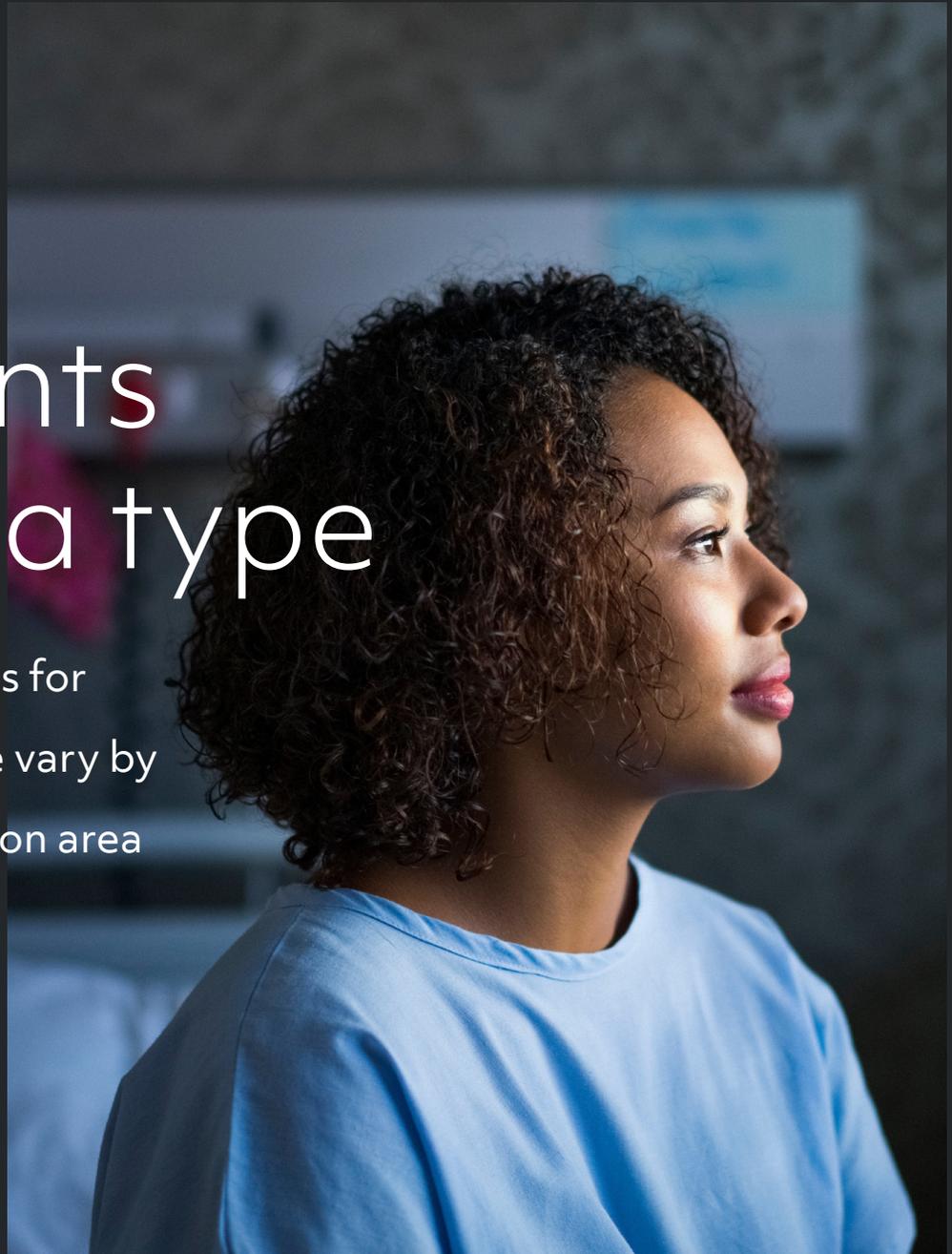


Patients have a type

How preferences for
clinical trial type vary by
race and condition area





Introduction

Difficulties with clinical trial patient recruitment and retention continue to slow research progress for a variety of reasons, including protocol complexity, low-performing research sites, and high costs of recruiting.

Historically, lack of interest from patients has been included on that list of barriers. Antidote's findings suggest, however, that patients are interested in being a part of research – they just need to be approached in the right way.

In 2018, Antidote worked with eight leading health organizations – American Kidney Fund, Allergy & Asthma Network, Healthline, JDRF, Lung Cancer Alliance (now GO2 Foundation for Lung Cancer), Lupus Research Alliance, Melanoma Research Alliance, and Multiple Sclerosis Association of America – to survey

nearly 4,000 patients and caregivers about clinical research. The initial survey work and analysis were conducted in partnership with SCORR Marketing.

Our survey results suggest that it's not a lack of interest in research that slows down patient recruitment. Instead, research teams and recruitment companies may not cater their outreach in a way that contextualizes clinical trial opportunities for patients and gives them the information they need to feel confident about volunteering.

Prior research on this topic has tended to focus on interest in research participation in general. We conducted an analysis that dove deeper into patient preferences to find out whether interest in participating varied based on the type of clinical trial: an observational trial, an interventional trial testing a new drug or device, an interventional trial testing a better alternative to an existing treatment, a treatment to lessen the side effects of an existing drug, or a cure for a condition. Our key findings included:

- Overall, white individuals surveyed were more willing to participate in clinical trials than their non-white peers (see table 1 for details on our sample and table 3 for responses by subgroup).
- Breaking this trend, non-white individuals expressed more interest in participating in an observational trial than white respondents did.
- Across all condition types, individuals were least likely to express interest in participating in a trial focused on managing side effects for a treatment they were already using.
- Individuals living with chronic conditions answered similarly to individuals living with cancer with one exception: These individuals were significantly more likely to be willing to partake in an observational trial (see table 4 for details).

All patients we surveyed had a high level of interest in participating in research in general. Because of each health organization's work in raising awareness around the importance of clinical trial participation, this fact by itself isn't surprising. However, results varied by type of trial, by race, or by condition area. Differences across condition area and race suggest that research teams must take diverse approaches to engage patients by demonstrating the benefits as well as the risks of taking part in each type of trial.



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Methods and respondent profile

Nearly 4,000 individuals (n=3,942) responded to an online survey between June 18, 2018, and August 21, 2018. The survey sample included individuals living with various conditions in the U.S. Survey participants were recruited through leading patient advocacy organizations.

Overall, the sample we collected was predominantly female and non-Hispanic white, though multiple races were represented. We compared answers from white versus non-white (including multi-racial) respondents.

In addition, we collapsed the categories of conditions into (1) oncology, (2) chronic with acute onset of symptoms,

and (3) chronic. We did this after noticing trends in responses by condition type and to better assess the relationship between condition and demographic characteristics on patients' willingness to participate in different types of trials.

We chose to ask the question of sex assigned at birth rather than gender as this is frequently the sex/gender assessment used to screen individuals for trial eligibility.

Differences in education level or income level among groups were not statistically significant. Around a quarter of respondents had participated in a clinical trial.

Table 1: Self-reported demographic characteristics

	Count	% of total sample
Race		
American Indian/Alaskan Native	27	0.7%
Asian	48	1.2%
Black/African American	295	7.5%
Native Hawaiian/Pacific Islander	10	0.3%
White	3,347	84.9%
Other, including multiple races selections	215	5.5%
Recategorized race category		
White	3,347	84.9%
Non-white	595	15.1%
Ethnicity		
Hispanic	186	4.7%
Non-Hispanic	3,673	93.2%
Prefer not to answer	83	2.1%
Sex assigned at birth		
Female	3,133	79.5%
Male	791	20.1%
Prefer not to answer	18	0.1%

Table 2: Self-reported condition and recategorized conditions

	Count	% of total sample
Condition		
Asthma/Allergy	595	15.1%
Gastro	218	5.5%
Kidney Disease	507	12.9%
Lung Cancer	241	6.1%
Lupus	375	9.5%
Melanoma	454	11.5%
Multiple Sclerosis	1,067	27.1%
Type 1 Diabetes	485	12.3%
Recategorized condition		
Oncology (lung cancer and melanoma)	695	17.6%
Chronic, acute onset of symptoms (asthma/allergy, gastro)	813	20.6%
Chronic (lupus, kidney disease, Type 1 diabetes, and Multiple Sclerosis)	1,957	61.7%

Interest in clinical research varies by race and trial type

Clinical trial participation rates have historically been lower for non-white patients and women. For example, African Americans represent 12% of the U.S. population¹ but only 5% of clinical trial participants. Of those who participate in cardiovascular device trials, 67% are male.

It's critical for the clinical research community to include diverse participants in all trials.

A close look at clinical trial preferences by race and trial type may offer clues that point toward the best ways to position clinical trial opportunities to non-white communities. For example, in our survey, relative to white individuals, non-white individuals are more likely to partake in an observational trial. The same is true for Hispanic patients and women (See table 3).

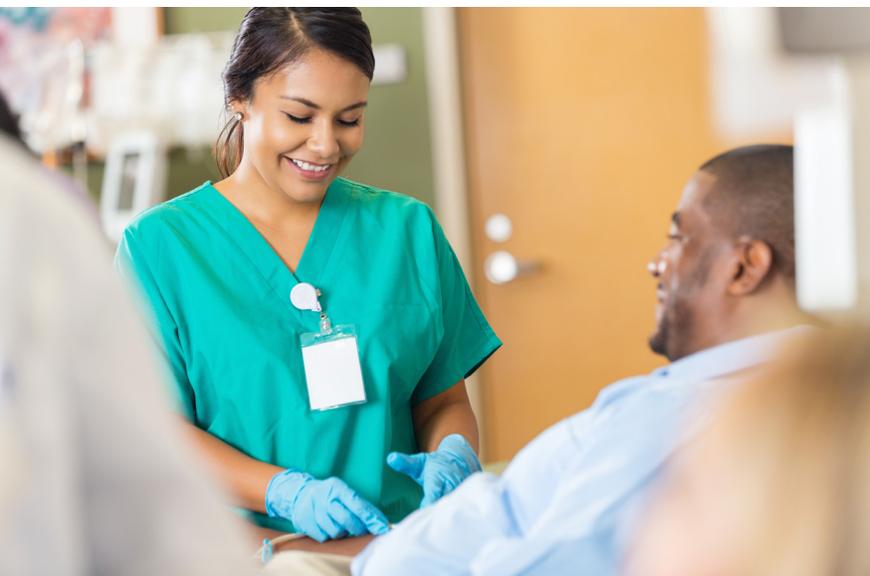


Table 3: Frequency of respondents who answered “likely” or “very likely” to partake in the specified type of trial by demographic categories, and odds ratios of responses by demographic information (referent group indicated as “Ref.”).

	A trial that does not involve a drug, therapy, treatment or medical device but that seeks to understand how the health of people living with my condition changes over time.	A trial for a new drug, therapy, treatment or device to address my condition.	A trial for a new drug, therapy, treatment or device that is intended to lessen a side effect of a treatment I am currently using.	A trial for a new drug, therapy, treatment or device to find a better alternative to an existing treatment.	A trial for a new drug, therapy, treatment or device to find a cure for my condition.
Race					
White	79.0%	75.3%	68.3%	78.5%	87.4%
Non-white	83.2%	68.4%	66.1%	72.8%	82.9%
Odds ratio: Non-white v. White (Ref.)	1.31 (1.04, 1.65)*	0.71 (0.59, 0.86)**	0.90 (0.75, 1.09)	0.73 (0.60, 0.89)**	0.70 (0.55, 0.88)**
Ethnicity					
Hispanic	86.6%	78.5%	71.0%	82.8%	91.4%
Non-Hispanic	79.5%	74.4%	68.1%	77.7%	86.7%
Odds ratio: Hispanic v. Non-Hispanic (Ref.)	1.66 (1.08, 2.55)*	1.26 (0.88, 1.80)	1.15 (0.83, 1.59)	1.38 (0.94, 2.03)	1.63 (0.97, 2.74)
Sex assigned at birth					
Female	81.6%	73.9%	67.9%	77.4%	86.2%
Male	72.3%	76.2%	68.1%	78.8%	88.8%
Odds ratio: Male v. Female (Ref.)	0.59 (0.49, 0.70)**	1.14 (0.95, 1.36)	1.01 (0.86, 1.20)	1.08 (0.89, 1.31)	1.26 (0.99, 1.61)

*p < .05

** p < .01

These findings suggest that non-white individuals are interested in participating in research, but the type of trial makes a difference in how likely they are to participate. Though we did not ask for the reasons behind these choices in our survey, the results make sense when weighed with other research conducted on attitudes toward clinical research in minority communities.

Historically, there has been lack of trust and fear among communities of color as it relates to clinical trials and research, due to unethical studies and injustices researchers subjected minority. At the same time, studies suggest that trust in research has improved. In a 2017 [study conducted by Research!America](#),² the percentage of respondents citing “lack of trust” as a reason to avoid medical research declined by as much as 15 percentage points among minority groups and the population overall compared to the results of a 2013 survey – 50% of African-Americans (11 percentage point decrease compared with 2013), 45% of Asians (six percentage point decrease), 43% of Hispanics (nine percentage point decrease), and 39% of non-Hispanic whites (15 percentage point decrease).

This modest, but promising, increase in trust may help researchers understand that while non-white patients are interested in participating in research, clinical trials associated with less risk, such as observational studies, tend to be more appealing.

Research conducted on health literacy in communities of color offers additional evidence related to trial-type preferences. Minority communities in the United States typically have less access to high-quality education and report [lower rates of health literacy](#).³ While health literacy is typically defined as the ability to navigate health information provided by a doctor, [one study](#)⁴ on minority patients diagnosed with cancer published by the National Institutes of Health also explored the interaction between health literacy and other

types of literacy, such as scientific and civic, and how these knowledge types interact with each other when discussing clinical research.

The study found that gaps in scientific literacy may lead to confusion about how clinical trials work. For example, survey questions revealed misconceptions about the way clinical trials are conducted, such as the false belief that all trials use a placebo.

The report also evaluated civic literacy, defined as the ability of individuals to identify and understand the sources of health information. Participants were critical of several players in clinical research, including the medical system, pharmaceutical companies, and the government. When researchers explained how institutional review board protections work, some participants remained skeptical, but others found the explanation reassuring. One participant said: “... even after being educated they still might decide not to participate, but ...I think more people would participate...upon learning about these regulations than would...participate if they didn't know.” Evidence in the NIH study indicates ensuring that potential participants understand how IRB protections work and that not all clinical trials use a placebo may help patients feel more comfortable participating in interventional trials.

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Trial type preferences by condition

In addition to analyzing survey results by race, we also looked for trends and differences in responses by condition type. In general, relative to oncology respondents, individuals living with a chronic condition were significantly less willing to partake in a trial testing a new drug or device (in all cases $p < 0.01$). Of note, testing a new drug for a cure ranked highest for all condition areas. These trends held when controlling for race, ethnicity, and sex.

Table 4. Frequency of respondents answering “likely” or “very likely” to participating in indicated trial type by condition. Odds of answering “likely” or “very likely” to partake in a given type of trial, when controlling for race, ethnicity, and sex. (Please note: Oncology served as the referent group for this analysis.)

	Frequency			Odds ratios	
	Oncology	Chronic	Chronic/ Acute	Chronic	Chronic/ Acute
A trial that does not involve a drug, therapy, treatment or medical device but that seeks to understand how the health of people living with my condition changes over time.	73.2%	80.4%	82.9%	1.50 (1.23, 1.82)**	1.77 (1.38, 2.27)**
A trial for a new drug, therapy, treatment or device to address my condition.	80.1%	71.1%	78.7%	0.61 (0.05, 0.75)**	0.92 (0.71, 1.18)
A trial for a new drug, therapy, treatment or device that is intended to lessen a side effect of a treatment I am currently using.	73.1%	65.5%	70.9%	0.70 (0.58, 0.84)**	0.90 (0.71, 1.12)
A trial for a new drug, therapy, treatment or device to find a better alternative to an existing treatment.	80.9%	75.1%	82.7%	0.71 (0.58, 0.88)**	1.13 (0.87, 1.47)
A trial for a new drug, therapy, treatment or device to find a cure for my condition.	91.4%	85.1%	87.6%	0.54 (0.40, 0.72)**	0.67 (0.48, 0.93)*

* $p < .05$

** $p < .01$

Patients facing cancer were found to be the most willing to participate in a clinical trial for a new treatment option, perhaps because the perceived benefits outweigh the risks for life-threatening conditions. This may also be because of the increased focus on emerging treatment approaches such as immunotherapy that until recently were only available through clinical trials, said Cody Barnett, Director of Communications at the Melanoma Research Alliance (MRA). Those with chronic conditions, on the other hand, may feel that they have less to gain from participating in higher-risk clinical trials, such as those testing a brand-new drug or device.

In general, our research found that individuals living with chronic conditions answered similarly to individuals living with cancer. One key exception was that those with chronic conditions were significantly more likely to be willing to partake in an observational trial, relative to oncology patients.

“With only one approved treatment specifically for lupus, people are taking medications borrowed from other diseases,” said Diane Gross, National Director of Advocacy and Programs at the Lupus Research Alliance. “Once people find a treatment regimen that works, they don’t necessarily want to take chances with something new.”

Patients may be more interested in trials that allow them to remain on the standard of care, whether as background therapy or instead of a placebo, Gross said.

Lupus is two to three times more common⁵ in women of color than in white women, so here, race may again play a role in patients’ interest in observational, rather than interventional, clinical trials. For clinicians, highlighting the

opportunity for patients of color to participate in observational trials may help researchers connect with populations that have historically been harder to engage. Participating in such trials may also help patients feel more comfortable with research in general, and eventually consider taking part in interventional trials.

“Observational trials may offer communities of color a gateway into being involved in research,” said Gross. “If someone has a positive experience in an observational trial and feels like a partner in research, they may be more interested in joining an interventional trial later on.”

When it comes to discussing interventional trials, it’s also important for research teams to empathize with patients and any concerns they may have while making clear the importance of well-designed clinical trials for bringing better treatments to patients. Research teams may also highlight which phase a trial is in and what that means, to demonstrate that some patients may already have tried the drug. It’s also important to share with patients that data from previous trials may be available, and for research teams to consider walking patients through past findings. Non-white patients may also benefit from learning that treatments sometimes work depending on someone’s genetic background, underlining the importance and impact of their participation. Finally, researchers and others involved in enrolling patients in trials should also emphasize the benefit to the patient in participating in any clinical trial. Patients who participate in clinical trials often receive closer and more frequent monitoring, may access treatments that work better for them, and have the opportunity to learn more about their condition from experts in the field.

“Observational trials may offer communities of color a gateway into being involved in research.”

Do the clinical trials we design meet patient needs?

First and foremost, respondents from all conditions were likely or very likely to participate in a trial for a cure for their condition. While trials researching a potential cure were most appealing in our survey, across all condition types individuals were least likely to express interest in participating in a trial for a side effect of a treatment they were currently using.

This finding highlights the need for the patient voice in clinical trial ideation and design. Before beginning a research project, drug developers should consider whether there is patient interest in a certain type of treatment or in participating in a certain kind of trial. If the need for a potential treatment is sound, researchers should interview patients to understand the best ways to frame clinical trials, particularly those that aim to mitigate side effects of an existing treatment. For example, one benefit of participating in this kind of trial may include free treatment with the existing standard of care.

Research teams can help patients understand how research focused on managing side effects of a certain medication can help make life easier or more comfortable for others living with their condition. It's also key to include endpoints in a study that resonate with patients. For example, 75% of patients

with diabetes⁶ said in a study that they would prefer that clinical trials include variables that measure the impact of a potential new treatment on their quality of life rather than on surrogate variables, such as HbA1c. Patients may be more interested in clinical trials related to medication side effects if they understand improvements the investigational treatment could make on their day-to-day lives.

Additionally, patients may be more interested in participating in clinical trials for new drugs if those trials directly address patient needs and concerns. Though the risk of participating in clinical trials for new drugs may be higher, the reward or potential benefit is more appealing if the treatment aims to improve symptoms in a way that resonates with patients.

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Conclusion

Patients are interested in accessing better treatments, and especially cures, for both themselves and for future generations. While interest is clear from our findings, our results also demonstrate the need for a tailored approach to clinical trial recruitment. The kind of study that appeals to one demographic may not interest the other – recruitment is not a one-size-fits-all approach.

The results of our condition-specific analysis also underline the need for patient involvement in the trial design process. Anecdotally, at Antidote we've found that patients of all backgrounds want to feel like they're more than just research subjects – they want to be a part of the entire process. We're reminded of a conversation we had with [Patrick Gee](#),⁷ an African American patient advocate living with chronic kidney disease. He's currently participating in an observational clinical trial researching the role of a particular gene in chronic kidney disease in people of African descent. He said of research participation:

"If I can understand how I got this, and if it's genetics, why is this affecting one particular gender, one particular race, one particular region of the country, it allows me to be better educated. Then when I go out and talk to other patients who may have similar issues, I can also reassure them that it would be good for you to share your voice. They want to hear from you."

Helping move research forward can be a meaningful experience for patients. Patients are interested in being a part of the process, but patients of color and those living with chronic conditions in particular may need more context and understanding before choosing to participate. In our next white paper, we'll explore how knowledge of clinical trials influences a patient's likelihood to take part and further deepen our understanding of why patients do – and don't – choose to participate in research. When we understand what matters most to patients, we can better create and frame clinical study opportunities that truly resonate with them.

To learn more about Antidote and our work, please get in touch

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¹ [https://www.fda.gov/files/science & research/published/White-Paper-on-the-Dialogues-on-Diversifying-Clinical-Trials-Conference.pdf](https://www.fda.gov/files/science%20&%20research/published/White-Paper-on-the-Dialogues-on-Diversifying-Clinical-Trials-Conference.pdf)

² <https://www.researchamerica.org/news-events/news/lack-trust-less-barrier-clinical-trial-participation-according-minority-populations>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5022195/>

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3712748/>

⁵ <https://www.lupus.org/resources/lupus-facts-and-statistics>

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4854260/>

⁷ <https://www.antidote.me/blog/after-a-surprise-kidney-disease-diagnosis-this-patient-turned-to-education-and-advocacy>