



# Clinically Relevant Size (CRS) Work Group Summary Statement

## Mission

The mission of the Clinically Relevant Size (CRS) workgroup is to provide the framework for the FDA GUDID system to facilitate correction of existing device size data in the GUDID and to accurately capture device size data for new entries into the GUDID.

## Background

### 1. GUDID

- Multiple fields exist in the GUDID to capture the components that comprise the concept of size
  - sizeType – this is intended to be the measurement type (length, width, height, etc.)
  - unit – this is intended to be the unit of measure (cm, mm, inches, etc.)
  - value – this is intended to be the number
  - sizeText – unsure on the intent of this field
  - Size information can also be in one or more of the device description fields
- GUDID set up to capture 2 size parameters
- GUDID issues (see Appendix below)
  - Data not being entered into GUDID consistently, correctly, or at all
  - Ambiguity as to what size data is to be captured
  - Ambiguity as to where to capture what piece of size data
  - Ambiguity of intent of sizeText field
  - Drop down choices are incomplete
  - Data field names need to be more intuitive i.e., self-correcting, etc.

### 2. Perspectives of data users

- Many devices come in multiple sizes
- Size is a primary attribute for selection of a specific device for a specific patient
- Clinicians have a high need for size information to be documented correctly at the time of implant – size information is frequently referenced at follow-up procedures, visits
- Size information is needed for analytics – e.g., clinical outcomes vary by size of device, and by relationship of size of device to patient parameters

### 3. Perspectives of FDA and National Library of Medicine (NLM)

- What is the FDA / NLM requesting, and what would be useful to return to FDA / NLM?
- What can FDA / NLM actually act upon, and what would nominally be out of bounds?
- If out of bounds, what would be the process to bring recommendations in bounds?
- NLM GUDID data model, potential / capacity to actually augment the GUDID database

### 4. Review the SUDID work of the Mercy demonstration project

- Demonstration project description: Drozda JP Jr et al., Healthc (Amst). 2016 Jun;4(2):116-9.
- SUDID component of the demonstration project: Tchong JE et al., Am Heart J 2014;168:405-413.e2



- 18 use cases (clinical care, supply chain management, consumer information, research, regulatory, and surveillance domains)
- 9 SUDID attributes (length, diameter, nonconventional property, structural material, coating(s), drug(s), strut thickness, expansion method, MRI compatibility)

## Understanding the Problem

- *Review of data returnable from the GUDID system*
  - Review the Clinically Relevant Size data elements in the GUDID
  - See Appendix 1 below for examples of coronary stent data returned from the GUDID (BUILD project)
  - Look-up other devices (examples from VANGUARD, RAPID projects)?
- *Identify use cases, stakeholders who will be using the data, needs of those stakeholders*
  - Are there other use cases than those identified in the Mercy demonstration?
  - Work group comprised of supply chain, registry personnel, clinicians
  - Are there other stakeholders that need to be included?
- *Perspectives of industry*
  - Supplying / updating / revising size information in the GUDID will require time, effort, and resources. What does best state look like from an industry perspective in terms of providing / updating clinically relevant size?

## Deliverables

- *Identify, articulate the principles to identify components of device size*
  - By class of device
  - Blue sky exercise
- *Recommendations and artifacts*
  - List of use cases
  - Recommendations for operational approach to managing size data (i.e., overall organization and governance)
    - Responsibility for continuing activity – NEST, MDEpiNet?
    - FDA / NLM administrative resources to organize and manage
  - Recommendations for operational approach to identifying device size attributes within a device class (i.e., governance of device class workgroups)
    - Principles about “what” and “who”, then adding the “how”
    - “Form” (or file format), process to submit size attributes list to NLM
    - Organizing manufacturers to update size data in GUDID
  - Technical recommendations
    - Changes to GUDID structure, data fields for capturing size data (including names, permissible values, instructions, etc.)
- *Review and dissemination*
  - Submission of recommendations to FDA and NLM
  - Posting to LUC, BUILD (Natalia Wilson), MDEpiNet, etc.
  - Posting via FDA channels
  - Manuscript opportunity

## Appendix 1

Notes about data currently in the GUDID system – using examples from 3 different manufacturers of coronary stents



To return information about a specific device, append either di=xxxxx or udi=xxxxx to the following URL as one long string. Note that the “di” or the “udi” must be **lower case**.

API: <https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.json?>

E.g.: For the Abbott Xience Alpine 3.5x28mm over the wire (OTW) drug-eluting stent (DES), where DI=08717648200274:

<https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.json?di=08717648200274>

E.g.: For the Medtronic Resolute Integrity 2.5x18mm over the wire (OTW) drug-eluting stent (DES), where DI=00613994793300:

<https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.json?di=00613994793300>

E.g. For the Boston Scientific Promus Element Plus 3.0x16mm monorail (RX) drug-eluting stent (DES), where DI=08714729807957:

<https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.json?di=08714729807957>

This returns the information in JSON format. Data can also be returned in .xml format – simply change the URL from lookup.json? to lookup.xml?.

*Returned information includes the following:*

*For the Abbott Xience Alpine stent:*

deviceDescription: "XIENCE Alpine Everolimus Eluting Coronary Stent System 3.50 mm x 28 mm  
/ **Over-The-Wire**"

gmdnPTName: "Drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated"

fdaProductCode – productCode: "NIQ", productCodeName: "Coronary drug-eluting stent"

deviceSizes: **null**

*For the Medtronic Resolute Integrity stent:*

deviceDescription: "Stent RSINT25018W MicroTrac 2.50X18**OTW**"

gmdnPTName: "Drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated"

fdaProductCode - productCode: "NIQ", productCodeName: "Coronary drug-eluting stent"

deviceSizes:

sizeType: "**Device Size Text, specify**";

unit:"";



value:"";

sizeText: "Stent Inner Diameter 2.5 MM"

sizeType: "Length"

unit: "Millimeter"

value: "18.0"

sizeText: null

#### For the Boston Scientific Promus Element Plus stent

deviceDescription: "Everolimus-Eluting Platinum Chromium Coronary Stent System"

gmdnPTName: "Coronary angioplasty balloon catheter, basic"

gmdnPTName: "Drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated"

fdaProductCode - productCode: "NIQ", productCodeName: "Coronary drug-eluting stent"

deviceSizes:

sizeType: "Device Size Text, specify"

unit: ""

value: ""

sizeText: "16 mm Stent Length"

sizeType: "Device Size Text, specify"

unit: ""

value: ""

sizeText: "3.00 mm Stent Diameter"

#### Notes

- GMDN nomenclature (gmdnPTName) of device classification APPEARS CONSISTENT – but only text
- FDA nomenclature (productCode, productCodeName) of device classification APPEARS CONSISTENT – productCode is a coded schema
- There is no discrete data field to differentiate RX vs OTW design → EDAD



- There is no convention for handling RX and OTW designations in the descriptions → data cannot be easily parsed
- There is no discrete data field to identify the drug that is eluted (Xience: everolimus; Resolute: zotarolimus; Promus: everolimus) – for Resolute, this isn't anywhere in the information; for Xience and Promus, it is in the name of the device → EDAD
- Application of clinically relevant size fields is completely inconsistent (these 3 examples were each a different permutation) → rework of clinically relevant size (a different workgroup)

## Appendix 2

### Further perspectives on Clinically Relevant Size

The RAPID group is starting a Clinically Relevant Size WG to discuss how to make the GUDID more useful with respect to device size types and units of measure. Clinically Relevant Size as it currently stands in the GUDID is not helpful and is a combination of text and standardized data (see Appendix 1 for examples of coronary stent data).

#### *Example:*

- Catheter 3mm length
  - Field called measurement type (length, width, height, etc.)
  - Field for unit of measure (ft, inches, cm, mm)
  - Field for number (1, 2, 3)
- Not being filled consistently, correctly (or at all)
- Drop downs are incomplete
  - Work group to determine what other selections are needed
- Work group comprised of supply chain, registry personnel, clinicians
  - Focused on peripheral vascular devices
- MDEpiNet to convene the meeting
  - Ask Steering Committee, Members at Large who wants to get involved
  - Develop a standard and apply to GUDID
- How to apply RAPID approach to all devices?
- Raising awareness