AWARE *for* All ATLANTA

VIRTUAL COMMUNITY EVENT

NOVEMBER 16-18, 2021
6:00 -7:00 PM EST

PROGRAM HANDBOOK

NOVEMBER 16TH

- Clinical Trial Overview Presentation
- Informational Exhibit Center Opens

NOVEMBER 17TH

- Panel Discussion
  - Hear from clinical trial participants and their perspectives on clinical research

NOVEMBER 18TH

- Panel Discussion
  - Healthcare professionals share their perspectives about their roles in clinical research

CISCRP

THANK YOU TO CISCRP'S

AWARE INDUSTRY CONSORTIUM

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. over these next four years through the ***AWARE for All***: **Clinical Research Education** program.

THANK YOU TO ALL MEMBERS OF THE AWARE INDUSTRY CONSORTIUM

Genentech – A Member of the Roche Group
Janssen Pharmaceutical Companies of Johnson & Johnson
Otsuka
Pfizer
WCG WIRB COPERNICUS GROUP
Biogen
Novartis
CSL Behring – Biotherapies for Life™
EMD Serono
IQVIA

2021 *AWARE FOR ALL* EVENTS SCHEDULE

To explore our ***AWARE for All*** events' resources and offerings, click on one of the event listings below or go to awareforall.org.

NORTHEAST - APRIL 15TH
NORTHWEST - MAY 20TH
MIDWEST - JULY 22ND
SOUTHWEST - OCTOBER 21ST
ATLANTA - NOVEMBER 16TH-18TH

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

Dear *AWARE for All* attendees, supporters, and friends: November 16, 2021

Welcome to *AWARE for All – Atlanta*. 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, EMD Serono, Genentech, IQVIA, Janssen, Novartis, Otsuka, Pfizer, and WCG.

A special thank you to Illumina Interactive for designing the custom interactive Informational Exhibit Center 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 Atlanta community has been encouraging and convinces us even more of the important need this program fills. With the assistance of our valued community partners, e-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

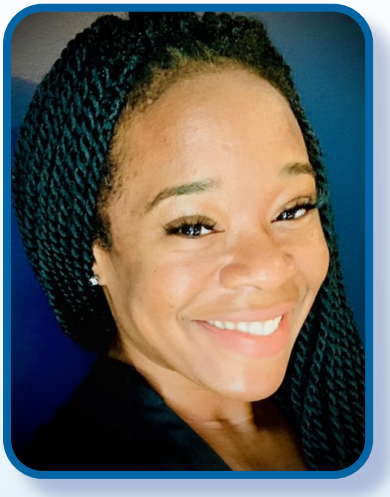
Joan A. Chambers
Senior Director,
Marketing & Outreach
CISCRP

Phyllis Kaplan
Senior Manager,
Events & Community
Engagement
CISCRP

Hope Ventricelli,
Manager,
Events & Community
Engagement
CISCRP

FEATURED SPEAKERS

November 17th | 6-7PM EST



Melissa Hardman, Faces of Research LLC

Glenn Bachman, Lymphoma Trial Participant

Ashley Nealy, COVID-19 Vaccine Trial Participant

Tina Berry, Breast Cancer Trial Participant

Terp Vairin, Mental Health Trial Participant

FEATURED SPEAKERS

November 18th | 6-7PM EST

Mary Slomkowski,
Otsuka

Meghan McKenzie,
Genentech

Leah Szumita,
Leukemia &
Lymphoma Society

Zach Mitchell,
iResearch Atlanta

Tamara Wakhisi,
Northside Hospital Central
Research Department

Phyllis Kaplan,
Type 1 Diabetes Trial
Participant

Yolanda Little,
Novartis

AWARE *for* All

Planning Committee

CISCRP thanks the *AWARE—Atlanta* planning committee for their dedication and all their hard work on this event, as well as their continued support of CISCRP.

Rachel Barber
iResearch Atlanta

De De Gardner
Allergy & Asthma Network

Shantoria Brown
Georgia NCORP

Cory Lewis
RedMoon Project, Inc.

Loren Ferguson
Good Samaritan Atlanta Health Center

Indya Hairston
SisterLove

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

Joan Chambers, Senior Director, Marketing & Outreach

Lindsey Elliott, Coordinator, Events Marketing & Communications

Julia Steele, Coordinator, Events Marketing & Communications

Phyllis Kaplan, Senior Manager, Events & Community Engagement

Hope Ventricelli, Manager, Events & Community Engagement

Justine Holleran, Senior Coordinator, Events & Community Engagement

MEDICAL HERO SPOTLIGHT

Meet Medical Hero Shauna Whisenton-- Sickle Cell Disease Advocate

Shauna Whisenton was once an individual living with sickle cell disease (SCD). Now she's an advocate for better therapies, a cure, and better understanding of SCD.

Whisenton, now 41, was born with SCD, a painful, inherited disorder where red blood cells are misshaped, restricting blood flow and oxygen to parts of the body. After the birth of her third son, her health took a turn for the worse. While nursing, she was admitted to the hospital every few weeks and, despite best efforts, was not replenishing enough fluids for her body to function properly and had major organ complications. Her doctor asked her to consider a bone marrow transplant clinical trial to cure SCD.

Read Shauna's inspiring story here.

Meet Medical Hero Reverend Donna Matlach-- Eosinophilic Asthma Advocate

Donna's medical journey has been arduous and at times, terrifying, but her upbeat nature shines through during our conversation about her experience with clinical research participation.

The severity of her symptoms sapped Donna of her physical strength, but not her inner fortitude. Taking matters decidedly into her own hands, Donna went on a cross-country journey in order to find medical advice and effective treatment. Conducting a lot of research on her own, Donna visited 28 doctors, the majority being pulmonary specialists, in 12 hospitals, nationwide.

Read Donna's inspiring story here.

AWARE *for* All

ATLANTA

VIRTUAL COMMUNITY EVENT

Join us at *AWARE for All* and tune in to our webinar which offers the opportunity to hear personal experiences from clinical trial participants and healthcare professionals in your community and across the country. Additionally, you can visit our virtual Informational Exhibit Center to connect with 30+ health and wellness organizations and access easy-to-read resources about clinical trials.

Click Here to Visit the *AWARE for All* - Atlanta Informational Exhibit Center

Click Below to Learn More About Our 2021 *AWARE for All* Events:

NORTHEAST	NORTHWEST	MIDWEST	SOUTHWEST	ATLANTA
Thursday, April 15	Thursday, May 20	Thursday, July 22	Thursday, October 21	November 16-18

Welcome to *AWARE for All- Atlanta*. 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, with support from local organizations.

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

Have you ever taken allergy medicine or a pain reliever?

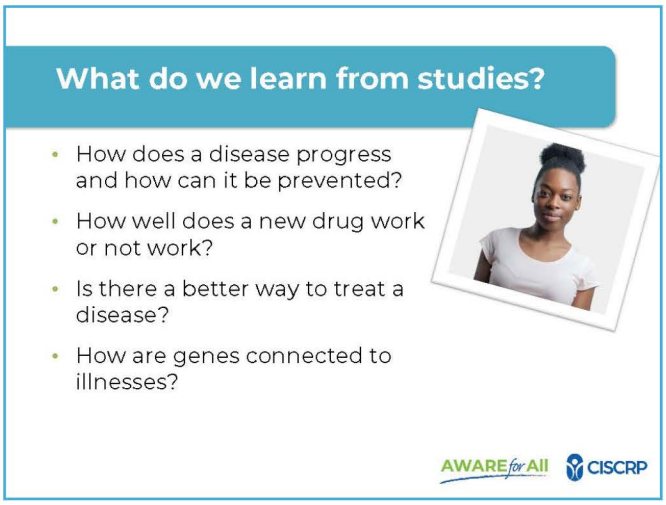
If so, you can thank clinical research participants.

Around the world, people are living longer and healthier lives because of the selfless individuals who take part in clinical research trials. These trials help find ways to prevent, treat and even cure certain medical conditions.

We like to call the participants "Medical Heroes."

At CISCRP, we believe study volunteers are important partners in the research process.

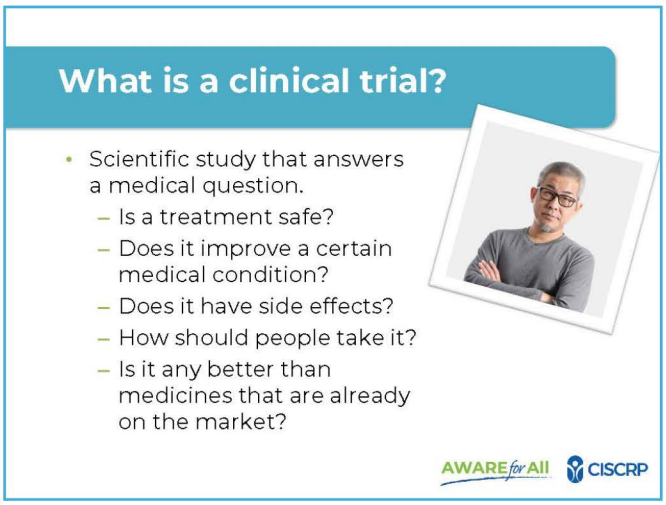
That's why our motto is "education before participation." Partnerships work best when everyone understands the overall goal, what may be expected of them, and how they are protected throughout the process. This includes clinical researchers too: the information medical experts learn from clinical trials improves public health and can even save lives.



And it all starts with these questions:

- 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?
- Does where people live affect their health?

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



A clinical trial is a carefully designed study in which a participant may be asked to take a new drug or treatment, so that researchers can answer a specific medical question.

These are questions like, is a treatment 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 treatments, there are risks to participants in a clinical trial. However, something valuable is always learned from clinical research studies that improve public health and can potentially lead to game-changing treatments.

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, they'll give you a treatment that has already been tested and approved by the government. This is called "routine" or "standard of care."

You can't fully understand something by studying just one group of people.

Gender, age, and ethnicity affect the way people respond to diseases and treatments. For example, Alzheimer's disease happens twice as often in women than in men. Type-2 diabetes and asthma are more common in people who are black and of African descent. Hispanic, Asian, and White women are more likely to develop osteoporosis.

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. But today, clinical trials welcome the participation of all people, and they are closely monitored for their safe and ethical treatment.

Today, health professionals are more aware than ever of the need to have diverse populations in clinical research.

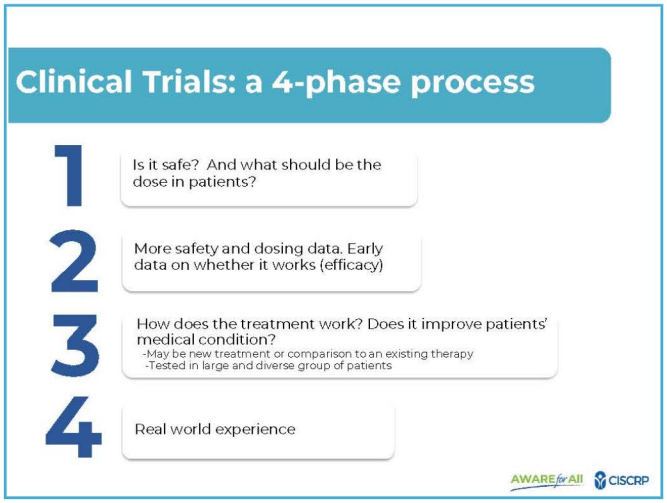
As a community, we are taking steps to break down participation barriers, improve diversity, and pave the way to a healthier future for everyone.

Several studies have shown that under-represented, minority populations consistently demonstrate a high willingness to participate in clinical research studies. 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. You may remember past abuses like the Tuskegee Syphilis Study, in which treatment was withheld from Black 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 experimented on patients without their consent and were not compensated for their participation.

Today, federal guidelines and ethical practices are in place to monitor the safety and to protect the rights of trial participants.

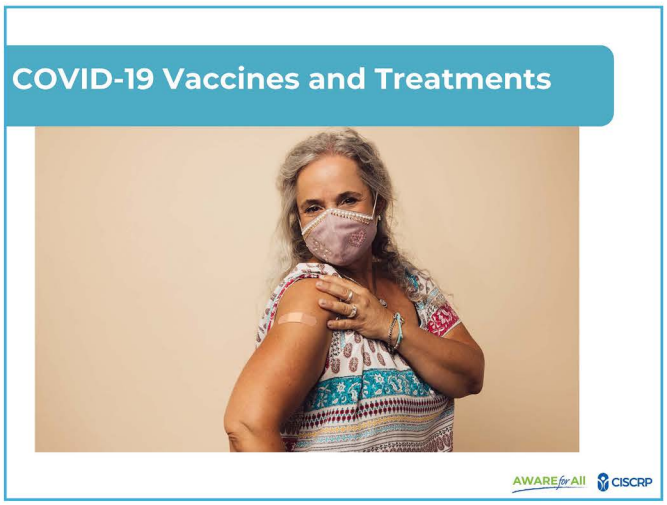
If we work together, we can solve these problems and make clinical trials far more accessible.



Let's talk a bit about how clinical trials move forward and how long it typically takes to advance a new treatment.

Clinical trials begin with a small number of participants. The goal of this is to learn more about how safe a new treatment is. Next, clinical trials recruit larger numbers of participants to test how well the treatment works and help researchers learn more about its safety. This part could take several years!

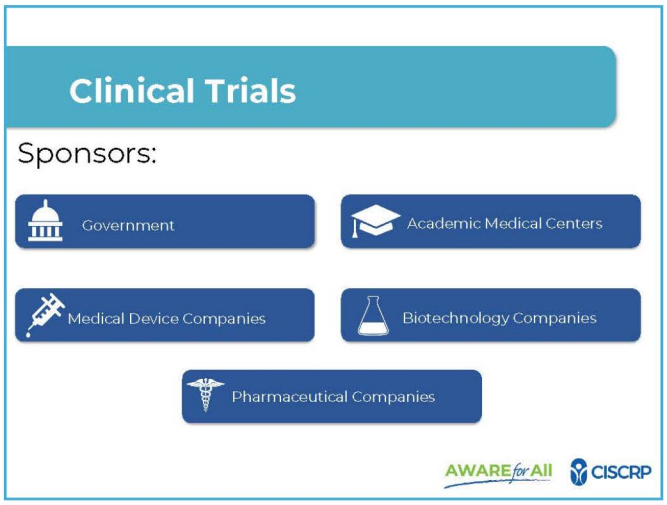
Researchers continue to study treatments after they have been approved. These trials usually involve large numbers of participants. In these trials, researchers look at real world experience and check to see if the treatment works well over a long time.



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

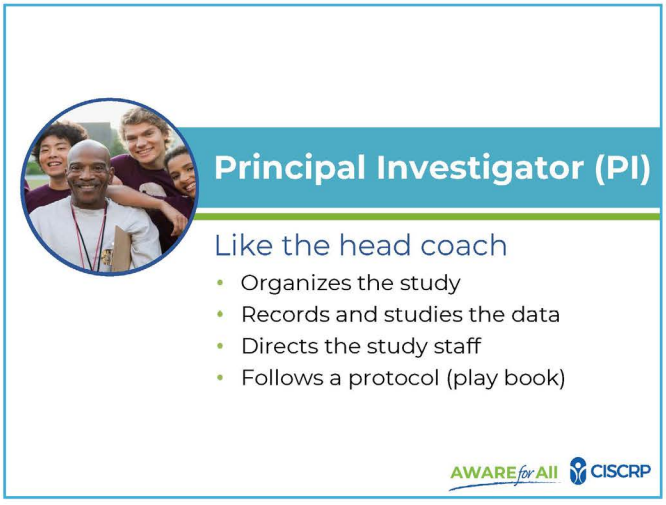
Vaccines and treatments for infectious diseases usually take nine or 10 years to develop. This seems like a long time, but it is necessary for understanding if a treatment is safe and effective at specific dosage levels.

However, the clinical trial process for COVID-19 treatments and vaccines is moving at a faster pace and may produce promising therapies in only 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.



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

Clinical trial research requires many different people, each of whom is critical to the process. Like members of a sports team, clinical trials have coaches, players, and referees, and each person has an important role to play.



The Principal Investigator (PI) is like the head coach of a team. They are responsible for organizing and leading the trial as well as recording and analyzing the data.

Like a head coach, the PI follows a play book, which is called the trial “protocol.” The protocol is a set of instructions that everyone on the team must follow.

The research staff members are like assistant coaches who help the PI.

The Clinical Research Coordinator handles the day-to-day activity at the research site. They work closely with the PI and are the main contact for participants.

Organizations that help protect the safety of participants are the referees.

The referees make sure teams follow the rules, review the trial before it starts, and keep participants safe. The number and type of referees involved in a trial depends on the research being conducted.

Every clinical trial is reviewed, approved, and supervised by an independent local ethics committee.

This committee makes sure a trial is ethical and fair and that there is not too much risk for participants.

During the trial, researchers must let the committee know if there are any changes in the trial plan. Or if participants experience serious injuries or side effects. The ethics committee can end a trial if it feels participants are not safe.

Referees from the federal government are also involved.

Agencies like the FDA or the European Medicines Agency review trials, inspect research centers, and monitor research groups to make sure they are following federal guidelines. These agencies have the final say in whether or not a treatment is approved.

Now let's talk about the most important members of the team: The trial participants. Participants 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. Research can include sick OR healthy participants.

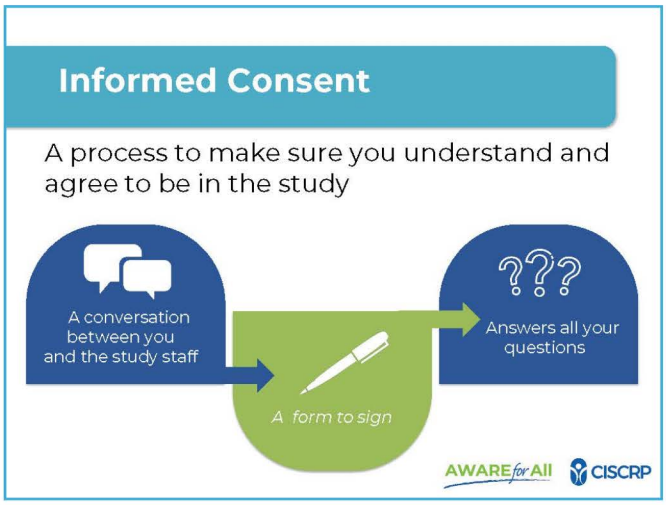
Your friends and family can be your support system while you are taking part in a trial. They can help you come up with questions to ask your doctor.

In the end it is your job to make the final decision if you will participate in the trial.

Everyone has the chance to participate in research, you just have to find the clinical trial that is right for you.

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

If you are considering a trial, be honest with researchers about your health. Lying or hiding information to get into a trial could endanger your safety and harm the research.



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 local ethics committees. Informed consent is one of the most important parts of research and it's a term you're going to hear a lot. Remember that informed consent is an ongoing process throughout the whole trial, not a single event.

If you decide you are interested in participating in a clinical trial, the trial staff will go through the informed consent form with you and answer any questions. Before you can participate in a trial, you must read, understand, and sign the informed consent form. It's important to note that you don't have to review the informed consent form in English if there's another language that you prefer to speak.

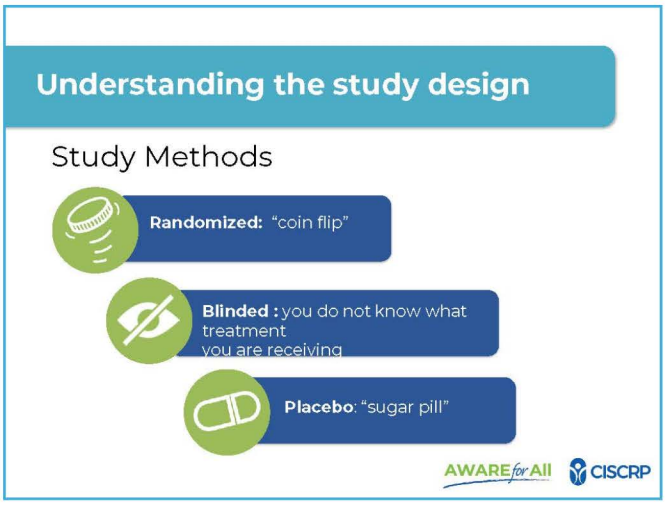
If you participate in a clinical trial, you have rights.

You have the right to understand the purpose, benefits, risks, and side effects of the clinical trial.

You have the right to ask questions and discuss your concerns. It's important for participants to ask questions until they fully understand the trial.

Most importantly, you have the right to quit the trial at any time for ANY reason. The research staff will help you do this safely!

Deciding to take part in a clinical trial is a personal decision. What's right for you may not be right for someone else!



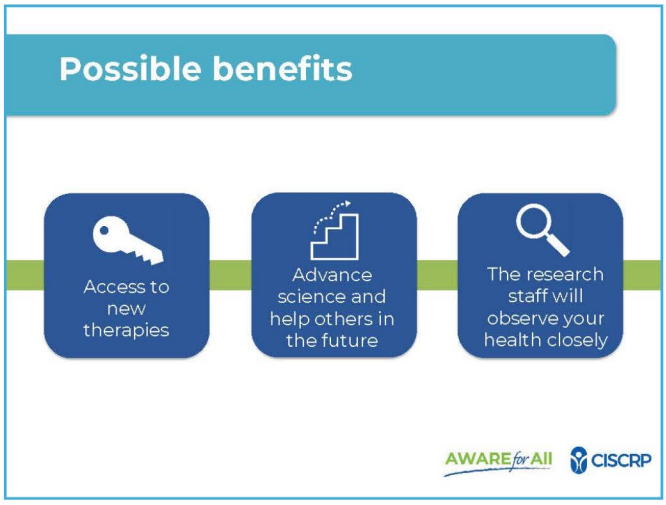
Researchers set up their studies so their trial will be fair. They also want their research to be accurate and unbiased. They don't want their own ideas about what they think should happen in a trial to influence the results.

To set up fair studies, participants may be randomly split into different trial groups. In this case, the researcher and the participants do NOT get to decide which group the participants will be in. This is called a "randomized" trial.

Sometimes, the participants do not know which treatment they are receiving. When the participants or researchers in a clinical study both do not know which treatment each participant gets, it is called "blinding".

In some trials, researchers will use a "placebo." A placebo looks like a trial treatment but does not have any medicine in it.

Sometimes the placebo in the form of a drug 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."



Deciding to participate in a clinical trial is a personal decision. Here are some of the reasons why you might consider getting involved in trials:

- Get access to new treatments that are not publicly available
- Advance science and help others who have the same condition as you
- Receive free and close health care monitoring

SOME, but NOT ALL clinical trials will pay for travel costs and for time and commitment. The amounts vary widely. These benefits are in addition to the help you will provide for health research.

Of course, all research involves risks.

- There can be physical risks. A sick participant may not get better. They may feel uncomfortable or their symptoms may get worse.
- There's an emotional risk. The trial can be demanding and participation may be stressful.
- Financially, there may be out-of-pocket expenses such as child care or missing work.

And when you agree to participate in research, you are giving permission for researchers to collect information about you.

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

The trial may end early. Even if you want to continue to participate, your doctor, the referees, or the company making the new drug can stop the trial at any time.

Unfortunately, many participants drop out of studies because they don't fully understand what they were signing up for. Here are some tips if you are in a trial:

- Do your homework. Read all the information provided by the trial staff. You can even go online to learn about the potential treatment being studied.
- Take your time. There is absolutely nothing wrong with asking a researcher to slow down.
- Ask questions. Bring up any concerns with the trial staff, your doctor, and your friends and family.
- Bring a friend or family member to ask questions too.

If you decide to join a trial, 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.

There are a lot of things to consider when you decide to participate in a clinical trial. 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 advocacy groups, and conferences.

You can also find more information in the CISCRP booth in the Informational Exhibit Center.

Clinical research participants truly are Medical Heroes without whom medical science cannot move forward. On behalf of all of us at CISCRP, "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."

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.

Call 1-877-MED-HERO or 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.

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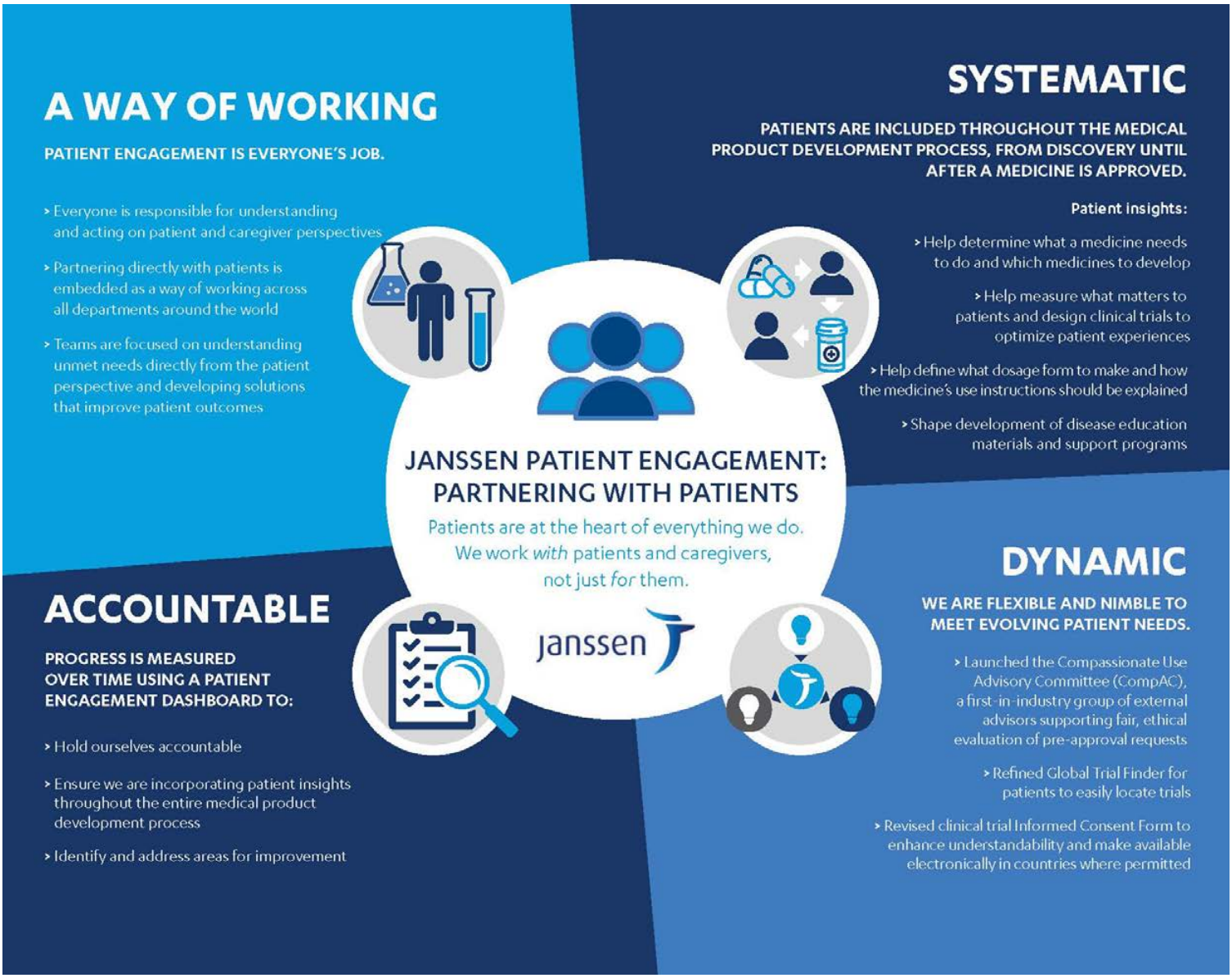
A WAY OF WORKING
PATIENT ENGAGEMENT IS EVERYONE'S JOB.
› Everyone is responsible for understanding and acting on patient and caregiver perspectives
› Partnering directly with patients is embedded as a way of working across all departments around the world
› Teams are focused on understanding unmet needs directly from the patient perspective and developing solutions that improve patient outcomes
SYSTEMATIC
PATIENTS ARE INCLUDED THROUGHOUT THE MEDICAL PRODUCT DEVELOPMENT PROCESS, FROM DISCOVERY UNTIL AFTER A MEDICINE IS APPROVED.
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› Help measure what matters to patients and design clinical trials to optimize patient experiences
› 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
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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
DYNAMIC
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› 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

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.

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All new medicines were once part of a clinical trial before being approved by the FDA.

Without patient involvement in research, clinical trials can't be successful.

Visit APFED.org to learn about trials that are seeking patients with eosinophil-associated diseases and consider if participation is right for you.

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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 an Editorial 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 *AWARE for All- Atlanta* event, we are extending a special invitation to have you join and participate in an Editorial Panel.

How It Works:

- Editorial 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

- Editorial 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
- Editorial 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 an Editorial 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

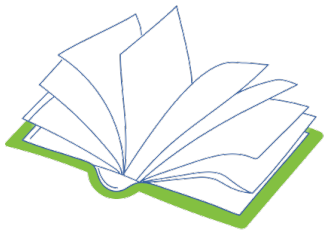
HEALTH COMMUNICATION SERVICES

CLINICAL RESEARCH RESOURCES

CISCRP offers an online library of resources to help the general public become more informed about clinical trial research and participation. The wide variety of resources—brochures, posters, videos, books, medical hero stories, and other materials—are easy-to-understand for everyone who is interested in learning more and staying informed. Visit CISCRP's Resources at https://www.ciscrp.org/education-center/resources/

Brochures: Variety of brochures about clinical trial participation and also available in multiple languages. A few examples:

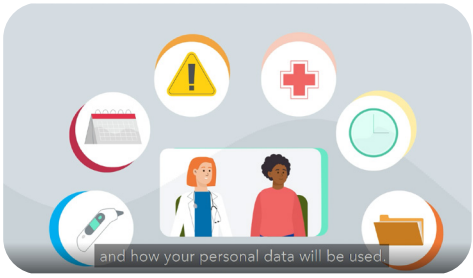
- Should I Participate
- African Americans & Clinical Research
- Should My Child Participate
- Los Hispanos y la Investigacion Clinica
- Debunking Common Myths About Clinical Trials
- And more



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. View more details: https://ciscrp-educational-resource-store.myshopify.com/

Educational Video's: Suite of brief videos covering a variety of clinical trial information that are easy-to-watch.
A few examples:

- 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
- And more



Medical Hero Stories: Patients share their inspiring stories about why they chose to participate in a clinical trial, their experiences and how by participating, it led them to be an advocate.

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

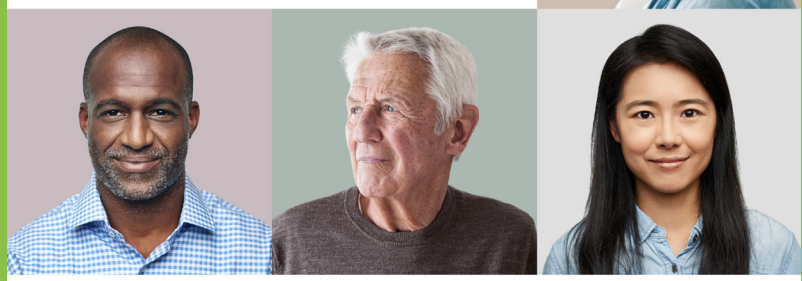
Search Clinical Trials: There are numerous online resources to help you find clinical trials in your geographic area and/or medical conditions. Learn more at https://www.ciscrp.org/services/search-clinical-trials/

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

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 regulatory 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

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/.

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

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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