# The Promise of Digital Health: How Is FDA Adapting Its Regulatory Approach to This Exploding New Technology?

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*Moderated by* **Ian Pearson**, Senior Associate, Jones Day

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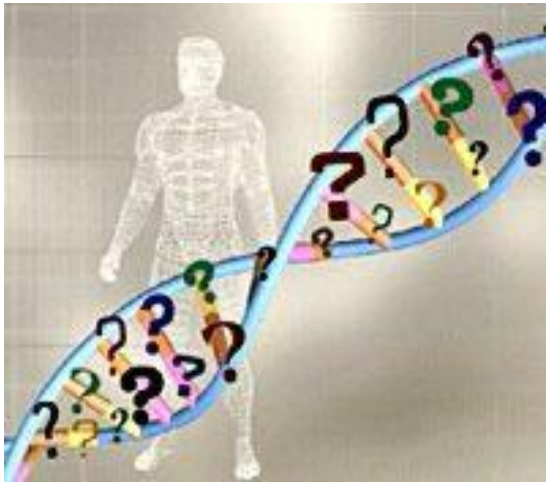
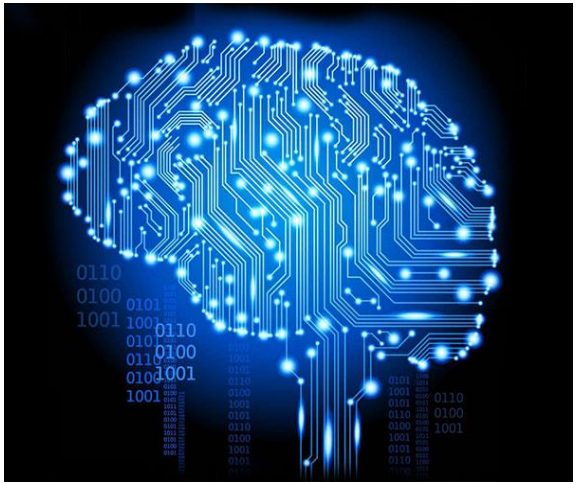
# FDA Regulation of Digital Health Products

Mobile Medical Apps



Genetic Testing



Artificial Intelligence

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# FDA Basics: Medical Devices

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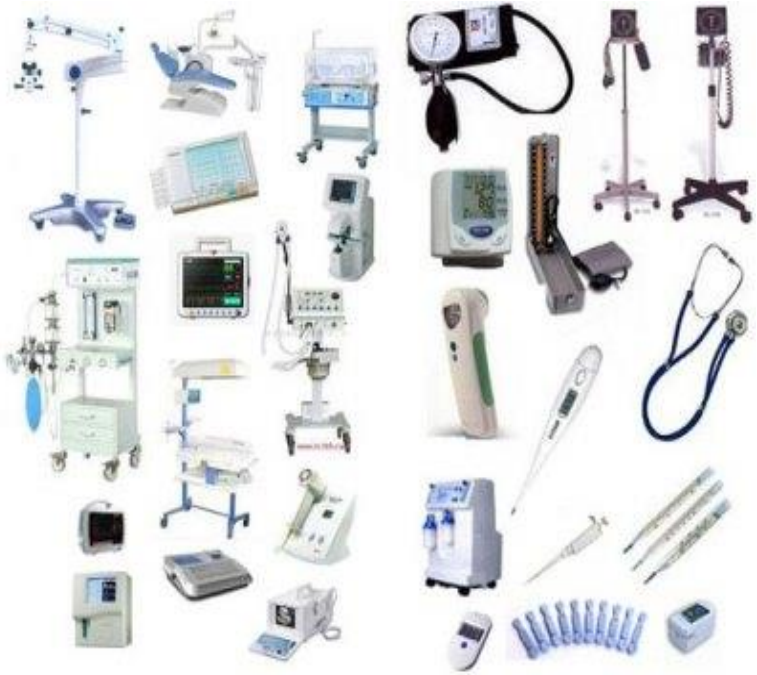
# What is a Medical Device?

- Section 201(h) of the Food, Drug and Cosmetic Act (FDCA) defines a medical device as any healthcare product that does not achieve its principal intended purposes by chemical action or by being metabolized.

- Does NOT include certain software functions per **21st Century Cures Act**



# Classification of Medical Devices

**Classes: Three classes depending on degree of regulatory control necessary to provide reasonable assurance of safety and effectiveness (FDCA 513(a))**

**Class I**

## General Controls

- Lowest risk devices (generally); subject only to controls applicable to all devices (adulteration, misbranding, GMP, recordkeeping, etc.)
- Most exempt from premarket notification

**Class II**

## Special Controls

- Moderate risk devices (generally); general controls not sufficient
- Subject to general controls and special controls; e.g., postmarket surveillance, patient registries, guidelines, performance standards

**Class III**

## Premarket Approval

- High risk devices (generally)
- General and special controls not sufficient
- Life supporting or life sustaining devices or for use of substantial importance in preventing impairment of health or present potential unreasonable risk of illness or injury

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# Marketing Pathways

- Premarket Approval – PMA
  - Most stringent application type, which requires demonstration of safety and effectiveness

- Premarket Notification - 510(k)
  - Applies to class I (limited) and class II devices
  - Premarket submission made to FDA to demonstrate **substantial equivalence** to a legally marketed predicate device (21 CFR 807.92(a)(3)) that is not subject to PMA
  - Substantial equivalence = same intended use and technological characteristics

- De Novo Request (Section 513(f)(2))
  - Provides a pathway to classify novel low to moderate risk devices for which there is no legally marketed predicate device
  - De Novo classification is a risk-based classification process
  - NOTE: De novo pathway has been often utilized for medical software and other digital products

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# Marketing Pathways Table

| Class | Risk | Controls | Submission Type |
|---|---|---|---|
| I | Low | General | • Exempt<br>• Limited 510(k) types<br>• De Novo |
| II | Moderate | General and Special | • Exempt (public notice)<br>• 510(k)<br>• De Novo |
| III | Risk | General and PMA | • Premarket Approval Application<br>• HDE |

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# Digital Health

# Digital Health Requires New Regulatory Paradigm

## Traditional Device Regulation

- Medical Device Amendments added to FDCA in 1976
- Meant to address hardware-based products at the time
- Slower development cycles and technology design changes

## Unique Aspects of Digital Health

- Digital health has brought new market participants
- Software development differs from hardware
- New safety issues (e.g., cybersecurity, data privacy, connectivity, AI, etc.)

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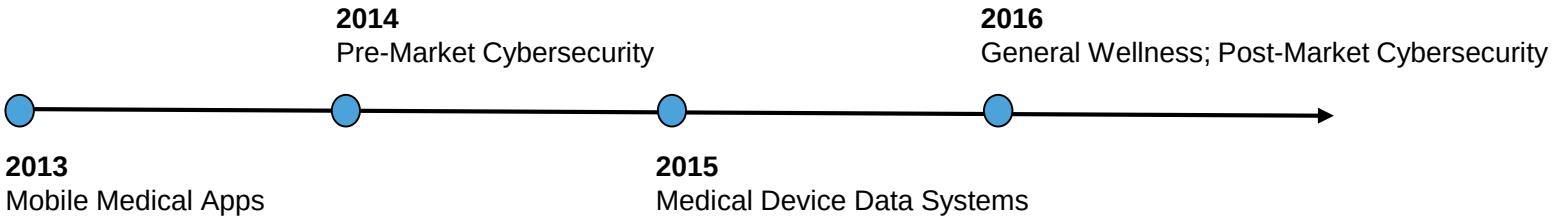
# FDA Regulation of Digital Products

- FDA recognition that traditional regulatory structure is not well suited for digital health oversight
- Creation of Digital Health Program in 2012 to address issues presented by new tech
- Although constrained by FDCA, several enforcement discretion guidances have been issued:



# The 21st Century Cures Act

- Enacted in December 2016, Section 3060 of the Cures Act removes certain types of medical software from FDA's regulatory jurisdiction, including software intended to:
    1. Support administrative functions;
    2. Encourage a healthy lifestyle;
    3. Serve as an electronic patient record;
    4. Transfer, store, convert formats, or display device data and findings; or
    5. Provide clinical decision support
        - See FDA draft guidance 2017 : Clinical and Patient Decision Support Software https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm587819.pdf

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# FDA Regulation of Digital Products

- FDA Health Innovation Action Plan (2017): https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf
  - Risk-based approach to regulating digital health technology will foster innovation
    - "FDA's traditional approach to moderate and higher risk hardware-based medical devices is not well suited for the faster iterative design, development, and type of validation used for software-based medical technologies."
  - FDA's regulatory plan in the digital health space includes:
    1. Issuing new guidance implementing 21st Century Cures Act
    2. Reimagining digital health product oversight through a novel pre-certification program for manufacturers
    3. Growing expertise and that will allow the agency to more efficiently regulate these emerging technologies

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# FDA Software Pre-Certification Pilot Program

- The Pre-Cert Pilot Program is intended to be a tailored approach to regulating software by focusing regulatory oversight on developers rather than the product
  - Will allow manufacturers to “demonstrate a culture of excellence”
  - Leveraging of real-world data and regulatory history
- If adopted, this developer-targeted review would be a significant departure from FDA’s historic approach of a evaluating each individual product
- Pilot participants include:


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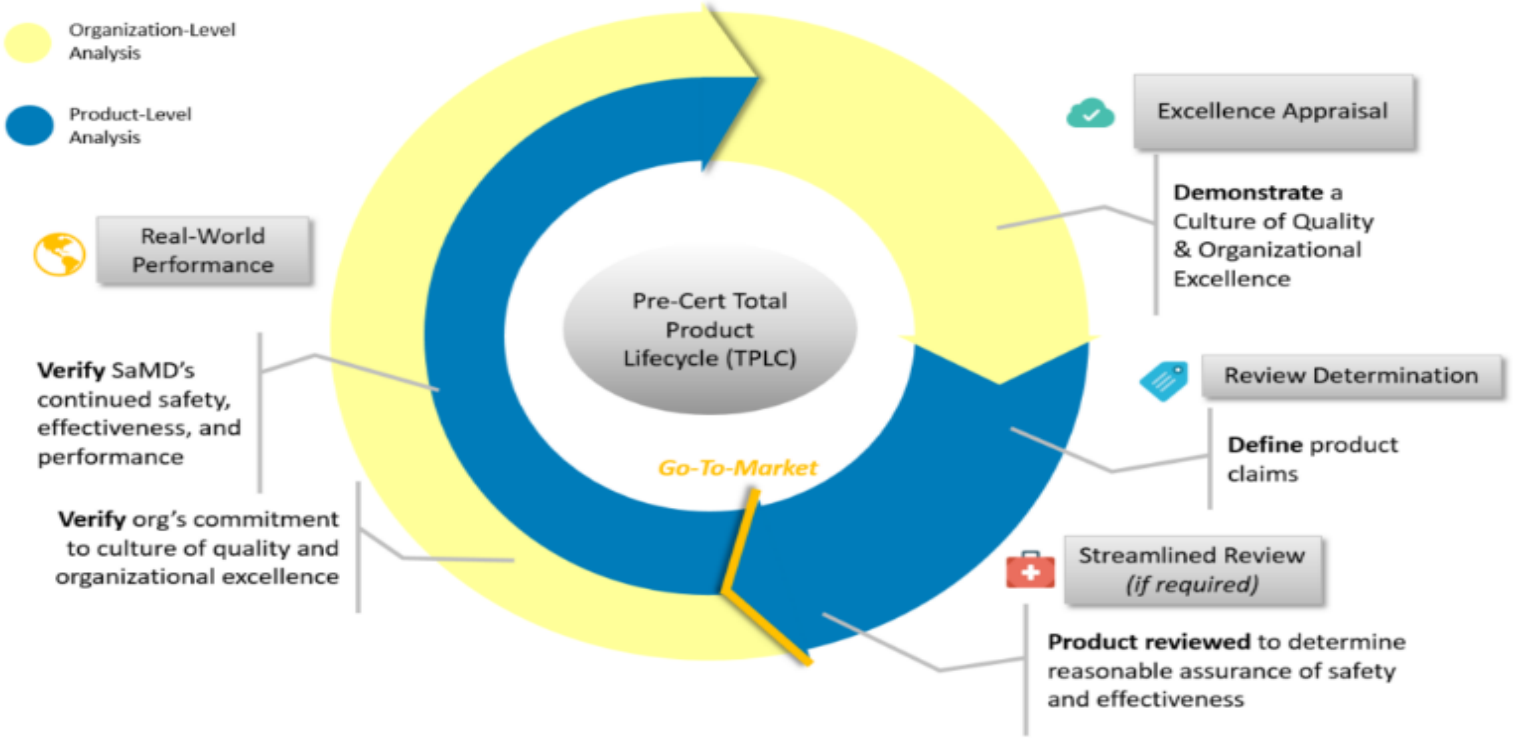
# Software Pre-Cert: Program Outline




***Source: FDA.gov***

# Evolving FDA Regulatory Landscape

- Continued uncertainty in the digital space, **but clear FDA trend encouraging innovation**
  - Expansion of FDA's own enforcement discretion policies and other new guidance
    - Draft Clinical and Patient Support Software Guidance (2017)
    - Software as a Medical Device Guidance (2017)
      - Collaboration with International Medical Device Regulators Forum (IMDRF)
    - Multiple Function Device Products Guidance (2017)

  - Software precertification pilot program updates
    - FDA Software Pre-Cert Test Plan for 2019
    - FDA activity seeking industry participation and advice; unique opportunity to shape new regulatory paradigm
    - Practical and legal questions remain, however, the agency remains committed to digital pathway

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