IMDRF International Medical Device Regulators Forum

Software as a Medical Device (SaMD)

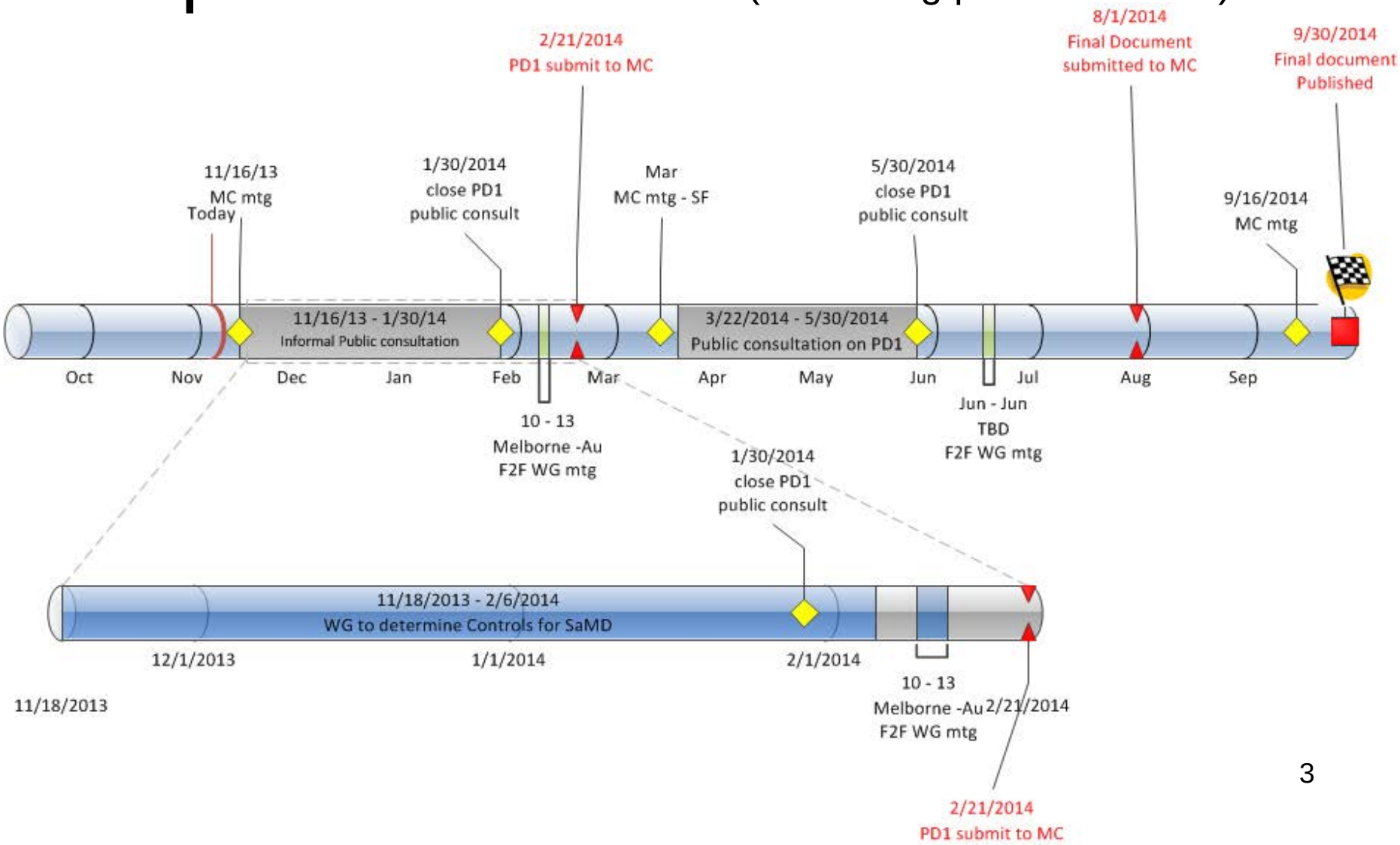
Framework for Risk Categorization and Corresponding Controls

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)



Approach

Phase I

- SaMD Key definitions

Final: December 2013
IMDRF/N10/R2

Combined effort for N12/PD1

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

SaMD Framework
IMDRF/N12/PD1-R5

Framework Overview

Common SaMD definition statement:

- Medical purpose
- Context of use
- Core functionality

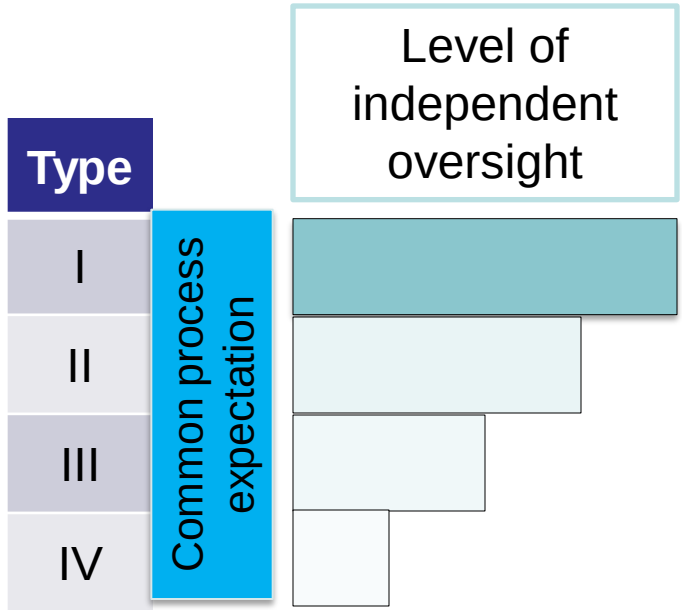
Risk Categorization

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



Corresponding controls

SaMD Definition Statement

A clear and strong statement enables common alignment in to 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

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

Types of SaMD

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

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.

Independent Oversight Corresponding to SaMD Types

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

Thank You