INTRODUCTION:
Pharmacokinetics (PK) may be defined as the absorption, distribution, metabolism, and excretion of an investigational drug. In a new drug development process, pharmacokinetic types of studies are conducted to examine what is happening to the drug within the body.

Graphs play an important role in interpreting drug concentration-time data as they provide a quick view of the general trend of the drug concentrations over time. A simple illustration of a concentration-time graph is presented below.

ILLUSTRATION:
Case 1:
Some clinical trials are designed to collect data over several periods of time, such as in the case of multiple-dose studies. One example of this study design is when subjects are dosed for series of days and blood samples are drawn at the particular time points. The graph below is one example of this study design. Subjects were dosed for series of days with trough (predose) and serial plasma samples were drawn on different study days.

Case 2:
Another way of presenting multiple-dose studies is to have multiple graphs in one page. An advantage of this type of presentation is, it provides graphical comparisons of concentration profiles over different time points. The graph below compares the relationship of two plasma samples on different study days.

Case 3:
Pharmacokinetic data can be visualized by subjects, and scatter plots are commonly used to display pharmacokinetic data by subject on a single graph. Scatter plots are particularly useful for interpreting PK data when there are a significant number of concentrations that are not quantifiable or missing, in which case mean concentration-time data may be misleading.

Case 4:
Another option for presenting individual concentration-time data is a spaghetti plot. Spaghetti plots show variability between individual concentration data at a given time. Moreover, there are cases where there is a need to overlay the mean +/- standard deviation (SD) concentration profile to have an overall clear understanding of the concentration-time data.

Case 5:
In addition to graph drug concentrations-time data, graphs that show relationships of pharmacokinetic parameters are often done as part of the analysis. Common pharmacokinetic endpoints are presented below:

Case 6:
It can be useful to plot clinical data such as vital signs and electrocardiogram (ECG) data against pharmacokinetic concentration data in order to spot existing relationships between the two parameters. Below is an example of a graph that shows ECG data (Change from Baseline QT measurement) plotted against the time-matched plasma concentration for each subject by treatment. Regression lines can then be added to display predicted values and confidence limits.

CONCLUSION:
Datasets that are not presented well can lead to misinterpretation of the data which may lead to an erroneous decision. This paper demonstrated some helpful ways to visualize pharmacokinetic data effectively. As seen in this paper, creating graphs using SAS® procedures such as PROC GPLOT and PROC GREPLAY together with the available plotting options, keeps the programming from becoming more complicated than it needs to be. The ultimate goal is to visually communicate the data at hand that scientists can use to interpret and draw conclusions.

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