IMDRF International Medical Device Regulators Forum

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Common post-market issues faced with software and how to address them?

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Problem types facing software – A regulators perspective

Clear information on reportability

Health care moves to @home care

Too many "anomalies"

What is an anomaly and why is it a software problem?

Intended use being too vague

Broad demographics, local implementation and value generation

Dependability and interoperability

Designing with the future in mind

Clear information on reportability

"Software increases possibilities and empowerment"

- Identification of incidents
  - What constitutes an incident?
- Reportability criteria
  - Informing the citizens/user

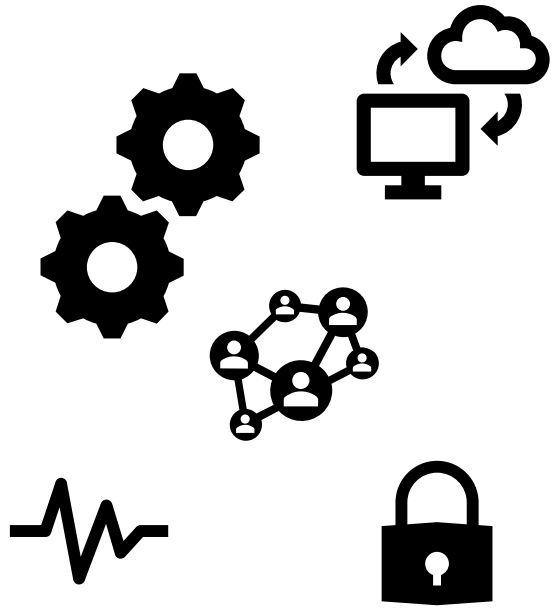
Solution:

Use understandable language and do not hide intentions

Too many "anomalies"

"Software can be anything, including complicated..."

- Can an anomaly occur in software?
  - Environmental effects
  - Interdependency
- Patches, recalls and corrective actions
  - Anomalies are often general



Solution:

Ensure testing matches the clinical workflow

Intended use being too vague

- Intended use should describe the device use
  - Often overreaches and generalize
  - More software requires local adaptation
- Ambiguous language
  - Feature creep and software updates "within" scope
  - Intentionally misleading the consumer

Solution:

Adapt the Intended Use formulation to meet the target

Dependability and interoperability

"Today, everything is connected"

- Software building blocks
  - EHR's, data pipelines etc.
  - Solid API's save lives
- Hardware and library dependency
  - The time of integration is here

Solution:

Develop your system into the use scenario

THANK YOU / QUESTIONS

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