FDA | U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Summary of *Fostering Digital Health Innovation: Developing the Software Precertification Program* Public Workshop Day Two Breakout Sessions on January 31, 2018

Introduction

The second day of the *Fostering Digital Health Innovation: Developing the Software Precertification Program* public workshop was dedicated to "Co-Creating the Program" with attendees. As outlined in the Digital Health Innovation Action Plan, this unique pilot program will be designed as a collaborative effort between the FDA and stakeholders so that the new regulatory pathway for software can best suit the interests and needs of our customers.

The purpose of this part of the workshop was to gather public feedback and input on the Software Precertification Pilot Program development by having the attendees serve as the "tenth" pilot participant. The day was divided into the following breakout sessions:
1. Enablers of Excellence
2. Measuring Results
3. Review of Sample Dashboards and Scorecards

The following is a summary of the discussions that took place during the breakout sessions.

Breakout Session One: Enablers of Excellence
Overview and Summary

The first breakout session was focused on identifying enablers of excellence in organizations and supporting metrics. Attendees were divided into subgroups that each focused on one of five discussion topics: Partnerships and Resources, People, Processes, Leadership, and Strategy.

Enabler	Definition*
Partnerships & Resources	Excellent organizations develop and manage external partnerships, suppliers and internal resources to support organizational strategies, policies, and effective operations. Systematic

	gap analyses inform efforts to develop internal and external resources needed to meet the mission and vision of the organization.
People	Excellent organizations value employees and create a culture that supports mutual development of organizational and personal goals. Employees have opportunities for development, and are recognized for demonstration of excellence.
Processes	Excellent organizations design, manage and improve processes, products and services to generate increasing value for customers and other stakeholders.
Leadership	Excellent organizations have leaders who shape the future of an organization, and model its ethical and responsible commitment to the principles of user safety and product quality, inspiring trust at all times. Leaders are flexible and adaptive, ensuring responsiveness to changing customer and societal needs.
Strategy	Excellent organizations develop and implement their mission and vision by focusing on user needs and the advancement of public health. Policies, plans, objectives and processes are developed and deployed to inform and drive the strategic goals of the organization.

*Adapted from European Foundation of Quality Management (EFQM) Enabler Definitions

Goals of Breakout Session One:
- To identify enabler characteristics that are representative of a digital health organization; and
- To identify metrics by which organizations can assess whether activities supporting such enablers are of value and are being consistently implemented.

Summary of Discussion from Breakout Session One:
The following notes capture the discussion of the meeting attendees and are not a reflection of FDA's position, nor necessarily of all the attendees collectively.

Partnerships and Resources
- Comments from attendees suggested the importance of companies having a systematic framework for creating partnership and resources.
- Within a network of partnerships, attendees felt like it was necessary to cultivate diversity, quality, and transparency amongst these partnerships. A score card or other ongoing periodic assessment of partnerships would be an example of a good practice.
- Comments from attendees suggested that relationships with partners and suppliers should be well managed, well developed, maintained, and transparent.
- Due to the variability of company types/sizes, attendees agreed on the importance of a scalable metric to fit different company types/sizes.

People
- Comments from attendees agreed that an open, transparent, employee-centric work culture was integral to the success of a company to include:
  - A work culture that makes employees feel valued;
  - Defined and effective communication channels;
  - Proper employee performance goals assessed at regular intervals;
  - Promotion criteria aligned with organizational priorities and values;

- o Performance ratings tied back to excellence principles and reflect the knowledge and capabilities of employees; and,
- o Performance assessments that include opportunities to develop new goals and skill sets.

Processes
- Attendees highlighted *processes* that aim to consistently produce safe and effective products, systems, and services that meet their intended use.
- Attendees commented that small companies may find it easier to build processes into their system. Scaling to size should not lower the bar for smaller companies.
- Attendees suggested that user feedback will be helpful to incorporate back into organizational processes.

Leadership
- Attendees expressed a need for a clear definition of leadership to be applied to companies of all sizes.
- Attendees suggested that a leader in a small company may be one person. who is easily accessible; yet in a larger company, there may be more people considered leaders that are harder to reach.
- Attendees iterated repeatedly that clear, scalable channels of communication to company leaders are important.
- Attendees believed that leaders ought to value safety, quality and patient satisfaction more heavily than profit in the company's mission and values. Leaders are also responsible for creating an employee culture of agility and continuous learning.

Strategy
- Attendees identified the following as characteristic of a good strategy:
  - o Adaptive to new stakeholder needs and requirements;
  - o Communicated and easily understood by both internal and external stakeholders;
  - o Includes a risk assessment component;
  - o An evaluative mechanism that establishes appropriate metrics to measure success;
  - o Scalable to varying companies; and,
  - o Clear channels to articulate, communicate, and measure whether the strategy is being properly implemented to meet stakeholder requirements and needs.
- Attendees suggested that company strategies are heavily dependent on regulatory decisions and that company strategies are constantly evolving, which may make it challenging to consistently communicate the current state of a strategy on an ongoing basis.

Additional General Comments
- Attendees suggested that "sustainability" could be an enabler of excellence category and should include the management of partners, suppliers, and communication.

Breakout Session Two: Measuring Results
Overview and Summary

The second breakout session focused on identifying downstream outcomes and results that would be indicative of an excellent Digital Health organization. Attendees were divided into subgroups that each focused on one of four discussion topics: Customers, People, Society, and Business.

Results	Definition*
Customers	Excellent organizations achieve and sustain outstanding results that meet or exceed customer needs and expectations.
People	Excellent organizations demonstrate success in recruitment, retention, and inspiration of employees to advance the mission and vision of the organization.
Society	Excellent organizations improve public health by developing safe and effective SaMD products that deliver value to users, patients, and healthcare systems.
Business	Excellent organizations achieve and sustain outstanding business results, evolving to adapt to changing stakeholder needs.

* Adapted from European Foundation of Quality Management (EFQM) Enabler Definitions

Goals for Breakout Session Two:
- To identify additional performance and perception metrics for result categories not identified through pilot participant site visits; and
- To indicate how the outcomes and results tie back to the drivers of excellence as well as the excellence principles.

Summary of Discussion from Breakout Session Two:
The following notes capture the discussion of the meeting attendees and are not a reflection of FDA's position nor necessarily of all the attendees collectively.

Customer
- Attendees suggested that the definition of "customers" be clarified, with consideration given to the full scope of the term, which may include users, payers, and other stakeholders.
- Attendees noted that while brand reputation is important to an organization, it is subject to external manipulation by competitors, skews to favor well-established organizations, and may be less relevant as a measure for the FDA.
- Attendees suggested that it may be difficult for start-up organizations to produce any relevant customer outcomes, as these metrics tend to be focused on response to marketed products.
- Attendees commented that many organizations struggle to incorporate customer views and impact into executive decision making.

People
- Attendees expressed concern that collecting and sharing a broad array of human resources and employee metrics may make the precertification process more burdensome that the current regulatory system.

- While having the right employee talent and a culture of quality is important to an organization, attendees noted that it was unclear how these metrics map to the excellence principles for FDA.
- While talent is often related to organizational performance, measuring talent and retention may bias against smaller organizations and those with dispersed or outsourced workforce.
- Attendees suggested that some metrics in this domain may be dependent on factors or influences external to an organization.

Society
- Attendees suggested that excellent organizations should be focused on advancement of public health, but disagreed about whether organizations should be required to publicly report these metrics.
- Attendees noted that patient safety as related to cybersecurity threats may be considered a public health measure, and should be tracked and reported by excellent organizations.
- Attendees noted that younger organizations may have few societal results to demonstrate because societal or public health outcomes are often significantly time-delayed, even those with marketed products.
- Attendees recommended that society and public health outcomes should include measures including accessibility, time to adoption, interoperability with existing systems, and user retention.

Business
- Attendees suggested that limited finances may make it difficult for small companies to become "pre-certified". A smaller company or startup may not have the financial capability to meet metrics for market share, growth, and investment in innovative technologies.
- Attendees recommended that FDA focus more on adequacy of resources and facilities, rather than on absolute values, as a small company or startup may have fewer resources and still achieve excellent results.
- Attendees suggested that while many metrics like year over year market growth, product defect rates, and product return rates are applicable, they could be collected only during post-market analysis.
- Attendees noted that metrics like market valuation, market penetration, and financial leverage ratios appear to be more relevant for internal business evaluation rather than for FDA precertification.

Breakout Session Three: Review of sample dashboards and scorecards
Overview and Summary

The third breakout session of the Fostering Digital Health Innovation Public Workshop was focused on the review of sample dashboards/scorecards and discussion over solving problem statements on evidence generation, evidence collection, and aggregation methodologies. Attendees were divided into subgroups that each focused on one of five discussion topics: Bounds of Pre-Cert, Considering Tiers for Pre-Cert, Mapping and Aggregation, Reducing Regulatory Burden, and Weighting and Measuring Thresholds.

*Please view slides 36 – 56 for the Scorecard Concepts in Break-out session Materials

Goals of Breakout Session Three:
- Discuss the benefits and risks of requiring organizations to meet a minimum threshold or score for each excellence principle;
- Discuss the benefits and risks of implementing a staged or tiered approach to precertification, and the criteria on which tiers might be based;
- Identify methods for the FDA to aggregate KPI scores across the excellence principles; and
- Identify types of evidence that would align with existing data collection practices for digital health organizations.

Summary of Discussion from Breakout Three:
The following notes capture the discussion of the meeting attendees and are not a reflection of FDA's position nor necessarily of all the attendees collectively.

Bounds of Pre-Cert
- Attendees suggested that a device-specific scorecard template may be developed to include items in breakout session one. Supplier management and verification, diversity and number of communication channels, and number of adverse events may be metrics for the scorecard.
- Attendees suggested that if a company does not have a product in the market they will need to have a strategic plan to collect data.
- An outstanding question attendees raised was:
  - Can larger companies that are already successful in another space get "pre-certified" and then design a prototype?

Considering Tiers for Pre-Cert
- Attendees emphasize that the precertification scope needs to be clearly defined; specifically, the definitions of each phase, hierarchy, and category.
- Attendees suggested that a self-assessment process could potentially help companies determine their staging status. Attendees also suggested that this assessment could be developed with a third party and could assess metrics based on validation, transparency, reliable partnerships, safety responses, processes etc. A startup that may not have all their processes in place may benefit from staging versus using tiers.
- Attendees commented that a product's risk assessment is a critical factor to creating meaningful tiers.
- Attendees suggested that a clear, traceable post-market surveillance plan for outcome assessment and integration be a factor in determining tiers.
- Attendees believe there needs to be clarity around defining business or business units, the product or product team. For instance, how does an enterprise organization that is acquiring companies all the time become "pre-certified"?

Mapping and Aggregation
- Attendees suggest that Key Performance Indicators (KPIs) be used consistently across all "pre-certified" companies and can transition through company growth. It's important to understand the variance/disparities between the companies to evaluate its improvements.

- Attendees suggested that if a KPI is not easily understood or an industry standard to measure performance, it would be helpful for the company to provide an explanation as to what the KPI indicates.
- Attendees commented that KPIs are widely understood to be company-specific and weighted accordingly.
- Attendees commented that a tiered precertification process may not be favorable for small companies.
- Attendees expressed concern that there exists a misconception that precertification is a free pass into market.

Reducing Regulatory Burden
- Attendees suggested the following questions for the FDA and companies to consider:
    - How often will KPIs be reported?
    - Who would look at KPIs?
    - What is the criteria for evaluating KPIs?
- Attendees suggested that scorecards could provide ways to improve performance for the company, and that the end user of the scorecard needs to be determined (e.g., end users, the FDA, and health care providers).
- Attendees suggested that there needs to be clarity and communication on the benefits of precertification compared to premarket review.

Weighting and Measuring Thresholds
- Attendees commented that financing the precertification process could pose as a challenge for small companies.
- Attendees believe that weighting should be higher for riskier devices. They also believe that product quality and patient safety should be weighted with more emphasis and have higher minimum thresholds.
- Attendees suggested that individual software developers could potentially design their own systems and then submit them to the FDA with justifications. Attendees also suggested that scores could be published so interested consumers can see how individual software developers stack against their competition to create an "objective and transparent playing field."

Conclusion

This summary captures feedback from individuals who attended the second day of the public workshop. The outcomes of the workshop will be considered in planning next steps for the Software Precertification Pilot Program.

The FDA continues to welcome input from stakeholders about the Software Precertification Pilot Program. If you would like to provide feedback to the FDA about this program, please comment in our Federal Register docket.

If you have any questions about the Software Precertification Pilot Program, email FDAPre-CertPilot@fda.hhs.gov.

For the full transcript of the *Fostering Digital Health Innovation: Developing the Software Precertification Program* workshop, please visit the workshop website.