24 Hour Summary of the Patient Engagement Advisory Committee
October 30, 2024

Introduction:

The Patient Engagement Advisory Committee to the Food and Drug Administration (FDA) met on October 30, 2024, to discuss and provide advice on "Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products." The individuals who volunteer to participate in clinical research play an integral role in advancing scientific knowledge and supporting the development of potentially life-saving therapies for patients in need. Informed consent is a key element in clinical studies and can be one of a patient's first interactions with the clinical community. Too often, however, informed consent forms are lengthy and difficult for potential research participants to understand. FDA has worked to improve informed consent over the years, including several recent activities such as developing a draft guidance in identifying key information in informed consent.

The Committee provided advice on the informed consent process and the areas of focus of the informed consent. The Committee also provided advice on factors to consider when communicating informed consent to clinical study participants to increase the likelihood participants understand the key elements of research.

FDA Questions and Committee Discussion:

The Committee heard presentations from FDA, industry, academia, clinicians, patients, and other interested parties.

Improving informed consent practices may increase the likelihood that patients clearly understand informed consent materials, including the key information and all other aspects of the informed consent for clinical studies before they or their family members decide to participate.

Question #1: Informed consent forms and the discussions that occur with the health care provider prior to signing the form contain various key elements, including the purpose of the study, risks and benefits of participation, and the steps that will occur at the end of the study.

a) What do you believe are important elements (sections) to include in the key information of the informed consent form?

The Committee generally agreed important elements for the key information of the informed consent form include, but are not limited to, an identified point of contact to answer the participant's questions during the study and post-study; risks associated with study participation; a clear statement of the obligations for study participants and the clinical study team. The Committee noted the balance between the information included in the informed consent to be both comprehensive and clear. Information provided should be simple and include a dynamic range of information potential participants are seeking but also coupled with clarity. The context of the benefit and

risk for participating in the study throughout their patient journey should also be clear.

The Committee expressed concerns of health and research literacy for diverse populations. The Committee generally agreed that the specific population(s) being sought to participate in the study should be considered when selecting the important elements in the key information, as different information may be most important to various communities. The Committee also described the need to strike a balance between the consistency of the information provided during the informed consent process versus tailoring to the individualized needs of the participants. The Committee agreed that the ecosystem around the delivery of informed consent should be consistent, account for individual needs, and account legal and compliance requirements. The Committee felt special attention is needed post-study including impacts to ongoing care. The Committee suggested that it should be made clear to the potential participant what their post-trial experience will involve and where to access information. Another concern the Committee expressed was about post-trial considerations for medical devices. For example, device maintenance, software updates, lifespan of the device, where potential participants can find information and providing them with a point of contact if their healthcare provider is not knowledgeable of the new device.

Question #2: How could the contents of the key information be presented to help participants decide whether to participate in a clinical study?

The Committee generally agreed that the presentation of the informed consent is a process and not a one-and-done activity and should clearly state what participants can expect in terms of interactions with the study team. To help potential participants decide whether to participate in a clinical study, the informed consent key information contents should include 1) language that states the clinicals study is research, voluntary and clearly explains what the participant is being asked to do during and after the clinical study, as well as, the risks involved with participating and the probable benefits; 2) The purpose of the clinical study must be front and center and must be in lay language, easily understandable to the patient and not overly scientific. It should indicate why the study is important to increase medical knowledge, as well as, why the study is relevant to the participant; 3) The duration of the trial and post-trial information. The Committee agreed that the order of key information content will be situational and that the information upfront should reflect what is most important to the potential participant whose consent is being sought.

The Committee also agreed that the accessibility of the informed consent form should support the diverse needs of the participants, for example accounting for participants with differing physical or visual needs. The informed consent presentation should be dynamic and include multiple formats, such as, visual and auditory videos with transcriptions. The Committee agreed the informed consent process should include other health equity and cultural considerations, and that appropriate timing is essential, allowing time for the participant to reflect on what is being asked of them and not feeling compelled to provide consent on the spot. It should also provide the

participant the opportunity to decide where and when consent happens. The Committee also generally agreed that a checklist with guiding questions for discussion is beneficial not just to confirm all items have been completed but also an opportunity to engage in conversation with participants and address unknowns and concerns they may have regarding the clinical study. For example, instead of asking if potential participants have any questions, consistently asking them to explain what they understand about participating in the study to check comprehension.

Question #3: What are the most effective approaches to providing information in the informed consent form and through the overall informed consent process?

a) **How can informed consents be tailored to meet the needs of all populations?**

The Committee generally believes consent should be accessible and effective for all potential participants and the most effective approaches to providing information in the informed consent form and through the overall informed consent process includes content that is culturally competent and relevant. The Committee suggested working with trusted community centers and those who understand the needs of the community. The Committee also agreed the content should resonate with multiple groups and that it should use gender neutral words. Rural and other populations may need paper versions due to broadband access issues or other barriers. Information included in the informed consent form should also be age appropriate. The Committee generally agreed assent should be verbal and written and that there should be protection for children. Children need to be developmentally capable of understanding and the Committee generally agreed that what it means to be developmentally capable needs to be clearly defined.

b) **How can technology (i.e., video, multi-media, computer-based techniques) be leveraged in the development of informed consent materials and process for a clinical study? What are important areas to consider in implementing electronic/digital consent in clinical studies?**

The Committee generally believes that technology can be leveraged in the development of informed consent materials and process for a clinical study. The Committee agreed that there should be numerous pathways for a participant to provide consent, including both electronic and paper options. The Committee also agreed that data management is an area to consider in implementing electronic/digital consent in clinical studies. Data collected during the clinical study should be anonymous, however, the patient should have access to the data they provide. The Committee suggested that a repository similar to ClinicalTrials.gov for informed consent could be helpful.

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