FDA Actvities Update

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Center for Devices and Radiological Health (CDRH)

US Food and Drug Administration (FDA)

FDA CDRH 2016-2017 Priority
Establish a National Evaluation System for Medical Devices

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

FDA CDRH 2016-2017 Priority
Establish a National Evaluation System for Medical Devices

Obtain Access to Real World Data from:

- Electronic patient records, national and international clinical registries, and claims data – UDI, as available

To Generate Real World Evidence

FDA CDRH 2016-2017 Priority
## Establish a National Evaluation System for Medical Devices

Use of Real World Evidence for:

- Identifying and clarifying potential safety signals

- Leveraging current registry infrastructures to study iterative improvements to approved devices

- Expansion of label/indications

What is a UDI?

1st requirement *…the label of every medical device shall bear a unique device identifier (UDI)…*

2nd requirement *…the labeler of a device must provide the information required … for each model or version required to bear a unique device identifier (UDI)…*
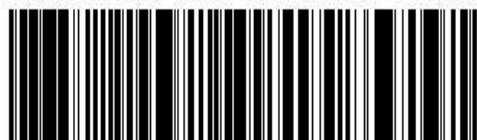
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ACCESS
GUDID
IDENTIFY YOUR MEDICAL DEVICE

accessgudid.nlm.nih.gov

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ACCESS
GUDID
MEDICAL DEVICE

>1,100,000 DI Records

accessgudid.nlm.nih.gov

Implementation Timeframe

FDA

Compliance Date	Must bear a UDI & submit data to GUDID
September 24, 2014	• Class III devices, incl. class III stand alone software • Devices licensed under the PHS Act
September 24, 2015	• Implantable, life-supporting and life-sustaining (I/LS/LS) devices, incl. stand alone software • Direct Marking of I/LS/LS for certain intended uses
September 24, 2016	• Class II devices • Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses
September 24, 2018	• Class I devices and devices not classified class I, II or III • Direct Marking of class II devices for certain intended uses
September 24, 2020	• Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses

Principles for UDI Adoption in EHI

- UDI is part of Real World Data – need to understand
- Data resides at source of truth - GUDID
- Use APIs to access data
- Focus on developers **and users**
- Include rigorous informatics principles
- Design for the 80% rule; supplemental data later
- Everything is free
- UDI and the data in GUDID will be adopted when it **provides value and is USEFUL**

Building Infrastructure:

UDI *as* Standard and UDI *in* Standards

- **HL7 CCDA** - Consolidated Clinical Document Architecture
- **HL7 FHIR** - Fast Health Care Interoperability Resources
- **NCPDP** - National Council for Prescription Drug
- **IHE** - Integrating the Healthcare Enterprise
- **ANSI X12** – American National Standards Institute X12
- **National Library of Medicine** – Terminology services
- **Various data models** – e.g. OMOP, Sentinel

BEGIN...
...with the END *in mind!*

Building Infrastructure: Access to Standard Device Identification Data: OpenFDA

OpenFDA allows public users to merge the GUDID device identification data with other FDA data sets. You will currently find an association from GUDID to FDA Classification data with plans to link to other FDA data sets in the future.

Building Infrastructure:
Access to Standard Device Identification Data: AccessGUDID

EXAMPLE PRODUCT: BLENDER

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STANDARD DI RECORD ATTRIBUTES

FDA

DEVICE: Blender (10846446001969)

DOWNLOAD: XML | JSON   PRINT

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

⊖ DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Blender   Primary DI Number: 10846446001969
Version or Model: 10501   Issuing Agency: GS1
Catalog Number: Device Count: 1
Company Name: Carefusion Corporation
Device Description: MBLENDER,LOFLO,EME

CLOSE

⊖ DEVICE CHARACTERISTICS

What MRI safety information does the labeling contain?	MR Unsafe
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):	No
Device labeled as "Not made with natural rubber latex":	No
For Single-Use:	No
Prescription Use (Rx):	Yes
Over the Counter (OTC):	No
Kit:	No
Combination Product:	No
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P):	No

⊕ GMDN [?]
⊕ FDA PRODUCT CODE [?]
⊕ STERILIZATION

MORE DI RECORD ATTRIBUTES

⊖ GMDN [?]

GMDN Names and Definitions: © Copyright GMDN Agency 2015. Reproduced with Permission from the GMDN Agency.

GMDN Preferred Term Name	GMDN Definition
Oxygen/air breathing gas mixer	An independent mechanical device designed for accurate mixing of air and oxygen (O2) with O2 concentrations ranging from 21% to 100% (oxygen/air proportioner) that are appropriated for breathing in patients who need a concentration of O2 above the normal concentration in air. The mixer receives air and oxygen from either the hospital gas pipeline or from compressed gas cylinders; it may include a pressure-regulating mechanism. The mixer may deliver the gas to the patient through devices such as ventilators, tracheostomy tubes, endotracheal (ET) tubes, oxygen tents, and/or masks.

CLOSE

⊖ FDA PRODUCT CODE [?]

Product Code	Product Code Name
BZR	Mixer, Breathing Gases, Anesthesia Inhalation

CLOSE

⊕ STERILIZATION
⊕ STORAGE AND HANDLING [?]
⊖ CLINICALLY RELEVANT SIZE [?]

Size Type Text
No Device Sizes

CLOSE

⊕ DEVICE STATUS
⊕ ALTERNATIVE AND ADDITIONAL IDENTIFIERS

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Test the Infrastructure
UDI as part of CDEs in RWD

FDA

BUILD
Building UDI Into Longitudinal Data Sets for Medical Device Evaluation
CARDIOVASCULAR DEVICES
See http://mdepinet.org/build/

RAPID
Registry Assessment of Peripheral Interventional Devices
PERIPHERAL VASCULAR DEVICES
See http://mdepinet.org/rapid/

RAPID project Work Products

Testing and Evaluating the Infrastructure

VQI Registries:

Carotid Artery Stent

Carotid Endarterectomy

Endovascular AAA Repair

Hemodialysis Access

Infra-Inguinal Bypass

IVC Filter

Lower Extremity Amputations

Open AAA Repair

Peripheral Vascular Intervention: 100,700 procedures

Supra-Inguinal Bypass

Thoracic and Complex EVAR

Varicose Vein

Procedure Variables
Common Data Elements

Procedure Information

Access

Number Access Sites [2 ▾]

	Site 1	Site 2
Site	Femoral Retrograde ▾	Femoral Retrograde ▾
Side	Right ▾	Left ▾
Access Guidance	U/S ▾	U/S ▾
Largest Sheath Size	6	8
Closure Device Type	None ▾	Perclose ▾
Hemostatic Skin Patch	InsituSeal ▾	
Closure Device Successful		Yes ▾

Procedure

Fluoro Time [30] minutes   DAP [60] Gy.cm2   Contrast Volume [75] ml   C02 [No ▾]

Anticoagulant [Heparin ▾]   Protamine [Yes ▾]   CIN Prophylaxis [Bicarb ▾]

Treatment Details

Number of Arteries Treated [1 ▾]

Artery 1

Indication [Occlusive Disease ▾]

Artery Treated [SFA ▾]

Side [Left ▾]

Site of Prior Treatment [No ▾]

TASC Grade [B ▾]

Total Treated Length [2] cm

Total Occlusion Length [1] cm

Calcification [Mild ▾]

Integrate UDI in PSO/Device Registry Vascular Quality Initiative

FDA

VQI offers three ways to enter stents/stent grafts:

1. Product number or Catalog Number

2. Manufacturer

3. Device Identifier (GUDID)

*See VQI website for more information: http://www.vascularqualityinitiative.org/

Vascular Quality Initiative Product Number

Vascular Quality Initiative

Auto Populates Company/Brand/Size:

Artery 1

Number Treatment Types | 1 ▾

Device 1

Treatment Type | Stent ▾

Product Number or UDI | PRB35-05-100-080 UDI:00821684033746

Manufacturer | Covidien LP ▾

Type | Protege EverFlex ▾

Diameter | 5 Millimeter ▾

Length | 100 Millimeter ▾

Vascular Quality Initiative
Selecting by Length

Improving the data: AHRMM Leading a Learning UDI Community
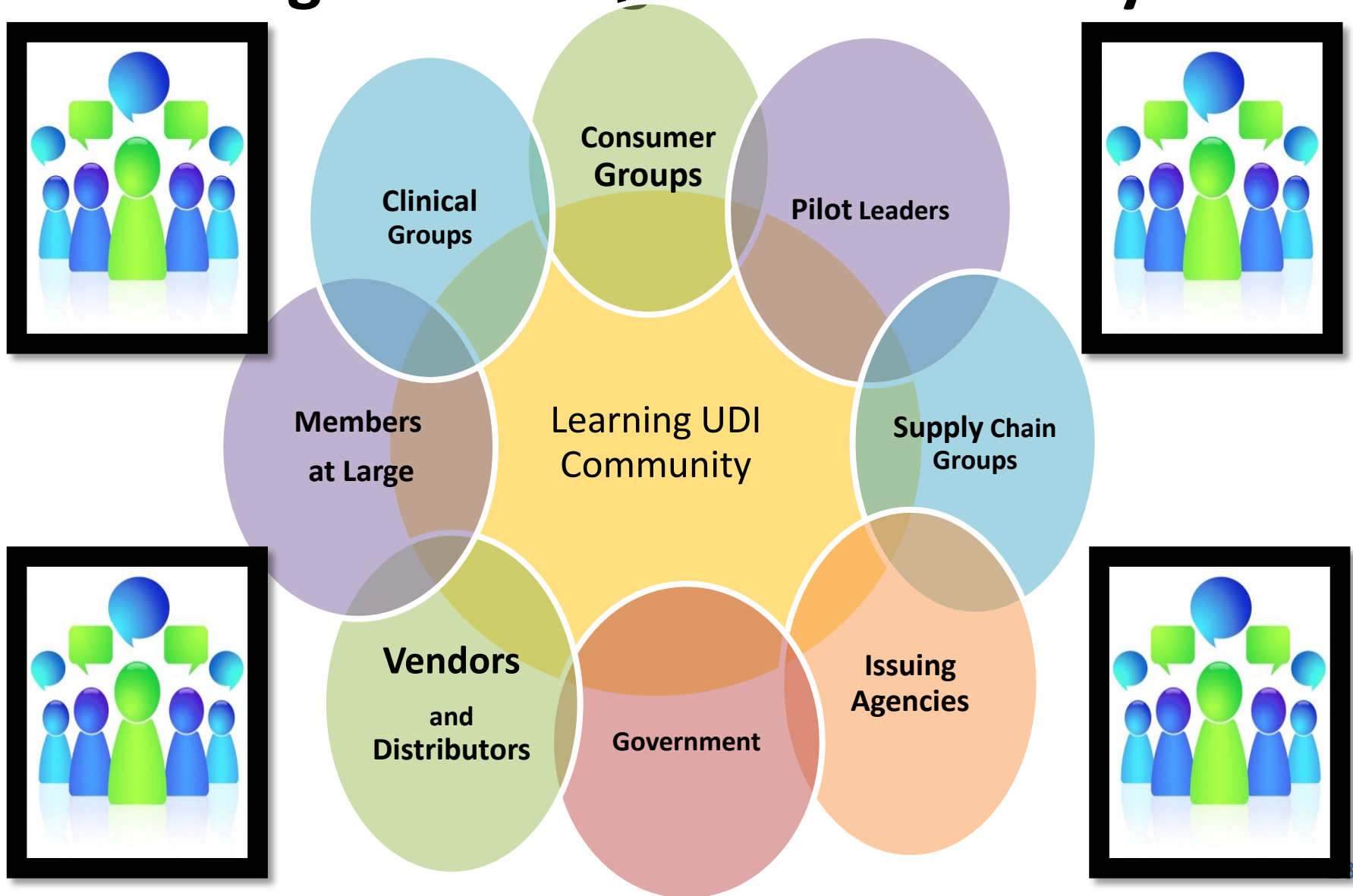
AHRMM
Leading a Learning UDI Community

Active Workgroups

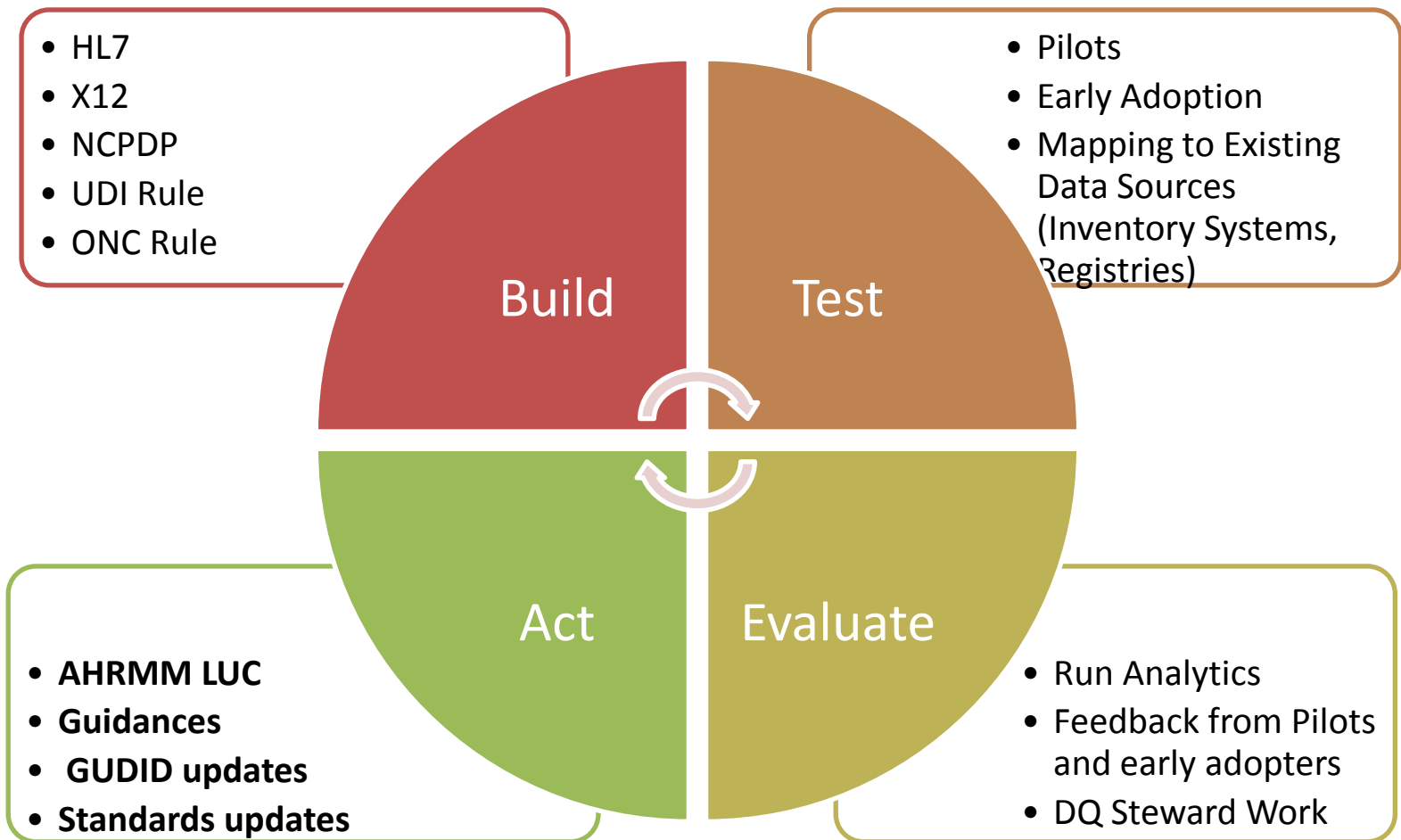Understanding the Meaning

- Unit of Use

- Recognition of AIDC

- Clinically Relevant Size

- Product Categorization

UDI Adoption
Continuous Quality Improvement

Build
- HL7
- X12
- NCPDP
- UDI Rule
- ONC Rule

Test
- Pilots
- Early Adoption
- Mapping to Existing Data Sources (Inventory Systems, Registries)

Act
- **AHRMM LUC**
- **Guidances**
- **GUDID updates**
- **Standards updates**

Evaluate
- Run Analytics
- Feedback from Pilots and early adopters
- DQ Steward Work

Other ideas?