Fellowship in Clinical AI
NHS Digital Academy Programme

Integrating AI safely: Post-Market Surveillance for a Class I AIaMD

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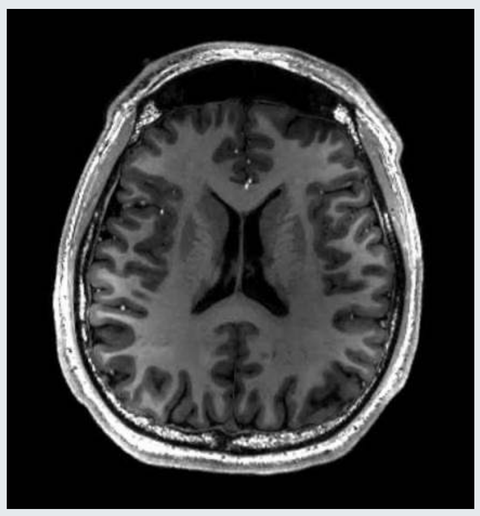
Background

- Magnetic resonance imaging (MRI) is central to diagnosis of a wide spectrum of neurological conditions. Reporting delays can have significant consequences, such as delayed treatment, poorer patient outcomes and elevated healthcare expenditures. Rising radiologist workloads, without a comparable increase in the workforce, has contributed to a trend of increasing reporting times for brain MRI scans. To mitigate these challenges, MIDI has been developed.
- MIDI is a radiological computer-aided triage and prioritisation software which is indicated for use in the analysis of brain MRI in adults aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by using an artificial intelligence algorithm to analyse images and flag suspected actionable radiological findings (i.e. an abnormality). The abnormality score can classify each scan as routine/abnormal which can be used by downstream hospital systems to triage/prioritise radiology reporting worklists. MIDI will be deployed in around 12 NHS Trusts as part of a multi-centre cluster randomised crossover trial.



Post Market Surveillance

- Post market surveillance (PMS) describes ongoing monitoring of safety and performance after deployment. It recognises even after clinical evaluation, completion of trials, and/or UKCA markings, new risks can occur or existing risks can change, due to workflow differences, user behaviours, real-world populations, software updates and data drift.
- Post market surveillance is a regulatory requirement, under The Medical Devices (Post-Market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024.
- It is the responsibility of the manufacturer and is required throughout the device life-cycle.

Developing a PMS Plan for a Class I AIaMD

Developing the PMS plan required close collaboration with the wider multidisciplinary team, such as the technical lead and Person Responsible for Regulatory Compliance, to establish a shared understanding of its purpose, scope and regulatory requirements.

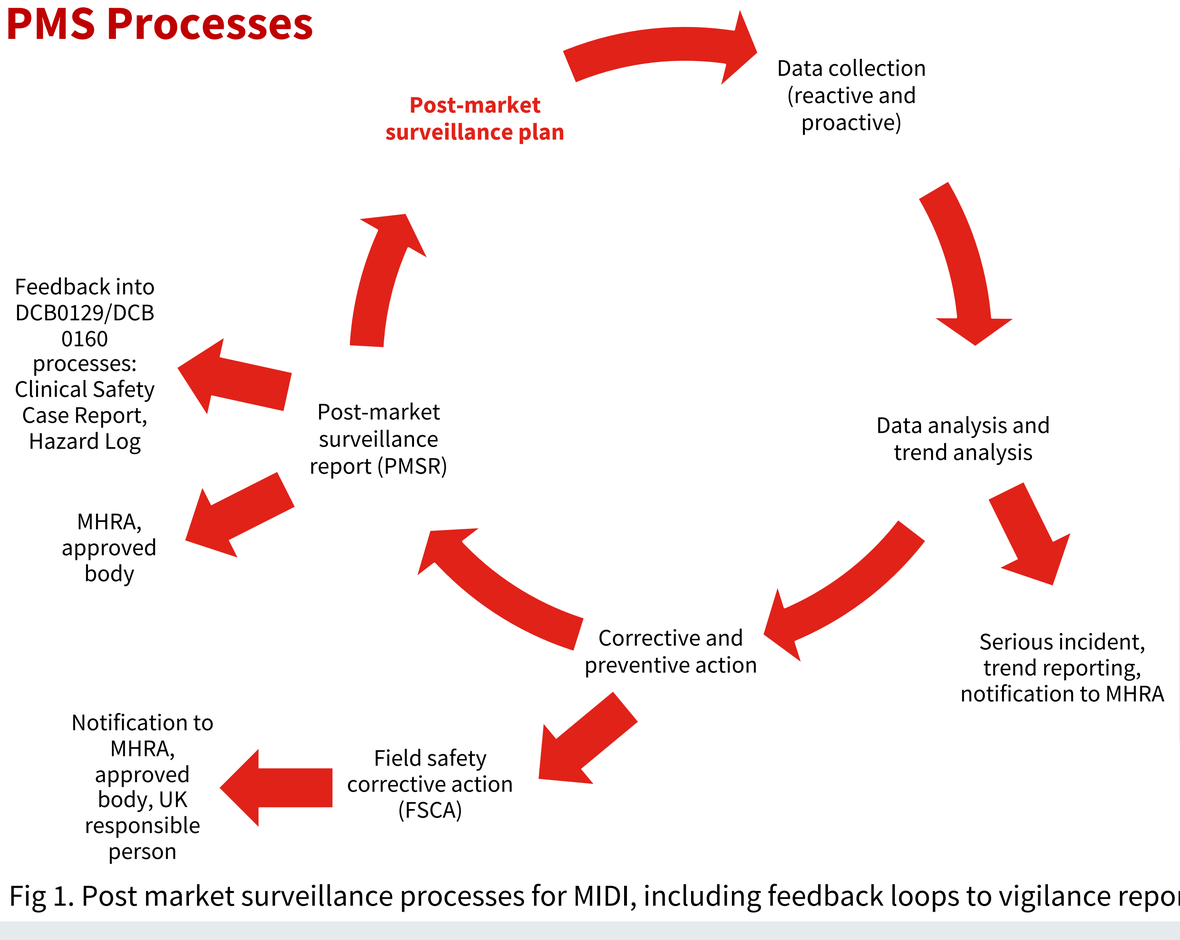
The objectives of the PMS plan were to:

- Monitor device safety and performance
- Detect and evaluate risks
- Verify risk benefit ratio
- Ensure compliance with regulatory reporting

Both reactive and proactive data collection methods were incorporated. Reactive surveillance included the review of complaints, incidents, user feedback and reported safety concerns. Proactive surveillance drew on data already being collected through the TRIAGE trial, which was used as the Post-Market Clinical Follow-up study. This reduced duplication and enabled continued assessment of MIDI.

The PMS plan was closely integrated with the MIDI Quality Management System, which provided the framework for delivering PMS activities. This included processes for data review, risk management, trend analysis, incident escalation, corrective and preventive actions, document control and regulatory reporting. The plan maintains clear links between the PMS plan, risk management documentation and the wider QMS to ensure that any emerging evidence can be translated into appropriate action. The PMS plan supported the successful UKCA marking of MIDI as a Class I AI medical device and the PMS system will remain operational throughout the post-market surveillance period.

PMS Processes



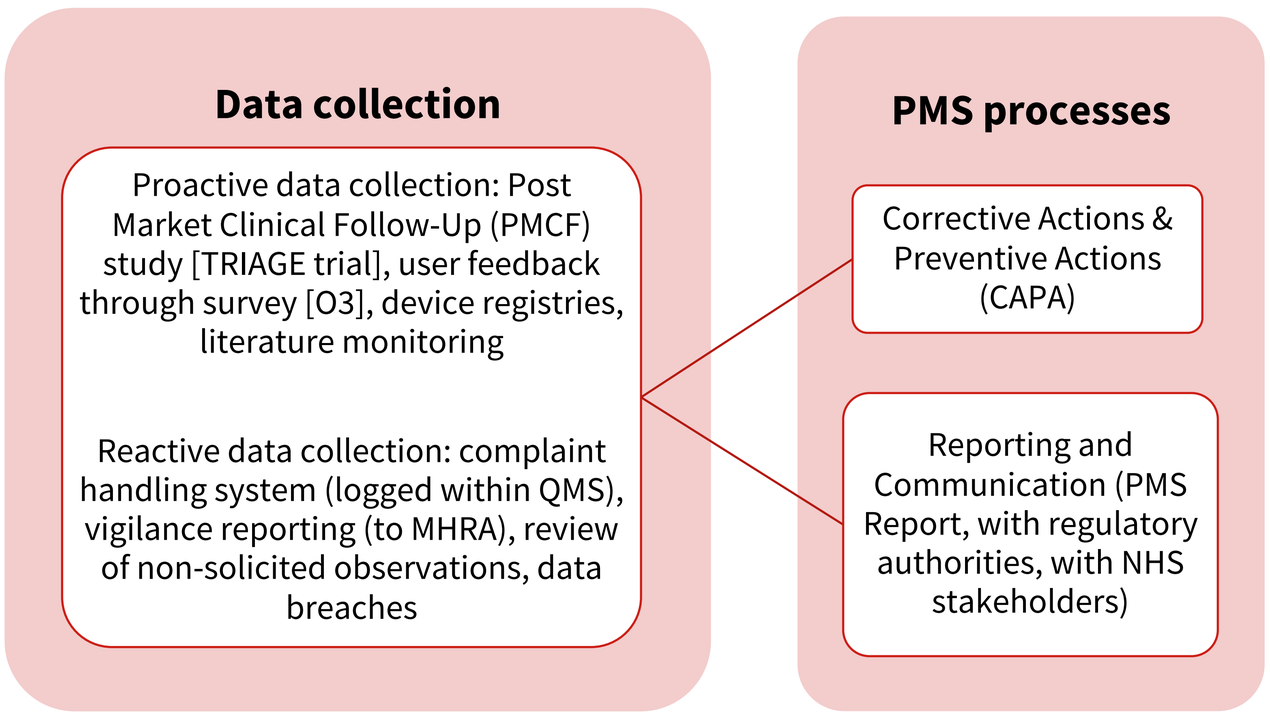


Fig 1. Post market surveillance processes for MIDI, including feedback loops to vigilance reporting

Reflections and Learnings

- Translating a post market surveillance plan into practice requires careful operational planning. First, reliable data flows are required from deployment sites into QMS-based PMS processes. Users need clear and accessible routes for raising concerns and complaints, supported by processes that ensure feedback is complete and sufficiently detailed. Second, PMS findings must feed into manufacturer clinical-safety documentation, including the DCB0129 Hazard Log and Clinical Safety Case, while also supporting deploying organisations' DCB0160 processes. Third, surveillance must align with local incident-reporting and governance arrangements. An effective PMS system should be easy to contribute to and capable of producing timely, actionable information.
- PMS processes will also need to keep up with any future changes in the regulatory landscape. An MHRA AI airlock report identified a need for improvement in PMS processes, including a need for better clarity on which aspects of system behaviour should be monitored and frequencies of this, with AI-specific surveillance measures.

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Acknowledgements
With thanks to my supervisor Professor Thomas Booth, the KCL MIDI team and the NHS Fellows in Clinical AI working alongside me on this project.