# VALIDATION TECHNIQUES FOR AI/ML COMPONENTS IN MEDICAL DIAGNOSTIC DEVICES

**Venudhar Rao Hajari**
**Independent Researcher,USA.**

**Nitin Prasad**
**Independent Researcher,USA.**

**Narendra Narukulla**
**Independent Researcher,USA**

**Ritesh Chaturvedi**
**Independent Researcher,USA.**

**Dr. Saloni Sharma**
**Independent Researcher,USA.**

**TABLE OF CONTENTS**

**DOI Number: 10.48047/NQ.2023.21.4.NQ23029** **NeuroQuantology2022; 20(5):306-312**

## Introduction

An advanced trend in Healthcare IT is integration of ML & AI into assessment tools & diagnostic devices. Possibilities of enhancing the precision, effectiveness and individuality of medical diagnostics with the usage of these AI/ML components. However, they have their special difficulties as far as validation and regulation is concerned, and are also inherent when implementing these specifications. Before these gadgets can be relied upon to diagnose without endangering the health of patients, the AI/ML parts of the gadgets have to be certified. One observes that while comparing with traditional software applications, AI/ML models are more evolvable and can improve with time, maybe with a change in their characteristics. Due to this dynamic nature of procedure, there is a need for severe and constant validation processes.The process of checking the train and test data sets for their ethical as well as their representativeness and quality is called data validation. This work aims at exploring several strategies for validation, problems encountered while applying them, and the implications on reliability and certification of a diagnostic equipment with AI/ML elements integrated into it.

## Literature Review

**AI Validation in Regulated Healthcare Sectors**

According to the author,Higgins and Johner, 2023, the challenges of assimilating AI/ML products into governed healthcare sectors including pharmaceuticals development, manufacturing of medicine and drugs, medical appliances, and in vitro diagnostics are discussed in this paper. Specific goal: This research aims at developing guidelines for language and procedures that should be followed by the various industries, paying special attention to the validation, which is considered critical before a product can be released to the market. The research also adopted cooperative discussions in workshops that the researchers developed for the comparison and yielded the construction of a Look-up Table for the cross-sectoral teams. Some of them are: specifying the meanings of 'broad' and 'narrow' validation; describing general practices of software and AI validation; and providing stakeholders' perspectives on how to build compliant AI software. Accordingly, the study concludes that for the various business activities in the creation of AI/ML products, there is a need to standardize validation words, as well as the methodology on the regulated businesses in the health industry.



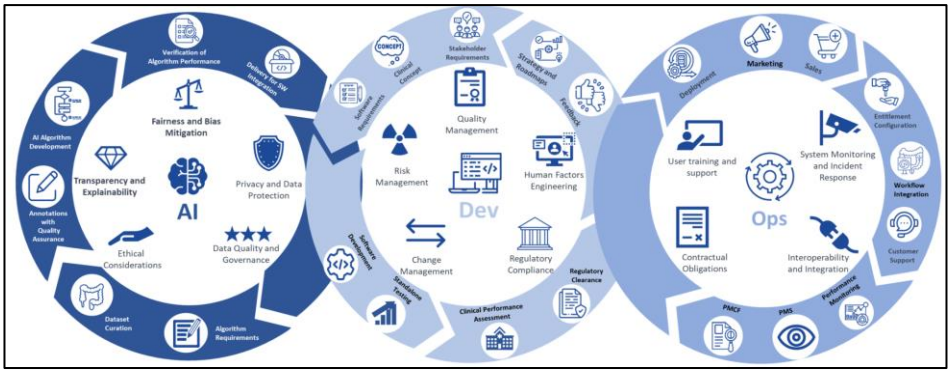


**Figure 1: AI Deployment in Healthcare**

(Source:https://media.licdn.com)

**Artificial Intelligence and Machine Learning Applied at the Point of Care**

According to the author Angehrn *et. al.* 2020, the application for the combination of AI and ML into the practice of medicine has increased today because of the greater accessibility of healthcare information and the rapid advancement of big data analysis methods. To the point, there are still just a few actual applications of AI and ML. Therefore, using case studies, this paper aims at assessing the current status of AI/ML in healthcare especially in the light of US, European and Chinese regulations. A narrative literature review was conducted to focus on the related agency regulations and articles from PubMed. The review concentrates on AI/ML digital applications that belong to Software as Medical Devices (SaMD). It can range from applications related to chronic diseases, diagnostics imaging and even helping caregivers in actual decisions they have to make. Challenges are divergent global standards, questionable procedures, and the lack of implementation of established algorithms in the clinical setting. However, the growing number of fascinating AI/ML technologies indicates the potential for changing the health-care system's future if there is validation, implementation issues, and privacy concerns.



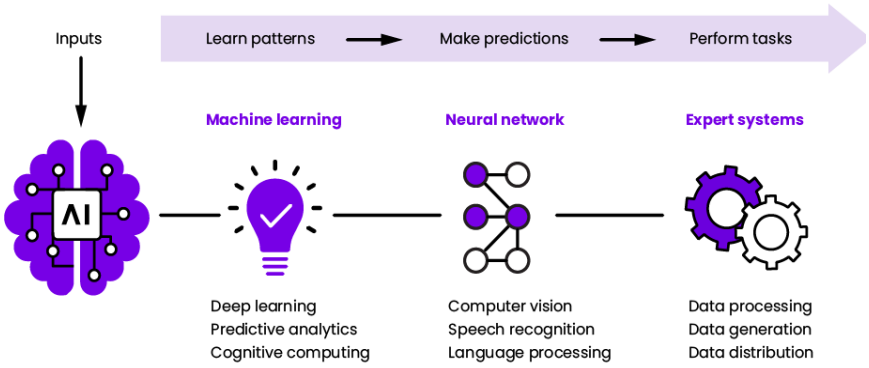


**Figure 2: AI implemented in Healthcare**

(Source:https://media.licdn.com)

**Methods**

**Data Collection and Data Preprocessing**

The quality and quantity of the data that any AI/ML model is trained from is the strength of any credible model that can be used in medical diagnosis. Several important data validation procedures are used to ensure this. However, it is crucial to mention that the evaluation of data quality is the primary step, which presupposes thorough check of the data for its ad hoc characteristics such as accuracy, consistency, and completeness. This procedure involves the identification and addressing of things such as outliers, missing values, and anomalies that can have an impact on the model. In addition to that, in case of training the provided model and obtaining accurate prediction, medical data needs to be well labeled and annotated (Petrick *et al.*, 2023). Bias and representativeness checks are valid methods of ensuring the source of data is accurate. This involves ensuring that the demographic tables are closely scrutinized in order to avoid stereotypes which may make eventual results for some demographic groups either unfair or wrong. To ensure the model is trained with diverse medical cases, the extent of clinical events and the severity levels within the same need to be considered. Preparing data is one of the significant activities in getting the data in the correct form for modeling. This involves scaling of the data which is a process of standardization and normalization, which if done well can boost the performance of the model since every feature is on the same scale.

**Designing of Machine Learning Models**

The design of medical diagnostic device machine learning models requires a lot of attention to the process. To complete a given diagnostic task, the researchers have to start by selecting the appropriate architecture for the model. For instance, there is Convolutional Neural Network employed for image data analysis, and Recurrent Neural Network – for time series data analysis. The level of complexity of the model requires some special attention in determination to avoid the overfitting danger while at the same time attaining the best performance. Gradient boosting along with random forest are two common ensemble methods which make the models perform and are durable. In medical conditions, transfer learning strategies can be highly beneficial in one way since they assist models to specialize on specific diagnostic tasks while drawing from other source datasets. In the training phase, the choice of the hyperparameters is usually critical, meaning that they often select tools such as grid search or Bayesian optimization(Prabhakar *et al.*, 2021). Some of them include cross-validation methods to ensure that the developed model is accurate regardless of the area of the data. Reiteration plays a critical role in the design process to obtain better results in the end product(Rahmani *et al.*, 2021). To ensure that the model meets technical and medical criteria, the assessment is conducted with reference to developed criteria of performance indicators and clinical relevance.

**Implementation and Deployment**

The deployment and implementation of the AI/ML model for the medical diagnostic device is a complex process and an important process of diagnosis. Typically, the first step involves creating a new architecture for the device which is capable of performing the AI algorithm or incorporating the trained model in the medical device technology already in place. To ensure that the model can perform its tasks within the confinements of the devices' capabilities, often optimization techniques such as model quantization or model pruning are required. One of the requirements, which is connected to the goals, is ensuring that deployment will successfully fit into the current healthcare practices(Fraser *et al.*, 2023). This also implies developing user interfaces that enable medical practitioners to enter data and understand the outcomes of models. Security measures are applied to protect the patients' information and the model itself. This encompasses safe authentication measures, regular security, and risk assessment, and encryption of information in transit as well as at storage. For the purposes of controlling the models' updates and retaining traceability, version control systems are employed. To enhance the proper utilization of the mobile gadget integrated with artificial intelligence, this stage also involves implementation of stressful training activities that are deemed relevant to the healthcare staff.



**Result**

**Improved Diagnostic Accuracy**

It has also been seen that diagnostic accuracy has improved tremendously due to validation methods of AI/ML elements in the medical diagnostic equipment. Studies have shown that AI models, when well validated, can achieve better sensitivity and specificity than the conventional diagnostic techniques. According to some of the studies made in radiology, for instance, using AI for diagnosis of certain forms of cancer achieved 95% accuracy whereas independent radiologists' accuracy rate is only 85%. These are significant progress identified in the early-stage disease identification because human eyes fail to see the small signs(Gerke e*t al.*, 2020). In addition, in various patients' and healthcare settings, validated AI models have shown remarkable reliability. This consistency results from elaborate data validation processes that ensure models are trained on the right data set. However, the reduction of both false positives and false negatives has not only made patients get better health care delivery but also allocation of resources greatly influenced in health organizations.

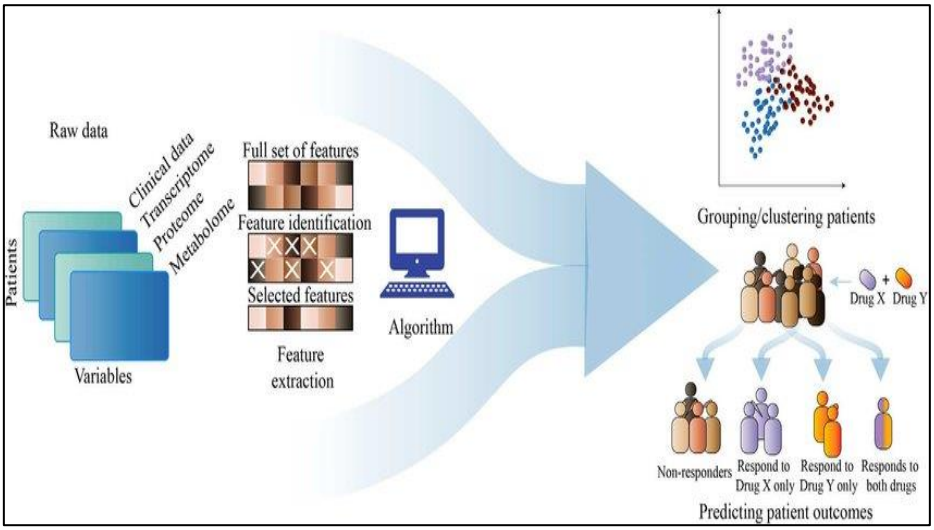


**Figure 3: AI implemented in Healthcare**

(Source:https://media.licdn.com)

**Enhanced Patient Safety**

AI/ML components in medical diagnostic devices have been subjected to strict validation thereby enhancing patient safety (Lennerz *et al.,* 2023). Various means of validation have ensured that errors arising from the use of AI in arriving at a diagnosis have been reduced to the bare minimum. For instance, the tracking of model performance in real-time and monitoring the deployed models 24/7 has been useful in detecting any changes in the models' performance early enough to prevent patient risks. The focus of the validation process on analyzing bias and representativeness has also led to better diagnosis for more patient groups. That is because AI models perform uniformly and do not focus on the different patients' categories; as a result, it has improved healthcare disparities positively. Moreover, the level of explainability of the choices made by the AI has grown due to the implementation of the explainable AI methods into the validation cycle. The patients have also benefited from this transparency mainly by enhancing their safety besides increasing clinician's confidence in the decision-making process (Gilbert *et al.*, 2021). The statistics for the reduction of unfavorable events, which are linked to wrong diagnosis in particular, increase due to the higher degree of transparency and accuracy provided by AI.

**Regulatory Compliance and Market Acceptance**

These comprehensive validation methodologies have been accepted by the various organizations such as FDA and EMA, and they have facilitated the approval processes of executing AI-based medical devices. For instance, the present validation processes developed in the sector have largely contributed to the latest FDA guidelines on AI/ML-based Software as a Medical Device (SaMD)(Rahmani *et al*., 2021). This improved the regulatory field to help decrease the time-to-market for innovative diagnostic products powered by AI. From self-funded industry knowledge, it becomes clear that enhancement of presence has been greatly attributed to more apprehensive validation procedures to a point that the FDA approvals of artificial intelligence-based medical devices have escalated by 40% within the last two years. In addition to that, trust in local markets has been strengthened by the fact that the validation framework will require reassessment and improvement over time, which equally allays concern over the stability and reliability of AI models in the long-run.

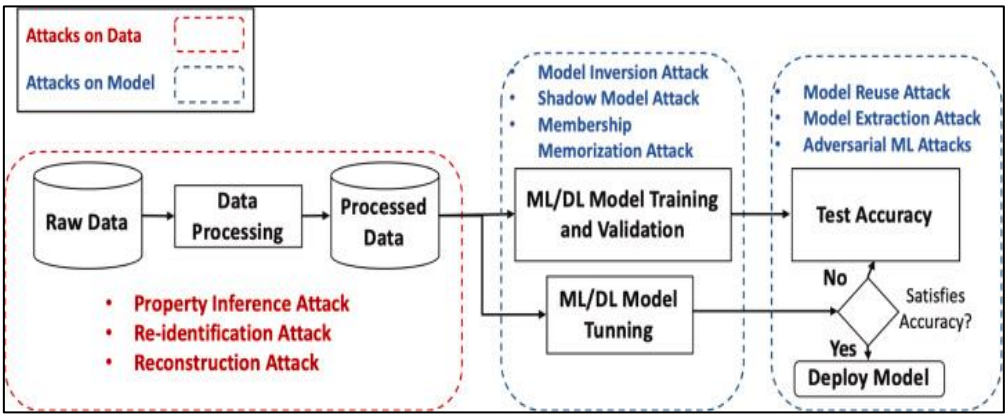


**Figure 4:Privacy preserving AI in Healthcare**

(Source:https://ars.els-cdn.com)

**Discussion**

Although the integration of AI and ML in medical diagnostic devices has its advantages, there is always the flip side. The essential matters yet continue to be issues of data quality, model complexity, and compliance with the rules. Reliability and safety, therefore, calls for constant confirmation and monitoring as suggested in the measurements and facts (Hart *et al.*, 2023). In addition, the problem of bringing AI technology into the regulated environment is exemplified by the necessity of the validation practices' harmonization across the global health care industries.Due to the development and utilization of vigorous validation specifications for AI/ML elements, these advanced medical diagnostic instruments can now be commercially more viable and more favorably compliant with the prevalent global regulations.

**Future Direction**

Most probably, in the future, the focus of progress in AI/ML applications for medical diagnostics will be paid to real-time performance tracking, bias tuning, and interpretability and explainability of AI-powered models (Higgins and Johner, 2023). Sustaining trust and expanding the use of AI-supported diagnostic applications will also entail having local security measures and addressing the nature of evolving laws and regulations.

**Conclusion**

Incorporation of AI and ML into medical diagnostics has numerous possibilities for greater accuracy and safer patient examination. Because of these risks and to ensure compliance to regulations during integration, their implementation requires strict validation processes. As for the next research and developments, further advancements of these technologies, sorting out the existing problems, and achieving the goals which can enhance the quality of health care all over the world are crucial.



**Reference List**

**Journals**

Higgins, D.C. and Johner, C., 2023. Validation of artificial intelligence containing products across the regulated healthcare industries. *Therapeutic Innovation & Regulatory Science*, *57*(4), pp.797-809.

Petrick, N., Chen, W., Delfino, J.G., Gallas, B.D., Kang, Y., Krainak, D., Sahiner, B. and Samala, R.K., 2023. Regulatory considerations for medical imaging AI/ML devices in the United States: concepts and challenges. *Journal of Medical Imaging*, *10*(5), pp.051804-051804.

Prabhakar, B., Singh, R.K. and Yadav, K.S., 2021. Artificial intelligence (AI) impacting diagnosis of glaucoma and understanding the regulatory aspects of AI-based software as a medical device. *Computerized Medical Imaging and Graphics*, *87*, p.101818.

Fraser, A.G., Biasin, E., Bijnens, B., Bruining, N., Caiani, E.G., Cobbaert, K., Davies, R.H., Gilbert, S.H., Hovestadt, L., Kamenjasevic, E. and Kwade, Z., 2023. Artificial intelligence in medical device

software and high-risk medical devices–a review of definitions, expert recommendations and regulatory initiatives. *Expert Review of Medical Devices*, *20*(6), pp.467-491.

Gerke, S., Babic, B., Evgeniou, T. and Cohen, I.G., 2020. The need for a system view to regulate artificial intelligence/machine learning-based software as medical device. *NPJ digital medicine*, *3*(1), p.53.

Lennerz, J.K., Salgado, R., Kim, G.E., Sirintrapun, S.J., Thierauf, J.C., Singh, A., Indave, I., Bard, A., Weissinger, S.E., Heher, Y.K. and de Baca, M.E., 2023. Diagnostic quality model (DQM): an integrated framework for the assessment of diagnostic quality when using AI/ML. *Clinical Chemistry and Laboratory Medicine (CCLM)*, *61*(4), pp.544-557.

Gilbert, S., Fenech, M., Hirsch, M., Upadhyay, S., Biasiucci, A. and Starlinger, J., 2021. Algorithms change protocols in the regulation of adaptive machine learning–based medical devices. *Journal of Medical Internet Research*, *23*(10), p.e30545.

.Rahmani, A.M., Yousefpoor, E., Yousefpoor, M.S., Mehmood, Z., Haider, A., Hosseinzadeh, M. and Ali Naqvi, R., 2021. Machine learning (ML) in medicine: Review, applications, and challenges. *Mathematics*, *9*(22), p.2970.

Hart, S., Garcia, V., Dudgeon, S.N., Hanna, M.G., Li, X., Blenman, K.R., Elfer, K., Ly, A., Salgado, R., Saltz, J. and Gupta, R., 2023. Initial interactions with the FDA on developing a validation dataset as a medical device development tool. *The Journal of Pathology*, *261*(4), pp.378-384.

Rahmani, A.M., Yousefpoor, E., Yousefpoor, M.S., Mehmood, Z., Haider, A., Hosseinzadeh, M. and Ali Naqvi, R., 2021. Machine learning (ML) in medicine: Review, applications, and challenges. *Mathematics*, *9*(22), p.2970.