# Guide to Lupus Resources

## Overview

The Lupus ABC Lupus Voices Council (LVC) met in Bethesda, Maryland for an ideation session where they discussed projects focused on support and education for those living with lupus, their care partners, and other stakeholders encountered throughout the lupus treatment development process. This guide to lupus resources serves as a tool to share information on ways to learn about and potentially get involved in existing projects.

Based on the robust conversation from the ideation session, the Lupus ABC team has organized the ideas into the following categories: Professional Education, Clinical Trial Input, Trial Support Initiatives, and Lupus and Clinical Trial Education and Awareness. Within each of these topic areas, you will find existing resources or projects corresponding to ideas discussed as well as avenues to potentially participate in them.

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# I. Professional Education

Many ideas generated at the LVC meeting were related to Professional Education. In this case, professionals are defined as healthcare workers, academic researchers, and those who provide care to people living with lupus.

## Ideas

- **"Speakers Bureau"** comprised of those living with lupus that go into communities or hospitals/clinics and educate about lupus and clinical trials.

- **Toolkit** for clinicians and their staff on best practices for talking to people with lupus about clinical trials, and discussing protections in place for patients, such as informed consent forms.

## Resources

The American College of Rheumatology's **Lupus Initiative** offers many in-person and online projects that target community centers, hospitals, and clinics to educate people about lupus and clinical trials.

Community Healthcare Worker Programs

Community Health Worker Lupus Clinical Trials Training (LuCTT) Program

Materials to Increase Minority Involvement in Clinical Trials (MIMICT)

They also offer projects targeted toward clinicians/medical staff that educate them on discussing clinical trials with their patients.

Medical School Outreach Project

Materials for Medical Schools

Teaching Fellows in Lupus Project

### Lupus Therapeutics – Patient Visits

Lupus Therapeutics (LT), the clinical affiliate of the Lupus Research Alliance, offers a Patient Visit service where one or many individuals with lupus can visit the headquarters of a biopharmaceutical company to share their story and the importance of advancing lupus treatment development. Please note that grant funding or sponsorship would be needed to further expand this program.

# II. Clinical Trial Input

A number of ideas generated at the LVC Meeting were related to clinical trial input. Specifically, this section explores ideas and resources pertaining to the incorporation of the patient perspective and lived experience in clinical trials.

## Ideas

- People living with lupus **partnering with pharmaceutical companies** and having input on clinical trial protocols and endpoints.
- **Survey or focus groups** to better understand perceived risks and benefits of lupus treatments and what is important to those with lupus in treatment development.

## Resources

The Lupus Therapeutics (LT) Patient Engagement & Education team works with the lupus patient community to offer **Patient Advisory Boards (PABs), the Patient Protocol Review Council (PPRC),** and Patient Visits to pharmaceutical companies. These initiatives include direct communication with companies on their clinical trial materials, study goals, endpoints, and protocols.

While there have been efforts made to capture the patient perspective through surveys, panels, and focus groups, there can be focused conversations within LVC meetings and through other LRA initiatives to gather these insights.

**If interested in getting involved with these LT programs, please fill out this survey created by the LT Patient Engagement & Education team.**

Outside of clinical trial input, eligibility criteria for studies may act as a barrier for those interested in participating in research. If there is a concern about not being eligible to participate in a trial, the LRA does offer the Lupus Landmark Study (LLS), a five-year initiative with minimal eligibility criteria designed to accelerate the development of personalized treatments for those with lupus. To do this, it collects medical information through study visits, online patient survey data, and biological samples, with the goal of building a first-of-its-kind database to better understand lupus and design more impactful research.

# III. Trial Support Initiatives

Trial support, specifically within clinical studies, was a recurrent theme among the LVC. This section provides existing programs directly designed to offer closer connections and support among peers. Other programs listed provide potential assistance for the logistical side of clinical trial participation.

## *Trial Navigation Services*

### Ideas

- **Patient assistance program** (similar to employee assistance program) that can provide resources, contact information, and general support for those participating in a trial.
- Counselors/social workers/patient navigators acting as **liaisons for those participating in a clinical trial.**
- **Clinical trial matching program** to assist individuals with lupus in finding a lupus clinical trial that is best for them, in terms of diagnosis, location, and other preferences.

### Resources

**Counselors/social workers/patient navigators assisting those participating in a clinical trial**

This type of resource is dependent on the individual site's regulations and funding. Some clinical trials may have this support system set up, but it varies between studies. Other variations of patient assistance programs may also exist, but again, are dependent on site funding.

**Clinical trial matching programs**

To better identify clinical trials that fit the individualized needs of the patient population, the LT clinical trials website tab and clinicaltrials.gov are helpful tools.

# III. Trial Support Initiatives

## *Peer Support*

### Ideas

- Patient Advocates for Lupus Studies (PALS) Program – leveraging Trial Buddy program to offer **support to those participating in a clinical trial.**
- **Support group** for people participating in a clinical trial and/or their caregivers.
- **Hotline** run by patient advocates where patients could call to ask questions and receive support if struggling with a clinical trial.

### Resources

The **PALS Program** wrapped up its **successful pilot program** in 2021, and the LT Patient Engagement and Education team has been developing its next phase by expanding the program into 2 components, Early Education and Trial Buddy. Trial Buddy is still being piloted to test out logistics and evaluate its success. Once the team identifies a proper and phased approach for other internal and external entities partnering with the PALS program, this will be shared. Lupus Therapeutics has also discussed a PALS navigator that, if approved and funded, could provide comprehensive assistance and support in the clinical trial space.

While **support groups** centered on clinical trials are not currently available in lupus, there are existing general support groups across many different organizations. Hospital for Special Surgery (HSS) offers free, national lupus support and education programs that provide a safe space for vulnerable conversations in a support group setting. Click on the links below to learn more.

LANtern® (Lupus Asian Network)

SLE Workshop

Charla de Lupus (Lupus Chat)®

Charla Teen, Young Adult & Parent Support Group

The Lupus Foundation of America (LFA) also has many options for support groups across various states. Please note while these spaces are not centered in clinical trial participation, those conversations may be welcomed if individuals want to share their experience or ask questions about clinical trials.

The HSS **LupusLine®** is a peer-support program offering education and support through one-on-one phone conversations. However, please note that this is not specific to clinical research and has generally been used for support.

# III. Trial Support Initiatives

## *Logistical Assistance*

### Ideas

- **"Meals on Wheels"** service to provide transportation, meals, or other basic needs to the patient and their support system while undergoing a trial.
- Uber/Lyft Voucher system that provides **transportation** for those going to their trial site and back home.

## Resources

### Meals on Wheels as a support network

"Meals on Wheels" has not specifically been identified as a service for clinical trial participants; however, Give in Kind and Meal Train are services that family and friends can utilize for the specific and unique needs related to clinical trial participation. Please note this type of activity would be trial-specific and done through the sponsor.

### Uber/Lyft Voucher System

In terms of transportation to and from clinical trials sites, this type of resource is dependent on the individual site's regulations and sponsor funding. Uber does have a program for businesses that allows healthcare visits, and there may be room for expansion with clinical research in the future. Some clinical trials may have this support system set up, but it varies between studies.

# IV. Lupus and Clinical Trial Education and Awareness

The LVC enthusiastically agreed that providing educational resources and tools about lupus and clinical research is a critical step to an individual learning about their disease, its management, and its impact on communities most impacted. This section dives into existing projects, resource hubs, and toolkits that serve to educate and support the lupus patient community.

## *Highlighting Diverse Perspectives*

### Ideas:

- **Educational video campaign** or PSAs that amplify lupus as a heterogeneous disease, featuring patients from different backgrounds and describing how they successfully navigated clinical trials while maintaining current responsibilities.
- **Written testimonials** from those living with lupus who have successfully participated in a clinical trial.

### Resources

The Lupus Foundation of America rolled out a video regarding diverse participation in clinical trials through their "Expert Series." A few videos have also been created on the Lupus Research Alliance YouTube page on clinical trial participation. The LT Patient Engagement and Education (PE) team, in collaboration with the LRA Communications team, has also been working on assets to highlight different perspectives related to clinical trial participation. If LVC members would like to share their clinical trial (CT) experience, LT might be able to promote an educational campaign on CT participation.

**Please contact the Lupus ABC team if interested in making a video about your experience participating in a CT.**

# IV. Lupus and Clinical Trial Education and Awareness

### *Highlighting Diverse Perspectives*

## Resources, continued

In 2023 Fall, the LRA unveiled their 5-year strategic plan – one striving to have a world free of lupus. As part of the initiatives in this strategic plan, the organization plans to amplify/raise awareness of lupus and its impact through new and existing programs/initiatives in the coming years. The LRA YouTube channel features videos and testimonials about living with lupus. The PALS program also has a set of handouts that discuss the signs and symptoms of lupus, how lupus is treated, and the need for lupus clinical research. Additionally, Lupus Therapeutics (LT) has future plans to develop short videos or animations on lupus for medical school programs. The LFA also has an impactful video and several personal accounts on their YouTube channel showcasing the heterogeneity of lupus.

**Please contact the Lupus ABC team if you are interested in participating in an advisory or review committee for upcoming communications assets for LT.**

The LFA website features many written testimonials from those living with lupus. Antidote and The Center for Information and Study on Clinical Research Participation (CISCRP) have also shared testimonials of people living with lupus and participating in research. Additionally, the LT website will be featuring a community perspectives page in the near future where those living with lupus can share about CT experiences.

**Please contact the Lupus ABC team if interested in sharing a written testimonial on the LT website about your experience participating in a CT.**

### NMQF Beyond Lupus Empowerment Toolkit

Developed by the National Minority Quality Forum (NMQF), the Beyond Lupus Empowerment Toolkit offers culturally responsive, easy-to-understand resources to support people living with lupus. The toolkit includes videos, fact sheets, and guidance designed to help individuals make informed decisions about lupus care and participation in clinical trials. Visit the toolkit here.

# IV. Lupus and Clinical Trial Education and Awareness

## *Highlighting Resource Sharing*

### Ideas

- **Education portal** to share resources.
- Patient advocacy organizations **sharing information** about clinical trial phases and lupus treatment development to address lack of knowledge on trials.
- **Toolkits** for:
  - Those with lupus and their care partners aiming to **demystify clinical trials** and address historical mistrust of clinical research.
  - Those with lupus showing how to best navigate a clinical trial, **communicate with a provider** about trials, and feature testimonials from others with lupus who have participated in trials.
  - Friends/colleagues in the network of the person living with lupus that **explains lupus** and clinical trials more generally.

## Resources

### Resource Centers

The Lupus Initiative has a resource hub on lupus disease management. Videos, testimonials, and resources are shared on this site. The LT site will also be featuring a resource hub specific to clinical trials in the near future. Information regarding trial phases is part of the LT website, along with new releases on research advances on the LRA and LT websites.

The LFA has a helpful search feature for support-related resources on their website and a regular email series with tips on managing lupus. They also have an educational series where people with lupus and their family/friends can learn more about the latest in lupus research and managing the disease. There are several resources from NIAMS, the CDC, ACR, and LRA that explain lupus, its causes, and symptoms in more detail.

# IV. Lupus and Clinical Trial Education and Awareness

## *Highlighting Resource Sharing*

## Resources, continued

### Research-focused Information Sharing

Information regarding trial phases is part of the **LT website**, along with new releases on research advances on the LRA and LT websites. The Lupus Initiative features the **MIMICT Project**, which helps clinical trials sites and providers collaborate to deliver accurate, trusted, and understandable information to people with lupus. ACR has also released **guidelines** for treating SLE and most recently, Lupus Nephritis. Additionally, LFA shares research updates on their **website**.

### Clinical Research Participation and Navigation

The LRA YouTube channel features **stories** about navigating trials. LT is also working on a video series that highlights how to communicate with a provider about clinical research. CISCRP has an **FAQ** on clinical research participation and resources for various communities of color on these topics.

The LFA has a helpful **FAQs page** on clinical trial participation. LRA also has a **Community Education toolkit** that features English and Spanish resources.

# V. Resources At-A-Glance

This Guide to Lupus Resources provides many resources. Below is a list of all resources linked throughout the guide grouped by organization/society or general theme.

## American College of Rheumatology

- Community Healthcare Worker Programs
- Community Health Worker Lupus Clinical Trials Training (LuCTT) Program
- Materials to Increase Minority Involvement in Clinical Trials (MIMICT)
- Medical Schools Outreach Project
- Self-Management Tools for People Living with Lupus
- Materials for Medical Schools – The Lupus Initiative
- Teaching Fellows in Lupus Project
- ACR guidelines for treating SLE

## Hospital for Special Surgery

- LANtern® (Lupus Asian Network)
- SLE Workshop
- Charla de Lupus (Lupus Chat)®
- Charla Teen, Young Adult & Parent Support Group
- LupusLine®

## Lupus Foundation of America

- Video: Participating in Clinical Trials
- Video: What is lupus?
- National Resource Center on Lupus
- 12-week email series on managing lupus
- LFA News
- Lupus & You - educational series
- Personal Stories of living with lupus
- FAQs page – clinical trials
- RAY: Research Accelerated by You

## Lupus Research Alliance and Lupus Therapeutics

- Lupus Research Alliance website
- PALS Program Overview
- PALS publication on successful pilot program
- Lupus Clinical Trials Q& A Video
- Patient Advisory Boards (PABs)
- PAB Interest Survey
- Patient Protocol Review Council (PPRC)
- Community Education toolkit
- Lupus Clinical Trials Information
- Lupus Therapeutics website
- Clinical Trials FAQ
- Lupus Landmark Study

## Additional Resources

- General Lupus Education Resources from NIAMS, CDC, & ACR
- CISCRP – Definitive Guide to Clinical Research
- Clinicaltrials.gov
- Logistical Resources: Give in Kind, Meal Train, Uber
- NMQF – Beyond Lupus Empowerment Toolkit

LUPUS
ACCELERATING
BREAKTHROUGHS
CONSORTIUM

# VI. Acknowledgments

## Thank You & Acknowledgments

The Lupus ABC team is appreciative of the collaborative effort and ideas from the Lupus Voices Council. It is our hope that this guide to lupus resources may be utilized to learn more about existing projects designed to offer support and knowledge to those living with lupus and other key partners in the lupus treatment development space. Additionally, if you have any question about anything linked or featured in the guide or want to learn more, please do not hesitate to contact the Lupus ABC team.

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The **Lupus Accelerating Breakthroughs Consortium (Lupus ABC)** is a public-private partnership with the U.S. Food and Drug Administration (FDA) that unites individuals with lupus and their advocates, industry, clinicians, researchers, and other key partners to identify and pursue the most effective ways to accelerate lupus drug development. Visit LupusABC.org for more information.

The **Lupus Voices Council (LVC)** is made up of people living with lupus, caregivers, family members, and other members of the lupus community. The LVC is responsible for providing the Lupus ABC Research Committee with the perspectives and needs of individuals with lupus, including the symptoms and experiences that matter most.

**For more information about Lupus ABC or LVC, contact:**

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