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

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TGA Health Safety Regulation

COVID-19 vaccine roll-out: preparation & response

2020

- Preparing processes
- Enhancing capacity
- Technical improvements

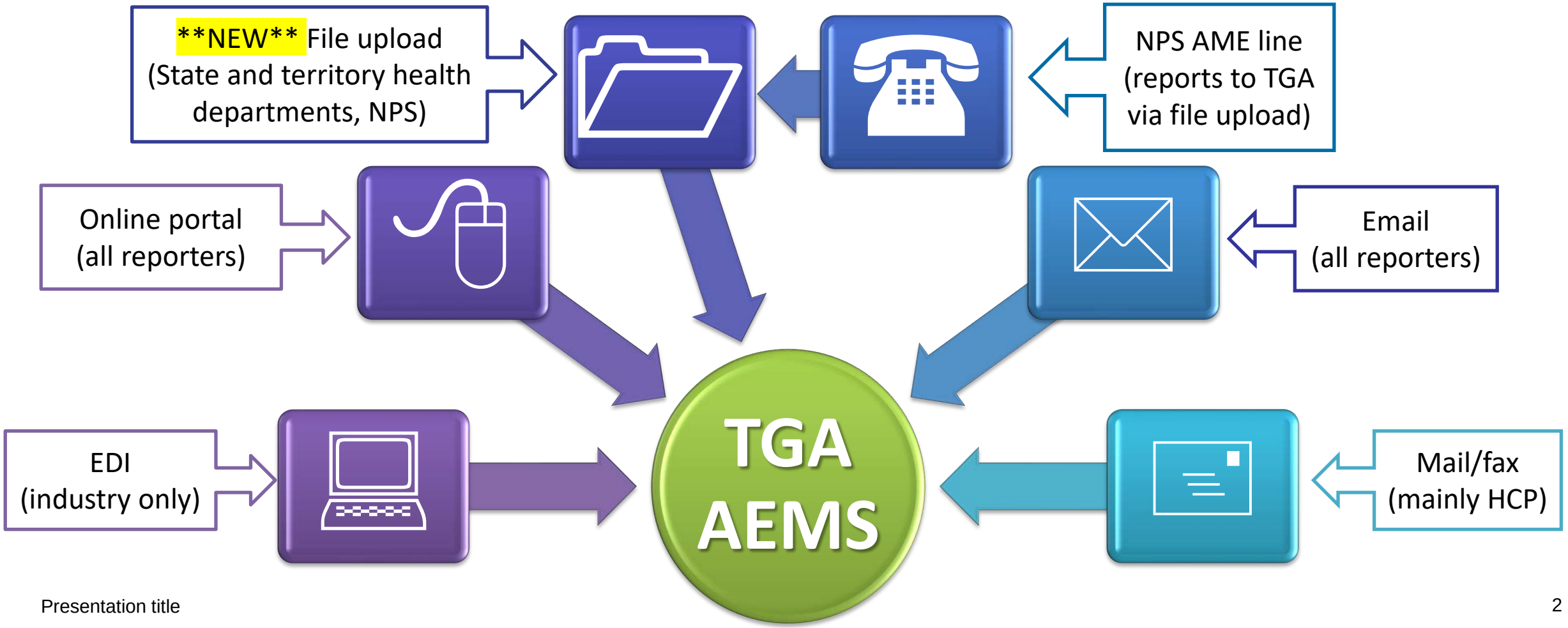
2021

- Agile approach to process
- Further expand data entry capacity
- DAEN changes and IT enhancements

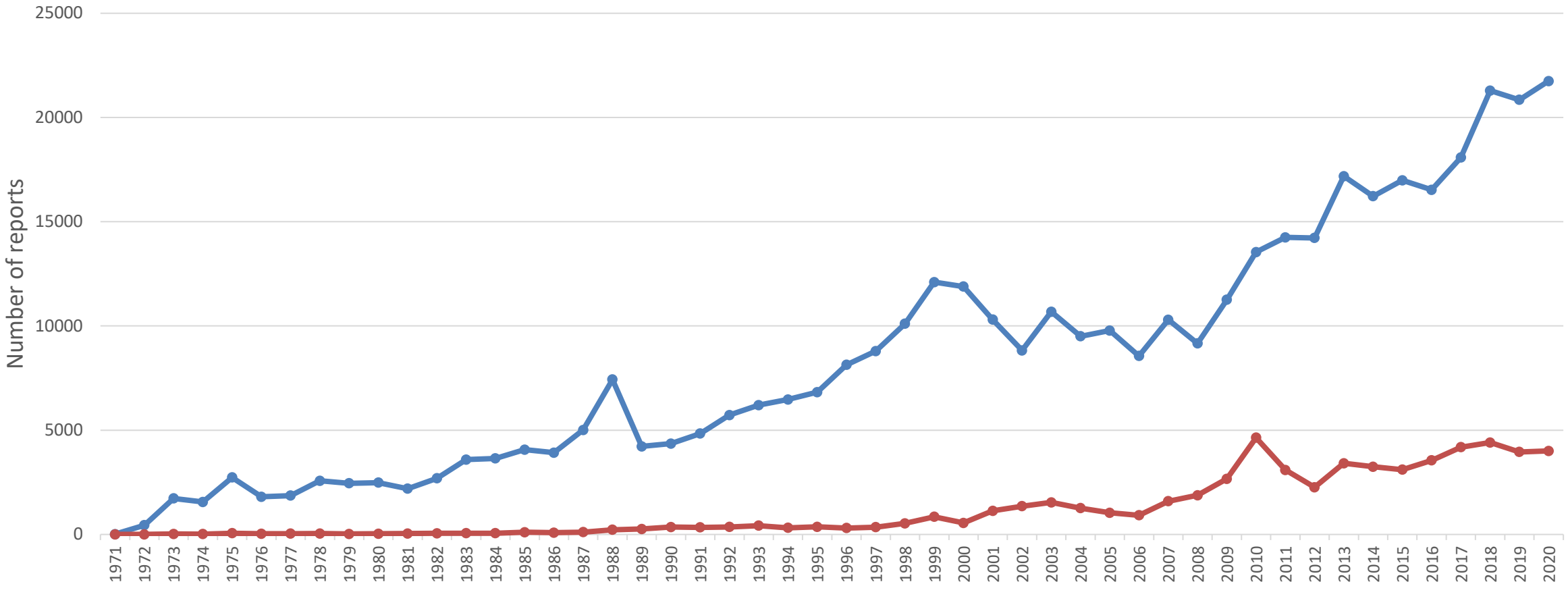
2022

- Review and consolidate process changes
- Forecast team contraction
- MAEDX project ongoing

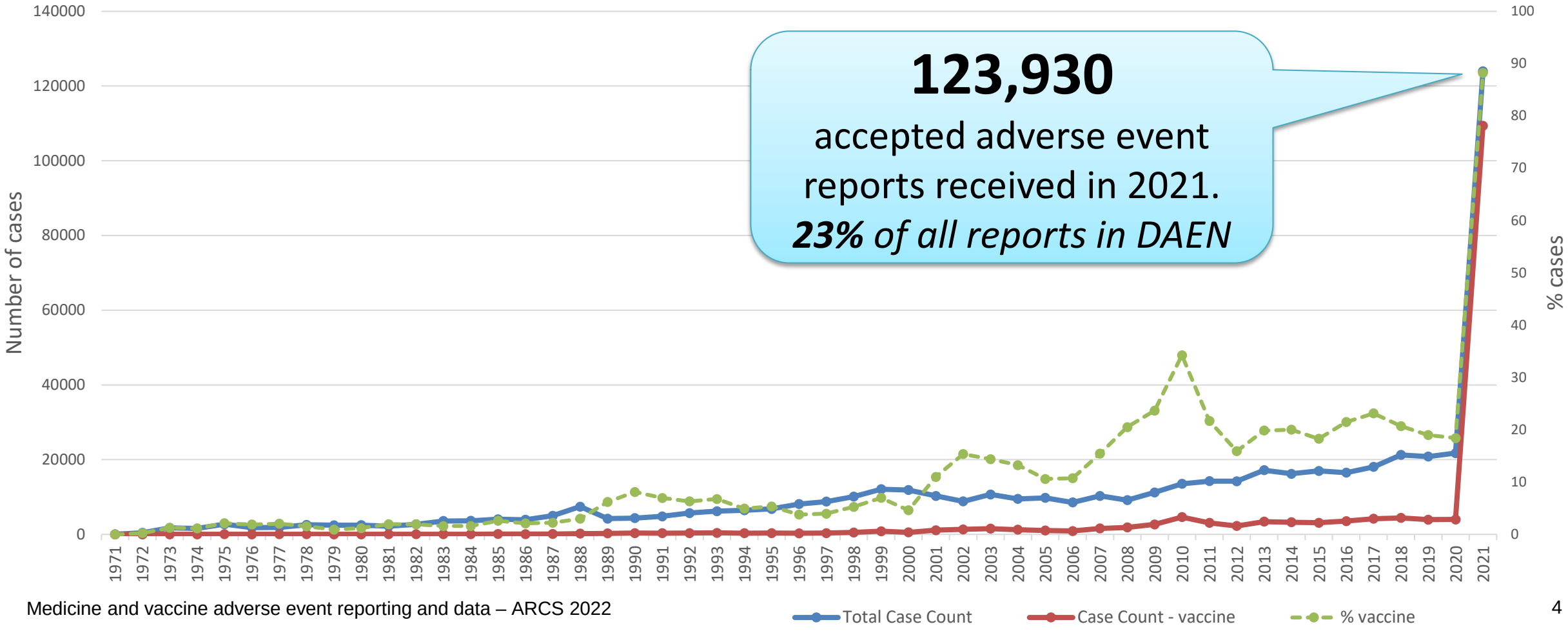
New reporting channel



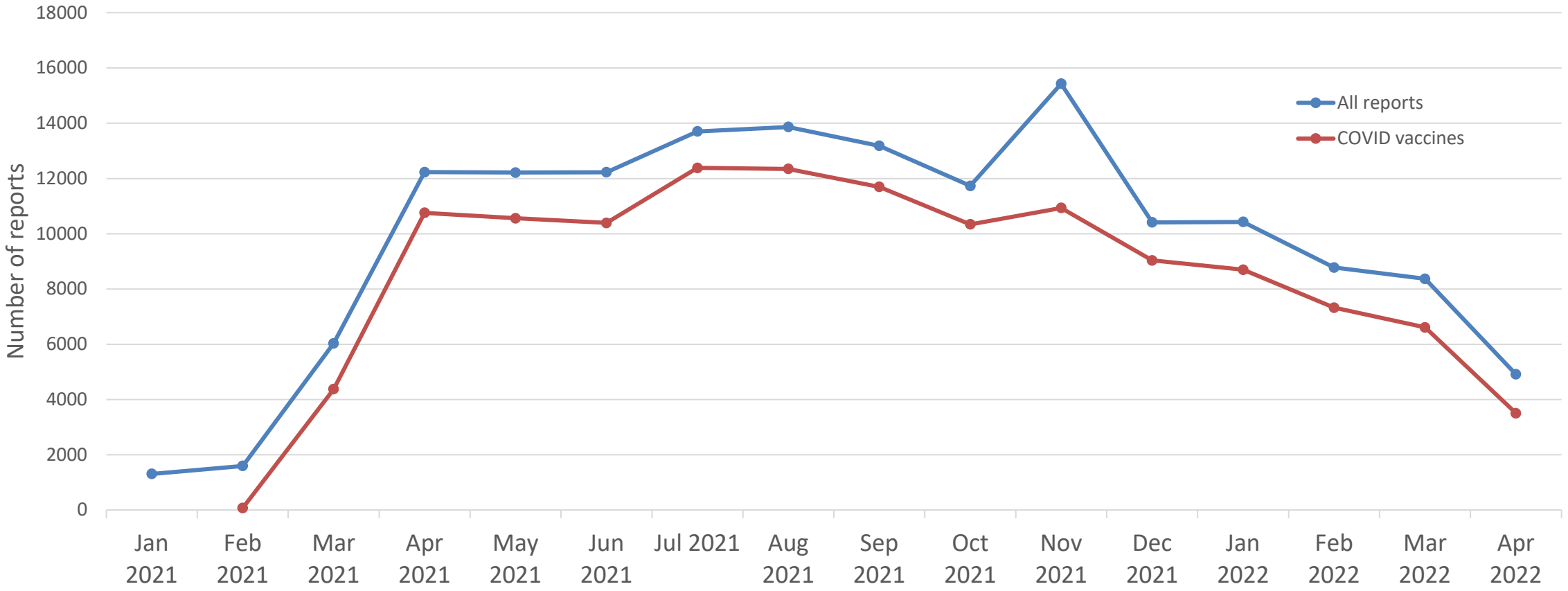
Adverse event reporting to 2020



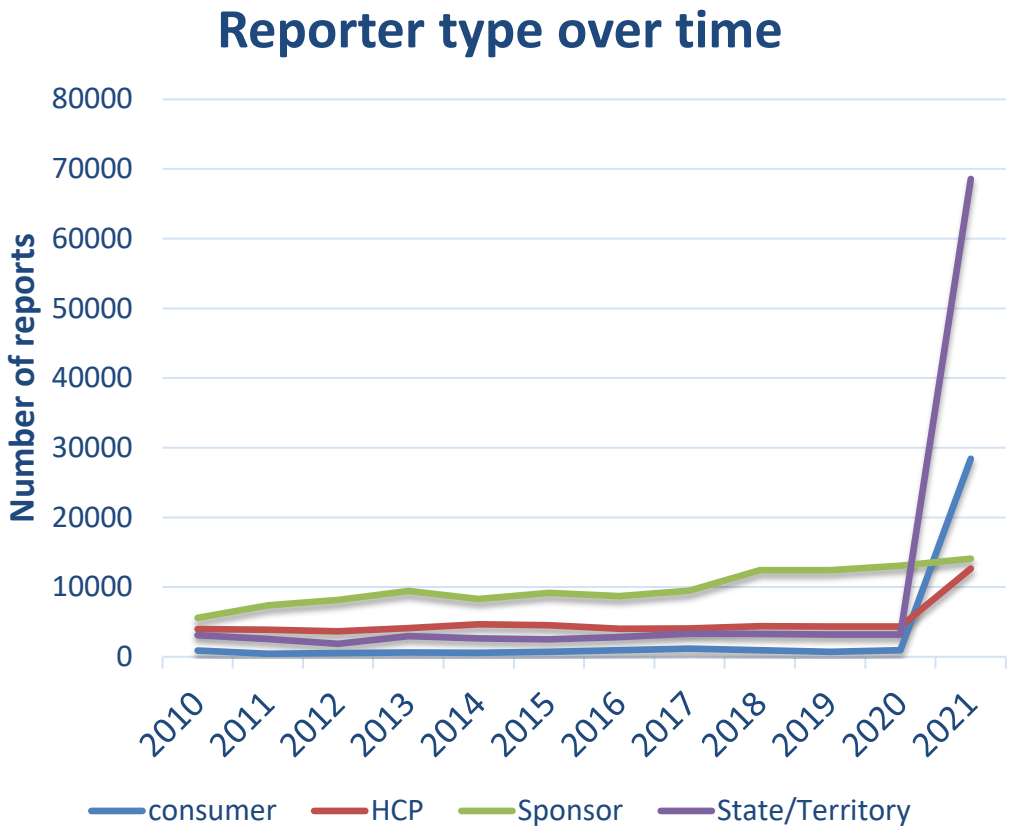
Adverse event reporting in 2021

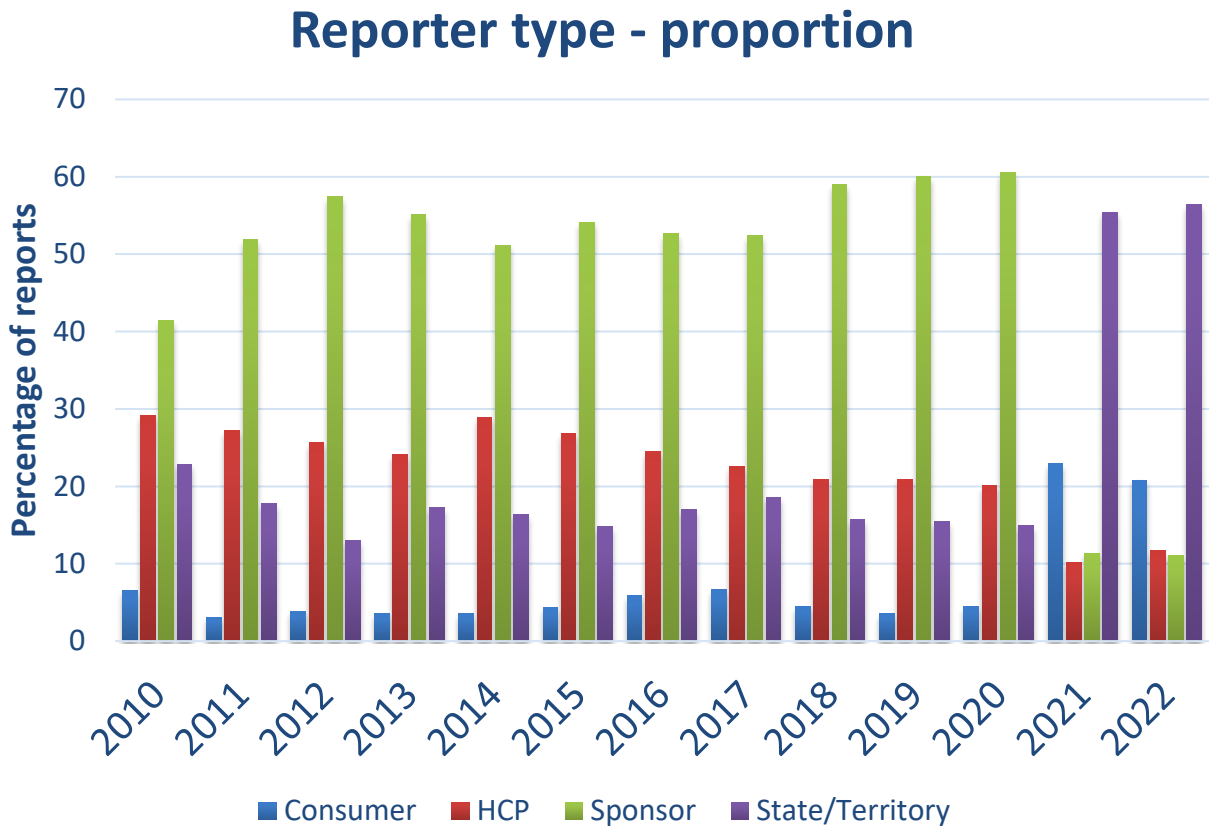


Reporting levels – 2021-22

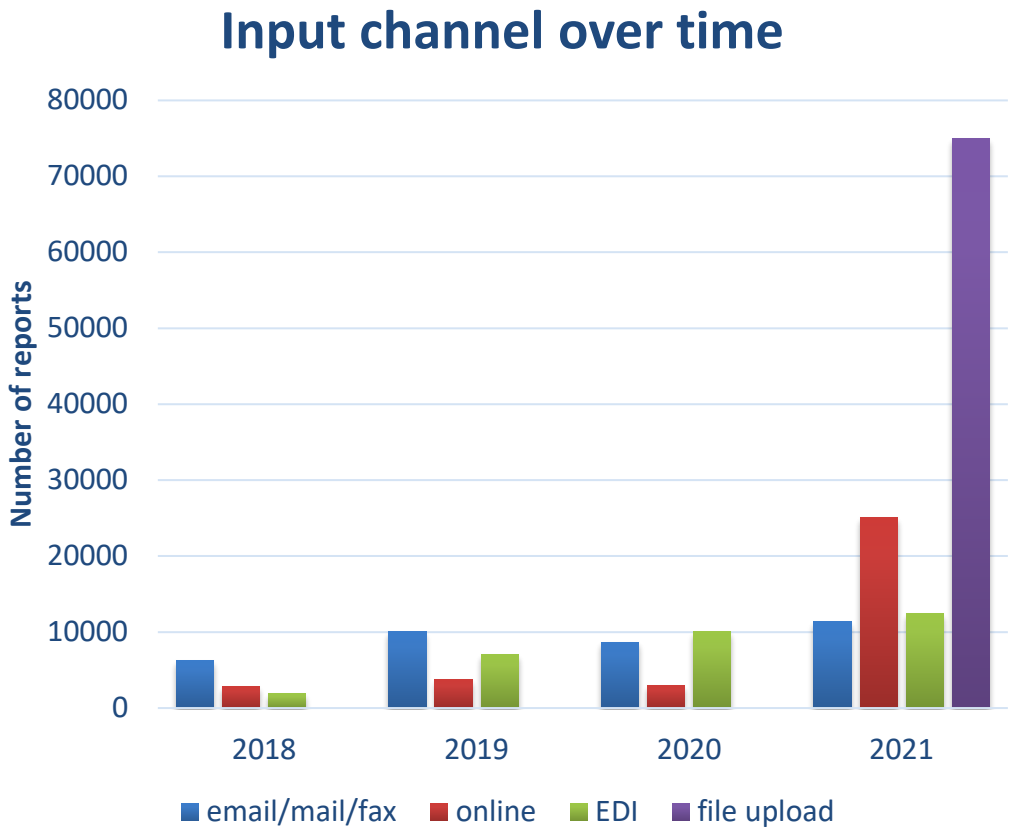


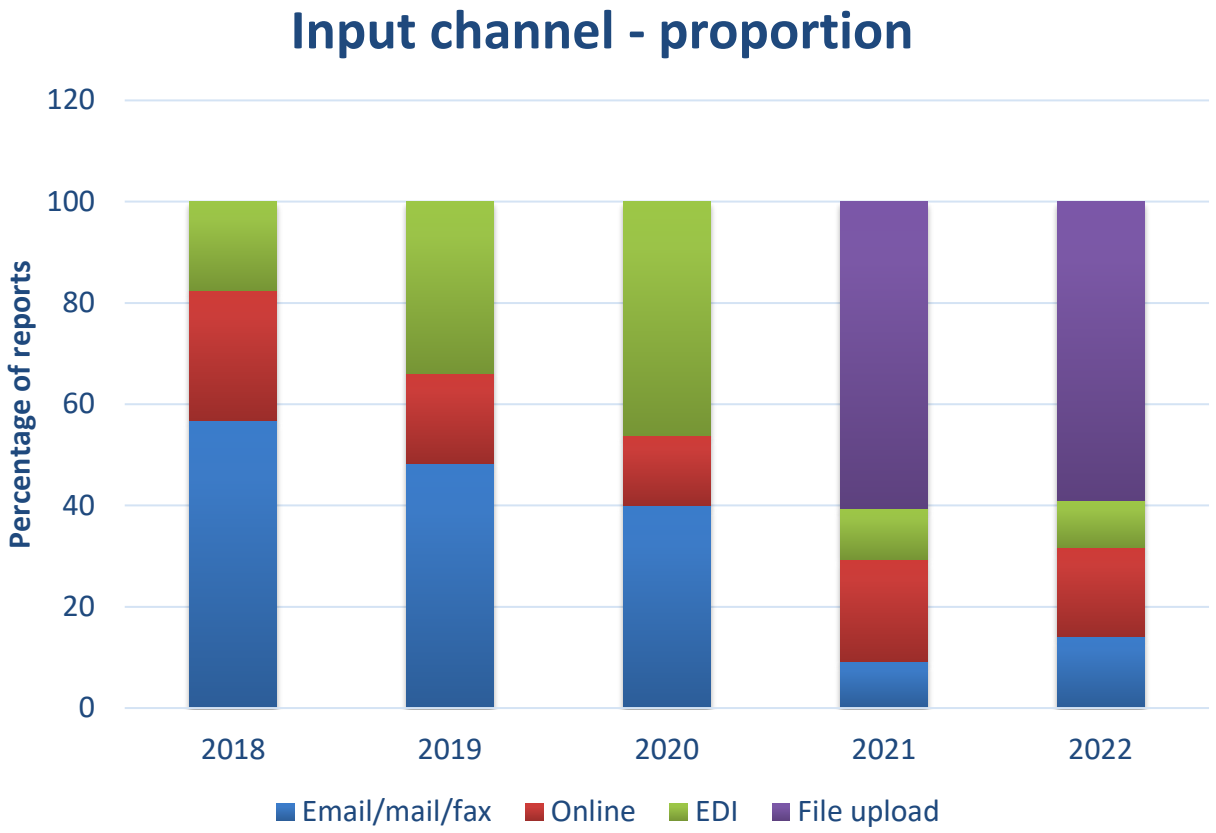
Changing sender types





Changing channels

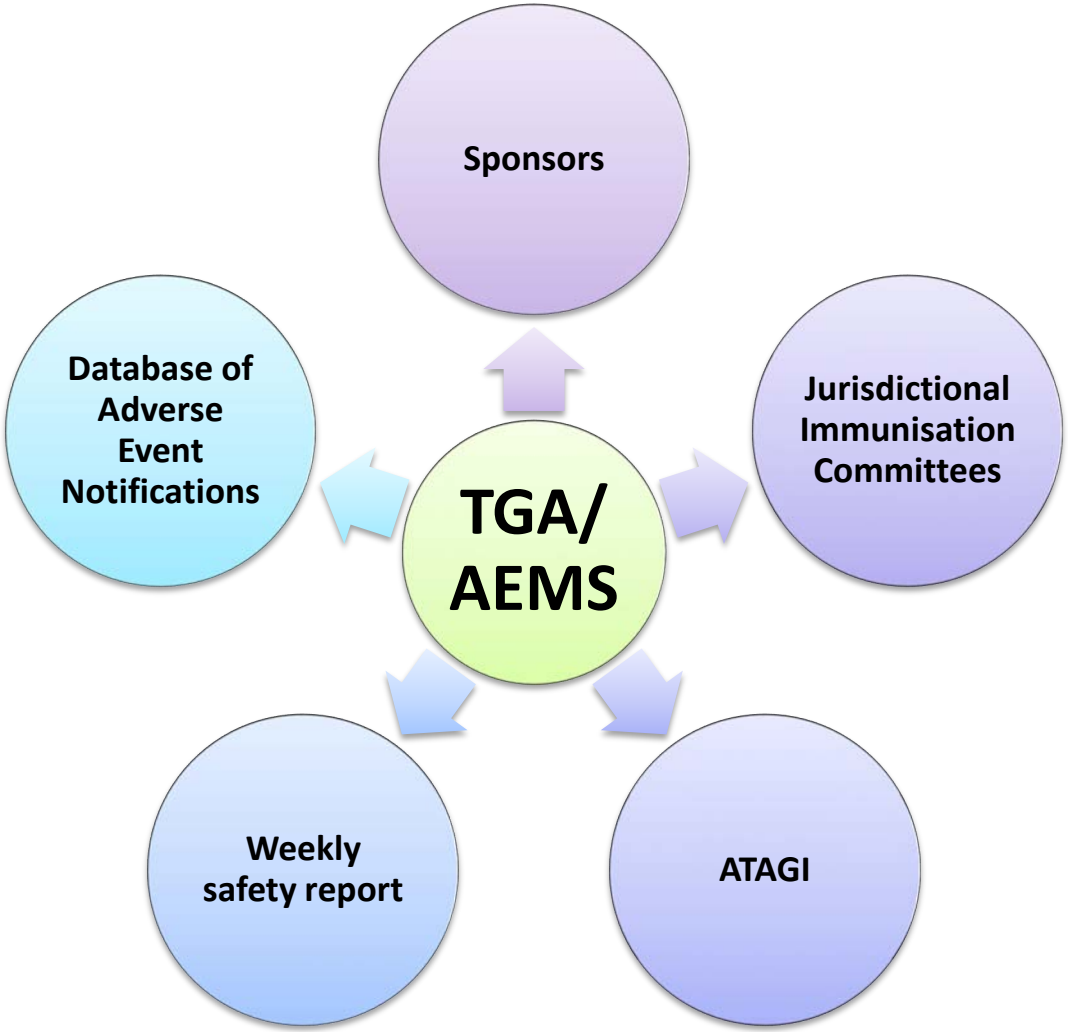




Sharing COVID-19 vaccine adverse event data

Increased frequency and intensity of sharing adverse event data

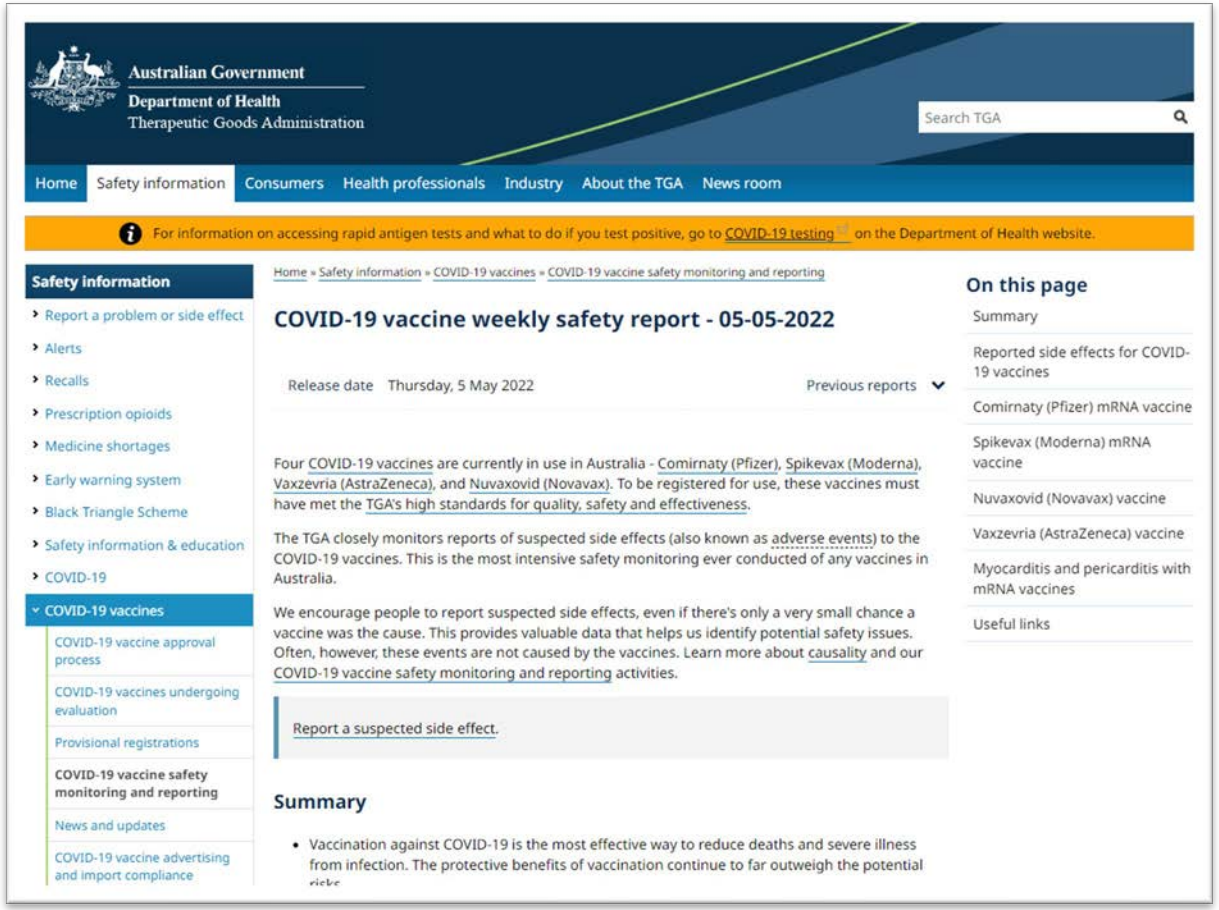
- Decreased time lag for DAEN from 90 to 14 days
- Weekly sharing of information through multiple channels



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



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

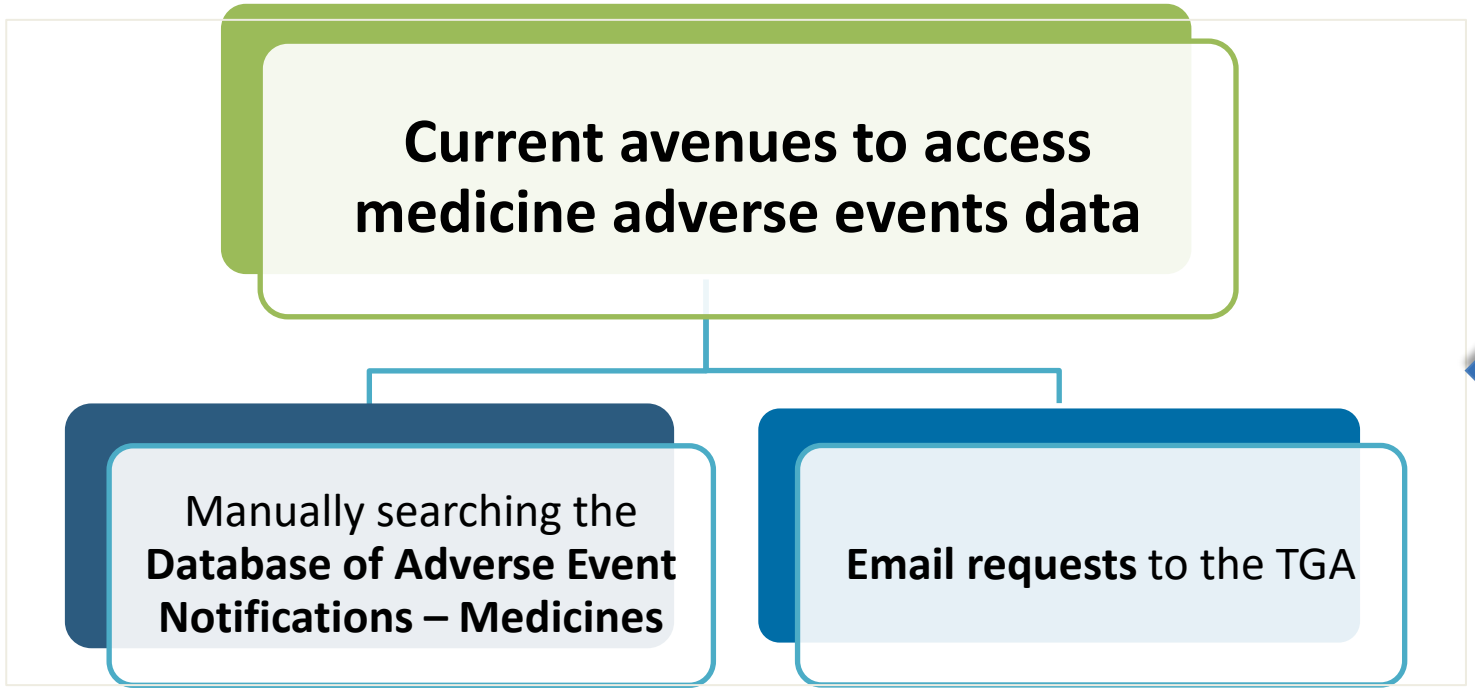
Adverse event reporting into the future

- 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…



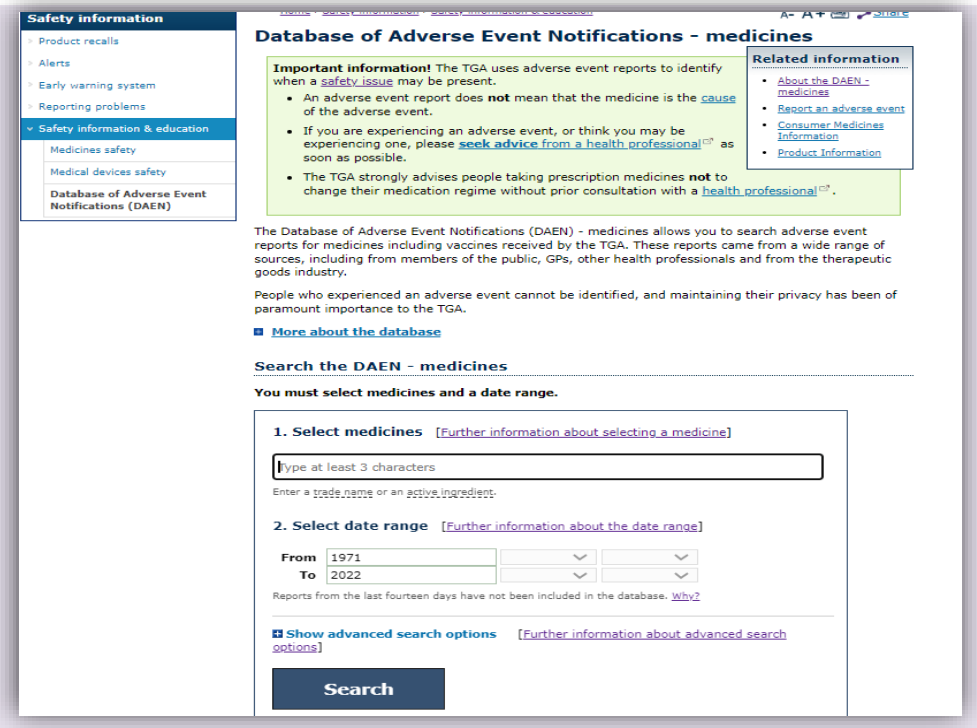
Both methods are inefficient, causing delays in access to important safety information

What you told us…

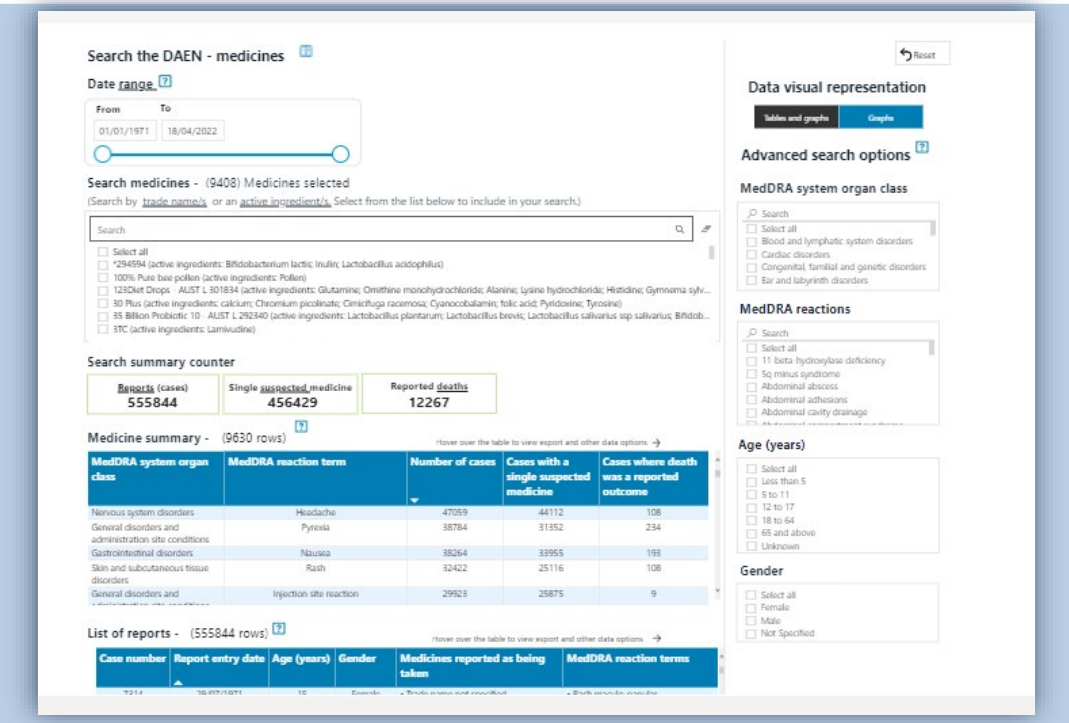
- Need ability to view and export relevant data from TGA systems
- System-to-system data transfer via EDI Gateway
- Need more data to help identify duplicates
- Use of E2B R3 to submit cases – must be voluntary

The future… now: DAEN – medicines beta

Current DAEN – medicines

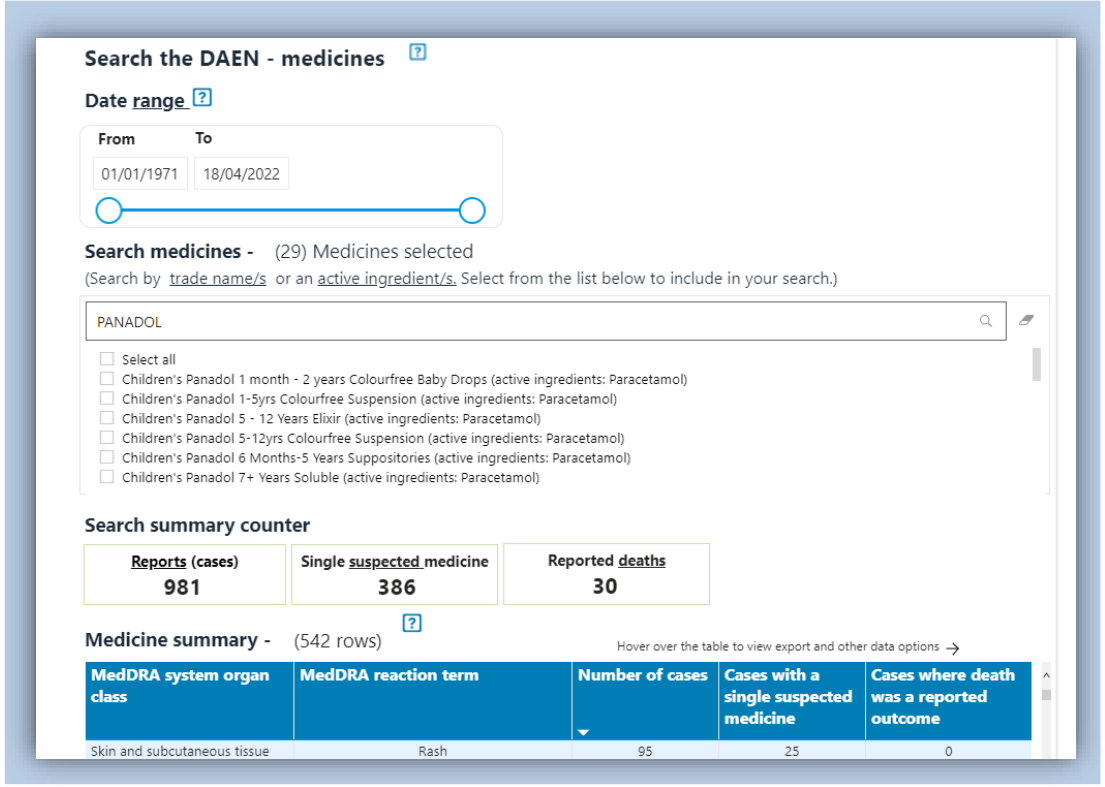


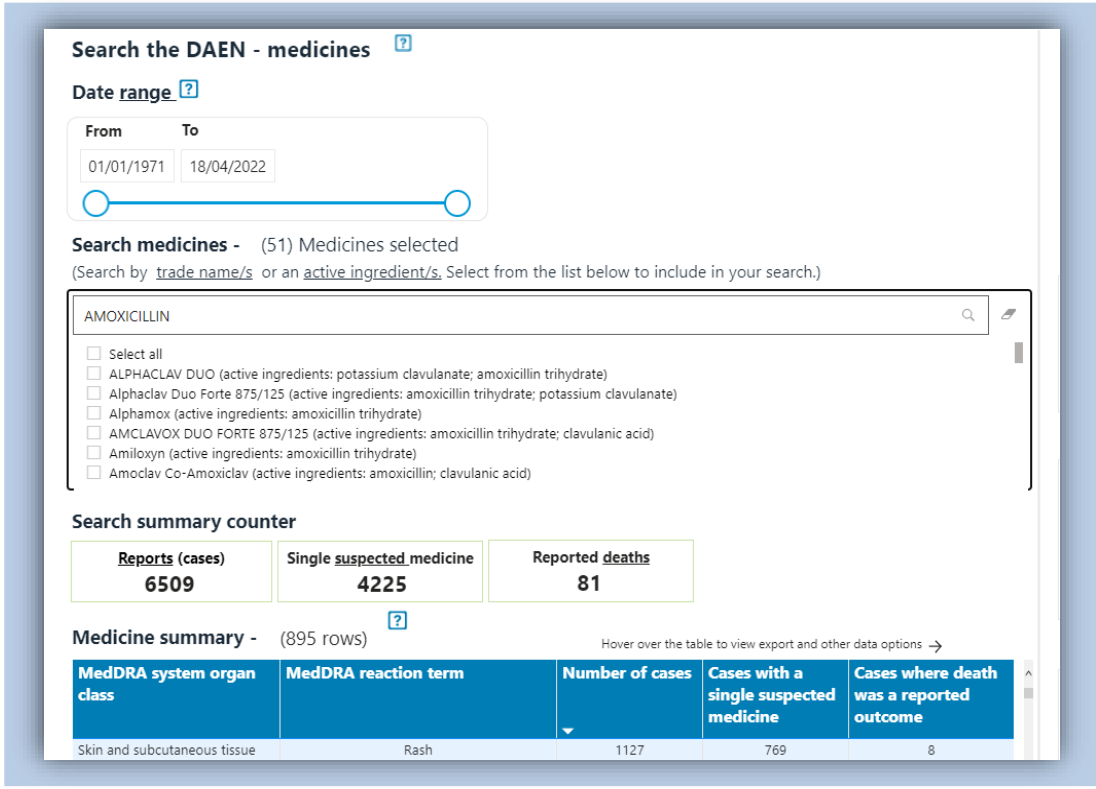
DAEN – medicines beta



The future… now: DAEN – medicines beta

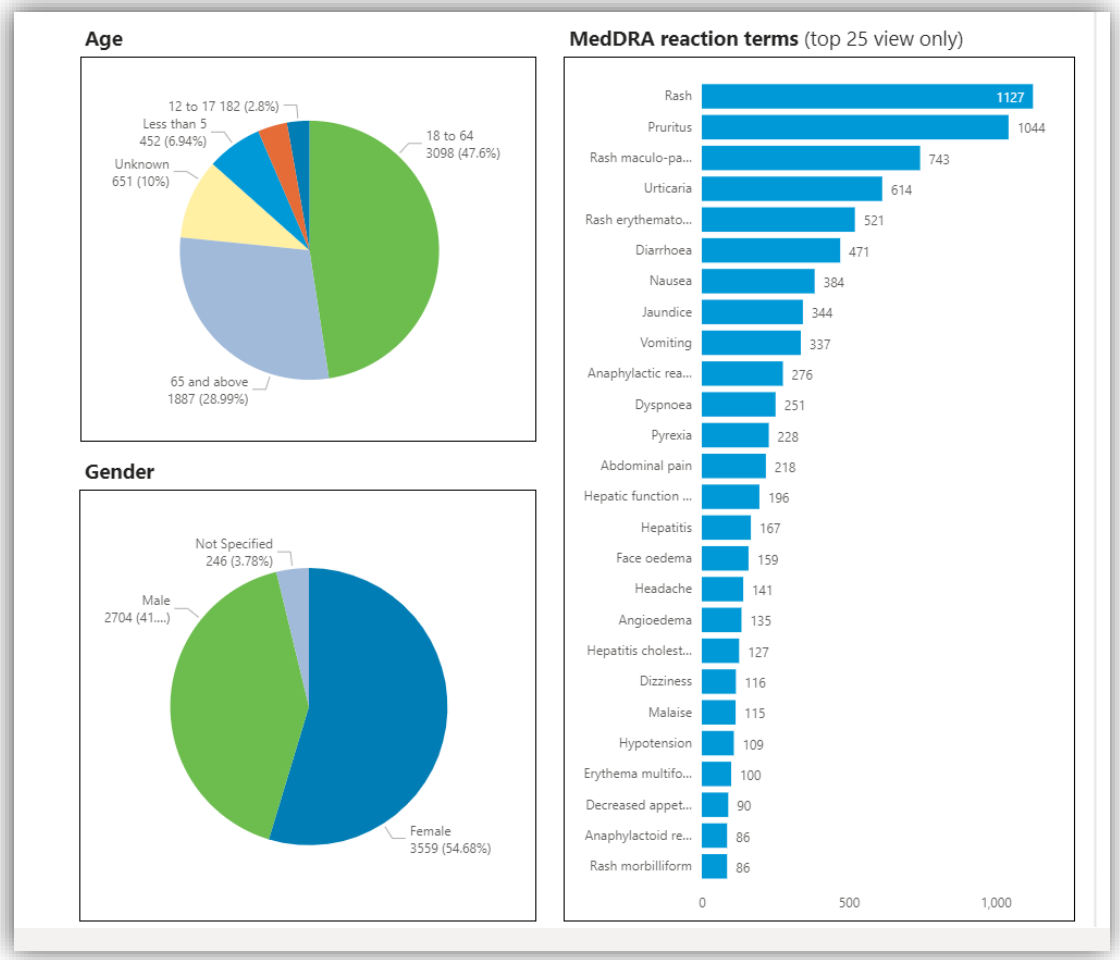
Searching by tradename or active ingredient

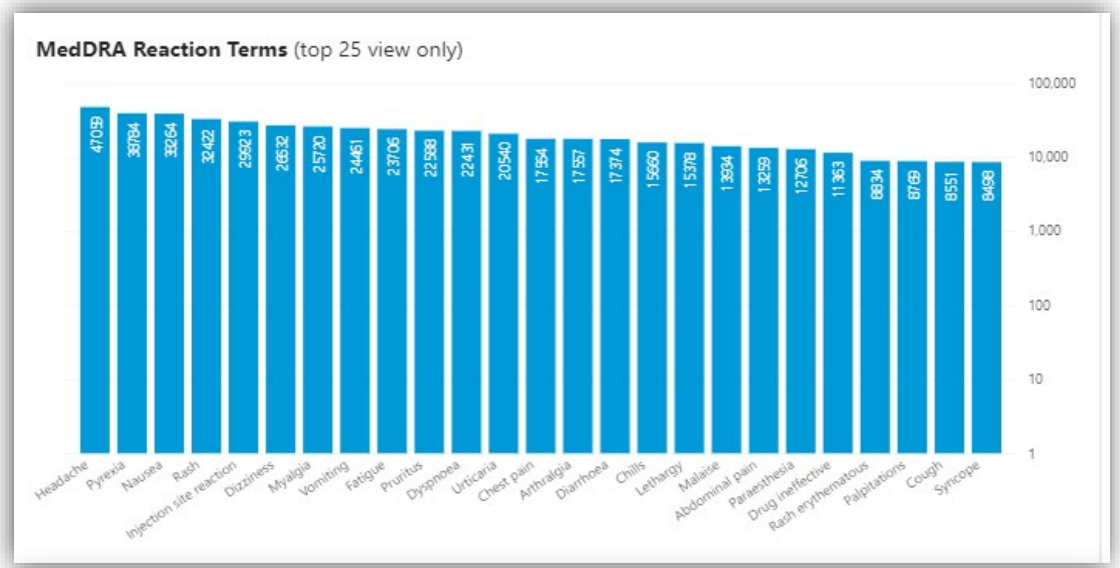


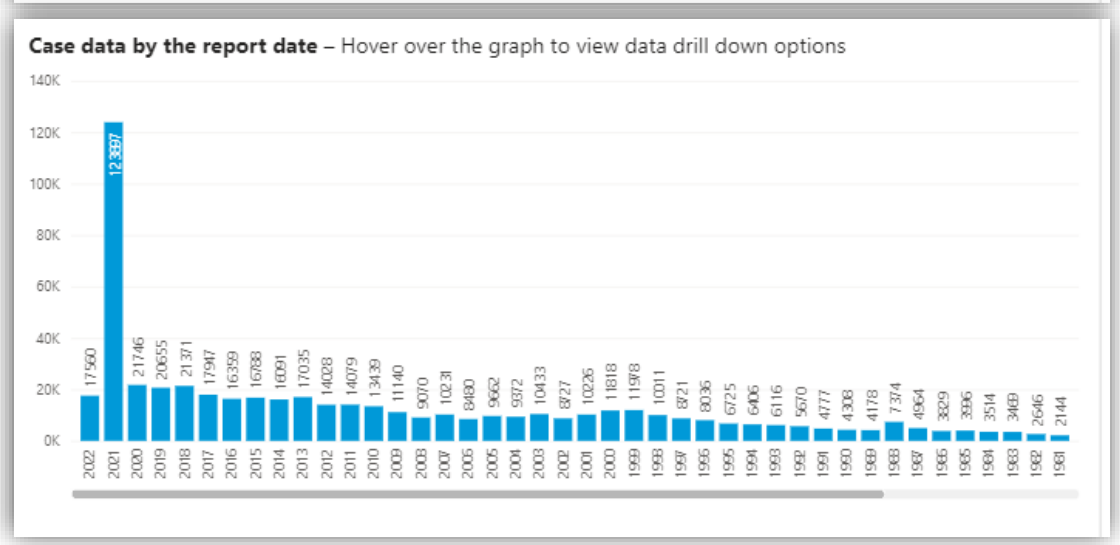


The future… now: DAEN – medicines beta

Visual representation of data

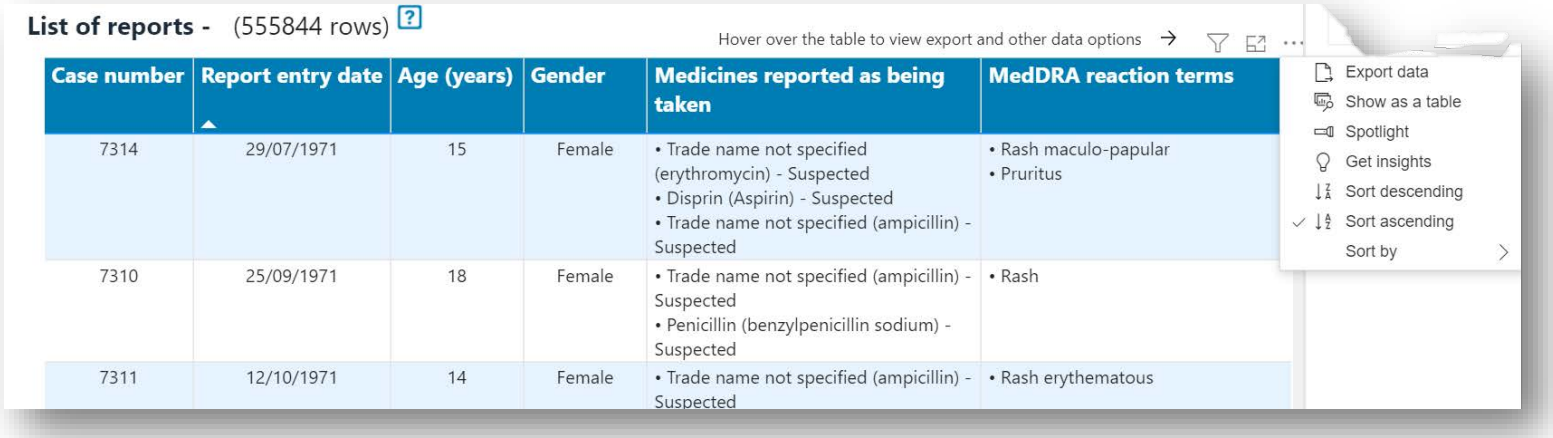


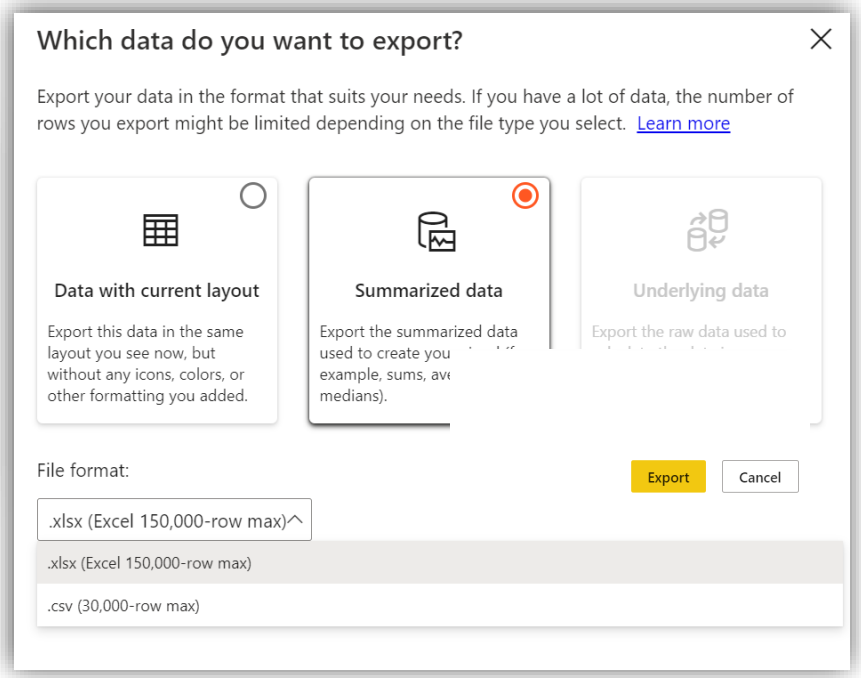




The future… now: DAEN – medicines beta

Exporting data





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

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