



Australian Government

Department of Health

Therapeutic Goods Administration

Medicine and vaccine adverse events reporting and data

Now and into the future

Dr Claire Larter and Jola Samoc
Pharmacovigilance Branch
Medicine Regulation Division, TGA

ARCS

25 May 2022

TGA Health Safety
Regulation

COVID-19 vaccine roll-out: preparation & response

2020

Preparing processes

Enhancing capacity

Technical improvements

2021

Agile approach to process

Further expand data entry capacity

DAEN changes and IT enhancements

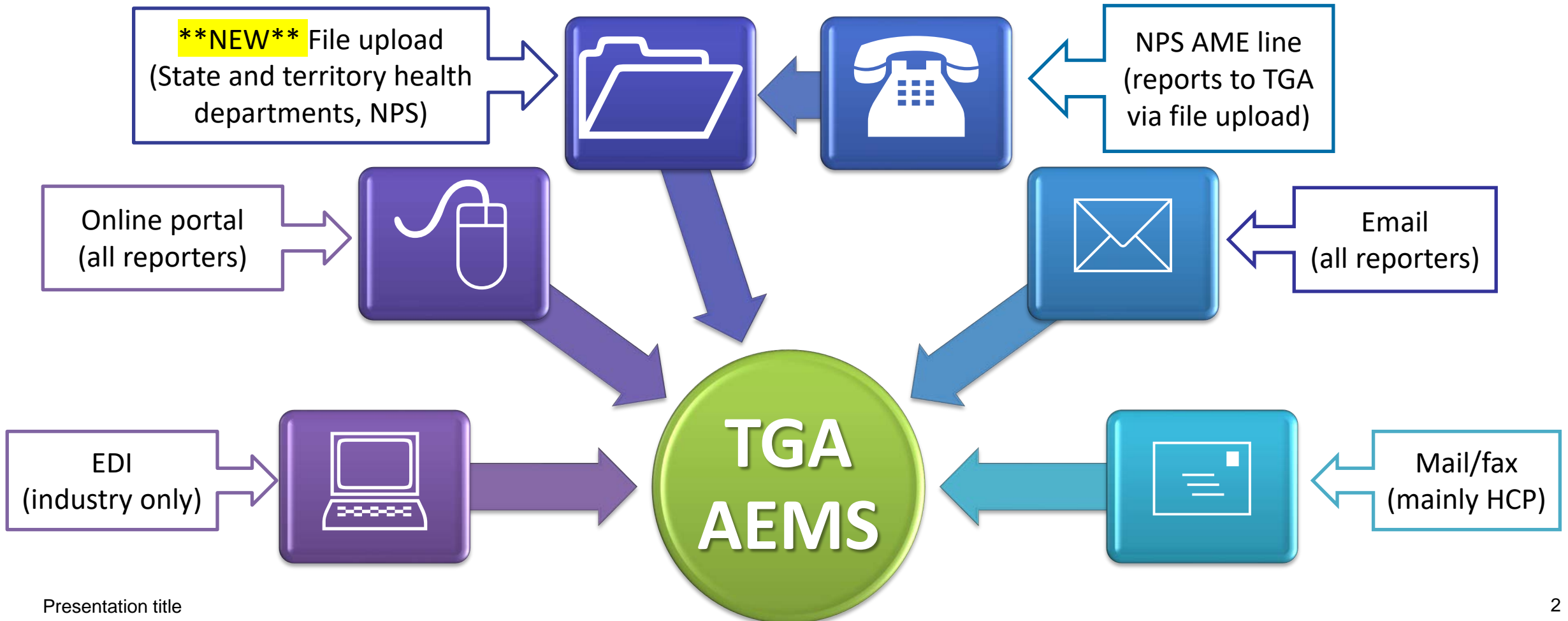
2022

Review and consolidate process changes

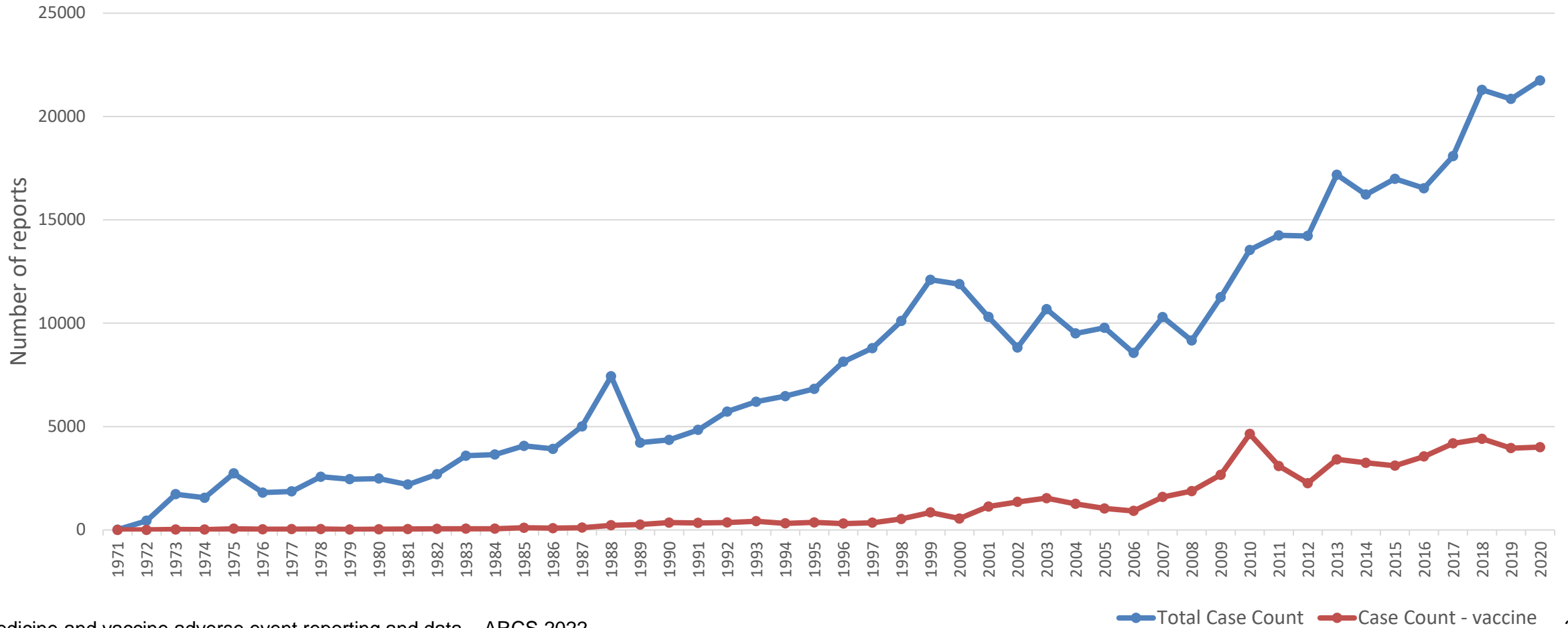
Forecast team contraction

MAEDX project ongoing

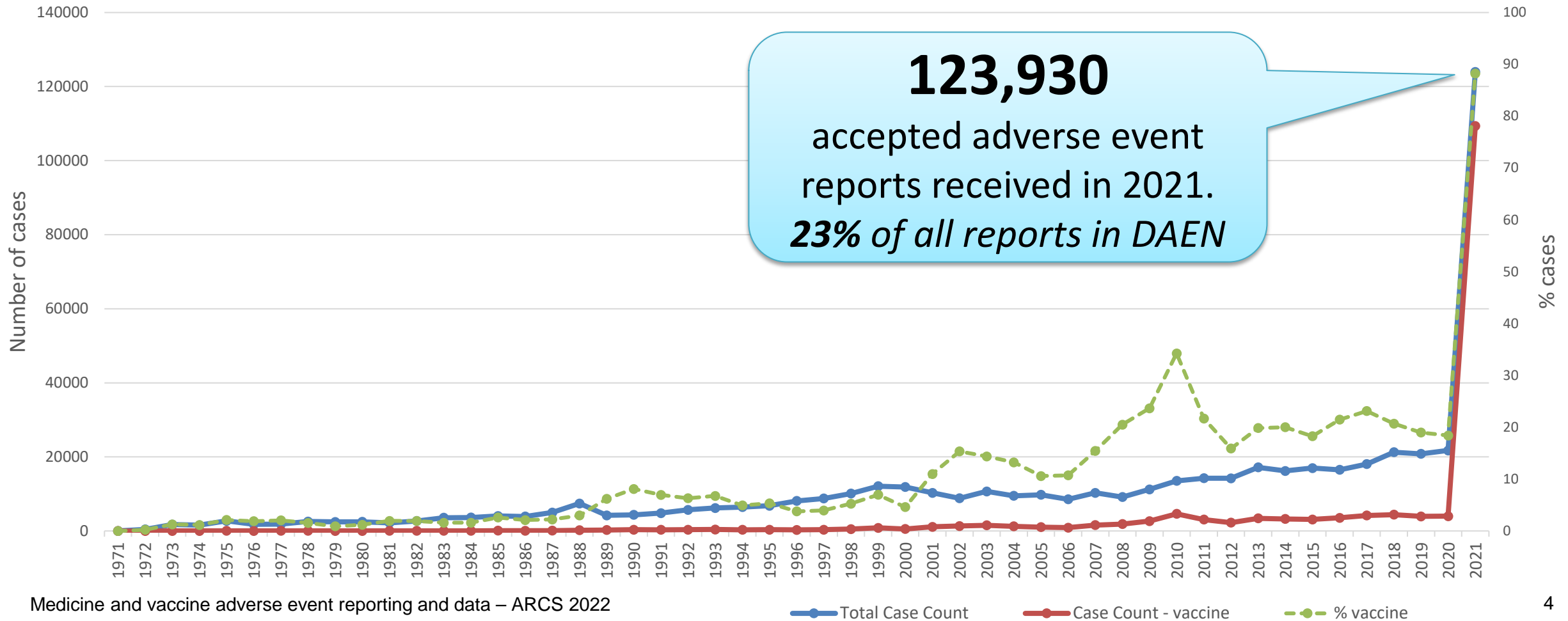
New reporting channel



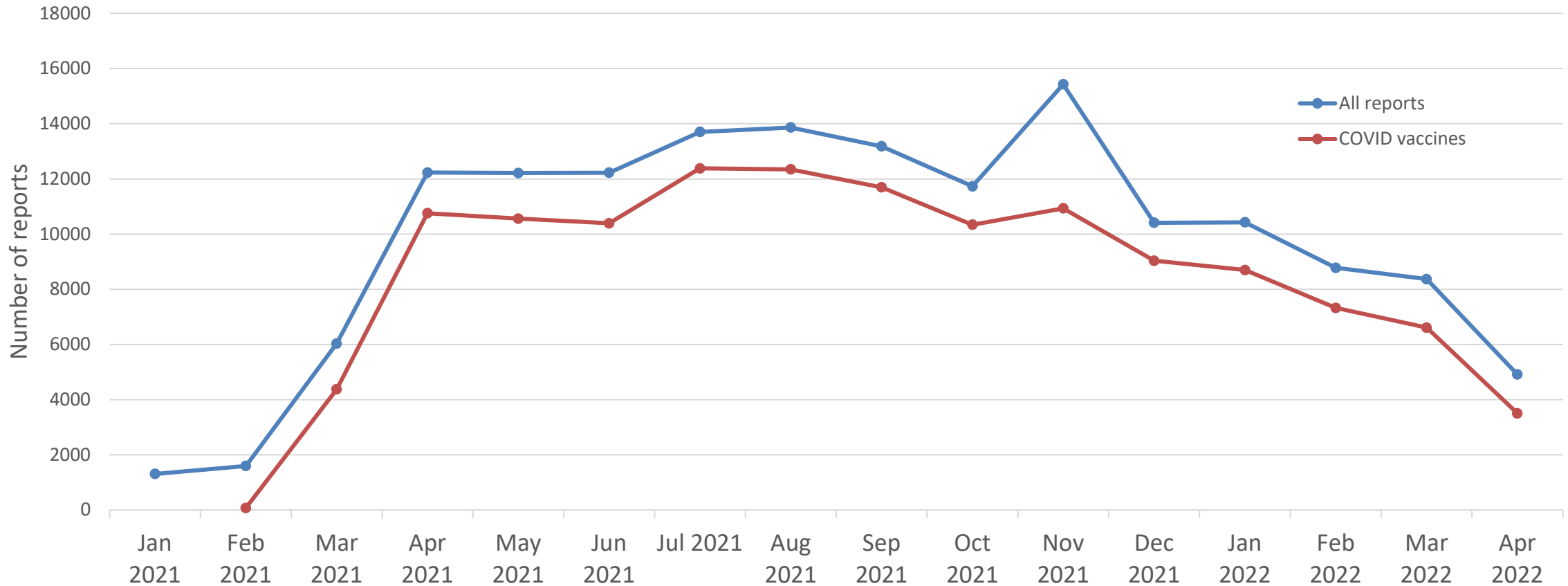
Adverse event reporting to 2020



Adverse event reporting in 2021

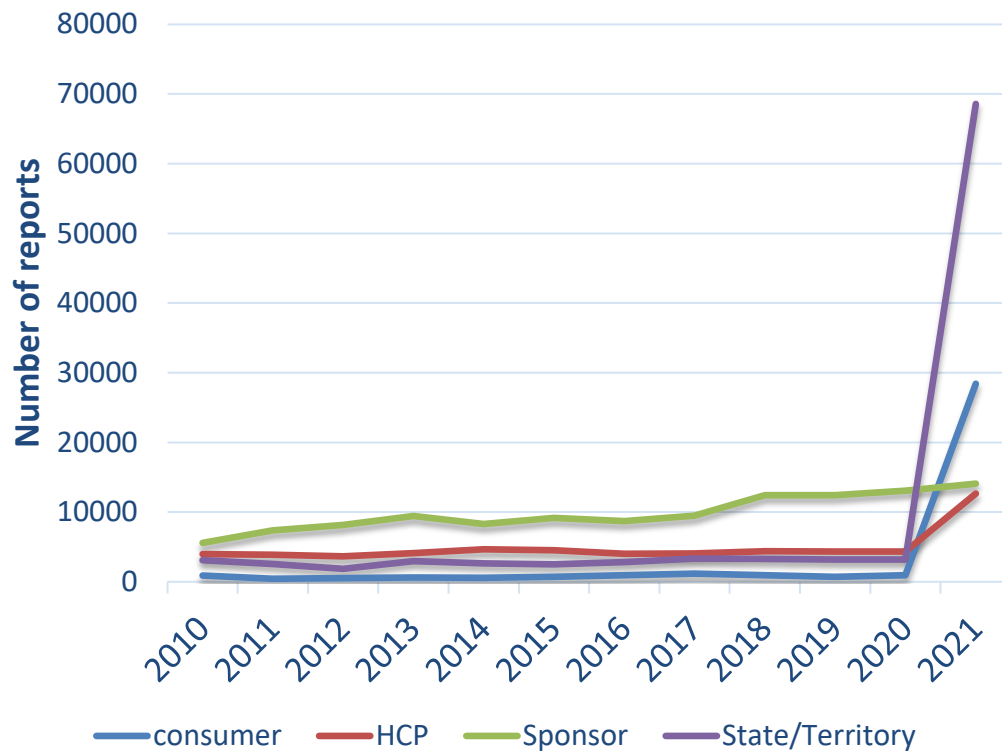


Reporting levels – 2021-22

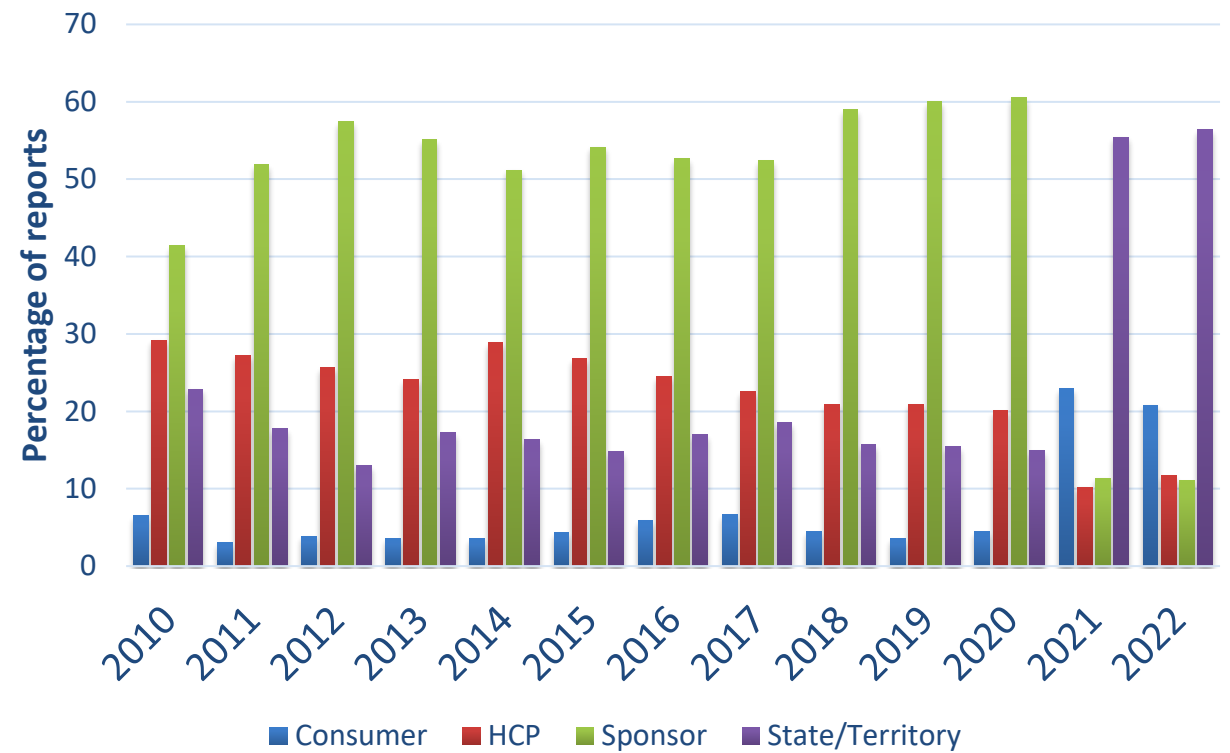


Changing sender types

Reporter type over time

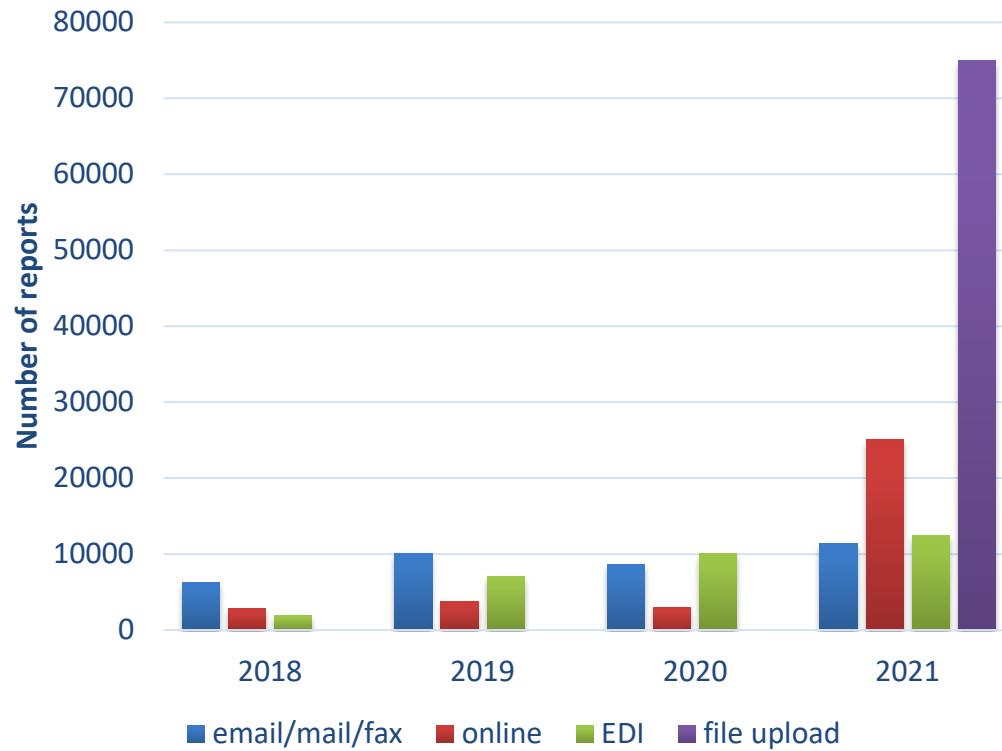


Reporter type - proportion

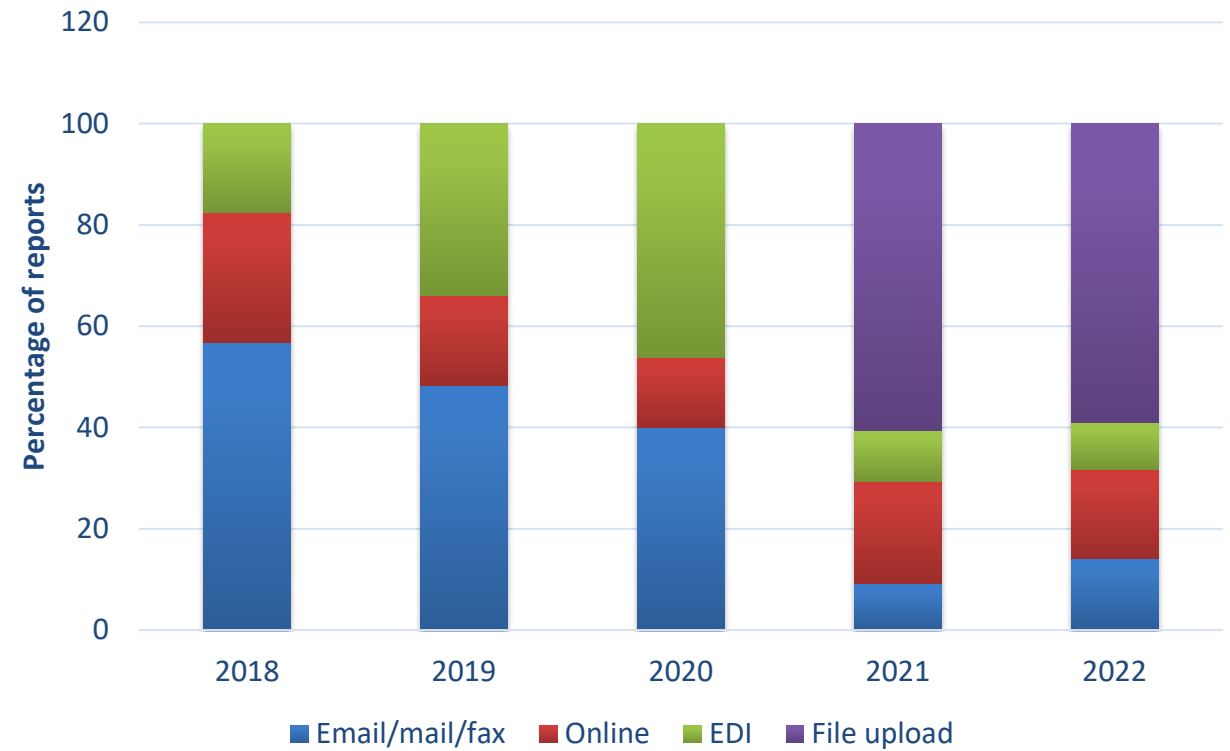


Changing channels

Input channel over time



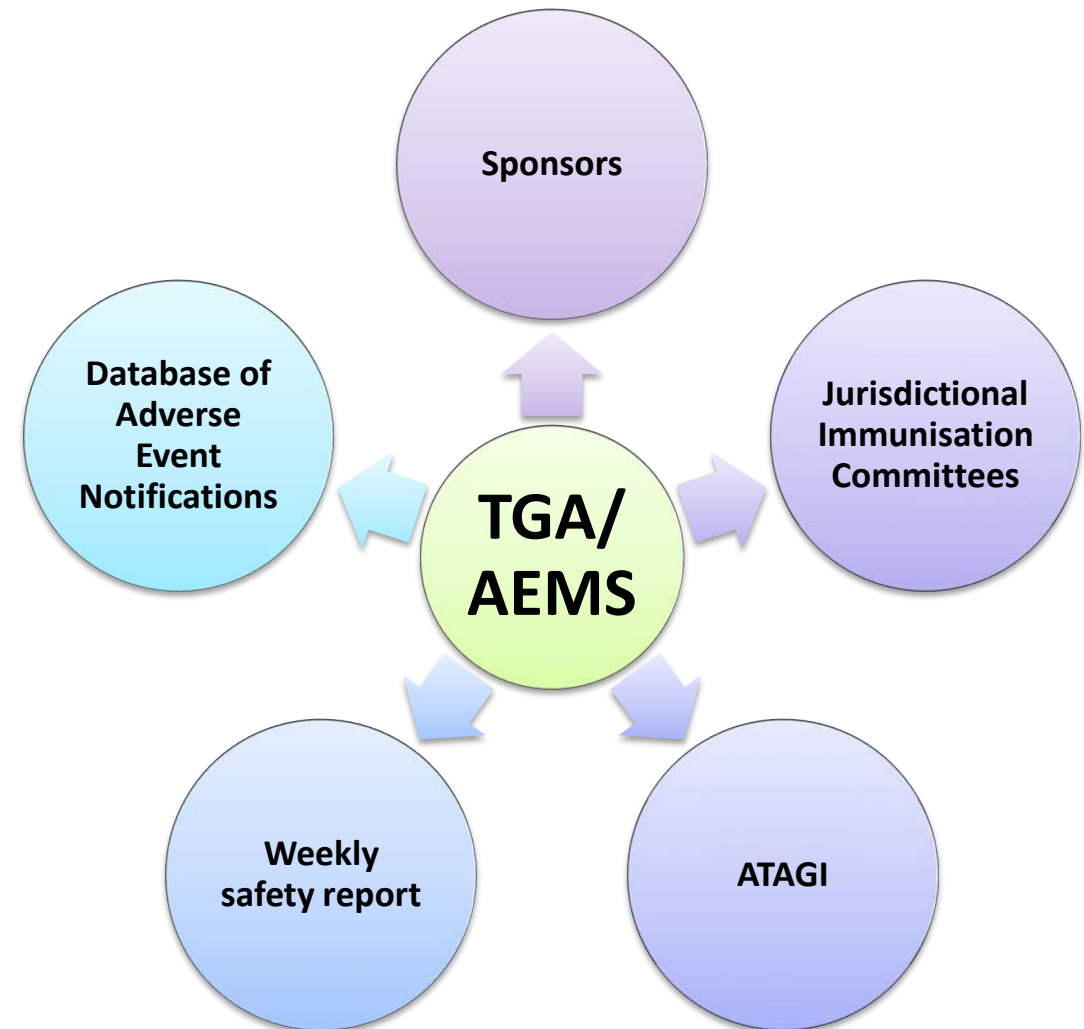
Input channel - proportion



Sharing COVID-19 vaccine adverse event data

Increased frequency and intensity of sharing adverse event data

- Decreased time lag for DAEN from 90 to 14 days
- Weekly sharing of information through multiple channels



COVID-19 vaccine weekly safety report

Weekly report includes:

- Reporting statistics
- PI changes
- Updates on signal investigations
- VSIG outcomes
- Special interest topics, e.g.
 - ❖ children
 - ❖ boosters
 - ❖ AEs of interest, such as menstrual disorders, lymphadenopathy

The screenshot displays the TGA website's 'Safety information' section for COVID-19 vaccines. The page title is 'COVID-19 vaccine weekly safety report - 05-05-2022', released on Thursday, 5 May 2022. The main content states that four COVID-19 vaccines are currently in use in Australia: Comirnaty (Pfizer), Spikevax (Moderna), Vaxzevria (AstraZeneca), and Nuvaxovid (Novavax). It notes that these vaccines must meet the TGA's high standards for quality, safety, and effectiveness. The TGA closely monitors reports of suspected side effects (adverse events) to these vaccines, which is the most intensive safety monitoring ever conducted in Australia. A call to action encourages reporting suspected side effects, even if the chance is small, as this helps identify potential safety issues. A 'Summary' section highlights that vaccination against COVID-19 is the most effective way to reduce deaths and severe illness from infection, with protective benefits outweighing potential risks. The page also includes a navigation menu, a search bar, and a list of related links on the right side.

Tackling misinformation

- Intense scrutiny of vaccine rollout, including adverse event reports
- Questions about safety via:
 - Media (including ‘fact checks’)
 - Freedom of Information
 - Direct enquiries
- Require clear and consistent messaging
- Weekly report played a key role



Adverse event reporting into the future

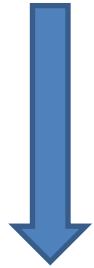
Build on public awareness

Improve data sharing with stakeholders

New channels for reporting



**Easier sharing of medicine
and vaccine adverse
events data**



Medicine Adverse Event Data Exchange (MAEDX)



Now...



What you told us...

- Need ability to view and export relevant data from TGA systems
- System-to-system data transfer via EDI Gateway
- Need more data to help identify duplicates
- Use of E2B R3 to submit cases – must be voluntary



The future... now: DAEN – medicines beta

Current DAEN – medicines

Safety information

- Product recalls
- Alerts
- Early warning system
- Reporting problems
- Safety information & education**
- Medicines safety
- Medical devices safety
- Database of Adverse Event Notifications (DAEN)

Database of Adverse Event Notifications - medicines

Important information! The TGA uses adverse event reports to identify when a **safety issue** may be present.

- An adverse event report does **not** mean that the medicine is the **cause** of the adverse event.
- If you are experiencing an adverse event, or think you may be experiencing one, please **seek advice from a health professional** as soon as possible.
- The TGA strongly advises people taking prescription medicines **not** to change their medication regime without prior consultation with a **health professional**.

Related information

- About the DAEN - medicines
- Report an adverse event
- Consumer Medicines Information
- Product Information

The Database of Adverse Event Notifications (DAEN) - medicines allows you to search adverse event reports for medicines including vaccines received by the TGA. These reports came from a wide range of sources, including from members of the public, GPs, other health professionals and from the therapeutic goods industry.

People who experienced an adverse event cannot be identified, and maintaining their privacy has been of paramount importance to the TGA.

[More about the database](#)

Search the DAEN - medicines

You must select medicines and a date range.

- Select medicines** [\[Further information about selecting a medicine\]](#)

Type at least 3 characters

Enter a trade name or an active ingredient:

- Select date range** [\[Further information about the date range\]](#)

From: 1971 To: 2022

Reports from the last fourteen days have not been included in the database. [Why?](#)

[Show advanced search options](#) [\[Further information about advanced search options\]](#)

Search

DAEN – medicines beta

Search the DAEN - medicines

Date range: 01/01/1971 to 18/04/2022

Search medicines - (9408) Medicines selected

Search summary counter:

Reports (cases)	Single suspected medicine	Reported deaths
555844	456429	12267

Medicine summary - (9630 rows)

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	47059	44112	108
General disorders and administration site conditions	Pyrexia	38784	31352	234
Gastrointestinal disorders	Nausea	38264	33955	195
Skin and subcutaneous tissue disorders	Rash	32422	25116	108
General disorders and administration site conditions	Injection site reaction	29923	25875	9

List of reports - (555844 rows)

Case number	Report entry date	Age (years)	Gender	Medicines reported as being taken	MedDRA reaction terms
1214	18/07/2021	10	Female

Data visual representation

Advanced search options

MedDRA system organ class

MedDRA reactions

Age (years)

Gender

The future... now: DAEN – medicines beta

Searching by tradename or active ingredient

Search the DAEN - medicines [?](#)

Date range [?](#)

From: 01/01/1971 To: 18/04/2022

Search medicines - (29) Medicines selected
 (Search by [trade name/s](#) or an [active ingredient/s](#). Select from the list below to include in your search.)

Search: PANADOL

- Select all
- Children's Panadol 1 month - 2 years Colourfree Baby Drops (active ingredients: Paracetamol)
- Children's Panadol 1-5yrs Colourfree Suspension (active ingredients: Paracetamol)
- Children's Panadol 5 - 12 Years Elixir (active ingredients: Paracetamol)
- Children's Panadol 5-12yrs Colourfree Suspension (active ingredients: Paracetamol)
- Children's Panadol 6 Months-5 Years Suppositories (active ingredients: Paracetamol)
- Children's Panadol 7+ Years Soluble (active ingredients: Paracetamol)

Search summary counter

Reports (cases) 981	Single suspected medicine 386	Reported deaths 30
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Medicine summary - (542 rows) [?](#)
 Hover over the table to view export and other data options →

MedDRA system organ class	MedDRA reaction term	Number of cases	Cases with a single suspected medicine	Cases where death was a reported outcome
Skin and subcutaneous tissue	Rash	95	25	0

Search the DAEN - medicines [?](#)

Date range [?](#)

From: 01/01/1971 To: 18/04/2022

Search medicines - (51) Medicines selected
 (Search by [trade name/s](#) or an [active ingredient/s](#). Select from the list below to include in your search.)

Search: AMOXICILLIN

- Select all
- ALPHACLAV DUO (active ingredients: potassium clavulanate; amoxicillin trihydrate)
- Alphaclav Duo Forte 875/125 (active ingredients: amoxicillin trihydrate; potassium clavulanate)
- Alphamox (active ingredients: amoxicillin trihydrate)
- AMCLAVOX DUO FORTE 875/125 (active ingredients: amoxicillin trihydrate; clavulanic acid)
- Amioxyn (active ingredients: amoxicillin trihydrate)
- Amoclav Co-Amoxiclav (active ingredients: amoxicillin; clavulanic acid)

Search summary counter

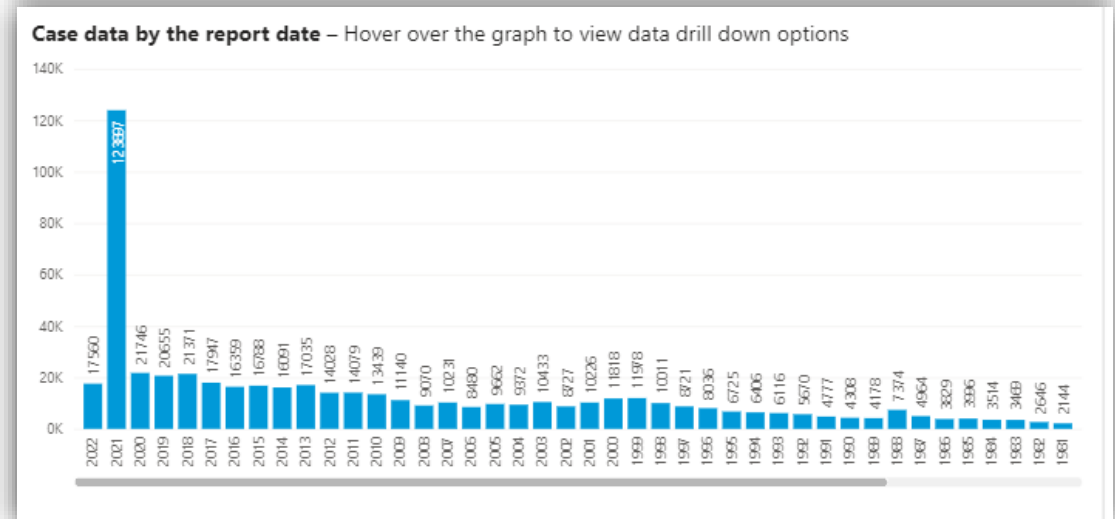
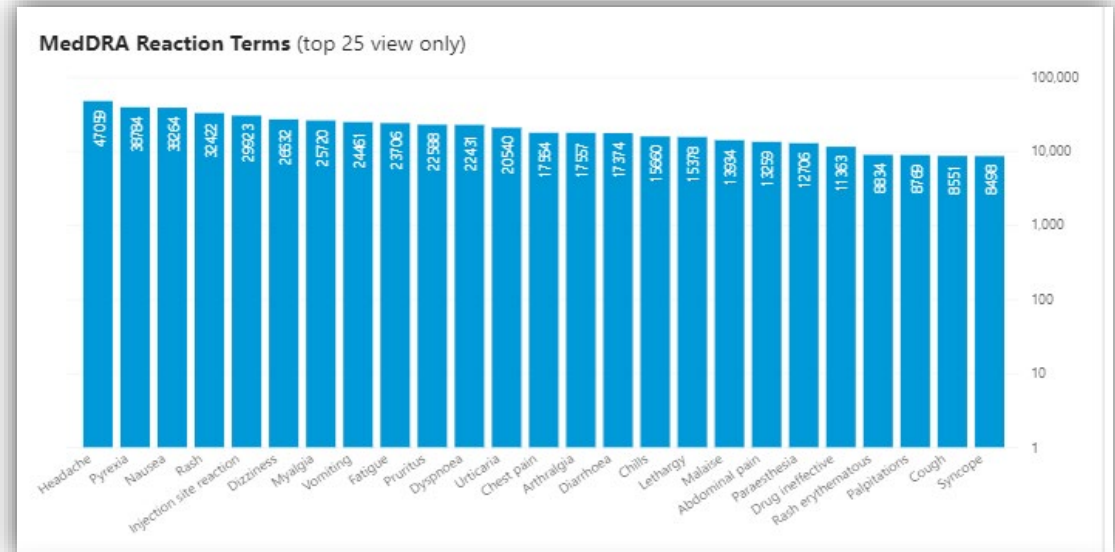
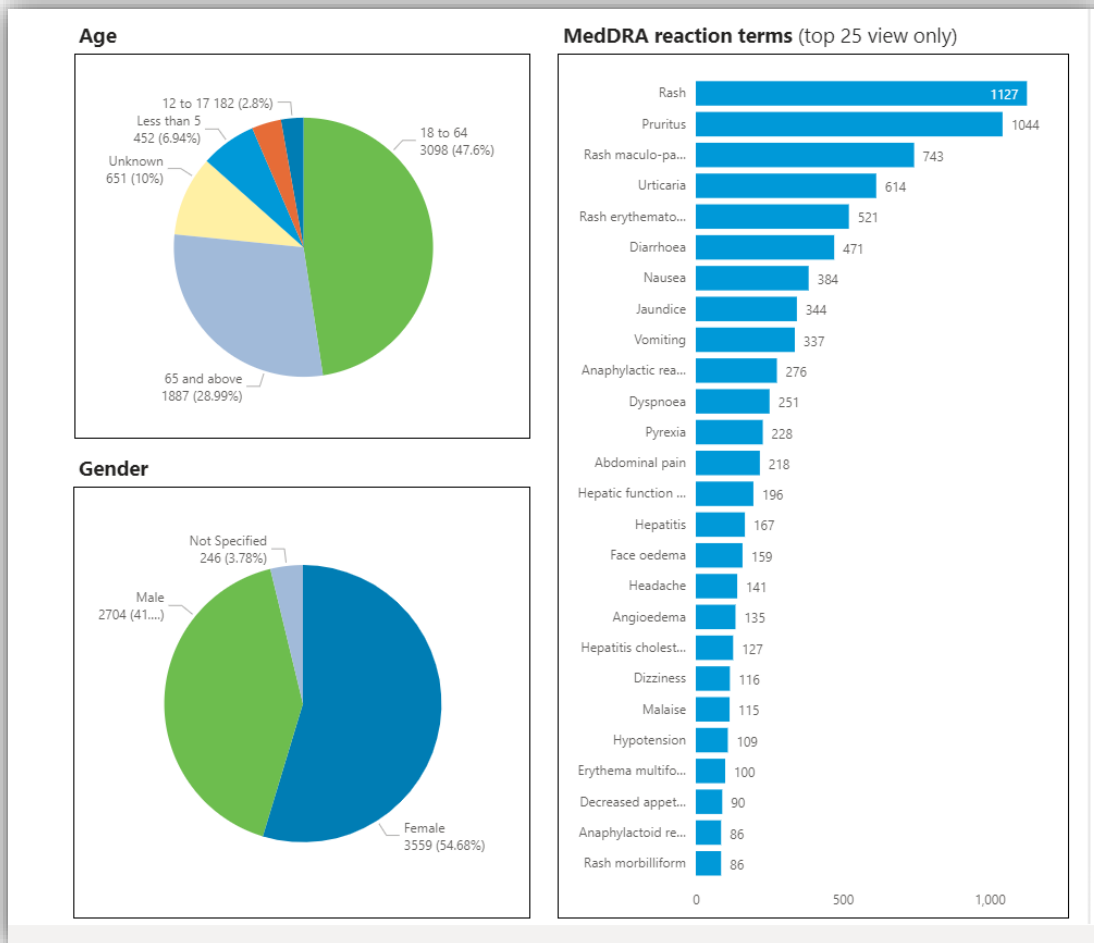
Reports (cases) 6509	Single suspected medicine 4225	Reported deaths 81
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Medicine summary - (895 rows) [?](#)
 Hover over the table to view export and other data options →

MedDRA system organ class	MedDRA reaction term	Number of cases	Cases with a single suspected medicine	Cases where death was a reported outcome
Skin and subcutaneous tissue	Rash	1127	769	8

The future... now: DAEN – medicines beta

Visual representation of data



The future... now: DAEN – medicines beta

Exporting data

List of reports - (555844 rows) ?

Hover over the table to view export and other data options →

Case number	Report entry date	Age (years)	Gender	Medicines reported as being taken	MedDRA reaction terms
7314	29/07/1971	15	Female	<ul style="list-style-type: none"> Trade name not specified (erythromycin) - Suspected Disprin (Aspirin) - Suspected Trade name not specified (ampicillin) - Suspected 	<ul style="list-style-type: none"> Rash maculo-papular Pruritus
7310	25/09/1971	18	Female	<ul style="list-style-type: none"> Trade name not specified (ampicillin) - Suspected Penicillin (benzylpenicillin sodium) - Suspected 	<ul style="list-style-type: none"> Rash
7311	12/10/1971	14	Female	<ul style="list-style-type: none"> Trade name not specified (ampicillin) - Suspected 	<ul style="list-style-type: none"> Rash erythematous

- Export data
- Show as a table
- Spotlight
- Get insights
- Sort descending
- Sort ascending
- Sort by

Which data do you want to export? ✕

Export your data in the format that suits your needs. If you have a lot of data, the number of rows you export might be limited depending on the file type you select. [Learn more](#)

Data with current layout

Export this data in the same layout you see now, but without any icons, colors, or other formatting you added.

Summarized data

Export the summarized data used to create your report (for example, sums, averages, medians).

Underlying data

Export the raw data used to create your report.

File format:

Export Cancel

What's next: easier access to PCDs

- Self-service access to Public Case Details (PCDs) using existing authentication
- Ability to extract data to upload into own pharmacovigilance system

What's needed:

- Move AEMS components to Cloud
- Privacy impact assessment
- Legislative instrument to support release of data



Later on: system-to-system data exchange

- Additional E2B (R3) input channel
- System-to-system data sharing via EDI

What's needed:

- Further investigation of system requirements



How will it help?

- More reliable access to information
- Better access to data of interest
 - Access to data subsets using additional search, sort, and filtering functionality
 - Consume data in multiple formats
 - Visual (graphic) representation of overview data of key interest through DAEN-medicines beta
- Improved user experience
- Continued currency of data



Questions





Australian Government

Department of Health
Therapeutic Goods Administration