MDIC Governance Survey Results

November 28, 2018
Introduction

In preparation for CY2019, a survey concerning the development of a governance structure for a voluntary CDRH Quality Maturity Program using the Medical Device Discovery Appraisal Program was performed.

The purpose of the survey was to gain insights on the strategy for future governance of the program as it transitions from pilot to an official FDA program established to continuously learn, adapt, and evolve to meet the challenges in the increasing complexity of the medical device ecosystem.
Survey Results
Which Best Represents You?

Survey results indicate that more than **52 percent** of the participants who participated in the survey identified as a Pilot Participant.

n=48
Survey Results
Should a separate governance group be established specifically for this Program?

• Over **43 percent** of the responses indicated that the current structure under the CfQ is sufficient while roughly **23 percent** of participants would like to see a new governance group to be established.

• The majority of Pilot Participants and CMMI Institute Reps indicated that the current structure is sufficient.
Survey Results
What should be the main purpose(s) of a governance group that would oversee the Program?

- Facilitate active collection of feedback and interactions with relevant stakeholders; Collective data, decisions, activities, and objectives should be transparent to relevant stakeholders at an appropriate cadence
- Patient safety and improved health outcomes are primary objective, followed by maximizing value to all stakeholders.
- Encourage and facilitate partnerships and collaboration
- Collectively set improvement priorities, safety objectives, and program goals
- Provide prioritization and integration of various Case for Quality activities
- Must account for iterative learning and rapid program adjustment to maintain relevance
- Write-In Comments

Approximately 60 percent selected the top 3 purposes and 48 percent selected all six.
Survey Results

Should a new governance group report to the CfQ Steering Committee or directly to MDIC Board independent of Case for Quality?

- **35 percent** of responses were non-applicable
- **31 percent** of responses believe the Governing Committee should report as a subcommittee to the Case for Quality Steering Committee
- **21 percent** of responses believe the Governing Committee should report to the MDIC Board
Survey Results

Based on your current understanding of the pilot, who should be involved in a governance group, and specifically, key Program decisions?

<table>
<thead>
<tr>
<th>Role</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td>46</td>
</tr>
<tr>
<td>Program Participants</td>
<td>36</td>
</tr>
<tr>
<td>CMMI Institute</td>
<td>35</td>
</tr>
<tr>
<td>CMMI Appraisers</td>
<td>28</td>
</tr>
<tr>
<td>MDIC members</td>
<td>22</td>
</tr>
<tr>
<td>Medical Device healthcare ecosystem stakeholders (e.g. non-manufacturers)</td>
<td>17</td>
</tr>
<tr>
<td>Non-Participant Industry Organizations</td>
<td>6</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
</tr>
</tbody>
</table>

- Roughly **96 percent** of the responses indicated that the FDA should be involved.
- **75 percent** want program participants included in the governance group.

![Bar chart showing the distribution of responses for each role.](chart.png)
Survey Results
How many members should be part of a new governance group?

- **46 percent** of the survey participants agreed that between 5 to 9 members should be part of the new governance group.
- **19 percent** of the respondents agreed that the new governance group should have 11 to 15 members.
- **21 percent** of respondents chose not applicable because they felt the current CfQ Steering Committee is sufficient.
Survey Results

Should a new governance group also include membership from select industry trade associations that represent various industry subsectors?

- The majority of respondents, 48 percent, agreed that membership for a new governance group should include industry trade associations that represent various industry subsectors such as AdvaMed.
- 39 percent agreed that none of the options provided in the survey should be included in the new governance.
Survey Results
A new Program Charter should be created in CY2019.

- The majority of respondents (58 percent) agree that a new charter should be created in CY 2019.
Survey Results
Should sub-group(s) be created for any of the following?

- **Sustainability** (responsible for growth and sustainability of the program): 21 votes
- **Communications** (responsible for internal and external communications associated with the program): 19 votes
- **Charter** (responsible for reviewing the charter and recommending any necessary changes on an annual basis): 14 votes
- **None required**: 13 votes
- **Other (please write in)**: 12 votes

- The majority of respondents, **48 percent**, agreed that a sustainability sub-group should be created.
- **43 percent** of respondents agreed that a communications sub-group should be formed.
- **32 percent** agreed that a charter sub-group should be created.
- **30 percent** of respondents felt that not additional sub-groups should be created.
## Survey Results

What should be the name of the program starting in CY2019 or are there certain key principles that should be captured in the name of an official program?

<table>
<thead>
<tr>
<th>Name of Program</th>
<th>Number of Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device Discovery Appraisal Program (MDDAP)</td>
<td>14</td>
</tr>
<tr>
<td>Medical Device Maturity Appraisal Program (MDMAP)</td>
<td>11</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
</tr>
<tr>
<td>Quality and Capability Maturity Appraisal Program (QCMAP)</td>
<td>5</td>
</tr>
<tr>
<td>Quality Maturity Appraisal Program (QMAP)</td>
<td>5</td>
</tr>
<tr>
<td>Medical Device Quality Maturity Appraisal Program (Medical Device QMAP or MDQMP)</td>
<td>3</td>
</tr>
<tr>
<td>Voluntary Medical Device Manufacturing and Product Quality Program (VMDMPQP)</td>
<td>2</td>
</tr>
<tr>
<td>Medical Device Quality and Capability Maturity Appraisal Program (Medical Device QCMAP or MDQCQM)</td>
<td>1</td>
</tr>
</tbody>
</table>
Survey Results
What should be the name of the program starting in CY2019 or are there certain key principles that should be captured in the name of an official program? (Cont.)

- The majority of the Pilot Participants agreed that the program should be called MDMAP
- The majority of respondents agree that the program should be called MDDAP
- The majority of the MDIC Steering Committee, and the FDA agree that the program name should be changed to QMAP