IMDRF International Medical Device Regulators Forum

Activities of Software as a Medical Device (SaMD) Working Group (WG) in International Medical Devices Regulators Forum (IMDRF)

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Quick Overview of SaMD WG

Under the cooperation among IMDRF and stakeholders including those in industries, the WG;

1. Developed "**Key Definition**" document (IMDRF/SaMD WG/N10)
2. Developed "**Possible Framework for Risk Categorization and Corresponding Considerations**" document (IMDRF/SaMD WG/N12 FINAL:2014)
3. Developed "**Application of Quality Management System**" document (IMDRF/SaMD WG/N23 FINAL:2015)
4. Completed a **SaMD public survey**, and is starting new activities related to **SaMD clinical evaluation**

Software as a Medical Device Definition

Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device

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Framework Overview

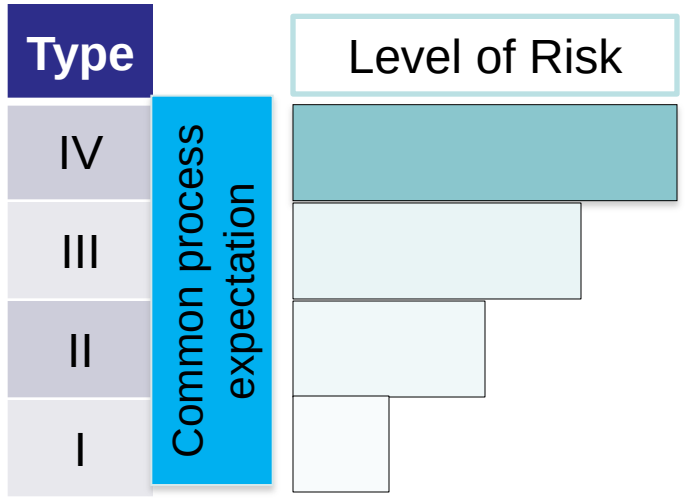
SaMD definition statement:
- Significance of recommendation
- Context of use

Risk Categorization

9 criteria based on definition statement

4 Categories based on similarity of impact

General and Special Controls Considerations



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

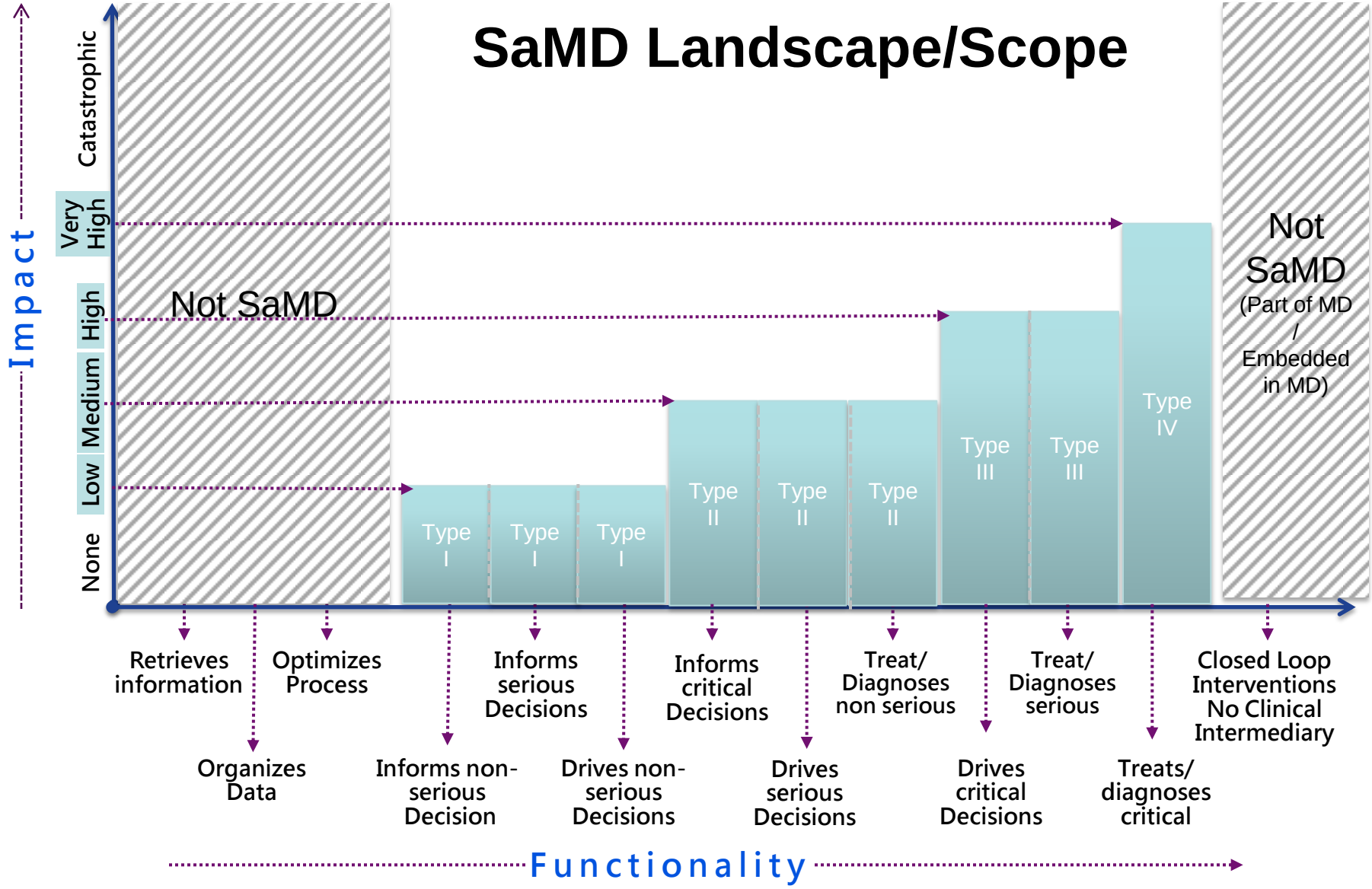
- To treat or to diagnose
  - To provide therapy to a human body;
  - To diagnose/screen/detect a disease or condition
- To drive clinical management
  - To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.
  - To aid in making a definitive 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


SaMD Landscape/Scope
Impact
Catastrophic
Very High
High
Medium
Low
None
Not SaMD
Type I
Type I
Type I
Type II
Type II
Type II
Type III
Type III
Type IV
Not SaMD
(Part of MD / Embedded in MD)
Retrieves information
Optimizes Process
Informs serious Decisions
Informs critical Decisions
Treat/ Diagnoses non serious
Treat/ Diagnoses serious
Closed Loop Interventions No Clinical Intermediary
Organizes Data
Informs non-serious Decision
Drives non-serious Decisions
Drives serious Decisions
Drives critical Decisions
Treats/ diagnoses critical
Functionality

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Goals

- International convergence and common understanding of how existing medical device QMS regulations and standards apply to Software as a Medical Device (SaMD).

- Provide guidance to SaMD manufacturers, often new to medical device regulations, on how to apply medical device quality management principles for safe and effective SaMD.

- Help software manufacturers advance the safety, performance and effectiveness of SaMD by highlighting certain QMS requirements from a clinical and technological perspective.

PD1 Development Process

Proposed Draft Feedback

- ~500 comments received
- 34 organizations
- Increased feedback from software developers, clinicians and software researchers
- Increased global feedback

Stakeholders

Regulators

- Australia
- Brazil
- Canada
- China
- EU
- Japan
- USA

Thank You

Industry

- AdvaMed
- Coach
- DITTA
- Eucomed/EDMA
- ITAC
- GMTA
- Medec
- ABIMED/ABIMO
- Standards
- SW Developers

Feedback Themes

- ✓ Clarify document objective, scope, target audience, not a QMS or software practice tutorial
- ✓ Use 13485 as a reference and not regulations
- ✓ Provide roadmap to existing QMS
- ✓ Provide clear lines to patient safety
- ✓ Provide additional clarity and content for outsourcing and cybersecurity
- ✓ Align concepts between section content and examples

Target Audience

The document targets software development organizations that apply good software quality and engineering practices but may not be familiar with "medical device QMS" principles.

Organizations New to SaMD and New to MD QMS

Organizations Experienced in MD QMS and New to SaMD

SaMD Quality Management Principles

Model for QMS activities from a Software perspective

- ***An organizational structure –*** that provides leadership, accountability, governance, and an organization with adequate resources to assure the safety, effectiveness and performance of SaMD;
- ***SaMD lifecycle support processes –*** a scalable set of quality processes that apply commonly across the SaMD lifecycle realization and use processes;
- ***A set of key realization and use processes –*** that is scalable for the type of SaMD, the size of the organization and takes into account important elements required for assuring the safety, effectiveness and performance of SaMD.

- Leadership and organizational support provides a ***foundation*** for SaMD lifecycle support processes
- SaMD lifecycle support processes ***apply across*** the SaMD realization and use processes.

Document Key Points

"overview of scope and approach"

- Not a new QMS
- Not in conflict with current QMS requirements
- Assumes developers are using good software engineering practices
- Not a tutorial for software practices or QMS
- Uses common software quality terminology and practices
- Groups QMS principles from a software perspective

- Reinforces medical device quality principles that should be appropriately incorporated for an effective SaMD QMS
- Highlights clinical and technological considerations of medical device QMS in elements of software practices
- Links to IMDRF N12 SaMD risk framework document (SaMD types and general and special considerations of SaMD)

"reinforces medical device quality principles and how they apply to SaMD lifecycle processes"

- Highlights key medical device QMS points for effective SaMD QMS
  - *Patient Safety and Clinical Environment Considerations*
  - *Technology and Systems Environment Considerations*

- Uses examples to Illustrate how SaMD QMS principles can be applied from two different perspectives (two fictitious companies):
  - *Magna — a large organization*
  - *Parva — a small start-up*

- Uses ISO13485:2003 as the QMS reference.

Aligning software industry practices with medical device QMS

Terminology

Document uses terminology common in the software industry to illustrate how typical software-engineering activities translate to equivalent activities in a medical device QMS

Examples

Software Industry		Medical Device QMS
Software requirements	⇔	Product requirements
Testing	⇔	Verification & Validation (V&V)
Configuration Management	⇔	Configuration Identification and Traceability

Processes

Document organizes QMS principles based on processes commonly found in software engineering lifecycle approaches with leadership and management of the organization as the foundation

Examples

Document Sections		Medical Device QMS
Product Planning (Section 7.1)	⇔	Planning, Planning of Product Realization, Design and Development Planning
Managing Outsourced Processes, Activities, and Products (Section	⇔	Purchasing Process, Purchasing Information
Maintenance	⇔	Customer Communication, Production and Service Provision, Servicing Activities, Feedback

Aligning regulations to software practices

Appendix A — Maps Medical Device Regulations to IMDRF/SaMD N23

for the jurisdictions represented by the current IMDRF SaMD WG members

N23	Topic	ISO 13485:2003 [13, 14]	Australia [15]	Brazil RDC 16/2013	China MD GMP ([2014]64)	Japan MHLW QMS Ordinance	US 21 CFR
5.0--SAMD QUALITY MANAGEMENT PRINCIPLES	Quality management strategy	4	All	2.1	3,24	5	820.5
	Management responsibility	5			5-7,78		
6.0--SAMD LEADERSHIP AND ORGANIZATIONAL SUPPORT							
6.1--LEADERSHIP AND ACCOUNTABILITY IN THE ORGANIZATION	Management responsibility	5	All				
	Management commitment	5.1		2.2.5, 2.2.6	6	10	820.20b
	Customer focus	5.2				11	
	Quality policy	5.3		2.2.1	6	12	820.20a
	Quality planning	5.4			6	13, 14	820.20d
	Responsibility and authority	5.5		2.2.3	5	15	820.20b1
	Management representative	5.5.2		2.2.5	7	16	820.20b3

Applicability to Health Canada regulations:

•The Medical Devices Regulations require class II, III and IV medical devices to be manufactured …

Applicability to Europe Union regulations:

•EU legislation foresees the QMS to be assessed by third parties only for certain classes of …

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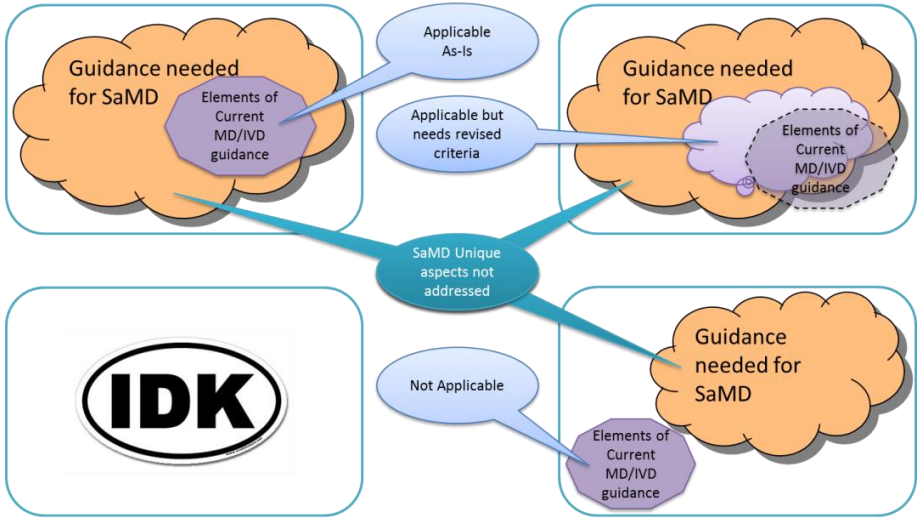
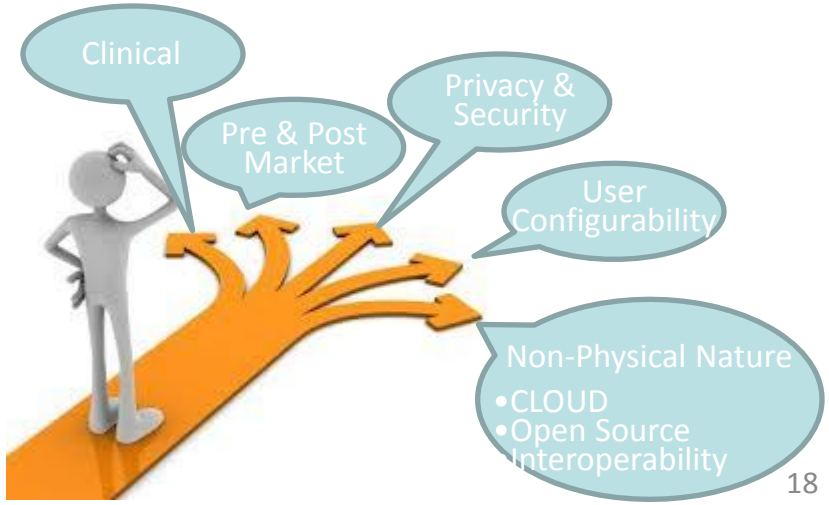
2- Part goal of the survey

1. Understanding applicability and coverage of existing MD/IVD guidance to SaMD

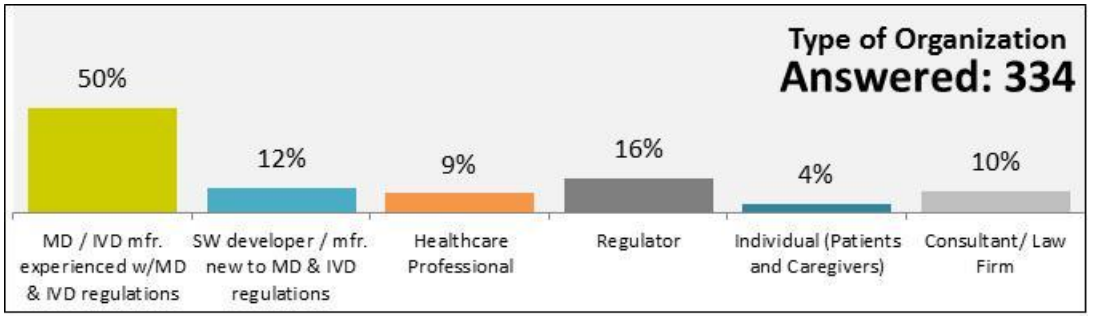


2. Prioritizing further IMDRF convergence efforts for SaMD

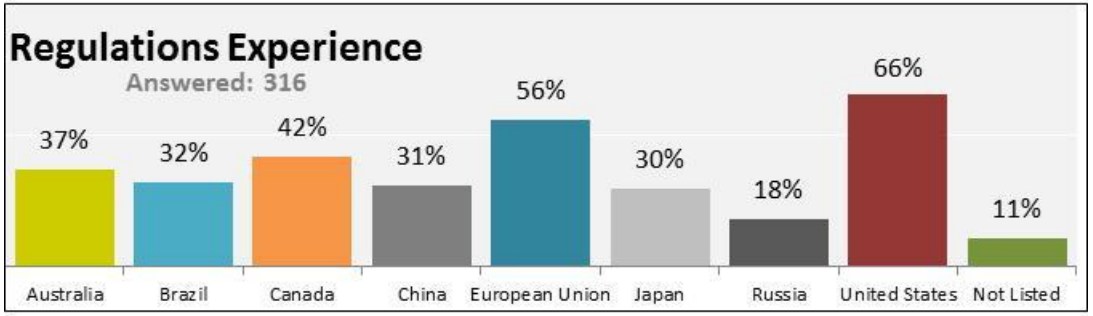


Survey succeeded with broad global outreach

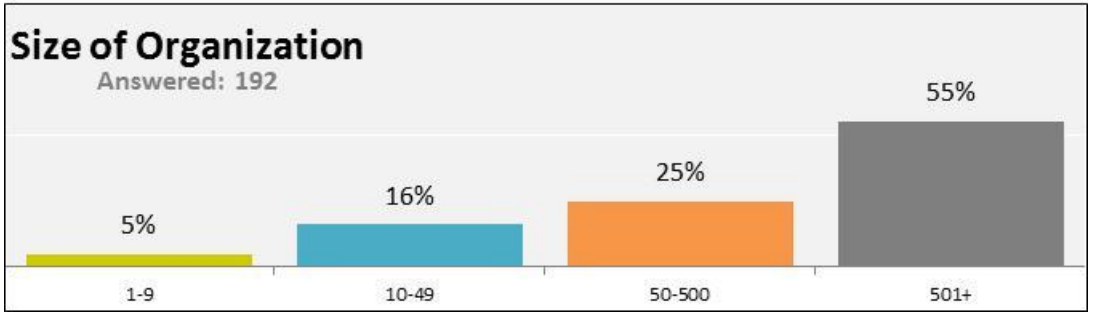
334 respondents of which 25% were **new** to MD/IVD regulation



~ half of respondents have experience in regulations/guidance across multiple countries; the other ~ half in one country.



21% of responses were from individuals from very small and small organizations.



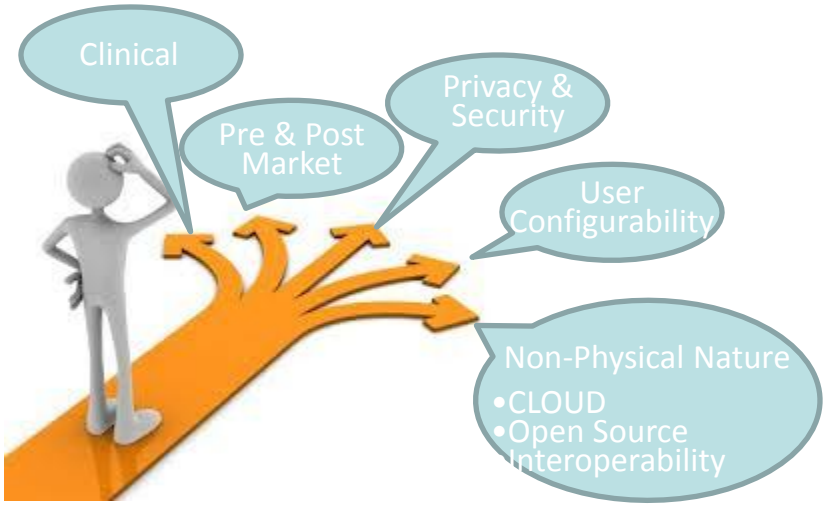
Key observations

- There is lot of interest on convergence related to SaMD.
- Need clarity on unique aspects related to SaMD.
- Need clarity on applicability of current IMDRF/GHTF MD and IVD guidance for SaMD.

Respondents highlighted additional aspects

(comments analysis)

Survey identified aspects



Additional identified aspects

Guidance needed for SaMD

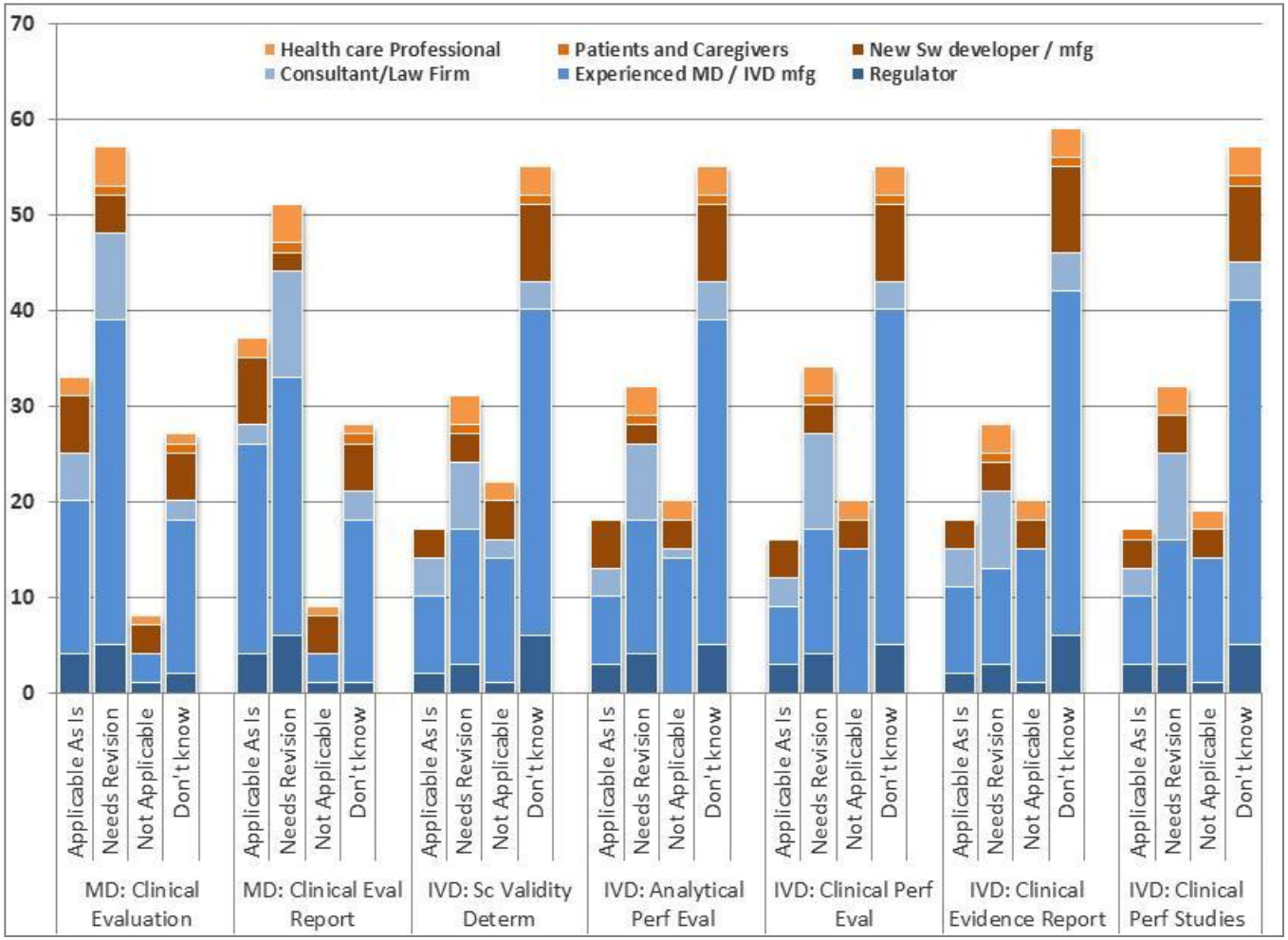
NEW

- **Data**
- **Ease of Iterations**
- **Systems**
- **Responsibilities**

❖ *Software specifics in standards fragmented/missing*

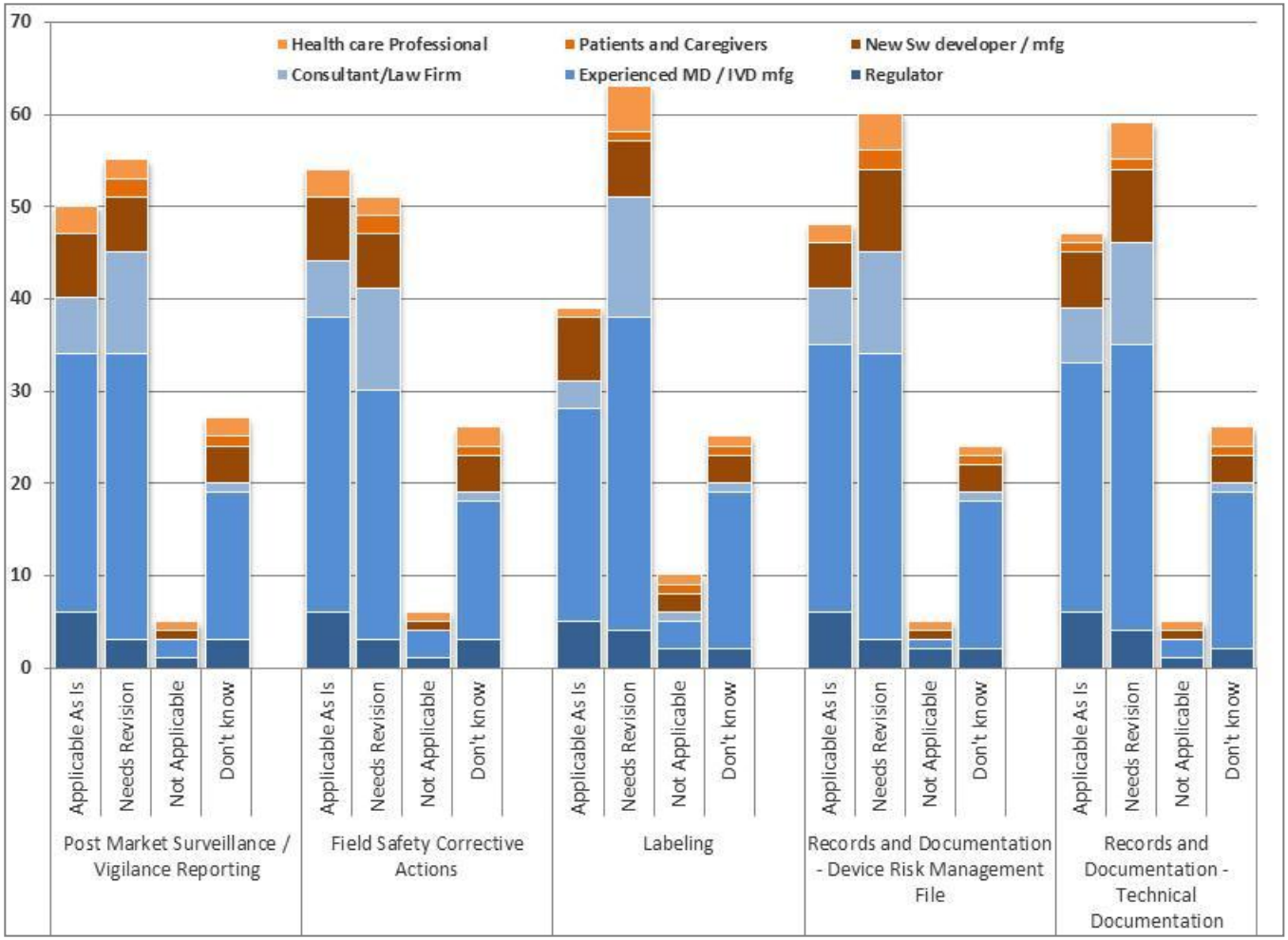
… need convergence/alignment efforts to address uniqueness of s/w in standards

Responses to applicability of clinical guidance to SaMD (n=152)



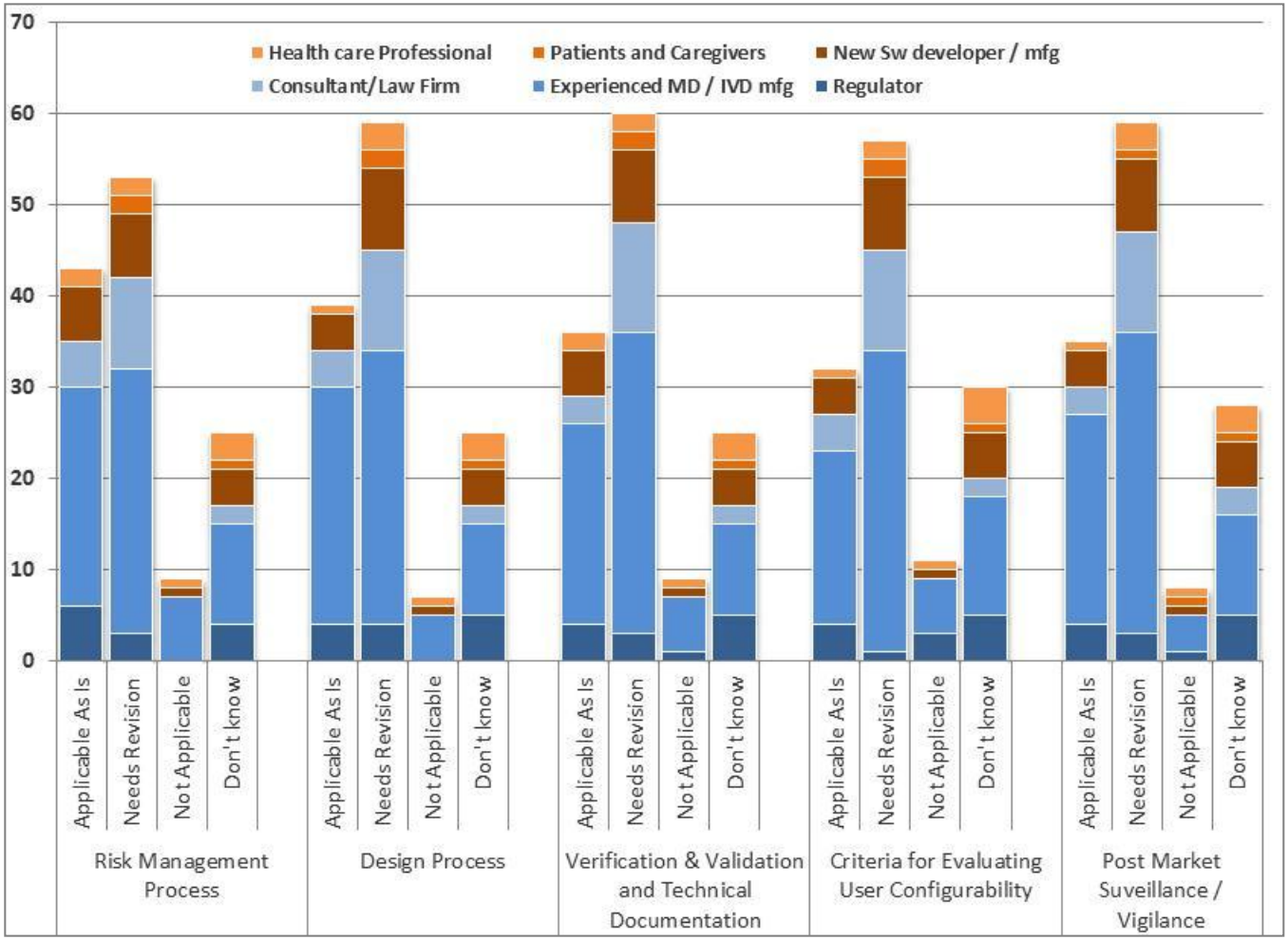
Marked difference between MD and IVD in applicability and awareness

Responses to applicability of current Pre and Post Market Guidance to SaMD (n=138)



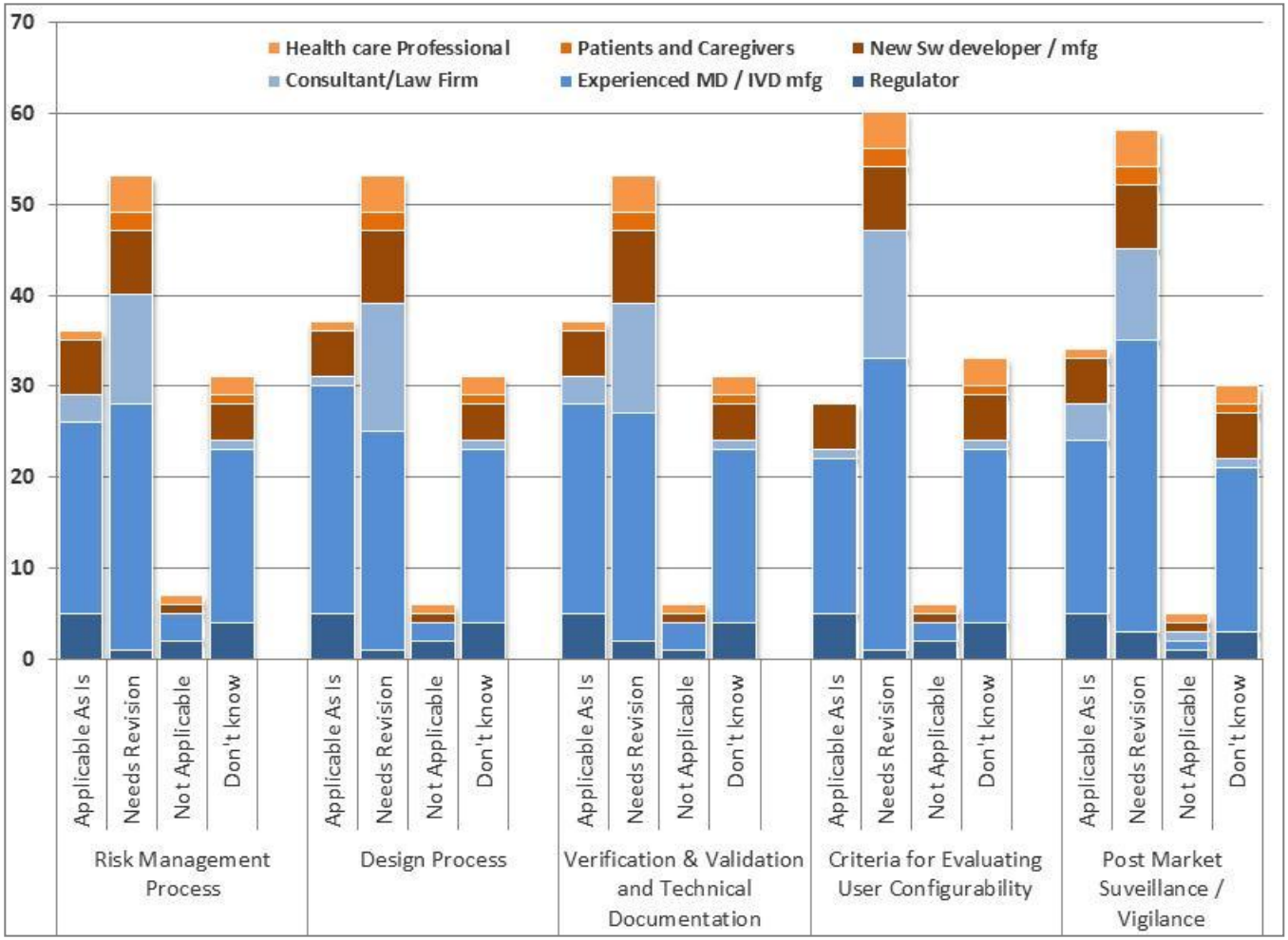
Consistently shows current pre and post market guidance is applicable as-is or needs revision

Responses to applicability of current guidance to SaMD Privacy & Security (n=131)



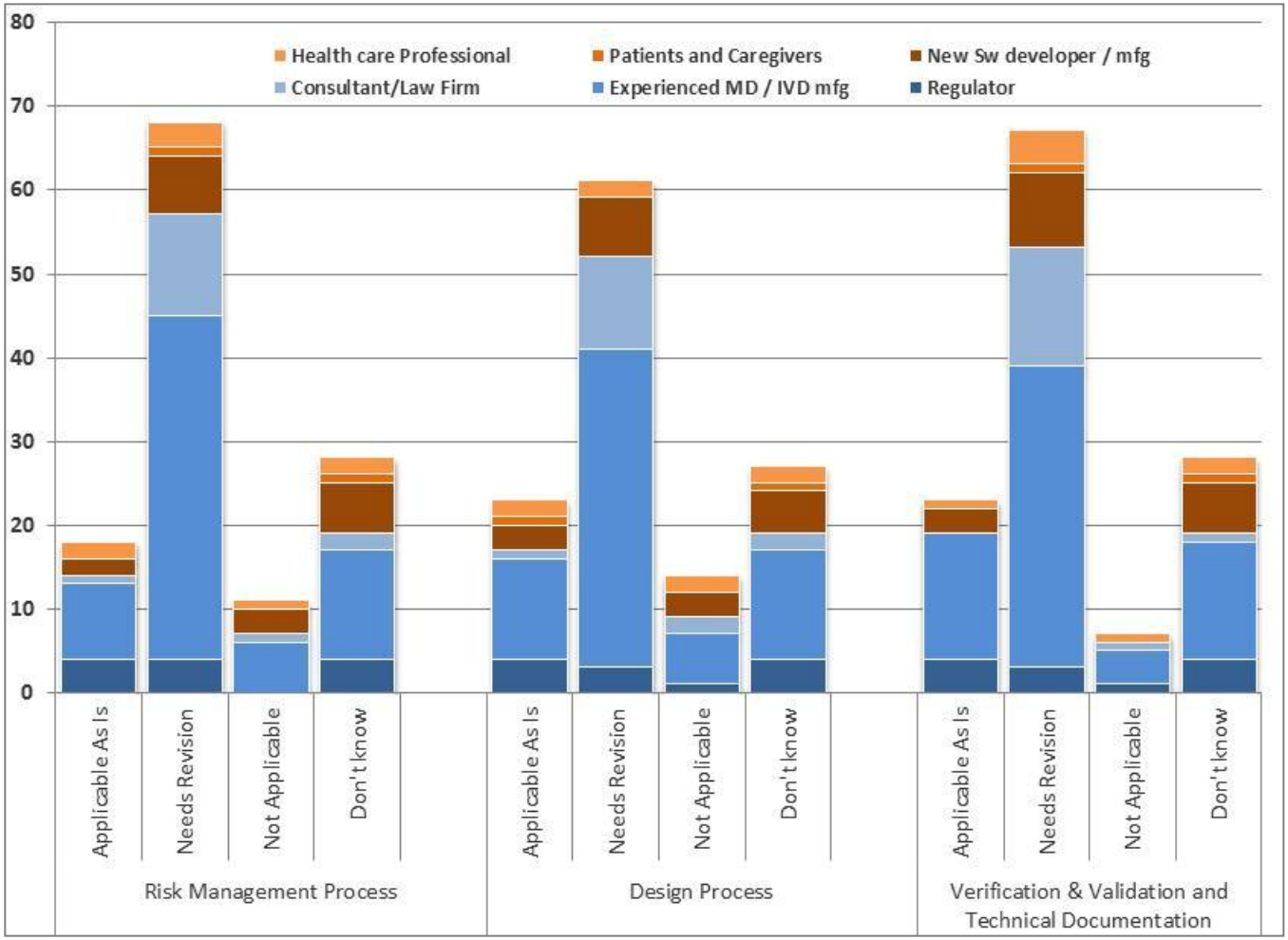
Consistently shows need for revision to address privacy and security

Responses to applicability of current guidance to SaMD User Configurability (n=128)



Consistently shows need for revision to address SaMD user configurability

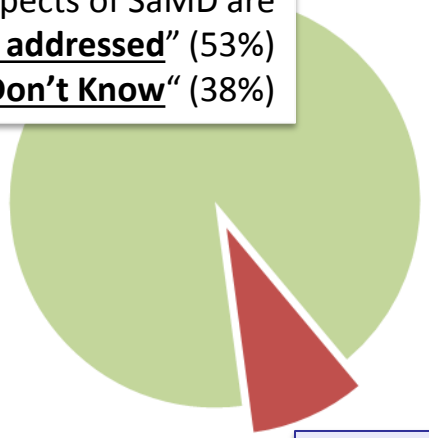
Responses to applicability of current guidance to non-physical nature of SaMD (n=126)



Consistently shows need for revision to address non-physical nature of SaMD

Most respondents seek guidance on "clinical evaluation"

91% believe unique aspects of SaMD are "**not addressed**" (53%) **OR** "**Don't Know**" (38%)



Survey Question (n)	Clarity needed / Don't Know ++	No clarity needed ++
Clinical (n=152)	95%	5%
Pre and Post Market (n=138)	90%	10%
Privacy and Security (n=131)	89%	11%
User Configurability (n=128)	91%	9%
Average	91%	9%

9% of respondents believe current MD/IVD guidance are "**applicable as-is**" **AND** "**address all aspects unique to SaMD**".

++ Analysis done by comparing responses for Q8 with Q9; Q10 with Q11; Q12 with Q13 and Q14 with Q15.

SaMD: Next Step

- **SaMD: Clinical Evaluation** has been approved in September 2015.
- A guideline to be prepared by this WG is expected to help drive a common understanding on the way to obtain the clinical data needed to support market authorization for an original SaMD and modification to a SaMD based on categorization principles set in IMDRF SaMD N12.
- Members in SaMD WG are under recruitment from IMDRF MC jurisdictions as well as stakeholders including industries.

Thank you

Acknowledgment of the very hard work performed and the outstanding results by IMDRF Working Group representatives.