



Australian Government
Australian Digital Health Agency



Assessment framework for mHealth apps

Intended use

The Assessment framework for mHealth apps is the result of extensive consultation domestically and internationally. It is published here as national guidance and a useful reference tool for app developers working on mHealth apps for release in Australia.

While the framework provides a solid basis for further research and analysis, future consultation is needed on when and how it would be implemented. Any future implementation is planned to be voluntary assessment, rather than regulation.

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The project Steering Committee was chaired by Queensland Health and included: Australian Digital Health Agency clinical reference leads and consumer advisers; representatives of the Australian Therapeutic Goods Administration (TGA) and jurisdictional representatives from Victoria, Tasmania and New South Wales.

The following organisations were consulted as part of this project and influenced the development of this document:

Allied Health Professions Australia	Australian Primary Healthcare Nurses Association	ORCHA
Amazon	Black Dog Institute	Pharmaceutical Society of Australia
ANDHealth	Cerner	Pharmacy Society of Australia
Apple	Consumer Health Forum	Queensland Health
Australian College of Nursing	Coordinare PHN	Queensland University of Technology
Australian College of Rural and Remote Medicine	CSIRO	Royal Australasian College of Surgeons
Australian Commission on Safety and Quality in Health Care	Deakin University	Royal Australian and New Zealand College of Psychiatrists
Australian Communications Consumer Action Network	Digital Health CRC	Samsung
Australian Diagnostic Imaging Association	Gippsland PHN	Southwestern Sydney PHN
Australian Digital Health Agency staff, clinical leads and experts	HealthDirect	Tasmanian Department of Health
Australian Government Department of Health and Aged Care	Health Navigator New Zealand	Therapeutic Goods Administration
Australian Healthcare and Hospitals Association	Institute of Electrical and Electronics Engineers	This Way Up, St Vincent's Health Network
Australasian Institute of Digital Health	Medical Software Industry Association	Victorian Department of Health and Human Services
Australian Institute of Health and Welfare	Mental Health Australia	WA Health
	Ministry of Health New Zealand	WA Primary Health Alliance
	National Aboriginal Community Controlled Health Organisation	
	NHSX	



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FRAMEWORK SUMMARY

Mobile health (mHealth) technology has been widely adopted in many countries worldwide and is expected to continue growing due to the increasing adoption and usage of mobile phones, tablet devices and the internet.

There are estimated to be hundreds of thousands of mobile health applications (mHealth apps), with numbers ranging from around 54,000 to over 350,000.¹ Until now there has been no national framework for mHealth app assessment across Australia that covers the broad range of apps on the market.

This Assessment Framework for mHealth apps aims to promote innovation in health service delivery by increasing the adoption and use of mHealth apps that are safe and have the potential to improve health outcomes for Australians.

The framework achieves this by:

- providing app developers with guidance and certainty about what is required when developing mHealth apps
- helping consumers choose credible mHealth apps
- helping healthcare professionals make informed choices when recommending or ‘prescribing’² mHealth apps to patients
- supporting the integration of effective and safe mHealth apps into clinical workflows.

Importantly, the framework is voluntary and assurance-focused rather than regulatory. Apps will not be mandated for assessment. Instead, apps would be nominated for assessment under the framework. Any mHealth apps that may require regulatory assessment as a Software-Based Medical Device will be referred to the Therapeutic Goods Administration (TGA) in the initial phase of assessment.

Apps will be assessed through a four-stage process against a maximum of five domains and 13 criteria. Most apps will be assessed against a smaller set of domains and criteria based on the outcome of an initial app ‘triage’ phase, which will determine an assessment pathway for each app.

App assessment outcomes will be published in an mHealth apps library through a two-tiered approach that will include a badge of endorsement and a more detailed assessment summary that will provide a star rating for each assessment domain. This will assure consumers and health professionals that apps that have been assessed are safe, effective, trustworthy, useful and usable. Users of the library will be able to select and compare mHealth apps. Assessments will be periodically updated to ensure that information published in the library remains up to date.

mHealth apps library

This framework refers to an mHealth apps library. This library will need to be established before it can be used with the framework.

1. IQVIA Institute (2021) [Digital Health Trends: Innovation, Evidence, Regulation, and Adoption](#), accessed 9 June 2022.

2. In this context, ‘prescribing’ refers to a clinician advising a patient to use a particular mHealth app.

The framework has been developed through a review of similar frameworks operating both domestically and internationally, along with broad consultations with both Australian and international stakeholders. It has also been designed to complement similar Australian frameworks, such as the National Safety and Quality Digital Mental Health (NSQDMH) standards and accreditation scheme developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC). Both the framework and its relationship to the ACSQHC NSQDMH standards will be considered further as both processes are implemented and mature.



ANALYSIS OF OTHER FRAMEWORKS

The assessment domains and criteria were developed based on a March 2021 horizon scan that reviewed existing frameworks in place in Australia and overseas. There was an in-depth analysis of the assessment criteria in the following frameworks:

- Regulatory approach of the TGA for software-based medical devices including the essential principles
- National Safety and Quality Digital Mental Health Standards (NSQDMH) by the Australian Commission on Safety and Quality in Health Care (ACSQHC)
- Health and wellness apps — Quality and reliability (ISO 82304-2:2021 released July 2021)
- HL7 Consumer Mobile Health Application Functional Framework (cMHAF), Release 1
- NHSX Digital Technology Assessment Criteria for health and social care (DTAC) (UK)
- Queensland Health draft mobile apps Assessment Framework
- Victorian Health Promotion Foundation's Healthy Living Apps Guide
- Apple App Store Review Guidelines and Google Developer program policy.

Following this initial work, the proposed assessment domains and criteria were refined through review of the World Health Organization — ITU mHealth Hub in EU report D2.1 KT1 Health Apps Assessment Frameworks,³ and meetings with international operators of similar frameworks, including:

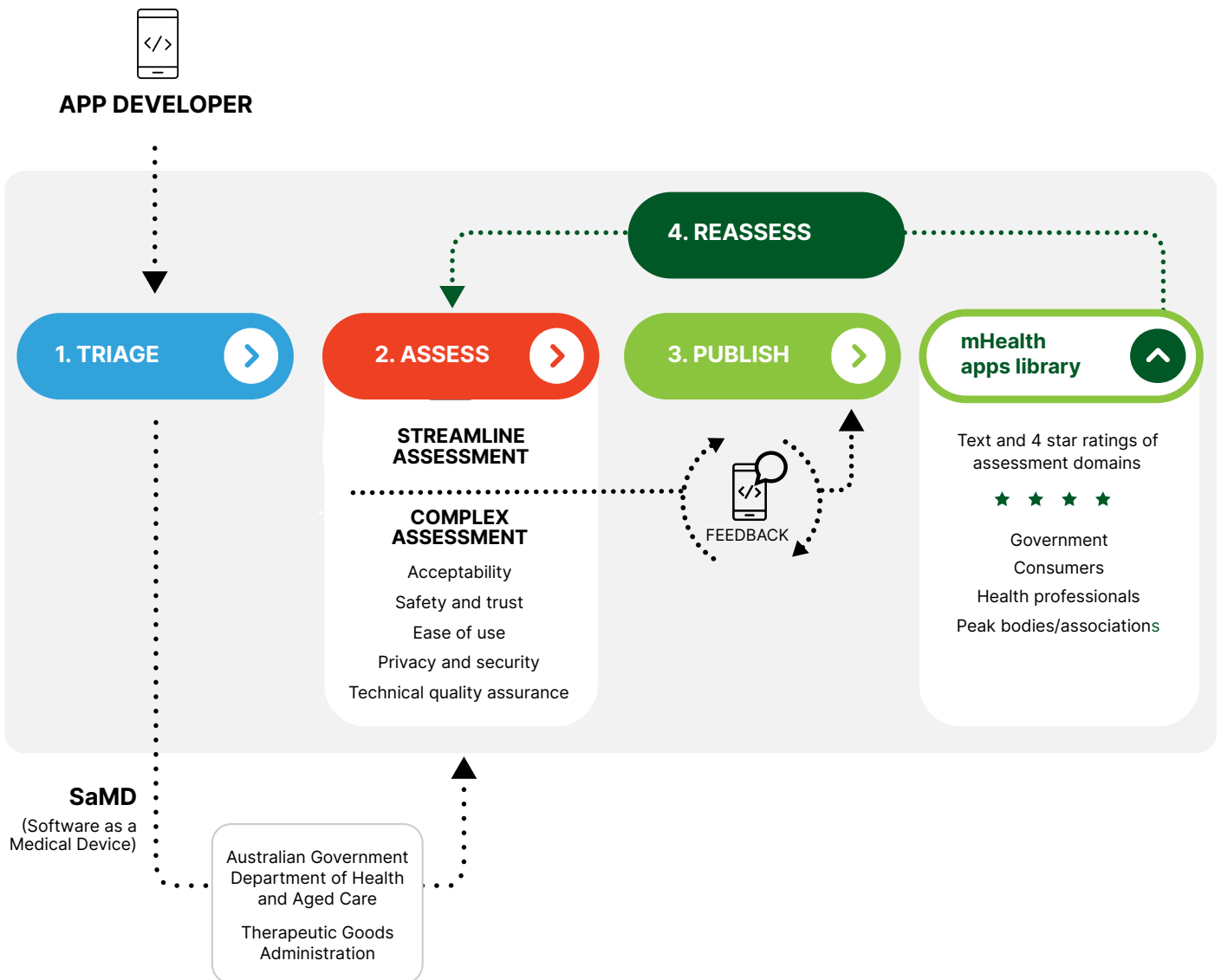
- the New Zealand Ministry of Health
- NHSX, United Kingdom.

3. Sourced from <https://mhealth-hub.org/documents>

Framework on a page

The Assessment Framework and mHealth apps library will help consumers, health professionals and other users to select safe, trustworthy and effective mHealth apps based on a voluntary, four-stage assessment process.

Figure 1: Framework overview





FRAMEWORK DESIGN

The framework sets out a four-phase assessment to ensure that mHealth apps added to the library are relevant and high quality, as well as providing detailed information to help potential users select an appropriate app for their unique health situation.

Phases 1 and 2 of the framework collect information on the apps and assess their eligibility and quality against the domains and criteria in Figure 2 (on page 6). In Phase 3, app information and assessment ratings are published in the app library. Phase 4 ensures a periodical reassessment of all apps is undertaken as the library matures and apps are developed.

Each phase of the framework has been designed so that both individuals and healthcare providers can have confidence in the quality, safety and potential health outcomes of each app. It has also been designed with the following policy objectives:

- protect the public from harm
- assist consumers in their selection of credible apps
- assist healthcare professionals to make informed choices when recommending or 'prescribing' digital applications to their patients (in this context, prescribing refers to a clinician advising a patient to use a particular mHealth app)
- provide vendors with guidance and certainty about what is required when developing mHealth apps
- support the integration of effective and safe mHealth apps into clinical workflows.



Apps covered by the framework

For the purpose of this document, mHealth apps include mobile software applications that run on a computing platform that is used specifically for managing, maintaining or improving the health of individual persons, or the delivery of care.

This definition currently does not include apps with intended uses such as:

- digital mental health services, which should be assessed using the ACSQHC NSQDMH standards. Recognising that the framework and the ACSQHC NSQDMH standards are in early stages, this can be re-evaluated once they are fully operational. This will also avoid duplication with the head to health website which currently lists a range of mental health apps that are available. Assessments under the NSQDMH are planned to commence in late 2022.
- apps used solely to administer or manage health processes or facilities
- communication apps without any additional health or wellbeing benefits
- apps that provide a read-only view of an electronic medical record.

The assessment framework does not include an assessment of the hardware. The library will have a disclaimer confirming that this assessment is only for the app and does not assess the accuracy of any hardware, sensor or device, or data exchanges with hardware, sensors or devices (inbuilt or third party).

Eligibility

To be eligible for inclusion in the library, an app must:

- a) be within scope
- b) submit all information required to undertake the assessment process
- c) pass all mandatory assessment measures
- d) agree to licence terms and conditions.

Domains, criteria and definitions

The framework has a manageable number of domains, criteria and measures. Additional domains, criteria or measures may be added over time as the framework matures. Figure 2 provides an overview of the Assessment Framework domains, criteria and definitions.

Figure 2: Assessment Framework domains, criteria and definitions

DOMAIN	CRITERION	DEFINITION
ACCEPTABILITY	User	The app takes into account the user's holistic experience (i.e. physical, cognitive, emotive, beliefs, preferences, or behaviours) and considers the system and the context of use where relevant.
	Cultural	The app is designed to support the cultural needs and safety of diverse population groups, including Aboriginal and Torres Strait Islander peoples.
	Health professional	The app is suitable for the intended purpose and, from a health professional's perspective, has the potential to achieve the health benefits claimed.
SAFETY AND TRUST	Protection from harm	The app does not cause reasonably foreseeable harm to users, be it of a physical, mental, social or financial nature.
	Evidence and expertise	The app uses appropriate evidence and clinical expertise to support health benefit claims.
	Transparency	The app enables users to understand who is distributing, financing (including the use of advertising), and developing the app and how to contact them. Additionally, the app enables users to make an informed choice based on an understanding of the financial costs and health interventions required to achieve the health benefits claimed.
EASE OF USE	Accessibility	The app is designed and delivered in such a way that facilitates ease of use for the widest user base possible, taking into account different physical or mental abilities or impairments (where relevant) as well as level of comfort, engagement with and adherence to the app.
	Usability	The app is designed and delivered in such a way it can be used by intended users to achieve the specified benefits.
PRIVACY AND SECURITY	Privacy	Where applicable, user privacy rights are respected in line with the requirements of the Privacy Act 1988, including ensuring users understand what information they are giving to the app, how their information will be used, and that personal health data is protected from accidental or malicious data privacy breaches.
	Consent and user control	The app processes personal data only on the basis of a valid legal base (i.e. consent).
	Security	The app is secure to threats altering the information or functionality of the app and ensures secure management of personal health data whether it is stored or transferred (i.e. the app uses up-to-date security standards and considers cybersecurity capabilities in line with Australian standards). The app does not require more information than needed for the purpose of the app.
TECHNICAL QUALITY ASSURANCE	Performance and build	The app is developed using best practices and is technically robust, reliable, and scalable, with an established maintenance process.
	Interoperability and data standards	The app, where relevant, can successfully exchange data (read and write) to different information systems (such as electronic health records) using Australian interoperability and data standards.

ASSESSMENT PROCESS

The assessment process has been conceptualised as a cycle, reflecting the need for assessments to be regularly updated to account for changes to apps, app developer characteristics and the framework. Figure 3 summarises the four-phase process for app assessments. The four phases of the assessment process are summarised below.

Figure 3: mHealth apps assessment process



Phase 1: Triage

Basic information on the app and app developer is collected. This is used to determine:

- whether the app is eligible for assessment
- whether the app qualifies for a streamlined (that is, reduced) assessment because it complies with other regulations or standards such as:
 - TGA regulation
 - ISO 82304-2 Health software — Part 2: Health and wellness apps — Quality and reliability
- the complexity of the app, which will inform the type of assessment criteria and measures it will be assessed against.

Phase 2: Assess

The domains and criteria are used to determine if an app is safe, trustworthy, effective, useful and usable, and therefore qualifies for inclusion in the library. Each app will be assessed against criteria and measures that will vary based on the outcome of the triage process. However, there are mandatory criteria and measures that all apps must meet to be published in the library.

The outcome of the assessment will then be communicated to the app developer, who will have the opportunity to raise any issues or questions or contest the assessment outcome before it is published in the library.

Phase 3: Publish

App information and assessment outcomes are published in the library.

Phase 4: Reassess

This ensures that app assessments published in the library are current and reliable. Reassessments will be conducted at least every three years, or whenever an app developer provides more information about a major change or changes that may impact the previous assessment outcome.

Table 3 in Appendix A outlines the roles and responsibilities of the assessing organisation and app developers across each phase of the assessment process.



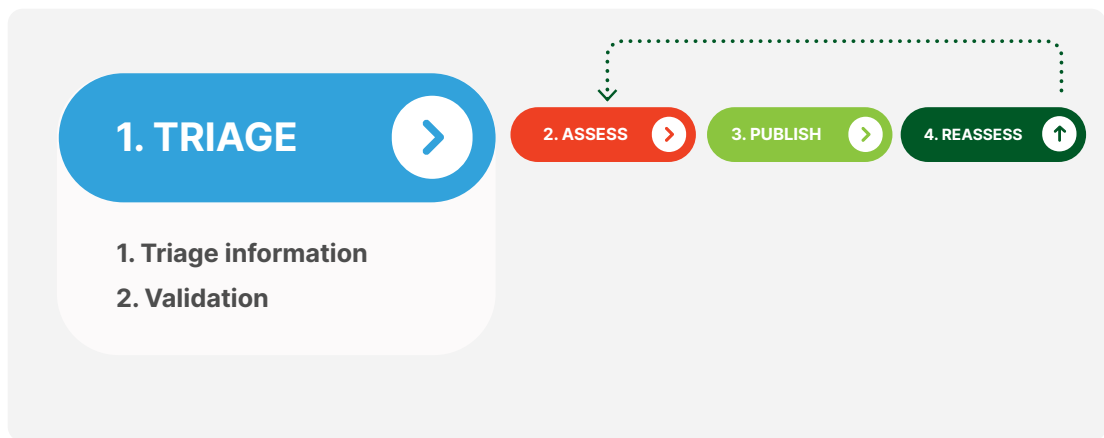
TRIAGE

The triage phase is used to:

- focus assessment resources on apps that align with a framework's objectives (eligibility and priority)
- target the level of assessment to the app's complexity
- identify apps that qualify for a streamlined assessment because they have undergone other recognised assurance processes.

This section describes the processes and questions associated with this phase of the assessment process (Figure 4).

Figure 4: Triage within the assessment process



The triage phase performs a 'filtering' function and ensures that assessment requirements are not prohibitive for low-risk apps and those that do not need to be assessed against the full range of measures. This phase has two parts: provision of information and validation.



1.1 Triage information

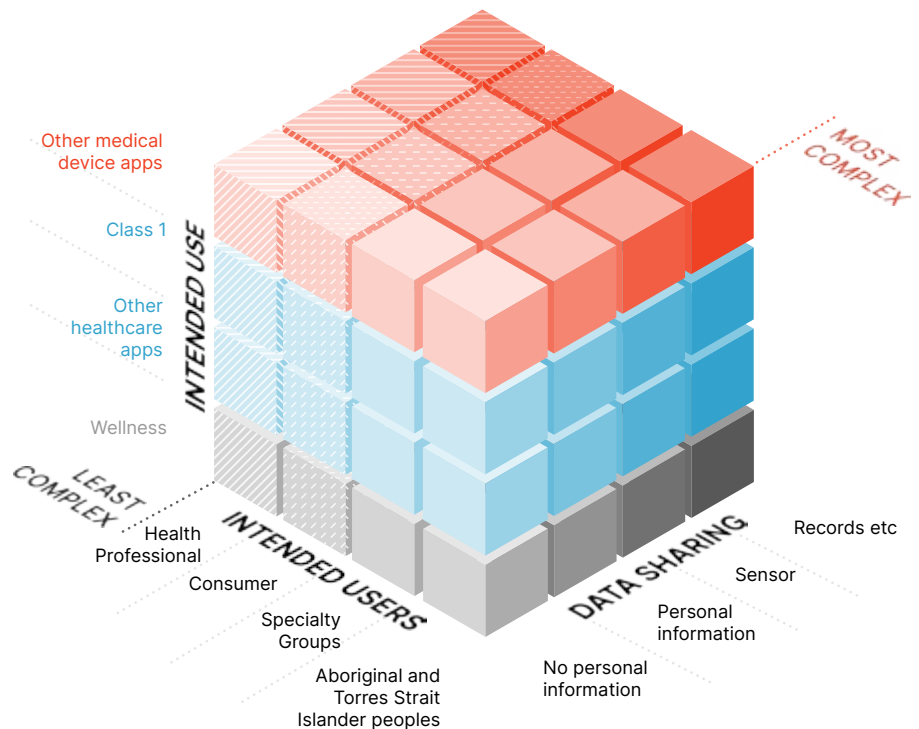
App developers will be asked to answer questions on a web-based portal and may be asked to provide additional evidence for some questions.

The data collected (triage information) will be used to determine whether an app is eligible to be assessed for inclusion in the library. If an app is not eligible, the app developer will be notified, and the process ends. Some evidence provided by the app developer may require validation in the next part of Phase 1.

Triage information will also be used to determine whether an app is a current priority for assessment. Table 5 in Appendix B contains indicative questions for assessing priority. These questions intend to identify proposed apps that fit into targeted health issues categories that the library may promote. The triage questions gather detailed information about the app to identify apps that are not a current priority. This ensures assessment resources can be focused on key areas.

For apps that are to be assessed, triage information will also be used to determine the complexity of each app in relation to the assessment measures. The complexity level of an app will influence the type and extent of information that app developers will be asked to produce during assessment in Phase 2. The process to determine complexity level is summarised in Figure 5.

Figure 5: Complexity matrix





The complexity assessment process has three dimensions:

- intended use
 - other medical device apps that meet the TGA's definition of Software as a Medical Device (SaMD)
 - Class 1 medical device apps that meet the TGA's definition of SaMD
 - other healthcare apps
 - wellness apps
- intended users
 - clinicians and health professionals
 - consumers
 - specific population groups or Aboriginal and Torres Strait Islander peoples
- data collection and sharing
 - collection of personal information
 - collection of data from a sensor or device (inbuilt or third party)
 - exchange of data with a third-party product.

Finally, triage information will be used to identify whether the app has already been assessed under a comparable framework and therefore qualifies for a streamlined assessment process.

To obtain the necessary triage information, apps will be assessed using a set of proposed triage measures that cover themes including:

- whether the app has previously been classified or assessed
- the technical aspects and functionality of the app
- intended uses and users
- privacy considerations
- app developer details.

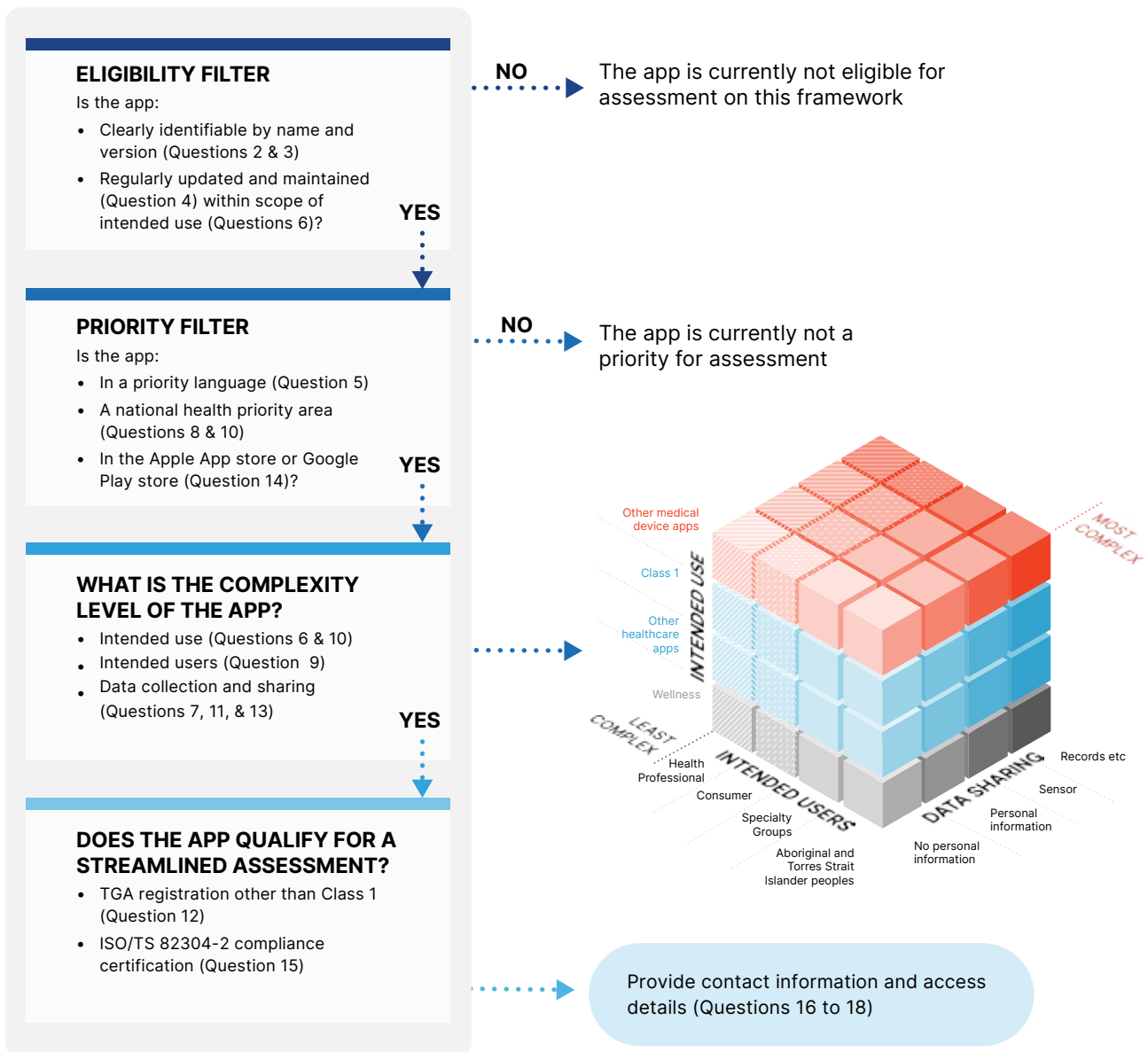
The full set of triage measures can be found in Table 5 in Appendix B.

1.2 Validation

App developers may be asked to provide more evidence, which will be validated for eligibility, priority and qualification for streamlining (as outlined in Table 6 in Appendix C). Where necessary, this process will include a request for more information or clarification from the app developer.

Figure 6 provides a flow chart of the triage questions and how the responses and evidence provided by app developers will be used.

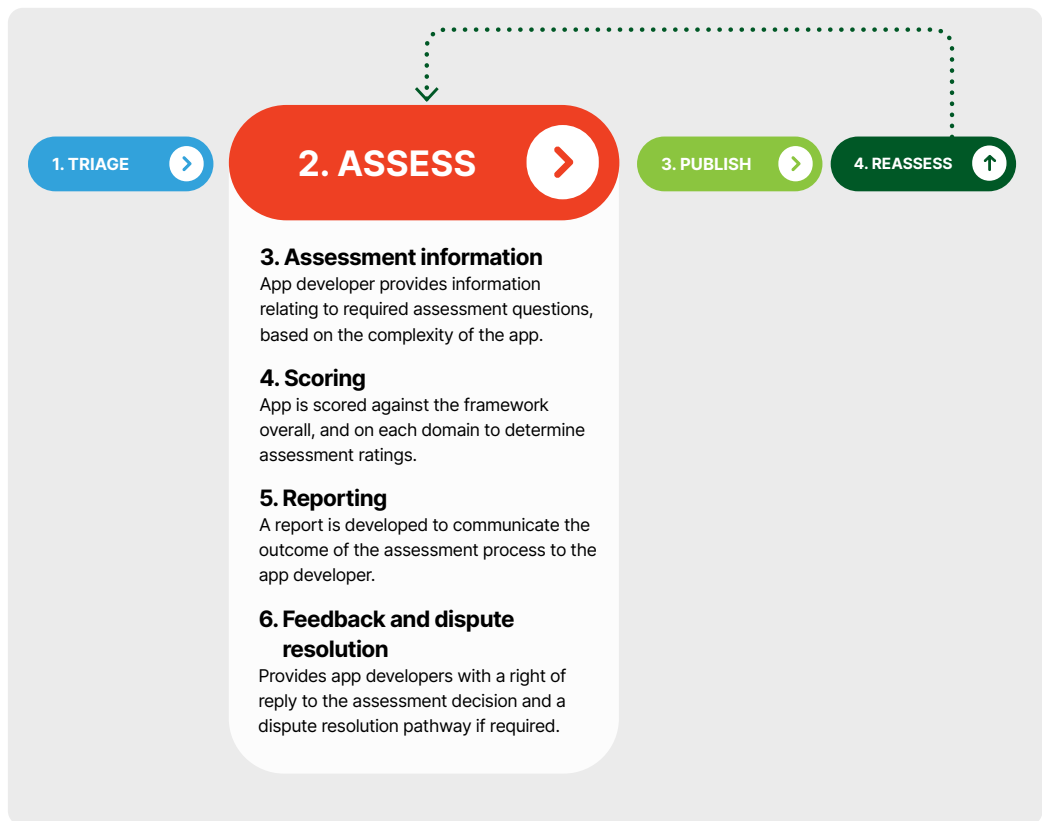
Figure 6: Triage process flow



ASSESS

The assessment process has been designed to be straightforward for app developers, while ensuring assessments are robust, evidence-based and trustworthy for users of the library. Importantly, the assessing organisation will report assessment outcomes to app developers before publishing them in the library, allowing app developers to provide feedback. This section outlines the processes and questions used to conduct the app assessment process (Figure 7). It also describes the feedback mechanisms that will be established between the assessing organisation and app developer after the assessment decision.

Figure 7: Assessment stages within the assessment process



The assessment questions have been developed based on comprehensive research into similar assessment frameworks. Where suitable, assessment questions have been aligned to existing standards and regulations, particularly the TGA's regulation of software-based medical devices and the NSQDMH. This alignment will maximise the opportunities for evidence to be recognised and assessment processes streamlined.

To ensure the framework is best practice and internationally relevant, questions are also aligned to the ISO 82304-2:2021 Health software — Part 2: Health and wellness apps — Quality and reliability standard, a mapping of which is below in Table 1:

Table 1: Mapping of assessment domains to ISO 82304-2 Health software — Part 2: Health and wellness apps — Quality and reliability standard

PROPOSED ASSESSMENT DOMAIN	ISO 82304-2:2021	NOTES
<p>Acceptability User, cultural and health professional acceptance that the app is suitable for its intended purpose.</p>	Not included	This domain has been added to ensure alignment to the needs of the Australian health and wellbeing ecosystem including health care needs, intended users, models of care and our diverse multicultural population.
<p>Safety and trust The app is free from unacceptable risk, the information included can be trusted and implications of using the app are transparent to the intended user.</p>	Healthy and Safe	There is a strong alignment in these areas. Some of the risk measures are recommended for implementation in a later version of the Assessment Framework as medium to high risk assessment is covered by TGA. This will allow time for the assessing organisation to mature.
<p>Ease of use The app is designed and delivered in such a way that it is accessible and usable by its intended users.</p>	Ease of Use	
<p>Privacy and security The app is designed and delivered to secure it from threats, complies with Australian Privacy legislation and processes personal data only with consent.</p>	Secure Data	Privacy and Security has been modified to reflect Australian legislation and standards with the addition of Consent Management and User Control as requested by stakeholders.
<p>Technical quality assurance The app is developed using best practices and is technically robust and, where relevant, can successfully exchange data using Australian recognised standards.</p>	Robust Build	This has been modified to reflect Australian standards and the maturity of the app developers and assessing organisation.

The purpose of the assessment phase is to:

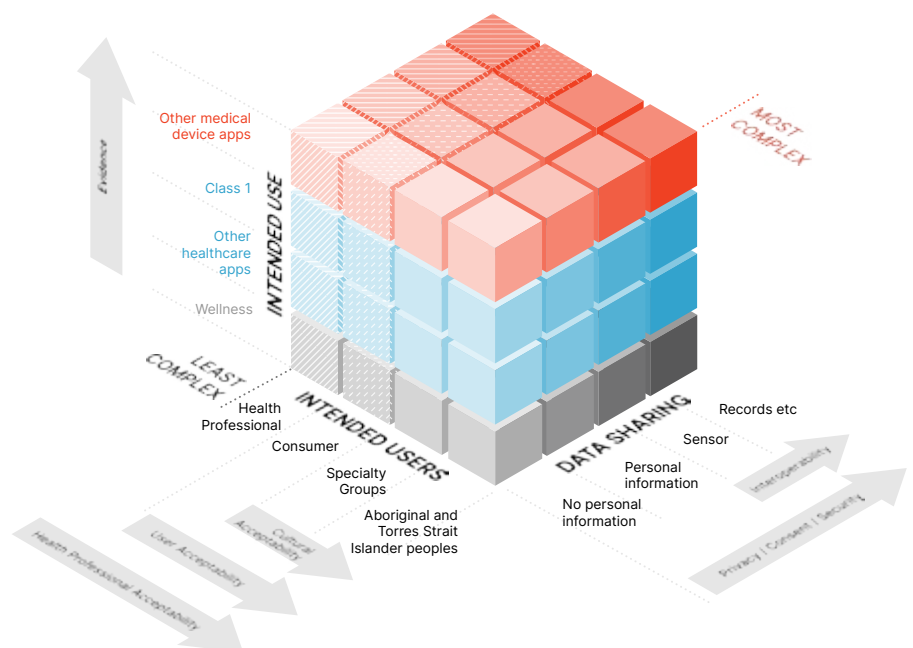
- conduct assessments in a way that minimises the burdens on app developers and the assessing organisation
- communicate assessment outcomes to the app developer and allow them to provide feedback or further information, or to dispute the assessment outcome
- resolve any questions or issues so that assessment outcomes can be published in the library.

2.1 Assessment information

Assessment measures (questions) have been developed to assess apps against the domains and criteria shown in Figure 2 in the framework design section on page 6.

An app's complexity level determines what information is requested from the app developer in the assessment phase. Figure 8 below shows which criteria are affected by each of the complexity dimensions (intended use, intended users, data collection and sharing). For example, the intended use affects evidence requirements, while the intended users determine whether the user and cultural acceptability assessments are needed. Whether personal information is collected and how it is stored and exchanged impacts the level of assessment necessary for the Privacy, Consent, Security and Interoperability criteria.

Figure 8: Complexity overview





A set of assessment measures has been developed for consideration in the initial phase of implementation of the framework. These measures will provide app developers with guidance on what is expected when developing safe, trusted, effective mHealth apps for use in Australia.

The measures cover areas including:

- user, cultural and clinician acceptability
- protection from harm
- transparency
- accessibility and usability
- consent and user control
- security
- performance and build
- interoperability and data standards.

Assessment measures are detailed in Table 6 in Appendix C.

As the assessing organisation and the framework mature and evolve, these assessment measures will need to be reviewed. It is recommended that a review be conducted in the third year of the framework's operation. This review should include an examination of other frameworks and standards, including ISO standards, and consider the need for any changes or additions to the measures in the framework. Appendix D includes some measures for consideration in future updates.

Table 1 references ISO/TS 82304-2:2021. The measures in this standard are of equal or greater scope than the corresponding framework measures. Apps that have met ISO/TS 82304-2:2021 Health software — Part 2: Health and wellness apps — Quality and reliability qualify for streamlined assessment on these measures.

2.2 Validate and score

The assessment determines whether the app is approved for inclusion in the library. The required measures (denoted with 'Required' in the 'Weight' column of Table 6 in Appendix C) must be answered 'yes' or 'not applicable' for the app to be included in the library. Where an app qualifies for streamlined assessment against a required measure, an automatic pass will be applied for that measure.

All other measures (denoted with numeric values in the 'Weight' column of Table 6 in Appendix C) will be used to establish a star rating for all domains except 'Acceptability'. The 'Acceptability' domain only includes required measures and will not be scored. The star rating is determined by the sum of the 'Weight' values for all measures in that domain that have a positive answer or are not applicable. Where an app qualifies for streamlined assessment against the measure (Apple, Google, ISO or TGA where relevant), the full weight of that measure is applied.

The assessing organisation will need to further develop the numeric thresholds for star ratings in each domain. An example is provided in Table 2.

Table 2: Numeric thresholds for star ratings, by domain (example only)

DOMAIN	★	★★	★★★	★★★★
Safety and trust	0 to 9	10 to 12	13 to 14	15 to 16
Ease of use	0 to 4	5 to 6	7 to 8	9 to 10
Privacy and security	0 to 4	5 to 7	8 to 10	11 to 13
Technical quality assurance	0 to 4	5 to 6	7	8

Table 6 in Appendix C outlines the type of validation required for each assessment measure and sets out when more evidence needs to be provided.

2.3 Reporting

After an assessment, the app developer will receive a report setting out:

- whether the app is approved for publication in the library
- the overall assessment outcome, including whether the app obtains a 'badge' of endorsement that indicates it is safe, effective, trustworthy, useful and usable
- domain scores
- an example of how the assessment outcome will be communicated to the public in the library.



The report will be accompanied by a spreadsheet showing which domains and measures were used to assess the app, providing transparency as to how assessment scores were calculated.

This reporting-back process fulfils several objectives, providing:

- a record of the assessment outcome for future audit and assurance purposes
- feedback to app developers to support the improvement of their app(s)
- a mechanism for app developers to understand the rationale for the assessment outcome, and to contest the outcome if they wish.

Once app developers indicate that they accept the assessment outcome, the app will be published in the library.

2.4 Feedback and dispute resolution

Questions or disputes may be raised by either app developers or library users. Records of all decisions will be kept by the assessing organisation for auditing and assurance purposes.

2.4.1 App developers

After receiving the report on the assessment decision, app developers will have 14 days to lodge questions or to contest part or all of the assessment outcome.

The process to resolve the issue or complaint will depend on the concerns raised by the app developer. More complex complaints may require independent review or reassessment. Complex disputes will be handled through a formal dispute resolution process overseen by the assessing organisation.

Once the issue, complaint or dispute has been resolved, the agreed assessment outcome will be published in the library.

2.4.2 Consumers and other stakeholders

Consumers and other stakeholders may experience issues using apps published in the library. The assessing organisation's website will host a form through which consumers or other stakeholders can raise a concern about an app.

Consumers who have concerns about harm that they or somebody else has experienced because of using an app published in the library will be referred to an appropriate government organisation. Consumer comments will not be published in the library but may trigger a reassessment (see Phase 4).

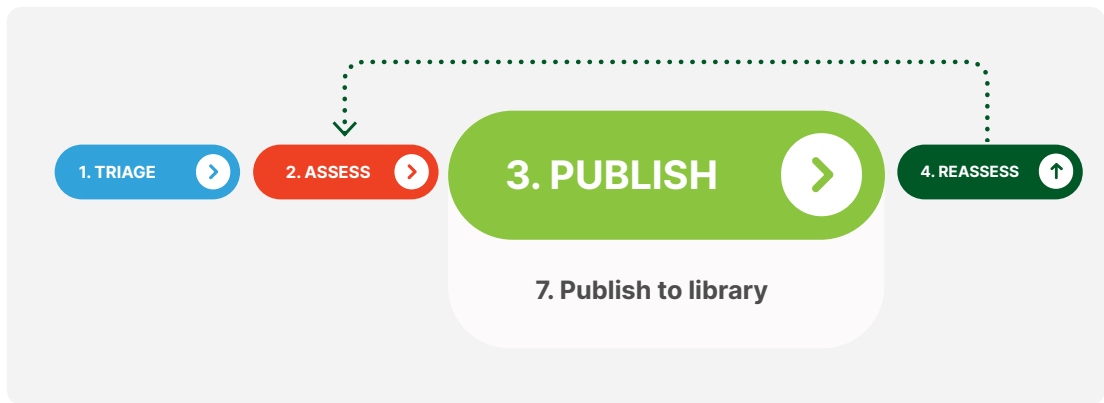
PUBLISH

Publication of the assessment outcome is the culmination of the assessment process and will provide the mechanism through which library users make decisions about which apps to use (or recommend to others). The assessment outcome information published in the library will need to be relevant and digestible for a range of audiences with different:

- levels of health literacy
- reasons for using the library
- expectations about how they will use the information.

The purpose of this phase is to ensure that assessment outcomes are communicated in a way that meets the needs of diverse user groups. This section outlines how the information about the mHealth app, including the outcome of the assessment, will be published in the library (Figure 9).

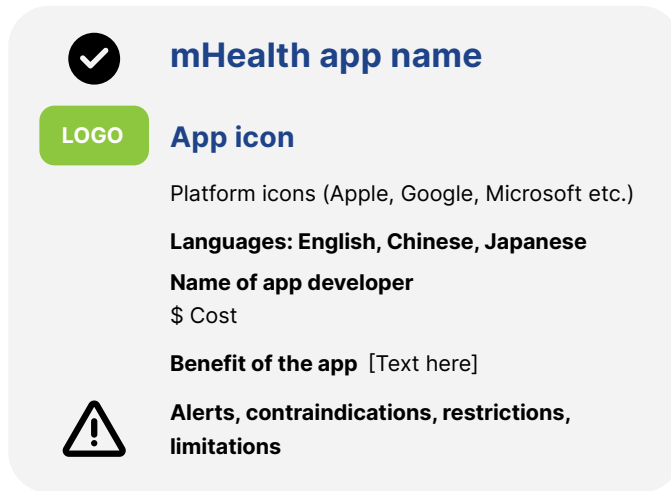
Figure 9: Publication within the assessment process



3.1 Assessment output

To cater to the needs of different users, it is proposed that the library will provide two descriptions of app information with different levels of detail: a basic description, which will include an overall badge of attainment; and a detailed description (see Figure 10 and Figure 11 below). Stakeholder feedback suggested that consumers may prefer to see a succinct description that quickly summarises whether an app is safe, trustworthy and effective, whereas clinicians may wish to examine how the app performs regarding specific domains. Star ratings give a succinct summary of an app’s overall assessment and its performance across specific domains, providing more detail than a simple ‘thumbs up or down’ rating.

Figure 10: Proposed basic description



A light gray rounded rectangular card containing a checklist of items for an mHealth app. The items are: 'mHealth app name' with a checkmark icon; 'App icon' with a 'LOGO' label and a description of platform icons; 'Languages: English, Chinese, Japanese'; 'Name of app developer'; '\$ Cost'; 'Benefit of the app [Text here]'; and 'Alerts, contraindications, restrictions, limitations' with a warning triangle icon.




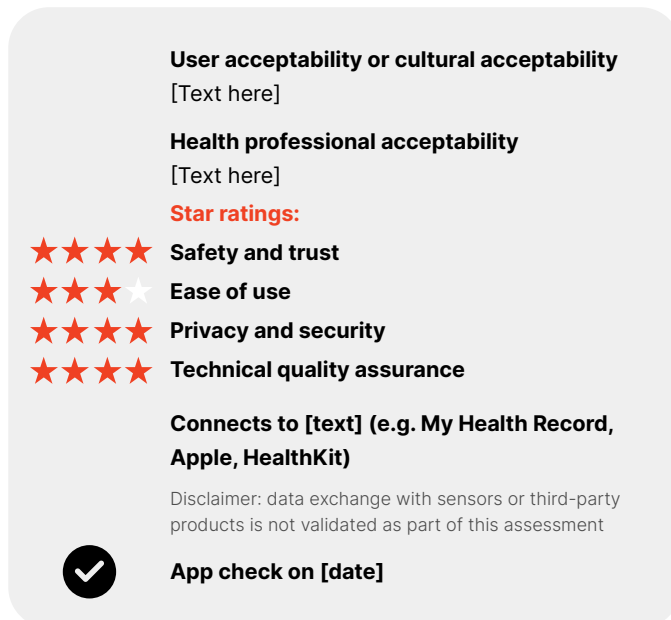

-  **mHealth app name**
-  **App icon**
Platform icons (Apple, Google, Microsoft etc.)
- Languages: English, Chinese, Japanese**
- Name of app developer**
- \$ Cost**
- Benefit of the app [Text here]**
-  **Alerts, contraindications, restrictions, limitations**

Figure 11: Proposed detailed description



A light gray rounded rectangular card containing a checklist of items for a detailed app description. The items are: 'User acceptability or cultural acceptability [Text here]'; 'Health professional acceptability [Text here]'; 'Star ratings:' followed by five red stars and the text 'Safety and trust'; five red stars and the text 'Ease of use'; five red stars and the text 'Privacy and security'; five red stars and the text 'Technical quality assurance'; 'Connects to [text] (e.g. My Health Record, Apple, HealthKit)'; a disclaimer: 'Disclaimer: data exchange with sensors or third-party products is not validated as part of this assessment'; and 'App check on [date]' with a checkmark icon.

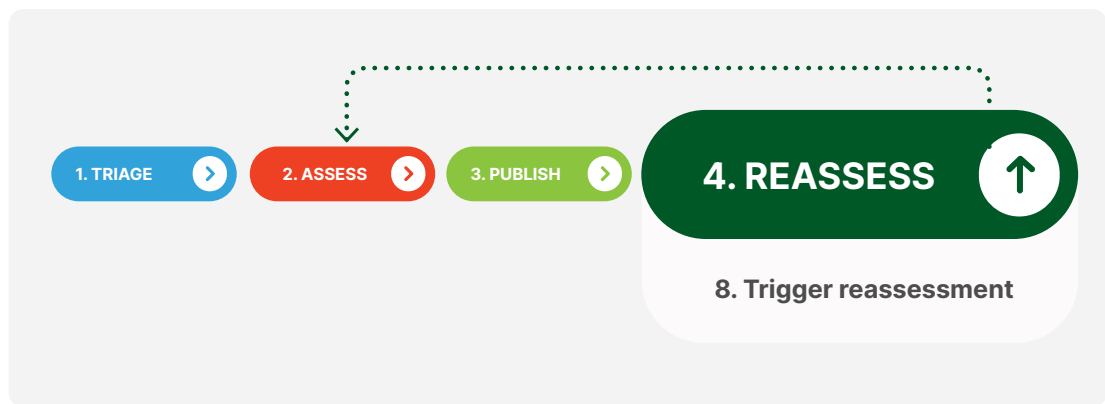
- User acceptability or cultural acceptability [Text here]**
- Health professional acceptability [Text here]**
- Star ratings:**
 - ★★★★★ **Safety and trust**
 - ★★★★★ **Ease of use**
 - ★★★★★ **Privacy and security**
 - ★★★★★ **Technical quality assurance**
- Connects to [text] (e.g. My Health Record, Apple, HealthKit)**
- Disclaimer: data exchange with sensors or third-party products is not validated as part of this assessment
-  **App check on [date]**



REASSESS

This section describes how assessments conducted under the framework would be kept up to date and reflect changes in apps, app developer characteristics or standards underpinning the proposed assessment criteria (Figure 12). This will help ensure that the library is a trusted source of information for app developers, health professionals, consumers and other stakeholders.

Figure 12: Reassessment within the overall assessment process



4.1 What triggers reassessment?

Material changes to an app or to app developer characteristics will trigger a partial or full revision of the previous assessment. At least every 12 months, app developers will be required to attest that there have been no material changes to the app or organisational characteristics since the last assessment. Additionally, app developers will be required to notify the assessing organisation where a material change has occurred. Guidelines and definitions for what constitutes a material change will need to be developed by the assessing organisation, with reference to key criteria in the framework. To minimise resource impacts, reassessment will be limited to criteria and measures relevant to characteristics that have changed.

Reassessment can also be triggered by a TGA Adverse Event Report or a serious consumer complaint. While published user comments are not a recommended feature of the library, there will be a mechanism for disclosure of serious complaints, such as complaints about false or misleading information (outlined above in 2.4.2).

Finally, all apps will be required to undergo a full reassessment at least every three years.



APPENDICES

Appendix A: Roles, responsibilities and guidance information

A.1 Roles and responsibilities

The roles and responsibilities of the assessing organisation will be considered in the development and evaluation of operating model options.

Table 3: Roles and responsibilities of app developers and the assessing organisation at each stage of the assessment process

Assessment phase	Assessing organisation	App developer
Prior to applying for assessment	<ul style="list-style-type: none"> Provide clear and relevant information that is easy to find about the library, the framework, the assessment process and any dispute resolution processes that are available to app developers. Answer all requests for information and questions in a timely manner. Log common questions as part of a 'Frequently Asked Questions' guide on its website. 	<ul style="list-style-type: none"> Read all available information to understand the purpose and operation of the framework before submitting an application for inclusion in the library. Ask questions of the assessing organisation where more clarity is needed.
Phase 1: Triage	<ul style="list-style-type: none"> Provide a simple, secure web-based process to quickly identify: <ul style="list-style-type: none"> if an mHealth app is eligible to be assessed for inclusion in the library if an mHealth app is a current priority to be assessed for inclusion in the library the level of evidence that will be needed for the assessment process (based on the app's assessed level of complexity) if an mHealth app qualifies for a streamlined assessment. Provide licence agreement. 	<ul style="list-style-type: none"> Complete application fully and provide all requested information in a timely manner. Complete requirements associated with any other relevant assessment pathways (e.g. TGA). Sign licence agreement and acknowledge onus of proof and accuracy of information is the responsibility of the app developer, and commit to keeping the assessing organisation informed of changes to the app or their corporate information over time etc. Pay any fee that may be associated with completion of the triage phase (if required).
Phase 2: Assess	<ul style="list-style-type: none"> Identify and communicate all information app developers will need to provide as part of assessment based on the outcome of Phase 1. Maintain clear, current, easy-to-interpret guidance information and decision support tools for assessors to ensure assessments are conducted. Ensure all assessors have appropriate clinical or technical expertise and training, to competently complete assessments. Complete assessments in a timely manner, applying a consistent approach across all apps that are assessed. Communicate the assessment outcome to the app developer and allow sufficient time for response prior to the assessment outcome being published in an mHealth apps library. Work with the app developer to resolve any dispute using appropriate and objective dispute resolution pathways. 	<ul style="list-style-type: none"> Submit information requested by the assessing organisation in line with the level of detail that is requested. Respond in a timely manner to enquiries from the assessing organisation, including the provision of more information. Raise any concerns about the assessment outcome through the Assessment Framework dispute resolution pathway. Provide accurate information to inform evaluation of any dispute that may be raised in relation to the assessment outcome. Submit to the outcome of the dispute resolution process. Pay any fee associated with completion of the Assessment phase (if required).

Appendix A: Roles, responsibilities and guidance information (cont.)

Assessment phase	Assessing organisation	App developer
Phase 3: Publish	<ul style="list-style-type: none"> • Publish agreed results of app assessments on an mHealth apps library in a manner that is clear, accessible and provides relevant information to key user groups that can help them make informed decisions about their usage of mHealth apps. • Ensure that the library is kept up to date. 	<ul style="list-style-type: none"> • Provide current information (such as web links, app screen shots and app logos) that will allow users of the app library to engage meaningfully with the app(s). • Pay any fee associated with completion of the Publication phase (if required).
Phase 4: Reassess	<ul style="list-style-type: none"> • Undertake reassessments of apps: <ul style="list-style-type: none"> - that have not had a full assessment completed in three years - where app developers notify the assessing organisation of changes that may materially impact the last assessment - in response to an TGA Adverse Event Report or a serious complaint. • Communicate the assessment outcome to the app developer and allow sufficient time for response prior to the assessment outcome being published on an mHealth apps library. • Work with the app developer to resolve any dispute using appropriate, objective dispute resolution pathways. • Publish updated assessment results on the public apps library. 	<ul style="list-style-type: none"> • Ask any questions of the assessing organisation as required to clarify questions regarding the reassessment process. • Respond to information provided by the assessing organisation regarding updates to app assessment criteria to clarify whether the app should be reassessed. • Proactively notify the assessing organisation of changes to corporate information or app characteristics that may require reassessment. • Apply for reassessment where material changes in corporate information or app details occur. • Provide all information required to complete reassessments in a timely manner. • Raise any concerns about the assessment outcome through the Assessment Framework dispute resolution pathway. • Provide accurate information to inform evaluation of any dispute that may be raised in relation to the assessment outcome. • Submit to the outcome of the dispute resolution process. • Pay any fee associated with completion of the Reassess phase (if required).

A.2 Guidance and information

The assessment process will be supported by clear guidance to the public, app developers and health care providers. Guidance and information would be published on the assessing organisation's website and would cover issues such as those outlined in Table 4.

The guidance provided on the website will need to include clear information on the assessment criteria and standards against which apps would be assessed. This information will act as a key reference point for app developers wishing to be assessed under the framework, to ensure development activity can be focused on meeting key assessment requirements.

Table 4: Proposed guidance material and information needed to support the framework

Issue	Purpose
The purpose and objectives of: <ul style="list-style-type: none"> an mHealth apps library the framework 	To ensure key user groups understand what the library and the framework intends to do, what objectives and benefits it intends to achieve and who can benefit from using it.
How the mHealth apps Assessment Framework relates to similar pathways and frameworks operated by other government departments or agencies, such as the ACSQHC's NSQDMH and TGA's approach to regulating software based medical devices	To provide clarity about the purpose of related frameworks and the circumstances in which app developers should apply to be assessed under the mHealth apps framework, as opposed to others. To provide a clear referral pathway for apps that should be directed to the TGA's pathway as a prerequisite to being assessed under the framework.
What apps are eligible to be assessed under the framework for inclusion in the library	To ensure the resources of the assessing organisation are directed towards assessing apps that are deemed to be in-scope.
What domains and criteria are considered as part of the assessment process	To provide app developers with clarity about what is required when developing mHealth apps for use in Australia. To provide confidence to end users that the assessment process is robust, to support broad-based usage of the framework and the library.
How the assessment process works	To provide clarity and transparency for app developers and users of the framework and library about what is involved in assessing an mHealth app. To provide app developers with information on the level and type of information that is needed as part of the assessment process.
Costs associated with assessment	To support informed choice for app developers about costs when considering whether or not to have their app assessed under the framework for inclusion in the library.
Dispute resolution processes	To provide a transparent process for app developers to contest assessment decisions, the circumstances in which disputes can be lodged and what information needs to be provided as part of dispute processes.
Disclaimers and licences	To provide information on the responsibilities of app developers that apply to be assessed under the framework to provide accurate, timely, up-to-date information to support the quality and currency of assessments. It is recommended that the assessing organisation develops: <ul style="list-style-type: none"> a disclaimer on the library such as the NHS Apps Library disclaimer https://www.nhs.uk/apps-library/disclaimer/ (with modification for the Australian ecosystem) and this is clearly accessible to all users of the library a licence agreement to be signed by the app developers during the assessment process is recommended extra agreements with external assessment partners where relevant.
Privacy and Information Security	To provide an overview of the assessing organisation and library Privacy and Information Security policies.

Appendix B: Triage measures

Table 5 provides the proposed triage assessment questions.

Note: It is recommended that detailed evidence requirements and validation guidance is developed by the assessing organisation to be used by the assessors for all relevant measures to ensure consistency of validation (which is outside the scope of this project).

Table 5: Triage measures to determine if an app is to progress to more detailed assessment

ID	Measure	Response	Response outcome	Additional evidence?	Library content?	Type of validation	Assessment objective	Reference/ Based on
1	Have you completed the TGA SaMD online classification tool?	Yes No Not applicable	If "No", no further questions.	Yes		Eligibility assessor	Review the evidence for appropriateness.	
2	What is the name of the app?	Text	N/A	N/A	Yes	N/A	N/A	DTAC A2 QLD
3	Are the current version number and current build number of the app accessible by, and identifiable to, users of the app in English; and may also be in any other language?	Yes No	NOTE: If "No", then it is not eligible for assessment. No further questions.	Yes	Yes	Eligibility, priority and streamline assessor	Review the evidence for appropriateness.	TGA 13B
4	Has the app been updated in the last 18 months? Note: This includes updates and tests to ensure app has not been impacted by version changes in the operating platforms.	Yes No	If "No", no further questions. Note: If app is not recently updated, then it is not eligible for assessment.	Yes	No	Eligibility, priority and streamline assessor	Review the evidence for appropriateness.	QLD
5	In which language is the app available?	Multiple-choice: English Mandarin Arabic Cantonese Vietnamese Aboriginal and Torres Strait Islander languages (please specify) None of the above	Note: If "None of the above" the app is not currently prioritised for assessment. However, the priority will be reassessed on a regular basis and the website updated. No further questions.	N/A	Yes	N/A	N/A	
6	What is the intended use(s) of the app?	Consumer healthcare apps that make claims about diseases or conditions Consumer health and wellness apps that do not make claims about diseases or conditions Apps intended to provide alerts or additional information to health professionals in relation to patient care Other (please specify)		Yes	Yes	Eligibility, priority and streamline assessor	Used to confirm the eligibility & complexity of the product.	
7	Does the app collect personal information?	Yes No	if "No", app qualifies for reduced complexity assessment. (Privacy and Security questions).	Yes	Yes	Eligibility, priority and streamline assessor	Review the evidence for appropriateness.	
8	Does the app make any health benefits claims?	Text	Response used as part of assessment in next phase.	N/A	Yes	N/A	N/A	
9	Who are the intended users of the app?	Anyone/Persons with, or at risk of, specific health issues informal carers children under 12 Health professional (please specify) Aboriginal and Torres Strait Islander specific ethnic group (please specify) other (please specify)	N/A	Yes	Yes	Eligibility, priority and streamline assessor	A) Used as part of the complexity assessment to identify: - Aboriginal and Torres Strait Islander peoples (requires cultural assessment) - specific ethnic groups (requires cultural assessment) - health professional (may be lower risk) also may require speciality assessors for example allied health. B) Clinical safety: provides clarity around the intended clinical use.	
10	Is the app focused on a specific health condition or issue?	Multichoice priority categories to be added by the assessing organisation, such as apps focused on certain chronic conditions (for example, hypertension), apps focused on Aboriginal and Torres Strait Islander peoples etc.	N/A	Yes	Yes	Eligibility, priority and streamline assessor	The assessing organisation may want to give priority to certain conditions to promote completeness of the library and hence uptake by consumers that this is a trusted and comprehensive source (NHSX).	

Appendix B: Triage measures (cont.)

Table 5: Triage measures to determine if an app is to progress to more detailed assessment (cont.)

ID	Measure	Response	Response outcome	Additional evidence?	Library content?	Type of validation	Assessment objective	Reference/ Based on
11	Does the app expose any Application Program Interfaces (API) or integration channels specifically for the exchange of data?	Yes No	If "No", app qualifies for reduced complexity assessment. Interoperability questions).	N/A	No	N/A	N/A	DTAC C4.1
12	If the app falls within the Therapeutic Goods (Medical Devices) Regulations 2002, is it registered with the TGA?	Yes (provide registration number) In progress (provide Class) Exempt No Not applicable	If "No or Not applicable", but have answered (6) (a to d) then display warning "it looks like the app may fall under the Therapeutic Goods (Medical Devices) Regulations 2002 please review before proceeding".	If the Therapeutic Goods (Medical Devices) Regulations 2002 are applicable, please provide the app's Declaration of Conformity and, if applicable, certificate of conformity issued by a Notified Body / TGA Approved Body	Yes	Eligibility, priority and streamline assessor	Review the evidence for appropriateness. - If "In progress" then the app may qualify for a streamlined assessment process. However, full approval will not be provided until completion of the TGA process".	
13	Does the intended purpose of the app require the collection of data from a sensor/device (inbuilt or 3rd party)?	Yes No	If "Yes", a note will be added to the library content confirming that this assessment is only for the app and does not assess the accuracy of any sensor/device or the data exchange with the sensor/device (inbuilt or 3rd party).	N/A	Yes	N/A	N/A	
14	Is your app available for download via Apple App Store, or Google play?	Multi selection allowed — Not on a digital marketplace Apple App Store Google play Other. If "other" selected, provide the name of the digital marketplace	In Phase 1, "Apple App Store, Google play" will be prioritised this will be reviewed on a regular basis.	URL(s) of digital marketplaces	Yes	Eligibility, priority and streamline assessor	Review the evidence for appropriateness.	QLD
15	Has the app been assessed against the ISO/TS 82304-2:2021 Health software — Part 2: Health and wellness apps — Quality and reliability standard?	Yes No	If "Yes", then app may qualify for a streamlined assessment process.	If the app has been assessed against the ISO/TS 82304-2:2021 please provide the app's result and details of the issuing body	Yes	Eligibility, priority and streamline assessor	Review the evidence for appropriateness.	
16	What is the name of the app manufacturer?	Text	N/A	N/A	Yes	N/A		QLD, DTAC A1,
17	Provide the email address and telephone number of the person who is authorised to represent the app manufacturer.	Text + number	N/A	N/A	No	N/A		DTAC a4, a5, a6 and QLD
18	Provide app access instructions. Note 1 : Provide an active demo account and login information, plus any other hardware or resources that might be needed to review your app (e.g. login credentials or a sample QR code). Note 2: Enable backend services so that they're live and accessible during review. Note 3: Include detailed explanations of non-obvious features and in-app purchases in the app review notes, including supporting documentation where appropriate. Note 4: Test information input during app assessments should not affect normal use of the app or data derived from its normal use.	Text	N/A	N/A	No	N/A		Apple App store

Appendix C: mHealth app assessment measures

Table 6 provides the proposed assessment questions.

Note: It is recommended that detailed evidence requirements and validation guidance is developed by the assessing organisation to be used by the assessors for all relevant measures to ensure consistency of validation (which is outside the scope of this project).

Table 6: Proposed mHealth apps assessment measures

ID	Measure	Response	Additional evidence?	Type of validation	Validation objective	Weight	Apple / Google	Streamline by type		Reference/ Based on
								Other	TGA other than Class 1	
ACCEPTABILITY										
1 User acceptability										
1.1	Does the app consider the user's holistic experience (i.e. physical, cognitive, emotive, beliefs, preferences, or behaviours) and considers the system and the context of use where relevant as assessed by its intended users? CONDITION: Not required where cultural acceptability is assessed or if intended user = Health Professional only.	N/A Assessment only	N/A	User assessment	Review the app.	Required				
2. Cultural acceptability										
2.1	Are cultural safety challenges for Aboriginal and Torres Strait Islander peoples and challenges for other culturally diverse population groups of the app assessed with intended users or associations? Additionally, does the app consider the user's holistic experience (i.e. physical, cognitive, emotive, beliefs, preferences, or behaviours) and considers the system and the context of use where relevant as assessed by its intended users? Cultural safety is defined with reference to the experience of the Indigenous health care consumer, of the care they are given, their ability to access services and to raise concerns. Some of the essential features of cultural safety include an understanding of one's culture, an acknowledgment of difference, and a requirement that caregivers are actively mindful and respectful of this difference. The presence or absence of cultural safety is determined by the experience of the recipient of care and is not defined by the caregiver (National Aboriginal Community Controlled Health Organisation). CONDITION: Where intended users = Aboriginal and Torres Strait Islander peoples or specific diverse population groups.	Yes No	Names of users and/or associations involved, issues discussed, challenges and responses	Cultural safety assessment	Review the evidence for appropriateness by relevant assessor (Aboriginal and Torres Strait Islander peoples or other populations limited by language priorities).	Required				
3 Health professional acceptability										
3.1	Is the app suitable for the intended purpose and has the potential to achieve the health benefits for the intended users as claimed from a health professional's perspective?	N/A Assessment only	N/A	Clinical assessment	Review the app.	Required				

Appendix C: mHealth app assessment measures (cont.)

Table 6: Proposed mHealth apps assessment measures (cont.)

ID	Measure	Response	Additional evidence?	Type of validation	Validation objective	Weight	Apple / Google	Streamline by type		Reference/ Based on
								Other	TGA other than Class 1	
SAFETY AND TRUST										
4 Protection from harm										
4.1	Does the app include objectionable content, increase the risk of abuse or exploitation or diminish the dignity of users or use their devices in a way that risks harm (physical, mental, social or financial)? Note this includes: <ul style="list-style-type: none"> content that is misleading, offensive, defamatory, discriminatory or objectionable in any way, or urging users to participate in activities (like bets, challenges, etc.) or use their devices in a way that risks harm (physical, mental, social or financial) to themselves or others, or increasing the risk of abuse of users and where relevant, their support people, or increasing the risk of exploitation of users and where relevant, their support people, or diminishing the dignity of users and where relevant, their support people? 	Yes No	N/A	Validation — if not eligible for streamline	Review of app for compliance.	Required	✓			Apple / Google and NSQDMH
4.2	Are all restrictions, contraindications, limitations and risks transparent to the intended users (e.g. including age restrictions)? Note: “Not applicable” indicates that the app does not have restrictions, contraindications, limitations or risks.	Yes No Not applicable	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	Required		ISO	TGA	QLD
4.3	Have you undertaken Clinical Risk Management activities for this app?	Yes No	Yes	Clinical assessment — if not eligible for streamline	Review the evidence for appropriateness.	Required		ISO	TGA	DTAC
4.4	Is a process available to collect Clinical Safety Case Reports and are all incidents logged? Note: “Not applicable” indicates that the app does not have any health risks.	Yes No Not applicable	Yes	Validation — if not eligible for streamline	Validate that a process exists.	3		ISO	TGA	DTAC
4.5	Does the app, or associated website clearly declare that the information or services provided do not replace a recommendation, opinion or diagnosis made by a healthcare professional? Note: “Not applicable” indicates that the app does not need the support of a health professional, or that the app is solely for use by health professionals, not by consumers.	Yes No Not applicable	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	2	Apple only	Apple/ISO	Apple/ISO	QLD
4.6	Were ethical principles reviewed in relation to the design and development of the app?	Yes No	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	1		ISO	TGA	NSQDMH
5. Evidence and expertise										
5.1	Is appropriate evidence available to support any health benefit claims made? Note: “Not applicable” means the app makes no health benefit claims (see Triage).	Yes No Not applicable	Yes	Validation — if not eligible for ISO/TGA streamline	Review the evidence for appropriateness.	Required		ISO	TGA	QLD

Appendix C: mHealth app assessment measures (cont.)

Table 6: Proposed mHealth apps assessment measures (cont.)

ID	Measure	Response	Additional evidence?	Type of validation	Validation objective	Weight	Apple / Google	Streamline by type		Reference/ Based on
								Other	TGA other than Class 1	
5.2	Were health professionals involved in the development of the app?	Yes No Australian Health Professionals International Health Professionals (please specify)	Yes	Validation — if not eligible for TGA streamline	Review the evidence for appropriateness.	3 if Australian 2 if international			TGA	
5.3	Is the health information displayed in the app regularly reviewed and updated? “Not applicable” indicates that the app does not display health information.	Yes No Not applicable	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	1		ISO	TGA	QLD
5.4	Does the app, or associated website, cite the evidence base of its content and method of operation (e.g. widely accepted medical guidelines or protocols, theoretical constructs, or scientific validation)?	Yes No	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	2		ISO	TGA	QLD
6. Transparency				TGA						
6.1	Does the app clearly identify the app manufacturer or app sponsor with contact details (for questions or support) with all relevant legal claims and disclaimers including Intellectual property?	Yes No	Yes	Validation	Review the evidence for appropriateness.	Required				
6.2	Does the app, or associated website, disclose authorship, affiliations, credentials, commercial interests (investors and shareholders), conflicts of interest, and disclaimers?	Yes No	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	1		ISO	ISO	QLD
6.3	Is the use of advertising in the app disclosed to intended users? Note: “Not applicable” indicates that the app does not contain advertisements.	Yes No Not applicable	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	3	✓ (TBC)			
EASE OF USE										
7 Accessibility										
7.1	Is the app international Web Content Accessibility Guidelines (WCAG) 2.1 level AA compliant?	Yes No	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	3		ISO	TGA	DTAC
8 Usability										
8.1	Has your app been co-designed with intended users?	Yes No	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	2		ISO	ISO	NZ

Appendix C: mHealth app assessment measures (cont.)

Table 6: Proposed mHealth apps assessment measures (cont.)

ID	Measure	Response	Additional evidence?	Type of validation	Validation objective	Weight	Apple / Google	Streamline by type		Reference/ Based on
								Other	TGA other than Class 1	
8.2	Does the app alert the user and/or healthcare professional if any inputs or outputs are out of accepted normal ranges or other foreseeable use errors? Note: "Not applicable" indicates that use errors or misuse is not possible given the nature of the app.	Yes No Not applicable	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	1		ISO	TGA	QLD
8.3	Does the app, or associated website, clearly provide product information and instructions for use of the app?	Yes No	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	3		ISO	TGA	QLD
8.4	Is information and support available to help intended users who experience problems with the app?	Yes No	Yes	Validation — if not eligible for streamline	Review the evidence for appropriateness.	1		ISO	TGA/ISO	HL7
PRIVACY AND SECURITY										
9 Privacy										
9.1	Is the minimum necessary amount of a user's personal information collected? CONDITION: IF personal information = Yes (7 triage).	Yes No	Yes	Privacy and security validation — if not eligible for streamline	Review the evidence for appropriateness.	3		ISO	TGA/ ISO	HL7
9.2	Does your app have a privacy policy? CONDITION: IF personal information = Yes (7 triage).	Yes No	Yes	Privacy and security validation	Review that privacy statement addresses answers to personal information and health-related personal information (triage 7)	Required		ISO	TGA	NZ
9.3	Is the privacy statement compliant with the Australian Privacy Principles Guidelines Privacy Act 1988? CONDITION: IF personal information=Yes (7 triage).	Confirmed Unable to confirm	Yes	Privacy and security validation — if not TGA other medical device app (other than Class 1)	Review the evidence for appropriateness.	Required				
9.4	Is the privacy policy easy to locate on the app, or associated website and easy to understand? CONDITION: IF personal information=Yes (7 triage).	Yes No	N/A	Privacy and security validation — if not eligible for streamline	Review the app for appropriateness.	3		ISO	ISO	QLD
9.5	Do you have a process to report personal information breaches to the users and relevant authorities? CONDITION: IF personal information=Yes (7 triage).	Yes No	Yes	Privacy and security validation — if not eligible for streamline	Review the app for appropriateness.	3		ISO	ISO	

Appendix C: mHealth app assessment measures (cont.)

Table 6: Proposed mHealth apps assessment measures (cont.)

ID	Measure	Response	Additional evidence?	Type of validation	Validation objective	Weight	Apple / Google	Streamline by type		Reference/ Based on
								Other	TGA other than Class 1	
10 Consent and user control										
10.1	<p>Does the app have consent and user control mechanisms in place as appropriate for the complexity of the app and in line with the Australian Charter of Healthcare Right?</p> <p>Note including:</p> <ul style="list-style-type: none"> a. consent to the use of personal data and records for any purpose beyond direct care b. withdraw or withhold consent for the collection, storage or distribution of their personal data and records c. opt out from the sharing of their personal data and records d. access, copy and amend their personal data and records e. request deletion of their personal data and records f. review the app's Terms of Use before personal data about the user is collected and used g. accept the app's Terms of Use which is logged before a user account is authorised h. before receiving notifications and alerts from an app. <p>CONDITION: IF personal information=Yes (7 triage).</p>	Yes No	Yes	Privacy and security validation — if not eligible for streamline	Review the evidence/app for appropriateness.	Required				NSQDMH 1.32
10.2	<p>If the app conducts health-related human subject research, does it gain consent from participants or, in the case of minors, their parent or guardian? Such consent must include:</p> <ul style="list-style-type: none"> i. the nature, purpose, and duration of the research j. the procedures, risks, and benefits to the participant k. information about confidentiality and handling of data (including any sharing with third parties) l. a point of contact for participant questions m. the withdrawal process. <p>CONDITION: IF personal information=Yes (7 triage).</p>	Yes No	Yes	Privacy and security validation — if not eligible for streamline	Review the evidence/app for appropriateness.	Required	Apple only			Apple app store 5.1.3 (iii)
11 Security										
11.1	<p>Please confirm where the app store and process data is located (including any third-party products your product uses) and, if stored outside of Australia, confirm the name of the country and how those storage arrangements comply with current Australian legislation.</p> <p>CONDITION: IF personal information=Yes (7 triage).</p> <p>Note: "Not applicable" indicates that the app does not store or process data.</p> <p>Note: See Australian Privacy Principle 8 — Cross-border disclosure of personal information. Australian Privacy Principles Guidelines Privacy Act 1988</p>	Australia Other	Yes	Privacy and security validation — if not eligible for streamline	Review the evidence for appropriateness.	Required				DTAC

Appendix C: mHealth app assessment measures (cont.)

Table 6: Proposed mHealth apps assessment measures (cont.)

ID	Measure	Response	Additional evidence?	Type of validation	Validation objective	Weight	Apple / Google	Streamline by type		Reference/ Based on
								Other	TGA other than Class 1	
11.2	Have the app manufacturer and all organisations providing associated services implemented the Australian government information security manual standards? Note: https://www.cyber.gov.au/acsc/view-all-content/advice/using-australian-government-information-security-manual	Yes No	Yes	Privacy and security validation — if not eligible for streamline	Review the evidence for appropriateness.	1			TGA	DTAC
11.3	Does the app require login and password protection? If the app requires user authentication, are password and identity information secured appropriately? CONDITION: IF personal information=Yes (7 triage).	Yes No	Yes	Privacy and security validation — if not eligible for streamline	Review the evidence for appropriateness.	1		ISO	TGA/ ISO	QLD
11.4	Does the app use industry-standard encryption of data at rest and before transmission to remote systems? CONDITION: IF personal information=Yes (7 triage).	Yes No	Yes	Privacy and security validation — if not eligible for streamline	Review the evidence for appropriateness.	1		ISO	TGA/ ISO	QLD
11.5	Does the app, or associated website, provide an information security policy?	Yes No	N/A	Privacy and security validation — if not eligible for streamline	Review the app for appropriateness.	1		ISO	ISO	QLD
TECHNICAL QUALITY ASSURANCE										
12 Performance and build										
12.1	Is the app technically robust (i.e. complete (not a beta version) and designed and produced in a way that ensures performance, reliability and repeatability of the software?)	Yes No	N/A	Technical validation — if not eligible for streamline	Review the app for appropriateness.	Required	✓			TGA 12.1.1 (a)
12.2	Is the app developed, produced and maintained having regard to the generally acknowledged state of the art (including for design, development life cycle, development environment, version control, quality and risk management, security, verification and validation, change and configuration management, and problem resolution)?	Yes No	Yes	Technical validation — if not eligible for streamline	Review the evidence for appropriateness.	3		ISO	TGA	TGA
13 Interoperability and data standards										
13.1	Are all APIs documented and freely available? CONDITION: IF API=Yes (11 triage).	Yes No Not applicable	Yes	Technical validation — if not eligible for streamline	Review the evidence for appropriateness.	1		ISO	ISO	DTAC
13.2	Does the API documentation include standards used such as Health Level Seven International (HL7)/FHIR, terminology or terminologies used? CONDITION: IF API=Yes (11 triage).	Yes No	Yes	Technical validation — if not eligible for streamline	Review the evidence for appropriateness.	1		ISO	ISO	DTAC



Appendix D: Potential future measures

Measures for consideration in later versions of the framework.

SAFETY AND TRUST

Protection from harm

Has the app developer established and maintained a risk management system?

Are users informed of any residual risks that have been identified?

Was an independent ethics board used in the development of this app?

Evidence and expertise

Does the app, or associated website, list peer-reviewed evidence that directly measures app effectiveness with the target audience?

Does the app make societal benefits claims and is evidence available to support these claims?

Does the app, or associated website, list publish peer-reviewed evidence that directly measures societal benefits claims?

Do you have a benefits case that includes your objectives, the benefits you will be measuring and the metrics you track?

Transparency

Are the benefits of paying for a service or feature clearly stated in a manner that allows the intended user to make an informed decision about making or declining an in-app payment?

Does the app or associated website clearly describe the health interventions required to achieve the intended benefits claimed for users?

Does the app disclose all conditions and time limitations governing rewards?

Does the app declare the degree of admission of liability (publisher's acceptance or disclaimer of responsibility) regarding the selection and use of the app's content?

Does the app developer provide documentation to show that the app developer has adequate resources to continue to develop, maintain and support the product (e.g. human resources, finances, IP rights, facilities, equipment, tools)?

Is the app in product sales or advertising compliant with Australian Consumer Law and regulatory requirements?

Are all potential customers and users made aware of the estimated data usage requirements for using this app?

EASE OF USE

Accessibility

Does the app require web access to function and is the user made aware access is required?

Are measures taken for intended users to access information and interact with user interfaces compliant with WCAG2.1 AA?

Are measures taken for intended users to understand both the information and the user interface compliant with WCAG2.1 AA?

Is the app appropriate for minors (children and young people)?



Appendix D: Potential future measures (cont.)

PRIVACY AND SECURITY

Privacy

Does the app store or process health-related personally identifiable information?

Does the privacy policy include information on the ability to erase or review the data stored?

If the app connects to any third-party products, do all third parties comply with all privacy and security claims made for this app?

Does the app developer have a nominated data protection officer?

What practices, procedures and systems have been implemented by the app developer to ensure Australian Privacy Principles compliance?

Note: see [Section 1.4 Australian Privacy Principles Guidelines Privacy Act 1988](#)

Consent and user control

Does the app, as a default setting, seek consent before the transmission of data?

For programs used by minors, does the app require the approval of a legal guardian?

Security

Does the app developer have information security management systems and use a risk-based approach to ensure:

- personal information is managed as claimed in the privacy statement
- no unauthorised access or modifications to source code and health information displayed?

List the risk assessment findings in terms of their potential effect on adequately securing an individual's personally identifiable information including any protected health information (PHI) and information used to access an EHR/PHR (e.g. login credentials).

Has all custom code had a security review, including third-party libraries?

Have logging and reporting requirements been clearly defined?

Please provide the summary report of an external penetration test of the product that included Open Web Application Security Project (OWASP) Top 10 vulnerabilities from within the previous 12-month period.

Performance and build

Are the product requirements documented for this and future versions of the app?

In development, did the app developer follow secure coding and practices using an established risk assessment framework?

Has the product been load tested?

Does the app developer monitor and document conflicts or compatibility issues of the app with other apps, device features (e.g. camera), or connected devices?

Do you continuously develop your product?

Does the app, or associated website, provide a review schedule or update process to ensure accuracy and clinical relevance?



Appendix D: Potential future measures (cont.)

Does the app prompt the user to the availability of a new version of the app when a new version is available?

Do you provide a Service Level Agreement to all customers purchasing the product?

Do you report to customers on your performance with respect to support, system performance (response times) and availability (uptime) at a frequency required by your customers?

Does the app function in older operating systems (e.g. all OS, or up to N-3 from current OS)?

If the app has collected personal health information, does the app developer guarantee continuity of data use across different versions of the app?

Interoperability and data standards

Do the specifications and implementation guides for all the APIs include Australian approved standards for interoperability?

How have you validated all interactions with third-party products?

Appendix E: Glossary

In the table below, if the term appears in a published standard, the reference is provided.

Term	Description	Reference
accessibility	Extent to which products, systems, services, environments and facilities can be used by people from a population with the widest range of user needs, characteristics and capabilities to achieve identified goals in identified contexts of use. Note 1 to entry: Context of use includes direct use or use supported by assistive technologies.	ISO 9241-220:2019(en) , 3.1
accessibility assessment	The app is designed and delivered in such a way that facilitates ease of use for the widest user base possible, taking into account different physical or mental abilities or impairments (where relevant) as well as level of comfort, engagement with and adherence to the app.	
assessing organisation	Organisation that evaluates apps for inclusion in an mHealth library.	ISO/TS 82304-2:2021(en) , 3.2.2
authentication	Process of validating a user or process to verify that the user or process is not a counterfeit. Note 1 to entry: Methods to validate the identity of the user of an app may include password, Face ID, Touch ID, OAuth2.	ISO/IEC/IEEE 9945:2009(en) , 3.31
authorisation	Process of verifying that a user or process has permission to use a resource in the manner requested. Note 1 to entry: To ensure security, the user or process would also need to be authenticated before granting access.	ISO/IEC/IEEE 9945:2009(en) , 3.3.2
clinical assessor	Assessor with relevant expertise to review the clinical aspects of the app (acceptability, evidence of effectiveness).	
consent and user control assessment	The app processes personal data only on the basis of a valid legal base (i.e. Consent).	
cultural acceptability assessment	The app is designed to support the cultural needs and safety of diverse population groups, including Aboriginal and Torres Strait Islander peoples.	
cultural acceptability assessor	Assessor with relevant expertise to review the cultural acceptability aspects of the app.	
developer/app developer	A developer is the person or company taking legal responsibility for the development of a digital product (the name on the label, or the name under which the product is supplied). The manufacturer of a medical device is responsible for the design, production, packaging and labelling of the device, but does not necessarily need to perform these activities themselves.	TGA How the TGA regulates software based medical devices
ease of use assessment	The app is designed and delivered in such a way that facilitates ease of use for the widest user base possible, taking into account different physical or mental abilities or impairments (where relevant) as well as level of comfort, engagement with, and adherence to, the app.	
effectiveness	Ability to produce the intended result.	ISO 81001-1:2021(en) , 3.2.5
efficiency	Resources used in relation to the results achieved. Note 1 to entry: Typical resources include time, human effort, cots and materials.	ISO 9241-11:2018(en) , 3.1.13
evidence	Directly measurable characteristics of a process and/or product that represents objective, demonstrable proof that a specific activity satisfies a specified requirement.	ISO/IEC 21827:2008(en) , 3.19
evidence and expertise assessment	The app utilises evidence and clinician expertise appropriate to support the health benefit claims.	
harm	Injury or damage to the health of people or damage to property or the environment.	ISO/TS 82304-2:2021(en) , 3.3.3

TERM	DESCRIPTION	REFERENCE
hazard	Potential source of harm.	ISO/TS 82304-2:2021(en) , 3.3.4
health	State of complete physical, mental and social wellbeing not merely the absence of disease or infirmity.	WHO Constitution (1948)
health benefit	Positive impact or desirable outcome of the use of health software on the health of an individual.	
health intervention	An act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions.	International Classification of Health Interventions (ICHI)
health issue	Representation of an issue related to the health of a subject of care as identified by one or more health care actors. Note 1 to entry: According to this definition, a health issue can correspond to a health problem, a disease, an illness or another kind of health condition. For example, a loss of weight, a heart attack, a drug addiction, an injury or dermatitis.	ISO/TS 82304-2:2021(en) , 3.1.8
health need	Deficit in the current health state compared to aspects of a desired future health state.	ISO/TS 82304-2:2021(en) , 3.1.9
health professional acceptability assessment	The app is suitable for the intended purpose and has the potential to achieve the health benefits as claimed from a clinician perspective.	
health software	Software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care. Note 1 to entry: Health software fully includes what is considered software as a medical device. Note 2 to entry: The scope of IEC 82304-1 refers to the subset of health software that is intended to run on general computing platforms.	ISO/TS 82304-2:2021(en) , 3.2.4
health software product	Combination of health software and accompanying documentation.	ISO/TS 82304-2:2021(en) , 3.2.5
intended purpose	Health-related use for which a product, process or service is intended according to the specifications, instructions and information provided by the developer. Note 1: The intended health benefit, patient population, part of the body or type of tissue interacted with, user profile, use environment and operating principle are typical elements of the intended use. Note 2: A health app has an intended use irrespective of whether it is a medical device. A concept of "intended use" is used in a more restrictive sense in some medical device regulations.	ISO/TS 82304-2:2021(en) , 3.1.10
intended users	Group(s) of people for whom a product is designed. Note 1: In many cases the actual user population is different from that originally intended by the developer. The intended user group is based on realistic estimations of who the actual users of the product will be.	ISO/TS 20282-2:2013(en) , 4.11
interoperability	Ability of two or more systems or components to exchange information and to use the information that has been exchanged.	ISO/TS 27790:2009(en) , 3.39

TERM	DESCRIPTION	REFERENCE
interoperability and data standards assessment	The app, where relevant, can successfully exchange data (read and/or write) to different information systems (such as electronic health records) using Australian interoperability and data standards.	
medical device	Instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other related article, intended by the developer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: <ul style="list-style-type: none"> - diagnosis, prevention, monitoring, treatment or alleviation of disease - diagnosis, monitoring, treatment, alleviation of or compensation for an injury - investigation, replacement, modification or support of the anatomy or of a physiological process - supporting or sustaining life - control of conception - disinfection of medical devices - providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. 	ISO 17665-1:2006(en) , 3.23
mHealth app	Software applications (web-based or native apps) created specifically for use on a wireless/mobile platform, such as smartphones and tablets, intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care. This includes stand-alone apps and those that are linked to a medical device. They may also be used on desktops, but they are primarily created for mobile use.	Scoping paper (with inclusions of ISO definition of health and wellbeing app)
performance and build assessment	The app is developed using best practices and is technically robust, reliable, scalable, with an established maintenance process.	
personal information	Any information that can be: <ul style="list-style-type: none"> - used to establish a link between the information and the natural person to whom such information relates - is or can be directly or indirectly linked to a natural person. 	ISO/IEC 19944-1:2020(en) , 3.3.1
privacy	Freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual.	ISO/TS 27790:2009(en) , 3.56
privacy assessment	Where applicable, user privacy rights are respected in line with the requirements of the Privacy Act 1988 including ensuring users understand what information they are giving to the app, how their information will be used, and that personal health data are protected from accidental or malicious data privacy breaches.	
processing of personal information	Operation or set of operations performed upon personal information.	ISO/IEC 29100:2011(en) , 2.23
quality	Degree to which a set of inherent characteristics of an object fulfils requirements.	ISO/TS 82304-2:2021(en) , 3.1.18
quality assurance	Those planned, systematic corrective and preventive actions that are required to ensure that materials, products or services will meet specified requirements.	ISO 13628-10:2005(en) , 3.1.38
reliability	Ability of a device or a system to perform its intended function under given conditions of use for a specified period of time or number of cycles.	ISO/TS 82304-2:2021(en) , 3.1.19

TERM	DESCRIPTION	REFERENCE
residual risk	Risk remaining after risk control measures have been implemented.	ISO/TS 82304-2:2021(en) , 3.3.8
risk	Combination of the probability of occurrence of harm and the severity of that harm.	ISO/TS 82304-2:2021(en) , 3.3.5
risk analysis	Systematic use of available information to identify hazards and to estimate the risk.	ISO/TS 82304-2:2021(en) , 3.3.6
risk control	Process in which decisions are made and measures implemented by which risks are reduced to, and maintained within, specified levels.	ISO/TS 82304-2:2021(en) , 3.3.7
safety	Freedom from unacceptable risk.	ISO 10393:2013(en) , 2.18
satisfaction	Extent to which the user's physical, cognitive and emotional responses that result from the use of a system, product or service meet the user's needs and expectations. Note 1 to entry: Satisfaction includes the extent to which the user experience that results from the actual use meets the user's needs and expectations. Note 2 to entry: Anticipated use can influence satisfaction with actual use.	ISO 9241-11:2018(en) , 3.1.14
security assessment	The app is secure to threats altering the information/functionality of the app and ensures secure management of personal health data whether it is stored or transferred (i.e. the app uses up-to-date security standards and considers cybersecurity capabilities in line with Australian standards). The app does not require more information than needed for the purpose of the app.	
security	Condition that results from the establishment and maintenance of protective measures that ensure a state of inviolability from hostile acts or influences. Note 1 to entry: Hostile acts or influences could be intentional or unintentional.	ISO/TS 82304-2:2021(en) , 3.1.22
session management	Process of securing repeated access of a user to the health app, once authentication has been established, for example automatic logout after a certain time of inactivity.	ISO/TS 82304-2:2021(en) , 3.2.7
Sponsor	A person or company who does one or more of the following: <ul style="list-style-type: none"> - exports therapeutic goods from Australia - imports therapeutic goods into Australia - manufactures therapeutic goods for supply in Australia or elsewhere - arranges for another party to import, export or manufacture therapeutic goods. 	
transparency assessment	The app enables users to understand who is distributing, financing (including the use of advertising), and developing the app and how to contact them. Additionally, the app enables users to make an informed choice based on an understanding of the financial costs and health interventions required to achieve the stated health benefits claimed.	

TERM	DESCRIPTION	REFERENCE
Trust	Degree to which a user or other stakeholder has confidence that a product or system will behave as intended.	ISO/IEC 25010:2011(en) , 4.1.3.2
usability	Extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.	ISO/TS 82304-2:2021(en) , 3.1.23
usability assessment	The app is designed and delivered in such a way it can be used by intended users to achieve the specified benefits or goals in a specified intended purpose.	
use error	Reasonably foreseeable misuse.	ISO/TS 82304-2:2021(en) , 3.1.25
User	Person who interacts with a system, product or service. Note 1 to entry: Users of a system, product or service include people who operate the system, people who make use of the output of the system and people who support the system (including providing maintenance and training).	ISO 9241-11:2018(en) , 3.1.7
user acceptability assessment	The app takes into account the user's holistic experience (i.e. physical, cognitive, emotive, beliefs, preferences, or behaviours) and considers the system and the context of use where relevant.	
user experience	A person's perceptions and responses resulting from the use and/or anticipated use of a product, system or service. Note 1 to entry: User experience includes all the users' emotions, beliefs, preferences, perceptions, physical and psychological responses, behaviours and accomplishments that occur before, during and after use. Note 2 to entry: User experience is a consequence of brand image, presentation, functionality, system performance, interactive behaviour and assistive capabilities of a system, product or service. It also results from the user's internal and physical state resulting from prior experiences, attitudes, skills and personality and the context of use.	ISO 9241-11:2018(en) , 3.2.3
validation	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Note 1 to entry: The objective evidence needed for a validation can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents. Note 2 to entry: The activities carried out for validation are sometimes called a qualification process. Note 3 to entry: The word "validated" is used to designate the corresponding status.	ISO/TS 82304-2:2021(en) , 3.2.8
verification	Confirmation through the provision of objective evidence that specified requirements have been fulfilled. Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents. Note 2 to entry: The activities carried out for verification are sometimes called a qualification process. Note 3 to entry: The word "verified" is used to designate the corresponding status.	ISO/TS 82304-2:2021(en) , 3.2.8



Australian Government

Australian Digital Health Agency

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