Case Study Competition – Final Presentation

Track	*Data Visualization*
College/University	*University of Calcutta*
Software/tool used	*Power BI*

Student Name	Email ID	PG Course	Current semester/Year
Mainak Kunai	*mainakunai98@gmail.com*	*M.Sc.*	*3rd Semester*
Oyendrilla Pradhan	*oyendrilla.stats1300@gmail.com*	*M.Sc.*	*3rd Semester*
Preetam Biswas	*pbiswas5300@gmail.com*	*M.Sc.*	*3rd Semester*

Mentors: Pricil Kurian, Priyanka Sarode, Vivek Bolshette

About the data

- **CDISC**: The dataset is collected from CDISC (Clinical Data Interchange Standards Consortium), which is a consortium that works in developing guidelines and requirements that influence the standards for both clinical and nonclinical data.
- We are given three datasets named **ADSL**, **ADAE**, and **ADVS**.
- **ADSL** stands for Subject Level Analysis Dataset. This dataset contains variables that include information on demographics and baseline characteristics like age, height, weight, BMIs, and others of each individual. The structure of the ADSL dataset allows merging with other ADaM and SDTM datasets.
- **ADAE** stands for Adverse Event Analysis Dataset. This dataset contains crucial information on adverse events and their random side effects for each individual. It also has adverse event outcomes such as “Recovered” or “Not Recovered”.
- **ADVS** stands for Vital Signs Analysis Dataset. It contains different weeks’ observations for each subject starting from week 2 up to week 26.

Demographics and Baseline Characteristics by Treatment

- Since the ages of the volunteers vary from 51 to 89 years, hence they are all adults. It is observed that there are 6 underweighted volunteers with BMI levels of 12 to 18. Next, the BMI range of 18 to 24 (normal BMI range) has the highest number of subjects viz. 115. Additionally, there are 104 overweighted volunteers with a BMI range of 24 to 30 and 26 obese volunteers with a BMI range over 24.
- The corresponding height distribution for the subjects shows that the heights of 140 cm to 160 cm have more females than males whereas, for the heights of 170 cm to 180 cm, there are a greater number of male subjects.
- Additionally, for the weight group of 45 kgs to 60 kgs, there is maximum number of volunteers viz. 95.
- The corresponding pie charts segregated the subjects between males and females.

Demographics (continued) with Age Groups, Race and Ethnicity

- The age of the volunteers ranges from 51 to 89.
- For the race of "*American Indian and Alaska Native*", there is only one male subject (with ID 01-701-1275, aged 61 years), and he has been applied with treatment B only. He is also a subject of ethnicity "*Not Hispanic or Latino*".
- There are 23 subjects belonging to the race "*Black or African American*" and ethnicity "*Not Hispanic or Latino*".
- For the "*White*" race, there are the maximum number of subjects, viz. 229 with 94.76% of them of ethnicity "*Not Hispanic or Latino*" and the remaining from "*Hispanic or Latino*".
- There are a greater number of females between the ages of 70 to 85, whereas for the males this ranges from 65 to 80.
- The pie chart have the proportion of the individuals from different age groups.

Overview of TEAEs (Treatment Emergent Adverse Events) and Event Rate

- Firstly, from the rate of subjects against various disposition reasons; it is observed that the highest rate is the rate of completion of the trials. But on the contrary, it can also be observed that the rate of occurrence of adverse events is almost close to the completion rate. Upon drilling further, we can see that the symptom '*Pruritus*' is seen to be the most, and among many symptoms '*Influenza*', '*Fatigue*', '*Hypertension*', '*Chest Pain*' is seen to be the least happening during adverse events.
- The treemap depicts the proportion of individuals subject to different treatments (TRT A, TRT B, TRT C) who have completed the trial as well as discontinued from the study.
- Now, from the data given, it is seen that adverse events have further 3 outcomes: either the adverse event is resolved or is not resolved or comes out to be fatal. Though most of the cases have the outcomes of Resolved with 64.85%, there are 34.73% of the cases have "Not Resolved" status. Additionally, only 0.42% of the cases have fatal outcomes.
- The subject with IDs 01-701-1211, 01-704-1445, and 01-710-1083 have those fatal outcomes of death due to adverse events.

Distribution of days on study to AE (Adverse Events) onset for subjects with AE (Adverse Events)

- The first diagram has the count of volunteers in Y-axis and the duration from the treatment start date till the start date of adverse event in X-axis.
- 8 female volunteers have entered any treatment with already having adverse event symptoms. 6 of them recovered from the symptoms, but 2 of them (with IDs 01-703-1100, aged 84, Treatment A; 01-705-1393, aged 84, Treatment C) didn’t recover.
- 3 male volunteers (with IDs 01-701-1294, aged 67, treatment C; 01-708-1253, aged 61, treatment A; and 01-709-1309, aged 65, treatment B) have entered into the treatment already having an adverse event symptom. But all three of them have been out of the symptoms of the adverse event before the end of corresponding treatments.
- The second diagram has the count of volunteers in Y-axis and the duration from the end date of adverse event till the treatment end date in X-axis.
- There are 39 female and 31 male volunteers who still have the symptoms of adverse events after the ending of their corresponding treatment dates.

Distribution of BMI (Body Mass Index) across visits

- It is observed that as the number of weeks increases, the subject count decreases.
- The pattern of subject counts for different BMI levels is the same, viz., there is always a maximum number of volunteers with BMI levels between 24 to 30. Then, the next BMI level with a greater number of volunteers is between 18 and 24. Further, the grouping continues with the range 30 to 36 (obese); then 12 to 18 (underweight), and lastly over 36.
- According to the treatments, there are a greater number of female subjects who have been applied with treatment A and treatment C. Additionally, treatment B has been applied to more male subjects.
- For BMI levels 18 to 24, there is a maximum number of female subjects, whereas, for males, the BMI level ranges from 24 to 30, which is standardized as the overweighted range of BMI.

Additional Findings on Average Daily Doses and Treatment Duration

- We can observe that most of the subjects have been under observation within the range of 180 to 195 days from the starting date of any treatment.
- Approximately 20% of the subjects have been under treatment A for the treatment duration between 180 and 195 days.
- Treatment A, B and C have been applied to 86, 84 and 83 subjects respectively.
- For the age group of 75-80, subjects have been induced with a greater number of daily doses than other age groups.
- Furthermore, maximum number of subjects from that age group belongs to 45-60 kgs of females and the corresponding height of those females varies from 140 to 165 cm.

Acknowledgements

We would like to express our special thanks of gratitude to our mentors **Pricil Kurian**, **Priyanka Sarode**, and **Vivek Bolshette** as well as our Head of the Statistics Department, University of Calcutta **Prof. Rahul Bhattacharya** who gave us the golden opportunity to do this wonderful presentation on the topic "*Case Study Competition – Final Presentation*", which also helped us in doing a lot of Research and we learned about so many new things. We are thankful to them.

Finally, we would also like to thank our friends and seniors who helped us a lot in finalizing this project within the limited time frame.

THANK YOU