



Australian Government  
Australian Digital Health Agency



# Assessment framework for mHealth apps **SUMMARY**

## Intended use

This summary document has been developed to provide an overview of the Assessment framework for mHealth apps for a general audience.

The complete framework is the result of extensive consultation domestically and internationally. It is published 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 need for a national mHealth assessment framework

Mobile health (mHealth) technology has been widely adopted worldwide and is expected to continue growing as a global market. There are estimated to be hundreds of thousands of mobile health applications and, until now, there has been no national framework for mHealth app assessment across Australia that covers the broad range of apps on the market.

The Australian Digital Health Agency, Queensland Health, the project steering committee and supporting reference group have developed the mHealth Apps Assessment Framework to fill this gap and promote innovation in health service delivery. The framework aims to increase the adoption and use of mHealth apps that are safe and have the potential to improve health outcomes for Australians. It achieves this by:

- guiding app developers creating mHealth apps
- helping consumers choose credible mHealth apps
- helping healthcare professionals make informed choices when recommending or 'prescribing' mHealth apps to patients
- supporting the integration of effective and safe mHealth apps into clinical workflows.

This document summarises the framework for a general audience while the complete framework has been created for those requiring further information, such as app developers and health professionals. The complete framework details the framework methodology and the assessment process, including the assessment questions asked at each phase. It is available on [digitalhealth.gov.au](https://digitalhealth.gov.au).

The framework is a voluntary process, meaning app developers can nominate their apps to be assessed for inclusion in an mHealth apps library. Apps will be assessed through a four-stage process designed to measure an app's acceptability, safety, trustworthiness, ease of use, privacy and security, and technical quality, as well as complement similar Australian and international frameworks. Each of these 'domains' has criteria that structure the assessment process.

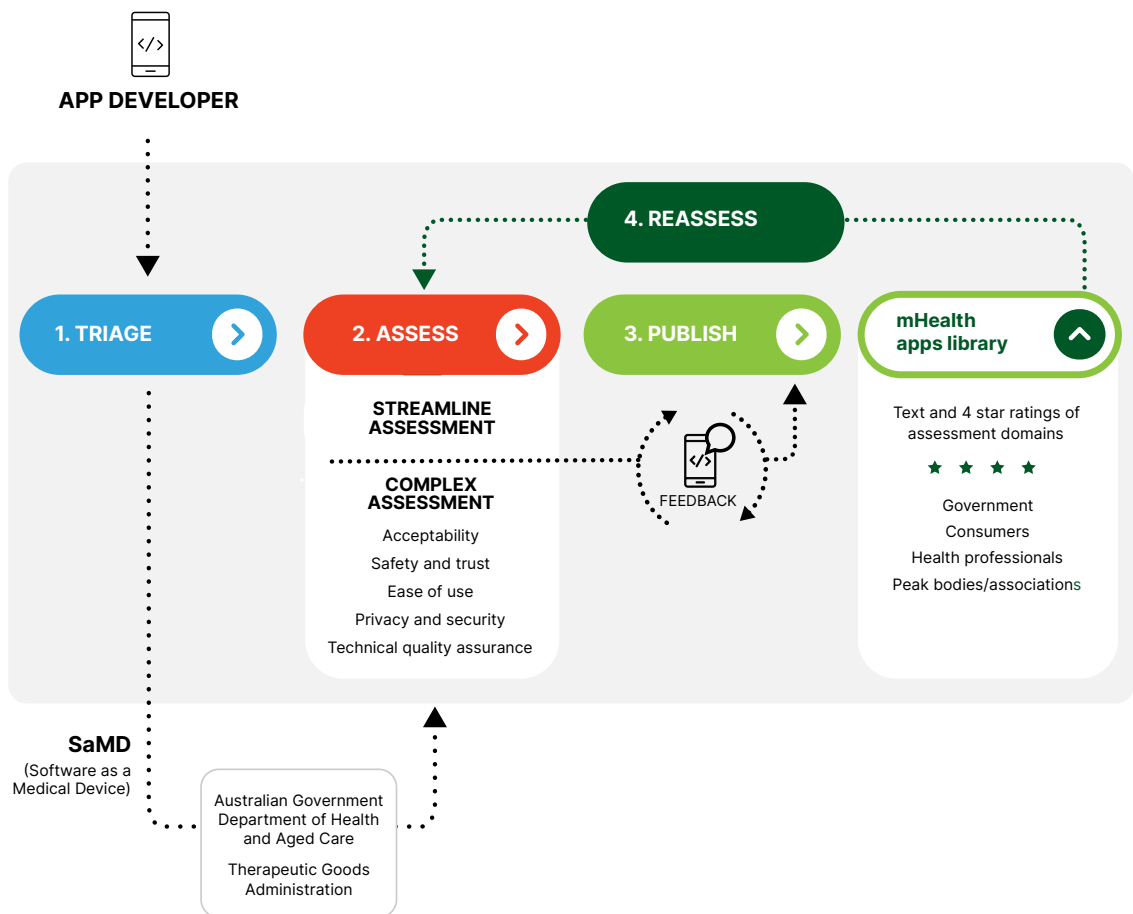
| DOMAIN    | ACCEPTABILITY       | SAFETY AND TRUST       | EASE OF USE   | PRIVACY AND SECURITY     | TECHNICAL QUALITY ASSURANCE         |
|-----------|---------------------|------------------------|---------------|--------------------------|-------------------------------------|
| CRITERION | User                | Protection from harm   | Accessibility | Privacy                  | Performance and build               |
|           | Cultural            | Evidence and expertise | Usability     | Consent and user control | Interoperability and data standards |
|           | Health professional | Transparency           |               | Security                 |                                     |

This framework can also be used as guidance for app developers even if they are not being assessed by this process.

## mHealth apps assessment process

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 specific criteria. 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.



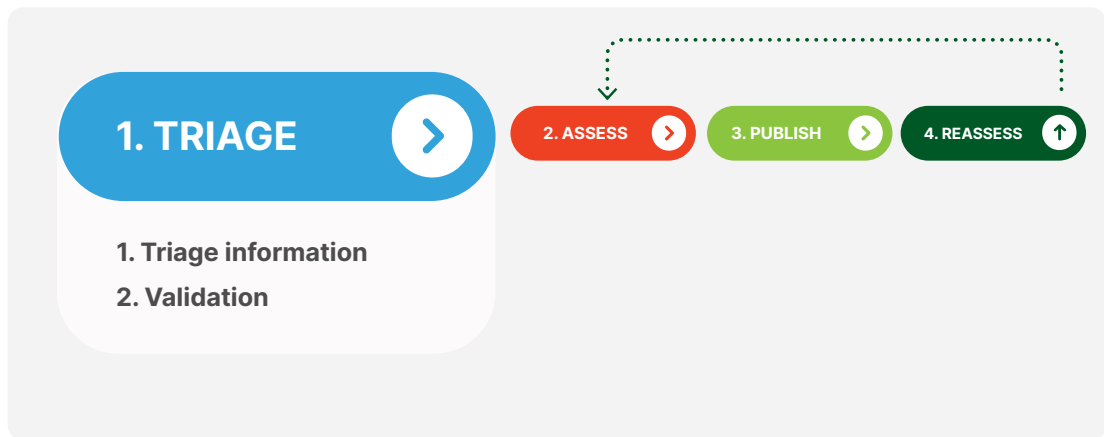
The framework is the result of extensive consultation both domestically and internationally.

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.

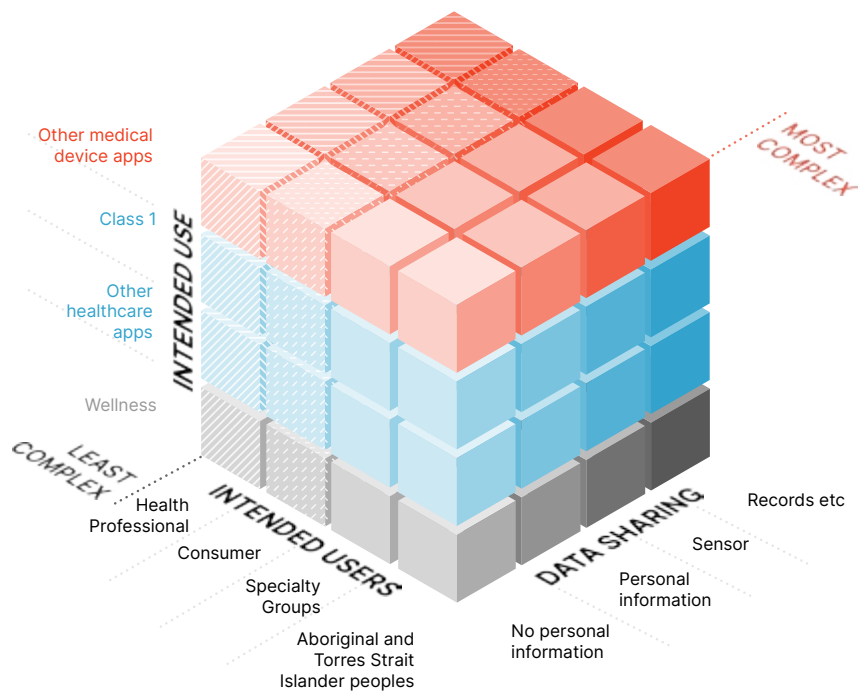
The assessment process is a continuous cycle, reflecting the need for assessments to be regularly updated to account for changes to apps, app developer characteristics and the framework.

# 1. TRIAGE

The framework assessment process begins with the triage phase, which has a series of questions that determine whether an app is eligible for assessment and how complex the app is which will inform the type of criteria and measures. This phase also determines if an assessment can be streamlined, to ensure apps that have already been assessed by another framework, or those that are low-risk, move more quickly through the process.



More information or evidence may be required of the app developer depending on how complex their app is. The framework assesses apps against a complexity matrix:



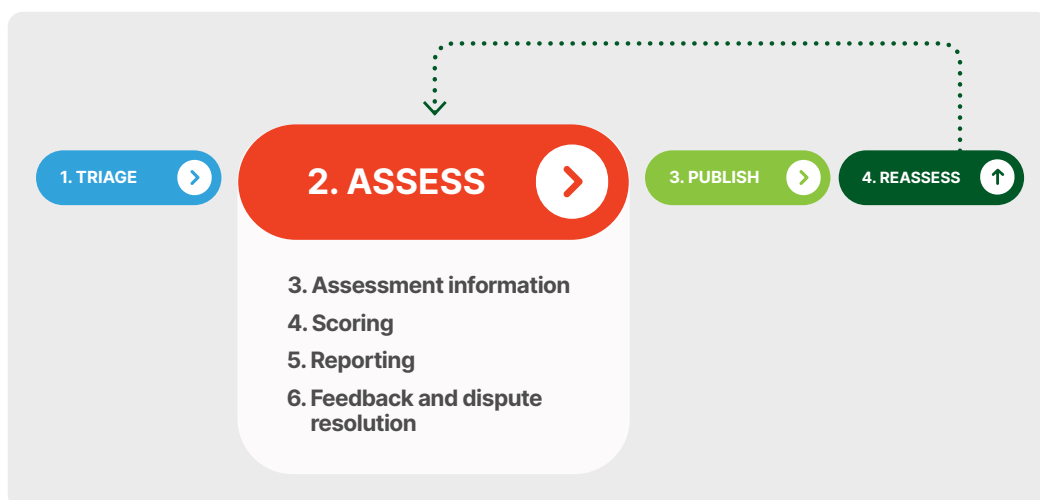
## 2. ASSESS

The framework's second phase is an evidence-based assessment process. The assessment questions are based on research into similar assessment frameworks and aligned to existing standards.

App developers answer questions based on the outcome of the triage phase, and those responses are validated and scored against five key assessment domains:

1. Acceptability
2. Safety and trust
3. Ease of use
4. Privacy and security
5. Technical quality assurance

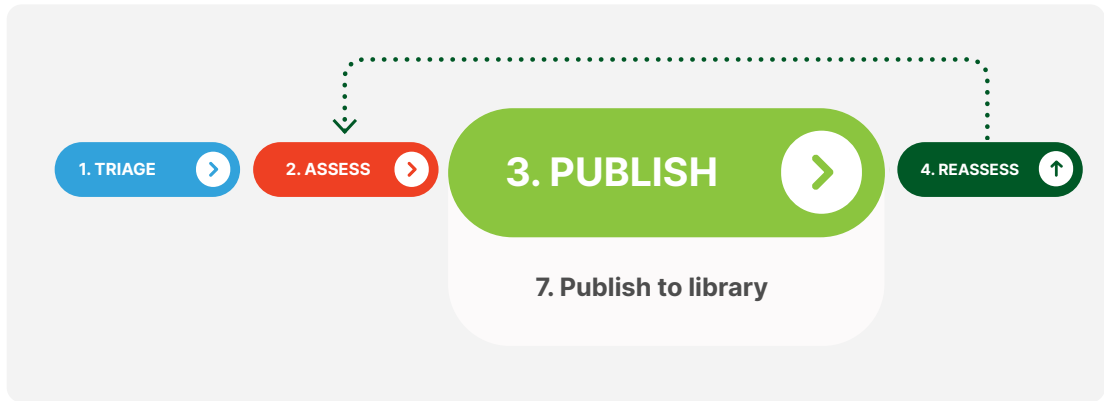
The outcome of the assessment will be sent to app developers, letting them know whether the app was approved for the library. Successful apps will receive a 'badge of endorsement' (which indicates it is safe, effective, trustworthy and useful), as well as the domain scores and how the app will be presented in the library.





### 3. PUBLISH

Apps will be published in the third phase, letting library users make decisions about which apps to use and which to recommend to others. The outcome of the assessment will be communicated to meet the needs of users with different levels of health literacy, reasons for accessing the library and expectations about how to use the information.




Each app will have two different descriptions: a basic description and a detailed description.

The basic description summarises whether an app is safe, trustworthy and effective, where the app is available (i.e. Android, Apple and Google), the languages and other basic app information.

The detailed description will have a star rating that summarises the app's overall assessment and its performance across the five domains.

*Proposed basic description*

- mHealth app name**
- LOGO** **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**

*Proposed detailed description*

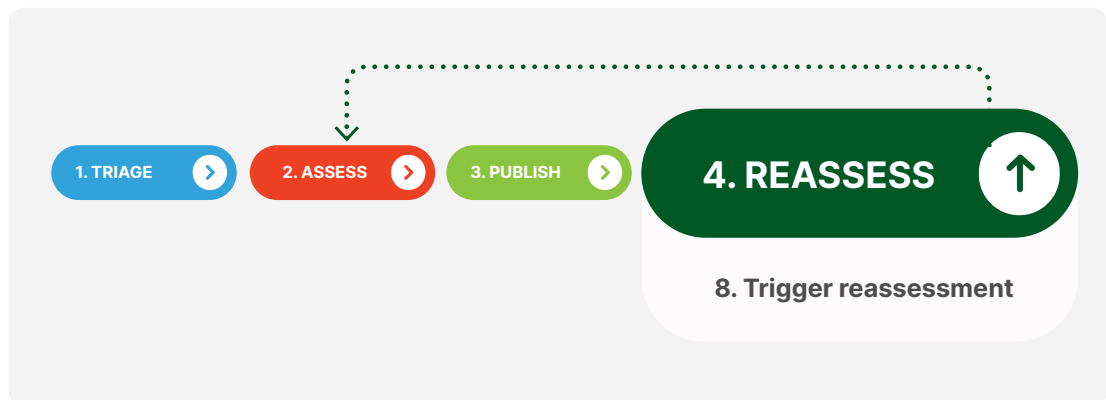
- User acceptability or cultural acceptability**  
[Text here]
- Health professional acceptability**  
[Text here]
- Star ratings:**
- ★★★★★ **Safety and trust**
- ★★★★☆ **Ease of use**
- ★★★★★ **Privacy and security**
- ★★★★★ **Technical quality assurance**
- Connects to [text] (e.g. My Health Record,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



## 4. REASSESS

To ensure the library remains a trusted source of information for health professionals and users, the framework has a reassessment process. An app reassessment can be triggered in three ways:

1. If an app developer makes changes to an app on the library or to their own organisational characteristics (e.g. corporate information).
2. If there is a serious consumer complaint or the TGA issues an Adverse Event Report.
3. All apps will be required to do a full reassessment at least every three years.



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