IMDRF International Medical Device Regulators Forum

Comments template – for submitting comments on proposed IMDRF documents.

Once completed, please forward to <Software.Regulation@tga.gov.au>[1].

Interested parties should respond by close of business **Wednesday 27 May 2015.**

Document number: **IMDRF/SaMD WG (PD1)/N23R3** Title: Software as a Medical Device (SaMD): Application of Quality Management System

Submitted by (name): **A/Prof Christopher Pearce** Affiliated to: **Australasian College of Health Informatics** On: / /

Comment Number	Page / Section / Line	Editorial or Technical	Comment and rationale	Proposed revised text	IMDRF Decision (& date)
1	8		SaMD generally does not exist in isolation. SaMD often integrates either with specific hardware (which supplies the raw data) or other software that may take the output. Therefore the QMS for SaMD should include an integration map of data flows outside the software.		
2	8		Generally, SaMD is to be used in a clinical environment, therefore the QMS for SaMD should include a separate, robust clinical governance structure. Clinical safety should be		

1 (The TGA will collate comments received for submission and send on to the working group).

			removed from its current position and placed within the clinical governance structure.		
3	6.1		The leadership structure should include clinical leadership where the software is to have clinical impact.		
4	251/2		Clinical safety is a crucial part of any clinical software development.	an existing member *must* take on the additional role of ensuring adherence to patient safety and	
5	392		Add an extra dimension	Clinical Risk: does the use of the device create a clinical risk, either by its use influencing other factors or by its output influencing clinical activities.	
6	590		Patient safety and Clinical Environment considerations. Governance of SaMD should include a robust clinical governance framework as specified earlier. This governance should be expressed in clinical oversight and control of clinical activities.	Software used in a clinical environment should be subject to a clinical functional assurance process that includes clinical signoff that the software is fit for purpose.	
7	630		Importance of useability.	Design of SaMD should prioritise useability as not just desirable, but crucial to delivering clinical benefit and maximising patient safety.	
8	715		Importance of detailed clinical informatics input – by a clinical function assurance process rather that simple user acceptance testing	Software used in a clinical environment should be subject to a clinical functional assurance process that includes clinical	

				signoff that the software is fit for purpose.	