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In **partnership** with INFONYX

THERAPEUTIC GOODS ADMINISTRATION

Data Systems to Support Mandatory Reporting of Medical Device Adverse Events

Final Report

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LIST OF ABBREVIATIONS

AEMS	Adverse Event Management System (for medicines)
AGIS	Australian Government Investigation Standards
API	Application Programming Interface
ARTG	Australian Register of Therapeutic Goods
CRM	Customer Relationship Management
DAEN	Database for Adverse Event Notifications
DII	Device Incident Investigation
DIR	Device Incident Report
DoHAC	Department of Health and Aged Care
DPMM	Devices Post Market Monitoring (team)
eBS	Electronic Business portal
FHIR	Fast Healthcare Interoperability Resources
FTE	Full Time Equivalent
HPRG	Health Products Regulation Group
InfoLeader	Adverse Event Management System (for medical devices)
IT	Information Technology
Level 1	Investigation to gather additional information
Level 2	Investigation of an individual DII
Level 3	Investigation of a group of related DIIs
MAEDX	Medicines Adverse Events Data Exchange
MDSB	Medical Devices Surveillance Branch
PI	Prediction Interval
QLIK	A proprietary data analysis platform
TGA	Therapeutic Goods Administration
TRIM	An electronic document and records management system
UDI	Unique Device Identifier
US	United States (of America)
WI	Work Instruction

DISCLAIMER

Executive Summary

The task

This project was commissioned to undertake scoping work related to data systems to support future mandatory reporting of adverse events relating to medical devices. Specifically, the project was required to:

- Investigate the broader context of Health Products Regulation Group (HPRG) Transformation Program being implemented across the Therapeutic Goods Administration (TGA).
- Investigate and review existing systems and processes that are occurring to manage adverse event notifications relating to medical devices within the Medical Devices Surveillance Branch (MDSB). A comparison of approaches to medicines adverse event notification processing was also undertaken.
- Identify, review, and describe current and future capability needs of Information Technology (IT) systems (and to a lesser extent processes) to address changes in the volume of adverse event notifications associated with the introduction of mandatory reporting for medical devices.
- Align current and proposed future systems (and where relevant processes) with the broader HPRG Transformation Program.
- Develop a high-level overview of how a new system might work to support development of a business case for future investment and describe the high level strategic and operational priorities for implementation in this stage that might be considered by the TGA.
- Provide a draft and final report in word format, focusing upon table summaries and descriptive text addressing each of the key questions.

Imperatives for change

New legislation making it mandatory to report serious adverse events suspected to involve a medical device to the TGA will come into effect after March 2025.

The requirement, which will affect all public and private health services, day procedure centres and state and territory health departments, will result in an increase in the volume of notifications the TGA will be required to handle.

The consultation process with the effected stakeholders has already committed the TGA to examine improvements in technology to facilitate this requirement. Commitments include potential development of Application Programming Interface (APIs), batch reporting capabilities, improved user interface and timely feedback to support introduction of the legislation.

The current system has several limitations that will inhibit its ability to manage the increase in volume and fulfil the public benefit intent of the new legislation. Key limitations include:

- Highly manual and labour-intensive work processes, which in part is driven by the current channels for receiving notifications (e.g., website forms, emails including pdf attachments) which impacts upon the translation and transfer of data for analysis.

- Limitations in the interoperability and automation of current databases necessary for assessing adverse event notifications. The present triage system requires manually processing every report, 'one report at a time' rather than adopting a more automated and risk-based approach.

Findings

The key findings of the project revealed that:

- Adverse event reporting is not an immediate or short-term priority area for the HPRG Transformation Program. Notwithstanding, many elements of the HPRG Transformation Program can be incorporated into future adverse event reporting systems.
- Whilst further developments in medicines adverse event reporting have progressed in parallel to other systems developments, more recent re-scoping of this work has become necessary. Improvements in device adverse event reporting might also progress in parallel to other systems developments, with regular updating to the HPRG Transformation Program.
- Current work processes to manage medical device adverse event reports are heavily influenced by the functionality of the existing IT systems. With around 1/3-1/2 of key activities likely to be amenable to greater integration and automation.
- Current systems are unlikely to efficiently accommodate systematic, or high-volume adverse event reporting by public or private health facilities, or sponsors/manufacturers.
- The project was unable to identify any off-the-shelf products that are in use or available that are tailored to deal with adverse event reporting (outside of those under development to improve medicines adverse event reporting). The current system, Information Leader, was itself an adaptation of software originally developed for quality control.
- Changes for medical devices will be necessary for the management of an increasing number of stakeholders, an increasing number of reports, commitments made to improve channels of reporting to the TGA including consideration of implementation of APIs and batch processing.
- Increased automation and analytic capability are likely to assist in prioritising cases for follow-up or deeper investigation – to fulfil the intent of the public value of changes to the legislation.
- Improvements in data storage and integration will also streamline and improve coherence across the TGA.
- Resources will be required to 'staff up' additional reporting demands if IT systems do not change. Alternatively, IT systems are anticipated to free up existing staff resources through processing efficiencies. Realistically, process efficiencies and staff resources need to be considered in tandem with available IT developments.

In summary, the review highlighted three distinct areas that need to be considered and addressed:

1. Mechanisms to improve **data translation and transfer** (e.g., from health services to the TGA).
2. Options for **data storage and retrieval** to improve interoperability and automation (e.g., of medical adverse event information, and/or enterprise [TGA] level storage and processing).
3. Increasing efficiency and effectiveness of **data analysis capability** (e.g., for medical device information, and for the organisation as a whole).

A range of solutions to improve data systems and operational processes have been recommended to accommodate the anticipated future demand for adverse event reporting. These solutions can be implemented as separate components or as integrated components for systems improvement.

Selection of specific solutions will need to be determined by the TGA after further investigations about the level of departmental support for existing (legacy) systems, the capacity to modify current data analysis platforms (by the software vendor) to meet future requirements, and the timing and extent of further system developments implemented as part of the HPRG Transformation Program.

It is important to note that although there are three distinct areas that have been identified for consideration in relation to current data systems; the interrelated and interdependent nature of data technology restricts the ability to provide clearly distinct options and solutions that separately address each of the identified areas noted above. In short, there is no one-to-one association between the identified areas and the potential solutions described below.

Accordingly, six solutions have been grouped into three overall approaches which are described in brief below and fully explored in Section 9 of the report. The solutions have been designed to allow for stepped implementation where necessary.

Solution 1: Technology Status Quo: Staff up the existing system

The first solution is simply to staff up the existing operating system. Whilst this remains an option for consideration, it is associated with significant caveats, namely:

- It is an unrealistic approach given the costs associated with staffing discussed in simulation modelling provided in Section 7.
- It fails to meet commitments to key stakeholders relating to API and batch reporting capabilities.

Notwithstanding, estimating the likely increase in levels of staffing does provide a basis for quantifying the notional funding that might be used to guide alternative investment in IT solutions.

Solution 2a): Technology Short-term approach: Implement 'devices' API and batch processing

This solution delivers on commitments made to health services about streamlining the reporting of medical device related adverse events to the TGA. This approach can also be applied to sponsors and other large-scale reporters of adverse events (e.g., different Australian jurisdictions). Specifically, this solution:

- Is likely to be able to be achieved by March 2025 or soon thereafter to meet the anticipated increase in volumes.
- Should not be constrained by HPRG Transformation Program priorities for implementation.
- Can progress in parallel with other technology solutions.

Solution 2b): Technology Short-term approach: Maximise automation of existing systems

This solution is another short-term option that could be considered but is heavily dependent upon the availability of ongoing departmental IT support, and the capacity to upgrade the existing system (InfoLeader). If support and capability of the existing system permit:

- It *might* support API and batch reporting (although this is to be confirmed)

- It *might* extend the use of the current system.

Regardless of the capacity to upgrade InfoLeader, this solution does not guarantee more efficient processing of data or integration with other IT improvements (e.g., portal development, integrated storage, and linkage of data, upgraded analytics, etc.)

Solution 3a): Technology Strategic Approach: Adapt end-to-end AEMS capability

Time and progress permitting, a solution that expands and adapts Adverse Event Management System (AEMS) capability might be considered. However:

- It is highly unlikely to produce functional capability for medical device incident notification processing within the regulatory timelines required to implement mandatory reporting.
- The extent of additional capability and capacity of the improved *AEMS* system that is suitable to accommodate the needs for devices remains to be determined.

Solution 3b): Technology Strategic Approach: Pursue an end-to-end device platform

This solution would develop a current and next generation IT system for specific processing of medical device adverse event notifications and enable retirement of the current system (which would be particularly important if InfoLeader will no longer be supported by departmental IT or be amenable to modification that addresses the current and emerging needs of medical device incident notification staff).

Timely action to pursue this solution will be necessary to achieve functionality by the required implementation timeframes in 2025.

If undertaken this solution is most likely to:

- Deliver on the commitment to stakeholders for more user friendly and accessible data analytics capabilities.
- Assure integration with API and batch processing capability enhancements, together with changes in any portal arrangements for stakeholders (including consumers, healthcare providers, sponsors, and health facilities across Australia).
- Align and integrate with implementation of other TGA and HPRG Program initiatives
- Fit within the criteria and preferred directions of the broader information technology ecosystem of the TGA and the department.

Solution 3c): Technology Strategic Approach: Streamline 'devices' data integration and storage

This solution involves improved integration of data storage and processing across all areas of the TGA including for medical devices and could be considered as an accompanying component to upgrades to the existing InfoLeader system or integrated into an end-to-end device platform specifically developed for medical device adverse event notification processing.

Alternatively, if similar activities are planned for broader implementation across the TGA (i.e., as part of the HPRG reforms) then these could be subsequently integrated into an upgraded InfoLeader or a specific devices end-to-end solution. If an enterprise response does not occur within a reasonable time frame (e.g., 2-4 years), independent progress to maximise the efficiencies of medical devices and medicines adverse event notification processing could be considered.

Key considerations for the TGA

There is only a narrow window of time for deciding on how to address the likely surge in reports after March 2025, recognising that whatever the preferred course, there are lead times required for either for a technology, or a staffing solution.

Although complete alignment with the broader enterprise HPRG Transformation Program would be ideal, the consultations with stakeholder in this area suggest that neither the Transformation Program nor the work for the Medicines Adverse Events Data Exchange (MAEDX) project will allow for progressing work for the MDSB at the required pace.

The imperative to have an improved ability to deal with the likely volumes following commencement of mandatory reporting suggests that the TGA would likely gain most benefit by progressing two courses of action in parallel. The two courses with the most compelling features are presented as Approach 2a together with Approach 3b. More detailed analysis of these options against a range of evaluation criteria are presented in further detail within this report.

2. Background

A need to improve medical device adverse event detection

An independent review

In 2016 an independent review of Medicines and Medical Devices Regulation called for a range of improvements to medical device adverse event detection and reporting, including (but not limited to):

- More comprehensive monitoring of medical devices.
- More timely analysis of hospital information about adverse events associated with medical devices.
- The introduction of electronic reporting for adverse event information to streamline the provision of information by product sponsors/ manufacturers and other key stakeholders.
- Enhanced collaboration with State and Territory jurisdictions to improve the sharing of information about early indicators of medical device adverse events and actions undertaken to minimise the impact of medical device problems upon the broader community.

An Action Plan for medical devices

In 2019 the TGA published an Action Plan for improving Australia's Medical Device Regulatory Framework, that focused upon a range of activities including (but again not limited to):

- Increasing the rigor of the medical device assessment process
- Investigating mandatory reporting for serious adverse events
- Examine the introduction of unique medical device identifiers.
- Enhanced post market inspections and reviews.
- Greater analysis and sharing of data with hospitals.
- Publish more information about regulatory decisions.
- Improve consumer awareness and methods of reporting to the TGA.

Subsequent stakeholder consultations

A wide range of ongoing stakeholder consultations have occurred since these publications to determine:

- If reporting of medical device adverse events should be mandatory – this has been agreed and legislation will come into effect in March 2025.
- If exemptions to reporting by product sponsors/manufacturers of certain adverse events associated with medical devices should be removed.
- An appropriate range of methods for improving reporting of adverse events to the TGA by consumers, health care professionals and product sponsors / manufacturers.
- Improvements to the provision of information by the TGA about notifications and investigations into medical devices.

3. The Challenge

An increasing number of medical device notifications

As a result of the major changes that are occurring in the way medical devices are regulated over the coming years, there will be:

- A **greater number of stakeholders reporting adverse events** to the TGA (e.g., consumers, health professionals, product sponsors/manufacturers, governments, all public and private health facilities operating across Australia).
- A **greater number of adverse event reports,** both serious (e.g., via mandatory reporting) and less serious (e.g., exemptions to reporting) to the TGA.
- A need to investigate upgrading (at least) of existing event notification and other information management systems used by the TGA.
- An ongoing need to revise approaches to incident triage and assessment for medical devices.
- A need for adopting a proactive and strategic approach to system investment rather than a short-term solution to meet an immediate need.

Whilst it is accepted that a significant increase in adverse event reporting will occur based upon the regulatory changes implemented by the TGA, there is less certainty about the magnitude of this increase. A range of different data sources have been used to estimate the likely increase.

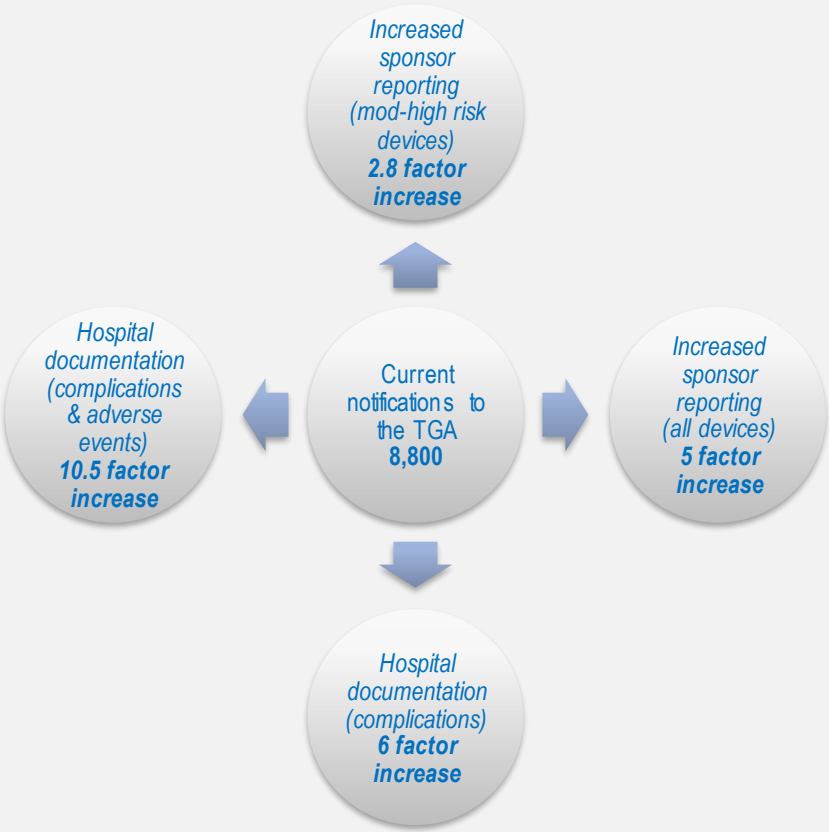
- Estimates of the increase in sponsor / manufacturer reporting with the removal of 'exemptions' indicates an increase of between **three and five times the current levels** of adverse event notifications reported to the TGA

Changes in medical device-related regulation, assessment, and data management

- **New legislation making it mandatory, after March 2025, to report serious adverse events** suspected to involve a medical device to the TGA by all Australian public and private health facilities.
- The **removal of exemptions** to adverse event reporting by product sponsors / manufacturers.
- Development and progressive implementation of data systems to support the **introduction of Unique Device Identifiers** for medical devices listed on the ARTG.
- **Updating approaches to incident investigation** in accordance with the new AGIS (published in 2022).
- Developing **more efficient methods of electronic data exchange,** decreasing the need for manual processing (e.g., via eBS portal).
- Improving **web forms** and developing a **web-based application for reporting** of adverse events by computers or other personal devices.
- Improving **access to incident notification and investigation data** published in the DAEN (i.e., sorting and electronic download capability).
- Updating data fields to accommodate ongoing **changes in incident classification** terminology (IMDRF).

- Counts of the World Health Organisation's International Classification of Diseases (ICD) coding across Australian hospitals, published by the AIHW indicate a significantly higher number of adverse events are occurring that may relate to medical devices (at least **10 times higher than current notifications**).
- Importantly, it is appreciated that the level of current ICD coding is most likely to be an under-capture of the 'true' level of adverse events related

Estimates of the potential increase in medical device adverse event notifications to the TGA per annum



Aspex Consulting (2019). Rapid review of adverse event reporting and data analysis for medical devices. Report prepared for the TGA.

4. Review approach

Current information management systems and processes

The TGA has commissioned a review of existing medical device related systems and processes, focusing upon:

- **Alignment** of future demands and processes with the TGA's HPRG Transformation Program and other key strategy documents.
- **Mapping** of **current systems and processes** used to manage notifications about medical device related adverse events.
- **Analysis** of system/process **gaps in capacity** together with an overview of market options that might address areas of need.
- Assessment of **approaches** for potential system changes against **other developments** within the TGA.
- A description of **approaches** to **change in business processes and outcomes** that might occur under any new information management systems and/or processes.
- An **outline of high-level activities and timelines** that are required to shift from current systems and processes to approaches that will accommodate an increase in adverse event notifications.

It is noted that this work does not form part of any technical specification per se but will be **a 'scoping review' of the adequacy of current and anticipated future arrangements and potential roadmap for future action by the TGA** in the context of implementation of mandatory reporting.

Approach

1 The first stage of the engagement was to understand the broader context of HPRG Transformation Program being implemented across the TGA which is intended to articulate the overall enterprise-level objectives and priorities for IT investment, providing a context for updating systems and process that might be needed to support future adverse event notification.

2 The next stage of the review related to understanding existing systems and processes occurring to manage adverse event notifications relating to medical devices within the MDSB. This stage also served to scope the potential overlap in future system requirements between other sections of the MDSB. This included examining current workflows, key decision points and information available to support decisions and mapping of data interfaces between existing systems to promote future integration.

3 The third stage of the engagement was about identifying and describing current and future capability needs of IT systems (and to a lesser extent processes) to address changes in the volume of adverse event notifications associated with the introduction of mandatory reporting for medical devices. This included describing the apparent gaps between current capability and future needs, a preliminary discovery of a range of possible alternatives to address identified gaps and prioritisation of a number of alternative approaches to meet the likely future operational needs of the MDSB.

4 This fourth stage of the engagement related to aligning current and proposed future systems (and where relevant) identifying processes that align with the broader HPRG Transformation Program. This included alignment of proposed system components and/or changes with other data-related activities planned for implementation across different areas of the TGA.

5 This fifth stage of the engagement is to develop a high-level overview of how a new system might work – describing the key characteristics that are intended to result from any system changes. It is intended that the high-level concept of operations would support future development of a business case for investment and sustainability of proposed changes to data systems. This includes a description of process improvements associated with proposed changes and of the potential costs/savings associated with the proposed changes.

6 This stage of the engagement was to describe the high-level strategic and operational priorities for implementation that might be considered by the MDSB, the Medical Devices and Product Quality Division, and other areas of the TGA.

7 This final stage of the engagement provides documentation of key findings associated with each of the major questions into a draft and final report.

5. Alignment

Q:

How does mandatory reporting of adverse events associated with medical devices align with the TGA Health Products Regulation Group (HPRG) Transformation Program and other key IT strategies?

A:

Adverse event reporting is not an immediate or short-term priority area for the HPRG Transformation Program.

Notwithstanding, many elements of the HPRG Transformation Program can be incorporated into future adverse event reporting systems.

Medicines adverse event reporting has progressed in parallel, with regular updating to the HPRG Transformation Program.

Devices adverse event reporting can also progress in parallel, with regular updating to the HPRG Transformation Program.

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Current HPRG Transformation Program and medical device notifications

Discussions with key TGA and Department of Health and Aged Care stakeholders and a review of available documentation indicates:

- Mandatory reporting of serious adverse events associated with medical devices is not an immediate or short-term priority area for the HPRG Transformation Program.
- The increase in stakeholder reporting of medical device adverse events, and timelines over which this reporting will increase have not been fully appreciated outside of the MDSB.
- Consequently, priorities for managing the increase in demand placed upon the TGA from medical device adverse events reports have not been accommodated in short-term strategic activities.
- Notwithstanding, several components of the current HPRG Transformation Program are applicable to any changes or development of post market adverse event reporting systems.

Many features of the HPRG Transformation Program have been introduced or are planned for introduction across several transformation projects that are running in parallel with the HPRG Transformation Program, including:

- Development and implementation of the MAEDX.
- The development and implementation of a Unique Device Identification (UDI) system for medical devices approved for use in Australia.

Components of the current HPRG Transformation Program that could apply to future medical device adverse event reporting and investigation systems.

- Development of a **single portal** for sponsors and the Department of Health and Aged Care (including the TGA). It is noted that MDSB would require the portal to also cater for facilities, health professionals and reporters, as well as having the ability to enable machine to machine transfer of data.
- The introduction of a **'case management' system** of processing information requests/reports (when further information about detail is available and tested against the requirements of medical device adverse event notification processing)
- Increased **user access to and ability to modify** information reported to the TGA.
- A move to **cloud-based** information capture, storage, and processing.
- The development of a more integrated **master data store**.
- Improved **systems for validation** of data prior to information processing.
- Increasing **automation** of information processing.
- Improved **capacity to manipulate data** by TGA staff and examine key themes and underlying/emerging trends in reported information.
- Greater **automation of information inputs and outputs** between key stakeholder groups and the TGA.
- Clear articulation of a **technology stack** to support future solutions architecture.
- Enhanced **program of planned retirement** of legacy platforms and systems.

Where parallel initiatives have been implemented alongside the TGAs HPRG Transformation Program, they have continuously reported progress to the HPRG Board and been undertaken in close collaboration with the Department of Health and Aged Care's Information Technology and Solutions Architecture teams.

Ideally, to progress the capacity of upgraded data systems to support the increase in demand for post market medical device vigilance and monitoring, it would be desirable to:

- Plan for the ultimate uptake of key components of the HPRG Transformation Program and align new system upgrades or components with the broader Department of Health and Aged Care IT strategy.
- In the interim, move ahead in parallel to the HPRG Transformation Program and upgrade systems to deal with an increase in demand that will commence after March 2025.
- In the longer term, integrate medicines and medical devices information management systems so that developments in both areas do not need to be 're-invented' due to differing priorities for implementation.

Example of longer-term integration between medical devices and medicines capability

Both medical devices and medicines wish to improve the capacity to electronically report adverse event information from product sponsors/ manufacturers (decreasing the amount of manual processing of data). However, other short-term priorities diverge between the two areas of the TGA, with:

- Medical devices having to focus upon methods of receiving high volumes of adverse event reports from all Australian public and private health care facilities by March 2025; whilst,
- Medicines are making headway in methods of receiving individual adverse event reports from medical practitioners' rooms via updates to practice software.

Ultimately both approaches will benefit each area (e.g., as the scope of medical device adverse event reporting extends to individual medical and other professional's clinical practices which can be designated as "health care facilities"). However, this is not anticipated to occur within the next 5 years for medical devices.

Challenges in assuming devices are the same as medicines

Whilst longer term integration is desired, it is only desired where medical devices can continue to implement their regulatory responsibilities. In this context, it is important to remain mindful of differences in the range of issues, approaches to investigation and timelines associated with medical device adverse events (compared to medicines). For example,

- There are **many more medical devices** (approximately 1.4 million) listed on the Australian Register of Therapeutic Goods (ARTG) than medicines (approximately 40K), and thus the **range of potential problems** is larger.
- Medical devices typically have **significantly longer lifecycle** compared with medicines.
- Medical devices also typically have **more complex chains of delivery**, installation, calibration and/or maintenance over a longer product life cycle compared with most medicines.
- Consequently, medical device adverse events are considerably more complex than those that are associated with medicines, they are more likely to involve a **longer sequence of steps to establish potential causal or contributing factors** and are typically associated with **longer latency periods for potential problems to emerge.**
- Accordingly, device incident investigations are typically single case investigations, which need to be undertaken by **appropriately qualified staff** who are subsequently trained in **Australian Government Investigation Standards**.

Things that go wrong – medical devices compared with medicines

	Devices	Medicines
Activation, Positioning or Separation problem	✓	×
Calibration problem	✓	×
Chemical problem	✓	✓
Communication or Transmission problem	✓	×
Compatibility problem	✓	×
Computer Software problem	✓	×
Connection problem	✓	×
Contamination / decontamination problem	✓	✓
Electrical problem	✓	×
Electronic Property problem	✓	×
Environmental Compatibility problem	✓	×
Human	✓	✓
Infusion or Flow problem	✓	×
Installation	✓	×
Labelling, Instructions for Use or Training problem	✓	✓
Manufacturing, Packaging or Shipping problem	✓	✓
Material Integrity problem	✓	✓
Mechanical problem	✓	×
Optical problem	✓	×
Output problem	✓	×
Patient Device Interaction problem	✓	✓
Protective Measures problem	✓	×
Temperature problem	✓	✓
Use of Device problem	✓	✓

6. Analysis

Q:

How well can the current medical device adverse event reporting systems and processes accommodate an increase in demand associated with mandatory reporting and other regulatory changes?

A:

Current work processes to manage medical device adverse event reports are heavily influenced by the functionality of the existing IT systems impacting the user experience of both TGA staff and product sponsors.

Of up to 27 work processes, 7 occupy the greatest amount of staff time.

Around 1/3-1/2 of these may be amenable to greater integration and automation – saving time and resources when increased notifications occur.

All work activities can be summarised into 12 functional capabilities that staff require from existing and future IT systems.

Current information management processes

Discussions with key Devices Post-Market Monitoring (DPMM) Section staff and a review of available documentation indicated that around 27 separate work instructions capture key processes involved in processing medical device adverse event notifications to the TGA.

1. Receipt of individual notifications via **Electronic Business (eBS) portal** from sponsors.
2. Receipt of individual notifications via **web-forms** from sponsors.
3. Receipt of individual notifications via **web-forms** from professionals.
4. Receipt of individual notifications via **web-forms** from users.
5. Receipt of notifications via **email ± attachments** from sponsors.
6. Receipt of notifications via **email± attachments** from governments.
7. **Run quarterly reports** on notifications received & stages of progress.
8. **Re-entry of notification data** via email by members of the Devices Post Market Monitoring (DPMM) team.
9. **Process web-form data** received from users.
10. **Searching for relevant device ARTG numbers** if absent in reports.
11. **Review initial sponsor reports**.
12. **Review follow-up sponsor reports**.
13. **Prepare final sponsor reports** for triage.
14. **Prepare amended final sponsor reports** for triage.
15. **Prepare initial/final reports** (from users or professionals) for triage.
16. **Follow-up overdue reports** from sponsors.
17. Conduct **triage of all notifications** to determine level of risk, priority and type of ongoing action (monitoring, investigations).
18. Determine if additional **information is required** for sponsor reports.
19. **Request further information** from sponsors (“pushbacks”).
20. **Cleanse report information** for publication of incident on DAEN.
21. Present and **confirm borderline cases** for investigation.
22. Conduct **Level 1 Investigation** – if indicated (request for information).
23. Conduct **Level 2 Investigation** – if indicated (single case review).
24. Conduct **Level 3 Investigation** – if indicated (related case review).
25. Undertake **peer review** of selected cases.
26. **Audit** peer reviewed cases.
27. **Close (related) notifications** and submit case for ongoing monitoring.

Further discussions with key Devices Post-Market Monitoring Section staff also revealed that of the distinguishable work processes undertaken by staff:

- **Seven** are reported to be the **most time intensive** for staff (if they are required to be performed to process an individual adverse event notification).
- Observation of these processes with staff indicated that around **half of these activities were implemented to deal with short comings in the current information technology platform** (e.g., re-entry of data submitted by email attachment) and/or unavailability of more up-to-date technology that could streamline necessary activities (e.g., searching and comparing revised document submissions for new information, searching multiple platforms manually to identify missing ARTG numbers from device reports).

Seven most time intensive activities undertaken to process medical device adverse event notifications

- Processing Initial or Initial/Final Device Incident Reports (**DIRs) received via email** from Sponsor or Manufacturer (WI 1.19)
- **Searching** for the ARTG Number (WI 1.22)
- Processing an **Amended Final DIR** submitted from Sponsor or Manufacturer for Triage (WI 1.18)
- Undertaking a **risk assessment and triage** of medical device incident reports (WI 1.2)
- Medical Device Incident Investigation Process for **Level 1 Investigations** (WI 1.3)
- Medical Device Incident Investigation Process for **Level 2 Investigations** (WI 1.3)
- Medical Device Incident Investigation Process for **Level 3 Investigations** (WI 1.10)
- **Closing** Device Incident Reports (WI 1.13)

Analysis of the most time-consuming work instructions extracted around 110 activities or functions that need to be performed. A detailed list of these functions is presented below.

These functions were subjected to preliminary classification to indicate those that may be subject to re-distribution or automation, and those that required performance by an appropriately qualified and trained investigator.

Key functions involved in medical device incident notification.

1. **Receive** single report data - digitized.
2. **Receive** single report data – web-forms - digitized.
3. **Receive** single report data – email ± attachments.
4. **Receive** batch data – email ± .csv or .pdf attachments!
5. **Run quarterly reports on progress of incident processing.**
6. **Enter** web-form (user) and emailed data (.pdf or .csv or excel)
7. **Search** for relevant device ARTG numbers were absent in reports
8. **Read** and **enter** new information in additional sponsor reports.
9. **Communicate** with sponsors regarding overdue reports.

Classify notification information for triage, by determining if:

10. Severity of incident (using TGA scale 1-10).
11. The 'manufacturer has documented same/similar risks'.
12. There have been any 'recalls for similar incidents'.
13. There are any 'current recall actions'.
14. The 'number of incidents over the past 6-months'.
15. If '3+ incidents have occurred in the product same batch'.
16. If '3+ incidents have occurred in same geographic district'.
17. If '3+ incidents have occurred in the same device model'.
18. If any of a list of identified 'contributing factors' is present.
19. If any of a list of identified 'sensitivities' is present.
20. Determine the level of follow-up required for the notification.
21. Determine the level of priority required for the follow-up.
22. Refer the report to the relevant team for ongoing action.
23. **Determine** if additional information is required for sponsor reports.
24. **Request** further information from sponsors ("pushbacks").
25. Cleanse report information for publication of incident on DAEN.
26. Present and confirm borderline cases for investigation.

Conduct **Level 1 Investigation** – if indicated (request for information).

27. **Determine** key information from clinical event description.
28. **Determine** key information from report information.

29. **Determine** key information from sponsor investigations.
30. **Determine** key information from risk analysis.
31. **Determine** key information from investigation summary (latest).
32. **Determine** key information from records management data.
33. **Determine** or **enter** new reason for investigation.
34. **Determine** anticipated sources of evidence.
35. **Determine** expected data of evidence available.
36. **Enter** date evidence was received.

Conduct **Level 2 Investigation** – if indicated (single case review).

37. **Determine** key information from clinical event description.
38. **Determine** key information from report information.
39. **Determine** key information from sponsor investigations.
40. **Determine** key information from risk analysis.
41. **Determine** key information from investigation summary (latest).
42. **Determine** key information from records management data.
43. **Determine** or **enter** new focus of investigation.
44. **Determine** up to five key investigation questions.
45. **Determine** possible referrals as part of the investigation.
46. **Determine** and enter potential risks to investigation.
47. **Determine** questions to product sponsor to address questions.
48. **Enter** anticipated sources of evidence.
49. **Determine** expected data of evidence available.
50. **Enter** date evidence was received.
51. **Determine** if responses to questions are sufficient.
52. **Determine** if each of the key evaluation questions.
53. **Determine** facts, issues, and reasoning for each answer.
54. **Code** findings of investigation.
55. **Code** decisions arising from investigation.
56. **Code** actions arising from investigation.
57. **Determine** key evidence, findings, conclusions, outcomes.
58. **Close** notification (or refer for further investigation).
59. Undertake **regulatory actions** (as required).

Conduct **Level 3 Investigation** – if indicated (related case review)

60. **Determine** key information from clinical event description.
61. **Determine** or **enter** new scope of investigation.
62. **Determine** or **enter** new out-of-scope for investigation.

63. **Determine** or **enter** focus of investigation.
64. **Determine** or **enter** sensitivities of the investigation.
65. **Determine** or **enter** treatment of sensitivities.
66. **Determine** up to five key investigation questions.
67. **Determine** possible referrals as part of the investigation.
68. **Enter** advice received from each referral.
69. **Determine** anticipated sources of evidence.
70. **Enter** sources of evidence
71. **Identify** expected date of evidence.
72. **Enter** date evidence received.
73. **Determine** information from post market reviews.
74. **Determine** adequacy of information as evidence.
75. **Determine** information from recalls.
76. **Determine** adequacy of information as evidence.
77. **Determine information from annual reports.**
78. **Determine** adequacy of information as evidence.
79. **Determine** information from quarterly reports.
80. **Determine adequacy of information as evidence.**
81. **Determine** information from lab results.
82. **Determine** adequacy of information as evidence
83. **Determine** information from registry reports.
84. **Determine** adequacy of information as evidence
85. **Determine** information from overseas reports.
86. **Determine** adequacy of information as evidence
87. **Determine** information from media reports.
88. **Determine** adequacy of information as evidence
89. **Determine** information from other sources of evidence.
90. **Determine** adequacy of information as evidence
91. Refer for any laboratories testing.
92. **Determine** possible legislation/essential principal breaches.
93. **Determine** possible legislative mechanisms for enforcement.
94. **Code** findings of investigation
95. **Code** decisions arising from investigation.
96. **Code** actions arising from investigation.
97. **Determine** key evidence, findings, conclusions, outcomes.
98. **Close** notification (or refer for further investigation).

99. **Refer** for peer review if case is selected.

100. Undertake **regulatory actions** (as required).

101. Undertake **peer review** of selected cases.

102. **Audit** peer reviewed cases.

Close (related) notifications and submit case for ongoing monitoring.

103. **Code** investigation conclusions.

104. **Code** investigation outcomes.

105. **Cleanse** investigation outcome report for publication on DAEN.

106. **Cleanse** response to investigation to notification reporter.

107. **Send** response to investigation to notification reporter.

108. **File** relevant reports in TRIM.

109. **Close** notification report.

Analysis of separate work functions indicated that:

- Around one in three (27%; 29/109 - in blue text) might be amenable to re-distribution to other individuals (e.g., product sponsors) or otherwise automated.
- However, half (56%; 61/109 – in orange text) required the skills of a qualified and trained medical device investigator.
- Whilst some of the tasks undertaken by investigators might be subject to uptake by longer-term advances in information technology (e.g., automation of components of the review of evidence gathered to address specific evaluation/investigation questions), others would still need human involvement or at least human supervision to ensure that they were performed to the required Australian Government Investigation Standards (2022) – for example; formulation of or selection of pre-suggested investigation questions that were unique to the nature of alleged medical device malfunctions; determining the adequacy of information available for investigations.

Contrasting with medicines approach to notifications

The approach undertaken to process medical device adverse events can be contrasted with the approach adopted to process medicines. Safety signals relating to medicines are established via several channels, including:

- Disproportionality Analysis Reports or other investigations using data stored in the AEMS);
- Periodic Safety Update Reports or other analyses or notifications from product sponsors / manufacturers;
- Referrals from other areas of the TGA;
- Information from other overseas regulators; or
- Information identified from the peer reviewed medical literature.

Once a signal is identified it is listed in the OPR Issues Database and guidance is sought about the level of subsequent investigation.

If a full signal investigation is determined (e.g., the issues is not already known to the TGA / has been previously investigated), then a series of standardized steps are taken in accordance with specified work instructions.

Processes of investigation follow a comparable pathway to medical devices, including:

- Identification of the problem;
- Identification of the therapeutic good (products / ingredients);
- A description of the safety concern;
- Examination of any current risk management strategies;
- A review of the peer-reviewed literature (which does not form a systematic component of medical device reviews);
- Examination of a range of post-market adverse event reports received by the TGA or other regulators; and
- A discussion, conclusion, and summary of any recommendations.

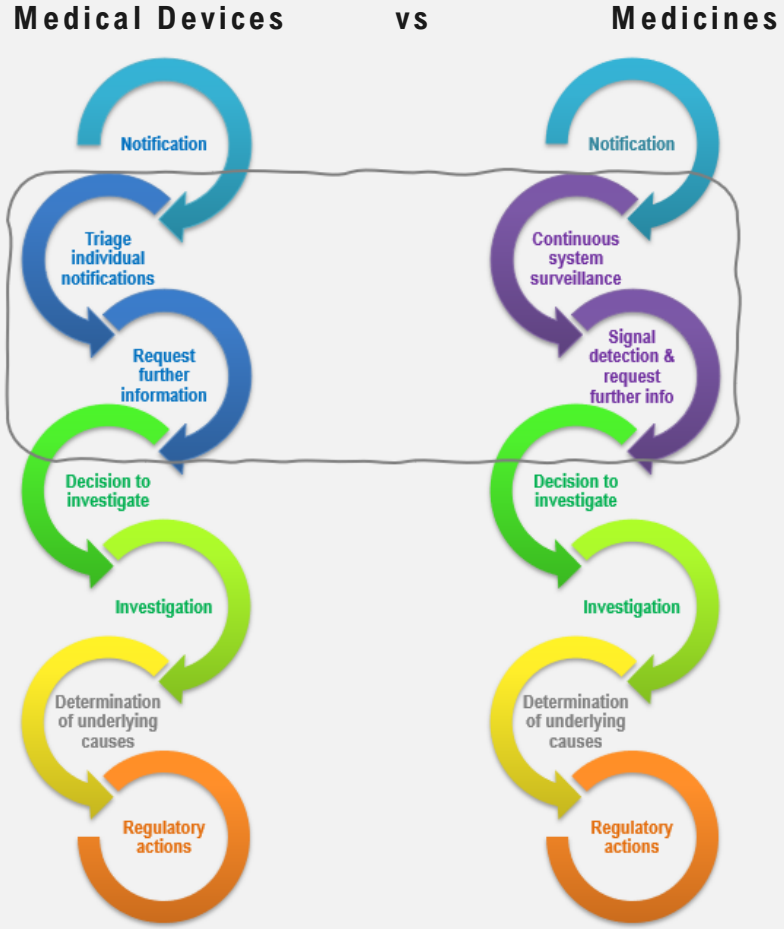
Medical device outcomes are also subject to international coding of key elements of the event notification, types and processes undertaken to investigate a notification, and the findings, outcomes, conclusions, and any regulatory actions (in accordance with the International Medical Device Regulators Forum classification schemes).

Thus, there are two primary differences in the pathways to investigation between medical devices and medicines relates to the process of signal detection.

Medical devices use a severity scale and other factors to triage each individual notification to the TGA. By contrast, medicines enter all notifications into a database for ongoing system surveillance and detection of cases that occur at a differential rate to what is otherwise expected. It might be considered that the evidence base allowing medicines to adopt this approach is stronger for medicines compared with medical devices. Notwithstanding, the automation of initial signal detection is something worth considering by medical device (albeit focused upon the triage process).

One additional difference between the two areas of the TGA relates to the investigation protocols – whilst standardized to each area, medical devices approach complies with the Australian Government Investigation Standards. This is not evident for medicines.

An overview of the approach to adverse event reporting and investigation by medical devices and medicines



Current information management systems

Analysis then focused upon current information management systems used to process medical device adverse event notifications. Twelve systems were identified. These were only partially integrated.

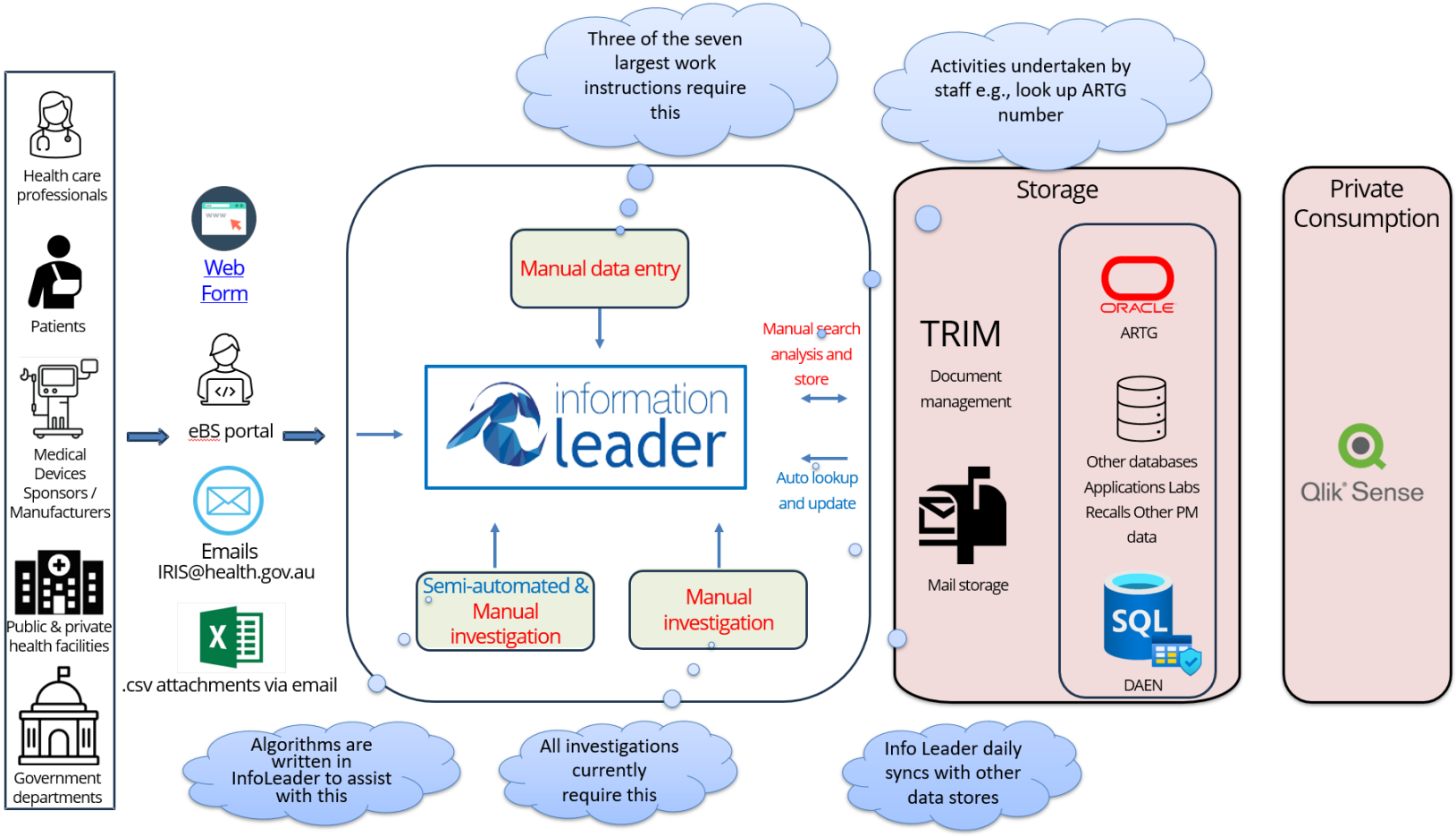
- Notifications are received, mostly by sponsors / manufacturers via the **eBS Portal**, also from users or professionals via **Website forms**, or via **email**
- Notifications from Web forms or the eBS portal are automatically sent to **InfoLeader** as the main database for storage and processing of medical device adverse event related information.
- Notifications are published, following authorization by the DPMM team, from InfoLeader onto the **Database for Adverse Event Notifications** (DAEN). Results of investigation findings are also published on the DAEN once the investigations are completed.
- Information from the **ARTG** is automatically uploaded into InfoLeader, the DAEN and the **QLIK Sense Application** which is used to analyse patterns in adverse event reporting data.
- The QLIK application is interrogated as a routine part of incident notification triage and investigation and receives selected updates from other TGA databases which may also be independently interrogated for further information as part of device notification processing.
- Additional databases include, but are not necessarily limited to, the **Applications database**, **Laboratories database**, **Recalls database** and **Post Market Review database.**
- Electronic copies of incident notifications sent via email, correspondence, or other key reports or information that relate to individual device incident notifications are stored by TGA staff in the **TRIM** database.

The partial integration of existing systems means that TGA staff must undertake a significant degree of manual processing of information, including (but not limited to):

- Conversion (re-entry) of emailed reports into electronic data.
- Interrogation of each of the major data systems.
- Storage and/or retrieval of documents via TRIM.

There may be capacity to improve data linkages between InfoLeader and other TGA systems to reduce the level of disparate interrogation required by staff. However, it is likely that internal IT support for this approach may be limited given new and emerging cybersecurity standards which result in difficulty maintaining the ongoing operational security of older platforms (this will need to be confirmed in future with the Department of Health and Aged Care (DoHAC) IT Department).

Map of the current state information technology system



Criteria for evaluating future IT systems

If alternatives to upgrading InfoLeader are to be pursued, a set of criteria is required that will help establish the utility and success of any future changes to medical device adverse event notification and processing systems and work activities.

The criteria for future operation will need to be consistent with the TGA HPRG Transformation Program Vision, Benefits and new capabilities that are being implemented for other business processes across the TGA.

Additionally, criteria will need to focus upon the regulatory requirements, improvement objectives and day-to-day operations of the MDSB (recognising that the latter may change with improvements to IT systems, and reports from industry and the public).

A set of potential criteria to evaluate the success of future IT systems and changes in work activities is presented in the adjacent box.

These criteria would need to be applied to assess the appropriateness of any recommended changes to improve the functional requirements of the current system – which are discussed in the following pages.

Potential criteria for evaluating the success of future IT systems changes and work activities

1. **Flexibility to adapt to current & future need** & technology.
2. **Transparency** for user learning & authorized modification.
3. **Connectivity to key internal and external platforms.**
4. Positive **stakeholder experiences** of engaging with the system.
5. Positive **staff experiences** of working with the system.
6. Maximal **use of available data** to inform decision making.
7. Internal **data quality and control** mechanisms.
8. Maximum **analytic capacity** for readily accessible insights.
9. **Reliable platforms** that operate with a range of systems.
10. Adoption of systems with foreseeable **windows of support.**
11. Ease and minimal **cost of ongoing maintenance / upgrades.**
12. Consistency with DoHAC and TGA implementation priorities.
    a. A new, **industry/sponsor portal** providing a single-entry point for authorized and authenticated users.
    b. **Cloud-based** capture, analysis and storage of information.
    c. Minimal need to re-enter **pre-existing information.**
    d. Adoption of **automated workflows** to promote efficiency.
    e. Data **Audit and Traceability** i.e., data lineage.
    f. **Master Data** Store, Business Glossary.
13. Capacity to adopt current/emerging **data standards and formats** (e.g., Fast Healthcare Interoperability Resources (FHIR).
14. Compliance with a range of **privacy legislation**.
15. Maximum **data security** and compliance with Standards.
16. Retirement of **legacy platforms and end of lifecycle** systems.

Functional requirements of future IT systems

A summary of the 12 current functional requirements of the information systems involved in processing medical device adverse event notifications are presented on page 34. Ten major functional areas have been identified to address the areas of data translation and transfer, storage and retrieval and efficiency and effectiveness of data analysis capability.

- The first functional area involves the need for **data submission** by those reporting medical device-related adverse events to the TGA. Currently this typically involves device users, health care professionals and product sponsors / manufacturers (who provide most reports).
- The TGA has committed to regulatory improvements involving streamlining of reporting arrangements and introducing electronic (batch) reporting for product sponsors. Systems for large scale electronic reporting of device data, such as those used by the US Food and Drug Administration are worthy of investigation by the TGA, given their familiarity to current product sponsors and likely utility for a medical device regulator.
- In addition, mandatory reporting requirements will mean the 'on-boarding' of all public and private health facilities across Australia and/or an increase in reporting by States/Territories (responsible for public health facilities) and private corporations (who operate private health facilities).
- The second functional area involves the need for **data re-entry** by DPMM staff. The most common circumstance where this occurs is when the current IT system is 'down' and sponsors are unable to submit individual notifications through the eBS portal. Staff estimate that the current system is down approximately 2 hours each week. Staff also indicate that system downtime is commonly encountered by sponsors who are attempting to report through the eBS portal at the end of a day.
- Data entry is also required when sponsors provide additional information for a report given the current system does not allow for reporter amendment/update of initial report information.
- To a lesser extent, some manual data entry is required for reports submitted via email by users of a device or from health care professionals.
- The third functional requirement of the current system is **data storage**. This currently occurs across a variety of platforms (as previously outlined on page x). Data that enters the system through the eBS portal or via current web forms is transferred through to and stored in InfoLeader. InfoLeader is the main database used to enter and store adverse event information for medical devices, from notifications, staff inputs and other databases across the TGA. InfoLeader is a relatively old database by current standards that is managed by a third-party proprietor (Theta Technologies).
- Incident notifications (and ultimately the findings of any investigation) are separately stored on the DAEN. All documents and correspondence are stored in TRIM. In addition, and as previously identified, there is partial integration with other databases including the ARTG, Laboratories, Applications, Recalls and other Post Market Reviews, Analysis of trends or patterns in notifications is undertaken through the QLIK sense application tool.
- Plans are underway to integrate a range of other data sources into a Master Data Store. It is unclear whether this will incorporate InfoLeader
- The fourth functional requirement of current information technology systems includes the capacity to **request additional data** from product sponsors / manufacturers. Most commonly this includes manufacturer documentation about a reported device such as the Instructions for Use.

- Other information may also be requested from product sponsors or manufacturers including rates of adverse events that are known to have occurred in Australia and other overseas jurisdictions, or any other information deemed appropriate to conduct a sufficient and thorough investigation of a medical device incident by the TGA.
- The need for further information may be apparent from blank fields in final reports submitted through web-forms, or on the eBS portal, or through examination of reports prior to or following incident triage (where pushbacks for further information may occur). Alternatively, ongoing missing information may need to be followed up as a Level 1 investigation or as part of other investigation processes.
- The fifth functional requirement for incident processing includes the capacity to **search for data** by the DPMM team, either an ARTG number for a device reported by a user or health care professional, or for other information required to triage notifications or investigate notifications. These searches are required across a variety of internal platforms (e.g., Applications, Recalls, Laboratories, other internal databases or analytic platforms such as QLIK), and also across other external data bases or sources (e.g., the internet, media reports, clinical registry information, overseas regulator databases, etc.).
- In future, analytic platforms will need to continue searching across all incident notifications to identify any patterns of reporting that may indicate a cluster or group of related incidents in need of investigation – particularly incidents associated with lower severity outcomes that may not otherwise be priorities for investigation (given the overall increase in notifications to the regulator).
- The sixth functional area for adverse event systems is the capacity to **compare data** in existing reports with data or other information that is submitted in follow-up reports by product sponsors. Currently this is a manual process whereby staff read new and pre-existing information and copy and paste new information under older data in relevant InfoLeader fields.
- It is understood that medicines have identified an electronic capacity to scan product information to determine whether adverse events have been previously reported by medicines manufacturers. This will be further investigated for application to device manufacturers "instructions for use" and previous reports of "similar incidents" that are "known to occur", in addition to the capacity to adapt this technology to compare older and newer sponsor reports with a view to identifying and extracting updated information automatically.
- **Classification and coding** of submitted information is the seventh functional capability required to process device incident notifications. Initial adverse event information is subject to coding as part of the incident triage process.
- Key information classified as part of the triage process has been previously described as functions 11-20. These might be undertaken by product sponsors / manufacturers in future and audited by the DPMM team to assess their accuracy. Rather than the team having to classify all reports, algorithms could be applied to sponsor coded data to automate the triage process.
- In addition, the DPMM team has been involved in implementation of the recently developed International Medical Device Regulators Forum (IMDRF) international coding system for medical device-related incidents. This involves assigning up to three codes across (potentially) seven areas relating to the device incident, including:
  - Device problems
  - Types of investigation

- Investigation findings
- Investigation conclusions
- Clinical signs, symptoms, or conditions
- Health Impacts
- Medical device components

- Interestingly, medicines sponsors or manufacturers who submit adverse event reports to the TGA undertake adverse event coding (via the MedDRA international coding scheme). Options to shift responsibility for medical device coding to product sponsors / manufacturers might also be considered (to align with international approaches).

- The eighth functional capability involves the capacity to derive **analytic insights** from new and existing data held across the TGA. The QLIK sense application is currently used to achieve these analyses which focus upon analysis of the number of past notifications to the TGA, identifying patterns and trends in data, and examining outcomes of past investigations.

- The ninth functional area for adverse event systems is the capacity **make determinations from the data** available, about:

  - The decision to investigate a particular case.
  - The outcomes of a Level 2 investigation.
  - The outcomes of a Level 3 investigation.

- In these circumstances, DPMM staff must decide if there is sufficient evidence to address specific questions framed for investigation (according to the Australian Government Investigation Standards (AGIS), 2022), determine the extent of any legislative breach, and determine the legislation or regulations that will be required for any further actions by the regulator.

- Determinations from the data require appropriately qualified staff who are trained in government investigation standards to make the appropriate decisions. In the short term it is not anticipated that updates to information technology will assist with these specific activities.

- The tenth functional ability required of information systems supporting medical device adverse event processing is the **cleansing of data**. Cleansing refers to the "tidying up" of written information including formatting and redaction of potentially identifying or proprietary information from data about adverse event notifications and any investigation findings published in the DAEN. Cleansing is also required of automatic correspondence generated to "close the loop" with incident reporters.

- The eleventh major functional capability required from information processing systems includes the **capacity to audit** the processing of device incident notifications, including the levels of triage assigned to each case, and the outcomes of Level 1 to Level 3 investigations. These are currently performed manually for a selection of reports.

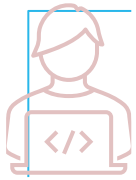
- It is noted that there is minimal current auditing of the level of compliance (versus overrides) of algorithms used to assist triage. Analysis of data produced for this project indicates a significant level of algorithm over-rides and this implies that either, the algorithms are no longer fit-for purpose, and/or that cases may be unnecessarily upgraded for investigation (or priority for investigation) – creating additional work for the DPMM team, and/or that cases may be inappropriately down-graded to avoid certain levels of investigation (or the priority for investigation). This needs further auditing and action by the DPMM team as a matter of priority.

- Additionally, if algorithms are introduced to detect patterns in adverse event reporting across the broader health system, then these algorithms will also require auditing on a programmed basis to ensure that they are detecting cases appropriately.
- The twelfth functional area for adverse event systems is the capacity **to close the loop** with key stakeholders, including:
  - Providing correspondence back to incident reporters.
  - Publishing the findings of investigations on the DAEN.
  - Providing updates or other correspondence to key stakeholders who may be interested in the identification of specific medical device related incidents and/or the findings of investigations.

Summary of functional requirements for medical device incident processing

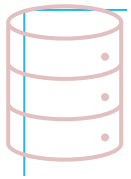
1. Data submission

- By sponsors / manufacturers
- By public and private health facilities
- By governments / corporates



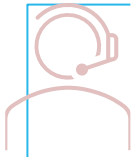
2. Data re-entry

- Email submission by sponsors
- User reports
- Health Care Professional reports



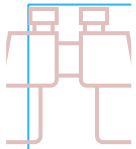
3. Document and data storage

- Data in InfoLeader
- Documents in TRIM
- Information published on the DAEN



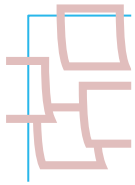
4. Request for data

- Initial request for information
- Push-backs
- Level 1 investigations



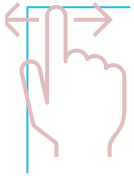
5. Searching for data

- ARTG number search
- Pattern recognition - future notifications
- For triage and investigations



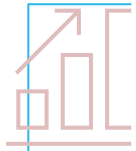
6. Comparisons of data

- Follow-up reports
- Final reports
- Amended final reports



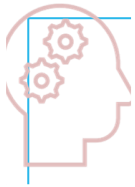
7. Classification & data coding

- IMDRF coding
- Severity, documentation, recalls, similar incidents (batch, location, model), sensitivities, considerations



8. Analytic insights

- Number of notifications to the TGA
- Patterns and trends in data
- Outcomes of past investigations

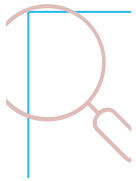


9. Determinations from data

- Decisions to investigate
- Level 2 investigations
- Level 3 investigations

10. Cleansing of data

- Notifications published on DAEN
- Findings published on DAEN
- Letters back to incident reporters



11. Auditing of data

- Regular reports of work progress
- Peer reviews, algorithm checks
- Searching & exporting of data

12. Closing the loop with reporters

- Letters back to event reporters
- Publishing updates on the DAEN
- Communication with key stakeholders

7. Mapping

Q:

What gaps need to be addressed and what market capabilities exist to meet mandatory reporting requirements?

A:

Current systems do not accommodate systematic, or high-volume adverse event reporting by public or private health facilities, or sponsors/manufacturers.

Resources will be required to 'staff up' additional reporting demands if IT systems do not change.

Alternatively, IT systems will need to free up existing staff resources through processing efficiencies.

Realistically, process efficiencies need to be considered in tandem with available IT solutions.

Capacity, capability and risks in ability to manage an increasing number of reports

Returning to the major work processes undertaken by the DPMM team, observation and discussion with key staff was able to provide an estimate of the minimum and maximum time taken to perform each activity. An estimate of the proportion of cases falling into the minimum or maximum time allocations was also provided by staff. Taken together, these tasks were considered to occupy approximately 90% of the total time taken by team members to process device incident notifications.

- Taken together, these estimates indicate that a single medical device adverse event notification can take as little as 85 minutes to as long as 31 days depending upon the manner of reporting (web portal vs email), the detail in the reporting (e.g., inclusion of an ARTG number), complexity of follow-up, and level of investigation.
- Simulation modelling was undertaken to identify the impact of these times upon the number of Full Time Equivalent (FTE) required to process the current volume of incident notifications.
- Results are presented in the following pages.

Seven most time intensive activities undertaken to process medical device adverse event notifications

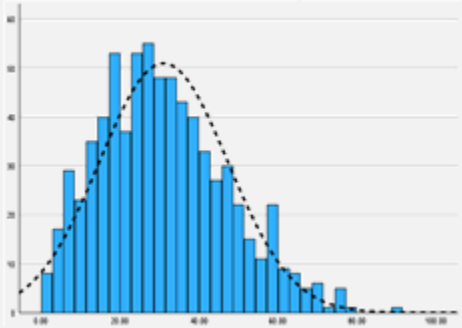
- Processing Initial or Initial/Final DIRs received via email from Sponsor or Manufacturer (WI 1.19)
  Between 15 and 45 minutes per notification
- Searching for the ARTG Number (WI 1.22)
  Between 10 and 60 minutes per notification
- Processing an Amended Final DIR submitted from Sponsor or Manufacturer for Triage (WI 1.18)
  Between 20 and 60 minutes per notification
- Undertaking a risk assessment and triage of medical device incident reports (WI 1.2)
  Between 20 and 120 minutes per notification
- Medical Device Incident Investigation Process for Level 1 Investigations (WI 1.3)
  Between 60 and 180 minutes per notification
- Medical Device Incident Investigation Process for Level 2 Investigations (WI 1.3)
  Between 0.5 and 10 days per notification
- Medical Device Incident Investigation Process for Level 3 Investigations (WI 1.10)
  Between 1.5 and 30 days per notification
- Closing Device Incident Reports (WI 1.13)
  Between 20 and 60 minutes per notification

- Simulation modelling across the seven most time intensive work processes estimates that at least 2087.8 days of activity are undertaken each year to process medical device adverse events.
- This equates to approximately 12.78 FTE positions (95% PI 11.46 FTE to 14.10 FTE) required to process medical device related adverse events. Interestingly, the estimated FTE represented 85.2% of the 15 current FTE available to undertake work on adverse event incident processing (with the remaining FTE consistent with other work activities performed by team members).
- Line-item analysis was then undertaken of each of the seven main work instructions. Analysis revealed that 3 of the most 'time intensive' work processes were almost completely amenable to potential automation. An additional three work processes appear to remain manually intensive until such time as new technologies replace current systems. One remaining work process was potentially automatable by around half of all work activities.

An example of simulation modelling

Searching for the Australian Register of Therapeutic Goods (ARTG) Number (WI 1.22)

- Each case is estimated to take between 10 minutes (12.5% of cases) and 60 minutes (5% of cases) – these are the tails of a distribution of possible time taken to complete this task.
- The number of notifications requiring this work process is estimated (725 per annum).
- A distribution can be simulated to replicate the estimated number of notifications with the specified proportion of cases falling within the approximated cutoff points (of 10 and 60 minutes) – as outlined below. Alternatively, the precise number of cases occurring between the two tails can be subject to exact calculation (see Appendix 1).
- The total time under the simulated distribution (or calculated through exact methods) is summed to estimate the total time spent in this work process per annum.



- The sum of time is converted to total FTE for the DPMM team by dividing the total work process hours by the total 'available hours' for each position each year across the team of 15 FTE (2087.8 days per annum, divided by an average 139.19 days per staff member).
- Using the above method, this work process occupies approximately xx FTE (averaged across all DPMM team members) each year.

The total available hours for a team leader is estimated to be 108.04 days per year (from 365 days - 104 weekend days -10 public holidays -20 days annual leave -12 days sick/carers/other leave taken - 110.96 days in non-direct processing tasks (93.44 days meetings, 5.84 days training, 11.68 days IT outages = 110.96 days) = 108.04 available days x 5 staff = 540.20 days.

The total available hours for a non-team-leader is estimated to be 154.76 days per year (from 365 days - 104 weekend days -10 public holidays -20 days annual leave -12 days sick/carers/ other leave taken – 64.24 days in non-direct processing tasks (46.72 days meetings, 5.84 days training, 11.68 days IT outages = 64.24 days) = 154.76 available days x10 staff = 1547.6 days.

- Importantly, the most readily automatable work processes had been developed and implemented to compensate for a lack of automation in current information systems (see side Box for examples).
- Thus, there is a marginal potential savings of up to 0.59 FTE (95% PI 0.39 FTE – 0.79 FTE) in automation of current systems and processes (from automation of the first three of the seven most time intensive work activities).
- However, further savings in staff time are anticipated. All current work instructions / processes are at least a partial byproduct of the design and operation of the main database used to receive and process medical device incident notifications – InfoLeader.
- As the functionality of this or other future databases improve, and systems are integrated, existing work processes can be further streamlined.

Work processes created to compensate for shortcomings in current information systems

- Example 1 – Loss of functionality in the current eBS portal: Manual entry of device incident reports (WI 1.19) was required when the current eBS portal was unable to receive electronic reports from sponsors / manufacturers. In these circumstances, reports were sent via email (typically as attachments) which requires direct entry of data by TGA staff.
- Example 2 – Lack of integrated search capacity: Searching for an ARTG Number (WI 1.22) necessitates a manual lookup process by staff across at least 7 different areas and around four separate platforms that have no common integrated search capacity.
- Example 3 – Lack of authorised user access to update data: Updating an amended final report from a sponsor / manufacturer (WI 1.18) requires manual review, comparison of new information entered after a previous report (in each section of the report), and manual re-entry of data by the DPMM team. This would be almost eliminated if sponsors had authorized access to their own reports and could update them on-line (where meta data would distinguish the time and range of updated information).

When each of the other most significant work activities are separately considered:

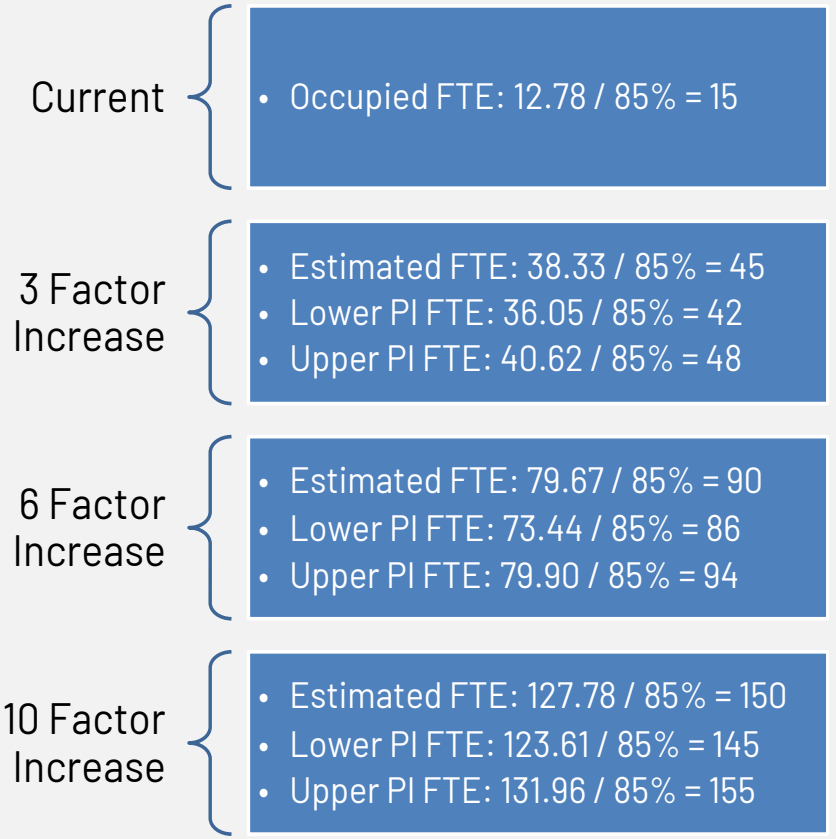
- Triage activities are estimated to account for approximately 5.62 FTE per annum (95% PI 4.60 - 6.64 FTE).
- Level 1 investigation activities are estimated to account for approximately 0.12 FTE per annum (95% PI 0.03 - 0.21 FTE).
- Level 2 investigation activities are estimated to account for approximately 5.17 FTE per annum (95% PI 4.53 – 5.81 FTE).
- Level 3 investigation activities are estimated to account for approximately 0.60 FTE per annum (95% PI 0.16 – 1.03 FTE).

When estimated increases in adverse reporting of medical devices to the TGA are considered, the corresponding FTE required to conduct all 7 of the most time-consuming adverse event notification processes increases substantially from **15 current FTE** to **45 FTE per annum** for a **3 factor increase**, **90 FTE** for a **6 factor increase**, and **150 FTE** for a **10 factor increase** in reporting.

FTE estimations were converted into indicative costs by assuming:

- The average team member is employed at a band of APS6 (24 months after commencement of the 2019-22 EA) at $ 97,912 per annum.
- The average team leader is employed at a band of EL1 (24 months after commencement of the 2019-24 EA) at $121,640 per annum.
- The average FTE cost represents a proportion of one team leader to every two staff ($ 121,640 + 2 x $ 97,912 = $317,464 / 3 =) $105,821 per average FTE member per annum.

Estimated FTE to manage possible increases in medical device related adverse event reporting



These estimates indicate that the costs of staffing requirements alone could range from the current $1.5m to as little as $4.4m per annum (under a 3 factor increase in adverse event reporting), to as high as $15.8m per annum (under a 10 factor increase in reporting).

These estimates also provide some baseline against which the cost of potential efficiencies in processes and/or costs of future IT improvements / upgrades / solutions may be evaluated.

- A range of other options might also be considered to reduce the manual workload placed upon the DMPP teams.
- These options would require the writing of additional code in current systems (if this is permissible), or future systems to allow for a more risk-based approach to identification and processing of medical device incident notifications.
- Alternative risk-based approaches would also require more timely upgrades of the eBS sponsor / manufacturer reporting portal with the view to setting mandatory reporting fields and/or cross validation algorithms that require certain minimum information to be submitted at specified timelines for reporting.
- Discussion with current team leaders in DPMM and other staff across the MDSB indicate a range of functional improvements that might be considered to reduce the load for manual processing and reduce the need to manually process 'one report at a time'. These are outlined on the following pages.

Estimated cost to manage possible increases in medical device related adverse event reporting

Current	• Current est. salaries: $1,587,180
3 Factor Increase	• Estimated: $4,761,540 • Lower PI: $4,444,104 • Upper PI: $5,078,976
6 Factor Increase	• Estimated: $9,523,080 • Lower PI: $9,099,832 • Upper PI: $9,946,328
10 Factor Increase	• Estimated: $15,871,800 • Lower PI: $15,342,740 • Upper PI: $16,400,860

Functional improvements to enhance processing of medical device incident notifications

- Introduce **APIs** to extract information from public and private hospital incident information management (and possibly other selected software) for data submission to the TGA. This issue is currently under consideration between the TGA, State/Territory jurisdictions and corporate health providers across Australia.
- Introduce **batch processing** for sponsor / manufacturer reports and from larger public and private health care facilities across Australia.
- Authorized and authenticated **user access to previous reports for updating** in a common health portal (to the TGA or across the TGA and the Department of Health and Aged Care).
- Implementation of sponsor / **manufacturer reporting of IMDRF coding** (akin to MedDRA coding of medicines adverse event reports by sponsors / manufacturers).
- Move to **cloud-based data storage** and implementation of a common **Master Data Store** that included information from the ARTG, sponsor / manufacturer contact details, and other data (e.g., UDI) required for and/or input as part of medical device adverse event reporting.
- Introduce **document scanning and digitization software** for manual reports submitted via email when the eBS portal functionality is compromised – to allow automatic processing of information re-submitted in manual forms into InfoLeader.
- Use a **sponsor/ manufacturer 'reported' severity code** (identical to the one used by the DPMM team) submitted as part of a medical device notification to prioritise cases for triage and investigation. This may need to start with a severity code of 5 (Illness/injury resolved after health professional treatment) to be consistent with the legislation for mandatory reporting for health care facilities. Over time the threshold may be increased to 6 (ongoing minor impairment) or 7 (ongoing serious impairment) depending upon changes in the acceptance of 'risk' (of under identifying true positive cases) by the TGA weighted against the number of cases that are forwarded for manual triage and/or investigation.

Functional improvements to enhance processing of medical device incident notifications

- Introduce **additional questions, currently answered by the DPMM team at the point of triage**, to the sponsor / manufacturer reporting forms so that information critical for triage can be incorporated into machine processing of data. **Current algorithms** written into the triaging software could reference these responses and provide an automated recommendation for 'routine monitoring', or Level 1-3 'investigation'.
- Information required to triage a notification that could be reported by sponsors / manufacturers **include additional checkboxes** for 'manufacturer documented issues or complications', 'recalls for similar incidents', 'current recall actions', 'number of incidents over the past 6-months', '3+ incidents in same batch', '3+ incidents in same district', '3+ incidents in same model'.
- Consider software for automatic **scanning of instructions for use** of individual medical devices to determine if adverse event notifications are "previously documented" – equivalent to the current approach adopted for medicines.
- Sponsors / manufacturers will also need to be provided with checklists to select potential **'contributing factors' and 'sensitivities'** (adopting the same list as is used by the DPMM team) to automate triaging of all incident notifications.
- Introduce systematic scanning algorithms in QLIK to review all notifications and **detect clusters of more than 3 events** occurring (at all, in the same batch, in the same district, in the same model). Then refer any 'potential batch' trigger for Level 3 investigation.
- Introduce **forcing functions in sponsor reporting** to require minimum information that is the most common trigger for a Level 1 (follow-up) investigation, including but not limited to:
  - Attaching instructions for Use
  - Listing relevant recall numbers in the notification
- Human supervised **automatic scanning of missing information and automation of correspondence** to sponsors / manufacturers to request additional information.

Functional improvements to enhance processing of medical device incident notifications

- Implement **software to compare updated versions of documents** and identify and transpose new information into InfoLeader (obviating manual handling).
- Update QLIK sense application to commence exploration and utilisation of the Artificial Intelligence and Machine Learning capabilities of this software.
- Explore the future utilisation of automation in software to summarise evidence collected for investigations, and machine learning capabilities to enable automation of lower severity or more common types of investigations. Automation and machine learning capabilities may also be used to improve efficiencies in assessing common incidents as part of a Level 3 investigation.
- **Automation through software may also be implemented to "cleanse" documentation** prior to approval for publication on the DAEN or sent as correspondence to reporters.
- Upgrade the DAEN to allow for more sophisticated incident searching capability and the capacity to download multiple cases as electronic documents (e.g., .csv files) expanding the current capacity of the DAEN to download single .pdf notifications or investigation findings.

- When approaches to potential automation of work processes are considered, it is important for staff to remain aware of the processes that have been automated and the criteria that are used in any algorithm. If decision making criteria are 'hidden' from staff, they become de-skilled in understanding the conditions for escalation of a device incident notification.
- In this context, it is observed that previous criteria used by algorithms for classifying the 'level of priority' and the 'level of investigation' have been removed from more recent work instructions, creating 'black box' processes that are hidden from awareness. This should be immediately reversed.
- Hiding criteria creates a foreseeable risk to notification processing that can be averted. Algorithms may become out of date or no longer fit for purpose and staff will be unaware that this has occurred.
- Staff remain responsible for the decisions that they take and should be fully informed about the criteria used to automate decisions (including any used in the future). These same criteria should be used as a rationale for any overriding automated decisions made using pre-existing algorithms.

Implementation of an audit program to check use of algorithms (and whether they remain fit for purposes), monitor sponsor coding of data, and the quality of triage and investigation processes

- It will be important for the TGA to supplement and of the previously suggested risk-stratified approaches with **an 'audit' program** that assesses the accuracy of data reported by sponsors / manufacturers (compared with the determinations of DPMM team), and the accuracy of automated processes implemented by the TGA.
- Auditing should focus upon an ongoing random sample of reports that are classified immediately **at and immediately below the selection threshold**. For example, if 5 (Illness/injury resolved after health professional treatment) is the threshold, auditing would focus upon a random number of notifications classified at this level (to confirm rated levels of severity) and a random sample coded at 4 (Illness/injury resolved without treatment by a professional) to monitor for any potential or systematic 'down coding' of reports to evade further scrutiny.
- Auditing should also review notifications where **algorithm-based decisions are changed** by the DPMM team – to see if the algorithms remain fit for purpose (as previously described).

- The estimated impact of introducing partial automation to the triage process as outlined in the adjacent box, is estimated to be around 2,648 cases, saving at least 258.9 days (30%) or 1.87 FTE to the DPMM team.
- Under this scenario, the severity scale currently used to triage cases by the DPMM team would be provided to sponsors / manufacturers for self-classification of their adverse event reports.
- Any reports submitted that achieved the minimum standard specified in legislation for mandatory reporting by health facilities of 5/10 would be referred for manual triage by the team (i.e., cases where treatment has had to be provided to ameliorate or resolve harm that was suspected to involve a medical device).
- If confidence in reported data could be confirmed via regular audit of sponsor classifications and the fitness of algorithms used to assess information provided by sponsors – a greater level of automation of triage processes might be considered.
- However, the accompanying audit program would need to be rigorous and ongoing to assure data confidence.
- A summary of the suggested improvements that could be considered for current medical device adverse event reporting and analysis systems is presented on the following page.
- Suggested improvements are classified according to the functional capabilities they are best targeted to improving and should be assessed against the previously identified criteria for evaluating the success of future IT systems changes and work activities.

Implementation of an audit program to check use of algorithms (and whether they remain fit for purposes), monitor sponsor coding of data, and the quality of triage and investigation processes

Assuming:

- Additional responses via checkbox are required from sponsor reports.
- The current severity scale used by the DPMM team are provided to sponsors for self-rating.
- Sponsors / manufacturers assess severity in a similar manner to members of the DPMM team (to be confirmed via an audit program).
- Severity threshold is set to 5/10 consistent with mandatory reporting conditions for health facilities (e.g., “treatment was required for an event with suspected involvement of a device”).
- An audit program is implemented to check the results of automation.
- Current algorithms used for triage can be applied (or modified slightly) to accommodate sponsor reported fields (rather than DPMM manual classifications of the same fields).

The total number of 8000 case notifications triaged over the past 12 months would be reduced by approximately 30% based upon the following distribution of severity outcomes over the same period:

- Severity 1–3 (no harm ratings)
- Severity 4 (injury/illness resolved without professional care)
- Severity 5 (injury/illness resolved with professional care)
- Severity 6-10 (ongoing, life-threatening, or public health threat)

This would result in 5,544 cases referred for manual triage. Simulation of this number of cases results in a total of 2.29 FTE notionally ‘saved’ or otherwise ‘available’ to offset any increases in adverse event reporting, particularly associated with mandatory reporting by health services (noting that additional time taken to audit a random selection of cases would need to be added back into the DPMM FTE).

Note: IT system changes will still be required.

Summary of potential functional improvements to enhance capacity

1. Data submission
- API
- Batch processing
- eBS / HPSP

2. Data re-entry
- Scanning & digitization of attachments
- Scanning & digitization of emails
- Improved data validation at portal

3. Document and data storage
- Data in InfoLeader, TRIM, DAEN
- Cloud based storage
- Integration with Master Data Store

4. Request for data
- Improved data validation at portal
- Automated id of missing information
- Supervised automation of letters

5. Searching for data
- Integration of data systems
- Supervised automation
- Authorised automation software

6. Comparisons of data
- Search & compare software
- Auto select & paste software
- Search algorithms into QLIK

7. Classification & data coding
- Classification by sponsors
- Coding by sponsors or search software
- Implement auditing program to check

8. Analytic insights
- Update QLIK to identify patterns
- Use QLIK to sample for audit
- Implement QLIK automation functions

9. Determinations from data
- Risk-based selection of cases (severity >=5, cases >= 3 in 6 months)
- Automation to summarise evidence
- ML based on past case determinations

10. Cleansing of data
- Supervised automation to “clean” correspondence and reports submitted for publication on the DAEN

11. Auditing of data
- Stratified sampling according to risk
- Automation to re-extract evidence
- Search/compare software to review

12. Closing the loop with reporters
- Auto generate correspondence
- Electronic download of data from DAEN
- Summary reports for stakeholders

Short term implementation < 16 months | *Medium term implementation 18 - 24 months* | *Longer term implementation + 24 months*

8. Assessment

Q:

How do any proposed changes align with planned business developments across the TGA?

A:

Proposed changes for medical devices are also necessary and planned for other TGA initiatives, including:

- **Management of an increasing number of stakeholders.**
- **Management of an increasing number of reports.**
- **Improvements to channels of reporting to the TGA.**
- **Implementation of APIs and batch processing.**
- **Increased automation and analytic capability to prioritise cases for follow-up or deeper investigation.**
- **Improved data storage and integration.**

Potential business developments that might arise from improved information processing systems

From a business operational perspective, pending the availability of suitable information technology platforms and capabilities, the following business 'improvements' / changes in medical device adverse event notification processing might be implemented.

1. **Improved reporter control over individual notifications** submitted to the TGA via a Business to Business (B2B) portal that can track the version of reports and distinguish new vs preexisting information submitted in individual versions of reports about the same incident. In other words, the reporter can see and edit previously submitted information which are visible as 'tracked amendments' that can be viewed by both reporter and DPMM staff. Technological capability can be introduced whereby DPMM staff may then 'accept' edits that are highlighted through this technology (rather than the current requirement to identify, copy and paste new information manually).
2. Improved understanding, **stakeholder data mapping and automated data submission** directly from pre-existing stakeholder information systems (e.g., via APIs) into TGA incident information processing systems.
3. Streamline and improve capacity to **receive multiple reports** from any stakeholder group (e.g., batch reporting) into TGA incident information processing systems.
4. **Updating of reporting fields** for sponsors / manufacturers that require **classification of information** according to **key variables** to enable automated triage of reports by the DPMM team.
5. Exploration of a longer term move to having sponsors / manufacturers code the type of incidents and the nature of previous or current investigations using **IMDRF coding** using supplied reference data from the TGA.
6. Automated data **security checks (e.g., anti-virus or malware) and validation at the point of data entry** sponsor / manufacturer reports through improved portal technology (using a variety of handheld or desk top devices), including identification and requests for 'missing' information.
7. **Expanding the type of data** that can be uploaded via improved portal technology for analysis from text to picture and video, or other types of data as part of one submission.
8. **Decreased necessity to manually re-enter** incident notifications received via email (when existing IT systems are unable to process reports) via the use of technology.
9. Increased **automation of correspondence** to reporters, sponsors / manufacturers, and other stakeholders arising from InfoLeader or other incident notification software.
10. Investigation of the utility and necessity (given changes in sponsor reporting forms) of **document search software** to facilitate incident triage and investigation processes, as has been reportedly used by medicines (e.g., to determine if a specific adverse event is documented in product instructions for use).
11. Investigation of the utility of **search software to facilitate IMDRF coding** by DPMM staff from incident descriptions.
12. The updating / writing of **algorithms to automatically triage** incident information reported by sponsors / manufacturers and determine:
    a. The potential level of **severity** of an incident
    b. The level of **follow-up required** by the DPMM team (e.g., further triage, investigation, monitoring)

c. The level of **priority** for follow-up

13. The **implementation of signal detection algorithms to inform triage** through writing, implementation and supervision of algorithms to scan the nature of incident notifications and compare these to previous incidents to determine changes in the frequency of reporting via QLIK (e.g., via implementation of QLIK SAAS).
14. Move **from manual triaging all events to governing algorithms** that select cases for manual triage. As an example only, the TGA may determine that it will manually triage and follow-up notifications where:
    a. A sponsor / manufacturer **severity score of 5** or higher has been reported; and/or
    b. More than **three similar event types** have occurred over the past 6-month period.
15. The **introduction of a systematic program of auditing information** that has been classified by sponsors / manufacturers to suppress the chances of further independent scrutiny by the DPMM team.
16. The implementation of **improved incident search and electronic download capabilities** for interested stakeholders via DAEN.

Longer term changes in business operations that might be considered when information technology systems are more advanced, include the possibility of:

17. Automated standardisation of information in incident descriptions and investigation reports (negating or minimizing the need for manual 'cleansing' of reports by TGA staff).
18. **Automated detection and reporting of missing information** (e.g., ARTG numbers from user or health care professional reports).
19. The implementation of **machine learning to assist in investigations** by comparing key characteristics of current investigations with similar, previous investigations.
20. The implementation of **greater sponsor access to and analysis of authorised incident information** (e.g., via access to analytic functions for authorised and authenticated users).

Potential changes to the architecture of information systems

The following discussion outlines **potential changes to the overall architecture of information systems** to enable the business processes described on previous pages to occur. This approach identifies where changes are made in the flow of data processing (which can be different from the functional operations required by the DPMM team).

Broadly speaking, five "stages" of information management can be distinguished including:

- The **stakeholders who report data** into the TGA.
- The **submission channels** used to report data into the TGA.
- Information **collection and management** relating to medical device adverse events.
- Data **storage** across the TGA.
- Data **consumption** (by members of the DPMM team, and in future by other authorised and authenticated stakeholders).

Data and platform security will also need to be identified across these five main stages. Other regulatory and data compliance requirements for information

management will also need to be addressed. Platform operations (e.g., maintenance, support, upgrades/ enhancements, etc.) will also need to be provisioned.

Several changes to current information systems and business processes are anticipated to occur and/or may be considered at each of these five stages. Changes at each stage are described below.

Changes in stakeholders who report data about medical devices

Currently, there are three main groups of stakeholders who report information to the TGA, including sponsors/manufacturers (who report most adverse events), health care professionals (who report the next highest proportion of adverse events), and consumers/patients (who currently report the smallest proportion of adverse events).

From time-to-time, individual health services and government departments may also report adverse event notifications about medical devices to the TGA. However, under new legislation, public and private health facilities across Australia (including day hospitals and procedure centers) will be required to undertake regular reporting to the TGA. Thus, the number of stakeholders reporting data about medical device adverse events, and the number of events reported by these stakeholders will increase.

In addition, it is anticipated that the removal of certain exemptions to current reporting by product sponsors / manufacturers will result in an additional increase in the number of sponsors reporting to the TGA and the number of events being reported by these sponsors.

Government department reporting may also increase, and this must be factored into consideration (depending upon whether any individual jurisdiction decides to undertake batch reporting on behalf of their public health facilities).

Thus, government departments, public health facilities and private health facilities will feature more prominently in adverse event reporting and methods by which they can achieve this reporting will need to be considered.

Changes in submission channels used to report to the TGA

Currently there are three main submission channels when reporting medical device adverse event information to the TGA including the eBS portal, web forms, and email reports (with or without attached documents).

The two main channels of reporting (eBS and web forms) enable single case notification only. Sponsors / manufacturers have already expressed a desire to batch report notifications to the TGA and the TGA has committed to enabling this capability for both sponsors/manufacturers as well as for health facilities and government departments following implementation of mandatory reporting.

Depending upon changes to DPMM business processes and practices (e.g., shifting the focus of certain reporting back onto sponsors to enable automation of triaging processes), changes to the current web forms will also be required.

A significant area of ongoing uncertainty relates to whether the TGA will continue to support eBS for medical devices, have its own integrated data submission portal, or whether this will be part of a more comprehensive portal involving other functions of the DoHAC (in addition to who may have access to any portal).

The anticipated timelines for managing and/or developing these platforms will need to be considered in relation to potential future changes required for medical device adverse event reporting (discussed below).

Heath facilities and government departments will also need a capacity to submit data to the TGA in a more efficient manner than manual completion of web-forms or eBS portal fields.

Current discussions with health facilities and jurisdictions are canvasing the options of developing APIs to facilitate the extraction of existing data and transfer of this information to the TGA.

It is noteworthy that development and implementation of API capability is also being explored in relation to the transfer of information to and from the TGA about medicines, and the transfer of information to the TGA from a variety of sources to support implementation of UDIs.

In this context, the development and implementation of APIs to support medical device adverse event notifications will need to co-ordinate with planning and progress achieved in other areas of the TGA (including the Information Technology Division of the DoHAC).

However, it is also understood that the focus of API development in other areas of the TGA does not necessarily align with changes needed to facilitate mandatory reporting of information from all public and private health facilities across Australia by early 2025. Trade-offs may need to be negotiated between timelines and technology to facilitate mandatory reporting versus organisational 'readiness' to move to API implementation under pre-specified or 'ideal' conditions (e.g., not until all data storage and information processing is occurring in a cloud and/or designated vendor environment).

Thus, further discussions with health facilities and jurisdictions, and further internal discussions across the TGA and with the DoHAC are required to negotiate the best pathway for implementation of APIs and batch processing, within a short timeframe, for health facilities and jurisdictions (and potentially longer term for sponsors / manufacturers).

Data security mechanisms must also be addressed in any new data submission and/or transfer arrangements.

Similarly, initial data validations will need to be determined and implemented to promote maximum integrity of information.

Changes in collection and management of device data

InfoLeader remains the major platform for collection and management of information relating to medical device adverse event data.

The capacity of InfoLeader to handle larger volumes of adverse event notifications and processing is unknown. Consultation with the software vendor is required to determine future capability.

Notwithstanding, InfoLeader does have the capacity to utilise algorithms based upon the content of completed information fields to generate outcomes of the triage process for review by staff.

Assessment of current algorithm usage indicates that the conditions specified by existing algorithms need to be updated to reflect work practices of the DPMM team.

Updated algorithms can also be extended to focus upon 'new information' reported by sponsors (currently manually entered by TGA staff) and should automate the 'first parse' of adverse event notification processing – to assign priority and level of follow-up for staff to review.

In this context, automatic triage of notifications could then be subject to 'signal based' investigation for the DPMM team, analogous to medicines, where algorithms are adjusted according to the risk appetite for comprehensive / manual triage of individual notifications.

Consultation with the Information Technology Division of DoHAC is also required to identify elements of InfoLeader that may no longer be supported (e.g., the application of specific Macros) or may have a limited shelf-life for

ongoing support, based upon the Department's need to comply with Australian Cyber Security Centre or other information management standards (e.g., the Essential Eight). These consultations are required to estimate the remaining time within which InfoLeader will be fit for purpose in its current form.

Information about ongoing support for the platform can then be taken to the software vendor to discuss a range of issues, including but not limited to:

- The addition of new data fields (e.g., for information reported by sponsors).
- The updating of current algorithms.
- The extension of current algorithms to automate triage.
- Any capacity limitations of the current system and the type of trade-offs that may be encountered by operators as the volume of reports increase over time (e.g., delays in information processing, system down-time, system maintenance requirements, maintenance costs, etc.).
- Other changes in the user experience associated with any upgrades/enhancements or changes to the existing information management platform.
- The capacity of the system to initially 'land' information from future APIs and/or batch reporting arrangements that are introduced.
- The capacity of the system to migrate to the cloud.
- The ability of InfoLeader to validate data (e.g., free text data entries) and maximise the quality of outputs for subsequent analysis.
- The capacity of the system to integrate with other elements of the technology ecosystem and broader digital enterprise strategy (of the TGA and DoHAC), particularly as these are updated over time.

If routine algorithms and signal detection capability is not an 'out of the box' component of InfoLeader, the TGA will continue to need to design, pay for and maintain work arounds for the current system (i.e., background algorithms or the use of additional applications such as QLIK).

If InfoLeader is unable to initially 'land' data from APIs or batch processing approaches that need to be developed ahead of other technology advances across the TGA (and/or DoHAC), then an appropriate platform will need to be identified that can:

- Perform this function (land data from APIs or batch submissions of data);
- Pass information through an initial reconciliation with a master data store (if developed in time to be used); and
- Feed into InfoLeader for further processing.

Ultimately, a decision will need to be made about migrating InfoLeader data (historical and ongoing) onto an alternative cloud-based platform to be compatible with either an improved AEMS type (MAEDX project) system or a tailored medical device system (e.g., using D365)

Once IT systems are updated or upgraded, investigation processes could then be subject to machine learning (from past comparable cases) and other ongoing automations.

Changes in data storage across the TGA

Current data storage systems utilized during the processing of medical device adverse event notifications resides across several different platforms. Work is already underway to develop a master data store. This work can be integrated into medical device adverse event reporting information technology architecture as soon as it becomes available.

It is assumed that the master data store will incorporate a range of definitional data including Customer Relationship Management (CRM) data, the ARTG and ultimately other key data sources such as the UDI database.

In addition to the creation and integration of a master data store future data storage systems for medical devices can be upgraded to provide.

- An internal landing site (i.e., a data lake) that integrates all the different data sources utilized for medical devices reporting (e.g., Labs, Recalls, Applications, Other Post Market Databases, DAEN, TRIM, Mail Storage). This landing site could also potentially integrate other databases that may be beneficial to the analysis of adverse event notifications from other areas of the DoHAC (e.g., Prescribed (previously Prostheses List) or other overseas regulators.
- A processing facility for linking relevant information from these data sets, standardizing key terms (via master data), and performing quality checks.
- A facility for housing a common repository of linked data (a.k.a. a common data model) that is integrated for the specific purposes of accurate and efficient medical device adverse event notification processing.

Changes to data consumption

Current data consumption relating to medical device adverse events is currently undertaken by members of the DPMM team and other areas across the TGA. The application used to consume (process and interrogate) adverse event reports and other data relating to specific adverse event notifications is QLIK.

Advances in the QLIK Sense application that allow for implementation of automatic data processing and machine learning could be implemented once data storage and integration systems have been upgraded.

In future the range of applications used to consume data may expand to enable use of multiple platforms (e.g., Power BI).

Additionally, it is already known that sponsors / manufacturers and other stakeholders (e.g., health facilities, government departments) are requesting an improved capacity to consume information generated by the TGA about medical device adverse events. Whilst this is immediately limited to requests for improved searching capability and electronic downloads of multiple case information from the DAEN, in future applications may be used to allow stakeholders to interrogate patterns of data or other information stored or generated by the TGA. Such facilities are already being planned for medicines stakeholders (via the MAEDX project).

A process of implementing the changes described over the previous pages is outlined in the following section.

Implementation solutions have been staged as part of a five-part journey to reform the information systems and business practices associated with medical device adverse event notification processing.

Each solution requires further discussion with a range of stakeholders and negotiations with different areas within the TGA – most notably the transformation and medicines implementation timelines – to identify trade-offs that will need to be made to support the implementation of regulatory changes in adverse event notification for medical devices.

9. Solutions

Q:

How might medical devices and other TGA functions operate under any proposed changes to ICT systems or processes?

A:

Implementation solutions can be 'partitioned' according to different components of the information technology system.

Decisions to upgrade or enhance existing systems will depend upon their level of adaptability and ongoing support.

Decisions to implement new technology components will need to be made according to legislative timelines and requirements (rather than TGA planning timelines).

Ultimately new components should integrate in the overall technology eco-system.

The review highlighted three areas of limitations relating to data management that require consideration by the TGA in relation to the needs of MDSB.

1. Mechanisms to improve **data translation and transfer** (e.g., from health services to the TGA).
2. Options for **data storage and retrieval** to improve interoperability and automation (e.g., of medical adverse event information, and/or enterprise [TGA] level storage and processing).
3. Increasing efficiency and effectiveness of **data analysis capability** (e.g., for medical device information, and for the organisation as a whole).

However, the interrelated and interdependent nature of data technology restricts the ability to provide clearly distinct options and solutions that separately address each identified area noted above. There is no one-to-one association between the identified areas and the potential solutions described in this section.

A range of potential solutions to improve data systems and operational processes have been recommended to accommodate the anticipated future demand for adverse event reporting. These solutions can be implemented as separate components or as integrated components for systems improvement which have varying degrees of effectiveness in addressing the current limitations. Importantly, the solutions have also been designed to allow for staged adoption and implementation.

Selection of specific solutions will need to be determined by the TGA after further investigations about the level of departmental support for existing (legacy) systems, the capacity to modify current data analysis platforms (by the software vendor) to meet future requirements, and the timing and extent of further system developments implemented as part of the HPRG Transformation Program.

Six solutions have been grouped into three overall approaches, which focus upon:

1. **Maintaining the status quo** by increasing the level of staffing that use the current systems.

This approach **will not address the current limitations** relating to data translation and transfer, storage and retrieval or analysis capabilities.

2. **Implementing short term solutions** that aim to:
   a. Introduce API and electronic batch submission of data for new (e.g., health facilities) and existing (e.g., product sponsors / manufacturers) reporters.
   b. Attempt to bolster the capacity and capability of the existing InfoLeader system (if it will be supported by the Department IT service and if the software vendors can accommodate current and emerging changes required to more efficiently process incident notifications).

Introducing an API as proposed in 2a extends an opportunity to address **data translation and transfer**, which in turn has the potential to improve storage and analysis capability.

3. **Adopting a more integrated strategic approach** to processing incident notifications via:
   a. Modification/renovation of systems currently in the process of design for medicines (despite uncertainties associated with this approach).
   b. Implementing a tailor-made/new solution for medical devices (as a properly tailored solution that is more likely to integrate more smoothly with current and emerging technologies introduced within the information technology ecosystem of the TGA and the Department.

c. A final element of this approach is to design or await integration of more updated systems of data standardisation, storage, linkage, and preparation of devices data for internal and external consumption (which will ultimately need to be undertaken as part of broader IT reforms across the TGA).

The approaches in 3b and 3c have the potential to address or ameliorate limitations in data translation and transfer, data storage and retrieval and data analysis capability.

Each group of solutions is presented diagrammatically on the following page and discussed thereafter.

Potential approaches to implementation

1. Technology Status Quo

Status quo: Staff up the existing system

- Direct health facilities and government stakeholders to report via web-forms or current eBS portal (no API or batch processing)
- Increase staff to deal with influx of adverse event notifications
- Upgrade existing algorithms to check manual triage outcomes

2. Technology Short-term Approach

a. Implement 'devices' API and batch processing

- Introduce APIs & batch processing function for health facilities
- Implement initial landing database for API, batch, .csv and email
- Apply checks from master data for all incoming data (if ready)
- Use pre-existing data stores and data consumption via QLIK

Y/N

b. Maximise automation of existing system

- Change sponsor reporting forms (web forms) and portal fields
- Make all triage subject to algorithm in the first instance
- Implement signal detection for significant events (via QLIK)
- Consider options to digitize text from emailed notifications

3. Technology Strategic Approach

Y/N

a. Adapt end-to-end AEMS capability post MAEDX project

- Leverage capability and build additional capacity in AEMS (MAEDX project)
- Enhance to enable data checks and validation when submitting data
- Process device data via D365 and other integrated data stores
- Consume data (internal and external) via QLIK and Power BI.

Y/N

b. Pursue an end-to-end devices platform

- Enable data checks and validation when submitting data
- Replace Info Leader and process device data via cloud module
- Enable authorized external consumption of data by stakeholders
- Longer term integration into broader technological eco-system

TBD

c. Streamline 'devices' data storage

- Implement internal landing area from all TGA data stores
- Link, standardize and integrate data and perform quality checks
- Store a common repository of linked data for medical devices
- Use pre-existing methods of internal consumption via QLIK

Key

Confirmed | Y/N Decision Point | TBD To be Determined

1. Technology status quo: Staff up existing system

The first solution involves maintaining the current information technology capability, upgrading existing algorithms to assist with triaging of cases, but otherwise continuing to process each adverse event notification manually.

To manage the anticipated increase in adverse event reporting the TGA would simply increase the number of staff employed to undertake the current range of medical device adverse event notification processes.

This solution assumes that the TGA can recruit, provide ongoing training, provide sufficient infrastructure (physical equipment and space to accommodate staff), and sufficient supervision and quality control to accommodate the increased demand for processing of device notifications.

At the current point in time, the DPMM team is operating at around 50% of allocated FTE, indicating that recruitment alone could be a significant challenge to the organisation.

Moreover, as previously estimated, a six factor increase in reporting (median estimate) may result in the need for an additional 75 FTE to continue manually processing all event notifications. This would place significant additional demands upon the physical infrastructure of the organisation.

Summary of assumptions and risks

Assumptions:

- It is assumed that enough skilled staff can be recruited or trained to meet the increased workload.
- Efficient management and coordination of the expanded data entry workforce are assumed to ensure timely data entry.
- Effective quality control mechanisms are assumed to be in place to identify and rectify data entry errors.

Risks:

- Increased operational costs due to the hiring and maintenance of additional human resources.
- Higher susceptibility to data entry errors attributed to the manual nature of the process.
- Limited scalability and speed of scaling as event reporting surges with increased adoption once the reporting law is enacted.

This solution assumes additional stakeholders will come on board as reporters, including all public and private health facilities across Australia (in addition to a possible increase in reporting from States/Territories), despite any new reporters being limited to single case reporting through the existing eBS portal and web-forms.

This solution also accepts that there will be no API facilitated data transfer of information and no upgrade to the current portal to allow for batch reporting (from existing sponsors / manufacturers, or health facilities).

Consequently, adoption of this solution will create a significant ongoing and additional burden of reporting for businesses and other stakeholders that are anticipated to be submitting the largest ongoing number of notifications to the TGA. Importantly, this accepts that a fundamental commitment to stakeholders will not be met.

This solution will also require significant stakeholder management to cope with existing and emerging frustrations. It will undermine efforts to implement mandatory reporting by health facilities to the TGA within the required timelines of early 2025. Consequently, the TGA is likely to incur a high degree of reputational damage due to its inability to meet commitments to stakeholders associated with the introduction of mandatory reporting. It will also undermine efforts to remove exemptions to current sponsor / manufacturer reporting (given the increased regulatory burden).

DPMM staff will continue to be involved in work processes that are time consuming and could otherwise be prevented by having greater reporter control over the channels of information submission to the TGA (e.g., scanning and entry of new information in updated sponsor reports, re-entry of data, follow-up of missing or additional information).

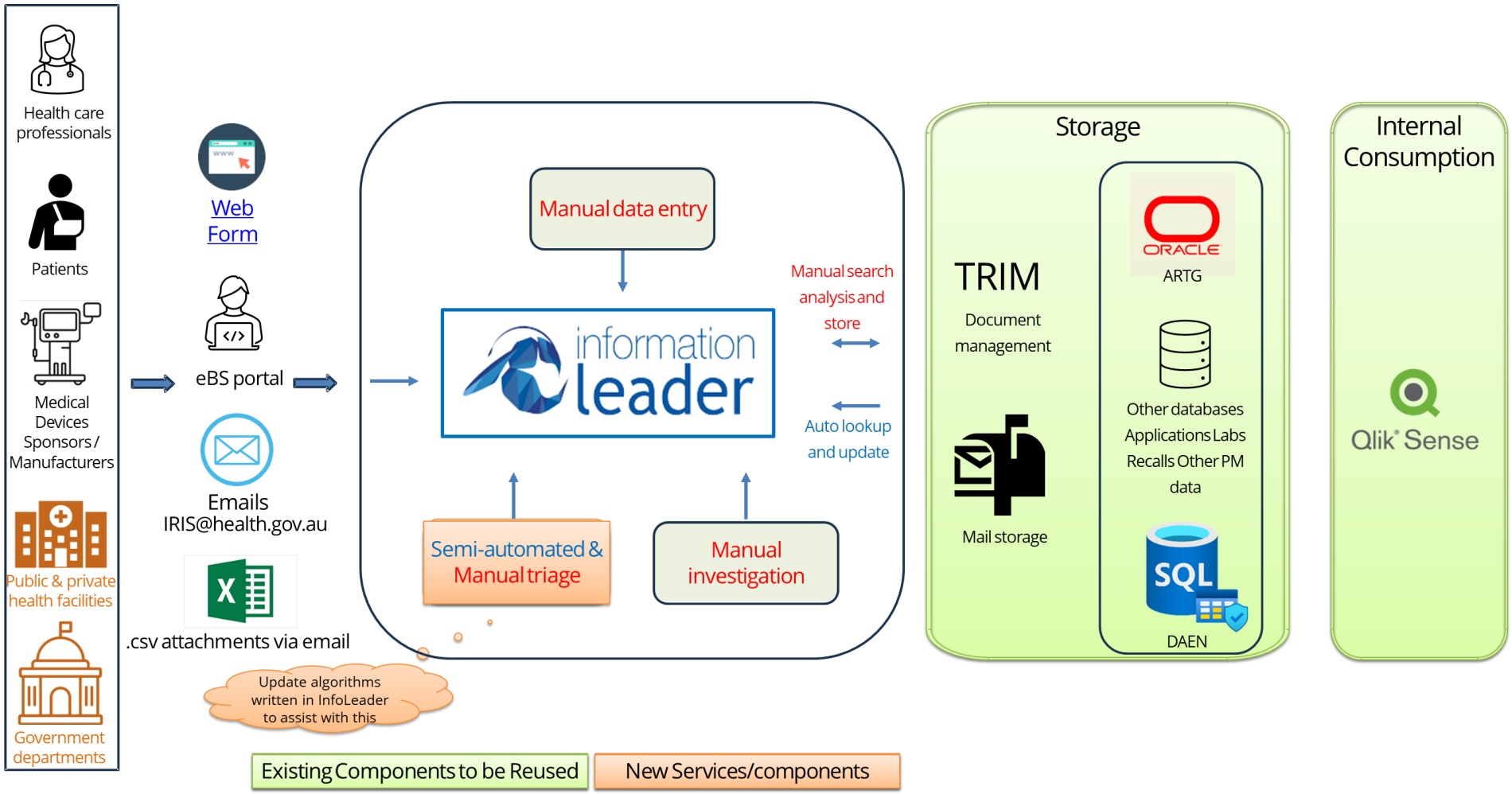
As previously noted, the capacity of InfoLeader to manage an increase in the volume of reports remains unknown (and will need to be investigated). Thus, the implication of additional reporting volumes upon the operational capacity of the existing system will need to be estimated and carefully monitored.

Similarly, the scale and schedule of additional staff recruitment remains difficult to determine (given the ultimate difficulty in estimating the quantum and rate of increased reporting demand). This is likely to result in challenges 'smoothing' out peaks and troughs in workload and could result in significant periods of under or over employment of DPMM staff.

Notwithstanding these challenges, an operational depiction of this solution is outlined on the following page and is the same as the current system (previously described).

As previously noted, this solution will not address the current limitations relating to data translation and transfer, storage and retrieval or analysis capabilities.

1 Technology status quo: Staff up existing system



Data translation and transfer

2a. Technology short-term solution: Introduce API/Batch submission

The adoption of APIs and batch submission is a commitment that has been made to stakeholders as part of the engagement that has occurred for the introduction of mandatory reporting.

It provides an initial step that just focuses upon enhancing information submission and provides the basis for leveraging a range of other potential changes to reporting fields, and automations in InfoLeader.

This solution also automates other forms of data submission through early data landing and information processing technologies (e.g., Power Automation) may be required that enable preliminary data to be reconciled with any available master data (if available) prior to automatic loading into InfoLeader for further processing.

Implementation of API and batch processing capability will be required prior to 2025 to maintain faith and momentum in current negotiations to facilitate mandatory reporting of adverse events between the TGA and public and private health facilities (their jurisdictions and/or corporate organisations).

This solution would ideally be implemented with a chosen data submission platform that can accommodate data integrity and security checks, electronic reporting, reporter editing of previously submitted data, automatic identification and notification of missing report information.

There are no other downstream changes to the TGA IT infrastructure in this scenario.

Introducing an API will address data translation and transfer for a good proportion of stakeholders required to report to the TGA. Improved data translation and transfer mechanisms that include data integrity and security checks amongst other functionality will also have a bearing on the quality of the data available for analysis. Optional improvements to data landing have been included to enhance data storage capability if this cannot be accommodated in InfoLeader.**Summary of assumptions and risks**

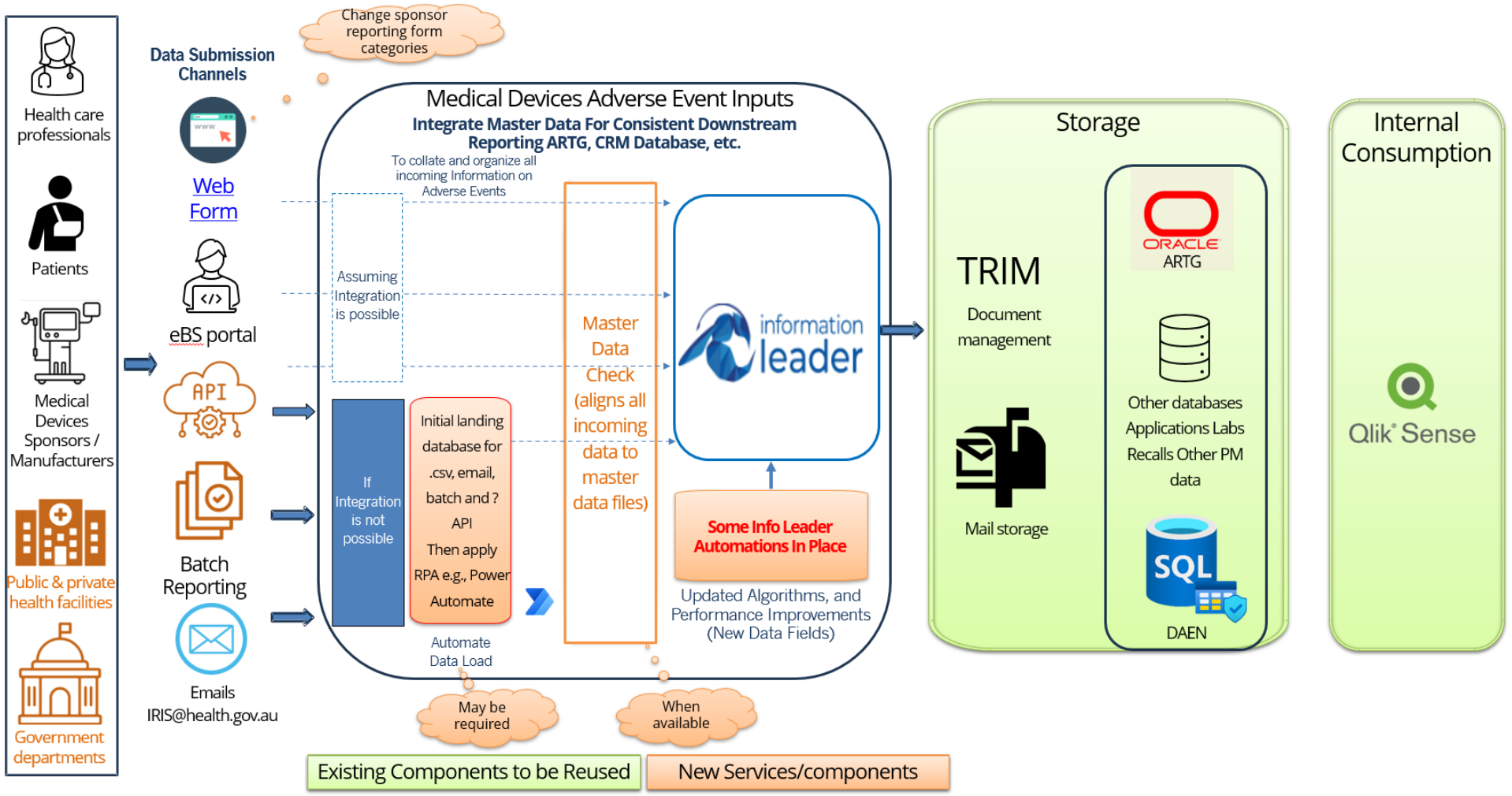
Assumptions:

- That InfoLeader can operate with early data landing platforms and master data stores.
- That an appropriate data submission portal is identified to enable ongoing reporting of single adverse event notifications.
- That current DoHAC security and technology approvals allow for APIs and batch processing of information from Australian health facilities.

Risks:

- Delaying mandatory reporting of medical device adverse events due to the inability to receive information from existing health facility information systems (via API or batch processing).
- That early data landing technology may require custom development to interface with InfoLeader.
- That InfoLeader may require migration to cloud hosting to integrate with selected data landing technology.
- That master data readiness is unavailable for integration into early data standardisation.

2a Technology short-term solution: Introduce API and batch submission



2b. Technology short-term solution: Maximise automation of the existing system

The second solution, which can occur either independent of or in conjunction with the development of APIs and batch processing, involves maximising the capacity to automate the existing information processing system (InfoLeader). This would be achieved by:

- Changing the sponsor / manufacturer reporting categories (on web forms and via the eBS portal) to include additional classifications of information that is currently classified by the DPMM team (as previously described).
- Developing algorithms in InfoLeader that use the classified information fields to fully automate the triage process and reduce demands upon TGA staff to manually review every medical device incident notification.
- Leveraging QLIKs advanced automation capabilities to scan previous notifications together with current notifications and identify where recent 'clusters' of potentially similar adverse events may have occurred.

In this sense, coded incident information (by product sponsors / manufacturers) can be used to 'signal detect' cases that require manual follow-up for confirmation of triage classification, the priority for further follow-up, and/or the level of further follow-up.

This solution would need to be accompanied by an audit program of a sample of cases to assure the TGA that sponsor / manufacturer reporting was being conducted at an acceptable standard (e.g., no downward classification or coding in the hope of avoiding further scrutiny of incident reports). It would also be a shift to 'risk based' follow-up of cases by the TGA. A cut off would need to be selected for referral of triaged cases for further scrutiny by the DPMM team.

Summary of assumptions and risks

Assumptions:

- That the MDPQD is prepared to move to a signal-based detection method of identifying higher risk notifications for further triage and investigation.
- That an appropriate quality control mechanism is introduced to monitor the standard of coding by sponsors / manufacturers (e.g., audit program).
- That current DoHAC security and technology approvals allow for upgrades/enhancements to the existing information management platform (InfoLeader).

Risks:

- Organisational support and direction to staff to shift to focusing only upon the higher risk, or more frequent, types of notifications.
- Staff willingness to follow automation without reverting to manual processing of all cases.
- Sponsor / manufacturer complaints about the increase in regulatory burden associated with increased reporting.
- Failure to shadow the implementation of any automation with ongoing existing processes to determine what may be overlooked and tightening or modification of algorithms in InfoLeader and QLIK to improve specificity of case identification.

Solution 2b would be an appropriate interim solution prior to the planning and implementation of other changes in business processes and information technology improvements (assuming InfoLeader is able to accommodate the implementation of new data fields and algorithms to process coded data).

This solution might also be considered before any changes in staffing level are determined, to identify the impact of increased InfoLeader automation upon the workload of the current FTE.

Notwithstanding, despite automation, several (previously described) limitations would continue and need to be addressed by upgrades to other parts of the information technology system.

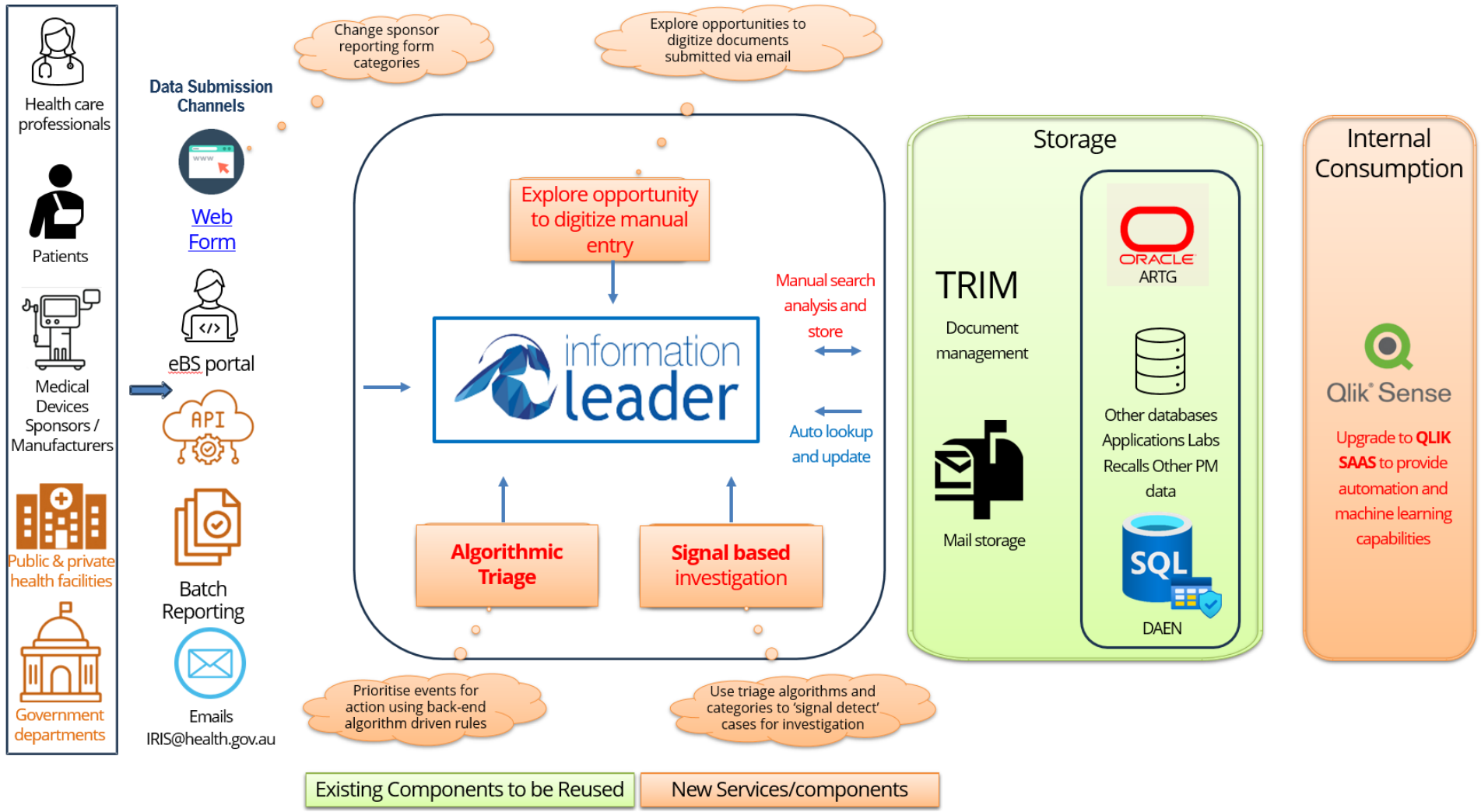
Examples of ongoing limitations include:

- No reporter control over updates in information submitted to the TGA resulting in the need for manual updates to amended reports by DPMM staff.
- The ongoing need for ad hoc re-entry of sponsor reports by the DPMM team when the IT system is experiencing 'down time' or when additional information is provided following initial report.
- The need to follow-up missing data (that might otherwise be identified at the point of data entry through a more updated information submission portal).
- The need to develop APIs and batch processing capabilities for existing and new reporters (i.e., sponsors and all public and private health facilities).
- Ongoing challenges in searching multiple, non-integrated databases for absent information (e.g., ARTG numbers in consumer or health professional reports).

Notwithstanding these limitations, solutions 2a and 2b together have the potential to provide an interim means for addressing several aspects of the current limitations in relation to data translation and transfer, (data storage as previously described) and to improve the data analysis capability of DPMM staff.

An operational depiction of this solution is outlined on the following page.

2b Technology short-term solution: Maximise automation of the existing system



Data translation/transfer, data storage, data analysis

3a. Technology strategic solution-: Leverage adverse event management system (AEMS) capability post MAEDX project

This solution represents an opportunity to consider integrating future changes that need to be made for medical devices (e.g., improved submission channels, introduction of APIs and batch processing, upgrading of information processing platforms, enhanced data storage, improved data consumption capabilities) with equivalent upgrades/enhancements planned for the processing of medicines adverse event notifications.

The decision to integrate systems will be heavily influenced by the timelines within which certain functionality is required to process medical device adverse events (e.g., by early 2025).

Decisions to integrate information technology requirements might be considered in two components:

- Technology involved in an upgraded, secure data submission portal – including the capacity to submit data to the TGA via API and batch processing from key reporters.
- Technology involved in processing adverse event data including an adverse event information database, improved data integration and storage capability across the TGA, and enhanced data consumption capability for internal and any authorised external users of information.

Discussions with relevant areas of the TGA indicate that the current MAEDX project to improve the current 'on-prem' AEMS is under revision and replanning with the intent of migrating to the cloud due to occur prior to March 2025.

Consequently, the timelines for delivery of any single component of the new system are unconfirmed.

Summary of assumptions and risks

Assumptions:

- MAEDX project timelines align with Medical Devices Adverse Events readiness requirements.
- Decommissioning of the existing TGA Device Adverse Event Notification system, "Information Leader," is assumed to facilitate the transition.
- The availability of well-documented investigation engine rules for reuse is expected to expedite the integration process, noting InfoLeader is propriety software.

Risks:

- MAEDX project is under replanning/refinancing and revised timelines are still unconfirmed.
- Integrating new capabilities into a platform still under development multiplies the delivery complexity (as medicines and medical devices data is different).
- The AEMS platform will require architecture assessment and potentially increased capacity due to increased workloads and data.
- D365 customization 'may' be required to accommodate for medical devices business requirements which may be complex and is some cases may be limited.

In addition, it is acknowledged that despite initial conceptualization of AEMS to serve both medicines and devices, it has been designed with the specific requirements of medicines adverse event processing, rather than any unique elements that would be required to process medical device adverse events.

It is important to recognise that the capacity of the planned improvements to AEMS (MAEDX project) has not considered expansion to incorporate processing of medical devices. It is also unknown how well any future improvements/extension of AEMS (MAEDX project) will seamlessly integrate with the needs of medical devices.

In short, **a deeper dive into the assessment of the current and proposed refinements/improvements to AEMS architecture is required to understand how well this system could support the processing of medical device adverse events.**

Further, the adoption of an AEMS solution **would require early collective decisions** about:

- **Integrating** medicines and medical devices reporting in one integrated portal.
- **Undertaking parallel design** of APIs for medicines (focusing upon medical practitioners), with APIs and batch processing capabilities for medical devices (focusing upon all Australian health care facilities and jurisdictions).
- **Decommissioning and migration off** InfoLeader (e.g., to D365) assuming functionality could be continued.
- Upgrading of **information storage** across the TGA.
- Upgrades to internal and possibly external **data consumption** by medical device related stakeholders.
- Additional **integration of IT security**, and any requirements to uplift the ongoing support and maintenance of the platform to include medical device incident processing.

Alternatively, these decisions could be implemented in a staged manner allowing assessment of the impact of iterative changes to medical device related information technology platforms.

Until further developments of AEMS as part of the ongoing MAEDX project are available for consideration, it will remain unclear about the timeliness with which adaptations and implementation of this system can alleviate current business inefficiencies in processing medical devices for commencement of mandatory reporting, including:

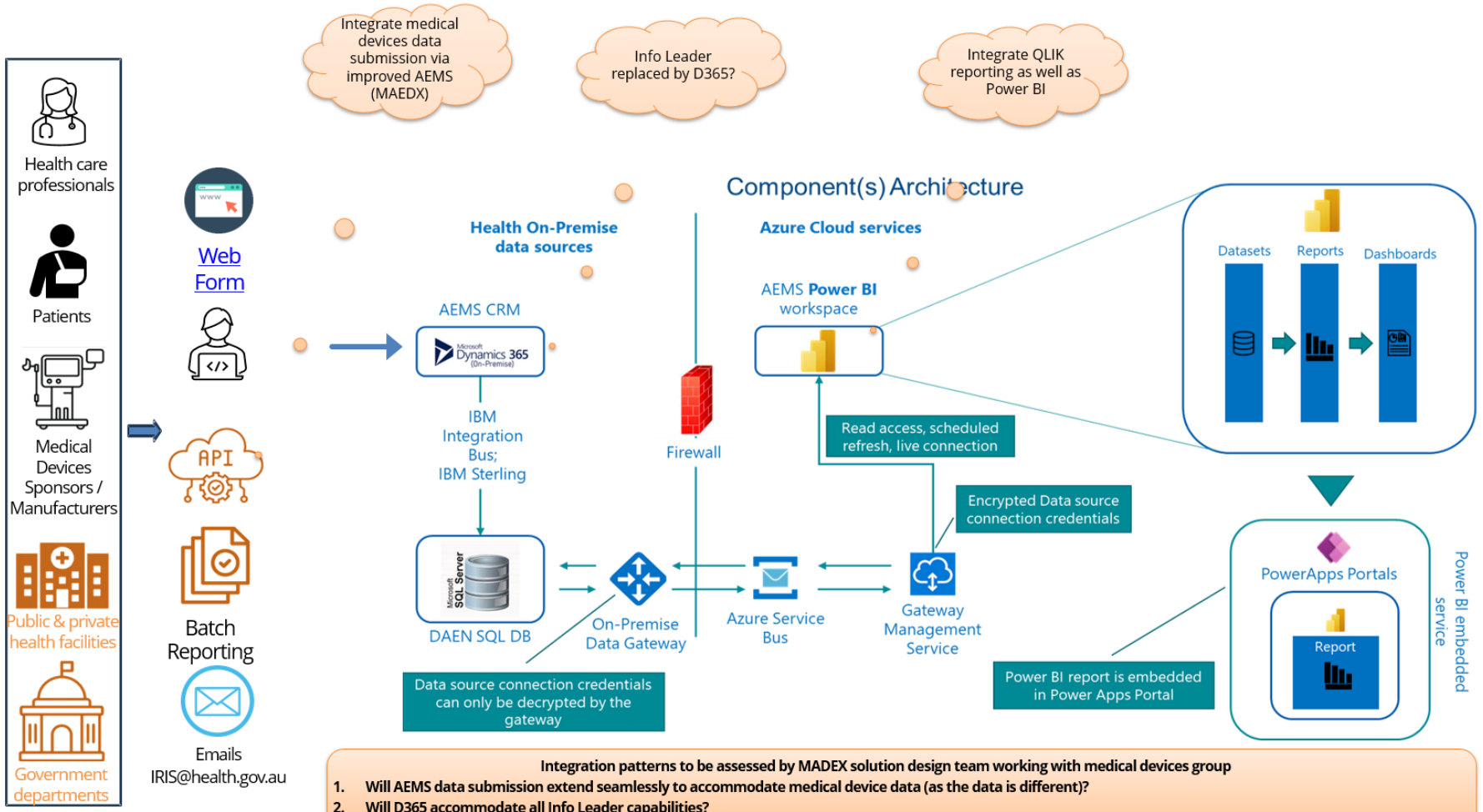
- The lack of reporter control over updates in information submitted to the TGA resulting in the need for manual updates to amended reports by DPMM staff.
- The ongoing need for ad hoc re-entry by the DPMM team of sponsor reports when the IT system is experiencing 'down time' or when additional information is subsequently provided.
- The need to follow-up missing data (that might otherwise be identified at the point of data entry through a more updated/enhanced information submission portal).
- The level of 'signal detection' that can be implemented.
- The speed of developing APIs and batch processing capabilities for existing and new reporters (i.e., sponsors and all Australian public and private health facilities).
- Ongoing challenges in searching multiple, non-integrated databases for absent information (e.g., ARTG numbers in consumer or health professional reports). It is acknowledged that there is a future opportunity

for work on unique device identification (UDI) to assist in deriving the ARTG number directly if the UDI is provided in the Adverse Event report. However, given the recognised lead times for medical device adverse events to manifest, benefits from UDI implementation will take a very long time to accrue.

Based on the information available to the review, this solution has the potential to address all three limitations of data management described above. However, this solution is highly contingent upon resolving the range of prevailing uncertainties.

An overview of how the currently known improvements to AEMS in the context of the current MAEDX project might provide a high level 'fit' to the requirements of medical device adverse event reporting are outlined on the following page.

3a Technology strategic solution-: Leverage adverse event management system (AEMS) capability post MAEDX project



3b. Technology strategic solution-: Pursue a devices platform

This solution represents a decommissioning and migration of the current medical device information systems (InfoLeader), together with upgrades to the existing data analysis capability (QLIK).

Changes represent a sequential step from improvements to data submission channels (incorporating APIs and batch processing) and replaces InfoLeader with a new triage and investigation module for medical device incident notifications.

This solution would allow for 'out of the box' automation and have the capacity to implement machine learning to streamline major incident notification activities (i.e., SMART Investigation). It would also involve upgrading of data analysis capabilities – through upgrading of the current QLIK version to QLIK SAAS that incorporates automation and machine learning for data analytics. This functionality could be used to streamline and enhance signal detection-based identification of cases for specific interrogation by the DPMM team.

Data analytics could also be extended to authorised content for examination by external consumers using QLIK or other relevant and familiar analytics platforms (e.g., Power BI).

This solution in conjunction with solution 2a has the potential to address both issues related to translation and transfer as well as analytics. It also has the potential to improve data storage in relation to the initial landing of API data, and the storage and processing of medical device information contained in any InfoLeader replacement.

Summary of assumptions and risks

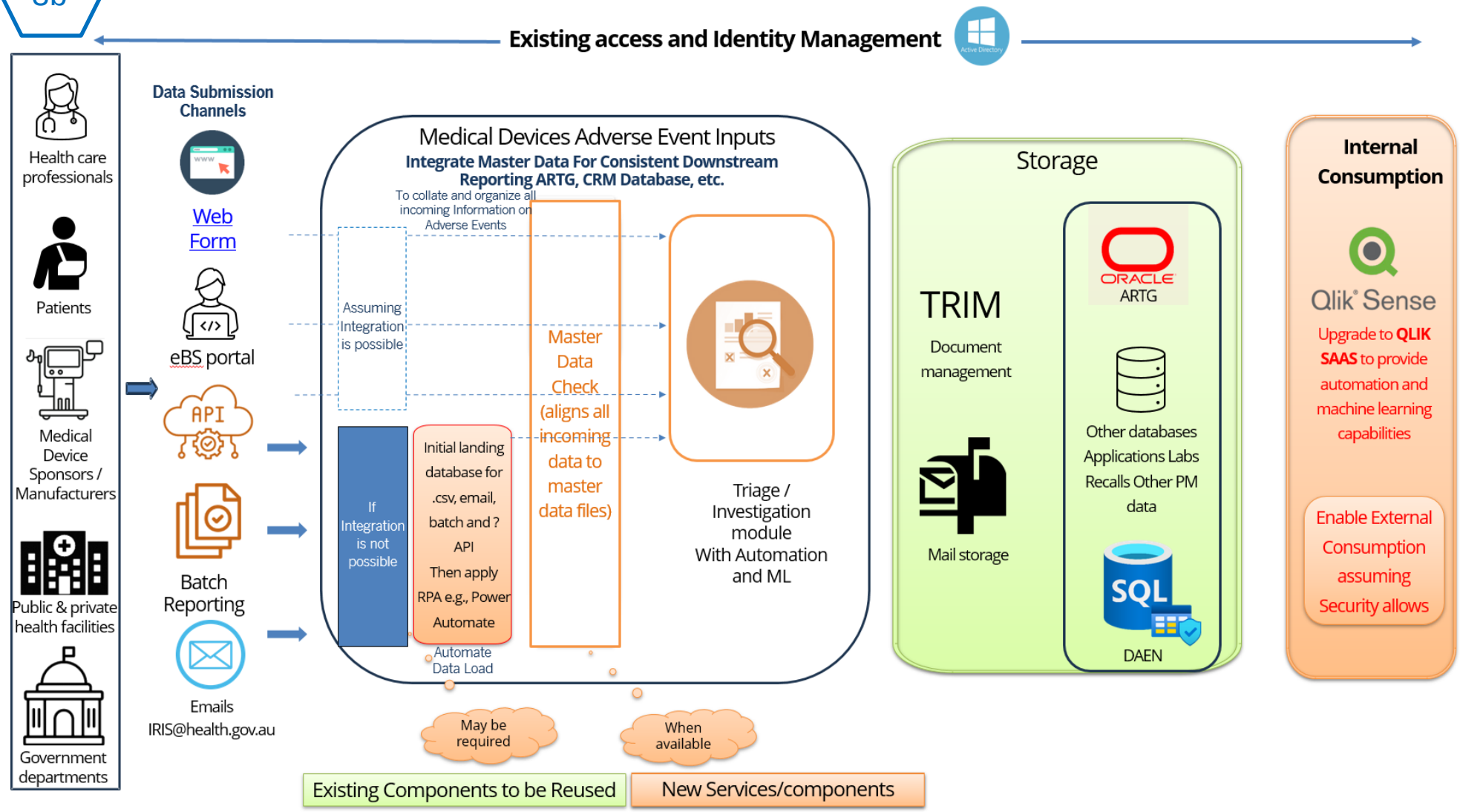
Assumptions:

- Systems for migration of InfoLeader are consistent with existing technology endorsements.
- The future system will represent superior functionality to the current platform (e.g., out of the box rather than back-end automation).
- The future system will enable migration of historical data to allow ongoing identification of clusters of similar events and apply machine learning to enhance ongoing incident notification processing.
- Future integration with the broader ecosystem is planned as part of the broader HPRG Transformation Program.

Risks:

- Detailed mapping of the current system and planning for migration and upgraded functionality will be required.
- The availability of business users (as required) to assist implementation of this solution will be critical to success.
- Licensing costs may vary based upon the number of users accessing and consuming reported data.

3b Technology strategic solution: Pursue a devices platform



3c. Technology strategic solution-: Streamline devices integration and data storage

This solution completes a series of planned improvements to focus upon more efficient identification, linkage, standardisation, integration, and storage of medical device related information for subsequent data consumption (analysis) by the DPMM team.

Under ideal circumstances this stage would integrate into planned enterprise level upgrades to data storage across the TGA and thus represent an integration rather than a separate upgrade of relevant systems.

As previously outlined, this technology would provide an internal landing site (i.e., a data lake) that integrates all the different current data sources utilized for medical devices reporting (e.g., Labs, Recalls, Applications, Other Post Market Databases, DAEN, TRIM, Mail Storage) and in future with the proposed UDI database (AusUDID). This landing site could also potentially integrate other databases that may be beneficial to the analysis of adverse event notifications from other areas of the DoHAC (e.g., Prescribed (Prostheses) List) or other overseas regulators.

A processing facility for linking relevant information from these data sets, standardizing key terms (via master data), and performing quality checks would also be implemented.

Finally, a facility for housing a common repository of linked data (common data model) that is integrated for the specific purposes of accurate and efficient medical device adverse event notification processing would be introduced.

This technology would permit more efficient searching and analysis of medical device adverse event data for ongoing signal detection, event triage, investigation and systems monitoring.

This data storage solution would contemporise the system, improve data governance, simplify and make data consumption consistent across different stakeholders, and ideally be amenable to integration with future developments in IT systems planning and the broader IT ecosystem. In short, implementation of this solution would complete the data system redevelopment necessary to address the range of current limitations. Specifically, this option addresses enterprise level (TGA) efficiencies in storage and retrieval of data used for medical device adverse event processing and a range of other functions undertaken by other areas of the TGA.

Summary of assumptions and risks

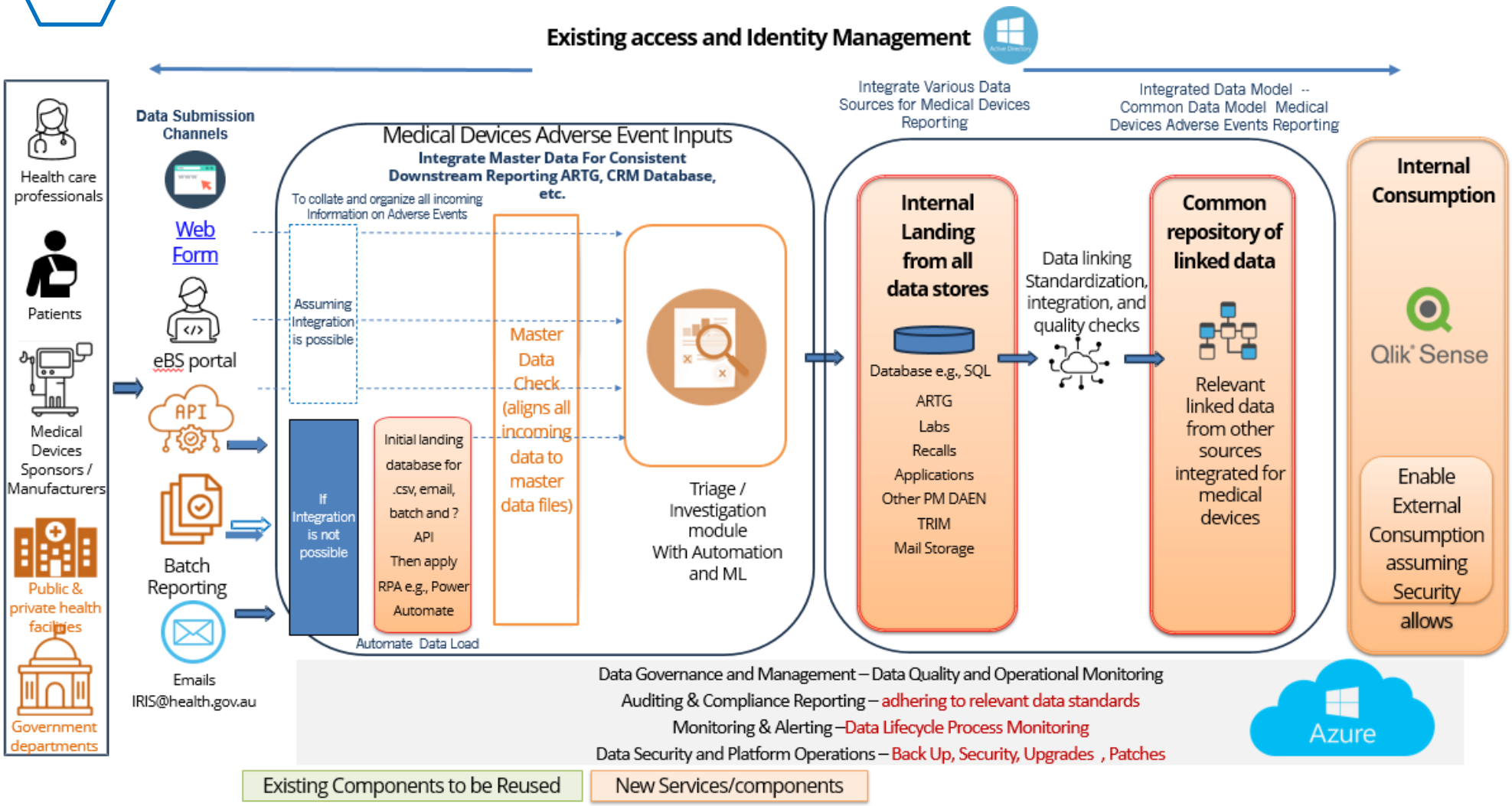
Assumptions:

- Data storage systems have not already been upgraded across the TGA.
- Pre-existing data storage systems continue to produce significant inefficiencies in processing particular elements of medical device incident notifications (e.g., detection of missing ARTG numbers in consumer or health care professional reports; delays in or reductions in quality or timeliness of signal detection of signification medical device adverse events).
- Timelines for enterprise level data storage upgrades have not progressed to implementation by 2027.

Risks:

- Implementation of information technology systems that may not have been introduced at an enterprise level.
- The replacement system is capable of being integrated with systems that are eventually implemented at an enterprise level.
- The replacement system is consistent with the HPRG Transformation Program and is able to evolve with strategic technology toolsets still under discussion.

3c Technology strategic solution: Streamline devices data integration and storage



Assessment of recommended improvements

Each of the recommended solutions will need to be assessed against the previously identified criteria for evaluating the success of future IT systems changes. This appraisal has been summarised (Figure 9-1) and indicates that automation of the existing system will bring some immediate benefits.

Uncertainties regarding the rescoping and timelines for implementation of the improved AEMS (MAEDX project) remain the greatest limitations of considering this solution, in addition to the potential scale and scope of re-design to incorporate the needs of medical devices (within the next two years).

Accordingly, systematic upgrades of some components are going to be needed to more completely address the medical devices business needs within the required timelines (at least up to and including implementation of API and batch processing).

If the existing system (InfoLeader) is unable to integrate with future IT developments, upgrades to the system itself and accompanying data analytics will also be required.

Figure 9-1: Assessment of recommended improvements against criteria

		Simplification & flexibility	Transparency	Connectivity	Stakeholder experience	Staff experience	Use of available data	Data quality and control	Analytic capacity	Interoperability	Ongoing IT support	Operational cost	Single entry point portal	Cloud based	Use pre-existing data	Automated workflows	Audit and traceability	Master data	Data standards	Privacy	Security	Retirement of legacy
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
1	Status Quo: Staff up existing system	✗	✗	✗	✗	✗	?	?	?	?	?	?	✗	✗	✗	✗	-	-	?	?	?	✗
2a	Short-Term: Implement 'devices' API and batch reporting	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-
2b	Short-Term:Maximise automation of existing system	?	✗	?	?	✓	✓	?	✓	?	?	?	✗	✗	✗	✓	?	?	?	?	?	?
3a	Strategic: Adapt end-to-end AEMS capability	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?
3b	Strategic: Pursue end-to-end devices platform	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	✓	✓	✓
3c	Strategic: Streamline 'devices' data storage	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	✓	✓	✓

Key

✓ Meets criterion
✗ Does not meet criterion
✓ Could potentially meet criterion
? Insufficient information to determine at this stage
- Not applicable

10. High-level next steps to be considered for implementation

Q:

What are the next high-level steps required to implement the proposed changes?

A:

In principle decisions about stakeholder commitments and TGA compliance with mandatory reporting and other regulatory changes will need to be confirmed.

Regulatory timelines will need to dictate when new technology components are to be introduced.

Uncertainty in current planning or other initiatives cannot delay decisions about medical device information systems.

Attempts should be made to integrate new systems with those planned for future implementation.

Key considerations for the TGA

This section sets out key factors that the TGA Executive needs to consider when examining the alternative solutions provided.

Solution 1 – *Technology Status Quo: Staff up the existing system* (i.e., do nothing to current information systems). The key considerations are that:

- It is an unrealistic solution.
- It fails to meet commitments to key stakeholders relating to API and batch reporting capabilities.
- It does not address the key considerations identified in relation to mechanisms to improve data translation and transfer, data storage and retrieval or for increasing efficiency and effectiveness of data analysis capability.
- It does, nevertheless, provide a basis for quantifying the notional funding (for staffing) that might be used to guide alternative investment in IT solutions.

Solution 2a – *Technology short-term solution: Implement 'devices' API and batch reporting*. This solution:

- Is required by March 2025 or soon thereafter to meet the anticipated increase in volumes.
- Would fulfil the commitment to stakeholders and is a functionality required under all technology solutions going forward depending on its end-stage design and implementation.
- Should not be constrained by HPRG Transformation Program priorities for implementation.
- Can progress in parallel with all technology solutions.
- Represents a stepwise improvement in data translation and transfer, which in turn has the potential to improve analysis capability.

Solution 2b – *Technology short-term solution: Maximise automation of existing systems*. This solution can be undertaken in conjunction with the implementation of a 'devices' API and batch reporting and would:

- Involve upgrade/enhancement to InfoLeader.
- Be heavily dependent upon ITD and vendor support.
- Require consideration of the cost of 'back end' upgrades in functionality to the current system versus other solutions that enable greater inbuilt user control and ongoing changes to updates/enhancements in functionality that are required.
- Need to consider the cost of upgrades/enhancements and future scalability to extend the system for evolving requirements.
- Require consideration of 'out of the box' capability to integrate with other systems (e.g., landing of API data).
- Need to consider immediate investment versus future proofing for proposed DTS implementation, Specifically, InfoLeader's readiness to adapt to proposed developments.
- Together with 2a, this solution has the potential to provide an interim means for addressing several aspects of the current limitations in relation to data translation and transfer and to improve the data analysis capability of DPMM staff.

Solution 3a – *Technology strategic solution: Adapt end-to-end AEMS post MAEDX project capability.* Significant considerations for this solution relate to several unknowns for devices. This includes:

- That it is highly unlikely to produce functional capability for medical device incident notification processing within the regulatory timelines required to implement mandatory reporting.
- The extent of additional capability and capacity of the improved *AEMS* system suitable to accommodate the needs for devices.
- The likely timelines for a major modification to currently planned processes to accommodate the needs of both medical devices and medicines.
- Is highly contingent upon resolving the range of prevailing uncertainties.

Solution 3b - *Technology strategic solution: Pursue an end-to-end 'devices' platform.* Important considerations for this solution include:

- The TGA's appetite to pursue a solution for devices ahead of the HPRG Transformation Program readiness to proceed at a pace that would meet regulatory timelines for mandatory reporting.
- The capacity of the replacement system to be able to migrate all historical data and minimise operational disruption in the transition to a new system.
- The corporate appetite to potentially use devices as the test case (pilot) for moving to a more contemporary (cloud based) solution whilst ensuring alignment with foreshadowed developments in the HPRG Transformation Program.
- The TGA's appetite and government budgetary capacity to accommodate immediate investment in a more permanent solution, as opposed to significant investment in potentially redundant solutions (increasing staff or short-term enhancements to InfoLeader) that does not have the capacity to be subsequently pivoted to a more strategic (longer-term) technology solution.
- This solution would be able to deliver on the commitment to stakeholders for more user friendly and accessible data analytics capabilities. Upgrades to QLIK are relatively easy to implement (pending the approval and support of ITD).
- Together with 2a this solution has the potential to address both issues related to translation and transfer as well as analytics. It also addresses data storage relating to the initial landing of API data and processing of medical device adverse event information (by replacing InfoLeader).

Solution 3c – *Technology strategic solution: Streamline 'devices' data storage.* This component can be implemented as part of the short-term or strategic technology solutions and is not contingent upon other decisions per se. It does however, close the loop on a comprehensive IT system and should be considered as either specific to devices or await the outcome and implementation of the enterprise level HPRG Transformation Program. The caveat being that the enterprise solution would need to be delivered within the next 2-3 years.

Considerations in relation to this solution include that:

- In real terms this may be delayed until such time as the HPRG Transformation Program can address an overall enterprise level data storage solution.
- If an enterprise response does not occur within a reasonable time frame (e.g., 2-4 years), independent progress to maximise the efficiencies of

medical devices and medicines adverse event notification processing could be considered.

- This solution would complete data system redevelopment necessary to address the range of current limitations including data storage at the (TGA) enterprise level.

Next steps

The following slides provide a table of the high-level tasks and timeframe required to enable implementation of the legislative changes requiring mandatory reporting of adverse incidents associated with medical devices.

The course of action to be undertaken by the MDSB requires some early critical decisions at an Executive level.

Based on the key considerations from the previous pages, these decisions are conditional upon the TGA's preparedness to:

- Accept a level of unprocessed or delayed processing in device notifications due to lack of staffing.
- Conversely, the over/under employment of staff, and the cost of accommodation and training of additional staff until the increase in demand has stabilized.
- Implement changes to streamline current business processes for medical devices prior to the increase in adverse event notifications (March 2025) and before the DTS and other areas of the organisation can 'catch up' with the needs of medical devices – specifically in the need for:

d. Developing and implementing APIs and batch processing of data, noting the commitment to stakeholders not to create additional burden from the new legislative requirements.
e. A submission portal that -
   - Has additional fields for sponsors to classify adverse event data. (This could be done using the existing eBS portal).
   - Can accommodate APIs and batch processing of information.
   - Can allow for more reporter control over amendments to previously reported information.
   - Has more updated/enhanced security and data validation mechanisms.
f. Upgrades to devices information processing systems that are shorter term (e.g., to InfoLeader) and not necessarily built into the existing system (i.e., back end 'fixes'), versus the development of more updated and tailored solutions to enable greater user control and integration with other information system upgrades across the technology ecosystem.
g. An updated/enhanced analytics capacity that:
   - Can automate analyses and apply machine learning to compare incoming incident notifications with previous incident notifications and identify clusters of potentially related events for ongoing analysis.
   - Potentially streamline triage and investigation processes through the application of machine learning.

High level tasks and timelines

***Excluding internal processes of the TGA and the Department and* depending upon agreed solution -**

Implementation Focus	Responsibility	Tasks	1-3 Months	4-7 Months	8-15 Months	16-21 Months	22 Months
Assess solutions for informed endorsement	MDSB	Undertake investigations with ITD and current InfoLeader vendor	*				
		Review outcome of investigations with ITD and current vendor	*				
		Undertake investigations to confirm **12-month readiness of current and alternative data submission channels and upgraded versus replacement adverse event processing systems and interactive data analytic capabilities** to handle increased volumes of adverse event reporting via existing/planned enterprise architecture.	*				
		Develop **indicative** implementation plan for Executive consideration including proposed next steps based on scenarios	*				
		Prepare Executive Paper including - likely increases to reporting, identify risks associated with inaction, outcomes of discussions with InfoLeader vendor, findings on 12-month readiness of current versus alternative systems. **Propose priority and timeframes for further action specifying alternative solutions based on initial investigations with current vendors and ITD and 12-month readiness of current versus alternative systems.**	*				
		Present to Executive	*				
Endorse preferred solution	**Executive**	**Confirm** enterprise risk, commitments, priority, actions and timelines for implementation.	*				
		Endorse preferred solution based on assessment of enterprise risk including meeting regulatory timeframes.	*				
Draft Implementation Plan	MDSB	**Prepare detailed implementation plan for preferred solution.**	*				
		Present to Executive	*				
Endorse Implementation Plan	Executive	**Endorse** an agreed course of action and Implementation Plan to enable implementation of Mandatory Reporting in line with legislative imperatives.	*				
Stakeholder Management	MDSB	**Brief** staff on strategic directions of TGA (expectation setting)	*				
		Continue negotiations with sponsors / manufacturers on strategic directions of TGA	*				
		Continue negotiations with public and private health facilities on strategic directions of TGA	*				
Commence Implementation of Preferred Solution		***Indicative Tasks and Timelines***					

Implementation Focus	Responsibility	Tasks	1-3 Months	4-7 Months	8-15 Months	16-21 Months	22 Months
Design, Develop & Build API	MDSB	**Work with contracted provider to determine devices requirements for APIs, both** functional (business capabilities) and non-functional (security and service level). Specifically, to: ▪ Define and document data exchange requirements (interface agreements) ▪ Define access requirements and enable authentication by defining permissions and controlling how much access an individual has when they access an API ▪ Determine control - what data is accessible within an API, enabling an additional layer of protection by ensuring selective data release to ensure that all data is not available to all users with access to the API	*				
		Contract and manage design of API based on the requirements including confirmation on API development technology		*			
		Contract and manage development API (Define Operations, implement applicable security) and implementation of APIs with complete CI (Continuous Integration)/CD (Continuous Development), automatic testing, and rapid deployment)			*		
		Test Planning and Test API for various scenarios			*		
		Publish/deploy API for production usage with ongoing management of APIs.			*		
Enhance InfoLeader	MDSB	Tasks will be dependent upon advice from software vendor on ability to accommodate necessary enhancements and within appropriate timelines.	*				
		MDSB to define enhancement requirements contingent upon acceptability to internal key stakeholders (ITD, DoHAC)		*			
		Design, develop, test and implement enhancements		*	*		
		Plan, test and execute implement system enhancements/modifications				*	*
AEMS post MAEDX project	MDSB	Define detailed Medical Devices Adverse Events Requirements	*				
		Assess and Confirm technology Alignment with AEMS platform for its applicability to medical devices		*			
		Assess Detailed AEMS improvement Architecture (MAEDX project) aligns with Devices Adverse Events Requirements		*			
		Assess and Confirm MAEDX project readiness of AEMS improvements versus regulatory timeline readiness requirements		*			
		Plan and execute implementation, (change Management timeline versus March 2025 deadline)			*		

Implementation Focus	Responsibility	Tasks	1-3 Months	4-7 Months	8-15 Months	16-21 Months	22 Months
End to end device platform	MDSB	Define medical devices adverse events reporting requirements (functional and non-functional and change management)	*				
		Contract solutions architect to develop and plan end to end delivery of the new device platform	*	*			
		Design and development of data submission channels with capabilities such as APIs and batch processing		*	*		
		Design, develop and test new triage and investigation systems with embedded SMART leveraging automation and machine learning capabilities moving from manual to an extensively digital process		*	*		
		Design, develop and test end-to-end to data platform with data governance, master data and reporting consumption thereby delivering a tightly integrated , linked and trusted data environment		*			
Streamline or integrate devices storage	MDSB	At a minimum, assess current medical devices data storage and data reporting environments – tools, technology, hosting, data governance, data integration and data quality	*	*			
		Identify and assess simplification opportunities to rationalize various data storage repositories into a single linked and integrated data set i.e., an opportunity minimize the number of current disparate databases			*		
		Assess opportunity to simplify data transfer thereby improving the quality and reliability of data for consumption via QLIK			*		

A1. Technical proofs of estimated workload

Fitting of specific distributions to estimate the time taken to perform the longest work activities was undertaken by Professor Ian Gordon, Director of the Statistical Consulting Centre at the University of Melbourne. Technical calculations for overall time (in days) are presented immediately below followed by a description of the approach for a statistically informed reader. The description is based upon Standard Operating Process 1.22 (searching for an ARTG number).

	minutes											hours							T = total	var(T)
	shortest t1	p(X < t1)	t1 (hours)	longest t2	P(X < t2)	t2 (hours)	log(1-p1)	log(1-p2)	beta	alpha		mean	sd	median	n	estimate (hours)	PI low	PI high		
Work Instruction 1.19:	15	0.1	0.25	45	0.9	0.75	-0.10536	-2.30259	2.807542	5.164002		0.496	0.191	0.489	50	25	22	27	3.3	1.8
Standard Operating Process: 1.22	10	0.125	0.17	60	0.95	1	-0.13353	-2.99573	1.736063	2.995732		0.474	0.281	0.430	725	343	329	358	45.8	57.4
Work Instruction: 1.18	20	0.6	0.33	60	0.9	1	-0.91629	-2.30259	0.838744	2.302585		0.406	0.486	0.239	600	244	220	267	32.5	141.9
Work Instruction: 1.2	20	0.4	0.33	120	0.925	2	-0.51083	-2.59027	0.906086	1.382247		0.733	0.811	0.467	8000	5867	5725	6009	782.3	5257.2
Work Instruction: 1.3 L1	60	0.12	1.00	180	0.9	3	-0.12783	-2.30259	2.631556	0.127833		1.942	0.794	1.901	65	126	114	139	16.8	40.9
Work Instruction: 1.13	20	0.2	0.33	60	0.7	1	-0.22314	-1.20397	1.534269	1.203973		0.798	0.531	0.698	900	718	687	749	95.7	253.3
	days											days								
Work Instruction: 1.3 L2	0.5	0.1	0.50	10	0.95	10	-0.10536	-2.99573	1.117442	0.228592		3.596	3.224	2.699	200	719	630	809	719	2078.5
Work Instruction: 1.10	1.5	0.05	1.50	30	0.85	30	-0.05129	-1.89712	1.205225	0.031465		16.570	13.810	13.011	5	83	22	143	83	953.6
																		sum	1778.5	8784.7

This note explains the methods involved in deriving an estimate and 95% prediction interval for the total amount of time, based on samples of independent times coming from the same underlying distributions. It is assumed that there are several different distributions, and the sample sizes vary from case to case.

First, I describe the approach for fitting a distribution in one case.

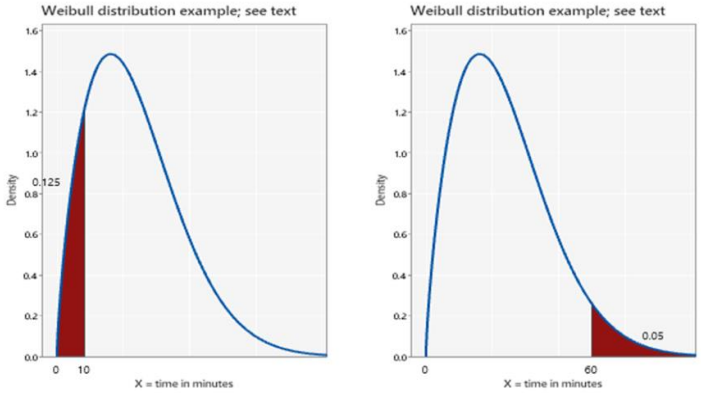
We are given two values for the cumulative distribution, at two specified times. For example, it may be assumed for the variable X (representing a time) that 12.5% of the times are less than 10 minutes, and 95% of the times are less than 60 minutes (hence 5% are greater than 60 minutes). In general, it is not assumed that the distribution is symmetric.

A simple distribution that is positive (as times must be) and not, in general, symmetric, is the Weibull distribution. It depends on two parameters, α and β. The cumulative distribution is a function of these two parameters, and hence it is possible to equate the given two values at the specified times to the functional form of the cumulative distribution function and solve two simultaneous equations to obtain the unique values of α and β leading to the numerical values given.

The mean and standard deviation of the Weibull distribution depend on α and β; they are non-simple functions involving the gamma function.

For the example given, the values of α and β are found to be α = 2.996 and β = 1.736. The corresponding values of the mean and standard deviation are 28.4 minutes and 16.9 minutes, or in hours: 0.474 hours and 0.281 hours respectively.

This derived distribution is shown in the following figure, with both of the specified quantiles shown.



Suppose that the number of instances of times from this distribution is 725, and we may assume that the times are statistically independent. The total time has a distribution with a mean equal to 725 × 0.474 ≈ 343.37 hours, and with the assumption of independence, the variance of the total time is equal to 725 × 0.2812; hence the standard deviation of the total time is 7.58 hours.

Due to the Central Limit Theorem, the distribution of the sum is approximately Normal, with mean equal to 343.37 hours and standard deviation equal to 7.58 hours.

This provides the derivation of the approximate distribution of the total time for one case.

There are several cases. They can all be dealt with in the same way, giving several approximate Normal distributions for the relevant total times, each with their own mean and standard deviation.

Finally, there is the aim of determining the distribution of the total time across the several cases.

The mean and variance can be obtained by summing the means, and summing the variances, assuming that the data from each of the several cases are statistically independent. This total time distribution may also be assumed to be approximately Normal, since the sum of random variables that have Normal distributions also follows a Normal distribution.

The distribution obtained for the total time altogether gives the basis for a 95% prediction interval for the total time, as mean ± (1.96 × standard deviation). Note that this is a prediction interval for a random variable (the total time) and not a confidence interval for an unknown parameter.

APRIL 25

Future state solution design and roadmap

Medical Device Adverse Event and Investigations Solution

Australian Government
Department of Health and Aged Care

Contents

Slides 3-8 contain only information that is out of scope of this FOI application.

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02. Current state findings

CURRENT STATE FINDINGS

Current state insights

Current state research uncovered 6 key insights to address in the future state solution design work. Detailed insights can be found at Appendix 1 and project opportunity areas in Appendix 2.

INSIGHT 1

Missing information and underreporting lead to difficulties with using adverse event data, and limit its reliability.

> *… so yeah, quite a bit of under reporting happening…*

INSIGHT 2

Medical device data is scattered across locations resulting in each team manually searching for, and requesting the data they need.

> *One thing I would say is it would be nice if all the data is captured in the one place…*

INSIGHT 3

Individuals across teams spend significant amounts of time manually processing and analysing data.

> *All of those things come into us as PDFs or a Word document. None of it's electronic.*

INSIGHT 4

The use of adverse event data to answer questions and inform teams' work is limited due to its accessibility, usability and presentation.

> *… it's not the most intuitive system or systems I would say…*

INSIGHT 5

Systems lack the functionality to alert teams of trends and risk factors to inform targeted work.

> *The main point as well in not having something alert us.*

INSIGHT 6

Risk assessments are dependent on specialist knowledge, as decision-making is highly complex.

> *It's kind of case by case. It depends on what the situation is like.*

Slides 11-46 contain only information that is out of scope of this FOI application.

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A1. Current state insights

INSIGHT 1

Missing information and underreporting lead to difficulties with using adverse event data, and limit its reliability

Missing information and underreporting were key issues consistently identified by teams using adverse event data. Staff wanted more information about the device, particularly technical detail. They also said that under-reporting means that they have an incomplete picture of adverse events in Australia.

Another key issue was ARTG numbers, that are often missing in reports submitted by hospitals and patients. The Device Support Team has to spend extra time manually deducing the ARTG number, occasionally making errors in this and contacting the wrong sponsor.

- Devices Post Market Reviews Section
- Devices Post Market Monitoring Section
- Medical Devices Authorisation Branch
- Devices Clinical Surveillance Section

"Yeah, there's data there, whether it's high quality data or not, I guess that can be, yeah, debated further, but that's down to the quality of the reporting from the sponsors as well."

"You're going to have sometimes more of a story that's not telling us what the actual issue is with the device, just their experience in the healthcare setting maybe."

"…So yeah, quite a bit of under reporting happening..."

INSIGHT 2

Medical device data is scattered across locations resulting in each team manually searching for, and requesting the data they need

Many teams shared that they used adverse event data in combination with other data sources. As this data is in multiple locations, teams must manually bring it together. Some of this data must be requested from the sponsor, adding additional time and effort.

There is also nowhere to store information once it has been brought together, so each team is duplicating the data gathering process. While teams varied in how they cut the data and the specific data sources they focused on, many asked for data to be combined into one place, forming a 360-degree view of the device. This would decrease time-consuming manual work, making it easier for teams to use the data for their specific purposes.

- Devices Post Market Reviews Section
- Devices Post Market Monitoring Section
- Medical Devices Authorisation Branch
- Devices Clinical Surveillance Section
- Devices Clinical Evaluation Section

"I think the data that we have access is to is generally quite good, but I think it's more just the manual pulling of all of that data and kind of platform to see it all together… so blue sky thinking we would love all of that to be in the one area to enable us to actually see the signal when it's there…"

"One thing I would say is it would be nice if all of that data is captured in the one place. So for example if I go in and look at a device output and try and get that information, everything associated with that particular device with the GMDN and the recalls output and if there's any DIRs or adverse events."

INSIGHT 3

Individuals across teams spend significant amounts of time manually processing and analysing data

Many people we spoke with shared that completing tasks with adverse event data was a manual process. This was because the dataset is highly unstructured and contains duplicate or misclassified reports. We heard that this leads to a significant amounts of time cleaning, moving, combining and manually analysing the data. Teams also shared that targeted searches on the information, such as searching for keywords to help identify signals, is challenging because of this.

Additionally, teams need to manually consume data presented in images, PDFs and word documents. For example, teams are reading sponsors annual reports to gather their adverse and inform signals.

- Devices Post Market Reviews Section
- Devices Post Market Monitoring Section
- Medical Devices Authorisation Branch
- Devices Clinical Surveillance Section

"All of those things come into us as PDFs or a Word document. None of it's electronic. It's really crappy trying to put all that information together in any useful way."

"So that's like two searches that we have to do then for the same device and then by doing that then it populates a spreadsheet… then I mean I haven't found a fast way to do this other than like having to manipulate around with Excel. But then you know some of those might be duplicates… devices or events that have been misclassified…"

INSIGHT 4

The use of adverse event data to answer questions and inform teams' work is limited due to its accessibility, usability and presentation

Some teams shared that the systems and highly manual data processes created barriers for their team members with lower data analysis competency and IT literacy. Other interviewees were comfortable using tools like Qlik but preferred more visual data tools not available in the software.

Another key barrier teams faced in answering questions using adverse event data is the lack of annual supply or sales data. This information must be requested from sponsors and without it they cannot determine the rate of adverse events.

Devices Post Market Reviews Section

Devices Clinical Surveillance Section

Medical Devices Authorisation Branch

"… I would say for like a new starter or even someone who's been in the field for like a year, it's not the most intuitive system or systems I would say."

"… it's basically not being utilised to it's full potential because of the lack of I guess uniform access to all of the piece of information that we would like at our fingertips."

"we don't have any ability to compare safety profiles and rates of particular adverse events across the full range of devices that are available on the ARTG."

INSIGHT 5

Systems lack the functionality to alert teams of trends and risk factors to inform targeted work

Throughout interviews we heard that there is a need to better enable the targeting of reviews and investigations through data trends and flags.

We heard that the process has continued to remain manual over time, however with the introduction of the new mandatory reporting legislation, there will be a need to change the process, with resources not being increased in line with increased reports.

Devices Post Market Reviews | Labs | Devices Manufacturing Quality Section

"The main point as well in not having something alert us. For us having to go in always to look for where there may or may not be a signal rather than having a system that is alerting us to 'this is a new or emerging risk that has been identified or there is an increase in trend in this particular risk with this particular kind of device' – that would be great."

"So I have to go into each individual one and change the review status".

INSIGHT 6

Risk assessments are dependent on specialist knowledge, as decision-making is highly complex

Interviewees relayed to us the specialist and experienced skill set of the people making risk assessment decisions for medical device investigations. They also explained the complexity of variables that need to be considered when making a risk assessment. Example variables include:

- The severity of an adverse event is dependent on the health of the patient.
- Devices can be high risk or low risk, which effects their risk assessment.
- A large number of adverse events for low-risk devices may lead to an investigation.

Devices Post Market Reviews Section

Devices Post Market Monitoring Section

Medical Devices Authorisation Branch

Labs

Devices Clinical Evaluation Section

“I’m also seeing now over time that corporate knowledge walks out the door when people leave.”

“We haven’t got, you know, a specific algorithm or anything like that which kind of helps us.”

“It’s kind of case by case. It depends on what the situation is like. Some of them might get referred to use when there’s been a string of adverse events for one particular device or it might be that just there’s been one or two but it’s this really serious significant safety issue like there were deaths or like serious injury”.

Slides 54-113 contain only information that is out of scope of this FOI application.

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