IMDRF International Medical Device Regulators Forum

Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations

Proposed Final

IMDRF WG(PF)/N12 R10

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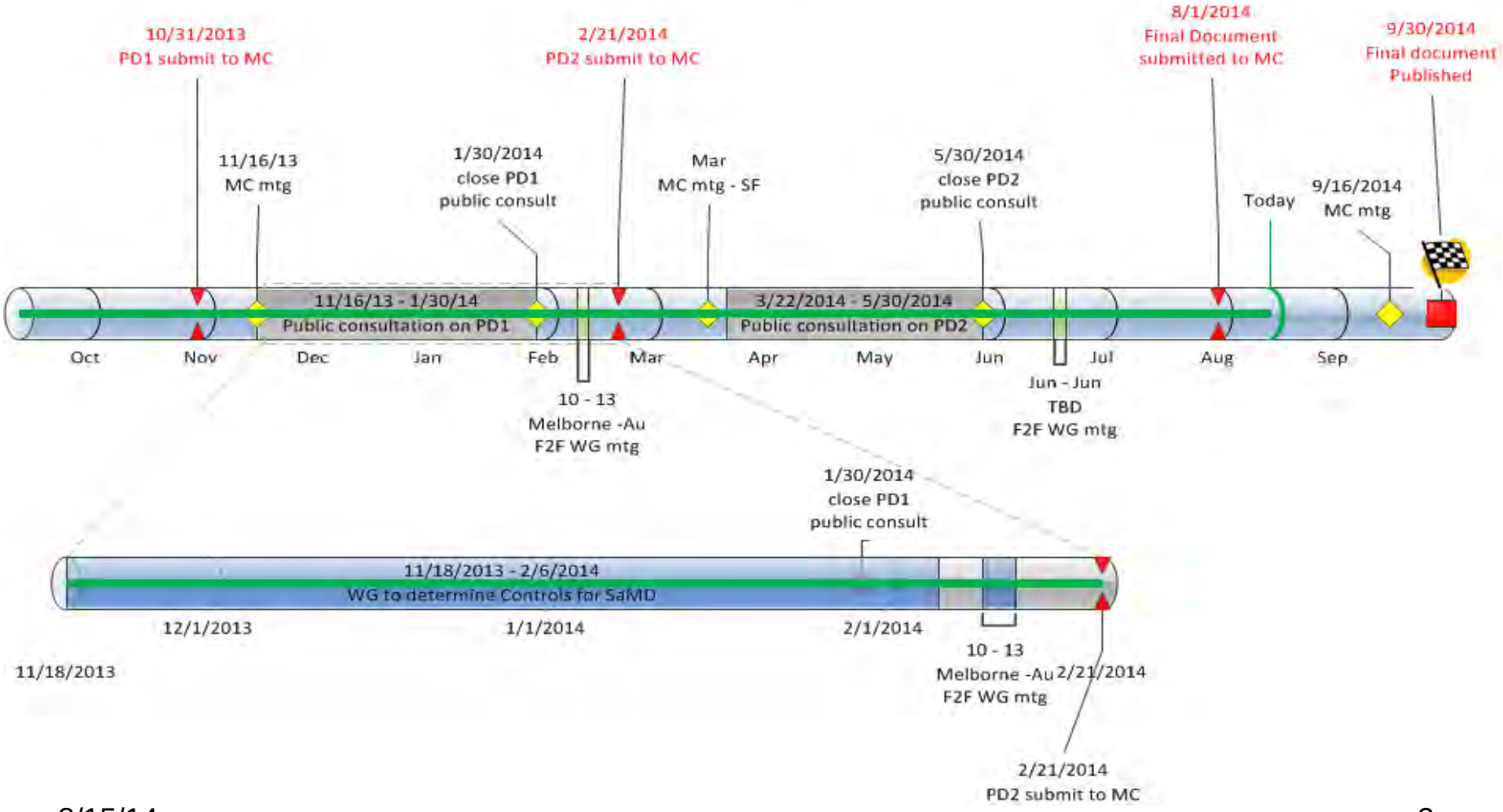
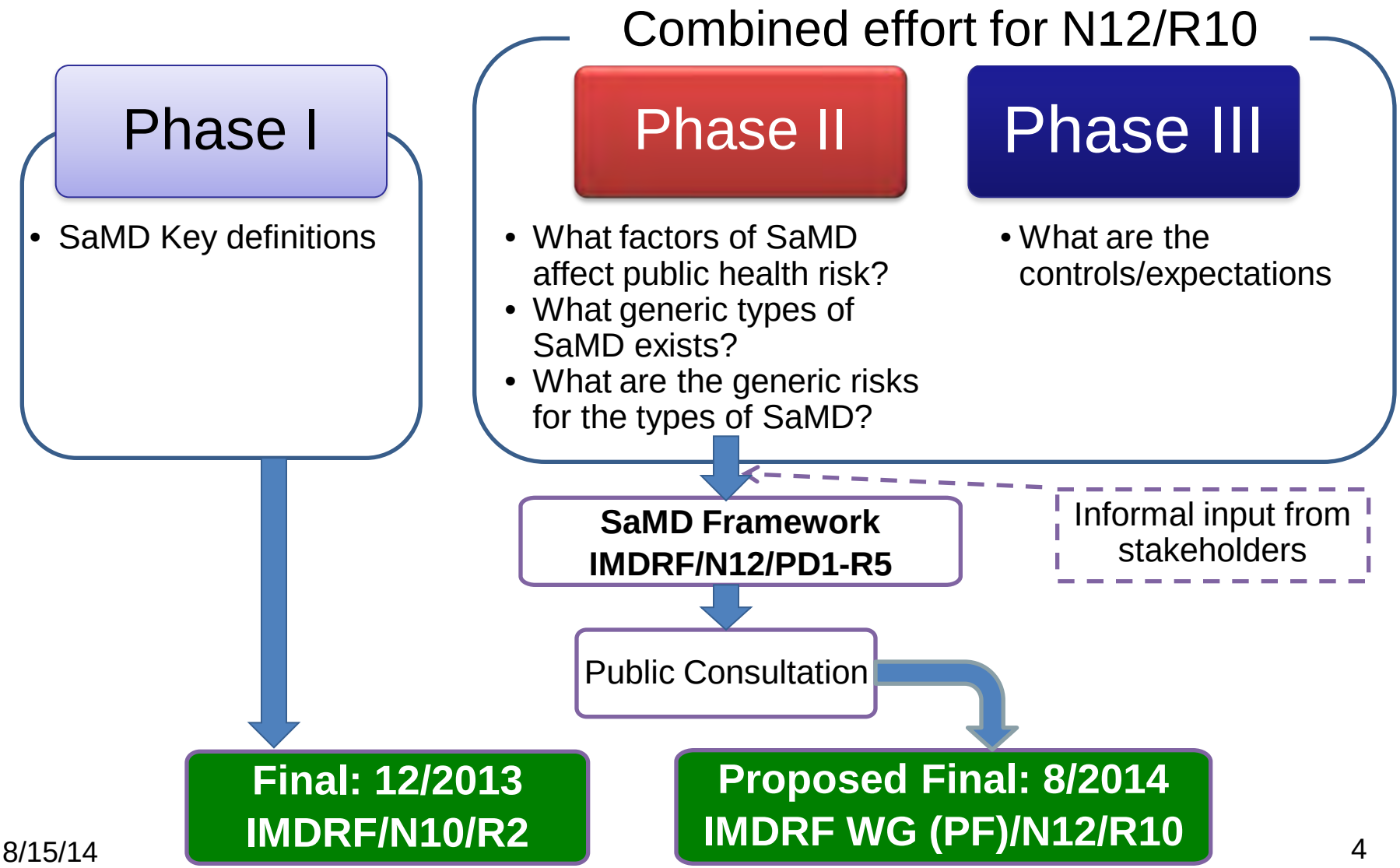
Goals

- 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.

Final Timeline




Combined effort for N12/R10
Phase I
• SaMD Key definitions
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
SaMD Framework
IMDRF/N12/PD1-R5
Informal input from stakeholders
Public Consultation
Final: 12/2013
IMDRF/N10/R2
Proposed Final: 8/2014
IMDRF WG (PF)/N12/R10

Public feedback towards PD

Public Feedback → **Key Themes**

- 2 month public commenting period (April/May 2014)
- 700+ comments
- Reviews and Q&A sessions with regulators, trade associations

Regulators (Canada, FDA, EU, Japan)
Industry (AdvaMed, CDS Coalition, DITTA, Eucomed, ITAC / COACH, JIRA, Medec)

- ✓ Scope:
  - Who is Intended audience (regulators, industry
  - What is in/out of scope (classification)
- ✓ Framework:
  - Define terms & concepts unique to SaMD:
    - ☑ Definition statement
    - ☑ Health Conditions (context of use)
    - ☑ Medical purpose of information (treat/diagnose, drive, inform)
  - Align SaMD Types logic
  - Expand/clarify examples
- ✓ Controls: Recommend general and special considerations for SaMD

Public Feedback drove key changes from PD to PF

Key Changes	Comment to Proposed Document	Final Document
Key terms	Key terms not explained	Key terms explained
factors and rationale	Rationale and explanation of other factors not explained	Added section explaining aspects related to factors for framework.
Nomenclature	Inconsistent use of terms	Consistent use of terms
SaMD Numbering	I = Very High to IV = Low	Reversed ➔ I = Low to IV = Very High
Examples	Too few, some not aligned to SaMD logic	Added examples, aligned to SaMD logic
Controls	Section for 'Recommended Controls & Oversight'	Section for 'General and Special Considerations for development and manufacture of SaMD'
Classification	Alignment to classification not addressed	Analysis of SaMD categories to regulatory classification added to appendix

Framework Overview

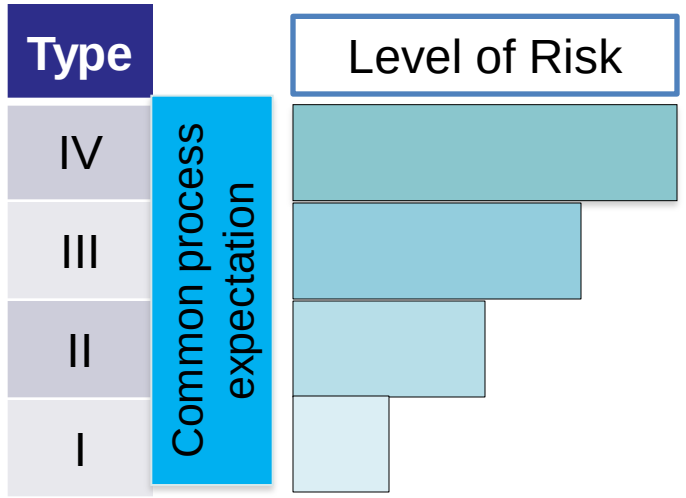
SaMD definition statement:
- Significance of recommendation
- Context of use

Risk Categorization

9 criteria based on definition statement

4 Categories based on similarity of impact

General and Special Controls Considerations



SaMD Definition Statement

A clear statement that identification of SaMD category

Includes the following key information:

- **The significance of information provided by** SaMD: Treats or diagnose, Drives clinical management; informs clinical management
- 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 that will determine considerations for managing changes.

SaMD Categorization Principles

- SaMD impact and resultant category relies on an accurate and complete SaMD definition statement provided by the manufacturer
- Categories are a result of combination of significance of the information provided by the SaMD to the healthcare decision and the healthcare situation or condition
- Categories are based on the levels of impact on the patient or public health
- Categories are in relative significance to each other. Category IV has the highest level of impact, Category I the lowest.
- SaMD functionality that span across multiple healthcare situations or conditions or provide information of varying significance are categorized at the highest level of impact when can be used
- SaMD has its own category even when interfaced with other SaMD, other hardware medical devices, or used as a module in a larger system

Criticality of context

- Critical situation or condition
  - where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health.
- Serious situation or condition
  - where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions
- Non-Serious situation or condition
  - where an inaccurate diagnosis and treatment is important but not critical for interventions

Significance of information

- To treat or to diagnose
  - To provide therapy to a human body;
  - To diagnose/screen/detect a disease or condition
- To drive clinical management
  - To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.
  - To aid in making a definitive diagnosis.
  - To triage or identify early signs of a disease or conditions.
- To Inform clinical management
  - To inform of options
  - To provide clinical information by aggregating relevant information

SaMD Categorization

Increasing significance

Increasing criticality

State of Healthcare Situation or Condition	Significance of Information Provided by SaMD to Healthcare Decision		
	Treat or Diagnose	Drive Clinical Management	Inform Clinical Management
Critical	IV	III	II
Serious	III	II	I
Non-Serious	II	I	I

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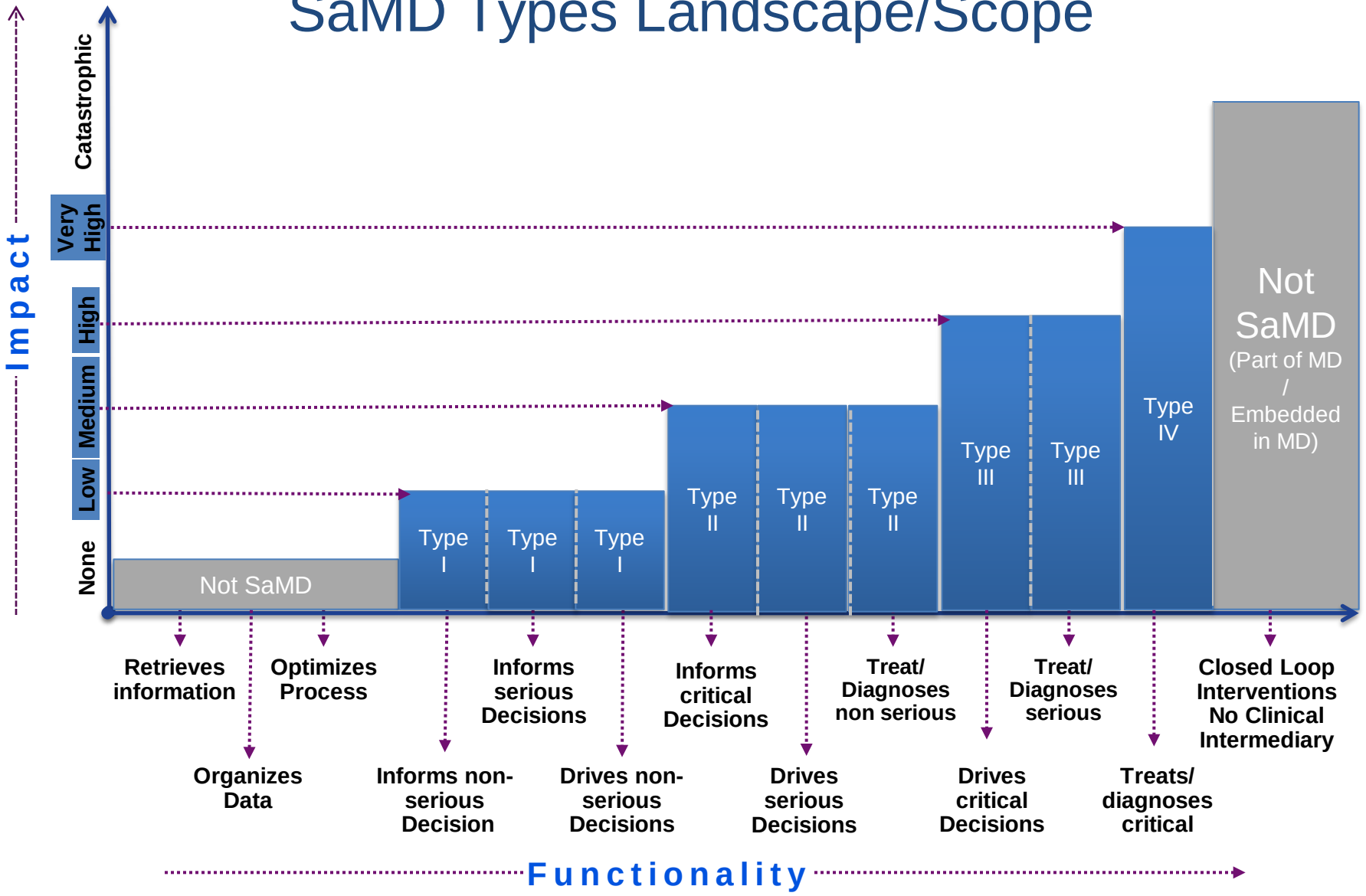
SaMD Types Landscape/Scope



General and Special Considerations for SaMD

- SaMD often forms part of a clinical workflow
- Issues with design/implementation of SaMD can lead to user error
- Software testing generally recognized as not sufficient to determine safety

General Considerations

- Design and development
- Changes

Special Considerations

- Socio-technical environment
- Technology and system environment
- Information security with respect to safety

The combination of risk management, quality management and methodical and systematic systems engineering according to industry best practices can help SaMD manufacturers follow a clearly structured and consistently repeatable decision-making process to promote safety for SaMD

General Considerations for SaMD

Design and Development

- Safety needs to be addressed early in the design and development process

Changes

- SaMD changes may have a significant unforeseeable effect on the healthcare situation or condition and socio-technical environment of use if not managed systematically, not only with respect to a design change in itself, but also to the impact of the changed software after it is installed and implemented

Special Considerations for SaMD

Socio-technical environment

- Proper and safe functioning of SaMD is highly dependent on a sufficient and common understanding of the socio-technical environment that includes the manufacturer and the user

Technology and system environment

- SaMDs are always dependant on a hardware platform and often a connected environment. SaMD can be affected by cross-link interconnections – both physical connections and interoperability, i.e., the seamless communication between devices, technology and people. Information security with respect to safety

Information security with respect to safety

- Incorrect management or transmission of information by an SaMD can lead to incorrect or delayed diagnosis or treatment

NWIP - Quality Management Systems for Software as a Medical Device (SaMD)

Scope

•Translate and adapt existing quality management system requirements to common software practices

•Explain how quality system requirements are applicable and adapted to typical software development, maintenance and management practices.

Rationale -- The scope and complexity of the quality management system are influenced by the range of different SaMD types, software development practices, maintenance practices, and other quality processes that are unique to software. there is no clear guidance on, how should a developer of SaMD follow and comply QMS requirements, examples of issues include

- software quickly using modules, how should a develop comply with regulatory expectations?
- some of the processes used to develop SaMD are automated, what expectations are reasonable for the principles outlined in the quality systems regulations and standards?

Proposed Timeline

•Publish Proposed Document for Public Comment in April and May 2015.

•Publish Final Document in October 2015

Summary and Next Steps

- Publish Final Document IMDRF/WG/N12 R10

- Upon approval by MC begin development of new work item (Guidance on Quality Management Systems for Software as a Medical Device (SaMD))

Thank you