Supplemental UDI Data for RAPID

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SUDID is now AUDI

- **Supplemental UDI Data (SUDID)**
  - Term used in Mercy's UDI Demonstration
  - Clinically relevant coronary stent attributes not found in the GUDID
- **Augmented UDI Data (AUDI)**
  - Term we are now using for all medical device types
  - References augmenting the FDA's Global UDI Database (GUDID)
- **Associated with the DI portion of the UDI**

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Mercy UDI Demonstration

- **Aim 1: Implement a coronary artery stent UDI-based surveillance system in the EHR in a multi-hospital system (Mercy)**
- **3 Key Components:**
  1. Create Draft UDIs & associate with base attributes in the FDA's Global UDI Database (GUDID)
  2. Create clinically meaningful supplemental attributes to be stored in a reference database
  3. Create UDI data flow through ERP to cath lab to EHR to UDI data set

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

The Expert Work Group

- **The Expert Panel: Five interventional cardiologists appointed in conjunction with ACC and SCA&I**

- **"*Ex officio*" members**
  - FDA representatives
  - Coronary Stent manufacturer representatives
  - HTG hospital system representatives
  - NCDR representatives

Tasks for Expert Work Group

- Develop a constrained list of coronary stent clinical attributes to supplement the GUDID attributes
- Propose a permanent home for UDI clinical attribute database (SUDID)
- Recommend a governance structure for the SUDID
- Develop a proposal for an organization and processes for ongoing maintenance of the SUDID

Table 3: SUDID Clinical Attributes and Parameters

Attribute	Definition	Parameter	Data Type
Length	Nominal length per manufacture specification	Fractional dimension in mm	4 significant digits, w/1 precision
Diameter	Nominal (inner) diameter per manufacturer specification	Fractional dimension in mm	4 significant digits, w/2 precision
Non-conventional Property	Stent having nonconventional design, variable or multiple length/diameter parameters	Covered stent Bifurcation Stent Tapered Stent	Alphanumeric
Structural Material	Composition of principal structural element	Constrained list e.g. L605 cobalt chromium -- Constrained list to be developed	Alphanumeric
Coating(s)	Non-Structural material covering surface of structural element	Constrained list -- Constrained list to be developed --Need to handle multiples --name that would be mostly referenced --start with what is in the IFU --accommodate multiple coatings	Alphanumeric
Drug(s)	Active agent released from stent	NDC directory (default) --Use name if no applicable NDC code—do it uniformly	Alphanumeric
Strut Thickness	Maximum nominal thickness of stent struts on a radius from the center of the stent	Dimension in microns	4 integer digits
Surface to Artery Ratio*	Percentage of the surface area of the artery covered by the stent at nominal expansion of the stent		3 significant digits, w/1 precision
Expansion Method	Method used to achieve nominal stent deployment	Balloon Self	Alphanumeric
MRI Compatibility	MRI compatibility category per testing	4 categories per existing standard: --Safe --Conditional --Unsafe --Not tested	4 Categories

*This attribute was originally selected by the Expert Panel but subsequently withdrawn
SUDID = Supplemental Unique Device Identifier Database; IFU = Instructions for Use; NDC = National Drug Code; MRI = Magnetic Resonance Imaging

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Options for Device Comparisons

- **Baseline patient characteristics**
  - Demographic
  - Clinical (lab, diagnoses, etc.)
- **Devices**
  - Device identifier +/- production identifier
  - Attributes
- **Outcomes (MACE)**
  - Individual
  - Combined

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Obstacles

- **Agreeing on:**
  - Industry-wide standards
  - Device attributes
  - Organizational infrastructure and support for designing and maintaining a UDI system
  - The business case for all stakeholders

MDEpiNet AUDI Workgroup

- **MISSION:** Provide the framework for best practices in expanding the UDI-associated device system to manage clinically relevant attributes not currently found in the GUDID
- **COMPOSITION:** Industry, clinical, and regulatory representatives
- **FOCUS GROUPS:** Structure & Hosting, Operations & Informatics, Governance, Funding

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- **Principles (selected)**
  - Start small and move forward gradually
  - Leverage device attribute data that are already published
  - Anticipate that AUDI requires and self-defines a device classification system (AUDI attributes describe families or types of devices)
  - AUDI will raise awareness of issues with the GUDID - but the goal is not to ‘fix’ the GUDID

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- **Assumptions (selected)**
  - Examples of clinically relevant attributes are size, composition, and risk for cyberterrorism
  - Fields recommended for inclusion in AUDI may also be proposed for eventual inclusion in the GUDID
  - AUDI data fields may be specific to certain types of devices / certain classes of devices
  - The AUDI database is a reference database containing current attributes that may be accessed in real time or near-real time.
  - AUDI is not covered under regulation and represents a voluntary database under multi-stakeholder governance.

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- **Use Case Examples**
  - Device selection at the time of implantation based on clinically relevant characteristics
  - Comparative Effectiveness Research
- ***Operations & Informatics***
  - AUDI will be responsible for bringing together subject matter experts from clinical medicine, professional societies, industry, the public, and hospital systems to identify parsimonious sets of clinically relevant device data elements for specific device types / specific device classes.

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AUDI in RAPID

AUDI for DCB Example

Attribute Long Description
~~Balloon Type (POB, DCB, cutting)~~
Balloon ~~Subtype~~ Compliance
Balloon Diameter xx.x (mm)
Balloon Length xx.x (mm)
Catheter Configuration (OTW, RX)
Catheter Length xxx (cm)
Nominal Balloon Pressure xx.x (atm)
Rated Burst Pressure xx.x (atm)
Maximum Guidewire Diameter 0.xxx (inches)
Minimum Introducer Sheath xx.x (Fr)
Crossing Profile 0.xxx (inches)

Attribute Long Description
Coating Formulation Active Pharmaceutical Ingredient (API)
Coating Formulation Excipient(s)
Coating Formulation API Surface Concentration
Coating Formulation API Total Dosage
~~Transit Time per Balloon (sec)~~
~~Inflation Time per Balloon (sec)~~
~~Maximum Pressure of Inflation per Balloon (atm)~~
~~Balloon to Vessel Ratio (Inflated Diameter/RVD)~~

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What's happened since October?

- **Received AUDI drug coated balloon data element values from 1 manufacturer**
- **UDI won't be used in Phase II/SPEED but will be in Phase III**
- **Efforts to use Global Medical Device Nomenclature (GMDN) to create PAD device categories**
  - GMDN is basis of GUDID classification system
  - Identify other DCB manufacturers
  - Create categories for AUDI attributes
    - Atherectomy devices
    - Stents
- **Current AUDI efforts: Atherectomy devices**

GMDN as a Categorizaton Tool

Device	CT Tree	Final Term(s)
ATHERECTOMY DEVICES		
a. Excisional (cutting) atherectomy • **HawkOne, SilverHawk, TurboHawk (scrape / shear / capture) – Medtronic** • **Pantheris (scrape / shear / capture, with ultrasound guidance) – Avinger** • **Jetstream – (front cutting with flush/aspiration) – Boston Scientific** • **Phoenix (Archimedes screw with aspiration) – Philips**	CT130: Catheters and associated devices → CT1581: Catheters → CT477: Cardiovascular catheters → CT1025: Angioplasty / atherectomy catheters → CT1588: Peripheral angioplasty/atherectomy catheters	Mechanical atherectomy system catheter, coronary/peripheral Mechanical atherectomy system catheter, peripheral [no directly matching terms]

GMDN as a Categorization Tool

- **Desired Categories and Subcategories**
  - Atherectomy Devices
    - Excisional
    - Rotational
    - Ablative
  - Stents
    - Balloon Expanding
    - Self Expanding
    - Covered
  - Balloons
    - Plain
    - Atherectomy
    - Drug Coated
    - Temperature modulation (cryo)
- **Of the 10 subcategories, explicit matches for 3**
- **Conclusion: Have some work left to do to create a system of sufficiently robust device classification for our purposes.**

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Summary

- Supplemental UDI data (AUDI) are clinically relevant device attributes
- AUDI augments GUDID device data
- AUDI data are to be housed in a reference database linked to research database by DIs
- AUDI database is a rich source of device covariates
- RAPID AUDI attributes chosen for drug coated balloons
- Next steps: 1. Atherectomy device attributes
  2. Stent attributes
  3. Categorizaton schema

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Thanks!

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