Health Sciences Authority, Singapore

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

	Data Source	Data Source Type	Stage of use for PV	Status
1	National Electronic Health Record	Electronic Health Record	Interest	Preliminary stage, exploring access to records
2	Electronic medical records from one local hospital	Laboratory data, discharge summaries, discharge prescriptions, primary & secondary diagnosis (~1.5 years)	Research	Developed an algorithm for the detection of statin myopathy signals from electronic medical records. Paper published online in Clinical Pharmacology & Therapeutics. Chan SL, Tham MY, Tan SH, Loke C, Foo B, Fan Y, Ang PS, Brunham LR, Sung C. Development and validation of algorithms for the detection of statin myopathy signals from electronic medical records. *Clin Pharmacol Ther* . 2016 Oct 5. doi: 10.1002/cpt.526.
3	Electronic medical records from one local hospital	Discharge summaries (200 records)	Research	Towards Human–Machine Collaboration in Creating an Evaluation Corpus for Adverse Drug Events in Discharge Summaries of Electronic Medical Records. Ang PS, Fan Y, Tham MY, Tan SH, Sally Soh BL, Belinda Foo PQ, Hu S, Sung C. Big Data Research. 2016 Jun; 37–43.
4	Electronic medical records from one local hospital	Inpatient drug records, laboratory data (4.5 years)	Research	Application and optimisation of the Comparison on Extreme Laboratory Tests (CERT) algorithm for detection of adverse drug reactions: Transferability across national boundaries. Tham MY, Ye Q, Ang PS, Fan LY, Yoon D, Park RW, Ling ZJ, Yip JW, Tai BC, Evans SJ, Sung C. Pharmacoepidemiol Drug Saf. 2017 Nov 6. doi: 10.1002/pds.4340. [Epub ahead of print]
5	Spontaneous AE reports	Spontaneous AE reports	Research	Data mining spontaneous adverse drug event reports for safety signals in Singapore – a comparison of three different disproportionality measures. Ang PS, Chen Z, Chan CL, Tai BC. Expert Opin Drug Saf. 2016 May; 15(5):583-90. doi: 10.1517/14740338.2016.1167184.
6	Spontaneous AE reports	Spontaneous AE reports	Research	Detecting Signals of Disproportionate Reporting from Singapore's Spontaneous Adverse Event Reporting System: An Application of the Sequential Probability Ratio Test. Chan CL, Rudrappa S, Ang PS, Li SC, Evans SJW. Drug Saf. 2017 Aug;40(8):703-713. doi: 10.1007/s40264-017-0531-4.
7	Others	Survey	Research	A Survey on Pharmacovigilance Activities in ASEAN and Selected Non-ASEAN Countries, and the Use of Quantitative Signal Detection Algorithms. Chan CL, Ang PS, Li SC. Drug Saf. 2017 Feb 28. doi: 10.1007/s40264-017-0510-9.

Please provide the status of the above activites and any additional activities

TGA-Australia

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
1. Medicare Benefits Schedule (MBS)	1. Administrative Health data	1. Proof-of-Concept	
2. Pharmaceutical Benefit Schedule (PBS)	2. Administrative Health data	2. Proof-of-Concept	
3. Admitted Patients Data Collection	3. Clinical/Administrative Health Data	3. Interest	
4. My Health Record (MHR)	4. Electronic Health Record	4. Interest	
5. Australia Childhood Immunisation Register (ACIR)	5. Clinical register	5. Interest	
6. Medicine Insight	6. Electronic Medical Records from approximately 500 General Practices	6. Interest	
7. Research study - medicines post- marketing signal verification using the 45 and Up Study and linked services datasets	7. Survey data (from the 45 and Up Study which includes 10% of the above 45 population of New South Wales), administrative health data (MBS, PBS), clinical health data (Admitted Patients Data Collection, Emergency Department Data Collection), other administrative data (eg from the Register of Births, Deaths and Marriages), registry data (Cancer Registry)	7. Feasibility study/ proof of concept	7. Ethics approval obtained, data has been linked, awaiting delivery of data from data custodians. Data analysis expected to commence in May 2017
8. Project - Medicines post-market signal detection using Prescription Sequence Symmetry Analysis (PSSA) of PBS data	8. Administrative Health data	8. Feasibility assessment/ proof of concept	8. Currently engaging consultants for the project

Please provide the status of the above activites and any additional activities

ANVISA-Brazil

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
1. Information System Mortality SIM	1. Eletronic Health Record	1. Interest	1. Interest
2. Outpatient Information System SIA SUS	2. Eletronic Health Record	2. Interest	2. Interest
3. Hospital Information Sytem SIH SUS	3. Eletronic Health Record	3. Interest	3. Interest
4. São Paulo Pharmacovigilance System PERIWEB	4. ADR Reports	4. Interest	4. Interest
5. Information System of the National Immunization Program SI-PNI	5. Eletronic Health Record	5. Interest	5. Interest
6. Surveillance System Adverse Events After Vaccination SI-EAPV	6. ADR Reports	6. Interest	6. Interest
7. National System of Toxic-Pharmacologic Information SINITOX	7. Eletronic Health Record	7. Interest	7. Interest

Please provide the status of the above activites and any additional activities

HC-Canada

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
1. Canadian Institute for Health Information (CIHI)	1. Administrative data	1. Active	Hospitalization data is being used ad hoc to support select signal assessments (e.g. acetaminophen).
2. Canadian Primary Care Sentinel Surveillance Network (CPCSSN)	2. Cleaned data from Electronic medical rec	2. Proof-of-Concept	Recent activities include group discussions on potential uses of data in vigilance activities
3. IMS Evidence 360	3. Electronic Medical Records	3. Interest	Unchanged
4. Drug Safety and Effectiveness Network (DSEN) Social Media Study	4. Social Media	4. Scoping	The scoping review started in June 2016 and is now in the final stages of completion. It will be used to inform the development of a pilot platform for use of social media for pharmacovigilance in Canada The development/adaptation of a social media analytics platform started in Jan 2017 which will be used to explore the utility of social media for pharmacovigilance by the regulator within a Canadian context.
5. Canada Vigilance	5. Electronic reporting of Adverse events	5. Deployed	Currently in production, in 2013 electronic reporting was introduced, expanding the dataset to include foreign reports

Please provide the status of the above activites and any additional activities

AIFA-Italy

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
National Pharmacovigilance Database	Spontaneous ADRs report	Routine	Interest
AIFA Registries	Administrative, health and pharmacy records data	Research	Interest

Please provide the status of the above activites and any additional activities

PMDA-Japan

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
1. Medical Information Database-Network (MID-NET)	1. Distributed Electronic Medical Records	1. Pilot and Validation	Full implementation planned in 2018
2. Commercially available Japanese claims data	2. Small-scale Claims database	2. Routine since 2014	Full Implemetation from 2014
3. Natinal Database (NDB)	3. National Claims Database	3. Pilot	Pilot ongoing
4. Clinical Innovation Network (CIN)	4. Patients Registries targetd for some diseases (ALS, D	4. Project started in 2016	System Architecture started in 2016

Please provide the status of the above activites and any additional activities

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
1. Lareb	1. ADR reports from HCPs and patients	1. Routine	Ongoing
2. Pharmo	2. Electronic Medical Records registries, linked to registries (eg cancer, pathology, perinatal)	2. Research	Ongoing
3. IPCI	3. Electronic Medical Records from GPs	3. Research	Ongoing
4. ERGO	4. Population-based cohort study in elderly living in Rotterdam	4. Research	Ongoing
5. LASA	5. Population-based cohort study in elderly in multiple areas in NL	5. Research	Ongoing
6. NIVEL Primary Care database	6. Electronic Medical Records from GPs	6. Routine and Research	Ongoing
7. IKNL	7. Dutch cancer registry	7. Research	Ongoing
8. WEB-RADR	8. Collaboration to Mine Social Media for PhV	8. Research	Ongoing

Please provide the status of the above activites and any additional activities

MOH-New Zealand

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
1. The Centre for Adverse Reactions Monitoring (CARM)	ADR reports from HCPs and patients	Routine	Ongoing
2. National Collections	Health and disability information (eg, mortality, cancer registry, laboratory testing, pharmaceutical collection for subsidised dispensings)	Research	Ongoing
3. Electronic prescribing and administration (ePA)	Electronically recorded prescribing, dispensing and administration of medicines	Interest	Under consideration
4. Medication Error Reporting Programme (MERP) with the Health Safety Quality Commission (HQSC)	Medication error reports (and close calls) from HCPs	Research	Ongoing

Please provide the status of the above activites and any additional activities

Health-South Africa

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
1. Pregnancy Registry	1. Sentinel cohort	1. Routine	
2. Targeted Spontaneous reports	2. ADR reports	2. Routine	
3. Spontaneous reports	3. ADR reports	3. Routine	
4. Surveillance and health information system	4. Administrative health data, electronic laboratory, admission and pharmacy records	4. Under exploration	
5. Published or unpublished local studies	5. HIV/AIDS and TB Cohorts hospital active ADR surveillance studies, and clinical trials	5. Routine	

Please provide the status of the above activites and any additional activities

MPA-Sweden

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
Quality Registries	Clinical register	Data submitted from Quality records v	Routine
Medical Record System	Electronic Health records	Pilot planned for direct reporting from	Pilot study 2017
ADR and genetic factors. International study using spontaneous reports as a source to study specific diagnosis	Spontaneous ADRs	Use of reports registered at the MPA	Research
The Swedish Poisons Informations Centre	Clinical register	Cases of intoxication when using drug	Ongoing
The Swedish Medical Birth Register	Clinica register	Interest	Interest
Other national Health registries e.g. Admitted Patient Data Collection and the Cancer Register	Clinical register	Data collection and compilation in diff	ad hoc
The MPA ADR database	ADR from HCPs and patient	Regular and routine use	Ongoing
Published studies	ADR reports / information	Regular and routine use	Ongoing

Please provide the status of the above activites and any additional activities

Swissmedic-Switzeland

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
1. National Pharmacovigilance Database	1. Spontaneous ADRs Reports	1. Routine	1. Interest
2. eHealth Suisse	2. Electronic Health Records	2. Interest	2. Interest

Please provide the status of the above activites and any additional activities

MHRA-UK

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
1. Clinical Practice Research Datalink (CPRD)	1. Distributed Electronic Medical Records	1. Routine	
2. WEB-RADR	2. Collaboration to Mine Social Media for PV	2. Research	

Please provide the status of the above activites and any additional activities

EMA

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
THIN	Longtitudinal database of UK primary care electronic health record	Routine	
IMS	Longtitudinal database of primary care electronic health record in Germany and France	Routine	
Eudravigilance	Adverse drug reaction database	Routine	
PSUR Repository	Single central platform for PSURS and related documents used by all regulatory authorities and pharmaceutical companies in EU	Routine	
EPITT	Tracking table of pharmacovigilance issues discussed within the EU Regulatory network	Routine	
Regulatory submissions	Extedo Universal Review system (EURS) - contains all documents relevant to a marketing Application. For example all new versions of RMPS are automatically uploaded on submission	Routine	
Article 57 database	The Article 57 database (also known as the eXtended EudraVigilance Medicinal Product Dictionary) is a repository of structured and quality-assured information on medicinal products authorised in the EEA (i.e. nationally and centrally authorised products).The database contains around 500,000 current, unique medicinal product entries submitted by marketing-authorisation holders (MAHs) under the Article 57(2) requirements.	Routine	
PROTECT ADR database	The PROTECT ADR database is a downloadable Excel file listing of all MedDRA PT or LLT adverse drug reactions (ADRs). It is a structured Excel database of all adverse drug reactions (ADRs) listed in section 4.8 of the Summary of Product Characteristics (SPC) of medicinal products authorised in the EU according to the centralised procedure. It is based exclusively on MedDRA terminology and updated annually. The database also includes information on gender, causality, frequency, class warning and source of information for ADRs for which additional information is provided in the SPC.	Routine	
Clinical trial data portal	EMA-managed website providing registered users access to a database of published clinical data.	Under development - not currently in use for PHV issues	

Table 1. Big Data Sources of Interest for Pharmacovigilance (PV)

Data Source	Data Source Type	Stage of use for PV	Status
WHO Global ICSR database	SRS data	Routine	In use for nearly 5 decades
Public Health Programmes (HIV, TB Malaria etc) in different countries	Active surveillance data	proof of concept/phase 4 studies	Completed in some countries, ongoing in others