PATIENT CONSIDERATIONS:

A PATIENT PERSPECTIVE ON KEY CONSIDERATIONS FOR SPONSORS IMPLEMENTING PATIENT TECHNOLOGY IN CLINICAL TRIALS

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ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

Patient Considerations Introduction

Patient-facing digital technologies (PT or Patient Technology*) have the potential to serve a variety of functions in clinical trials. This can include, among other things, better engaging patients and facilitating remote study conduct. Due to the direct impact of introducing PT into clinical trials for patients, it's critical for sponsors to take into account and/or deliberately address patient input or considerations related to the PT in question during study design.

To assist sponsors looking at adopting PT, the TransCelerate Patient Technology Initiative spoke with a diverse set of patients to understand the topics or considerations they would like sponsors to think about when designing studies using PT. The result of these conversations is a list of considerations by category. When addressed, these considerations may improve the patient experience of using PT. Each consideration and topic listed below was suggested or validated by the engaged set of patients. There is no single right or wrong answer for any of these considerations or questions.

Note: *Patient Technology can include any digital technology that a clinical trial participant interacts with during the course of a study. For example, mobile applications, wearable devices, electronic diaries, electronic consent, etc. are all considered PT.

Patient Consideration Categories:

- Patient Benefits
- Patient Burden
- Patient Compliance
- Patient Consent and Comprehension
- Patient Experience
- Patient Safety
- Patient Willingness to Participate
- Privacy
- Technology Maintenance
- Technology Support
- User Experience Design

Current list of considerations[1]

#	Category	Consideration
1	**Patient Benefits**	Does the proposed PT offer any benefits for patients, outside of its primary use within the trial? (e.g. simple notification reminders, possible alert of adverse events, or allow for continued use after trial completion)
2	**Patient Benefits**	Consider ways to return value to participants throughout the trial (e.g., feedback on use of device, potential for sharing routine data collected by the PT that is not unblinding, gamification, etc.)
3	**Patient Burden**	Do the benefits to the study offered by use of the PT justify the potential added burden for patients or sites?
4	**Patient Compliance**	Consider the types of challenges that may impact planned use of the PT in your patient population. For example: • Geographical (e.g. internet accessibility) • Socioeconomic (e.g. internet accessibility, access to smart devices) • Cultural (e.g. placement of wearable impacting cultural dress, religious practices) • Age (e.g. technical literacy, suitability for children) • Political (e.g. censorship)
5	**Patient Compliance**	Is there a social stigma associated with the given device? (e.g. visible perceived impact on patient appearance as a result of audio signals, visual lights, vibrations, etc.) Consider whether the PT might reveal its user as ill or draw unwanted attention.
6	**Patient Compliance**	For the given patient population, are there any specific physical or cognitive limitations that may impact proper usage of the PT? For example, is the patient too weak to hold a tablet device?

[1] The considerations identified below are general considerations that sponsors should take into account when implementing Patient Technologies. Depending upon the specific circumstances, there may be different or additional considerations that a sponsor may want or need to take into account to ensure that its trial design reflects a patient-centric approach.

7	**Patient Compliance**	How will patient compliance be monitored and actioned (e.g., reminder alerts sent to patients)?
8	**Patient Consent and Comprehension**	Is the use of the PT sufficiently described in the informed consent materials? Can all information be understood by a lay person?
9	**Patient Consent and Comprehension**	Have clear expectations been set with participants about safety monitoring during the trial as a result of the PT being used? Does the patient understand that the use of the PT does not substitute seeking medical attention for emergent situations?
10	**Patient Consent and Comprehension**	Has the training been developed with patient input? Does training material account for differences in audience, learning styles, and language preference? Is training readily available to and accessible by all involved parties (patients, caregivers, site staff, others) on-site and off-site? Is enough time given for training completion?
11	**Patient Consent and Comprehension**	Are all patient-facing materials (including consent, training, privacy, and support materials) as simple as possible? Are the materials designed to meet the needs of study participants, including those with low health and/or technical literacy? Consider summarizing the most important points into an overview. Plan to offer follow up support for patients who may require it.
12	**Patient Consent and Comprehension**	Do patients understand the purpose of the PT (e.g. to gather data, deliver medicine, etc.)? Consider educating patients about the benefits of the PT and how it impacts the trial.
13	**Patient Experience**	How will patient experience using the PT be evaluated during the study. (e.g. a survey to collect patient feedback such as the TransCelerate Study Participant Feedback Questionnaire or Patient Technology Site Feedback Questionnaire)?
14	**Patient Experience**	Will using the PT bring new awareness to the patient that might change their behavior at any point in the trial and bias the outcome?
15	**Patient Safety**	Are there any safety risks to consider with the device? • Are patients informed about all possible risks? • Is the device safe for use in your patient population? Should a patient require medical treatment outside of the trial, are instructions or precautions available for patients and medical staff?

16	**Patient Willingness to Participate**	Will caregivers need to be involved? If so, will this impact results? Would it impact patient perception of trial burden (e.g. unwillingness to "burden" caregiver)? Does the involvement of multiple or 'rotating' caregivers impact use? Could the need for caregiver involvement affect study participation?
17	**Patient Willingness to Participate**	Is PT use balanced with human interaction or does it replace human interaction to the point where patients may feel less cared for? Are measures in place to reassure patients' confidence in care (e.g. discussions with patient on the benefits of the PT such as reduced burden by less frequent office visits)?
18	**Patient Willingness to Participate**	Have the drawbacks of both in-person visits and remote communication methods, including when each may be most appropriate, been carefully weighed? Does the study protocol allow for patients' personal preferences to be considered?
19	**Privacy**	How is patient privacy as well as privacy of others (e.g., caregivers, site staff, etc.) protected during the use of the PT? Does the PT require additional permissions that could impact patient privacy? (e.g. mobile application access to microphone, location-tracking, etc.) Does the patient know how their data is used and stored? Is privacy and use of data described in the informed consent form?
20	**Technology Maintenance**	How easy is maintenance of the device by patients? E.g. how often does it need to be charged or cleaned? Are patients aware that maintenance is required (as applicable)? Are software updates the responsibility of the patient or are they automatic?
21	**Technology Support**	Is technical/user support readily available for patients and sites? • Is the support system accessible 24 hours a day, seven days a week? • Should the support system allow for virtual-video troubleshooting? • Is it clearly communicated to patients and sites who to contact in case of technology issues, malfunctions, etc.? • Is support easily facilitated (e.g. no long waits, complicated menu options, department transfers, etc.) Is support available in all of the languages of informed consent materials?
22	**User Experience Design**	What is the time investment expected of patients using the PT and is this reasonable? • Set up (e.g. profile creation, initial login, device calibration) • Routine use (e.g. expectation of frequency of patient interaction with the technology) • Close out (e.g. data upload, return/destruction of device)

23	**User Experience Design**	How does the PT affect the patient's activities of daily living and/or comfort (positive or negative)? Does the PT affect showering, sleeping, driving, eating, shopping, etc.? Is there a need to carry or wear the PT at all times? Does the study protocol include provisions for less than 24-hour use/wear of the device?
24	**User Experience Design**	What is the frequency of data collection and transmission? Does this require direct patient interaction or is collection/transmission passive? To what extent does this interfere with patient lifestyle (e.g., travel, time zone changes, airplane luggage/carry-on restrictions, sleeping, working, etc.)
25	**User Experience Design**	Is the solution designed with the end-user in mind? (e.g. interface design, specific docking or charger stations, instruction material, not too many logins). Has the PT been previously tested and/or used by the patient population?
26	**User Experience Design**	Does the protocol design allow for opting out of using PT by a patient or site? Does the protocol design account for the termination of use of a PT by a patient or site during the study for any reason?