الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Artificial Intelligence (AI)-Enabled Medical Devices – SFDA Regulatory Practice

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SFDA Published Guidance

- Guidance for Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices (MDS – G010).

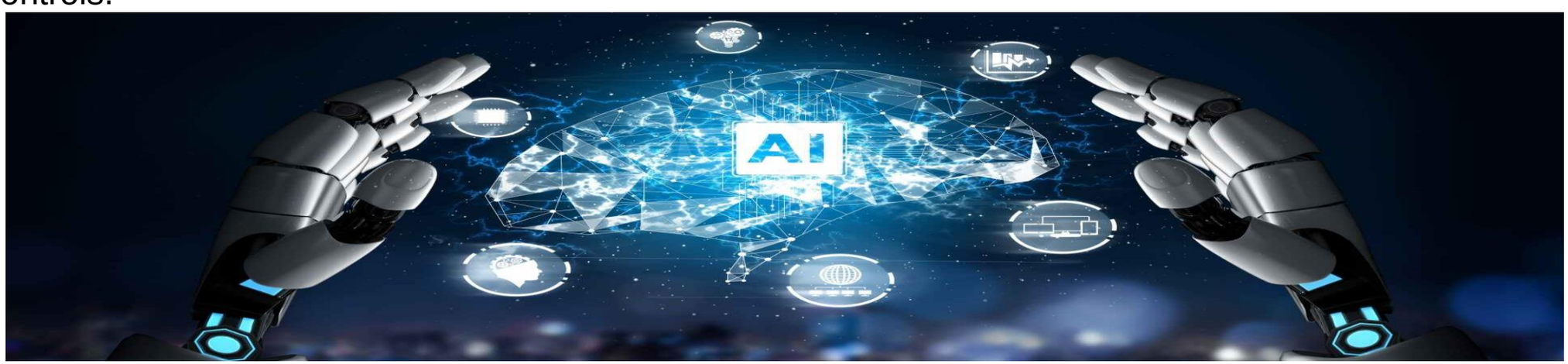
AI-Enabled Medical Device

The intended use will determine whether it will be regulated as a medical device or not.

The intended use is based on:

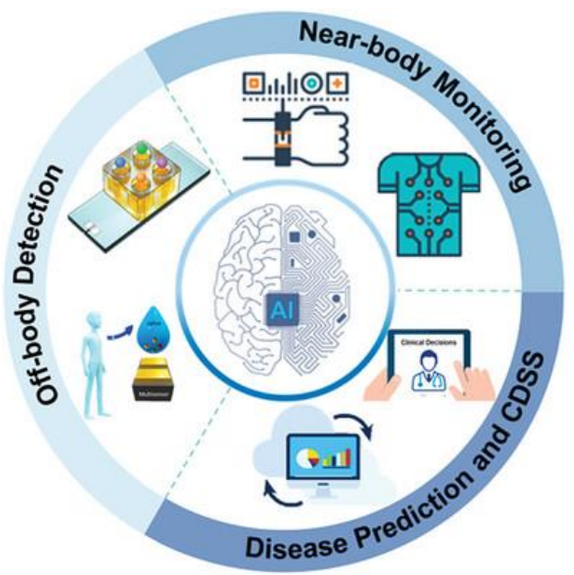
1. Product specifications; and
2. Instructions of use.

If the AI-enabled device is intended by the manufacturer to be used for investigation, detection, diagnosis, prognosis, monitoring, treatment, or management of any medical condition, disease, anatomy or physiological process, then, it will be classified as a medical device subject to SFDA's regulatory controls.



Examples of AI-Enabled Devices that are Classified as Medical Device

- In-vitro diagnostic tools that has the ability to recognize different types of cells, quantify and analyze the results.
- AI-enabled biosensors that predict tendencies and probability of disease.
- AI-enabled software in radiology that identify diseases and medical conditions from images – such as CT scans, MRIs, and X-rays.



Classification of AI-Enabled Medical Devices (MDS-G008)

AI-enabled medical devices are classified based on:

1. Intended use of the medical devices; and
2. Degree of potential risk to human body upon use.

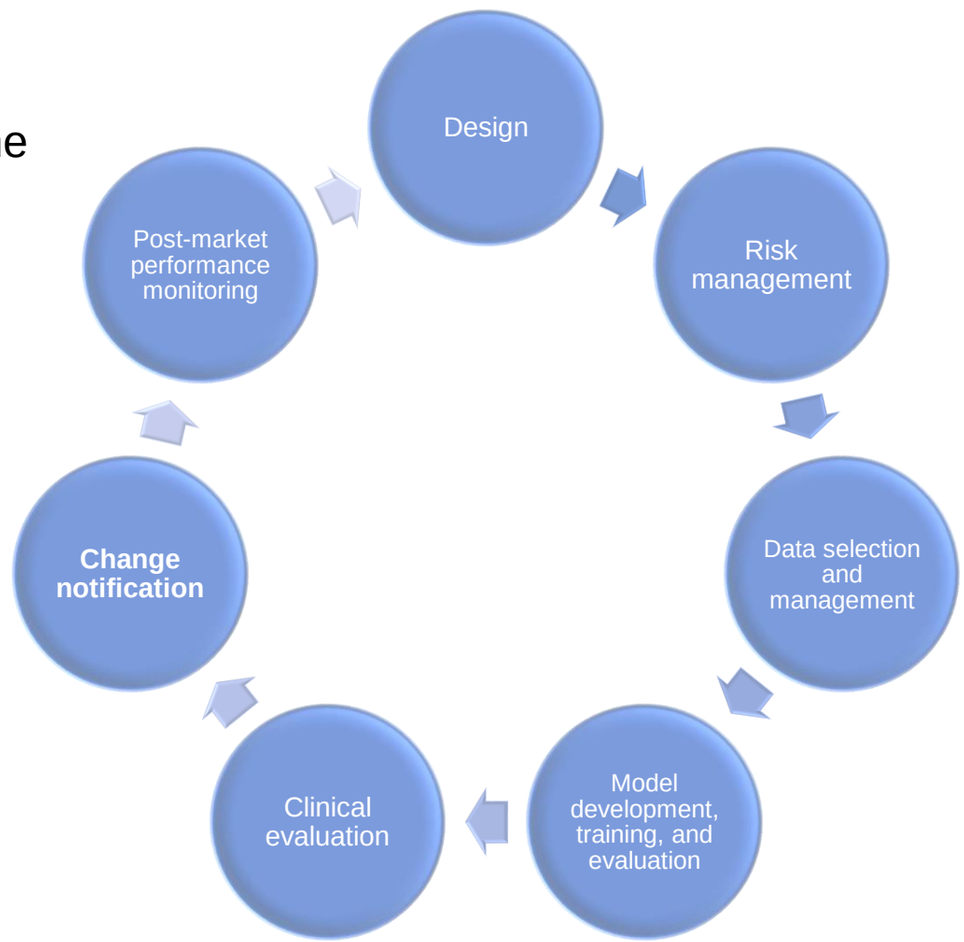
Class A	• Low risk
Class B	• Low-medium risk
Class C	• Medium- high risk
Class D	• High risk

Regulatory Approach to AI-Enabled Medical Devices

A process-oriented approach, whereby all relevant processes and phases of the product lifecycle are considered, in order to demonstrate the safety and effectiveness of an AI-enabled medical device.

AI-enabled medical device lifecycle includes the following components:

- Design.
- Data selection and management.
- Model development, training, and evaluation.
- Clinical evaluation.
- Risk management.
- Change notification.
- Post-market performance monitoring.



Design

The manufacturer of AI-enabled medical device is expected to demonstrate the following requirements:

1. Device description requirements.
2. The intended use requirements.
3. The intended user and intended context of use requirements.
4. Stakeholder requirements.
5. Functionality and performance requirements
6. User interface requirements
7. Additional software requirements
8. Labeling requirements

Data Selection and Management

The manufacture of AI-enabled medical device is expected to provide the following elements:

- Descriptions of the training, validation and test datasets used to develop and evaluate the model, such as:
  - Sample size, clinical and demographic characteristics and statistics.
  - Justifications to support the dataset characteristics, for example, subgroups analysis.
  - A comparison between the prevalence within the dataset and the intended population.
  - Data collection source, methods, and environments in which the data were collected.
- Description of the procedure for data annotation, if applicable.
- Description of the procedure for pre-processing of collected data, before data is used to train or test the model.
- Datasets inclusion and exclusion criteria with a justification for any excluded data.
- A description of how data integrity was maintained and how data quality and accuracy were ensured, including a description of any data augmentation practices.
- Descriptions of techniques and methods used to address data imbalances.
- An explanation of how bias in the datasets was controlled during development.

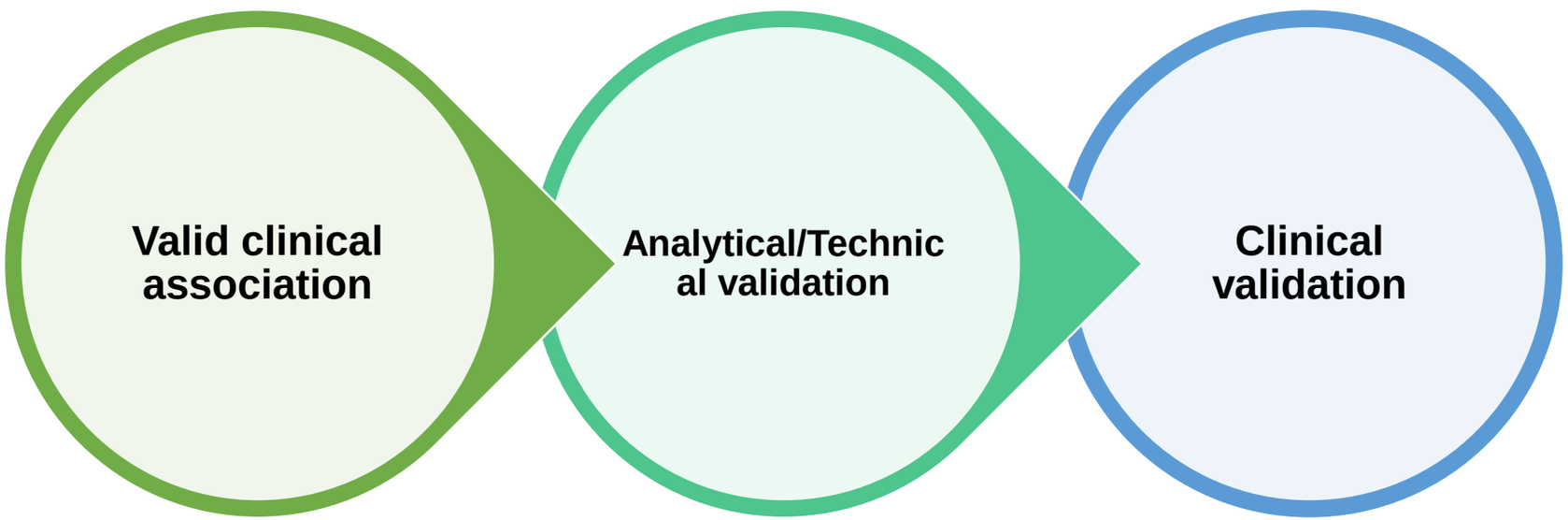
Model Development, Training, and Evaluation

The manufacture of AI-enabled medical device is expected to provide the following elements:

- A description of the methods used to develop, train and tune the AI model and a justification to support these methods.
- A description of the inputs and parameters used to develop the AI model and any features extracted from the input data along with justification.
- An explanation of the selection and calculation of performance metrics, which is used to select the final model during the training, and how the model performance was tested.
- test specification and test results for the final evaluation of the model with new test data.
- A characterization of the reference standard used in training and tuning, including:
  - The process and methodology used to define the reference standard.
  - A justification to support the chosen reference standard.
  - A description of the uncertainty and associated limitations.

Clinical Evaluation

The manufacturer of AI-enabled medical device is expected to provide clinical evidence of the device’s safety, effectiveness and performance before it can be placed on the market. The manufacturer needs to generate evidence to demonstrate:



Valid Clinical Association

A valid clinical association between the output of AI-enabled medical device and the targeted clinical condition.

The manufacturer need to provide evidence that the device output is clinically accepted based on: existing evidence in published scientific literature, original clinical research, and/or clinical guidelines, and demonstrate the relevance of available data to the clinical problem and current clinical practice, and that it aligns with the device's intended use.

If the manufacturer cannot confirm the scientific validity of the device based on an established body of evidence, new evidence needs to be generated, for example, through conducting secondary data analysis or a clinical trial.

Analytical/Technical Validation

Evaluates the correctness of input data processing by the device to create reliable output data.

- Evidence that the device specified requirements have been fulfilled, and demonstrate that the device meets its specifications for a specific intended use.

- This evidence is generated during the verification and validation activities using independent reference datasets reflecting the intended purpose and the diversity of the intended population and setting.

    1. Verification that the model meets its design requirements;
    2. Validation that the model performs as intended;
    3. Validation that the device will perform safely and within specification when used under normal conditions and abnormal conditions that are reasonably likely to occur (e.g. receives data outside of specification, connects to an unintended device or system).

Clinical Validation

- Clinical validation measures the ability of the AI-enabled medical device to yield a clinically meaningful outcome associated to the intended use of the device output in the target population in the context of clinical care.

- The clinical validation should list the **data sources** that have been evaluated and that both **support** and **contradict** the manufacturer claim that the benefits have been achieved.

- The types of data necessary to assure safety and effectiveness during the clinical validation will depend on the function of the device, the intended use, and the risk it poses to users.

- If the clinical evaluation is based on a comparator device, the manufacturer must demonstrate sufficient technical equivalence of the other device, including explicit evaluation of the AI model.

- The manufacturer should carry out usability testing that verifies the information provided to the user to connect to the device correctly in order to ensure product adoption within clinical workflow and clinical setting.

Risk Management

The manufacturer should conduct the necessary risk management as described in (ISO 14971), and is expected to provide risk management file that include:

- The scope of risk management activities.
- Assignment of responsibilities.
- Requirements for review of the activities.
- Risk acceptability criteria.
- Method to evaluate overall residual risk.
- Activities of the implementation and effectiveness of the risk control measures.
- Activities to collect and review post-production information.
- The criteria used to trigger an update, risk management of the update process itself, and provisions for returning the product to a previous version if necessary.
- Risks related to interoperability and cybersecurity.

AI Risks and Hazards can be around:

- Data management
- Feature extraction
- Algorithm training
- Model evaluation
- Cybersecurity

Risk Management

Example of risk items that should be considered in the risk analysis

- Erroneous outputs
- Misuse
- Bias
- Lack of transparency
- Continuous learning
- Overfitting & Underfitting
- Degradation of model performance
- Automation bias
- Alarm fatigue

Change Notification

The SFDA shall be informed, via the electronic system “GHAD”, within (10) days of the occurrence of any significant change to the relevant device or within (30) days for non-significant change.

Significant Change

It could reasonably be expected to directly affect the safety or effectiveness of a device. Examples include, but not limited to, the following: modification of the algorithm that affects the diagnostic or therapeutic function, addition of new features or software applications that affect any diagnostic or therapeutic functions, addition or removal of alarm function that may affect the treatment of patient, change to the operation system platform.

Non-Significant Change

It could reasonably be expected to indirectly affect the safety or effectiveness of a device. Examples include, but not limited to, the following: A simple bug fix to correct the display error, disable certain functions that does not affect the performance of the device or interact with other functions, modify the appearance of the user interface that does not impact the device performance.

Post-Market Surveillance

The manufacturer of AI-enabled medical device is expected to provide a post-market surveillance plan and post-market clinical follow-up plan to monitor the device safety, effectiveness, and performance post-implementation and generate evidence of sustained clinical impact.

Guidance for Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices (MDS – G010)

- Introduction.
- AI-Enabled Medical Device Classification Criteria.
- Design.
- Data Selection and Management.
- Model Development, Training, and Evaluation.
- Clinical Evaluation.
- Risk Management.
- Change Notification.
- Post-market Surveillance.

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Thank You

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