

SUMMARY OF THE PATIENT ENGAGEMENT ADVISORY COMMITTEE MEETING OCTOBER 11-12, 2017

Introduction:

The Patient Engagement Advisory Committee to the Food and Drug Administration (FDA) met on October 11-12, 2017, to discuss and make recommendations on the topic of patient input into medical device clinical trials. The discussions included topics such as patient involvement in the design of clinical trials; patient recruitment, enrollment and retention; and communication of study results to trial participants.

Round Table Discussions:

During the roundtable discussion the audience was asked to discuss amongst their table the 3 scenarios presented to them on the topics of patient involvement in the design of clinical trials; patient recruitment, enrollment and retention; and the dissemination of trial design and results to participants and other patients. Concluding each scenario discussion FDA representatives presented comments generated by the audience.

Presentations:

The FDA presented on Clinical Trials and Medical Devices, as well as, the Center for Devices and Radiological Health's Patient Engagement Efforts.

Guest Speaker, Ms. Bray Patrick-Lake, from the Duke Clinical Trials Research Institute presented on the Patient Engagement Efforts with the Clinical Trial Enterprise.

Guest speakers from AstraZeneca and the National Cancer Institute, as well as, Ms. Anna McCollister-Slipp presented on the topic of Patient Involvement in the Design of Clinical Trials.

Guest Speakers from Johnson & Johnson, Boston Scientific, Patient Centered Outcomes Research Institute (PCORI) and the National Organization for Rare Diseases (NORD) presented on the topic of Patient Recruitment, Enrollment and Retention.

Guests Speakers from ClinicalTrials.gov and Sage Bionetworks presented on the topic of Communication of Study Results to Trial Participants.



Open Public Hearing:

Over the course of two days there were 16 open public hearing speakers that presented and provided comments. Speakers included patients, research organizations, industry, patient advocacy groups and other members of the public.

FDA Questions and Committee Discussion:

The Committee discussed the opportunities and barriers that patients experience when attempting to collaborate with industry on the design of clinical trials. There are multiple parties involved in educating patients to remove barriers and improve accessibility for patients in the clinical trial arena. The Committee did have consensus stating that some type of framework must be developed by the FDA and Industry to de-mystify the clinical trial process. The framework should include information on where to direct patients to find more information about clinical trials. The framework should identify how to address the many barriers patients face including but not limited to socioeconomic factors, cultural variables, and literacy. Comments were also made to reach across cultural barriers, to move to a digitally accessible database to retrieve patient information, patient training and earlier patient involvement in clinical trials.

The Committee discussed challenges of the trial design that contribute to retention issues for patient enrollment. The committee agreed that it is important to take time in the iterative process of educating the patient prior to, during and after the trial. The Committee mentioned that using simpler language and illustrations in patient materials including informed consent would facilitate patient involvement in clinical trials. To increase the diversity of trial participants, the Committee suggested involving underrepresented investigators. Video explanations of clinical terms and protocols would also be helpful. Meaningful outcomes for patients are very important when designing clinical trials. Clinical trial directors should minimize the frequency of visits for patients as much as possible and utilize technology as an easier follow up method. Clinical trials must have an aggressive outreach perspective and clearly delineate what is expected of participants throughout the trial. The length of the trial should be made clear and distinguish the length of time the patient will participate in the trial from the length of the entire trial.

The Committee discussed the most effective means of recruiting and enrolling patients. Agencies such as the Patient-Centered Outcomes Research Institute (PCORI) have made recommendations on ways to increase trial diversity, including strengthening strategic partnerships with other patient groups, physicians and organizations. Obtain patient feedback and utilize the patient recommendations as the best practice to design clinical studies to support retention. Utilizing more flexible inclusion/exclusion criteria will also help to obtain more patients in the rare disease arena.

Clinical trials must obtain not only patient feedback but also feedback from the family and set expectations in order to keep patient trust and maintain retention. In order to facilitate patient retention clinical trials should extend



common courtesies, such as entertainment for children, facilitating travel, providing food, lodging and compensation. Clinical trials should always value the participant as a person.

The Committee discussed factors that should be considered when communicating clinical trial results to the trial participants and to the public. They emphasized the importance of detailing the communication plan as part of the protocol development process. The method of communication should be accessible and easy to read. The final results should be shared to keep the patients engaged with clinical research.

The future topics the committee recommended included but were not limited to:

- Postmarket Processes for Medical Devices
- Data Privacy and Cybersecurity
- Patient Reported Outcomes
- Digital Health and Mental Health

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