

LRAN Lupus Research Action Network

by **Lupus Foundation of America**

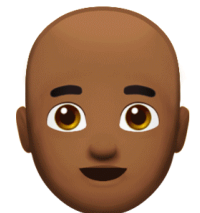
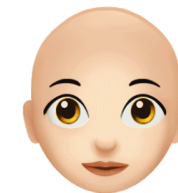
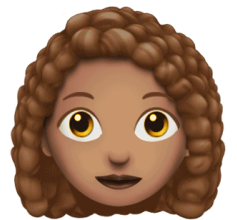
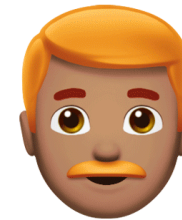
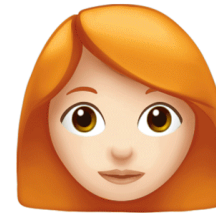
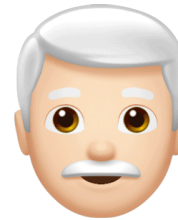
December 2, 2024

Today's Agenda

- Welcome
- Review of LRAN member expectations
- RAY: Research Accelerated by You Updates
- Lupus 101
- Questions?

WELCOME!

- Let's get to know each other:
 - Name
 - Location
 - What three emojis describe you?



Help Us Solve
The Cruel Mystery

LUPUSTM

FOUNDATION OF AMERICA

Improving Minority Participation and Awareness of Clinical Trials (IMPACT+)

Stephanie Slan, MBA, ACRP-CP

Project Director, IMPACT+

Lupus Foundation of America

IMPACT+ Project

Improving Minority Participation and Awareness of Clinical Trials

- Program Intention:
 - The LFA's IMPACT+ project seeks to increase the participation and retention of Black/African American participants in lupus clinical trials.
 - Demonstrate the effectiveness of engagement and tools for increasing minority participation in lupus-related clinical trials.
- Funded by a grant from the HHS Office of Minority Health

Lupus Research Action Network

Overview

- What is LRAN?

The Lupus Research Action Network (LRAN) is a group of Individuals living with lupus who are committed and empowered to advance lupus research through advocacy, awareness and education.

- What is LRAN's Goal?

Increase knowledge about and participation in lupus research, including clinical trials, through a trusted peer network, including a focus to increase engagement in lupus research among racial and ethnic minority groups.

LRAN Member Role

What are we looking for from LRAN members?

- Knowledgeable about lupus and living with the disease
- Have an interest in lupus advocacy, research, and clinical trials
- Willing to connect with people living with lupus in their communities and networks
- Passionate about advancing lupus research and elevating the patient voice in research and clinical trials

LRAN Member Expectations

- Attend in-person LRAN training session in Washington, DC;
- Attend online continuing education sessions and complete feedback surveys;
- Share your experience with lupus research at a variety of lupus community events;
- Connect one-on-one with people with lupus interested in lupus research

LRAN Member Expectations

- Encourage other people with lupus to enroll in Research Accelerated by You (RAY)
- Represent the Foundation during various outreach opportunities such as patient panel discussions, tabling events, and more
- Promote the Foundation's work to their networks on social media

LRAN Member Opportunities

As a member of LRAN, benefits include:

- Invitations to future LRAN trainings and events, including those held in conjunction with the National Lupus Advocacy Summit
- Opportunities to work with the Foundation and our partners to move lupus research forward
- Opportunities to review Foundation resources related to lupus research--ensure they connect with the target audience
- Contribution to the innovation of new therapies and treatments for people with lupus

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RAY[®]: Research Accelerated by You

Safoah Agyemang, MS

Manager, Research and Health Outcomes

Lupus Foundation of America



LFA is Devoted to Improving Quality of Life for those Impacted by Lupus



Lupus Foundation of America's (LFA) mission is to improve quality of life for all people affected by lupus through programs of research, education, support and advocacy through focusing on reducing time to diagnosis, accelerating treatment development and improving access to treatment and care



To support this mission, LFA established Research Accelerated by You (RAY®), a patient and caregiver registry designed to better understand clinical care access, highlight health disparities within the lupus population, and support patient focused drug development and drug value assessments

Lupus Drug Development Pipeline

LUPUS CLINICAL TRIALS
(WORLD WIDE)

1,265

LUPUS CLINICAL TRIALS
(USA)

528

135
ACTIVE LUPUS
CLINICAL TRIALS IN
USA

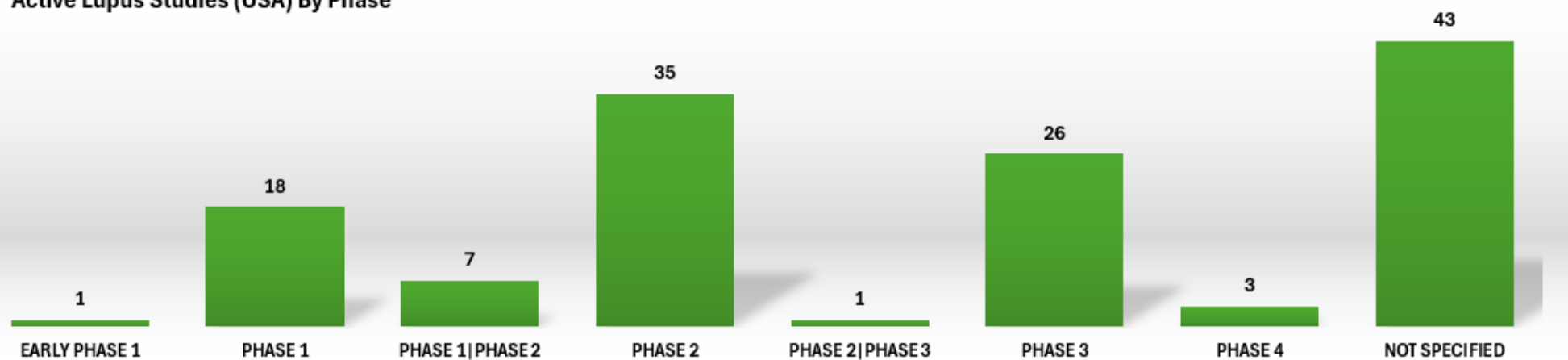
66

TOTAL # OF CAR STUDIES
(WORLD WIDE)

13

OF ACTIVE CAR STUDIES
IN USA

Active Lupus Studies (USA) By Phase



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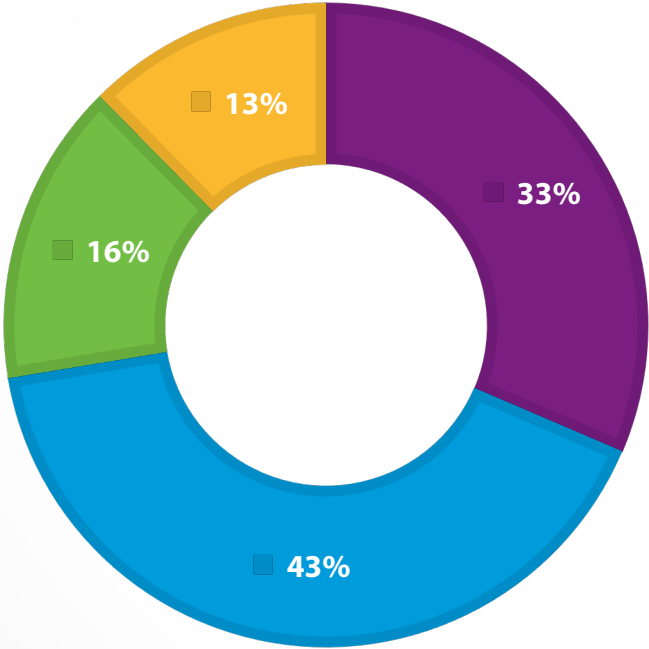
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SOURCE: ClinicalTrials.gov. (as of September 26, 2024)

Trial Participants DO NOT Represent The Lupus Population

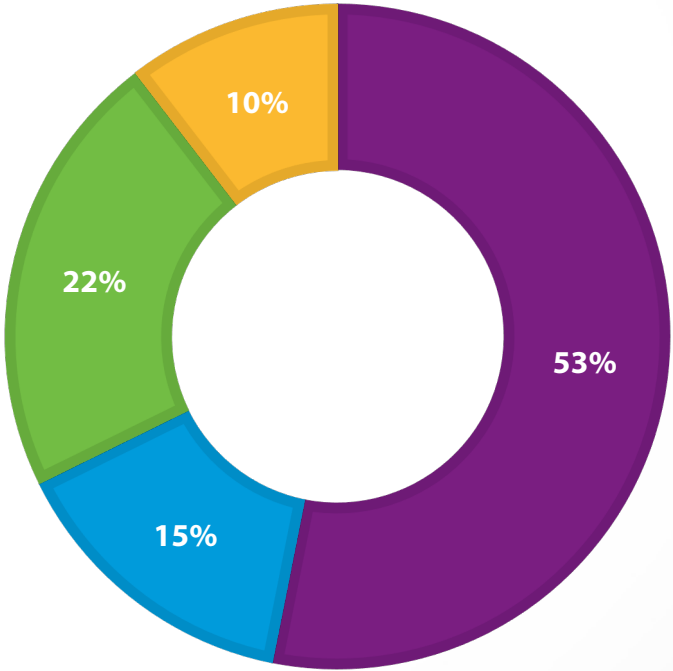
SLE PREVALENCE IN USA

■ White ■ Black/African American ■ Hispanic/Latinx ■ Asian



SLE REPRESENTATION IN CLINICAL TRIALS (USA)

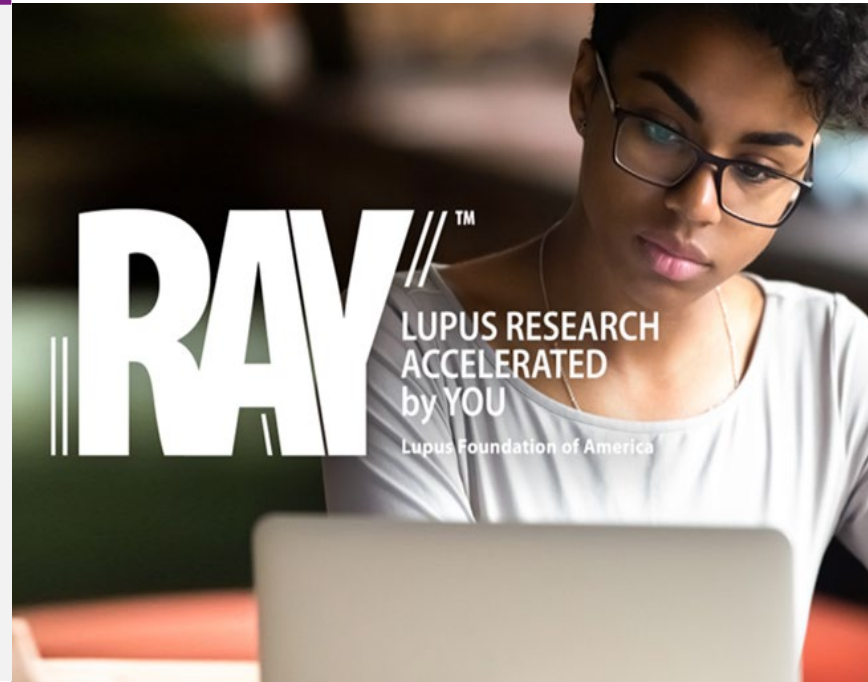
■ White ■ Black/African American ■ Hispanic/Latinx ■ Asian



Overview of RAY[®] Registry

Background

- Launched in **October 2020**
- **Patient-powered** lupus patient and caregiver registry
- Collects uniform **self-reported data** from patients and caregivers interested in participating in clinical research
- **Longitudinal** design **collecting data every 6 months**
- Reaches **4,000+** individuals impacted by lupus



- Improve the understanding of the **natural history of lupus**
- Support **pre- and post- market Patient Focused Drug Development (PFDD)**
- Advance the development of **patient-centric treatments, clinical trials, and research studies** to improve health outcomes
- **Connect people living with lupus and their caregivers to research opportunities** in their geographic vicinity

Objectives

RAY[®] Collected Patient Experience Data

A longitudinal, bidirectional patient-powered registry and data portal

NOT EXHAUSTIVE

Diagnosis	Impact of Lupus	Lupus Research Experience	More About You	Symptoms	Treatments	What is Most Important to You
<ul style="list-style-type: none"> Lupus type Symptoms leading to diagnosis (e.g., anemia, pregnancy complications, fatigue, fever, hair loss, headaches, etc.) Year diagnosed Provider specialty and diagnosis accuracy (e.g., dentist misdiagnosed, nephrologist suspected diagnosis,, etc.) 	<ul style="list-style-type: none"> General health Physical activity Social activity Mental well-being <i>Fatigue (FACIT-F)</i> <i>Work productivity (WPAI)</i> 	<ul style="list-style-type: none"> Clinical trial participation (e.g., how did you find out about research, would you consider joining a clinical trial, etc.) 	<ul style="list-style-type: none"> Birthdate Employment status Gender Highest degree of education Primary language Household income Race/ethnicity Zip code 	<ul style="list-style-type: none"> Impact of lupus on various organ systems (e.g., central nervous system, gastrointestinal tract, kidneys, joints, lungs, muscles, skin, reproductive system, etc.) Comorbidities (e.g., psoriasis, scleroderma, Sjögren's Syndrome, ulcerative colitis, etc.) 	<ul style="list-style-type: none"> Investigational drugs taken (past, present, etc.) Current medications (e.g., blood pressure, blood thinners, steroids, NSAIDs, biologics, etc.) Medication history (e.g., daily, past month, past 3 months, past year, etc.) 	<ul style="list-style-type: none"> What is the biggest downside of your current treatment? When choosing treatment, what is most important to you? How do the following common side effects affect how likely you are to choose a certain treatment? (e.g., injection and infusion site reactions, headache, eye problems, etc.)

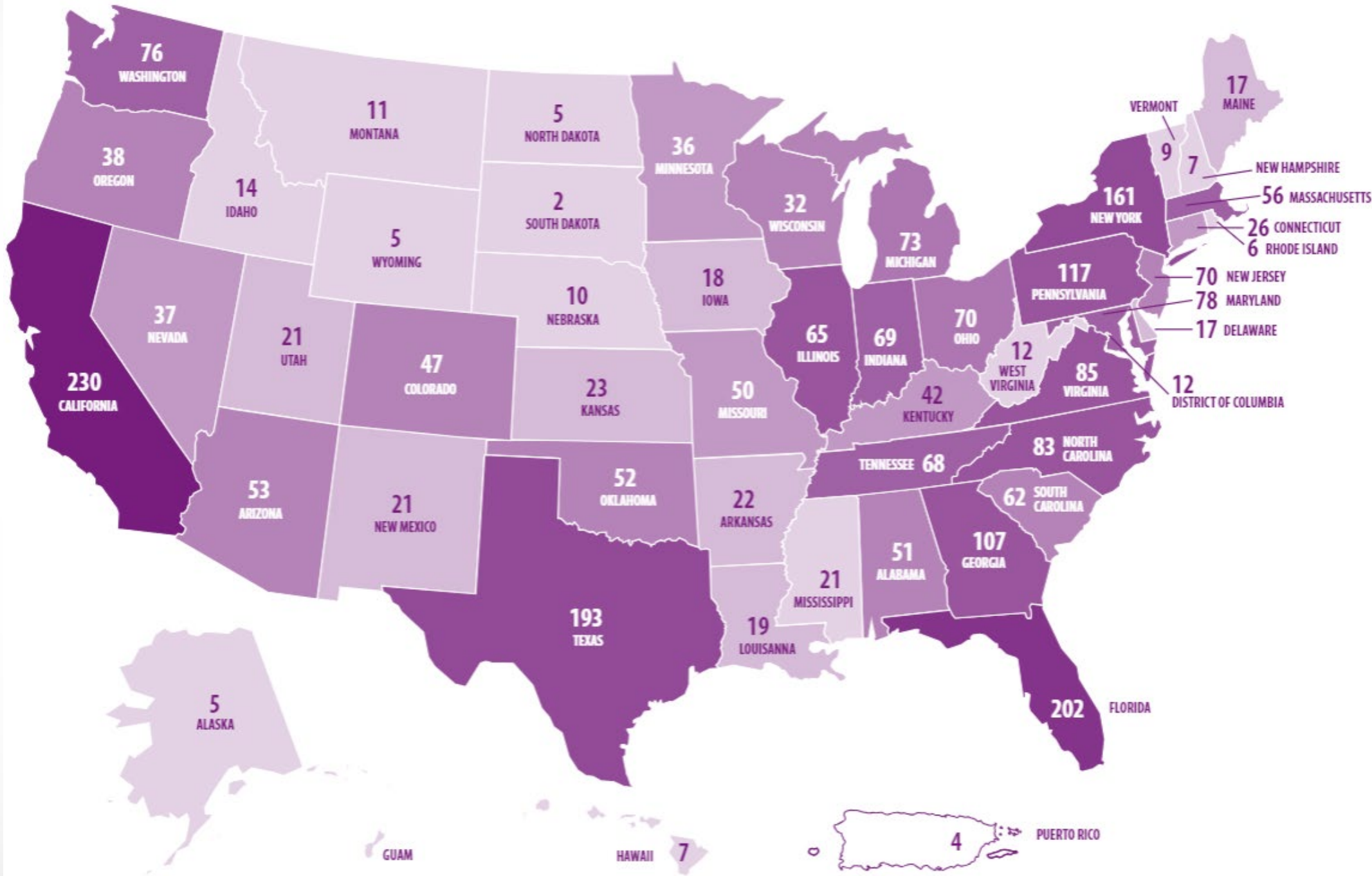
Who is In RAY®?

Race	
White	66%
Black/African-American	16%
Asian	5%
Native American/Alaska Native	4%
Hawaiian/Pacific Islander	<1%
Other/Not Specified	6%

Ethnicity	
Hispanic/Latino Origin	13%

Lupus Diagnosis	
Systemic Lupus Erythematosus (SLE)	88.2%
SLE + Lupus Nephritis (LN)	8.5%
Discoid Lupus (DLE)	1.6%
Subacute Cutaneous Lupus (sCLE)	1.7%
Drug-Induced Lupus	<1%

U.S. Distribution of RAY[®] Participants



Your Impact on Lupus Research Through RAY

Amplify **your voice** and contribute to decisions about how lupus therapies are developed

Improve health outcomes for **yourself** and **others** living with lupus

Your Impact on Lupus Research Through RAY

Industry/Academic
Partners

12+

Types of Trials
Supported
**CAR-T, SLE, Lupus
Nephritis, DLE, Other
Cell Therapy (Non-
CAR)**

Number of Trials
Supported

12+

Methods of Support:
**Protocol
Development,
Advisory Panels,
Study Education (e-
Blasts), Recruitment**

Success Stories and Impact

“Being a part of RAY has given me access to research opportunities I would never have come across. When I was diagnosed with lupus, I didn’t know much about it. Most of what I’ve learned about my diagnosis has been through the Lupus Foundation of America and RAY. I was fortunate to be involved in a patient advisory panel that came about because of RAY. That was the first time I met other people living with the same type of lupus as me; It was such a positive experience. RAY was very easy to sign up for and it’s clear to me that my information is confidential. I encourage others to at least sign up for RAY to see how it may benefit them and ultimately help to move lupus research forward.”

RAY® Participant

“I wanted to participate in RAY because I wanted to see what options were available to me in lupus research and get involved. It’s important for me to know which clinical trials I’m eligible for, and to share that information with my mom, who is a Black/African American lupus warrior, as well. RAY has given me the educational background and knowledge about lupus clinical trials to be able to share with my family, caregivers, and even my doctors.”

RAY® Participant

Questions?

Compensation is available for those who complete the initial survey!



Help Us Solve
The Cruel Mystery

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Lupus 101

Khadija Dantata, MD, MHA

Health Education Specialist



What is Lupus?

What is Lupus?

Lupus is a **chronic autoimmune** disease that can damage any part of the body such as skin, joints and/or organs.

Lupus Is...

Chronic

long-lasting, not curable

Heterogeneous

different for each person

Unpredictable

ranging in symptoms and characterized by increases in disease activity and inflammation (flares) and/or inactivity (remission)

What is NOT Lupus?

Lupus Is Not ...

Related to cancer

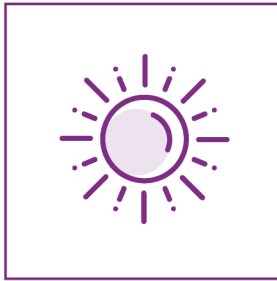
Contagious, not even
through sexual contact

Like or related to HIV (human
immunodeficiency virus)

Sign and Symptoms



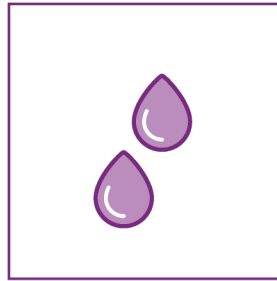
**Swelling (Edema)
in Feet, Legs, Hands
and around Eyes**



**Sun or
Light-sensitivity
(photosensitivity)**



Fever



**Abnormal
Blood Clotting**



Hair Loss



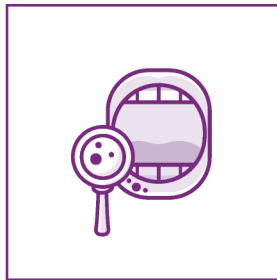
**Painful or
Swollen Joints**



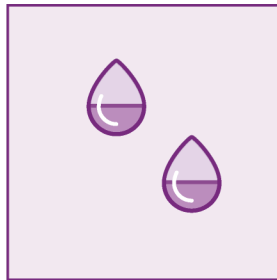
Headaches



**Extreme
Fatigue**



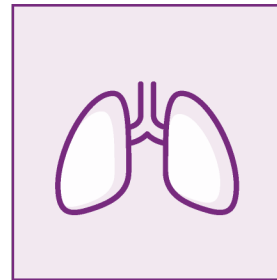
**Mouth Sores
or Nose Ulcers**



Anemia



**Butterfly-shaped
Rash Across Cheeks
& Nose**

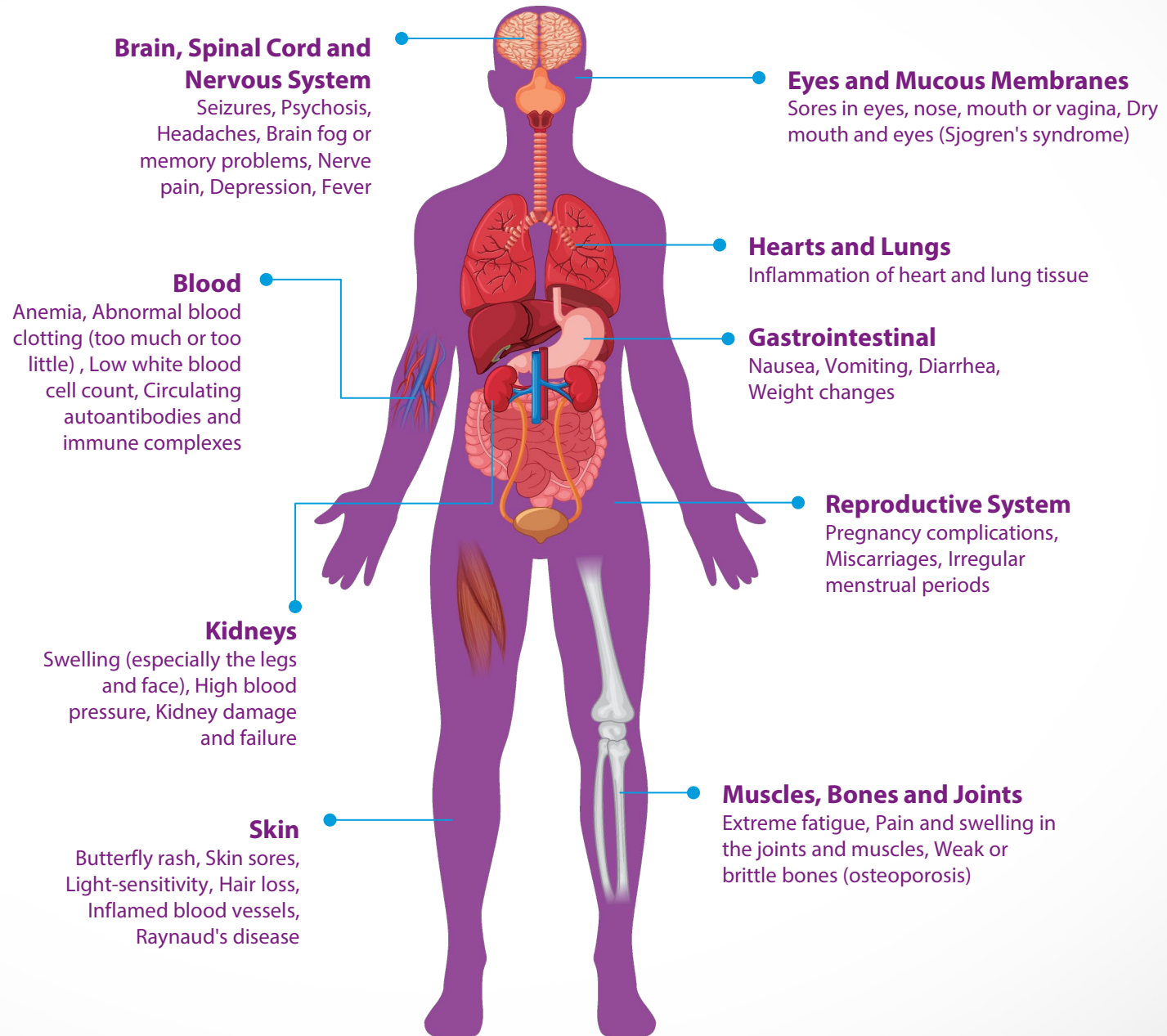


**Pain in Chest or
Deep Breathing
(Pleurisy)**



**Fingers Turning
White or Blue
When Cold
(Raynaud's Phenomenon)**

How Lupus Affects the Body



Lupus is hidden, **unpredictable**,
undefined, and **misunderstood**.

It **ravages** different part of the body and
can range from a skin rash to a **heart
attack...**

... there is **no known cause** and **no
known cures** for lupus.

Lupus is the Cruel Mystery

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The Cruel Mystery
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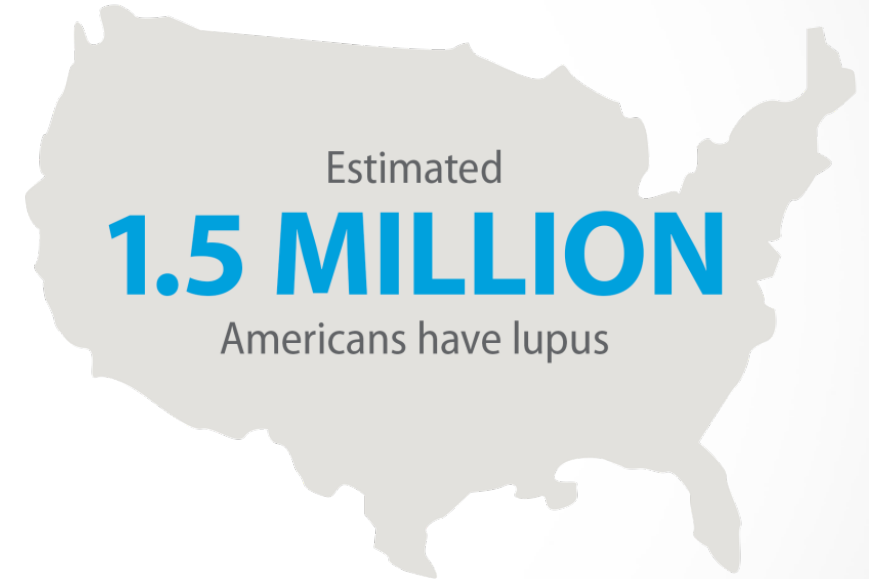
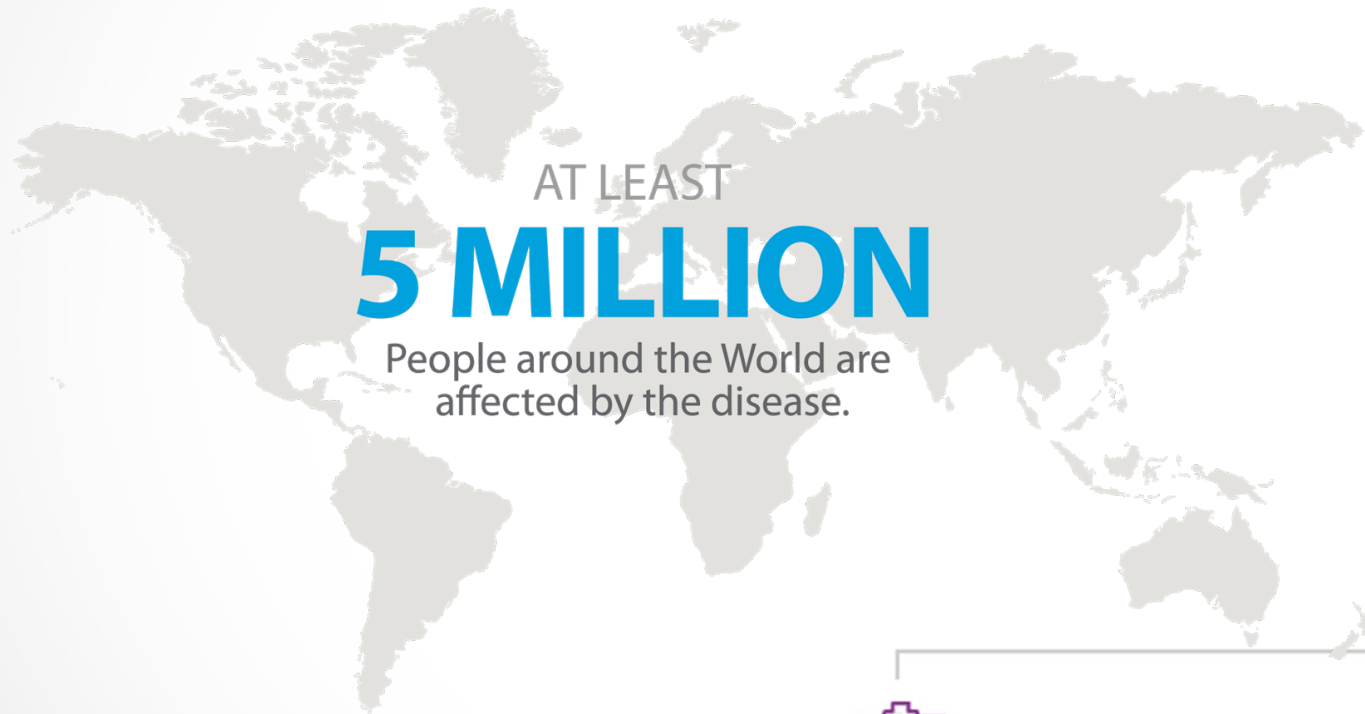
MARIA,
diagnosed age 21





Who Gets Lupus

Lupus in the US and Around the World



16,000

new cases of lupus are reported each year.



90%
are women.



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TONI BRAXTON,
diagnosed age 40



More Prevalent Among Racial and Ethnic Minority Groups

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ANGEL,
diagnosed age 12



Childhood Lupus

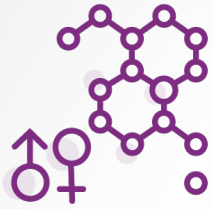
- 15-20% of SLE diagnosed in childhood with greater lupus nephritis prevalence among childhood SLE.

Men Get Lupus Too

- Same typical clinical signs and symptoms of lupus as women
- Certain key symptoms may be more pronounced



Causes of Lupus



What Causes Lupus?

- Many scientists believe that lupus develops in response to a combination of factors both inside and outside of the body:
 - Hormones
 - Genetics
 - Environment
 - UV rays
 - Drugs
 - Illness
 - Stress
 - Injury
- Most researchers today think that an environmental agent randomly encountered by a genetically susceptible individual, acts to trigger the disease.





Types of Lupus

What are the Different Forms of Lupus?

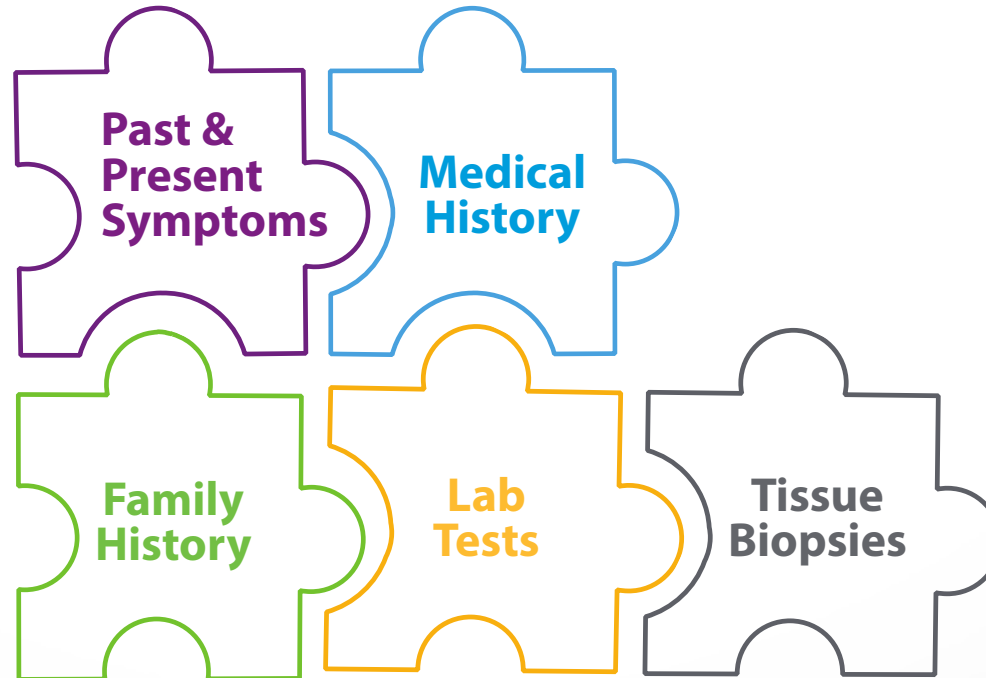
1. Systemic Lupus Erythematosus (SLE)
 - Commonly referred to as “Lupus”
 - 70% of lupus cases are SLE
2. Cutaneous Lupus Erythematosus (CLE)
 - Referred to as, “Skin lupus”
 - 10% of lupus cases are CLE
3. Drug-Induced Lupus Erythematosus (DILE)
 - Makes up 10% of all lupus cases
4. Neonatal Lupus
 - Neonatal lupus is not true lupus. It is a rare condition associated with antibodies from the mother that affect the fetus.



How is Lupus Diagnosed?

How is Lupus Diagnosed?

- Making a lupus diagnosis is kind of like putting together a puzzle
- The doctor will look at several different puzzle pieces:





How is Lupus Diagnosed?

- Laboratory tests:
 - ANA is positive in 97% of lupus cases.
 - No single test is used to diagnose lupus.
 - An array of different laboratory tests can help arrive at a diagnosis. These tests may include:
 - A complete blood count (CBC)
 - Antibody tests
 - Blood clotting time tests
 - Complement tests
 - AVISE® CTD
 - Urine tests



Treatment Approach

Choose the Right Doctor

- A rheumatologist, a doctor who specializes in diseases of the joints and muscles, typically treats people with lupus
- If lupus has caused damage to specific organs, other types of doctors may be needed such as:
 - Dermatologist- a doctor who specializes in diseases of the skin such as cutaneous lupus
 - Cardiologist - a doctor who specializes in diseases of the heart
 - Nephrologist - a doctor who specializes in diseases of the kidney
 - Neurologist - a doctor who specializes in diseases of the brain and nervous system

Treatment Goals

- Treatment plans depend on age, symptoms, general health and lifestyle
- The goals of any lupus treatment plan are to:
 - Control symptoms like joint pain and fatigue
 - Reduce inflammation caused by lupus
 - Suppress the overactive immune system
 - Prevent flares and treat them when they occur
 - Minimize damage to organs



Commonly Used Medications

- Anti-inflammatories
 - Non-steroidal anti-inflammatory drugs (NSAIDs)
- Corticosteroids
 - Prednisone, prednisolone, methylprednisolone, and hydrocortisone
- Antimalarials
 - Hydroxychloroquine (Plaquenil®) and chloroquine
- Biologics
 - Monoclonal antibodies belimumab (Benlysta®) and anifrolumab-fnia (Saphnelo®)
- Immunosuppressives
 - Cyclophosphamide (Cytoxan®), voclosporin (Lupkynis™), methotrexate (Rheumatrex™), and azathioprine (Imuran®)
- Anticoagulants
 - Aspirin, heparin (Calciparine®), and warfarin (Coumadin®)

Timeline of FDA Approvals

Approved Lupus Therapies

- Aspirin (approved by FDA, 1948)
- Corticosteroids (approved by FDA, 1948): prednisone, prednisolone, methylprednisolone, and hydrocortisone
- Anti-malarials Plaquenil® (approved in 1955), HCQ, Chloroquine (Aralen®), Quinacrine
- **BENLYSTA**® (Belimumab) FDA approved in 2011 as first lupus-specific treatment for SLE and then for lupus nephritis in 2021
- **LUPKYNIS**™ (Voclosporin) FDA approved in 2021 for treatment of lupus nephritis
- **SAPHNELO**™ (Anifrolumab) FDA approved in 2021 for SLE

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Managing Lupus

Ways to Manage Lupus

**Avoid Lupus
Flare Triggers**

**Be Proactive
in Your Care**

**Eat Healthy
and be
Physically
Active**

**Manage
Fatigue and
Pain**

Manage Stress

**Protection
from UV light**

**Avoid
Infections**

Lupus Flares

- A lupus "flare" or "flare up" is when lupus symptoms worsen and the person feels ill as a result
 - *A flare is defined as: A measurable increase in disease activity in one or more organ systems involving new or worse clinical signs and symptoms and/or lab measurements. The increase must be considered clinically significant by the assessor (physician or clinical researcher) and in most cases, should prompt the consideration of a change or an increase in treatment.*
- Remission is when the symptoms improve, and the person feels better
- Some flares happen without symptoms

Lupus Flare Triggers

- What can trigger a lupus flare?
 - Emotional stress such as a divorce, death in the family, or other life complications
 - Anything that causes physical stress to the body such as surgery, physical harm, pregnancy, or giving birth
 - Infections, colds or viral illnesses
 - Exhaustion
 - Severe exposure to ultraviolet rays
 - An injury

Be Proactive in Your Care

- Follow instructions from doctors
- Take medicines as prescribed
- Keep a medical diary to record symptoms, medicines, and side effects
- Talk with the doctor about questions and concerns
 - Especially if there are medication side effects
- Pay attention to how they feel, and share what they notice with their doctors
- Tell their doctor right away if their symptoms change or get worse

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Thank You!

ANY QUESTIONS?



REMINDERS:

- Please complete the feedback survey:
 - https://lupus.qualtrics.com/jfe/form/SV_0H5v1PNbY24q3UG



Next Training Dates



- January 14th 2025
 - [Clinical Trials 101](#)
- February 13th, 2025
 - [History of Racism in Clinical Trials](#)
- March 20th, 2025
 - [Barriers and Facilitators](#)
- May 4- 6th, 2025
 - [In Person LRAM training & National Lupus Advocacy Summit](#)

2025 Advocacy Summit

May 4-6, 2025

