Australian Government
Department of Health
Therapeutic Goods Administration

Update on software as a medical device (SaMD)

The TGA and IMDRF perspectives

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ARCS Scientific Congress Canberra 2016

11 August 2016

TGA Health Safety Regulation

Australian Government
Department of Health
Therapeutic Goods Administration

Overview

1. What is a “Medical Device”?
   - Definition and Regulation but not classification
2. Software as a Medical Device (SaMD)
   - IMDRF working group update (NOT a regulation framework)
3. Pre and Post-market perspectives
   - Issues and challenges of software Devices
4. Q&A
   - Time permitting…

Is it a “device”? Definition

41BD What is a *medical device*

(1) A ***medical device*** is:

(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and ***including the software necessary*** for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, _____, monitoring, treatment, alleviation of or compensation for an injury or disability;

(iii) investigation, replacement or modification of the anatomy or of a physiological process;

(iv) control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means (cont…)

AUSTRALIA

Therapeutic Goods Act 1989

No. 21, 1990

Compilation No. 64

Compilation date:	10 March 2016
Includes amendments up to:	Act No. 12, 2016
Registered:	12 April 2016

Is it a “device”? Definition

41BD What is a *medical device (cont.)*

…and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or

(ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or

(b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).

Note: Declarations under subsection (3) exclude articles from the scope of this definition. Declarations under section 7 can also have this effect: see subsection 7(4).

Is it a “device”? What’s the Intended Purpose?

41BD 2 Intended Purpose

- “Intended Purpose” is to be derived from labelling, instructions, advertising material and technical documentation, provided by the Legal Manufacturer
  - (the person under whose name the main equipment).
- NOTE:
  - The Secretary may declare particular things, devices, classes, types, or articles to be Medical Devices

  … or NOT!
  - *Such a declaration under this section does not stop articles from being therapeutic goods.*
  - *Such a declaration takes effect on the day on which the declaration is published – unless specified.*

Is it a “device”? Software becomes a device…

…when it meets the definition of *what is a medical device.*

That is, when the legal manufacturer intends for the software to be used in:*

- diagnosis,
- prevention,
- monitoring,
- treatment, or
- alleviation, of disease

*The intention is ascertained from statements made by the Manufacturer in labelling, instructions, advertising material or any other documentation provided with or about the software.

Is all “medical software” regulated by TGA?

- NO (please see previous discussion)
- EXCLUSIONS **may** include:
  - Software that is limited to managing and presenting information (HIS, dosage calculator)
  - Software that are simply sources of information (like a textbook) or advice to health professionals or consumers
    - (except if it relates to the advertising of therapeutic goods, labelling, and instructions for use)
- INCLUDED **likely** includes
  - Software that has a role in diagnosing or managing illness
  - Software that analyses clinical data, such as the results of blood tests or ECGs
- The TGA already regulates medical device software used for therapeutic purposes under the medical devices regulatory framework. Mobile apps would be considered within this framework.

Is it regulated? Software regulated by TGA

- Software Used in Manufacturing
- Software for maintaining QMS
- Software systems and toolsets
- Software with a therapeutic purpose
  - Firmware/embedded Software in
    - Monitors, Defibrillators, Pumps
    - In vitro diagnostic devices
    - Implantable (Pacemakers etc)
  - Traditional Applications
    - Central Station on a PC
  - **Standalone Software (on a disk only)**
  - **Apps (from app store)**

Generally NOT Regulated:

- No therapeutic purpose
  - (not itself, nor part of, a device)
- HIS, LIMS, PACS…
  - Info storage and retrieval only with no “device” functions/features

Possible room for doubt:

- Configuration/Setup Software
- Service Tools
- “Measurement” displays (graphs etc)

How is software regulated by TGA?

- The TGA regulates medical device software used for therapeutic purposes under the **medical devices** regulatory framework (if they meet the definition).
  - Mobile apps would be considered within this framework
  - Standalone Software would also be considered within this framework
- Regulation is risk based, and depends on the **intended purpose**
- Manufacturers of medical device software products (other than Class 1 - lowest risk) to obtain Conformity Assessment certification,
- All medical devices are expected to meet the Essential Principles for safety and performance.
- For further information, please refer to Section 13 in Part 2 of the Australian Regulatory Guidelines for Medical Devices (ARGMD).

Measuring functions – a point of contention

1.4 Medical devices with a measuring function

(1) For these Regulations, a medical device has a ***measuring function*** if the device is intended by the manufacturer to measure:

(a) quantitatively a physiological or anatomical parameter; or

(b) a quantity, or a qualifiable characteristic, of energy or substances delivered to or removed from the human body.

(2) The measurements given by a medical device that has a measuring function:

(a) must:

(i) be displayed in Australian legal units of measurement or other units of measurement approved by the Secretary for the particular device; or

(ii) be compared to at least one point of reference indicated in Australian legal units of measurement or other units of measurement approved by the Secretary for the particular device; and

(b) must be accurate to enable the device to achieve its intended purpose.

IMDRF International Medical Device Regulators Forum

SaMD Quality Management Principles

: A grouping of QMS activities from a Software perspective

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

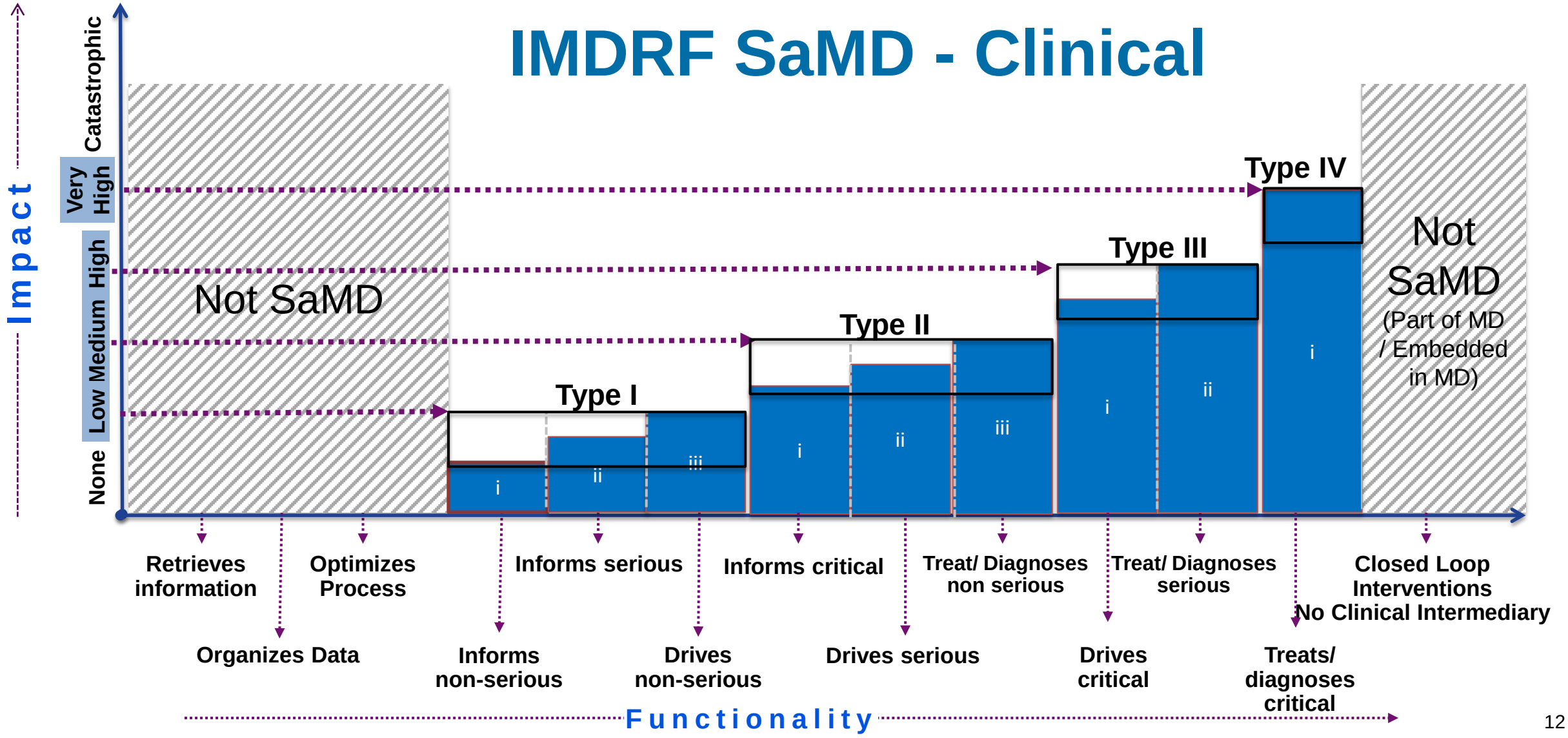
- Leadership and organizational support provides a ***foundation*** for SaMD lifecycle **processes**
- SaMD lifecycle **processes** ***support and apply across*** the SaMD lifecycle **activities**.

Source: www.imdrf.org

IMDRF – SaMD: several key achievements

- Definitions paper – what is SaMD
- Risks paper – framework for classifying risk
- Quality Management Systems (QMS) – translating QMS into SaMD development
- Clinical Evidence - WIP

IMDRF SaMD - Clinical



Pre-market – Some general issues

- **Evidence** – having Adequate/appropriate evidence regarding
  - Performance
  - Algorithms
  - Design and Quality documentation
  - Instructions

- **Classification** – accessory or device?
  - Classification rules for devices

Post-market – some general issues

- **Feature Creep** - crossing the definitional line, one feature at a time
- E.g. a blood sugar level (BSL) tracking app:
  - Record BSL (rev 1.0)
  - Graph BSL (rev 1.3)
  - Trend BSL (rev 2.3)
  - Alert BSL (rev 2.7)
- **Blind to the Regs** – not being aware of building a regulated Medical Device
  - Home tinkerers
  - An “obvious” extension of an existing product – remote view
- **Feature obfuscation** – deliberate “de-emphasising” of features to down-classify a device – practiced in USA
- **Media and Public Interest** – matching the promise to reality
  - Health market to reach **$26 billion** by 2017 (was just $700 million in 2011!)

Post-market incidents and complaints

- Learning to recognise reportable incidents is a big challenge – users may think…
  - Software issues are managed by a "reboot" – so no report is needed… wrong.
  - Software issues are misidentified as "user issues" – no report needed… wrong.
- Software issues most evident immediately after an update/upgrade
- Upward trends (relating to quality) are reportable

- Capturing and tracking incidents and complaints – a big challenge
- Linking incidents to risk management – closing the feedback loop
- TGA's Recognise, Retain, and Report campaign

Post-market regulatory actions

Challenges

- Safety related updates under URPTG – not widely known in Software industry
- Software expected to follow IEC 62304 – recognised as state-of-the-art – linked to Essential Principles
- Proliferation of “manufacturers” – with limited or no medical domain knowledge
- Software recalls - fixed by the time its reported

Benefits

- Software recalls - fixed “overnight” - everywhere, globally...
- Feedback in stores for possible complaint records
- Some ecosystems (e.g. Apple) can “force” updates or disabling of features and apps

Summary

- What is a “Medical Device”?
  - Something that meets the definition in the Act
- Software as a Medical Device (SaMD)
  - If it looks like a duck…
  - IMDRF paper open for comment
- Post-market Perspectives
  - Tracking and reporting incidents
  - Updates aligned to correct regulatory pathway
- Q&A (Time permitting…)

Questions?

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Advice on software/apps regulation

The TGA web statement – worth a read:

- www.tga.gov.au/regulation-medical-software-and-mobile-medical-apps

Some highlights follow…

Other useful sources:

- FDA: Mobile Apps Guidance
  www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf
- IMDRF: SaMD – more on that shortly
  www.imdrf.org/consultations/cons-samd-aqms-150326.asp

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