Software as a Medical Device (SaMD)

Framework for Risk Categorization and Corresponding Controls
IMDRF/WG/N12 Proposed Document (PD1)R5
Goals

• International convergence and common understanding of Software as a Medical Device (SaMD):
  – Generic types of SaMD
  – Generic risks of SaMD that affect public health
  – Expectations of controls required to minimize generic risk

• Establish a framework for regulators to incorporate converged controls into their regulatory paths or classifications.
Proposed Timeline (combining phase II and III)
Phase I
- SaMD Key definitions
  Final: December 2013
  IMDRF/N10/R2

Phase II
- What factors of SaMD affect public health risk?
- What generic types of SaMD exists?
- What are the generic risks for the types of SaMD?

Phase III
- What are the controls/expectations

Informal input from stakeholders

Combined effort for N12/PD1

SaMD Framework
IMDRF/N12/PD1-R5
Framework Overview

Common SaMD definition statement:
- Medical purpose
- Context of use
- Core functionality

Conditions (1-7) based on definition statement and risk.

Type I, II, III, IV are groupings by similarity in risk profile

Risk Categorization

Corresponding controls

Level of independent oversight

Common process expectation

Type
- I
- II
- III
- IV
SaMD Definition Statement

A clear and strong statement enables common alignment into appropriate SaMD type

Includes the following key information:

- **The medical purpose** of the SaMD: how it meets the definition of a medical device.
- The **Context of use** of the SaMD: who is it for, how used, patient condition, target population, target disease, limitations of SaMD output.
- A **Description of** the SaMD’s **core functionality**: what features/functions are essential to the intended medical purpose and context of use.
SaMD Categorization and Types

Categorization conditions based on:

- The information included in the Definition Statement (purpose, context of use)
- Risk profile:
  - The importance of the information to the user:
  - The impact of an invalid result

Types based on similarity of risk

<table>
<thead>
<tr>
<th>Type</th>
<th>Impact Level</th>
<th>examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Very High</td>
<td>Skin cancer diagnosis</td>
</tr>
<tr>
<td>II</td>
<td>High</td>
<td>analyzes rhythm to detect if a patient condition under intensive care has critically deteriorated</td>
</tr>
<tr>
<td>III</td>
<td>Medium</td>
<td>presents heart rate or other physiological parameters during routine checkups to track long term progression of a condition</td>
</tr>
<tr>
<td>IV</td>
<td>Low</td>
<td>Used by patients to monitor their physiological health on a daily basis</td>
</tr>
</tbody>
</table>
## Types of SaMD

<table>
<thead>
<tr>
<th>For a disease or condition when the information is used…</th>
<th>Type I Very High Impact</th>
<th>Type II High Impact</th>
<th>Type III Medium Impact</th>
<th>Type IV Low Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>as a primary or the only information (sole determinant) to treat or to diagnose:</td>
<td>In a Critical or imminent life threatening or life sustaining situation</td>
<td>In a Serious situation</td>
<td>In a Non-Serious situation</td>
<td></td>
</tr>
<tr>
<td>to drive clinical management which includes information that:</td>
<td>To prevent or mitigate in a Critical situation</td>
<td>To prevent or mitigate in a Serious situation</td>
<td>To prevent or mitigate in a Non-Serious situation</td>
<td></td>
</tr>
<tr>
<td>• aids in treating, diagnosing or screening;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• aids in predicting or risk scoring;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• aids in monitoring</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>to inform clinical management which includes information that:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• prevents / mitigates;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• supplements clinical management</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Key Highlights of Corresponding Controls

• Specifically, the recommended controls for all types of SaMD are:
  – a quality management system (QMS), including
  – a system for post-market surveillance,
  – technical documentation.

• All manufacturers are recommended to
  – Utilize international standards to perform risk management and quality management practices.
  – Be transparent in their labeling (including information used in the definition statement)
  – Follow general principles for Clinical Evaluation in GHTF SG5/N2R8:2007, and document as appropriate clinical safety, effectiveness, and performance data.
### Summary of Controls

<table>
<thead>
<tr>
<th>Summary of Controls</th>
<th>Type I</th>
<th>Type II</th>
<th>Type III</th>
<th>Type IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Management – ISO 14971</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Software development lifecycle – IEC 62304 class A requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Software development lifecycle – IEC 62304 class B requirements</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Software development lifecycle – IEC 62304 class C requirements</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Labeling accompanying the device</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Clinical effectiveness</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Clinical safety and performance</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Clear clinical efficacy statement accompanying the SaMD may be based on bench</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>test, simulated, or already available set of data.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Independent Oversight Corresponding to SaMD Types**

X indicates where independent verification (3rd party) or regulatory oversight is recommended.
Thank You