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## Pursuing a New Paradigm, Inclusive Research That Meets Communities Where They Are

The Advancing Inclusive Research (AIR) Site Alliance is comprised of clinical research centers that collaborate with Genentech, a member of the Roche group, to deliver novel medicines and improved representation of patients in oncology and ophthalmology clinical trials.

Launched in June 2021, this coalition is uniquely positioned to establish a new standard for making clinical research accessible to communities who have been historically underrepresented by evaluating recruitment and retention approaches, and developing industry-wide best practices to achieve healthcare access for all.

Genentech's commitment to addressing barriers to clinical study participation ensures clinical trial participants are representative of the broader patient population affected by the disease being studied. Clinical trials often fail to represent real-world patients, with approximately 80% of participants being White despite non-White communities making up nearly 40% of the U.S. population.<sup>2</sup> Key barriers to participation include distrust in the healthcare system, lack of trial awareness, and systemic inequities.<sup>3,4,5,6</sup>

Recognizing these gaps, regulatory bodies such as the Food and Drug Administration (US-FDA) have emphasized the importance of transparency and accountability in clinical trial enrollment, requiring strategies that will contribute to racially and ethnically diverse patient participation.<sup>7,8,9</sup> The AIR Site Alliance strives to address disparities in healthcare and research by ensuring that clinical trials reflect patient diversity. This is achieved through deep collaboration with various stakeholders—including patients, community leaders, and thought leaders—to promote inclusive research and facilitate patient participation.<sup>1</sup>

Structurally, the six oncology and three ophthalmology research sites were selected through an extensive data-driven process, strategically focused on maximizing their reach to historically underrepresented patients in clinical trials. Site selection criteria included patient engagement initiatives, community outreach, research experience, and commitment to enrolling underrepresented populations. Factors like patient demographics, staff diversity, clinical trial infrastructure, and community engagement capabilities were also simultaneously considered. As our efforts to advance inclusive research evolved, we have worked collaboratively to share knowledge and explore innovative ways of increasing clinical study access for every patient, including co-creation of a more inclusive Protocol Entry Criteria Guidelines. The sites include:

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<sup>1</sup> Garrick, "Advancing Inclusive Research: Establishing Collaborative Strategies to Improve Diversity in Clinical Trials"

<sup>2</sup> Turner, "Race/Ethnicity reporting and representation in US clinical trials: a cohort study"

<sup>3</sup> Stephanikova, "Perceived Discrimination and Privilege in Healthcare: the role of socioeconomic status and race"

<sup>4</sup> Loree, "Disparity of race reporting and representation in clinical trials leading to Cancer Drug Approval, 2008-2018"

<sup>5</sup> Unger, "Systematic review and meta-analysis of the magnitude of barriers to Cancer Clinical Trial Participation"

<sup>6</sup> Smirnoff, "A paradigm for understanding trust and mistrust in medical research: the community VOICES study"

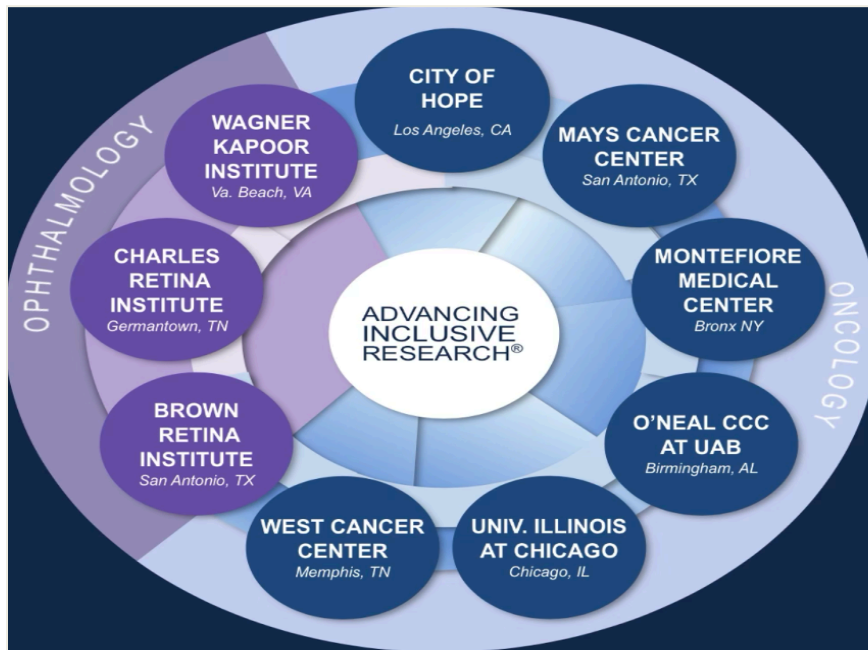
<sup>7</sup> Clinical Leader, "3 Ways the FDA is Taking Action on Lack of Diversity in Cancer Clinical Trials"

<sup>8</sup> FDA, "Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Population in Clinical Trials; Draft Guidance for Industry"

<sup>9</sup> FDA, "FDA Takes Important Steps to Increase Racial and Ethnic Diversity in Clinical Trials"

- City of Hope in Los Angeles, CA
- Mays Cancer Center in San Antonio, TX
- Montefiore Einstein Comprehensive Cancer Center in Bronx, NY
- O'Neal Comprehensive Cancer Center at University of Alabama, Birmingham
- University of Illinois Cancer Center in Chicago
- West Cancer Center and Research Institute in Memphis, TN
- Retina Consultants of Texas in San Antonio, TX
- Charles Retina Institute in Germantown, TN
- Wagner Kapoor Institute in VA Beach, VA.

## ADVANCING INCLUSIVE RESEARCH<sup>®</sup> SITE ALLIANCE



## CO-CREATING EDUCATION WITH SITES & PATIENTS TO IMPROVE REPRESENTATION IN CLINICAL RESEARCH

A cornerstone of the AIR Site Alliance's strategy is also co-creating educational materials for patients, their caregivers, family members, healthcare providers (HCPs), and clinical study teams. This collaborative approach ensures that any education provided is relevant, comprehensive, and resonates with the needs of all stakeholders and patient populations. The Alliance's bi-directional communication efforts incorporate both the perspectives of HCPs and input from underrepresented patients. Through this partnership, the Alliance has created educational resources that effectively bridge knowledge gaps and empower patients in the healthcare decision making journey.

## Patient Educational Videos, Postcards, and Flyers

Genentech's AIR Site Alliance has developed patient and HCP-facing animated educational videos which have been translated from English into Spanish, as well as 10 other languages. These videos provide easy-to-understand information about the clinical research study process, emphasizing the importance of representation and inclusion. The content equips HCPs with engagement strategies for the communities they serve, and empowers patients with the knowledge they need to make informed decisions about participating in a clinical research study. Along with these videos, the AIR Site Alliance has developed print materials such as flyers, brochures, and postcards) for site use in lobbies, waiting rooms, websites, and emails.<sup>10,11</sup>

Genentech's AIR educational resources have also been showcased at regional and national events, including health equity regional symposia and medical congresses, to educate patients, caregivers, and healthcare professionals, such as healthcare providers (HCPs) on clinical trials. <sup>2</sup>As a testament to their impact, the video "What Is a Clinical Research Study?" won the Telly Award, and "Why Hispanic/Latino Representation in Clinical Research Matters?" video secured Digital Health, W3, and Telly Awards.<sup>12</sup>

In recent efforts to advance inclusive r, the Genentech AIR Education team, in collaboration with the Bravo Group, published a new AIR Site Alliance Ophthalmology video. All of our non-animated videos educate internal and external audiences on the significance of inclusive research and including diverse patient populations in ophthalmology studies.

Healthcare is rapidly evolving with the integration of new developments of Digital Health Technologies (DHTs).<sup>13</sup> Videos can simplify complex concepts, focus attention, efficiently present information, and evoke emotional responses, all of which likely contribute to increased audience retention. Empirical evidence supports the value of QR codes, and other innovative sharing methods in disseminating essential information.<sup>15</sup>

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<sup>10</sup> Genentech Inc, "What Is a Clinical Research Study"

<sup>11</sup> Genentech Inc, " Is a Clinical Research Study Right for Me"



<sup>12</sup> Supplementary Resource 3, Link to Resources

<sup>13</sup> US FDA, "Digital Health Technologies (DHTs) for Drug Development

<sup>14</sup> Brodie et al., " Applications of Quick Response (QR) Codes in Medical Education

<sup>15</sup> Almeman, "The Digital Transformation in Pharmacy: Embracing Online Platforms and the Cosmeceutical Paradigm Shift "

Video Title	Respective QR Codes [Scan for Instant Video Access ]
What is a Clinical Research Study? [English]	
What is a Clinical Research Study? [Spanish]	
Is a Clinical Research Study Right for Me? [English]	
Is a Clinical Research Study Right for Me? [Spanish]	
Why Advancing Inclusive Research Matters, Trailer [English]	
Why Advancing Inclusive Research Matters [Full Length], [English]	

<p><b>Why Advancing Inclusive Research Matters in Ophthalmology Studies, [English]</b></p>	
<p><b>Why Hispanic/Latino Representation in Clinical Research Matters, [Spanish]</b></p>	

*Table 1. QR codes for publicly accessible video materials created by the AIR Site Alliance*

## **Health Practitioner AIR Education on Unconscious Bias and Cultural Humility Simulations**

A key barrier to enrolling historically underrepresented patients in clinical trials is unconscious bias among HCPs. The HCP AIR Education Program was developed by Genentech and the AIR Site Alliance community educators to focus on raising awareness about historical injustices against racial and ethnic minority populations in clinical research and the importance of inclusive research.

The program modules delve into the historical context and the current demography in U.S. clinical trials, while simultaneously examining how conscious inclusion can improve patient care and clinical trial participation. By fostering cultural safety, the training aims to eliminate preconceived notions and improve patient engagement.<sup>16</sup> This self-paced program also includes scenario-based practice modules and pre- and post-assessments. Upon adoption, 91% of participants reported increased knowledge and 64% indicated an intent to change behavior towards diverse patient populations.

## **Genentech’s Advancing Inclusive Research® Site Alliance Builds Trust in Communities through the Health Equity Regional Symposium Program**

Building trust within communities is critical to achieving better health access and increasing participation in clinical research among underrepresented populations. The Health Equity Regional Symposium Program, initiated by Genentech’s Chief Diversity Office, convenes a wide range of stakeholders - patients, caregivers, healthcare providers, administrators, public officials, payers, patient advocates, community health workers, researchers, policymakers, and community leaders. These symposia foster solution-driven discussions to address healthcare disparities. Each symposium focuses on local issues and features presentations and panel discussions on topics such as diversity in clinical trials, personalized medicine, social drivers of health, health literacy, and women’s health.

From 2021-2024, the AIR Site Alliance sites conducted 33 regional health equity symposia with attendance averaging from 50 to over 300 participants per event. These symposia explored health access strategies for clinical research, the benefits of preventative cancer screenings, and the importance of diverse patient participation in clinical studies. Each

symposium's goal is to foster meaningful dialogue and identify actionable steps in improving patient outcomes and trust in the clinical research process.

## Enhanced Patient Support Services in Clinical Research Trials

Sites reported the need for more patient support and navigation during clinical studies, so we created the “Enhanced Patient Support Services” for study budgets to ensure that patients receive the guidance and resources they need to participate confidently in clinical research.<sup>17, 18</sup> This program provides reasonable reimbursement for sites to provide additional support that enables trial appointment adherences, such as study visit transportation and child care services related to study participation. The support demystifies the clinical research process, and helps meet people where they are with the ultimate aim of building stronger relationships between patients and the broader medical community. Genentech offers this additional budget to all U.S. sites who choose to provide these services.

## Data Insights - Catchment Area Demographic and Enrollment Strategies

The AIR Site Alliance leverages data-driven strategies for enrolling a diverse patient population. A stratified, data collection approach was taken to assess sites for potential selection in the AIR Site Alliance. The team initially evaluated about 20,000 sites with historically diverse enrollment in oncology and ophthalmology trials. In a secure screening process sites with experience enrolling Black and Hispanic patient populations in studies were identified; then the list was further refined to focus on about 40 sites who enrolled the highest number of racial and ethnic minorities in studies. Final site selection involved in-depth assessments, including surveys and site interviews to understand Phase I-IV operational capabilities, regional challenges, staff capabilities for community outreach, and alignment with Genentech's commitment to inclusive research.

By focusing on sites with demonstrated success in engaging underrepresented populations, the AIR Site Alliance has made significant strides. Recent analyses show its oncology sites deliver a patient population that is 91% more diverse, while its ophthalmology sites achieve a 53% higher diversity rate compared to their peers on the same studies. These findings underscore the effectiveness of targeted enrollment strategies, community engagement efforts, and innovative actions designed to integrate diversity and inclusion into every aspect of patient care and our business.

## The AIR Site Alliance Is A Blueprint

The AIR Site Alliance serves as a blueprint for industry players to facilitate patient participation in clinical trials regardless of where they live, work, or receive medical care. The collective efforts of the AIR Site Alliance provide a practical model for making clinical research more accessible and innovative. At Genentech, we understand health inequities are complex

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<sup>16</sup> Cooper, “The Associations of Clinicians' implicit attitude about race with medical visit communication and patient rating of interpersonal care

<sup>17</sup> Loo, “ Patient navigator team perceptions on the implementation of a citywide breast cancer patient navigation protocol: a qualitative study”

<sup>18</sup> Natale - Pereira, “ The role of patient navigators in eliminating health disparities”

and cannot be solved overnight. Best practices established through the creation of the AIR Site Alliance model can be leveraged across the healthcare landscape to encourage inclusive behavior, such as enrolling diverse patient groups in clinical studies and delivering medicines to patients who need them most. As the US Alliance yielded successful results, in partnership with the Roche group, we've expanded to seven other countries: South Africa, the United Kingdom, Kenya, Morocco, India, Nigeria, and Canada.

As the AIR Site Alliance develops, there are opportunities for expansion beyond current indications, such as inflammatory bowel disease. With regulatory mandates by the FDA starting in 2025, pivotal clinical studies will be required to submit a plan for ensuring diversity among trial participants by way of Diversity Action Plans (DAPs). **Ahead of the regulatory mandates, Genentech has already submitted 35 DAPs in 2023 and 2024.**

Leadership and staff diversity are vital in fields such as oncology, ophthalmology, and cardiovascular research, where underrepresentation is prevalent.<sup>19</sup> Addressing these disparities requires bold and innovative actions. Pharmaceutical and biotech companies must ensure clinical trials are accessible to underrepresented patients by promoting education, fostering community relationships, supporting patients and sites, gathering insights, and simplifying protocols. This comprehensive approach will advance science and healthcare access, ensuring that trial results are representative of all populations. The ultimate goal is for each clinical trial to mirror the community it serves, providing inclusive and equitable healthcare solutions for all.

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<sup>2</sup>[Race/ethnicity reporting and representation in US clinical trials: A cohort study](#)

<sup>3</sup>[Supplementary Material 1: Site Profiles](#)

<sup>4</sup>[Supplementary Material 2: Inclusive Protocol Entry Criteria Recommendations](#)

<sup>5</sup>[Supplementary Material 3: Links to Resources](#)

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