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From Start to Finish: Considerations and Decisions for Al Wearable SaMDs

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Agenda

- -Introduction
- -Concept
- -Design and Development
- -Verification and Validation
- -Submissions and Post-market





Introduction



SaMD on Wearables





What makes SaMD Wearables unique?



Consumer grade inputs

Consumer wearables are always part of a larger ecosystem



Processing power on wearables



Screen space on wearables limited

- Sensors used for both medical and non-medical purpose
- Need to consider interaction with the mobile platforms in addition to the wearable platform
- How to split computing on wearables vs
 mobile/cloud

Usability/accessibility big factors









Common Themes during this presentation



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Concept





Intended Use and Indications





Algorithm training and testing

AI/ML model

Testing/Validation

Test Data Set: A set of data that is never shown to the ML training algorithm during training, that is used to estimate the ML model's performance after training.

Medical device validation: Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

Data curation refers to the selection, management and assessment of the independent and dependent attributes (labels) of data sets.

Conflicting interpretations of the term validation: data validation, ML model tuning, and medical device validation

Training/Re-training

Process intended to establish or to improve the parameters of a ML model, based on an ML training algorithm, by using training data.

optional tuning phase can be combined with the Training phase to optimize the ML model selection







Considerations 7 **** HEALTHCARE AFDC AFDO RAPS PRODUCTS 10 RAPS COLLABORATIVE



Example

Heart rhythm feature?

ECG

Need ECG sensors

PPG

Need optical sensor.

What else? e.g. accelerometer







Design and Development





Planning

		3 rd Party Wearable	1 st Party Wearable	Details
1	Wearable launch	\times		• Usually SaMD for 1 st party to be available at the same time as the wearable availability
2	Scalability	\times	\checkmark	 Consider 1st party wearable and portfolio
3	Change Management	×		 Consider QMS processes involving pre-alpha versions of wearables









Specifications

Development

Consider the compatible wearables 2 to be put forward for the submission **Training**Initial specs considered in the

training set

Change Management

Consider the pre-determined specifications for changes









Usability

Why	 AI/ML algorithms are a black box to lay users More information → help users understand if they are eligible to use the product
What	 Results user is likely to see Reliability of the result → testing and performance
How	 Design to ensure the user does not misinterpret the results Design to ensure that there is no overreliance on the device









V&V Plan

1st party wearables

- Plan for when the wearable prototypes will be available for testing
- Assess the stage at which the prototype can be used for the device testing
- Pre-testing schedule to be completed before final testing







Verification and Validation





Clinical



PRODUCTS

COLLABORATIVE

RAPS

AFDO

RAPS

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HFE

HFE Testing

• Does the user interpret the information and results provided to them appropriately?









Software V&V

Software V&V

- Similar to general software V&V
- Scale testing based on types and #compatible wearables









Non-Clinical

Non-clinical

- Bench test planning

 Scale
- Novel sensors require innovative bench testing
- Combination of testing
 - Aggressor
 - System
 - Hardware







Submission and Post-market





Submission

Submission

- Similar to general software submissions
- Pre-submissions recommended









Change Control

Change Control

- Possible changes
 - Hardware
 - **OS**
 - Firmware updates
 - New compatible wearables
- Process to test and assess for changes → submit premarket application for significant changes







Real-world metrics

Real-world metrics

- Large amounts of data
- Frequent data processing
- Postmarket metrics can be as frequent as monthly/quarterly
- Possibilities for new training data for continuous update







Thank you!

