CISCRP

PERCEPTIONS AND INSIGHTS STUDY 2021

PARTICIPATION EXPERIENCE

INTRODUCTION

The 2021 Perceptions & Insights Study collected information on the experiences of over 5,500 clinical research participants - more than any prior study - shedding light on the most burdensome aspects of participation and ways to best overcome these challenges.

In this report, CISCRP provides a summary of participation experiences at critical time points - before, during and after - as well as the impact of the COVID-19 pandemic on participation. Learnings can help guide best practices for future clinical research studies.

HIGHLIGHTS

- Compared to 2019, the proportion who learned about clinical study from their doctor declined while social media rose.
- During participation, more reported disruption to daily routines compared to previous years, citing length of visits, travel, and diagnostic tests as top burdens.
- Increased use of technology and other convenience-enhancing initiatives - smart phone apps, text messaging, and video conferencing with study doctors were cited as most helpful.
- Overall, more frequent communication was reported, both during and after participation.
- Among those enrolled during the pandemic, top reported changes were virtual visits and the use of telemedicine – with a strong desire to continue both post-pandemic.

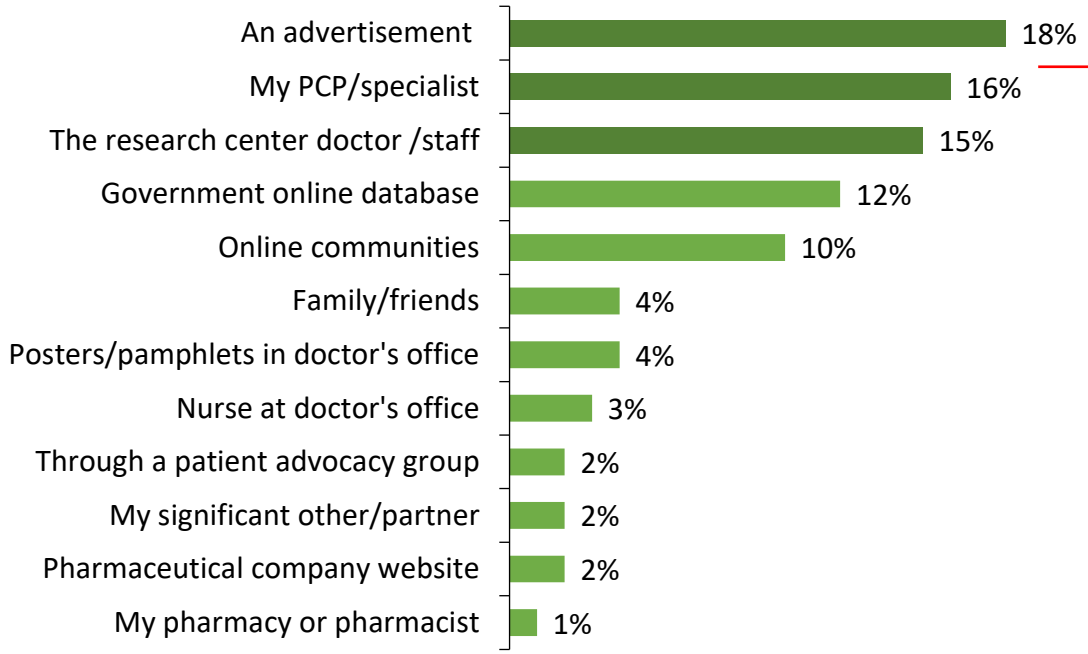
RESEARCH SERVICES

LEARNING ABOUT CLINICAL RESEARCH STUDIES

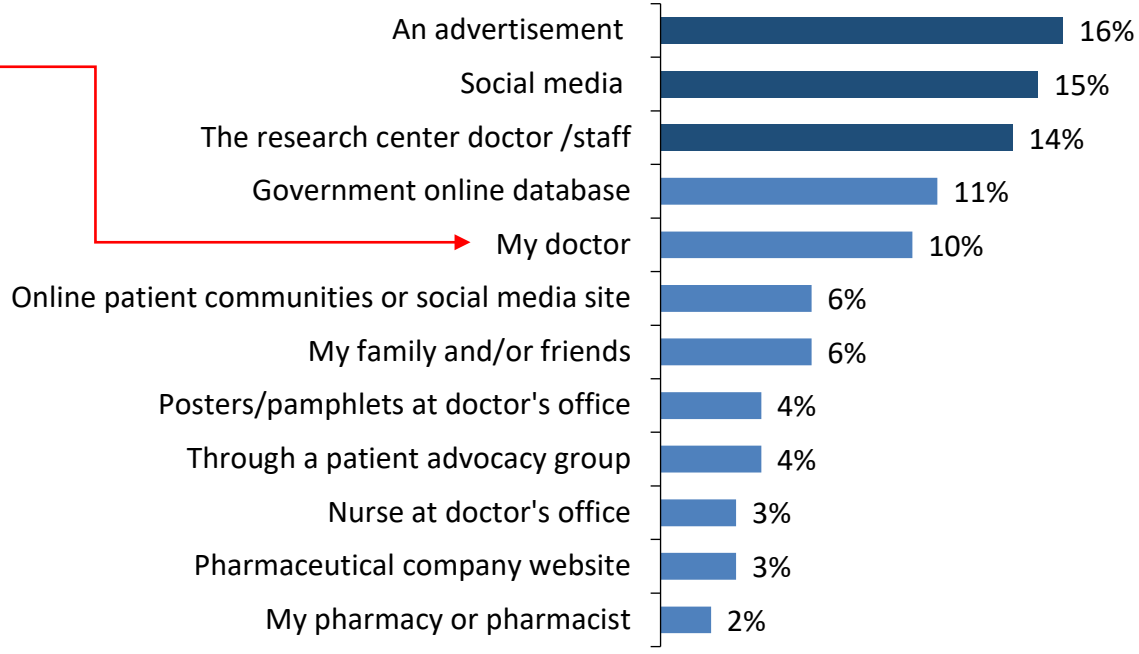
Advertisements (e.g., on the TV, radio, newspaper, public transportation) remain the primary source where clinical research participants learned of the study opportunity, followed closely by social media and the research center staff.

- Notably, a rise in engagement via social media (15%) is present, whereas a decline was displayed in learning from their doctor (16% in 2019 to 10% in 2021).

Where did you learn about the clinical research study?



Sample Size = 3,654; Base: Those who have participated in clinical research, 2019



Sample Size = 5,505; Base: Those who have participated in clinical research, 2021

South American respondents were more likely to hear about a clinical research study through social media (24%) than respondents in Europe (12%).

As a general trend, White respondents were more likely to learn of a clinical research study from their doctor (12%) than Black (6%), Asian (6%), or any other races (6%).

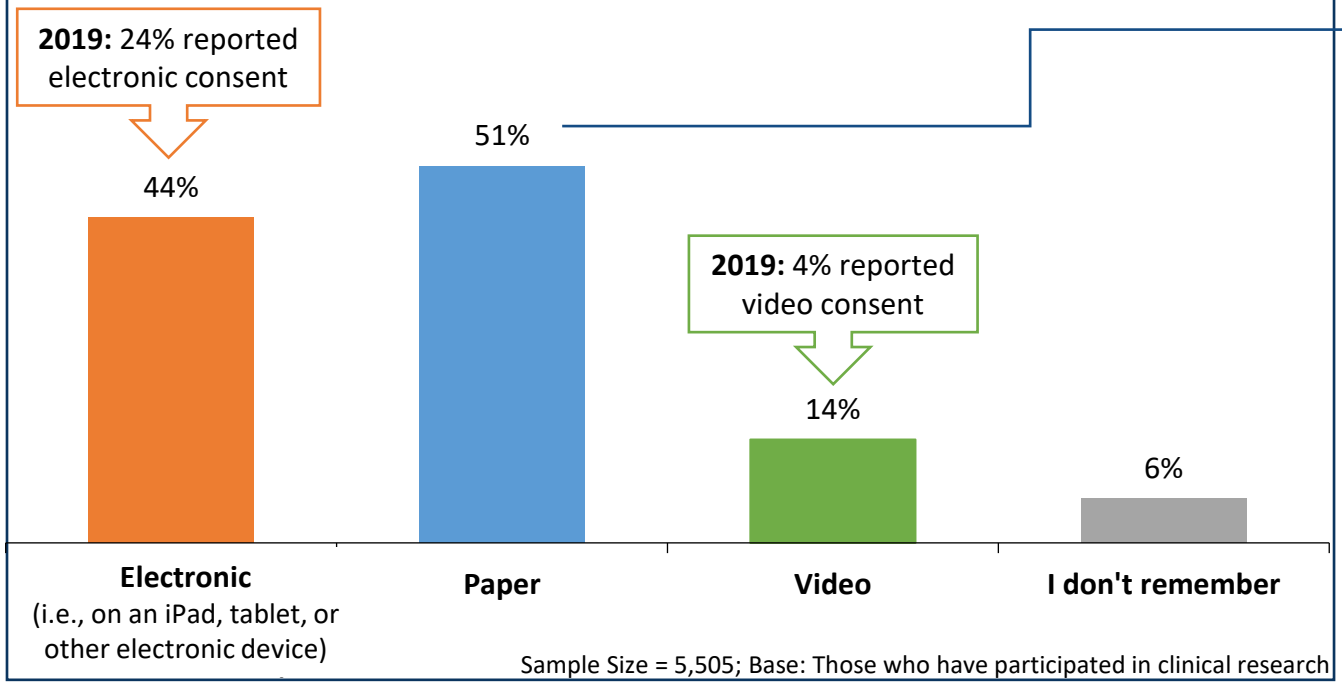
Non-Hispanic respondents were more likely to learn about the clinical research study from the research center doctor/staff (16%) than Hispanic respondents (11%).

INFORMED CONSENT FORMATS

Compared to 2019, there is an increase in the use of electronic and video informed consent. For those who provided consent on paper, 44% report the document being more than 10 pages – an increase since 2019.

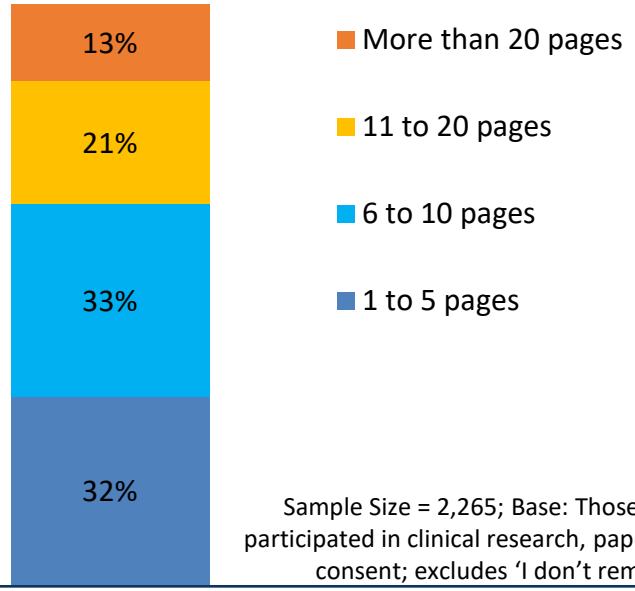
- Individuals identifying as Black and Hispanic were significantly more likely to receive the informed consent form electronically or via video compared to their White and non-Hispanic counterparts.

In what format did you receive the informed consent form for your most recent study? *(Select all that apply)*



Sample Size = 5,505; Base: Those who have participated in clinical research

About how many pages was the informed consent form for your most recent study? *(Paper Only)*



Sample Size = 2,265; Base: Those who have participated in clinical research, paper information consent; excludes 'I don't remember'

European respondents were significantly more likely to receive a paper informed consent (72%) compared to all other regions.

Hispanic respondents more commonly received their informed consent electronically (59%) or via video (25%) than non-Hispanic respondents (35%, 7% respectively).

Younger respondents (18-34 years) were more likely to report receiving an informed consent of 6 to 10 pages (46%), compared to all other ages.

2019

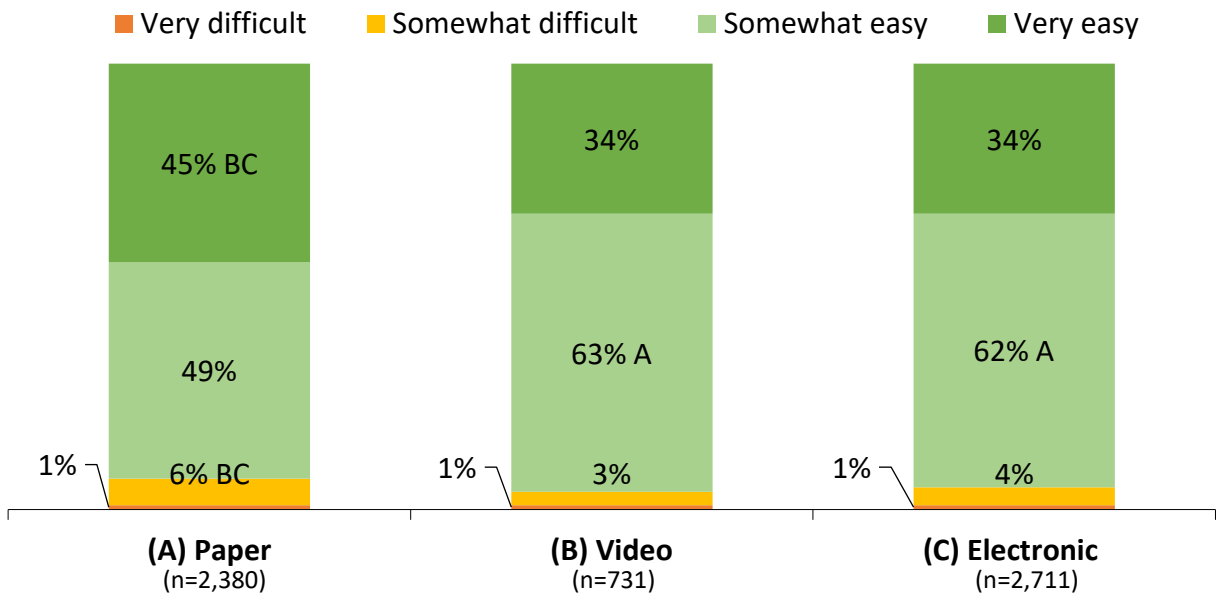
✓ In 2019, 29% of paper consents were more than 10 pages.

UNDERSTANDING THE INFORMED CONSENT FORM

The Informed Consent Form is generally self-reported to be easy to understand, with nearly half of respondents reviewing with the study coordinator and one third with the Principal Investigator (PI).

- Notably, respondents who received electronic consent forms were more likely to report they did not review with anyone, compared to those who completed paper or video consent.

In general, how easy or difficult was it to understand your informed consent form?



Sample Size = 5,115; Base: Those who have participated in clinical research, excludes 'I don't remember'

Letters indicate statistical significance at 95%

What member of the study team reviewed the informed consent form with you?

Sample Size = 5,171

Base: Those who have participated in clinical research, excludes 'I don't remember'

North American respondents were more likely to report it was 'Very Easy' to understand their Informed Consent Form compared to those in Europe (33%) and Asia-Pacific (32%).

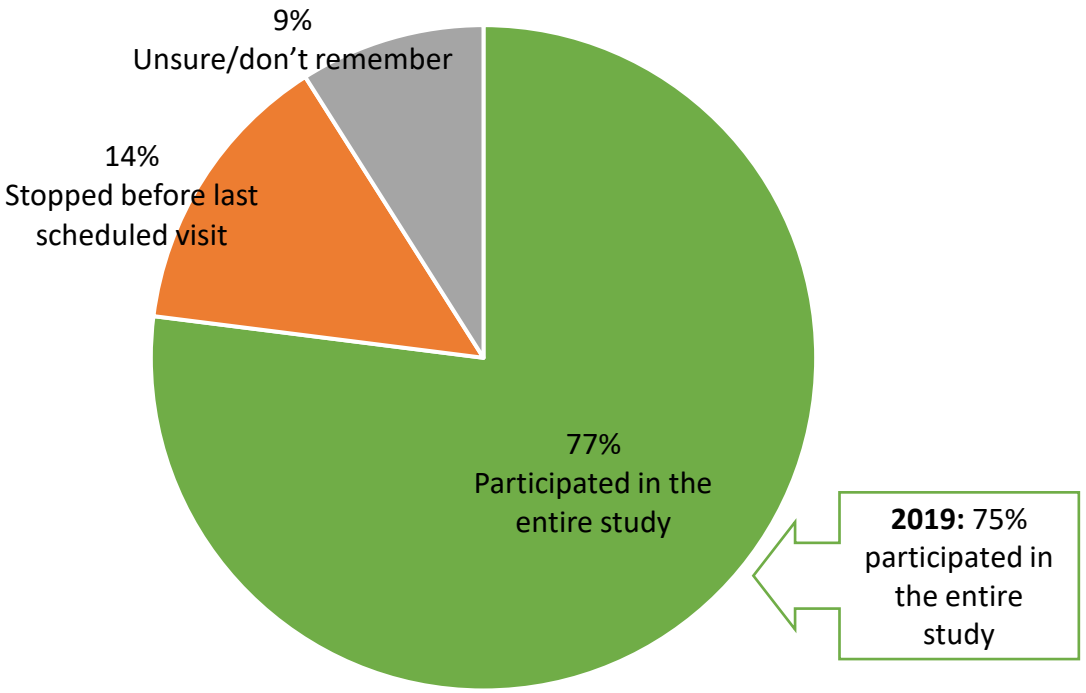
Female respondents (42%) were more likely than men (36%) to report it was 'Very Easy' to understand the Informed Consent Form, regardless of format.

Generally, respondents who reviewed the form with a principal investigator/study doctor were significantly more likely to report 'Very Easy' to understand.

European respondents were more likely to have the principal investigator/study doctor review the Informed Consent Form with them (42%).

STOPPING PARTICIPATION

Did you participate in the entire clinical research study or did you stop before your last scheduled study visit?



Sample Size = 5,505; Base: Those who have participated in clinical research

Of those with clinical research experience, the majority of respondents cited participating in the entire study – an increase from 2019.

- Notably, White and Black respondents participated in the entire clinical study more frequently (82% and 78%, respectively) than Asian respondents (66%).

Of those who stopped participation, concerns were raised regarding communication, travel, and overall health/safety.

- Hispanic subgroups were more likely to stop due to the location of the study center (23%) than non-Hispanic subgroups (13%).

Why did you stop your participation in the clinical research study?

(Top Mentions)

- **There was poor communication with the study center (18%)**
- **The location of the study center (18%)**
- **The side effects of the study drug (16%)**
- **The procedures during my study visits were too cumbersome (16%)**

North and South American respondents were less likely to report being asked to participate in a clinical research study (52% and 41%) than those from Europe (62%), Asia-Pacific (62%), and Africa (63%).

2019

✓ In 2019, 'time commitment was too much' was a top mention (11%).

PARTICIPATION BURDENS

Consistent with 2019 findings, travel to the study clinic remains a top burden of participation, with a quarter of respondents traveling over an hour one-way for in-person clinic visits. As a result, preference for virtual visits and reduced travel time are indicated.

- Required tests and assessments (e.g., diagnostic, lab work, questionnaires) also contributed to the experienced burden for study participants.

How burdensome was each of the following? % 'Somewhat' or 'Very' Burdensome	**2019** (n=3,654)	**2021** (n=5,505)
Traveling to the study clinic	29%	44%
Undergoing diagnostic tests (e.g., x-rays, MRIs)	21%	42%
The length of the study visits	21%	40%
Lab work (e.g., blood tests, urine)	17%	38%
Taking the clinical study medicine	15%	37%
Completing health questionnaires	18%	32%

Sample Size = 5,505; Base: Those who have participated in clinical research

As a general trend, North American respondents were significantly more likely to cite all indicators were more burdensome than respondents from Europe.

How long did it take you to travel to the clinic (one-way)?*

- ✓ 15 minutes or less: 10%
- ✓ 15 to 30 minutes: 29%
- ✓ 30 minutes to 1 hour: 38%
- ✓ 1 to 2 hours: 17%
- ✓ 2 to 3 hours: 5%
- ✓ More than 3 hours: 3%

**Base: Excludes not having to travel and don't remember*

Providing alternative options to in-person clinic visits or site clinics located closer to home were top recommendations to help reduce disruption and minimize burden.

What could have made your participation in the clinical research study less disruptive? *(top mentions)*

- ✓ Virtual study visits (38%)
- ✓ Not having to travel as far to get to my study visits (32%)
- ✓ Having a study nurse or doctor come to my home for some of my study visits (31%)
- ✓ Receiving a pre-paid debit card for study-related expenses (27%)
- ✓ Having help/assistance traveling to and from the study (24%)

TECHNOLOGY USE

An increased use of technology is present compared to 2019. Notably, participants report text messaging (49%), video conferences with the study doctor (49%) and smart phone apps (47%) as most helpful to participation.

- Compared to 2019, fewer people reported that no technology was used during their participation (27% in 2019 to 13% in 2021).

Which of the following were used during your clinical research study?	2019 % Mentioning	2021 % Mentioning	2021 % Indicating 'Very' Helpful
Surveys to collect information on my clinical trial experience	29%	30%	44%
Smartphone apps for study data collection	15%	24%	47%
Text messaging	21%	22%	49%
Informed consent on an electronic tablet	15%	21%	38%
Supportive services	11%	19%	42%
Wearable devices	13%	19%	40%
Some or all of my study visits were conducted at my regular doctor's office rather than the study doctor's office	n/a	18%	42%
Some or all of my study visits were conducted at my home or my office	8%	16%	39%
Social media	5%	16%	35%
Video conference with the study doctor	4%	13%	49%
Childcare or childcare reimbursement	2%	6%	35%
None of the above	27%	13%	-

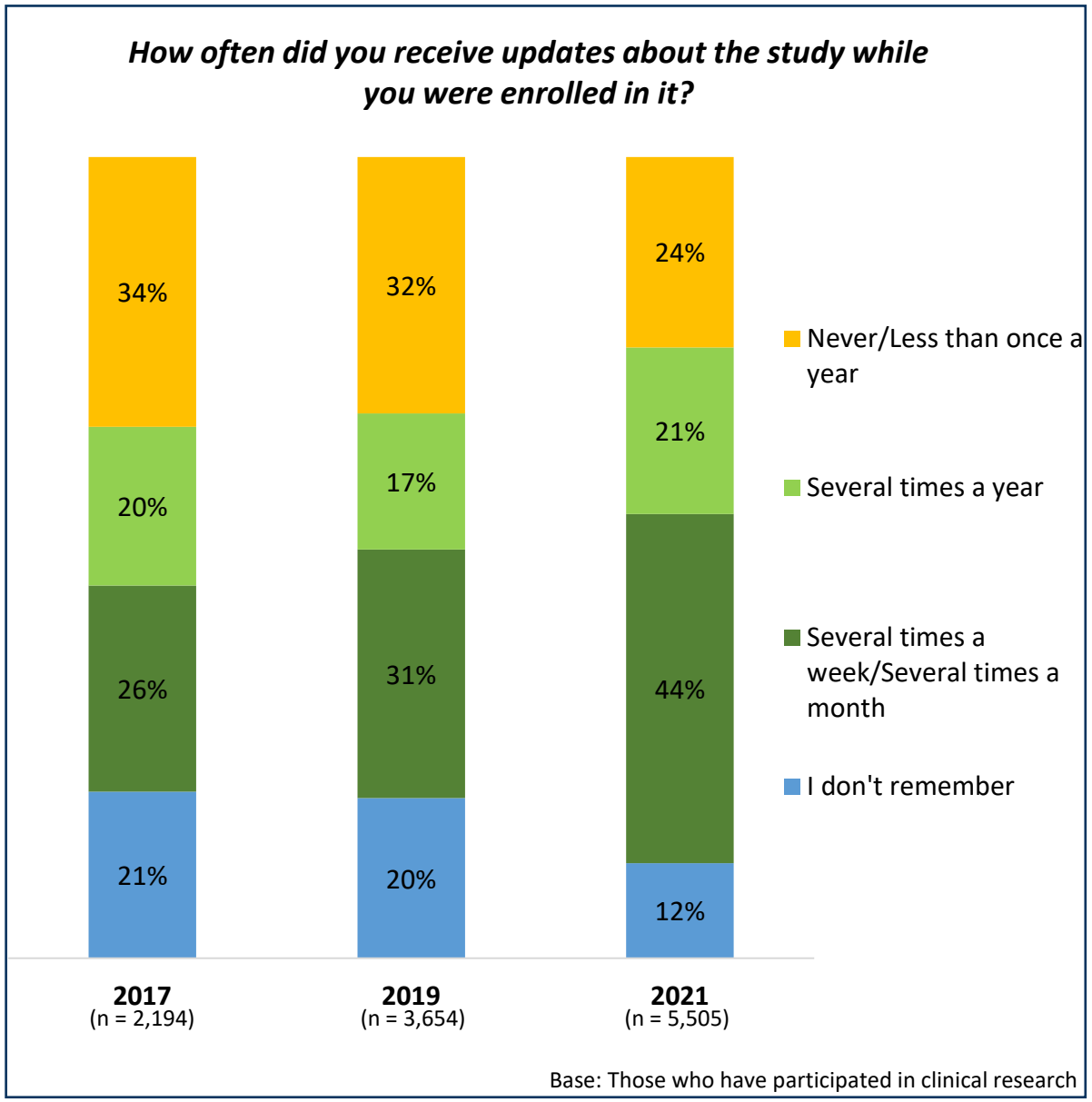
Sample Size = 5,505; Base: Those who have participated in clinical research

Respondents residing in suburban areas were more likely to think that text messaging in a clinical research study was 'Very Helpful' (62%) than those in rural (40%) or urban areas (44%).

Respondents with a self-reported medical condition were more likely to think that having some or all of their study visits conducted at their home or office was 'Very Helpful' (57%) than those without a self-reported medical condition (33%).

No significant differences were found by region for engagement via text messaging. Those from North America, however, were more likely to use smartphone apps (28%) and video conference (15%) than those from Europe (14%, 6% respectively).

PARTICIPATION UPDATES WHILE ENROLLED



More respondents reported receiving updates several times a year/month (44%) compared to previous years, which may be attributed to the COVID-19 pandemic.

- Those in a traditional study (22%) were significantly more likely to report 'Never' receiving updates compared to those in remote/virtual (5%) and hybrid studies (10%).
- As a general trend, those who were in a clinical study when the COVID-19 pandemic began received updates more frequently than those who were not.

COMPENSATION

Of those who participated in a clinical research study, nearly all received some sort of compensation (85%), whether it was for their time, reimbursement of expenses, or being allowed to keep the technology provided.

- For individuals who reported some of the costs were not covered, transportation (e.g., parking, gas, tolls), accommodation and food were top mentions.

Did you experience any of the following as part of the clinical research study? *(top 3 mentions)*

I received compensation for my time (50%)

I was allowed to keep the mobile device or other technology that was provided as part of the study after my participation ended (28%)

I was reimbursed for my out-of-pocket expenses through cash or check (26%)

POST-PARTICIPATION COMMUNICATION

A greater number of respondents indicate receiving a report or update on the results once their study finished (43%) compared to previous years (32%, 2019; 30%, 2017).

- Hispanic respondents were more likely to receive updates (57%) than those identifying as non-Hispanic (35%).
- White respondents were less likely to receive updates (39%) than Black (51%) respondents.

A summary of the study results, individual study results and information about upcoming research studies are top mentions among information provided. Participants find information about their individual study results to be most helpful, closely followed by whether they received the study drug or placebo.

- As a general trend, respondents in later phase clinical studies were more likely to receive information on whether they received the study drug or placebo – 47% in Phase IV compared to 22% in Phase I.
- White and non-Hispanic respondents mentioned higher instances of receiving a summary of the study results (50%, 50%) than those identifying as Black (35%), Asian (31%), or Hispanic (34%).

What information did you receive?	% Mentioning	% Indicating 'Very' Helpful
A summary of the study results	43%	45%
My individual study results (i.e., procedures and test results)	42%	51%
Information about upcoming clinical research studies	33%	45%
Whether I received the study drug or placebo	28%	49%
Drug approval status by the regulatory agency in your country	28%	45%
The brand name for the study drug	27%	40%
Information about scientific publications	21%	37%

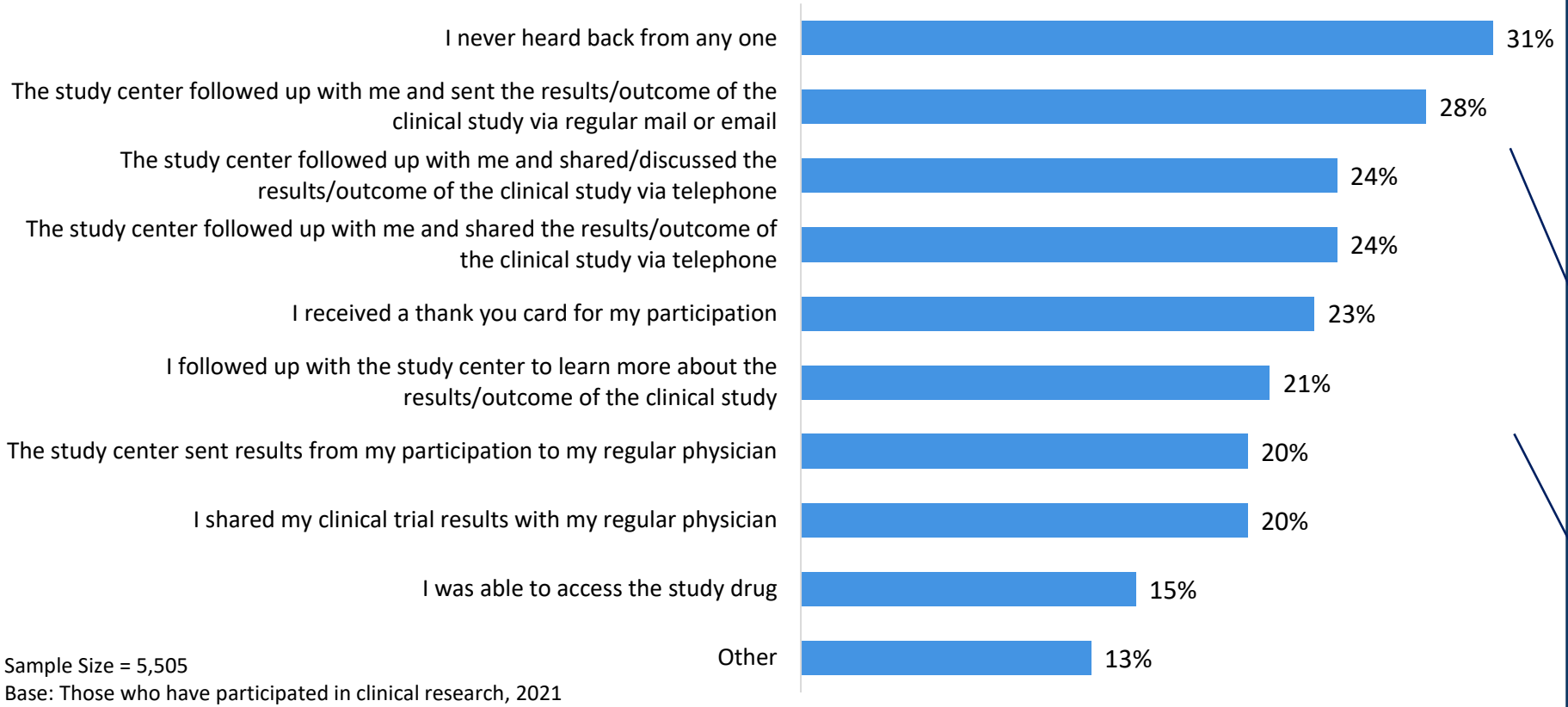
Individuals from Europe were more likely to receive a summary of the study results (50%) than individuals from South America (26%) or Africa (19%).

POST-PARTICIPATION COMMUNICATION (cont'd)

There was a noted increase in communication following participation compared to 2019. However not hearing back from anyone was still a common theme among a large proportion of participants.

- Hispanic respondents were more likely to follow up with the study center to learn more (32%), have the study center follow up with them via regular mail or email (34%), and/or discuss the results via telephone (35%) compared to those identifying as non-Hispanic (14%, 24%, 18%).

Which of the following happened after you completed your participation in the clinical research study?



Sample Size = 5,505
Base: Those who have participated in clinical research, 2021

✓ The number of respondents who never heard back decreased from 2019 (39%), as centers following up by telephone (16%) and individuals following up with the study center (13%) increased from 2019.

Female respondents were more likely to report they never heard back from anyone (35%) compared to males (29%).

White respondents were less likely to follow up with the study center to learn more about the clinical study (17%) than Black (27%), Asian (24%), or respondents identifying as All Other Races (31%).

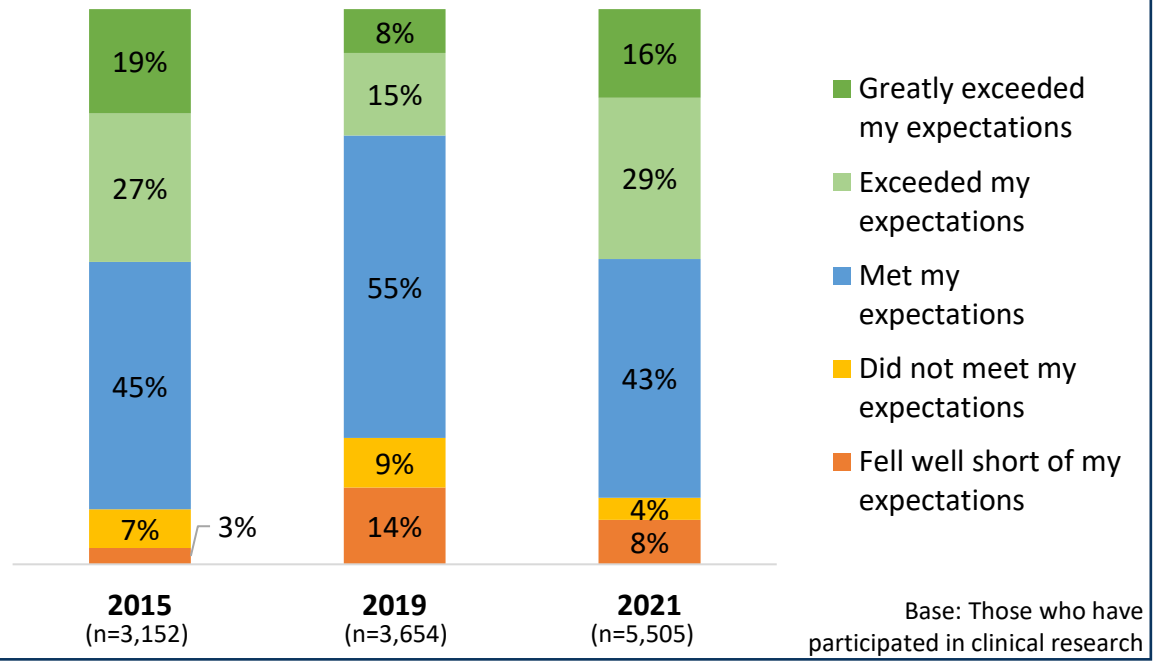
Those from Europe were more likely to never hear back from anyone (41%) than those from North America (30%), Asia-Pacific (24%), and Africa (24%).

OVERALL SATISFACTION

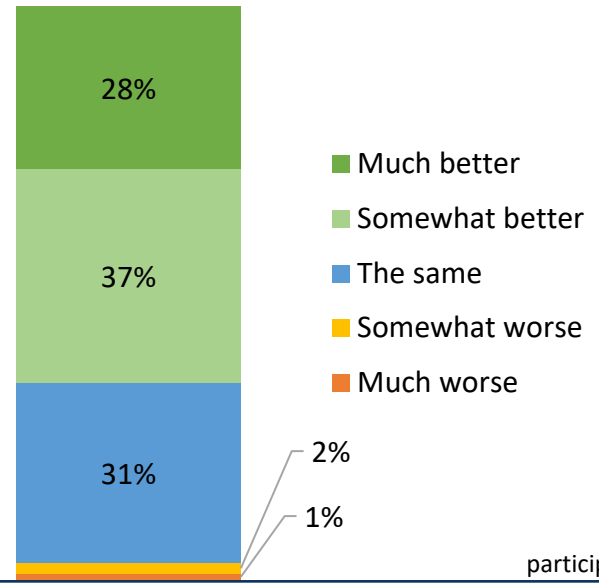
Overall satisfaction with participation experiences improved from years past, with the majority having their expectations met or exceeded. Satisfaction may be attributed to the care and attention received while enrolled.

- Hispanic respondents were significantly more likely to report participation 'Exceeded' or 'Greatly Exceeded' their expectations (58%), compared to non-Hispanic respondents (38%), citing the care and attention received was 'Much' or 'Somewhat' better (84% and 55%, respectively).
- As a general trend, younger respondents were more likely to cite higher levels of satisfaction.

How well did the clinical research study meet your overall expectations?



How would you rate the care and attention you received in managing your condition in this clinical research study when compared to the standard care you would have otherwise received?



European respondents were more likely to cite participation 'Met my expectations' (52%) and the care received was 'The same' (40%) than those from North America (42%, 31%), Asia-Pacific (41%, 28%), and Africa (34%, 12%).

2019

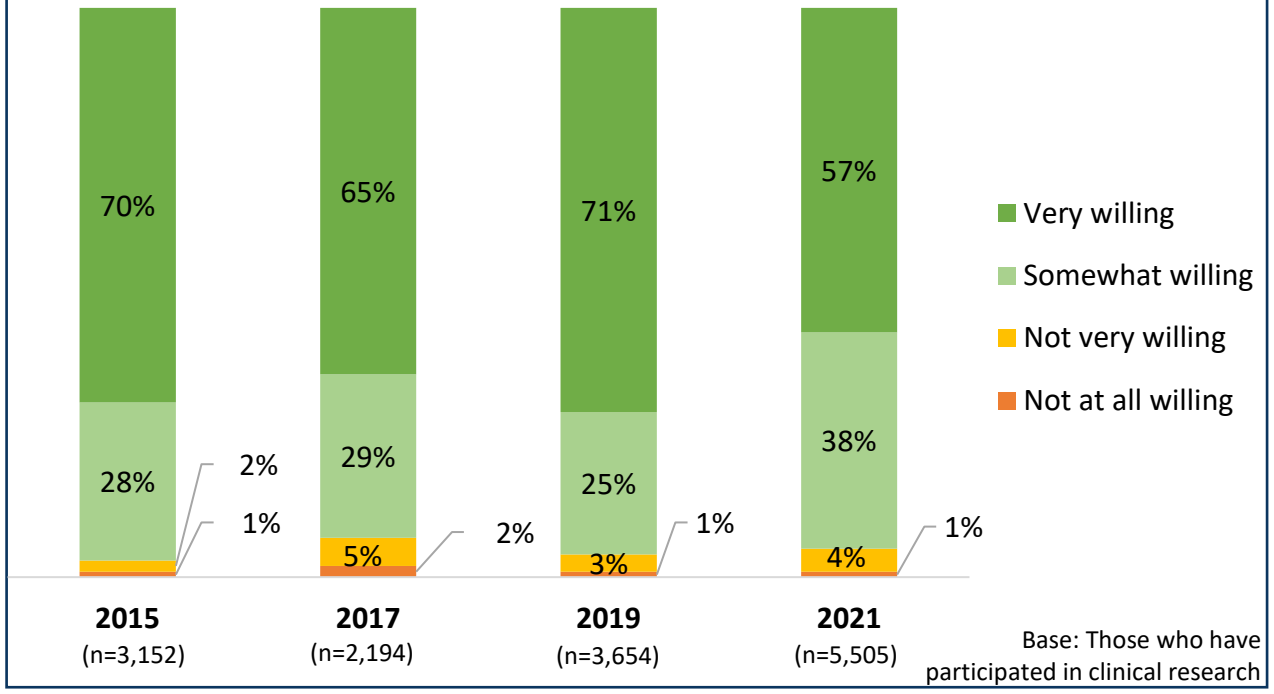
✓ In 2019, 45% reported 'Much' or 'Somewhat' better care, compared to 65% in 2021.

FUTURE PARTICIPATION AND RECOMMENDATIONS

The majority of respondents (95%) are still generally willing to participate again. However, a lower proportion of those are 'Very Willing' when compared to prior years.

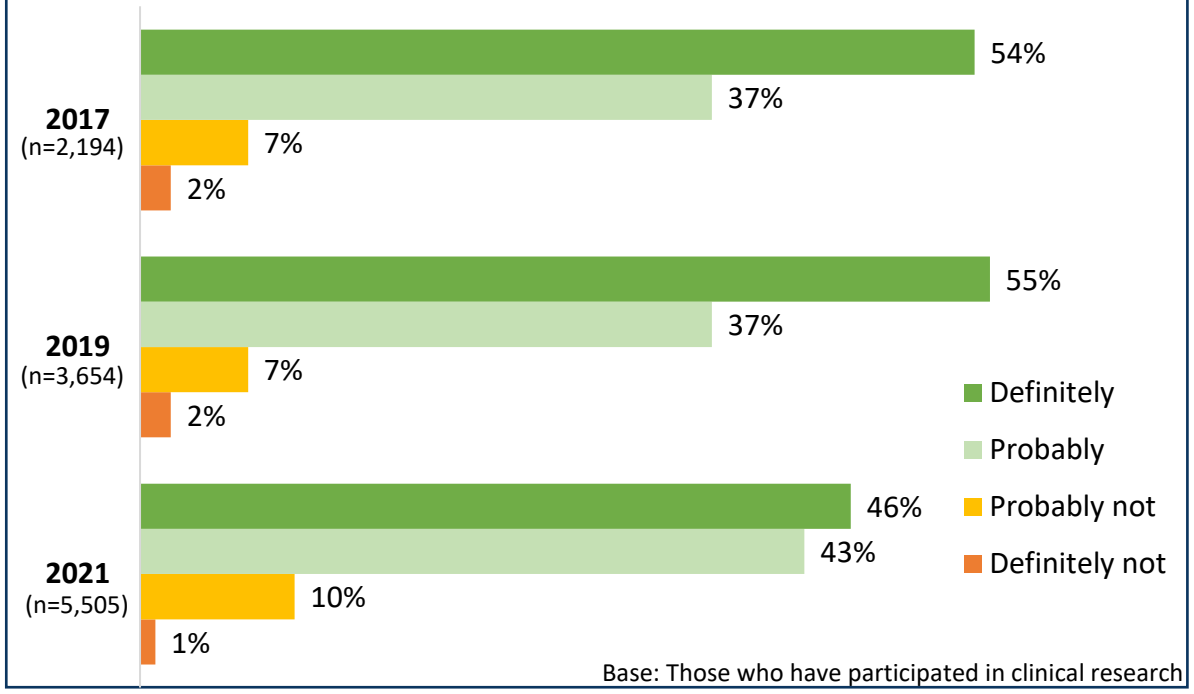
- No significant difference in willingness to participate in the future was found between those enrolled in a clinical research study during the start of the COVID-19 pandemic and those who were not.
- However, those enrolled in a remote study were less likely to report they would 'Definitely' recommend participation (30%) compared to those in a traditional (55%) or hybrid (45%) study.

How willing would you be to participate in another clinical research study in the future?



Base: Those who have participated in clinical research

Would you recommend participating in a clinical research study to your family and friends, if the trial was appropriate for them?



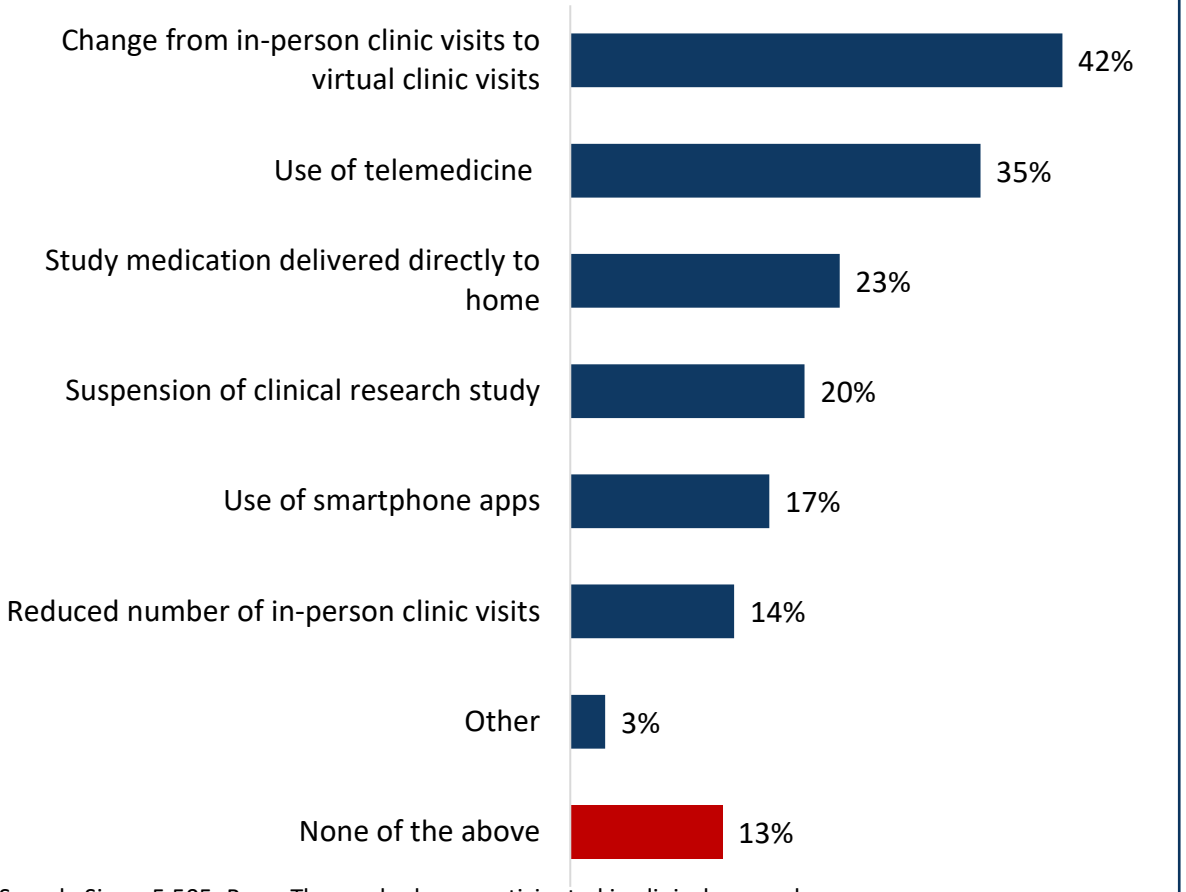
Base: Those who have participated in clinical research

Respondents who participated in a traditional clinical research study were more likely to report 'Very Willing' to participate in another study (67%) as compared to hybrid (54%) or remote (39%) clinical research study participants.

White and Black respondents were more likely to 'Definitely' recommend participation (51% and 45%, respectively) than Asian respondents and those identifying as All Other Races (32% and 34%, respectively).

IMPACT OF COVID-19 PANDEMIC ON PARTICIPATION

What types of changes, if any, did you experience in your clinical research study because of the COVID-19 pandemic?



Sample Size = 5,505; Base: Those who have participated in clinical research

Respondents in North America were more likely to report changing to use of telemedicine because of the COVID-19 pandemic (42%) than respondents in South America (11%), Europe (17%), and Africa (22%).

Over one third (35%) of respondents reported being enrolled in a clinical research study when the COVID-19 pandemic began in February 2020. Top reported changes as a result were shifts from in-person to virtual visits and the use of telemedicine.

- As a general trend, respondents who participated in a clinical research study with a more severe medical condition were less likely to report switching to the use of telemedicine.

Post-pandemic, half of respondents said they desire the use of telemedicine and virtual clinic visits to continue, either replacing or in addition to in-person clinic visits.

- Hispanic and Black respondents were significantly more likely to show preference for the continuation of virtual clinic visits (61%, 56%) than non-Hispanic (42%) and White (44%) respondents.

What changes, if any, do you think should continue to be a part of clinical research studies even after the pandemic has ended?

(Top Mentions)

Use of telemedicine (54%)

Change from in-person clinic visits to virtual clinic visits (49%)

Study medication delivered directly to home (32%)

Use of smartphone apps and other technologies (31%)

Reduced number of in-person clinic visits (28%)

ABOUT THIS STUDY

The objectives of this study are to establish routine global assessments of public and patient perceptions, motivations, and experiences with clinical research in order to monitor trends and identify opportunities to better inform and engage the public and patients as stakeholders and partners in the clinical research enterprise.

Between April and July 2021, CISCRP conducted an online international survey. The survey instrument was based in part on questions posed in past surveys. CISCRP received input and support from pharmaceutical, biotechnology, and contract research organizations, and from investigative sites. The survey instrument was reviewed by an ethical review committee. CISCRP collaborated with Clariness, AES, CureClick, Benchmark Research, and IQVIA to reach and engage respondents.

A total of 11,793 respondents completed the survey. Respondent characteristics are as follows:

Gender	51% Female | 45% Male | 4% All other genders
Region	69% North America | 3% South America | 19% Europe | 6% Asia-Pacific | 3% Africa
Age	31% 18 - 34 years old | 16% 35 - 44 years old | 14% 45 - 54 years old | 18% 55 - 64 years old | 21% 65 or older
Race	74% White | 7% Black or African American | 5% Asian
Ethnicity	72% Non-Hispanic | 28% Hispanic
Incidence of participation in a clinical trial	53% have never participated | 47% have participated

Note: Percentages throughout this report may not total 100 due to rounding

ABOUT CISCRP

The Center for Information and Study on Clinical Research Participation (CISCRP) is an internationally recognized non-profit organization dedicated to educating and informing the public and patients about clinical research. CISCRP works to raise awareness, enhance experiences, and strengthen communication and relationships among participants, research professionals, and the public through various services and events.

RESEARCH SERVICES

Insights guiding public and patient engagement in clinical research

- Perceptions & Insights Study
- Patient Advisory Boards
- Patient Clinical Trial Journey Workshops
- Custom Research Projects

COMMUNITY ENGAGEMENT

Educational and engaging events held in local communities to build clinical research awareness and trust

- AWARE-for-All
- Medical Heroes Appreciation 5K
- Journey to Better Health Traveling Exhibit

HEALTH COMMUNICATION SERVICES

Information in plain and easy-to-read language

- Trial Results Summaries
- Educational Brochures
- Health Communication Projects
- Review Panels

INTERNATIONAL EDUCATION & AWARENESS

Helpful facts and information about clinical research

- Content Licensing
- Media Awareness Campaigns: USA Today, Patient Diversity
- Website Content Development
- New Brochure Development

CISCRP

Engage

Educate

Inform