



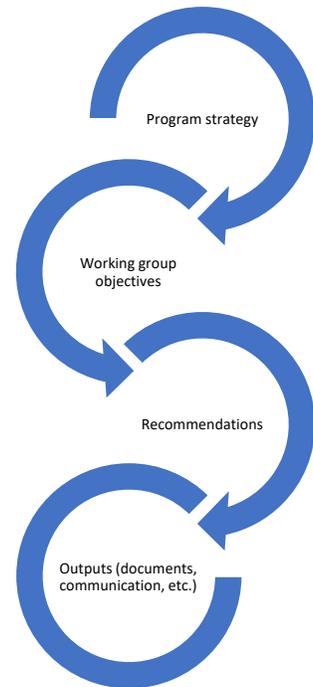
Case for Quality Voluntary Improvement Program Strategic Plan – 2021

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I. Overview

This document describes the overall strategic plan as defined by the Case for Quality Collaborative Community (CfQcc) Voluntary Improvement Program (VIP) Governing Committee (GC). The Program's strategic objectives are then filtered into Working Group (WG) objectives. The WGs will create recommendations and outputs (i.e., documents, communication, etc.) to achieve those objectives. Updates on the CfQcc VIP will be provided in MDIC public forums throughout the year.



II. Program Strategic Objectives

The following are the CfQcc VIP objectives for 2021:

- Align CfQcc VIP Governing Committee structure with CfQcc VIP Program Charter approved December 2020. (2021 Q2)
- Complete update to Concept of Operations for CfQcc VIP (2021 Q2)
- Transition from pilot to program via formal public announcement (2021 Q2)
- Further develop aspects of the program through WGs (2021 Q4)
 - Define CfQcc VIP WG activities (2021 Q1)
 - Define topics within/outside the scope of work for CfQ VIP WG (2021 Q2)
- Continue to enroll new sites into the program (2021 Q4)

III. Active Working Group Objectives

WG objectives are categorized as follows:

- 1.X = short-term
- 2.X = long-term
- 3.X = parking lot

Regulatory Benefits

1.1 Objective: To identify, develop, test, and finalize any additional regulatory benefits in consideration for participants of the Program.

- 1.1 Target Date:
 - CY 2021 Q2/Q3
- 1.1 Deliverables:
 - Identify in a final report the effectiveness of regulatory benefits achieved in VIP (for both manufactures and FDA).
 - Investigate gaps in knowledge for how to use VIP regulatory benefits.
 - Define guidelines for when and how to use regulatory benefits considerate of industry and FDA.
 - Update VIP 30-day change notice template.

- Update VIP 180-day site change submission template.

2.1 Objective: Identify, develop, test, and finalize new regulatory benefits in the Program.

- 2.1 Target Date:
 - CY 2021 Q3/Q4
- 2.1 Deliverables:
 - Investigate and potentially develop a VIP design change benefit.
 - Investigate and potentially develop a VIP 510(k) benefit.
 - Investigate and potentially develop a VIP contract manufacturer benefit.
 - Investigate opportunities for new VIP regulatory benefits.

Success Criteria:

- WG has defined a regulatory benefit development lifecycle (including a pilot phase).
- WG has developed clear guidelines for applying new and existing regulatory benefits, tools, and templates.
- WG has defined success metrics for benefits.
- WG is tracking success metric actuals against targets.
- WG considers a variety of regulatory benefits.

Accomplishments:

- Reviewed, tested, and provided input to the current revisions of:
 - Streamlined 30-day change notice document
 - Streamlined site transfer submission
 - Streamlined original PMA manufacturing module

Performance Measures

1.1 Objective: Clarify performance report activity, value, and expectations.

- 1.1 Target Date:
 - CY 2021
- 1.1 Deliverables:
 - Define the intent of collecting performance metrics in the performance report.
 - Provide guidelines to organizations in identifying which metrics to share that best meet the intent of the performance report.
 - Investigate potential case study opportunities.

2.1 Objective: Define correlations between the performance report and the CMMI model.

- 2.1 Target Date:
 - CY 2021
 - *Need to further define in 2021, identify partner to do heavy lifting, WG to review*
- 2.1 Deliverables:
 - Investigate any correlations performance measures and model capabilities.
 - Test the program hypothesis (continuous improvements against the CMMI model will help organizations improve their performance and product quality).

3.1 Objective: Implement improvements to the performance report template and process.

- 3.1 Target Date:
 - N/A
- 3.1 Deliverables:

- Re-evaluate the seven domains of quality provided by the MDIC Analytic Outcomes working group.
- Investigate a method of sharing an industry performance benchmarking view for organizations.

Success Criteria:

- WG has developed clear guidelines and case studies for how to use the performance report and identify metrics that best meet the intent of the performance report.
- WG has investigated correlations between the performance report and the CMMI model.
- WG considers and incorporates improvements to the performance report template, process, and data analysis methodologies.
- WG actively collaborates with other WGs as needed.

Accomplishments:

- Shared performance report data.
- Analyzed overall submissions for themes.
- Reviewed initial guidelines.
- Helped shift participants from compliance-oriented metrics to quality-oriented metrics.

Sunset Condition:

- If/when able to converge with MDIAS.

Reappraisals

1.1 Objective: Identify the nuances of conducting reappraisals.

- 1.1 Target Date:
 - CY 2021 Q2
- 1.1 Deliverables:
 - Define guidelines for considering multi-site appraisals across Y2+ sites.
 - Collaborate with the Multi-Site Appraisals WG.
 - Define guidelines for completing quarterly check points for reappraisals, including the submission of the performance report.
 - Collaborate with the Performance Measures WG.
 - Define guidelines for a reappraisal improvement journey.

1.2 Objective: Investigate the incorporation of virtual activities in reappraisals.

- 1.2 Target Date:
 - CY 2021 Q2
- 1.2 Deliverables:
 - Define guidelines for when and how to leverage a virtual, onsite, or mixed virtual/onsite approach in reappraisals during COVID-19 and post-pandemic.

2.1 Objective: Identify the broader program requirements for reappraisal activities.

- 2.1 Target Date:
 - CY 2021 Q4
- 2.1 Deliverables:
 - Define guidelines for reappraisal activities as it relates to regulatory benefits.
 - E.g. greater transparency, selection of PAs, objective evidence.
 - Collaborate with the Regulatory Benefits WG.

- Define requirements for post-appraisal engagement and escalation points.
- Define guidelines for when/how the frequency/approach of reappraisals can change in relation to other program engagement activities.
 - Collaborate with the Performance Measures WG.
 - Collaborate with the Regulatory Benefits WG.

Success Criteria:

- WG has developed clear guidelines for conducting reappraisals.
- WG has provided a recommendation to the VIP GC regarding program requirements for reappraisal activities and engagement.

Accomplishments:

- Considered flexible tailoring of PAs in Y2.
- Added value with documented objective evidence in Y3.
- Discussed breadth of org scope vs depth of evaluation.
- Drafted initial reappraisal guidelines.

Multi-Site Appraisals

1.1 Objective: Complete a retrospective analysis of previous multi-site appraisals.

- 1.1 Target Date:
 - CY 2021
- 1.1 Deliverables:
 - Gather, collect, analyze the experience (participants and appraisers) with the multi-site appraisals.
 - Identify in a final report the quantitative and qualitative outcomes and what was effective or not.

1.2 Objective: Investigate the incorporation of virtual activities in multi-site appraisals.

- 1.2 Target Date:
 - CY 2021
- 1.2 Deliverables:
 - Define guidelines for when and how to leverage a virtual, onsite, or mixed virtual/onsite approach in multi-site appraisals during COVID-19 and post-pandemic.

1.3 Objective: Investigate why sites choose (not) to participate in multi-site appraisals.

- 1.3 Target Date:
 - CY 2021
- 1.3 Deliverables:
 - Investigate in a final report the decision of both single sites and multi-site Sponsors and Coordinators.

2.1 Objective: Identify the nuances of conducting multi-site appraisals with reappraisals.

- 2.1 Target Date:
 - CY 2021
- 2.1 Deliverables:
 - Define guidelines for when and how multiple sites can be considered in a single appraisal.

- Define guidelines for considering multi-site appraisals after individual baseline appraisals have been completed.
- Define guidelines for considering multi-site appraisals across Y1 and Y2+ sites.
 - Collaborate with the Reappraisals WG.
- Define guidelines for considering a multi-site appraisal when some PAs may not apply to all sites.
- Define guidelines for completing quarterly check points for multi-site appraisals, including the submission of the performance report(s).
 - Collaborate with the Performance Measures WG.
- Define guidelines for the delivery of combined and distinct appraisal results in multi-site appraisals.

Success Criteria:

- WG has developed clear guidelines for conducting multi-site appraisals.
- WG defines the outcomes of both successful and failed multi-site appraisals.

Accomplishments:

- Reviewed previous multi-site appraisals.
- Defined conditions for approach to be considered.
- Drafted initial set of guidelines.

Medical Device Context

1.1 Objective: To define, build, and formally develop the additional CMMI model context to support the intended tailoring for the medical device industry.

- 1.1 Target Date:
 - CY 2021 Q1/Q2
- 1.1 Deliverables:
 - Complete the development of RDM and EST context.

1.2 Objective: Develop broader continuous improvement context that is not specific to a PA.

- 1.2 Target Date:
 - CY 2021 Q2/Q3
- 1.2 Deliverables:
 - Define guidelines for general continuous improvement efforts.

2.1 Objective: Evaluate opportunities to develop context that can (1) support industry in adopting CMMI continuous improvement opportunities and/or (2) support appraisers in evaluating industry.

- 2.1 Target Date:
 - CY 2021 Q3/Q4
- 2.1 Deliverables:
 - Analyze appraisal data for trends that may be opportunities to develop context.
 - Solicit industry and appraiser feedback for opportunities to develop context.
 - Investigate in a final report any opportunities to develop context across different categories of industry.
 - Contract manufacturing, sterilization, design, class, size, location, etc.

- Investigate in a final report any opportunities to develop context for reappraisals and multi-site appraisals.
 - Collaborate with the Reappraisals WG.
 - Collaborate with the Multi-Site Appraisals WG.
- Investigate in a final report any opportunities to develop context for different practice group levels within various PAs.
- Develop a change request board for new opportunities to develop context.

2.2 Objective: Evaluate the effectiveness of medical device context.

- 2.2 Target Date:
 - CY 2021 Q4
- 2.2 Deliverables:
 - Identify in a final report effectiveness of different mechanisms to share information regarding the context being developed by the WG.
 - Identify in a final report the effectiveness of context developed by this WG.

Success Criteria:

- WG has defined success metrics for context.
- WG is tracking success metric actuals against targets.

Accomplishments:

- Identified PAs for which stakeholders most desired context.
- Began collecting potential content.

Sunset Condition:

- If stakeholders do not see value in PA context.

IV. Retired Working Group Accomplishments

Program Features

Objective:

- To identify, develop, test, and finalize new desired features of the Program, as well as identify, analyze, and resolve any undesirable features of the Program.

Accomplishments:

- Updated the MDDAP Internal Appraisal Team Member certification pathway
- Outlined draft of a “Rainy Day” policy

EU Agencies

Objective:

- To explore and identify approaches to share the value and success of the Program with EU Agencies, EU medical device groups and associations, and EU device makers.

Accomplishments:

- Outlined the high-level approach to have VIP considered by European regulators
- Identified initial inroads to pursue

Notes:

- Participants can continue this work unofficially

V. Plan Approvals:

Revision	Approver	Date
A	CfQ VIP Governing Committee	