

A SMART Web-Based Sample Size Calculator

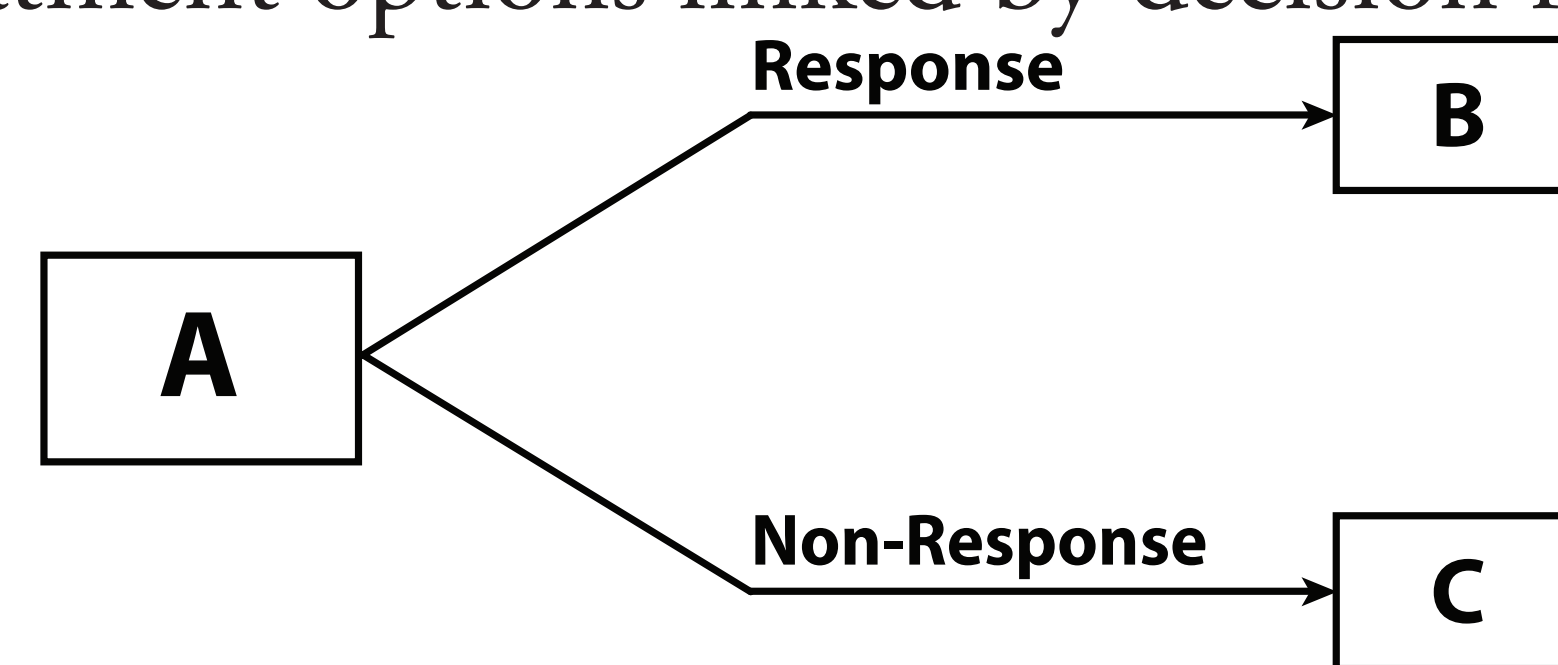
Nicholas J. Seewald* Daniel Almirall, Ph.D.[†] Kelley M. Kidwell, Ph.D.*

*Department of Biostatistics, University of Michigan, Ann Arbor, MI
[†]Survey Research Center, University of Michigan, Ann Arbor, MI



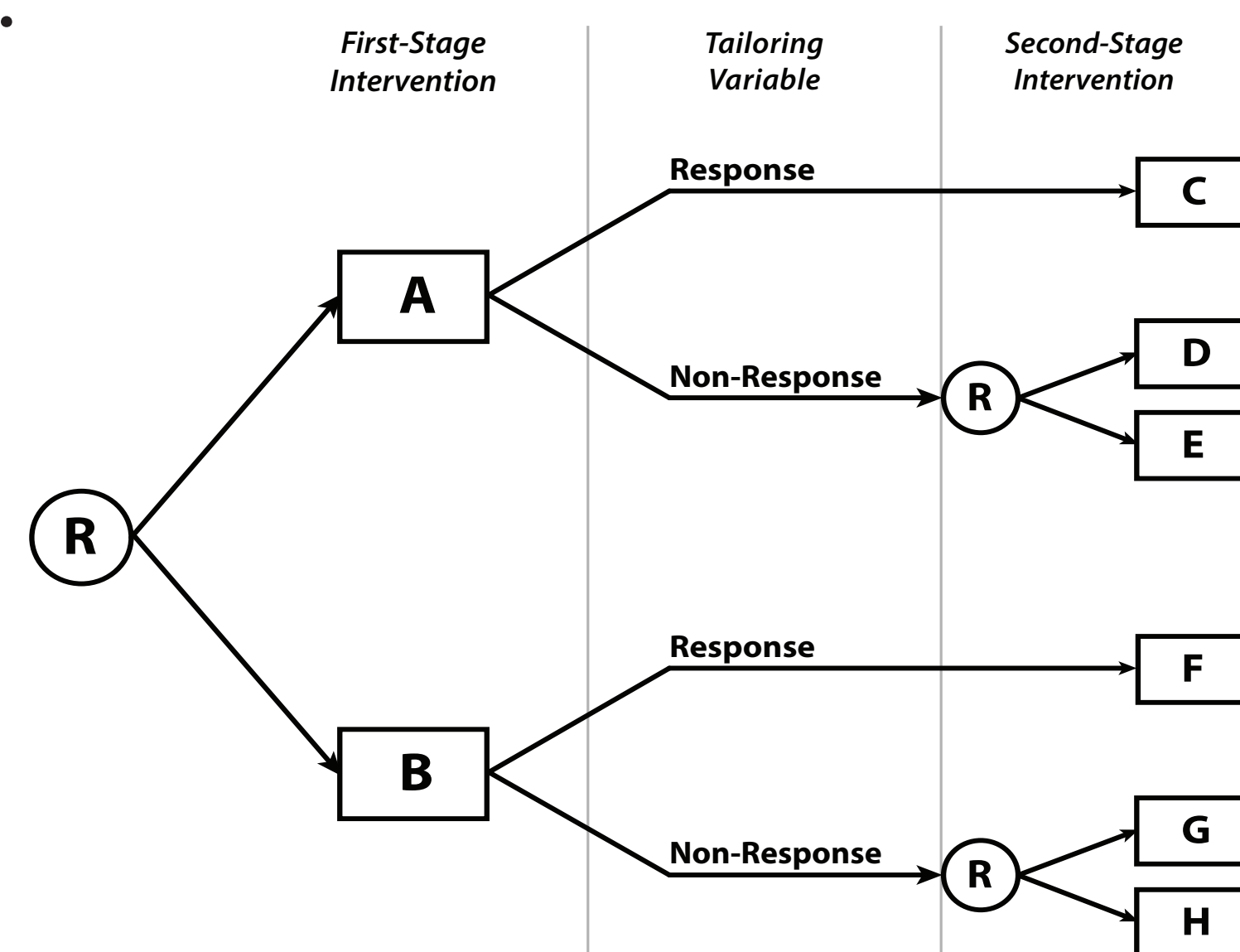
Dynamic Treatment Regimen

- A **dynamic treatment regimen** (DTR) leads to a sequence of treatments or interventions tailored to an individual.
- Treatment options linked by decision rules.



SMART

Sequential multiple assignment randomized trials (SMARTs) are used to develop effective DTRs.



Computing Sample Size

This is the first web-based sample size calculator for SMARTs in which the primary aim is to compare two embedded dynamic treatment regimens. For example, we can use it to size a trial powered for the comparison

*“Give A; if response, give C,
if no response, give D”*

versus

*“Give B; if response, give F,
if no response, give G”.*

Binary Outcomes

Is the outcome of interest binary or continuous?
☒ Binary
☐ Continuous

Which two adaptive interventions would you like to compare? Choose two from the menus below. The image below will change to highlight the AIs you select.

Compare AI: ArCnrD to AI: BrFnrG

Concerning the tailoring variable, please provide the probability of response to the first-stage intervention. If you are unsure, leave as 0 for a conservative estimate.

Probability of Success for First AI: 0.6

Concerning the primary outcome, please provide the probability of success for each of the AIs of interest.

Probability of Success for First AI: 0.45

Probability of Success for Second AI: 0.65

If you prefer to provide different information, check the appropriate box below.

☐ Cell-Specific Success Probabilities
☐ Target Difference in Success Probabilities
☐ Target Odds Ratio

Are you interested in finding sample size or power?
☒ Sample Size
☐ Power

Do you want to perform a one- or two-sided test?
☐ One-Sided
☒ Two-Sided

Type I Error (α): 0.05

Power of Trial (1- β): 0.8

Results

N=269

We wish to find the sample size for a trial with a binary outcome where the probability of response to first-stage interventions is 0.6 and the overall probabilities of success in the two AIs of interest, ArCnrD and BrFnrG, are 0.45 and 0.65, respectively. Given a two-sided test with 5% type-I error, we require a sample size of at least 269 to make this comparison with 80% power.

- 1 Choose type of **outcome**.
- 2 Choose which **dynamic treatment regimens** to compare.
- 3 Provide **probability of response** to first-stage treatment.
- 4 Provide **success probabilities** for each DTR (binary) or effect size (continuous). For binary outcomes, optionally choose an alternative input method (“cell-specific” success probability,

Continuous Outcomes

Is the outcome of interest binary or continuous?
☐ Binary
☒ Continuous

Which two adaptive interventions would you like to compare? Choose two from the menus below. The image below will change to highlight the AIs you select.

Compare AI: ArCnrD to AI: BrFnrG

Concerning the tailoring variable, please provide the probability of response to the first-stage intervention. If you are unsure, leave as 0 for a conservative estimate.

Probability of Success for First AI: 0.6

Concerning the primary outcome, please provide the standardized effect size between the AIs of interest.

Standardized Effect Size: 0.4

Are you interested in finding sample size or power?
☒ Sample Size
☐ Power

Do you want to perform a one- or two-sided test?
☐ One-Sided
☒ Two-Sided

Type I Error (α): 0.05

Power of Trial (1- β): 0.8

Results

N=275

We wish to find the sample size for a trial with a continuous outcome where the probability of response to first-stage interventions is 0.6 and the standardized effect size between the two AIs of interest, ArCnrD and BrFnrG, is 0.4. Given a two-sided test with 5% type-I error, we require a sample size of at least 275 to make this comparison with 80% power.

- 5 Specify desired **result** (sample size or power) choice of **one- or two-sided test**, **type-I error**, and desired **power** (or sample size).
- 6 Clear explanation of results.

Try it out:



bit.ly/SMARTcalc