

Participation and Representation of Women in Clinical Trials

Recent FDA Action: Awareness and Recommendations Over Inclusion Requirements

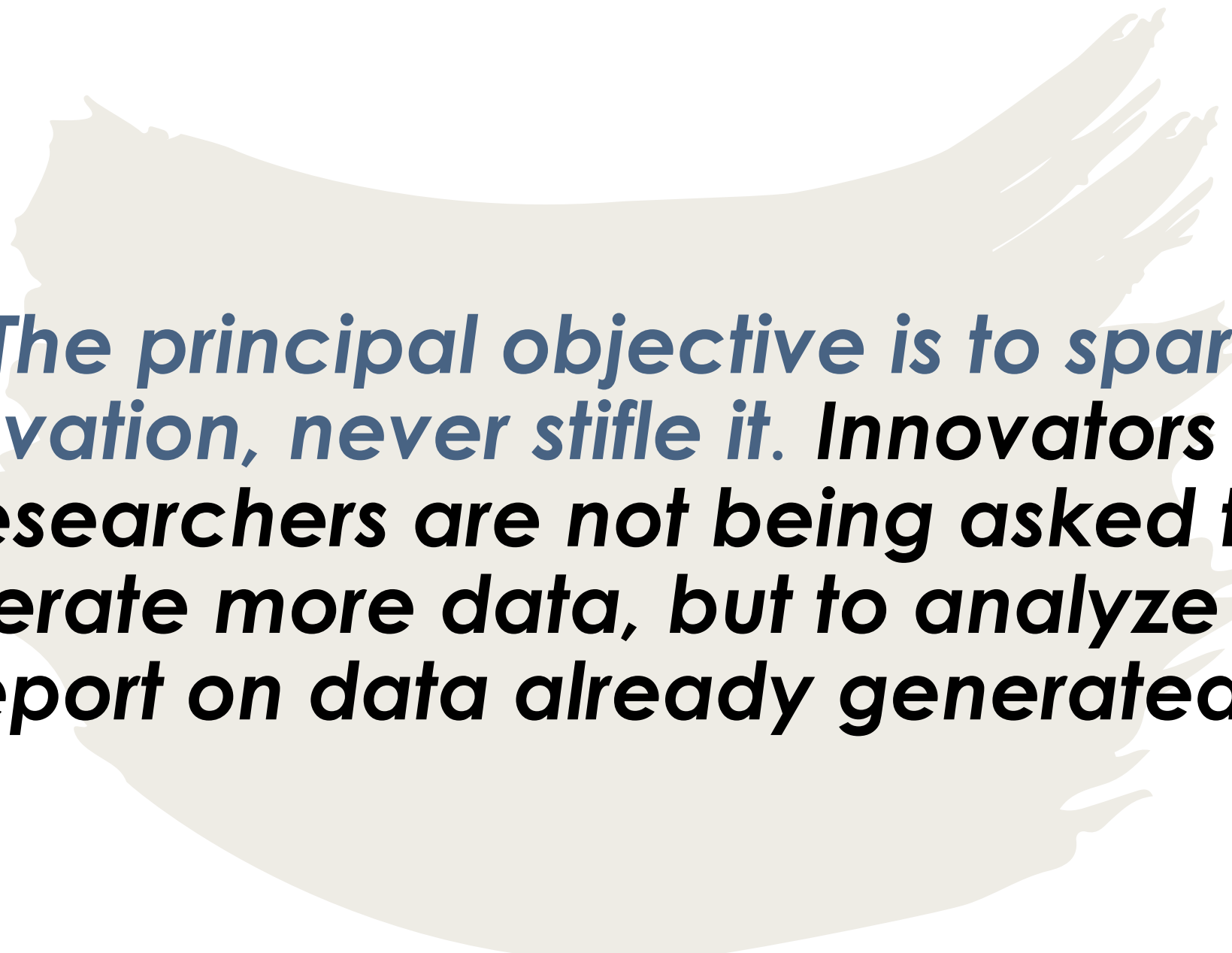


- 2016 Diverse Women in Clinical Trials Initiative includes a consumer awareness campaign and provides resources for clinicians and researchers
- 2020 FDA guidance provided recommendations to improve the diversity of clinical trial participants

CDRH Health of Women Program: Lack of Focus on Clinical Trial Inclusion

The program's 2022 strategic plan identified "Inclusion of women in clinical trials" as a common goal and promised to "seek to identify areas where clinical trial enrollment can be better balanced for women", but increased inclusion not an intended outcome of the program





"The principal objective is to spark innovation, never stifle it. Innovators and researchers are not being asked to generate more data, but to analyze and report on data already generated."