Sharing adverse event data for medicines and vaccines

Dr Claire Larter
Director, Adverse Event and Medicine Defect Section
Pharmacovigilance Branch
Department of Health and Aged Care, TGA

- 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

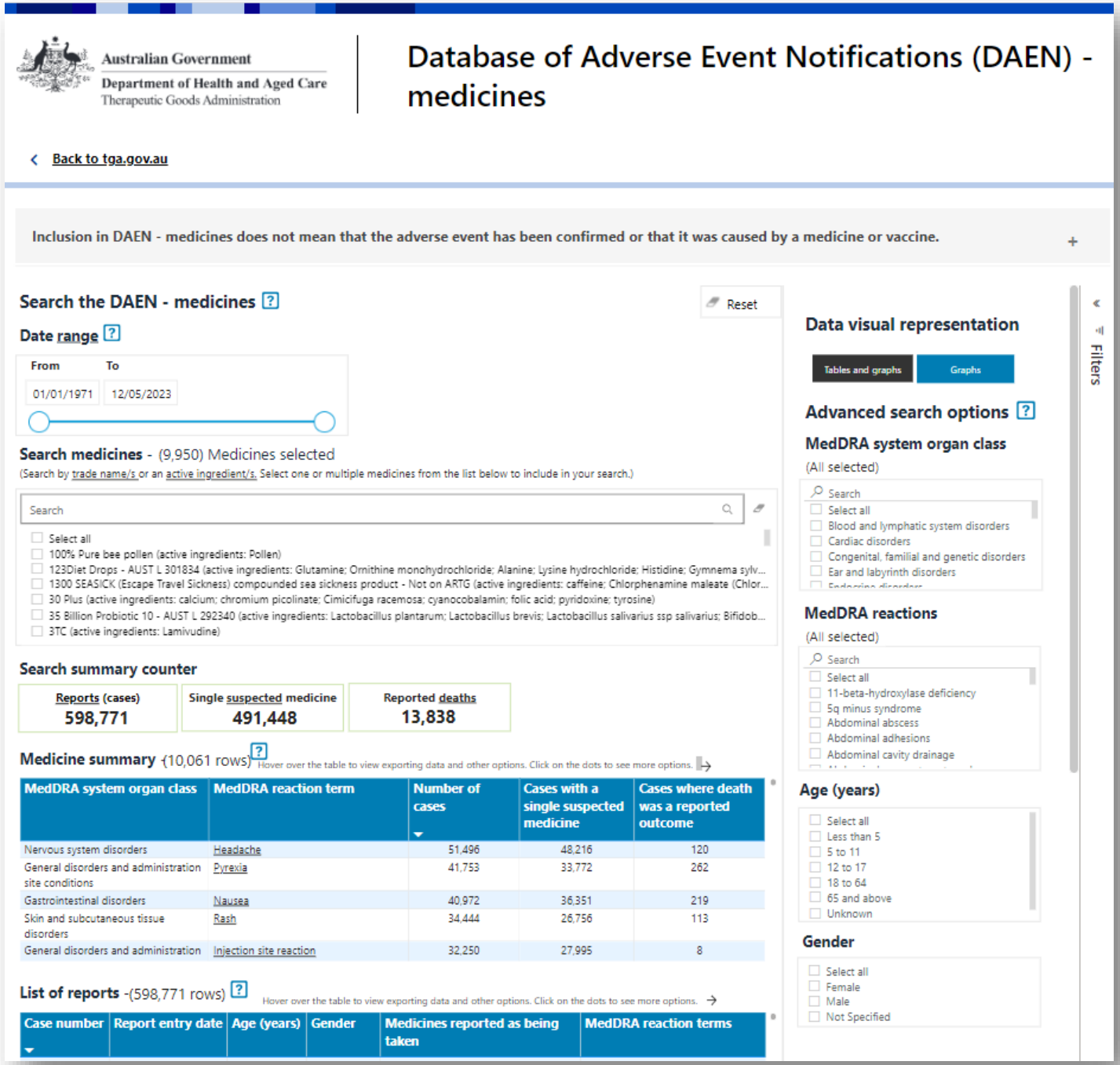
How has the TGA improved sharing of AE data?

- New DAEN – medicines
- Automated AEFI sharing
- Sponsor adverse event search

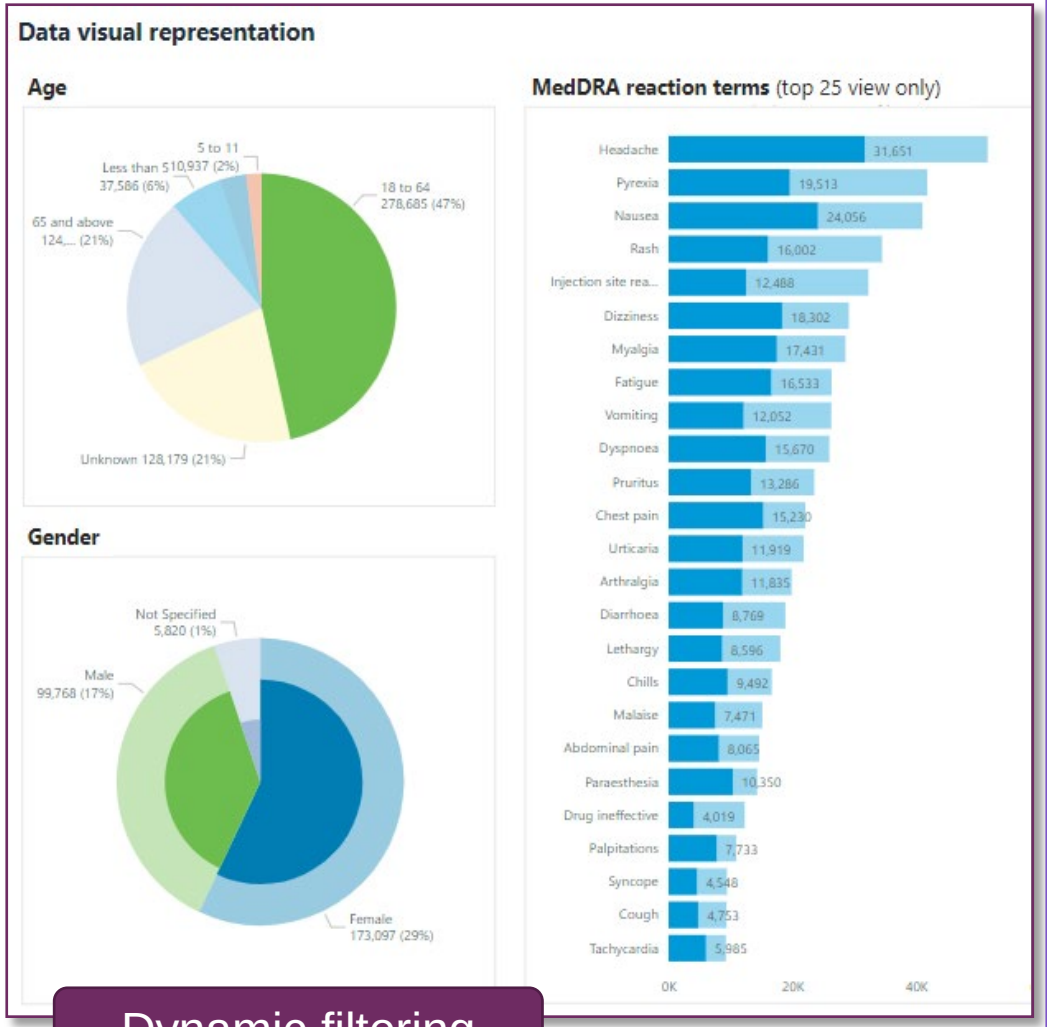
DAEN – medicines

One year after launch

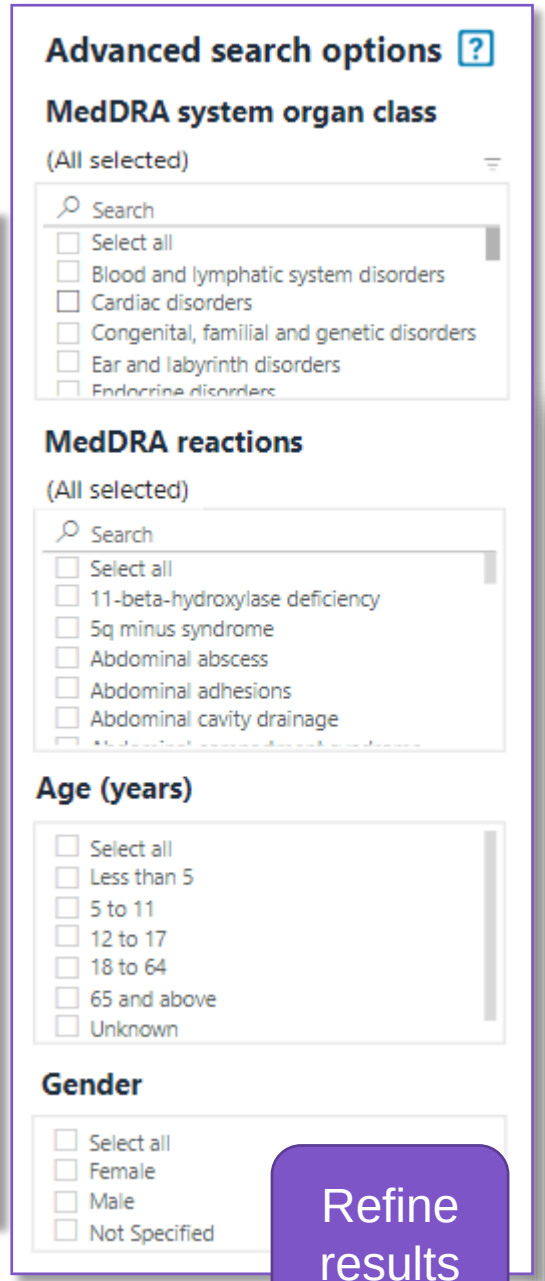
- User feedback sought on beta version in October 2022
  - ✓ 70% of respondents preferred the new DAEN
  - ✓ 60% of respondents found the graphs were useful
  - ✓ Updated user guidance to address areas of concern
- Beta version has replaced old version



Features of new DAEN

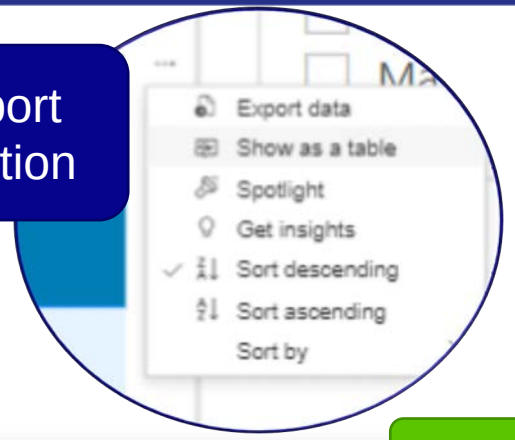


Dynamic filtering

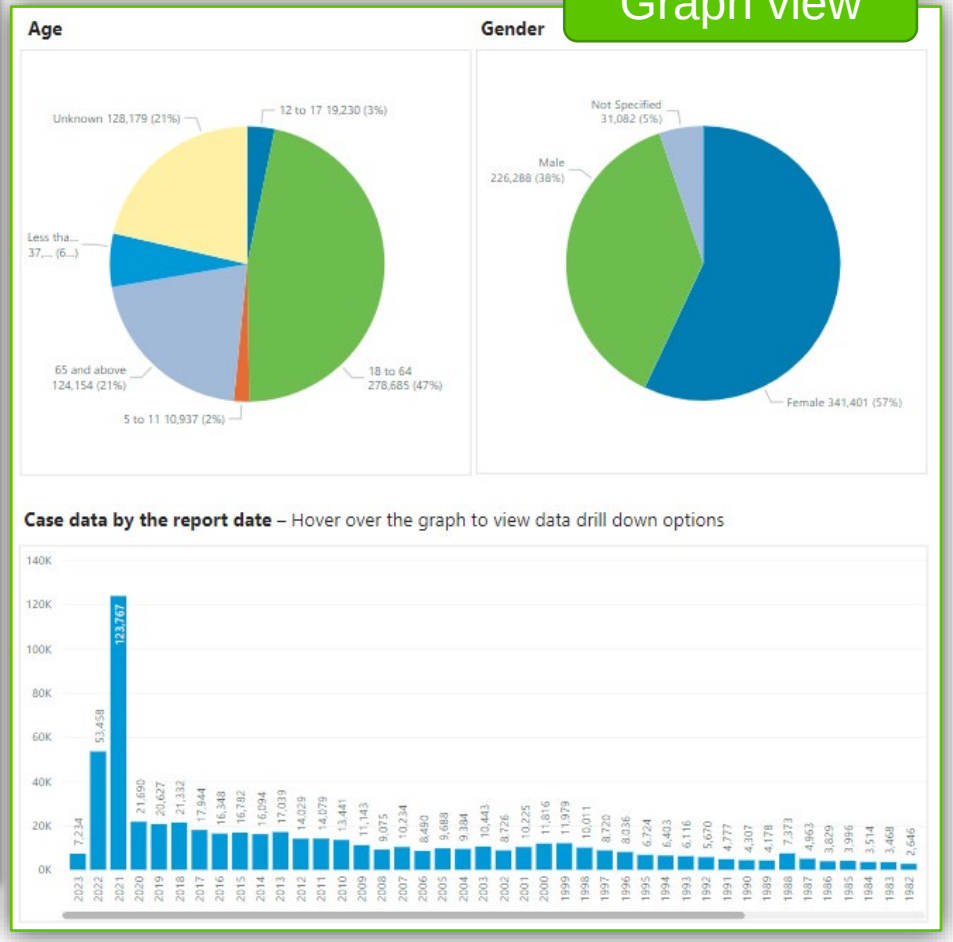


Refine results

Export function



Graph view



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 state

  to 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.

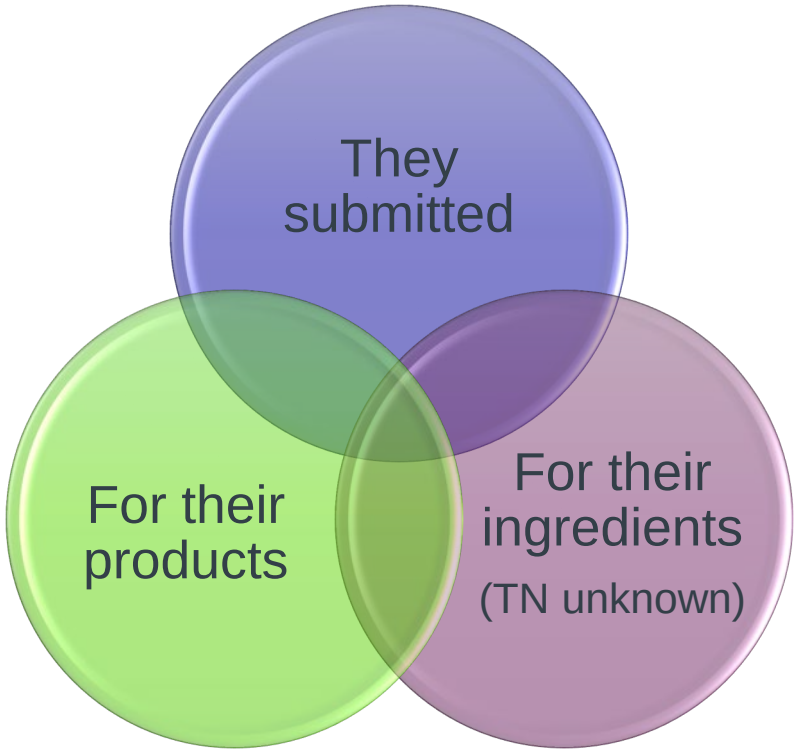
Sponsor adverse event search

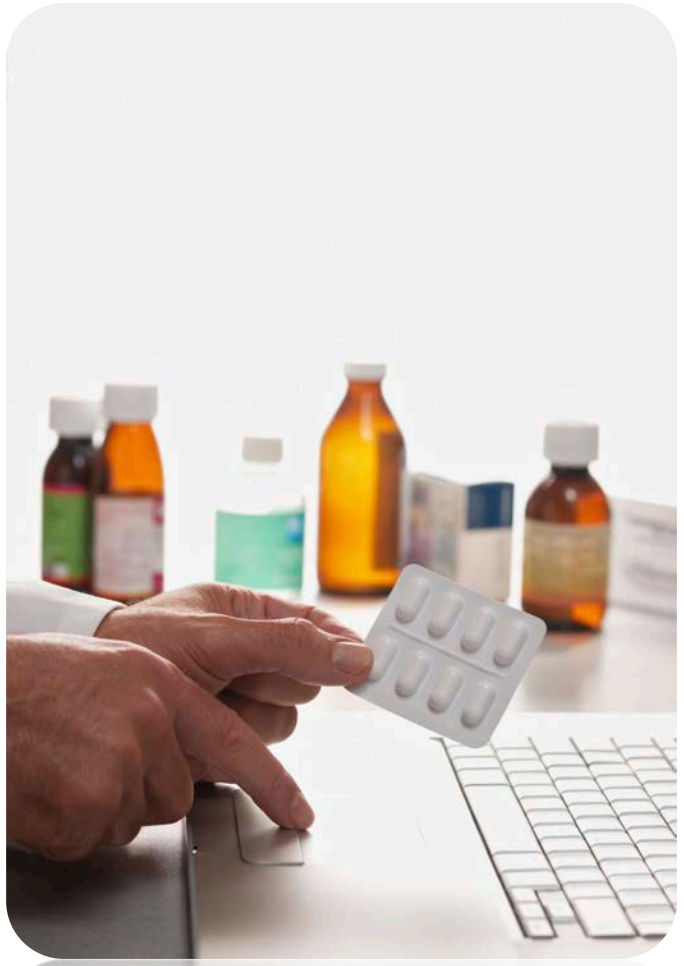
NEW functionality will enable sponsors to:

- **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

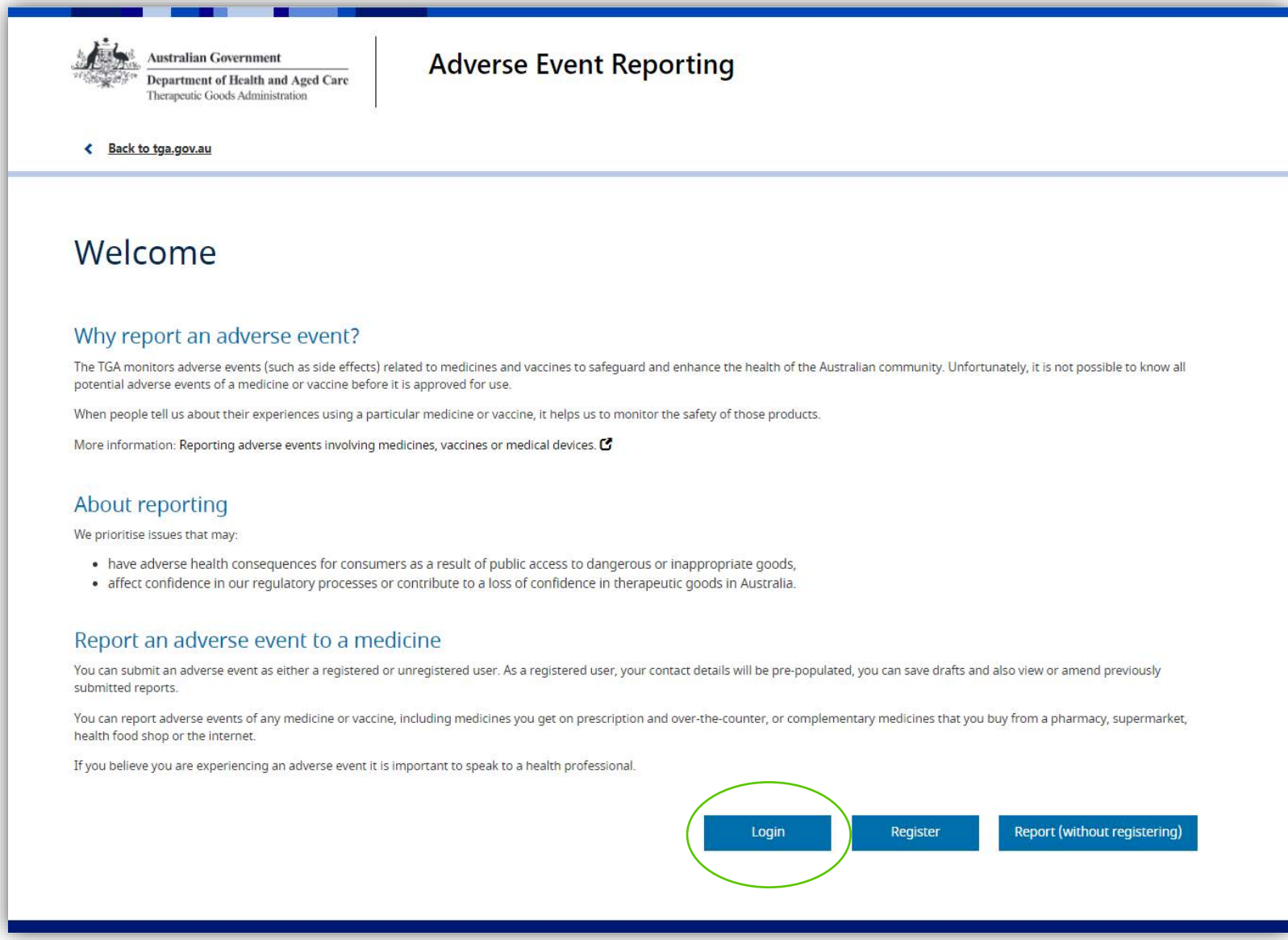
  Arrangement under subsection 7C(1) of the *Therapeutic Goods Act 1989* for use of computer programs to release de-identified adverse event information to sponsors relevant to their therapeutic goods.

How does it work?

Accessed via TGA online

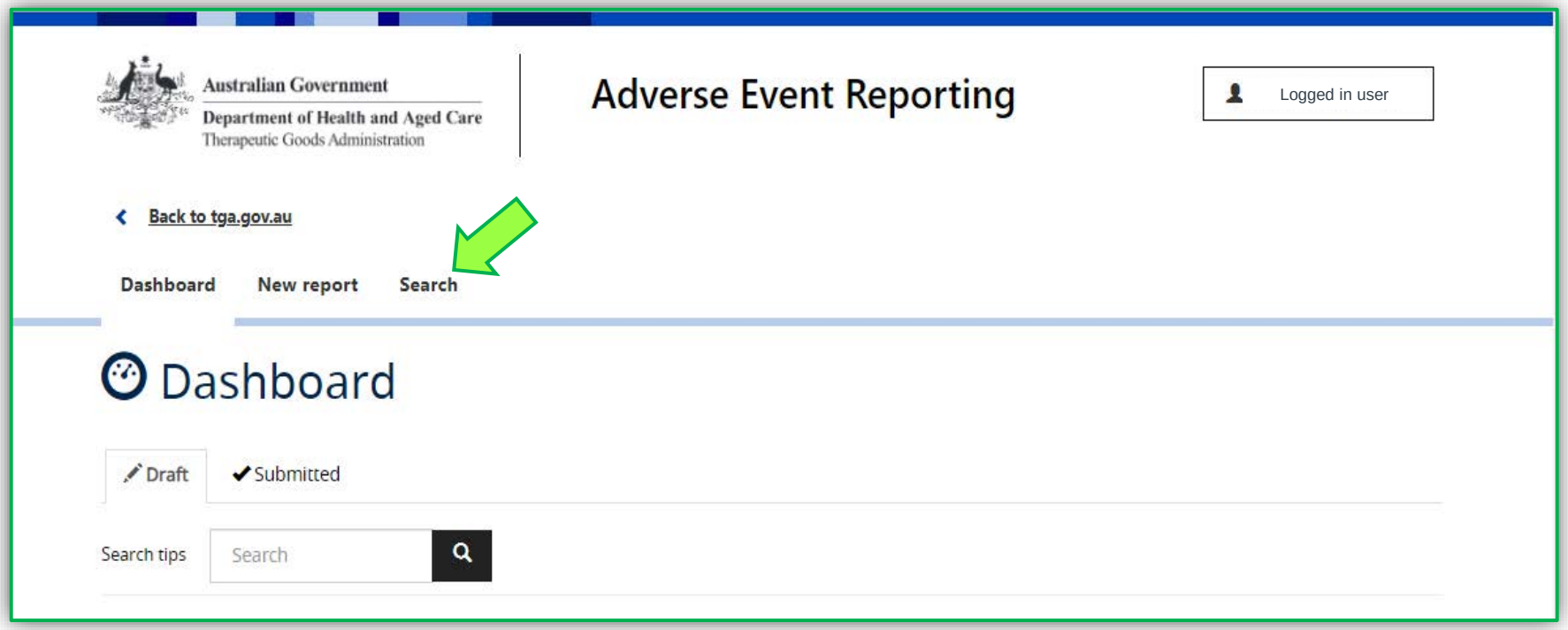
Use eBS credentials to login.

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

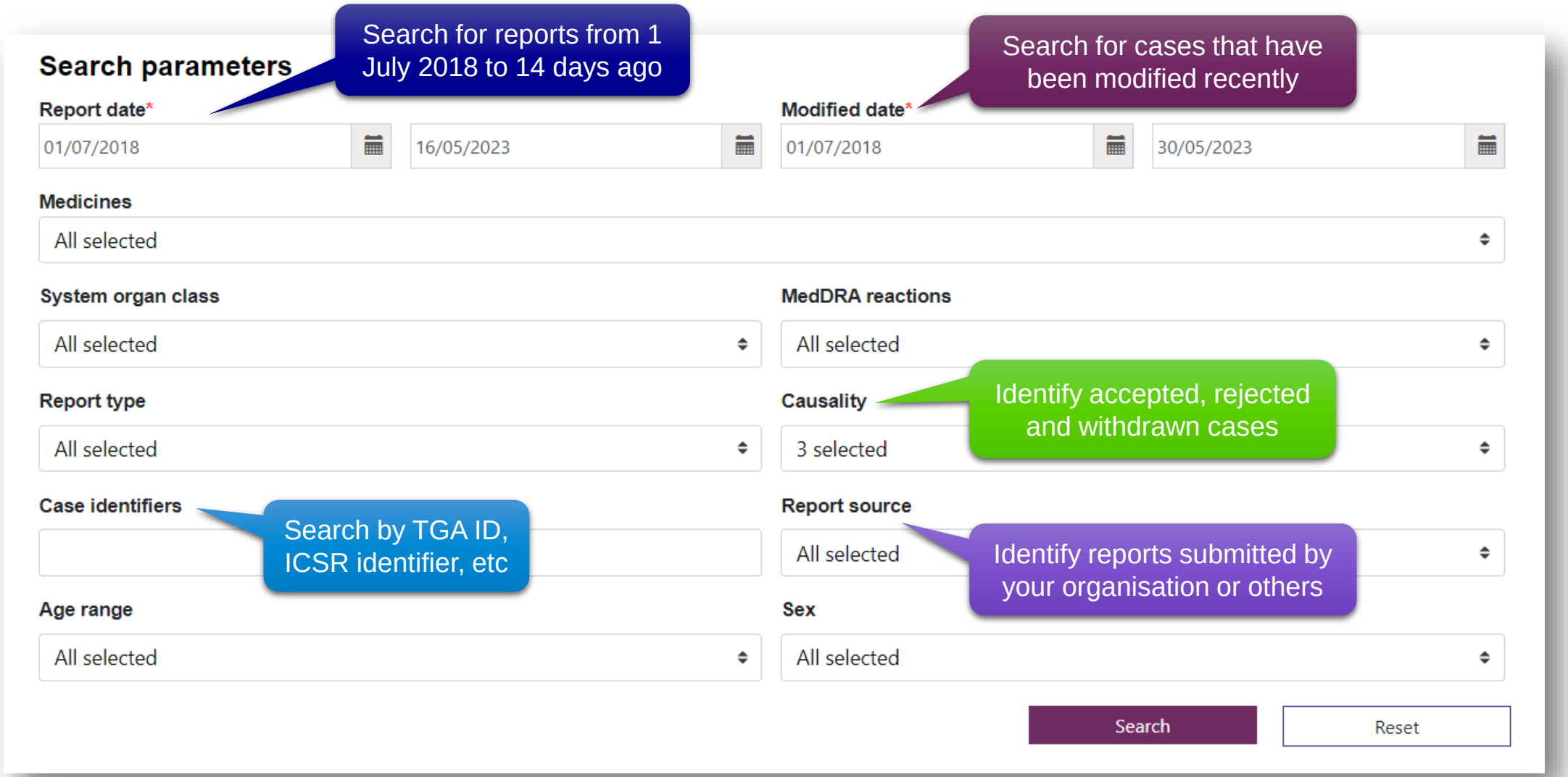


New menu item for registered sponsors/agents

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



Search parameters

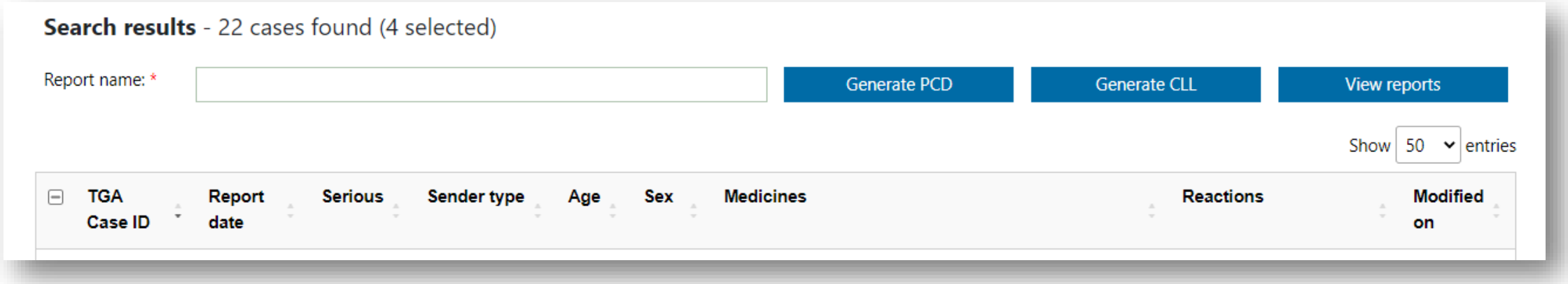


Generate reports

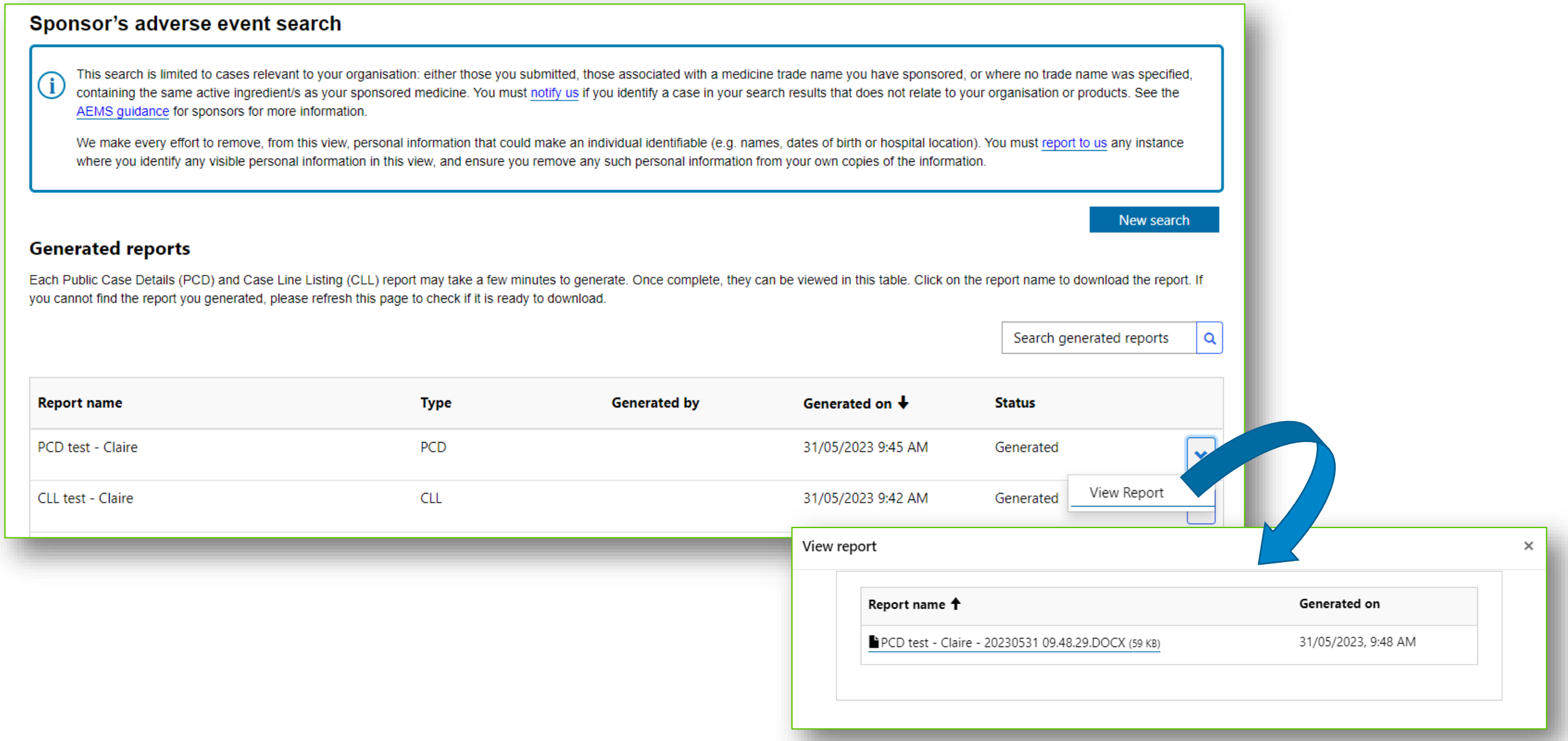
Reports can be generated using selected cases

Report format available as:

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



Download reports



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:

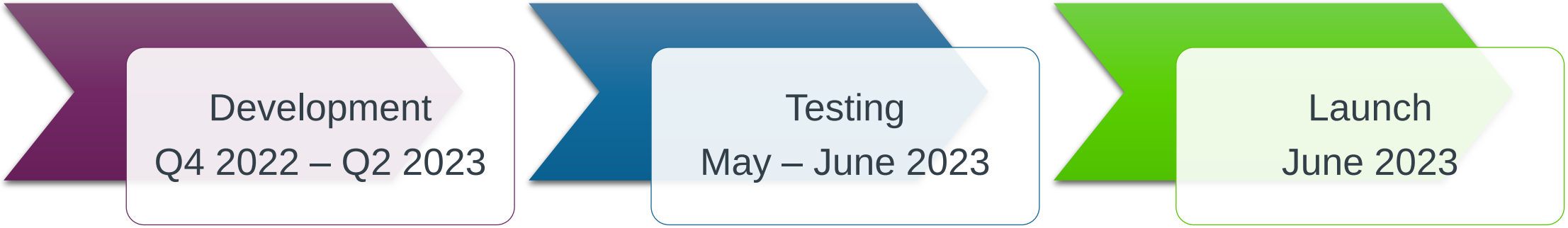
(1) Suspect medicine (active ingredient) - Suspect	
Dosage Information:	
Treatment Details:	
Indication:	
Action Taken:	

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?

www.tga.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration