Australian Government
Department of Health
Therapeutic Goods Administration

Software based medical devices

Current considerations of the regulatory mindset in the design and development of software based medical devices

Dr David Hau
Medical Devices Authorisation Branch
Australian Government Department of Health, TGA
ARCS Annual Conference 2022

23 May 2022

TGA Health Safety Regulation

In this presentation:

I would like to note that the Government is in caretaker mode and in accordance with the caretaker conventions I will be limiting my statements today to factual issues and matters of administration.

Overview

- When is software a medical device – current framework?
- Key regulatory considerations
- Combination products

When is software a medical device?

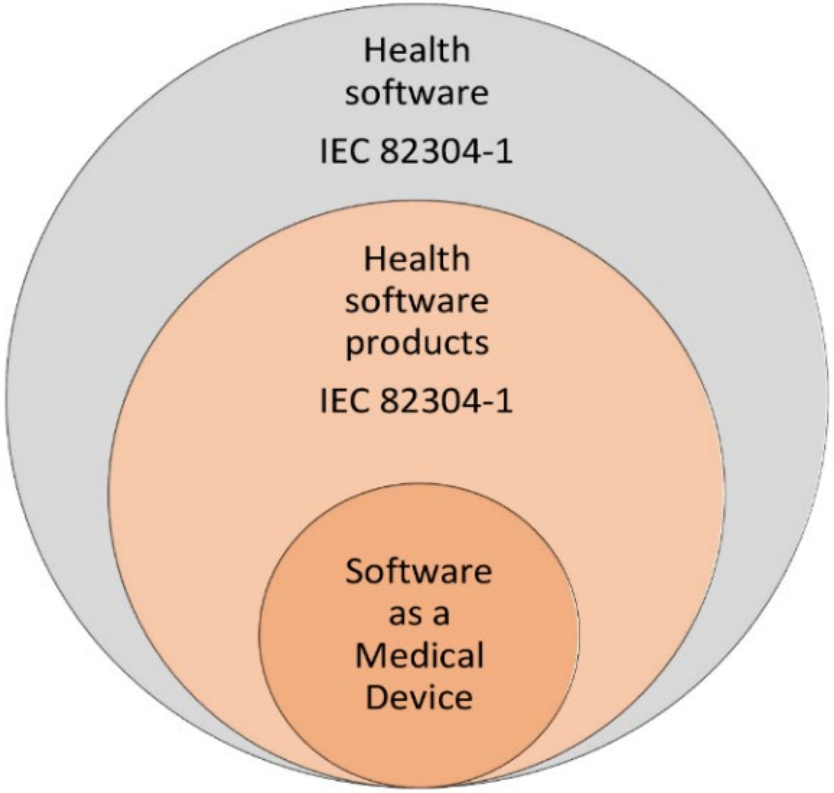
A **medical device** is: any instrument, apparatus, appliance, **software,** implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, for:

- **diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, injury or disability**

This means:

- digital - software on **any computing platforms** (computers, tablets, smartphones, browsers);
- software that is **part of a medical device** - is regulated as part of that device;
- apps that **control a medical device** - are regulated as an accessory or a device;
- apps that **rely on medical device hardware** in addition to a general computing platform (e.g. sensors) - are part of a medical device.

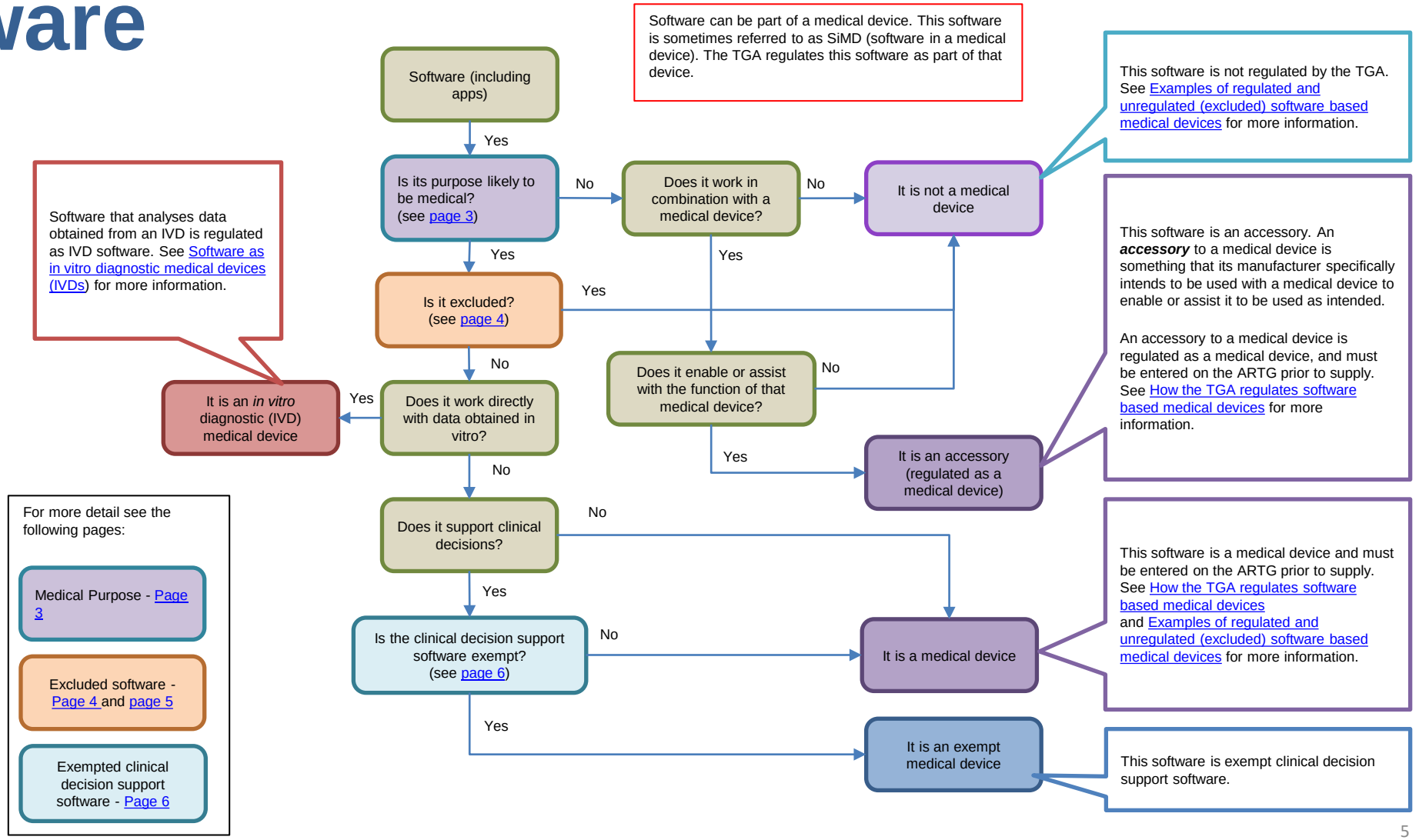
Not all health software is a medical device



Most health software is not a medical device and is not regulated by the TGA

- Some “carved out” if very low risk to safety or if under alternative oversight systems (known as excluded or exempt devices)

Is my software regulated?



Recent regulatory changes for software

- New risk classification rules for diagnosis, monitoring and treatment
- Essential principles – changes for cyber security, version control, data and information
- Clarifications of the boundary of regulation – resulting in the “carve outs”

Software “carved out” with conditions

- Some **Clinical Decision Support Software** exempted from some aspects of regulation; and

- 15 product types (grouped into 6 categories) excluded from regulation
  - **Consumer** health products - prevention, management and follow up devices that do not provide specific treatment or treatment suggestions
  - **Digital mental health tools**
  - **Enabling** technology - for telehealth, remote diagnosis, healthcare or dispensing
  - **Digitisation** - of paper based or other published clinical rules or data including simple calculators and Electronic Medical Records
  - **Analytics** - population based
  - **Laboratory Information Management Systems**

Classification of medical devices – risk of harm

Classification	Class I	Class Im	Class IIa	Class IIb	Class III
Risk	Low risk	Low-Medium risk		Medium-High risk	High risk
Software Example	Hearing loss diagnosis	Goniometer	ECG app	ICU breathing monitoring	Melanoma diagnosis to consumer

Classification principles and rules are defined in *Therapeutic Goods (Medical Devices) Regulations 2002,* Part 3 Division 3.1 and Schedules 2

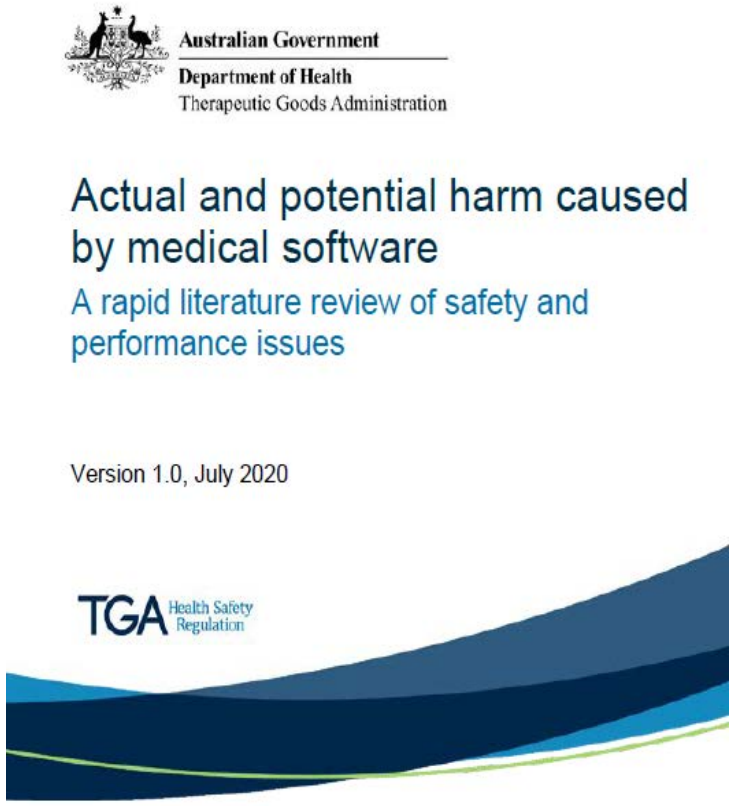
It’s only software…so why regulate it?

- **Risk of poor performance** for software is greater than for physical devices due to complexity – it’s another layer, and

  - Software developers have **not done as thorough clinical testing as for physical** devices

  - More limited information in the refereed literature on clinical or analytical validation

- While products are improving, there are reports **of products incorrectly diagnosing or monitoring serious conditions** e.g. melanoma, arrhythmia or diabetes
- **Human factors** – people use software in unexpected ways



Global Digitalisation- Observations

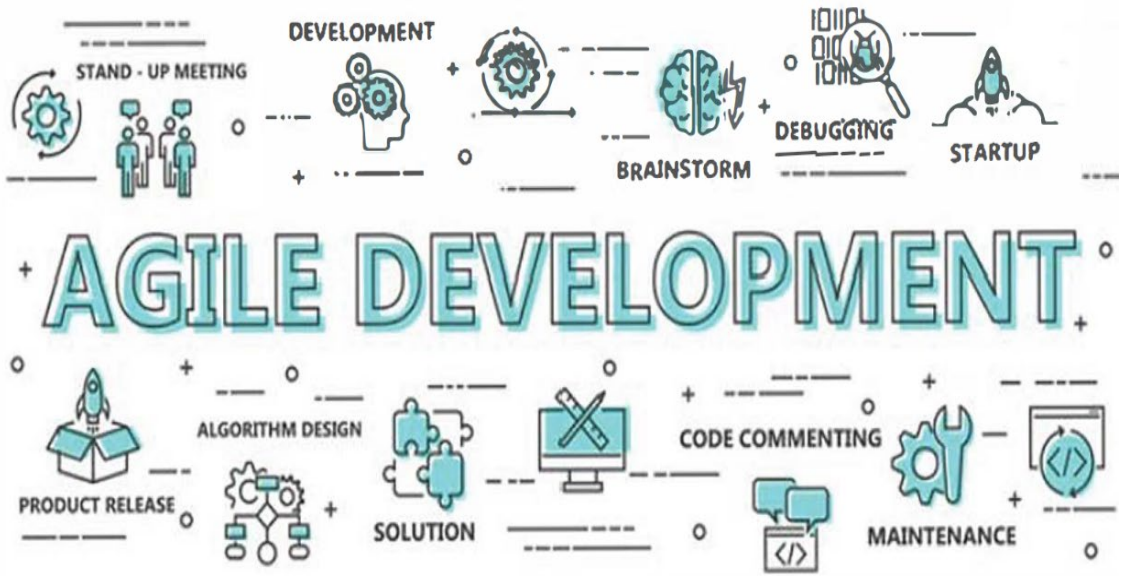
- Intensified and accelerated during COVID-19 pandemic
- Continued a digitalisation trend already underway, with new models of delivery
- Reach directly to consumers/patients – consequences are different than for health professional users (including involvement)
- Normalised telehealth and enhanced innovation (driven by demand)
- Brought many digital therapeutics / software products into TGA scope
- Compressed development timeframes – keeping a focus on quality / performance whilst responding to clinician or consumer demand for enhancements
- Collecting enormous quantity of data (driving machine learning, artificial intelligence (AI) – use of real world data), cloud storage, privacy, consent

Some challenges

- Many new players innovating who are new to regulation (or not aware!!)
- Breadth of applications of digital technology and increasing sophistication
- “Move fast, break things” – speed of getting to market may compromise quality
- Human factors – how people use software vs its design (intended purpose)
- Change control and user configuration of software after release (function creep)
- Traceability of errors and their role in adverse events
- Big data and what it means for medical devices – connected data
- Real world evidence: how, what, where? Is there bias?
- Are standards and guidance keeping up?

Design and development considerations

- Ensure architecture and design are documented – regardless of methodology
- Validation – strategy, approach and results – evidence
- Version control and change control – have a strategy
- Human factors studies
- Cyber security – be aware – essential eight



Design and development - software

Some key artefacts:

- Overall description of functions / requirements
- Software architecture and design, physical and logical.
- Validation artefacts
  - Test strategy, test cases, requirements traceability, test data, test results and defect rates. Includes clinical validation.
  - Functional, performance and sociability testing.
- Defect management process and known defects
- Human factors –usability and accessibility
- Cybersecurity
- Data privacy - Australian privacy and data protection law.

Design and development – AI

Rapidly evolving area, however typically looking for:

- Overarching statement of model objectives
- Algorithm and model design, including tuning techniques
- Data
  - Training and testing – and generalisability
  - Synthetic data would not be considered suitable for the COVID RAT use case. Further policy work on this for other use cases
  - Size of data sets - statistically credible.
  - Population data and justification for suitability to the Australian population.
- Black box – shine a light inside the box

Combination products

- New kinds of products which combine elements of drug and biological therapies are appearing in the market that utilise SOFTWARE as part of the overall therapy
- Some of these products are coming to the TGA via enquiries or post webinars
- Mix of global and local products
- SaMD regulatory framework applies
- Currently considering novel issues they present and how to regulate them in the future – in what situations regulatory changes or clarifications are needed

Other initiatives – in Australia

- Published Cybersecurity guidance and reviewing guidance by Australian Centre for Cybersecurity
- mHealth mobile apps framework – work with Australian Digital Health Agency and others
- Digital Mental Health – further work with Australian Commission for Safety & Quality in Healthcare
- University of Queensland – focus on regulatory aspects of development of AI tools
- Department of Health – Primary Care GP data and electronic clinical decision systems
- Clinical Decision Support Software – industry consultation on further more detailed interpretative guidance
- Further TGA policy reforms continue through 2022 (as a result of previous consultations)
- COVID-19 Rapid Antigen Test Software – guidance published
- Emerging areas – technology transfers, diagnostic tests and use of software, ML and AI, updated clinical guidance, clinical trials
- Partnerships and collaborations with ANDHealth, Digital CRC, Advanced Manufacturing (3D)

Ask us a question

Digital Devices team

digital.devices@tga.gov.au

General medical device enquiries

devices@tga.gov.au

1800 141 144

Regulation of software based medical devices

https://www.tga.gov.au/regulation-software-based-medical-devices

www.tga.gov.au

Australian Government

Department of Health

Therapeutic Goods Administration