MDEpiNet Registry Assessment of Peripheral Interventional Devices (RAPID) Working Group Meeting

Clearly identifying a device as part of real-world evidence

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2010 What is UDI ?

Medical Procedures [1]

1,000,000 Cardiac Catheterizations

719,000 Total Knee Arthroplasties

332,000 Total Hip Replacements

New Cars Sold [2]

1,230,500 Hondas

908,600 Nissans

358,500 Volkswagens

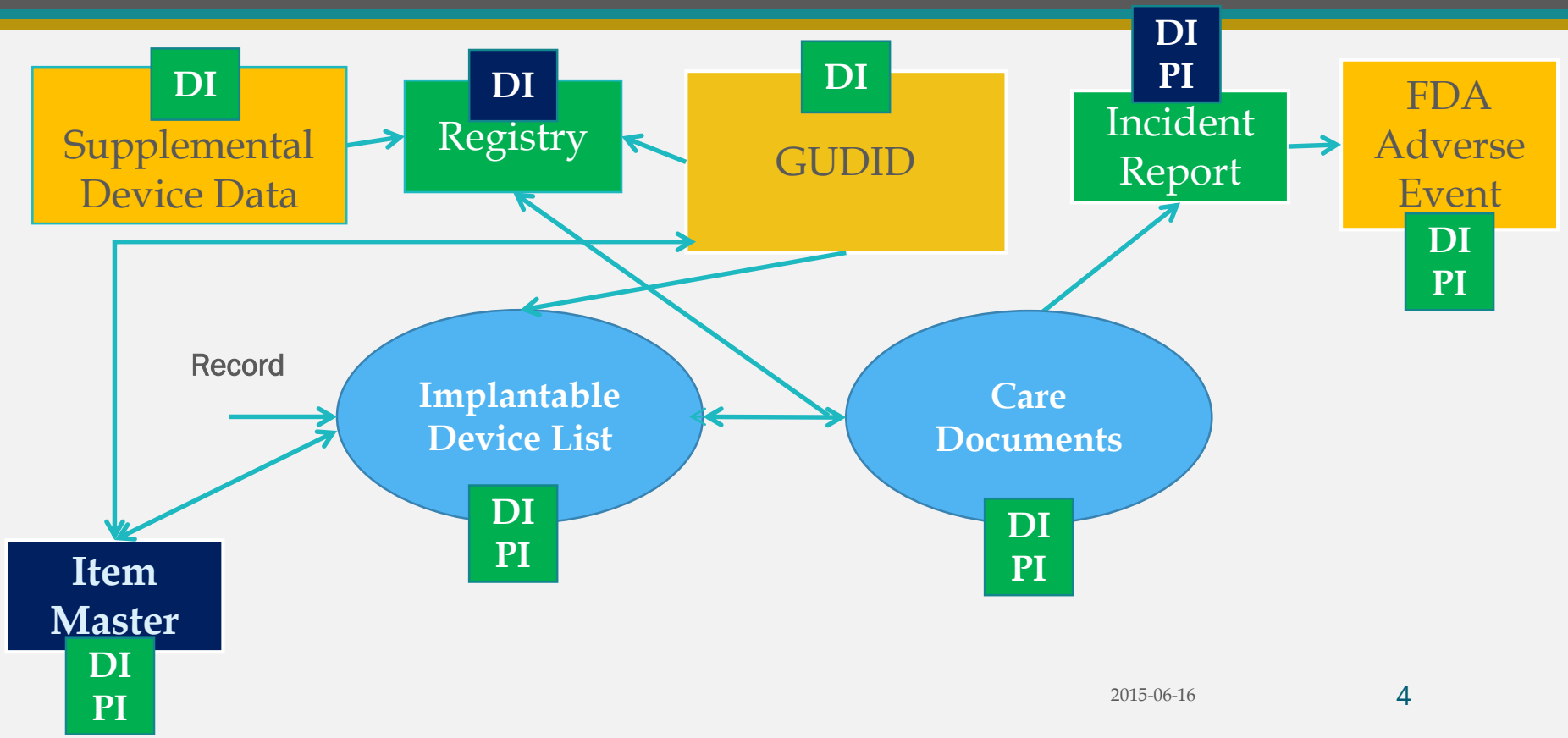
[1] Source: CDC/NCHS National Hospital Discharge Survey, 2010

[2] Source: WardsAuto - 2010 New Vehicle Sales

Why UDI integration is important to Registries

- Adds the device identifier (DI) and reference data set (GUDID) to standard registry device data
- Provides more efficient and consistent mechanism for linking device records across registries and with other data sources.
- Points to need for development of methodologies and linking tools that can be used to ease the transition from unstructured device data to use of UDI and GUDID.

UDI System for Implants



Goals and Objectives of GUDID WG

Goal:

- To develop recommendations for integrating UDI data into the RAPID core data set for use in contributing registries and as a linking mechanism to other data sources

Members of GUDID Workgroup

- Aaron Lottes, Cook Medical
- Daniel Bertges, Society for Vascular Surgery
- Carrie Bosela, Society for Vascular Surgery
- Carah Kucharski, Boston Scientific
- Megan Brandt, Cardiovascular Systems, Inc (CSI)
- Daniel Canos, CMS
- Barb Christensen, American College of Cardiology
- Jack Cronenwett, Society for Vascular Surgery
- Barry Daniels, GMDN Agency
- Joe Drozda, Mercy Health System
- Jeremy Durack, Society of Interventional Radiologists

Members of GUDID Workgroup

- Jackie Elkin, Medtronic
- Hitinder Gurm, University of Michigan
- Elisa Hebb, Volcano Corp/Philips Health Technology
- Mitchell Krucoff, Duke Clinical Research Institute
- Robert Lookstein, Society of Interventional Radiology/Mount Sinai Medical Center
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- Roseann White, Duke/DCRI
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- Bret Wiechmann, Society for Interventional Radiology
- Ke Zhang, M2S

GUDID Core Data Elements

- Device Identifier
- Company name
- Brand
- Catalog/Product number
- GMDN term/SNOMED
- Device Description
- Clinically relevant size
- Version or Model

GMDN Terms for Data Extraction

- Stent
- Stent Graft
- Plain Balloon
- Specialized Balloon
- Closure device
- Filter
- Atherectomy device
- Re-entry device
- Mechanical thrombolysis device

Key Learnings

- **DI and Ref/Catalog Number** or Product Number are crucial for linking GUDID to registry data
- Importance of capturing **clinically relevant size** in distinct fields for size type, unit of measure and quantifier
- Importance of **GMDN** as the potential terms that could be used to pull data from GUDID via enhanced APIs.
- Need to develop processes that facilitates **manufacturer updates** to GUDID data

DI Linking to Ref/Catalog Number

- Inconsistencies across manufacturers in pre-UDI number used
- Inconsistencies in format for this number
- Optional field in GUDID
- Used in electronic health information
- Transition plans should include this number

Clinically Relevant Size

- GUDID has basic size information
- GUDID enhancement needed to more accurately enter size data with appropriate units of measure
- Elements of size vary by device type

Additional Findings

- Recognize that GUDID does not contain:
  - International Data
  - No longer commercially available

Global Medical Device Nomenclature

- GMDN is assigned by manufacturer and linked to approved uses
- GMDN codes are proprietary; linked to SNOMED via AccessGUDID API
- The frequency of GMDN changing the status of a term to obsolete combined with the inability to enter obsolete codes in GUDID could potentially impact usefulness of GMDN as a standard for use in APIs

Next Steps

- Spend more time on GMDN assignment that is fit for purpose. Follow-up from NLM and manufacturers
- Ensure formal linkage to Phase II through coordination of UDI work with Clinical and Informatics WGs
- Ensure that stent device type is included in Phase II work