INDUSTRY REPORT

Considerations for LGBTQ+ Inclusion in Clinical Research

Teckro engaged the Center for Information and Study on Clinical Research Participation (CISCRP), an independent non-profit organization, to organize and facilitate a virtual advisory meeting among LGBTQ+ patients and community members. The purpose of this initiative was primarily to help inform clinical study staff and industry on considerations and best practices when engaging with the LGBTQ+ community, ultimately optimizing clinical trial experiences in the future.

The key objectives of this project were to:

- Better understand general healthcare experiences of individuals in the LGBTQ+ community, as well as relationships and interactions with healthcare providers
- Assess awareness of clinical research and potential drivers for participation and retention, as well as highlights and lowlights of past clinical trial experiences
- Identify ways to raise awareness among and better engage the LGBTQ+ community in clinical research

In total, seven participants contributed to four hours of virtual discussion. This paper provides the key findings and recommendations when engaging the LGBTQ+ community in healthcare and clinical research.

Individuals eligible to participate in the advisory meeting were those who self-identified as members of the LGBTQ+ community. They are patients living with a chronic medical condition and/or general advocates in their community. We sought a diverse mix of age and race. The final advisory meeting consisted of seven participants – six reside in the United States and one in Canada. Below are anonymized descriptions of the participants based on the inclusion criteria.

Participant	Chronic Medical Condition	Age	Race	Clinical Research Experience
Gay male	HIV patient	30s	White	Previously participated in observational research
Queer female	Crohn's disease patient	20s	White	No clinical trial experience
Gay male	Prostate cancer/melanoma patient	60s	White	No clinical trial experience
Transgender male	Patient with BRCA1 mutation (high risk for ovarian/breast cancer)	40s	White	Previously participated in observational research
Non-binary person	Ovarian cancer patient	60s	White	Previously participated in a clinical trial for osteoarthritis of the knee
Transgender male	Epilepsy patient/advocate	40s	African American	Previously participated in a clinical trial for pre-exposure prophylaxis (PrEP)
Queer female	Breast cancer patient	30s	Asian/mixed race	No clinical trial experience

General Healthcare Experiences

Overall, the advisors described challenging and largely negative experiences with healthcare and discussed a collective understanding of this sentiment being common across the LGBTQ+ community. Several described experiencing anxiety and discomfort each time they visit a medical facility due to negative, non-affirming, or invasive interactions with medical staff without training in specialized LGBTQ+ care. As a result of stigma and previous poor treatment experiences, the advisors reported that they and others in their communities avoid seeking care, or disclosing their LGBTQ+ identity with healthcare providers.

When disclosing their LGBTQ+ identities, several advisors indicated uncomfortable, ignorant, and offensive treatment by healthcare providers and medical office staff. Specifically, the group discussed providers not having inclusive forms or clinical lines of questioning to capture a range of LGBTQ+ identities. Several advisors talked about the risks they perceive: revealing their pronouns could lead to receiving sub-optimal care and using incorrect pronouns could lead to not receiving care from the most suitable providers.

Advisors are often misgendered and receive inappropriate questions about their identities not relevant to the medical treatment. Several advisors shared experiences where providers have given inaccurate and misaligned medical advice based on the healthcare goals and treatment risks of the gender they were assigned at birth. For example, mandating birth control in conjunction with a treatment known to cause birth defects, confusing a request for a hysterectomy with gender reassignment surgery, requesting menstrual cycle documentation, reviewing breast reconstruction options post mastectomy, etc.

"I had a family doctor who said I didn't need Pap tests because I don't sleep with men. And that's just medically inaccurate."

The group shared that many members of the LGBTQ+ community are estranged from their families as a result of their identity, and discussed the impact this has on the care and support they receive along their healthcare journey. Many providers assume that patients have families at home who are willing and able to assist with care and this is not the case for all LGBTQ+ patients. Several members of the advisory group have undergone or are undergoing treatment for cancers where advocacy has been highly gendered and spoke about feeling excluded when seeking support from patient advocacy communities.

Overall, each of the advisors described a healthcare journey that requires them to find providers who either identify as being part of the LGBTQ+ community or who outwardly promote their experience or training with the community. This training and experience is distinct from the experience several in the group described, of providers attempting to relate to them or prove their "ally" status by sharing a specific personal experience. In fact, there was consensus among the group that providers discussing their personal experiences/connections to LGBTQ+ community via family members or friends is unwanted, performative and self-serving.

Despite having overwhelmingly negative experiences with healthcare in the past, several advisors are beginning to see positive changes in their care and noted certain healthcare systems that are making progress with appropriate LGBTQ + treatment and inclusivity. Those systems that are performing well have diverse representation among their providers and staff and provide patients with the opportunity to choose their providers based on demographic characteristics (e.g., gender, race, ethnicity, LGBTQ+ identity, etc.).

"My primary care physician is gay, and I sought him out because of that. And the facility certainly lists that on their site when you're choosing a doctor, so I did appreciate that."

Most of the group have been able to identify providers or healthcare systems that specialize or have some training in LGBTQ+ health but only after ample personal research/ vetting. One patient also shared their satisfaction with being assigned a case manager, who helped to coordinate care between providers, and provided an outlet to discuss any unpleasant care experiences they may have had based on their LGBTQ+ identity.

Together, the group of advisors shared best practices healthcare providers should employ to help improve experiences for LGBTQ+ patients:

- Do not make assumptions about gender identity/ expression, sexual orientation, or medical history – proactively ask patient their preferred name, pronouns, and partners they are interested in,
- Avoid asking questions related to a perceived, documented or divulged LGBTQ+ identity that are not medically relevant to the issues being treated,
- Ask patients what their medical needs and preferences are and tailor care accordingly when possible,
- Be mindful of the language you use and avoid gendering body parts; treat patients from the perspective of caring for a human body, rather than a person of a particular sex or gender,
- When a patient discloses their LGBTQ+ identity, consider your reaction and be aware of body language, facial expressions, and other actions that could be perceived as reactive or judgmental,
- Reduce the need for patients to "come out" and disclose their LGBTQ+ identity to multiple providers repeatedly – seek patient permission to include a note in their file, and coordinate across providers.

Clinical Research Perceptions and Experiences

Advisors had mixed perceptions of clinical research. Some expressed hesitancy and scepticism towards clinical research, associating it with *experiment, guinea pig*, and *not the standard of care*. Others recognized the importance of clinical research in developing new treatments, and associated the term with *hope*. The group discussed the distrust that the collective LGBTQ+ community has for clinical trials, given prior negative experiences with healthcare in general, and the historical injustices that have occurred with racially/ethnically diverse and LGBTQ+ populations in medical research.

There was consensus across the group that willingness to participate ultimately depends on what the clinical trial was testing and the perceived value of participation for them and their broader communities. For several advisors, access to free or low-cost medication and medical care are significant motivators for participation. A few talked about having an interest in clinical trials but have found them difficult to access due to strict eligibility criteria, limited site locations and complicated tests and procedures required for participation.

Overall, the group had somewhat negative perceptions of pharmaceutical companies, primarily due to the high, seemingly exploitative cost of medications and overall profit motivations. A small number of advisors shared favorable experience, where pharma companies were making efforts to be more inclusive and invite the perspectives of LGBTQ+ individuals to the table.

"I was approached by the doctor, but I engaged with the clinical trial simply because there was no research around trans men on PrEP."

Several advisors have been presented with clinical trials or observational research study opportunities by their doctors and two previously participated in clinical trials. For both, they were motivated primarily by an interest in advancing scientific knowledge and treatment options that include the LGBTQ+ community and their specific disease communities. Those who participated described generally positive experiences with knowledgeable and affirming site staff, thorough and engaging informed consent processes, patient-centered materials, flexible scheduling of study visits, and personalized care coordinators. One patient expressed appreciation for text reminders prior to each clinic visit that were accompanied by links to the visit schedule and the tests/procedures they would be undergoing in the visit. Both patients wanted more support and transparency from site staff related to potential side effects and discomfort associated with drug administration, as well as more timely communication about trial results.

Information Sources

When looking for information on healthcare and clinical studies, most advisors turn to online resources. Some only look to those they considered credible, such as PubMed and Google Scholar and others mentioned vetting information through non-profit advocacy groups or well-known local hospitals/medical facilities. Discussions with peers and other community members were additionally important when considering involvement with a specific provider, medical facility, organization, or research study. Some turned to online forums and community groups (e.g., Facebook groups) to learn from LGBTQ+ peers about their experiences with specific providers, facilities, and sponsors.

Those who had participated in studies were typically referred to studies and resources by their doctors. One patient had seen a study advertised in a community newspaper and reached out to the contact listed for more information. Several advisors talked about the focus of LGBTQ+ health information on issues of sexual health and sexually transmitted disease and less on educating and supporting those seeking general care or those living with and managing chronic conditions.

Improving Clinical Research Awareness and Engagement

On effectively spreading the word about clinical trial opportunities to LGBTQ+ patients, advisors recommended appropriate marketing for the target study population and the inclusion of images, phrases, and language that are representative of and relevant to LGBTQ+ patients. Specifically, sponsors and sites should be mindful of gender-related language/terminology and binary language to be sure they are not unintentionally excluding transgender or non-binary individuals. In any clinical trial-related messaging it is important to clearly convey the purpose of including LGBTQ+ participants – greater medical/scientific understanding, a commitment to principles of diversity and inclusion, the promise to individual patients of advanced treatment, etc. LGBTQ+ community members want to feel included and not tokenized, nor feel that they are being used to "fill a quota" or "check a box."

"Make sure the whole picture is painted. We're being asked and called into this study because it's going to help our community."

Reflecting on the broad distrust of the medical system that is common among LGBTQ+ patients, several advisors suggested partnering with credible community organizations – particularly LGBTQ+ community and specialized health centers – to share clinical trial opportunities and conduct recruitment.

Ideal Clinical Trial Design and Experience

Advisors were asked to brainstorm the ideal clinical trial participation experience for LGBTQ+ community members. A summary is provided here.

If you were to participate in a clinical trial, what would the ideal study clinic or study visit look like?

- Easily accessible, local study clinics that don't require extensive travel – if extensive travel is required, provide reimbursement or transportation assistance,
- Provide a clear agenda of what will happen at each study visit in advance,
- Use forms that are gender neutral and list multiple options for gender identity,
- Include pronouns on nametags of site staff; provide nametags for study participants with their selected pronouns included,
- Design clinic spaces to be gender neutral (i.e., colors, pictures on the wall, all-gender restrooms),
- Make values and mission statement clearly visible; include a flag or other images to visually represent it is a safe space for LGBTQ+ patients,
- Overall, provide options and recognize there is no "one size fits all" approach.

What would you expect from the site staff and study personnel?

- Convey an interest in study participants (i.e., ask participants how they are, share small personal details/make connections),
- Help study participants understand the bigger picture of the research and how it may benefit others in their community,
- Have diverse site staff that are representative of the patient population being studied,
- Provide an opportunity to meet the study lead investigator,
- Ensure site staff are informed and have reviewed participants' chart/medical history before interacting with them.

What other practices, strategies, or supportive resources could be implemented by site staff and study personnel to promote greater inclusivity of the LGBTQ+ community in clinical trials and reduce the overall burden of trial participation?

- Provide study participants with swag (e.g. pen, notebook, information portfolio) so they feel appreciated, and like part of the team,
- Ensure site staff are trained on LGBTQ+ health and how to appropriately interact with LGBTQ+ patients,
- Provide a list of study FAQs to participants that they can take home; have plain language resources as well as more advanced scientific content available,
- Provide information on confidentiality and data privacy protection measures in place,
- Provide study participants with a travel stipend or travel reimbursement; provide incentives or compensation for time spent at visits,
- Consider the varying socioeconomic and living situations of study participants; incorporate flexibility into site procedures to accommodate their needs (e.g., allow participants to arrive at clinic early for visits/leave late if needed),
- Provide a care navigator or case manager for study participants who may need additional support or coordination with their other medical care,
- After participation, ensure long term follow-up/check-ins with participants are maintained; share the results/ progression of study when available.

What clinical trial model (in-person, remote/ virtual, or hybrid) would be most appealing to you?

A hybrid model is preferred among most of the advisors. A hybrid approach gives reassurance of seeing a provider in-person and being thoroughly monitored during clinic visits, along with the convenience and flexibility of completing some study activities at home.

However, there are some considerations that should be discussed with the patient:

- Access to personal technology required to support remote trials and a willingness to use technology for patient-facing data collection, reminders, and to receive encouragement from the care team,
- Comfort levels of allowing medical providers to enter their home, which some patients may value to reduce the burden of traveling to a clinic and alleviate anxiety in medical settings; others may feel it is intrusive and may not have living situations where they have privacy or are comfortably "out,"
- Comfort with telehealth and virtual visits, which some patients will appreciate the convenience of, while others may have privacy concerns and may not have a safe location to take calls,
- Options, if possible, to have trial medication delivered to the participant's home,
- Options, if possible, to meet study staff virtually before meeting in-person so patients feel safer and less anxious at the first in-person visit.

Health Technology Perceptions and Experiences

Perceptions of health technology varied among advisors with some expressing appreciation for the convenience and ease of tracking health and medications with smartphones and wearables and others feeling skeptical of health technology due to concerns over data privacy and protection. The majority were currently using smartphones and Apple watches as well as apps and patient portals associated with their primary care facility. The most frequently used features and capabilities of these technologies included medication reminders, fitness tracking, appointment scheduling, requesting prescription refills, and viewing lab results. Several advisors voiced a preference to text or direct message their providers through an app or patient portal versus traditional methods of communication (phone, email, etc.)

"I think that's the most fantastic for me. Because I don't like talking to people on the phone, especially my doctors. I literally just send a text through the app and I love it."

The majority of advisors would be willing to use a smartphone or wearable device for health monitoring in a clinical trial, but noted a few key considerations:

- Provide a clear explanation of the types of data being collected and the measures in place to protect that data and maintain participant anonymity/confidentiality,
- Provide clear instructions on how to use all technology and have support available in the instance that technology breaks or malfunctions – support staff should be trained in appropriate interactions with LGBTQ+ patients,
- If a wearable is used, consider participants' privacy and physical safety – is the device clearly visible/noticeable to draw questions or put the patient at risk of theft?

Conclusion

Diversity, equity and inclusion in clinical research starts with awareness of the perceptions of different communities. Repairing and reducing mistrust within underrepresented communities requires time and effort from medical providers; who must learn to recognize the obstacles and increase sensitivity for inclusion. As a broad category of community, it is important to recognize that there is no one-size-fits-all to engaging LGBTQ+ individuals in clinical research or in healthcare overall. Through the advisory meeting hosted by CISCRP, our goal was to surface some of the issues that create barriers to care for the LGBTQ+ community.

Out of the advisory board meeting, we believe there are some simple steps for inclusivity of LGBTQ+ individuals and the LGBTQ+ community in all aspects of care:

- Remove unnecessarily gendered language, imagery and décor from forms, patient materials, and clinical areas,
- Create inclusive options on multiple-choice forms to account for all LGBTQ+ identities,
- Refine approaches to clinical lines of questioning to ensure sensitivity to LGBTQ+ identities and focus on questions required for care and research,
- Include trusted LGBTQ+ advocacy organizations and local community centers in health and research initiatives.

Through projects such as this collaboration between Teckro, CISCRP and our community advisors, we hope to invite patient and prospective patient voices from a breadth of communities to inform actions that advance inclusion in clinical research. For more information or to talk about the advisory board meeting in greater detail, please contact your Teckro account representative or email **connect@teckro.com**.

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