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Perspective of Post-market Surveillance under MDR

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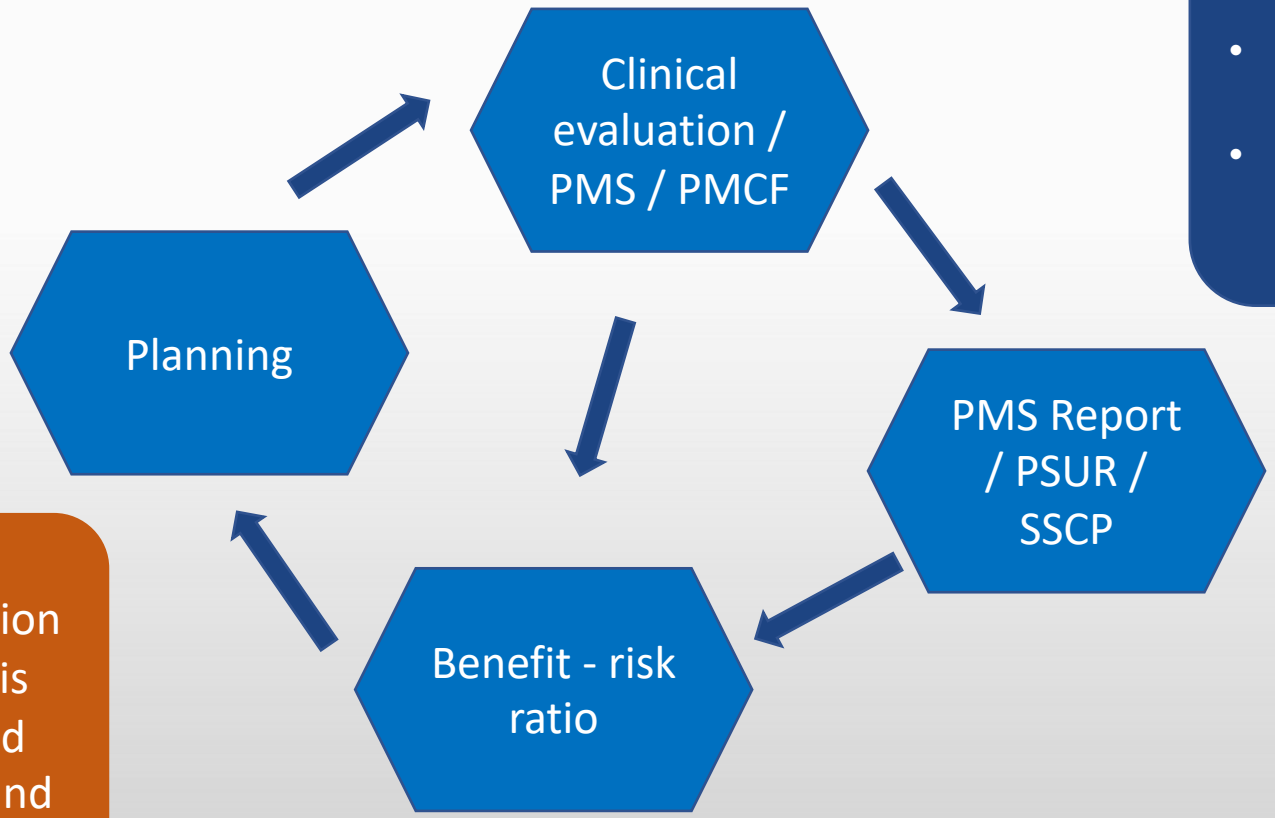
Safety and Performance data

- Literature review
- Pre-clinical testing
- Pre-market clinical study
- Post-market clinical study
- Non-clinical / clinical PMS



- Data collection
- Analysis method
- Links and triggers

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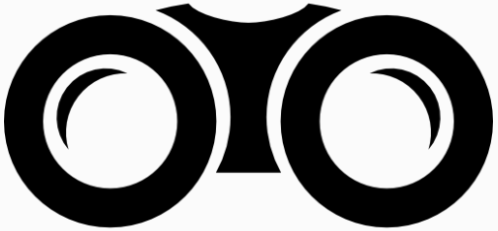

‘Post-Market Surveillance’- Article 2(60) [paraphrased]

“activities to <u>proactively</u> collect and review post-market experience for identifying any corrective or preventative action necessary.”

Monitoring (Proactive)

Monitoring the market for early warnings of problems, incl. for any competitor or similar device

MDR Chapter VII – Section 2

+

Vigilance (Reactive)

Reaction to problems in the market with own devices

MDR Chapter VII – Section I

Compliance is about demonstrating control of the product **even after a sale**.

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Examples of proactive data collection

Survey to practitioners

1. The device comb
   comfort and an e
   - Yes [ ]
   - No [ ]
2. With the device
   see safely and co
   same time?
   - Yes [ ]
   - No [ ]

Medical Practitioner

Sample Clinic

Country

of the medical

ensure the

Field studies

1. Information collection on medical background of patients
2. Questions to patients / practitioners
3. Assessment of specific functions within the clinical setting
4. ….

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Post-Market Surveillance System – Article 83

- Play an active role by **systematically gathering information** throughout entire lifetime

- PMS activities are proportionate to risk class & device type, but always include the following:
  - Plan
  - Document
  - Implement
  - Maintain
  - Update

- Cooperate with the national competent authorities

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PMS – reactive / proactive data

- Sales volume and device usage
- Complaint data
- Software malfunctions
- Trend reporting – analyse rate of non-reportable safety related events
- Meteriovigilance incidents (FSN/FSCA)
- Installation, maintenance and servicing reports
- Regulatory monitoring of standards, guideline, legislative
- Residual risk

- Assessment of competitor information
- Specialist and technology websites, (competent) authorities
- Serious incidents for equivalent and / or similar device
- Clinical literature review
- Surveys
- PMCF studies

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What are examples of pro-active PMS activity?

Customer Survey, Distributor survey, Interviews of users, Conference activities, Continued clinical trial, Search of literature or registries

What type of information should be actively collected?

Performance > Accuracy, sensitivity, specificity, revision rate, survivor rate
Safety > Side effects, minor incidents, trends, new hazards
Usability > Misuse, comprehension of instructions, long-term use effects, environmental effects, training effectiveness

What are examples of decisions/actions based on PMS activities? [based on info collected]

New side effect, decrease in expected performance, different user group > update V&V
Device failure: instrument breakage, sensor malfunction, battery failure, impendence failure leading to electrode burns -> CAPA, design change, RM update, contact NB

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Post-Market Clinical Follow-up

Legal Manufacturer

MDR

Article 10(3)

General obligations of manufacturers

"Manufacturers **shall conduct a clinical evaluation** in accordance with the requirements set out in Article 61 and Annex XIV, **including a PMCF**"

ISO TR 20416: Medical devices — Post-market surveillance for manufacturers

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Post-Market Clinical Follow-up

Source of PMCF data

- Planned customer surveys
- Post-market clinical studies (prospective or retrospective)
- Manufacturer-supported, investigator-initiated studies
- Extended clinical investigation
- Planned analysis of registries, hospital databases, etc.

NOT PMCF data

- User feedback
- Customer complaints and vigilance system
- Published data from registries
- Investigator-initiated studies
- Expert opinions

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PMCF versus PMCF studies

Assessment of PMCF study need

- Residual risk
- Uncertainties or unanswered questions
- Rare complications
- Uncertainties regarding medium- and long-term performance
- Uncertainties regarding safety under widespread use

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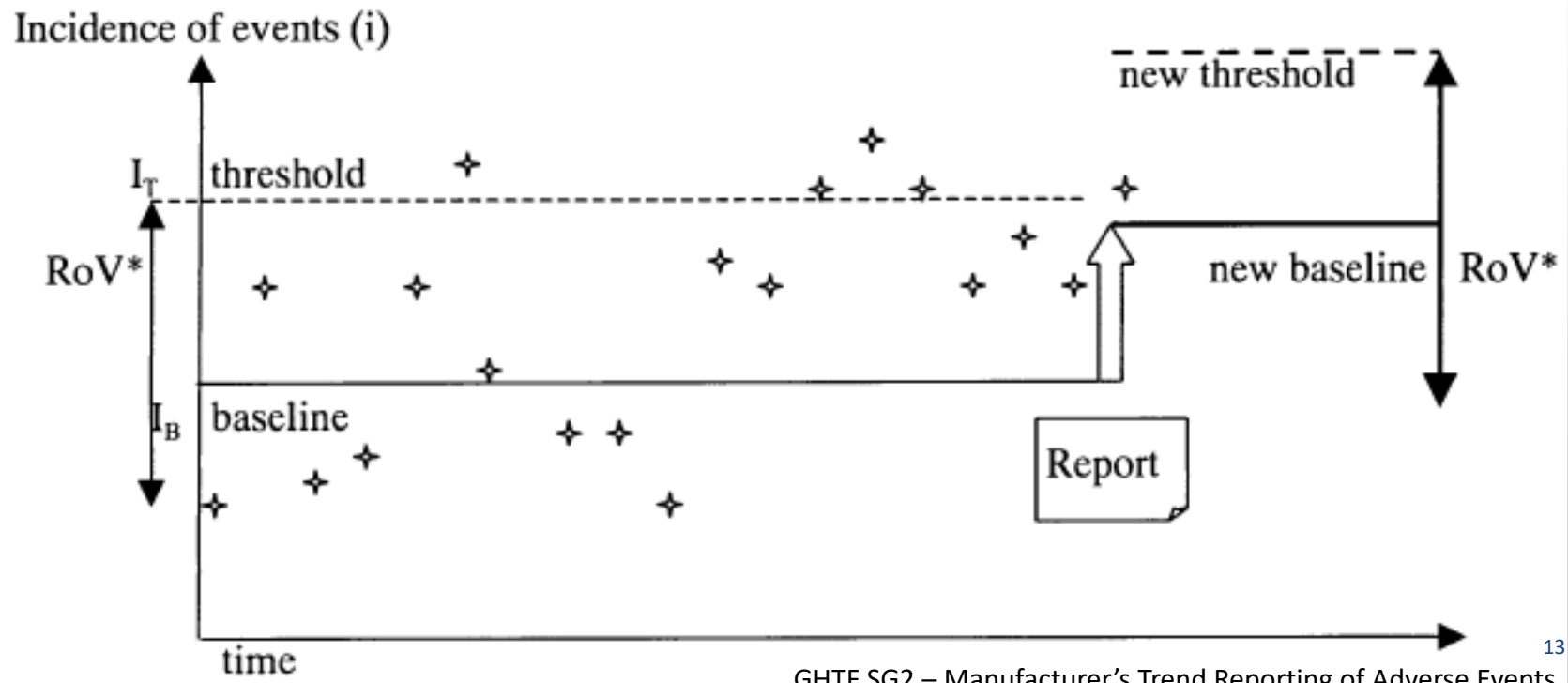
Trend Reporting – MDR Article 88

"… statistically significant increase in the frequency or severity of incidents that are <u>not serious incidents</u> or that are <u>expected undesirable side-effects</u> that could have a significant impact on the benefit-risk analysis…



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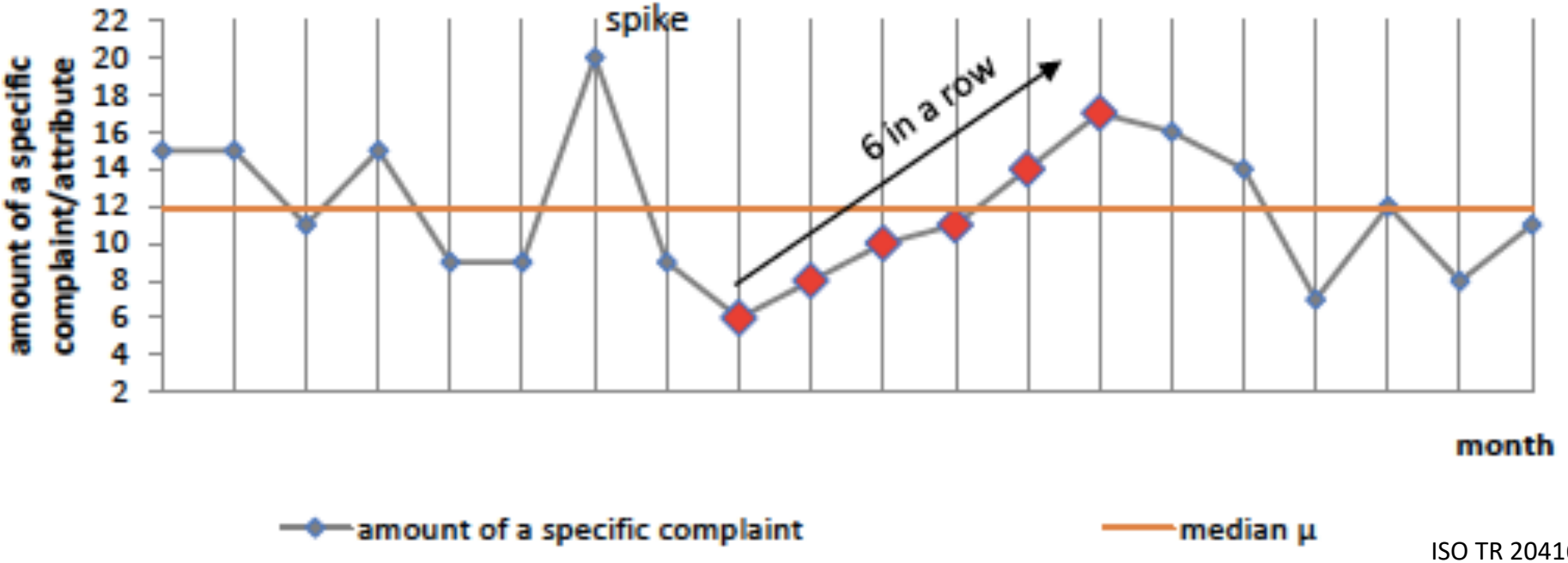

ISO TR 20416

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PMS – Market Observations

- Data related to **phased out devices** is not present in your PMS plan – Dekra GmbH
- **Linkage to CAPA/ improvement** process is not clearly defined – Dekra GmbH
- Collection of **proactive data** elements for analyzing the feedback is not included – Tüv Süd
- Commitment of management to adhere to established quality policy '*continuously meet customer requirements*' cannot be justified – Tüv Süd (**linkage of PMS data to management review** and also **review frequency** of PMS data is not justified)

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PMS – Learnings from observations

SOP Improvement System

SOP CAPA

SOP CER

Proactive data

Reactive data

SOP - PMS

Life cycle of the devices

Review frequency

SOP Vigilance

SOP …

SOP Risk Management

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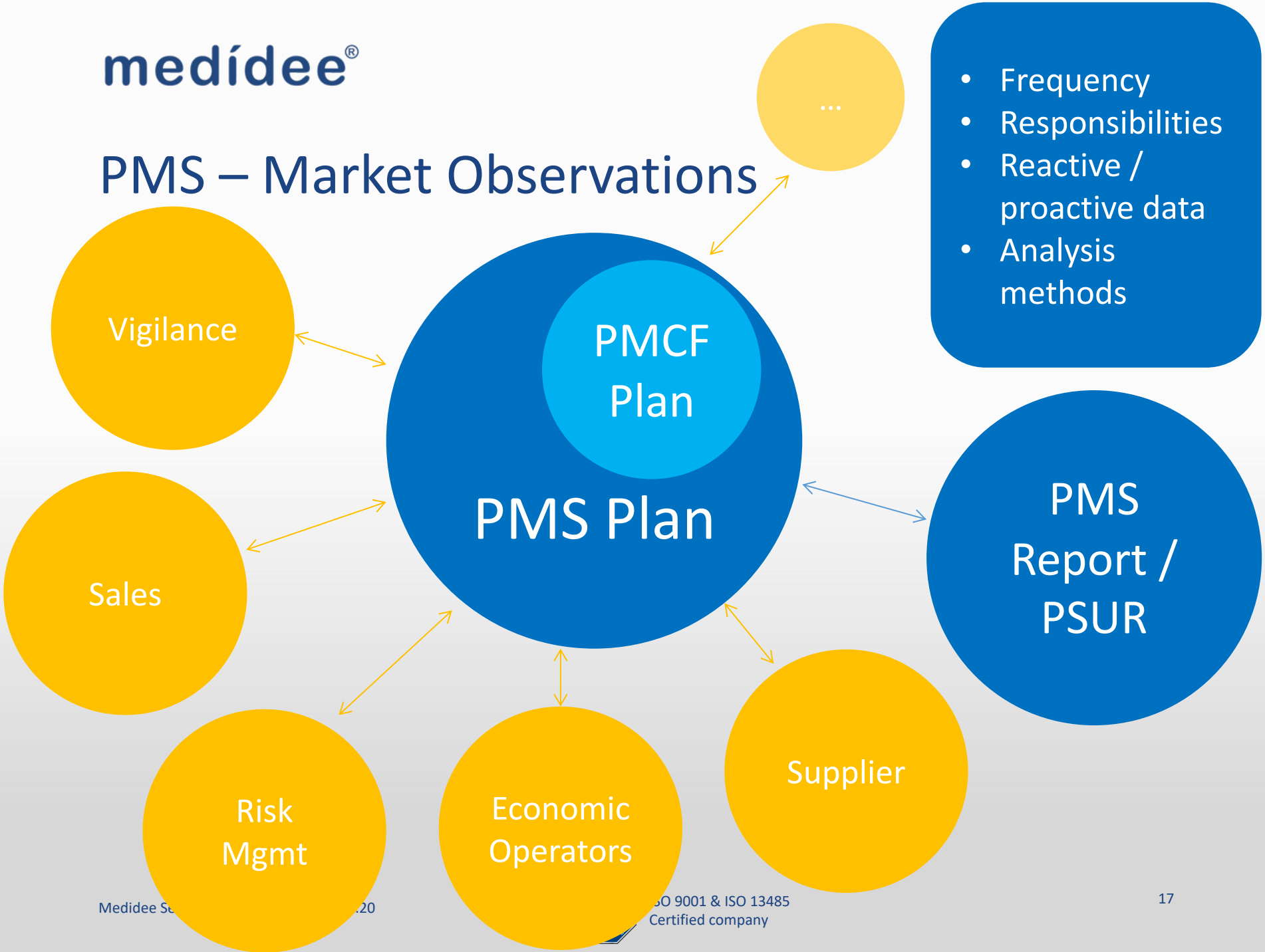
PMS – Market Observations



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PMS - best practice recommendations

- **Distributor** contracts that allow/facilitate PMS collection
- Log and investigate **complaints** from all potential sources
- Systematically collect **feedback from sales, conferences**, etc.
- Start systematic **trend analysis** of PMS data
- Ensure PMS findings **reviewed by management** and translated into **action** (Risk mgmt., CER & IFU updates, etc.)

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What can you do right now?

1. Do I have enough data to demonstrate safety and performance?
2. How can I **proactively** collect PMS data?
3. Does my QMS System include the necessary **links** and **actions** between processes?
   - Risk management process
   - Clinical evaluation process
   - PMS process
   - CAPA process
   - Improvement process
   - …

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Thank you for your attention!

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