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

A Report of the Case for Quality Collaborative Community of the Medical Device Innovation Consortium (MDIC)

January 12, 2021

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GLOSSARY

- **Action Plan** – The manufacturing site’s plan to address the FDA observations/violations, CMMI appraisal gaps, and incorporate Residual Risk Assessment.

- **Broad Agency Announcement (BAA)** – The BAA outlines research areas of interest that will help fulfill the FDA requirements to utilize capabilities for state-of-the-art advancement and achieve improvements in technology, materials, processes, methods, devices, or techniques in specific topics.

- **Compliance Dossier** – Document which lists the compliance gaps, the processes impacted by any enforcement action, and the progress of actions to address these gaps.

- **CMMI** – Capability Maturity Model Integration, is a framework that includes a set of proven best practices grouped into practice areas, as well as a method by which to appraise an organizational unit (project, department, facility, organization, etc.) against any subset of these best practices.

- **ISACA** – Information Systems Audit and Control Association, is the nonprofit organization that owns the IP for the CMMI (model and appraisal method). Manages the quality control of appraisals and appraisers (training, certification, auditing).

- **Appraisal** – An examination of one or more organizational processes by a trained team of appraisers using CMMI as the basis for determining strengths, gaps, and opportunities.

- **Appraiser** – An individual trained in the CMMI framework to understand the model

- **Practice Area (PA)** – A collection of similar practices that together achieve the defined intent, value, and required information described in that practice area.

- **MDIC (Medical Device Innovation Consortium)** – is the first-ever public-private partnership created with the sole objective of advancing medical device regulatory science for patient benefit.

- **Residual Risk Assessment** – product-specific assessment utilizing the residual risk assessment tool developed by Mgmt-Ctrl, Inc. The residual risk assessment measures the ‘state of the art benefit’ of patient safety to provide an indication if the device poses “an unreasonable risk of substantial harm to the public health.”

- **Manufacturer** – Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.
**PILOT STUDY PURPOSE**

The objective of this pilot study is to leverage a quality system maturity and integration approach to provide manufacturers with systemic insight that may improve the effectiveness of the quality system; focus and accelerate improvement efforts to reach a state of sustainable compliance faster; structure systems for continuous improvement; identify objective performance metrics, and develop reports that may provide the agency with the information it needs to oversee product safety throughout the pilot process.

To encourage manufacturers to enroll and participate, this pilot study will cover the costs of the activities listed and defined in this playbook.

**PILOT STUDY SCOPE**

This pilot study is run and facilitated by MDIC. Once enrolled, the pilot will run at a site for approximately **18 months**.

- The pilot study consists of the initial appraisal, residual risk analysis, action plan, quarterly checkpoints, and performance metrics. The organization may choose to continue to fund follow-up appraisals because they see the value.
- All pilot sites must have an established Quality Management System (QMS) (see 21 CFR Part 820).

**INITIAL PILOT STUDY ACTIVITIES**

The following section outlines the initial Pilot Study Activities and their purpose.

**Residual Risk Assessment:**

An external risk assessment will be conducted utilizing the Mgmt-Ctrl, Inc. residual risk assessment tool (Product Specific Assessment).

Publicly available market data will be used to create and compare the overall residual risk experienced with a specific medical device against the risk that is typically found inherent with the use of competitively marketed devices.

The following steps will be used for each pilot participant:

1. An **initial residual risk assessment** using MAUDE data will be completed.
2. Mgmt-Ctrl, Inc. will **provide a heatmap** highlighting ‘red’ products that should be further evaluated (See Figure 1 below).
3. The manufacturing site will **review the heatmap with Mgmt-Ctrl Inc.** to provide any data/context needed (e.g., mapping to FDA product codes) to ensure it accurately
reflects the manufacturer’s products). The use of the residual risk tool is a new activity; therefore, the CfQ Staff at CDRH will also be in attendance to observe and learn from this process.

- **A detailed report will be provided to the site** for any product that is consistently red (Red = Level 3 = > 3 risk indicators = Level of Concern) for the last 13 months. Additionally, a report for any other product that was red at any time during the last 13 months can be requested by the site. (See Figure 2 below)
  - A site, on its own or in collaboration with Mgmt-Ctrl (Optional, fees not covered by pilot), can leverage market share and complaint data to confirm an identified Level of Concern.
  - It is recommended that the manufacture conduct to reconsider the risk control measures associated with a device that has a confirmed ‘Level of Concern’.
  - If safety-related issues demonstrating a ‘Level of Concern’ are observed within the residual risk assessment results, the manufacturer will be asked to engage with the Agency to define a remediation plan. *[Remediation plan could include any combination of responses to the residual risk assessment, from a correction of inaccurate data, an improved risk control measure, etc.]* The remediation plan should be incorporated into the manufacturer’s action plan developed to address identified pilot results (e.g. CMMI, Compliance Residual Risk).
  - Mgmt-Ctrl, Inc. services are optionally available in support of internal risk assessment/response efforts. If requested, the cost for this support would be the responsibility of the manufacturer.
  - **Note:** FDA does not intend to use this assessment as a benchmarking tool between manufacturers. The goal of this pilot is to provide an environment where transparency is encouraged.

4. The heatmap will be shared with the CMMI Appraisers. Products that demonstrate a ‘Level of Concern’ will be considered as an input to the CMMI appraisal scoping activity.
Figure 1: Heatmap Example

![Heatmap Example](image1.png)

Figure 2: Risk Indicators Example

![Risk Indicators Example](image2.png)
CMMI Appraisal:
Manufacturers enrolled in the ASC pilot will engage with the CMMI appraisers through the appraisal process, impact prioritization process, and subsequent quarterly checkpoints. See Figure 3 for a visual depiction of Inputs/Outputs described within the next two sections of the Playbook.

**Figure 3: CMMI Appraisal and Checkpoint Inputs and Outputs**

ISACA will target completion of the appraisal within 90 days after enrollment (or as soon as possible due to the pandemic).

**Appraisal Planning:**
- Manufacturer will complete a standard Compliance Dossier as an input to CMMI Appraisal planning.
- Manufacturer’s residual risk heatmap will be an input to CMMI Appraisal planning (See above).

**Appraisal duration:**
- 5 days is the target for the appraisal team’s time on site, with additional time for planning and post-appraisal activities as needed.
Appraisal Practice Areas (Potential):

<table>
<thead>
<tr>
<th>CMMI Practice Areas</th>
<th>F-Tier 1</th>
<th>F-Tier 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Core</strong></td>
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<td>CM Configuration Management</td>
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<td>GOV Governance</td>
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<tr>
<td>II Implementation Infrastructure</td>
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<tr>
<td>MPM Managing Performance &amp; Measurement</td>
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<tr>
<td>RDM Requirements Development &amp; Management</td>
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<td></td>
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<tr>
<td>RSK Risk &amp; Opportunity Management</td>
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<td></td>
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<tr>
<td><strong>F-Tier 1</strong></td>
<td></td>
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<tr>
<td>CAR Causal Analysis &amp; Resolution</td>
<td></td>
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<tr>
<td>PQA Process Quality Assurance</td>
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<tr>
<td>PI Product Integration</td>
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<tr>
<td>SAM Supplier Agreement Management</td>
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<td>TS Technical Solutions</td>
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<td>V&amp;V Verification &amp; Validation</td>
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<tr>
<td><strong>F-Tier 2</strong></td>
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<tr>
<td>DAR Decision Analysis &amp; Resolution</td>
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<tr>
<td>EST Estimating</td>
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<tr>
<td>MC Monitor &amp; Control</td>
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<tr>
<td>OT Organizational Training</td>
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<td>PR Peer Reviews</td>
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<td>PLAN Planning</td>
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<td>PD Process Asset Development</td>
<td></td>
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<tr>
<td>PCM Process Management</td>
<td></td>
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<tr>
<td>CONT Continuity</td>
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<tr>
<td>SDM Service Delivery Management</td>
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<tr>
<td>STSM Strategic Service Management</td>
<td></td>
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<tr>
<td>SSS Supplier Source Selection</td>
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<tr>
<td>IRP Incident Resolution &amp; Prevention</td>
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</tbody>
</table>

- **Core PA’s** are required. The rest are ‘Flexible’. **F - Tier 1** PA’s must be included unless justification is provided for their removal based upon scoping inputs. **F – Tier 2** PA’s can be added based upon scoping inputs. The Lead Appraiser will work with the Manufacturer to identify which Pas will be included in the Appraisal.

- Each Appraisal will require an Objective Evidence review. The following are options for consideration. The Lead Appraiser will work with the Manufacturer to identify what will be included in the Appraisal.
  - Tour
  - Observing Meetings
  - Metrics Data
  - Systems/Demos
  - Interview
  - Artifact (e.g., documents, spreadsheets, power points, pdf, work boards, etc.)
  - Compliance Dossier

**Appraisal Engagement:**
• ISACA or MDIC will be able to stop the appraisal or other activities at any time in the pilot study process if there is a lack of pilot participant transparency, engagement, or confidentiality. The pilot escalation process defined below should be followed when escalating concerns or issues.

  o Pilot Escalation Process Guidelines:

  1. If any collaborator (e.g. enrolled manufacturer/appraiser/ISACA/MDIC) has a concern, they will address issues directly with the concerning party by communicating the concern and requesting a change. If concerns are not resolved in a timely manner, this could be a cause for escalation.

  2. The concerned collaborator should escalate to the appropriate group for review. The Lead Appraiser will escalate to ISACA and the manufacturer will escalate to MDIC (CfQ Program Director). In both cases, ISACA and MDIC will escalate to MDIC, FDA CfQ Staff, ISACA for review.

Appraisal Schedule:
The CMMI Appraisals are managed per schedule that is documented within the Appraisal Plan. The Appraisal Plan will include the following elements at a minimum:

1. Objective Evidence Reviews
2. Appraisal Kick-off meeting
3. Site Tours
4. Practice Area Interviews
5. Validation Sessions
6. Executive Report-out
7. Final Site-wide Appraisal Report-out
8. On-site Retrospective
9. Quarterly Appraisal Checkpoints

Appraisal Outputs and Information Sharing:
A sub-set of the CMMI Appraisal results will be shared with FDA.

• Overall scores will be sent to FDA (Similar to VIP).

• Scores characterized by PA’s will be sent to FDA (See Figure 1 below)
Note: To better understand the gaps, FDA will leverage the impact prioritization and action plan to gain visibility of the site's intent to do the right thing and remediate the issues/gaps identified.

Note: It must be understood that a ‘Deficient’ score might not have as big an impact, thus not requiring action. “Scores” are simply an indication of whether an organization is meeting the intent of a given practice area in the CMMI model; however, it does not include a weight to determine impact or priority.

**Figure 4: % Practice Area (PA) Characterization Example**

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**Action Plan Development:**
The Site action plan needs to incorporate remediation gaps the participating manufacturer is going to close based on assessments completed; FDA inspection (as applicable), CMMI Appraisal, Residual Risk Assessment.

- **Required domains of knowledge:**
  - **CMMI Appraisal:** The site will have an opportunity to discuss results with the lead appraiser.
  - **Residual Risk Assessment:** The site will have an opportunity to discuss the results with Mgmt-Ctrl.
  - **FDA inspection observations, if applicable:** The site should have the expertise to provide input to this plan. If FDA is needed, the site can opt-in or out to have FDA as a part of the impact prioritization discussion and action plan.
development. This engagement will be with FDA CfQ team members and Office of Health Technology (OHT) reviewers, and ORA.

- **Required Action Plan Elements (Format can vary):**
  - **Prioritization and impact analysis:** Appraisers will work with the participating manufacturer to arrive at the impact and subsequent prioritization of each individual ‘result’ line item.
    - These line items will be grouped into projects by the site (see below).
    - Projects will be prioritized based on a combination of these ‘impacts’.
    - This impact analysis will be started during the appraisal and finished before the 1st checkpoint. (the participating manufacture must have the subsequent action plan complete before the 1st checkpoint.)
  - **Selected Improvement Actions;** (Minimum Requirements)
    - The manufacture will have the responsibility to understand/translate which CMMI Appraisal gaps will have an impact on the speed of closure and sustainability of compliance observations and/or violations.
    - The manufacturer will also have the responsibility to understand/translate potential improvements in response to the residual risk assessment data.
      - Products with confirmed Levels of Concern are inputs to the action plan.
      - Note: In the pilot, we are not looking at residual risk indicators. This is just an additional input we are providing to help inform their action plan. The pilot is not looking for compliance/gaps against the ISO 14971 / TR 24971 / ISO 13485’s regulations/standards.
    - Both CMMI Appraisal gaps & the Residual Risk tool together help an organization focus their efforts on which actions would have a bigger impact on the organization and compliance gap closures.
    - An organization does not have to respond to all red indicators/appraisal gaps. An organization should take all the data provided by the pilot to create an improvement action plan.
    - For non-self-identifying sites, manufacturers are encouraged to also submit a response to the FDA 483 or Warning Letter/Untitled Letter to the Agency as they typically would. Engagement provides the
manufacturer an opportunity to update the Agency on their compliance journey, corrective action plan, and progress.

- The owner, operator, or agent in charge of a device establishment may submit a request for nonbinding feedback to FDA regarding actions the firm has proposed to take to address certain kinds of inspectional observations that have been documented on an FDA 483 and issued to the firm upon completion of an inspection of the firm’s establishment. For more information about the non-binding feedback process, refer to non-binding feedback.

- The MDIC ASC pilot working group will monitor the manufacturer’s response decision if, when, and at what frequency they engage with the Agency throughout the pilot process.

  - **Documented Action Plan (Criteria):**
    - All results from pilot activities (e.g., compliance gaps, residual risk results, appraisal results)
      - Identify projects the organization will be completing.
      - Identify/map how projects will resolve the prioritized gaps/results.
        - One project can address multiple results.
        - Multiple projects can address a single result.
        - Include a rationale for pilot gaps/results that will not be addressed as a part of the action plan — compliance gaps must be addressed.
      - Project milestones.
      - Progress to milestones.
      - Red/Yellow/Green status.
      - Sample Template is available (Optional)
        - How this information is reported may be variable depending on the preferences/existing templates of the site.

**Follow up Appraisal**

**Following the pilot,** the organization may choose to continue to fund follow-up appraisals because they see the value.
Certificate of Foreign Governments (CFGs)

Following the development of the action plan, 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 and the Exports Team within CDRH’s Office of Regulatory Programs (ORP), Division of Establishment Support using exportcert@cdrh.fda.gov.

ONGOING PILOT STUDY ACTIVITIES

The following section outlines the Pilot Study Activities that will continue at a defined cadence after the CMMI Appraisal is complete.

Quarterly Checkpoints:

Pilot Site progress will be monitored quarterly at checkpoints with the Lead Appraiser.

- Quarterly Checkpoint Elements:

  1. **What has changed since the previous checkpoint** that could impact the business, and/or the way work is done.
  2. **Residual risk assessment results**

    - Mgmt-Cntrl will make the risk assessment available to the Lead Appraiser and the manufacturer 1 week prior to the checkpoint.
    - The intent of reviewing residual risk trends is to help identify which improvement actions could potentially have an impact on product safety. Negative trends should be evaluated to ensure control.
      - Note: This is a lagging indicator and changes might not be seen at the next checkpoint.
      - Note: It is recognized that trends may be negative during the transition, but the goal is for the manufacturer to have early visibility to the cause to allow steps to be taken if needed.
    - After Mgmt-Ctrl works with the manufacturer to map products to the appropriate product codes during the initial assessment, a residual risk
assessment can be quickly refreshed without additional input from the manufacture.

3. **Action Plan Status** (R/Y/G) and any plan deviations.
   - The action plan will be finalized at the 1st checkpoint.
   - The site will start tracking against the action plan in the 2nd checkpoint.

4. **Performance Metrics** within the categories of safety, effectiveness, availability, reliability, patient satisfaction, and usability.
   - The specific metrics are to be identified by the site. (A template will be provided.)
   - The introduction of performance metrics will be included in the action planning meetings. Performance metrics should be included as a part of the action plan at the first checkpoint, and the resulting metrics data included in all checkpoints thereafter.
   - The manufacturing site will provide 2 quarters of historical information at the 1st checkpoint, if available.
   - A recommendation is to capture the data monthly if the organization is capable.

- **Expected Checkpoint Timing:**
  - Quarterly is the minimum required frequency. May meet as frequently as desired by participants.
    - Assumption: 3-6 hours in total. This could consist of 1-3 different 2-hour meetings. It can be broken up any way the site would like.
  - The site is to measure the actual checkpoint time required during the pilot (Variation is expected).

- **Expected Checkpoint Format:**
  - It will be a remote/online activity.

- **Checkpoint Outputs and Information Sharing (See Table 1 below):**
  - **Shared with FDA:**
    - After 1st Checkpoint Only - Action Plan will be shared (including impact prioritization).
    - Upon request, FDA intends to provide input into the action plan to ensure compliance observation and/or violations are addressed.
- Action Plan status will be shared (as measured against the initial action plan - red/yellow/green).
- Performance Metrics will be shared.
  - **Shared with CMMI:**
    - Checkpoint Report will be shared. This report documents the conversation between the site and CMMI.
    - Residual Risk Assessment results will be shared.

### Table 1: CMMI Appraisal and Checkpoint Information Flow Summary

<table>
<thead>
<tr>
<th>Activity</th>
<th>Creator Site</th>
<th>Creator CMMI Appraiser</th>
<th>Ctrl-Mgmt</th>
<th>Output Site</th>
<th>Output CMMI</th>
<th>Output MDIC*</th>
<th>Output FDA</th>
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<tr>
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<td>CMMI Appraisal</td>
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<td>PA practices covered</td>
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<td>N</td>
<td>PA Excel Workbook</td>
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<td>Appraisal Results Presentation</td>
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</tr>
</tbody>
</table>

* MDIC will only receive access to de-identified data and some of this data will only be provided upon request. MDIC will not store any data.

### Lessons Learned Data Collection:

Information will be collected from the participating manufacturer at different times throughout the Pilot Study. The collected information will cover all aspects of the pilot through the use of interviews, surveys, and/or other data collection tools. It is important that identified stakeholders are transparent, engaged, and timely with their responses as this will be used to shape the current pilot and future direction of the program. Data will be protected as outlined in the Confidentiality Controls section of this Playbook.
FDA INSPECTION

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. 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.

- 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.

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.

CONFIDENTIALITY CONTROLS

Pilot sites must reach out to the appropriate contact listed below as soon as possible to ensure the necessary master service agreements and confidentiality controls are in place to support the pilot.

MDIC:

This is an MDIC-led pilot and the information provided to MDIC is protected through confidentiality and non-disclosure agreements established between MDIC and the manufacturer. All materials received by MDIC during this Pilot Study will be handled in accordance with confidentiality and non-disclosure agreements executed between MDIC and consistent with MDIC’s policy for the protection against disclosure of non-public information. Manufacturers should mark materials as confidential or as containing confidential commercial information or trade secrets to help identify and communicate that the materials may contain information that should not be disclosed. Initially, MDIC will have access to de-identified data from ISACA and Mgmt-Ctrl, and should there be a need for them to have access to more detailed site data sets this can be requested and the needed CDA activities completed. This allows MDIC access to as much data as needed for the report but prevents the need for
confidentiality agreements should that level of data not be necessary. (MDIC Contact: Desiree Steele - dsteele@mdic.org)

ISACA:
ISACA has been contracted by MDIC to deliver services in this Pilot Study. Any and all information collected is protected through the confidentiality section of the Master Services Agreements established between ISACA and the pilot participants and as defined by the Method Definition Document for all CMMI appraisals. From time to time, ISACA will be required to make a subset of information available to MDIC and FDA, but this will never include trade secrets, intellectual property, or other confidential company or product information. Information shared with MDIC and FDA may include, but is not limited to: a subset of appraisal results (individual and aggregate views), demographic data (company size, location, device class), performance report data (if not shared directly by participants), lessons learned, and program success metrics (adoption, effectiveness, etc.). (ISACA Contact: Kim Kaplan - kkaplan@cmmiinstitute.com)

Mgmt-Ctrl (MC):
Mgmt-Ctrl has been contracted by MDIC to deliver services in this Pilot Study. Any and all information collected is protected through the confidentiality section of the confidentiality agreements established between Mgmt-Ctrl and the pilot participants. From time to time, Mgmt-Ctrl will be required to make a subset of information available to MDIC and FDA, but this will never include trade secrets, intellectual property, or other confidential company or product information. Information shared with MDIC and FDA may include, but is not limited to Residual Risk Report (4 indicators) and the heat map. (Mgmt-Ctrl Contact: Larry Mager - larry@mgmt-ctrl.com)

FDA:
All materials received by FDA during this Pilot Study will be handled consistent with all applicable protections, procedures, and legal requirements that protect against disclosure of non-public information (See e.g., 21 U.S.C. §§ 331(j) and 360j(c), 18 U.S.C. § 1905, and 21 C.F.R. Part 20). This includes protection of information considered to be trade secret and confidential commercial information (“CCI”) as those terms are defined in 21 C.F.R. § 20.61. The protection of this information is of the utmost importance to the Agency. Like all information shared with FDA, information shared throughout the pilot is subject to the Freedom of Information Act.
(“FOIA”) (5 U.S.C. § 552). Processing of FOIA requests will not differ from FDA’s typical FOIA process. FDA reviews all responsive records prior to release to redact information pursuant to FOIA and its regulations in 21 C.F.R. part 20. Participant should mark materials as confidential or as containing CCI or trade secret to help flag that the materials may contain information that should not be disclosed.

**RULES OF ENGAGEMENT ON SAFETY ISSUES**

- The manufacturer understands that they are responsible for complying with all applicable laws and regulations, including the Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations (e.g., 21 CFR 803, 806, 807, 820, etc.), before, during, and after their participation in the pilot.
- MDIC may remove a participant manufacturer from the pilot, as described in the [CMMI Appraisal and Quarterly Checkpoints](#) document. After removal from the pilot, the manufacturer would engage with the Agency utilizing the traditional (normal) process established.
- As required by 21 CFR 806, the manufacturer understands that they are responsible for reporting certain actions concerning device corrections and removals throughout the pilot study. In addition, manufacturers may send a courtesy notification to the Case for Quality Staff at [Caseforquality@fda.hhs.gov](mailto:Caseforquality@fda.hhs.gov) regarding issues in their products, signals, or recalls. FDA (CfQ Staff, OHTs and ORA) intends to proactively engage and interact with the manufacturer to mitigate risks to health posed by the device, unless the issue involves [Allegations of Regulatory Misconduct](#). FDA intends to follow its current defined process to follow up on [allegations of regulatory misconduct](#).
- FDA is a regulatory agency with an established mandate to protect the public health. The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. A manufacturer’s participation in this pilot program does not prevent FDA from citing particular inspectional observations during inspections or otherwise taking regulatory action when appropriate.
- As required by 21 CFR part 803, the manufacturer understands that they are responsible for reporting deaths and serious injuries that a device has or may have caused or contributed to the pilot study. In addition, the manufacturer may also send a courtesy notice to the Case for Quality Staff at [Caseforquality@fda.hhs.gov](mailto:Caseforquality@fda.hhs.gov). FDA (CfQ Staff, OHT
and ORA) intends to work interactively with the manufacturer to address any issues noted.

**FAQs**

This section provides answers to the most frequently asked questions.

| 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: |
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<td></td>
<td>• <strong>2+ Voluntary Self-Reporting Manufacturers</strong>* — The manufacturer is self-identifying major deficiencies with the Quality System regulation as defined in the <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-program-7382-845">Compliance Program 7382.845</a>.</td>
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<td>• <strong>2+ Manufacturers</strong>* that received an FDA 483 during a recent inspection — The manufacturer has major deficiencies with the Quality System regulation as defined in the <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-program-7382-845">Compliance Program 7382.845</a> 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 <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-procedures-manual">Regulatory Procedures Manual</a>.</td>
</tr>
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<td>• <strong>2+ Manufacturers</strong>* 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 <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-procedures-manual">Regulatory Procedures Manual</a>.</td>
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Note: Sites with a Consent Decree are not eligible for this pilot study.

| 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/](https://mdic.org/project/case-for-quality-accelerate-sustainable-capability-pilot/) |

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*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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<th>Question</th>
<th>Answer</th>
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<td>Will the status of my enrollment be made public?</td>
<td>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.</td>
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<td>What happens if my site is not accepted into the pilot?</td>
<td>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.</td>
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<td>What happens if I can’t meet the pilot study expectations after I’ve enrolled?</td>
<td>There is an escalation process built into the pilot process. The Site would notify the MDIC Case for Quality Program Manager (<a href="mailto:dsteele@mdic.org">dsteele@mdic.org</a>) 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.</td>
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| What is the expected investment by my Site once enrolled? (Time, Effort, Cost) | 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).  
  - CMMI must be used for the Appraisal and Mgmt-Ctrl must be used for the residual risk assessment tool.  
  
  Additionally, regular lessons learned sessions, participant surveys, and pilot study data collection activities will be completed with the Site.  
  
  The Site will be enrolled in the pilot study for approximately 18 months after application approval.  
  - 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.  
  
  The on-site CMMI Appraisal is typically 5 days, with additional time required for planning and post-appraisal activities as needed. |
• 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 and the Exports Team within CDRH’s Office of Regulatory Programs (ORP), Division of Establishment Support using exportcert@cdrh.fda.gov.
Who were the stakeholders involved in defining the pilot study?
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

How will my Site’s information be used from the Appraisal and Residual Risk tool?
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.

How will pilot participation impact FDA inspections?
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.

FDA intends to confirm the adequacy of the corrective actions taken to address the previously cited observations and/or violations through a follow-up inspection. Specifically, FDA intends to conduct an inspection after the MDIC ASC Pilot Study activities have been completed.

• Following the pilot, the Agency intends to follow its normal processes when creating the work plan and determining when the manufacturer will be inspected.

If the follow-up inspection observes major deficiencies as noted on 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 pathway to engage with the manufacturer. If this situation does occur, the MDIC ASC Working Group intends to engage
with the manufacturer to learn more about what could have been done better and whether there was a need to add additional PA’s into the appraisal process or engage differently with the manufacturers.

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<th>When can my Site enroll in the CFQ Voluntary Improvement Program (VIP)</th>
<th>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.</th>
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|  | • **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/](https://mdic.org/project/case-for-quality-accelerate-sustainable-capability-pilot/) |

| 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). |
Contact information

For more information, please contact Alan Baumel at abbaumel@mdic.org