

UDI – THE KEY TO IMPROVING PATIENT OUTCOMES DRIVING PROACTIVE QUALITY AND INNOVATION

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What role does UDI play in improving patient outcomes? In other words, what is the value of UDI beyond simply putting lines on products to meet regulatory requirements?

The short answer: UDI goes well beyond meeting a regulatory requirement to add a product to the GUDID database and ensuring the printing of appropriate identifiers. UDI is the key to improving patient outcomes by driving proactive quality and innovation. UDI implementation results in shortened innovation cycles allowing for more product introductions, changes, configurations as well as faster product obsolescence. In addition, financial pressures are compelling industry to evaluate the costs and benefits associated with device complexity.

To compete in a global environment companies need to be constantly open to change, whether it be technology, business, cultural or regulatory. To excel, Medical Device organizations must execute corporate strategies that recognize and reward continuous improvement in product quality, patient safety and innovation to support improved patient outcomes.



To delve into these and other important issues, Axendia hosted a discussion with Terrie Reed, Sr. Advisor, UDI Adoption, FDA and Arie Halpern, Business Consultant Director, Dassault Systemes, titled: “[Are You Done with UDI? Or, Is It Just the Beginning.](http://www.barcodeart.com/artwork/paintings/stencils/custom.html)” This brief covers some of the key points addressed in that dialog.

Source: Barcode Art by Scott Blake

<http://www.barcodeart.com/artwork/paintings/stencils/custom.html>

HOW CAN UDI DRIVE VALUE ACROSS THE DEVICE ECOSYSTEM?

“UDI may be an acronym for unique device identification, but what it really stands for is better information, better access to safe and effective medical devices, and ultimately, better patient health,” said Dr. Jeff Shuren, Director CDRH, USFDA¹. “By promoting incorporation of UDIs into electronic health information, a vast quantity of untapped real-

¹ Identifying Medical Devices Will Strengthen Safety, FDA Voice, September 20, 2013
<http://blogs.fda.gov/fdavoices/index.php/2013/09/identifying-medical-devices-will-strengthen-safety/#sthash.amP6IAx9.dpuf>

UDI – THE KEY TO IMPROVING PATIENT OUTCOMES

world data from clinical experience with devices housed in EHRs and other electronic information sources may become available for use in understanding the benefit-risk profiles of medical devices,” he added².

Terri Reed provided an example to illustrate the value of UDI: “Use real-world data (i.e. electronic patient records, clinical registries, claims data and UDI as part of all those systems) to support regulatory decision-making for expanding labels or indications for use for a particular product based on real-world evidence, identifying potential safety signals and leveraging registries to improve devices and innovation of devices.”

BENEFITS OF UDI

UDI is an enabler. It is the primary key that, linked across all data sources and integrated into existing systems, joins information between manufacturers, regulators, providers and patients to drive proactive quality and innovation to ultimately improve patient outcomes.

The value of UDI is much more than a fancy track and trace system. Benefits include:

- ▲ Unlocking real-world data that can be used for clinical purposes
- ▲ Improving patient safety by identifying and removing unsafe and counterfeit products from use
- ▲ Providing data that can be transformed into intelligence about product quality
- ▲ More accurate understanding of device benefit-risk profiles with the ability to better evaluate product performance
- ▲ Facilitating device innovation

Terrie Reed noted that in some ways UDI’s can be compared with automotive VIN numbers, as each are unique to a single product. However, she observed “...the notification and the access to performance data is very different...as an implant associated with (a recall) is not currently strongly tied to the UDI.”

If you bought a car in 2010 you would be notified of a recall even if you have moved multiple times. However, if you had an implanted device it is not likely you would be notified unless you are in the care of the same physician who diligently tracked your implant and stayed in touch with you.

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² Statement of Jeffrey Shuren, M.D., J.D. before the Committee on Health, Education, Labor and Pensions, April 28, 2015
<http://www.help.senate.gov/imo/media/doc/Shuren3.pdf>

UDI – THE KEY TO IMPROVING PATIENT OUTCOMES

With the implementation of the National Evaluation System for Health Technology (NEST) as a central repository for UDI information, the ability to find you in the case of a recall may one day be a reality (HIPAA issues notwithstanding.)

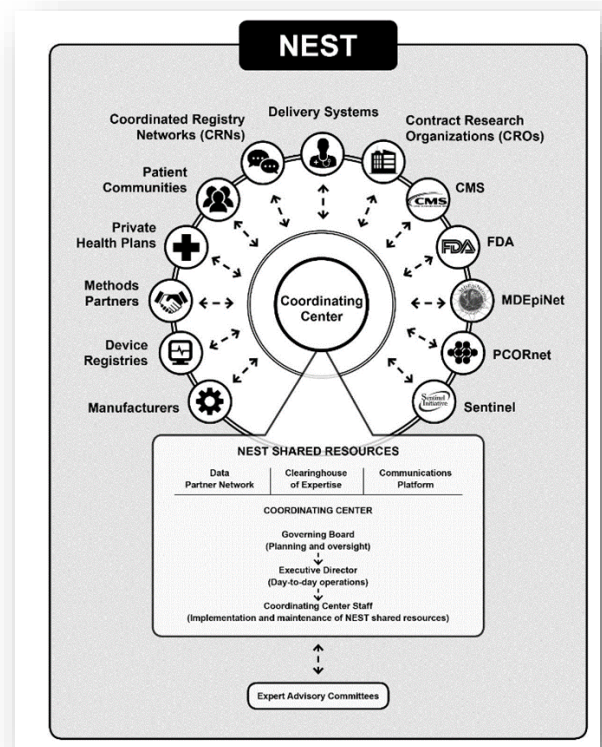
From a medical device company perspective, Arieh Halpern commented that UDI can be effectively used to improve product quality during manufacturing and post product launch from Complaints and CAPA to eMDR notification to the FDA.

UDI also provides traceability throughout a distribution chain including patients, distributors and health facilities. In a clinical setting, it can be effectively used to track and link the devices used to the actual trial sites, to each respective patient that is part of the trial and the reporting clinician – thereby effectively closing the loop when entering an observed anomaly or adverse event into the clinical trial log. Another completed loop would be the end user's ability, using a device's UDI, to send product information, experience, observations and recommended improvements directly to the manufacturer.

Halpern also used another analogy – that UDI through DI (Device Identification) and PI (Product Identification) is almost like DNA representation of a product. When improving product quality, for example, or submitting an adverse event notification to the FDA, the UDI can quickly identify product attributes such as product model, manufacturing location, lot and batch runs, and serial number(s). Having an UDI provides companies the ability to more effectively manage product complaints and resolutions and also allows them to more effectively address non-conformance reports.

UDI provides an effective means of reducing a company's exposure to high costs in cases of product recalls or field actions. It allows companies to quickly identify affected products and manufacturing location and implement corrective actions efficiently, thereby reducing time and cost in managing product recalls or direct customer notifications, regionally or globally.

It also has direct application in post market launch surveillance as part of receiving end user feedback regarding the application and use of the product (form, fit, function), resulting in new product enhancements / requirements for on-going product improvements both from a feature perspective and quality.



Source: The National Evaluation System for health Technology (NEST)

UDI – THE KEY TO IMPROVING PATIENT OUTCOMES

Once the UDI is fully implemented as part of a company's global business operation, the opportunities for improving quality, streamlining regulatory reporting, and ultimately driving innovations forward are finally possible.

UDI, THE GATEWAY TO PRECISION MEDICINE?

In the white paper "[UDI Implementation - The Key to Unlock Personalized Medicine](#)" we pointed out that optimizing meaningful data collection will allow healthcare providers to take appropriate and better focused corrective and preventive actions. The [Precision Medicine Initiative](#) recently launched by FDA will allow doctors to select which treatments will work best for which patients.

Dr. Shuren believes that "...through collaborative public and private efforts, the Precision Medicine initiative will *leverage advances in genomics, emerging methods for managing and analyzing large data sets*, and health information technology to *accelerate biomedical discoveries*, all while protecting patient privacy."³

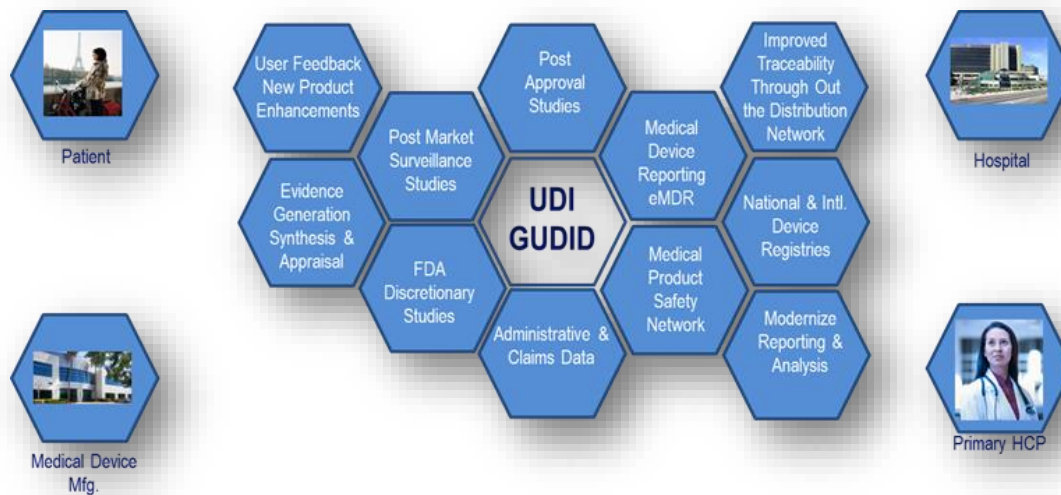
The combination of UDI and unique patient identification are vital keys to associate device follow-up and patient outcomes across systems

A major component to achieving precision medicine is the ability to exchange information more effectively. To support this alternate approach to personalized care, UDI must be incorporated into the health information systems of healthcare organizations. The combination of UDI and unique patient identification are vital keys to associate device follow-up and patient outcomes across systems.

The traditional vision for personalized medicine often revolved around producing of a drug or device based on the individual patient. In other words, manufacturing a batch size of one based on that patient's unique anatomy, physiology, genetics, etc. While the batch size of one is the ultimate goal of personalized care, recent conversations with healthcare providers, payers, industry executives and regulators has uncovered a new approach to personalized care: identifying which currently marketed product will work best on a patient, based on that individual's unique needs, anatomy, physiology, genetics, etc.

³ Continuing America's Leadership: Realizing the Promise of Precision Medicine for Patients, Jeffrey Shuren, May 5, 2015. <http://www.fda.gov/newsevents/testimony/ucm446525.htm>

UDI – THE KEY TO IMPROVING PATIENT OUTCOMES



This approach relies upon the creation of Coordinated Registry Networks aimed at analyzing and modeling de-personalized real-world clinical data contained in electronic health records.

NEST is at the center of Precision Medicine for medical devices, and UDI is the primary key that aligns all the data.

LEVERAGING UDI DRIVES IMPROVED PRODUCT QUALITY

Effective use of UDI positions an organization to continually improve product quality. The [Case for Quality Initiative](#), a partnership between FDA, MDIC, Medical Device manufactures and other constituents are developing a consumer report-like evaluation of medical device quality based on information that is available.

When UDI is combined with an enterprise platform, it essentially becomes the single source of truth, providing for digital continuity which facilitates complete transparency and traceability of products throughout the product lifecycle, from development through user evaluations / clinical trials, regulatory submissions, manufacturing, distribution chains, to healthcare facilities and end users, to end-of-life of the product.

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UDI – THE KEY TO IMPROVING PATIENT OUTCOMES

Many benefits can be derived from such a system. A few examples:

- ▲ **NEW PRODUCT FEATURES:** Enhancements and product line extensions through additions of new features can be traced back to the original UDI of that product make and product line.
- ▲ **PREVENTATIVE PATIENT SAFETY RISK:** UDI allows manufacturers of medical devices to be more efficient in notifying registered owners of medical devices of any issues with their product which may warrant removal from service and or information regarding the continued use of the product thereby reducing patient risk.
- ▲ **SUPPLY CHAIN MANAGEMENT:** Effective means for supply chain management for coordinating parts and manufacturing bills across hundreds of parts and various manufacturing locations including third party distributors.
- ▲ **CAPA / COMPLAINTS:** UDI can be used across the entire CAPA / Complaints process linking root cause analysis to requirements change, design change, verification and validation through changes in manufacturing process, field corrective actions and regulatory notifications.
- ▲ **ADVERSE EVENT NOTIFICATION:** Recording and timely notification of anomaly events and adverse event notifications to the FDA and manufacturer within the hospital to improve efficiency and patient safety.
- ▲ **LOWERING HEALTHCARE COSTS:** Scanning the UDI of each billable patient-applied product ensures proper billing and reduces over billing, thereby reducing cost.
- ▲ **END-of-SHELF LIFE / PATIENT SAFETY:** Improving upon patient safety by avoiding the use of products which have exceeded their end-of-shelf life dates. UDI provides an effective means for healthcare facilities to identify early on which products are nearing their end-of-shelf life, allowing inventory management to move them up on the usage list and or remove them from use thereby avoiding patient safety issues.
- ▲ **USE TRACKING:** UDI provides for effective-use tracking and re-ordering of consumables for diagnostic systems, also reducing costs.
- ▲ **PRODUCT IMPROVEMENTS:** UDI provides medical device companies with the ability to quickly attain direct end-user feedback (i.e., healthcare providers, patients) regarding the functional use of the product (form, fit, function) resulting in new VOC product requirements for on-going product improvements from both a feature perspective and quality improvements.

UDI – THE KEY TO IMPROVING PATIENT OUTCOMES

ADVANTAGES OF AN ENTERPRISE PLATFORM

With global distributive manufacturing locations, an enterprise platform unites operations and supports a single source of truth. This facilitates cross-collaboration, not only among internal business units but also external (vendors, third-part subcontract manufacturers). Halpern stressed the importance that all stakeholders are sharing the data from one common source of information under one single unified change management control system – to do otherwise is counterproductive and inefficient.

In a globalized world, keeping track of issues associated with multiple devices is a monumental task. UDI provides for a streamlined approach to device tracking easily and efficiently. Employing an enterprise platform, with real-time dash boards, provides the ability to quickly obtain status updates on all events, by product and by country. Events can be easily traced to device type, patients, location, noted observation(s), and manufacturing site, facilitating review and corrective action, if needed. Simply put, it provides manufacturers with the ability to more effectively manage the products that are sold in different countries. Think of UDI as the next evolution in product identification systems.

In an effort to reduce inventory carrying costs, many manufacturers are trying to implement just-in-time manufacturing. Having an enterprise platform can allow manufacturing operations to more effectively manage the procurement of parts and production builds by product model and by the respective manufacturing operations. Linking that information to sales distribution provides insight to exactly which products are being sold into which countries and what the booking rate is, relative to production shipping.

In managing GUDID submissions, enterprise systems provide the needed information to the appropriate department. With a common platform, the department has the ability to have access to a common set of data regarding the complete status of GUDID submissions. Having an enterprise system also provides remote regulatory affair departments with the ability to access the required data necessary for completing the DI record from a single source of information for that local country's UDI submission system.

Perhaps most critically, enterprise systems allow senior management within companies the ability to have a global status overview regarding all of the DI submissions and approvals by product and by country, thereby knowing at any one time where they are in the final approval process necessary for product launch for those countries which have implemented a UDI solution.

CONCLUSION

There are long-term technical challenges incorporating UDI's into electronic health information. It is relatively a new concept, as is FDA's approach to educating, providing resources and including manufacturers, healthcare providers and others in the supply chain in the conversation.

UDI – THE KEY TO IMPROVING PATIENT OUTCOMES

As Dr. Shuren said, by promoting the incorporation of UDI into electronic health information, we can unlock an untapped amount of real-world data that can be used for clinical purposes. It could be used to develop digital twins, to better support and bring products to market and closing the loop on improving product quality and understanding the benefits and risk profiles of medical devices.

At the end of the day, what we're talking about is that the value of UDI goes well beyond meeting a regulatory requirement to add a product to the GUDID database and ensuring the printing of appropriate identifiers. UDI is the key to improving patient outcomes by driving proactive quality and innovation.

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