U.S. FOOD & DRUG ADMINISTRATION

Vision for a Global UDI System

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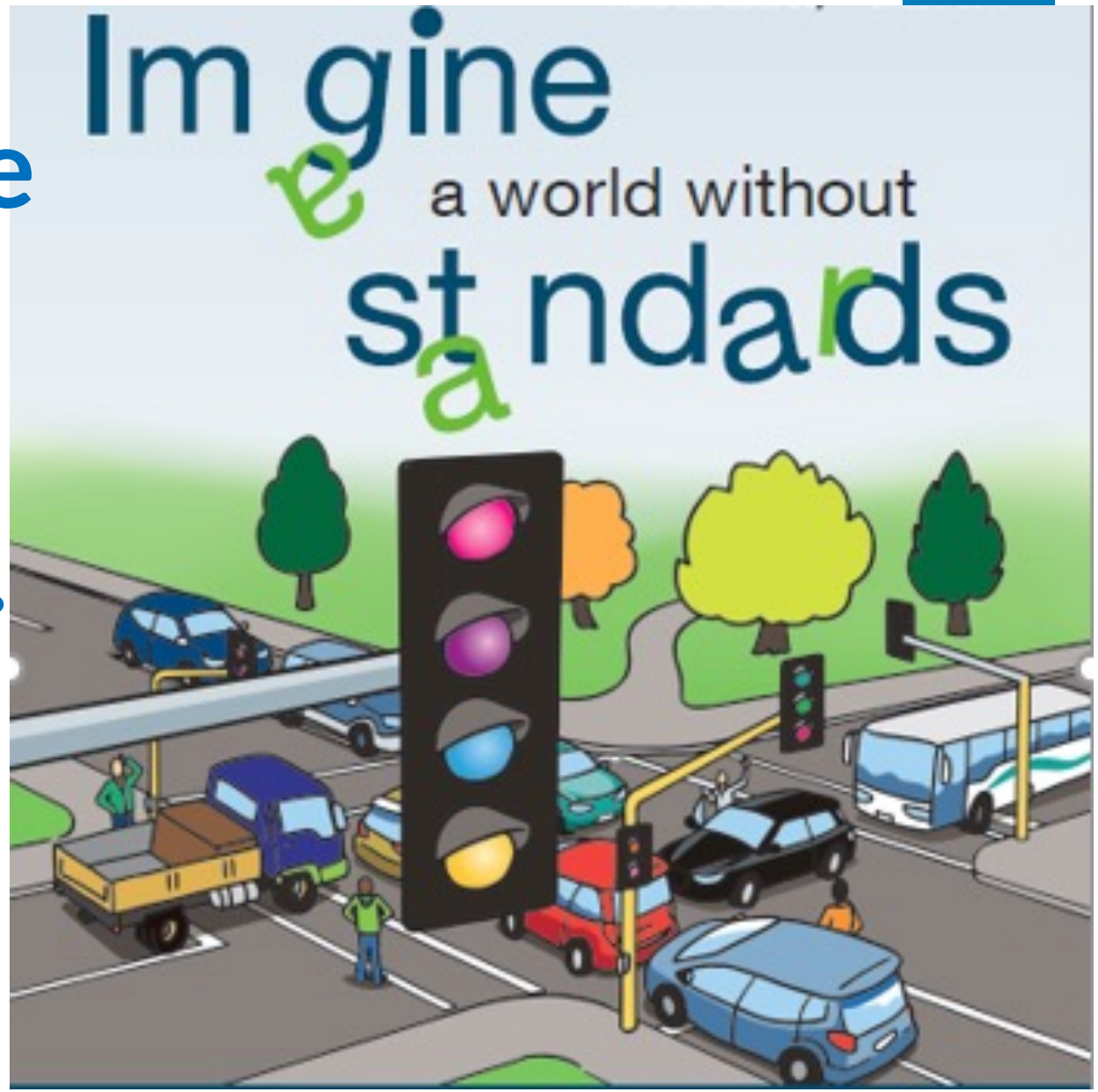
Why Standard Device Identifiers?

..take a moment and..



To each his own….identifier

Device: Syringe 3ml, 22 Gauge Needle

Catalog Number: 12345

Product Number: AB678

Item Number: XYZ90

Manufacturer

Distributor

Hospital

One Number, Many Devices…

Number	BD Product	Other Supplier
382268	382268 - 14 G x 3.25 in. BD Angiocath™ peripheral venous catheter (2.1 mm x 83 mm) made of FEP polymer. (10/sp, 50/ca)	Dentsply 03-822-68 SS GLD 018X022 14IN PKG 10
381705	381705 - 18 G x 1.16 in. BD Angiocath™ Autoguard™ shielded IV catheter (1.3 mm x 30 mm) made of FEP polymer. (50/sp, 200/ca)	Mallinckrodt 3817-05 CHEMICAL DRY SODIUM PHOSPHATE DIBASIC
371073	371073 - BD E-Z Scrub™ surgical scrub brush impregnated with 4% CHG. Color coded red. (30/sp, 300/ca)	Codman 371073 DEBAKEY BULLDOG CLAMP RING HANDLE ANGLED 90? STRAIGHT SHAFT 41MM JAW 4 3/4" (120MM)
305905	305905 - 3 mL BD SafetyGlide™ syringe with 23 G x 1 in. shielding intramuscular injection needle, regular bevel, regular wall. Detachable needle. (50/sp, 400/ca)	CARL ZEISS 305905 FLOORSTAND S-1 COMPLETE, W/ARTICULATED ARM SYSTEM FOR OPMI & ACCESS 2.5-7 KG.

…..so what?

*Table Courtesy BD, Dennis Black

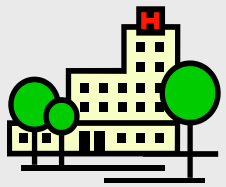
Additional Data Issues

350+ Ways to Spell BD

B D VACUTAINER DIV	B-D DIAGNOSTICS
B-D SUP CHAIN SVCS	BD / ELASTIC HEALTH SUPPORT
BD BLOODCOLLECTION	B D ACUTECARE
B-D LABWARE	B-D VASCULAR ACCESS
BD ACUTECARE	BD CONVENTION NEEDLES
B D DIAGNOSTIC	B-D MICRO BIOLOGY SYSTEMS
B.D. MICROBIOLOGY	BD ACUTECARE DIV
BD CRITICAL CARE	B DICKINSON
B-D MICROBIOLOGY	BARD PARKER
BD ACUTECARE DIV.	BD DBA BECTON DICKINSON AND CO
B&D	B-D MICROBIOLOGY SYSTEMS
BARD-PARKER	BD BIO SCIENCE
BD DIAGNOSTIC	B-D
B-D PRIMARY CARE	BARD-PARKER RESPIRATORY
BD BIO SCIENCES	BD DIAGNOSTIC INSTRUMENT SYST
B-D / VISITEC	B-D PRIMARY CARE DIAG

Many Product Numbers for Each Product

BD	329461
BD	00382903294619
CARDINAL HEALTH	BF329461
OWENS & MINOR	0722329461
OWENS & MINOR	0723329461
AMERICAN MEDICAL DEPOT	777127217
AMERICAN MEDICAL DEPOT	777127218
GOVERNMENT SCI SOURCE	FSC1482679CS
GOVERNMENT SCI SOURCE	FSC1482679PK
ALLIANCE JOINT VENTURE	888021932
THOMAS SCIENTIFIC	8938M25
THOMAS SCIENTIFIC	8938M28
VWR INTERNATIONAL	BD329461



Just 1 Hospital

Many Proprietary Numbers for Each Customer

St. Michaels	St Michaels	St. Michael's	Saint Michaels	100084547	CA2053
50003000431	1000014082	1000014769	1000042141	1000118699	50003000306
50003000308	50003000309	50003000312	50003000313	50003000314	50003000315
50003000316	50003000330	50003000366	50003000406	50003000422	50003000426
50003000431	50003000432	50003000433	50003000440	50003000442	50003000453
50003000456	50003000468	50003000472	50003000473	50003000476	50003000477
50003000480	2104372	2104379	2108919	JGGG	(178 Total)

*Slide Courtesy BD, Dennis Black

Challenges without Standard Identification

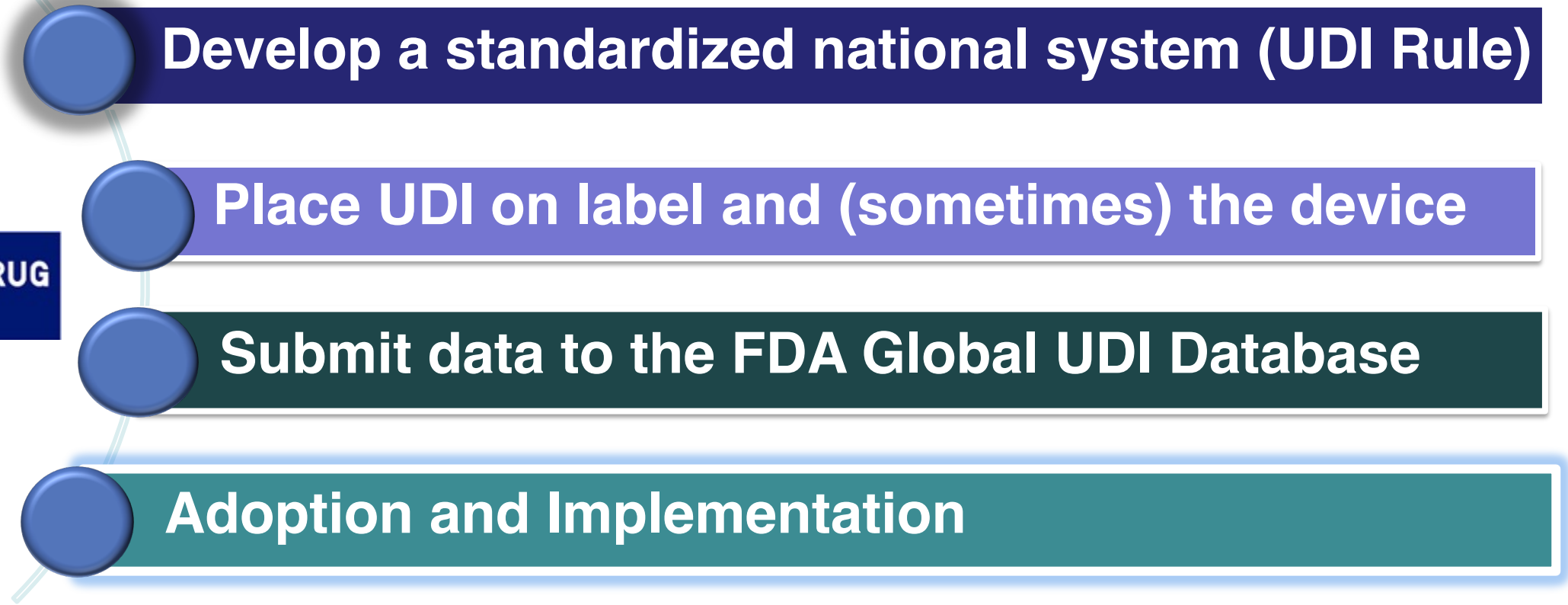
- Need multiple attributes for correct device identification
  - Manufacturer Name + Brand Name + Catalog/Item Number, etc.
- Increased health care costs
  - Each point in supply chain needs to maintain and update redundant data, reconcile data issues
- Increased chance for medical errors
- Inability to aggregate device data for safety issues
- Inefficiencies in recall management

Benefits of Standard Identification

Adequately identify devices through distribution and use

- Facilitate rapid and accurate identification of a device
- Provide a standard way to document device use in real world data sources such as electronic health records, clinical information systems, claims data sources and registries
- Allow for more accurate reporting, reviewing, and analyzing of adverse event reports for device evaluation over time
- Enable more effective management of medical device recalls

Steps to a Standard Identification System



How Standard Identifiers are Created

Rule requires UDIs be issued under a system operated by an FDA-accredited Issuing Agency.

An Issuing Agency operates a standard system for issuing UDIs to labelers.

Each labeler receives unique labeler identifier from Issuing Agencies

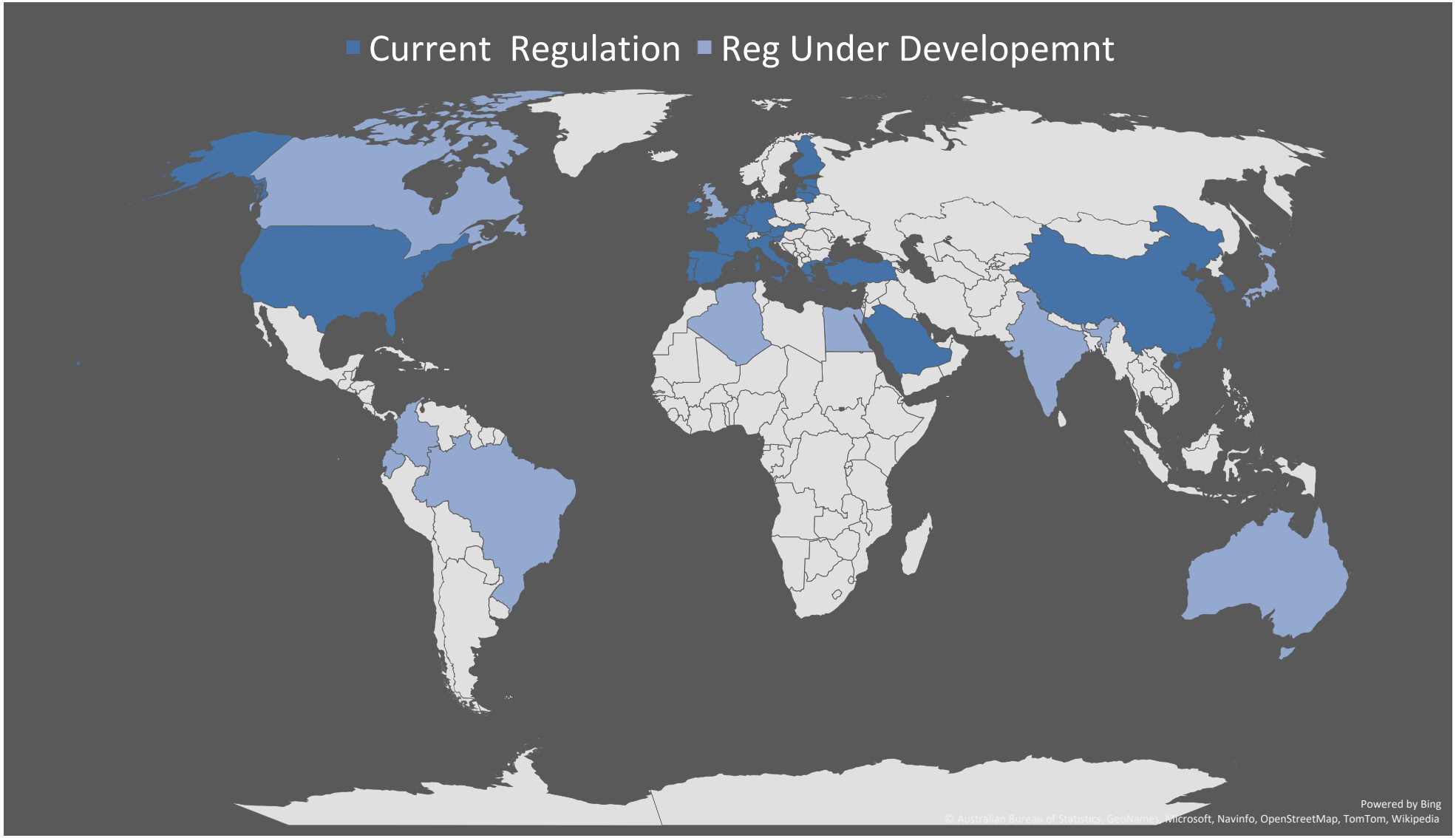
Using the Issuing Agency system, Labeler establishes and maintains DIs for each version or model of device.

Vision for a Global UDI System

- Globally Harmonized system for accurate identification of medical devices
  - Harmonize UDI core elements and definitions across jurisdictions
- Centralized repository of Device identification information
- Effective integration of UDI through the supply chain and point-of-care to advance patient safety globally

Global UDI Landscape

Current UDI Regulation
USA
EU
China
South Korea
Turkey
Saudi Arabia
Taiwan



UDI Reg Under Development
India
Equador
Japan
Australia
Brazil
Singapore
UK
Columbia
Algeria
Egypt

“Nothing is more difficult to undertake, more perilous to conduct or more uncertain in its outcome, than to take the lead in introducing a new order of things.

For the innovator has for enemies all those who have done well under the old and lukewarm defenders amongst those who may do well under the new. ”

— Niccolò Machiavelli