Population Representativeness of SPRINT

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What is Population Representativeness?

• The population representativeness metric is an estimate of the fraction of the real-world patients that is represented in the study population.

• Can be calculated based on:
  1. Restrictiveness of eligibility criteria
  2. Characteristics of enrolled participants
Our Claim

Participant-based Representativeness is less than Eligibility-based Representativeness

• Why?

Because not all eligible patients are enrolled!
Calculating Representativeness

• Eligibility-based: GIST 2.0 (Sen et al. JBI 2016)
• Participant-based: STASI (extension of GIST)

• What’s novel about these?
  – Explicit modeling of the relationship between study traits.
  – Non-uniform importance for the study traits
Representativeness of SPRINT

- Eligibility based – 0.18
- Participant based (using only the eligibility traits) – 0.10
- Participant based (using all available traits) – 0.0062
What more information can we get?

- Which traits caused participant based representativeness to drop?
  - SBP, Age

- What are the differences across different demographic groups?
  - Males 0.0074 vs. Females 0.0052 (due to HDL)
  - Black 0.0071 vs. Hispanic 0.0050 vs. White 0.0039 (due to DBP, triglycerides)
So what next?

• More extensive subgroup analysis
  – Identifying over-represented and under-represented subgroups

• Further development and validation of STASI