

Throughout this slide deck, if there is a note, for you the presenter, it will be in italics. Otherwise, the text is there for you to read as you show the slide.

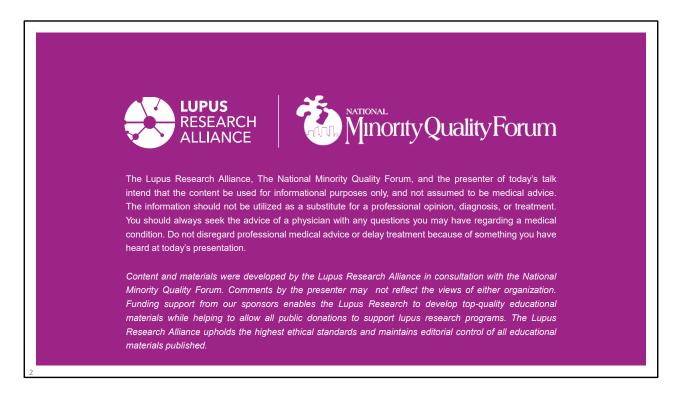
References are included on many slides in case you would like to learn more if one of the attendees asks.

Take a minute to thank your audience for coming and to introduce yourself and why lupus awareness is important to you

My name is	and I am a volunteer for the Lupus Research Alliance. It is important
to me to spread aware	ness about lupus because

Note: This slide deck is part of an education program. If you have obtained a copy of this slide deck and are interested in learning more, please contact

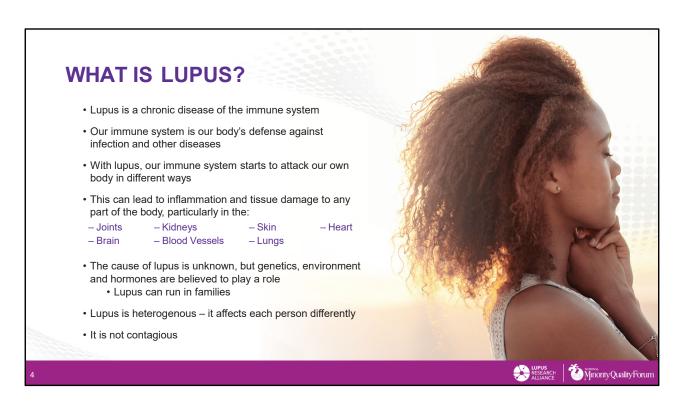
<u>Advocacy@lupusresearch.org</u> and ask about the What You Need to Know About Lupus Toolkit.



This presentation is meant to be an overview of lupus and not meant to substitute for medical advice



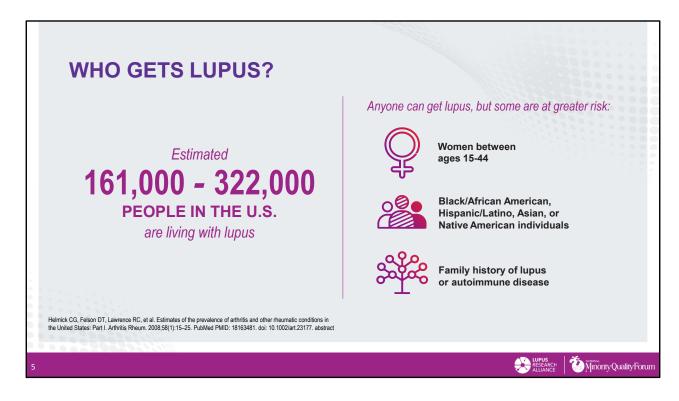
This is what we'll be covering in the presentation



Lupus is a chronic disease of the immune system that can affect anyone. The immune system is our body's defense against infection and disease. With lupus, a complex autoimmune disease, your immune system attacks healthy cells by mistake – this can potentially damage many parts of the body. Lupus can affect the joints, skin, brain, lungs, kidneys, heart, and blood vessels, potentially causing widespread inflammation and tissue damage. The exact cause of lupus is not known, but genetics, environment and hormones are believed to play a role. Lupus affects everyone differently. Currently, there is no cure for lupus. Lupus is not a contagious disease.

### References:

www.lupusresearch.org



It's estimated that over 300,000 people in the US are living with lupus right now. Anyone can get lupus. However, some people are at greater risk such as:

- Women between the ages of 15-44
- People with a family history of lupus and/or other autoimmune disease
- Black/African American, Hispanic/Latino, Asian, or Native American individuals Children and men get lupus too; however, ninety percent (90%) of people with lupus are women.

## **TYPES OF LUPUS Systemic Lupus Cutaneous (Skin) Lupus Erythematosus (SLE)** · Causes a rash or lesion on the skin Typically triggered by exposure to sunlight Most common type of lupus · Discoid is the most common type · Affects many parts of the body of cutaneous lupus **Drug-Induced Lupus Neonatal Lupus** • Caused by a reaction to certain medications · Rare condition where mother's SLE antibodies are shared with the fetus • Symptoms usually disappear when · Usually resolves with no long term effects medication is stopped Minority Quality Forum

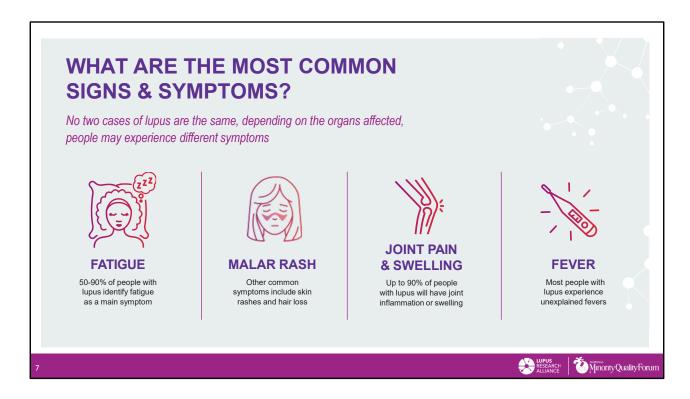
During this presentation when we discuss "lupus," we are usually referring to the most common type of lupus: systemic lupus erythematosus, or SLE, which affects many parts of the body.

### Other types of lupus are:

- Cutaneous lupus, which causes a rash or lesion on the skin, usually when exposed to sunlight.
- Drug-induced lupus, similar to SLE, which is caused by an overreaction to certain medications. Symptoms usually disappear once the medicine is stopped.
- Neonatal lupus, which occurs in infants who acquire SLE from their mothers, though usually resolves without long-term effects
- People can have both SLE and cutaneous lupus

#### Reference:

- www.lupusresearch.org
- www.utsouthwestern.edu



One reason why lupus is so difficult to diagnose is that no two cases of lupus are the same. There are, however, a number of general symptoms that people with lupus often experience:

50 to 90 percent of people with lupus identify **fatigue** as one of their main symptoms. Fatigue can significantly impact patients' quality of life, including lessening the ability to function at home and at work.

About 30 percent of people with lupus experience a **malar rash**, also known as a butterfly rash, which covers the cheeks and bridge of the nose. There are other types of rashes people with lupus get.

Up to 90 percent of people with lupus will have arthritis, which is **inflammation or swelling of the joints**. The most common symptoms of arthritis are stiffness and achiness, most often in the hands and wrists. Symptoms of arthritis can come and go and move from one joint to another. Pain and stiffness tend to be worse in the morning and improve as the day goes on. People with lupus can also experience pain in the joints without swelling or tenderness.

Most people with lupus experience unexplained **fevers** (temperature over 100°F (37.8°C)).

### References:

- www.lupusresearch.org
- www.hopkinslupus.org
- www.mayoclinic.org
- www.cedars-sinai.org
- Medicine. Morbidity and mortality in systemic lupus erythematosus during a 10-year period: a comparison of early and late manifestations in a cohort of 1,000 patients. 2003.
- Neuropsychiatric Disease and Treatment. Risk of epilepsy in patients with systemic lupus erythematosus a retrospective cohort study. 2014.



Lupus symptoms are not predictable – they may be mild, moderate, or severe, persist or resolve, and may come on suddenly or gradually develop over time.

When symptoms come on suddenly, this is known as a "flare." A flare in lupus is characterized by a worsening of disease activity. Flares may be characterized by any group of symptoms that can affect many different parts of the body, including the muscles and bones, skin, heart, nervous system and cause many other complications.

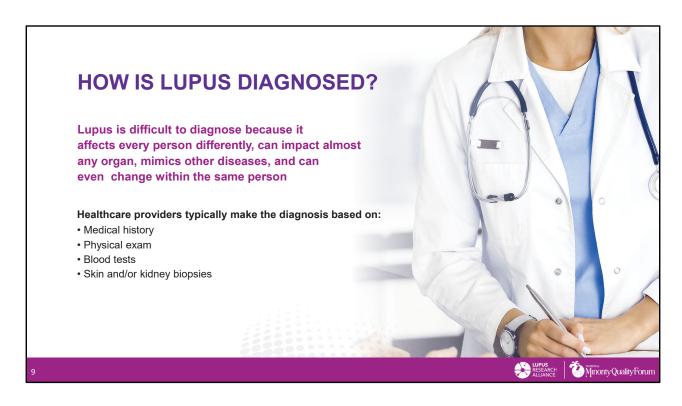
Lupus flares are often triggered by environmental factors. These factors may include stress, sunlight exposure, weather/temperature changes, infection, and other factors.

When a flare occurs, patients are encouraged to see their doctor to see if any immediate steps should be taken.

Lupus can also go into remission, a period of low disease activity that can last from a few months to years.

### Reference:

• International Journal of Chronic Disease. The lived experience of lupus flares: features, triggers, and management in an Australian female cohort. 2014.

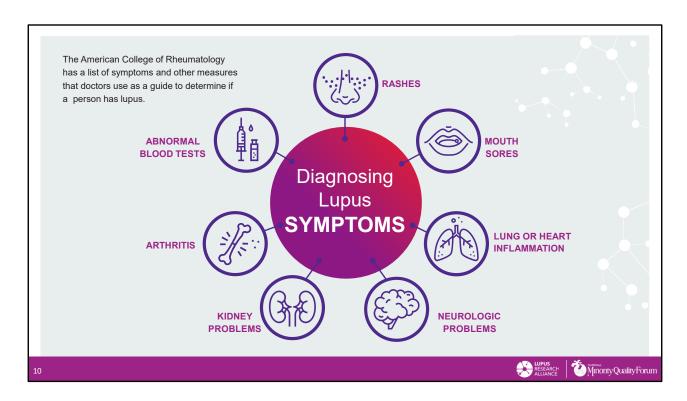


Lupus is difficult to diagnose because it affects every person differently, can impact almost any organ, mimics other diseases, and can even change within the same person.

Right now, there is no single test for lupus. Instead, clinicians look at several factors to make a diagnosis, such as: medical history, physical exam, blood tests, and biopsies of the skin or kidney.

### Reference:

www.lupusresearch.org



The American College of Rheumatology provides this list of symptoms and other measures that doctors can use as a guide to determine if a patient with symptoms has lupus

If you or someone you know has some combination of these symptoms, it's important to consult with a healthcare provider

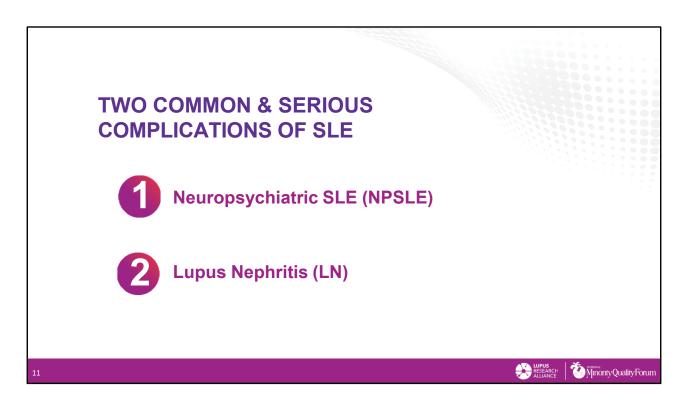
### Rashes:

- Butterfly-shaped rash over the cheeks referred to as a malar rash
- Red rash with raised round or oval patches known as a discoid rash
- Rash on skin exposed to the sun
- Mouth sores: Sores in the mouth or nose lasting from a few days to more than a month
- Arthritis: Tenderness and swelling in two or more joints that lasts for a few weeks
- Lung or heart inflammation: Swelling of the tissue lining the lungs (referred to as pleurisy or pleuritis) or the heart (pericarditis), which can cause chest pain when breathing deeply
- Kidney problems: Blood or protein in the urine, or tests that suggest poor kidney function
- Neurologic problems: Seizures, strokes or psychosis (a mental health problem)
- Abnormal blood tests: Some common tests include
  - Low blood cell counts: Anemia, low white blood cells or low platelets

 Positive antinuclear antibody (ANA) result: Antibodies that can cause the body to begin attacking itself that are present in nearly all people with lupus

## Reference:

• www.lupusresearch.org



Two common and serious complications of SLE to be aware of are neuropsychiatric SLE and lupus nephritis



# **NEUROPSYCHIATRIC SLE (NPSLE)**

- Neuropsychiatric lupus describes feelings of depression, headaches, and lupus fog trouble thinking or remembering due to lupus
- Neuropsychiatric lupus affects 80-90% of people with lupus.
- 25% of lupus patients experience major depression and 37% have major anxiety, research shows.
- Healthcare providers can help relieve mental health issues caused by lupus, often by changing medications or adding one for anxiety or depression.

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Neuropsychiatric SLE, or NPSLE, describes feelings of depression, headaches, and lupus fog – trouble thinking or remembering due to lupus. Researchers estimate that up to 90 percent of people with lupus may have neuropsychiatric lupus.

Overall, 25 percent of people with lupus experience major depression, and nearly 40 percent have major anxiety. Healthcare providers can help address and relieve these mental health issues, often by changing or prescribing appropriate medications.

### References:

www.lupusresearch.org



# **LUPUS NEPHRITIS (LN)**

- · Lupus nephritis inflammation of the kidneys -- occurs in up to half of people with lupus.
- Renal/kidney inflammation can go undetected and can lead to renal failure and dialysis.
- · Regular monitoring of urine and blood pressure is important.
- Signs include blood in the urine or foamy urine which can mean that there is excess protein; swelling of legs, ankles, hands or tissue around the eyes; weight gain due to fluid the body isn't getting rid of; high blood pressure; joint/muscle pain; high levels of waste (creatinine) in the blood; and impaired/failing kidney.
- · Invasive surgical biopsies may be used to diagnose lupus nephritis.
- · Serious outcomes can be prevented by seeking treatment at the first signs of kidney disease.
- There are now two approved treatments for lupus nephritis Benlysta® (belimumab) and Lupkynis™ (voclosporin).

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When your kidneys become inflamed because of lupus, it is called lupus nephritis, or LN. It affects about half of people with lupus.

Lupus nephritis can go undetected and lead to potentially serious issues, like kidney failure. Finding lupus nephritis early with regular monitoring is critical and can prevent damage to the kidneys and worsening of symptoms. Signs of lupus nephritis include blood in the urine or foamy urine which can mean that there is excess protein; swelling of the legs, ankles, hands or tissue around the eyes; weight gain due to fluid the body isn't getting rid of; high blood pressure; joint or muscle pain; high levels of waste (creatinine) in the blood; and impaired or failing kidney. A surgical biopsy of the kidney where the doctor takes a small sample of kidney tissue may be required to diagnose lupus nephritis.

For those with lupus nephritis, there are two newly approved treatment options - Benlysta (belimumab) and Lupkynis (voclosporin).

### References:

www.lupusresearch.org

### **HOW IS LUPUS CURRENTLY TREATED?**

Treatment depends on symptoms. While there is no cure, treatments can help you feel better and improve symptoms. The goals of treatment are to:

- Prevent flares
- Treat symptoms when they happen
- Reduce organ damage and other problems

#### Treatment might include medicines that:

- Reduce swelling and pain
- Calm the immune system to prevent it from attacking the organs and tissues in your body
- · Reduce or prevent damage to organs and joints

# Medicines commonly used to treat lupus symptoms include:

- · Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Corticosteroids
- Antimalarial drugs
- · BLyS-specific inhibitors
- · Immunosuppressive agents/chemotherapy

# Only three medicines have been specifically developed for lupus:

- Benlysta® (belimumab) for general lupus and lupus nephritis
- Lupkynis™(voclosporin) for lupus nephritis
- Saphnelo™ (anifrolumab-fnia) for general lupus

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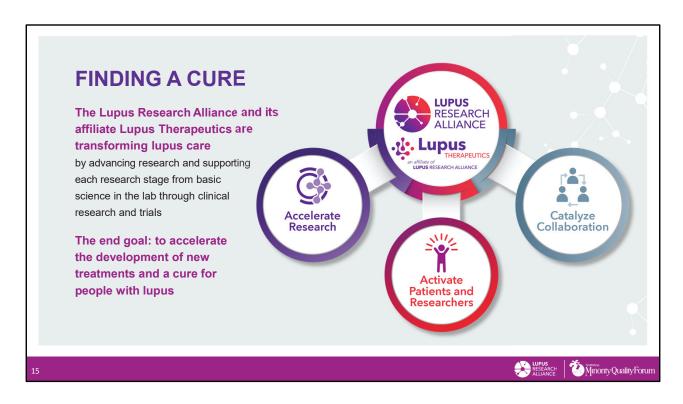
While no cure for lupus currently exists, there are treatments that can help you feel better and improve specific symptoms.

Treatment might include medicines that help to reduce swelling and pain, calm the immune system to prevent it from attacking the organs and tissues in your body, reduce or prevent damage to organs and joints, or address other specific lupus effects.

There are a range of medicines commonly used to treat lupus symptoms. Until recently only one medicine was specifically developed for the disease. Two new medications were just approved by the FDA in 2021.

### References:

- Rheum Dic Clin North America. Health-related quality of life and employment among persons with systemic lupus erythematosus. 2010.
- www.lupusresearch.org



Lupus is a complex autoimmune disease that is difficult to diagnose, treat, and defeat. The Lupus Research Alliance and its clinical research affiliate Lupus Therapeutics are committed to transforming lupus care by advancing research and supporting each research stage from basic science in the lab through clinical research and trials.

The end goal of this work is to accelerate the development of new treatments and a cure for people with lupus.

### Reference:

1. www.lupusresearch.org



Better treatments are only possible with results of clinical studies. Sometimes people refer to clinical trials as clinical research.

Clinical research is the study of health and illness in people intended to add to our medical knowledge.

There are two main types of clinical studies, which we'll go through on the next slide: Interventional and Observational

### **TYPES OF CLINICAL STUDIES**

### Interventional Studies

(also known as clinical trials) are studies where researchers test new ways to prevent, detect, or treat disease.

- Participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so researchers can evaluate the effects of the interventions on health outcomes.
- Which treatment each participant receives is determined by the study's protocol that outlines its objectives, design, and methods.

### **Observational Studies**

allow scientists to find an association between things but cannot prove that one thing causes another.

- Data are collected by monitoring volunteers and may include answering surveys and providing biological samples such as blood or urine.
- Can help researchers come up with a hypothesis to later test in a clinical trial.

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**Interventional Studies** (also known as clinical trials) are studies where researchers test new ways to prevent, detect, or treat disease.

In clinical trials, people volunteer to try new treatments, interventions or tests, so researchers can determine what does and doesn't work. Clinical trials also help researchers and doctors decide if the benefits outweigh possible side effects.

Participants in these studies are assigned to groups that receive one or more interventions or treatments, or no intervention so researchers can evaluate the effects of the of what they are testing on health outcomes.

Other types of studies that are not testing an intervention are called observational studies.

**Observational Studies** aim to allow scientists to find an association between things but cannot prove that one thing causes another. These studies can help scientists and researchers develop hypotheses that will be tested in later clinical trials. Data in these studies are collected by monitoring volunteers and can include tasks like answering surveys and providing biological samples, such as blood or urine.

# CONSIDER TAKING PART IN A CLINICAL TRIAL

### What is the purpose of a clinical trial?

Clinical trials help to answer the question, "will this drug help people and is it safe?"

 Clinical trial volunteers work with researchers to find safer, more effective ways to diagnose, prevent, and ultimately cure lupus

#### Advantages

- · Take greater control over your health and care
- · Close attention to your treatment by experts in the field
- Try cutting-edge potential treatments before they are available
- Help others with lupus by advancing research

#### Disadvantages

- Treatment may not work
- · Side effects are possible
- · Can take more time and effort with clinic visits and at-home monitoring





Emotionally, taking part in a trial is very empowering. I feel like I have a sense of responsibility to the lupus community to do everything I can to help everyone dealing with this disease.

- Kaamilah

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Lupus research has been greatly advanced by the caring people who participate in clinical trials. Clinical trials help to answer the question, "will this drug help people and is it safe?"

In these studies, scientists and participants work together to find safer, more effective ways to diagnose, prevent, and ultimately cure lupus.

Participating in trials can provide people with lupus with a range of benefits, including access to cutting-edge potential treatments. They can be an empowering way to take greater control over your health and contribute to the care of others.

There are disadvantages, as well. Some treatments may not work, some may produce side effects, and participation can require a time/effort commitment.

# THE IMPORTANCE OF INCREASING DIVERSITY IN CLINICAL RESEARCH

- Participants in clinical trials must reflect the demographics of the disease the product is intended to treat to know that it is safe and effective for those people
- A recent review of lupus trials found 51% of trial participants were white, 21% Hispanic and 14% were Black while Black people make up 43% of lupus cases
- This is not unique to lupus. Participation in clinical trials by people who are Black has decreased in recent years
- Low participation by minority populations in lupus clinical trials results in a lack of clinically significant data on the effectiveness, safety, and side effects of treatment within populations at greatest need
- Barriers to participation include mistrust of the research and community, lack of access to healthcare, lack of
  understanding and knowledge about clinical research, and challenges healthcare providers have in referring
  patients to trials. Also, healthcare providers may not ask minorities to participate.
- COVID-19 highlighted many of these issues. Lupus Therapeutics is working with its Lupus Clinical Investigators Network, the pharmaceutical industry, clinical researchers, healthcare providers, and people with lupus to make clinical trials more diverse and patient-centric

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In order to develop better treatments and progress toward the end goal -- a cure for all people with lupus -- it's critically important that diversity of the types of people in the trials be increased in clinical research. Participants in clinical trials must reflect the demographics of the disease any product is intended to treat to know that it is safe and effective for those and all people.

However, data show that this is not the case and is a trend not unique to lupus trials. Since minority populations are most affected by lupus, their low participation in lupus clinical trials results in a lack of clinically significant data on the effectiveness, safety, and side effects of treatment within groups with the greatest need.

Common barriers to participation include mistrust of the research and medical community, lack of access to healthcare, lack of understanding and knowledge about clinical research, and challenges healthcare providers may have in referring patients to trials.

Also, some healthcare providers may not think to ask their patients, particularly minorities, to participate.

The COVID-19 pandemic has brought many of these issues to the forefront and there are changes happening in how clinical trials are run. Lupus Therapeutics is working hard to make lupus clinical trials more diverse and patient-centric.

### WHAT IS THE LRA/LT DOING TO ADVANCE RESEARCH AND ENSURE DIVERSITY? Ensuring people of color have the Encouraging people of color to opportunity to join clinical trials by: pursue science/research careers · Supporting patients with lupus at major medical centers on their • Fostering diversity among lupus researchers by decision to get involved in clinical trials through our Patient awarding grants to pursue careers in the field Advocates for Lupus Studies (PALS) program · Mentoring new researchers to promote career · Organizing the MultiCultural Outreach Task Force to educate success and retention people of color about lupus and research Educating people of all races and ethnic backgrounds about ways to get involved in clinical research including collaborations with groups like the National Minority Quality Forum

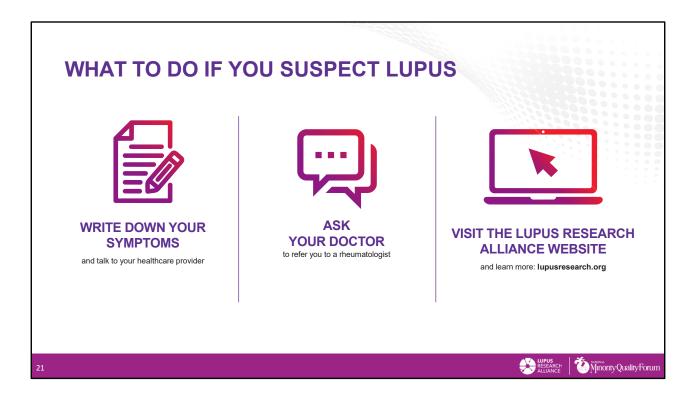
LRA and Lupus Therapeutics are collaborating with the pharmaceutical industry, clinical researchers, healthcare providers, and people with lupus to make clinical trials more diverse and patient-centric, and to reduce barriers to participation.

We're working to ensure people of color are represented in clinical trials by:

- Supporting people with lupus at major medical centers on their decision to get involved in clinical trials through our Patient Advocates for Lupus Studies (PALS) program which pairs people considering a trial with someone who has been through the experience.
- Organizing the MultiCultural Outreach Task Force to educate people of color about lupus and research
- Educating people of all races and ethnic backgrounds about ways to get involved in clinical research by collaborating with groups like the National Minority Quality Forum who are committed to this goal.
- Facilitating clinical trials across the U.S.

The Lupus Research Alliance is also encouraging people of color to pursue science and research careers by providing specific new awards and fostering mentorship.

Minority Quality Forum



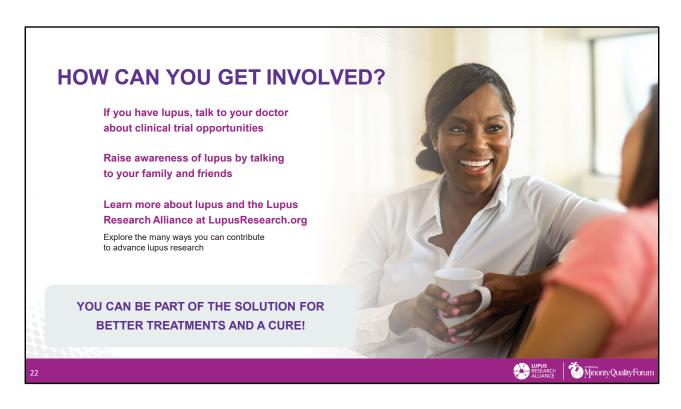
If you suspect that you or a loved one has lupus, the first step is to write down your symptoms and talk to a healthcare provider like your primary care physician.

Your healthcare provider may refer you to a specialist called a rheumatologist who specializes in arthritis and other inflammatory diseases. Lupus is generally treated by a team of physicians led by a rheumatologist.

If you'd like to find more information, you can visit the Lupus Research Alliance website.

### Reference:

www.lupusresearch.org



If you're interested in getting involved in lupus research, or helping to spread awareness, you can do so in many different ways.

If you have lupus, talk to your doctor about participating in a clinical trial. Raise awareness of the disease by talking to family members, friends, and others about lupus and your own experience.

You can explore more ways to contribute to the advancement of lupus research by visiting lupus research.org.

If you are interested in learning how you can volunteer for the Lupus Research Alliance such as by giving this presentation, you can email <a href="mailto:advocacy@lupusresearch.org">advocacy@lupusresearch.org</a> or talk to me after the presentation.

If anyone is interested in how they can become a presenter, please ask them to email <a href="mailto:advocacy@lupusresearch.org">advocacy@lupusresearch.org</a>



You can learn more by following the LRA on social media and by visiting lupusresearch.org where you can learn more about lupus, learn about other opportunities to get involved, and sign up for their mailing list.

This fact sheet has some key information about lupus to help you remember and share what you learned today.



This program from the Lupus Research Alliance is made possible by the generous support of these sponsors.

Thank you for joining me and helping raise awareness of lupus.