

## The LRA Initiates a Public-Private Partnership with FDA to Accelerate Lupus Drug Development

The **Lupus Research Alliance** (LRA) has joined with the **Food and Drug Administration** (FDA) in a public-private partnership to accelerate the pace of lupus drug development. Through the newly created **Lupus Accelerating Breakthroughs Consortium** (Lupus ABC), the LRA will convene the many lupus stakeholders from academia, industry, government, including the FDA, medical societies, those living with lupus, and advocacy groups to advance the development of urgently needed, personalized treatments for lupus.



The new initiative is founded on the shared commitment to actively engage patients as stakeholders—pointing the way to a dramatic reset of the way lupus clinical research is approached and conducted.

*“It took many hands to get us to this juncture,”* said LRA President and CEO, **Albert T. Roy** when he announced the formation of the consortium on March 23, 2023. *“The Lupus ABC will make lupus drug development faster, more efficient, and ultimately more beneficial to the people who need it most.”*

The Consortium adds to a long list of LRA research advances—essential building blocks that led to the development of three FDA-approved lupus therapeutics. While these drugs have made a world of difference to many, much more work is needed to overcome the debilitating symptoms and significant health risks experienced by people living with lupus, each of whom are affected by the disease differently.

### CHANGING THE NARRATIVE

*“The Lupus ABC was formed precisely to increase the speed with which new therapies can be made available to everyone at risk—particularly women from Black and Hispanic communities,”* said **Gary Koretzky, MD, PhD**, Lupus ABC Research Committee Co-Chair as well as Vice Provost for Academic Integration and Professor of Medicine at Weill Cornell Medical College.

Lupus ABC has two interlocking aims **1)** define the barriers that impede successful drug development, and **2)** develop and implement collaborative solutions with the greatest potential to:

- ▶ **Better evaluate the impact of potential treatments**—We’re refining existing measurement tools now used in clinical research to assess a drug’s effectiveness more adequately.
- ▶ **Fully incorporate patients’ voices into drug development**—We’re putting greater emphasis on prioritizing patient perspectives to improve the development of treatments.

### ACKNOWLEDGING PATIENTS AS STAKEHOLDERS

The Lupus ABC aims to shift the clinical trial paradigm by giving patients and caregivers a platform where they can be heard as equal stakeholders. *“As someone who has lived with the disease for many years, I know that having a voice in this process is immensely important,”* said **Veronica Vargas Lupo**, co-lead of the Consortium’s **Lupus Voices Council**. *“It is critical for our perspectives to be considered when designing clinical trials and measuring outcomes to develop tailored therapies in lupus.”*

The Consortium gives people living with lupus the opportunity to share their expertise and experiences with doctors and researchers. And this representation is a crucial step in accelerating advances in lupus treatments.

The formation of this partnership represents a turning point in the LRA’s efforts to address unmet needs in lupus treatment. *“This first-of-a-kind endeavor marks the beginning of an exciting new era in lupus research,”* said LRA President and CEO **Albert T. Roy**. *“With the FDA—and support from our family of steadfast donors—we’re picking up the pace of development for more safe and effective treatments, offering relief to the broadest number of people, and ultimately, fulfilling the promise of a cure for lupus. This truly is a momentous moment.”*

### IN THIS ISSUE

The LRA Initiates a Public-Private Partnership with FDA to Accelerate Lupus Drug Development	1
2022: A Year of Bold, New Advancements in Lupus Research	2-3
Where There’s a Will ...There’s a Way to Advance Discovery	4

# 2022: A Year of Bold, New Advancements

**Keeping Lupus Research Front and Center**—In 2022, the LRA made remarkable progress on many fronts by **investing more, discovering more, and delivering more** to those most affected by lupus.

Illustrating the power of compassion, the following is a sampling of the LRA's extraordinary success in catalyzing exciting new developments in research—thanks to the generosity of its supporters:



- ▶ **The LRA awarded \$18.3 million to the world's most pioneering lupus research**—investigations that are understanding more about the underlying causes of lupus and heterogeneity ... identifying pathways to target with potential treatments ... and evaluating the safety and efficacy of new investigational therapeutics.
- ▶ The year saw **FDA approval of belimumab—the first and only treatment for children whose lupus has attacked their kidneys**. The LRA is proud of this milestone—and our role in funding early research that contributed to the development of this treatment.
- ▶ Our funding of CAR T Cell Therapy helped lay the foundation of a **small clinical trial that induced lupus remission** in five patients who had not responded to standard treatments.

**ADVOCATE  
FOR LUPUS  
RESEARCH  
2023**



## ADVOCATING FOR GREATER GOVERNMENT SUPPORT

In a virtual training, 151 people—representing 115 Congressional Districts—learned about becoming effective lupus research advocates by participating in the **Take it to the Hill to Advocate for Lupus Research** program throughout March.

The participants were asked to schedule meetings and ask their members of Congress to:

- **Allocate** \$15 million for the Lupus Research Program operated under the Defense Health Program.
- **Increase** funding to the National Institutes of Health to at least \$51 billion to fund research to fight diseases, including lupus.
- **Co-sponsor** The DIVERSE Trials Act to increase diversity in clinical trials and make it easier for all people with lupus to participate.

## TWO ONLINE CALLS TO TAKE ACTION

1. The LRA set up the **Legislative Action Center** on its website so that even more advocates could participate—and 79 individuals reached 67 members of the House of Representatives and 45 senators.
2. Each year, members of the House of Representatives are asked to sign a letter organized by the **Congressional Lupus Caucus** to the Appropriations Committee leadership. Over the course of a week, emails were sent by 131 advocates to 86 members of the House of Representatives. Fifty-five representatives signed the letter.

If you would like to learn more, visit **Action Center - Fighting Lupus | Lupus Research Alliance**  
[www.lupusresearch.org/advocate/action-center/#/50/](http://www.lupusresearch.org/advocate/action-center/#/50/)

# ments in Lupus Research

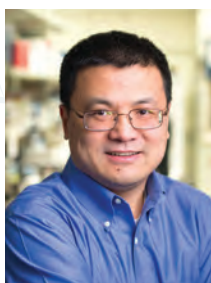
## PAVING THE WAY TOWARD PERSONALIZED MEDICINE –

Initiated in 2022, the LRA's largest research investment, the **Global Team Science Award**, was granted to three outstanding international research teams from 14 institutions across four continents. With \$3 million in funding, each team has made headway in exploring why lupus differs from person to person—with the end goal of tailoring a treatment approach specific to each patient.

## GLOBAL TEAM SCIENCE AWARD

## RECOGNIZING EXTRAORDINARY CONTRIBUTIONS TO LUPUS RESEARCH –

The two outstanding recipients of the **2022 Distinguished Innovator Award** were **Hongbo Chi, PhD** and **Joseph Craft, MD**. They received the award in order to further their groundbreaking T Cell work to uncover disease mechanisms and drug targets for innovative treatments of lupus.



Hongbo Chi, PhD,  
St Jude Children's Hospital



Joseph Craft, MD,  
Yale School of Medicine

## CONDUCTING OUR OWN CLINICAL TRIALS –

The LRA recognizes the importance of partnering closely with the biopharmaceutical industry to advance lupus drug development with the goal of enabling patient-centric therapies to improve lupus clinical care. Hence the formation of the clinical trial affiliate, **Lupus Therapeutics**, which has partnered with 19 biopharmaceutical companies for 25+ studies and continues to bring new opportunities to the **Lupus Clinical Investigators Network** (LuCIN).

## DRIVING EQUITABLE AND INCLUSIVE PATIENT-FOCUSED RESEARCH –

On January 27, 2022, the LRA announced that it would take the lead on two fronts to eliminate fundamental barriers that prevent underrepresented groups from getting involved in lupus clinical trials and seeking careers in lupus scientific research.

Clinical affiliate Lupus Therapeutics, in partnership with LuCIN, officially launched **Project CHANGE** to increase meaningful, equitable, and supported clinical trial awareness, participation, and engagement among African Americans diagnosed with lupus.

And throughout the year, the LRA's **Diversity in Lupus Research Program**—in an effort to support research pathways for minorities—worked to alleviate the lagging representation of minorities in scientific research through ... various grant mechanisms.

## LUPUS THERAPEUTICS UNDER NEW LEADERSHIP

The LRA is pleased to announce the appointment of **Stacie J. Bell, PhD** as Executive Vice President of Lupus Therapeutics—the organization's clinical research arm.



Dr. Stacie J. Bell

Dr. Bell is an accomplished research scientist and organizational leader with more than 25 years experience in discovery research, clinical development, and patient engagement. More recently she formed and served as CEO and President of the Global Nutrition Project.

Earlier, Dr. Bell served as chief scientific and medical officer leading the Research & Medical Affairs department at the National Psoriasis Foundation.

*"Dr. Bell brings exactly the right blend of academic, pharmaceutical, and nonprofit experience to guide Lupus Therapeutics to new heights. With her deep knowledge of evolving science and technology, as well as her ability to galvanize an impassioned patient community, Dr. Bell possesses all the skills to propel our vision—addressing urgent unmet medical needs and one day, eradicating lupus."* commented **Albert T. Roy**, LRA President and CEO and former Executive Director of Lupus Therapeutics.

**Welcome aboard, Dr. Bell!**

## Where There's a Will ... There's a Way to Advance Discovery

LRA donors have transformed the organization into the world's largest private funder of lupus research. But if LRA donors mirror the general population, nearly two-thirds of them do not have estate plans and are missing a valuable opportunity to protect the people and causes they care about.

This is why the LRA is pleased to announce that we have partnered with **FreeWill**—an estate planning tool that is 100% free to create a legal will. So if you choose to designate a legacy gift to the LRA to propel lupus research well into the future, it will be at no cost to you.



## Other Ways to Leave a Legacy Gift

There are many ways to leave a legacy gift and some of them may provide financial and tax benefits to you and your family. **A Charitable Gift Annuity** and a **Charitable Remainder Trust**, for example, can provide income to you and/or your beneficiaries.

Gifts of land, vacation homes, art, and IRAs can all be part of a person's estate planning.

There are many options, but all planned gifts make use of legal and tax strategies and/or financial products and usually require a donor to utilize the assistance of a professional.

If you would like more information, please email [plannedgiving@lupusresearch.org](mailto:plannedgiving@lupusresearch.org)



Visit [lupusresearch.org](http://lupusresearch.org) to make a donation, learn more about lupus and our funded lupus research, or find out about our *Walk with Us to Cure Lupus* program.



ManyOne Can.  
**walk** WITH US  
TO CURE LUPUS

100% of all donations goes to support lupus research programs because the Lupus Research Alliance Board of Directors funds all administrative and fundraising costs.

For the latest, up-to-date information about lupus you can join our online community on:

 [facebook.com/lupusresearchalliance](https://facebook.com/lupusresearchalliance)

 [twitter.com/lupusresearch](https://twitter.com/lupusresearch)

 [youtube.com/lupusresearchorg](https://youtube.com/lupusresearchorg)

 [pinterest.com/lupusresearch](https://pinterest.com/lupusresearch)

 [instagram.com/lupusresearchalliance](https://instagram.com/lupusresearchalliance)

 [lupusresearch.org/community](http://lupusresearch.org/community)



©2023 Lupus Research Alliance. All Rights Reserved. Lupus Research Update is published by the Lupus Research Alliance. Contents herein may not be reproduced, republished, or distributed without the prior written permission of the Lupus Research Alliance. To request permission to reproduce, republish, or distribute any part of this newsletter, contact us at **212-218-2840** or email [info@lupusresearch.org](mailto:info@lupusresearch.org).