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Original Research Article

Clinical trial perceptions and knowledge: the results of three surveys administered to U.S. physicians, surgeons, nurses, clinic administrators and clinical research industry professionals

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ABSTRACT

Background: Surveys were administered to clinicians and non-clinicians on various clinical trial-related topics including their understanding of FDA medical device terminology, investigator-initiated trials (IITs), the level of institutional support for clinical trials at their respective sites and the use of wearable technologies in collecting trial data.
Methods: Three online surveys were, collectively, administered to over 350 respondents in the United States using an online tool.
Results: The surveys found that the majority of the surveyed clinicians and clinical research professionals do not know the difference between FDA-approved and FDA-cleared devices, awareness of IITs and institutional support for clinical trials varies by medical specialty, and there are noteworthy differences between orthopedic surgeons and oncologists as to whether wearable technologies should be used to collect trial data.
Conclusions: The study concluded that there are many physicians and surgeons who cannot accurately distinguish between FDA-approved and FDA-cleared devices, yet they claim to know the difference. It was also observed that oncology centers are more likely to be supportive of clinical trials, as reported by clinicians, as compared to orthopedic centers. Less than half of the surveyed oncology respondents are supportive of the use of wearable technologies in a clinical trial setting-whereas more than half of the orthopedic respondents are supportive of the same. The study also found that most of the surveyed oncologists are familiar with IITs whereas most of the orthopedic surgeons are not familiar with IITs.

Keywords: Clinical trials, Investigator-initiated studies, Wearable technologies, FDA Approved

INTRODUCTION

Clinical trials serve as a key gateway to bringing innovative, safe, and effective treatments to patients. They are globally recognized by virtually all healthcare professionals as a fundamental part of the evidence-based approach to medicine. The diligent analysis of results from clinical trials drives improvements to pharmaceuticals and medical devices, which in turn supports better prognoses from diseases and overall trends to better health outcomes. In fact, the medical advances that in many ways shaped the 20th and 21st centuries were born out of careful and deliberate clinical trial efforts that showed which treatments, drugs and devices improve health outcomes, and just as importantly, which are detrimental to human health.[1]

The objective of the study was to determine which factors motivate physicians, surgeons, nurses, researchers, and administrators to participate in clinical trials, and their opinions concerning various clinical trial conduct topics. As part of this-two surveys were administered to more

than 300 clinicians and non-clinicians working in various orthopedic and oncology-related roles across the United States. Separately, a third survey was administered to colleagues who are clinical research professionals in the United States.

The results of the surveys provide valuable insight to clinicians, clinical trial managers, research administrators and pharmaceutical and medical device professionals involved in the planning and execution of clinical trials. The findings allow us to take a close look at how patient-facing professionals view trials, what can be done to further promote their willingness to participate in clinical research efforts, and how trials can be improved to more accurately reflect the observations of those who are in contact with the research participants.

METHODS

This was a descriptive cross-sectional study. The online survey monkey tool (http://www.surveymonkey.com) was used to develop and administer two quantitative surveys collecting data on clinical trial perceptions among physician and non-physician professionals who work for oncology and orthopedic departments, clinics, research centers, community-based providers and other organizations across the United States. The contact information for the oncology survey participants was obtained from the attendee list of the 2019 American society for clinical oncology (ASCO) annual meeting. Institutional review board (ethical) approval was not obtained as the survey was anonymous, it did not collect protected health information (PHI) and it posed no risk to the survey respondents. Chi-square and p values were reported for the survey responses.

The orthopedic survey was distributed to professionals whose contact information was obtained via the 2019 attendees list of the American academy of orthopedic surgeons (AAOS) annual meeting. As with the oncology survey, institutional review board (ethical) approval was not obtained as the survey was anonymous, it did not collect PHI and it posed no risk to the survey respondents. Appendix 4 provides the survey questions for the orthopedic survey.

A simple representative sample of at least 150 participant responses was chosen for each of the two surveys. The survey was administered between November 18, 2019 and November 26, 2019 in an online setting to participants across the United States. Although the sample size is not statistically powered, the use of controlled contact lists serves to partly address this issue. There is a very slim chance that anyone who is not involved in orthopedics or oncology attended the annual meetings of the two respective organizations, or in turn completed the surveys which were only sent to meeting attendees. The orthopedic survey was distributed to 13,072 contact email addresses. The 584 emails could not be delivered thus leaving an audience of 12,488 orthopedic survey recipients. The oncology survey was administered to 21,000 contact email addresses. 1,222 emails could not be delivered thus leaving an audience of 19,778 oncology survey recipients. Three days after receiving the respective surveys, recipients who had not completed, or who had only partially completed, the survey were sent an automated reminder via email. Following receipt of the initial survey email, recipients could opt out of receiving further communication regarding the surveys. 733 of the orthopedic survey recipients opted out of receiving further survey-related communications. 768 of the oncology survey recipients did the same. For both surveys, respondents received a thank you email following the successful completion of the survey.

The original draft of the oncology and orthopedic surveys were developed with 60 questions each. A group of seven colleagues from a Washington-based clinical research organization, nor consult, LLC., performed a qualitative evaluation of the draft surveys to establish face and construct validity. Collectively, this group are experts in clinical research practices, including data collection using survey questionnaires across various therapeutic areas including both oncology and orthopedics.

The group includes both clinicians and non-clinicians. The group's evaluation resulted in each survey being reduced to the final respective numbers of questions which were deemed to be most relevant to the research topics. The questions were reworded as needed, and the final order of the questions was established with the help of the abovementioned group. Efforts were made to remove questions that may be perceived as leading or otherwise biased.

Additional validation could not be performed as the surveys to a large degree measure subjective data such as how the respondents feel about particular questions, or their opinions, values and attitudes. As noted by DeFranzo, "subjective questions about the thought processes and feelings of a respondent are not directly verifiable through direct observation".[2] Attempts to establish concurrent validity via correlation to other surveys were futile, as no comparable surveys could be identified. Degrees of measurement-error cannot be ruled out as the surveys partially measure subjective data, although this was addressed by the question-wording efforts described above.

The specialties of orthopedic surgery and oncology were specifically chosen as they allow for diverse points of view from clinicians who primarily work with medical devices (orthopedic surgeons) and clinicians who primarily work with drugs (oncologists)-thus representing two distinct sides of the clinical research spectrum.

Each of the two groups completed separate yet almost identical surveys, thus allowing for comparisons of responses by medical specialty.

The final oncology and orthopedic surveys asked 23 and 24 questions, respectively. The third survey, which was also developed via the SurveyMonkey tool, was administered to 25 clinical research industry professionals who work in managerial or higher positions. These were personal contacts, and to protect their anonymity, they are not named. They included professionals from global drug and medical device companies such as Novo Nordisk, Takeda and Depuy Synthes. This survey differed from the orthopedic and oncology surveys as it was targeting an audience that is not directly involved in patient care and which is more actively engaged in the managerial side of clinical trials. The response rate for this survey was 100% (25 completed surveys out of 25 sent surveys). The surveys were descriptive.

RESULTS

Survey participants

In total, 359 survey respondents participated in the three separate surveys. This included: 145 orthopedic surgeons, two orthopedic nurses, seven other orthopedic clinicians, three orthopedic researchers and two orthopedic administrative staff members. This resulted in 159 total responses to the orthopedic survey. Also, 70 oncologists, 42 oncology nurses, 25 other oncology clinicians, 15 oncology researchers and 23 oncology administrative staff provided their responses. This resulted in 175 responses to the oncology survey. The orthopedic survey was distributed to 13,072 contact email addresses. The 584 emails could not be delivered thus leaving an audience of 12,488 orthopedic survey recipients. The oncology survey was administered to 21,000 contact email addresses. 1,222 emails could not be delivered thus leaving an audience of 19,778 oncology survey recipients. The respective survey response rates were 1.2% for the orthopedic survey (159 of 12,488) and 1.8% for the oncology survey (359 of 19,778). Although the response rates were low, the use of controlled contact lists serves to address this issue as there is a very low chance that anyone who is not involved in orthopedics or oncology attended the annual meetings of the two respective organizations. Thus, there is a very low risk that anyone who was not a member of the target population participated in the either survey. Also, low response rates are to be expected in this scenario as previous research has shown that response rates "dip to 1% or less when the recipient doesn't know the sender of the email invite" and physician response rates to surveys are notably low.[3,4] Three days after receiving the respective surveys, recipients who had not completed, or who had only partially completed, the survey were sent an automated reminder via email. Although completing the survey was a requirement, not all survey participants answered the same number of questions as some questions were only to be answered by physician/surgeons whereas other questions were only to be completed by non-physician/non-surgeon survey participants.

The professional background of the participants in the orthopedic and oncology surveys are shown in the Table 2. This includes the percentages of total responses for each survey. These results showed that 70 (40%) of the oncology survey respondents and 145 (91%) of the orthopedic survey respondents reported their primary role as physician/surgeon. Nurses, with a frequency of 42 (24%), were the second most frequently primary role reported by the oncology survey respondents, whereas "researcher" was the second most reported role by the orthopedic survey respondents. In addition, a chi-square test was performed to compare the responses from the two surveys. The results of this test represented that there was the statistically significant difference between the two groups regarding their primary role, χ^2=97.749, p<0.001.

Table 1: Number of respondents and the response rate for the two primary surveys.

Survey respondents	Respondents	Response rate (%)
Oncology survey	175	1.8
Orthopedic survey	159	1.2

Table 2: Survey respondents primary role/job title.

Variables	Physician/ surgeon	Researcher	Nurse	Other clinician	Administrative staff	Chi-square	P value
Oncology survey responders (%)	70 (40)	15 (9)	42 (24)	25 (14)	23 (13)	97.749	<0.001
Orthopedic survey responders (%)	145 (91)	3 (2)	2 (1)	7 (4)	2 (1)		

Most of the clinical research professionals had primarily worked in drug research., followed by medical devices and biologics. None of the respondents had primarily worked in cosmetic clinical research. The distribution is expected as it is known that there are more resources like (Including staffing) allocated to the biologics as well as drug research than device research. Specifically, according to the U. S. national library of medicine there are four times more reported biologics and drug trials than medical device trials.[5] Table 3 shows the descriptive results of the respondents who self-identified as working

in each of the four clinical research fields, in addition to one respondent who worked in a different field.

Table 3: Primary experience of the clinical research professionals.

Primary experience	Frequency	Percentage (%)
Medical devices	8	32
Drugs	10	40
Biologics	6	24
Other	1	4

Lack of knowledge concerning key FDA terminology

Medical device marketing terminology, including the three various device classes and clearance vs. approval has been the subject of confusion since the 1976 medical device amendments went into effect.[6] In 2018, a popular Netflix documentary highlighted the safety concerns associated with the loosely defined regulations and their loopholes.[7]

The survey respondents were asked to confirm whether they are very confident in their knowledge concerning the distinctions between FDA-approved and FDA-cleared medical devices. The surveys provide evidence that there is a significant lack of knowledge amongst physicians and surgeons across the two specialties as it relates to what constitutes an FDA-approved device vs. an FDA-cleared device (Table 4). Less than half (46%, n=73) of the orthopedic survey respondents and less than half (44%, n=77) of the oncology survey respondents confirmed that they are "confident" in their knowledge as it relates to the two designations. Also, only 56% (n=14) of the surveyed clinical research professionals confirmed that they were "confident" in their knowledge pertaining to these two drastically different FDA designations. According to the results of the chi-square test, no significant difference was observed in the responses of the three respondent groups, χ^2=1.276, p=0.515.

Table 4: I am very confident in my knowledge concerning the distinctions between FDA-approved and FDA-cleared medical devices.

Variables	True (%)	False (%)	Chi-square	P value
Clinical research professionals	14 (56)	11 (44)	1.276	0.515
Oncology survey respondents	77 (44)	98 (56)		
Orthopedic survey respondents	73 (46)	86 (54)		

Shockingly, nearly 8 out 10 (78% n=60) of oncologists who answered that they are confident in their knowledge concerning FDA-approved versus FDA-cleared designations incorrectly stated that all permanent implantable devices must be FDA-approved (Table 5). This is false as there are thousands of widely used FDA-cleared permanent implantable devices ranging from esophageal prosthesis, fallopian tube prosthesis to bone void fillers (FDA, 2015).[8] Orthopedic surgeons provided only slightly more comforting responses as 58% (n=42) of those who claimed to have a very good understanding of the regulations provided the same incorrect answer. This is particularly troublesome when considering that orthopedic surgeons perform two of the five most common medical device surgeries performed on an annual basis in the United States. Knee arthroplasty and hip-replacement surgeries, respectively, are the 1st and 4th most common operating room procedures according to data from 2003-2012.[9] Further, according to a 2016 study, 88% of orthopedic medical devices, including implantable products, are FDA 510 (k) products that are not approved.[10] Similarly to the clinicians, 71% of the clinical research professionals responded incorrectly. The chi-square test also showed that there was a statistically significant difference in the responses of the three types of groups who had asserted to be confident in their knowledge regarding the distinction between FDA-approved and FDA-cleared medical devices, χ^2=7.263, p=0.027. The implications for this lack of knowledge are further discussed below.

Institutional support for participation in clinical trials

We know that "most patients are willing to enroll [in clinical trials] yet very few are invited".[11] To remain competitive, healthcare provider organizations need to make concerted efforts to build and maintain their clinical research units and meet the demands of their patients. To determine how well the institutions are meeting this objective, from the perspective of their staff, the oncology and orthopedic survey participants were asked to confirm to what extent their institutions are supportive of clinicians participating in clinical research efforts. The results show that more than eight out of 10 surveyed oncology respondents believed that their institutions are supportive of their clinicians participating in clinical research efforts. Only four respondents (2%) reported that their institutions are not supportive of clinical research participation. On the other hand, the orthopedic respondents provided less positive feedback concerning their institutions and participation in clinical research efforts. More than 15% (n=24) responded that they disagreed or strongly disagreed that their institutions are supportive of clinical trials participation. Further, one in three respondents neither agreed nor disagreed. This shows that among the sample, orthopedic facilities were less inclined to support clinical trial efforts than cancer treatment facilities. In addition, a chi-square test was conducted to compare the responses of the oncologists and orthopedics. The results of this test showed that there was a statistically significant difference in the responses of the two groups, χ^2=44.899, p<0.001 (Table 6).

Wearable technologies

The surveys also collected data on the opinions concerning the use of wearable technologies in clinical trial efforts (Table 7). The results showed that 56% (n=14) of clinical research professionals reported that such devices should be used in clinical trials, while 16% (n=4) were against the use of such devices in clinical trials and 28% (n=7) did not have an opinion on the topic. In contrast, 42% (n=72) of oncology survey participants agreed that such technologies should be applied in the context of clinical trials, whereas 6% (n=11) disagreed

and the majority (52%, n=91) had no opinion on this topic. The orthopedic survey respondents had the most favorable attitudes toward the implementation of wearable technology tools in clinical trials. 59% of orthopedic survey respondents were supportive of it, only 2% were against it and 39% had no opinion. In addition, a chi-square test was conducted to compare these three survey responses. According to the results of the chi-square test and p value, a significant difference was observed in the response of these three types of groups, χ^2=19.694, p<0.001.

IITs

IITs are research studies that are initiated and managed by an entity other than the marketer of the product. IITs serve an important role in clinical development as they are guided by scientific curiosity rather than commercial interests. Research has shown that IITs can contribute valuable evidence and that they are often extremely rewarding to the investigator.[12] A variety of pharmaceutical companies, such as AstraZeneca (2021) and Sandoz (2021), have programs in place to help to fund IITs.[13,14] These programs provide the financial compensation to the investigator but keep the company at arms-length from the operational aspects of the trial. The survey participants were asked to confirm whether they are familiar with the concept of IIT. Most of the orthopedic survey respondents (64%, n=100) reported that they are not familiar with IITs. Awareness levels were almost the exact opposite for the oncology survey respondents with 65% (n=111) indicating that they are familiar with IITs. The results of the chi-square test presented in Table 8 revealed that there was a statistically significant difference in the responses of orthopedics and oncologist, χ^2=27.456, p<0.001.

Table 5: In order for a permanent implantable medical device to be legally marketed in the United States, it must be FDA approved.

Variables	True (incorrect answer per current regulations) (%)	False (correct answer per current regulations) (%)	Chi-square	P value
Clinical research professionals	10 (71)	4 (29)	7.263	0.027
Oncologists	60 (78)	17 (22)		
Orthopedic surgeons	42 (58)	31 (42)		

Responses limited to survey participants who claimed to be "confident" in their knowledge of FDA designations.

Table 6: My institution is supportive of its clinicians participating in clinical research efforts.

Variables	Strongly agree or agree (%)	Neither agree or disagree (%)	Strongly disagree or disagree (%)	Chi-square	P value
Oncologists	142 (86)	20 (12)	4 (3)	44.899	<0.001
Orthopedics	79 (52)	49 (32)	25 (16)		

Table 7: Wearable technologies are valuable tools for clinical trials and their use should be encouraged.

Variables	True (%)	False (%)	Don't know/ no opinion (%)	Chi-square	P value
Clinical research professionals	14 (56)	4 (16)	7 (28)	19.694	0.001
Oncologists	72 (42)	11 (6)	91 (52)		
Orthopedics	93 (59)	3 (2)	62 (39)		

Table 8: I am familiar with the concept of IITs.

Variables	Yes (%)	No (%)	Chi-square	P value
Oncology survey respondents	111 (65)	59 (35)	27.456	<0.001
Orthopedic survey respondents	57 (36)	100 (64)		

DISCUSSION

FDA-approved vs. FDA-cleared

The most impactful finding from this research was learning about the many physicians and surgeons who cannot accurately distinguish between FDA-approved and FDA-cleared devices yet claim to know the difference. This is a substantive finding as it shows that there is a disconnect between the regulations and those who are working with these devices daily. It is obvious that such products are used in orthopedics, but it should also be noted that they are present in oncology. Examples include devise that deliver chemotherapy directly to the target area inside the body. Examples include the advanced chemotherapy technologies device for pancreatic cancer and the implantable micro-electromechanical systems iMEMS chemotherapy administration device.[15,16]

More than half of orthopedic surgeons admitted that they were not confident in their knowledge concerning the difference between medical device FDA approvals and FDA clearances. This is despite this type of information being available in the marketing and other materials provided by the manufacturer to the surgeons. This lack of knowledge means that many orthopedic surgeons either read the materials and do not fully understand them yet continue to use the devices, or they simply assume FDA-cleared and FDA-approved are synonymous. Either way, it is a significant error on their behalf. This is a very disturbing finding as clinicians in this field work with these devices daily. Orthopedists should be aware that between 2003 and 2013, there were more than 700 recalls for knee devices and their components.[17] It is reasonable to suspect that at least some of these recalls would have been prevented if the devices in question had reached market by way of the rigorous requirements of the FDA IDE and PMA approval process (which results in FDA-approval) rather than the 510k clearance process (which results in FDA-clearance).

Tellingly, only 12% (n=3) of the clinical research professionals answered that, in their opinion, most U.S. healthcare providers have a good understanding of FDA-approved vs. FDA-cleared devices. Also, many of them reported personally not knowing the difference between FDA-approved and FDA-cleared devices (44%, n=11).

This raises serious ethical questions such as: is it the surgeon's fault that s/he is not educated on the specifics concerning FDA-approved vs. FDA-cleared? Is it the fault of the FDA which has not properly disseminated this information to physicians and surgeons? Is it the fault of the medical device industry which is selling billions of dollars of implantable devices to surgeons without explicitly informing them that the devices have not been clinically tested? Industry, regulatory agencies, and clinical research educators must more effectively inform physicians and surgeons about these two very distinct regulatory categories. Further, they must highlight the potentially greater risks associated with FDA-cleared versus FDA-approved devices-especially for devices that are new to the market.

Institutional support

Depending on the type of research program, building the necessary infrastructure to support clinical trials may require a substantial investment in time and resources.[18] Without support from their organization's leadership, it is very challenging if not impossible for investigators to participate in trials-especially interventional studies. Simpler studies (e.g., a retrospective chart review) may be conducted by the PI only, although this approach still poses challenges. Nearly half of the orthopedic survey respondents noted that they do not receive such support from their institutions. The implication of this is that there may be many orthopedic surgeons who are willing to participate in trials as investigators but are unable to do so due to their organization's stance on clinical research. Similarly, many of their patients who may be willing to participate as clinical trial subjects will not be given the opportunity to consider available investigational interventions for their medical condition. Leaders of orthopedic surgery centers should consider whether expanding their practices to offer clinical trial participation is a worthwhile investment based on their region, surgeon interest and patient volume. By becoming clinical trial research centers, they would be able to offer patients new and potentially better treatments than standard-of-care, while also helping to contribute to the revenue flow of their centers. As expected, most of the surveyed oncologists reported strong support for clinical trial conduct at their respective centers. Oncology is by far the most lucrative and well-established field of clinical research with approximately five times more trials taking place in oncology over the past 20 years than the next most-commonly researched therapeutic area (cardiovascular diseases).[19]

Wearable technology

Wearable devices such as the Apple watch, Fitbit or Bluetooth headphones continue to grow their market share in the category of personal electronic devices. Already almost half of Americans own a wearable technology device (Russey) and according to estimates, the market will grow nearly 18% between 2019 and 2024.[20,21] Many of today's wearables can track sleep patterns, measure heart rates, estimate calories burned and more. Some are being used in healthcare settings.[22] However, they are still very uncommon in clinical trial settings. This is likely due to a combination of factors including cost, data accuracy, data reproducibility, reliability and confidentiality concerns. These reasons may be why more than half (52%, n=91) of the oncology survey respondents answered that they have no opinion as to whether wearable technologies should play a greater role in clinical trials. However, across all three surveys,

just 5% (n=18) of the respondents answered that they do not support the use of wearable technologies in clinical trials. Most (59%, n=93) of the orthopedic survey respondents answered that wearables should more often be utilized for data collection in clinical trials. It is likely that orthopedic surgeons have much more experience with such devices in their clinical practice compared to oncologists. Pedometers ("step counters") are arguably the most popular wearable technologies on the market, and they track what is inherently a joint and muscle activity.[23] There are many known benefits to the expanded use of wearable technologies in clinical trials. For example, we know that a patient's assessment of their own functional outcomes is not always accurate. However, without tracking the patient for 24 hours per day, researchers must rely on their self-reported assessments without question. For example, following surgery, a patient who enjoys significant mobility may incorrectly report to the researchers that their mobility is highly limited. If the patient wore a wearable technology gadget with a movement tracker, the researchers could independently confirm that the subject's observations are inaccurate. Similarly, as the cost of wearable technologies decreases, collecting data remotely via a wearable technology will become more cost-effective than conducting in-person or over-the-phone interviews with the subjects.

Data confidentiality and integrity are arguably the biggest obstacles to overcome before wearable technologies become mainstream gadgets in clinical research. At present, "wearables" are consumer goods that may not be built to comply with stringent data protection laws such as the health insurance portability and accountability act (HIPAA)/EU general data protection regulations (GDPR). According to Dr. Bill Byrom, a senior director at ICON research, the FDA is working to address the topic of wearable devices in clinical research but the current lack of regulations "causes some discomfort".[24] Until there are clearer regulations and guidelines for use of wearables in clinical trials/ until wearables designed specifically for clinical trial use developed, it is unlikely that their use in this context will become widespread.

IITs

The surveys showed that many physicians and surgeons are not familiar with the concept of IITs, including most of the surveyed orthopedic surgeons. This is despite the fact that four out of the five biggest orthopedic manufacturers in the world including Johnson and Johnson, Medtronic, Zimmer Biomet and Arthrex Inc. have in place IIT programs open to all practicing clinicians.[25-29] Forward-thinking drug, device and biologics companies will use IIT research to guide their clinical development efforts as it provides real-world evidence for what clinicians find to be of interest. Further, many IITs can be granted FDA exemptions for certain regulatory reporting requirements thus resulting in much more cost-effective research than a traditional industry trial. The industry can tackle this lack of knowledge about the availability of IITs by encouraging their sales representatives, who often meet with clinicians, to spend some time educating them about IIT opportunities during their visits to doctors' offices. Alternatively, electronic or hard copy materials concerning IITs can be sent to the physicians in order to more effectively promote such studies.

Limitations

The limitations of this study include that the sample size is insufficient for making generalized conclusions across the respective fields of oncology, orthopedics, and clinical research management. Further, there is little prior published literature on the questions that were included in the survey-thus making it difficult to compare the survey results to prior publicly available information. In addition, the COVID-19 pandemic has impacted various aspects of clinical research. The surveys were administered prior to the pandemic and it's possible that opinions have since shifted given more prevalent interest in clinical trials in both the general media and amongst clinicians. Additional research is necessary to confirm whether reported findings hold true in other countries.

CONCLUSION

The study aim was to collect information from clinicians (oncologists and orthopedists) as well as non-clinicians involved in healthcare and medical research to learn about their understanding of clinical trial-related topics. The results showed that there are distinct differences in the respondents' comprehension of the topic based on their medical specialty. The key finding showed that there are many physicians and surgeons who cannot accurately distinguish between FDA-approved and FDA-cleared devices. Among those who reported that they know the difference, many were unable to correctly identify the relevant device characteristics. This is a substantive finding as it shows that there is a detachment between regulators and those who are working with these devices daily. It was also observed that, as reported by clinicians, oncology centers are more supportive of clinical trials than orthopedic centers. Concerning wearable technologies, which are increasingly becoming popular in the consumer goods sector, less than half of the surveyed oncology respondents are supportive of their use in a clinical trial setting-whereas more than half of the orthopedic respondents are supportive of the same. The survey results also showed that most of the oncologists are familiar with IITs whereas most of the orthopedic surgeons are not familiar with IITs. This is despite such programs being offered by many of the top orthopedic manufacturers.

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