

What Is Patient-Centricity?

By Norman M. Goldfarb

The recent CHI Summit for Clinical Ops Executives (SCOPE) conference in Miami offered almost 1,300 attendees from pharmas, biotechs, CROs and other service providers numerous sessions on patient-centricity and a broad range of other topics.

Most clinical research professionals would probably agree that patient-centricity is very important, but we lack a common understanding of the term. This article will propose a definition for patient-centricity and identify characteristics that make a clinical study patient-centric.

Defining “Patient-Centricity”

The first principle in defining patient-centricity is that the term itself should be patient-centric. In other words, when patients read the definition, they should agree with it from *their* perspective. Patient-centricity is not about *our* goal of recruiting more patients for clinical studies — it’s about *their* goals when they participate in a clinical study. It is not about *our* methods for communicating information to patients — it’s about *their* preferences for obtaining information.

Since different patients have different goals, concerns and preferences, the second principle of patient-centricity is that it must be specific to each individual patient, or at least each group of patients with like characteristics. Patient-centric studies provide a personalized experience for each study participant.

The third principle of patient-centricity is that it begins when a study is contemplated and ends when the patient’s experience is complete.

The fourth principle of patient-centricity is that it applies when a person is a patient, when he or she becomes a study participant, and when he or she returns to being a patient. (In this article, the terms “patient” and “participant” will be used interchangeably.)

Based on these principles, we can now propose a definition of patient-centricity:

A clinical study is patient-centric when, from each study participant’s perspective, it achieves his or her goals in a manner sensitive to his or her individual concerns and preferences, over the entire life cycle of the study.

Although it has not been proven empirically, patient-centricity should also help achieve the study sponsor’s goals.

Characteristics of a Patient-Centric Clinical Study

The degree to which a study is patient-centric is based on the following characteristics:

- The study meets the standards for human subjects protection, i.e., the risks and benefits for the study participants and the public at large (i.e., other patients) are acceptable.
- The participants agree that the study’s endpoints are worthwhile to them.
- The study employs principles of precision medicine to focus on the patients most likely to benefit from the study.

- The study considers the patient's environment, e.g., cultural attitudes, social structures, healthcare system, physical infrastructure, and the available standard of care.
- The participants agree (in descending priority) that the study might solve their medical problem during the study, that it is relevant to their clinical care after the study (e.g., in a pragmatic study), or that it contributes to the health of their community (i.e., altruism).
- A patient advisory board contributes to the design of the study and finds the resulting design satisfactory or better.
- Because of their empowered involvement as collaborative partners, patients feel informed, respected, valued and engaged with the study, sharing ownership of and responsibility for it.
- Patients can easily learn about the study. Recruitment communications are tailored for patient preferences (e.g., media, culture, language, physical capabilities, technology, intermediaries and communities) and address the patient's perspective.
- The informed consent process provides information each patient wants or needs, in language he or she can understand. If eConsent is not practical, a paper consent form can be structured with a summary and appendices. The consent process includes a substantive discussion in which site personnel *listen* to the patient and talk *with* him or her. Patients leave the consent process with adequate understanding of the study and realistic expectations.
- Research sites determine each patient's goals, preferences and concerns, and keep them in mind when interacting with the patients. For example, why is this particular patient interested in this particular study? Research sites should not enroll patients whose needs are not met by the study.
- Participation in the study is convenient. For example, visits should be minimal in number, convenient in timing, and short in duration. Procedures should be minimized in number, invasiveness, pain and discomfort. Transportation and parking should be easy. Home visits and virtual (telemedicine) visits maximize convenience.
- Wearable devices are used if they improve the patient's experience, e.g., by reducing the number of visits or the need to manually record data. Patients might also prefer wearable devices if they generate data that increase the value of the patient's participation in the study.
- Research sites conduct the study in the context of the patient's existing and emerging medical conditions, addressing comorbidities in an appropriate manner.
- Patients are treated as important individuals throughout the process. For example, receptionists should be able to recognize study participants on sight (based on photos) and greet them by name.
- The needs of primary care physicians, caregivers, family members, and other patient supporters are addressed.
- Patients receive their study data and the overall study results (with the necessary caveats) in an understandable form and in a timely manner.
- Everyone who interacts with a study participant or contributes to the interaction is trained in patient-centricity as it relates to their role.
- There is a quality assurance and improvement process during and after the study for measuring patient-centric performance and patient satisfaction, and addressing any shortcomings.
- Study participants are satisfied with their experience, would participate again, and would recommend participation to their friends.

Conclusion

This article presents many but not all characteristics of a patient-centric study. As a general rule, the first question to ask when designing and conducting a clinical study is thus: "How will this decision benefit the patient, especially from his or her point of view?"

The second question to ask is: "How will implementing patient-centricity affect the study's cost, speed, quality and mix of required resources?" Each patient-centric characteristic will affect these metrics differently for each study. Some will improve one or more of these metrics, others will offer tradeoffs, and some might make all of them worse. The success of patient-centricity for a specific study and as a long-term trend depends on identifying the characteristics that generate the most patient-centricity at the lowest price in terms of cost, speed, quality and mix of required resources.

Each patient-centric characteristic will also have different impacts on the sponsor and the site. Sites will tend to welcome patient-centric studies that benefit, rather than burden the site. In other words, site-centricity is important too.

Patient-centricity also affects the public's perception of clinical research, with broad, lasting impacts on patient recruitment and public policy. These impacts cannot be quantified but might tip the balance in favor of incorporating more patient-centricity in a study.

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