

Data Quality: Compliant vs. Valuable

April 24th

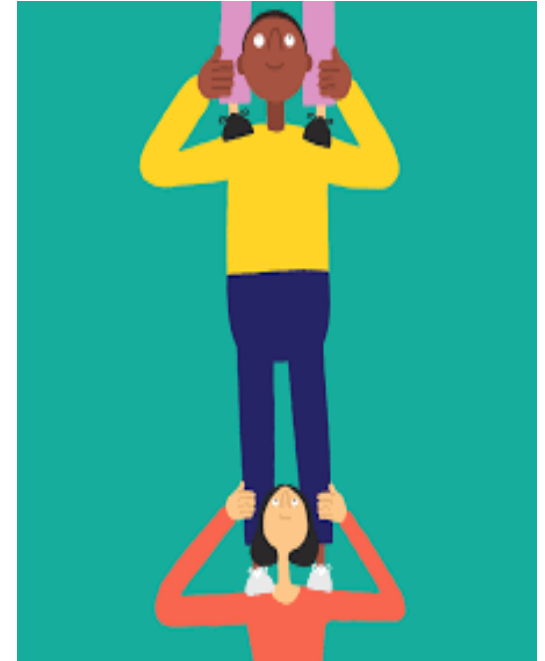
Behnaz Minaei, FDA
Michael Schiller, AHRMM
John Terwilliger, Abbott

FDA Committed to Data Quality

- GUDID's Unlock to Edit
- AccessGUDID – Status, Public Device Record Key
- Data Element Reference Table update
- DQ emails (Brand Name and Check digits)
- UDI Website updated to include links to ongoing Data Quality efforts

AHRMM Learning UDI Community – Share Responsibility

- Data value and integrity workshops held with both the supplier and provider communities
- Despite the investment, challenges remain within both these communities
- Leveraging data in the GUDID to achieve cost, quality, and outcomes for their organizations and the healthcare ecosystem
- **Seek. Solve. Share**



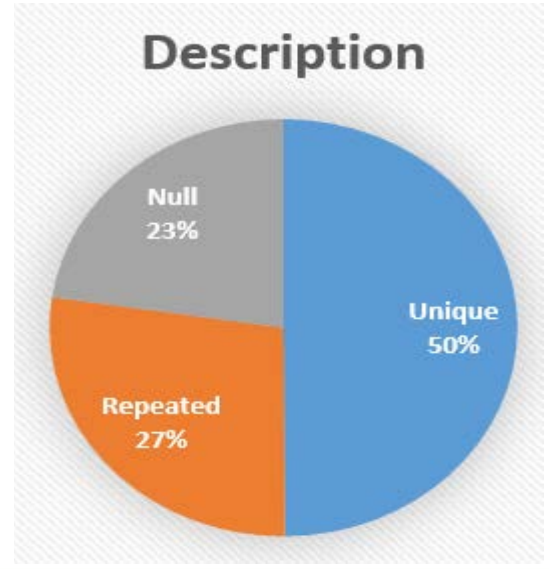
UDI: It's about the data

- Data – is as important as the product
- Data – is the foundation of the transactional supply chain
- Data – is the foundation of clinical use
- Data – is the foundation of the electronic health record
- Data – is the foundation of regulatory compliance
- Data – is the foundation of post market surveillance and recalls
- The request is always for more data, not less

UDI: It's not a project, it's a process

- Data – is difficult to find, manage, maintain, and ensure accuracy
- Data accuracy/collection/update must be built into the process of product development, product launch, ongoing product update/improvements, and end-of-life
- Ensure data is harmonized, e.g. GUDID, product data to customers, EUDAMED, etc.
- ***Meeting compliance is the bare minimum, the expectation is valuable data!***

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Description Not required to be compliant BUT required
GUDID data to be useful to patients and providers



Our Device-00440552112033

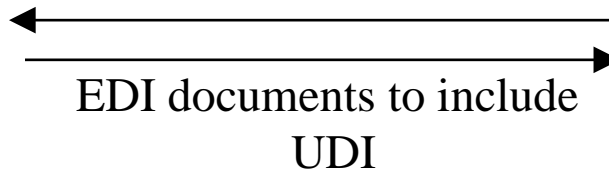
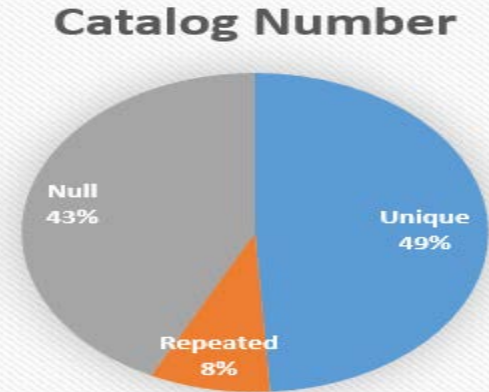
No Description

Company Name: MedSup **Version or Model: A0031**

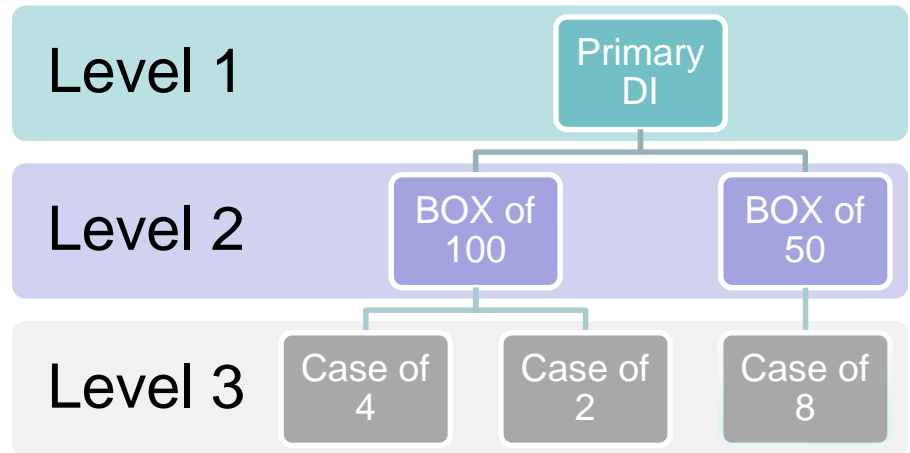
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Present: Populate **Catalog Number**, the number used by providers to purchase, establishes a cross-walk between the UDI and the catalog number within their item masters

Future: Use UDI in all transactions and in Supply Chain



Data Quality: Compliant vs. Valuable Unit of Use



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Multiple Device Identifiers

Hospital Item Master	
Brand Name	MaxStent
Manufacturer	MedSup
Catalog	1245
Device ID	?

Brand Name	MaxStent
Device ID	00999911000012
Catalog	1245
Company	MedSup
Brand Name	MaxStent
Device ID	00999911000013
Catalog	1245
Company	MedSup



Data Quality: Compliant vs. Valuable

Multiple Barcodes at the Point of Care

- UDI Barcode covered by another label
- Multiple Bar codes on the label
- Barcode on a shiny surface and only DI
- Barcode only on the box and not on the device

REF

1120434



Wisp Magnetic Headgear
Clips, RP



LOT 160520

Made in China

GS1-128



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