FDA Discussion Questions

Patient Engagement Advisory Committee Meeting
October 11 and 12, 2017

1. What opportunities and barriers (perceived or real) might patients and patient groups experience when attempting to collaborate with industry on the design of clinical trials?
    a. How might those opportunities be expanded?
    b. How might those barriers be overcome?
2. In general, what aspects of the trial design contribute to enrollment and participant retention challenges? What are methods to better address these challenges? Please consider the following in your discussion: informed consent, randomization, outcomes meaningful to patients, frequency and number of visits, assessments performed, and study duration.
3. What do you believe to be the most effective means of recruiting and enrolling patients? Should recruitment and enrollment approaches be customized to better meet the needs of the following:
    a. Rare disease populations (e.g., flexible inclusion and exclusion criteria);
    b. Different racial/ethnic/socioeconomic/ religious/gender and sexual orientation groups (e.g., sociocultural sensitivities and economic barriers);
    c. Different age groups (e.g. pediatric and elderly assent/consent process); and
    d. Mentally or physically disabled groups (e.g., visit burdens)?
4. What are various methods that could be used to facilitate participant retention throughout the duration of the clinical trial? Would the methods be different for aforementioned groups (i.e., rare disease population or members of different age, racial, ethnic, socioeconomic, religious, gender or sexual orientation, or disabled groups)?
5. What factors should be considered when communicating clinical trial results to the trial participants and to the public? Please consider the following in your response:
    a. Method (e.g., social media, email blasts, texts, brochures or newsletters);
    b. Vehicle (e.g., participant involvement in communicating results to others);
    c. Language (e.g., types, literacy level, use of pictures/images); and
    d. Timing (e.g., interim results, final results)