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SEXUAL AND GENDER MINORITY (SGM) INCLUSION IN CLINICAL TRIALS

• AT A GLANCE •

BOTTOM LINE

1. Inclusion of patients from SGM communities in clinical trials advances knowledge to address cancer-related disparities.
2. Collecting sexual orientation and gender identity data (SOGI) allows researchers to identify potential disparities in health outcomes.

KEY CONSIDERATIONS, TIPS, AND BEST PRACTICES

ASCO is committed to addressing the health of sexual and gender minority (SGM) persons and including SGM patients with cancer in oncology clinical research. Clinical trial data has not routinely included sexual orientation and gender identity (SOGI) information of patients, nor are these data available in large patient registries. In order for cancer disparities in SGM populations to be identified, understood and addressed, it is critical that SOGI data be collected in ALL clinical trials. Clinical research teams should be aware that language that assumes a participant's gender identity is reflected in their sex assigned at birth or anatomy, or assumes they are heterosexual, may hinder clinical trial participation. Collecting SOGI data and increasing patient-centered clinical trial access for patients who identify as SGM will improve the relevance and application of cancer research to SGM populations.

Ensuring SGM inclusion in clinical trials and including SOGI data collection in trial design may build the foundation to understand and decrease SGM cancer outcome disparities.

Considerations for SGM-Inclusive Clinical Trial Protocols & Environments

Data collection elements, consent forms, and documentation:

- ❑ Systematically collect sexual orientation and gender identity (SOGI) data on all participants enrolled in clinical trials. See below for guidance on collecting these data elements.
- ❑ Systematically collect the names that participants use (do not assume they are the same as legal names), along with their pronouns (he/his, she/her, they/them, etc.). Document these data for all trial participants and subsequently use them correctly. To normalize data collection, clinical trial staff should provide their own pronouns and preferred name verbally and/or with identification badges.
- ❑ Refer to trial volunteers by the documented name that they use, as "[First Name] [Last Name]" rather than "Ms." or "Mr."
- ❑ Decouple gender, sex assigned at birth, and anatomy. For example, phrases like "men with prostate cancer" or "women may wish to undergo egg retrieval" can be replaced with non-gendered alternatives like "persons" or "people may wish to undergo egg retrieval or sperm preservation…"
- ❑ When describing future options for having children in trial documentation, include options such as surrogacy or sperm donors.
- ❑ Adding objectives should be considered that elucidate disparities when relevant AND the sample size would support it.

Inclusion and exclusion criteria:

- ❑ Clinical trial eligibility criteria should be examined to ensure they do not exclude SGM people. Be clear about the mechanisms being studied and, as needed, revise eligibility criteria to focus on specific characteristics of trial volunteers (e.g., sex chromosomes, anatomy, hormone balance) rather than using gender to determine eligibility.
- ❑ People on gender-affirming hormone therapy (e.g., estrogen, testosterone, etc.) should be included in trials except in cases of clear contraindication. There are no data that associate gender-affirming hormone therapy with hormonally-driven cancers.
- ❑ If hormone use is not an exclusion criterion for the trial, explicitly advise whether estrogen, testosterone, or other hormone therapy is permitted while on trial.

Considerations for Collection of Sexual Orientation and Gender Identity Data

SOGI data collection items:

- ❑ Answers to SOGI questions should always be voluntary, never mandatory.
- ❑ Most patients prefer to be asked about SOGI via a written form or questionnaire, rather than verbally.
- ❑ All Electronic Medical Record systems (EMR; e.g., Epic, Cerna) have the capacity to collect SOGI data. Where possible, link clinical trial documentation of SOGI to documentation of these data in your EMR by using the same or similar items.
- ❑ If linking SOGI data collection to existing items in the EMR is not possible or preferred, sexual orientation can be assessed with a validated item, widely used in many national surveys. See the Resource section.
- ❑ Transgender/gender diverse versus cisgender (or non-transgender) identities should also be assessed. See the Resource section for several different options for collecting these data.
- ❑ Many institutions recommend a two-step method for assessing gender: asking first about gender identity and then about sex assigned at birth. TGD people may find questions asking about sex assigned at birth stigmatizing and may not answer them. See the Resource section for data collection options that do not ask about sex assigned at birth.
- ❑ Some trials may wish to collect data on reproductive organs a volunteer currently has or has had in the past. If relevant to the scientific question being asked, consider using an organ inventory. See Resource section.
- ❑ Before collecting SOGI data as part of your trial, consider training all trial staff and investigators to increase cultural humility and reduce implicit bias when working with SGM persons.

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OTHER RESOURCES

- ASCO Education, Cultural Literacy Course Collection
- The Fenway Institute, Tools To Help Healthcare Organizations Collect Sexual Orientation And Gender Identity Data To Improve Quality Of Care And Reduce LGBT Health Disparities
- NIH 2021–2025 Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities
- Methods and Measurement in Sexual & Gender Minority Health Research, Examples of Sexual Orientation and Gender Identity (SOGI) Questions
- The World Professional Association for Transgender Health, Standards of Care

- Optimizing gender-affirming medical care through anatomical inventories, clinical decision support, and population health management in electronic health record systems (Grosso et. al. 2021)
- NIH All of Us Research Program

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