EMWA Professional Development Programme

Using Statistics in Medical Writing

Workshop status: Foundation

Workshop leader: Dr. Barry Drees

Abstract

Objectives
At the end of the course participants should understand the following:

- Populations to be analyzed: intent-to-treat, per-protocol, safety-evaluable, worst-case.
- Sensitivity analyses: making up data and how to measure robustness
- Descriptive statistics: mean, median, mode, range, percentiles, box plot, normal and non-normal distributions, parametric and nonparametric tests, coefficient of variation
- Estimates and confidence intervals: probability, standard deviation, standard error of the mean, p-values
- Sample size calculations and what they mean

Workshop content
We all write about statistics, but how many of us really have an intuitive feel for what we're writing about? This workshop is designed for participants who have little or no background in statistics. The following statistical concepts will be covered in depth: study populations, sensitivity analyses, summary statistics, estimation and confidence intervals, and sample size calculations. Emphasis will be placed on understanding statistical presentations and reporting statistical information, not on calculations or mathematical explanations.

Participant profile
Medical writers and editors with any level of experience who wish to learn more about the statistics they work with.

Pre-workshop assignment
1 hour

Post-workshop assignment
1 – 2 hours (depending on how long you look for an example)

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Workshop outline

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Pre-workshop assignment

Objectives
To briefly introduce participants to some of the key statistical concepts that will be presented in the workshop using exercises.

Content
Participants will receive an assignment to read, complete, and return to the workshop leader before the workshop consisting of:

1. Statistical Populations
2. Confidence in Confidence Intervals.
3. A Brief Introduction to Probability

Assessment criteria
Participants must complete and return parts 1 and 3 to receive EPDP credit.

Resources/material required
A brain and the course materials provided.

Time required
3 – 4 hours

Instructions
Read, complete, and return your answers to Barry Drees at the address below to obtain credit for the EPDP certificate.

Please return to:
Dr Barry Drees
Mobile: +49-179-1417744
barry@trilogywriting.com

EXERCISE

Here are the results of a clinical study:

Variable	Number of subjects		
	Wonderdrug	Placebo	Brand X
Total randomized	180	98	165
Responder rate			
Responder	128	50	112
Non-responder	32	3	43
Missing	20	45	10
Symptoms – Day 1			
Yes	157	55	138
No	13	7	17
Unknown	10	36	10
Symptoms – Day 5			
Yes	50	18	25
No	115	36	104
Unknown	15	44	36

1) Calculate the responder rate using:

- an intent-to-treat population (% responders of total subjects randomized)
- a per-protocol population (% responders of subjects with response, i.e. excluding those with “missing” from the total)

Now write a concluding sentence for each calculation.

Are your sentences different?

Which is more accurate?

How would you explain the difference?

Would it influence your decision to know whether the missing values were due to poor monitoring or to subject withdrawal, and if withdrawal, whether it was due to lack of efficacy or unrelated adverse events?

How would your conclusions differ if you calculated non-responder rate instead?

2) Calculate the change from Day 1 to Day 5 in percentage of subjects with symptoms and without symptoms for intent-to-treat and per-protocol populations.

Notice any differences?

Which analysis is more accurate now?

3) If you were preparing a report on this for an important client, what would you recommend they present most prominently for responder rate? For alleviation of symptoms? Why?