

Sharing adverse event data for medicines and vaccines

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Why does the TGA share adverse event data?

New Database of Adverse Events Notifications – Medicines (1 year on)

Automated AEFI sharing with State and Territory health departments

NEW – sponsor adverse event search functionality



Why does TGA share adverse event data?

- Transparency – include reported AEs in the DAEN - medicines
- Provide context to DAEN information – e.g. MSU, COVID-19 vaccine safety report
- Cooperative approach for AEFI with states and territories
- Support sponsors in meeting their pharmacovigilance obligations
- Global pharmacovigilance

How has the TGA improved sharing of AE data?

New DAEN – medicines

Automated AEFI sharing

Sponsor adverse event search

DAEN – medicines

One year after launch

- User feedback sought on beta version in October 2022
 - ✓ 70% of respondents preferred the new DAEN
 - ✓ 60% of respondents found the graphs were useful
 - ✓ Updated user guidance to address areas of concern
- Beta version has replaced old version

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Database of Adverse Event Notifications (DAEN) - medicines

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Inclusion in DAEN - medicines does not mean that the adverse event has been confirmed or that it was caused by a medicine or vaccine.

Search the DAEN - medicines [?]

Date range [?]

From: 01/01/1971 To: 12/05/2023

Search medicines - (9,950) Medicines selected
(Search by [trade name/s](#) or an [active ingredient/s](#). Select one or multiple medicines from the list below to include in your search.)

Search

- Select all
- 100% Pure bee pollen (active ingredients: Pollen)
- 123Diet Drops - AUST L 301834 (active ingredients: Glutamine; Ornithine monohydrochloride; Alanine; Lysine hydrochloride; Histidine; Gymnema sylv...
- 1300 SEASICK (Escape Travel Sickness) compounded sea sickness product - Not on ARTG (active ingredients: caffeine; Chlorphenamine maleate (Chlor...
- 30 Plus (active ingredients: calcium; chromium picolinate; Cimicifuga racemosa; cyanocobalamin; folic acid; pyridoxine; tyrosine)
- 35 Billion Probiotic 10 - AUST L 292340 (active ingredients: Lactobacillus plantarum; Lactobacillus brevis; Lactobacillus salivarius ssp salivarius; Bifidob...
- 3TC (active ingredients: Lamivudine)

Search summary counter

| | | |
|-----------------------------------|---|----------------------------------|
| Reports (cases) 598,771 | Single suspected medicine 491,448 | Reported deaths 13,838 |
|-----------------------------------|---|----------------------------------|

Medicine summary (10,061 rows) [?]
Hover over the table to view exporting data and other options. Click on the dots to see more options. [↔]

| MedDRA system organ class | MedDRA reaction term | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome |
|--|-------------------------|-----------------|--|--|
| Nervous system disorders | Headache | 51,496 | 48,216 | 120 |
| General disorders and administration site conditions | Pyrexia | 41,753 | 33,772 | 262 |
| Gastrointestinal disorders | Nausea | 40,972 | 36,351 | 219 |
| Skin and subcutaneous tissue disorders | Rash | 34,444 | 26,756 | 113 |
| General disorders and administration | Injection site reaction | 32,250 | 27,995 | 8 |

List of reports -(598,771 rows) [?]
Hover over the table to view exporting data and other options. Click on the dots to see more options. [→]

| Case number | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
|-------------|-------------------|-------------|--------|-----------------------------------|-----------------------|
| ▼ | | | | | |

Data visual representation

Tables and graphs | Graphs

Advanced search options [?]

MedDRA system organ class
(All selected)

Search

- Select all
- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders

MedDRA reactions
(All selected)

Search

- Select all
- 11-beta-hydroxylase deficiency
- 5q minus syndrome
- Abdominal abscess
- Abdominal adhesions
- Abdominal cavity drainage

Age (years)

- Select all
- Less than 5
- 5 to 11
- 12 to 17
- 18 to 64
- 65 and above
- Unknown

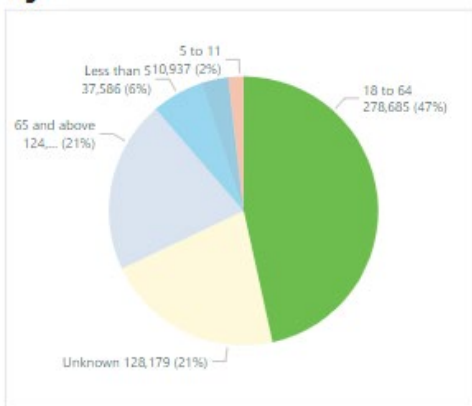
Gender

- Select all
- Female
- Male
- Not Specified

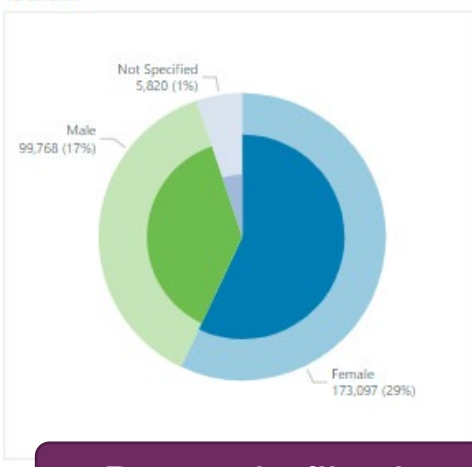
Features of new DAEN

Data visual representation

Age



Gender



Dynamic filtering

MedDRA reaction terms (top 25 view only)



Advanced search options ?

MedDRA system organ class

(All selected)

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MedDRA reactions

(All selected)

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- Select all
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- Abdominal abscess
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- Abdominal cavity drainage

Age (years)

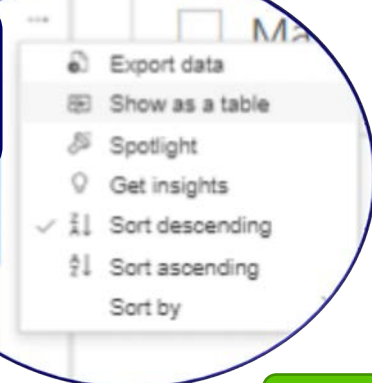
- Select all
- Less than 5
- 5 to 11
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- 65 and above
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Gender

- Select all
- Female
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- Not Specified

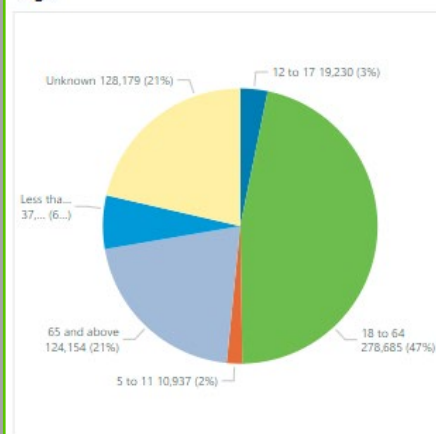
Refine results

Export function

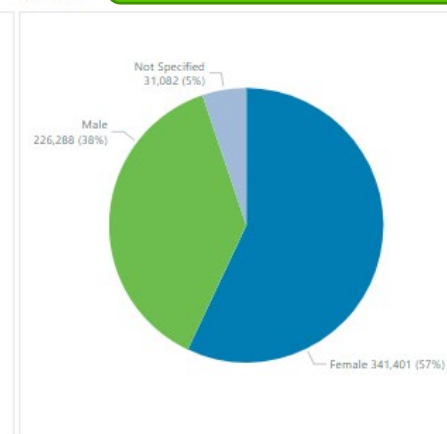


Graph view

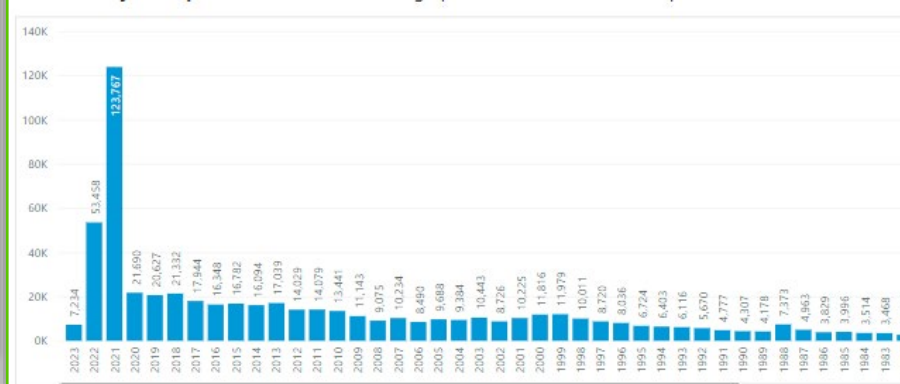
Age



Gender



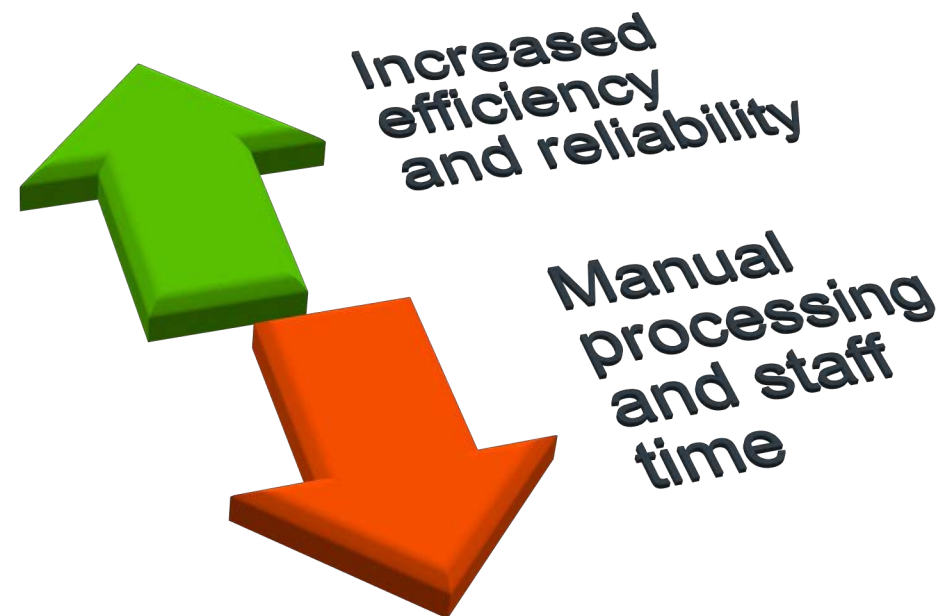
Case data by the report date – Hover over the graph to view data drill down options



Sharing AEFI information with jurisdictions

State and Territory public health units play a critical role in the investigation of individual reports of adverse events following immunisation

- Each fortnight TGA provides, via email:
 - a national case line listing for all AEFI, and
 - full case details for:
 - cases relevant to their jurisdiction
 - cases with unknown patient stateto every state and territory.
- Since late December 2022 these documents are created and sent using an automated system
- Serious AEFI are still sent manually to the relevant jurisdiction when they are received.



Sponsor adverse event search

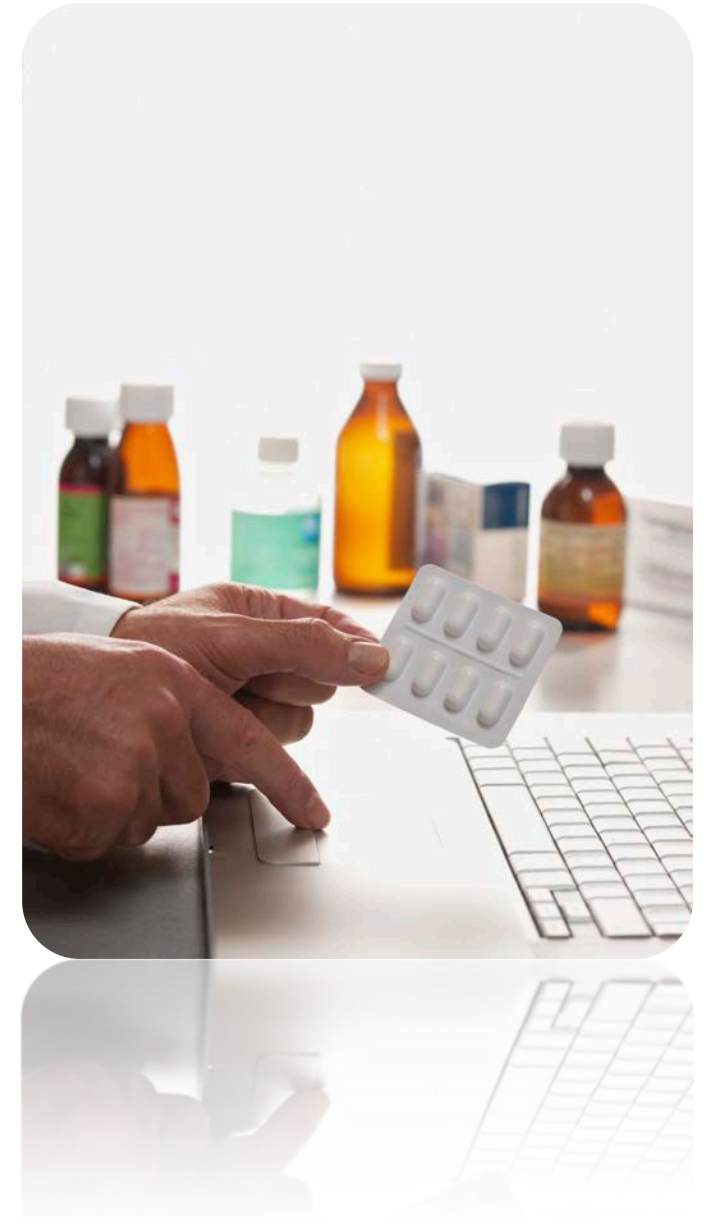
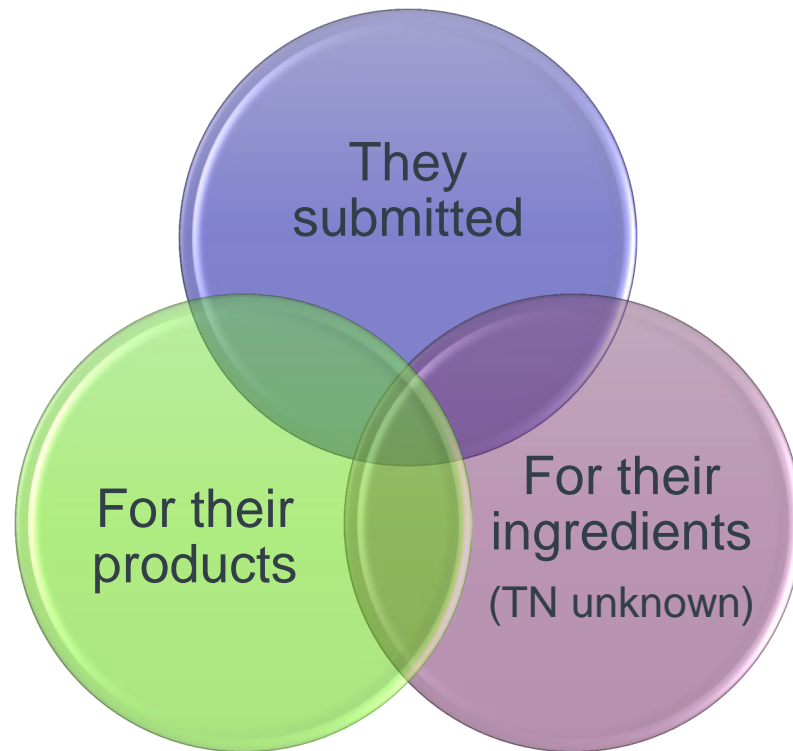
NEW functionality will enable sponsors to:

- **Search** for adverse events related to their products
- **Refine** search results
- **Download** adverse event data:
 - ✓ Public case details
 - ✓ Case line listings



What information can be accessed?

Using the system, sponsors can access reports:



In initial release, agents can only access reports they submitted to TGA

How is the information released?

Under 2 new legal instruments

- [Therapeutic Goods \(Adverse Event Management System - Sponsors\) \(Information\) Specification 2023](#)



Specifies certain therapeutic goods information relating to adverse events involving medicines or biologicals that the Secretary may release to the sponsor (and persons authorised to act on behalf of the sponsor) of the relevant goods under subsection 61(5AA) of the Act.

- [Therapeutic Goods \(Adverse Event Management System - Sponsors\) \(Arrangement for Computer Programs\) Instrument 2023](#)

Arrangement under subsection 7C(1) of the *Therapeutic Goods Act 1989* for use of computer programs to release de-identified adverse event information to sponsors relevant to their therapeutic goods.

How does it work?

Accessed via TGA online

Use eBS credentials to login.

- ✓ Users can only see reports relevant to their organisation
- ✓ New user guidance will be available

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Adverse Event Reporting

[Back to tga.gov.au](#)

Welcome

Why report an adverse event?

The TGA monitors adverse events (such as side effects) related to medicines and vaccines to safeguard and enhance the health of the Australian community. Unfortunately, it is not possible to know all potential adverse events of a medicine or vaccine before it is approved for use.

When people tell us about their experiences using a particular medicine or vaccine, it helps us to monitor the safety of those products.

More information: [Reporting adverse events involving medicines, vaccines or medical devices.](#)

About reporting

We prioritise issues that may:

- have adverse health consequences for consumers as a result of public access to dangerous or inappropriate goods,
- affect confidence in our regulatory processes or contribute to a loss of confidence in therapeutic goods in Australia.

Report an adverse event to a medicine

You can submit an adverse event as either a registered or unregistered user. As a registered user, your contact details will be pre-populated, you can save drafts and also view or amend previously submitted reports.

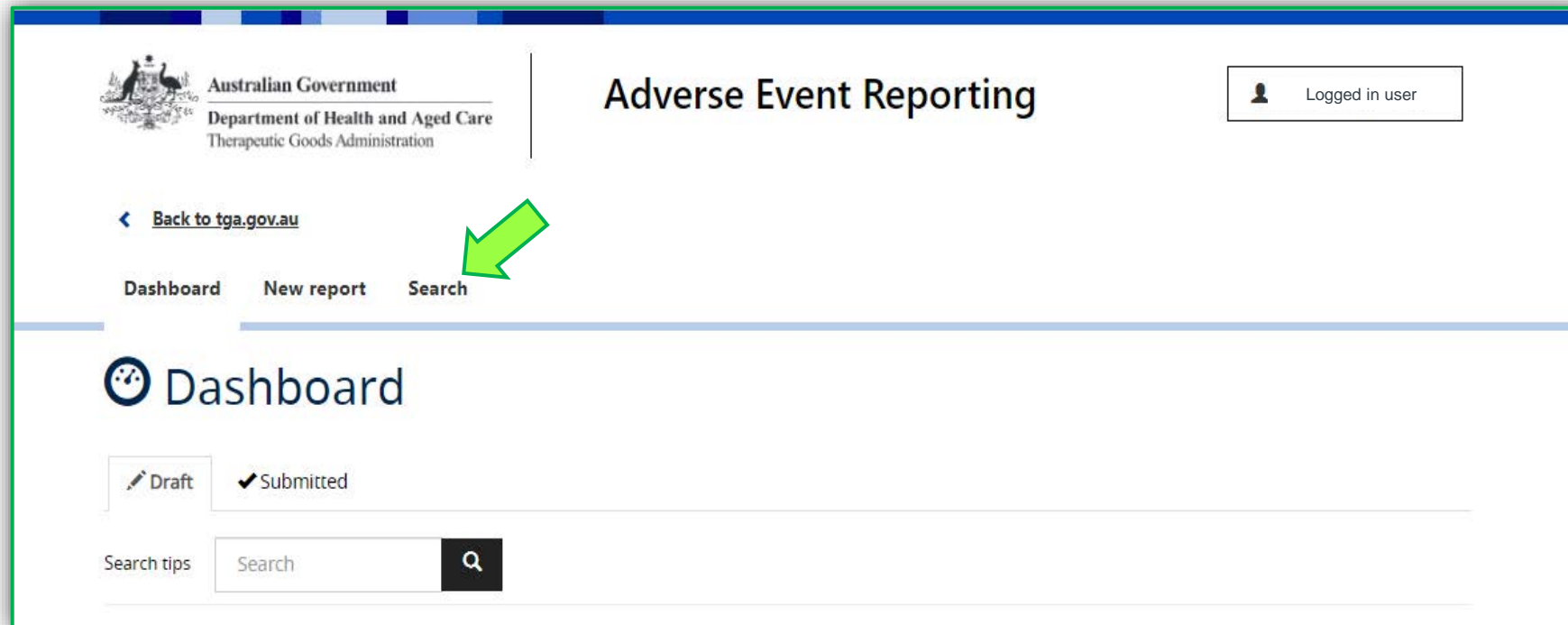
You can report adverse events of any medicine or vaccine, including medicines you get on prescription and over-the-counter, or complementary medicines that you buy from a pharmacy, supermarket, health food shop or the internet.

If you believe you are experiencing an adverse event it is important to speak to a health professional.

[Login](#) [Register](#) [Report \(without registering\)](#)

New menu item for registered sponsors/agents

Menu item *not* available for registered consumers or health professionals



Search parameters

Search parameters

Report date* Search for reports from 1 July 2018 to 14 days ago

01/07/2018 16/05/2023

Modified date* Search for cases that have been modified recently

01/07/2018 30/05/2023

Medicines

All selected

System organ class

All selected

MedDRA reactions

All selected

Report type

All selected

Causality Identify accepted, rejected and withdrawn cases

3 selected

Case identifiers Search by TGA ID, ICSR identifier, etc

Report source Identify reports submitted by your organisation or others

All selected

Age range

All selected

Sex

All selected

Generate reports

Reports can be generated using selected cases

Report format available as:

- ✓ Case line listing (CLL) or
- ✓ Public Case Details (PCD)

Search results - 22 cases found (4 selected)

Report name: *

[Generate PCD](#) [Generate CLL](#) [View reports](#)

Show entries

| <input type="checkbox"/> | TGA Case ID | Report date | Serious | Sender type | Age | Sex | Medicines | Reactions | Modified on |
|--------------------------|-------------|-------------|---------|-------------|-----|-----|-----------|-----------|-------------|
|--------------------------|-------------|-------------|---------|-------------|-----|-----|-----------|-----------|-------------|

Download reports

Sponsor's adverse event search



This search is limited to cases relevant to your organisation: either those you submitted, those associated with a medicine trade name you have sponsored, or where no trade name was specified, containing the same active ingredient/s as your sponsored medicine. You must [notify us](#) if you identify a case in your search results that does not relate to your organisation or products. See the [AEMS guidance](#) for sponsors for more information.

We make every effort to remove, from this view, personal information that could make an individual identifiable (e.g. names, dates of birth or hospital location). You must [report to us](#) any instance where you identify any visible personal information in this view, and ensure you remove any such personal information from your own copies of the information.

New search

Generated reports

Each Public Case Details (PCD) and Case Line Listing (CLL) report may take a few minutes to generate. Once complete, they can be viewed in this table. Click on the report name to download the report. If you cannot find the report you generated, please refresh this page to check if it is ready to download.

Search generated reports

| Report name | Type | Generated by | Generated on ↓ | Status |
|-------------------|------|--------------|--------------------|-----------|
| PCD test - Claire | PCD | | 31/05/2023 9:45 AM | Generated |
| CLL test - Claire | CLL | | 31/05/2023 9:42 AM | Generated |

View Report

View report

Report name ↑

Generated on

PCD test - Claire - 20230531 09.48.29.DOCX (59 KB)

31/05/2023, 9:48 AM

Report format – CLL

Excel document with following data fields:

Report

- Case No.
- Report Type
- Study Type
- Report Date
- Worldwide ID
- Modified On
- Causality
- Is Serious Case

Sender

- Sender Type
- Sender's ICSR Identifier

Patient

- Sex
- Age
- State
- Ethnicity
- Sub-ethnicity

Medicine and reaction

- Reaction
- Onset Date
- Reaction Outcome
- Medicine (Onset Time)
- Case narrative

Report format – PCD

Word document

Public Case Details

Filter(s):

Report date: >= 01/07/2018 <= 17/05/2023

Modified date: >=07/12/2021 <=31/12/2021

Medicine(s): ALL

Case identifiers: ALL

System organ class: ALL

MedDRA reactions: ALL

Report source: ALL

Report type: ALL

Causality: Causality certain; Causality probable/likely; Causality possible

Age: 18 to 64

Sex: ALL

Number of cases in this report: 4

Case ID: AU-TGA-0000#####

Case details:

Report Type: Spontaneous report

Study Type: Unknown

Report Date: 10/04/2023

Worldwide ID: Example ID #####

Modified on: 27/04/2023

Causality: Causality possible

Serious ICSR: Yes

Patient details:

Sex: Female

Age:

State:

Ethnicity:

Ethnicity sub-group:

Reporter details:

Qualification: Other health professional

Sender details:

Type: Pharmaceutical Company

ICSR identifier: Example ID 12345

Case narrative:

Example text for illustration

Reactions:

| Preferred term | Onset Date | End Date | Management of Event | Outcome |
|------------------|------------|----------|---------------------|----------------------|
| Example reaction | | | | Recovering/resolving |

Drug information:

(1) Suspect medicine (active ingredient) - Suspect

Dosage Information:

Treatment Details:

Indication:

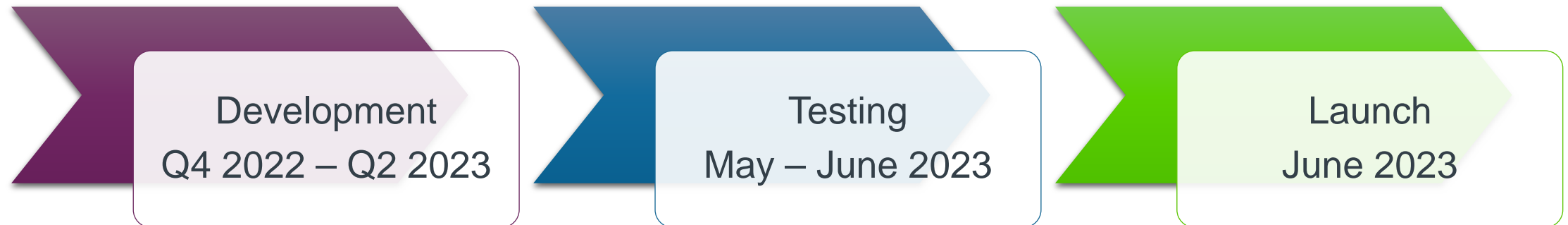
Action Taken:

Test and procedures:

| Test name | Test date | Normal range | Test result | Comment |
|--------------|------------|--------------|---------------------|---------|
| Example test | 22/11/2020 | Not Provided | Test Result: normal | |

When will the sponsor adverse event search be available?

Currently in final stages of testing, to be followed by soft launch prior to publication



Website references

TGA website

www.tga.gov.au

Database of Event Notifications (DAEN)

<https://daen.tga.gov.au/medicines-search/>

Adverse Event Reporting

<https://aems.tga.gov.au/>

TG Adverse Event management System –Specifications 2023

<https://www.tga.gov.au/section-7c-instruments>

TG Adverse Event Management System – Instrument 2023

<https://www.tga.gov.au/specifications>

Therapeutic Goods Administration (TGA)

Exhibition booth No.1

Want to chat with me further? Come visit us.





Questions?

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