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# Pressure Points of FDA AI Regulation

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# Typical Types of AI Powered Devices

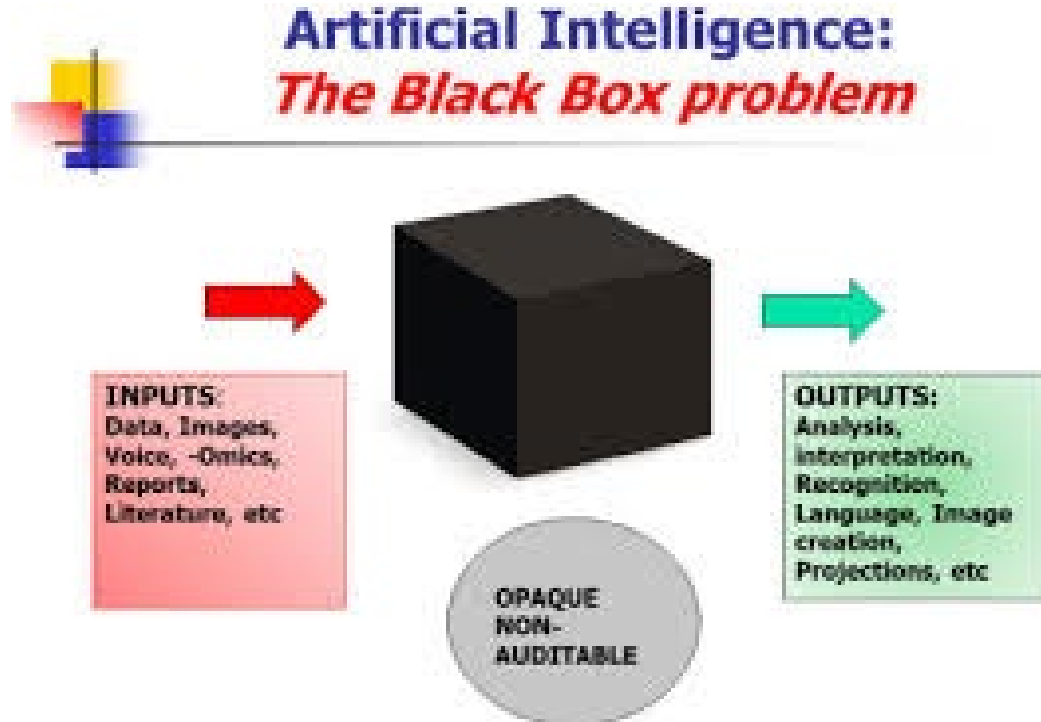
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- CAD – Computer Assisted Detection
  - Auto segmentation of features
  - Detection of regions of interest
  - Diagnosing pathology
  - Triaging review order
  - CT/MRI/ultrasound/histology/OCT/etc.
- Novel interpretation of data to make a prediction or diagnosis
  - Non-traditional assessment of data from traditional sensors (Afib from PPG)
  - Combination of non-traditional inputs to determine a risk score (risk score of Alzheimer's based upon sleep data and speech analysis)
  - Patient specific treatments (recommendation to use a specific anti-depressant due to various physiological outputs)

- AI-enabled devices are regulated under same regulatory paradigm as all other medical devices
  - “AI refers to a machine-based system that can, for a given set of human defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments.”<sup>1</sup>
- AI-enabled devices have all the same challenges as clinical decision support software
- However, AI also raises unique regulatory challenges
  - FDA current thinking published in GD: **Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations**
  - Some of this guidance is already common practice, some are yet to be enforced.
- This leads to unique pressure points

# The Fundamental Challenge with AI

At the end of the day, all FDA cares about is that your data supports device effectiveness in the general US population



- Due to the Black Box problem, FDA is more skeptical about the applicability of validation testing to the general US population than deterministic algorithms. This leads to many of FDA's pressure points

# FDA Regulates Software Based on Perceived Risk

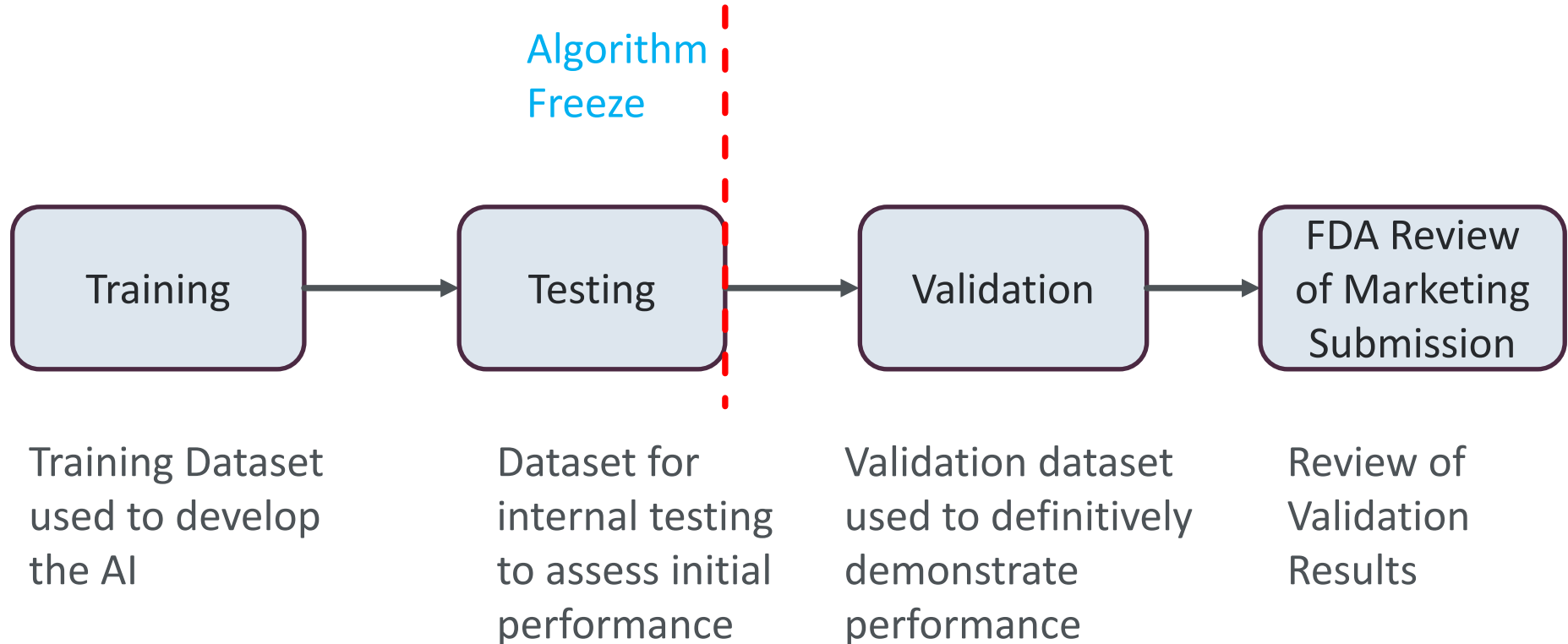


**IMDRF** International Medical  
Device Regulators Forum

State of Healthcare Situation or Condition	Significance of information provided by SaMD to the healthcare decision		
	Treat or Diagnose	Drive Clinical Management	Inform Clinical Management
Critical	IV	III	II
Serious	III	II	I
Non-Serious	II	I	I

- All AI CDS software is defined as a medical device as the user cannot independently verify the software's output
- Risk strongly depends on the device output and target audience
- Different levels of risk can lead to different regulatory pathways and data expectations

# Steps of AI Algorithm Development



- A statement that AI is used in the device
- A description of the device inputs and device outputs, and clarify if entered manually or automatically
  - FDA wants a very detailed description of the user interface that makes it clear what information is provided to the user and when in the workflow it is provided
- An explanation of how AI is used to achieve the device's intended use.
- A description of the intended users
- A description of the intended use environment
- A description of all configurable elements
  - Things the user can turn on or off
  - What is auto-populated and what needs to be confirmed by the user

- Statement that AI is used in the device and how AI is used to achieve the device's intended use
- **Model inputs**, including instruction how the user should prepare input data
- **Model output(s)** and how they are to be used
- **Model Architecture** - High level description of the methods and architecture used to develop the model
- **Model Development Data** - Description of the development data used to train and test the algorithm
- **Performance Data and Metrics** - Description of the validation data and how the device performed, including across important subgroups
- **Limitations** – Disclosure of any known limitation, such as subgroup in which the device was not adequately trained/validated

- Software should comply to **ANSI/AAMI/ISO 14971** Medical devices - Applications of risk management to medical devices and **AAMI CR34971** Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning
- Risk of user misunderstanding device output is higher for AI devices
- FDA also has increased concern with use related risks
- **Included in the software risk management file**

- Describe how training/testing/validation data is collected, processed, annotated, stored, controlled, and used.
  - Demonstrate adequate separation of training, testing, and validation data
- The performance and behavior of AI systems rely heavily on the quality, diversity, and quantity of data used to train and test them. FDA is looking for possible sources of bias.
  - Over-training leading to over-fitting to a specific characteristic
  - Inadequate subpopulation representation leading to poor performance in the subgroup
  - Inadequate/inconsistent truthing of data or annotation
  - OUS data
- Justify representativeness of data in terms of disease conditions, population subgroups, and diverse data collection sites
- **Included in the performance testing section of submission**

# Model Description and Development

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- **Model description**
  - inputs and outputs;
  - architecture;
  - features and parameters;
  - description of any pre/post processing of data
- **Model Development** - describing how the model was trained
  - optimization methods,
  - training paradigm (e.g. supervised, etc.),
  - training hyperparameters,
  - summary of training performance
  - explanation how any thresholds were determined
- **Included as part of software description in software section**

- Stand-alone validation vs. reader study
- Similar to other validation studies except for additional focus on subgroup analyses
  - Sex
  - age,
  - race,
  - ethnicity,
  - disease variables,
  - clinical data site,
  - data acquisition equipment
- Only need to be powered if intending to make a claim for the specific subgroup

- **Monitoring Plans** track device performance in the real-world environment to assess presence of drift or identify poor performing subgroups
  - Not generally required for 510(k)s
  - May be required for de novos if identified as a special control
  - May be a condition of approval for PMAs
  
- AI also presents some unique concerns and mitigations for cybersecurity
  - Primary related to the risk of altering the data used to train the algorithm

- Big push for increased transparency to the patient/user
- 510(k) Summary should include:
  - A statement that AI is used in the device and how achieves the device’s intended use.
  - A description of the class of model (e.g., convolutional neural network, recurrent neural network, support vector machine, transformers) and limitations of the model
  - A description of the development and validation datasets (size, source of data), including information about the demographic characteristics in the training and validation data,
  - A description of the statistical confidence level of predictions
  - A description of how the model will be updated and maintained over time, if applicable.
- FDA proposed a “Model Card” for a standard format for the presentation of this information
  - See Appendices E and F of the GD

# FDA Pressure Points and How to Handle Them

## Pressure Point

## Successful Approach

Applicability of training dataset to validation dataset

- Training bias
- Poor truthing

- Minimize differences in training dataset and validation dataset in terms of truthing methods and population characteristics
- Completely separate datasets
- Company risk, not FDA risk, but can affect data requirements

Applicability of validation data to general US population

- Training bias
- Unknown effect of geographic factors
- Unknown effect of patient characteristics

- Validation typically needs to be in the US, in at least 3 geographically diverse sites
- Force diversity in validation population for factors that may affect algorithm performance
- Preplanned subgroup analyses to check for factors that are affecting performance

# FDA Pressure Points and How to Handle Them

## Pressure Point

## Successful Approach

AI will replace human judgement

- People are lazy
- Less trained/skilled users

- The less involved a HCP is, the greater the risk the device presents.
- Limit what information is presented to the user,
- Require user to confirm/review AI output

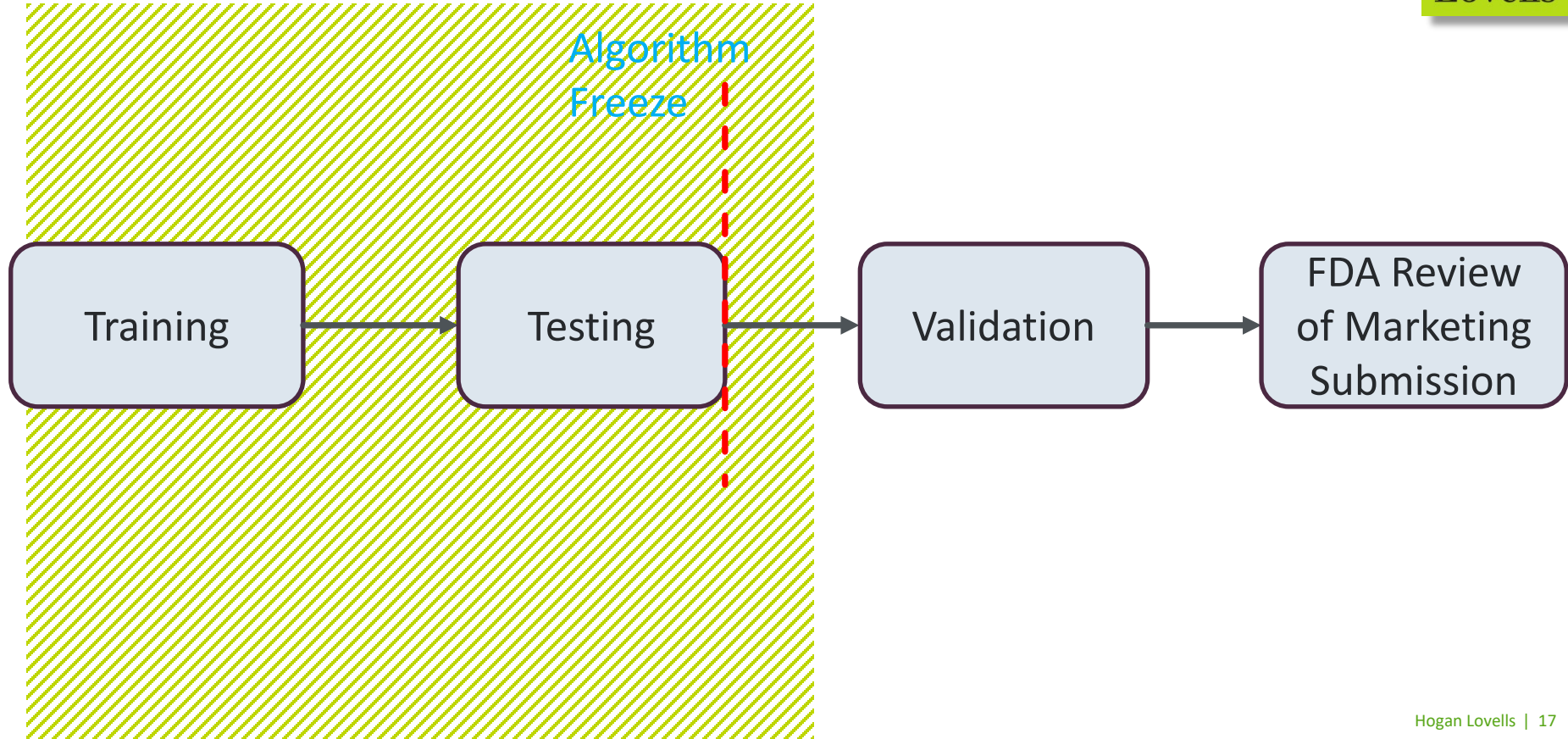
AI continues to learn

- Freeze algorithm prior to validation
- Predetermined Change Control Plan

AI algorithm is a black box to the user

- Increased transparency in the labeling and public facing documents

# When to Approach FDA with a Presubmission



# Questions?



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