

UDI Implementation

We are "On Our Way"

Wednesday, June 24, 2015

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FDA Center for Devices and Radiological Health

UDI Basics

Statutes and Regulation

FDA Amendments Act, 2007

FDA Safety and Innovation Act, 2012

UDI Rule, September 24, 2013

Establish a UDI System



- Develop a standardized system to create the UDI
- Place UDI on label and (sometimes) the device
- Create and maintain the Global UDI Database
- Adoption and Implementation

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What is a UDI?



Qty: 1 each Size: 20mm x 12.5mm **REF** Z1234

UDI = DI + PI

(01)12345678901234 (17)140102(11)100102(10)A1234(21)1234

2014-01-02 2010-01-02 **LOT** A1234 **SN** 1234

45°C **UPPER LIMIT OF TEMPERATURE** **KEEP DRY**

Manufacturer **CompuHyper GlobalMed, LTD** XXX-867-5309 (USA)
101 Innovation Drive, New Sales, MD 20999-0000 XXX-555-3226 (Outside USA)
<http://www.compuhypergm.com>

Compliance Date

Must bear a UDI & submit data to GUDID

September 24, 2014

- Class III devices, incl. class III stand alone software
- Devices licensed under the PHS Act

September 24, 2015

- Implantable, life-supporting and life-sustaining (I/LS/LS) devices, incl. stand alone software
- Direct Marking of I/LS/LS for certain intended uses

September 24, 2016

- Class II devices
- Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses

September 24, 2018

- Class I devices and devices not classified class I, II or III
- Direct Marking of class II devices for certain intended uses

September 24, 2020

- Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses

UDI Benefits

JUNE 24 & 25, 2015
Hilton Baltimore, Baltimore, MD

- | | |
|---|---|
| <ul style="list-style-type: none">• Simplify integration in data systems | <ul style="list-style-type: none">• Reduce medical errors |
| <ul style="list-style-type: none">• More rapid and precise identification of medical devices | <ul style="list-style-type: none">• Better-focused and more effective FDA safety communication |
| <ul style="list-style-type: none">• Foundation for global, secure device supply chain | <ul style="list-style-type: none">• Pinpoint specific device in adverse events and recalls |
| <ul style="list-style-type: none">• Address counterfeiting and diversion and shortage issues | <ul style="list-style-type: none">• Facilitate more useful electronic patient records |
| <ul style="list-style-type: none">• Prepare for medical emergencies | <ul style="list-style-type: none">• Support provision of high-quality medical services |

October 2014 to June 2015

An Eventful 8 Months

October 2014



An Eventful 8 Months

October 2014



June 2015



GUDID Status

October 2014

- 33,000 DI Records
- 240 Labeler Accounts
- 4,000+ Helpdesk Inquiries
- 91% Closure Rate

June 2015

- 75,000 DI Records
- 425 Labeler Accounts
- 8,000+ Helpdesk Inquiries
- 95% Closure Rate

Achievements

- UDI Roadmap: Realizing the Benefits
- Education and Outreach
- Launched AccessGUDID

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Challenges

- Helpdesk
- Clarifications and Guidance
- Data Quality

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Emerging Solutions

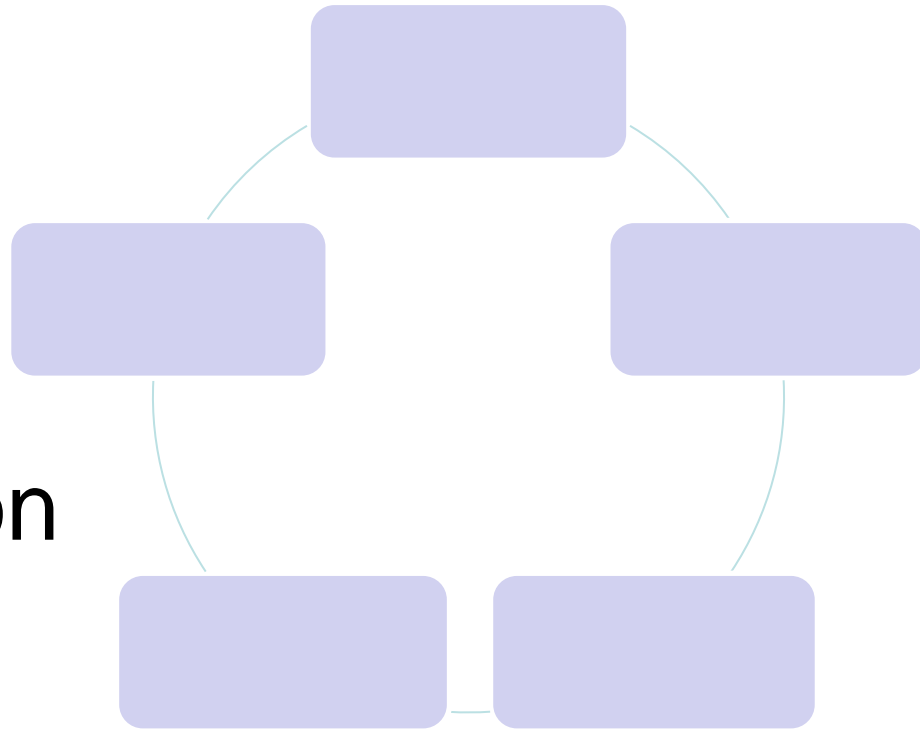
- UDI in ONC Certification Criteria
- Pilots and Studies
- Standards Development Organizations

What's Next

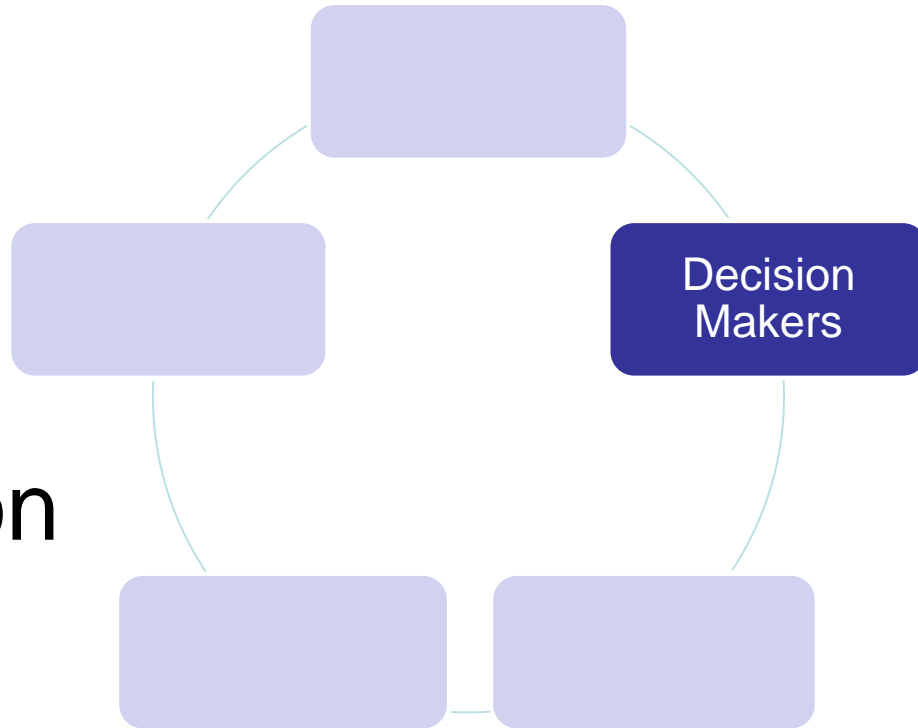
- AccessGUDID – Advanced search and web services
- Guidance – Direct Marking, Convenience Kit, FAQs Vol. 2
- Opening GUDID for Class 2 – After January 1, 2016
- Adoption – Reap the benefits of investment

Vision: Realizing the Benefits of UDI

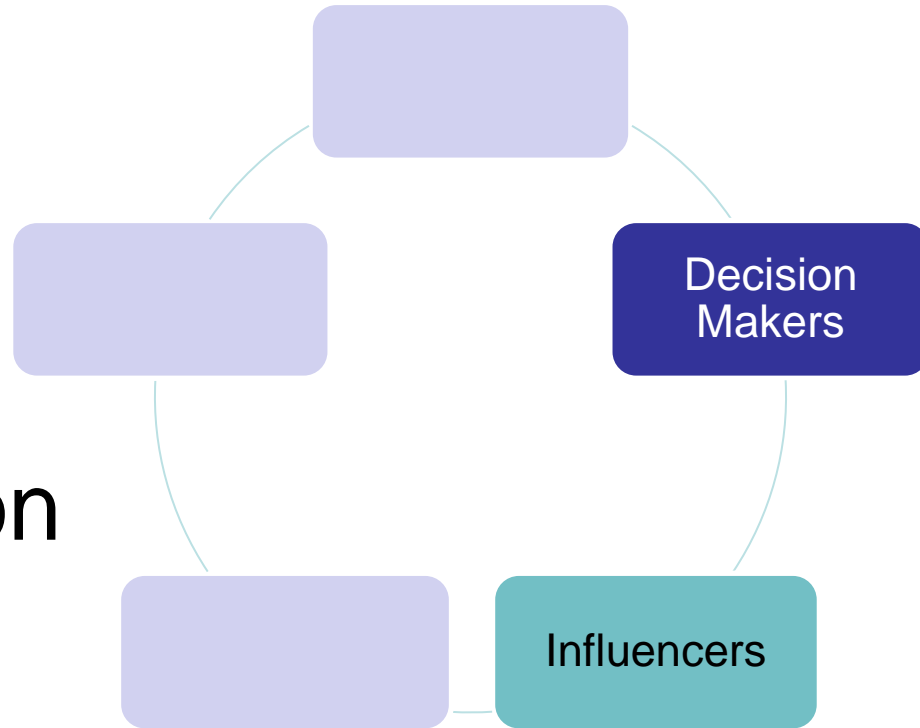
UDI Implementation Roles



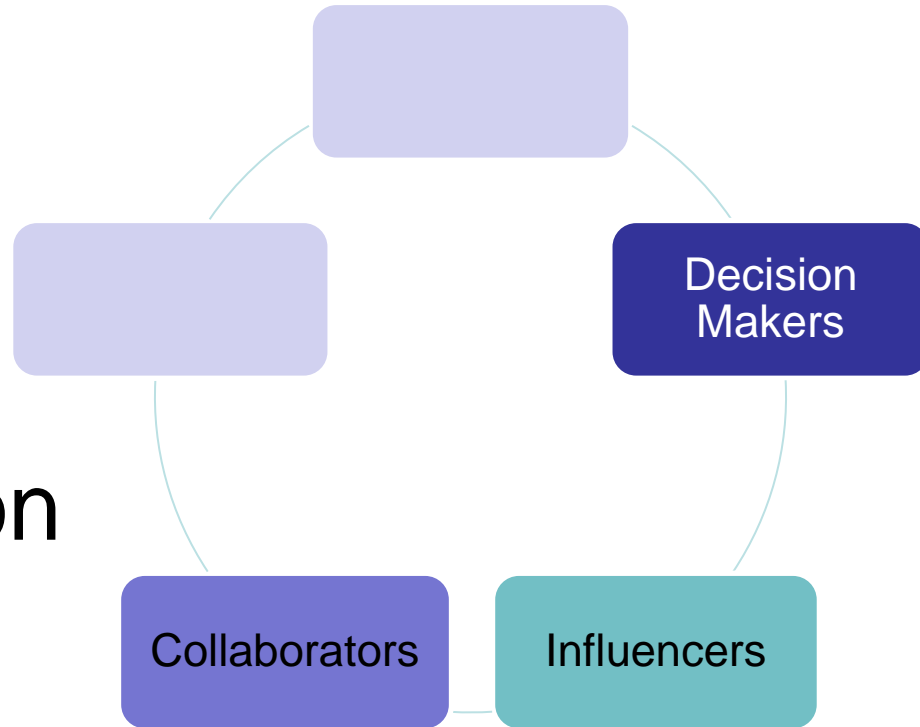
UDI Implementation Roles



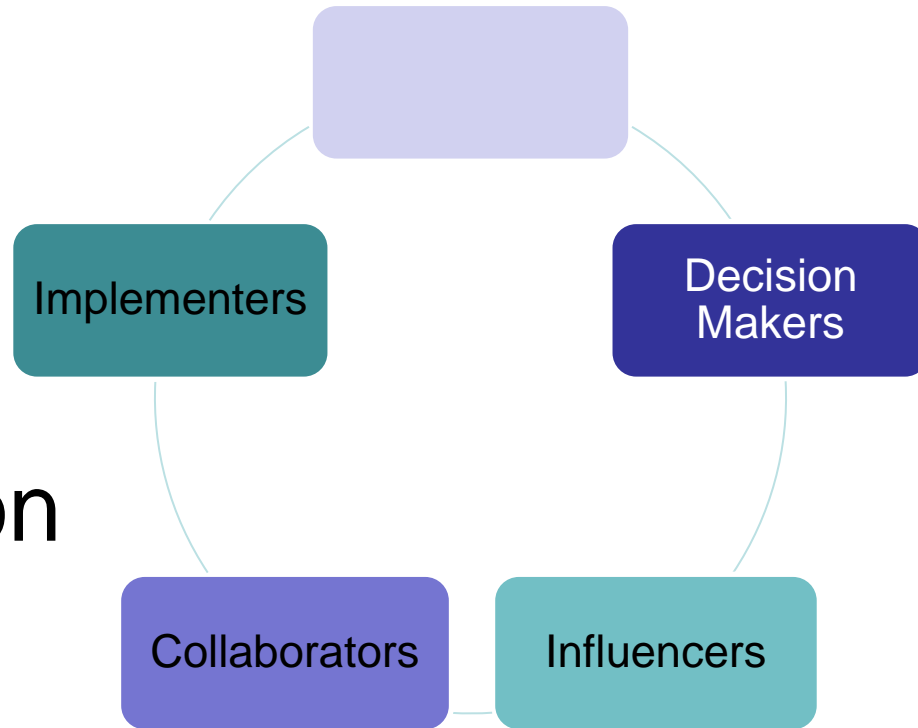
UDI Implementation Roles



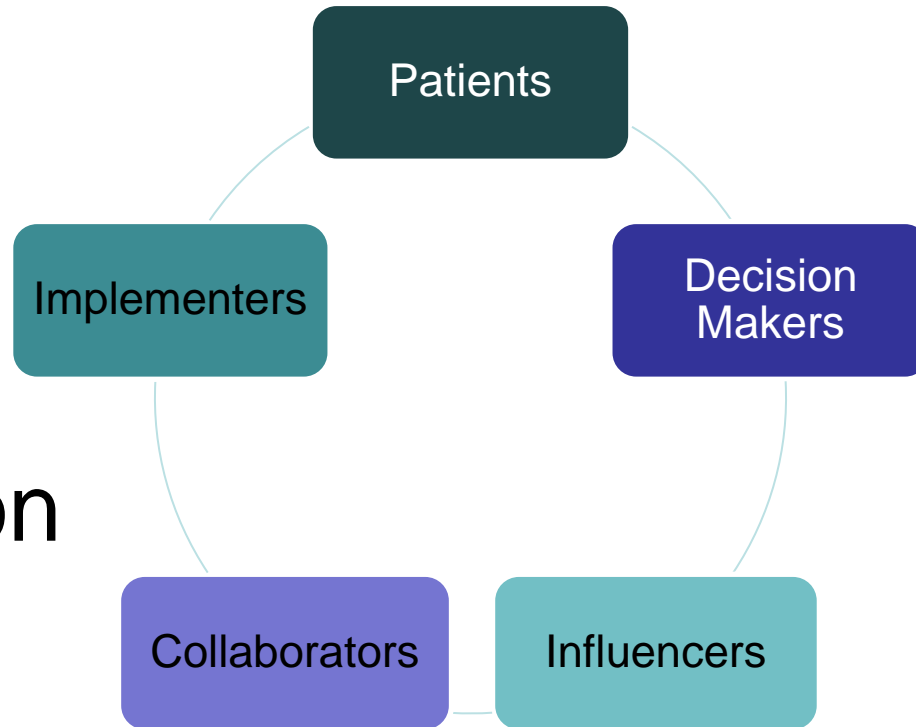
UDI Implementation Roles



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UDI Implementation Roles



Come Meet the FDA Team

Wed June 24

- Noon to 2 pm
- 3 to 3:45 pm

Thu June 25

- 8 to 9:30 am
- 10:30 to 11:30 am
- 1 to 2:30 pm

On Our Way

