



UDI Capture - Work Group Charter

WORK GROUP TOPIC: UDI Capture

Categorization of existing successful UDI capture processes, the exploration of new solutions and/or technologies, and work group updates to the Learning UDI Community Steering Committee.

WORK GROUP LEADERS:

James Phillips, Franciscan Missionaries Of Our Lady Health System,
James.Phillips@fmolhs.org

Peter Casady, Champion Healthcare Technologies, pcasady@championht.com

PARTICIPATING MEMBERS:

ADA, Mohammed Harunani, MD

Albany Medical Center, Bob Matthews, Assist VP Supply Chain

Automatic Identification Systems, Inc., Jeff Nolan

Automatic Identification Systems, Inc., Mike Nolan

BDCH, Jordan Noyes, CMRP, Contract Operations Specialist

Bio Pro, Dave Mrak, Director of Product Development

Champion Medical Technologies, Pete Casady, CEO & Co-Founder

Children's Hospital Association, Jo Ellen Humphrey, Manager of Analytics

Epic, Kenny Jackelen

FDA, Terrie Reed

FDA Informatics Team, Minaei Behnaz

FMOLHS, James Phillips, Consulting Manager DSI

Medegen Medical Products, Ron Prybella, Senior Director of Marketing

Mercy/HTG, Matthew Mentel

Mount Sinai Health System, Franco Sagliocca, MBA, FACHE, Corporate Director, Supply Chain

National Recall Alert Center, Mark N. Cohen, MD. CEO/FOUNDER- National Recall Alert Ctr

Novant Health, Susan Stimpson, Director for Procurement and Business Systems



Philips, Jodi King

Philips, Zita Yurko

Sargent Healthcare Strategies., Jean Sargent

Stanford Health Care, Jim Booker, Manager, Master Data Management

UF Health Shands Hospital, Laura Kowalczyk, JD, MPH, Associate Vice President Supply Chain Services

University Health Network-Toronto Canada, Wendy Watson, OR Supply Chain Manager

Vuemed, Lana Makhanik, COO

Zebra Technologies, David Coons, Vice President, Advanced Markets & Technologies

CHARTER:

The ultimate goal of our work group is to identify opportunities for case studies, initiate them and bring answers to the greater Learning UDI Community to foster learning and hopefully, shorten the adoption curve for capturing UDI's within healthcare.

BACKGROUND:

One of the first steps for any healthcare provider to benefit from UDI labeled devices, is to begin capturing the data they contain. Whether through bar code scanning, RFID or other means, capturing the UDI in a system capable of receiving and parsing data fields allows the UDI to become useful. All of the benefits of the UDI vision become possible including managing recalls, post market surveillance of devices, comparative effectiveness, automated expiration date notifications, standardization of ordering, standardization of device registries, and many more. Ultimately, capturing UDI's allows providers the opportunity to begin reducing costs while improving patient safety and outcomes for the benefit of the entire healthcare system.

AFFECTED STAKEHOLDERS:

Medical Device Manufacturers
Distributors of medical devices
Hospital staff responsible for tracking devices
Hospital supply chain VP's, Directors, Managers
UDI Capture Solution Providers

REQUIRED STAKEHOLDERS: (Are there other stakeholders that are not represented in this work group that should be, e.g., manufacturers, providers, clinicians, technology companies, etc.)

Tissue Banks not under FDA device rules
ERP Administrators
EHR Administrators
GS1
HIBCC
FDA



AHRMM
Healthcare Associations
Recall Notification Services

DELIVERABLES:

- GUIDANCE
- CASE STUDIES
- SOLUTIONS
- TOOLS

COMMUNICATION PLAN:, e.g., briefly describe the affected stakeholders and recommendations for how to communicate your recommendations.

The goal of the Capture Work Group is to communicate real world examples of the successes, challenges and ultimately the recommendations in capturing UDI information in an automated process that is reproducible. By sharing the provider experiences in the Work Group through case studies we hope to accomplish this goal. Case studies must include the specific solutions and tools used to capture UDI data and also provide guidance to providers motivated to begin their own automated capture process.

As of October 24, 2016, Stanford Health, FMOLHS and Beaver Dam Community Hospital have volunteered to participate in creating case studies. The Work Group case studies will also include the systems that are used to capture and share UDI information within existing hospitals systems including EHR, ERP or MMIS, Hemodynamic Systems, etc. Where applicable, the case studies will also capture the sharing of UDI information to external systems like device registries.

Work Group Time Frame:

6 months