



Foundation for Sarcoidosis Research

Ignore No More Campaign on Clinical Trials Diversity:

Advancing Clinical Trial Equity for Black Patients with Sarcoidosis



Foundation for Sarcoidosis Research

<http://www.stopsarcoidosis.org>

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A Letter from Our CEO

Dear Reader:

Sarcoidosis is a disease of disparities. Black and African Americans are 2.5x more likely to have sarcoidosis than White Americans, are more than 2x as likely to have a family member with sarcoidosis, are more likely to experience chronic and severe symptoms resulting in hospitalization rates that are 9x higher than White Americans, are 12xs more likely to die from sarcoidosis and at a younger age than White Americans, and receive higher cumulative doses of steroids which have harmful effects on mental health, fatigue, and stress.

We believe that we must address these issues and needs in the future by hearing directly from patients, clinicians, community groups, and industry partners. This white paper is a culmination of nearly two years of extensive efforts initiated by the creation of patient and clinician advisory committees and the launch of a national awareness campaign, followed by a nationwide IRB-approved patient survey, key opinion thought leader workshop and patient focus group focused on clinical trials. To understand sarcoidosis, and any disease of disparities, we must understand how it impacts those with the highest prevalence.

We have captured the learnings from this work as a critical first step to advance the discussion beyond recognition of the problem and to catapult us into action. Though this white paper speaks to the issues and needs of the Black Sarcoidosis community, it reveals truths and action items relevant to all chronic conditions, especially those with a higher prevalence and worse outcomes for Black Americans.

Though we see this as a critical first step, we believe there is much work left to do. We know we cannot do this work alone. We want to thank all the partner organizations and sponsors who have made this vitally important work possible and invite others to join us in our ongoing efforts to improve access and opportunity for Black American's participation in clinical trials.

Our sincerest gratitude to the patients, clinicians, community partners, and advisory panels for all your assistance throughout this process. We are excited to share these learnings with you and invite you to join us as we work to advance clinical trial diversity and to make all trials accessible for anyone impacted by chronic disease.



Sincerely

A handwritten signature in cursive script that reads "Mary E. McGowan".

Mary E. McGowan, CEO
Foundation for Sarcoidosis Research (FSR)

Executive Summary

Black Americans experience the highest incidence of sarcoidosis in the United States and have the highest hospitalization and mortality rates of all groups. They are 2.5x more likely to have sarcoidosis than White Americans and experience more severe and chronic forms of sarcoidosis leading to hospitalization and mortality rates that are 9x and 12x that of their White counterparts, respectively.^{1,2,3}

These statistics elicit questions about the origin of these disparities and whether they can be attributed to biological, environmental, or social factors – or perhaps a combination of all three. Though the cause is unknown, and we understand there are systemic, racial, and socioeconomic factors contributing to these outcomes, more research is needed to better understand sarcoidosis, its manifestations, and why it has such a profound impact on the Black community. While clinical trials and research can reveal the answers needed to illuminate the source of these inequities and provide a pathway for better care and treatment for Black Americans, underrepresentation of Black Americans is stifling the potential for such a breakthrough. According to the U.S. Federal Drug Administration, Black Americans only represent 16% of all clinical trial participants in the U.S. and only 9% when looking at clinical trials for rare diseases specifically.

FSR launched the [*Ignore No More: ACTe Now! Campaign \(Advance Clinical Trials for Equity in Sarcoidosis\)*](#) to address the underrepresentation of Black Americans in clinical trials. As part of the campaign, FSR conducted the first of its kind, IRB-approved national patient survey for Black Americans to better understand the challenges and experiences Black Americans with sarcoidosis face as it pertains to clinical trials and their disease journeys. FSR also conducted a Key Opinion Leaders Thought Workshop (KOL) and Patient Focus Group to explore the findings in greater depth and to identify recommendations for how to improve clinical trial access and overall care of Black sarcoidosis patients.

A majority of the survey respondents report the healthcare team as having the most influence on their healthcare decisions, despite concerns of racial bias in medical settings and clinical

¹Desai M. Recruitment and retention of participants in clinical studies: Critical issues and challenges. *Perspect Clin Res.* 2020 Apr-Jun;11(2):51-53. doi: 10.4103/picr.PICR_6_20. Epub 2020 May 6. PMID: 32670827; PMCID: PMC7342339.

² Morgan, C.J. Statistical issues associated with terminating a clinical trial due to slow enrollment. *J. Nucl. Cardiol.* 24, 525–526 (2017). <https://doi.org/10.1007/s12350-016-0702-1>

³ Clinical Trials ARENA Clinical Trial Delays: America's Patient Recruitment Dilemma. 2012. Jul 18, 2019. <https://www.clinicaltrialsarenacom/analysis/featureclinical-trial-patient-recruitment/>

trials. Yet, approximately 60% report never being asked to participate in clinical trials. Furthermore, respondents raise concerns about taking time off from work, repercussions of employers finding out about their diagnosis, and barriers associated with travel, cost, and side effects disrupting their personal and professional lives.

Insights gained from both working groups support the need for more patient and physician education, greater acknowledgement of the historical and continued role race plays in healthcare, trust-building between physicians and patients as a means to further engage patients, and the need for more substantial support mechanisms to reduce barriers associated with time, travel and financial burden. FSR's findings indicate the presumed strength of the relationship between race and discrimination may be less influential on clinical trial participation than other factors, which illuminate a viable path to engaging Black patients in clinical trials.

Some recommendations that emerged include building a blueprint for clinical trial design that increases access and supports diversity, clinical trial navigation and support specifically targeted for Black patients, and educational toolkits to better educate patients and physicians about trial opportunities and engagement.

Though this campaign was specific to Black Americans with sarcoidosis the learnings are relevant to improving access to clinical trials for all Black Americans.

About Foundation for Sarcoidosis Research (FSR)

The Foundation for Sarcoidosis Research (FSR) is the leading international organization dedicated to finding a cure for sarcoidosis and improving care for sarcoidosis patients through research, education, and support. FSR works with world-leading experts in sarcoidosis, invests in innovative, patient-centered research efforts and provides educational resources, support, and opportunities to accelerate research to patients worldwide.

Since its establishment in 2000, FSR has fostered over \$6 million in sarcoidosis-specific research initiatives. To grow the pipeline of sarcoidosis clinicians and researchers and to deepen the understanding of sarcoidosis, its causes, and its impact on the patients, FSR supports:

- Annual fellowships
- Pilot grant programs
- Multi-site clinical studies
- Manifestation-specific grants
- Critical, innovative research

Along with other programs, FSR helps build a functional disease model to provide insights into the mechanisms of the disease and to allow for the exploration of the efficacy of potential drugs being explored for clinical trials.

Additionally, FSR is committed to keeping the patient at the center of clinical studies and trials. Through our clinical trial support and recruitment program, FSR has developed a robust curriculum to assist academic investigators and pharmaceutical companies in advancing clinical care improvement and drug development. FSR supports patient-driven feedback loops to help researchers and industry ensure that patients' needs and desires are the main driving force for all trials. Furthermore, by ensuring timely patient recruitment, FSR reduces the time it takes to conduct a trial and, therefore, supports the acceleration of drug development.

In 2015, FSR launched our patient registry to expand the understanding of the patient journey and to better capture how sarcoidosis impacts quality of life and financial well-being. We now have over 6,000 participants in the registry and launched an annual survey to gather longitudinal data. We are currently looking into ways to expand the survey to further capture the mental and emotional burden of the disease.





In addition to our efforts to drive research forward, FSR remains committed to providing patients with much-needed community and educational tools to further their understanding of how to live with this complex rare disease. FSR has developed numerous tools to empower and amplify the patient voice, including our Patient Advisory Committee, Speakers Bureau, and our *Ignore No More: Women of Color* and *ACTe Now!* Patient Advisory Committees. Each of these groups helps drive patient awareness, educational programming, community outreach, and marketing, as well as serving as a sounding board for researchers and industry looking to better understand the sarcoidosis journey.

FSR has developed a comprehensive volunteer advocate program with 99 community-level volunteers, virtual support groups, and 1:1 peer support for those newly diagnosed or dealing with the complexities of a flare or new manifestation of the disease. FSR provides an online chat forum that allows for sharing and community engagement through FSR’s Inspire Community, [Stop Sarcoidosis](#). Additionally, FSR launched the FSR Global Sarcoidosis Clinic Alliance (FSR-GSCA), a member program consisting of clinics, hospitals, individual providers, patients, and caregivers committed to finding a cure and offering evidence-based, patient-centric care for those living with sarcoidosis. Through this alliance, FSR trained 60 volunteer leaders to lead community support groups and conduct community outreach in partnership with sarcoidosis clinics and hospitals nationwide, empowering and educating sarcoidosis patients and care partners.



GSCA Members as of May 9th, 2023

Finally, FSR offers extensive educational programming to patients and clinicians to improve diagnosis, treatment management, and resources to support those living with sarcoidosis.

Background

About Sarcoidosis

Sarcoidosis (pronounced SAR-COY-DOE-SIS) is an inflammatory disease of unknown cause characterized by the formation of granulomas—tiny clumps of inflammatory cells—in one or more organs of the body. When the immune system goes into overdrive, and too many of these clumps form, they can interfere with an organ's structure and function. When left unchecked, chronic inflammation can lead to fibrosis, which is the permanent scarring of organ tissue. This disorder affects the lungs in approximately 90% of cases, but it can affect almost any organ in the body.⁴



Approximately 5-10% of all patients diagnosed will suffer from advanced sarcoidosis. While several off-label treatments have been proposed for these individuals, including recommendations based on the involved organs^{5,6}, more research into the effectiveness of these treatments is required.

Despite increasing advancements in research, sarcoidosis remains difficult to diagnose, with limited treatment options, and no known cure.⁷ Fortunately, the successful progression of viable clinical trials for sarcoidosis has increased in recent years. There are now more trials than ever before focused on improving treatment options for sarcoidosis, so the time is ripe to focus clinical trial diversity to ensure adequate representation of those most impacted by the disease – Black Americans.

⁴ Baughman R, Field S, Costabel U, Crystal R, Culver DA, Drent M, Judson, Wolff G. (2016). Sarcoidosis in America. Analysis Based on

Health Care Use. *Ann Am Thorac Soc*. Aug;13(8):1244-52. DOI: 10.1513/AnnalsATS.201511-760OC

⁵ Baughman, R. P., Valeyre, D., & Korsten, P. (2021). ERS clinical practice guidelines on treatment of sarcoidosis. *Eur Respir J*; in press <https://doi.org/10.1183/13993003.04079-2020>

⁶ Diagnosis and Detection of Sarcoidosis. An Official American Thoracic Society Clinical Practice Guideline Crouser, E. D., Maier, L. A., Wilson, K. C., Bonham, C. A., Morgenthau, A. S., Patterson, K. C., Abston, E., Bernstein, R. C., Blankstein, R., Chen, E. S., Culver, D. A., Drake, W., Drent, M., Gerke, A. K., Ghobrial, M., Govender, P., Hamzeh, N., James, W. E., Judson, M. A., . . . Baughman, R. P. (2020). Diagnosis and Detection of Sarcoidosis. An Official American Thoracic Society Clinical Practice Guideline. *Am J Respir Crit Care Med*, 201(8), e26–e51. <https://doi.org/10.1164/rccm.202002-0251ST>

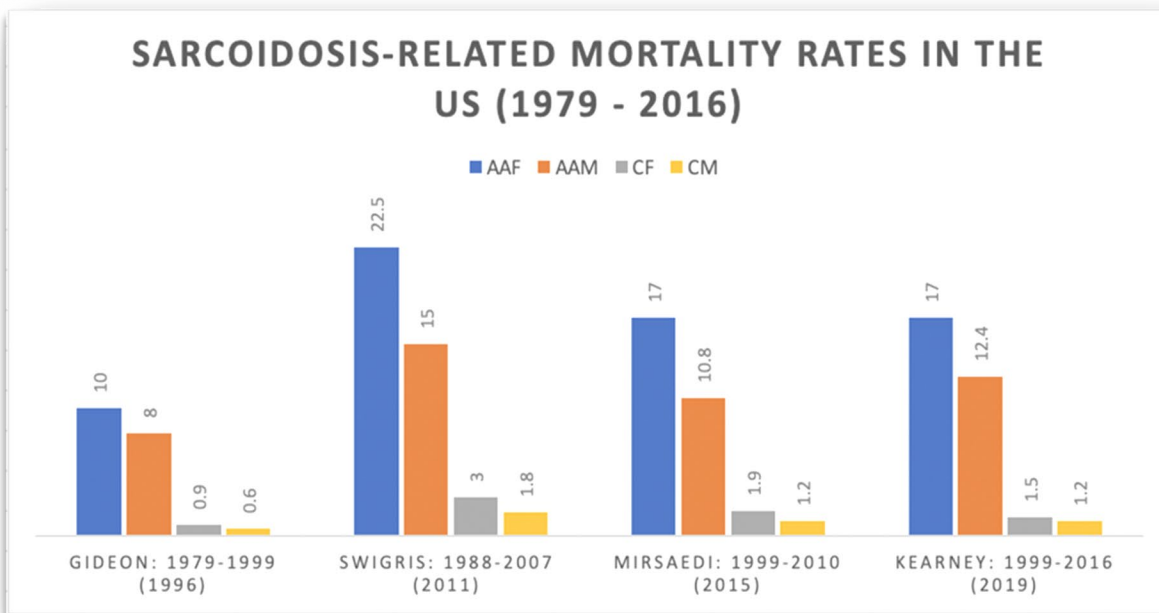
⁷ Hunninghake GW, Costabel U, Ando M, Baughman R, Cordier JF, du Bois R, Eklund A, Kitaichi M, Lynch J, Rizzato G, et al. ATS/ERS/ WASOG statement on sarcoidosis. American Thoracic Society/ European Respiratory Society/World Association of Sarcoidosis and Other Granulomatous Disorders. *Sarcoidosis Vasc Diffuse Lung Dis* 1999;16:149–173

Demographics

Black Americans and Sarcoidosis

The estimated prevalence of sarcoidosis in the US ranges between 150,000 and 200,000⁸, with an estimated 1.2 million individuals with sarcoidosis worldwide. Sarcoidosis can impact any race, ethnicity, and gender. Although sarcoidosis can affect people of all ages, it most commonly develops in middle-aged adults – for men peak age of incidence is between 30-50 years of age and for women peak age is between 50-60 years of age.⁹ In general, women of all races have a slightly higher prevalence of the disease compared to their male counterparts, yet for Black American women, not only do they have the highest prevalence of all groups, they are almost twice as likely to have the disease than their male counterparts, who experience the second highest prevalence of all groups.¹⁰

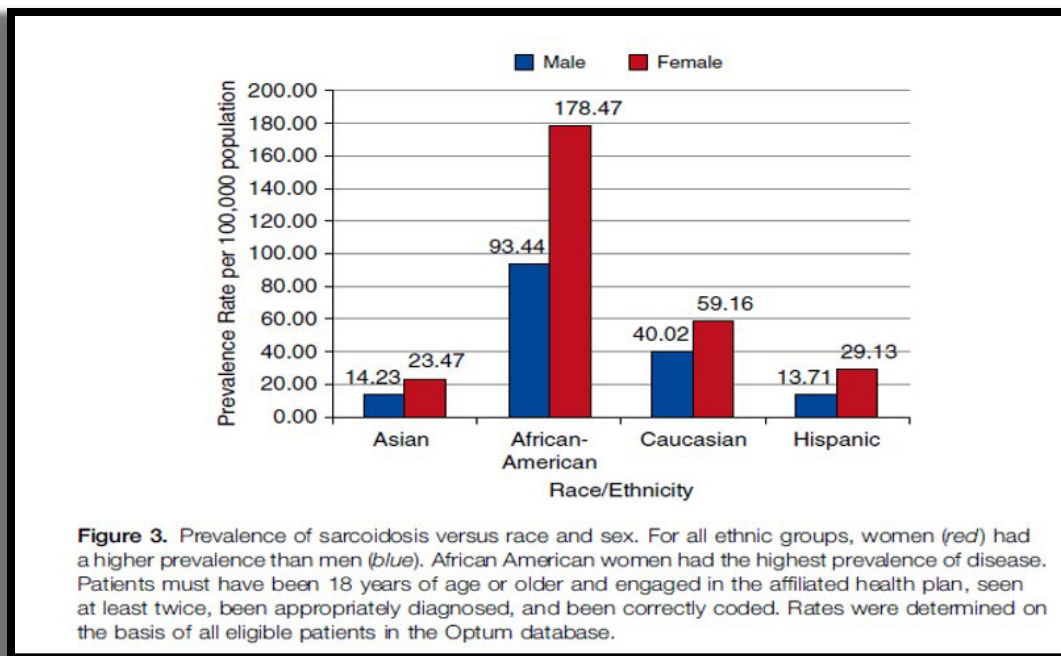
In addition to having the highest prevalence, Black American women bear the greatest burden when compared to all other groups impacted by sarcoidosis in the United States. They experience the highest hospitalization and mortality rates and are more severely impacted by the disease with more organ involvement and severe symptoms.



⁸ Baughman R, Field S, Costabel U, Crystal R, Culver DA, Drent M, Judson, Wolff G. (2016). Sarcoidosis in America. Analysis Based on Health Care Use. *Ann Am Thorac Soc.* Aug;13(8):1244-52. DOI: 10.1513/AnnalsATS.201511-760OC

⁹ Drent, Challenges of Sarcoidosis and Its Management

¹⁰ Hena, K. M. (2020). Sarcoidosis Epidemiology: Race Matters. *Frontiers in immunology*, 11.



Black American women:

- Are 3x more likely to develop sarcoidosis than White sarcoidosis patients.¹¹
- Have an increased hospitalization rate 10x - 18x higher than White patients, and more than double that of Black American men.¹²
- Have a mortality rate 12x higher than that of White patients and one and a half times higher than that of Black American men.¹³

While Black American women experience the worst outcomes, as a group, Black Americans in general have a higher incidence of sarcoidosis and have poorer outcomes and experiences compared to other groups.

¹¹ Hena, K. M. (2020). Sarcoidosis Epidemiology: Race Matters. *Frontiers in immunology*, 11.

¹² Foreman, M. G., Mannino, D. M., Kamugisha, L., & Westney, G. E. (2006). Hospitalization for patients with sarcoidosis: 1979-2000. *Sarcoidosis, vasculitis, and diffuse lung diseases: official journal of WASOG*, 23(2), 124-129.

¹³ Swigris JJ, Olson AL, Huie TJ, Fernandez-Perez ER, Solomon J, Sprunger D, Brown KK. Sarcoidosis-related mortality in the United States from 1988 to 2007. *Am J Respir Crit Care Med*. 2011 Jun 1;183(11):1524-30. doi: 10.1164/rccm.201010-1679OC. Epub 2011 Feb 17. PMID: 21330454; PMCID: PMC3137141.

Black Americans:

- Are 2.5x more likely to develop sarcoidosis than White Americans.¹⁴
- Are more than twice as likely to have a family member with sarcoidosis.¹⁵
- Have more severe and chronic forms of sarcoidosis leading to increased complications and higher hospitalization rates compared to other groups.¹⁶
- Experience more complications from sarcoidosis as well as side effects from treatments used to manage the disease. Black Americans receive higher cumulative doses of steroids which have harmful effects on mental health, fatigue, and stress.¹⁷
- Have a hospitalization rate 9x higher than White Americans.¹⁸ Are 12x more likely to die from sarcoidosis and at a younger age, than White Americans.¹⁹

¹⁴ <https://osteopathic.org/2017/06/06/once-a-rare-disease-sarcoidosis-now-afflicts-nearly-three-percent-of-african-american-women/>

¹⁵ Rybicki, B. A., Iannuzzi, M. C., Frederick, M. M., Thompson, B. W., Rossman, M. D., Bresnitz, E. A., ... & ACCESS Research Group. (2001). Familial aggregation of sarcoidosis: a case-control etiologic study of sarcoidosis (ACCESS). *American journal of respiratory and critical care medicine*, 164(11), 2085-2091.

¹⁶ Hena, K. M. (2020). Sarcoidosis Epidemiology: Race Matters. *Frontiers in immunology*, 11.

¹⁷ Gideon NM, Mannino DM. Sarcoidosis mortality in the United States, 1979–1991. *Am J Med* 1996; 100: 423–427. 3. Reich JM

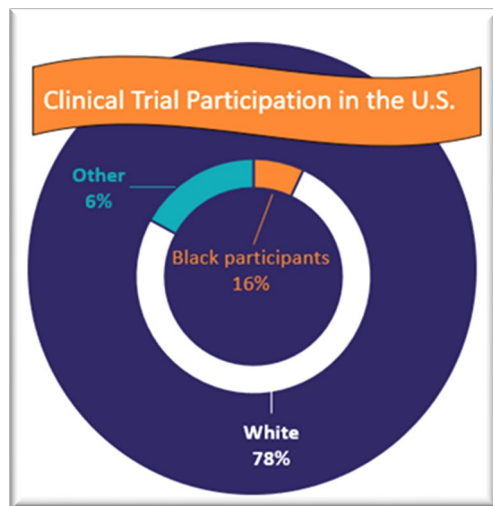
¹⁸ Hena, K. M. (2020). Sarcoidosis Epidemiology: Race Matters. *Frontiers in immunology*, 11.

¹⁹ Sarcoidosis Vasc. Diffuse Lung Dis 2003;20:204-211; CHEST 2015; 147(2):438-449; *Respiratory Medicine* 149 (2019) 30–35

Clinical Trial Participation

Though there are systemic, racial, and socioeconomic factors contributing to these outcomes, it is evident more research is needed to better understand this disease, its manifestations, and why it has such a profound impact on the Black community.

Current medications prescribed for sarcoidosis were determined without adequate representation of Black Americans in clinical trials. According to the US Food and Drug Administration, Black patients only represent 7% of all clinical trial participants, globally, and 16% of clinical trial participants domestically, while White participants represent 76% and 78% respectively. Furthermore, when looking at clinical trials for rare diseases specifically, Black



patients only represent 9% of clinical trial participants, compared to 70% for White participants.²⁰ By understanding more about how the disease works, we can improve and advance treatment options that are effective for Black Americans and applicable to all sarcoidosis patients.

Although sarcoidosis is a rare disease, the disparate outcomes among Black patients with this condition are not rare or unique to this population. Racial disparities in health are pervasive and persistent. People of color and Black Americans specifically, remain disproportionately burdened by chronic conditions. Black Americans have disproportionate rates of

morbidity and mortality across the spectrum of chronic diseases.²¹

Clinical trials are the pathway to progress, and this lack of inclusivity not only stifles the potential for breakthroughs, but it also reduces the applicability of the findings to all groups. Clinical trial enrollment is critical to the acceleration of scientific discovery, the reduction of the disease burden on individuals and the economy, and the improvement of lives of all Americans impacted. Increasing representation of Black Americans in clinical trials will provide more robust and comprehensive data which will lead to more effective protocols, treatments, and equitable outcomes for Black Americans and all patients suffering from chronic conditions.

²⁰ U.S. Food & Drug Administration 2015-2019 Drug Trials Snapshot Summary Report Retrieved August 1, 2022, from <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots>

²¹ O'Hara, D. (2018, February 21). David Williams studies health disparities in America. American Psychological Association. <https://www.apa.org/members/content/williams-health-disparities>

About The Foundation for Sarcoidosis Research *Ignore No More* Initiative

The *FSR Ignore No More* Initiative is a call to action for patients and providers to partner to reduce health disparities by confronting the factors contributing to disparate health outcomes for Black Americans. It is a call to action for patients to listen to their bodies and be proactive participatory agents in their healthcare journeys. It is also a call for health care providers to listen to Black Americans, acknowledge the massive health disparities that impact their care, and take active steps to address the interpersonal and systemic barriers that fuel mistrust and lead to poorer outcomes.

FSR launched the first of two campaigns in 2021, the [*Ignore No More: African American Women & Sarcoidosis Campaign*](#), to raise awareness of sarcoidosis among the group experiencing the highest prevalence and worst outcomes – Black and African American women. The objective of this campaign was to educate the broader community on how sarcoidosis impacts Black women to improve diagnosis, treatment, and outcomes. FSR worked with 23 partners²² to elevate this campaign and expand its reach nationwide. In addition to the campaign sponsors, Global Genes and Mallinckrodt Pharmaceuticals, FSR secured two media sponsors, 12 non-profit partners, and 7 hospital partners.



1 Full size poster in Appendix H

²² Full list of *Ignore No More: African American Women & Sarcoidosis* partners listed in Addendum

FSR created an educational infographic, comprehensive website, and facilitated a series of educational awareness activities to reach Black women nationwide. Activities associated with this campaign included a Twitter Chat, national and international speaking engagements, an educational public service announcement video featuring celebrity spokesperson Jeryl Prescott-Gallien, a social media kit to engage the community in the *Ignore No More* social media campaign, and traditional media which yielded over 16 articles and blogs, five tv segments and radio shows, and seven podcasts, reaching over 500,000 people.

Full size poster in Appendix H

Get Involved!
Take the Survey at stopsarcoidosis.org/ACTNOW

THE TIME TO ACTE IS NOW!

Current medications prescribed for sarcoidosis were determined without adequate representation of Black Americans in clinical trials, despite their being 2.5x more likely to have sarcoidosis than White Americans.

ADVANCE CLINICAL TRIALS FOR EQUITY IN SARCOIDOSIS

TAKE THE FIRST STEP
Complete FSR's Patient Survey for Black Americans with sarcoidosis (incentives provided) by visiting:
STOPSARCOIDOSIS.ORG/ACTNOW

Increasing representation of Black Americans in clinical trials and research is the pathway to developing and identifying the most effective treatments and better health outcomes for Black patients with sarcoidosis.

According to the FDA: **Only 7% of clinical trial participants are Black***

Without proper representation of Black Americans in clinical trials, therapies may not account for greater health risks, comorbidities, and higher hospitalization and mortality rates.

THERE ARE MORE SARCOIDOSIS CLINICAL TRIALS THAN EVER BEFORE, SO THE TIME TO ACTE IS NOW

BENEFITS INCLUDE...

- more frequent communication with providers
- increased access to medication, expert clinicians, and advanced technologies
- monitoring regardless of insurance status

CLINICAL TRIALS & RESEARCH CAN BE AS SIMPLE AS...

- surveys, patient registries, or interviews
- health education programs
- trying medications that have been FDA approved for safety in other diseases
- a simple blood draw
- trying new potential therapies with close oversight

IGNORE NO MORE!

Help improve care for yourself, family members impacted by sarcoidosis, and future generations! Be part of the solution.

ACTe Now, Learn How. Visit stopsarcoidosis.org/ACTNOW

*Supported by Biogen (Biogen, Chimerix, Genzyme, and Mallinckrodt Pharmaceuticals) and made possible in part by a grant from The Clara Zetserberg Initiative. All images used with the website.

FSR
FUNDATION FOR SARC
LARGE SCALE RESEARCH

Building on the successful foundation laid by the first campaign, FSR launched Phase II: [Ignore No More: ACTe Now! \(Advancing Clinical Trial for Equity in Sarcoidosis\) Campaign](#). This campaign went beyond raising awareness of the vast disparities that exist in sarcoidosis and focused on a specific pathway patients can take to improve care and treatment for Black Americans – clinical trial participation. Through this campaign, FSR sought to identify challenges and barriers that contribute to lower participation by Black Americans in clinical trials to develop recommendations to improve care and treatment for Black Americans in the sarcoidosis community. The campaign launched with an educational infographic on clinical trials and Black Americans and a national patient survey for Black Americans. Following the survey, FSR hosted a Key Opinion Leadership Workshop and a Patient Focus Group to dig deeper into the data and findings of the survey.

Overview of *Ignore No More: ACTe Now! (Advance Clinical Trial Diversity for Equity in Sarcoidosis)*

Patient & Clinical Advisory Committees

Incorporating patient and clinical perspectives and expertise are integral components of building impactful programs, materials, and campaigns. Following this model, FSR developed several committees to guide the creation of each campaign component, as well as to serve as public advocates raising awareness of this critical information nationwide.

FSR created three committees:

The Women of Color Patient Advisory Committee

- Trained to share their stories on the public stage as part of the initial Ignore No More Campaign. This 13-person committee comprised of 12 patients and a care partner, served as the boots on the ground participating in speaking engagements and events to educate and promote opportunities for Black Americans to engage in the campaign.

The ACTe Now! Patient Advisory Committee

- A committee of five Black sarcoidosis patients – men and women – whose primary role was to develop and test campaign and marketing materials to ensure materials both resonated with Black patients and could be clearly understood by our target audience.

The ACTe Now! Clinical Advisory Committee

- Comprised of four clinicians and an epidemiologist, the CAC brought a wealth of clinical and research experience, and rich data specific to Black Americans with sarcoidosis which helped ensure the survey incorporated the questions necessary to meet our intended goals.

1Women of Color Patient Advisory Committee Members listed in the Addendum ACTe Now! Patient Advisory Committee Members listed in the Addendum ACTe Now! Clinical Advisory Committee Members listed in Addendum

Partners

This campaign was generously sponsored by Mallinckrodt Pharmaceuticals, Boehringer Ingelheim Pharmaceuticals, Kinevant, 23andMe, and made possible in part by the Chan Zuckerberg Initiative. In addition to the financial sponsors and partners, FSR secured one media sponsor, ten non-profit and foundation partners, and 35 hospital partners.²³ Partnering with these organizations and hospitals provided a platform to expand the reach of this campaign and patient survey opportunity, specifically to sarcoidosis patients within our target community.

Survey

As part of the campaign, FSR created the National IRB-approved Patient Survey for Black Americans with Sarcoidosis to give Black sarcoidosis patients a voice to share their experiences and shed light on the factors and experiences driving the behaviors, attitudes, and decision-making around healthcare, clinical trials participation, and comfort engaging with the medical community. This survey is the cornerstone of the campaign and served as the launching pad for further investigation into the factors contributing to disparate outcomes in care and representation in trials and research.



Key Opinion Leadership Workshop Meeting (KOL)

The Key Opinion Leadership Workshop Meeting took place on January 23, 2023. The purpose of the meeting was to convene clinicians, researchers, and other stakeholders in the sarcoidosis field to discuss survey findings and make recommendations for next steps to advance clinical trials and care equity in Black patients with sarcoidosis. Twenty-two participants including physicians, researchers, and industry representatives attended the meeting and participated in recommendation development.²⁴ Additionally, clinical expert representatives from the Diversity Equity & Inclusion Committee, one of seven leadership committees of experts developed as part of FSR's newly launched FSR Global Sarcoidosis Clinic Alliance,²⁵ actively participated in breakout groups. In addition, members of FSR staff supported the meeting through notetaking and small group moderation.

²³ Campaign Partners listed in Addendum

²⁴ List of Key Opinion Leadership Meeting attendees can be found in Addendum

²⁵ The Foundation for Sarcoidosis Research Global Sarcoidosis Clinic Alliance is a member program consisting of clinics, hospitals, and individual providers committed to finding a cure and offering evidence-based, patient-centric care for those living with sarcoidosis.

A high-level overview of select study results and basic demographics of respondents was shared before participants engaged in small groups focused on one of the three focus areas of the study: Clinical Trials Participation and Experience, Disease Burden, and Patient-Provider Relationships. An additional group of attendees focused more generally on the high-level insights of the survey for a broader view of next steps.

Patient Focus Group

The Patient Focus Group meeting was held on March 14, 2023. The purpose of the meeting was to convene a diverse group of patients to respond to and contextualize survey results, review, and provide input on the recommendations developed in the Key Opinion Leadership Meeting, and offer insights and ideas for additional recommendations. A high-level overview of the campaign, survey results, and basic demographics of survey respondents was shared in advance as optional pre-work prior to the meeting.

The meeting was structured into two sessions, one focused on eliciting feedback on the survey findings, and the other focused on discussing KOL recommendations and brainstorming additional recommendations to reduce barriers to participation and increase representation in clinical trials.

The graphic features a dark blue background with a stylized illustration of three diverse people's profiles (two women and one man) in shades of brown, tan, and purple. The man on the right is wearing large blue headphones. In the top left, there is a white dotted arc above the text 'IGNORE NO MORE!' in orange and blue, and 'ACTe Now!' in white and orange. Below this, a teal box contains the text 'Advance Clinical Trials for Equity in Sarcoidosis' in white. An orange banner at the bottom contains the text 'Patient Focus Group' and 'March 14, 2023 | 5:30 - 7:30pm ET'. The FSR logo and name are in the bottom left, and a small white box with the text 'All content is proprietary to FSR' is in the bottom right.

IGNORE NO MORE!
ACTe Now!

**Advance Clinical Trials
for Equity in Sarcoidosis**

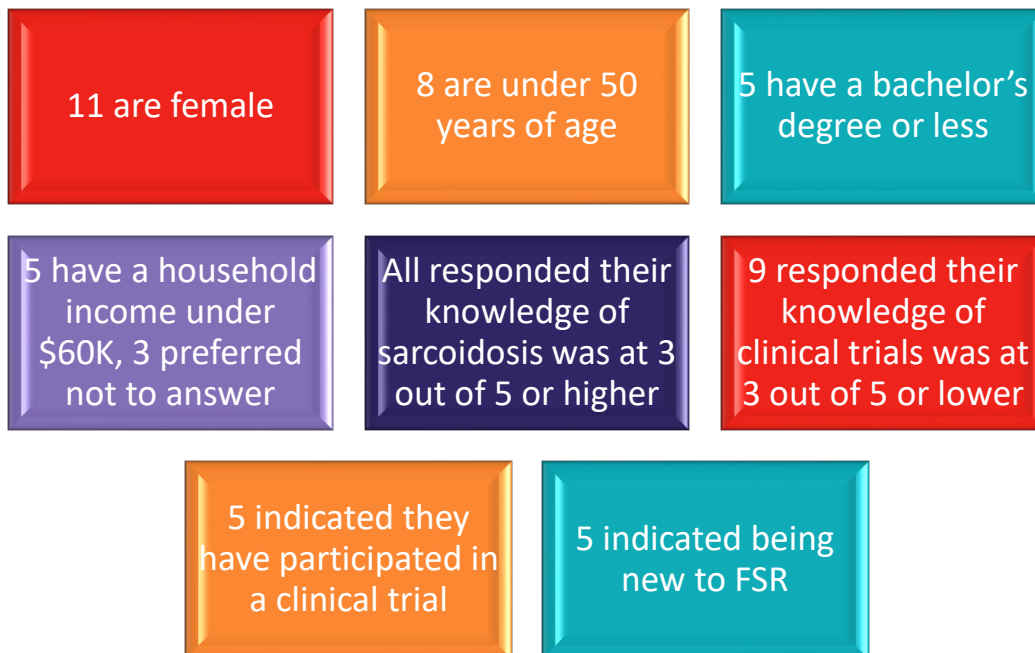
Patient Focus Group
March 14, 2023 | 5:30 - 7:30pm ET

FSR FOUNDATION FOR SARCOIDOSIS RESEARCH

All content is proprietary to FSR

As part of the survey, respondents had an opportunity to express interest in participating in a patient focus group to explore themes that emerged from the data. Participants were strategically selected from this interest list to attain diverse representation across a variety of areas including education, type of sarcoidosis, household income, knowledge, and level of engagement in clinical trials, and level of involvement with FSR. Additionally, special considerations were given to respondents that were underrepresented in the survey, which included Black males, those with less than a bachelor's degree, and those who reported little to no engagement with FSR. This strategy was employed to amplify the voices of these underrepresented respondents, so FSR could capture more in-depth insights from these sub-populations.

Attendee Snapshot: Of the twelve patients who attended:



Survey Development Strategy

Prior to launching, FSR conducted a thorough review of literature on Black Americans and clinical trials to identify key themes and inform the development of questions included in the survey. While there is a plethora of studies dedicated to this topic, FSR could not identify a study that focused on Black sarcoidosis patients specifically, so FSR reviewed studies that explored factors driving the attitudes and decisions of Black Americans to participate in clinical trials across a spectrum of chronic illnesses and diseases. The aim was to test the findings from literature focused on Black American patients, on our target population to identify areas where the findings aligned, as well as areas where the findings diverged for this unique rare disease population.

Additionally, given the expansive data on the health disparities that Black sarcoidosis patients experience, FSR also sought to explore additional insights on diagnosis journeys, treatment, care delivery and the relationship between providers and patients. Using this as a foundation, FSR developed a survey covering the following domains:

- **Clinical Trials Knowledge & Experience:** This area focused on gaining insight into the barriers and motivating factors to participation, as well as knowledge and experience with research and trials.
- **Experience with Healthcare:** This area focused on patients' experiences with the healthcare system in general, as well as their perceptions around relationships and trust-building with primary providers and specialists.
- **Disease Burden:** This area focused on the impact of sarcoidosis on their quality of life, including its impact on their emotional, financial, and social wellbeing. This section also sought to gain a deeper insight into familial links, diagnostic delays, and treatment paths throughout their journeys.
- **Social Support:** This area explored the social support available to the respondents, as well as their tendency to utilize support to cope with the disease.
- **Sociodemographics:** This area provided a deeper insight into the lives of the respondents and provided information on socioeconomic factors like household income, insurance status, and educational background, that may or may not play a role in their experiences and perceptions.

FSR enlisted Rx4Good, a consultancy that works with companies, government, academia, and nonprofits, to deliver on the promise to put patients first. They work with clients to thoughtfully integrate the patient perspective into the work, culture, processes, business decisions, and program activities. With expertise in research, strategy, and patient engagement, Rx4Good worked alongside FSR on survey development, analysis, and management of the Key Opinion Leadership Thought Workshop and Patient Focus Group meetings.

Throughout the survey development process, FSR also worked very closely with the patient and clinical advisory committees offering opportunities for them to review, provide feedback, and revise the survey, until a final tool was developed. This tool was then tested on Black sarcoidosis patient volunteers before being finalized and submitted for IRB approval.

The final survey had 51 questions including ranking, multiple choice, Likert-type scale items, and open-ended questions. Logic questions were included to minimize respondents' time spent on the survey, by ensuring they were only exposed to questions relevant to their experiences based on previous responses.

Survey Launch

The survey launched September 15, 2022. The survey was open to all sarcoidosis patients 18+ years, who identified as Black or African American and resided in the United States. FSR utilized a multi-prong approach to market the survey widely:

- Marketing Materials:
 - Launched the campaign webpage to educate patients on the clinical trials and the need for engagement. Additionally, the webpage included resources for sarcoidosis patients, education on health disparities, information on the survey, as well as partner, sponsor, and committee information.
 - Developed an educational infographic on Clinical Trials and Black Americans, which directed patients to the campaign webpage hosting the survey. This was created in collaboration with the ACTe Now! Patient and Clinical Advisory Committees.
 - Developed campaign branded business cards with the survey link for mass distribution.
 - Created an easy-to-share social media toolkit with images and template language for Twitter, Instagram, Facebook, and LinkedIn, to be utilized by partners and community members.

- Outreach Strategies:
 - Launched a limited traditional media campaign which garnered five article publications and three podcasts.
 - Sent email blasts & newsletters to the sarcoidosis community, and shared templates for campaign partners to disseminate to their constituents.
 - Coordinated a mass mailing of infographics and business cards to FSR's network of over 80+ hospitals to be posted throughout the hospital in high traffic patient areas and sarcoidosis clinic offices.
 - Provided campaign partners with information which they shared on social media, in clinics, and via websites and newsletters.
 - Activated the Women of Color Patient Advisory Committee to raise awareness of the campaign and survey opportunity in their local communities. They participated in speaking engagements, health fairs, podcasts, faith-based events, and social media awareness activities nationwide.

The survey closed November 15, 2022. The initial goal was to receive 250 respondents, which FSR surpassed by receiving 406 respondents.



Survey Results

The National Patient Survey for Black Americans with Sarcoidosis yielded findings that will illuminate a path forward to addressing clinical trial diversity in sarcoidosis, as well as other chronic conditions and diseases. The survey was available through FSR's website, which routed respondents to a secure online survey. Once the survey closed, the data was analyzed, and additional multi-variate analyses were run to explore probable correlations that emerged. The results were then reviewed by various staff and researchers to identify key findings. A high-level overview of the key findings can be found below in the following section

Despite the strategies employed to market the survey widely, FSR identified several limitations that should be acknowledged for their likely impact on the outcomes reported:

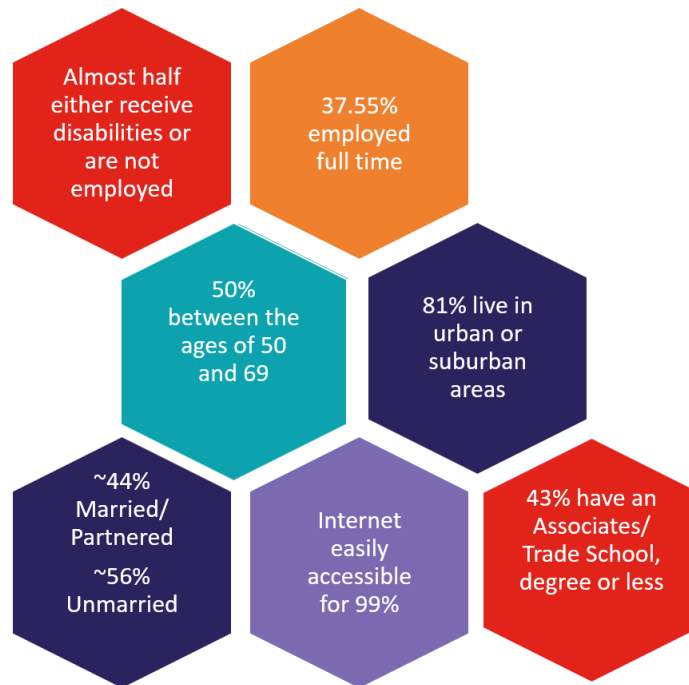
- Most participants reported hearing about the survey through FSR channels. The survey did not include questions that measure the level of involvement with FSR, therefore, the patient population surveyed may be more highly educated/connected than the average patient.
- 86% of respondents identified as biological females, which means Black male sarcoidosis patients and their experiences were not adequately captured in this survey. Though disproportionate, this aligns with the FSR constituent base and the profile for research in general.

Key Findings

Socio-demographics & Social Determinants of Health

To better understand the lifestyle and circumstances of the respondents, FSR asked a series of questions to ascertain more information on factors including education, access to internet, health insurance coverage, household income and transportation.

Sarcoidosis is a costly chronic disease to live with, particularly when the disease impacts multiple organs. It often requires seeing multiple specialists, in addition to the patient's primary provider. The time required to attend appointments, coupled with costs associated with transportation, co-pays, and treatments, are burdens respondents acknowledged as having an impact on their personal and professional lives.



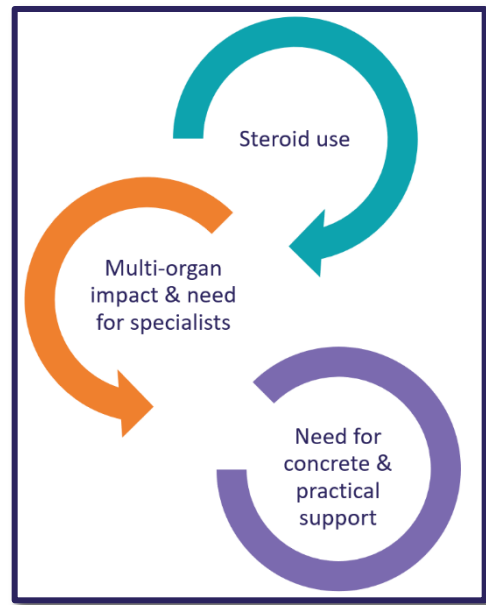
- 29.5% rely on transportation assistance to appointments, with 7.5% of those respondents paying for public or ride share transportation to and from appointments.
- 37.5% are employed full-time; while 47.8% receive disability benefits or are unemployed (and not job seeking).
- 41.3% have a household income less than \$60K.
- 98% have health insurance, of which 51% receive insurance through an employer.
 - Furthermore, when asked which areas of health insurance are insufficient, respondents reported the top three problems as: prescription coverage, deductible and co-pay amounts, and requirements for pre-approvals.
 - Despite many having health insurance coverage, a small percentage (14-15%) reported having to decide between paying for medications or bills/other necessary expenses.

There are some notable potential biases in these data based on the population of the respondents. Over 50% of respondents have sarcoidosis at a manageable state not requiring treatment, while 50% report fair or poor quality of life on most indicators. Therefore, this patient population may not be representative of highly impacted patients. Furthermore, 87% of respondents have either Medicare or employer-based health insurance. Most patients are insured so diversity in coverage and impact may not be representative.

Disease Burden

In addition to the financial impact, sarcoidosis can have a deleterious impact on the physical and emotional well-being of patients. The majority of the respondents reported that in the past 30 days, they felt emotionally bothered, fatigued, and pain that interfered with their life. In fact, 70% reported that their diagnosis negatively impacted their hobbies and activities, with 60% of respondents reporting a negative impact on their employment and romantic relationships.

- 90% of respondents report experience using steroids, with approximately 50% of them having been prescribed high dose steroids for 1+ years. This aligns with existing data that reports Black patients receiving higher doses of steroids and for longer periods of time compared to other groups. Steroid use, particularly when prescribed in high doses and for long periods of time, negatively impacts health outcomes and can lead to other health impairments like diabetes and obesity.²⁶
- The survey also supported existing data showing Black Americans' tendency to have more ultra-pulmonary organ involvement compared to other groups.²⁷ The survey revealed that 70% of respondents had 2-7 organs impacted. As stated earlier, multi-organ involvement can require more specialists and a holistic approach to care, which respondents reported difficulty accessing.
- When assessing the emotional impact on respondents, 77% report they could use more concrete or practical support in coping with living with sarcoidosis. Furthermore, many feel sharing about their sarcoidosis is a burden to others which may lead to feelings of isolation and increase the need for external support.



²⁶ Gideon NM, Mannino DM. Sarcoidosis mortality in the United States, 1979–1991. *Am J Med* 1996; 100: 423–427. 3. Reich JM

²⁷ Hena, K. M. (2020). Sarcoidosis Epidemiology: Race Matters. *Frontiers in immunology*, 11.

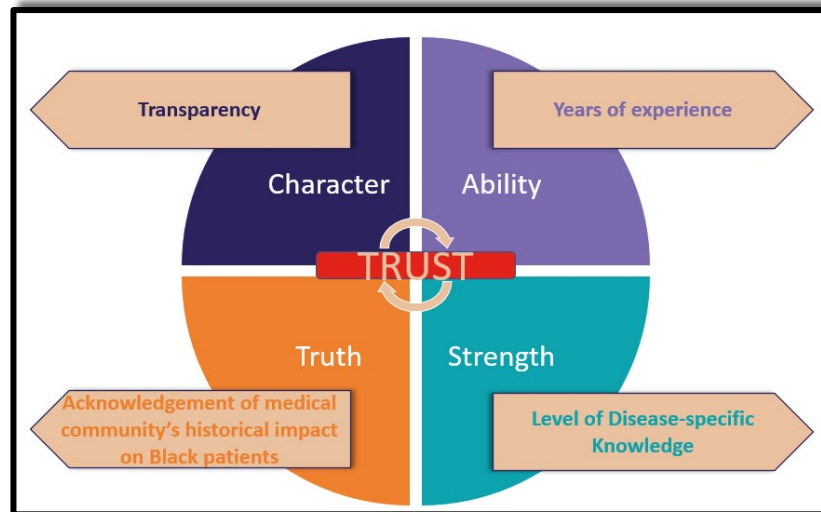
Trust: Physician/Patient Relationship

Trust is an indispensable factor in building any relationship and the physician-patient relationship is no exception. One would assume factors such as racial and cultural congruence would be strong determinants in Black patients' ability to trust and connect with their providers. Literature on the matter suggests race-matching would strengthen the ability of Black patients to trust their providers, thus improving communication and the quality of care they receive.^{28,29,30}

Interestingly, findings from the survey did not overwhelmingly support this ideology, and in fact, several factors were identified that superseded racial congruence and its impact on trust-building.

Given the survey sample and previously stated limitations, we cannot discount the benefits of racial

congruence, but our findings do offer an alternative path forward that doesn't require an immediate shift in the demographic of providers and sarcoidosis specialists. We maintain the need for more representation across the medical and research community, which can be accomplished through increased education, pipeline programs, targeted recruitment, mentorship, and other diversity initiatives.



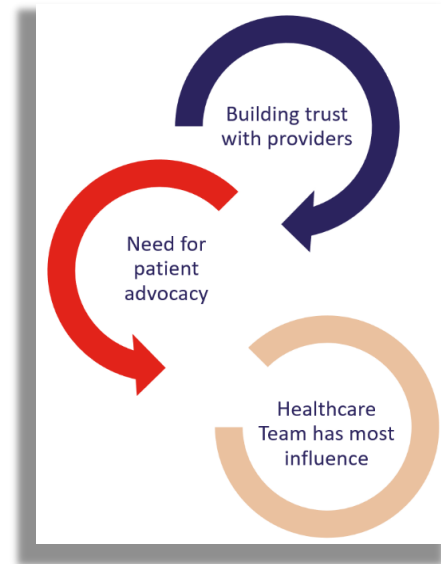
²⁸ Harper, L. J., Love, G., Singh, R., Smith, A., Culver, D. A., & Thornton, J. D. (2021). Barriers to care among patients with sarcoidosis: a qualitative study. *Annals of the American Thoracic Society*, 18(11), 1832-1838.

²⁹ LaVeist, T. A., Nickerson, K. J., & Bowie, J. V. (2000). Attitudes about racism, medical mistrust, and satisfaction with care among African American and white cardiac patients. *Medical Care Research and Review*, 57(1_suppl), 146-161.

³⁰ Cooper, L. A., Roter, D. L., Johnson, R. L., Ford, D. E., Steinwachs, D. M., & Powe, N. R. (2003). Patient-centered communication, ratings of care, and concordance of patient and physician race. *Annals of internal medicine*, 139(11), 907-915.

However, results in this area will take time to impact the medical field and the patients it serves. Developments from this survey on trust-building provide an opportunity for the medical community currently serving patients to adjust, garner, and maintain the trust of their Black patients and presumably other patients of color.

- When asked to measure to what degree each factor supports building trust, transparency, years of experience and level of disease-specific information/knowledge superseded shared culture, race, and other social factors. Survey respondents reported the following factors as supporting their trust-building either *some* or *a lot*:
 - 90.5% report level of healthcare/disease-specific information
 - 89.7% report years of experience
 - 84.5% report transparency
- Additionally, acknowledgement of inappropriate activity towards Black Americans in past research and acknowledgement of biases in the medical community ranked higher in building trust with patients, than racial and cultural congruence. A majority of respondents' sarcoidosis specialists are White or Asian, so this is an opportunity that can be addressed immediately while supporting pipeline initiatives to increase diversity in this field.
- There seems to be a disconnect between patient satisfaction and the perceived need to advocate for good care. The data indicates patients are satisfied, yet feel they have to advocate for that satisfactory care.
 - 88% of patients felt their provider did not treat black patients differently than non-Black patients, and 84.7% felt heard by their sarcoidosis provider. Despite many reporting contentment with their providers, over 66% felt they have to advocate to get the care and attention they need from primary care, and over 58% shared the same sentiment for sarcoidosis specialists.
- According to respondents, the healthcare team is in a prime position to drive this shift in participation rates by strengthening their relationships with their patients and serving as a reliable source of information. Most patients report receiving good care and having good communication with their providers. In fact, when asked who has the most influence on their healthcare decision making, an overwhelming majority of patients ranked the healthcare team as number one, above family, friends, and others. Additionally, the healthcare team was identified as the number one source patients used to find trusted health information, followed by sarcoidosis organizations, and the internet.



Clinical Trials

Perspective on Clinical Trials

There are several factors contributing to the lack of options and access to effective treatments for sarcoidosis patients. Reasons include lack of clinical trials and research focused on new therapies, lack of insurance coverage for FDA approved therapies used to treat other conditions found to be effective in sarcoidosis patients, and lastly, cost of alternative treatments as a barrier to patients who cannot afford them. This lack of access to effective and affordable treatments with limited side effects was identified as the primary motivating factor in this study for clinical trial participation.

When asked to rank the most important benefits to clinical trial participation, an overwhelming majority of respondents reported options that included access to therapies. The top two benefits reported were the possibility of developing new lifesaving therapies and early access to alternative therapies regardless of insurance. Furthermore:

- 93% agreed clinical trials are an integral part of developing new treatments,
- 92.4% agreed they were important in developing effective therapies, and
- 85% felt clinical trials are worth the risk.

History has shown [people of color], the medical industry can't be trusted. Mistrust gets passed down. Took me reading peer reviewed journals and educating myself to build my confidence to become open minded to clinical trials.

- Sarcoidosis Patient

While there was an overall strong sentiment that clinical trials are both important and necessary for the advancement of treatment for sarcoidosis, the responses revealed some areas of hesitation and opportunities for increased education.

Only 40% reported having a higher-level understanding of clinical trials, which means the majority of respondents (60%) demonstrated more need for education and information on clinical trials. Additionally,

when exploring the relationship between historical discriminatory practices and Black patients' perspectives on clinical trials, there was no consensus on whether clinical trials discriminate against people of color. Approximately, 58% disagreed with this sentiment, while 42% agreed that clinical trials indeed discriminate against people of color. Additionally, when asked about factors that would inhibit participation, the number two reason included "Not trusting or feeling safe participating in research based on history of discrimination (~18.5% selected this as a factor)." Both of these findings demonstrate the need for more education around what clinical trials are, how they work, and the benefits of participation. Furthermore, given the

impact discrimination and racial bias has on a significant number of Black patients, it is essential for providers to be educated on the historical and ongoing experiences of Black patients and its impact on the community's perspective of research and the medical community, to better connect, educate, and partner with them.

"The saying 'that's in the past' is in the discrimination playbook." - Sarcoidosis Patient

Figure 1

MEDICAL EXPLOITATION OF BLACK AMERICANS

It is widely known that there is a long history of people of color and Black people specifically, being subjected to unethical treatment under the guise of medical research and advancement. Examples include Dr. James Marion Sims "The Father of Modern Gynecology" who experimented on Black slaves without anesthesia¹, the mustard gas experiments of World War II on Black and Puerto Rican soldiers², chemical experiments on Philadelphia prisoners spanning from 1950s-1970s³, and many more.

Most notably is the "USPHS Syphilis Study at Tuskegee" (most commonly referred to as the Tuskegee Experiment). The study launched in 1932 and exclusively included Black men, with and without syphilis. Despite the emergence of penicillin in 1940 as an effective treatment to cure syphilis, the study continued for decades without participants' informed consent or access to treatment, leading to participants dying and/or passing on the disease to their loved ones. The study was found to be unethical in 1972, but not before generations of family – wives and children – were impacted. In 1973, the Secretary of the Department of Health, Education, and Welfare (now known as DHHS) was instructed to provide medical care for the survivors, and this decree was expanded to cover wives and children in 1975. To put this in perspective, the last surviving participant died in 2004 and participants' children continue to receive medical care.⁴

¹Ojanuga, D. (1993). The medical ethics of the 'father of gynecology', Dr J Marion Sims. *Journal of medical ethics*, 19(1), 28-31.

²Smith SL. Mustard gas and American race-based human experimentation in World War II. *J Law Med Ethics*. 2008 Fall;36(3):517-21. doi: 10.1111/j.1748-720X.2008.299.x. PMID: 18840244.

³Hornblum, A. M. (1998). *Acres of skin: human experiments at Holmesburg Prison: a story of abuse and exploitation in the name of medical science*. Psychology Press.

⁴<https://www.cdc.gov/tuskegee/timeline.htm>

Participation in Clinical Trials

There are many factors contributing to the low representation of Black Americans in clinical trials, which include a lack of trust in the medical community, low prioritization of minority recruitment in trials, hesitancy to ask minority patients to participate, as well as barriers associated with accessibility, time, and financial commitments.

For those who expressed hesitation toward participating in future research, results varied. However, the top three factors that would stop patients from participating in a clinical trial are:

- (1) Not being given information about clinical trial opportunities. A staggering 61% of respondents report never being invited to participate in a clinical trial. Furthermore, only 6% report being invited and opting not to participate. The reason Black Americans are not being asked to participate in clinical trials is unclear. It may be due to assumptions made on the part of the provider that the patient would not participate or could not afford to participate. Other theories may include the provider's lack of knowledge about eligible clinical trials; however, other groups are being asked, so this needs to be further explored to better understand the source of this discrepancy.
- (2) Not trusting or feeling safe participating in research based on the history of discrimination against people due to their race, ethnicity, sexual orientation, gender identity, or religion.
- (3) Expensive to participate due to missed work, childcare, transportation, or other potential financial losses.

"I know most research [is] on white males so I'm happy that FSR is looking at African Americans. I understand how important research is for this disease, however I am very skeptical about clinical trials, how the data will be used and who will have access to the data."

- Sarcoidosis Patient

Despite the history, studies show Black patients tend to be pragmatic when considering participation and engagement with the medical and research community. Respondents reported being more likely to participate in clinical trials if they:

- Receive clear information on how the trial benefits them or others.
- Receive support for clinical trial participation, including monetary stipends to cover travel expenses, lodging, and other financial support.
- Hear from other patients who are part of the clinical trial.

Of the survey respondents, 16.7% reported being enrolled in clinical trials³¹, with 85.5% of them saying they either completed the clinical trial or are currently enrolled in the trial (*still ongoing*). Of those who participated in clinical trials, approximately 11% left the trial early for reasons such as unreliable administration, poor communication, no follow-up, inadequate training information, and declining physical or mental health (*COVID was also mentioned specifically*).

When exploring more about the patients who participated in clinical trials and research, 84.7% stated they were likely to participate again in the future. This finding signals an opportunity for researchers to utilize clinical trial participants to serve as champions in their communities to encourage engagement and to disarm those who are hesitant or lack access to information on clinical trials.

³¹There have not been a lot of clinical trials in sarcoidosis which may be part of the reason this number is so low. It worth noting that this is still more than double the level of participation in clinical trials in general as indicated by the FDA. This may be another marker that clinicians treating those living with sarcoidosis have built more trust with the Black community.

Learnings from the Experts: Sarcoidosis Patients & Experts Weigh in On Results

There were several themes that emerged from the discussions and breakout groups held as part of the Key Opinion Leadership Thought Workshop and Patient Focus Group Meetings. Hearing the perspectives of representatives across pharmaceutical companies, healthcare organizations, clinicians, and researchers, coupled with the experiences and perspectives of Black patients – experts in their own right – proved to be an insightful exercise on the importance of partnership through understanding and collaboration. Insights gained from both groups yielded the following learnings:

- There is a profound need for provider and patient education, including the importance of advocacy.
- Acknowledging race, the role it plays in healthcare, and its impact on patients and providers matters.
- Building trust with patients is essential to strengthening the patient-physician relationship and serves as the gateway to further engagement with the medical community.
- Black patients experience substantial barriers to participating in clinical trials.

There is a profound need for provider and patient education, including the importance of advocacy.

There's one paragraph in the medical school curriculum dedicated to sarcoidosis. Most medical students advance through medical school and enter the medical field with little to no knowledge of what the disease is, its symptoms, or how best to treat or support a patient living with the rare disease.

As a result, many patients report difficulty navigating a system with debilitating symptoms and no answers, often leading to delayed and misdiagnoses. About 21% of respondents say it took 2-6+ years to receive a diagnosis, after expressing concerns of symptoms with their provider. Furthermore, focus group participants referenced the hardships experienced while seeking answers in an effort to receive a diagnosis. One patient recalls how relieved she was to finally see a provider that was knowledgeable after an 18-year diagnostic journey. These delays can have deleterious effects on sarcoidosis patients, considering the nature of the disease and how it can progressively and permanently damage the organ(s) it impacts.

In addition to the physical ramifications, this lack of knowledge among providers serves to further disadvantage patients in need of information and access to resources. There's a

“I think that's where the knowledge gap may be. If we're not receiving the information, we don't know about it. I think because a lot of our physicians don't even know about it. So that's a lot of times our first line of people we go to when we have an issue. I just think a lot of them don't know about it either to be able to offer the clinical trials, or at least tell us about them.” - Patient

uninformed, or they are forced to advocate and research on their own. When discussing the lack of information being shared from her provider, one patient was quoted as saying, “We have no choice but to turn to Dr. Google”. Other patients described reading medical journals to learn about their disease, to understand what questions to ask their team, and to empower themselves to advocate for better treatment, even if that means getting a new provider.

“We need to make sure we help Black Americans navigate advocating for themselves after they get diagnosed and knowing when to switch providers for better outcomes.” – Sarcoidosis Patient

Key Opinion Leaders also felt strongly about the need for self-advocacy. They reported self-advocacy as the key to getting better care, stating that patients need to know how to advocate, and they need to feel empowered to do so. There's a need for physicians to empower patients to advocate for themselves, ask questions, and serve as true partners in their health journeys.

profound need for more education for patients to better understand their disease, the care they deserve and how to receive it; and for providers who may not know about sarcoidosis, to have a better understanding of the disease, treatment options, and clinical trials and research opportunities.

According to the survey, the healthcare team is the number one source of healthcare information. If providers are not knowledgeable about sarcoidosis, available resources, or research opportunities, patients either remain

“Patients who advocate more tend to get a lot more attention, get more detailed information, and get a lot more out of the system. You [must] be empowered to advocate. It takes a certain amount of knowledge, confidence, and being able to advocate. There are certain patients you need to learn to empower.”

– Physician KOL Participant

Acknowledging race, the role it plays in healthcare, and its impact on patients and providers matters.

The subject of race and its impact on perspectives and engagement with the medical community, as well as how it permeates the medical community through implicit and explicit biases was a recurring theme for both groups. The impact of race was discussed in the context of the importance of racial congruency (race matching) for patient-physician relationships, intergenerational mistrust of the medical community due to unethical treatment of Black patients, and implicit and explicit biases that emerge in clinical settings and discussions through stereotyping and minimizing patients' symptoms, experiences, and feelings.

“Oh, let me be clear - I TOTALLY believe that there is discrimination in the medical field. Just thinking it's no different in clinical trials than the medical field overall. My grandmother died of undiagnosed breast cancer from the only doctor in her town who was racist and sexist, so I have those stories as well. Historical mistrust.”

– Sarcoidosis Patient

Racial Congruence

KOL participants found the survey data on the importance of racial congruence to be surprising considering other studies and anecdotal information from patients. One expert noted that general research supports the notion that patients do better or have more trusting relationships when they have physicians who reflect their own race and background. Despite the survey results, most KOL participants agreed on the importance of diversity and increasing representation in the field.

When presented to the patient group, there was consensus on prioritizing expertise and transparency above racial congruency, but

upon further exploration, the reasons varied. Some patients provided further insight by explaining why expertise was more important. One patient explained that the likelihood of finding a sarcoidosis specialist that shared the same race/ethnicity as him was so low that it was something he accepted and in turn prioritized other factors, which he had a greater chance of attaining. However, most patients emphasized the importance and ease of having providers who shared their racial and cultural background. There seemed to be a consensus that race is not an indicator of how good the doctor is; however, racial congruency eases a burden that Black patients carry during interactions with their providers. Patients report that providers who share their race tend to be more empathetic and compassionate. One patient noted that despite having good experiences with providers that did not share her background, race has been a very powerful factor for her because people that look like her can “automatically permeate a wall of apprehension and mistrust that allows for easier discussion without fear of judgement.” She went on to explain that when working with other providers who do not share

her background, she feels she typically has the burden of explaining herself and they often appear to lack empathy.

“Doctors who see me and identify me and can consider me somebody that they could know in life, are often more sympathetic.” – Sarcoidosis Patient

Based on the patient perspectives, it appears racial congruency is important and impactful in that it alleviates the emotional burden often experienced by Black patients navigating as the ‘other’ in clinical settings; however, there’s consensus that being an experienced and trustworthy provider is paramount.

Stereotyping and Biases

Biases don’t have to be explicit to have harmful and long-lasting effects. Biases can be hidden within the most well-intentioned people; and when these people are authoritative figures these attitudes can unconsciously guide decision-making which have very real consequences. When the authoritative figure is a health care provider, these consequences can translate into poor communication, mistrust of the healthcare system, ineffective treatment plans, dismissal of symptoms and pain, late/misdiagnosis and much more. There is extensive evidence and research that finds unconscious biases can lead to differential treatment of patients by race, gender, weight, age, language, income, and insurance status.

There was a common theme of providers not believing patients’ concerns, mis/underdiagnosis and stereotyping. Throughout both of FSR’s *Ignore No More* campaigns, there has been a recurring theme around black women in particular, being told they need to lose weight and obesity being the source of the symptoms or challenges they express. The patient focus group affirmed this sentiment, with one patient stating, “I feel like long time stereotypes of Black Women as fat and lazy interact really powerfully with [doctors’] response to complaints of fatigue.” Another patient shared that her doctor told her all her issues were rooted in her need to lose weight; however, she actively struggled with the ability to breathe due to her pulmonary sarcoidosis and limited lung function. Additionally, many patients reported extreme and rapid weight gain as a side effect of the medications they were prescribed for sarcoidosis and complained of the difficulty losing weight. Overall patients report feelings of being dismissed due to racial stereotypes.

Clinical Trials & Race

The survey showed that there was no consensus on whether there was racism in clinical trials, with approximately half of the respondents reporting they felt there wasn't. However, this may be explained by different perspectives on the same phenomenon. For patients who recognize the high level of racism in healthcare in general, clinical trials was viewed as an extension of the healthcare system, therefore, it was expected and accepted as the norm. They were less likely to see clinical trials as particularly racist, biased, or discriminatory. However, for those that did not view clinical trials as an extension of or part of health care in general, they tended to acknowledge racism in clinical trials specifically. All patients understood the presence of bias in the medical field and clinical trials, so they valued providers who understood and acknowledged the presence of racism and how it impacts their patients. Patients also expressed the need for researchers to consider people of color when designing clinical trials, emphasizing the need for doctors to set up trials to understand how race impacts patients' lives.

Building trust with patients is essential to strengthening the patient-physician relationship and serves as the gateway to further engagement with the medical community.

In alignment with the data, patients agreed trust was an essential factor in building a healthy partnership with their physician, which made them feel safe to openly communicate about their care and treatment plans and would make them more likely to engage in discussions about clinical trials and research.

Most patients noted finding a trustworthy provider and building a trusting relationship is challenging and often takes a long time with significant self-advocacy. Many have had a long journey to finding a provider they are confident in.

"So, I don't think it's that level that they are intending to discriminate. But the white bias is there. I don't think trials are any more discriminatory than any other medical setting and maybe that's why the 50/50, because the medical system has racial biases. But I feel like I have more trust in a doctor if they understand that there are racial biases. I don't want to hear that's in the past. I don't want to hear that we've all got it together."

- Sarcoidosis Patient

"I trust my doctor now, but that's after, like, 18 years of a diagnostic journey. By the time I got to this team, I had a list of statements and questions for them, and he wasn't defensive; he showed active listening, he shared with me the research that he was basing the diagnosis on and went through it with me, he didn't build up walls between us, and he understood me as an active participant in my care."

-Sarcoidosis Patient

There was a mix of people who felt they trusted doctors until they were given a reason not to, and that mistrust resulted in patients being more conscience in the future with who they choose to be their provider. Being seen as a whole person, truly listened to, being invested in, sincerity, and genuineness by providers make the difference in disarming patients and building a foundation of trust. Providers who show their investment in patients through their actions (such as making themselves accessible or advocating) and see patients as whole people become trusted.

Overall, there were two camps the patients aligned with, and they had varying strategies on how they approach building relationships with providers. One approach was automatically trusting your provider as the expert until they lose your trust through their actions. The other approach was to enter the relationship cautiously until the provider earned the patient's trust. Most patients shared that trust needs to be built for them, either because that has always been how they interact with providers or based on having past negative experiences with providers breaking trust.

"Yeah, in the beginning, I did go in trusting the doctor, but after that, they definitely had to earn my trust. Because it was hard, and it was very frustrating."

Sarcoidosis Patient

"I always go in with trust. I trust them right offhand because they are the experts, like I wouldn't be going to them if I knew the information, if I could treat myself and diagnose myself, so I automatically trust until they let me down."

Transparency often emerged as an essential characteristic for providers to build trust with patients. Patients recognize that many providers don't know much about sarcoidosis, and even sarcoidosis specialists don't have all the answers because it is a rare disease that manifests differently in everyone. The expectation of Black patients isn't for providers to have all the answers; it's for them to be honest about what they do and don't know and to be open to working with the patient through their journey of finding the answers.

Building trust boils down to seeing the patient as a person and treating them as you would your own family or someone you care about, not a statistic or an appointment. Patients emphasized the importance of partnering with the patient and learning about them – ask about their family, environment, lifestyle, and goals for their prognosis. Then use that information to work with them on a plan they can successfully follow.

Black Patients Experience Substantial Barriers to Participating in Clinical Trials.

Barriers to clinical trials participation exist for patients of all backgrounds, not just Black patients. However, Black patients are unique in that they face additional barriers associated with their race. Sarcoidosis experts tended to focus on barriers associated with challenges with patient outreach, communication, and clinical trial design; while patients focused on the many barriers fueling their hesitation to participate like mistrust, fear of side effects, travel and time constraints, and financial burden.

We've discussed one barrier in particular to a great extent - mistrust due to historical and ongoing biases within the health care system – so this section will focus on the additional barriers that emerged from the KOL and Patient Focus Group meetings.

“I think that part of trust is transparency, and doctors who are willing to tell you what they know and what they don't know and then work with you as a member of the team. Doctors who are willing to say, let's work together. Let's find out. Let's investigate together. I think that that is the most helpful.”

-Sarcoidosis Patient

Not Being Given Information about Clinical Trial Opportunities.

A majority of the survey respondents report the healthcare team as having the most influence on their healthcare decisions, despite concerns of racial bias in medical settings and clinical trials. Furthermore, 94.5% of patients felt their providers communicate in ways they can understand, and a majority felt heard by their provider and that they were responsive to patient needs. While survey results tended to show a higher satisfaction rate with providers, the patient focus group participants exposed the underpinnings of this data by providing more context. Though patients may feel satisfied with their current care, many reported a long road of failed provider relationships and self-advocacy to get there.

Despite the challenging journey, most patient feedback reported satisfaction with their current providers, yet a staggering 61% still report never being asked to participate in clinical trials. Furthermore, of the 39% that were invited, only 6% opted not to participate. This is a lost opportunity for the medical community to engage Black patients in research. The reason Black Americans are not being asked to participate in clinical trials is unclear. It could be due to assumptions made on the part of the provider that the patient would not participate due to mistrust or could not afford to participate. Other theories may include the provider's lack of knowledge about eligible clinical trials; however, other groups are being asked, so this needs to be further explored to better understand the source of this discrepancy. Clinical trial opportunities need to come from trusted sources like sarcoidosis organizations (e.g., FSR), friends and family, or a trusted provider. Providers need education on both sarcoidosis and sarcoidosis specific trials so they can bring awareness and opportunities to their patients.

Are providers hesitant to ask because they assume Black patients will not participate due to mistrust? Are they avoiding the discussion all together?

"I'm struck by the stat showing that Black Americans are just as likely to participate in trials when asked. But [the] next statistic, which is much more common narrative, is that there's a lack of trust. Is that an excuse to not ask/engage?"

- KOL Expert Participant

In addition to providers discussing clinical trials with their patients, KOL experts brought up the need to connect with the Black community more broadly to educate them on clinical trials and inform them of opportunities to engage. One physician noted that, “We have to diversify the patients, but we also need to diversify the physicians and reach out to them, through the associations, to share the information and recruit patients to trials.” Other sarcoidosis expert suggestions included building stronger partnerships between community providers and physicians at academic institutions, partnering with predominantly Black physician associations, and utilizing more grassroots approaches to reach community members where they are such as salons, barber shops, churches, and community centers.

“Don’t recruit in a standard way. Go where the patients are. Email and phone can’t be the only way to recruit, go directly to the patient.”

-KOL Expert Participant

Fears of Jeopardizing Their Health and Employment.

Patients reported having reservations of participating in clinical trials due to health concerns. Many patients have spent years getting a diagnosis and developing an effective treatment plan that works for them. Sarcoidosis is an unpredictable disease with sporadic flare ups and the never-ending possibility of manifestations affecting new organs and causing more symptoms. Patients live with the dread of not knowing when something new will appear and change the trajectory of their disease journey. Once they have sarcoidosis “under control” with an effective treatment plan, it is difficult to risk disturbing that by participating in a clinical trial that may result in withdrawal from their current treatment to either take a different therapy or be assigned to a control group where they do not receive treatment at all. One patient described coming off prednisone (steroids) resulting in his body reacting poorly. He went on to express that “there is a lot of risk associated with not knowing how your body will react,” and stated that if he were assigned to a control group, he would quit the trial just knowing how his body responds without medicine.

“Sarcoidosis is precarious, and I can have a flare up at any time, and it takes significant effort to get a response from my current care team so that causes a lot of anxiety. If I come off my medication and get put in a control group, what happens if an emergency occurs? When my disease is being managed, I have to consider the risk of disrupting my life, work, etc.”

--Sarcoidosis Patient

Patients also noted that most clinical trials required substantial travel to the nearest academic center, where most clinical trials are housed. One patient questioned the distance of most trials and how that would impact her health and the ability to be appropriately monitored asking,

“Who is to monitor me locally if my doctors don’t know about sarcoidosis? How do I stay safe when I’m not at the trial site?”

In addition to the fear of how participation will impact their health, patients reported anxiety around how a change in their health status would impact their personal and professional lives. They expressed concerns over child and family care responsibilities, as well as how it would impact their ability to perform at work.

“The rigor of the trial is that visits continue. . . If you want marginalized groups, [you] must make sure that their needs are being met.”

- KOL Expert Participant

“My job has been very accommodating, but it turns out I was being undertreated last semester and was in really bad shape. What would my provost say if I said, oh, yeah, I was on a clinical trial, and it didn’t work out. But now you need to be at the brunt of my not being able to work at my fullest capacity. So, all of that still kind of goes through my head.”

-Sarcoidosis Patient

“I don't want to make the assumption. But being a person of color and not knowing about clinical trials, I think that's like obvious. There's a discrimination. I have different nationalities of friends, I hear them talking about clinical trials for their MS and stuff like that. But I don't hear the black community talking about that. I don't understand. So, to hear you even talk about it. I want to know more. I want all the information on it, you know everything that you have because I know nothing. I'm not even being offered. I think it is a problem.”

- Sarcoidosis Patient

The Financial and Logistical Toll of Clinical Trial Participation.

In addition to health concerns, patients discussed substantial barriers associated with missed work, child and family care, transportation, and financial burden. Patients and KOL experts expressed concern over clinical trials being concentrated in certain regions of the country and predominantly through academic institutions. This limits the pool of eligible patients and discounts patient communities, often marginalized communities, who are receiving treatment locally and do not have the funds or time to travel long distances to actively participate. Routine and extensive travel requires time off work which is especially difficult for those who are

overrepresented in industries that tend to pay hourly, have limited job flexibility, and lower wages and benefits. One patient also noted the complexity of familial responsibilities for people of color, stating that their responsibilities tend to extend beyond childcare, with many having intergenerational households and caregiving duties beyond children and pets that they must consider. Furthermore, travel impacts patients who have care partners and immediate family members who must also make accommodations to support their participation, which can further impact the household, leading to additional lost wages, time off work, and other resounding effects.

“I've looked up clinical trials to see what was out there. A lot of those trials, closest I've seen in 2021 was in the Keys an 8-hour drive, or I [saw] one in Miami and that's 6.5 hours from me. Taking off work to go down there, I mean and having my wife to take off work to go down there [with me] because that drive is no joke...there's nothing here.” - Sarcoidosis Patient

KOL experts discussed strategies to change the design of trials to address this barrier, insisting on partnering with local and community physicians and utilizing technology like telehealth appointments, which can limit the need for participants to travel frequently to host sites. Additionally, they discussed expanding the hours of operation for participants by offering weekend hours, to alleviate or reduce interruptions to work.

“Patients need more clarity on what costs they may incur in trial participation. It’s already hard with your own insurance, but harder with trials.”
-KOL Expert Participant

Moreover, patients and experts discussed the need to compensate clinical trial participants adequately and minimize inconveniences of disrupting daily life to participate. One KOL expert participant expressed the need for patients to receive adequate stipends for participation and to make patients aware of all costs they may incur during the trial prior to enrollment. Further supporting the need for transparency and adequate stipends, one patient recalled her experience participating in a clinical trial sharing, “The last study I was in, it was like \$5 for each time I had to go and that doesn’t even pay for the subway, and I actually can’t ride the subway. I don’t need to get paid, but also need to not pay you all.”

It is paramount researchers consider the complexity of the lives of people of color, when incentivizing patients to engage in clinical trials. To increase access to clinical trials for Black patients, it is evident that researchers need to commit to including diversity as a goal during the design phase to account for the many barriers that serve as roadblocks to participation for this population. These challenges should be discussed up front so there are strategies in place to effectively recruit, retain, and support Black patients throughout the process. While it seems clear these accommodations would increase enrollment among Black patients, it will also make clinical trials more patient-friendly for all motivated patients experiencing similar barriers to clinical trial engagement.

“I don’t need to get paid, but also need to not pay you all.”

-Sarcoidosis Patient

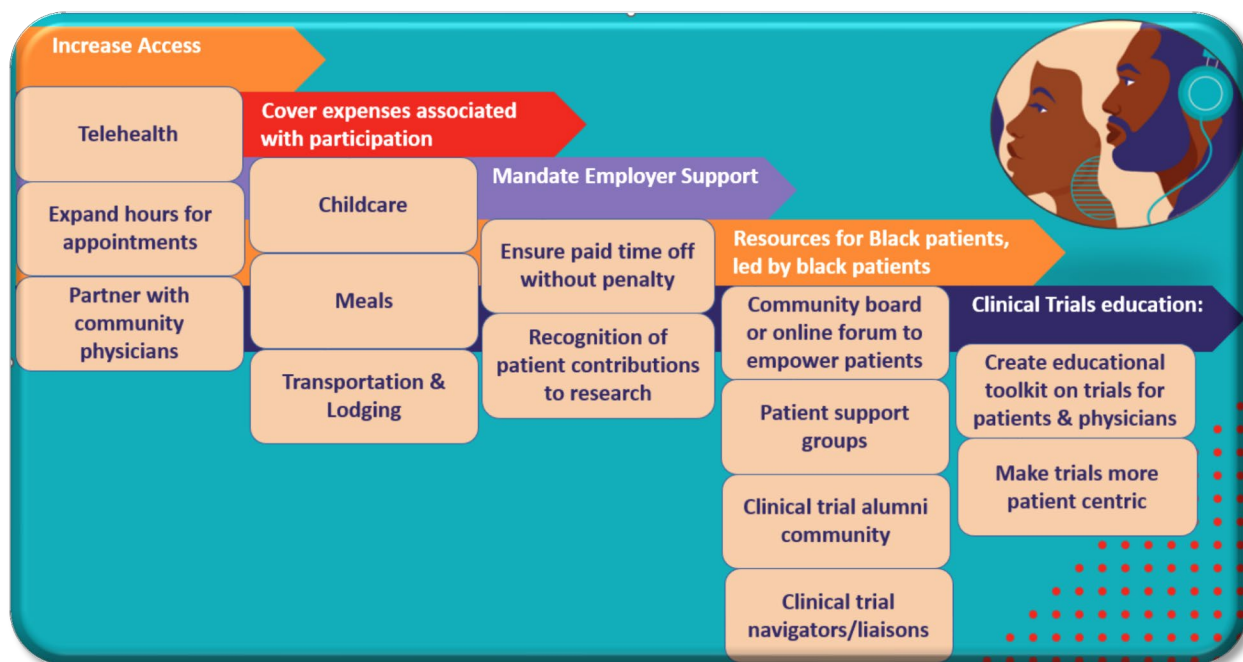
“Opportunity costs for participating may be too high...some research requires a significant amount of time, discomfort, and effort from participants [versus] very disproportionate incentives.”

-Sarcoidosis Patient

Recommendations

During the KOL Thought Workshop Meeting, experts developed a set of recommendations that was then reviewed by Patient Focus group participants. Patients provided input and ideas related to each of the recommendations presented and were also provided the opportunity to suggest additional recommendations. The input provided by patients ranged from detailed additions or changes to language of presented recommendations, to broad suggestions to improve the relevance and usefulness of the recommendations presented. Some also provided new recommendations to include for consideration. This exercise further underscored the importance of including patients at every level and ensured the patient voice was incorporated in meaningful ways throughout the study, including when final determinations for recommendations were created.

Some of the recommendations highlighted during the Patient Focus Group include:



Final Recommendations

Create a Blueprint for Clinical Trial Design that Supports Clinical Trial Diversity and Access.

This recommendation includes strategies to increase access to clinical trials and to set expectations for pharmaceutical companies, researchers, and employers vis-a-vis government mandates and tax incentives, to cover certain participant needs.

- Strategies suggested to increase access include the utilization of telehealth technology, expanding hours of the clinic to accommodate appointments outside of ‘work hours,’ and engaging community physicians to partner with research institutions as a local touchpoint that can assume some of the monitoring and testing required by clinical trial participants.
- The need for support services for study participants was cited multiple times throughout the discussion, particularly the need for financial support for participants who are underemployed. Support services mentioned included travel cost reimbursement for the patient and companion (if needed), family care and pet care coverage, access to compensation for food and lodging, and legislation requiring employers to support clinical trial participation, providing job security and paid time off to participants through FMLA. Additional support services mentioned, focused on increasing communication and access to education. Patients recommended the utilization of support liaisons who could be readily available to answer questions and provide information in a more patient-centric safe space.

Provide Support Tailored to Black Patients.

An important concept that emerged was the importance of self-advocacy and self-empowerment, particularly as a community, and the power that safe spaces hold where patients can be vulnerable and connect with others like them without judgement or masking. This recommendation included strategies to create these safe spaces for Black patients like online forums and support groups led or moderated by other Black patients or professionals in this space.

- Patient Focus Group participants were split on whether the groups needed to be solely for Black patients; however, the consensus of the patients and KOL participants, was that this type of structure would be beneficial to allow for more tailored discussions and talks about the negative consequences of assumptions about Black patients, managing cost of medications, providing care where patients are, and other areas impacting the experiences of Black patients.
- Additional suggestions for this recommendation included creating a clinical trial alumni community for patients to connect with other patients who have experience participating in research or clinical trials. Lastly, both groups felt a community liaison or

“clinical trial navigator” that could offer the 1:1 support for patients’ needs, would provide an additional layer of support, connection, and education to help patients stay informed.

- Improving access and quality of care, and the trustworthiness of researchers and institutions to appropriately care for Black patients and run equitable and inclusive trials, were common throughout the feedback on this recommendation. Strategies suggested include partnering with other health organizations prominent in the Black community to raise awareness of sarcoidosis and clinical trial participation. Others offered the use of social media as a probable solution, leveraging ‘influencers’ and physician collectives to educate Black Americans.

Create an Educational Toolkit for Patients on Enrollment and Participation to Be Distributed Through Health Care Providers and Other Trusted, Easily Accessible Sources.

The need for education of patients and for providers was a recurring thread to ensure patients understand clinical trials, services, and expectations; and that providers are well versed in the disease and clinical trial opportunities. This recommendation was developed in direct response to the reported need for more education on clinical trials for patients and physicians.

Developing a toolkit would serve this dual purpose and serve as a conduit for physicians and patients to discuss clinical trial options.

- Input on this recommendation included specific information that should be included such as listing the patient’s legal and ethical rights as participants, a cost benefit analysis of participation so patients can make informed decisions, examples of the impact of research.
- Other suggestions included specific topics on disease education such as information for loved ones and instructions on how to talk about clinical trials.
- Additionally, focus group participants discussed approaches to disseminate the toolkit which included social media, high profile figures prominent in the Black community, and providing forum, training, areas for physicians that would encourage them to learn more about rare diseases and how their specialties are incorporated.

Additional Recommendations.

Ideas for additional recommendations included opportunities for physician education, increasing disease awareness and specific approaches to sharing clinical trial opportunities. Creating pathways for Black and African American students to become physicians, nurses and researchers was suggested, as was connecting to specific communities. Many of these ideas may be taken into consideration under the umbrella of one of the recommendations above.

Legislative Ask

Foundation for Sarcoidosis Research developed a policy brief: *Removing Obstacles to Clinical Trials and Improving Health Outcomes*, which will be distributed during the Congressional Briefing on Clinical Trials Diversity. The policy brief can be found in the [Appendix G](#).³²



³² FSR Policy Brief: Removing Obstacles to Clinical Trials and Improving Health Outcomes

Next Steps

“What we need to do is think big!”

– Sarcoidosis Expert KOL Participant

Referencing the input provided from KOL and Patient Focus Group participants, paired with the raw data and discussions around survey findings, several next steps come to light:

- Educate physicians on how to build trust with patients of color, how to assess and address their own biases, and how to empower patients through information and open communication. Additionally, physicians need to be educated on available clinical trial opportunities and how to broach conversations with historically marginalized groups impacted by histories of unethical medical injustices.
- Create targeted materials for Black patients explaining what clinical trials are, how they work, benefits of participation, and how to stay up to date on opportunities they may be eligible for.
- Utilize multi-prong approaches to disseminating information by partnering with trusted champions in the Black community.
- Build a commission of health organizations, businesses, health institutions, and other stakeholders committed to clinical trial diversity to support the legislative ask by advocating for clinical trial participation to be explicitly protected under FMLA and for providing financial support that for those choosing to participate in trials through a tax credit or tax deduction and other financial support programs; therefore, expanding job protection and benefits for patients interested in engaging in clinical trials.

Conclusion

“Researchers should be involved in raising the level of care for all patients and then outreach for research can be appreciated and more trusted.”

- Sarcoidosis Patient

Patients in this study were highly engaged and committed to participating in the improvement and accessibility of care and the inclusion of Black patients with sarcoidosis in clinical trials. Despite the acknowledgement of mistrust, lack of information, and reported barriers, Black patients demonstrate a strong willingness to engage in clinical trials, understanding the important role diversity plays in advancing treatments that will benefit their community. To increase access to clinical trials, physicians must actively build trust with their patients by being transparent, empathetic, compassionate, and by partnering with them on their health journeys. Trust-building is the gateway through which providers and patients can begin to discuss clinical trials, including any reservations that may emerge. This step is instrumental to engaging Black patients, who have demonstrated a propensity to participate in clinical trials when asked. Despite this propensity, and previous studies to support it, Black patients are not being offered the opportunity. The need for provider education about sarcoidosis, clinical trial opportunities, and providing equitable care for Black patients emerged as necessary to begin to bridge this gap in care. Lastly, clinical trials cannot operate as a one size fits all operation. Researchers must be explicit in developing strategies that address and reduce barriers particularly experienced by Black patients, so clinical trials can be designed in a manner that encourages inclusivity and incentivizes participation. These strategies must be built from the ground up, considering appropriate outreach and education mechanisms to reach targeted communities, and should incorporate patients in each step of the work. FSR is having a Congressional Briefing on Clinical Trial Diversity to educate the general public and representatives on the challenges specific to Black patients with sarcoidosis and make a case for legislative action to address the barriers that emerged in our findings. We plan to continue our work in this space, and dig deeper into the data, learnings, and recommendations to expound on this work for years to come.

Sponsor Acknowledgements

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Appendix

Appendix A: Full list of *Ignore No More: African American Women & Sarcoidosis* Partners



TRANSPLANT INSTITUTE

Appendix B: Women of Color Patient Advisory Committee Members



In order (left to right): Kathryn Washington, Garrie Farrow, C. Ann Scott, Marsha Henderson, Cheryl Bradford, Ora Riley, Erica Courtenay Mann, Jessica Propps, Jessica Reid, Brenda Harris, Rhonda Underhill, Mary Oldham, Gloria McDaniel, Jonette Harper, Chasta Posey

Appendix C: *ACTe Now!* Patient Advisory Committee Members



In order (left to right) Mytle Bell, Erica Courtenay-Mann, Calvin Harris, Rhonda Underhill, Purvis Hunt, Mary Oldham. Not pictured: Kathryn Washington

Appendix D: ACTe Now! Clinical Advisory Committee Members



In order (left to right) Yvette C. Cozier, DSc, MPH, Sotonye Imadojemu, MD, MBE, Divya Patel, DO, W. Ennis James, MD, Ogugua Ndili Obi, MD, MPH, MSc

Appendix E: *Ignore No More: ACTe Now!* Campaign Partners



Appendix F: FSR Key Opinion Thought Workshop Participants

Name	Key Opinion Leader Type	Organization
Andra Stratton	Sponsor Representative	Chan Zuckerberg initiative – Rare as One
Brian McBride (Catherine Jackson)	Sponsor Representative	Mallinckrodt Pharmaceuticals, Inc.
Craig Lipset, MPH	Board of Directors for the Decentralized Trials & Research Alliance (Co-Chair), Foundation for Sarcoidosis Research (Vice President) and the MedStar Health Research Institute.	Former Head of Clinical Innovation at Pfizer
Craig S. Conoscenti, MD, FCCP, ATSF	Physician, Pulmonologist	Boehringer Ingelheim Pharmaceuticals, Inc
Divya Patel, DO	Physician, Pulmonary, FSR Women of Color and ACTe Now Clinician Advisory Committee Member	University of Florida Gainesville, FSR Global Sarcoidosis Clinic Alliance Member
Elliott Crouser, MD	FSR Scientific Advisory Board Chair	Ohio State University, FSR Global Sarcoidosis Clinic Alliance Member
Ennis James, MD	Physician, Pulmonologist, FSR Women of Color and ACTe Now Clinician Advisory Committee Member, FSR Scientific Advisory Board Member	Medical University of South Carolina, the Susan Pearlstine Sarcoidosis Center of Excellence, FSR Global Sarcoidosis Clinic Alliance Member
Grace Levy-Clarke, MD	Physician, Ophthalmologist	West Virginia University, FSR Global Sarcoidosis Clinic Alliance Member
Isabel Pedraza, MD	Physician, Pulmonologist	Cedars-Sinai Advanced Lung Disease Program, FSR Global Sarcoidosis Clinic Alliance Member
Janie Shelton	Sponsor Representative	23andMe

Name	Key Opinion Leader Type	Organization
Leslie Serchuck, MD	FSR Board of Directors	Children’s Hospital of Philadelphia
Line Kemeyou, MD	Physician, Cardiologist	University of Utah Sarcoidosis Multidisciplinary Clinic, FSR Global Sarcoidosis Clinic Alliance Member
Logan Harper, MD	Physician, Pulmonologist	Cleveland Clinic Sarcoidosis Center of Excellence, FSR Global Sarcoidosis Clinic Alliance Member
Louise M. Perkins, PhD	FSR Board of Directors, President	Former, Chief Science Officer Emerita of Melanoma Research Alliance
Maneesh Bhargava, MD	Physician, Pulmonologist	University of Minnesota, FSR Global Sarcoidosis Clinic Alliance Member
Mary McGowan	CEO	Foundation for Sarcoidosis Research
Mary Willis, MD	Physician, Pulmonologist	University of Mississippi Medical Center, FSR Global Sarcoidosis Clinic Alliance Member
Michelle Sharp, MD, MHS	Physician, Pulmonologist	Johns Hopkins Sarcoidosis Clinic, FSR Global Sarcoidosis Clinic Alliance Member
Ogugua Obi, MD	Physician, Pulmonologist, FSR Women of Color and ACTe Now Clinician Advisory Committee Member, FSR Scientific Advisory Board Member	East Carolina University
Peter Sporn, MD	Physician, Pulmonologist	Northwestern FSR Global Sarcoidosis Clinic Alliance Member
Rayne Rodgers, MPH	Sponsor Representative	Kinevant Sciences

Name	Key Opinion Leader Type	Organization
Teresa Teeman, RN BSN	Sponsor Representative	Boehringer Ingelheim Pharmaceuticals, Inc
Tima Lawal	Sponsor Representative	Mallinckrodt Pharmaceuticals, Inc.
Yvette Cozier, D.Sc., MPH	FSR Board of Directors, Epidemiologist, FSR Women of Color and ACTe Now Clinician Advisory Committee Member	Boston University School of Public Health

Appendix G: FSR Policy Brief: Removing Obstacles to Clinical Trials and Improving Health Outcomes

Executive Summary: Removing Obstacles to Clinical Trials and Improving Health Outcomes

Clinical trial enrollment is critical to the acceleration of scientific discovery, the reduction of the disease burden on individuals and the economy, and the improvement of lives of all Americans impacted. Low enrollment in clinical trials is noted as the single most significant reason for clinical trial termination or delay. Additionally, clinical trials are severely lacking in representation from underserved and minority populations which can further limit effectiveness of the approved therapies.

Clinical trial participants are performing a public service, not only for those impacted by their particular disease, but for scientific discovery and future generations. If we are truly committed to improving the physical and financial well-being of all Americans, we must reframe our understanding and approach to clinical trials by creating a pathway in clinical trials that addresses two of the most significant barriers to clinical trial participation - time off from work and the financial expenses associated with travel. As detailed below, we will outline a public policy proposal to help improve clinical trial enrollment and advance more equitable access to trials.

Background

KEY FINDINGS: FSR surveyed the sarcoidosis community and heard from over 600 respondents. Key findings included:

- Over 40% of respondents named time or distance to clinical trial sites as a primary concern for not participating in clinical trials; and
- 35% of respondents indicated that they consider the financial impact of participation in a trial.

Across the globe, 38-55% of all trials are terminated due lack of enrollment^{33,34} and over 80% of trials need their timeline extended,³⁵ resulting in billions of dollars of costs in order to reach full enrollment.

RACIAL DISPARITIES: Furthermore, according to the Food and Drug Administration (FDA), Black Americans only represent:

³³ Desai M. Recruitment and retention of participants in clinical studies: Critical issues and challenges. *Perspect Clin Res.* 2020 Apr-Jun;11(2):51-53. doi: 10.4103/picr.PICR_6_20. Epub 2020 May 6. PMID: 32670827; PMCID: PMC7342339.

³⁴ Morgan, C.J. Statistical issues associated with terminating a clinical trial due to slow enrollment. *J. Nucl. Cardiol.* 24, 525–526 (2017). <https://doi.org/10.1007/s12350-016-0702-1>

³⁵ Clinical Trials ARENA Clinical Trial Delays: America's Patient Recruitment Dilemma. 2012. Jul 18, 2019. <https://wwwclinicaltrialsarenacom/analysis/featureclinical-trial-patient-recruitment/>

- 7% of all clinical trial participants globally; and
- 16% of clinical trial participants in the United States

Furthermore, when looking at clinical trials for rare diseases specifically, Black Americans only represent 9% of clinical trial participants.³⁶

Black and African Americans are 2.5 times more likely to have sarcoidosis than White Americans.³⁷ They experience more severe and chronic forms of sarcoidosis, worse health outcomes, and a higher hospitalization and mortality rate than other groups.

Public Policy Change: removing obstacles to patient participation

As was highlighted in our recent survey, public policy that helps to provide an opportunity for time off from work, as well as financial support for participation, would help remove significant obstacles to patient interest and ability to participate in clinical trials, especially among underrepresented communities.

Included in the 2022 omnibus legislation (H.R. 2617)³⁸ was the Food and Drug Omnibus Reform Act of 2022 (“FDORA”). FDORA enacted a number of provisions aimed to promote diversity in clinical trial enrollment, encourage the growth of decentralized clinical trials, and streamline clinical trials processes. Building on these important advancements, advancing new public policy that allow for time off from work and financial assistance will make important strides towards making clinical trials more accessible to all.

- **Participation As Public Service:** We propose that a critical first step to improving clinical trial enrollment and advancing more equitable access to trials is ensuring that the Family & Medical Leave Act (FMLA) covers participation in a clinical trial.
 - If clarified through US Department of Labor administrative action or legislation, patients volunteering for clinical trials would not need to consider stressors like time off work or job loss and, instead, would be able to focus on their health. As a result, clinical trials would receive increased participation and representation, which will improve overall effectiveness of the final medications.
- **Tax Credit:** We further propose that for patients enrolling in clinical trials a federal tax credit for up to \$5,000 for travel expenses associated with clinical trial participation should also be considered as part of this public policy response.

Conclusion

³⁶ U.S. Food & Drug Administration 2015-2019 Drug Trials Snapshot Summary Report Retrieved August 1, 2022, from <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots>

³⁷ <https://osteopathic.org/2017/06/06/once-a-rare-disease-sarcoidosis-now-afflicts-nearly-three-percent-of-african-american-women/>

³⁸ Consolidated Appropriations Act, 2023 (H.R. 2617) <https://www.appropriations.senate.gov/imo/media/doc/JRQ121922.PDF>

If we are serious about advancing science and research and improving the lives of those impacted by chronic illness, we need to shift our focus around clinical trials and take steps to honor the incredible gift that all participants are providing to our scientific understanding and future generations. We need to take action to increase the opportunity for patient participation and need to seriously consider the financial and employer-based barriers that limit the opportunity for patients, especially those from underrepresented communities, to participate.

Bold action to increase clinical trial participation opportunities will lead to more advanced therapies, reduced medical costs, and improve quality of life for all impacted by chronic illness.

- By taking the small but important steps of recognizing clinical trials under FMLA and providing financial assistance through a tax credit, we expand the opportunity for more individuals to volunteer for these important trials.
- Moreover, if we can diversify clinical trials to address the disparities gap in health care costs in the United States we could decrease the overall healthcare expenditures by as much as \$1.2 trillion over a three year period.³⁹

By increasing opportunity for clinical trial participation, we will help improve health outcomes for all Americans and broaden our conception of civic responsibility.

³⁹ Laveist T.A., Gaskin D., Richard P. Estimating the economic burden of racial health inequalities in the United States. *Int J Health Serv.* 2011; 41: 231-238

IGNORE NO MORE!

African American women have more severe and chronic forms of **sarcoidosis**, and higher rates of **hospitalization and mortality**.

AFRICAN AMERICAN WOMEN

3X are nearly **3x more likely** to develop sarcoidosis than white women and white men. They are also up to **2x more likely** to have the disease than African American men.

-  Have more severe and chronic forms of sarcoidosis.
-  More chronic and severe forms of pulmonary sarcoidosis
-  More organ involvement outside of the lungs (lymph nodes, eyes, skin, liver)
-  More difficult to treat, advanced forms of sarcoidosis

 Have a higher mortality rate than other groups.

- 13X**  White Men & Women
- 1.5X**  African American Men

 Have the highest hospitalization rates compared to all groups.

- 2X**  African American Men
- 10X**  White Women
- 18X**  White Men

ASK about the symptoms.

ENGAGE in the treatment.

CONNECT with your community.

SARCOIDOSIS is a rare disease characterized by the creation of tiny clumps of cells that cause inflammation in one or more organs of the body. When too many of these clumps form, they can interfere with an organ's function, leading to serious and sometimes fatal complications. Sarcoidosis affects roughly 200,000 Americans.

 FOUNDATION FOR SARCOIDOSIS RESEARCH

Sponsored by Global Genes and Mallinckrodt Pharmaceuticals.

 **LEARN MORE** ▶ stopsarcoidosis.org/aaaws-campaign/

All sources for data available on the website.

Figure 2 You may download this at https://www.stopsarcoidosis.org/wp-content/uploads/AAWS_Campaign_Infographic.pdf



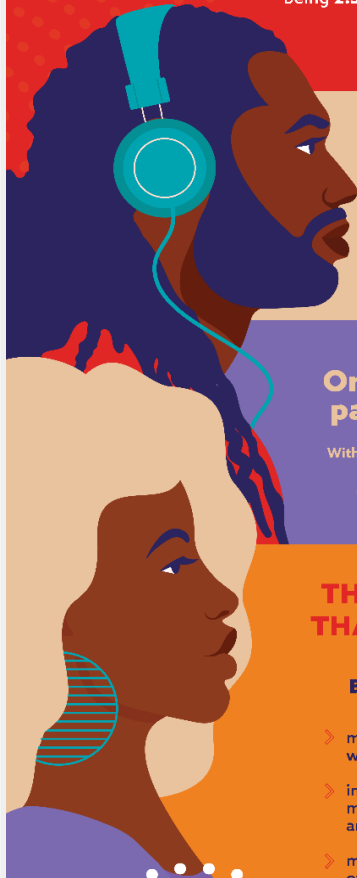
Get Involved!
Take the Survey at
stopsarcoidosis.org/ACTNOW

THE TIME TO ACTe IS NOW!

Current medications prescribed for sarcoidosis were determined without adequate representation of Black Americans in clinical trials, despite their being **2.5x more likely** to have sarcoidosis than White Americans.

ADVANCE CLINICAL TRIALS FOR EQUITY

IN SARCOIDOSIS



TAKE THE FIRST STEP

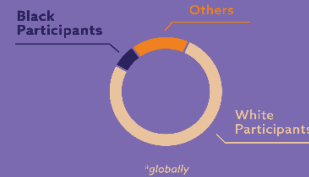
Complete FSR's Patient Survey for Black Americans with sarcoidosis (incentives provided) by visiting:

STOPSARCOIDOSIS.ORG/ACTNOW

Increasing representation of Black Americans in clinical trials and research is the pathway to developing and identifying the most effective treatments and better health outcomes for Black patients with sarcoidosis.

According to the FDA:
Only 7% of clinical trial participants are Black*

Without proper representation of Black Americans in clinical trials, therapies may not account for greater health risks, comorbidities, and higher hospitalization and mortality rates.



THERE ARE MORE SARCOIDOSIS CLINICAL TRIALS THAN EVER BEFORE, SO THE TIME TO ACTE IS NOW

BENEFITS INCLUDE...

- › more frequent communication with providers
- › increased access to medication, expert clinicians, and advanced technologies
- › monitoring regardless of insurance status

CLINICAL TRIALS & RESEARCH CAN BE AS SIMPLE AS...

- › surveys, patient registries, or interviews
- › health education programs
- › trying medications that have been FDA approved for safety in other diseases
- › a simple blood draw
- › trying new potential therapies with close oversight

IGNORE NO MORE!

Help improve care for yourself, family members impacted by sarcoidosis, and future generations! Be part of the solution.

ACTe Now. Learn How.
Visit stopsarcoidosis.org/ACTNOW

Sponsored by Boehringer Ingelheim, Kinavant Sciences, and Mallinckrodt Pharmaceuticals and made possible in part by a grant from the Chan Zuckerberg Initiative. All sources available on the website.




FOUNDATION FOR SARCOIDOSIS RESEARCH

Figure 3 Download at https://www.stopsarcoidosis.org/wp-content/uploads/FSR_ACTeNow_Infoographic_Final.png

You may find more graphics to download at <https://www.stopsarcoidosis.org/aaws-campaign/> and <https://www.stopsarcoidosis.org/actnow-social-kit/>.





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Foundation for Sarcoidosis
Research (FSR) and our efforts
to improve diagnosis
pathways, treatments, and to
accelerate drug development,
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