

Schedule of Documents: FOI 4940

Any documents that detail the protocol and/or methodology that was intended to be used to quantitatively and/or statistically identify potential safety signals related to the covid-19 vaccines in the TGA's Adverse Event Management System.

VSS/V-STRS documents:

File	Doc size	TRIM reference
DPAR WI	13 pages	D22-6235093
WI for observed versus expected analyses	17 pages	D21-2715234
Observed versus expected incident rate calculator	Excel doc	D21-3006342
OE ratio confidence interval calculator	Excel doc	D21-2741807
AIR Health Data Portal access guide	9 pages	D22-6228059
WI for assessment of individual AEFI reports against VSIG criteria	22 pages	D23-5292900
TGA COVID-19 vaccine safety monitoring plan	14 pages	D21-2120135

SIU documents:

File	Doc Size	TRIM reference
Vaccine specific		
Vaccine SOP – Surveillance and monitoring of adverse events following immunisation (issued in 2019)	26 pages	D18-11209492
Working Template for fortnightly scanning	3 pages	D18-11263731
Work instruction - Vaccine Safety Investigation Group v1.0 - SIU - FINAL 7 Jan 2019	13 pages	D18-10878760
Non-vaccine specific		
SOP -Process for conducting a medicine signal investigation (referred to in the Vaccine SOP above) – April 2019	29 pages	D17-770082
SIU Targeted Signal Investigation Template – June 2020 DRAFT	3 pages	D20-917085
SIU Signal Investigation Template – DRAFT June 2019	6 pages	D19-5620140
Process for Conducting a Medicines Safety Review (July 2015)*	13 pages	R15/400261

*Not used very often, hence why not updated

VERA documents:

File	Doc size	TRIM reference
Process for escalating AEFI reports from AEMDS to SIU WI	4 pages	D20-3235619
List of medically significant AEFI to escalate from AEMDS to SI WI	6 pages	D20-3235571
ACV 25 2021-9 Request for advice COVID-19 vaccine pharmacovigilance plan	3 pages	D21-3100560
Reporting rate confidence interval analysis copy	8 pages	D21-3100550
VERA WI signal investigation draft	4 pages	D21-3003675
COVID-19 vaccine statistical surveillance methods draft	34 pages	D20-3444155
Analysis plan: sequential analysis for near real-time surveillance of COVID-19 vaccine safety	4 pages	D21-2859756
DPAR comparison 6 months post COVID-19 vaccine rollout	Powerpoint (34 slides)	D21-3003643
Signal investigation slides: DPAR comparison 6 months post COVID-19 vaccine rollout	Powerpoint (10 slides)	D21-3469356
COVID-19 vaccine signal detection and investigation framework draft	8 pages	D20-3725525
Signal priority	4 pages	D22-5396479
AESI list Feb 2022	33 pages	D22-5152358
Revised AESI list Sept 2021	33 pages	D21-3074579
VERA signal investigation case definitions	Container that stores 7 documents relating to case definitions of adverse events	E21-352682
VSS COVID19 vaccine AESI list and MedDRA codes working document last updated 24 May 2021	56 pages	D20-3595626