



# Accelerate Sustainable Capability (ASC) Pilot Study: Pilot Site Playbook FAQs

## FAQs

This document provides answers to the most frequently asked questions about the Accelerate Sustainable Capability Pilot Study.

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### What are the pilot eligibility considerations?

- Domestic or Outside the U.S. Manufactures marketing devices in the U.S.
- Must have an established QMS in accordance with 21 CFR Part 820.
- Manufactures meeting the following test case scenarios:
  - **2+ Voluntary Self-Reporting Manufacturers\*** –The manufacturer is self-identifying major deficiencies with the Quality System regulation as defined in the [Compliance Program 7382.845](#).
  - **2+ Manufacturers\* that received an FDA 483 during a recent inspection** – The manufacturer has major deficiencies with the Quality System regulation as defined in the [Compliance Program 7382.845](#) observed during an inspection; with no advisory action by FDA (e.g. WL, UL) or Regulatory Meeting as defined in Chapters 4 and 10 of the [Regulatory Procedures Manual](#).
  - **2+ Manufacturers\* where Agency has issued an Advisory Action or Requested a Regulatory Meeting** – Manufacturer with open Warning Letter, Untitled Letter, or Regulatory Meeting as defined in Chapters 4 and 10 of the [Regulatory Procedures Manual](#).

Note: Sites with a Consent Decree are not eligible for this pilot study.

- See 820.3(o) for definition of a manufacturer

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### How do I apply?

Go to the Medical Device Innovation Consortium (MDIC) website.  
Link: <https://mdic.org/project/case-for-quality-accelerate-sustainable-capability-pilot/>

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<b>Will the status of my enrollment be made public?</b>	A Site’s enrollment will be kept confidential unless it provides permission for its participation in the pilot study to be made public. This option must be selected on the application form linked to the MDIC Site.
<b>What happens if my site is not accepted into the pilot?</b>	MDIC will notify the Site that it was not accepted. It is recommended that applicants should continue engaging as they normally would with the Agency.
<b>What happens if I can’t meet the pilot study expectations after I’ve enrolled?</b>	There is an escalation process built into the pilot process. The Site would notify the MDIC Case for Quality Program Manager (dsteele@mdic.org) that it cannot meet the expectations. If no path forward can be identified, the Site will be removed from the pilot, and engagement with the Agency will follow its normal process.
<b>What is the expected investment by my Site once enrolled? (Time, Effort, Cost)</b>	<p>There is an expectation that the Site will engage fully in the pilot study, this includes the CMMI appraisal, residual risk analysis, action plan, quarterly checkpoints, performance metrics, and FDA follow-up inspection (if applicable).</p> <ul style="list-style-type: none"> <li>• CMMI must be used for the Appraisal and Mgmt-Ctrl must be used for the residual risk assessment tool.</li> </ul> <p>Additionally, regular lessons learned sessions, participant surveys, and pilot study data collection activities will be completed with the Site</p> <p>The Site will be enrolled in the pilot study for approximately 18 months after application approval.</p> <ul style="list-style-type: none"> <li>• Specific sites could take longer to close compliance gaps and /or improvements identified as a part of this pilot. However, pilot data collection will end after 18 months.</li> </ul> <p>The on-site CMMI Appraisal is typically 5 days, with additional time required for planning and post-appraisal activities as needed.</p>

- Appraisal Planning Activities could require 3-5 days for a small number of site resources.

A Site does not have to respond to all identified CMMI and/or Residual Risk tool gaps. It should take all the data provided by the pilot to create an improvement action plan in a way that positively impacts the closure of their compliance gaps and the sustainability of impacted processes.

The cost of the pilot is covered by MDIC. If the Site decides to further engage with Mgmt-Ctrl beyond the residual risk assessment tool or enrolls in a follow-up CMMI appraisal, the Site must cover the cost of this additional work.

**What are the benefits of enrollment?**

MDIC will cover the costs of the CMMI Appraisal and other activities conducted under the pilot. This includes the development of an action plan that is agreed upon with FDA, and that is intended to address any FDA inspectional observations, concerns communicated in FDA advisory actions, CMMI appraisal gaps, and residual risk assessment concerns.

During the pilot study, the FDA intends to forgo planned routine inspections for participating manufacturers; however, the agency intends to continue to conduct “for cause” inspections of such manufacturers as necessary and appropriate. Participants will have the opportunity to complete the improvements to product quality and safety as specified on their action plan.

Additionally, the participating manufacturer may request a Certificate for Foreign Governments (CFG), if needed. The participating manufacturer may request a Certificate of Foreign Governments (CFGs) consistent with the [Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices](#). If the participants request a CFG, they are encouraged to engage with the CDRH’s Case for Quality team [caseforquality@fda.hhs.gov](mailto:caseforquality@fda.hhs.gov) and the Exports Team within CDRH’s Office of Regulatory Programs (ORP), Division of Establishment Support using [exportcert@cdrh.fda.gov](mailto:exportcert@cdrh.fda.gov).

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<p><b>Who were the stakeholders involved in defining the pilot study?</b></p>	<p>The pilot study process was intentionally defined in partnership with both ISACA (i.e., representatives of the Appraiser community) and FDA. Industry, Mgmt-Ctrl, ISACA, CDRH, ORA, MDIC</p>
<p><b>How will my Site’s information be used from the Appraisal and Residual Risk tool?</b></p>	<p>The purpose of this pilot study is to evaluate the effectiveness of the CMMI Appraisal model and the Mgmt-Ctrl residual risk tool at aiding a site in its journey towards compliance and a culture of continuous improvement. Information shared with CMMI Appraisers and Mgmt-Ctrl would remain confidential as maintained by formal agreements with the site.</p>
<p><b>How will pilot participation impact FDA inspections?</b></p>	<p>During the pilot study, the FDA intends to forgo planned routine inspections for participating manufacturers; however, the agency intends to continue to conduct “for cause” inspections in response to safety signals, Class I recalls or Allegations of Regulatory Misconduct of such manufacturers as necessary and appropriate.</p> <p>FDA intends to confirm the adequacy of the corrective actions taken to address the previously cited 21 CFR 820 observations and/or violations through a follow-up inspection, as they normally would, for those participating manufacturers that have an open advisory action (i.e. Warning Letter, Untitled letter) or regulatory meeting. FDA intends to conduct this inspection after the MDIC ASC Pilot Study activities have been completed or when the participating manufacture informs the agency of their readiness to closeout the advisory action (i.e. WL, UL) or regulatory meeting.</p> <p>If the follow-up inspection observes major deficiencies as noted in section A,1 of part V, regulatory/administrative follow up of “Compliance Program Guidance Manual; Inspection of Medical Device Manufacturers” FDA intends to follow the traditional (normal) established process to engage with the manufacturer.</p>

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The MDIC ASC working group will engage with the manufacturer to learn more about what could have been done better as part of the pilot and whether there is a need to add additional PA's into the appraisal process or engage differently with the manufacturers.

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**When can my Site enroll in the CFQ Voluntary Improvement Program (VIP)**

Once a state of compliance has been achieved and the adequacy of the corrective actions is verified through FDA inspection; the Site may seek enrollment into the CfQ VIP program once the program becomes operational, and if the enrollment criteria for the CfQ VIP pilot program have been met.

- **Enrollment Criteria Link** (ISACA Website):  
[https://cmmiinstitute.com/medicaldevice#MDDAP\\_Program\\_Requirements](https://cmmiinstitute.com/medicaldevice#MDDAP_Program_Requirements)
- **Pilot Study Application Link** (MDIC Website):  
<https://mdic.org/project/case-for-quality-accelerate-sustainable-capability-pilot/>

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**How does this connect with other FDA initiatives?**

The ASC pilot study is facilitated by MDIC; FDA and other stakeholders are contributors to this MDIC effort. It leverages learnings from the Case for Quality Voluntary Improvement Program (VIP), but it is a separate activity. Enrollment on the ASC pilot is voluntary and would not preclude the site from enrolling in other pilots or programs (e.g., MDSAP).

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## Contact information

For more information, please contact  
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