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

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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

Device / Components
- Medical device problem
- What was the problem at device level?
- Component
- Which components were involved?
- What were the probable causes of the problems?
- Cause investigation

Patient / User
- Health effect
- What was the effect of the adverse event on the patient, user or any other persons?
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

Sandbox of a Decision support system

Device / Components

Medical device problem
What was the problem at device level?

Component
Which components were involved?

Cause investigation
What were the probable causes of the problems?

Patient / User

Health effect
What was the effect of the adverse event on the patient, user or any other persons?
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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  - Which components were involved?
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IMDRF
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