

# Data sharing and Medical Device standardization in Japan

American Medical Devices and Diagnostics  
Manufacturers' Association (AMDD)

*S. Masukawa*

*M. Kawai*

# Senior Managing Director



## Shigeyuki Masukawa

<b>AMDD</b> Senior Managing Director	2021~present
<b>AMDD Health Technology and Policy Institute</b> Deputy Director	2019~present
<b>Boston Scientific Japan</b> Executive of Operations (Supply Chain Management , Facility Management, General Affairs), IT, Dealer Management and Government Affairs	2006~2020
<b>Baxter</b>	1997~2005
<b>IBM Japan</b>	1982~1996
<b>Hitachi Soft</b>	1979~1982

### Industry Activities

<b>AMDD Distribution/IT Committee Chair</b>	2018~2019
<b>AMDD RFID Working Group Leader</b>	2018
<b>AMDD UDI Working Group Leader</b>	2016
<b>AMDD Board of Director</b>	2012~2014
<b>AMDD Membership Committee Chair</b>	2011~2018
<b>AMDD member</b>	2010~2020

# Strategy Management Office



## Makoto (Mark) D. Kawai

<b>Zimmer Biomet</b> Director Government Affairs	2018.10 ~ present
<b>Procter &amp; Gamble</b>	1995.4 ~ 2018.9

### Industry Activities

<b>AMDD Strategy Management Office</b>	2020 ~ present
<b>AMDD Public Affairs Committee Chair</b>	2020 ~ present
<b>AMDD Orthopaedic Committee Chair</b>	2019 ~ present
<b>AMDD Distribution/IT Committee Vice-Chair</b>	2020 ~ present
<b>ACCJ Healthcare Committee Co-Chair</b>	2020 ~ present
<b>ACCJ Healthcare Committee Vice-Chair</b>	2019 ~ 2020

# About AMDD

Established: April 1, 2009

Initially established as the Medical Devices Task Force within the American Chamber of Commerce in Japan (ACCJ) in 1980s

Members: Japanese subsidiaries of U.S.-based corporations that handle medical devices and in-vitro diagnostics & Japanese companies that handle medical devices and in-vitro diagnostics in US

Mission: Provide high-value medical technology and information

Key Activities: Make high-value medical technologies

- to be a choice for patients
- to be available for and appropriately used at hospitals
- recognized/apprised by medical insurance system

# About AMDD – Regular Member Profile

Number of member companies	74 (incl. 13 associate members)
Number of employees	Full time 137,281 <sup>*1</sup> Others 8,140 <sup>*1</sup>
Length of business in Japan	Ave. 29.0 years <sup>*2</sup>
Number of companies with R&D capability in Japan	16
Female management ratio	16.4% <sup>*3</sup>

As of Dec.31.2021

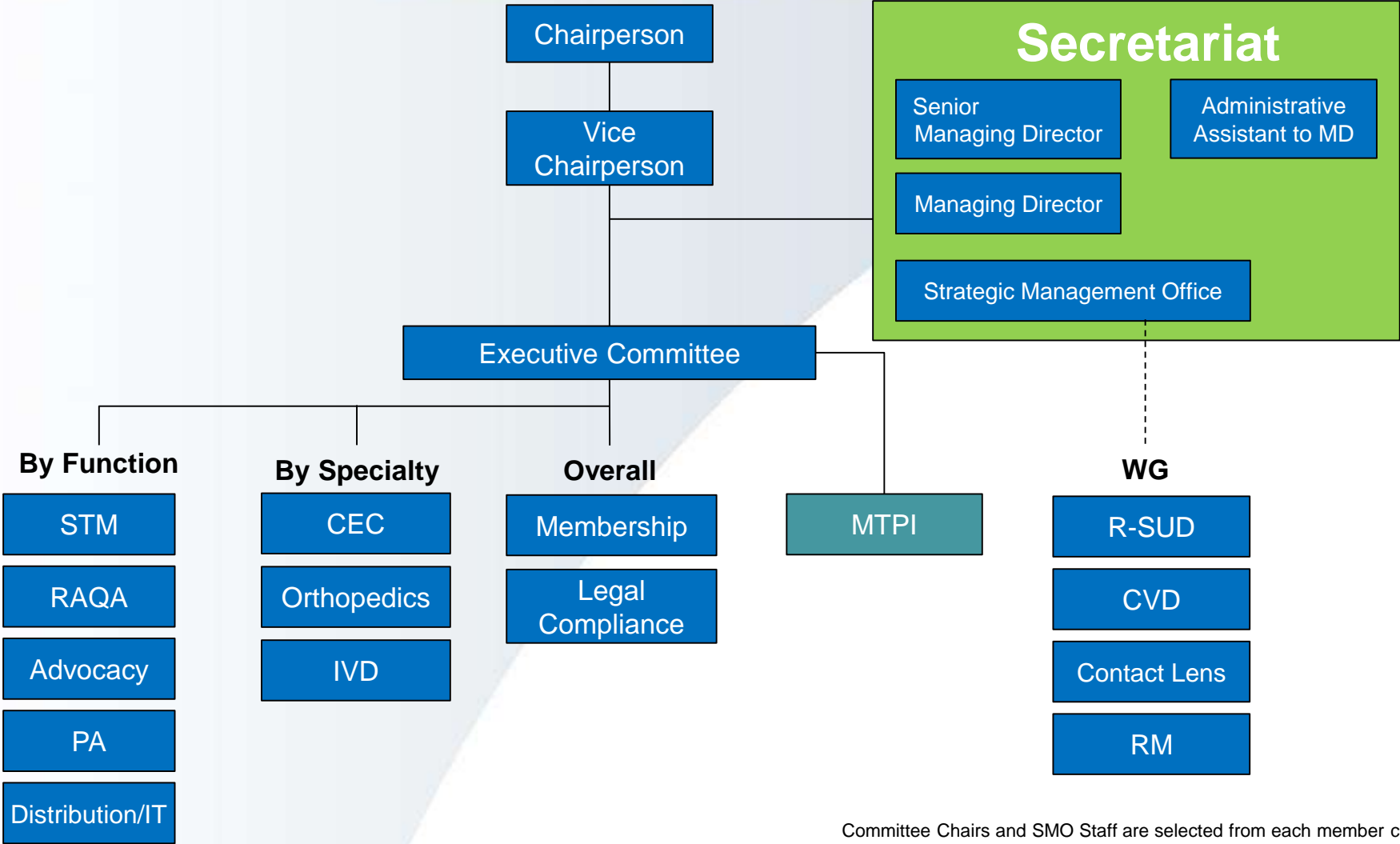
## Note

<sup>\*1</sup> Average of 54 companies

<sup>\*2</sup> Average of 55 companies

<sup>\*3</sup> Average of 46 companies

# Organization



Committee Chairs and SMO Staff are selected from each member companies



# Part 1

## Improve medical device distribution system by using RFID

Shigeyuki Masukawa  
Senior Managing Director  
AMDD

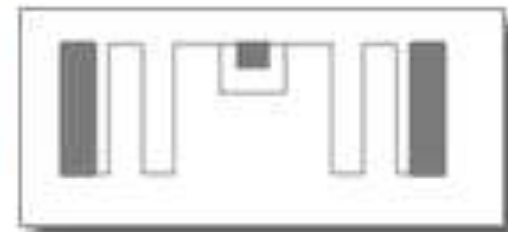
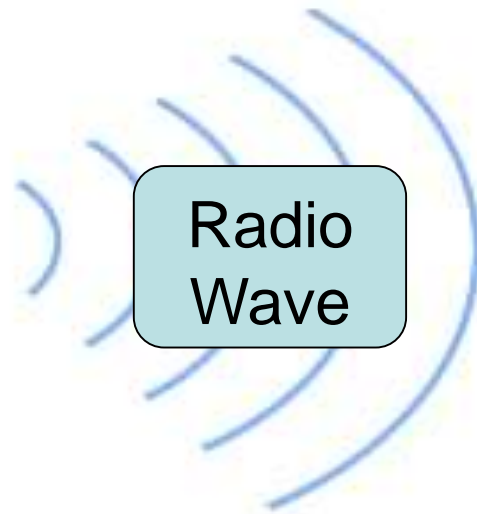
# What is RFID

RFID : Radio Frequency IDentification



Handy Terminal for RF Tag

RF Reader/ Writer

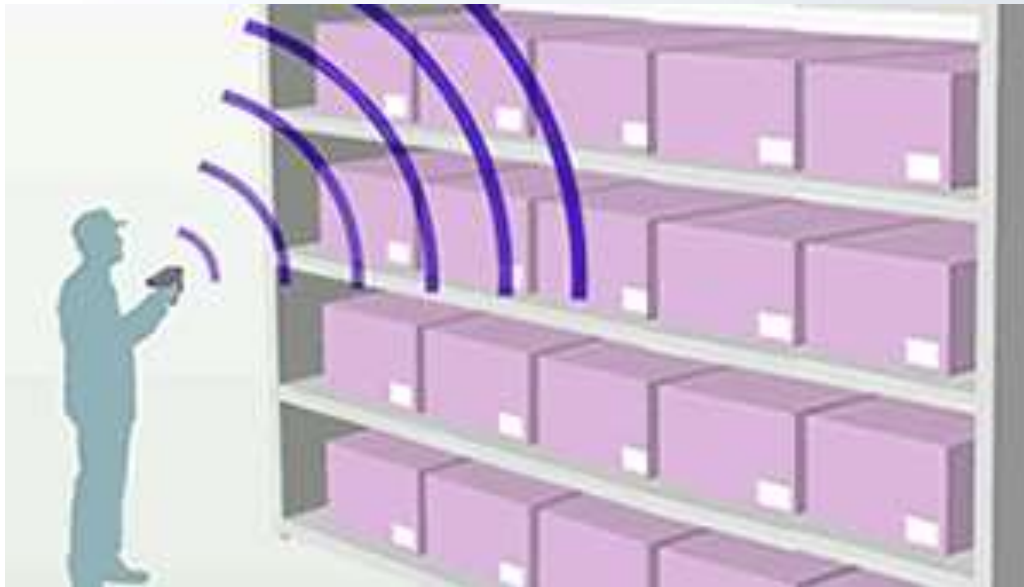


RFID Tag  
(IC Chip)



# Merit of RFID

- Reads and writes RF tag data in a **contactless manner** using radio waves.
- **Multiple tags** can be scanned **at once** with radio waves.
- Reading is possible even if **tags are far**, as long as the radio waves reach.



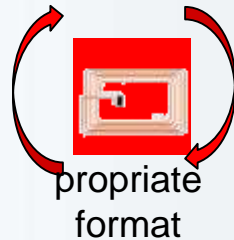
# Why RFID Data Format Standardization required?

- Increasing medical expenditure under highly aged society puts us as healthcare providers tremendous pressure to be more effective and efficient.
- Distribution/Supply chain is one of those areas where ministry/government is seriously looking for more opportunities to reduce cost
- Orthopedic manufacturers in Japan are leading the use of RFID.  
Hospitals, dealers, and Cardiovascular manufactures follow up and are beginning to show effects.
- However, with partial optimum for each hospital, dealers and manufacturers, it is difficult to create enough new value against pressure to be more effective/efficient

# Partial Optimum to Overall Optimum

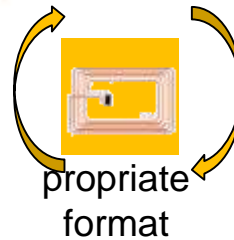
## Manufacture

Shipping/Return  
In House Inventory  
Cycle Count



## Dealer

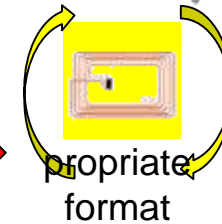
Field Inventory Visibility  
Actual Consumption  
Cycle Count



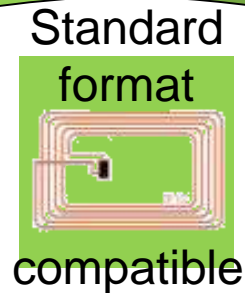
incompatible

## Hospital

Actual Consumption  
Capital Equipment



incompatible



# Why RFID Data Format Standardization required?

- Increasing medical expenditure under highly aged society puts us as healthcare providers tremendous pressure to be more effective and efficient.
- Distribution/Supply chain is one of those areas where ministry/government is seriously looking for more opportunities to reduce cost
- Orthopedic manufacturers in Japan are leading the use of RFID. Hospitals, dealers, and Cardiovascular manufactures follow up and are beginning to show effects.
- However, with partial optimum for each hospital, dealers and manufacturers, it is difficult to create enough new value against pressure to be more effective/efficient
- **As AMDD, it is important to facilitate activities to standardize RFID data format and promote utilizing RFID in medical device distribution**

# RFID-related activities in the Japanese Medical Device Industry

## 2017

- ❑ Four Orthopedic companies discussed about RFID Tag format and communication frequency standardization for source tagging (RFID Tag is attached at the time of product shipment from distribution center in Japan)

## 2018

- ❑ Cardiovascular company conducted proof of concept test about RFID/data platform with two hospitals and two dealers
- ❑ Start AMDD RFID working group to discuss about Data format standardization

## 2019

- ❑ Established AMDD recommendation of RFID Data format
- ❑ AMDD RFID working group plays a central role in starting research to realize a medical device data platform for **the SIP (Strategic Innovation Program)** managed by the Japan Cabinet Office
- ❑ Start Development of Prototype of Data Platform

## 2020

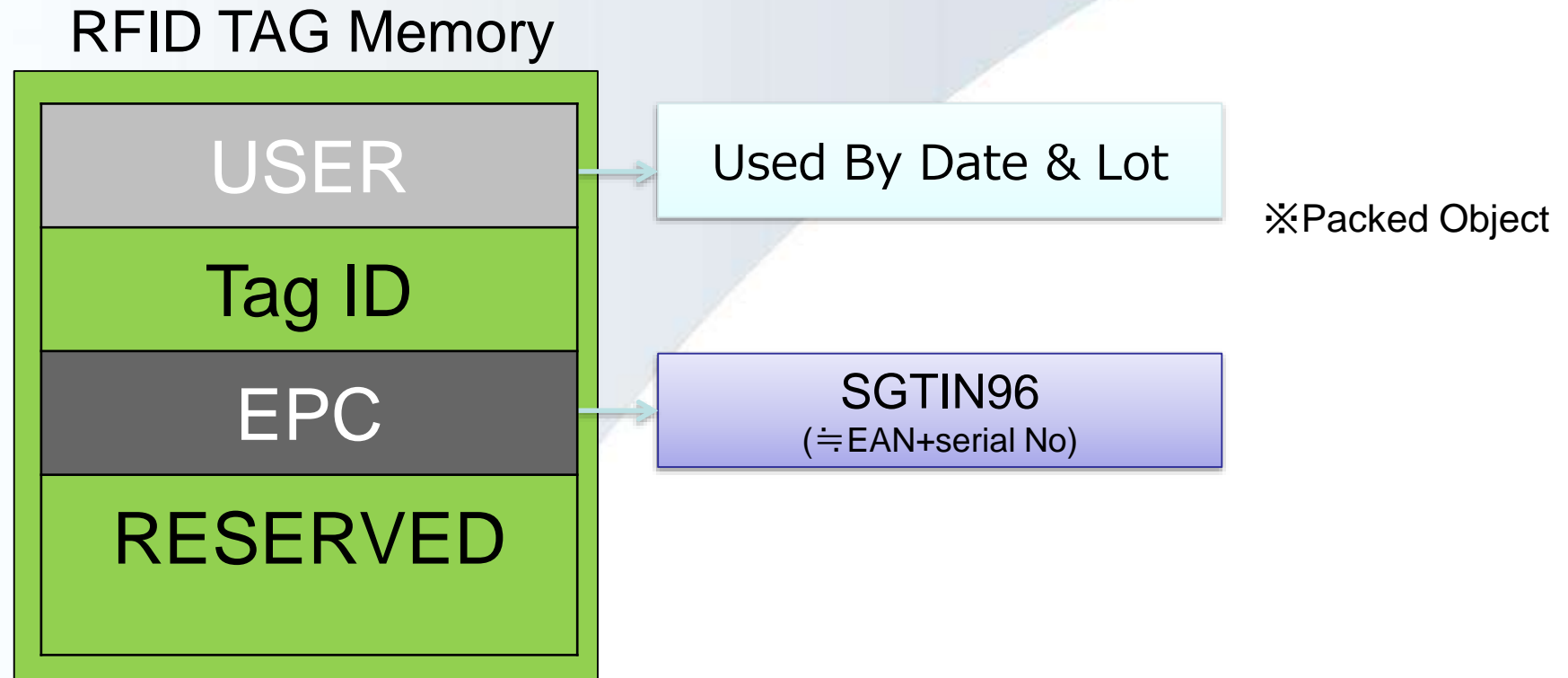
- ❑ Proof of Concept using Prototype

# AMDD Recommended RFID Data Format

- Follow GS1 RFID Data Format recommendation
  - **GS1 is an international organization** concerning the management and distribution standards of distribution
  - **The GS1-128 symbol** is a barcode in which data expressed in accordance with AI (GS1 application identifier) is expressed in code 128 as a one-dimensional symbol of **international standard (ISO / IEC 15417)**.
  - In 2008, the MHLW Economic Affairs Division issued a notice to the Medical Device Industry on the implementation of standard bar code display from the viewpoint of traceability building and medical accident prevention.  
With this notice, it was requested to display **GS1-128** symbols on medical device / materials, and implementation began.
  - Even after the Pharmaceutical and Medical Device Act was amended to require the affixing of symbols that ensure traceability, RFID with the same information as GS1-128 is considered useful.

# AMDD Recommended RFID Data Format

Identical to GS1-128 Symbol





# Identified Technical Issues

## GS1 recommended Encode

- In the EPC memory bank, the identification code is encoded in SGTIN format.
- USER Encode other attribute information in Packed Objects format to memory bank.
- Dedicated software is required for encoding and decoding in Packed Objects format.

## Existing Standard of IC Reader and IC Tag

- Batch reading is available only for EPC memory banks  
(USER memory banks are not subject to batch reading)
- A large memory size is required to store the GS1-128 data format, which increases the cost of the tag.  
It is necessary to wait for the development of inexpensive TAG with large memory or reduce the cost by joint purchasing etc.

## Intermediate Tagging

- There is no clear rule as to what GTIN company code to use when a dealer attaches a tag to a product that the manufacturer has not source-tagged.  
If the manufacturer's company code is used, there is a possibility that an RFID TAG with the same information will exist when the manufacturer starts source tagging in the future



# Part 2

# Medical Device Data Platform

# RFID in Orthopedic implant industry

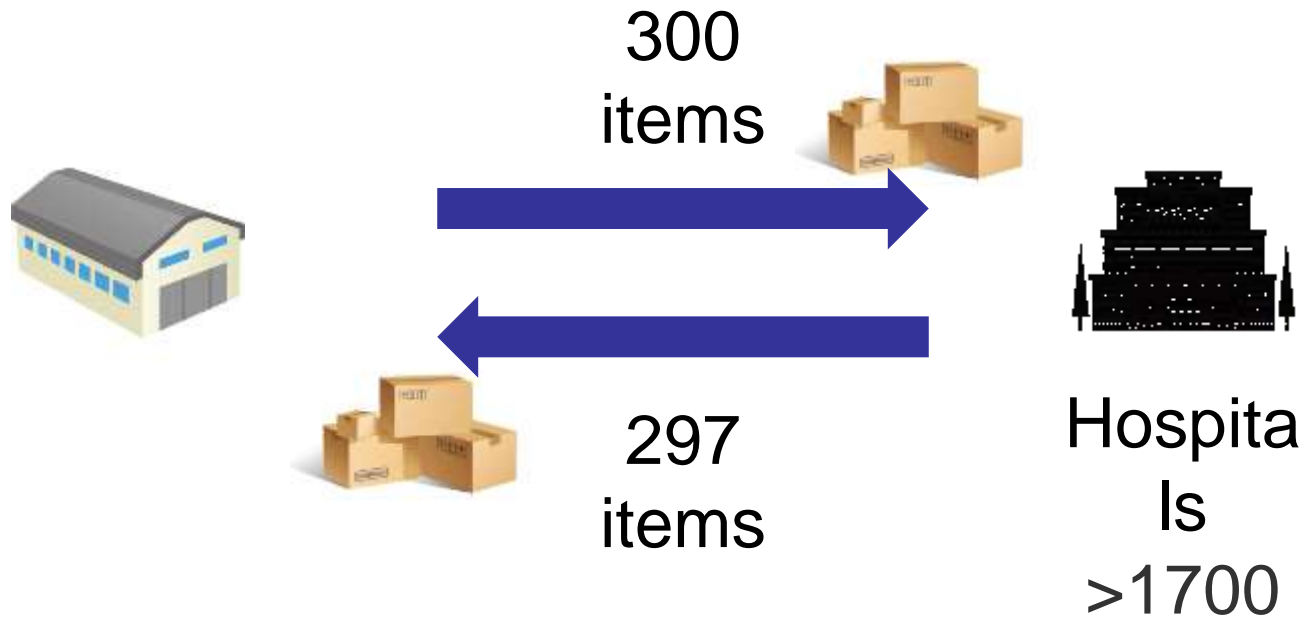
## 15 years of experience

- 2005      Australia
- 2006      Japan

- Productivity increase
  - Less time
  - Less mistake
  - Less people

# Orthopedics in Japan

## Lending Model



Background

# Shipping & Receiving



# GS1 Standards for RFID Tags

2018

Zimmer Biomet **HF**

J&J  
Stryker  
Medtronic  
Boston **UHF**



**Notification: AMDD Recommends GS1 Standards for RFID Tags**  
May 1, 2019

AMDD recommends its members to adopt GS1 standards for "encoding of information" of radio frequency identification (RFID) tags onto medical device and to use the UHF spectrum for "radio frequency for transmission."

RFID, non-contact information recognition and matching system, is gaining momentum across various industries, including the medical device industry. It is expected that utilization of RFID will streamline processes across medical device manufacturers, marketers, agents, dealers, as well as healthcare institutions. Also, use of RFID will secure patients access and higher safety.

Healthcare institutions, which use medical devices, and distributors/agents, who need to distinguish among various products from multiple producers, will benefit from an aligned "encoding of information" and "radio frequency for transmission." Therefore, AMDD set up a RFID Working Group in October 2018 to discuss and decide on the aligned "encoding of information" and "radio frequency for transmission" regarding RFID tags. Incorporating 23 AMDD member companies (see attachment 1), in March 2019, the Working Group concluded that "AMDD is to recommend GS1 standards and UHF radio waves." The conclusion was submitted to and approved by the Executive Committee during the same month.

**RFID tag format**

Encoding information	Merchandise information - SGTIN96 or SGTIN198 lot #, expiry date
Radio frequency for transmission	UHF

**AMDD-recommended format: GS1 approved format**

<https://amdd.jp/en/RFID/>

# Medical Device Industry

## Vision

Improve

- **Safety & Quality** by increasing Healthcare Traceability
- **Operational efficiency** of Healthcare System

Single Company → **Industry**

# Medical Devices Data Platform

## 1. Standardized RFID Format

Barcode (as UDI, GS1 128 Format)

## 2. Share Information

via e-mail

via Data Platform



# Medical Devices Data Platform

## Cross-ministerial Strategic Innovation Promotion Program in Japan

### SIP Smart Logistics Service

To overcome the logistics crisis

Building of Logistics/Commercial  
Distribution Data Platform to  
Connect Supply Chains



Managing Agency's Website : <https://www.pari.go.jp/sip/about/english.html>



# Medical Devices in SIP

Early 2019

## Hearing

Companies within supply chain

11 industries

50 companies

**Boston Scientific**

**Zimmer Biomet**

IT Companies

Venture companies

Companies outside of Japan: Platformers, China, Europe,

~ Aug. 2019

Research program for

## Business Model

Consumer goods

Drug store

Drugs

Appliance

## Medical Devices

Fishery products

Apparel

Regional logistics

Nov. 2019 ~ **Current**

## Prototype Development

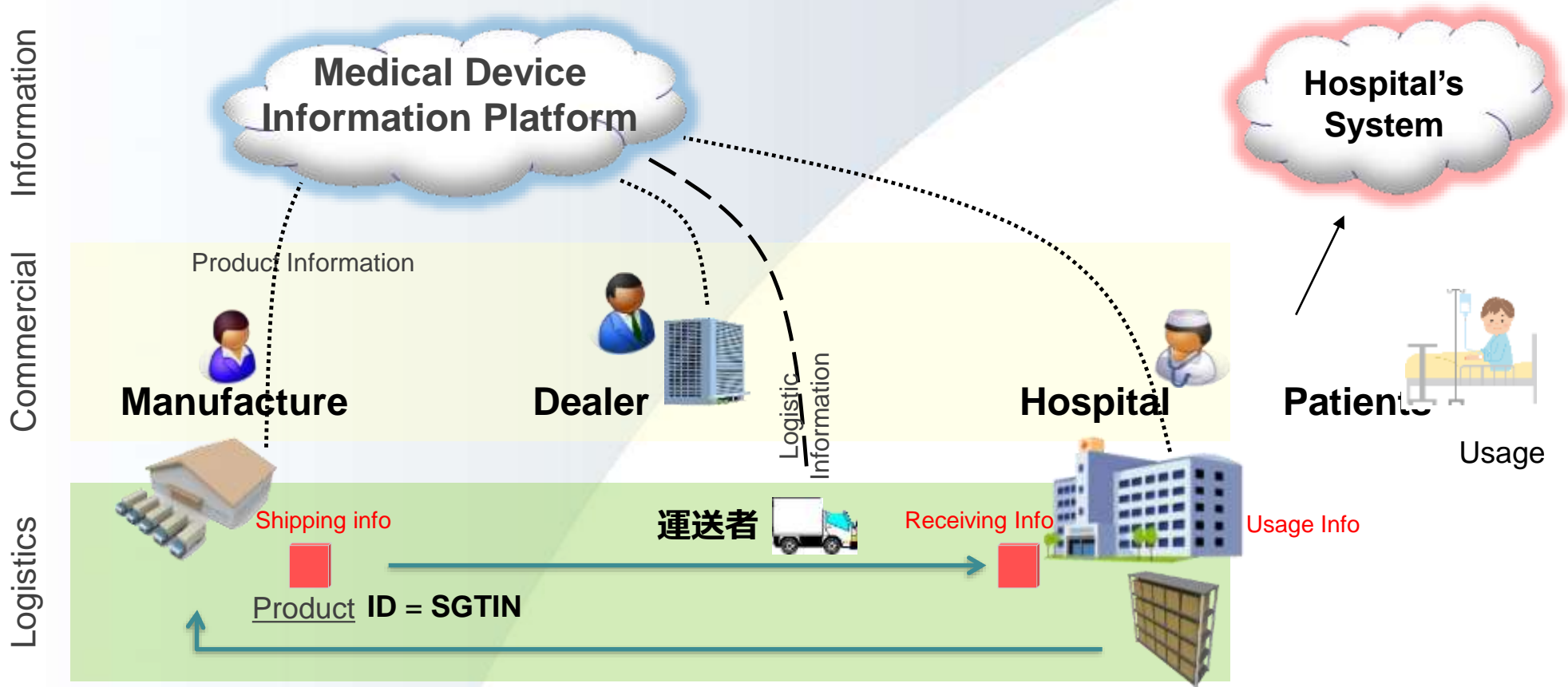
Consumer goods

Drug & Convenience store

Drugs & **Medical devices**

Regional logistics

# Medical Devices Data Platform

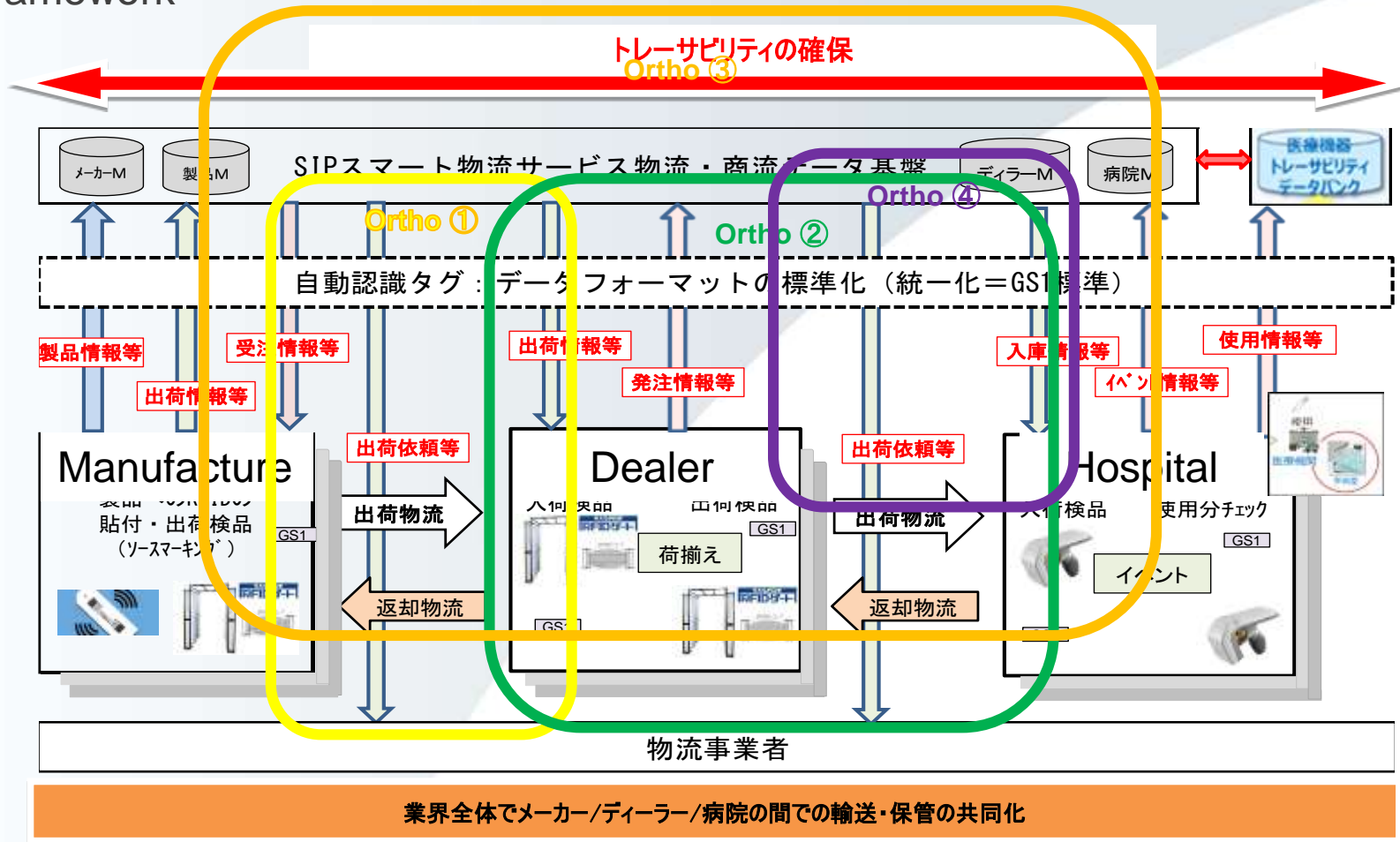


# Pilot Studies Conducted under SIP

No.	Category	Type	Scope
1	Ortho	Ortho ①	Dealer/Maker common warehouse model
2		Ortho ②	Direct shipment model by sharing shipping data
3		Ortho ③	Milk run collection model by representative dealer
4		Ortho ④	Joint shipment model by representative dealer
5	Cardio	Cardio ①	Inventory control model by representative dealer
6		Cardio ②	in market tagging and usage data collection model (storage)
7		Cardio ③	in market tagging and usage data collection (rapid)
8	Hospital	Regular	Regular medical device management
9		Ortho Implant	Orthopedic implants used at surgery room
10		Transability	Healthcare Traceability Bank

# Pilot Studies: Ortho

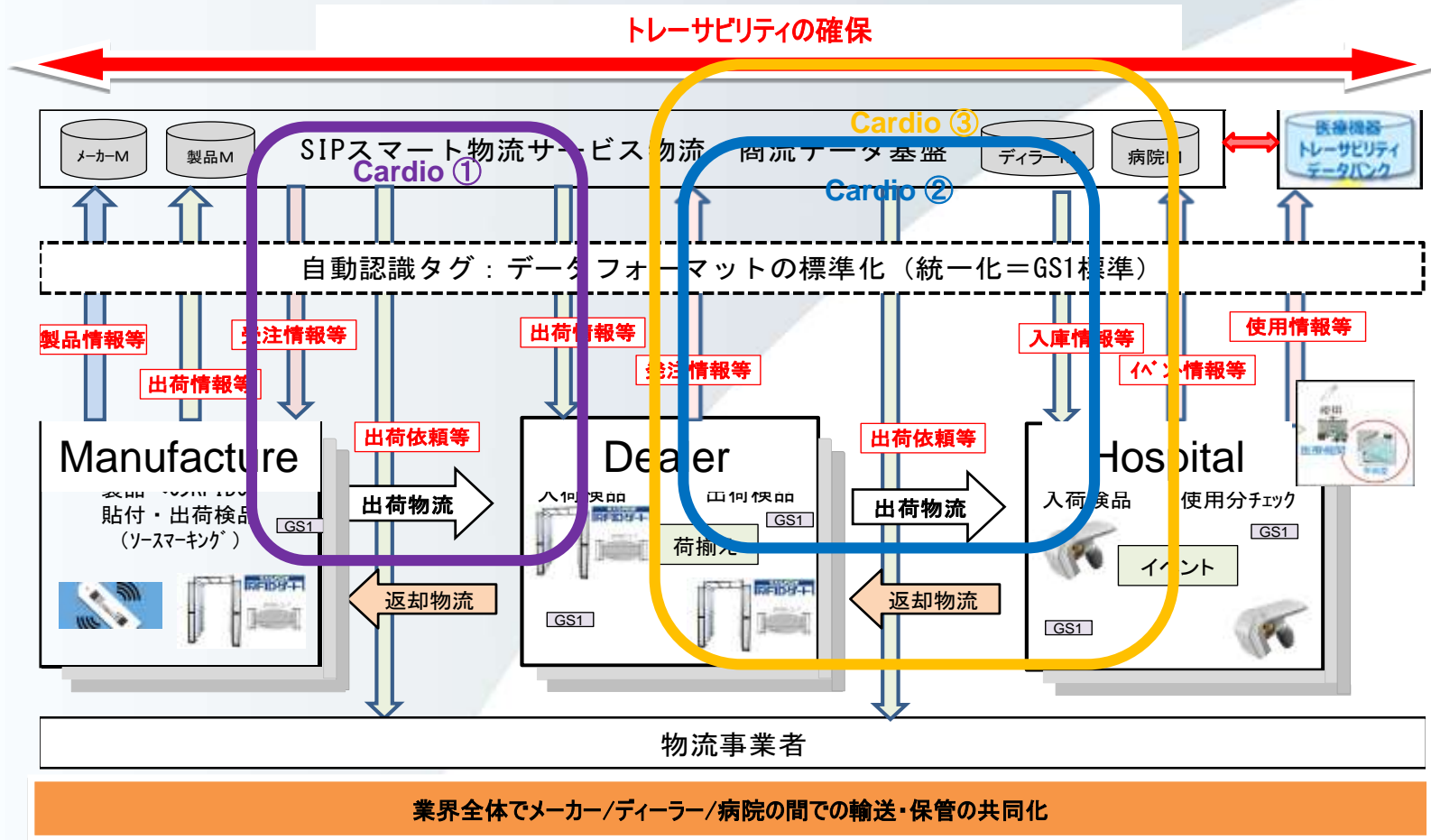
## Framework





# Pilot Studies: Cardio

## Framework







# @Hospitals



# Point of Care

- Products used captured into the system (Patient ID – Product ID)





# Prototype Data Platform Developed by SIP

## Trace Products by SGTIN

### 製品情報

製品番号(SGTIN)	明細番号	GTIN13	GTIN14	MK品番	製品名称	規格	使用期限	ロット番号	シリアル番号	製品オーナー名	EPC
(01)04547038248777(21)81002152164	GOCOL9164-005	4547038248777	04547038248777	11-5049-011-01	体外診断用機器	null	2024/06/30	64427856	null	MKNAME0029	null

### 履歴情報

Product ID (SGTIN)

Location

製品番号(SGTIN)	注文種別	注文番号	日付	イベント区分名	イベントオーナー名	出荷元	出荷先
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-22T15:00:00	ディーラー出荷指示	DLNAME10004	WHNAME10004	WHNAME20006
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-22T17:30:00	メーカー出荷検品	MKNAME0029	WHNAME00029-1	WHNAME10004
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-22T18:00:00	メーカー荷渡し	MKNAME0029	WHNAME00029-1	WHNAME10004
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-22T18:01:00	ディーラー入荷	DLNAME10004	WHNAME00029-1	WHNAME10004
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-22T18:15:00	ディーラー入荷検品	DLNAME10004	WHNAME00029-1	WHNAME10004
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-27T07:00:00	ディーラー出荷	DLNAME10004	WHNAME10004	WHNAME20006
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-27T07:01:00	配送荷受け	DELINAME30002	WHNAME10004	WHNAME20006
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-27T09:59:00	配送完了	DELINAME30002	WHNAME10004	WHNAME20006
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-27T10:00:00	病院預かり	HSPNAME20006	WHNAME10004	WHNAME20006
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-27T10:30:00	病院預かり検品	HSPNAME20006	WHNAME10004	WHNAME20006
(01)04547038248777(21)81002152164	管理ID	000437952	2020-07-29T10:30:00	病院返却指示	HSPNAME20006	WHNAME20006	WHNAME10004

# Medical Devices in SIP

Visualization of

- **Products**
- **Logistics**

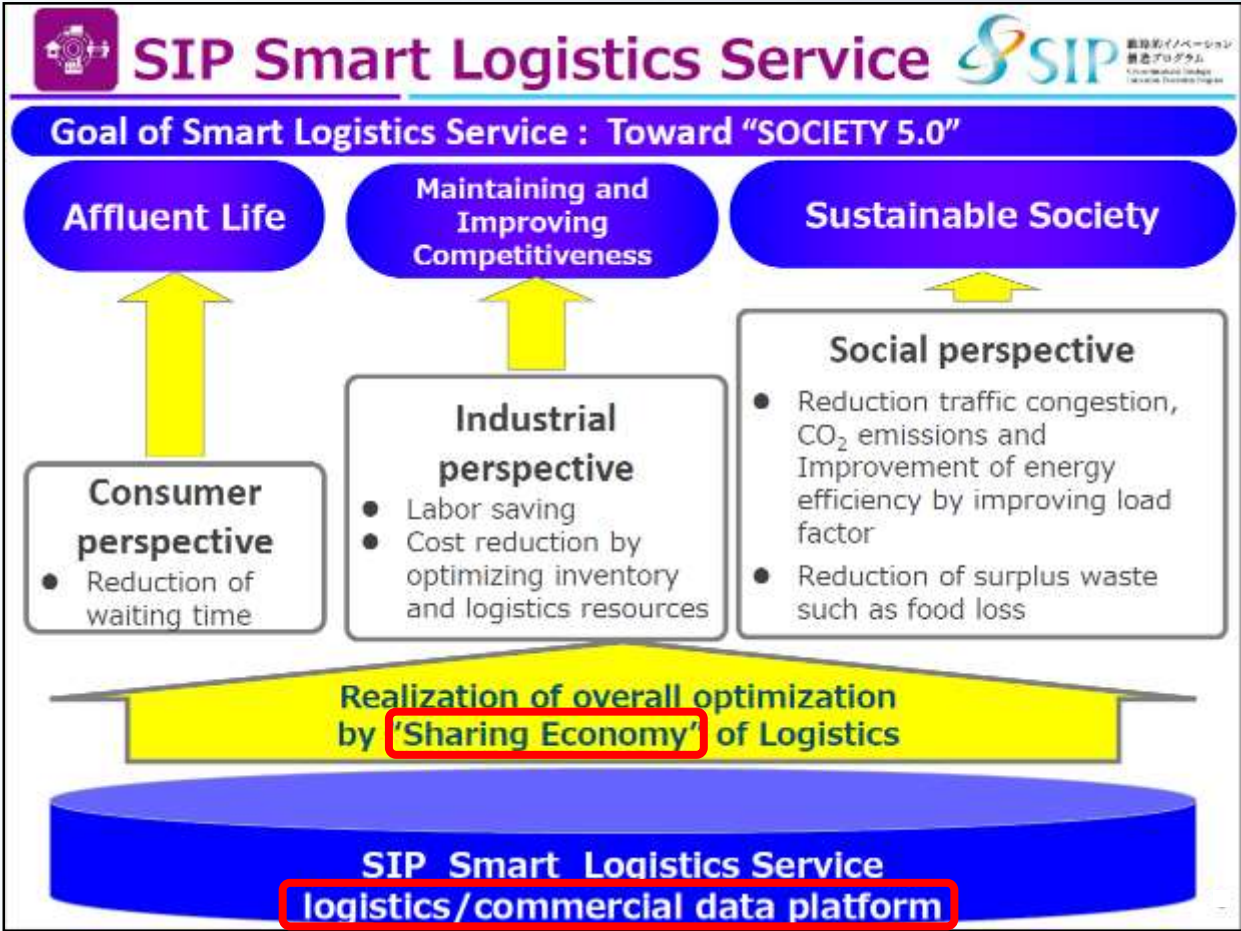
Can quickly identify

- **Product Detail**
- **Location**

by **sharing data via data platform**

→ Toward SIP's Goal (i.e. Realization of Society 5.0),

# SIP Smart Logistic Service



# Medical Devices in SIP

## Implication

Improvements in

- **Traceability** (safety/quality)

- Manufacturer → Hospital

- **Operational efficiency**

- Master Data
- Connectivity

**Product ID** ↔ **Patient ID**

**Single Company** → **Industry**