



— NATIONAL —
MINORITY QUALITY
— F O R U M —



ALZHEIMER'S CLINICAL TRIAL LEARNING COMMUNITY (CTLC)

Advisory Board Executive Report

Recommendations and Strategies for the Alzheimer's CTLC Expansion





Thank you to **Biogen, our advisory board members, and community partners** for making the CTLC an impactful model for reducing barriers to clinical research.



Introduction

Established in 2020, the National Minority Quality Forum (NMQF) and Biogen developed the Clinical Trial Learning Community (CTLC) model to identify and mitigate disparities in clinical research. Together with NMQF, Biogen, and its community partners, the CTLC serves as a space where local clinical researchers, physicians, patients, community leaders, and others work toward a common objective: reducing disparities in care and outcomes for underrepresented patient populations living with serious, chronic diseases by ensuring awareness of and access to available clinical trials close to home.

The CTLC model has six core priorities to ensure the initiative is sustainable, impactful and community-driven:



Improve the engagement and inclusion of underrepresented communities in clinical research by influencing infrastructure development and outreach strategies, engaging community partners to make a difference.



Improve access to clinical trials education by influencing targeting strategies, site infrastructure development and sponsor and community readiness efforts.



Improve relevance of clinical operations to patient community by influencing protocol inclusion/exclusion criteria and operational activities.



Focus on community investment to help address the SDOH factors contributing to health disparities.



Offer an empathetic, community-based, holistic, and trustworthy support system and source of disease-related insights, without cultural and social silos.



Do no harm and engage ethically with patients, caregivers and the community.

Powered by the data derived from the Biogen Clinical Trials Index and by adopting the SHC quality improvement and education (QIE) and community engagement models, the CTLC initiative began focusing on building a Lupus learning community in the DC-Maryland-Virginia region, and it has achieved ample success as a model for systemic change.

NMQF partners with the Faith Health Alliance, HAIR Wellness Warriors, local health systems and others to increase knowledge and access related to clinical research. The learning community offers a place where recommendations, guidelines and metrics can be developed and propagated to foster changes within the local care network so they can operate to increase diversity in clinical trial recruitment. Additionally, this initiative is focused on helping primary care practices, patients and community groups better understand the importance of research participation among people of color.

Given the success of the Lupus CTLC model in addressing disparities and increasing both access and education to clinical trials, Biogen and NMQF are expanding the initiative to also focus on Alzheimer's disease and related dementia.

This new expansion involves developing a CTLC on the topic of clinical trials, with a special focus on Alzheimer's Disease. The CTLC members in the region will establish shared goals, including creating opportunities for practitioners, community leaders, researchers, and patient groups to meet, share local data, discuss notable practices, and build community conversations around clinical research opportunities, challenges, and solutions. The CTLC members will also participate in developing and disseminating the specific informational and educational content that they identify as a priority.



NMQF and Biogen Project Leads for the CTLC Initiative



Kelelaye Emiru, MBA
VP, Center for Professional and Strategic Alliances,
National Minority Quality Forum



Michael DeSalvo Solarte, MSW
Program Manager, Center for Professional and Strategic Alliances,
National Minority Quality Forum



Chinonso "Chinnie" Ukachukwu, MPH
Senior Director, Quality Improvement & Equity, Center for Sustainable Health Care Quality & Equity,
National Minority Quality Forum



Akeia Blue, MPH, MS
President, Center for Sustainable Health Care Quality & Equity,
National Minority Quality Forum



Mary Malooly
Intern, Center for Professional and Strategic Alliances,
National Minority Quality Forum



Savine DaCosta, MBA
Clinical Trial Diversity Site Lead,
Biogen



Kate Wilson
Head of Clinical Trial Diversity,
Biogen

Alzheimer's CTLC Advisory Board

Beginning in April 2024 and concluding in August 2024, NMQF convened a virtual advisory board, focused on Alzheimer's Disease, to help determine the new selected geography for CTLC expansion, as well as develop guidelines and recommendations, to overcome the barriers related to clinical trial participation and improve access to resources related to Alzheimer's Disease. Physicians, patient advocates, and researchers were brought together in a virtual setting to develop a model for maintaining the learning community in the selected geography. Multiple interactions were held, including virtual meetings and surveys, designed to collect recommendations from the advisory board.

Members of the advisory board and their respective position on the board:



Marcia Henne
Program Manager/Director of
Memory Advocate Peers,
CaringKind.
Caregiver Representative



Stephanie Monroe, JD
Vice President and Senior Advisor
on Equity, UsAgainstAlzheimer's.
Patient Advocacy Leader



Suzan Rush
President of the
Alzheimer's/Gathering Place Ministry,
Brentwood Baptist Church.
Patient Representative



Rev. Nicole Slater
Pastor, Payne Chapel African
Methodist Episcopal Church.
Faith Leader



Sandra Carmona Torres
Executive Director of Patient
Engagement, Marketing and
Diversity, K2 Medical Research.
Clinical Researcher



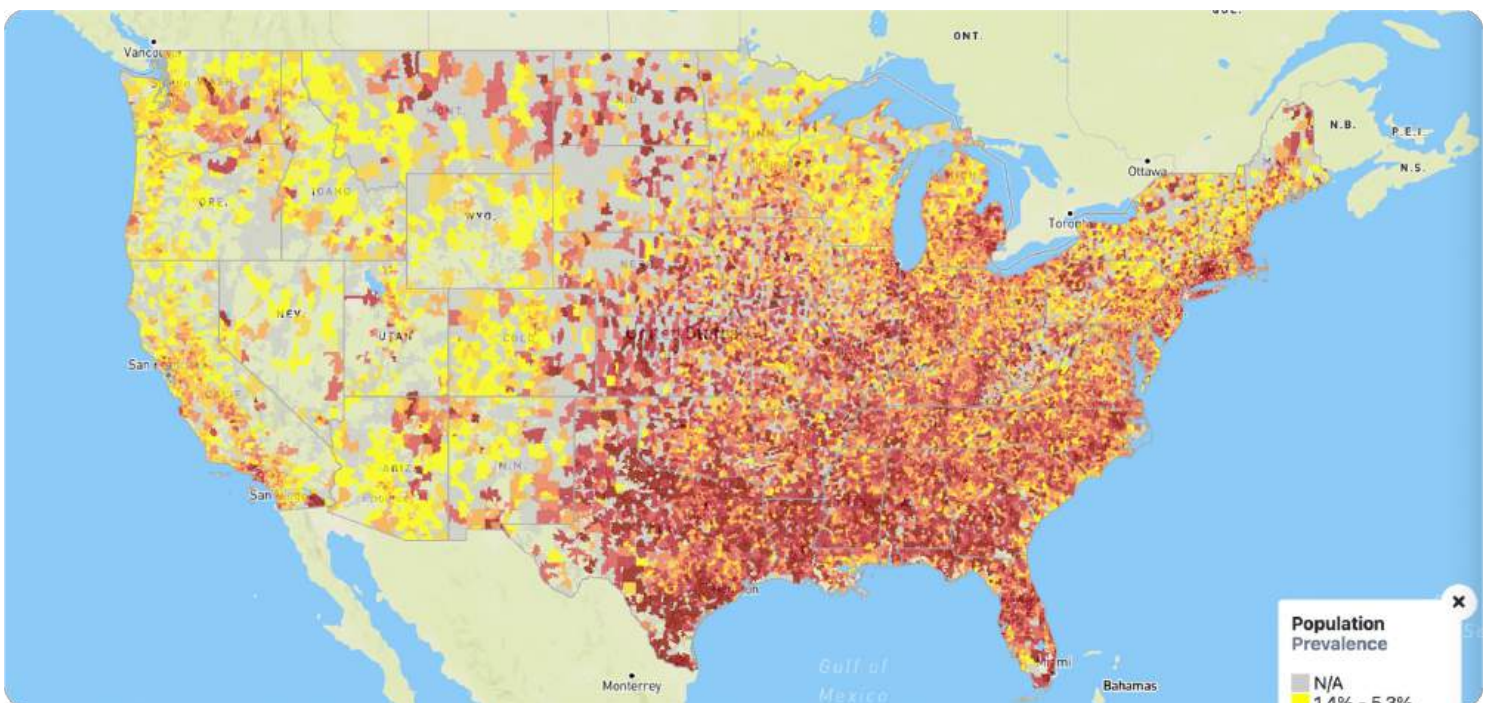
Sheila Baez-Torres, MD
Medical Director of Diversity, Principal
Investigator, K2 Medical Research.
Physician

List of advisory board interactions:

- Five virtual meetings lasting between 60-90 minutes each (April 5, April 22, April 25, June 5, and final report read-out scheduled for August 2024).
- Three Google surveys focusing on the following topics: Perceptions of Alzheimer's patients and clinical research; Informational and educational content; Top resources and strategies.

Decision on Expansion into Newly Established Alzheimer's CTLC

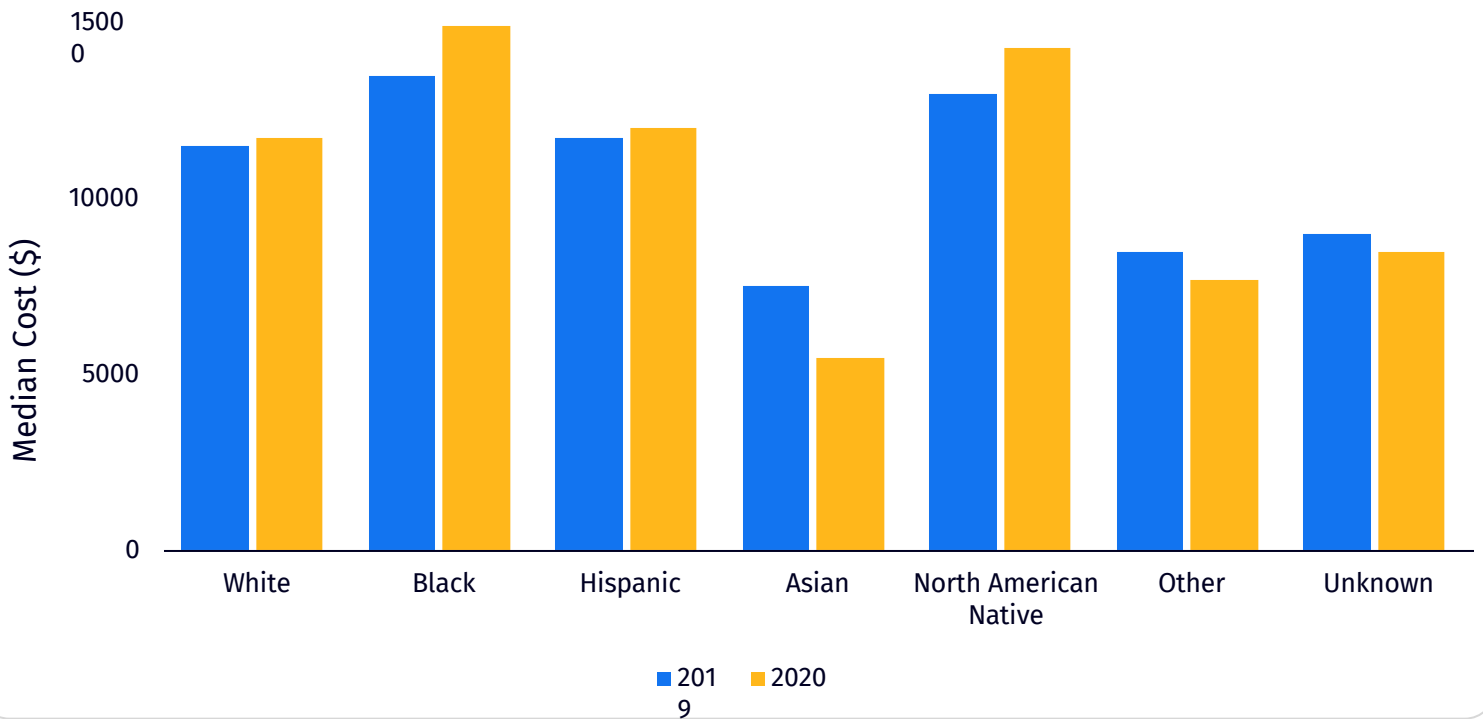
Alzheimer's and related dementia impacts millions of Americans and their families, including patients of color, who face additional barriers and burdens to diagnosis, treatment and clinical trials. According to the Clinical Trials Index, developed jointly by NMQF, prevalence of Alzheimer's and related disorders is widespread.



According to the Clinical Trials Index, nearly 3 million Medicare FFS beneficiaries have Alzheimer's, related dementia or a similar condition, with the number of cases climbing. African Americans face 2-3 times greater risk of developing Alzheimer's disease (AD) compared to white counterparts and data projections indicate up to four times the amount of ADRD cases by 2060 among African American patients. Additionally, less than 10% of African Americans and other minoritized patient populations participate in Alzheimer's clinical trials, limiting the generalizability of findings and hindering progress in understanding ADRD risk factors and treatments.

NMQF and Biogen recognize that underrepresented communities are disproportionately diagnosed with Alzheimer's Disease at later stages, in addition to having less access to new and advanced treatments. NMQF's research team developed an analysis related to Alzheimer's Disease within the Medicare FFS for data years 2019-2020, and these findings are being utilized to better understand more about the Alzheimer's patient population and prevalence of disease across the country. This analysis utilized the raw CMS Alzheimer's data to determine the scope of prevalence and other key statistics among the selected population to ultimately inform the action plan and geography of focus for the CTLC expansion.

Median Cost Burden of Alzheimer’s Disease and Related Dementia or Senile Dementia by Race/ Ethnicity amongst Medicare Beneficiaries 2019 and 2020



The previously referenced analysis found that while the majority of Alzheimer’s Disease and Related Dementia (ADRD) patients are white, the Black and Asian patient population have higher prevalence rates than the white population. The prevalence rate stays consistent with the majority population for age and gender. Additionally, while the majority of ADRD patients are white and female, Black, Asian, North American Native, and males have higher median healthcare costs.

Given the increase in diagnosis of Alzheimer’s disease, especially among minoritized beneficiaries, and the importance of clinical research, the CTLC model is expanding to provide resources, engagement and support for Alzheimer’s patients, caregivers and the community at large, especially focusing on minoritized patients.



High-Level Summary of Findings and Main Recommendations from Advisory Board Members

Improving Education and Outreach to Immigrant, Underserved and Low-Income Populations Impacted by Alzheimer's and Related Dementia

There is a demographic shift happening in America today, meaning both communities of color and immigrant communities are expanding. It's imperative that outreach related to clinical trial education for Alzheimer's and related dementia is culturally competent and focuses on connecting with communities historically minoritized and underserved. Many communities have never been offered the opportunity to participate in clinical research. The advisors highlighted the challenges many of their patients still face in accessing healthcare, clinical trials and other resources. This includes inequities in healthcare access and resources between different zip codes, rural communities and among undocumented people. Pre-screening of Alzheimer's is also fundamental in improving outcomes in marginalized communities. Through the CTLC model, the advisors agreed on the need to expand education and opportunities to screen and work directly in these populations, focusing on Alzheimer's and other comorbidities impacting patients and caregivers' wellbeing.



Improving Education and Engagement with Physicians and Other Medical Professionals

Physicians and other medical personnel play a crucial role in both knowledge sharing and recruitment of patients and caregivers to clinical trials. Often, many patients solely rely on their primary care doctor, neurologist, pharmacist or other medical professionals to relay important information on both disease management and on clinical trial education/recruitment. Improving engagement and education of medical professionals in clinical research is essential for advancing medical knowledge, improving patient care, and fostering evidence-based practice. The CTLC model has been working directly with medical professionals to expand their knowledge on cultural competency and the importance of clinical research via virtual training modules and community town halls/educational sessions. Additionally, hearing patients and community concerns related to clinical research will lead to further minimizing barriers to trials.

During the advisory board's interactions and via the survey feedback, they emphasized increased training and the availability of promotional materials within physician practices. Importantly, the continuation of NMQF's "Lunch and Learn" model for Alzheimer's was heavily valued and recommended by the advisors as a way to connect neurologists, primary care providers and patients/caregivers to reduce myths and misconceptions about clinical research and improve understanding of Alzheimer's disease management. By building upon this direct community-provider communication pipeline, knowledge on the disease and clinical research will increase, in addition to increased participation in clinical trials.

Improving Trust and Addressing Mistrust in Clinical Trials for Diverse Communities

The advisors discussed the importance of building trust and addressing mistrust in healthcare, particularly within Black and Brown communities. Mistrust among marginalized communities regarding clinical trials still exists today due to historical abuse and other factors. The advisors stressed the importance of establishing long-term relationships with community leaders, addressing specific health concerns, and learning from past failures. Additionally, the advisors emphasized the necessity of shifting the focus from research to the patient side and presenting specific and measurable goals, using data to illustrate benefits, and focusing on the needs of the community. The team acknowledged the challenges of engaging policy makers and the community but stressed the importance of clear communication, patience, and understanding.

Partnering with community organizations, specifically churches, in educating and encouraging participation in clinical trials is of paramount importance, especially since we want the community to drive discussions and narratives related to research. The need to dispel fear and misinformation by providing accurate information and statistics is crucial, too. The advisors agreed on the necessity of educating individuals, particularly in smaller, close-knit communities, to make informed decisions about their health and clinical trials as an option, which will improve trust in diverse communities.

Strengthening Community Relationships for Alzheimer's Care

Building strong community relationships and being available for those in need of information and support, particularly for caregivers of Alzheimer's patients, will drastically improve patient outcomes. The focus of the CTLC model is to unite community stakeholders in order to drive knowledge and participation in clinical research. Via our work in Lupus and continuing with Alzheimer's disease, we've seen success by dismantling silos and bridging resource gaps. Creating a community of trusted stakeholders, physicians, patients, researchers and caregivers is the main way in which we can build connections and bridge gaps to better serve those impacted by Alzheimer's. The value of creating a non-transactional learning community, in one's own neighborhood, is also key in addressing mistrust and barriers to clinical research.

Addressing Barriers to Clinical Research and SDOH Needs

There are a myriad of barriers preventing patients from enrolling in clinical trials that negatively impact the efficacy of therapeutics and cause further disparities in healthcare access. The advisors noted the importance of understanding a patient's background and experience to bridge barriers to clinical research effectively, which includes outreach to physicians, bridging communication gaps, and partnering with trusted stakeholders in the community. The team discussed ongoing work via the CTLC model to increase patient health confidence and decision-making. Community investment to help address the SDOH factors contributing to health disparities is crucial, and will have a positive impact on a patient's wellbeing. In addition to this, ensuring patients and caregivers are able to manage comorbid conditions can lessen barriers to clinical trials and improves outcomes for those with Alzheimer's. Addressing resource gaps, access to education and advocacy is key to eliminating barriers, in addition to centering community voice when it relates to research in a patient's neighborhood.



Ensuring Our Work is Community-Centric, Community-Driven and Sustainable

Since its foundation, the CTLC model's mission is to center community voice and ensure the community is the one driving research in their own backyard. Centering community voice in research is crucial for ensuring that research is relevant, diverse, impactful and ethical. The advisors recommended four key areas to ensure the CTLC model is community-driven and supportive of patients and caregivers.

First, co-creation of knowledge and sharing that information fosters better collaboration and dispels myths related to clinical research. Secondly, ongoing engagement by involving the community from the start ensures proper design of a clinical trial, sharing of results, and lessens barriers to accessing a clinical trial close to home. Thirdly, the advisors emphasized respect and cultural competency, recognizing and valuing local experience and traditions by centering marginalized voices and community-based knowledge systems to provide a more comprehensive understanding of issues impacting the community. Lastly, the advisors recommended building sustainable, long-term partnerships that last well beyond the specific initiative or project in the community.

Bridging the Resource Gap and Ensure Caregivers are Supported

Marginalized and underserved communities face additional challenges when accessing health and other necessary resources to lessen disease burden. Additionally, it's well documented that marginalized communities have a greater risk of late-stage diagnosis of Alzheimer's disease and worse outcomes than white patients.

Via the CTLC model, patients and caregivers have access to increased education and resources to be better informed about clinical research and disease burden. The advisors identified three key factors to bridge resource gaps among Alzheimer's patients and caregivers.

First, increasing both awareness and access to early detection and diagnosis of Alzheimer's disease is crucial. Secondly, establishing support groups, providing emotional, financial and disease-related support to caregivers participating in clinical trials will empower them with the tools needed to provide quality care to their loved ones who may want to participate in a clinical trial. Lastly, establishing partnerships with community-based organizations, faith-based groups, and health systems to leverage existing networks and resources for Alzheimer's disease awareness and clinical trial education will improve outcomes for those with Alzheimer's and increase conversations related to clinical research. This work has been central in the success of the CTLC model and will continue to be leveraged in the expansion of the Alzheimer's CTLC initiative.

Next Steps and Expansion of the Alzheimer's CTLC

One of the main purposes of the advisory board was to help identify the new geography for the CTLC model's expansion into Alzheimer's disease. Utilizing data from the Clinical Trials Index and NMQF's analysis, in addition to selecting a region with established community partnerships and easily accessible trial sites, NMQF, Biogen and the advisors selected **New York City**, mainly centering in the borough of Queens, as the Alzheimer's CTLC area of focus.

Given high prevalence of Alzheimer's in Queens and reliable community partnerships, in addition to a large immigrant community who may have limited access to clinical trial opportunities and Alzheimer's related-resources, we believe the CTLC model will achieve ample success in the community.

Why was Queens and the surrounding area chosen?

- Strong partnership with NYC Health + Hospitals Elmhurst.
 - NYC Health + Hospitals network across the five boroughs can easily refer patients within their system to various providers, including neurologists, and has a strong social services network we can potentially partner/work with.
- Capacity to support Alzheimer's and Lupus education, outreach and referrals to care and clinical trials.
- Strong partnership with Our Lady of Sorrows Roman Catholic Church in Corona, Queens, which is a predominantly Spanish-speaking congregation. Helen Arteaga, a NMQF partner and CEO at NYC Health + Hospitals Elmhurst, is also a member of Our Lady of Sorrows. Can consider recruiting additional churches with support from NMQF's Faith Health Alliance.
- Can recruit new HAIR Wellness Warriors in Queens and surrounding areas.
- Queens and the Bronx are areas of high Alzheimer's prevalence and have significantly large Spanish-speaking and immigrant communities.
- Potential to partner with Marcia Henne, advisor to this project and program manager at CaringKind, to support the CTLC with outreach and education.
- Can refer patients and caregivers to nearby clinical trials if they are interested in participating.

Overview of Our CTLC Partners and Clinical Trial Site Locations



1. NYC Health + Hospitals Elmhurst.
2. Our Lady of Sorrow Roman Catholic Church.

The blue dots represent active Alzheimer's clinical trials in the New York City region, sourced from the clinicaltrials.gov overlay via the Clinical Trials Index. There are approximately 22 active clinical trials related to Alzheimer's near both the church and health system partners.

Given the close proximity of active Alzheimer's clinical trials in the NYC region to our church and health system partners, we can ensure patients and caregivers have easier access to clinical trial opportunities and disease related resources near their homes.

What does Alzheimer's look like in NYC?

There is high prevalence of Alzheimer's and related disorders in the NYC/Queens area, which is above the national average in the Medicare FFS program. According to the Clinical Trials Index, rates of prevalence among beneficiaries with Alzheimer's Related Disorders in the 3-digit zip code 113 (Elmhurst and surrounding neighborhoods) is 7.5% and increases to 8.5% when combined with Alzheimer's Disease. NMQF's Alzheimer's data analysis also notes NYC has above average prevalence of Alzheimer's. Additionally, late stage diagnosis of Alzheimer's and related Dementia is of concern, especially among minoritized communities.

Proposed action(s) in NYC/Queens

The proposed plan in NYC/Queens is to establish a CTLC in the area via NMQF's partnerships with our Faith Health Alliance, HAIR Wellness Warriors, and health system partner, with the goal of providing education and increased opportunities to participate in clinical trials to the broader community in NYC/Queens, especially among the Latino and African American patient population.

Contact us: [Michael DeSalvo Solarte, MSW](#)



Program Manager, Center for Professional & Strategic Alliances
National Minority Quality Forum
mdsolarte@nmqf.org | (202) 519-2022



— NATIONAL —
MINORITY QUALITY
— F O R U M —

