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## **Decentralized Clinical Trial (DCT) Strategies to Enhance Patient Satisfaction and Future Participation**

**Syndicated Publication**

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# About the Author

Life Science Strategy Group, LLC (LSSG) report authors draw upon extensive business, consulting and life science experience and backgrounds.

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Mr. Meyer has managed consulting engagements in a variety of areas including brand equity assessments, strategic planning, service line opportunity assessments, pricing strategy, forecasting, competitive benchmarking, positioning and messaging strategy and clinical trial benchmarking and analysis. Prior to LSSG, Mr. Meyer was a Director in the Life Sciences Division at Navigant Consulting, Inc. and conducted preclinical drug development in the department of inflammatory disease at Roche Bioscience. Mr. Meyer holds Masters Degrees in Biomedical Science and Business Administration.

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# Executive Summary

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# Where do clinical trial participants first learn about trials and why do they decide to participate?

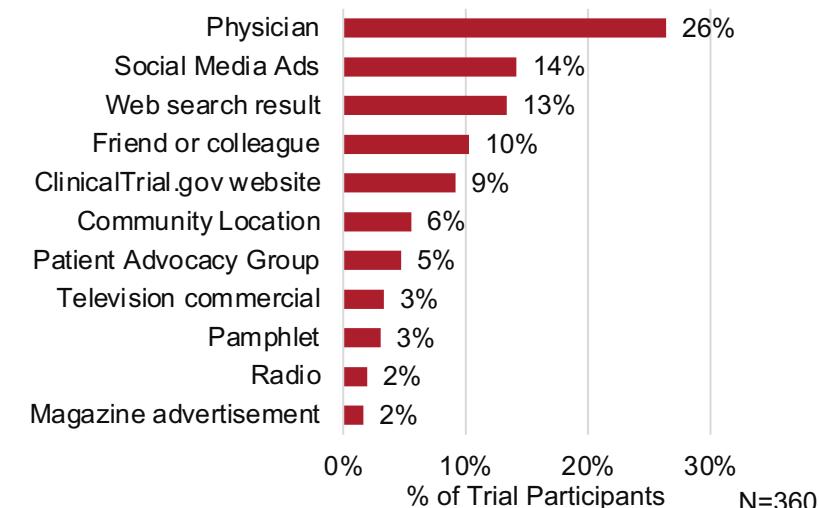
## Most clinical trial participants first learn about their trial from their physician.

- Social media and web searches are also utilized as channels to provide information about clinical trials.
  - Traditional methods (TV commercials, radio, magazine advertisement) are not common sources.
- More Europeans hear about studies from physicians than North Americans (34% vs 21%, respectively).

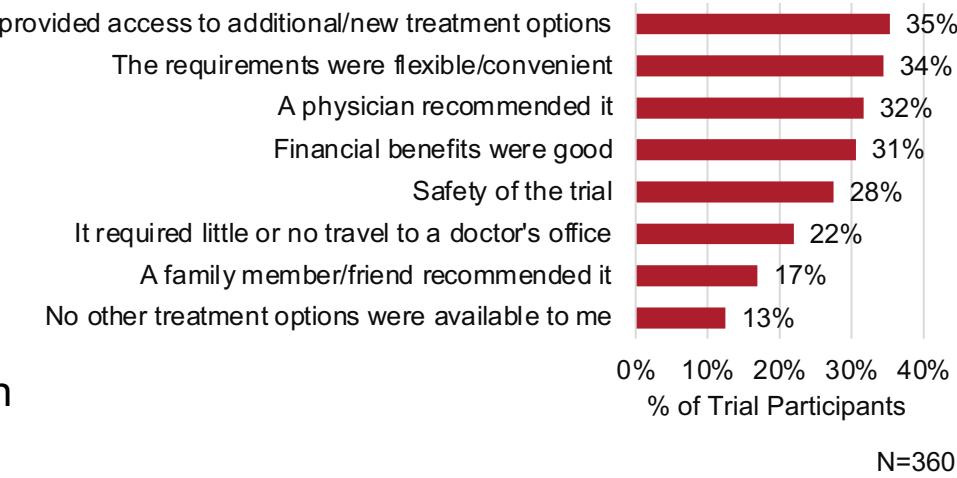
## Trial participants typically join a study to receive additional/new treatment, because the requirements are convenient or because their physician recommended it.

- While the desire to receive treatment is a top reason for joining a trial, surprisingly, flexible and convenient trial requirements is cited by more trial participants as a reason to join than physician recommendation.
- More trial participants aged 61 and over care about convenience than those under 30 (47% vs. 14%, respectively).
- 18% of those who have not participated in a clinical trial note that the inflexible/inconvenient trial requirements is a significant barrier to participation (the #3 reason for not participating after safety concerns and no need).

## Methods for Learning About Trials



## Rationale for Joining Trial



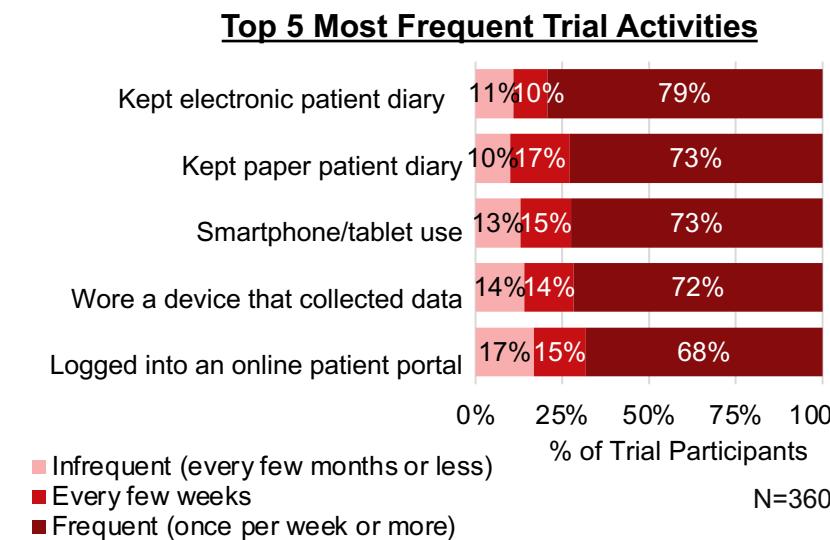
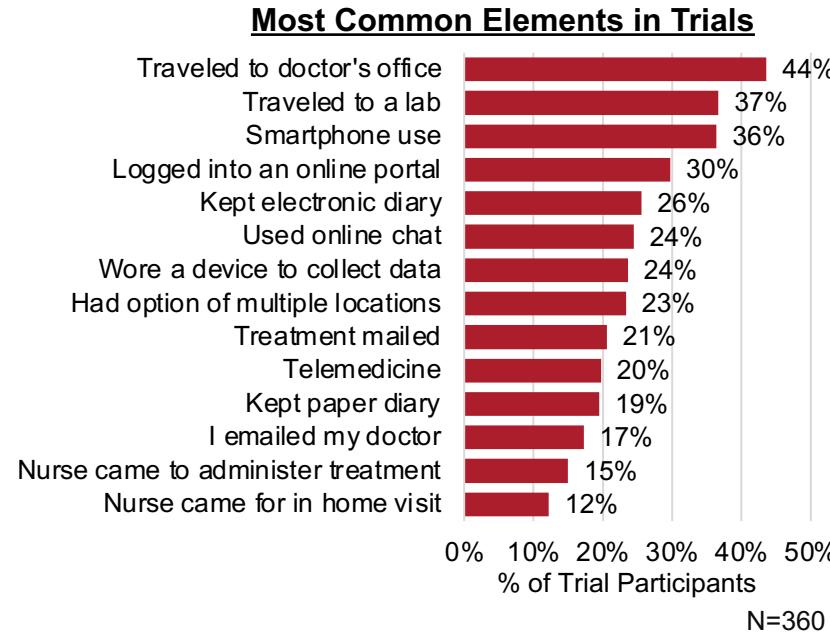
# Which traditional and decentralized activities are most common to clinical trials and how frequently are they performed?

**Traveling to the doctor's office, traveling to a lab for blood work or diagnostic test and using a smartphone to record health information to upload to the internet are the activities that most trial participants perform for their clinical trial.**

- Nurses coming to visit in-home or to administer treatment in-home are the least common elements (12% and 15%, respectively) but are well-received by trial participants.

**Keeping a paper patient diary, wearing a device that collects data and uploads it to the internet, and keeping an electronic patient diary are the most frequently-performed activities.**

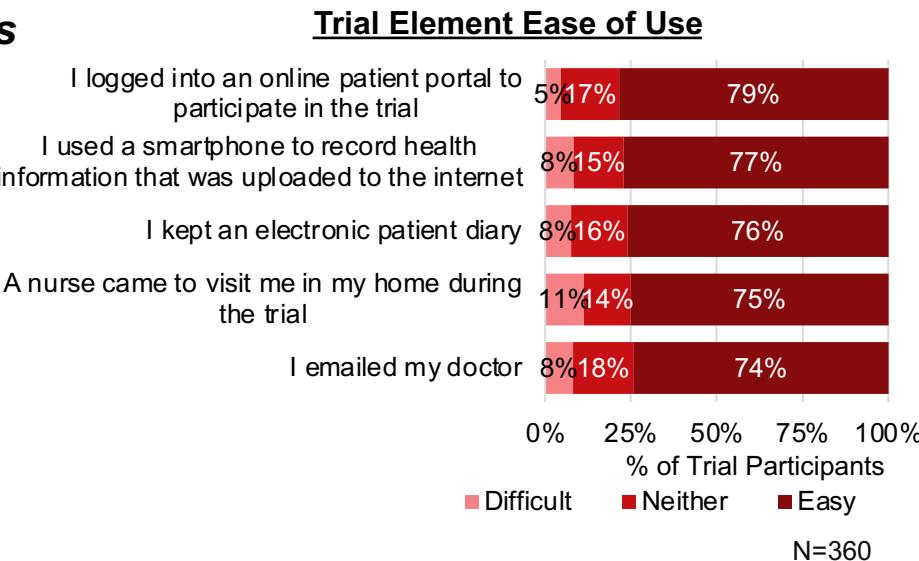
- 66% of trial participants kept a patient diary at least a few times each week, compared to 61% who wore a device and 60% who kept an electronic patient diary.
- While elements requiring travel are common in clinical trials, they are not typically performed very frequently. Having the option to go to multiple study locations occurred a few times each week for 20% of trial participants, traveling to the doctor's office for 15%, and traveling to a laboratory for 12% of participants.
- More North Americans keep a paper patient diary at least a few times per week compared to Europeans (75% vs. 58%, respectively).



# How easy or difficult are clinical trial activities to complete? Are there differences among trial participants?

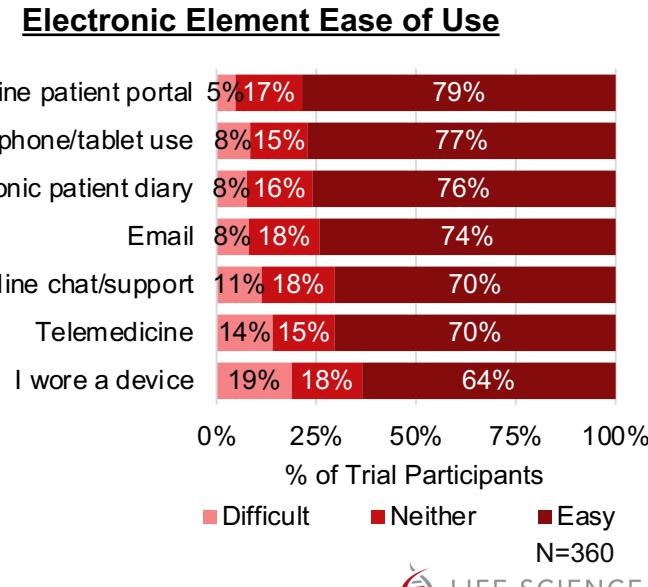
## In general, decentralized clinical trial activities are easier for trial participants to complete than those requiring travel.

- Decentralized trial elements, namely, in-home treatment and use of technology are generally perceived as easier to complete.
- Trial participants 61 and older find telemedicine visits with doctor easier than going to the doctor's office for a visit (100% vs. 56%, respectively).
- Travel to the physician for treatment and the laboratory is more difficult for trial participants (18% and 11% difficulty, respectively).



## Use of “familiar” technology is generally perceived to be easier than “unfamiliar” technology and devices.

- Collecting health information via one's smartphone/tablet exceeded wearable devices serving the same purpose in terms of ease (77% vs. 64%, respectively).
- More North Americans find telemedicine calls with a doctor and using an online portal easy compared to Europeans (77% and 85% vs. 58% and 66%, respectively).



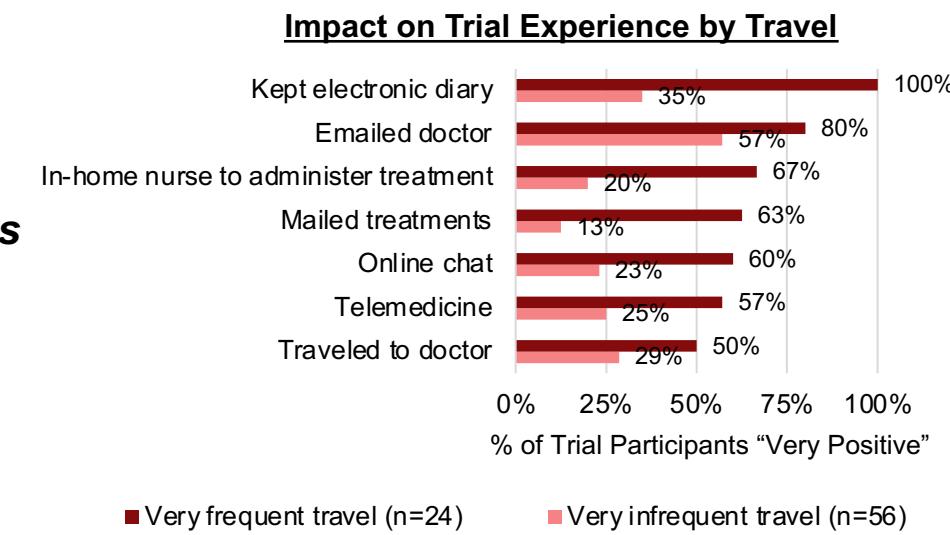
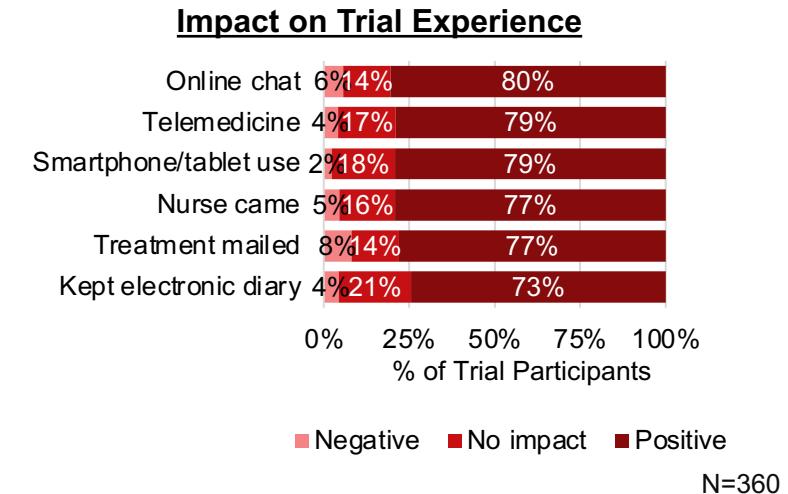
# Which trial activities have the greatest impact on clinical trial satisfaction?

## Decentralizing clinical trial activities improves trial participants' experience with their clinical trial, but in-person physician/lab visits are also important.

- In home visits by nurses, receiving treatment at home and use of remote technology drive greater satisfaction than activities involving travel.
  - In home activities consistently comprise the easiest and most impactful trial elements, regardless of segmentation.
  - Use of technology including smartphone/tablet use, online chat and telemedicine have substantial positive impact on both trial experience and completion (79%, 80%, 79% and 81%, 76%, 75% of participants, respectively).
  - Activities involving travel score relatively lower; however, trial participants do want to see their physician in person (79% of participants state telemedicine has a positive impact on trial experience while 66% state visiting a doctor in office has a positive impact).

**Trial participants that travel very frequently cite greater satisfaction with decentralized elements compared to those traveling very infrequently. This is likely due to convenience decentralization offers.**

- Trial participants that travel very frequently (a few times per week or more) have a more positive experience with decentralized elements such as keeping an electronic diary and emailing the doctor than those who travel every few months or less (100% and 80% vs. 35% and 37%, respectively).



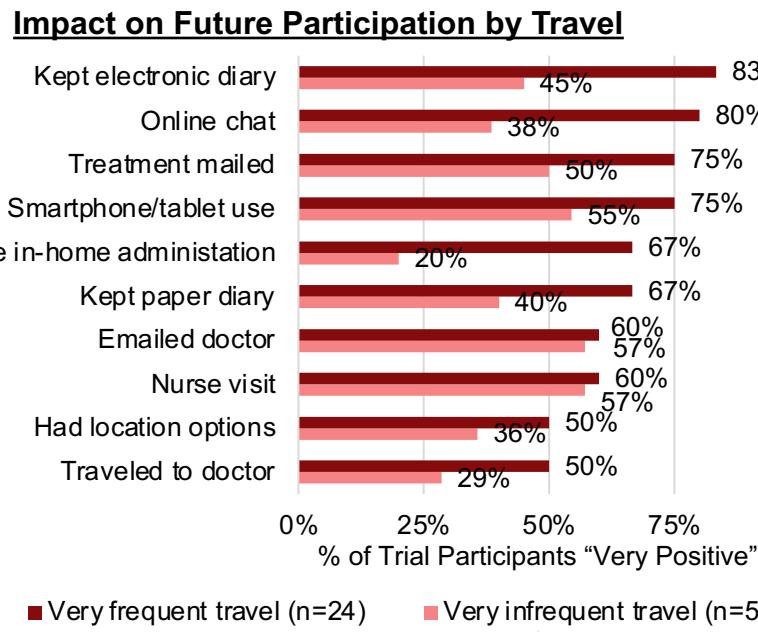
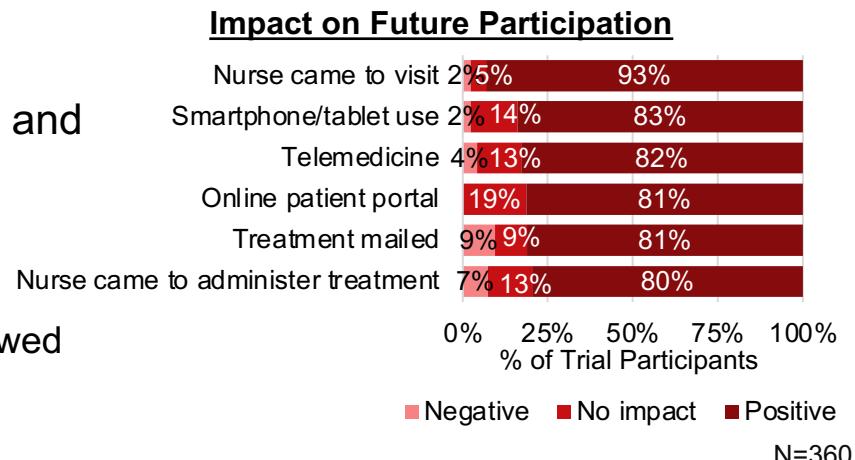
# Which clinical trial activities have the greatest impact on trial participants' willingness to participate in a future clinical trial?

## In-home treatment and use of familiar technology have the greatest, positive impact on trial participants' willingness to participate in a future clinical trial.

- Decentralized trial activities including in-home visits by nurses, receiving treatment and technology have the greatest positive impact on future participation.
  - Traveling consistently ranks lowest for ease of use, beneficial impact on experience, positive influence on continuation of participation, and future willingness to participate.
- At the same time, interactions that come along with travel, like those with physicians, are viewed favorably (66% of trial respondents note positive experience with traveling to doctor's office).
  - Treatment mostly done at home or doctor's office close to home is a more important factor for future participation for trial participants 61 and over than 30 and under (78% and 80% ranked top 3 vs. 59% and 48% ranked top 3, respectively).
- Use of technology that is "familiar" has a greater impact on trial participants' willingness to participate in the future than unfamiliar technology.
  - Following personal safety, access to new treatment, and advancing medicine, having someone available to answer questions (57% rank top 3) and treatment mostly done at home (61% top 3) have the greatest impact.

## General population respondents who have not participated in clinical trials are attracted to trials with flexible, convenient, at-home options.

- Inflexible requirements are the third most-cited reason for not participating in clinical trials, trailing only the lack of need to participate and the safety of the trial (23%, 34% and 29% of respondents, respectively).



# What are attitudes towards decentralization of future clinical trials? Which decentralized activities can have the greatest positive impact on future participation?

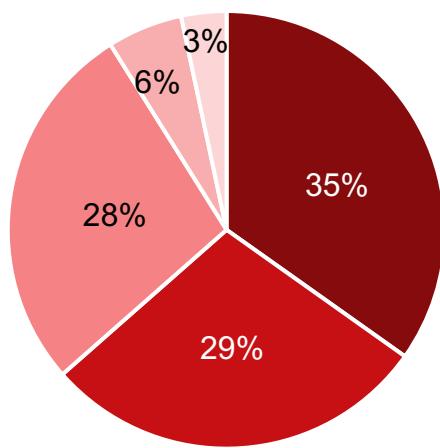
**There is clear preference among both trial participants and the general population for greater decentralization of future clinical trials as it improves convenience.**

- 64% of trial participants and 68% of the general population would prefer greater trial decentralization (in-home elements).

**In-home nurse visits, using smartphones or tablets to record/upload health information, telemedicine calls with a doctor, online patient portals and mailing treatments to the home are the decentralized activities that can have the greatest impact on future participation.**

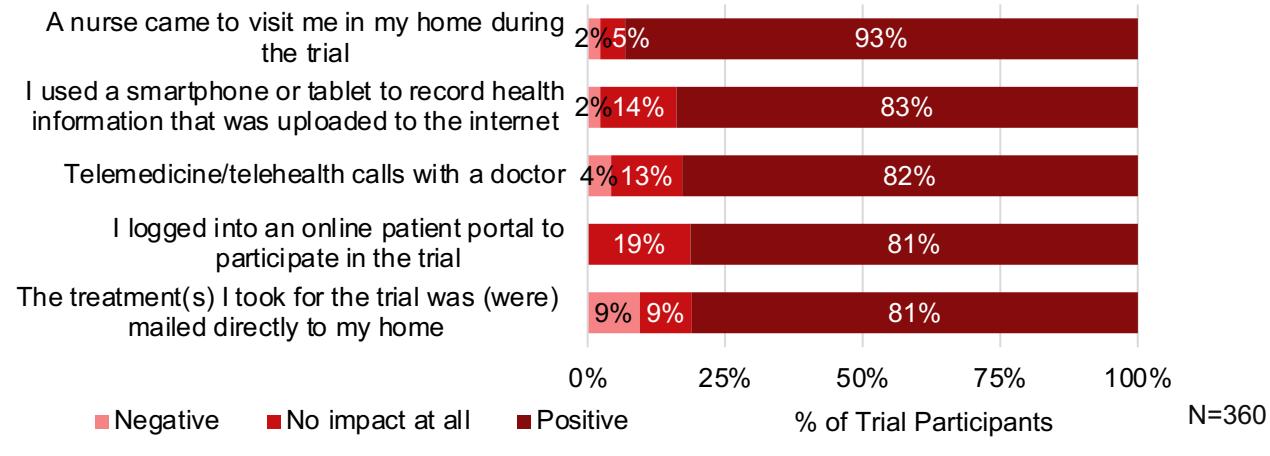
- More Europeans note telemedicine has a positive impact on future participation than North Americans (92% vs. 77%, respectively).

**Attitudes towards Future Participation**



N=360

**Top 5 Decentralized Elements Impacting Future Trial Participation**



# Conclusions and Recommendations

- Physician recommendation, social media and online searches are the most common ways trial participants first learn about clinical trials, while “traditional” methods (e.g., radio, televisions, print) are the least common.
  - **Patient recruiting, one of the top challenges with clinical trials, by Sponsors, CROs and vendors should focus on physician outreach, as well as leveraging social media to raise awareness about trials and online information sources like clinicaltrials.gov.**
- While there is widespread use of decentralized trial elements (e.g., in-home treatment and technology), clinical trials include a significant degree of travel-related activities, which are perceived as less convenient/attractive. This is reinforced by a direct relationship between frequent travel and greater satisfaction with decentralized elements.
  - **Trial requirement flexibility/convenience is a top reason for participating/not participating in a clinical trial. As such, Sponsors should work to incorporate more decentralized trial elements, giving greater convenience, into protocols to drive greater participation.**
- While decentralized trial elements are generally more attractive than activities requiring travel, some in-person interaction with a physician is an important activity/reason for trial participation and satisfaction.
  - **Sponsors should optimize the design of future clinical trials to increase decentralized elements and reduce (but not eliminate) travel-related activities including physician and laboratory visits, as they do positively impact satisfaction and participation. Risk-based monitoring strategies can also be further utilized to reduce travel while ensuring safety/quality.**
- For the decentralized trial elements evaluated, in-home treatment (e.g., nurse visits, telemedicine and receiving drug treatments at home) and the remote use of “familiar” technology (e.g., use of smartphone to record/upload information, keeping electronic diaries, use of online chat to ask questions) are the top drivers of satisfaction and willingness to participate.
  - **Trial sponsors can offset in-person physician office and laboratory visits with greater use of in-home visits/treatment and familiar technology which should positively impact patient satisfaction and recruiting rates.**
  - **Greater use of decentralized elements can also reduce clinical trial site burden, which should in turn increase site satisfaction and site-Sponsor relationships.**

# Study Goal and Objectives

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# Study Methodology

## Methodology

The primary research for this report was fielded in August and September, 2022. Study participants include clinical trial participants within the past two years (n=360) and those in the general population who have not participated in a clinical trial (n=440).

All study participants were prescreened by LSSG to ensure either participation in 1-2 clinical trials within the past two years, or no participation in a clinical trial. All data analysis and reporting was performed by LSSG.

## Report Terminology

For the purposes of this report, the following clinical trial activities are considered decentralized clinical trial strategies/approaches:

- Telemedicine/telehealth calls with a doctor
- Keeping an electronic patient diary
- Wearing a device that collects data and transmits/uploads it to the internet (e.g., Fitbit, apple watch, continuous glucose monitor, etc.)
- Using a smartphone or tablet to record health information that is uploaded to the internet
- A nurse coming for an in-home visit during the trial
- A nurse coming for an in-home visit to administer treatment for the trial (e.g., an injection or IV infusion)
- Mailing treatment(s) for the trial mailed directly to the patient's house
- Logging into an online portal to participate in the trial
- Using online chat/support to ask questions and seek information
- Emailing a doctor

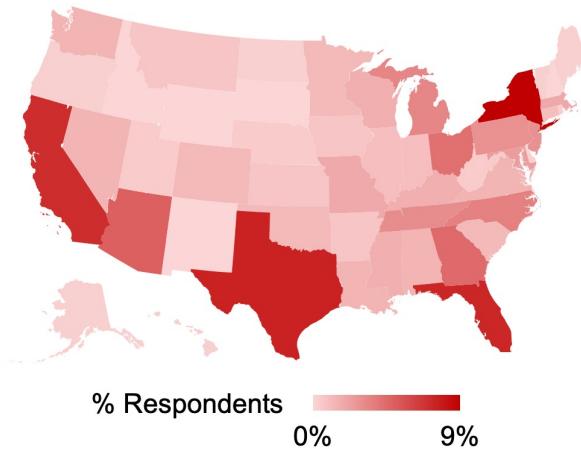
# Respondent Demographics

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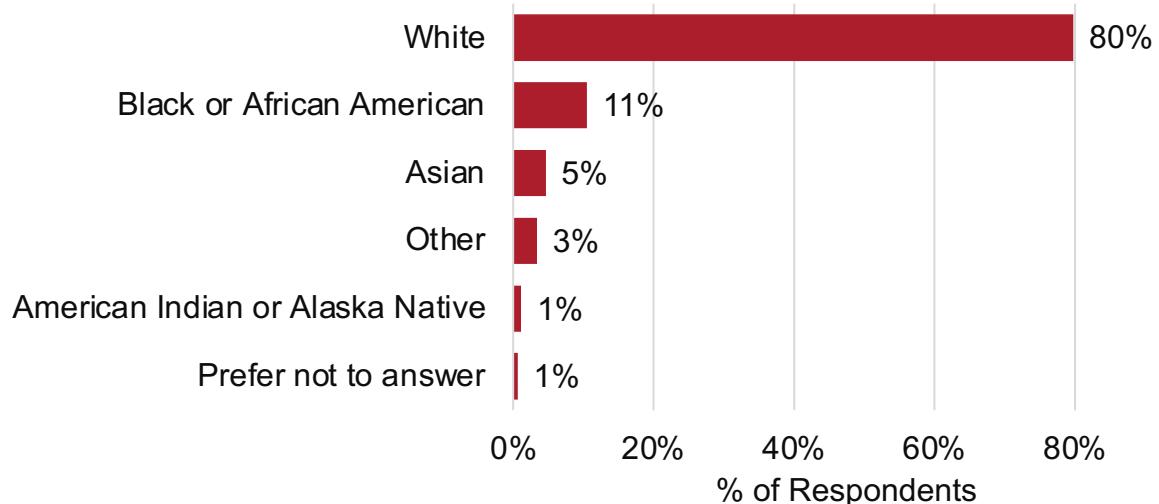
# Respondent Demographics

- A total of 800 respondents participated in LSSG's online quantitative survey.
- **53%** (n=427) of respondents are located in North America and **47%** (n=373) in Europe.

## State Representation



## Race & Ethnicity

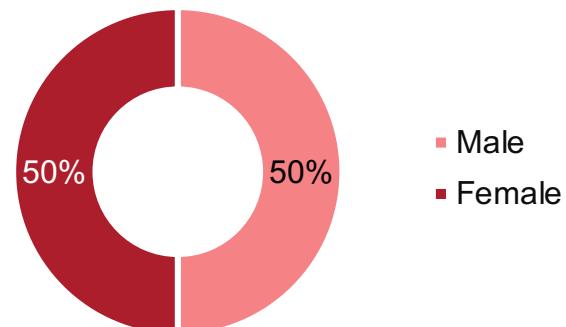


## Age Range (Years)



S1. Where are you located?  
S2. What state do you live in? (Note: if from Canada, put N/A)  
S3. How old are you?  
S4. With which gender do you identify?  
S5. What is your ethnicity?

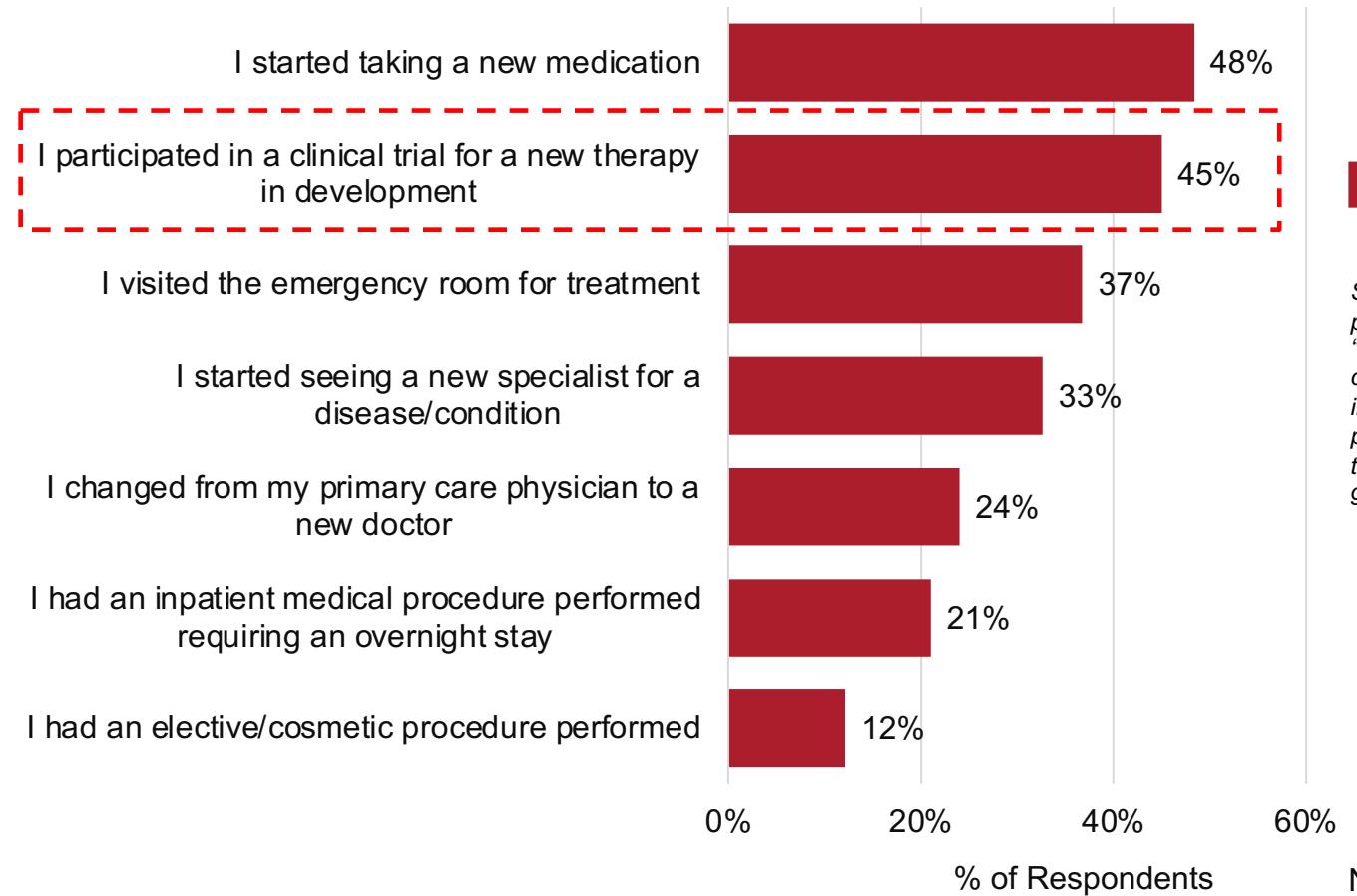
## Gender



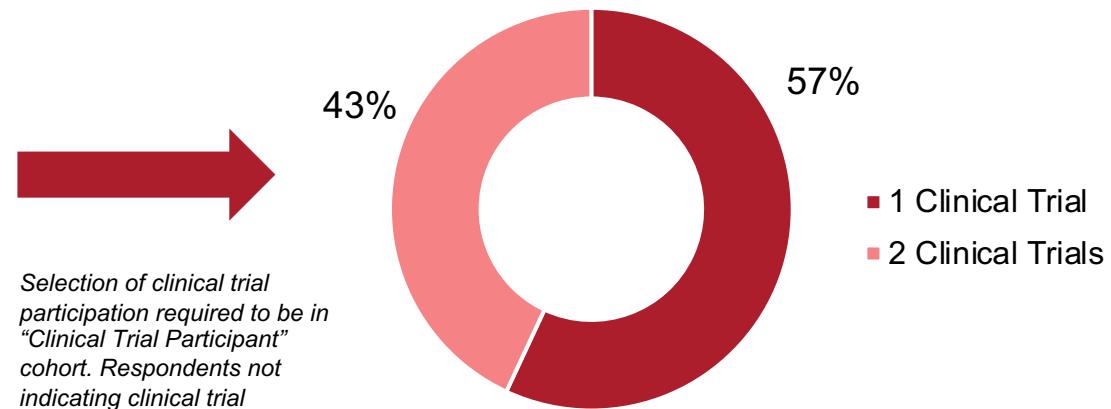
N=800

# Respondent Demographics

## Activities Participated In Over Past 2 Years



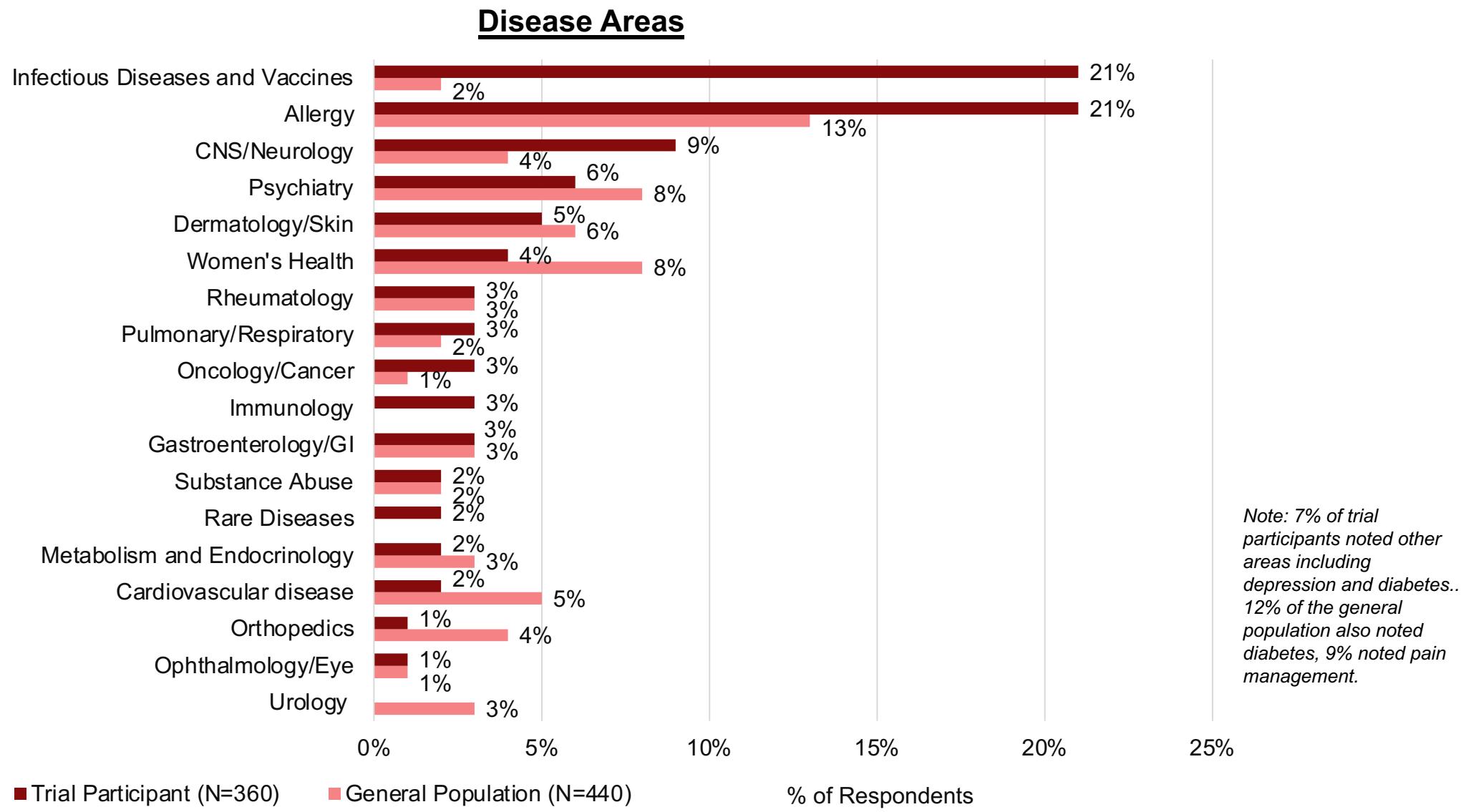
## Number of Clinical Trials in Past 2 Years



*Selection of clinical trial participation required to be in "Clinical Trial Participant" cohort. Respondents not indicating clinical trial participation are classified in the "general population" group.*

*Note: Trial participants with >2 trials excluded to avoid "routine" participants.*

# Respondent Demographics



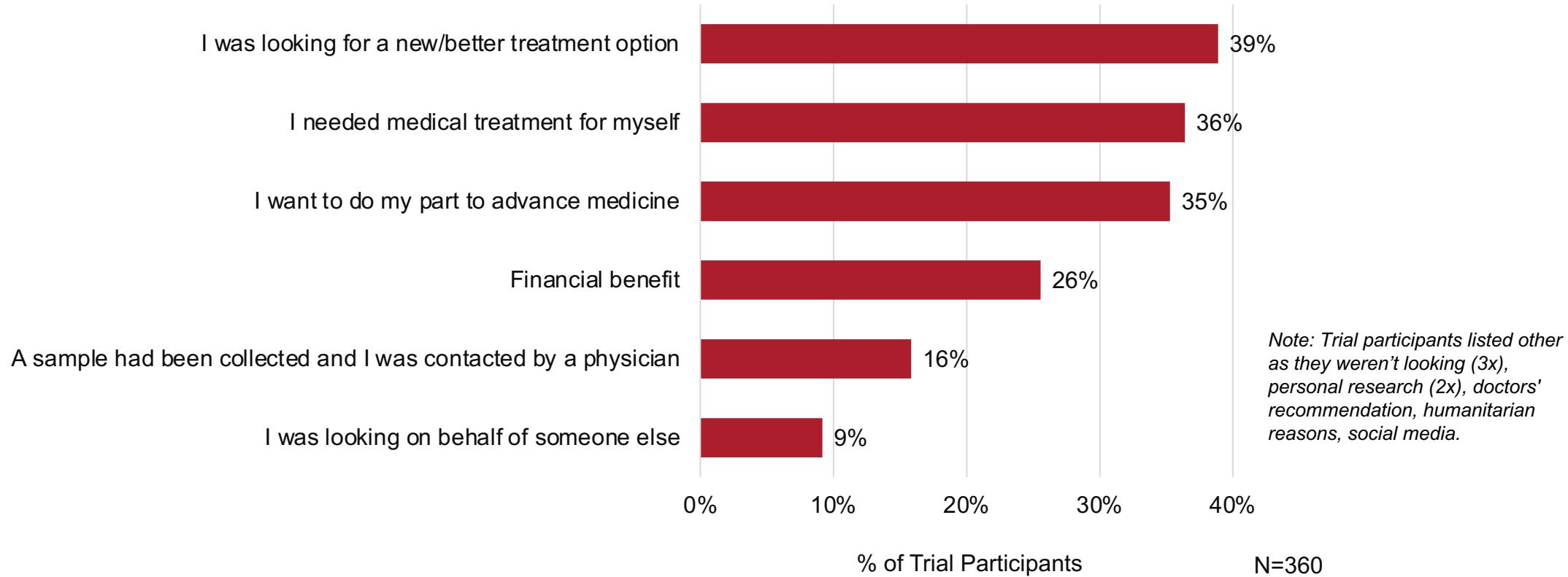
# Clinical Trial Participants

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Trial participants typically search for clinical trials to seek better treatment for themselves and for the altruistic advancement of medicine.

- Trial participants typically search for clinical trials because they need treatment or to find a better option.
- North America is more financially driven when searching for clinical trials than Europe (30% vs. 19%, respectively).

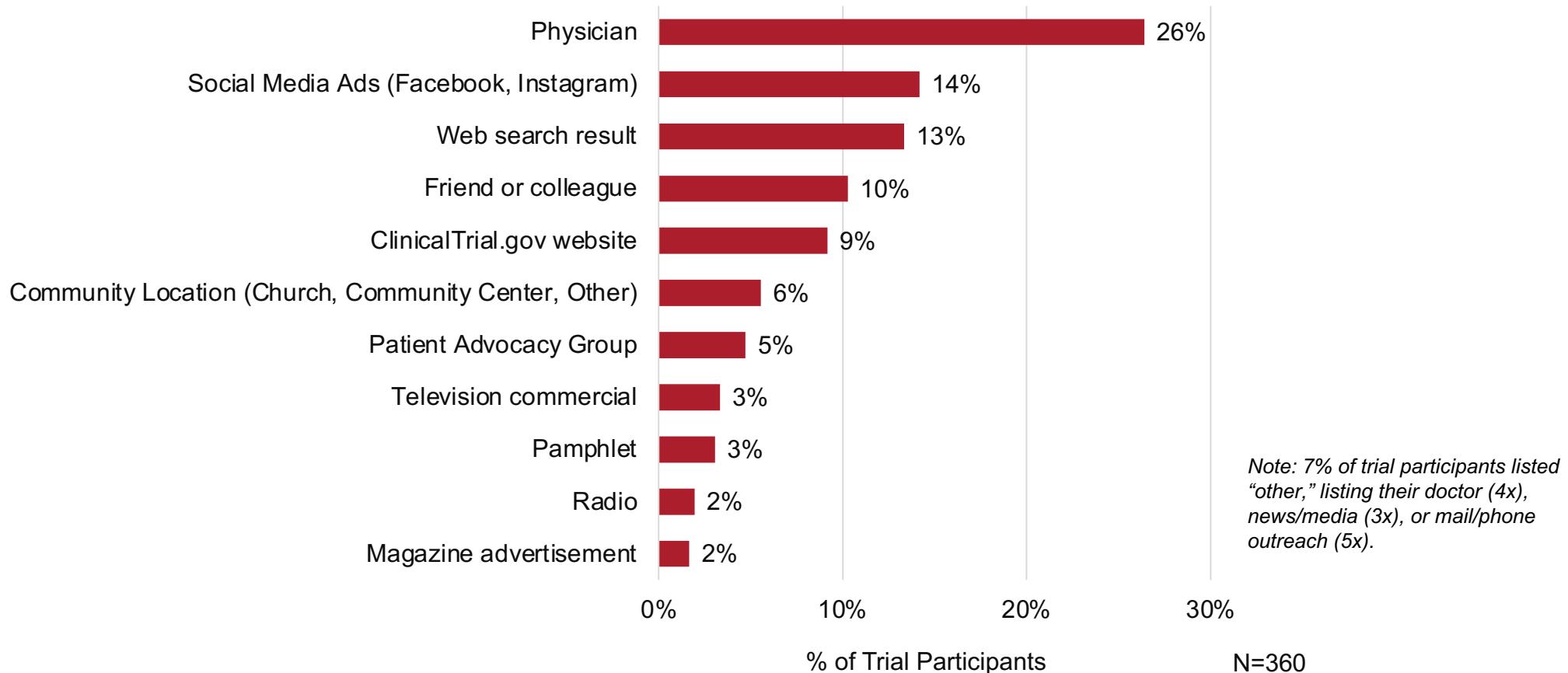
### Rationale for Searching for Clinical Trial



# Despite widespread use of social media, online sources and traditional outlets, most people first learn about their clinical trial from their physician.

- More than half of trial participants first learned about their study through their physician, social media, or a web search.
- “Traditional” outlets such as television commercials, the radio, and magazine advertisements are not a common first source of information.

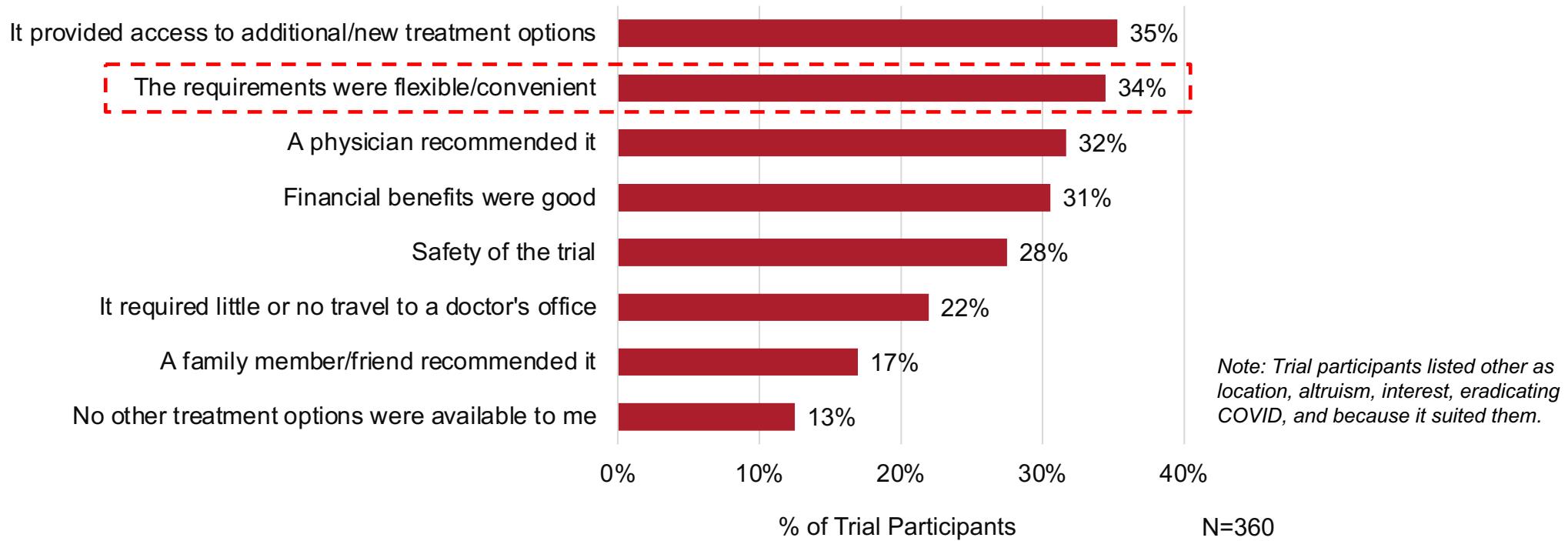
## Source Where Patients First Learned About Their Clinical Trial



# Flexible and convenient trial requirements are a top reason patients decide to participate in a trial – even exceeding physician recommendation and perceived safety.

- Rationale for joining clinical trials varies, with access to additional treatments and convenient requirements most common.
- Interestingly, flexible and convenient trial requirements are the second-most common reason for joining at 34% of trial participants.
- Trial participants aged 61 and over were more likely to join clinical trials due to flexible requirements than those 30 and under (47% vs. 14%, respectively).

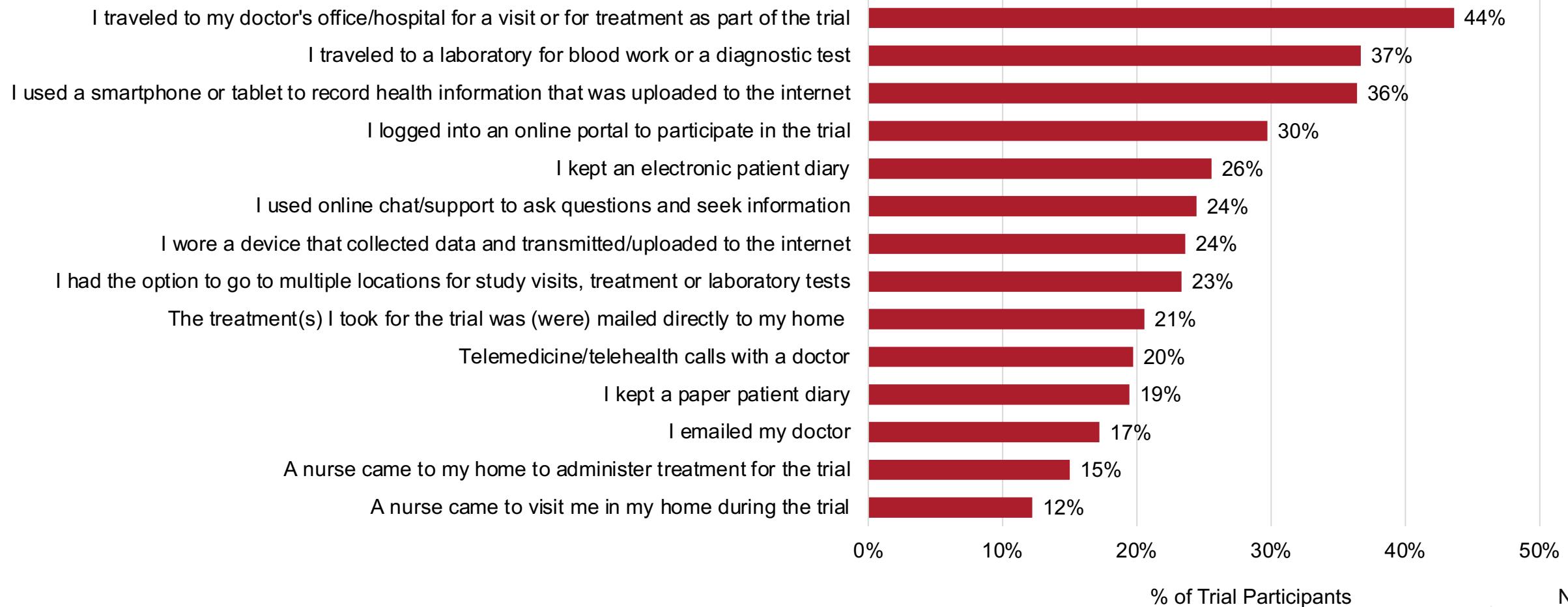
## Rationale for Joining Specific Clinical Trial



Traditional clinical trial elements, including travel to the doctor's office and laboratories, remain most common, as well as the remote use of technology to record information.

- More North Americans logged onto an online patient portal than Europeans (35% vs. 23%, respectively).
- Trial participants 30 and under had more nurse visits in home for administration of treatment than those 61 and older (16% vs. 0%, respectively).

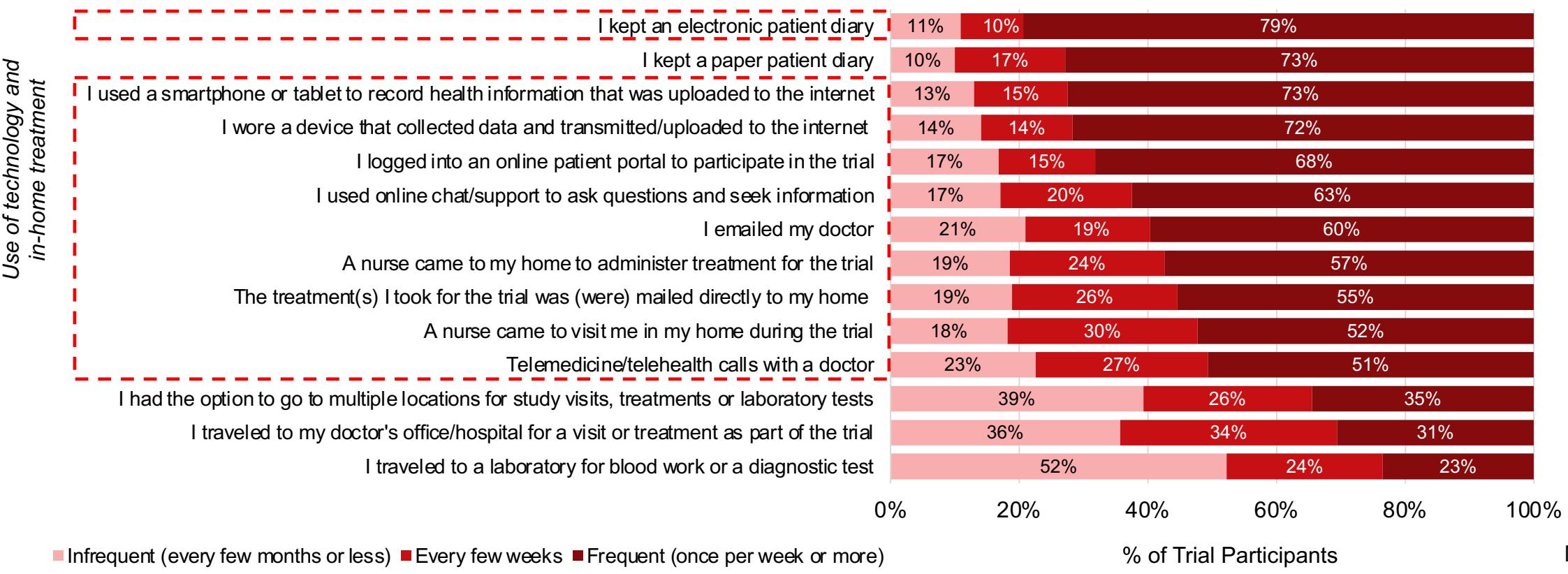
### Elements in Clinical Trial



# Remote use of technology to record/upload information and ask questions related to the trial and in-home treatment are the most commonly-performed clinical trial activities.

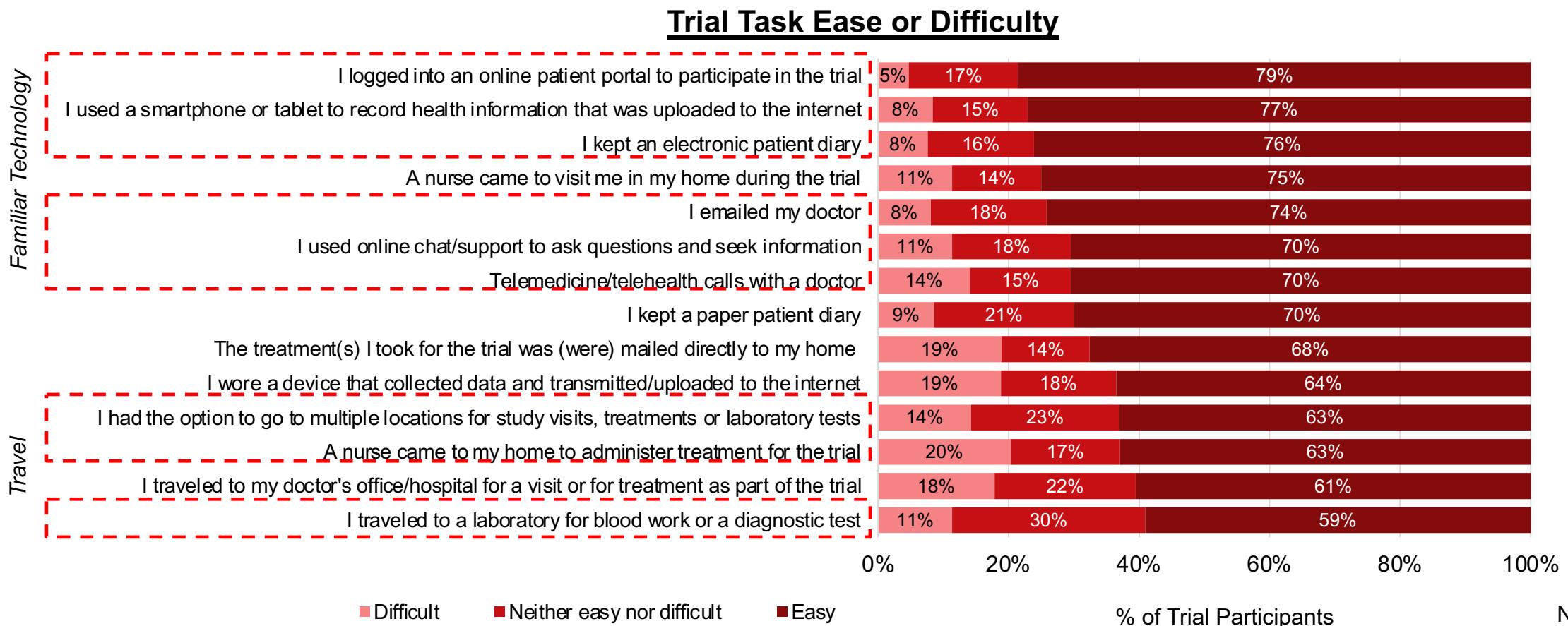
- Trial participants aged 61 and over are less likely to travel to the doctor's office, travel to a laboratory, or go to multiple locations for study visits once per week or more (0%, 0% and 11%, respectively).
- Those age 30 and under are less likely to email their doctor once per week or more than trial participants 61 and over (35% vs. 100%, respectively).
- Europeans are more likely to collect and upload data electronically, while North Americans are more likely to use paper diaries and receive medication by traditional mail.

## Frequency of Trial Activities



Tasks involving familiar technology (e.g., patient portal, smartphone, tablet) and wearable technology are considered easy by more people than traveling.

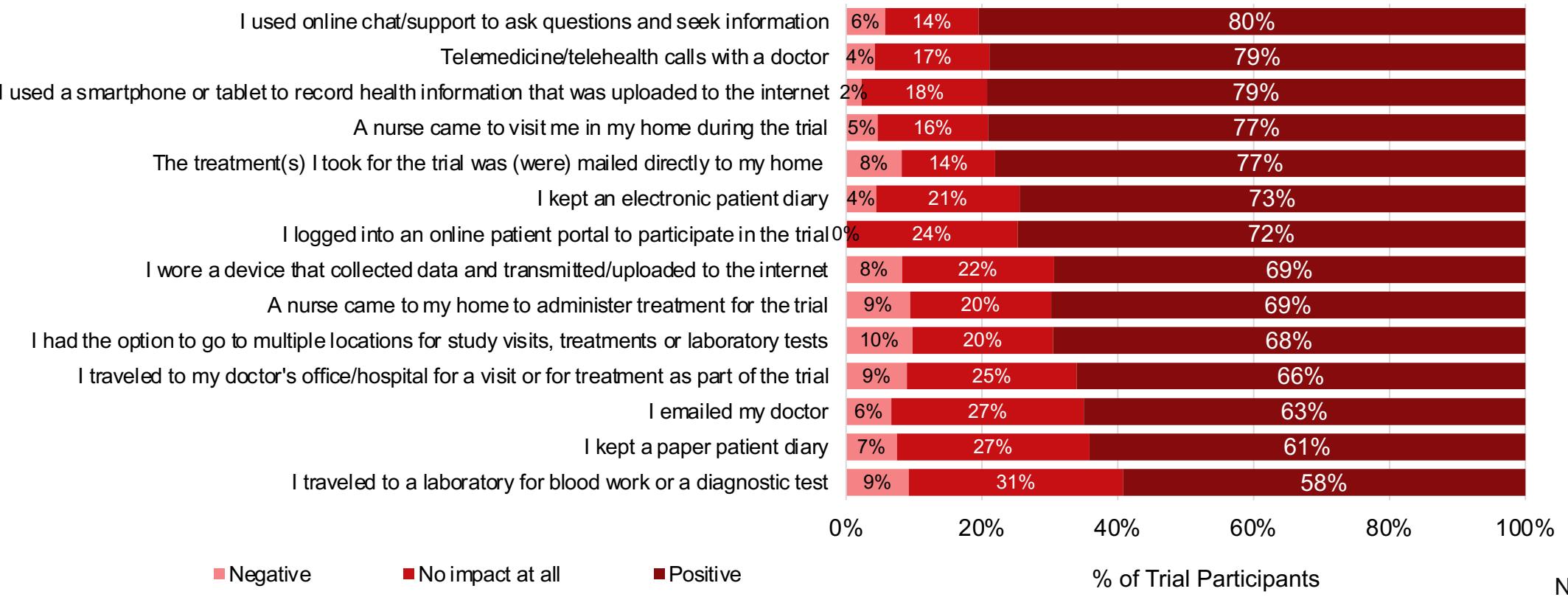
- Activities involving in-home treatment (either by a nurse or self-administration), wearing devices to collect data, and travel are more commonly mentioned as difficult.
- More North Americans feel telemedicine visits and logging onto an online portal is easy than Europeans (77% and 85% vs. 58% and 66%, respectively).



# Using technology at home to ask questions and record information, and telemedicine visits/receive treatment at home have a positive impact on most participants' trial experience.

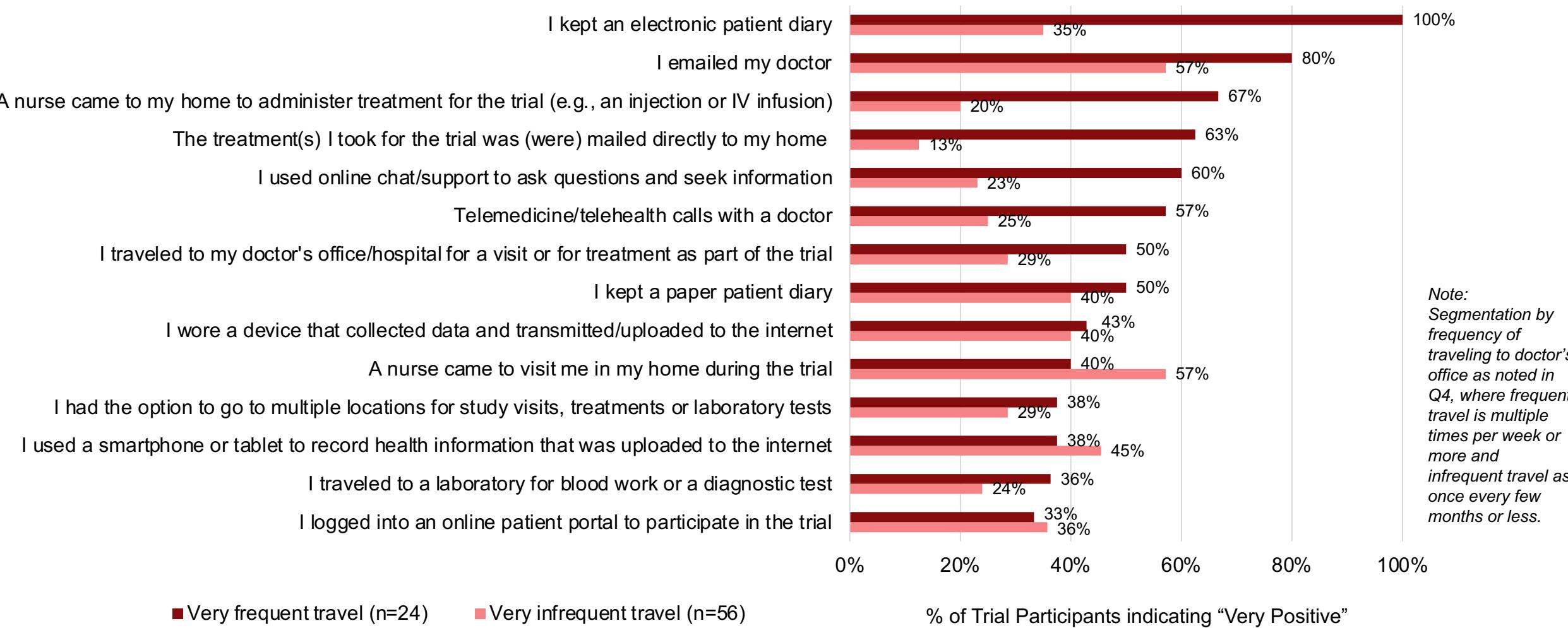
- Trial participants that travel to their doctor's office more frequently report emailing their doctor and online chat have a more positive impact than those who travel less frequently (80% and 60% vs. 57% and 23%, respectively).
- More North Americans report having an in-home nurse visit or in-home treatment for the trial has a positive impact than Europeans (75% and 84% vs. 59% and 68%, respectively).

## Impact on Clinical Trial Experience



For those that travel very frequently for their trial, in-home treatment/technology has a greater positive impact on their trial experience than those who travel very infrequently.

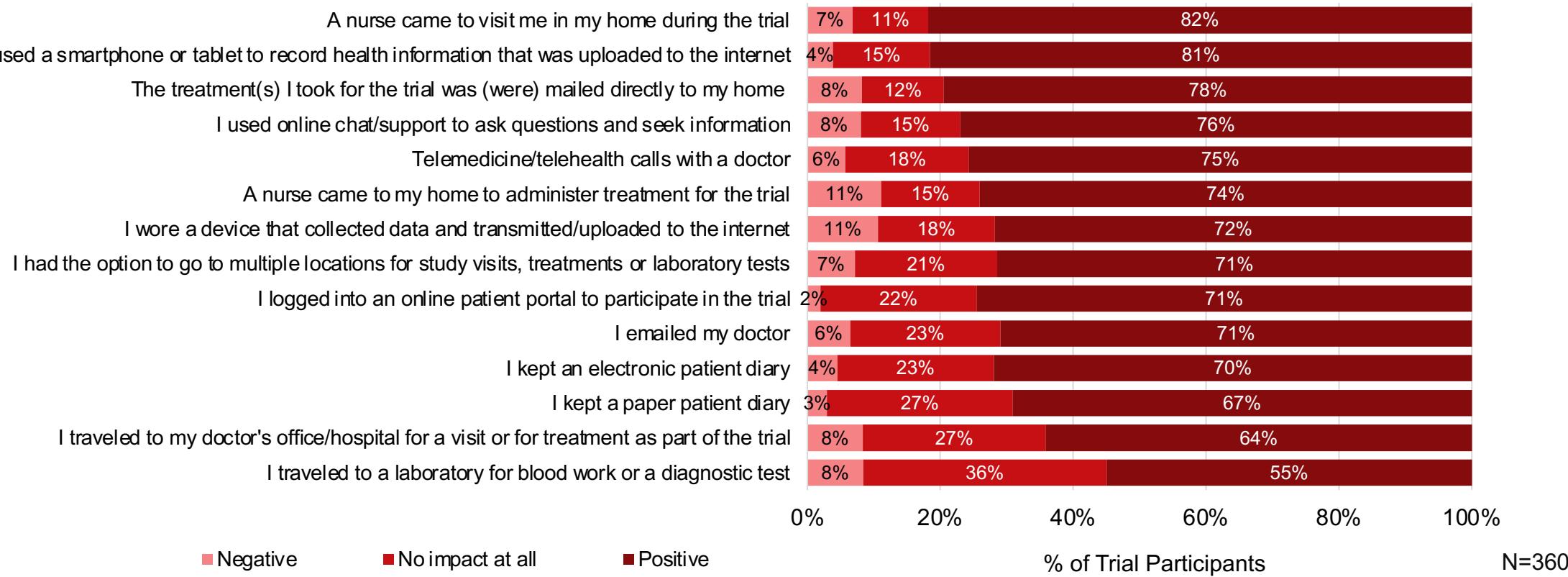
### Impact of Very Frequent or Infrequent Travel on Trial Experience



# Activities moving trial elements in the home (e.g., nurse visits, mailing medication, and using technology to record information/answer questions) most positively influence trial completion.

- The most influential factors leading to trial completion are predominantly decentralized components, such as in-home nurse visits, smartphone/tablets and online chat use.
- Travel has a positive impact on trial completion but less so than other activities that are more convenient for the trial participant.

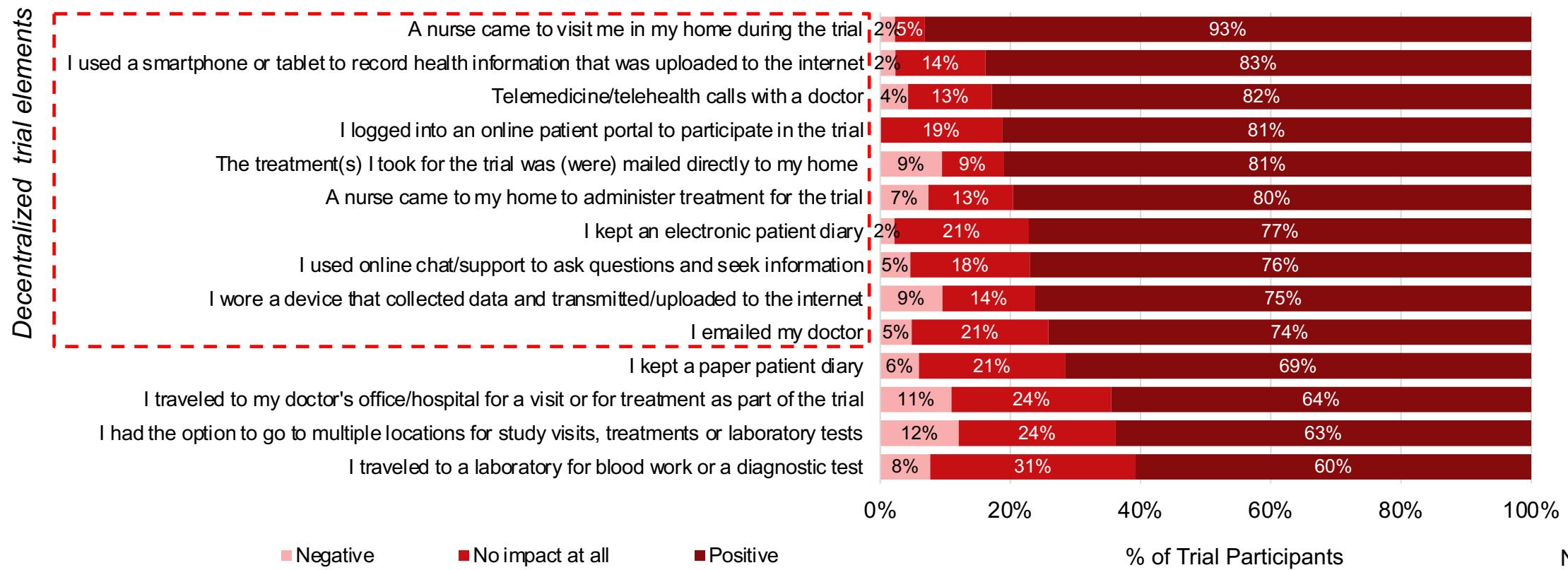
## Influential Factors in Trial Completion



# Elements offering in-home or from home options have a larger positive impact on future clinical trial participation than other activities like in-office visits and multiple locations for visits.

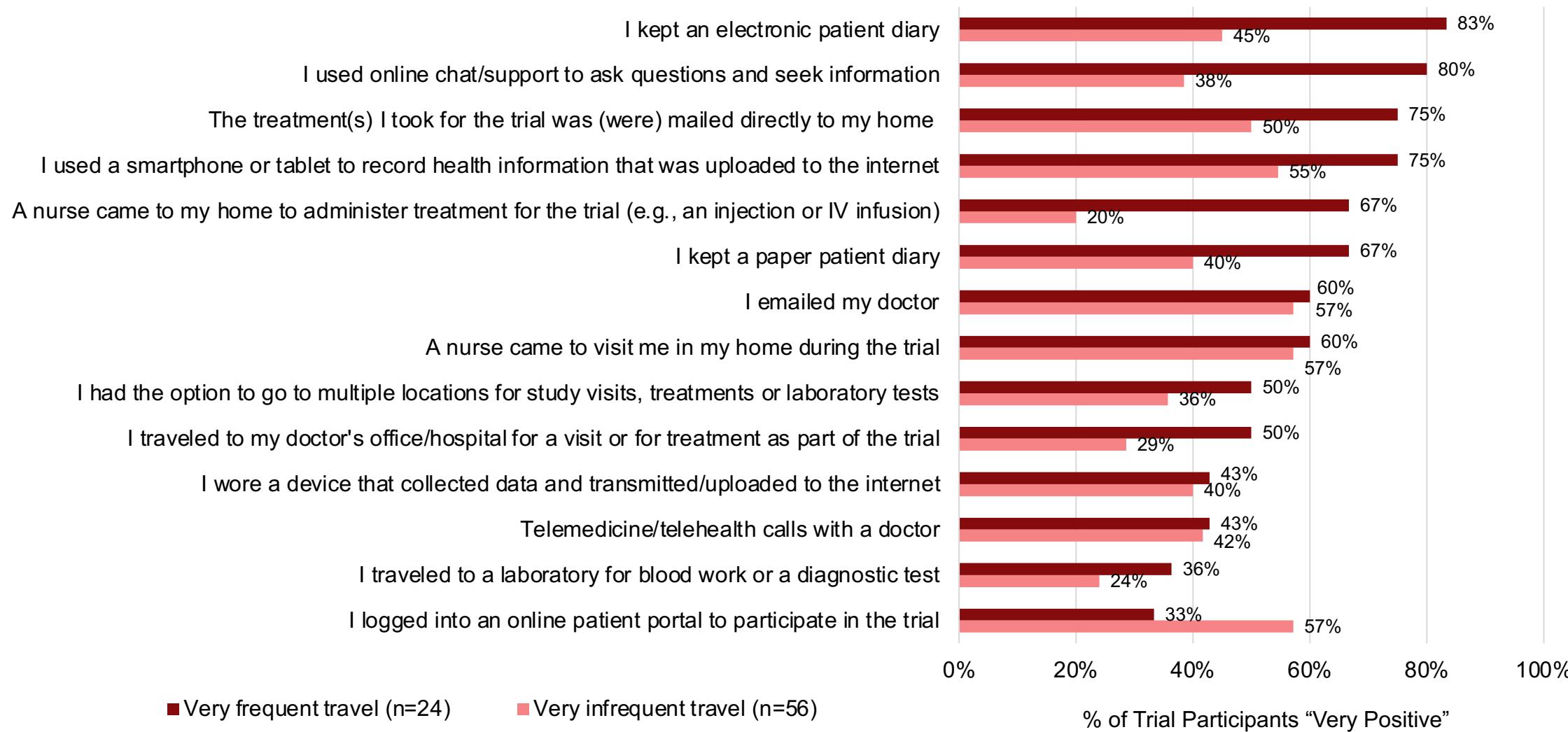
- In-home nurse visits, recording health information electronically, and telemedicine calls have the greatest impact on future willingness to participate with 93%, 83% and 82% of trial participants indicating a positive impact.
- Treatments mailed to the home have a more positive impact for trial participants 30 and under than for those 61 and over (89% vs. 67%, respectively).
- More North Americans indicate wearing a device that collects data and logging into an online patient portal have a positive impact on future participation than Europeans (84% and 85% vs. 66% and 74%, respectively).

## Impact on Willingness for Future Participation



For those traveling very frequently for their trial, in-home treatment/technology has a greater positive impact on their future participation than those traveling very infrequently.

### Impact of Very Frequent or Infrequent Travel on Future Trial Participation



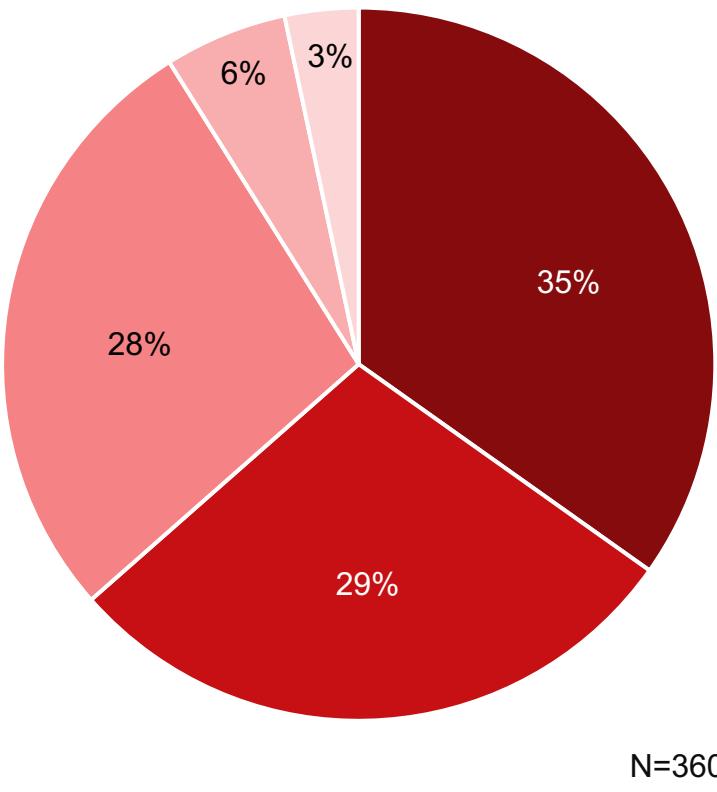
Note:  
Segmentation by frequency of traveling to doctor's office as noted in Q4, where frequent travel is multiple times per week or more and infrequent travel as once every few months or less.

Nearly three-quarters (64%) of trial participants would prefer more in-home elements if participating in a future trial (vs. 9% preferring fewer).

- More North Americans, would prefer clinical trials to have more in-home elements compared to Europeans (68% vs. 57%, respectively).
- As trial participant age increases preference for in-home elements decreases (73% 30 and under vs. 66% 31-60 vs. 24% 61 and over).

**Attitudes Toward Future Participation**

- I would strongly prefer a trial to have more in-home elements
- I would prefer a trial that had more in-home elements
- I have no preference
- I would prefer a trial that had fewer in-home elements
- I would strongly prefer a trial that had fewer in-home elements



Age (Years)

30 and under

73%

n=244

31-60

66%

n=479

61 and over

24%

n=77

Region

Europe

57%

n=373

North America

68%

n=427

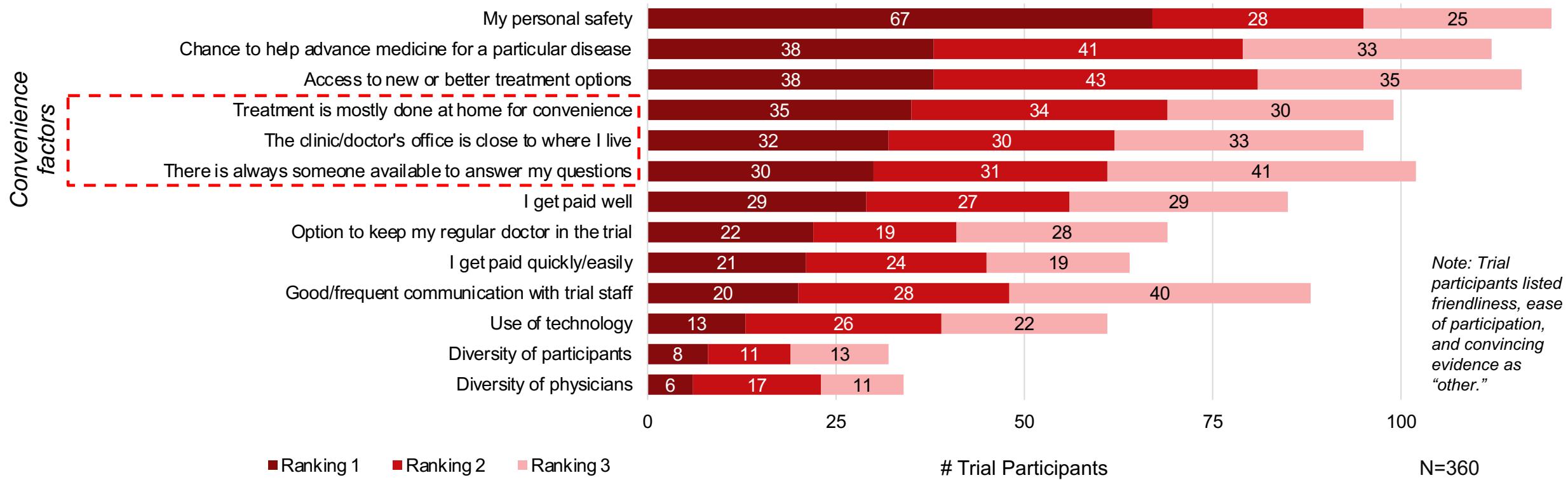
- Prefer a trial that had more in-home elements
- I have no preference

- Prefer a trial that had fewer in-home elements

Beyond safety, altruism and access, elements making the trial more convenient (e.g., treatment at home, close clinic, answers to questions) are top factors considered for future participation.

- Someone available to answer questions (60% rank top 3) and personal safety (63% rank top 3), and treatment mostly done at home (59% rank top 3) are the most important factors for trial participants 30 and under, while the chance to advance medicine (68% rank top 3), personal safety (70% in top 3), and a close doctor's office (80% in top 3) are most important factors for trial participants 61 and older.
- North American trial participants are more likely to include the use of technology and convenience of in-home treatment as important factors than Europeans (71% and 67% vs. 53% and 51% in top 3, respectively).
- For those who did not travel for their clinical trial, the use of technology is more important (69% vs. 50% rank top 3, respectively) than it is for those who have traveled.

### Factors Impacting Clinical Trial Participation



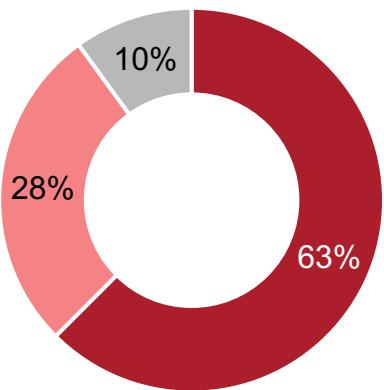
# General Population

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Nearly two-thirds (63%) of the general population have considered participating in a clinical trial, motivated by financial benefit, treatment and altruistic reasons.

- Surprisingly, more people mention financial benefit (43% of general population vs. 26% of trial participants) as the the top reason for considering participation, exceeding new/better treatment, and the advancement of medicine.
- North America is more financially driven than Europe when considering participation in a clinical trial (53% vs. 32%, respectively).

### Consideration of Participation in Clinical Trial

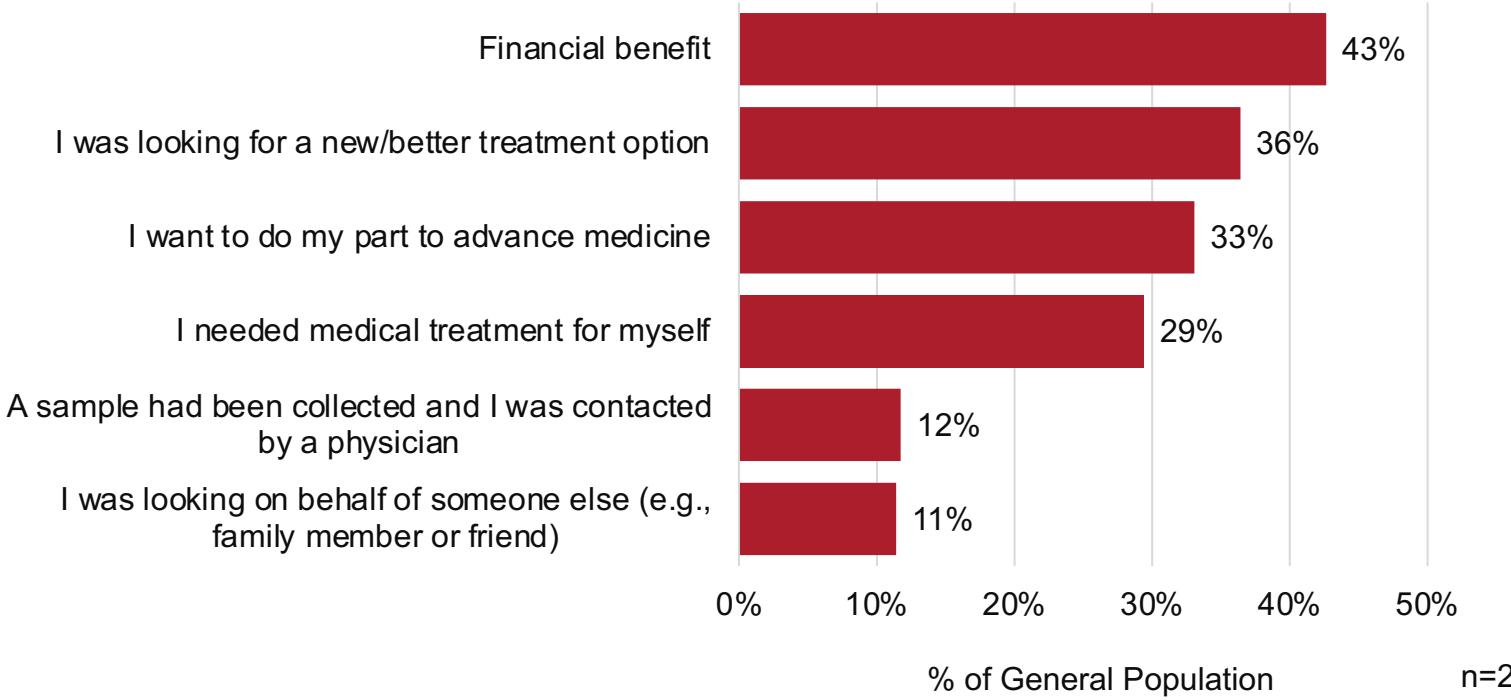


- Yes
- No
- Not sure

N=440

*Note: Q2 only shown to general population members who considered participating in a clinical trial in Q1.*

### Rationale for Consideration of Participation in Clinical Trial

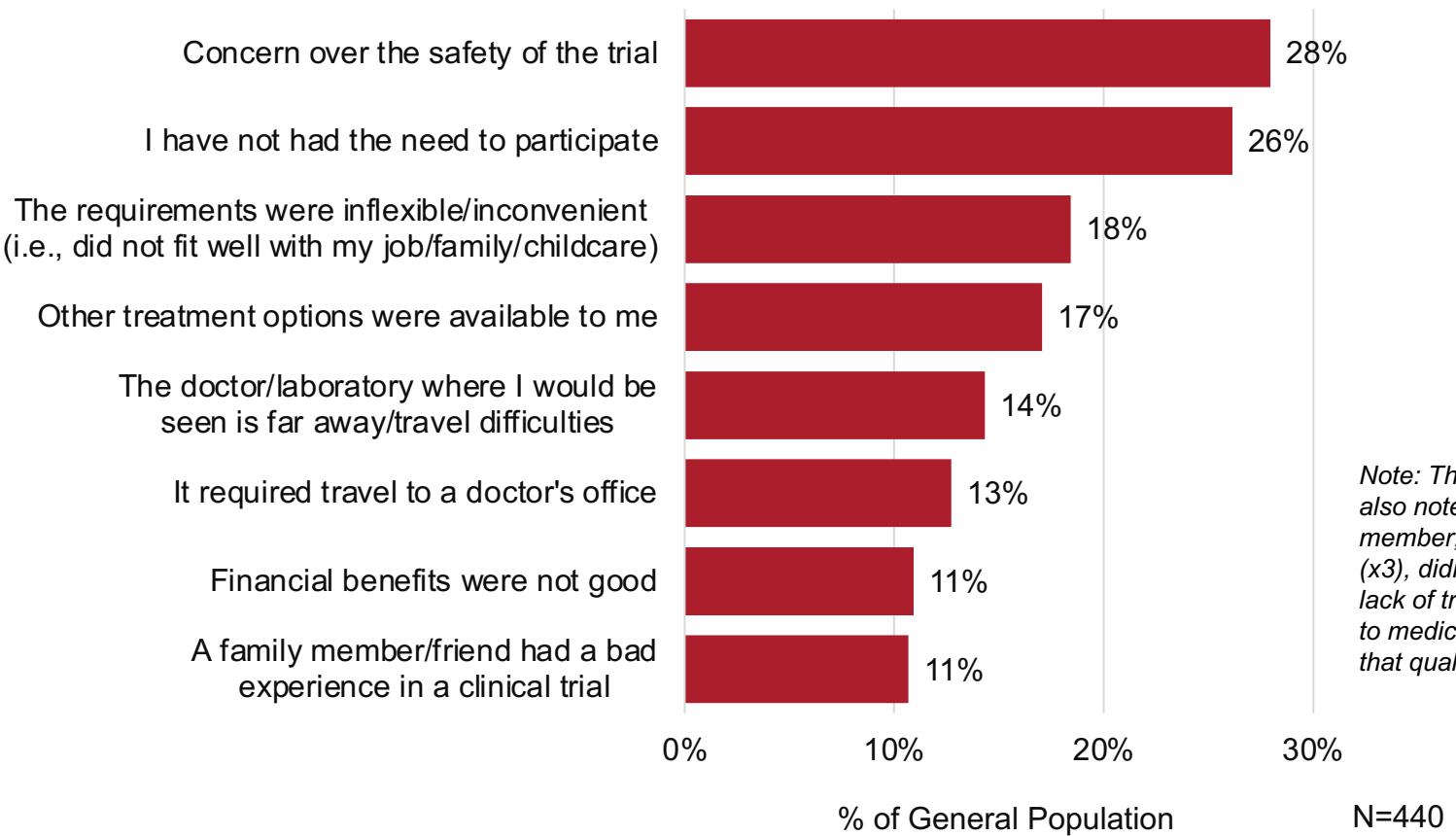


*Note: General population members also noted free time and desire to fight COVID-19 specifically.*

While concern over safety and lack of need are clear roadblocks to participation, inflexible trial requirements are a key barrier to participation.

- More general population respondents 30 and under cite inflexible/inconvenient trial requirements as top reason for not participating compared to those 61 and over (23% vs. 10%, respectively).

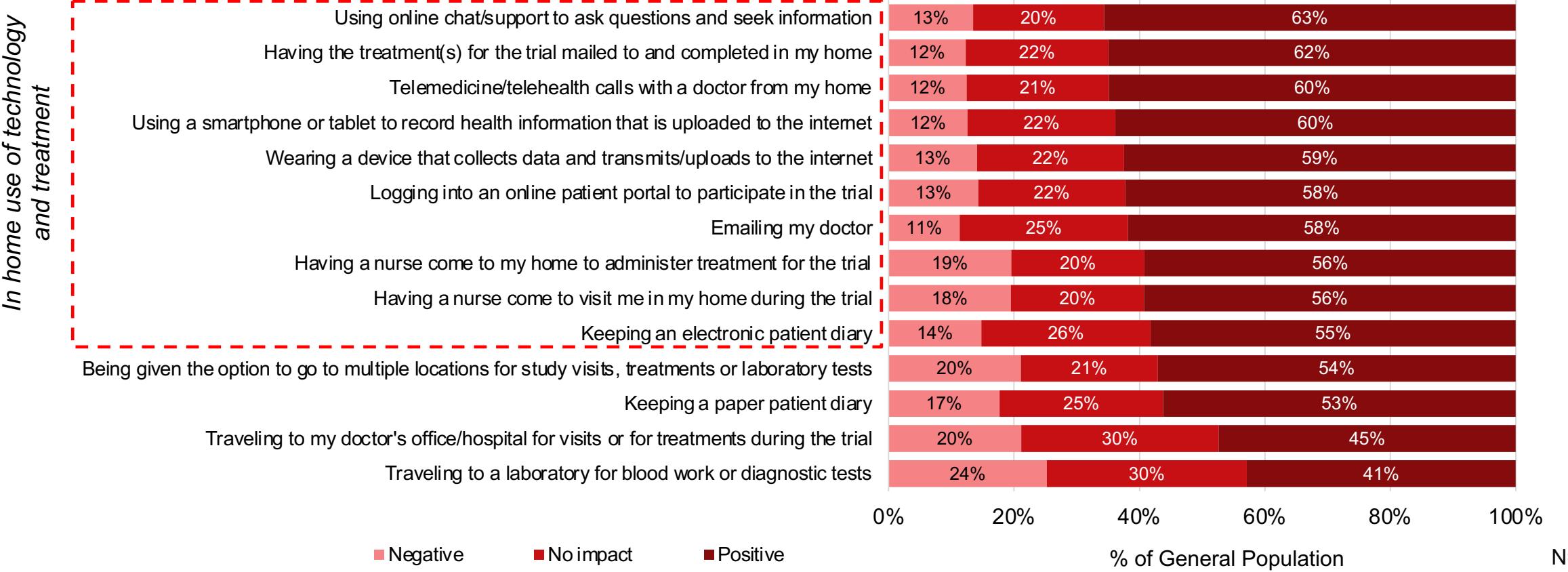
### Rationale for Not Participating in Clinical Trials



The use of technology and treatment in the home that reduces travel would have a positive impact on the general populations' willingness to participate in a future trial.

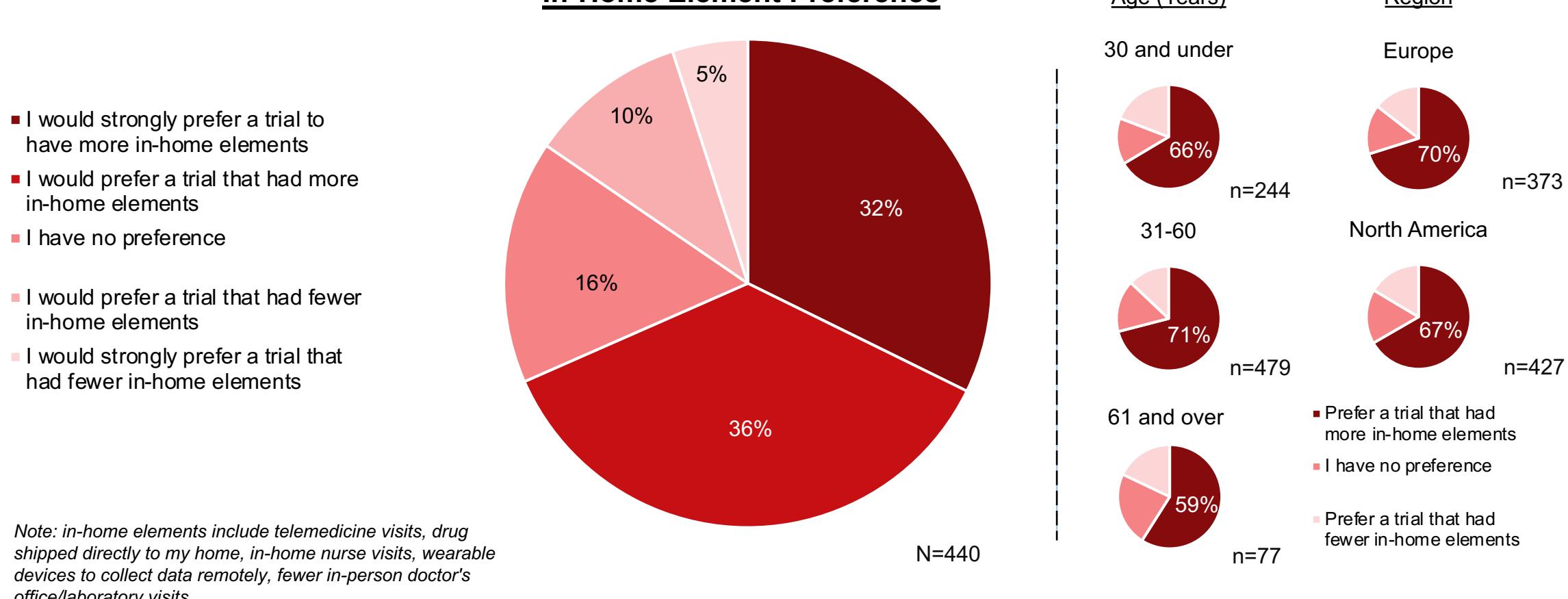
- Travel-related activities are viewed negatively by more general population respondents than other activities (i.e., 20%-24% negative impact).
- Europeans view a nurse in-home visit or a nurse administering treatment in-home more positively than North Americans (62% and 62% vs. 49% and 51%, respectively).

### Impact on Willingness for Future Participation



More than two thirds (68%) of the general population would prefer more in-home elements if participating in a future trial.

- More general population respondents that have not participated in a trial due required travel to a doctor's office prefer more in-home elements than those who cite other reasons for lack of participation (47% vs. 30%, respectively).



The option to have most of the treatment at home is a top factor (trailing only personal safety) in the general populations' consideration of future trial participation.

- Members of the general population age 61 and over note that treatment mostly done at home is most important to their choice to participate (73% rank in top 3), while this is the third most important factor for those 30 and under (55% rank in top 3).

### Impact Factors for Clinical Trial Participation

