2017 Perceptions & Insights Study

Public and Patient Perceptions of Clinical Research

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Report on

The Participation Experience

Stakeholders in the clinical research enterprise have exhibited a strong commitment to improving study volunteer experiences and have implemented a variety of patient-centric initiatives to achieve this goal. These initiatives have ranged from incorporating the patient voice in the study design process, integrating various technologies such as eConsent and wearables, home clinic visits, and providing study result summaries. To what extent have these initiatives impacted the clinical trial experience? What aspects matter the most to study volunteers? How did they view the Informed Consent process? Patients and the public from around the world provide answers to these important questions and more in this latest survey.

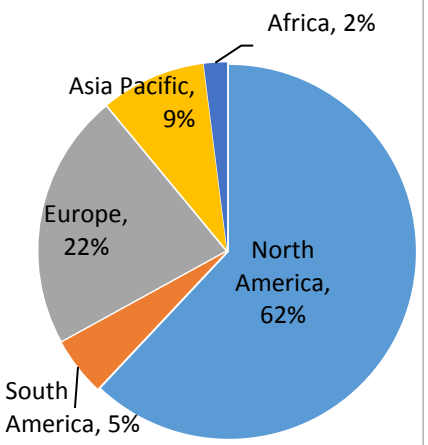
In this report, CISCRP explores various aspects of the clinical research participation experience and highlights new opportunities to enhance this experience and achieve higher levels of study volunteer engagement.

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.

Study Participant Profile

The survey captured the responses and feedback of 2,194 former clinical research participants from around the world. A diverse community of participants were represented with a balanced mix of socio-economic characteristics.

PARTICIPANTS BY REGION



RACE	
White	84%
Black/African American	7%
Asian	5%
American Indian	2%
Prefer not to answer/Other	5%

ETHNICITY	
Non-Hispanic	90%
Hispanic	6%
Prefer not to answer	4%

GENDER	
Female	57%
Male	42%

Sample Size = 2,194, Base: Clinical trial participants

EMPLOYMENT						
Retired	**Full-time**	**Part-time**	**Homemaker**	**Unemployed, looking**	**Student**	**Other**
43%	27%	12%	4%	4%	2%	8%

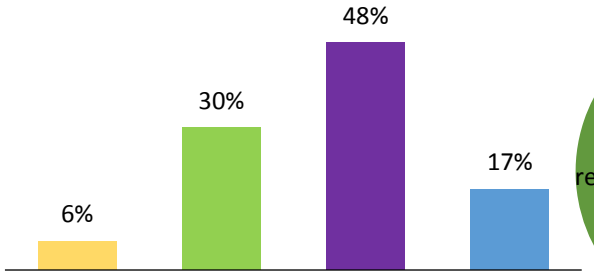
AGE				
18-34	**35-44**	**45-54**	**55-64**	**65+**
9%	8%	15%	29%	39%

Study Duration and Frequency of Visits	
Study duration (Avg.)	**# Study visits (Avg.)**
12 months	6.5 visits

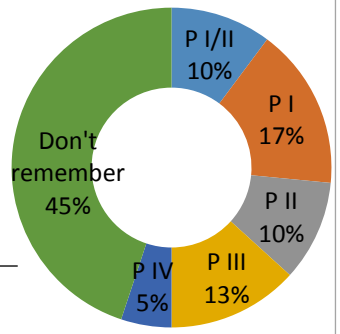
What kind of study did they participate in?

Close to half of study participants joined an interventional study. A wide variety of medical conditions were represented. An average study duration of 12 months was reported, with about 6 study visits.

Study Type



Phase



Sample Size = 2,194, Base: Clinical trial participants

Top Reported Medical Conditions	
25%<	Arthritis 32% ▪ Allergies 27%
20%-25%	Pain 25% ▪ Heart/cardiovascular 24% ▪ Diabetes 22%
15%-20%	Sleep 20% ▪ GI 18% ▪ Other 16%
10%-15%	Headache/Migraine 14% ▪ Mental Health 14% Cancer 11% ▪ Eye 11% ▪ Neurology 13%
≤ 10%	Musculoskeletal 10% ▪ Immune Condition 10% Skin 10% ▪ Lung 9% ▪ Kidney/Bladder 8% Endocrine 7% ▪ Blood 6% ▪ Male Sexual Health 6%
≤ 5%	Metabolism 5% ▪ Female Sexual Health 4% ▪ Infection 1%

Sample Size = 1,711, Base: Clinical trial participants who reported having a medical condition

Severity of Condition		
Healthy volunteers/(NA)	**Very mild/mild**	**Moderate/severe**
21%	25%	45%

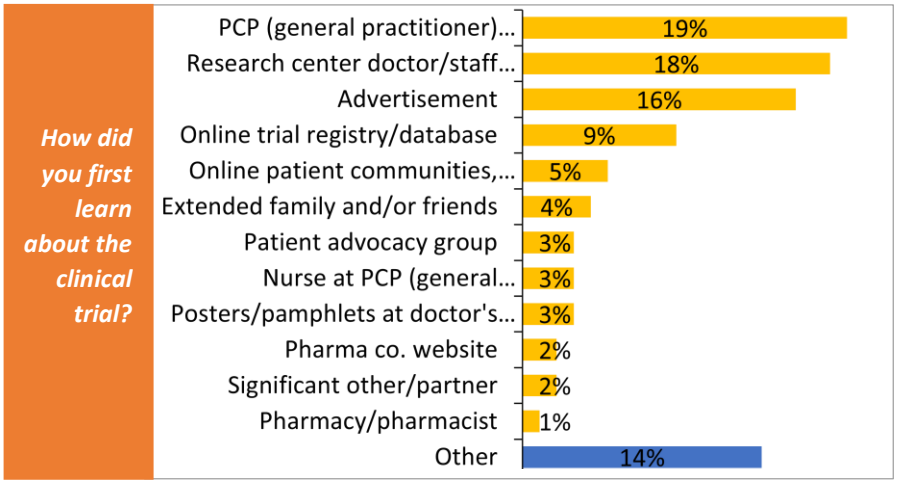
Sample Size = 2,194, Base: Clinical trial participants

How do study participants first learn about clinical research opportunities?

As in the 2015 study, primary care doctors or specialists, research center doctors or study staff, and advertisements remain where study participants most often first learn about their clinical trial.

A lower proportion of Hispanic study participants report learning about their clinical trial from their primary care doctor than non-Hispanics. Hispanics were more likely to learn of a study from their significant other, pharmacist or pharmaceutical company website.

Younger people were more likely to have first learned of a clinical trial from online patient communities or through social media.



Sample Size = 2,194, Base: Clinical trial participants, Red shaded cells indicate statistical significance within row at the 95% CL

ETHNICITY	
LEARNED FROM PCP/SPECIALIST	
Non-Hispanic	Hispanic
20%	7%

AGE				
LEARNED FROM ONLINE PATIENT COMMUNITY, SOCIAL MEDIA				
18-34	35-44	45-54	55-64	65+
10%	8%	6%	4%	5%

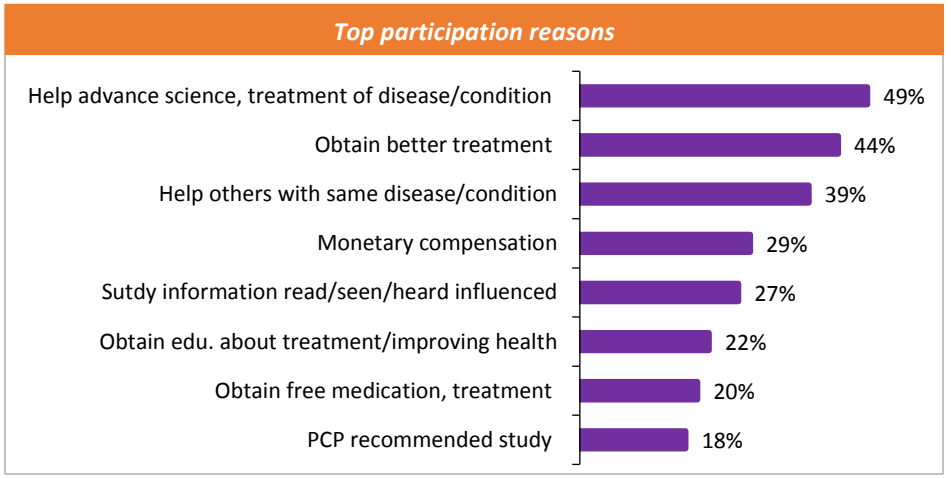
Indicates statistical significance at the 95% CL

Altruistic reasons and obtaining better treatment continue to be the strongest participation motivators

Top participation drivers remain unchanged. Altruistic reasons and obtaining better treatment are the most common participation motivators followed by monetary compensation.

People from South America were more likely to list recommendations from extended family members and significant others as a top reason for participation compared to other regions.

As a next step in the decision making process, the majority of people contacted the study site on their own to find out more information after learning of the clinical trial. People from North America were the most proactive as a larger proportion indicated following up directly with the site on their own prior to participating. Family members were more likely to follow up with the site on behalf of younger people.



Sample Size = 2,194, Base: Clinical trial participants, Red shaded cells indicate statistical significance within row at the 95% CL

REGION *% Contacted site on their own as next step*				
North America	Africa	Europe	South America	Asia Pacific
66%	57%	56%	53%	51%

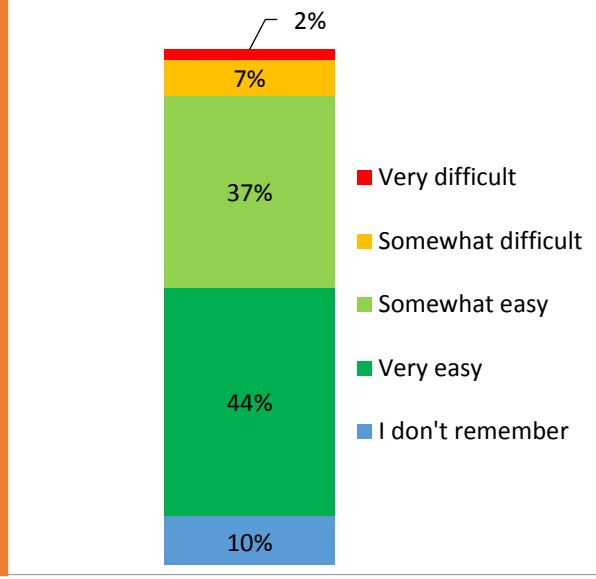
Indicates statistical significance at the 95% CL

Looking at the Informed Consent Form

On average, Informed Consent Forms (ICF) were reported to be 12 pages long and were viewed as being 'easy' to understand by the majority of study participants, with about 10% of people reporting having difficulty. It is important to note that it is self-reported understanding of the ICF and is not necessarily an indicator of actual comprehension.

Additionally 15% of former study participants reported that they had once qualified for a study, but decided not to move forward after reviewing the ICF associated with the clinical trial mainly because the side effects scared him/her, there were too many study visits and/or medical procedures were too invasive.

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



Sample Size = 2,194, Base: Clinical trial participants

Top reasons participants decided to not take part in a clinical trial after reviewing ICF		
TOP MENTIONS	**Side effects scared me**	29%
	Too many study visits	24%
	Medical procedures too invasive	18%
	Afraid of receiving placebo and too many medical procedures	14%

Sample Size = 337 Base: Those who have participated in a clinical trial but who reported having decided not to participate after reviewing an ICF

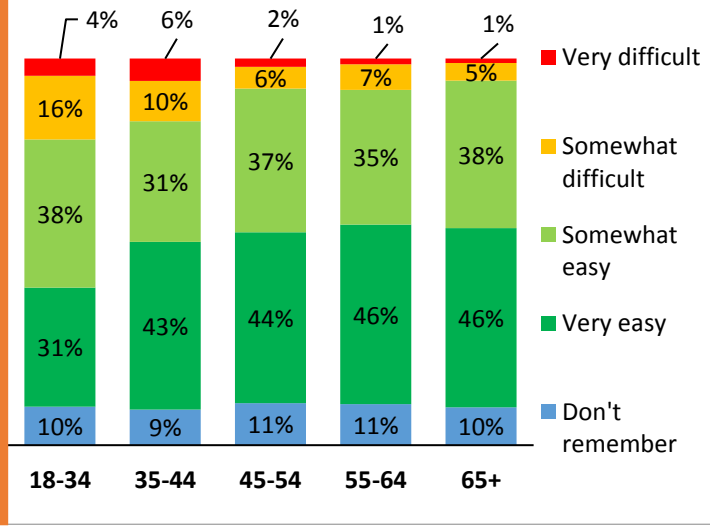
Some populations had a more difficult time understanding the ICF than others

Asian and Hispanic populations, males, and younger individuals found the ICF to be more difficult to understand. Similar patterns among younger populations were evident in past Perceptions and Insights studies as well.

The principal investigator or study coordinator generally reviewed the ICF with the study participant. In cases where the ICF was reviewed with an administrative staff member (14%), participants generally reported a lower level of understanding.

AGE

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



Sample Size = 2,194, Base: Clinical trial participants

ETHNICITY

	Non-Hispanic	Hispanic
Very difficult	2%	6%
Somewhat difficult	6%	14%
Somewhat easy	36%	36%
Very easy	45%	39%
I don't remember	10%	6%

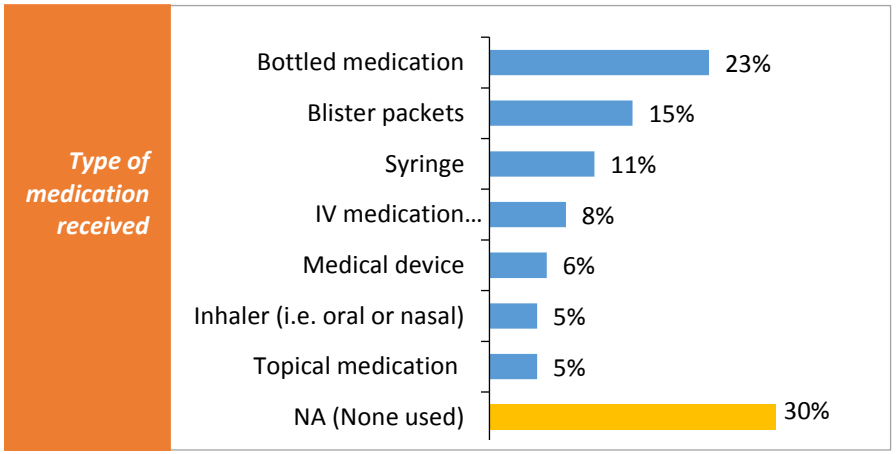
Indicates statistical significance at the 95% CL

Study staff who reviewed ICF	
CRC, Study Nurse	43%
PI/Study Doctor	23%
Administrative	14%
Don't Remember	12%
Not Discussed	3%
Other or online	5%

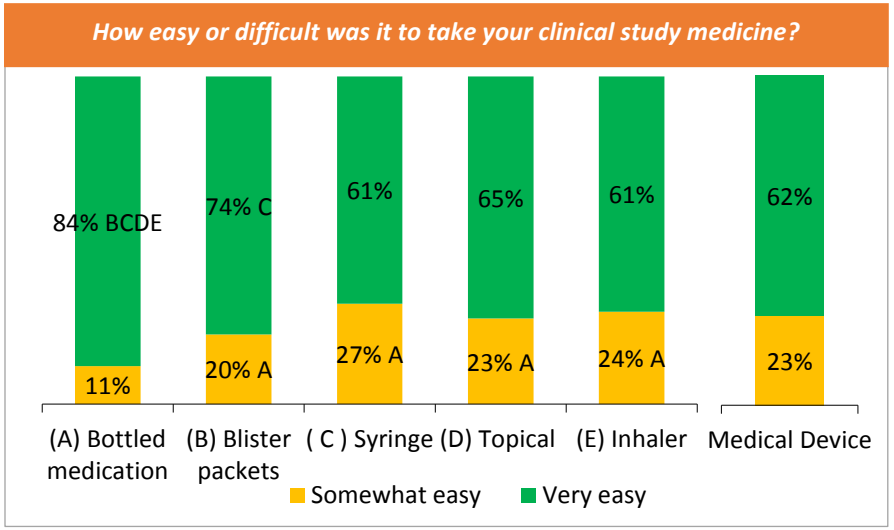
A closer look at the study medications received

Bottles, blister packets and syringes were the top reported types of medication received. About 30% of study participants did not receive any medication or medical device as part of their trial.

Study participants receiving study medicine in a bottle found this type of packaging to be the easiest to administer or take.



Sample Size = 2,194, Base: Clinical trial participants



*Sample Size = 1,248, Base: Those that received medicine/medical device *Letters indicate statistical significance at the 95% CL*

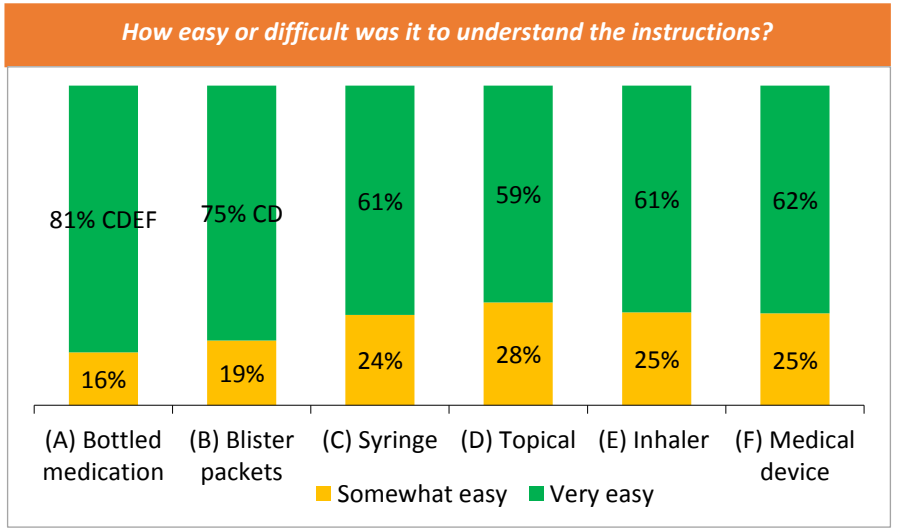
Bottled study medication also viewed as easiest to remember to take

Clinical study participants receiving study medicine in a bottle also found this type of packaging to be the easiest to remember to take (96%). The associated instructions with bottled medicine and blister packs were reported to be the easiest to understand.

In general, younger people experienced a more difficult time remembering to take their medications and understanding the instructions compared to older age groups.

Black/African American and Hispanic populations also found instructions to be more difficult to understand compared to other races/ethnicities.

Overall, most study participants (68%) felt that study staff answered questions related to the medicine 'very well'.



*Sample Size = 1,248, Base: Those that received medicine/medical device *Letters indicate statistical significance at the 95% CL*

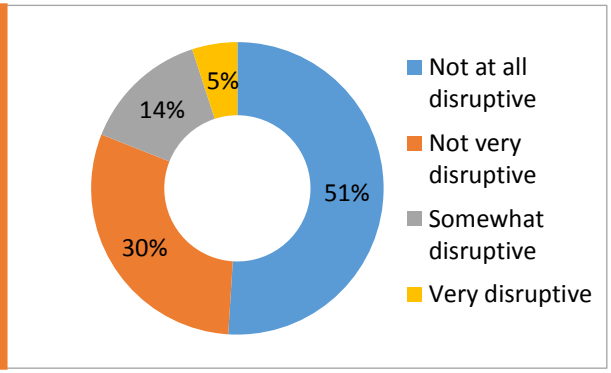
What impact does participation have on daily life?

While half of the study participants reported at least some degree of disruption to their daily life and general routine, only 5% of former clinical trial participants found their clinical trial experience to be 'very disruptive' overall.

Study participants who received certain medication types were more likely to report an increased sense of disruption to their daily routine. Those who received IV medication administered at the study site, syringe medication, or medical device found participation to be more disruptive than those who received a different type of medication.

Self-reported level of disruption was also a function of employment status, race, ethnicity variables, and age.

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



Sample Size = 2,194, Base: Clinical trial participants

Percent reporting participation to be 'not at all disruptive'

RACE			ETHNICITY	
White	Black/African American	Asian	Non-Hispanic	Hispanic
52%	49%	38%	53%	36%

EMPLOYMENT					
Retired	Unemployed, looking	Part-time	Homemaker	Full-time	Student
60%	51%	48%	44%	40%	27%

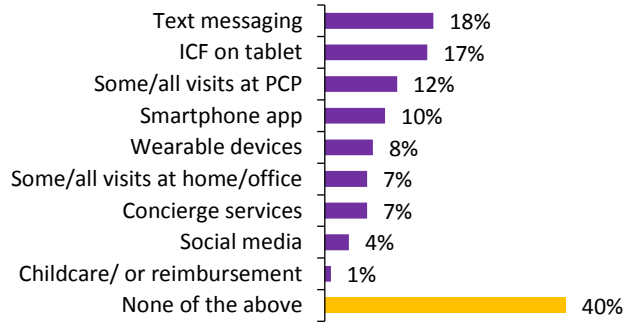
□ *Indicates statistical significance at the 95% CL*

Text messaging and eConsent were the most used technologies during trials but at low levels

The most reported service/technology currently used during clinical studies was text messaging, followed closely by Informed Consent on a tablet. But overall, the participants that reported their use was low. Text messaging use varied by region with study participants in Africa and Asia Pacific reporting higher use. Top desired services included smart phone apps, concierge services and home study visits.

Younger participants were more likely to report using smart phone apps, wearable devices, and social media during their study compared to other age groups. They also desired these services more so than older people.

What services or technologies were used in your study?



Sample Size = 2,194, Base: Clinical trial participants

REGION *% reporting use of text messaging in study*				
North America	Africa	Europe	South America	Asia Pacific
13%	31%	25%	35%	26%

AGE *% reporting use of social media in study*				
18-34	35-44	45-54	55-64	65+
19%	12%	4%	1%	2%

□ *Indicates statistical significance at the 95% CL*

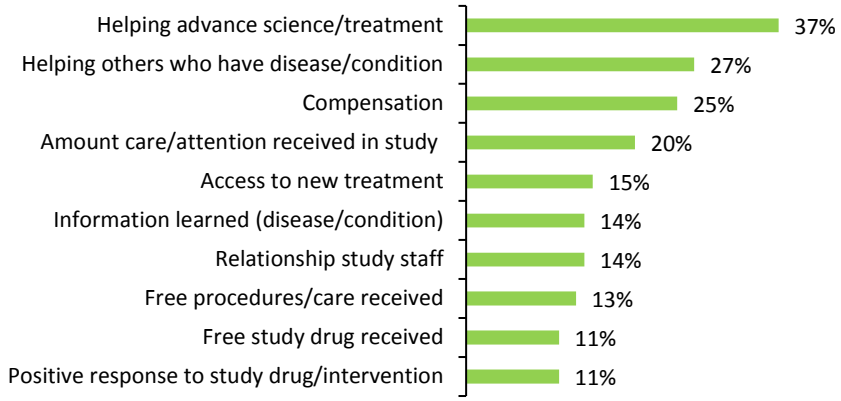
What do clinical study participants like the most and the least about their experience?

The things participants liked the most and the least about their participation remain unchanged from prior studies. Helping advance science, helping others, compensation and the amount of care received were mentioned most often. Participants disliked the possibility of receiving a placebo and the location of the study site the most.

A higher proportion of Hispanic and Asian populations reported disliking missing work and the time commitment than other ethnicities/races.

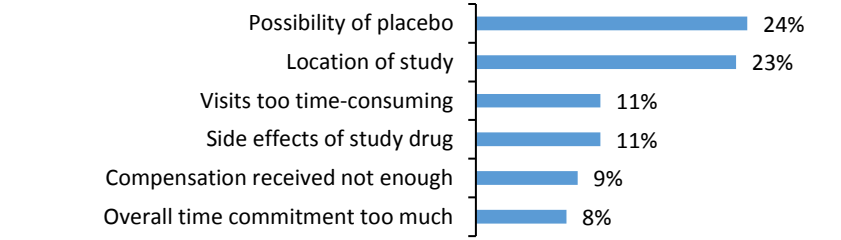
Younger people mentioned disliking unfriendly staff, the lack of compensation, time commitment, missing too work, and child care costs more so than older people.

What did you like most?



Sample Size = 2,194, Base: Clinical trial participants

What did you like least?

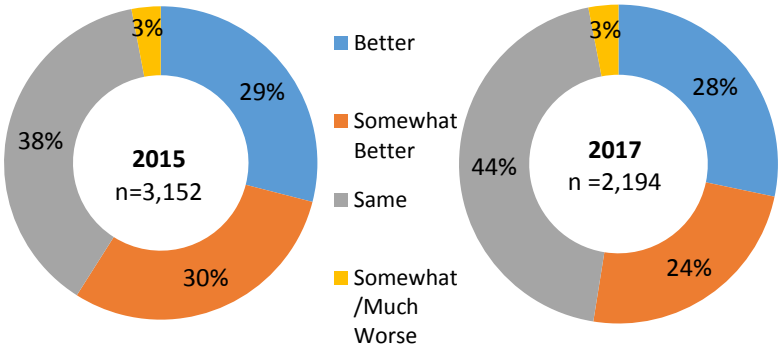


What do clinical study participants like the most and the least about their experience?

Overall, over half felt the care they received during their trial was better than the standard care they would have otherwise received. These sentiments were similar to feelings expressed in the 2015 study.

More participants from South America and Africa reported care to be 'much better'. More Black/African American individuals, Hispanic populations, and younger people reported their care was better as well.

How does the care received in clinical trials compare to standard care?



Sample Size = 2,194, Base: Clinical trial participants

Identified care and attention received as 'much better'

AGE					RACE		
18-34	35-44	45-54	55-64	65+	White	Black/African American	Asian
41%	29%	27%	29%	24%	27%	40%	27%

Indicates statistical significance at the 95% CL

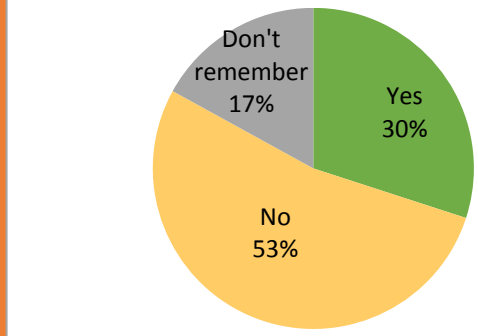
Receiving summaries and updates remain very important to clinical research participants

As found in prior studies, the majority (91%) of the public finds receiving a study summary after participation to be very important. Yet 53% of those who have participated in a clinical trial have never received a report or an update on the study results once it ended. Furthermore, about a quarter of study participants reported never receiving any updates while they were enrolled.

Top information people would like to receive after they complete the trial, in addition to the study summary, are individual study results and whether they received the placebo or not.

Receiving a study summary is particularly important to older people. Those from Europe and the Asia Pacific regions found this to be less important.

Did you receive an update or report after you finished your study?



Did you receive an update or report after you finished your study?

REGION					
	North America	Africa	Europe	South America	Asia Pacific
% Never received	59%	31%	51%	25%	42%

Sample Size = 2,194, Base: Clinical trial participants

How important is it to you to receive results of a study?

REGION					
	North America	Africa	Europe	South America	Asia Pacific
Very	66%	68%	57%	68%	55%
Somewhat	27%	28%	32%	25%	30%

Sample Size = 12,427, Base: All respondents
Indicates statistical significance at the 95% CL

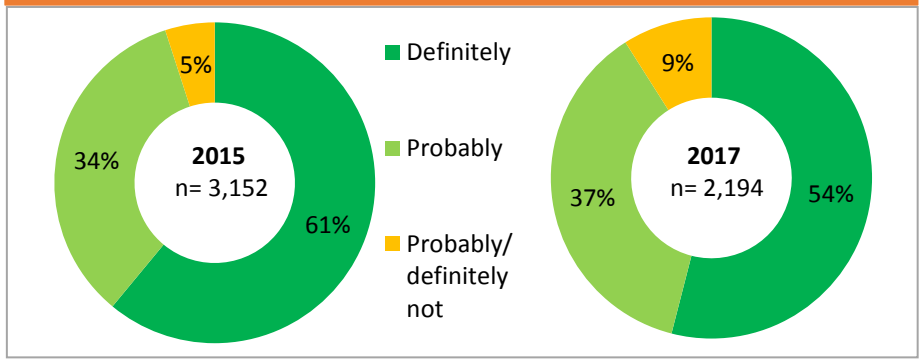
Most would participate again and would recommend participation to others

Similar to findings in prior years, the vast majority (94%) of clinical trial participants reported being willing to participate in another clinical study. And most would also recommend participation to others if appropriate.

Higher proportions of older people indicated being likely to participate again and recommend participation to others. This also held true for people from North America.

Black/African American populations were the most likely to report being willing to participate again, while Asians reported being far less likely.

Would you recommend participation to family/friends if appropriate?



How willing are you to participate in another study?

RACE			
	White	Black/African American	Asian
Somewhat willing	28%	21%	46%
Very willing	66%	78%	38%

Sample Size = 2,194, Base: Clinical trial participants
Indicates statistical significance at the 95% CL

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 May and July 2017, 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, CureClick, HealthUnlocked, and Quintiles to reach and engage respondents.

A total of 12,427 respondents completed the survey. Respondent characteristics are as follows:

Gender:	59% Female | 40% Male
Region:	46% North America | 7% South America | 28% Europe | 14% Asia-Pacific | 5% Africa
Age:	13% 18 - 34 years old | 11% 35 - 44 years old | 19% 45 - 54 years old | 27% 55 - 64 years old | 29% 65 or older
Race:	81% White | 6% Black or African American | 5% Asian
Ethnicity:	88% Non-Hispanic | 8% Hispanic
Incidence of participation in a clinical trial:	82% have never participated | 18% have participated

**Throughout this report, [ ] indicates statistical significance at the 95% CL with one or more values in the row.*

About CISCRP

Founded in 2003, the Center for Information and Study on Clinical Research Participation (CISCRP) is an independent, Boston-based, globally focused nonprofit organization. In addition to conducting periodic research on public and patient attitudes and experiences, CISCRP also provides a variety of educational initiatives including:

AWARE for All clinical research education programs designed to introduce individuals to their local research community through sessions, workshops, and free health screenings. Between 2003 and 2015, these live and online programs have reached 450,000 households in cities across the United States and in Europe.

Medical Heroes public service campaigns raise awareness and appreciation for the brave individuals who give the gift of participation in clinical research each year. Our Medical Heroes communications generate over 120 million impressions quarterly.

Educational books, DVDs, and brochures cover a wide range of topics for research participants, in culturally sensitive 6th to 8th grade reading level language, and are translated into two dozen languages. Since 2004, investigative sites, sponsors, and CROs have distributed nearly one million copies.

SearchClinicalTrials.org is a "high touch" service designed to manually search for relevant clinical trials on behalf of patients, family, and friends overwhelmed by the online search process. CISCRP performs searches for nearly 5,000 unique requests annually.

Patient Advisory Board panels are an invaluable approach to engaging study volunteers and enhancing their participation experience. Patient advisory boards also provide unprecedented insight into improving study feasibility, recruitment and retention, and in understanding patient perceptions and receptivity to current approaches, new practices and technology solutions. CISCRP has collaborated with top pharmaceutical companies on patient advisory boards in various therapeutic areas.

Clinical trial results communication program—one of our most active and fastest growing initiatives—involves the translation of technical clinical trial results for study volunteers who participated in those trials. CISCRP is now collaborating regularly with nearly 30 major pharmaceutical companies to provide non-technical, plain-language clinical trial results summaries.

For more information about any of our services, contact CISCRP at 617-725-2750 or visit our web site at www.ciscrp.org.

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