Promoting Transparency – A Developer’s Perspective

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AI-devices should be developed and validated with data representative of their intended use, including variation in:

- Intended Use Patient Population
- Intended User
- Data Inputs
- Intended Use Environment

Reflected in Product Claims and “Labeling”
Important Considerations for the Promotion of AI-Device Transparency


- Applying human factors and usability engineering during all stages of development is critical for ensuring safety, effectiveness, and transparency in relation to AI-devices.

- Summary information should be provided to users when it is not possible to provide comprehensive details (e.g., training an algorithm using federated learning).

- Explainability can enhance transparency should be considered in the context of the overall risk-benefit profile of the AI-device.
An Intuitive User Interface Promotes Transparency


Predetermined Change Control Plans Benefit Patient and Public Health and Should Address Change Transparency

**Predetermined Change Control Plan (PCCP)***

- Describes the device update strategy to ensure continued safety and effectiveness post deployment

- An essential mechanism for deploying significant changes for AI-devices in a safe and effective manner
  1) Ensures patients and healthcare professionals will receive timely and innovative updates in a safe and effective manner
  2) Enables the iterative nature of AI-devices
  3) Optimizes Agency resources

**A PCCP should describe how software changes will be transparent to users**

- Rationale for the software update
- Description of changes in product claims
- Description of changes in performance
- Review of instructions for use

*Source: Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD), US Food and Drug Administration.*
Doing now what patients need next