FDA’s Draft Guidance for Interoperable Medical Devices

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Medical Device Interoperability

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Digital Health – a convergence of people, information, technology and connectivity in healthcare
• Enable “patient centered” public health as digitization touches every aspect of health care

• Foster trust in innovative technologies as an enabler of a new healthcare paradigm

• Prepare a "digital-future ready” infrastructure @CDRH that understands innovators needs and expectations
Why Interoperability?

- **New benefits**
  - Lowered cost
  - Allows best of breed coexistence
  - Smart interventions...

- **New opportunities**
  - Device safety behavior
  - Detecting errors in a interconnected environment
  - Maintaining safe interoperable use...
CDRH Interoperability Objective

 Advance the role and ability of medical devices in a connected system to exchange and use information safely and effectively

 With other medical devices and other information technology

 to increase safety and efficiency in patient care.
Milestones on the Journey

• In 2010, the FDA hosted a 3-day workshop on medical device interoperability

• In 2012, FDA - AAMI Summit on Medical Device Interoperability

• In 2013, the agency officially recognized a set of standards manufacturers could use to improve patient care by making sure devices work well together.

• In 2015, final policy on medical device data systems (MDDS) encouraging manufacturers to share data.
Next milestone – Draft interoperability Guidance

Design for interoperability

Anticipate interoperable scenarios

Manage and minimize risks

Create transparent or standards based medical device interface

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Building a Case

Understand Needs

Engage

Advance

Medical device interoperability

Manufacturers
Standards developers
Researchers
Regulators
Patients
Hospitals systems

Patient
Safety
Business
Providers

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You advance interoperability, how will, hmm? Yes, hmmm.