Journey to Better Health

AWARE for All | New York City

Thursday, May 19th, 2022
5:00-8:00 PM
New York Academy of Medicine

Program Handbook

5:00 PM:
The Informational Exhibit Center Opens

6:00 PM:
Welcome & Opening Remarks

6:10 - 6:30 PM:
Clinical Research Overview Presentation + Q&A

6:30 - 7:30 PM:
Panel Discussion

7:30 - 7:45 PM:
Closing Remarks & Raffle

CISCRP

www. ciscrp.org . One Liberty Square, Suite 1100 . Boston, MA 02109 . awareforall@ciscrp.org

FEATURED SPEAKERS

ASHLEY GIACOBBI

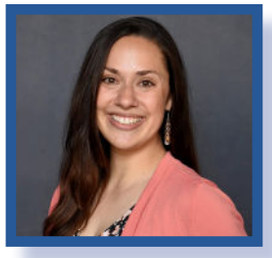
Clinical Trial Nurse Navigator,
Clinical Trial Support Center,
Leukemia & Lymphoma Society

PANKAJ PATEL

Head of Diversity and
Inclusion for Clinical Trials,
R&D, IQVIA

SHIRA KAPLAN-WALKER

Lupus Clinical Trial
Participant



ELLYN GETZ

Director, R&D Patient Partnerships,
R&D Strategic Operations,
CSL Behring

MAKEIDA STUBBS

Clinical Trial Diversity
Operations Lead, Pfizer

Dear attendees, supporters, and friends, May 19, 2022

Welcome to Journey to Better Health | *AWARE for All – New York*. Today serves as an important milestone in building awareness about clinical research participation and the crucial role that clinical research volunteers play in advancing new treatments.

We are very grateful to our AWARE Industry Consortium: Biogen, CSL Behring, Eli Lilly, EMD Serono, IQVIA, Janssen, Otsuka, Pfizer, and WCG.

Thank you to our outreach partners, All of Us, Alzheimer's Association, Christopher and Dana Reeve Foundation, Columbia Research Unit, Columbia University Herbert Irving Comprehensive Cancer Center, Harlem United, ICAP at Columbia - Harlem Prevention Center, Leukemia & Lymphoma Society, Lung Cancer Research Foundation, Lupus Research Alliance/Lupus Therapeutics, National Ovarian Cancer Coalition, New York Academy of Medicine, The Tisch Cancer Institute, and all our local supporters. Be sure to visit their booths in the Informational Exhibit Center!

The warm response this program has received from the New York Community has been encouraging and convinces us even more of the important need this program fills. With the assistance of our valued community partners, brochures were distributed, flyers were shared, and announcements and articles were included in newsletters and on websites throughout the region.

We are also very grateful to today's researchers for sharing their knowledge and expertise with *AWARE for All* attendees. In addition, we would like to thank our study participant panelists whose personal stories are captivating, powerful, and inspirational.

To continue the conversation and learn about other helpful resources, we encourage you to visit www.ciscrp.org.

Kind regards,

Ken Getz
Founder & Board Chair
CISCRP

Joan A. Chambers
Senior Director, Marketing & Outreach
CISCRP

Hope Ventricelli
Senior Manager, Community Events & Programs
CISCRP

Justine Holleran
Senior Coordinator, Community Events & Programs
CISCRP

Key Community Supporters & Exhibitors

We encourage you to visit our valued exhibitors in the Informational Exhibit Center to learn more about their work and to review their resources.

Organizations

- All of Us Research Columbia
- Alzheimer's Association
- Biogen
- Christopher & Dana Reeve Foundation
- Columbia Research Unit
- Columbia University Herbert Irving Comprehensive Cancer Center
- CSL Behring
- EMD Serono
- Eli Lilly
- Harlem United
- ICAP at Columbia- Harlem Prevention Center
- IQVIA
- Janssen
- Leukemia & Lymphoma Society
- Lung Cancer Research Foundation
- Lupus Research Alliance & Lupus Therapeutics
- National Ovarian Cancer Coalition
- New York Academy of Medicine
- Otsuka
- Pfizer
- The Tisch Cancer Institute at Mount Sinai
- WCG

THANK YOU!

MEDICAL HERO SPOTLIGHT

Meet Medical Hero Richie Kahn:

Wolfram-like Syndrome Advocate

Richie Kahn shares, "I am a public health professional by training, and a clinical researcher by trade. I was working in full-service ophthalmology, developing new products for the eye, when I found out I was losing my vision."

The diagnosis of glaucoma was initially confirmed through exams with an optometrist and an ophthalmologist who specializes in the disease. The ophthalmologist said that the good news was that they knew what Richie had, and the better news was that there were excellent treatment options available.

At an industry conference in the autumn of 2019, Richie met a key opinion leader (KOL) in the glaucoma field, who invited Richie to meet with him to review his case. This was the third medical opinion Richie had sought. Richie's care team had performed the necessary screenings and followed treatment guidelines for glaucoma. In that appointment, Richie received disturbing news.

"With relatively few signs and symptoms, I had lost about 15% of my vision," says Richie. "That was the first indicator that what I had was not, maybe, so clear-cut."

Richie's optic nerve was pale, and the doctor was concerned. Tests were conducted to determine whether Richie had suffered a series of small strokes or had a tumor. Just after Thanksgiving in 2019, the test results came back negative. The KOL recommended that Richie confer with a neuro-ophthalmologist that was in the same building. After a lengthy appointment that didn't provide any further insight, the neuro-ophthalmologist recommended genetic testing.

In late February of 2020, just before the global pandemic began shutting down the US, Richie received more unsettling news, via a phone call with the neuro-ophthalmologist.

"I could hear from the tone in this doctor's voice, he was not familiar with the diagnosis he was sharing," says Richie. The doctor told Richie that the genetic tests indicated that he had Wolfram Syndrome, and that he should meet with a genetic counselor. Richie asked for his test results and he started researching the disease on his own.

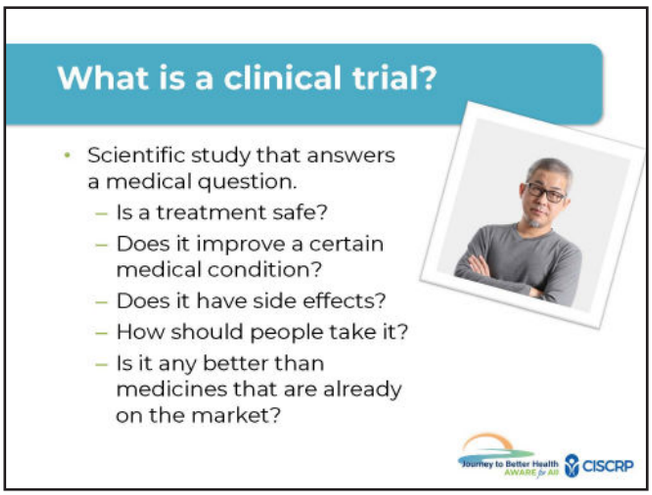
NORD (National Organization for Rare Disorders) describes Wolfram Syndrome, in part, as "...an inherited condition that is typically associated with childhood-onset insulin-dependent diabetes mellitus and progressive optic atrophy. The symptoms and rate of progression of Wolfram Syndrome can be quite variable. Neurological symptoms such as poor smell, poor balance, an awkward, unbalanced way of walking (ataxia) and central sleep apnea can occur." It also impacts the brain stem and affiliated critical bodily functions, including breathing.

Richie decided to contact the KOL on Wolfram Syndrome, Dr. Fumihiko Urano, MD, PhD, of the Washington University School of Medicine in St. Louis, Missouri, and received a response. A meeting was scheduled with Richie, his wife, Dr. Urano and the clinical research nurse. Dr. Urano determined that Richie did not have Wolfram Syndrome but had Wolfram-like Syndrome.

To read more of Richie's story and access other Medical Hero articles, click here.

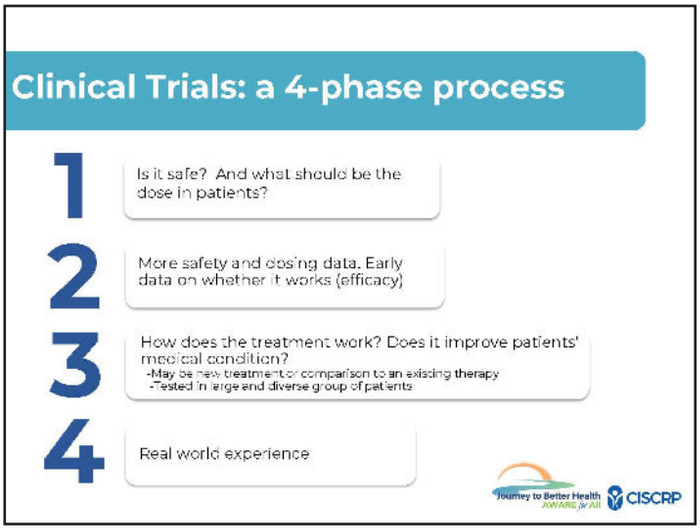
- Welcome to Journey to Better Health | *AWARE for All - New York City.*
- This program is brought to you by CISCRP, the Center for Information and Study on Clinical Research Participation, with support from local organizations.
- Our goal is to help you understand the clinical research process – including the risks and benefits of participating.

- People everywhere are living longer and healthier lives because of the individuals who take part in clinical trials. These trials help find ways to prevent and treat certain medical conditions. We like to call the participants “Medical Heroes.”



- Gender, age, and ethnicity affect the way people respond to diseases and treatments.
- For many years, most clinical trials included white men only. This meant that the information collected in those trials was not complete and could not tell us how treatments affected other groups.

- Today, federal guidelines and ethical practices are in place to monitor the safety and protect the rights of trial participants.
- Health professionals are aware of the need to have diverse populations in clinical research. As a community, we are taking steps to break down participation barriers, improve diversity, and pave the way to a healthier future for everyone.


Clinical Trials: a 4-phase process
1
Is it safe? And what should be the dose in patients?
2
More safety and dosing data. Early data on whether it works (efficacy)
3
How does the treatment work? Does it improve patients' medical condition?
-May be new treatment or comparison to an existing therapy
-Tested in large and diverse group of patients
4
Real world experience
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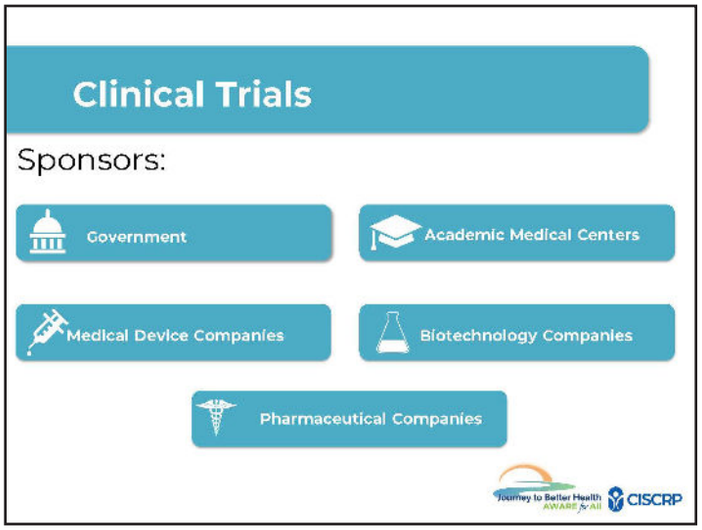
Clinical Trials
Sponsors:
Government
Academic Medical Centers
Medical Device Companies
Biotechnology Companies
Pharmaceutical Companies
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Part 2: The Research Team and Informed Consent
All members of the team are important
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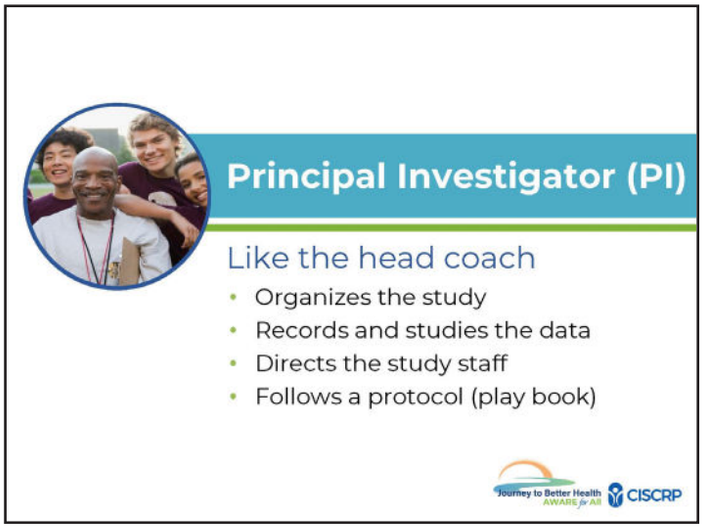
Principal Investigator (PI)
Like the head coach
Organizes the study
Records and studies the data
Directs the study staff
Follows a protocol (play book)
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Clinical Research Coordinator (CRC)

Like the assistant coach

- Handles day-to-day activities
- Works with principal investigator (PI)
- Main contact for volunteers

Volunteer Protections

Like the referees

- Review the study before it starts
- Make sure the team follows the rules
- Keep you safe and informed

Volunteer Protections

Institutional Review Boards (IRB)

- Make sure a trial is ethical and fair
- Make sure a trial is not too risky for volunteers
- Receive continuous updates on trial status
  - Serious side effects from study drugs
  - Change in study plan
- Can end a trial if it feels volunteers are not safe

Volunteer Protections

Food and Drug Administration

- Reviews studies
- Inspects research centers
- Monitors research groups
- Has the final say as to whether or not a treatment is approved


Volunteers
Like the players
• The MOST important team member
• Wide range of studies available (clinicaltrials.gov)
• Healthy volunteers needed too!
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Eligibility Criteria
Who is the right player for the game?
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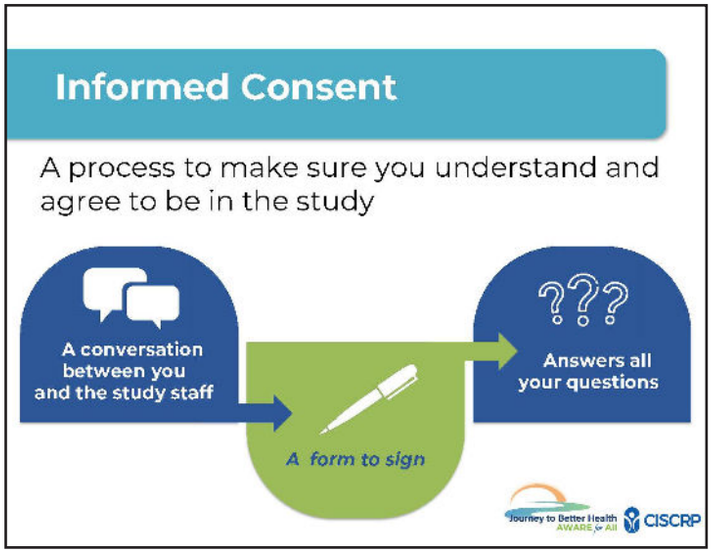
Informed Consent
A process to make sure you understand and agree to be in the study
A conversation between you and the study staff
A form to sign
Answers all your questions
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You have rights and responsibilities
To understand the study
To ask questions and get answers
To quit at any time
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Part 3: Should I or Shouldn't I?
What's right for me?
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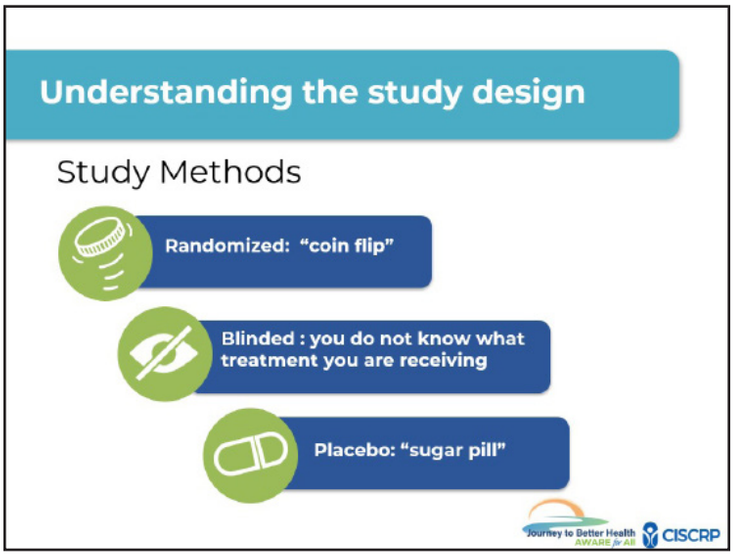
Understanding the study design
Study Methods
Randomized: "coin flip"
Blinded : you do not know what treatment you are receiving
Placebo: "sugar pill"
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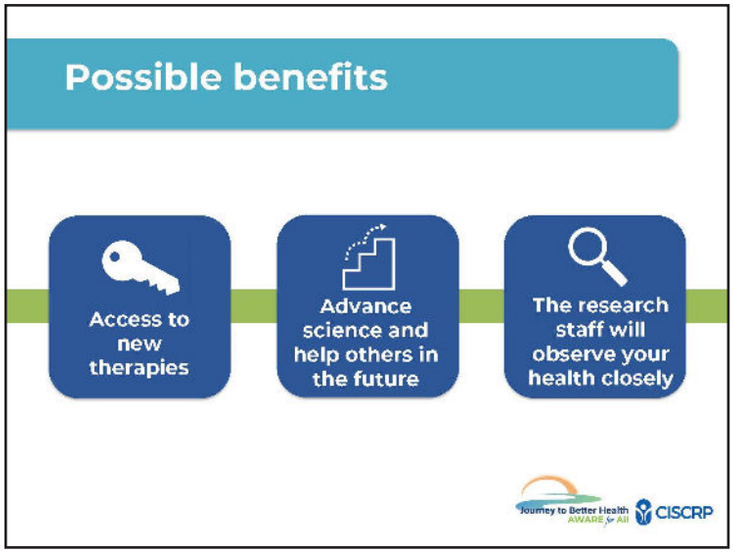
Possible benefits
Access to new therapies
Advance science and help others in the future
The research staff will observe your health closely
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Possible risks
Physical
Emotional
Financial
Privacy and confidentiality
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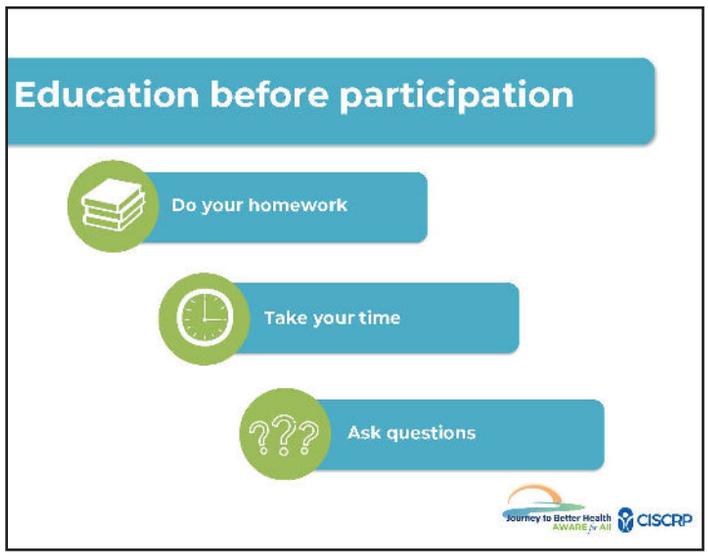
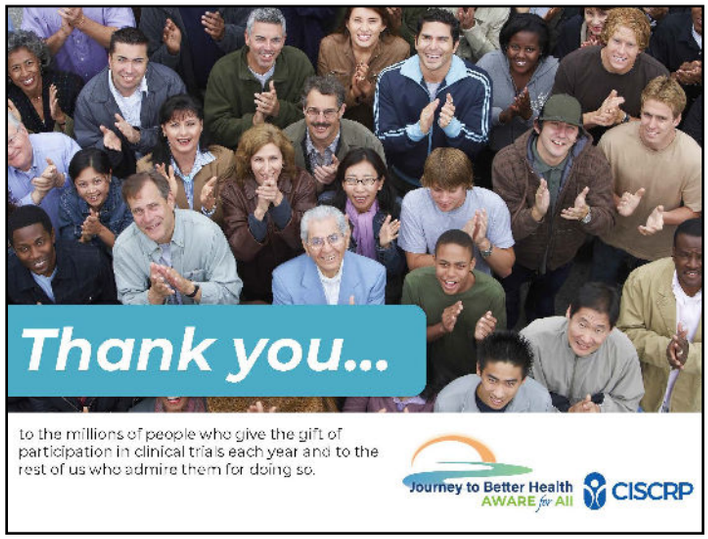




- Clinical research participants truly are Medical Heroes without whom medical science cannot move forward. On behalf of all of us at CISCRP, “Thank you to the millions of people who give the gift of participation in clinical trials each year."
- We appreciate you taking time today to learn about the clinical research process. And we strongly encourage you to share what you’ve learned with your friends, family, and people throughout your community.

For more information visit:
www.ciscrp.org

CISCRP provides a free search service designed to help patients find trials that might be right for them.

Visit: www.searchclinicaltrials.org

SHOULD I, OR SHOULDN'T I?

How to Weigh the Benefits and the Risks

Participating in a clinical trial is an intensely personal decision, and the stakes differ for each person.

Each individual should consider the risks and benefits, and how trial participation might affect his or her life.

Potential Benefits

There are several reasons that people may choose to participate:

To gain access to new investigational drugs
Depending on the trial, there may be an opportunity to get an investigational drug that is not available to others.

To advance science and help others who have the illness
Helping researchers learn about new drugs or potential treatments that could aid patients and advance science is a powerful motivation. Many participants are willing to assume some risk because they feel they are helping to make a valuable contribution to research.

To receive compensation for time and commitment
Along with complimentary medical care, sometimes study volunteers receive compensation for the time and commitment that they must give complying with the study protocol.

To receive free medical care
The investigational drug or treatment is usually free to the participant. The participant also has their health and medical condition monitored by the trial doctor or staff during the trial.

"I know what I went through with chemotherapy treatment. If I can in any way help someone else not go through that, it can't be anything but good. The trial I'm in is for a possible new treatment for breast cancer and could help millions of people down the road. That in itself outweighs any possible chances of major side effects [for me]."

-Jennie, a participant in a breast cancer relapse prevention trial

SHOULD I, OR SHOULDN'T I?

Potential Risks

There are many things to consider:

Getting a placebo (a pill or treatment that has no effect) instead of the study drug

Some trials include a control group that gets a placebo so that comparisons can be made between the placebo and the investigational drug. A participant might be randomly chosen to get the placebo and not to receive the investigational drug.

Exposure to harmful side effects

There are potential risks with any experimental drug or treatment. It's important to know what potential medical problems are associated with the drug or treatment being studied.

The investigational drug or treatment may not help more than the standard treatment

A participant might stop taking their current treatment and find that the investigational treatment does not help their disease or condition.

Inconvenience

The trial procedures and visits may interfere with a participant's daily life. There will often be a disruption to the participant's normal schedule.

Unexpected costs

Although the costs for the investigational drug or treatment and procedures are usually covered, there could be other expenses. These might include travel or hotel costs that may not be covered by the sponsor.

SHOULD I, OR SHOULDN'T I?

How to Decide

Two key questions can help you make this important decision:

Do I have all the information that I need to make an informed choice?

It's important to know as much as possible about the experimental drug or treatment and the clinical trial requirements. This way, you can weigh all the factors. Get information about the trial purpose, the potential risks, and what the protocol requires of you.

Start by getting information from the research center that will be conducting the clinical trial but use other information sources as well.

Get a second opinion about the clinical trial you're interested in; ask your doctor, other health professionals, family, and friends.

Are the risks and impact to my daily life 'worth it'?

Only you can answer the question of how hard you're willing to push yourself to get the information you need and to be willing to comply with the clinical trial requirements.

This article was originally published in the June/July 2009 issue of CISCRP's Medical Heroes newsletter and remains an informative resource still today.

FREQUENTLY ASKED QUESTIONS ABOUT CLINICAL STUDIES

Choosing to participate in a clinical study is an important personal decision. These frequently asked questions will give you some basic information about what clinical research is and what it means to be a participant. If you have more questions about clinical research in general or about specific studies, talk to your doctor, research staff, family, and friends, Also, please take advantage of the resources in this handbook.

What Is a Clinical Research Study?

A clinical research study involves research with human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: interventional studies (clinical trials) and observational studies.

Clinical Trials

In a clinical trial (also called an interventional study), participants receive specific interventions according to the research plan (protocol) created by the sponsor of the study. An intervention may be a drug or device, a procedure, or a change in behavior. Clinical trials may compare a new medical approach to a standard one that is already available. They may compare a new drug to a placebo that contains no active ingredients.

When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than alternatives that are already available. Researchers try to determine if an intervention is safe and if it works by measuring certain outcomes in the participants. For example, researchers studying a new blood pressure drug might want to find out if participants have lower blood pressure after taking the drug.

Observational Studies

Participants do not receive a specific intervention as part of an observational study. Researchers assess health outcomes in groups of participants according to a protocol or research plan, but the participants get only their routine medical care. For example, researchers may observe a group of older adults to learn more about the effects of different lifestyles on cardiac health.

Who Conducts Clinical Research Studies?

Every clinical study is led by an investigator, who is usually a medical doctor. Clinical studies also have a research team that may include doctors, nurses, social workers, and other health care professionals.

Clinical studies can be sponsored (funded) by pharmaceutical companies, academic medical centers, and other organizations. They can also be sponsored by federal agencies such as the National Institutes of Health, U.S. Department of Defense, and U.S. Department of Veterans Affairs. Physicians, health care providers, and other individuals can also sponsor clinical research.

Where Are Clinical Research Studies Conducted?

Clinical studies can take place in hospitals, universities, doctors' offices, and community clinics. They may also take place at other locations. The location depends on who is conducting the study.

How Long Do Clinical Research Studies Last?

The length of a clinical research study varies, depending on what is being studied. Participants are told how long the study will last before they join.

FREQUENTLY ASKED QUESTIONS ABOUT CLINICAL STUDIES

Why Are Clinical Research Studies Conducted?

In general, clinical studies are designed to increase medical knowledge about the treatment, diagnosis, and prevention of diseases or conditions. Some common reasons for conducting clinical studies include:

- Evaluating one or more interventions for treating a disease, syndrome, or condition
- Finding ways to prevent the initial development of a disease or condition, or its recurrence
- Evaluating one or more interventions aimed at identifying or diagnosing a particular disease or condition
- Examining methods for identifying a condition or risk factors for that condition
- Exploring and measuring ways to improve the comfort and quality of life for people with a chronic illness through supportive care

How Are Clinical Research Studies Conducted?

A clinical study is conducted according to a research plan known as the protocol. The protocol is designed to answer specific research questions, as well as to safeguard the health of participants. It contains the following information:

- The reason for conducting the study
- Who may participate in the study (the eligibility criteria)
- The number of participants needed
- The schedule of tests and procedures
- How often the investigational drug or treatment will be given and its dose
- The length of the study
- What information will be gathered about the participants

Who Can Participate in a Clinical Research Study?

Clinical research studies have guidelines that describe who can participate. These are called eligibility criteria, and they are listed in the protocol. Some studies seek participants who have specific illnesses or conditions that will be researched. Other studies invite healthy participants to join. And some studies are limited to a select group of people who are asked by researchers to enroll. The eligibility criteria include factors that allow someone to participate in a clinical study, as well as factors that would disqualify someone from participating. These are based on characteristics such asage, gender, disease type and stage, and treatment history.

How Are Participants Protected?

One way that participants are protected is through the Informed consent process. During this process, researchers provide potential and enrolled participants with information about a clinical study. This information helps people decide whether they want to join the study and continue to be in the study. The informed consent process should provide enough information for a person to understand the risks and potential benefits of the study. It should also provide information about possible alternatives to being in the study. In addition to the informed consent document, the consent process may include recruitment materials, verbal instructions, question-and-answer sessions, and activities to measure participant understanding.

In most cases, a person must sign an informed consent document before entering a study. The signature confirms that he or she was given information on risks, potential benefits, and alternatives, and that he or she understands this information. Signing the document and providing consent does not create a contract. A participant may withdraw from a study at any time, even if the study is not over. See below “Questions to Ask” for ideas about what to discuss with a halth care provider or researcher about participating ina clinical study.

FREQUENTLY ASKED QUESTIONS ABOUT CLINICAL STUDIES

Institutional Review Boards

Each federally supported or conducted clinical study and each study of a drug, biological product, or medical device regulated by FDA must be reviewed, approved, and monitored by an institutional review board (IRB). An IRB is made up of physicians, researchers, and members of the community. Its role is to make sure that the study is ethical and that the rights and welfare of participants are protected. This includes, among other things, making sure that research risks are minimized and thatthey are reasonable in relation to any potential benefits. The IRB also reviews the informed consent document before it is provided to potential participants.

Some clinical studies are also monitored by data monitoring committees (also called data safety and monitoring boards). These committees look at safety results during the study and help make decisions about how the study should be conducted to minimize risks to the participants.

Various federal agencies, including the Office of Human Subjects Research Protection (OHRP) and FDA, have the authority to determine whether sponsors of certain clinical studies are adequately protecting research participants.

Does Participating in a Study Affect Usual Health Care?

Typically, participants continue to see their usual health care providers while enrolled in a clinical study. While most clinical studies provide participants with medical products or interventions related to the illness or condition being studied, they do not provide extended or complete health care. If the participant's usual health care provider communicates with the research team, the participant can make sure that the study requirements don't conflict with their usual care.

What Are Some Considerations for Participation?

Even when there is no direct personal benefit to being in a study, participation contributes to medical knowledge. What is learned in clinical studies can make a difference in the care of future patients. Study results provide information about the benefits and known risks of new or existing interventions. Clinical trials provide the basis for the development and marketing of new drugs, biological products, and medical devices.

Some other important considerations:

- The safety and the effectiveness of the experimental approach or use may not be fully known at the time of the study.
- Some studies may provide participants with the prospect of receiving direct medical benefits, while others do not.
- Most studies involve some risk of harm or injury to the participant. (For trials approved by IRBs, the IRB has decided that the risks of participation are balanced in relation to anticipated benefits.)
- Many studies require participants to undergo additional procedures, tests, and assessments based on the study protocol. These will be described in the informed consent document for a particular study.
- A potential participant should discuss the informed consent document and study protocol with members of the research team and with his or her usual health care provider.

FREQUENTLY ASKED QUESTIONS ABOUT CLINICAL STUDIES

Questions to Ask

Anyone interested in participating in a clinical research study should find out as much as possible about the study and feel comfortable asking the research team questions about the study. The following questions might be helpful during such a discussion. Answers to some of these questions would be provided in the informed consent document. Most of these questions are specific to interventional studies, but some also apply to observational studies.

- What is the purpose of the study?
- What are the possible interventions that I might receive during the study?
- Why do researchers believe the intervention being tested might be effective? Why might it not be effective?
- Has the intervention been tested before?
- How will it be determined which interventions I receive (for example, by chance)?
- Who will know which intervention I receive during the study? Will I know? Will members of the research team know?
- How do the possible risks, side effects, and benefits of this study compare with those of my current treatment?
- What will I have to do if I participate? What tests and procedures are involved? How often will I have to visit the hospital or clinic? Will hospitalization be required?
- How long will the study last, and how long will I be in the study?
- Who will pay for my participation?
- Will I be reimbursed for expenses?
- What type of long-term follow-up care is part of this study?
- If I benefit from the intervention, will I be allowed to continue receiving it after the study ends?
- Will results of the study be provided to me?
- Who will oversee my medical care while I am in the study?
- What are my options if I am injured during the study?

Information adapted from resources provided by ClinicalTrials.gov, a service of the National Institutes of Health.

CLINICAL RESEARCH RESOURCES

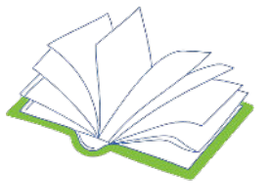
CISCRP offers an online library of resources to help the public become more informed about clinical trial research and participation.

Visit CISCRP's Resources page at www.ciscrp.org.

Brochures: Variety of brochures about clinical trial participation are also available in multiple languages. Some examples include:

- Should I Participate
- Information About Clinical Research for Black and African American People
- Should My Child Participate
- Los Hispanos y la Investigación Clinica

Book: *The Gift of Participation*, 3rd edition: Easy-to-read book on the clinical research process, participation, and practical information to know such as insurance coverage, compensation, and more.



Educational Videos: Suite of brief videos covering a variety of clinical trial information that are easy-to-watch. Some examples include:

- General Overview of the Clinical Research Process
- Basics of Clinical Trial Participation
- The Clinical Research Team
- Informed Consent / eConsent
- Nuestro Mundo y los Ensayos Clínicos
- MT Pharmacy

Medical Hero Stories: Participants share their inspiring stories about why they chose to participate in a clinical trial and their overall experience.

COVID-19: Different resources to stay informed about COVID-19 and vaccines.

Search Clinical Trials: There are numerous online resources to help you find clinical trials in your geographic area and/or medical conditions.

SHARE YOUR INSIGHTS AND PERSPECTIVES

CISCRP provides clinical trial participants with the results of their clinical trial in a friendly, easy-to-read and understand format through our Trial Results Summary Programs.

The Trial Results Summary Program includes medical and healthcare professionals, patient advocates, patients, and members of the public from around the world to form a Review Panel who review the trial results in plain language—not scientifically written—before they are shared with the clinical trial participants for that specific trial.

As an attendee of the Journey to Better Health | *AWARE for All - Birmingham* event, we are extending a special invitation to have you join and participate in a Review Panel.

How It Works:

- Review Panel Members review the trial result plain language summary that match their area of medical condition expertise or interest
- Each member's objective review helps CISCRP deliver friendly and easy-to-understand, yet scientifically accurate summaries to clinical trial participants around the world

- Review Panel Members share their insights and perspectives on:
  * Specific area(s) within the summaries that may be confusing
  * Potential bias
  * Sections that may be missing information
- Time commitment is minimal:
  * 1 hour to complete a review
  * All correspondence is by email
  * 5 business days to complete the review
- Review Panel Members may include:
  * People familiar with a specific medical condition
  * People interested in helping to improve health communications
  * Patient advocates
  * Medical and healthcare professionals

Contact us today to learn more about joining and participating on a Review Panel. This is an opportunity to share your objective insights and perspectives on trial result summaries remotely from your home.

Email CISCRP at info@ciscrp.org

HEALTH COMMUNICATION SERVICES

Advancing health equity goals to better meet the needs of underrepresented patients around the world

At Biogen, we are pioneering new science that takes us deep into the body's nervous system, and stretches wide across digital networks and patient communities, to better understand, and preserve, the underlying qualities of our essential human nature.

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Who must be included in clinical research? *Everyone.*

Research includes me
Diversity • Equity • Inclusion in Clinical Trials

What is a clinical trial?

- A clinical trial is also called a clinical research study
- A clinical trial is designed to evaluate or study investigational medications
- Clinical trials are conducted by doctors, nurses, and other healthcare providers

PHASES OF CLINICAL TRIALS

PHASE 1	PHASE 2	PHASE 3	PHASE 4
First study in humans of 20-100 participants in healthy volunteers.	Small studies of 100-500 participants.	Large studies of 500 or more participants to determine if a drug will be approved by authorities for public use.	Large studies after the medicine has received approval.
Each phase is conducted to investigate:			
• Safety of the study medication • How the study medication is absorbed by the body and what dosage should be used • How the study medication is removed from the body • Potential side effects	• Ongoing safety • Whether the study medication works for a particular disease • The appropriate dose of the study medication	• Safety and side effects in bigger populations • Whether the study medication works for a particular disease • How the treatment compares to already existing standard therapies	• Side effects during day-to-day use in the population • Risks and benefits over a period of time

Why should we participate?

Certain medicines work differently based on sex, gender, age, race, and ethnicity. Some diseases and conditions are more common in certain groups of people. For example:

- In the United States, 87 percent of tuberculosis cases occur in racial and ethnic minorities, particularly in Black Americans, Asians, and Hispanics[1]
- Black Americans have higher rates of diabetes, hypertension, and heart disease than other groups. Black adults are 60 percent more likely than non-Hispanic White adults to be diagnosed with diabetes[2]
- Hispanic women are 40 percent more likely to be diagnosed with cervical cancer and 20 percent more likely to die from cervical cancer, as compared to non-Hispanic White women[3]
- Asian-Americans have disproportionately high rates of certain types of cancer, tuberculosis, and hepatitis B[4,5]

And yet...

- Patients participating in clinical trials for new medicines and treatments are mainly White — in some cases, 80 to 90 percent. Participation by people of color, including Black/African-Americans, Hispanics/Latinos, and other racial or ethnic minorities, is much lower[6]
- The United States Food & Drug Administration 2019 Drug Trials Snapshot assessed the clinical trial participation rates associated with 11 new drug approvals. A total of 3,593 patients participated in the trials that led to the approvals of 11 new drugs. Overall, 38% of all participants were women, 73% were White, 18% were Asian, 4% were Black or African American, 5% were Hispanic, 59% were 65 years and older, and 24% were from sites in the United States[7]
- African-Americans are more likely to suffer from respiratory conditions, like asthma, than White Americans. Yet as of 2015, only 1.9 percent of studies of respiratory diseases included African-American participants[7]

This is why everyone needs to be included in clinical research!

Your safety is the priority!

- Researchers and the pharmaceutical companies that sponsor the trials must follow strict rules and ethical guidelines
- Trials are reviewed and monitored by an independent body called an Institutional Review Board to ensure the trials are conducted ethically
- The FDA also monitors trials and must approve the medicines before the public can use them.
- Researcher must follow a study plan called a 'protocol' that outlines what will happen in the study
- Participants must give permission by signing a document called the Informed Consent Form
- If you decide to take part in a clinical trial, you can change your mind and withdraw from the trial at any time

It is important to consider the risks and opportunities for participating in a clinical trial.

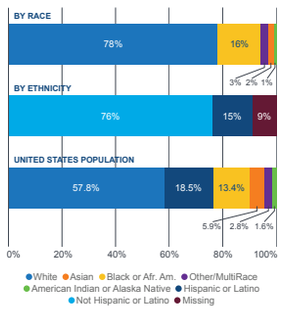
There may be opportunities when you take part in a clinical trial.

- Supporting the development of effective medicines for all
- Increasing diverse representation in clinical research
- Expanding knowledge for all about a disease or condition
- Pushing science closer to achieving health equity for all
- Increasing awareness of clinical research
- Building trust in new medicines by increasing diverse representation

There are potential risks that come with being part of a clinical trial.

- The investigational medication may be uncomfortable or cause mild to moderate side effects. In some cases side effects may be serious
- The investigational medicine may not work, or it may not be better than existing treatments
- You may have to provide samples for several lab tests and procedures
- Being a clinical trial participant may require hospital stay and travel
- Your current condition may not improve while in the clinical trial
- You might be selected to be in the placebo (control) group
- Clinical trial participation can be time consuming

Clinical trial participation



Our goal is to find new and better ways to treat conditions and diseases.

Clinical trials can help answer important questions about study medications:

- Is the study medication safe?
- How well does the study medication work?
- How does the medication act in the body?
- Does the medication work better than other available medicines?
- How does the medication affect certain diseases or conditions?
- What are the side effects and reactions of the medication?
- Are there any differences in the way the medicine acts due to gender, age, race, ethnicity, or any other factors?

Deciding to participate in a clinical trial is an important decision.

As you think about your decision to participate in a clinical trial the clinical trial team must explain:

- The purpose of the clinical trial
- What to expect as a clinical trial participant
- The possible risks and possible benefits of participating in the trial
- The visits and tests required in the clinical trial
- Any other questions you may have

If you agree to participate, you'll be asked to sign a Informed Consent Form and remember, participation in a clinical trial is voluntary.

Important questions to ask

- Why is the study being done?
- Has this drug been tested before?
- What will be expected of me?
- What kinds of procedures/tests are involved?
- Will I be reimbursed for my expenses?
- How will I know that the treatment is working?

What happens after the clinical trial?

Depending on the clinical trial's results a healthcare authority, such as the Food and Drug Administration (FDA), may approve the investigational medication for public use.

Investigational medications are approved when: they are generally proven to be safe and effective or the benefits of using the medicine outweighs the risks for the intended population.

Learn more: www.reasearchincludesme.com

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Science is resilient.
It can overcome diseases,
create cures, and, yes,
even beat pandemics.
It has the methodology
and the rigor
to withstand even
the most arduous scrutiny.
It keeps asking questions and,
until there's a breakthrough,
it isn't done.
That's why, when the world
needs answers, we turn to science.
Because in the end,
Science will win.

Scientific discoveries are made possible by the hundreds of thousands of people who participate in clinical trials. We all play a part in advancing science. Together, breakthroughs are possible.

Learn more at ***www.Pfizer.com/WhatToExpect***

WCG Patient Advocacy Presents:
A Call to Action - WCG's Patient Forum

Visit our website to watch our recent Patient Forum:
www.wcgclinical.com/patient-forum

www.wcgclinical.com

From research.

To the right patient.

To real breakthroughs that offer hope.

We believe when patients are offered clinical research as a care option, they get something far greater – hope. That's why we look beyond what's expected in healthcare to see what's possible in areas such as clinical research.

Others may offer a way forward.
IQVIA gives you a way further.

Learn more about clinical research at
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YOUR
WAY
FURTHER

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At Otsuka, our purpose is to defy limitation, so that others can too.

We have an unwavering belief in going above and beyond—under any circumstances—for patients, families, providers, and each other. This deep-rooted dedication drives us to uncover answers to complex, underserved medical needs, so that patients can push past the limitations of their disease and achieve more than they thought was possible.

We are grateful to all clinical trial participants, as they are integral to help advance care on behalf of all those we seek to serve.

Otsuka

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February 2022 01US22EUC0014

Lupus has too few treatments,
and it's time we change that.

Learn about lupus clinical studies at **LupusTrials.org.**
Your participation can help improve care
and find a cure!

LUPUS RESEARCH ALLIANCE

Lupus THERAPEUTICS
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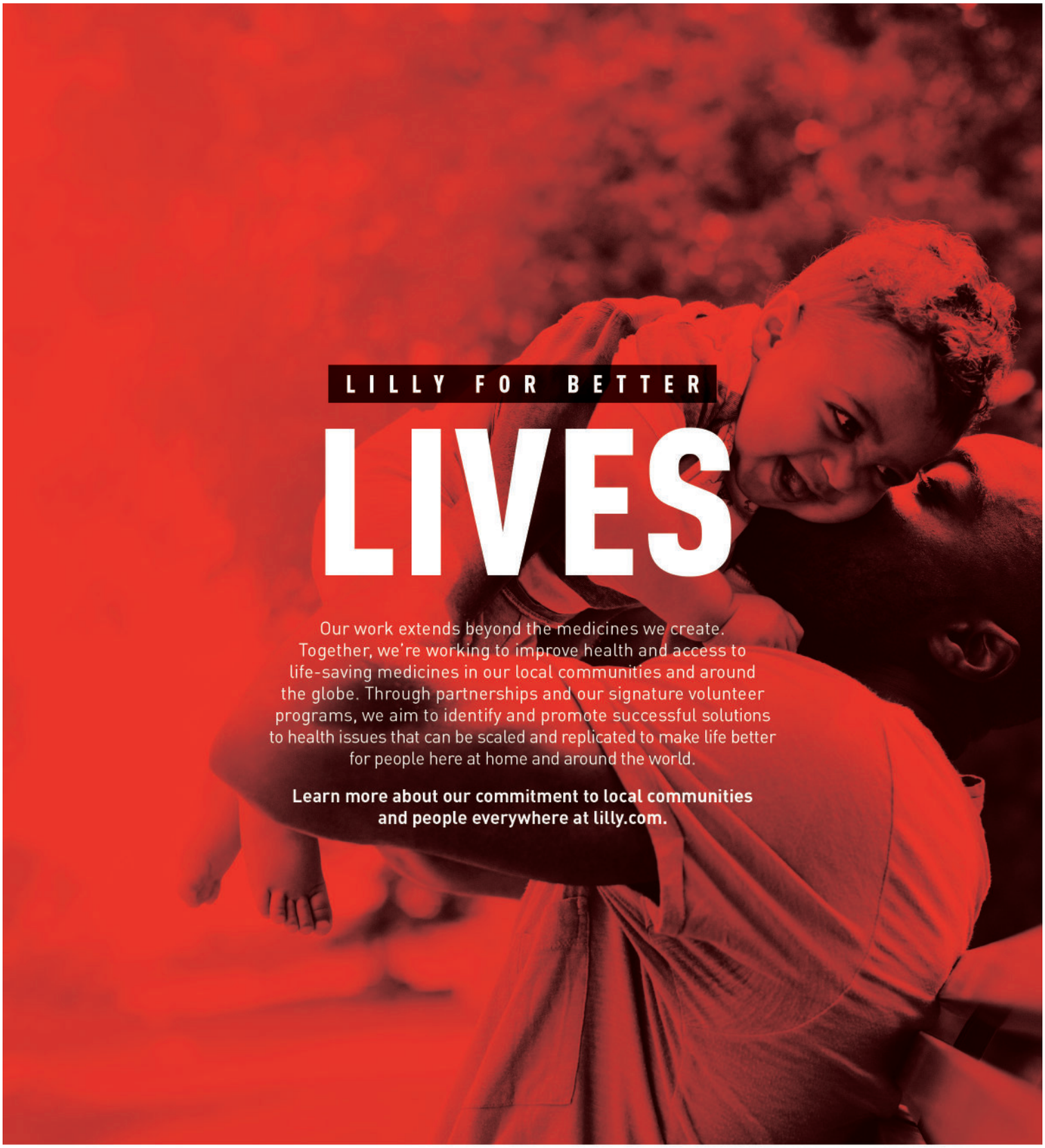
Driven by Our Patients

Thank you to patients, plasma donors, study participants, care partners, advocates and researchers who help us discover, develop, and deliver innovative therapies and vaccines.

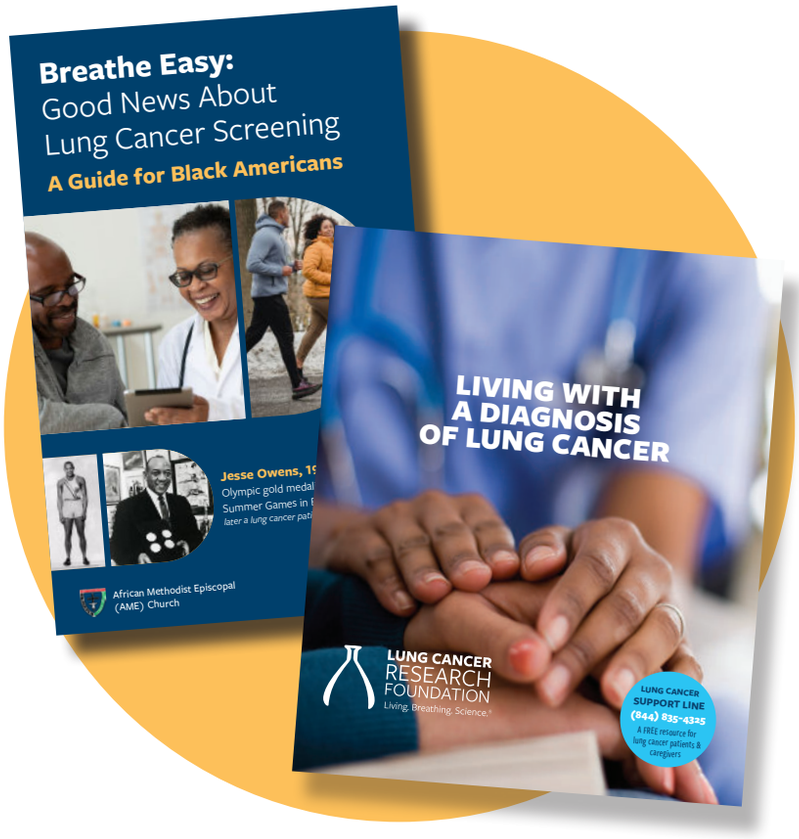
Visit CSLBehringTrials.com to learn about clinical studies, conditions we specialize in, and our research and development activities.



Lilly

Our goal: a world without lung cancer.

Until then, we're here to help.



Our ability to breathe has been in the spotlight over these past two years. But anyone who has faced a lung cancer diagnosis already knew that every inhale – every exhale – is something precious.

The Lung Cancer Research Foundation exists to serve patients with lung cancer and those who care about them. LCRF funds innovative projects that demonstrate promise and ingenuity – **because ultimately, research saves lives.**

Understanding lung cancer goes a long way towards easing anxiety, helping people with lung cancer and their caregivers prepare for what's to come. LCRF offers **world-class materials** that can explain clinical trials, biomarkers, immunotherapy, and other topics in language you don't need a medical degree to decipher.

All materials are available **free of charge** from LCRF.org/resources or by calling the Lung Cancer Support Line at (844) 835-4325.

Order free educational materials at LCRF.org/resources

Changing what it means to face a lung cancer diagnosis starts with research.

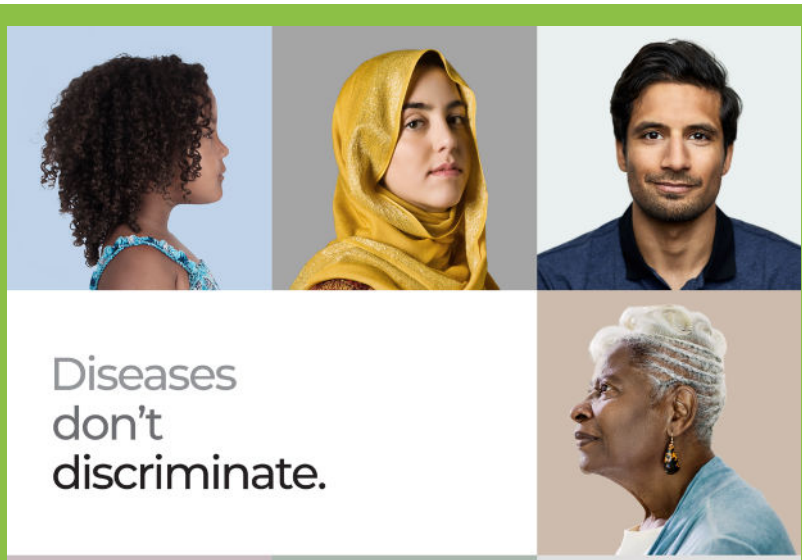
The Lung Cancer Research Foundation brings the community together to support this important work through events as well as awareness and educational programs. Find out more and learn about the research your donations make possible at **LCRF.org**.

LUNG CANCER
RESEARCH
FOUNDATION
Living. Breathing. Science.®

DIVERSITY IN CLINICAL TRIALS BRINGS NEW TREATMENTS TO EVERYONE.

Participation in clinical trials not only helps patients gain access to new medical therapies but also advances knowledge about how treatments work safely and effectively in the diverse communities represented in those clinical trials. Visit medicalheroes.org to learn more.

CISCRP



Diseases don't discriminate.

Diversity in clinical research has never been more important. And with more volunteers, medical advancements can become even better. Visit **medicalheroes.org** to learn more.

CISCRP

Together, we are shaping the future of health care.

We thank the millions of volunteers and professionals who participate in clinical research each year. Because of you, health care advancements are possible. **To learn more about clinical research, please visit CISCRP.org.**

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www. ciscrp.org . One Liberty Square, Suite 1100 . Boston, MA 02109 . awareforall@ciscrp.org

THANK YOU TO CISCRP'S

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We are grateful to the *AWARE* Industry Consortium (AIC) for their support to bring grass-roots education and awareness to diverse communities throughout the U.S. through the **Journey to Better Health | *AWARE for All***:
Clinical Research Education program.

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To explore our *AWARE for All* events' resources and offerings,
visit www.awareforall.org

FIND A CLINICAL TRIAL THROUGH THE CISCRP TEAM

Our free service where we work with you to find the right clinical trial.

Scan the QR code to learn more.