SaMD and AI Regulatory Opportunities and Solutions

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Overview

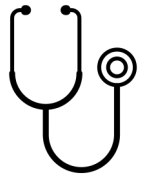
1. SaMD Challenges & Opportunities
2. IMDRF Considerations
3. Global Considerations
4. Artificial Intelligence
5. Change Management

SaMD: Regulatory Challenges & Opportunities

 Nature of software is different than other medical devices	**More rapid iteration** **-High volume of submissions** **Unique risks (ie cybersecurity)** **Delivery methods (not physical supply chain channels)**
 Need to develop expertise and capacity	**Regulators and industry**
 Need to develop risk-based fit-for-purpose approaches	**Review and life cycle management**

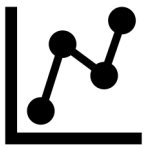
IMDRF Considerations

1. Software as a Medical Device (SaMD): Key Definitions (2013)
2. Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations (2014)
3. Software as a Medical Device (SaMD): Application of Quality Management System (2015)
4. Software as a Medical Device (SaMD): Clinical Evaluation (2017)

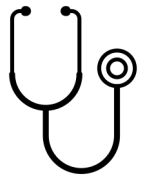


Qualification – Am I regulated as a device?

Classification – If I am a device what is my risk classification?



Clinical Evaluation – What kind of data is needed to support?



Quality Systems – What considerations apply?

Qualifications

Am I Regulated as a Device?

- "A subset of software used in healthcare meets the definition of a medical device"
- Per IMDRF, meets definition of a device when intended for medical purpose
- Definition varies by jurisdiction (US and EU very different)
- Interpretation also varies by jurisdiction

Appropriate determination allows regulators to focus their resources on software that presents the highest risk to patients

Classification

If I am a device what is my risk classification?

- IMDRF proposes a 9-category risk classification scheme
  - Based on significance of info to healthcare decision and state of the healthcare condition
- While appropriate, it is difficult to align with traditional risk classifications for devices

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

**IMDRF Risk Classification for SaMD Devices*

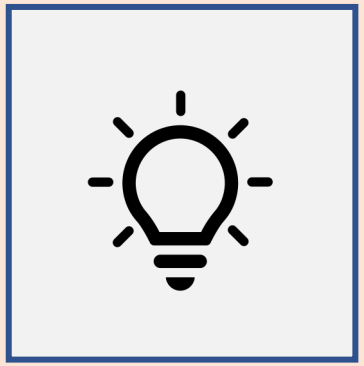
Clinical Evaluation

What kind of data is needed to support?

- IMDRF proposes an approach to map out the clinical evaluation processes
- 3 major components
  - Valid Clinical Association
  - Analytical Validation
  - Clinical Validation
- Not generally implemented or well understood

Drivers of patient access to safe and effective products

Good Regulatory Practice



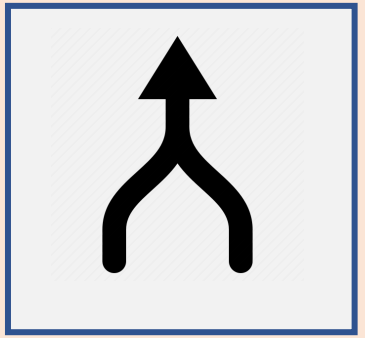
Novel regulatory approaches to life cycle management

Leveraging and increase in recognized standards

Capacity Building

Multiple function devices

Minimization of country-specific requirements including certifications



Global convergence/predictability of requirements

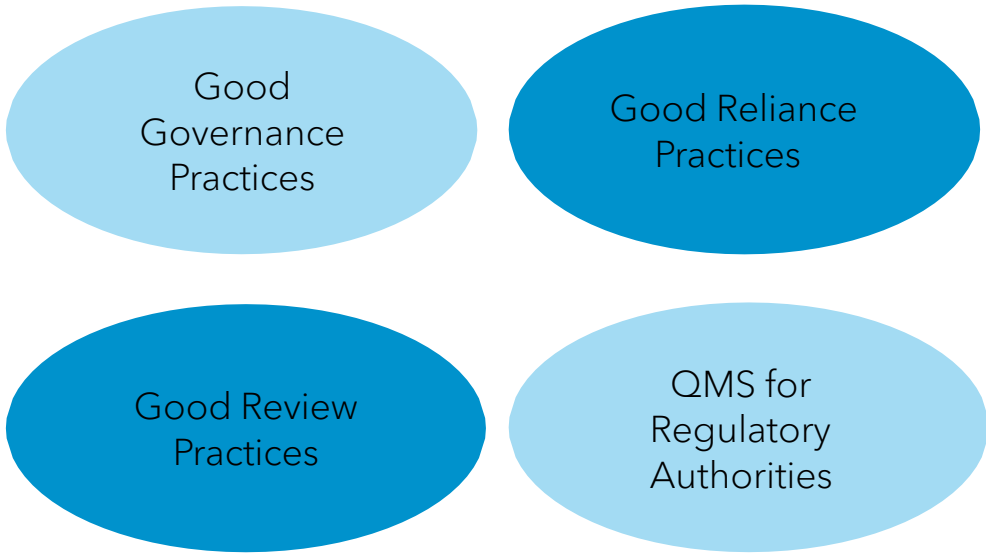
Good Regulatory Practice

WHO Good Regulatory Practices

Objectives:

- Ensure sound and effective regulation of medical products.
- Higher-quality regulation, better regulatory decision-making and compliance.
- More efficient regulatory systems and better public health outcomes.
- Up to date regulatory systems.
- Promote trust among regulatory authorities and other stakeholders.
- Facilitate international cooperation.

Complemented By:



https://www.standardsalliance-mdrc.org/wp-content/uploads/2022/07/Panel-2-Agnes-Good-Regulatory-Practices_medical-devices-regulation-WHOHQ_FPI.pdf

Capacity Building

Reliance & Recognition

- Number of Staff

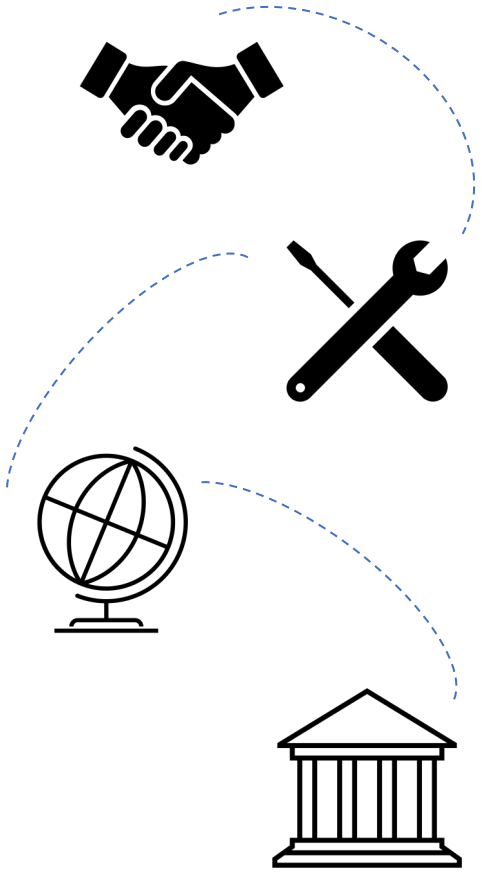
Technical Training

- Expertise of Staff

Infrastructure

- Ability to Review Software per Regulatory Requirement

Principles of Reliance



International cooperation essential to ensure the safety, quality and efficacy/performance of locally used medical products.

Regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority in reaching its own decision. Relying authority remains independent and accountable.

Make best use of available resources and expertise, avoid duplication and concentrate regulatory efforts and resources where most needed.

Promote more efficient approach to regulatory oversight to improve access to quality-assured, effective and safe medical products

Other Global Considerations

- Exclude low risk functionalities
- Multiple function approaches
  - Only those functions which have a medical device intended use subject to oversite

- Minimization of country-specific requirements
- Leveraging and increase in recognized standards
- Novel regulatory approaches to life cycle management

Artificial Intelligence

AI-enabled Medical Devices

- Medical device software that incorporates artificial intelligence is still a medical device and should be regulated through existing frameworks.
- Regulatory frameworks must meet unique and iterative aspects of software products including novel regulatory approaches that enable AI-based technologies.
- Should be regulated based on intended use and the risk of product

Change Management

Need for Innovative Approaches

- Software products are intended to be updated on a regular and frequent basis
- Machine learning potentially allows for more frequent (or continual) optimization of algorithms
- Innovative approaches are needed to change management that support the iterative nature of SaMD and SiMD, including AI

Predetermined Change Control Plans PCCP)

- Submitted with initial premarket submission
- Provides description of planned future changes and methods to achieve and control any risks associated with those changes
- Can make identified changes after regulator approval while still ensuring safety and effectiveness through execution of approved PCCP