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Patient Engagement in Clinical Studies

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The recent CHI Summit for Clinical Ops Executives (SCOPE) conference in Miami offered almost 1,400 attendees from pharmas, biotechs, CROs and other service providers numerous sessions on patient engagement and other topics important to clinical research.

"Patient engagement" is the process of attracting and integrating a study participant into a clinical trial. An engaged study participant *feels* that he or she *belongs* to the *team* conducting the trial, rather than being an object upon which the trial acts, as suggested by the term "study subject." An engaged study participant feels like an *insider* who is *contributing* to an *exclusive club*. An engaged study participant feels *esprit de corps*, i.e., the pride, fellowship and loyalty shared by the members of a tight group.

An engaged patient (or person who is not the investigator's patient) is more likely to enroll in a clinical study, to stay in the study, and to adhere to the study's requirements. Engaged patients are more likely to be satisfied with their study experience, to enroll in future studies, to help enlist others in clinical studies, and to say positive things about clinical research.

Patient engagement is closely related to patient-centricity. In simple terms, patient engagement is about bonding with patients, while patient-centricity is about putting patients first. Patient-centricity drives patient engagement.

Small Unit Cohesion

In military combat, otherwise sensible people risk and even intentionally sacrifice their lives for their comrades because of "small unit cohesion." The military has found that small unit cohesion — and the associated esprit de corps — can be a more powerful motivation in battle than patriotism, idealism, hatred or even self-preservation. Clinical researchers do not want study participants to sacrifice their own health, i.e., metaphorically throw themselves on live hand grenades. However, they do ask patients to accept the pain, discomfort, inconvenience and life disruption often associated with participating in a clinical trial. Patient engagement is a less extreme version of military small unit cohesion.

In clinical research, the equivalent of the military's "small unit" consists of the investigator, the study coordinator, and the study participants at a specific site in a specific clinical trial. The concept of small unit cohesion suggests that clinical researchers should focus their patient engagement efforts on the small unit, rather than on the research site, the study sponsor, the patient-recruitment firm, or the study. While the study sponsor can do much to promote patient engagement, most of its efforts must be indirect, i.e., helping the investigator and study coordinator engage with patients.

Engagement is about *people*. It requires personal, face-to-face interaction. Study coordinators need to do more than just perform the study procedures at each visit. Similarly, it will be difficult for the investigator to engage with study participants without face-to-face interactions from time to time.

Researchers seldom encourage interactions among study participants. However, full patient engagement requires these interactions, albeit with due care to avoid damaging the study by, for example, allowing study participants to compare their symptoms and thereby

distorting their perceptions or even unblinding the trial. Including study participants creates a *community*.

An engaged study participant feels like a *partner*, an *insider* (one of *us*), a *contributor* to the team, and an *owner* of the study. He or she feels *connected*, emotionally *and* intellectually engaged, and that the study team (ideally, including other participants) *really cares* about and *appreciates* him or her.

Regulatory Compliance

Patient and study participant engagement programs must comply with applicable regulations. An IRB might consider engagement messaging and techniques so powerful as to create undue influence. For example, can a study coordinator be so kind and friendly as to cast a spell over a potential study participant? Does the loyalty created by small unit cohesion interfere with the study participant's free will?

Sites should inform their IRB if there are any elements in their engagement program that might constitute a problematic inducement to enroll or stay in a study.

Disclosing a patient's identity and personal information to other study participants requires his or her permission.

Study Design

Patient recruitment and retention is easier when a study is appealing and when study participants feel ownership in its design. Patient and advocacy group advisory panels can help accomplish both of these objectives, although the engagement is indirect for most or all of the patients who eventually enroll in the study.[2] Nevertheless, communicating the patients' and advocates' role in designing the study reinforces engagement with potential and actual study participants.

Awareness

Most people are only vaguely aware of clinical research. There is a good chance they have a negative attitude toward it based on movies, television shows, and news reports. Few people find it inherently appealing to have experimental drugs or devices tested on them. However, when people get sick, their attitudes can change. When they realize the good they can do for others, altruism might kick in. For whatever reason, millions of people connect with a research site every year and then participate in a clinical study.

Patient engagement can begin well before enrollment in a study. Community outreach, word of mouth (especially through previous study participants), and other methods can increase awareness of a specific study or clinical research in general. In the earliest stages of engagement, the primary objectives are to open people's minds to the possibility of participating in clinical research and make them aware that a specific physician or research site might offer something of interest to them.

Patient Recruitment

Engagement moves beyond awareness during the recruitment process. Recruitment scripts, ads and other materials should talk about how people can join and contribute to the team, and should be specific about the team members: the investigator, the study coordinator, and, without naming names, other study participants at the site.

The sooner the person begins to engage with the study team, the better. Recruitment specialists and firms can be highly effective. They allow study coordinators to focus on study visits. However, the study team should be part of the story from the beginning. The handoff from the recruitment team to the study team should attempt to preserve any sense of engagement that has already been created.

The recruitment specialist can be part of the study team, provided he or she retains contact with the study participants and continues to serve a useful function from the study participant's point of view. For example, the recruitment specialist could be in charge of facilitating interactions among study participants.

If a physician/investigator initiates the recruitment process with his or own patients, engagement is off to a good start. However, the hand-off to the patient recruitment specialist or study coordinator should preserve the physician's presence in the new relationship, while making clear the distinction between the physician and investigator roles.

Informed Consent

The informed consent process is the best time to cement the patient's relationship with the investigator and the study coordinator, so both of them should participate in obtaining consent. Since engagement is an important, albeit secondary, goal in the consent process, the interactions should consist of more than just the business of obtaining consent.

Electronic informed consent (eConsent) can be more engaging than a paper consent document, provided it is sensitive to the patient's interests and needs. Ideally, the investigator and/or study coordinator should be present in electronic form. For example, the eConsent system could utilize their pictures, voices or videos at key points.

Normally, other study participants are not present during the consent process, but sometimes they can be. For example, in high-volume vaccine studies, it is common to begin the consent process with a group presentation and Q&A, followed by one-on-one meetings. The group dynamic can start creating comradery among study participants.

Another way to start connecting study participants to one another is to make a current study participant available to a patient considering participation (with mutual permission and proper guidance). Who can describe the study participant experience better than an actual study participant (properly selected and trained)?

Retention and Adherence

Study participant retention and adherence (compliance) can be serious problems for clinical trials. Engaged study participants are more likely to adhere to study requirements and stick it out to the end.

Military units, sports teams, start-up companies, and support groups like Alcoholics Anonymous all employ engagement methods to improve retention and adherence. For example, the mentoring system of Alcoholics Anonymous can be applied to clinical research.

Sites can employ a variety of techniques to improve adherence and retention. Many of these techniques promote engagement. For example, a text message reminder to take a pill or visit the site is a form of engagement. If the text message comes from the investigator or study coordinator, it further enhances engagement.

When issues arise in a study, e.g., patient enrollment falls behind schedule or adherence falters, ask study participants for advice and later tell them what you ended up doing. Not only might they contribute good ideas, but these steps will also increase their sense of engagement, especially if it's a group process.

After the Study

The best customer prospects (for a good product) are current and former customers. The same can be said for study participants, who become part of an "engagement network" for the site. Word of mouth further expands that network and begins the process of engagement with future study participants. It is thus essential to satisfy study participants and encourage them to share their experiences with members of their personal networks. To satisfy someone, it helps to ask, from time to time, if they have any issues or complaints and to make the person feel comfortable speaking frankly.

When a site closes a study, it is important to stay engaged with study participants (and people who were interested in the study but did not enroll). Ask for their feedback on the experience, and use it. To the extent possible, share their test data and study results with them. Hold a "thank you" party. Send periodic updates on your site and ask how they are doing. Encourage them to maintain connections with each other.

Engaging Communications

Engagement requires engaging communications, such as the following:

- Communicate in terms people understand, especially during the informed consent process, when complex and unfamiliar concepts can be overwhelming.
- Speak their language, whether local or native, informally.
- Use stories and pictures (with IRB approval).
- Ask questions, e.g., "What interests you about this study?" (Note the absence of "why" in this question. "Why" questions can be hard to answer.)
- Really listen. Use active listening techniques (e.g., repeating back) to demonstrate that you hear what they saying.
- Try to understand their point of view.
- Empathize with their feelings, experience and situation.
- Be sensitive to cultural and generational preferences.
- Be flexible with the different ways people go about making decisions.
- Take your time.
- Say "thank you."
- Respond quickly and thoughtfully to their questions and other communications. If you cannot respond quickly, tell them when you *can* respond.
- Use multiple communication channels, from face-to-face conversations to newsletters.
- Personalize your communications, e.g., remember their birthday and other important dates and people in their lives.
- Involve their family members, caregivers and healthcare providers.
- Give them your direct telephone number and maybe even your mobile number.
- From time to time, check in just to see how they are doing.
- If your handwriting is legible, occasionally send a hand-written note.

Digital Engagement

Digital media offer numerous ways to engage patients. They can streamline timely, low-cost communications. Some digital communications, e.g., email, can be personalized for

recipient name, content and timing. However, digital communications can also dehumanize communications and make people feel like a faceless name on a mailing list.

Digital media support outgoing, incoming and interactive communications. They also enable something new: large-scale "social listening" of Facebook postings, discussion groups, tweets, etc. In some cases, study sponsors (or consultants) are listening into social media discussions among study participants about complaints, adverse events, and ways to unblind treatments. Sponsors can provide insights to sites on issues of concern to patients and study participants so sites can engage people appropriately. Care is required to avoid the perception that Big Brother is watching.

Smartphone study apps offer the ultimate engagement tool for study participants who experience the world through their mobile devices.

Concierge Treatment

In a fine hotel, the concierge makes guests feel special. They provide personal care like reservations at restaurants that have no open tables when you call for yourself. Sites, often with help from the study sponsor, can engage study participants with concierge-level care that makes them feel understood and appreciated, for example:

- A special waiting room for study participants, stocked with snacks and beverages
- Flexibility on visit dates and times
- Home visits
- Stipend payments on debit cards
- Uber or Lyft transportation with no receipts or reimbursement needed

Conclusion

Patient and study participant engagement takes attention and effort. The payoff comes in higher rates of enrollment, retention and adherence. The extra work required to engage patients should be well rewarded. With fewer problems and delays, the net amount of effort might actually decline.

Many of the patient engagement principles discussed in this article also apply to sponsor/site and other relationships. For example, how engaged does an investigator feel after an investigator meeting ends and everyone disappears? How engaged does a study coordinator feel when he or she has to work with 10 different vendors without technical support contact information? How engaged does a site feel when a sponsor or CRO contact seems to be blocking, not facilitating communications? How engaged does a site feel when a study ends and the sponsor seems to forget it exists? Study sponsors can get better performance from sites by engaging with them so this type of things does not happen.

Reference

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