Korea UDI Introduction

to Medical Devices

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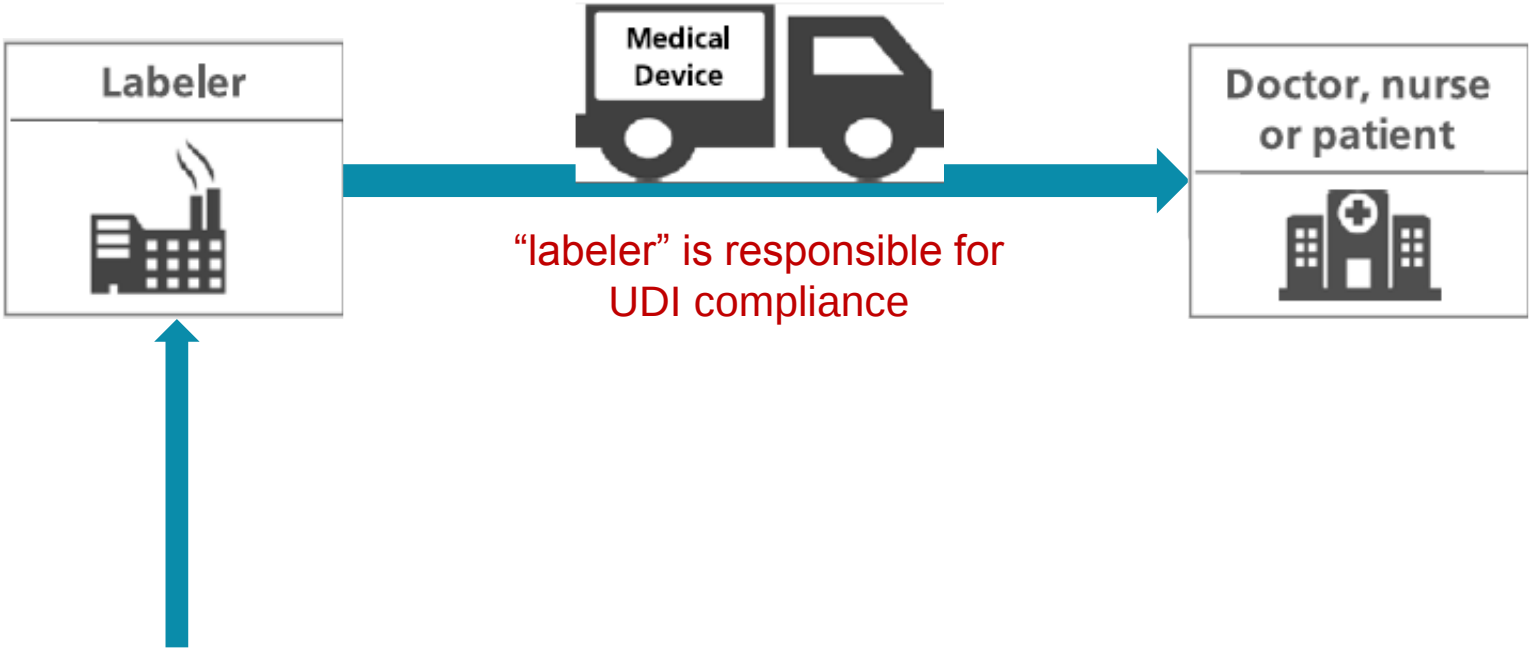
- **Why UDI**
- **Korea UDI Regulation**
- **Implementation**
- **Expectations**

UDI

The Vision of Global Traceability



Labeler is the entity that applies the final label to the device – this could be internal/ external manufacturer, re-processor, re-packager, re-labeler

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Background of Korea

2014

Pilot program for tracking of medical device (MFDS)

2015

Reuse issue of single-use medical device(hepatitis C infection)

2016

UDI rule proposed and reviewed by urgency

Medical Device Act rev. (December 2, 2016)

The current law is not able to grasp the relevant situation from the stage of manufacture and import of medical devices to the stage of distribution, and it is necessary to establish a system that can manage the entire period from the production of medical devices to the safe use. Therefore, UDI of the medical device should be indicated, the supply history report must be made to the manufacturer, and UDI system for medical devices should be established and operated.

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Introduction of Regulation

Medical Device Act, Main Contents
(Partial Amendment for UDI, '16.12.2)

Article 2, 20

- The definition of the standard code for medical devices shall be established and shall be stated on containers or packaging of the medical device

Article 31-2

- Medical device manufacturers, importers, distributors, and lessors shall report the supply details to the Minister of Food and Drug Safety when medical device is supplied

Article 31-3

- Establish and operate the integrated information system for medical devices, and a manufacturer, etc. shall register standard codes and information on medical devices in the central system

Article 31-4

- The Minister of Food and Drug Safety shall entrust the medical device information center with the task

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Requirements for a Compliant Label

- Drafted details: harmonization with global standard & regulation
  - ✓ Every medical device sold in Korea
  - ✓ UDI format: GS1 basis / HIBCC* / ICCBBA**
  - ✓ UDI = DI + PI
  - ✓ Identifier = the label in both plain text and barcode technology
  - ✓ Labeled location: appropriate package or container
  - ✓ "Directly Marked" for devices intended for reuse or reprocessing
  - ✓ UDI registration: via. Korea UDI system
  - ✓ Pilot to start Q3 of 2018
  - ✓ Phased implementation
    from Class IV on Jan. 1st, 2019

* Health Industry Business Communications Council
** International Council for Commonality in Blood Banking Automation

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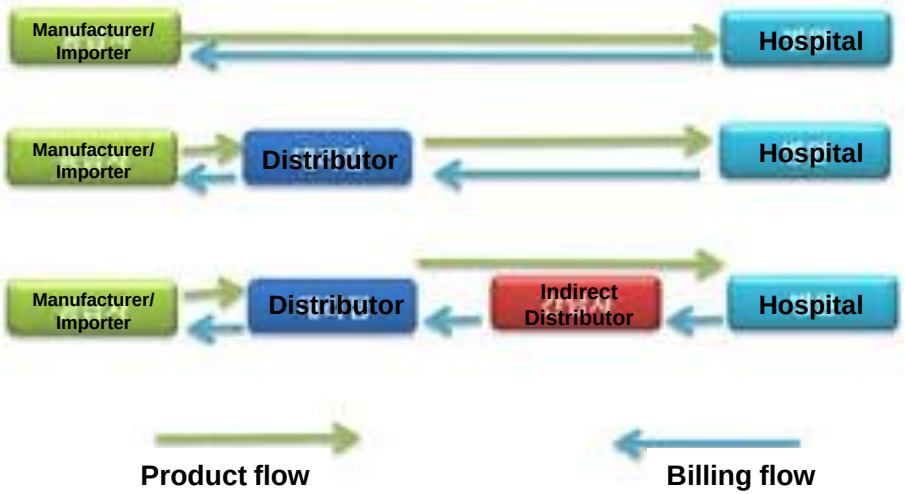
Requirements for Supply Reporting

- Legislated reporting of medical device supply history with UDI
- Reporter: MD manufacturers, importers, distributors, and lessors
- Drafted details:
  - ✓ Reporting subject: All MD supplied to Medical Institutions
  - ✓ Reporting items: UDI, Supply information incl. Supplier, Lot Number, Packaging Unit, Quantity, Date, Unit price by sale price*
  - ✓ Monthly reporting: via. Korea UDI system
  - ✓ Phased implementation from Class IV on Jul. 1st, 2020



*Price is required only MD notified by Regulations on Standards for the National Health Insurance Health Care Benefit

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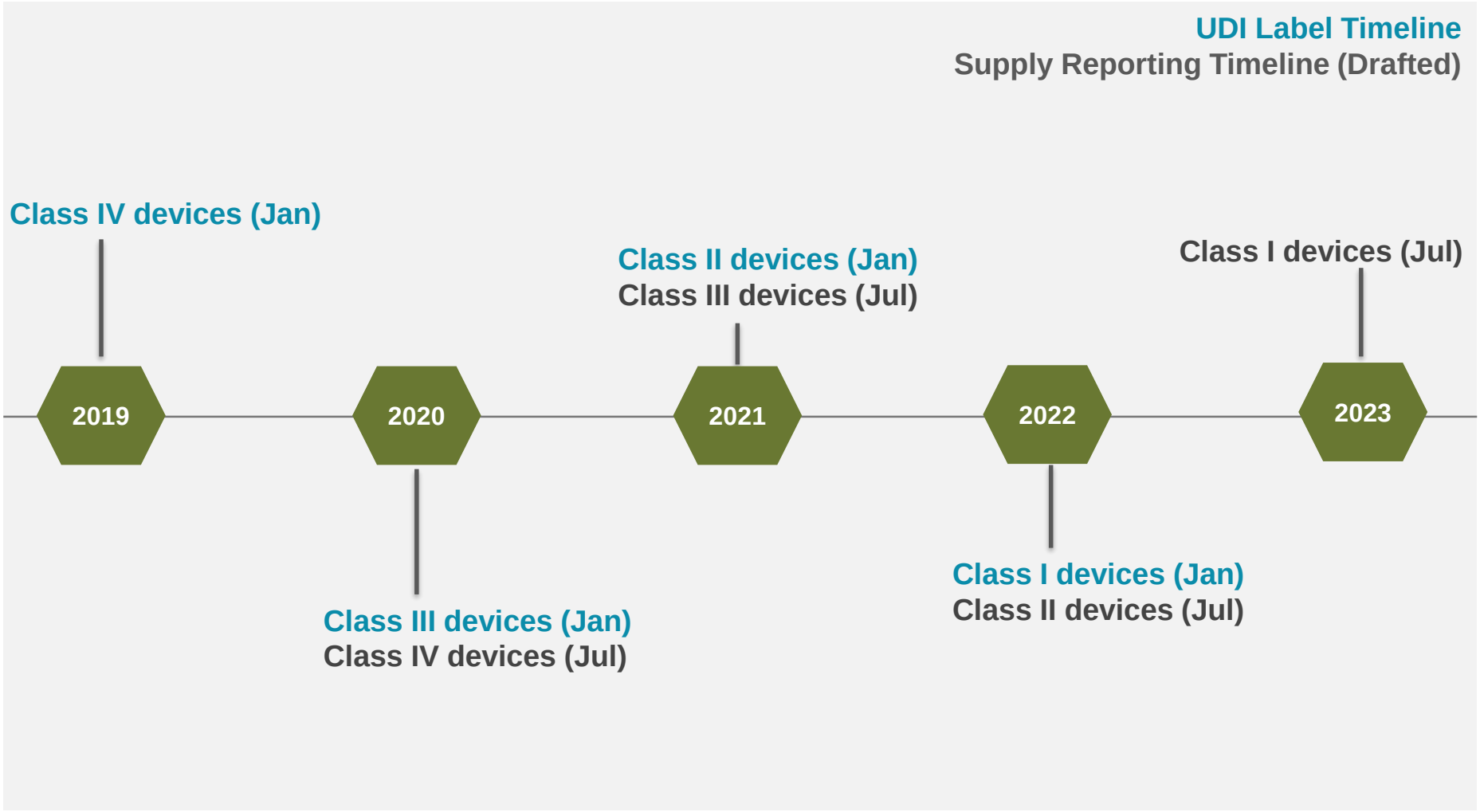
Korea Compliance Timetable



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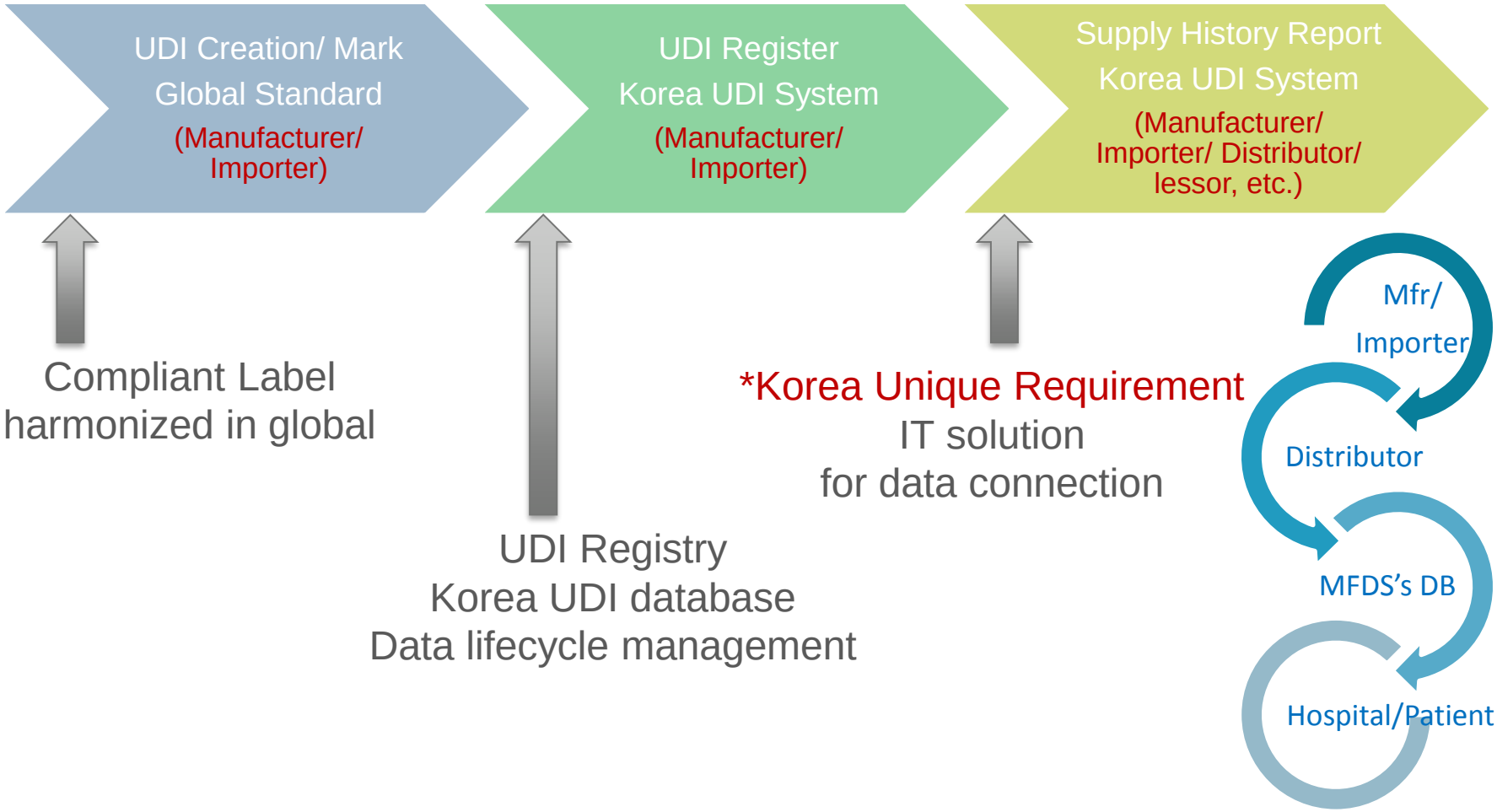
Implementation



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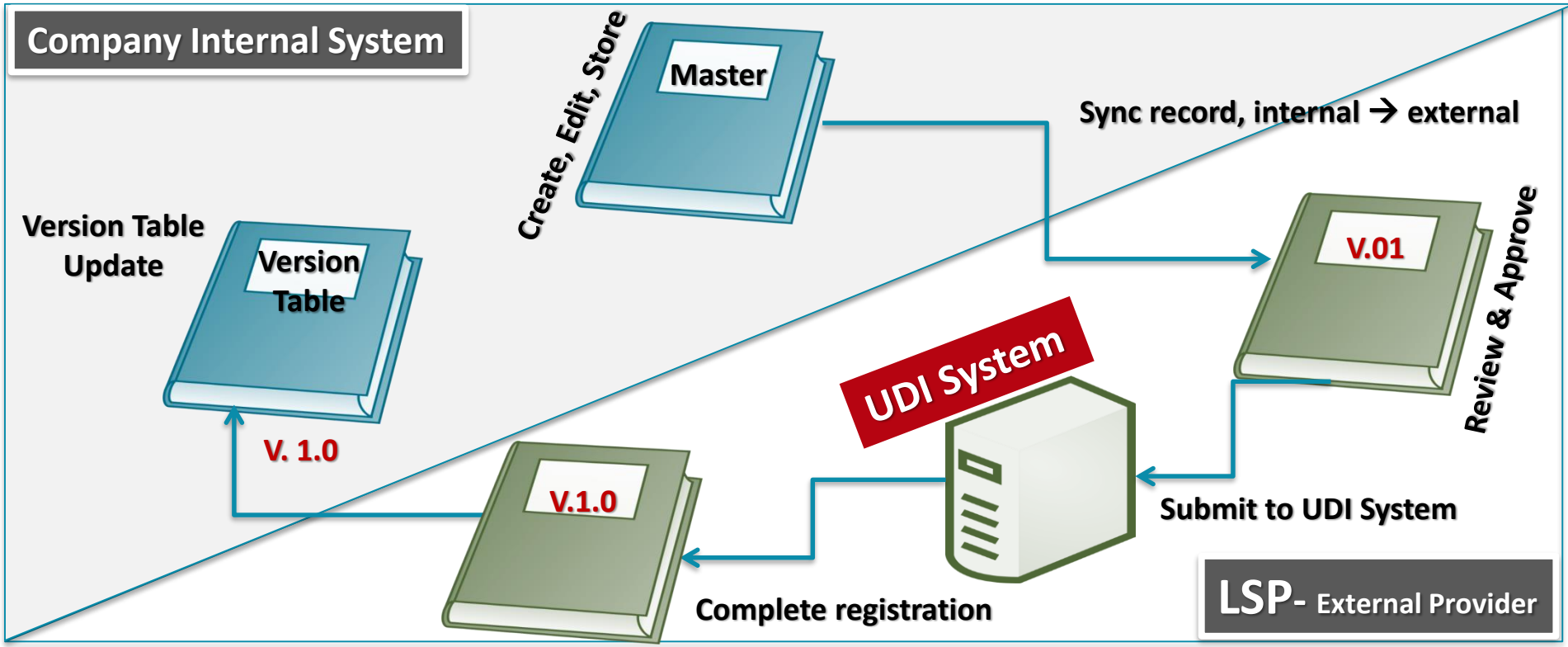
Life Cycle Record - Example



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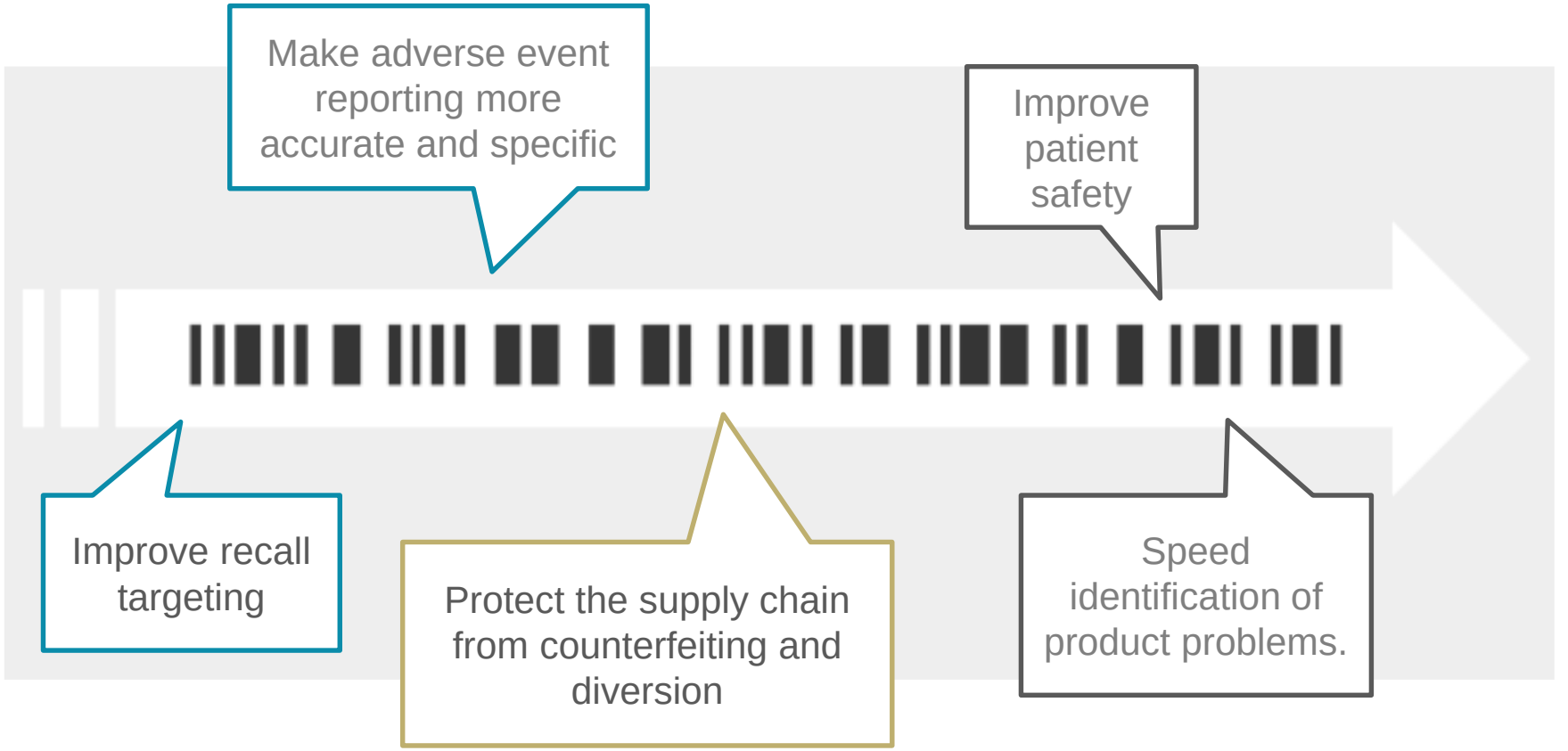
Benefits – Expectations Value beyond compliance

Once fully implemented UDI will be used to identify medical devices through distribution and use.



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Global Harmonization

Questions?


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