



Unique Device Identification (UDI) and Health Information Standards

HIT Standards Committee

March 27, 2013

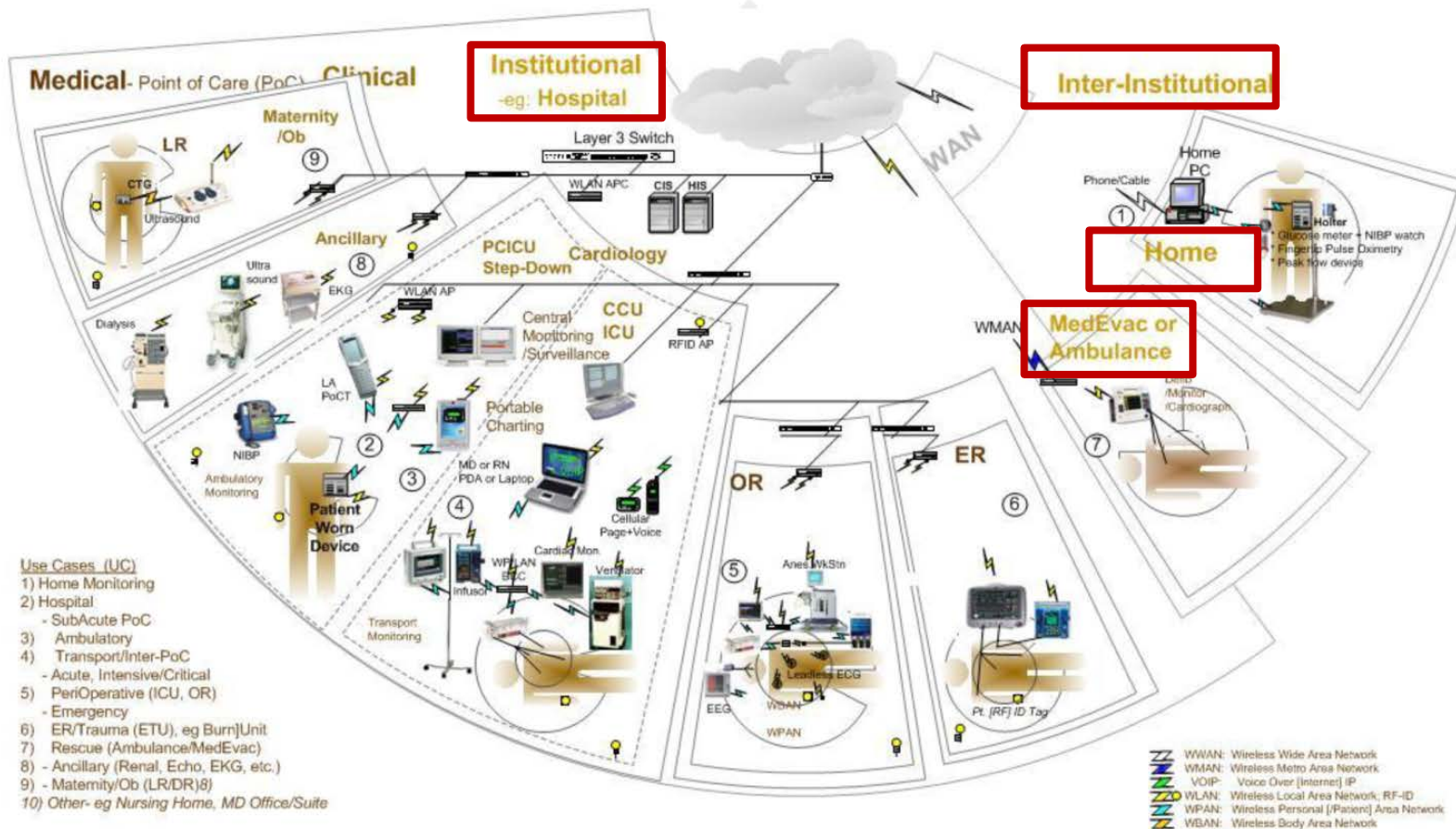
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FDA, Center for Devices & Radiological Health**

Definition of a Medical Device (FD&C Act)

Section 201(h) **“A medical device is: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:**

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the **diagnosis of disease** or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”

Medical Devices – Include Point Of Care Devices* and...



*Source IEEE 11073-00101TM-2008, Figure 2. -Originally developed by Jan Wittenberg/Philips Healthcare

...a Range of Other Devices with No UDIs...

Example: 1/2 mL insulin syringe/28 G needle

Business Name	Item Number Type	Item Number
BD	Mfg Catalog Number	329461
BD	GTIN	00382903294619
Cardinal Health	PV Order Number	BF329461
Owens & Minor	PV Order Number	0722329461
American Medical Depot	Vendor Catalog Number	777127217
Government Sci Source	Vendor Catalog Number	FSC1482679CS
Alliance Joint Venture	Vendor Catalog Number	888021932
Thomas Scientific	Vendor Catalog Number	8938M25
VWR International	Vendor Catalog Number	BD329461



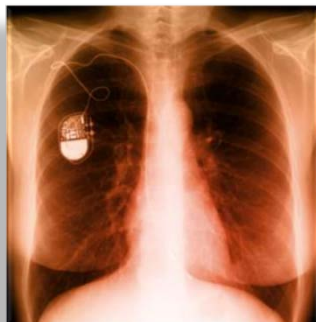
Syringes



Catheters



Surgical Instruments



Implants

UDI Legislation to Address Standard Identification

FDAAA 2007; FDASIA 2012

Not later than December 31, 2012, the Secretary shall issue proposed regulations **establishing a unique device identification** system for medical devices requiring the **label of devices** to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall **adequately identify the device through distribution and use**, and may include information on the lot or serial number. *The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.*

Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to create the unique device identifiers (UDI) - a foundational element – unambiguously identifies a specific device at its unit of use
2. Place the UDI in human readable and/or AutoID on a device, its label, or both
3. Create and maintain the Global Unique Device Identification Database (GUDID)
4. Implementation

1st – Developing the UDI

- Develop UDI code according to ISO 15459 [Issuing Agencies - GS1, HIBCC, ICCBBA]
- Under the FDA proposed rule, the UDI will be required to appear on the label of a medical device and will be composed of two parts:
 - Device Identifier (DI) - a unique numeric or alphanumeric code specific to a device version or model; The DI meets the requirements to uniquely identify a device through its distribution and use.
 - Production Identifier(s) (PI) - identifier(s) that define the production information for a device. The four defined production identifiers are: lot or batch number; serial number; expiration date; and manufacturing date.

2nd – Applying the UDI

- Unique UDI applied to “base package” AND higher levels of packaging
- Default location is the label
- Human readable and encoded in a form of automatic identification technology
- No specific technology (technology neutral)
- ALSO Direct Part Marking (DPM) for
 - an implantable device (>30 days)
 - intended to be used more than once, and intended to be sterilized before each use
 - stand-alone software

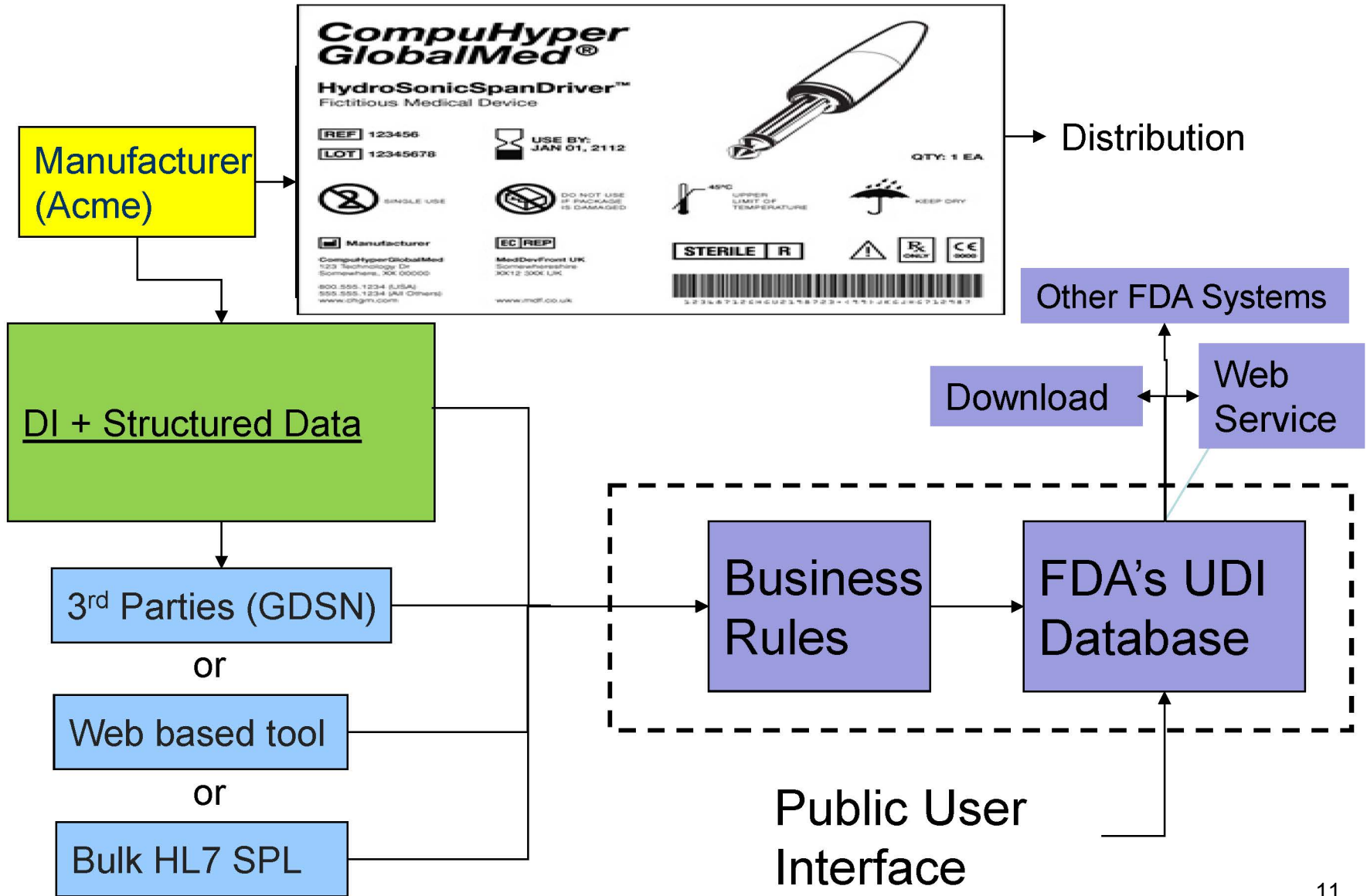
3rd – Storing in Global UDI Database (GUDID)

- GUDID is Catalog using device identifier (DI) as primary key to identify down to the model/version of a Device
- Identifiers (primary, secondary, packaging) are used to link history and packaging configurations of same device
- Device Identifier (DI) is look-up to associated device identification data attributes.
- DI and associated attributes are accessible via Internet search, database download, and/or web services capability.
- Submitted data attributes meet regulatory requirements – guidance to match label

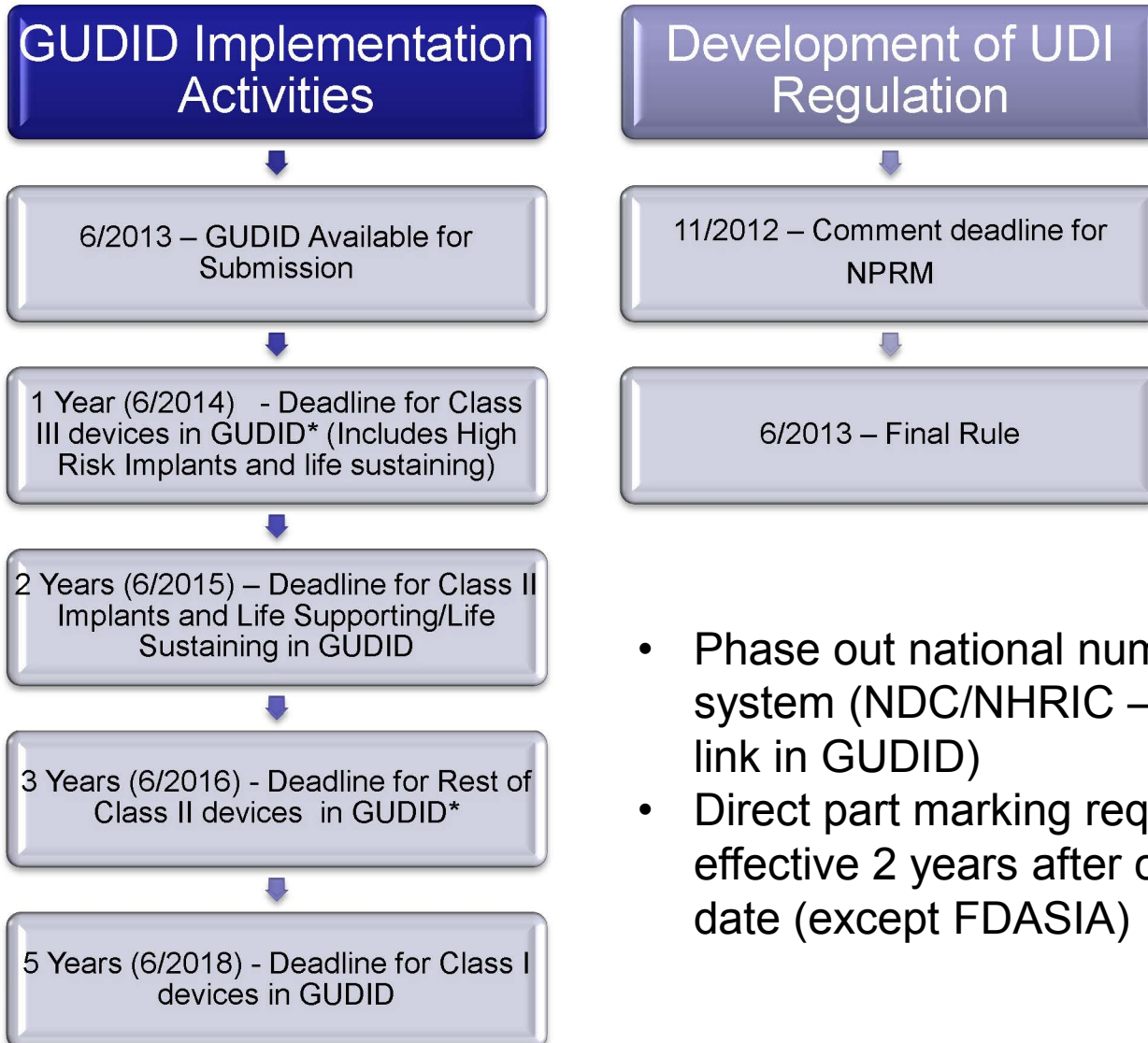
3rd – GUDID Data Attributes (select)

For each DI:

- Manufacturer, Make/model, Brand/Trade Name
- Clinically relevant size
- Contact information
- Sterility information
- Natural Rubber Information
- FDA premarket authorization (510k, PMA)
- FDA product code (procode)
- Marketing Status/date
- For single-use
- Higher levels of packaging
- Rx – OTC
- GMDN/SNOMED



4th - Proposed GUDID Timelines



- Phase out national numbering system (NDC/NHRIC – included as link in GUDID)
- Direct part marking requirements are effective 2 years after class effective date (except FDASIA)

GUDID – Points to Remember

- GUDID is Device Catalog not a Patient Registry
- GUDID does NOT contain patient or device specific production information, such as lot or serial numbers – and is NOT for track/trace or other similar purposes requiring the full UDI.
- GUDID contains only “static” identifying and product information.
- GUDID provides link to product information- not a replacement for FDA Recalls/Adverse Event Databases.
- Benefits accrue only if adopted by all stakeholders- EHRs, Claims, Inventory Systems, ...

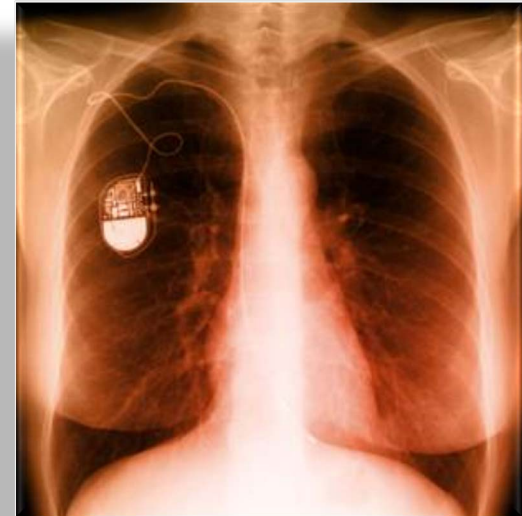
UDI: Adoption in Electronic Health Records

Proposal: UDI will be the code used in Health IT Systems to link a patient with specific devices used as part of his/her care.

- Linking UDI of Medical Implants to a patient's EHR record is a start – UDI of other devices will follow
- Scan UDI at point of care
- Store UDI and sufficient UDI and other data attributes (to be determined by expert groups) to maximize benefit to patient, care providers and other stakeholders
- Certification and/or Meaningful Use criteria should facilitate ability to search, exchange, alert, and patient/provider access to patient's device information.

Why Start with Implants?

- Implants are:
 - High Risk and Prevalent (see HCUP data in backup slides)
 - Complete Data Source meeting MU requirements – All implants must be submitted 2 years from Final Rule.
 - Device/ID Not visible to human eye
 - Persistent to Patient beyond original care site
 - Coordination of care issues
 - Contrast to devices tied to patient visit (IV pump, ventilator, bed)
 - Device data already captured to support patient charging



OPERATIVE CASE RECORD

Manufacturer: Acumed **Item:** Plate **Size:** left/low profile **Cat #:** 70-0126
Site: Clavicle, Left **Serial #:** [REDACTED] **Qty:** 1 **Lot #:** [REDACTED]

Screw/Other Part List:

Description	Size	Catalog #	Qty Used	Pkg. Intact	Lot #	Serial #	Exp. Date
1 Screw, Locking	2.3 x 16 mm	CO-T2316	1	N/A			
2 Screw, Locking	2.3 x 14 mm	CO-T2314	1	N/A			
3 Screw	3.5 x 10 mm	CO-3100	1	N/A			
4 Screw	3.5 x 14 mm	CO-3140	3	N/A			
5 Screw	2.3 x 16 mm	CO-N2316	4	N/A			

Manufacturer: Wright Medical **Item:** Other:See Additional Information **Size:** 4 cc **Cat #:** 876P0400
Site: Clavicle, Left **Donor/Serial #:** [REDACTED] **Qty:** 1 **Lot #:** [REDACTED]

Add'l. Info.: Wright Ignite mini powder mix.



10566	NC	DRSG COBAN LTXFR STER 4IN 5YD	1
10715	NC	CLEANER CAUT TIP	1
11977	NC	SUT PRLN 3-0 SH 30IN BLU	1
13318	NC	SOLN IV LR 1000ML	1
13328	NC	SOLN NACL .9% BTL F/IRR 500ML	1
13502	NC	SUT VIC 2-0 CT1 36IN UDY	0
17675	C17675	NDL MAYO CAT 1/2TPR .05X1.535	1
19400	C19400	STAPLER SKIN MULTIDIRECT 35W	0
20382	NC	SUT MNCRYL 4-0 PS2 27IN UDY	0
24551	NC	DRSG PETROLATUM XEROFORM 1X8IN	0
32612	NC	SYR IRR BULB	1
36830	NC	DRSG TEGADERM 6X8IN	4
37181	NC	DECANTER VIAL	0
37793	C37793	RETRIEVER SUT, STER DISP SM TEL	1
39717	NC	CAUT PENCIL HND CTRL NDL TIP	1
65491	NC	INSTR SUCT YANKAUER FLX FIN TI	1
68883	NC	COVER FLUORSCAN C-ARM	1
13416	NC	SUT VIC 3-0 27IN UDY SH	1
14900	C14900	PACK ORTHO SPORTS SHLDR HH	1

EHR Certification Criteria Possibilities

RECEIPT and PARSING

- EHR Accept electronic UDI data via:
 - Scanned bar code – at a minimum various bar code standards must be supported
 - Other accepted emerging technologies as used in by healthcare systems (e.g. RFID)
- EHR Capture multiple UDIs per patient visit and per procedure within patient visit
- EHR Parse out the DI and PI information to store as part of patient case
- EHR Use the DI to capture the GUDID attributes from the GUDID using web services.

EHR Certification Criteria Possibilities

STORAGE

- EHR Store the UDI at the level of unit of use.
- EHR Recognize and store secondary device identifiers.

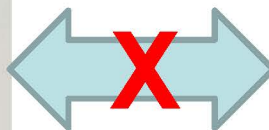
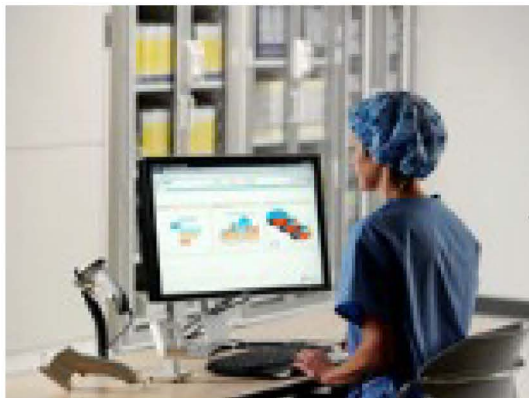
EXCHANGE

- EHR Use UDI as the code to identify and exchange device information between other systems and modules within a system

EHR Certification Criteria Possibilities

Access to Patient-Device Information

- Make DI, PIs, and select device identification attributes accessible to the EHR for reporting purposes (e.g. adverse event reporting, registry population)
- Allow user to **LOOK-UP UDI** information by UDI elements and retrieve the **associated patients/cases and clinical data**
- Allow user to **LOOK-UP PATIENT** and retrieve **associated device**



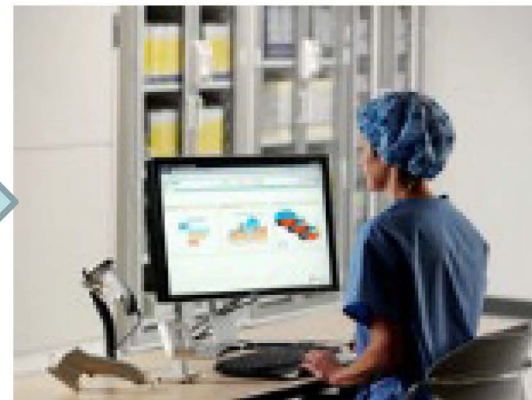
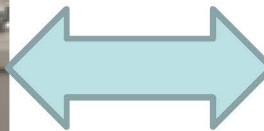
The screenshot shows a software window titled "Implantable Medical Devices" with a search icon, a plus sign, a minus sign, and a power icon in the top right. The form contains the following fields:

- User* (dropdown)
- Item name* (text)
- Reason* (text)
- Description (short) (text)
- Description (long) (text area)
- Physician* (dropdown)
- Facility* (dropdown)
- Accessories (Y-N)* (checkbox)
- Accessories - list* (text area)
- Notes (text area)
- Report Number (text)
- Attachments (text)
- Manufacture* (dropdown)
- Model number* (text)
- Model revision* (text)
- Serial number* (text)
- Capacity* (text)
- Unit of Measure* (dropdown)
- Date implanted* (text)
- Estimated life (text)
- Manufacture contact (text)
- Manufacture phone # (text)

At the bottom, there is a status bar with "Record: 1 of 1", "No Filter", and a search box.

Medication Criteria as Model for Devices

- Scan at Point of Care
- Access between pharmacy information system and EMR
- Drugs associated with patient in all EHR modules and at discharge
- Clinical Decision Support available in EHR



Making the Link between Patient & Device..

Clinical Care Benefits

- Supports Care Coordination in hospital
- Informs future patient care
- Improves Recall effectiveness
- Improves ability to conduct Active Surveillance by hospital
- Makes device available for Summary Views of Patient – patient lists, summary documents
- Links device to Diagnosis and other elements of Patient Care
- Enables device maintenance – Vascular Access Port, Pacemaker
- Provides rapid access to accurate, standardized device information when needed (ER, MRI, Recall)
- Enables building of meaningful quality and performance measures and clinical decision support tools – natural rubber latex, MRI capability

Public Health Benefits

- FDA will use information received to:
 - Improve decisions related to adverse event reports
 - Better understand the risk profile of particular devices
 - Mine population-based data sets to better understand the risks and benefits of device use within certain patient populations and indications
 - Better and more quickly address new concerns raised in premarket submission

Adoption of UDI into EHRs – Stakeholder Roles

FDA

- Will regulate and work with manufacturers on submission and storage of UDI in GUDID
 - Data Quality and Data Management Principles
- Will provide access to GUDID via search, download and web service
- Works with Data Standards and Healthcare groups to educate and align with other EHR standards/activities

Manufacturers - label devices to meet regulatory timeframes and submit DI and attributes to GUDID

Contributors to UDI Adoption in Healthcare

- Brookings - Roadmap for Adoption including Expert Panels
- UDI Pilots –UDI integration in EHRs
- Office of National Coordinator –Ongoing Collaboration
- Health IT Policy and Standards Committee –
 - Clinical Operation Workgroup/Vocabulary Comments to UDI Rule
 - Patient Engagement– Consumer group/Care providers in Brookings Expert Panels
- Many Others

Questions for Health IT Standards Committee

- How can I make the patient-device link use case more clear, more compelling, for including in EHR Certification and Meaningful use criteria?
- I have presented a preliminary use case. Are there other use cases to include in the preliminary stages of UDI being added to the EHR?
- What data attributes of the GUDID should be combined with the patient record to create a meaningful minimum dataset to support adding UDI to EHR Certification?
- Who are the best experts/what is the best mechanism for defining the minimal dataset and ensuring that they become the foundation for storage, exchange and access to patient-device data?
- What should I expect as next steps/outcomes of this presentation?
- What can FDA do to assist in moving forward? What can other stakeholders do?
- How can UDI assist with development of data standards for Registries?
- Are there any considerations beyond those presented regarding collection, parsing, and exchange of data?
- Comment that UDI database maintenance must be timely – marketing status changes?



Unique Device Identification

www.fda.gov/UDI

Email: cdrhudi@fda.hhs.gov



Back-up Slides



Patient Implant Data

Discharge Data* -Select Orthopedic and Cardiovascular Procedures				
Orthopedic Implants		2008	2009	2010
Hip	65-84 yrs	135,613	140,794	144,391
	Total All other age groups**	140,557	143,661	157,027
Knee	65-84 yrs	333,569	337,623	351,209
	Total All other age groups**	281,481	282,003	304,814
Shoulder	65-84 yrs	17,800	21,597	25,864
	Total All other age groups**	8,805	11,275	13,208
Cardiac Implants	65-84 yrs	34,783	32,053	23,721
	Total All other age groups**	34,200	31,724	26,304
	TOTAL IMPANTS	986,808	1,000,730	1,046,538

*Courtesy AHRQ HCUP Website

**All other Age groups: < 1 yr; 1-17 yrs; 18 - 44 yrs; 85+years

Issuing Agencies

- Issuing agencies accredited after Final Rule
- Groups that currently meet ISO 15459
 - GS1 Healthcare (GTIN) –
 - 35 Years ago – created UPC, for the retail and grocery
 - Global Healthcare – local chapters in 35 countries
 - Goal of Global Healthcare User Group - to be recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders who are seeking input and direction for global standards in healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation.

Issuing Agencies

HIBCC - Health Industry Business Communications Council

- ANSI-accredited organization, sees primary function as facilitating electronic communications by developing appropriate standards for information exchange among all health care trading partners
- Created industry codes for medical products (the Labeler Identification Code) and healthcare providers (the Health Industry Number)
- Repository for unique product numbers, UPN®, developed in 1990's by the U.S. DoD - includes HIBCC and GS1 product codes.

Issuing Agencies

ICCBBA - International Council for Commonality in Blood Banking Automation

- Standard – ISBT 128
- Global standard for the terminology, identification, labeling, and information transfer of human blood, cell, tissue, and organ products across 60 countries widely endorsed.