Unique Device Identification (UDI)-Key to Interoperability

RAPID Phase II

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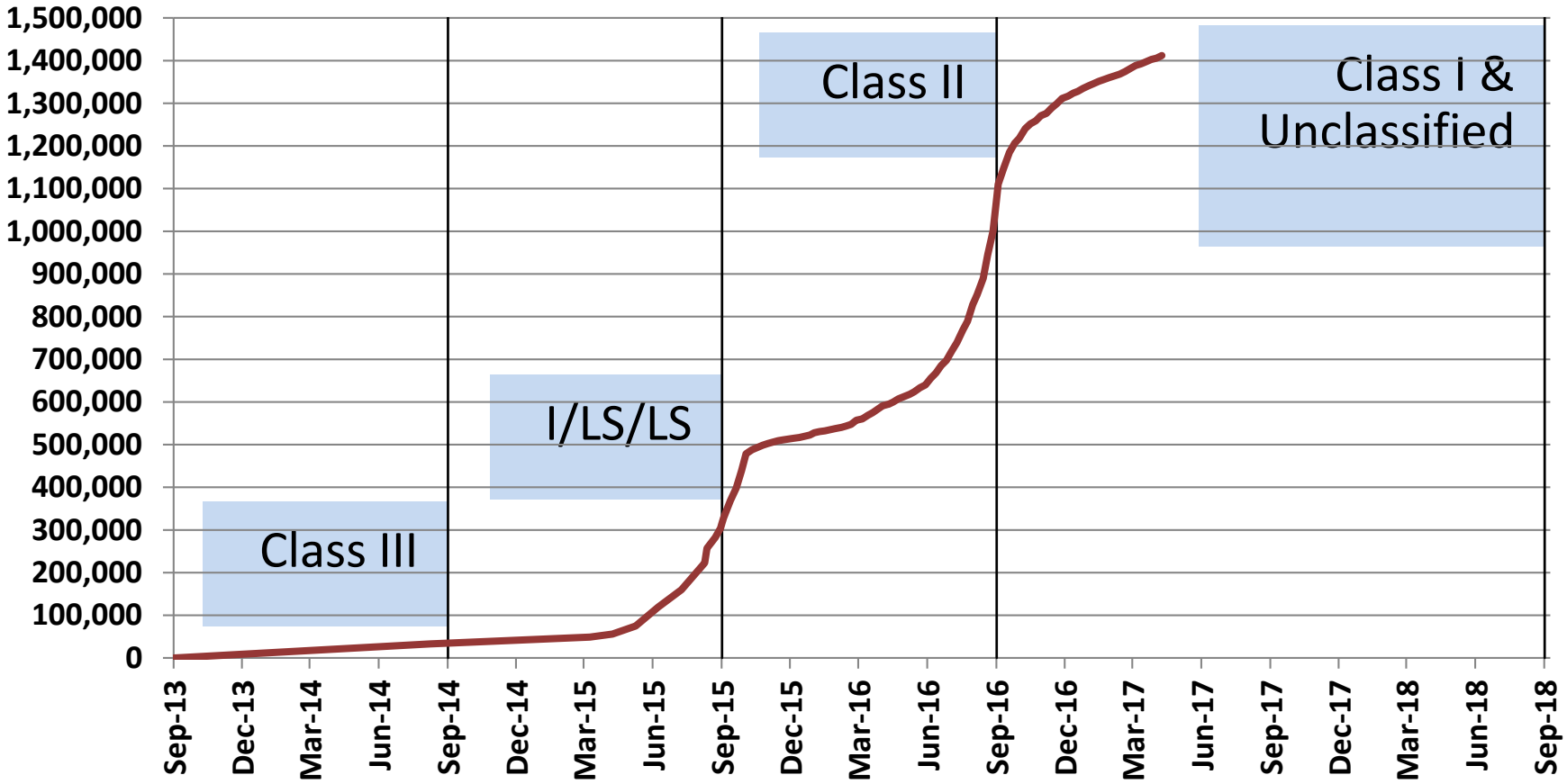
Global Unique Device Identification Database (GUDID) Records and Submission Compliance Deadlines

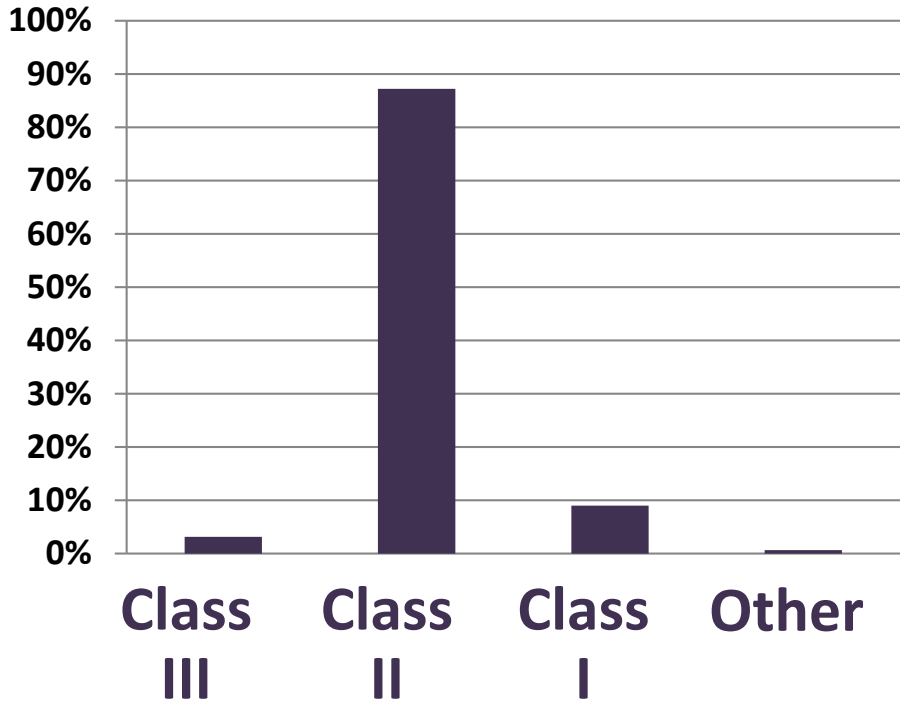
Data Current as of May 1, 2017

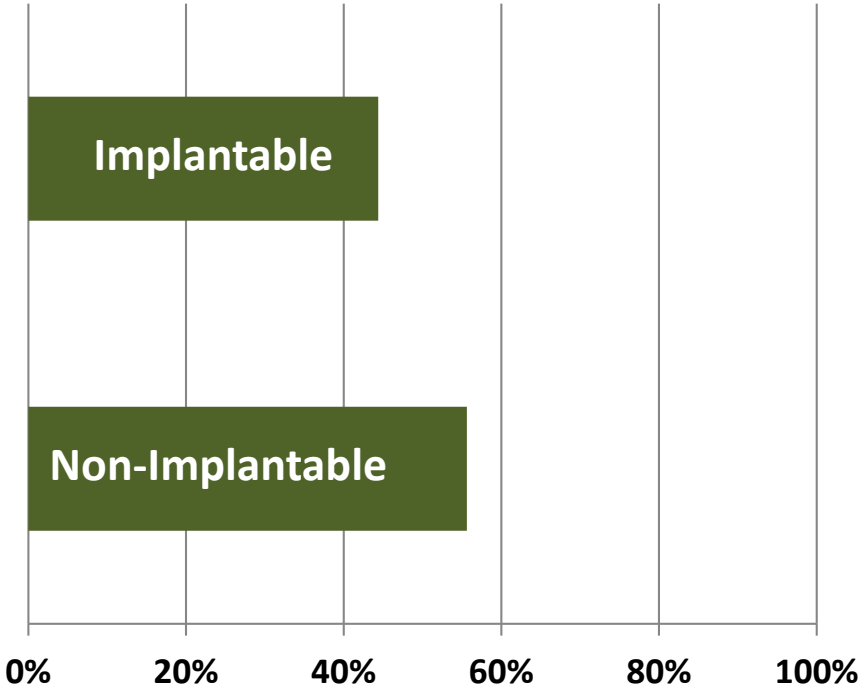


Most GUDID Records are Class II; Almost Half are Associated with Implantables

"Implantable" Devices are those Assigned FDA Product Codes Associated with Implantable Devices, Systems and Accessories

Data Current as of May 1, 2017

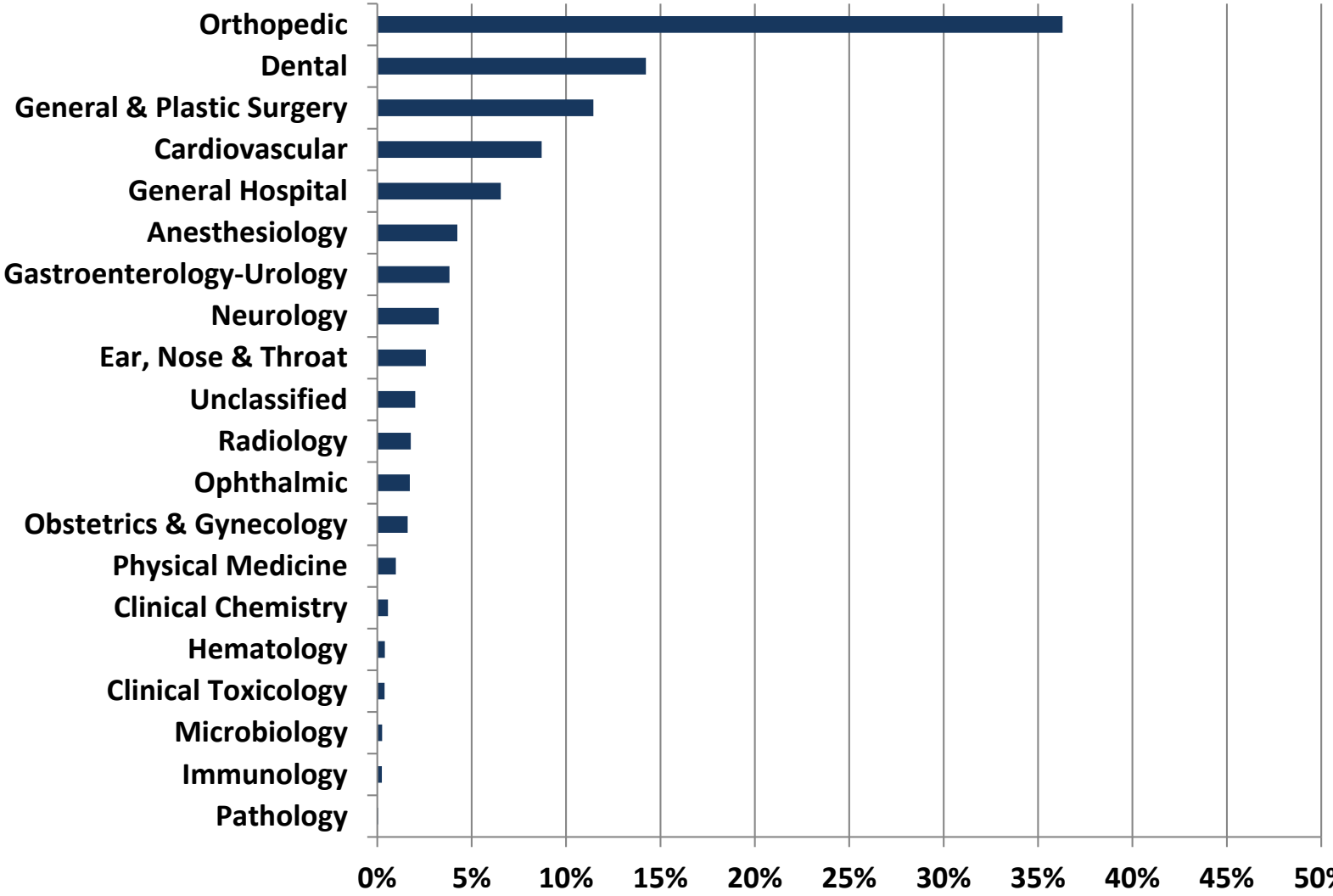




Medical Specialties in GUDID

Data Based on FDA Product Codes

Data Current as of May 1, 2017



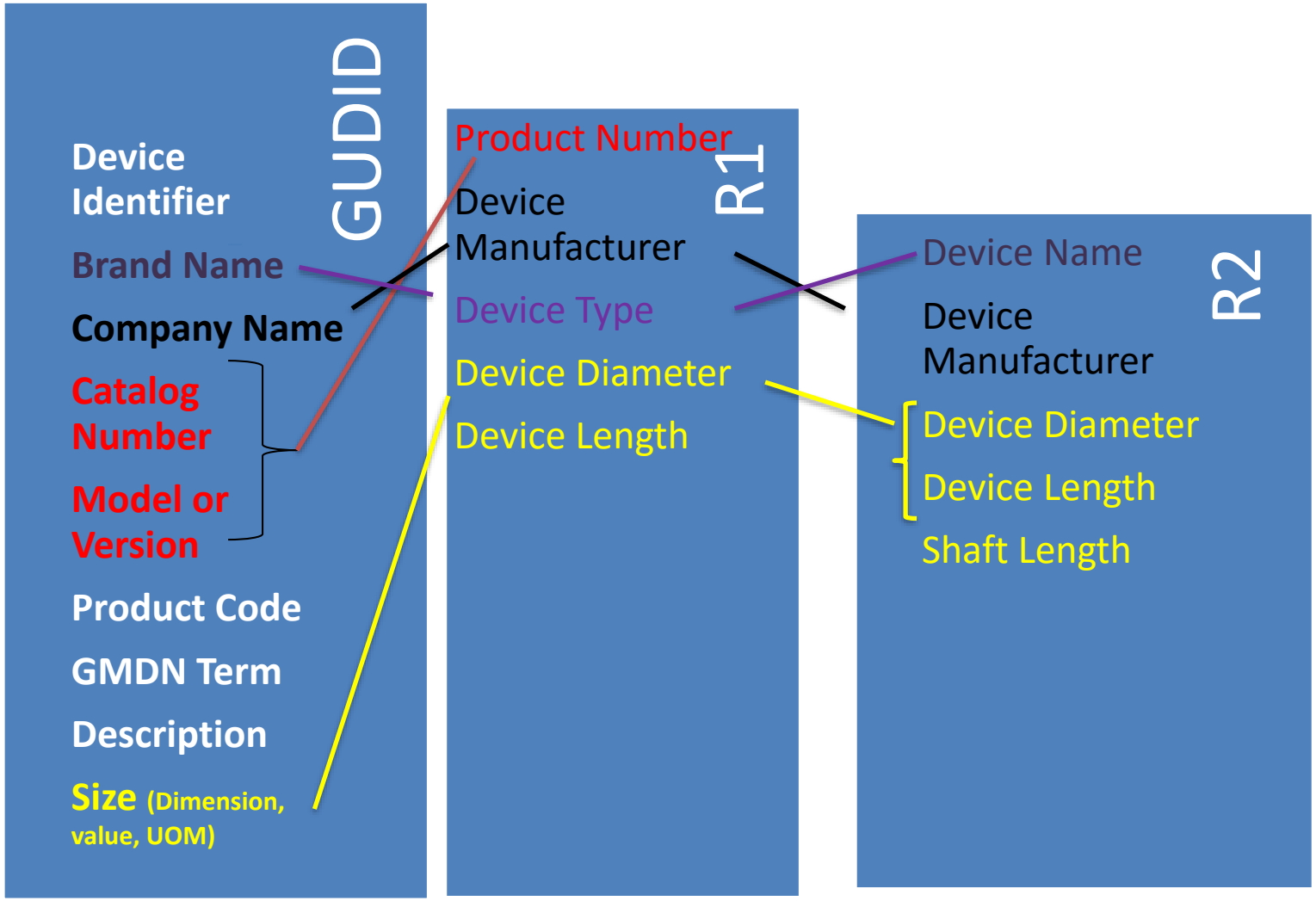
RAPID GUDID - Phase 1

GUDID Integration Workgroup

- This phase consists of identifying the minimal set of core data elements for registry assessment of peripheral arterial interventional devices, including a method for registries to extract Unique Device Identifier (UDI) data for relevant peripheral arterial vascular intervention devices.

  - GUDID as a Reference
  - GUDID Core data elements
    - Brand Name
    - Catalog Number
    - Version or Model
    - GMDN/SNOMED
    - Company Name
    - Size
    - UDI

Comparison of 3 Data Sources



Analysis of One Record

GUDID		R1		R2	
Field Name	**Field Value**	**Field Name**	**Field Value**	**Filed Name**	**Field Value**
Device Identifier	08714729805885				
Brand Name	**Epic™ Vascular**	Device Type	**Epic Vascular Self Expanding Stent (120 CM shaft)**	Device Name	**Epic Vascular Stent System 9.0 mm x 100 mm**
Company Name	**BOSTON SCIENTIFIC CORPORATI**	Device Manufacturer	**Boston Scientific**	Device Manufacturer	**Boston Scientific Corporation**
Catalog Num.	H749**392000910**20	Product Num.	**39200-09102**		
Model or Version	H74939200091020				

GUDID as a Reference

DI Record can be used to auto-populate EHRs, Registries etc

WL GORE

Vascular Quality Initiative

DEVICE: GORE VIABAHN Endoprosthesis (00733132614387)

DOWNLOAD: XML

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: GORE VIABAHN Endoprosthesis
Version or Model: VBC050202
Catalog Number:
Company Name: W. L. Gore & Associates, Inc.
Device Description: No description.

Primary DI Numbe 00733132614387
Issuing Agency: GS1
Device Count: 1

Treatment Type: Stent Graft
Product Number or DI: VBC
Manufacturer
Type
GUDID Diameter
GUDID Length

VBC050202 DI:00733132614387
VBC050502 DI:00733132614394
VBC051002 DI:00733132614400
VBC051502 DI:00733132614417
VBC060202 DI:00733132614424
VBC060501 DI:00733132614431
VBC060502 DI:00733132614448

Device 1

Treatment Type: Stent Graft
Product Number or DI: VBC050502 DI 00733132614394
Manufacturer: W. L. Gore & Associates, Inc.
Type: GORE VIABAHN Endoprosthesis
GUDID Diameter: 5 Millimeter
GUDID Length: 5 Centimeter

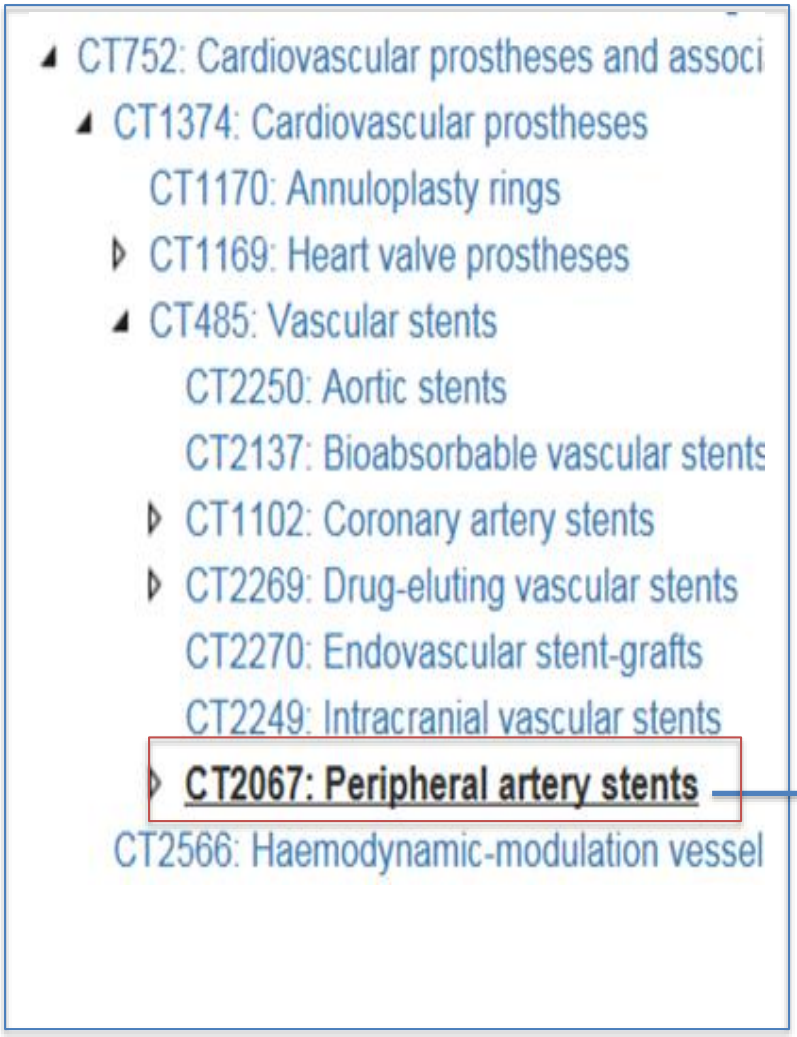
RAPID Phase II

- Mdepinet/Learning UDI Community(LUC)
  - Size Workgroup
  - Device Categorization
- LUC Catalog Number
- Ensuring GUDID can be used as reference source by providers
  - Update GUDID Edit process
  - Update AccessGUDID with record versioning

Size

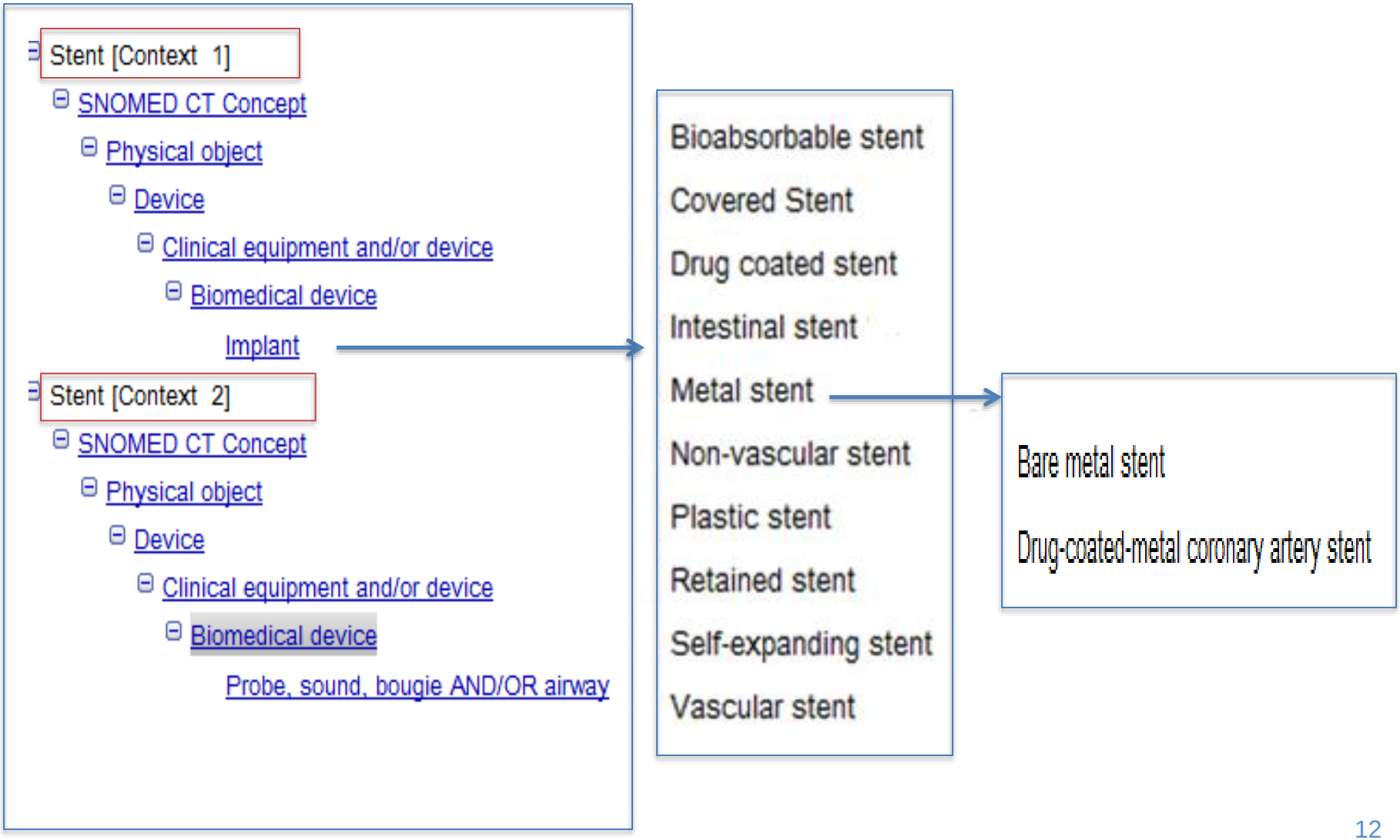
- GUDID coronary stents includes
  - length
  - Nominal stent deployment diameter,
- does NOT include
  - maximum distensible stent diameter or
  - catheter working length

Device Categorization GMDN

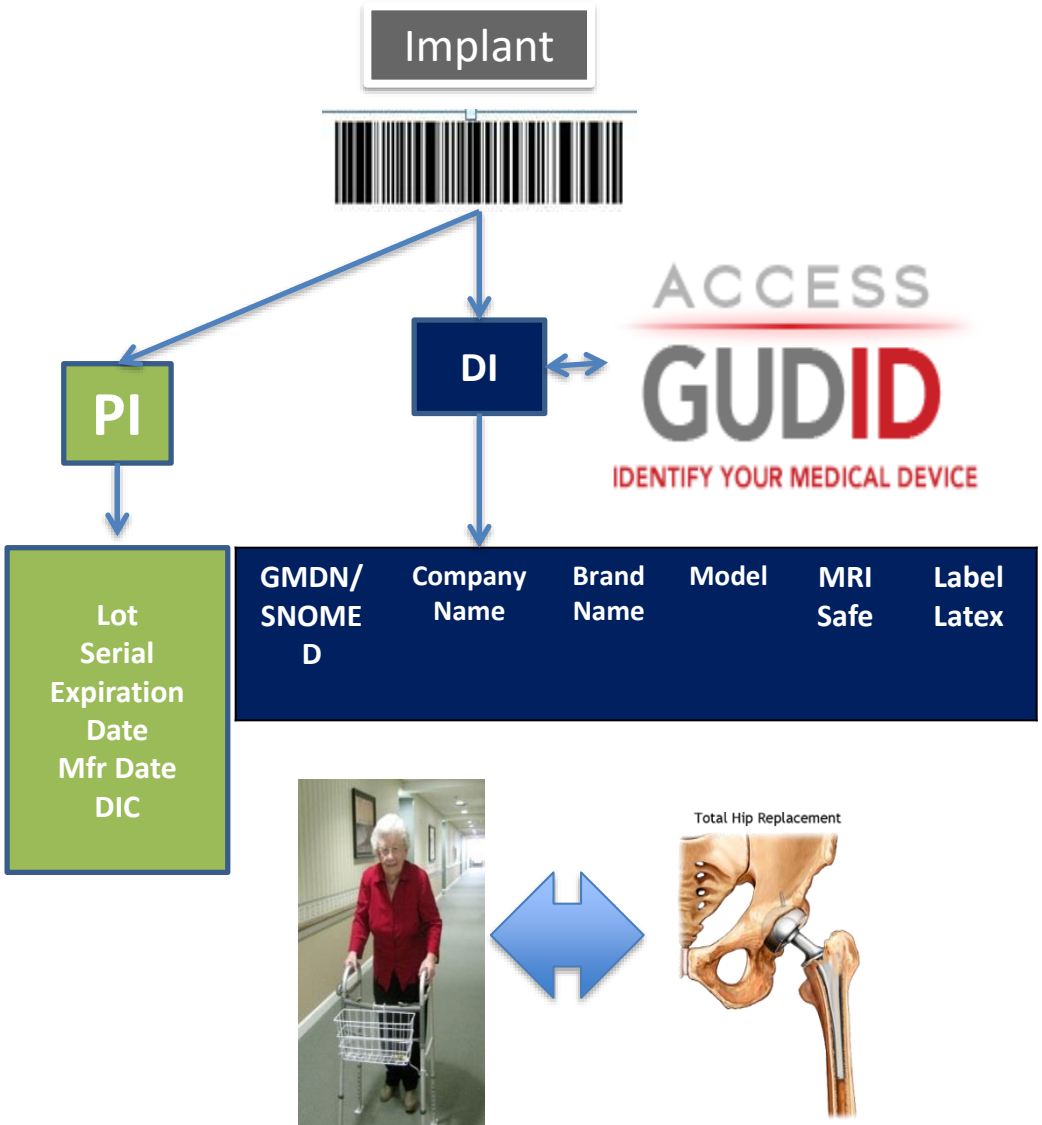


- Aortic arch branch vessel endovascular stent-graft
- Bare-metal carotid artery stent
- Bare-metal renal artery stent
- Drug-eluting carotid artery stent
- Drug-eluting femoral artery stent
- Drug-eluting infrapopliteal artery stent, bioabsorbat
- Drug-eluting infrapopliteal artery stent, non-bioabsc
- Drug-eluting renal artery stent
- Iliac artery stent, bare-metal
- Iliofemoral artery endovascular stent-graft
- Mesh-sleeve carotid artery stent
- Multiple peripheral artery stent, bare-metal
- Multiple peripheral artery stent, bioabsorbable

Device Categorization SNOMED



2015 Edition §170.315(a)(14) Implantable Device List
January 2018

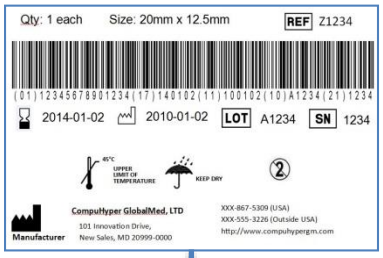


Certified Health IT Product List

Edition	Developer	Product
2015	Epic Systems Corporation	EpicCare Inpatient EHR Suite
2015	MEDHOST	MEDHOST Enterprise
2015	Netsmart Technologies	myAvatar Certified Edition
2015	Allscripts	Sunrise Acute Care
2015	Allscripts	Sunrise Ambulatory Care
2015	Medical Transcription Billing Corporation (MTBC)	TalkEHR
2015	Evident	Thrive EHR
2015	Evident	Thrive Provider EHR

As of 4/5/2017

UDI System Success



Record

Electronic Health Record

DI
PI

Summary of Care Documents

DI
PI

Claims

DI

Item Master

DI
PI

GUDID

DI

Registry

DI
PI

1. Label as source of data capture for device being used
2. Device Identifier captured in all data sources.
3. Data in GUDID is authoritative source to augment scanned device