MDIC and the Case for Quality

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
Align › Achieve › Accelerate

CDRH Case for Quality Public Meeting
October 10, 2017

Introducing MDIC

MDIC is a 501(c)(3) non-profit organization and is the first-ever public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit

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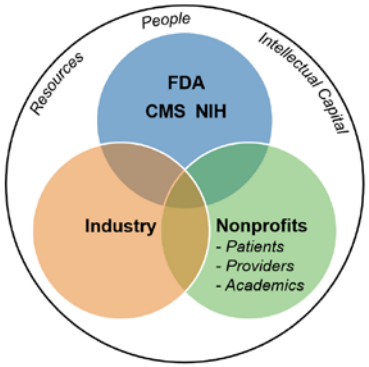

Align Resources

Accelerate Progress

Achieve Results

WORKING COOPERATIVELY
to re-engineer pre-competitive technology innovation

REDUCING TIME
and resources needed for new technology development, assessment, and review

HELPING PATIENTS
gain access to new medical technologies sooner

MDIC HIGHLIGHTS

62 participating member organizations

Leading resource on issues important to the Medtech innovation ecosystem

6 Projects have been initiated

Congressional testimony on modernizing clinical trials

Over $35m funding from grants and contracts for Program initiatives.

Strategies to Advance Regulatory Science

Create A Forum For Collaboration & Dialogue

- Flexible governance structure
- Multi-stakeholder involvement
- Focus on patient benefit

Make Strategic Investments In Regulatory Science

- Improve efficiency & cost-effectiveness
- Focus on unmet needs
- Improve innovation cycle time

Provide Tools To Drive Innovation

- Evidence generation
- Patient engagement & access
- Quality & patient safety

A brief history of Case for Quality: Collaboration across the industry

2011 – CDRH launches the Case for Quality

2014 – MDIC awarded BAA

2014-16 – MDIC Case for Quality project initiatives

2017 – Putting the pieces together

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MDIC Case for Quality

Vision

*Elevate the focus of **all medical device stakeholders***

*from baseline regulatory compliance to **sustained, predictive practices***

*that **advance** medical device quality and safety to achieve better **patient outcomes.***

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Goals

Develop new ***tools, methods and metrics***

for ***innovators, manufacturers, regulators, and providers***

that improve ***product quality*** *and* ***patient experience***

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MDIC Case for Quality

Focus areas

- An ongoing **Case for Quality Forum** that encourages stakeholders to participate in discussion around opportunities for improving device quality within the industry
- A **Maturity Model** program focused on developing a means for using an independent assessment of quality maturity at a device manufacturer.
- A **Product Quality Outcomes Analytics** program aimed at creating a standard, independent, and reliable source of information on device quality, using registries and patient reported data
- **Provide research and stakeholder input** to CDRH to inform the development of voluntary quality program and pilot proposal to be announced in December 2017

2017 Maturity Model

Develop a **voluntary** program which leverages **CMMI** as the **standard maturity model** by which **Industry** may measure their capability to produce **high quality devices**

FDA will adjust their engagement **activities** and submission requirements as a **recognition of this independent assessment of quality maturity**.

Reduced defects and cost

Accelerated time to market

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Increased Customer Satisfaction

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Product Quality Outcomes Analytics

Develop an **independent evaluation of product quality.**

Methods and a proof of concept to **compare device related experience**, and patient outcome for **use by healthcare provider stakeholders** through use of data describing

- **Safety**
- **Efficacy**
- **Reliability**
- **Patient perspective**
- **Usability**
- **Compatibility**
- **Availability**

Get Involved

- Enroll in the Voluntary Quality Program Pilot: http://mdic.org/enroll
- MDIC Case for Quality Forum November 15: http://mdic.org/cfq/register

More details at: http://mdic.org/CFQ

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