LRAN

Lupus Research Action Network

by **Lupus Foundation of America**

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2024 Lupus Research Action Network Agenda

Sunday, May 19 - Lupus Research Action Network (LRAN) Training

9:00am – 10: 00am	Registration and Breakfast	**Capitol Foyer**
10:00am – 10:15am	**Welcome to LRAN Training**	Pat Wildman and Stephanie Slan
10:15am – 10:55am	Why Diversity Is Vital to Clinical Trials	Dr. Joan Merrill
10:55am – 11:30am	The Power of YOUR Voice	Dr. Rosalind Ramsey-Goldman
11:30am – 12:00am	Empowering Lupus Advocates	Dr. Edith Williams/ Hetlena Johnson
12 pm -2 pm Lunch/Break		**Salon E**
2: 00pm – 3:00pm	How to Talk about Trials	Dr. Edith Williams/ Hetlena Johnson
3:00pm – 3:45pm	Your Action Plan	Breakout Groups
3:45pm – 4:00pm	Post Training Assessment	Dr. Melicent Miller

6:00pm–7:00 pm

Welcome Reception at the JW Marriott **Penn Ave Terrace**

Join us at the JW Marriott for an informal evening reception with Summit attendees and Lupus Foundation of America staff. Receive your materials for the Summit and enjoy light refreshments as you get to know lupus advocates from across the country.

LRAN Speaker Biographies

Joan T. Merrill, MD
OMRF Professor of Medicine
University of Oklahoma Health Sciences Center
Adjunct Professor, School of Pharmacy University of
Oklahoma Health Sciences Center LFA, Chief Advisor
for Clinical Development

Dr Merrill is a Professor at the Oklahoma Medical Research Foundation and the Lupus Foundation of America's Chief Advisor for Clinical Development. She is a leader in lupus trial design, to address the problem that one drug at one dose will not be best for all patients with lupus. Therefore, she has championed the use of advanced technology to sort patients into well-defined groups to begin to sort out how we might identify in advance, those who are more or less likely to respond to a given treatment and what sort of blood tests might help to find the best possible dose for each individual living with lupus

Dr. Merrill set a precedent with an innovative approach to testing lupus treatments which showed that study results are easier to interpret if you can taper down the drugs that people are taking in the background. Other ways in which she works to help make studies of new drugs more interpretable include working with the LFA to train investigators how to evaluate patients in trials, to study simplified ways to score improvement or worsening of disease, and to incorporate the patients' voice so that we can get a more accurate analysis of whether people are getting better on a treatment or not.

She has received many grants from the government and foundations and has published more than 320 papers in medical journals, most of which involve testing new treatments for lupus or figuring out how to better select the best treatments for individual people.

Rosalind Ramsey-Goldman, MD, DrPH
Gallagher Research Professor of Rheumatology
Northwestern University Feinberg School of Medicine

Rosalind Ramsey-Goldman, MD, DrPH, is the Gallagher Research Professor of Rheumatology at Northwestern University Feinberg School of Medicine (NUFSM) and an attending physician for Northwestern Medicine. She is the director of the Patient-Oriented Clinical Research Program in lupus with continuous funding from NIH, foundations, philanthropy, and industry since 1991 when she joined the faculty at NUFSM. Her research program examines risk factors to minimize complications in lupus including osteoporosis, malignancy, renal, and cardiovascular disease.

Through national and international collaborations, she studies genetic risk factors for disease severity/susceptibility; collaborates on investigations studying pathogenesis of disease; develops disease classification criteria, flare assessments, nephritis guidelines, disease impact (damage and frailty), and assessment of patient-reported outcomes (including an investigator-initiated NIAMS/NIH funded clinical trial testing an intervention to mitigate fatigue, a pervasive problem affecting 90% of patients with lupus). She is active in designing, monitoring, and performing clinical trials, identifying novel biomarkers, and testing innovative therapies. Many of these clinical investigations incorporate analysis of lupus in multiethnic cohorts examining clinical, laboratory, and health related outcomes. An underlying theme for these investigations is a longstanding interest in documenting health disparities in lupus and experience working with communities.

Edith Williams, PhD, MS

Founding Director, Office of Health Equity Research
University of Rochester Medical Center

Dr. Edith M. Williams brings a rich combination of research expertise and demonstrated ability to bring researchers and community members together to elevate the role of science in achieving health equity. She currently serves as the Director of the Center for Community Health and Prevention and Founding Director of the Office of Health Equity Research and is appointed as the Dean's Associate Professor of Health Equity Research, with a primary academic appointment in Public Health Sciences and secondary appointment within the Division of Allergy, Immunology, and Rheumatology at the University of Rochester Medical Center. Previously, she was appointed as an Associate Professor within the Department of Public Health Sciences and Division of Rheumatology and Immunology at the Medical University of South Carolina and served as Deputy Director for Research and Sustainability for the Institute for Partnerships to Eliminate Health Disparities at the University of South Carolina. She received her B.A. from the University of North Carolina at Chapel Hill, and her M.S. and Ph.D. from the State University of New York at Buffalo.

She has a robust research portfolio that includes a Pfizer fellowship in Health Disparities, National Institute for Arthritis and Musculoskeletal Disorders (NIAMS)/NIH Mentored Research Scientist Career Development Award (K01), and National Institute for Nursing Research (NINR)/NIH R01 to examine whether a new, culturally tailored peer mentoring intervention improves disease self-management, indicators of disease activity, and quality of life in African American women with SLE. Dr. Williams has received numerous recognitions including recognition as a Research Innovator and Eminent Scholar by the Medical University of South Carolina College of Medicine. Dr. Williams serves as a research consultant to address lupus healthcare disparities, mentoring, diversity and inclusion. She is the current Diversity, Equity, and Inclusion (DEI) Associate Editor of Arthritis & Rheumatology and standing member of the NIH Community Influences on Health Behavior (CIHB) study section. Her community service activities include having served on a number of non-profit and community boards.

Hetlena Johnson, Ed.S.

Lupus Warrior, Trainer, Author

Hetlena is a nationally recognized author, international speaker, and professional trainer devoted to helping others face the trials of life with an open mind. Hetlena Johnson is a cheerleader for handling life's challenges with laughter and spirited resilience. Not shy to take on the fears and pushing limits beyond the restrictions of lupus, she believes in living your best life while living with lupus.

Hetlena has over 25 years of experience in the field of education as a classroom teacher, an instructional coach, and as an administrator at the school, district, state, and federal levels. Positive energy has allowed her to present at several conferences internationally and around the country including TEDxDenverED. As the former Chief Volunteer Officer for LFA South Carolina Community Partner, she played a key role in connecting local lupus community efforts with the National Lupus Foundation of America, Inc. With a certification as a National School Reform Faculty Critical Friends Group Coach, she wrote the first lupus/medical nightmares protocol. Living and thriving with lupus for the past 30 years, Hetlena continues to provide strong leadership in facilitating lupus support groups, including co-host of the LFA National Lupus Sisters Support group.

Her 25 years of experience in education has allowed her to coordinate strategies, design solutions, and provide consultations to national health coordinators, medical community members, and lupus education leadership for peer group activities. Hetlena decided to keep a personal diary of her confusion, fear, and challenges associated with being diagnosed with Lupus. She shares many of her trials and most tender moments of peace in her book, "Diary of a MAD Lupus Patient." In her words, "I've had the opportunity to work full-time traveling the United States to deliver trainings. While living with Lupus! I am blessed!" You can follow Hetlena Johnson on social media platforms using the handle, @TheLupusLiar.

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2024 Lupus Research Action Network
Participant Role Description & Benefits

Program Overview

The Lupus Foundation of America (Foundation) created the Lupus Research Action Network (LRAN) in 2019 to engage people with lupus to increase clinical research knowledge among their peers in the lupus community, including clinical trials. LRAN participants will be trained via a comprehensive curriculum designed to enhance their ability to facilitate conversations about lupus research participation and educate, encourage, and empower participants from underserved and diverse communities to participate in lupus research.

Participant Qualities

While previous experience with lupus research is not necessary, the ideal LRAN participant will be:

- Knowledgeable about lupus and the Foundation's work;
- Able to demonstrate interest in lupus advocacy and lupus research;
- Able to connect to people with lupus within diverse or underserved communities;
- Comfortable engaging with and speaking to audiences both large and small; and
- Trustworthy, professional, and responsive.

Participant Responsibilities

LRAN participants will work closely with the Foundation to advance lupus research through advocacy, awareness and education, including by:

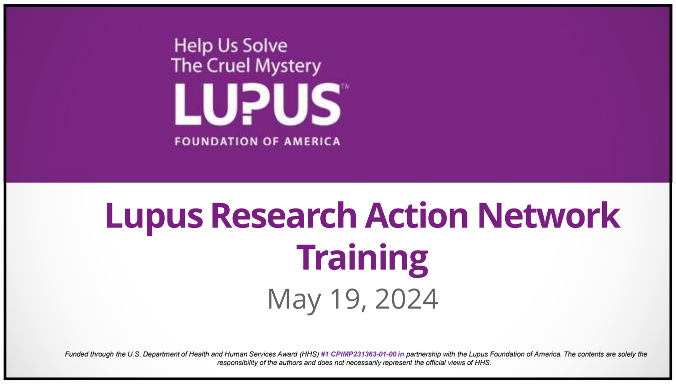
- **Attending in-person LRAN training session;**
- Attending online continuing education sessions and completing feedback surveys;
- Sharing their experience with lupus research at a variety of lupus community events;
- Connecting one-on-one with people with lupus interested in lupus research;
- Encouraging other people with lupus to enroll in Research Accelerated by You (RAY), the Foundation's patient-powered database;

- Representing the Foundation during various outreach opportunities such as patient panel discussions, tabling events, and more; and
- Promoting the Foundation's work to their networks on social media.

Participant Benefits

As a member of the Lupus Research Action Network, 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 to ensure they connect with their target audience.
- Contributions to the creation of new therapies and treatments for people with lupus everywhere
- Helping to solve the cruel mystery!



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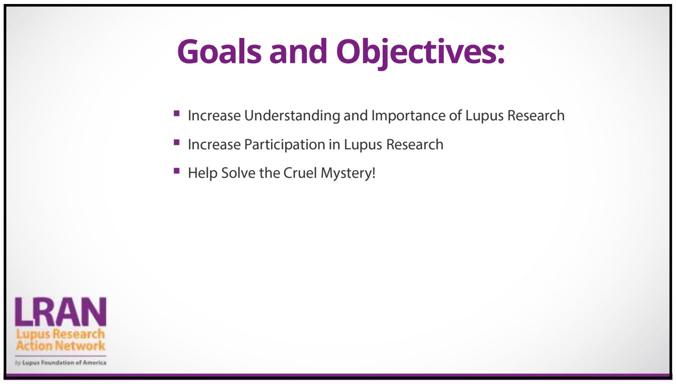
Lupus Research Action Network Training

May 19, 2024

*Funded through the U.S. Department of Health and Human Services Award (HHS) **#1 CPIMP231363-01-00 in** partnership with the Lupus Foundation of America. The contents are solely the responsibility of the authors and does not necessarily represent the official views of HHS.*



Goals and Objectives:

- Increase Understanding and Importance of Lupus Research
- Increase Participation in Lupus Research
- Help Solve the Cruel Mystery!

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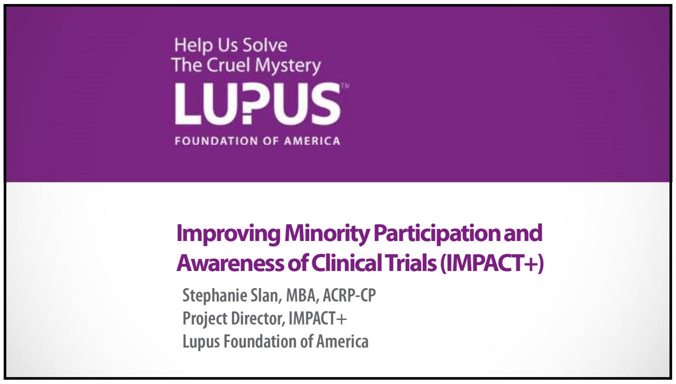

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Improving Minority Participation and Awareness of Clinical Trials (IMPACT+)

Stephanie Slan, MBA, ACRP-CP
Project Director, IMPACT+
Lupus Foundation of America

IMPACT+ Project

Improving Minority Participation and Awareness of Clinical Trials

- Grant funded by the Office of Minority Health as part of the National Lupus Outreach and Clinical Trials Educations Program
- Program Goal: Demonstrate the effectiveness of interventions for increasing racial and ethnic minority enrollment and retention in lupus-related clinical trials
- Focus on capacity building of LRAN members and improved targeting of marketing materials and enrollment in Research Accelerated by You (RAY), our patient powered database.

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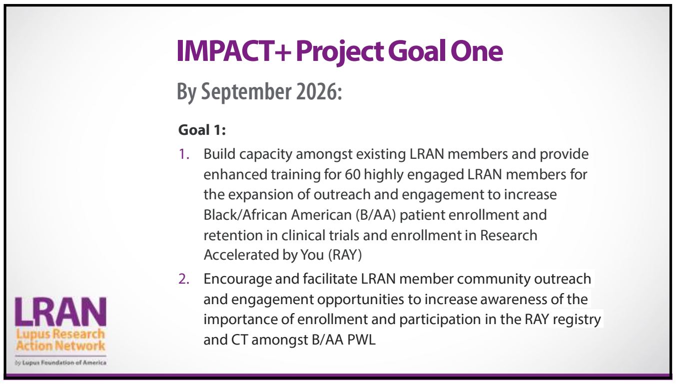

IMPACT+ Project Goal One

By September 2026:

Goal 1:

1. Build capacity amongst existing LRAN members and provide enhanced training for 60 highly engaged LRAN members for the expansion of outreach and engagement to increase Black/African American (B/AA) patient enrollment and retention in clinical trials and enrollment in Research Accelerated by You (RAY)
2. Encourage and facilitate LRAN member community outreach and engagement opportunities to increase awareness of the importance of enrollment and participation in the RAY registry and CT amongst B/AA PWL

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IMPACT+ Project Goals

By September 2026

Goal 2:

1. Explore B/AA motivations and preferences for registry and clinical trial participation and translate motivations and preferences into targeted recruitment and communication strategies that are both culturally and linguistically appropriate
2. Pilot test newly developed strategies to examine effectiveness and acceptability within the target population
3. Increase Black/African American enrollment in the RAY patient and caregiver registry by 200 new B/AA participants to ensure inclusive access to the adapted Lupus Conversations Program and clinical trial engagement opportunities sponsored by academic/industry partners using newly developed, multi-level communication strategies

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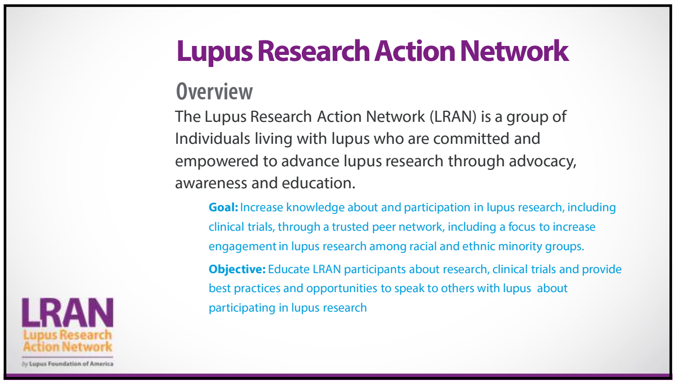

Lupus Research Action Network

Overview

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.

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.

Objective: Educate LRAN participants about research, clinical trials and provide best practices and opportunities to speak to others with lupus about participating in lupus research

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Your Role as an LRAN Member

What are we looking for from LRAN Members?

- LRAN Members will be:
  - 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

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LRAN Member Engagement

How will LRAN members reach others?

- Sharing personal experiences with lupus research at a variety of lupus community events
- Represent the Foundation and lupus community on lupus research focused panel discussions, focus groups, etc.
- Connect one-on-one with people with lupus interested in lupus research
- Share the Foundation's research work among networks on social media
- Report outreach efforts to Regional/Chapter staff upon completion
- Share with other Lupus Warriors how they can learn more about lupus research and take a first step by enrolling in the Research Accelerated by You (RAY) registry

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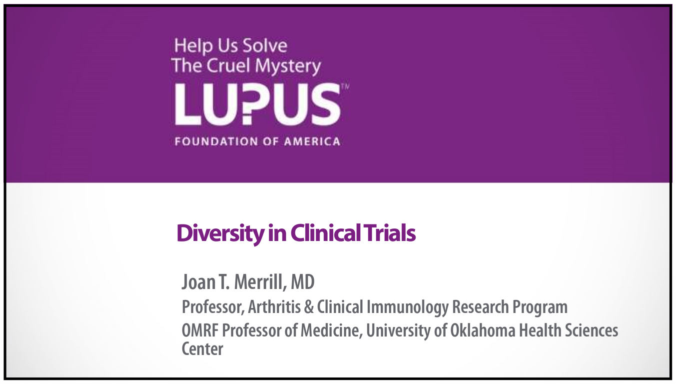

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Diversity in Clinical Trials

Joan T. Merrill, MD
Professor, Arthritis & Clinical Immunology Research Program
OMRF Professor of Medicine, University of Oklahoma Health Sciences Center

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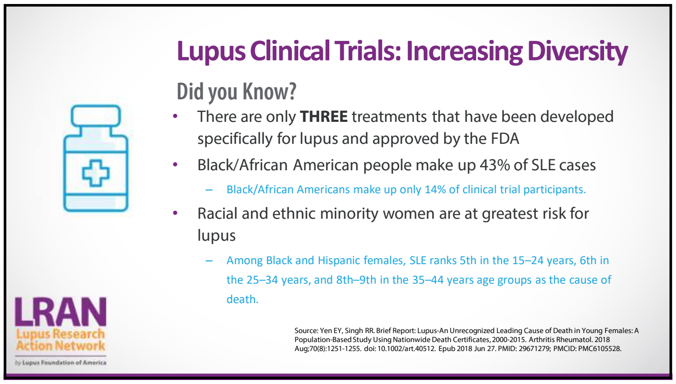

Lupus Clinical Trials: Increasing Diversity

Did you Know?

- There are only **THREE** treatments that have been developed specifically for lupus and approved by the FDA
- Black/African American people make up 43% of SLE cases
  - Black/African Americans make up only 14% of clinical trial participants.
- Racial and ethnic minority women are at greatest risk for lupus
  - Among Black and Hispanic females, SLE ranks 5th in the 15–24 years, 6th in the 25–34 years, and 8th–9th in the 35–44 years age groups as the cause of death.

Source: Yen EY, Singh RR. Brief Report: Lupus-An Unrecognized Leading Cause of Death in Young Females: A Population-Based Study Using Nationwide Death Certificates, 2000-2015. Arthritis Rheumatol. 2018 Aug;70(8):1251-1255. doi: 10.1002/art.40512. Epub 2018 Jun 27. PMID: 29671279; PMCID: PMC6105528.

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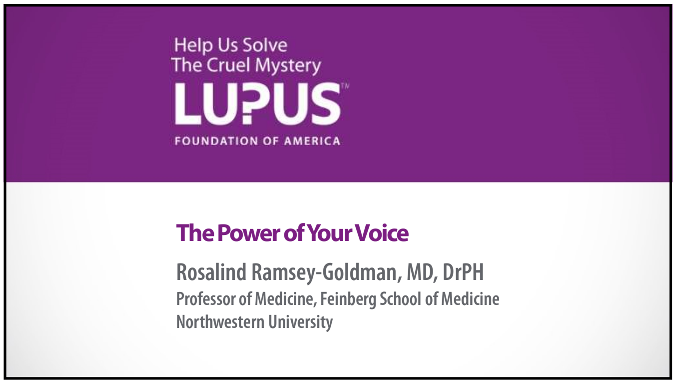

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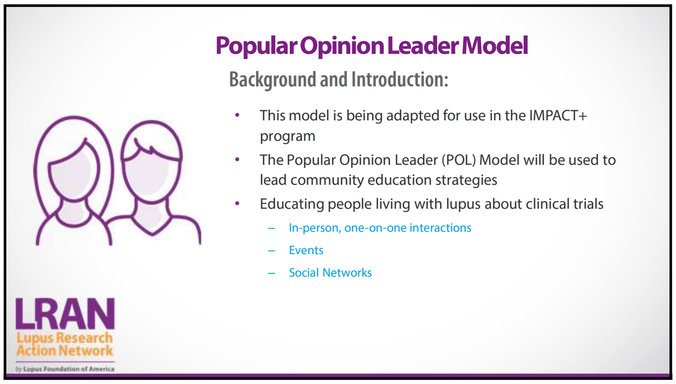
The Power of Your Voice

Rosalind Ramsey-Goldman, MD, DrPH
Professor of Medicine, Feinberg School of Medicine
Northwestern University



Popular Opinion Leader Model

Background and Introduction:

- This model is being adapted for use in the IMPACT+ program
- The Popular Opinion Leader (POL) Model will be used to lead community education strategies
- Educating people living with lupus about clinical trials
  - In-person, one-on-one interactions
  - Events
  - Social Networks

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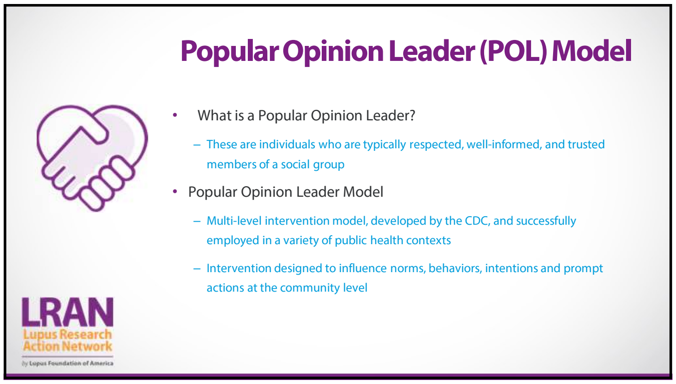

Popular Opinion Leader (POL) Model

- What is a Popular Opinion Leader?
  - These are individuals who are typically respected, well-informed, and trusted members of a social group
- Popular Opinion Leader Model
  - Multi-level intervention model, developed by the CDC, and successfully employed in a variety of public health contexts
  - Intervention designed to influence norms, behaviors, intentions and prompt actions at the community level

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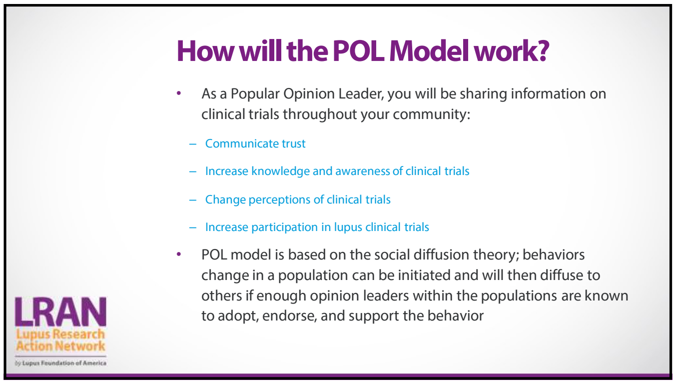

How will the POL Model work?

- As a Popular Opinion Leader, you will be sharing information on clinical trials throughout your community:
  - Communicate trust
  - Increase knowledge and awareness of clinical trials
  - Change perceptions of clinical trials
  - Increase participation in lupus clinical trials
- POL model is based on the social diffusion theory; behaviors change in a population can be initiated and will then diffuse to others if enough opinion leaders within the populations are known to adopt, endorse, and support the behavior

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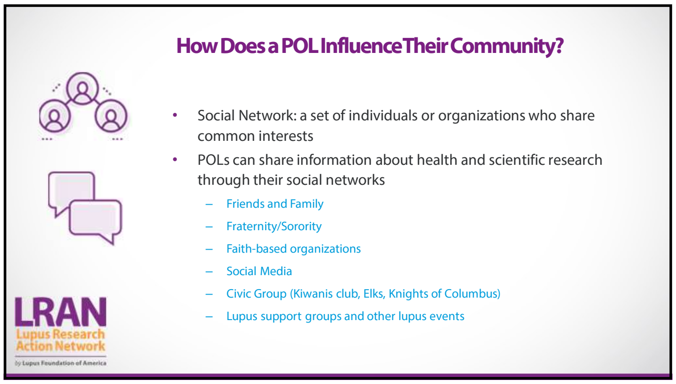
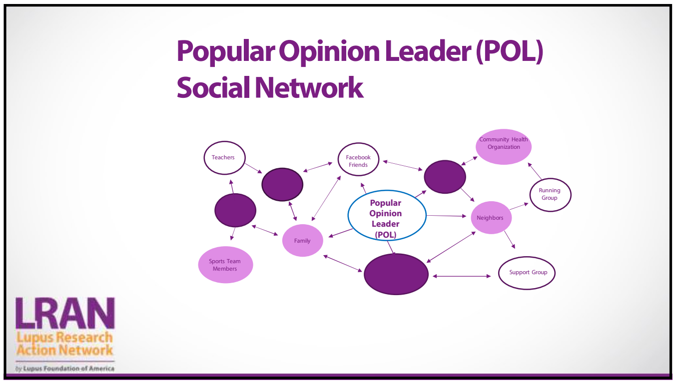


How Does a POL Influence Their Community?

- Social Network: a set of individuals or organizations who share common interests
- POLs can share information about health and scientific research through their social networks
  - Friends and Family
  - Fraternity/Sorority
  - Faith-based organizations
  - Social Media
  - Civic Group (Kiwanis club, Elks, Knights of Columbus)
  - Lupus support groups and other lupus events



Popular Opinion Leader (POL) Social Network

Teachers

Facebook Friends

Community Health Organization

Running Group

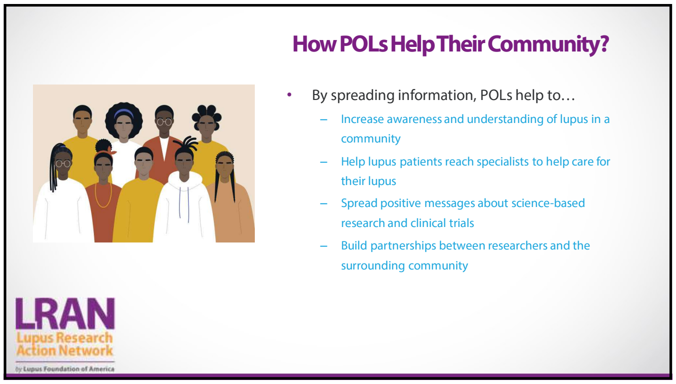
Popular Opinion Leader (POL)

Neighbors

Family

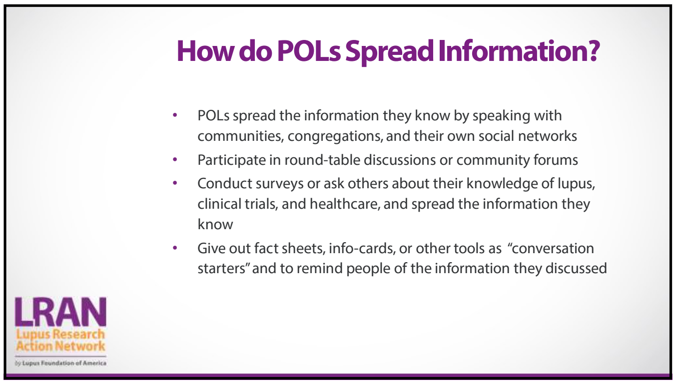
Sports Team Members

Support Group



How POLs Help Their Community?

- By spreading information, POLs help to…
  - Increase awareness and understanding of lupus in a community
  - Help lupus patients reach specialists to help care for their lupus
  - Spread positive messages about science-based research and clinical trials
  - Build partnerships between researchers and the surrounding community



How do POLs Spread Information?

- POLs spread the information they know by speaking with communities, congregations, and their own social networks
- Participate in round-table discussions or community forums
- Conduct surveys or ask others about their knowledge of lupus, clinical trials, and healthcare, and spread the information they know
- Give out fact sheets, info-cards, or other tools as "conversation starters" and to remind people of the information they discussed

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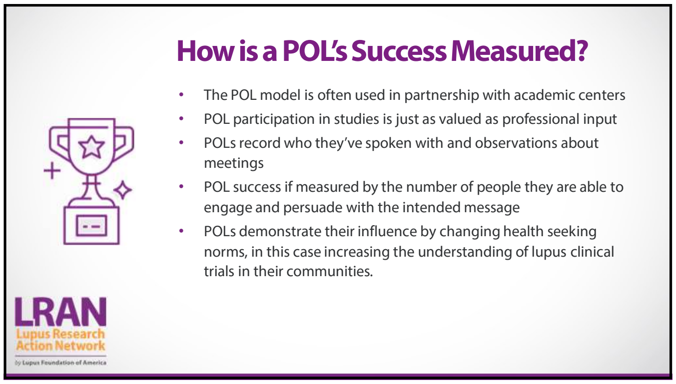

How is a POL's Success Measured?

- The POL model is often used in partnership with academic centers
- POL participation in studies is just as valued as professional input
- POLs record who they've spoken with and observations about meetings
- POL success if measured by the number of people they are able to engage and persuade with the intended message
- POLs demonstrate their influence by changing health seeking norms, in this case increasing the understanding of lupus clinical trials in their communities.

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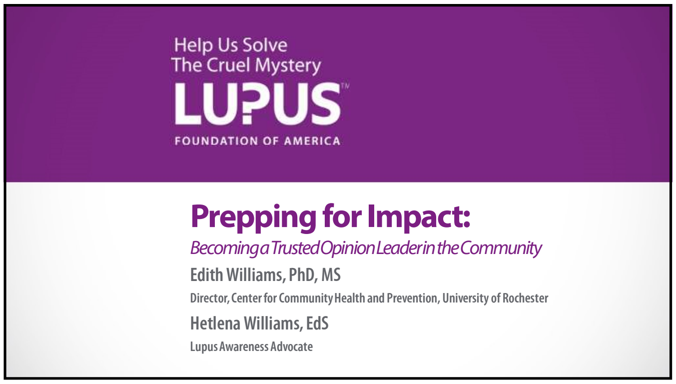

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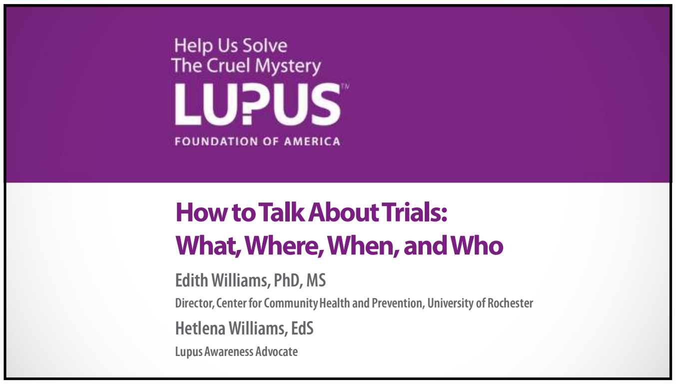
Prepping for Impact:

Becoming a Trusted Opinion Leader in the Community

Edith Williams, PhD, MS
Director, Center for Community Health and Prevention, University of Rochester
Hetlena Williams, EdS
Lupus Awareness Advocate



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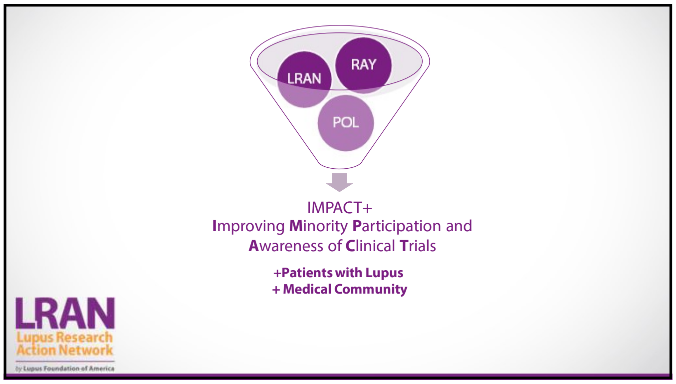
How to Talk About Trials: What, Where, When, and Who

Edith Williams, PhD, MS
Director, Center for Community Health and Prevention, University of Rochester

Hetlena Williams, EdS
Lupus Awareness Advocate



IMPACT+
Improving **M**inority **P**articipation and
Awareness of **C**linical **T**rials

+Patients with Lupus
+ Medical Community

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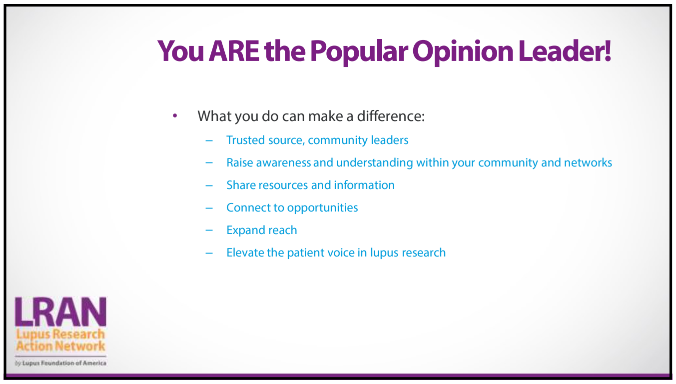

You ARE the Popular Opinion Leader!

- What you do can make a difference:
  - Trusted source, community leaders
  - Raise awareness and understanding within your community and networks
  - Share resources and information
  - Connect to opportunities
  - Expand reach
  - Elevate the patient voice in lupus research

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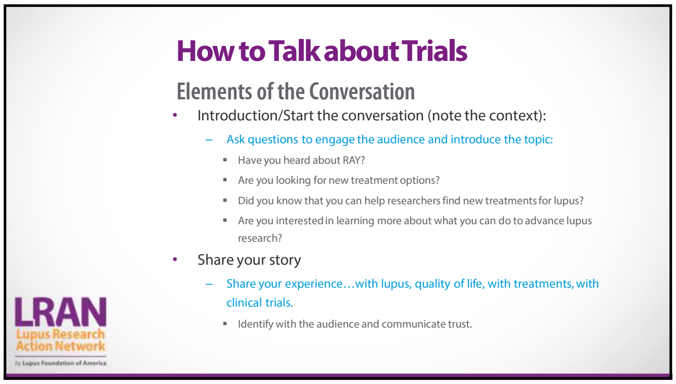

How to Talk about Trials

Elements of the Conversation

- Introduction/Start the conversation (note the context):
  - Ask questions to engage the audience and introduce the topic:
    - Have you heard about RAY?
    - Are you looking for new treatment options?
    - Did you know that you can help researchers find new treatments for lupus?
    - Are you interested in learning more about what you can do to advance lupus research?
- Share your story
  - Share your experience…with lupus, quality of life, with treatments, with clinical trials.
    - Identify with the audience and communicate trust.

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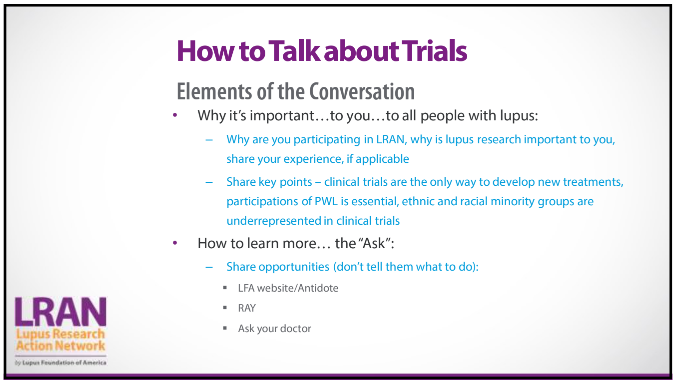

How to Talk about Trials

Elements of the Conversation

- Why it's important…to you…to all people with lupus:
  - Why are you participating in LRAN, why is lupus research important to you, share your experience, if applicable
  - Share key points – clinical trials are the only way to develop new treatments, participations of PWL is essential, ethnic and racial minority groups are underrepresented in clinical trials
- How to learn more… the "Ask":
  - Share opportunities (don't tell them what to do):
    - LFA website/Antidote
    - RAY
    - Ask your doctor

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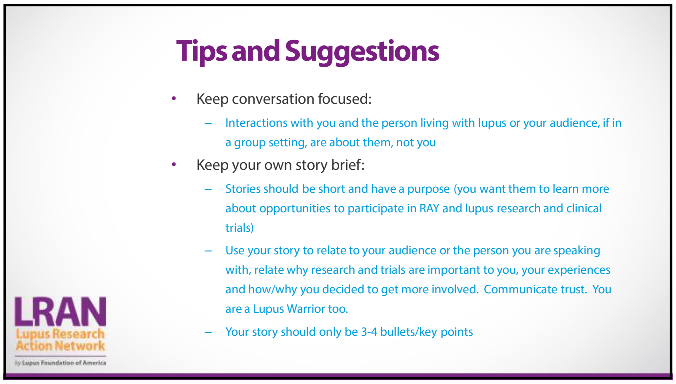

Tips and Suggestions

- Keep conversation focused:
  - Interactions with you and the person living with lupus or your audience, if in a group setting, are about them, not you
- Keep your own story brief:
  - Stories should be short and have a purpose (you want them to learn more about opportunities to participate in RAY and lupus research and clinical trials)
  - Use your story to relate to your audience or the person you are speaking with, relate why research and trials are important to you, your experiences and how/why you decided to get more involved. Communicate trust. You are a Lupus Warrior too.
  - Your story should only be 3-4 bullets/key points

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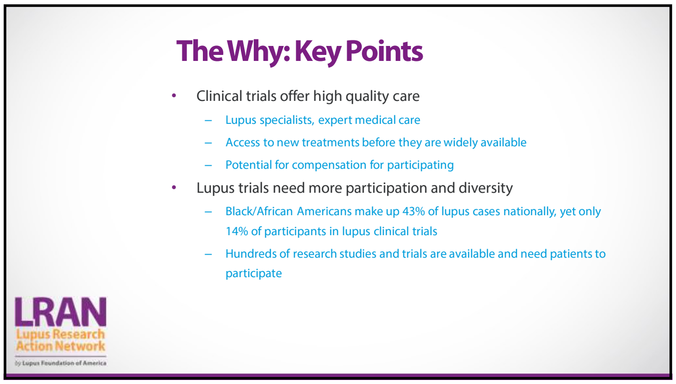

The Why: Key Points

- Clinical trials offer high quality care
  - Lupus specialists, expert medical care
  - Access to new treatments before they are widely available
  - Potential for compensation for participating
- Lupus trials need more participation and diversity
  - Black/African Americans make up 43% of lupus cases nationally, yet only 14% of participants in lupus clinical trials
  - Hundreds of research studies and trials are available and need patients to participate

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The Why: Key Points

- Clinical trials are the only way to get new treatments
  - There are seven FDA approved treatments (three developed specifically for lupus)
  - Lupus affects each person differently, a diverse group of people living with lupus participating in research helps to ensure treatments have the greatest effect on the largest number of patients
- Participation is always voluntary, and safety is a priority
  - Your decision to participate is not permanent, you may choose to leave the study at any time
  - Researchers follow detailed protocols and safety requirements to make each trials as safe as possible

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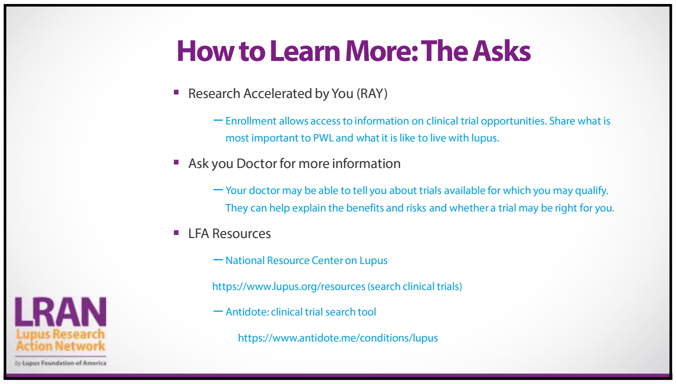

How to Learn More: The Asks

- Research Accelerated by You (RAY)
  - Enrollment allows access to information on clinical trial opportunities. Share what is most important to PWL and what it is like to live with lupus.
- Ask you Doctor for more information
  - Your doctor may be able to tell you about trials available for which you may qualify. They can help explain the benefits and risks and whether a trial may be right for you.
- LFA Resources
  - National Resource Center on Lupus

    https://www.lupus.org/resources (search clinical trials)
  - Antidote: clinical trial search tool

    https://www.antidote.me/conditions/lupus

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Where to Talk about Trials

We will share opportunities with you!

- Lupus Walk
- Lupus and You Meetings
- Support Group Meetings
- Advocacy Summit
- Doctor's Office
- Social and community gatherings, such as church or other community organizations you are involved with
- Engaging with other Lupus Warriors
- Social Media

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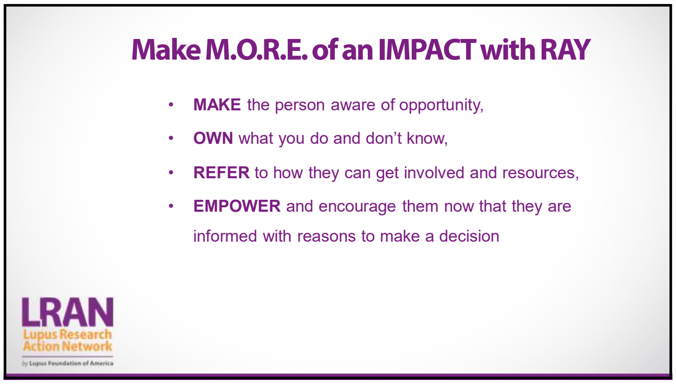

Make M.O.R.E. of an IMPACT with RAY

- **MAKE** the person aware of opportunity,
- **OWN** what you do and don't know,
- **REFER** to how they can get involved and resources,
- **EMPOWER** and encourage them now that they are informed with reasons to make a decision

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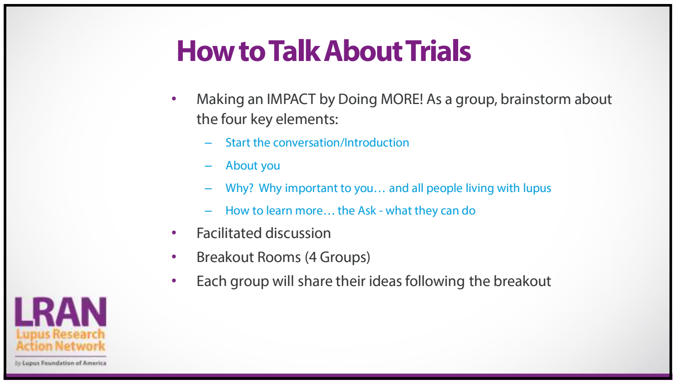

How to Talk About Trials

- Making an IMPACT by Doing MORE! As a group, brainstorm about the four key elements:
  - Start the conversation/Introduction
  - About you
  - Why? Why important to you… and all people living with lupus
  - How to learn more… the Ask - what they can do
- Facilitated discussion
- Breakout Rooms (4 Groups)
- Each group will share their ideas following the breakout

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How to Talk About Trials:

Example Conversation

- This approach aims to engage the audience, share personal experiences, and acknowledge the specific concerns of the community, ultimately fostering a more open and trusting dialogue about clinical trials.
- Key Elements:
  - Start the Conversation
  - Share Your Story
  - Engage the Audience
  - Identify with the Audience and Communicate Trust

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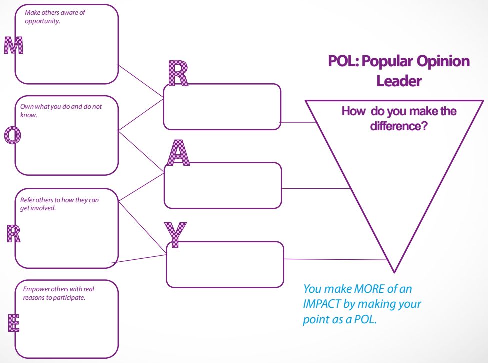
Your Action Plan:

Next Steps and Resources



POL: Popular Opinion Leader

How do you make the difference?

You make MORE of an IMPACT by making your point as a POL.

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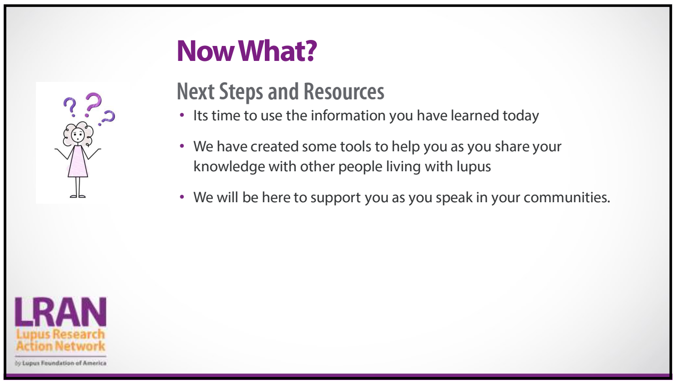

Now What?

Next Steps and Resources

- Its time to use the information you have learned today
- We have created some tools to help you as you share your knowledge with other people living with lupus
- We will be here to support you as you speak in your communities.

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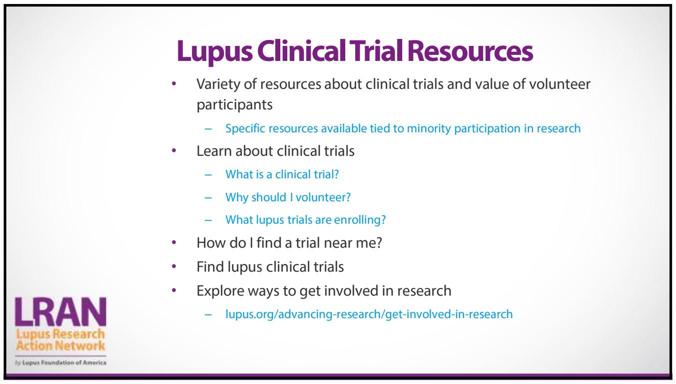

Lupus Clinical Trial Resources

- Variety of resources about clinical trials and value of volunteer participants
  - Specific resources available tied to minority participation in research
- Learn about clinical trials
  - What is a clinical trial?
  - Why should I volunteer?
  - What lupus trials are enrolling?
- How do I find a trial near me?
- Find lupus clinical trials
- Explore ways to get involved in research
  - lupus.org/advancing-research/get-involved-in-research

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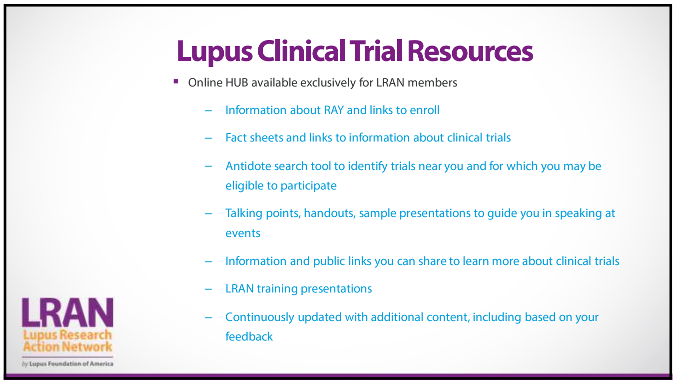

Lupus Clinical Trial Resources

- Online HUB available exclusively for LRAN members
  - Information about RAY and links to enroll
  - Fact sheets and links to information about clinical trials
  - Antidote search tool to identify trials near you and for which you may be eligible to participate
  - Talking points, handouts, sample presentations to guide you in speaking at events
  - Information and public links you can share to learn more about clinical trials
  - LRAN training presentations
  - Continuously updated with additional content, including based on your feedback

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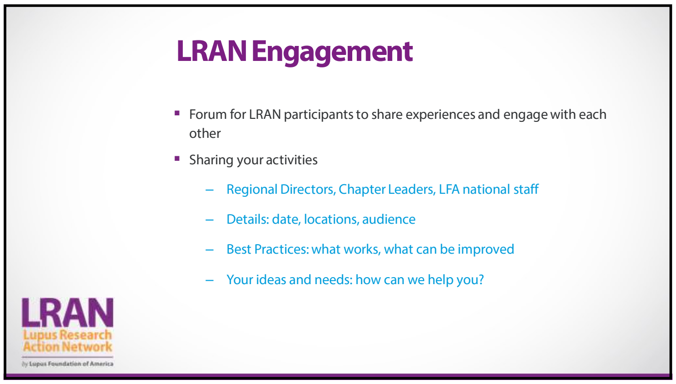

LRAN Engagement

- Forum for LRAN participants to share experiences and engage with each other
- Sharing your activities
  - Regional Directors, Chapter Leaders, LFA national staff
  - Details: date, locations, audience
  - Best Practices: what works, what can be improved
  - Your ideas and needs: how can we help you?

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How to Talk About Trials:
What, Where, When, and Who

How to Talk about Trials

Elements of the Conversation

- Introduction/Start the conversation (note the context):
  - Ask questions to engage the audience and introduce the topic:
    - Have you heard about RAY?
    - Are you looking for new treatment options?
    - Did you know that you can help researchers find new treatments for lupus?
    - Are you interested in learning more about what you can do to advance lupus research?
- Share your story
  - Share your experience…with lupus, quality of life, with treatments, with clinical trials.
    - Identify with the audience and communicate trust.

How to Talk about Trials

Elements of the Conversation

- Why it’s important…to you…to all people with lupus:
  - Why are you participating in LRAN, why is lupus research important to you, share your experience, if applicable
  - Share key points – clinical trials are the only way to develop new treatments, participations of PWL is essential, ethnic and racial minority groups are underrepresented in clinical trials
- How to learn more… the “Ask”:
  - Share opportunities (don’t tell them what to do):
    - LFA website/Antidote
    - RAY
    - Ask your doctor

Tips and Suggestions

- Keep conversation focused:
  - Interactions with you and the person living with lupus or your audience, if in a group setting, are about them, not you

- Keep your own story brief:
  - Stories should be short and have a purpose (you want them to learn more about opportunities to participate in RAY and lupus research and clinical trials)
  - Use your story to relate to your audience or the person you are speaking with, relate why research and trials are important to you, your experiences and how/why you decided to get more involved. Communicate trust. You are a Lupus Warrior too.
  - Your story should only be 3-4 bullets/key points

The Why: Key Points

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- Social Media

Make M. O. R. E. of an IMPACT with R.A.Y.

- **Make** the person aware of opportunity,
- **Own** what you do and don't know,
- **Refer** to how they can get involved and resources,
- **Empower** and encourage them now that they are informed with reasons to make a decision

How to Talk About Trials: Example Conversation

☐ This approach aims to engage the audience, share personal experiences, and acknowledge the specific concerns of the community, ultimately fostering a more open and trusting dialogue about clinical trials.

- **Start the Conversation:**

"Good [morning/afternoon/evening], everyone. Have you heard about RAY? Are you looking for new treatment options? Did you know that you can help researchers find new treatments for lupus? Are you interested in learning more about what you can do to advance lupus research?"

- **Share Your Story:**

"I'd like to share my experience with lupus and the impact it has had on my quality of life. I understand the challenges of finding effective treatments and the importance of advancing research in this area."

- **Engage the Audience:**

"I'm sure many of you have your own stories and experiences with lupus, quality of life, treatments, and possibly even clinical trials. It's important to have these conversations and learn from each other."

- **Identify with the Audience and Communicate Trust:**

"I understand that there may be concerns and hesitations about clinical trials, especially given the historical mistreatment of Black and Hispanic Americans in medical research. It's important to acknowledge these concerns and work towards building trust and transparency in the research process."

Let’s Practice Scenario Group 1

- Scenario
  - You are at a Lupus Walk at the Lupus resources table *(Informal, high foot traffic)*
- Warm Introduction
  - "Hi there! Can I answer any questions you have about lupus resources?"
- Your Story & Who You Are
  - (Briefly) "I'm [Your Name], and I've been living with lupus for [Number] years. It's been a journey, but I'm here because of research advancements."
- Why Research & Trials Matter
  - "Research is finding new ways to manage lupus symptoms and improve quality of life. Clinical trials help test these new therapies."
- Why How to learn more… the Ask - what they can do
  - "Curious about getting involved? Let me show you some resources from the NRC and LFA!"

Let's Practice Scenario Group 2

- Scenario
  - You are at a support group meeting *(Established group, open atmosphere)*
- Warm Introduction
  - "Welcome everyone! I'm [Your Name], and I'm grateful for this supportive community. Today, I want to talk about research and its impact on lupus."
- Your Story & Who You Are
  - Share a personal story) "When I was diagnosed, treatment options were limited. Now, thanks to research, we have more choices. But there's still a lot to learn."
- Why Research & Trials Matter
  - "We all deserve better treatment options. Clinical trials are the key to unlocking new possibilities. Every person who participates contributes to a brighter future."
- Why How to learn more… the Ask - what they can do
  - " Have you considered participating in a trial? Let's discuss the resources available to help you decide."

Let’s Practice Scenario Group 3

- Scenario
  - You have been asked to present at a Lupus & You (L&Y) education event. *(Formal audience, dedicated time)*
- Warm Introduction
  - "Thank you for inviting me. I'm [Your Name], a person living with lupus. Today, we'll explore the vital role of research and clinical trials in the fight against lupus."
- Your Story & Who You Are
  - *(Expand on your story, connect it to research breakthroughs)* "Research has helped me manage my symptoms in ways I never thought possible. It gives me hope for the future, not just for myself, but for everyone affected by lupus."
- Why Research & Trials Matter
  - *(Use visuals, data, and patient testimonials)* "Research isn't just about statistics. It's about real people living better lives. Clinical trials pave the way for those advancements."
- Why How to learn more… the Ask - what they can do
  - "Let's empower ourselves through knowledge. I encourage you to visit these resources and consider becoming advocates for research funding."

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Let’s Practice Scenario Group 4

- Scenario
  - You are at the National Lupus Advocacy Summit *(Passionate audience, focus on action)*
- Warm Introduction
  - "Good morning, fellow advocates! I'm [Your Name], and like many of you, I rely on research to manage my lupus. But research needs our support!"
- Your Story & Who You Are
  - *(Powerful story highlighting unmet needs)* "Imagine a future where lupus doesn't steal our dreams. Research can make that a reality. But without continued funding and clinical trial participation, progress stalls."
- Why Research & Trials Matter
  - *(Challenge the audience, use strong language)* "We are the driving force behind change! Together, we can demand more research funding and break down barriers to clinical trials."
- Why How to learn more… the Ask - what they can do
  - "Let's raise our voices! Visit these resources to learn how to advocate and connect with research initiatives."

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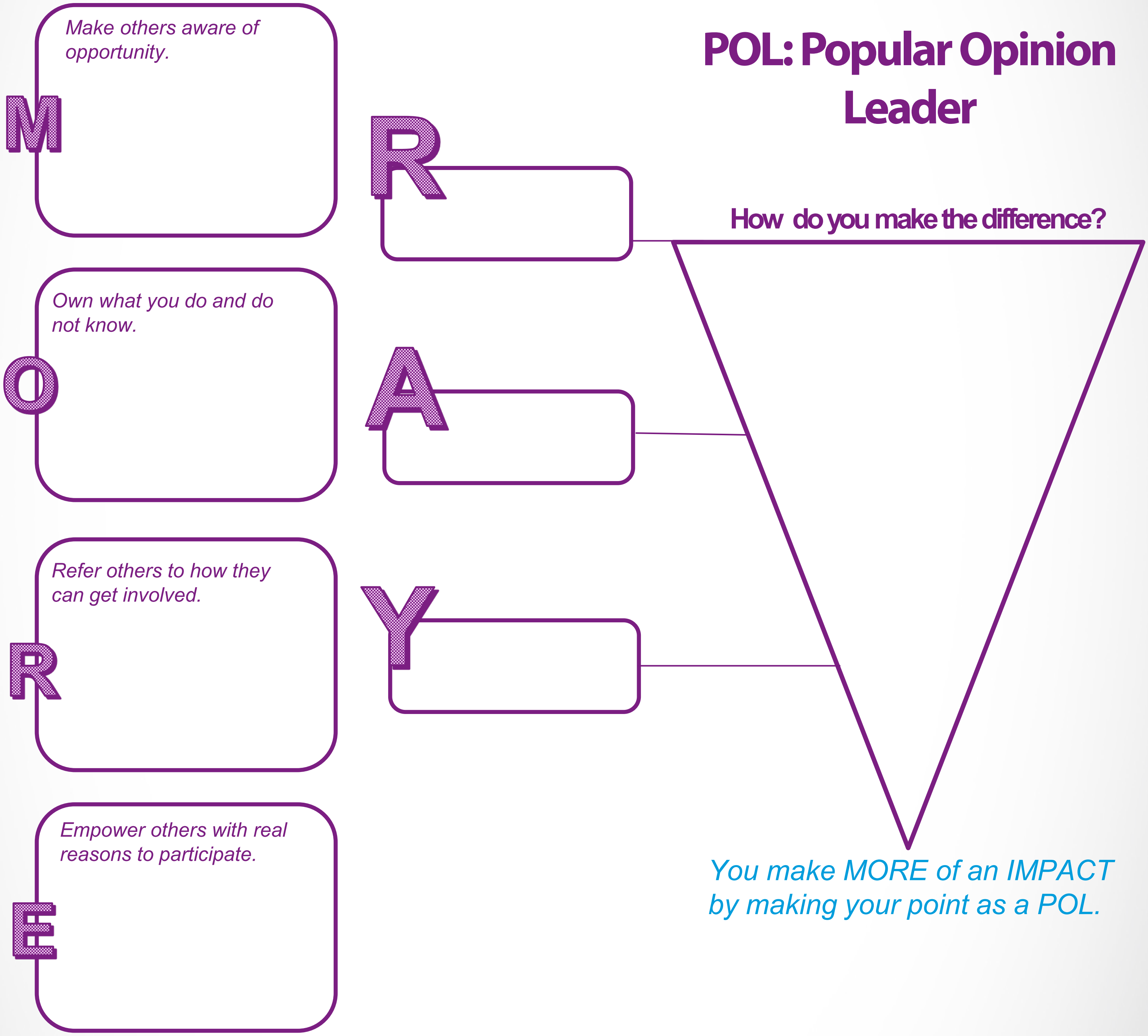
Your Action Plan: Next Steps and Resources

IMPACT

Improving Minority Participation and Awareness of Clinical Trials



M

Make others aware of opportunity.

O

Own what you do and do not know.

R

Refer others to how they can get involved.

E

Empower others with real reasons to participate.

R

A

Y

POL: Popular Opinion Leader

How do you make the difference?

You make MORE of an IMPACT by making your point as a POL.

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Popular Opinion Leader

P

Popular:

What ways do I communicate with my network?

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O

Opinion:

What are some conversational barriers and questions I may need to consider?

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L

Leader:

What solutions can I provide in terms of awareness and sharing?

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Research Accelerated by You

R

Research – real people, recruitment, reasons

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A

Accelerated --- advocacy, accountability, awareness

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Y

You ---- make a difference, complete the data, sign up others to participate, share a RAY resource

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Table addressing specific concerns:

This table provides structured responses to each specific concern, along with tailored messages to encourage participation and address the patient's hesitations. Feel free to adjust the language or add more examples as needed to fit the specific context of your clinical trial.

Patient's Reason for Not Participating	**Response to Counter**	**Response to Encourage Participation**	**Response of Encouragement**
1. Concern about blood draw volume	Trials use minimal blood samples for necessary tests.	Your contribution is vital but minimally invasive.	We prioritize your comfort and well-being.
2. Lack of childcare resources	Some trials offer childcare assistance or flexible scheduling.	Participation can lead to better resources for families.	Your family's needs are important, and we'll support you.
3. Concern about pay	Many trials offer compensation for time and inconvenience.	Participating contributes to medical progress and may offer financial compensation.	Your time and effort are valued, and compensation is provided.
4. Fear of being away from work	Trials often offer flexible scheduling to accommodate work commitments.	Your participation contributes to future treatments that may reduce work absences.	Your job is important, and we'll work with you to minimize disruptions.
5. Fear of pain or discomfort	Trials prioritize patient comfort and provide pain management options.	Participation can lead to discoveries that improve pain management techniques.	Your comfort is our priority, and measures are in place to minimize discomfort.
6. Concern about travel expenses	Some trials offer travel assistance or reimbursements for expenses.	Your participation contributes to advancements that may reduce the need for extensive travel in the future.	We'll assist with travel expenses to ensure your participation is not hindered.
7. Fear of the unknown or unfamiliar environment	Trial staff provide detailed information and support to address concerns.	Participation allows you to learn and gain experience in a supportive environment.	We understand your apprehension, and we're here to guide you through the process.
8. Lack of understanding of trial procedures	Trial staff provide thorough explanations and answer any questions.	Participation provides an opportunity to learn about medical research and treatments.	Your questions are important, and we're here to provide clarity and support.
9. Concern about the duration of the trial	Trials vary in duration, and trial staff can provide information on specific timelines.	Your participation contributes to medical advancements, regardless of trial duration.	We'll work with you to find a trial with a duration that fits your needs.
10. Fear of commitment or obligation	Trials offer options for participation with varying levels of commitment.	Participation is voluntary, and you can withdraw at any time without penalty.	Your decision to participate is entirely up to you, and we respect your autonomy.

Participant Discussion Guide:

Groups will brainstorm and practice short role-playing scenarios where they initiate a conversation about clinical trials with a community member.

Participant Discussion Guide:

Groups create short scripts or role-playing scenarios where they initiate a conversation about clinical trials with a community member. Refer to M.O.R.E. worksheet

Introduction: Start the Conversation

(Smile warmly at the audience)

Example 1: Good morning/afternoon everyone! My name is [Your Name], and I'd like to thank you for being here today. I'm not a doctor, scientist, or renowned expert. But I am someone who knows lupus firsthand. For the past [Number] years, I've been living with this unpredictable companion, a dance partner who sometimes twirls me gracefully and other times throws me off balance.

Example 2: "Good [morning/afternoon/evening], everyone. Have you heard about RAY? Are you looking for new treatment options? Did you know that you can help researchers find new treatments for lupus? Are you interested in learning more about what you can do to advance lupus research?"

My Story:

(Share a brief, impactful part of your lupus journey. It could be the moment of diagnosis, a particularly challenging flare-up, or a victory you've had over the disease.)

Example 1: Remember that day when [Share a specific event]? The world seemed to shift on its axis, and uncertainty became my constant companion. But amidst the confusion, a spark ignited within me - a determination to understand this disease, to fight for myself, and ultimately, to contribute to finding a cure.

Example 2: "I'd like to share my experience with lupus and the impact it has had on my quality of life. I understand the challenges of finding effective treatments and the importance of advancing research in this area."

Why Research & Trials Matter: Engage the audience/listener in why it is important to you… and all people living with lupus

(Shift the focus to the broader significance of research)

Example 1: Lupus isn't just my story; it's a story woven from millions of threads, each as unique as the person it touches. And every thread deserves a brighter ending. That's where research and clinical trials come in. They're the keys that unlock new treatments, unravel the mysteries of the disease, and empower us to take control of our lives.

Think of it like navigating a dark forest. Research illuminates the path, clinical trials test the bridges, and together, we pave the way for a future where lupus doesn't dictate our dreams. These efforts aren't just for me; they're for every child who deserves to play without pain, every parent who craves a worry-free hug, and every individual who yearns to live beyond the limitations of lupus.

Example 2: "I'm sure many of you have your own stories and experiences with lupus, quality of life, treatments, and possibly even clinical trials. It's important to have these conversations and learn from each other."

Participant Discussion Guide:

Groups will brainstorm and practice short role-playing scenarios where they initiate a conversation about clinical trials with a community member.

How to Learn More: The Ask …what they can do

(Provide concrete ways for the audience to engage)

Example 1: This journey doesn't happen in isolation. We're not alone in this forest. There are resources that can equip you, communities that can embrace you, and voices that can amplify yours. Organizations like [List relevant organizations] are beacons of information and support. They offer resources, connect you with fellow warriors, and empower you to become an advocate for yourself and others.

Example 2: Knowledge is power. Educate yourselves, ask questions, and become an active participant in this fight. Together, let's raise our voices louder than the whispers of doubt, let's shine a light on the darkness of lupus, and let's walk this path, not just for ourselves, but for the generations to come.

End with a confident smile and an open invitation for further engagement.

Example 1: Thank you for considering taking better care of you while helping others.

Example 2: "I understand that there may be concerns and hesitations about clinical trials, especially given the historical mistreatment of Black and Hispanic Americans in medical research. It's important to acknowledge these concerns and work towards building trust and transparency in the research process."

(End with a confident smile and an open invitation for further engagement.)

Tips to Remember:

- Personalize the script with your own unique experiences and stories.
- Highlight the emotional impact of your journey to connect with the audience.
- Emphasize the collective power of research and community support.
- Provide concrete resources and actionable steps for further engagement.
- By sharing your story and sparking curiosity, you can inspire others to learn more, get involved, and contribute to the fight against lupus.

Participant Example Script:

Make more of an IMPACT in your conversations about clinical trials with a community member.

Introduction:

(Smile warmly at the audience)

Good morning/afternoon everyone! My name is [Your Name], and I'd like to thank you for being here today. I'm not a doctor, scientist, or renowned expert. But I am someone who knows lupus firsthand. For the past [Number] years, I've been living with this unpredictable companion, a dance partner who sometimes twirls me gracefully and other times throws me off balance.

My Story:

(Share a brief, impactful part of your lupus journey. It could be the moment of diagnosis, a particularly challenging flare-up, or a victory you've had over the disease.)

Remember that day when [Share a specific event]? The world seemed to shift on its axis, and uncertainty became my constant companion. But amidst the confusion, a spark ignited within me - a determination to understand this disease, to fight for myself, and ultimately, to contribute to finding a cure.

Why Research & Trials Matter:

(Shift the focus to the broader significance of research)

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(Provide concrete ways for the audience to engage)

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Thank you for considering taking better care of you while helping others.

(End with a confident smile and an open invitation for further engagement.)

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L.E.A.R.N. Model of Communication

Component	Description	Application in Conversations About Clinical Trials
Listen	Actively listen to the concerns, questions, and perspectives of the individual.	- Begin the conversation by asking open-ended questions to understand their knowledge, concerns, and perceptions of clinical trials.
	Allow them to share their experiences and thoughts without interruption.	- Listen empathetically to any historical mistrust or fears they may express and validate their feelings.
	Demonstrate genuine interest in their perspective.	- Use reflective listening to paraphrase their concerns, ensuring they feel heard and understood.
Explain	-Provide clear and concise information about the clinical trial, its purpose, and potential benefits.	- Offer a detailed yet understandable explanation of the clinical trial, including its goals, procedures, and potential impact on health outcomes.
	Use plain language and avoid jargon to enhance comprehension.	- Explain how the trial aligns with broader health goals and contributes to scientific knowledge that can benefit the community.
	Address any misconceptions or myths about clinical trials.	- Correct any misinformation and emphasize the ethical standards, safety measures, and oversight in place for the trial.
Acknowledge	Acknowledge and validate the individual's concerns, emotions, and perspectives.	- Recognize the historical context, including past injustices and unethical medical practices, and express understanding of their impact on trust.
	Empathize with any fears or apprehensions they may have.	- Acknowledge the importance of their perspective in shaping a more inclusive and equitable healthcare system.
	Acknowledge the diversity within the African American community and the uniqueness of individual experiences.	- Recognize that individuals may have varying reasons for their apprehension and tailor the conversation accordingly.
Recommend	Provide personalized recommendations based on their concerns and interests.	- Suggest additional resources, such as informational materials, support groups, or community events related to clinical trials.
	Recommend seeking advice from trusted healthcare providers or community leaders.	- Share success stories of individuals from similar backgrounds who have participated in clinical trials, emphasizing positive outcomes.
	Encourage them to consult with family members or friends who may have experience with clinical trials.	- Recommend that they explore the trial in-depth and ask questions to make informed decisions about participation.
Negotiate	Collaboratively discuss any reservations or conditions they may have for participation.	- Negotiate a plan that addresses their specific concerns, whether related to logistics, potential risks, or personal commitments.
	Be open to compromise and finding common ground.	- If applicable, discuss potential accommodations or adjustments to address barriers, such as transportation issues or scheduling conflicts.
	Allow them time to consider the information and express any additional questions or concerns.	- Facilitate an ongoing dialogue, allowing them to take an active role in the decision-making process and ensuring that their needs are considered.

DETERMINATION

"If you don't like something, change it.

If you can't change it, change your attitude."

-Maya Angelou

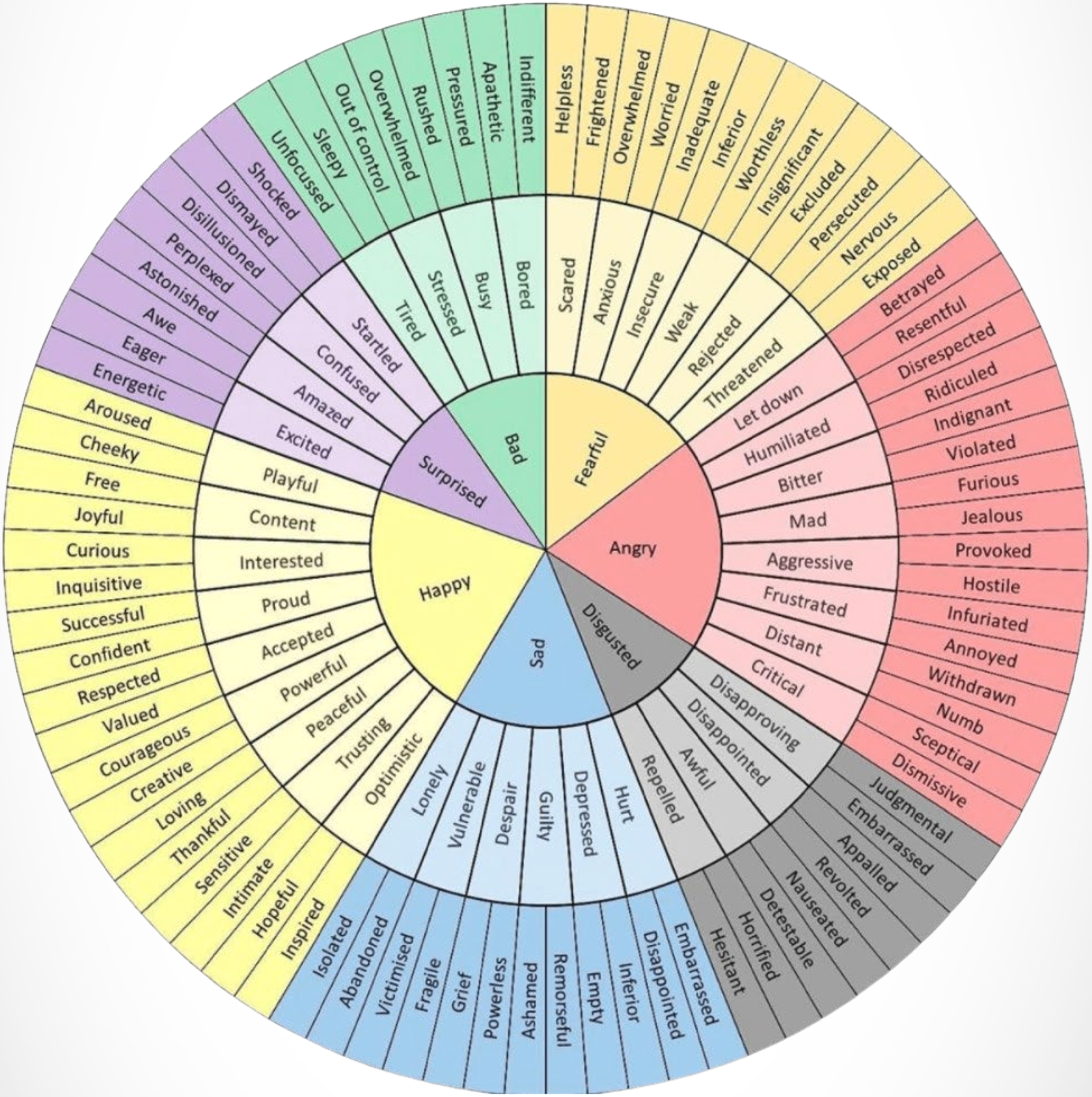
ATTITUDE

by Charles Swindoll

"The longer I live, the more I realize the impact of attitude on life. Attitude, to me, is more important than facts. It is more important than the past, than education, than money, than circumstances, than failures, than successes, than what other people think, say or do. It is more important than appearance, giftedness or skill. It will make or break a company... a church... a home. The remarkable thing is we have a choice every day regarding the attitude we embrace for that day. We cannot change our past... we cannot change the fact that people will act in a certain way. We cannot change the inevitable. The only thing we can do is play the one string we have, and that is our attitude... I am convinced that life is 10% what happens to me and 90% how I react to it.

And so it is with you... we are in charge of our attitudes"

Feelings Wheel



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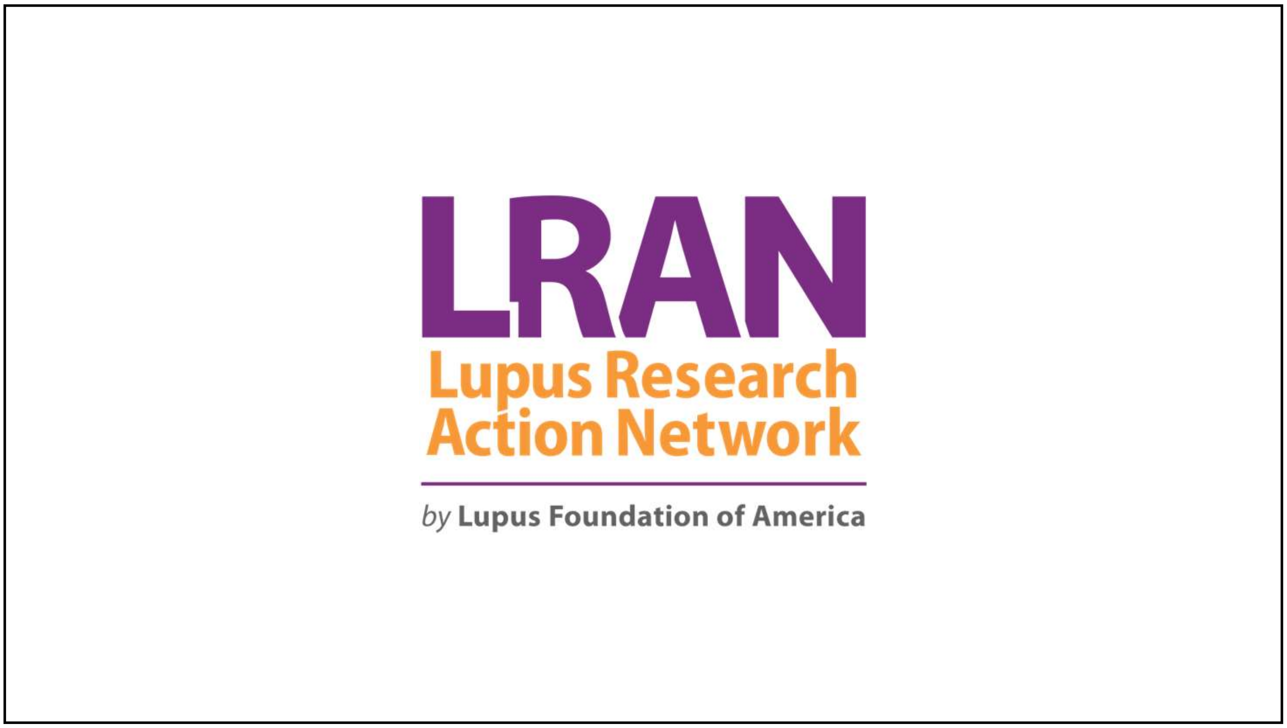
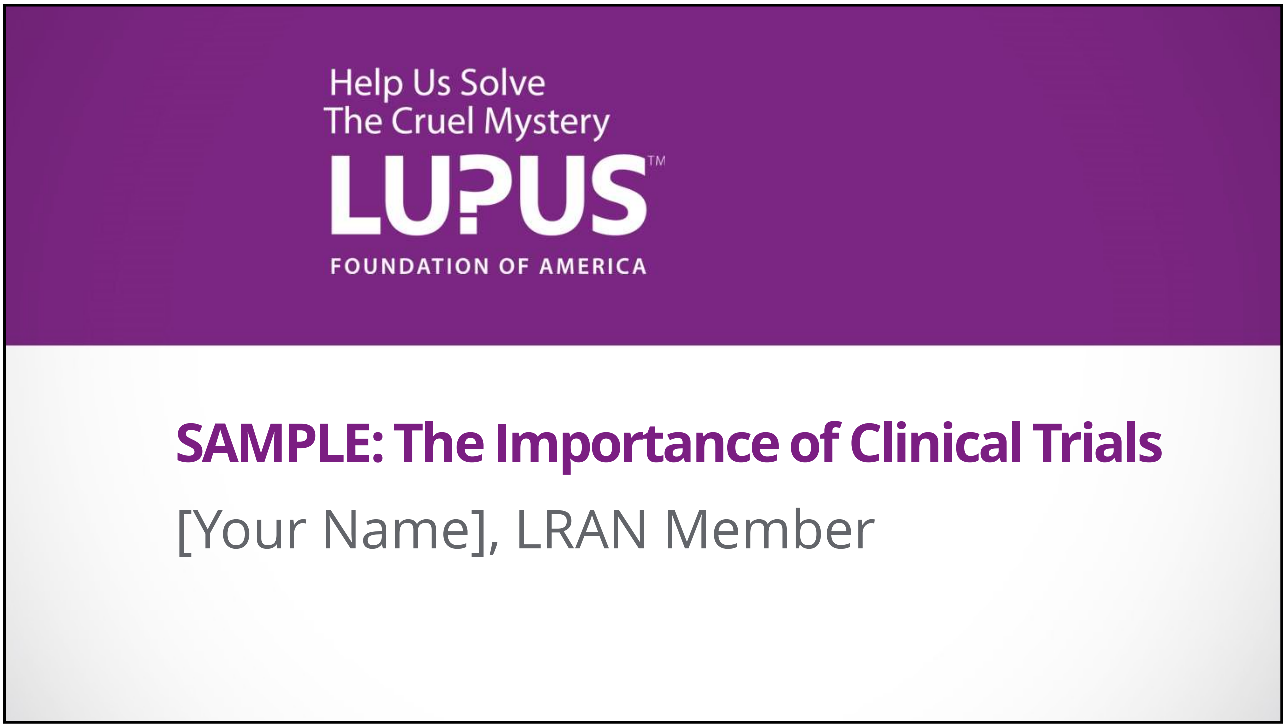
Adapted from source: https://imgur.com/tCWChf6 Feelings Wheel - Geoffrey Roberts



LRAN

Lupus Research Action Network

by Lupus Foundation of America



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SAMPLE: The Importance of Clinical Trials

[Your Name], LRAN Member

Introduction:

- Who am I?
- What has my lupus experience been like?
- Why am I here?

LRAN
Lupus Research
Action Network
by Lupus Foundation of America

Lupus Research Action Network

- 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 the goal of LRAN?

  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
Lupus Research
Action Network
by Lupus Foundation of America

Importance of Clinical Trials

- Lupus is ranked in the top 10 leading causes of death for Black/African American and Hispanic/Latino women ages 15 to 44 years
  - Black people are estimated to make up to 43% of lupus cases, they are only 14% of participants in lupus clinical trials
- We need to increase the participation of the Black/African American lupus community in clinical trials to determine whether new treatments are safe and effective for them

---

What Does it Mean to Participate in a Trial?

- Participation is voluntary
- Study staff (doctors, nurses, research/study coordinators) are required to follow strict procedures to protect your safety and rights
- Participating in research helps other lupus warriors by contributing to medical research

How do I get involved in Lupus Research?

- Talk to your doctor
- Check out the National Resource Center on Lupus
- Enroll in Research Accelerated by You (RAY)

RAY® - A First Step to Increase Participation in Lupus Trials

- It's easy to do!
  - Can be done from the comfort of your own home!
- Learn more about research and engagement opportunities that will help advance lupus drug development
  - Clinical research and clinical trial opportunities
  - Focus group/listening session opportunities
    - FDA
    - Pharmaceutical companies

QUESTIONS?

LRAN
Lupus Research Action Network

by **Lupus Foundation of America**

LUPUS RESEARCH ACTION NETWORK: MEMBER TOOLKIT

Funded through the U.S. Department of Health and Human Services Award (HHS) #1 CPIMP231363-01-00 in partnership with the Lupus Foundation of America.
The contents are solely the responsibility of the authors and does not necessarily represent the official views of HHS.

This toolkit contains the following materials:

- You Can Make a Difference: Lupus Clinical Trials and African Americans
- Is a Clinical Trial Right for Me?
- Clinical Trials and Lupus: Frequently Asked Questions
- Helpful Resources for Lupus and Clinical Trials
- Lupus in the Body

YOU CAN MAKE A DIFFERENCE

LUPUS CLINICAL TRIALS AND AFRICAN AMERICANS

What Is A Clinical Trial?

Clinical trials are studies that research medications, vaccines, devices or procedures to determine if they are safe and work in people who have diseases such as lupus. These studies may show which medical approaches work best for certain groups of people. People who participate in clinical trials are always volunteers.

Why Participate?

Doctors and health experts agree that all medical treatments need to be studied in diverse populations to make sure that they are safe and effective. This includes African Americans, Latinos, Asians and other minority groups. Because lupus affects everyone differently, lupus clinical trials depend on the help of volunteers like you. Now and for future generations, it is important for African Americans to join studies that search for better treatments and cures for this complex disease.

What Are The Types Of Clinical Trials?

Clinical trials look at new ways to detect, prevent or treat disease. There are various types of trials:

- **Screening** trials focus on finding or improving a test that can find a disease or condition earlier.
- **Diagnostic** trials focus on finding better procedures or tests to diagnose or monitor a specific disease or condition.
- **Prevention** trials focus on vaccines, medications and even lifestyle changes that help prevent diseases.
- **Treatment** trials focus on testing new or existing medications, devices, interventions or treatments.
- **Quality-of-life** (*or supportive care*) trials focus on chronic diseases and look for ways to improve the mental and social impact a disease may have on patients.

Your full understanding of the clinical trial process, your safety, privacy of your medical records and your health are guiding factors of all clinical trials.

But Why Me? Why Should I — As An African American Be Part Of A Clinical Trial?

Participation in clinical trials — specifically lupus trials — is important for you because:

- Lupus is not only more common in African Americans, it is typically more serious.
- African Americans participate at lower rates in clinical trials than other groups.
- African Americans may respond differently to certain treatments than other racial groups. That's why it is critical that African Americans volunteer for clinical trials — to know these drugs will be safe and work in our population.

Are Clinical Trials Safe For Me?

Clinical trials follow a series of steps that are developed to protect YOU as a volunteer participant in the trial. Your full understanding of the clinical trial process, your safety, privacy of your medical records and your health are guiding factors of all clinical trials. There are rules that the government has put in place to protect patients and to make sure that they understand the clinical trial process. Informed consent is the process of providing potential participants with the key facts about a clinical trial before they decide whether to participate.[1]

- ### THE APPROVAL AND OVERSIGHT

  Before a clinical trial can begin, the study is typically approved by a group called an Institutional Review Board or "IRB." An IRB is an independent committee with members who are physicians, scientists, other health professionals and members of the community. The purpose of the IRB is to make sure that the study is safe, that the risks are manageable and known and that the rights and safety of the participants in the trials are protected. The IRB's role is to initially review and approve or deny the proposed trial and then to monitor all clinical trials.[1]

It is important that you have an open discussion with the clinical research team anytime that you have a question or concern.

THE TEAM

Every clinical study is led by a principal investigator — often a physician. Clinical studies also have a research team that is led by a research/study coordinator and may include doctors, nurses, social workers and other health care professionals. Clinical studies can take place in many locations, including hospitals, universities, doctors' offices and in the community. The length of a clinical study varies, and volunteers are told how long the study will last before they enroll.[2]

THE RULES

The clinical trial team must develop and follow a step-by-step plan to carry out the study. This is called the protocol. The purpose of the protocol is to define and explain the specific research area to be studied (the medication, treatment, procedure, etc.) and the way that the research will be carried out. The protocol also focuses on protecting the health and welfare of participants in the study.

The protocol describes:

- Why the study is being conducted
- Who may participate in the trial (eligibility)
- Details about tests, procedures, medications and dosages
- The length of the study and what information will be gathered
- How the information will be used[1]

THE KNOWLEDGE

Informed consent is very important in clinical trials. A clinical trial team works with the volunteer to provide as much information as possible. The informed consent process gives the volunteer the information needed to make a decision about participating in the study — information such as why the trial is being conducted, how long it will last, what the volunteer can expect, the risks and possible benefits of the trial and exactly who to contact with questions or concerns. The informed consent process occurs at the beginning of the trial and throughout the entire process. It is important that:

- Volunteers understand what's involved in the clinical trial and ask questions at any point during the clinical trial process. The clinical trial team will explain the study, and volunteers will be given a document to sign stating that they understand the process.
- Volunteers understand that they can withdraw from the study at any time, even after they sign the informed consent document.

THE RISKS

Clinical trials have potential benefits and risks. It is important to understand both before agreeing to participate in a clinical trial. Possible risks include:

- The medication or treatment may not work in general and/or specifically in you.
- You may not receive the "active" treatment, and instead a placebo.
- There may be side effects.

Your time may also be a factor, as your participation will require frequent visits to the research center. It is important that you have an open discussion with the clinical trial team anytime that you have a question or concern.

What Is Lupus?

LUPUS is a serious disease that causes your body to "fight" against itself. Lupus is three times more prevalent in African American women, but people of all races and genders are diagnosed with the disease. To find out more about lupus visit Lupus.org/Impact

Visit Lupus.org/Impact to find a lupus clinical trial near you.

LUPUS is a serious disease that causes your body to “fight” against itself.

IS A CLINICAL TRIAL Right for Me?

Here are a few important reasons to consider participating in a lupus clinical trial:

1. It is very important for African Americans to participate in clinical trials. Many of the medications and procedures that are currently being used to treat lupus have not been fully studied in African Americans. Participation in clinical trials helps doctors and healthcare providers understand how certain medications, vaccines and procedures work in our population.
2. Your participation in clinical trials can help increase medical knowledge and save or improve lives.
3. Participation allows you to take an active role in your own health.
4. You may be able to benefit from new or improved treatments before they are available to the general public. When you volunteer in a lupus clinical trial, you will have a team of lupus experts who will closely monitor you and are available to give advice, answer questions and provide support as needed.
5. Treatment may come at no cost to you. Be sure to discuss this with the clinical trial team and get a good understanding of what is and is not covered.
6. In some instances, you may be compensated for your participation.
7. Your participation in a clinical trial can also help the overall health of your community by making new drugs and treatments available faster and safer. Your voluntary participation in a clinical trial leaves a legacy to help future generations.

Citations:
1. National Institutes of Health. www.nih.gov
2. Clinicaltrials.gov https://clinicaltrials.gov/ct2/about-studies/learn#WhoConducts

This project is supported by Grant Number 1 CPIMP161122-01-00 from the U.S. Department of Health and Human Services Office of Minority Health. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the HHS, OMH.

FOR MORE INFORMATION, VISIT LUPUS.ORG/IMPACT

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Clinical Trial Education Tools and Resources

Clinical Trial Participation: Key Background and Reference Pages

Name	Description	Link
Get Involved in Lupus Research	Landing page on Lupus.org dedicated to sharing opportunities to engage in lupus research.	lupus.org/advancing-research/get-involved-in-research
Lupus Clinical Research Brochure	A brochure highlighting the importance of clinical trial participation.	lupus.org/s3fs-public/pdf/clinical-trials/CCTEBrochure_National_2020.pdf
***Learn about Clinical Trials and Lupus* - Expert Series Video**	Video highlights different types of research, what you need to understand before agreeing to participate, standard of care during a clinical trial, and associated costs.	lupus.org/clinical-trials/learn-about-lupus-research
Clinical Trial and Lupus Frequently Asked Questions	Frequently asked questions about clinical trial involvement.	Handout: https://s3.amazonaws.com/lupusorgnrcl/IMPACT/Frequently-Asked-Questions-about-Clinical-Trials.pdf On Lupus.org: lupus.org/resources/frequently-asked-questions-about-participating-in-clinical-trials
Points to Consider About Clinical Trial Involvement	An overview of what you should know about participating in a clinical trial.	lupus.org/resources/points-to-consider-before-agreeing-to-participate-in-research
The Ins and Outs of Participating in a Clinical Trial	A resource on what it means to be part of a clinical trial.	lupus.org/resources/the-ins-and-outs-of-participating-in-a-clinical-study
Addressing the Legacy of Distrust in Clinical Trials	An overview of the importance of clinical trial participation and why it can be challenging to find participants.	lupus.org/resources/addressing-the-legacy-of-distrust-in-clinical-trials

Minority Participation in Clinical Trials

Name	Description	Link
Lupus Clinical Trials and African Americans	An overview of the importance of clinical trial participation.	https://s3.amazonaws.com/lupusorgnrcl/IMPACT/You-can-make-a-difference_Lupus-CTs-and-AAs.pdf
Improving Minority Participation in Clinical Trials	A video highlighting the need to increase minority participation in lupus trials.	youtube.com/watch?v=ePR9nMoFX2M&feature=emb_title
FDA's Role in Clinical Trial Diversity	A video discussing why minority participation is important to the FDA.	youtube.com/watch?v=wSjjS7M5jts&index=15&list=PLey4Qe-UxcxbdJTzbekD712YosmrV78uE

Ways to Get Involved in Furthering Lupus Research

Name	Description	Link
RAY: Research Accelerated by You	A lupus data platform where people with lupus and caregivers share information about their lupus experience to help researchers accelerate the development of new treatments and improve disease outcomes.	lupus.org/research/enroll-in-a-lupus-registry
PARTNERS Research Network	A patient-powered research network that brings together children, their families, and health care organizations to improve health care and advance medical knowledge in the field of pediatric rheumatology.	lupus.org/partnerships-and-collaborations/partners-research-network
Featured Research Studies	A page that spotlights key lupus research studies actively looking for volunteers.	lupus.org/clinical-trials/featured-research-studies
Search for Clinical Trials	A quick search function to find clinical trials provided by Antidote.	lupus.org/get-involved-in-research/search-for-clinical-trials
Become an Advocate	Sign up to receive alerts on when you can take action to support lupus research.	lupus.org/advocate/become-an-advocate

Additional Lupus Foundation of America Resources

Name	Description	Link
The Expert Series	A monthly educational video series featuring empowering presentations from leading lupus experts with a focus on helping people live well with lupus.	lupus.org/resources/lupus-the-expert-series

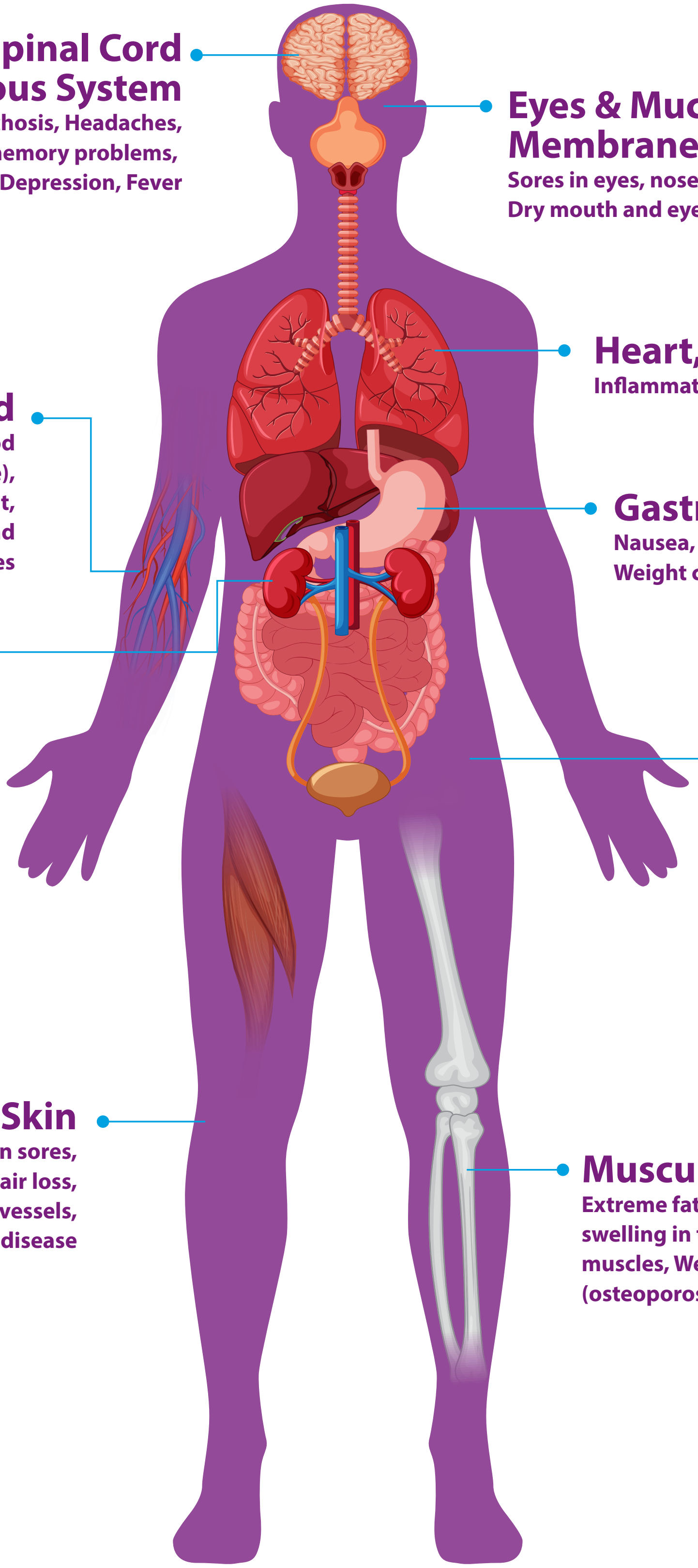
Additional Lupus Foundation of America Resources (continued)

LupusConnect	An online community where members can engage with others to share experiences and find emotional support.	lupus.org/lupusconnect
Take Charge	A 12-week email series designed to help people who have lupus learn how to manage their disease.	lupus.org/take-charge
National Health Educator Network	Our National Health Educator Network is composed of health educators that are specially trained to provide people affected by lupus with non-medical counseling, disease education, information and helpful resources.	lupus.org/care-support/ask-a-health-educator
Support Groups	A safe and understanding environment where people with lupus can come together to ask questions, listen to others, or lend a helping hand.	lupus.org/resources/find-support-near-you

Other Articles of Interest

Name	Description	Link
Study Finds Opportunities to Improve Lupus Drug Trial Participation – Especially Among Minority Groups	An overview of research looking at ways to improve clinical trial participation.	lupus.org/news/study-finds-opportunities-to-improve-lupus-drug-trial-participation-especially-among-minority
Improving Clinical Trial Design	A look at the Foundation's Collective Data Analysis Initiative (LFA CDAI), a first-in-lupus collaboration among multiple companies with a shared goal – to improve clinical trials so we can have an arsenal of treatments needed for people living with lupus.	lupus.org/news/lfa-research-improving-clinical-trial-design

How Lupus Affects the Body



Brain, Spinal Cord and Nervous System
Seizures, Psychosis, Headaches, Brain fog or memory problems, Nerve pain, Depression, Fever

Eyes & Mucous Membranes
Sores in eyes, nose, mouth or vagina, Dry mouth and eyes (Sjögren's syndrome)

Heart, Lungs
Inflammation of heart and lung tissue

Blood
Anemia, Abnormal blood clotting (too much or too little), Low white blood cell count, Circulating autoantibodies and immune complexes

Gastrointestinal
Nausea, Vomiting, Diarrhea, Weight changes

Kidneys
Swelling (especially the legs and face), High blood pressure, Kidney damage and failure

Reproductive System
Pregnancy complications, Miscarriages, Irregular menstrual periods

Skin
Butterfly rash, Skin sores, Light-sensitivity, Hair loss, Inflamed blood vessels, Raynaud's disease

Musculoskeletal
Extreme fatigue, Pain and swelling in the joints and muscles, Weak or brittle bones (osteoporosis)

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Please turn over for more information.

Lupus Foundation of America | To learn more, call 800.558.0121 or visit Lupus.org.

Find Help, Get Answers

National Resource Center on Lupus

A collection of up-to-date resources and information on lupus. The Resource Center educates, empowers and connects you to lupus resources, programs and support services. Visit Lupus.org/Resources to learn more.

Health Education Specialists

Our certified health education specialists are available to answer questions and provide caring support to people with lupus, their families and caregivers. **Visit Lupus.org/HealthEducator** to contact a health education specialist today (in English or Spanish).

Inside Lupus Research

From clinical trials to new treatment breakthroughs, Inside Lupus Research is your one-stop location for learning about all the latest lupus research news that matters to you. Visit Lupus.org/InsideLupusResearch to subscribe today.

Participate in Research

People with lupus and their caregivers can advance lupus research from the convenience of their home by simply sharing their lupus experience using RAY®: Research Accelerated by You. This online registry will help researchers accelerate the development of new treatments and enhance the quality of care for people with lupus. To learn more, visit Lupus.org/RAY.

Local Support & Programs

We provide opportunities to engage locally and participate in education events and support groups dedicated to improving the lives of people affected by lupus.

Our on-the-ground experts can help you find resources, support groups and get involved in the fight to end lupus. Visit Lupus.org/Local-Support.

SELF

The SELF app (Strategies to Embrace Living with Lupus Fearlessly) is our free self-care program for people with lupus that provides customized support in managing symptoms, stress and medications. Visit Lupus.org/SELF to sign up.

Lupus & You: Answers. Advocacy. Action.

Our free educational series offers people with lupus, their families and friends the opportunity to learn about the latest in lupus research and helpful resources for managing the disease. Register at Lupus.org/Lupus-and-You.

Take Charge

This weekly educational email series is designed to introduce people with lupus, including those recently diagnosed, to tips and resources that can help them better manage the disease and its everyday challenges. Sign up at Lupus.org/TakeCharge and find our program en español at Lupus.org/TomeControl.

The Expert Series

Our educational podcast series features empowering episodes from leading lupus experts with a focus on helping you live well with lupus. New episodes are released throughout the year on the National Resource Center on Lupus. Visit Lupus.org/TheExpertSeries.

E-newsletter

Stay connected and sign up to receive our monthly e-newsletter that includes the latest research news and articles on living with lupus. Sign up at Lupus.org.

Social Media

For daily updates on lupus news and information, follow us here:

LupusFoundationofAmerica
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LupusOrg

OCT 2023

RAY®
LUPUS RESEARCH
ACCELERATED
by YOU
Lupus Foundation of America

Share Your Lupus Experience to Help Advance Research

Patient-Powered Research

The **Research Accelerated by You (RAY)** is the Lupus Foundation of America's patient registry that welcomes people with lupus and their caregivers from all backgrounds. RAY® uses an online survey to collect information on the experiences and preferences of people living with lupus. Researchers use the data collected through RAY® to better understand the disease and help connect people with lupus to research and resources that matter to you. Sharing your experiences with lupus may help move research and clinical care forward, including clinical trial design and the development of new therapies to treat lupus.

Compensation is available for people who complete the initial survey.

Learn more at Lupus.org/RAY

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MAR 2023

MAY 2024 //
ANNUAL REPORT

RAY®

LUPUS RESEARCH ACCELERATED by YOU

Lupus Foundation of America

TABLE OF CONTENTS

ABOUT THE LUPUS FOUNDATION OF AMERICA

The Lupus Foundation of America (LFA) is the largest national patient advocacy organization dedicated to improving the lives of individuals affected by lupus through research, patient support, education, and advocacy. With a steadfast commitment to lupus research, the LFA works tirelessly to support scientific initiatives that will identify the causes of lupus, discover better ways to control symptoms, find pathways to new treatments and ultimately a cure. The LFA offers a wide range of services, including educational programs, support groups, and hundreds of trustworthy resources. The Foundation also plays a crucial role in raising awareness about lupus, helping to reduce the time to diagnosis, and fostering a community of hope and empowerment for patients and their families.

SOURCE OF DATA

All data in this report was provided by the participants of the *Research Accelerated by You* (RAY®) lupus registry maintained by the Lupus Foundation of America.

SUGGESTED CITATION

Research Accelerated by You (RAY®) registry
2024 Annual Report - PARTICIPANTS
Washington, D.C.

FIGURE PERMISSIONS

To request use of charts and data provided in this report, contact the *Research Accelerated by You* (RAY®) registry team by e-mail at research@lupus.org.

SPECIAL ACKNOWLEDGMENTS

Those who contributed to the maintenance of the RAY® registry, analysis of data, and creation of this report:

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Safoah Agyemang, MS – Research and Health Outcomes Manager, Lupus Foundation of America

Michael Fisher, PhD, MHSA – Director of Research, Lupus Foundation of America

Patrick Wildman – Senior Vice President, Advocacy and Government Relations,
Lupus Foundation of America

Sara Chang – Senior Director, Advocacy and Government Relations, Lupus Foundation of America

Mike Donnelly – Vice President, Communications, Lupus Foundation of America

Kym Norris – Creative Director, Lupus Foundation of America

HORIZON GSK

We appreciate and acknowledge the generous support of our funders, Horizon Therapeutics and GSK, whose contributions have been critical for the continued success of the RAY registry.

Dear Lupus Warriors and Caregivers,

We are pleased to share the 2024 *Research Accelerated by You* (RAY®) Annual Report. Due to your participation, the longitudinal, interactive RAY registry stands as one of the most robust lupus patient and caregiver data libraries. Launched in 2020, the RAY registry was developed with a clear and noble mission: to amplify awareness about lupus research and clinical trials, demystify the research participation process, and foster an environment of positivity toward clinical trials. Moreover, the registry provides insights on barriers to access that will inform the development of comprehensive, multipronged approaches to expanding access to care.

Today, the registry acts as a guiding resource for therapy development and approval of new treatments, especially under the Patient-Focused Drug Development (PFDD) framework. As an invaluable hub of patient experiences, treatment preferences, patient-reported outcomes, and real-world evidence, the registry is paving a path for a new era in lupus research and access management.

At present, close to 3,000 participants have contributed their personal experiences and insights to one of the most comprehensive lupus databases in existence. Furthermore, over 3,300 participants have enriched our Legacy registry (LFA launched the Research.forMe Registry in 2017). This initial registry sought to create a comprehensive database of people living with lupus who were interested in participating in clinical trials and research studies.

Since then, more than 6,000 lupus warriors have signed up to participate in the registry. Benefits of joining the registry include receipt of information on clinical trials, participation in shaping the pipeline of clinical research and drug development, sharing insights into healthcare access challenges, and participation in LFA's patient-focused drug development initiatives.

We are grateful for your continued contributions to the success of the RAY registry, and most importantly, we thank people living with lupus and their families who share their lupus experiences. Thank you all for your hard work throughout the year and your commitment to the lupus community and the Lupus Foundation of America.

Joy Buie, Ph.D., MSCR, RN
Vice President of Research
Lupus Foundation of America

ABOUT RAY®

RAY is an online patient and caregiver registry dedicated to collecting data from people living with lupus that clearly highlights the experiences of those living with lupus and patient-centric values in drug development and care. RAY is helping expedite the development of new treatments, improve patient outcomes, and contribute to regulatory decision-making and health plan engagement. The RAY platform collects patient-reported longitudinal data, ensuring the perspectives of those affected by lupus play a significant role in advancing lupus research. Furthermore, RAY not only bolsters the Foundation's comprehensive policy efforts but also collects significant data to help assess the efficacy and value of medical treatments. This information plays a key role in shaping insurance coverage policies, providing insights into the root causes of health disparities in lupus, and working to ensure that patients have access to the care they need.

> ***"I participated in a lupus study through the RAY registry. I found it very rewarding to hear others' stories and possible treatment options. I look forward to participating in other studies in the future!"***
>
> – DOUG, RAY Participant

LUPUS FOUNDATION OF AMERICA LED INITIATIVES

Improving Minority Participation and Awareness in Clinical Trials (IMPACT+) Lupus Research Action Network (LRAN) Training

RAY enrollment is a primary outcome measure for the Improving Minority Participation and Awareness in Clinical Trials (IMPACT+) research program which is funded by the Office of Minority Health. RAY has been featured during in-person and virtual training sessions of the Foundation's Lupus Research Action Network (LRAN), a peer-to-peer education and training program designed to increase participation in lupus research and clinical trials. LRAN participants were informed and educated about the RAY registry and learned that participation in RAY provides them access to information on clinical trial opportunities through on-demand resources and targeted information shared with them. LRAN members in training are encouraged to inform peers in their communities about RAY via their own social networks and during other gatherings of the lupus community, such as lupus support groups, educational events, and walks.

RAY SUPPORTED DRUG DEVELOPMENT INITIATIVES

Industry Collaborations

The Lupus Foundation of America continues to partner with industry to fill lupus patient advisory panels, an important part of the clinical trial process, which help to ensure that the patient voice is incorporated at each step. In the past year and a half, participants from the RAY registry have participated in three advisory panels, collaboration councils, and focus groups with different pharmaceutical partners.

RAY®
LUPUS RESEARCH
ACCELERATED
by YOU
Lupus Foundation of America

Take a look at a snapshot of the average lupus experience among the thousands of lupus warriors in ***Research Accelerated by You*** **(RAY®)**. RAY is an online lupus research platform where people with lupus and caregivers share information about their lupus experience to help researchers better understand the disease and accelerate the development of new treatments.

WHO WE ARE

47
Average Age

92%
Women

From all 50 US states
& over 50 countries

RACE

71% White	4% American Indian or Alaskan
16% Black	1% Native Hawaiian/ Pacific Islander
6% Asian	2% Not Specified
2% Other	

ETHNICITY
(HISPANIC/LATINO/SPANISH ORIGIN)
13% Yes

DIAGNOSIS EXPERIENCE

average time to SLE diagnosis
6.5
years

OF HEALTHCARE PROFESSIONALS SEEN PRIOR TO DIAGNOSIS
48%
saw 4 or more

TYPES OF LUPUS*

86.6% SLE
9.3% SLE w/ LN
1.9% SCLE
1.8% DLE
0.4% Drug-Induced

LUPUS TREATMENT EXPERIENCE

MOST COMMON DRUGS TAKEN
NSAIDS, Steroids, Antimalarials

CLINICAL TRIAL PARTICIPATION
71% No 10% Yes
22% Not Specified

LIVING WITH LUPUS

ORGANS/BODY PARTS MOST IMPACTED
Joints
Muscles
Brain
Skin
Eyes

TOP SYMPTOMS
Fatigue &
Joint Pain

IMPACT ON LIVES
46%
have challenges: working, around home, and going to school

TYPES OF LUPUS*
SLE: systemic lupus erythematosus
SCLE: subacute cutaneous lupus erythematosus
DLE: discoid lupus erythematosus
LN: lupus nephritis

We invite people living with lupus and their caregivers to join RAY, see how your experiences compare to others living with lupus and take the important step to help advance lupus research. Visit Lupus.org/RAY to learn more.

May 2024

FIGURE 1.
2024 RAY Infographic

PATIENT-FOCUSED DRUG DEVELOPMENT AND ACCESS TO CARE

Patient-Focused Drug Development (PFDD) is a regulatory initiative that aims to incorporate patient perspectives and experiences into the drug development and regulatory decision-making processes. PFDD seeks to understand the impacts of diseases on patients' lives, identify their treatment priorities and preferences, and assess the benefits and risks of potential therapies from the perspective of patients. Through PFDD, patients are provided a platform to contribute their valuable insights, fostering more patient-centered and informed decision-making at every stage of the drug development and regulatory processes and throughout the broader healthcare system. The RAY® registry focuses on enhancing PFDD by collecting patient preference and experience data directly from people living with lupus in the United States and worldwide.

The RAY registry also collects additional information from people living with lupus, such as demographic and socioeconomic information, experience in clinical trials, and source of insurance to provide a clearer picture of the disease and those living with it (See Figure 1). In addition to contributing their own experiences to RAY, participants are empowered to elevate the patient voice in drug development and regulatory decisions through participation in advisory committees, Food and Drug Administration (FDA) engagement opportunities such as patient listening sessions and the FDA patient representative program, focus groups and other efforts designed to learn more about patients' experiences living with lupus and accessing care and their preferences in treatments, benefit and risk, outcomes and clinical trials. Importantly, the RAY registry enables bidirectional communications and is a vehicle to share information about clinical trials with people with lupus, including communicating directly to people who meet trial eligibility criteria.

The RAY registry has been developed in concert with changes in the policy and regulatory environment, including the evolution of FDA's PFDD program, the development of the four PFDD guidance documents and additional changes focused on trial design and diverse participation in clinical trials. Partnerships have been formed and the RAY steering committee includes people living with lupus, key opinion leaders, and industry experts who help to ensure the RAY registry responds to the perspectives of people living with the disease and the changing regulatory landscape. This ensures that information collected in RAY is meaningful, is representative of the lupus population, and can inform regulatory decision making at every stage of the drug development process, from preclinical to post approval.

DATA FROM THE RAY® REGISTRY

Enrollment

RAY enrollment began August 2020 and was officially launched October 1, 2020. The current total enrollment as of March 31, 2024 is 2,894. Since publishing the 2023 RAY report (June 2023), 915 new participants have been enrolled.

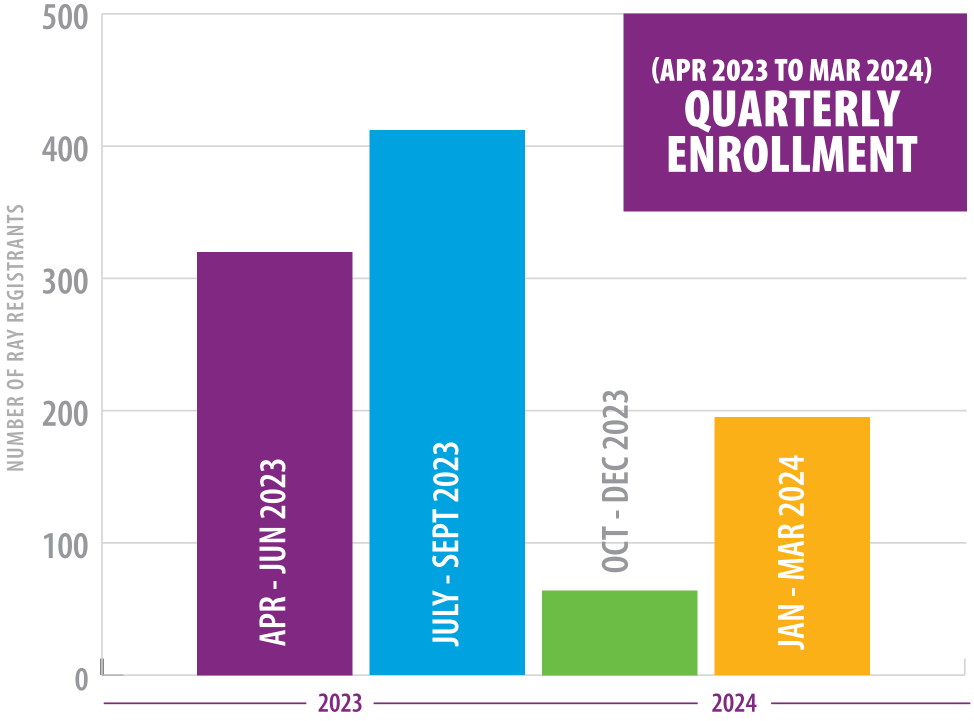


FIGURE 2.
RAY Quarterly Enrollment from April 2023.

GEOGRAPHIC DISTRIBUTION OF RAY® PARTICIPANTS*

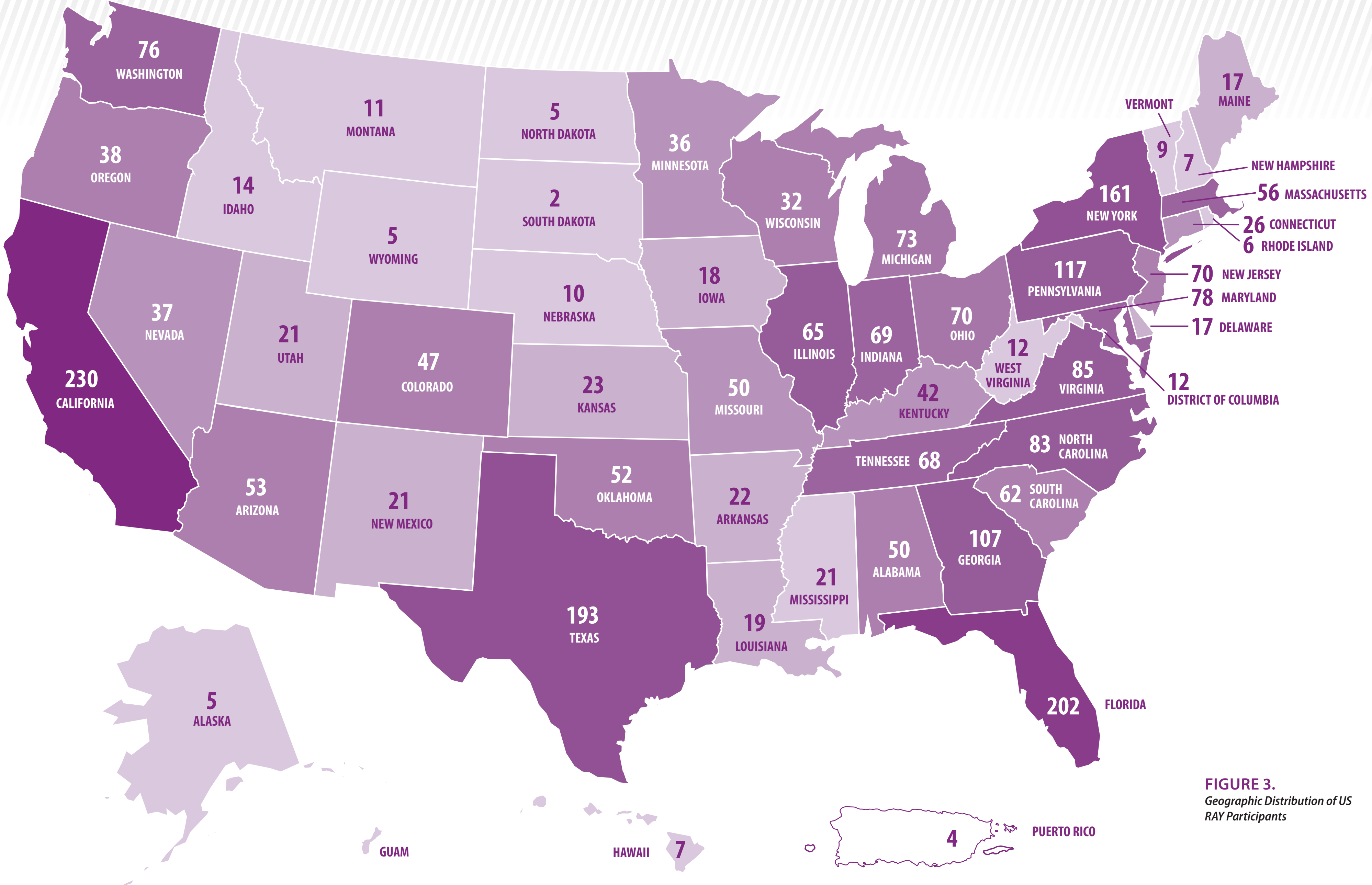


FIGURE 3.
Geographic Distribution of US RAY Participants

*Participants of the RAY registry are located in **all 50 states** – with higher concentrations in states that are popular clinical trial states such as California, Texas, Florida, and New York.

Race & Ethnicity In RAY®

Studies have consistently shown that lupus is more prevalent and more severe among African American, Native American/Alaska Native and Hispanic populations. These communities have a higher prevalence of lupus and more severe lupus nephritis, higher incidence of certain cardiovascular complications, and higher organ damage accrual rates. These populations also tend to experience barriers to treatment, limited access to high-quality, specialized care, and lower medication adherence rates due to negative social determinants of health. Using RAY, the LFA is striving to address these disparities by building a registry that is representative of the population living with lupus. Broad representation ensures that research and drug development efforts benefit those communities facing the greatest burden of disease.

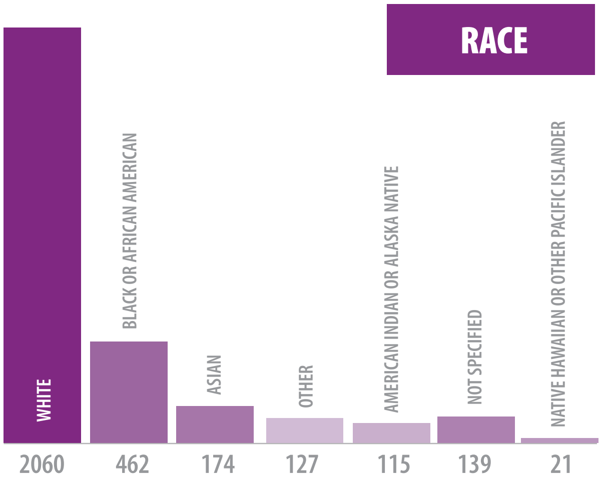


FIGURE 4. *As of March 2024, the RAY registry is comprised of 71% White participants, 16% Black or African American participants, 6% Asian participants, 4% American Indian or Alaskan Native participants, 2% other race participants, and 1% Hawaiian/Pacific Islander participants.*

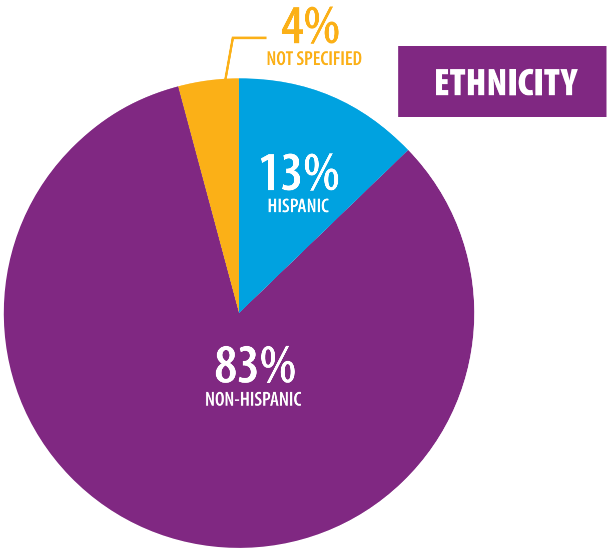


FIGURE 5. *Approximately 388 RAY participants identify as Hispanic, while 2389 do not identify as Hispanic. .*

Employment

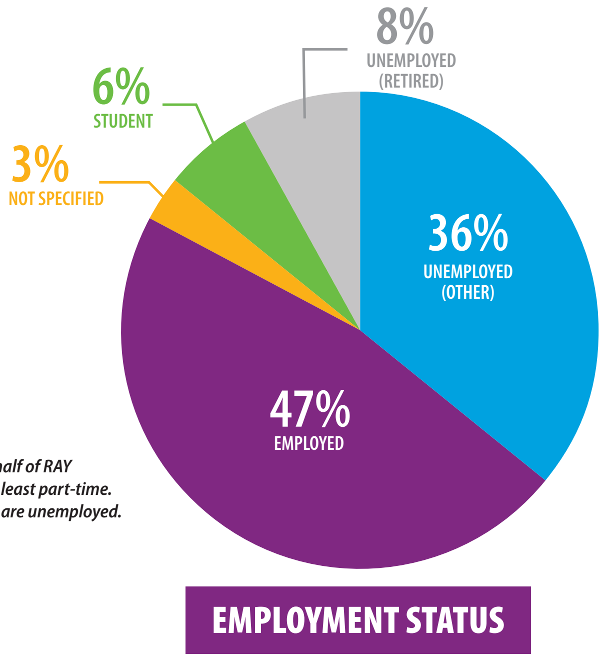


FIGURE 6. *A little under half of RAY participants are employed at least part-time. Whereas approximately 36% are unemployed.*

Reported Symptoms

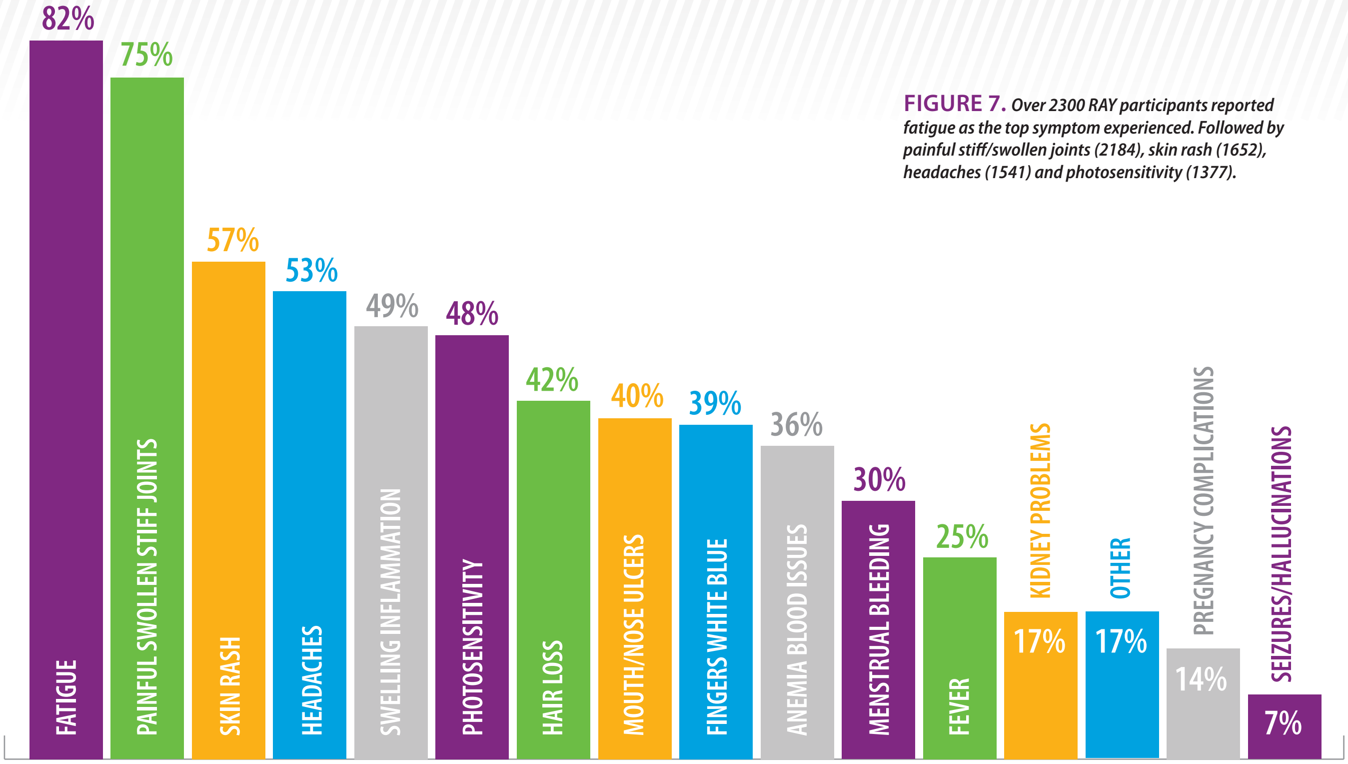


FIGURE 7. *Over 2300 RAY participants reported fatigue as the top symptom experienced. Followed by painful stiff/swollen joints (2184), skin rash (1652), headaches (1541) and photosensitivity (1377).*

Current Medications

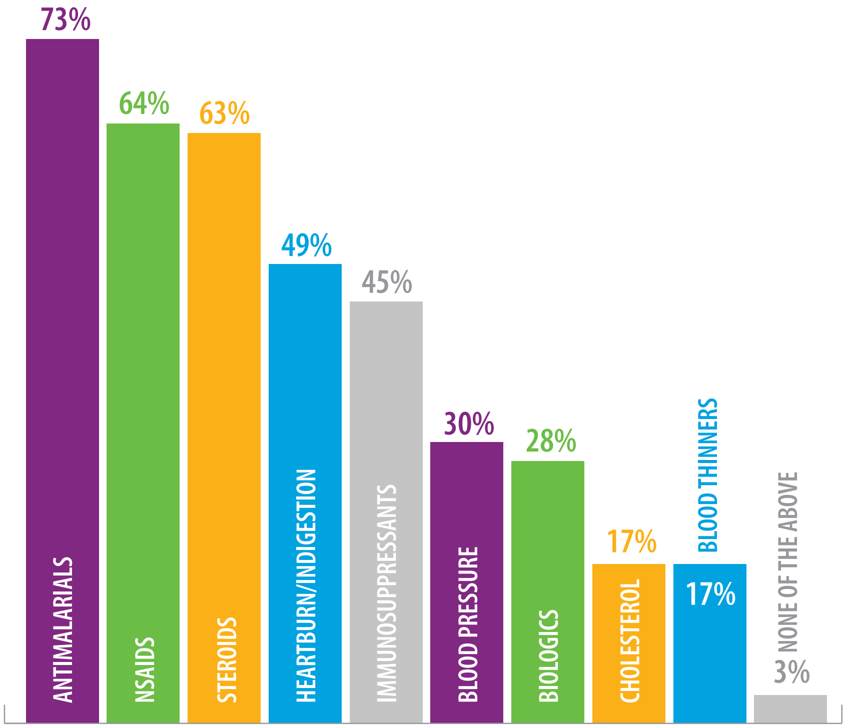


FIGURE 8. *The top three most reported current medications amongst RAY users include antimalarials, NSAIDs, and steroids.*

Clinical Trial Participation Interest

Clinical trial participation is crucial for advancing medical knowledge and improving healthcare outcomes. By participating in clinical trials, individuals contribute to the development of new treatments, medications, and interventions that can potentially benefit future patients. Diverse clinical trials ensure that the benefits and risks of medical advancements are understood across different populations, leading to more equitable and effective healthcare for all.

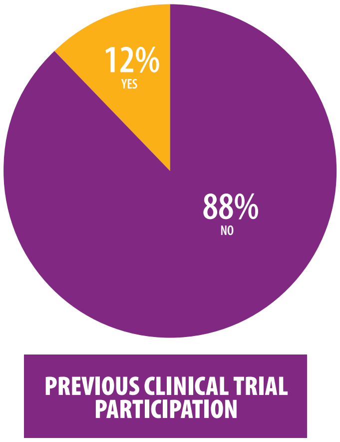


FIGURE 9. *Currently in the RAY registry, about 12% of participants have had some prior clinical trial experience.*

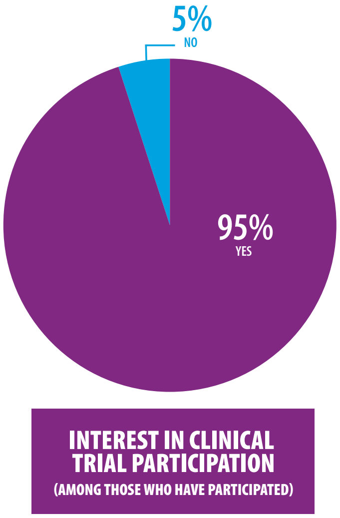


FIGURE 10. *An overwhelming majority (95%) of individuals who have previously participated in a clinical trial would consider participating in another trial.*

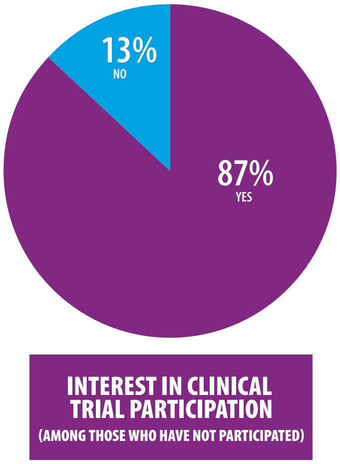
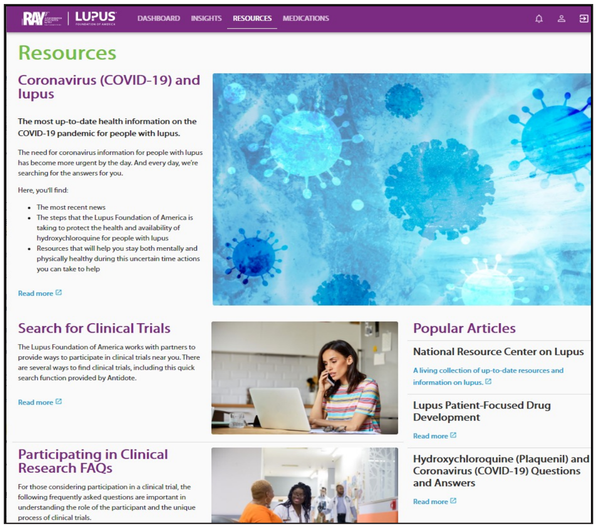


FIGURE 11. *Additionally, 87% of participants who have not previously participated in a clinical trial, would be interested in future participation.*

RESEARCH OPPORTUNITIES THROUGH RAY®

RAY is a critical step to increasing clinical trial participation. The Resources page within the RAY registry aims to provide registry participants with tailored up-to-date information and resources about clinical trial opportunities in their geographic locations, and recent lupus medication and clinical trial news.



Resources

Coronavirus (COVID-19) and lupus

The most up-to-date health information on the COVID-19 pandemic for people with lupus.

The need for coronavirus information for people with lupus has become more urgent by the day. And every day, we're searching for the answers for you.

Here, you'll find:

- The most recent news
- The steps that the Lupus Foundation of America is taking to protect the health and availability of hydroxychloroquine for people with lupus
- Resources that will help you stay both mentally and physically healthy during this uncertain time actions you can take to help

Read more

Search for Clinical Trials

The Lupus Foundation of America works with partners to provide ways to participate in clinical trials near you. There are several ways to find clinical trials, including this quick search function provided by Antidote.

Read more

Participating in Clinical Research FAQs

For those considering participation in a clinical trial, the following frequently asked questions are important in understanding the role of the participant and the unique process of clinical trials.

Popular Articles

National Resource Center on Lupus

A living collection of up-to-date resources and information on lupus.

Lupus Patient-Focused Drug Development

Read more

Hydroxychloroquine (Plaquenil) and Coronavirus (COVID-19) Questions and Answers

Read more

Summary

RAY is a cornerstone program for the Lupus Foundation of America and serves as the premier source of lupus patient information for guiding PFDD and patient-centric research. With our continued work, we will form partnerships with lupus centers across the country to spread awareness about RAY to ensure that no patient is left behind and that every patient's voice is heard by investigators, policymakers, and payers.

Help Us Solve
The Cruel Mystery

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