Covid Treatment Clinical Trial Data Analysis

**ANSWER KEY**

Begin by opening the data set provided by your teacher. Work with your group to come up with responses to the questions below.

1. What is the sample size of this trial? (In other words, how many participants were in the trial?)

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| 60 |

1. Is this sample size representative for phase 2 clinical trials?

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| Phase 2 clinical trials usually use hundreds of volunteers (only 60 here so the data is manageable) |

1. How many male and how many female participants?

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| F = 30  M = 30 |

1. Make a single graph that shows the number of participants with each pre-existing condition.

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| --- | --- |
| One possible graph | Another possible graph |
| Chart | Chart |

1. Make a graph that shows the number of participants who got the Treatment and the number who got the Placebo.

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| --- | --- |
| One possible graph | Another possible graph |
| Chart | Chart |

# Looking at Just the Placebo Data

1. What happens to people’s outcomes (from primary to secondary) who get the placebo. Provide visual evidence.

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| In order to answer this question, I used columns J, K & L of the Teacher data. The mean difference of those who received the placebo is -1.533 meaning that the average person to receive the placebo got worse by 1.5 letter grades (as seen in the Outcome Measures tab). |

1. Which group(s) are most impacted? How do you know this? Provide visual evidence.

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| By sorting Column I to display only E, F, & G, we see that the 2 biggest pre-existing conditions (other than “None”) are Heart Condition and Asthma. This is a pie-chart of that sorted data. Other visualizations and conclusions are possible.  Chart |

# Looking at Just the Treatment Data

1. What happens to people’s outcomes (from primary to secondary) who get the treatment. Provide visual evidence.

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| Using the same steps as above, those who received the Treatment improved by 1.567 on average. |

1. Which group(s) does the treatment help the most? How do you know this? Provide visual evidence.

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| By sorting Column L in the teacher data set and then filtering out the “0”, & “1”, we see that other than the “None” condition, “Heart Condition” followed by “Asthma” have the highest % of benefit. There are other, better ways to represent this. Ask students to describe their process and rationale.  Chart |

# To Proceed or Not?

* If you were NIH (National Institutes of Health) and were tasked with deciding whether this treatment should proceed to phase 3 clinical trials, would you approve or not? Please explain your answer.

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| Not necessarily a right or wrong answer here (especially as the data is limited to make it manageable) - it’s about getting students to explain their reasoning. Valid reasons could refer to the severity/frequency of side effects identified, the balance of risks (side effects vs effect of the treatment). Phase 3 will expand the sample size so it’s about deciding whether the treatment is safe enough to scale up with a larger population sample (thousands). |

* What additional information do you think you would want to know?

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| Lots of potential answers here: proposed doses, schedule of immunizations, ethnicity data (impact of different demographics/backgrounds). Students may also want to know data on any investigations that took place with regards to the adverse effects and deaths that occurred during the clinical trials (and whether a causal link was established). |