

# Clinical Trials

A portrait of Katie Klatt, a woman with long, wavy blonde hair, wearing an orange V-neck sweater. She is smiling and looking slightly to the right of the camera. The background is a soft-focus outdoor setting with a building and a cloudy sky.

## Katie Klatt

The athlete, nurse, and student is using her experience as a COVID-19 patient to advance clinical research

Discover how pediatric patients and their parents perceive the benefits and risks of clinical trial participation

Learn more about the importance of clinical research in diverse and underserved communities

# Why Clinical Trial Participants Are Medical Heroes



During this pandemic, we hear news every day about the many promising therapies and vaccines in development for COVID-19. Wide coverage in the media has made us all more aware of the important role that clinical trials play in protecting and advancing public health.

**T**he success of these medical innovations and the availability of the thousands of drugs and interventions for all types of diseases depends entirely on people who participate in clinical trials. We call these brave participants medical heroes, and they can be found everywhere.

## True heroes

Medical heroes are people like you and me who have chosen to give the extraor-

inary gift of their participation in research studies to find new treatments and cures for diseases. Their decision to be a clinical trial volunteer is a selfless act because it always carries risk, but it may not result in any direct personal benefit.

Even with higher media attention on clinical trials, the majority of people know very little about what it means to be a study volunteer. Most people only look at clinical trials in earnest when they are faced with



**Ken Getz**

Founder and Board Chair, CISCRP; Professor, Tufts University School of Medicine

the sudden and often unexpected prospect of a serious and debilitating illness for which no medication is available or adequate.

## Raising awareness

At that moment, patients, their families, friends, and their healthcare providers must gather information quickly to make decisions about whether to participate in a clinical trial. This rush to navigate the unfamiliar terrain of clinical trials feels overwhelming and confusing. Seventeen years ago, the Center for Information and Study on Clinical Research Participation (CISCRP) was founded to provide outreach and education to all people

and their support networks considering participation in clinical trials.

It is true that participation may bring hope to clinical trial volunteers and their loved ones. But ultimately, future generations are the direct recipients of the gift of participation. Medical heroes, in partnership with clinical research professionals, contribute profoundly to our collective knowledge about the nature of disease, its progression, and how and how not to treat it. □

The findings of a recent pediatric survey illustrate perceptions and insights on what matters most to patients and their parents. It also offers ways to best support and inform prospective pediatric volunteers and their guardians before, during, and after the clinical research process.

During the month of April 2020, the Center for Information and Study on Clinical Research Participation (CISCRP) conducted an online United States-based survey among 500 parents and their children. The goal of this survey was to gain insight into general perceptions of pediatric trials, preferred channels of communication, key information parents and their children would want about pediatric clinical trials, as well as past or current experiences participating in pediatric clinical trials.

# Key Insights Into Clinical Research Perceptions Among Parents and Children

## Awareness & Understanding

Parents generally self-report high levels of understanding about clinical research, and generally high willingness to have their child participate in a clinical research study. Awareness, understanding, and willingness to have their child participate was greatest among parents whose children have previously participated in clinical research.

Among children, levels of awareness of clinical research vary by a child's age, as older children were more likely to have heard of clinical research compared to younger children. Overall, few reported that they understood clinical

research "very well." Though many were not sure whether they would want to participate, 50 percent reported that they would be willing. The top motivation to participate was altruistic, as children wanted to advance science through their participation.

## Participation Experiences

During participation, parents reported highly burdensome experiences and high levels of disruption to their daily routine. Top burdens included traveling to the study clinic and having their child complete lab work like blood draws and urine tests. However, the majority of parents said that

they received updates or study results once their child finished participation.

Results also indicate that children generally received adequate information about their participation. Ninety-two percent remembered getting information about the clinical trial before they joined, and 85 percent found this information "kind of" or "very easy" to understand. Despite these expectation-setting measures, children reported some study requirements as difficult to complete, most notably taking the study medication and undergoing blood draws. However, though children report burdensome

study experiences, most indicate that the study exceeded their expectations, and that they would be willing to participate again.

## Doctors are Key

A consistent theme throughout the survey findings was the critically important role that healthcare professionals play along the journey toward participation. For example, parents discuss clinical research with their child's doctors often and cite their child's doctors as the top way they learn about participation opportunities. Children would also most prefer to learn about clinical research through their doctor. Doctor recommendations were ultimately the top reason that parents decided to have their child participate. □

Shalome Sine, Research Associate, CISCRP Research Services

## What if you went to the pharmacy and there was *nothing there*?



Without volunteers in clinical trials, pharmacy shelves would literally be... *empty*.

Watch the **MT Pharmacy** video to learn how participation in clinical trials helps shape the future of health care.



[Link to Video here](http://www.ciscrp.org/mt-pharmacy)  
[www.ciscrp.org/mt-pharmacy](http://www.ciscrp.org/mt-pharmacy)

CISCRP is a non-profit organization dedicated to educating the public & patients about the role clinical research plays in advancing public health. "Education before, during & after participation."



**CISCRP**  
[www.ciscrp.org](http://www.ciscrp.org)

# How One Nurse Is Using Her Personal COVID-19 Experience to Advance Clinical Research



PHOTO: ALEXANDER L. TAYLOR

**Katie Klatt is a lot of things: an athlete, a nurse, and a student working on a master's degree in public health. Her new role this year as a COVID-19 patient, however, has changed her life and sharpened her focus.**

Katie Klatt, a pediatric intensive care nurse who started a public health program at the Harvard Chan School in January, got sick during the early days of the pandemic. She is still not sure how she contracted the coronavirus.

"Lockdown happened a few days before I got symptoms, so I could have literally gotten it from anywhere, because I was still doing all the normal things in the community before everything closed," she says.

Her symptoms included a bad headache, light-sensitivity, and body aches. She also had a body rash and a fever of 103°F for 10 days.

At first, Klatt saw her doctor via virtual appointments. But a week into her illness, her doctor advised her to go to the hospital. She did not have a car, so she walked 40 minutes to the emer-

gency room. She did not want to expose anyone on public transportation or in a car service.

At the hospital, doctors diagnosed her with COVID-19, a sinus infection, and possibly pneumonia. They gave her a prescription for an antibiotic to treat the sinus infection and sent her home. She isolated herself from her roommates and four days later, she started to feel better. Slowly, the Australian and Gaelic football leagues athlete started to gain her strength back.

## Research

Next, she wanted to help further the medical understanding of the coronavirus. She connected with researchers who had started studying COVID-19.

"The only way that the COVID-19 pandemic will get better is if we know

more about it and know how to handle it," says Klatt. "What's a better way to figure it out than being able to study how it works in your body?"

Klatt has been a patient participant in a COVID-19 antibody clinical study since April. She does monthly blood draws to check her antibody levels. Klatt also signed up for a COVID-19 dermatology study since she had that full-body rash.

Participating in the research studies has been easy for Klatt, and she encourages other people who've had COVID-19 to participate in research, too.

"There's so much misinformation out there about COVID-19, and there's so much we don't know," she says. "The more people that join studies, the better the knowledge is going to be, and the more accurate we can be when we're making estimates."

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After beginning her participation in these studies, Klatt then contacted Boston Emergency Medical Service and started working as a nurse on their COVID-19 infection control team. She and the team of doctors and fellow nurses connected with EMTs and paramedics.

"I found it was helpful having had COVID-19. I could talk to the employees who had gotten it, and we kind of commiserated together and understood what each other had gone through. It just gave me a better appreciation for the importance of better understanding COVID-19," she says.

## Readiness

Klatt says the pandemic underscores the need for research and readiness to understand changing health situations as best as possible.

"This experience made me realize the importance of preparedness and planning for emergencies," says Klatt, who will graduate in the spring and plans to work in emergency management. □

Kristen Castillo



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# The Importance of Clinical Research in Underserved Communities

**The importance of clinical research is widely recognized, and while many decide to participate in clinical trials, there is a lack of representation of individuals from underserved communities.**

In 2019 alone, 46,391 individuals participated in clinical trials that resulted in the approval of 48 new drugs. However, a limited number of study volunteers identified as Black/African American, Asian, and/or Hispanic.

Current efforts to address this lack of representation include a guidance document released by the FDA encouraging pharmaceutical

companies to broaden their eligibility criteria. While these efforts are critical in increasing diversity and inclusion in clinical trials, it is equally important to understand how clinical research is viewed from a broad audience.

Every two years, the Center for Information and Study on Clinical Research Participation (CISCRP) conducts a global online study to gather insights on the public and patients' perceptions and experience with clinical research. Responses from over 12,450 individuals were collected, with representation from many communities, including Black (6 percent), Asian (10 percent),

and Hispanic (13 percent) communities.

## **Importance of clinical research**

Individuals across many races and ethnicities acknowledge the value of clinical research studies. Many consider clinical trials to be "somewhat" or "very important" to the discovery and development of new medicines. Additionally, the greatest benefits of participation in clinical research include helping to advance science and the treatment of patient's disease/condition (26 percent) and the possibility of improving or saving the lives of others with the same condition (21 percent). This

highlights how individuals perceive and understand the positive impact participation can have. However, few individuals had recently seen or heard about a clinical trial opportunity.

## **Where do we look?**

Many would begin looking for a clinical trial opportunity by asking their healthcare provider or by using an online resource. For example, over half of Black individuals (52 percent) would use an online clinical trial registry, such as [clinicaltrials.gov](http://clinicaltrials.gov), and 42 percent of Asian individuals would use an internet search engine like Google. Recommendations from family

members are also important to underserved populations in their search for clinical trials.

The relationship between healthcare providers and their patients can be leveraged to increase awareness of and participation in clinical trials. It is important to many that their healthcare provider be aware of ongoing clinical trials in their local communities. Pharmaceutical companies can take an important first step by informing healthcare providers about new clinical trial opportunities in underserved communities. □

**Stephanie Loomer, MS, Project Manager, CISCRP Research Services**

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Boehringer Ingelheim is proud to work alongside the unsung heroes of clinical research and medical progress, including our patient participants, investigators and research staff that help lead the way to the identification of new medicines and therapies. We value the gift of patient participation from all backgrounds, especially as health disparities persist and the need exists to optimize diversity to promote balanced representation for all populations.

We are committed to advancing this change and taking steps by listening to our patients and striving to ensure their perspectives and inclusion are at the center of advancing public health and treatments available today, tomorrow and for future generations.

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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](http://CISCRP.org).**

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

