

### The Science (and Art!) of Interpreting and Writing About Clinical Trial Data

#### Speaker

**Kim Jochman, PhD, RAC**

*Merck & Co., Inc., Apex, NC*

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*On March 18th, Kim Jochman, PhD, RAC presented a synopsis on how to accurately interpret and summarize clinical trial data. Dr. Jochman is the Senior Director of Medical Writing at Merck & Co., Inc., former AMWA Carolinas Chapter President, and dedicated member of the medical writing community.*

Data interpretation is a critical skill for medical writers and was well-summarized by Dr. Jochman as “pulling meaning from data to craft statements” that allow a reader to answer specific questions about presented data. Her presentation provided recommendations for proper interpretation of clinical trial data using both inferential statistics and descriptive statistics, which are described below.

**Inferential statistics** are applied when data collected from a sample of a population are used to make inferences about the total population. Analysis of these data includes calculation of a point estimate, and the standard error, which is the estimated variability across sub-samples of a total population. Both values are used to calculate a confidence interval, which represents a range that is likely to contain the true population value for a given measurement.

Confidence intervals are often used in clinical trials to determine whether two groups are different, and there are two common ways that they are calculated. The

first is to calculate the confidence interval around the point estimate for each group. To interpret these data, a writer will assess whether there is overlap between the confidence intervals of the two groups. If there is overlap, then the two groups might not differ. If the confidence intervals do not overlap, then the two groups are likely different.

The second method calculates the confidence interval for the *difference* between point estimates. In this case, a single confidence interval is calculated to compare the two groups. If the confidence interval contains zero, then you cannot conclude that the groups are different. If the confidence interval does not contain zero, then there is likely a difference between the two groups.

Additional statistical tests can be used to calculate p-values, which frequently report the probability of obtaining a result in a trial sample if there were *no difference* between groups. A common p-value cut-off to state there is a significant difference between groups is  $p < 0.05$ . This value indicates there is less than 5% chance of observing that result if there were no difference between the groups.

#### Example statements to interpret inferential statistics:

- *Participants who received treatment A had a lower mean heart rate compared to participants who received placebo ([if indicated, include p-value here]).*
- *The mean heart rate of participants who received treatment A was not*

*different from the placebo group ([if indicated, include p-value here]).*

**Descriptive statistics** are applied when data collected from a sample population are used to make summary statements about that sample. Analysis of descriptive statistics begins by calculating frequency of an endpoint, central tendencies (mean and median), variation (range and standard deviation), and position (percentile ranks, quartile ranks). These data are often presented in tables to summarize population characteristics such as demographics or adverse events. When crafting summary statements about descriptive statistics, it is important to establish cut-off points for using comparative terms such as “higher”, “lower”, “infrequent” or “most” within your writing team. For example, group differences of more than 10 percentage points could be highlighted and group differences of less than 10 percentage points could be considered comparable. These cut-offs should be discussed and agreed upon with stakeholders, and consistent usage will limit biased emphasis or interpretation of data and allow for consistency throughout a document.

**Example statements to interpret descriptive statistics:**

- *The most commonly reported adverse events (>20% of participants) were headache, dizziness, and nausea. The incidence of adverse events was comparable between groups except for fainting, which was experienced by a higher percentage of participants who received treatment B.*

Thank you, Dr. Jochman for a wonderful and interactive session that allowed participants

to practice and discuss different ways to interpret clinical trial data!

*Acknowledgements:*

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