



JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
415 N. Washington Street, 2nd Floor
Baltimore, Maryland 21231

16 May 2022

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: What every epidemiology and biostatistics graduate should know about clinical trials

Epidemiology in Last's dictionary of Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control health problems.

Epidemiology in Merriam-Webster is a branch of medical science that deals with the incidence, distribution, and control of disease in a population. Biostatistics in Merriam-Webster is statistical processes and methods applied to the collection, analysis, and interpretation of biological data and especially data relating to human biology, health, and medicine.

A clinical trial in Merriam-Webster is a scientifically controlled study of the safety and effectiveness of a therapeutic agent (such as a drug or vaccine) using consenting human subjects.

To be sure, clinical trials are done by all manner of people inside and outside academic institutions, but the most common academic home for "trialists" are departments of epidemiology and biostatistics in schools of public health.

I am a hybrid trialist. Educated in biostatistics and housed in a department of epidemiology. Leaving me, as an educator, with the question in the subject line of this memo.

As educators what do you expect students of biostatistics and epidemiology to know about clinical trials when they graduate?

My list of questions is below. Some of them may look familiar from my pop quiz distributed 13 January 2022. Now is your chance to even the score with questions you expect finished students to know about trials.

No.	Question
1	What is the difference between a cohort study and a trial?
2	What are “per protocol” and “intention to treatment” analyses?
3	Where are trials registered?
4	Who was James Lind?
5	What does “control treatment” mean?
6	What is “stratification”?
7	When is a person counted as enrolled in a randomized trial?
8	What is a “placebo”?
9	What do the letters IRB stand for?
10	What are the principles discussed in the Belmont Report?
11	What are the characteristics of good randomization procedures in trials?
12	Who was Ronald Fisher?
13	What does “double masked” mean in trials?
14	What is a crossover trial?
15	What are stopping rules for in trials?