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Improving Diversity in Lupus Clinical Trials



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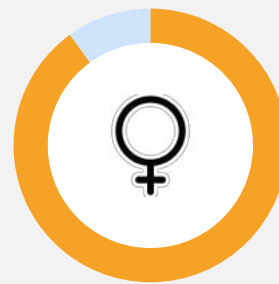
Background

Lupus is a chronic, auto-immune disease that can cause inflammation and pain in any part of the body. Lupus causes a person’s immune system to attack healthy cells and tissue by mistake and it most commonly affects the skin, joints, and internal organs, such as the kidneys and heart.



According to the Lupus Foundation of America, it’s estimated that **1.5 million Americans** have lupus.

Most people with lupus develop the disease between the ages of **15-44**.



90%
of people with lupus were assigned female at birth

Black and Hispanic women are particularly susceptible to lupus. Both of these groups are more likely to experience severe symptoms compared with other groups and Black women are also more likely to develop lupus at a younger age.

Over the years, there has not been much innovation in lupus treatment. However, there are currently innovative treatments being studied and brought to market. Unfortunately, due to a lack of diversity in clinical trials, the Black and Hispanic women who are most in need of treatments are not being properly represented in these studies. Mistrust in the healthcare system, a lack of education from healthcare providers and a lack of awareness among the patient population are all contributing factors to the disparities in clinical trials.

NMQF and Biogen recognized the need for improved clinical trial diversity and partnered together to engage in several activities to raise awareness of and improve clinical trial diversity.

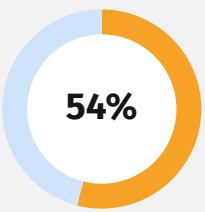



Using Data to Inform Clinical Trial Diversity

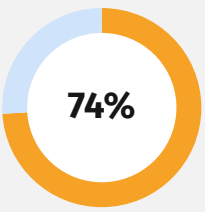
Utilizing Medicare and Medicaid claims data from the Centers for Medicare & Medicaid Services (CMS), NMQF's Center for Health Information Strategy & Services (HISS) designed a platform with the functionality to search claims by indication to see the patient counts, prevalence of conditions among beneficiaries, and the associated demographics. The platform, known as the NMQF Clinical Trials Index, is a searchable database and visualization tool that maps clinical trial sites, allowing partners to make informed and equitable decisions when developing and/or maintaining sites.


NMQF partnered with Biogen to examine data in the NMQF Clinical Trials Index to conduct a detailed analysis of geographies with a high prevalence of lupus and comorbid diseases, with a specialized understanding of how multiple conditions can cause greater disparities and worse outcomes, especially among marginalized and underserved communities. The data allowed NMQF and Biogen to ascertain an accurate picture of where Medicare and Medicaid beneficiaries with lupus are located, in addition to determining where clinical trials are needed based on high prevalence of disease.

The NMQF Clinical Trials Index identified some key disparities in the Washington D.C., Maryland, Virginia area (DMV), specifically:



 **Medicare**
patients with Lupus SLE are **non-white**



 **Medicaid**
patients with Lupus SLE are **non-white**

Black and Hispanic Medicare beneficiaries with Lupus SLE have higher emergency room (ER) visit rates than their white and Asian counterparts.

Black and Hispanic Medicare beneficiaries with Lupus SLE have higher costs than white and Asian counterparts in:



Emergency Room



Annual Costs



Hospitalization Costs

This data led NMQF and Biogen to partner together to create a Clinical Trial Learning Community (CTLC) Model in the DMV area. **The CTLC offers an empathetic, community-based, holistic, and trustworthy support system and source of disease-related insights, without cultural and social silos.** It is designed to overcome the barriers that have historically plagued the participation of minoritized people in clinical trials through collaboration among local providers, community leaders, investigator sites, policymakers, and industry stakeholders. The CTLC develops recommendations, guidelines, and metrics that meet the following priorities:

1. Improve the engagement and inclusion of underrepresented communities in clinical research by influencing infrastructure development and outreach strategies.
2. Improve access to clinical trials education by influencing targeting strategies, site infrastructure development and sponsor and community readiness efforts.
3. Improve community support of lupus patients by providing resources to inform and encourage them about pursuing clinical research as an early option for care.

CTLC Key Takeaways:

- ✓ Rebrand clinical research so that it is known as community driven and supportive
- ✓ Ensure that the people who provide their data are fully aware of how it is being used and where it is going
- ✓ Follow up is important for patients, even beyond the end of the study
- ✓ Patient voice and experience is important to encourage others to participate
- ✓ Consider the role that allied professionals and community members can have as trusted partners in helping to educate patients



Make sure that you make people feel like you really took the time to do your homework to be able to provide the best outcomes and know the area.

**Ana Vasquez,
Advisory Board Member**

Thank you to our Lupus CTLC Advisory Board Members:

Nandan Baruah, Patient Advocate; **Ashira Blazer**, MD, Assistant Professor in the New York University School of Medicine Division of Rheumatology; **Bishop J. L. Carter**, Pastor, Ark Church/Faith Health Alliance; **Donney John**, PharmD, Executive Director, NOVA Scripts Central; Chief Clinical Officer, Pharmacist Partners; **Rev. Dr. Terris King**, King Enterprise Group/Liberty Grace of God Church; **Megan Lockwood**, MD, MedStar; **Mercedes Erica Quinones**, MD, Howard University; **Talitha Stewart**, Patient Advocate; **Dr. Stephen B. Thomas**, University of Maryland; **Ana Vasquez**, Lupus patient/health worker; **Mitzi Williams**, MD, Joi Life Wellness Center; **Peter M. Izmirly**, MD, Associate Professor, Department of Medicine, NYU School of Medicine

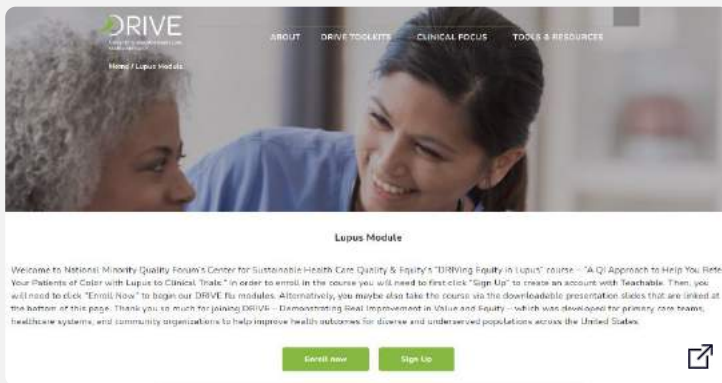
Developing a CTLC





Partnering with Community Leaders and Healthcare Providers to Increase Education

To establish a CTLC advisory board and activate community engagement, NMQF's Center for Sustainable Health Care Quality and Equity (SHC) provided strategic oversight to inform the recruitment and convening of community leaders and healthcare providers that were aligned with the goals of the CTLC.



SHC also launched its

Demonstrating Real Improvement in Value and Equity (DRIVE) program

specifically for lupus and clinical trial diversity to improve primary care physicians' knowledge and awareness of the need for increased clinical trial diversity in lupus.

The DRIVE toolkit provides the most effective tools and resources based on learnings from healthcare systems and primary care practices working in underserved areas and the communities they serve, resulting in a six-step rapid Quality Improvement (QI) cycle approach with a strong patient-, clinician-, and team-orientation. The DRIVE toolkit reached over 150 clinicians with information and resources to support them with improving health equity in lupus care and clinical trials.

Along with the DRIVE toolkit, SHC worked with members of its Faith Health Alliance (FHA) and HAIR Wellness Warriors programs to engage faith health leaders, hair stylists and barbers to deliver health information about lupus and clinical trials to the community members they regularly come in contact with. These community leaders were given tools and resources to plan and host educational events in their communities, including a [communications toolkit](#) to guide their discussions.

SHC directly hosted lupus events at two churches in the FHA network: Purity Baptist Church in Washington, DC and Ark church in Baltimore, MD to raise awareness of lupus and clinical trials within their congregations. Ark Church had a particular investment in lupus, as the First Lady of the church and several other church members live with lupus. The two discussions brought together leading experts in lupus, Dr. Sarfaraz Hasni from the National Institutes of Health (NIH) and Dr. Megan Lockwood from Georgetown University Hospital to discuss racial disparities in lupus diagnosis and care and the importance of clinical trials. Additionally, the Pastor and First Lady from Ark Church joined Dr. Hasni for a NMQF webinar to discuss the topic.



“

I knew a couple of people that had symptoms of lupus but were never diagnosed. They were instead dismissed and were believed to be possessed of evil spirits. I am grateful to have been able to learn more about lupus, how it presents itself and especially the opportunity for people of color to participate in clinical trials so that more women of color will eventually have access to effective treatment.

Purity Baptist Event Participant

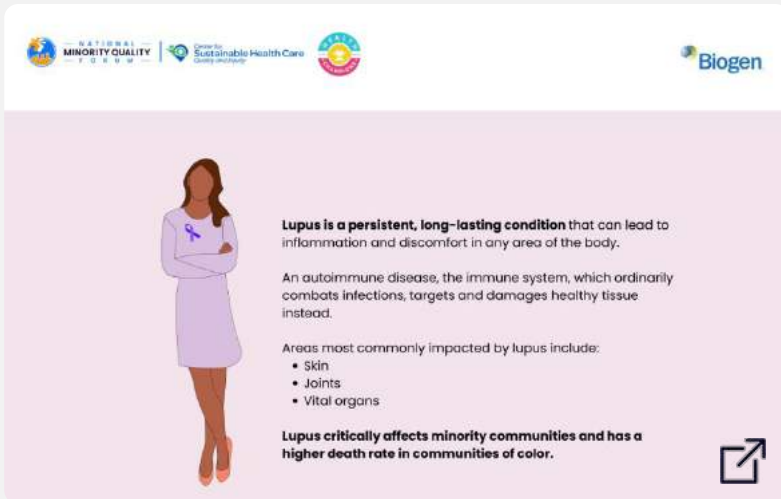
The in-person events were attended by approximately 65 people and the webinar was attended by approximately 75 people.

Beyond the work in the DMV, six other FHA churches worked directly with their local Lupus Foundation of America chapters to host lupus educational events. Furthermore, five HAIR Wellness Warriors hosted both in-person and Facebook Live educational events to share information about lupus and clinical trials. In total, the events and outreach activities provided information directly to over 800 people, including Black women within the age range most often diagnosed with lupus.



Reaching Patients Directly to Increase Awareness

To raise awareness of clinical trial opportunities to treat lupus, encourage behavioral change, and promote the work of the CTLC, NMQF's Center for Public Affairs and Communications (COMMS) conducted outreach to Black and Hispanic women between the ages of 18-45 with information about lupus and clinical trials. Women were provided information about disparities in care and about the need for participation in clinical research.



Lupus is a persistent, long-lasting condition that can lead to inflammation and discomfort in any area of the body.

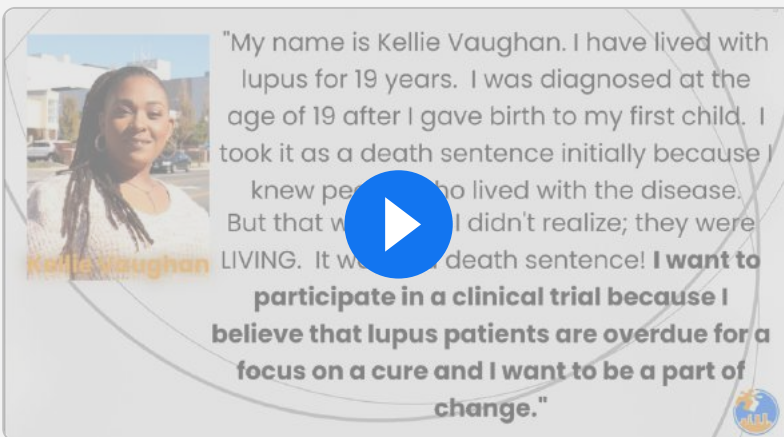
An autoimmune disease, the immune system, which ordinarily combats infections, targets and damages healthy tissue instead.

Areas most commonly impacted by lupus include:

- Skin
- Joints
- Vital organs

Lupus critically affects minority communities and has a higher death rate in communities of color.

COMMS developed a **landing page** with general information about lupus and clinical trial diversity. The landing page holds the communications toolkit that was made for the FHA and HAIR Wellness Warriors to assist them with communicating within their communities.



"My name is Kellie Vaughan. I have lived with lupus for 19 years. I was diagnosed at the age of 19 after I gave birth to my first child. I took it as a death sentence initially because I knew people who lived with the disease. But that was not a death sentence; they were LIVING. It was a death sentence! I want to participate in a clinical trial because I believe that lupus patients are overdue for a focus on a cure and I want to be a part of change."

This page also holds a **public service announcement (PSA) video** developed by NMQF that features quotes from women living with lupus about their desire to have better treatment options and the need for increased diversity in clinical trials.

Additionally, COMMS pushed out organic social content to educate about lupus, clinical trials and the lack of diversity in clinical trials. This social content was pushed out on LinkedIn, Instagram and X (formally Twitter) to reach both patients and providers with the information.

Furthermore, the PSA was pushed out on social media in both English and Spanish and was backed with paid promotion to reach women in five cities (Orlando, Los Angeles, Washington, D.C., Miami and Tampa) during the weekends of corresponding Lupus Foundation of America walks. These cities also have active Biogen clinical trial sites, to ensure that any women who saw the PSA and were interested in learning more or signing up to participate would be able to do so. The videos directed viewers to BiogenTriallink.com to learn more about Biogen's available clinical trials.



I never knew about clinical trials for people of color until later years. I am excited to have the opportunity to become a participant in clinical trials. It is important that new medicines are created to treat this disease. It is important that I become a part of advancing science.

Cora, Lupus Patient

Using the PSA, COMMS was able to reach **1.2 million** people, primarily in the intended audience, with a click-through-rate of **1.5%** (well above the industry average of 0.83%) to the Biogen Trial Link website.

Additionally, COMMS was able to build a network of approximately 50 Black and Hispanic women living with lupus in the various cities where the campaign videos were launched.

Moving Forward

NMQF and Biogen will continue to partner to improve diversity in clinical trials for lupus. NMQF will continue to share data with Biogen to inform clinical trials, providing updated data and numbers. Additionally, NMQF is further working to educate clinicians by collaborating with three medical practices to host “lunch and learns” led by Drs. Hasni and Lockwood to provide clinicians with information and resources, as well as practical tips to engage Black and Hispanic women with lupus in treatment and research.

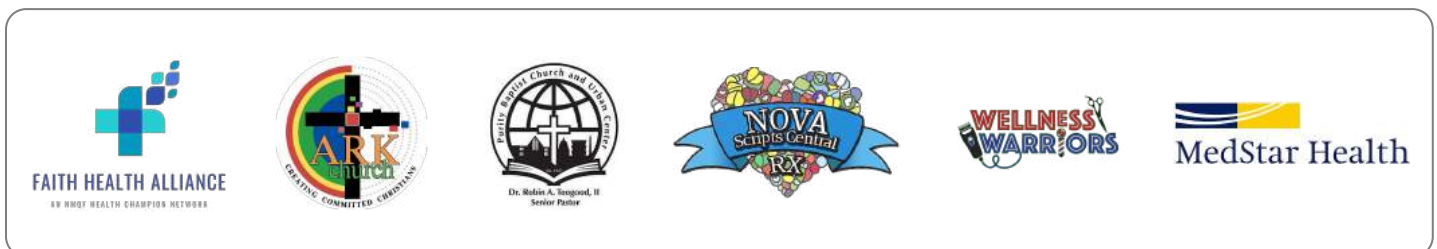
Additionally, direct to patient outreach will continue using a new animated PSA that will be pushed out on social media, continuing to drive women to Biogen Trial Link and increasing awareness of disparities in lupus care and the need for improved diversity in lupus clinical trials. The women in the patient network will continue to be engaged moving forward and will be given the opportunity to act as ambassadors for lupus and clinical trials to continue to raise awareness.

NMQF and Biogen are partnering to replicate and expand on the success of the lupus work into other disease areas, including Alzheimer's, to reduce disparities in care and increase diversity in clinical trials for these as well.

Patients and/or caregivers of patients with lupus should talk to their doctors and visit biogentriallink.com for more information about lupus and to see available clinical trial options. Providers should discuss clinical trials for lupus with their patients to ensure that patients are aware of all options available to them.



Thank you to our Lupus CTLC Partners:





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