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## ACP: Algorithm Change Protocol

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## **ACP Purpose and Goal**





- Present comprehensive protocol that supports the planned modifications outlined in the Software Prespecification Plan (SPS) and explains how modifications will be implemented.
- The ACP can leverage the methods used to obtain SaMD/SiMD clearance/approval.
- The ACP focuses on what needs to be done differently/accounted for to implement an algorithm change/modification as part of the Predeterminded Change Control Plan (PCCP) without requiring regulatory resubmission.





## **ACP Content**

#### Performance Evaluation & Monitoring Plan

- Algorithm Testing/Monitoring in Post-market
- Frequency of assessments/Triggers for Evaluation
- Statistical Analysis Plan

#### Algorithm Retraining & Rollback Plans

- Retraining Criteria/Objectives
- Algorithm Assessment/Evaluation for IFU expansion

Backup/Recovery Procedures

## Data Management Plan

- Training & Test Data collection Protocols
- Quality Assurance
- Data Usage

## Algorithm Update Plan

- Version Tracking and Control
- V&V Methods
- Update Triggers and Procedure
- User Communication Plan





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## Data Management Plan

#### **Data Collection**

- Can be dependent on the type of AI/ML algorithm employed
- Data description
- Data sources/Provenance
- Development Training Set vs Test Set

#### QA and Data Usage

- Data quality and methods to ensure data quality is maintained is critical
- Data usage dependent on:
- Prevalence/data set balance
- Data set size
- Model feature suitability & data profile

#### **Bias Minimization**

- Steps taken to minimize bias against age, gender, race/ethnicity, disease, etc.
- Describes steps or methods to avoid or be aware of known bias in the results
- Ensure the device is properly labeled so that the end user can be aware of device limitations.



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## Performance Evaluation and Monitoring Plan

Performance Evaluation:

- Dependent on model type such as:
  - Classifier Model predict discrete class label (e.g. true/false, dog/cat/mouse, etc.)
  - Regression Model predict continuous quantity (e.g. price of a home or stock in the future)
- Statistical analysis plan
  - Methods for comparing the distributions of the various sets of features in the algorithm
  - Methods used to estimate the strength of evidence needed to support the change
  - Methods for assessing device performance
- Performance Evaluation and Monitoring go hand in hand
  - Comparing algorithm outputs over time
  - How performance matches up with expected prevalence
  - Use of device in different environments

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• Frequency of error or invalid results



## Algorithm Update Plan

## Software V&V

• Ensure the model performs as intended utilizes the methods discussed in the prior slide.



#### **Update Triggers and Procedure**

- Criteria for triggering an update is prespecified in the SPS
  - Can be based on time intervals, performance degradation, availability of new data, end of life
- Procedure details how updates will be implemented/delivered to the end user
  - Outlines the test set used, personnel responsible for verifying results, and testing environment
  - Includes communication and training plans where applicable

## Version Tracking and Control:

- Critical to ensure reproducibility and identify "performance drift" ×
- Does not just apply to the overall algorithm, but also each element that feeds into the process.

## Algorithm Retraining and Rollback Plans



VS

- Retraining involves more work to salvage a current version with objective:
  - Improve model performance/predictability
  - Change model functionality within an intended use
  - Adapt to changes in monitored population



- Rollback involves reverting back to a prior version with known stability and acceptable performance expectations
  - $\circ$  Based on pre-establish rest criteria.
  - Expected to be highly utilized for continuous learning algorithms
  - Can serve as a stopgap during the retraining phase





# ACP Examples!



**MDICx: AI/ML Framework Public Comment** 

**Coming Soon!** 

## Software in a Medical Device (SiMD)



## Blood-based diagnostic test for breast cancer

- IVD Assay, IVD instrument, & ML-based algorithm to provide a diagnosis using analytes in a plasma sample.
- High score or a positive classification may indicate the presence of undiagnosed breast cancer.

#### **Proposed Modifications**

- Improved performance claims via retraining
- Use of new analyte(s)
- Expand IFU to cover new disease space – Lung cancer

#### What Do We Think?

Do these all seem reasonable for a PCCP?



## Software as a Medical Device (SaMD) – Tool Claim

## Smartphone-Based IVD White Blood Cell Count Test

- Consists of a IVD Assay, IVD standard control imaging card, & ML-based algorithm to analyze and provide numerical output.
- Imagine it is a point of care white blood cell counter, capable of providing accurate white blood cell counts for a variety of clinical uses.

## Proposed modifications

- Expand smartphone compatibility for use with other models and vendors.
- Expands compatibility to allow applications to run on other "3<sup>rd</sup> Party" assays.

#### What Do We Think?

Do these all seem reasonable for a PCCP?



## SaMD – Clinical Claim



## Smartphone-Based IVD athome test for diagnosing Influenza A&B

 Consists of an IVD assay, IVD imaging card, & MLbased algorithm to provide a diagnosis.

#### Proposed Modifications

- Expand compatibility to use different analytes and reagents.
- Expand the IFU to include an already cleared SARS-CoV-2 test.

#### What Do We Think?

Do these all seem reasonable for a PCCP?





## **Thank You!**





