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Enhancing Health Equity Outcomes through Comprehensive Data Collection of Marginalized Populations including Sexual Orientation, Gender Identity and Intersex Status (SOGI)

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ABSTRACT

The collection of comprehensive data from marginalized populations is essential for advancing health equity in clinical trials. The LGBTQIA+ community has faced significant healthcare shortcomings over the years, largely due to discrimination, lack of education among healthcare providers, and systemic inequities leading to underrepresentation from these populations, causing disparities in health outcomes and access to medical advancements.

INTRODUCTION

This paper aims to evaluate the impact of broader data collection on health equity outcomes by incorporating diverse subject characteristic data, such as Sexual Orientation, Gender Identity and Intersex Status from marginalized groups into the standards data collection practices in clinical trials. The abstract will demonstrate best practices for influencing organizations why this data can lead to improving FDAs request for more real world data. It will share some basic guidelines for internal stakeholders.

HISTORY

Members of the LGBTQIA+ community often encounter discrimination and microaggressions in healthcare settings, which can deter them from seeking necessary medical care. This includes outright discrimination and subtle biases that affect the quality of care received. The HIV/AIDS crisis in the 1980s was a pivotal moment for LGBTQIA+ healthcare. The virus disproportionately affected marginalized groups, particularly Black and Latinx gay men and transgender women. The initial response was marred by widespread misinformation and prejudice, further exacerbating the health crisis. Many healthcare providers lack adequate training on LGBTQIA+ health issues, leading to misdiagnoses and suboptimal treatment. This is particularly true for transgender and non-binary individuals who require gender-affirming treatments. LGBTQIA+ individuals who belong to other marginalized groups, such as racial minorities or those with disabilities, face compounded healthcare challenges. These intersecting identities can lead to even greater disparities in health outcomes. Despite these challenges, there have been significant efforts to address these disparities. Organizations and activists have been advocating for anti-discrimination legislation and better education for healthcare professionals to create more equitable and affirming healthcare environments. [1]

Historically, clinical trials have underrepresented LGBTQIA+ populations, leading to a lack of data on how medical treatments affect these groups. This underrepresentation contributes to health disparities and limits the effectiveness of medical interventions for LGBTQIA+ individuals. Studies have shown that a significant portion of LGBTQIA+ individuals are willing to participate in clinical trials. For example, 65% of LGBTQIA+ respondents expressed interest in participating in future clinical trials. [2] However, many are not aware of opportunities to participate, highlighting the need for better outreach and inclusive recruitment practices.[3]

Preliminary findings indicate that the inclusion of comprehensive data from marginalized populations, including LGBTQIA+ individuals, leads to improved health equity outcomes. For instance, targeted interventions based on Sexual Orientation and Gender Identity (SOGI) data have resulted in better management of chronic conditions among sexual gender minorities, such as breast cancer and depression.

Regulatory bodies like the FDA encourage the inclusion of diverse populations in clinical trials, including those defined by sexual orientation and gender identity. This is crucial for developing personalized treatment plans and ensuring that new therapies are effective for all demographic groups.

Engaging the LGBTQIA+ community in the clinical trial process is essential for building trust and ensuring that data collection is sensitive and respectful. This approach not only improves participation rates but also enhances the quality of data collected, leading to more effective and inclusive healthcare solutions.

By addressing these disparities and increasing LGBTQIA+ participation in clinical trials, the healthcare system can develop more effective treatments and interventions that cater to the unique needs of this community, ultimately contributing to a more inclusive and equitable healthcare system.

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2. Center for Patient Research and The Harris Poll, "Underrepresented groups are interested in clinical trials – but aren't being asked". PAN Foundation. October 8, 2024. Available at https://www.panfoundation.org/underrepresented-groups-are-interested-in-clinical-trials-but-arent-being-asked/
3. https://www.fda.gov/news-events/fda-voices/advancing-clinical-trial-participation-lgbtqia-community (moved link, see below)
4. Grossi, Giuliana. "FDA Quietly Removes Draft Guidance on Diversity in Clinical Trials Following Executive Order on DEI". AJMC. January 31, 2025. Available at https://www.ajmc.com/view/fda-quietly-removes-draft-guidance-on-diversity-in-clinical-trials-following-executive-order-on-dei

DEFINITIONS

SOGI – Sexual Orientation, Gender Identity and Intersex Status

METHODS

- **Expanded Demographic Categories:** Utilize expanded sex categories to ensure accuracy in identifying subgroup-specific health risks. This helps in developing targeted interventions for specific groups
- **Ethical Considerations:** Ensure that clinical trials benefit all groups equally by embedding diversity, equity, and inclusion within data solutions
- **Personalized Medicine:** Collect data that contributes to personalized medicine by identifying population-specific responses. This includes SOGI information e.g.: laboratory data and interpreting normal ranges may not be straight forward.
- **Regulatory Compliance:** Align data collection methods with federal guidelines for inclusivity and comply with updated standards for demographic diversity
- **Electronic Health Records (EHRs):** Use EHRs to assist with trial recruitment and track health disparities among the patients served

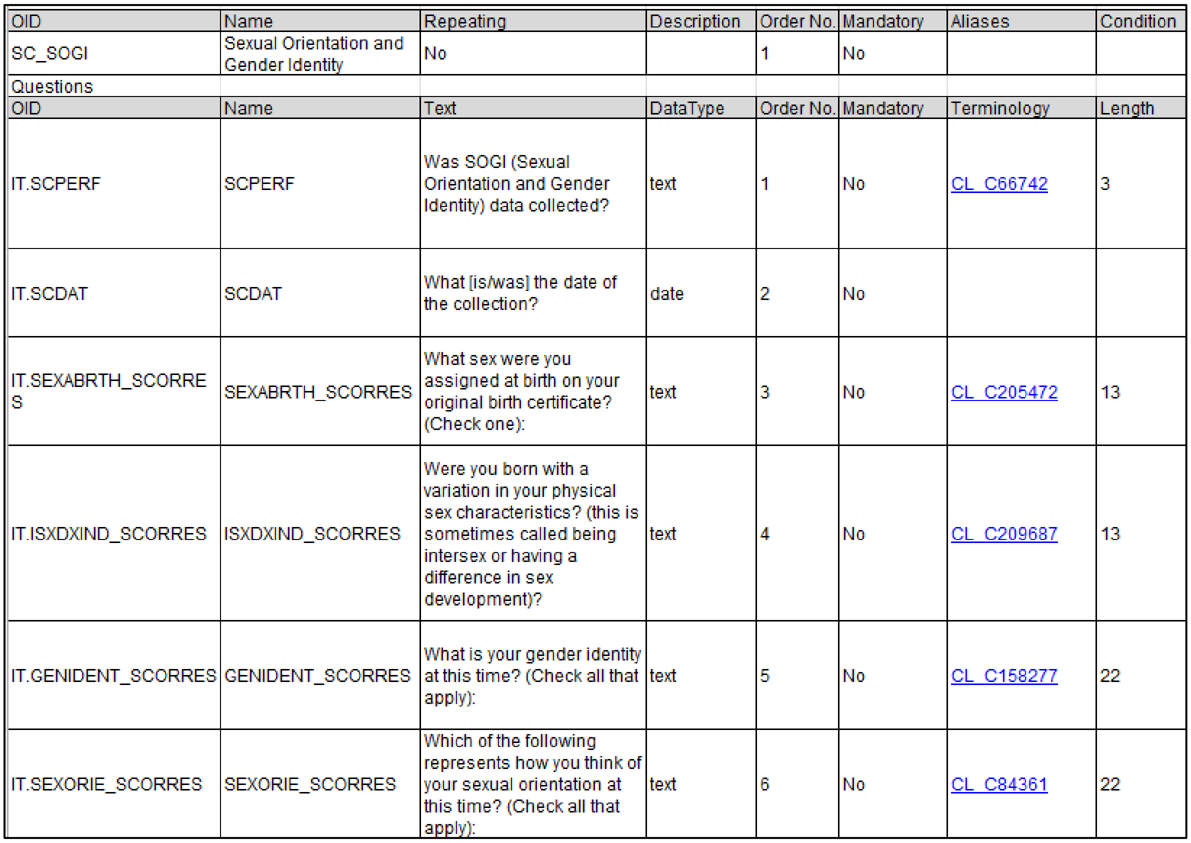
The examples shared will involve a diverse cohort of participants from various marginalized communities, including racial and ethnic minorities, LGBTQ+ individuals, and those with disabilities. Data collection will encompass a wide range of variables, such as social determinants of health, genetic information, and patient-reported outcomes where available and applicable. Advanced data analytics and machine learning techniques will be demonstrated to analyze the collected data and identify patterns and correlations that can inform targeted interventions.

CDISC SOGI FORM

Error! Reference source not found. **is a sample of the CDISC SOGI Form published in 2024.**

CDISC SOGI METADATA - CDISC SOGI Metadata Package

Figure 2. CDISC published metadata



OID	Name	Repeating	Description	Order No.	Mandatory	Aliases	Condition
SC_SOGI	Sexual Orientation and Gender Identity	No		1	No		
Questions							
OID	Name	Text	DataType	Order No.	Mandatory	Terminology	Length
IT.SCPERF	SCPERF	Was SOGI (Sexual Orientation and Gender Identity) data collected?	text	1	No	CL_C66742	3
IT.SCDAT	SCDAT	What [is/was] the date of the collection?	date	2	No		
IT.SEXABRTH_SCORRES	SEXABRTH_SCORRES	What sex were you assigned at birth on your original birth certificate? (Check one):	text	3	No	CL_C205472	13
IT.ISXDXIND_SCORRES	ISXDXIND_SCORRES	Were you born with a variation in your physical sex characteristics? (this is sometimes called being intersex or having a difference in sex development)?	text	4	No	CL_C209687	13
IT.GENIDENT_SCORRES	GENIDENT_SCORRES	What is your gender identity at this time? (Check all that apply):	text	5	No	CL_C158277	22
IT.SEXORIE_SCORRES	SEXORIE_SCORRES	Which of the following represents how you think of your sexual orientation at this time? (Check all that apply):	text	6	No	CL_C84361	22

CONCLUSION

Preliminary findings indicate that the inclusion of comprehensive data from marginalized populations leads to improved health equity outcomes. For example, targeted interventions based on SOGI data have resulted in better management of chronic conditions among sexual gender minorities including breast cancer and depression. Additionally, personalized treatment plans informed by SOGI data have shown promising results in reducing health disparities among LGBTQ+ individuals. The abstract will also highlight the importance of community engagement and sensitive approaches in collection of this data.

Broadening the scope of data collection to include marginalized populations is crucial for achieving health equity in clinical trials. By leveraging diverse data points and utilizing platforms and tools, researchers can develop more effective and personalized interventions that address the unique needs of these populations. This approach not only improves health outcomes but also fosters trust and participation among marginalized groups, ultimately contributing to a more inclusive and equitable healthcare system.

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As we continue to evolve and make progress, I encourage everyone to connect with the SGM Alliance. They offer invaluable best practices to help organizations address health disparities in their research through innovative methods. Together, we can make a difference and drive positive change.

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