IMDRF International Medical Device Regulators Forum

IMDRF Software as a Medical Device (SaMD)

SaMD Working Group Survey Results

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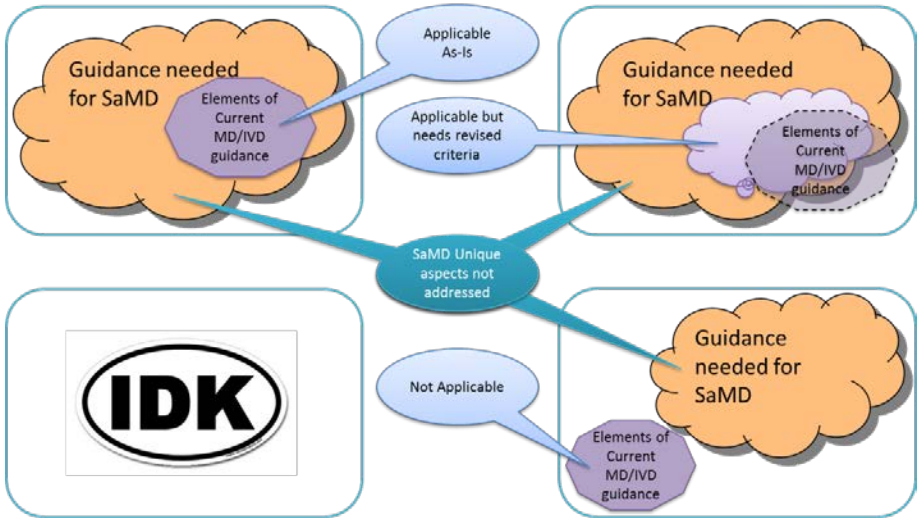
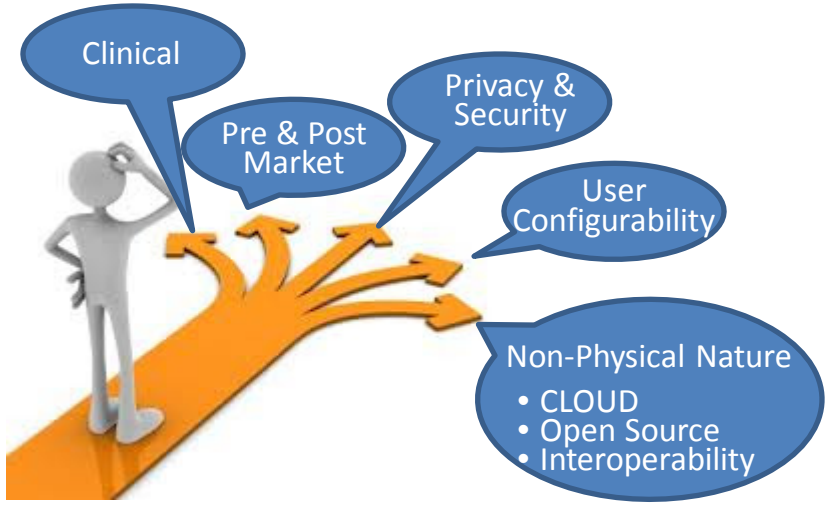
2- Part goal of the survey

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

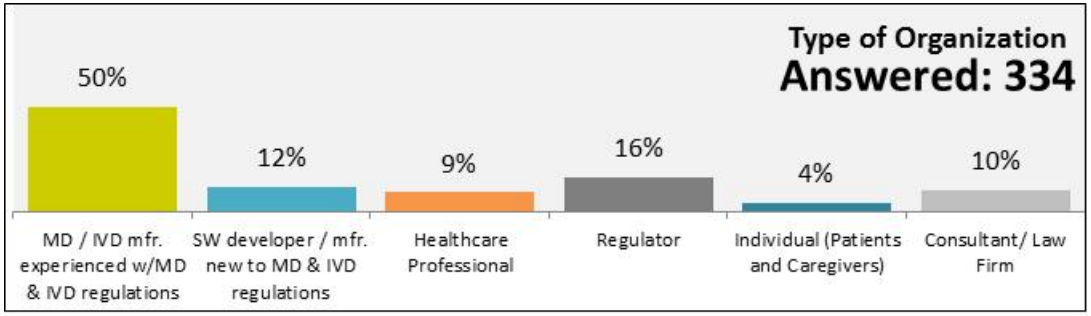
2. Prioritizing further IMDRF convergence efforts for SaMD



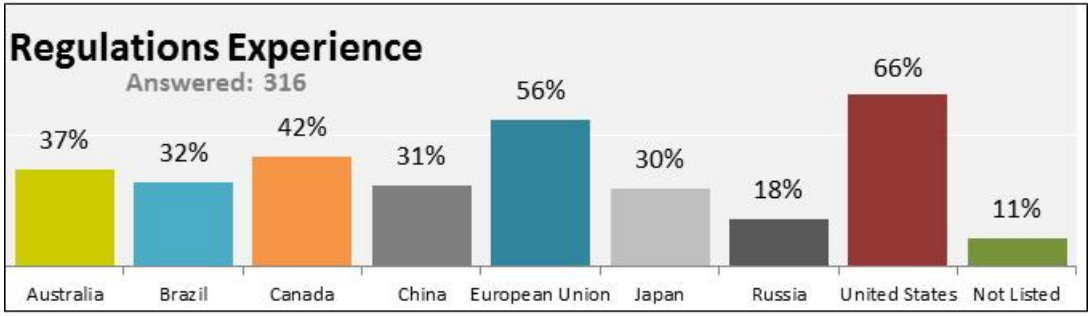


Survey succeeded with broad global outreach

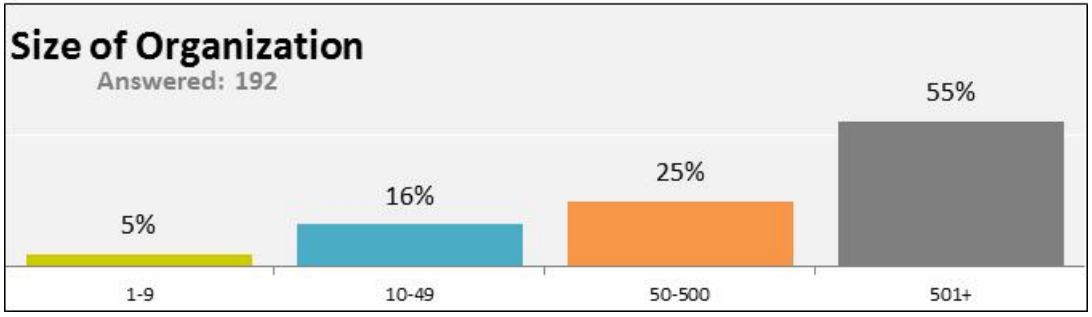
334 respondents of which 25% were **new** to MD/IVD regulation



~ 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.



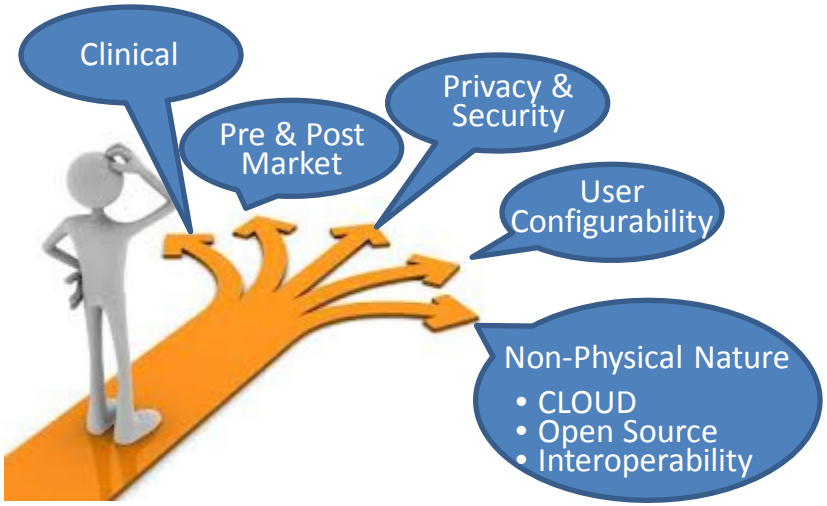
Key observations

- 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

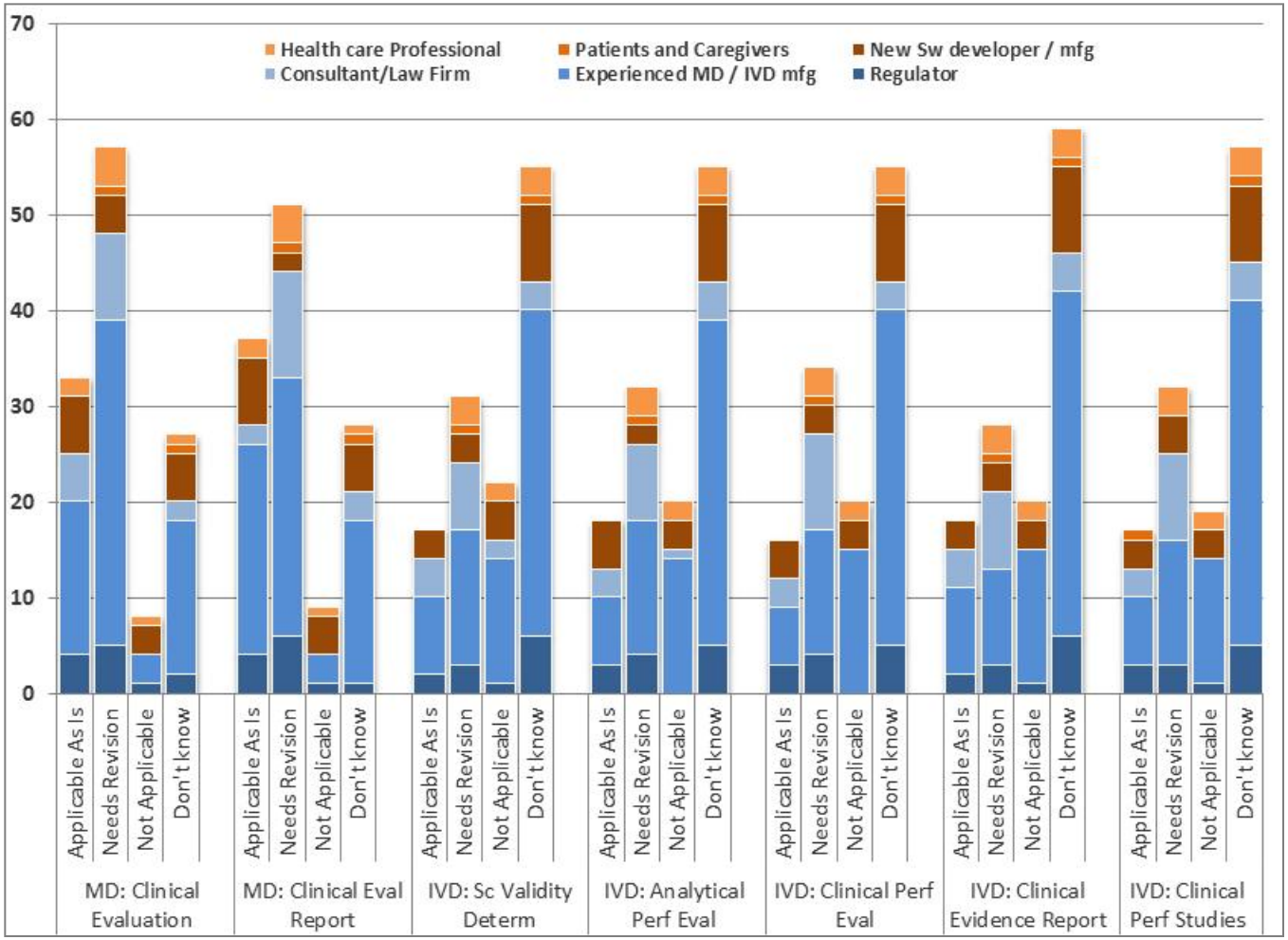
- **Data**
- **Ease of Iterations**
- **Systems**
- **Responsibilities**

❖ *Software specifics in standards fragmented/missing*

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

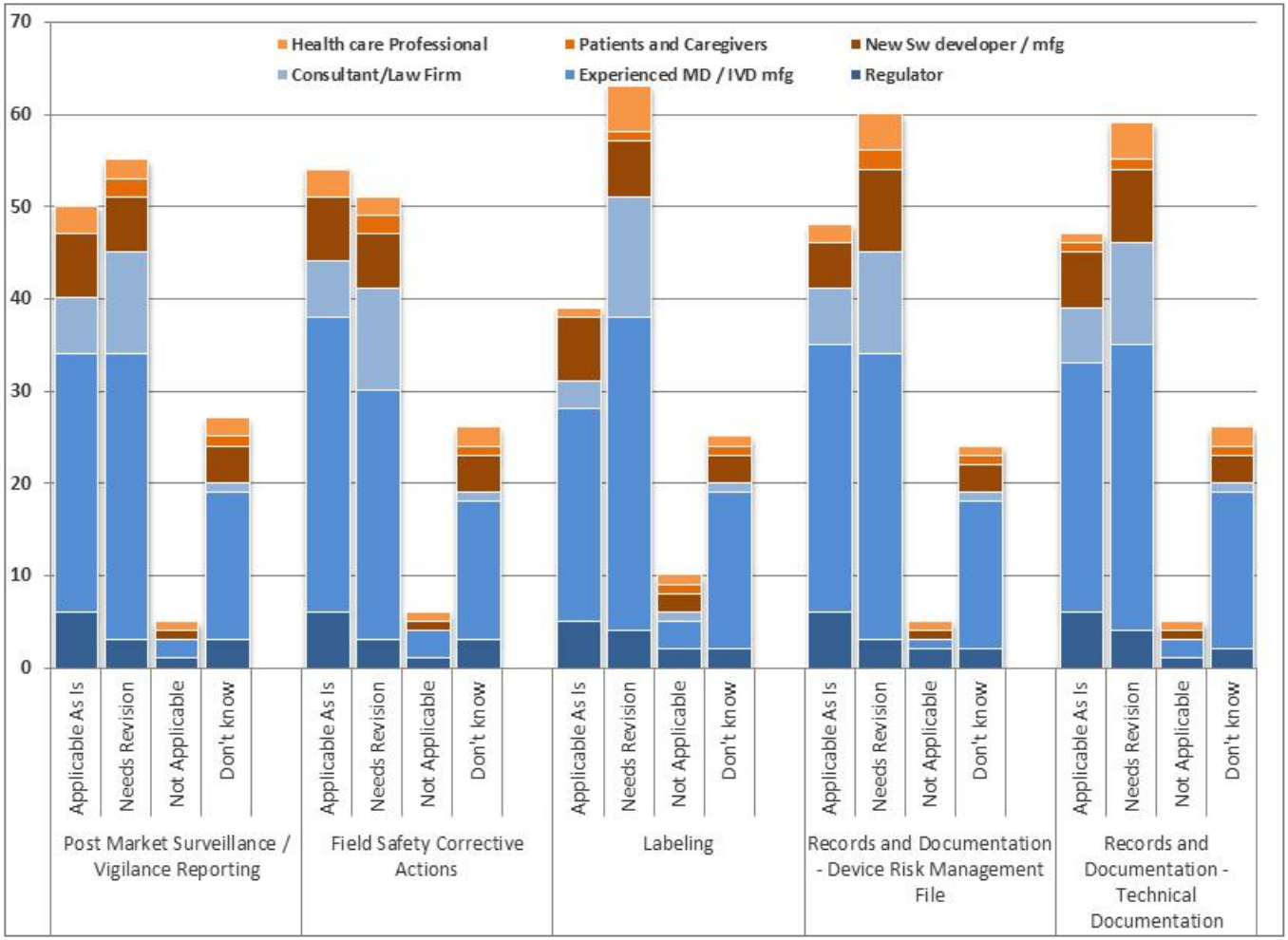
Responses to applicability of clinical guidance to SaMD

(n=152)



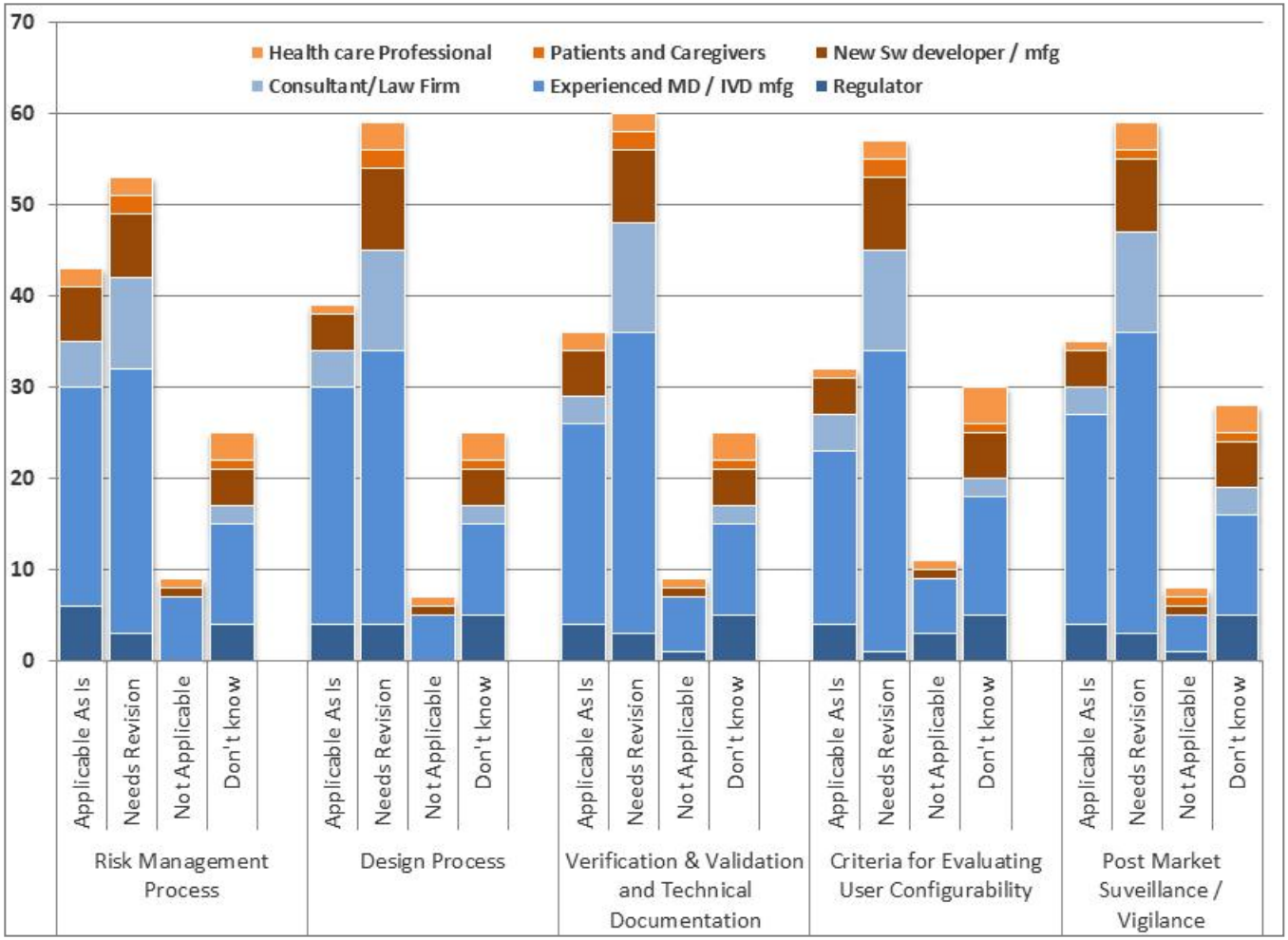
Marked difference between MD and IVD in applicability and awareness

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



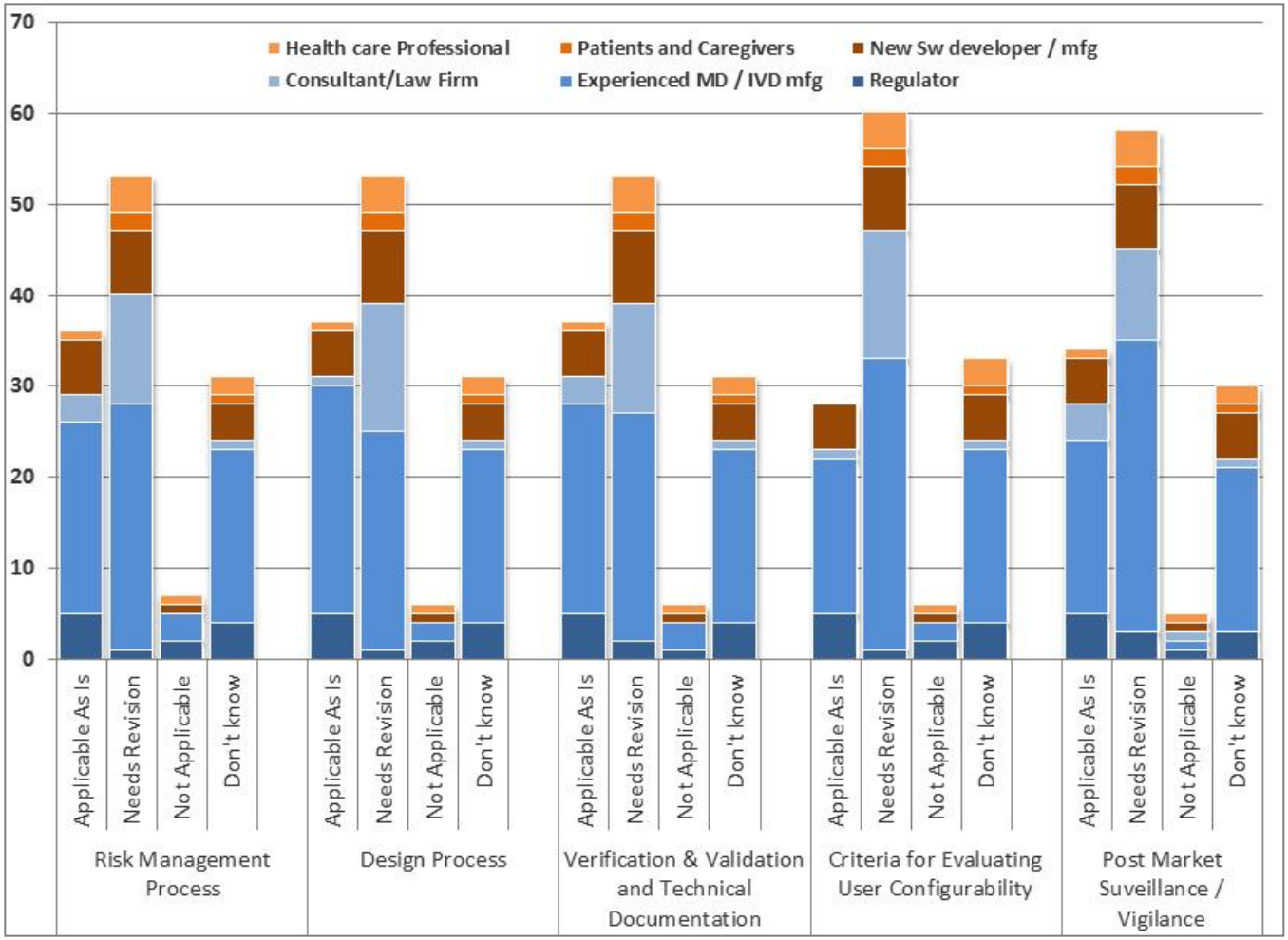
Consistently shows current pre and post market guidance is applicable as-is or needs revision

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



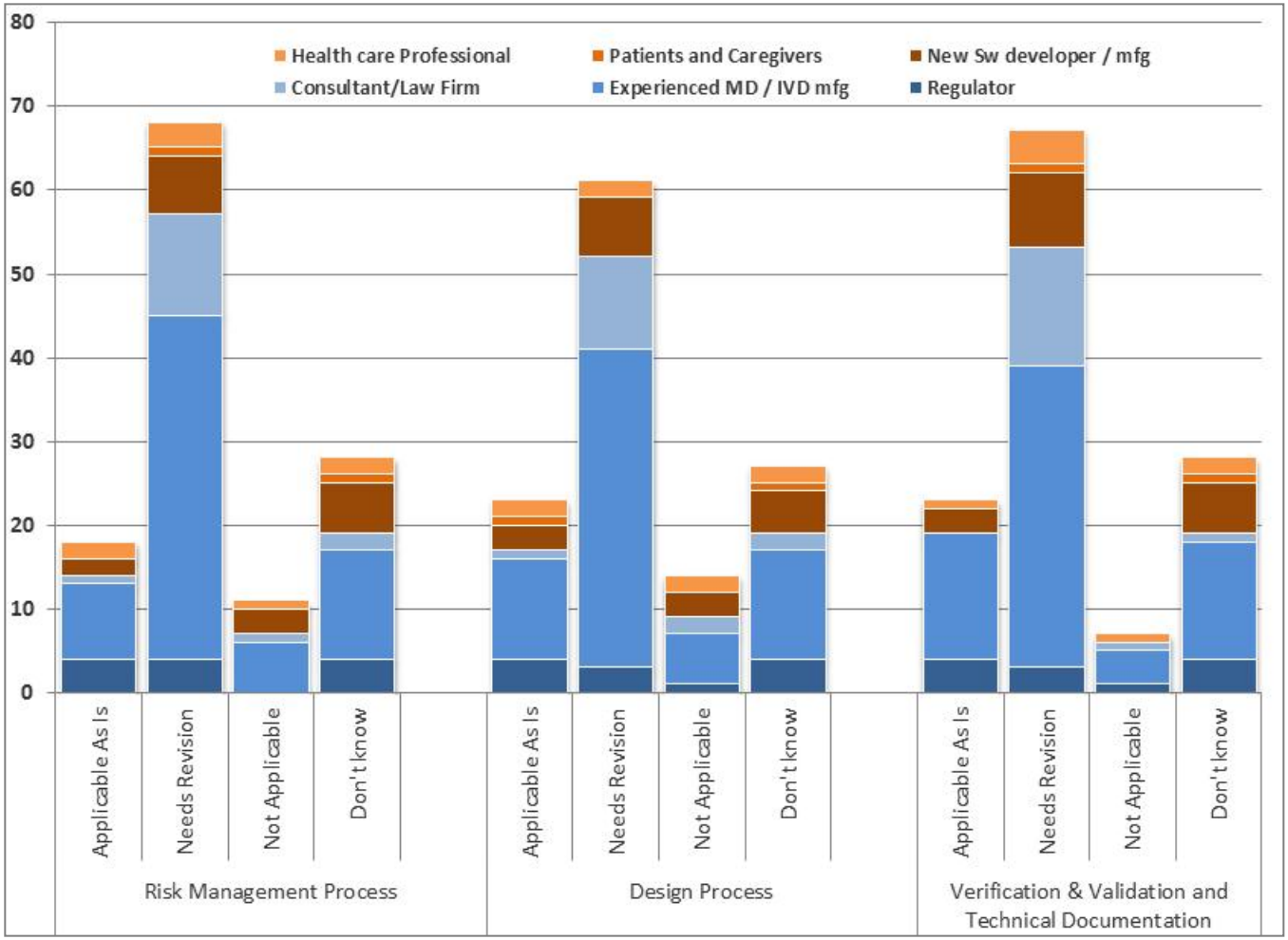
Consistently shows need for revision to address privacy and security

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



Consistently shows need for revision to address SaMD user configurability

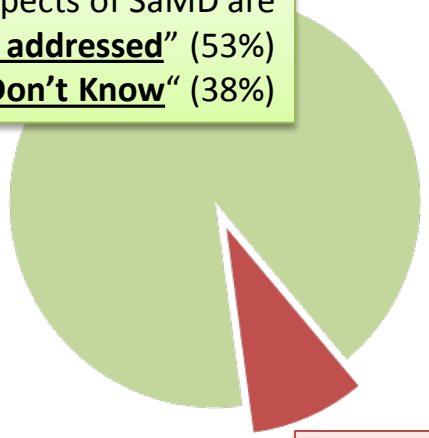
Responses to applicability of current guidance to non-physical nature of SaMD (n=126)



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.*

NWIE Proposal - Software as a Medical Device (SaMD): Clinical Data

Purpose: To give detailed guidance on when clinical data may be needed for an original SaMD and for a modification to a SaMD based on the risk classification for SaMD (SaMD N12) adopted by IMDRF to support market authorization.

Rationale: Though current clinical guidance are intended to be relevant across a broad spectrum of technology, SaMD operates in a complex socio-technical environment heavily influenced the inherent nature of software that enables a highly interactive and iterative technological environment. A majority of the respondents (from the IMDRF survey) either believe current clinical guidance needs to be revised with criteria specific for SaMD, or don't know whether it applies to SaMD.

Alignment with goals/objectives: A common understanding on the application of clinical evaluation and clinical evidence processes and the need for clinical data to support market authorization will lead to increased transparency and promoting a converged thinking on this topic.

General Work Plan and Timeline

Milestone	Timeline
Appointment of SaMD working group (WG) with clinical expertise	Month 1
Develop initial Work Plan (which will include review of relevant regulations, local guidances, etc.)	Months 1-3
Develop WD	Months 3-6
Submit WD to IMDRF MC and publish for public comment	Months 7-8
Resolve comments and produce FD	Months 9-10
Submit FD to IMDRF MC and publish	Months 11-12

Areas frequently highlighted in “free-form” comments