

# PEAC Roundtable Scenarios & Questions

Patient Engagement Advisory Committee Meeting  
October 11 and 12, 2017

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## A. Patient Involvement in the Design of Clinical Trials

**Scenario:** Company XYZ is developing a clinical trial to study a novel device that is intended to treat obesity. The primary goal of this trial is to show that the device causes weight loss. Company XYZ does not usually work with patients when developing their clinical trial protocol. The company usually seeks input from key opinion leaders who are often healthcare providers. Because obesity is widespread and a major public health concern, the company is interested in engaging with patients during this clinical trial design process to help them better understand and capture patient perspectives.

1. How should Company XYZ approach recruiting patients who could contribute to the design of the clinical trial?
2. What concerns do you think Company XYZ might have with involving patients in the design of the clinical trial?
3. What concerns might patients have with providing input to Company XYZ about the clinical trial design?
4. What recommendations do you have for Company XYZ to make the trial more responsive and sensitive to patients' needs and concerns? Consider the inclusion and exclusion criteria for the participants, the different outcomes that would be meaningful to the patients, and the burdens and benefits of study participation.
5. How can Company XYZ continue to connect and build relationships with patients who reflect the real world population affected by the condition?

### *Moderator Probes:*

- 1) *What are different ways for Company XYZ to involve patients in the review of the clinical trial protocol? Please consider concerns regarding the company's intellectual property and confidentiality.*
  - a. *How should companies decide what patient recommendations should be implemented?*
  - b. *Whether this information should be relayed back to the patient groups?*
- 2) *What elements of clinical trial design are of most concern to patients?*
  - a. *Who will be included and excluded from the trial?*
  - b. *The outcomes used to determine trial success?*
  - c. *Are there quality of life measures or other metrics that would help patients make decisions about therapies?*
  - d. *How long the trial will last and how often do patients need to be seen?*
  - e. *The additional testing and evaluation outside of their usual care?*

## B. Patient Recruitment, Enrollment, and Retention

**Scenario:** Company XYZ has developed the clinical trial using input from the patients. The trial is designed to last 2 years and has frequent follow up visits.

Company XYZ wants to ensure that the on-label indication includes adolescents as well as adults, given the increasing prevalence of childhood obesity. In addition, Company XYZ wants to ensure that they have diversity with respect to race, ethnicity, and gender to address theoretical concerns about safety differences. Company XYZ is also concerned about potential challenges recruiting patients from these different groups. Company XYZ is

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planning the recruitment strategy as well as developing ways to increase enrollment and retention of diverse groups throughout the trial duration.

1. What barriers might Company XYZ encounter in trying to identify patients from diverse racial and ethnic backgrounds, different genders, and in younger age groups?
2. What additional barriers might be encountered when trying to recruit each of these groups to take part in a clinical trial?
3. What strategies would you recommend to the company to ensure that they are able to recruit and enroll patients from diverse racial and ethnic backgrounds, different genders, as well as from younger age groups?
4. What issues or barriers, if any, might participants face that could cause them to prematurely withdraw from the clinical trial?
5. What tactics might Company XYZ employ to ensure that patients stay in the trial for the duration of the study?

## *Moderator Probe Questions:*

- 1) *What are the biggest challenges for patients to participate in a clinical trial (e.g., finding relevant trials, logistics, insurance)?*
- 2) *What are the methods the company should use to recruit and enroll patients?*
- 3) *What are possible challenges with the informed consent process and do you have possible solutions?*
- 4) *How should the company ensure that they have diversity (ethnicity, race, socioeconomic status (SES), geographic location, religious, gender, sexual orientation, spectrum of disease) in their trial?*

## C. Dissemination of Trial Data and Results to Participants and Other Patients

**Scenario:** Company XYZ has completed the trial. The results show that the device did not cause clinically significant, maintained weight loss among participants of any specific racial or age group, though many participants lost noticeable amounts of weight and were pleased with their appearance. Company XYZ does not plan to publish the results.

1. Should Company XYZ share the results with the trial participants and with the patient community? Why or why not?
2. If you believe that they should share the results,
  - a. Should the method of sharing the results be customized to the different trial participant subgroups (e.g., age groups, literacy levels, languages)? Why or why not?
  - b. How should the results be communicated with the different trial participant subgroups?

## *Moderator Probe Questions:*

*In order to assure that patients receive trial results and necessary data:*

- 1) *What information from the trial would you be interested in hearing about?*
- 2) *What might be the most effective ways for sponsors to distribute results and data to study participants and patients?*
- 3) *Do current privacy protections help or obstruct access to your trial data?*
- 4) *Would having a forum for patients who have participated in a trial help facilitate information sharing and patient support needs?*

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5) *How can the trial participants facilitate sharing and communicating trial results?*