FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF CUSTOMER SATISFACTION SURVEYS (0910-0360)

The generic clearance will only be used for customer satisfaction and website usability surveys where FDA seeks to gather information that is planned for internal use only, and can provide a justification for qualitative or anecdotal collections that may nonetheless produce useful information for program and service improvement.

TITLE OF INFORMATION COLLECTION: Feedback on Virtual Course Titled "IMPACT Bootcamp: Navigating the Journey from Digital Health Technologies to Meaningful Patient Outcomes"

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

We will be holding virtual course on digital health technologies and patient outcomes on March 9, 2021 and wish to evaluate the quality of the course so that we can properly plan future public engagement efforts around this topic. Our intent is to gauge the level of satisfaction with the current course, as well as elicit feedback and recommendations on how to improve future courses to meet the needs of all attendees. We will not solicit other types of feedback from respondents.

2. Intended use of information:

We intend to use this information within CDRH to improve our future public courses.

3. **Description of respondents:**

Only attendees of the "IMPACT Bootcamp: Navigating the Journey from Digital Health Technologies to Meaningful Patient Outcomes" virtual public course will be asked to provide feedback. We expect members of the medical device industry, universities, research organizations, and potentially investment organizations to join us for the virtual course.

4. Date(s) to be Conducted:

March 9, 2021 – March 23, 2021

5. How the Information is being collected:

At the conclusion of the virtual public course held through Zoom, we will send an email to attendees with a link to an online survey using the secure REDCap platform or Qualtrics platform, requesting their feedback. Attendees may respond to the survey online.

6. Confidentiality of Respondents:

Using the statement below, we will inform respondents that their participation is completely voluntary and that their responses will be kept private.

"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."

7. Amount and justification for any proposed incentive

No incentive proposed.

8. Questions of a Sensitive Nature (Data will be kept private to the extent allowed by the law)

We will not be collecting data that is of a sensitive nature.

9. Description of Statistical Methods

This survey collects qualitative information. We will use standard descriptive statistics (e.g., measures of distribution and central tendency, dispersion, etc.) when appropriate. For non-numerical feedback, we will cluster ideas by topic.

BURDEN HOUR COMPUTATION (*Number of responses* (X) *estimated response or participation time in minutes* (X) *estimated response or participation time in minutes* (X)

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Online Course Attendee	95	10 minutes	16

REQUESTED APPROVAL DATE: March 8, 2021

NAME OF PRA ANALYST & PROGRAM CONTACT:

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