Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: White Paper on Medical Device Software Regulation - Software Qualification and Classification

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1. Introduction

Software plays an increasingly important role in medical devices, especially in the field of mobile healthcare; however, the rapid evolution, particularly in relation to standalone software and mobile technology, presents new and complex challenges for regulatory agencies, globally.

With increasing variety of software capabilities, there is need to identify medical software currently distributed, assess which software types require control based on their risk profile, and determine the degree of regulatory control necessary for the particular risk profile medical software.

A set of guidelines to allow member economies to assess the appropriate level of controls pertaining to software, and facilitate a harmonized approach to the regulation across member economies, is currently lacking.

While some regulatory bodies have taken approaches in developing definitions and frameworks for software that have common public health goals, there are variations in approach. This paper aims to provide a summary of the regulatory guidelines from such regulatory bodies for medical software established and implemented, and serves as an environmental scan to provide direction on the guidelines on a proposed regulatory framework for adoption, based on best practices.

We have referenced some regulatory bodies and jurisdictions – Australia TGA, China FDA, the European Union, Health Canada, MHLW Japan and US FDA – specifically to their published guidelines for medical software regulation. Notably, the International Medical Device Regulators Forum (IMDRF) is referenced for its focus on the recent developments in defining "software as a medical device" (SaMD).

The main aim of developing guidelines for medical software regulation is to facilitate member economies to establish and harmonize an economic and effective approach to the control of medical software in the interest of public health and in the continued innovation of medical software development.

2. Definitions

Various definitions have been provided by jurisdictions and international organisations to assist in the qualification and classification of software and defining regulatory requirements. Existence of such definitions in use across jurisdictions should be noted and adopted where practical for convergence of interpretation across jurisdictions.

- **Active medical device** (1; 2)**:** Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical

devices intended to transmit energy, substances or other elements between an active medical device and the patient without any significant change, are not considered to be active medical devices. Standalone software is considered to be an active medical device.

- **Mobile Medical Application** (3): A software application that meets the "medical device" definition and can be executed (run) on a mobile platform, or a web-based software application that is tailored to a mobile platform but is executed on a server. It either:
    - Is used as an accessory to a regulated medical device; or
    - Transforms a mobile platform into a regulated medical device.

- **Mobile platform** (3): A commercial off-the-shelf computing platforms, with or without wireless connectivity, that are handheld in nature. Examples of these mobile platforms include mobile computers such as the iPhone®, BlackBerry® phones, Android® phones, tablet computers, or other computers that are typically used as smart phones or personal digital assistants (PDAs).

- **Health software** (4)**:** software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care.

  The term "health software" is defined in IEC 82304-1 (under development) to capture the notion that the terms "medical device" and "medical software" are regulatory terms that may have different meanings in different jurisdictions. "Health software" includes a broader range of software than "medical software", yet still relates to software for health purposes for individual humans.

- **Standalone software**: software intended to be used for one or more medical purposes and is able to perform its medical purpose without being embedded in a hardware medical device or being dependent on specific or proprietary medical purpose hardware

  Note that the term "standalone software", while still used frequently, is considered confusing. Software that is made available without hardware -even when its intended use is to drive a hardware medical device- is also often designated as "standalone software". A globally accepted term, however, has not yet been agreed upon. See also chapter 5.1.1, where the IMDRF term SaMD is introduced: "software as a medical device", with approximately the same description as given here.

3. Types of Software that are Regulated as Medical Devices

Across jurisdictions, software which fall under the respective jurisdiction's medical device definition are regulated as medical devices. It is noted that the medical device definitions, although vary in wording between jurisdictions, in general encompass products intended to be used in the treatment, mitigation, diagnosis, monitoring or prevention of a disease or abnormal physical condition.

As the medical device definitions are high level criteria that broadly cover forms, presentations and scope of intended use, relying solely on the definition would mean a substantial level of granularity would be lacking in determining whether certain software should be qualified as medical device.

As such, in addition to the medical device definition, regulatory bodies have found it necessary to publish specific guidelines in relation to software qualification and classification, providing clarity on types of software that would be regulated as medical devices in their jurisdiction.

4. Forms of Medical Device Software

Software presents in a range of forms and functionality. There may be need to identify the form of medical software currently in the market such that controls may then be tailored based on the understanding of software forms and distribution modes on the market.

The identification of software forms should be an on-going process due to rapid advancements in software development and regulatory bodies would need to continue to keep abreast of developments in medical device technology. This is done to achieve and maintain a reasonable level of control, as a balance between ensuring public health and safety and avoid stifling of innovation and development of new technology.

Medical software can be broadly classified into three categories:

a) Software that drives a medical device or influences the use of a device. This typically refers to embedded software, incorporated as a component or part of accessory of a medical device. *E.g. imaging software in diagnostic ultrasound system, software in pacemaker, mobile software that controls insulin pump delivery rate.*

b) Software intended to be an accessory to a medical device
E.g. Software that accepts data transmitted from medical devices

c) Software that is a medical device in its own right
Software related to the functioning of a medical device may be part of a device or a device in its own right if it is placed on the market separately from the related device.
E.g. Treatment planning software, data analysis software for the purpose of directly aiding in the treatment or diagnosis of a patient

The above-stated categories include such software that is able to perform its medical purpose without being embedded in a hardware medical device or being dependent on specific or proprietary medical purpose hardware. This would refer to software capable of running on general purpose (non-medical purpose) computing platforms. The current IMDRF guidance defined such software as 'software as a medical device' (SaMD) (2).

Two modes of presentation of SaMD identified are recognised below (non-exhaustive):

a. Software applications that are supplied via download, transfer and/or installation directly to the end-user, and may be used as an accessory to a regulated medical device, or transform a general purpose platform (e.g. mobile platform) into a regulated medical device

b. Web-based software which is executed on a server, such as a web browser. A web-based software would involve the delivery of computing as a service rather than a product.

   A web system for the monitoring of clinical data may interact with a medical device (e.g. implanted devices or homecare devices), and uses a transmitter to send the information over the internet, a landline telephone or a mobile network.

   The information is collected and stored on a web server usually run by an external party who is generally the manufacturer of the system. The information can be reached by authorized health professionals or the patient through an internet connection.

Of the above two modes of presentation for SaMDs, while the general principles of software qualification, classification and design verification and validation do not differ, it is however noted there are potential differences in mechanisms employed for their post-market control, including traceability of end-users.

Per IMDRF guidelines, existing regulations adequately address public health risks of software when embedded in a traditional medical device. However, existing regulations do not readily translate or address the unique public health risks posed by standalone software nor assure an appropriate balance between patient/consumer protection and promoting public health by facilitating innovation.

Existing regulatory controls may have limited applicability when software can be developed, distributed, and accessed in a distributed environment through the internet.

The below environment scan will cover controls in place for SaMD in other regulatory agencies.

5. SaMD Medical Device Software Classification Globally

5.1. International Medical Device Regulatory Forum (IMDRF)

5.1.1. IMDRF qualification criteria

The IMDRF released a finalized a set of definitions for device software. This document defines "software as a medical device," or SaMD, as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical devices." In defining SaMD, the guidance highlights a list of characteristics of SaMD:

- SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device.
- SaMD is capable of running on general purpose (non-medical purpose) computing platforms
- without being part of" means software not necessary for a hardware medical device to achieve its intended medical purpose;
- Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device.
- SaMD may be used in combination (e.g., as a module) with other products including medical devices;
- SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software
- SaMD includes mobile apps that meet the definition of an SaMD as set out in the guidance

It also provides examples of the various tasks that medical software may perform, primarily qualifying software that perform medical purposes within the scope of the medical device and In Vitro Diagnostic (IVD) medical device definitions. This includes software that can perform, or aid in the course of, the diagnosis, monitoring or treatment of, physiological status, predisposition or disease.

The guidance also briefly mentions on possible changes to SaMD during its lifecycle, which includes changes as part of the software maintenance phase. Such maintenance changes may be adaptive (e.g. keeps pace with the changing environment), perfective (e.g. recoding to improve software performance), corrective (e.g. corrects discovered problems), or preventive (e.g. corrects latent faults in the software product before they become operational faults).

5.2. Australia TGA

5.2.1. TGA qualification criteria

TGA's guidelines on software controls were published in Sept 2013, and the guidelines issued are relatively general. It is noted that TGA is actively participating in the IMDRF working group for SaMD, and TGA may update their guidance in light of the Working Group's ultimate recommendations (3).

Per TGA's guidelines, a software product is considered a medical device if it fits the definition in section 41BD of the Australian Therapeutic Goods Act 1989.

In line with EU guidelines on **information systems**, TGA's stand on software products limited to managing and presenting information - such as a medical records management system or a dosage calculator - would not usually come within the medical device definition unless it also incorporates a therapeutic or diagnostic function.*(Note: The dosage calculation described in the TGA guidance is presumed to only perform simple calculations routinely used in clinical practice, and not using patient specific data.)*

The TGA has a noted similar approach in software qualification as EU for software which play a role in diagnosing or managing illness through clinical data analysis, such as the results of blood tests or ECGs. Such software would, if they come within the definition above, be considered to be medical devices under TGA's purview.

Similar to the approach under FDA's guidelines for mobile medical applications, the TGA would not consider mobile apps that solely provide information (e.g. general health advice to consumers) to fall under their purview as medical devices.

5.2.2. Risk classification of software in TGA

Medical device software products that use a source of electrical energy to perform their functions are considered to be active medical devices under the classification rules contained in Chapter 4 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Medical device software intended to control or influence the functions of a device will generally fall into the same classification as that device.

However, medical device software intended as an accessory to a medical device would be classified separately from the device with which it is used.

5.3. China

5.3.1. CFDA qualification criteria

SaMD, based on its intended use, is considered in its own right as medical device in China, whether the software itself is the medical device or an accessory. This would include processing-type software and data-type software. In 2012, the China Food and Drug Administration (CFDA) published detailed guidelines on the re-registration requirements for medical device software, including standalone software.

5.3.2. Risk classification of software in CFDA

For the purpose of defining submission requirements, CFDA has categorised software into three classification levelsbased on level of concern, in a adopting the classification approach in the IEC 62304 standard on software life cycle processes: Class A (unlikely to cause injuries or hazards to health), Class B (may cause non-serious injury), Class C (may cause death or serious injury). The guidance also provides corresponding software submission requirements for each category.

5.4. European Union

5.4.1. EU qualification criteria

Guidelines MEDDEV 2.1/6 published by the European Commission refers to "standalone software" for medical device qualification (1). Such software would first need to have a medical purpose to be qualified as medical device. It is clarified that only the intended purpose as described by the manufacturer of the product is relevant for the qualification and classification of any device.

The guidance also clarifies some criteria for the qualification of standalone software as medical devices. Some qualification criteria are highlighted in the guidance:

- Not all standalone software used within healthcare can be qualified as a medical device.
- Standalone software can directly control an apparatus (e.g. radiotherapy treatment), can provide immediate decision triggering information (e.g. blood glucose meters), or can provide support for healthcare professionals (e.g. ECG interpretation).
- The operating systems or virtual environments on which a software may run do not impact the qualification criteria.
- Standalone software might also be an accessory of a medical device.
- The risk related to a malfunction of the standalone software used within healthcare is in itself not a criterion for its qualification or not as a medical device.

Tables 1 & 2 contains some examples on EU qualification for software with specific intended use. The MEDDEV guidance clarifies that the examples given were drafted in the light of today's state of the art and there may be more examples added in future in MEDDEV guidances in light of technological progress.

A software may comprise of a number of applications, where each of these applications are correlated with a module, some of whichmay have a medical purpose and some may not. In EU, medical device modules must comply with the medical device requirements while non-medical device modules are not subject to these requirements. However, if the modules are intended for use in combination with other modules of the whole software structure or other devices, the whole combination, including the connection system, must be safe and must not impair the specified performances of the modules which are subject to the MD Directives.

In relation to the medical device Directives, a proposal is currently underway for replacement of the existing three EU Medical Device Directives by two sets of regulations - Regulations of the European Parliament and of the Council on medical devices (4) and in vitro diagnostic medical devices (5). The draft is noted to propose additional general safety and performance requirements under Annex I, specifically for standalone software, including considerations for software operating on mobile computing platforms.

More recently, a Green Paper on mobile Health ("mHealth") (6) had been released by the European Commission in April 2014 for comments, describing the increased use of mobile platforms in replacing traditional methods in healthcare, as well as the concomitant need to ensure a level of public protection and safety with such technologies. Areas of safety concern

highlighted include telecommunication networks, personal data and safety and performance of mHealth software applications. Certain mHealth software applications will be regulated as medical devices under the current medical device directives (MDD), with reference to the above discussed MEDDEV 2.1/6 guidelines. However, lifestyle and wellbeingapps are largely excluded from device controls and hence the performance and safety requirements of the MDD.

5.4.2. Risk classification of software in EU

The risk classification of medical devices in EU is via a risk-based system based on the vulnerability of the human body taking account of the potential risks associated with the devices. The classification rules are set out in Annex IX of the EU Directive 93/42/EEC.

Standalone software that meets the definition of a medical devices are considered as an 'active medical device', meaning that the risk classification rules 9, 10, 11 and 12 of Annex IX of the EU Directive 93/42/EEC may apply.

Software type	Hospital Information Systems (HIS)	Information Systems		Communication Systems (Tele-medicine)		Web Systems for monitoring of data		Decision Support Software
		Electronics Patient Record	Additional modules in Electronics Patient Record for diagnosis, therapy and follow-up					
Intended use	Patient admission, scheduling patient appointments, insurance and billing purpose	Store & transfer electronic patient records. Archives all kinds of documents & data related to a specific patient (e.g. vital parameters, patient identification, scheduling, examination results, image identification details & other documented clinical observations. - *Clinical Information Systems (CIS)/ Patient Data Management Systems (PDMS)* - *Pre-hospital ECG System* - *Radiological Information Systems*	Modules that are intended to provide additional information that contributes to diagnosis, therapy and follow-up, e.g. - *Image viewer with functionality for diagnosis* - *Medication module* - *Generate alarms* - *Provide information to start patient's treatment to paramedics when patient is transported*	General communication systems (email, mobile, video, paging etc.) for general purposes - *Home care monitoring* - *Video appointment*	Telesurgery software - intended to conduct a surgical procedure from a remote location. Remote control software used in combination with telesurgery robots.	Monitoring of non-medical performance of medical devices (software monitoring medical devices in hospital for maintenance & report)	Monitoring of performance of medical devices	Computer based tools which combine medical knowledge databases and algorithms with patient specific data *e.g. Radiotherapy treatment planning systems (calculate ionizing irradiation dosage), drug/chemotherapy planning systems (calculate drug dosage administration) & Computer aided detection system (automatically read x-ray images or interpret ECG)*
EU qualification	Not MD	Not MD	**MD** (modules only)	Not MD	**MD**	Not MD	**MD**	**MD**

Table 1: Examples of software types and their qualification as general medical devices in EU

Software type	Laboratory Information Systems (LIS) and Work Area Managers (WAM)	Expert System	Interpretation of raw data	Home care monitoring
Intended use	Support the process from patient sample to patient result. Management & validation of incoming information from IVD analysers (e.g. calibration, QC, product expiry, feedback) through interconnection with various analytical instruments. Takes care of communication of data (results, statistics) to external databases. Results are available, readable and understandable without the intervention of the software.	Intended to capture and analyse together several results obtained for one patient by 1 or more IVD devices, to provide information falling within the definition of an IVD medical device e.g. differential diagnosis. e.g. - Software that uses algorithm to characterize viral resistance to various drugs, passed on nucleotide sequence generated by genotyping assays	Used to render raw data (obtained from an IVD test) readable for the user	Intended for archiving patient results or for transferring results from home to healthcare provider. Results are available, readable and understandable by the user without the intervention of the software.
EU qualification*	Not MD	IVD MD	**IVD MD**	Not MD

Table 2: Examples of IVD software types and their qualification as IVD medical devices in EU

Note: All above software may be used with additional modules. These modules might be qualified in their own right as medical devices.

5.5. Health Canada

5.5.1. Health Canada qualification criteria

Per guidelines as set out in Canada, software that is intended or represented for use in the diagnosis or treatment of an abnormal physical state of a patient meets the definition of a medical device under the Food and Drugs Act and must therefore comply with the requirements of the Medical Devices Regulations in Canada.

In a published FAQ, software regulated as medical devices is further specified as such software that:

1. provides the only means and opportunity to capture or acquire data from a medical device for aiding directly in diagnosis or treatment of a patient; or
   (e.g. picture archiving and communication system (PACS) and other types of software that have traditionally been licensed since they are adjuncts or accessories to medical devices)
2. replaces a diagnostic or treatment decision made by a physician.

5.5.2. Risk classification of software in Health Canada

Per Health Canada guidelines, medical device software that meets the definition of a medical device would therefore be classified in accordance with the classification rules for medical devices as stated in the Regulations.

As such, medical device software is considered to be an active device because it relies on a source of energy other than energy generated by the human body or gravity, and as such the risk class rules for the active medical devices would apply.

Software type	**Hospital Information Systems (HIS)**	**Information Systems**		**Communication Systems (Tele-medicine)**				**General fitness, health or wellness**	**Decision Support Software**
		Electronic Medical Records	**Additional modules in Electronics Patient Record for diagnosis, therapy and follow-up**						
Intended use	Perform administrative calculations and manipulations (such as determining time between appointments, or workflow management),	Electronic Medical Records (EMRs), Electronic Patient Records (EPRs), and Electronic Health Records (EHRs) Medical Device Data System Software that display, store, or transfer medical device data in its original format	Modules that are intended to provide additional information that contributes to diagnosis, therapy and follow-up, e.g. - *Image viewer with functionality for diagnosis* - *Medication module* - *Generate alarms* - *Provide information to start patient's treatment to paramedics when patient is transported*	Display medical device data to perform active patient monitoring	Software intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease Analyzing device-provided data for the purpose of directly aiding in the treatment or diagnosis of a patient	Intended to be used to view images, or other real time data, as an adjunct to the monitoring device itself, for the purpose of aiding in treatment or diagnosis of a patient	Middleware - software that connects two or more software applications so that they can exchange data	Intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness e.g. Wii Fit video game, personal BMI calculators and pedometer software used for fitness	Data manipulation, data analysis, data editing, image generation, determination of measurements, identification of a region of interest in an image, or identification (by an alarm or alert) of results from a monitor that are outside of an established range
Health Canadaqualification		Not MD	**MD**	**MD (Class I)**	**MD (Class II)**		Not MD	Not MD	**MD**

Table 3: Examples of software types and their qualification as medical devices in Health Canada

5.6. MHLW Japan

5.6.1. MHLW Japan qualification criteria

Embedded software which are intended to operate the medical device is regulated as unbroken part of the Hardware (medical device), have been regulated as medical devices under the current and original legal framework. MHLW, in taking such standalone software as medical devices, had done so in considering the appropriate regulation for the medical software, due to the importance of regulatory control on these products.

It is noted, from an update in Nov 2012, that the relevant Japanese industry associations, JIRA/JAHIS/JEITA, have formed a joint work group with the goal of make recommendations on the range of the regulations on software.

Revised Pharmaceutical Affairs Law (PAL) was adopted by the Diet, and announced on 27 November 2013. Standalone medical device software will be regulated by the revised PAL. Currently the details on the regulatory framework like the qualification, classification and control of the standalone software are being discussed. The revised law will be enforced in November 2014.

5.7. US FDA

5.7.1. US FDA qualification criteria

Under the US FDA regulations for medical devices, any software that meets the legal definition of a device under section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act, is deemed a device and is known as medical device software.

Similar to the EU, there are further general criteria specified by the US FDA to be considered for qualification of medical device software:

- Operating systems or virtual environments on which a software may run do not impact the qualification criteria.
- Qualification is based on the intent of the product, and is not based on the engineering definition of software functionality
  If software intent falls under the legal definition, software is still a device regardless of the means by which the software is delivered to the end user (factory-installed, field-installed, embedded, etc)

With the Mobile Medical Applications guidance published in Sept 2013 by the US FDA, the agency has broadly categorized mobile applications (MAs) as (1) MAs that are the focus of FDA's regulatory oversight, (2) MAs that are not medical devices and (3) MAs that, although qualify as medical device, FDA intends to exercise enforcement discretion as they pose a low risk to patients.

5.7.2. Risk classification criteria in US FDA

Medical devices are categorised into 3 classes, Class I, II, III, based on the device's risk. Rather than providing a set of general guidelines as other reference agencies, the FDA defines specific device categories under Title 21 of the Code of Federal Regulations, each of which has a regulation number, and assigns the risk classification accordingly.

The Mobile Medical Applications guidance provides a consolidated list of already existing classifications for regulated medical devices, which pertain to devices that potentially contain or are presented as software, the Class according to which they are regulated and the corresponding submission type to the US FDA. The list is noted as a reference starting point for mobile medical app manufacturers in identifying regulated medical devices and is likely not meant to be exhaustive.

Software type	Hospital Information Systems (HIS)	Information Systems			Communication Systems (Tele-medicine)			Decision Support Software		Mobile apps that transform mobile platforms into medical devices	Automate tasks for health care providers
		Medical Device Data System	Patient management/ information	Access electronic/public health records							
Intended use	Patient admission, scheduling patient appointments, insurance and billing purpose	Software that display, store, or transfer medical device data in its original format	Help patients: • Self-management disease/ conditions without providing specific treatment or suggestions • Organize and track their health information • Access information related to theirhealth conditions or treatments • Document, show, or communicate potential medical conditions to health care providers	Enable individuals to interact with PHR systems or EHR systems	Display medical device data to perform active patient monitoring	General communi-cation systems (email, mobile, video, paging etc.) for general purposes - *Video appointment*	Remote Medication Management System software intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease Mobile apps that connect to an existing device type for purposes of controlling its operation, function, or energy source	Computer based tools which combine medical knowledge databases and algorithms with patient specific data *e.g. Radiotherapy treatment planning systems (calculate ionizing irradiation dosage), drug/chemotherapy planning systems (calculate drug dosage administration) & Computer aided detection system (automatically read x-ray images or interpret ECG)*	Perform simple calculations routinely used in clinical practice • Body Mass Index (BMI) • Total Body Water / Urea Volume of Distribution • Mean arterial pressure • Glascow Coma Scale score • APGAR score • NIH Stroke Scale • Delivery date estimator	Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices	Automate simple tasks for health care providers
US FDA qualification	Not MD	**MD** (Class I, 21 CFR 880.6310)	MD (Enforcement discretion applied to not regulate)	MD (Enforcement discretion applied to not regulate)	**MD**	MD (Enforcement discretion applied to not regulate)	**MD**	**MD**	MD (Enforcement discretion applied to not regulate)	**MD**	MD (Enforcement discretion applied to not regulate)

Table 4: Examples of software types and their qualification as medical devices in US FDA

6. Summary of regulatory agency qualification of software as a medical device

Based on currently published guidelines across the jurisdictions, it is clear that software form – embedded, standalone, mobile application – plays little to no role in determining whether the software is qualified as a medical device based on the medical device definition. With the enormous complexity and rapid advancements in software technology, it would be appropriate to follow suit and avoid defining software forms in any guidelines on software qualification to be developed. The focus of determining regulatory control has been emphasized to be passed on the intended use of the software, and hence the degree of risk to the user.

The US FDA and Australia TGA have additionally specified that general platforms, on which such medical software may run or be distributed, are not intended by their manufacturer to be used for therapeutic purposes would not be regulated as a medical devices. Such examples of platforms include general-use mobile phones, computers and tablets, which are not entities that exclusively distribute medical software.

In regards to specific software types, a similar trend is observed in qualification of types of software as medical devices, although guidelines from each jurisdiction may specify certain software types that are not identified in other jurisdictions' guidelines, while some software types addressed differ in qualification status across jurisdictions.

A cross reference summary for Software as Medical Device for US FDA, European Union (EU) and Health Canada (HC) is provided in Table 5.

Hospital Information Systems (HIS)/ Workflow Management Systems – Non-medical device

Such software intended for **communication and management in a clinical setting not related to patient therapy and diagnosis**, such as appointment scheduling, billing and workflow management, are generally recognised across jurisdictions as not medical devices.

Electronic Health Records – Non-medical device

Per Australia TGA, EU and Health Canada guidelines, **information systems** that only intended to store and view patient information (for example: age, weight, notes about a patient's appointment, patient test results, order processing, scheduling, or managing patient movement) would not besubject to medical device regulation. These are such software types that simply act to replaces a patient's paper file. However, additional modules in such systems that are intended to provide additional information that contributes to diagnosis, therapy and follow-up would be regulated as medical devices.

General well-being – Non-medical device

Information systems that are solely sources of information, i.e. providing general health advice to health professionals or consumers, are not regulated as medical devices per US FDA and TGA guidelines. In addition, software intended for developing or maintaining

general fitness, health or wellness of persons, without specific intention for the diagnosis of a disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, are not regulated as medical devices per US FDA and Health Canada guidelines.

Communication Systems for patient monitoring – Variation in qualification guidelines

Communication Systems intended for active patient monitoring have been qualified as medical devices under US FDA and Health Canada guidelines. However, the current Australia TGA guidelines do not specify qualification of such software. Under EU guidelines such telemedicine devices intended for home care monitoring are not considered as medical devices.

Communication Systems for controlling medical devices – Medical Device

It is noted that, across the regulatory agencies, communication software that connects to an existing device type for purposes of **controlling a medical device's operation, function** are regulated as medical devices. Such examples include software for performing tele-surgery, wireless remote controls or synchronization devices for computed tomography (CT), X-Ray machines, infusion pumps.

Decision Support Software – Medical Device

Across jurisdictions, **decision support software**, with their role in provide additional information that contributes to diagnosis and therapy are regulated as medical devices.Such software may combine medical knowledge databases and algorithms with patient specific data, or suggest treatments for specific patient conditions. This would includeradiotherapy treatment planning systems that calculate ionizing irradiation dosage, drug or chemotherapy planning systems and computer aided detection systems that automatically read x-ray images or interpret ECG. As such software would indeed directly influence in the treatment and diagnosis of the patient, such software would fit into the medical device definitions across the jurisdictions.

Software type	Hospital Information Systems (HIS) / Workflow Management System	Information Systems				Laboratory Information Systems (LIS) and Work Area Managers (WAM)	Communication Systems(Tele-medicine)					Web Systems for monitoring of data (Device Monitoring)		Decision Support Software/ Expert System (EU IVDD) / Interpretation of raw data (EU IVDD)		Automate tasks for health care providers	General fitness, health or wellness
		Medical Device Data System	Patient management/ information (US) / Home care monitoring (EU)	Access electronic/ public health records	Additional modules in Electronics Patient Record for diagnosis, therapy and follow-up		Any Platform				Mobile apps that transform mobile platforms into medical devices						
Intended use– EU Interpretation	Patient admission, scheduling patient appointments, insurance and billing purpose		Intended for archiving patient results or for transferring results from home to healthcare provider. Results are available, readable and understandable by the user without the intervention of the software.	Store & transfer electronic patient records. Archives all kinds of documents & data related to a specific patient (e.g. vital parameters, patient identification, scheduling, examination results, image identification details & other documented clinical observations. - *Clinical Information Systems (CIS)/ Patient Data Management Systems (PDMS)* - *Pre-hospital ECG System* - *Radiological Information Systems*	Modules that are intended to provide additional information that contributes to diagnosis, therapy and follow-up, e.g. - *Image viewer with functionality for diagnosis* - *Medication module* - *Generate alarms* - *Provide information to start patient's treatment to paramedics when patient is transported*	Support the process from patient sample to patient result. Management & validation of incoming information from IVD analysers (e.g. calibration, QC, product expiry, feedback) through interconnection with various analytical instruments. Takes care of communication of data (results, statistics) to external databases. Results are available, readable and understandable without the intervention of the software.		General communication systems (email, mobile, video, paging etc.) for general purposes - *Home care monitoring* - *Video appointment*	Telesurgery software - intended to conduct a surgical procedure from a remote location. Remote control software used in combination with telesurgery robots.			Monitoring of non-medical performance of medical devices (software monitoring medical devices in hospital for maintenance & report)	Monitoring of performance of medical devices	MDD: Computer based tools which combine medical knowledge databases and algorithms with patient specific data *e.g. Radiotherapy treatment planning systems (calculate ionizing irradiation dosage), drug/chemotherapy planning systems (calculate drug dosage administration) & Computer aided detection system (automatically read x-ray images or interpret ECG)* *IVDD Expert System*:Intended to capture and analyse together several results obtained for one patient by 1 or more IVD devices, to provide information falling within the definition of an IVD medical device e.g. differential diagnosis. e.g. - Software that uses algorithm to characterize viral resistance to various drugs, passed on nucleotide sequence generated by genotyping assays IVDD Interpretation of raw data: Used to render raw data (obtained from an IVD test) readable for the user			
EU qualfication	Not MD (MDD)		Not MD (IVDD)	Not MD (MDD)	**MD (MDD)** (modules only)	Not MD (IVD)		Not MD (MDD)	**MD (MDD)**			Not MD (MDD)	**MD (MDD)**	**MD (MDD)** **MD (IVDD)**			
Intended use– HC Interpretation	Perform administrative calculations and manipulations (such as determining time between appointments, or workflow management),			Electronic Medical Records (EMRs), Electronic Patient Records (EPRs), and Electronic Health Records (EHRs) Medical Device Data System Software that display, store, or transfer medical device data in its original format	Modules that are intended to provide additional information that contributes to diagnosis, therapy and follow-up, e.g. - *Image viewer with functionality for diagnosis* - *Medication module* - *Generate alarms* - *Provide information to start patient's treatment to paramedics when patient is transported*		Display medical device data to perform active patient monitoring	Middleware - software that connects two or more software applications so that they can exchange data	Software intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease Analyzing device-provided data for the purpose of directly aiding in the treatment or diagnosis of a patient	Intended to be used to view images, or other real time data, as an adjunct to the monitoring device itself, for the purpose of aiding in treatment or diagnosis of a patient					Data manipulation, data analysis, data editing, image generation, determination of measurements, identification of a region of interest in an image, or identification (by an alarm or alert) of results from a monitor that are outside of an established range			Intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness e.g. Wii Fit video game, personal BMI calculators and pedometer software used for fitness
HCqualification				Not MD	**MD**		**MD (Class I)**	Not MD	**MD (Class II)**	**MD (Class II)**				**MD**			Not MD
Intended use– US Interpretation	Patient admission, scheduling patient appointments, insurance and billing purpose	Software that display, store, or transfer medical device data in its original format	Help patients: • Self-management disease/ conditions without providing specific treatment or suggestions • Organize and track their health information • Access information related to their health conditions or treatments • Document, show, or communicate potential medical conditions to health care providers	Enable individuals to interact with PHR systems or EHR systems			Display medical device data to perform active patient monitoring	General communi-cation systems (email, mobile, video, paging etc.) for general purposes - *Video appointment*	Remote Medication Management System software intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease Mobile apps that connect to an existing device type for purposes of controlling its operation, function, or energy source		Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices			Computer based tools which combine medical knowledge databases and algorithms with patient specific data *e.g. Radiotherapy treatment planning systems (calculate ionizing irradiation dosage), drug/chemotherapy planning systems (calculate drug dosage administration) & Computer aided detection system (automatically read x-ray images or interpret ECG)*	Perform simple calculations routinely used in clinical practice Body Mass Index (BMI) Total Body Water / Urea Volume of Distribution Mean arterial pressure Glascow Coma Scale score APGAR score NIH Stroke Scale Delivery date estimator	Automate simple tasks for health care providers	
US FDA qualification	Not MD	**MD** (Class I, 21 CFR 880.6310)	MD (Enforcement discretionapplied to not regulate)	MD (Enforcement discretionapplied to not regulate)			**MD**	MD (Enforcement discretionapplied to not regulate)	**MD**		**MD**			**MD**	MD (Enforcement discretionapplied to not regulate)	MD (Enforcement discretion applied to not regulate)	

Table 5: Summaries of software types and their qualification as medical devices in EU, HC and US FDA

7. Conclusion

In regards to specific software types, it can be observed that there is a general trend in qualification of types of SaMD, although guidelines from each jurisdiction do have unique software types identified that are not addressed in other jurisdictions' guidelines, while some software types addressed differ across jurisdictions in their qualification status as medical devices.

Broadly, the paper has also attempted to identify trends across jurisdictions in the qualification of SaMD, where a possible identification of best practice approach in software qualification can be explored.

In regards to software classification, referenced jurisdictions generally have not produced new classification criteria specifically for SaMD, instead providing additional guidelines for software referring back to the existing classification guidelines to determine software risk class. Given that majority of such guidelines specify classification assignment based on intended purpose and degree of risk the end user is exposed to, their application to SaMD, which is also qualified based on intended function and risk, still would remain appropriate.

It is proposed that the next steps for the AHWP would be to adopt a position on the qualification and classification of SaMD, with a view to align as far as possible to global harmonisation or convergence of SaMD guidelines. Following which, development of regional documentation or guidance on software qualificationand definition, submission format and software change evaluation, as well as maintain follow-up with developments in medical device regulatory activities, internationally.

In the course of establishing recommendations for software regulatory controls throughout the software lifecycle, software international standards that are currently available can be identified that may facilitate regulators and manufacturers compliance to medical device safety and performance requirements (7; 8).

The group will also follow closely on the progress of and work together as far as possible with the International Medical Device Regulators Forum (IMDRF) Standalone Medical Device Software Working Group, to ensure a harmonised approach in software regulatory controls, globally.

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Note: *As of the publication of this paper, amendment1 to IEC 62304:2006 is in preparation; the CDV version was published in April 2014. Under consideration is the development of a 2nd edition of IEC 62304, with a scope extension to "health software" (see chapter 2, Definitions). Decision on such 2nd edition is expected later in 2014.*

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