



FOUNDATION
FOR SARCOIDOSIS
RESEARCH

**BLACK AMERICANS ARE
2.5 TIMES
MORE LIKELY TO HAVE
SARCOIDOSIS
THAN WHITE AMERICANS.**



**JOIN US ON
THE PATH
TO FINDING
OUT WHY.**



ACTe NOW! **2**
ROADMAP
PROGRESS

**ADVANCE CLINICAL TRIALS
FOR EQUITY IN SARCOIDOSIS**

Participating in a clinical trial is a significant decision.

This guide aims to provide you with the necessary information to start conversations, ask the right questions, and consider your options.

Black Americans and Sarcoidosis: A Call for Action

Genetic and biological differences can lead to variations in how people respond to treatments. Black Americans experience the highest prevalence of sarcoidosis and the worst health outcomes, yet they are underrepresented in clinical trials. This limits our understanding of how effective current and potential treatments are on Black patients living with sarcoidosis. With only 10% of rare diseases having an FDA-approved treatment, it's crucial to increase clinical trials research for sarcoidosis and ensure Black patients are properly represented to enhance treatment options. Now, with more sarcoidosis trials than ever, you have an opportunity to drive change for yourself and your community.

Understanding Clinical Trials

A clinical trial tests new medical treatments or procedures in people to check if they are safe and effective. There are different types of clinical trials, each designed with a specific purpose.

- **Prevention and Screening trials** look for better ways to prevent or screen for early detection of disease.
- **Treatment trials** test new treatments, medicines, or procedures.
- **Behavioral trials** test ways to help people make healthy changes in their lifestyle habits (e.g. exercise or diet).

Starting Your Journey

Take the Next Step Towards Your Health Journey: If you or a loved one is battling sarcoidosis, your participation in clinical trials can pave the way for groundbreaking treatments and a better understanding of this condition.

STEP 1: Take an active role in understanding patient rights and safety standards.

STEP 2: Understand the phases of clinical trial design.

STEP 3: Talk to your provider about your interest in clinical trials.

STEP 4: Involve your support network in your decision-making process.



STEP 1

TAKE AN ACTIVE ROLE:

SHEDDING LIGHT ON PATIENT SAFETY

You won't be left in the dark when participating in a clinical trial. Clinical trials have built-in protections to ensure you are well-informed and protected every step of the way.



YOU are your biggest advocate!

Researchers are required to provide information about the trial to ensure you understand the risks, benefits, and rights before agreeing to participate. Your agreement to participate is voluntary and you can leave the study at any time without cause or explanation.

Food & Drug Administration

All clinical trials must be approved by the FDA and can only progress if the potential benefit of the treatment is greater than the risk a participant would assume.

Institutional Review Board

Most clinical trials in the United States are approved and monitored by an IRB - an independent committee responsible for reviewing research to protect the rights and safety of participants, both before the research starts and as it proceeds.

STEP 2

UNDERSTAND CLINICAL TRIAL DESIGN

PHASE 1: Is it safe?

The treatment is tested in a small group of healthy participants to understand the body's reaction to the treatment and any side effects that may occur. **About 70% of these trials advance.**

PHASE 2: Does it work?

The treatment is tested in a larger group of participants to help the medical team understand how much medicine should be given to effectively treat the condition. **Only 33% of these trials advance.**



Trials must advance through **three phases** before approval for the general population. It's important to understand the trial's purpose, eligibility, and which phase it is in when considering participation.

PHASE 3: Is it ready?

The treatment is tested on an even larger group of participants, and tests:

- How effective the treatment is compared to other available treatments currently being used to treat the condition.
- How the treatment affects people of different backgrounds to make sure it has the same beneficial impacts on all people with the condition.
- How safe the treatment is long term, by monitoring long term side effects that may exist.
- How the treatment works in real life scenarios, as opposed to controlled settings. Does the treatment impact the participant's life?

Only 25%-35% of these trials receive FDA approval. If the FDA approves at this phase, the trial is considered successful and a new and beneficial treatment is introduced for use by all patients suffering from the specified condition(s).

Understanding Eligibility

The clinical trial should outline factors that they are looking for (inclusion criteria) and factors that will disqualify you from participating (exclusion criteria).

STEP 3

Consider potential risks, benefits, and side effects with your healthcare team.

It's important to know how the trial might impact your life. Visit stopsarcoidosis.org/Roadmap2Progress for a list of questions to ask when considering participation in a clinical trial.



SCAN TO LEARN MORE

STEP 4

Involve your support network by sharing the benefits of clinical trial participation and dispelling untrue myths.

The benefits of clinical trial participation can include:

- Receiving more frequent and careful medical attention from experts.
- Receiving increased access to new treatments, experts, and advanced technologies before they are widely available.
- Helping your community by contributing to knowledge about new treatments or procedures and their effectiveness in Black patients.

CONTINUES ON BACK OF PAMPHLET

MYTH: You have to give up your usual treatments to join a clinical trial.

FACT: Joining a clinical trial doesn't mean giving up existing treatments; some trials require you to continue your current treatment while participating.

MYTH: There are always people in the trial that don't get the treatment.

FACT: Depending on the trial's design, some patients receive the treatment being tested, while others take a placebo. In other trials, the new treatment is compared to the standard treatment. There are many options.

THE HISTORY OF MEDICAL RACISM IS NO MYTH.

In **FACT**, there is a long history of unethical treatment of Black individuals in research that has had a lasting impact on the healthcare system and its relationship with Black patients. But with efforts to rebuild trust and improved ethical and patient safety standards, recent studies show progress. Black patients are now just as likely to participate *when asked*. So, start the conversation with your provider.

YOUR DESTINATION

"Initially, I had reservations due to mistrust. However, I soon discovered a sense of freedom, knowing I could withdraw at any time, and would receive additional support from a team of specialists. I encourage you to seek a clinical trial where you feel empowered to make a meaningful impact because each insight gained brings us closer to improved treatments and perhaps a cure."

PATIENT TESTIMONIAL

For more information and sources, please visit :
stopsarcoidosis.org/Roadmap2Progress

Sponsored by Mallinckrodt Pharmaceuticals, Amgen, and made possible in part by a grant from the Chan Zuckerberg Initiative.