

Adverse Event Reporting
**“The Traceability of Concerned devices
and reporting of Adverse Event”**

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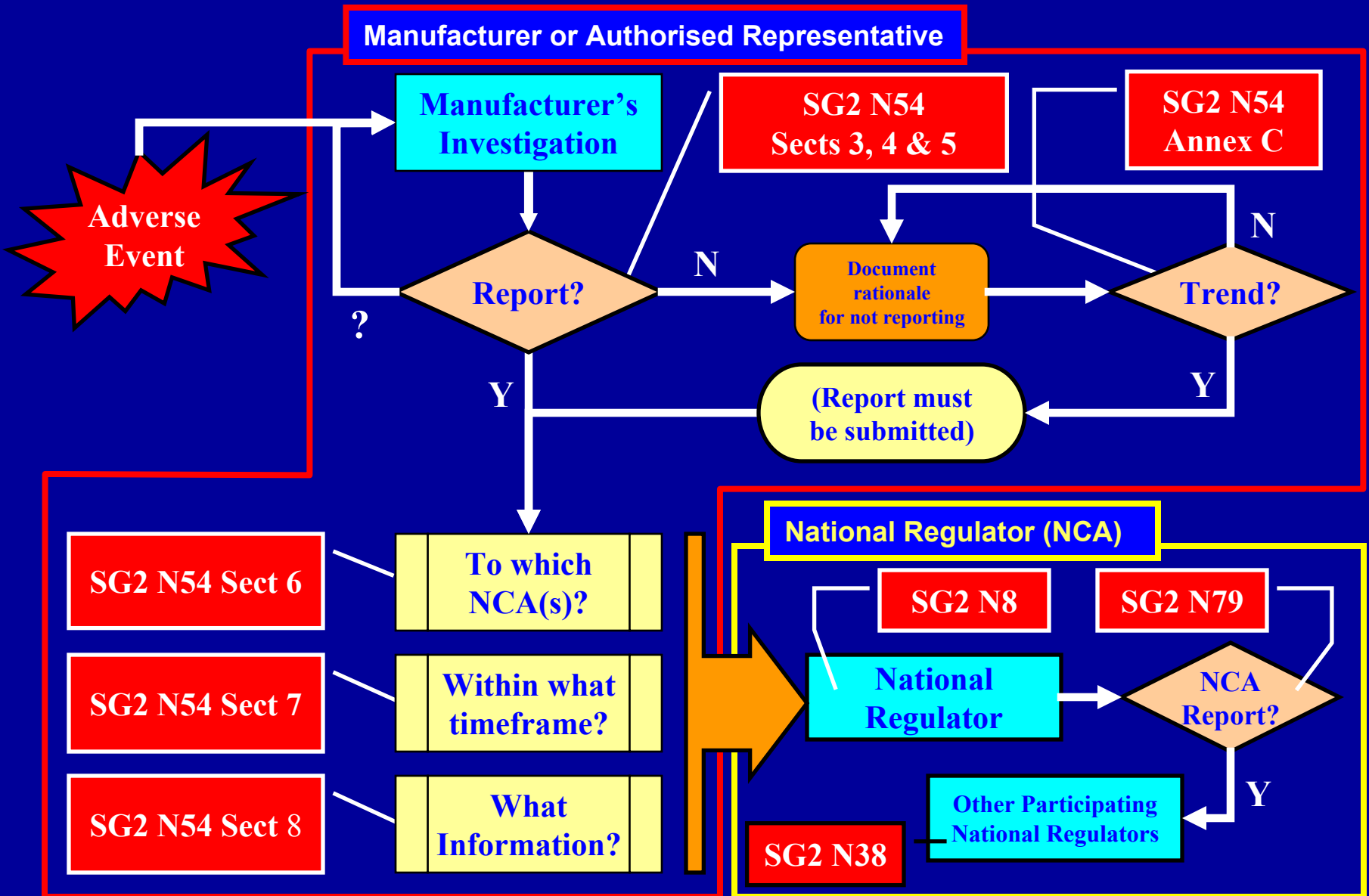
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1. Adverse Event Reporting

1.1 What is the contents of AE report

Map of SG2 Guidance on AE Reporting



What is the contents of AE report

GHTF N54 (Manufacturer report to NCA)

- 1. Administrative Information**
- 2. Clinical Event Information**
- 3. Healthcare Facility Information**
- 4. Device Information (Repeat this section for each device involved)**
- 5. Results of Manufacturer's Investigation**
- 6. Patient information (Repeat this section for each patient involved)**
- 7. Other Reporting Information (to be included in final reports only)**
- 8. Comments**
- 9. Manufacturer Disclaimer**

What is the contents of AE report

GHTF N54 (Manufacturer report to NCA)

1. Administrative Information

A. Report Control Number

B. Report Type (select one)

C. Date of this report

D. Date the adverse event occurred

E. Classification of event

F. Mfr. awareness date defined as the date that a manufacturer first learned about a reportable event

G. Expected date of next report

H. Person, or authorized rep, submitting this report

I. Identify to what other NCAs this report was *also* sent.

What is the contents of AE report

GHTF N54 (Manufacturer report to NCA)

2. Clinical Event Information

- A. Event description narrative
- B. Number of patients¹ involved
- C. Number of devices involved

3. Healthcare Facility Information

- A. Name
- B. Address
- C. Phone
- D. Fax
- E. Electronic mail address
- F. Contact Name at the Site of the Event

What is the contents of AE report

GHTF N54 (Manufacturer report to NCA)

4. Device Information

A. Device Information

B. Operator of device at the time of the event

C. Usage of Device

D. Generic Device Information

E. Device Disposition/Current Location

F. Device approval information

5. Results of Manufacturer's Investigation

A. Manufacturers Device Analysis Results

B. Remedial Action/Corrective Action/Preventive Action

What is the contents of AE report

GHTF N54 (Manufacturer report to NCA)

5. Patient information

A. Age of patient at time of event

B. Gender

C. Weight in Kilograms

D. List of Devices involved with each patient, see Section 9

E. Patient-focused Resolution of Events and Outcomes

7. Other Reporting Information

8. Comments

9. Manufacturer Disclaimer

1.2 Why do we need those AE information?

Why do we need those information?

NCA

- **What kind of Adverse Event happened**
- **What kind of Medical Device is related(GMDN)**
- **What kind of Patient is related**
- **What kind of medical procedure conducted**
- **How about the other Devices**
- **Specific User issue or not**
- **Do necessary to inform to other NCAs for prevention or for global consideration**
- **Dose this event require an immediate action to be taken**
- **The corrective action is suitable and applicable**
- **Do necessary to inform publicly**

Why do we need those information?

Manufacturer

- Why did this event occur?
- What is the root cause (Hazard)
- CAPA investigation
- What kind of action should prevent from the subsequent or repeatedly happened event
- Implementation of suitable and necessary corrective action
- Notice to customer
- The hazardous situation is already recognized or not.
- What is the Harm
- The Risk is same as the latest assessment

Why do we need those information?

User Side (Hospital or Medical Facilities)

- **Why did the event happened?**
- **How to prevent this hazardous situation ?**
- **How to prevent the “Hiyari Hat” even which is not a reportable even as AE. ?**
- **Take the preventive action by the Field Safety Notice**
- **Lesson learned from the other Hospital event**

2. Traceability

Traceability for User

When User required the tractability

- To keep record of usage or making Log book.
- To ensure safety measures are implemented according to the manufactures recommendations
- For inventory control

When the same medical devices is used in several Hospital wards. (e.g. Infusion pumps, Ventilators)

Traceability for Manufacturer

When Manufacturer requires the traceability

- **To locate the concerned Medical Device, including those in use.**
- **How was those used?**
- **What condition are those? (still in use or stop using)**
- **To identify whether any similar events happened**
- **To analyze the cause of the defect**
- **To decide what should be the counter measures**
- **To ensure the Safety Corrective Action have been implemented in all concerned Medical Devices**

Traceability for NCA

When dose the NCA need to trace the Medical device?

- To ensure the Safety corrective action which relevant Manufacture took
- To analyze the Event and make public the preventive measures adopted by the manufacturer,when appropriate.

Issue of Traceability

Without notice to Original Manufacture or Distributor

- Donate(domestic or to overseas)**
- Export**
- refurbish and sales**
- reprocess and use or sales**
- Counterfeit product**

Issue

Distributor could not trace the device

**Manufacturer could not trace the device and therefore
Safety related corrective action could not be
implemented**

3. Information related Post market safety purpose

Traceability and Information

AE Information Items of the List

The **outcome, number of cases** and **corrective measures** taken are listed for each malfunction and health hazard.
(JPN Case)

In future model name and manufacturer name.

“Hiyari Hat “ Event Report

The details information about the incident , and **measures** taken in the User's facility (JPN Case)

User could study and review by themselves from those hazardous situation for prevention from future event or receiving safety notice from the said manufacturer.

Traceability and Information

GHTF SG2N57

Content of Field

Safety Notices

Notice to the User about FSCA action

FSCA means

- Return of a medical device to the manufacturer or its representative**
- Device modification**
- Device exchange**
- Device destruction advice given by manufacturer regarding the use of the device**

Traceability and Information

GHTF SG2N57 Content of Field Safety Notices

Content:

- A clear title like such as “Urgent Safety Notice” on the notice itself, the envelope if sent by mail and the subject line if sent by email or fax
- The intended Audience: clear statement about the intended recipient of the notice.
- Concise description of subject device, model/batch/serial number
- A factual statement explaining the reasons for the FSCA, including description of the problem

Traceability and Information

GHTF SG2N57

Content of Field

Safety Notices

- A clear description of the **hazards** associated with the specific failure of the device and, where appropriate, the likelihood of occurrence, being mindful of the intended audience
- The **recommended action(s) to be taken by the recipient** of the Field Safety Notice including any action(s) recommended for people that have previously used or been treated by affected devices
- Where appropriate, include time frames by which the action(s) should be taken by the manufacturer and user.
- **Designated contact point for the recipient of the Field Safety Notice** to use to obtain further information.

Traceability and Information

Information about How to use the medical devices

- User need to have access to the relevant information when they lost the IFU
- User required to ensure the Medical Devices maintenance
- User to verify implementation of the Field Safety Corrective Action of concerned Medical Device

Other Safety related information

- AE information
- “Hiyari Hat” situation and prevention contents
- Recall information from NCA
- Manufacturer FSCA information
- Other safety related information issued from NCA
- Other safety related information issued from Academia

4. What do we need for Database(DB) from the PMS view

Database for PMS

From the various purpose of PMS and various needs from stake holders following items may required for each DB

Manufacture

- **Model Name**
- **Record of sales to Distributor/Exporter/(End user)**
- **Each S/N or Lot number or butch number**
- **Incase of software version number**
- **FSCA**
- **Complaints**

(Except Design and or manufacturing process issue)

Database for PMS

User

- **Model Name**
- **Manufacture Name**
- **Purchase Information (From who and when)**
- **Information about Usage / sterilization**
- **Information Discarded (when and how)**
- **Each S/N or Lot number or butch number**
- **Instruction for use (inhibition etc)**
- **Maintenance Information and its record**
- **Complaints / Hiyari Hat (Contents ,when)**
- **AE**
- **FSCA information**

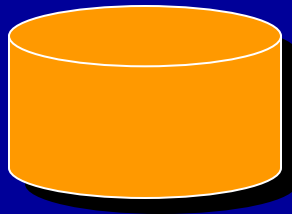
Database for PMS

Distributor

- **Model Name**
- **Manufacture Name**
- **Purchase Information(from who and when)**
- **Sales Information(when and to who)**
- **Each S/N or Lot number or butch number**
- **Customer claim Information**
- **FSCA Information and its record (when received and when done)**

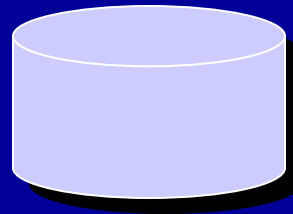
Database for PMS

Manufacturer



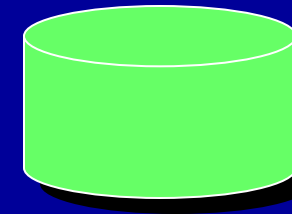
- **Model Name**
- GMDN
- **S/N, Lot NBR**
- Record of sales
- AE report
- **FSCA information**
- Complaints

Distributor



- **Model Name**
- GMDN
- Manufacture Name
- Record of Purchase
- **S/N ,LOT Number**
- Record of Sales
- Record of claims
- **FSCA information**

User facility

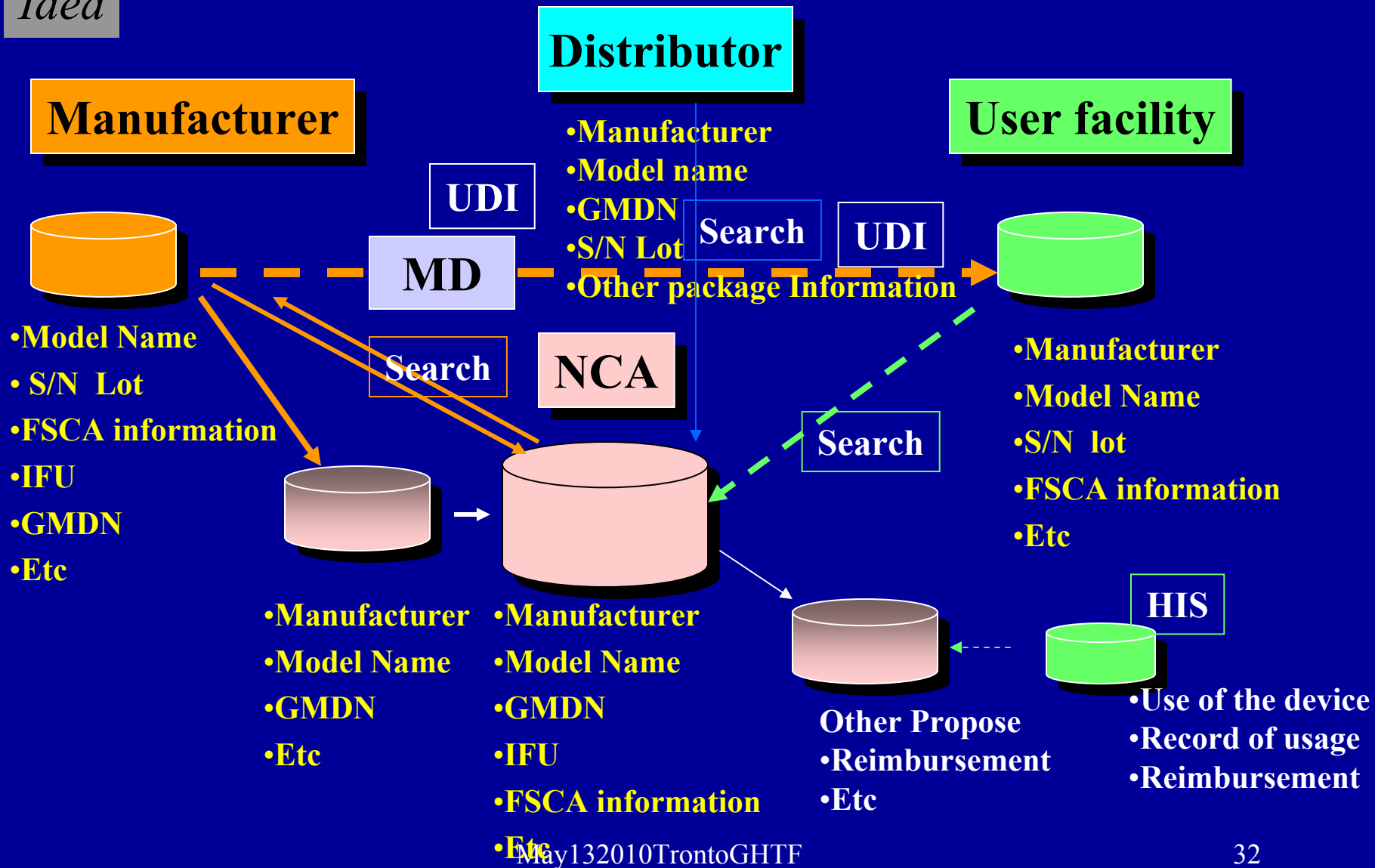


- **Model Name**
- Manufacture Name
- Record of Purchase
- **S/N ,LOT Number**
- Record of discarded
- IFU
- Record of maintenance
- Record of claims
- Record of AE or Hiyari hat
- **FSCA information**

5. What relation with UDI system

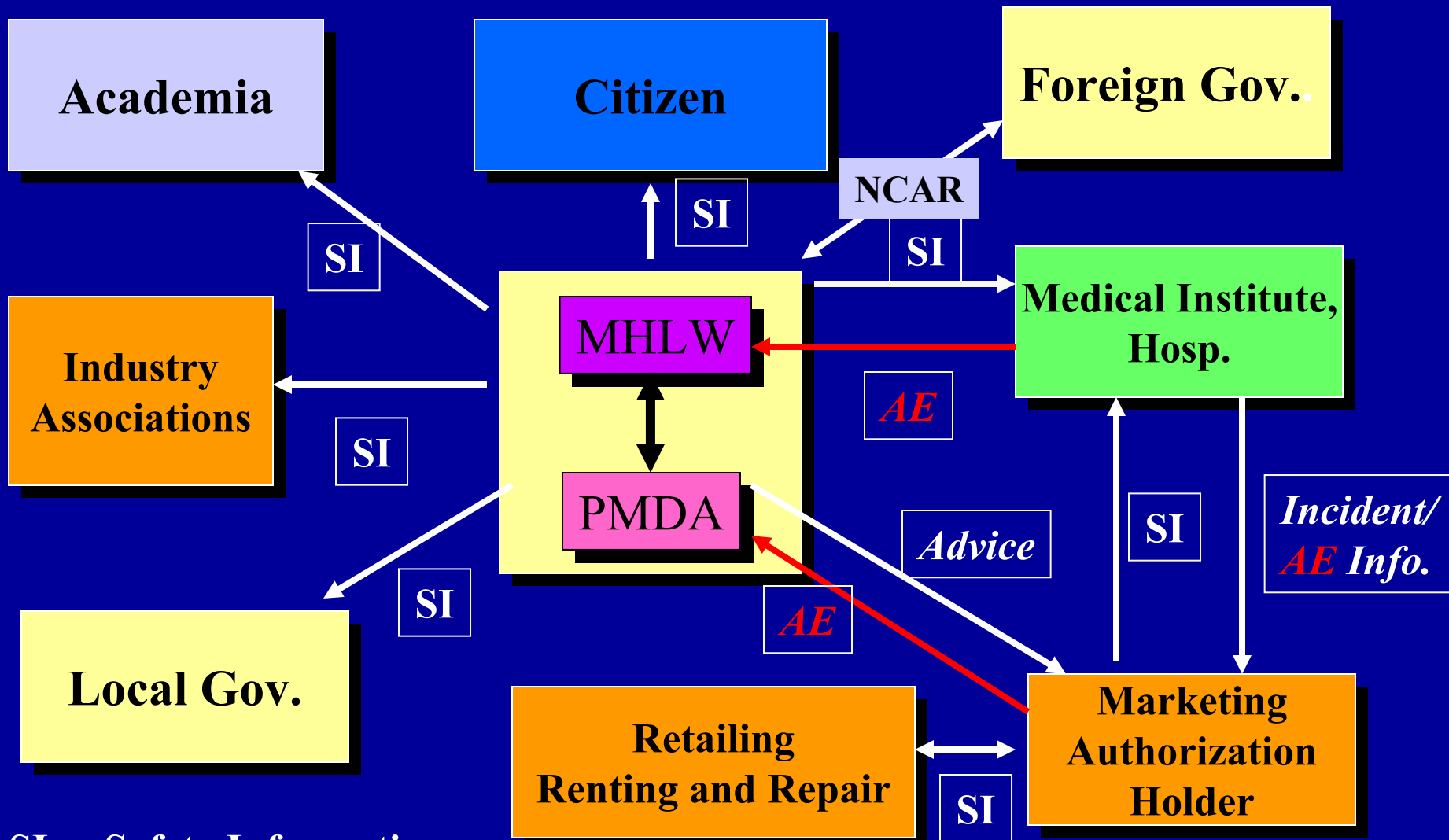
Relation with concept of UDI system

Idea



6. Japan Current Process

Safety Information System in Japan

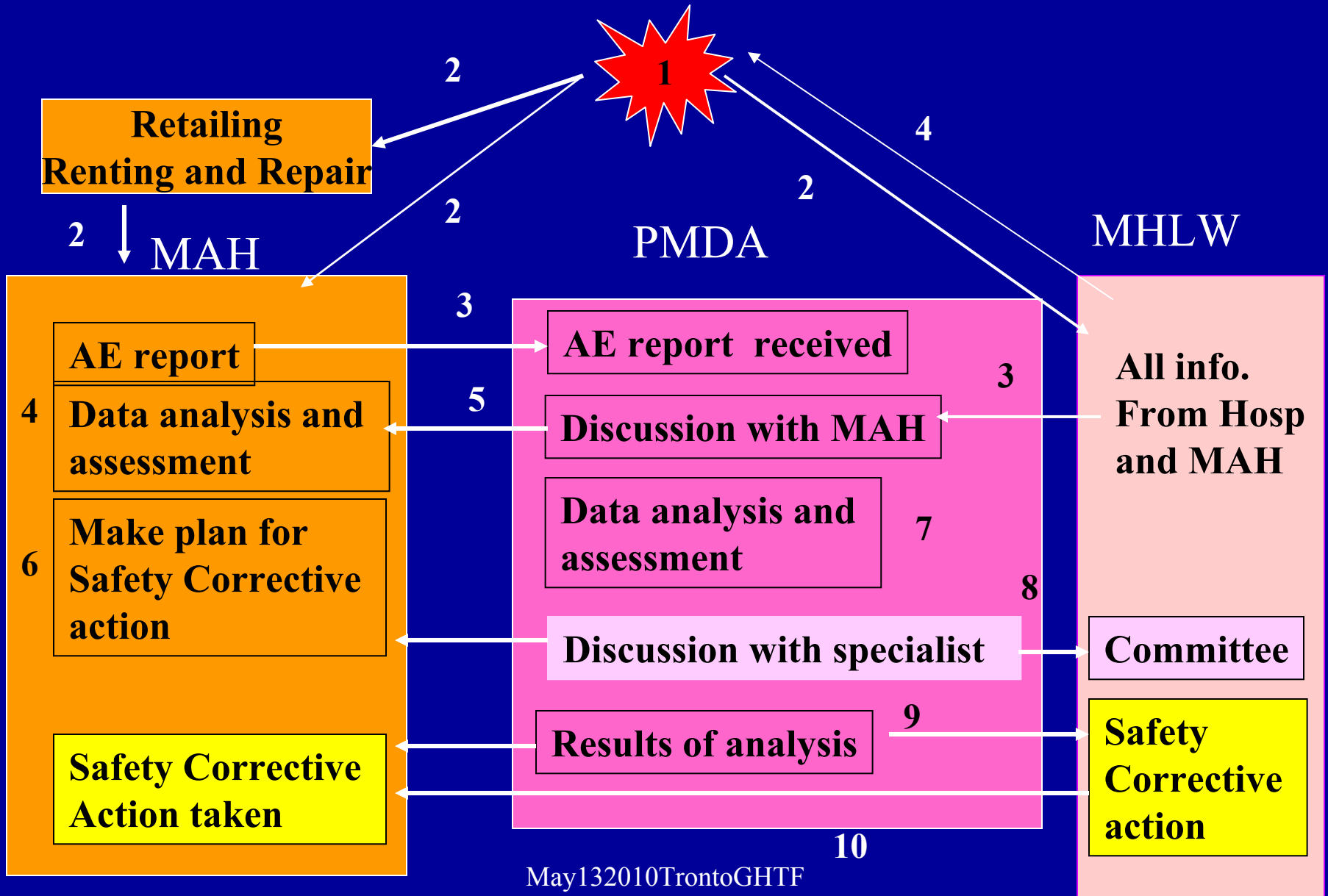


SI : Safety Information

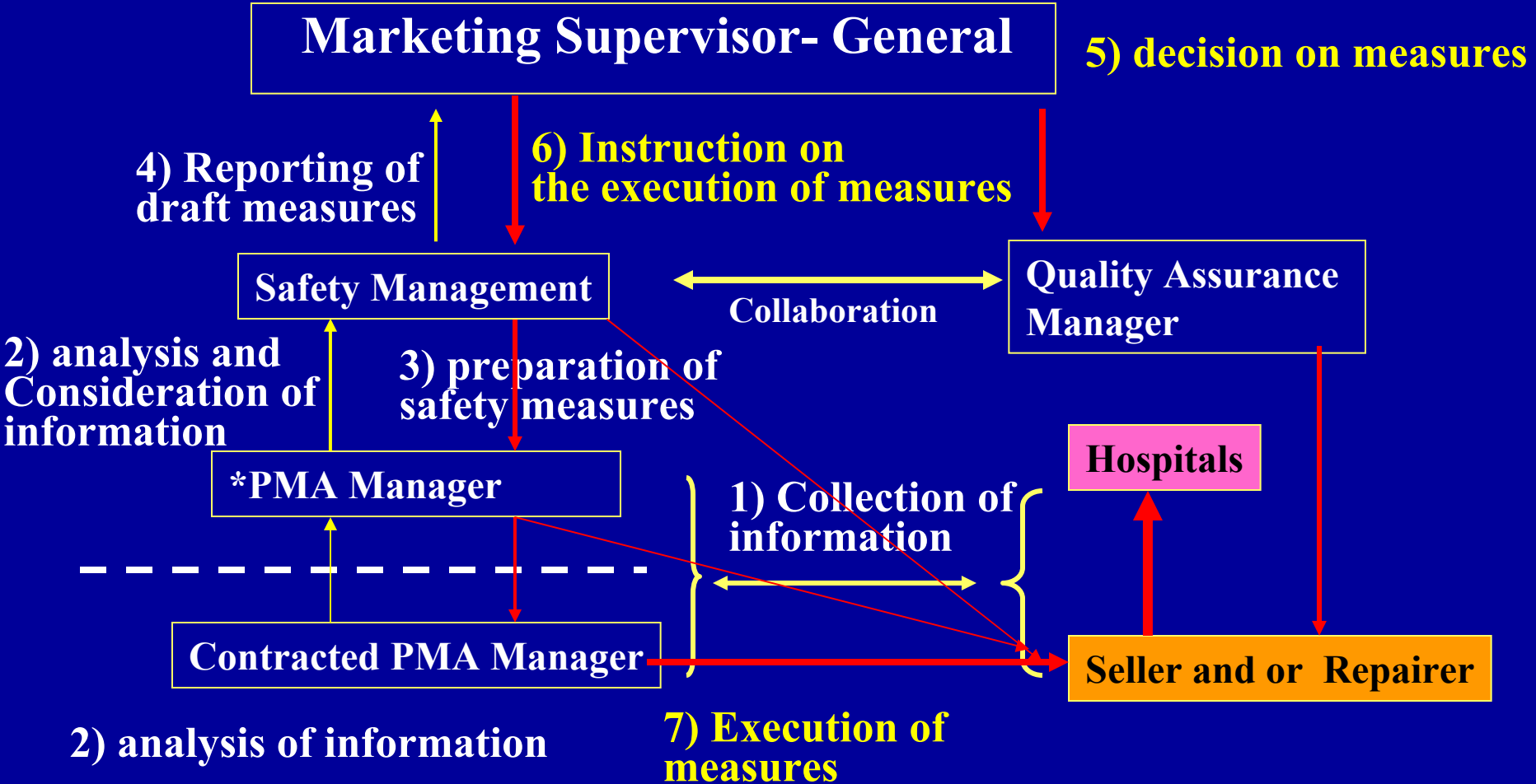
AE: Adverse Event Reporting

May132010TrontoGHTF

AE Reporting System in Japan



GVP Duties



***PMA Manager: Acting manager for Safety Manager**

Tenmp Bunsyo

The contents of “Tenmp Bunsyo”

- **One of the labeling material which contains mainly for safety information for user, including general information about the relevant Medical Devices.**
- **This “Tenmp Bunsyo” must be attached to the device. There is a limitation of pages so an IFU is provided for most Medical Devices.**
- **Starting to introduce this information electronically on the PMDA Web site as well as other FSCA, notice from NCA.**

Tenmp Bunsyo

Contents of “Tenmp Bunsyo”

- **Manufacturer Name and its information**
- **Sales Name Catalogue Number etc.**
- **JMDN(GMDN) and other related information required for approval such as risk class**
- **Intended of use**
- **Safety instruction for use (Inhibition, warning)**
- **Information about AE (Previously happened)**
- **Product Life**

**Thank you very much
for your kind attention**