

Case study: A phase 3 study of a candidate HIV vaccine

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Disclaimer

- The views expressed are my own and do not represent the views of the NIH, DHHS, or any other US government agency

The vaccine

- You are part of a research network trying to develop an affordable HIV vaccine
- One candidate vaccine has been through phase 1 and 2 testing for safety and immunogenicity
- Phase 3 study necessary to show effectiveness in preventing HIV infection

A proposed study

- **Design:** Randomized placebo-controlled trial
- **Study population:** 1000 female sex workers from cities in sub-Saharan Africa
- **Exclusion:** HIV-positive
- **Standard of care:** HIV-testing, counseling about risk behaviors
- **Primary endpoint:** HIV status after 3 years

Questions

1. Is this an appropriate study population?
2. Is the preventive standard of care sufficient?
3. What should the researchers offer to
 - Potential participants who are screened out because HIV-positive?
 - Participants who sero-convert during the study?