Australian Government

**Department of Health**
Therapeutic Goods Administration

# Medical Device Incident Reporting (MDIR) Guide

## Sponsor Guide to MDIR 2021

Version 2.1, November 2021

**TGA** Health Safety Regulation

# Contents

# Introduction

Welcome to the Medical Device Incident Reporting (MDIR) system. This is just one of a number of systems accessible from the TGA Business Services (TBS) website. The MDIR is the primary method of submission of medical device adverse event reports by sponsors of medical devices.

This document is a user guide for sponsors in regard to the MDIR system. It outlines the initial steps to access the MDIR system and then describes how to use the system, with step by step instructions and examples as required.

It is assumed that users have a valid TBS username and password; assistance with obtaining a TBS account can be found here: https://www.tga.gov.au/tga-business-services-getting-started-tga. Information is secure because users access the MDIR system with their TBS username and password.

The MDIR system has been enhanced to enable sponsors and manufacturers to monitor and track device incident reports. You will be able to lodge reports electronically, update previously reported incidents with additional information, review the status of reports, update initial and follow-up reports, and view past reports. All submitted reports and updates are received immediately by the Therapeutic Goods Administration (TGA).

# Getting started

You can access the MDIR system directly through the MDIR login web page or via the TBS web page.

## Navigating to the MDIR login screen on the TGA website

Use a web browser to navigate to the TGA's MDIR portal (https://apps.tga.gov.au/prod/mdir/mdirsummary.aspx).



Your TBS password will need to be regularly updated; it expires every 90 days.

# Accessing the MDIR system via TBS

You can also access the MDIR system through your TBS portal (https://www.tga.gov.au/tga-business-services).

ⓘ Note: If you have any issues accessing the TGA Business Services (TBS) system (including the creation of a new account) please contact the TBS helpdesk on 1800 010 624.

Select 'Open TGA Business Services'.



Enter your TBS user name and password and click on 'Login'.

ⓘ Note: Links to reset or retrieve a forgotten password can be found on this TBA login page (https://www.tga.gov.au/tga-business-services).

Click the 'Applications' tab located towards the top left of the screen to view a drop-down list and select 'Medical Device Incident Reporting'.



As TBS and the MDIR system operate from different platforms, you will be required to enter your user name and password again. This will ensure the information remains secure.

# New incident reports

## Creating a new incident report

After logging in, you will see a summary of all the existing sponsor incident reports.

To create a new adverse event report click on the 'New Report' button at the top right of the screen.



## Entering incident details

You will be taken to the Medical Device Incident Report. Enter the report details as required.



All fields marked with an asterisk (*) and outlined in red are **mandatory** – you will not be able to submit the report without filling them in. If you do not have information requested in a non-mandatory field, leave the field blank and save report as a draft to complete once information is available.





Some fields provide assistance to clarify what information is required. To view the help, click on the question mark symbol 🔸 and further information is displayed.
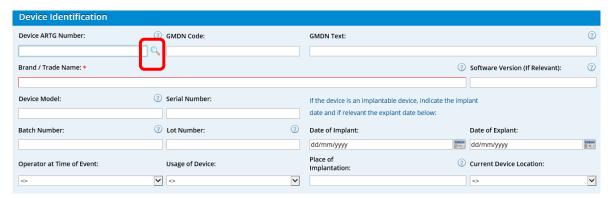
## Health care facility

Even though this information is non-mandatory, completion of these fields, if relevant, will assist in identifying potential duplicate adverse event reports submitted by patients, health professionals, or healthcare facilities. This information will also assist in trend analysis of health care facilities to potentially identify storage or transport issues, variances in clinical practice, and identifies areas that would benefit from additional education.

| Healthcare Facility Details | | | |
| --- | --- | --- | --- |
| Title: | First Name: | Surname of Contact: | Company / Institution: |

## Device identification

Some of the details in this section of the report can be auto-populated if you enter an Australian Register of Therapeutic Goods (ARTG) entry and then click on the magnifying glass. Even though the only fields which are mandatory are the '***Brand/Trade Name***' and the manufacturer's '***Company Name***', completion of other fields will assist in identifying potential duplicate reports submitted by consumers, health professionals, or healthcare facilities, as well as eliminate or confirm batch-related issues if similar reports have been received by the TGA.



If you select an ARTG entry which is not one that you are the sponsor for you will no longer be able to view the information once you submit this form. The submitted report will only be viewable within the MDIR portal of the sponsor who is associated with this ARTG entry.

## Clinical event information

The information provided in the '***Description of Event or Problem***' will be used to inform the text that is published on the Database of Adverse Event Notifications (DAEN) (https://www.tga.gov.au/database-adverse-event-notifications-daen). Any patient or healthcare information that is mistakenly placed here by the TGA will be redacted; however, we do encourage you not to provide information of this kind in this section of the report. There are other fields before and after this field which can be used for healthcare facility and patient information. The information provided here should relate to the clinical event and not the root cause identified by the manufacturer's investigation; there is a separate area for information related to the root cause later in the form.

**Clinical Event Information** — Please DO NOT include the names of hospitals or persons involved in the event. Use the section above 'Healthcare Facility Details' for this information.

Description of Event or Problem: *

The following fields regarding the patient, their clinical care, and outcomes are non-mandatory, but completion of these fields, if relevant, will assist in identifying potential duplicate adverse event reports submitted by patients, health professionals, or healthcare facilities. Provision of this information at this stage may also negate the need for the TGA to request this information from you at a later stage.

**Patient Information** — Please do not provide the name of the patient.

Sex:
Age (Years, Months):
Weight (Kg):

Corrective Action Taken Relevant to Care of Patient:

Patient History (Co-morbidities & Medication):

Patient Outcome / Consequences:

If during the course of this adverse event there were other medical devices involved that may have been integral to the occurrence of the event, you can provide the information in the '***Other Devices Involved in Event***' field whether you are the sponsor of these devices or not

**Other Devices Involved in Event**

Do you want to add any other devices involved in this event?:

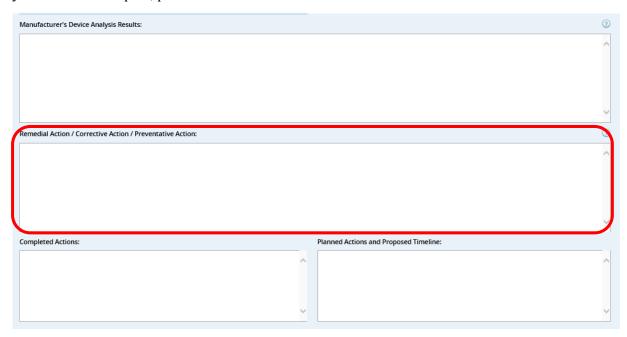&lt;&gt; | If **Yes** please tell us about them...

## Results of manufacturer's investigation

Provide the name or the code (often an alpha-numeric code) assigned by the manufacturer to any corrective and preventive actions (CAPA) put in place to address issues related to the reported adverse event. A summary of the CAPA can be inserted in the '***Remedial Action / Corrective Action / Preventive Action***' field (highlighted below) or the CAPA report can be attached. Attaching the CAPA report may prevent further requests for this information. If you do provide the documents as attachments, please make a note of that you have done so in the '***Remedial Action / Corrective Action / Preventive Action***' field. If a formal CAPA has not been raised by the manufacturer, a comprehensive summary of all corrective and/or preventive actions put in place to address issues related to the reported adverse event should be provided in this field.

A comprehensive summary of the manufacturer's investigation of the reported event, including findings of any electrical, biological, material, software or other device analysis undertaken, is to be provided in the '***Manufacturer's Device Analysis Results***' field of the report. These results

should include the root cause for the issue. If the root cause has not been established a clear reason for this should also be documented.

When an investigation is complex and/or the report lengthy you can [attach the full report](#) to your submission. Attaching a copy of the full manufacturer's report for a final adverse event report could address questions that the TGA may have if we only receive a summary report. If you do attach a report, please reference the attachment within this field.



The '*Completed actions*' and '*Planned Actions and Proposed Timeline'* relate to the CAPA actions. This information should include any expected completion dates for those actions.

> The '*Remedial Action/ Corrective Action / Preventive Action', 'Completed actions'*, and '*Planned Actions and Proposed Timeline'* fields are to be completed when there is, or has been, action taken by the manufacturer to remediate an issue**.**

## Similar Events

The reporting form allows for presentation of similar event information within the free text field '*Other Similar Events Manufacturer / Sponsor aware of'*.

The rate of similar adverse events is required for analysis of incident trending to determine if there is an emerging issue. Therefore, providing data for a three year period separated into the year of the adverse event, one year prior and two years prior is required.

A total number of events, similar to the reported event, which have occurred in Australia and Worldwide are reported here. The information needs to include the details of any other similar events reported to the sponsor or manufacturer as a **number** and **actual incidence rate (%).**

The **number** needs to include the total actual number of occurrences and also the number of devices sold/supplied over the three year time period or since inclusion in the ARTG, if the device has been included in the ARTG for less than three years. If no events have occurred write 'Nil similar events'.

The **actual incidence rate** needs to be provided in the form of a percentage generated using the calculation (# of similar events/number supplied x 100). For example: There have been 12

similar events from 3,187 units (0.37%) sold in Australia in 2018; 10 similar events from 2,675 units (0.37%) sold in Australia in 2017; and 2 similar events from 1,234 units (0.16%) sold in 2016. Worldwide, there has been 235 similar events from 68,078 units sold (0.34%) in 2018; 325 similar events from 86,078 units sold (0.38%) in 2017; and 253 similar events from 68,708 units sold (0.37%) in 2016.

Other Similar Events Manufacturer / Sponsor Aware of:

If the device identified as being associated with the adverse event is reusable, express the adverse event rate in relation to the number of consumables (if one consumable equates to a single use of the device), or anticipated uses of the device per day/week/month/year. For example, if the device is a glucose meter, the rate for the adverse event can be calculated by the number of events/glucose strips sold x 100, or the number of times a day a patient may be reasonable expected to use a glucose meter. If this method is being used in the calculation, this information should be clearly conveyed.

> Both Australian and worldwide figures are to be provided for a three year time period (where available) for context and must include the date in which the reported event occurred. This information is to be presented in 1, 2, and 3 year format.

If there have been similar incidents with this medical device internationally, the countries in which they occurred should be listed. A breakdown of the number of similar events that have occurred in each country is often helpful and may negate the need for the TGA to request this information later (e.g. United Kingdom – 188, Belgium – 7, New Zealand – 4).

Countries Where These Similar Adverse Events Occurred:
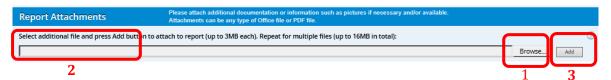
Additional Comments:

Please include any additional information that relates to the similar events in the '***Additional Comments***' field. This may include information regarding the life cycle of the product, such that it is new to market and therefore three years data is not available yet, or conversely that the product is discontinued or obsolete.

# Attaching supporting information

You are able to attach supporting documents, images, or other electronic files to the incident report using the 'Report Attachments' section located towards the end of the report. To add an attachment:

1. Click the 'Browse' button and select a file from your computer.

2. Once you have selected a file, its name will be displayed on the form.

3. Click the 'Add' button to add it to the report.

Once a file has been added, you can continue to add more files to the report. To remove an attachment click on the paper clip symbol next to the title of the attachment you wish to remove.



There is a limit to the size of each attachment of 3MB and a limit to the total size of all attachments of 16MB. Attachments that are outside of these limits should be sent to the TGA via email, to iris@tga.gov.au, referencing the device incident report (DIR) number.

## Submit your Report

When you have completed your report and are ready to submit it, click on the 'Submit to TGA' button. You will receive a confirmation screen with the new Device Incident Report (DIR) number for your reference.



You can then return to the list of 'Open' reports by clicking the 'Back to Summary' button.

You can also update the details in the initial report form you just submitted and submit it to the TGA as a follow-up or final report by clicking on the 'Submit to TGA'. Final reports are required to be submitted within 120 days of the initial report being submitted to the TGA.

## Saving and printing your report

To save a copy of the submitted report form you will need to:

1.  ensure that you have PDF creator on your computer;

2.  click on the 'Print Report' button;

3.  select PDF creator from the list in 'Select Printer';

4.  click on the 'Print' button;

5.  click on the 'Save' button in the PDF Creator pop up box;

6.  select the location on your system where you want to save the document in the 'Save as' pop up box; and

7.  then click on the 'Save' button.

Alternatively, if your web browser allows, you can use the keyboard shortcut of pressing the CTRL and P keys simultaneously.

# Viewing/editing reports

## Viewing a list of open reports

Once you have logged into the MDIR system you will see a list of all your 'Open' reports that have been submitted to the TGA as well as those reports you have in 'Draft'.



You can order the list of 'Open' reports by any of the column headings. To do so click on the column heading you wish to sort by. The default order is by date of adverse event (with the most recent first).

If you have many open reports, you can use the navigation bar located at the end of the page to view other pages/more reports.



## Viewing a list of closed reports

You can change the view to display a list of all your 'Closed' reports using the 'List Report Currently' drop down which is located towards the top left of the page. Click on the down arrow and select 'Closed', then wait for the page to reload to show a list of all relevant closed reports.

You can order the list of 'Closed' reports by any of the column headings. To do so click on the column heading you wish to sort by. The default order is by date of adverse event (with the most recent first).



# Searching for reports

You can also search using the 'Search Results For' box by entering part or all of the DIR Number, Brand/Trade Name or Reporter's Reference. Type the detail in the 'Search Results For' textbox located towards the top right of the page and press the Enter button on the keyboard to perform the search.



# Opening an existing report for editing

Reports in the 'Open' summary view with a 'Type' status of 'Initial' or 'Follow-up' can be opened for editing. Once you have located the report you would like to edit, hover the mouse over the report so it is highlighted and click once. The report will then open up for editing.

You can then update your information including adding additional file attachments. Once you've updated your information, click the 'Submit to TGA' button towards the bottom of the page



You will then receive a confirmation message that the update has been successfully submitted, or a notification that a mandatory field requires completion prior to a successful submission.



Reports that are updated, that is their status is changed from 'Initial' to 'Follow-up' and 'Final', will have more mandatory fields than an initial report. Please check that you complete all field that have a red asterisk (*) and are outlined in red.

# Providing additional information for a closed report

If you receive additional information for a report that has been closed, you can provide that information, along with the DIR number, to the TGA by email (iris@health.gov.au). The TGA will then add the information to the report.

# Logging out

It is important to log out of the system properly to ensure the security of your submitted information. Once your report has been submitted and you have finished reviewing your information, make sure to click the 'Log Out' button located towards the top right of the screen prior to closing your web browser.



# Help

## Accessing help

At present this user manual is available from the TGA website, the TBS website, and via email upon request.

## Help desk

If you are experiencing problems with the system, contact the Device Vigilance and Monitoring staff from the Medical Devices Branch on:

- Email:    iris@health.gov.au

- Phone:    1800 809 361

# Version history

| Version | Description of change | Author | Effective date |
|---------|----------------------|--------|----------------|
| V1.0 | Original publication | Therapeutic Goods Administration | July 2013 |
| V2.0 | Update to images and field definitions | Device Vigilance and Monitoring Section, Medical Devices Branch | 20 August 2019 |
| V2.1 | Included final report and additional information requirements following amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 | Medical Device Surveillance Branch | 29 October 2021 |

**Therapeutic Goods Administration**