ETHICAL ISSUES IN DATA ANALYSIS AND DATA REPORTING

Dr. Kyaw Swa Mya
Associate Professor/Head
Department of Biostatistics
University of Public Health

THE ARTICLES USED FOR THIS PRESENTATION WERE MENTIONED IN REFERENCE LIST.

1. Ethical Issues in medical statistics - SEYYED MOHAMMAD TAGI-Il AYATOLLAHI, Ph.D., FSS, C. Stat. mjiri.iums.ac.ir/article-1-1390-en.pdf

2. Research Ethics: Ethical Issues of Data Reporting and the Quest for Authenticity - CATHERINE A. MARCO, MD, GREGORY L. LARKIN, MD, MS, MSPH https://onlinelibrary.wiley.com/.../j.1553-2712.2000.tb02049.x

3. **Ethical Issues** in the **Statistical**. Analysis of Clinical **Research** Data. Roger J. Lewis, MD, PhD. Department of Emergency Medicine. Harbor-UCLA Medical Center. www.saem.org/.../research/ethical_issues_in_stat_analysis_of_cli...

STATISTICS

- Statistics is the science of collecting. summarizing, presenting, and analyzing data.
- This analysis may lead to conclusions and subsequent decisions.

STATISTICS IS USED TO ANSWER THE RESEARCH QUESTION.

- Is this new drug or procedure better than that commonly in use? How much better?
- What, if any, are the risks or side effects associated with its use?
- In testing a new drug how many patients must be treated, and in what manner, in order to demonstrate its worth?
- What is the normal variation in some clinical measurements?
- How reliable and valid is the measurement?
- What is the magnitude and effect of laboratory and technical error?
- How does one interpret abnormal values?

HOW THE STATISTICAL ASPECTS AFFECT THE ETHICS?


Planning
Design
Data collection
Ethics is concern in all research process!
Presentation
Interpretation
Publication

STATISTICAL QUALITY VS. ETHICAL CONCERN

- “Statistical quality” is linked to validity and truthfulness.
- Quality statistical analysis is ethical statistical analysis.

DATA CENTERED SCIENTIFIC MISCONDUCT

- Data fabrication
- Data falsification
- Data stealing
- In this workshop, I am not talking about above topics instead I will focus on more subtle aspects of ethical statistical practice

UNETHICAL STATISTICAL ISSUES

1. FAILING TO INCLUDE NUMBER OF ELIGIBLE PARTICIPANTS.

- If a large number of eligible participants refused consent, or
- Were not included for other reasons, failure to report this may falsely mislead the reader to believe that study participants are representative of the entire body of eligible participants.

2. INACCURATE REPORTING OF MISSING DATA POINTS.

- For example, in a study with a large number of participants, but high fractions with missing data points, the reporting of data could be manipulated to camouflage missing data points.

3. FAILING TO REPORT ALL PERTINENT DATA.

- Some researchers purposely neglect to report sections of data that are inconsistent, or unexplainable, with other results.
- This unscientific selection of data points is misleading.

4. FAILING TO REPORT NEGATIVE RESULTS.

- Although positive results appear more interesting, and may carry increased probability of acceptance for publication, negative results are scientifically as important to report.
- A failure to demonstrate a statistically significant difference between groups is not a failure to demonstrate meaningful results.
- Demonstration of negative results may be valuable to the medical community, and may obviate the need for additional financial or time investments from other researchers.
- Particularly in this era of cost containment, the demonstration of a lack of benefit of a new therapy may be valuable.

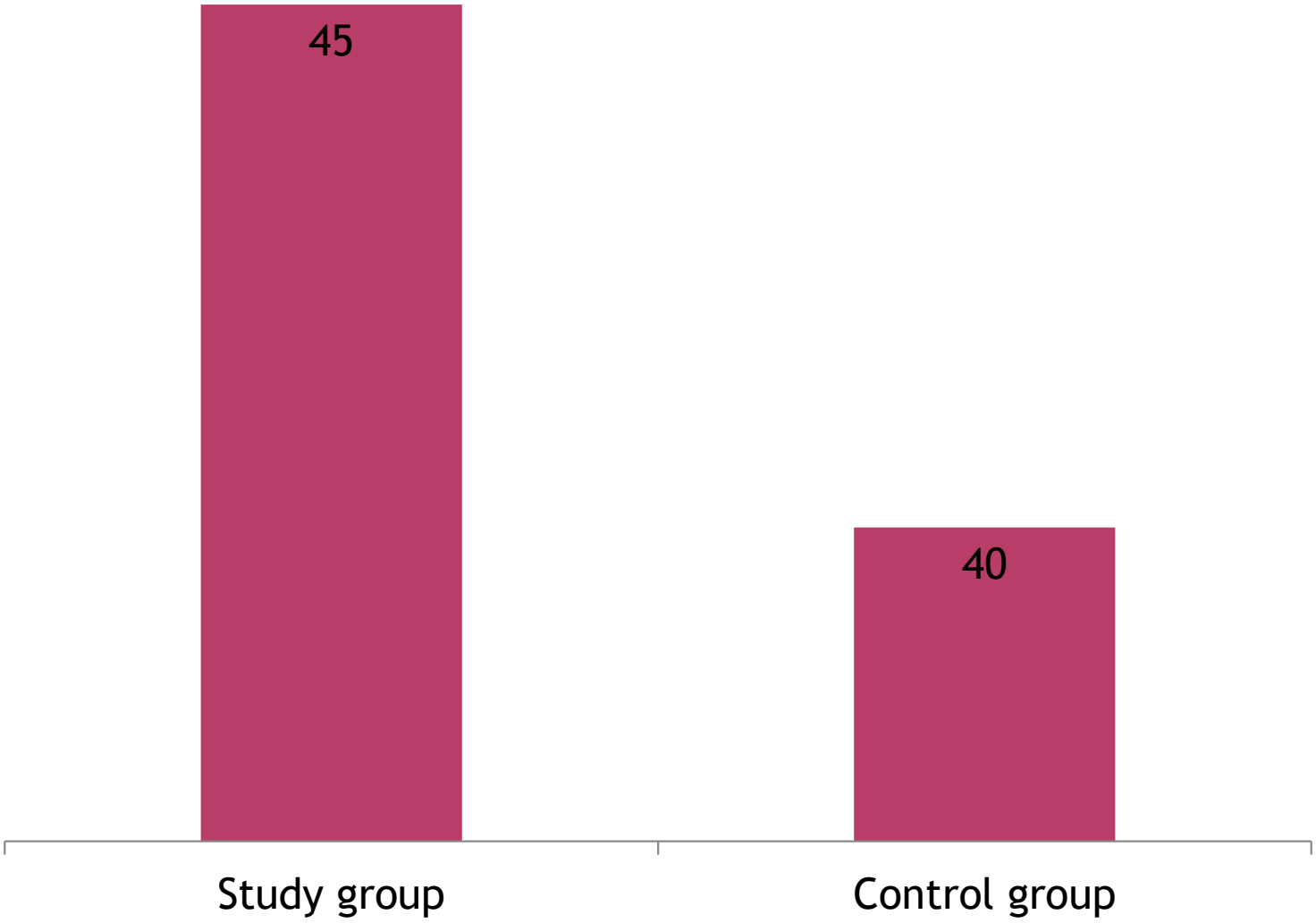
5. ALLOWING RESEARCH SPONSORS TO INFLUENCE REPORTING OF RESULTS.

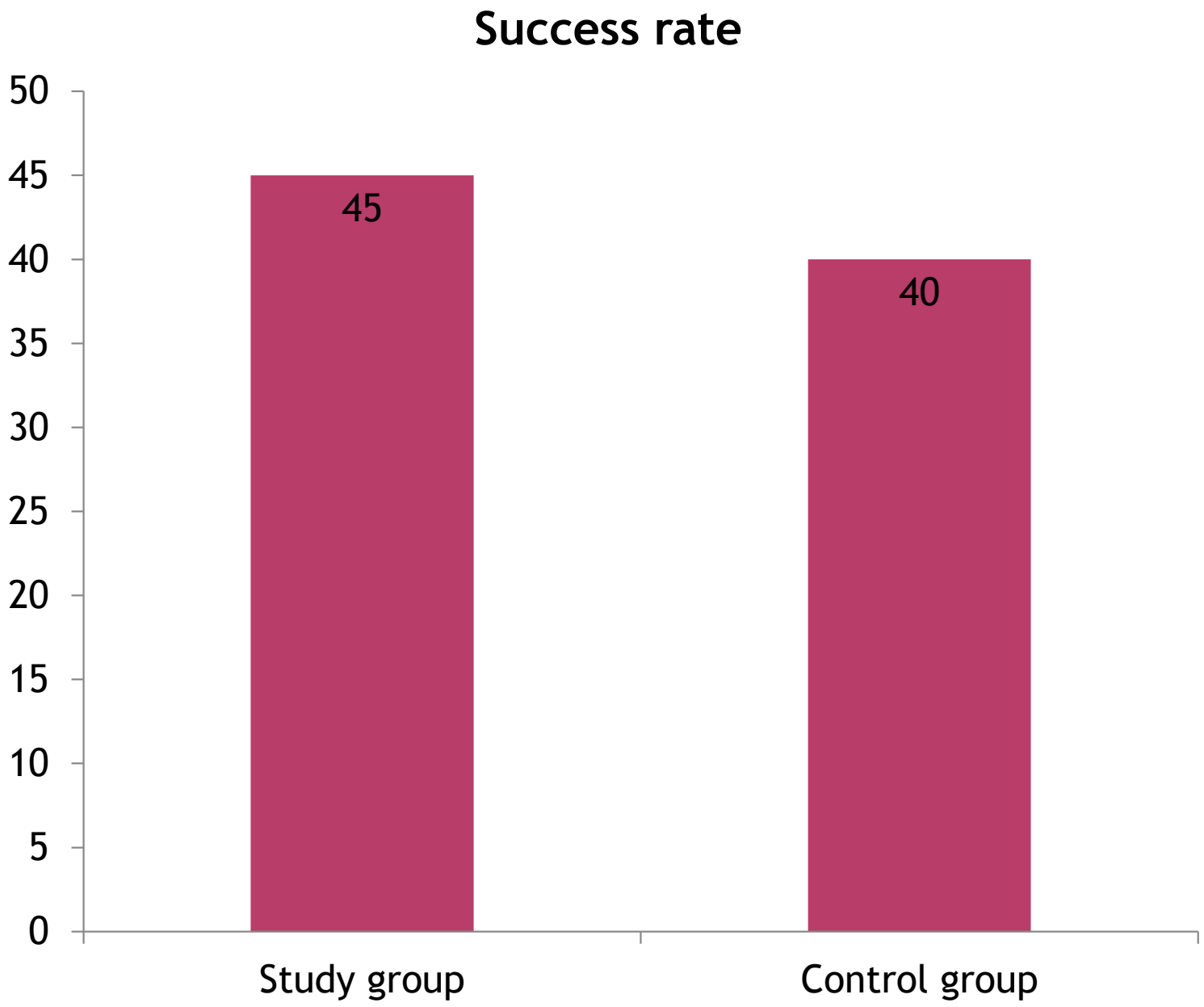
- For example, pharmaceutical sponsors may pressure researchers to report only results favorable to their product or may prohibit presentation or publication of the results altogether.

6. INAPPROPRIATE GRAPH LABELS.

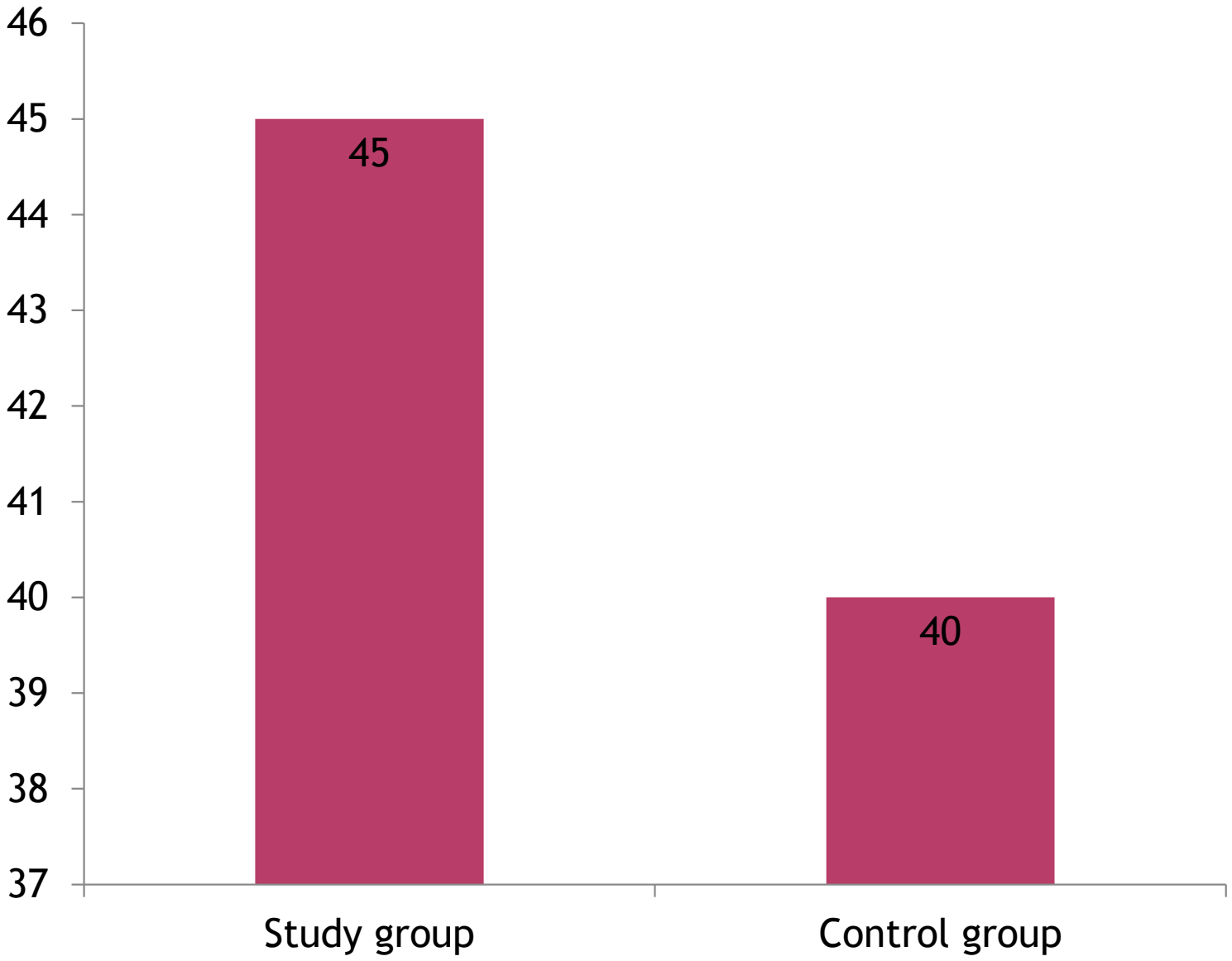
- For example, showing only a fraction of the y-axis scale, or unclear axis labeling, may magnify small differences between data points.

Success rate




Success rate
50
45
40
35
30
25
20
15
10
5
0
45
40
Study group
Control group

Success rate



7. Reporting percentages rather than actual numbers.

- Although this may be appropriate in some cases, if the intent is to deceive, it represents inaccurate and perhaps unethical reporting.
- Percent fallacy

8. Reporting results of inappropriately applied statistical tests.

- For example, several statistical tests may be applied to the same data set, and the researcher may elect to report only the test that yielded the most favorable results, rather than determining a priori the most appropriate statistical tests to use.

9. Reporting differences, when statistical significance is not reached.

- For example, although the p-value is not significant, some researchers report a "trend" toward significance.
- This is inaccurate, as, per convention, unless otherwise stated, a p value < 0.05 is accepted as not significant; that is, a difference was not found.
- Some authors suggest that reporting confidence intervals is a superior method of reporting, because of improved informational content, in a more explicit and precise format.

10. Reporting no difference, when power is inadequate.

- If the study sample size is too small, a type II error may be committed.
- Although power of 0.8 is acceptable by convention, this allows a 20% chance of incorrectly accepting the null hypothesis.
- In some cases, researchers should consider being more fastidious, and strive for a power of 0.9 or higher.
- In any case, alpha and beta should be considered prior to beginning the study and a determination should be made of what type I or type II errors are acceptable.

11. DATA "DREDGING."

- Although for some studies, multiple looks at the data may be appropriate, merely performing multiple tests to search for significant associations can be misleading and statistically inaccurate.
- If multiple comparisons are used, correction should be performed, using a test such as the Bonferroni or Scheffe methods.

12. SPLITTING DATA INTO MULTIPLE PUBLICATIONS.

- Related data from a single study are usually most powerful when presented in a single publication, although this may not always be feasible, especially in abstracts.
- Splitting data into multiple publications, merely for the purpose of increased number of publications, is unethical and should be avoided.

13. INAPPROPRIATE USE OF TERMINOLOGY WITHOUT PRECISE DEFINITIONS.

- For example, words such as “rarely” and “commonly” may have differing implied meanings to researchers and readers.
- If only 48% of patients had a given outcome, it is probably misleading to report this occurred “rarely.”

14. REPORTING CONCLUSIONS THAT ARE NOT SUPPORTED BY DATA.

- Opinion or conjecture should not be presented as research findings.

15. IGNORING CITATIONS OR PRIOR WORK THAT CHALLENGE STATED CONCLUSIONS OR CALL CURRENT FINDINGS INTO QUESTION.

- Rather than considering disparate citations as a threat, they may be used as important components of discussion.

16. INFLATION OF RESEARCH RESULTS FOR THE MEDIA.

- Although media coverage of significant research is important, the quest for a pithy sound bite ought not supersede the duty to accurately portray findings in the most intellectually honest way.

INTERIM DATA ANALYSIS

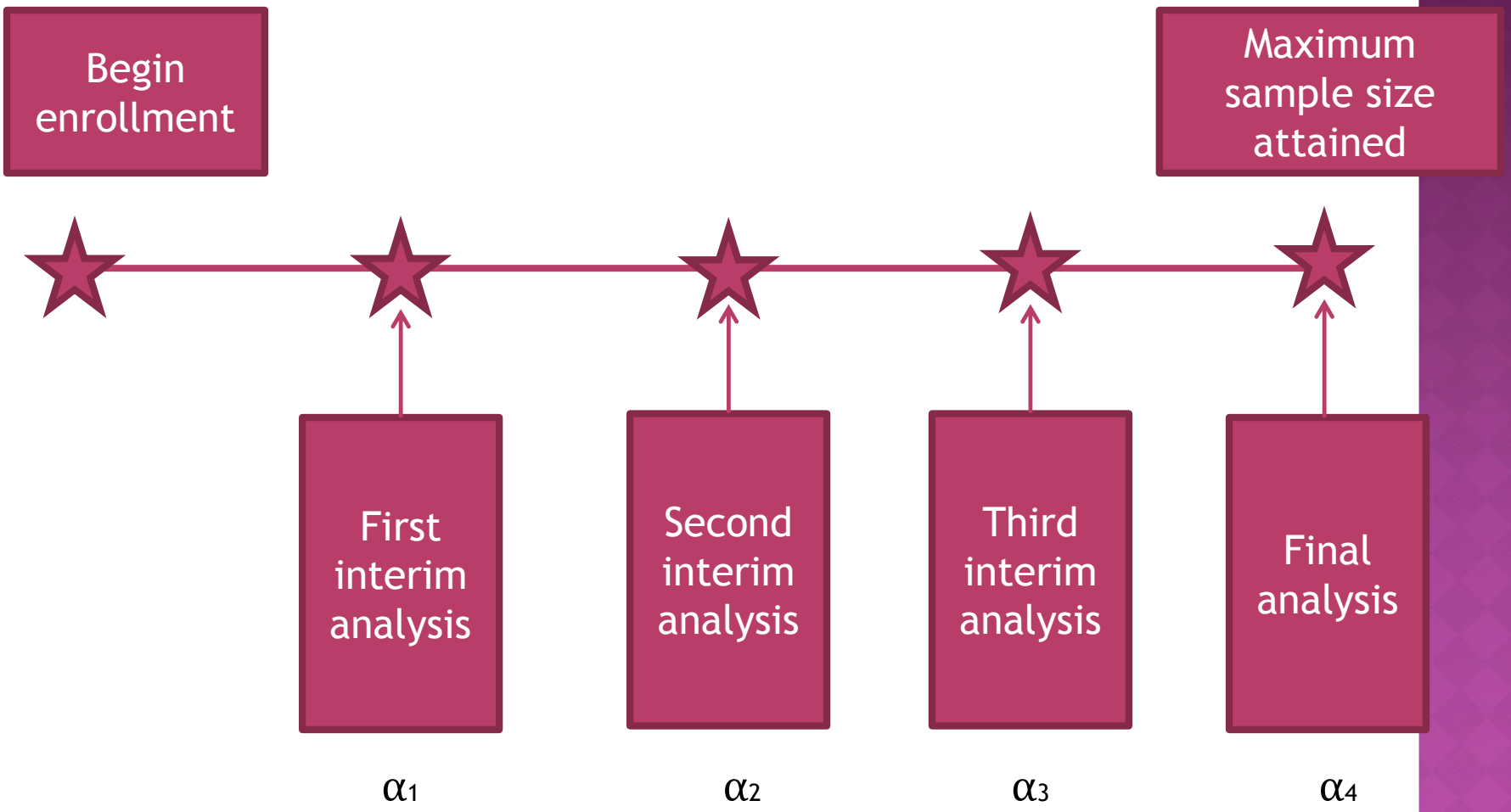
INTERIM DATA ANALYSES: ETHICS

- During a clinical trial, data accumulate sequentially.
- If you were the last person enrolled to this clinical trial, wouldn't you want to know the previous results
- Interim analyses are used to see if a difference clearly exists between the two groups, so the trial can be stopped early, and future patients can receive the best treatment.
- In other words, to stop the trial as soon as a reliable conclusion can be drawn from the available data.

CONTROLLING TYPE I ERROR

- Interim data analyses are generally conducted at a few predetermined points throughout the trial to determine if the trial should be stopped because of demonstrated benefit or harm.
- The nominal alpha (α) (maximum significant *p* value) at each analysis are reduced so that the overall risk of a false positive result, if no treatment effect, is 0.05.

GROUP SEQUENTIAL TRIAL WITH THREE INTERIM ANALYSIS AND A FINAL ANALYSIS



EXAMPLE 1

- Prospective interventional clinical trial.
- Planned sample size of 240 patients.
- Abstract deadline approaching and current enrollment is 180 patients.
- Issues:
  - Power;
  - Stopping the trial early;
  - Interim analysis/actual intent; and
  - Reporting

EXAMPLE 2

- Prospective, randomized clinical trial with a generally negative result.
- Some enrolled patients are found to never have taken their prescribed study medication.
- After completion, some patients are also found to have met prospectively-defined exclusion criteria.
- Issues:
  - Purpose of clinical research;
  - Inclusion/exclusion and Intention To Treat principle; and
  - Reporting

EXAMPLE 3

- Prospective clinical trial with generally negative result.
- "Exploratory" analyses show statistically significant difference in a clinically-important subgroup.
- Issues:
  - Avoiding this scenario
  - Data torturing/data dredging
  - Reporting
  - Interpretation

THANK YOU!

POSSIBLE OUTCOMES OF HYPOTHESIS TESTING

	True Null	False Null
Reject	Type I error (α) False positive	Correct decision Power (1-β)
Failed to reject	Correct decision	Type II error (β) False negative