Making the invisible visible: translating SOGI advocacy into systematic industry implementation for HIV trials

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Introduction

- Sexual and gender minority (SGM) populations comprise ~5 to 9% of national populations and 20%+ of Gen Z adults
- SGM populations represent 70% of new US HIV diagnoses
- Sexual orientation and gender identity data collection published as feasible and acceptable in healthcare and research since ~2013
- Pharma-facing CDISC announced SOGI data standards in 2024
- There is no global standard for SOGI collection in healthcare
- Many clinical trials – including HIV trials – do not collect SOGI
- Lack of SOGI data in clinical trials leads to avoidable gaps in patient safety, treatment efficacy, and population effectiveness

Methods

- SGMA recruited subject matter experts (SMEs) to compile and review case studies of SOGI data collection in clinical trials
- SGMA conducted financial modeling to estimate return on investment (ROI) for including SOGI data in clinical trials
- SGMA consulted with industry, healthcare, and academic SMEs to build a framework showing how SOGI data supports patient care, public health, and ROI by clinical trial stage
- SGMA convened sponsors, clinical research organizations, and clinical research sites to identify operational best practices in SOGI data integration in EDC systems, CDISC-compliant CRF templates, global cultural considerations, data privacy protocols, and clinician training

Results

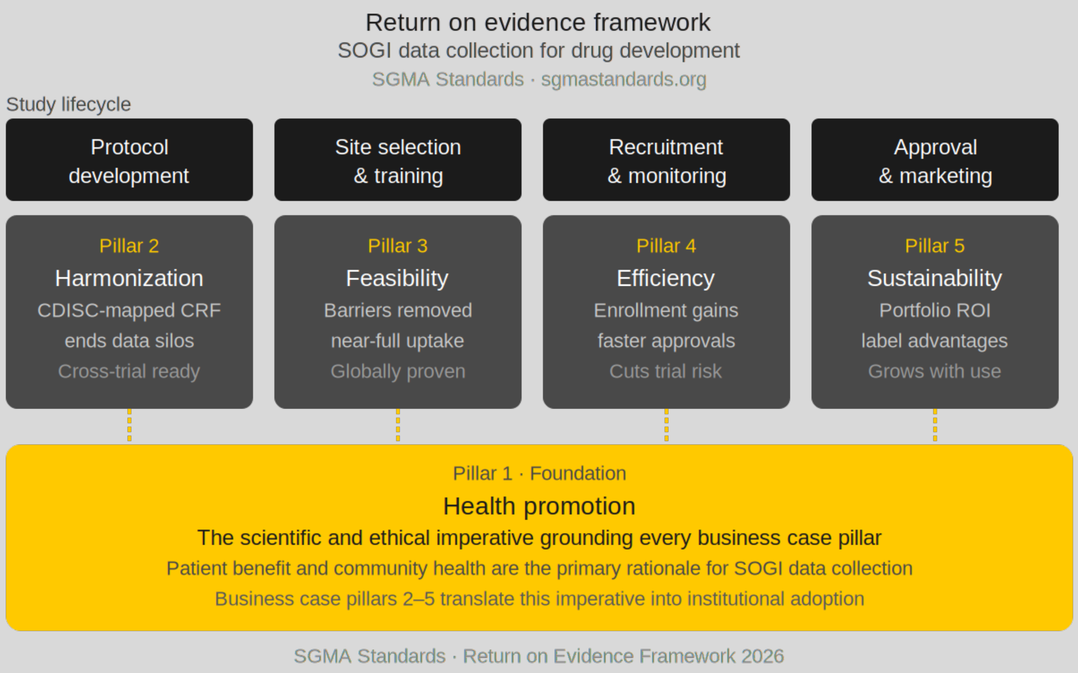


Figure 1: Return on Evidence Framework Illustrating how SOGI Data Collection Supports Patient Care, Public Health, and Return on Investment

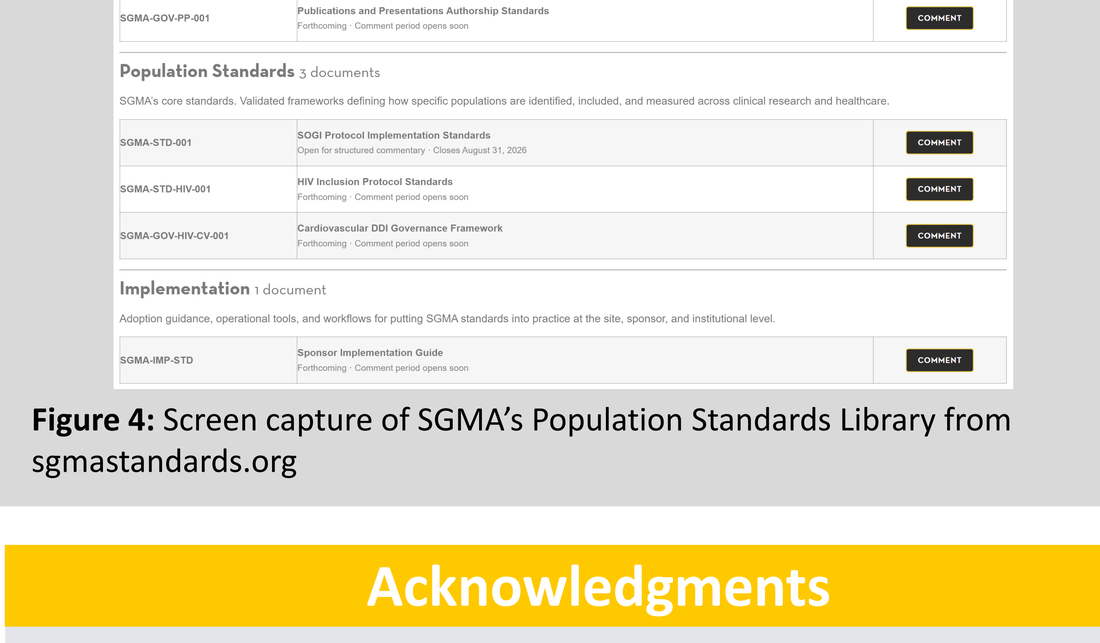
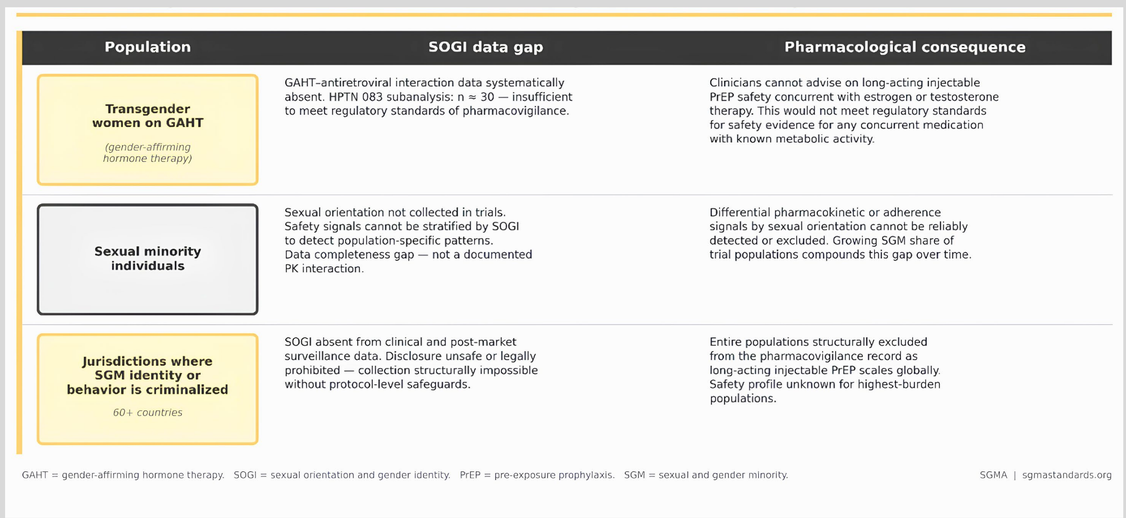


Figure 3: Distribution of SGM disease burden across 5 therapeutic areas



Population	SOGI data gap	Pharmacological consequence
Transgender women on GAHT *(gender-affirming hormone therapy)*	GAHT–antiretroviral interaction data systematically absent. HPTN 083 subanalysis: n ≈ 30 — insufficient to meet regulatory standards of pharmacovigilance.	Clinicians cannot advise on long-acting injectable PrEP safety concurrent with estrogen or testosterone therapy. This would not meet regulatory standards for safety evidence for any concurrent medication with known metabolic activity.
Sexual minority individuals	Sexual orientation not collected in trials. Safety signals cannot be stratified by SOGI to detect population-specific patterns. Data completeness gap — not a documented PK interaction.	Differential pharmacokinetic or adherence signals by sexual orientation cannot be reliably detected or excluded. Growing SGM share of trial populations compounds this gap over time.
Jurisdictions where SGM identity or behavior is criminalized *60+ countries*	SOGI absent from clinical and post-market surveillance data. Disclosure unsafe or legally prohibited — collection structurally impossible without protocol-level safeguards.	Entire populations structurally excluded from the pharmacovigilance record as long-acting injectable PrEP scales globally. Safety profile unknown for highest-burden populations.

GAHT = gender-affirming hormone therapy. SOGI = sexual orientation and gender identity. PrEP = pre-exposure prophylaxis. SGM = sexual and gender minority. SGMA | sgmastandards.org

Figure 2: Case study overview of pharmacovigilance impact of lack of SOGI data collection in clinical trials. Figure adapted from Reference 1.

Figure 4: Screen capture of SGMA's Population Standards Library from sgmastandards.org

Discussion

- SGMA frameworks and standards fill key gaps preventing harmonized SOGI data collection in global clinical trials
- SGMA-ARC-001 defines SOGI population standards architecture
- SGMA-STD-001 SOGI Protocol Implementation Standards extends CDISC by defining clinical logic, protocol implementation methods, and pharmacovigilance governance
- SGMA-IMP-STD-001 describes how sponsors can implement SGMA-STD-001 at the workflow level of detail
- SGMA-STD-HIV-001 and SGMA-GOV-HIV-CV-001 describe how to modernize HIV clinical trials inclusion criteria (See Poster LB64)

Acknowledgments

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References

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Conflict of Interest: G. Kiledjian is Founder and CEO of SGMA. SGMA-STD-HIV-001 is cited in Discussion as the evaluative benchmark; no commercial interests are associated with its use. **Contact**: Lauren.Beach@northwestern.edu; info@sgma.global