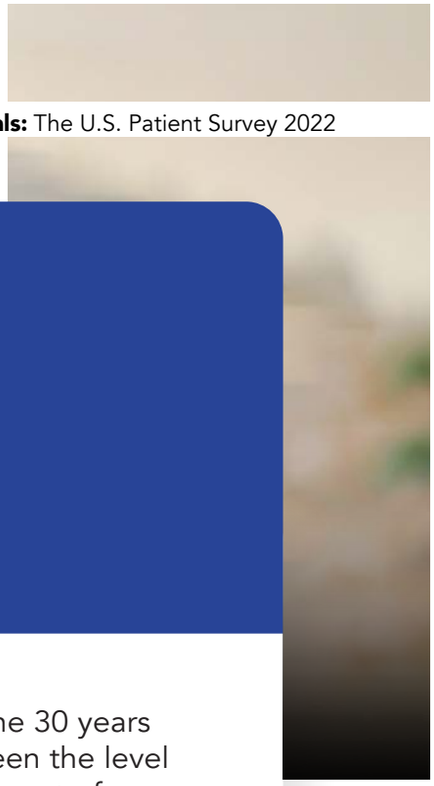
Velocity
CLINICAL RESEARCH

Clinical trials:
The U.S. Patient Survey 2022

Decentralisation in clinical research



Introduction

A Note from Velocity Clinical Research's Chief Executive

From over-the-counter headache treatments to innovative new cancer drugs, pharmaceutical research and development has revolutionized health care. These breakthroughs are the product of decades of clinical research, and clinical trial volunteers are the irreplaceable heroes of the story. Their willingness to participate in the research process is critical to bringing these compounds to market and improving lives.

The general public is mostly unfamiliar with clinical research, but the topic of clinical trials exploded into public consciousness during the COVID pandemic. The industry, regulators, and the general population pulled together at unprecedented speed to get COVID-19 vaccines tested and approved for use around the world.

The pandemic also gave rapid rise to the use of new technology and study design in clinical research, as data still had to be collected despite nation-wide lockdowns. As in many parts of our lives, we had to find ways of carrying on from home.

The topic of diversity was brought to the fore in a way it hadn't before. Whilst this has always been an issue in the 30 years of my career, we had never seen the level of attention that the development of a COVID vaccine paid to having a fully representative subject population. For the first time in most people's memories, we actually saw trials effectively slowed down in order to get the right mix of patients enrolled in the Operation Warp Speed studies.

Clinical studies are notorious for delivering late. Most delays are at the point of contact with the patient. Yet, during the COVID pandemic, clinical trials were delivered at unprecedented speed. Each COVID vaccine called for studies with upwards of 30,000 subjects and were delivered in weeks, not months. Evidently, the problem of scaling clinical research can be overcome. The question remains — was this is an exceptional case or can we truly scale clinical trials to deliver faster?

Although patient recruitment is the slowest part of clinical research, COVID-19 demonstrated that recruiting patients to trials can speed up if engagement increases. As a result, there are drives to decentralize clinical research so that

Dr G. Paul Evans,
CEO of **Velocity Clinical Research**

more people can take part. This year the FDA announced new guidance to increase racial diversity of subjects in clinical trials.

Whether or not the COVID vaccine developments were a major catalyst or not, there is no doubt that the winds of change are blowing through clinical research. Patients are at the heart of them. Therefore, it seems sensible that we have a better understanding of the patient experience in clinical research and how they react to the changes afoot.

In 2022 Velocity undertook the first national survey in the U.S. of patients who have previously taken part in clinical research, receiving **1,129 responses**. We wanted to gauge views and attitudes on taking part in clinical research, including thoughts regarding decentralization and the use of technology.

The results led us to three key insights and some surprising subgroup differences, which are laid out in detail in this report. The results gave us a great deal of insight, some unexpected, into our patient population. We plan to continue collecting patient survey data and will publish more in the future.

Insight 1

Technology is not widely used in research today, nor is it sophisticated. However, volunteers of all ages are overwhelmingly willing to use it.

Insight 2

Home visits will not solve racial and ethnic diversity issues, and could exacerbate them.

Insight 3

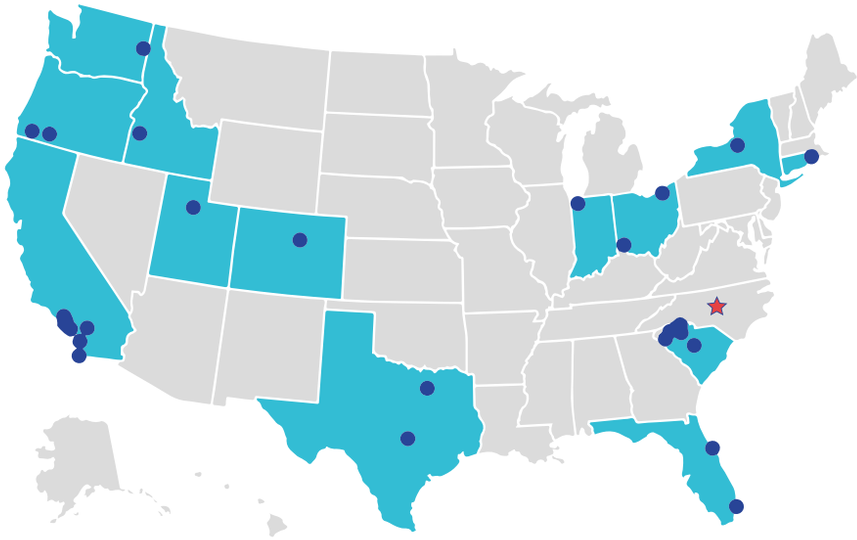
60 percent of volunteers aged 18-34 have participated in multiple studies.

Methodology

The patient survey was conducted by Velocity Clinical Research, an integrated site company with 39 locations across the U.S. Emails with an anonymous survey link were sent to study volunteers in the company's database during H1 2022. There were 1,129 responses. The survey questions focused on study design decentralization methods, and were divided into two categories:

1. What was your experience in the trials you have completed?

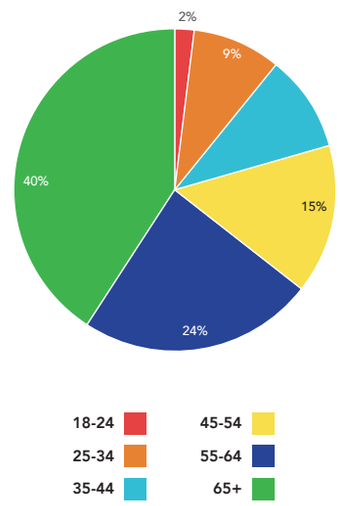
2. What are your preferences for future trials?



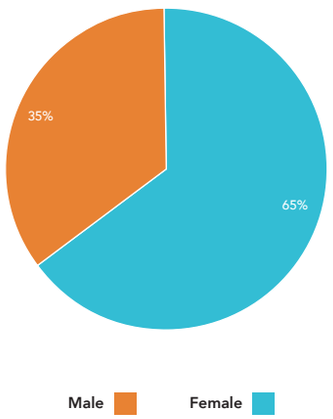
Velocity Clinical Research site locations - US

Survey participant demographics

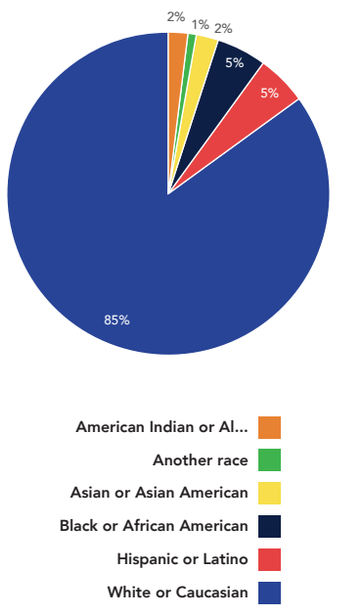
Age breakdown of survey participants

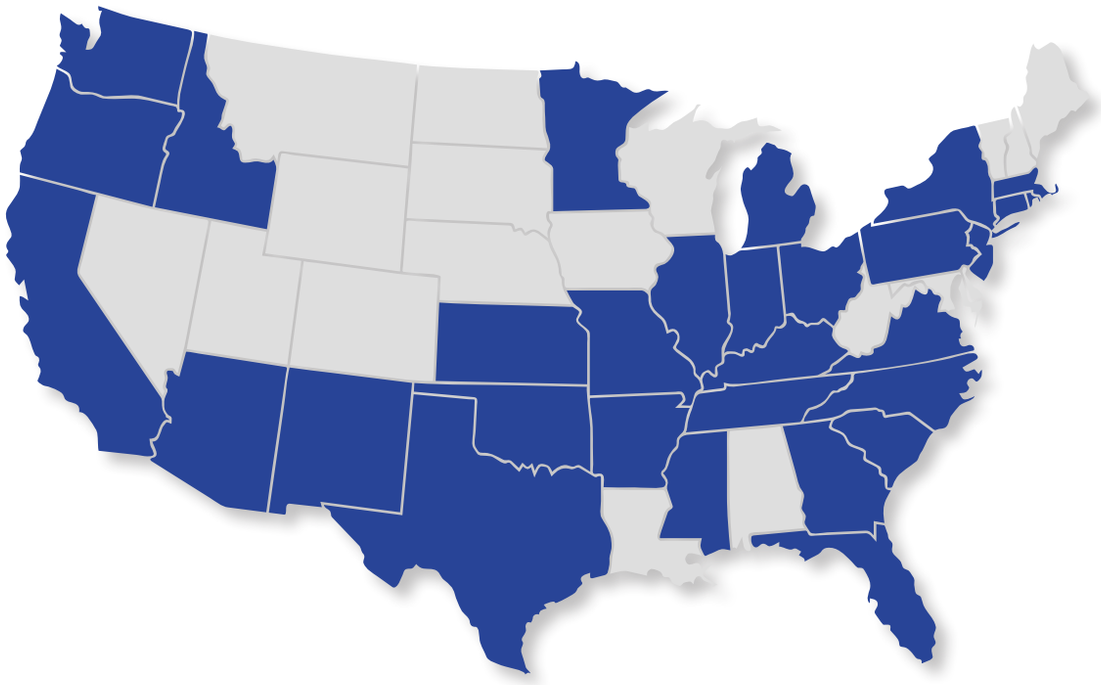


Gender breakdown of survey participants

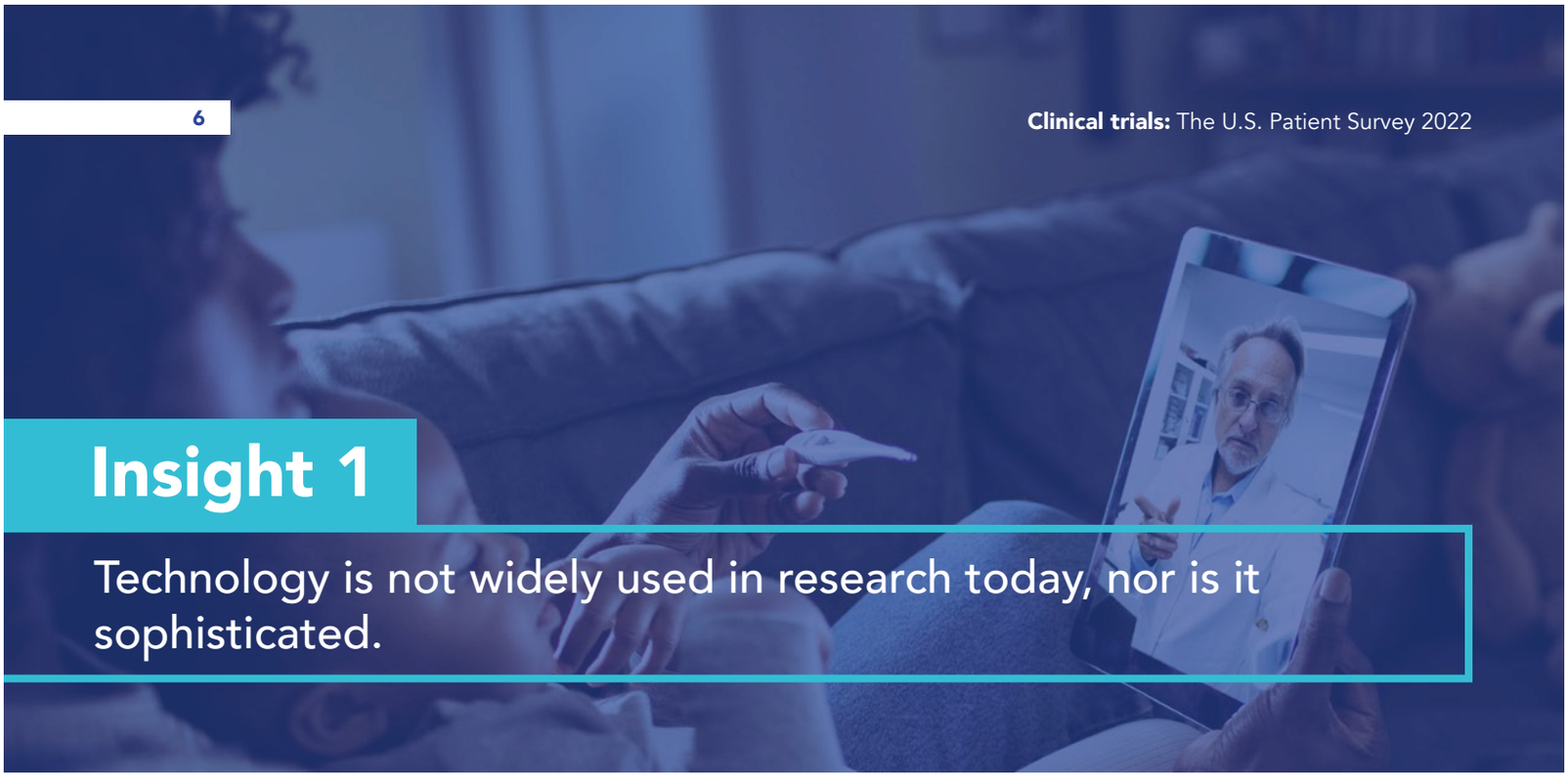


Ethnic breakdown of survey participants





US States represented by respondents



Insight 1

Technology is not widely used in research today, nor is it sophisticated.

Patient experience with telehealth and other technology in clinical research remains low. The older a participant is, the less likely they have used telehealth options such as phone calls, texts and in-person home visits, in a clinical trial. This is crucial because these mechanisms for remote communication with patients are a large part of the movement toward study decentralization.

Just less than half (43 percent) of patients surveyed across all age groups had no experience at all with study-related phone calls, texts, or home visits. Interestingly, that number rises to 50 percent for volunteers aged 18 to 24. Fewer than three percent of volunteers over the age of 45 had experience with all three remote mechanisms, which is important because clinical trial participants tend to skew older.

Did your participation in a clinical trial include any remote or home-based visits? Check all that apply

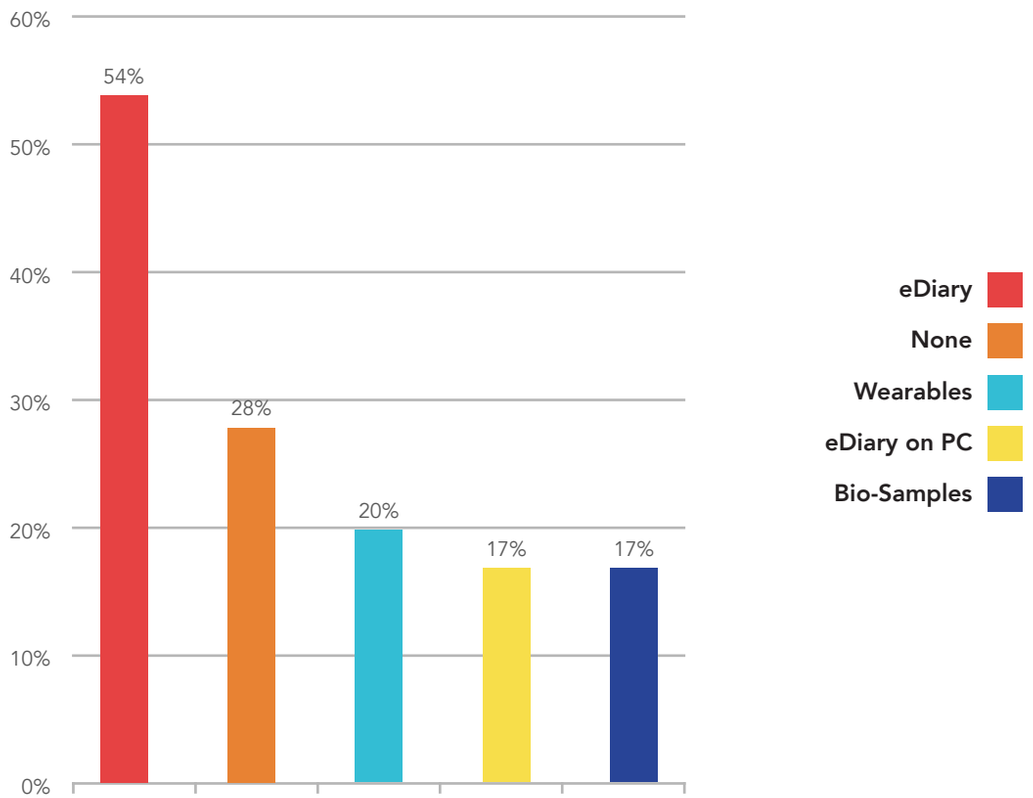
Age 1	None of the above	Phone calls only	Phone and text	Text only	Phone, Text and Home
18-24	50%	25%	25%		
25-34	29%	29%	25%	13%	4%
35-44	44%	30%	22%	4%	
45-54	37%	25%	27%	8%	2%
55-64	45%	23%	26%	5%	1%
65+	49%	27%	18%	6%	1%

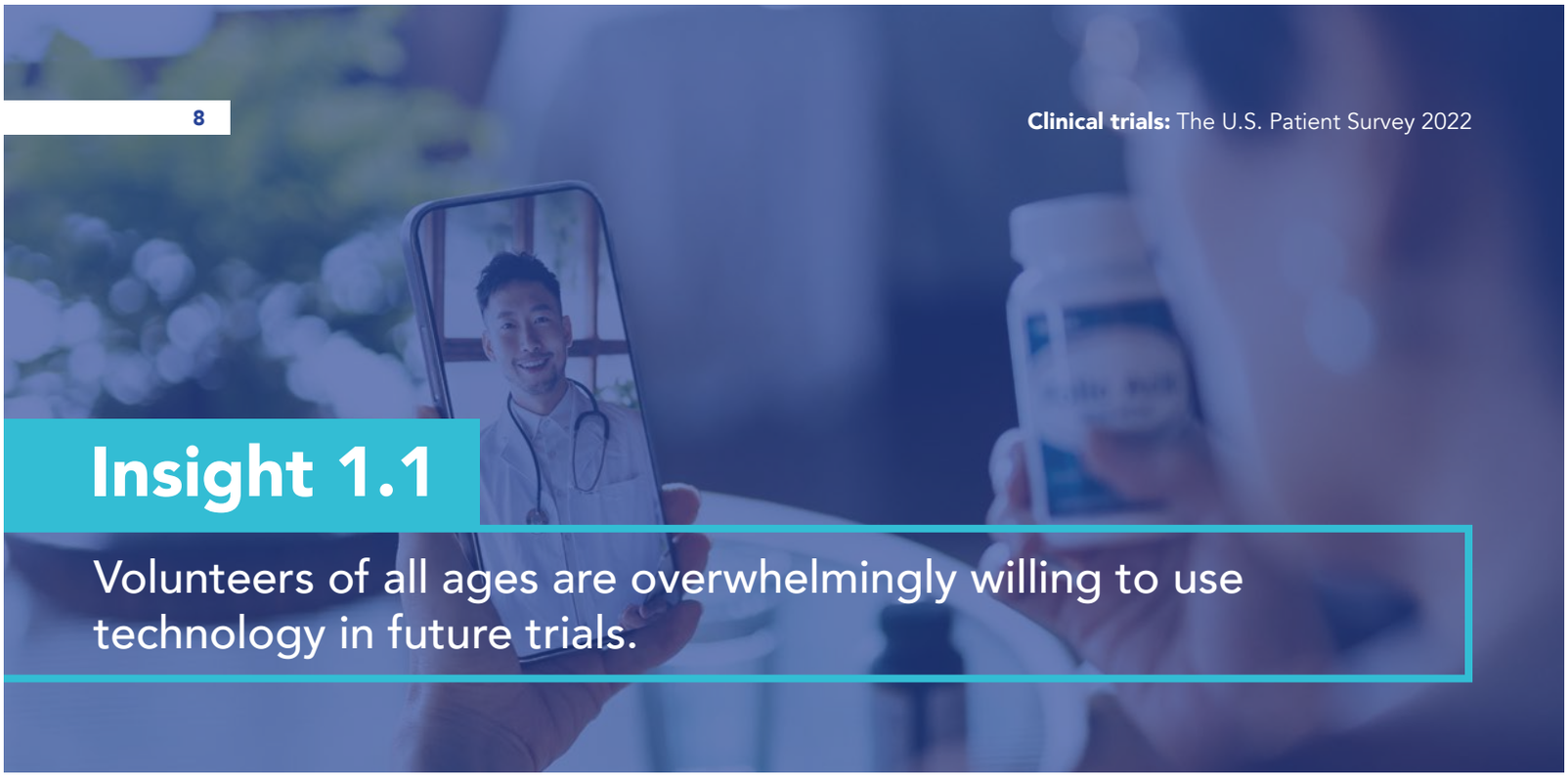
The pandemic provided stimulus for a higher usage of more advanced technology in clinical research, as the industry sought alternative ways to collect data. The technology most used to date are e-diaries and other tools are becoming more prevalent. A recent explosion of technology providers coming into the space provide solutions to meet the demand for more remote data collection. Despite this accelerated adoption of technology usage in clinical research, the options being deployed are still fairly unsophisticated relative to mass market phone apps and digital devices.

Survey participants were asked to indicate what home-based technology or procedures they had experience of using whilst taking part in a clinical trial. Options included, electronic diaries on both mobile and desktop, collecting bio samples and using wearable technology to measure health remotely such as blood pressure, heart rate and glucose monitors.

More than half (54 percent) of survey participants have used an e-diary, 20 percent have used wearables, and 17 percent have collected biosamples at home. Almost a third (28 percent) of people who have previously taken part in clinical research had not used any decentralized elements. This points to the penetration of decentralized technology in trials to still be at a low level. Technologies that are deployed are at the less sophisticated end of the spectrum.

Technology used previously in clinical research by survey participants





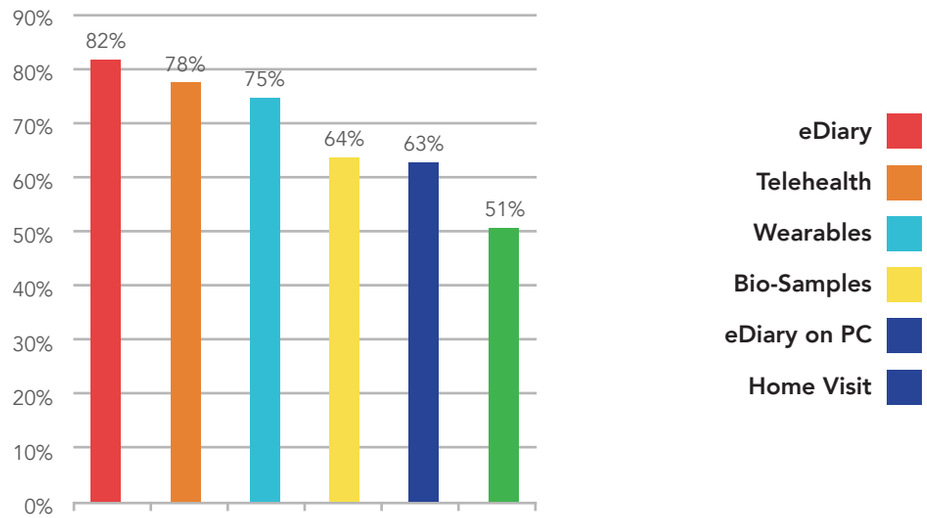
Insight 1.1

Volunteers of all ages are overwhelmingly willing to use technology in future trials.

A majority of study volunteers are comfortable with the idea of using technology for study visits and data collection. The respondents strongly supported the use of e-diaries (82 percent), telehealth visits (78 percent), wearables and home monitoring devices (75 percent), and at-home collection of bio-samples (64 percent) during future participation in clinical research.

Home visits, strikingly, are the least desirable decentralized option, with only 51% of research participants favoring this for future trial participation. Subgroup analysis tells a more nuanced story, with some groups having a strong preference against home visits.

Decentralization preferences for future participation in clinical trials

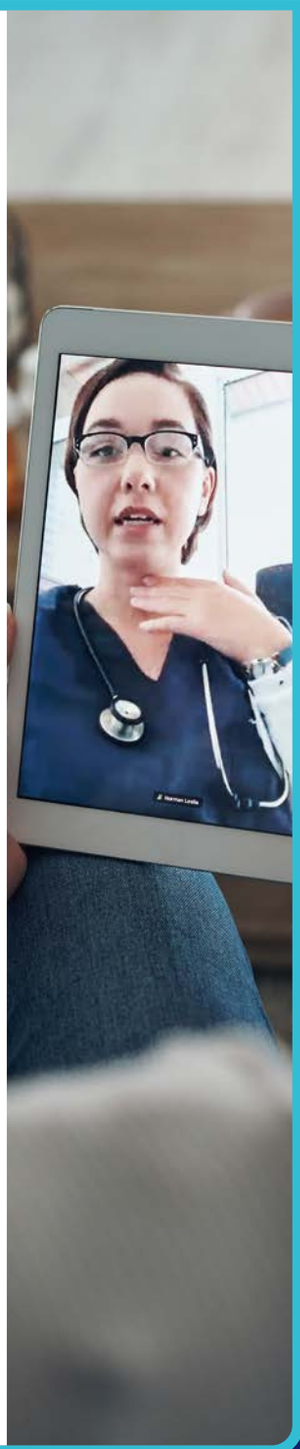


Telehealth

When asked about the use of telehealth (virtual) for future participation, older participants are more likely to want to opt for this than younger ones. The older a participant is, the stronger their preference is for telehealth options, except for people over the age of 65:

- **Female**
  - 18-24 > 45 percent
  - 25-34 > 63 percent
  - 35-44 > 81 percent
  - 45-54 > 83 percent
  - 55-64 > 90 percent
  - 65+ > 73 percent (drops)
- **Male**
  - 18-24 > 57 percent
  - 25-34 > 61 percent
  - 35-44 > 69 percent
  - 45-54 > 83 percent
  - 55-64 > 82 percent
  - 65+ > 73 percent (drops)

- The strongest preference for telehealth options is among women ages 55-64 (90 percent).
- 78 percent of study volunteers would likely use telehealth options in future trials. There is a marginal increase to 81 per cent in people's preference for these options If they have experience with telehealth in previous trials.
- Preference for telehealth options is lower among younger participants. Only half (50 percent) of 18–24-year-olds would use telehealth, rising to 65 percent of volunteers ages 25-34.
- Younger women are less likely to opt for telehealth, with only 35 percent of women aged 18-34 feeling comfortable using telehealth options in the future.



Key takeaway:

Telehealth options are more attractive to older patients who may find it more difficult to get to a site for physical or lifestyle reasons. We predict that the more prevalent telehealth options become in routine medical care, the more comfortable patients will be to use them in future clinical research.

Bio-Samples

Patients were asked about how comfortable they were with collecting their own bio samples, including nasal swabs, finger stick and urine samples etc. There is a stark difference in age and willingness to collect biosamples. Only a third (33 percent) of 18-34 year olds feel comfortable collecting bio samples remotely. Contrastly, three quarters (75 percent) of people aged between 34 and 65 would collect their own bio samples. Over the age of 65, this drops slightly to 65 percent.

Overall nearly two thirds (64 percent) of people indicated they would collect their bio samples remotely whilst participating in future research. The split between men and women is fairly similar:

- Men - 62 percent
- Women - 65 percent

Key takeaway:

Young people probably have less experience with collecting bio samples. Technology providers must design this technology that is non-invasive and easy to use.

E-diaries

- There is a higher preference overall to complete e-diaries on mobile (82 percent) than on desktop (63 percent)
- Men ages 55-64 have the strongest preference (75 percent) to use a desktop for their e-diary submissions.
- Over 80 percent of women are happy to use e-diaries on a mobile device. This is particularly pronounced among women ages 45-54 (95 percent). This drops only slightly for men in the same age group (89 percent).

Key takeaway:

E-diary technology should focus on sophisticated, user-friendly mobile apps. They should be designed in a way that reduces patient burden.

Wearables

In this survey, wearables were defined as monitors for measuring things like blood pressure, heart rate and glucose levels. Whilst experience of using wearable technology was low, there was a strong preference to use remote technology for data collection in the future.

- 20 percent of participants had used wearable technology in previous research.
- Nearly two thirds (60 percent) of volunteers would be willing to use wearables in future research. This rises to 70 percent for men and is on par with the female average of 60 percent.
- Only 46 percent of African American males would want to use wearables in future research and this rises to 65 percent for African American females.
- 55 percent of people over the age of 35 are more comfortable with the use of wearables in clinical research than younger participants aged 18-34 (35 percent).

Key takeaway:

Young people are not familiar with the use of wearables in clinical research. Designers must think how these technologies could be built into devices that young people already use, such as smartphones and fitness trackers.

Home visits

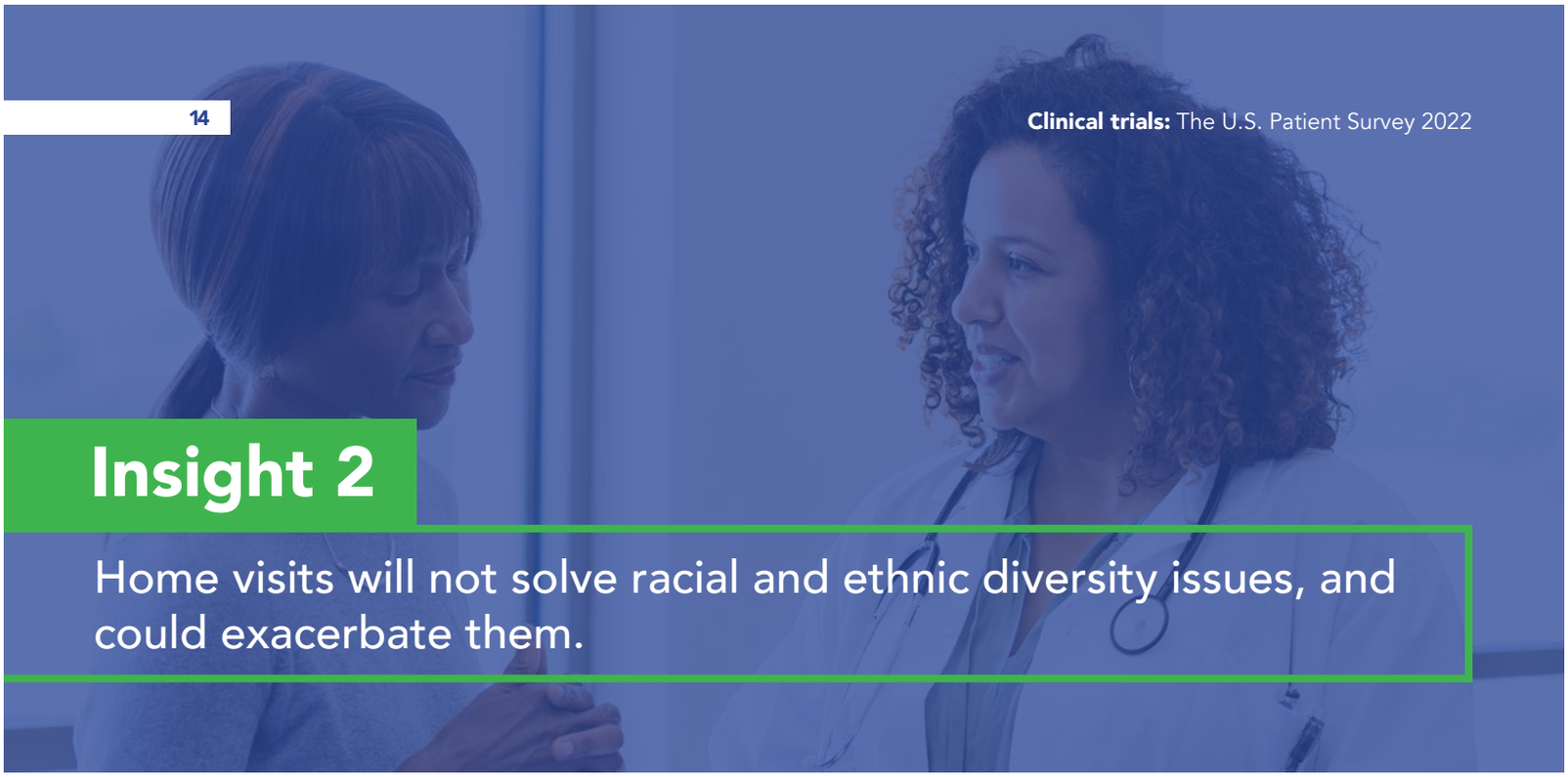
Home visits were the least desirable option out of all decentralization options for future participation in clinical research; only 51 percent of respondents would be willing to participate in at-home visits. 66 percent of volunteers under the age of 35 do not want home visits and only 45 percent of study participants over age 65 said they would like a healthcare professional to come to their home.

Older women and Gen Z have the same preference. 79 percent of women over 65 and 82 percent of females under 25 want to go to a clinic. The biggest cohort of people who would like more virtual visits are women ages 45-54 (59 percent).

The lack of preference for telehealth solutions has a strong correlation with lack of appetite for home visits. 85 percent of people who said they did not want to use telehealth in future trials also did not want to use home visits as an option.

Key takeaway:

Younger people are more likely to live in shared accommodation, making these conditions difficult for healthcare professionals to come to their home. Middle-aged women are more likely to opt for home visits, perhaps due to lifestyle and responsibilities making it difficult to have time away from home. A majority of patients would prefer hybrid solutions for meeting with healthcare professionals, combining in-clinic and virtual visits.



Insight 2

Home visits will not solve racial and ethnic diversity issues, and could exacerbate them.

Overwhelmingly, participants in Velocity's U.S. patient survey would prefer to attend a clinic for visits with healthcare professionals (76 percent), compared with conducting study visits at their homes (26 percent). This trend is slightly more skewed to men (76 percent) versus women (73 percent). This is even more pronounced among people from racially and ethnically diverse populations.

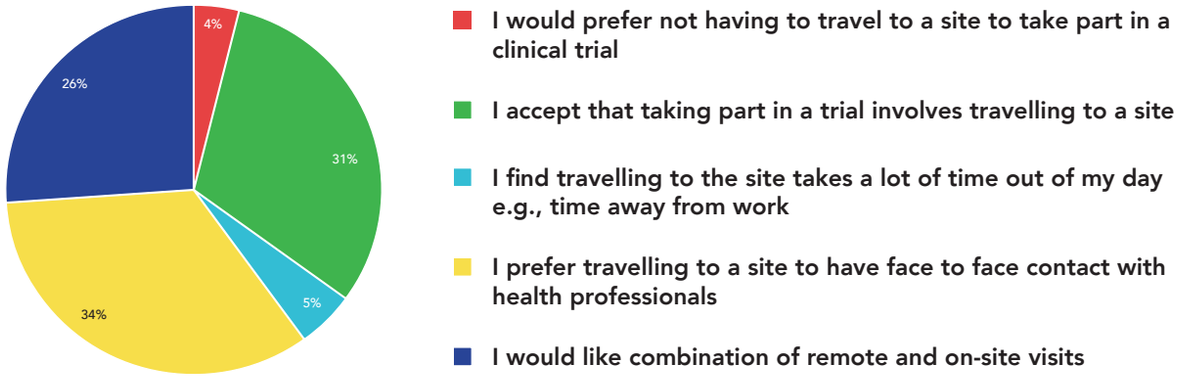
70 percent of young black women under the age of 35 and 90 percent of older black women aged 55-64 want to go to a clinical trial site to take part in a study. **No black female respondents** chose 'home visit' when given the options of '*home visits*', '*virtual appointments*' or '*in clinic appointment*' for future participation in clinical trials.

Hispanic women are more likely to be open to the idea of home visits than women from other minority backgrounds. Over half (55 percent) of hispanic women between the ages of 35-54 indicated they would be open to having healthcare professionals visit their home, compared with just over a third (35 percent) women from other diverse backgrounds.

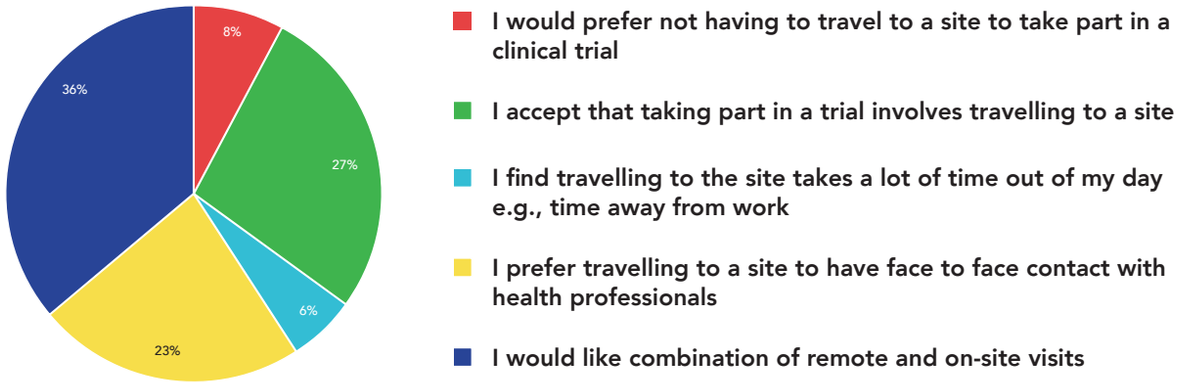
Those surveyed were asked to pick the statement that best reflects their view, when it comes to visiting a research site for their trial:

- I prefer traveling to a site to have face to face contact with health professionals
- I accept that taking part in a trial involves traveling to a site
- I find traveling to the site takes a lot of time out of my day, e.g., time away from work
- I would prefer not having to travel to a site to take part in a clinical trial
- I would like a combination of remote and on-site visit

Male responses – clinical trial survey



Female responses – clinical trial survey



Of the people surveyed who have previously taken part in clinical research, there is a strong preference for a hybrid solution of clinic-based and telehealth options for health practitioner appointments. Travel is an accepted part of taking part in a clinical trial (28 percent). When given the option, 80 percent of people changed from home visit to telehealth and half (50 percent) changed their preference from traveling to a clinic to telehealth.

Clinical trial participation is more likely to take time away from work from women than it is for men. 74 percent of women aged 45-54 said that taking part in clinical research takes time away from work. Only 26 percent of men in this age group concurred. For 65 percent of men, travel is not an issue.

Key takeaway:

Home visits are not the most suitable strategy for increasing diversity in clinical research. Instead, trial design must focus on a hybrid solution, such as extending operating hours of sites and using more telehealth options.

Insight 3

60 percent of volunteers ages 18-34 have participated in multiple clinical trials.

Millennials and Gen Z are taking part in more studies. Up until the age of 35, both men and women are more likely to take part in more than one clinical trial.

In our group of respondents, half of women (50 percent) ages 18-24 and 58 percent of women ages 25-34 had taken part in multiple trials. This rose slightly for men in the same age categories at 57 percent and 64 percent, respectively.

Interestingly, there was a 20-year age difference between men and women in the cohorts who had taken part in the fewest number of studies. Women ages 55-64 had taken part in the fewest number of studies (37 percent) compared to the other age groups. For men, the age group with the lowest participation was 35-44 (32 percent).

Participation rate: Men

- Nearly two thirds of men (64 percent) ages 25-34 enrolled in two or more clinical trials.
- The ratio flips immediately after they cross the age of 35. Only approximately 40 percent of men over the age of 35 have participated in more than one study.
- Men ages 35-44 have the lowest return rate for multiple trials (32 percent).

		Q1. How many clinical trials have...		
Gender	Age	1	2	3
Male	18-24	43%	43%	14%
	25-34	36%	18%	46%
	35-44	68%	21%	11%
	45-54	66%	13%	21%
	55-64	58%	19%	23%
	65+	55%	25%	20%

Participation rate: Women

- Similar to men, women ages 25-34 are the most likely to participate in more than one clinical trial, though the percentage is slightly lower than their male counterparts (58 percent to 64 percent).
- Women ages 55-64 are the least likely to participate in additional studies (37 percent).
- The percentage of women (37 percent) in the lowest returning cohort is higher than the male equivalent (32 percent).

		Q1. How many clinical trials have...		
Gender	Age	1	2	3
Female	18-24	50%	30%	20%
	25-34	42%	37%	21%
	35-44	55%	23%	22%
	45-54	61%	16%	23%
	55-64	63%	19%	18%
	65+	52%	27%	21%

Key takeaway:

Millennials and Gen Z tend to be highly committed to socially responsible behaviors, and anecdotal evidence suggests they are taking part in clinical research because they want to advance scientific discovery for the benefit of others. It is also more likely that the younger age groups are less likely to have family commitments, competing for their time. There could be other factors at play here as to why the younger participants surveyed are taking part in multiple studies, such as stipends and more healthy volunteer research being conducted, like vaccines.

Nevertheless, the findings are encouraging because we need greater diversity in clinical trials on multiple variables, including ethnicity, age, and gender. The data suggests that sponsors and sites may have even higher volunteer return rates if they focus on increasing patient stickiness.

Conclusion

The evidence of this survey of patient experience suggests that the remote technology used to date in trials is fairly elementary. When it comes to health, people feel less comfortable using invasive technology on their own without human intervention.

However, the use of technology is appropriate for certain tasks, like recording an e-diary, especially for age groups that have less time to travel to clinical sites. The more comfortable people become using technology in trials, and in health care in general, the more prevalent it will become in clinical research.

Many advocates of decentralization in clinical research have suggested home visits as a way to increase participation in trials and, in particular, increase diversity. However, our survey data shows that people do not necessarily want home visits, and this is more pronounced in people from racially and ethnically diverse communities. Anecdotal evidence suggests extending clinic hours, including weekends, may be a more effective change to increase study participation, although that clearly does not address the problem of geographic accessibility.

Women are more likely to consider participating in a clinical trial as taking time away from their work compared with men. Women are also more likely to choose options that do not require travel to a site. Nevertheless, there is a strong preference for visiting physical sites or using telehealth options across all age groups and ethnic backgrounds, rather than at-home visits.

The observation that younger participants are more likely to volunteer to participate in more than one study is perhaps not surprising. In general, a younger age group is less likely to have competing demands on their time. Although this survey is not able to address this point, from what we have observed of patients at Velocity, young people are more likely to participate in well-paid, healthy volunteer studies.

COVID-19 studies signaled a turning point for patient recruitment and the research industry at large, addressing diversity issues, raising awareness and increasing access to clinical trials through decentralization. Decentralized methodologies have attempted to re-engineer patient interaction so fewer clinical trial sites are needed and access to studies can be expanded. This survey indicates we may need to think more about hybrid solutions to increase patient engagement.

Patients are clearly open to using decentralized elements in trials but these need to be carefully designed to target the people who will use them. Anecdotal evidence suggests that patient focused technologies are not as patient-centric and user friendly as they could be, but if we want to speed up drug development, we must continue to put patient considerations at the heart of clinical research.

If we want to speed up drug development from vaccines to migraine treatments,

we need to put patient considerations at the heart of clinical research.

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