

AWARE *for* ALL

RALEIGH, NC

VIRTUAL COMMUNITY EVENT



THURSDAY, OCTOBER 22nd, 2020

4:00-6:00PM EDT

4:00 PM – 4:05 PM:
Welcome from CISCRP

4:05 PM – 4:40 PM:
Overview Presentation and Q&A
with speaker Stefanie Belanger

4:50 PM – 5:00 PM:
Lung Cancer Risk Assessment

5:00 PM – 5:45 PM:
Panel Discussion and Q&A

5:45 PM – 5:50 PM:
Shibashi Movement Exercise

5:50 PM – 6:00 PM:
Med Hero Ceremony & Raffle

PROGRAM
HANDBOOK

THANK YOU TO CISCRP'S



We are grateful to the AWARE Industry Consortium (AIC) for their support to bring grass-roots education and awareness to diverse communities throughout the US over these next five years through the *AWARE for All: Clinical Research Education* program.

THANK YOU TO ALL MEMBERS OF THE
AWARE INDUSTRY CONSORTIUM



2020 AWARE FOR ALL EVENTS SCHEDULE

CHICAGO, IL - JULY 16TH

PHILADELPHIA, PA - OCTOBER 1ST

RALEIGH, NC - OCTOBER 22ND

LOS ANGELES, CA - NOVEMBER 18TH

MIAMI, FL - DECEMBER 8TH

To learn more about the AWARE Industry Consortium
email awareforall@ciscrp.org



Dear AWARE for All attendees, supporters, and friends:

October 22, 2020

It is with great pride and excitement that we welcome you to AWARE for All – Raleigh. Today serves as an important milestone in building awareness about both clinical research participation and the crucial role that clinical research volunteers play in advancing new medicines.

We would like to thank all the members of the planning committee for their assistance in converting our live event to a virtual educational program. We are very grateful to our AWARE Industry Consortium: Biogen, Boston Scientific, CSL Behring, EMD Serono, IQVIA, Janssen, Merck, Otsuka, Pfizer, and WCG.

A special acknowledgement to our various local Raleigh sponsors: national support from the Allergy and Asthma Network; Pillar Sponsorship from PRA Health Sciences; Benefactor Sponsorship from Javara; Patron Sponsorship from Brain Injury Association of North Carolina; and In-kind outreach support from Debbie’s Dream Foundation, Duke—Office of Clinical Research, Hemophilia of North Carolina, LGBT Center of Raleigh, Lung Cancer Initiative, Lupus Research Alliance, Parkinson Association of the Carolinas, and Ronald McDonald House of Chapel Hill.

A special thank you to Illumina Interactive for designing and developing the custom Virtual Health Fair aimed to simulate a real-life experience of attending an AWARE Information Alley to connect with different health and wellness organizations.

The warm response AWARE for All has received from the Raleigh community has been encouraging and convinces us even more of the important need this program fills. With the assistance of over 350 community partners, e-brochures were distributed, flyers were shared, and announcements and articles were included in newsletters and on websites throughout the state.

We are 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

Ellyn Getz,
Associate Director, Development &
Community Engagement
CISCRP

Joan A. Chambers,
Senior Director, Marketing
& Outreach
CISCRP

Justine Holleran,
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Planning Committee

CISCRP wishes to thank the AWARE—Raleigh planning committee for all their hard work and dedication to bring this program to fruition!

Lung Cancer Initiative

Colleen Christensen
Engagement Coordinator

Allergy & Asthma Network

Mary Hart
Director of Research

Study Volunteer and Patient Advocate

Tomma Hargraves

The Center for Information & Study on Clinical Research Participation (CISCRP)

Joan Chambers, Senior Director, Marketing & Outreach
Ellyn Getz, Associate Director, Development & Community Engagement
Justine Holleran, Events Coordinator
Julia Steele, Events Marketing & Communications Coordinator
Hope Ventricelli, Manager of Events and Community Engagement



Key Community Supporters

Thank you to the many individuals and organizations who helped to engage the community about this educational initiative. A big thanks to the following teams who extensively promoted this program and provided us with educational and health resources.

- | | |
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| AAIPharma | Central Carolina Black Nurses Council |
| Abbott | Clinical Trials of North Carolina |
| Accel Clinical Services | Coastal Orthopaedics and Spinal Surgery |
| aCRONordic | Community Care of North Carolina |
| ACRP | Crohns and Colitis Foundation of America |
| Acurian | Cumberland Research Associates, LLC |
| Aerotek Scientific, LLC | Cystic Fibrosis Foundation |
| Altavant | Debbie's Dream Foundation |
| Allergy & Asthma Network | Dementia Alliance of North Carolina |
| Allphase Clinical Research, Inc. | Down Syndrome Association of Charlotte |
| Alliance of AIDS Services | Duke University |
| Alpha IRB | Duke University Medical Center |
| Alzheimer's Association | Duke—Office of Clinical Research |
| American Cancer Society | East Carolina University |
| American Diabetes Association | Epilepsy Alliance of North Carolina |
| American Institute of Healthcare and Fitness Clinical Research | FirstHealth of the Carolinas |
| American Institute of Pharmaceutical Technology | Friends For An Earlier Breast Cancer Test |
| American Liver Foundation | General Federation of Women's Clubs |
| American Lung Association | Glenwood Clinical Monitoring, Inc. and North State Signs |
| Arthritis Foundation | Greater Gift |
| ASG, Inc. | Guardant Health |
| Aspire IRB | Heart Bright Foundation |
| Associated Urologists of North Carolina | Hemophilia of North Carolina |
| Autism Society of North Carolina | High Point Clinical Trials Center |
| Brain Injury Association of North Carolina | ICON Clinical Research |
| Brenner Children's Hospital | Javara |
| Bridges Pointe Sickle Cell Foundation | Juvenile Diabetes Research Foundation |
| Carolina Digestive Diseases, PA | Kate Reynolds Foundation |
| Carolina Medical Trials | Kay Yow Cancer Fund |
| CDISC | Kinston Medical Specialists |
| CEDRA | Legacy Healthcare Services |

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LGBT Center of Raleigh	Raleigh Neurology Associates
Lupus Research Alliance	Regional Center for Infectious Disease
Lyndhurst Gynecologic Associates	Research Triangle Association of Diabetes Educators
Mayo Clinical Trial Services	REX Healthcare
MedFocus	RHO
MedTrials	Roche
Medtronic, Inc.	Ronald McDonald House of Chapel Hill
National Kidney Foundation of North Carolina	RTI
NC A&T State University	Rx Trials
NC Biotech	Schulman & Associates IRB
NIEHS Clinical Research Unit (CRU)	Sickle Cell Regional Network
NAACP	Sister Network Inc.
North Carolina Neuropsychiatry	Southpoint Clinical Research
North Carolina Clinical Research	Susan G. Komen for the Cure
NCCHCA	St. Luke's Hospital Foundation
NCHRC	Triangle Down Syndrome
North Carolina Victim Assistance Network	Triangle Heart Associates
Novant Clinical Research Institute	Triangle Medical Research
Onward Healthcare Clinical Research Services	Triangle Older Women's League
PAREXEL	Triangle Orthopedic Associates
Parkinson Association of the Carolinas	Trio Clinical Research
Pharmaceutical C-Trials, Inc.	UNC Chapel Hill
Piedmont Medical Group	UNC Lineberger Comprehensive Cancer Center
Pinehurst Medical Clinical, Inc.	University of North Carolina
PMG Research	Urban League of Central Carolinas
PRA—Rare Disease Center	Wake Forest Baptist Comprehensive Cancer Center
Precise	Wake Forest School of Medicine
Premier Research	Wake Med
Pretty in Pink Foundation	Wake Research
Quorum Review	Wilmington Gastroenterology

Group Health Exercises (throughout webinar 4:00PM—6:00PM ET)

Shibashi Exercise lead by Suzy Edmonson, Occupational Therapist
Lung Cancer Risk Assessment by the Lung Cancer Initiative



Agenda

4:00 PM—4:05 PM: Welcome from CISCRP

4:10 PM – 4:40 PM: Overview Presentation and Q&A

Stefanie Belanger, Assistant Director, Clinical Research Operations, Clinical Protocol Office, UNC Lineberger Comprehensive Cancer Center

4:55 PM—5:00 PM: Virtual Health Exercise

Shibashi, lead by Suzy Edmonson, Occupational Therapist

**5:00 PM—5:35 PM: Panel Discussion about Clinical Research in Raleigh
Q&A**

Moderated by Ken Getz, Founder and Board Chair, CISCRP

Deputy Director and Research Professor (PHCM), Tufts Center for the Study of Drug Development

Tomma Hargraves, Study Volunteer

Pablo Graiver, Vice President, Patient Engagement, Digital Strategy Lead, IQVIA

Mary Hart, Director of Research, Allergy & Asthma Network

Purvi Parikh, Medical Director, Allergy & Asthma Associates of Murray Hill

Brian Rothman, Associate Director, Global Clinical Development, Otsuka

5:40PM—5:45PM: Virtual Health Assessment

Lung Cancer Risk Assessment, Lung Cancer Initiative

**5:45PM—6:00PM: Ceremony to Honor Study Volunteers (Medical Heroes)
Raffle & Closing Remarks**



Welcome to AWARE for All—Clinical Research Education Day. We’re thrilled that so many of you are joining us to learn more about clinical research.

This program is brought to you by CISCRP, the Center for Information and Study on Clinical Research Participation.

Our goal is to help you understand the clinical research process—including the risks and benefits of participating.



Have you ever taken an allergy medicine? Have you ever given your child a pain reliever? Perhaps you have a friend or a family member who is a cancer survivor.

If so, you can thank clinical research volunteers.

Around the world people are living longer, healthier lives because people they never met volunteered to take part in clinical research studies. And those studies helped find ways to prevent, treat and even cure certain medical conditions.

We like to call these volunteers “Medical Heroes.”



Most people don’t understand what clinical research is all about. Some people are afraid. They may think clinical research volunteers are treated like “guinea pigs.” Or they’ve heard news stories about clinical trials that have gone wrong. Or they still remember past abuses when there were no protections in place for clinical research volunteers.

That’s why at CISCRP we believe in ‘Education before Participation.’ We think the more people understand the clinical research process, the more they’ll appreciate those who volunteer to participate in clinical research.

What do we learn from studies?

- How does a disease progress and how can it be prevented?
- How well does a new drug work or not work?
- Is there a better way to treat a disease?
- How are genes connected to illnesses?



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What we learn from clinical research studies improves public health.

And it all starts with these questions.

Researchers can only answer these questions with the help of clinical research volunteers.

What is a clinical trial?

- Scientific study that answers a medical question.
 - Is a treatment safe?
 - Does it improve a certain medical condition?
 - Does it have side effects?
 - How should people take it?
 - Is it any better than medicines that are already on the market?



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What is a clinical trial? It is a carefully designed study where researchers ask volunteers to do something -- like take a new drug or investigational treatment -- so they can answer a specific medical question.

Is the study drug safe? Does it improve a certain medical condition? Does it have side effects? How much should people take? Is it any better than medicines that are already available?

Because researchers are studying new, investigational treatments, there are risks to participating in a clinical trial. But in all cases, something is learned from clinical research studies that helps inform medical knowledge and improve public health.

A clinical trial is NOT the same as standard of care

- Standard of Care
 - Routine care
 - Has been tested and approved
 - Works for most people
- Clinical Trial
 - Looks for answers to a scientific question
 - Still learning how it works



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It's important to understand that being in a clinical trial is not the same as going to your doctor for care. When you go to your doctor, she will give you a treatment that has already been tested and approved by the government. This is called "routine" or "standard of care."

This is the care we know works for most people. This is the care you would get if you go to the doctor for regular appointments or if you had a health problem.



You cannot fully understand something by studying just one group of people.

We know that things like being male or female, young or old, race and ethnicity – affect the way people respond to diseases and treatments.

For example, Alzheimer's disease happens twice as often in women than men. Type-2 diabetes and asthma are more common in African Americans. Hispanics, Asian and White women are more likely to develop osteoporosis. Children respond to drugs differently than adults.

That's why scientists need all different types of people to volunteer for research.



Some people remember past abuses like the US Public Health Study of Syphilis in Tuskegee Alabama, in which treatment was withheld from African American men for many years. Or the story of Henrietta Lacks and what are now known as HeLa cells, one of the most commonly used cell lines in scientific research. These studies gathered information about patients without their consent and remuneration for their participation. People wonder if this could happen today. The answer is that it is not likely: Federal guidelines and ethical practices are in place to monitor the safety and to protect the rights of study volunteers.

Today the public and professionals are more aware than ever of the need to have diverse populations in clinical research. And we are taking steps to break down participation barriers, improve diversity, and pave the way to a healthier future for everyone.

Several studies have shown that under-represented, minority populations consistently demonstrate an equal or higher willingness to participate in clinical research studies than do their white counterparts. Individuals within these communities have said that lack of access to clinical trials is the primary reason why they don't participate. This includes outreach and communications that failed to reach them; health and research professionals not asking them to participate; clinical trials that are too far away; and participation requirements that are too difficult to follow.

If we work together, we can solve these problems and make clinical trials far more accessible.

COVID-19 Vaccines and Treatments



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You've probably heard a lot in the news lately about the development of vaccines and treatments for COVID-19.

Vaccines and treatments for infectious diseases usually take nine or 10 years to develop. This seems like a long time, but it is necessary for understanding the real effects of a new therapy and determining whether it is safe and effective at specific dosage levels.

The clinical trial process for COVID-19 treatments and vaccines is moving at a faster pace and may produce promising therapies within a few years. Some treatments and vaccines have a head start because they are based on research that was

conducted for viruses that are similar to COVID-19. The pandemic has mobilized much higher levels of coordination between companies and government agencies, which helps speed up the process. In the educational handbook that you will be receiving, you'll find a number of resources about COVID-19 studies and new therapies in development.

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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During phase 1 studies, a drug is tested for the first time with a very small number of volunteers. And often these are healthy volunteers. The goal of these studies is to learn if an investigational drug is safe and at what dose. And how does it work in the body? Is it harmful?

In phase 2 studies, researchers begin to understand how well a drug may work. And if it is safe for patients who have a specific disease or condition. Like phase 1, safety is still the main goal. Phase 2 studies look to answer such basic questions as: how much should people take? And what are the usual side effects?

Only about one-third of drugs that enter clinical testing ever successfully complete phase 2 and progress to larger groups of patients in phase 3 studies. At this stage, researchers may check the drug's safety and how well it works in different groups of patients. The trial may also compare the new drug with an already approved drug.

Phase 4 studies happen after a treatment has been approved by the Food and Drug Administration. They usually involve large numbers of patients. Phase 4 studies look at real world experience and check to see if the drug works well over a long time.

This clinical research process from Phase 1 to 3 takes seven or more years!

Clinical trials



Clinical trials can be sponsored by the government, academic medical centers, pharmaceutical companies, biotechnology companies or medical device companies.



Research involves a lot of people who do different things. Like members of a sports team, clinical trials have coaches, players, and officials, and each person has an important role to play.



Principal Investigator (PI)

Like the head coach

- Organizes the study
- Records and studies the data
- Directs the study staff
- Follows a protocol (play book)



The Principal Investigator (PI) is like the head coach of a team. He or she is responsible for organizing and leading the study as well as recording and studying the data. The PI also directs the team.

Like a head coach, the principal investigator follows a play book, which is called the study “protocol.” The protocol is a set of instructions that everyone in the game must follow. It’s the plan for how the study will be carried out.



Clinical Research Coordinator (CRC)

Like the assistant coach

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



The research staff members are like assistant coaches who help the Principal Investigator. The Clinical Research Coordinator handles the day-to-day activity at the research site. He or she has easy access to the principal investigator and is the main contact for volunteers.

If you have questions about the trial or your health, ask the coordinator.



Volunteer Protections

Like the referees

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



Referees help protect the safety of volunteers by making sure teams follow the rules. The referees review the study before it starts. The referees keep you safe and give you all the information. The number and type of referees involved in a trial depends on the research being conducted.



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



Every clinical trial is reviewed, approved and watched over by an independent local committee called an Institutional Review Board or IRB. It's the law.

The IRB makes sure a trial is ethical and fair and that there is not too much risk for volunteers. During the trial, researchers must let the IRB know if there are any changes in the study plan. Or if volunteers experience serious injuries or side effects. The IRB 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



Referees from the federal government are also involved.

The Food and Drug Administration reviews studies, inspects research centers and monitors research groups to make sure they are following federal guidelines. The FDA has the final say in whether or not an investigational treatment is approved.



Volunteers

Like the players

- The MOST important team member
- Wide range of studies available (clinicaltrials.gov)
- Healthy volunteers needed too!



Now let's talk about the most important members of the team: The research volunteers. Volunteers are like the players on the field. Without them, clinical research can't happen.

We need all different types of people to participate in clinical research. You do not even need to be sick. A lot of research involves healthy volunteers.



Friends, family and your supporters

Like the fans

- People to talk to about the study
- Help you ask questions about the study
- Support you during the study



Your friends and family may provide you a support system while you are taking part in a study. It is good to talk to your friends and family about the clinical trial. They can help you come up with questions to ask your doctor. They can also support you while you participate. In the end it is your job to make the final decision if you will participate in the study.



Eligibility Criteria

Who is the right player for the game?

Everyone has the chance to participate in research - you just have to find the study that is right for you.

Just like a football game there are rules and not everyone can be on the field at the same time.

The research team has a list of requirements for the participants - just like the coaching staff draft players. Both the coaches and the players have to know the game and agree to work together.

Let's talk about eligibility first. A 10-year-old would never be allowed to play on a pro football team, right? Why? Because it would be too dangerous.

Just like in sports, clinical trials have "eligibility criteria." These are guidelines that indicate who can or can't be in a study. Eligibility criteria ensure that the clinical trial is studying the right people under the right conditions.

If you're considering a trial, you must be honest with researchers about your health. Lying or hiding information to get into a trial could endanger your safety and ruin the study.

Informed Consent

A process to make sure you understand and agree to be in the study



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OK, let's assume the coaches say you're eligible to play. The next question you have to ask yourself is: Do I choose to play?

You cannot say whether or not you want to participate without understanding the rules of the game. What are your responsibilities as a player? How long will the game last? What are the risks and benefits of playing?

The "informed consent" process is designed to answer all these questions and is required by the FDA and IRB. This is one of the most important parts of research and it's a term you're going to hear a lot.

Before any volunteer can participate in a trial, he or she must read, understand and sign the informed consent form. This is a long form that lists your rights as a volunteer. It includes details about the trial. It describes your role as a volunteer and any procedures or tests you'll need to have. It will warn you about any known or possible unknown side effects of the study drug. It describes the benefits of participating in the trial. By signing the form you're saying that you understand the clinical trial and are agreeing to follow the protocol.

The informed consent form is a complex document. The study staff should go through it carefully with you and answer all your questions. You should never feel rushed or pressured to sign the form.

It is important to note that the IRB can ask the researcher to translate the informed consent form to multiple languages that study volunteers prefer to speak.

You have rights and responsibilities



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As a research volunteer you have rights. You have the right to understand the purpose, benefits, risks and side effects of the clinical trial.

You have the right to ask any questions and discuss any concerns with the research staff at any time during the trial. And you have the right to full, complete and clear answers.

Most importantly, you have the right to quit the trial at any time for any reason. You are a volunteer and are free to leave the trial if you choose to. The research staff will help you do this safely!



You've heard a lot about clinical trials and your rights and responsibilities as a volunteer.

Deciding to take part in a clinical trial is a personal decision. What's right for the person sitting next to you may not be right for you.

Understanding the study design

Study Methods



Scientists set up their studies so that their research will be fair. They also want their research to be accurate and unbiased. In other words, they don't want their own ideas about what they think should happen in a trial to influence the results.

To set up fair studies, volunteers may be split into different study groups. This is usually done by chance using a computer program and is similar to a coin toss. The researcher and the volunteer do NOT get to decide which group the volunteer will be in. This is called a "randomized" study.

Sometimes researchers will go a step further and "blind" a study. This means that the volunteer and the researcher both do NOT know which treatment the volunteer is receiving.

In some trials, researchers will use a "placebo." A placebo looks like medicine but has no medicine in it. Sometimes the placebo is referred to as a "sugar pill." What's interesting is that even though the placebo has no medicine in it, there are times when people who are taking a placebo improve or feel better during a trial. This is called the "placebo effect." As a clinical research volunteer, even if you are on a placebo, you will be closely monitored.

Possible benefits



Deciding whether or not to participate in a clinical trial is an important, personal decision. Here are some of the reasons why people say they get involved in research trials.

- ✓ Get access to brand new therapies that are not yet available on the market;
- ✓ Advance science and help others with their condition
- ✓ The research staff will observe your health closely

SOME, but NOT ALL trials will pay for volunteers' travel costs and pay you for your time and commitment. The amounts vary. Getting paid should never be your only reason for volunteering.

Possible risks



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All research involves risks

- There can be physical risks. You may not get better. You may even get worse or you may be uncomfortable.
- Emotional risk - the protocol can be demanding and participation may be stressful.
- Financial risk – there may be out-of-pocket expenses, such as child care and missing work.
- Privacy and confidentiality – When you agree to participate in research, you are giving permission for researchers to collect information about you. Researchers must follow rules that protect your privacy and your information.

Things to consider...



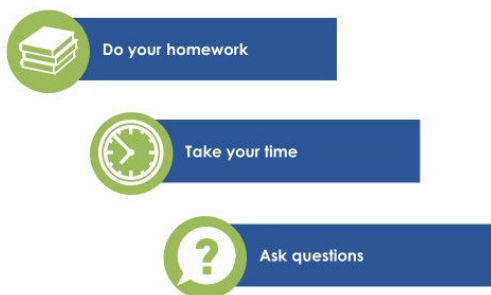
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Be sure to let all your doctors know you are in a clinical trial and have a contact number to reach the research staff in case of an emergency.

Volunteering takes time and effort. You can work with the study staff to try to accommodate your schedule.

Even if you want to continue to participate, your doctor, the referees, or the company making the new drug could stop the study.

Education before participation



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Many volunteers drop out of studies because they didn't fully understand what they were signing up for.

- ✓ Do your homework: Learn about the clinical trial and ask questions. Read all the information provided by the study staff.
- ✓ Take your time. There is absolutely nothing wrong with asking a researcher to slow down or explain.
- ✓ Ask questions. Talk about your concerns with the study staff, your doctor and your friends and family. Bring a friend or family member to study visits so they can ask questions, too. Try tape recording your visits or taking notes so you can refer to the information later and follow up with questions as needed.

If you decide to join a study, you should feel confident that you have made an informed choice. You should feel comfortable that the clinical trial staff will support you and answer all your questions.

Your decision at every step



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Here's a handy way to think about it, at every step.

You start by becoming aware of a clinical trial. You think you're interested so you discuss it with your doctor. If you're still interested, you need to know all the details. So you talk to the research staff and find out whether you're eligible. If it sounds like something that's right for you, you can choose to sign the informed consent form.

But even while you're taking part in the study, continue to ask questions and decide whether you choose to complete the clinical trial or not. Informed consent is an on-going process – not a single event.

Where should you go to learn more?



- www.searchclinicaltrials.org
- www.clinicaltrials.gov
- www.centerwatch.com
- www.ciscrp.org

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Today's presentation is an important first step. Now it's up to you to learn more about clinical trials.

The best place to start is with your doctor. You can also get information from local research centers, disease and advocacy groups, medical journals and conferences.

There are also websites devoted to clinical trials: ClinicalTrials.gov is a site maintained by the National Institutes of Health (NIH) that includes trial and enrollment information. CenterWatch.com lists trials that are enrolling volunteers. You may also check SearchClinicalTrials.org and ResearchMatch.org to learn about clinical trials and connect with study teams. In addition, many pharmaceutical and biotechnology companies list active trials on their websites.

You can also call 617-725-2750. CISCRP provides a free search service designed to help patients find trials that might be right for them. Or you may talk to patient advocacy groups, friends and family to help find resources for you.



Thank you...

to the millions of people who give the gift of participation in clinical trials each year and to the rest of us who admire them for doing so.



Research volunteers truly are Medical Heroes without whom medical science cannot move forward. Thank you for taking time today to learn about the clinical research process. We encourage you to share what you've heard with your friends, family and people throughout your community.

On behalf of all of us, I'd like to say "thanks to the millions of people who give the gift of participation in clinical trials each year; and to the rest of us who admire them for doing so."

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.

Call 1-877-MED-HERO or visit

www.searchclinicaltrials.org

Debunking Common Myths About Clinical Trials

MYTH: *Clinical trial volunteers are merely human guinea pigs.*

FACT: Strict guidelines are in place to ensure that all clinical trial volunteers are treated fairly and ethically. Before an investigational drug can be given to people who participate in clinical trials, scientists must do thorough tests of the drug in the lab. Additionally, every clinical trial has an informed consent process to help participants understand their rights, including the right to leave the trial at any time.

MYTH: *Informed consent is just reading and signing a piece of paper.*

FACT: Informed consent is more than just signing a document—it is a process. The informed consent document contains information to help volunteers make a decision about taking part in a clinical trial. This includes all the known information about the safety of the investigational drug and how it might work. The informed consent document describes the purpose of the trial and explains what will happen during the trial. It also includes the possible risks and benefits of participating. The informed consent process, however, is an ongoing one. It involves conversations with the trial doctor and staff and the chance to ask questions. It is a continuing, interactive discussion, rather than a one-time informational session.

MYTH: *Clinical trials are dangerous because they use new practices and medicines.*

FACT: Clinical trials are designed for research purposes, and as a result, some level of risk is involved. However, an investigational drug is given to clinical trial participants only after the drug has been tested in a lab and the FDA has decided the drug may be tested in humans. The safety of trial participants is a top priority for those involved in running the trial. All clinical trials are reviewed before they start by an Institutional Review Board (IRB). This is a committee made up of doctors, scientists and community members who have the responsibility to protect clinical trial participants. The purpose of the IRB review is to make sure that appropriate steps are taken to protect participants' safety and rights both before and during the trial. During the trial, researchers assess and monitor participants' safety.

MYTH: *Once I decide to participate in a clinical trial, I will not be able to change my mind.*

FACT: Clinical trials rely on voluntary participation. You are free to leave a clinical trial at any time, even after you have signed an informed consent document and received the investigational drug. However, you should always let the trial doctor or staff know before you decide to leave the trial. This way, they can help you stop safely.

MYTH: *All clinical trials include painful or unpleasant parts.*

FACT: While all trials involve some risk and many involve some discomfort or pain, each trial is different. The procedures may also be different. The trial doctor will talk to you about what to expect, and the procedures and risks will be listed in the informed consent document. The IRB will ensure that the risks and benefits are carefully weighed and that the trial is reviewed for unnecessary harm or discomfort before it starts.

MYTH: *Some people who want to volunteer for a clinical trial are told they cannot participate, for no reason.*

FACT: Every clinical trial has a protocol, which is a plan that describes how the trial will be conducted. The protocol also includes "eligibility criteria" for who can and cannot take part in the trial. These are guidelines that include the details of the population to be studied in the trial. This includes age range and gender, health condition, and other important details. These eligibility criteria are used to make sure that the researchers can answer the questions about the investigational drug that they plan to study. The criteria can also help identify the population believed to be most likely to benefit from the clinical trial.

MYTH: *I have nothing to gain from being in a clinical trial.*

FACT: Before you decide to participate in a clinical trial, you should speak with the trial doctor or staff about the possible risks and benefits of participating. In some trials, participating may mean that you have the opportunity to receive an investigational drug that is not available to people outside the trial. You may also get additional tests and lab work that might not be part of your usual care. While you may not get a health benefit from being in a trial, you may find it helpful in other ways. According to CISCRP's 2013 Perceptions and Insights study, some trial volunteers felt great personal satisfaction in the fact that they played a key role in helping to advance medical science.

MYTH: *Being in a clinical trial is expensive and isn't covered by medical insurance.*

FACT: Clinical trial volunteers are rarely responsible for the costs related to participating in the trial. There are two types of costs associated with a clinical trial: research costs and patient care costs. Research costs are those associated with conducting the trial. They include costs for data collection and management, research physician and nurse time, and tests performed purely for research purposes. These costs are usually covered by the sponsoring organization, such as a biopharmaceutical company. Patient care costs are those that are not covered by the research sponsor doing the clinical trial. These include costs for routine care such as visits to a primary care doctor, and clinical trial-related activities that would be done even if a participant was not in the trial. Many health insurance carriers will cover patient care costs, but you should ask the trial doctor or staff which costs will be your responsibility. You should also check with your health insurance carrier about the coverage they provide for clinical trial participants before deciding whether to participate in a clinical trial.

MYTH: *If there is a clinical trial that might help me, my doctor will tell me about it.*

FACT: The best place to start is with your doctor, but your doctor may not know about all available clinical trials that might benefit you. You can get information from local research centers, friends and family to help find resources for you. Here are a few websites that might help:

- www.clinicaltrials.gov is a site maintained by the National Institutes of Health (NIH) that includes trials and enrollment information.
- www.searchclinicaltrials.org is a free search service, organized by CISCRP that's designed to help people find trials that may be right for them. You can also call 617-725-2750 to speak with a CISCRP team member who can manually search for you and connect you with a study team.
- www.centerwatch.com lists trials that are enrolling volunteers.

You might also contact a patient advocacy organization by phone or email to help you navigate the process. Many of them have tailored services that can help you with your search and help you understand the options.

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

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.

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.

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.

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 as age, 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 health care provider or researcher about participating in a clinical study.

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 that they 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:

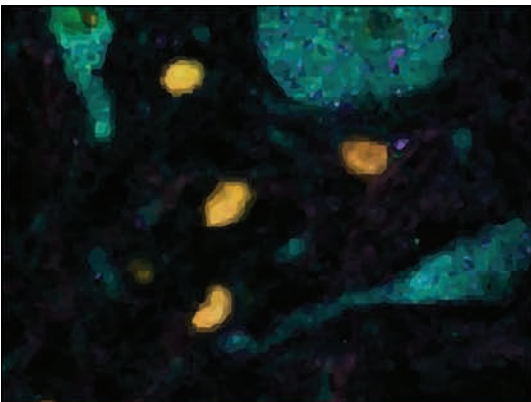
- The safety and the effectiveness of the experimental approach or use may not be fully known at the time of the study.
- Some studies may provide participants with the prospect of receiving direct medical benefits, while others do not.
- Most studies involve some risk of harm or injury to the participant. (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.

Questions to Ask

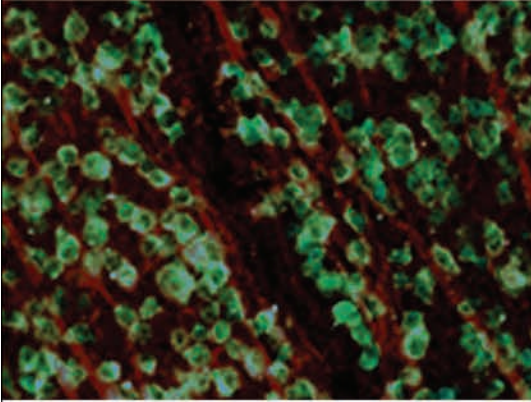
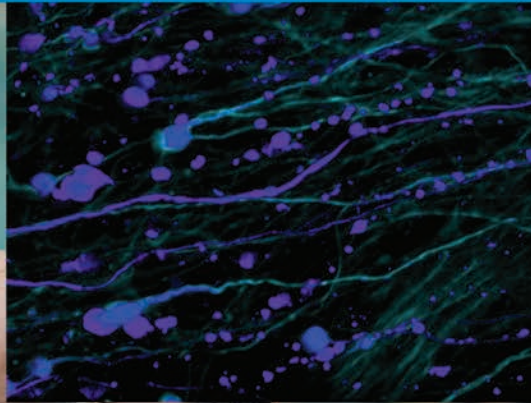
Anyone interested in participating in a clinical research study should find out as much as possible about the study and feel comfortable asking the research team questions about the study. The following questions might be helpful during such a discussion. Answers to some of these questions would be provided 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.



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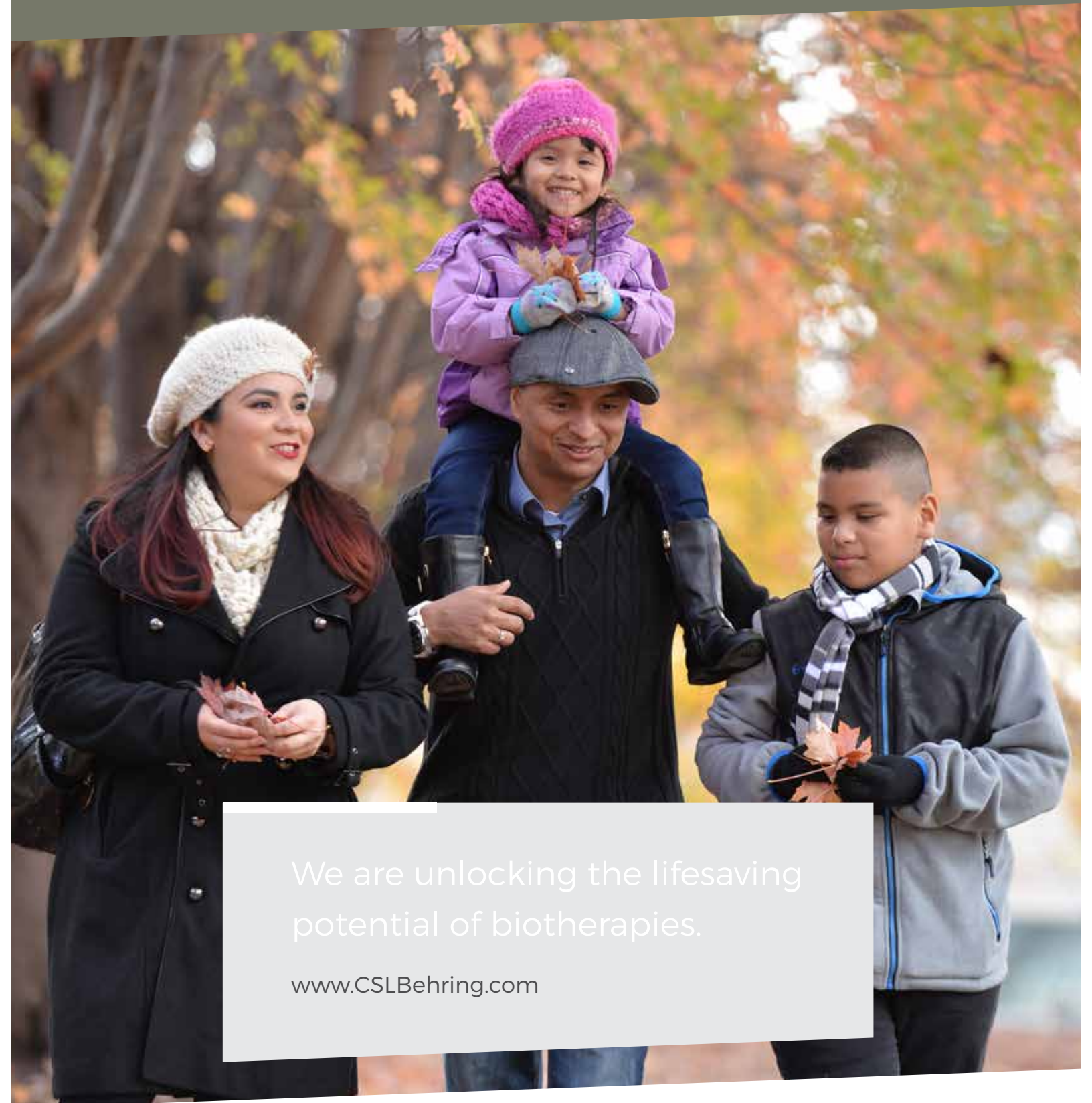
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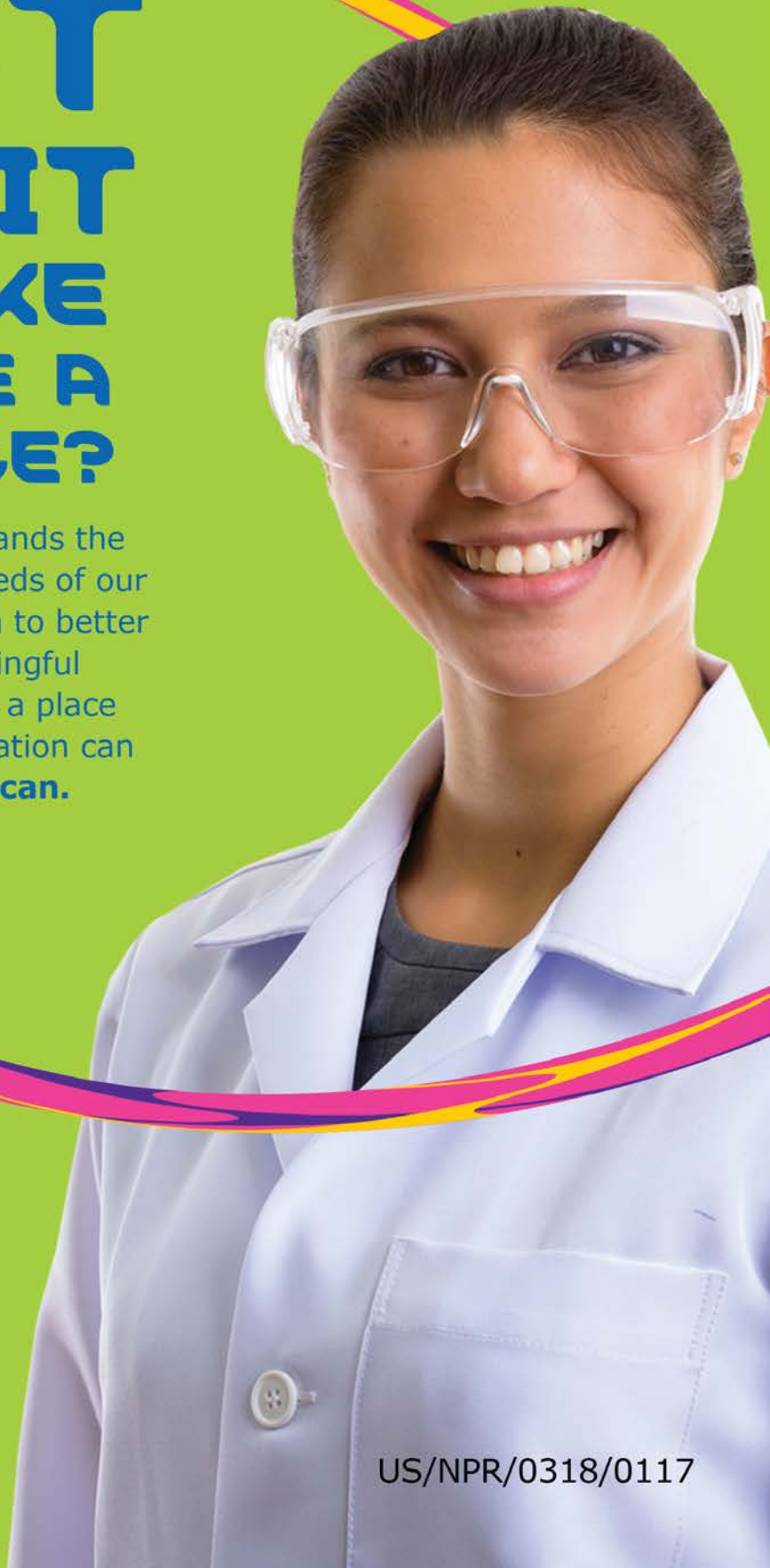
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- > Teams are focused on understanding unmet needs directly from the patient perspective and developing solutions that improve patient outcomes



ACCOUNTABLE

PROGRESS IS MEASURED OVER TIME USING A PATIENT ENGAGEMENT DASHBOARD TO:

- > Hold ourselves accountable
- > Ensure we are incorporating patient insights throughout the entire medical product development process
- > Identify and address areas for improvement

SYSTEMATIC

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- > Help define what dosage form to make and how the medicine's use instructions should be explained
- > Shape development of disease education materials and support programs

DYNAMIC

WE ARE FLEXIBLE AND NIMBLE TO MEET EVOLVING PATIENT NEEDS.

- > Launched the Compassionate Use Advisory Committee (CompAC), a first-in-industry group of external advisors supporting fair, ethical evaluation of pre-approval requests
 - > Refined Global Trial Finder for patients to easily locate trials
- > Revised clinical trial Informed Consent Form to enhance understandability and make available electronically in countries where permitted



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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



Connecting Patients to the Right Clinical Trial

WCG is proud to support CISCPR's *AWARE for All* campaign.

For decades, WCG has advanced the protection and ethical treatment of patients in clinical trials, helping our clients and partners connect the right patients to the right trials.

We believe in:

Education: Part of our mission is to provide patients with access to resources that inform them about clinical research and participation.

Patient-centricity: There is no substitute for the patient voice. WCG incorporates it in every step of the clinical trial process, from protocol design to regulatory review.

Representation: WCG and our partners strive to make clinical studies more diverse. Inclusivity is good public policy *and* good science.

WCG supports, empowers and protects patients throughout their clinical journey while helping companies conduct safer, more efficient trials.

Learn more at www.wcgclinical.com/covid-19/covid-19-patient-resources/.



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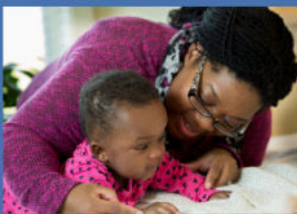
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MEDICAL HERO SPOTLIGHT

KATIE KLATT

At the beginning of the pandemic in mid-March, Katie Klatt, a nurse on a COVID-19 infection control team, received the news that she had contracted the virus herself.

"I wasn't too surprised," Katie said. "I kind of knew, but the actual confirmation was a little bit scary. It was early on so no one in the US really understood how bad it was." A healthcare professional, Katie's background includes working as a PICU nurse and she had just moved to Boston to pursue her Master in Public Health at the Harvard Chan School. Now fully recovered, Katie is a patient participant in a COVID-19 antibody clinical study. This is her story.

Katie contacted her primary care physician when she started having symptoms. "I was treated in two different ways. The first week I was seen via telehealth, and that was literally the same week that so many medical professionals and patients were turning to that option. My doctor was retiring, so I didn't really have anyone following me. The onus was on me to check in and report my symptoms." At the end of the first week, Katie was advised to be seen in person, at an urgent care clinic. However, being symptomatic, she could only be seen at the urgent care if she was a previous patient. Being new to the area, this was not the case. Her only other option was to go to an emergency room.

"At first, I didn't think I was sick enough to go to the ER. I didn't want to take an Uber and infect anyone else and I was too tired to ride my bike. So I waited until the Tylenol kicked in and walked 40 minutes to the hospital. At the emergency room, they were really well set up. When I walked in, people started to call 'Rule out!' which means a COVID-19 patient is entering the area, so people started to move away from me as I passed by. After I was seen, Security escorted me out the back door to protect other patients and staff," Katie said.

The hospital pharmacy was closed, so Katie was handed a paper prescription to have filled elsewhere. Even though she was wearing a N-95 mask her mother had sent to her a few weeks before she got sick, Katie realized she should not enter a store. She was also concerned about handing the paper prescription to a pharmacy technician. Katie called a friend who met her at the pharmacy with a clear plastic sandwich bag. She dropped the prescription in it and her friend brought it inside and had it filled.

In addition to having COVID-19, Katie also had a sinus infection. When she was diagnosed, Katie knew what to do. "Stay at home, isolate, hydrate and rest," Katie stated plainly. "As a healthcare provider, we tend to minimize our own complaints because we've seen so much worse, so my view of it was skewed. Having a 103 degree temperature for 10 days, it was almost like I got used to having the chills and feeling exhausted constantly."

Katie socially isolated from her roommates, staying in her room and only entering the kitchen when they were not present. "I had the presence of mind, despite the high fever, to clean everything I touched – that's from my nursing background. I'm happy to say my roommates didn't get the virus." Family and friends sent care packages and checked in with phone calls and texts which helped buoy Katie's spirits.



Katie Klatt — COVID-19 Clinical Study Participant and Infection Control Team Nurse with Boston Emergency Medical Services

A few days after starting medication, Katie began to rapidly recover. She attributes this, in part, to being a lifelong athlete, playing in Australian and Gaelic football leagues. "When I got COVID-19, I lost about 10 pounds in a week and I lost a lot of my fitness. When my taste started to come back, I was able to eat more and work towards regaining my fitness."

Katie is using her experience with COVID-19 to assist others. "A friend of mine who is a nurse told me about a clinical study, so I registered for it. The purpose of the study is to monitor levels of COVID-19 antibodies present to see how long they last in a recovered patient's body. It's a two-year commitment." On a monthly basis, Katie's blood is drawn and analyzed. Currently, she has not been notified of recent results and she hopes to be informed soon.

In her role as a nurse on the COVID-19 infection control team at Boston Emergency Medical Services, Katie shares her story with EMTs and paramedics who have been exposed to or have contracted the virus while treating and transporting patients. "This is an isolating disease," Katie explained. "Not having a stigma attached to it is important. It helps them when I explain what I went through when I was sick."

When asked if she is concerned about contracting COVID-19 again, Katie said "I probably should be. I have reached the same fatigue that everyone in the world has now, around COVID-19. It's hard to maintain that level of high alert. But I am being careful, more for others than for myself. I wear a mask everywhere, even when I am running outside. I do it because I don't want anyone else to get it."

Katie cautions others to be just as vigilant. "Just because we're opening up, it's not over. Wear a mask to protect yourself and others. Keep talking about it so that people don't forget."

JOIN AN EDITORIAL PANEL

CISCRP's Trial Results Summary program provides study participants with the results of their clinical trial. To help develop the summaries, we call upon medical professionals, patient advocates, and patients from around the globe to form Editorial Panels. These panels review the plain language summaries and communications before they are sent to study participants. Our Editorial Panels are essential to the review process of lay summaries. This independent review is conducted remotely, by individuals in their own locale.

Editorial panelists review summaries and plain language communications that match their area of expertise or interest. This helps us deliver easy-to-understand, yet scientifically accurate summaries to study participants around the world.

Panelists:

- Highlight areas that may be confusing to study participants
- Identify potential bias
- Note sections that seem to be missing information

Editorial Panel participants may include:

- People who are familiar with a specific disease or condition
- People who are interested in helping to improve health communications
- Patient advocates
- Healthcare professionals

Time commitment for this is minimal. Typically, it takes about an hour of one's time to complete a review and all correspondence can be done via e-mail. Participants are given a total of 5 business days to complete their review.



If you are interested in participating or would like to learn more about this opportunity, please contact:

Lauren Menna

Editorial Panel and Quality Associate

Email: lmenna@ciscrp.org

Phone: 617-725-2750 x116

How Are New, Promising Therapies Developed?

There has been a substantial amount of information about how government agencies, industry, health care professionals and others are responding to COVID-19. However, there is limited information about why clinical trials are a critical part of the process.

With generous support from Biogen, Bristol Myers Squibb, Janssen, Lilly, Merck and Takeda, CISC RP has launched a new video series to walk through how therapies are developed, how ongoing trials are adapting, and how study volunteer experiences may change with emerging technologies and new clinical trial models.

We hope you find these educational resources helpful.



[Video #1](#) General Clinical Research Overview

[Video #2](#) How Ongoing Clinical Trials Are Adapting in The Current Environment

[Video #3](#) Participating in COVID-19 Clinical Trials & Emerging New Clinical Trial Models

To watch the videos and learn more, please visit [FindingTreatmentsTogether.org](https://www.findingtreatments.together.org) and don't forget to subscribe to our [Youtube Channel!](#)



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](https://www.medicalheroes.org) to learn more.

A Look at COVID-19 Vaccines and Treatments

You've probably heard a lot in the news lately about the development of vaccines and treatments for COVID-19. But what exactly will these treatments look like and what are researchers doing to discover them?

Researchers are testing a number of approaches in clinical trials that involve introducing a weakened or inactive form of the virus into the body to prompt an immune response without causing harmful disease. If the body reacts as desired by creating antibodies to attack the virus, then it may build protection against future infection. Vaccines like this have been successfully developed to prevent many diseases like measles, mumps, rubella, smallpox, and chickenpox. Other vaccines under investigation, such as genetically engineered DNA or mRNA vaccines, try to trick the coronavirus into mutating into a form the body can more easily and effectively attack. Another category of vaccines are those intended to block the virus from attaching to healthy cells in the body and reproducing to cause widespread infection.

As researchers work to uncover an effective vaccine for prevention, they are also testing treatments in specific patient populations that are already infected with COVID-19. These treatments look to lessen the severity of symptoms and shorten recovery times. Some treatments currently in development seek to moderate the body's own immune response to the virus.

The necessary steps

Vaccines and treatments for infectious diseases usually take nine or 10 years to develop, and most will fail to complete the process or obtain regula-

tory approval. This seems like a long time, but it is necessary for understanding the real effects of a new therapy and determining whether it is safe and effective at specific dosage levels.

Clinical trials follow a set progression: They begin with a small number of people to assess whether a treatment is safe, then grow to further evaluate safety and efficacy. At each stage of this progression, researchers review the results of clinical trials and get approval to move on to a subsequent stage.

Accelerating the process

The clinical trial process for COVID-19 treatments and vaccines is moving at a faster pace and may produce promising therapies within a few years. The pandemic has mobilized much higher levels of coordination between companies and government agencies. Some treatments and vaccines have a head start because they are based on research that was conducted for viruses that are similar to COVID-19.

Fast-tracked treatments and vaccines in clinical trials have received a lot of attention in the news. They include Moderna's vaccine (mRNA-1273), Gilead Sciences' treatment (remdesivir), Regeneron and Sanofi's Kevzara treatment (sarilumab), and the antimalarial drugs hydroxychloroquine and chloroquine.

In some instances, for the most promising treatments and vaccine candidates, the Food and Drug Administration (FDA) may issue an emergency-use provision so patients, doctors, nurses, and other essential workers can begin using it. Under emergency-use conditions, even more information about a new vaccine or treatment will be used to inform researchers and the FDA about safety and efficacy. □

Katherine Marriott, Marketing Program Manager, CISCRP



What to Expect in Remote and Virtual Clinical Trials

Since the outbreak of COVID-19, many clinical trials that would once be conducted in-person have moved to patients' homes to minimize exposure and observe social distancing requirements. Here's what you can expect if you're participating in a clinical trial while staying at home.

For many remote and virtual clinical trials, participants are loaned a smartphone or handheld device preloaded with a study application and data plan that allows for secure, video-based telemedicine visits, and grants the ability to directly communicate with the study coordinator at any time.

These devices can be used to send text and email reminders to complete questionnaires, perform simple procedures, and take study medicines. Participants may also receive devices to measure their own vital signs (e.g., blood pressure, temperature, pulse rates) during telemedicine visits with the research staff. In some clinical trials, participants may be asked to wear sensors, such as a Fitbit or Apple smartwatch, to continuously measure health data, including heart rate and activity levels.

In-home visits

Trained nurses and clinicians who visit patients' homes typically bring all of the necessary equipment to home-based visits, and the procedures occur just as they would at the study site.

Study volunteers will need to record when they take their study medication. Samples are usually processed in the patient's home and then sent to labs for analysis. Mobile nurses and clinicians notify the principal investigator immediately to report side effects. They also submit reports following each visit and discuss any important details with the study staff.

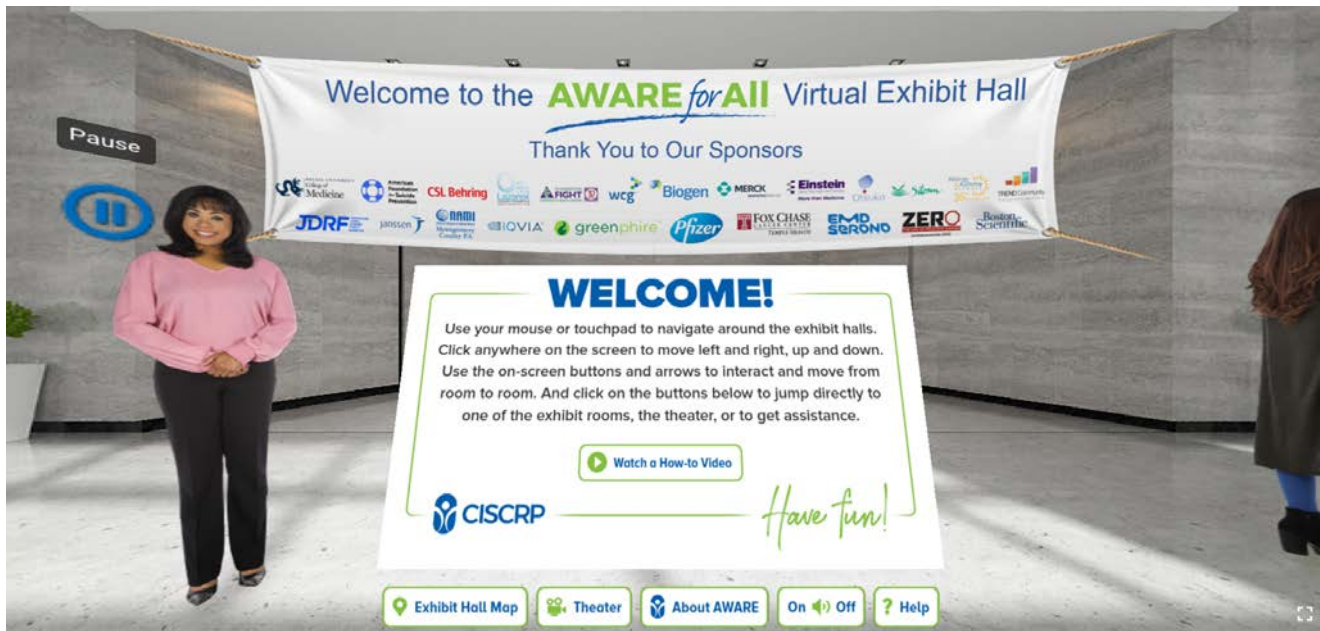
For some virtual clinical trials, investigational drugs may be shipped directly to and administered in the patient's home. Depending on the particular study, patients and their caregivers will either receive instructions on how to take the medicines themselves, or the visiting nurse or clinician will administer the study treatment during the home visits.

CISCRP Editorial Staff



There are many useful resources that provide real-time information about COVID-19 vaccines and treatments. To learn more, visit www.ciscrp.org/services/search-clinical-trials/. If you would like to learn more about the clinical trial process and the phases of clinical research, visit <https://www.ciscrp.org/education-center/>.

AWARE FOR ALL VIRTUAL HEALTH FAIR



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We are excited to launch our new and improved online AWARE for All program with a virtual exhibit hall. Connect with health and wellness organizations and visit our virtual cinema!



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Thank you to everyone involved in clinical research for pushing the boundaries of medicine to find new treatments and vaccines.

Medical advancements wouldn't be possible without the millions of people who take part in clinical research. Together, we are making discoveries that can help us improve medicine for generations to come.

To learn more about clinical research and to show your appreciation, visit [CISCRP.org](https://www.ciscrp.org).

A sincere thank you to all medical heroes from the following organizations:



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