OMB Control No: 0910-0360 **Expiration Date**: 10/31/2020

Feedback on Patient Preference Information and Patient-Reported Outcomes Workshops

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0360. The time required to complete this information collection is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRAStaff@fda.hhs.gov.

We invite you to share your feedback regarding the September {29th / 30th} virtual public meeting {*Using Patient-Preference Information in Medical Device Regulatory Decisions: Benefit-Risk and Beyond / Patient-Reported Outcomes (PROs) and Medical Device Investigations: From Conception to Implementation*. We appreciate your candid responses.

Your participation/non-participation is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services. All respondent identification and information will be anonymous unless otherwise indicated. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection fully complies with all aspects of the Privacy Act, and data will be kept secure to the fullest extent allowed by law.

.

1. Overall, how would you rate the virtual meeting?
    a. 1 – Very Poor
    b. 2 – Poor
    c. 3— Average
    d. 4 – Good
    e. 5 – Excellent
2. How would you rate the length of the virtual meeting?
    a. Too short
    b. About right
    c. Too long
3. Did the virtual meeting meet your expectations?
    a. This meeting exceeded my expectations
    b. This meeting met my expectations
    c. This meeting was below my expectations

4. Overall, the speakers were helpful in conveying the information.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
5. Please rate each session(s) on a scale of 1(Not informative) to 5 (Very informative).
    a. Importance of Patient-Reported Outcomes (PROs)
    b. Incorporating PRO Instruments in the Healthcare Ecosystem
    c. Bridging PRO Instruments: Examples of Ensuring Relevancy Across Demographics
    d. Developing PRO Instruments When One Does Not Exist
    e. Multi-Stakeholder Collaborations for Instrument Development
6. How likely are you to attend another FDA workshop or conference on patient science?
    a. 1 (Not at all likely) – 10 (Extremely likely)
7. How likely are you to recommend FDA conferences on patient science to a friend or colleague?
    a. 1 (Not at all likely) – 10 (Extremely likely)
8. Do you feel the use of technology (streaming platform, app, etc.) allowed for you to be adequately engaged throughout the event?
    a. 1 (Not at all) – 5 (Very much so)
9. How can we improve this virtual meeting?
10. What topics would you like to see covered in future public meetings on patient science and engagement?

Alternative question for #5 to be used for PPI virtual meeting:

1. Please rate each session(s) on a scale 1-5 from not informative to very informative.
    a. Introduction to and Background of Patient-Preference Information (PPI)
    b. Case Studies for Use of PPI in Medical Device Decision-Making Processes
    c. Methodologic Issues for PPI Studies
    d. Implementation / Process of Obtaining and Using PPI – the 'Beyond'