Biotech Essential Statistics: Statistical Insights for Biotech Professionals.

Effective evidence-based decision-making requires an understanding of the statistical methodologies employed in the analysis of clinical trial data and the results that these methodologies generate.

In the third and final webinar of the **Phastar Biotech Essential Statistics webinar series**, the company's **Associate Director of Statistics and Technical Solutions, Stephen Corson**, offered a topline overview of some common statistical concepts and how to interpret their results, in a bid to help biotech professionals have more meaningful conversations about clinical data with their statistical colleagues/team members.

Interpreting confidence intervals

When conducting an experiment, we use the observed data to generate a statistic, or numerical summary of these data (e.g., mean, proportion) to get a value for what we are interested in. However, if we repeat the same experiment multiple times and each time we calculate the same statistic, we will not get the same answer. There will be variability in our results and so we need a method of quantifying this variability. **Confidence intervals (CIs)** give us a tool for doing just that.

A CI helps answer the question **"How big of an error might we be making when we use the sample statistic as an estimate of the population statistic?"**. It essentially gives us a range of values which are likely to contain the true population value.

The width of the CI depends on multiple factors, such as the sample size, the level of confidence we want to have, and the amount of variability in the data. A 95% CI, as often quoted in clinical data, means that there is a 95% chance that the true population value is contained within the given interval.

Decoding P-values

P-values are synonymous with clinical trials and are used to determine the efficacy of a treatment or the success or failure of a clinical trial. They are numerical quantities with a range of 0 to 1 which are used to measure the strength of evidence against a null hypothesis. Values close to 0 suggest that the observed difference between the groups is likely to be due to chance, whereas a p-value close to 1 suggests that it is highly unlikely that the difference observed is due to chance and so it may be attributable to differences in treatment regimens.

Conventionally, researchers tend to use a threshold of <0.05 to demonstrate a statistical significance. However, there has been much discussion within the scientific community about the modern-day use of p-values, with many arguing that there is an overreliance on them. Recommendations from discussions suggest that p-values be reported alongside estimates of effect size and confidence intervals to add context.

Unravelling odds ratios

Odds relate to a binary outcome, simply that an outcome either does or does not occur, and how likely that outcome is to occur, relative to it not occurring. By extension, **odds ratios (OR) are measures of association that compare the odds of the event happening in two groups.**

Imagine a clinical trial where (a) there are two groups (control and treatment) and (b) a subject can either experience a myocardial infarction (MI) or not. In this example, the odds of having an MI is the number of subjects who experienced an MI divided by the number of subjects who did not in each group. The OR is the odds of MI in the control group divided by the odds of MI in the treatment group. This tells the researcher how much more likely those in the control group are to have an MI than those in the treatment group.

If the odds were the same in both groups, the OR would be 1. **An OR of 1 or close to 1 suggests that there is no evidence of a relationship between the intervention and the outcome.** Sometimes in the literature, the OR will be accompanied by a p-value, which relates to how likely it is that the difference between the observed OR and 1 was due to natural variation. As discussed earlier, small p-values (i.e., those <0.05) suggest that the observed difference is unlikely to be caused by natural variation and could be attributable to differences in exposure/treatment.

Grasping hazard ratios

Whereas an OR compares the odds of an event occurring in two groups, **the hazard ratio (HR) compares the risk of an event occurring in two groups at any one particular point in time and evaluates how one group changes relative to another.**

In clinical data, HR is often used to measure the time from an intervention or procedure to an event, such as disease progression or mortality, for example. This allows researchers to understand the difference in outcomes between the control and the treatment group.

A HR of 1 means the hazard of the event is the same in both groups, whereas an HR of <1 can indicate the intervention provided some protection against the event. An HR of 1.2, for example, means the risk of the event occurring is 20% more likely in the control group.

HRs are often presented alongside CI, which indicates how certain the researchers are that the cited figure could be extrapolated to the target population.

To learn more about essential statistics, watch the full webinar.