



FDA Unique Device Identification Public Workshop

Panel 3: The Unique Device Identifier Database

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Key Points

- *DoD Supports the UDI Concept*
- *UDI success requires product data standards & a support infrastructure*
- *DoD Mission has a need for product data standards*
- *DoD has a UID mandate similar to FDA UDI*
- *DoD has a long record in seeking standards*
- *DoD & Industry collaboration*
- *DoD sponsored pilots as proof of principle*
- *DoD will follow the Healthcare Industry's lead in a UDI solution*



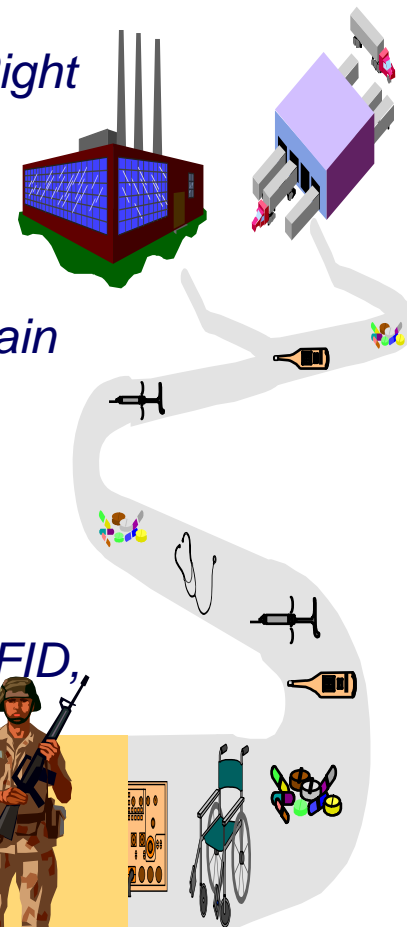


DoD Warfighter Needs

DoD Medical Logistics Challenge: To facilitate faster identification, sourcing and response to warfighter requirements

- *Standardized product identification is key to getting Right item at Right place, price & time to the Warfighter*
- *No standard item identification in the med/surg industry*
 - *Bad data throughout healthcare supply chain & DoD supply chain*
 - *DoD Medical relies on commercially based supply chain*
 - *Commercial products & product ID vs. NSN*
 - *Close synergy & reliance on commercial supply chain*
- *IT solutions hindered by bad data & lack of standard product ID (RFID, Electronic Health Record)*

Right data/product ID is the link to Readiness!





DoD Challenges

Effected by Lack of Common Product ID

- **Deployment Issues**

- Multiple organizations (Internal/External)
- Short notice & delivery timeframe
- Items ordered with hodgepodge descriptors, identifiers, etc.
- Resource-intensive cross-referencing for equivalents

- **Joint Interoperability**

- National Emergency Situations
- Disaster Response
- Federal Collaboration (HHS, CDC, VA, DoD, DHS, FEMA)

- **Marketplace Issues**

- New Items entering marketplace & Obsolete items leaving marketplace
- Disconnects - Manufacturer naming, Part number & Packaging





DoD Data Standards History

Industry Collaboration

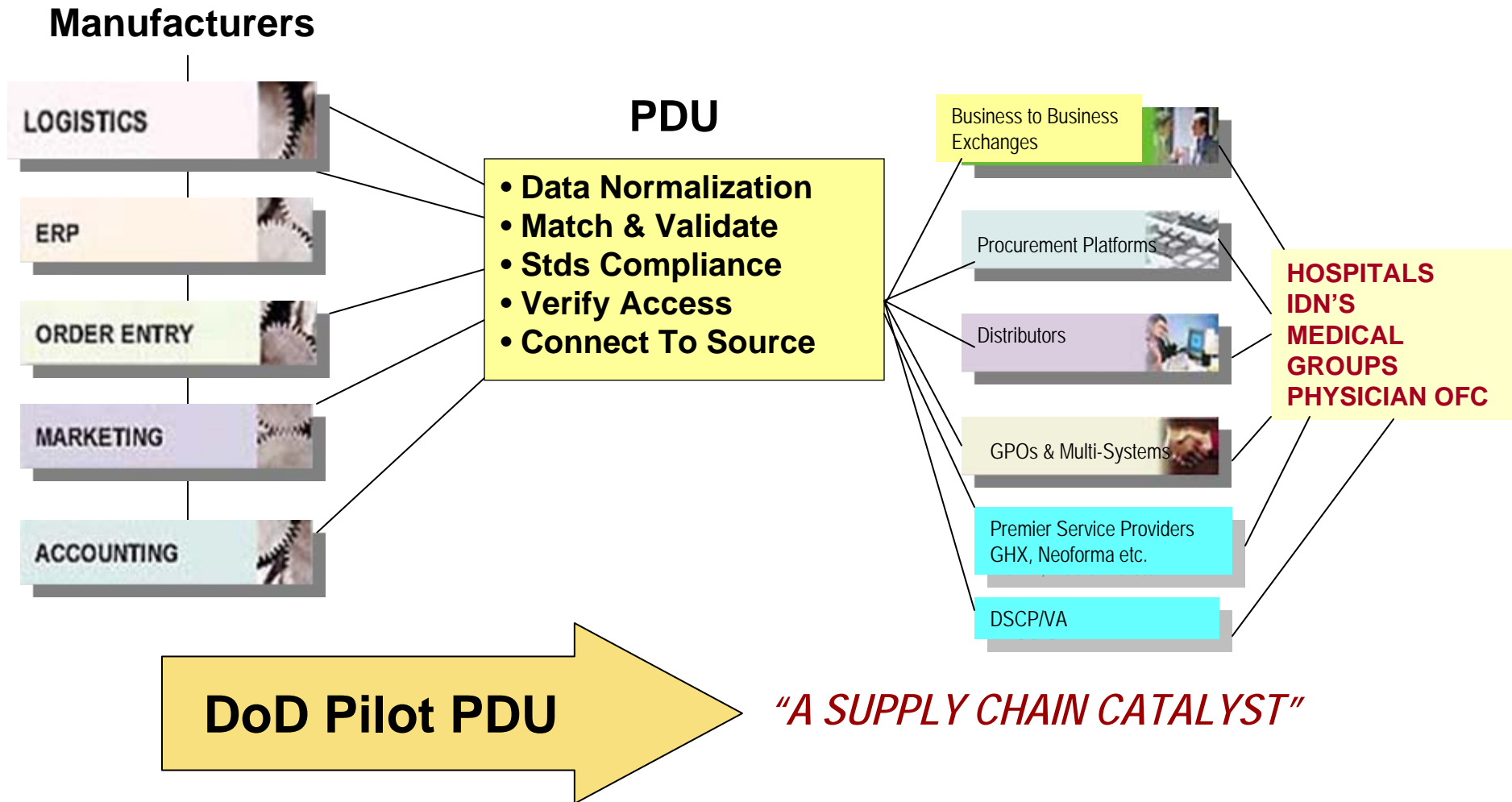
- UPN Initiative – 1990's
 - *Numbers assigned but no process to control & industry buy-in (PDU concept)*
- Readiness/Deployment Issues – 2002
 - *Call to action – intensive work with industry partners to solve*
- Collaboration with Healthcare Organizations (CHeS, HSCSC, SMI) - Common goal – data standards
 - *Captured successes in other industries*
 - *Studied unique dynamics of healthcare market*
 - *Outlined framework for DoD & Healthcare Industry partnership/pilots*
- DoD pilot PDU - 2004
- DoD GDSN Industry pilot – 2006
- VA partnership – 2006

“How We Evolved”

*End Goal:
Industry Sponsored
PDU*



Basic Model of a Product Data Utility





Data Sync Programs & Pilots

Six Year effort – With Success

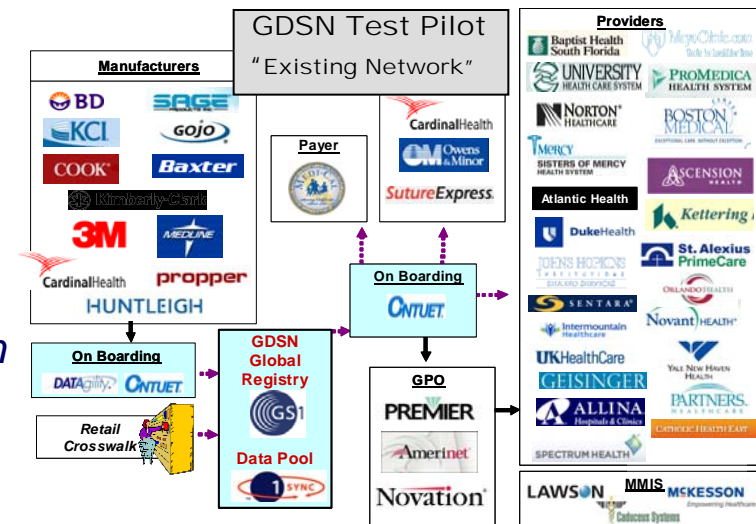
Initial DoD Pilot & Data Sync Tools “Build Own”:

- Created on-going DoD & Supply Chain platform to execute PDU test pilot & synchronize product data
- DoD pilot PDU process resulted in better data for decision making with savings of \$30M + to date
- Proved PDU “Proof of Principle” as Industry data solution



DoD Healthcare GDSN Pilot “Existing Network”

- Growing Momentum – 30+ participants
- Proved it can work – publish & subscribe mechanism w/adaptable data elements & build on healthcare attributes
- Catalyst platform for Healthcare Industry to build upon existing PDU solutions





DoD UID & FDA UDI

UID

- IUID Is Required For All Property Items Delivered To The Government if Acquisition Cost is More than \$5,000 or Item is DoD Controlled Piece of Equipment or Material Requiring Permanent Identification.
- GS1 Application Identifier for (01) and (21) GTIN are acceptable solution for DoD UID (other standard constructions are also acceptable)

01 = Application Identifier for Global Trade Item Identification Number (GTIN™)
21 = Application Identifier for Serial Number

UDI

- DSAD (FHP&R) 11 Nov 06 memo response to FDA use of Unique Device Identification system:
 - FDA should mandate UDIs for all medical devices
 - UDIs should be based on industry and/or global standards
 - Each UDI should be associated with industry agreed to mandatory standard product data attributes
 - The source of the UDI and associated product data attributes should be the manufacturer of the product
 - An Industry PDU should be a mandatory source for UDI related data



DoD - Lessons Learned



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- **DoD's UPN Initiative 1990's**
 - Assignment of numbers without a process in place to certify and distribute standardized data *did not work*
 - **Cleaning and standardizing data in-house is not enough.**
 - Decentralized approach is redundant, inconsistent & costly to healthcare
 - Need to utilize industry approved data standards
 - Need to adopt a centralized industry process (PDU) to ensure accuracy and consistency for the entire healthcare community
 - **Standardizing and accessing data from central utility:**
 - Reduces bad data & associated costs
 - Increases operational efficiencies/patient safety/recalls

