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Improving Information Exchange with Clinical Trial Participants: A Proposal for Industry

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Abstract

Background: Researchers are increasingly motivated to move toward patient-centric drug development. TransCelerate has identified improved "information exchange" as an important component of creating a more satisfying clinical trial experience for patients and their health care professionals (HCPs). *Methods:* Patients, sponsors, sites, and HCPs were engaged through surveys, interviews, and/or advisory boards to capture the current status of information exchange and identify possible future practices between the major stakeholders within the clinical research ecosystem. *Results:* Data suggest that patients have numerous desires and preferences for information exchange during their clinical trial journey that are not commonly met. Various opportunities exist to improve the clinical trial participants' experiences by improving information exchange practices across various stages of the participant's journey. *Conclusions:* A shift in industry focus toward more comprehensive information exchange with trial participants has the potential to positively impact many patients.

Keywords

TransCelerate, clinical research, patient engagement, drug development, health care

Background

As people have become increasingly empowered health care consumers, researchers will find an ever greater motivation to move toward patient-centric drug development (including device development).[1] There has always been an inherent ethical imperative to focus on the needs of patients in drug development. Consideration for the needs of the primary or specialty health care professionals (HCPs) in this context is important as they will often drive and facilitate patient access to health care services. However, the value of using a patient-centric approach to create a more satisfying clinical trial experience for the patients also should be considered, for the benefit of patients as well as the benefit of sponsors who might possibly improve patient retention and trial accrual.[2] This approach could be a critical contributor to a more efficient, appealing, and sustainable research enterprise over the long term.[3]

TransCelerate Biopharma Inc (TransCelerate) identified improved "information exchange" as an important component of creating a more satisfying clinical trial experience for patients and their HCPs. As described in this paper, information exchange includes the bidirectional sharing of information (such as data and feedback) between researchers and trial participants, with consideration given to the interdependent relationships among researchers, HCPs, and patients. "Researchers" include trial sponsors, clinical research organizations (CROs), research sites, and other research partners. We used a broad approach to understand the information exchange needs and preferences of patients and their HCPs, as well as practices by sponsors. The subsequent principles outlined in this paper can be considered by researchers who wish to improve information exchange with patients before, during, and after their participation in a trial.

Methods

TransCelerate interviewed sponsors, conducted surveys with patients and HCPs, and conducted advisory boards with patients and sites to capture the current status and identify possible future practices related to information exchange

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between the major stakeholders within the clinical research ecosystem. Where possible, the methods were designed to probe for deeper insights and nuances associated with complex information pathways.

This article does not contain any studies with human or animal subjects performed by any of the authors. Surveys and advisory boards with patients were submitted to New England IRB (NEIRB) and determined to be exempt from NEIRB review.

Patient Survey

The 52-question patient survey was conducted in August-September 2016 and distributed online globally to patients and caregivers with the support of the Center for Information and Study on Clinical Research Participation (CISCRP), Clariness, CenterWatch, and TransCelerate through outreach efforts within their patient/caregiver communities. Participants represented 36 countries across North America, Latin/South America, Europe, Asia Pacific, and Africa. Four countries (US, Canada, Germany, and Australia) contributed more than 250 respondents each. Respondents self-identified as patients (73.8%), caregivers (7.6%), or "other" (18.6%). This was a convenience sample and, as such, findings may not be representative of the opinions of the entire population.

Sponsor Interviews

Sponsor interviews were conducted with TransCelerate member companies in October 2016 using a standard eight-section discussion guide. A landscape exercise that was informed by member companies' own practices, available literature on the topic, and consultation with a Patient Advisory Board on preferences (refer to Patient Advisory Board method below) contributed to the development of a comprehensive list of information exchange practices for inclusion in the discussion guide. Interviewees were self-nominated by each member company and were asked to consider the current practices of their company on a global basis. Each interview was conducted using the same discussion guide, either by a third-party consultant or by a peer from within the member company who participates in TransCelerate's Clinical Research Access & Information Exchange initiative. Interviewers compiled the responses from each member company and then submitted them to a third-party consultant who blinded and aggregated the results. Of the 18 TransCelerate member companies asked to participate in the interview process, 14 companies (78%) responded.

Health Care Professional (HCP) Survey

The HCP survey was distributed and promoted by the SERMO survey platform via a Pulse Opinion Research Poll available August 1–6, 2016. A total of 462 responses were received from 7 countries and 6 specialty categories including General Practitioner/Family Practice (37%), Nursing (28%), Neurology (10%), Oncology (10%), Infectious Diseases (5%), and Pediatric Medicine (10%).

Patient Advisory Board (PAB)

TransCelerate commissioned a CISCRP-facilitated PAB in August (online) and October 2016 (in person). Ten patients, patient advocates, or caregivers, aged 21 to 70 years from the US (6), Canada (1), Europe (2), and Africa (1) participated. Half of the participants had previous trial experience. Participants represented gastrointestinal, metabolic, neurologic, oncologic, and hematologic conditions.

Site Advisory Group (SAG)

TransCelerate commissioned a Society for Clinical Research Sites (SCRS) SAG in August (online) and October 2016 (in person). Eight investigative site professionals located in the US (6) and Europe (2) participated. Participant experience ranged across clinical trial phases, therapeutic areas, and site types such as Family Medicine, research centers, specialty clinics, and/or hospital-based facilities.

Results

Patient Survey

Results from the patient survey are shown in Table 1. Most (74%) survey respondents reported that neither they nor the person they cared for had any experience with any clinical trial. However, regardless of clinical trial experience, the information preferences of all respondents remained largely similar and in the same order of preference, with minor exceptions.

Values are presented as number of respondents (%). Percentages are based on the total responses per question. Not all respondents answered every question.

Sponsor Interviews

Select results from interviews with TransCelerate member companies are shown in Tables 2 and 3. Discussions revealed that among this subset of clinical trial sponsors, there was significant room for improvement with respect to information exchange with patients who are considering, are currently, or were previously enrolled in clinical trials.

Most (75%) respondents feel that there are opportunities to improve their companies' current practices for exchanging information with patients to adequately meet patients' needs. Whereas some respondents openly expressed a capability gap in this area, others described ongoing initiatives to actively improve current capabilities, which are already showing signs of success. A general lack of awareness of the true patient preferences in this area and their corresponding value was evident. This was further reinforced by the finding that the majority of respondents (69%) do not currently measure the effectiveness of communications with patients or trial participants.

The most commonly cited mechanisms for conveying information to patients before or during enrollment in a trial included the informed consent form (ICF), government-sponsored clinical trial registries, sponsors' own trial websites,

Table 1. Patient Survey Results for Selected Questions.

Survey Question Response	Number (%) of Respondents per Question
Have you ever participated in a clinical trial or are you currently participating in a clinical trial?	n = 3045
Yes, currently	211 (7)
Yes, past	590 (19)
No	2244 (74)
Would you discuss clinical trial participation with any of your doctors or health care professionals before contacting a clinical trial location directly?	n = 2939
No	677 (23)
Yes	1655 (56)
I don't know	607 (21)
What would you like to discuss with your doctors or health care professionals prior to contacting a clinical trial location directly? (select all that apply)	n = 2262
Risk associated with participation in the clinical trial	1475 (65)
How participation in the clinical trial may benefit my overall health	1402 (62)
Whether he/she recommends participation in the clinical trial	1363 (60)
Whether I meet the requirements for participation in the clinical trial/help me better understand the requirements for participation (ie, eligibility criteria)	1186 (52)
Options for staying connected with my doctor or health care professional team during the clinical trial	928 (41)
What it is like to participate in a clinical trial	697 (31)
What is important for you to have or know before seriously considering clinical trial participation? (select all that apply)	n = 3045
Knowing the potential risks and benefits of the study	2462 (81)
Knowing the medical tests required and/or other activities involved with each visit to the clinical trial location	2037 (67)
Knowing the number and length of visits to the clinical trial location that would be required	2053 (67)
Knowing that my health and treatment record will be shared with me after my participation in the trial (eg, my personal results)	2018 (66)
Knowing what lifestyle changes or restrictions might be required (eg, dietary restrictions)	1870 (61)
Knowing what costs might be reimbursed and/or how much money I would receive to participate	1616 (53)
A discussion with my doctor	1469 (48)
Knowing the results of past studies (ie, phase I or phase II results) for the same study drug	1421 (47)
A discussion with the research staff working on the clinical trial	1341 (44)
Knowing whether or not I could potentially receive a placebo (eg, sugar pill/inactive substance) vs the active study medication	1207 (40)
The ability to visit the research site location and getting a firsthand look at the environment/setup	926 (30)
A discussion with someone who has already participated in the same clinical trial	617 (20)
A discussion with a trusted friend or family member	376 (12)
If you (or the person you care for) decided to participate in a clinical trial, what information would you want before the clinical trial begins? (select all that apply)	n = 3045
Who to contact/contact information of the medical center	2314 (76)
What to do in case of an emergency	2153 (71)
Information about patient support services (travel assistance, home health, etc)	1559 (51)
Contact information of other clinical trial participants/ability to connect with other clinical trial participants	1427 (47)
Activities to expect during the first visit	1389 (46)
Visit reminders or calendar	1342 (44)
Patient advocacy or patient support group information	756 (25)
If you (or the person you care for) were to participate in a clinical trial, what information would you want during the clinical trial? (select all that apply)	n = 3045
Your own information (test or lab results)	2468 (81)
Activities to expect during the next visit	2173 (71)
Statistics of the clinical trial (eg, number of doctors running the trial, countries participating, number of participants, etc)	1571 (52)
Visit reminders or calendar	1582 (52)
Information about patient support services (eg, travel assistance, home health care, etc)	1387 (46)
Contact information of other participants/ability to contact other participants	764 (25)
Advocacy or support group information	767 (25)
And how would you like to receive information during the clinical trial? (select all that apply)	n = 3045
By email	2204 (72)
From the clinical study staff/study doctor	1701 (56)
Online, with a secure username and password to access the information	1230 (40)
Live phone call (speak to a person)	1190 (39)
From my usual/primary health care professional/ doctor	682 (22)
By postal mail	664 (22)
Through an app on my smartphone	498 (16)
By text message	445 (15)
Automated phone call (recording)	151 (5)
If you (or the person you care for) were to participate in a clinical trial, what information would you want after the clinical trial ends? (select all that apply)	n = 3045
My lab and/or test results	2527 (83)
General results of the clinical trial	2422 (80)
Information on the status of my medical condition (ie, how you are doing)	2413 (79)
The name of the drug when approved	2149 (71)
Whether I received the study drug or placebo (eg, sugar pill/inactive substance)	2061 (68)
Whether this drug will be approved in my country	1886 (62)
Options available to me for support after the trial	1651 (54)

Table 1. (continued)

Survey Question Response	Number (%) of Respondents per Question
How would you prefer to receive information after the clinical trial ends? (select all that apply)	n = 3045
By email	2045 (67)
From the clinical study staff/study doctor	1593 (52)
Online, with a secure username and password to access the information	1107 (36)
Live phone call (speak to a person)	1036 (34)
By postal mail	1043 (34)
From my usual / primary health care professional / doctor	804 (26)
Through an app on my smartphone	372 (12)
By text message	285 (9)
Automated phone call (recording)	89 (3)

information submitted to patient advocacy groups, and brochures/leaflets printed by sponsors for use in clinical trial site settings. During a clinical trial, responding companies used ad hoc measures which rely heavily on site staff with information conveyed to staff who may share it with trial participants at their discretion. The same was true of information conveyed after trial participants had completed their involvement in a trial and of broad disclosure of trial information accessible to the general public after a trial ends.

None of the sponsor companies interviewed used a consistent process across all trials to collect feedback from patients or trial participants. The majority (71%) did not request feedback from patients/trial participants regarding trial logistics during or after a clinical trial. Some respondents collected feedback on an ad hoc basis or at the discretion of the clinical trial team. Feedback collected in a group setting, such as with advisory panels or focus groups, or indirectly via site investigators, appeared to be the most common method.

Health Care Professional (HCP) Survey

Selected results from the HCP survey are shown in Table 4. Most (66%) HCPs were interested in trial results at the end of a trial involving a patient whom they had referred. More than half of the HCPs were also interested in additional information after referral, including details of the patient's eligibility and data collected during the trial from/for the patient, indicating a desire to apply this information in the practice setting with the patient and/or a desire to be kept up-to-date on pertinent details of a patient's care while enrolled in a trial.

Patient Advisory Board (PAB)

Participants in the PAB articulated the expectation that both their primary HCP and relevant patient advocacy groups should be knowledgeable about and involved in available clinical trial opportunities, expressing a desire to gather and discuss information from sources viewed as "credible." Participants expressed the expectation of discussing trial participation with a primary care physician; however, this expectation often was not met. Word of mouth with peers and interactions with patient communities online seemed to be a more effective forum for exchanging information about clinical trials currently.

PAB participants voiced the importance of information prior to enrolling in a clinical trial that would help them evaluate the trial purpose and how participation would impact their daily lives. Confirmation of a governing body overseeing the trial and existence of clear trial objectives was deemed to be as important as having details about trial logistics, treatment administration, and lifestyle changes and/or restrictions required in between trial visits. Both during and after the trial, participants valued information that would contribute to their continued medical care. The ability to track personal biomarkers during the trial and to know as soon as possible whether they are responding to treatment was seen as a priority. After a trial, priority information included guidance on what to be aware of before proceeding with additional treatments for the condition, trial outcomes/results, whether a medication was launched as a result of the trial, and details on potential follow-on trials.

Site Advisory Group (SAG)

Participants in the SAG shared anecdotes of current sponsor-provided materials intended to facilitate information exchange between site professionals and trial participants as well as future desired materials to better inform trial participants. It was not expected that a single resource could address all anticipated information needs of a trial participant; however, the SAG advocated for more thorough documentation tailored to specific treatment plans, patient communities, and trials. It emphasized that sponsor-provided materials for use by sites should be created with the trial participant community in mind and be relevant for the trial participant and not the site professional. Having sponsors provide a consistent and simple set of materials at the start of every trial that is illustrative and easy to understand by the target patient population was proposed by the SAG as a potential best practice.

Discussion

The research in this paper suggests that patients have numerous desires and preferences for information exchange during their clinical trial journey that are not commonly met. Various opportunities exist to improve the clinical trial participant's experience by improving information exchange practices. Although every patient experiences a unique journey through the clinical trial process, an attempt to organize critical stages at a macro level is useful to generate understanding of opportunities to improve information exchange. Figure 1 describes these four critical stages, summarizing key patient questions and opportunities for information exchange at each stage.

Table 2. Information Shared by Sponsor Before, During, and After a Study.

Survey Question Response	Number (%) of Respondents n = 14			
	Company-Wide, Consistent Process Applied to All Studies	Flexible Process Applied on a Study-by-Study Basis (eg, Team Decision)	We Don't Have a Defined Process, but We Do Share Information	We Don't Share This Information
Before a study				
General education about drug development	3 (21)	2 (14)	6 (43)	3 (21)
Disease state information	0	6 (43)	4 (29)	4 (29)
Product-specific information	3 (21)	5 (36)	3 (21)	3 (21)
Program-specific information	2 (14)	4 (29)	5 (36)	3 (21)
Study design and logistics	8 (57)	1 (7)	3 (21)	2 (14)
During a study				
Study walk-through guide	2 (14)	9 (64)	3 (21)	0
Study visit preview and reminder	1 (7)	8 (57)	3 (21)	2 (14)
Study adherence acknowledgement recognition or feedback for patients	0	4 (29)	5 (36)	5 (36)
Study status	1 (7)	4 (29)	5 (36)	4 (29)
Patient-level data	0	1 (7)	4 (29)	9 (64)
Study-level data/results	2 (14)	1 (7)	3 (21)	8 (57)
After a study				
Patient-level data	1 (7)	1 (7)	1 (7)	11 (79)
Patient treatment code	4 (29)	3 (21)	2 (14)	5 (36)
Study-level data/results	6 (43)	1 (7)	2 (14)	5 (36)
Product-specific development information	0	1 (7)	3 (21)	10 (71)
Sponsor-generated thank-you letters to patients	2 (14)	3 (21)	3 (21)	6 (43)
Transition back to usual care or another study	0	2 (14)	2 (14)	10 (71)

Table 3. Patient, Participant, or Prospective Participant Information Requested by Sponsor.

Survey Question Response	Number (%) of Respondents n = 14			
	Company-wide, Consistent Process Applied to all Studies	Flexible Process Applied on a Study-by-Study Basis (eg, Team Decision)	We Don't Have a Defined Process, but We Do Request Information	We Don't Request This Information
From patients in general				
Feedback from patients regarding draft study outlines or protocols, informed consent form (ICF), and protocol/ICF amendments	0	4 (29)	5 (36)	5 (36)
Feedback from patients regarding draft study logistics	0	4 (29)	3 (21)	7 (50)
Feedback from patients who declined participation	0	0	1 (7)	13 (93)
From current clinical trial participants				
Feedback from study participants during study regarding logistics	0	2 (14)	2 (14)	10 (71)
Feedback from study participants only after they end treatment but are still continuing in the study	0	2 (14)	1 (7)	11 (79)
From past clinical trial participants				
Feedback from study participants only after they end their participation in the study	0	2 (14)	2 (14)	10 (71)
Feedback from study participants only after the study ends	0	2 (14)	1 (7)	11 (79)

Table 4. Health Care Professional (HCP) Survey Results for Selected Question.

Survey Question	Number (%) of Respondents
What information would you like to receive from a clinical trial site after referring a patient?	n = 462
Study results at study end	306 (66)
Determination of patient's eligibility	274 (59)
Reason for ineligibility if patient not suitable for clinical trial	249 (54)
Data collected during the clinical trial from/for the referred patient	236 (51)
Additional details on the operation of the clinical trial at the site level	228 (49)
I don't need any information from the clinical site after referral	11 (2)

Sponsors have an opportunity to evaluate new practices and approaches within their individual organizations for answering the key patient/trial participant questions in Figure 1 in a way that is meaningful to the individual patient and can be applied consistently across all trials. Although not an exhaustive list, the key communication opportunities may form the basis for the "new normal," a landscape of information touchpoints between patients and researchers that prospective, current, or past trial participants can expect.

These opportunities cannot be tackled by biopharmaceutical company sponsors alone. The input and support of other stakeholder groups are imperative for successful implementation of improvements in this highly complex environment (Figure 2).

In the current state, the most commonly established communication pathways in this complex stakeholder environment exist to support regulatory oversight and approval and the publishing of trial-level scientific data or results. Despite several advances in recent years to elevate the role of patients and patient groups in trial design and policy and the role of the individual patient in medical care decision-making, communication pathways connecting the patient, research community, and HCPs remain largely underdeveloped. Most biopharmaceutical company sponsors rely on traditional communication pathways, such as the ICF, to provide patients with information about the trial and trial participation. Robust information exchange to meet the needs and preferences of patients at each major stage of their clinical trial journey should be viewed with a much broader lens beyond the informed consent process, much like the increasingly accepted concept of patient involvement throughout medicines development as opposed to in isolated instances only.[3]

The complexity of information exchange with patients across multiple stakeholders involved in the clinical trial journey should not be underestimated. Sponsors must continually consider the impact of information exchange programs on sites and communicate options for information exchange with their site community well in advance of trial initiation. Trial participants might also prefer involvement of their primary HCP. At the participant's discretion, the HCP could play an enhanced role in conveying or clarifying key information provided before, during, and after a clinical trial. Ultimately, expanding the roles involved in information exchange with patients throughout a clinical trial could help build a more rewarding patient experience across all trials while also shaping a new set of shared expectations held by all stakeholders.[4]

Several real and perceived barriers have prevented sponsors from implementing sweeping changes quickly. Many sponsors are conditioned to almost entirely avoid contact with patients because of laws/regulations regarding promotional activity, patient privacy, safety event reporting, etc. However, considering patients' desires for a more transparent and informative trial experience, it is incumbent on industry to engage with health authorities around the globe to clarify acceptable boundaries with respect to information exchange. Additionally, clinical development time pressures often result in a tendency to standardize approaches wherever possible to capitalize on speed gained with repetition. To avoid perpetuating the status quo within an organization, champions of improved information exchange must present new programs and opportunities alongside measures which mitigate potential time delays for patient-facing material development and ethics committee reviews. These measures may also help to support ongoing culture and process change critical to ensuring new patient-focused initiatives are accepted.[5]

Despite the challenges, it is worth exploring how sponsors might approach improved information exchange practices. Design and implementation could be guided by the following principles:

1. Focus on patients: The content and format of the information are developed with input from patients and/or with patients' needs in mind. As a recipient of information, each patient is recognized as an individual with unique perspectives, interests, and expertise. The patient's life does not center on clinical trials; clinical trials must fit into the patient's lifestyle.
2. Establish clear objectives and expectations: The sponsor defines the objectives of information exchange based on an initial understanding of patients' needs and preferences and strives to avoid extraneous information that could overwhelm or distract patients. Requests for information from patients are designed to collect only the information that might reasonably be used and in the format that will allow the information to be used for the intended purpose. The requestor sets expectations about what actions might reasonably be taken in response to patient feedback and explains limitations upfront when possible. The sponsor and trial site staff should be open with patients about why information is being exchanged. Patient feedback is valuable even if it does not result in a change to the clinical trial.

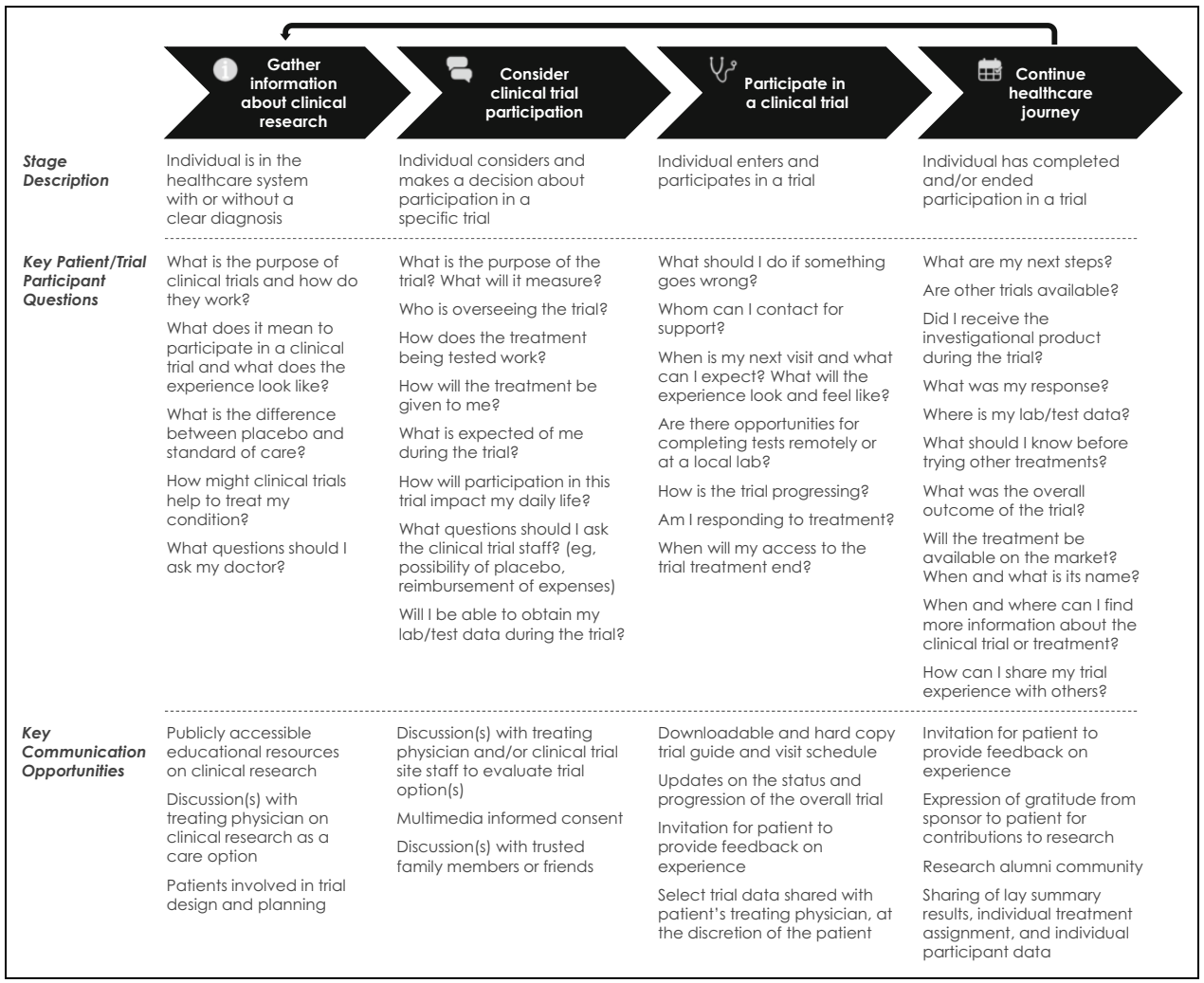

Figure 1. Critical stages of patient-researcher information exchange.

3. Be timely: The information shared with patients should be as current as possible, and note the date on which the information was obtained. For information that is requested from patients, the request should be timed as close as possible to the events of interest to ensure that patients can have accurate recall. Information exchange methods should account for the turnaround time for ethics committee review and approval.
4. Complete the feedback loop: After patients share information, summaries of that feedback and/or the actions taken based on the feedback should be shared with patients in return.
5. Maintain the scientific integrity of the clinical trial: In order to honor the trial participants' investment in the research, information exchange does not introduce meaningful bias or in any way compromise the scientific rigor of the trial. For situations in which patients wish to share or receive information that would compromise the trial, the sponsor or study site staff provide an explanation to patients and indicate when in the future that information exchange might reasonably occur.

These principles may guide biopharmaceutical company staff as they develop information exchange plans during trial design, alongside additional efforts to design trials with the patient experience in mind. Companies might also consider development of a "toolkit" as one step in the initial development of an information exchange initiative and program plan design (Figure 3). Each development program might select the most appropriate approaches and communication pathways from the toolkit to be applied at various points in time across the program life cycle. Once the patient population and key trial elements are better defined, the approaches can be refined with direct patient input, such as patient ethnography, interviews, panels, or surveys.

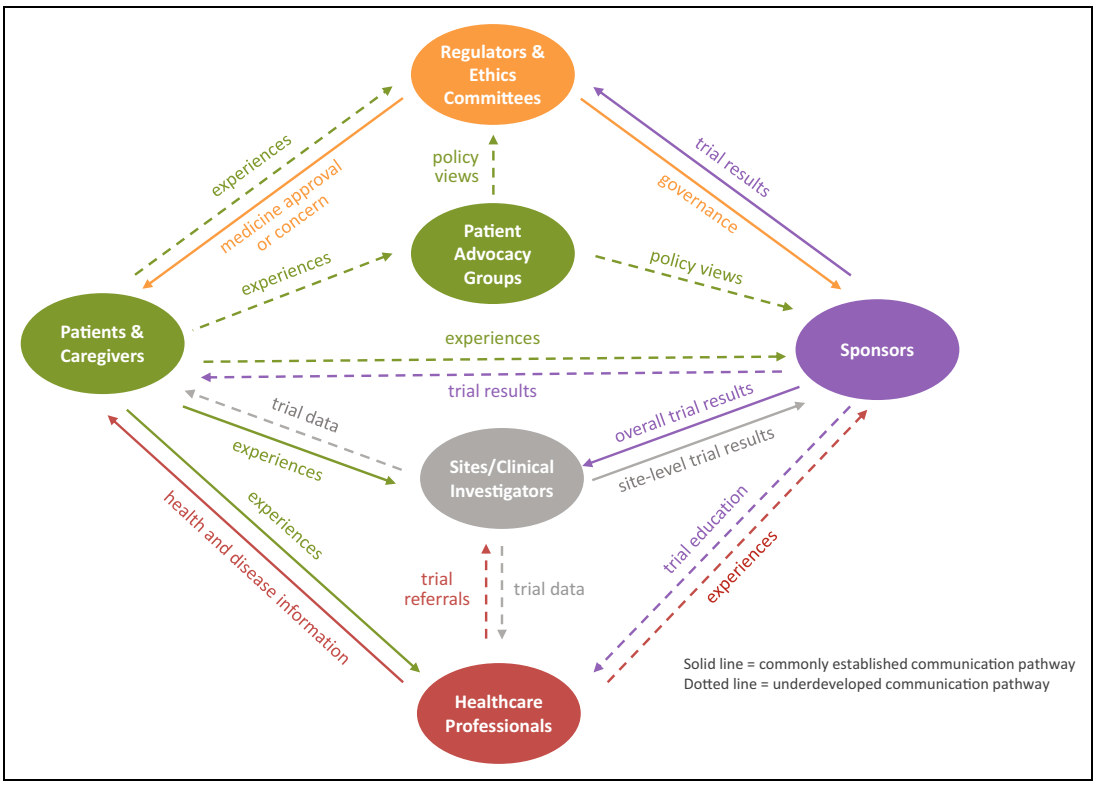

Figure 2. Stakeholders in patient-researcher information exchange.
Notes: "Researchers/Sponsors" is inclusive of research partners such as CROs. "Healthcare Professionals" depicts HCPs which are separate from the Investigator. "Trial data" encompass both individual- and trial-level information.

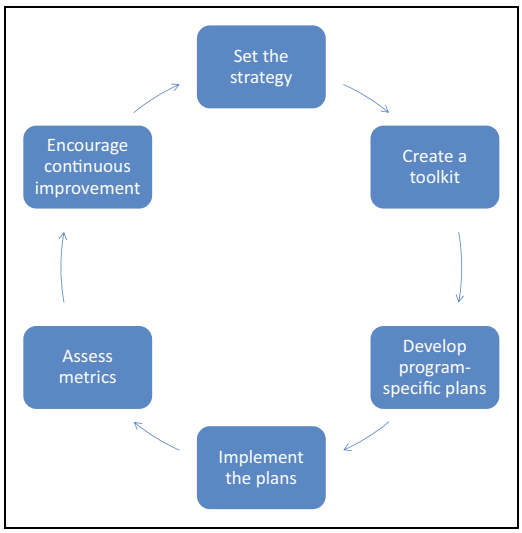

Figure 3. Six steps for information exchange initiative and program plan design.

Conclusions

A shift in industry focus toward more comprehensive information exchange with prospective, current, and past trial participants has the potential to positively impact millions of patients over the next decade.[6] Though more can be learned from patients regarding their needs and preferences for information exchange before, during, and after trials, it is evident that a gap currently exists for industry to fill, and steps can be taken by individual companies to improve the status quo. For the benefit of the research enterprise and the trial participants who sustain it, researchers, patients, HCPs, and health authorities must work together to improve partnership and transparency in clinical trials.

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Declaration of Conflicting Interests

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