TRIALS24
Accelerates Patient Recruitment

Climedo

2023

The Patient Perspective on Clinical Trials – What's Going Well, What Needs to Change?

Survey Results

Table of Contents

Executive Summary

In February 2023, Climedo and Trials24 launched a survey to better understand clinical trials from a patient's perspective and what they would like to change. For this, we surveyed patients with and without trial experience. A total of 124 respondents completed the survey, around 30% of whom had trial experience and 70% of whom did not but would consider joining a trial in the future. Patients who would not consider doing so have not been included in this evaluation.

The greatest barriers to trial participation were a lack of communication or information, long travel times and finding a suitable trial at all. More than half the patients believed that they would learn about a trial at the doctor's or via a patient group, while patients seemed to be less aware of digital platforms as potential recruitment channels, indicating that this recruitment channel might be underrepresented thus far, with room for disruption by digital recruitment companies. Nevertheless, to facilitate general access to trials, 64% of patients believed we need to embrace more digital technologies, such as wearables or telemedicine. Shorter travel times and more empathy were also key drivers here – two elements we see reflected throughout the results.

Once enrolled in a trial, patients prefer short journeys and limited on-site visits (53% would only want to travel for 30 minutes on a bi-weekly basis), while still valuing personal contact with healthcare professionals (HCPs). About half feel they could be reporting more information to HCPs and that they receive insufficient special attention from staff. To address this, telemedicine and other digital tools could provide alternative ways to maintain personal contact from within the home. Respondents ranked consistent contact persons, participation from home and empathy as the top factors that matter to them in a clinical trial.

Although healthcare is being revolutionized by digital technologies, almost half the patients (44%) with trial experience said they had used no such technologies so far. Among those who had used digital tools, ePRO (electronic patient-reported outcomes), EHR (electronic health record), eConsent and wearables were named. Most patients (over 50%) would like to use ePRO, a patient cockpit and EHR. On average, three-quarters of patients preferred digital channels for receiving or sending medical information and are willing to receive such information via digital channels more frequently, too. So patients' willingness to go digital is very much there – across all age groups – and it is now up to trial sponsors and sites to meet those expectations.

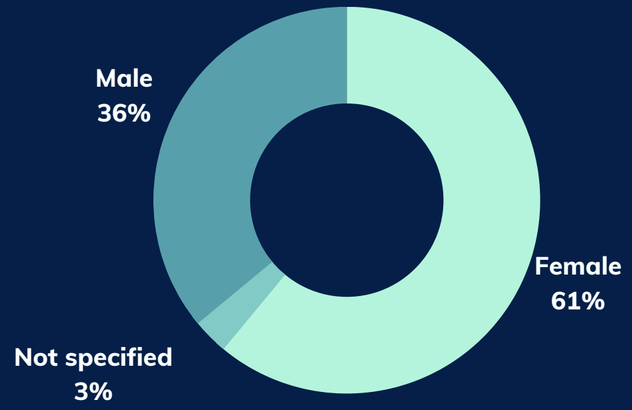
The majority of patients (83%) with trial experience would be willing to take part again in the future. Many cited contributing to valuable research, helping others with the same condition and the fact that trials are the only relief they have as reasons. In the closing comments, patients also highlighted the importance of attention towards rare diseases, mental health in trials and vulnerable communities.

Overall, these survey results have underlined the strong need for digital tools, flexible participation and empathy from HCPs in clinical trials.

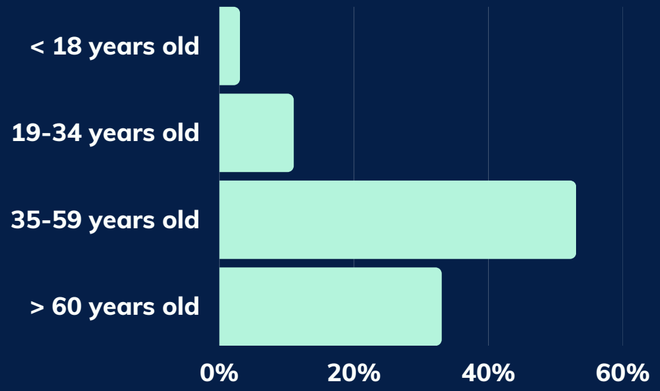
DEMOGRAPHICS

Patients with trial experience (n=36, 29%)

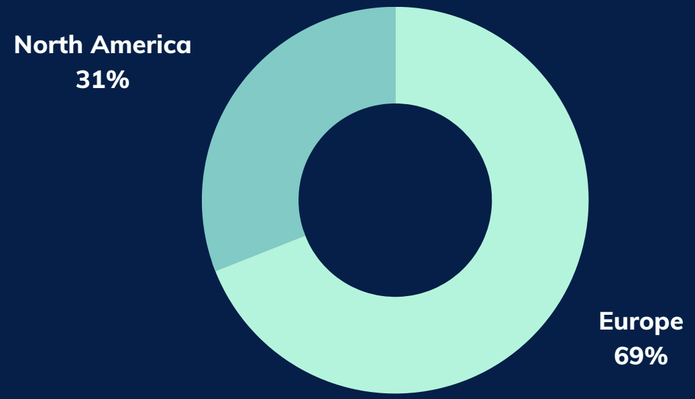
Gender



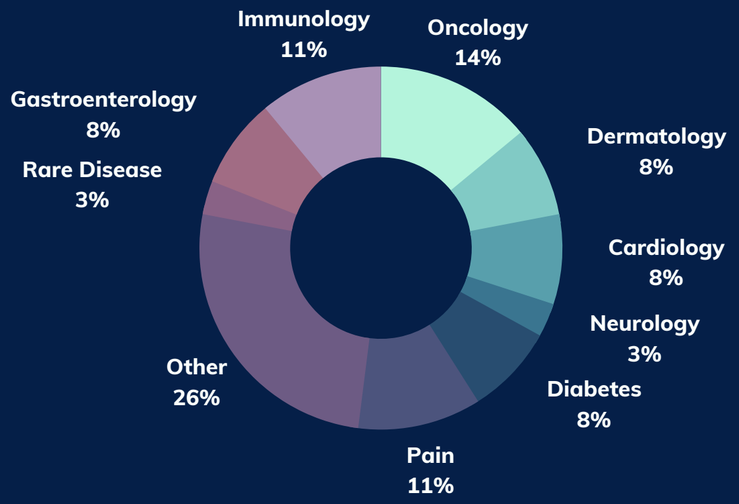
Age



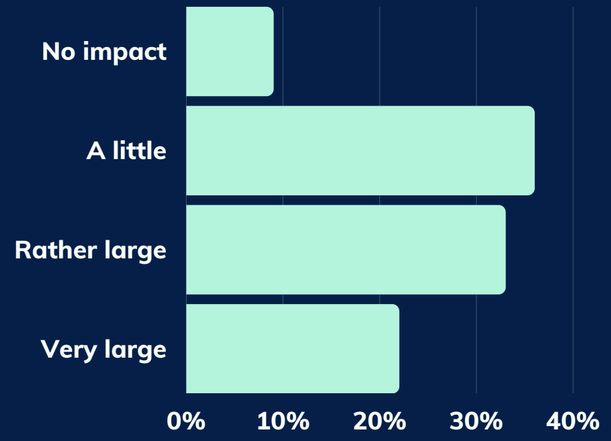
Location



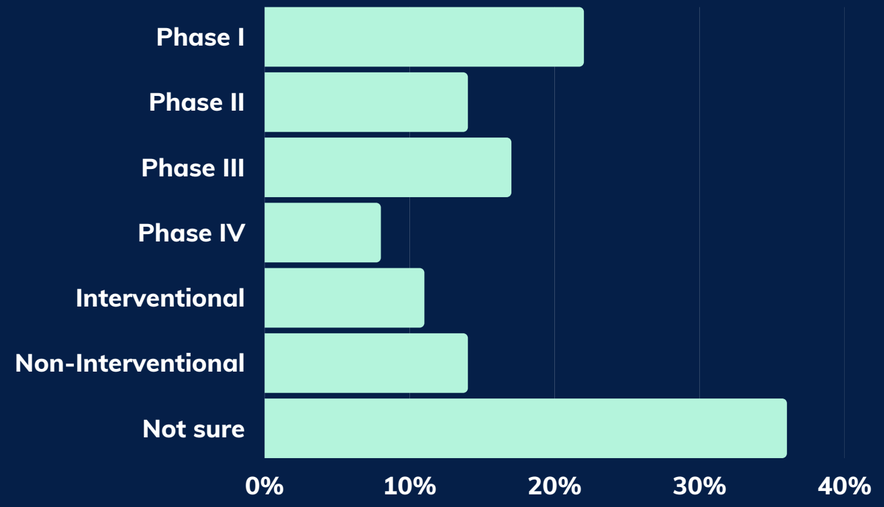
Disease Area



Impact of Disease on QoL

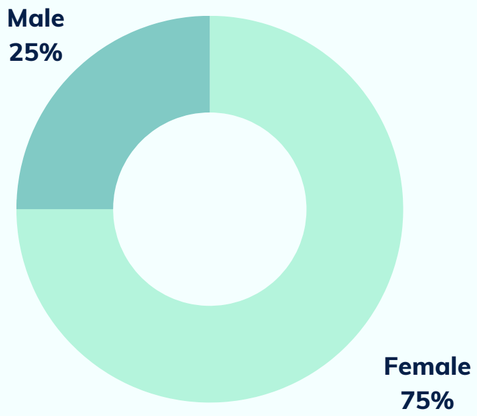


Study Phase

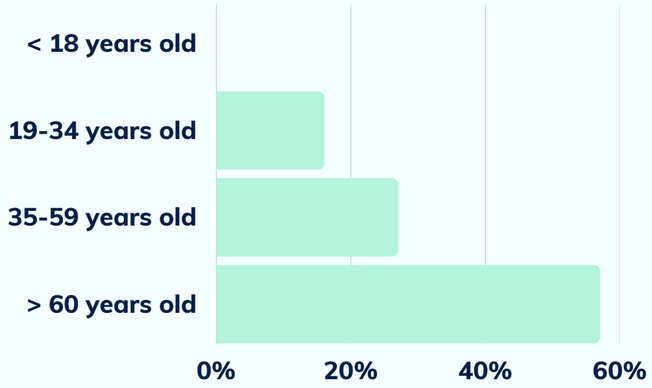


Patients without trial experience (n=88, 71%)

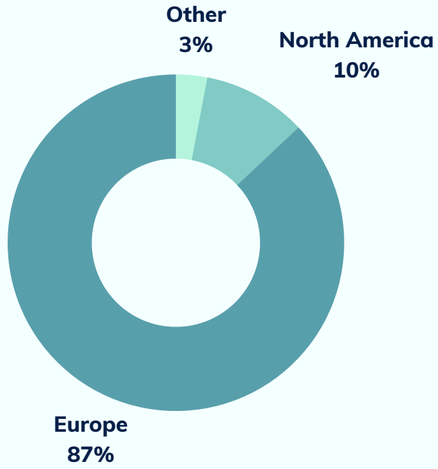
Gender



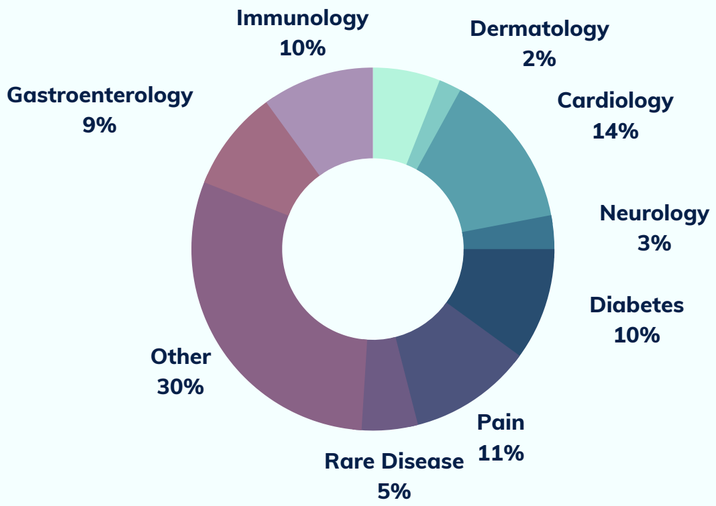
Age



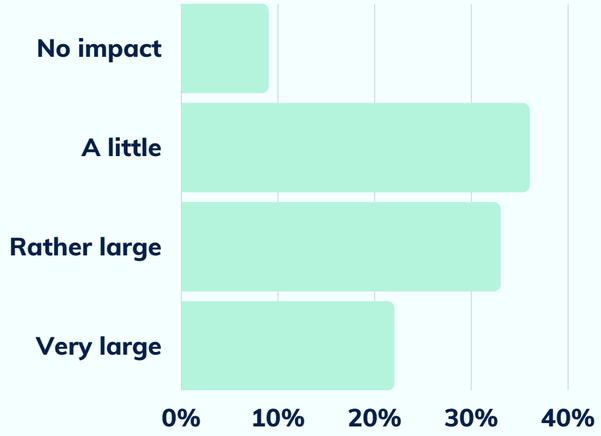
Location



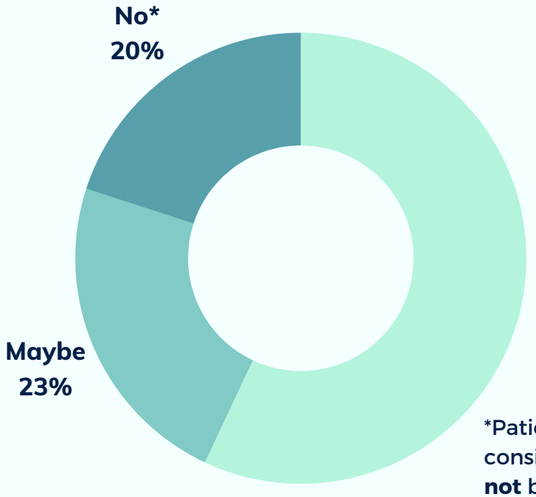
Disease Area



Impact of Disease on QoL



Openness towards joining a trial in future



*Patients who would not consider joining a trial have **not** been included in the evaluation

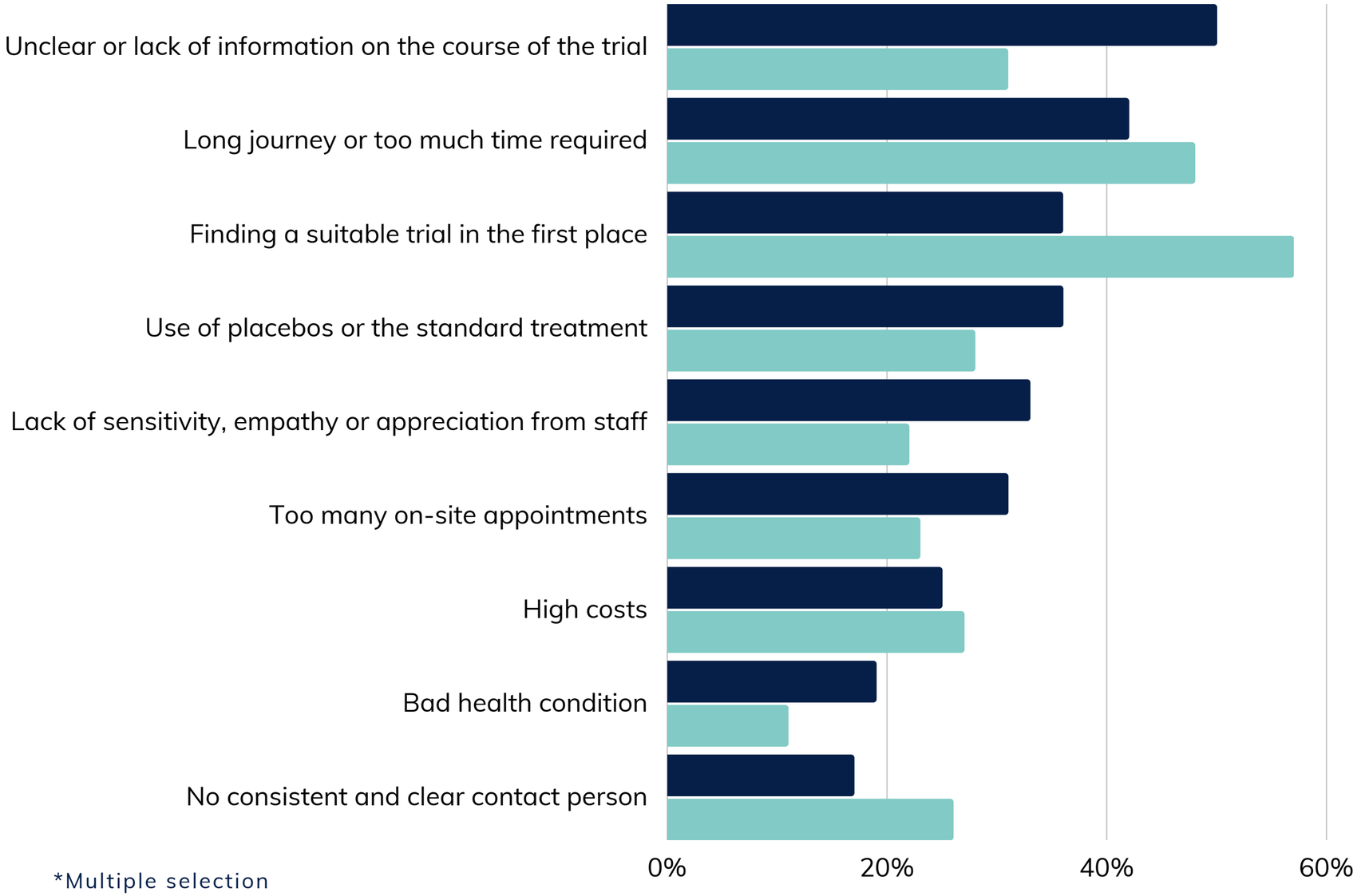
PATIENT ACCESS TO TRIALS

Lack of information and long travel are top barriers to joining a clinical trial

With trial experience

Without trial experience

What are the greatest barriers to joining a trial?*



For patients with trial experience, the top three barriers are centered around information handling, i.e. "Unclear or lack of information on the course of the trial" (50%) and "Finding a suitable trial in the first place" (36%), as well as travel: "Long journey or too much time required" (42%).

For patients without trial experience, the top three barriers were the same, but in reverse order, with "Finding a suitable trial in the first place" as the top barrier (57%).

One point worth mentioning is that the perceived lack of information was more prevalent for patients with trial experience, indicating room for improvement on how we communicate with patients during trials beyond enrolment and informed consent.

*Multiple selection

With trial experience | Without trial experience

Other barriers to joining a trial (open comments)

What are the greatest barriers to joining a trial?*

No obstacles. (named by 3 respondents)

No feedback of the results after finishing the trial. I had specifically asked for feedback / a summary of results.

Lack of objective measures in areas that are important for my illness.

Lack of information by the sponsor.

I haven't found one for CIDP (Chronic inflammatory demyelinating polyradiculoneuropathy).

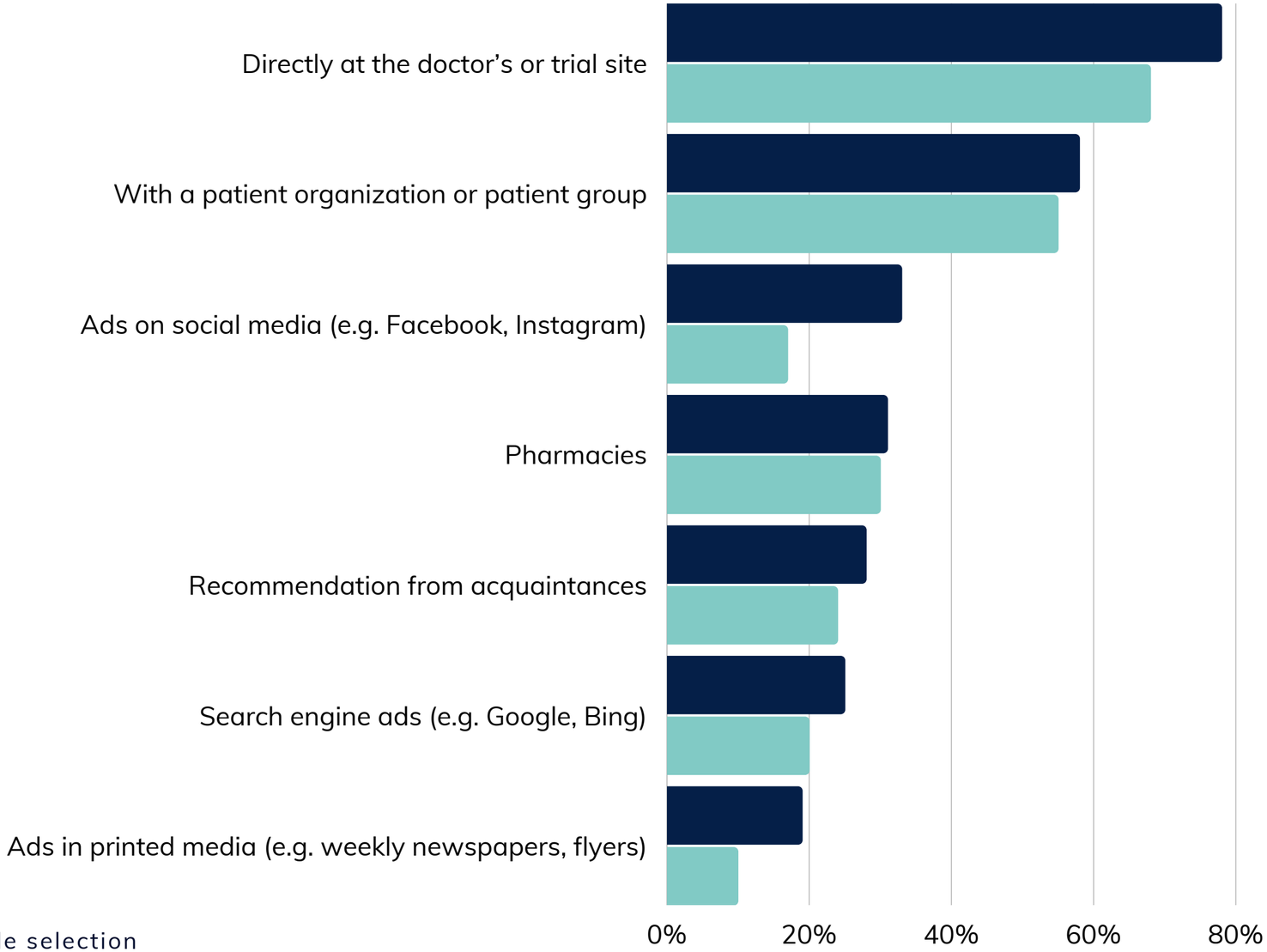
No obstacles.

With trial experience

Without trial experience

The doctor's office / trial site and patient groups are still the best places for patient recruitment

Where would you most likely find out about a clinical trial?*



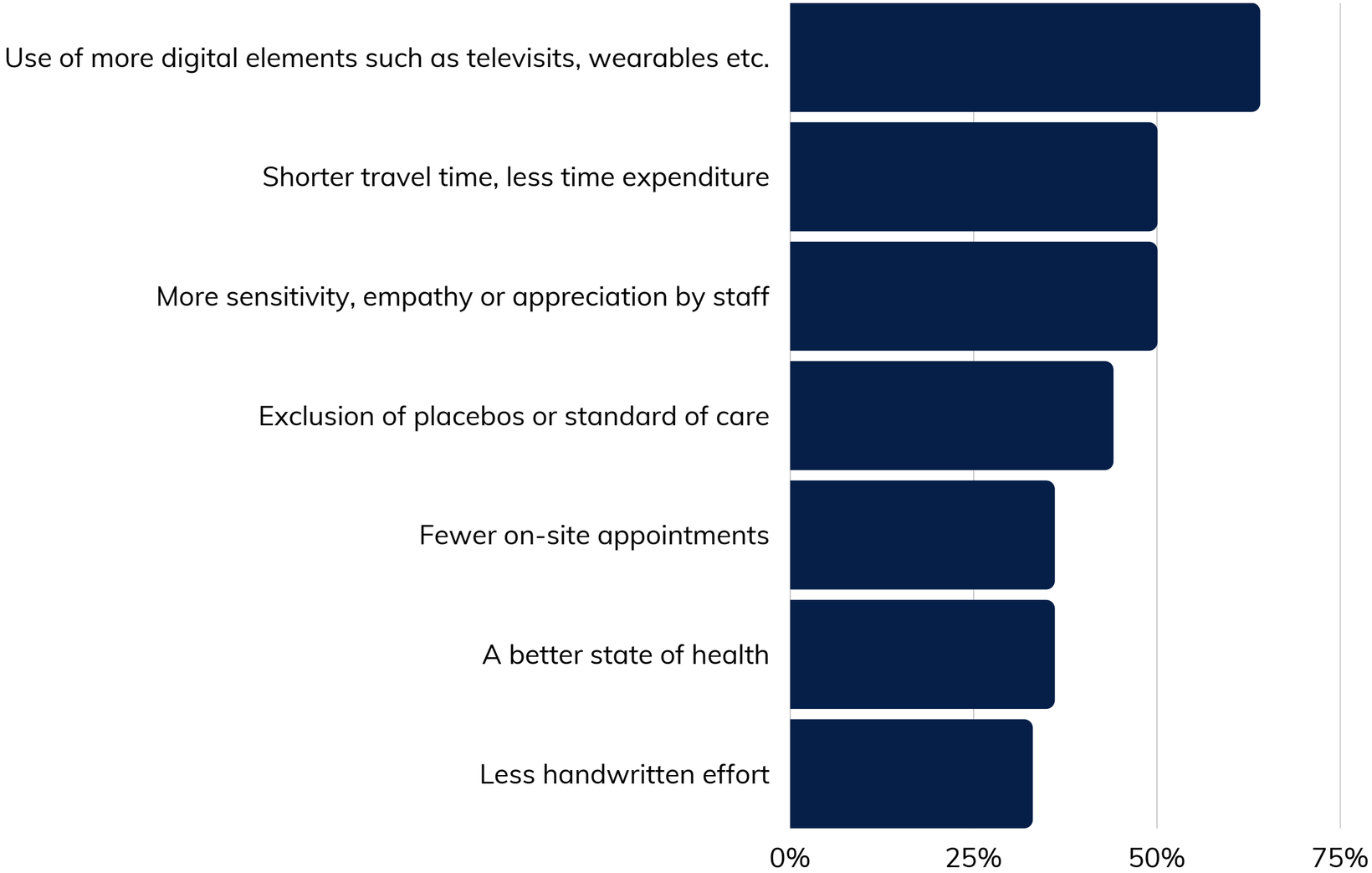
Despite their overall openness towards digital elements that we will see later on, when it comes to trial recruitment, the majority of respondents said they would be most easily reached via offline channels, such a doctor's office / a trial site (Ø 73%) or patient groups (Ø 57%). Clearly, the use of digital patient recruitment channels needs to be optimized (e.g. in terms of target group, displayed content) and isn't without its legal implications. Perhaps many patients are not aware of these platforms as potential channels, since they have not seen trial advertisements on them yet.

If we look at digital channels in isolation, however, patients with trial experience were slightly more open to them (e.g. social media (33%) or search engines (25%)), compared to patients without trial experience (17% and 20%, respectively). This trend could be related to patients who were in fact recruited through digital channels.

*Multiple selection

Digital elements, lower time investments and more empathy as key drivers for facilitating trial access

What would make you more likely to take part in a clinical trial in the future?*



Almost two thirds (64%) of patients said digital technologies, such as televisits or wearables would make their trial participation easier in future. With these elements, medical information can be shared from the comfort of their own home and unnecessary journeys can be avoided. Consistent with this preference, half the patients named "Shorter travel times" in second place.

"More sensitivity, empathy or appreciation by staff" was just as important as shorter travel times – also named by 50%.

It is important to note that this question also included older participants (aged 60 and above) who, on average, showed the same degree of openness to digital technologies as younger patients did.

*Multiple selection

Key drivers for facilitating trial access (Open comments)

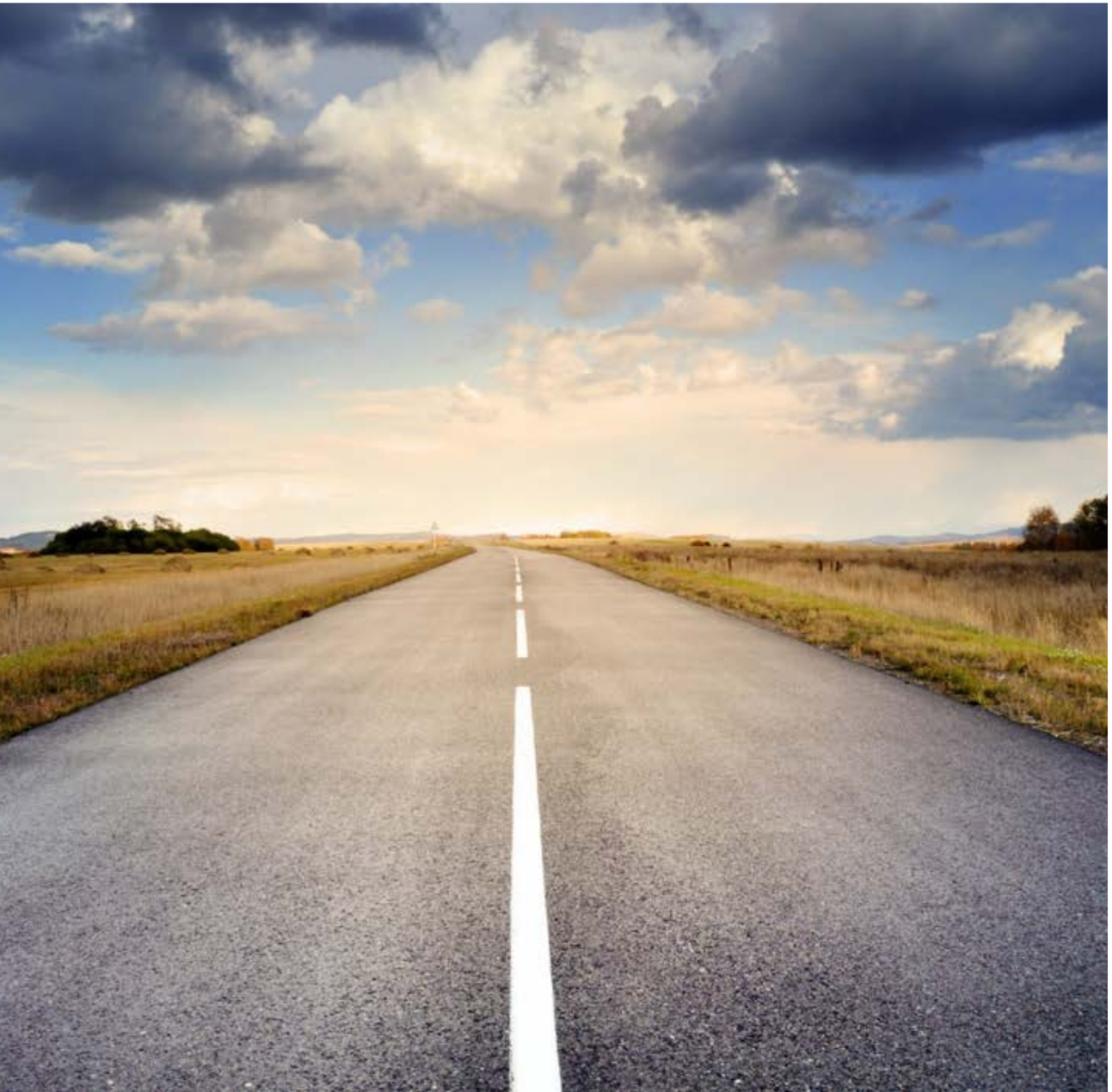
What would make you more likely to take part in a clinical trial in the future?

No overnight stays.

Personal and Public Involvement (PPI).

Availability of studies for my disease.

More objective measures to ensure results are accurate.



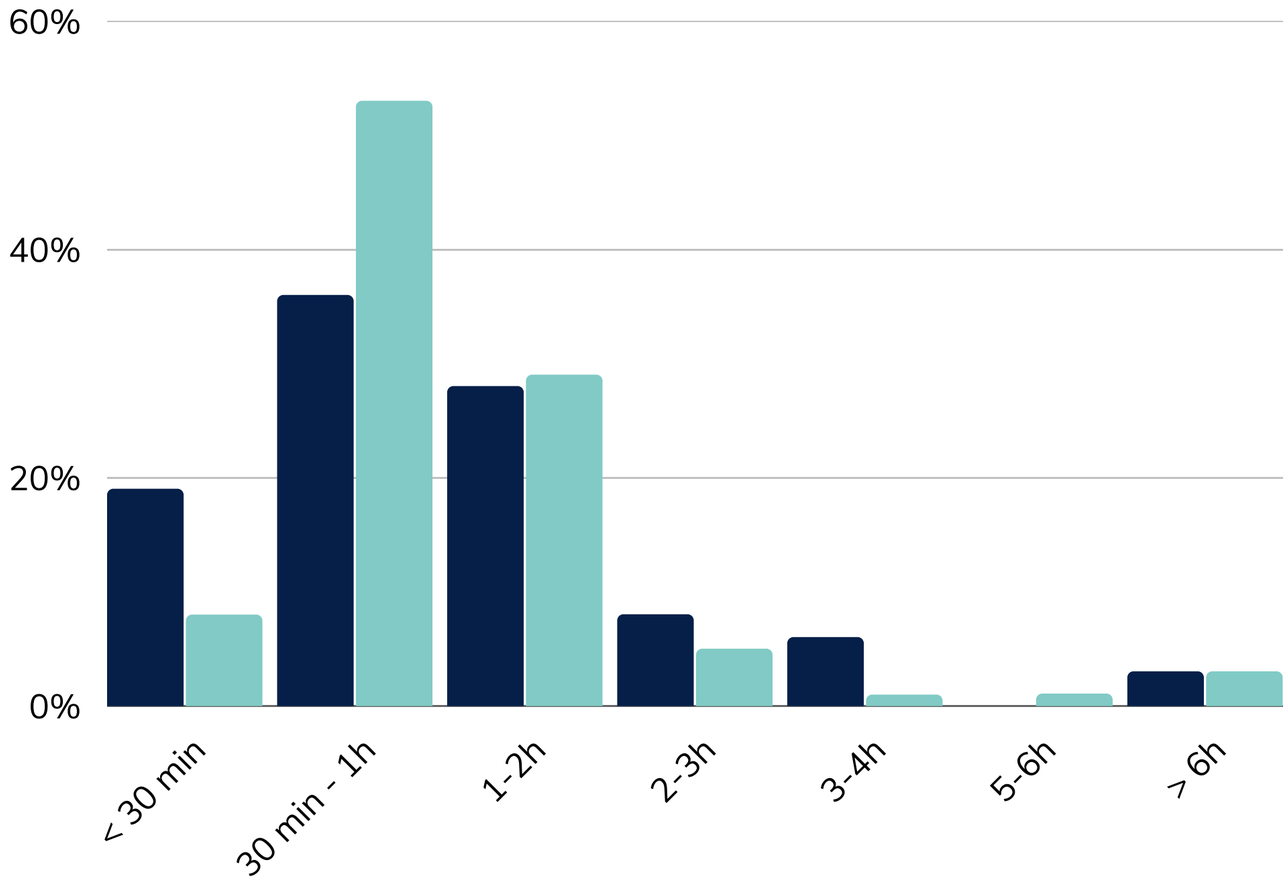
ON-SITE VISITS, COMMUNICATION AND TRAVEL

With trial experience

Without trial experience

Less frequent on-site visits mean higher tolerance for longer journeys

Suppose you had a clinical trial on-site visit every 2 months for 2 years.
What travel time would be acceptable for you to take part in the trial?



Every 2 MONTHS
for 2 years

If expected to travel to a site every 2 months for 2 years, 36% of patients with trial experience are willing to travel between 30 minutes and 1 hour. About one fifth of them would prefer to keep it under 30 minutes.

Just over half (53%) of the surveyed patients who have not experienced on-site visits of this kind say they would travel for up to one hour for an on-site visit.

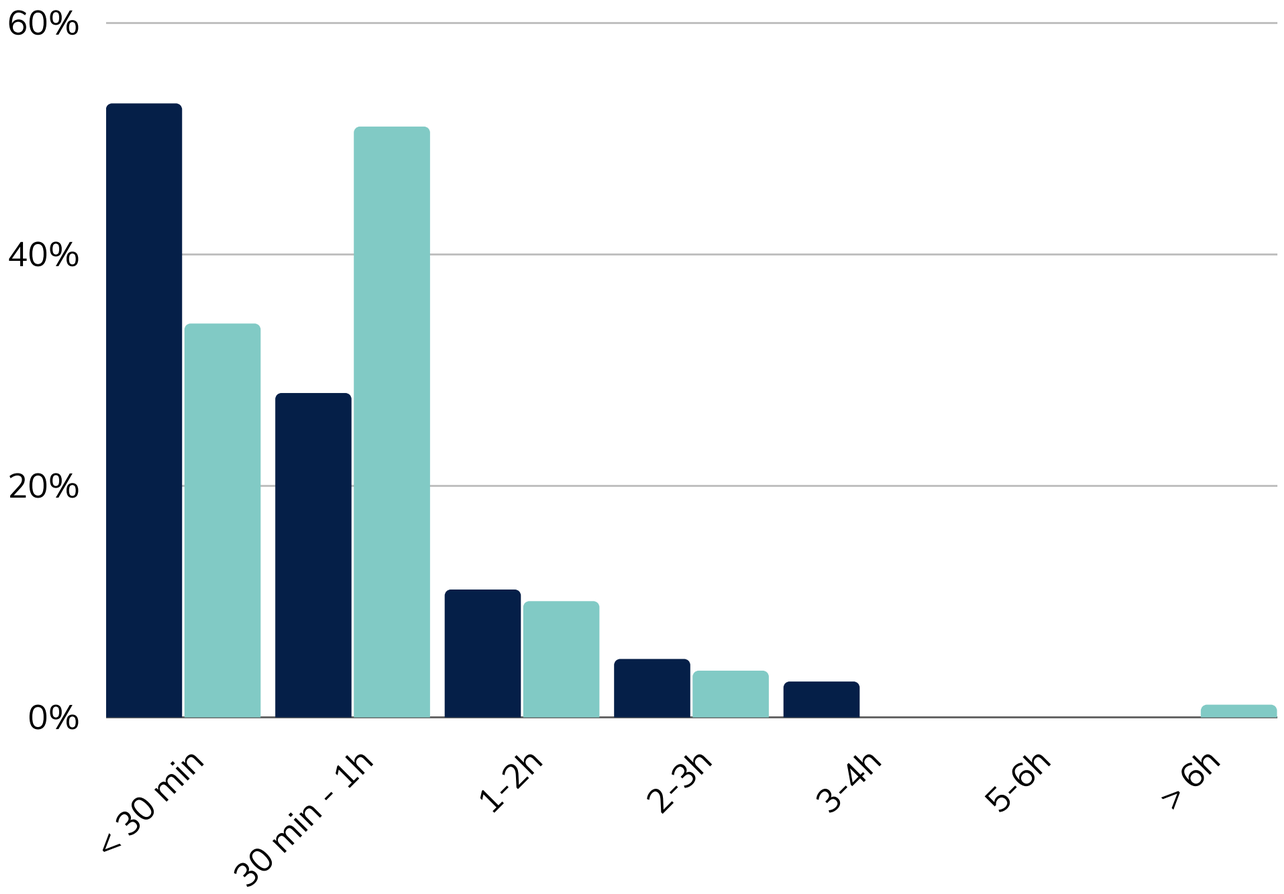
In both groups, just under 30% would be willing to travel 1-2 hours at this frequency.

With trial experience

Without trial experience

More frequent on-site visits mean lower tolerance for long journeys

Now, suppose you had a clinical trial on-site visit every 2 weeks for 2 years.
What travel time would be acceptable for you to take part in the trial?



Every 2 WEEKS
for 2 years

When it comes to bi-weekly travel over a two-year period, however, we see a shift: Half the patients with trial experience (53%) are willing to travel for 30 minutes at most. Patients without trial experience are more tolerant, with 51% of them willing to travel for up to an hour for a bi-weekly visit.

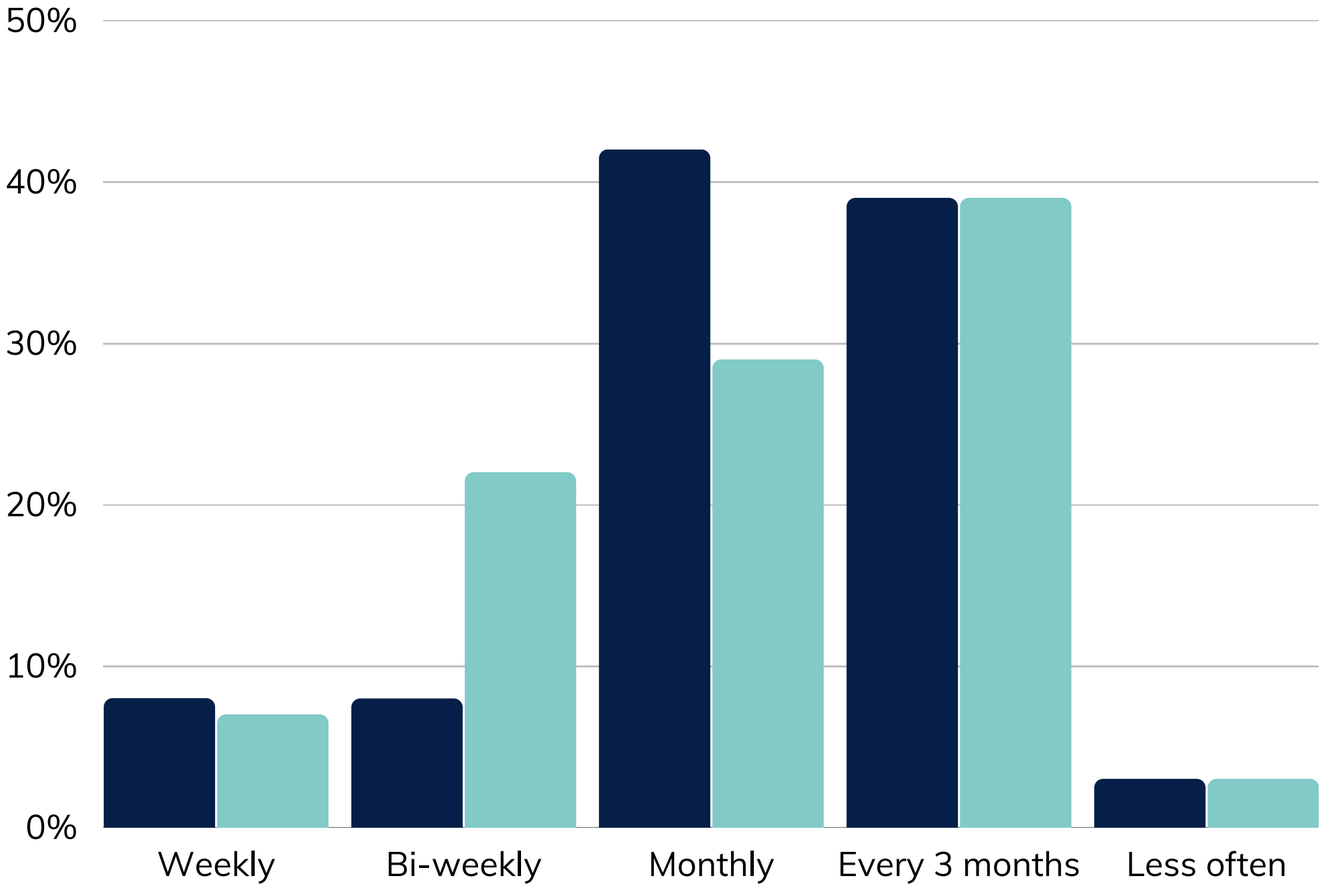
Notably, patients with trial experience appear to be more sensitive to an increased frequency of on-site visits than patients without trial experience (cf. also previous slide). This suggests that patients without trial experience may currently underestimate the impact of frequent travel on their stress and effort levels.

With trial experience

Without trial experience

In-person feedback should be kept to a minimum

How often would you like to receive feedback on your health progression from an on-site physician in a trial?



We have seen that receiving clear information is very important to patients (slide 8), but this does not mean that it always has to be in person. Over 70% of patients with trial experience would prefer to receive feedback from an on-site physician on their health progression on a monthly basis at most or less often.

Patients without trial experience are open to receiving such feedback from an on-site physician more regularly, e.g. "Bi-weekly" was cited by over one fifth. At the same time, these patients have not yet experienced the burdens this entails first-hand and may change their mind after joining a trial.

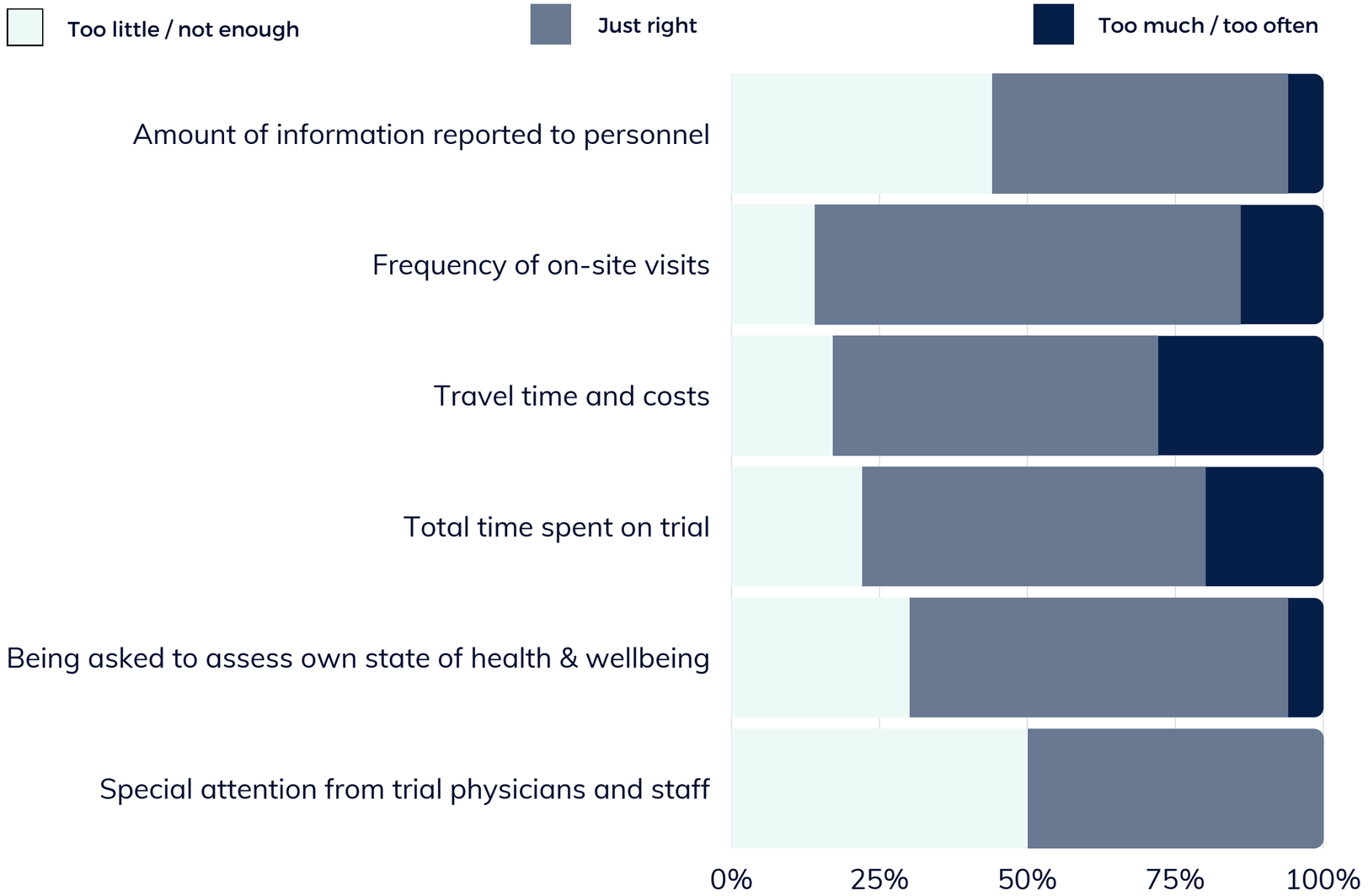
As we will see on slide 24, if such information were exchanged digitally, patients are willing to receive it much more frequently.

*Bi-weekly = occurring every two weeks

With trial experience

Patients are willing to report more information and would like more attention

How would you evaluate the use of the following elements in a clinical trial?



Insufficient information flow is a recurring theme throughout the survey. The "Amount of information reported to personnel" and "Special attention from trial physicians or staff" were perceived as "Not enough" by (almost) half the survey participants with trial experience. This lack of information appears to go in both directions: On slide 8, "Unclear or lack of information" was a top barrier to trial participation for patients, and several of them said they received no information on the trial results upon completion (slide 9).

As for aspects occurring too often/too much, travel time and costs are mentioned most often (about one quarter of all respondents). This is consistent with previous results (cf. slides 8 and 11). Ironically, some patients say there is too little travel.

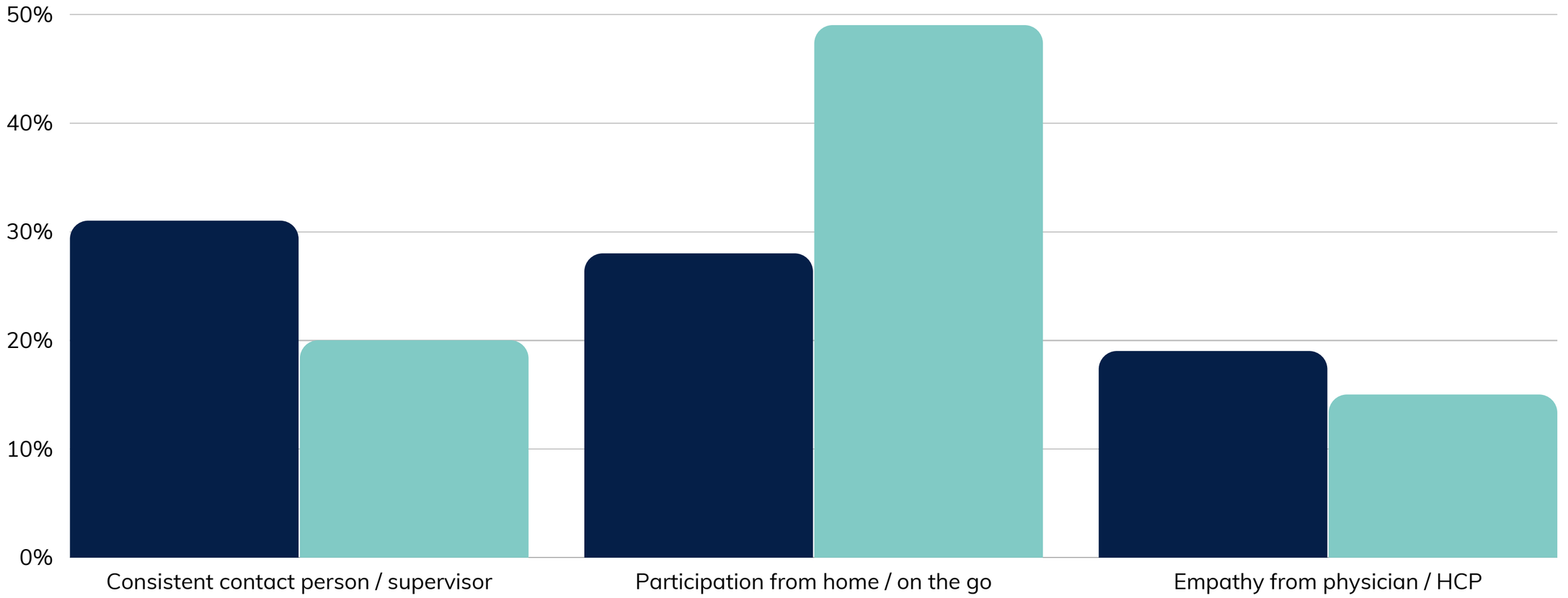
With trial experience

Without trial experience

Consistent contact persons, participation from home and empathy matter most to patients

For this question, respondents ranked certain aspects of a trial from highest to lowest importance. We looked at the three aspects that were most frequently ranked in 1st place. For patients with trial experience, these were "Consistent contact persons" (31%), "Participation from home / on the go" (28%) and "Empathy from physicians / HCP" (19%). Interestingly, patients without trial experience placed even greater emphasis on flexible participation and less emphasis on consistent contact persons or empathy.

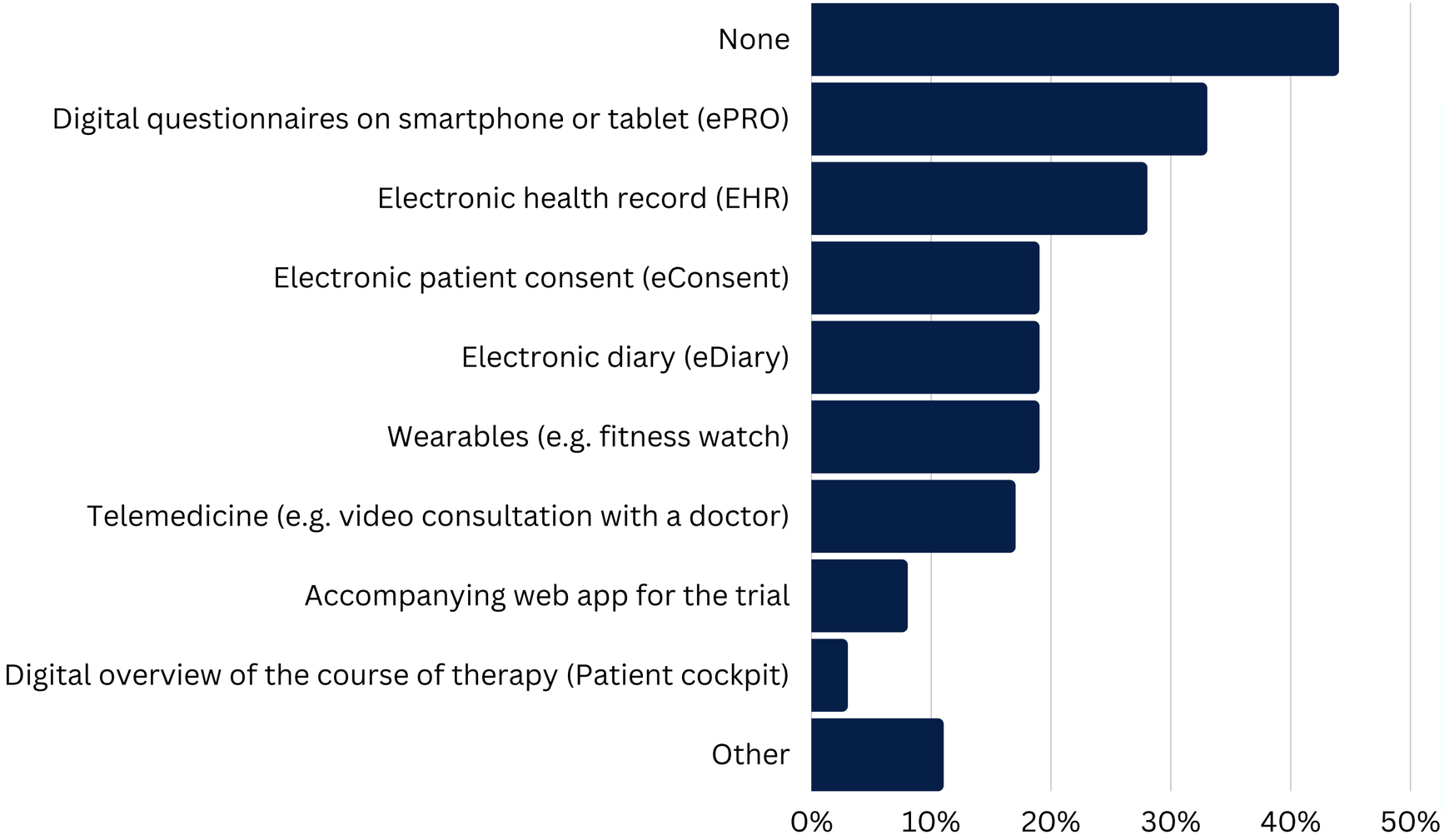
Which aspects would you consider most important in a trial? Please sort the answers from high to low importance.



DIGITAL TECHNOLOGIES IN TRIALS

ePRO and EHR are among the most frequently used tools in trials so far

Which digital technologies have you already used in a clinical trial?*



Surprisingly, 44% of patients with trial experience say no digital technologies were used in their trials, meaning there is still much untapped potential in this area.

In second place 33% of patients named ePRO (electronic patient-reported outcomes), i.e. digital questionnaires which can be completed on a smartphone or other device. Just under 30% had used EHR (electronic health records), while just almost one fifth had used eConsent, eDiaries and wearables.

Telemedicine, accompanying web apps or so-called patient cockpits still appear to be relatively rare occurrences in trials. But as the next slide shows, many patients are interested in the cockpit idea.

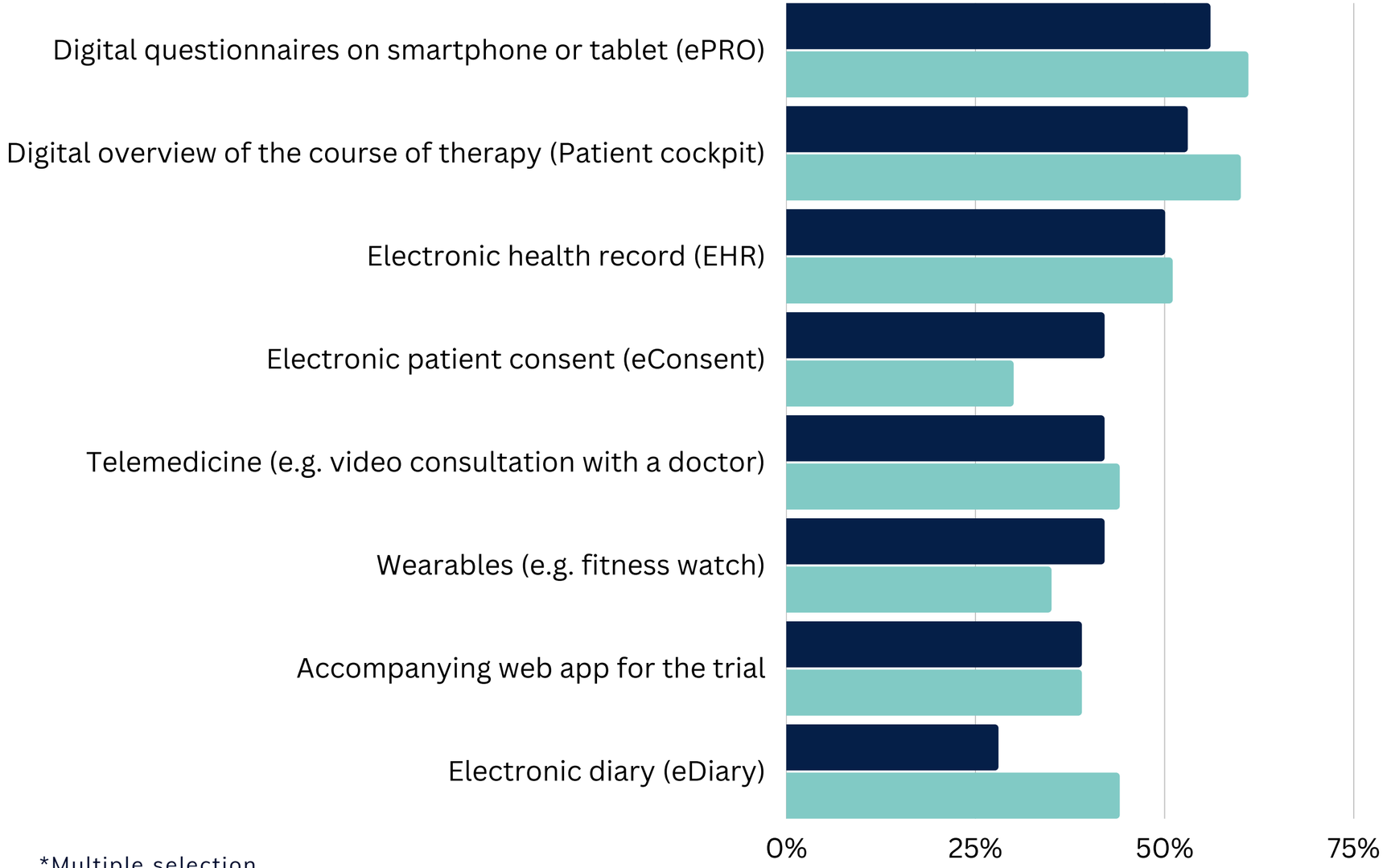
*Multiple selection

With trial experience

Without trial experience

Most patients would like to use ePRO, a patient cockpit and an electronic health record

Which digital technologies would you like to use in a clinical trial?*



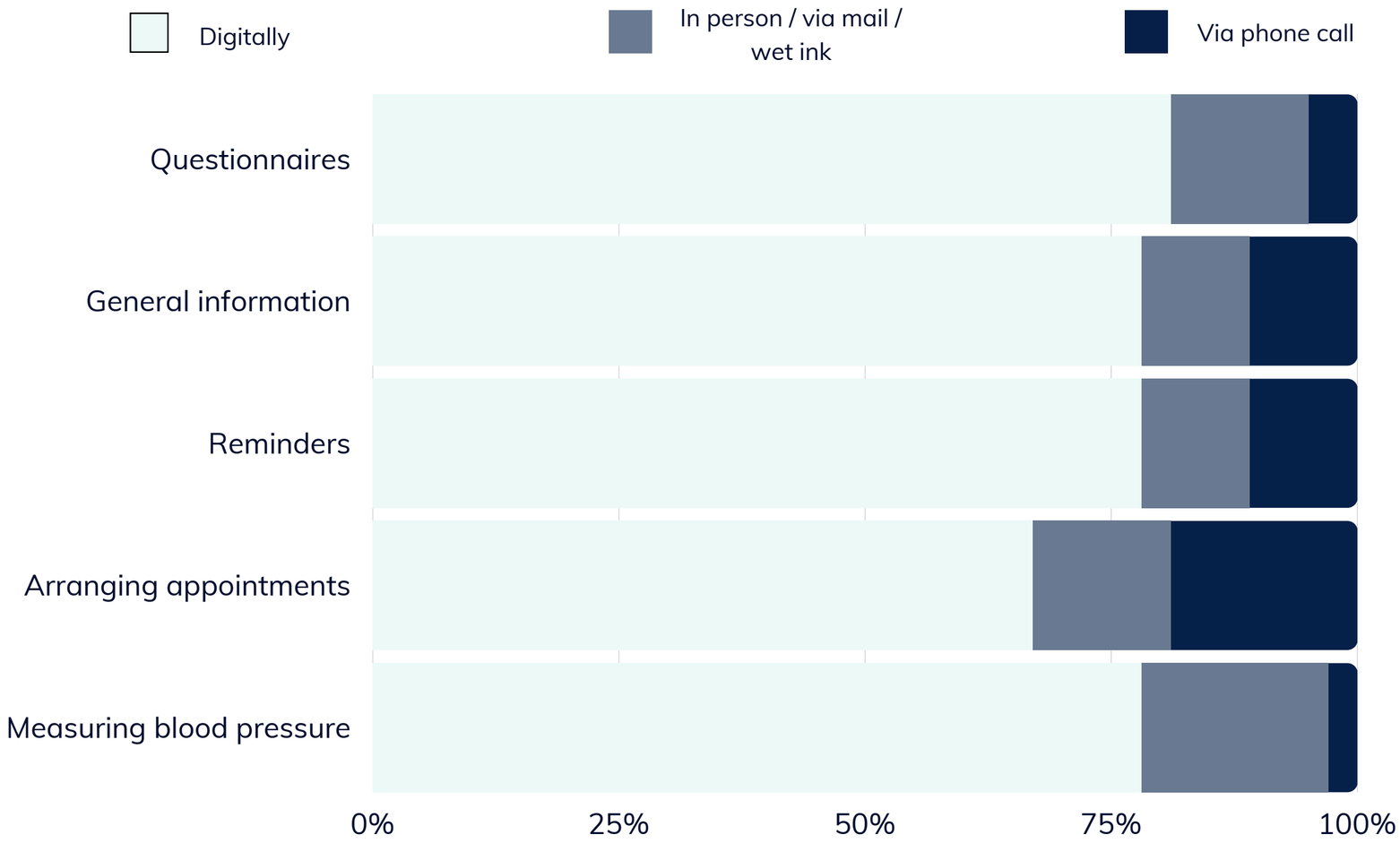
When asked which technologies they would like to use, 56% of patients with trial experience named ePRO (which, as the previous chart showed, has already been used by a third of this group – i.e. this could mean it is a popular tool for patients), a patient cockpit (53%) and the EHR (50%). The idea of the patient cockpit giving a digital overview of the therapy course supports patients' strong need for clear information that we perceived in other questions. eConsent, Telemedicine and Wearables also bear a lot of potential for this sub-group, each cited by 42%.

Patients without trial experience paint a very similar picture for the top three: 61% of them would like to use ePRO, 60% are interested in a patient cockpit and 51% named EHR.

*Multiple selection

Patients with trial experience prefer digital channels

How would you prefer to record your condition, symptoms and other clinical aspects in questionnaires or be informed about them?

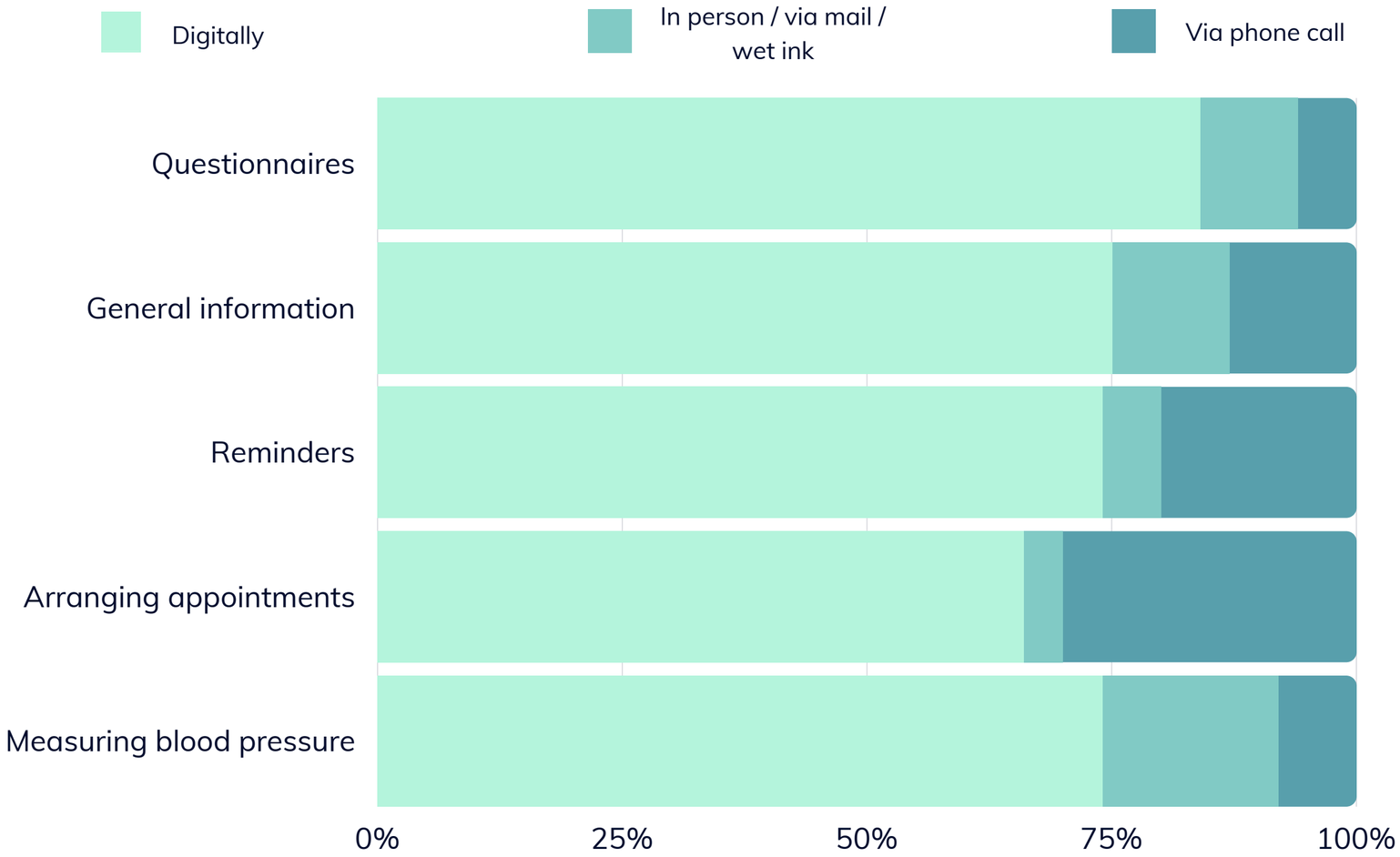


76%

On average, 76% of patients with trial experience would like to record their health condition and symptoms or receive important information in a digital format.

The same goes for patients without trial experience

How would you prefer to record your condition, symptoms and other clinical aspects in questionnaires or be informed about them?



75%

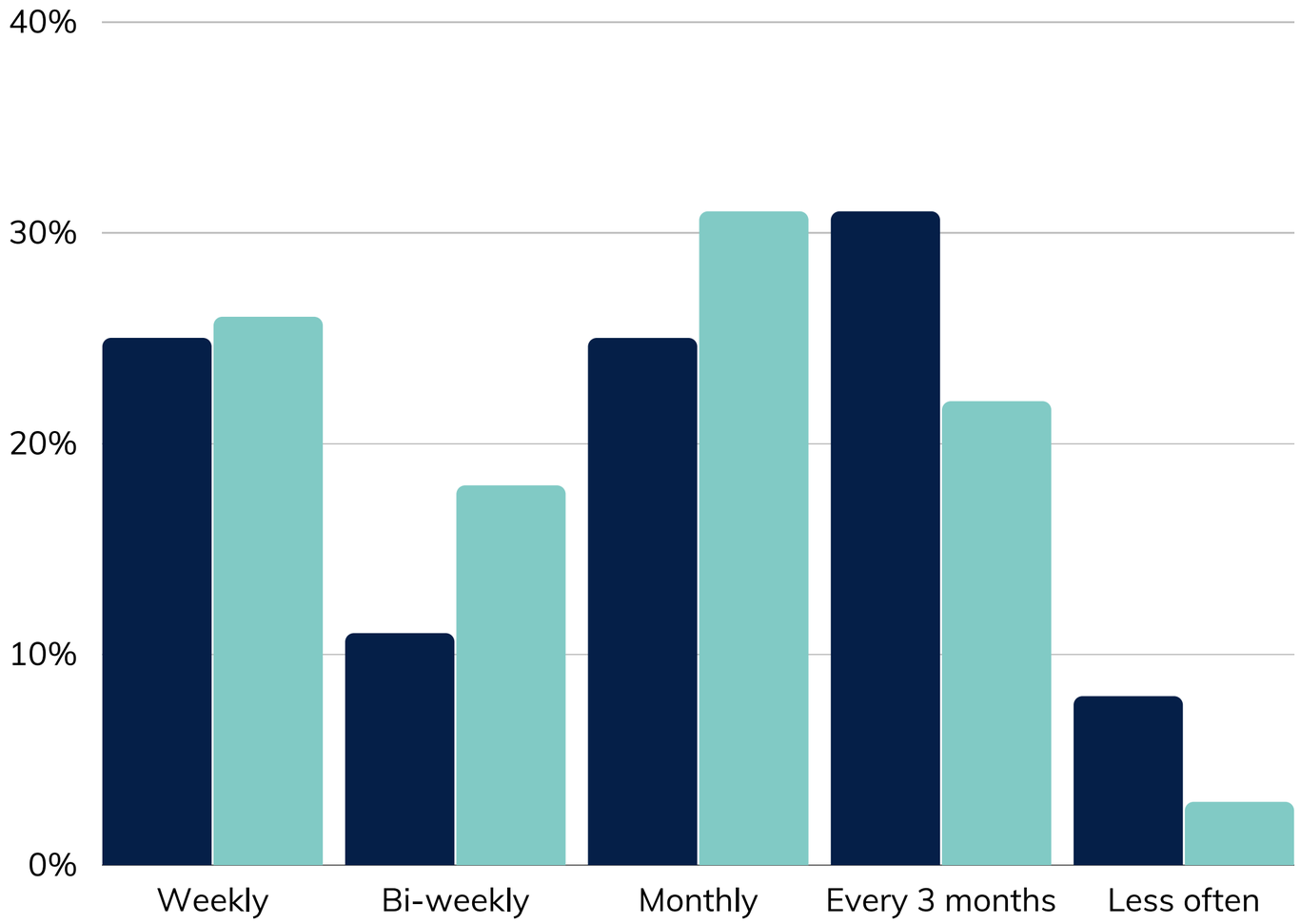
On average, 75% of patients without trial experience would like to record their health condition and symptoms or receive important information in a digital format.

With trial experience

Without trial experience

Feedback on health progression via digital channels (video, email, app) could occur more regularly

How often would you like to receive feedback via digital channels in a trial?



*Bi-weekly = occurring every two weeks

When it comes to digital channels, patients are more open open to receiving information more regularly compared to in-person (cf. slide 16) – 36% of patients with trial experience cited a "Weekly" or "Bi-weekly" basis.

44% of patients without trial experience are open to receiving such feedback via digital channels on a weekly or bi-weekly basis.

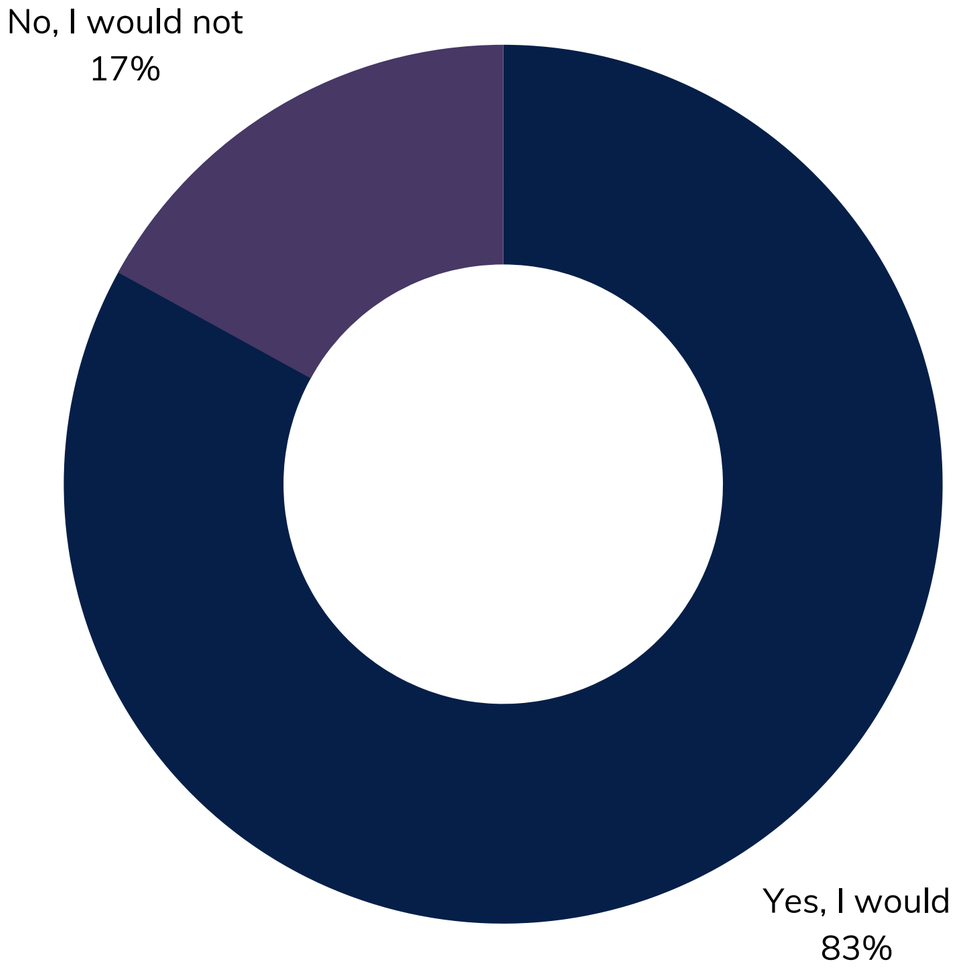
This supports the clear tendencies seen on slides 23 and 24 – digital channels are popular and patients are willing to use them more frequently than in-person communication channels.

A LOOK AT THE FUTURE & FINAL COMMENTS

With trial experience

Most patients would be willing to take part in a clinical trial again

Would you be willing to take part in a clinical trial again?



With trial experience

Open comments for "Yes"

Please explain your answer

> I'm aware of the necessity of studies. And while in a study, I am still better cared for than without a study, i.e. as a normal patient at my GP.

> Anything to help others in my position. I feel that I can make a difference, that the results are relevant to the patients' health and wellbeing.

> [...] I think it is very important to run studies to improve my quality of life. However, it is important integrate the study better into my daily life.

> I had exhausted all traditional treatments [...]. I am currently in my 4th trial and this has been the only way to get relief.

> Without trials, there can be no improvement of healthcare.

> The financial reimbursements are unclear and have left me out of pocket [...], but [...] I believe I am benefitting from the medication, [...].

> Yes, as long as it's without overnight stays.

> I received treatment sooner than if I'd waited for the treatment to be commercially available.

> My disease has no cure, so participating in a trial would be my only hope.

> The staff were amazing, and it felt good to know that I contributed to an understanding of my rare disorder [...]. I learned a lot about [...] its effects on my health.

> I have multiple medical issues. If I can get the slightest bit of relief, it is worth it.

> I want the best care available for myself, loved ones and future generations.

With trial experience

Open comments for "No"

Please explain your answer

> Given my comorbidity, I do not want to run the risk of getting further medical issues due to additional side effects.

> The time and costs involved are too high, e.g. having to appear to on-site visits in person.

With trial experience

Closing remarks by respondents with trial experience

Is there anything else you would like to share with us?

> I would imagine that some patients were unable to answer every question.

> Great way to get important information.

> For me, the relevance of the research question and proactive PPI (not just a tick-box exercise) are important.

> Such questionnaires are very important.

> Happy to be involved in patient care and wellbeing!

Closing remarks by respondents without trial experience

Is there anything else you would like to share with us?

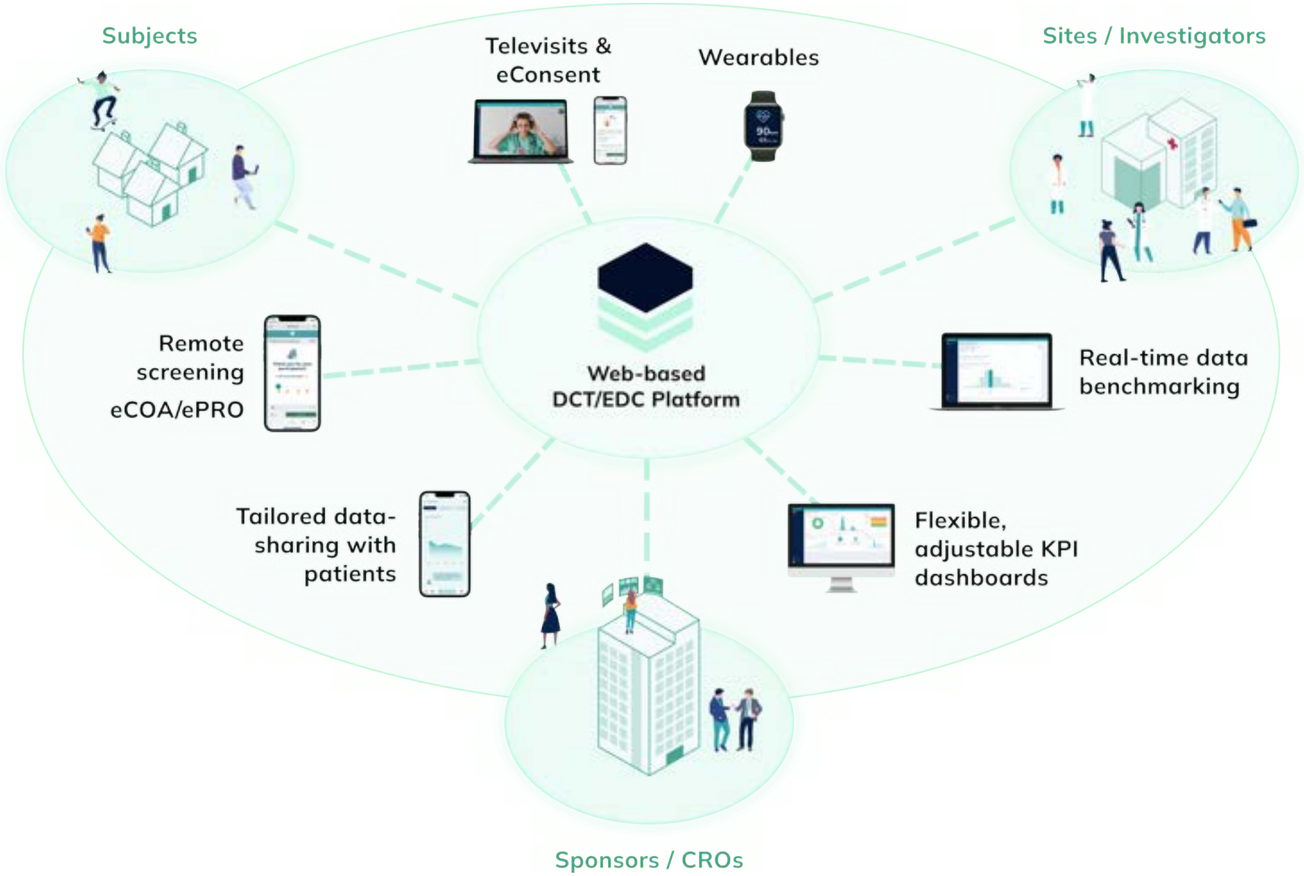
> With rare diseases, [...] I think is important that [...] there is psychological support [...]. [...] it is not just the body that goes through it, but also the mind.

> In general, we should learn more about trials and the results [...] in the news (often it is very positive news). I am very interested and always feel that I have to search [...] and/or learn about it by chance.

> I would like to take part in a study on osteoporosis because I think that this disease and its effects on the patient are not given enough attention by doctors.

> I have participated in a lot of [...] trial design advisory boards where I advocate for a more empathetic recruitment design strategy. Most of the [...] trial design don't do enough to build trust with vulnerable communities.

> The bureaucratic burden on individual groups in self-help organizations urgently needs to be reduced.



CONTACT DETAILS & ABOUT CLIMEDO AND TRIALS24

Any questions? We look forward to hearing from you!

Catherine Higginson

Marketing &
Communications Lead
Climedo

catherine.higginson@climedo.de
+49 89 3220939 47

Dr. Matthias Roos

Associate Director
Strategy
Climedo

matthias.roos@climedo.de
+49 89 3220939 421

Dr. Tobias Kruse

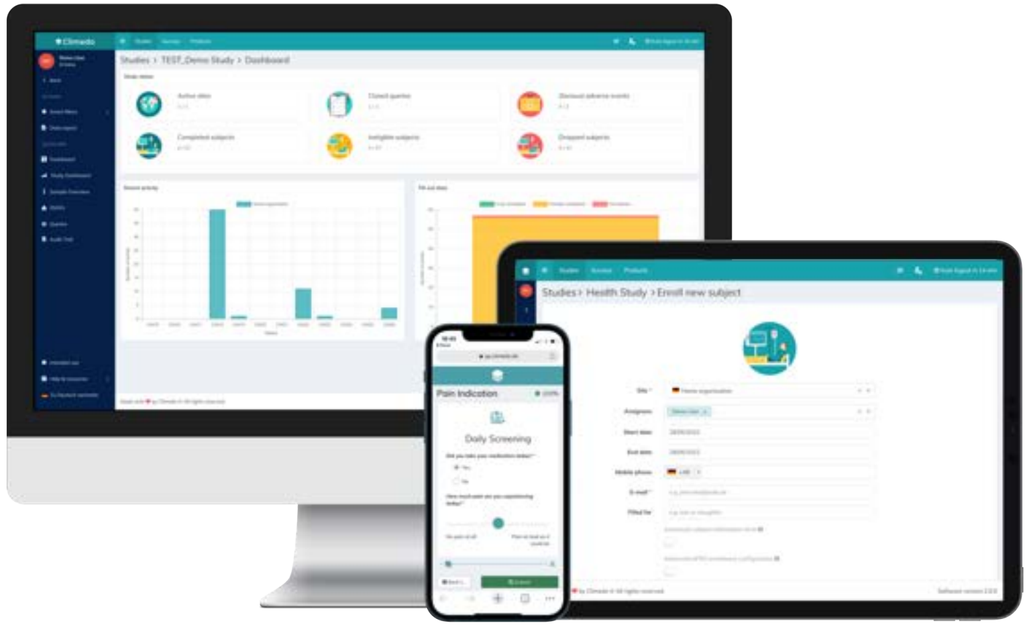
Founder & CEO
Trials24

tobias.kruse@trials24.com
+49 89 21537 4991

www.climedo.com
www.trials24.com

About Climedo

Climedo offers a digital health platform for hybrid clinical trials and observational studies. Its easy-to-use, modular and secure solutions for data management include electronic data capture (EDC), ePRO, eCOA and Telemedicine. This enables pharma and medtech companies to validate their medical innovations more efficiently in the post-market phase and to capture data in decentralized, real-world settings. As a result, they accelerate studies, save costs, and improve data flow and quality, while fostering innovative trial designs. By connecting all stakeholders (industry partners, study sites, physicians and patients) in one cloud-based system, Climedo is revolutionizing clinical research and making trials more accessible and patient centric.



Learn more at www.climedo.com.

About Trials24

Trials24 accelerates patient recruitment to help biopharmaceutical companies and CROs complete their clinical trials on time, bringing innovative drugs to patients faster.
Trials24 speeds up your clinical trial's patient recruitment by finding patients outside your site's databases. This OutSite™ approach finds patients when the site's databases reach their limit. Their proven end-to-end process identifies patients not registered at your clinical trial sites. Trials24 finds patients online, through patient organizations, or at their treating physicians, triple-prequalifies them, and delivers them to your site for enrollment. Trials24's OutSite™ approach works in all clinical trial phases and for many indications – including complex ones like cancer and rare diseases.

Learn more at www.trials24.com.