Session II. Promoting Transparency

FDA’s Role in Promoting Transparency Through Labeling and Public Facing Documents

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Presentation Topics

• Background
  – FDA Premarket Review

• Sources of Information
  – Medical Device Labeling
  – FDA Public Databases

• Discussion Topics
  – Current Challenges
  – Transparency Principles for Discussion
Background - Premarket Review

- FDA conducts a premarket review for mid- to high-risk AI/ML-enabled devices

- Evaluation of safety and effectiveness based on:
  - Intended use
  - Device description / design
  - Performance assessment
  - Labeling
  - and more...e.g., human factors, software quality, cybersecurity as applicable
Background - Premarket Review

- The study design and performance must support the intended use of the AI/ML device, taking into consideration...
  - Safety and effectiveness of the device
  - Generalizability to the intended use population (e.g., acquisition hardware, patient demographics, disease variations)
  - Best practices in study design and statistics (e.g., data independence, pre-specified endpoints, sources of bias)
  - and more...

- Does the labeling contain sufficient information to support safe and effective use?
• What is labeling, and what information is available to users in the device labeling?
Medical Device Labeling

• Labels and other written, printed, or graphic matters on or accompanying the device

• All medical devices have some of the same general requirements, unless exempted by regulation

• Additional labeling requirements depend on the submission type and/or are enacted as part of “special controls” (device-type specific risk mitigation)
Medical Device Labeling

• Premarket submissions include proposed labeling that describes:
  – The device
  – Intended use
  – Directions for use (which may include relevant information based on performance testing)
Medical Device Labeling

• For AI/ML-enabled devices:
  – Operation/workflow
  – Identification of compatible hardware/software (inputs/outputs)
  – Details of the validation, including dataset characteristics, sub-analyses stratified by relevant confounders
  – Other information to help users understand its use, requirements, limitations, and generalizability
• What information on AI/ML-enabled devices is available from FDA’s public databases?
FDA Public Databases

- FDA posts information on authorized medical devices
- The format, content, and details depend on the submission type and underlying regulatory requirements
## FDA Public Databases - Overview

<table>
<thead>
<tr>
<th>Database</th>
<th>Documents</th>
<th>Overview</th>
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</thead>
<tbody>
<tr>
<td><strong>510(k)</strong></td>
<td>Decision Letter Indications for Use 510(k) Summary/Statement</td>
<td>A brief summary of the device, intended use, and summary of the performance testing relied upon for the decision.</td>
</tr>
<tr>
<td><strong>De Novo</strong></td>
<td>Reclassification Order FDA Decision Summary</td>
<td>Regulatory definition of the new device-type classification, including any special controls. The Decision Summary includes the device description, intended use, review of performance testing, etc. for the authorized device.</td>
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<tr>
<td><strong>PMA</strong></td>
<td>Approval Order Summary of Safety &amp; Effectiveness Labeling</td>
<td>Detailed summary of information submitted for the device, including device description, performance testing, and copies of labeling.</td>
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FDA’s List of AI/ML-Enabled Devices

- Public list of authorized AI/ML-enabled medical devices with key information (e.g., device and company name, link to summary)
- Increases transparency about these devices and the FDA’s work in AI/ML-enabled devices
- ~300 devices (through June 2021)
Transparency Challenges

• Device labeling
  – Is not posted online by FDA, except for Original and Panel Track PMAs
  – May not be easy to find or readily available to all end-users

• FDA’s public databases
  – The information will vary based on the submission type
  – The information reflects the performance at authorization, and not real-world performance

• Lack of a standard template for reporting on AI/ML-enabled devices
Transparency Principles for Discussion

• Users should be provided ready access to clear, relevant information that is appropriate for the intended audience (e.g., clinicians or patients), including:
  – The intended use and indications for use
  – The basis for decision-making when available
  – Performance of the model for appropriate subgroups
  – Characteristics of the data used to train and test the model
  – Acceptable inputs
  – Known limitations
  – User interface interpretation
  – Clinical workflow integration of the model
  – Device modifications and updates from real-world performance monitoring
  – User are provided a means to communicate concerns to the developer
Summary

• FDA conducts an in-depth premarket review of AI/ML-enabled devices

• Device labeling includes information on the intended use, performance, generalizability, limitations, etc.

• FDA public databases provide information on authorized devices

• More can be done to develop and implement best practices for promoting transparency