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SPS: Software Pre-Specification

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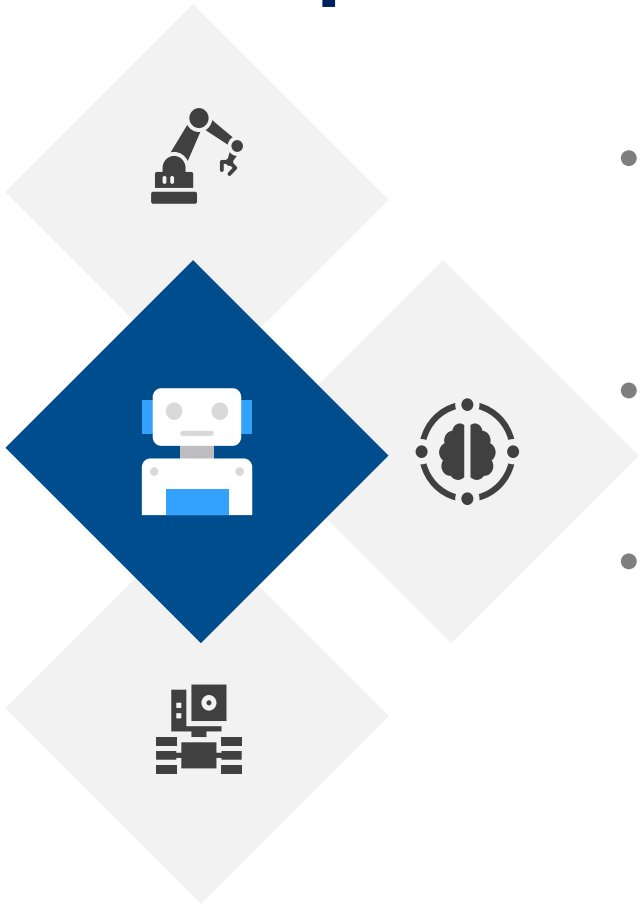
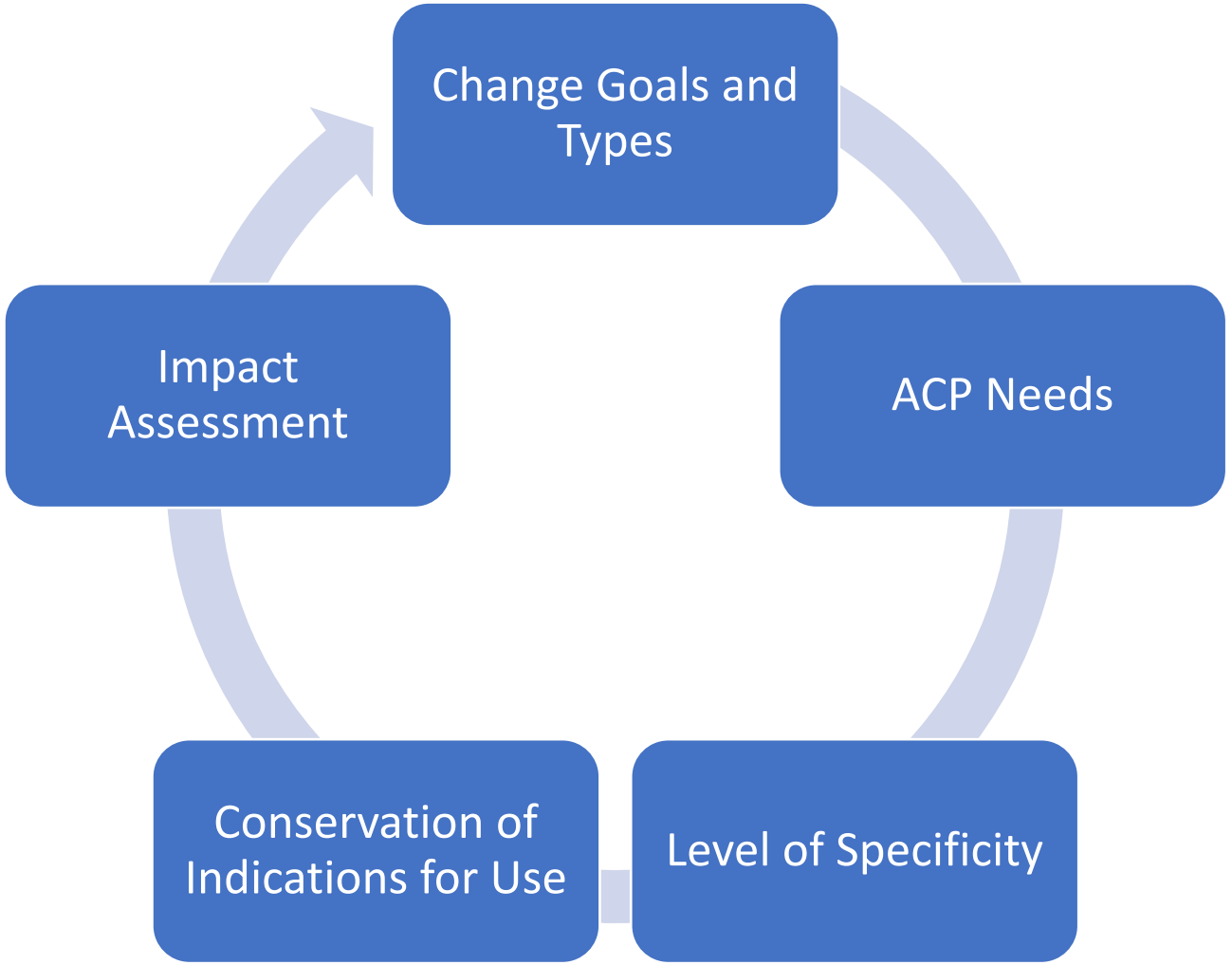
SPS Purpose and Goal



- SPS is a means by which to Pre-specify changes to “performance” or “inputs” or changes related to the “intended use” for a software post clearance/approval.
- The SPS draws a “region of potential changes” around the initial specifications and labeling of the original device.
- The SPS focuses on the specific changes proposed or change goals as part of the Predetermined Change Control Plan (PCCP) without requiring regulatory resubmission

SPS Content

- Can these changes be achieved by existing change guidance?
- Are they specific enough?
- Is intended use conserved?
- What's the impact?
- Is my ACP relevant?



Types of Potential Change Goals in an SPS

Type 1 – Modifications Related to Performance

- Changes that result in improvements to analytical and clinical performance
- Changes to Archetecture
- NOT a change in intended use
- NO change in fundamental use claims

Type 2 – Modification related to Inputs

- Expanding the SaMD's range of inputs, such as new input signals.
- Can be changes in input manufacturers for the same general data type.
- Can be different signals used to improve the performance of the model.
- NO change in outputs

Type 3 – Modifications to Intended Use

- Change in the significance of the output
- Expand intended patient population
- Can be challenging to conserve indications for use / intended use

Algorithm Change Protocol Needs

Interrelationship between proposed SPS Changes and ACP

- The ACP developed should apply to all of the proposed changes in SPS.
  - Analogous to software requirements, a good requirement is validateable. Similarly, good change goals should be able to be to be supported by the ACP.
  - ACP content will be dependent on type of changes proposed and the impacts of those changes.
- More detail in Jeff's Presentation on ACP implementation

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Level of Specificity key for a successful SPS

Type 1 Changes – Changes in Performance

- Easiest to prespecify
- Performance is often measured using the same methods the device is initially cleared using
  - Sensitivity/specificity
  - AUC, PPV, NPV, etc.
  - Changes should not change intended use

Type 2 Changes – Changes in Input

- More challenging to prespecify because the inputs should also be prespecified
- List of data sources should not be open ended
- The source of data should be well known and have fixed specifications.
- Typically these should be established using existing sources of data, not under development.
- If specs are available to limit scope, they should be included.

Type 3 Changes – Change in Intended Use

- Changes in intended use are the most difficult to prespecify
- The proposed changes should not change the verbatim indications for use.
- Changes in intended use would conserve substantial equivalence for the initially cleared 510k (for 510k) and conserve the written indications for use for PMA.

Conservation of indications for use, intended use

- These concepts apply regardless of regulatory pathway PMA vs 510k/de novo
- For Type 1 & Type 2 Changes both apply intended use/indications for use should both be conserved
- For Type 3 changes, intended use may change but indications for use would need to be conserved.
- Perhaps with future legislation these concepts can be flexible, but difficult to speculate.
- Currently hard to imagine a situation where indications for use change without FDA oversight due to PCCP.

Impact Assessment

- Can these changes be done already without a PCCP?
- What is the impact of the changes on the baseline represented by the cleared/approved device?
- Do the changes introduce new risks?
  - Does improved performance change the perception of intended use?
  - Does change in inputs change the intended use of the device?
  - Does change in intended use change the indications for use?
- Are the proposed change goals specific enough? i.e. are they too broad?
- Do the proposed changes change the indications for use in a way that necessitates a new indications for use statement?
- What new labeling is needed to support the changes once implemented?
- Are best practices being followed?
- Are old results updated or tied to version numbers?

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SPS Examples!

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SPS Examples

SiMD – TENS Stimulator

- Transcutaneous electrical nerve stimulation of the elbow for tendonitis (tennis elbow).
- Unlocked ML Algorithm balances stimulation intensity vs perceived pain and adapts to patient preferences.
- Modifications:
  - Improved patient customization
  - Use of a new electrodes and user input from smartphone
  - Expand IFU to cover new body part– Knee

SaMD – Radiological Triage

- Radiology – Computer Aided Triage & Notification
- Incidental Lung Nodule Notification from Chest X-Ray
- Modifications:
  - Expand X-Ray scanner compatibility to allow for use with other models and vendors
  - Improve Performance

SaMD – Digital Therapeutic

- Smartphone-Based Augmented Reality for treatment of PTSD.
- Uses AI to make therapy recommendations from sensor inputs from off the shelf smart watches.
- Modifications:
  - Expanding IFU to include different stressors.
  - Expand sensor inputs to include smart watches.

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SiMD – TENS Stimulator

SiMD – TENS Stimulator for Tennis Elbow

- Device is a closed loop stimulator applied to the elbow for relief from tendonitis.
- App takes feedback from the user on discomfort from the stimulation vs relief from the tendonitis and uses fixed AI model to set amplitude and frequency of stimulation.
- Can be overridden by manual mode.
- Validated on iPhone which connects via Bluetooth to the stimulation module.
- Can accept inputs from an Apple Watch.

Proposed Change Goals

- Enable Unlocked ML to provide customized TENS therapy sessions for users.
  - Conditional unlock based on gathering enough data from a patient to build model.
  - Generated model interactively tested with feedback from the user for model updates.
  - User has the option to revert to previous versions.
- Allow any new platforms to be used to run the control/feedback software (smartphones, tablets).
- Allow new inputs (new feedback questions, smart watch inputs) to be used as inputs to the algorithm (inputs locked when deployed). Output will remain the same (stimulation frequency and amplitude).

Discussion:

- Are all of these valid change goals?
- What is the impact of an unlocked ML algorithm being used to create new patient customized therapy sessions?
- What is the impact of new inputs on the unlocked ML customization algorithm?

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SiMD – Radiological Triage

SaMD- Radiological Triage

- Device detects incidental nodules in the lung greater than 3mm and send a notification to a specialist to prioritize follow-up for the images.
- Device does not have any outputs other than the notification, intended to draw attention to the time sensitive (i.e. leads to detection of incidental nodules images that may be normally missed).

Proposed Change Goals

- Allows new X-Ray scanners to be validated with the algorithm, specifically new scanners and existing scanners not tested in the 510k dataset (Manufacturer X with 70% Market Share in the US) scanners as they are cleared by FDA.
- Improve performance of the algorithm from 0.72 Sensitivity to 0.95 Sensitivity. Human radiologists are known to perform the task at 0.84 sensitivity.

Discussion:

- What is the impact of improving beyond the sensitivity that radiologists can achieve?
- What is the impact of known scanners vs new scanners being used as new inputs?

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SaMD – Digital Theraputic

SaMD – Augmented Reality for PTSD for arachnophobia

- Device helps patients with arachnophobia become more accustomed to the presence of spiders.
- The device measures heart rate via proprietary sensor to either increase or decrease the level of therapy.

Proposed Change Goals

- Expanding intended use to include different stressors (snakes).
- Expand sensor inputs to include smart watches.

Discussion:

- Does including new stressors conserve the indications for use? Intended use?
- What is the impact of including new inputs from heart rate sensors from OTS Smart Watches?

Thank You!