

New Effort to Include People With HIV or on PrEP in Clinical Trials [VIDEO]

Of 46 recent clinical trials that led to the approval of cancer drugs, 30 had language excluding people with HIV.

June 21, 2024 By [Trent Straube](#)

When clinical trial researchers write their guidelines and decide on eligible participants, most continue to copy and paste outdated boilerplate language from the early days of the AIDS epidemic. As a result, clinical trials exclude people living with [HIV](#) as well as those who are HIV negative but take antiretrovirals as [pre-exposure prophylaxis \(PrEP\)](#) to prevent HIV. Similarly, [LGBTQ people](#)—also referred to as SGMs for “sexual and gender minorities”—are underrepresented in clinical studies.

This means that these individuals are excluded from lifesaving cancer [clinical trials](#) as well as studies on infectious diseases, such as COVID-19, mpox, syphilis, gonorrhea and hepatitis, many of which disproportionately affect SGMs and people with HIV.

A new initiative by the SGM Alliance, a nonprofit based in Miami, aims to correct that shortcoming. Joining forces with leading pharmaceutical and health care companies, such as AstraZeneca and Gilead Sciences, the alliance has issued a global call to action to support health equity for SGMs (and people with HIV or on PrEP) by having them better represented in clinical trials.

Outdated restrictions from the 1990s have prevented
HIV-positive individuals and those on PrEP from
participating in...

Posted by [SGM Alliance](#) on [Thursday, June 6, 2024](#)

To raise awareness, the alliance also released a video featuring award-winning actor Billy Porter, who is living with HIV and diabetes, along with health experts and SGM Alliance leaders. You can [watch the video on Vimeo](#) and at the top of this article.

A [statement issued by SGM Alliance](#) and signed by the health care leaders states:

“Our companies are dedicated to advancing equal representation of sexual and gender minorities (SGM) in clinical research, life sciences and the evolution of healthcare. We seek to mobilize strategy that will drive industry stakeholders to adequately address historical disparities and champion change, allowing LGBTQIA+ individuals to navigate an equitable health care system with dignity.

“We are proud to join this initiative, spearheaded by the SGM Alliance, as allies of the organization’s mission to amplify SGM voices to ensure that their particular health care needs are addressed and understood. Through this partnership, SGM Alliance is actively engaged in dialogue with standards organizations and governmental stakeholders on setting best practices for diversity, equity, and inclusion. Together, we can combat the systemic disregard of SGM populations in terms of health care access and outcomes.

“To this end, in commemoration of Pride Month, we call on other companies in the health care industry to join us in promoting inclusivity and diversity in clinical studies. Together, we can break barriers and make history—the time to act is now.

“For more information on this first-of-its-kind partnership, visit sgmalliance.org or email press@sgmalliance.org.”

AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Daiichi Sankyo, Eli Lilly, Gilead Sciences, Genentech, Pfizer, StudyKIK, Syneos Health and Takeda Pharmaceuticals have all signed on to the initiative.

SGM Alliance CEO Garo Kiledjian [told The Bay Area Reporter](#) that excluding people with HIV and AIDS from clinical trials made sense back in the 1980s and '90s when they were not expected to live long lives; including them in clinical trials would likely have skewed the resultant data. But the advent, in 1996, of lifesaving HIV meds changed that.

“There are zero arguments about our position because it’s based on fact,” he told the newspaper.

Leading scientists, such as Tom Uldrick, MD, the deputy head of global oncology at the Fred Hutchinson Cancer Center in Seattle, have also been bringing this issue to light. A 2019 Fred Hutch article titled “[Breaking Down HIV Exclusions in Cancer Clinical Trials](#)” noted that Uldrick had “surveyed 46 recent clinical trials that led to the approval of cancer drugs, and he found 30 contained explicit exclusions for patients with HIV and nine others where an exclusion was implied.”

In that same article, HIV advocate Jeff Taylor, who founded the [HIV & Aging Research Project—Palm Springs](#), succinctly declared: “There was a time when there was a reason for exclusions, and that time is over.”