

ASCA Pilot Evaluation Plan- Accreditation Body and Testing Laboratory Survey Questions

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I. Summary

The ASCA Pilot will be evaluated using data analyses with respect to premarket submissions and survey responses from stakeholders. This document describes the types of survey questions intended for accreditation bodies and testing laboratories. Survey questions were developed using an approach similar to that described in the [Report to Congress: Least Burdensome Training Audit](#) and using [Surveys 101: A Simple Guide to Asking Effective Questions](#) by Stephanie Beadell.

II. Background

The evaluation of the ASCA Pilot is intended to support commitment D.8.a. in the MDUFA 4 Commitment Letter- “by the end of FY2022: FDA will have piloted and provided a report on the viability of an ASCA program....”

III. Accreditation Body Survey

Objectives

- **Objective 1:** Determine whether ASCA-recognized accreditation bodies believe the ASCA Pilot is good idea and worth continuing
- **Objective 2:** Determine the experience that ASCA-recognized accreditation bodies have had with the ASCA Pilot

Cohort

All accreditation bodies with *ASCA Recognition* at the time the survey is sent. This cohort includes accreditation bodies whose *ASCA Recognition* has been withdrawn.

Questions

The below questions are being asked to determine the effectiveness of the ASCA Pilot. Your input is important in determining what the ASCA Pilot looks like in the future.

Objective 1: Determine whether ASCA-recognized accreditation bodies believe ASCA Pilot is good idea and worth continuing

| Question | Response Options |
|---|--|
| The ASCA Pilot supports international harmonization by encouraging stakeholders to utilize consensus standards. | Agree, Neutral, Disagree |
| The ASCA Pilot supports conformity assessment activities | Agree, Neutral, Disagree |
| The ASCA Pilot should be continued in MDUFA 5 | Agree- ASCA Pilot should continue as is (write in box for why) Agree, With Changes- ASCA Pilot should continue with some changes (write in box for changes) Neutral Disagree- ASCA Pilot should not continue even with changes (write in box for why) |

| | |
|---|--|
| I would like to participate in the ASCA Pilot if it continues in MDUFA 5 | Yes, Neutral, No |
| The ASCA Pilot would benefit from including additional standards | Agree, Neutral, Disagree |
| I believe the following categories of standards would add value to the ASCA Pilot | Open Ended (may update to include specific options as well as open ended response) |

Objective 2: Determine experience ASCA-recognized accreditation bodies had with the ASCA Pilot

| Question | Response Options |
|--|--------------------------|
| Participating in the ASCA Pilot requires as much work as I expected | Agree, Neutral, Disagree |
| I feel confident that if/when I provide feedback to FDA regarding the ASCA Pilot, FDA will address my concerns | Agree, Neutral, Disagree |
| Information about the ASCA Pilot is easy to locate | Agree, Neutral, Disagree |
| The processes and policies of the ASCA Pilot are well described | Agree, Neutral, Disagree |
| FDA follows the processes and policies of the ASCA Pilot Guidance document | Agree, Neutral, Disagree |

Evaluation Method

Survey results will indicate the frequency of each response for each question. At a minimum, results will be provided separately for (a) all respondents, (b) all respondents currently ASCA-recognized, and (c) all respondents that have ever been withdrawn.

IV. Testing Laboratory Survey

Objectives

- **Objective 1:** Determine whether ASCA-accredited testing laboratories believe the ASCA Pilot is good idea and worth continuing
- **Objective 2:** Determine the experience that ASCA-accredited testing laboratories have had with the ASCA Pilot
- **Objective 3:** Determine the extent to which device manufacturers have used an ASCA-accredited testing laboratory
- **Objective 4:** Determine the perceived impact of the ASCA Pilot on medical device testing

Cohort

All ASCA-accredited testing laboratories at the time the survey is sent. This cohort includes testing laboratories whose *ASCA Accreditation* has been suspended or withdrawn.

Questions

The below questions are being asked to determine the effectiveness of the ASCA Pilot. Your input is important in determining what the ASCA Pilot looks like in the future.

Objective 1: Determine whether ASCA-accredited testing laboratories believe the ASCA Pilot is good idea and worth continuing

| Question | Response Options |
|---|--|
| The ASCA Pilot supports international harmonization by encouraging stakeholders to utilize consensus standards. | Agree, Neutral, Disagree |
| The ASCA Pilot supports conformity assessment activities | Agree, Neutral, Disagree |
| The ASCA Pilot should be continued in MDUFA 5 | Agree- ASCA Pilot should continue as is (write in box for why) Agree, With Changes- ASCA Pilot should continue with some changes (write in box for changes) Neutral Disagree- ASCA Pilot should not continue even with changes (write in box for why) |
| I would like to participate in the ASCA Pilot if it continues in MDUFA 5 | Yes, Neutral, No |
| The ASCA Pilot would benefit from including additional standards | Agree, Neutral, Disagree |
| I believe the following categories of standards would add value to the ASCA Pilot | Open Ended (may update to include specific options as well as open ended response) |

Objective 2: Determine the experience that ASCA-accredited testing laboratories have had with the ASCA Pilot

| Question | Response Options |
|--|--------------------------|
| Participating in the ASCA Pilot requires as much work as I expected | Agree, Neutral, Disagree |
| I feel confident that if/when I provide feedback to FDA regarding the ASCA Pilot, FDA will address my concerns | Agree, Neutral, Disagree |
| Information about the ASCA Pilot is easy to locate | Agree, Neutral, Disagree |
| The processes and policies of the ASCA Pilot are well described | Agree, Neutral, Disagree |
| FDA follows the processes and policies of the ASCA Pilot Guidance document | Agree, Neutral, Disagree |

Objective 3: Determine the extent to which device manufacturers have used an ASCA-accredited testing laboratory

| Question | Response Options |
|---|---|
| To the best of my knowledge, device manufacturers are aware of <i>ASCA Accreditation</i> | Agree, Neutral, Disagree |
| To the best of my knowledge, device manufacturers understand what <i>ASCA Accreditation</i> means | Agree, Neutral, Disagree |
| I have conducted testing for a device manufacturer under the <i>ASCA Pilot</i> | Yes, No |
| I have conducted testing for the following number of device manufacturer(s) under the <i>ASCA Pilot</i> : | 0 1-5 5-10 >10 |
| I have conducted testing for device manufactures I did not work with prior to the <i>ASCA Pilot</i> . | Yes, No |
| The testing I conducted for a device manufacturer was included in a premarket submission to FDA | Yes, No, Unknown, N/A (I have not conducted testing for a device manufacturer under the <i>ASCA Pilot</i>) |
| The testing I conducted for a device manufacturer was used to meet U.S. regulatory requirements beyond FDA (e.g., OSHA, etc.) | Yes, No, Unknown, N/A (I have not conducted testing for a device manufacturer under the <i>ASCA Pilot</i>) |
| The testing I conducted for a device manufacturer was used to meet regulatory requirements of countries and/or jurisdictions outside the U.S. (e.g., CE Mark) | Yes, No, Unknown, N/A (I have not conducted testing for a device manufacturer under the <i>ASCA Pilot</i>) |

Objective 4: Determine the perceived impact of the *ASCA Pilot* on medical device testing

| Question | Response Options |
|--|--------------------------|
| Device manufacturers consider whether a testing laboratory has <i>ASCA Accreditation</i> when selecting a laboratory | Agree, Neutral, Disagree |
| Having <i>ASCA Accreditation</i> has improved my value proposition to device manufacturers | Agree, Neutral, Disagree |

Evaluation Method

Survey results will indicate the frequency of each response for each question. At a minimum, results will be provided for (a) all respondents, (b) all testing laboratories with *ASCA Accreditation* at the time of the survey, (c) all testing laboratories with *ASCA Accreditation* suspended at the time of the survey, and (d) all testing laboratories with *ASCA Accreditation* withdrawn at the time of the survey.