



Note for file

TGA REF	AU-TGA-0000682908
Date and time	23 December 2021
Type of event	Fatal AEFI Assessment Team Meeting
Topic	Fatal report & COVID-19 Vaccine AstraZeneca

Participants

Name	Details
s22	Acting MO5 VERA, PVB TGA
s22	MO4 VERA, PVB TGA
s22	MO2 VERA, PVB TGA
s22	Assistant Director VERA, PVB TGA
s22	APS5 VERA, PVB TGA

Key points

- 89 Female
- s22
- s22
- s22
- CVA, s22

Rereviewed 03/02/2022

- COD Unrelated to vaccination - s22

Follow-up action (include action)

- Regulatory or programmatic action for consideration by TGA or OHP;

required, action
officer, agreed date/s)

- [Communication with JIC and ACV](#); RFI sent 17/12/2021 – confirm if a death.
- [Any other follow-up actions required.](#)

Decisions

- Unlikely Causality



Australian Government
Department of Health
Therapeutic Goods Administration

Department of Health **s22**

Email Address: **s22**

Dear Sir/Madam

Re: TGA AE Reference: AU-TGA-0000682908
Drug: COVID Vaxzevria (AstraZeneca)
Your Reference: **s22**

Thank you for your report documenting a fatal outcome in a patient who had been taking COVID Vaxzevria (AstraZeneca). Your report was entered into the Therapeutic Goods Administration's (TGA)'s Australian Adverse Event Management System (AEMS) in 17/12/2021. To assist with the assessment of this case, I would be grateful if you could provide the following additional information, quoting the AER Reference Number AU-TGA-0000682908 in your reply:

- Could you please clarify if this report refers to a fatal outcome? The case narrative refers to the patient being discharged home and we would appreciate clarification of this before we proceed with our investigation.

If the report does refer to a fatal outcome, could you please provide the following:

- The date, circumstances and mode of death
- The daily dose, dates of and reasons for administration of COVID Vaxzevria (AstraZeneca) and any other medications which were being taken by the patient in the lead up to death
- Details of treatment of the reported event
- If the patient died in hospital a copy of the inpatient summary and consultant's report
- Whether a post-mortem examination was performed. If so a copy of the post-mortem report should be forwarded promptly as soon as it becomes available to your company
- Whether the case was referred to the Coroner. If so a copy of the coroner's report should be forwarded promptly as soon as it becomes available.

Please note that these details are requested by the TGA in respect of reports of fatal outcomes associated with adverse event reports.

Please refer to the Privacy Statement at the end of this letter for information about how the TGA handles information of this kind. The TGA does not include any personal information in

our database that may have been inadvertently provided in the report, such as patient names but does keep information on the Sender of the report in case any clarification is needed.

The TGA undertakes regular analysis of the AEMS to identify new and emerging safety issues (signals) that may be related to medicines in use in Australia. When a signal is detected, further review is undertaken by the TGA to determine whether any action is required - such as changes to Product Information (PI), labelling or packaging, recall of a product or provision of information on the issue to prescribers and consumers of a medicine, including the issuing of Alerts.

Further information about medicines, such as Product Information, Consumer Medicine Information and Alerts can be found on the TGA website at <http://www.tga.gov.au>

If you wish to receive regular updates about Safety Information on medicines and devices you can subscribe to our notification system. Information about subscribing can be found at <http://www.tga.gov.au/newsroom/subscribe-rss.htm> Thank you in anticipation of your ongoing assistance.

Yours sincerely,

The Adverse Event & Medicine Defect Section
on behalf of the Head
Pharmacovigilance Branch
17/12/2021

PRIVACY STATEMENT

For general privacy information, go to www.tga.gov.au/about/website-privacy.htm

Information in this report is collected to assist in the post market monitoring of the safety of therapeutic goods under the *Therapeutic Goods Act 1989* (the Act). All reports are assessed and entered into the TGA database for adverse events. Further information about how the TGA uses adverse event information that is reported to it is available at <https://www.tga.gov.au/reporting-adverse-events>

The TGA collects personal information in this report to:

- Assess the safety of medicines and vaccines under the Act.
- Contact the reporter of the adverse event if further information is required.
- Contact representatives of entities that supply therapeutic goods, to discuss reported adverse events.
- Check that the same information has not been received multiple times for the same adverse event.

At times, this information is collected from someone other than the individual to whom the personal information relates. This can occur when an adverse event is reported to a person or an entity other than the TGA (such as a health professional or a hospital), and that person or entity passes the information on to the TGA.

Personal information collected in this report may be disclosed by consent or where the disclosure is required by, or authorised under, a law (for example, under section 61 of the Act). Where a report relates to vaccine events, personal information about the reporter or the patient may be disclosed to State and Territory health agencies under subsection 61(3) of the Act.

Acknowledgement email

Email	s22
Email from	adr.reports@health.gov.au
Email cc	
Subject	TGA Adverse Event (AE) Report AU-TGA-0000682908 [SEC=OFFICIAL]
Date and Time	17/12/2021 01:44:43 PM
Attachments	AU-TGA-0000682908 - 20211217024036-Request-for-information-regar ding-an-adverse-reaction-resulting-in-death.pdf

Dear s22

This email is related to your submission to the TGA's Australian Adverse Event Management System (AEMS). Please refer to the attachments.



Australian Government
Department of Health
Therapeutic Goods Administration

Department of Health s22

Email Address s22

Dear Sir/Madam

Re: TGA AE Reference: AU-TGA-0000682908
Drug: COVID Vaxzevria (AstraZeneca)
Your Reference: s22

Thank you for submitting your adverse event report, which was entered into the Therapeutic Goods Administration's (TGA)'s Adverse Event Management System (AEMS) on 24/12/2021. To assist in the TGA's assessment of this report, could you please provide the following additional information:

- Could I please clarify if this was a fatal case as in the narrative the patient was discharged, however the reactions stated Fatal.

Please refer to the Privacy Statement at the end of this letter for information about how the TGA handles information of this kind. The TGA does not include any personal information in our database that may have been inadvertently provided in the report, such as patient names but does keep information on the Sender of the report in case any clarification is needed.

The TGA undertakes regular analysis of the AEMS to identify new and emerging safety issues (signals) that may be related to medicines in use in Australia. When a signal is detected, further review is undertaken by the TGA to determine whether any action is required - such as changes to Product Information (PI), labelling or packaging, recall of a product or provision of information on the issue to prescribers and consumers of a medicine, including the issuing of Alerts.

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If you wish to receive regular updates about Safety Information on medicines and devices you can subscribe to our notification system. Information about subscribing can be found at <http://www.tga.gov.au/newsroom/subscribe-rss.htm> Thank you in anticipation of your ongoing assistance.

Please quote the TGA AER Reference AU-TGA-0000682908 in your reply. If you have any queries about this report then please don't hesitate to contact me via adr.reports@tga.gov.au

Yours sincerely,

The Adverse Event & Medicine Defect Section
on behalf of the Head
Pharmacovigilance Branch
24/12/2021

PRIVACY STATEMENT

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Information in this report is collected to assist in the post market monitoring of the safety of therapeutic goods under the *Therapeutic Goods Act 1989* (the Act). All reports are assessed and entered into the Therapeutic Goods Administration's (TGA's) Australian Adverse Event Management System. Further information about how the TGA uses adverse event information that is reported to it is available at <https://www.tga.gov.au/reporting-adverse-events>

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- Check that the same information has not been received multiple times for the same adverse event.

At times, adverse event information is collected from someone other than the individual to whom the personal information relates. This can occur when an adverse event is reported to a person or an entity other than the TGA (such as a health professional or a hospital or a sponsor), and that person or entity passes the information on to the TGA. In those cases, the TGA will not collect the name and contact details of patients. However, the TGA may collect other information relating to patients including the date of birth or age, gender, weight, initials and information about the relevant adverse event.

Personal information collected in your report may be used or disclosed as permitted under the Privacy Act 1988, including by consent or where the disclosure is required by, or authorised under, a law (for example, under section 61 of the Act). Where a report relates to vaccine events, any personal information in the adverse event report may be disclosed to State and Territory health agencies under section 61(3) of the Act.

Acknowledgement email

Email	s22
Email from	adr.reports@health.gov.au
Email cc	
Subject	TGA Adverse Event (AE) Report AU-TGA-0000682908 [SEC=OFFICIAL]
Date and Time	07/01/2022 01:04:16 PM
Attachments	AU-TGA-0000682908 - 20220107020232-Request-for-information-regar ding-an-adverse-reaction-resulting-in-death.pdf

Dear

This email is related to your submission to the TGA's Australian Adverse Event Management System (AEMS). Please refer to the attachments.



Australian Government
Department of Health
Therapeutic Goods Administration

Department of Health s22

Email Address s22

Dear Sir/Madam

Re: TGA AE Reference: AU-TGA-0000682908
Drug: COVID Vaxzevria (AstraZeneca)
Your Reference: s22

Thank you for your report documenting a fatal outcome in a patient who had been taking COVID Vaxzevria (AstraZeneca). Your report was entered into the Therapeutic Goods Administration's (TGA)'s Australian Adverse Event Management System (AEMS) in 15/12/2022. To assist with the assessment of this case, I would be grateful if you could provide the following additional information, quoting the AER Reference Number AU-TGA-0000682908 in your reply:

- The mode of death/death certificate if available
- Details of treatment of the reported event
- A copy of the inpatient summary and consultant's report from the reported hospital admission
- Whether a post-mortem examination was performed. If so a copy of the post-mortem report should be forwarded promptly as soon as it becomes available to your company
- Whether the case was referred to the Coroner. If so a copy of the coroner's report should be forwarded promptly as soon as it becomes available.

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Yours sincerely,

The Adverse Event & Medicine Defect Section
on behalf of the Head
Pharmacovigilance Branch
7/1/2022

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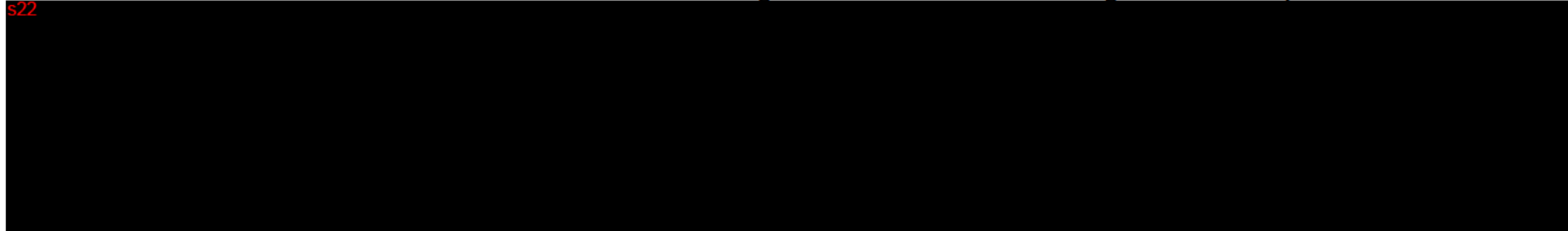
The TGA collects personal information in this report to:

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- Check that the same information has not been received multiple times for the same adverse event.

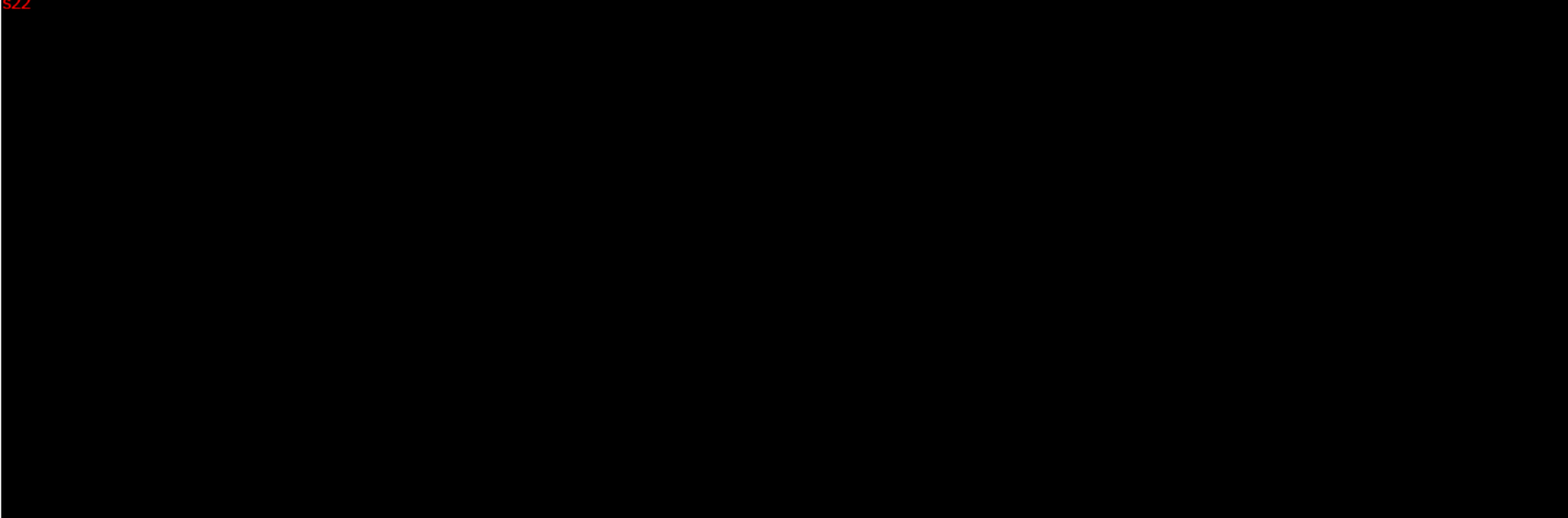
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TGAICSRIdentifier	Vaccine	Age	Sex	State	Agedcare	ReportDate	VAXDate
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AU-TGA-0000682908	COVID-19 Vaccine AstraZeneca	89	Female	SZZ	-	15/12/2021	SZZ
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Death	TTD	Reaction	Reportertype
s22			

- - Cerebrovascular accident ; Concomitant disease aggravated ; Fall Regional Pharmacovigilance Centre

s22			
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CaseNarrative

DOB

Patient_Atsi_Category

Medicalhistory

s22

s22

s22

s22

reportersviewoncausality

Triage

Referredtocoroner

Commentsotherinformation

Panel Review Date

s22

not stated

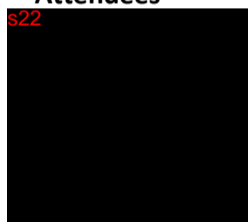
5

23/12/2021

s22

Attendees

s22



Outcome Other Notes

s22

Not fatal report s22 to contact AEMS

Outcome Other notes Rereview Outcome Notes

s22

522

TGAICSRIdentifier

Vaccine

Age

Sex

State

Agedcare ReportDate

VAXDate Death

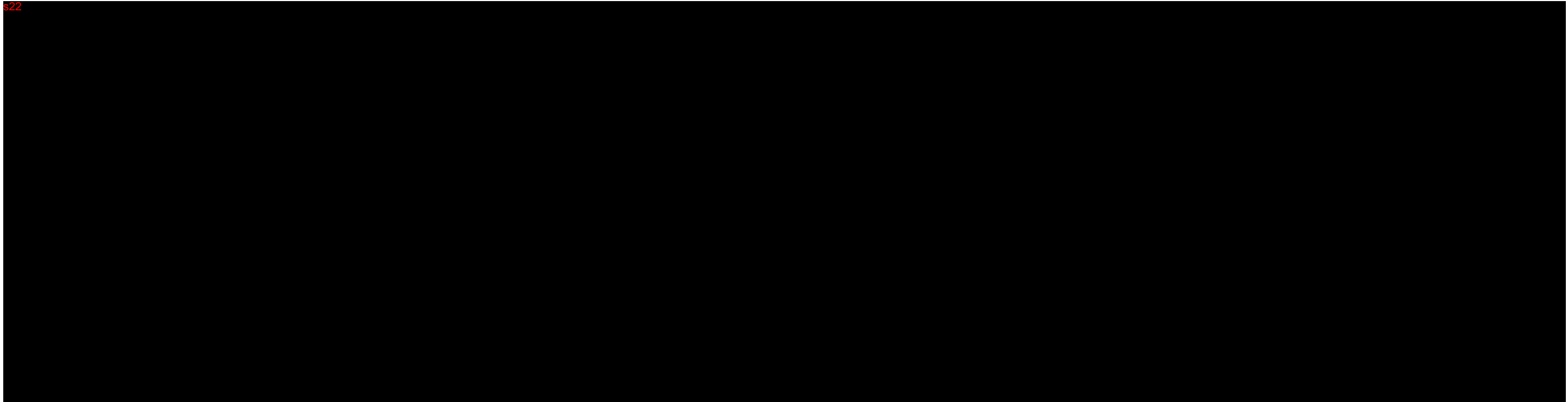
TTD

Reaction

s22



Case Updates



AU-TGA-0000682908

COVID-19 Vaccine AstraZeneca

89

Female

s22

-

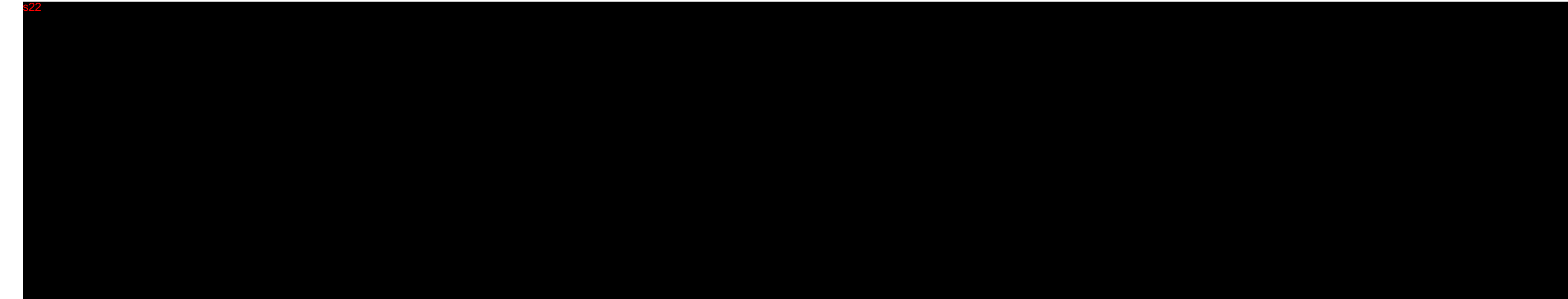
15/12/2021

s22

-

-

Adverse event following immunisation ; Cerebrovascular accident ; Fall



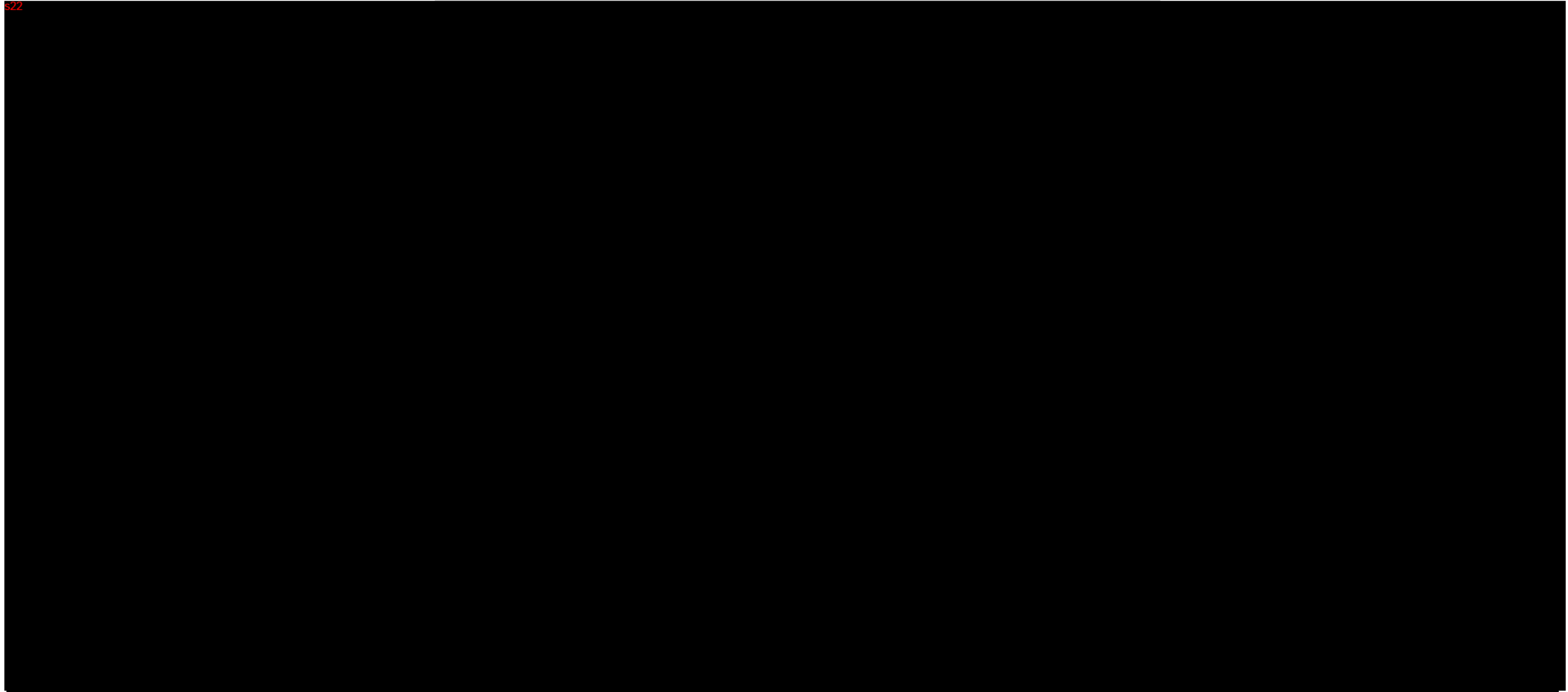
Reportertype

CaseNarrative

DOB

Patient_Atts SenderOrg
i_Category anisation Dose

522



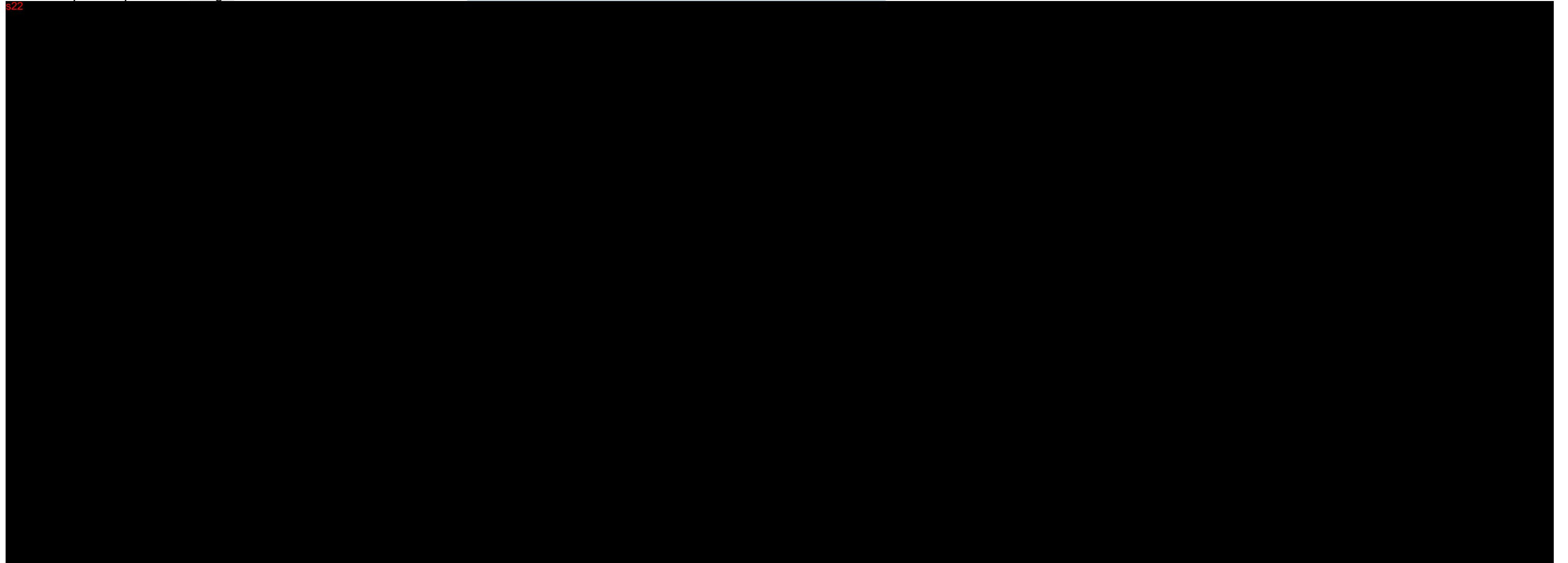
s22

s22

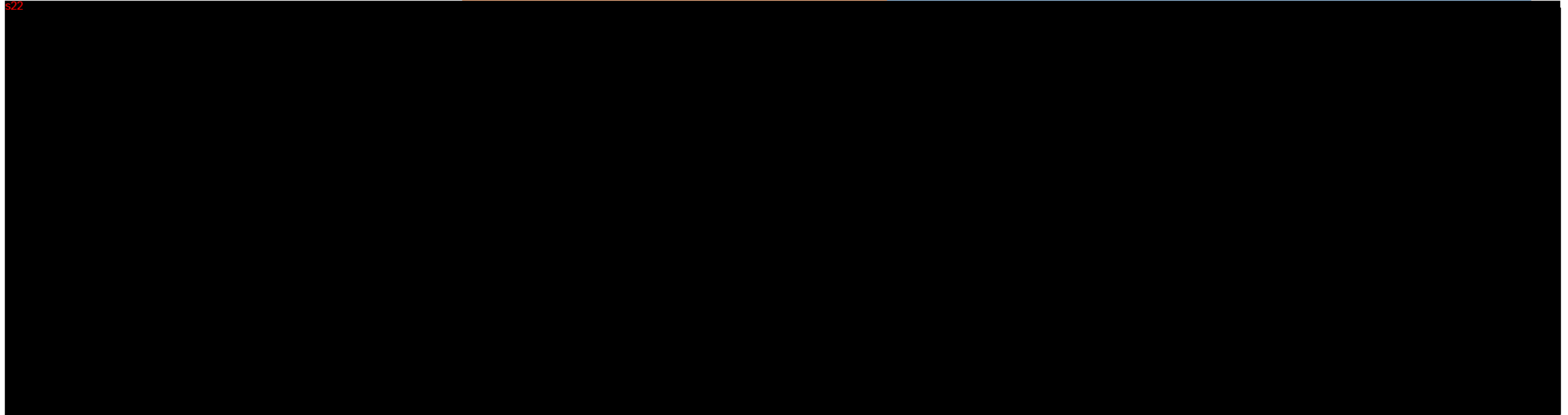
Regional Pharmacovigilance Centre

reportersvi	Referredt	Panel review
Medicalhi ewoncausal	ocoroners	date
story	ity	Triage
Comments	otherinformati	Outcome
on		Other notes

522



Panel review



s22

not stated 5

23/12/2021 Reject

Not A Fatal Report

3/02/2022 Unlikely

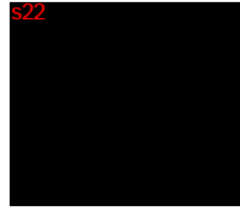
Unrelated to vaccination

s22

s22

Attendance

s22



Acknowledgement email

Email	s22
Email from	adr.reports@health.gov.au
Email cc	
Subject	TGA Adverse Event (AE) Report AU-TGA-0000682908 [SEC=OFFICIAL]
Date and Time	24/12/2021 02:26:41 PM
Attachments	AU-TGA-0000682908 - 20211224032437-Acknowledgement-request-for -additional-information.pdf

<p style="margin:0cm 0cm 10pt;line-height:normal;">Dear </p><p style="margin:0cm 0cm 10pt;line-height:normal;">This email is related to your submission to the TGA's Australian Adverse Event Management System (AEMS). Please refer to the attachments.</p>