

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

William H. Maisel, MD, MPH – CSRC/MDEpiNet 2016



Keys to Patient Access

Evidence



Value



Reimbursement



Market





CDRH Strategic Priority 2014-2015

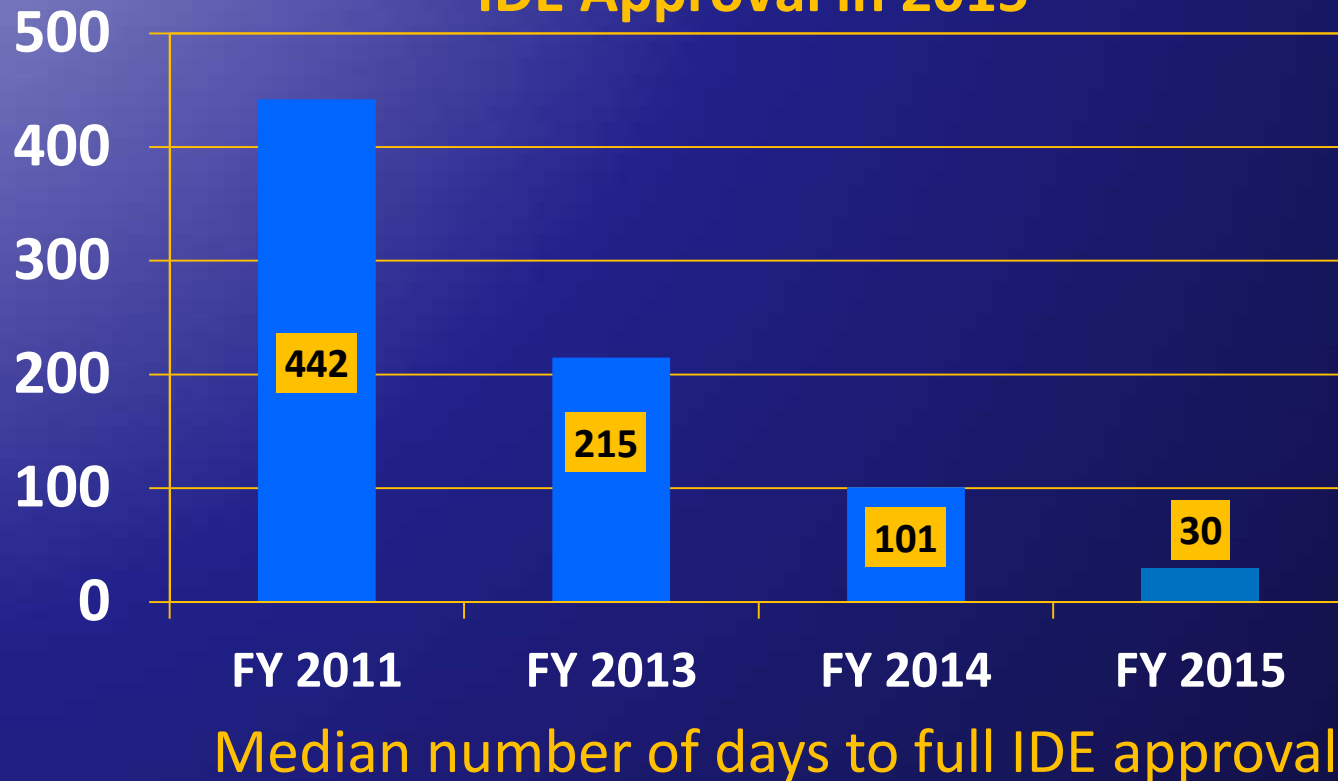


Strengthen the Clinical Trial Enterprise
in the US



Strengthen the Clinical Trial Enterprise

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





Scientific Evidence to Support Device Approval

One Size DOES
NOT Fit All

Important differences
between drugs and devices

- Masking
- Placebo
- Adverse Events
- Randomization
- Learning Curve





Health Care Delivery Is Changing



Wireless
Connectivity
IN MEDICAL DEVICES

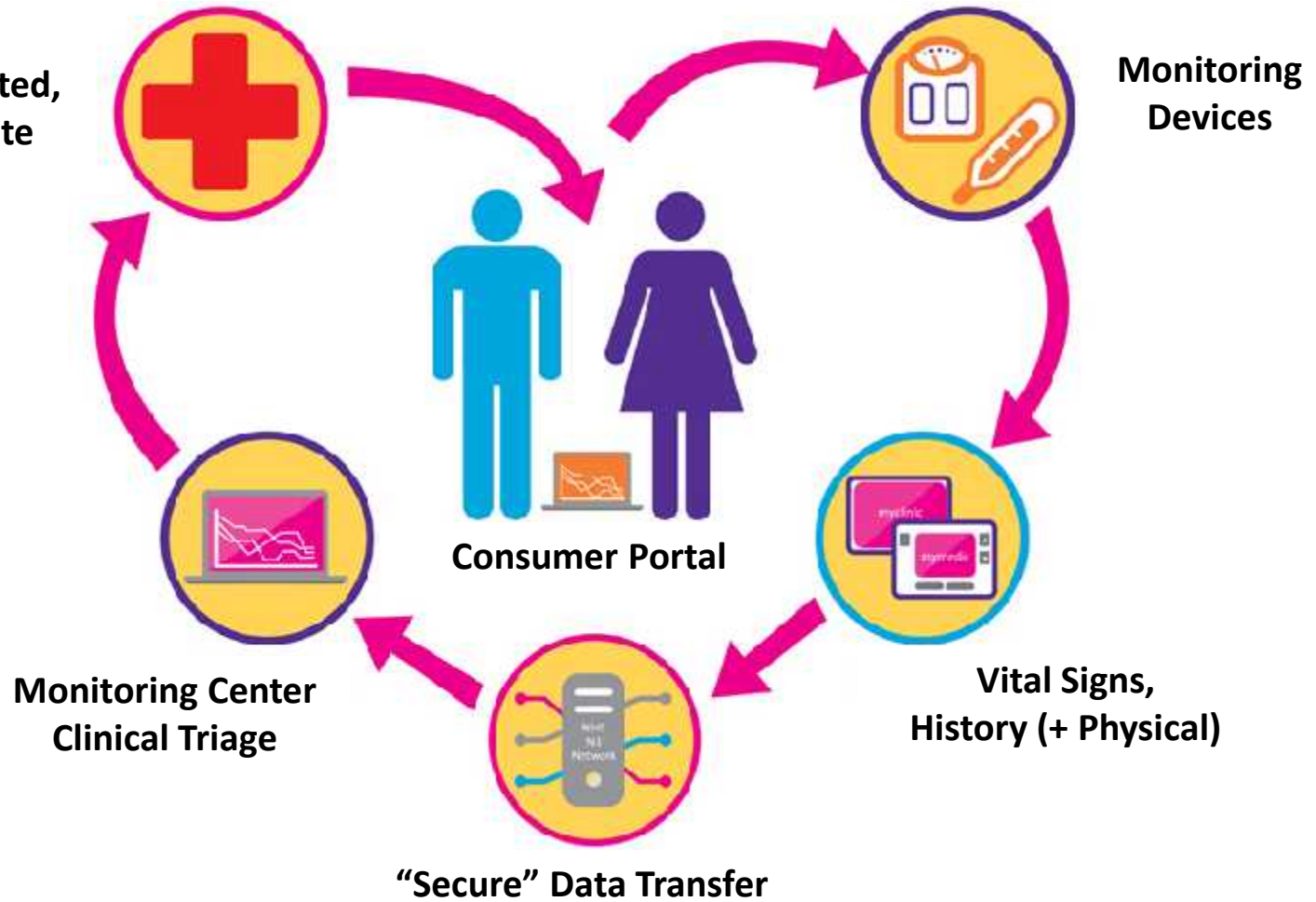
Home
Health





The World Today

Clinician Alerted,
if appropriate



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



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



UDI Implementation



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 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

CSRC and MDEpiNet 2016

The Role of Endpoint Adjudication in Medical Device Clinical Trials

Introductory Remarks



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