

**Total 32 points (4+4+2+6+2+2+4+6+2)**

**Submission Guidelines:** Please submit this part in PDF format such that it is named as your roll number. Please make sure that it is clear which question and which part are you answering.

We learnt about RCTs in the lecture, but we didn't get to details of conducting RCTs. The purpose of this question is to extend your understanding of RCTs through self-learning. Along the way, you will also be able to add to your knowledge of the current state of vaccines for the major issue facing the world today: the Covid-19 pandemic!

You will need to read the following guide on clinical trials for this question:

"A simplified guide to randomized control trials"

<https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1111/aogs.13309>

**Q1:** Despite randomization, what sort of investigator bias can creep into RCTs and how can it be prevented?

**Q2:** What are type I and type II errors in RCTs?

**Q3:** What guiding principle does one need to know in order to calculate the sample size that will be sufficient for an RCT?

**Q4:** Consider the following clinical trial advertisement for Covid-19 vaccine:

<https://www.shifa.com.pk/trial/>

What do the terms double-blind, placebo-controlled, Phase I, II, and III trial refer to here?

**Q5:** Consider the following Coronavirus vaccine tracker:

<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

1. What does pre-clinical testing mean in a clinical trial mean? Why do we need it?
2. What should an investigator do when observing negative effects in an RCT?
3. Why are certain vaccines more broadly approved than others? For example, Moderna: "Approved in Switzerland" vs. Pfizer-BioNTech: "Approved in several countries"?

**Q6:** Consider the following statement:

"Based on [evidence from clinical trials](#), the Pfizer-BioNTech vaccine was 95% effective at preventing laboratory-confirmed COVID-19 illness in people without evidence of previous infection" taken from:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html>

1. Explain what does “95% effective” mean here by capturing the RCT study set-up as well as how to interpret the RCT results.
2. What are your comments on the demographic data (in the link above) used in the clinical trial?