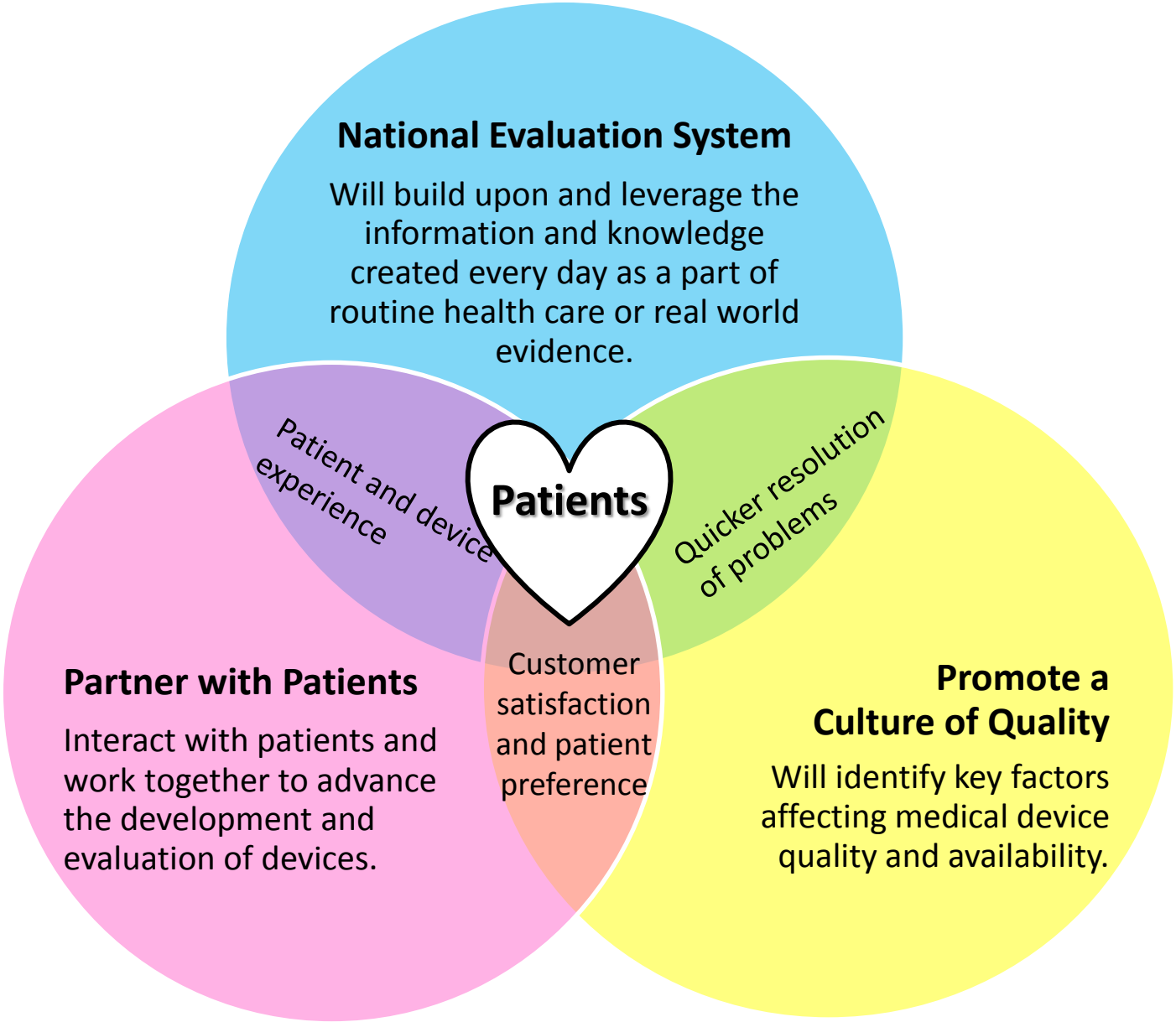
Update from the Office of Compliance: Priorities and Strategies for 2017

Robin W. Newman MSN EdD
Director, Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

CDRH Strategic Priorities

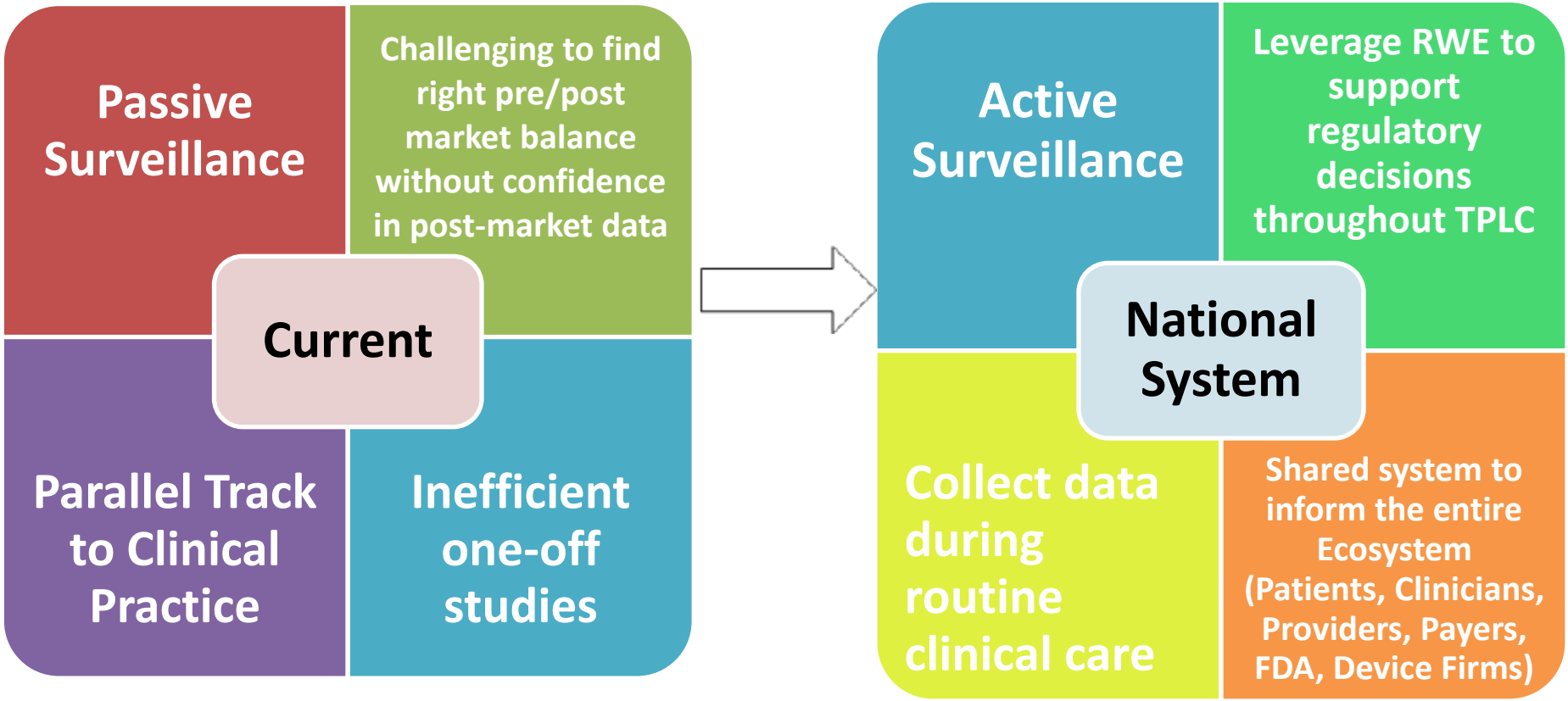


2016-17 Office of Compliance Top Priorities

- National Evaluation System
- Partnering with Patients
  - Benefit Risk
- Promoting a Culture of Quality
  - Quality in the Office
  - Case for Quality
- On the Horizon
  - Program Alignment
  - Total Product Life Cycle

National Evaluation System

Medical Device Evaluation Paradigm Shift:
Today and Tomorrow



FDA's Vision for a National System

For the Ecosystem, Governed by the Ecosystem

- Develops and communicates an evolving understanding of device benefits and risks throughout their marketed life using high-quality, linked electronic health information
- Identifies potential safety signals in near real-time from a variety of privacy-protected data sources serving as a safety net
- Reduces burdens and costs of medical device postmarket surveillance
- Facilitates clearance and approval of new devices or new uses of existing devices

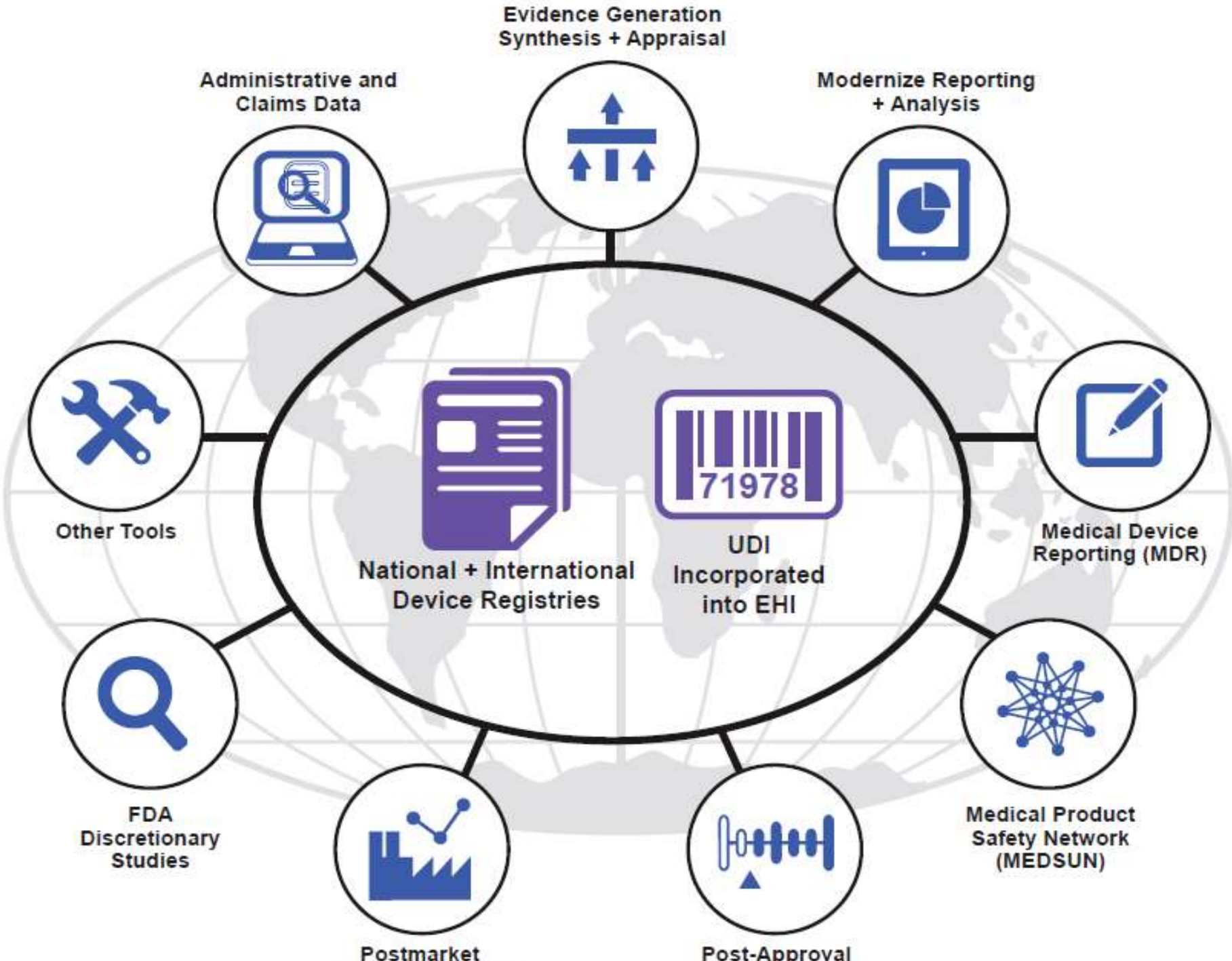
“Big Data” for Regulatory Decision Making

- Develop infrastructure
- Statistical and analytical tools and models
- Information retrieval and processing tools
- Accessible software for Big Data

Real-world evidence

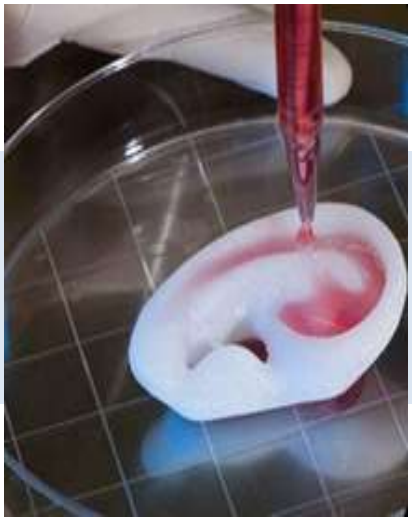
Leverage and employ evidence synthesis across multiple domains in regulatory decision making:

- Use disparate observational data sources
- Develop analytic methods


Evidence Generation
Synthesis + Appraisal
Administrative and
Claims Data
Modernize Reporting
+ Analysis
Other Tools
National + International
Device Registries
71978
UDI
Incorporated
into EHI
Medical Device
Reporting (MDR)
FDA
Discretionary
Studies
Medical Product
Safety Network
(MEDSUN)
Postmarket
Post-Approval

Partnering with Patients

Patients are at the Heart of All 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.

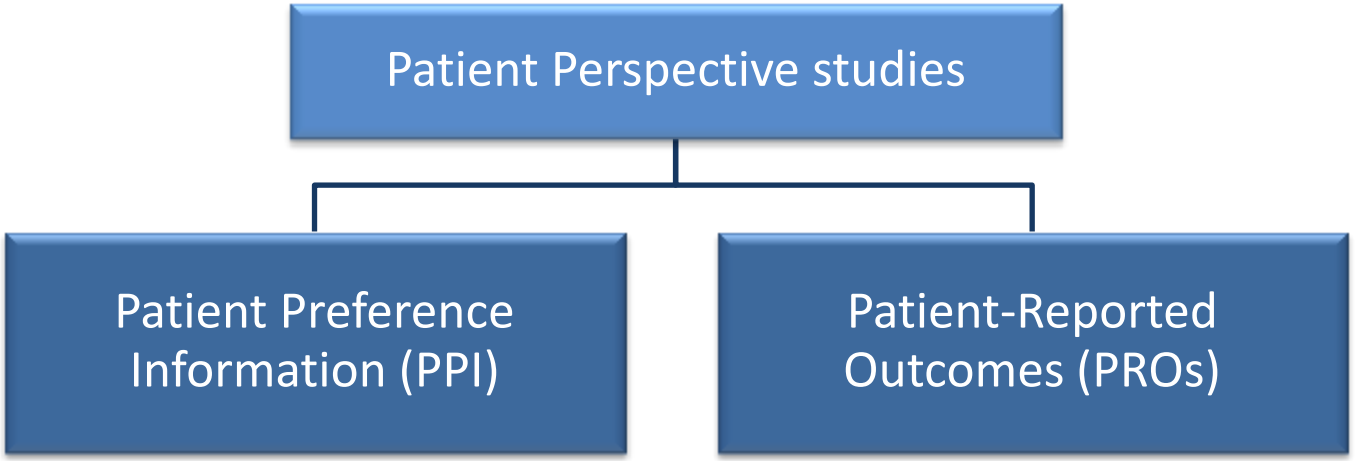
Investing in Culture

Partner with Patients

We interact with patients as partners and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices.

1. Promote a culture of meaningful patient engagement by facilitating CDRH interaction with patients.
2. Increase use and transparency of patient input as evidence in our decision-making.

Patient Perspective Studies



Patient perspective on trade-offs of benefits and risks

Health status reported from patient without involvement of physician

Best Practices for Patient Preference Studies

Well-designed and conducted patient preference studies can:

- Provide valid scientific evidence regarding patients' risk tolerance and perspective on benefit.
- Inform FDA's evaluation of a device's benefit-risk profile during the PMA, HDE application, and *de novo* request review processes

All about Patients	Good Study Design	Good Conduct and Analysis
Patient centeredness	Effective benefit-risk communication	Logical soundness
Capturing heterogeneous patient preferences	Minimal cognitive bias	Robustness of result analysis
Comprehension by study participants	Relevance	

Organization Adoption of Patient Science

Guidance:

- *"Patient Preference Information – Voluntary Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling"*

Staff Training:

- PRO and PPI science
- PPI Guidance

Research:

- Collaborative PPI research in obesity, neurology, oncology, pediatrics, women's health
- PRO research in traumatic brain injury, urology, and women's health
- Novel complimentary PPI/PRO research in ophthalmics and prosthetics

Patient Engagement

Goal:

Promote a culture of meaningful patient engagement by facilitating CDRH interaction with patients.

December 2016

50% of CDRH employees will interact with patients as part of their job duties.

Establish ***one or more new mechanisms*** for employees to obtain patient input on key pre- and postmarket issues and foster participation of ***10 groups*** to participate.

December 2017

90% of CDRH employees will interact with patients as part of their job duties.

Foster participation of at least 20 patient groups to participate in these mechanisms.

Patient Engagement: 2016 in Numbers

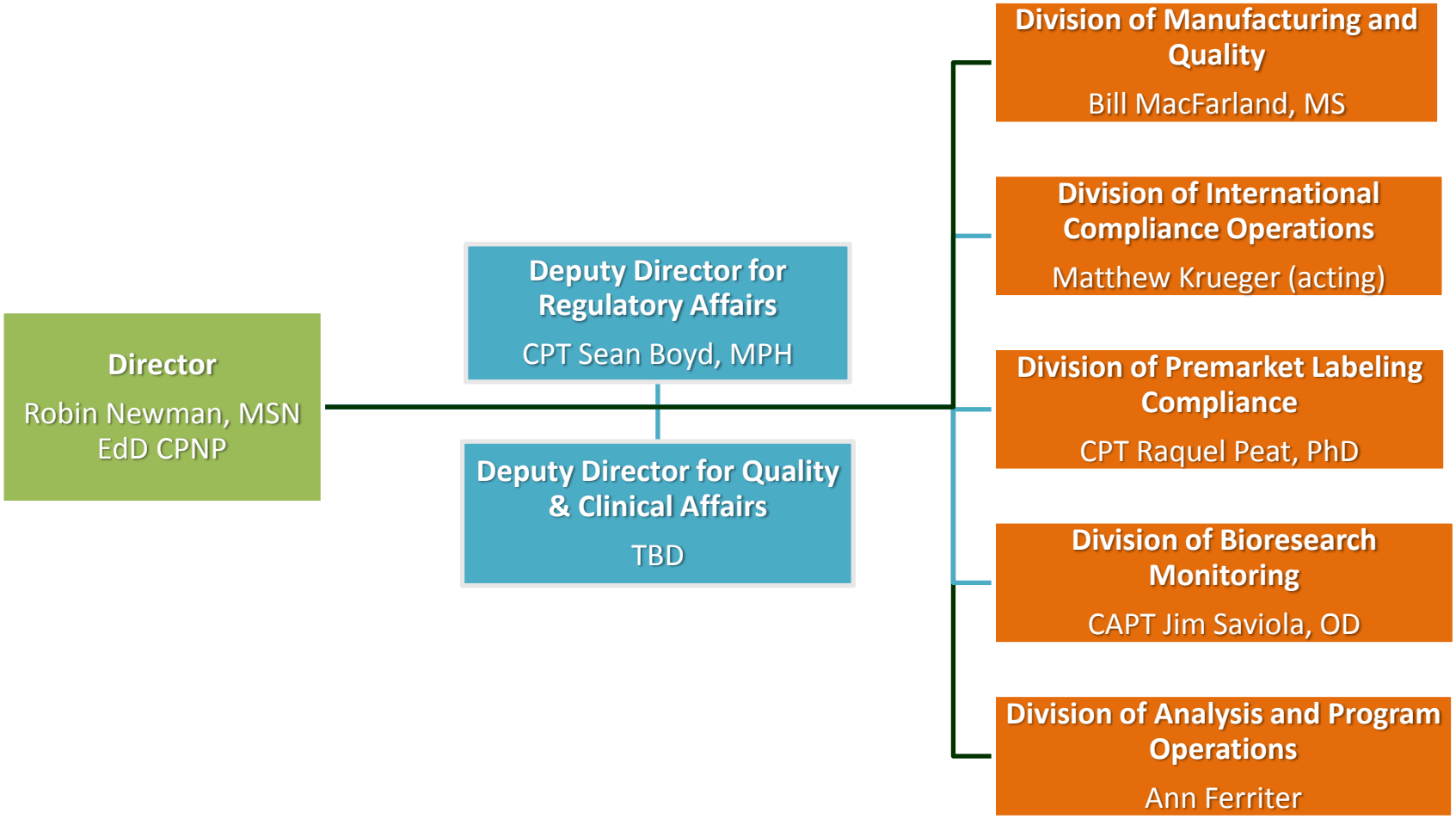
How did we do?

- By December 31, 2016, establish ***one or more new mechanisms*** for employees to obtain patient input and foster participation of ***10 groups.***
  - ✓ ***6*** ***new mechanisms developed and in progress***
  - ✓ ***21*** ***on and off site patient engagement opportunities***
  - ✓ ***34*** ***patient groups participated***

- By December 31, 2016, ***50% of CDRH employees*** will interact with patients as part of their job duties
  - ✓ ***68%*** ***of staff interacted with patients by November 31, 2016***

Promoting a Culture of Quality

CDRH Quality in the Office



CDRH Quality in the Office

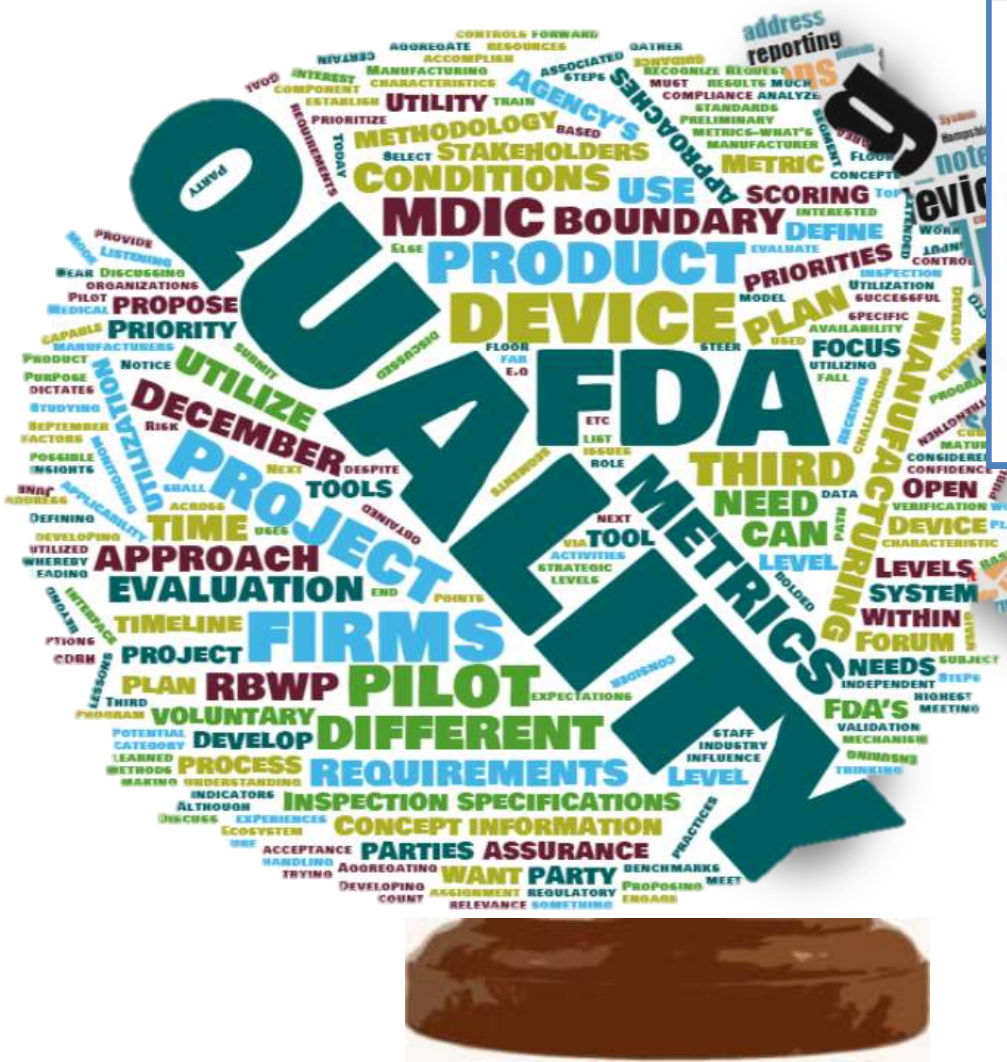
Goals:

- Develop systems and procedures to support the Center goal to be eligible for ISO 9001 certification
- Develop tools and structures to support decision making that assesses safety and compliance across a product's life cycle.
  - Better collaboration between pre and post market staff
  - Increase in the number of staff members who can work in roles across the product lifecycle: pre-market, post-market, and compliance

The Case for Quality

Our Future Approach

- Need to emphasize patient safety and product quality across the product lifecycle
- Shared goals among stakeholders



Compliance ≠ Quality

"…one device manufacturer can meet FDA requirements and *still* make a poor quality device whereas

a second manufacturer may not comply with all FDA requirements and yet make a high-quality device"

Jeff Shuren, M.D., J.D.,
Director CDRH

*****NOTE: Compliance to regulations is still important, as it is required – a high quality product is not a substitute for a compliant product under our current statutory situation**
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm

Case for Quality Goals

- ☑ Identify new metrics and measures to see how device quality is measured, monitored and controlled
- ☑ Collaborate to see what performance and organizational expectations result in higher quality
- ☑ Explore how we should change our policies and practices to foster a culture of quality
- ☑ Advance solutions for increasingly complex and dynamic ecosystems
- ☑ Address needs of the public by ensuring availability of high quality medical devices

FDA Regulatory Paradigm Shift

What does a focus on quality mean for FDA?

- Increased manufacturing and product confidence
- Faster time to markets, better information to drive regulatory decisions, improved resource allocation
- What is most important to patients

Program changes beyond inspections:

- Remove participants from the agency work plan for routine inspections
- Waive pre-approval inspections where appropriate
- Engagement and meetings on issue resolution
- Reduced submission requirements and faster FDA response
- Accelerated approval path
- Competitive market around product excellence

Value of Quality

=

Why?

- Bring CfQ Teams and MDIC Teams together around one concrete deliverable to develop the elements needed for building a voluntary quality-focused program
- Ground the theoretical discussions in program deliverables to drive momentum
- Demonstrate FDA commitment through establishing “wins” for external stakeholders

Case for Quality Proposal

Focused Project Activity

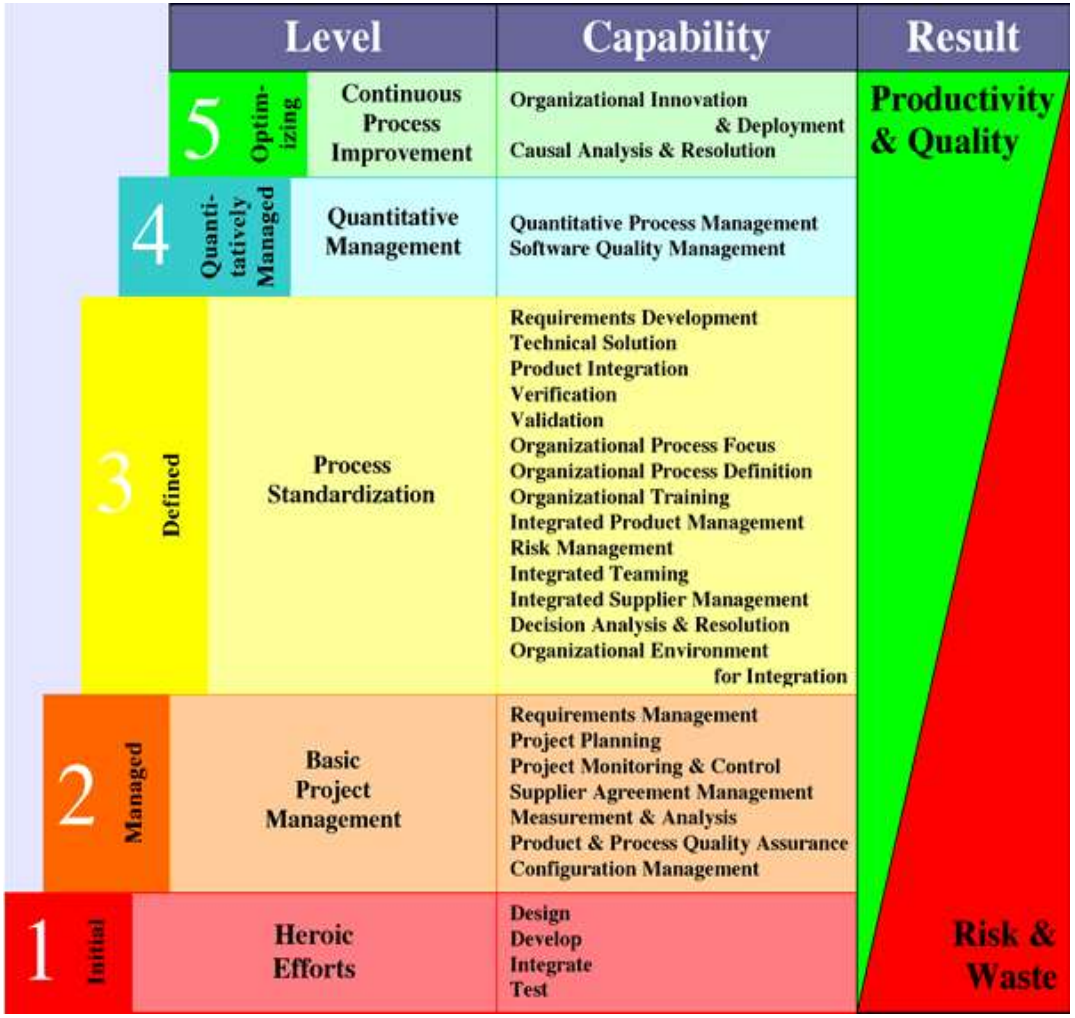
- **Manufacturing Module**
  - Cross center FDA teams establish program centered around full manufacturing with support from external MDIC teams
  - Develop 3rd party assessment evaluating organizational touch points
  - Reduce submission requirements for manufacturing activities

Benefits

- Focused direction
  - **Tangible** objectives
  - **Measurable** data and metrics easier to define
  - **Adaptable**: Allows for the development of program that can be easily adapted for additional areas
- Submission reduction can be easily monetized
- FDA resource utilization can be quantified
- Data collection to begin feeding outcomes can begin

Quality Maturity Model

- FDA is engaged with MDIC to evaluate the use of a Quality Maturity Model and maturity assessment process
- The Capability Maturity Model Integration (CMMI) has been selected as the appropriate model
- FDA and MDIC are working collaboratively to develop a proof-of-concept that will provide insight into the applicability of CMMI model to the medical device industry.



MDIC Outcomes

Maturity Team

- Assessment strategy for relevant practices
- Assessor oversight and training
- Monitoring strategy and metrics
- Data collection and analysis mechanism
- Feedback mechanism for evolving practices

Analytics Team

- Method for collecting data to feed outcomes
- Standardized comparison method
- Outcome measures that can be collected from manufacturer
- Continued development of data sources

Program Operation

- Input from MDIC on Program proposal
- Development of information sharing expectations
- Development of decision making process and participation rules
- Coordination of additional stakeholders

Case for Quality Key Milestones

March 30, 2017	Present proposal at MDIC forum.
March-June 2017	Define manufacturing focused module
March-November 2017	Define and integrate quality program implementation
April-May 2017	FR Notice for Program Announcement
July-October 2017	Define development focused module
August 2017	Public meeting
September 2017	FR Notice for the Final Program Pilot
November-December 2017	Deliver public announcement (webinar or MDIC Forum)

Where is CfQ Going?

2017

2018

- FDA announces a voluntary, quality focused program ready to pilot

2019

- Voluntary program pilot
- Management of results using quality tools
- Begin collecting and monitoring outcome metrics

2020

- Focus on improvement and enhancement of the program
- Share outcome indicators publicly
- Expand resources for new innovators and firms struggling with compliance

- Expand program options and tools
- Improve premarket/post market decisions
- Leverage real world data for regulatory decisions

On the Horizon

On the Horizon—Program Alignment

Establish commodity-based and vertically integrated Regulatory Programs

- Delayering/streamlining
- Specialization
- Training
- Work planning
- Compliance and quality policy, enforcement and engagement
- Import operations
- Lab optimization

Program alignment—what does this mean?

- Investigators, compliance officers and managers specialized by program
- Increased understanding of technology and manufacturing processes
- Development of team-based approaches and streamlined decision-making
- Shared strategic priorities & program goals
- Work planning based on risk and global inventory

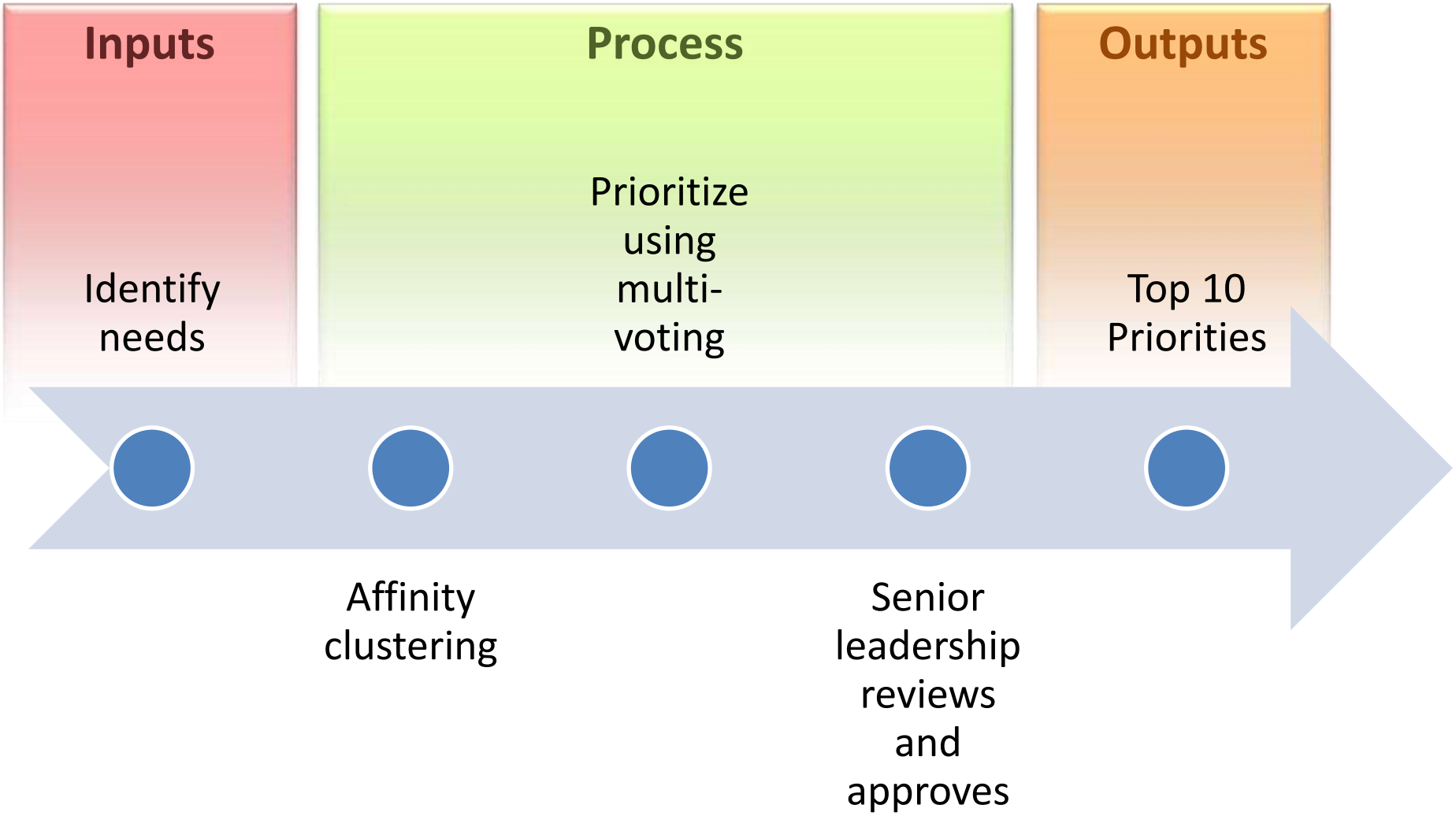
Program Alignment—More to Come

- Finalize decisions, organizational models, roll-out individual assignments
- Launch and continue transition activities through FY17
- Points of contact may change over time
- Continuous Improvement… including evaluating and measuring success

On the Horizon—Regulatory Science Priorities

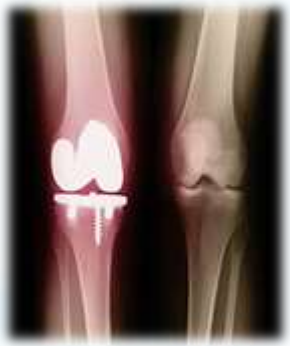
Regulatory science consists of the development of new tools, standards and approaches to assess the safety, efficacy, quality and performance of all FDA regulated products.

Regulatory Science Prioritization: Process Outline



FY 2017 Regulatory Science Priorities

- Big Data
- Biocompatibility
- Real-World Evidence
- Clinical Trial Design
- Computational Modeling
- Digital Health and Cybersecurity
- Infection Control
- Patient Input
- Predicting Clinical Performance
- Precision Medicine and Biomarkers



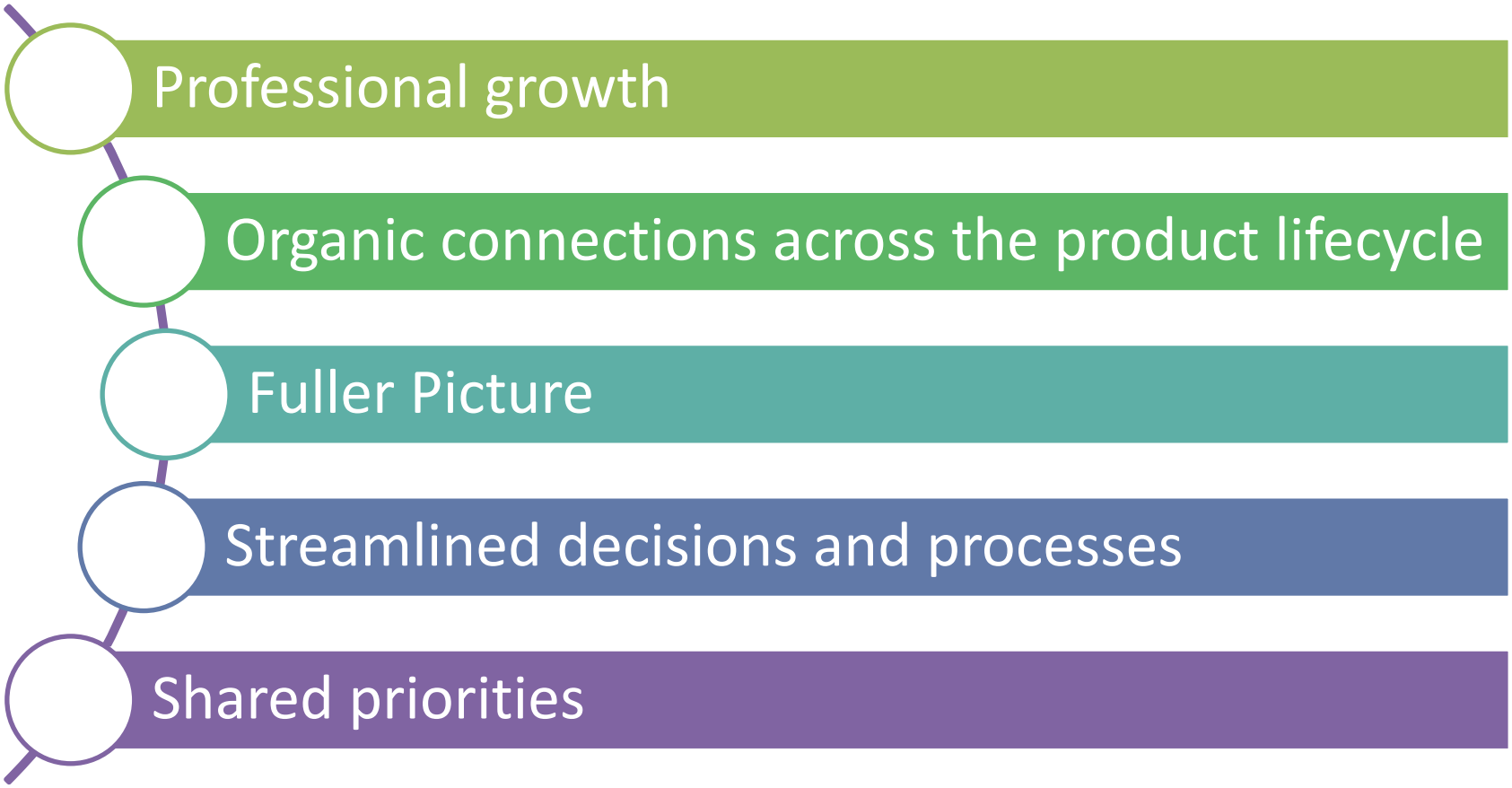
On the Horizon - Total Product Life Cycle Initiative (TPLC)

- Provides visibility of a device, a firm, or class of devices from cradle to grave
- Blends premarket, postmarket, and compliance information and functions
- Incorporates information and approaches broadly in all pre and post approval decision making

TPLC Goals

- Promote focus on “Big Picture,” holistic, patient centered decision making
- Promote increased responsibility and accountability for urgent safety issues
- Leverage knowledge from postmarket and compliance programs to make better informed premarket decisions, and vice versa
- Increase FDA knowledge about specific devices
- Increase staff access to and integration of total product lifecycle information about the medical devices for which they are responsible
- Minimize delays in information sharing
- Ensure process consistency
- Facilitate policy consistency
- Support timely review of all work products

TPLC Benefits



TPLC Timeline

Cross-Center TPLC Group formed

December 2015

January 2016

Offices begin work to develop and evaluate models

Recommend exploring TPLC further

May *2016*

TPLC Timeline

Four subgroups created

June 2016

September 2016

Center publishes working group reports

Center decision to implement TPLC CDRH-wide

January 2017

FDA U.S. FOOD & DRUG ADMINISTRATION

Thank You!


FDA
U.S. FOOD & DRUG
ADMINISTRATION