Property	Supporting FDA Guiding Principles[1]	Example Recommendations
Generalisability Generalisability or generalisation refers to the model's ability to adapt properly to new, previously unseen data.	Training data sets are independent of test sets (FDA principle 4) Model design is tailored to the available data and reflects the intended use of the device (FDA principle 6)	During development, increase robustness by - considering the diversity and size of the training dataset, - using algorithmic approaches that reduce the tendency to over-fitting, - avoid inference of patterns based on incidental features that are not related to the pathology. During validation, perform external validation studies. - Ideally these studies show that performance is maintained despite being exposed to different populations representing the diversity of people that are within the intended use.
Unbiased The opposite which is bias refers to the phenomenon that arises when an algorithm delivers systematically biased results because of erroneous assumptions of the machine-learning process.	Clinical study participants and data sets are representative of the intended patient population (FDA principle 3)	When selecting training data, the following source of bias should be identified and addressed: - **Data Bias:** Occurs when the data used to train an AI system is not representative of the population it is meant to serve. - **Algorithmic Bias:** Occurs when the design or implementation of a machine learning algorithm produces biased results. This can happen due to various factors, such as the selection of training data (data bias), the choice of features, or the use of biased models. - **User Bias:** Occurs when users of AI systems exhibit bias, intentionally or unintentionally, in the input data they provide to the system. This can happen, for example, when users enter discriminatory or inaccurate data that reinforce existing biases in the system. - **Technical Bias**: Occurs when the hardware or software used to develop or deploy AI systems introduces bias into the system. For instance, a machine-learning system that is trained on a limited dataset due to a lack of computing power or storage capacity.
Interpretability Models are interpretable when humans can readily understand the reasoning behind predictions and decisions made by the model.	Focus is placed on the performance of the human-AI team (FDA principle 7) Users are provided clear, essential information (FDA principle 9)	Conduct usability studies that ensure outputs themselves are easily interpretable to the user without ambiguity. It is particularly important to provide evidence that consideration has been given to the extent to which human interpretation of these outputs may cause variation in performance and be a risk to patient safety.
Applicability **(Local assurance prior to active deployment)** The model performs safely within their setting and when used for their local intended population.	Testing demonstrates device performance during clinically relevant conditions (FDA principle 8)	The regulatory bodies are likely to require evidence of how the AIaMD is likely to perform safely within the intended setting and when used for their local population. Strategies might include: - Showing good generalisability across previous studies that reflect diverse populations and diverse settings. - Comparing the extent to which those previous studies align with their local situation and may therefore be expected to predict AIaMD behaviour in their setting and population. - Conducting a local pre-deployment evaluation in silico in which the AIaMD is tested on previously collected data from the local institution (retrospective evaluation) - Conducting a local silent trial in which the AIaMD is placed within the health pathway with the intent of not to influence human decisions but rather to evaluate what the AIaMD performance would have been in that local setting if it had been acted on (prospective silent evaluation)
Observability **(Proactive safety monitoring)** Ability to continually provide insights into how a machine-learning model or AI system performs in production over time.	Deployed models are monitored for performance and re-training risks are managed (FDA principle 10)	Both the health provider and the AIaMD manufacturer have a responsibility to ensure the safety of the AIaMD and should work jointly to achieve this. AIaMD can show significant deterioration over time which goes unnoticed by a human user resulting in a negative change in performance either gradually (e.g. population demographic shift) or suddenly (e.g. model update). Therefore, thresholds of performance that necessitate action need to be established. Error analysis and detection of failure modes require direct access to health data at the individual patient level: - Create a feedback loop: Establish a mechanism for collecting feedback from users, clinicians, and patients regarding the AI system's performance and safety. Encourage reporting of any adverse events or incidents related to the AI system and ensure a clear channel for communication. - Implement real-time monitoring: Set up a system to monitor the AI system's performance in real-time. This can involve continuous data collection, tracking of user interactions, and analysing outcomes to identify any potential safety issues or deviations from expected behaviour.
Adaptivity The capability to periodically update the model through exposure or availability of new data.	Multi-disciplinary expertise is leveraged throughout the total Product Life Cycle (FDA principle 1) Good Software Engineering and Security Practices Are Implemented (FDA principle 2)	The process of updating models in AIaMD should follow a systematic and controlled approach to ensure patient safety, regulatory compliance, and improved performance[2,3].

[1] https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles
[2] https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf
[3] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1120503/RHC_regulation_of_AI_as_a_Medical_Device_report.pdf