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**Sexual Orientation, Gender Identity, and Intersex Status Data
Collection Implementation at Bristol Myers Squibb**

Presented by: Donna Sattler, Associate Director, Clinical Data Standards, Bristol-Myers Squibb
Stacey Panfil, Senior Manager, External Data Acquisition, Bristol-Myers Squibb

Meet the Speakers

Donna Sattler

Title: Associate Director, Clinical Data Standards

Organization: Bristol-Myers Squibb

I've worked in various Data Management and Programming roles for over 25 years. I made a career change 20 years ago, bringing me into the world of clinical research and data standards. I am deeply motivated by helping to influence, educate, and communicate Data Standards, through process improvements and best practices across the enterprise.



Stacey Panfil

Title: Senior External Data Acquisition Specialist

Organization: Bristol-Myers Squibb

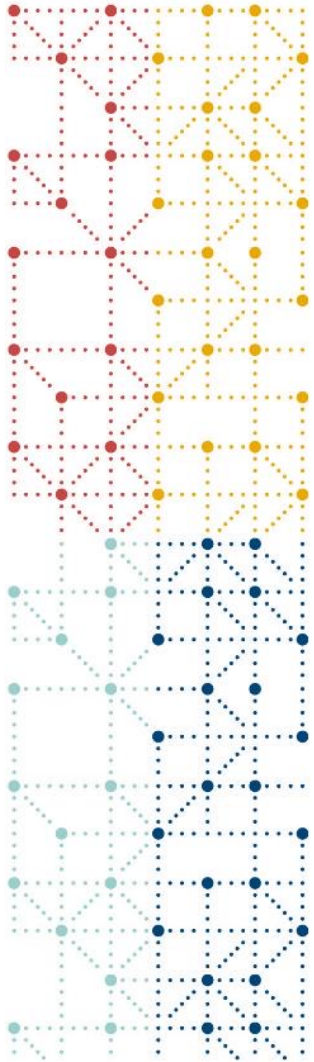
I've worked in the Pharmaceutical Industry for approximately 13 years. I moved from Pre-Clinical Research to Clinical Data Management 5 years ago. I've held positions of increasing responsibilities within my team and have represented Global Data Management and Centralized Monitoring on enterprise level continuous improvement projects. I look forward to expanding my knowledge in Data Standards.





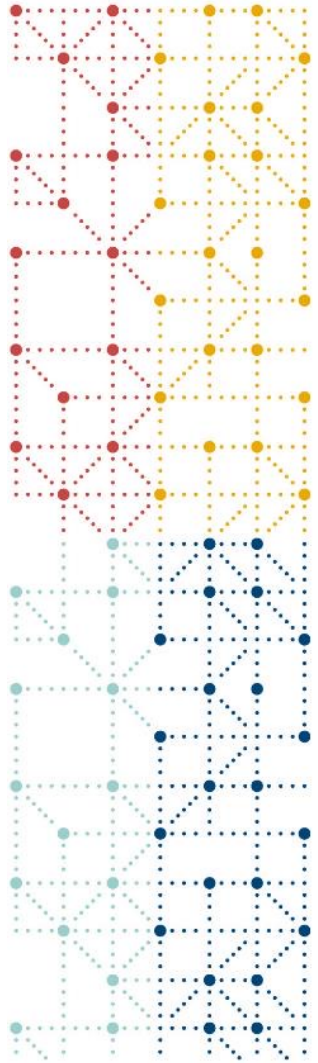
Disclaimer and Disclosures

- *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.*



Agenda

1. Sexual Orientation, Gender Identity and Intersex Status (SOGIIS) Background
2. Healthcare Disparities and Why This Data Matters
3. BMS's Journey to Implementation
4. SOGIIS Data Collection
5. Lessons Learned – BMS
6. Helpful Resources and Links



Sexual Orientation, Gender Identity and Intersex Status (SOGIIS) Background



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**



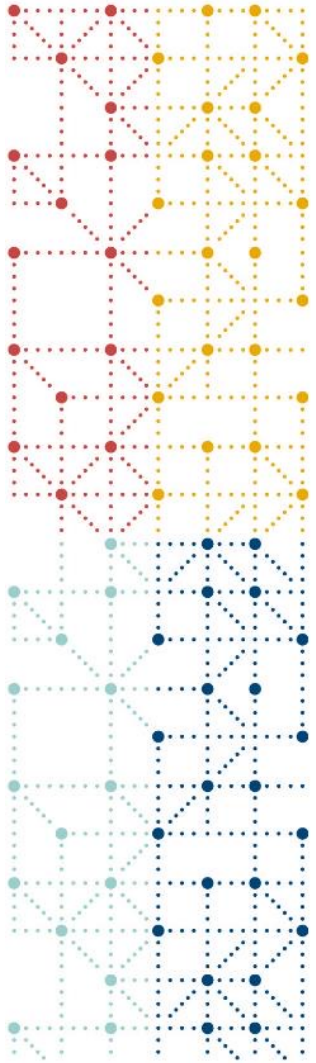
Sexual and Gender Minorities: Health Equity Challenges and Opportunities

1. Many health inequities exist for the Sexual and Gender Diverse (SGD) population, leading to poorer health outcomes
2. Though concerted efforts to reduce health disparities in many domains (e.g., race/ethnicity, social class, disability, geographic location) have occurred, **limited societal efforts have occurred to address disparities by sexual orientation, gender identity and intersex status (SOGIIS), rooted in the lack of available data**
3. Lack of clinical study data inhibits healthcare system understanding of this population
4. Institutions that shape industry and academic practice recommend action



Why BMS has standardized this data collection:

- To obtain novel SGD (sexual and gender diverse) information from clinical trial participants for analysis of new patient characteristics to identify and mitigate health disparities that may exist within the SGD populations
- BMS has a business objective to cultivate a diverse and inclusive global community in their clinical trials where participation in less represented populations is lessened



Healthcare Disparities and Why This Data Matters



What does Health Equity mean?

“Research shows that **LGBTQ+ populations of all ages disproportionately experience more instances of mental health and substance use disorders, suicidality, and poorer wellbeing outcomes compared to their heterosexual and cisgender peers.** The CoE LGBTQ+ BHE’s mission is to bring information and resources to the behavioral health field to enhance culturally responsive care and decrease disparities for this population.”

<https://www.samhsa.gov/lgbtq-plus-behavioral-health-equity>





Background A history of medical bias against the LGBTQ+ community

| | |
|----------|---|
| Pre-1973 | Homosexuality and gender dysphoria considered mental disorders |
| 1973 | Homosexuality removed from of the American Psychiatric Association’s Diagnostic & Statistical Manual of Mental Disorders (“the DSM”) |
| 1980 | Gender identity disorder introduced into the DSM as a psychopathological condition |
| 2003 | Homosexual activity decriminalized in Lawrence v Texas |
| 2012 | Gender identity disorder replaced with gender dysphoria in DSM |
| 2016 | NIH formally designated Sexual and Gender Minorities (SGM) as a health disparity population for NIH research |
| 2020 | Discrimination on the basis of sexual orientation or gender identity ruled unlawful in Bostock v Clayton based on Title VII |



LGBTQI+ Health Disparity: Cancer

- **5.6 percent of the U.S. population self-identifies as belonging** to the SGM population, but the percentage of SGM individuals experiencing illnesses like cancer are difficult to estimate, as demographic data is lacking and disclosure is still hindered by stigma and discrimination.
- Some studies have shown **worse long-term physical outcomes** for SGM people with cancer compared to non-SGM people.
 - In one study, SGM people who felt their provider was not competent about SGM health experienced unmet needs related to depression, stress, and sexual dysfunction.
 - In another study, bisexual women with a history of cancer have been found to be 3-times more likely to report psychological stress



Health Equity Pivot Point - Regardless of historic biases, key institutions have made a health equity pivot

The National Academies of SCIENCES ENGINEERING MEDICINE

Understanding the Well-Being of LGBTQI+ Populations (2020), Recommendation 1:

“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.”



The NEW ENGLAND JOURNAL of MEDICINE

Ensuring That LGBTQI+ People Count (2021):

“...the widespread lack of comprehensive data collection means that many more disparities — and the policy and programmatic interventions that might address them — remain unknown.”

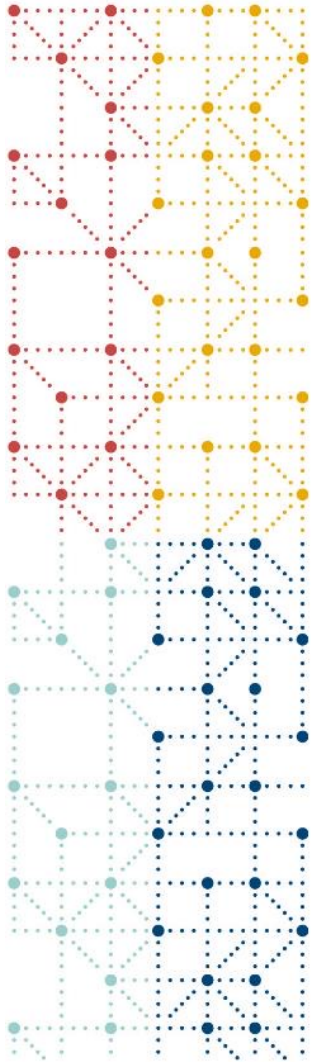
“According to the National Academies report, there are several types of data-collection activities that should routinely include measures of sexual orientation, gender identity, and intersex status. These are population surveys, ... clinical trials and other research....”



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 co-morbidity.

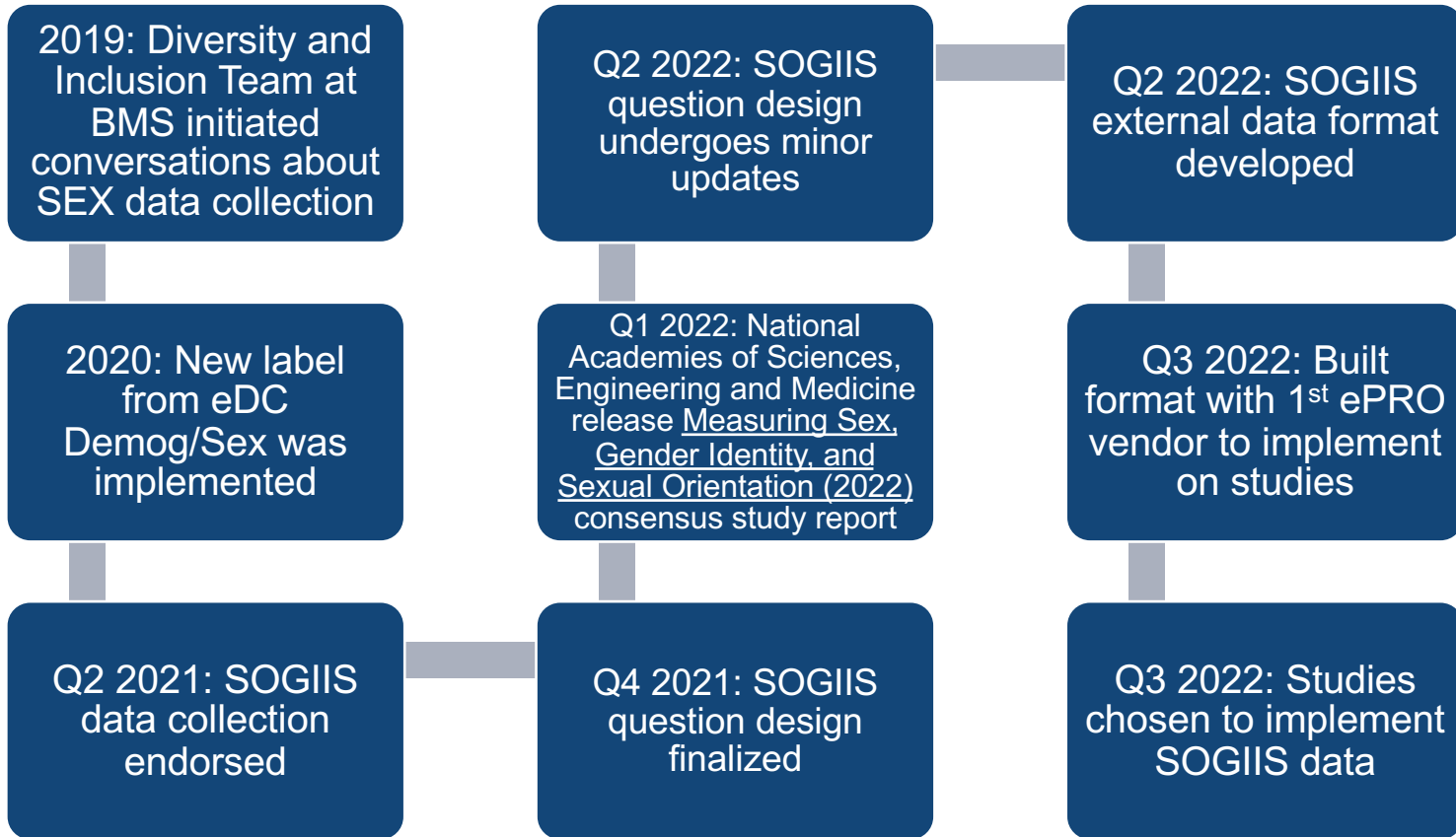
FDA encourages sponsors to also submit plans that help ensure the adequate participation of relevant and underrepresented populations and analyses of data collected from clinically relevant subpopulations.



Journey to Implementation



BMS Journey to Implementation





BMS Journey to Implementation

Pre-Requisites (Study Level at BMS)

1. US Only
2. Only adult study participants
3. Protocol and Informed Consent includes SOGIIS data collection rational
4. Studies must already plan to utilize ePRO vendor for data collection
5. Planned diversity training for sites to address potential biases
6. Analysis considerations





BMS Journey to Implementation

SDTM Subject Characteristics Evolution

The structure for demographic data is fixed and includes date of birth, age, sex, race, ethnicity, and country...

SDTMIG 3.2 – 26Nov2013

SDTMIG 3.3 – 20Nov2018

- The structure of subject characteristics is based on the CDISC SDTMIG 3.2 structure.
- Subject characteristics are collected at the start of the trial and are not to change during the trial or whose change is not of interest after the initial collection..

SDTMIG 3.4 – 29Nov2021

- The structure of subject characteristics is based on the CDISC SDTMIG 3.4 structure.

level, marital status, and national origin.

Subject characteristics may be collected periodically over time.



BMS Journey to Implementation

ePRO vs eDC

| | ePRO | eDC |
|--------------|--|--|
| Definition : | Electronic Patient Reported Outcomes allows patients to answer questions and report on their health through an electronic device | Electronic Data Capture is the computerized collection and management of clinical trial data from patients and participants. |
| Who? : | Patient/Participant | Site/Investigator |



BMS Journey to Implementation: Many Collaborations

**PBRG Lead, PRIDE Alliance
Diversity in Clinical Trial Lead (DiCT)**

Cross-Functional Teams:

- Clinical Data Standards
- External Data Acquisition
- eCOA Management
- ePRO Vendor Management
- Clinical
- Global Biostatistics and Data Sciences
- Legal
- Regulatory

SOGIIS mini-study team

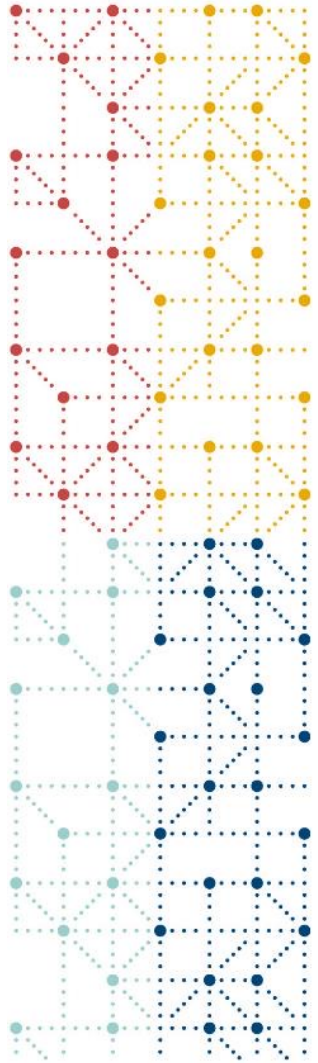
Formed in Q2 2022 to address implementation and downstream analysis plan. SOGIIS mini-study team functions as an extension of the PBRG Pride Alliance and comprised of 20+ members representing all facets of the BMS organization

Roadshows:

Functional-specific information was gathered on specific questions about what information does your function need for its part in SOGIIS data collection implementation? Presentations created for specific BMS functions were rolled out in Q3 2022

CDISC CDASH SOGIIS Working Group:

Meetings have begun around the SDTM CT implementation strategy. Subject Characteristics and the SCTEST CT list will be utilized. New CT will be requested per examples shown.



SOGIIS Data Collection

SOGIIS Data Collection

Questions asked privately in ePRO 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

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

Gender Identity

What is your current gender? (check all)

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

This answer is 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

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

SOGIIS Data Collection Non-CRF Specification

| VARIABLE # | VARIABLE NAME | VARIABLE LABEL | LENGTH | PRECISION | TYPE | GENERAL INFORMATION | FORMAT GUIDANCE | REQUIREMENT FOR POPULATION | DICTIONARY |
|------------|---------------|------------------------|--------|-----------|------|---|--|----------------------------|---------------------|
| 1 | PROJECT | STUDY | 10 | | Char | BMS protocol number as defined in the Data Specification Package | Format = AB999-XXX or AB999-XXXX as applicable where AB is alphabetical and in uppercase. XXX or XXXX can be numeric or alphanumeric and in uppercase | Required | |
| 2 | SUBJECT | SUBJECT IDENTIFICATION | 10 | | Char | Subject identification | Four character BMS investigator original SITE number (right justify, zero fill), a blank space, the five character original SUBJECT number (right justify, zero fill) e.g., 0001 00001 | Required | |
| 3 | X_SEX | Vendor Sex at Birth | 1 | | Char | Subject's sex at birth | Should contain one of the following Codes: M (for male), F (for female). | Required | SEX_NCF |
| 4 | X_BRTHDAT | Vendor Date of Birth | 11 | | Date | Subject's Full Date of Birth from birth up to, but not including 2 years old. 01 JUL as imputed Day and Month of Birth with Subject's Actual Year of Birth for all subjects 2 years or older. | Subjects less than 2 years old format: DD MMM YYYY Month abbreviation must be capitalized (e.g., 08 AUG 1996). All Subjects 2 years or older format: 01 JUL YYYY. | Required | |
| 5 | FOLDER | Visit Folder | 16 | | Char | Visit Folders as defined by BMS | Format defined in Visit Mapping table (BMS Visit Code column) within the Data Specification Package. | Required | |
| 6 | M_SCDAT | Collection Date | 11 | | Date | Assessment collection date | DD MMM YYYY month abbreviation must be capitalized (e.g., 08 AUG 2001). If interval collection, this is the END DATE. | Required | |
| 7 | M_SCTIM | Collection Time | 8 | | Time | Assessment collection time | 24 hr format: HH:MM:SS (e.g. 13:10:00). If not collected, this field is empty. If interval collection, this is the END TIME. | Optional | |
| 8 | M_SCNAM | Vendor Name | 100 | | Char | Vendor responsible for assessment | Defined by BMS in the Data Transfer Frequency Table within the Data Specification Package. | Required | |
| 9 | M_SCREFID | Accession Number | 26 | | Char | Vendor's unique internal accession number or assessment tracking number. | Accession number should be unique per time point. | Required | |
| 10 | M_SCCAT | Questionnaire Name | 200 | | Char | Description of questionnaire | Name of Questionnaire : SEXUAL ORIENTATION, GENDER IDENTITY AND INTERSEX STATUS | Required | SCCAT_SET_NCF |
| 11 | M_SCSCAT | Subcategory | 40 | | Char | Subcategory | See Relational Table immediately following this file format: SEX ASSIGNED AT BIRTH, SEXUAL ORIENTATION, GENDER IDENTITY, INTERSEX STATUS | Conditional | SCSCAT_NCF |
| 12 | M_QVAL_QSVN | BMS SCALE IDENTIFIER | 3 | | Char | BMS identification of the scale and version number | Please see BMS LANGUAGE CODE and SCALE table immediately following this file format | Required | |
| 13 | M_QVAL_LANGID | BMS LANGUAGE CODE | 3 | | Char | Language of questionnaire used by BMS | Please see BMS LANGUAGE CODE and SCALE table immediately following this file format | Required | LANGID_SET_NCF |
| 14 | M_SCTESTCD | Question Test Code | 8 | | Char | Question Test Code | See Relational Table immediately following this file format. | Required | SCTESTCD_NCF |
| 15 | M_SCORRES | Response | 200 | | Char | Original Response | See Relational Table immediately following this file format. If Field 16 is ND, this field will be blank. | Conditional | SCORRES_NCF |
| 16 | M_SCSTAT | Completion Status | 40 | | Char | Completion status indicates question not done. Should be null if a result exists in original results. | Should contain the following: ND *Note: Field may be left blank; If full questionnaire was not completed, each question should still be accounted for with a ND record. | Conditional | ND |
| 17 | M_SCREASND | Reason Not Done | 200 | | Char | Reason the question was not completed by the patient. | Please provide one of the following: INSTRUMENT NOT AVAILABLE, DEVICE NOT FUNCTIONING, ADMINISTRATIVE DISEASE FACTORS, SUBJECT FACTORS, SUBJECT REFUSED, OTHER, LOGICALLY SKIPPED, SITE OPTED OUT. *This field will only be populated when field 20 is populated | Conditional | NOTOBTAINED_SET_NCF |



SOGIIS Data Collection Relational Table



| Variable 11 M_SCSCAT | Variable 14 M_SCTESTCD | Question Test Dictionary Decoded Data M_SCTEST NOT TRANSFERRED | Variable 15 M_SCORES |
|-------------------------|---------------------------|---|---------------------------------------|
| CONSENT | SOGI101 | Do you agree to the collection and use of information about the gender you identify with, sexual orientation, and intersex status for these purposes? You will be able to take part in this study regardless of which option you choose: | YES |
| | | | NO |
| SEX AT BIRTH | SOGI102 | What sex were you assigned at birth, on your original birth certificate? (check one): | FEMALE |
| | | | MALE |
| | | | DON'T KNOW |
| | | | PREFER NOT TO ANSWER |
| SEXUAL ORIENTATION | SOGI103 | 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 |
| GENDER IDENTITY | SOGI104A | What is your current gender? (check all that apply) : FEMALE | YES NO |
| GENDER IDENTITY | SOGI104B | What is your current gender? (check all that apply) : MALE | YES NO |
| GENDER IDENTITY | SOGI104C | What is your current gender? (check all that apply) : TRANSGENDER | YES NO |
| GENDER IDENTITY | SOGI104D | What is your current gender? (check all that apply) : NON-BINARY OR GENDERQUEER, NEITHER EXCLUSIVELY M NOR F | YES NO |
| GENDER IDENTITY | SOGI104E | What is your current gender? (check all that apply) : I USE A DIFFERENT TERM | YES NO |
| GENDER IDENTITY | SOGI104F | What is your current gender? (check all that apply) : DON'T KNOW | YES NO |
| GENDER IDENTITY | SOGI104G | What is your current gender? (check all that apply) : PREFER NOT TO ANSWER | YES NO |
| INTERSEX STATUS | SOGI105 | 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 |

SOGIIS Data Collection

Mock Data Set

| PROJECT | SUBJECT | X_SEX | X_BRTHDAT | FOLDER | M_SCDAT | M_SCTIM | M_SCNAM | M_SCREPID | M_SCCAT | M_SCCAT | M_QVAL_QSVN | M_QVAL_LANGID | M_SCTESTCD | M_SCORRES | M_SCCAT | M_SCREASND |
|-----------|------------|-------|-------------|--------|-------------|----------|----------------|--------------|--|--------------------|-------------|---------------|------------|----------------|---------|----------------|
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | CONSENT | A.0 | ENU | SOGI101 | YES | | |
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | SEX AT BIRTH | A.0 | ENU | SOGI102 | MALE | | |
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | SEXUAL ORIENTATION | A.0 | ENU | SOGI103 | LESBIAN OR GAY | | |
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104A | NO | | |
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104B | YES | | |
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104C | NO | | |
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104D | NO | | |
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104E | NO | | |
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104F | NO | | |
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104G | NO | | |
| XX123-123 | 0001 00001 | M | 01 Jul 1990 | SCRN | 29 Jul 2022 | 13:10:00 | SIGNANT HEALTH | AB0000000012 | SEXUAL ORIENTATION AND GENDER IDENTITY | INTERSEX STATUS | A.0 | ENU | SOGI105 | NO | | |
| XX123-123 | 0011 00002 | M | 01 Jul 1988 | SCRN | 14 Jun 2022 | 16:20:00 | SIGNANT HEALTH | AB0000432032 | SEXUAL ORIENTATION AND GENDER IDENTITY | CONSENT | A.0 | ENU | | | ND | SITE OPTED OUT |
| XX123-123 | 0011 00002 | M | 01 Jul 1988 | SCRN | 14 Jun 2022 | 16:20:00 | SIGNANT HEALTH | AB0000432032 | SEXUAL ORIENTATION AND GENDER IDENTITY | SEX AT BIRTH | A.0 | ENU | | | ND | SITE OPTED OUT |
| XX123-123 | 0011 00002 | M | 01 Jul 1988 | SCRN | 14 Jun 2022 | 16:20:00 | SIGNANT HEALTH | AB0000432032 | SEXUAL ORIENTATION AND GENDER IDENTITY | SEXUAL ORIENTATION | A.0 | ENU | SOGI103 | | ND | SITE OPTED OUT |
| XX123-123 | 0011 00002 | M | 01 Jul 1988 | SCRN | 14 Jun 2022 | 16:20:00 | SIGNANT HEALTH | AB0000432032 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104A | | ND | SITE OPTED OUT |
| XX123-123 | 0011 00002 | M | 01 Jul 1988 | SCRN | 14 Jun 2022 | 16:20:00 | SIGNANT HEALTH | AB0000432032 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104B | | ND | SITE OPTED OUT |
| XX123-123 | 0011 00002 | M | 01 Jul 1988 | SCRN | 14 Jun 2022 | 16:20:00 | SIGNANT HEALTH | AB0000432032 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104C | | ND | SITE OPTED OUT |
| XX123-123 | 0011 00002 | M | 01 Jul 1988 | SCRN | 14 Jun 2022 | 16:20:00 | SIGNANT HEALTH | AB0000432032 | SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104D | | ND | SITE OPTED OUT |

| M_SCCAT | M_SCCAT | M_QVAL_QSVN | M_QVAL_LANGID | M_SCTESTCD | M_SCORRES |
|--|--------------------|-------------|---------------|------------|----------------|
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | CONSENT | A.0 | ENU | SOGI101 | YES |
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | SEX AT BIRTH | A.0 | ENU | SOGI102 | MALE |
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | SEXUAL ORIENTATION | A.0 | ENU | SOGI103 | LESBIAN OR GAY |
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104A | NO |
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104B | YES |
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104C | NO |
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104D | NO |
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104E | NO |
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104F | NO |
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | GENDER IDENTITY | A.0 | ENU | SOGI104G | NO |
| 2 SEXUAL ORIENTATION AND GENDER IDENTITY | INTERSEX STATUS | A.0 | ENU | SOGI105 | NO |



SOGIIS Data Standardized

SDTM Subject Characteristics – Annotated

SCCAT = Sexual Orientation, Gender Identity, and Intersex Status

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

SEX AT BIRTH

Female

Male

Don't Know

SCTEST = Sex Reported at Birth (NCI CT)

SCTESTCD = SEXRBRTH

SCORRES = choices to the left

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

SEXUAL ORIENTATION

Lesbian or gay

Straight, that is, not gay or lesbian

Bisexual

I use a different term

Don't know

Prefer not to answer

SCTEST = Sexual Orientation

SCTESTCD = SEXORNT

SCORRES = choices to the left

SCSTRESC = SCORRES

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

- Female
- Male
- Transgender
- Non-Binary or Genderqueer, neither exclusively male or female
- I use a different term

GENDER IDENTITY

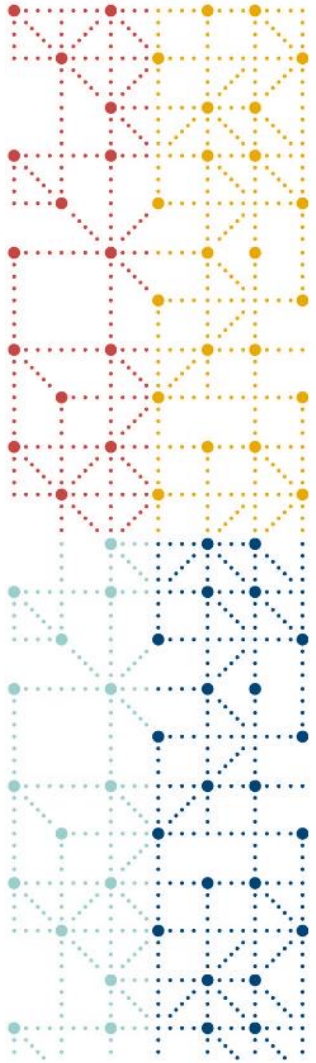
SCTEST = Gender Identity (NCI CT)
SCTESTCD = GENIDENT
SCORRES = choices to the left
SCSTRESC = SCORRES
SCSPID
SCSEQ

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 the standard definitions for male or female? (check one):

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

SCTEST = Intersex Status
SCTESTCD = INTRSEX
SCORRES = choices to the left
SCSTRESC = SCORRES

INTERSEX STATUS

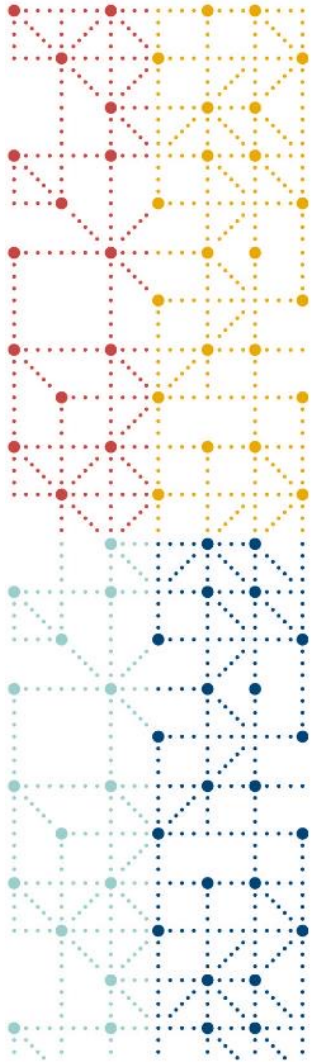


Lessons Learned



What we've learned along the way...

- Lack of healthcare data to close the gaps in understanding the burden of this underrepresented population, SOGLIS data collection can help.
- Include multiple functions of the organization to be a part of the conversation as well as to decide which studies can adopt at study start-up
- Engage teams for example regulatory, legal, medical writing, informed consent, and protocol template processes.
- Continuously stay engaged with the LGBTQ+ communities for new data revelations
- Remain patient when asked the same questions. We are all learning.



Helpful References and Links



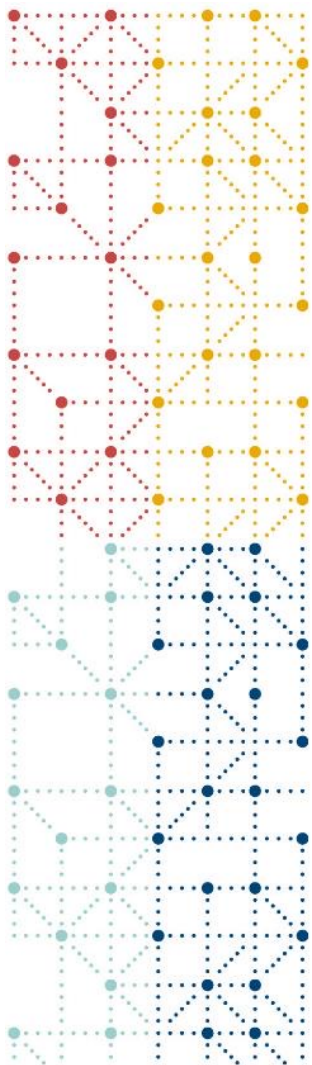
References

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. [NIH-Measuring Sex, Gender Identity, and Sexual Orientation](#)
2. [Fenway Health-SOGI-Data-Collection](#)
3. [National Academies Sciences Engineering & Medicine](#)
4. [ExecutiveSummary \(cancer-network.org\)](#)



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Definitions

SOGI = Sexual Orientation and Gender Identity

SGM = Sexual and Gender Minorities (often used in research settings)

LGBTQI = Lesbian, Gay, Bisexual, Transgender, Queer, Intersex

Sexual Orientation:

Gender one is attracted to

- **Heterosexual:**
Opposite-sex attraction
- **Homosexual/Gay/Lesbian:**
Same-sex attraction
- **Bisexual:**
Both opposite- and same-sex attraction
- **Asexual:**
Not attracted to any gender

Gender Identity:

One's internal self-understanding of their gender

- **Cisgender:**
One's internal self-understanding of their gender matches their sex assigned at birth
- **Transgender:**
One's internal self-understanding of their gender does not match their sex assigned at birth
- **Non-binary or Gender Queer:**
Individuals who may identify partly with either sex or neither, regardless of biological traits

Intersex:

People born with primary or secondary sex characteristics that do not fit binary medical definitions of male or female reproductive or sexual anatomy; Intersex traits are widely heterogeneous.