



Identify and Rectify the minutest Human error in their Randomization plan?

Introduction

In clinical trials, accurate application of randomization is crucial for obtaining reliable results in the analysis of study data. However, human errors can significantly impact outcomes, leading to incorrect conclusions. This case study explores a scenario where human error in randomization led to discrepancies between the mean and standard deviation of glucose levels reported by KITE-Ai and Client analyses.

Background

The data presented in this case study is from a diabetes study, where subjects were randomized to active treatment and placebo groups, focusing on glucose levels. Two tables were created, each containing two columns: SUBJID (subject ID) and Glucose Level. Analyses were conducted simultaneously by KITE-Ai and the Client. However, the mean and standard deviation of glucose levels reported by each team did not match, indicating a potential issue.

The tables are as follows:

Active Treatment	1	3	5	7	9	11	13	15	17	19	21	23	25	27	29	31
Placebo	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32

Kite-Ai Analysis	
SUBJID	GLUCOSE
1	74
3	84
5	81
7	86
9	81
11	89
13	114
15	140
17	135
19	138
21	175
23	196
25	134
27	126
29	131
31	138

Client Analysis	
SUBJID	GLUCOSE
1	74
3	84
5	81
7	86
9	81
11	89
12	136
14	160
17	135
19	138
21	175
23	196
25	134
27	126
29	131
31	138

Mean 120.12
Std Deviation 34.490714

Mean 122.75
Std Deviation 35.64846

Data Analysis

The discrepancy was traced back to errors in randomization applied by the Client. Specifically:

- **SUBJID 23** and **SUBJID 27** were incorrectly included in Active Treatment arm.
- **SUBJID 28** and **SUBJID 31**, who were supposed to be part of Active Treatment arm, were excluded.

This misallocation of subjects caused incorrect glucose level data to be used in the Client's analysis, thereby affecting the final computed mean and standard deviation values.

Impact of Human Error

The incorrect randomization had significant consequences:

1. The **mean glucose level** reported by KITE-Ai was **120.12**, whereas the Client reported 122.75.
2. The **standard deviation glucose level** reported by KITE-Ai was **34.49071**, while the Client reported **35.64846**.
3. The inclusion of incorrect subjects (**SUBJID 23** and **SUBJID 27**) in the Client's analysis introduced erroneous data, resulting in a higher mean value.
4. These discrepancies could lead to incorrect conclusions about the efficacy or safety of the treatment under study.

Conclusion

This case study highlights the critical importance of accurate randomization in clinical trials. Human errors, such as incorrect subject inclusion, can result in significant discrepancies in data analysis, potentially jeopardizing the validity of the trial's conclusions. It underscores the need for meticulous data management and rigorous verification processes to minimize the risk of such errors and ensure reliable results. Although the case study is from live studies, actual study data is not used here to protect data privacy and dummy is presented here for illustration.