AFRICAN AMERICAN AND AFRICAN NATIONALS
CLINICAL TRIALS MANUAL

African American population adaptation of information and culture relevance by: Carolina Aristizabal, MD, MPH; Leora Kirk; Cynthia Quince; Eduardo Ibarra, BS; Valentine Onwudiwe; Mariana C. Stern, PhD; and Lourdes Baezconde-Garbanati, PhD, MPH.

Office of Community Outreach and Engagement at Norris Comprehensive Cancer Center - University of Southern California

"Optimizing enrollment of Blacks living in Los Angeles County in Clinical Cancer Trials: Engaging African Americans and African Nationals."
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PARTNERSHIPS

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Department of Population and Public Health Sciences

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RESEARCH PROJECT: OPTIMIZING ENROLLMENT OF BLACKS LIVING IN LOS ANGELES COUNTY IN CLINICAL CANCER TRIALS:
ENGAGING AFRICAN AMERICANS AND AFRICAN NATIONALS

USC NORRIS COMPREHENSIVE CANCER CENTER
OFFICE OF COMMUNITY OUTREACH AND ENGAGEMENT

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FOR MORE INFORMATION

PLEASE VISIT: HTTPS://USCNORRISCANCER.USC.EDU/COMMUNITY-OUTREACH-ENGAGEMENT/

OR CALL
(323)442-1315

OR EMAIL DR. CAROLINA ARISTIZABAL, MD, MPH, CHES MANAGER, OFFICE OF COE AT CARISTIZ@USC.EDU
"I KNOW, I GOTTA GO, I GOTTA GO. AND I GOT ONE LAST THING AND I SAID IT BEFORE, AND I WANT TO SAY IT AGAIN. CANCER CAN TAKE AWAY ALL MY PHYSICAL ABILITIES. IT CANNOT TOUCH MY MIND, IT CANNOT TOUCH MY HEART AND IT CANNOT TOUCH MY SOUL. AND THOSE THREE THINGS ARE GOING TO CARRY ON FOREVER. I THANK YOU AND GOD BLESS YOU ALL."

-JIM VALVANO, FOUNDER OF THE V FOUNDATION.
INTRODUCTION

HOW IS THIS MANUAL ORGANIZED

This handbook has been developed for the Black population in the United States. This includes US and non US born populations who trace their origin and experiences to Africa and Afro Caribbean countries and slavery throughout the Americas. The goal is to increase awareness, support policy and advocacy, promote recruitment, and retention in clinical trials. This may include patients and families of cancer survivors, health advocates and the faith-based community who work with those communities of interest.

We hope this tool kit is used to engage in discussions of important questions on the topic, helping to navigate Black communities to increase their enrollment in clinical trials.

"Research is formalized curiosity. It is poking and prying with a purpose." -Zora Neale Hurston

The Diverse Trial Act is a legislative proposal that would fund research supporting outreach, education, and recruitment in clinical trials involving underserved communities and the diseases that disproportionally affect them.

This manual will equip community members with the knowledge to ensure they know what to expect when participating in clinical trials: how to enroll into clinical trials and what questions to ask their doctor and researchers.

GIVE INSTRUCTION TO A WISE MAN, AND HE WILL BE YET WISER: TEACH A JUST MAN, AND HE WILL INCREASE IN LEARNING. ~PROVERBS 9:9
WHAT IS A CLINICAL TRIAL?
A clinical trial is a study of how people react to new and promising treatments. Carefully managing clinical trials can be the fastest and safest way to find treatments that may work for different types of cancer. Studies must show the treatment being examined to prevent or treat a medical condition is safe and effective for people so that it can be approved for use. Precautions are taken to ensure a safe trial and all participants are guaranteed to receive something comparable to the standard of care. Without clinical trials and the volunteers who participate in them, there would be no modern day medicine.

WHO CAN PARTICIPATE IN CLINICAL TRIALS?
All clinical trials have guidelines about who can participate. Specifics such as age, gender, type and stage of disease, previous treatment history, and other medical conditions will affect whether or not a patient is able to participate in a specific trial. These measures are meant to identify appropriate candidates for the trial in order to keep patients safe. These measures are not used to reject people personally. This also ensures that researchers will get answers to questions they plan to study.

WHY PARTICIPATE IN CLINICAL TRIALS?
People participate in clinical trials to gain access to new treatments before they are widely available and to help others by contributing to medical research. In some cases, clinical trials offer the only option. In this way, participants can stay engaged in fighting their disease and have a more active role in their own health care.

WHERE ARE CLINICAL TRIALS DONE?
Clinical trials take place in many locations nationwide including hospitals, university institutions, doctors’ office and clinics. They are primarily sponsored by pharmaceutical companies.

HOW TO PARTICIPATE IN A CLINICAL TRIAL?
People interested in participating in a clinical trial can start by asking their doctor or primary care physician if there are any trials that may be a good option for them. Their doctor can usually provide more information and answer any clinical trial questions they may have.

People interested in joining a clinical trial can also call the National Cancer Institute (NCI) Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) and select option #2. This will take them through a series of steps to gather more information on their cancer diagnosis, find clinical trials suited for their specific illness, give them contact information on the team running the clinical trial, provide the opportunity to ask questions, and make an appointment.

To find clinical trials at USC Norris Comprehensive Cancer Center go to: http://uscnorriscancer.usc.edu/CLTrials

There, people can search any clinical trial by way of anatomy (body part or organ), or diagnosis. One can also search for clinical trials by typing in keywords. Once they find a clinical trial they are interested in, consult with doctor, family, and friends if this is a right treatment option.

As iron sharpens iron, so one person sharpens another.

Proverbs 27-17

Source: Lazarex.org
WHY DIVERSITY IN CLINICAL TRIALS IS IMPORTANT?
Diversity in clinical trials helps researchers ensure that the treatment and medication being studied works. As we know, cancer does not discriminate and can develop in any person of any skin color, young or old. Researchers have discovered that one's genetic makeup has significant importance on how effective a treatment drug can be. Cancer affects people of color negatively in unusually large numbers. If a clinical trial is focused on only one race/ethnicity and is eventually FDA approved, there will be little to no information on how people from different backgrounds will react to the medication or if it will even work for them. Participating in clinical trials makes certain that treatments will also work for those in similar communities. The new medicine is safer and more effective for everyone when a diverse population participates in clinical research.

"ONE OF THE PROBLEMS THAT WE FACE RIGHT NOW IS THAT MOST OF THE DATA THAT'S USED TO MAKE DRUG APPROVALS IS LARGELY DERIVED FROM A GROUP OF PATIENTS THAT ARE ALMOST ALL WHITE. BUT AGAIN, WE REALLY DON'T UNDERSTAND HOW EFFECTIVE THAT DRUG WILL BE ACROSS ALL GROUPS OF PEOPLE ALL POPULATIONS."
-DR. JOHN CARPTEN

"SOME OF THE MORE RARE FORMS OF CANCER THAT REPRESENT HEALTH CANCER DISPARITIES WERE PARTICULARLY RELATED TO AFRICAN AMERICANS. PROSTATE CANCER, TRIPLE-NEGATIVE BREAST CANCER, COLORECTAL CANCER, CERTAIN FORMS OF LIVER CANCER. THESE CANCERS HAVE A HIGHER BURDEN AMONG BLACK AND BROWN PEOPLE, ESPECIALLY WHEN WE THINK ABOUT THE PREVALENCE OF CANCER AND EVEN MORE IMPORTANTLY, THE DEATH RATES AND THE MORTALITY RATES ARE SO MUCH HIGHER. IF WE WORK TOGETHER, PERHAPS WE CAN BEGIN TO REDUCE THOSE LEVELS SO THAT WE BEGIN TO SEE A LEVELING OFF IN THOSE OUTCOMES. AND I THINK DIVERSIFYING CLINICAL TRIALS IS GOING TO BE ONE OF THOSE THINGS THAT ARE GOING TO HELP US ACHIEVE THAT."
-DR. JOHN CARPTEN

Source: American Cancer Society & FDA.gov
According to “A Demographic Profile of Black Caribbean Immigrants in the US,” there were more Black immigrants of Caribbean descent (1.7 Million) than there were Black immigrants of African descent (1.1M) in the US, in the years 2008-2009. The top four Caribbean countries in which Black individuals immigrated from were Jamaica (36%), Haiti (31%), Trinidad & Tobago (11%), and Dominican Republic (6%). (See figure below.)

Minorities, especially in the Black community, are more likely to experience a health-related illness. Heart disease is the leading cause of death in both men and women and in the Black/African American race. While cancer takes second place in the leading cause of death in the United States with 20.2% in the Black community. These illnesses are the top two leading causes of death in the United States. The percentages of illnesses affecting our community are too high and clinical trial enrollment rates are too low.

Source: acrpnet.org and census.gov
Clinical Trial Enrollment Rate by Race at USC Norris Comprehensive Cancer Center in Los Angeles County

In the United States, the gender difference of the population when participating in clinical trials usually results in fewer women than men. In the figure above, 62% of men are more likely to register in clinical trials. The majority of the population is White/Caucasian, 50% of the participants were 65 years or older.

The figure above, which represents enrollment by Race in Los Angeles County at Norris Comprehensive Cancer Center, shows why health professionals need to improve the enrollment of under-represented patients such as African Americans/African Nationals (AA/AN) and other minorities in clinical trials. The lack of awareness of clinical trials in Black communities in the US has led to low participation from this particular population. For many Black Americans such as African Nationals and African Caribbeans, lack of transportation, barriers to health insurance, honest health professionals, and the cost of clinical trials can be a problem. Moreover, lack of trust in the medical field among the Black community contributes to lack of participation. This problem started due to abuse Black individuals suffered through the Tuskegee Syphilis Study.

Dr. Joyce Richey, Associate Dean for Diversity and Inclusion Education at Keck School of Medicine of USC, stated “We, in the African American Community, have a lot of mistrust when it comes to the medical profession… [The Tuskegee Syphilis Study] was a case where African American men who had syphilis were studied over 40 years and even during a time where a therapeutic had become available, they were not informed. So, they weren’t injected with syphilis they were just allowed to suffer once a therapeutic was found.” She proceeds to reiterate that with so many therapeutics out now, one only disengages themselves if they deny current or future groundbreaking vaccines, treatments, or medications.

TRUST THE PROCESS.
- DR. JOYCE RICHEY

Source: acrpnet.org and census.gov
Increasing the transparency and honesty between clinical researchers and the community will allow for greater participation in clinical trials by minorities. A way to draw in the Black community is to fix the loss of trust between African Americans/African Nationals (AA/AN) and healthcare professionals. What needs to happen is to focus on clear communication training for all health professionals throughout the US population to build a better relationship with the patients. To enroll and keep AA/AN in clinical trials, health professionals need to be culturally sensitive when working with individuals. At the end of the trials, health professionals should also keep up with the participants to make sure that they received their results on time.

The graph above displays how there is a disconnection between clinical researchers and the community. In one cancer/clinical trials focus group study lead by USC Norris Comprehensive Cancer Center on African American cancer patients' wives, a participant explained her doubt: "I'm just not very comfortable with some of the historical information [regarding African Americans and clinical studies] that I learned about how we've been used in studies." Although, she adds that she would not discourage anyone from joining or participating in a clinical trial. Building trust through clear communication is a step towards the right direction in the future of clinical research.

This graph clearly shows the inequities in death rates among the Black community. The opportunity that clinical trials give by finding new disease screening, prevention options, and new treatment options can decrease the number of deaths in Black males and females and in minority groups. According to a report about African American women's viewpoint of clinical trials, "The community having knowledge of what goes on in clinical trials and how to overcome the historical negative views related to all kinds of clinical trials" is very important to know.

We have to begin to move forward as a society and work together to overcome the challenges of lack of fair healthcare in our communities. As Dr. John Carpten, Professor of Translational Gemonics Keck School of Medicine USC, said "The most important priority for us in the research field of cancer health disparities, is diversifying clinical trials. We have to improve in that area so that everyone can have the opportunity to benefit from these healthcare innovations." This is the best way for groundbreaking medicine and treatments to work for all.
MINORITY REPRESENTATION AS INVESTIGATORS AND PARTICIPANTS IN CLINICAL TRIALS

As the image above shows, there is very little minority representation in clinical trials as participants and as researchers. Expanding minorities within the health professions and into positions as researchers in clinical trials will help build that connection between research and community. In a focus group study conducted by USC NCCC on elderly African American males, many participants stated there was an unwillingness to join a clinical trial because of the general lack of trust in the medical field, professionals, and in the community. One African American participant in the focus group expressed “Many [of us wonder] what are you [clinical researchers] going to do with those tests? Why are you wanting to screen us?” The suspicion and disconnection are clearly there. By adding minority researchers, it can increase the participation of minorities in clinical trials. And through good research practice and good study results, trust can begin to build between research and the community.

Even in today's current events, African Americans are not taking measures to protect themselves from illnesses. From the figure above, it is noticeable that Black/African Americans are the least vaccinated against COVID-19 among different race/ethnicity groups in Los Angeles County. As of September 2021, a total of 60,694 African Americans in the 12-15 and 18-29 age range are vaccinated against COVID-19, compared to 209,089 Asians, 615,077 Latinx, and 283,754 Whites in a similar age range.

It all starts with getting informed and seeking resources. Being active in one’s health decisions can go a long way: being informed on COVID-19 vaccine safety and usefulness; being informed on what a clinical trial is; being informed on new cancer treatment options that can help prolong the lives of Black individuals in this city, state, and country.
PILOT STUDIES
A study done on a smaller group in preparing for a larger investigation. Generally, they test trial enrollment and recall, how are they going to deliver the treatment being tested, and data collection methods.

PREVENTION CLINICAL TRIALS
Medical researchers study new ways to prevent disease and illness from developing or returning. This can include medications, vaccines, vitamins and supplements, or healthier lifestyle changes.

SCREENING CLINICAL TRIALS
Medical researchers study new ways to detect diseases or illnesses at an early stage.

TREATMENT CLINICAL TRIALS
Medical researchers are studying new treatment findings such as new medicine, therapy, or new ways of providing surgery or radiation/chemotherapy.

OBSERVATIONAL CLINICAL TRIALS
A study done by observing a large group of people without giving them new medicine or treatment devices. Researchers assess health outcomes effected by the participants lifestyles.
PHASES OF CLINICAL TRIALS

PHASE 1
A small group of participants (20-100) help researchers understand the amount and safety of the medicine being studied by taking it and providing feedback on side effects and any other issues. Doctors do multiple clinical exams and lab work to calculate the treatment. This can typically take a few weeks to several months.

PHASE 2
Similar to Phase 1, participants help researchers better understand the advantages of the medicine that is being studied, along with side effects, but in a larger group. Usually several hundreds of people. This takes an average of 1 to 2 years. (This phase follows phase 1.)

PHASE 3
The medicine is then studied on hundreds to thousands of people who have the medical condition being studied. This helps researchers find out and confirm if the medicine is safe for people with the condition. This can take an average of 1 to 4 years. (This phase follows phase 2.)

PHASE 4
After the medicine is approved, several thousands of people can still participate in clinical trials to understand the outcome of approved medicine over time. This phase can give additional information on drug risks, benefits, and proper use. This process can take more than a year. (This phase follows phase 3.)

"WE ACTUALLY HAVE SEEN PATIENTS BENEFIT GREATLY EVEN FROM EARLY PHASE TRIALS, INCLUDING PHASE ONE."
-DR. ANTHONY EL-KHOUEIRY

Source: clinicaltrials.gov
HEALTH AND SAFETY MEASURES FOR PARTICIPANTS

The upmost priority in clinical trials is to keep patients safe. To ensure this, the first step is for the researchers to send the description of the clinical trial plan to the Institutional Review Board (IRB). The IRB then decides if the study is useful and ensures the safety of the participants in the trial. The research team will go over an Informed Consent form with the patient, which will explain the details of the clinical trial. This form will describe what is known about the treatment being studied, how long the study will be, along with the potential risks and benefits, and how they will protect your identity in the study. Patients will sign this form after all questions and concerns are answered. When the clinical trial begins, the IRB watches over the process and takes note of any problems. The Office of Human Research Protections (OHRP) also keeps a close eye on the progress of the study. They make sure the rules from the study protocol, as described on the informed consent form, are followed and can stop the clinical trial whenever a problem has been found.

During the beginning of the clinical trial enrollment, patients may also go through blood tests and/or imaging tests, and/or surveys before they start the actual clinical trial treatment. This gives doctors a good understanding of their medical background and history to make sure of their safety in the research.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

One has the right to stop participating in a clinical trial at any point during the process. If that is what the participant decides, the doctors will let them know what are the best treatment options available to them. The clinical researchers may follow up with patients to check on their progress and any side effects that may occur in the future. Regardless of the reason, if they decide to exit the clinical trial, they always have that choice. Whether speaking with their doctor, family, or friends, participants decide what is the next best step for them.
THE ROLE OF FAITH AMONG AFRICAN AMERICAN COMMUNITIES

HOW CAN THE FAITH-BASED COMMUNITY ENCOURAGE CLINICAL TRIAL ENROLLMENT?

It is written: “Get wisdom; develop good judgment. Don’t forget my words or turn away from them. Don’t turn your back on wisdom, for she will protect you. Love her, and she will guard you. Getting wisdom is the wisest thing you can do! And whatever else you do, develop good judgment. If you prize wisdom, she will make you great. Embrace her, and she will honor you. She will place a lovely wreath on your head; she will present you with a beautiful crown.” -Proverbs 4:5-9

Faith Leaders hold an important place in communicating to the community the positive effects of clinical trials; as clinical trials can save lives and have a positive effect on future generations.

Faith plays an important role in helping overcome the fears and concerns of individuals within the African American community. Even though education is important, each person’s drive to want to learn more about clinical trials will help them make better choices about their care. Each person will then be able to take charge of their care while feeling confident in the choices that they make.

It is written in Proverbs 4: 20-22 “My son, pay attention to my words and be willing to learn; Open your ears to my sayings. Do not let them escape from your sight; Keep them in the center of your heart. For they are life to those who find them. And healing and health to all their flesh.”

Gaining an understanding of what clinical trials are, and their benefits, is important when providing equal access to healthcare. In the Black Community, the lack of trust in the leaders and providers in the healthcare field comes from past abuse of authority. In this present time, and moving forward, healthcare is more welcoming and open with the care of all patients no matter their ethnicity. The success of informing and preparing individuals within the African American community depends on the support of the local churches. Faith Leaders within the Black community hold the key to bringing resolution to the problems of the past and the corrections to improve the present.

Source: Biblegateway.com
LIFE DURING CLINICAL TRIALS
A participant in a clinical trial will have treatments done in a hospital or a doctor's office. A benefit of being in a clinical trial is receiving extra medical attention, where doctors watch over the patient closely and have more tests done than usual.

It may be suggested to patients to keep a health journal in order to record how they are feeling on a day-to-day basis as well as any symptoms or side effects. This can help doctors find out if their symptoms are from the medication, if they need special medical attention, or if a treatment change is needed.

A participant in a clinical trial will still have the chance to see their regular doctor or primary care physician. Their doctor will work alongside the research team to find out how they are doing and understand what is the best care for them.

Some clinical trials may take place in specific areas. So, depending on the clinical trial, participants may need to travel to a different county, city, or state. Asking the research team about helping financially with travel and overnight stay will set the patient up to plan ahead.

LIFE AFTER CLINICAL TRIALS
After a clinical trial ends, researchers will carefully examine data results from the entire study and figure out the performance levels and safety. If the researchers find successful results they will move on to the next steps in getting the medicine out to the general public. Researchers will also continue to closely watch clinical trial participants for potential side effects.

Each participant will also have an exit interview. During this interview, researchers ask about their symptoms and side effects, along with their experience in the trial. This is the perfect time for them to ask any questions or comment on any concerns they may have. The research team is required to inform one about treatment options that are best for them. Once the clinical trial ends, the medication being studied is not readily available. Although in some cases a participant can still continue in the clinical trial treatment, it is more likely that it will first need to get approved by the FDA.

The transition back to regular life can take some time to adjust to because of the demands of the clinical trial. Taking time to do activities and hobbies one loves will make the transition easier to bear with.
USC Norris Comprehensive Cancer Center held a Prostate Cancer Town Hall Meeting on September 26th, 2020. This was an online Zoom event, free and open to the public. USC’s Doctor John Carpten gave an opening speech on the importance of cancer awareness and clinical trials.

Dr. JOHN CARPTEN
Professor and Chair of Translational Genomics
Director, Institute of Translational Genomics
Royce and Mary Trotter Chair in Cancer Research

LINK TO ACCESS THE VIDEO:
https://bit.ly/DrCarptenVideo
Dr. Joyce Richey of USC Keck School of Medicine gave a presentation to the parents of USC NAI students about the importance of getting vaccinated against COVID-19 and explained some history about the Tuskegee study.

Dr. Joyce Richey
Associate Professor of Clinical Physiology & Neuroscience
Associate Dean for Diversity and Inclusion (Education)
Chief Diversity Officer

LINK TO ACCESS THE VIDEO:
VIDEOS

USC NCCC PROSTATE CANCER & CLINICAL TRIALS TOWN HALL MEETING

USC Norris Comprehensive Cancer Center held a Prostate Cancer Town Hall Meeting on September 26th, 2020. Along with Dr. John Carpten, Dr. Anthony El-Khoueiry from USC also gave a speech about the phases of clinical trials and what is needed for new medicine to get approved.

Dr. Anthony El-Khoueiry
Associate Professor of Clinical Medicine
Norris Cancer Center CISO Chair

LINK TO ACCESS THE VIDEO:
CALL TO ACTION

AFTER READING THIS TOOLKIT, HERE ARE SOME RECOMMENDATIONS OF WHAT YOU CAN DO:

- Share the information in this guide with your family, friends, and others you love.

- Check out the links of the websites and the videos included.

- Talk to your doctor and get screened when the time is right.

- Share the information you learned about clinical trials within your networks.

- Now that you have read this Toolkit, please take a few minutes to provide us your feedback about it by completing a short survey which you can access by clicking on this link: [https://usc.qualtrics.com/jfe/form/SV_0j4JAY6WWnk8rBk](https://usc.qualtrics.com/jfe/form/SV_0j4JAY6WWnk8rBk)
LAZAREX CANCER FOUNDATION

https://lazarex.org/

Through community outreach and engagement and patient navigation in FDA clinical trials, Lazarex Cancer Foundation aims to improve the outcome in cancer care in cancer patients and the medically underserved. They aspire to improve the cancer survival rates by providing resources and screenings for early detection. Lazarex is also a clinical trial reimbursement program, where they help with monetary issues of going through a clinical trial. They help with costs such as, traveling to and from medical appointments and overnight stays. You can apply for help with patient navigation at https://lazarex.org/helping-you/patient-assistance-forms/ or for medical financial assistance at https://lazarex.org/helping-you/medical-representative-access/.

CLINICALTRIALS.GOV

https://clinicaltrials.gov/

A handy resource when searching for a clinical trial any where in the nation that best fits anyone going through a cancer diagnosis. Clinicaltrials.gov is a resource provided by the United States National Library of medicine. There, one can search for a clinical trial by condition or disease, drug name, investigator, or even country. They also provide resources to learn about studies and common terms used during a trial.
NATIONAL INSTITUTES OF HEALTH (NIH)

https://www.nih.gov/

The NIH seek knowledge in understanding the nature and behavior of all human systems to optimize health and quality and quantity of life. Although they are based in Bethesda, Maryland, most of their clinical studies are also conducted in institutions and centers across the nation. The NIH conducts clinical trials for many diseases, infections, and viruses. To search for a clinical trial and get more information on criteria, location, and contact information of the research teams go to https://clinicaltrials.gov/.

AMERICAN CANCER SOCIETY (ACS)

https://www.cancer.org/

A nationwide health organization committed to eliminating cancer as a major health issue by providing support and resources along with encouraging prevention and screening. The ACS has a breakdown of general information, the risks and preventions, early detection and diagnosis, and treatment options regarding all types of cancer. They also have tools to help patients find a clinical trial by visiting https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-you-need-to-know/picking-a-clinical-trial.html.

AMERICAN ASSOCIATION FOR CANCER RESEARCH (AACR) CANCER DISPARITIES PROGRESS REPORT 2020

https://www.aacr.org/

The AACR aims to increase the public understanding of cancer in the community and how it disproportionately affects minorities such as Black and Hispanic/Latinx individuals. The report emphasizes the significance of cancer research and the importance of government funding for cancer research to save lives. From graphic information further explaining cancer rates and deaths, to explaining the different factors that affect underserved populations, and survivor stories, the AACR Cancer Disparities Progress Report 2020 is a good source to understand cancer health disparities in underserved communities and to highlight the importance of clinical trial diversity.
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