Post-Market Surveillance – considerations for artificial intelligence software

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Scope - 2 considerations

Consideration 1 - Monitoring devices with AI

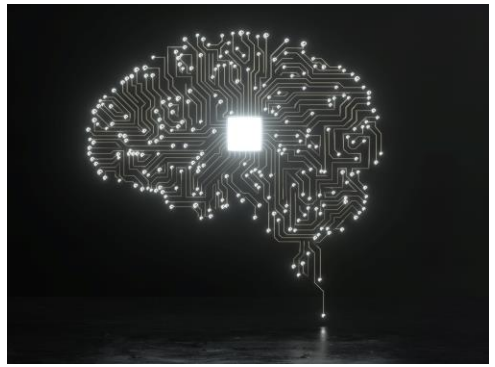
Criteria, methods, and strategies to monitor safety and performance: specific considerations for AI (ML)

Consideration 2 – Using AI data

Challenges and opportunities when collecting or generating data for digital medical devices

Consideration 1: Monitoring devices with AI

Regulatory requirements and what is acceptable are important and critical considerations to how and what is monitored

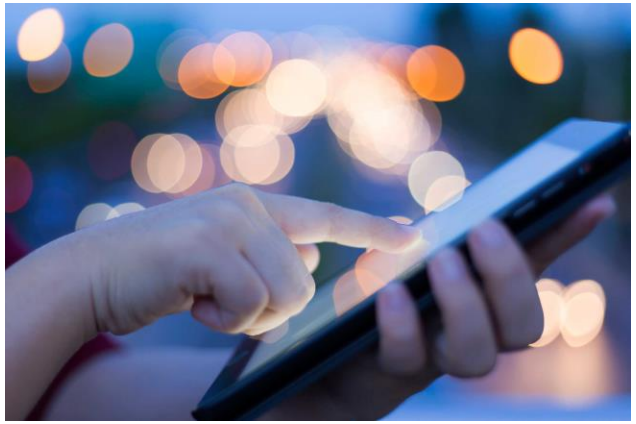


For AI software, some of the main areas under consideration for post-market surveillance include:

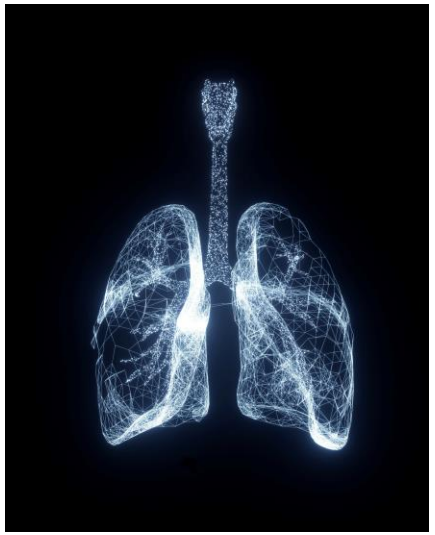
- Transparency
- Labelling
- How general software trends are applicable to AI
- Which medical specialisations are adopting AI most quickly
- How health professionals use AI products
- Signal evolution and design
- Governance of AI and data for adaptive systems
- Adverse event surveillance and what ‘manufacturer’ activities are undertaken

Some challenges

- New players do not have well-developed processes to support ongoing post market obligations
- Increasing sophistication/version updates not always factored into post market changes (especially if the changes do not require regulatory re-approval)
- Human factors – how people use software vs its design (intended purpose) and reporting of adverse events – do users KNOW it is an adverse event?
- Traceability of errors and their role in adverse events
- Some differences in classification of devices globally and post market obligations
- Using AI which may have bias and/or not be applicable to certain population cohorts – does this skew adverse event data?



Transparency and surveillance



Looking **inside** the product and using this information for surveillance

- Data AND model
- AI often sits inside a software “shell”
- What data is needed by regulator for post market issues that is specific to AI? e.g. logging and beyond

Using the product and what channels

- Human factors – consumers, patients, health professionals
- Understanding the purpose
- Scale of deployment

Signal evolution and design for AI products

- Clear leading medical specialisations – target surveillance design to these
- Digitalisation of pathology – significant changes in workflow and processes
- Keeping up with changes to theory/literature
- Target efforts
- For consumer products – speed of adoption
- Consider whole life cycle from design
- Still need to consider other software signals not just AI

Ongoing responsibilities post-approval

Building in good practices through the lifecycle

Governance, monitoring and surveillance systems are critical to:

- periodically verify that the product continue to work as intended
- detect if it develops any unintended bias or further performance drift

AI and software generally

- Focus on getting to market means AI/software living environment may not be adequately addressed
- Ecosystem compatibility maintenance
- Consumer facing devices, or self-management of a serious condition face further requirements to mitigate patient risks through its service life
- Updates or patches as ‘recall’ actions or notifications based on regulatory requirements

Adverse event surveillance

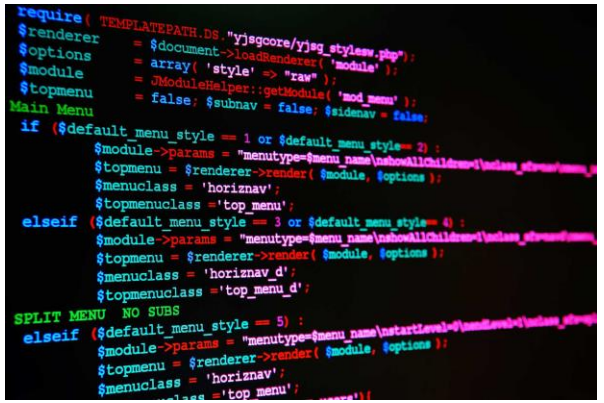
Planning for the unthinkable

- Ongoing surveillance and monitoring of complaints and adverse events regarding harm to a user or patient
- Software design should have data capture/ logs
- Manufacturer adequately resourcing the quality and post-market team
- Planning for timeframes and resourcing needed to investigate, respond, notify regulatory authorities and minimise risks from adverse events or issues
- Manufacturer needs channels to contact local agents or distributors for complaints and regulatory action, that are across different geographic regions
- Communication channels for updates, patches, recall actions to end users, or patients, or health providers

Consideration 2: Using AI data

Collecting or generating data

Regulatory requirements and what is acceptable for post market surveillance are important and critical considerations for manufacturers



- Clinical evidence guidance
- Real world evidence and real world data guidance
- Clear feedback to manufacturers by the regulator on what is expected

Real world evidence and real world data

Key points in relation to post-market surveillance:

- Real-world data collected from AI software in a proper study design can contribute to post-market clinical follow up
- Create real-world evidence for any applicable extension of intended purpose.
- Sources can include device output, sensors, patient entered data, EMRs, among others

Challenges

Post market challenges for use of data generated by AI

- Experience with other software shows that data may be difficult to get and timeliness becomes significant Monitoring for performance including development of bias and data drift – as for other AI
- Analysis of population segments and other sub-groups to check performance across spectrum of intended use including target population, equipment, user
- Monitoring for repeatability and reproducibility
- Variability of device output across use on same or similar patients/conditions, by same or different operators
- Opaque or black box models may introduce further risk and thus warrant higher stringency of monitoring
- Clinical reference standard may not be available for novel AI models

Opportunities

Post-market monitoring of data generated by AI can:

- Give further external validation of devices to support generalisability of model performance, i.e. ability to perform in a new use environment or new sample of patients.
- Track further clinical endpoints beyond model accuracy, for example mortality, rate of ICU admission, or other patient outcomes.
- Under a proper study design - create real-world evidence for subsequent pre-market decision making on indication expansion.
- Confidence in accuracy of generated data is paramount

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