

A Guide to Participation and the Search for Treatments

# Clinical Trials

A portrait of Shanelle Gabriel, a Black woman with short, curly dark hair, looking off to the side with a slight smile. She is wearing a colorful, patterned tank top, a gold chain necklace, and large hoop earrings. Her hands are on her hips.

## Shanelle Gabriel

The poet and singer talks about how clinical trials transformed her lupus treatment

The measures being taken to deliver a COVID-19 cure quickly

How clinical trials are proceeding amidst a pandemic

**MEDIA  
PLANET**



# The Priceless Gift of Clinical Trial Participation

Many clinical trial participants don't directly benefit from the study. However, their participation is an invaluable gift to future generations.

New medical discoveries made during the past decade — fueled by improvements in detecting disease, and new understanding about the root causes of diseases and how to treat them — have moved more than 4,000 experimental drugs and interventions into active clinical trials globally.

In the past several months alone, the world has seen the public and private sectors collaborate at unprecedented levels and speed to develop several hundred new vaccines and treatments in response to the COVID-19 pandemic.

But the ultimate success of all of these innovations depends entirely on the millions of people who volunteer to participate in clinical trials.

These are everyday people who choose to give the extraordinary gift of participation in clinical research.

Their decision to participate is a selfless act — an altruistic gift — because it always carries risk and is unlikely to bring any direct personal benefit. Through their participation and partnership with clinical research professionals, study volunteers profoundly contribute to society's collective knowledge about the nature of disease, its progression, and how to treat it. Ultimately, future generations are the direct recipients of the gift of each clinical trial volunteer's participation.

## Unfamiliar territory

Although there has been a lot of news coverage about treatments and vaccines in



**Ken Getz**

Founder, The Center for Information and Study on Clinical Research Participation (CISCRP); Professor, Tufts University School of Medicine

clinical testing for COVID-19, the vast majority of people know very little about actually participating in clinical trials. Most people stumble upon clinical trials when faced with the sudden and often unexpected prospect of a serious and debilitating

illness for which no medication is available or adequate.

Typically patients, their families, their friends, and their healthcare providers must gather information quickly to identify an appropriate clinical trial, and to determine whether to participate. This rush to navigate the unfamiliar terrain of clinical trials can be overwhelming and confusing.

## A valuable resource

In 2003, the Center for Information and Study on Clinical Research Participation (CISCRP) was founded to provide outreach and education to people considering participating in clinical trials. Based in Boston, but with global reach, our nonprofit organization focuses its energy and resources on raising aware-

ness, educating patients and the public, and enhancing study volunteer experiences during and after clinical trial participation.

This special supplement is part of CISCRP's ongoing effort to raise public awareness about the importance of clinical research, and to increase public recognition of the millions of study volunteers and clinical research professionals who, together, help advance medical knowledge. We hope you find this campaign informative and inspiring.

At the very heart of successfully developing new life-saving and life-changing treatments and vaccines lies the clinical trial volunteers to whom we owe our deepest appreciation for the profound gift of their participation. ■

# 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.

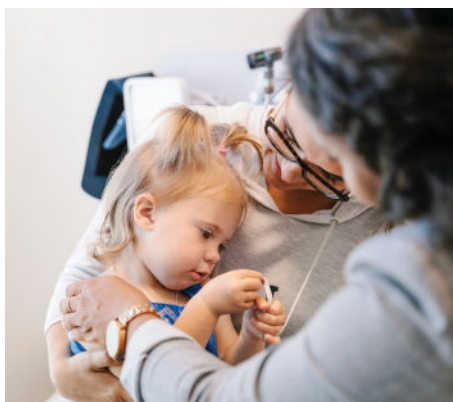
**CISCRP Editorial Staff**

There are many useful resources that provide real-time information about COVID-19 vaccines and treatments. To learn more, review [www.ciscrp.org/services/search-clinical-trials/](https://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/>.



# How a Clinical Trial Helped Shanelle Gabriel Manage Her Lupus

Shanelle Gabriel has always been a hard worker focused on pursuing her dreams as an artist. So it's no surprise that the spoken-word poet and singer tried to push through tiredness, stiffness, and body aches.



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**W**hen Gabriel was in college, she always felt tired and would wake up feeling stiff. She dismissed it as general soreness from working out with her dance team.

The Brooklyn-native Gabriel, then 21, went to her doctor, who told her she probably had sinus problems and encouraged her to take allergy medicine.

### Diagnosis

A turning point came a month later when she noticed patches of hair missing. She went to a different doctor who asked her a series of questions, including about how tired she was and whether her hands changed colors when they got cold. After testing, Gabriel was diagnosed with lupus, an autoimmune disease.

At the time, there weren't medications specifically designed to treat lupus. Instead, doctors had a blanket approach and prescribed a variety of medicines, including steroids, to treat

symptoms, but nothing was specific to the illness.

"Nobody knew how much pain I was in," said Gabriel, now 36, who describes lupus as, "a hidden disease."

Many of the medicines had side effects, including increased risk for liver and kidney problems, as well as cataracts and glaucoma.

She still had flare ups that sent her to the hospital, including an inflammation of the membrane around her heart. It was so bad, she had to leave an internship and quit the dance team.

After graduating, Gabriel toured the country as a poet and singer. While in Montana for a performance, she suffered an episode that caused her to be hospitalized due to a lupus-related condition that causes blood clots."

### Clinical trials

When her doctor suggested trying a clinical trial for a new lupus treatment, Gabriel, who's African American, balked. She was worried because, histor-

ically, people of color have been taken advantage of during medical trials.

She later found out the trial was a success and her doctor prescribed the approved drug. The treatment worked but it was demanding, as Gabriel needed to take a full day off from work to receive IV therapy.

Next, Gabriel decided to participate in the next clinical trial, which tested that approved medicine as a self-administered, weekly therapy.

For Gabriel, this drug helped make her symptoms more manageable allowing her to discontinue her use of steroids.

### Stigma

While Gabriel was initially nervous about clinical trials, she's glad she talked with her doctor and other medical professionals, and realized that clinical trials are essential for finding new therapies and cures.

"Due to a lack of participation by women of color in a lot of these trials, (researchers) were not able to actually

track if it worked for us," she said. "There's only one way to find out if it works; somebody has to do it."

"I just felt like, 'You know what? I'm fine with that, because there could be a really great benefit from it.' And I did end up benefiting from it."

Gabriel is on the patient advisory boards for The Center for Information and Study on Clinical Research Participation, a non-profit dedicated to educating and engaging the public and patients about clinical research.

She encourages patients with lupus and other diseases to consider clinical trials, which have many safeguards to minimize danger for participants. She recommends doing your own research, asking questions, and talking to your doctor about clinical trials.

She's sharing her story and hopes to inspire others.

"It's becoming a community of people that are advocating and I think there is hope for a cure," Gabriel said. □

**Kristen Castillo**

PHOTO: COURTESY OF SHANELLE GABRIEL



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# Clinical Trials: Every Person Can Play A Powerful Role

The global race to combat the current pandemic has put medicine development in the spotlight and made clinical trials front page news. To go beyond the headlines, we spoke with **Marie-Pierre Hellio La Graverand, M.D., Ph.D., a leader in drug development for Pfizer**, and asked her for three takeaways she'd want people to have about clinical trials, what they are and why they matter.

## We all need clinical trials to develop new medicines. And clinical trials need us too.

Marie-Pierre's training as both a physician and scientist has provided her with a unique perspective on what it takes to translate insights from the laboratory into life-changing new medicines.

It's a perspective that makes her especially grateful to the thousands of people who volunteer each year to participate in clinical trials.

"One of the big reasons I chose to devote my career to drug development was that it's an opportunity to bring new medicines and vaccines to help people across the world," she says. "New medicines have the potential to change and save lives. And those new medicines would not be possible without the thousands of people who participate in clinical trials."

As Marie-Pierre explains, every prescription medicine we depend upon today was first tested in a clinical trial. And every medicine we hope to develop for tomorrow depends on the people that continue to participate in these clinical trials.



## Clinical trials are always safety-first.

Advancing science and helping develop new medicines is the goal of each clinical trial.

But as Marie-Pierre explains, it's the people who join clinical trials who are always the priority.

"It starts with careful safety planning, long before a single person joins," she says. Potential participants are carefully evaluated to be sure it's the right trial for them, and each trial

site is run by a specialized team of doctors and medical staff, with oversight provided through continuous monitoring. "The focus is always on the participants, keeping people's safety top of mind," Marie-Pierre says. "Their health and well-being is always our top priority."

## We all have a part to play.

Medicines being studied to help one patient population or age group

require volunteers from that specific population. "But most new medicines and vaccines also depend on the participation of healthy volunteers," Marie-Pierre says.

"The medicines we rely on today benefited from the help of thousands of healthy people, representing all our global diversity.

"In order to ensure that new medicines and vaccines can help everybody, everybody has to be represented in these studies," she explains. "We all have something we can contribute to making the world a healthier place." □

**Pfizer, Inc**

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To hear more voices and perspectives on clinical trials, from site partners to participants, please join us at [www.pfizer.com/WhatToExpect](https://www.pfizer.com/WhatToExpect). Together, breakthroughs are possible.

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It can overcome diseases,  
create cures and, yes,  
even beat pandemics.  
It has the methodology  
and the rigor  
to withstand even  
the most arduous scrutiny.  
It keeps asking questions and,  
until there's a breakthrough,  
it isn't done.  
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Scientific discoveries are made possible by the hundreds  
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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://CISCRP.org).**

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

