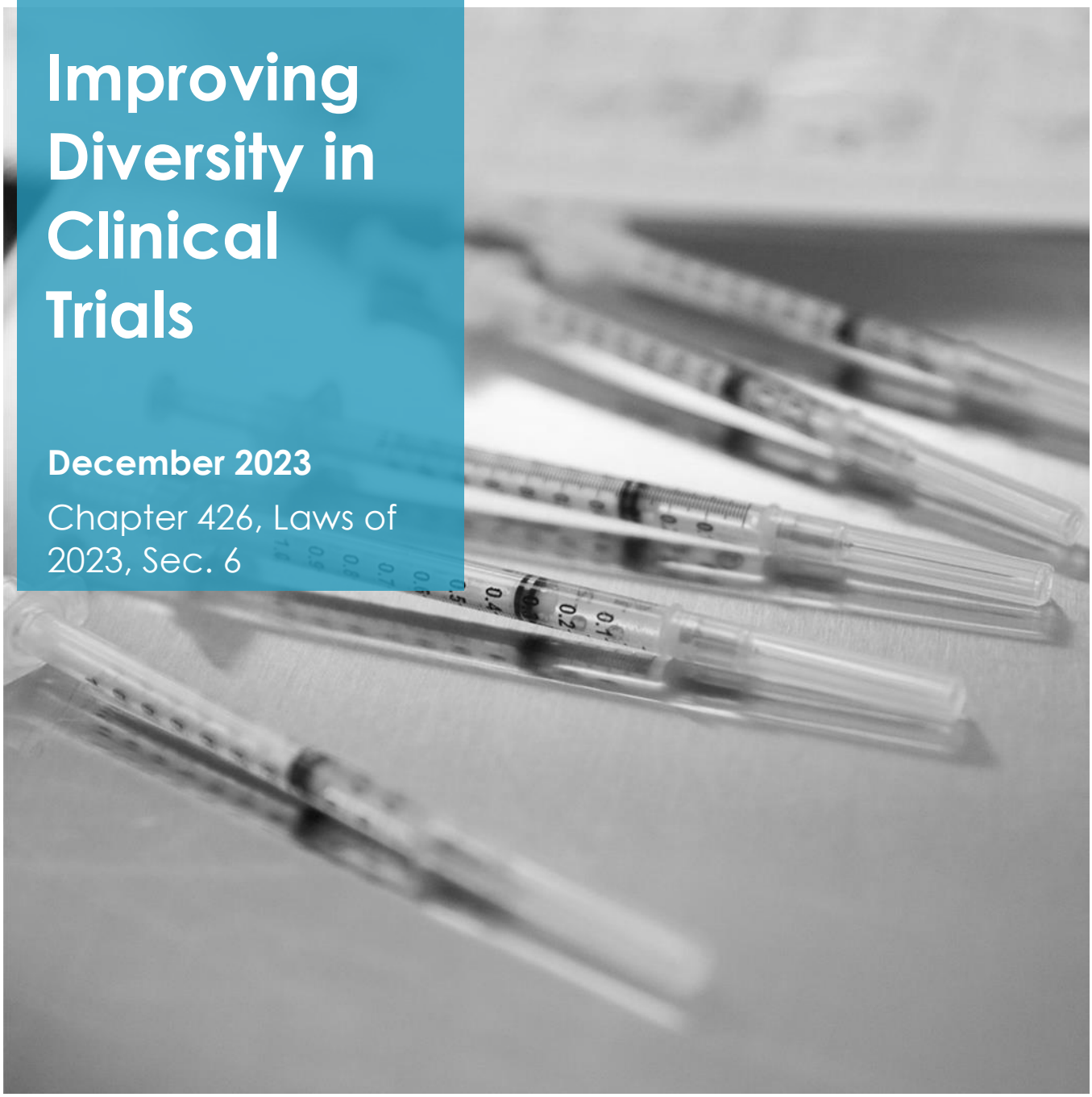
Report to the Legislature

Improving Diversity in Clinical Trials



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Executive Summary

Clinical trial research is a fundamental step in the development of novel treatment, whether for drugs, medical devices, or behavioral change interventions, and it helps researchers understand both the safety and efficacy of new treatments. Diversity among clinical trial participants is a critical element in understanding research findings, as a patient's response to treatment can greatly depend on demographic characteristics like race, ethnicity, sex, and age. Historically, however, clinical trials have not been comprised of diverse participants, which has limited our understanding of treatment options for Black, Indigenous, and other People of Color (BIPOC) populations, women, and other historically and consistently marginalized populations.

Efforts to improve diversity at the federal and research institution levels have been ongoing for decades. While improvements have been made, we still see clinical trial underrepresentation for populations that are already experiencing disparities in health outcomes. To better understand who is underrepresented in clinical trials, the barriers they face, and how researchers can better engage underrepresented communities and demographic groups in Washington State, the Washington State Legislature passed Second Substitute House Bill 1745 during the 2023 legislative session.

Section 6 of the bill tasks the Washington State Department of Health (Department) to consult with the University of Washington (UW), Washington State University (WSU), other relevant research organizations, the Andy Hill Cancer Research Endowment (CARE) Fund, Washington State community health boards and initiatives, and community-based organizations (CBOs) to analyze and provide recommendations on:

1. What demographic groups and populations are currently represented and underrepresented in clinical trials in Washington, including geographic representation;
2. Barriers for persons who are members of underrepresented demographic groups to participate in clinical trials in Washington, including barriers related to transportation; and
3. Approaches for how clinical trials can successfully partner with community-based organizations and others to provide outreach to underrepresented communities.

To complete this report, the Department consulted with UW, WSU, Andy Hill CARE Fund, Seattle Children's Hospital, Fred Hutchinson Cancer Center, the Department's Community Collaborative, the Commission on Asian and Pacific American Affairs, and the Commission on Hispanic Affairs. In addition, the Department conducted interviews and surveys through its Center for Health Promotion and Education and conducted a review of the scientific literature.

Due to current practices around demographic data collection, aggregation, and reporting, it is not currently possible to get an accurate picture of representation in clinical trials in Washington without considerable time and effort by research institutions that would extend beyond the time frame provided for this report. This effort would likely require review and

approval by one or more of the Washington State Institutional Review Board (IRB), the Portland Area Indian Health Service (IHS) IRB, and individual IRBs for each clinical research institution. Further, there is not clearly established guidance for defining representation in clinical trials or agreement upon which demographic data is salient to clinical research findings and analysis.

Despite these limitations, the Department identified general barriers to clinical trial participation, solutions for addressing these barriers, and approaches for partnership between clinical trial researchers, their institutions, and CBOs. Importantly, the Department found that barriers to clinical trial participation are myriad and they can and do vary by population and by disease or condition being studied. Additionally, the recommendations identified throughout the Department's engagement, consultation, and research, require sufficient funding to support community involvement and changes to how clinical trial researchers and research institutions facilitate improved clinical trial diversity.

Due to these findings, the recommendations provided within this report should be understood as a starting point, but not as an exhaustive list of solutions to this complex problem. Clinical research institutions and CBOs will likely require funding support to identify and implement appropriate solutions. Ultimately, to meaningfully improve diversity among clinical trial participants, clinical research institutions will need to develop partnerships with tribes and underrepresented communities and populations to identify tailored solutions and build trusting, collaborative relationships.

Background

An individual's age, sex, race, ethnicity, and other demographic characteristics all influence how they respond to medical treatment.[1] For this reason, clinical trials for drugs, medical devices, and behavior change require diverse representation among trial participants, which allows for generalizable population-level results and disaggregated analysis for specific demographic groups. Clear understanding about the safety and efficacy of treatments across different populations improves a health care provider's ability to offer competent and effective care to their patients. For populations that already experience structural health inequities and lower access to health care, lack of clinical trial diversity only serves to increase those disparities by limiting our understanding of how a treatment may or may not work for them.[2]

Historically, clinical trials have been predominantly comprised of non-Hispanic white, male participants. Where clinical trials were focused on women or Black, Indigenous, and other People of Color (BIPOC) populations, violence and harm were intentionally inflicted upon participants in the name of scientific advancement. In the 1990s, federal legislation was passed to seek to improve representation among women and BIPOC populations in clinical trials and to further protect patients and trial participants from harm.[3] Still today, after decades of efforts to protect clinical trial participants and improve clinical trial representation, we continue to see a lack of diversity within clinical trials.

Historical Legacies of Medical Research

The United States has a long history of medical violence committed against African Americans, Indigenous peoples, people with disabilities, women, immigrants, and other vulnerable or exploited populations. This medical violence was predominantly committed in the name of medical research or the provision of health care, but in reality has served to sterilize populations or exploit and steal from individuals in these populations to further medical and scientific knowledge. Instances of medical violence, eugenics, exploitation, and coerced experimentation include:

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[1] National Institute on Minority Health and Health Disparities (2023). *Diversity and Inclusion in Clinical Trials*. National Institutes of Health. https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html

[2] Gray, D.M., Nolan, T.S., Gregory, J., & Joseph, J.J. (2021). Diversity in clinical trials: an opportunity and imperative for community engagement. *The Lancet Gastroenterology & Hepatology, 6*(8), 605-607. https://doi.org/10.1016/S2468-1253(21)00228-4

[3] National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research; Bibbins-Domingo K, Helman A, editors. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington (DC): National Academies Press (US); 2022 May 17. 3, Policies to Improve Clinical Trial and Research Diversity: History and Future Directions. Available from: https://www.ncbi.nlm.nih.gov/books/NBK584404/

- The development of gynecology in the United States through forced experimentation on enslaved African American women in the 19th century;
- Compulsory sterilization of Native American, African American, and Puerto Rican women throughout the 20th century, in the name of eugenics;
- Eugenics laws permitting the sterilization of disabled women, upheld by the 1924 Supreme Court case, Buck v. Bell;
- The Tuskegee Syphilis study, which ran through the 1970s and left Black men untreated for Syphilis without their knowledge or consent, despite effective treatment being available;
- The theft of DNA to contribute to medical advancements, including the theft of DNA from Henrietta Lacks, an African American woman, and Native American tribal members, such as the Havasupai tribal members;
- Modern-day sterilization of prisoners and immigrant detainees in the United States.[4,5,6,7,8,9]

The impact from these atrocities is still felt today and contributes to a strong mistrust in health care and medical research institutions and practitioners. While mistrust and relationship building will be addressed later in this report, it is critical to acknowledge and highlight up front the role this history plays in underrepresentation of marginalized populations in clinical research trials.

Improving Diversity in Clinical Trials in Washington State

In 2023, the Washington State legislature passed Second Substitute House Bill 1745: Improving Diversity in Clinical Trials (2SHB 1745), which directs the Washington State Department of Health (Department) to report on barriers and solutions to diversity in clinical research trials. Section 6 of the bill tasks the Department to consult with the University of Washington (UW), Washington State University (WSU), other relevant research organizations, the Andy Hill Cancer Research Endowment (CARE) Fund, Washington State community health boards and initiatives, and community-based organizations (CBOs) to analyze and provide recommendations on:

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[4] Nuriddin, A., Mooney, G., & White, A.I.R. (2020). Reckoning with histories of medical racism and violence in the USA. *The Lancet, 396*(10256), 949-951. https://doi.org/10.1016/S0140-6736(20)32032-8

[5] Manian, M. (2020, September 29). *Immigration Detention and Coerced Sterilization: History Tragically Repeats Itself*. American Civil Liberties Union. https://www.aclu.org/news/immigrants-rights/immigration-detention-and-coerced-sterilization-history-tragically-repeats-itself

[6] Blakemore, E. (2023, July 11). *Why the Navajo Nation Banned Genetic Research*. History. https://www.history.com/news/why-the-navajo-nation-banned-genetic-research

[7] Chappell, B. (2013, July 9). *California's Prison Sterilizations Reportedly Echo Eugenics Era*. NPR. https://www.npr.org/sections/thetwo-way/2013/07/09/200444613/californias-prison-sterilizations-reportedly-echoes-eugenics-era

[8] Harmon, A (2010, April 21). Indian Tribe Wins Fight to Limit Research of Its DNA. The New York Times.

[9] Capriccioso, R (2010, April 21). Havasupai blood case settled. Indian Country Today.

1. What demographic groups and populations are currently represented and underrepresented in clinical trials in Washington, including geographic representation;
2. Barriers for persons who are members of underrepresented demographic groups to participate in clinical trials in Washington, including barriers related to transportation; and
3. Approaches for how clinical trials can successfully partner with community-based organizations and others to provide outreach to underrepresented communities.

In the bill, underrepresented demographic groups and communities are those defined as being "more likely to be historically marginalized and less likely to be included in research and clinical trials represented by race, sex, sexual orientation, socioeconomic status, age, and geographic location."

The analyses and recommendations included in this report will serve as a starting point for clinical trial researchers, research organizations, and policymakers in determining appropriate courses of action to improve diversity in clinical trial research. Clinical trial diversity is a heavily researched area, with longstanding efforts to improve trial diversity at both the federal and research organization levels. Scientific literature supports conflicting methods for defining clinical trial representation and suggests that barriers and facilitators to clinical trial participation vary by disease or condition being studied and by demographic sub-group, which means that solutions will not take a one-size-fits all approach. (See Appendix D for additional clinical trial diversity resources collated by the Fred Hutchinson Cancer Center, University of Washington, and Seattle Children's Cancer Consortium's Task Force on Inclusion & Equity in Research).

Department of Health's Approach

To evaluate the questions posed by Section 6 of 2SHB 1745 and provide recommendations for improving diversity in clinical trials, the Department consulted with the UW, WSU, Seattle Children's Hospital, Fred Hutchinson Cancer Center, and the Andy Hill CARE Fund. Consultation with these clinical trial research partners consisted of two work groups. The first focused on community engagement and partnership between clinical trial researchers and underrepresented communities. The second focused on data and literature regarding representation in clinical trials.

For further consultation, the Department released a Dear Tribal Leader and Tribal Partners Letter, requested consultation with Washington's community health boards and initiatives, and engaged the Department's Community Collaborative. Resulting conversations with the Washington State Commission on Asian and Pacific American Affairs (CAPAA), the Washington State Commission on Hispanic Affairs (CHA), and the Department's Community Collaborative provided insights into partnership opportunities between clinical trial researchers and CBOs. Conversations with CAPAA and CHA also supported our findings on barriers to participation in clinical trial research.

To understand barriers faced by clinical trial participants and potential participants, the Department's Center for Health Promotion and Education engaged the Health Hub Market Research Online Community (MROC) and conducted in-language surveys in 16 languages for participants who speak a primary language other than English plus a 17th in-language survey in American Sign Language.

Limitations

Comprehensively addressing the questions posed by Section 6 of 2SHB 1745 would venture into the realm of human subject research and require an Institutional Review Board (IRB) review and approval, which the timeline of this report did not permit. The Department's initial consultations with institutional research partners underscored that the matter of diversity in clinical trial research is more complex than suggested by the questions posed in the bill.

Evaluating the current state of clinical trial diversity for underrepresented demographic groups in Washington requires additional time, resources, collaboration with communities, and coordination between clinical researchers, their IRBs, the Washington State IRB (WSIRB), and the Portland Area Indian Health Service (IHS) IRB. To fully address all aspects of Section 6 of 2SHB 1745, four specific needs were not feasible due to the timeframe for this report:

- The need for IRB approval to do new research that could be used to address the objectives in Section 6
- The depth of community relationship building, and engagement required to detail all underrepresented group's perspectives and experiences
- Appropriately defining underrepresentation for specific populations
- Aggregation of generalizable clinical trials data that reports on recruitment and participation for underrepresented groups

Generalizability of Findings

Although the Department's engagement with the Community Collaborative, Health Hub MROC, in-language survey participants, CAPAA, and CHA all provided valuable insights to inform this report, it is important to note that these are not generalizable findings. Rather, these activities identified important areas for further study, research, and community engagement and partnership by clinical research institutions in Washington State and the Washington State legislature.

Where the Department consulted with community members and community leaders in the Community Collaborative, questions were limited to the topic of partnership and collaboration between research institutions and community-based organizations. Community members and leaders were not asked about personal experiences, barriers, or identities. Rather, they were asked broadly about how these partnerships could occur and be effective. No personally

identifiable information was collected from members or leaders within the Community Collaborative.

When engaging with Washington State health board and initiative commissioners, the Department requested broad feedback and comments on the report components listed in the bill, and again did not ask about or collect information about personal experiences with barriers or personal opinions about underrepresentation in clinical trials.

Finally, the Department's Health Hub MROC and in-language survey programs have an IRB exemption for 2023, although findings from these activities are not intended to act as generalizable knowledge about the topic under consideration, nor are they structured to allow for generalizable findings. Rather, they are intended as policy informing programs. While these programs seek diverse representation among participants, they are not structured or conducted in a manner that allows for conclusions to be made by demographic groupings of participants.

Producing generalizable analysis of clinical trial data to determine which demographic groups and communities are underrepresented likely requires original human subject research. This would require review by the WSIRB, at minimum. At maximum, it might require additional review by institutional and Portland Area IHS IRBs. In addition, the growth of community-based IRBs and research-ethics boards suggests clinical researchers and institutions may need additional layers of community review and involvement throughout the process.[10] Regardless, this research should be community-driven and in direct collaboration with communities and tribes across our state. This is especially true if seeking access to any data that includes identifiers, or when collecting new data about the experiences and perspectives of potentially underrepresented groups that may participate in any clinical trials.

Representation in Clinical Trials

The first objective in Section 6 of 2SHB 1745 is for the Department to analyze which demographic groups and populations are currently represented and underrepresented in clinical trials in Washington, including geographic representation. While seemingly straightforward, the Department faced three major challenges in identifying these groups:

1. There is no clear or established definition of underrepresentation or representation in clinical trials
2. Demographic data beyond sex, race, and ethnicity on clinical trial participants is not consistently collected or reported by clinical trial researchers. Sex is consistently collected, but race and ethnicity do not have standardized definitions that allow for direct comparisons between studies.

[10] Shore N, Drew E, Brazauskas R, Seifer SD. Relationships between community-based processes for research ethics review and institution-based IRBs: a national study. J Empir Res Hum Res Ethics. 2011 Jun;6(2):13-21. doi: 10.1525/jer.2011.6.2.13. PMID: 21680973.

3. Access to demographic data on clinical trial participants is not readily accessible beyond funding agency requirements. Funding agencies may not require collection for all types of underrepresented demographics cited in the bill.

Defining Underrepresentation

Inclusion of underrepresented populations in clinical trials is not a new challenge nor is it unique to Washington. Inclusion of women and underrepresented racial and ethnic groups has been a federal policy priority for several decades, and studies consistently show that the country continues to face significant problems increasing diversity, particularly amongst American Indian and Alaska Native (AI/AN), Black, and Hispanic populations.[11] Some advocate for a population representation approach to identifying benchmarks for recruitment of underrepresented population.[12] Others suggest that a disease burden approach will yield more accurate and generalizable interventions, particularly for underrepresented groups that have a higher rate of specific diseases (e.g., cardiovascular diseases and BIPOC populations).[13]

Efforts to improve data collection and reporting continue. In 2015, the Food & Drug Administration (FDA) began reporting on diversity of participants in clinical trials with the Drug Trials Snapshots initiative to improve transparency.[14] This includes both annual reports, and an aggregate report covering clinical trials from 2015-2019. The Drug Trial Snapshots reports participation rates by sex (women), race (white, black, and Asian), ethnicity (Hispanic), and age (65 years and older) for novel drug trials across three main therapeutic areas: Oncology, Neurology, and Infectious Diseases. The 2020 snapshot shows overall participation across these three domains, and the participation rates for 54 novel drugs trials. Table 1 compares the demographics reported in the snapshot to the nation's population.[15] While those age 65 and older are overrepresented in clinical trials, this implies that younger populations are underrepresented. White populations are overrepresented, while Black and Hispanic populations are underrepresented. The FDA's report excludes AI/AN and Native Hawaiian and other Pacific Islander (NHOPI) populations and does not attempt to report on other forms of

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[11] Bibbins-Domingo K, Helman A, Dzau VJ. The Imperative for Diversity and Inclusion in Clinical Trials and Health Research Participation. JAMA. 2022 Jun 21;327(23):2283-2284. doi: 10.1001/jama.2022.9083. PMID: 35579885.
[12] Chen S, Li J. Participation of Black US Residents in Clinical Trials of 24 Cardiovascular Drugs Granted FDA Approval, 2006-2020. *JAMA Netw Open.* 2021;4(3):e212640. doi:10.1001/jamanetworkopen.2021.2640
[13] Medpace. (2023). *Cardiovascular Clinical Trials with Patient Diversity: Challenges and Considerations*. https://www.medpace.com/wp-content/uploads/2023/03/Article-Cardiovascular-Clinical-Trials-with-Patient-Diversity-Challenges-and-Considerations.pdf#:~:text=Cardiovascular%20clinical%20trials%20must%20have%20a%20diversity%20plan,emphasizing%20the%20need%20for%20diversity%20in%20clinical%20trials.
[14] U.S. Food & Drug Administration. (2021, February). *2020 Drug Trials Snapshots Summary Report*. https://www.fda.gov/media/145718/download?attachment
[15] U.S. Census Bureau. (2022). *QuickFacts: United States*. https://www.census.gov/quickfacts/fact/table/US/POP010220

diversity including gender identity, sexual orientation, socio-economic status, language, immigration, disability status, or place.

Table 1: Comparing Demographics in Clinical Trials and the United States Population (2020)

Demographic Groups	Clinical Trial Population	US Census Population
Age 65 and Older	30%	17%
Asian	6%	6%
Black or African American	8%	14%
Hispanic	11%	19%
White	75%	59%
Women	56%	50%

Data Source(s): FDA 2020 Drug Trial Snapshots, U.S. Census Bureau Quick Facts (2020)

One approach to assessing diversity in clinical trials uses both objective population-representative benchmarking and disease burden (using mortality outcomes) criteria and reveals significant challenges with this approach.[16] The study compares clinical trial demographic diversity data using National Institutes of Health (NIH)-mandated diversity variables (sex, ethnicity, race), other underrepresented groups (age 80 and over, disability, gender identity, and sexual orientation), and intersectionality or overlap of underrepresented populations to population data from the U.S. Census Bureau. Of the 162 clinical trials included in the study,

- 90% reported sex of participants
- None reported sexual orientation
- 50% reported participants identifying as African American
- 30% reported participants identifying as Asian and Asian American
- 20% reported participants identifying as American Indian or Alaska Native
- Less than 10% reported participants identifying as Native Hawaiian or Pacific Islander
- Less than 66% included breakdowns of racial categories needed for benchmarking
- 90% did not report socioeconomic status, disability status, or living arrangements

[16] National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research; Bibbins-Domingo K, Helman A, editors. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington (DC): National Academies Press (US); 2022 May 17. Appendix C, Improving Representativeness in Clinical Trials and Research: Facilitators to Recruitment and Retention of Underrepresented Groups. Available from: https://www.ncbi.nlm.nih.gov/books/NBK584402/

- None reported on intersectionality of multiple underrepresented characteristics

The study points to the challenges using objective population-representative benchmarking and mortality (disease burden) data methods to evaluate the inclusion of underrepresented populations in clinical trials. Significant challenges include:

- Randomly selected clinical trials do not consistently report on all three NIH-mandated diversity variables, which is the bare minimum for assessing diversity
- The lack of reporting on additional underrepresented populations identified by 2SHB 1745
- Accurately calculating population-representation of underrepresented groups
- Need for relevant disease burden or mortality outcome data for underrepresented populations
- Making comparisons at the appropriate geographic levels
- How to assess clinical trials with either recruitment or treatment sites that are outside of Washington.
- This report also finds that only 45 percent of clinical trials included in *ClinicalTrials.gov* conducted in Washington report their baseline characteristics (see the *ClinicalTrials.gov* Database section)

Data Limitations

Beyond a lack of consensus on definitions for representation in clinical trials, the Department faced significant challenges securing clinical trial data. Institutions cited in 2SHB 1745 do not require clinical researchers to collect specific types of demographic data. Clinical researchers are expected to abide by federal regulations governing human subjects research which are verified by each institution's IRB. Depending upon the funding source, clinical research might be required to meet the minimum reporting requirements set by the NIH, which include federal law (42 USC 289a02) mandating the inclusion of women and minorities, and NIH policy (NOT-OD-18-014) mandating that clinical research include sex/gender, race, and ethnicity. The NIH requires this information be submitted to the *ClinicalTrials.gov* database.

Institutions have not previously needed to centralize clinical trial data collection and cannot currently report on all underrepresented demographic groups defined in 2SHB 1745. Even when institutions are prepared to independently report on diversity in clinical trials, they will not always have full representations of each type of underrepresented group, depending on the nature of the research they conduct. Demographic information is only collected in research studies if linked to the study design, hypothesis, or theoretical or biological models. Collection of all types of demographic information may not only be superfluous but may be deemed as an unethical practice. Requesting demographic information not directly relevant to the study could be seen as stigmatizing or produce a chilling effect.

In addition, the UW provided an overview of their clinical trials management system and participant demographic data from a selection of clinical research studies, including but not limited to clinical trials of drugs and medical devices, from FY2019-FY2023, and including a limited number of sites outside of Washington State (see Appendix E). This data is limited and was provided after the completion of this report, demonstrating that additional time and resources are required to comprehensively account for clinical trial representation across the state.

To overcome these limitations, the Department did a preliminary analysis of *ClinicalTrials.gov* data, which did not require WSIRB approval or waiver due to the limited nature of the analysis (see the ClinicalTrials.gov Database section). Researchers should submit WSIRB applications if using these data beyond the brief overview below.

ClinicalTrials.gov Database

The *ClinicalTrials.gov* database maintained by the NIH's National Library of Medicine is the most comprehensive and authoritative data source when identifying clinical trials conducted in Washington.[17] The resource does not necessarily include every single clinical trial conducted in the country. Study sponsors and investigators submit studies based on laws, policies, or by choice. However, FDAAA 801 mandates that basic results are reported for applicable clinical trials involving drugs or devices approved by the FDA. Applicable clinical trials include the following criteria:

- Phase 2 to 4 interventional studies;
- Studies involving drugs, biological products, and medical devices regulated by the FDA; and
- Studies having at least one site in the United States or are conducted under an investigational new drug application or investigational device exemption; and
- Studies initiated or ongoing as of September 27, 2007, or later.[18]

Unfortunately, the database is not suitable for aggregate analyses of diversity in clinical trials. To address the challenge of systematic analysis, the Clinical Trials Transformational Initiative created the Aggregate Analysis of ClinicalTrials.gov (AACT) Database.[19] The AACT is a publicly available database that includes all information reported in *ClinicalTrials.gov* and can be mined for analysis of demographic representation in clinical trials.

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[17] National Library of Medicine. (n.d.). *ClinicalTrials.gov*. National Institutes of Health. https://www.clinicaltrials.gov/

[18] Tse T, Williams RJ, Zarin DA. Update on Registration of Clinical Trials in ClinicalTrials.gov. Chest. 2009 Jul;136(1):304-305. doi: 10.1378/chest.09-1219. PMID: 19584213; PMCID: PMC2821288.

[19] Clinical Trials Transformation Initiative. (2016). *Researcher's Guide to Using Aggregate Analysis of ClinicalTrials.gov (AACT) Database*. https://aact.ctti-clinicaltrials.org/points_to_consider

At minimum, *ClinicalTrials.gov* and the AACT database includes the Study Record, Condition/Disease, and Intervention/Treatment. A fewer number include the Results and/or the Study Protocols. The Study Protocol is important for understanding a study's objectives, design, type of intervention, population of interest, inclusion criteria, statistical methods, ethical commitments, and the scientific rationale for conducting the study. Combined, the Study Record, Study Protocols, and Results allow researchers to explore trial locations, eligibility criteria, the purpose of the study, the intended population, recruitment strategies and barriers, participant demographics, clinical trial type and disease studied.

It is important to note that clinical researchers are required to decide which demographic characteristics are relevant to the study. Therefore, many studies do not report on one or more types of demographic diversity specified in 2SHB 1745. Table 2 summarizes the availability of Results and Study Protocols for clinical trials conducted in Washington. Of the 13,365 clinical trials reported, only 45% include the Results, 19% include the Study Protocols, and 18% include both Results and the Study Protocols.

Despite gaps in data reporting, *ClinicalTrials.gov* and the AACT remain the most comprehensive, publicly available, data source of clinical trials conducted in Washington, including trials at the University of Washington, the Fred Hutchinson Cancer Center, and Washington State University.

Table 2: Clinical Trials in Washington (as of Oct 20, 2023)[1]

	All Studies[2]		Studies Started Since Jan 18, 2017[2]	
Clinical Trials by Status and Results	Number	Percentage[3]	Number	Percentage[3]
Total Number of Clinical Trials	13,365		4,281	
Trials Publishing Results	6,033	45%	1,091	25%
Trials Publishing Study Protocols	2,543	19%	1,150	27%
Trials Publishing Study Protocols and Results	2,470	18%	1,091	25%
Total Number of Completed Trials	8,594	64%	1,352	32%
Completed Trials Publishing Results	4,854	36%	748	17%
Completed trials Publishing Study Protocols and Results	1,777	13%	748	17%
Active (not recruiting) Trials with Study Protocols and Results	257	2%	100	2%
Recruiting or Enrolling trials by Invitation with Study Protocols and Results	2	<.01%	0	0%

Data Notes: [1]Data pulled from ClinicalTrials.gov database as of 10/20/23. Studies updated daily.

[2]Database includes studies starting as early as July 1994. FDAAA 801 Final Rule clarifying and expanding race and ethnicity reporting obligations took effect Jan 18, 2017.

[3]Percentages are rounded to the nearest percent and calculated using the Total Number of Clinical Trials for All Studies (n=13,365) or Studies Started Since Jan 18, 2017 (n=4,281)

Barriers to Participation in Clinical Trials

The second objective in Section 6 of 2SHB 1745 asks the Department to analyze barriers that persons from underrepresented demographic groups face regarding participation in clinical trials in Washington, including barriers related to transportation. Because the matter of which demographic groups are underrepresented in Washington State is not readily ascertainable, the Department conducted a review of the scientific literature and conducted surveys through the Health Hub Market Research Online Community (MROC) and its in-language survey community to understand barriers to participation in clinical trials generally, and those experienced by individuals from underrepresented communities as defined by 2SHB 1745.

Barriers in the Literature

Barriers to participation in clinical trials are vast and well documented in the literature. They range from upstream to downstream barriers, occurring at the systems and policy level, researcher or clinician level, and individual participant level. Commonly reported barriers reported include:

- **Study Burden:** concerns about the lack of or cost of transportation, time commitment and work schedule conflicts, childcare or other family care matters;
- **Lack of information:** lack of communication and education about the clinical trial process, information being communicated in a manner that does not support understanding in potential participants, or patient concerns going unaddressed;
- **Fear and anxiety:** fear of randomization, receiving a placebo, the risk or side effects associated with participation, or even the risk of receiving a new diagnosis when the potential participant otherwise feels healthy; and
- **Mistrust:** mistrust of the medical system, the pharmaceutical industry or health care providers due to historical and modern instances of medical experimentation and harm, or because of personal negative experiences with the health care system, and concerns about being exploited or experimented on through trial participation. [20,21,22]

These barriers are considered acceptance or refusal barriers, as they arise when a potential participant is faced with deciding whether to enroll in a clinical trial study. Notably, barriers that potential participants experience vary by the disease or condition being studied and by demographic population, meaning there will often not be a one-size-fits-all solution available for these types of barriers.

Much of the literature on barriers to participation in clinical trials covers barriers related to acceptance or refusal of participation, however it does acknowledge barriers related to awareness and opportunity to participate. Barriers related to awareness of clinical trials refer to awareness that a trial is taking place. Following awareness of a clinical trial, individuals must be given the opportunity to participate before they can reach barriers related to acceptance or refusal. Barriers related to opportunity can reflect structural or systemic factors, rather than factors related to participants. One analysis found that only 9% of Americans reported being

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[20] Office of Research on Women's Health. (n.d.). *Review of the Literature: Primary Barriers and Facilitators to Participation in Clinical Research*. National Institutes of Health. https://orwh.od.nih.gov/sites/orwh/files/docs/orwh_outreach_toolkit_litreview.pdf

[21] Houghton C, Dowling M, Meskell P, Hunter A, Gardner H, Conway A, Treweek S, Sutcliffe K, Noyes J, Devane D, Nicholas JR, Biesty LM. Factors that impact on recruitment to randomised trials in health care: a qualitative evidence synthesis. Cochrane Database of Systematic Reviews 2020, Issue 10. Art. No.: MR000045. DOI: 10.1002/14651858.MR000045.pub2.

[22] Rodríguez-Torres, E., González-Pérez, M.M., & Díaz-Pérez, C. (2021). Barriers and facilitators to the participation of subjects in clinical trials: An overview of reviews. *Contemporary Clinical Trials Communications, 23*(100829). https://doi.org/10.1016/j.conctc.2021.100829

invited to participate in a trial study.[23] Two major barriers related to opportunity are access to health care and eligibility criteria.

A major avenue to participation in clinical trials is referral from an individual's health care provider, as participation in a clinical trial can occur when traditional treatment options have failed for a patient. The FDA suggests that "[o]ne good way to find out if there are any clinical trials that might help you is to ask your doctor."[24] Research also shows that "a majority of Americans (59%) would go to their health care provider first if they needed information about a clinical trial."[25]

Reliance on referrals from healthcare providers introduces multiple barriers to participation in clinical trials for patients. Most notably, not everyone has access to healthcare, and disparities in accessing care are influenced by social drivers of health. Data from the Washington State Office of Financial Management show a significant disparity in accessing preventive care for those with Medicaid insurance coverage compared to those with commercial insurance or Medicare Advantage, suggesting that there are barriers to participation driven by socioeconomic status.[26]

Further, not everyone who has access to healthcare has access to culturally appropriate or responsive healthcare. A Commissioner from the Washington State Commission on Asian and Pacific American Affairs noted that Korean Americans in Washington often travel to South Korea for routine medical care, where they will be screened for stomach cancer, which they experience at disproportionately higher rates than those from other racial or ethnic backgrounds.[27] Anecdotally, Korean and Korean American individuals in Washington State do not regularly receive this important screening. Without a diagnosis, an individual would not have access to clinical trial participation.

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[23] National Cancer Institute. (2022). *Health Information National Trends Survey Number 48*. National Institutes of Health. https://hints.cancer.gov/docs/Briefs/HINTS_Brief_48.pdf#:~:text=Relatively%20low%20clinical%20trial%20enrollment%20rates%20have%20remained,or%20complex%20eligibility%20criteria%2C%20limit%20access%20to%20trials

[24] U.S. Food & Drug Administration. (2023). *Basics About Clinical Trials*. https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials

[25] National Cancer Institute. (2022). *Health Information National Trends Survey Number 48*. National Institutes of Health.

[26] Washington State Office of Financial Management. (n.d.). *Washington state HEDIS quality measures (claims based) - data dashboard.* https://ofm.wa.gov/washington-data-research/health-care/health-care-access-utilization-and-quality/washington-state-hedis-quality-measures-claims-based-data-dashboard. Accessed 25 October 2023.

[27] Kim TH, Kim IH, Kang SJ, Choi M, Kim BH, Eom BW, Kim BJ, Min BH, Choi CI, Shin CM, Tae CH, Gong CS, Kim DJ, Cho AE, Gong EJ, Song GJ, Im HS, Ahn HS, Lim H, Kim HD, Kim JJ, Yu JI, Lee JW, Park JY, Kim JH, Song KD, Jung M, Jung MR, Son SY, Park SH, Kim SJ, Lee SH, Kim TY, Bae WK, Koom WS, Jee Y, Kim YM, Kwak Y, Park YS, Han HS, Nam SY, Kong SH; Development Working Groups for the Korean Practice Guidelines for Gastric Cancer 2022 Task Force Team. Korean Practice Guidelines for Gastric Cancer 2022: An Evidence-based, Multidisciplinary Approach. J Gastric Cancer. 2023 Jan;23(1):3-106. doi: 10.5230/jgc.2023.23.e11. Erratum in: J Gastric Cancer. 2023 Apr;23(2):365-373. PMID: 36750993; PMCID: PMC9911619.

Eligibility criteria for participation in clinical research trials has been shown to serve as a structural barrier to diversity in clinical trial research. Eligibility criteria is used to ensure patient safety and to define the patient population under study.[28] However, research has shown that both overly restrictive criteria and subjective criteria often based on a clinician's assessment of participant behavior can unnecessarily exclude potential participants and increase disparities in research participation. One analysis found that traditional eligibility criteria for trials related to pancreatic cancer was more likely to exclude black patients, while changes that reduced eligibility exclusions without jeopardizing patient safety or study validity showed a decrease in eligibility disparities.[29] Further, eligibility of a potential participant can be a subjective determination, based on a clinician's assessment of a patient's history of alcohol or drug use or their beliefs about a patient's likelihood of adhering to complex study protocols. Research shows that Black patients are more likely to have "at least one negative descriptor" in their health record and to be deemed ineligible due to concerns about subjective behavioral criteria.[30]

Alongside eligibility criteria, clinicians themselves face barriers to referring patients for clinical trials. These barriers include a lack of awareness of appropriate clinical trials for their patients; provider attitudes or beliefs, including an unwillingness to lose a patient, or treatment preferences; and study burden for the provider, including administrative burden and concern about low reimbursement for trial costs.[31]

Barriers Reported by Health Hub Market Research Online Community and In-Language Survey Participants

Participants in the Health Hub Market Research Online Community (MROC) and in-language communities reside in Washington State. Health Hub MROC participant demographic data is reported in Appendix A. In-language surveys are conducted in 17 non-English languages and American Sign Language (see Appendix B). While these activities are not designed to produce generalizable knowledge about their survey topics nor provide conclusions about the

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[28] Kim ES, Bruinooge SS, Roberts S, Ison G, Lin NU, Gore L, Uldrick TS, Lichtman SM, Roach N, Beaver JA, Sridhara R, Hesketh PJ, Denicoff AM, Garrett-Mayer E, Rubin E, Multani P, Prowell TM, Schenkel C, Kozak M, Allen J, Sigal E, Schilsky RL. Broadening Eligibility Criteria to Make Clinical Trials More Representative: American Society of Clinical Oncology and Friends of Cancer Research Joint Research Statement. J Clin Oncol. 2017 Nov 20;35(33):3737-3744. doi: 10.1200/JCO.2017.73.7916. Epub 2017 Oct 2. PMID: 28968170; PMCID: PMC5692724.

[29] Riner, A. N., Girma, S., Vudatha, V., Mukhopadhyay, N., Skoro, N., Gal, T.S., Freudenberger, D.C., Herremans, K.M., George, T.J., & Trevino, J.G. (2022). Eligibility Criteria Perpetuate Disparities in Enrollment and Participation of Black Patients in Pancreatic Cancer Clinical Trials. *Journal of Clinical Oncology 40*(20), 2193-2202. https://doi.org/10.1200/JCO.21.02492

[30] Snyder, R.A. (2022). Clinical Trial Eligibility Criteria: A Structural Barrier to Diversity in Clinical Trial Enrollment. *Journal of Clinical Oncology 40*(20), 2183-2185. http://ascopubs.org/doi/full/10.1200/JCO.22.00537

[31] Unger JM, Vaidya R, Hershman DL, Minasian LM, Fleury ME. Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician and Patient Barriers to Cancer Clinical Trial Participation. J Natl Cancer Inst. 2019 Mar 1;111(3):245-255. doi: 10.1093/jnci/djy221. PMID: 30856272; PMCID: PMC6410951.

experiences of specific demographic groups, they do provide insights into the barriers faced by individuals within Washington from demographic groups that experience barriers to participation in clinical trials.

Similar to the academic literature, in-language survey participants reported fear, risks, confusion or lack of understanding, lack of trust, and lack of culturally appropriate trials. In the Arabic-speaking group, some participants specifically mention coming to the US for safety as a refugee and not wanting to engage in risk. The Mandarin-speaking group mentions that their Chinese culture discourages experimenting with their body. They also express higher trust and willingness to experiment with Eastern medicine compared to Western medicine." Below are two quotes from in-language survey that speak to these themes:

"Across segments, feelings or emotions that come up when thinking about clinical research trials are curiosity, fear, gratitude, safety, anxiety, and confusion around what the trials are and how they work. Some participants express gratitude towards those who participate in clinical research trials, but express fear and anxiety about volunteering themselves."

"Across segments, the main barriers to participating in clinical trials are fear of adverse side effects and/or negative long term health consequences and a lack of awareness about clinical trials. Some participants also mention a lack of in-language information and resources."

Of 306 Health Hub MROC participants surveyed by the Department, 75% have heard of opportunities to participate in clinical trials. By contrast, about two-thirds of the participants interviewed through the Department's in-language survey have never heard of opportunities to participate, suggesting that awareness may be an area of opportunity within Washington State for individuals whose primarily language is not English.

Barriers identified through Health Hub MROC activities align with barriers found in the literature, specifically mistrust, lack of awareness about trials and trials processes, and study burden. About two-thirds of respondents listed the possibility of negative sides effects as a factor that would prevent them from participating in a study, while just over one-half listed low or no compensation for their time as a limiting factor. In their own words, Health Hub MROC respondents who have not participated in a clinical trial study express the following concerns or barriers:

- "Trials are usually located in large cities and require a lot of travel for too little money."
- "The clinical trials I see are for those who have specific medical conditions. I do not have those specific conditions to qualify for."
- "I don't know where I would find information about participating, and I don't know if I would qualify."
- "I did not participate because I was unsure of what was involved, how long the treatment would take, how to get to the location where treatment was, and was concerned about side effects with a new drug that is being tested..."

Health Hub MROC and in-language survey findings support the general categories of barriers identified in the literature. They also support the findings that different demographic populations experience different barriers to participation in clinical trial research and solutions to barriers will need to be tailored to each population of interest.

Fostering Inclusivity and Trust in Clinical Trials through Community Collaboration

The third objective in Section 6 of 2SHB 1745 is for the Department to identify approaches for how clinical trial researchers can successfully partner with community-based organizations (CBOs) and others to provide outreach to underrepresented communities. To approach this question, the Department engaged the Community Collaborative and consulted with Washington State clinical research institutions, some of which have collaborated on this topic through the Institute of Translational Health Sciences.

Community Recommendations for Collaboration

Ensuring the diversity of clinical trial participants and fostering trust in BIPOC communities is a pressing challenge that demands collaborative efforts between clinical trial researchers and CBOs. The following explores the insights gathered during the community-led breakout groups organized by the Washington State Department of Health's Community Collaborative. We analyzed the responses to two critical questions:

Question 1: How can clinical trial researchers partner with community-based organizations (CBOs) to recruit more diverse clinical research participants?

The responses provided valuable insights, underlining the need for a multifaceted approach to bridge the trust gap between communities and researchers:

- Incorporate Community Members in Research Teams: One key strategy is including knowledgeable community members in research teams, ensuring that study designs consider the community's unique perspective.
- Address Historical Distrust: Recognize the historical fear of experimentation and unfair treatment experienced by BIPOC communities and initiate outreach with humility and respect.
- Bias Awareness: Acknowledge and rectify biases in research studies, shifting the focus from attributing health outcomes to communities to critiquing research methodology.
- Consider Geography: Recognize the geographical disparities in Washington State, prioritizing access to clinical trials in rural and non-dominant regions.
- Communication Abundance: Deliver information through multiple platforms and materials, enabling broader accessibility to potential participants.

- Community Compensation: Develop clear compensation plans for participants, acknowledging their time and expertise while avoiding exploitation. Along with continued community partnership and development outside of the trials.
- Focus Groups: Engage with community members through focus groups to understand their hesitations and concerns about participating in research.
- Cultural Competency: Address language access and cultural competency challenges, emphasizing the importance of community liaisons who understand the culture.
- Community-Based Participatory Research: Approach research with the end goal in mind, considering CBOs as stakeholders rather than mere resources.
- Trusted Messengers: Leverage trusted community members as messengers and interviewers to enhance acceptance and trust in clinical trials.
- Partnerships Over Transactions: Public health agencies should build long-term relationships with communities, engaging in ongoing collaboration beyond study participation requests.

Question 2: How can researchers better engage with BIPOC communities in Washington State to build trust and understanding around the importance of clinical trial participation?

To effectively engage with BIPOC communities and establish trust, these strategies emerged:

- Diverse Representation: Include community representatives in research teams and decision-making processes, ensuring a diverse perspective that can lead to different, more inclusive outcomes.
- Accountability to the Community: Be available for community questions, conduct townhall meetings, and engage community leaders to facilitate trust-building.
- Transparency and Data: Share data to illustrate the benefits of clinical trial participation, emphasizing the importance of closing health disparities through community involvement.
- Leadership Exchange: Foster collaboration and trust among community leaders from diverse backgrounds, creating a more extensive network of trust within and across communities.
- Culturally Appropriate Outreach: Engage grassroots organizations to deliver culturally and linguistically appropriate information to communities.
- Meaningful Connections: Establish relationships with communities that are long-term and focused on building trust, rather than transactional interactions.
- Compensation and Value: Compensate community members for their time and trust, showing that their involvement is genuinely valued.
- Data Sharing: Share data demonstrating the effectiveness of clinical trials within specific communities to encourage more diverse participation.

Building trust and fostering inclusivity in clinical trials require multifaceted strategies that incorporate community voices, engage community leaders, and prioritize transparency, equity, and long-term commitment. Collaboration between researchers and CBOs, backed by robust community driven legislation, can pave the way for a more diverse and representative clinical trial landscape, ultimately benefiting the health of all communities in Washington State.

Collaborative Approaches and Best Practices in Washington State's Academic and Research Institutions

Washington State is home to several esteemed academic and research institutions, including the University of Washington (UW), Washington State University (WSU), the Andy Hill Cancer Research Endowment (CARE) Fund, Fred Hutch Cancer Center, and Seattle Children's. These institutions play a vital role in advancing scientific research, innovation, and community engagement. This section analyzes the approaches and best practices adopted by these academic and research partners, gathered through workgroup meetings and the provided resources.

Community Partnership Guide for Engaging with Academic Researchers

The document titled "Community Partnership Guide for Engaging with Academic Researchers"[32] aims to support CBOs in partnering with research teams on research that relates to their communities. It provides valuable insights into the principles and strategies identified by the Health Equity Community Advisory Council for Seattle Children's and the Institute of Translational Health Sciences. These approaches include:

- Community-Centered Research: Academic partners emphasize the importance of involving the community from the project's inception. Community members are treated as collaborators, shaping research questions, methodologies, and implementation.
- Ethical Considerations: Academic partners are guided by ethical principles that prioritize the well-being and autonomy of community participants. Informed consent, transparency, and the protection of vulnerable populations are central to their approach.
- Cultural Competency: Recognizing the diverse cultures within Washington State, academic partners invest in cultural competency training for researchers to ensure respectful and equitable engagement.
- Building Trust: Institutions must actively work on building trust with communities through long-term engagement, open communication, and demonstrating a commitment to shared goals.

[32] Institute of Translational Health Sciences. (n.d.). *Community Partnership Guide for Engaging with Academic Researchers*. https://www.iths.org/wp-content/uploads/Community-Partnership-Guide-for-Engaging-with-Academic-Researchers-v1.0.pdf

Washington State University Executive Policy 41

Washington State University's Executive Policy 41: Policy on Tribal Engagement, Consultation, and Consent for Joint WSU-Tribal Research Activities and Projects outlines the commitment of WSU to the responsible conduct of research and meaningful support of tribal sovereignty. This policy establishes the formal policies and procedures that govern interactions and activities between Washington State University and Tribal governments. This is in addition to the Memorandum of Understanding entered into by and among Washington State University and the several Native American Tribal governments that are signatories.

The policy statement is as follows:

- WSU recognizes that its locations statewide are built on the homelands of Native peoples of the Pacific Northwest, who have occupied these lands since time immemorial. WSU holds deep respect for Tribal cultures, traditions, customs, symbols, beliefs, laws, regulations, sovereignty, and jurisdiction over its lands.
- Further, the University values the Tribes' significant contributions to society through their knowledge, labor, technology, science, philosophy, resources, and arts and has benefitted from Tribal homelands and successful relationships with the Tribes.
- This policy reflects and reaffirms WSU's enduring commitment to strengthening its relationship and on-going communication with the Tribes built on mutual respect and collaboration.
- It provides the framework and procedures for carrying out this important government-to-government relationship, and outlines responsibilities and guidelines of WSU administration, staff, faculty, and students when conducting research, projects, programs, and activities that affect Tribes or citizens and descendants of Tribes. [33]

Institute of Translational Health Sciences Community Partnerships

The Institute of Translational Health Sciences (ITHS) is a collaborative partnership between UW, Fred Hutchinson Cancer Center, Seattle Children's, and regional collaborators across Washington, Wyoming, Alaska, Montana, and Idaho. The ITHS is dedicated to moving scientific research into the clinical setting and fostering community partnerships, and their work has led to recommendations for institutional best practices for facilitating engagement of diverse populations in clinical trials (See Appendix C). Their approach includes:

- Community Advisory Boards: ITHS collaborates with community advisory boards, which provide invaluable input, ensuring research aligns with community needs and values.
- Training and Capacity Building: ITHS supports capacity building within communities, empowering them to actively engage in research activities.

[33] Washington State University. (2021). *EP41 – Policy on Tribal Engagement, Consultation, and Consent for Joint WSU-Tribal Research Activities and Projects*. https://policies.wsu.edu/prf/index/manuals/executive-policy-manual/ep41/

- Research Accessibility: ITHS prioritizes making research accessible and understandable to the broader community, reducing barriers to participation.

Many of Washington State's academic and research institutions are committed to building strong, ethical, and community-focused partnerships. These institutions actively practice principles such as community-centered research, ethical conduct, cultural competency, and transparency. By fostering a culture of collaboration and community engagement, these institutions contribute to the well-being of Washington State's diverse communities.

Recommendations

Based on the analyses of 1) which demographic populations and communities are underrepresented in clinical trials, 2) what barriers individuals from these groups face in participating in clinical trials, and 3) how can clinical trial researchers collaborate with CBOs to improve diversity in clinical trials, the Department was tasked with making overall recommendations for improving clinical trial diversity.

The recommendations that follow were sourced from the scientific literature, community consultation activities, and consultation with clinical research institutions in Washington State. They require both time and funding and are offered as avenues of exploration for clinical research institutions. They are not intended to be implemented all at once nor are they all feasible given existing resources. Institutions should identify where they can take action now and begin to plan for community engagement and collaboration (if not already ongoing) and implementation of more complex solutions in the future.

Introduction of state level requirements could have the unintended consequence of impacting competitiveness for federal or private funding for clinical trial research and risk the loss of funding for trials in Washington State. Any legislation that seeks to require institutions to implement the recommendations made here should be pursued only after close consultation with clinical research institutions, tribal governments, and CBOs rooted in communities that are underrepresented in clinical trials.

Recommendations for Identifying Underrepresented Populations

There is currently a lack of insight into which demographic groups and communities are underrepresented in clinical trials because demographic data on clinical trial participants is not regularly aggregated by institutions nor is it regularly reported by research institutions or by individual researchers. Further, policies that require or encourage collection of demographic data are often limited to age, sex, and race/ethnicity, with race and ethnicity data further limited to large umbrella categories. To improve understanding about which groups are represented and underrepresented, the Department makes the following recommendations:

- Clinical researchers, institutional IRBs, the WSIRB, and the Portland Area HIS IRB, should develop a standard for securing clinical trial data for the purposes of determining progress on diversifying clinical trials. This work should be done in close collaboration with underrepresented demographic and community groups.
- Clinical research institutions should conduct original research asking underrepresented communities and demographic groups about their experiences with and recommendations for increasing diversity in clinical research.
- Underrepresented populations identified in 2SHB 1745 and institutions conducting clinical trials in Washington should collectively develop consistent definitions, standards, and methods for assessing representation of underrepresented populations.

- The Legislature should rely upon the publicly available *ClinicalTrials.gov*, or the Clinical Trials Transformational Initiative's Aggregate Analysis of ClinicalTrials.gov (AACT) Database, for evaluating efforts to increase diversity in clinical trials conducted in the state overall, until each institution named in 2SHB 1745 can begin independently reporting aggregate demographic data, eligibility criteria, barriers, and recruitment strategies.
- Clinical research institutions, in partnership with underrepresented communities and demographic groups, should identify which demographic characteristics are necessary for collection and reporting, including demographic categories beyond those listed in 2SHB 1745. Clinical research institutions should then collaborate on creating robust and respectful tools to collect demographic characteristics so that institutions can aggregate across trials within an institution and so that cross-institution aggregation is feasible. Just as trial research requires expanded demographic data to better understand intervention impacts across populations, researchers and institutions should avoid collecting and reporting on unnecessary demographic data to protect patient privacy and reduce any associated chilling effects.[34]

Recommendations for Addressing Barriers to Participation

It is paramount for clinical trial researchers, research institutions, research funders, and policymakers to recognize that barriers to clinical trial participation vary by population and by the disease or condition being studied. The recommendations provided for addressing participation barriers should therefore be understood as context dependent solutions that are not universally applicable and that for some groups, may create additional barriers. The Department makes the following recommendations for clinical research institutions, sponsors, and researchers:

- Clinical research institutions should acknowledge the harm inflicted on underrepresented populations through the health care system and medical research industry and work to repair trust in these communities through relationship building and demonstrating the trustworthiness of the research institution.
- Clinical trial researchers, institutions, and funders should reduce study burden experienced by participants by:
    - Compensating for meals, lodging, and transportation (e.g., cab or bus fare) or providing transportation to trial sites for both participants and accompanying caregivers;

[34] Call CC, Eckstrand KL, Kasparek SW, Boness CL, Blatt L, Jamal-Orozco N, Novacek DM, Foti D; Scholars for Elevating Equity and Diversity (SEED). (2023). An Ethics and Social-Justice Approach to Collecting and Using Demographic Data for Psychological Researchers. *Perspect Psychol Sci., 18*(5):979-995. doi: 10.1177/17456916221137350. Epub 2022 Dec 2. PMID: 36459692; PMCID: PMC10235209.

    - Allowing health care providers to host routine care activities that are part of a study, collecting data in nontraditional locations such as churches or community centers, or offering care in a virtual setting, including needed technology and resources for participants to engage;[35,36]
    - Offering childcare options for participants;
    - Compensating participants for their time.
- Further research should be conducted regarding participant compensation and concerns about inducement. Potential solutions have been suggested by Washington State clinical research institutions, including:
    - The establishment of a nonprofit organization to support reimbursements, to avoid direct payment from clinical trial institutions;
    - Clarification through legislation or IRBs to guide clinical trial researchers in fair compensation that does not become inducement;
    - Development of clear and equitable processes for determining what compensation is provided and to whom.
- Clinical researchers should provide clearer communication about the trial study process, purpose, procedures, risks, and safety measures during the recruitment phase. This information should already be covered during the informed consent phase, but the salience of this barrier during the recruitment process suggests that it needs to be addressed sooner.
- Clinical trial information should be translated from English into multiple languages. This includes recruitment materials and any ongoing communication about the trial throughout the entire process to support both recruitment and retention. All translated materials should be assessed for cultural relevance and translated at an appropriate reading level. To support translation needs, research institutions can offer translation template documents with standard language to support individual researchers.
- Clinical trial sponsors should explore and reduce potential biases in participant outreach and engagement, including revisions to trial eligibility criteria to reduce unnecessary exclusionary criteria, which disproportionately rejects individuals from underrepresented groups.[37]

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[35] Office of Research on Women's Health. (n.d.). *Review of the Literature: Primary Barriers and Facilitators to Participation in Clinical Research*. National Institutes of Health. https://orwh.od.nih.gov/sites/orwh/files/docs/orwh_outreach_toolkit_litreview.pdf

[36] Fairly, R., Christian, C., Lipset, C., Alspach, C., & Sandoval, F. (2023, September 26). *Exploring New Inroads for Clinical Trial Diversity: Where Do We Go From Here?* [Webinar]. Alliance for Health Policy.

[37] Center for Drug Evaluation and Research & Center for Biologics Evaluation and Research. (2020). *Enhancing Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs: Guidance for Industry*. U.S. Food & Drug Administration. https://www.fda.gov/media/127712/download

Recommendations for Community Partnership

Implementation of recommendations on data collection and reporting and addressing participation barriers necessarily relies on partnership and collaboration between clinical research institutions, individual researchers, and underrepresented communities and demographic groups. Collaboration and partnership that goes beyond community engagement is paramount, as the goal is not to improve diversity for diversity's sake, but rather to improve opportunities for health for members of these communities. Crafting solutions will therefore require the meaningful involvement of these groups.

The approaches to community partnership offered by the Community Collaborative as outlined in the Fostering Inclusivity and Trust in Clinical Trials through Community Collaboration section of this report are a robust and comprehensive set of recommendations for research institutions to engage in community partnership. In addition to those recommendations, the Department further recommends:

- Clinical research institutions should hire community engagement coordinators to foster ongoing, respectful, and mutually beneficial community partnerships at the institutional level if they have not already done so. Current practice for recruiting diverse study participants primarily relies on individual researchers approaching communities on behalf of their particular study. An institutional level approach will better support relationship building with communities.
- CBOs and individuals from underrepresented communities and demographic groups should be compensated for engaging with research institutions to identify and address barriers to clinical trial participation. Community member engagement is a crucial element for success and compensation both facilitates and recognizes the importance of community member contributions. Whether this funding should come from the state legislature or clinical trial funders should be further explored.

Additional Recommendations

Through workgroup discussions between the Department and numerous Washington State research institutions, the following recommendations were identified:

- Washington State research institutions should create a statewide collaborative to share best practices, particularly around institutional policies that support diverse engagement, and discuss challenges and opportunities across institutions and relevant partners, including tribes and underrepresented community and demographic groups. Some institutions are already carrying out or pursuing recommendations contained in this report and their experiences could provide valuable guidance to peer institutions. The state legislature should consider funding support for this collaborative.
- Clinical research institutions should create diversity in clinical trial road maps, outlining short, medium, and long-term goals in order to support progress and planning. The

Department recommends community engagement and partnership as a first step, so that community input is a part of every stage and that community voices inform what each stage looks like.

- Clinical research institutions should create an equity in clinical trials checklist for the pre-award process to support individual researchers in incorporating best practices into their study process and design from the beginning.
- Clinical research institutions should consider what might be helpful to ask for regarding potential future legislation and budget requests. They should identify what resources they need to implement these solutions and make appropriate requests to the legislature and to research trial funders.
- The Washington State legislature should consult with CBOs and with clinical research institutions when considering future legislation to improve diversity in clinical trials. While clinical research institutions should be held accountable for improving diversity in clinical trials, care should be taken to ensure that further policymaking supports these efforts and avoids requirements and restrictions that may reduce competitiveness for federal funding.

Conclusion

Section 6 of 2SHB 1745 tasked the Department with analyzing and making recommendations on which communities and demographic groups are underrepresented in clinical trial research, what barriers individuals from those groups face in clinical trial participation, and how clinical trial researchers can partner with CBOs to improve diversity in clinical trial participation.

The Department identified that demographic data on clinical trial participants is inconsistently reported and collected, and it is not currently possible to produce an accurate understanding of clinical trial participant diversity in Washington State. Broadly speaking, scientific literature demonstrates that across the country, consistently marginalized populations tend to be underrepresented in clinical trials and despite decades of efforts to improve trial diversity, populations that experience health disparities continue to be underrepresented in clinical trials.

Potential clinical trial participants experience barriers related to study burden, mistrust, fear and anxiety, and lack of understanding about the clinical trial process. Structural barriers related to health care access and clinical trial eligibility are significant but have received less attention in the scientific literature. Importantly, barriers differ by demographic group and by disease or condition being studied. As such, the Department's strongest recommendation is for clinical research institutions to strengthen relationships with communities and work to partner with CBOs and community members to better identify and tailor the best solutions for each group of focus. The Washington State legislature is encouraged to allocate resources for community participation and to further support clinical research institutions in these efforts.

Appendix A: Health Hub Market Research Online Community Report

Health Hub MROC: Clinical Trials
September 2023

NOTE:

- *This report includes data from the Health Hub Market Research Online Community. The MROC includes 598 pre-screened members from Washington state.*
- *This activity was in field from 8/23/2023 – 8/29/2023 and is considered short-term research, therefore this research only provides a current snapshot in time.*
- *This is meant to be qualitative research, meaning this is more directional than predictive.*

AUDIENCE:

- All community members. Per request for this specific study, demographic information is listed at the end of the report (pages 17-18).

FIELD DATES:

- 8/23/2023-8/29/2023

TOTAL COMPLETES:

- n=306

KEY FINDINGS:

Knowledge + Feelings

- **93% know what clinical research trials (referred to as CRTs throughout) are** and when asked to describe them many respondents commonly mention they are a **method to test a medication/drug, treatment/process, vaccine, or product/device primarily to evaluate its effectiveness** as well as **its safety and potential side effects.**
    - Some also mention CRTs are a part of the **FDA approval process**, they are done on **humans who volunteer to participate** – sometimes the **general population, other times for those with specific health conditions**. Some others are also aware of aspects of the methodology such as **having a placebo/control group and a treatment group** as well as using **blind or double-blind methodology**.
- **Most respondents** express **positive emotions** when considering clinical research trials, such as **hope, optimism, excitement/eagerness** as well as **satisfaction/contentment/relief** and **care/compassion**. However, **some** express more **negative feelings** such **as worry, anxiety,** and **fear.**
    - Those who express **positive emotions** such as **hope/optimism** and **excitement**/eagerness often view CRTs as critical to the advancement of medicine and the health of humanity. Some also believe that CRTs can bring hope and progress to those battling health conditions/diseases that otherwise might not have an effective treatment. Furthermore, CRTs make some participants feel **positive and hopeful** about helping others. Those who report feeling **satisfied, contented, or relieved** often believe CRTs are crucial to discovering new treatments. Those who express **care and compassion** feel that they/those participating in CRTs are helping others.
    - Those who express more **negative emotions** such as **worry, anxiety, or fear** tend to mention concerns about potential side effects or unknown outcomes.

Perception

Awareness + Experience

- **75% of respondents have heard** about opportunities to participate in clinical research trials; however, **19% have not heard** about any opportunities to participate in CRTs, and **6% are unsure**.
- Though many have heard about opportunities to participate in CRTs, **only about a quarter of respondents (24%)** have participated in a clinical research trial. **74% have not participated in a CRT** and **2% are unsure**.
    - Those who have participated in a CRT often mention they decided to participate to **access treatment for a health condition they have, to contribute to medical advancement,** or **for monetary compensation**.
    - Those who have not participated in a CRT often mention reasoning such as **they have not been informed about opportunities or how to participate, have not qualified/don't think they would qualify, are concerned about potential side effects or bad outcomes, are too far from the CRT location site, would be too much of a time commitment,** or **the compensation has been too low**.

Barriers

- According to respondents, the **most common reasons they/others in their community do not participate in clinical research trials** include **fear of side effects or bad outcomes** (e.g., long-term, death, etc.), **concerns about safety, a lack of awareness or understanding of CRTs** (e.g., potential benefits/value, fear of the unknown), as well as **insufficient compensation/associated costs** (e.g., time, travel, risk, etc.).
    - In addition, respondents frequently mention they **don't get information about how to participate in CRTs** (e.g., lack of advertisement, how to participate, who qualifies, etc.). Some also mention **skepticism about the motives behind the research** as well as **misinformation or misunderstandings about CRTs** (e.g., will have a bad outcome/side effects, will treat me like a 'guinea pig,' only for sick people, might only get a placebo, etc.).
    - There are also **logistical barriers** mentioned, such as the **location and accessibility/transportation to the location,** especially for rural/non-urban residents, **time commitment** (e.g., too busy, work, travel time, inconvenient), and **not meeting the qualifications/requirements**. A few mention **access to quality healthcare/insurance** and **data privacy/confidentiality concerns**.
    - Despite the question asking respondents to consider race and ethnicity, few specifically mention their community as a racial/ethnic group. However, some bring up **language barriers** and knowledge of/concerns about how **certain groups have historically been mistreated/abused in clinical research trial settings**, including people of color, LGBTQ+ folks, women, etc. Some also mention the **need for more diversity in CRTs**.
- When asked (aided) to select which listed factors, if any, would prevent them from participating in a clinical research trial, the most common factors are **possible negative side effects (66%)** and **a lack of compensation for their time (54%),** followed by the belief that **possible health risks outweigh potential benefits (48%), time required to participate (44%),** and **a lack of knowledge about clinical trials (43%).**
    - **Some** also indicate barriers such as **a lack of awareness of clinical trials (33%), having to stop other treatments that are currently helping them (32%), distrusting**

the people/organization conducting the trial (26%), and **a lack of transportation to/from the trial site (23%).**

Willingness

- When asked to indicate their willingness to participate in a clinical research trial studying the safety, benefits, and effects of particular treatments, respondents indicate **higher willingness** for treatments that may be perceived as **less invasive or risky**, such as those involving **external medical devices (90% at least somewhat willing)** and **alternative therapies (89%).**
    - **Many** are also **at least somewhat willing** to participate in **regenerative medicines (77%), pharmaceutical drugs (66%),** and **vaccines (66%).**
        - It is noteworthy given the current vaccine climate that **willingness to participate in a vaccine CRT is somewhat polarizing**, with 23% not at all willing, 35% somewhat willing, 31% extremely willing, and 10% unsure.
    - Respondents are slightly **less likely** to participate in clinical research trials involving **internal medical devices (51%)** and **surgical procedures (49%).**

Factors

- In assessing the importance of various factors when considering participating in a clinical research trial, respondents rate **safety measures** as the **most important factor** in making their decision **(with an average rating of 4.6 out of 5),** followed **by information and education (4.5)** and **open communication (4.4).**
    - Other important factors include **compensation and incentives (4.1)**, the **location and proximity of the clinical trial site (4.1)**, the **impact of the research on others (4.1)**, the **level of time commitment (4.1**), and the **personal benefit (4.1).**
    - **Past success stories for the disease/area of research or the particular researcher (3.8), source of recommendation (3.7),** and **inclusion and diversity (3.6)** are **moderately important**.

Parents

Pre-screen + Background

- **45% of respondents** indicate they are **currently a parent, guardian, or caretaker,** or **they or their partner are pregnant/expecting.**
- **About half of parents (52%)** have child(ren) between the ages of **0 to 5 years old**, **28% between 6 and 9, 33% between 10-13,** and **33% between 14 and 17 years old.**

Parent Willingness

- When parents were asked to indicate their willingness to allow their child(ren) to participate in a CRT, they show **lower overall willingness across all treatment types.** However, parents similarly indicate a higher willingness to allow their child(ren) to participate in what they perceive to be less invasive or risky treatments, such as **external medical devices (77% at least somewhat willing)** and **alternative therapies (73%).**
    - Less than half of parents are **at least somewhat willing** to allow their child(ren) to participate in testing **regenerative medicines (47%), pharmaceutical drugs (45%),** and **vaccines (44%).** Parents are **least willing** to allow their child(ren) to participate in clinical research trials involving internal **medical devices (31%)** and **surgical procedures (29%).**
        - In line with respondents' levels of personal willingness, it is noteworthy that willingness to allow their child(ren) to participate in a **vaccine CRT** is **somewhat polarizing**, with 44% indicating they would be not at all willing, 28% somewhat willing, 16% extremely willing, and 12% unsure.

- When asked to elaborate on their level of willingness, parents generally express **apprehension** about allowing their child(ren) to participate in CRTs because they **feel responsible for their health and do not want to cause them harm**. However, despite their hesitancy, parents often mention they feel **more open about less invasive or risky treatments such as external devices or alternative therapies**. Many would also be more willing to allow them to participate **if they had a health condition that could benefit from the treatment** or **if it was their only treatment option.**

DETAILED FINDINGS:

Knowledge + Feelings

93% of respondents know what clinical research trials are.

Table 1. Clinical Research Trials

Do you know what clinical research trials are?	**Total (n=306)**
Yes	**93%**
No	2%
Unsure	5%

Overall, most respondents would describe a **clinical research trial (referred to as 'CRT' throughout)** as something that tests a **medication/drug, treatment/process, vaccine, or product/device** primarily to evaluate its **effectiveness**. Respondents primarily mention CRTs are used to understand effectiveness; however, many also understand they are also used to understand **safety/potential side effects.** Some also say that CRTs are an initial step in the **FDA approval process** and are done before being released to the public/greater population.

In addition, many understand that the testing is done on **humans who volunteer to participate**. Some specify that studies may research the **general population** while others may focus on **individuals with specific health conditions**.

Some are also aware that there is typically a **placebo/control group and a treatment group**. Some even mention that these are done using **blind or double-blind methodology**.

What do you think a clinical research trial is? How would you describe it? Please be as detailed as possible. **Total (n=306)**

In their words:

- *"Clinical research trials are tests to see how well unapproved drugs and treatments for medical conditions work for a diverse range of humans and involve voluntary participation of people."*

- *"They are ongoing trials for new drugs/medications/technologies/etc. that are not currently FDA approved but are in the process of completing trials to become approved, and people can sign up to participate in them to a) contribute to the medical research for a drug, b) be part of the clinical research trial/study, and c) gain access to a drug that they may really need but that isn't approved yet."*
- *"A clinical research trial is where a company tests a medical product or medication by administering either the medication or a placebo and looking to confirm the effectiveness of the medication against the placebo. These are usually done blind (and likely double-blind where neither the researcher nor the participant knows what the participant is receiving until after the analysis is done)."*
- *"A clinical research trial is a study of specific types of people to gauge their reactions to various medical interventions. Some studies may research healthy participants and some may research people with specific illnesses or diseases. Often, clinical research trials offer paid compensation to participants."*

Participants were asked to read the following description of clinical research trials before continuing.

> *Clinical research trials are experimental research studies in which people volunteer to test potentially new treatments to determine their safety and effectiveness. These studies help determine the safety or effectiveness of drugs, medical devices (like a pacemaker, for example), vaccines, other therapies, and more*

Overall, **most respondents tend to express positive feelings** when considering clinical research trials. Many often indicate feelings of hope, optimism, and excitement/eagerness as well as satisfaction/contentment/relief and compassion/care.

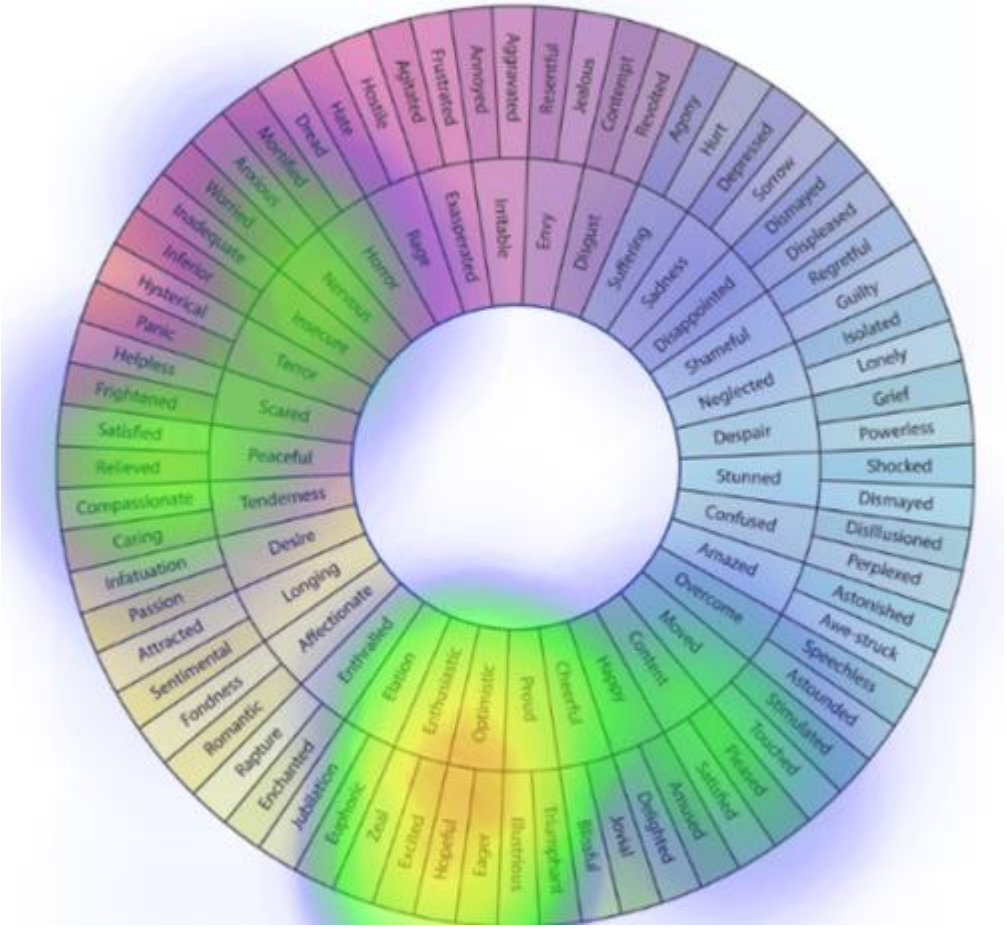
Those who express **hope, optimism, and excitement/eagerness** tend to view CRTs as critical to the advancement of medicine and the health of humanity. While many speak more generally about the potential for CRTs to discover new treatments, some others say CRTs can bring hope and progress to those battling health conditions or diseases that otherwise have limited or no effective treatment options. Some also mention that participating in CRTs makes them feel positive and hopeful about helping others.

Those who express feelings of **satisfaction, contentment, and relief** often believe CRTs are an important/necessary part of the process of discovering new treatments. Those who express feelings of **care and compassion** express feeling like they or others are doing something to help other people.

Though most feelings are positive, **negative feelings arise for some,** such as worry, anxiety, and fear. Those who express these feelings often mention the uncertainty of the potential side effects or unknown outcomes. Some describe partaking in clinical research trials as risky.

Table 2. Feelings

Keeping in mind the above definition, what feelings or emotions do you have when thinking about clinical research trials? Please select the primary emotion you feel from the below wheel and explain why you feel this way.
Total (n=306)



Positive Feelings – In their words:

- *"Knowing that no condition has been left as 'unsolvable' really helps, that people are researching and volunteering to find out how to make a lot of people's lives better is a very good thing."* – **Hopeful**
- *"I am hopeful about the success of clinical research trials in finding treatments, cures, and prevention for various medical issues people face."* – **Hopeful**
- *"In order to progress in finding new ways to treat illnesses or conditions, we must go through this process."* – **Satisfied**

Negative Feelings – In their words:

- *"While I understand the need for clinical research trials and I generally am positive about finding new cures and treatments, they also scare me a bit because the nature of them means that they could have unknown side effects."* – **Nervous**
- *"I would be worried to do a trial myself because it seems very risky and could lead to negative side effects."* – **Worried**

Perception

Awareness + Experience

Participants were asked to continue to keep the description of clinical research trials in mind while answering the next questions.

Many respondents (75%) have heard of opportunities to participate in a clinical research trial.

Across the demographic subsets included*, most respondents have heard about opportunities to participate in clinical research trials. A slightly higher percentage of those who identify as Black, African, or African American, Hispanic and Latino, Latina, or Latinx, and LGBTQ+ have heard of opportunities to participate in a clinical research trial.

Table 3. Opportunities

Have you ever heard of any opportunities to participate in a clinical research trial?	**Total (n=306)**	Asian or Asian American (n=40)	**Hispanic, Latino, Latina, or Latinx (n=18)**	**Black, African, or African American (n=17)**	<$50k HHI (n=79)	**LGBTQ+ (n=50)**
Yes	**75%**	75% (n=30)	83% (n=15)	88% (n=15)	75% (n=59)	80% (n=40)
No	19%	20% (n=8)	17% (n=3)	6% (n=1)	18% (n=14)	10% (n=5)
Unsure	6%	5% (n=2)	0% (n=0)	6% (n=1)	8% (n=6)	10% (n=5)

**Note: Data from some traditionally underrepresented groups are included – please also note these are small subsets.*

Though most respondents (74%) have not participated in a clinical research trial, **nearly a quarter of respondents (24%)** have participated.

Those who indicate they have participated in a clinical research trial often mention they decided to participate to **access treatment for a health condition they have, to contribute to medical advancement,** or **for monetary compensation**.

Many who have not participated in a CRT **have not been informed about opportunities or how to participate, have not or do not think they would qualify, are concerned about potential side effects or bad outcomes, are too far from the CRT location site**, mention it **would be too much of a time commitment**, or **the compensation was too low.**

Across the demographic subsets included*, most respondents have not participated in a clinical research trial, however, a slightly higher percentage of those who identify as LGBTQ+, or have an annual household income up to $50k have participated in a clinical research trial.

A slightly lower percentage of those who are Asian or Asian American have participated in a clinical research trial. These results are consistent with in-language findings among Mandarin-speaking participants that suggest cultural barriers to participating in CRTs due to discouragement of bodily risk or alteration.

Table 4. Participated

Have you ever participated in a clinical research trial?	**Total (n=306)**	**Asian or Asian American (n=40)**	Hispanic, Latino, Latina, or Latinx (n=18)	Black, African, or African American (n=17)	**<$50k HHI (n=79)**	**LGBTQ+ (n=50)**
Yes	24%	10% (n=4)	28% (n=5)	24% (n=4)	29% (n=23)	34% (n=17)
No	**74%**	90% (n=36)	72% (n=13)	71% (n=12)	67% (n=53)	60% (n=30)
Unsure	2%	0% (n=0)	0% (n=0)	6% (n=1)	4% (n=3)	6% (n=3)

**Note: Data from some traditionally underrepresented groups are included – please also note these are small subsets.*

"Yes" – In their words:

- *"I have participated in several studies. Many have benefited me and my health but I feel good that my participation also advanced knowledge about particular medical conditions and other possible treatments."*
- *"I am currently part of a trial to test a new migraine treatment protocol. I appreciate that clinical research trials are a way to help researchers seek to test new treatment options and am excited about helping when I can."*
- *"I participated because it not only gave me the opportunity to assist in the development of a medication to help others but it also gave me the opportunity to benefit financially."*

"No" – In their words:

- *"Trials are usually located in large cities and require a lot of travel for too little money."*
- *"The clinical trials I see are for those who have specific medical conditions. I do not have those specific conditions to qualify for."*
- *"I don't know where I would find information about participating, and I don't know if I would qualify."*
- *"I did not participate because I was unsure of what was involved, how long the treatment would take, how to get to the location where treatment was, and was concerned about side effects with a new drug that is being tested..."*

Barriers

The most common reasons respondents say prevent them/others in their community from participating in clinical research trials are **fears of potential side effects or bad outcomes** (e.g.,

long term), **concerns about the safety and risks**, **lack of awareness or understanding of CRTs** (e.g., potential benefits/value, fear of the unknown), and **not enough compensation/associated costs** (e.g., for time, travel, risk, etc.).

It is also common for respondents to mention they **don't hear about or get information about how to participate in CRTs** (e.g., lack of advertising, how to get involved/participate, who qualifies, etc.). Some also bring up a **lack of trust in the medical/healthcare community or skepticism about the motives behind the research** as well as **misinformation or misunderstandings about CRTs** (e.g., will have a bad outcome/adverse side effects, will treat me like a guinea pig, only for sick people, might only get placebo, etc.).

Many also mention **logistical barriers** such as **the location and accessibility/transportation to the location site** (esp. those in rural areas, traveling into the city/urban areas), **the time commitment required** (e.g., too busy, work, travel time, inconvenient), and **not meeting the required qualifications**. A few mention not having **quality healthcare** or **insurance** and **concerns about data confidentiality/privacy**.

Though respondents were asked to consider this question in terms of race and ethnicity, few specifically mention this, however, some bring up barriers such as **language** as well as **knowledge of and concerns about ways in which certain groups have historically experienced mistreatment/injustice/abuse in clinical research trial settings**, such as people of color, LGBTQ+ folks, women, etc. A few also mention the **need for more diversity** in CRTs.

Thinking about you and your community (in terms of race and ethnicity, etc.) in Washington state, what do you think prevents people from participating in clinical research trials?

Total (n=306)

In their words:

- *"Worry about side effects, worry about what's in drugs or vaccines, compensation isn't great enough for what's required."*
- *"The lack of advertising giving awareness to the public about clinical opportunities."*
- *Lack of opportunity. I've never seen anything advertised about clinical trials around here. Tacoma, Seattle, Portland, Vancouver- Yes. Not Chehalis, Washington!"*
- *"I rarely hear about opportunities to participate in Washington state, so I guess I think other people don't hear either and that is probably what prevents them from participating. The risks associated are probably a secondary cause, but really if you don't hear about them, you can't participate. People are busy too, so if they are being asked to volunteer their time with no compensation, I imagine many people can't justify that."*
- *"Some fear the possible side effects, others distrust the people doing the studies as there have been abuses in the past against specific races before there were laws created to prevent these types of abuse."*
- *"I know that there's been a lot of issues in the past, and likely present, of clinical trials doing unethical 'experiments' on Black people, such as the Tuskegee experiment and the foundation of gynecology. I'm pretty sure it's also a thing that a lot of clinical trials*

only accept white patients, so POC have fewer opportunities to receive newer life-saving treatment."

- *"I know that the information doesn't necessarily always go out to each group of people for example my Native American relatives do not get much information on studies that are about to start out on the reservations in particular they are quite far behind the times in my opinion."*
- *"People may be worried that they are being utilized as a certain demographic to test new/untested health related items."*
- *"I think accessibility is one issue preventing people from participating in research trials- being able to get to and from the trial and even being able to access the trial in terms of language barriers. Another thing that could prevent people from participating is having to take time off work or for some people, finding childcare."*

When asked to select which factors, if any, would prevent them from participating in a clinical research trial, respondents most commonly indicate **possible negative side effects (66%)** and **a lack of compensation for their time (54%)**. In addition, many indicate other barriers such as their belief that **possible health risks outweigh potential benefits (48%),** the **time required to participate (44%),** and **a lack of knowledge about clinical trials (43%),** would prevent them from participating.

About a third of respondents indicate that a **lack of awareness of clinical trials (33%)** and **having to stop other treatments that are currently helping them (32%)** would prevent them from participating in a CRT.

About a quarter would not participate in a CRT due to **distrusting the people/organization conducting the trial (26%)** and **a lack of transportation to get to/from the trial site (23%).**

13% of respondents would not participate **if they did not see any personal benefits**, and **12%** would not participate **if there was no childcare available to assist them during the trial.**

Only a few perceive **a lack of language resources/accessibility (4%)** or **cultural or religious preferences/beliefs (2%)** as barriers to participating in a CRT.*

**Note: MROC respondents are English-speaking which may affect these responses.*

Table 5. Factors

What, if anything, would prevent you from participating in a clinical research trial? Please select all that apply.	**Total (n=306)**
Possible negative side effects	**66%**
Low or no compensation for my time	54%
My belief that the potential risks to my health outweigh the potential benefits	48%
Time required to participate in the clinical trial	44%
Don't know/have enough information about the clinical trial	43%
Lack of awareness of clinical trials	33%
If I need to stop other treatments that are currently helping me	32%
Don't trust the people/organization conducting the trial	26%
Lack of transportation to get to/from the clinical trial location	23%
I don't see any potential personal benefits	13%
Lack of childcare to help during the clinical trial	12%
Lack of language resources/accessibility (i.e., translation services, bilingual staff, written documents and materials in-language)	4%
Cultural or religious preferences/beliefs	2%
Other	2%
None of the above	5%

Willingness

Overall, respondents are more willing to participate in **less invasive or potentially risky** trials such as **external medical devices (90% at least somewhat willing)** and **alternative therapies (89%).**

Furthermore, many are **at least somewhat** open to participating in CRTs testing **regenerative medicines (77%)**, **pharmaceutical drugs (73%),** and **vaccines (66%)**. It is noteworthy given the current vaccine climate that willingness to participate in a **vaccine CRT is somewhat polarizing**, with 23% not at all willing, 35% somewhat willing, 31% extremely willing, and 10% unsure.

Though **about half** are **at least somewhat willing,** respondents are **less willing** to participate in clinical research trials involving **internal medical devices (51%)** and **surgical procedures (49%).**

Table 6. Willingness

Assuming you were medically qualified for each treatment listed below, please indicate your willingness to participate in a clinical research trial studying the safety, benefits, and effects of that particular treatment by marking it with either *"Not at all willing," "Somewhat willing," "Extremely willing," or "Unsure."* **Total (n=306)**	**Not at all willing**	**Somewhat willing**	**Extremely willing**	**Unsure**
External medical devices – devices/tech worn or placed outside the body to diagnose, monitor, or treat, such as wearable sensors	5%	30%	**60%**	5%
Alternative therapies – therapies or treatments outside of US mainstream medicine, such as acupuncture, herbal remedies, etc.	7%	32%	**57%**	4%
Regenerative medicines – new procedures involving stem cells, tissue engineering, etc. to replace/repair damaged cells or tissues	12%	**44%**	33%	11%
Pharmaceutical drugs – new medications or therapies designed to treat specific diseases or conditions	19%	**47%**	26%	8%
Vaccines – new vaccines to prevent or reduce the severity of the effects of infectious diseases	23%	**36%**	31%	10%
Internal medical devices – devices/tech placed inside the body for diagnostic, therapeutic, or monitoring purposes such as a pacemaker, stents, joint replacements, etc.	**36%**	**36%**	15%	13%
Surgical procedures – new surgical techniques being evaluated for safety and effectiveness	35%	**38%**	11%	16%

Factors

When asked to rate the importance of various factors when considering participating in a clinical research trial, respondents rate **safety measures as the most important factor in their**

decision-making (with an average rating of 4.6 out of 5), followed by **information and education (4.5),** and **open communication (4.4).**

Other important factors include **compensation and incentivization (4.1), clinical trial site location/proximity (4.1), the impact of the research on others (4.1), level of time commitment (4.1),** and **personal benefit (4.1).**

Moderately important factors include **past success stories for the disease/area of research or the particular researcher (3.8), source of recommendation (3.7),** and **inclusion and diversity (3.6). Language accessibility (2.4)** and **access to childcare (2.0) are less important among respondents.**

**Note: MROC respondents are English-speaking which may affect these responses. Similarly, not all who answered this question are parents, which may have affected the importance of access to childcare.*

Table 7. Factors

If you were considering participating in a clinical trial, how important would each of the following factors be in making your decision? *Please rate on a scale of 1 to 5, where 1 is not at all important and 5 is extremely important.* **Total (n=306)**	**1 – Not at all important**	**2**	**3**	**4**	**5 – Extremely important**	**Avg Wt. ↓**
Safety measures – information on the safety measures in place and assurance of independent review and oversight (e.g., safety review boards, FDA, etc.)	1%	1%	4%	26%	68%	**4.6**
Information and education – about the clinical trial, its purpose, potential risks/benefits, participant rights, FAQs).	2%	1%	7%	25%	65%	4.5
Open communication – establishing communication between participants and researchers, ensuring questions can be asked at any time, participant rights/participants can drop out at any time	1%	3%	9%	30%	57%	4.4
Compensation/incentivization – monetary or other compensation for participation	3%	5%	17%	29%	46%	4.1
Clinical trial site location/proximity	1%	4%	17%	42%	36%	4.1
Impact of the research on others - learning more about a disease, creating new treatments, improving healthcare for everyone	3%	4%	15%	39%	39%	4.1
Level of time commitment (i.e., number of study-related visits, number of procedures required, etc.)	1%	3%	20%	38%	38%	4.1

Personal benefit – a potential positive outcome for my own health	2%	5%	19%	32%	42%	4.1
Past success stories for the disease/area of research or the particular researcher – to demonstrate real stories of positive impact, provide reassurance and hope, etc.	3%	7%	23%	39%	28%	3.8
Source of recommendation - someone I trust (e.g., my doctor, family member, religious or other community leader) recommends that I participate	6%	10%	24%	32%	28%	3.7
Inclusion and diversity – ensuring opportunities and safe treatments for all	13%	8%	19%	26%	34%	3.6
Access to transportation services to and from the clinical trial	26%	15%	18%	19%	22%	3.0
Diversity within the research team (i.e., researchers from different racial/ethnic groups, etc.)	22%	18%	29%	17%	14%	2.8
Language accessibility (i.e., translation services, bilingual staff, written documents, and materials in language, etc.)	41%	15%	20%	13%	11%	2.4
Access to childcare during the clinical trial	58%	11%	13%	9%	9%	2.0

Parents

Pre-screen + Background

Nearly half of participants (43%) are currently a parent, guardian, or caretaker to child(ren) under the age of 18.

Table 8. Parental Status

Are you currently a parent or guardian/caretaker to any child(ren) under the age of 18?	**Total (n=306)**
Yes, currently a parent/guardian/caretaker	43%
No, but I am/my partner is currently pregnant or expecting our first child	2%
No	**55%**

About half of parents (52%) have child(ren) between the ages of **0 to 5 years old**, **28% between 6 and 9, 33% between 10-13,** and **33% between 14 and 17 years old.**

Table 9. Age(s) of Child(ren)

Select which of the below age range(s) your child(ren) fall into. Please select all that apply	**Total (n=134)**
Me or my partner is currently pregnant or expecting	4%
0-6 months	4%
7-12 months	4%
13-24 months	10%
2-5 years old	30%
6-9 years old	28%
10-13 years old	**33%**
14-17 years old	**33%**

Parent Willingness

Parents are overall **less willing** to allow their child(ren) to participate in a clinical research trial. Despite this, **many parents** are **somewhat willing** to allow their child(ren) to participate, and likewise are **more willing** to allow their children to participate in what they consider **less invasive or potentially risky** treatments, including **external medical devices (77% at least somewhat willing)** and **alternative therapies (73%).**

In addition, less than half are **at least somewhat willing** to allow their child(ren) to participate in testing **regenerative medicines (47%), pharmaceutical drugs (45%),** and **vaccines (44%).** Similar to levels of personal willingness, it is noteworthy that parents' willingness to allow their child(ren) to participate in a **vaccine CRT** is **somewhat polarizing** with 44% indicating they would be not at all willing, 28% somewhat willing, 16% extremely willing, and 12% unsure.

Parents are **least willing** to allow their child(ren) to participate in clinical research trials involving **internal medical devices (31%)** and **surgical procedures (29%).**

When asked to elaborate on their level of willingness to allow their child(ren) to participate in clinical research trials, parents often express that they are **more apprehensive** about their child(ren) participating in clinical research trials because they **feel responsible for their health** and **do not want to cause them harm**.

While most feel cautious about CRTs for their child(ren), many parents express they are **more open to less invasive or risky** treatments such **as external medical devices** or **alternative therapies**. Parents also mention they would **allow their child to participate if the treatment would possibly improve their health/health condition** or **if it was their only treatment option.**

A few parents say that they **would want their child(ren) to be involved in the decision-making process rather than making the decision for them.** A couple mention their child is too young to make an informed decision for themself.

Table 10. Parent Willingness

Assuming your child(ren) is medically qualified for each treatment listed below, please indicate your willingness to allow your child(ren) to participate in a clinical research trial studying the safety, benefits, and effects of that particular treatment by marking it with either "Not at all willing," "Somewhat willing," "Extremely willing," or "Unsure." **Total (n=139)**	**Not at all willing**	**Somewhat willing**	**Extremely willing**	**Unsure**
External medical devices – devices/tech worn or placed outside the body to diagnose, monitor, or treat, such as wearable sensors	17%	**40%**	37%	6%
Alternative therapies – therapies or treatments outside of US mainstream medicine, such as acupuncture, herbal remedies, etc.	19%	36%	**37%**	8%
Regenerative medicines – new procedures involving stem cells, tissue engineering, etc. to replace/repair damaged cells or tissues	**36%**	27%	20%	17%
Pharmaceutical drugs – new medications or therapies designed to treat specific diseases or conditions	**40%**	30%	15%	15%
Vaccines – new vaccines to prevent or reduce the severity of the effects of infectious diseases	**44%**	28%	16%	12%
Internal medical devices – devices/tech placed inside the body for diagnostic, therapeutic, or monitoring purposes such as a pacemaker, stents, joint replacements, etc.	**56%**	22%	9%	13%
Surgical procedures – new surgical techniques being evaluated for safety and effectiveness	**52%**	23%	6%	19%

In their words:

- *"I am ok with any clinical trial involving external medical device or alternative therapy as it is non-invasive. However, I won't try any drugs, vaccine, or internal device related study for their potential side effects."*
- *"My daughter has a regenerative disease. She doesn't have much time. I'd be willing to try anything to extend her life."*

- *"The same factors that apply to myself around my previously stated concerns would prevent myself or my allowing my child to participate in select trials. If I was a lifesaving clinical treatment for a rare condition, I would be more open to the idea of 'trying anything'."*
- *"I think I would be less willing to allow my child to be involved in certain things. She is still too young to be able to make the decision on her own. If she was older and able to comprehend what was being asked of her and wanted to participate, then I would.*

Demographics

Gender	Total (n=306)
Female	205
Male	94
Gender Variant/Non-binary	7

Age	Total (n=306)
18-24	18
25-34	47
35-44	88
45-54	71
55-64	56
65+	26

Ethnicity	Total (n=306) *multi-select
Asian or Asian American	40
Black, African, or African American	17
Hispanic, Latino, Latina, or Latinx	18
Middle Eastern or North African	0
Native American or Alaska Native	6
Native Hawaiian or Pacific Islander	1
Mixed race	4
White	222
As something else	1
Prefer not to answer	3

LGBTQ+	Total (n=306)
Yes	50
No/Prefer not to answer	256

Household Income	Total (n=306)
Up to $35,000	55
$35,000-$49,000	24
$50,000-$74,000	67
$75,000-$99,000	47
$100,000-$149,000	53
$150,000-$199,000	25
$200,000-$249,000	7
$250,000 or more	11
Prefer not to answer	17

Education Level	Total (n=306)
Some high school or less	1
High school/secondary school graduate	31
Some college	55
Trade/vocational school graduate	9
Bachelor's degree	108
Associate's degree	36
Master's degree	40
Advanced degree	12
PhD or Doctorate	3
Specialty degree (J.D.)	11

Appendix B: In-Language Survey Report

Research Overview

Since 2020 Washington DOH has partnered with C+C to conduct long-term research focused on understanding the health-related views and opinions of Washington residents who speak the 17 most represented languages (other than English). These include Cantonese, Mandarin, Korean, Vietnamese, Cambodian Khmer, Tagalog, Russian, Ukrainian, Hindi, Punjabi, Amharic, Marshallese, Somali, Arabic, French, Spanish, and American Sign Language (ASL). The research initially focused on COVID-19 and in 2022 began to expand to other health topics.

Research Approach

C+C recruited and trained 17 moderators who speak the target languages. These moderators then recruited 8-12 participants from their communities to take part in the research.

Participant criteria included they be over 18 years old; speak the target language; believe COVID-19 exists; not be categorically against vaccination; and not employed in a medical, public health, or media capacity.

This phase of research was conducted using a 30-45 minute survey (comprising of mostly open-ended questions), which participants had the choice of completing in written form or via a phone call with the moderator.

Survey questionnaires were drafted by C+C with input from the DOH and translated and administered by moderators. Moderators translated responses back into English and provide notes and verbatims from participants back to C+C for analysis and reporting.

Moderators were also asked to provide their own comments and interpretation of the results, which are included verbatim in this report.

Surveys Completed: 160*

Survey Field Dates: 7/24/23 – 8/11/23

*As this study was designed using a qualitative research approach, all data should be considered directional, rather than predictive.

About this Document

This document provides key findings and individual summaries from the in-language research. It summarizes key findings and language-specific findings for all 17 languages: Russian, Cambodian, Punjabi, Tagalog, Cantonese, Korean, Spanish, Ukrainian, Vietnamese, Somali, Amharic, ASL, Arabic, Hindi, French, Marshallese, and Mandarin.

Clinical Research Trials

1. **The majority of participants say they know what clinical research trials are.** The Korean, Russian, and Punjabi-speaking groups express the highest levels of understanding, while the Arabic and Somali-speaking groups express the lowest levels of understanding.
    - 32 No
    - 27 Unsure
    - 101 Yes
2. **When asked to describe a clinical research trial, participants give varied answers and levels of detail. Many mention testing new medications, vaccines, or drugs, testing on a group of human volunteers, and testing for safety and efficacy.** A few participants across segments think it is a trial that involves animal testing.
3. **Across segments, feelings or emotions that come up when thinking about clinical research trials are curiosity, fear, gratitude, safety, anxiety, and confusion around what the trials are and how they work.** Some participants express gratitude towards those who participate in clinical research trials, but express fear and anxiety about volunteering themselves.
4. About two-thirds of participants have never heard of any opportunities to participate in clinical research trials. The Tagalog speaking language group has a notably higher number of participants that have heard of an opportunity (n=7).
    - 102 No
    - 8 Unsure
    - 49 Yes
5. Very few participants have participated in a clinical research trial before. Notably, one participant in the Deaf community attempted to participate in one but was rejected because of their deafness.
    - 153 No
    - 7 Yes
6. Across segments, the main barriers to participating in clinical trials are fear of adverse side effects and/or negative long term health consequences and a lack of awareness about clinical trials. Some participants also mention a lack of in-language information and resources.
    a. In the Arabic-speaking group, some participants specifically mention coming to the US for safety as a refugee and not wanting to engage in risk.
    b. The Mandarin-speaking group mentions that their Chinese culture discourages experimenting with their body. They also expressed higher trust and willingness to experiment with Eastern medicine compared to Western medicine.
7. Participants think that reassurance about safety, better education around clinical trials, financial incentives, and the knowledge that they are helping others could encourage people in their communities to participate in clinical research trials. Some participants say that they don't think there is anything that could help people feel more comfortable participating. Other participants think that positive testimonials from others in their community that have participated in clinical research trials would be a motivator.

Appendix C: Institutional Best Practices for Facilitating Engagement of Diverse Populations in Clinical Trials

This document was created to support the HB 1745 community engagement workgroup and provides a summary of best practices that research institutions can implement to help achieve the goal of diverse participation in clinical trials. These best practices have been compiled by the Integrating Special Populations Program of the Institute of Translational Health Sciences (ITHS), based on critical input from the Health Equity Research Community Advisory Council, which advises ITHS and Seattle Children's Research Institute.

Institutional Best Practices

Building, supporting, and training a diverse research workforce

An important strategy for increasing the diversity of clinical trial participants is to increase the diversity of the research workforce by building pathways for people of color, lower income populations, rural populations, LGBTQIA+, and those otherwise underrepresented in biomedical and health research fields. A more diverse research workforce is essential for conducting the best science, and when individuals are asked to participate in research, it is critical that they can see themselves reflected in the research team.

- Implement programs (e.g., paid summer internships, career developmental awards, mentorship programs) that offer individuals underrepresented in biomedical and health research, opportunities to gain exposure to or enter the field at multiple points in their education and career. (See Seattle Children's Research Institute Summer Scholars Program, as an example.)

Equity, diversity, and inclusion (EDI) in research will only increase through changes in both intra- and inter-personal attitudes and behaviors among research teams and changes within institutional structures, policies, and opportunities that enable equitable research practices.

- Provide research-focused EDI training and education for research teams. EDI trainings are becoming more common in academic and research institutions, yet most organizations do not offer EDI training that is specific to researchers or research teams. EDI excellence in research training has been developed by the Integrating Special Populations Program at the Institute of Translational Health Sciences (ITHS) and has been offered by Seattle Children's Research Institute.

Establish language access for participants who speak a language other than English

- Include translation (written) and interpreter service (spoken) costs in budgeting and negotiations for all clinical trials
- Provide translation and interpreter services to research teams regardless of budget
- Hire bilingual and multilingual research staff
- Provide language certification consistent with the needs of the research environment for bilingual and multilingual research staff
- Offer a library of templates for IRB consent and other documentation available in multiple languages
- Provide a process to enable rapid translation and approval for research materials (e.g., consent forms) in multiple languages
- Consider utilizing alternatives to written materials (e.g., videos for IRB consent, audio and voice communication for web-based surveys on smartphones), and make these available in multiple languages

Offer flexible research processes for participation

- Allow the research team to select the participant incentive method(s) that best serves their research population; these may include electronic gift cards, payment cards, and cash.
- Ensure policies exist and are utilized that provide guidance about and require fair compensation for participants
- Provide needed supports for participating in research such as transportation to study visits or childcare
- Offer remote methods of participation (e.g., telehealth study visits), as well as the supports needed to access them (e.g., wifi hotspots, devices)

Engage community stakeholders

- Ensure community voices from diverse populations are included in research policy discussions and decision making at the institutional level
- Include, train, and appropriately compensate community members on IRB committees, and other councils, taskforces, or committees that inform research policies and practices or research studies.
- Provide needed supports such as transportation, interpreters, child care, and fair compensation to reduce barriers to participation for community members.
- Create opportunities for research participants and community members who are not already engaged in research to share their research priorities, concerns, and feedback
- Integrate community/patient/participant leaders from diverse communities into research administration and leadership

Eliminate barriers to effectively partner with communities in research

- Ensure that policies exist and are utilized that allow research teams to easily partner with and compensate community organizations for their partnership in research. Examples of this include the "community collaborator" policy at Seattle Children's, which gives research teams a mechanism to pay community members for their expertise.
- Enable use of participant-centered strategies for study visits and data collection (e.g., photoenhanced translated instructions to help with parking kiosks, building names, and locations, clearly marked Uber/Lyft drop off location near building, Zoom/phone options for completing forms, evening/weekend study visits, escort to/from parking/bus and clinic).

Strengthen IRB and other review to ensure that trials have a clear plan to use equitable practices for participants

- English-only studies should be discouraged, and only approved when researchers have clearly exhausted all possibilities to expand language access.
- Studies should demonstrate a plan and ability to recruit a diverse patient population—when this is not clearly stated, the IRB can refer researchers to an institution-provided consultation service for EDI in research planning.
- Establish institution-supported consultation services regarding EDI in research planning, implementation, and dissemination
- Require plain language on all participant-facing content

Appendix D: Cancer Consortium Task Force on Inclusion & Equity in Research Resource Library

Task Force on Inclusion & Equity in Research

Fred Hutch/University of Washington/Seattle Children's Cancer Consortium

Resource Library

June 29, 2022

BOOKS:

How We Do Harm: A Doctor Breaks Ranks About Being Sick in America by Otis Brawley

Available in print at Fred Hutch Arnold Library: https://fredhutch.on.worldcat.org/oclc/740628608 (scroll down and click on "Other Libraries Worldwide" button for availability at other local libraries and beyond)

PUBLICATIONS:

Health Equity

Seewaldt VL, Winn RA. Residential Racial and Economic Segregation and Cancer Mortality in the US-Speaking Out on Inequality and Injustice. JAMA Oncol. 2023 Jan 1;9(1):126-127.

Winn RA. Enrollment Matters: The Reality of Disparity and Pursuit of Equity in Clinical Trials. Cancer Discov. 2022 Jun 2;12(6):1419-1422.

Rebbeck TR, Bridges JFP, Mack JW, et al. A Framework for Promoting Diversity, Equity, and Inclusion in Genetics and Genomics Research. JAMA Health Forum. 2022;3(4):e220603.

- Free full text: https://jamanetwork.com/journals/jama-health-forum/fullarticle/2791195

Boulware LE, Corbie G, Aguilar-Gaxiola S, Wilkins CH, Ruiz R, Vitale A, Egede LE. Combating Structural Inequities - Diversity, Equity, and Inclusion in Clinical and Translational Research. N Engl J Med. 2022 Jan 20;386(3):201-203.

- https://pubmed.ncbi.nlm.nih.gov/35029847/

Croyle RT, Sanchez JI, Doose M, Kennedy AE, Srinivasan S. Avoiding Pro Forma: A Health Equity-Conscious Approach to Cancer Control Research. Am J Prev Med. 2021 Dec 22:S0749-3797(21)00563-8.

- https://pubmed.ncbi.nlm.nih.gov/34953667/

Editors, Rubin E. Striving for Diversity in Research Studies. N Engl J Med. 2021 Oct 7;385(15):1429-1430.

- https://pubmed.ncbi.nlm.nih.gov/34516052/

Lansey DG, Hefka TA, Carducci MA, Kanarek NF. Problem Solving to Enhance Clinical Trial Participation Utilizing a Framework-Driven Approach. Clin Adv Hematol Oncol. 2020 Aug;18(8):468-476.

- https://pubmed.ncbi.nlm.nih.gov/32903246/

Systematic Reviews of Cancer Clinical Trials

Unger JM, Hershman DL, Till C, Minasian LM, Osaogiagbon RU, Fleury ME, Vaidya R. "When offered to participate:" A systematic review and meta-analysis of patient agreement to participate in cancer clinical trials. J Natl Cancer Inst. 2020 Oct 6:djaa155

- https://pubmed.ncbi.nlm.nih.gov/33022716/
- Free full text: https://academic.oup.com/jnci/article/113/3/244/5918345
- A prior systematic review and meta analysis established that 3 out or 4 cancer patients do not participate in clinical trials because no trial is locally available, or one is available, the patient is ineligible. This study addressed the follow up question about how often patients who are offered a trial agree to participate. The study showed that the overall rate of agreement to participate if offered a trial was 55.0%, much higher than typically assumed. Moreover, there was no evidence that rates of agreement to participate differed by race/ethnicity. This suggests that observed racial/ethnic disparities in trial participation manifest earlier in treatment decision-making, and indicates that a good way to improve enrollment of minority patients is to ensure they are invited to participate.

Unger JM, Vaidya R, Hershman DL, Minasian LM, Fleury M. Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician/Patient Barriers to Cancer Clinical Trial Participation. J Natl Cancer Inst. 2019 Mar 1;111(3):245-55

- https://pubmed.ncbi.nlm.nih.gov/30856272/
- Free full text: https://academic.oup.com/jnci/article/111/3/245/5307078
- Although patient-level barriers have been a focus of research into low rates of adult cancer patient participation in clinical trials, this study showed for the first time that the root cause of low trial participation rates is a clinical trial system beset with structural and clinical barriers. In fact, for more than 3 out of 4 cancer patients, trial participation was not possible because a trial was not locally available, or if available, the patient was ineligible.

Disparities by Race and Ethnicity

Riner AN, Girma S, Vudatha V, Mukhopadhyay N, Skoro N, Gal TS, Freudenberger DC, Herremans KM, George TJ, Trevino JG. Eligibility Criteria Perpetuate Disparities in Enrollment and Participation of Black Patients in Pancreatic Cancer Clinical Trials. J Clin Oncol. 2022 Jul 10;40(20):2193-2202.

- https://pubmed.ncbi.nlm.nih.gov/35316089/

- Free full text: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9273372/

Hantel A, Luskin MR, Garcia JS, Stock W, DeAngelo DJ, Abel GA. Racial and ethnic enrollment disparities and demographic reporting requirements in acute leukemia clinical trials. Blood Adv. 2021 Nov 9;5(21):4352-4360.

- https://pubmed.ncbi.nlm.nih.gov/34473244/
- Free full text: https://ashpublications.org/bloodadvances/article/5/21/4352/476759/Racial-and-ethnic-enrollment-disparities-and

Adamson BJS, Cohen AB, Gross CP, Estévez M, Magee K, Williams E, Meropol NJ, Davidoff AJ. ACA Medicaid expansion association with racial disparity reductions in timely cancer treatment. Am J Manag Care. 2021 Jul;27(7):274-281.

- https://pubmed.ncbi.nlm.nih.gov/34314116/
- Free full text: https://doi.org/10.37765/ajmc.2021.88700

Gormley N, Fashoyin-Aje L, Locke T, Unger JM, Little RF, Nooka A, Mezzi K, Popa-McKiver M, Kobos R, Biru Y, Williams TH, Anderson KC. Recommendations on eliminating racial disparities in multiple myeloma therapies: a step toward achieving equity in healthcare. Blood Cancer Discov. 2021 Mar;2(2):119-124.

- https://pubmed.ncbi.nlm.nih.gov/34179821/
- Free full text: https://aacrjournals.org/bloodcancerdiscov/article/2/2/119/2099/Recommendations-on-Eliminating-Racial-Disparities

Vyas DA, Eisenstein LG, Jones DS. Hidden in Plain Sight - Reconsidering the Use of Race Correction in Clinical Algorithms. N Engl J Med. 2020 Aug 27;383(9):874-882.

- https://pubmed.ncbi.nlm.nih.gov/32853499/
- Free full text: https://www.nejm.org/doi/10.1056/NEJMms2004740

Unger JM, Hershman DL, Osarogiagbon RU, Gothwal A, Anand S, Dasari A, Overman M, Loree JM, Raghav K. Representativeness of Black Patients in Cancer Clinical Trials Sponsored by the National Cancer Institute Compared With Pharmaceutical Companies. JNCI Cancer Spectr. 2020 Apr 24;4(4):pkaa034

- https://pubmed.ncbi.nlm.nih.gov/32704619/
- Free full text: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7368466/
- This study showed that the very low representation of Black patients in trials leading to new FDA drug approvals was due primarily to the fact that such trials are almost entirely conducted by pharmaceutical companies, which have poor outreach to community and minority and underserved sites. In contrast, representation of Black patients to federally sponsored trials of the NCI – which have dedicated programs of outreach to the

community for cancer clinical trials – was 3x greater (9% versus 3%). This suggests that the enrollment programs of the NCI provide a ready model that pharma might emulate to improve representation of racial and ethnic patient groups.

Loree JM, Anand S, Dasari A, Unger JM, Gothwal A, Ellis LM, Varadhachary G, Kopetz S, Overman MJ, Raghav K. Disparity of Race Reporting and Representation in Clinical Trials Leading to Cancer Drug Approvals From 2008 to 2018. JAMA Oncol. 2019 Aug 15:e191870

- https://pubmed.ncbi.nlm.nih.gov/31415071/
- Free full text: https://jamanetwork.com/journals/jamaoncology/fullarticle/2748395
- This seminal paper examined enrollment patterns by race in clinical trails leading to new FDA drug approvals, which were predominantly (97%) conducted by pharmaceutical companies. The authors showed that for these critical studies leading to new FDA oncology drug approvals, although White and Asian patients were well represented, Hispanic and Black patients were substantially underrepresented. In fact, Black patients comprised only 3.1% of all trial enrollments, compared to 14.1% in the corresponding set of cancers in the U.S. cancer population.

Chavez-MacGregor M, Unger JM, Moseley A, Ramsey S, Hershman DL. Survival by Hispanic ethnicity among cancer patients participating in SWOG clinical trials. Cancer. 2018 April 15;124(8):1760-69

- https://pubmed.ncbi.nlm.nih.gov/29370458/
- Free full text: https://acsjournals.onlinelibrary.wiley.com/doi/10.1002/cncr.31241
- This study of nearly 30,000 patients found that Hispanic patients were more likely to be younger and from areas of lower income and education, but that adjusting for these and other important covariates, Hispanic patients participating in trials (who received uniform treatment and follow-up) were found to have similar survival outcomes compared with non-Hispanic patients.

Disparities by Age

Unger JM, Coltman CA Jr, Crowley JJ, Hutchins LF, Martino S, Livingston RB, Macdonald JS, Blanke CD, Gandara DR, Crawford ED, Albain KS. Impact of the year 2000 Medicare policy change on older patient enrollment to cancer clinical trials. J Clin Oncol. 2006 Jan 1;24(1):141-4

- https://pubmed.ncbi.nlm.nih.gov/16330670/
- Free full text: https://ascopubs.org/doi/full/10.1200/JCO.2005.02.8928
- Examined enrollment patterns by age before vs. after the Medicare policy change, and observed an increase in older patient enrollment overall, but primarily among those with Medicare + private insurance. Implications: Marginal additional costs of trial participation (i.e. co-pays, co-insurance) were likely still barriers for patients

Hutchins LF, Unger JM, Crowley JJ, Coltman CA Jr, Albain KA. Underrepresentation of patients 65 years of age or older in cancer-treatment trials." N Engl J Med. 1999 Dec 30;341(27):2061-7

- https://pubmed.ncbi.nlm.nih.gov/10615079/
- Free full text: https://www.nejm.org/doi/10.1056/NEJM199912303412706
- An evaluation of accrual rates by demographic factors, showing that women and blacks were fairly represented in treatment trials from 1993-1996 but that older patients were dramatically underrepresented. This study provided crucial evidence for an IOM report that was the basis of Medicare changing its policy in 2000 to cover the routine care costs of clinical trials.

Disparities by Income or Socioeconomic Variables

Unger JM, Moseley AB, Cheung CK, Osarogiagbon RU, Symington B, Ramsey SD, Hershman DL. Persistent Disparity: Socioeconomic Deprivation and Cancer Outcomes in Patients Treated in Clinical Trials. J Clin Oncol. 2021 Mar 17:JCO2002602

- https://pubmed.ncbi.nlm.nih.gov/33729825/
- Free full text: https://ascopubs.org/doi/10.1200/JCO.20.02602
- Socioeconomic issues can extend beyond access to trials to outcome disparities for patients actually enrolled in trials. We examined whether survival outcomes in clinical trials differed according to area level socioeconomic deprivation. Clinical trials databases represent an opportune vehicle to address disparities in outcomes for cancer patients, since participation in a trial ensures access to guideline-based care, thus limiting access to care as a likely confounder when comparing groups. We found that among 41,000 patients examined from 55 trials, patients from areas with the greatest deprivation compared to the least had a 28% increased risk of death even after adjusting for prognosis, insurance status and other key demographic variables.

Unger JM, Blanke SD, LeBlanc M, Barlow WE, Vaidya R, Ramsey SD, Hershman DL. Association of Patient Demographic Characteristics and Insurance Status With Survival in Cancer Randomized Clinical Trials With Positive Findings. JAMA Network Open. 2018 Apr 30;3(4):e203842

- https://pubmed.ncbi.nlm.nih.gov/32352530/
- Free full text: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2765202
- Using data from 19 different trials for which the experimental therapy improved overall survival compared to standard of care, we found that the benefits of the new treatment were experienced in most important patient groups, including by age (<65 vs. >=65 years), race (minority vs. not minority), and sex (male vs female), and for those with private insurance. However, patients with Medicaid or no insurance did not experience the same additional benefit of new proven treatments, raising questions about how patients with lower socioeconomic status continue to experience negative health outcomes over the longer term, even after receiving quality, guideline-based care.

Unger JM, Gralow JR, Albain KS, Ramsey SD, Hershman DL. Patient Income Level and Cancer Clinical Trial Participation: A Prospective Survey Study. JAMA Oncol. 2016 Jan 1;2(1):137-9

- https://pubmed.ncbi.nlm.nih.gov/26468994/
- Free full text: https://jamanetwork.com/journals/jamaoncology/fullarticle/2457394
- This study used data from a prospective survey study of to confirm the results of the prior study about income barriers (Unger et al., JCO, 2013), demonstrating that individuals with household income <$50k/year) were 30% less likely to participate in cancer clinical trials.

Unger JM, Hershman D, Albain KS, Moinpour CM, Petersen J, Burg K, Crowley JJ. Patient Income Level and Cancer Clinical Trial Participation. J Clin Oncol. 2013 Feb 10;31(5):536-42

- https://pubmed.ncbi.nlm.nih.gov/23295802/
- Free full text: https://ascopubs.org/doi/10.1200/JCO.2012.45.4553
- Examined participation patterns by demographic and socioeconomic variables, which had previously not been done because patient level socioeconomic variables are not routinely captured for patients
- enrolling in trials. This study utilized instead a web-based survey for newly diagnosed cancer patients, and showed that patients with lower household income (<$50k/year) were 30% less likely to participate in clinical trials. The study also demonstrated that lower income patients were much more concerned about how to pay for clinical trial treatment than higher income individuals.

Financial Impacts on Patients

Watabayashi K, Steelquist J, Overstreet KA, Leahy A, Bradshaw E, Gallagher KD, Balch AJ, Lobb R, Lavell L, Linden H, Ramsey SD, Shankaran V. A Pilot Study of a Comprehensive Financial Navigation Program in Patients With Cancer and Caregivers. J Natl Compr Canc Netw. 2020 Oct 1;18(10):1366-1373.

- https://pubmed.ncbi.nlm.nih.gov/33022646/
- Free full text: https://jnccn.org/view/journals/jnccn/18/10/article-p1366.xml

Shankaran V, Unger JM, Darke AK, Hershman DL, Ramsey SD. Design, data linkage, and implementation considerations in the first cooperative group led study assessing financial outcomes in cancer patients and their informal caregivers. Contemp Clin Trials. 2020 Aug;95:106037.

- https://pubmed.ncbi.nlm.nih.gov/32485324/
- Free full text: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8171354/

Yezefski TA, Le D, Chen L, Speers CH, Chennupati S, Snider J, Gill S, Ramsey SD, Kennecke HF, Shankaran V. Comparison of Treatment, Cost, and Survival in Patients With Metastatic Colorectal Cancer in Western Washington, United States, and British Columbia, Canada. JCO Oncol Pract. 2020 May;16(5):e425-e432.

- https://pubmed.ncbi.nlm.nih.gov/32298222/
- Free full text: https://ascopubs.org/doi/full/10.1200/JOP.19.00719

Unger JM, Fleury ME. Reimbursing Patients for Participation in Cancer Clinical Trials. JAMA Oncol. 2019 Jul 1;5(7):932-934.

- https://pubmed.ncbi.nlm.nih.gov/31169875/

Impact of COVID-19 on Clinical Trial Enrollment including by Demographic Variables

Unger JM, Xiao H, LeBlanc M, Hershman DL, Blanke CD. Cancer Clinical Trial Participation At the One Year Anniversary of the Outbreak of the COVID-19 Pandemic. JAMA Netw Open. 2021 Jul 1;4(7):e2118433

- https://pubmed.ncbi.nlm.nih.gov/34323986/
- Free full text: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2782530
- One year into the COVID-19 pandemic, we examined the full one-year experience of cancer clinical trial enrollment, including whether patterns of enrollments differed over time in conjunction with COVID-19 mortality waves, and whether existing inequities in trial participation were exacerbated. Using interrupted time series analysis with indicator variables to account for seasonal variation, among N=29,398 patients, we found a 9% weekly reduction in enrollments compared to expected rates during the initial COVID-19 wave, which compounded weekly. Enrollments recovered at a rate of 4% per week during the initial recovery period, but then dropped again during the very severe winter 2020/2021 wave, although the drop was much milder at only 2% per week. Overall, during the entire first year of the pandemic, there was a 23% relative reduction in enrollments to all trials combined, although for treatment trials, we found only a 9% reduction compared to expected, compared to a much greater 46% reduction for cancer control and prevention trials. Moreover, for both treatment and CCP trials, there were proportionally fewer patients enrolled during the pandemic from states with higher COVID-19–related excess death rates, whereas for states with low COVID-19 related excess deaths, rates were similar. Patterns of changes within demographic subgroups were similar.

Unger JM, Blanke CD, LeBlanc M, Hershman DL. Association of the Coronavirus Disease 2019 (COVID-19) Outbreak With Enrollment in Cancer Clinical Trials. JAMA Netw Open. 2020;3(6):32010651

- https://pubmed.ncbi.nlm.nih.gov/32478845/
- Free full text: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766577
- A clear correspondence between increasing COVID-19 cases in the U.S. and decreasing enrollment to cancer clinical trials was demonstrated. This reduction in enrollments was especially notable among cancer control and prevention trials, although reductions for treatment trial enrollment was also noted. There were no significant differences in patterns of decreased enrollment by age, race, or ethnicity.

Fleury ME, Farner AM, Unger JM. Association of the Coronavirus Disease-2019 (COVID-19) Outbreak with Patient Willingness to Enroll in Cancer Clinical Trials. JAMA Oncol. 2020 Nov 12:3205748

- https://pubmed.ncbi.nlm.nih.gov/33180102/
- Free full text: https://jamanetwork.com/journals/jamaoncology/fullarticle/2772839
- Using a convenience sample of cancer survivors participating in the American Cancer Society Cancer Action Network's Survivor Views panel, this study revealed that nearly 1 in 5 cancer patients were less likely to enroll in a cancer clinical trial because of fears surrounding COVID-19. These patterns were similar across demographic and socioeconomic groups, and suggest that as long as high rates of COVID-19 cases exist, cancer patients may be less likely to consider trial participation even when sites return to prepandemic status

Patient Perspectives

Anampa-Guzmán A, Freeman-Daily J, Fisch M, Lou E, Pennell NA, Painter CA, Sparacio D, Lewis MA, Karmo M, Anderson PF, Graff SL; Collaboration for Outcomes using Social Media in Oncology. The Rise of the Expert Patient in Cancer: From Backseat Passenger to Co-navigator. JCO Oncol Pract. 2022 Mar 28:OP2100763.

- https://pubmed.ncbi.nlm.nih.gov/35344398/
- Free full text: https://ascopubs.org/doi/full/10.1200/OP.21.00763

Forster VJ. What cancer survivors can teach cancer researchers. Nat Rev Cancer. 2022 Mar 23.

- https://pubmed.ncbi.nlm.nih.gov/35322227/

Pate L, Desmedt C, Metzger O, Burgess Hutcheson L, Turner C, Freeney S, Oesterreich S. How Researchers, Clinicians and Patient Advocates Can Accelerate Lobular Breast Cancer Research. Cancers (Basel). 2021 Jun 22;13(13):3094.

- https://pubmed.ncbi.nlm.nih.gov/34206261/
- Free full text: https://www.mdpi.com/2072-6694/13/13/3094/htm

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- https://pubmed.ncbi.nlm.nih.gov/30629092/
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- Patients with comorbid conditions were notably less likely to participate in clinical trials, even for comorbidities not directly related to eligibility, suggesting that the impression of frailty or comorbidity could prohibit trial offers even when not relevant to the trial.

Unger JM, Moseley A, Symington B, Chavez-MacGregor M, Ramsey SD, Hershman DL. Geographic Distribution and Survival Outcomes for Rural Patients With Cancer Treated in Clinical Trials. JAMA Network Open. 2018 Aug 3; 1(4):e181235

- https://pubmed.ncbi.nlm.nih.gov/30646114/
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- In this study of 37,000 patients, 19.4% of patients were from rural areas, the same proportion of individuals who live in rural areas in the U.S. This demonstrated the remarkable success of NCI network group trials in reaching out beyond large urban centers to enroll patients in the community and in rural areas. In multivariable regression, rural patients participating in trials (who received uniform treatment and follow-up) were found to have similar survival outcomes compared with their urban counterparts.

Unger JM, Barlow WE, Martin DP, Ramsey SD, LeBlanc M, Etzioni R, Hershman DL. Comparison of survival outcomes among cancer patients treated in and out of clinical trials. J Natl Cancer Inst. 2014 Mar 1;106(3):dju002

- https://pubmed.ncbi.nlm.nih.gov/24627276/
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- This study compared presenting characteristics and survival patterns between clinical trial patients to the U.S. cancer population. There were no differences in presenting characteristics by stage or race, small differences by sex, and persistent, large differences by age, confirming that older patients are routinely underrepresented in clinical trials to a large degree.

ONLINE RESOURCES:

Biomarker Testing – Equitable Access: providing/mandating insurance coverage

Washington Senate Bill SB 5822: Senate Bill 5822

- Link to legislative text.
- Link to committee summary (bill report).

Black Patients Underrepresented in Pivotal CAR T-Cell Trials – Regulatory Affairs Professional Society

https://www.raps.org/news-and-articles/news-articles/2022/4/study-black-patients-underrepresented-in-pivotal-c

Clinical Trials Participation Among U.S. Adults – NCI Health Information National Trends Survey (HINTS) Briefs March 2022

https://hints.cancer.gov/docs/Briefs/HINTS_Brief_48.pdf

Decentralized Cancer Clinical Trials Can Overcome Barrier to and Disparities in Participation. Here's How.

https://dailynews.ascopubs.org/do/10.1200/ADN.22.200880/full/

Delaware is shrinking racial gaps in cancer death. Its secret? Patient navigators

https://www.npr.org/sections/health-shots/2022/03/07/1084317639/delaware-is-shrinking-racial-gaps-in-cancer-death-its-secret-patient-navigators

Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry: Draft Guidance – Food & Drug Administration

https://www.fda.gov/media/157635/download

Equity by Design in Clinical Research: Cancer Trials (6 module course) – Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard and the Center for Cancer Equity and Engagement at the Dana-Farber/Harvard Cancer Center

https://cpd.partners.org/content/equity-design-clinical-research-cancer-trials#group-tabs-node-course-default1

Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry

https://www.fda.gov/media/127712/download

Overcoming Barriers to Diversifying Clinical Trials – National Academies

Workshop materials and recordings: March 29, 2021

https://www.nationalacademies.org/event/03-29-2021/overcoming-barriers-to-diversifying-clinical-trial-workshop

2nd Public Workshop materials and recordings: June 1, 2021

https://www.nationalacademies.org/event/06-01-2021/overcoming-barriers-to-diversifying-clinical-trials-2nd-public-workshop

3rd Public Workshop materials and recordings: September 13, 2021

https://www.nationalacademies.org/event/09-13-2021/overcoming-barriers-to-diversifying-clinical-trials-third-public-workshop

Payment and Reimbursement to Research Subjects – FDA

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects

Public Workshop on Use of Population Descriptors in Genomics Research – National Academies Workshop : February 14-15, 2022 and April 4-7, 2022

https://www.nationalacademies.org/our-work/use-of-race-ethnicity-and-ancestry-as-population-descriptors-in-genomics-research

Racial Disparities in Clinical Medicine: Conversations, Perspectives, and Research on Advancing Medical Equity by NEJM Group

https://store.nejm.org/media/assets/nejm/register/pdf/NEJM_Group_Racial_Disparities_in_Clinical_Medicine.pdf

Racism in Medicine CME series – King County Medical Society

- Michelle Terry, MD: Introduction to the CME
- Estell Williams, MD and Edwin Lindo, JD: Keynote: The History of Bias in Medicine in our Society
- Lara Oyetunji, MD: Impacts of Race on Cardiovascular Disease
- Elina Quiroga, MD: Specific Examples of Biased Medicine: Diabetes
- Yaw Nyame, MD: Disentangling Racial Disparities in Prostate Cancer
- John Vassall, MD: Health Disparities and Inequities: Colon Cancer
- Rajneet Lamba, MD and Sen. Manka Dhingra: Covid-19 and What It Has Revealed
- Ben Danielson, MD: A Metamorphosis in Representational Diversity Training; what should young professionals in training experience?
- Q&A Session

https://kcmsociety.org/cme-racism-in-medicine/

Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care by the National Academy of Sciences

https://www.nap.edu/catalog/12875/unequal-treatment-confronting-racial-and-ethnic-disparities-in-health-care

Appendix E: Representation in Selected University of Washington Clinical Trials[38]

The diversity, equity and inclusion (DEI) information for the University of Washington (UW) and UW Medicine was obtained from the OnCore Clinical Trial Management System (CTMS). Our CTMS instance serves as a single, centralized, web-based resource to support clinical research activities conducted across both UW and Fred Hutchinson Cancer Center (FHCC). For more information, please visit our CTMS Program Office website at https://www.iths.org/ctms/. For additional questions, please contact the UW Clinical Trials Office at uwcto@uw.edu.

The CTMS installation was completed in phases with Oncology and Hematology related trials entered into the system in fiscal year 2019 (Sep 2018). Clinical research studies from other disciplines were not entered until the end of FY2023 (May 2023). Because the provided DEI data are looking at the subject enrollment information from **FY2019-FY2023** period, these initial data are mostly from the oncology and hematology related studies. These studies represented roughly **60-65%** of our clinical trial portfolio during the reported period.

The reported study subject data included the following elements:

- **Biological Sex** with Male and Female values. Unknown value was listed when no other value was present.
- **Age** organized into 0-39 years old, 40-59 years old and 60+ (60 and above) group categories. Unknown value was listed when no other value was present.
- **Race** with the following values: American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Pacific Islander; White; Another Race; Declined to Answer; Unable to Collect; Unknown. In instances where multiple race values were reported, each race was counted and reported individually (study participant counted multiple times).
- **Ethnicity** with the following values included in the system: Hispanic or Latino; Non-Hispanic; Declined to Answer; Unable to Collect; Unknown.

Overall the provided data represents **44,076** study participants across **1,515** clinical trials and clinical research studies, with **70% (1,065)** accounting for Interventional protocols and **30%** Non-Interventional (Retrospective and Prospective Observational studies, Ancillary protocols, Comparative Effectiveness research). About **69% (1,039)** of protocols involved investigational drug and **5% (81)** involved investigational device.

The funding for the reported trials came primarily from industry biopharma and biotech sponsors **(46%)** and Federal government **(15%)**. The remaining **39%** of the protocols were funded by academic and non-profit institutions. Where multiples sources of funding were

[38] Data description and tables prepared and provided by University of Washington

present, protocols were attributed to Federal government if it was at least one of the listed sponsors or to other academic/non-profit category if it was at least one of the listed sponsors with no Federal government listed.

Research participants were enrolled across multiple locations with majority at Seattle Cancer Center Alliance (presently integrated into FHCC), accounting for **42%** of all accruals. Fred Hutch total subject accruals accounted for **23%**, UW **21%** (UW Medical Center 14%, Harborview Medical Center 5%, other UW clinics 2%), Seattle Children's Hospital **7%** and other sites (with some in WA State but mostly out of State) accounting for the remaining **7%**.

Appendix E Table 1: Biological Sex by Age

Age	Subjects	Percentage
Female	**21,610**	**100%**
0-39	4,844	22%
40-59	7,026	33%
60+	9,185	43%
Unknown	555	3%
Male	**21,020**	**100%**
0-39	4,136	20%
40-59	*	*
60+	*	*
Unknown	485	2%
Unknown	**1,446**	
0-39	33	
40-59	*	
60+	*	
Unknown	1,396	
TOTAL	**44,076**	**100%**
0-39	9,013	20%
40-59	11,670	26%
60+	20,957	48%
Unknown	2,436	6%

* Values suppressed for n<10 and adjacent cells

Appendix E Table 2: Race by Biological Sex

Race	Subjects				
	Female	Male	Unknown	Total	Percentage
American Indian or Alaska Native	423	*	*	792	2%
Asian	1,242	*	*	2,457	6%
Black or African American	1,951	*	*	3,058	7%
Native Hawaiian or Pacific Islander	174	199	0	373	1%
White	16,665	16,756	45	33,466	75%
Another Race	92	101	0	193	0%
Declined to Answer	414	*	*	804	2%
Unable to Collect	19	15	0	34	0%
Unknown	943	1,153	1,391	3,487	8%

* Values suppressed for n<10 and adjacent cells

Appendix E Table 3: Ethnicity by Biological Sex

Ethnicity	Subjects				
	Female	Male	Unknown	Total	Percentage
Hispanic or Latino	1,262	*	*	2,528	6%
Non-Hispanic	18,558	17,450	46	36,054	82%
Declined to Answer	293	*	*	625	1%
Unable to Collect	13	10	0	23	0%
Unknown	1,484	1,971	1,391	4,846	11%

* Values suppressed for n<10 and adjacent cells


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