WHITE PAPER

A Consulting Approach to Unique Device Identifier (UDI) Adoption

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Abstract

With FDA's ruling on mandatory tagging of medical devices with a unique device identifier (UDI), a new market for the IT services sector has opened up to facilitate UDI adoption by device manufacturers. A detailed strategy for UDI adoption, from a consulting point of view, is detailed.

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Introduction

Consider these real business scenarios – (i) a company's breast implant ruptures inside a patient and upon confirmation of manufacturing defect, individual recall notices have to reach quickly to 30,000 women with similar implants; (ii) reports emerge of high-voltage ICD leads rupturing inside patients, resulting in inadvertent shocks being delivered to patients and subsequently leading to recalls being issued to individual patients; (iii) a device manufacturer's surgical clip is used to tie-off the renal artery of a kidney donor and hours later, the patient dies due to clip failure, and this happens despite the manufacturer previous written notifications to medical centers that the clip, while acceptable for other types of surgery, should not be used to tie off the renal artery of living kidney donors; (iv) a hospital receives a recall notice, with serial numbers of thousands of external defibrillators that have manufacturing defects, but the hospital is unable to act on the received information due to the absence of an appropriate inventory management system which tracks devices; (v) an infant heel warmer causes a second-degree burn on a baby, but no product lot information is available to make the adverse event reporting; (vi) in 2013, US Customs & Border Protection seizes more than 2,350 parcels containing counterfeit medical devices and pharmaceutical products valued at $83 million [1].

How can patient safety concerns be addressed in these adverse situations? How can medical device recall be expedited, errors be reduced, operational efficiency be increased, adverse event reporting be complete and effective, and how can counterfeit devices be stopped from seeping into the healthcare supply chain? The answer lies in the ability to mark and identify medical devices within the supply chain through a new identifying system called Unique Device Identifier (UDI). FDA has mandated all device manufacturers to label their products with a UDI and update a global device database – GUDID – with their product information. This mandate sets the stage to eventually trace a medical device as it moves through the healthcare ecosystem right from the device manufacturer all the way to insurance claim records.

UDI Adoption & Challenges

The UDI related FDA mandate came into effect in September 2013, with immediate implications for some classes of devices. Compliance dates for the different device classes are shown in Fig 1.

As device manufacturers rush to comply with the FDA ruling, a new market to facilitate UDI adoption has opened up. It is now estimated that mature device manufacturer companies with 1000+ employees and with existing ERP systems in place will make an aggregate first year investment of about $80 million for the software component of UDI adoption alone [2]. This IT spent includes software package installation, testing, integration with existing systems, validation and training costs.

Sorin was the first company in Europe to report full compliance with UDI adoption. The company started out with a global initiative that spanned across different business units, manufacturing sites as well as departments such as R&D, design, production, quality assurance, and regulatory affairs. To satisfy UDI requirements, the company gathered data from all units, aggregated them in a central location, cleansed the data and submitted them to GUDID [3].

Jay Crowley, a former senior advisor for patient safety and UDI architect at FDA, had mentioned in the early days of UDI development that the stakeholders' assumption of primary challenges associated with UDI implementation would mainly be enumeration of devices, but the more significant challenges could actually be centered on aligning the process, organization and business. He had also mentioned that gathering data together in one place, identifying methods for data storage, managing and submitting data, as well as managing the entire process subsequently would be an enormous challenge that most organizations may not be ready for [4].

Gartner also harps around the similar fact that for an efficient UDI compliance, companies have to build Master Data Management (MDM) capabilities that will help manage continually changing data [5]. However, it has been noted by interviewing representatives from device manufacturing companies that some significantly challenged with locating information as it is not in centralized systems and in a few cases, data is not documented at all. It has also been identified that even basic regulatory attribute data such as Market Authorization Codes, FDA Product Codes, and Country of Origin information is hard for manufacturers to source [6].

Consulting Approach to UDI Implementation

Developing a vision and strategy for a device manufacturer to completely adopt UDI involves looking at capabilities across different business functions and organization layers require a structured approach to deliver impactful results. IMPACT™ Methodology, developed by Infosys, is a business transformation tool that is leveraged to develop strategic solutions that are not just successful but also add true value to customers.

IMPACT™ has the necessary features to take into consideration the different elements which have an impact on defining the roadmap for UDI implementation for any device manufacturing company. IMPACT™ helps us assess the different aspects of company operations while developing the UDI strategy while at the same time tracking value for the company and its customers. The different phases of IMPACT™ outline the set of activities that

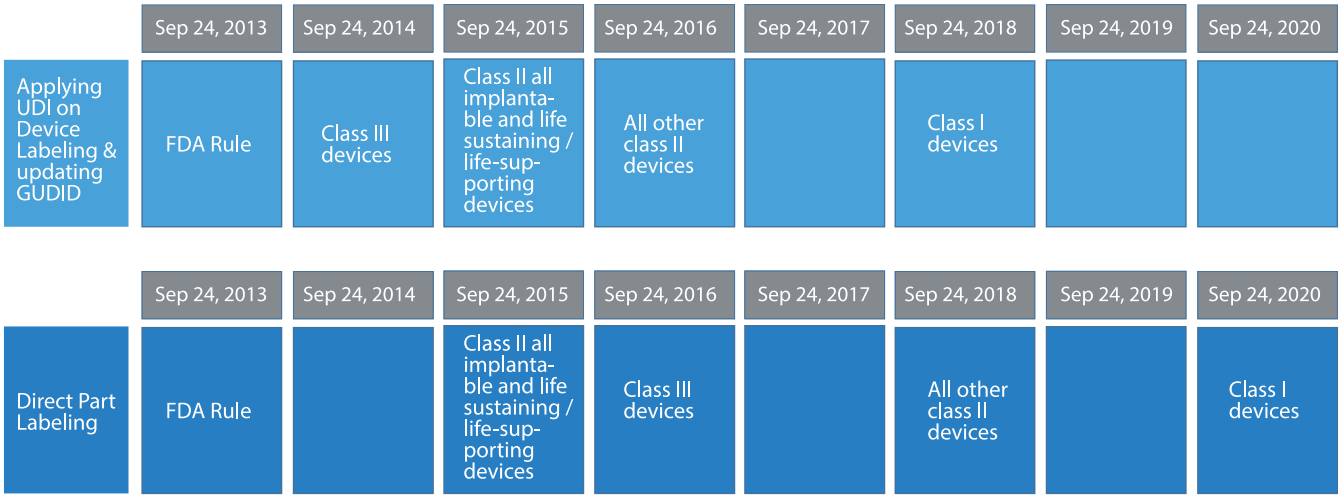

Fig 1. FDA-mandated UDI compliance dates for the different classes of devices

need to be performed as part of the entire UDI adoption journey. For this whitepaper, we will be focusing only on the Set Direction phase.

As part of Set Direction phase, we define three work streams to define the UDI strategy and implementation roadmap:

1) Process and Technology
2) Master Data Management
3) Organizational Change Management

What we do in the "Set Direction: Assess, Envision & Roadmap" Phase

This phase will analyze the AS-IS state of operations, outline the TO-BE UDI capabilities and come up with recommendations for UDI implementation roadmap.

Prior to starting the assessment, internal stakeholders from different business units within the organization will be identified. Internal stakeholders could be from Regulatory Affairs, Product Engineering, Manufacturing, Quality Assurance, Warehouse Management, Supply Chain, Sales, Operations, Marketing, Customer Service, Information Management, Information Technology, Program Management Office etc. Executive Steering Committee and Program Champion will also be identified.

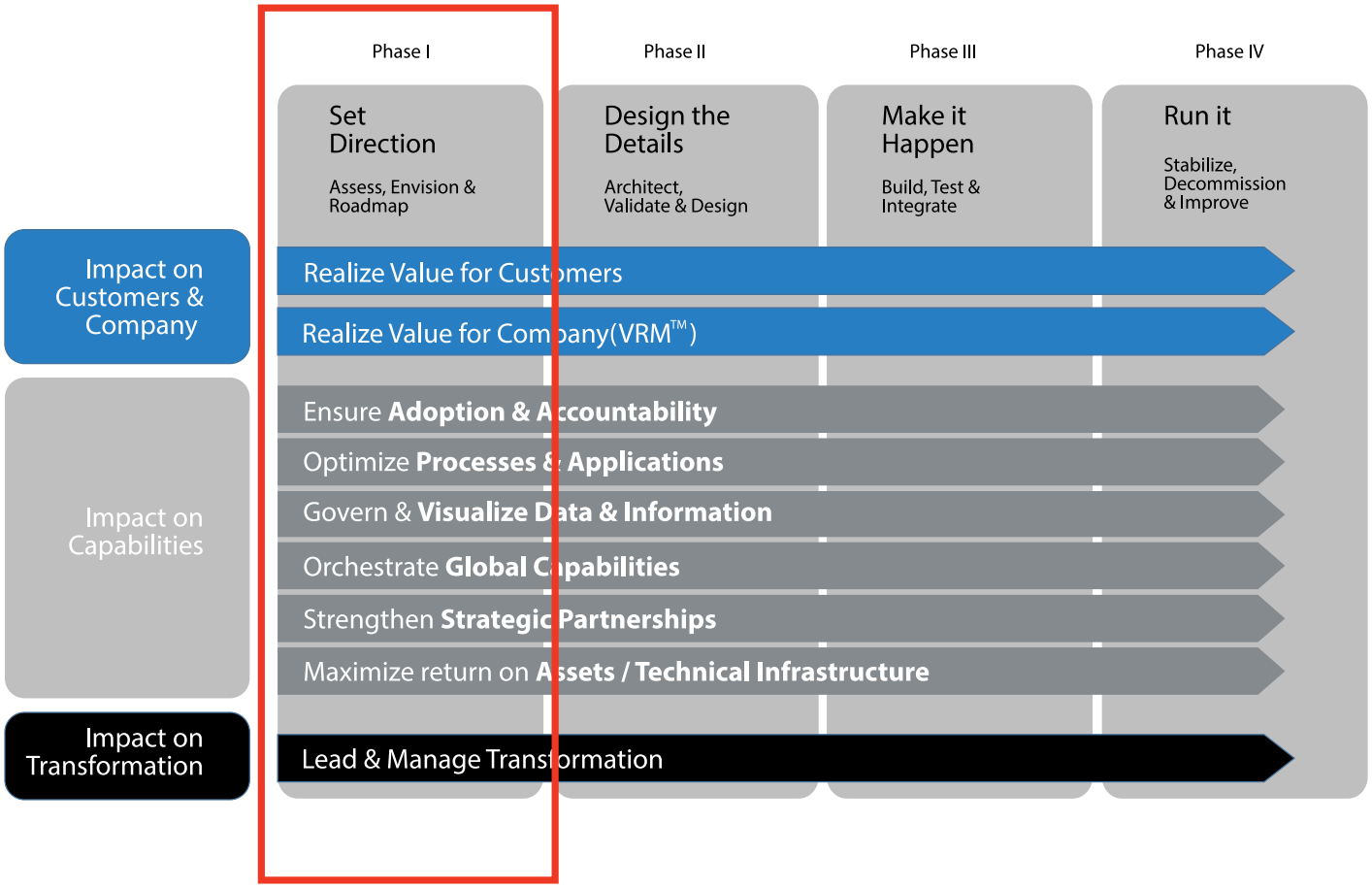

Fig 2. Infosys' proprietary IMPACT™ Methodology that is used in strategic engagements to develop solutions

As part of AS-IS analysis, workshops and interviews will be conducted with stakeholders to understand the product portfolio of the company and classify the product list into class I, II and III devices. FDA's UDI rule and requirements will be reviewed for the applicability of the company's products list. The UDI applicable products will be mapped with FDA compliance timeline (Fig 1). Also, effort will be made to understand the stakeholder's business objectives, expectations and potential challenges from UDI compliance, while also taking into consideration the organization's existing processes, initiatives, their statuses and UDI's impact on them. Gaps will be identified between the existing state of operations and future state based on UDI requirements.

As part of TO-BE analysis, a detailed strategy for UDI implementation will be defined that would include future policies, processes, operating model required to support the implementation. Recommendations will be chalked out along with timeline for adoption. Key business metrics for measuring the effectiveness of UDI strategy adoption will be identified and listed out as well. Workshops will be conducted with stakeholders to review and finalize the high level future state for UDI.

A robust UDI Strategy and implementation roadmap will be finalized and that would include compliance timelines. Prototype recommendation will also be part of this roadmap.

Work Stream 1 - Process & Technology:

UDI compliance involves assigning UDI to the product, labeling it, verifying the bar code, collecting data and submitting the data to GUDID in a three step process as shown in Fig 3.

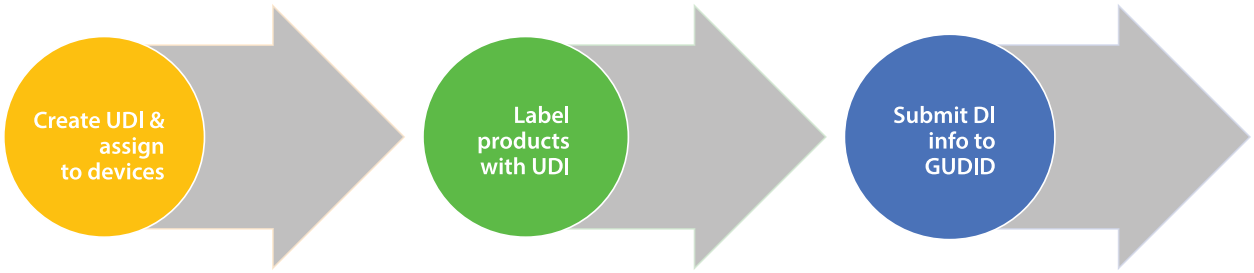

Fig 3 – A 3-step representation of the FDA UDI mandate for device manufacturers

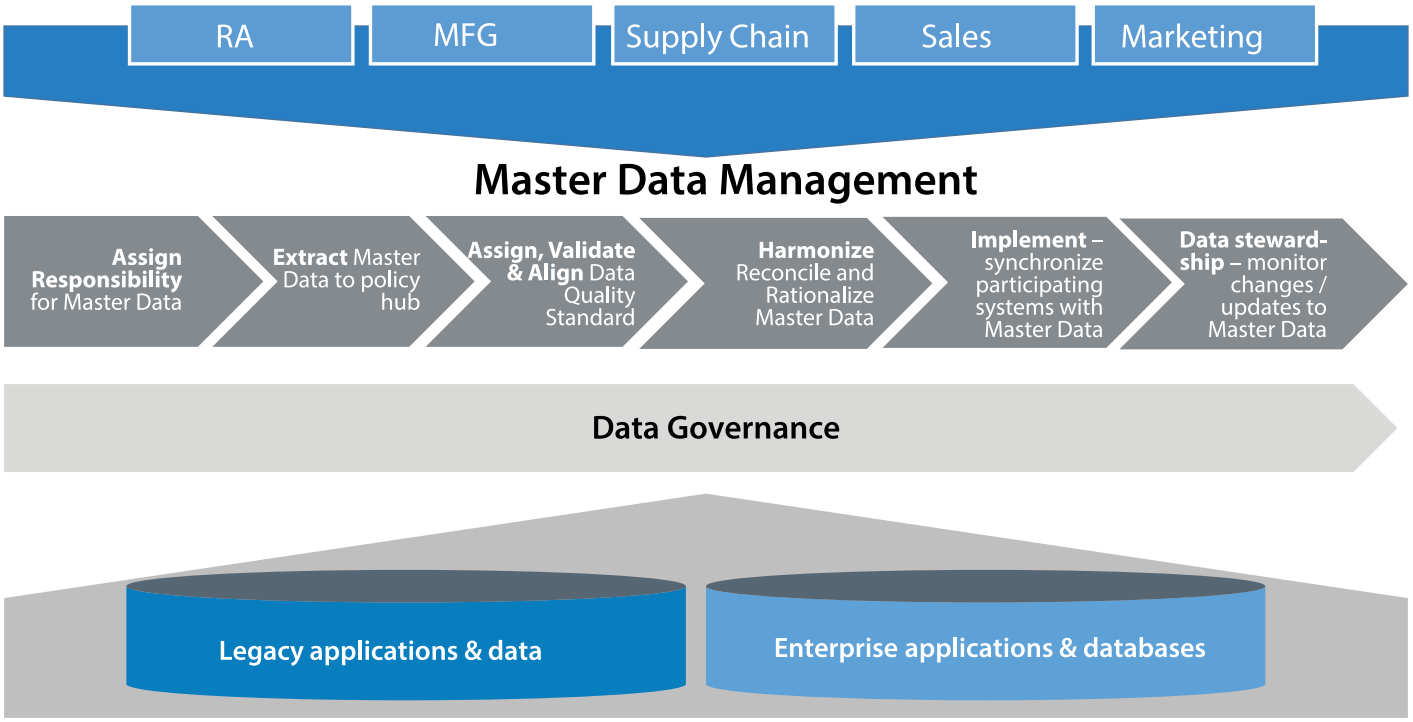

Fig 4. Proposed MDM methodology for UDI implementation

Work Stream 2 - Master Data Management:

One of the major challenges to comply with the UDI, as mentioned above, is the need to gather the data elements together, exchange data and manage data as it changes over time. To overcome these challenges, companies preparing for UDI implementation should employ a robust master data management strategy. Fig 4 provides an overview of the proposed MDM methodology for UDI implementation.

1) Assign Responsibility:

   Identify key entities such as product, customer and vendor master data across business functions for inclusion in MDM.

2) Extract Master Data to Policy Hub:

   Extracting product master data to policy hub will create an opportunity to clean, rationalize and store product data outside of the lines of business, enabling a standard way of creating a unique identifier as well as managing the necessary attributes of each product that is required for UDI implementation.

3) Data Quality Standards:

   The data quality criteria and processes should be modified as needed to align with changes to the business requirements of UDI rules. Data content for strategic data elements should be monitored regularly to ensure consistency, accuracy, timeliness and completeness. Data quality problems should be identified early so they can be corrected.

4) Reconcile and Rationalize:

   Monitor and reconcile data issues. Profile data to determine accuracy, completeness, structure, business rules compliance and uniformity.

5) Synchronize participating systems:

   Synchronize master data with company business processes, roles and systems on an ongoing basis.

6) Monitor changes or updates:

   'Data Stewardship' is the QA process through which cleansed master data is maintained. Assign ownership to ensure effective MDM and ongoing data stewardship. While individuals are assigned the responsibility of ensuring data quality, all personnel that interact with data directly or indirectly are accountable for data quality and integrity.

All steps listed above to develop robust MDM capabilities should be consolidated and coordinated through a governance strategy which will dictate how MDM will be governed from a program level, across lines of business and geographic

regions. Governance model must clearly define the policies, processes, roles and responsibilities required to drive and maintain data quality:

1) Policies can include rules identifying quality requirements, compliance protocols, systems of record, hierarchical structure, and how data will be rolled up across organizations and regions.

2) Processes are defined using clearly delineated flows which identify how master data elements are identified, defined, introduced, and applied.

3) Roles & Responsibilities are identified and communicated using RACI matrices mapped to process flows with clear hand-off points.

The more governance is centralized, the easier it is to get a "single version of the truth", suggested for UDI implementation. Best-in-class MDM strategies address the process, technology, architecture, organization and governance required for a "single version of the truth".

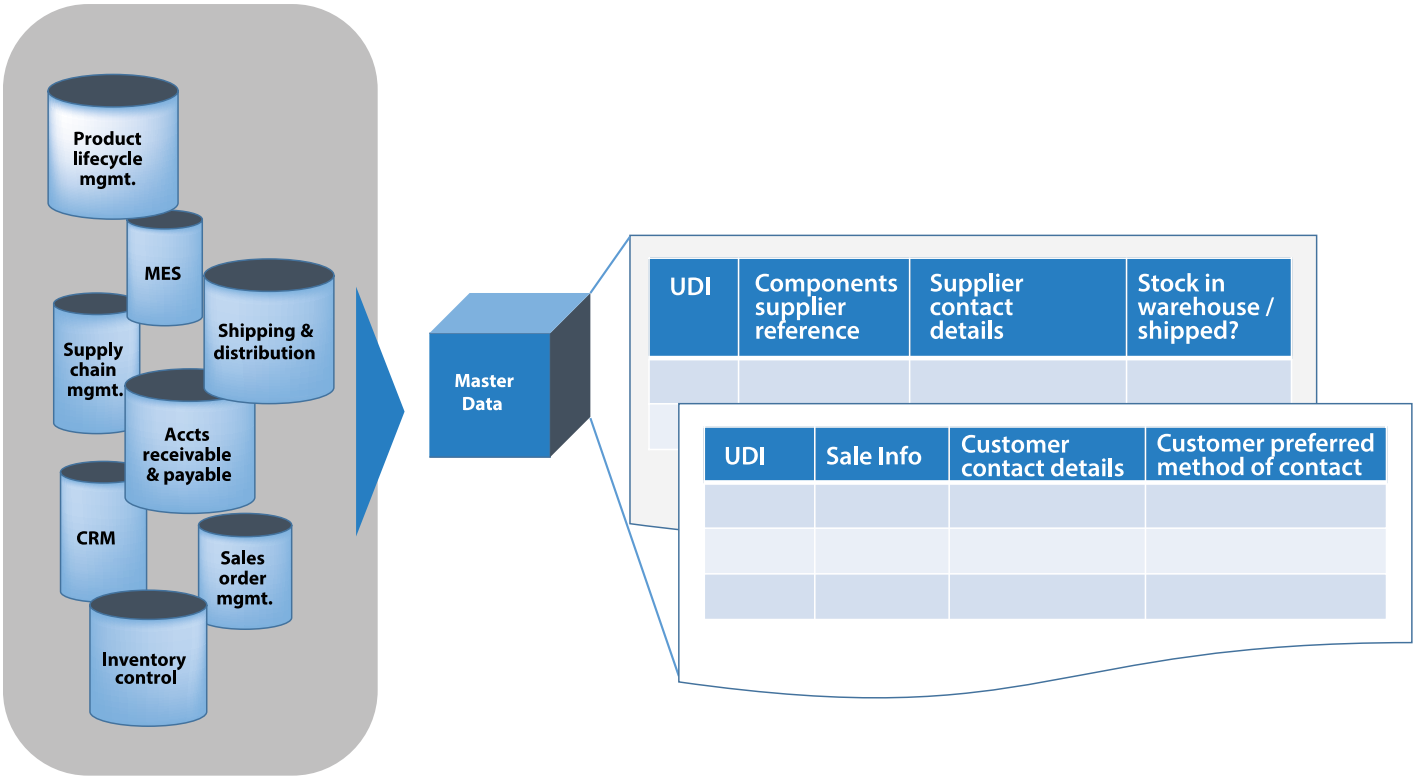

Fig 5. A representative Master Data that serves as the single source of truth for supplier management and customer data management

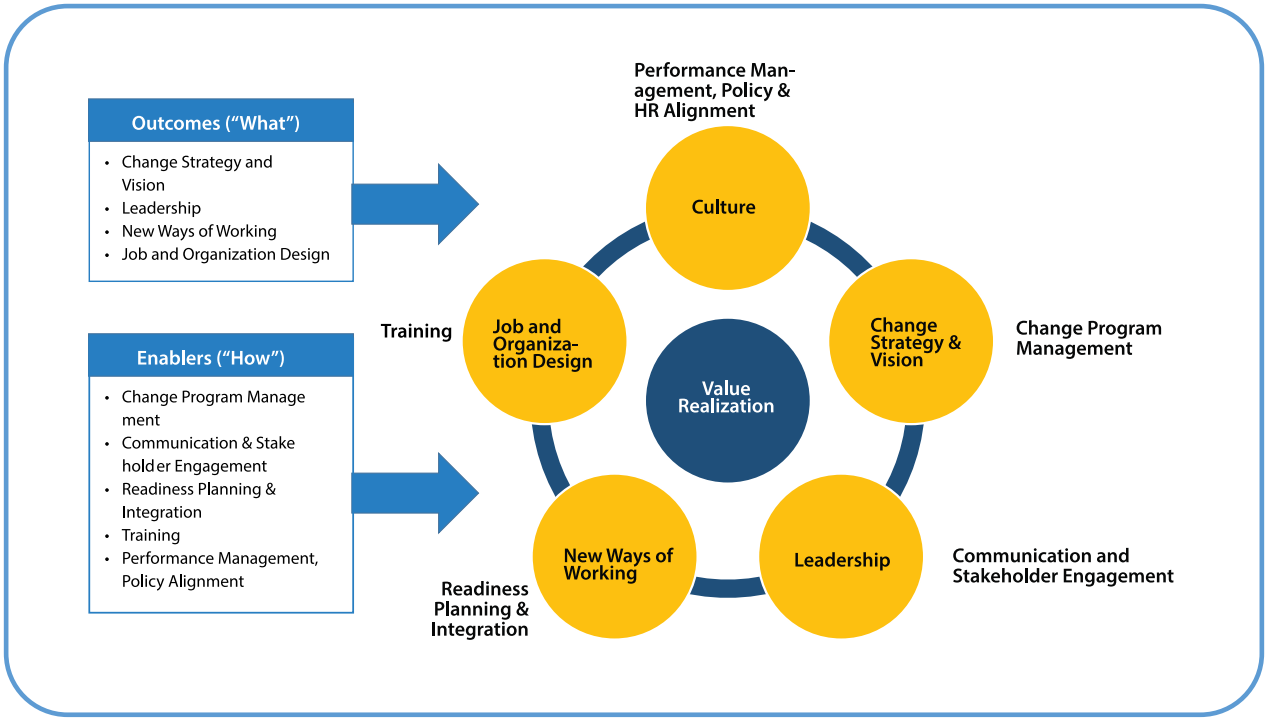

Fig 6. Proposed Organization Change Management Framework

Work Stream 3 - Organizational Change Management:

Apart from data management, organizational factors have been looked upon as challenges in UDI adoption. To drive successful UDI adoption, it is imperative to align the changes to key components of organization, understand the impacts of those changes, drive buy-in at all levels and engage leadership. Change Management Framework in Fig 6 is divided into five phases that will define the organization needed to achieve the expected outcomes from UDI adoption.

Change Strategy & Vision: Ensure that strategic objectives and business benefits for UDI implementation are understood and confidently articulated by all levels of people within various business units. The leadership vision should include embracing the differences across and within the business units whilst harmonizing and standardizing processes. Change management processes should be tailored to individual stakeholder groups by creating flexible and dynamic plans outlining the objectives and threats.

Leadership: Define, understand and engage with everyone working on and impacted by UDI implementation. Ensure that both internal and external stakeholders are informed about changes and impacts of UDI adoption, and create buy-in and ownership for new systems and processes.

Culture: UDI implementation is not about implementing a technical solution; it is more about change in business and processes along with technology. A clear understanding and respect for business identity and culture will drive and support engagement. To support changed culture in staffing, consider aligning person KPIs to UDI program KPIs so effective collaboration is achieved.

New Ways of Working (Work Changes): Document the understanding of impact that UDI implementation has on people, process and technology. Changes in these areas will mean new ways of working for most impacted roles. Work with different business units to mitigate impacts and integrate output with training strategy to deliver a role based view on new ways of working.

Job and Organization Design: Support design and implementation of new or changed roles and organizational re-alignment stemming from the change due to UDI implementation. The training program should elicit the practical usage of the new processes, technology and accountabilities. Processes, SOPs will need to be updated or created to address UDI data management, labeling, verification of coding readability, and maintenance of an RA Database and Master database.

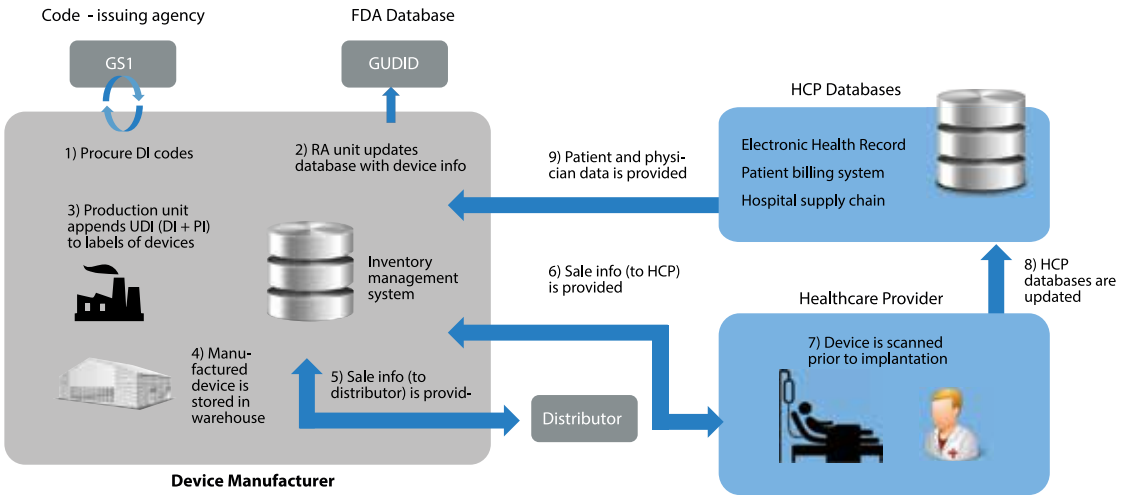

Fig 7. Workflow and transmission of data in a healthcare ecosystem that fully UDI compliant

Proposed Business Process explained through a Use Case

Consider the first business scenario of breast implant rupture to understand how UDI adoption will help with recall process.

Scenario - A company's breast implant ruptures inside a patient and upon confirmation of manufacturing defect, individual recall notices have to reach quickly to 30,000 women with similar implants, including Julie (details are provided below). It may be noted that breast implant manufacturers are mandated to track their products all the way to the person receiving the implant. To understand the full potential of UDI adoption, it is assumed that the implant manufacturer, distributor and the healthcare provider are UDI compliant.

Use case [7] - The manufacturer of the breast implant registers with the FDA-authorized code-issuing agency, GS1 to procure the code for its breast implant devices. The code-issuing agency provides the 'device identifier' code, which includes information about the device manufacturer, product category and implant model. The production unit of the implant manufacturing company provides the 'product identifier' code which includes information such as manufacturing date, expiration date, and production lot and serial numbers. The production unit derives UDI by combining the device and product identifier codes and affixes the combination code on their products as well as corresponding package labels. The regulatory affairs unit submits device information to GUDID through FDA's Electronic Submissions Gateway (ESG). The finished breast implant moves from the manufacturing plant to warehouse. During sale of this device to the distributor, automatic identification and data capture (AIDC) system captures the UDI and updates this information in the manufacturer's inventory management system. As part of sales out reporting to the device manufacturer, the distributor sends information of the healthcare provider to which the device has been sold to. The manufacturer's inventory management system maps the healthcare provider's information against the implant device's UDI number.

Julie is a cancer patient who needs a breast implant. As part of pre-surgery counsel, doctor provides her with information on the different breast implant brands that the hospital typically uses and that which may apply for her case. The hospital provides Julie the device information along with brand names. To make an informed decision, Julie, in addition to receiving doctor's counsel, looks up product related information in GUDID. Julie opts for the latest generation breast implant manufactured by the device manufacturer being discussed. Just prior to the surgery, the UDI for device to be implanted in Julie is scanned by nurses, and the information is updated in Julie's electronic health records (EHR), patient billing information system and the hospital's supply chain system. Julie provides her consent that her communication information be shared with the device manufacturer. The hospital shares Julie's information along with implant date and attending physician's details to the device manufacturer. The manufacturer's inventory management system is updated with patient's information against the particular implant's UDI number.

A couple of years later, the breast implant company issues an FDA-mandated recall due to rupturing of breast implant inside a patient. The device manufacturer has a very robust master data strategy for products, which tracks devices through the life cycle: with UDI as the key, company's products are mapped along with the contact information of the patients in whom the devices are implanted. The company has a wide clientele that includes hospitals, distributors, alternate care locations and patients. The manufacturer sends out recall letters to distributors, hospitals and patients based on their preferred method of contact for all affected UDI numbers. As Julie's details are available with the company, she also receives recall communication from the device manufacturer.

Future Potential of UDI

UDI adoption in the current form provides a huge step towards improving patient safety, increasing supply chain efficiency and providing a standard platform for device identification for the healthcare industry. Despite these benefits, we are no way close to leveraging the full potential of UDI adoption. In this section, we discuss some of those ideas which may benefit the entire healthcare ecosystem:

1. In addition to medical device manufacturers, FDA should actively encourage UDI adoption by stakeholders from the entire healthcare ecosystem – distributors, Group Purchasing Organizations (GPO), healthcare providers (HCP) and payers. This will benefit the entire healthcare ecosystem when interlinked and interoperable systems are created that bring together volumes of data all linked together by the UDI. Alternatively, stakeholders should also volunteer towards UDI adoption.
2. As HCPs integrate UDI into patient health records, especially EHRs, systems should be created to ensure a secure interoperability of HCP networks. Hospitals should be able to access EHRs of patients irrespective of where the hospitals are located. This will facilitate swift identification of devices during emergency clinical situations when the patient's prior medical history is not known.
3. National device registries, adverse event reporting systems and FDA communication systems should provide alert services that HCPs and patients can subscribe to so that any device related information, specific to a particular DI or UDI, can be sent to subscribers when new information is available. This will facilitate better monitoring of patients post their surgery.
4. Hospital's inventory management systems and EHRs should be upgraded to peruse recall notices, match recall UDI information with the hospital's existing inventory and prevent physicians from using those devices prior to surgery. This will ensure inadvertent medical errors do not occur even when recall alerts have been communicated by device manufacturers.
5. Success of UDI adoption should trigger the debate to develop a globally recognized medical device identification system with track and trace functionalities that cover not just life sustaining class III devices, but all devices that have risk of injury to the patient. Such a system should be built with enhanced security features so that patient's privacy is guarded. This system should be linked to hospitals' inventory management system so that the system can verify the device's origin every time a shipment is received from the manufacturer / distributor / sales representative. Such a system will ensure counterfeit devices do not enter into the healthcare supply chain.
6. UDI adoption throughout the healthcare ecosystem in the United States should serve as a reference model for other countries and their respective medical device regulatory agencies to develop similar device identification systems that will bring forth the same benefits as that of the UDI.

Conclusion

This whitepaper presents a consulting approach to FDA's rule on UDI compliance. Once implemented, the UDI system will improve patient safety and supply chain efficiencies along with several other benefits. Healthcare supply chain is lagging behind other industries such as retail or pharmaceuticals in adopting a standard model for device identification. To realize the full potential of the UDI system, all stakeholders involved in the healthcare ecosystem should adopt it.

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