



2023

US

INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER



Sexual Orientation, Gender Identity, and Intersex Status Data Collection Panel Discussion: A patient journey navigating SGM healthcare inequities

Facilitated by: Donna Sattler, BMS, **Panelist:** [Korey Henricks](#), BMS, [Garo Kiledjian](#), SGM Alliance, [Helena Sviglin](#), FDA, CDER, [NFN Scout](#),

Meet the Panel



Donna Sattler (she/her)

Title: Director, Clinical Data Standards
Organization: Bristol Myers Squibb



Korey Henricks, MA, LPCC

Title: Senior Manager, eCOA Mgmt.
Organization: Bristol Myers Squibb



Garo Kiledjian (he/him)

Title: Founder and CEO
Organization: SGM Alliance



Helena Sviglin

Office of Strategic Programs
Organization: FDA CDER



NFN Scout (they/he)

Title: Executive Director
Organization: National LGBT Cancer Network



Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *Additionally, the presenters are not presenting how their organization will analyze this data collection. It is too soon to demonstrate.*



FDA Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.



Agenda

1. SOGI Clinical Data Collection (recap)
2. Patient Journey
3. Implementation Perspectives
4. Call to Action
5. Questions

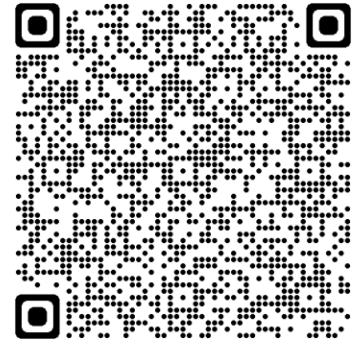
Representation and Diversity are BMS Values

- BMS is committed to doing its part to help ensure patients have a fair and just opportunity to achieve optimal health outcomes.
- BMS is working to improve the recruitment of a diverse participant population with the goal that the clinical trial becomes more reflective of the real-world population and the people impacted by the diseases studied.



...sexual and gender minorities...health disparity population

“In 2016, the NIH formally designated sexual and gender minorities as a health disparity population alongside racial/ethnic minorities, socioeconomically disadvantaged populations, and underserved rural populations.”



Regardless of historic biases, key institutions have made a health equity pivot

The National Academies of SCIENCES ENGINEERING MEDICINE



The NEW ENGLAND JOURNAL of MEDICINE



Understanding the Well-Being of LGBTQI+ Populations (2020)

“Entities throughout the federal statistical system; other federal agencies; state, local, and tribal departments and agencies; private entities; and other relevant stakeholders should consider adding measures of sexual orientation, gender identity, and intersex status to all data collection efforts and instruments, such as population-based surveys, administrative records, clinical records, and forms used to collect demographic data.”

Ensuring That LGBTQI+ People Count (2021):

“...the widespread lack of comprehensive data collection means that many more disparities... remain unknown.”

“According to the National Academies report, there are several types of data-collection activities that should routinely include measures of sexual orientation, gender identity, and intersex status. These are population surveys, ... clinical trials and other research....”

Diversity Draft Guidelines (2022)

“FDA advises sponsors to seek diversity in clinical trial enrollment beyond populations defined by race and ethnicity, including other underrepresented populations defined by demographics such as sex, gender identity, age, socioeconomic status, disability, pregnancy status, lactation status, and comorbidity.

FDA encourages sponsors to also submit plans... and analyses of data collected from clinically relevant subpopulations.

Federal Evidence Agenda on LGBTQ Equity (2022)

...Increasing this evidence requires federal agencies to promote and engage in inclusive and responsible data collection practices that safeguard privacy, security, and civil rights.

Health Equity Action Brief(2023)

Call to Action

- Educate HCPs on the importance of collecting and updating SOGI data
- Build trust ... in data collection and non discriminatory practices
- Develop comprehensive standards for SOGI data collection beyond gender while ensuring flexibility and inclusive language



SOGIIS means...

Sexual Orientation

- The gender or genders one is **attracted to, physically or romantically**

Gender Identify

- **One's psychological sense of their gender**, based on what they understand to be their options for gender, and how much they align (or don't align) with one of those options
- One's gender identity is independent of their sexual orientation; for example, a transgender male (who was assigned female at birth) can be attracted to women, men, both or neither

Intersex Status

- Intersex conditions, also referred to as **differences of sex development (DSD)**, are genitals, reproductive organs, or chromosomal patterns that do not fit standard definitions of male or female; can be present at birth or develop naturally in puberty
- Intersex conditions are **independent of one's sexual orientation or gender identity**

SOGIIS Data Collection

Questions asked privately in eCOA device setting only

Sex at Birth

What sex were you assigned at birth, on your original birth certificate? (check one):

- Female
- Male
- Don't Know
- Prefer not to answer
- Not reported

Sexual Orientation

Which of the following best represents how you think of yourself? (check one):

- Lesbian or gay
- Straight, that is, not gay or lesbian
- Bisexual
- I use a different term
- Don't know
- Prefer not to answer
- Not reported

Gender Identity

What is your current gender? (check all that apply)

- Female
- Male
- Transgender
- Non-binary or genderqueer, neither exclusively male nor female
- I use a different term
- Don't know
- Prefer not to answer
- Not reported

This answer can be compared to Sex At Birth (question 1) to identify non-cisgender subjects

Intersex Status

Have you ever been diagnosed by a medical doctor or other health professional with an intersex condition or a difference of sex development (DSD) or were you born with (or developed naturally in puberty) genitals, reproductive organs, or chromosomal patterns that do not fit standard definitions of male or female? (check one):

- Yes
- No
- Don't know
- Prefer not to answer
- Not reported

All questions include 'Prefer not to Answer' option – no requirement for subjects to answer SOGIIS questions for trial participation

Questions based on recommendations from [Measuring Sex, Gender Identity, and Sexual Orientation](#) (NA SEM, 2022)

Subject Characteristics Data

M_SCCAT	M_SCSCAT	M_QVAL_QSVN	M_QVAL_LANGID	M_SCTESTCD	M_SCORRES
SEXUAL ORIENTATION AND GENDER IDENTITY	CONSENT	A.0	ENU	SOGI101	YES
SEXUAL ORIENTATION AND GENDER IDENTITY	SEX AT BIRTH	A.0	ENU	SOGI102	MALE
SEXUAL ORIENTATION AND GENDER IDENTITY	SEXUAL ORIENTATION	A.0	ENU	SOGI103	LESBIAN OR GAY
SEXUAL ORIENTATION AND GENDER IDENTITY	GENDER IDENTITY	A.0	ENU	SOGI104A	NO
SEXUAL ORIENTATION AND GENDER IDENTITY	GENDER IDENTITY	A.0	ENU	SOGI104B	YES
SEXUAL ORIENTATION AND GENDER IDENTITY	GENDER IDENTITY	A.0	ENU	SOGI104C	NO
SEXUAL ORIENTATION AND GENDER IDENTITY	GENDER IDENTITY	A.0	ENU	SOGI104D	NO
SEXUAL ORIENTATION AND GENDER IDENTITY	GENDER IDENTITY	A.0	ENU	SOGI104E	NO
SEXUAL ORIENTATION AND GENDER IDENTITY	GENDER IDENTITY	A.0	ENU	SOGI104F	NO
SEXUAL ORIENTATION AND GENDER IDENTITY	GENDER IDENTITY	A.0	ENU	SOGI104G	NO
SEXUAL ORIENTATION AND GENDER IDENTITY	INTERSEX STATUS	A.0	ENU	SOGI105	NO

SCCAT	SCSCAT	SCTEST	SCTESTCD	SCORRES
SEXUAL ORIENTATION AND GENDER IDENTITY	Consent	Do you agree to provide SOGI responses	SOGI101	Y
SEXUAL ORIENTATION AND GENDER IDENTITY	Sex at Birth	Sex assigned at birth	SOGI102	M
SEXUAL ORIENTATION AND GENDER IDENTIT	Sexual Orientation	What is your sexual orientation	SOGI103	LESBIAN OR GAY
SEXUAL ORIENTATION AND GENDER IDENTITY	Gender Identity	What is your gender identity	SOGI104B	MALE
SEXUAL ORIENTATION AND GENDER IDENTITY	Intersex Status	Intersex Status	SOGI105	YES

Patient Journey



James, is an Asian study participant, whose sex was assigned female on their original birth certificate. James was not asked to self-report their demographic or subject characteristic data, nor were they asked about any gender affirming surgeries, procedures or gender affirming hormone therapy during their demographic data intake.



Patient Journey

Since you were in a clinical study and you were not asked about your sex assigned at birth or your gender identity, ultimately how did it make you feel?

James: “I felt like I could not disclose that part of my medical history.” They made assumptions when I was in the screening room, and I did not offer any information that I was not asked for.”

And did the data captured, correctly reflect you as a study participant?

James: Absolutely not. They collected samples that they assumed came from a cis man.

Patient Journey

If you could tell your patient journey by asking questions from the perspectives of Healthcare, LGBTQIA+ Community, FDA, Pharma,. What would you want to say?

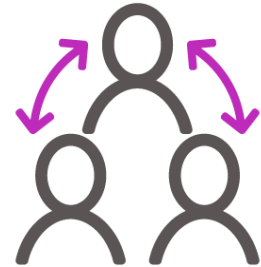
James: “Anyone undergoing gender transition medically is a patient. My medical journey for gender transition will be ongoing for the rest of my life, since I do not ever plan on stopping my gender affirming hormone therapy (GAHT).

Unfortunately, we are also patients that have difficulty finding proper affirming healthcare. It is critically important to include gender diverse people in clinical research and in healthcare. Gender diversity is only becoming more accepted and discussed with the next generation. More people will seek gender affirming healthcare, and it is critical that medical professionals understand how to provide proper care in a safe and affirming way.”



Industry & Community Perspectives

- Clinical, Healthcare, Non-Profit D&I Health Advocacy
- LGBTQIA+ Community
- FDA
- Pharmaceutical Industry and Community





Garo Kiledjian (he/him)

Title: Founder and CEO

Organization: SGM Alliance



Helena Sviglin

Office of Strategic Programs

Organization: FDA CDER



Korey Henricks, MA, LPCC

Title: Senior Manager, eCOA Mgmt.

Organization: Bristol Myers Squibb



NFN Scout (they/he)

Title: Executive Director

Organization: National LGBT
Cancer Network

Meet the Panel



Industry & Community Perspectives

What are the LGBTQIA+ healthcare disparities consequences if SGM data is not requested through self-reporting?



Industry & Community Perspectives

What do you dislike about going to the doctor? In your opinion, how can HCPs improve the experience of SGM patients when receiving care? What would an "inclusive" research site look like?



Industry & Community Perspectives

What are the kinds of questions healthcare should be asking you, to understand how you need to be cared for? Can you provide examples in addition to the SOGI questions (eg: is there value in organ inventory)?



Industry & Community Perspectives

What has been the most challenging aspect of implementing SOGI data collection?



Industry & Community Perspectives

What data endpoints should be considered to get to know SGMs unique healthcare needs and challenges better?



Industry & Community Perspectives

Who are you collaborating with to include all SGM opinions on their healthcare journey (as you may already know, the SGM community is comprised of multiple different communities including the transgender and non-binary community)?

Call to Action....

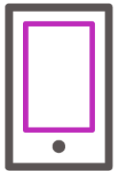
- Do...**Identify** a Senior Sponsor or Champion within your organization to carry and amplify message
- Do...**include multiple functions** of your organization to be a part of the conversation as well as to decide which studies can adopt during study start-up activities ie:(regulatory, legal, medical writing, informed consent, and protocol template processes)
- Do...**stay engaged** with LGBTQIA+ communities for new data revelations
- Do...**remain patient** when being asked repetitive questions. We are all continuously learning.



Stay in touch...

Please reach out to collaborate. A playbook is in the works.

donna.sattler@bms.com





Helpful References and Links

References

1. National LGBT Cancer Network. (2021). OUT: The National Cancer Survey
2. Dawson, L., Frederiksen, B., Long, M., Ranji, U., Kates, J. (2020). LGBT+ People's Health and Experiences Accessing Care. KFF Women's Health Survey.
3. Jones, Jeffrey M. (2021). LGBT Identification Rises to 5.6% in Latest U.S. Estimate. Gallup.
4. Institute of Medicine Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues. (2021). The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding. Washington (DC): National Academies Press.
5. Pratt-Chapman, M., Alpert, A., Castillo, D. (2021). Health outcomes of sexual and gender minorities after cancer: a systematic review.
6. American Association of Cancer Research. (2022). AACR Cancer Disparities Progress Report 2022.
7. Hutchcraft ML, Teferra AA, Montemorano L, Patterson JG. Differences in health-related quality of life and health behaviors among lesbian, bisexual, and heterosexual women surviving cancer from the 2013 to 2018 National Health Interview Survey. *LGBT Health*. 2021;8

Links

1. [Measuring Sex Gender Identity and Sexual Orientation for the National Institutes of Health | National Academies](#)
2. [Fenway Health-SOGI-Data-Collection](#)
3. [National Academies Sciences Engineering & Medicine](#)
4. [ExecutiveSummary \(cancer-network.org\)](#)
5. [Why LGBTQ+ Representation Matters to Me \(ghlf.org\)](#)
6. [Federal Register :: Agency Information Collection Activities; Submission to the Office of Management and Budget \(OMB\) for Review and Approval; Comment Request; American Community Survey Methods Panel: 2024 Sexual Orientation and Gender Identity Test](#)
7. [https://www.nimh.nih.gov/about/organization/od/odwd/coordination-of-sexual-and-gender-minority-mental-health-research-at-nimh.](https://www.nimh.nih.gov/about/organization/od/odwd/coordination-of-sexual-and-gender-minority-mental-health-research-at-nimh)

QR Codes SGM resources



[Measuring Sex Gender Identity and Sexual Orientation for the National Institutes of Health | National Academies](#)



[National Academies Sciences Engineering & Medicine](#)



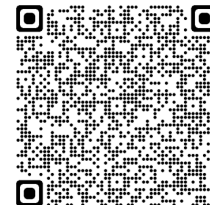
[Why LGBTQ+ Representation Matters to Me \(ghlf.org\)](#)



[Fenway Health-SOGI-Data-Collection](#)

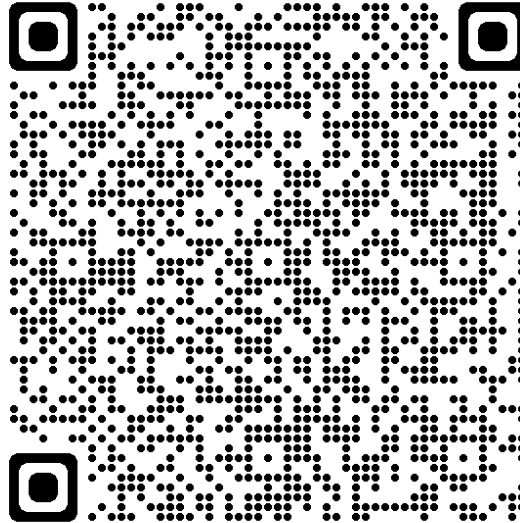


[ExecutiveSummary.pdf \(cancer-network.org\)](#)



<https://www.nimh.nih.gov/about/organization/od/odwd/coordination-of-sexual-and-gender-minority-mental-health-research-at-nimh>

Take action NOW!



[Federal Register :: Agency Information Collection Activities; Submission to the Office of Management and Budget \(OMB\) for Review and Approval; Comment Request; American Community Survey Methods Panel: 2024 Sexual Orientation and Gender Identity Test](#)

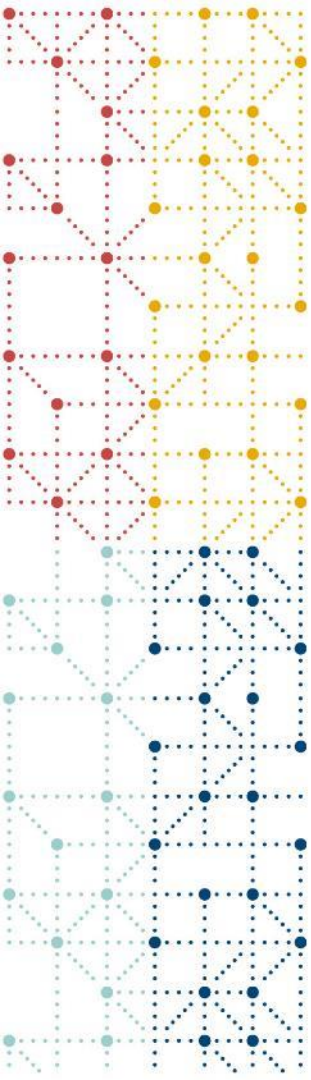


Thank You to our SOGI Champions!

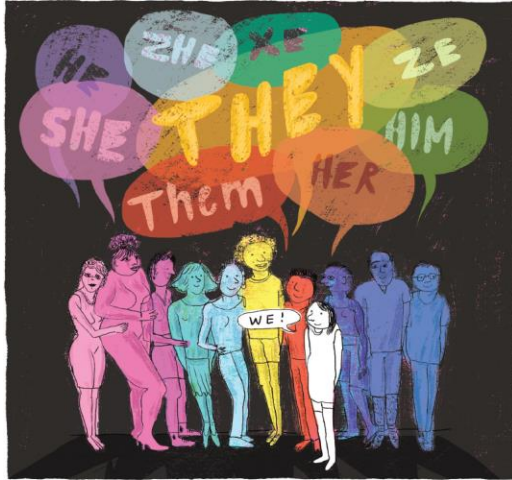
Special shout out to CDISC CDASH SOGI Team including Mitra Swartley, Chris Battiston, Shir Netanel, Natalia Khelmer, Diane Wold, Kelli Smith, Lorraine Spencer, Erin Muhlbradt and many others who contributed to this initiative.

Special recognition BMS's Diversity in Clinical Trials Initiatives, PBRG PRIDE Alliance organization, LGBT Cancer-Network, NIH, and many more industry leaders for taking courageous and thoughtful steps in reducing the healthcare disparities in the LGBTQIA+ Community by championing to normalize SGM data collection.





[This Photo by Unknown Author is licensed under CC BY-NC](#)



cdisc

 Bristol Myers Squibb™

NFN Scout (they/he)

Title: Executive Director

Organization: National LGBT Cancer Network



Executive Director of the National LGBT Cancer Network and the principal investigator of both the CDC-funded LGBTQ tobacco-related cancer disparity network and Out: The National Cancer Survey. They spend much of their time providing technical assistance for tobacco and cancer focusing agencies expanding their reach and engagement with LGBTQ+ populations. Scout has a long history in health policy analysis and a particular interest in expanding LGBTQ+ surveillance and research. They have faculty appointments at both Brown University and Boston Universities' Schools of Public Health. They are a new member of FDA's Tobacco Products Scientific Advisory Committee, a longtime member of the NIH Council of Councils, on the Advisory Panel for NIH's All of Us initiative, and the former Co-Chair of the NIH Sexual and Gender Minority Research Office Work Group. Their work has won them recognition from the U.S. House of Representatives, two state governments, and many city governments. Scout is an openly nonbinary and trans father of three, a vegetarian, an avid hiker and climber.

Helena Sviglin

Office of Strategic Programs

Organization: FDACDER



Current Contributions:

- Internal policy development and study data governance
- Chair, FDA Study Data Technical Conformance Guide (sdTCG) Working Group
- eData mailbox responses
- eCTD Technical Rejection Criteria policy development
- Chair, FDA Data Standards Catalog Subcommittee
- Chair, FDA Business Rules CCB

Garó Kiledjian (he/him)

Title: Founder and Chief Executive Officer

Organization: SGMAlliance



Garó Kiledjian is the Founder and CEO of SGM Alliance, a 501c3 nonprofit that focuses on educating and advocating for inclusive Sexual and Gender Minority (SGM) participation in clinical trials, life sciences, and the evolution of healthcare. Garó also serves as the Chief Operating Officer for Trialologic, a Site Network for one of the largest global LGBTQIA+ healthcare providers. He also serves on the Advisory Board for Arab Board for Clinical Research, is on the Membership Planning Committee for Society for Clinical Research Sites (SCRS) and is on the Executive Committee for the National LGBTQ Task Force, a social advocacy group that focuses on legislative and policy changes from the grassroots level in Washington, DC. He is passionate about DEI and offers a unique perspective on how the intersectionality of race and ethnicity overlap with gender and sexuality. Garó earned his Bachelor's from UCLA and studied Leadership and Global Strategy at Woodbury's Graduate School of Business.



Korey Hendricks, MA, LPCC

Title: Senior Manager, eCOA Management

Organization: Bristol Myers Squibb

Korey Hendricks is clinical research and treatment professional with over 23 years of experience, specializing in clinical outcome assessments, eCOA implementation, clinical training, LBGtQI+ mental health, and people and program leadership. Korey is a dedicated DEI advocate and leader. Korey worked in public mental health for 12 years providing treatment and program management for a range of programs serving severely mentally ill adults, while also running a private therapy practice focusing on LBGtQI+ treatment needs. For the past 12 years, Korey has worked in clinical trials as a centralized rater, clinical scientist, director overseeing clinical study delivery and rater training, and as an eCOA technical implementation expert. Korey is an out and proud member of the LBGtQI+ community and currently lives in San Diego with his husband, who he has been with for over 23 years.



Donna Sattler (she/ her)

Title: Director, Clinical Data Standards

Organization: Bristol Myers Squibb

Donna began her career in marketing and loved working with data. Donna switched her focus and made Clinical Research and Data Standards her home for over 20 years. She is deeply motivated by helping to influence, educate, and communicate Data Standards Best Practices, through cross functional engagement. Through her work with Diversity in Clinical Trials initiatives, Donna has become a fierce advocate for improving the gaps in enrolling diverse populations.