NATIONAL CLINICAL TRIALS STRATEGIC PLAN (NCTSP)

National Black Church Initiative
www.nationalblackchurch.com
Clinical Trials

AMERICAN CLINICAL HEALTH
DISPARITIES COMMISSION INC.

The National Clinical Trails Strategic Plan (NCTSP) is the largest and most comprehensive effort to combat mistrust, lack of awareness, barriers to access, and Equitable Access to Research and Addressing Health Disparities. We aim to inform, educate, empower, enroll, and maintain African Americans in clinical trials to improve our health outcomes.
blackchurchclinicaltrials.com

THE BLACK CHURCH ENCOURAGES ALL 27.7 MILLION MEMBERS TO EDUCATE THEMSELVES ABOUT THE BENEFITS AND RISKS OF CLINICAL TRIALS THROUGH NCTSP. BLACKCHURCHCLINICALTRIALS.COM

NCTSP IS THE ONLY INITIATIVE TO ADDRESS THIS IN A COMPREHENSIVE WAY

- **TARGETED RECRUITMENT:** EFFORTS ARE BEING MADE TO TARGET RECRUITMENT EFFORTS TOWARDS UNDERREPRESENTED POPULATIONS, SUCH AS THROUGH COMMUNITY OUTREACH AND PARTNERSHIPS.
- **PATIENT NAVIGATION:** PROVIDING EDUCATIONAL AND FACILITATIVE SERVICES CAN HELP PATIENTS NAVIGATE THE CLINICAL TRIAL PROCESS AND INCREASE THEIR WILLINGNESS TO PARTICIPATE.
- **ADDRESSING BARRIERS:** EFFORTS ARE BEING MADE TO ADDRESS BARRIERS TO PARTICIPATION, SUCH AS IMPROVING ACCESS TO TRANSPORTATION AND CHILDCARE.

THE IMPORTANCE OF INFORMED CONSENT

NO ONE CAN BE FORCED INTO A CLINICAL TRIAL. IT IS YOUR DECISION. THEY CAN NOT DO ANYTHING WITHOUT YOUR OK. PRAY ABOUT IT

THE INFORMED CONSENT PROCESS IS THE MOST CRITICAL ASPECT OF PARTICIPATING IN A TRIAL BEFORE YOU JOIN IT. USUALLY, THE INVESTIGATOR, RESEARCH NURSE, OR ANOTHER STUDY TEAM MEMBER WILL REVIEW THE CONSENT IN DETAIL WITH YOU. YOU'LL BE GIVEN AMPLE TIME TO LOOK OVER THE DOCUMENT, ASK QUESTIONS, AND TAKE NOTES. THIS IS THE TIME TO ASK QUESTIONS.

HOW DO YOU KNOW IF A CLINICAL TRIAL IS RIGHT FOR YOU?

You're thinking of participating in a clinical trial - what now? Consider the risks and benefits before deciding if a clinical trial is proper for you.

For Sha'Quanda Washington, 56, the decision to join a clinical trial was clear. With a recent multiple sclerosis diagnosis and a clinical trial offering either the study drug or an approved MS medication, the "nothing lost, nothing gain" situation made participation feel like the logical choice.

"I had just received my MS diagnosis and wasn't yet on any medication," she says. "I knew I would receive either the study drug or an approved MS medication - there was no placebo group."

But it's not always so straightforward. Deciding whether a clinical trial is the right choice involves weighing several essential factors beyond the potential benefits, including your personal health goals and how those compare to the risks and side effects.

Black Americans are significantly underrepresented in clinical trials, with participation rates often around 5-8% compared to their 13% share of the U.S. population, highlighting a need for increased inclusion and equitable access to research opportunities.

Here's a more detailed look:

Black Americans are consistently underrepresented in clinical trials, despite having a disproportionate disease burden for certain conditions.

Data:

- Black individuals account for 15% of participants overall but only 8.5% of oncology trial participants.
- In a study of 230 vaccine trials from 2011 to 2020, white participants tended to be overrepresented, while Black and other racial or ethnic minority participants tended to be underrepresented.
- A 2020 analysis of 32,000 individuals who participated in new drug trials in the U.S. showed that only 8% were Black.

Key Takeaways

- Clinical trials are research studies that test the safety and effectiveness of medical treatments, devices or procedures by evaluating their impact on health outcomes through volunteer participants. They are the cornerstone of progress in disease treatment.
- People choose to participate in clinical trials for a variety of reasons, most commonly for personal benefit, to help the greater good, for access to health care professionals or for financial benefit.
- Selecting the right trial is not an easy process for those involved. There are several factors to weigh when you're thinking about participating in a clinical trial, especially whether the purpose and design of the trial align with your goals.
- Clinical trials are carefully designed, reviewed and approved before they can start. They take place in phases: I, II, III and IV.

WHAT IS A CLINICAL TRIAL?

Clinical trials are research studies designed to test the safety and effectiveness of a treatment, device or procedure, such as vaccines or medications, using human volunteers. This research aims to evaluate how these specific interventions affect health outcomes.

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Phases of clinical trials

- **Phase 1 clinical trials.** Phase 1 trials look at safety and dosage, and typically include a smaller number of study participants – from 20 to 100 participants on average.
- **Phase 2 clinical trials.** Phase 2 includes up to several hundred participants. Dr. Sheryl Marks, a board-certified anesthesiologist, co-medical director and a clinical trial Investigator at Rainier Clinical Research Center in the greater Seattle area, explains that in this phase, you're looking for adverse events, toxicity and efficacy.
- **Phase 3 clinical trials.** Research in this phase will include several hundred to thousand participants. Once you've established safety and efficacy, Marks says you're looking for effectiveness in a larger group of people living with a disease in this phase. "Is it effective under less-restricted circumstances? Will it work in the real world?"
- **Phase 4 clinical trials.** In phase 4, the drug has been approved by the Food and Drug Administration. It's available to the public, and researchers conduct post-market safety monitoring in the general public.

"About 70% of trials make it out of Phase 1 into Phase 2," Marks says. "About only 33% of trials make it out of Phase 2 into Phase 3."

Reflect on why you're considering joining a clinical trial – there's no right or wrong answer. You may find that your motivation aligns with the most common reasons people choose to participate in clinical trials:

WHY PEOPLE PARTICIPATE IN CLINICAL RESEARCH

1. Personal benefit

There are several situations where the only way for a patient to receive a brand-new intervention, drug or device is participation in a clinical trial, says Dr. Mario Gaudino, a cardiothoracic surgeon at Weill Cornell Medicine and NewYork-Presbyterian Hospital, director for the Joint Clinical Trials Office at Weill Cornell Medicine and assistant dean for clinical trials at Weill Cornell Medicine in New York City.

Marks adds, "They are hoping that if they're in the trial, they may receive the active investigational product."

2. Access to healthcare professionals

Even if you don't receive the investigational product in the study, there's often a benefit of just being connected with health care providers – physicians, nurses, dietitians – to discuss what's going on with your disease state and getting "just a little bit of extra attention," Marks says.

3. Altruistic motivation

This refers to the desire to help others or contribute to the greater good. In this case, the participant isn't participating for personal

benefits, and often, they don't expect anything in return; rather, they're hoping to contribute to research and advance medical knowledge to improve treatments in the future.

For example, Gaudino notes one trial dedicated to studying cardiovascular outcomes in women. Participants have said, "I want to participate in these trials so that my daughter can have better care."

4. Financial benefits

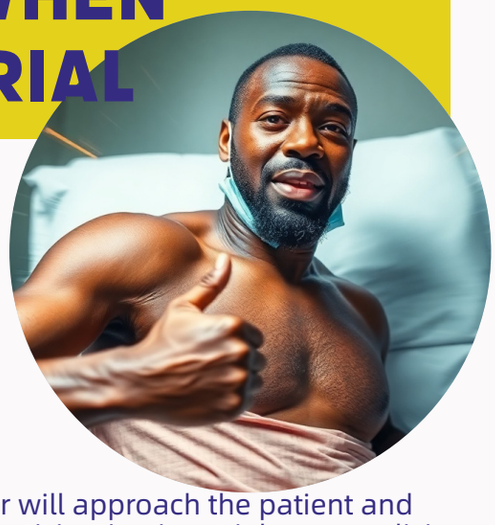
Some clinical trials offer compensation for participating, which can help cover travel expenses or time spent at the trial. Additionally, many trials provide free access to treatments, medical care and regular checkups, saving you thousands on medications or doctor visits.

Though Ms Washington's reasons for joining a clinical trial weren't financially driven, the financial gains were a nice perk.

"The biggest, unexpected benefit was having consistent access to an expensive MS medication (worth over $50,000 annually) during periods when I was unemployed or freelancing without health insurance," Gusher Delgado says.

She also eventually started receiving compensation for participating.

WHAT TO CONSIDER WHEN FINDING A CLINICAL TRIAL



"I'd encourage people to approach clinical trials with an open mind and gather all the information they can," Ms Washington says. "In my experience, transparency has been crucial – the study team has always been up front about everything, including potential side effects and any issues that arose."

There are several factors to weigh when you're thinking about participating in a clinical trial:

Your goals. What do you hope to accomplish by participating? "Consider your current circumstances – in my case, not being on any MS medication meant I had nothing to lose by trying," Ms Washington says.

Eligibility. Clinical trial eligibility, or inclusion criteria, refers to specific requirements someone must meet to participate in the trial. The researchers set criteria to ensure the results are valid and the participants are likely to benefit from the tested treatment. For example, participants may need to be within a certain age range or have a particular medical condition.

Location and time commitment. If in-person participation requires you to travel far regularly, this may be a barrier to participation. Consider the location of the trial site, how often you'll need to check in and how long the trial lasts. Marks says they do a knowledge check to ensure that people understand what they're signing – some of these trials can be 5-year commitments and involve some degrees of risk.

Potential benefits. Is the trial exploring a new treatment for your condition? Will it benefit you in the short-term or long run? Learning what you might gain – or how you'll benefit the greater good of society – will help you make an informed decision.

Potential risks and side effects. How might the treatment affect your health? Before agreeing to participate, it is important to understand the potential risks and side effects.

Financial considerations. Will you have out-of-pocket expenses for participating? Some clinical trials may offer compensation, and others may benefit you financially by giving you access to to drugs or treatments that would otherwise cost thousands of dollars.

Informed consent. It's essential to understand the purpose and design of the trial. "Ask questions about the study design – knowing there was no placebo group made my decision easier," Ms Washington said

Often, a doctor will approach the patient and recommend participating in a trial upon realizing they meet the inclusion criteria, Gaudino says.

A screening process occurs to ensure patients meet all criteria to enter the treatment phase. The criteria are universal and set by doctors overseeing the study. They include things such as appropriate medical history, qualifying laboratory values and lack of interfering risk factors. Once a person has met all these criteria, the physician in charge or principal investigator enrolls him or her in the trial and starts treatment.

The informed consent process is the most important aspect of participating in a trial, prior to you joining it. Usually the investigator, research nurse or another member of the study team will review the consent in detail with you. You will be given ample time to review the document, ask questions and take notes. This is the time to ask questions.

In order to do anything in the trial, it has to be addressed in informed consent, Marks says.

Through this process, "they're very well aware of the fact that there's a significant chance, based on how the trial is set up, that they will get placebo," she adds.

The researchers will go over information with you, and you'll have the opportunity to ask any questions along the way.

At any point during your participation in the clinical trial, you have the right to withdraw your consent and discontinue your involvement.

THE MORE INFORMATION YOU HAVE THE BETTER

THE BLACK CHURCH ENCOURAGES ALL AFRICAN AMERICANS TO JOIN A CLINICAL TRIAL- AFTER YOU HAVE PRAYED ABOUT IT, EDUCATE YOURSELF AND YOUR FAMILY, GIVE YOUR CONSENT, AND ASK A QUALIFIED AFRICAN AMERICAN HEALTH PROFESSIONAL OR YOUR DOCTOR!

QUESTIONS TO ASK BEFORE PARTICIPATING IN A CLINICAL TRIAL

Here are some key questions to ask if you're considering participating:

- **What is the hypothesis behind the trial?** Essentially, asking the researchers, '*Why are you doing this?*' Gaudino says. Participants need to understand precisely how the new intervention compares with the standard of care. This is the "most critical piece to understand" for potential participants, he says.
- **What did the Phase 1 trial data look like?** Often, you'll be looking at a Phase 2 or 3 trial for participation. Marks suggests asking about the outcomes of Phase 1 – for example, how many people were included and if there were any significant risks or concerns.
- **How many people will be randomized, and what is the placebo to active investigational product ratio?** Understanding your chances of getting the investigational product versus a placebo may help you decide.
- **What should I know about the drug and dosing?** Marks suggests asking about a drug's dose – if it's a combined product and what that means if you'll be getting a different dose than a different participant or if the dose increases throughout the trial.
- **What are the typical adverse events you see?** Though some adverse events may be less common than others, those can be more impactful in terms of risk for participants, Marks says.

Remember that no question is "too simple or not good enough," Gaudino says. Make sure to take the time to understand the trial and address any concerns – physicians will answer every question because that is in their best interest, too.

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Dr. Joseph Webster
Chair of ACHDC

"We need to find out whether or not the medicine works on African Americans and Latinos.

This is the sole reason we must increase our participation in Clinical Trials!"

Dr. James McCoy
Co-Chair of ACHDC

This brochure was created and based On Christine Comizio, MPH, and Lisa Esposito Medically reviewed by Paul Krieger, MD