



2019
Perceptions
and Insights
Study



Participation Experiences

Introduction:

Clinical trial participation experiences are undergoing profound change with the advent of emerging technologies and other convenience-enhancing solutions. These new initiatives are also reshaping the way clinical trials are being conducted and enabling increased access to clinical trials among broader patient populations. However, despite these new solutions, the traditional burdens of participation – such as travel to the study clinic and the duration of study visits persist.

In this report, CISCRP provides a summary of the results of the latest global survey of the general public and patient perceptions about clinical research – including valuable insights from over 3,650 prior study participants. The findings will help with the development of Informed Consent strategies and identify other ways to minimize study participation burden, as well as highlight opportunities to maintain engagement post-participation.



The Center for Information and Study on Clinical Research Participation (CISCRP), founded in 2003, is a non-profit organization dedicated to educating the public and patients about the important role that clinical research plays in advancing public health. As part of its mission, CISCRP provides a variety of services designed to assist clinical research stakeholders in (1) understanding public and patient attitudes and experiences and (2) improving volunteer participation experiences and satisfaction. Please consider making a charitable donation to support our mission.

Where did you learn about the clinical research study?

Top mentions



n=3,529 | Base: Those who have participated in a clinical trial

Clinical trial participants are most likely to learn about the study opportunity through an advertisement. However, healthcare professionals and online resources also play an important role.

- Though the percentage of those mentioning government online databases and online patient communities has increased since 2013, the top three sources of information (advertisement, general practitioner/specialist, and study center staff) are among the top mentions from 2013 to 2019.
- Those who identify as Black are significantly less likely to hear about their study through their general practitioner/specialist (8%), and significantly more likely to hear through a government online database (20%) than any other race subgroup.
- Those who describe the severity of their disease/condition as 'recovered' are significantly more likely to have learned about their study through their general practitioner/specialist (31%) than those who indicate their disease/condition as 'severe' (16%).

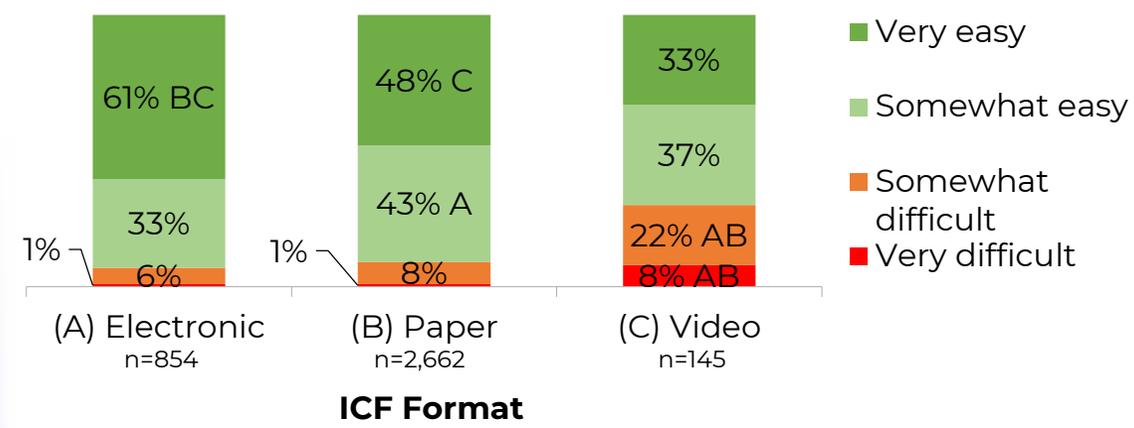
Please indicate which of the following are reasons you decided to participate in a clinical research study.

Top mentions n=3,654 Base: Those who have participated in a clinical trial	%
To help advance science and the treatment of my disease/condition	43%
To help others who may suffer from my disease/condition	35%
To receive monetary compensation (money)	34%
To obtain better treatment for my disease/condition	34%
To obtain education about treatment/improving my health	29%
The information I read/saw or had heard about the study influenced me	23%
To obtain free medication and/or treatment (if applicable in your country)	19%
My primary care physician and/or specialist recommended the study	16%
It gave me access to doctors that would otherwise not be accessible to me	15%

As seen in previous years, altruistic motivators such as the advancement of science and helping others with the same disease/condition are among the top reasons for participation.

- Older age groups (age groups over 45) are more likely to mention altruistic reasons for participation, like helping those who suffer from the same disease, compared to age groups 44 and under. However, age groups over 45 are also more likely to say that would like to participate because they want to obtain better treatment for their own disease/condition.
- Those from North America are most likely to be motivated by monetary compensation (43%) compared to all other regions.
- Those from Europe are the least motivated by free medication/treatment (8%) compared to people from all other regions (20%).

In general, how easy or difficult was it to understand your Informed Consent Form (ICF)?

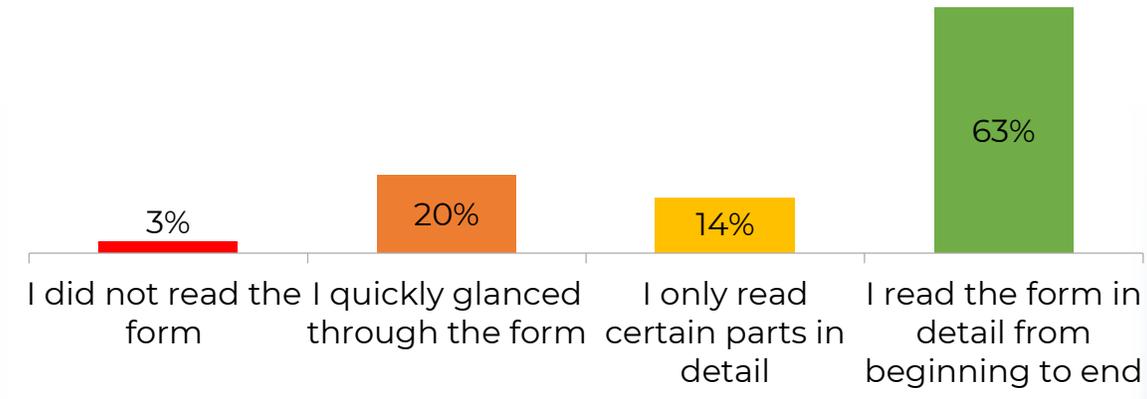


n=3,301 | Base: Those who have participated in a clinical trial; excludes "Don't remember"

Participants report that some formats of the ICF are easier to understand than others. However, the majority (85%) report that it is 'somewhat' or 'very easy' to understand their ICF, a slight increase compared to 81% in 2017.

- Though the majority (75%) report that they have received ICFs in paper format in the past, those who received their form in an electronic format report the easiest time understanding the document. Conversely, those who received their informed consent in a video format report the most difficulty understanding.
- Those who consider their medical conditions to be more severe have more difficulty understanding their ICFs compared to healthy volunteers or those reporting milder conditions.
- Those under 34 years of age report having more difficulty understanding their ICF than all other age groups.

Which of the following best describes how you read the Informed Consent Form?

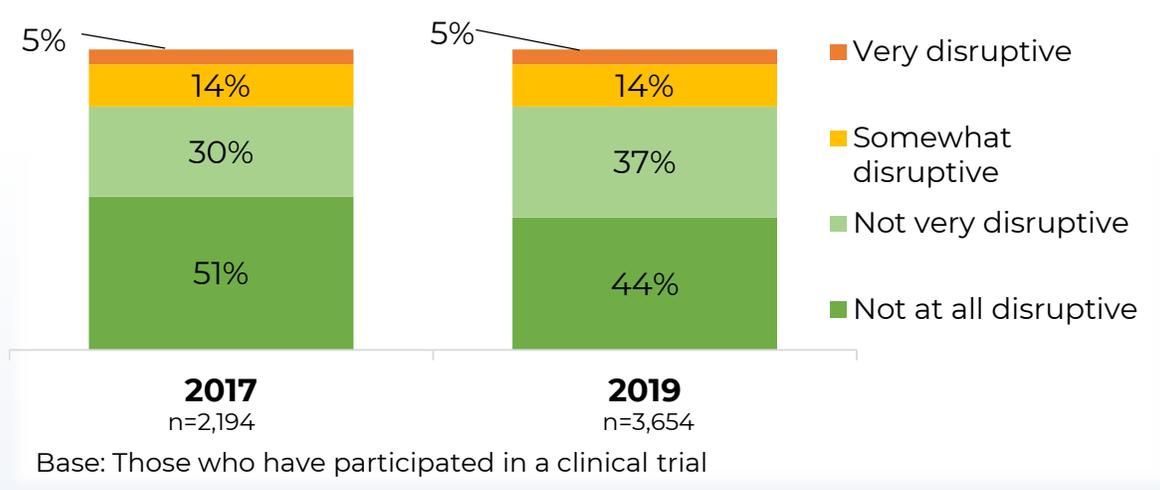


n=3,408 | Base: Those who have participated in a clinical trial; excludes "Don't remember"

Almost all participants self-report having read their ICF, and the majority report reading the document in detail from beginning to end.

- While those under age 34 have the hardest time understanding their ICFs, this group is also the most likely to report that they only read certain sections of their form in detail.
- 77% report signing the form within 24 hours of first receiving the document.
- The majority (57%) of those who have received paper ICFs in the past report that the forms were 10 pages or less.
- North Americans tend to review their ICF with a study coordinator or research nurse while all other regions tend to review their forms with the principal investigator or study doctor.

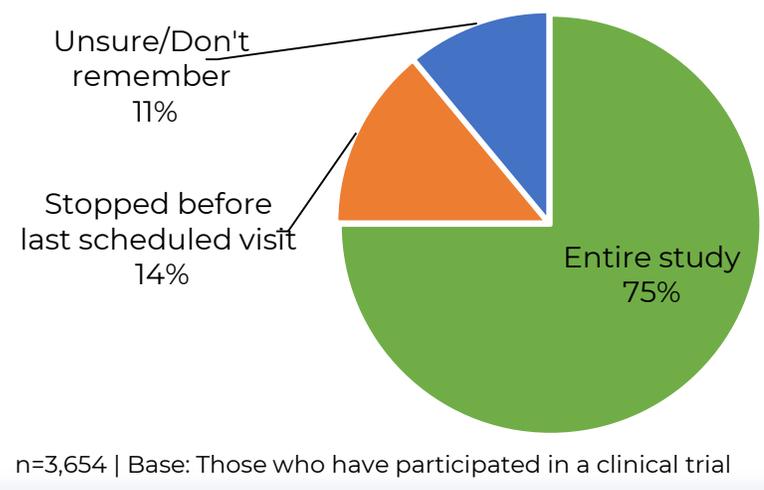
How much did your participation in the clinical research study affect your general daily routine?



There is a slightly higher proportion of participants who report some disruption to their routine compared to 2017. Top sources of this disruption include travel to the study clinic, the length of study visits, diagnostic tests, and health questionnaires.

- Less than half (44%) indicate that their one-way travel time to the study clinic was under 30 minutes. 33% say that their one-way travel time was between 30 minutes and 1 hour, and 22% report that their one-way travel time to the study clinic was more than an hour.
- All age groups 44 and under report more disruption to their daily routine due to their participation in a clinical study compared to age groups over 44. Those 44 and younger are also more likely to report that sources of disruption such as travel time, taking the study medication, and lab work are 'very burdensome.'

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



While the majority (75%) participated in the entire study in the past, 14% report that they stopped their participation early. These results are consistent with the 2015 results.

- Top reasons for stopping participation early include disqualification due to lab tests or other complications (20%), the side effects of the study drug (14%), the location of the study center (13%), poor communication with the study center (11%), and an overly burdensome time commitment (11%).
- The under 34 age group are more likely to stop their participation early compared to all older age groups. Those under 34 are also more likely to report that they stopped due to poor communication with the study center as well as painful or cumbersome study procedures.
- Similarly, those who identify as Asian also report a more burdensome experience and are more likely to stop their participation early.

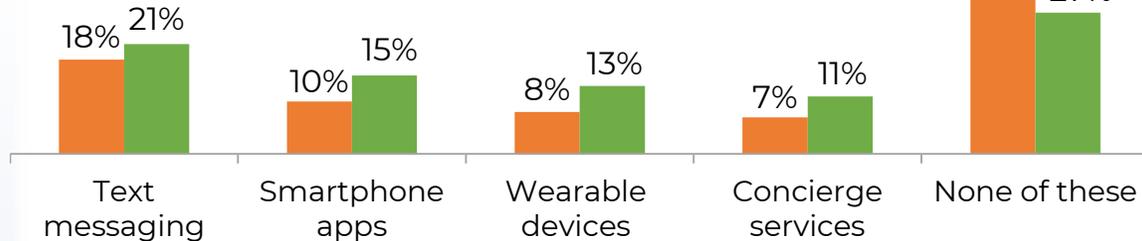
Which of the following were used during your clinical research study?

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

Areas of Growth in the Use of Convenience

Enhancing Solutions

% Mentioning

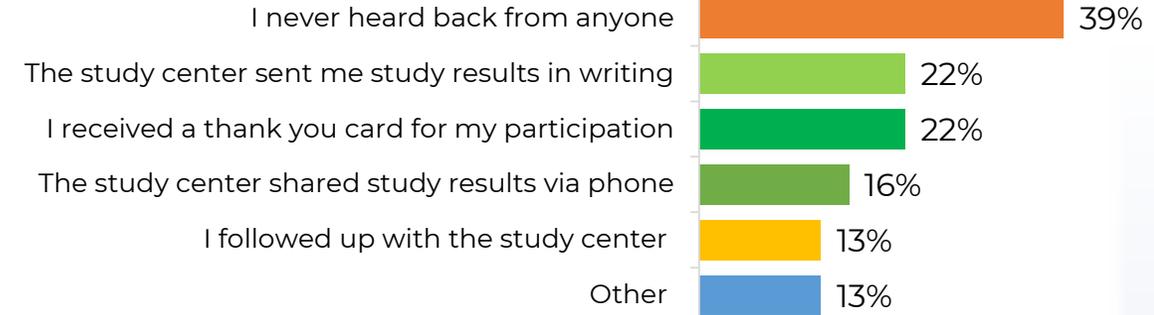


n=3,654 | Base: Those who have participated in a clinical trial

Top mentions of convenience enhancing solutions in 2019 include participation experience surveys (29%), text messaging (21%), electronic informed consent (15%), and smartphone apps (15%).

- Since 2017, the use of these convenience tools has expanded. Use of smartphone apps has grown from 10% in 2017 to 15% in 2019. Other areas of growth include wearable devices (5% increase in use since 2017), concierge services such as travel arrangement (4% increase), and text messaging (3% increase).
- Convenience enhancing solutions may positively impact the extent to which a study meets a volunteer's overall expectations. For example, those who report that their study offers childcare are more likely to report that the study exceeds their expectations (40%) compared to those who report that none of the listed convenience enhancing solutions are used during their study (14%).

% Mentioning

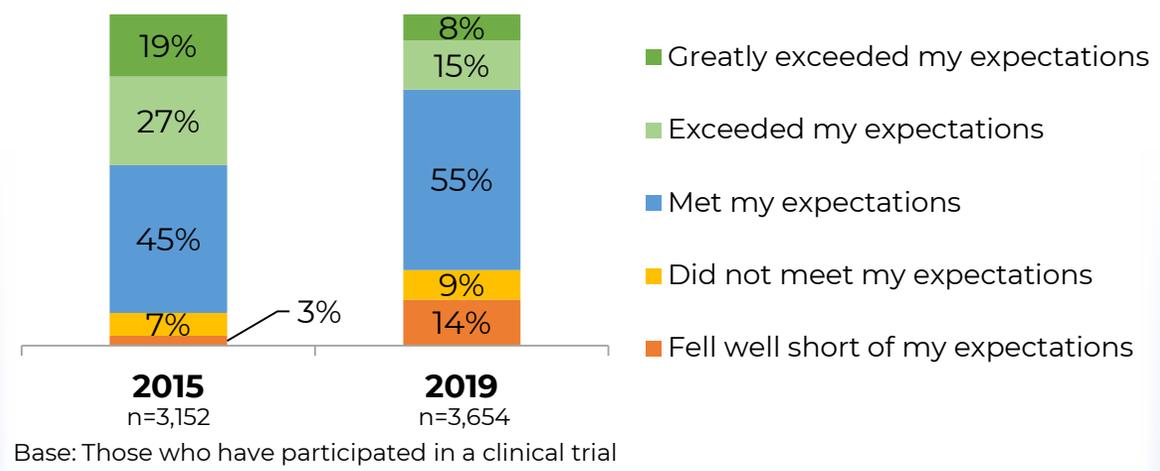


n=3,654 | Base: Those who have participated in a clinical trial

Many participants (39%) report that they never heard back from anyone after the study was over. Few participants (38%) report that they received study results in writing or by phone, and only 22% received a thank you card.

- Frequency of study updates received during a participant's study has largely not changed since 2017, with about one fourth reporting that they never received an update.
- 85% say that it is 'Somewhat' or 'Very important' to them to receive a summary of the results of the clinical research study. However, the majority (61%) report that they did not receive any reports or updates on the results of the study once they completed their participation. This number has not substantially changed since 2017 (64%).
- Compared to those who reside outside of North America, those who reside in North America are significantly less likely to receive study updates or reports post-participation.

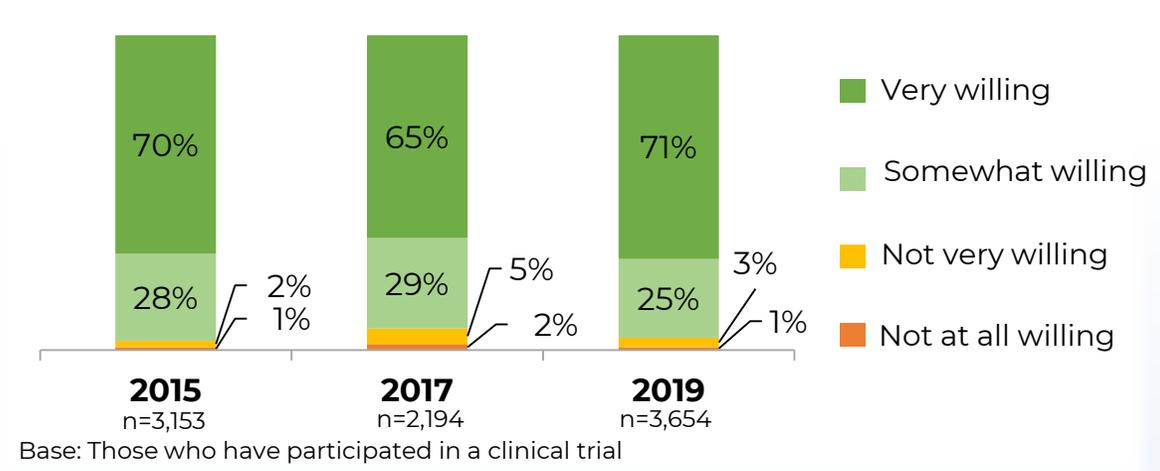
How well did the clinical research study meet your overall expectations?



Most participants report that their past clinical study experience met, exceeded, or greatly exceeded their expectations, but there is a decrease in satisfaction since 2015.

- 45% indicate that the care and attention they received during the study was 'Much better' (19%) or 'Somewhat better' (26%) than the standard care they would have otherwise received. However, another 45% report that the care was the same and 10% say it was worse.
- Those under age 34 are the most likely age group to report that the care and attention they received during their past clinical study experience was worse than the standard of care.
- When thinking about how they felt during their last study visit, 40% report feeling 'Calm'. Other top mentions include, 'Happy' (22%) and 'Enthusiastic' (21%).

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



Since 2015, the majority of participants consistently report that they are 'Very willing' to participate again.

- Most participants would 'Definitely' recommend participation to friends and family (55%). Another 37% would 'Probably' recommend participation, and only 9% would not recommend participation.
- Those under age 34 and those who identify as Asian are the least willing to participate again and the least likely to recommend participation.

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 participation 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 June and July 2019, 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 Acurian, Clariness, Continuum Clinical, CureClick, and IQVIA to reach and engage respondents.

A total of 12,451 respondents completed the survey. Respondent characteristics are as follows:

Gender	55% Female 44% Male 1% All other genders
Region	55% North America 6% South America 27% Europe 11% Asia-Pacific 1% Africa
Age	13% 18 - 34 years old 14% 35 - 44 years old 20% 45 - 54 years old 26% 55 - 64 years old 26% 65 or older
Race	80% White 6% Black or African American 10% Asian
Ethnicity	85% Non-Hispanic 13% Hispanic
Incidence of participation in a clinical trial	71% have never participated 29% have participated

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.



Insights guiding public and patient engagement in clinical research

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



Information in plain and easy-to-read language

- Trial Results Summaries
- Health Communication Projects
- Editorial Panels



Helpful facts and information about clinical research

- Content Licensing
- Media Awareness Campaign: USA Today; Patient Diversity
- Website Content Development; New Brochure Development
- Volunteer Community: Medical Hero's Alumni; Ambassador Network



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

- AWARE-for-All
- Medical Hero's Appreciation 5K
- Journey to Better Health Traveling Exhibit

Additional Resources

Designed to help professionals best engage patients as partners in the clinical research process. www.ciscrp.org Education Center, Quarterly eNewsletter, Search Clinical Trials, Sponsorship Opportunities, Webinars, Online Store