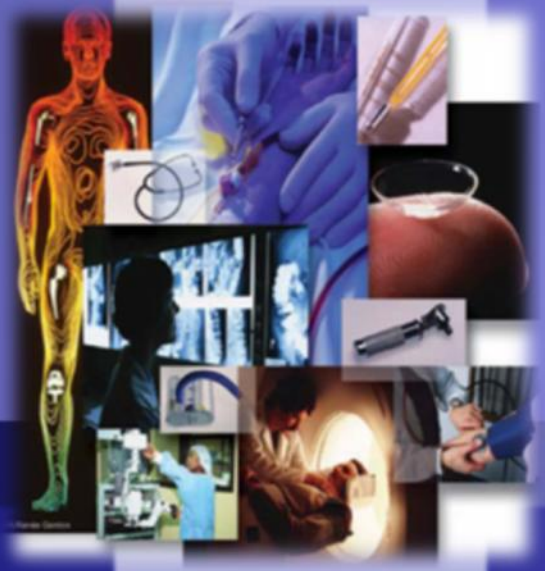

MDEpiNet PASSION II

2016 CDRH Priorities

William H. Maisel, MD, MPH
Deputy Director for Science and Chief Scientist
Director, Office of Device Evaluation (Acting)
FDA/ CDRH

Patients are at the Heart of What We Do

CDRH Vision: Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world

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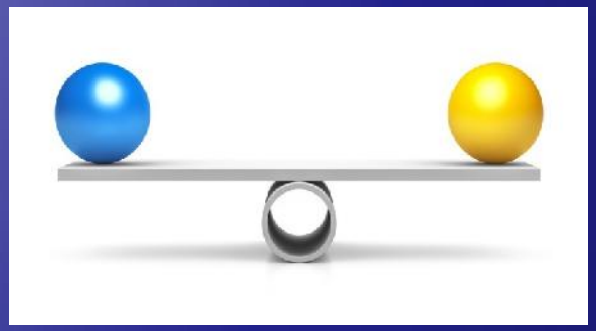
CDRH 2014-2015 Strategic Priorities



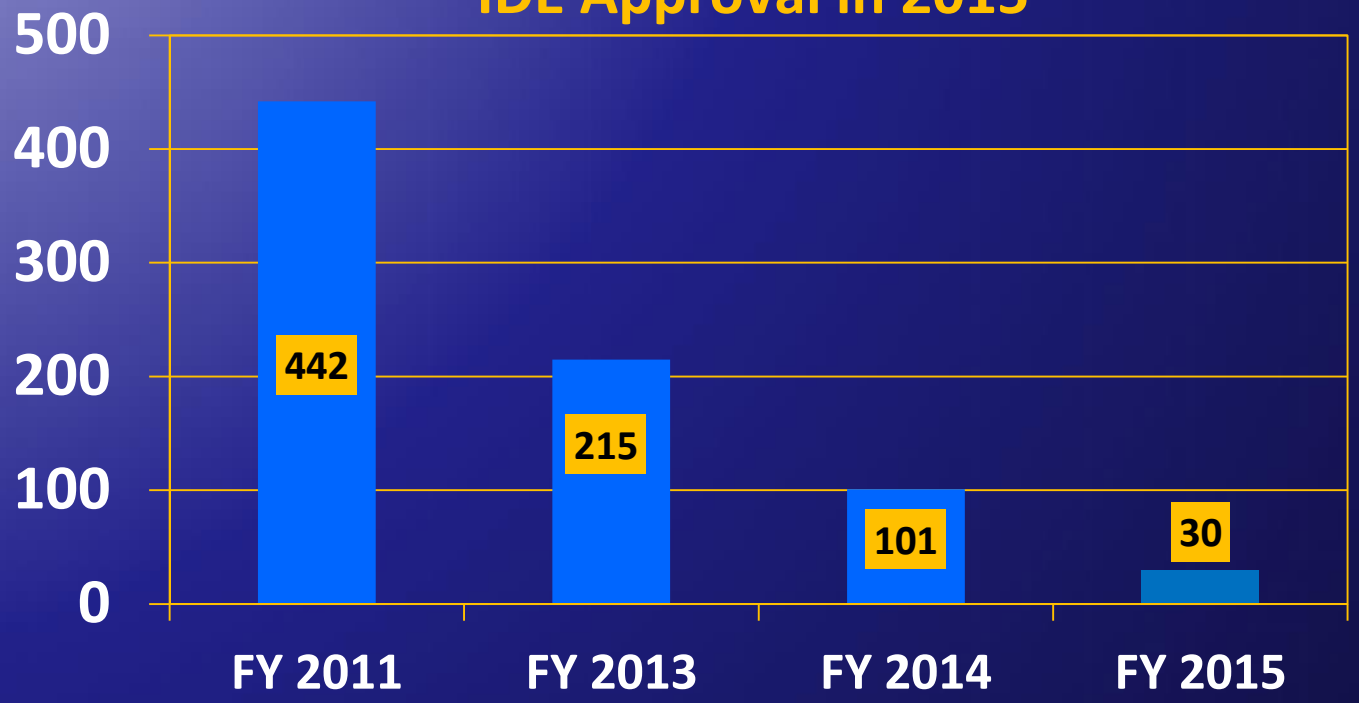
Strengthen the Clinical Trial Enterprise in the US

Strike the Right Balance Between Premarket and Postmarket Data Collection

Provide Excellent Customer Service

Strengthen the Clinical Trial Enterprise

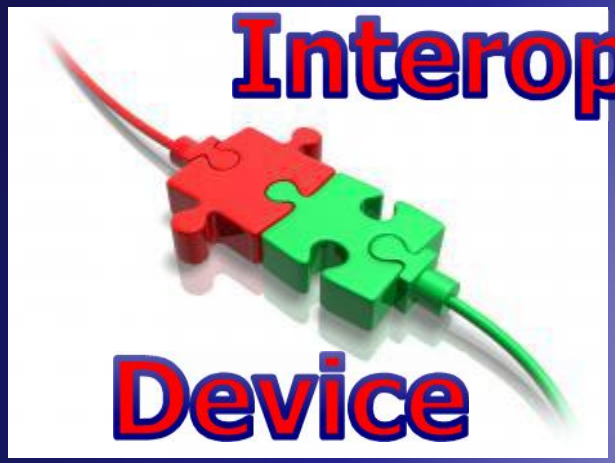
70% Reduction in Median Time to Full Appropriate IDE Approval in 2015



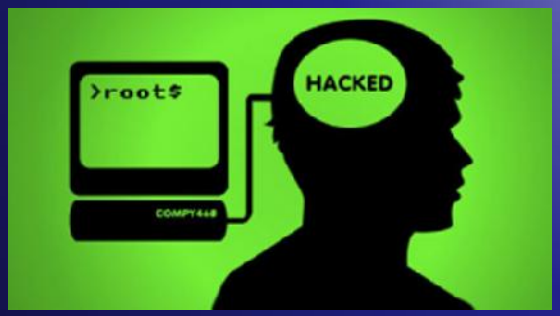
Median number of days to full IDE approval

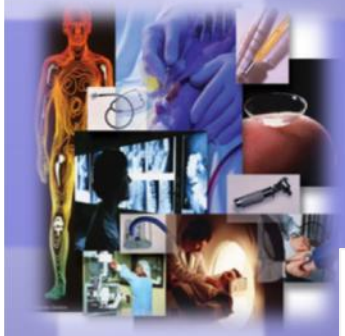
Digital Health and Big Data

Interoperability

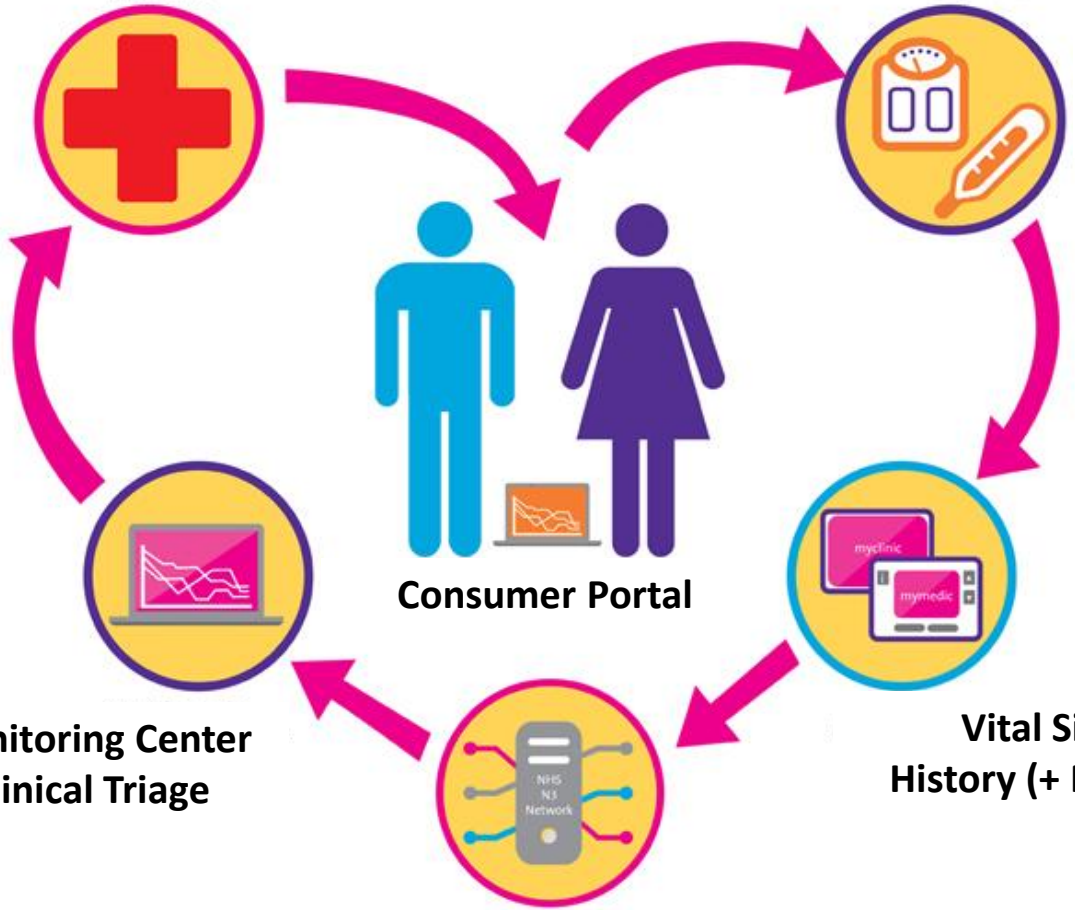


Device security





The World Today



Adapted from: http://www.tunstall.co.uk/what-we-do/telehealth

UDI Implementation

UDI System

Date	UDI Implementation
September 24, 2014	Class III devices
September 24, 2015	Implantable, life-supporting and life-sustaining devices
September 24, 2016	Class II devices
September 24, 2018	Class I devices Devices not classified into Class I, II or III

Evolving Use of Registries

Postmarket Surveillance

Leverage Infrastructure for Premarket Studies

"Real World" Use to Support Expanded Indications

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Link to Other Databases - EHR, Claims, etc.

Useful to Multiple Stakeholders

CDRH 2016-2017
Strategic Priorities

Establish a National Evaluation System for Medical Devices

Partner with Patients

Promote a Culture of Quality and Organizational Excellence

CDRH 2016-2017 Strategic Priority

Establish a National Evaluation System for Medical Devices

GOAL: Increase ACCESS and USE of Real-World Evidence To Support Regulatory Decision Making

Potential Benefits of a National Evaluation System for Medical Devices

- Better Leverage Real World Data
- More Efficient & Timely Postmarket Data Collection
- Help Strike the Right Premarket – Postmarket Balance
- Contribute to Premarket Indication Expansion
- Reduce Other Regulatory Burdens
- Meet Other Stakeholder Needs

CDRH 2016-2017 Strategic Priority

Partner with Patients

- **Patients are:**
  - using devices themselves especially in a home healthcare settings
  - more involved in shared decision-making and disease management with their healthcare professionals
  - communicating and connecting with each other through social media and other forums, sharing symptoms, side effects, advice, and providing support

CDRH 2016-2017 Strategic Priority

Partner with Patients

GOAL: Promote A Culture of Meaningful Patient Engagement By Facilitating CDRH Interactions With Patients

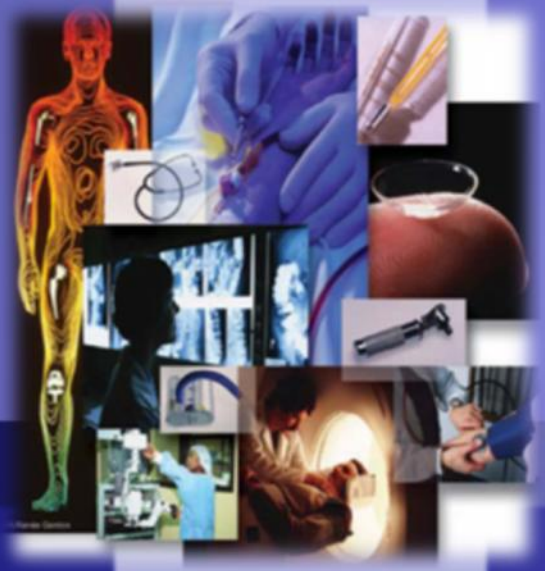
GOAL: Increase Use and Transparency of Patient Input as Evidence in Our Decision-Making

CDRH 2016-2017 Strategic Priority

Promote a Culture of Quality and Organizational Excellence

GOAL: Strengthen FDA's Culture of Quality Within CDRH

GOAL: Strengthen Product and Manufacturing Quality Within the Device Ecosystem



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