Machine Learning for Medical Devices

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Machine Learning for Medical Devices

Machine learning is being applied to many Medical Devices. Sunrise Labs discusses what makes a good device application for Machine Learning, common pitfalls, what issues can arise, some techniques to overcome them, illustrated by relevant case studies

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Terminology

Artificial Intelligence

Able to learn automatically/continuously to adapt and improve

- Feels like human intelligence

Classifier / Regressor

Algorithms that decide what something is or assign a value to it

- Separate into classes, i.e. Cancer vs. Non-cancer
- Regressors assign a predicted value

Machine Learning Search Engines

Used to evaluate data to optimize Classifiers and AI

- Tries many combinations
- Merit Function used to compare them

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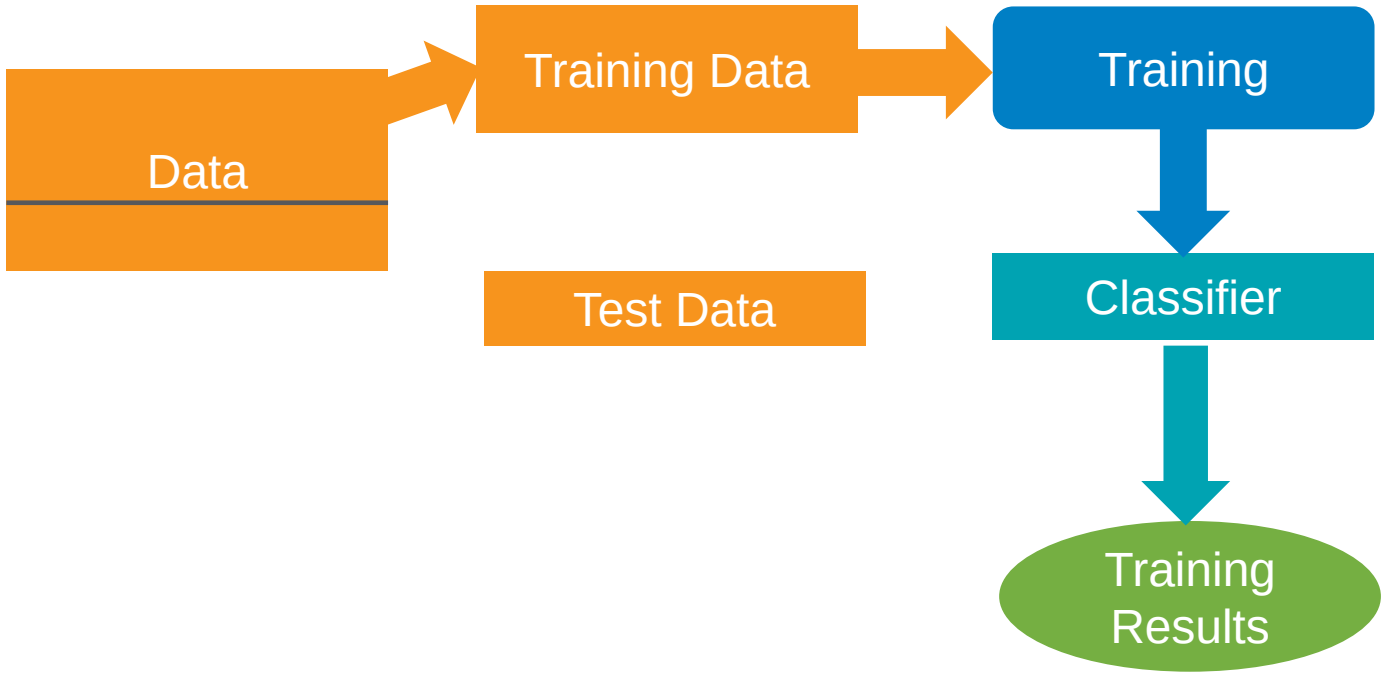
Testing and Training

Data Sets are split into:

1. Training
2. Testing



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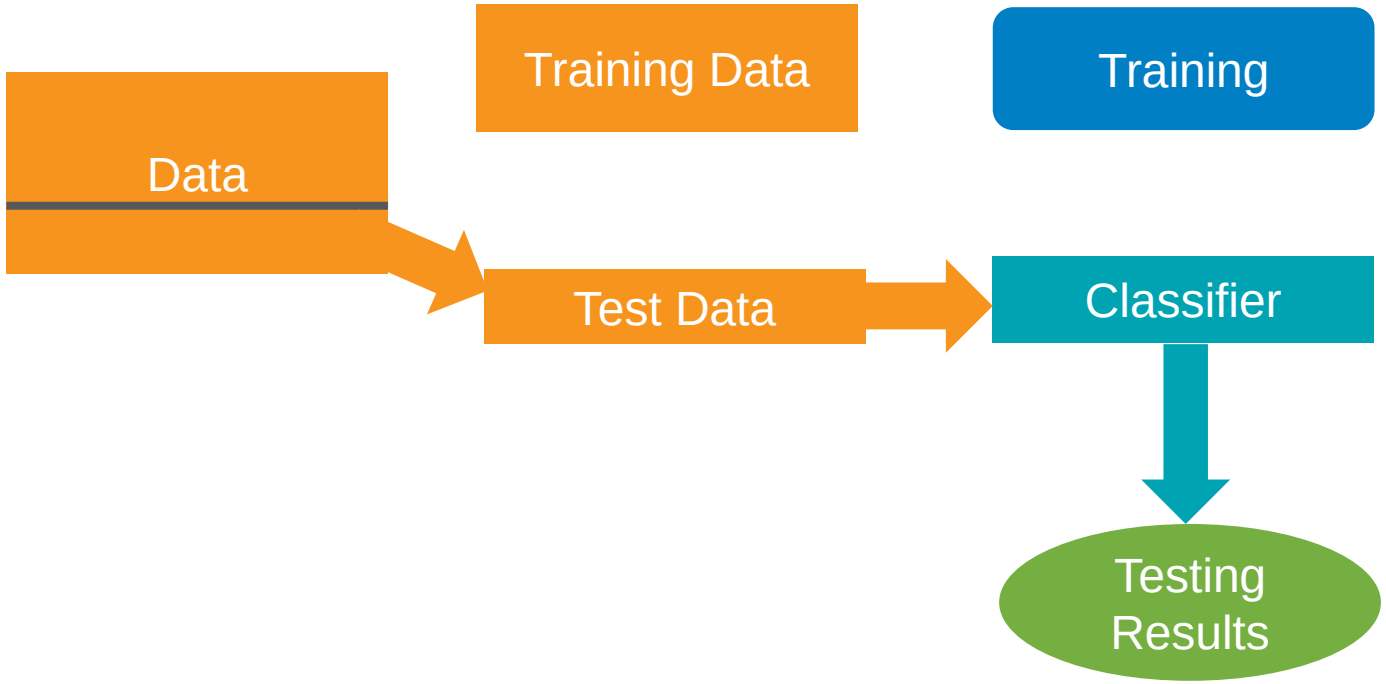

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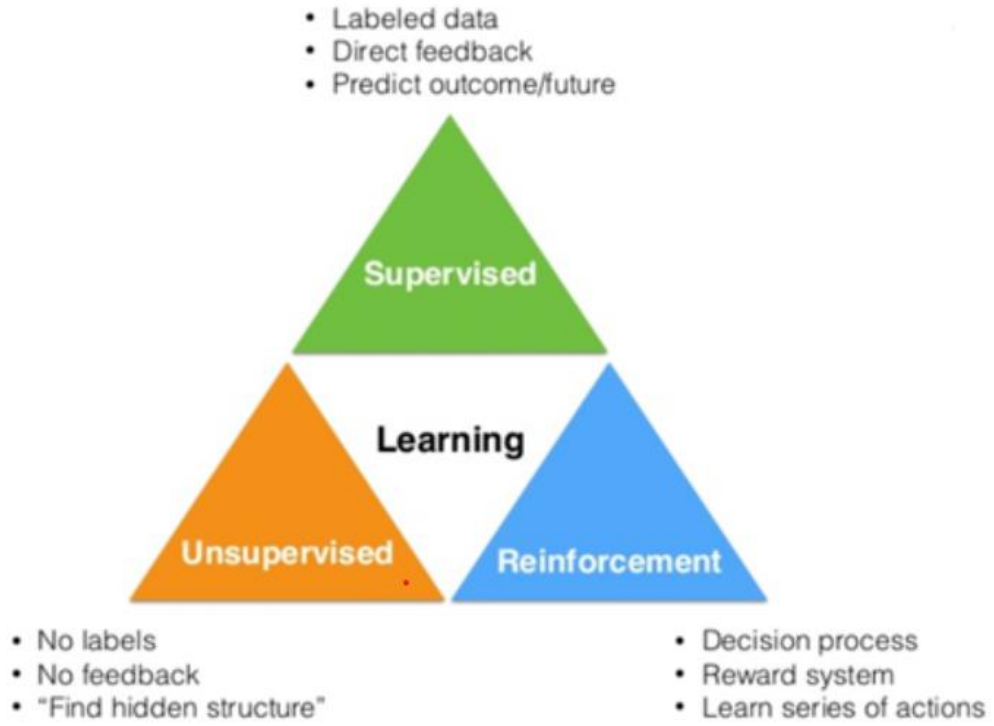
Supervised vs. Unsupervised Learning



Devices usually use Supervised Learning

- i.e. a Diagnostic device: whether a disease is detected
  - Uses another method to label data

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Gold Standard For Supervised Learning

Gold Standards

- Ground truths for labeling data with
  - Existing instruments
  - Panel of Experts, i.e.. Pathologists

- Lots of Data isn’t always helpful
  - Device Data from the field often does not come with a gold standard label

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Issues with Machine Learning in Medical Devices

- Small Data sets
- Overtraining
- Available Data sets not applicable
- Repeatability
  - Intra and inter instrument repeatability
  - Things that won't be repeatable (i.e. image rotation)

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Issues with Machine Learning in Medical Devices

- Finding the right application that ML will be useful for
- Outliers
- Latency

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Issues with Machine Learning in Medical Devices

Startup issues

- Overtraining with small data sets
  - Techniques re-use data in different combinations but can be misleading
- Gold standard or instrument design drift
- Presorting Data
  - Outpatient vs. inpatient
- Initial prototype data is often better to discard than keep

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What makes a good application for Machine Learning in Medical Devices?

- Easy to obtain Data
- An accurate Gold Standard
- Classifier not sensitive to instrument, technique
- Knowing what is good enough

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What makes a good application for Machine Learning in Medical Devices?

- Adequate information in data to inform classifier
- Does the information discern the gold standard?

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What makes a good application for Machine Learning in Medical Devices?

- Is Metadata available, reliable or helpful?

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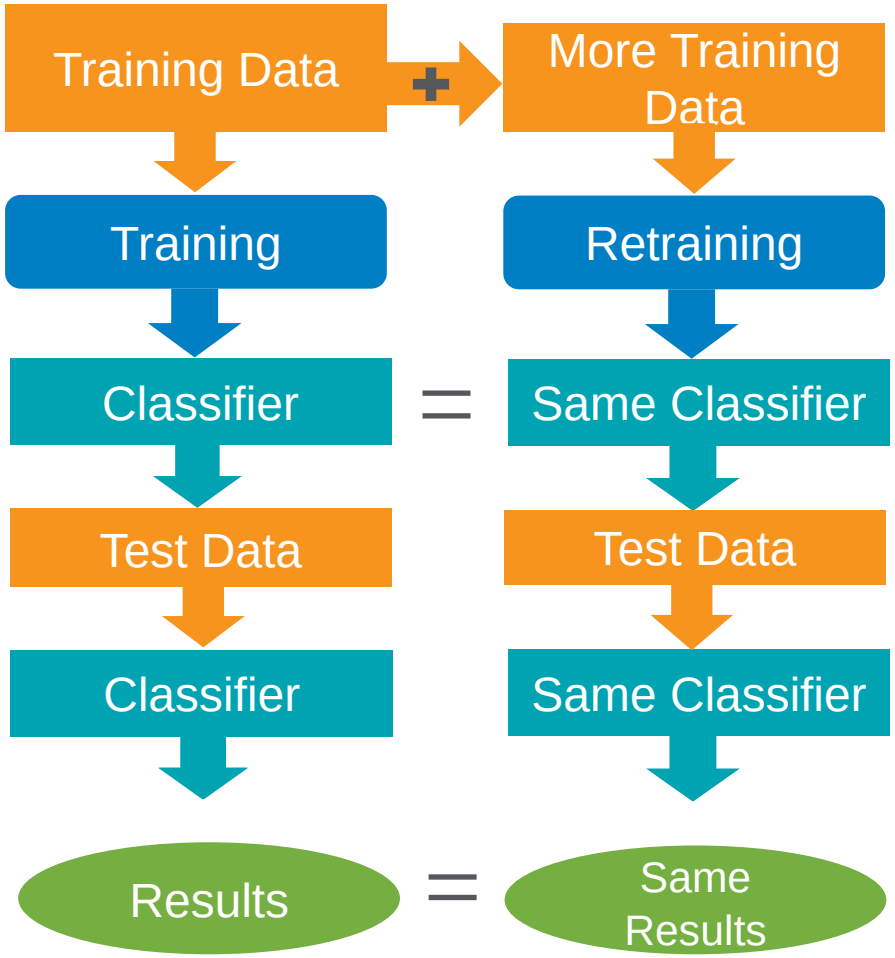
Convergence

Adding Data doesn't change classifier or test results



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Technique

- Don’t overtrain

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Repeatability

- Repeatable Instruments
- Operator Variability Minimized

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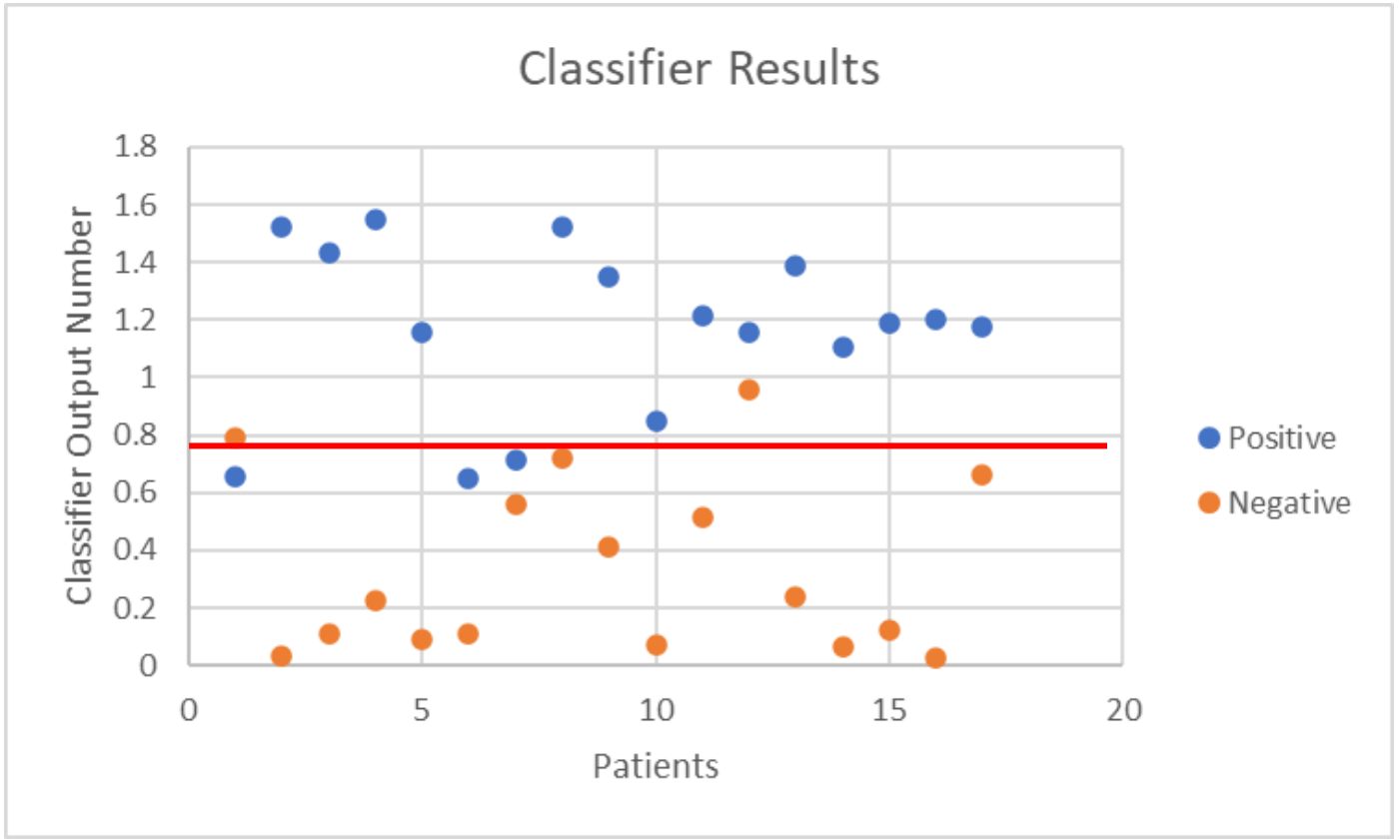
Repeatability

- Make Repeatable Instruments



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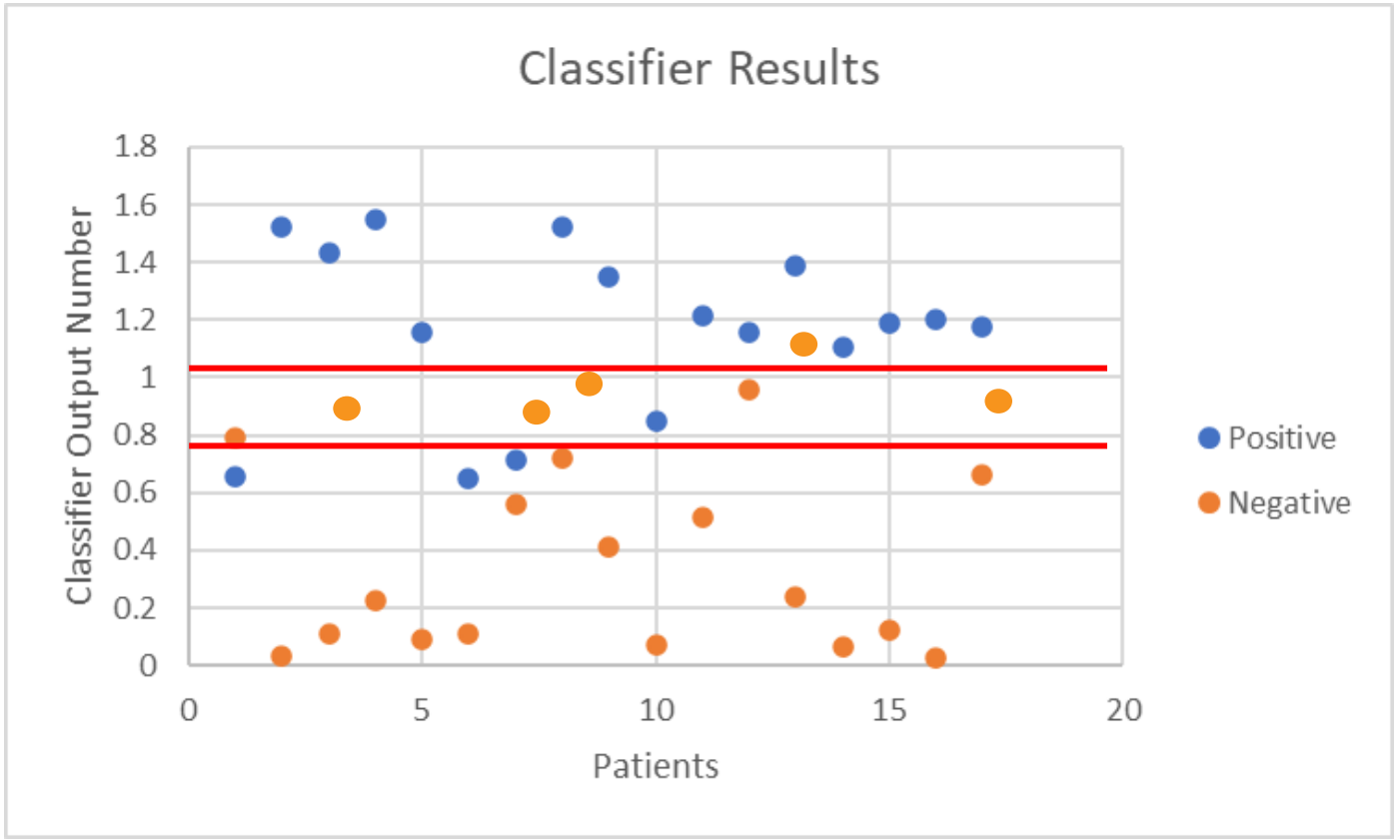
Repeatability

- Make Repeatable Instruments



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PreTraining

- Simulated Data
  - Generated from Mathematical Models
    - Make as close to reality as possible
    - Include noise and confounders
- Similar Data
  - i.e. cats vs. dogs

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Searching

- Auto search parameter optimization
  - AWS Autopilot
- Metadata to see what helps

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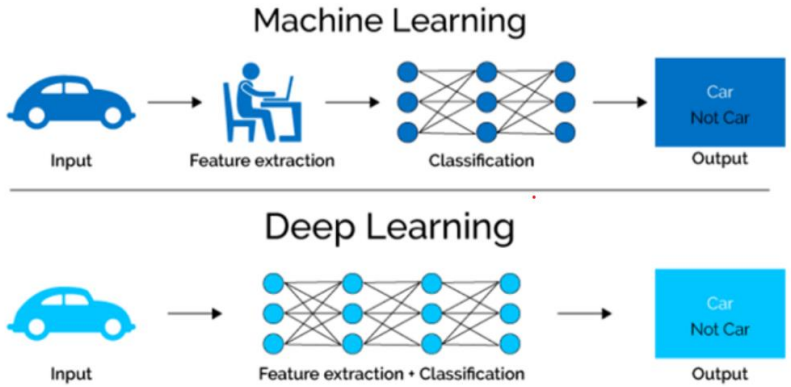
Techniques

- Pre-process the data to remove irrelevant information
  - Filter out 60 Hz
  - Normalize data
  - Instrument calibration
- Add Features to search space
  - Utilize knowledge about what matters



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FDA

- FDA published a discussion paper "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback"
- SaMD
- Changing Algorithms/Lifecycle Process

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FDA

- Risk Based

State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

SaMD IMDRF risk categorization (I = lowest, IV = highest)

Artificial Intelligence and Machine Learning in Software as a Medical Device (SaMD)

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Questions and Comments?

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THANK YOU!

Please visit our website for more information, and to view our portfolio: www.sunriselabs.com

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We look forward to learning more about your needs and development plans!!

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