Ministry of Food and Drug Safety

The New Regulation on UDI in Korea

GS1 Healthcare Conference

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Table of Contents

Current Status

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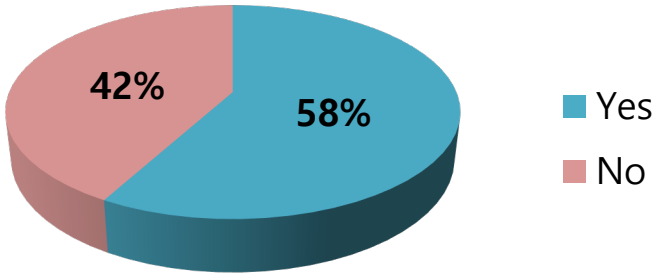
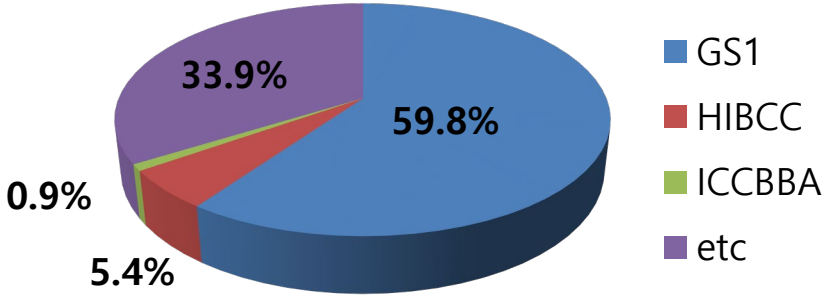
Statistics on Barcode Usage

Subject to 386 Medical Device Manufacturers

Barcodes Assignment



Types of Barcodes



* Source : Medical Device Information Integration Center, 2018

- 58% of MD manufacturers are using barcodes
- 60% of barcode-using MD manufacturers are using GS1
- 34% of barcode-using MD manufacturers' barcodes are not international standards
- More than 90 % of MD subject to tracking* are assigned barcodes

※ Medical devices subject to tracking
1. Devices implanted in human body more than a year
2. Devices for the life-sustaining purpose at places other than medical institutions

Overview of UDI Regulation History

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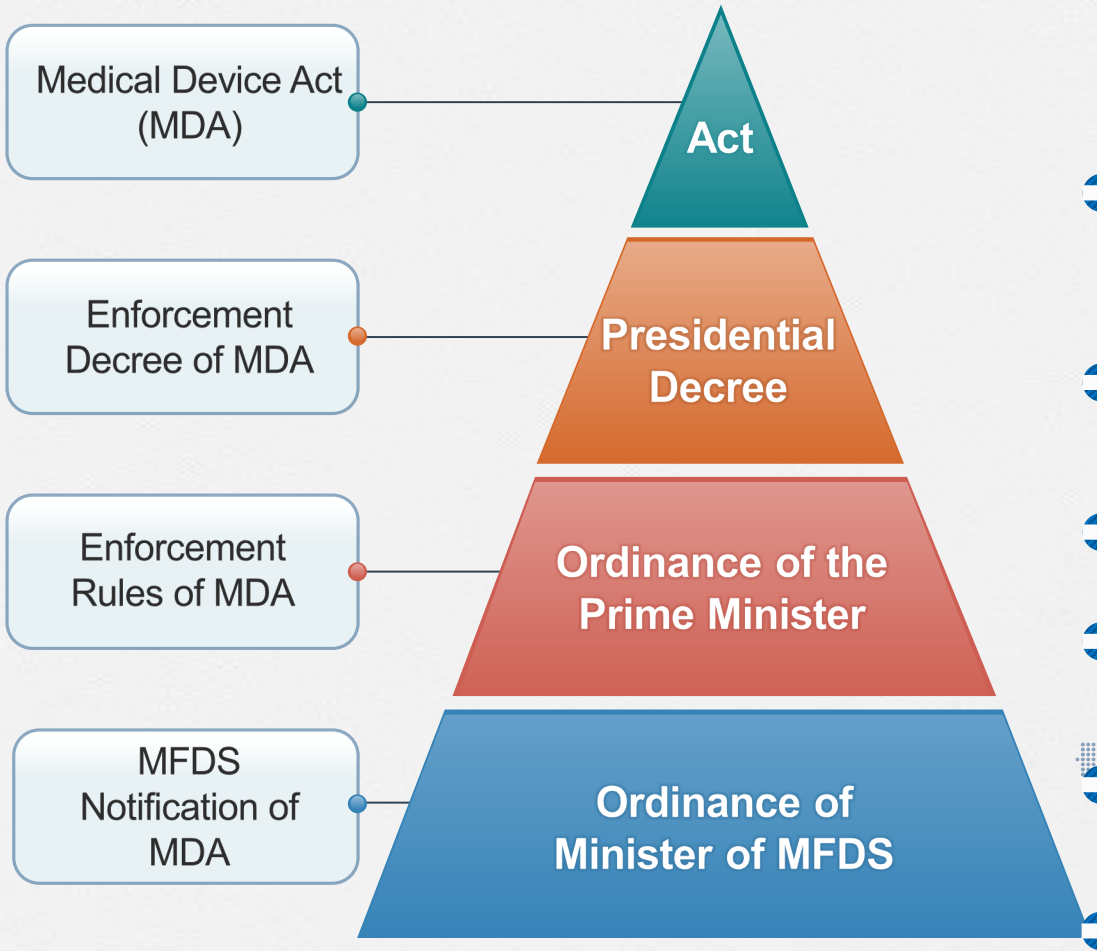
UDI Regulations



Dec, 2016
- Developed the UDI concept
- Introduced IMDIS*
  * Integrated Medical Device Information System
- Included RDR* requirement
  * Reporting Distribution Records

Aug, 2017
- Assigned NIDS* as MDIIC*
  * National Institute of MD Safety Information
  * Medical Device Integration Center

Nov, 2017~
- Planning to establish GIMP*
  * Good Information Management Practice

May, 2017~
- Planning to set forth RDR elements

July, 2018~
- Planning to develop requirements of UDI placement and management

Oct, 2018~
- Planning to set forth submission elements for Integrated medical device information

2019~
- Planning to establish good MDIIC management practice

UDI Regulation for Medical Devices

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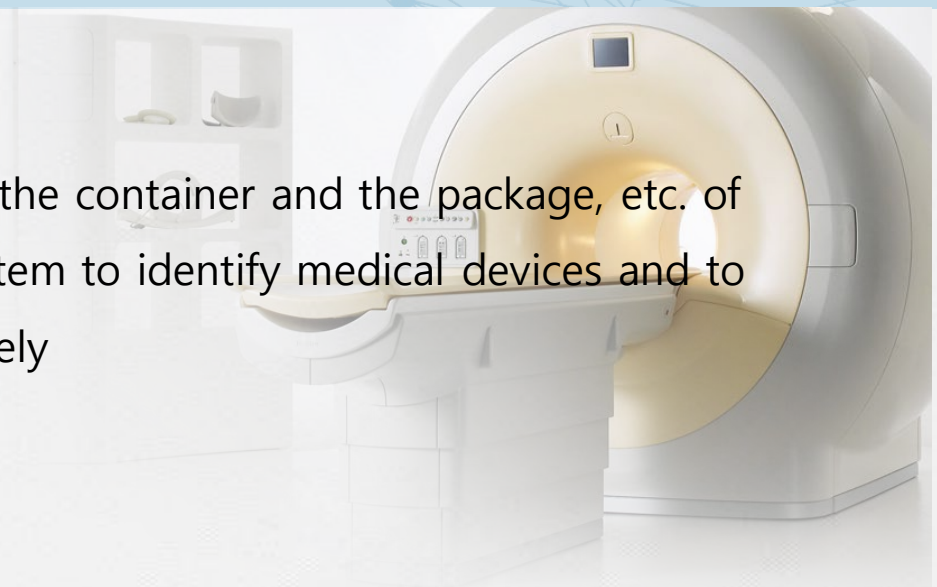

Definition of UDI

- Numbers and bar codes indicated on the container and the package, etc. of devices according to standardized system to identify medical devices and to manage them thoroughly and effectively
- UDI consists of UDI-DI and UDI-PI

Scope of UDI-DI and PI

- UDI-DI : A numeric or alphanumeric code specific to a model name or a package unit of medical devices

- UDI-PI : A numeric or alphanumeric code that identifies the unit of device production. It should include any one of the following information:
  - Manufacturing number(lot number or serial number)
  - Manufacturing date or expiration date
  - Software version information(only applicable to SaMD)

UDI Regulation for Medical Devices

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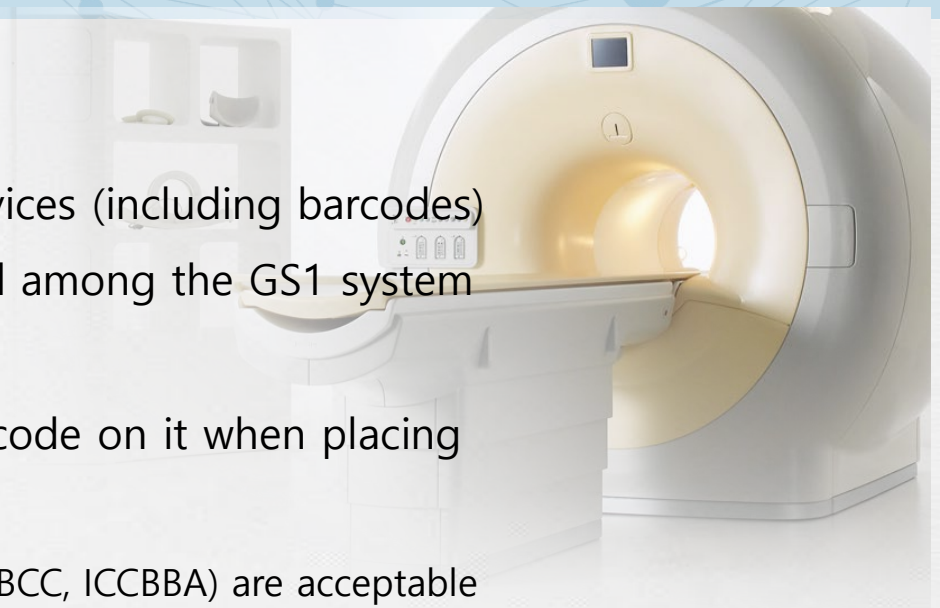

UDI labeling Requirement

- To be on the container, package or outside all the devices (including barcodes)
- EAN-13, GS1-128 and GS1-DataMatrix should be used among the GS1 system when barcodes are displayed on a medical device
- SGTIN-96 or SGTIN-198 should be used with the bar code on it when placing RFID TAG

* GS1 system is generally used and international standards(HIBCC, ICCBBA) are acceptable

Class	Available Barcode (GS1)	Type
Ⅰ	EAN-13	DI Only
	GS1-128	DI + PI
	GS1-DataMatrix	DI + PI
Ⅱ~Ⅳ	GS1-128	DI + PI
	GS1-DataMatrix	DI + PI

UDI Regulation for Medical Devices

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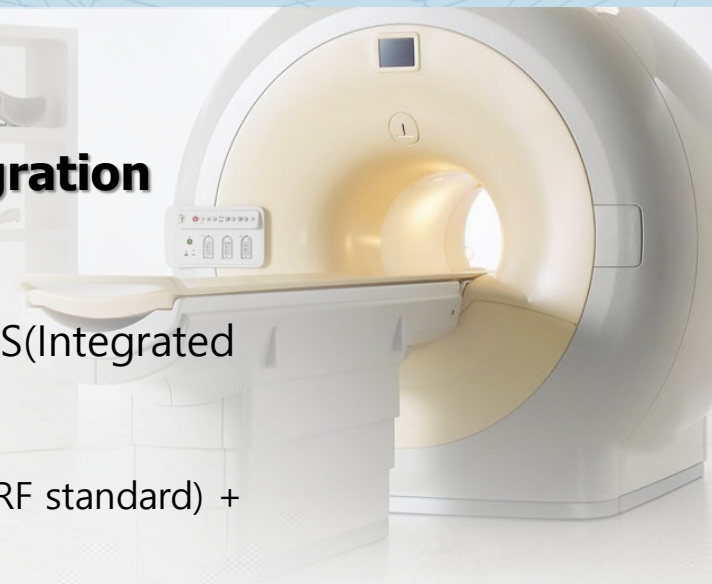

Registering/managing medical device information integration based on UDI

- integrated management of MD-related information with the IMDIS(Integrated Medical Device Information System)

  * UDI data(UDI-DI), info on manufacturers and products(similar to the IMDRF standard) + "Health insurance claiming codes(10% of MD)"

Good Information Management Practice(GIMP)

- Submitting UDI data to the IMDIS after approval prior to releasing, and store/maintain related records in their companies
- Be updated(modify within 10 days in case of changes), have persons in charge of managing MD consolidated information

IMDIS(Integrated Medical Device Information System)

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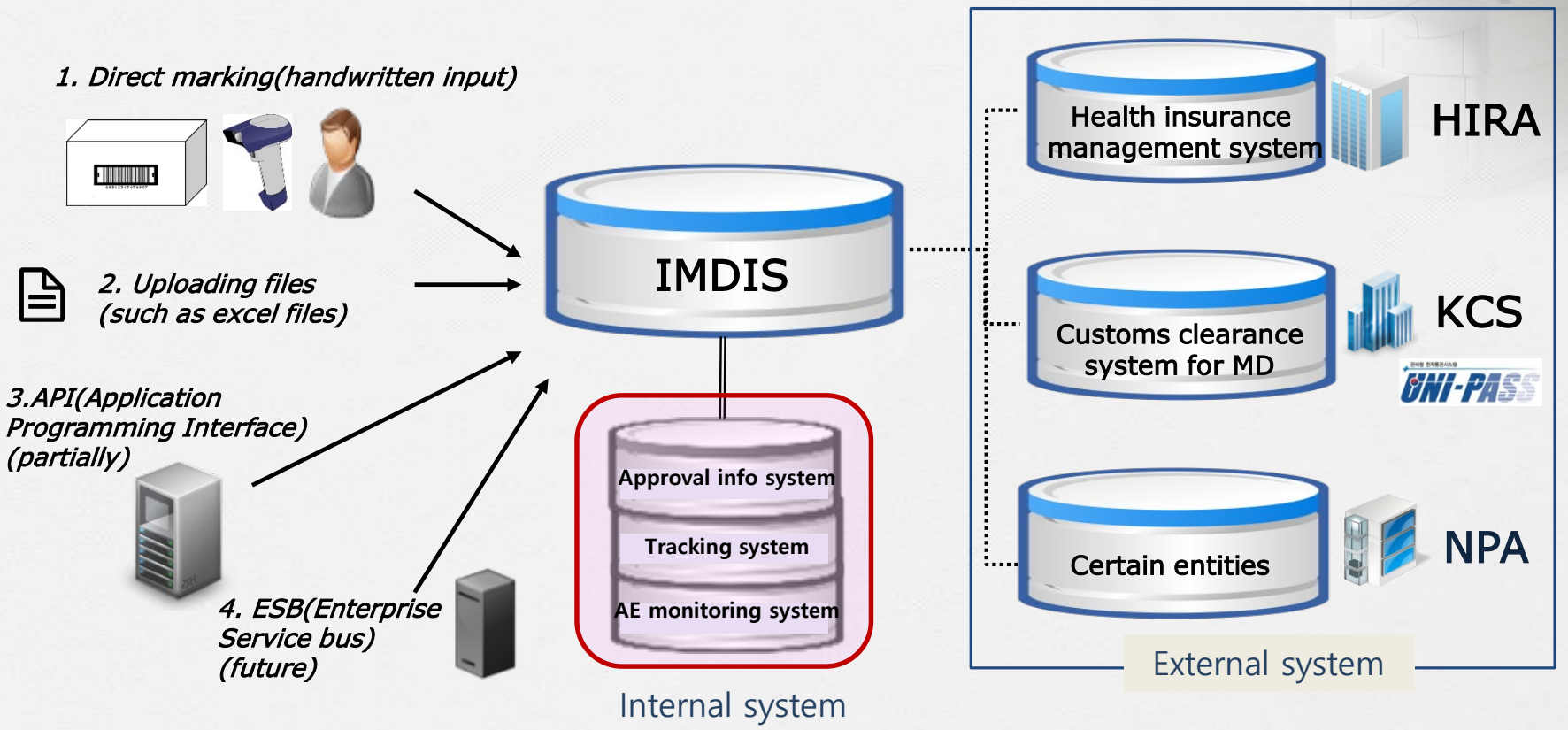
IMDIS (UDI DB + RDR DB)

- Electronic data storing & processing system for effectively maintaining information on MD from its approval, production, import, sales to its use(TPLC)



RDR(Reporting Distribution Records) for Devices

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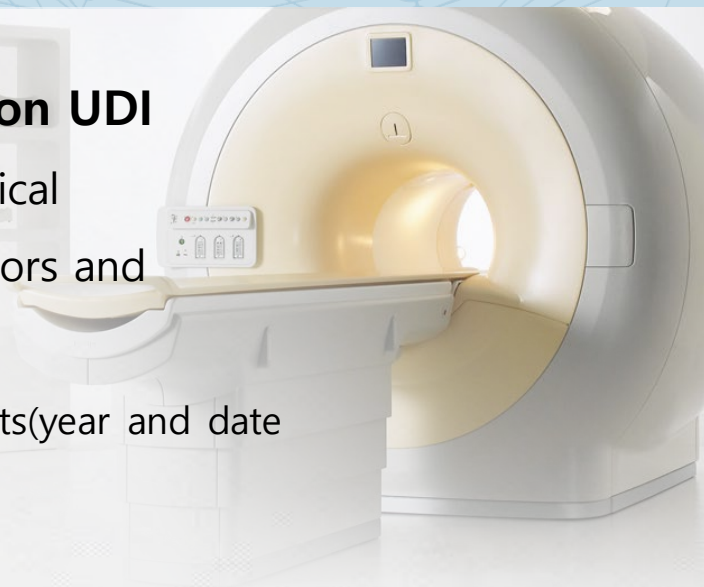
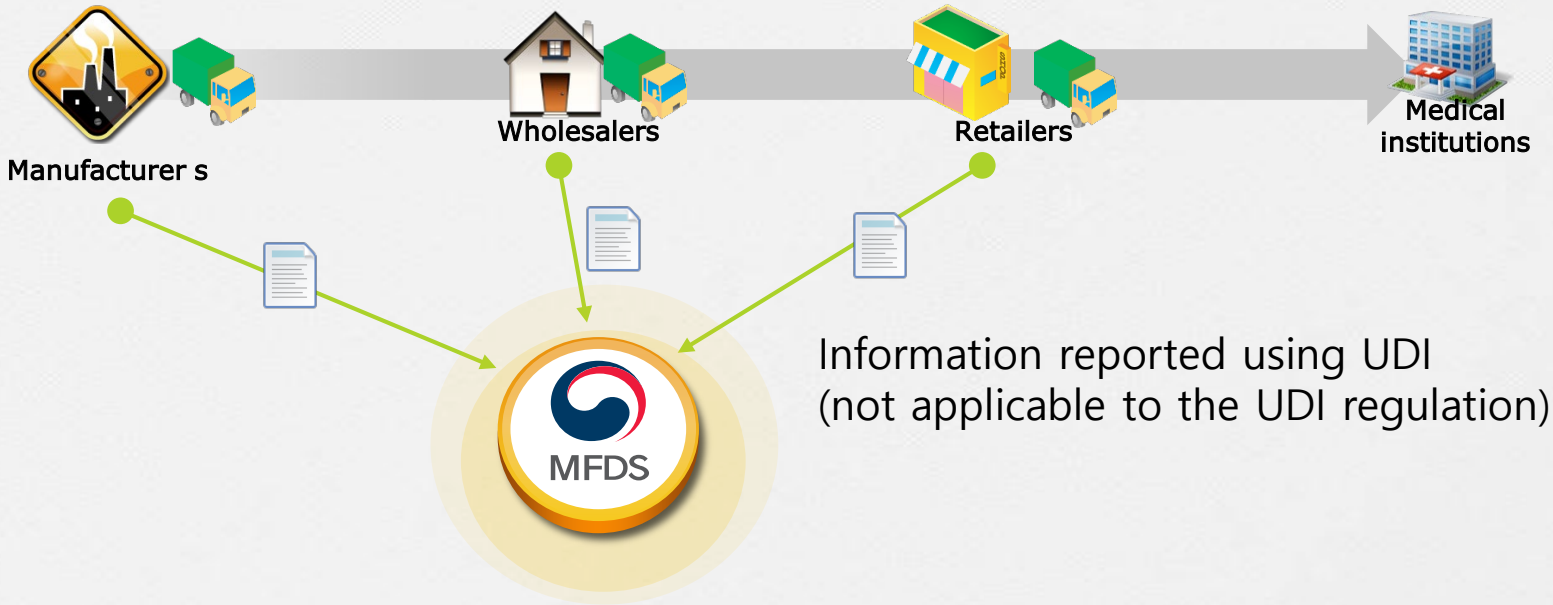


Reporting Distribution Records(distribution history) based on UDI

- RDR to the IMDIS incase the medical devices are delivered to medical institutions, vendors and renters by manufacturers, importers, vendors and renters (including used MD)

  * UDI data(UDI-DI), place to distribute, distributed volume, info on products(year and date manufactured, lot number or serial number, etc.)



MDIIC(Medical Device Information Integration Center)

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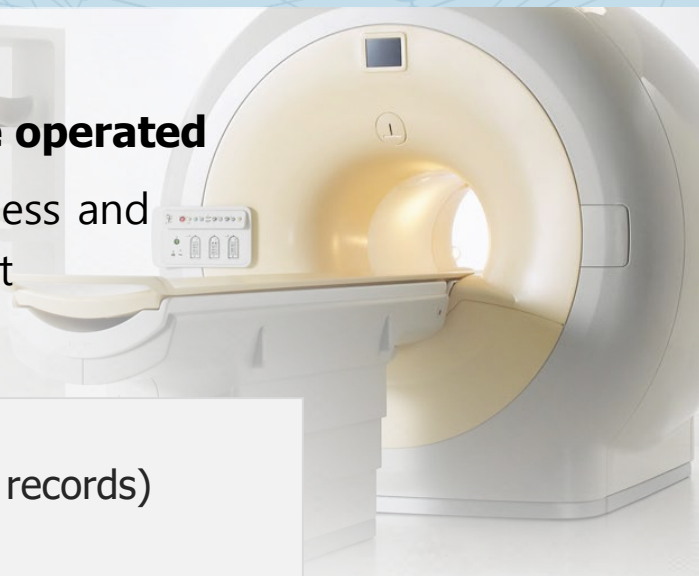

Accrediting medical device information integration center to be operated

- Run MD information consolidation system, collect/investigate/process and provide MD consolidated info and distribution info, and implement standardizing projects for MD consolidated info

Tasks

- Collect/investigate/process/provide UDI DATABASE and RDR info(supply records)
- Support in developing and disseminate programs needed for
- Manage IMDIS and consolidated info
- Research/educate/promote standardization of MD consolidated information

Medical Device Information Integration Center

Address integrated information

- Produce/manage/run standard codes
- Register/manage standard codes & integrated information
- Streamline regulations

Research on integrated information

- Develop the related guidelines
- Produce information to the public
- Investigate and research distribution status

Manage integrated information

- Manage DB for integrated info
- Run the information integration system

Plans on How to Apply the System

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Changes UDI System Brought in MD Safety Management System

Difficulties in identification with approval units (90 thousands) **and separate data**

QMS Conformity

Clinical Trial

Approval

Pre-market

UDI

Post-market

AE Reporting

Monitoring & Tracking

Recalls

Better identification with model units (more than a million) **through data integration** (Big Data)

UDI & RDR Timeline

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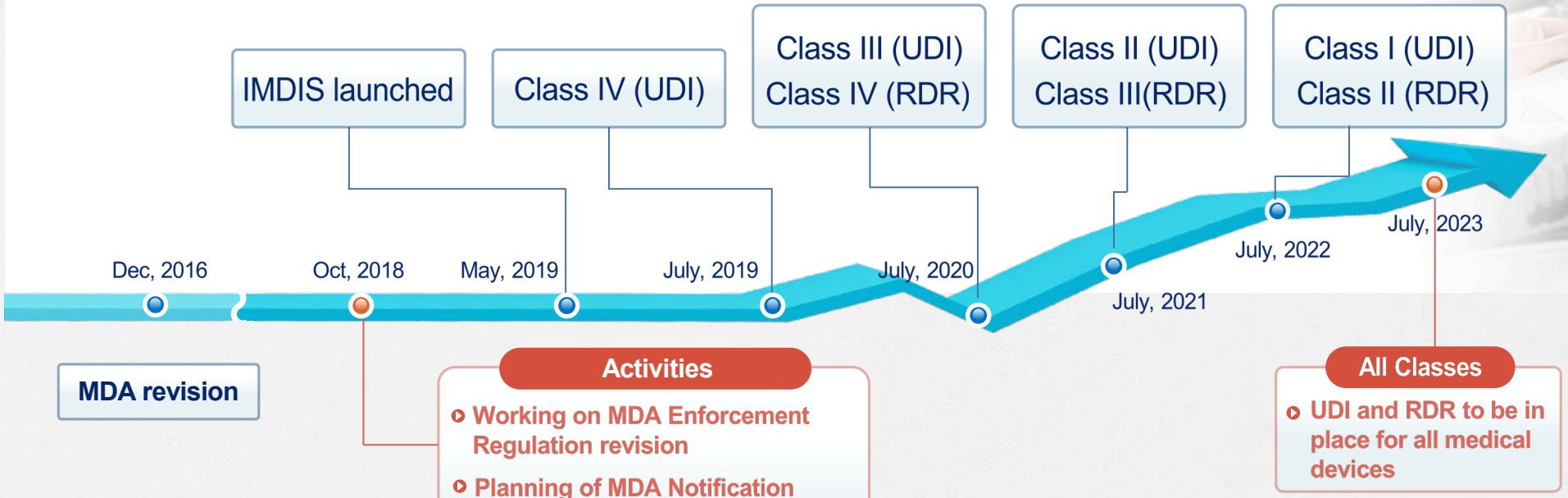
Plans on UDI and RDR System in Korea

- **UDI** : Class 4(July, 2019~), Class 3(July, 2020~), Class 2(July, 2020~), All Devices(July, 2022~)
- **RDR** : Class 4(July, 2020~), Class 3(July, 2021~), Class 2(July, 2022~), All Devices(July, 2023~)



Thank You

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