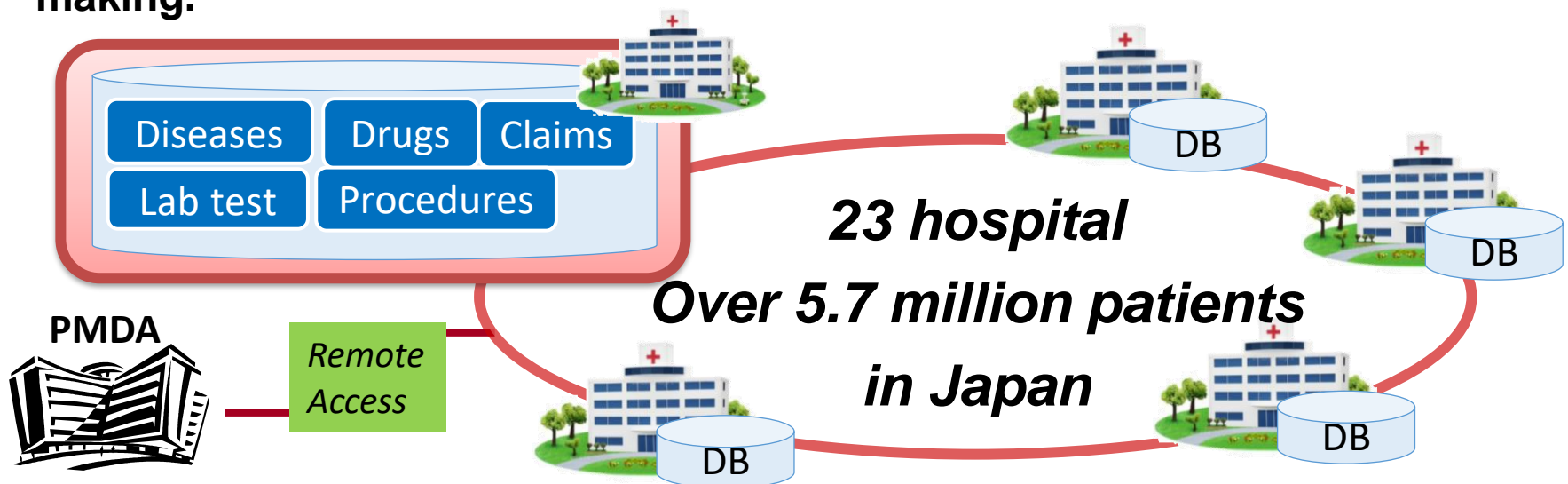# Operational Challenges of MID-NET ®
~ As a Reliable Medical Information Database ~

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Pharmaceuticals and Medical Devices Agency (PMDA)

MID-NET®（Medical Information Database NETwork）

- Officially Launched in April 2018 for a real-time assessment of drug safety.

- Uses common data model（can analyze collectively in PMDA onsite center）

- Includes 10 organizations(23 hospitals) , 5.7million patient's data.(as of December31,2021)

- Available diverse medical information data.
    - Claims data
    - Electronic medical record data (ordering, laboratory test results, etc.)

- Update data weekly.

- Ensuring data reliability for utilization as a basis of regulatory decision making.

Diseases | Drugs | Claims
Lab test | Procedures

PMDA

Remote Access

23 hospital
Over 5.7 million patients
in Japan

DB DB DB DB

2

Challenges in RWD Utilization in Japan

Just Collecting Data ≠ Analyzable database

Electronic Medical Records
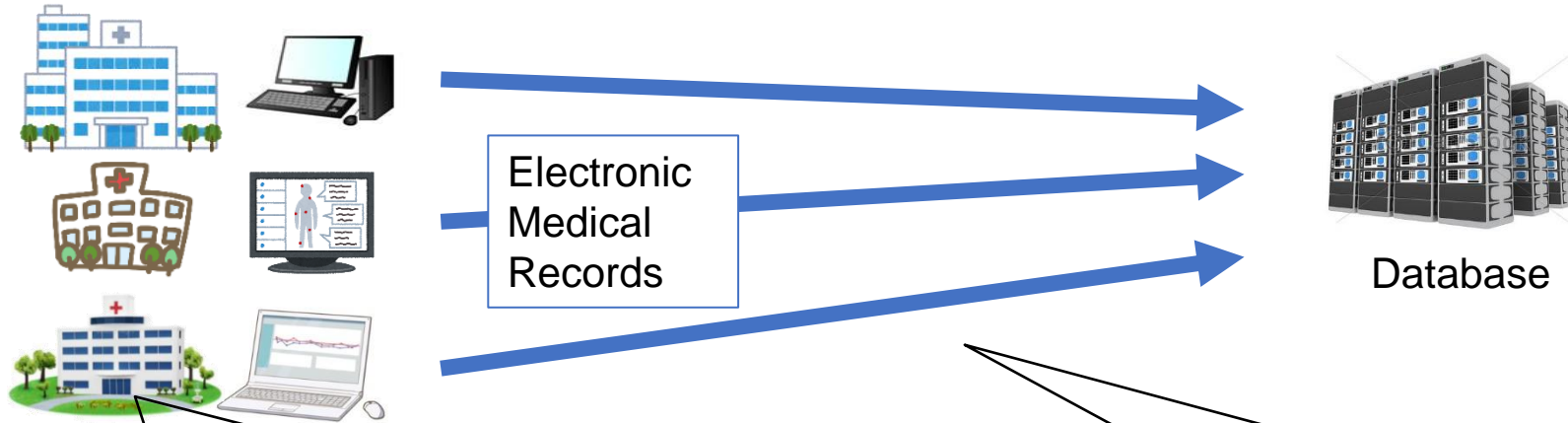
Database

Various types of EMRs among the hospitals

・Has different domestic rules for EMR operation and different EMR vendors

・Has different codes and units

Various types of Database

・various data format

・various methods for data standardization

・various systems

To create analyzable data from RWD in Japan, we need…

・Standardized Data （Unification of code and unit, etc.）

・Standardized Data Format

・Reliable System

・Reliable Data

→To manage and assure the quality of MID-NET®, we introduced procedures called **"MRDA"**

MID-NET® cleared these challenges

About MRDA

MID-NET® **R**eal-time **D**ata-quality **A**ssurance （**MRDA**）
→MID-NET management and operation are all based on MRDA

Knowledge acquired through the development of MID-NET

⬇

Consider possible risks

⬇

Create Quality Management Plan

⬇

*All the following steps require procedure manuals.

| **MID-NET**® **Management Operation** | ⬅ | **Internal inspection** | ⬅ | **Quality inspection** |

⬇

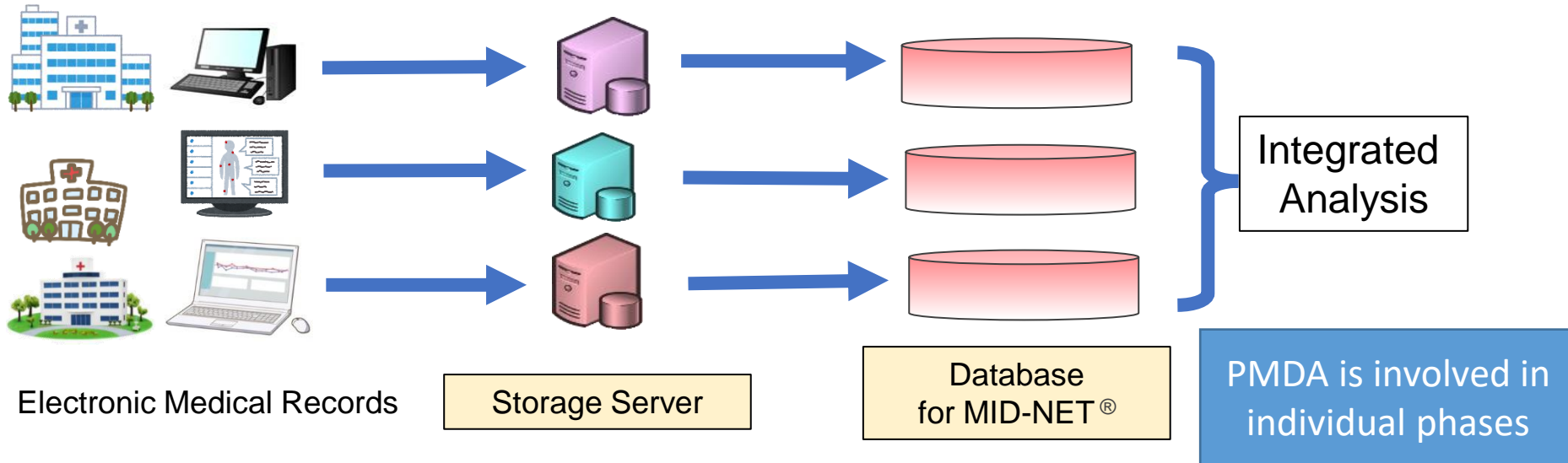**Detect incidents**   **Risk Assessment & Feedback （prevent for recurrence）**

⬇   ⬆

Identify the causes ➡ **Take measures** ➡ **Report**

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Functions of MID-NET® to utilize RWD

Electronic Medical Records | Storage Server | Database for MID-NET® | Integrated Analysis | PMDA is involved in individual phases

Data Migration（EMR→Storage Server）→**Standardized Data format**
・EMRs are sent in unified data format based on national regulations by using transmission system

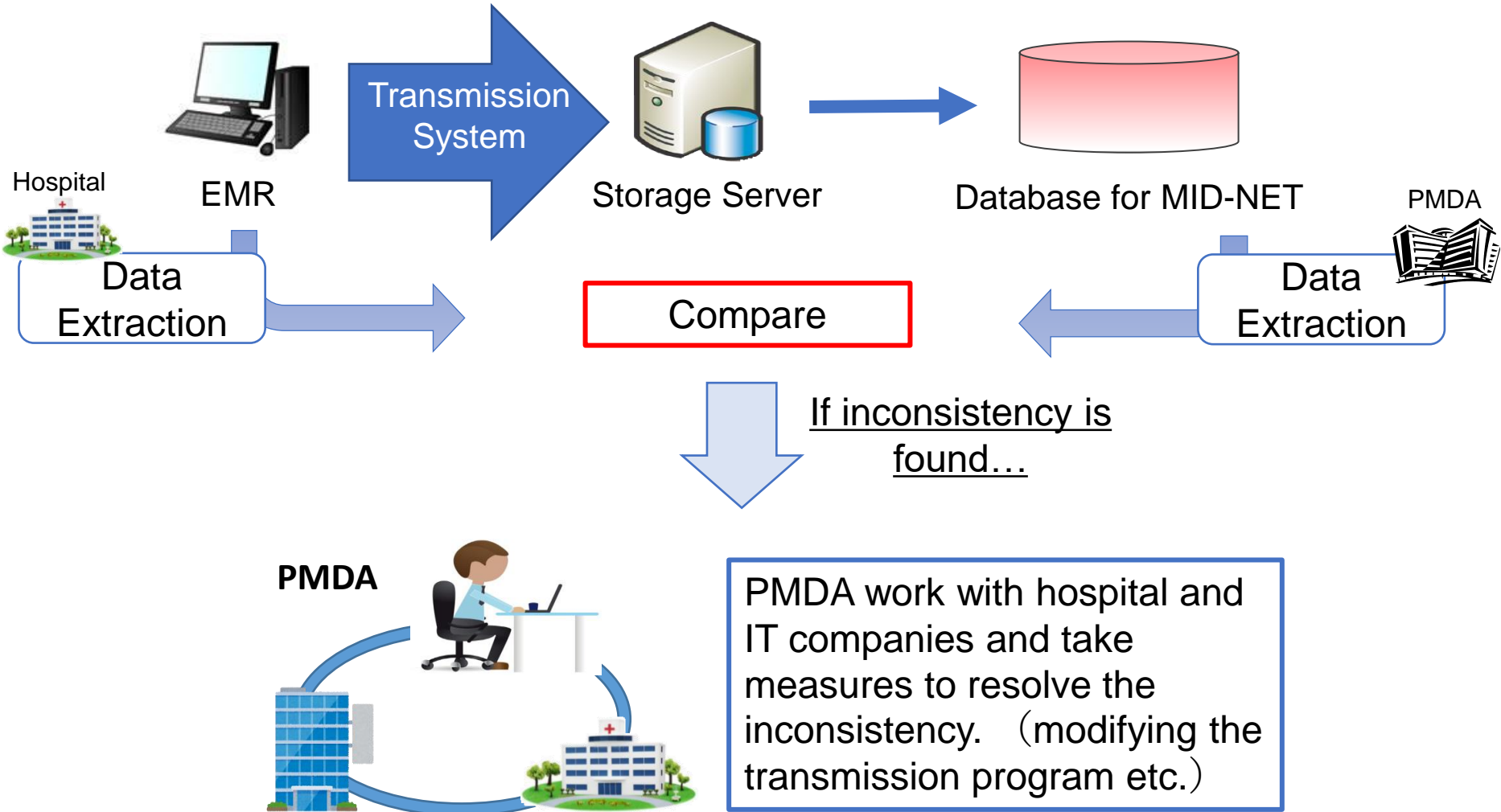Data Migration（Storage Server→MID-NET® database）→**Standardized Data**
・Convert Storage Server data to standard code using data coding table
・Reconvert imported data when data coding tables has been renewed

MID-NET® Quality Assurance　→**Reliable System, Reliable Data**
・ Having the procedure for assuring quality of MID-NET® system and data

Data Consistency Check

Check whether EMR has been correctly imported into the MID-NET database.

Transmission System

Hospital

EMR

Storage Server

Database for MID-NET

PMDA

Data Extraction

Compare

Data Extraction

If inconsistency is found…

PMDA

PMDA work with hospital and IT companies and take measures to resolve the inconsistency.（modifying the transmission program etc.）

Data Standardization of MID-NET®

Renewal of the data coding tables

Domestic codes and Standard codes are constantly added or changed

→Update of the data coding table is necessary for each hospital

→PMDA manages the processes in a unified way to select the most appropriate standard codes for keeping an original clinical implication

Storage Server   Data coding table   Database for MID-NET   Data coding table
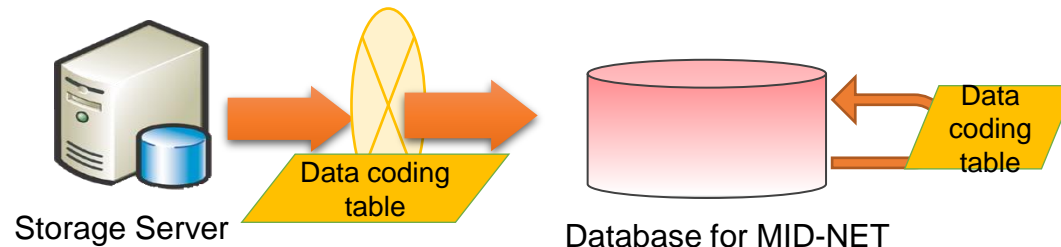
Flow of standard code confirmation

PMDA   Hospital

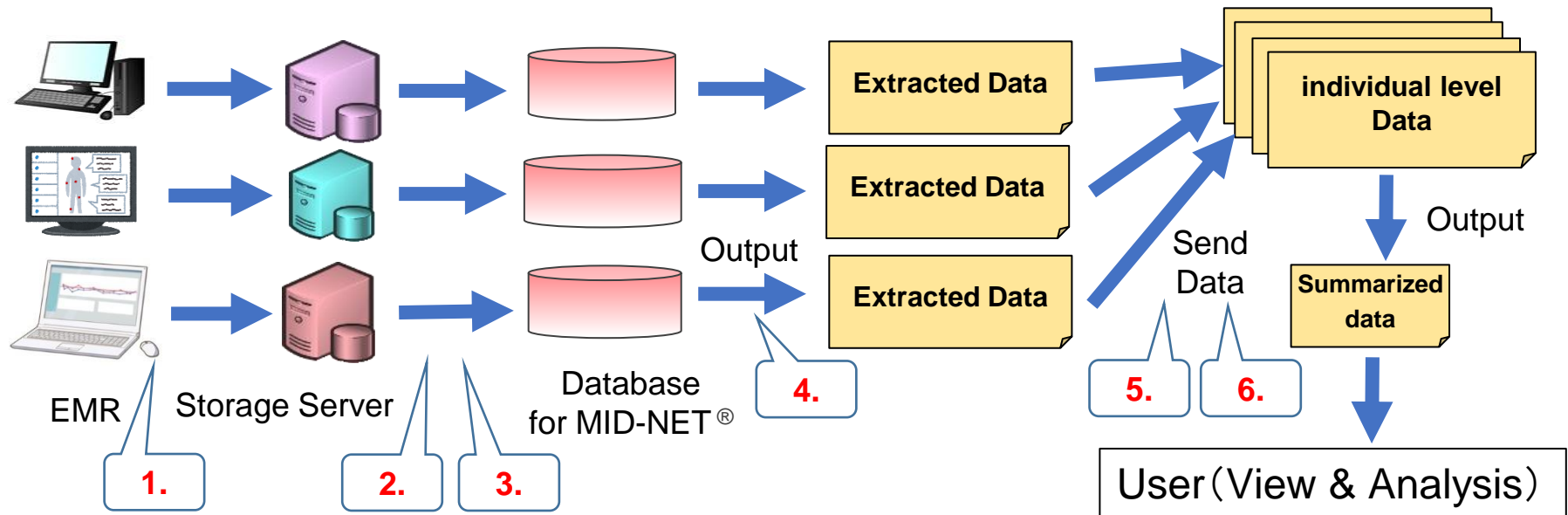| PMDA	Hospital
Consider possible standard code	Provide domestic code
Investigate whether the same code can be applied to all hospitals	Confirm the standard code whether it's appropriate for it's local code
Discuss until all hospitals agree on the standard code	

Quality Assurance in MID-NET®

PMDA check following points in order to
assure the reliability of data and system in MID-NET®

EMR Storage Server Database for MID-NET®

Extracted Data Extracted Data Extracted Data

Output

individual level Data

Output

Send Data

Summarized data

Output

User（View & Analysis）

1. **2.** **3.** **4.** **5.** **6.**

PMDA Technical Staff

1. Data monitoring (Daily)
Check of the reliability of the following systems
(When system introduced or refurbished)
2. Data migration system
3. Data standardizing system
4. Data extraction system
5. Data transfer system
6. Format conversion system

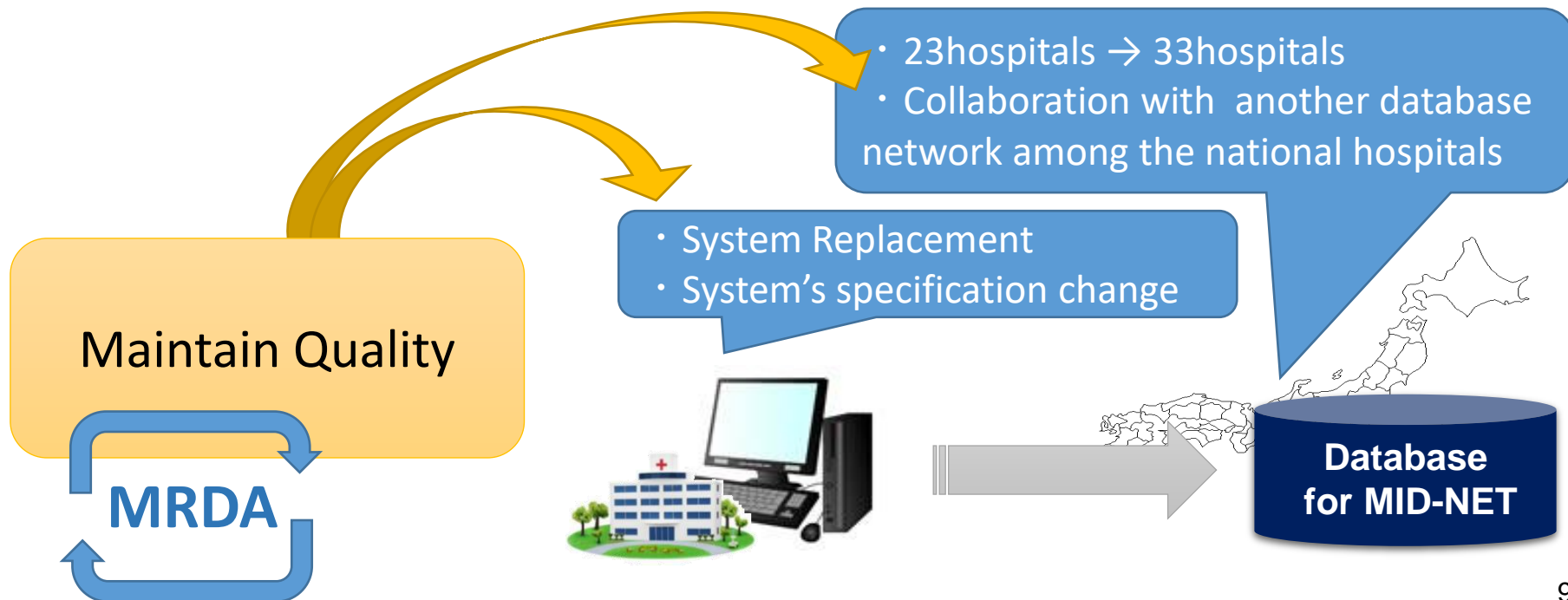# Challenges in Operation of MID-NET®

- Expansion of MID-NET®

MID-NET® are updating continuously to be a larger and convenient database.
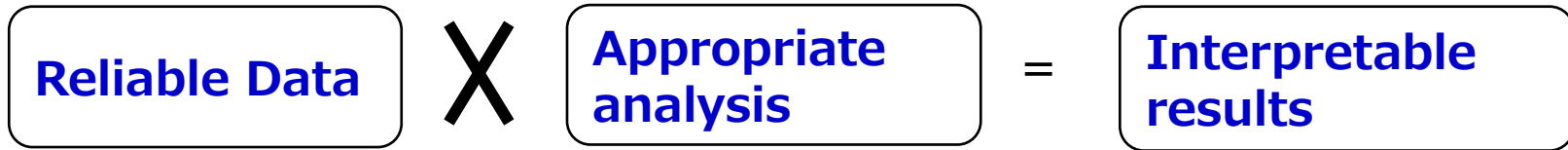➡MID-NET® must maintain its current quality no matter how larger and convenient the database turns into.

- Continuous Management of MID-NET®

In the real world situation, original data constantly change.
➡To maintain reliable & analyzable data despite fluctuations, continuous management of standardization and quality assurance is essential in MID-NET®

· 23hospitals → 33hospitals
· Collaboration with another database network among the national hospitals

· System Replacement
· System's specification change

Maintain Quality

MRDA

Database for MID-NET

Conclusion

Reliable Data X **Appropriate analysis** = **Interpretable results**

Appropriate Analysis

Data Quality Management
(Reliability & Standardization)

RWE(real world evidence)

$$RWD \neq RWE$$

RWD(real world data)

- Collection of RWD with high data quality and standardization is essential to obtain a useful RWE
- Continuous quality management is necessary to ensure high reliability data.

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■ **PMDA web site**

https://www.pmda.go.jp/english/index.html

Thank you for your attention ☺