



Patient Engagement in Clinical Trials Survey Report

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

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OVERVIEW

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.

Within our survey response populations, we discovered:

- Over 50% of industry respondents involved in protocol development never gained patient input to protocol development. A further 28% gained input less than 25% of the time.
- Figures were even greater for industry gaining patient input to operational study design after protocol finalization with over 80% involving patients never or less than 25% of the time.
- There were some disconnects in the perspective of industry vs patients with regards to the reasons patients might enroll in a clinical trial, particularly around the importance of doctor recommendation.

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.



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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 Development¹ 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. CISC RP² research suggests that 37% of sites under-enroll and 11% of sites fail to enroll a single patient whilst National Academy of Sciences³ research 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 design 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 is expected to have a positive impact on study recruitment, retention and compliance.

Our hypothesis from anecdotal conversations with device and diagnostic industry colleagues is that very little work has taken place in our industry to gather patient input to clinical trial/protocol design and we were keen to gather further evidence around this.

METHODOLOGY

Two surveys were created in a popular survey website to gauge current attitudes toward the role of patient input in clinical trial design. 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 he or she had previously participated in a clinical trial, the subsequent questions would be different than if he or she 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 American Sleep Apnea Association, 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 6th to July 16th, 2018.

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 which 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 26th to October 21st, 2018.

The sample sizes of the two 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. Likewise, medical device industry is not monolithic, and different companies have different priorities, market landscapes, regulatory burdens, and funding available for preliminary research.

RESULTS

Patient Survey

Of the 124 respondents, 28% (34/123) were under 55 years old, 35% (43/123) were 55-64, and 37% (46/123) were 65 years or older. 59% (63/123) were female. 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 the following figures.

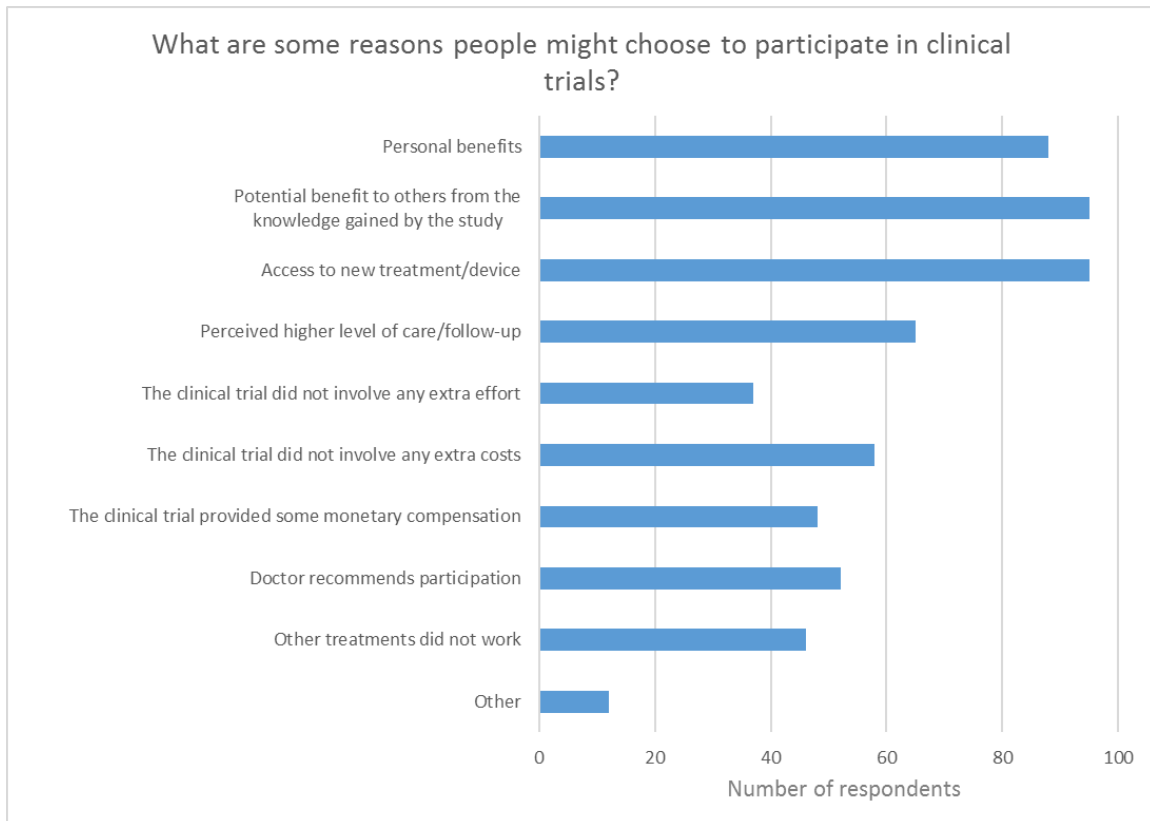


Figure 1

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.”

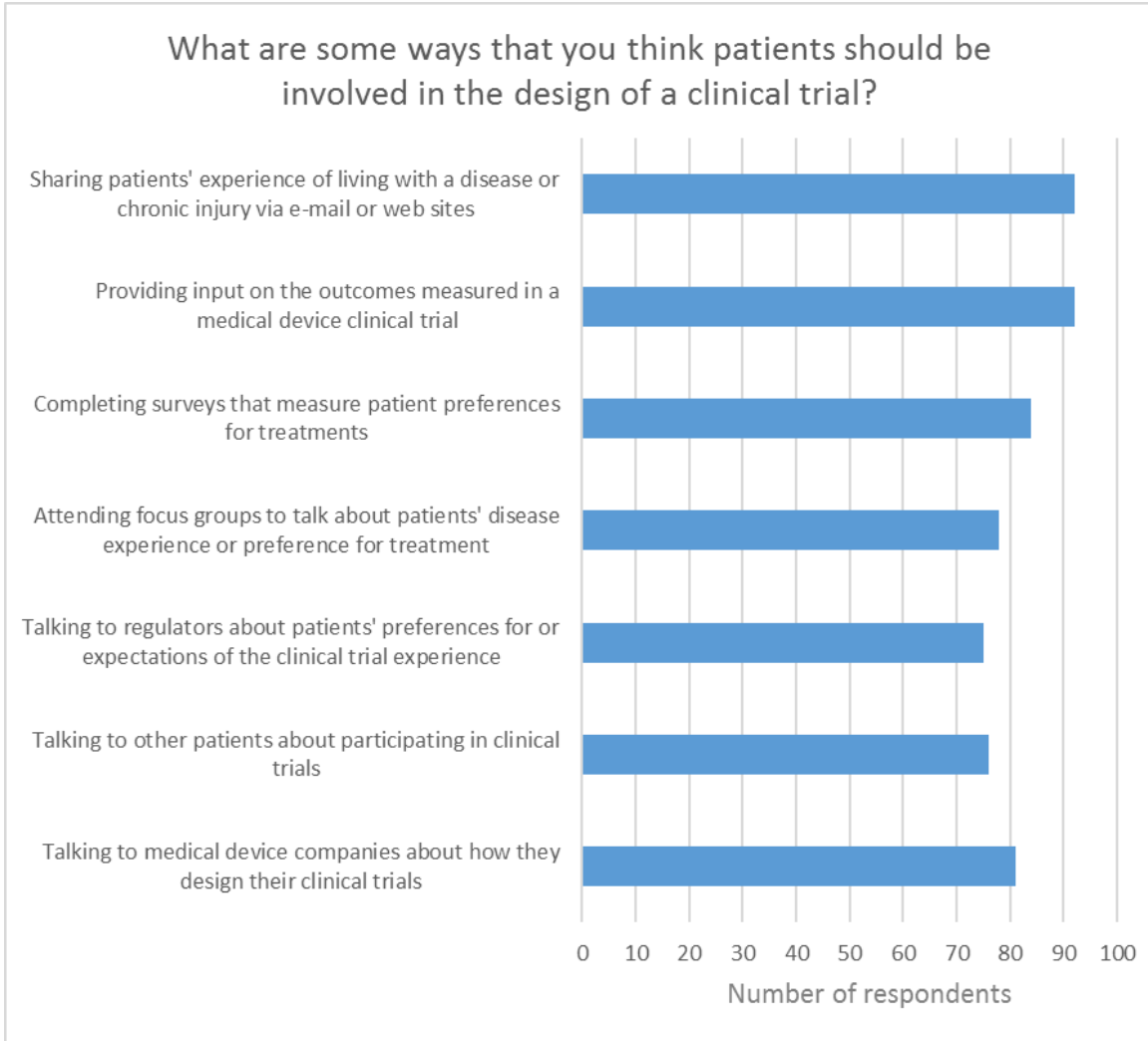


Figure 2

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 were:

- “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.”
- “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 pt’s life. Solutions have to be practical or they become one more problem/issue.”
- “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.”
- “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.”
- “Mainly to make the tools understandable to the population.”
- “Providing a venue (perhaps a support group meeting) where the trial can take place.”
- “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.”
- “Legislative advocacy to ensure more funding is available for research and clinical trials.”
- “Have FDA pre-approve researcher/industry proposals for treatment with patient and caregiver input, take design out of sole control of researcher/industry.”
- “Need to have a third party matchmaking service between patients and trial coordinators. Need concierge service to take patients door to door for participation.”
- “By sharing pros and cons from previous trials.”

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. 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 the following figure.

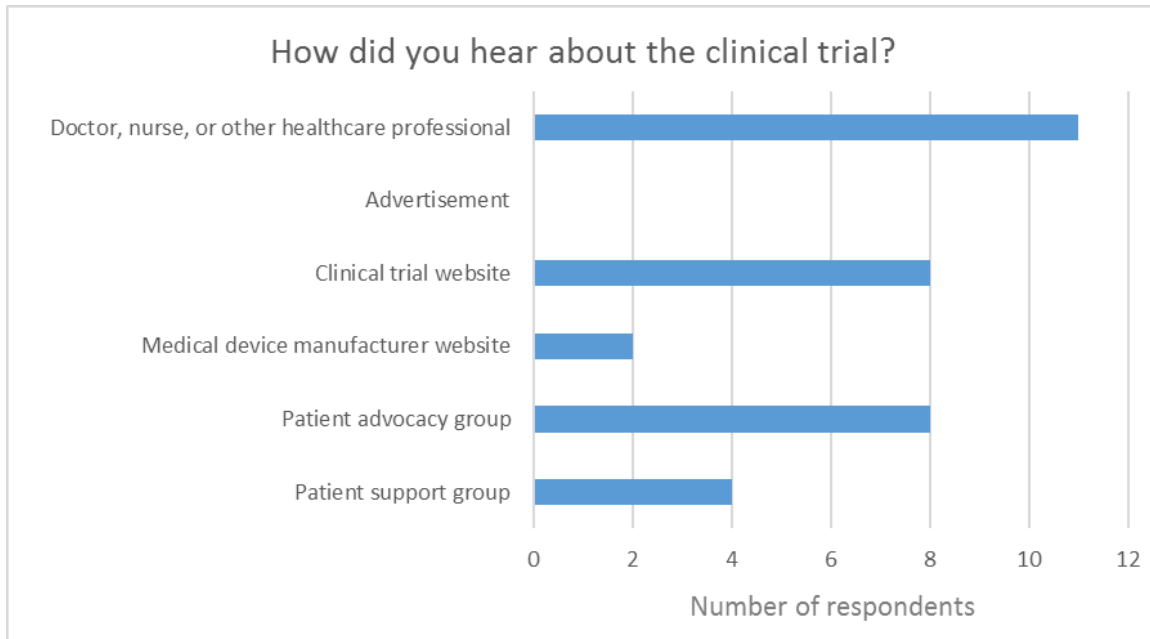


Figure 3

The patients who had participated in a clinical trial were asked a series of questions about their experience:

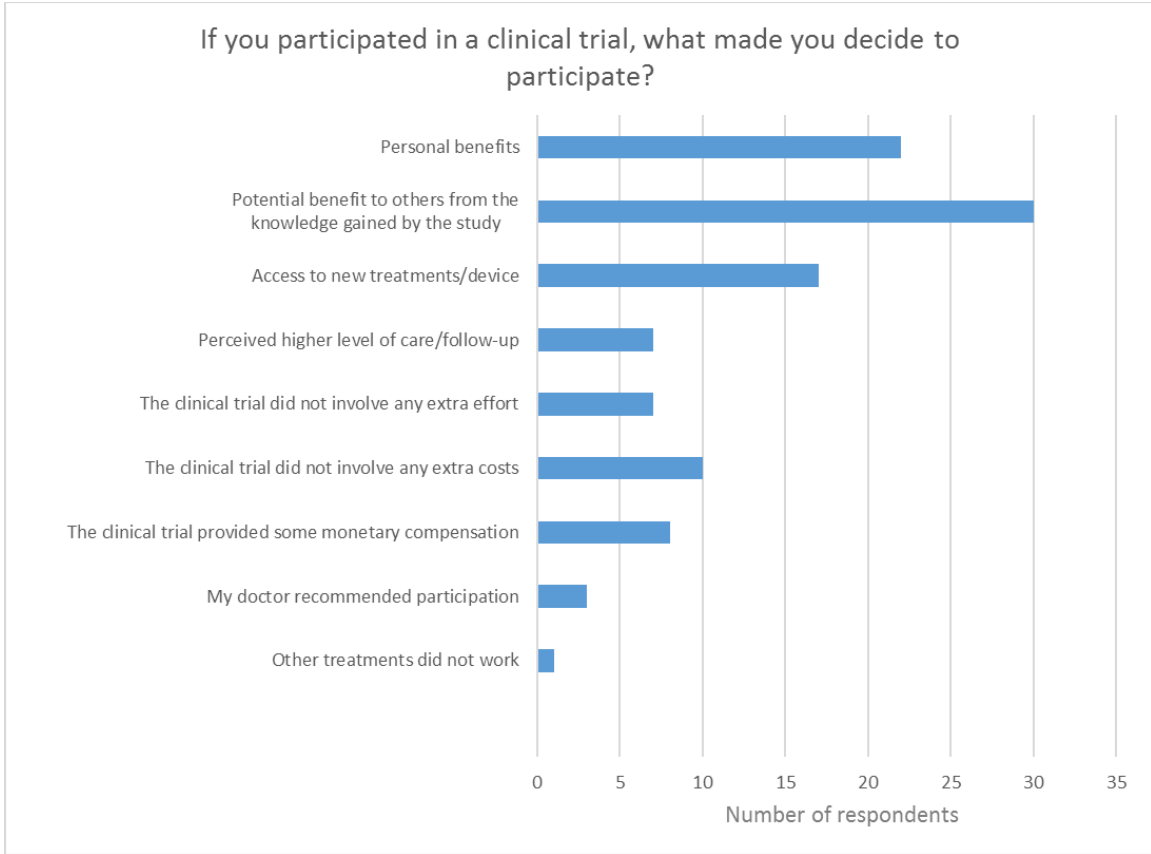


Figure 4

Please rate the following aspects of your experience participating in a clinical study:					
	Very satisfied	Satisfied	Neutral or no opinion	Dissatisfied	Very dissatisfied
Level of courtesy and professionalism of the staff	78% (25/32)	22% (7/32)	0%	0%	0%
Level of care and follow-up	50% (16/32)	22% (7/32)	28% (9/32)	0%	0%
Treatment outcome	23% (7/31)	13% (4/31)	58% (18/31)	6% (2/31)	0%
Explanation of the purpose of the clinical study and research	71% (22/31)	23% (7/31)	6% (2/31)	0%	0%
Explanation of the study's risks and benefits	71% (22/31)	19% (6/31)	6% (2/31)	3% (1/31)	0%
Amount of time required of you	45% (14/31)	35% (11/31)	16% (5/31)	3% (1/31)	0%
Number of extra visits you had to make just for being in the study	42% (13/31)	29% (9/31)	29% (9/31)	0%	0%
Number of side effects you experienced	42% (13/31)	19% (6/31)	39% (12/31)	0%	0%
Occurance of any unexpected side effects or other unexpected experiences	45% (14/31)	10% (3/31)	45% (14/31)	0%	0%
Chance of being assigned to the control (non-treatment) group	33% (10/30)	7% (2/30)	57% (17/30)	3% (1/30)	0%

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. 68% (21/31) of trial participants did not believe that they received better medical care due to their participation.

Trial sponsors directly met with patient participants 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 ClinicalTrials.gov.

Of those who participated in a clinical trial, 77% (24/31) had participated in more than one, and 96% (30/31) would be willing to participate in another. 93% (28/30) would be willing to recommend to others that they participate in a clinical trial.

Patients who had chosen not to participate in a clinical trial were asked about their concerns (presented in the figure below).

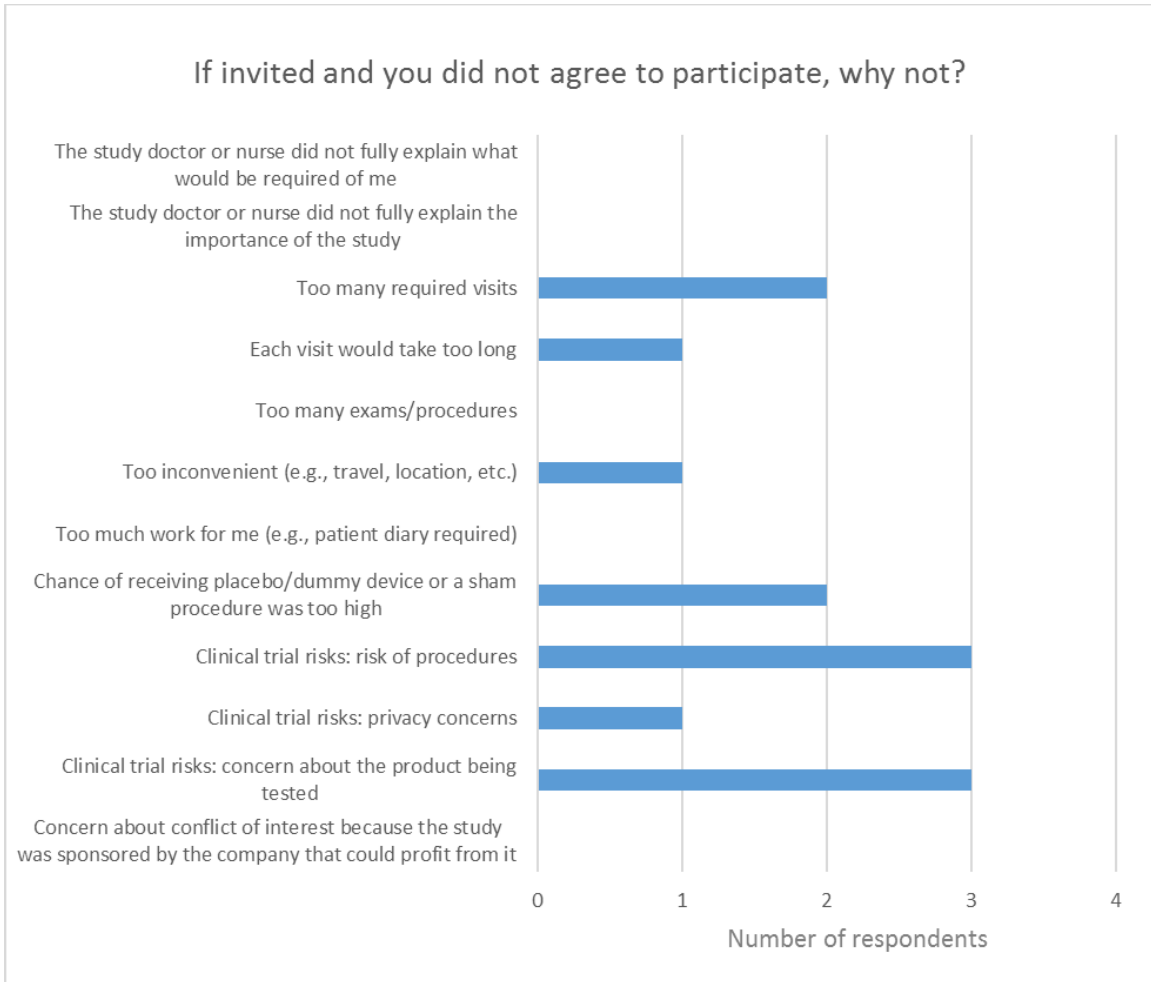


Figure 6

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 of the respondents were asked to consider various aspects of clinical trials that may affect their decisions to participate:

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?

	Much more likely	More likely	Neutral or no opinion	Less likely	Much less likely
Travel longer distance for study visits (somewhere other than where you typically receive care)	2% (2/96)	14% (13/96)	34% (33/96)	31% (30/96)	19% (18/96)
Attend multiple study visits	8% (8/97)	19% (18/97)	54% (52/97)	16% (16/97)	3% (3/97)
Undergo multiple examinations or tests	9% (9/96)	22% (21/96)	50% (48/96)	18% (17/96)	1% (1/96)
Have study staff come to your home to conduct examinations or tests	33% (32/96)	32% (31/96)	25% (24/96)	6% (6/96)	3% (3/96)
Be able to provide health information remotely, via website or smartphone app	52% (50/96)	32% (31/96)	13% (12/96)	2% (2/96)	1% (1/96)
Need to complete surveys or patient diary at home	26% (25/97)	36% (35/97)	32% (31/97)	3% (3/97)	3% (3/97)

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?

	Much more likely	More likely	Neutral or no opinion	Less likely	Much less likely
The study treatment is new or experimental, but it is not expected to have extra risks	38% (37/97)	42% (41/97)	14% (14/97)	2% (2/97)	3% (3/97)
The study treatment is new or experimental, and it may include some extra risks	5% (5/97)	16% (16/97)	32% (31/97)	39% (38/97)	7% (7/97)
There is a chance that you will be placed in the placebo, dummy device, or sham procedure group	7% (7/96)	13% (12/96)	47% (45/96)	20% (19/96)	14% (13/96)
A large amount of personal data being collected, even if it is being kept securely and not shared outside your care team	16% (16/97)	21% (20/97)	54% (52/97)	7% (7/97)	2% (2/97)
Your data being shared with other companies or government agencies, even if it cannot be traced back to you	18% (17/97)	16% (16/97)	41% (40/97)	22% (21/97)	3% (3/97)
Easy access to additional study information is available to you (e.g., dedicated telephone support, a website, or smartphone app)	37% (36/97)	42% (41/97)	19% (18/97)	0%	2% (2/97)
Easy access to sponsoring company representatives	22% (21/96)	39% (37/96)	32% (31/96)	3% (3/96)	4% (4/96)

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?					
	Much more likely	More likely	Neutral or no opinion	Less likely	Much less likely
Chance to gain more awareness about your condition	53% (51/97)	38% (37/97)	9% (9/97)	0%	0%
Chance to contribute to the body of knowledge about your condition	57% (55/97)	38% (37/97)	5% (5/97)	0%	0%
Chance to improve your own health	82% (80/97)	15% (15/97)	2% (2/97)	0%	0%
Access to new treatment(s) for your condition	71% (68/96)	26% (25/96)	3% (3/96)	0%	0%
Access to new technologies for treatments for your condition (e.g., a wearable or implantable version of a medical device you already use)	62% (60/97)	29% (28/97)	6% (6/97)	2% (2/97)	1% (1/97)
Access to new diagnostic testing or other new medical technology related to your condition (e.g., a new type of imaging scan)	59% (57/97)	34% (33/97)	6% (6/97)	1% (1/97)	0%
Strong reputation of the study doctor or the healthcare center where the study visits will take place	54% (52/97)	38% (37/97)	8% (8/97)	0%	0%
Your doctor's recommendation	40% (39/97)	39% (38/97)	20% (19/97)	1% (1/97)	0%
Your family or friends' recommendations	16% (15/96)	28% (27/96)	53% (51/96)	2% (2/96)	1% (1/96)
Monetary compensation for time and travel costs	34% (33/96)	27% (26/96)	35% (34/96)	2% (2/96)	1% (1/96)
Receiving periodic updates about the progress of the study	45% (44/97)	46% (45/97)	8% (8/97)	0%	0%
Receiving a summary of the study results once the study is finished	58% (56/97)	37% (36/97)	5% (5/97)	0%	0%

Figure 9

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.

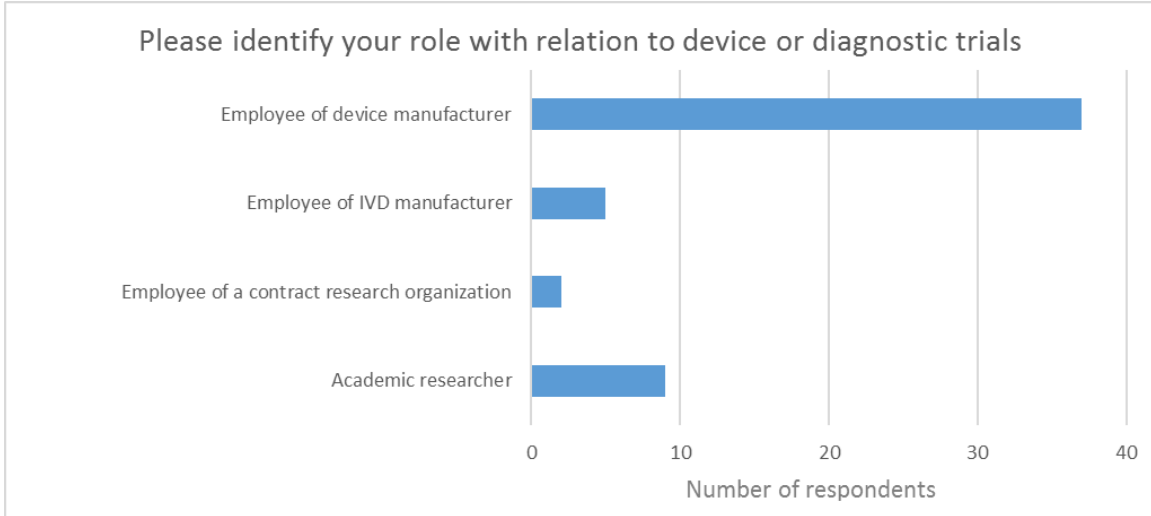


Figure 10

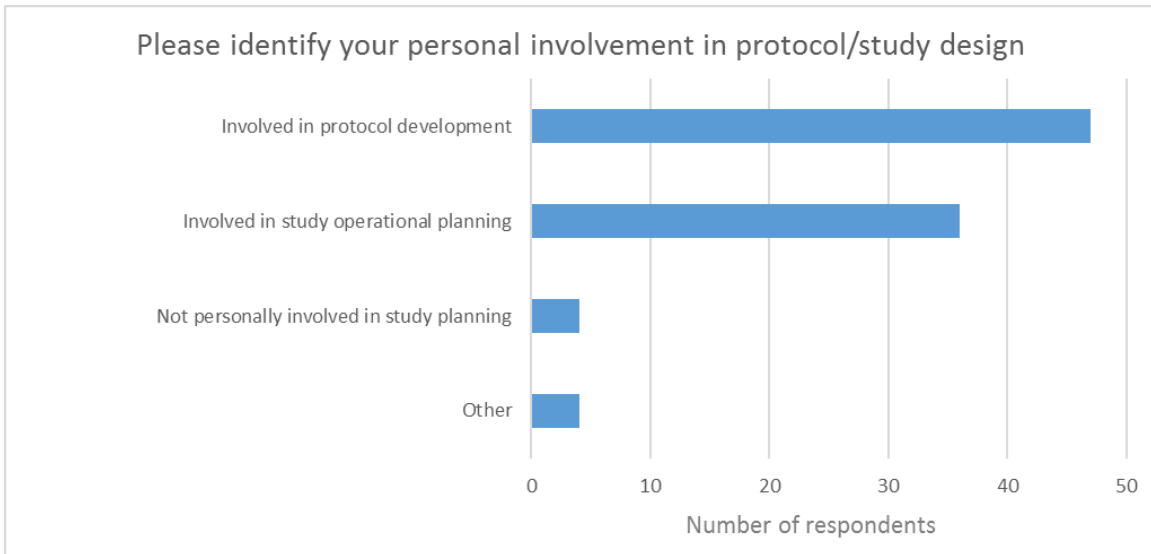


Figure 11

Then respondents were asked about their respective companies' practices for obtaining patient input into the planning of clinical trials and the relative value of the efforts.

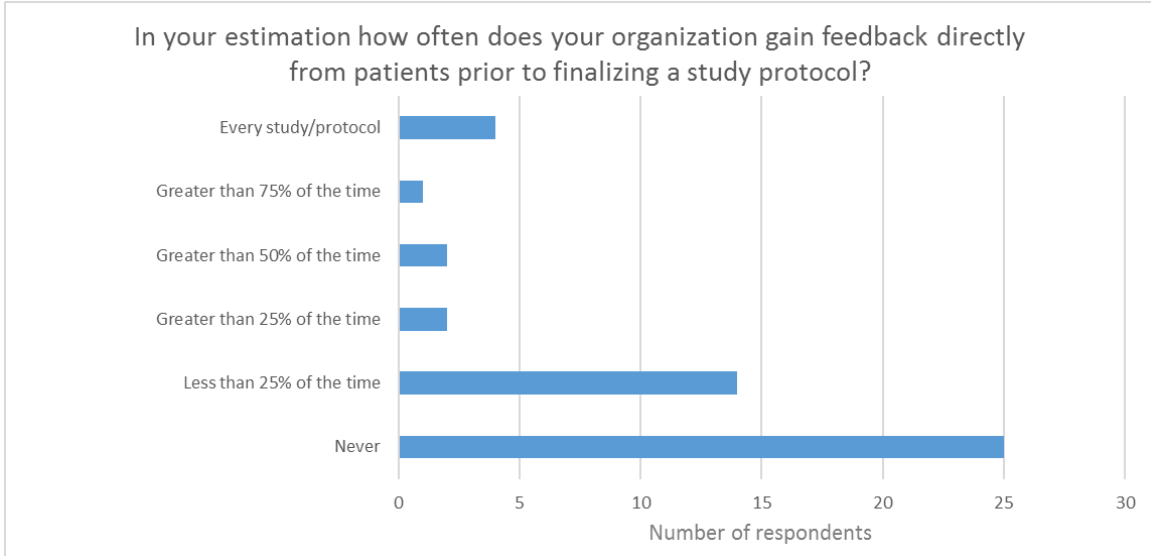


Figure 12

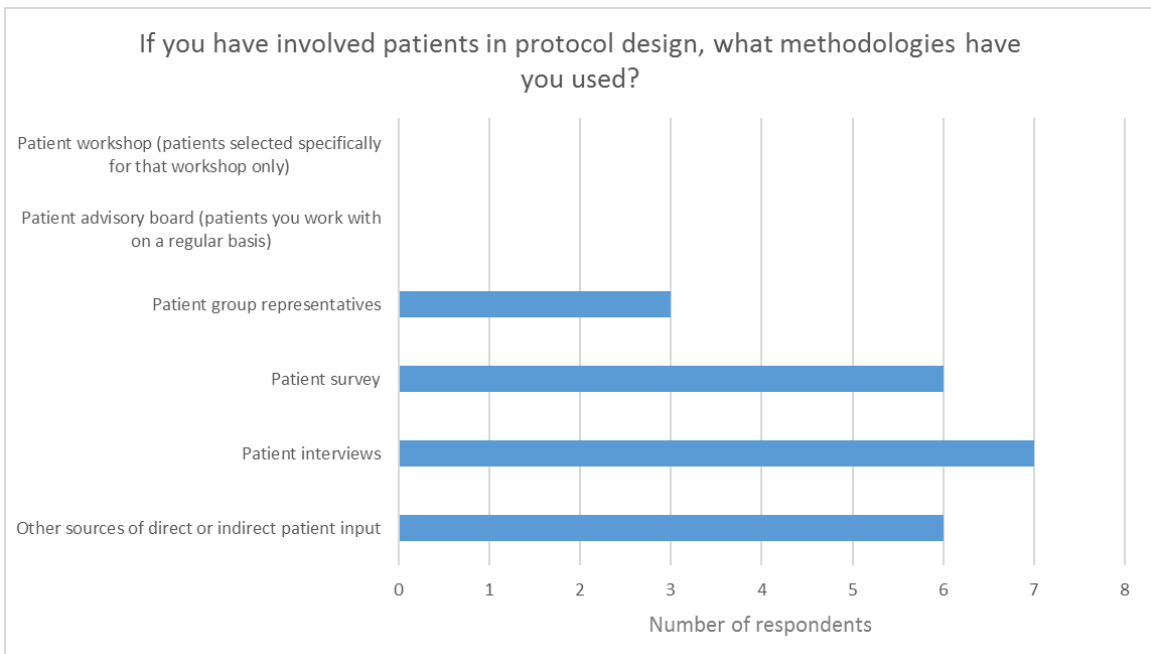


Figure 13

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.”

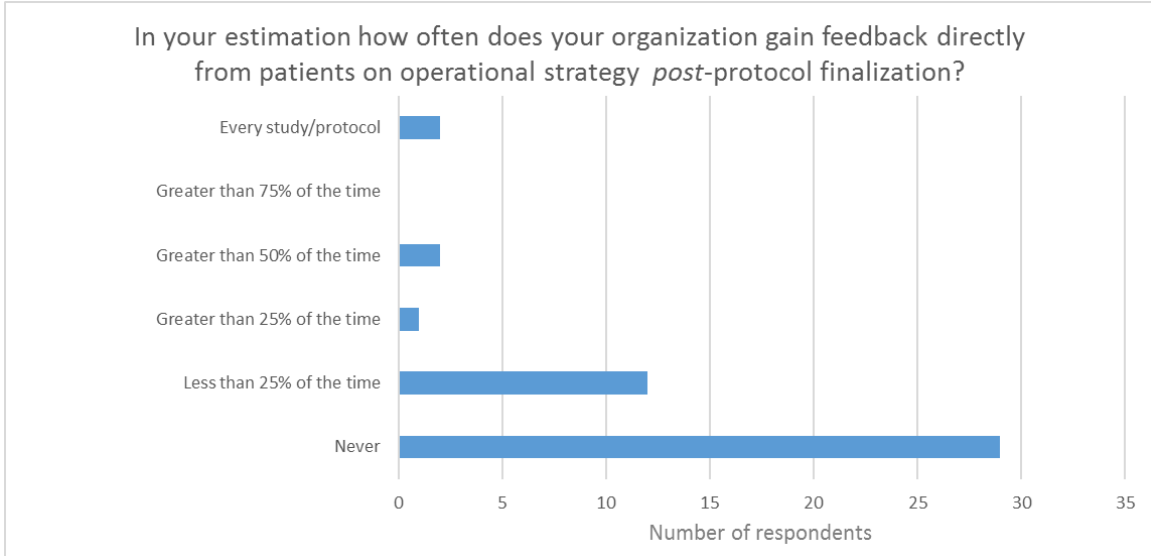


Figure 14

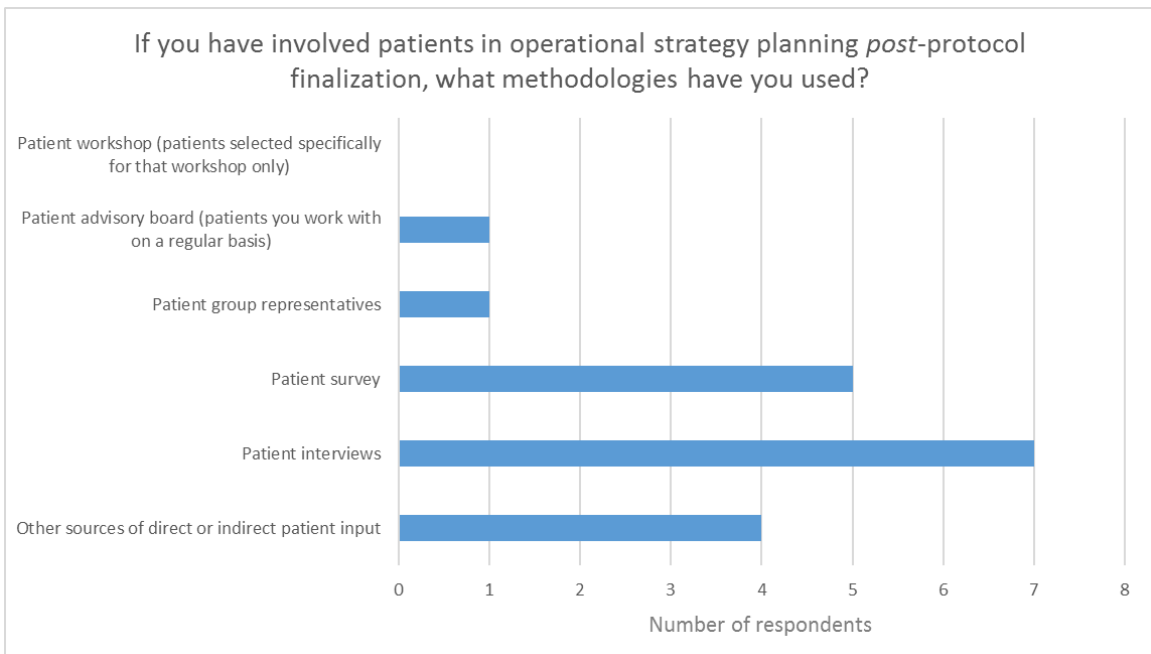


Figure 15

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

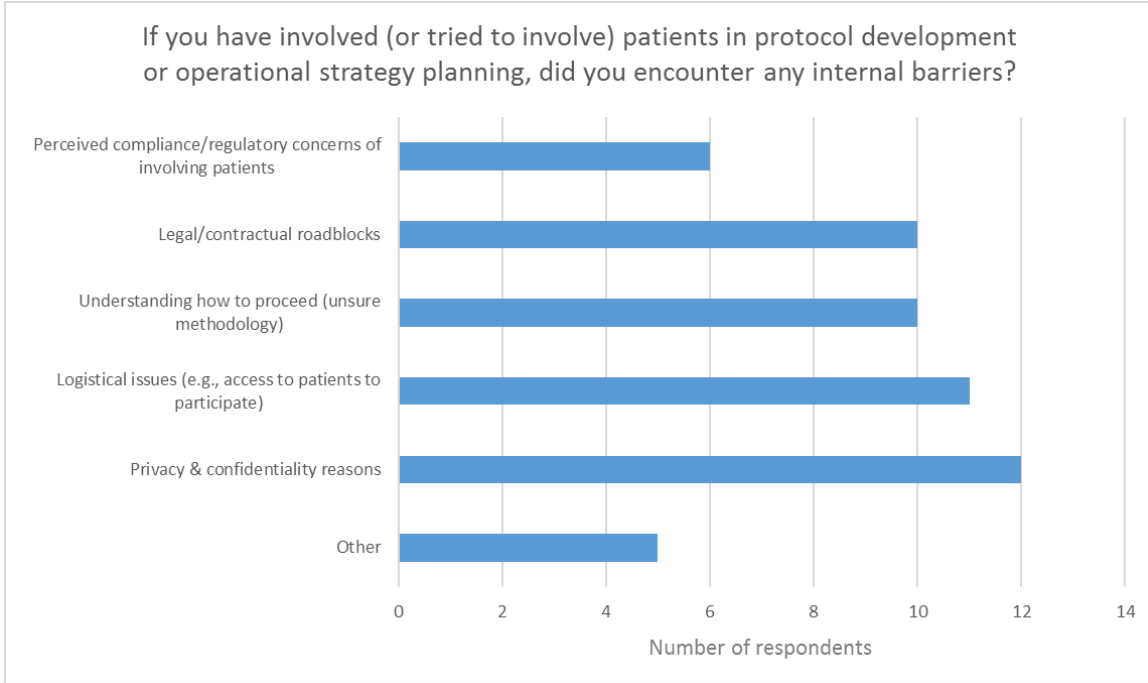


Figure 16

“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.

	Very positive	Positive	Neutral or no opinion	Negative	Very negative	N/A
Identified by participating sites or researchers	51% (20/39)	41% (16/39)	3% (1/39)	0%	0%	5% (2/39)
Referred by patient group	8% (2/38)	18% (7/38)	34% (13/38)	5% (2/38)	3% (1/38)	32% (12/38)
Digital/online advertising	3% (1/38)	18% (7/38)	24% (9/38)	16% (6/38)	3% (1/38)	37% (14/38)
Other advertising (e.g., radio, newspaper)	8% (3/38)	13% (5/38)	11% (4/38)	18% (7/38)	11% (4/38)	39% (15/38)
Working with local community (e.g., church or social groups)	0%	5% (2/37)	27% (10/37)	11% (4/37)	3% (1/37)	54% (20/37)

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.

	Very important	Important	Neutral or no opinion	Somewhat important	Not important
Personal benefit to their health	56% (22/39)	36% (14/39)	5% (2/39)	3% (1/39)	0%
Potential benefit to others from the knowledge gained by the study	15% (6/39)	64% (25/39)	10% (4/39)	10% (4/39)	0%
Access to new treatment/device/diagnostic	59% (23/39)	33% (13/39)	3% (1/39)	5% (2/39)	0%
Perceived higher level of care/follow-up	23% (9/39)	44% (17/39)	21% (8/39)	13% (5/39)	0%
Financial compensation	3% (1/39)	18% (7/39)	41% (16/39)	28% (11/39)	10% (4/39)
Perceived financial cost of participation	3% (1/39)	28% (11/39)	28% (11/39)	28% (11/39)	13% (5/39)
Doctor recommends participation	38% (15/39)	54% (21/39)	5% (2/39)	3% (1/39)	0%
Other treatments didn't work	34% (13/38)	50% (19/38)	8% (3/38)	5% (2/38)	3% (1/38)
Burden of participation (e.g., number of procedures, visits, etc.)	15% (6/39)	54% (21/39)	18% (7/39)	10% (4/39)	3% (1/39)
Distance required to travel to site	16% (6/38)	55% (21/38)	16% (6/38)	11% (4/38)	3% (1/38)

Figure 18

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

	Very positive	Positive	Neutral or no opinion	Negative	Very negative
Providing patients with educational material (printed or digital) to explain study purpose and expectations	14% (5/37)	70% (26/37)	16% (6/37)	0%	0%
Financial compensation for a patient's time and/or travel costs	19% (7/36)	50% (18/36)	31% (11/36)	0%	0%
Performing visits in a patient's home (e.g., sample collection)	15% (5/33)	21% (7/33)	58% (19/33)	6% (2/33)	0%
Providing patients with a travel "concierge" service to coordinate travel to sites	9% (3/32)	41% (13/32)	47% (15/32)	3% (1/32)	0%
Centralized telephone support for patients (in local language) other than the site (study call center)	16% (5/32)	38% (12/32)	44% (14/32)	3% (1/32)	0%
Being able to provide study data/health information remotely via website or smartphone app (e.g., ePRO)	18% (6/34)	41% (14/34)	41% (14/34)	0%	0%
Being able to provide study data/health information remotely via wearables or sensors	9% (3/33)	24% (8/33)	67% (22/33)	0%	0%

Figure 19

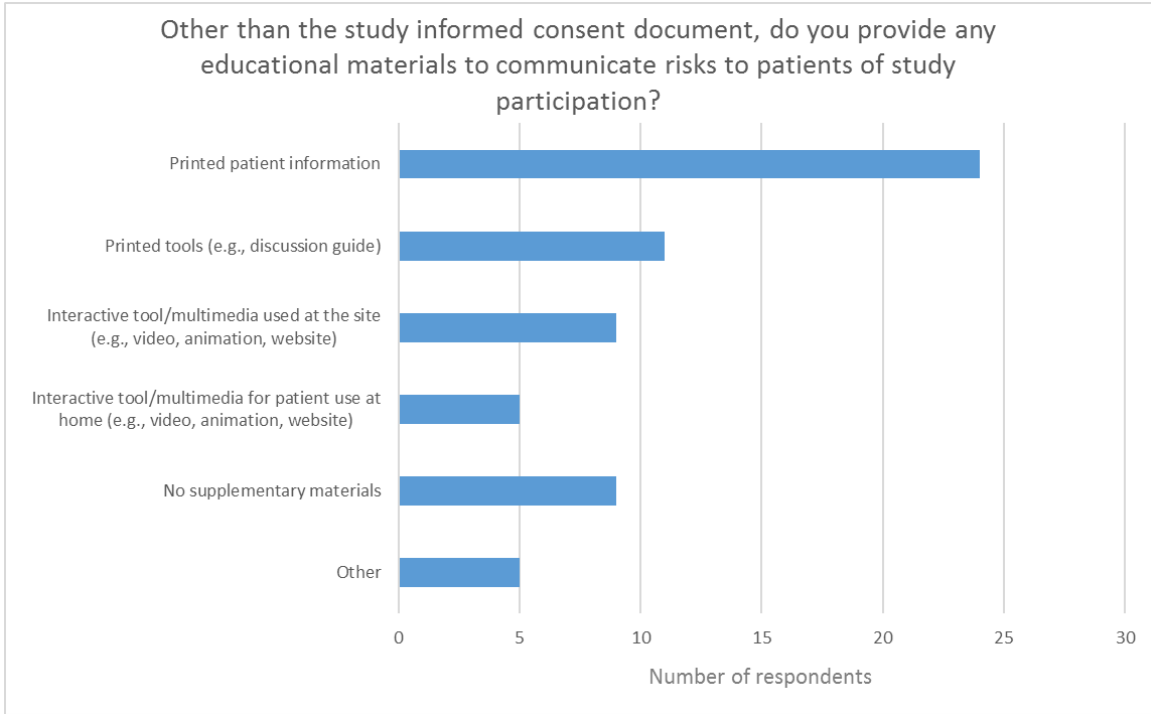


Figure 20

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

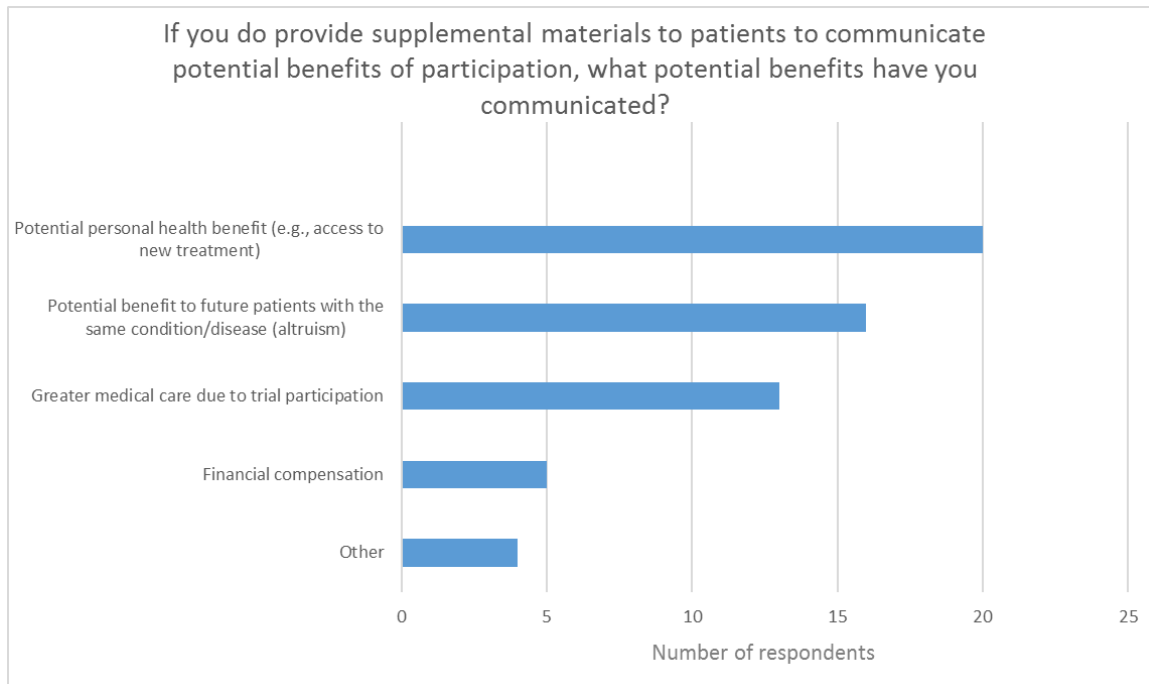


Figure 21

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, e.g., no electronic questionnaires. 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.”
- “This topic is uncharted for me as we have never (or considered) this type of collaboration.”
- “Plan for nontherapeutic healthy volunteers. We debate if their tests should be reviewed. Should we disclose incidental results. Plan to clarify informed consent is important.”



CONCLUSIONS

Within 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.

Guidance and considerations already exist within the pharmaceutical industry that may be applicable and valuable to device and diagnostic companies. However, there are some significant differences between a device (especially class III) or diagnostic trial and a drug study. MDIC intends to review existing work across the drug, device and diagnostic industry, assess key differences with device / diagnostic trials and develop industry specific considerations to increase the involvement of patients in clinical trials.

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