



Australian Government
Department of Health
Therapeutic Goods Administration

Global pharmacovigilance networks

A regulator's perspective

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TGA Health Safety
Regulation

In this presentation

- TGA engagement with the **International Coalition of Medicines Regulatory Authorities (ICMRA)**
 - Big data
 - Increasing adverse event reporting
 - Vaccine surveillance and risk communication
- Other engagement activities
- Better use of Global pharmaceutical companies databases in signal detection
- TGA's introduction of a new E2B (R2) **Electronic Data Interchange (EDI)** Service adhering to international standards
- TGA's introduction of the new **Black Triangle Scheme**
 - Background
 - Communication activities
 - Evaluation

Other engagement with overseas Regulators

- The TGA has regular contact through arrangements with other Regulators that include:
 - US FDA
 - Health Canada
 - SwissMedic
 - Health Sciences Authority Singapore
 - Medsafe New Zealand

TGA's approach

- Alignment with other regulators
- Harmonisation with international regulatory requirements
- Reducing administrative burden on industry but ensuring independence to be able to meet the needs of the Australian population.

Engagement with Global Pharma

- Pharmacovigilance is dependent of the reporting of adverse events to the regulator from sponsors, health care professionals and consumers
- Global pharma companies have access to more adverse event reports as they collect these from multiple jurisdictions and in much larger populations than Australia.
- While the TGA may receive 20,000 adverse event reports each year, a global company can receive over 1.2 million adverse event reports per year across multiple jurisdictions.
- There is a great opportunity to use global pharma companies to provide information on safety signals to the TGA and for the TGA to determine the significance of any safety signal in the Australian population.

▼ The Black Triangle Scheme

Background

New medicines are registered on the basis of **sufficient** clinical trial data to support safety and efficacy.

However, the safety profile is only **fully characterised** once the product has been used in a larger and more diverse population after registration and marketing.

▼ Identifies:

- New medicines
- Approved medicines being used in new ways

▼ Encourages the reporting of adverse events for these new medicines

▼ Aims to reduce the time taken for a medicine's full safety profile to be identified.

▼ Is based on a similar scheme in the UK and EU

The scheme started on 1 January 2018

Included products will remain in the scheme for at least 5 years.

The Black Triangle symbol and mandatory accompanying text will appear in:

- Product Information (PI)
- Consumer Medicine Information (CMI)

TGA is working with stakeholders to integrate the symbol into other sources of medicine information, including promotional material.



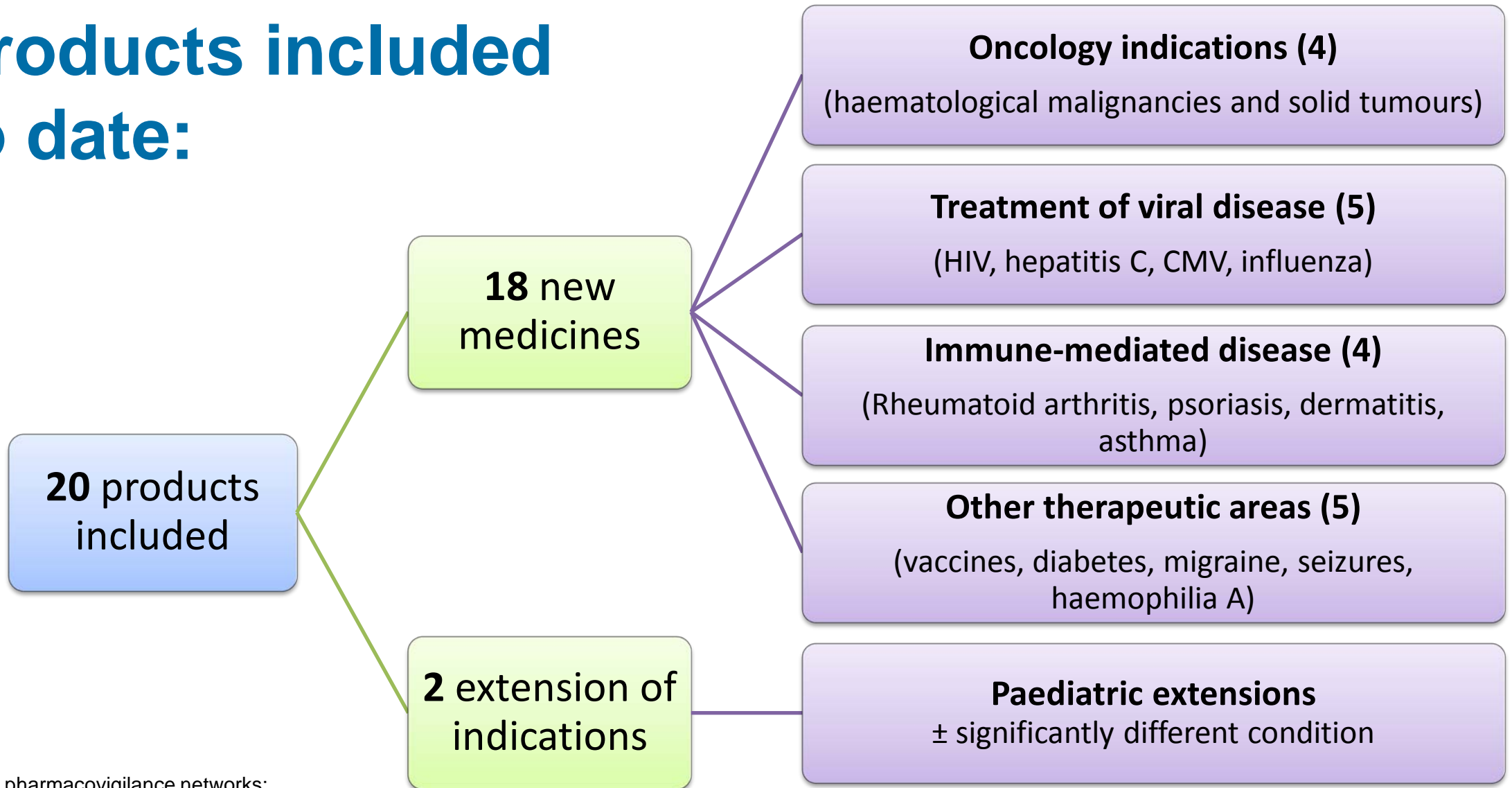
▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.



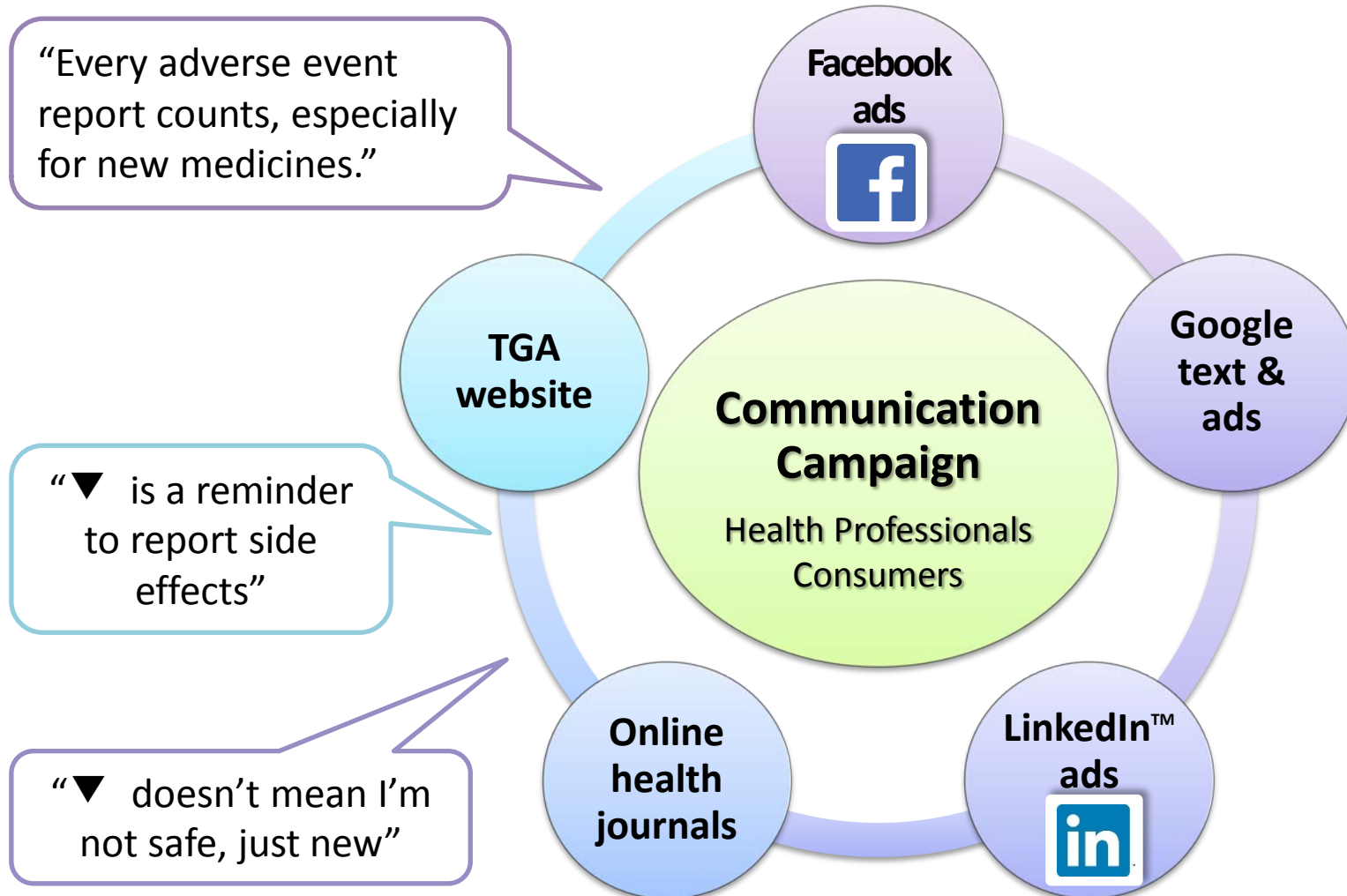
▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.



Products included to date:



Communication activities



Outcomes

- TGA social media activity reached more than 1.2 million unique users.
- There were more than 7.2 million ad impressions via Google.
- There was a 100 fold increase in visits to TGA's Black Triangle Scheme webpage.

We created a lot of material ...



... that appeared in places such as this

side effects medicines

Help Keep Medicine Safe | Report Side Effects | TGA.gov.au
www.tga.gov.au/BlackTriangle/Scheme
A Black Triangle Doesn't Mean a Medicine Isn't Safe, Just New. Learn More
Report Adverse Events · Medicines Information · Black Triangle Scheme

Common minor side effects of prescription drugs:

- Diarrhea.
- Dizziness.
- Drowsiness.
- Fatigue.
- Heart issues (palpitations, irregular heartbeats)
- Hives.
- Nausea and vomiting.
- Rash.

Side Effects of Drugs, Medical Devices & High-Risk Medical Cor
https://www.drugwatch.com/side-effects/

People also ask

- What is a side effect of a drug?
- What are common side effects of medications?
- How does medicine affect the human body?
- What are the side effects of allopathic medicines?

Australian Department of Health
19 April ·

The TGA is enhancing monitoring of medicines that are new or being used differently.

is a reminder to report adverse events and help us get the full picture.

WWW.TGA.GOV.AU/BLACK-TRIANGLE-SCHEME
New safety initiative
Improving medicine safety

Work stress 'contagion' affecting relationships
Dallas Bastian · June 8, 2018
Workplace stress can be transferred from one partner to another in the home, new ...

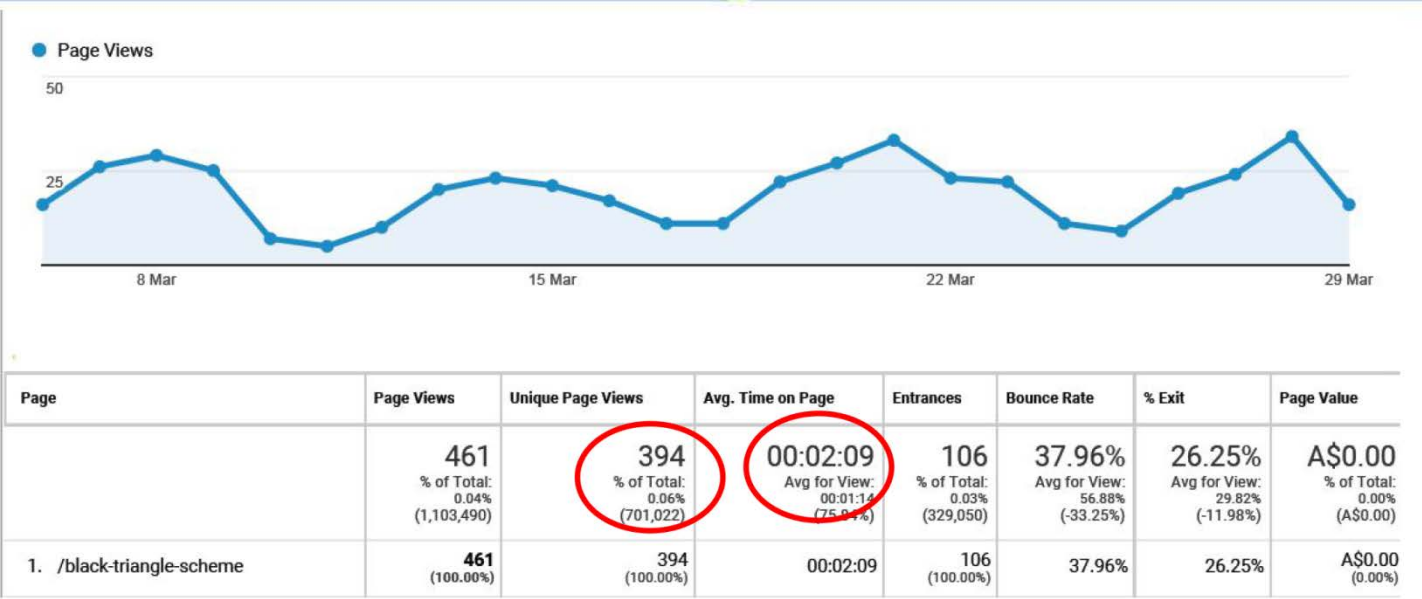
Children's hospital tracker advises parents on ED wait times
AAP and Dallas Bastian · June 7, 2018

Product Information
What does this symbol mean?

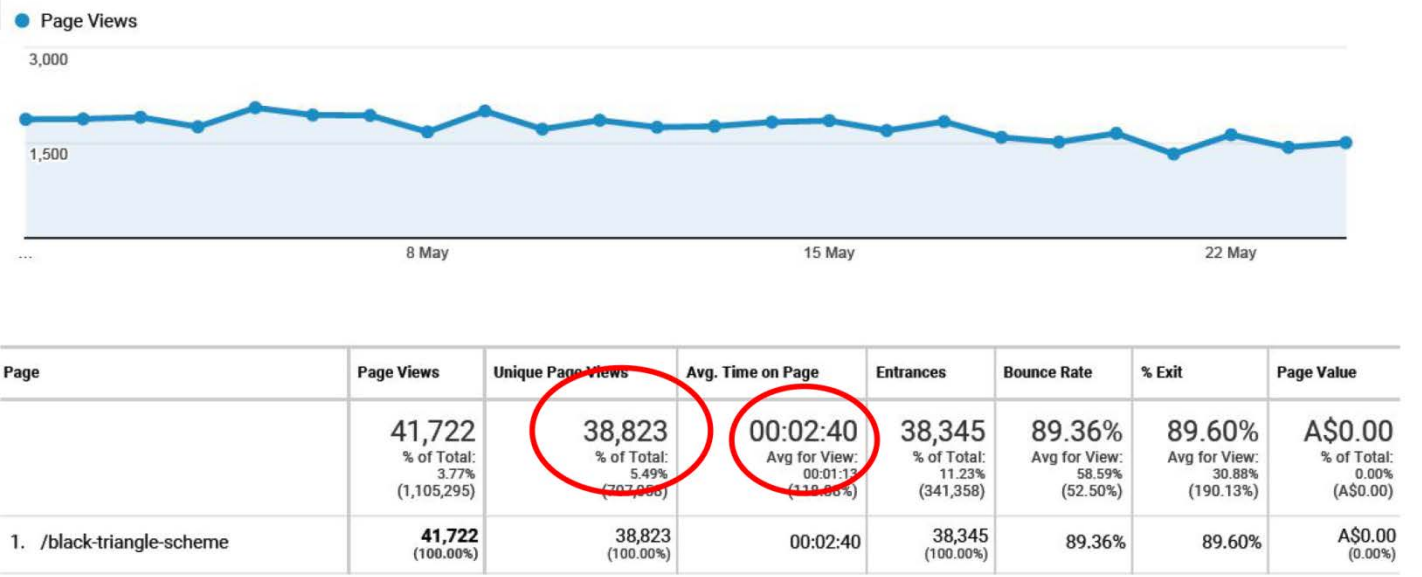
HESTA | your stories, our inspiration
Find out how

The results

- From this ...



- To this ...



Evaluation Plan



Surveys of health professional adverse event reporting awareness and behaviours



Surveys of consumer adverse event reporting awareness and behaviours



Data analytics – changes in adverse event reporting rates over time

Baseline survey completed

Surveys will be repeated ~2 and ~5 years after implementation

Patterns of adverse events reporting for new products will be compared before and after implementation of the scheme

Adverse events (side effects) surveys

- Two surveys – health professionals and consumer versions
- Questions on:
 - adverse events (AE) experience
 - AE reporting behaviours
 - How and when medicines information is provided and accessed
 - Attitudes towards AE reporting
- Surveys open April to July 2018

- >1160 responses from consumers
 - >1000 market research sample
 - >160 opt-in (via TGA website)
- >360 responses health professionals
 - **32%** Pharmacists
 - **31%** Nurses
 - **13%** Specialists (including anaesthetists, surgeons, psychiatrists)
 - **5%** General Practitioners

Conclusion

Through the implementation, promotion and evaluation of the Black Triangle Scheme, the TGA intends to reduce the time between regulatory approval and the identification of new safety concerns for new medicines, and approved medicines being used in new ways.

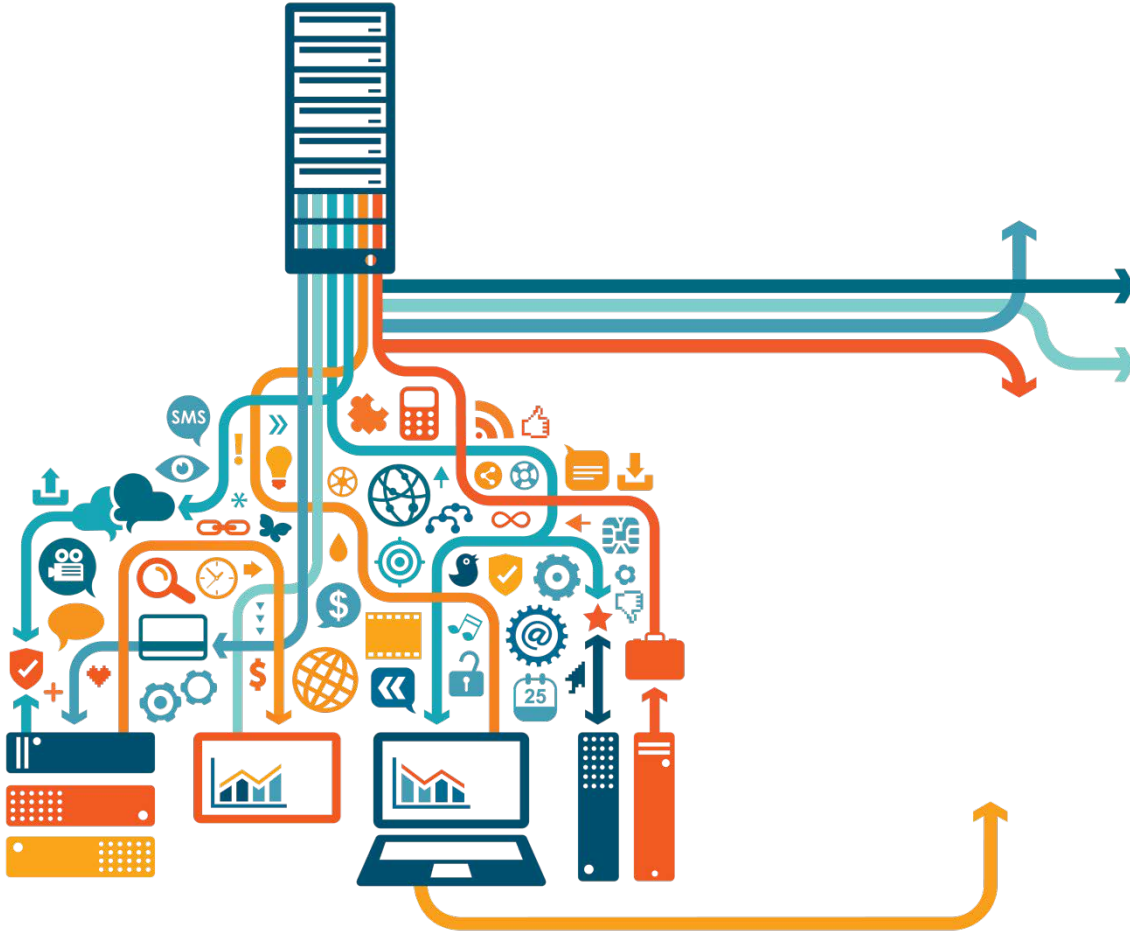


Adverse events reporting rates



Time to identify new safety information

ICMRA: Big Data



- Project commenced in 2016 with the aim of examining the opportunities and challenges for big data and analytics within the context of PV and to facilitate international collaboration in this area.
- Activities to date have included publication of a policy paper and an inventory of big data initiatives in PV.
- Members are currently participating in a series of webinars, led by member agencies, to explore regional big data PV initiatives in more detail.
- More info can be accessed via the ICMRA website: www.icmra.info/drupal/strategicinitatives/pharmacovigilance/bigdata

ICMRA: Increasing adverse event reporting

- TGA is a member of ICMRA's Increasing Adverse Event Reporting sub-project working group.
- TGA took the lead in creating and hosting an extensive online survey that collected a wide range of information on ICMRA members' reporting systems and strategies as well as data on adverse event reports and reporters.
- At the request of Health Canada, TGA also included additional questions regarding improving the quality of adverse event reports to help with a separate sub-project.
- Eleven international regulators provided data for the survey, representing: Australia, New Zealand, Canada, UK, EU, Sweden, Brazil, Japan, China, Mexico and Singapore.
- Analysis of the results is currently being undertaken.
- ICMRA's objective is to identify and share best practice among its members.
- The project subgroup may also explore how project outputs can be shared or utilised by other agencies via the WHO's global Pharmacovigilance Program.

ICMRA: Vaccine surveillance and risk communication

- This project commenced in late 2017.
- The aim of the project is to examine opportunities to improve the analysis and communication of vaccine adverse events.
- Activities to date have included a survey of the sub-project members to gain insights into the vaccine safety surveillance activities undertaken by regulatory agencies, and to identify vaccine risk communication ‘success stories’.



EDI: Easier reporting of adverse events

- TGA has implemented a new E2B (R2) Electronic Data Interchange (EDI) Service to make it easier for sponsors to report medicine and vaccine adverse events to TGA directly from their IT systems.
- The E2B (R2) format is a widely used and internationally agreed method to electronically exchange adverse event information.
- The format sets out the specific data elements to be included for electronic submission of adverse event data, the order of the elements, and their interrelationships.



- Adverse events that occur during clinical trials may also be reported using the service.

First cab off the rank, with more in the queue

- The TGA thanks **Actelion** as the first sponsor to successfully connect to and use the EDI Service. Actelion now submits all reports using the EDI.
- Five other sponsors have successfully connected to our test EDI service and successfully submitted test adverse event reports via this channel.
- We are working with these sponsors to transition to using the EDI service for submission of 'live data'.
- For those sponsors who are already progressing activities to connect to our test EDI service, we will continue to work with you to facilitate the testing process.



We want you! To consider joining our EDI service

- We encourage all sponsors to consider the benefits of joining the new EDI service.
- For those of you who are interested in using the new EDI Service, and would like to know more contact us at:

e2b.reports@health.gov.au



Any questions?



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