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 2.50X18OTW"
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 → AUDI
- 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 → AUDI
- 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)