

POST MARKET SURVEILLANCE

- COMMON ISSUES

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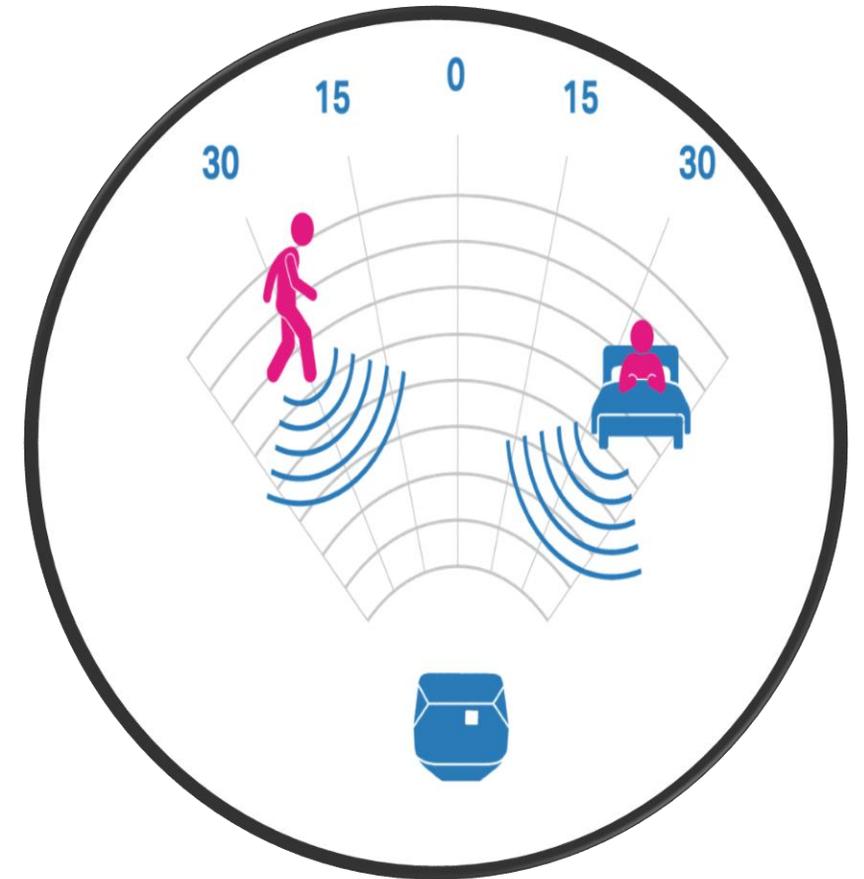
Common issues

- **Typical issues (and how to correct them)**

1. What is PMS (1)?

- It is not only vigilance activities
- It is not incident management

An integrated system connected to risk management and clinical performance evaluation, to secure data about a specific device throughout the lifetime



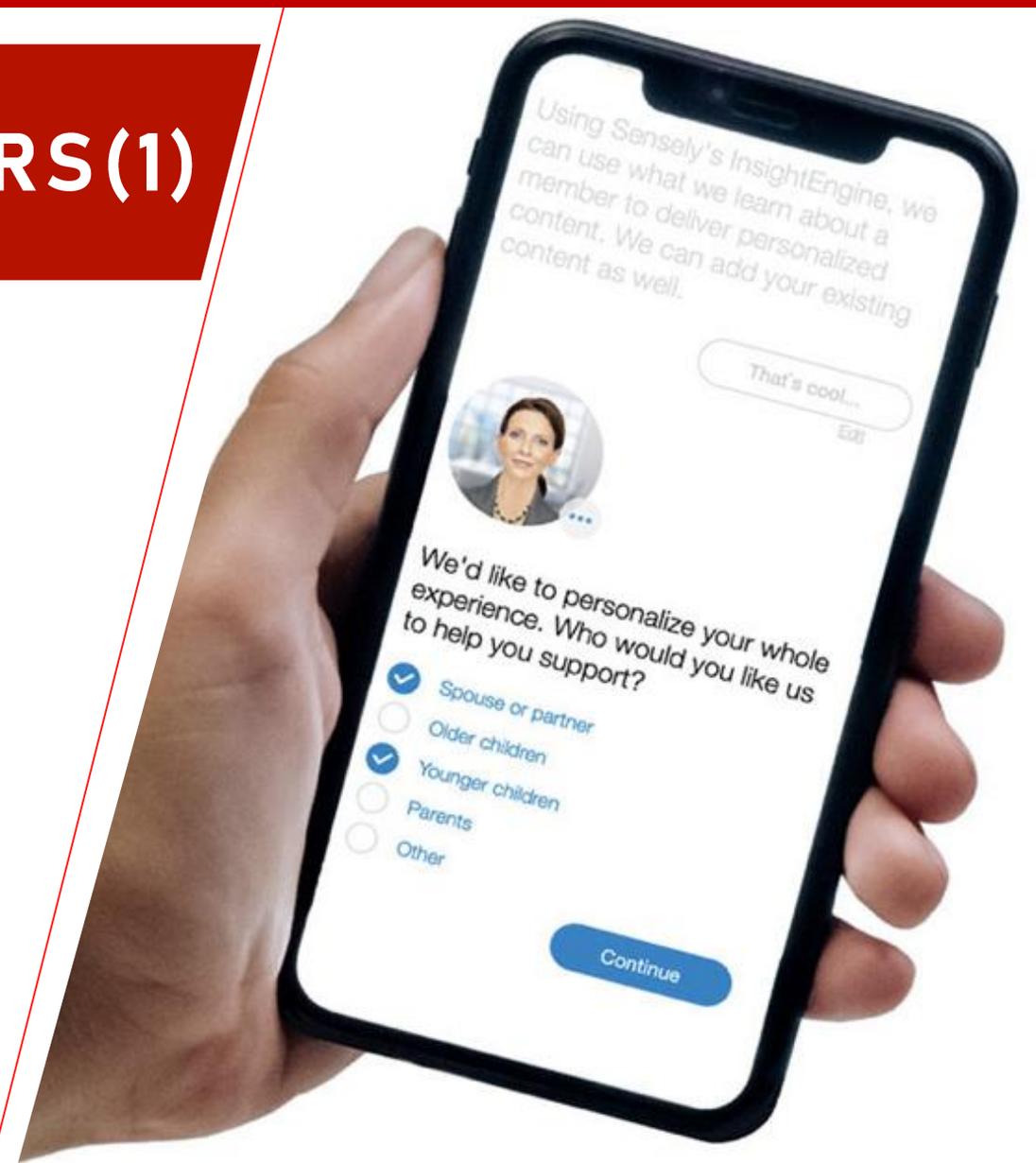
1. What is PMS (2)?

Management and different functions must know why this is important (and not only to meet regulatory requirements)

- External training
- Internal training
- Networking

2. UNCLEAR ACTION TRIGGERS(1)

- Thresholds in the plan!?
- This is to ensure the framework of when actions needs to be taken
 - Initiate investigations
 - Update design
 - Update risk management etc



2. Unclear action triggers (2)

Examples of thresholds:

- Overall complaint rate >0.5% of units sold/quarter
- Complaint increase > 20% increase in a quarter
- Death or serious incident 1 occurrence
- Scrap rate 3%
- Non conforming product >2%
- Supplier KPIs

3. GENERIC PMS PLANS

- One size very seldom fits all!
 - Seldom everything is the same
- Trigger points



4. IMPLEMENTATION (1)

- Time frames
- What information
- How data is gathered
- How is it analyzed

- Self assessment of compliance (internal audit)



4. Implementation (2)

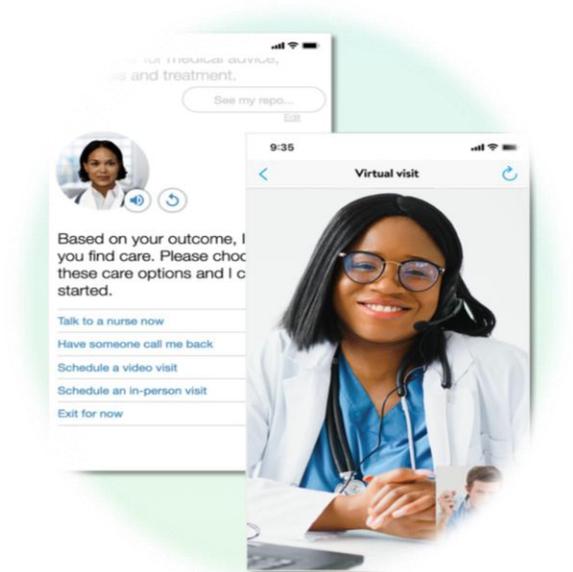
- Identify the stakeholders
- When will this be done (planning)
- Processes and reports to management

Time intervalls

Many class I manufacturer stated 5 years (2021-2022) when they transferred to MDR

5. Resources and sources (1)

- Who is responsible
- What knowledge is required
- How to setup



5. Resources and sources (2)

- **Sources:** **Complaints, vigilance, trend-reports,
literature, service and manufacturing data
Process and product ideas from customers**

- **Resources:** **Build up process and procedures involving
multifunctional resources**

Who is the right owner internally

WHAT WILL YOUR NB REQUIRE?

