Survey Findings

2020
Pediatric Perceptions and Insights Study

Generously supported by a grant from Parexel

2020 Pediatric Perceptions & Insights Study

Introduction:

Every two years, CISCRP conducts the Perceptions & Insights Survey – an online, global assessment 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.

In an effort to build off this work, Parexel engaged CISCRP to design a survey specifically for parents and their children in order to better understand perceptions and experiences related to pediatric clinical trials. Specifically, the goal of this survey was to gain insight into general perceptions of pediatric trials, preferred channels of communication, key information parents and their children would want about pediatric clinical trials, as well as past or current experiences participating in pediatric clinical trials.

During the month of April 2020, CISCRP conducted an online US-based survey among 500 parents and their children. The survey instrument was based in part on questions posed in past Perceptions & Insights studies with modified language for child respondents. The survey was distributed online. Parents would first take the adult section of the survey, then ask their children to complete the child section.

In this report, CISCRP provides a summary of these results and compares the results with the baseline Perceptions & Insights Study where applicable. The findings illustrate what matters most to patients and their parents and offer ways to best support and inform prospective pediatric volunteers and their guardians before, during, and after the clinical research process.

An executive summary of key learnings can be found on the next page of this report. Detailed findings are divided into two sections – parent findings and child findings.

CISCRP parexel

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.

2020 Pediatric Perceptions & Insights Study

Executive Summary:

Overall:

- Parents whose children have participated in clinical research report the highest levels of understanding of clinical research, awareness of studies actively enrolling, and willingness to have their child participate.
- Healthcare professionals are key at several points along the journey toward participation.
    - For example, doctor's recommendations are the top reason that parents decide to have their child participate.
    - Children would most prefer to learn about clinical research through their doctor.
- Though children report burdensome study experiences, most indicate that the study exceeded their expectations and they are willing to participate again.

Parents/guardians:

- Parents generally self-report high levels of understanding about clinical research.
    - Awareness and understanding are greatest among parents whose children have participated in clinical research.
- Parents discuss clinical research with their child's doctors often and cite their child's doctors as the top way they learn about participation opportunities.
    - Doctor's recommendations are also the top reason that parents decide to have their child participate.
- During participation, parents report highly burdensome experiences and high levels of disruption to their daily routine.

Children:

- Levels of awareness of clinical research vary by child's age, as older children were more likely to have heard of clinical research compared to younger children.
    - Overall, few report that they understand clinical research "Very Well."
- Though many were not sure whether they would want to participate, 50% report that they would be willing.
    - The top motivation was altruistic as children wanted to advance science through their participation.
- Despite reporting burdensome experiences, most children who had participated in a clinical trial indicate that participation was a better experience than they thought it would be.

2020 Pediatric Perceptions & Insights Study

Methods & Survey Sample:

Questionnaire Development:	U.S. based pediatric questionnaire developed in collaboration with Parexel, using the CISCRP 2019 Perceptions & Study as a base.
Data Collection Period:	April 2020
Methodology:	The survey was distributed online. Parents would first take the adult section of the survey, then ask their children to complete the child section.
Final Sample Size:	n=500, Parents and Legal Guardians | n=486, Children (Ages 10-17)
Analysis:	Results were analyzed for statistical differences across respondent demographics. Comparisons were drawn to the 2019 Perceptions and Insights study when appropriate. Throughout the report, percentages may not total 100% due to rounding.

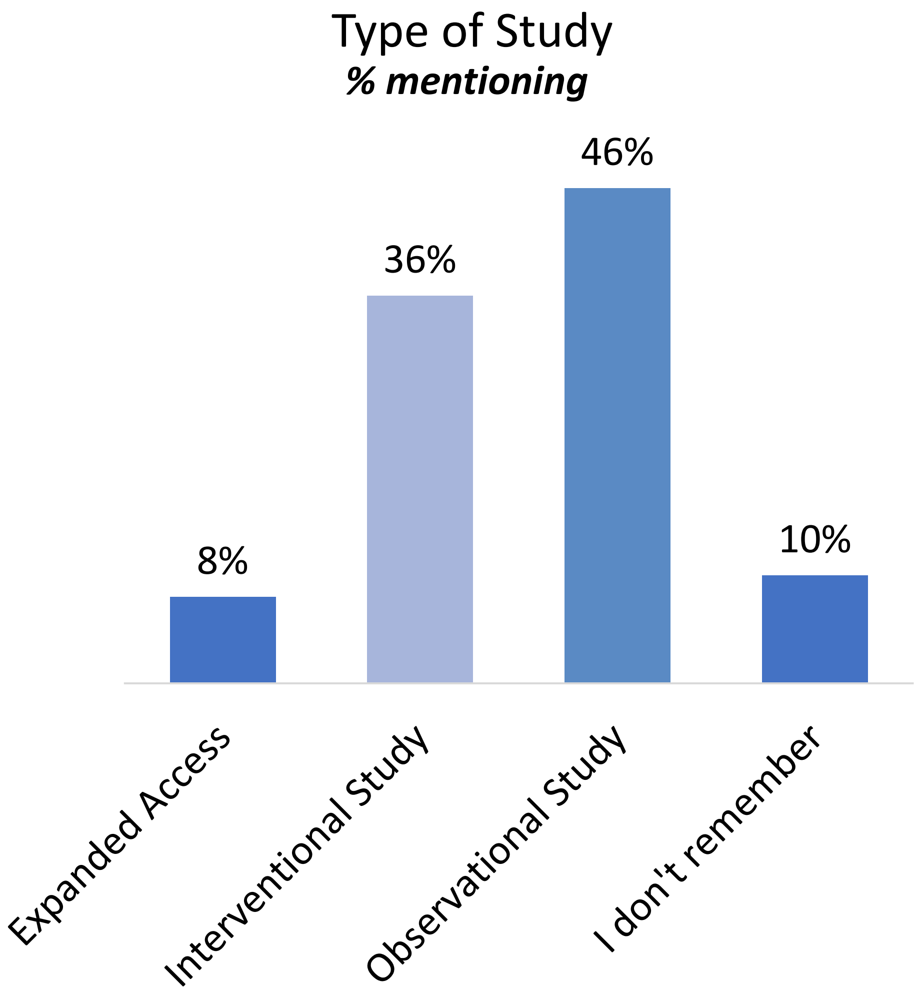
Respondent characteristics are as follows:

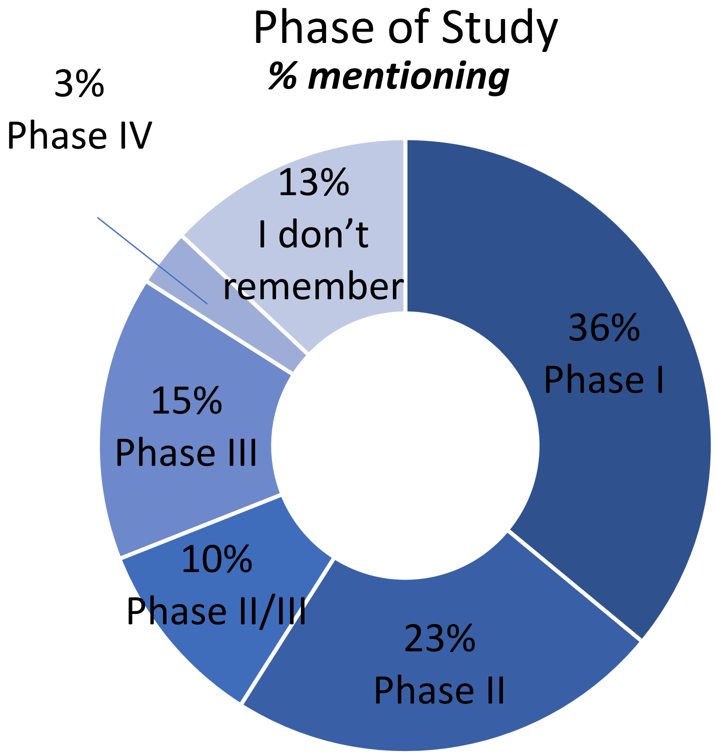
Parents (n = 500)	
Gender	62% Female | 38% Male |<1% Other
Age	23% 18-34 Years Old | 46% 35-44 Years Old | 26% 45-54 Years Old | 5% 55-64 Years Old | <1% 65 and Over
Race (top mentions)	75% White |16% Black | 8% Asian
Ethnicity (top mentions)	84% Not Hispanic/Latino | 15% Hispanic/Latino
Education	8% Less than high school | 11% High school/equivalent 37% Associates/Technical/Some College |27% Bachelor's Degree |17% Master's or above

Children (n = 486)	
Gender	46% Female | 54% Male |<1% Other
Age (child reported)	49% 10-13 Years Old | 51% 14-17 Years Old
Race (top mentions)	71% White |19% Black | 8% Asian
Ethnicity (top mentions)	82% Not Hispanic/Latino | 18% Hispanic/Latino
Medical Condition	50% Diagnosed w/Medical Condition 50% Not Diagnosed w/Medical condition
Clinical Trial Participation	12% Participated | 88% Never Participated

2020 Pediatric Perceptions & Insights Study

Pediatric Study Participant Profiles:





8% of the overall sample reported that their child participated in a clinical research study

Study Completion Rates:

- 74% Completed the study
- 21% Stopped before last visit
- 5% Don't remember

Number of Trials Participated In:

- Mean = 1.41

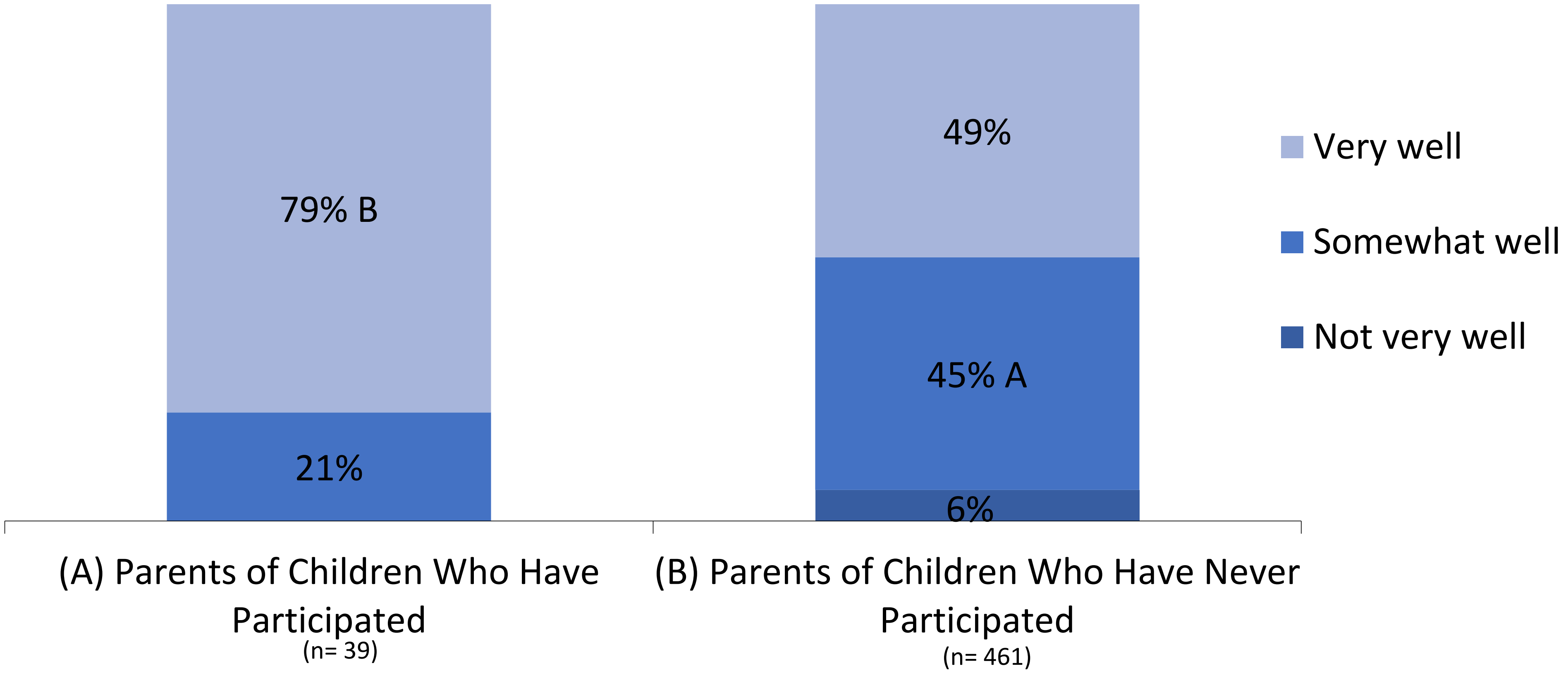
Sample Size = 39 Base: Parents reporting that child participated in a pediatric clinical research study

Parent/Guardian Findings

CISCRP

Parents whose children have participated are more knowledgeable about clinical research

How well do you understand what is meant by the term "clinical research study“?

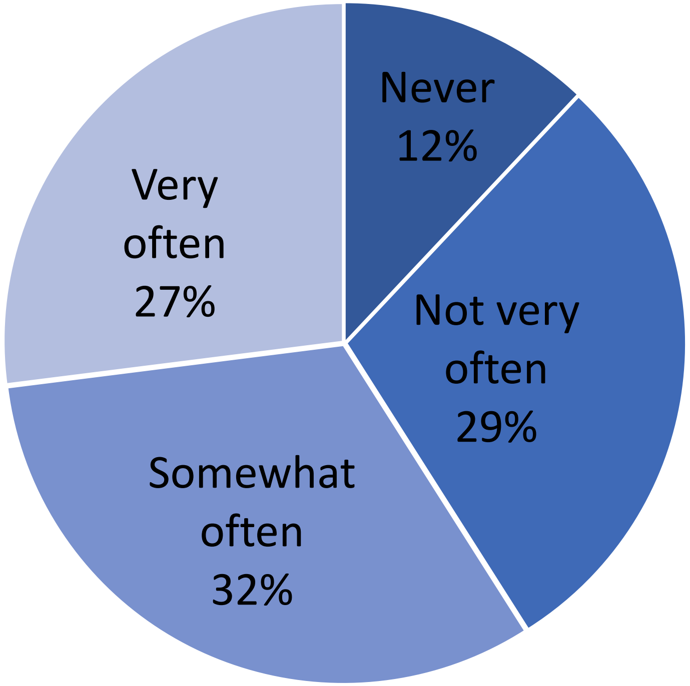


2019 Perceptions & Insights Study*:*

Adult clinical research participants were also more knowledgeable about clinical research compared to those who had never participated according to the 2019 Perceptions & Insights Study (n=12,451).

Parents discuss clinical research with their child's doctors often and feel it's important for these providers to be aware

In general, when discussing treatment or medication options with your child's doctor(s), how often do you consider clinical research studies as another option?



Sample Size = 500 Base: All parents

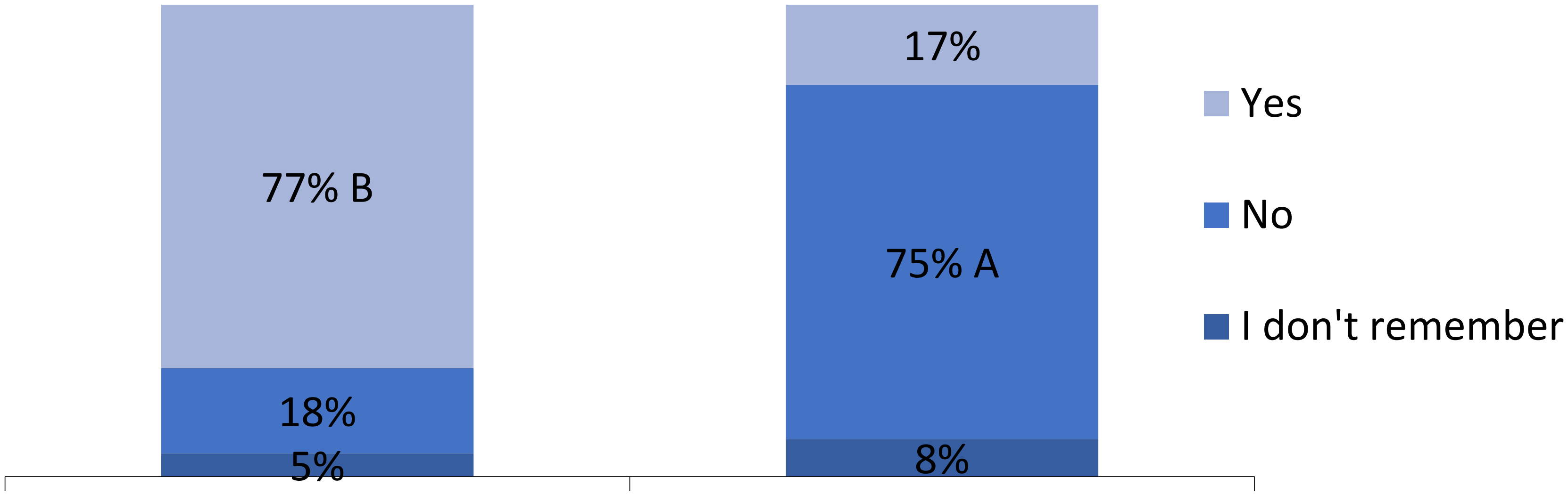
97% of all parents felt that it was 'Somewhat/Very Important' for their child's doctors to be aware of clinical research studies being conducted in their community

2019 Perceptions & Insights Study*:*

Parents discussed clinical research options with their child's doctors much more often than adults report discussing these options with their own doctors (less than 40% "somewhat/very often).

Parents whose children have participated are much more aware of studies actively enrolling

During the past six months, do you remember seeing or hearing about a clinical research study that was looking for pediatric or child volunteers?



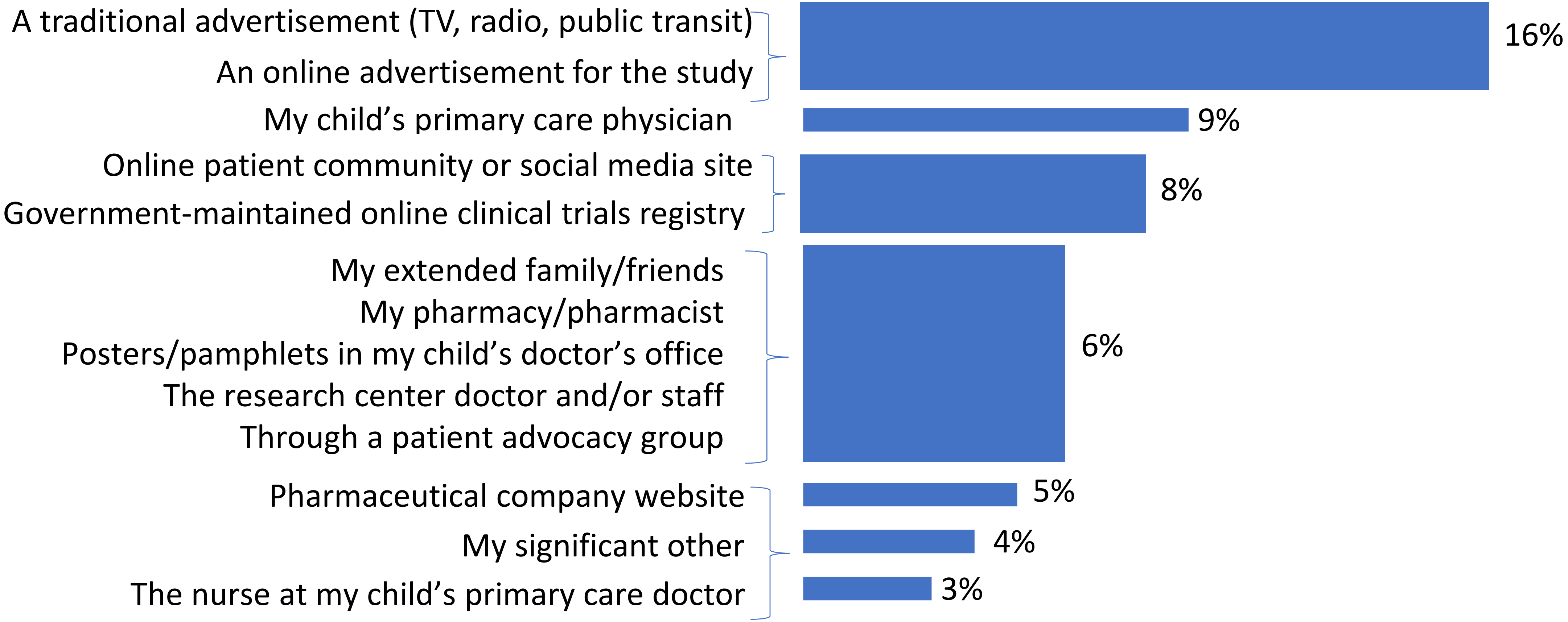
(A) Parents Whose Children Have Participated
(n= 39)

(B) Parents Whose Children Have Never Participated
(n=461)

Letters indicate statistical significance at 95%

Advertisements are the most common way parents hear about studies actively enrolling

Where did you see or hear about a clinical research study?



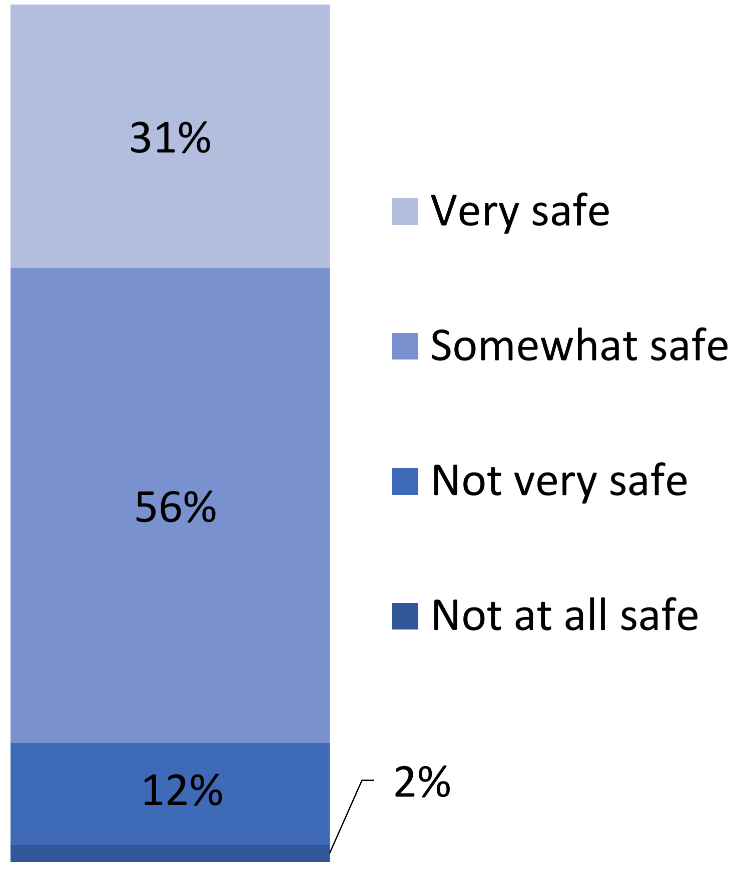
(n= 108) Base: Parents who have heard of a pediatric clinical trial actively enrolling in the last 6 months

2019 Perceptions & Insights

The 2019 Perceptions & Insights Study (n=12,451) also showed that the public heard about clinical research from multiple sources.

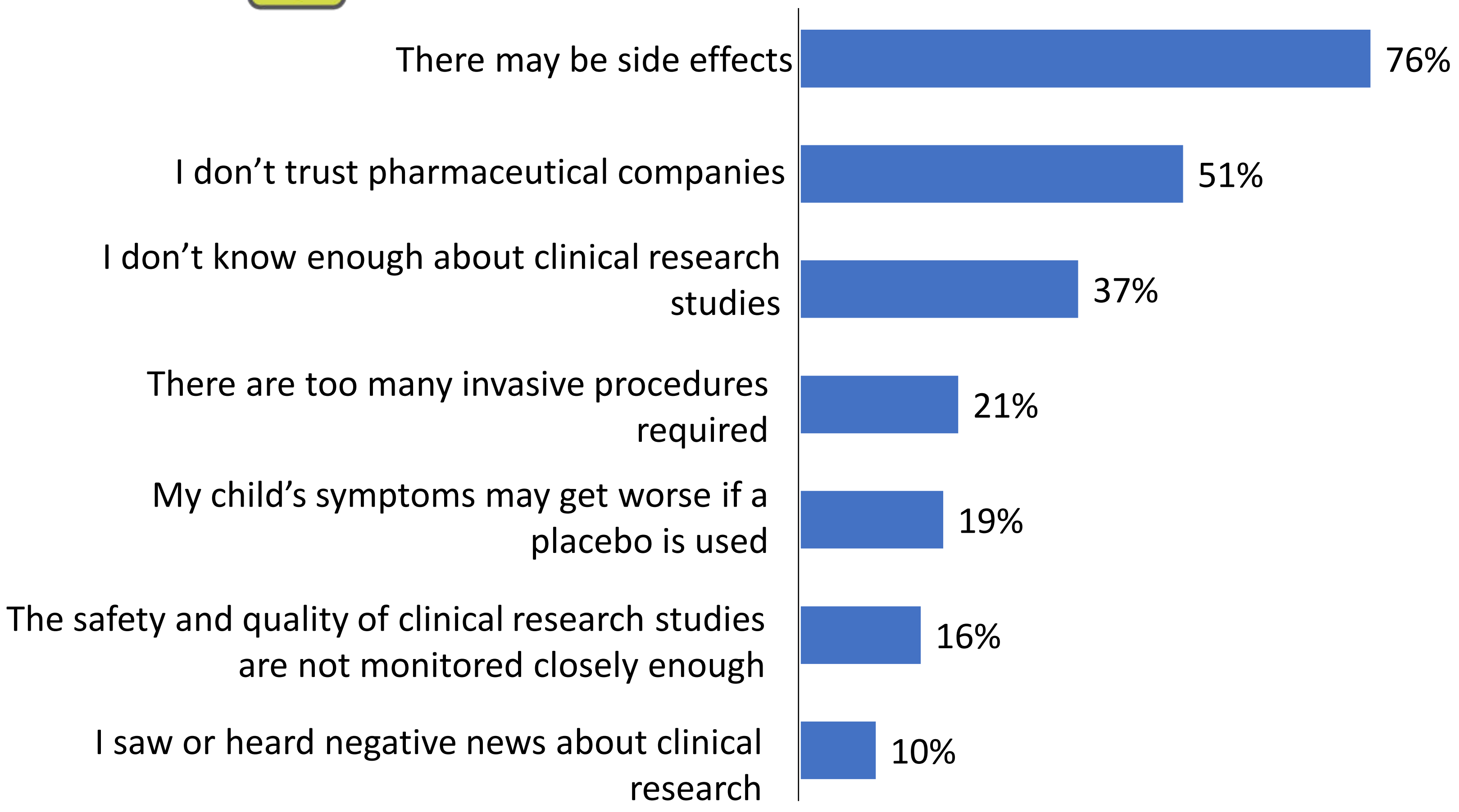
Most parents believe clinical research studies to be safe

In your opinion, how safe are clinical research studies?



Sample Size = 500 Base: All parents

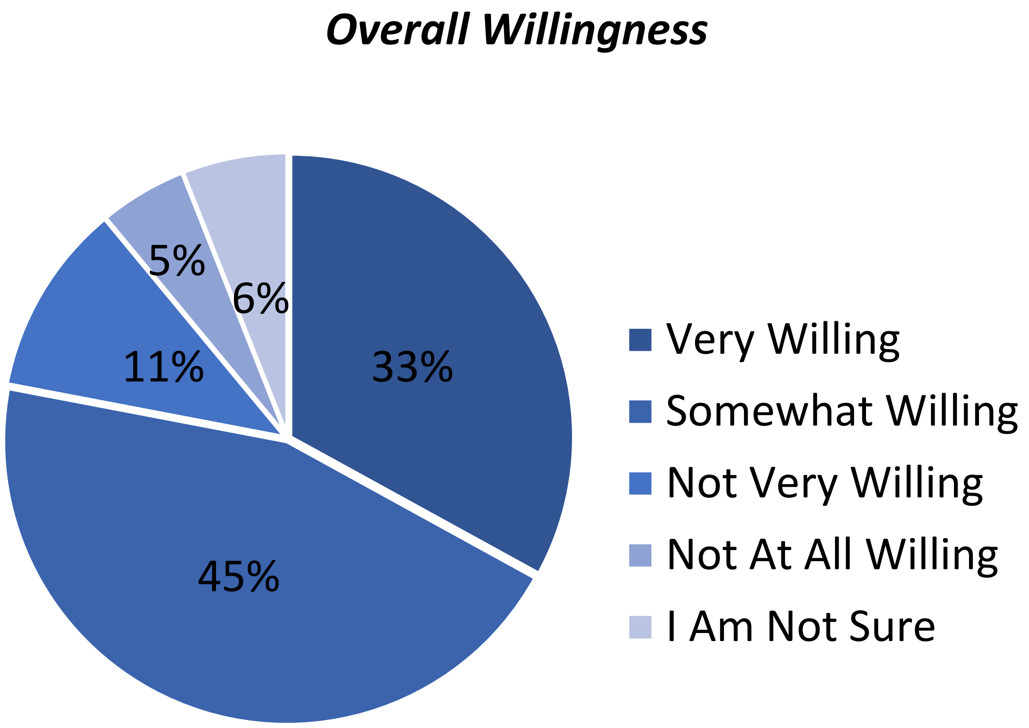
Why do you think clinical research studies are not safe?



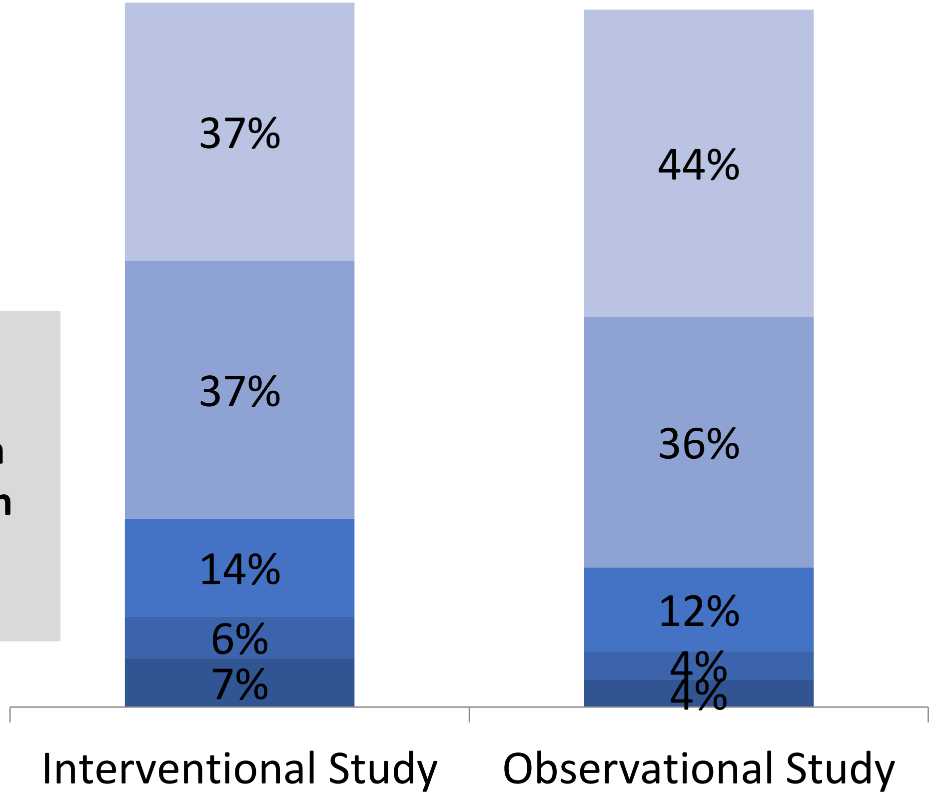
Sample Size = 67 Base: All parents who said that clinical research was "Not Very" or "Not At All Safe"

Most parents are willing to have their child participate – even more willing for observational research

In general, how willing would you be to have your child participate in a clinical research study?



No significant differences between those whose children had/did not have medical conditions



(n= 500) Base: All parents

Findings are similar to the 2019 Perceptions & Insights Study (n=12,451), as most were “Somewhat” (41%) or “Very Willing” (44%) to participate.

Parents are motivated for their children to participate to help others and find better treatments for their child

Please indicate reasons why you would (wouldn’t) be willing to have your child participate in a clinical research study?

Top 5 Motivations	%
Help others with the same disease/condition	42%
Better treatment for child	41%
Education about child’s treatment	41%
Advance science and new treatments	38%
Child’s doctor recommended	37%

(n= 390) Base: Parents who would be ‘Somewhat’ or ‘Very Willing’ to have their child participate

Top 5 Barriers	%
Concerns about the risks of clinical research	48%
Don’t want to take a chance with child’s health	46%
Don’t want child to be treated like a test subject	41%
Concerns about protecting child’s privacy	36%
I do not know enough about clinical research	32%

(n= 110) Base: Parents who would be ‘Not Very’ or ‘Not at all Willing’ to have their child participate, or were not sure

Altruistic motivations, like helping others and advancing science, were also top motivators among adult respondents in the 2019 Perceptions & Insights Study (n=10,479). Concerns about taking a chance with one’s health and the risks of clinical research were also top barriers among adult respondents in the 2019 Perceptions & Insights Study (n=1,974)

Study risks & benefits are the most important information for participation decision

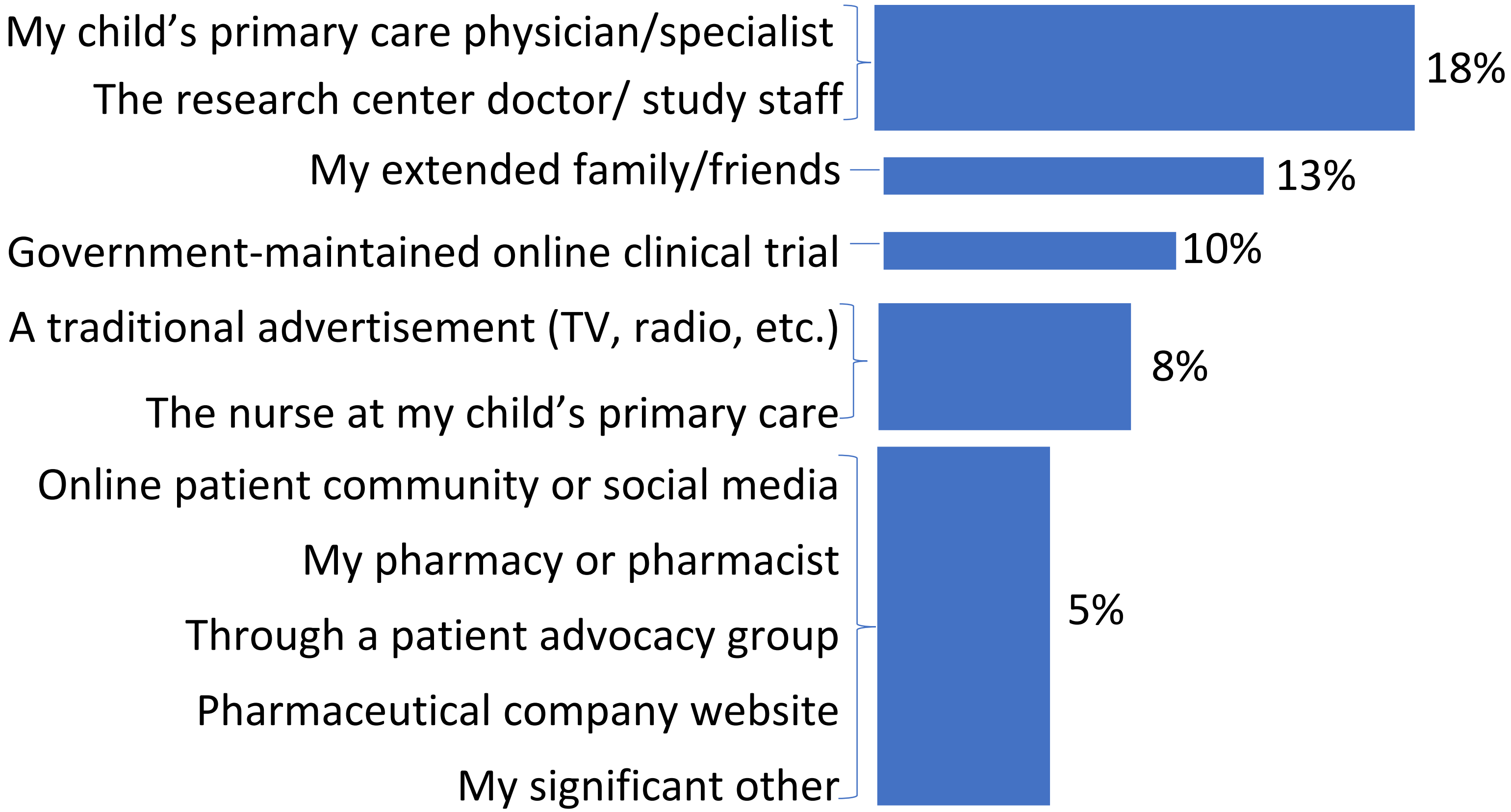
Before making a decision to have your child participate in a clinical research study, how important is it to you to know each of the following types of information?

% indicating "Very important" |TOP 10	All Parents (n=500)
Potential risks and benefits	79%
Types of medical procedures required	78%
Purpose of the clinical research study	73%
If my/our confidentiality would be protected	73%
Potential costs and reimbursements	67%
Duration of each study visit	65%
Length of participation in the clinical research study	64%
Results and information from earlier phase studies on the study drug	64%
If I would receive a summary of the study results after my participation ended	63%
Number of study visits	63%

The same top 3 considerations were seen among adult respondents making the participation decision for themselves. (n=12,451) However, parents place higher importance on logistical considerations, like study visit duration.

Parents whose children participated in studies are most likely to learn about these studies through their child's doctor or the study center

Where did you learn about the clinical research study?



n= 39 Base: Parents whose children have participated in a clinical research study

Primary care doctors/specialists and research centers/recruitment companies are also the top ways that children were asked to participate

n= 66 | Base: All parents whose children have been asked to participate in a clinical research study

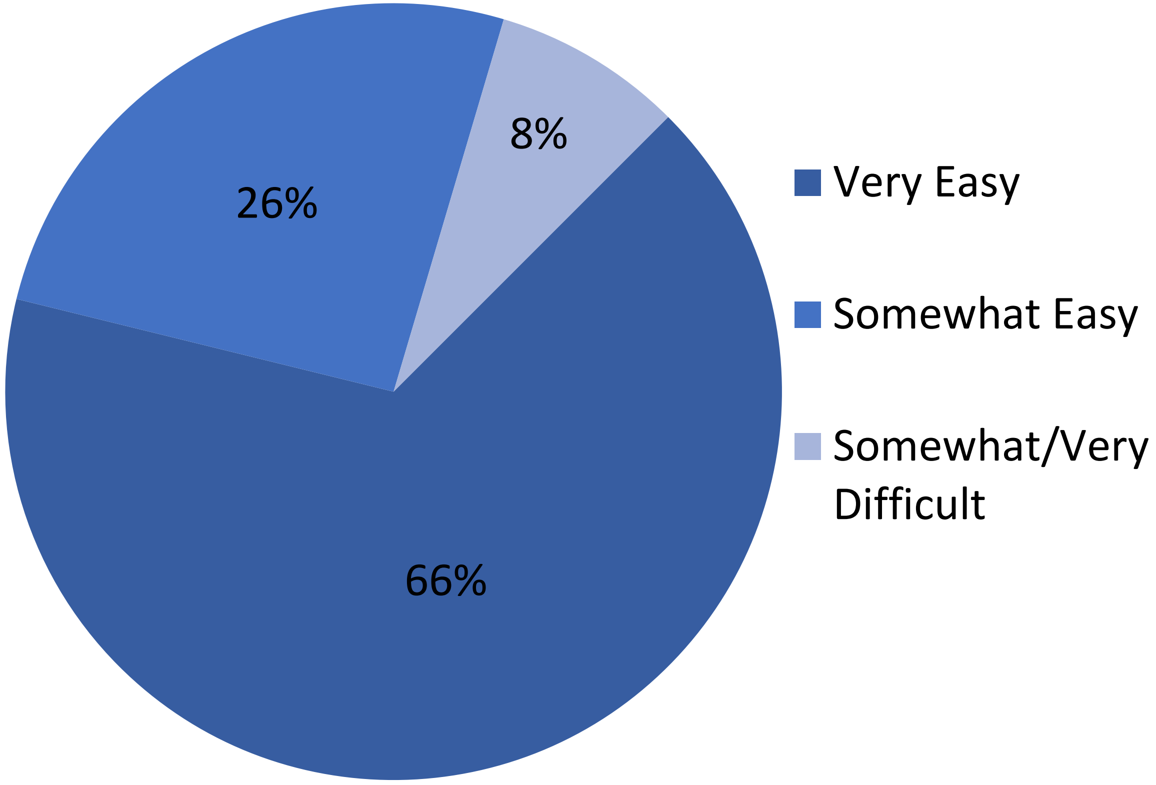
Parents are most likely to cite a doctor's recommendation as the reason they decided to have their child participate

Please indicate which of the following are reasons you decided to have your child participate in a clinical research study?

n= 39 | Base: Parents whose children have participated in a clinical research study	% (TOP 4)
My child's doctor recommended the study	38%
Help advance science and the treatment of my child's disease/condition	26%
To help others who suffer from my child's disease/condition	23%
My family or friends recommended the study	23%

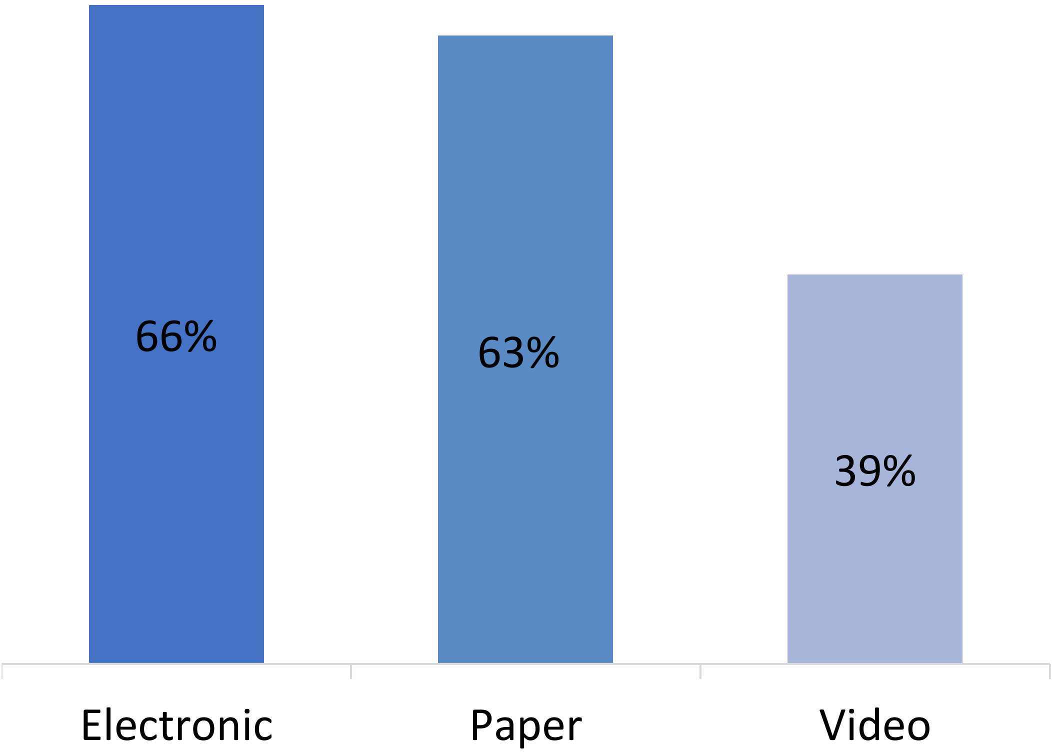
Most considered the informed consent form to be "Very Easy" to understand and report a number of format options to be available.

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



n= 39 | Base: Parents whose children have participated in a clinical research study

In what format did you receive the informed consent form for your child's most recent study?



The 2019 Perceptions & Insights Study found that only 48% of participants thought the consent form was "Very easy" to understand (n=3,654).

Supporting information is very important to parents during their child’s participation

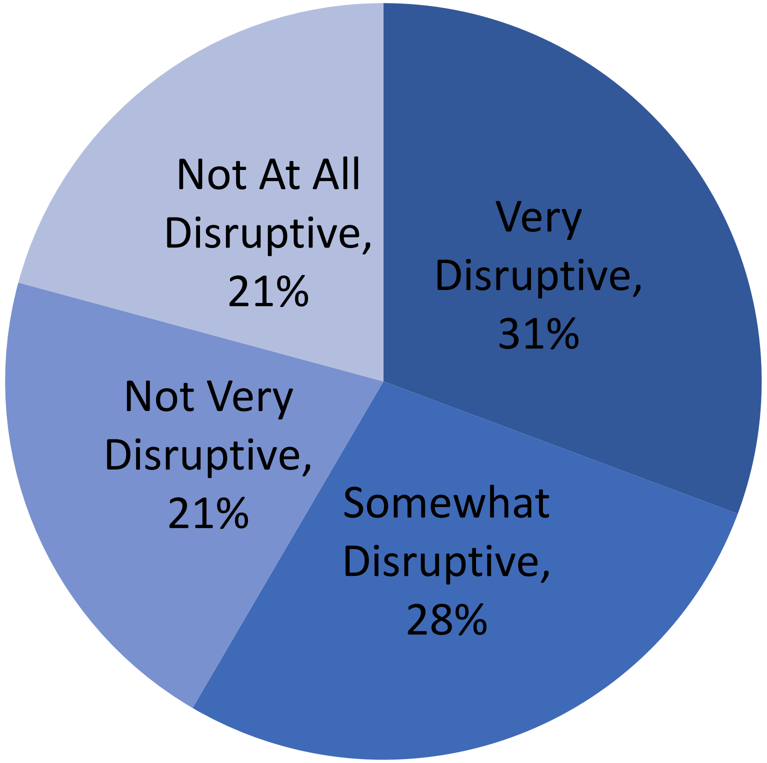
If you/your child were to participate in a clinical research study, how important are the following to your participation?

% indicating “Very important”	All Parents (n=500)
Provided with supporting information on the clinical research study	60%
Provided with supporting information on managing my health condition in general	58%
Availability of clinical research study information designed specifically for caregivers	54%
Clinical study medicine delivered to my home	49%
Availability of mobile applications (e.g., electronic surveys, visit reminders sent via text)	46%
Review and sign documents in electronic format	46%
Provided the opportunity to complete a satisfaction survey on your experience	45%
Concierge services	45%
Some or all study visits conducted at my home or my office	43%

Generally, the sequence of these considerations is consistent with adult Perceptions & Insights findings.

Most parents report the participation experience as burdensome and disruptive

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



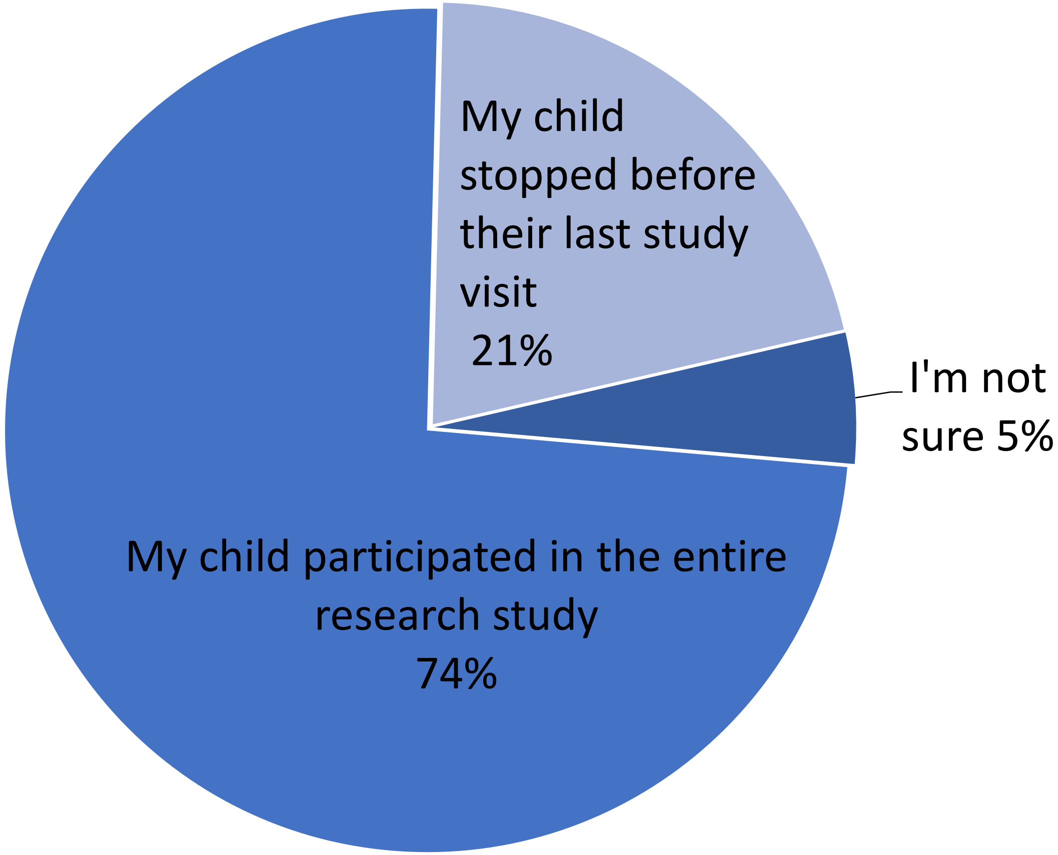
n= 39 | Base: Parents whose children have participated in a clinical trial

How burdensome was each of the following? % Somewhat or Very Burdensome	**Parents of children who participated (n=500)**
Traveling to the study clinic	64%
Lab work (e.g. blood tests, urine)	62%
The length of the study visits	54%
Completing health questionnaires	54%
Undergoing diagnostic tests (e.g. X-rays, MRIs)	51%
Taking the clinical study medicine	51%

By contrast, most (81%) of adult trial participants said that their experience was "Not Very/Not At All Disruptive." (n=3,654)

Despite burdens, most parents report that their children complete their study

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



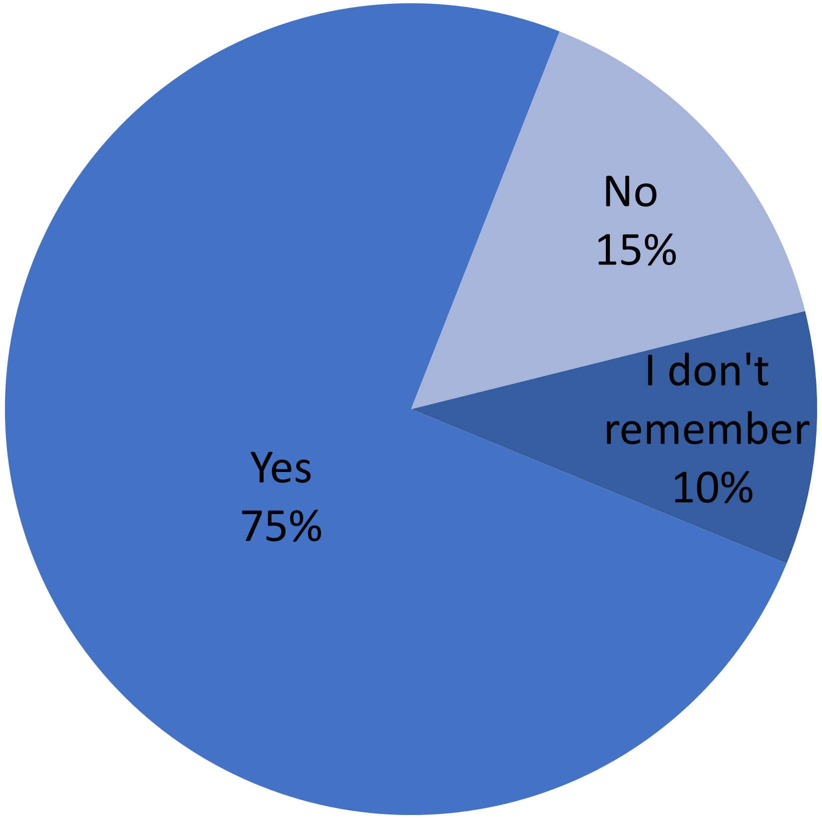
n= 39 | Base: Parents whose children have participated in a clinical trial

As the top reasons for stopping their child's participation early, parents cite fears that their child was receiving placebo (57%), and poor communication with the study center (43%)

n= 7 | Base: Parents whose children stopped participation early*
**Small Sample Size – view results with caution*

Most parents receive updates after their child's participation ends

Did you receive any reports or updates on the results of the study once your child finished the clinical research study?



n= 39 | Base: Parents whose children have participated in a clinical research study

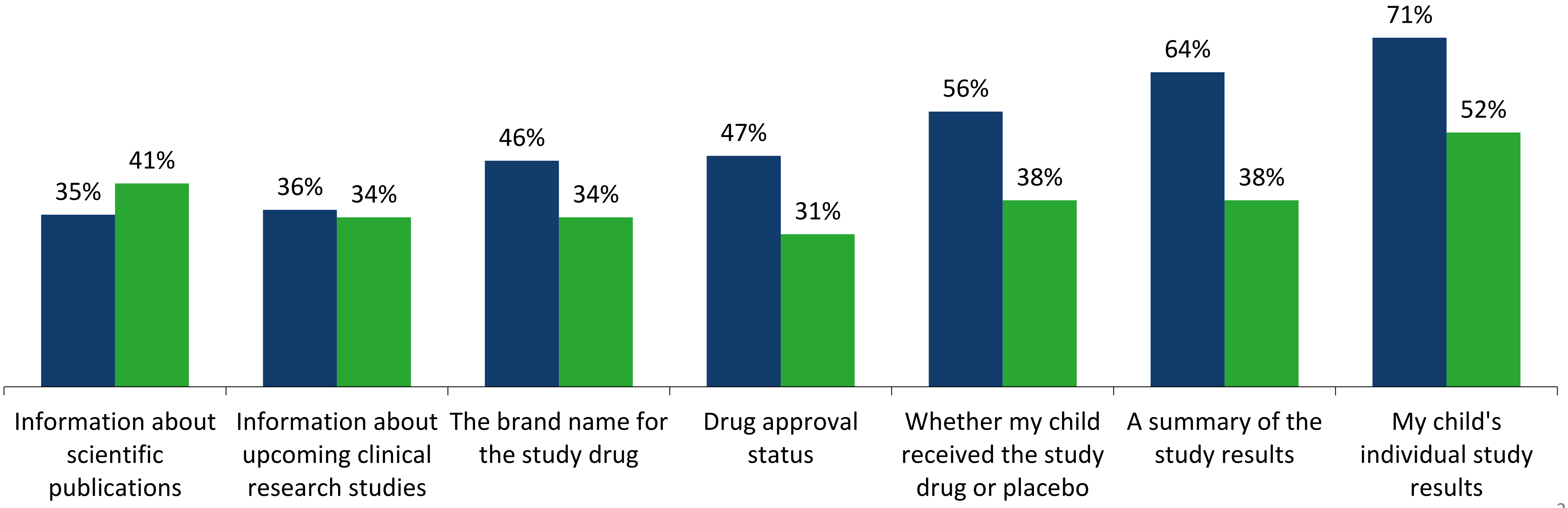
Most adult participants (52%) said that they did <u>not</u> receive reports/updates after participation.

However parents desire even more information than they receive

What information did you and your child receive? What information would you be most interested in?

🟦 ***If your child was to participate in a future clinical research study, what information would you be most interested in receiving after they completed their participation?*** n=500 | Base: All parents

🟩 ***What information did you and your child receive?*** n=39 | Base: Those whose children have participated in a clinical research study



Key Subgroup Differences Among Parents

By Gender and Race

Parent/Guardian Gender

- Fathers:
  - ✓ Report a better understanding of clinical research
  - ✓ Believed clinical research to be safer
  - ✓ Are more willing to have their child participate

- Mothers:
  - ✓ Are more likely to cite “I don’t want to take a chance with my child’s health” as a barrier to participation
  - ✓ Place greater importance on supporting information during participation

Parent/Guardian Race

- Parents who identified as Black report a better understanding of clinical research and were more willing to have their child participate compared to White parents.

- Parents who identified as Black also place more importance on the following compared to White parents:
  - ✓ Home visits
  - ✓ Information designed for caregivers
  - ✓ The ability to review documents electronically

Key Subgroup Differences Among Parents (continued)

By Education and Child’s Health

Degree of Education

- Parents who have completed higher levels of educational degrees:
  - ✓ Are more aware of pediatric studies actively enrolling
  - ✓ Discuss participation with their child’s pediatrician more often
  - ✓ Believe clinical research to be safer
  - ✓ Are more willing to have their child participate

Parent/Guardians of Children with Medical Conditions

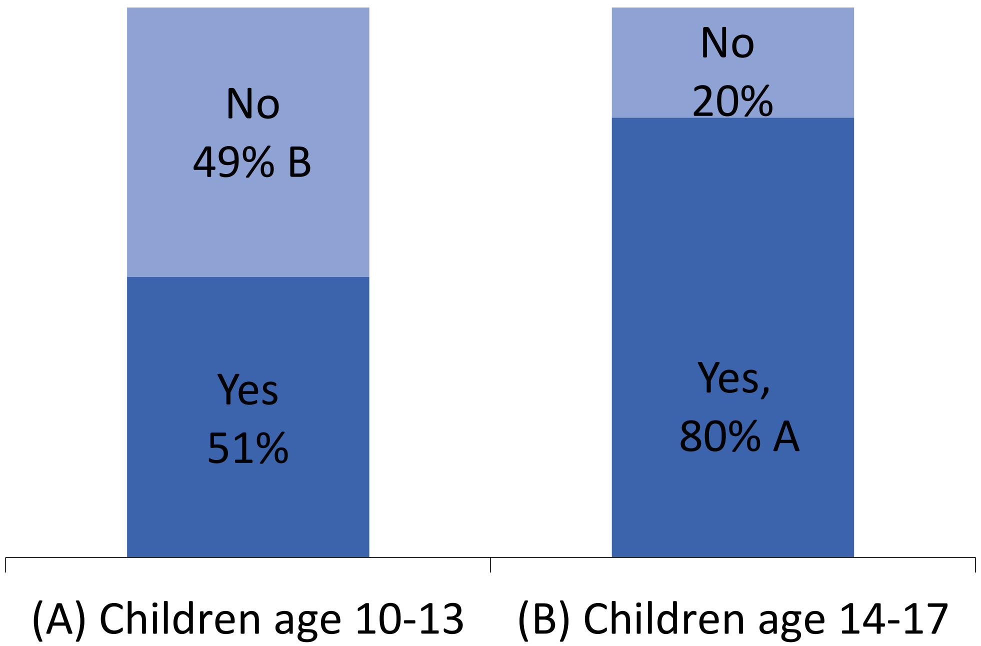
- Parents of children with medical conditions were apt to be:
  - ✓ Aware of pediatric studies actively enrolling
  - ✓ Discussing clinical research with their child’s doctors more frequently
  - ✓ Likely to say that their child was asked to participate
  - ✓ More willing to have their child participate in an interventional study

… Compared to parents whose children had not been diagnosed with a medical condition

Children Findings

Older children were more likely to have heard of clinical research

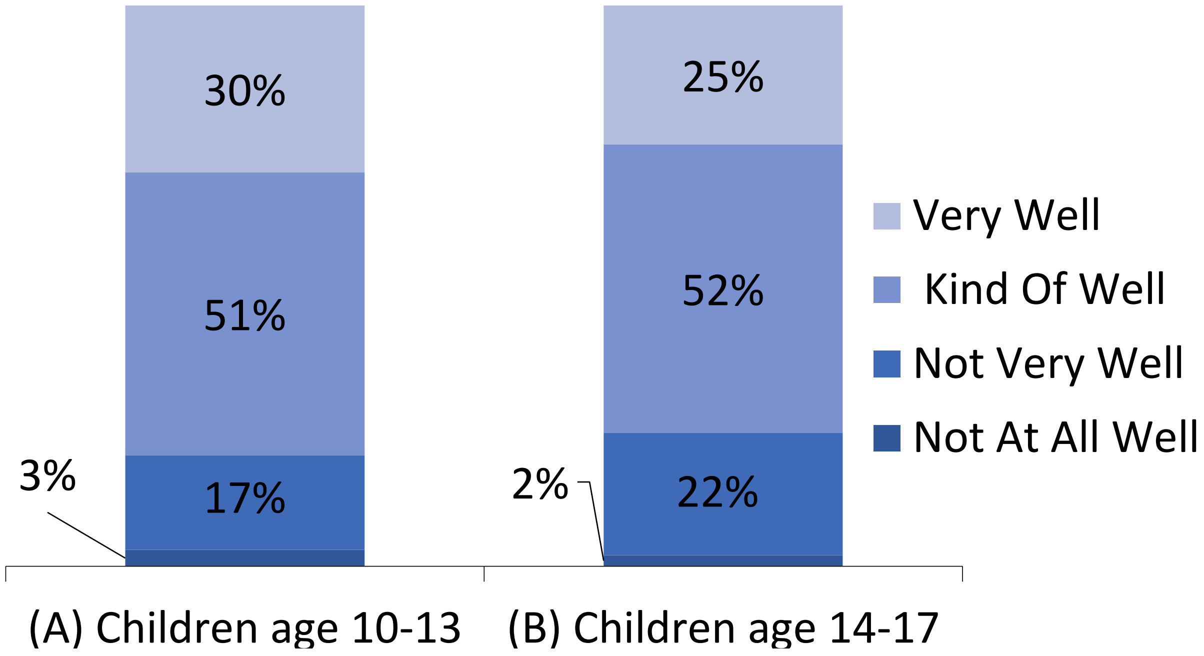
Have you ever heard of the words "clinical research study"?



n= 237 | Base: All children age 10-13

n= 249 | Base: All children age 14-17

[IF HEARD] How well do you understand what "clinical research study" is?



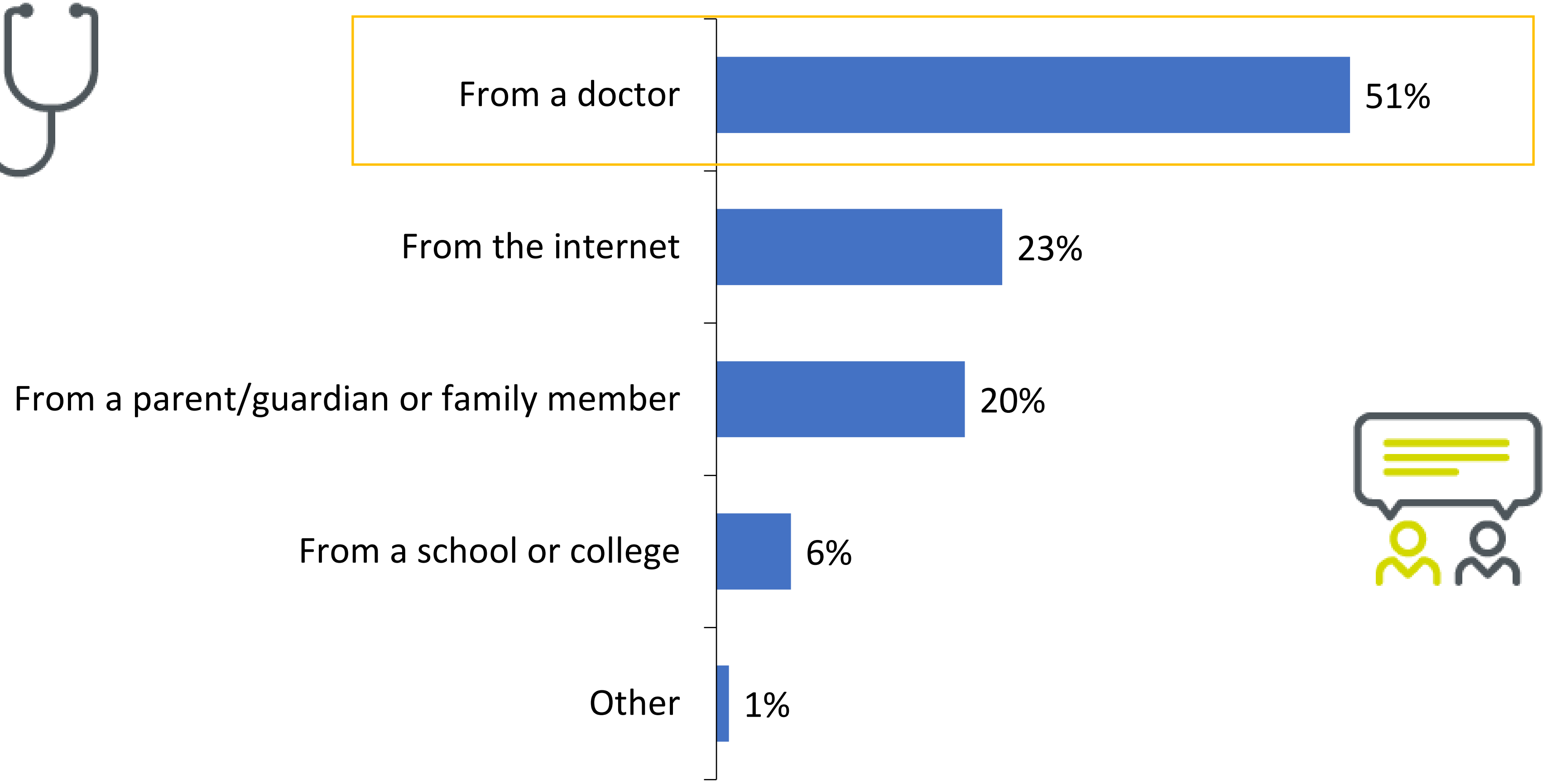
n= 120 | Base: Children age 10-13 who have heard of clinical research

n= 200 | Base: Children age 14-17 who have heard of clinical research

*Letters indicate statistical significance at a 95% CI

Children prefer to learn about clinical research studies through their doctor

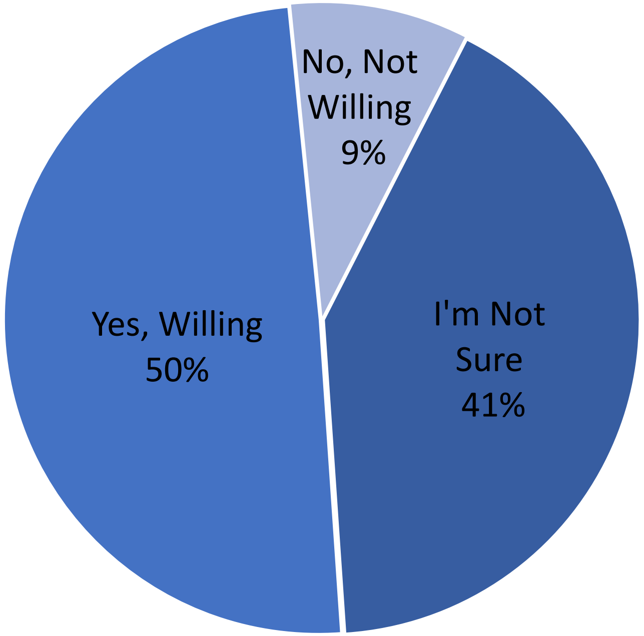
What is the best way kids and young people can learn about clinical research and find clinical research studies?



Sample Size = 486 Base: All children

Though half of children are willing to participate, many others are not sure if they are willing

Would you want to join a clinical research study? Why or why not?



(n= 486) Base: All children

What are some reasons you would want to participate? **Top 5 Motivations**	**%**
I want to help scientists and doctors learn more about my disease	**63%**
I want to get better medicine for my disease/condition	56%
My doctor and my family wanted me to join the study	33%
There are not many medicines or treatments for my disease	20%

(n= 239) Base: Children who would want to join a clinical research study

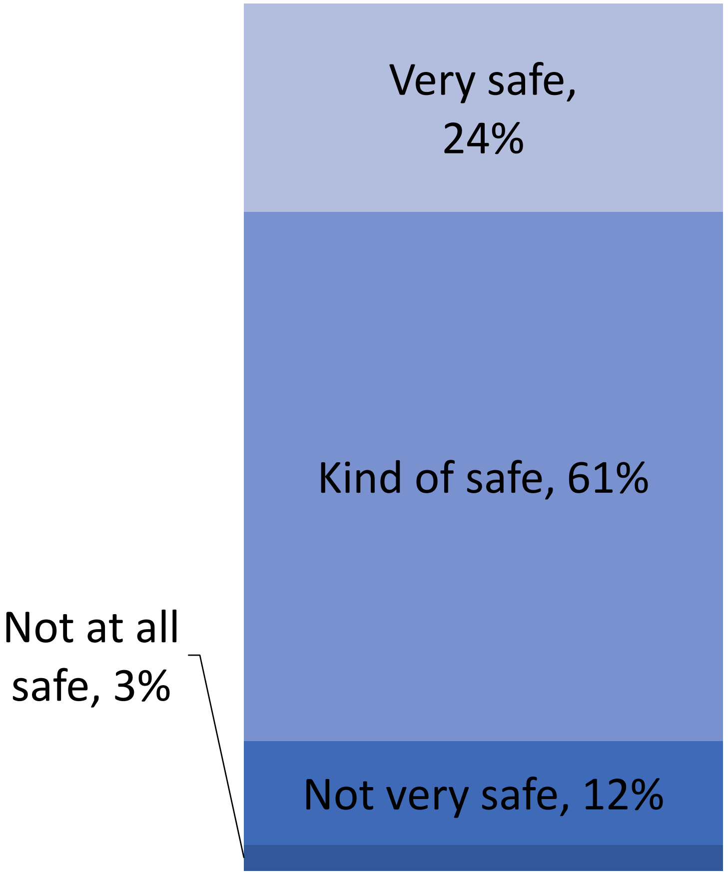
Top reason for participation is altruistic

What are some reasons you would not want to participate? **Top 5 Barriers**	**%**
I am scared something bad could happen and I could get more sick	62%
I am scared of needles for blood draws or shots	55%
I wouldn’t want to miss school or playing with my friends	40%
My regular doctor and my family would not want me to join	14%
I do not think the doctor in the study would take good care of me	8%

(n= 247) Base: Children who would not want to join a clinical research study or were not sure

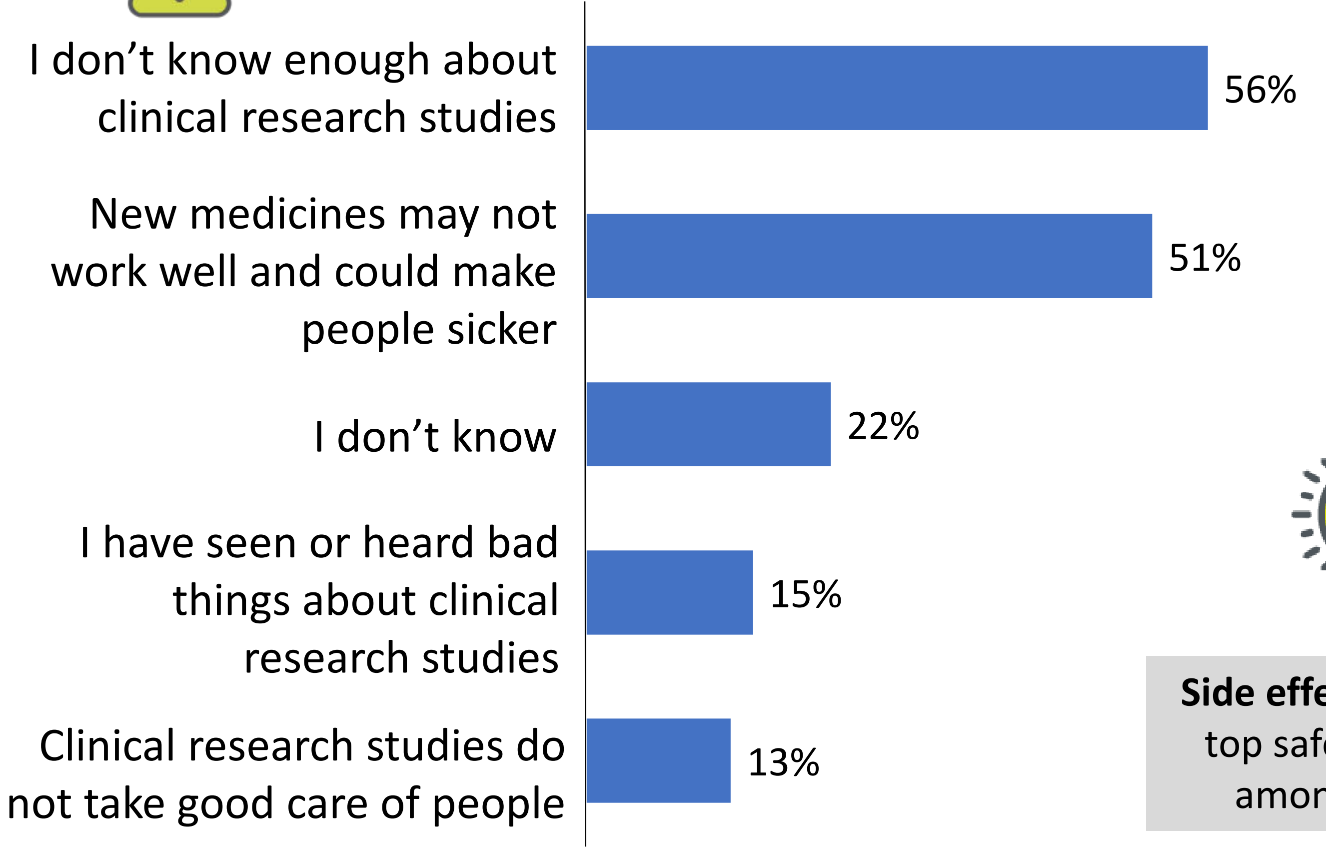
Most children believe that clinical research is safe; Those who are concerned indicate they don’t know enough about clinical research

How safe do you think clinical research studies are?



Sample Size = 486 Base: All children

Why do you think clinical research studies are not safe?



Side effects were the top safety concern among parents

Sample Size = 72 Base: All children who said that clinical research was “Not Very” or “Not At All Safe”

Children desire free Wi-Fi and snacks most during participation, but hearing from other pediatric participants is also highly important

If you were a part of a clinical research study, how important would these things be to you?

% indicating "Very important"	**All children (n = 486)**
Having free Wi-Fi at the research center	60%
Getting meals, snacks, and drinks while I am at the research center	59%
Getting to hear from other kids like me who have taken part in a study	58%
Being able to use apps on a smartphone for things like reminders for when I need to take medicine	53%
Being able to have some or all of my study visits done at home instead of having to go to the research center	52%
Getting information about how I can be healthier	49%

Children decide to participate because they want to advance science and get better treatment

Why did you decide to join the clinical research study?

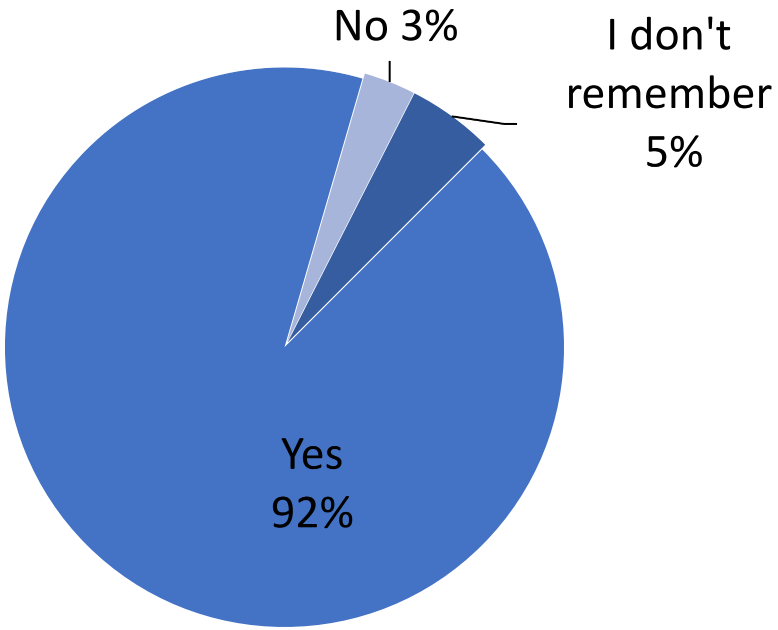
% Mentioning (Top 4)	Children who report participating (n = 59)
I wanted to help scientists and doctors learn more about my disease/condition	63%
I wanted to get better medicine for my disease/condition	58%
My doctor and my family wanted me to join the study	54%
There are not many medicines or treatments for my disease/condition	20%

Family or doctor recommendation is also a top motivator

Advancing science (31%) and getting better treatment (22%) were also among the top motivators for adult participants aged 18-34 (n=427).

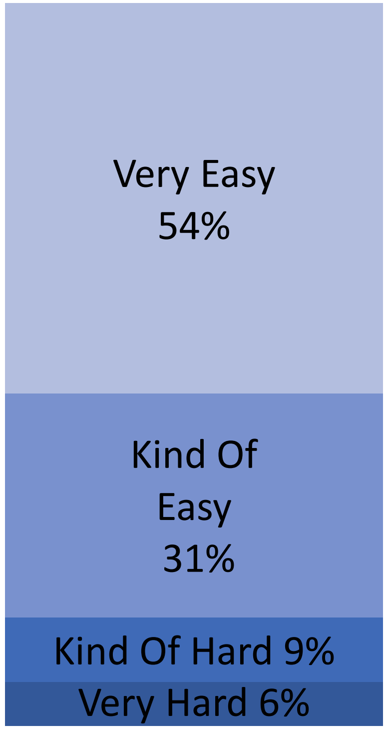
Most children remember getting information (i.e. Informed Consent Form), and were able to understand it

Do you remember getting information about the clinical research study before you joined?



(n= 59) Base: Children who self report having participated in a clinical research study

How easy or hard was it to understand this information?

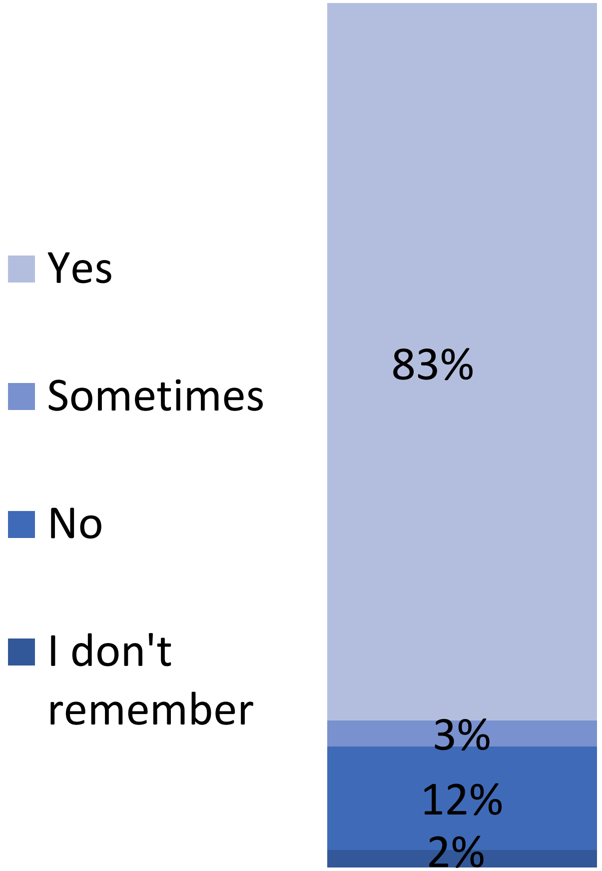


Sample Size = 54 Base: Children who remember receiving information about the study before they joined

Only 37% of adult participants age 18-34 thought the informed consent form was “Very Easy” to understand (n=427).

Most were able to continue with their daily routine – but found study medication and blood draws to be very burdensome

Were you able to do the things you normally like to do while you took part in the clinical research study?

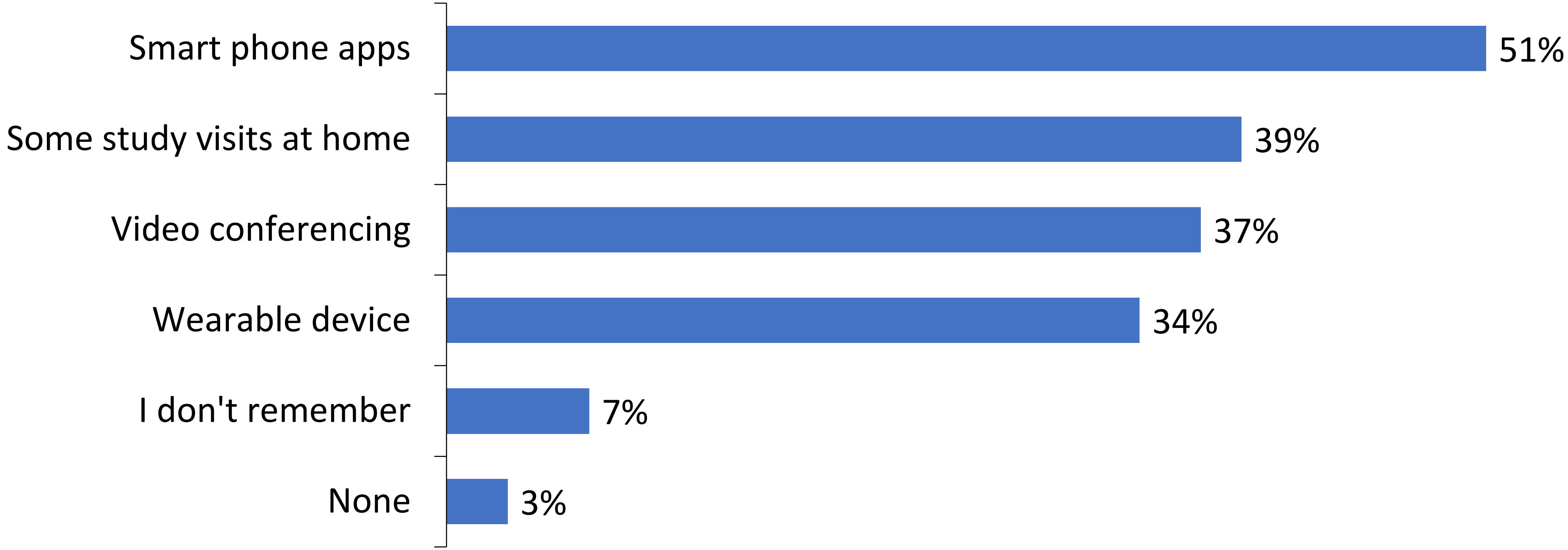


During the clinical research study, how hard were each of the following for you? % 'Kind Of' or 'Very Hard'	Children who reported having participated (n=59)
Taking the study medication	53%
Having a nurse take blood using needles	50%
Having medical tests done	49%
Having to answer questions on paper or on a tablet	46%
Having to miss school	44%
Having to pee in a cup	41%

n= 59 | Base: Children who self report having participated in a clinical research study

Most used smartphones and other technology during participation

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

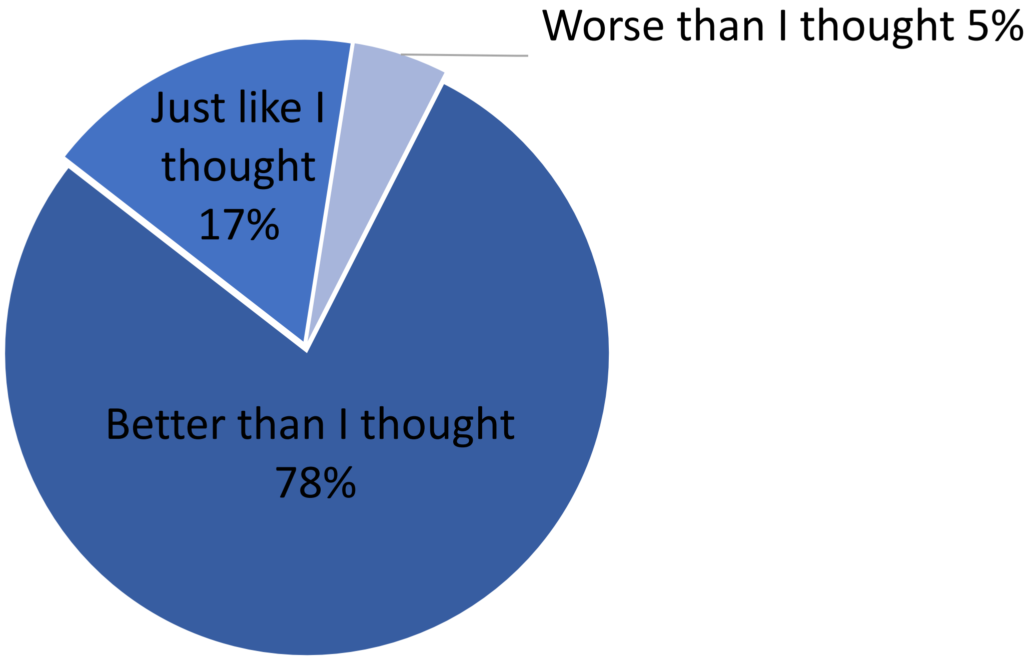


n=59 | Base: Children who self-report having participated in a clinical research study

Pediatric study participants report far more prevalent use of smartphone apps compared to adult participants, only 15% of whom said they used apps during participation (n=3,654).

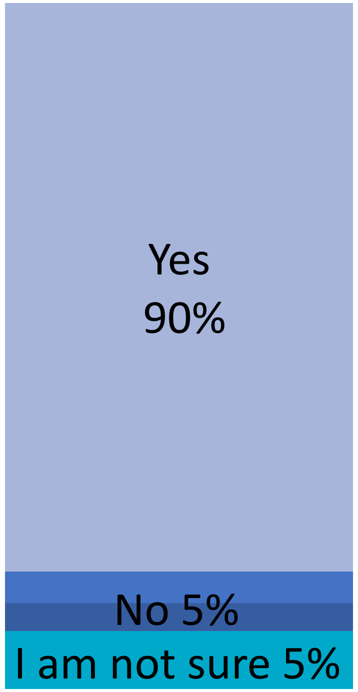
Most report a better experience than they expected, and would be willing to participate again

Did being part of the clinical research study end up being like you thought it would be?



(n= 59) Base: Children who self report having participated in a clinical research study

Would you want to join another clinical research study someday?



(n= 59) Base: Children who self report having participated in a clinical research study

Though children are very likely to want to participate again, younger adult participants age 18-34 were least likely (51%) to say that they would be ‘Very willing’ to participate again compared to older age groups (n=427).

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

HEALTH COMMUNICATION SERVICES

Information in plain and easy-to-read language

- Trial Results Summaries
- Health Communication Projects
- Editorial Panels

INTERNATIONAL EDUCATION & AWARENESS

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

COMMUNITY ENGAGEMENT

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

For more information about CISCRP and our services, contact us at 877-633-4376, email info@ciscrp.org or visit www.ciscrp.org

About Parexel

Parexel is focused on supporting the development of innovative new therapies to improve patient health.

- We do this through a suite of services that help life science and biopharmaceutical customers across the globe transform scientific discoveries into new treatments for patients.
- From clinical trials to regulatory and consulting services to commercial and market access, our therapeutic, technical and functional ability is underpinned by a deep conviction in what we do.
- We are proud to have helped develop 99% of the 200 top-selling biopharmaceuticals on the market.
- Our more than 16,000 colleagues across more than 100 countries are focused on keeping the patient at the heart of everything we do.
- For more information, visit our website and follow us on LinkedIn, Twitter and Instagram.