U.S. FOOD & DRUG ADMINISTRATION

Understanding Clinical Trial Data: Physician Interviews

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FDLI Advertising and Promotion Conference
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Collaborators

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Background

- Prescription drug promotion is correlated with increased prescribing frequency.[1]
- Physicians are influenced by the way clinical trial results are reported.[2,3]
- Physicians believe they have less knowledge than is needed to understand all clinical trial results.[4,5]

1. Spurling, et al. (2010); 2. Marcatto, Rolison, & Donatella (2013); 3. Bobbio, Demichelis, Giustetto (1994); 4. West & Ficalora (2007); 5. Windish, Huot, & Green (2007)

Objective

- To examine physicians' understanding of clinical trial data as presented in prescription drug promotional materials.

Participants

- 50 primary care physicians
- 22 endocrinologists
- > 50 prescriptions/week
- Geographic diversity within USA
- American Medical Association's demographics

Participants

- 64% large urban, 26% small urban, 10% suburban/rural

- 62% Male
- 60% 45 years of age or older
- 68% White, 21% Asian, 5.5% Black, 5.5% Latino

Method

- 60-minute interviews
- Telephone and computer

Method

- Promotional materials with clinical trial data:
  - Weight loss product
  - Diabetes product

- Promotional materials included:
  - Graphs
  - Descriptions of study design
  - Descriptions of analyses conducted
  - Trial results

- General questions (e.g., training)
- Specific questions (e.g., specific terms)

Method

How would you explain a non-inferiority randomized controlled trial to a medical student?

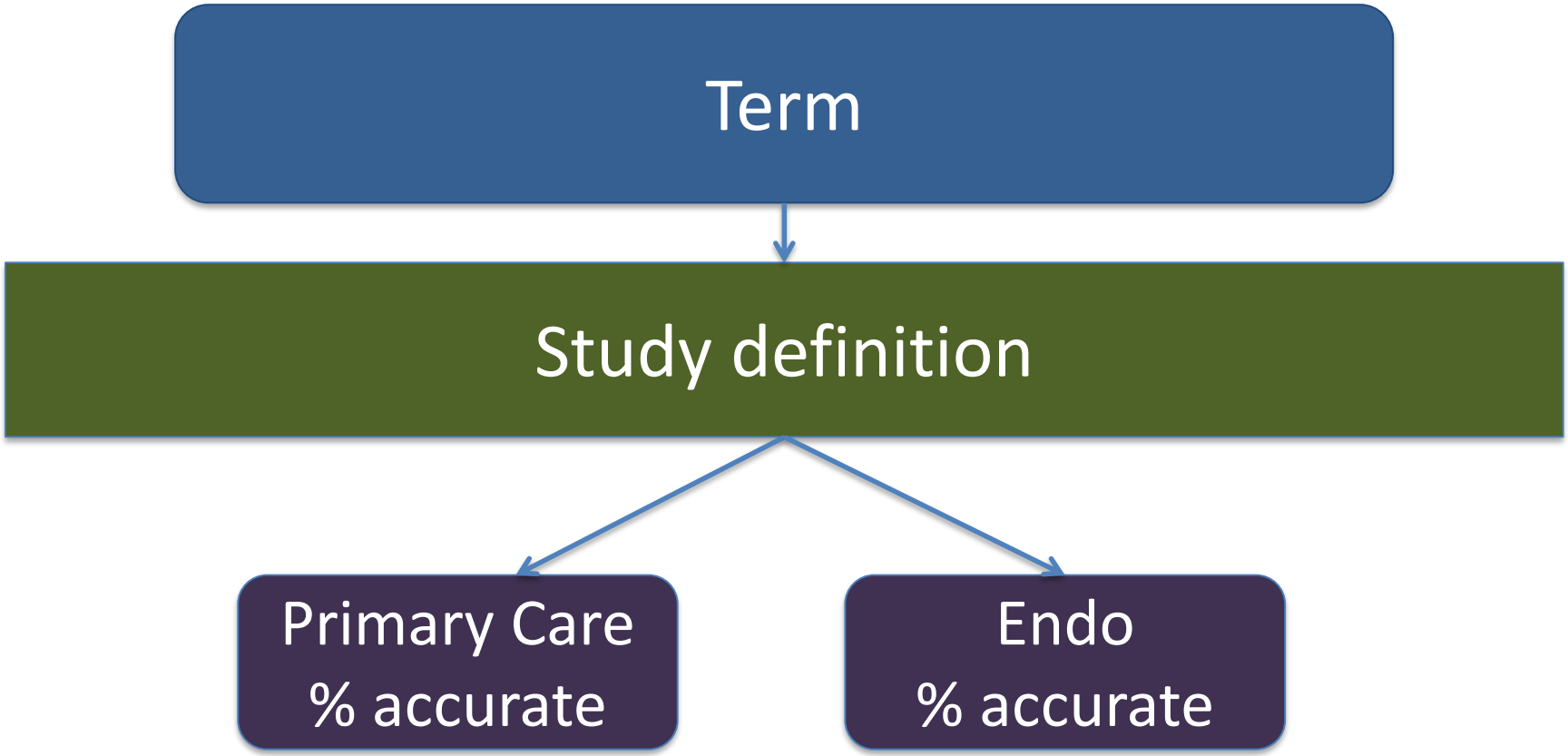
How would you explain intent-to-treat to a medical student?

Method

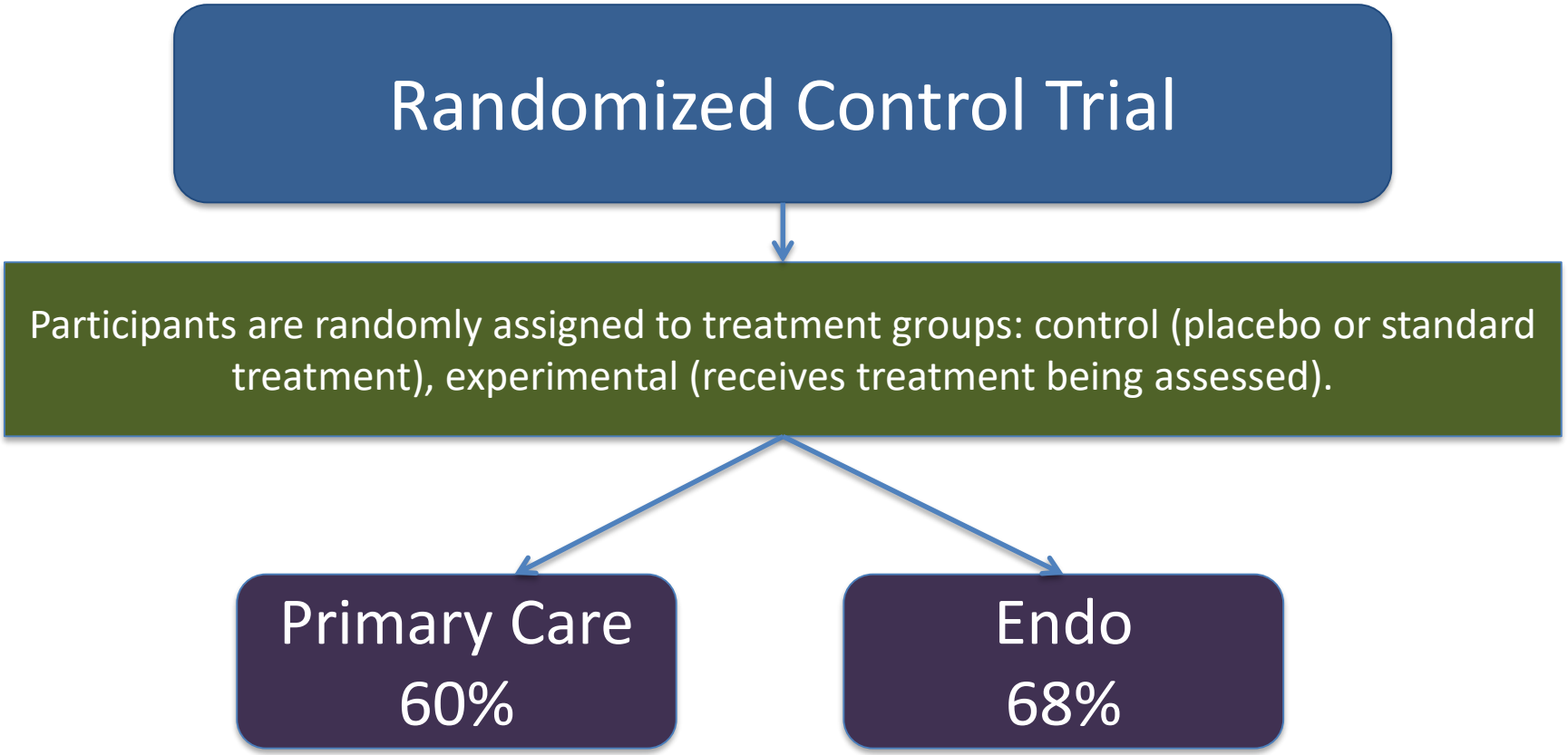
- Two researchers categorized responses to questions about specific terms as:
  - accurate
  - inaccurate
  - no response

- Good inter-rater reliability (*K* = .70).

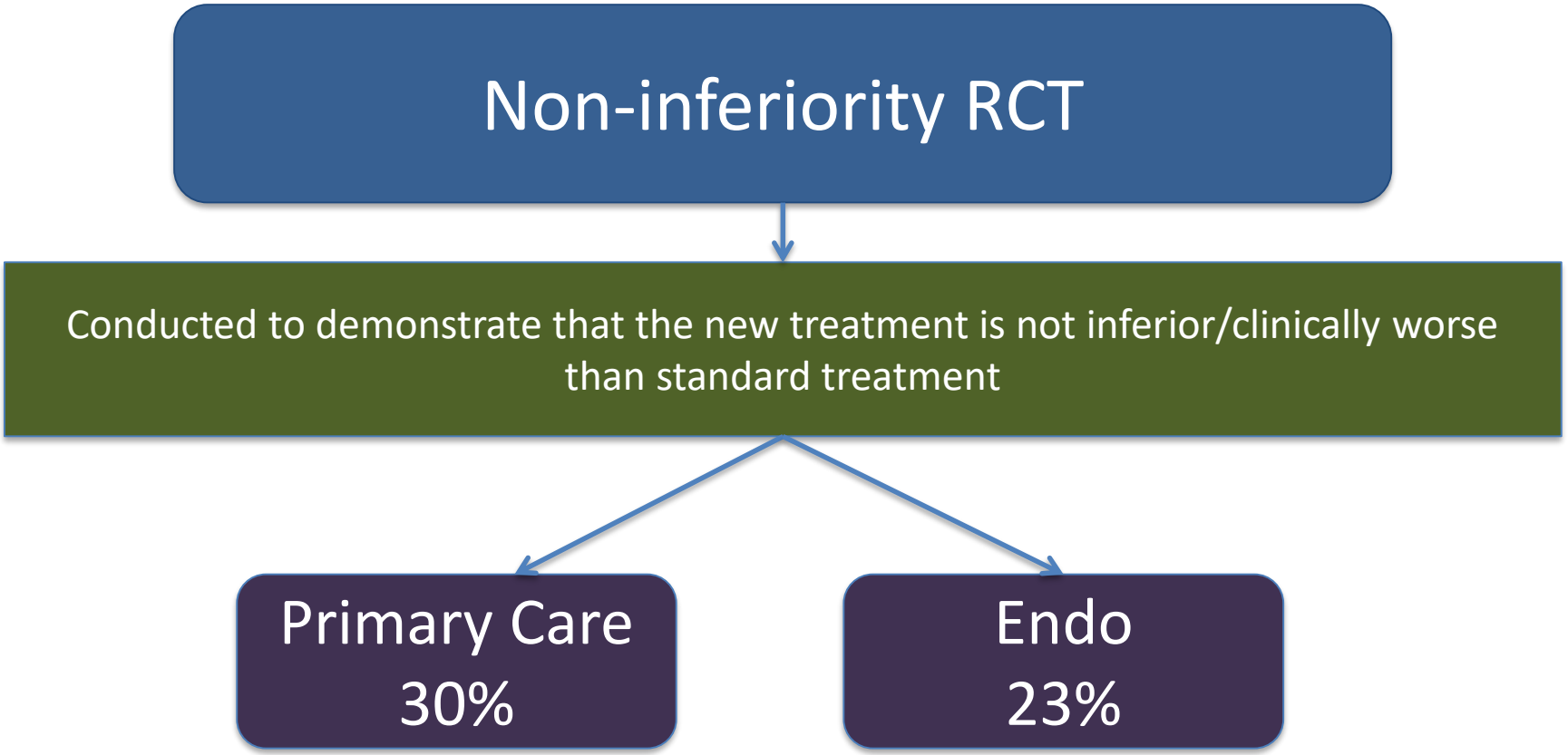
Results


Term
Study definition
Primary Care
% accurate
Endo
% accurate

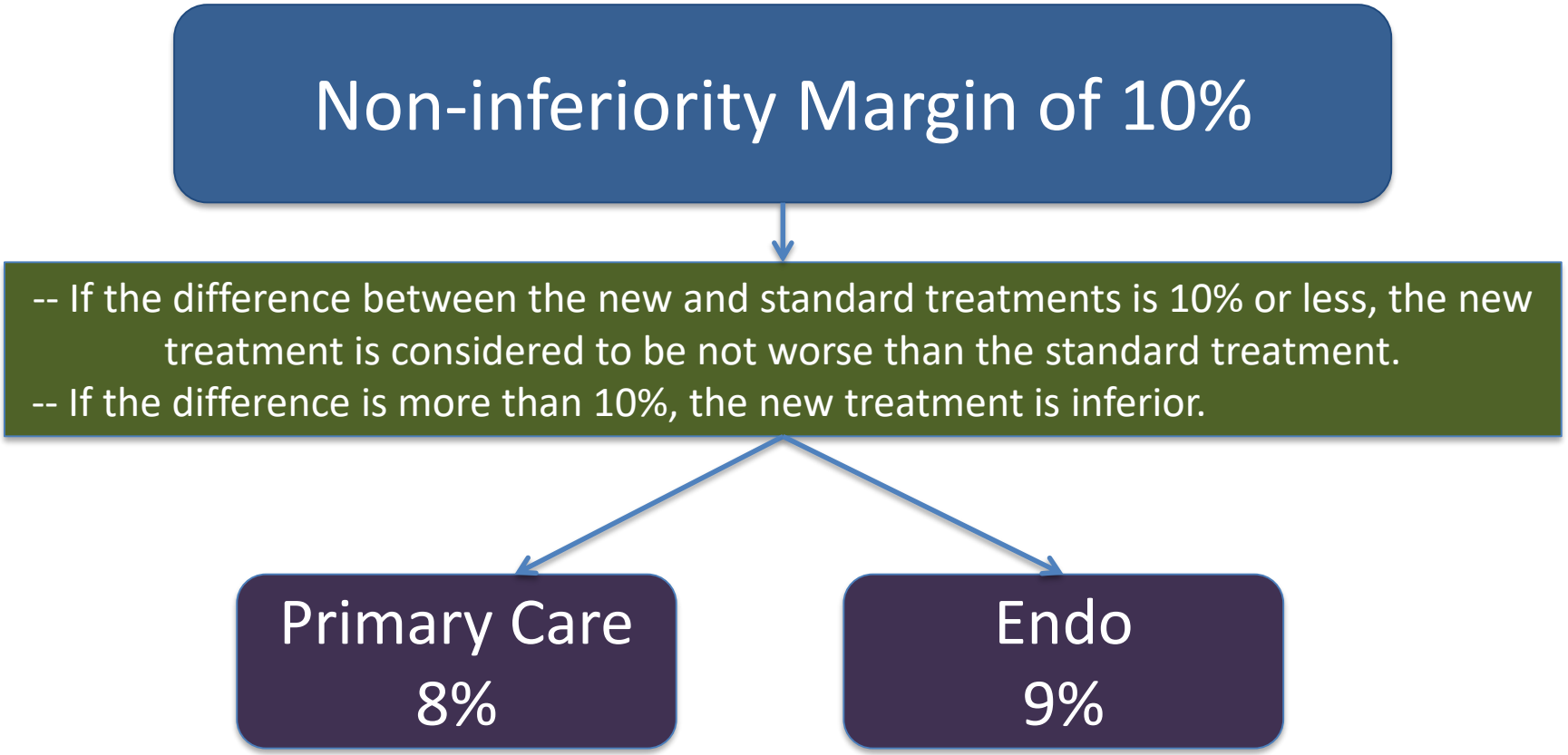
Results


Randomized Control Trial
Participants are randomly assigned to treatment groups: control (placebo or standard treatment), experimental (receives treatment being assessed).
Primary Care
60%
Endo
68%

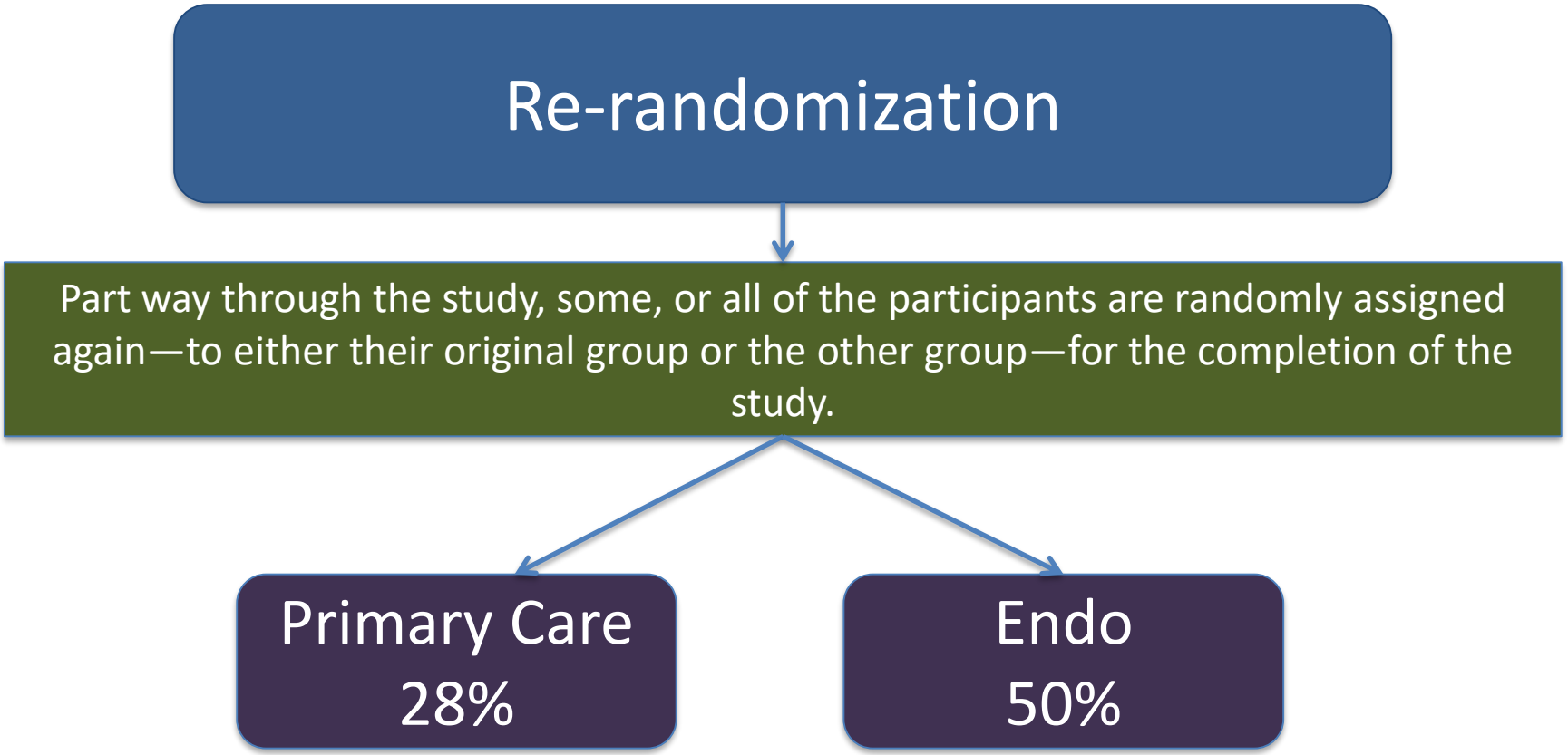
Results


Non-inferiority RCT
Conducted to demonstrate that the new treatment is not inferior/clinically worse than standard treatment
Primary Care
30%
Endo
23%

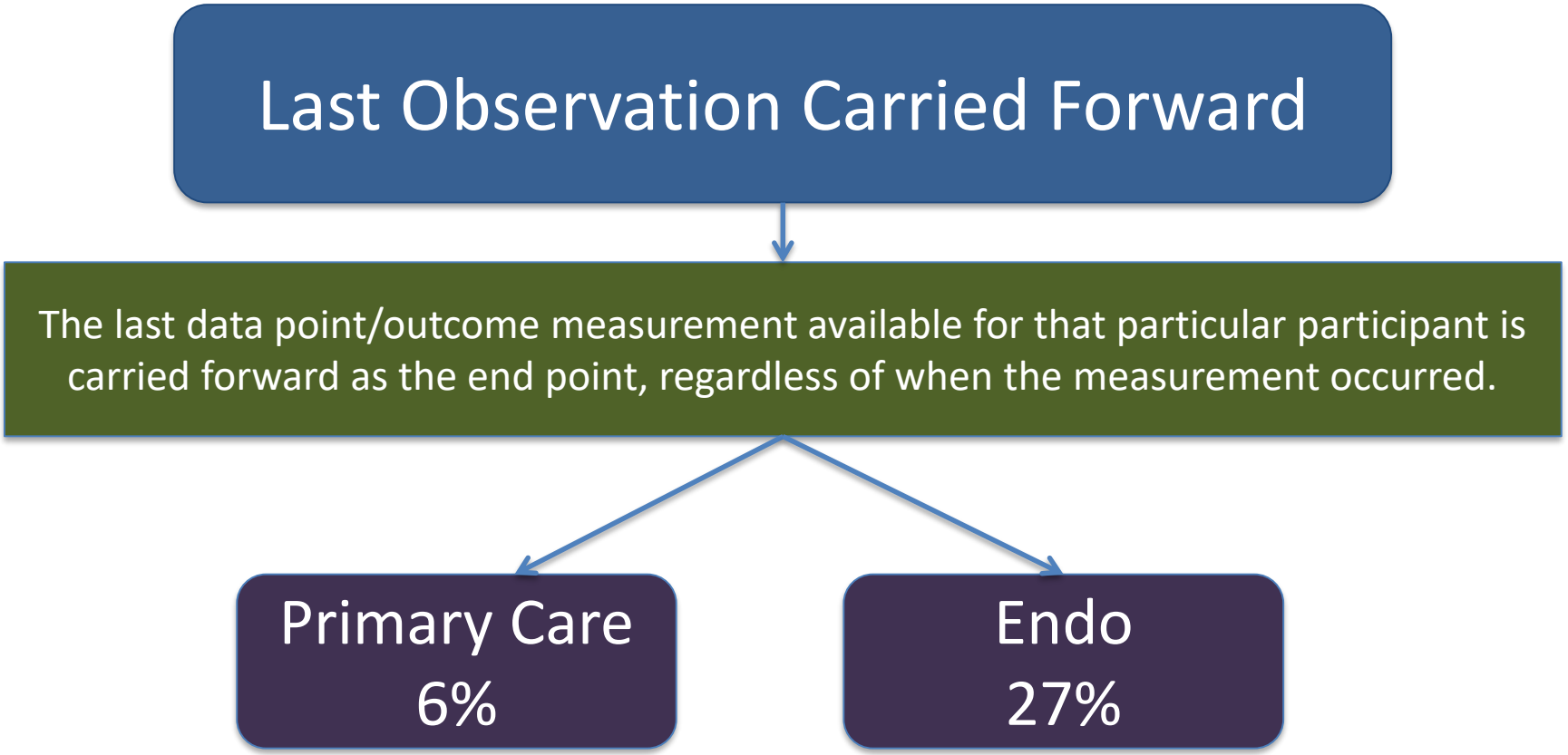
Results


Non-inferiority Margin of 10%
-- If the difference between the new and standard treatments is 10% or less, the new treatment is considered to be not worse than the standard treatment.
-- If the difference is more than 10%, the new treatment is inferior.
Primary Care
8%
Endo
9%

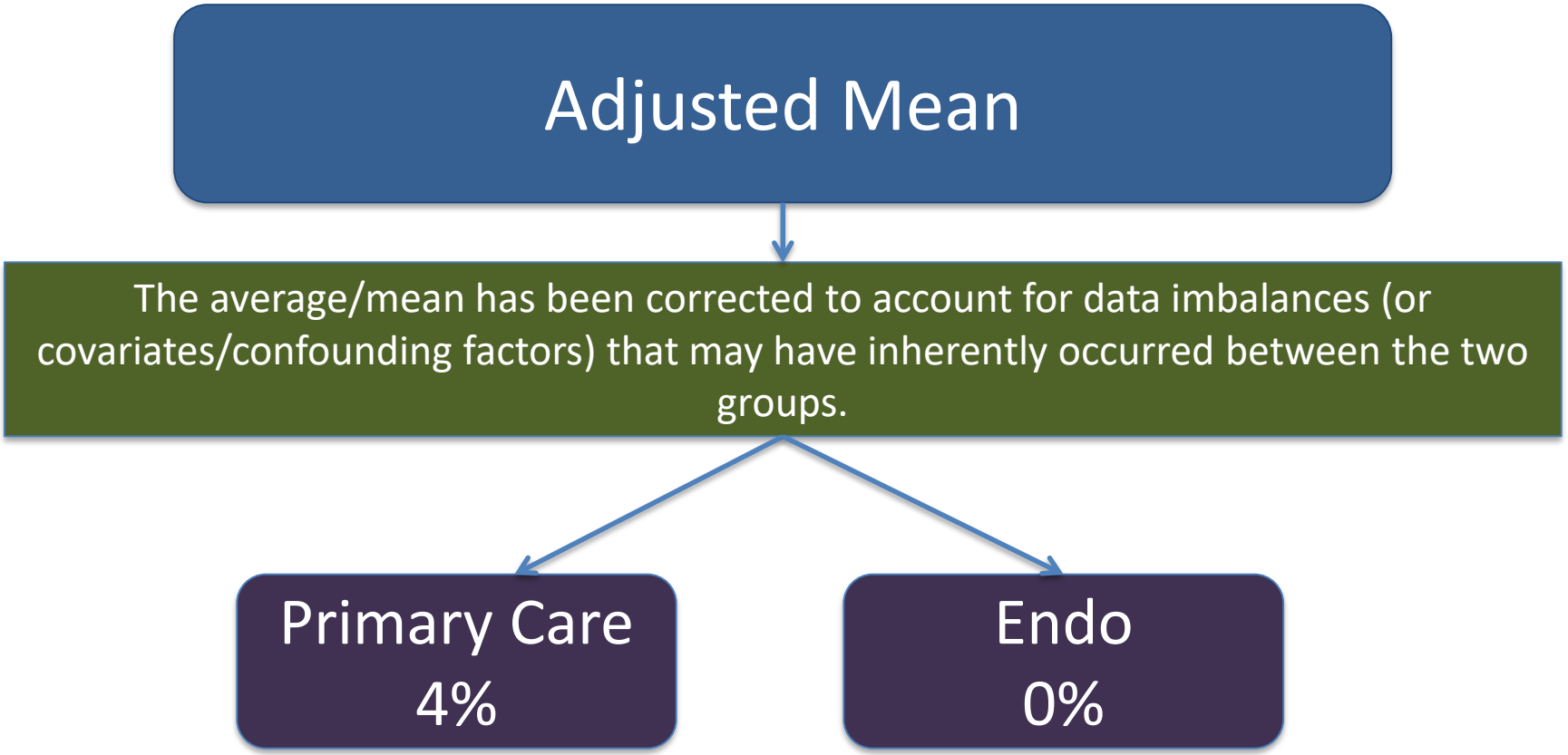
Results


Re-randomization
Part way through the study, some, or all of the participants are randomly assigned again—to either their original group or the other group—for the completion of the study.
Primary Care
28%
Endo
50%

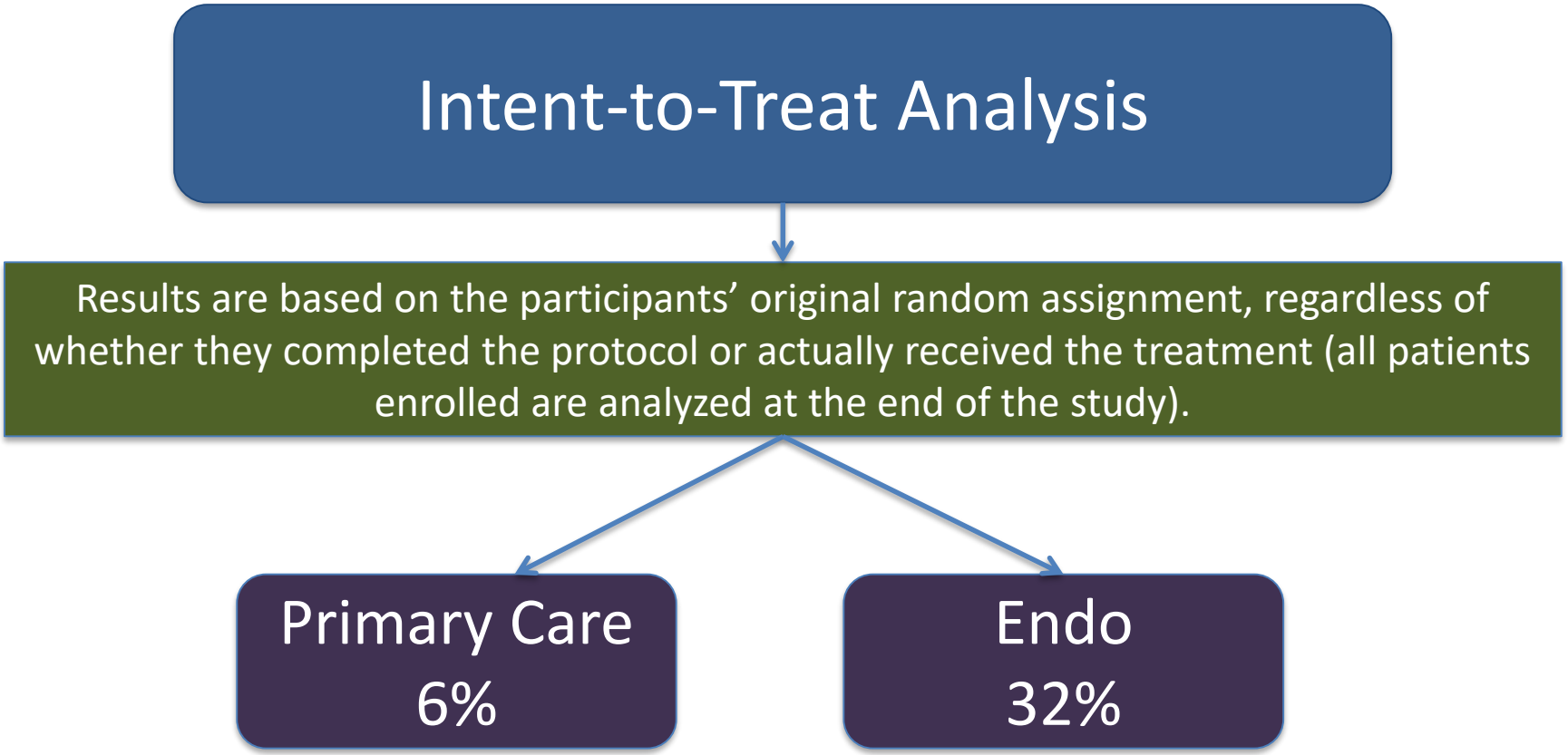
Results


Last Observation Carried Forward
The last data point/outcome measurement available for that particular participant is carried forward as the end point, regardless of when the measurement occurred.
Primary Care
6%
Endo
27%

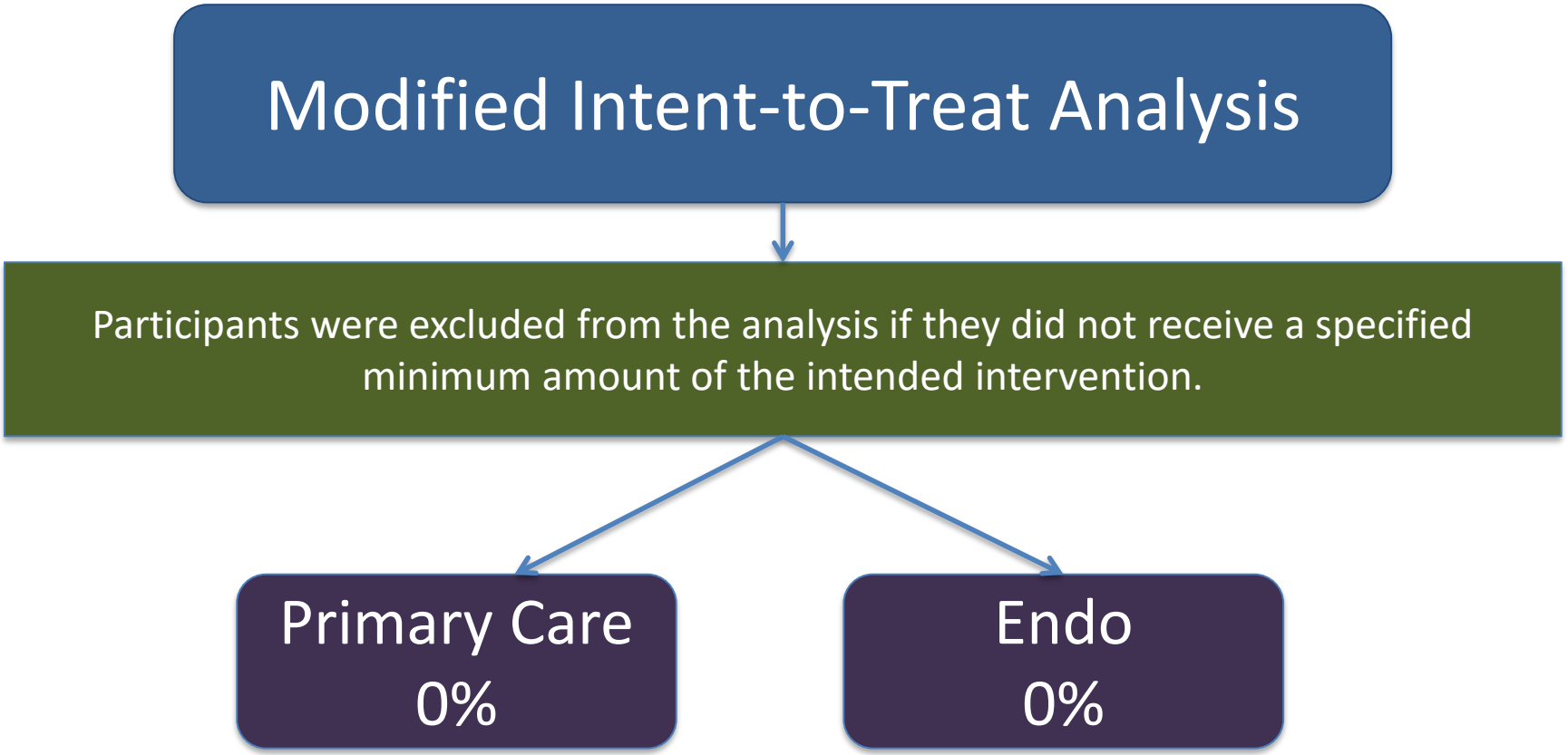
Results


Adjusted Mean
The average/mean has been corrected to account for data imbalances (or covariates/confounding factors) that may have inherently occurred between the two groups.
Primary Care
4%
Endo
0%

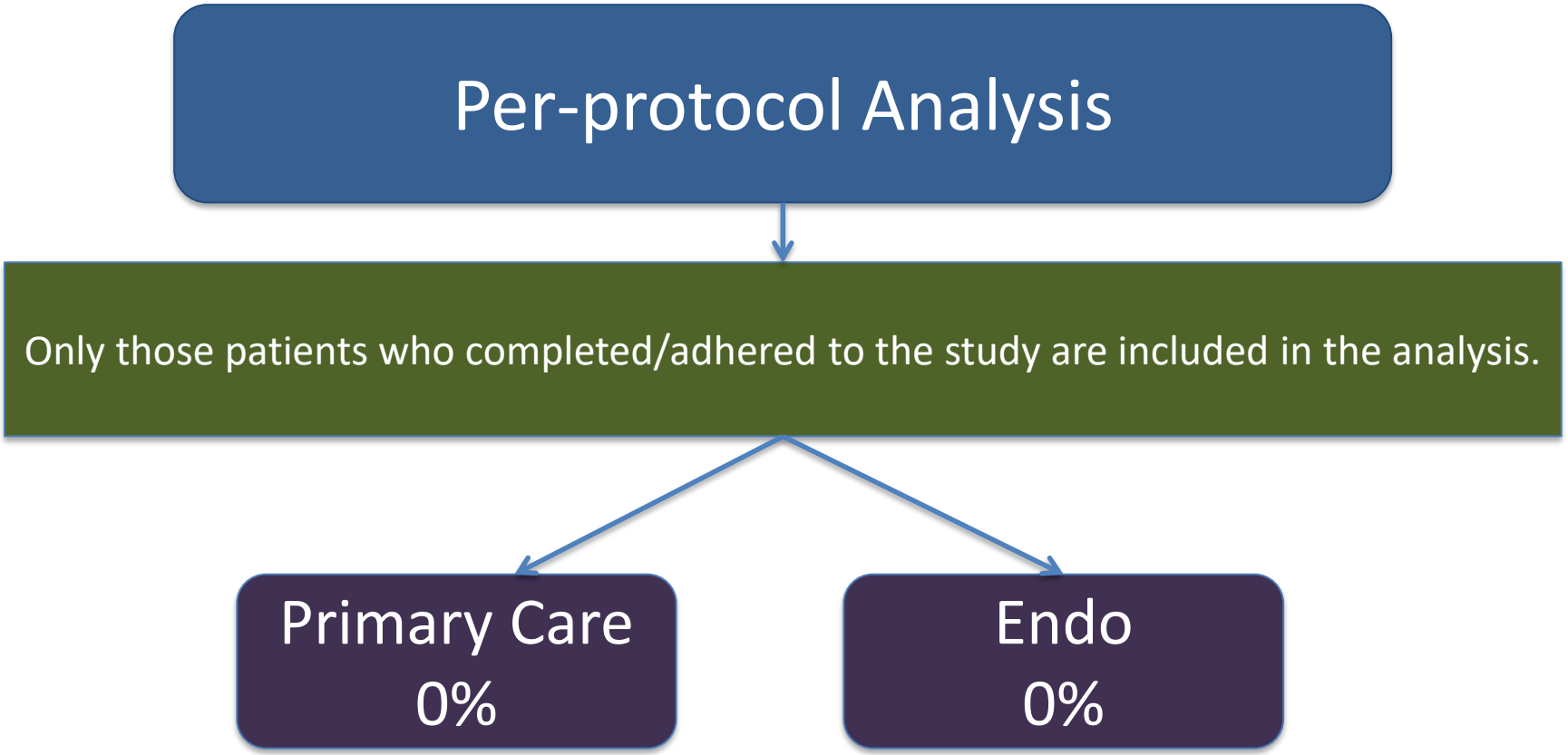
Results


Intent-to-Treat Analysis
Results are based on the participants' original random assignment, regardless of whether they completed the protocol or actually received the treatment (all patients enrolled are analyzed at the end of the study).
Primary Care
6%
Endo
32%

Results


Modified Intent-to-Treat Analysis
Participants were excluded from the analysis if they did not receive a specified minimum amount of the intended intervention.
Primary Care
0%
Endo
0%

Results


Per-protocol Analysis
Only those patients who completed/adhered to the study are included in the analysis.
Primary Care
0%
Endo
0%

Limitations

- Study versus real-world interaction with promotional materials
- Qualitative data are not generalizable
- We did not test the link between knowledge and quality of treatment decisions

Summary

- Physicians demonstrated low to moderate knowledge of specific terms used in promotion

- Need for research on the impact of clinical trial data in promotional materials on physicians' attitudes and decision-making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