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Patient Engagement in Clinical Trials: Patient, Industry, and Clinical Investigator Perspectives

A Report of the Science of Patient Input Program
of the Medical Device Innovation Consortium (MDIC)

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Overview

As part of its Science of Patient Input (SPI) project to develop a Framework for Patient Input in Medical Device Clinical Trials, the Medical Device Innovation Consortium (MDIC) conducted three surveys and one set of telephone interviews to compile information about patient engagement activities among device and diagnostic industry stakeholders, individuals identifying as patients, and a select group of medical device study investigators. Collectively, the information gleaned from these three surveys provides detailed perspectives on patient engagement during clinical research from key stakeholders in medical device clinical trials. This information will also be incorporated into the MDIC's report on Maximizing Patient Input in the Design and Development of Medical Device Clinical Trials.

In 2018, MDIC surveyed 53 device and diagnostic industry stakeholders and separately surveyed 123 individuals identifying as patients. The goal of the complementary surveys was to inform future work to develop guidelines for industry on how to involve patients in the design of clinical trials. For the third survey in 2020, we focused on investigators who received research funding from the Patient-Centered Outcomes Research Institute (PCORI) because PCORI requires investigators to engage patients and other stakeholders in their study. Of 33 investigators who received research funding from PCORI, seven responded to the online survey and five completed detailed telephone follow-up interviews during the period of March 16, 2018, to May 11, 2018.*

Within our survey response populations, we discovered:

- More than 50% of industry respondents involved in protocol development never gained patient input during protocol development. An additional 28% gained patient input less than 25% of the time.
- Figures were even greater for industry gaining patient input to operational study design after protocol finalization with more than 80% involving patients never or less than 25% of the time.
- There were some disconnects in the perspectives of industry versus patients with regard to the reasons patients might enroll in a clinical trial, particularly around the importance of doctor recommendation.
- Investigators who have received PCORI funding for their research are required to incorporate patient and stakeholder engagement in the development and conduct of their device studies, giving them experience in this area from which others in the device development field could learn.
- Engaging patients in the design and conduct of device trials takes time and requires consistent commitment on the part of study investigators to identify the right patient partners, ensure they have the training and resources needed to participate, and commit to valuing their input.
- Multiple methods are employed for engagement of patients in device trials, with multiple types of impact, including key elements of study design (e.g., inclusion/exclusion criteria, endpoints, conduct of the study).

The lack of patient involvement by industry in study design, contrasted with some of the differences in perspective that this survey uncovered, supports the need for further work to enable medical device and diagnostic companies to gather meaningful input from patients into the design of clinical trials. The device development field could benefit from additional resources and tools to support patient engagement in clinical trials, including establishment of a clearinghouse through which generalizable education and training materials for patient partners could be shared.

*This MDIC survey was launched in early 2020, just prior to the onset of the COVID-19 pandemic. Recognizing the disruption to investigators' activities due to this unprecedented set of circumstances, MDIC concluded that it had received sufficient responses to compile this report through the online instrument and the detailed phone interviews prior to the onset of COVID and therefore decided to close the survey.

Background

It is generally well accepted that clinical trials across the drug, device, and diagnostic industry have challenges recruiting and retaining patients. Research from Tufts Center for the Study of Drug Development[1] highlights that 60% of protocols require one or more amendments (average 2-3) of which 20% are due to protocol design flaws and difficulties recruiting study volunteers. In addition, sponsors suggested that 34% of amendments were deemed partially or completely avoidable. The Center for Information and Study on Clinical Research Participation (CISCRP) research[2] suggests that 37% of sites under-enroll and 11% of sites fail to enroll a single patient while National Academy of Sciences research[3] shows that on average, more than 30% of clinical trial participants drop out before becoming evaluable. Trials are becoming more complex for patients to be involved in, and competition for patients is increasing in many therapeutic areas.

Much work has been done in the pharmaceutical industry over the last few years to gather meaningful input from patients in the design of clinical trials and specifically to inform protocol development. The intention has been to better understand a specific trial patient population, enabling development of a meaningful protocol design that maximizes relevance to the patient and makes it as easy as possible for the specific population involved to participate in a study. In turn, understanding these factors upfront and designing trials accordingly are expected to have a positive impact on study recruitment, retention, and compliance.

The medical device industry is increasingly focused on the potential benefits of engaging patients in the design and execution of its clinical studies, with researchers, sponsors, and regulators collaborating to expand use of patient engagement within the clinical development process of devices by identifying and sharing best practices. The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) convened a Patient Engagement Advisory Committee (PEAC) meeting to discuss these issues in 2017,[4] and the agency issued draft guidance related to these topics in September 2019.[5]

By evaluating the current practices and perspectives of the three key stakeholder groups—device manufacturers, clinical investigators, and patients—this project provides important contributions to the evidence base supporting efforts to leverage the opportunity to engage patients to help create better, more successful clinical trials.[6,7]

Section 1: Methodology

SECTION 1

Methodology

Three surveys were created in a popular survey website to gauge current attitudes toward the role of patient input in clinical trial design. Links to the surveys were disseminated through a convenience sample of MDIC member organizations and other affiliated organizations as appropriate to the goal of each survey. Copies of the surveys can be found in the Appendix.

1.1 Patient Survey

The first survey was designed to obtain patients' interest in clinical trials and perspectives on various factors that would encourage participation in clinical trials or that may discourage participation. The patient survey contained 31 questions in a branched design (e.g., if a patient indicated they had previously participated in a clinical trial, then the subsequent questions would be different than if they had not). Prior to publishing, the survey questions were reviewed by the MDIC Science of Patient Input (SPI) Steering Committee, patient advocates, and self-identified patients. The link to the survey website was shared with patient groups, including the American Sleep Apnea Association, the American Heart Association, the diaTribe Foundation, the Michael J. Fox Foundation for Parkinson's Research, and Unite 2 Fight Paralysis. The survey received 124 responses from June 6, 2018, to July 16, 2018. Each organization was encouraged to share the survey with its members but did not report the actual number of recipients, so it was not possible to calculate a response rate.

1.2 Industry Survey

The second survey was intended to gather feedback from the medical device industry regarding the prevalence of and current practices for obtaining patient input into the design of clinical trials. The survey contained 14 questions that were reviewed by the MDIC SPI Steering Committee prior to publishing. The link to the survey website was shared with representatives from MDIC member companies as well as members of the AdvaMed Clinical Trials working group. The survey received 53 responses from August 26, 2018, to October 21, 2018. Each organization was encouraged to share the survey among its employees but did not report the actual number of recipients, so it was not possible to calculate a response rate.

1.3 Clinical Investigator Survey

The third survey was developed and approved by the working group and was designed to focus on investigators who lead medical device clinical trials and who are likely to have experience with patient engagement techniques. To identify these individuals, we focused on investigators who had received PCORI research funding.[†] While the MDIC survey was not limited to the investigators' PCORI-funded research, given that PCORI research awards require incorporation of patient input, it was hypothesized that investigators who had been successful in securing a PCORI research award would be likely to have insights about best practices for patient engagement in clinical studies.

The survey contained 10 substantive questions (6 open-ended and 4 with prespecified response options) and was distributed via email with a Survey Monkey link. The survey could be completed anonymously, or the investigator could choose to provide contact information. Respondents were also invited to participate in a follow-up telephone

[†]It should be emphasized that, while PCORI staff participated in the MDIC SPI working group, this survey was conducted solely under the auspices of MDIC, and investigators were clearly advised that their participation was neither required by PCORI nor would their responses be shared with PCORI.

interview (see interview guide in the Appendix). The survey was first sent out February 12, 2020, and remained open until May 4, 2020. Initial outreach was followed up with multiple follow-up emails and individual telephone calls to potential participants during the following weeks, seeking to boost the number of respondents. However, recognizing the disruption to investigators' activities due to the COVID-19 pandemic and a related unprecedented set of circumstances, MDIC concluded that it had received sufficiently detailed responses through the online instrument and the detailed phone interviews to compile a meaningful report. In total, 7 of the 33 investigators invited to participate completed online surveys. Of those 7 respondents, 5 completed a follow-up 30-minute telephone interview during which they were asked to provide insights through a series of questions that had been developed by the working group to gather additional qualitative information. Interviews were recorded and documented with detailed, real-time notetaking. While we did not use qualitative analysis software, we reviewed detailed interview notes and the open-ended survey responses to identify key words, consistent themes, and illustrative quotes, which have been included in this report.

Section 2: Results

SECTION 2

Results

2.1 Results: Patient Survey

Of the 124 respondents, 28% (34/123) were younger than age 55 years, 35% (43/123) were aged 55 to 64 years, and 37% (46/123) were aged 65 years or older. Females comprised 59% (73/123) of the respondents. Additionally, 74% (90/122) of respondents were actively involved in a patient group or advocacy organization, but of those, only 63% (55/88) previously had been approached about participating in a clinical trial.

Of all respondents, 82% (96/117) claimed to be familiar with medical device clinical trials, but 99% (102/103) ranked clinical trials as "very important" or "somewhat important."

Respondents were then asked a series of questions regarding patient priorities with respect to engagement in clinical trials, with the responses displayed in Figure 1 and Figure 2.

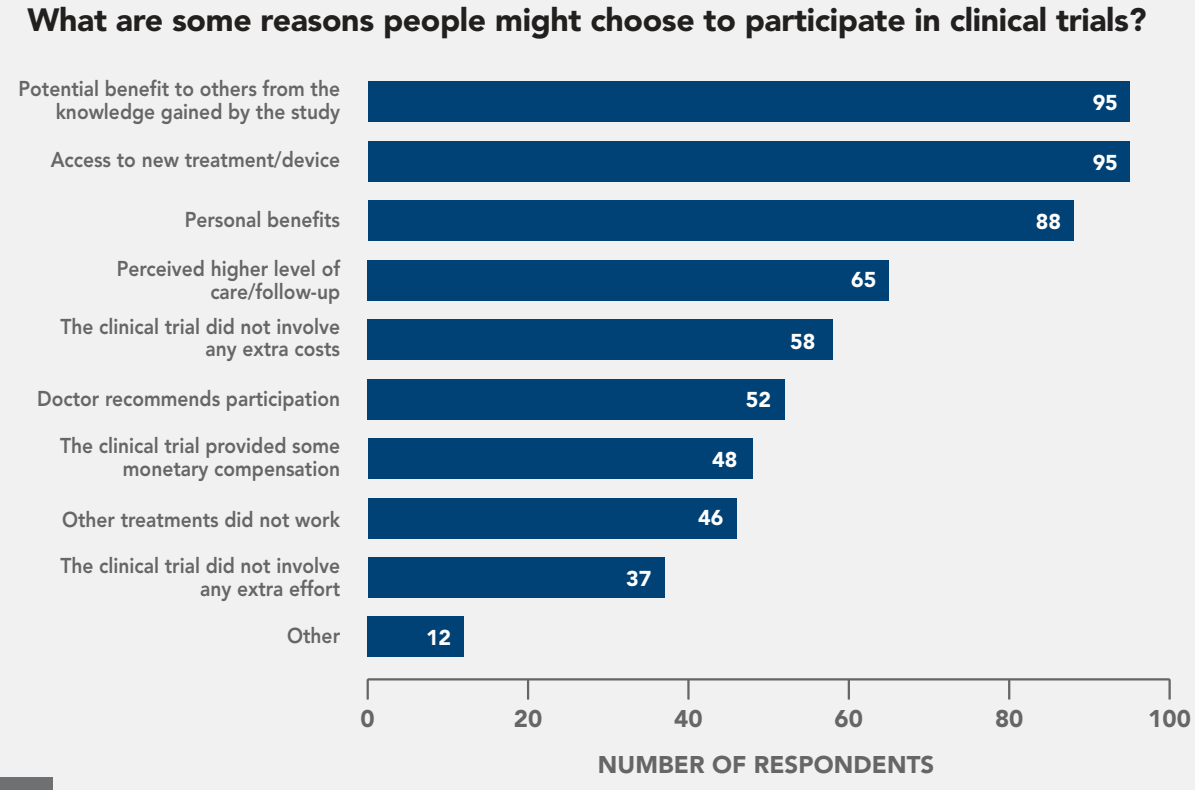

Figure 1

Some of the "other" reasons listed were "to make sure gender differences were addressed," "to lead by example," "because it's the right thing to do," and "due to frustration over nothing else to do."

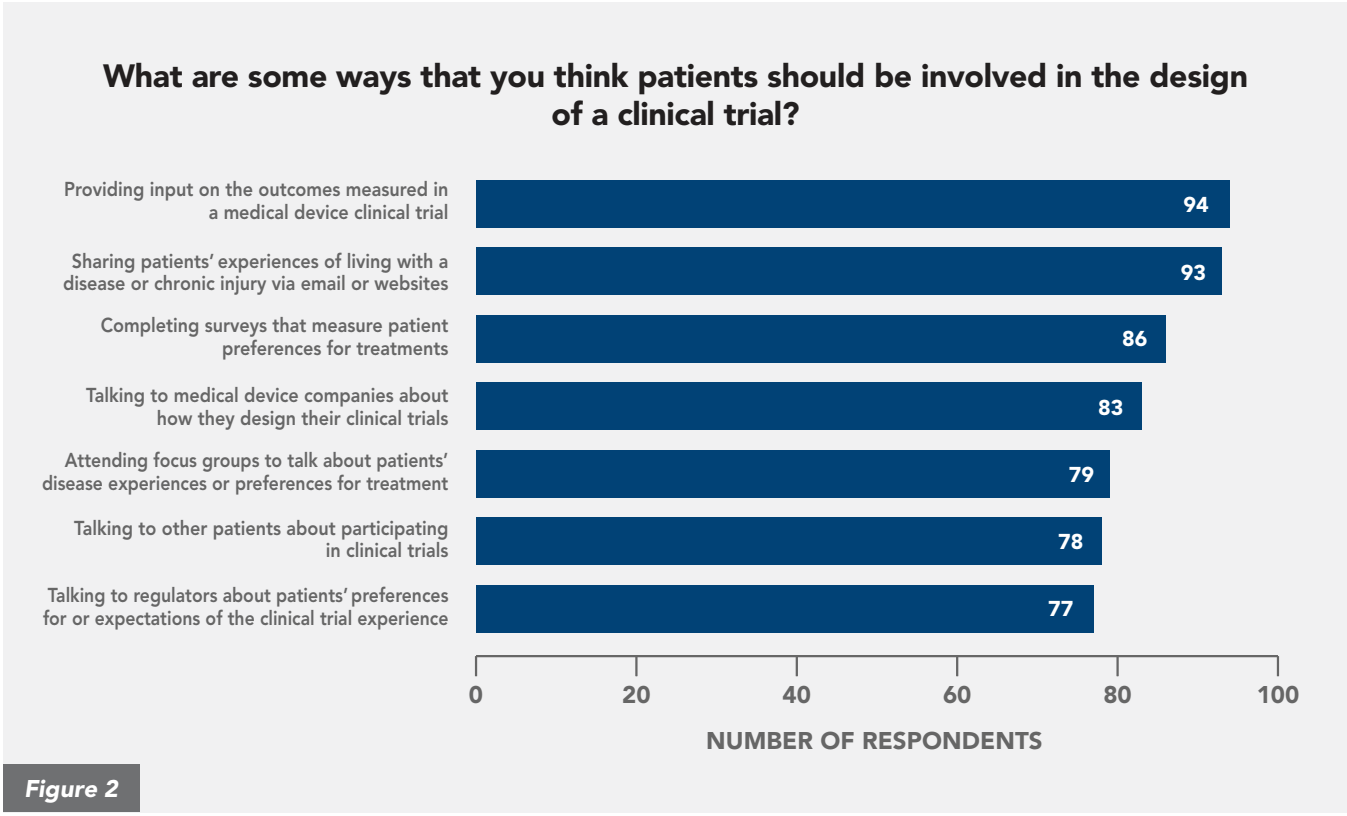
What are some ways that you think patients should be involved in the design of a clinical trial?
Providing input on the outcomes measured in a medical device clinical trial
94
Sharing patients' experiences of living with a disease or chronic injury via email or websites
93
Completing surveys that measure patient preferences for treatments
86
Talking to medical device companies about how they design their clinical trials
83
Attending focus groups to talk about patients' disease experiences or preferences for treatment
79
Talking to other patients about participating in clinical trials
78
Talking to regulators about patients' preferences for or expectations of the clinical trial experience
77
0
20
40
60
80
100
NUMBER OF RESPONDENTS

Figure 2

The patients were then asked if there are any other ways patients should or could get involved in the design or execution of medical device clinical trials. Some responses included the following:

"Yes, patients want to improve concurrent with the trial. Patients could help investigators design trials along their dynamic health trajectory rather than a static design of experiments."

"May assist in preparing the consent form to insure it provides the information subjects want and need."

"Making the consent forms more understandable. Sharing the outcome of the study with study participants."

"Have FDA pre-approve researcher/industry proposals for treatment with patient and caregiver input; take design out of sole control of researcher/industry."

"Mainly to make the tools understandable to the population."

"By sharing pros and cons from previous trials."

"Need to have a third-party matchmaking service between patients and trial coordinators. Need concierge service to take patients door to door for participation."

"Have a help number for the device manufacturer so a participant could ask a specific question. At the end of the trial, send results expected and obtained to participant, or at least show where they could get that information."

"I think it is vital to understand the patient's priorities. I often read a study and find what the clinician valued is NOT what is important to me. I also think it is important to consider the ease/reality/possible burden of incorporating the change into the patient's life. Solutions have to be practical or they become one more problem/issue."

"Providing a venue (perhaps a support group meeting) where the trial can take place."

"Legislative advocacy to ensure more funding is available for research and clinical trials."

"Patients having access to their health information as soon as blind portions of test complete. Adaptive trials that allow patients to incorporate improvements to their treatment rather than static a/b experimental trials."

"Actual patient experience once the device is on the market, evaluating how it is marketed, provided to the patient, and how the patient is oriented to its use."

Patients were asked whether they had ever been invited to participate in a medical device clinical trial; 84% (58/69) said they would participate in a clinical study if they were invited. Only 34% (36/106) had directly been asked to participate in a trial, and indeed, 86% (32/37) of those who were asked did agree to participate. Finally, 84% (26/31) of trial participants had completed participation in a trial at the time of the survey, and participation was ongoing for 29% (9/31).

The methods by which the patients were engaged are displayed in Figure 3.

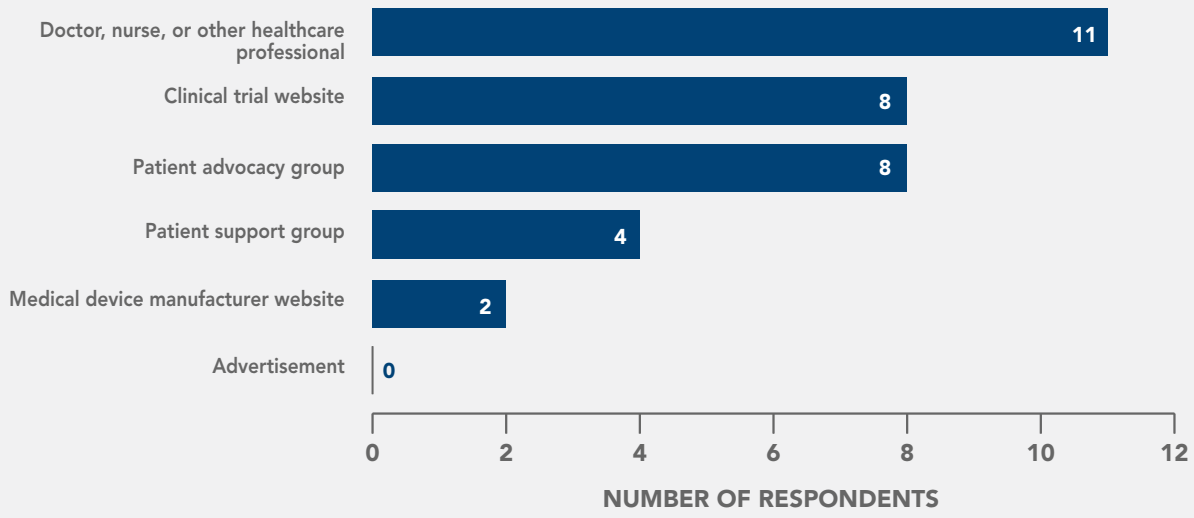

Figure 3

The patients who had participated in a clinical trial were asked a series of questions about their experience (Figures 4-5).

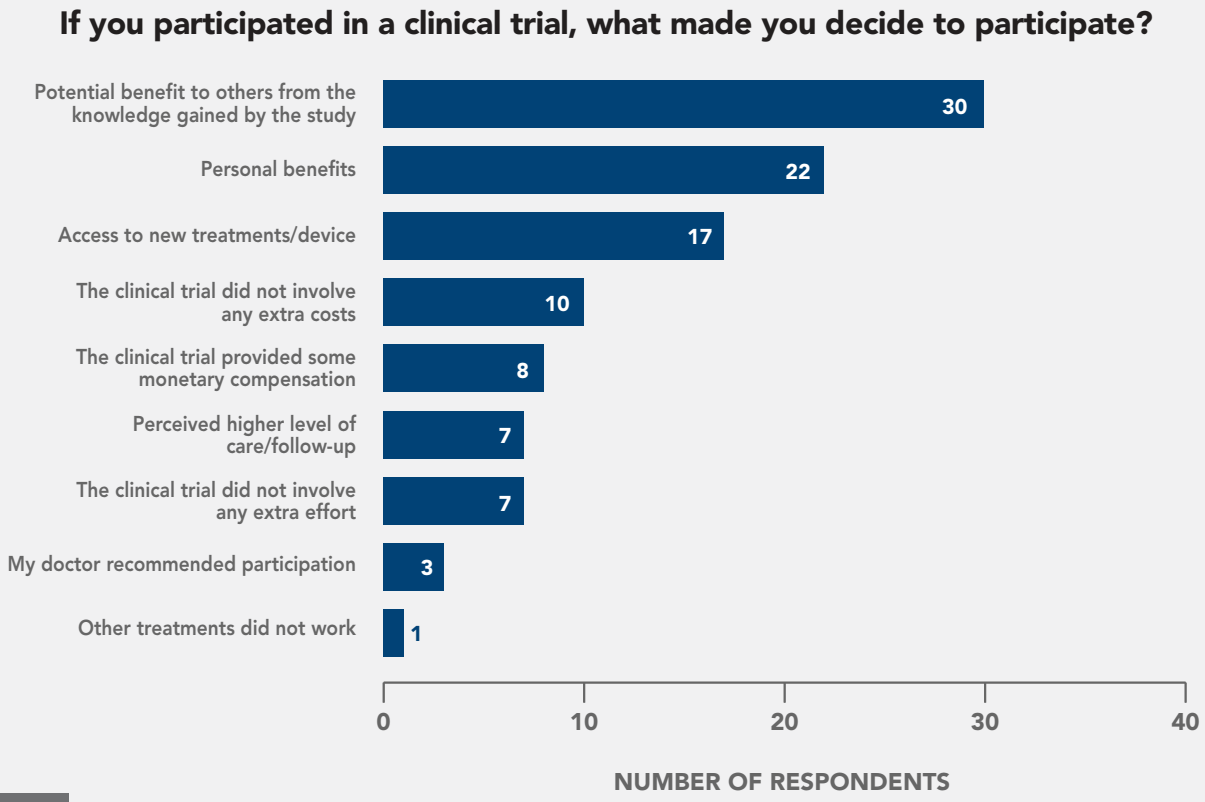

Figure 4

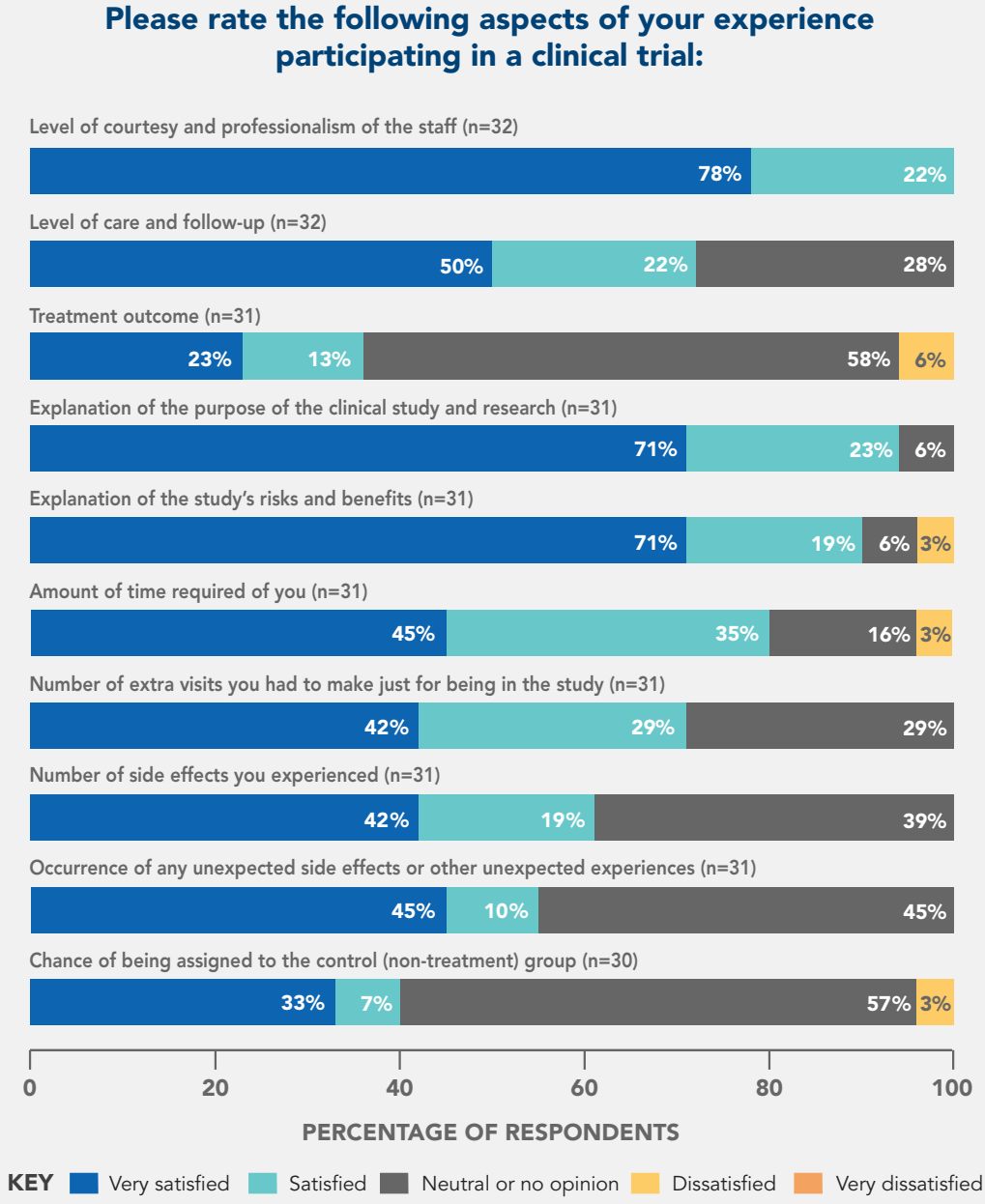

Figure 5

Of those who participated in a clinical trial, 93% (28/30) of respondents felt that participation in the clinical trial did not lead to any negative medical complications. Responses from 68% (21/31) of trial participants indicated they did not believe that they received better medical care due to their participation.

Patient participants reported meeting with representatives from the sponsor company 16% (5/31) of the time, and 4 of those 5 patients agreed that meeting the sponsor helped them feel more comfortable about the clinical trial. Of those

who had not met with the trial sponsor, half of them (7/14) thought that meeting the sponsor would help them feel more comfortable.

About half of trial participants (15/31) went online to find information about the clinical trial, either on the trial's own website or on ClinicalTrials.gov.

Of those who participated in a clinical trial, 77% (24/31) had participated in more than one, 97% (30/31) would be willing to participate in another, and 93% (28/30) would be willing to recommend to others that they participate in a clinical trial.

Patients who chose not to participate in a clinical trial were asked about their concerns (Figure 6).

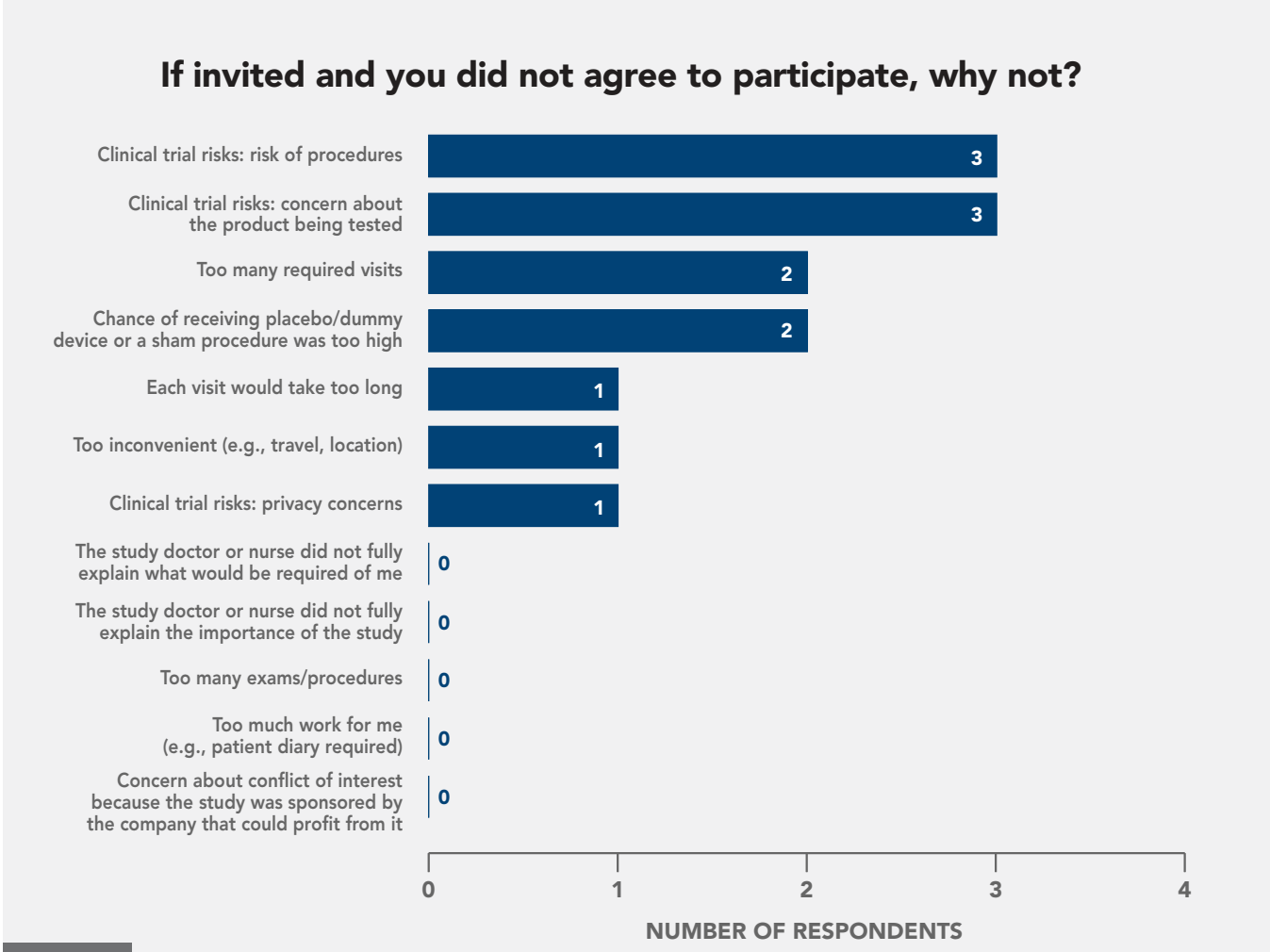

Figure 6

Some patients listed "other" reasons why they chose not to participate, including "involved needles," "want to be eligible for other clinical trials," and "I was going to be away for required follow-up meetings."

Finally, all the respondents were asked to consider various aspects of clinical trials that may affect their decisions to participate (Figures 7-9). In general, the patients reported that burdens such as travel to the study site would not deter them from participating; however, efforts to make trials more convenient, such as remote data reporting or at-home visits, would make them more likely or much more likely to participate in a study. The patients did not report significant concerns about data privacy or study design but did express a desire to have access to communication with study sponsor representatives. As might be expected, patients reported strong motivators for study participation are access to new treatments, the chance to improve their health, and reputation of the study investigator. However, they also reported that some simple things like progress reports throughout the study or a summary of the final study results would make most patients more likely or much more likely to participate in a clinical study.

If you were considering participating in a medical device clinical study, and the study required the following activities, how would each of these required activities affect your likelihood of participating in the clinical trial?

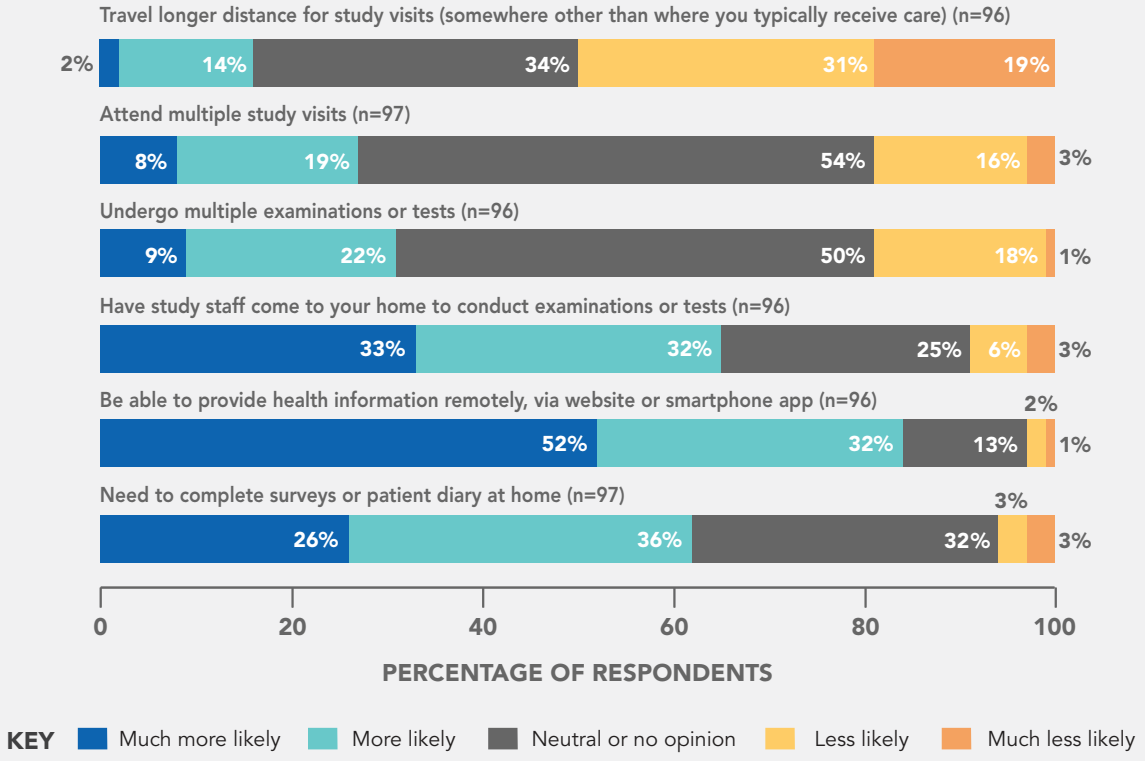

Figure 7

If you were considering participating in a medical device clinical study, and the following characteristics were true about the clinical trial, how would each of these characteristics affect your likelihood of participating in the clinical trial?

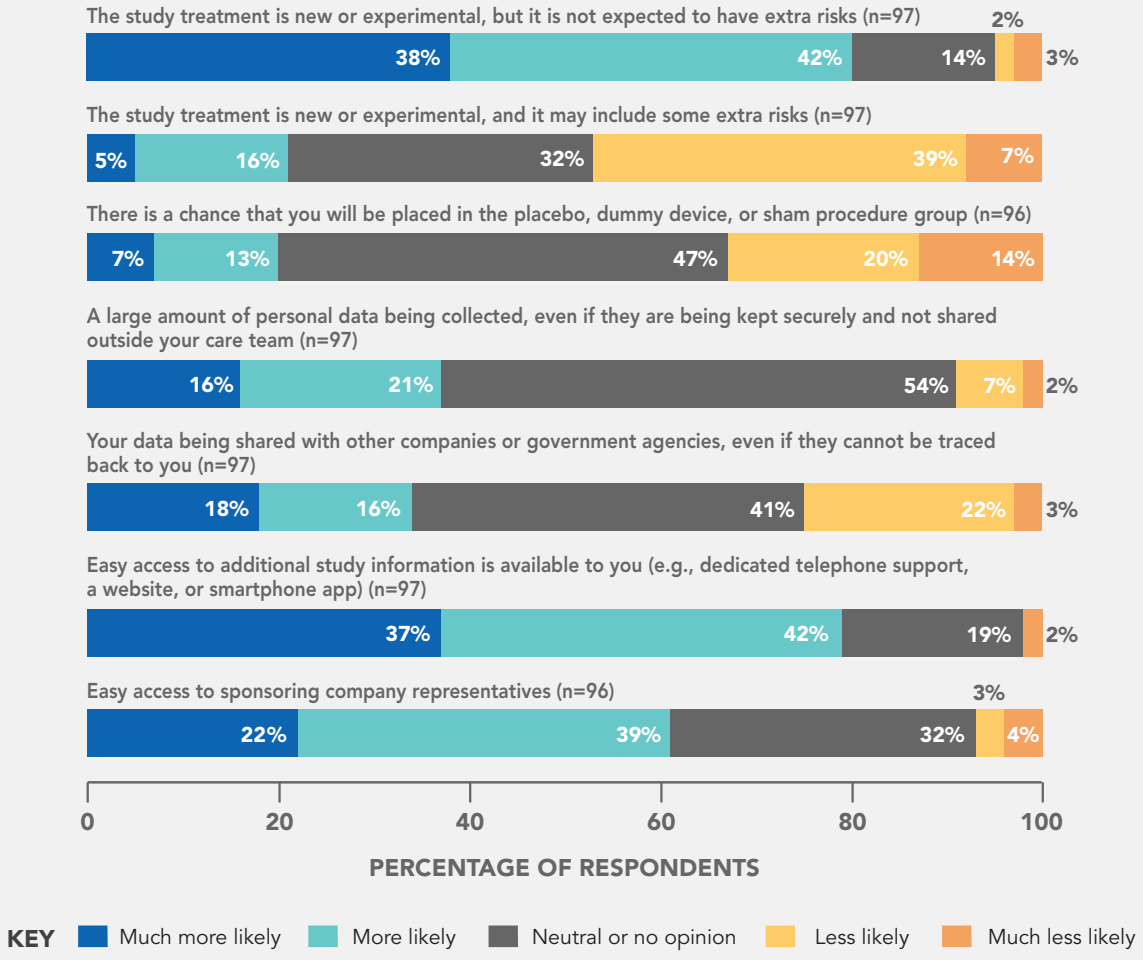

Figure 8

If you were considering participating in a medical device clinical study, how would each of the following items affect your likelihood of participating in the clinical trial?

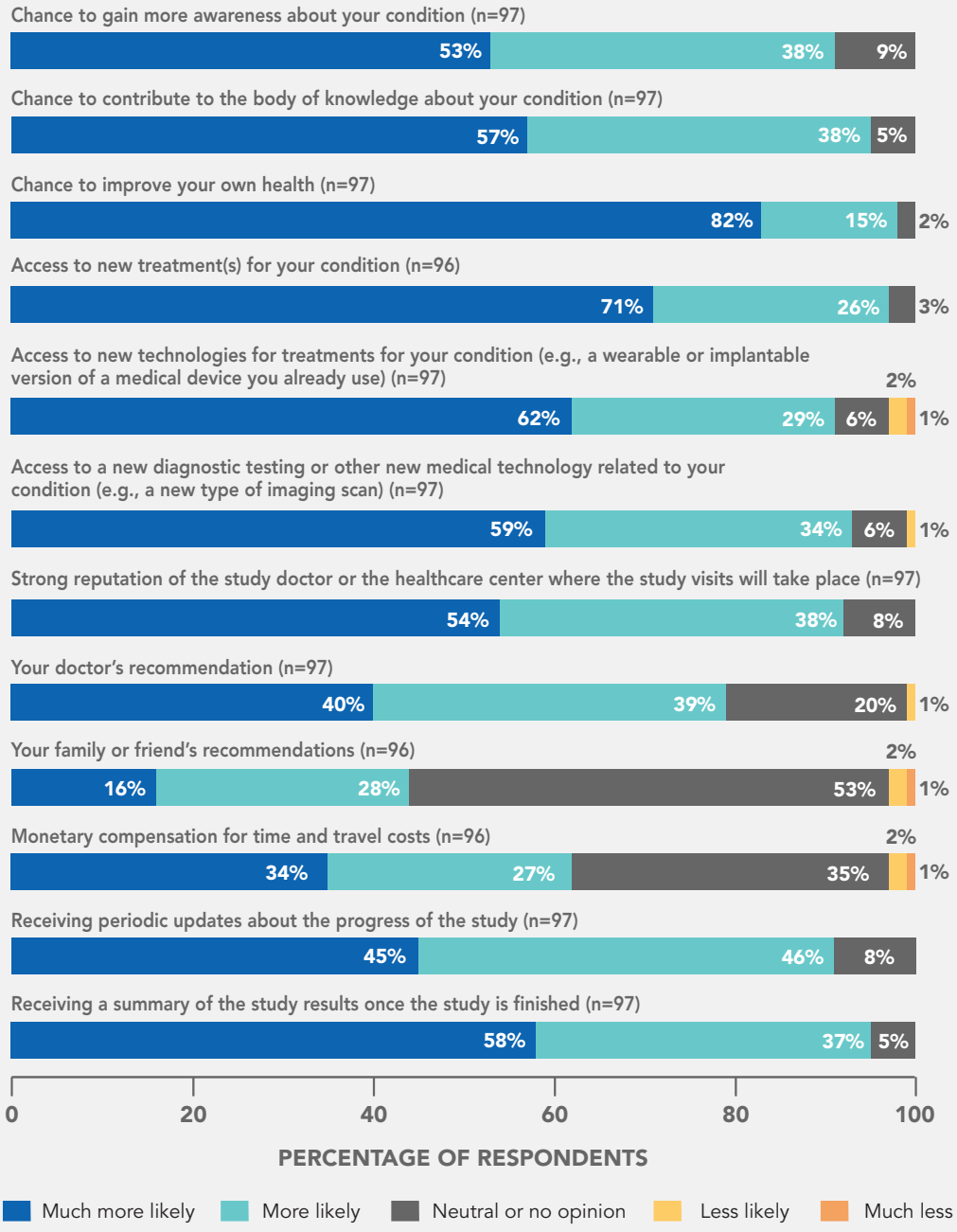

Figure 9

2.2 Results: Industry Survey

The first few questions of the industry survey were intended to gain perspective on the respondents' roles within their respective organizations, as they relate to clinical trials (Figures 10-11).

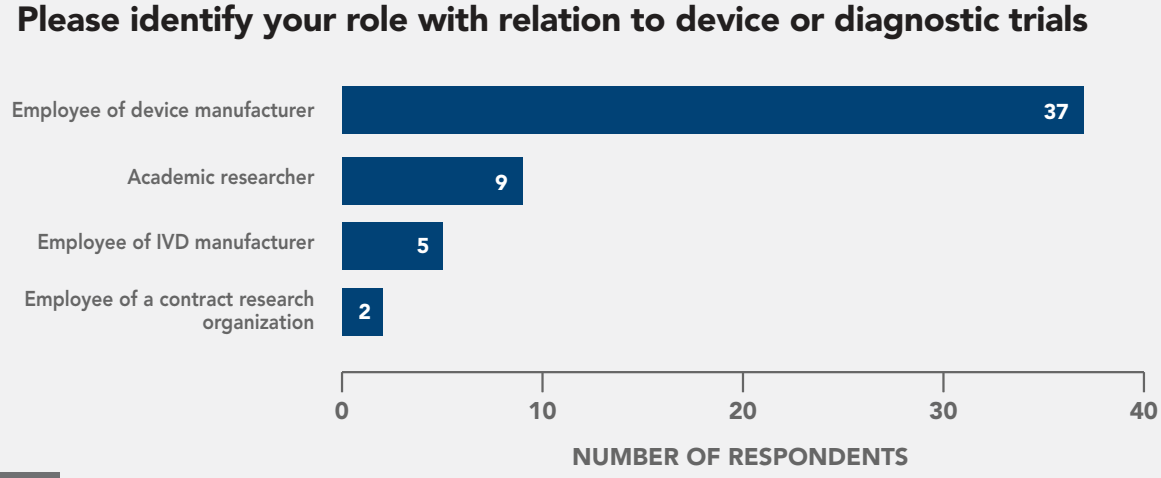

Figure 10

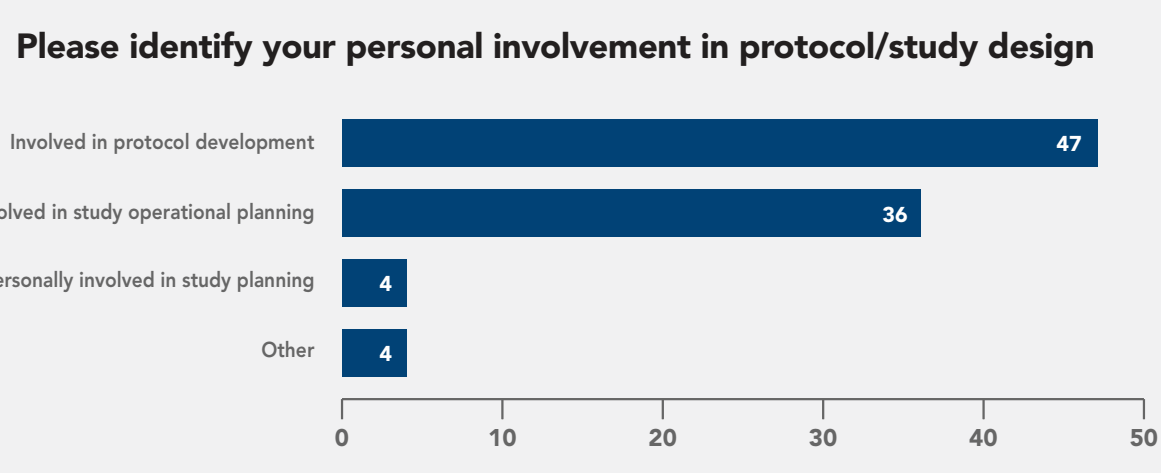

Figure 11

Then respondents were asked about their respective companies' practices for obtaining patient input in the planning of clinical trials and the relative value of the efforts (Figures 12-21).

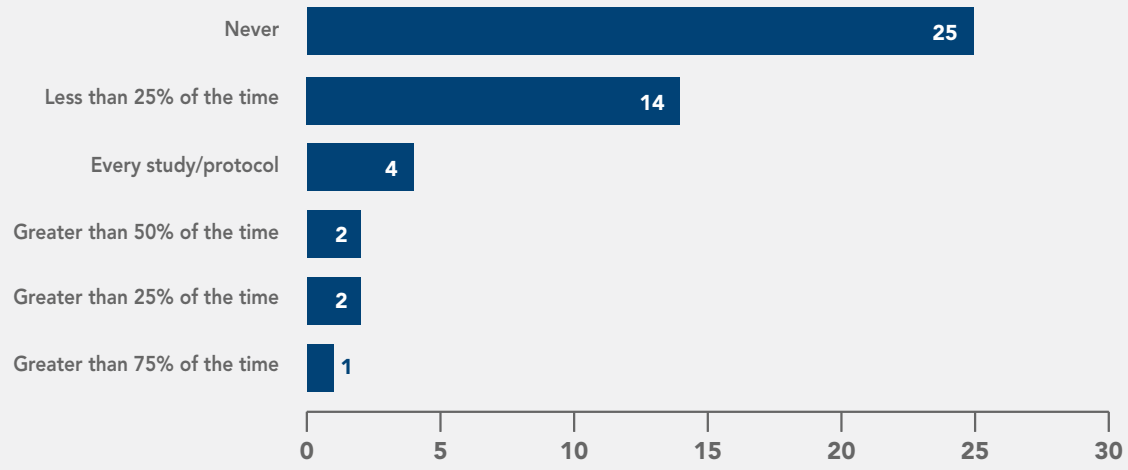

Figure 12

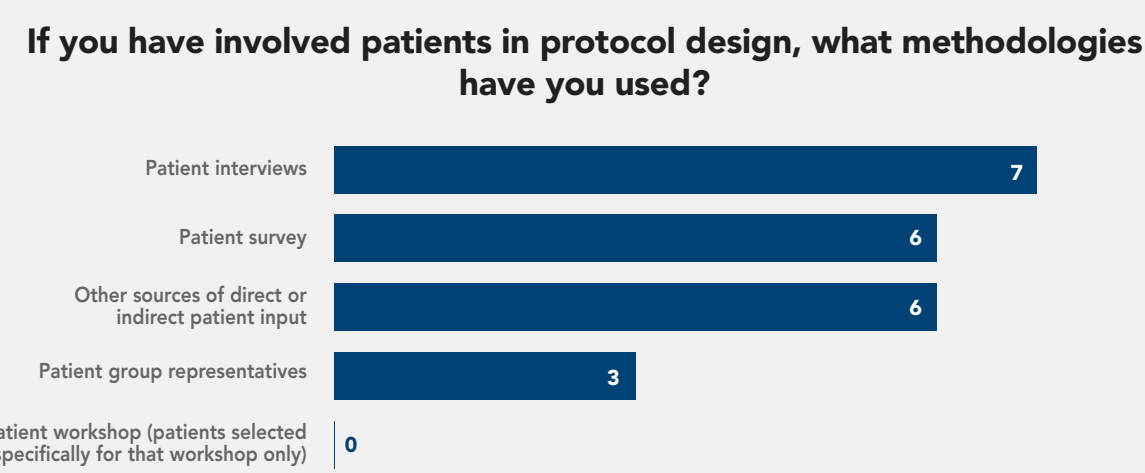

Figure 13

Some additional methods of patient involvement in protocol design were supplied by the respondents: "usability tests," "patient members of study steering committees," and "discuss protocol with several clinical research coordinators to understand the impact on the patient. Review past protocols/feedback from patients via the sites as well. Currently exploring direct patient feedback through surveys but have yet to implement."

In your estimation, how often does your organization gain feedback directly from patients on operational strategy *post*-protocol finalization?

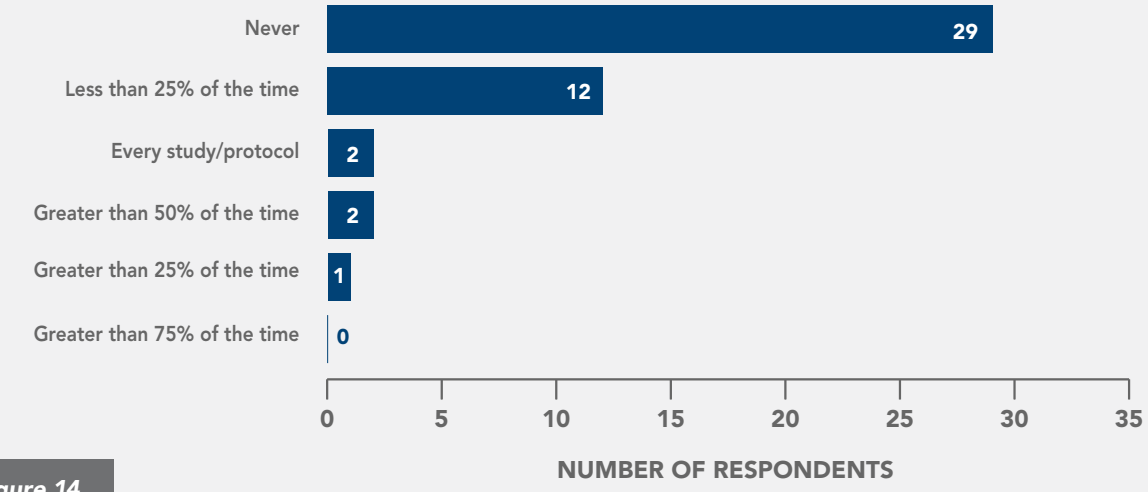

Figure 14

If you have involved patients in operational strategy planning *post*-protocol finalization, what methodologies have you used?

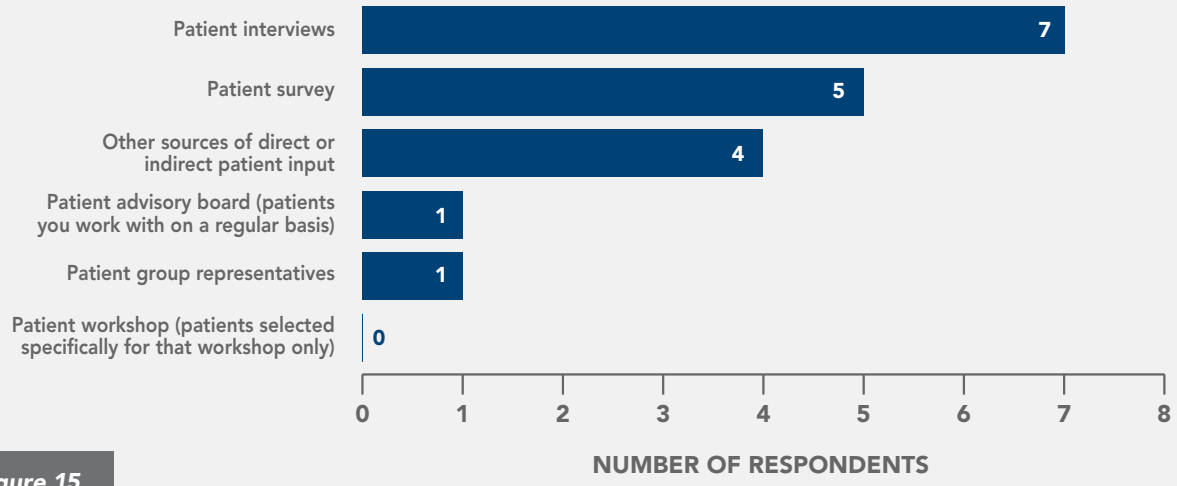

Figure 15

Additional methods supplied included "feedback provided by patient to site and back to sponsor" and "patient members of steering committees."

If you have involved (or tried to involve) patients in protocol development or operational strategy planning, did you encounter any internal barriers?

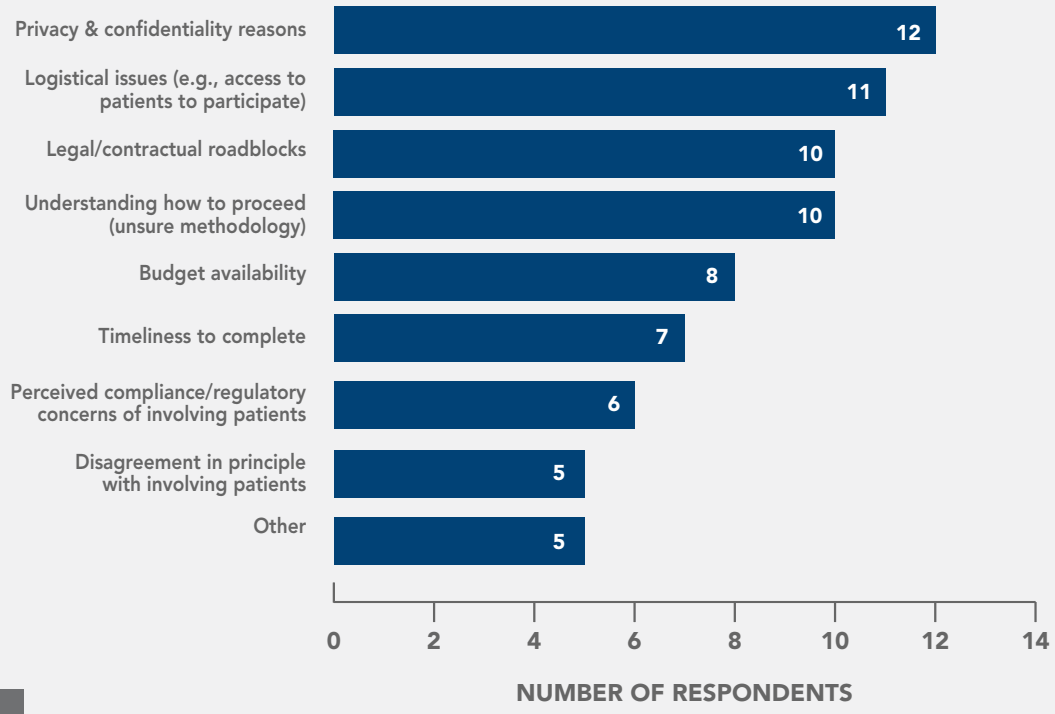

Figure 16

"Other" barriers provided included "logistics" and "have never involved patients."

How are patients usually identified for device or diagnostic/sample collection trials your company sponsors or you have been involved in? Please rank your view of their effectiveness.

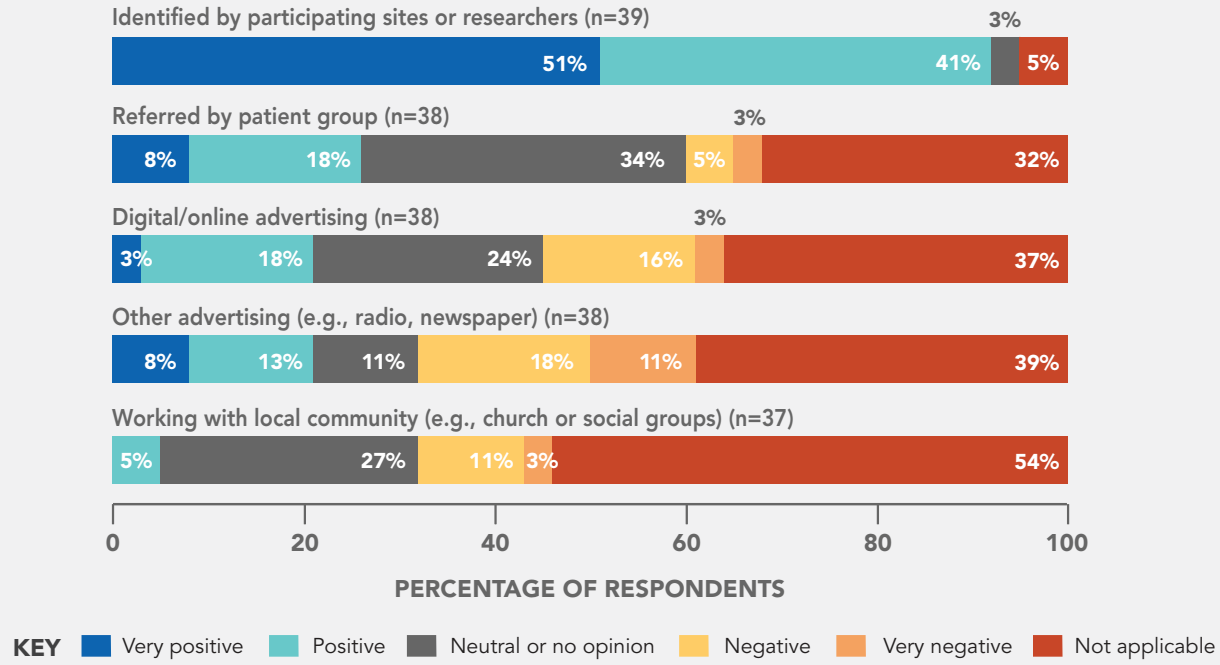

Figure 17

Other methods to identify trial patients were described as "social media effective" and "call center in-house and external, along with advertisements."

What do you believe are the most important factors to patients in deciding to enroll in a device or diagnostic/sample collection trial? Please rank your view of their importance.

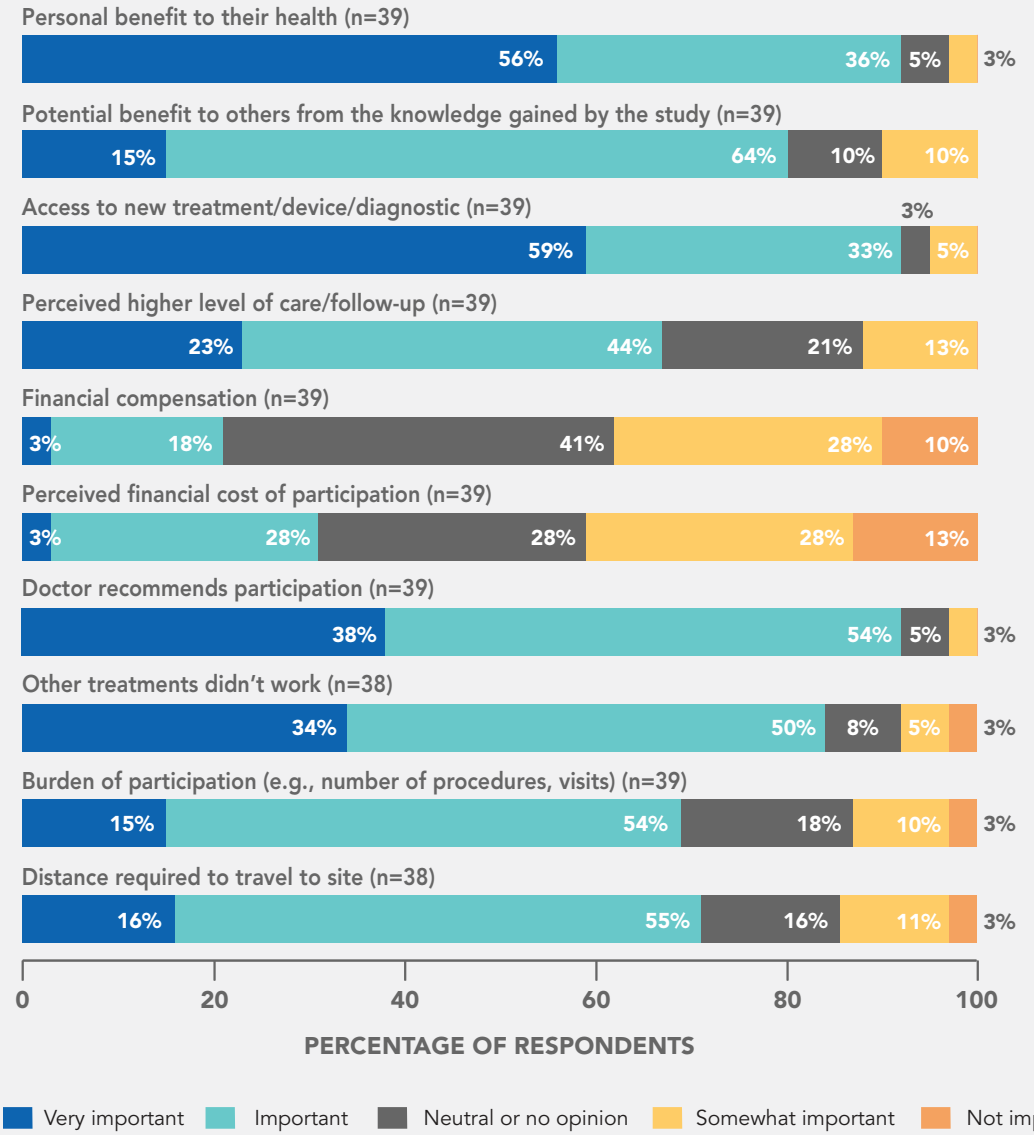

Figure 18

What methodologies have you seen used to reduce patient burden of participation in clinical trials? Please rank your view of their effectiveness.

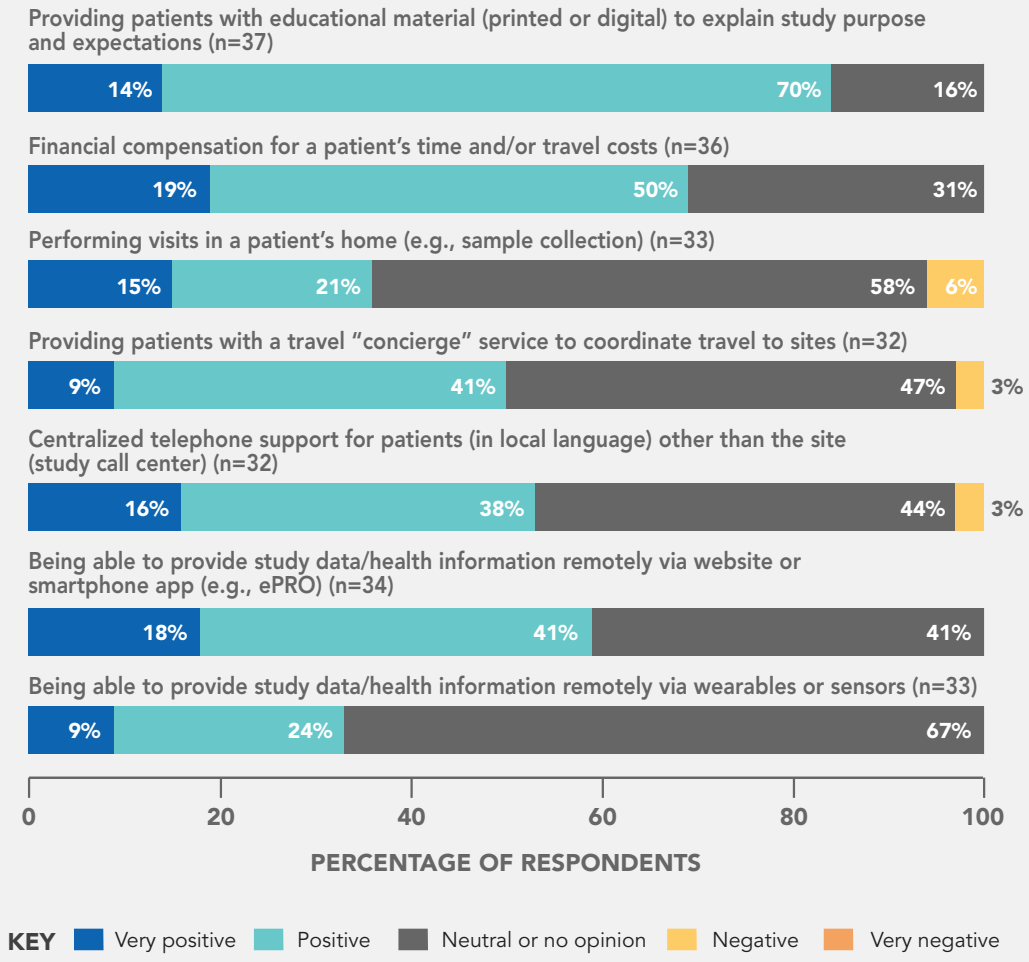

Figure 19

Other than the study informed consent document, do you provide any educational materials to communicate risks to patients of study participation?

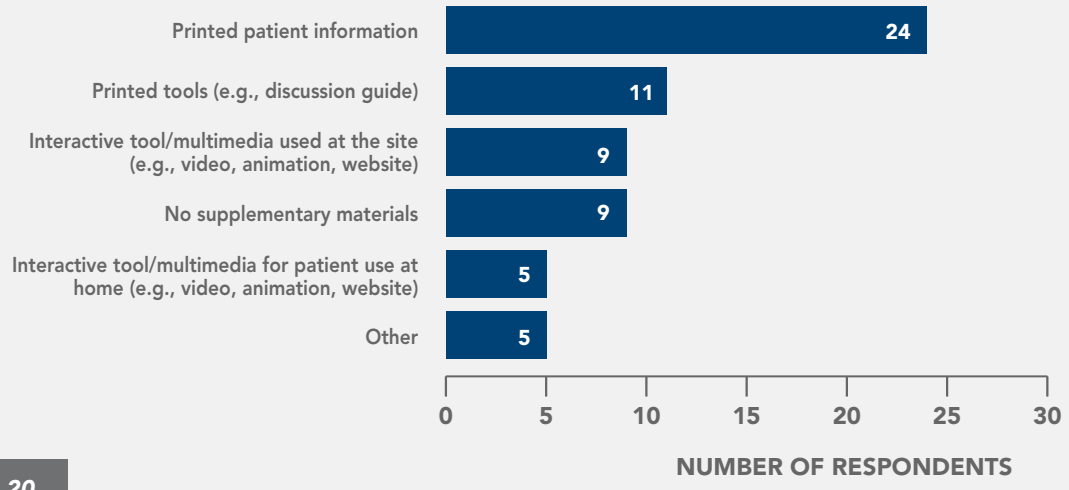

Figure 20

Other educational materials to expand on both risks and benefits included "patient call-in sessions with an investigator or office patient events with site research staff."

If you do provide supplemental materials to patients to communicate potential benefits of participation, what potential benefits have you communicated?

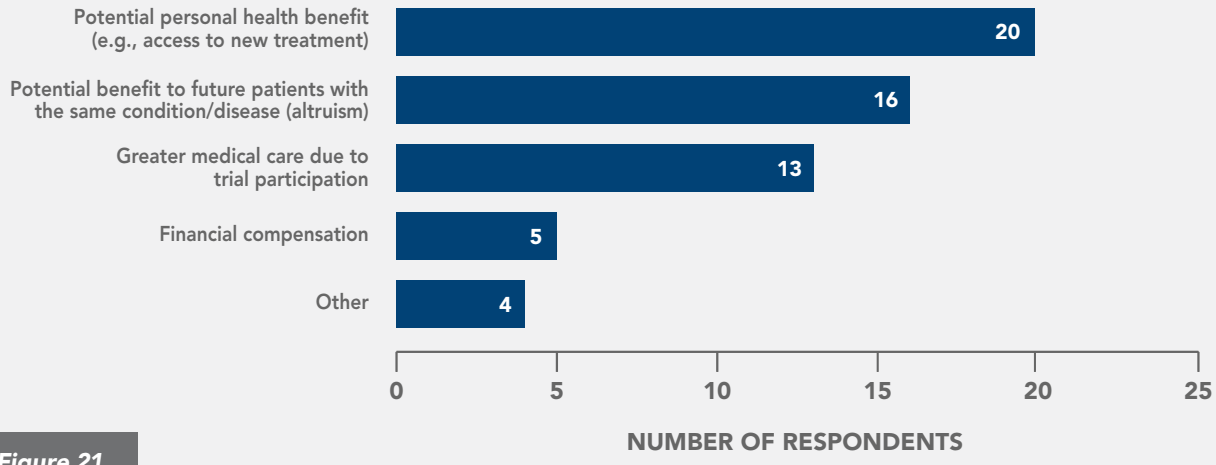

Figure 21

An "other" potential benefit of trial participation provided to patients was a "point-by-point comparison of treatment options."

Finally, the industry representatives were asked for any additional comments or feedback on working with patients in the design of clinical trial protocols. The responses were as follows:

"Logistics must be easy. Services must be readily accessible. Low to no touch points if dealing with elderly patients, for example, no electronic questionnaires. Principal Investigator (PI) interaction with patients is critical."

"Glad to see this being addressed. Patient input will most likely lead to better compliance and participation in clinical studies."

"Plan for non-therapeutic healthy volunteers. We debate if their tests should be reviewed. Should we disclose incidental results. Plan to clarify informed consent is important."

"This topic is uncharted for me as we have never had (or considered) this type of collaboration."

2.3. Results: Clinical Investigator Survey

2.3.1 Patient Engagement Frequency

At the outset of the survey, when asked about conducting patient engagement in clinical trials, all respondents said they had some experience with it, with most indicating they did this work regularly (43%, 3/7), and equal numbers indicating it is something they always or sometimes do (29%, 2/7) (Figure 22).

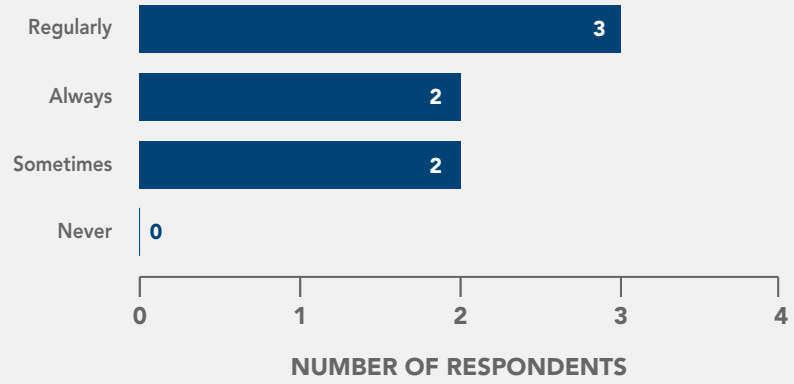

Figure 22

2.3.2 Patient Engagement Insights

Among the primary information or type of insights respondents provided when asked what they hoped to receive through patient engagement in planning and executing their device trials were understanding what matters most to patients (values and priorities), ideas about research questions, choosing outcomes, acceptability of intervention proposed, helping to make procedures within the study as manageable as possible for the participants, helping to interpret study findings, and helping to make patient-facing materials understandable to patients.

2.3.3 Methods for Engaging Patient Insights for Medical Device Clinical Trials

Respondents were asked to specify from among six methods for generating and incorporating patient insights into their medical device clinical trials, across four specified attributes of device trials that the working group had identified to be unique (as compared with drug trials). The six method choices offered to respondents (answers could include multiple selections) were Surveys, Interviews, Group Discussions, Preference Elicitation Techniques, Advisory Boards, and Patient Partner in the Research Team. The four attributes were defined as follows:

- Level of invasiveness (including implantable devices, impact on daily life, reversibility, and impact relative to disease state)
- Outcomes assessment (including selection of primary and secondary endpoints, selection of performance goals, required follow-up, and reporting of side effects)
- Trial enrollment (including study population, screening, inclusion/exclusion criteria, education needs)
- Trial design (including placebo/sham procedures; crossover options; single arm, unblinded, or adaptive designs; device modifications during the trial; and use of real-world evidence)

Group discussions, advisory boards, and patient partner in the research team were the most frequently chosen methods across all attributes, while preference elicitation techniques was the least chosen method, across all attributes (Figure 23).

What methods do you use to engage with patient partners to generate and incorporate patient insight into each of the following four categories?

	Surveys	Interviews	Group discussions	Preference elicitation techniques	Advisory boards	Patient partner in research team	No engagement
Level of invasiveness	57% (4/7)	57% (4/7)	**71% (5/7)**	14% (1/7)	57% (4/7)	57% (4/7)	14% (1/7)
Outcomes assessment	43% (3/7)	43% (3/7)	**86% (6/7)**	14% (1/7)	**71% (5/7)**	**86% (6/7)**	0%
Trial enrollment	29% (2/7)	29% (2/7)	**86% (6/7)**	14% (1/7)	57% (4/7)	57% (4/7)	14% (1/7)
Trial design	29% (2/7)	29% (2/7)	**71% (5/7)**	0%	**71% (5/7)**	57% (4/7)	0%

Figure 23

When asked to provide any other categories in which they had engaged with patient partners to design or conduct clinical trials, respondents listed multiple activities, including designing patient-facing materials, user-testing patient-facing portals for data collection, planned analyses, interpretation of findings, dissemination of findings, co-authorship or acknowledgement on manuscripts, development of bilingual materials, and inclusion of partners.

Respondents were given five options to choose from to describe how they selected the methods for patient engagement they used (Figure 24). All respondents cited their own prior experience as relevant to their decisions about methods to use. Two respondents included referring to PCORI's guidance/approach on the topic as an "other" response.

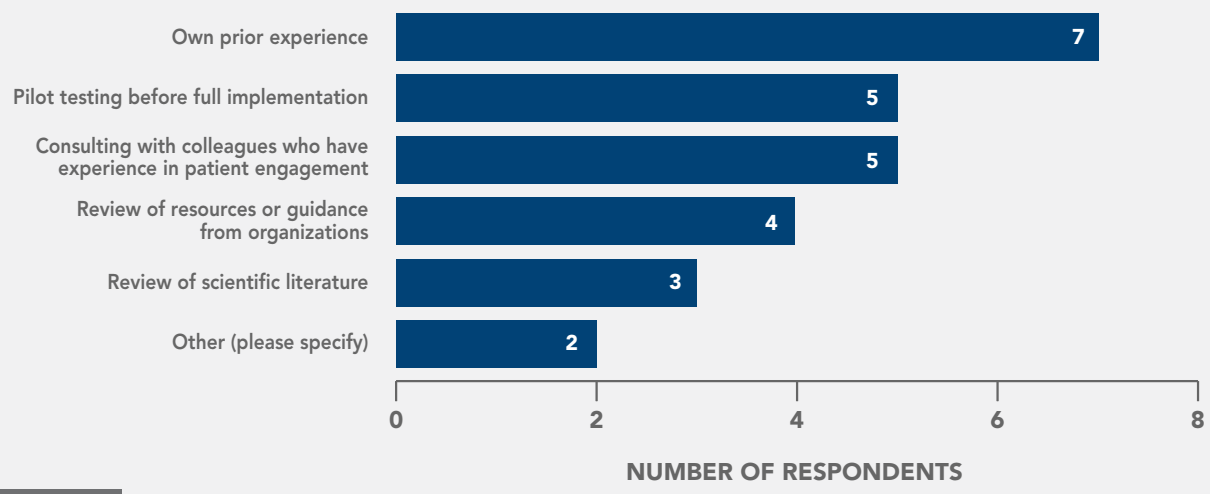

Figure 24

When asked about ways in which they evaluated effectiveness of their patient engagement methods, three respondents noted that they use surveys and exit interviews. These evaluation methods yield important feedback from patient partners that can be tracked and used to improve efforts in future studies.

2.3.4 Patient Engagement Challenges

On the topic of challenges experienced in implementing patient engagement activities before, during, or after device trials, several respondents referred to the concern that doing this work adds to the time it takes to develop a trial, as well as the potential for patient members of a research team to provide "off-topic," "misguided," "medically/scientifically naïve," or impractical feedback. Additionally, there may be a need to interpret patient input through a scientific lens to be able to incorporate it into the design of a trial. It was also noted that patients may not agree with each other about the best direction for a study. Finally, respondents raised the challenge of addressing differing levels of knowledge among patients regarding clinical trials, study design, statistical modeling, and analysis. One respondent noted the difficulty in maintaining engagement with patients with severe chronic conditions due to their illness/symptoms.

2.3.5 Patient Engagement Resource Gaps

When asked about gaps in available information and resources to facilitate patient engagement activities in device trials, three respondents indicated they saw none, while the other four cited the need for research training for patients to assist them in fully participating in trial planning and the need for additional guidance in best ways to access patients and engage them productively. The need to clarify what is meant by the term "device" was also raised as a gap to be addressed, as was the need for resources to engage adequate patient representation across demographics and background.

2.3.6 Patient Engagement Input Informing Changes to the Clinical Trial

Respondents reported that patient engagement led to or informed changes in trial design in a variety of ways, with 100% (7/7) of respondents indicating there had been impact on trial inclusion/exclusion criteria resulting from patient input, and 71% (5/7) indicating impact in the areas of endpoints, patient recruitment, and study-specific communications (Figure 25).

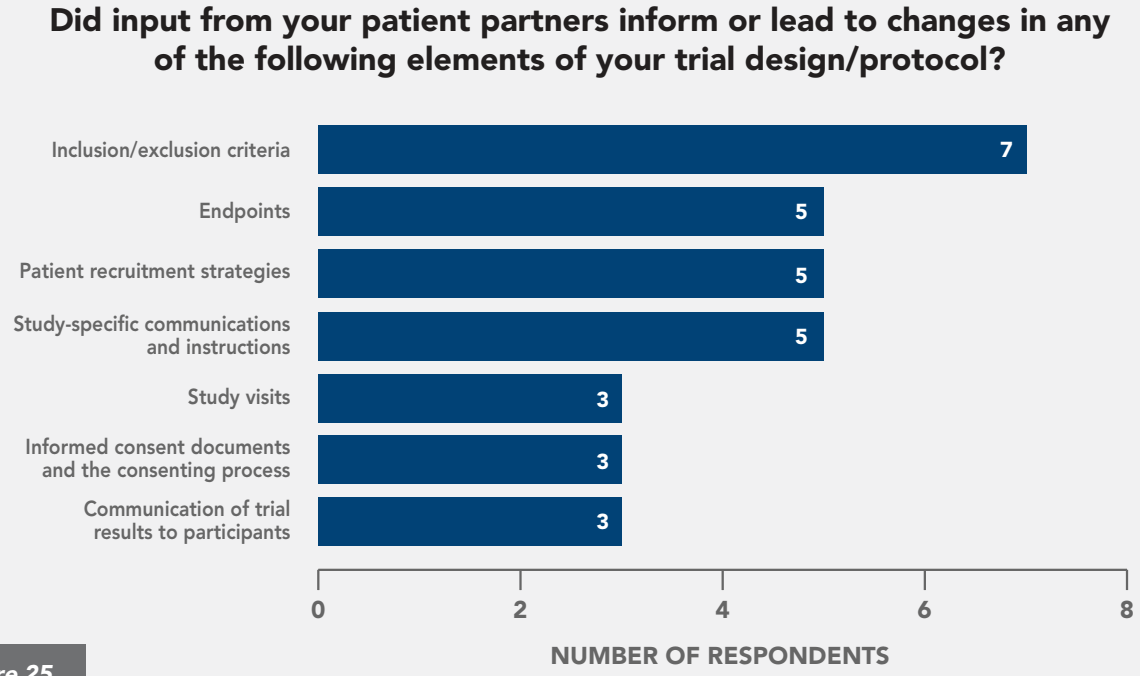

Figure 25

2.3.7 Patient Engagement Preparation of Partners

In describing steps taken/resources used to prepare their patient partners to serve in an advisory role for the clinical trial, respondents cited the importance of providing patients with education and training (including basic research training and human participant training), conducting meeting preparation, and assigning additional staff mentors to integrate patients into the research team.

2.4 Clinical Investigator Telephone Interview Results

As follow-up to the online survey, 5 respondents agreed to conduct 30-minute telephone interviews to provide additional detail. During the interviews, a series of questions were raised to delve deeper into the feedback provided during the survey, including identifying lessons learned and ongoing challenges in implementing patient engagement for medical device trials (see interview guide in the Appendix).

All respondents stressed the importance of engaging patients as partners in clinical studies. One respondent noted that while the concept of considering "stakeholders" in the healthcare arena has long focused on clinicians as "key opinion leaders" (KOLs), more recently, the need to engage the "customer" as a key stakeholder has emerged as learnings from the consumer/business world. In describing the impact of including patient stakeholders in the research team, another respondent stated "we have all benefited, and I wouldn't go back" to doing this work without patient involvement.

Among the themes that emerged from the interviews was the importance of being willing to accept input from patient partners. One respondent noted that, while investigators are experts in their field, "patients will always surprise you," and therefore it is necessary to have an open mind about learning from patient partners. Another stressed that patient engagement in clinical research is most successful when commitment to the process (including flexibility, willingness to provide resources, willingness to consider changes to study plans based on feedback from patient partners) stems from the study's principal investigator and permeates the entire study team.

Several respondents noted that it can take time and significant effort to successfully engage patient insights in device studies. For example, it may be time consuming to conduct the necessary outreach to the patient community to identify patients who are willing and able to serve as partners in a study team.

Finding the right patients and advocates to participate in trial development activities will often require multiple types of outreach and a willingness to adapt existing processes and plans. It may be necessary to combine various modes of engagement, including in-person meetings, online outreach, and individual connections made within the patient community. One respondent noted the importance of engaging patient advocacy organizations, while stressing that this effort should be made in addition to engaging with patients directly. Investigators also emphasized the importance of including diverse populations (across race, ethnicity, gender, age, geography, and other demographic characteristics) and conducting activities in a way that will encourage consideration of a range of experiences, including "mixing and matching" to bring stakeholders from a variety of perspectives together in providing input into the design or execution of a trial.

Multiple investigators emphasized that it is necessary to thoughtfully select and "vet" patient partners and onboard them appropriately to ensure they are well equipped and committed to participate fully in the process. One respondent described this process as "meeting patients where they are." It would be helpful to have a resource clearinghouse for investigators, including basic education and training materials for patients on technical topics relating to the conduct of clinical trials. As one respondent described it, having a "crash course on randomized clinical trials and statistics could help patients during team discussions so they don't have to struggle when we get nerdy."

Additionally, most respondents emphasized the importance of maintaining consistent communication with patient partners throughout the project through regular meetings (including virtual gatherings and separate meetings with/for the patient partners) and developing "feedback loops" to share results.

In summary, investigators interviewed for this project identified the following key considerations in engaging patient partners in their study teams:

- Willingness to be flexible and accept input/commitment to the process from study leadership
- Ability to recognize that successful patient engagement can take time
  - Finding the right patients and advocates to be appropriate patient partners
    - Engaging patient advocacy organizations
    - Tapping into diverse populations (across demographics)
    - Considering a range of experiences and perspectives
  - Thoughtful vetting
  - Providing education and training to ensure patient partners can fully contribute
- Consistent communication
  - Regular meetings
  - Feedback loop

Section 3: Conclusions

SECTION 3

Conclusions

The sample sizes of the surveys were limited by the response rate when the surveys were left open for a reasonable amount of time. The sample sizes are indicative of some patient populations and industry representatives, but larger sample sizes would allow for a more comprehensive view of attitudes toward clinical trials. Different patient populations have differing experiences, prognoses, expectations, and priorities, so it would be ideal to have as many represented as possible. Similarly, the medical device industry is not monolithic, as different companies have different priorities, market landscapes, regulatory burdens, and funding available for preliminary research. Finally, the pool of investigators chosen for the clinical investigator survey outreach all received grant funding from the same source, suggesting that they may be more active in conducting patient engagement efforts than the average medical device investigator.

Among the industry representatives we surveyed, it is obvious that limited involvement in protocol development or operational trial design takes place. In addition, there is some disconnect between industry and patient views regarding clinical trials. This suggests that more work is needed to make device and diagnostic companies aware of both the benefits and importance of patient input and, given the perceived barriers highlighted in the industry survey, some considerations for how gathering patient input can be obtained and used.[8,9]

In targeting the clinical investigator survey to PCORI-funded investigators, the working group anticipated that respondents would be well versed in techniques for patient engagement, with significant experience in incorporating patient insights into the design and conduct of their clinical studies. Although the sample size of respondents was small, feedback received through the survey itself and the follow-up interviews provided useful information about best practices, challenges, and resource gaps that will inform MDIC's ongoing work in developing its Framework for Patient Input in Medical Device Clinical Trials.

A key finding from this effort is the importance of ensuring that patients engaged in device study teams will need to receive training and mentoring (particularly if it is their first time) and may not agree with one another, so adjudication may be needed. These insights align with engagement challenges and strategies that can be found in the broader literature from health research and drug development.[10] Our findings underscore the importance of involving patients in the design of clinical studies and gaining their insights about certain unique aspects for devices (especially for implantable devices). Given the heterogeneity of many medical conditions for which devices are developed, our findings also support the importance of carefully selecting patient partners.

Results from all three surveys and the interviews provide a detailed picture of how various stakeholders view challenges and opportunities with patient engagement in device development and help to augment the evidence base for this work.

Section 4: References and Appendices

SECTION 4

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APPENDICES*

- Survey Instrument 1 (Patient Survey)
- Survey Instrument 2 (Industry Survey)
- Survey Instrument 3 (Investigator Survey)
- Telephone Interview (Investigator Survey)

**The appendices are not included in this document and can be accessed at https://mdic.org/combined-survey-report-index/*

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