Accelerating Adoption of Patient-Facing Technologies in Clinical Trials: A Pharmaceutical Industry Perspective on Opportunities and Challenges

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Abstract

Background: Patient-facing digital technologies (also called “Patient Technology” [PT]) have the potential to serve a variety of functions in clinical trials, such as capturing clinical endpoints, engaging patients, and facilitating remote study conduct. However, these technologies are not yet accepted as mainstream research tools, and the opportunities, challenges, and facilitators associated with their implementation in clinical trials have not been fully characterized.

Methods: In order to understand the factors affecting PT adoption, the TransCelerate Patient Technology Initiative conducted a series of surveys, interviews, and focus groups with approximately 600 subject matter experts, including pharmaceutical company representatives, clinical trial investigators at a number of trial sites worldwide, and clinical trial participants. All interview and survey responses were blinded and aggregated by a third-party consultant and themes were extracted.

Results: There was general consensus around the potential value of patient-facing technology as a clinical research tool, though a variety of challenges faced by each stakeholder were discussed. Detailed accounts of opportunities (improved patient experience, compliance, and engagement; clinical trial efficiencies; improved data quality and insights) and barriers (organizational and corporate cultural challenges, business-related challenges, user willingness and burden, and regulatory challenges) are reported.

Conclusions: While the barriers to PT adoption explored here were numerous, they were also generally consistent. A number of proposals for establishing more holistic, collaborative, and strategic approaches to PT implementation in clinical trials are discussed. Such approaches could facilitate more effective, widespread adoption of PT, and thereby a more patient-centric clinical trial paradigm.

Keywords

TransCelerate, mHealth, patient-facing technologies, clinical trial technology, digital R&D, patient centricity

Background

Patient-facing health care technologies (also referred to as “Patient Technology,” or “PT”) have the potential to change the way health care is managed at the personal and population levels, and their use both inside and outside the clinic is rising.^{1,2} PT includes any digital technology with which patients interact to participate in health care or clinical activities. When implemented effectively, these technologies can be used to increase access to timely, quality, or specialty care²⁻⁷; monitor disease progression^{2,6}; improve adherence to treatment regimens^{8,9}; and even improve patient outcomes.^{2,6,10-13}

Despite gains in routine health care, adoption of PT as a mainstream tool remains limited in interventional clinical research and the pharmaceutical industry.¹⁴ In 2016, a survey of pharmaceutical trial sponsors, eConsent vendors, and contract research organizations (CROs) reported only 28 pharmaceutical

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trials in 12 countries that had successfully used eConsent to consent patients.¹⁵ Similarly, though thousands of pharmaceutical clinical trials listed on the US National Library of Medicine's database (clinicaltrials.gov) include sleep or activity levels as endpoints, only 52 trials have included actigraphy in their published methods.¹ Only 8 of these trials were active at the time of this publication. While PT has the potential to capture clinical endpoints, encourage adherence, engage patients, acquire informed consent, enable decentralized trial conduct, or collect novel types of clinical data, many trials continue to rely on various in-clinic, manual, or traditional methods. As such, many of these benefits have not yet been realized.^{16,17}

While factors affecting implementation of PT in routine health care have been reported from the perspective of health care professionals, organizations, and patients,¹⁸⁻²³ the implementation of PT *in the clinical trial environment* poses several unique challenges that merit additional research. Specific factors affecting PT adoption—including those associated with the complex and highly regulated clinical trial environment, cultural attributes of the pharmaceutical industry, the development of novel digital endpoints for clinical trials, and the management of site and patient experiences—have yet to be thoroughly explored. As such, the industry itself does not have a clear vision of how to most effectively facilitate the adoption of PT and fully realize the benefits it may bring.

To inform this vision, the TransCelerate Patient Technology Initiative has been tasked with proposing solutions that enable and accelerate the adoption of PT in clinical trials. TransCelerate is an industry association comprised of clinical trial sponsors formed to resolve common problems and thereby drive innovation in clinical trials at an industry level. The PT Initiative is comprised of subject matter experts (SMEs) on the implementation of digital clinical trial technology representing expertise from a variety of functional, technological, therapeutic, and geographical areas.

This work, conducted as part of the PT Initiative, aims to explore the unique opportunities and challenges posed by the adoption of PT in clinical trials, as well as to form actionable model solutions and proposals for research, initiatives, and practices that can facilitate future PT adoption. These opportunities and challenges were explored through interviews, focus groups, and surveys with SMEs, including representatives from pharmaceutical companies, clinical trial site staff, and trial participants. In this work, PT of interest included any patient-facing digital technology with the potential to enhance patient experience and engagement, streamline clinical trial processes, or enable more efficient data collection in clinical trials.

Methods

Four research activities were conducted to understand the perceived opportunities and challenges that impact the adoption of PT in clinical trials:

1. A survey administered to SMEs in the pharmaceutical industry who work with clinical trials and patient-facing technology,
2. A series of interviews with a subset of these SMEs,
3. A survey administered to clinical trial investigational sites that have experience using patient-facing technology in clinical trials, and
4. A focus-group discussion with a patient advisory board (PAB).

In addition to general inquiries about the opportunities, facilitators, and challenges associated with patient-facing technologies in clinical trials, the surveys and interviews were also designed to elucidate specific opportunities and barriers related to each of the major clinical trial stakeholders: pharmaceutical companies, sites, regulators, and technology vendors. Processes were in place to ensure that collected data was blinded and aggregated, as appropriate, by a third-party consultant. This article does not contain any studies with human or animal subjects performed by any of the authors. Engagement with the PAB was deemed exempt from IRB review by the New England Independent Review Board.

Member Company Survey

An anonymous survey (Supplement 1) was administered to SMEs within TransCelerate member companies (MCs). Survey questions were developed by the PT Initiative after searching for and failing to find relevant literature in a PubMed search for terms related to PT adoption in clinical trials. Members of the PT Initiative identified SMEs within their own companies that had experience using patient-facing technology in clinical trials. Respondents were selected to represent a variety of functional areas (clinical operations, corporate strategy, regulatory affairs, information technology, clinical innovation, and patient engagement) from a global perspective. Differences between respondent functional areas and levels (eg, individual contributors, directors, or executives) were investigated using statistical methods. Most demographic questions prompted respondents to provide a single response from a list of multiple choices. In these cases, a 2-sample proportion test was conducted in Minitab 18 (Minitab Inc, Pennsylvania, PA). An alpha level of less than 0.05 was considered statistically significant. In the MC survey, respondents were allowed to select multiple functional areas that described their role. While statistical tests were explored to identify differences between functional area responses, an insufficient variety of functional area responses were received and this analysis was ultimately not conducted. A third-party consultant (author S.M.) administered the survey and compiled, blinded, and aggregated the results prior to dissemination to the TransCelerate Patient Technology team and the broader TransCelerate membership.

Member Company Interviews

Interviews with representatives from TransCelerate MCs were conducted between July and August 2017. Guidelines for interview conduct and a standard reporting form were agreed upon by all interviewers, and a standard presentation and interview guide were used to drive discussions in all companies (Supplement 2). Like the survey, the MC discussion guide was developed after searching for and failing to find relevant literature. Candidates for MC interviews were identified by members of the PT Initiative as described above.

Sessions were conducted by a person within the same company as the interviewee(s), either as one-on-one interviews or as group discussions with multiple interviewees who had similar expertise. The interviewers provided the results to the third-party consultant, who analyzed and blinded the data and redacted identifiers of specific respondents, companies, or vendors. The consultant then aggregated the data from each company and organized the blinded, aggregated data by common theme, such that industry trends could be identified. When appropriate, salient quotes were extracted. Interview responses were analyzed using a framework method in which a coding frame was developed and refined based on the content of the interviews.²⁴ For each theme, at least 2 individuals analyzed the blinded, aggregated data independently, and these analyses were compared and consolidated between the 2 reviewers. All reviewers were subject to confidentiality and nondisclosure agreements.

Clinical Trial Site Survey

TransCelerate distributed a 22-question, online survey (Supplement 3) to site study coordinators and physician investigators that had previously used or were currently using patient-facing technology in a clinical trial. The site survey was originally developed for the TransCelerate eSource Initiative but was edited and amended for use in this work. Therefore, some classifications and wording (eg, categories of PT) differed between the member company and site surveys. This survey was accessible to trial sites in July and August 2017, and was distributed to sites worldwide by members of the PT Initiative. The third-party consultant compiled, blinded, and aggregated the results prior to dissemination to the TransCelerate Patient Technology team and the broader TransCelerate membership. Differences in responses between study coordinators and physician investigators as well as differences between respondents who described their sites as “comfortable” or “uncomfortable” with technology were analyzed with a 2-sample proportion test as described for the MC survey. No regional analysis was conducted, and a more detailed study on international site experience and perception is needed to understand these differences.

Patient Advisory Board

TransCelerate commissioned a PAB to conduct focus-group type discussions about patient experience in clinical trials. The

discussion was conducted in June 2017 and facilitated by the Center of Information and Study on Clinical Research Participation (CISCRP) using a discussion guide developed by the PT Initiative (Supplement 4). The discussion specifically regarding PT lasted approximately 45 minutes and was conducted as part of a 1-day workshop on patient experience in clinical trials. Transcripts were analyzed, and major discussion points were extracted by representatives from CISCRP. Then, the results were provided to the Patient Technology team.

Results

Data and information were collected from individuals who responded to the MC and site surveys, who were interviewed by TransCelerate MCs, and who participated in the PAB. The overview of opportunities and challenges associated with PT presented here is based largely on input from the member company SMEs, and reflects the perceptions that SMEs in the pharmaceutical industry hold about PT adoption. When possible, these perceptions were compared to responses from site staff and patients to identify potential misconceptions that are commonly held in the pharmaceutical industry. While feedback from sites and patients was not comprehensive, it did inform gaps in current knowledge and identified areas where further engagement is required.

Discussions about opportunities and challenges focused on general organizational barriers within companies sponsoring clinical trials, site and patient willingness to use PT, site and patient experiences and burdens, the regulatory landscape, and the maturity of the technology landscape. Thus, these topics are presented in further detail.

Characteristics of Individuals Who Provided Data

Member Company Survey Respondents

Responses were received from 379 individuals representing 16 TransCelerate MCs, ranging from 1 to 100 responses per MC. Most respondents identified themselves as working within clinical operations (Table 1). Over 70% of respondents self-identified as individual contributors or project managers, while 24.8% were directors and 5.0% were executives.

In a brand- and vendor-agnostic manner, respondents identified the generic types of patient-facing technologies their companies had used and the corresponding therapeutic areas. The most frequently used PT were electronic patient-reported outcomes (ePRO) applications. The therapeutic areas in which respondents reported past use of PT were oncology, neurology/central nervous system (CNS) diseases, and cardiovascular diseases, among others (Table 1).

Member Company Interviewees

A total of 75 individuals from 9 TransCelerate MCs participated in either one-on-one interviews or small-group

Table 1. Member Company (MC) Survey Respondent Demographics.^a

Member Company Survey Question	Percent of Responses (n)
A. Respondents' functional roles	
Clinical operations	71.50 (271)
Interface with research sites	12.93 (49)
Design and execution of clinical trial	12.40 (47)
Innovation projects	11.35 (43)
Data management or analysis	10.82 (41)
Strategy development	6.86 (26)
Patient experience representative	5.28 (20)
Information technology	4.49 (17)
Regulatory/compliance	3.69 (14)
Other	8.71 (33)
B. Respondents' level	
Individual contributor/project manager	70.18 (266)
Director	24.80 (94)
Executive	5.01 (19)
C. PT used in clinical trials	
ePRO applications	72.82 (276)
Wearables or connected medical devices	31.93 (121)
eConsent	30.87 (117)
Applications for remote patient assessment	26.65 (101)
Digital educational patient-facing materials	26.65 (101)
Patient portals within a clinical trial	24.54 (93)
Digital patient recruitment	22.43 (85)
Notifications / engagement	20.58 (78)
Smart dosing / adherence monitoring	16.09 (61)
Telehealth—phone or video appointments	8.18 (61)
Online/connected scheduling or study logistics management (patient-facing)	7.65 (29)
Bring-your-own-device study	5.54 (21)
Company has not used PT	6.33 (24)
Unknown	4.49 (17)
Other	2.90 (11)
D. Therapeutic areas using PT	
Oncology	45.37 (152)
Neurology/ CNS disease	35.22 (118)
Cardiovascular / metabolic disease	30.75 (103)
Infectious disease	14.33 (48)
Activity measurement	10.45 (35)
Sleep assessment	3.88 (13)
Acute care	2.09 (7)
Other	33.13 (111)
E. Companies' technology adoption	
Early adopters	10.85 (41)
Fast followers	13.49 (51)
About average	39.68 (150)
Lagging/late adopters	25.66 (97)
Unknown	10.32 (39)

^aMC survey respondents were asked to self-report their roles, levels, and details about their experience with patient technologies (PT) from predefined lists. For some questions (A, C, D), respondents were instructed to select all applicable options. As a result, the sum of the percentages may exceed 100% in those questions. Percentages are based on n = 379 responses (A, B, C), n = 335 responses (D), and n = 378 responses (E).

discussions, conducted by personnel from each interviewee's own company. All MCs were eligible to participate, though representatives from only 9 of the 18 member

companies volunteered to conduct interviews. Participants of various levels of seniority represented clinical operations, corporate strategy, data management, clinical innovation, information technology, internal regulatory policy, patient engagement, and other relevant groups within TransCelerate MCs.

Site Survey Respondents

Responses were received from 186 individuals (Table 2). Of these respondents, 53.2% were study coordinators and 25.3% were physician investigators. The site survey represented various geographical areas, and respondents were mostly located in the Americas, Asia, and Europe. Respondents had conducted clinical trials in oncology, neurology, metabolic disease, respiratory, inflammation, infectious disease, rare disease, dermatology, and cardiovascular disease, and other therapeutic areas. Eighty-nine percent of respondents reported previous experience with PT, and most respondents reported that PT is used in at least 20% of studies at their current site. Of the respondents, 76.3% identified as comfortable or very comfortable with the use of technology in clinical research. A minority of respondents reported having some concerns (20.4%) or strong concerns (3.2%) about the use of these technologies in clinical research.

Patient Advisory Board Participants

The PAB consisted of 7 participants, aged 30 to 64 years, from 4 countries (Australia, Germany, the United Kingdom, and the United States of America). All participants had previously participated in clinical trials, representing 8 primary therapeutic areas and 3 additional therapeutic areas as comorbidities (Table 3). One participant had participated in more than 1 clinical trial, and 1 had participated as a healthy volunteer. Four of the 7 participants had direct experience with PT in their trials.

Opportunities Associated With Patient Technology

In the MC survey, respondents cited improving the patient experience in clinical trials, increasing trial efficiency, and decreasing the patient burden as the top 3 reasons PT is currently implemented in clinical trials (Figure 1). Respondents also rated the greatest future opportunities presented by PT for clinical research, many of which were also patient-centric (Figure 2). Opportunities for improved data collection, including patient-reported outcome collection, endpoint generation, and monitoring adherence were also cited in the MC survey. MC interviewees echoed and elaborated on the sentiments of the MC survey respondents, citing improved patient experience, improved patient engagement, time and cost savings, and improved data quality or insights as the greatest opportunities posed by PT (Table 4).

Table 2. Site Survey Respondent Demographics.^a

Site Survey Question	Percent of Responses (n)
A. Respondents by functional role	
Study coordinator	53.23 (99)
Physician	25.27 (47)
Nurse, nurse practitioner, physician's assistant	5.91 (11)
Nonphysician investigator	0.00 (0)
Other	15.59 (29)
B. Type of trial site	
Private research organization	45.70 (85)
Academic medical center	33.87 (63)
Government organization	6.45 (12)
Other	13.98 (26)
C. Site location	
North American	45.16 (84)
Asia Pacific	21.50 (40)
Europe	18.28 (34)
Latin/South America	11.29 (21)
Africa	0.00 (0)
Other	3.76 (7)
D. Therapeutic areas in which sites run clinical trials	
Oncology	43.55 (81)
Metabolic disease	30.65 (57)
Respiratory	29.03 (54)
Cardiovascular disease	24.73 (46)
Neuroscience	16.67 (31)
Infectious disease	15.05 (28)
Inflammation	11.83 (22)
Dermatology	11.83 (22)
Rare disease	6.99 (13)
Other	23.12 (43)
E. Experience with patient technology	
Personal experience using PT	89.25 (166)
No personal experience using PT	10.75 (20)
F. Use of patient technology at trial sites	
50% to 100% of studies use PT	38.71 (72)
20% to 50% of studies use PT	37.10 (69)
10% to 20% of studies use PT	13.44 (25)
Up to 10% of studies use PT	10.22 (19)
No studies use PT	0.54 (1)
H. Patient technology used in clinical trials	
eCOA/ePRO apps	85.45 (142)
Class I/II medical devices	52.41 (87)
Patient engagement apps	32.53 (54)
Class I/II medical app	15.66 (26)
eConsent apps	15.06 (25)
Medication adherence tracking device	12.05 (20)
Consumer-grade well-being device	10.24 (17)

^aRespondents were asked to self-report their functional responsibility, location, and experience with patient technologies (PT) from predefined lists. For some questions (D, H), respondents were instructed to select all options that apply. As a result, the sum of the percentages may exceed 100% in those questions.

Improve Patient Experience and Decrease Patient Burden

MC interviewees discussed a variety of opportunities related to patient centricity: safety, communication, access to data,

Table 3. Patient Advisory Board Demographics.

Patient Advisory Board Participant Demographics	
Number of participants	7 participants (4 female)
Participant age range	30-64 y (average: 50.3 y)
Countries represented	Australia, Germany, United Kingdom, United States of America
Previous experience with PT in clinical trials	4 participants
Therapeutic areas represented in clinical trials	Asthma (1 participant), chronic obstructive pulmonary disease (3), chronic urinary tract infection (1), irritable bowel syndrome (1), kidney disease (1), respiratory failure (1), tinnitus (1), type 2 diabetes (1), healthy control (1)
Therapeutic areas represented as comorbidities	High cholesterol (1 participant), sleep apnea (1), type 1 diabetes (1)

improved experience, reduced burden, and increased patient engagement. Most interviewees offered examples of how PT might reduce patient burden, including reducing frequency or duration of trial visits, making data collection more user-friendly, enabling remote participation, and alleviating physical burdens of symptom monitoring through passive rather than active data collection. One interviewee provided the example of spirometry; traditional forced exhalation maneuvers are physically burdensome for patients, and emerging passive monitoring technologies may reduce the burden associated with symptom evaluations. Some interviewees reported that patients appeared more engaged in trials using PT because feedback via PT can better help patients manage their disease and measure meaningful aspects of their health. Additionally, interviewees discussed the benefits of PT for patient learning. Examples included improving patient understanding of the trial through eConsent, improved communication between the patient and site staff, and increased access to study educational materials.

However, many of these opportunities remain theoretical, and reports of achieving these benefits in practice were limited. Some interviewees emphasized that sponsors should work to better understand patient demographics (eg, age, geography, therapeutic area) to assess how PT might impact patient experience and to select fit-for-patient technologies in future studies. One interviewee explained that “we need to learn to choose right-fit solutions for right-fit patients for right-fit study designs.”

Impact Patient Engagement and Compliance

Interviewees often cited patient recruitment and retention as potential benefits of using PT, as they believed that PT could increase engagement in a trial. Some interviewees commented that PT improved patient adherence or compliance to trial protocols, while others suggested that though PT does not always improve adherence, it does provide insight into non-adherence. Many also expressed the belief that by impacting adherence, PT

Figure 1. Current reasons for using patient technology in clinical trials. Respondents of the MC Survey were instructed to select the 1 or 2 most important reasons for using patient technologies from a predefined list (as a result, the sum of the percentages exceeds 100%).

Figure 2. Future opportunities posed by patient technology in clinical trials. MC Survey respondents were instructed to select up to 5 options from a predefined list (as a result, the sum of the percentages exceeds 100%).

had the potential to increase clinical trial efficiencies—including time and cost savings. However, many discussions were hypothetical, and the extent to which these benefits are theoretical versus realized in practice is unclear.

Increased Data Quality and Better Insights

Most MC interviewees also cited opportunities related to data collection (including data quality, volume, timeliness, and richness) as well as an improved ability to derive meaningful insights from clinical trials. Interviewees lauded the “richness” PT could bring to data collection by allowing patient-centric, real-world,

real-time measurements. Some discussed potential opportunities for additional product claims due to PT-related endpoints, and others described how PT could enable improved patient insights, higher data integrity, and better decision making.

Perceptions by Role and Level

In the MC survey, the vast majority of respondents represented functional roles in Clinical Operations, and the breadth of responses were insufficient to make statistical comparisons between roles (eg, Clinical Operations vs Information Technology). However, slight differences between respondents’ levels

Table 4. Opportunities Posed by Patient Technology (PT) Adoption Discussed in Member Company Interviews.

Theme	Description
Improve patient experience and decrease patient burden	In general, interviewees thought that PT had the potential to improve patients' experiences or reduce burdens associated with study conduct. Examples included reducing the number of procedures or site visits, providing meaningful interactions or feedback, and integrating study activities into patients' daily lives.
Improve patient engagement and compliance	Interviewees discussed ways that PT could be used to facilitate study recruitment, increase patient engagement, improve and track adherence, and improve retention rates.
Future time and cost savings	Many interviewees thought that PT had the potential to reduce study costs or make studies run more efficiently in the future. Opportunities for reducing study sizes, improving logistical efficiencies, decreasing study duration, and replacing current, costly processes were discussed.
Increased data quality and better insights	PT's ability to collect data remotely, in real time, posed several opportunities. Interviewees discussed the remote collection of existing endpoints of patient outcome data, the impacts of PT on data quality (eg, by time-stamping measurements and collecting contextual information), improved insights due to richer data sets, and the development of novel endpoints for regulatory submission.

(eg, individual contributor, director, or executive) did emerge. Individual contributors were more likely to rate improvements to trial efficiency, such as drug or protocol adherence ($P = .001$) and improving patient retention ($P = .011$) as top opportunities, while those at the director and executive levels were more likely to cite strategic opportunities, such as data collection of endpoints ($P = .0001$) and reducing patient burden ($P = .033$), respectively (Figure 2, subgroups not shown). Additionally, no significant differences were observed between respondents who categorized their companies as early adopters, fast followers, average, or lagging with respect to PT adoption.

Sites and patients were not asked to list overall opportunities posed by PT in clinical trials. However, both sites and patients provided data regarding willingness to use PT and the experiences or burdens associated with PT.

Challenges Associated with Patient Technology

Despite the consistencies across MC survey respondents and interviewees on the opportunities posed by PT, it became clear

that a variety of challenges are preventing wider adoption of PT in clinical trials. Challenges were organizational (eg, risk-averse corporate culture, strategy, and internal structure), business-related (eg, cost, impact on trial timelines, unclear value or return on investment) and external (eg, perceived site burden or patient burden, regulatory implications, and technology landscape) (Table 5).

Organizational Challenges

In the MC survey, top-cited organizational barriers included risk-averse company culture, lack of internal processes, and lack of internal expertise (Figure 3). Similarly, organizational factors discussed by interviewees included company culture (eg, level of risk aversion, tendency or lack thereof to communicate across functions); the presence or absence of pertinent corporate strategy and executive sponsorship; the presence, absence, or accessibility of internal expertise; and the amenability of corporate structure and processes to innovation and PT adoption. Several interviewees described how heavy regulation created a risk-averse corporate culture that slowed PT adoption. Many cited a specific lack of top-level strategy and limited sponsorship by senior leadership as a major barrier, indicating that companies and organizations often did not have a holistic view of how PT was being used. Interviewees often described their company's PT initiatives as disconnected, and indicated that lessons could be inconsistent and were often not shared from one pilot to another. Information about technology and regulatory implications was described as "diffuse," and difficulty locating internal expertise or past learnings due to organizational structure was also discussed. Organizational structure could serve as either a barrier or facilitator to PT adoption, and interviewees discussed the benefits and tradeoffs associated with multiple structural models for working with PT. Decentralization of expertise, forming dedicated groups of SMEs, and establishing disconnected "hubs" or innovation teams were all discussed as potential operating models.

Business-Related Challenges

Financial challenges were also widely cited as major barriers to PT adoption (Table 5). Trial cost was the most commonly reported barrier to PT adoption in the MC survey, while lack of clear value or return on investment (ROI) and impact on trial timelines were also frequently reported (Figure 3). MC interviewees reported that denial of funding is a major reason that PT initiatives are not undertaken. Impacts on trial startup time were also discussed, because delays in getting a drug to market represent an opportunity cost for the trial sponsor. The lack of a concrete business case and an unclear ROI for PT were also discussed repeatedly in the interviews. Notwithstanding these barriers, companies are beginning to adopt PT in their trials. This shows that sponsors are willing to make the investment in PT, which should become easier and less costly to adopt as patient technologies become more ubiquitous in clinical trials.

Table 5. Barriers impacting Patient Technology (PT) adoption discussed in the member company interviews.

Theme	Subtheme	Description
Organizational challenges	Corporate culture	Interviewees cited risk aversion, near-term focus, and willingness to collaborate as barriers to PT adoption.
	Strategy and sponsorship	Lack of a corporate strategy, leadership support and vision, and limited access to dedicated resources affected uptake of PT.
	Access to internal expertise and learnings	Interviewees reported that lack of internal expertise, limited access to or knowledge of past initiatives, and limited communication hampered progress and adoption of PT.
	Internal structure and processes	Organizational structure could be a barrier or facilitator to PT adoption, but rigid internal processes often negatively affected PT uptake.
Business-related challenges	Lack of concrete business case	The business case and expected return on investment for PT was generally considered unclear, and limited study sponsors' willingness to invest in PT in individual studies.
	Limited scalability	Technologies' maturity, lack of internal processes, and an unclear or inconsistent regulatory landscape limited the scalability of PT initiatives, preventing them from achieving economies of scale.
	Impact on budget and study startup	Interviewees reported that study budget was a major barrier to PT adoption, as PT often increased study costs. It was also perceived as posing risks to study timelines and conduct.
External challenges	Site willingness, experience, and burden	Factors increasing site burden or complexity included difficulty managing patient training and experience, accessing tech support, and managing redundant systems for different studies.
	Patient willingness, experience, and burden	While most believed that using PT can improve patient experience in clinical trials, many interviewees also reported instances of PT increasing patient burden.
	Maturity of technology landscape	Interviewees reported that varying levels of technology maturity, scalability or globalization of technology offerings, and limited product support were barriers to wider PT adoption.
Regulatory implications	Lack of specific guidance	In many cases, regulations affecting the use of PT in clinical trials either do not exist, are incomplete, are ambiguous, or can be interpreted in a variety of ways.
	Geographic variability	Many guidance documents, regulations, and interpretations thereof either vary or conflict in different parts of the world, limiting widespread implementation.
	Privacy and security	Risks involving data privacy, security, access, management, and transfer, as well as the impact of monitoring on patients' personal feelings of privacy, were seen as limitations of current technologies and barriers to adoption.
	Internal perceptions and misconceptions	Many interviewees reported that regulatory barriers were overestimated within their companies, and that this overestimation posed a challenge to PT adoption.

Several factors external to member companies were also found to affect the adoption of PT in clinical trials. Impact on sites and patients, as well as regulatory implications and the technology landscape, were discussed.

Site Willingness and Burden

MC survey respondents, interviewees, and site survey respondents provided information regarding site willingness to use PT, as well as the obstacles sites faced during trial conduct. Generally, topics discussed by MC respondents and site staff were concordant, though MC respondents tended to be more optimistic about the impacts of PT.

Site Willingness to Use PT

Most site survey respondents (68.7%) reported having good or very good experiences with the use of devices and apps in clinical research, and most (76.4%) were comfortable or very comfortable with technology (Table 2). When asked how technology components of a trial affect respondents' desire to participate as a site, a large majority of sites were either positive or neutral. Most reported that PT either increased their desire to participate (28.5%) or did not have an impact on their desire (65.6%). Very few (5.9%) reported decreased willingness to participate in trials with PT. MC survey respondents also described sites as generally willing to implement PT in clinical trials. Most (61.1%) respondents

Figure 3. Barriers to the adoption of patient technology in clinical trials, as perceived by trial sponsors. MC Survey respondents were instructed to select up to 5 options from a predefined list (as a result, the sum of the percentages exceeds 100%).

either agreed or strongly agreed that sites were willing to use PT in clinical research.

Many MC interviewees also discussed factors that increased a site's willingness to use PT, including a technology's reliability, ease of use, and its impact on patients' participation. Multiple interviewees agreed that sites are willing to use technology if it improved and eased the clinical trial experience compared with the existing process. Additionally, many interviewees believed that sites are willing to use technology if they believe it provides value to patients. A few interviewees reported that PT may also bring business value to sites, as it may reduce time spent entering data manually, and may allow sites to differentiate themselves or take on more complicated trials in the future.

Site Burdens Associated With PT Implementation

Despite sites' willingness to use PT, obstacles related to PT implementation were also reported. Site survey respondents reported that, in order to use PT in clinical trials, they had to manage a variety of systems and passwords, they had difficulty supporting patients with the use of technology, and that they struggle to get required technical support when issues with devices and systems arise (Figure 4). Free-text responses to this survey question included more detailed descriptions of connectivity and data transmission issues, managing instances of technology dysfunction in trials, and challenges associated with lack of a "back up" in the case of technology failure. Providing and receiving technical support during study conduct

was also cited as a challenge, with one respondent describing working with help desks as "onerous." Sites respondents also described spending time being trained repeatedly on systems that are used for multiple studies or by multiple sponsors.

Many of these obstacles were echoed by MC respondents, who cited the potential for increased site burden as a challenge posed by PT implementation (Figure 3). In alignment with the sites, MC interviewees suggested that complexities associated with training, using multiple or duplicative technologies, managing patient adherence and proactive notification features, and conducting administrative tasks associated with device management may impact sites' willingness to use PT. Malfunction of PT and inadequate technical support were also consistently cited by interviewees as obstacles for sites. Examples included connectivity issues, data transmission issues, and reverting to paper processes due to technical issues. Several interviewees agreed that technology-related support (such as help desks or troubleshooting assistance) for sites needed to be improved.

MC interviewees acknowledged that trial sponsors need to better understand the impact PT implementation may have on sites, so that the teams designing trials can assess and address these impacts in the future. They suggested that trial sponsors should engage with sites to manage assumptions and expectations, improve testing and vetting of technology for user acceptance, and ensure that sites understand the potential value of using the technology. Several interviewees indicated the need for more robust training programs, improved technological support in studies with PT, and mechanisms for collection of

Figure 4. Challenges associated with use of patient technology in clinical trials, as perceived by trial site staff. Site survey respondents were instructed to select all challenges that were applicable (as a result, the sum of the percentages exceeds 100%).

feedback. In light of this feedback, further engagement with investigational sites regarding implementation of PT in clinical trials should be the subject of future work.

Site experience: perceptions by role, comfort with technology, and frequency of use

Few differences occurred between investigator physicians and study coordinators when reporting challenges with PT. Physicians were more likely than study coordinators to report managing multiple passwords as a significant challenge in studies with PT components ($P = .025$), while study coordinators were more likely to report managing technical support as their biggest challenge ($P = .0009$). Responses were also compared between those who reported being comfortable or very comfortable with technology and those who reported having concerns or strong concerns with technology. Those who categorized themselves as comfortable with technology were more likely to report having “very good” experiences with devices and apps in clinical research ($P = .001$), while those who categorized themselves as having concerns with technology were more likely to report having bad experiences ($P = .001$) (Table 2, subgroups not shown). Those who categorized themselves as having concerns with technology were more likely to report query management ($P = .028$), systems not fitting into normal business workflow ($P = .007$), and managing technological support for patients ($P = .003$) as challenges than those who were comfortable with technology (Figure 4, subgroups not shown).

Patient Willingness and Burden

The potential impact of PT on patient centrality in clinical trials, including improvements to patient experience, increased

engagement, provision of better care, and reduction of patient burden, was clearly of interest to MC respondents and interviewees. However, respondents acknowledged that in some cases, patients’ willingness to use PT and the potential for increased burden on patients may serve as a barrier to PT adoption, and in such cases these issues must be addressed. As PT is at a nascent stage, firsthand reports from patients remain limited. With the exception of the PAB, data on patient experience with PT were collected from clinical operations and site staff who had firsthand or secondhand experience working with patients in clinical trials. These perspectives, while imperfect, reflect observations from past trials and can provide guidance while more comprehensive input from patients themselves is gathered.

Patient Willingness to Use PT

Both MC survey respondents and site survey respondents indicated that patients were generally willing to use PT in clinical trials, though many also reported mixed feelings. MC respondents tended to be more optimistic than site survey respondents regarding patients’ willingness to use PT (Table 6). Site staff reported that age, frequency of data collection, severity of a patient’s medical condition, and “tech-savviness” were the most influential factors affecting patients’ willingness to use PT (Figure 5). All 7 participants in the PAB expressed their openness to the use of PT in clinical trials, though only 4 had previous experience with PT.

Similarly, MC interviewees thought that younger patients are more likely to use PT as they are accustomed to it in their daily lives, while elderly populations may be less likely to use it. Several also suggested that patients are more willing to use

Table 6. Impact of Patient Technology on Patients in Clinical Trials – Member Company (MC) survey and Site survey comparison.^a

Question	Percentage (No.) of Individual Respondents	
	MC Survey	Site Survey
A. Patients are willing to use technology in clinical research		
Strongly agree or agree	75.00 (30)	42.17 (70)
Neutral or mixed feelings	20.00 (8)	48.80 (81)
Disagree or strongly disagree	5.00 (2)	8.43 (14)
Cannot assess or not applicable	0.00 (0)	0.60 (1)
B. Patients want clinical trials to be more digital		
Strongly agree or agree	37.50 (15)	15.66 (26)
Neutral or mixed feelings	47.50 (19)	54.22 (90)
Disagree or strongly disagree	7.50 (3)	25.30 (42)
Cannot assess or not applicable	7.50 (3)	4.82 (8)
C. Required use of technology often adds significant burden to the patient		
Strongly agree or agree	25.00 (10)	46.99 (78)
Neutral or mixed feelings	37.50 (15)	36.75 (61)
Disagree or strongly disagree	35.00 (14)	14.46 (24)
Cannot assess or not applicable	2.50 (1)	1.80 (3)
D. Technology has a positive impact on overall patient experience in clinical research		
Strongly agree or agree	50.00 (20)	40.96 (68)
Neutral or mixed feelings	35.00 (14)	41.57 (69)
Disagree or strongly disagree	7.50 (3)	16.87 (28)
Cannot assess or not applicable	7.50 (3)	0.60 (1)
E. Patients believe the benefits outweigh the burdens of using technology in clinical research		
Strongly agree or agree	42.50 (17)	31.33 (52)
Neutral or mixed feelings	32.50 (13)	47.59 (79)
Disagree or strongly disagree	10.00 (4)	15.66 (26)
Cannot assess or not applicable	15.00 (6)	5.42 (9)

^a Responses reflect the answers of 40 respondents who self-identified as having worked with or as having received feedback from (directly or indirectly) patients in a clinical trials or pilot projects.

PT if it betters the science, or if it allows them to measure more meaningful aspects of their lives (eg, activity, sleep quality, disease tracking). Familiarity with technology, ease of use, and disease sensitivity were also cited as factors that may moderate patients' willingness to use PT.

Patient experience and burdens associated with PT implementation

Generally, patients felt that there is no “one-size-fits-all” approach to the use of technology in clinical trials. One participant noted, “It depends on the clinical trial you’re doing. . . . It needs to be a good fit for you.” PAB participants suggested that the social structure and acceptability of a given technology, access to technology, access to a data plan, differing tolerance or acceptance of technology between patient populations, and access to information from the technology should be considered when designing a trial with PT. PAB participants also felt that technology should not replace all clinical trial interactions, as there is “something to be said for human interaction when it

comes to your health.” Rather, PT should be complementary to traditional patient/investigator interactions. Encouragingly, the 4 participants on the PAB who had used PT in a trial reported that the technology used in their studies was “really simple” and “made life so much easier.”

While MC survey respondents tended to believe that PT has a positive impact on patient experience in clinical trials, site respondents were more likely to report that requiring use of PT can add significant burden to the patient (Table 6). As most MCs reported that their primary purpose for using PT was to improve patient experience and decrease patient burden in trials, the actual impact of PT on patients should be more thoroughly explored.

While each trial and patient population may pose unique challenges to successful PT implementation, all stakeholders suggested some general barriers that patients face when using technology in clinical trials. MC interviewees discussed technical issues with PT, management of multiple devices, added complexity and frustration associated with using the technology, and having to complete additional trial tasks as barriers to successful adoption of PT. Site survey respondents rated access to connected devices, time and effort required to learn to use the trial's technology, and carrying an additional phone or mobile device dedicated to trial activities as the top challenges or burdens patients face when using PT (Figure 6).

Patient experience: perceptions by role, comfort with technology, and frequency of use

Site survey respondents tended to report a less positive impact of technology than MC survey respondents and were less optimistic about the impact of PT on patient experience and burden. No significant differences between MC respondent roles or levels emerged. Among site survey respondents, physicians were more likely than study coordinators to agree that patients are willing to use PT ($P = .037$), while study coordinators were more likely to report neutral feelings ($P = .030$).

Site survey respondents who characterized themselves as comfortable with technology were more likely to agree that patients are willing to use PT ($P = .032$) than those who characterized themselves as uncomfortable. Similarly, those who reported frequent use of PT at their sites (20% of studies or more) were more likely than those who used less PT to report that PT has a positive impact on overall patient experience in clinical research ($P = .020$). In contrast, those who characterized themselves as uncomfortable with technology were more likely to disagree ($P = .014$) or strongly disagree ($P = .009$) that technology has a positive impact on patient experience in clinical research. Those who used technology in less than 20% of studies were more likely to report a negative impact on patient experience ($P = .006$).

Regulatory Implications

MC survey respondents and interviewees also consistently reported regulatory implications as a major barrier to PT

Figure 5. Factors influencing patients' willingness to use patient technology in clinical trials, as perceived by trial site staff. Site survey respondents were instructed to select up to 5 of the options from the list (as a result, the sum of the percentages exceeds 100%).

adoption. In the MC survey, 43.5% of respondents indicated that regulatory implications were one of the top 5 barriers to technology adoption, making it the second-most frequently reported barrier (Figure 3). Of the regulatory hurdles discussed by MC interviewees, 4 themes emerged: lack of specific guidance, geographic variability of regulations and interpretations, patient privacy and data security, and internal misconceptions of regulatory impact on PT.

Lack of specific guidance

Interviewees tended to describe the US as open to technology adoption, citing the FDA's acceptance of eConsent, its dialogue around experimental technological endpoints, and its attempts to "move from a reactive to a proactive position" in the area of clinical technology regulation. Despite these advances, interviewees reported significant gaps in current guidance—both in the US and worldwide. Specifically, they cited lack of clarity or specificity (eg, what is required for a label claim or CE mark) and variable interpretation based on a technology's feature set or use case. One interviewee described challenges with internal interpretation of guidance when deciding whether and how to use PT. Some interviewees stressed the importance of engaging regulators in the design of novel PT studies, describing published guidance as either nonexistent or rapidly evolving.

Geographic variability of guidance, regulations, and interpretations

Several interviewees also reported that variations in regulations and interpretations across geographies hindered attempts to implement technologies more broadly. As examples, they cited geographic variations in the acceptance of eSignatures, medical device approval requirements, and inconsistent views about whether technologies counted as interventions in clinical studies.

Patient privacy and data security

Many interviewees reported inconsistent or unclear interpretations of data privacy laws and regulations and negative impacts on PT adoption. These challenges included inconsistent data privacy, storage, and transfer regulations by country, inconsistencies across ethics committees, lack of clarity around when specific laws (eg, HIPAA) apply, and the resulting impact of identifying and resolving privacy concerns within the trial timeline. As an example, the impact of data privacy regulations on the acceptance of eConsent in the EU was discussed repeatedly. In addition to the discussion of data, it was also noted that trial activities such as wearing or publicly using a device may affect patient privacy, and as such could also be raised by ethics committees as a privacy concern.

Figure 6. Challenges and burdens faced by patients with using patient technology in clinical trials, as perceived by trial site staff. Site survey respondents were instructed to select up to 5 options from the list (as a result, the sum of the percentages exceeds 100%).

Misconceptions of regulatory implications

While the regulatory barriers discussed here are real and challenging, interviewees from several companies suggested that the impact of many regulatory barriers may be misunderstood, overestimated, or even self-imposed by clinical trial sponsors. Despite “regulatory implications” being the second-most common barrier reported in the MC survey results (Figure 3), when asked to classify the magnitude of that barrier, 44% of respondents indicated that they could not provide an assessment (data not shown).

Technology Landscape

MC interviewees also discussed limitations in the technology landscape and how those limitations affect adoption of PT. Interviewees mentioned that there are both experienced and inexperienced vendors providing clinical trial technology. Some interviewees discussed difficulties identifying and selecting “fit-for-purpose” technologies for their trials. However, most trial teams do appear to be able to find technology to fit their needs. While several interviewees reported technology selection to be a major challenge, this ranked low on the overall list of barriers in the MC survey (Figure 3).

Key challenges in PT adoption mentioned by MC interviewees included technology standardization and validation. Technology compatibility with Good Clinical or Manufacturing Practices, health authority guidelines, and medical device approval were also mentioned as important factors that

influence the speed of PT adoption. Full deployment across global studies and expanding technology use to new therapeutic areas were also reported by member companies as challenges. Relatedly, challenges posed by language translation were also discussed as a barrier to scalability.

Interviewees also reported a greater need to consider the full range of user needs in designing clinical trial PT solutions; specifically, the need for greater patient involvement in technology design and increased consideration of site needs (eg, technology support requirements and improved interoperability) arose.

Discussion

This work sought to explore the perceptions and assumptions in large part held by trial sponsors, but also those held by clinical trial sites, and, to a limited extent, patients with regard to the adoption of patient-facing technology. A variety of perspectives on value, future opportunities, internal and systemic barriers, and suggestions for facilitating progress were collected.

There was general consensus around the potential value of patient-facing technology as a clinical research tool, and discussions provided affirmation that limited adoption of PT is indeed a problem worth solving. All stakeholders discussed potential benefits and opportunities posed by PT, though many of the reported benefits remained hypothetical. These results were consistent with recent perspective pieces on Digital

R&D,^{16,17,25} though this work provided increased detail from a larger pool of SMEs.

It also became clear that, to actually achieve the benefits posed by PT, several systemic barriers and industrial trends must be overcome. Some of these barriers may be addressed by sponsors independently while others, such as an uncertain regulatory environment, are much more abstract and outside of any single company's control. Fortunately, opportunities for trial sponsors and the broader pharmaceutical industry to address many of these barriers emerged.

Improve Communication and Engagement between Stakeholders

There is a clear need for improved understanding and communication between all clinical trial stakeholders—both in the design of individual studies and in planning for more mainstream implementation of PT. Trial sponsors have the power to reduce many of the barriers discussed in this work if patients, sites, technology vendors, regulators, and other stakeholders are engaged to inform trial design, and if experiences and lessons (both positive and negative) are more regularly used to improve future trials.

While sites were generally positive about use of PT in clinical trials, there is a clear need for sponsors to invest time and resource to understand site perspectives and experiences with PT. This engagement could include discussions of the impact that protocols with PT may have on sites, interoperability requirements, and features required of a robust tech support system. If trial sponsors are to adopt PT more ubiquitously, steps must be taken to reduce the PT-related obstacles sites currently face.

Similarly, study sponsors need to better understand the potential impacts of PT on *patients* in clinical trials. It appears that the actual effects of PT are falling short of trial sponsors' expectations regarding patient benefits, experiences, and burdens. To achieve these benefits, patient perspectives on value, usability, intrusiveness, and relative burden should be explored when selecting and implementing PT. Additionally, methods of collecting patient feedback and assessing patient experience and burden of technology should be established within the industry and used more regularly to inform future trial design. Confirming these findings with patients themselves, exploring patient perspectives on PT, and developing methods for incorporating patient perspective into PT study design are the subject of ongoing work in TransCelerate and the Patient Technology Initiative.

Additionally, the use of PT in clinical trials poses more complex functional, technical, support, and geographical requirements to vendors than use cases in routine health care or consumer health and fitness. Under Good Clinical Practice (GCP) guidelines,²⁶ for example, the need for verifiability and audit trail poses unique challenges to vendors seeking to design innovative products for use in the clinical trial environment. Sponsors should work with technology vendors to address

PT-specific challenges and to clarify these unique requirements and constraints.

MC interviewees also repeatedly reported that PT initiatives within their own companies were generally disconnected, that learnings were not communicated adequately across initiatives, and that internal expertise was not readily accessible. This resulted in inefficiencies and repeated missteps with PT, both within and between sponsors. Most respondents and interviewees felt that PT could positively impact patient experience and burden, though they clearly faced a steep learning curve associated with PT adoption. Sharing lessons more readily could facilitate more efficient PT implementation with fewer missteps, and could therefore enhance patient welfare and experience in future trials. Emphasizing training, education, and communication across clinical teams will increase awareness of past learnings and may allow application of those learnings in future initiatives.

Establish a Strategic Approach to PT Adoption

While MC interviewees discussed a variety of initiatives in which their companies had implemented PT, most of these pilots were relatively small-scale and use of PT was not yet standard practice. Numerous challenges related to scalability of these initiatives were discussed. While these challenges will require time and investment to solve, many (eg, realization of a value proposition or reduction of risk) may be resolved through a more strategic approach to PT implementation and planning with scalability in mind.

At the time of these interviews, respondents from some MCs reported having a PT-specific strategy in place while others explicitly discussed a lack of corporate strategy and its negative impacts on adoption. Many interviewees described how PT pilots were often uncoordinated, learnings were compartmentalized, and efforts did not necessarily build toward specific end goals. Without a clear, quantitative business case, a supporting strategy, or dedicated resources, individual PT initiatives were often deemed cost-prohibitive. Unfortunately, the greater value of PT and its return on investment may not be fully realized until technologies are implemented at scale, and direct returns may not be identifiable in individual trials. At the corporation level, development of a PT strategy or the adoption of a "portfolio" perspective may help to streamline such initiatives, allowing them to identify and build toward common goals through a more efficient, holistic, and internally coordinated approach. Through this approach, sponsors could outline strategic and financial goals for PT, establish common methods for monitoring value, and identify additional infrastructure or expertise requirements for scalable PT adoption. Such approaches are also explored by the TransCelerate eSource workstream.^{27,28}

"De-Risk" Patient Technology Outside of the Clinical Trial Environment

Interviewees also discussed risks associated with implementing a new, untried technology in clinical trials and difficulties

selecting “fit-for-purpose” technologies. While the need for strict control over trial protocols limits sponsors’ ability to introduce and test new approaches in clinical trials,²⁹ establishing a process to evaluate and “de-risk” technologies *outside of the clinical trial setting* may enable teams to make quicker, earlier determinations of a technology’s risks, viability, and value prior to pilot-scale investment. This “learn fast, fail fast” approach has been implemented successfully in other industries and may be a desirable approach to facilitate PT adoption, especially if it reduces the risk or complexity PT adds to actual clinical trials. It could also facilitate a more fit-for-purpose approach to technology selection and implementation, as technology could be directly tested for patients’ and sites’ experiences prior to implementation.

Engage With Regulators in Trial Design, Goal Setting, and Strategy

Despite recent efforts by regulators to develop guidance for the use of PT and to promote a more patient-centric clinical trial paradigm,^{30–33} it is clear that regulatory risk is still perceived as a major barrier to PT adoption in clinical trials. This is especially true in the development of novel digital endpoints for clinical trials, an area of mounting interest to study sponsors, regulators, and patients alike. Various guidance documents, international regulations, and local laws impact the use of PT,^{26,34–36} but they remain difficult to navigate because of ambiguous wording, regional variations in interpretation, or gaps in content.

The ambiguity and inconsistency of PT regulations reported in this work are consistent with previous discussions.^{37,38} To address this ambiguity, and to keep up with the diverse and rapidly evolving PT segment, MC interviewees indicated that close cooperation with health authorities is essential. Engagement should occur not just on a trial-by-trial basis, but also as an industry when planning for scalable PT implementation and novel digital endpoint development. Several collaborative initiatives addressing these ambiguities are ongoing, including the Critical Path Institute’s ePRO Consortium, and the Clinical Trial Transformation Initiative’s Mobile Clinical Trials Program, and TransCelerate’s Patient Technology Initiative. Some initial recommendations have been published.^{39–42} However, these recommendations are not yet comprehensive and will continue to mature with increasing use of PT. As such, an updated review of the specific regulations, policies, and gaps affecting the use of PT is warranted, and should be the subject of future work.

Limitations

While the topics discussed here were diverse, it was impossible to address all relevant perspectives in this work. Therefore, care should be taken when interpreting or acting upon these results. The only sponsor company views reflected in this paper are from TransCelerate MCs; therefore, interview responses may not represent practices across the entire industry. Additionally, responses to TransCelerate’s inquiries reflected

individuals’ perceptions and experiences, rather than official positions of the MCs themselves. Similarly, the site survey responses reflect experiences in sites that have previously conducted trials with PT, and who have experience working privately funded pharmaceutical trials. As such, the views expressed here may not be representative of the entire industry. Responses to the site survey primarily, though not exclusively, represented trial sites in North America. Additional research is required to understand global variation in the use of PT, especially with respect to sites’ experiences. Similarly, direct feedback from patients was limited to a single PAB, and more in-depth research to elucidate the patient perspective on PT and the proposed solutions is clearly warranted. Further engagement with patients regarding perceived value, experiences, and potential burdens associated with PT, as well as potential solutions, should be the subject of future work.

Clinical trials are developed and executed in highly complex environments, and many additional stakeholders play a role in PT implementation. While the perspectives explored here are foundational, the perspectives of CROs, technology vendors, payers, regulators, ethics boards, health technology assessment bodies (HTABs), and caregivers should also be considered.

Conclusions

Interest in the use of PT in clinical research is mounting, as PT poses opportunities to engage with patients in new and exciting ways. While the barriers to PT adoption discussed here were numerous, they were generally consistent across respondents. It became clear that trial sponsors could make significant strides toward more effective, widespread adoption of patient-facing technologies (and through them, a more patient-centric clinical trial paradigm) if the design of programs using PT are approached more holistically. Encouraging engagement with clinical trial stakeholders impacted by PT during planning could help teams mitigate challenges before clinical trials begin, and the development of more strategic approaches to PT could enable more impactful, scalable initiatives. Engagement could occur not just within individual programs, but also with other companies, consortia, associations, standard-setting bodies, and regulatory bodies that are working to facilitate PT adoption. As the principal decision makers in the design and implementation of clinical trials, pharmaceutical companies have the potential to make a significant and positive impact on any such approach.

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Supplemental Material

Supplemental material for this article is available online.

Note

- i. A search for trials using actigraphy to measure endpoints was conducted on clinicaltrials.gov in June 2018, with the search term “actigraphy.” All interventional clinical trials (Early Phase 1, Phase 1,2,3,4) studying drugs or biologics that were funded by industry were included in the search. Behavioral interventions or device trials were excluded. The use of actigraphy to generate an endpoint was confirmed manually for returned studies. “Active” studies were defined as those that were recruiting, enrolling, and active but not recruiting at the time of the search.

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