



The 2023 WCG Avoca State of the Industry Report

360° Assessment of the Clinical Trial Industry

June 2023

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Background

360° Assessment of the Clinical Trial Industry



Situation

Industry and regulatory focus on **patient centricity is imperative** to ensure the survival of the clinical trial industry. Most Sponsor and Provider organizations base their study designs on feedback from investigators and patients who are familiar with clinical trials. In order to expand the patient pool for clinical research, Sponsors must develop protocols that meet the needs of research-naïve patients and investigators.

Objective

This research looks across clinical research stakeholders -- Sponsors, Providers, Site Staff and Patients – *regardless of their clinical trial experience* to **identify opportunities for improvement of the experience for Patients and Sites.**

Small population of physicians and patients contribute to what we know about motivations and impediments toward clinical trial participation

3%

of **physicians** participate in clinical research

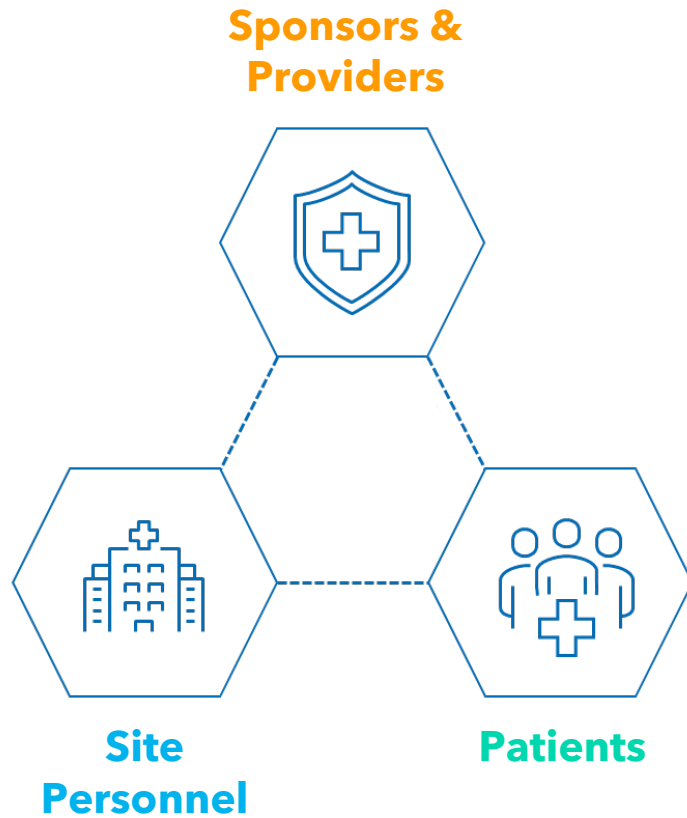
<5%

of **cancer patients** participate in clinical research



Methodology

Sample



Approach

- A **15-minute online survey** was developed.
- It was designed such that questions were asked in the context/language unique to each audience - but ensured **parallel lines of questioning to allow for comparison across audiences.**
- Fieldwork was conducted between **December 2022** and **March 2023.**

Recruitment

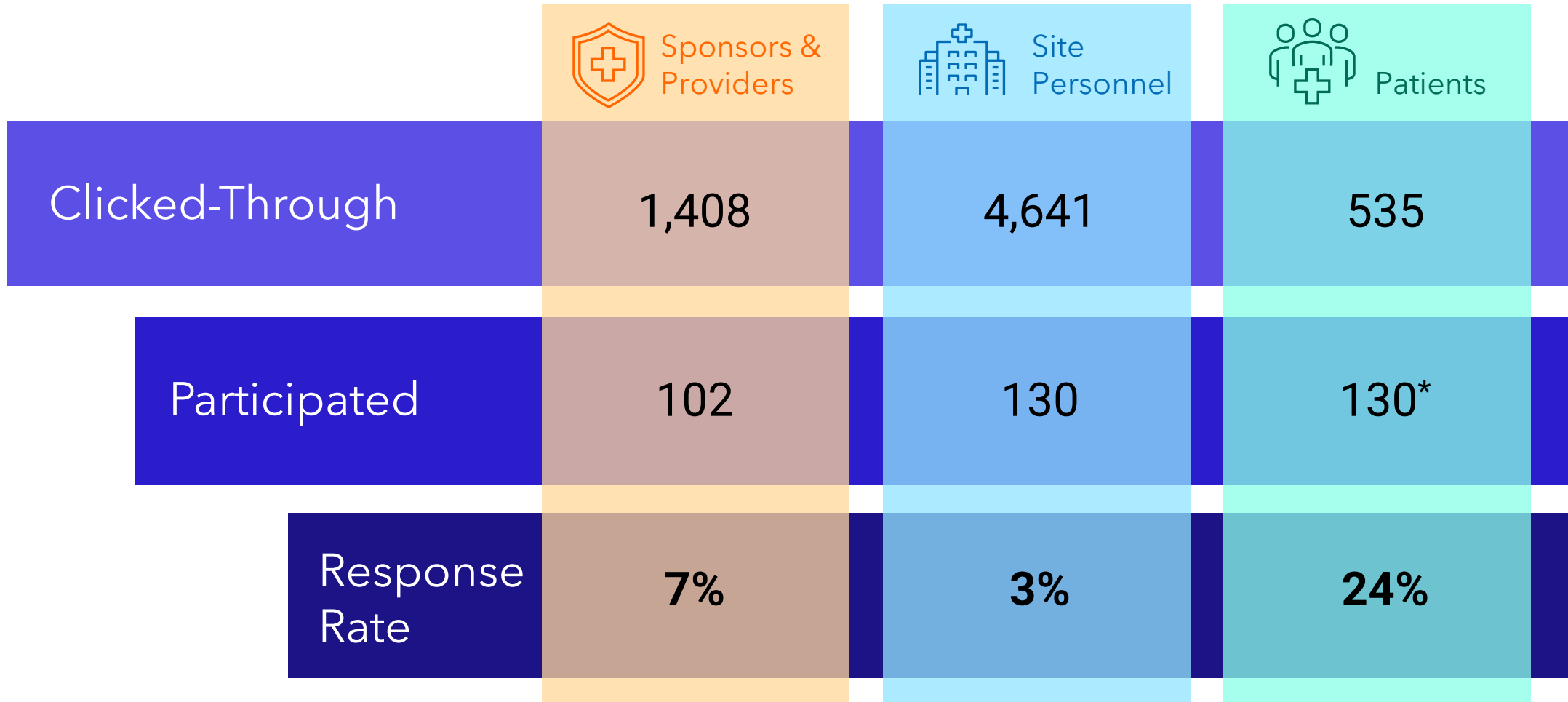
For each audience, a **variety of channels were used for survey recruitment**, including:

- WCG Sponsor and Site networks
- Avoca Quality Consortium (AQC)
- WCG Patient advocacy groups
- Social networks
- Relationships with partner organizations



360° Research Highlights

Recruiting participants is hard work



“Usual” recruitment methods yielded a highly skewed Patient sample

CENSUS*

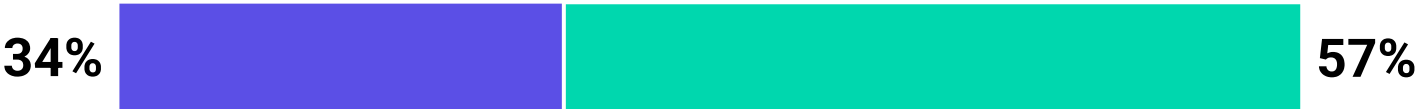


PATIENT SAMPLE

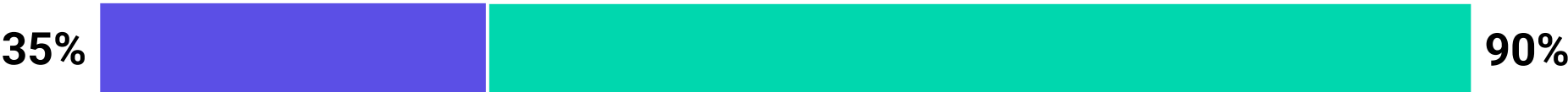
Gender: **Female**



Household Income: **\$100k +**



Education: **College/Advanced Degree**



We fell into the same trap we were trying to solve for...

...so, we **went back into the field to survey an additional N=200 Patient respondents** who reflect the national population in terms of key demographic and socioeconomic variables:

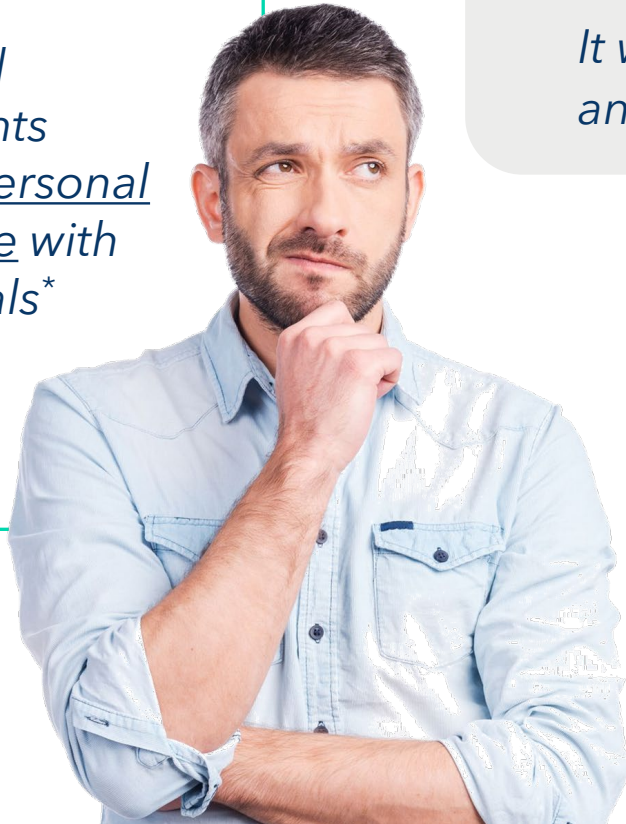
- Age
- Gender
- Ethnicity
- Household income
- Educational attainment
- Region



Clinical trials are uncharted territory; most have no engagement, there is skepticism and fear

75%

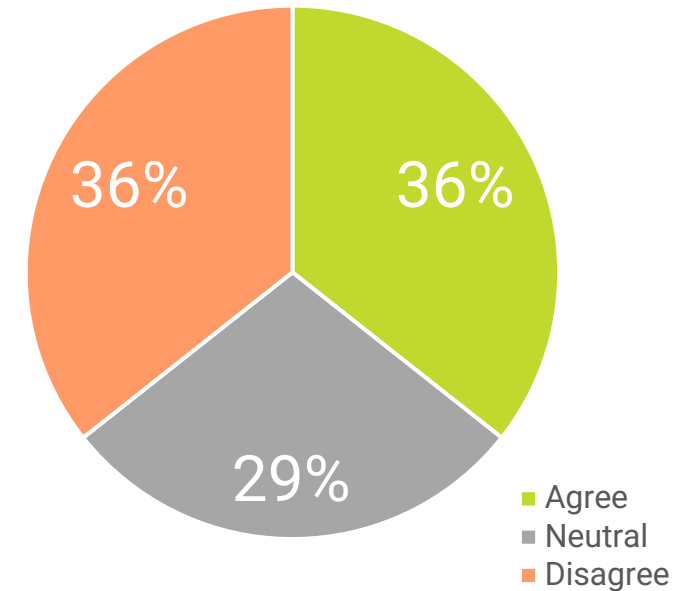
of national respondents have no personal experience with clinical trials*



“ Not open to trying things that haven't been proven to work. It would depend upon the trial and what was involved. ”

“ They **seem very scary**, and I feel usually they just look for the side effects and don't really care how bad a person can potentially get. ”

I believe clinical trials only benefit the pharmaceutical companies that run them.



In addition, there are also “tangible” concerns, such as feeling unwell, time commitment and requirements of participation

86% have concerns about **getting sick or feeling unwell**

“What happens to our bodies by participating in these experiments is my biggest concern.
Having significant side effects from the trial making my situation worse than it was before I got involved in the clinical trial.”

What am I committing to?



72% have concerns about **time commitment**



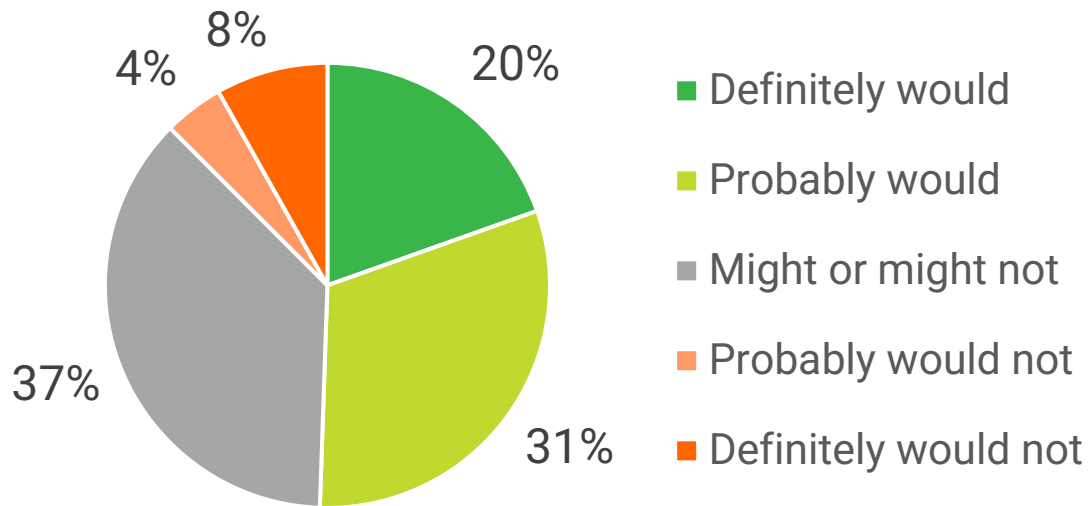
80% have concerns about **number of procedures** required



83% have concerns about **types of procedures** required

Given the concerns noted, interest in participating in a trial in the future is fragmented

Likelihood to Participate in a Clinical Trial



“ *The trial and any possible benefits would have to interest me greatly.*

[Might or might not]



“ ***It would depend on the risks involved, how much is known and whether I felt like the benefit outweighed the cost. I would be more likely to participate if I needed a certain treatment to be healthy.***

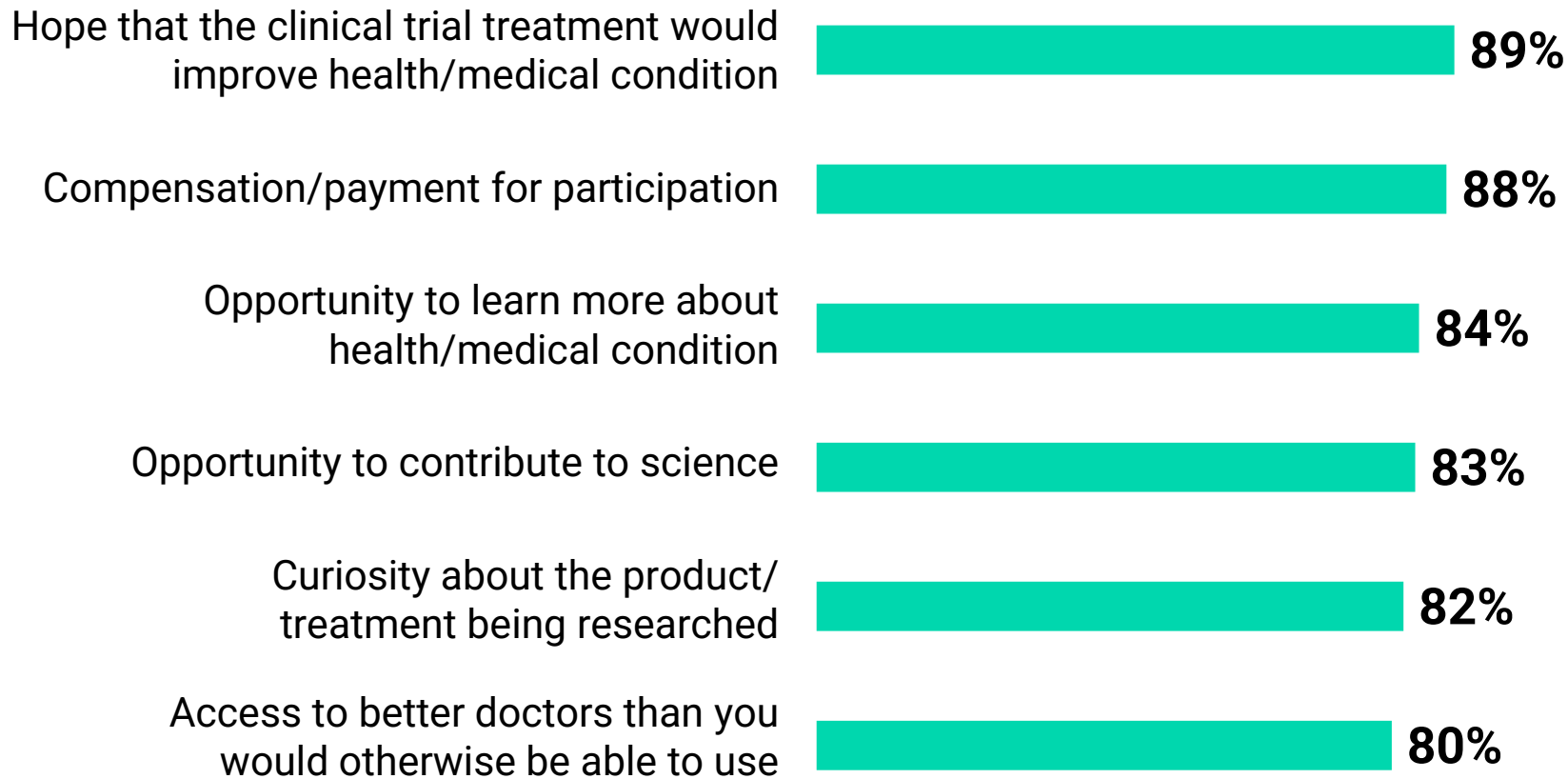
[Might or might not]



However, benefits around outcomes, compensation, opportunity to learn and contribute to science show potential to positively influence prospective participants



Influences on Desire to Participate*



“ **Helping other people.** Depending on the trial, it could help a condition you currently have. I’m sure they pay, too! ”

To the extent the experience can be made “personal” (access to records, see own doctor) this could be further motivation to participate

Top 3 Most Impactful Benefits



73%

able to **receive all of your personal data** and results from the clinical trial



70%

able to **see your regular or preferred doctor** for clinical trial visits



69%

provided with transportation, **reimbursement for travel expenses**



**What does the
experience
actually look like
for clinical trial
participants?**



Those who have participated generally report positive experiences

61% said they had **no issues with feeling sick or unwell**

“It was a good experience. My medical condition improved and I was able to contribute to science. The medication is now approved and is helping people.”

What was the experience like?



72% said their expectations on **time commitment** were met



72% said **tests and procedures** met expectations



80% **liked the healthcare professionals** they worked with

Overall, respondents with trial experience felt it was worthwhile and would participate again

85%

agree that *'the time I spent participating in this clinical trial was worthwhile'*

90%

said they would *'definitely'* or *'probably'* participate in a clinical trial again in the future'



"It was easy, the product being tested improved my skin, and I was paid - easy money."

This suggests there may be opportunity to leverage positive experiences to attract new participants

45%

say that a **friend or family member** would be among their **most trusted sources** for information on clinical trials



Healthcare professionals represent even greater potential to connect with patients - they are the **MOST** trusted source of info



45%

say that a **friend or family member** would be among their **most trusted sources** for information on clinical trials



79%

say that their **regular doctor or healthcare professional** would be among their **most trusted sources** for information on clinical trials



Understanding the **site** experience



Site staff generally agree that trials are designed with patients in mind and are likely to recommend participation to a friend



“ I have seen things **work miracles** for people that would've never even tried it because of cost. ”

65%

agree that 'clinical trials are designed with patients/ volunteers in mind'

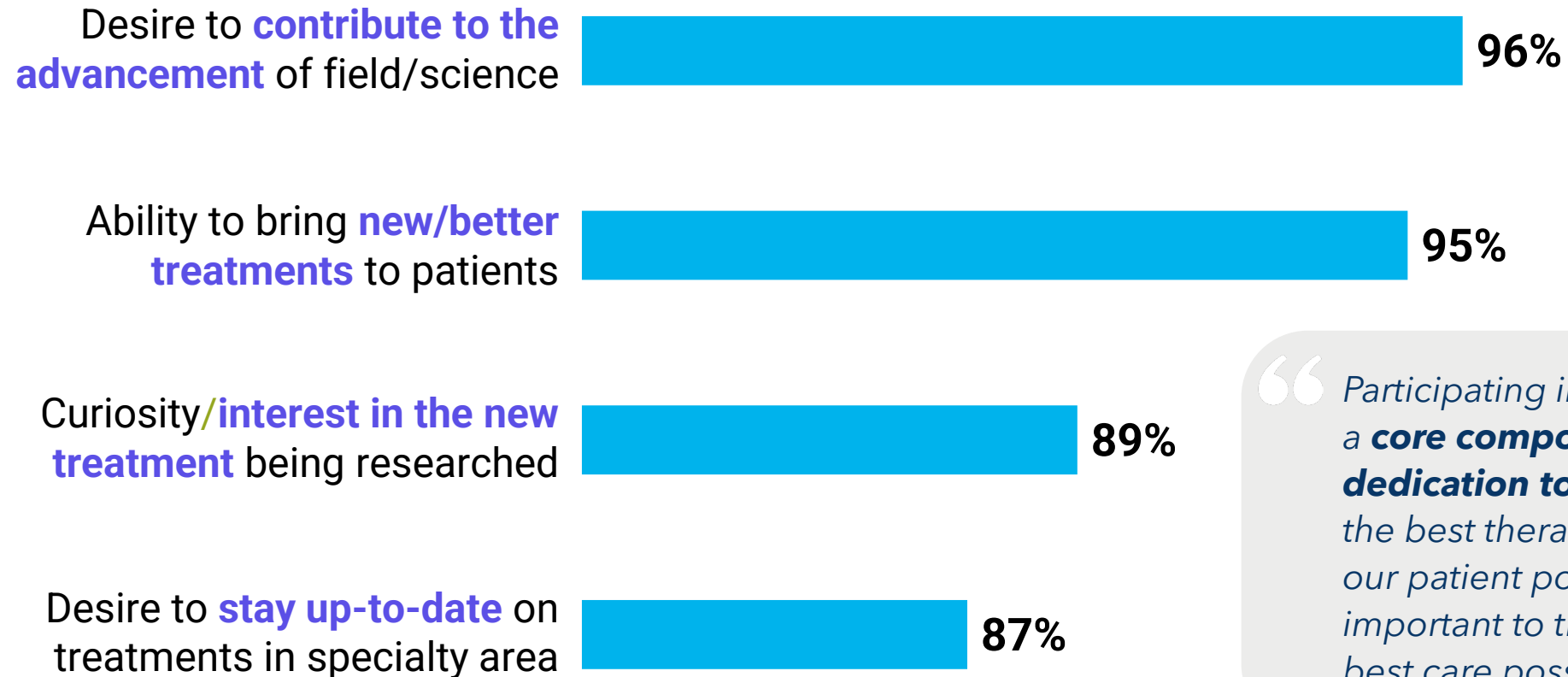
82%

said they would 'definitely' or 'probably recommend participating to a friend or family member'

Sites have altruistic motivation for participating - they have a strong desire to advance the field and bring patients new treatment options



Reasons for Participation



“Participating in clinical research is a **core component to our dedication to patients**. Ensuring the best therapies available for our patient population is important to them receiving the best care possible.”

Because of this, there is strong likelihood to participate again

84%

agree that *'the time I spent participating in this clinical trial was worthwhile'*

94%

said they would *'definitely'* or *'probably'* participate in a clinical trial again in the future'



“ Scientific innovation is exciting and groundbreaking, and it is fulfilling to be part of it. Especially given the vulnerability of our patient population, it is motivating knowing that our work makes or will potentially make a difference in their lives. ”

That said, the experience is not always “ideal” in terms of logistics and burden as it relates to site responsibility...

Start-Up

Maintenance

Closeout

% strongly agree



31%

'budget negotiation was timely & efficient'



31%

'contracting process was timely & efficient'

% strongly agree



38%

'protocol was clear & easy to follow'



29%

'study stayed on timeline'

% strongly agree



27%

'compensated fairly & on time'

“ The benefits for people and the improvements in medicine, far outweigh the stress, incompetence, issues, faulty devices or changes that occur during a clinical trial. They are all different, but they all have issues in one way or another. ”

...and only a minority feel that the site perspective is considered

15% *'strongly agree' that 'clinical trials are designed with sites/site staff in mind'*

“ **ASK SITES FOR INPUT ON YOUR PROTOCOL.** You are NOT an expert at boots-on-the-ground enrollment. Ask someone who is. ”

“ **Put clinical trialist physicians, nurses & pharmacists in charge of the research divisions with sufficient authority to run them properly.** It's clear that the companies are too interested in the financial aspects & care too little about the science or patient care aspects of pharmaceutical research. ”

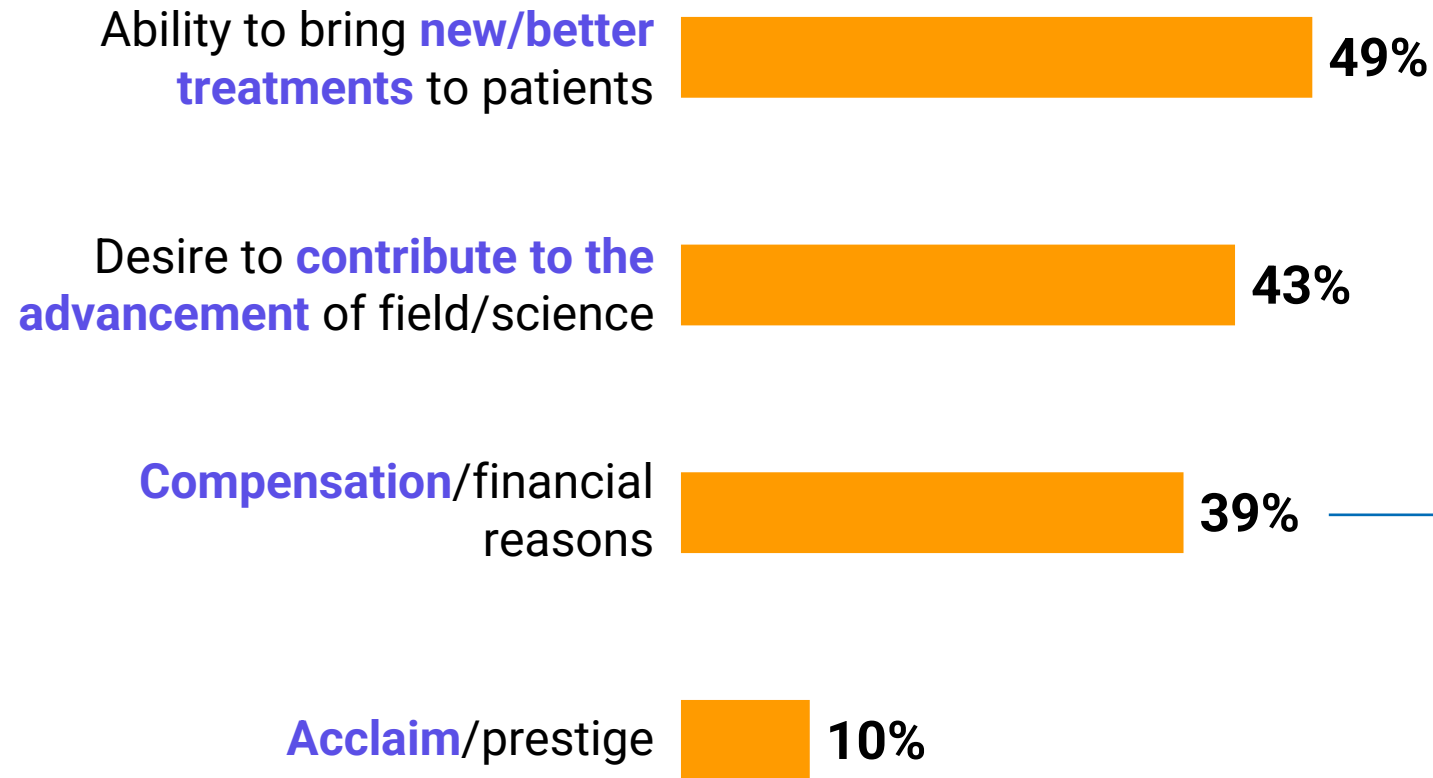


Sponsor & Provider Point of View



Sponsors/Providers have varied thoughts on why sites participate...

Reasons Sites Participate



“ **Ultimately, it's a business.** But it also **helps them provide their patients with potentially new/life-changing therapies** that they might not otherwise be able to get for a variety of reasons. ”

Only 63% of Sites said compensation influenced them, compared to 96% who want to contribute to science.

....but, do generally agree on barriers to site participation...

Site Burden:

Strain on time and staffing resources



“ **Available resources to conduct a clinical trial.** *Dedication of the investigator. Trained/skilled staff to conduct a specific trial.* ”

“ **Don't have the staffing,** *don't understand the amount of staffing required, **don't have the time,** don't have the patient population.* ”

....and acknowledge their own role in creating potential obstacles

“ **Overzealous protocols** and unclear information.

Bureaucratic start-up process and tight budgets with lack of support from the Sponsor.

Overly complicated and constantly amended protocols.

Start-up timelines, limited access to patient population, **potential benefit of trial vs. burden on patients/burden on staff.** ”

Complexity

“ Not being able to find the right patients to meet criteria. Not having enough time to conduct complex trials. And **even if the PI has a great interest in participating, some of those who coordinate may prefer a less complex trial to enroll subjects in because of the burden placed on them.** ”

Key Take-Aways



FINDINGS

IMPLICATIONS

PATIENTS



- Clinical trials are an “enigma” for most people
- Though actual trial participants generally report a favorable experience, there is a lack of understanding and awareness among the broader population

→ Suggests a need to **raise awareness and educate** to inform on trial benefits and reduce barriers to participation

SITES



- Site personnel are motivated to participate in trials, wanting the best for patients and insight into the latest science in their TAs
- They truly believe in the good that clinical trials can offer, but the experience is not always ideal

→ **Site perspective needs to be elevated in importance** - consider eliciting site feedback from the outset of study design

SPONSORS & PROVIDERS



- Sponsors & Providers generally understand that Sites are motivated by altruistic reasons
- That said, they realize that they are highly burdened by the strain on resources and complexity that trials bring

→ Opportunity **to revisit how trials are designed, staffed & compensated** to ensure sites are appropriately accommodated for their efforts



Learn more about WCG Avoca Industry Research

For more than 20 years, WCG Avoca has surveyed industry executives to gain an understanding of key trends affecting outsourced clinical development. Industry leaders rely on our insights to strengthen relationships and enhance R&D quality and productivity.

[Access Research Reports](#)

Thank you!



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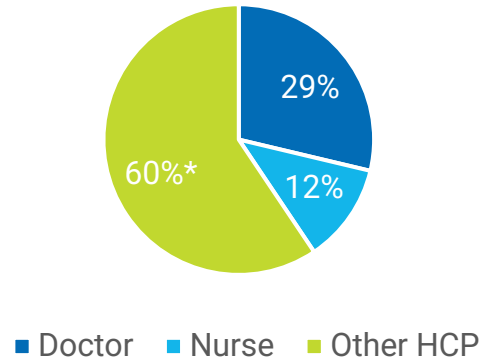


Additional Analysis

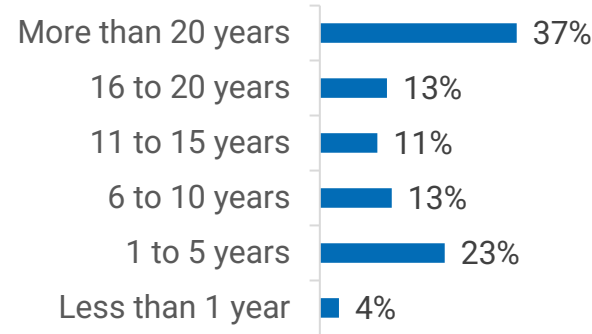
Site Personnel

Sample Composition

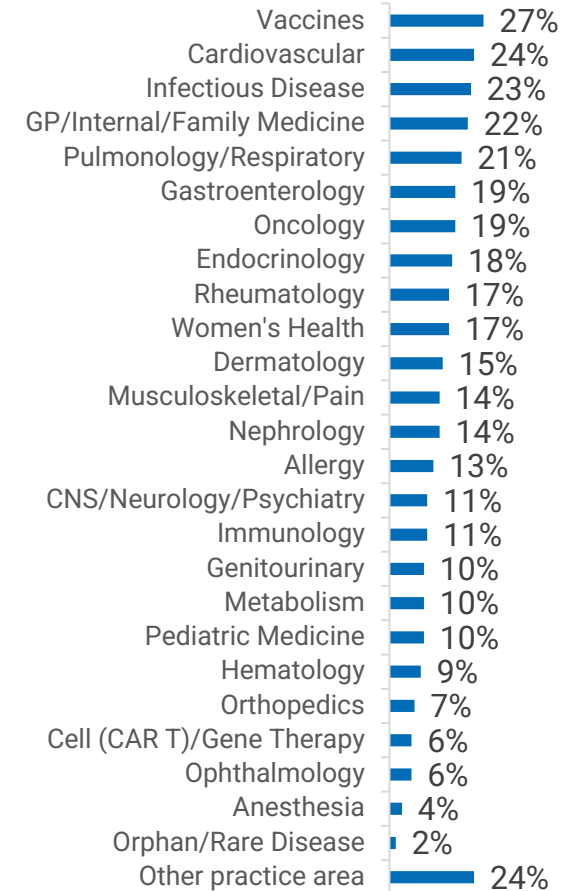
Role



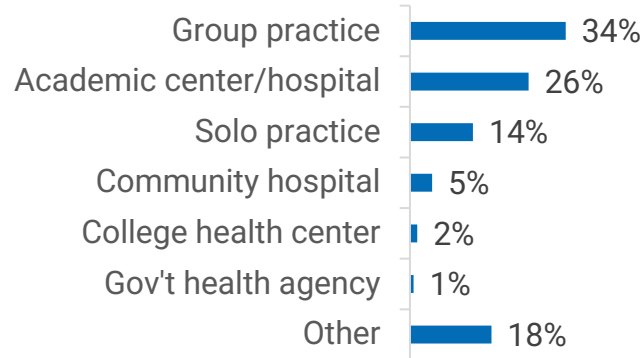
Tenure in Profession



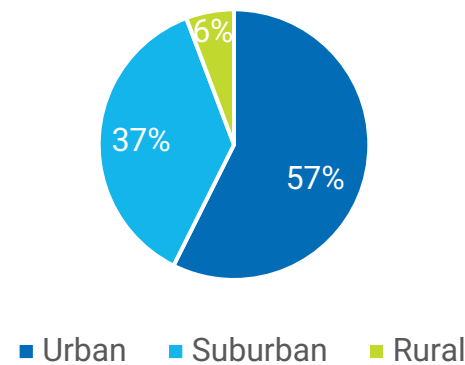
Specialty Area(s)



Practice Type



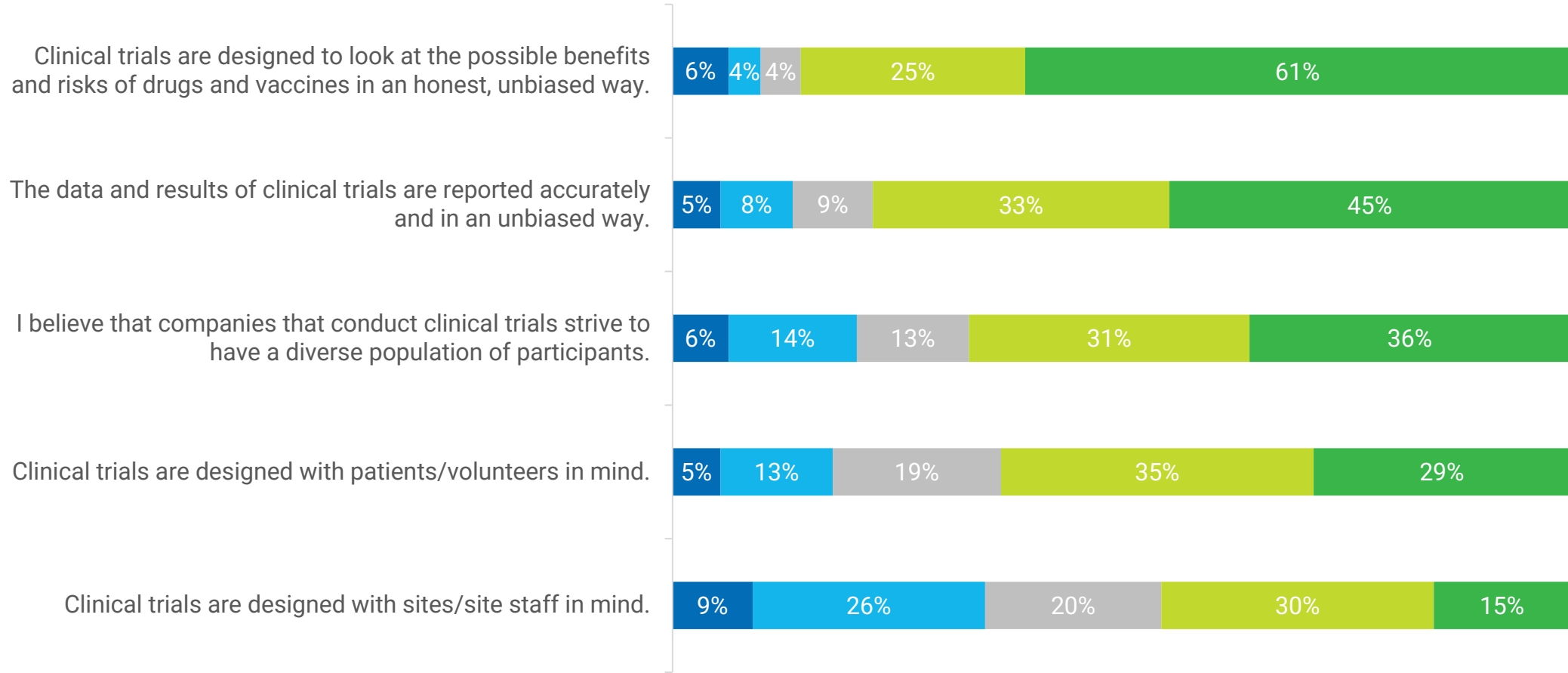
Practice Location



Agree/Disagree Statements



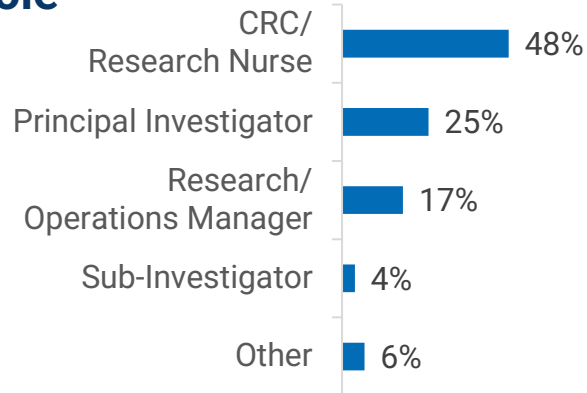
■ Strongly disagree
 ■ Somewhat disagree
 ■ Neither agree nor disagree
 ■ Somewhat agree
 ■ Strongly agree



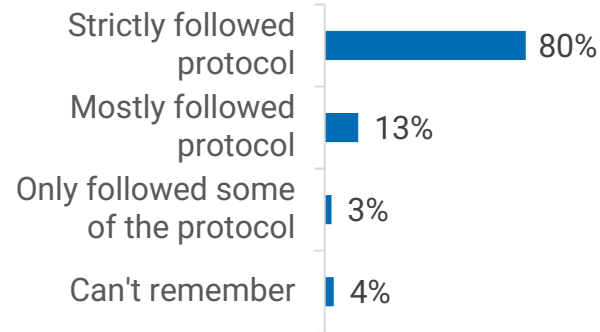
Most Recent Clinical Trial Experience



Role

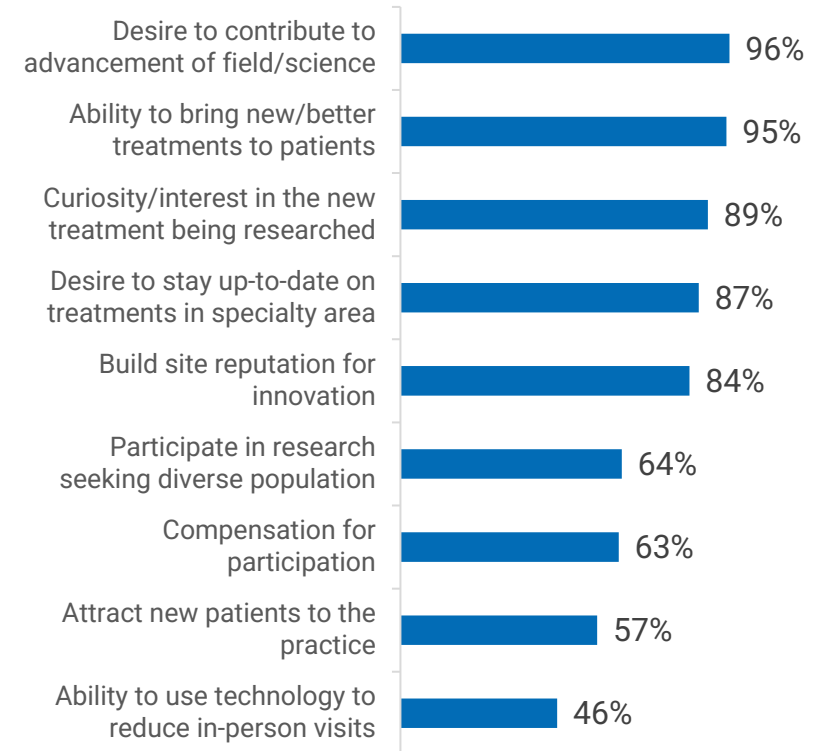


Site Compliance

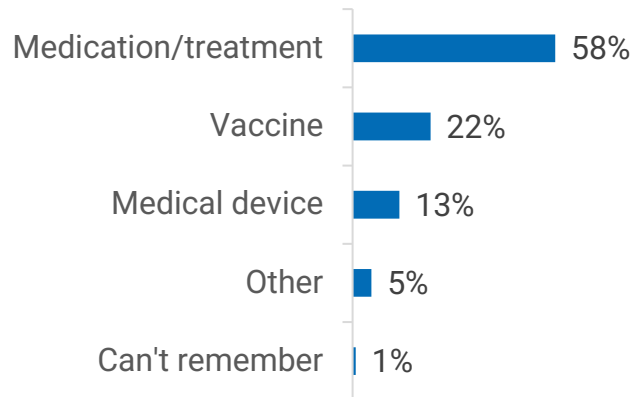


Influence on Participation

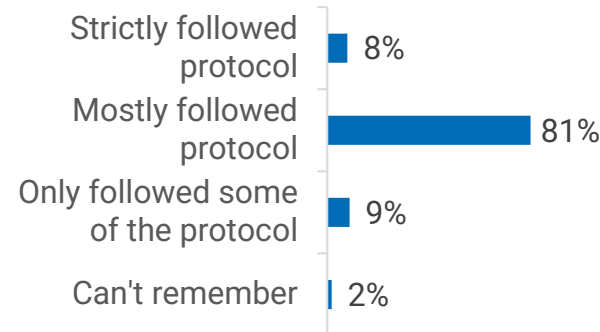
% indicating some/significant influence on decision to participate in trial



Product Under Investigation



Participant Compliance



Perceptions of Trial Experience

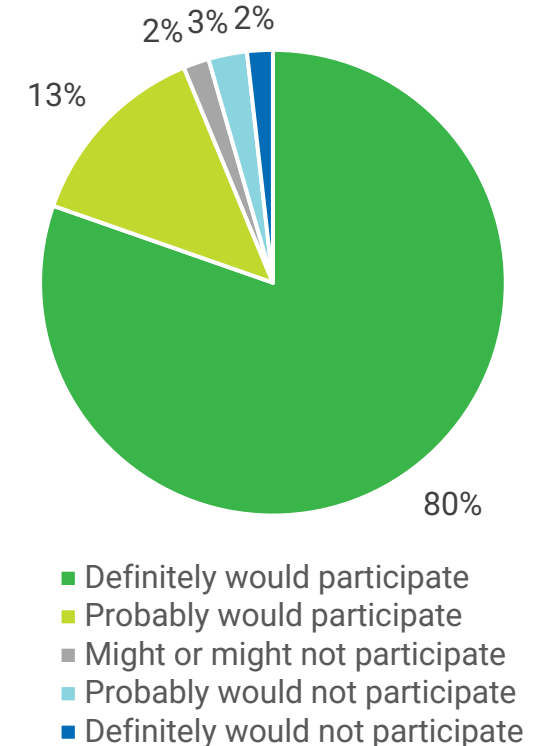


Ratings of Site Experience

% indicating they somewhat/strongly agree

I feel like we/I contributed to the advancement of our field/science because of our participation	90%
I learned something new about the treatment and/or condition being researched	89%
I feel that the time I spent participating in this clinical trial was worthwhile	84%
Participating in this trial allowed me/my site to stay-up-to-date on treatments in our specialty area	80%
We were able to bring new/better treatments to patients as a result of participating in this trial	78%
The study protocol was clear and easy for the site to follow	75%
Participation in this clinical research had a positive impact on our practice's reputation	75%
The CRA/study monitor was accessible and responsive	73%
The amount of time that I spent participating in the trial met my expectations	71%
The company sponsoring this research gave appropriate consideration for the patient perspective	70%
The technology the site was asked to utilize to conduct the study was easy to use	66%
The trial stayed on timeline, and started and finished as planned	56%
My site was compensated fairly and on time for participation in this trial	56%
The contracting process was done in a timely and efficient manner	52%
Budget negotiation was done in a timely and efficient manner	51%
We attracted new patients to the practice as a result of participating in this trial	50%

Likelihood to Participate Again





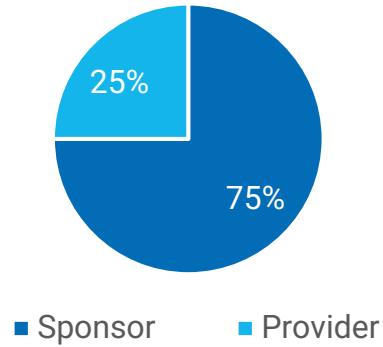
Additional Analysis

Sponsors/Providers

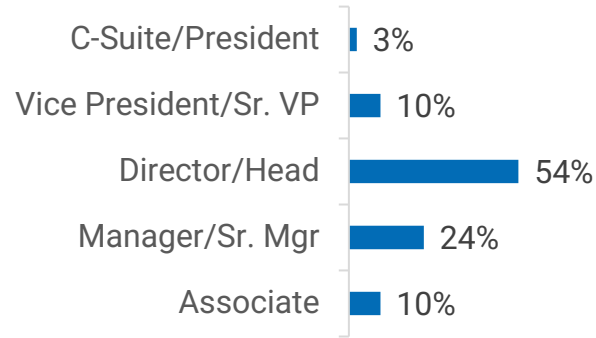
Sample Composition



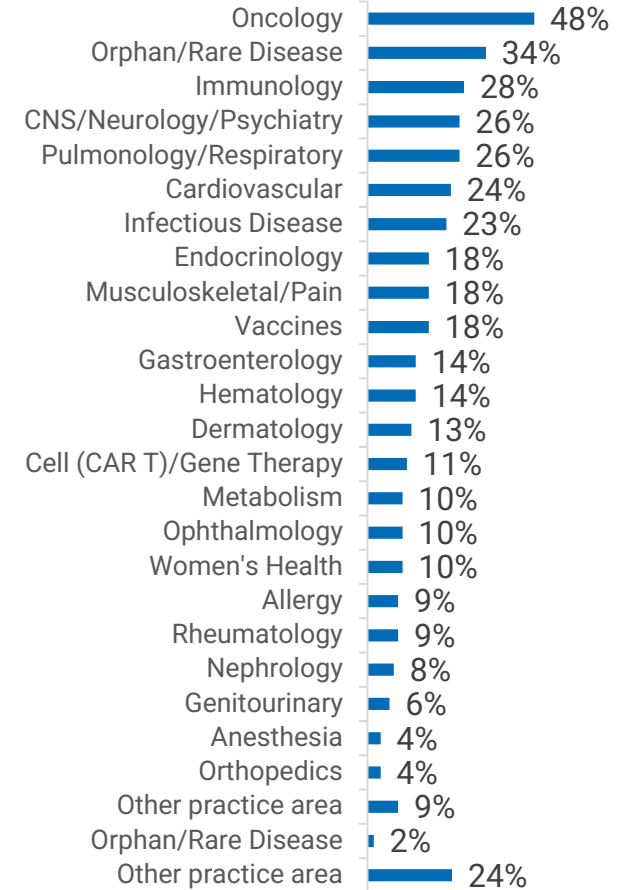
Company Type



Level/Role



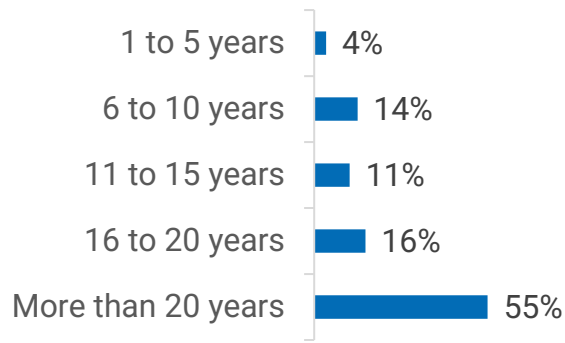
Specialty Area(s)



Function

Clinical Development/Operations	53%
Quality Assurance/Quality Control & Compliance	38%
Medical/Scientific	3%
Alliance Management/Partnering	1%
Business Development	1%
Data Management	1%
Executive Management	1%
Other	3%

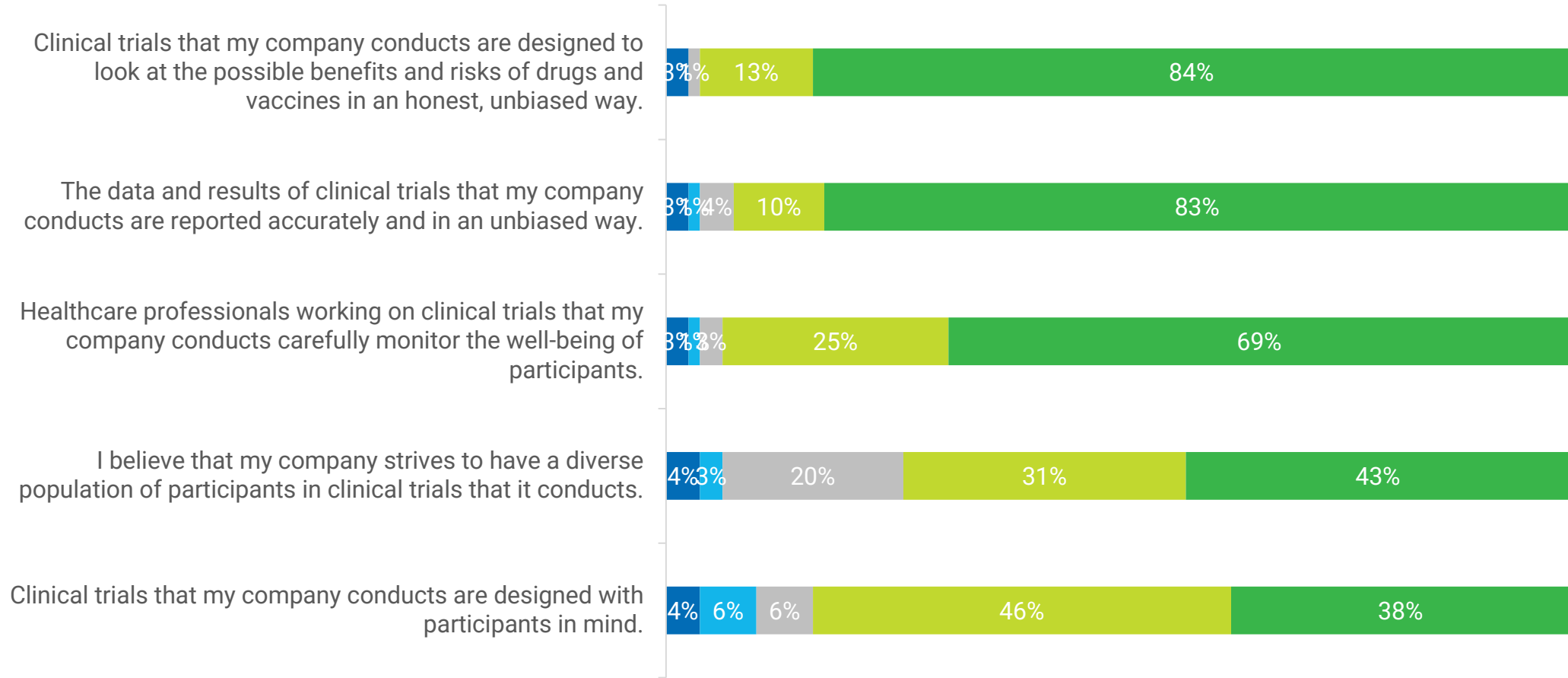
Tenure in Role



Agree/Disagree Statements

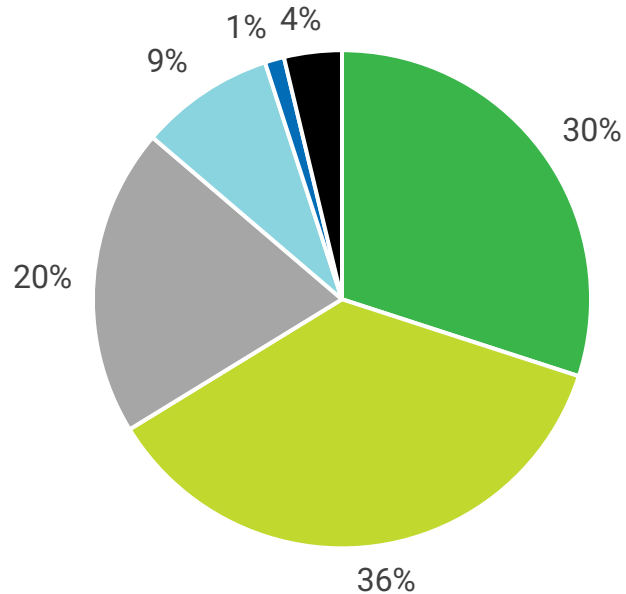


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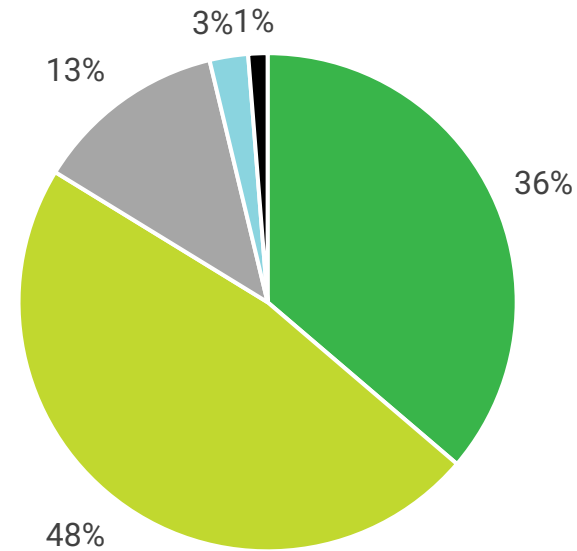
Implementation of DCT Elements in Clinical Trials

Adoption of DCT Elements in Past 2 Years



- Much more utilization of DCT elements than in previous years
- Somewhat more
- About the same
- Somewhat less
- Much less utilization of DCT elements than in previous years
- Don't know/NA

Adoption of DCT Elements 2 Years from Now



- Much more utilization of DCT elements than there is currently
- Somewhat more
- About the same
- Somewhat less
- Much less utilization of DCT elements than there is currently
- Don't know/NA

Perceptions of Clinical Trial Participants

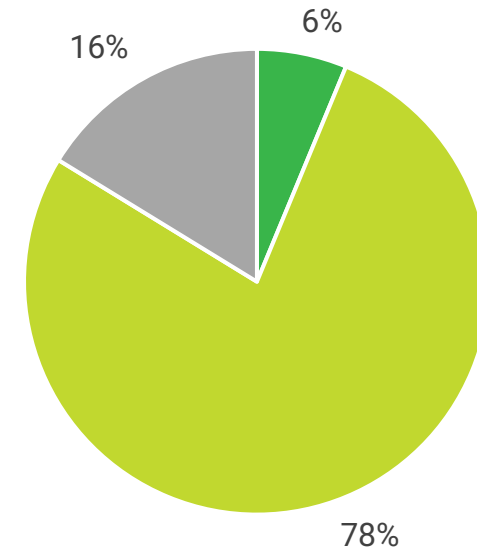


Influence on Decision to Participate in Clinical Trial

% indicating some/significant influence on decision to participate in trial

Hope that the clinical trial treatment would improve their health/medical condition(s)	99%
A doctor/healthcare professional suggests participation	96%
A friend or family member suggests participation	96%
Access to free healthcare	94%
Access to better doctors and hospitals than they would otherwise be able to use	91%
Compensation/payment for participation	91%
More contact with doctors/nurses than they would otherwise get	86%
Opportunity to contribute to science	84%
Curiosity about the product/treatment being researched	76%
Opportunity to learn more about health/medical condition(s)	76%
Ability to participate remotely using devices/technology	74%
Opportunity to take part in a trial that is seeking a diverse population of participants	44%
Curiosity about how clinical trials work	38%

Compliance with Protocol



- Strictly follow all of the instructions with no or little deviation
- Mostly follow all of the instructions
- Only follow some of the instructions

Base: N=80 Sponsor/Provider Sample (who have ever conducted clinical trial)

Q. We understand that there are many reasons why people decide to participate in clinical research trials. Please review the list of possible reasons below and for each, indicate the extent to which you believe these are influential to patients when deciding whether or not to participate in a clinical trial. Q. Based on your opinions and experience in the industry, which of the following best describes the extent to which you believe patients comply with clinical trial protocols?

Perceptions of Clinical Trial Sites

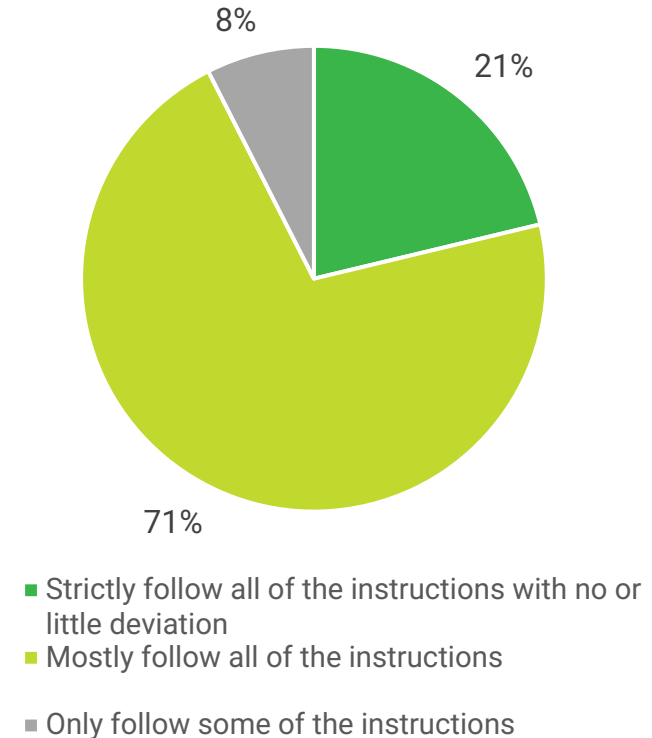


Influence on Decision to Participate in Clinical Trial

% indicating some/significant influence on decision to participate in trial

Ability to bring new/better treatments to patients	99%
Desire to contribute to the advancement of field/science	99%
Curiosity/interest in the new treatment being researched	99%
Desire to stay up-to-date on treatments in specialty area	98%
Build site reputation for having innovative treatment/approach	98%
Compensation for participation	94%
Attract new patients to the practice	76%
Ability to use technology/devices (such as tablets and wearables) to reduce amount of in-person visits/procedures with participants	71%
Opportunity to participate in research that is seeking a diverse patient population	61%

Compliance with Protocol



Base: N=80 Sponsor/Provider Sample (who have ever conducted clinical trial)

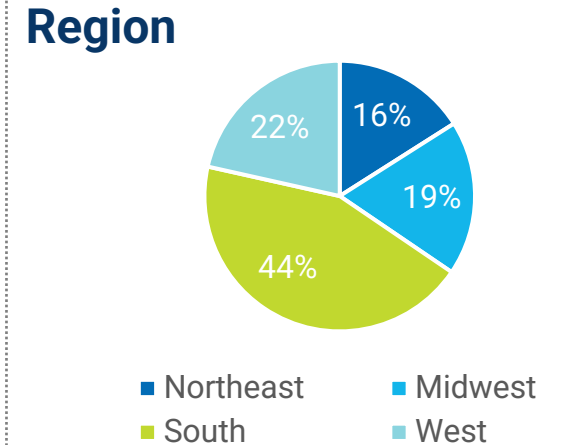
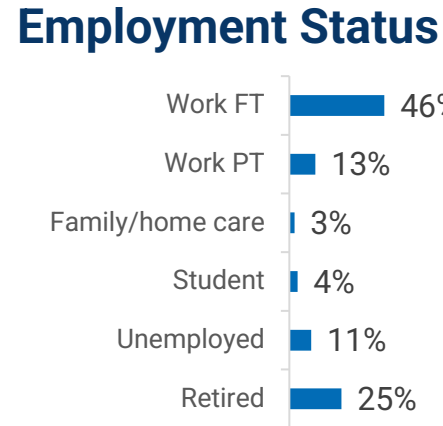
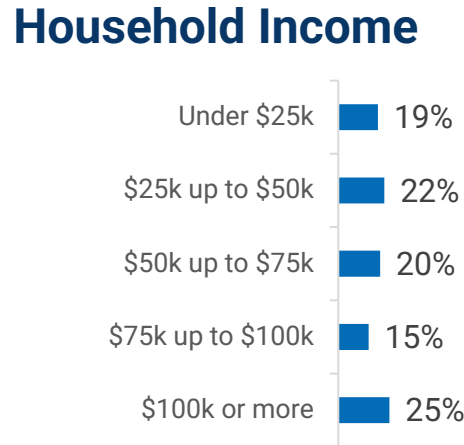
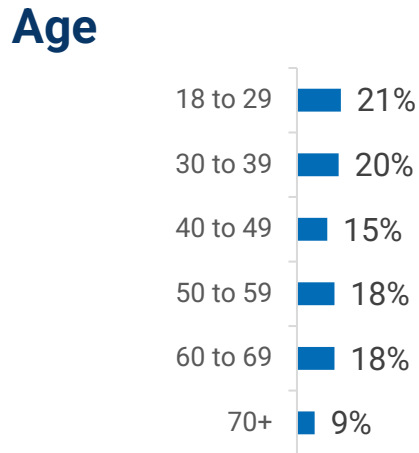
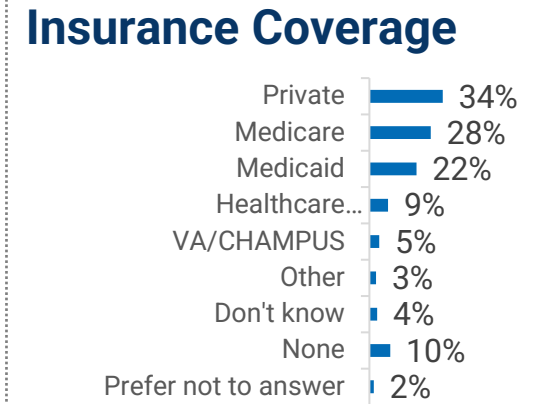
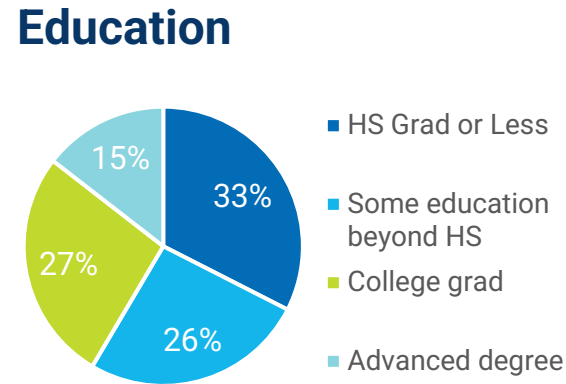
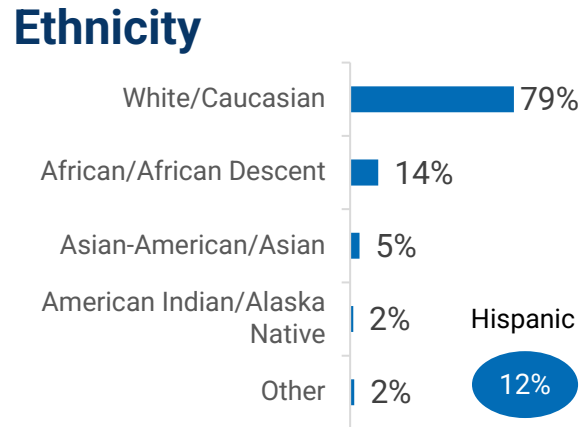
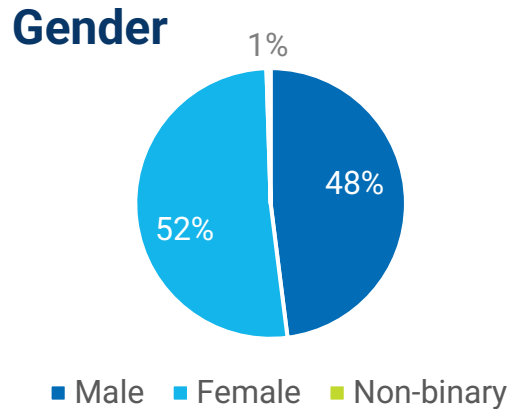
Q. We understand that there are many reasons why sites decide to participate in clinical research trials. Please review the list of possible reasons below and for each, indicate the extent to which you believe each is influential in a site's decision to participate in a clinical trial. Q. Based on your opinions and experience in the industry, which of the following best describes the extent to which you believe investigative sites comply with clinical trial protocols?



Additional Analysis

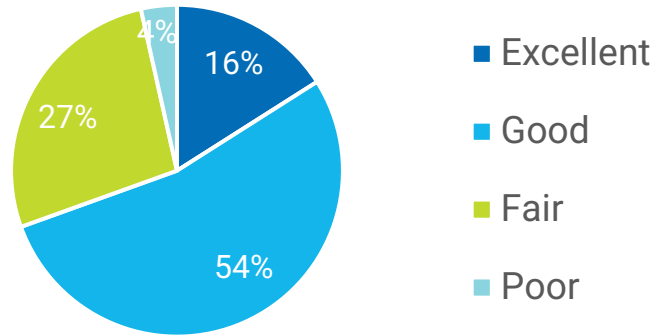
Patients

Sample Composition (National Sample)

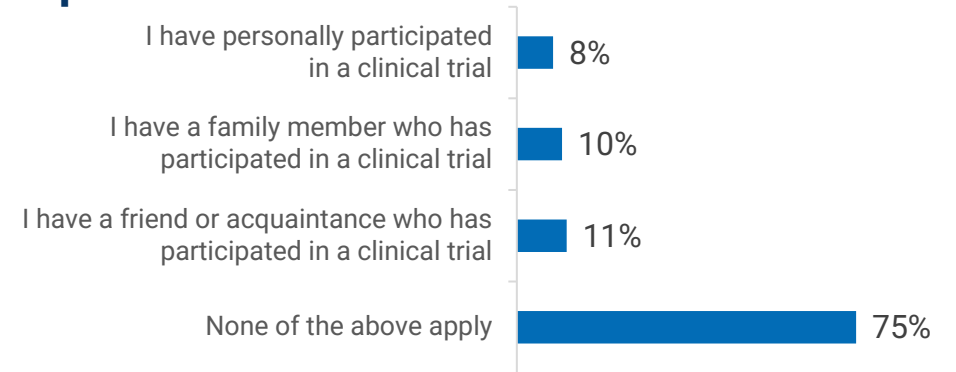


Health Profile (National Sample)

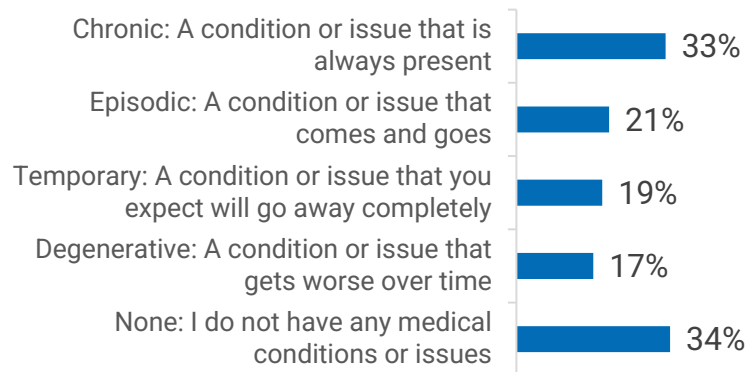
Overall Health



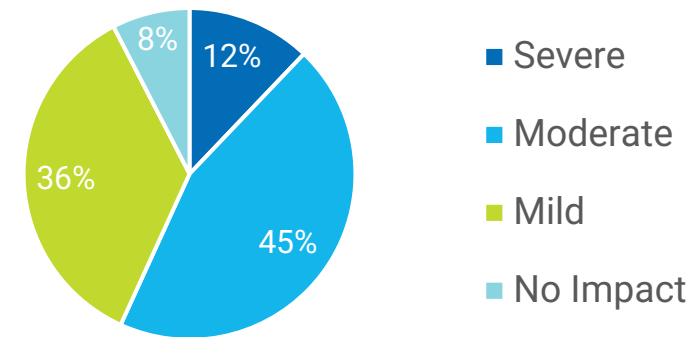
Participation in Clinical Trial



Presence of Medical Conditions



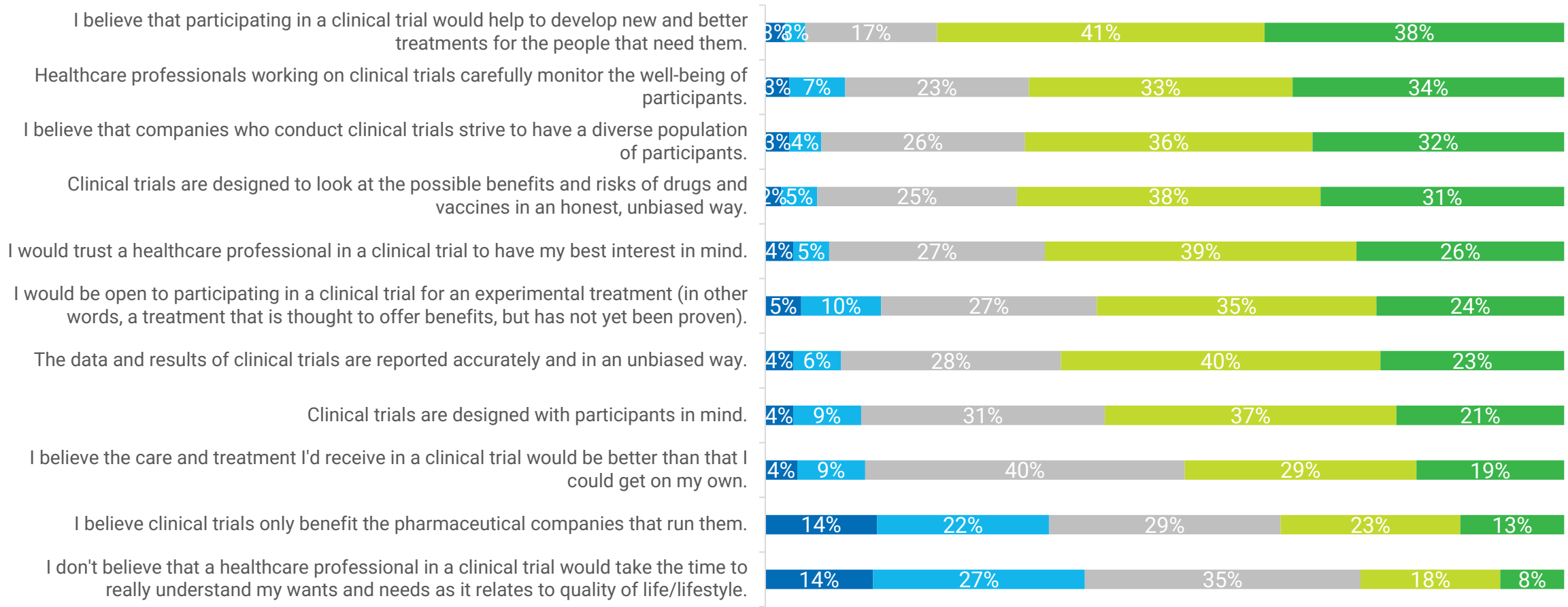
Impact of Conditions on Quality of Life



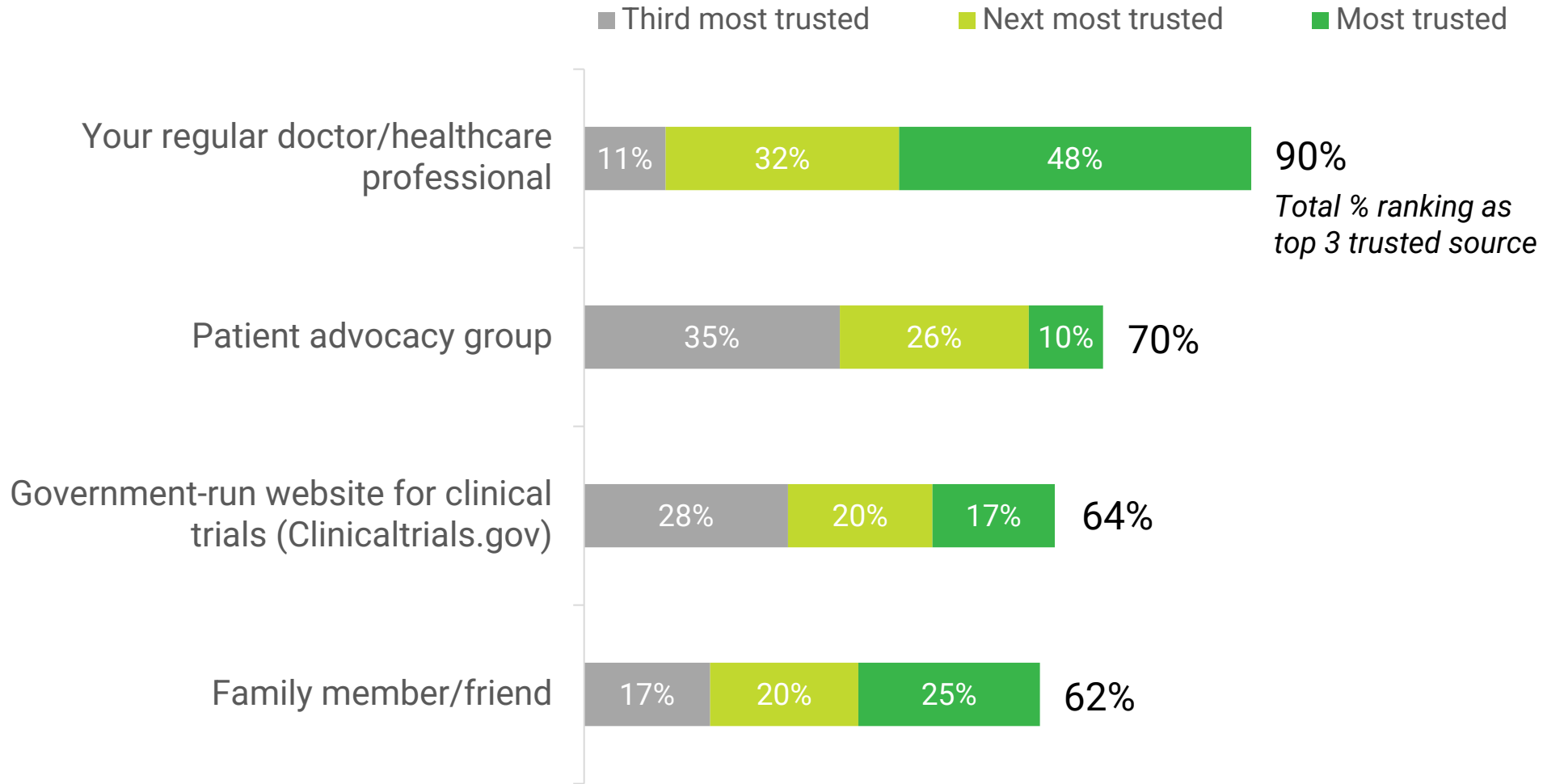
Agree/Disagree Statements (National Sample)



■ Strongly disagree
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 ■ Neither agree nor disagree
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 ■ Strongly agree



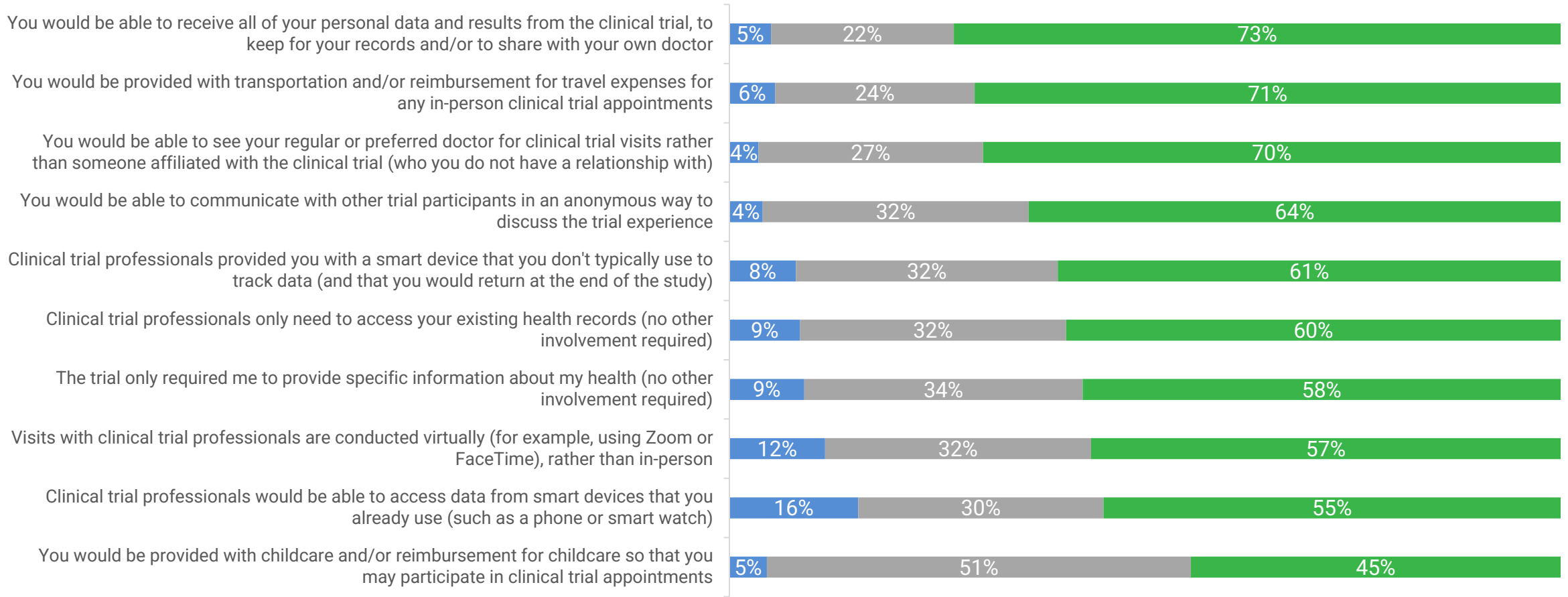
Trusted Sources of Info on Clinical Trials (National Sample)



Impact of Trial “Benefits” on Interest in Participating (National Sample)



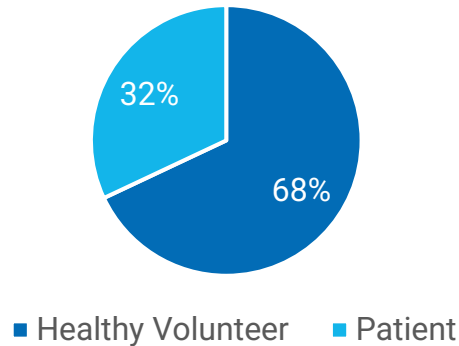
■ Very/somewhat negative impact
 ■ No impact
 ■ Very/somewhat positive impact



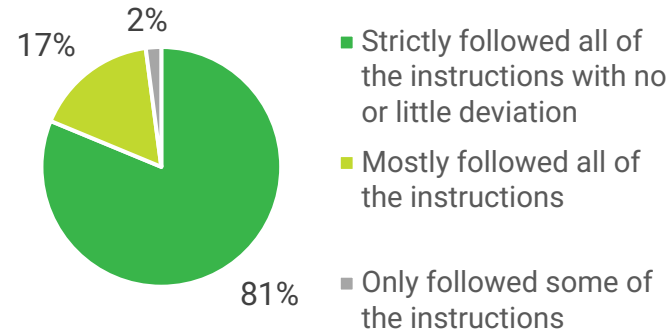
Clinical Trial Experience Among Participants



Participant Status



Compliance with Protocol

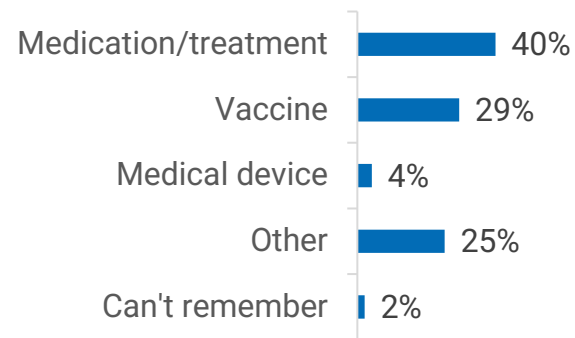


Influence on Decision to Participate in Clinical Trial

% indicating some/significant influence on decision to participate in trial

Opportunity to contribute to science	90%
Curiosity about the product/treatment being researched	83%
Opportunity to learn more about health/medical condition(s)	69%
Hope that the clinical trial treatment would improve my health/medical condition(s)	54%
Compensation/payment for participation	48%
Curiosity about how clinical trials work	42%
Access to free healthcare	33%
Ability to participate remotely using devices/technology	33%
A friend or family member suggested I participate	27%
A doctor/healthcare professional suggested I participate	25%
More contact with doctors/nurses than I would otherwise get	21%
Access to better doctors and hospitals than I would otherwise be able to use	21%

Product Under Investigation



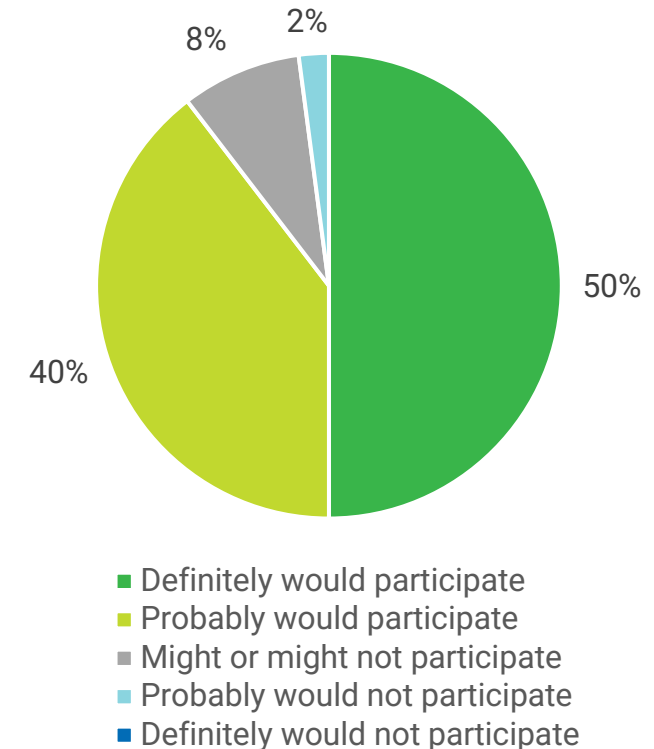
Clinical Trial Experience Among Participants (Continued)

Ratings of Patient Experience

% indicating they somewhat/strongly agree

It was easy to follow the instructions/directions I was given as part of the clinical trial	96%
I feel that the time I spent participating in this clinical trial was worthwhile	85%
I liked the healthcare professionals that I dealt with as part of this clinical trial	80%
The trial stayed on timeline, and started and finished as planned	76%
The tests and procedures I was required to do were consistent with my expectations	72%
The amount of time that I spent participating in the trial met my expectations	72%
I learned something about clinical trials by participating in this research	65%
My compensation was accurate and received in a timely manner	63%
I did not experience any sickness or other feelings of being unwell as a result of my participation in the clinical trial	61%
The technology/devices I was asked to use were user-friendly	48%
I learned something about my health/medical condition(s) by participating in this research	39%
I felt that the healthcare professionals I worked with offered better care and/or more expertise than I would get otherwise	35%
I saw improvement in my health/medical conditions as a result of my participation in the clinical trial	26%
I had more access to healthcare professionals as a result of my participation in this clinical trial	26%

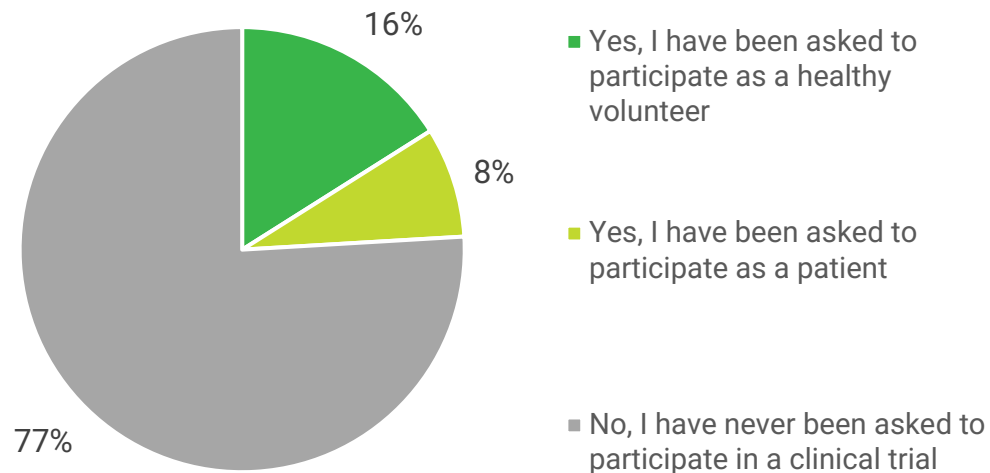
Likelihood to Participate Again



Base: N=46/48 Participants in Clinical Trials

Trial Naïve Respondents

Ever Asked to Participate in Trial



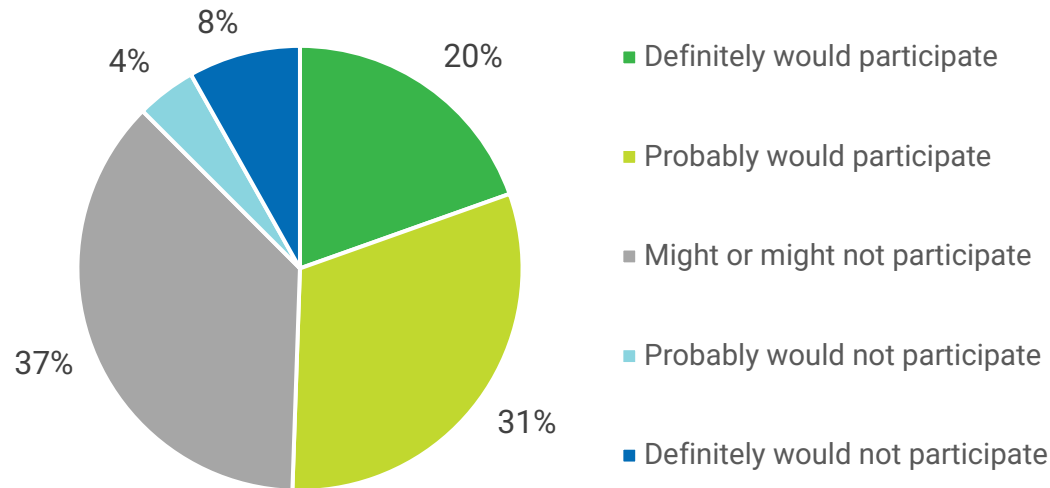
Concerns About Participating in a Clinical Trial

% indicating have some/significant concern

I would feel sick/unwell as a result of participating	86%
Type of tests/procedures required	83%
Number of tests/procedures required	80%
I would not see any improvement in my health/medical condition as a result of participating	73%
Compensation/payment would not be given as expected	72%
Time commitment/time taken out of your life	72%
Information/health data would not be private	70%
I could receive a placebo or other treatment that is not the treatment being researched	69%
I might not like the healthcare professionals I have to deal with as part of the clinical trial	67%
Would be difficult to comply/adhere to instructions	61%
Would be difficult to understand the trial instructions	59%
Technology/devices would be difficult to use	57%
I would feel sick/unwell as a result of participating	86%
Type of tests/procedures required	83%

Trial Naïve Respondents (Continued)

Likelihood to Participate in Clinical Trial in the Future



Influence on Decision to Participate in Clinical Trial

% indicating some/significant influence on decision to participate in trial

Hope that the clinical trial treatment would improve your health/medical condition(s)	89%
Compensation/payment for participation	88%
Opportunity to learn more about health/medical condition(s)	84%
Opportunity to contribute to science	83%
Curiosity about the product/treatment being researched	82%
Access to better doctors and hospitals than you would otherwise be able to use	80%
A doctor/healthcare professional suggested you participate	79%
Ability to participate remotely using devices/technology	79%
Access to free healthcare	76%
Curiosity about how clinical trials work	70%
More contact with doctors/nurses than you would otherwise get	68%
A friend or family member suggested you participate	66%