## FDA Seeks Older Adults for Panel Discussion on Medical Device Clinical Studies

The U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is seeking to engage with older adults who have had exposure to medical device clinical studies to participate in a virtual town hall for FDA CDRH staff on Thursday, September 4th, 2025, 11AM – 1PM EST.

The goal of this town hall is for FDA CDRH staff to understand the perspectives of individuals aged 65 and older as they detail their experiences and considerations when navigating medical device clinical studies.

The event will spotlight an FDA-moderated panel discussion with older adult participants who have had various levels of engagement with medical device clinical studies over the last 5 years.

Potential panelists:

• must be 65 years of age or older, AND

Within the last 5 years:

- enrolled and completed a medical device clinical study,
- enrolled but did not complete a medical device clinical study,
- were eligible to enroll in a medical device clinical study, but decided not to enroll, OR
- were interested in participating in a medical device clinical study, but were unable to enroll and/or were ineligible

Additional considerations for potential panelists include:

- Varying demographics (age, gender, race, location)
- Varying medical device needs and medical device types, including hearing devices and software applications
- A range of medical device-use experience (from new to experienced)

If selected, the total time commitment for this request is 5 hours, consisting of:

- An initial meet and greet (15-20 minutes),
- Administrative tasks, such as introductions, signing release forms, and photos (1 hour),
- Dry run meeting(s) (90 minutes), and
- The virtual town hall event (2 hours).

Following the initial meet and greet, confirmed participants can expect to:

- Share details about their experiences with medical devices and clinical studies
- Highlight barriers to full participation in a medical device clinical study
- Share considerations that may help improve access and participation of older adults in medical device clinical studies
- Answer discussion questions posed by the town hall moderators regarding their

consideration/decision process for potential participation in a medical device clinical study, the informed consent process, study participation, and potential improvements that could have been made throughout the experience (Participants will receive the discussion questions in advance.)

• Answer questions from town hall attendees regarding their experience

If interested in sharing your medical device clinical study experience, please contact Anaja Pinnock-Williams at <u>anaja.pinnock-williams@fda.hhs.gov</u> before **Friday**, **July 25**<sup>th</sup>, **2025** to discuss this opportunity further. Thank you for your consideration, and we look forward to speaking with you! Your participation will help inform the FDA's work.