.1

We intend to explore the counts of severe adverse events under the varying doses of Xanomeline High Dose.

1. As the average dose increases, the count of mild, moderate and severe cases are increasing.
2. In the case of mild and severe adverse events, the frequency increase in the range of (74 - 78.5).
3. In moderate adverse events, it is more in (53.999-58) it then decreases and gradually increases in the range(74 - 78.6).

Figure 4.2

The line chart shows the range of a particular parameter for hospitalized subjects under mild, moderate and severe adverse events separately.

1. The range of 12 lab parameters of subjects is visualized and the remaining parameters have been omitted due to constant values or missing values.
2. Under hospitalized cases, there are 3 subjects in mild, 6 subjects in moderate and 12 subjects in severe.
3. For example, in HGB parameter,
   1. In severe cases the highest range is observed for subject ID 01-710-1368 and lowest range is observed for 01-710-1066.
   2. In moderate cases, the highest range is observed for subject ID 01-701-1192 and lowest range is observed for 01-710-1142.
   3. In mild cases, the highest range is observed for subject ID 01-709-1259 and lowest range is observed for 01-709-1326 and 01-710-1002.