



FDA Activities 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

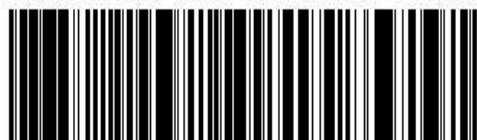
Use of Real World Evidence for:

- 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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accessgudid.nlm.nih.gov

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)...*



>1,100,000
DI Records

accessgudid.nlm.nih.gov

Implementation Timeframe

Compliance Date	Must bear a UDI & submit data to GUDID
September 24, 2014	<ul style="list-style-type: none"> Class III devices, incl. class III stand alone software Devices licensed under the PHS Act
September 24, 2015	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Class II devices Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses
September 24, 2018	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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



Building Infrastructure: Access to Standard Device Identification Data: OpenFDA



An official website of the United States Government



U.S. Department of Health and Human Services
Food and Drug Administration

Do not rely on openFDA to make decisions regarding medical care. Always speak to your health provider about the risks and benefits of FDA-regulated products. We may limit or otherwise restrict your access to the API in line with our [Terms of Service](#)

openFDA

openFDA > device > udi

Unique Device Identifier

api.fda.gov/device/udi

The unique device identification system was established to identify devices through distribution and use. Device labelers are required to include a unique device identifier (UDI) on device labels and packages. The Global Unique Device Identification Database (GUDID) contains key device identification information submitted to the FDA.

openFDA

About

Updates

Learn

API basics

API reference

API status

Analytics & research

API endpoints

Drugs

Devices

Foods

Community

Source code (GitHub)

Q&A (StackExchange)

@openFDA (Twitter)

openFDA Apps

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

 U.S. NATIONAL LIBRARY OF MEDICINE

 TOOLS AND RESOURCES ▼


IDENTIFY YOUR MEDICAL DEVICE



Enter Device Identifier, Name, or Company



ABOUT AccessGUDID

The **Global Unique Device Identification Database (GUDID)** contains key device identification information submitted to the FDA about medical devices that have **Unique Device Identifiers (UDI)**.

The FDA is establishing the unique device identification system to adequately identify devices sold in the U.S.- from manufacturing through distribution to patient use. You can use AccessGUDID to search for specific medical devices or download all the GUDID data at once. AccessGUDID also offers RSS feeds and APIs to connect you directly to the data.

[MORE INFO](#)
[ABOUT UDI](#)
[ABOUT GUDID](#)

DOWNLOAD

[Download Data](#)

 Download the latest full releases and update files provided to the NLM by the FDA.

API

[API Documentation](#)

 Resources for application developers to get the most out of AccessGUDID.

RSS

 Receive the latest files.

NEWS

[AccessGUDID News](#)

Posted: July 7, 2016
New SNOMED CT API in Beta

The [Device SNOMED API](#) accepts a DI or UDI and returns the [SNOMED CT](#) name and identifier associated with the device. A [UMLS single-use ticket](#) is required. User testing and feedback are welcome! Please [contact us](#) with your comments.

HELP

[Help using AccessGUDID](#)


 [Searching AccessGUDID](#)
[Downloading Release Files](#)
[NLM Web Guidelines](#)


FDA TOOLS AND RESOURCES

Accessgudid.nlm.nih.gov

EXAMPLE PRODUCT: BLENDER

ACCESS
GUDID
IDENTIFY YOUR MEDICAL DEVICE






[HOME](#) [ABOUT](#) [NEWS](#) [API](#) [DOWNLOAD](#) [HELP](#)

DEVICE: Blender **(10846446001969)**


[VIEW ALL SECTIONS](#) | [CLOSE ALL SECTIONS](#)


 **DEVICE IDENTIFIER (DI) INFORMATION**


Brand Name: Blender
Version or Model: 10501
Catalog Number:
Company Name: Carefusion Corporation
Device Description: MBLENDER,LOFLO,EME


Primary DI Number: 10846446001969
Issuing Agency: GS1
Device Count: 1

[CLOSE](#)

 **DEVICE CHARACTERISTICS**

 **DEVICE STATUS**

 **ALTERNATIVE AND ADDITIONAL IDENTIFIERS**

 **CUSTOMER CONTACT** [2]

STANDARD DI RECORD ATTRIBUTES

DEVICE: **Blender (10846446001969)**

[DOWNLOAD: XML](#) | [JSON](#) [PRINT](#)

[VIEW ALL SECTIONS](#) | [CLOSE ALL SECTIONS](#)

— DEVICE IDENTIFIER (DI) INFORMATION

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[CLOSE](#)

— DEVICE CHARACTERISTICS

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

Test the Infrastructure

UDI as part of CDEs in RWD

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



RAPID

[RAPID Initiative](#)[Phase I](#)[Phase II](#)[Phase III](#)[National Initiatives](#)[Publications](#)[Links](#)[RAPID Leadership Team](#)[RAPID Clinical Expert Working Group](#)[RAPID Informatics Working Group](#)[RAPID Global Unique Identifiers \(GUDID\) Integration Working Group](#)[Additional RAPID Stakeholders](#)[Work Products](#)

- [RAPID Phase I Deliverables Summary Document](#)
- [RAPID Use Cases](#)
- [RAPID Work Flow](#)
- [RAPID Core Data Elements](#)
- [GUDID Integration Workgroup Project Summary](#)

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

Site 1

Site

Side

Access Guidance

Largest Sheath Size

Closure Device Type

Hemostatic Skin Patch

Closure Device Successful

Site 2

Procedure

Fluoro Time minutes

DAP Gy.cm2

Contrast Volume ml C02

Anticoagulant

Protamine

CIN Prophylaxis

Treatment Details

Number of Arteries Treated

Artery 1

Indication

Artery Treated

Side

Site of Prior Treatment

TASC Grade

Total Treated Length cm

Total Occlusion Length cm

Calcification

Integrate UDI in PSO/Device Registry

Vascular Quality Initiative



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



Artery 1

Number Treatment Types

Device 1

Treatment Type

Device 2

Treatment Type

Product Number or UDI

Manufacturer VBC050202 UDI:00733132614387

Type VBC050502 UDI:00733132614394

Diameter VBC051002 UDI:00733132614400

Length VBC051502 UDI:00733132614417

VBC060202 UDI:00733132614424

VBC060501 UDI:00733132614431

VBC060502 UDI:00733132614448

VBC061001 UDI:00733132614455

VBC061002 UDI:00733132614462

Concomitant VBC061501 UDI:00733132614479

VBC061502 UDI:00733132614486

Vascular Quality Initiative



Auto Populates Company/Brand/Size:

Artery 1

Number Treatment Types

Device 1

Treatment Type

Product Number or UDI

Manufacturer

Type

Diameter

Length

Vascular Quality Initiative

Selecting by Length



Artery 1

Number Treatment Types

Device 1

Treatment Type

Product Number or UDI

Manufacturer

Type

Diameter

Length

☐ None

☐ Thrombolysis, Pharmacologic

☐ Thrombolysis, Mechanical

Concomitant ☐ Embolic Protection Device

☐ IVUS

☐ CTO Device

☐ Suction Thrombectomy

Final Technical Result

Multiple Device Matches

There are multiple devices which match your selection.
Please choose the specific device which was used for this treatment by clicking on the radio button.

☒ [UDI: 00821684033746](#)

Description: Self-Expanding Biliary Stent System

Model or Version: PRB35-05-100-080

Catalog Number: PRB35-05-100-080

Brand: Protege EverFlex

Device Sizes:

`{"sizeType": "Outer Diameter", "size": {"unit": "Millimeter", "value": "5"}, "sizeText": null}`

`{"sizeType": "Length", "size": {"unit": "Millimeter", "value": "100"}, "sizeText": null}`

☐ [UDI: 00821684034156](#)

Description: Self-Expanding Biliary Stent System

Model or Version: PRB35-05-100-120

Catalog Number: PRB35-05-100-120

Brand: Protege EverFlex

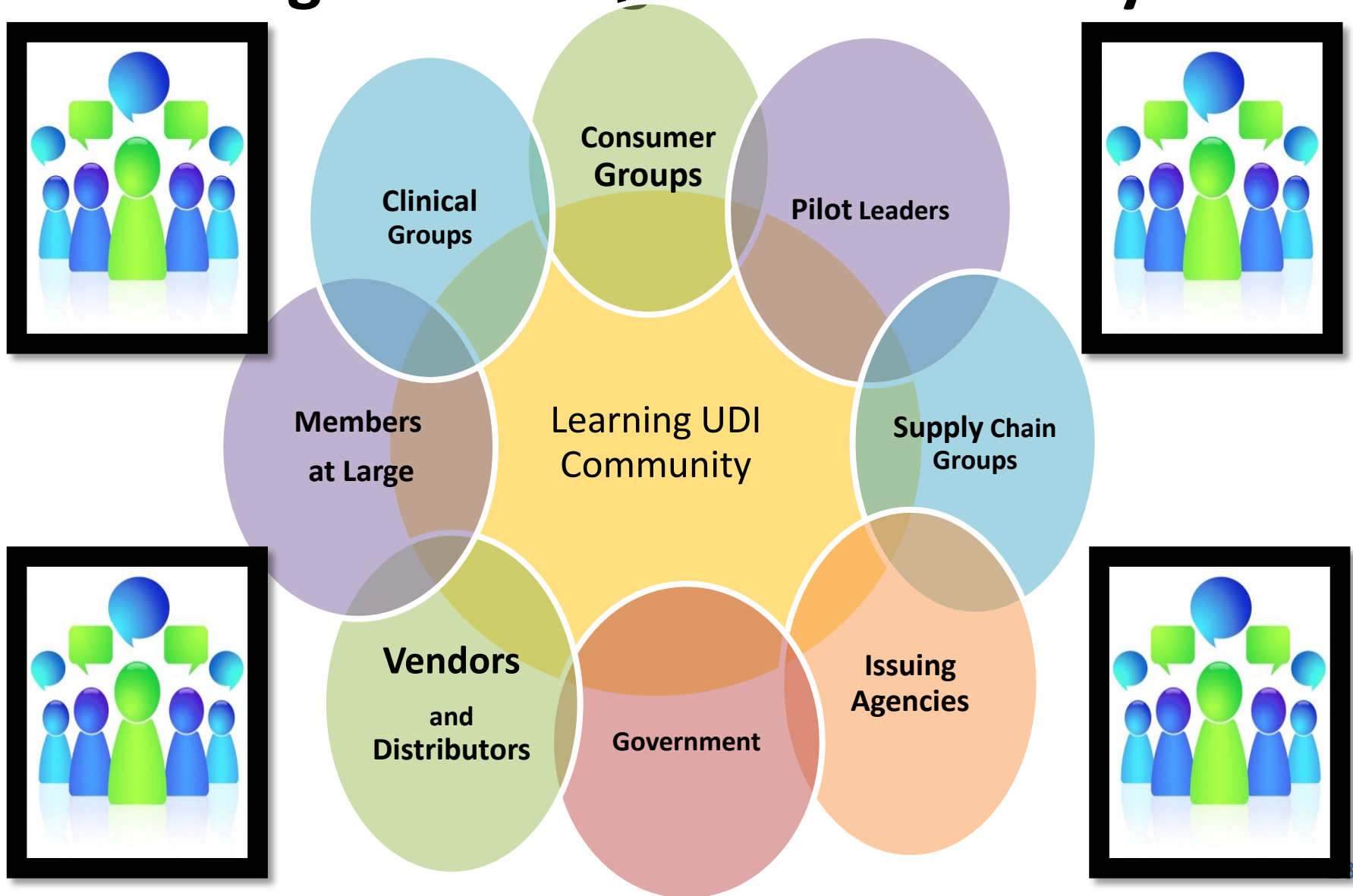
Device Sizes:

`{"sizeType": "Length", "size": {"unit": "Millimeter", "value": "100"}, "sizeText": null}`

`{"sizeType": "Outer Diameter", "size": {"unit": "Millimeter", "value": "5"}, "sizeText": null}`

Improving the data: AHRMM

Leading a Learning UDI Community



Leading a Learning UDI Community

Active Workgroups

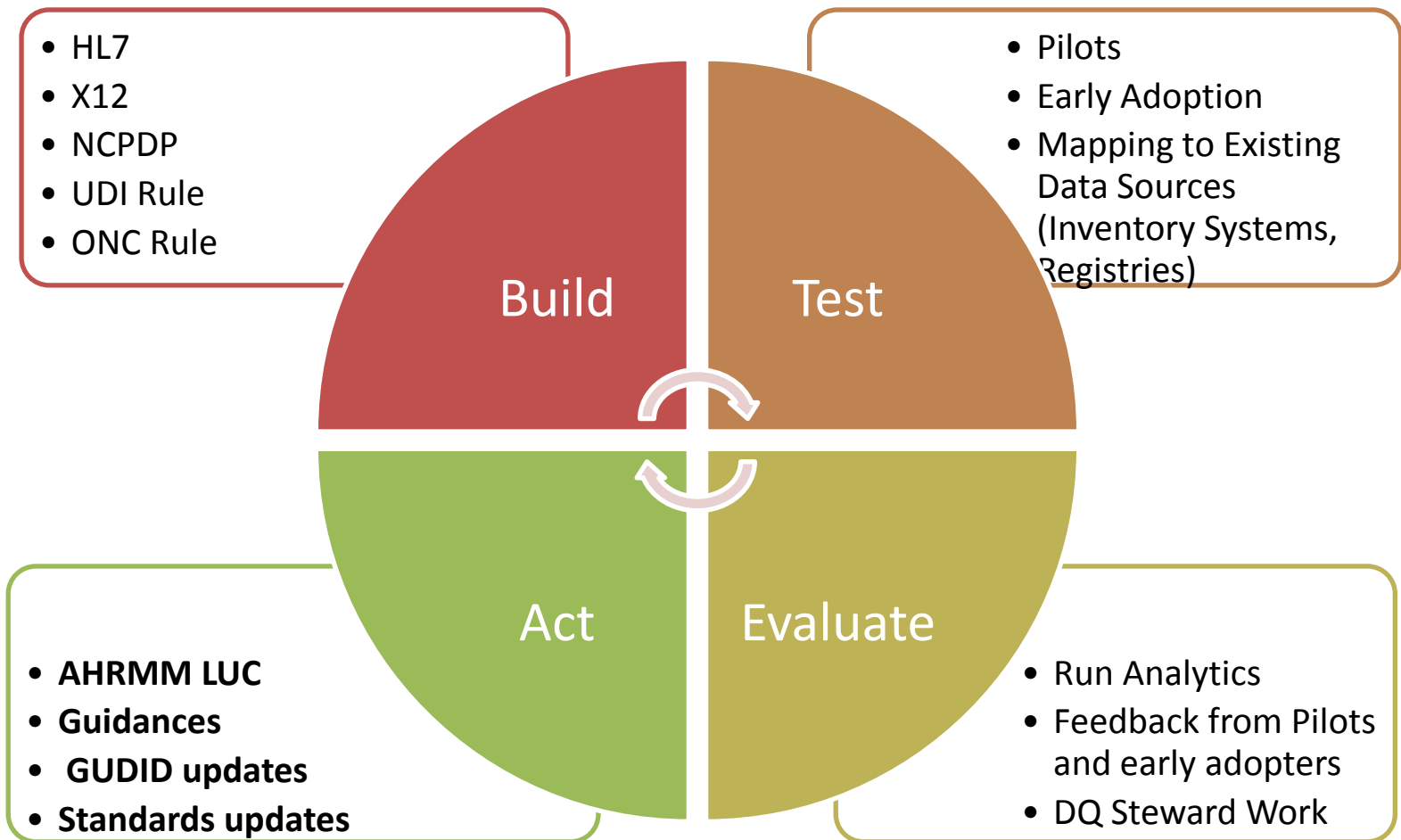
Understanding the Meaning

- Unit of Use
- Recognition of AIDC
- Clinically Relevant Size
- Product Categorization



UDI Adoption

Continuous Quality Improvement



Other ideas?