

Reliance in a Post Market Setting: What's next?

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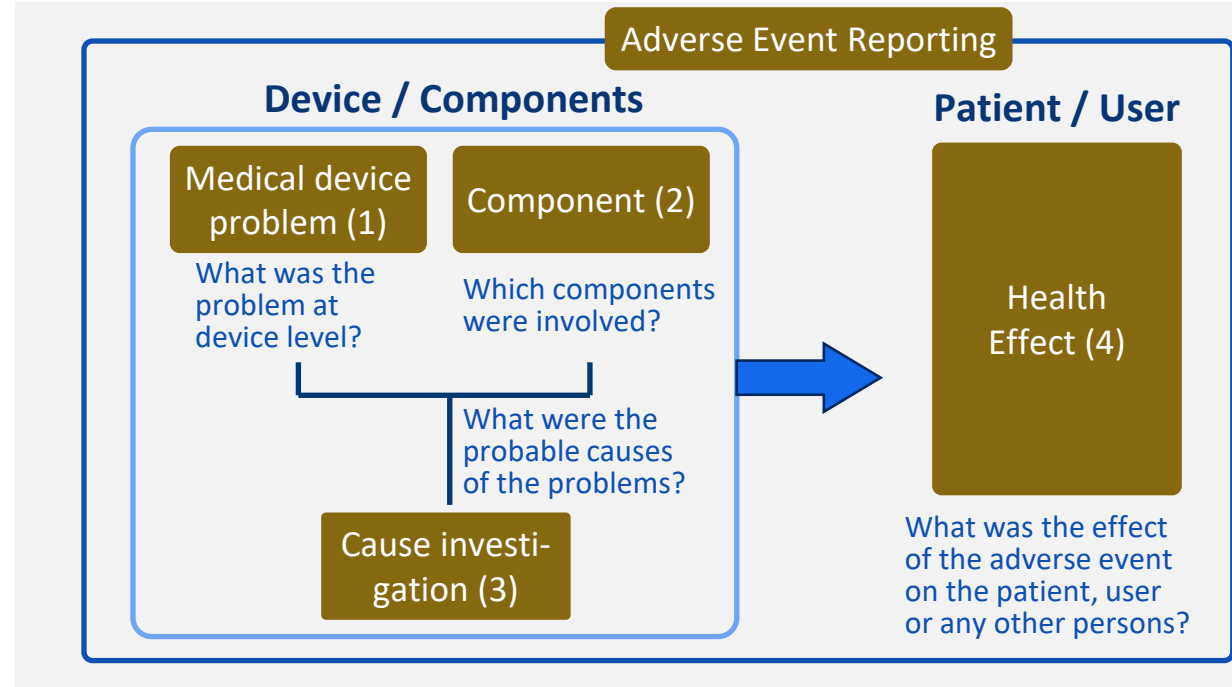
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Is the Adverse Event Reporting future proof?

Can an adverse event of a cybersecurity problem (1), found through a Common Vulnerability Scoring System (3) (CVSS), effecting (4) a sandbox (2) be reported in the future?

CAPA

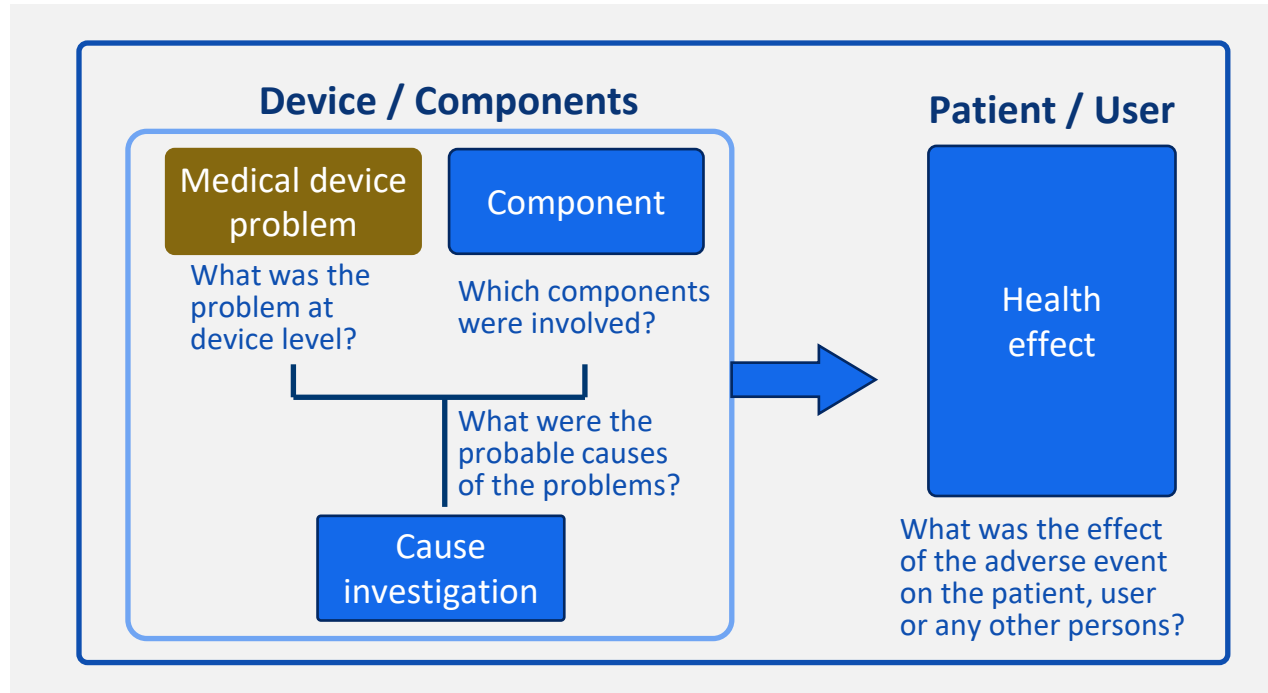
- A roll out within 48 hours can be achieved using a predetermined change control plan?



- One (Adverse Event) Reporting contact point
- One medical device problem - Annex A



- One problem reporting contact:**
- Medical Device Problem
 - Cybersecurity problem
 - Privacy problem
 - Artificial Intelligence problem
 - Data (leak) problem
 - Radiation safety problem
 - Fundamental rights problem
 - Equity problem
 - Clinical study problem
 - Logistical (shortage) problem



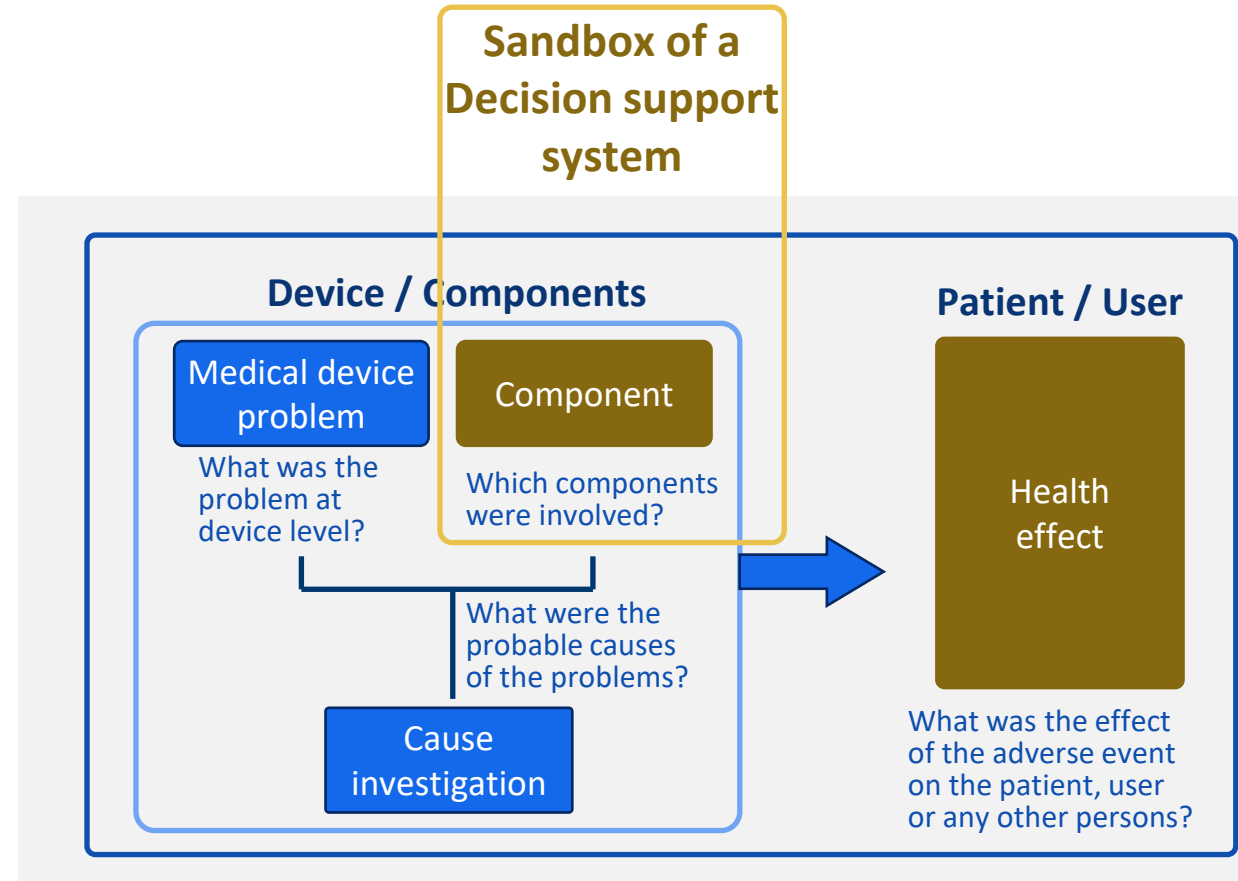
- One component - Annex G
- One effect - Annex E / F

Component / System:

- Sandbox (Component)
- Decision support system

One (health) effect:

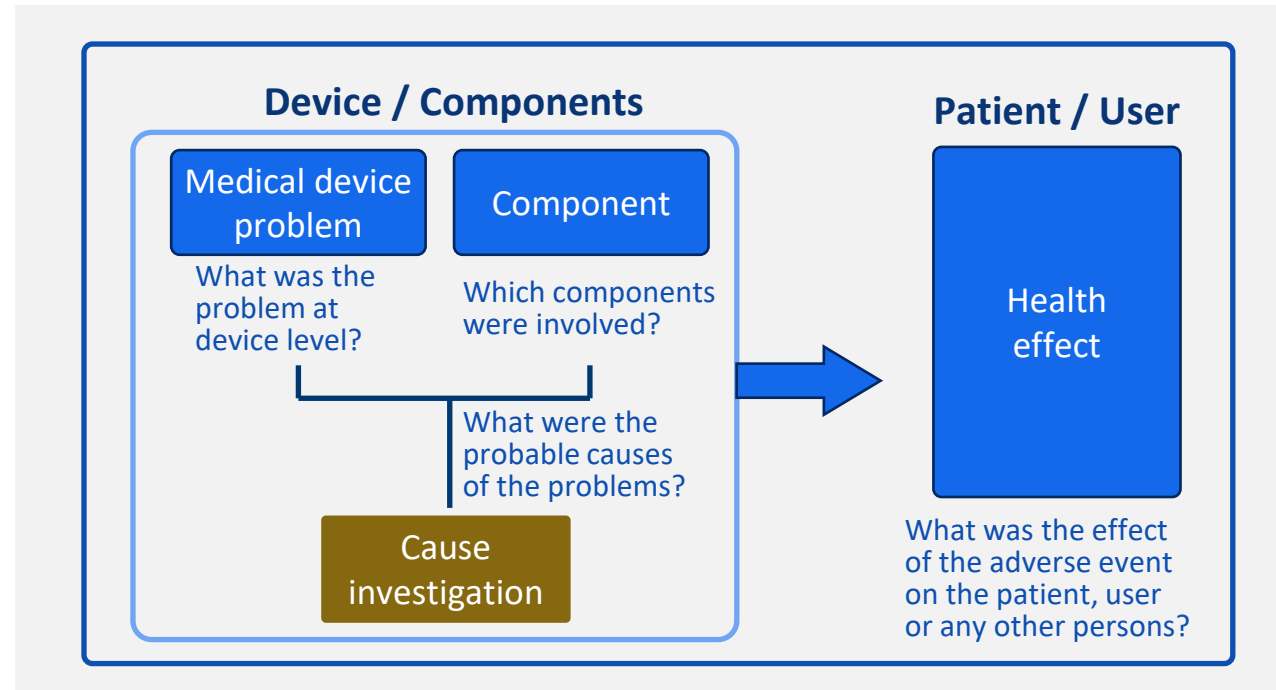
- On environment
- On cloud
- On society



- One cause investigation Annex B / C / D

One cause investigation:

- **Annex B: Cause Investigation - Type of Investigation / Threat investigation**
- **Annex C: Cause Investigation - Investigation Findings / ???**
- **Annex D: Cause Investigation – Investigation Conclusion / ???**



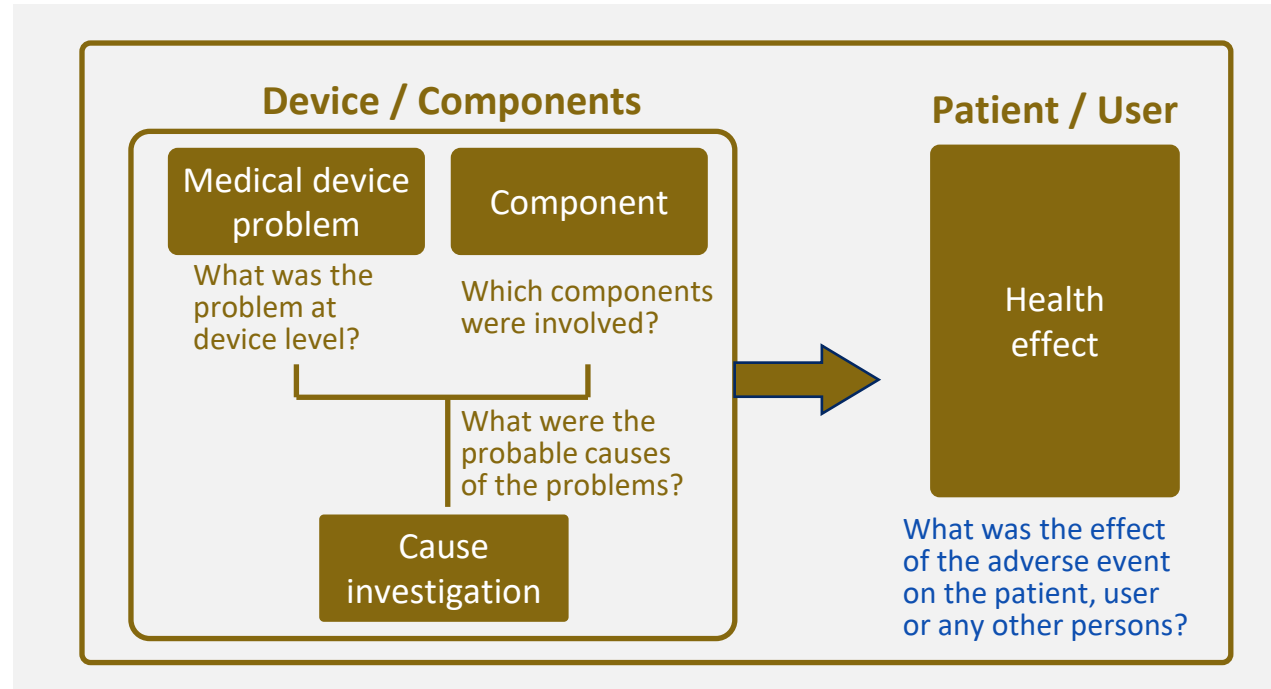
Adverse Event Reporting is not yet future, but it is achievable.

Please use:

- One reporting contact
- One approach for the problem, component, cause and effect.

Please involve industry stakeholders:

- Early to detect if the system meets the needs.
- Early to identify if it can be implemented.
- Broadly to gain support for the roll out.





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