5 February 2022

Dear Judge,

Thank you for considering this case.

Introduction

In the following I refer to the numbered paragraphs contained in the Decision Notice Ref. IC-107706-F9D4 (Annex 1).

I am appealing the Commissioner's decision stated in Par. 2, i.e., "the public interest favours maintaining the exemption". In my view the public interest favours the release of the information that I requested on Covid-19 vaccines adverse drug reactions (ADRs) that the Medicine and Healthcare Products Regulatory Agency (MHRA) holds. The Commissioner's gives his analysis of the Public Interest Test in Par. 25-36.

Below I give first my rationale against the arguments related to the Public Interest Test that the MHRA has presented, and that the Commissioner has upheld, to support its decision of non-disclosure of the requested information. I will then expand on some of my arguments supporting disclosure of the information to the public. The Commissioner has quoted my arguments, but he has not explained why he has given them less weight compared to the weight he has given to the MHRA arguments.

Against the argument that misinterpretation of the released data could undermine the Covid-19 vaccination programme

To support its decision of not releasing the requested information, The MHRA has brought forward the notion that releasing ADR data from the Yellow Card Scheme – the MHRA pharmacovigilance system – could lead to their misinterpretation, and potentially result in "catastrophic outcomes" of the vaccination campaign (Par. 32). The MHRA has produced as "evidence for this risk […] the termination of the Japanese Government of a human papillomavirus (HPV) vaccine programme following misinterpretation of published data" (Par. 31). To this end, it quoted an article from Reuters referring to research published in The Lancet (Annex 2).

The Japanese story is far from being an example supportive of the MHRA argument. Even from a passing read of the Reuters article and the several original editorials and studies appeared on the Lancet about the Japanese case (Annex 2-5), it is evident that the stated reason of the failure of the Japanese vaccine programme – which has not been terminated, albeit it is receiving little uptake from the population – has been the Japanese Government choice to completely halt the active promotion and proactive recommendation of the HPV vaccine following unconfirmed media reports of adverse reactions after vaccination. To the contrary, the unprecedented intensity and level of mainstream media funding with which the UK Government has promoted and is promoting the SARS-Cov-2 vaccines and

their related official research would more than mitigate the theoretical risk that the vaccination programme could be undermined by a few pieces of research by rogue scientists appearing on the much less funded alternative media.

Moreover, a fitting example showing that the MHRA fears are unfounded is the VAERS pharmacovigilance system (https://vaers.hhs.gov/data.html), which is the USA counterpart of the Yellow Card Scheme. VAERS allows the filtering and downloading of a plethora of Covid-19 vaccine reaction data for several categories, down to the vaccine batch number of each individual report. The approach has not translated into a halt of the USA vaccination campaign. Even if the USA vaccination rate is somewhat lagging behind the UK rate, this is likely more due to a combination of a later start of its vaccination programme, a higher logistical challenge due to the size and spread of the population, and perhaps stronger preexisting anti-vaccination sentiments in some part of the population, rather than to the public availability of the full body of individual records of Covid-19 vaccine reactions.

Against the argument that the data requested should be seen "in context" to mitigate the risk of misinterpretation, and that the MHRA needs time to provide that context

The notion that a page of disclaimers and caveats interspersed with guidance videos to accompany the publication of ADR data, i.e., what the MHRA calls the "context information" (Par. 34), would take the MHRA two years to complete (Par. 35) is preposterous. Surely the MHRA has cumulated experience in providing context for ADR data of all other vaccines and drugs on the market.

Most importantly, it is precisely the lack of context with which the MHRA provides its weekly Covid-19 vaccine ADR reports (sample in Annex 6) that contributed to my decision to request the full data set. The weekly data reports list only the cumulative absolute number of events for each category and sub-category of reactions, and nothing else. These numbers in isolation are what they are, just numbers, and do not provide actual information. Because of the lack of context that would instead be provided by the wider body of associated data – e.g., age and sex of the person who was reported as having reacted to the vaccine, or the period of onset of the reaction since vaccination – the bare numbers that the MHRA currently publishes are prone to be misused for scaremongering by those against Covid-19 vaccines.

Arguments supporting disclosure of the information to the public

First of all, the type of data that I have requested to the MHRA in relation to Covid-19 vaccine ADR data is nothing out of the ordinary, as the Commissioner has quoted (Par. 25). This type of data is routinely and timely made available by the MHRA to the public as interactive Drug Analysis Profiles (iDAPs) on the Yellow Card website (https://yellowcard.mhra.gov.uk/iDAP/). The iDAPs individual drug pages give access to comprehensive data-sets providing a plethora of details around ADRs for all drugs marketed in the UK. For vaccines, it is noted in the same web page that "information regarding suspected adverse reactions to vaccines is not currently available via the iDAPs but is available upon request". It is key to note that Covid-19 vaccines not only are 'black triangle drugs', i.e, they belong to the class of new medicines and vaccines that are under 'additional monitoring' (Par. 26) (https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals#black-

triangle-scheme), but they also are under conditional marketing authorisation (https://www.gov.uk/guidance/conditional-marketing-authorisations-exceptional-circumstances-marketing-authorisations-and-national-scientific-advice). To then make one simple comparison, for Brentuximab, also a black triangle drug under conditional marketing authorisation, the ADR data-set is currently available (https://info.mhra.gov.uk/drug-analysis-profiles/data/UK_EXTERNAL/NONCOMBINED/UK_NON_000182188964.zip). For this drug the latest data update is 31 December 2021, reporting all ADRs received up to end of year 2021. It seems unreasonable for the MHRA to maintain that in February 2022 it would be in public interest to withhold ADR data for Covid-19 vaccines that have been administered to tens of millions of individuals in the UK since 9 December 2020, and to delay sharing or publication of ADR data by an unspecified amount of time – for now in excess of 13 months – for the purpose of collating "contextual narrative" (Par. 33), when instead, for a vastly less used drug such as Brentuximab, the data is released with less than two months delay. The Commissioner refers to this argument (Par. 26), but did not provide a counter argument. It is precisely because the Covid-19 vaccines have the potential to affect millions of people that the minimum standard used in the publication of ADR data for all other drugs should also be applied to the Covid-19 vaccines.

Moreover, the combination of the qualifications of 'black triangle drug' and 'conditional marketing authorisation' makes for a higher monitoring need for Covid-19 vaccines, as there is a theoretical higher risk of harms to the public from these vaccines, by their very nature of new and incompletely tested drugs, especially considering that after only six months into the trials the placebo groups were unblinded and then most of their participants were offered and in turn accepted vaccination (https://www.bmj.com/content/bmj/373/bmj.n1244.full.pdf), jeopardising the opportunity of long term harm/benefit data. Surely it is for the public good to make Covid-19 vaccine ADR data available quickly to the public, and especially to the vast global research community, as the latter could provide valuable studies giving insights on possible vaccine harms – which incidentally is the very *raison d'être* of the public iDAP data portal. At Par. 27 the Commissioner refers to this argument and, again, does not offer a counter argument.

Importantly, the MHRA, without prior publication of a call for competition due to the urgency of the matter, awarded to Genpact (UK) Ltd an exclusive contract valued at £1.5M [https://ted.europa.eu/udl?uri=TED:NOTICE:506291-2020:TEXT:EN:HTML&src=0] for the provision of a modern artificial intelligence software tool to collect and analyse ADR data arising from spontaneous reports from healthcare professionals and individual members of the public in relation to Covid-19 vaccinations. It seems reasonable to expect that such a costly software would be capable to rapidly generate, at little cost, a data output to be shared timely and periodically on the iDAP – or directly with anyone making a specific requests, in line with what the MHRA promises for all vaccines.

In addition, data transparency on Covid-19 vaccines has been widely advocated by senior and chief editors of the British Medical Journal (BMJ), one of the oldest and most authoritative medical publications (Annex 7, https://www.bmj.com/content/376/bmj.o102.full.pdf). While we are far from achieving this at the level of pharmaceutical companies proprietary vaccine trial data on benefits and harms, it seems unreasonable for a public agency to refuse sharing with the public comprehensive, timely, and regular Covid-19 vaccine ADR data, when this data is deemed by the same agency to be worthy of being made available timely to all when it comes to all other drugs. This data originates within the public, is reported by the public, and, surely, it is collected for the public good (Par. 28).

Also, in a short contribution to the rapid response section of a BMJ article, I pointed out how that the MHRA had missed the serious blood clotting events caused by one the Covid-19 vaccines, the

AstraZeneca vaccine, that had been instead flagged up by the pharmacovigilance systems of other European countries (Annex 8, https://www.bmj.com/content/373/bmj.n931/rr-16). Two days after my response the Telegraph run an expanded story (Annex 9, https://www.telegraph.co.uk/global-health/science-and-disease/revealed-britains-regulator-missed-link-astrazeneca-jab-rare/). After only 120,000 national vaccinations, the Norwegian pharmacovigilance system identified 6 cases in previously healthy people of a serious rare condition, attributed to the vaccine, characterised by blood clotting with concomitant low platelets, a rate that translated in harms being higher than the benefits, leading the Norwegian Government to stop vaccination with AstraZeneca vaccine for those below age 40, with the MHRA following suit only some time later. At that point 20 million people had been injected with the AstraZeneca vaccine in the UK, and no concerns on harms/benefits ratio of the vaccine had been publicly reported by the MHRA. Not surprisingly, at the recent MHRA Board Meeting held in public in January 2022, one of the MHRA communication strategy implementation actions included the procurement for a supplier to help with "reputation management to support trust in the agency from the public and healthcare professionals" (https://www.youtube.com/watch?v=rsNM4mSQUoE&t=842s, time 14:02-14:12).

Even more concerning is that, despite these reactions being characterised by a very rare combination of clinical features, and hence standing out of the "noise" of more common conditions, the MHRA still was not able to extract a harm signal from its data and communicate it to the public. This equated to unnecessary deaths of young and healthy individuals who would have lived if the MHRA analysis had not been 20 times slower than the Norwegian, as for these individuals the vaccine conferred a risk of harm higher than the chances of benefit. This weakness of the MHRA artificial intelligence algorithms that are fed Covid-19 vaccines ADR data is one further reason for the MHRA data to be shared timely and widely for others to process in the name of safety. As a nurse teacher, vaccination centre supervisor, and licensed independent prescriber, at the time when these reactions were unfolding and discussed in the specialised literature I felt it my duty to obtain the data from the MHRA for careful analysis. What a disappointment since then.

Conclusion

In summary: 1) The MHRA argument that misinterpretation of ADR data could jeopardise the Covid-19 vaccination campaign is unfounded and not supported by the relevant evidence; 2) The argument that the MHRA has to take two years to provide "contextual information" to accompany ADR data is untenable for an organisation that deals regularly with analogous information; 3) The combination of the Covid-19 vaccines being incompletely tested drugs administered multiple times to tens of millions of individuals in the UK, the transparency on research data being advocated by the medical research community, and the previous inability of the MHRA to timely find harm signals from its own secret data, supports the notion that the public interest is in the timely publication of Covid-19 vaccine ADR data.

By sharing its data, the MHRA would allow the concerted human power of analysis harnessed from the combination of independent researchers across the world to work in parallel with its secret, expensive and, unfortunately, delayed artificial intelligence software tool.

Yours faithfully,

Marco Tullio Suadoni

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 26 January 2022

Public Authority: Medicines and Healthcare Products Regulatory Agency

Address: 10 South Colonnade
Canary Wharf
London
E14 4PU

Complainant: Marco Tullio Suadoni

Address: marco.suadoni@pm.me

Decision (including any steps ordered)

1. The complainant has requested information about adverse reactions to approved COVID-19 vaccines. The Medicines and Healthcare Products Regulatory Agency (MHRA) is withholding the information under section 22(1) of the FOIA as it intends to publish it at some future date.

2. The Commissioner's decision is as follows:

   - MHRA is entitled to withhold the requested information under section 22(1) of the FOIA and the public interest favours maintaining the exemption.

   - MHRA's refusal notice was inadequate and did not meet the requirements of section 17(3) of the FOIA.

3. The Commissioner does not require MHRA to take any remedial steps.

Request and response

4. On 19 March 2021 the complainant wrote to MHRA and requested information in the following terms:

"First of all, I am aware of the information available here: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

However, the information linked as above does no report all ADRs data, but only summary data. I request in spreadsheet or database format, e.g., comma-separated-values (CSV) (not PDF format), the full body of all anonymised raw data with the level of details as close as possible to that one available for Interactive Drug Analysis Profile (iDAP) and related CSV files, for all Covid-19 vaccines currently in use in the UK.

Especially to include for EACH event, but not limited to:

SEX
AGE
DATE
REPORTER
REPORT SUBMISSION
ROUTE OF ADMINISTRATION
SERIOUSNESS
SYSTEM ORGAN CLASS"

5. MHRA responded on 19 April 2021, refusing to disclose the information under section 22 of the FOIA. MHRA advised that it intended to publish all suspected reactions reported in association with available COVID-19 vaccines in an interactive format as interactive Drug Analysis Profiles (iDAPs), along with the Adverse Drug Reaction (ADR) summary that is published each week. MHRA went on to explain that the use of iDAPs will enable users to view the data by categories of their choice, such as age, sex and seriousness of reports.

6. MHRA public interest test position had shortcomings. MHRA said that it recognised that there is a strong interest in seeing this data and that it accepted that it should not be withheld. However, MHRA omitted to give any public interest arguments for withholding the information.

7. Following an internal review MHRA wrote to the complainant on 12 May 2021. It upheld its position but again, did not provide any public interest arguments to support its withholding of the information.

Scope of the case

8. The complainant contacted the Commissioner on 20 May 2021 to complain about the way his request for information had been handled.

9. The Commissioner's investigation has focussed on whether MHRA is entitled to rely on section 22(1) of the FOIA to withhold the requested information, and the balance of the public interest. He has also considered MHRA's refusal of the request.

Reasons for decision

10. Section 22(1) of the FOIA says that information is exempt information if:

> (a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not)
>
> (b) the information was already held with a view to such publication at the time when the request for information was made, and
>
> (c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in (a).

11. Section 22 is a qualified exemption which means it is subject to the public interest test.

12. In its submission to the Commissioner, and a subsequent conversation with him, MHRA confirmed that it holds the requested information. Of relevance here is MHRA's 'Yellow Card' website[1]. Through this website MHRA collects and monitors information on safety concerns such as suspected side effects or adverse incidents involving medicines and medical devices.

13. Interactive Drug Analysis Profiles for a wide range of medicines on the Yellow Card website contain complete data for all spontaneous suspected adverse drug reactions, or side effects, which have been reported on that drug substance to the MHRA via the Yellow Card scheme, from healthcare professionals and members of the public.

14. iDAPs enable people to interact with the data so they can understand more about the types of reactions that have been reported and, at a high level, about who experienced the side effects.

[1] https://yellowcard.mhra.gov.uk/

15. The iDAP for each medicine featured on the Yellow Card website report against a number of factors, including those referred to in the complainant's request: Sex, Age, Date, Reporter etc which he has drawn from the Yellow Card site.

16. However, medicines associated with coronavirus have their own Yellow Card reporting site[2]. At the point of the request, and currently, individuals can submit an adverse reaction report about a COVID-19 vaccine through the coronavirus Yellow Card site but are not able to access the same detailed iDAP data that is available for other medicines on the main site. However, the Coronavirus Yellow Card scheme publishes a weekly summary report of adverse reactions to approved COVID-19 vaccines[3].

17. Following discussion with MHRA and having considered the data that MHRA currently publishes about other medicines on the Yellow Card website, the Commissioner is satisfied that the data that the complainant has requested about the COVID-19 vaccines is data that MHRA holds and intends to publish. This is because it holds the same data about other medicines.

18. MHRA notes, correctly, that section 22 of the FOIA does not oblige it to commit to a specific, future publication date. However, MHRA has advised the Commissioner that it expects to publish the data in question by the end of 2022.

19. Turning to (b), MHRA has provided the Commissioner with email exchanges covering the period 23 February 2021 to 2 March 2021. In these exchanges members of MHRA staff discuss technical and presentational issues associated with the publication of the requested data. As such, the Commissioner is satisfied that, at the time of the request on 19 March 2021, MHRA held the data with a view to publishing it at a future date.

20. The Commissioner is satisfied that the first two criteria at paragraph 10 have been met; MHRA held the requested data with a view to publishing it at some future date and the data was held with a view to such publication when the complainant submitted his request.

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[2] https://coronavirus-yellowcard.mhra.gov.uk/

[3] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

21. Finally, the Commissioner has considered (c); whether it was reasonable in all the circumstances to withhold the requested data. The Commissioner's published guidance on section 22 acknowledges that there is some overlap between the factors to consider when deciding what is reasonable, and those which are relevant to the application of the public interest test. However, the Commissioner's guidance goes on to suggest that when determining whether or not it is reasonable, in all the circumstances, to withhold information a public authority should consider whether or not it is sensible, in line with accepted practices, and fair to all concerned. Of relevance here, the guidance advises that an authority may also wish to give thought to whether it is the right decision to manage the availability of the information by planning and controlling its publication.

22. Regarding planning and controlling the information's publication, MHRA says in its submission that it considers that the reasons it gave to the complainant in its April 2021 response are still valid. In addition, MHRA says it will be developing a more appropriate route to publication in summer 2022 that will allow it to mitigate the risks it has identified. It will begin implementing new systems for providing data across all medical products, including vaccines. This will enable MHRA to produce an improved and more suitable format for publishing data in general. Specifically in this case, alongside raw data MHRA will develop extensive communication materials to manage misuse of data, to mitigate any risks associated with misinterpretation of the data and to manage the resources associated with publishing the data. That is in addition to the continued MHRA response to the pandemic.

23. The Commissioner has taken account of MHRA's position above. The notion of 'fairness' is less of a factor in this case, but the Commissioner accepts too that withholding the information at the time of the request was sensible ie it was not totally illogical, and that it was in line with MHRA's accepted practices. This is because it is MHRA's practice to provide full and clear and context against each medicine reported on the Yellow Card site as having generated an adverse reaction.

24. The Commissioner considers that it was reasonable in all the circumstances for MHRA to withhold the requested information at the time of the request and the internal review. Since the three criteria at paragraph 10 have been met, the Commissioner's decision is that MHRA was entitled to withhold the information the complainant has requested under section 22(1) of the FOIA. He has gone on to consider the public interest test.

Public interest test

Public interest in disclosing the information

25. In his complaint to the Commissioner, the complainant has argued that the type of data he has requested – about COVID-19 vaccines and ADRs - is "nothing out of the ordinary" as it is the type of data that MHRA routinely makes available through the Yellow Card website, about other medicines.

26. The complainant refers to COVID-19 vaccines being 'black triangle drugs'; that is, they belong to the class of new medicines and vaccines that are under 'additional monitoring' and are also under 'conditional marketing authorisation'. The full ADR data sent is available [one the main Yellow Card website] for other 'black triangle drugs', such as Brentuximab and it is therefore unreasonable for MHRA to withhold the data associated with the COVID-19 vaccines.

27. The combination of being a 'black triangle drug' with 'conditional marketing authorisation' leads to the COVID-19 vaccines having a higher monitoring need, in the complainant's view. This is because they are new and "incompletely tested" drugs with a "theoretically higher risk of harms to the public". The complainant considers that, as such, there is a public interest in disclosing the data to the public and research community.

28. The complainant also argues that transparency about COVID-19 vaccines data has been advocated in recent medical literature; that the data "originates within the public", is reported by the public and is collected for the public good. Finally, the complainant has referred to it having been pointed out (for example in an article in 'The Telegraph') that MHRA's own analysis of COVID-19 vaccine ADR data has lagged behind similar analyses carried out in some European countries. He considers that disclosing the data would allow independent researchers across the world to analyse it in parallel to MHRA's own artificial intelligence algorithms.

29. MHRA has noted in its submission that there is a potential benefit and public interest in transparency about the COVID-19 vaccine ADR data.

Public interest in maintaining the exemption

30. In its submission to the Commissioner, MHRA has said that, in considering the public interest test, it took into account how releasing data on only those vaccines used in the COVID-19 pandemic could undermine the wider Government public health campaign for widespread COVID-19. MHRA concluded it was a risk to public health and safety, and not in the public interest.

31. MHRA says that the evidence for this risk can be seen, for example, in the termination by the Japanese Government of a human papillomavirus vaccine programme following misinterpretation of published data. In that instance, unsubstantiated claims around safety have been estimated to have the potential to result in eleven thousand deaths[4].

32. It is clear, in MHRA's view, that care must be taken in preparing vaccine data for publication to mitigate catastrophic outcomes. For that reason, MHRA confirmed its stance that maintaining the exemption outweighed any potential benefit in publishing the data [at the time of the request].

Balance of the public interest

33. MHRA says that it carefully weighed the disbenefit of publishing the data without context; the potential for misinterpretation and misuse of sporadic and isolated reports; and the potential subsequent tangible harm against the potential benefit of transparency and wider public interest in publishing the information now (ie at the time of the request). On balance, MHRA says, it remains of the view that the public interest is best served through publishing the data in the future, with contextual narrative. At that point, by providing context to the data and clear guidance on what is being presented, the risk of misuse will be minimised.

34. The Commissioner notes that the main Yellow Card website states that when people review the data within an iDAP it is important to do so in the context of the essential guidance at the bottom of the report (ie the 'context' information) to ensure that they do not misinterpret the data.

35. The Commissioner has noted the complainant's arguments. He fully appreciates the strong public interest there was, and is, in the COVID-19 vaccines and any adverse reactions people may have experienced after having received one. However, given the significance of the vaccines and the sensitivities surrounding them, the Commissioner considers that there is stronger public interest in MHRA being able to publish the iDAP data for the vaccines in line with its planned timetable. This will ensure that MHRA has had the time it needs to consider the risks associated with publishing this information; how best to present the information alongside context and guidance so as to minimise the risk of the information being misinterpreted or misused. That is a complex process.

[4] https://www.reuters.com/article/us-japan-hpv-vaccine-study-idUSKBN2050K9

36. As noted, a summary of adverse reactions to COVID-19 vaccines is published weekly and, in the Commissioner's view, this satisfies the public interest in the safety of the vaccines to an adequate degree.

Section 17 – refusal of request

37. Under section 17(3) of the FOIA a public authority that is relying on a qualified exemption to withhold information must, in its refusal notice, state the reasons for claiming that the public interest in maintaining the exemption outweighs the public interest in disclosing the information.

38. In this case, MHRA's refusal notice and its internal review response failed to provide any such reasons. The Commissioner therefore finds that MHRA's refusal of the request breached section 17(3) of the FOIA.

Right of appeal

39. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals
    PO Box 9300
    LEICESTER
    LE1 8DJ

    Tel: 0203 936 8963
    Fax: 0870 739 5836
    Email: grc@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

40. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

41. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed

Cressida Woodall
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Information Commissioner's Office
Wycliffe House
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HEALTHCARE & PHARMA

FEBRUARY 11, 2020 / 6:41 AM / UPDATED 2 YEARS AGO

Japan's halt of regular HPV vaccine to cause thousands of cancer deaths: study

By Reuters Staff

TOKYO (Reuters) - A decision by Japan to stop recommending adolescent girls receive a HPV vaccination will likely result in almost 11,000 deaths from cervical cancer if it is not reversed, according to a study in a prestigious medical journal.

The HPV vaccine has been a political lightening rod in Japan, where claims of side effects prompted the government to halt active recommendation of the shots in June 2013.

A study published in The Lancet Public Health on Monday said that policy would lead to more than 24,600 cervical cancer cases that could have been prevented.

Using Japanese population and medical data and forecasted cervical cancer incidence, the study found that, if nothing changes, there would be 10,800 preventable deaths from cervical cancer over the next 50 years.

"If the government were to resume promoting the HPV vaccine in Japan, our study shows that we could avoid most of this loss of life," said study co-author Sharon Hanley, a professor at Hokkaido University in northern Japan.

The Japanese government could not immediately be reached for comment on the Lancet
rt. Kei Tamura, deputy director of the Health Ministry's immunization office, said in an

interview in December that "there is a sort of inner conflict in that we are not aggressively, proactively recommending it, but I do think it's better to take it."

HPV, which stands for the human papilloma virus, causes genital warts in both sexes and cervical cancer in women. Each year, about 10,000 Japanese women are newly diagnosed with the cancer while 3,000 die from it.

Uptake was swift when the vaccine was introduced in Japan in 2009, with immunization reaching about 70% in adolescent girls.

However, the vaccination rate has since slid to below 1% after the health ministry suspended its active recommendation after reports of side effects including muscle pain, sleep disorders, and light and sound sensitivity.

Females aged 12-16 can still get free HPV vaccines under Japan's national healthcare system if they ask for it. Everyone else must pay out of pocket.

In November, ruling party legislator Junko Mihara, a cervical cancer survivor, said lawmakers would hold talks on the vaccine this summer. Tokyo Governor Yuriko Koike and eight other regional leaders signed a letter supporting HPV vaccination.

The Health Ministry said in December it was working on improving leaflets on the vaccine, but had no time table for a return to regular immunization.

Reporting by Rocky Swift; editing by Jane Wardell

Our Standards: The Thomson Reuters Trust Principles.

HPV vaccination crisis in Japan

Free vaccination against the human papillomavirus (HPV) began in December, 2010, for Japanese girls aged 12–16 years and since April, 2013, the vaccine was included in the national immunisation programme. However, in June, 2013, the Japanese Ministry of Health, Labour, and Welfare suspended proactive recommendations for the HPV vaccine after unconfirmed reports of adverse events following vaccination appeared in the media.[1] In January, 2014, the Vaccine Adverse Reactions Review Committee investigating these adverse events concluded that there was no evidence to suggest a causal association between the HPV vaccine and the reported adverse events after vaccination, but they still did not reinstate proactive recommendations for its use.[2] We report the resulting effects of such a decision by presenting data from Sapporo, a city of 2 million people in northern Japan.

Before public funding was introduced, we investigated correlates of HPV vaccine acceptance in mothers with adolescent daughters living in Sapporo. Although cost was a large barrier, with only 1·5% of parents willing to pay the full vaccine price, recommendation from a physician was a strong motivator (odds ratio 12·2, 95% CI 7·1–21·1).[3] In the years between becoming free (2011 in Sapporo) and before the suspension of recommendations (2013), rates of HPV vaccination in Sapparo ranged from 73·6–77·2% at initiation and 68·4–74·0% for three dose completion in girls in the 1994–98 birth cohorts (figure). However, in the first birth cohort of 7705 girls eligible for vaccination after suspension, completion rates plummeted to just 0·6%, with only 49 girls finishing the dosing course despite the vaccine still being part of the national immunisation programme and free.

We believe that Japan, whose uptake rates for cervical cancer screening have stagnated at about 30%, might have lost a real opportunity to decrease morbidity and mortality associated with cervical cancer. Other countries with successful HPV vaccination programmes (such as Australia and the UK), who have also dealt with similar adverse event crises, are already documenting substantial reductions in precancerous cervical lesions in those vaccinated.[4,5]

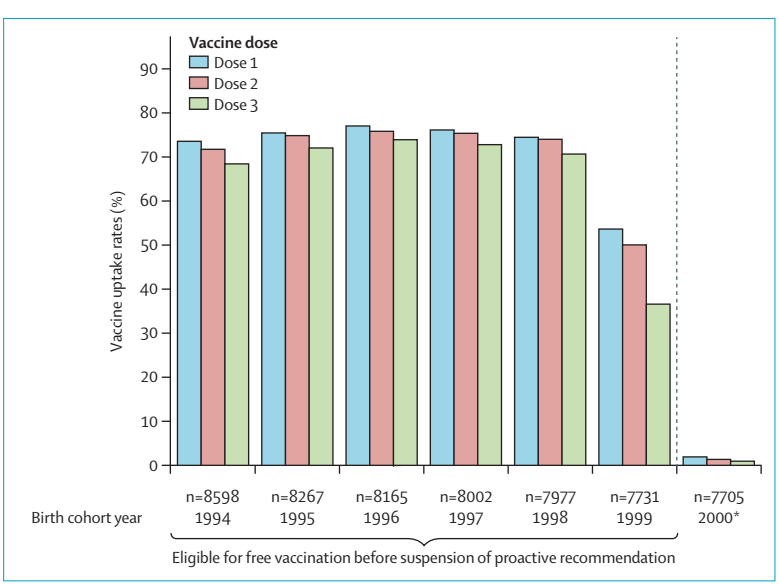

***Figure*: Uptake rates for the human papillomavirus vaccine in Sapporo, Japan, as of March, 2014**
Data are from the Department of Infection Control, Sapporo Health Board (Sapporo, Japan). n=number of girls in cohort. *The first birth cohort who were eligible for free vaccination after suspension of proactive recommendation.

No vaccine safety signal has been recorded in Japan. Instead, individuals who have the misfortune to be unwell with rare or difficult to treat disorders have been encouraged by antivaccination advocates to blame the HPV vaccine, especially in an unrestrained media environment and with little reassurance and systematic addressing of these events by the government.

According to the Global Advisory Committee on Vaccine Safety, "Allegations of harm from vaccination based on weak evidence can lead to real harm when, as a result, safe and effective vaccines cease to be used." Sadly, this is what has transpired in Japan.

We thank Keisuke Tamori and Julia Brotherton for their advice.

SJBH is part of the executive board of the People's Campaign Against Female Cancers (PCAF) and a committee member of the Japanese Expert Board for the Eradication of Cervical Cancer. SJBH reports lecture fees from Japan Vaccine and the Japanese Expert Board for the Eradication of Cervical Cancer. PCAF and the Japanese Expert Board for the Eradication of Cervical Cancer have received funding from Japan Vaccine and Merck Sharp and Dohme. EY, YI, and RK declare no competing interests.

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This online publication has been corrected. The corrected version first appeared at thelancet.com on July 3, 2015

For the **Global Advisory Committee on Vaccine Safety's statement on HPV vaccination** see http://www.who.int/vaccine_safety/committee/topics/hpv/GACVS_Statement_HPV_12_Mar_2014.pdf

Japan's HPV vaccine crisis: act now to avert cervical cancer cases and deaths

See Articles page e223

In May, 2013, a cluster of adverse events suspected to be linked to HPV vaccination were reported in the Japanese media, prompting the Japanese Government to suspend proactive recommendations for the vaccine in June, 2013. Despite no evidence of a link with HPV vaccination being found in the local investigation, and calls by WHO and the global scientific community to resume active recommendation of the cancer-preventing vaccine, the proactive recommendation of HPV vaccination remains suspended in Japan.

In 2017, the Japan Expert Council on Promotion of Vaccination—a body of 17 academic societies from a broad range of fields, including infectious disease, paediatrics, obstetrics and gynaecology, respiratory illness, travel health, and vaccinology—published a statement recommending renewed proactive support for the widespread use of the HPV vaccine.[1] This important public statement was barely mentioned in the local media and had little impact on political processes.

Now, the ground is shifting in the face of increasing numbers of cervical cancer cases and deaths[2] and growing frustration among health professionals. On Nov 26, 2019, the Liberal Democratic Party (LDP) in Japan took up the HPV vaccine challenge and launched a Parliamentary League to actively promote recommendation of the vaccine.[3] House of Representatives member, Junko Mihara, will chair the League, bringing her own experience and personal voice as a cervical cancer survivor to drive the effort.

The November LDP meeting also brought attention to a study by the Ministry of Health, Labour and Welfare,[4] confirming the safety of the vaccine and showing that the same rate of symptoms reported following HPV vaccination are also occurring among girls of the same age who have not been vaccinated. These findings echoed the conclusion of a European Medicines Agency review of HPV vaccine safety in 2016.[5,6]

Cervical cancer numbers have been increasing in Japan, particularly among young women in their 20s.[2] This age group also has a far lower rate of cervical cancer screening, at 22·2%, than other high-income countries. A perfect storm of changing sexual behaviours, low rates of cervical cancer screening, and negligible uptake of HPV vaccination have all contributed to a 9·6% increase in cervical cancer deaths over the past decade, even while other cancers have been on the decline in Japan.[2]

In *The Lancet Public Health*, Kate T Simms and colleagues[7] present estimates of the number of cases and lives lost due to HPV vaccine hesitancy in Japan, which provide crucial and compelling evidence for political action. The so-called vaccine crisis, which led to a rapid drop in HPV vaccination from over 70% uptake in 2013 to current rates of less than 1%,[8] is estimated to be responsible for 5000–5700 cervical cancer deaths among girls born between 1994 and 2007 who missed vaccination (the lower estimate represents a scenario of 71·9% cross-protection against HPV types 31, 45, and 52 lasting 20 years, and the upper estimate represents a worst-case scenario of no cross-protection). In addition, 24 600–27 300 preventable cervical cancer cases are estimated to occur in the same age group due to missed vaccination. Looking ahead, the study forecasts that for each year that the crisis continues, an additional 700–800 cervical cancer deaths could occur.[7]

This study calls attention to an opportunity to avert the numbers of cervical cancer cases and deaths if positive action is taken immediately. If HPV vaccination coverage is restored in 2020, including catch-up vaccination for those who missed their vaccination, 60% (14 800–16 300) of the projected cases of cervical cancer and 60% (3000–3400) of the related deaths could be prevented.

The stakes are higher than ever in the urgency to reinstate the proactive recommendation of HPV vaccination in Japan. A major challenge will be to reignite positive public awareness about the value of HPV vaccination, so that when the proactive recommendation is finally reinstated, the demand follows. As one local media source reported, "girls are unaware of the existence of this vaccine".[3] The time to act is now.

HJL reports grants from GlaxoSmithKline and serves on the Vaccine Confidence Advisory Board for Merck.

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The looming health hazard: A wave of HPV-related cancers in Japan is becoming a reality due to the continued suspension of the governmental recommendation of HPV vaccine

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Key words: Japan; Hpv vaccine; Cervical cancer; Screening; Birth year; Suspension of recommendation

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WHO adopted a global strategy towards eliminating cervical cancer by promoting HPV vaccine, cervical cancer screening and appropriate care and treatments. In Japan, cervical cancer incidence has been significantly increasing in recent years (annual percent change = 3.8, 95% confidence interval, 2.7−4.8; age-adjusted rate: 28.0 in 1976, 9.1 in 2000, 14.1 in 2012).[1] Japan started its HPV vaccination program for girls aged 13−16 in 2010. By 2013, Japan's vaccination rate was about 70%.[2] However, due to repeated media reports of diverse symptoms after HPV vaccination, the government announced a suspension of its proactive recommendation for the vaccine, leading to a decline in vaccination rates to less than 1%.[3] WHO noted that policy decisions based on weak evidence, leading to lack of use of safe and effective vaccines, can result in real harm.[4]

Due to continued suspension of the governmental recommendation of HPV vaccine, girls born in 2000 and thereafter, 'the vaccine-suspension generation', almost uniformly failed to get vaccinated. We predicted they will have higher HPV-16/18 infection rates[5] and higher incidences of and death from cervical cancer[6] compared to the 'vaccination generation' born in 1994−1999 who benefited from high HPV vaccination rates. The 'vaccine-suspension generation' are now reaching the starting age for cervical cancer screening in Japan, age 20.

We obtained data on the cumulative rate of HPV vaccination of girls aged 16 or younger under public subsidies, which did not include self-funded vaccinations. We also obtained the results of cervical cancer screening at age 20 (including those at 21 who skipped screening at age 20) for each birth year from 24 municipalities, corresponding to one-tenth of Japan's population. Among these 24 municipalities, HPV test was not used for cervical cancer screening at age 20.

We evaluated the changes over time in the cumulative HPV vaccination rate up to age 16 and the abnormal cytology rate at age 20, for each birth year. As for females of 'vaccine-suspension generation' born in 2000, the results of screening at age 21 are not yet included because they were not yet all 21. The screening rates at age 20, not including age 21, of 'vaccine-suspension generation' was 1.9%, which was not lower than that of 'pre-introduction generation' (1.8%) and 'vaccination generation' (1.4%), suggesting that change of background characteristics of those receiving cervical cancer screening due to COVID-19 pandemic was negligible.

The curves showed logarithmically approximated trends of the abnormal cytology rate at age 20 for each birth year of the "pre-introduction generation' from 1989 to 1993 and the 'vaccination generation' from 1994 to 1999, respectively, during the study period (Fig. 1). Abnormal cytology rate in the 'vaccination generation' was clearly lower than that predicted based on trends in the 'pre-introduction generation'. Similarly, the abnormal cytology incidence in the 'vaccine-suspension generation' was close to the expected rate from the trend of 'pre-introduction generation', and was higher

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Abbreviations: hpv, human papillomavirus; WHO, the World Health Organization

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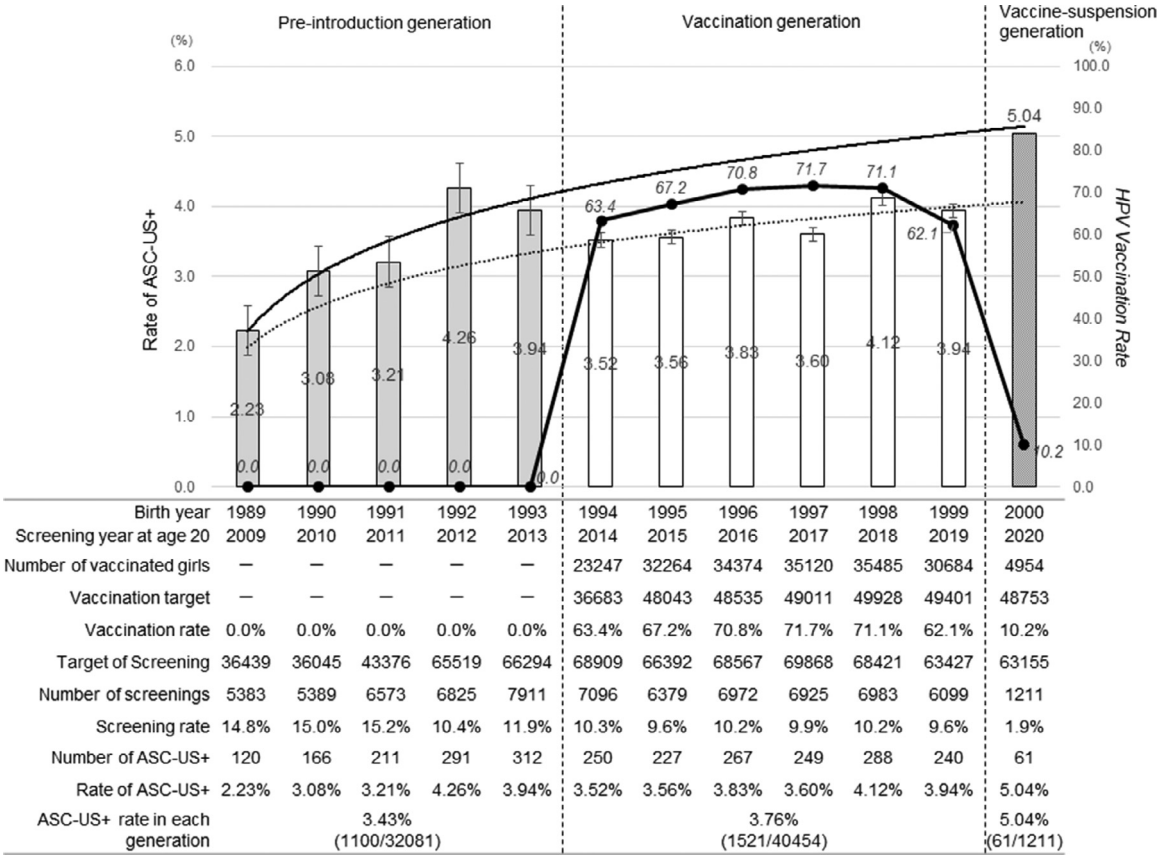

Birth year	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Screening year at age 20	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Number of vaccinated girls	–	–	–	–	–	23247	32264	34374	35120	35485	30684	4954
Vaccination target	–	–	–	–	–	36683	48043	48535	49011	49928	49401	48753
Vaccination rate	0.0%	0.0%	0.0%	0.0%	0.0%	63.4%	67.2%	70.8%	71.7%	71.1%	62.1%	10.2%
Target of Screening	36439	36045	43376	65519	66294	68909	66392	68567	69868	68421	63427	63155
Number of screenings	5383	5389	6573	6825	7911	7096	6379	6972	6925	6983	6099	1211
Screening rate	14.8%	15.0%	15.2%	10.4%	11.9%	10.3%	9.6%	10.2%	9.9%	10.2%	9.6%	1.9%
Number of ASC-US+	120	166	211	291	312	250	227	267	249	288	240	61
Rate of ASC-US+	2.23%	3.08%	3.21%	4.26%	3.94%	3.52%	3.56%	3.83%	3.60%	4.12%	3.94%	5.04%
ASC-US+ rate in each generation			3.43% (1100/32081)					3.76% (1521/40454)				5.04% (61/1211)

Fig. 1. Changes over time (by birth year) in the cumulative HPV vaccination rate and the incidence of abnormal cytology (ASC-US+) during cervical cancer screening at age 20.

than predicted based on the 'vaccination generation' tendencies. These trends were consistently the same even when linear or exponential approximation was used instead of logarithmic approximation (data not shown). The abnormal cytology rate at age 20 of the females born in 2000, 5.04%, significantly higher than that of the 'vaccination generation' (3.76%). These findings possibly suggested an increase of abnormal cytology rate among the 'vaccine-suspension generation' compared to the 'vaccination generation'. This increased rate of abnormal cytology in those born in 2000, the 'vaccine-suspension generation', compared to the 'vaccination generation', will correspond to the increase of nearly 3700 incidences and 900 deaths of future cervical cancer predicted in our previous study.[4]

We should continue to pressure our government to resume its vaccine recommendation, but at the same time we must recommend that women of the 'vaccine-suspension generation' receive 'catch-up HPV vaccinations', although its effectiveness was unfortunately shown to be limited for females older than 20 in Japan.[7] Those females should be strongly encouraged to undergo regular cervical cancer screening and receive appropriate treatments for cervical lesions.

The statistical data were provided from 24 municipalities for this research project. The bold line graph represents the cumulative HPV vaccination coverage up to age 16 for each birth year. The bar graphs represent the incidences of abnormal cytology (ASC-US+). The thin solid and broken curves are logarithmically approximated trend of the abnormal cytology rate at age 20 for each birth year of the "pre-introduction generation' from 1989 to 1993 and the 'vaccination generation' from 1994 to 1999, respectively, during the study period.

Informed consent and ethical approval

Informed consent was obtained by an opt-out method. This study was approved by the ethics committees of the Osaka University Hospital.

Declaration of interests

A.Y., M.S., and T.E. have received a lecture fee from Merck Sharp & Dohme. Y.U. received lecture fees from

GlaxoSmithKline/Japan Vaccine and Merck Sharp & Dohme. E.M. received lecture fees from Merck Sharp & Dohme, as well as grants from Merck Sharp & Dohme. T.K. received lecture fees and a funding for another research (grant number J550703673) from MSD.

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COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

All UK spontaneous reports received between 9/12/2020 and 25/01/2022 for mRNA Pfizer/BioNTech vaccine analysis print.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
Anaemia deficiencies		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	4	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Pernicious anaemia	2	0
Anaemias NEC		
Anaemia	138	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
Anaemias haemolytic NEC		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	7	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	17	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
Warm type haemolytic anaemia	1	0
Anaemias haemolytic mechanical factor		
Microangiopathic haemolytic anaemia	1	0
Bleeding tendencies		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	53	0
Spontaneous haematoma	2	0
Coagulation factor deficiencies		
Acquired factor VIII deficiency	1	0
Acquired haemophilia	4	0
Coagulopathies		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	6	0
Coagulopathy	27	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	3	0
Eosinophilic disorders		
Eosinophilia	13	0
Haematological disorders		
Blood disorder	6	0
Bone marrow disorder	1	0
Bone marrow oedema	1	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	10	0
Methaemoglobinaemia	1	0
Haemolyses NEC		
Haemolysis	6	0
Intravascular haemolysis	1	0
Jaundice acholuric	1	0
Leukocytoses NEC		
Leukocytosis	3	0

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Lymphocytic infiltration	1	0
Lymphocytosis	6	0
Neutrophilia	12	0
Leukopenias NEC		
Leukopenia	4	1
Lymphopenia	4	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	3	0
Hilar lymphadenopathy	3	0
Lymph node pain	2211	0
Lymph node ulcer	1	0
Lymphadenitis	178	0
Lymphadenopathy	13365	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	3	0
Lymphatic insufficiency	1	0
Necrotic lymphadenopathy	4	0
Pseudolymphoma	12	0
Retroperitoneal lymphadenopathy	1	0
Marrow depression and hypoplastic anaemias		
Aplasia pure red cell	2	0
Aplastic anaemia	1	1
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	8	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	41	0
Platelet disorders NEC		
Platelet anisocytosis	1	0
Platelet disorder	3	0
Polycythaemia (excl rubra vera)		
Polycythaemia	3	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	1	0
Red blood cell abnormal findings NEC		
Macrocytosis	2	0
Polychromasia	2	0
Red blood cell abnormality	2	0
Spleen disorders		
Spleen atrophy	1	0
Splenic infarction	3	0
Splenic lesion	1	0
Splenic thrombosis	2	0
Splenic vein thrombosis	2	0
Splenomegaly	12	0
Thrombocytopenias		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	81	0
Thrombocytopenia	232	1
Thrombocytopenic purpura	8	0
Thrombotic thrombocytopenic purpura	6	0
Thrombocytoses		

Case Series Drug Analysis Print

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Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Thrombocytosis	7	0
Blood disorders SOC TOTAL	**16579**	**4**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Cardiac disorders		
Aortic valvular disorders		
Aortic valve incompetence	2	0
Cardiac conduction disorders		
Atrioventricular block	27	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	2	0
Atrioventricular block second degree	3	0
Bundle branch block	2	0
Bundle branch block left	4	0
Bundle branch block right	4	0
Trifascicular block	1	0
Cardiac disorders NEC		
Acute cardiac event	7	0
Cardiac disorder	83	2
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	2	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	8	0
Intracardiac thrombus	5	0
Cardiac hypertensive complications		
Hypertensive heart disease	2	1
Cardiac infections and inflammations NEC		
Carditis	9	0
Cardiac neoplasms NEC		
Pericardial cyst	1	0
Cardiac signs and symptoms NEC		
Cardiac discomfort	33	0
Cardiovascular symptom	2	0
Palpitations	5598	1
Cardiac valve disorders NEC		
Cardiac valve disease	2	0
Heart valve incompetence	3	0
Cardiomyopathies		
Cardiomyopathy	13	0
Congestive cardiomyopathy	7	0
Stress cardiomyopathy	3	0
Coronary artery disorders NEC		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	7	3
Coronary artery dissection	1	0
Coronary artery occlusion	3	0
Coronary artery thrombosis	5	2
Endocarditis NEC		
Endocarditis noninfective	1	1
Heart failures NEC		
Cardiac failure	79	9
Cardiac failure acute	6	1
Cardiac failure chronic	2	0
Cardiac failure congestive	4	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
Ischaemic coronary artery disorders		
Acute coronary syndrome	8	1

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Acute myocardial infarction	26	1
Angina pectoris	293	1
Angina unstable	4	0
Arteriospasm coronary	4	0
Microvascular coronary artery disease	3	0
Myocardial infarction	270	39
Myocardial ischaemia	10	6
Left ventricular failures		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	8	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiac ventricular scarring	1	0
Cardiomegaly	45	4
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dysfunction	13	0
Left ventricular enlargement	2	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	7	0
Myocardial haemorrhage	1	0
Myocardial injury	17	0
Myocardial necrosis	1	0
Myocardial oedema	7	0
Myocardial rupture	1	0
Right atrial enlargement	1	0
Right ventricular dysfunction	2	0
Right ventricular enlargement	1	0
Ventricular dysfunction	2	0
Ventricular hypertrophy	1	0
Ventricular hypokinesia	4	0
Noninfectious myocarditis		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	681	1
Myocarditis post infection	1	0
Noninfectious pericarditis		
Pericarditis	457	2
Pericarditis constrictive	1	0
Pleuropericarditis	1	0
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	42	2
Pericardial fibrosis	1	0
Pericardial haemorrhage	4	3
Pericardial rub	2	0
Rate and rhythm disorders NEC		
Arrhythmia	176	1
Arrhythmia neonatal	1	0

Case Series Drug Analysis Print

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Data Lock Date: 25-Jan-2022 18:32:39

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Bradycardia	72	0
Bradycardia foetal	2	1
Cardiac flutter	584	0
Extrasystoles	204	0
Heart alternation	3	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	29	0
Tachyarrhythmia	8	0
Tachycardia	2128	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Right ventricular failure	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	16	0
Atrial fibrillation	271	1
Atrial flutter	41	0
Atrial tachycardia	11	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	8	0
Sinus bradycardia	13	0
Sinus node dysfunction	1	0
Sinus tachycardia	75	0
Supraventricular extrasystoles	4	0
Supraventricular tachycardia	46	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	6	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	120	44
Cardio-respiratory arrest	1	1
Pulseless electrical activity	5	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	31	0
Ventricular fibrillation	9	1
Ventricular tachycardia	15	0
Cardiac disorders SOC TOTAL	**11775**	**139**

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Congenital disorders		
Autosomal chromosomal abnormalities		
Trisomy 8	1	0
Cardiac disorders congenital NEC		
Heart disease congenital	16	0
Cardiac hypoplasias congenital		
Ventricular hypoplasia	1	0
Cardiac septal defects congenital		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
Cardiac valve disorders congenital		
Bicuspid aortic valve	1	0
Central nervous system disorders congenital NEC		
Spina bifida	2	1
Syringomyelia	1	0
Cerebellar disorders congenital		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
Cerebral disorders congenital		
Anencephaly	2	0
Cerebral palsy	3	0
Congenital hydrocephalus	1	0
Chromosomal abnormalities NEC		
Cytogenetic abnormality	1	0
Coagulation disorders congenital		
Factor IX deficiency	1	0
Haemophilia	2	0
Congenital disorders NEC		
Foetal malformation	1	0
Heterotaxia	1	0
Connective tissue disorders congenital		
Ehlers-Danlos syndrome	4	0
Gastrointestinal tract disorders congenital NEC		
Gastroschisis	3	0
Genetic polymorphisms		
Genetic polymorphism	1	0
Great vessel disorders congenital		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
Haematological disorders congenital NEC		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
Haemoglobinopathies congenital		
Congenital methaemoglobinaemia	1	0
Immune system abnormalities congenital		
Combined immunodeficiency	1	0
Inborn errors of lipid metabolism		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
Inborn errors of metabolism NEC		
Alpha-1 antitrypsin deficiency	1	0
Inborn errors of porphyrin metabolism		
Porphyria	1	0
Laryngeal and tracheal disorders congenital		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Laryngomalacia	1	0
Lymphatic system disorders congenital		
Cystic lymphangioma	3	0
Male reproductive tract disorders congenital		
Cryptorchism	1	0
Micropenis	4	0
Penoscrotal fusion	1	0
Phimosis	1	0
Musculoskeletal and connective tissue disorders of limbs congenital		
Developmental hip dysplasia	1	0
Limb malformation	1	0
Musculoskeletal and connective tissue disorders of skull congenital		
Platybasia	1	0
Musculoskeletal and connective tissue disorders of spine congenital		
Block vertebra	1	0
Brachyolmia	1	0
Musculoskeletal disorders congenital NEC		
Dysmorphism	1	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Neurofibromatosis	1	0
Tourette's disorder	3	0
Ocular disorders congenital NEC		
Colour blindness	4	0
Congenital eye disorder	1	0
Palate disorders congenital		
Cleft lip and palate	2	0
Peripheral nervous system disorders congenital NEC		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
Pulmonary and bronchial disorders congenital		
Congenital cystic lung	1	0
Retinal disorders congenital		
Retinitis pigmentosa	1	0
Sex chromosomal abnormalities		
Turner's syndrome	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Acral peeling skin syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Vascular anomalies congenital NEC		
Congenital LUMBAR syndrome	1	0
Venous disorders congenital		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	**98**	**1**

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear canal erythema	1	0
Ear congestion	37	0
Ear discomfort	99	0
Ear disorder	24	0
Ear haemorrhage	13	0
Ear inflammation	1	0
Ear pain	1126	0
Ear pruritus	12	0
Ear swelling	39	0
Otorrhoea	6	0
Paraesthesia ear	1	0
Eustachian tube disorders		
Eustachian tube disorder	5	0
Eustachian tube dysfunction	9	0
Eustachian tube obstruction	5	0
External ear disorders NEC		
Auricular swelling	2	0
Excessive cerumen production	12	0
External ear pain	6	0
Red ear syndrome	2	0
External ear infections and inflammations		
External ear inflammation	2	0
Hearing disorders NEC		
Auditory disorder	6	0
Diplacusis	2	0
Hearing losses		
Conductive deafness	1	0
Deafness	281	0
Deafness bilateral	11	0
Deafness neurosensory	22	0
Deafness transitory	9	0
Deafness unilateral	36	0
Hypoacusis	218	0
Sudden hearing loss	50	0
Hyperacusia		
Hyperacusis	70	0
Misophonia	3	0
Inner ear disorders NEC		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	13	0
Vestibular disorder	14	0
Inner ear infections and inflammations		
Inner ear inflammation	11	0
Inner ear signs and symptoms		
Motion sickness	67	0
Phobic postural vertigo	1	0
Tinnitus	2327	0
Vertigo	1587	0
Vertigo labyrinthine	13	0
Vertigo positional	82	0
Mastoid disorders		

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Mastoid effusion	1	0
Middle ear disorders NEC		
Middle ear disorder	3	0
Middle ear effusion	1	0
Middle ear infections and inflammations		
Middle ear inflammation	1	0
Tympanic membrane disorders (excl infections)		
Tympanic membrane perforation	3	0
Ear disorders SOC TOTAL	**6250**	**0**

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Reaction Name	Total	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	3	0
Thyroiditis	23	0
Thyroiditis acute	3	0
Thyroiditis subacute	5	0
Adrenal cortical hypofunctions		
Addison's disease	2	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	16	0
Adrenal gland disorders NEC		
Adrenal disorder	3	0
Adrenal haemorrhage	3	0
Anterior pituitary hyperfunction		
Pituitary-dependent Cushing's syndrome	1	0
Anterior pituitary hypofunction		
Hypopituitarism	1	0
Endocrine abnormalities of gonadal function NEC		
Oestrogen deficiency	1	0
Endocrine abnormalities of puberty		
Delayed menarche	4	0
Premature menarche	20	0
Female gonadal function disorders		
Anovulatory cycle	58	0
Ovulation delayed	35	0
Male gonadal function disorders		
Androgen deficiency	1	0
Thyroid disorders NEC		
Autoimmune thyroid disorder	1	0
Goitre	16	0
Thyroid disorder	10	0
Thyroid mass	2	0
Thyroid pain	11	0
Thyroid hyperfunction disorders		
Basedow's disease	11	0
Hyperthyroidism	48	0
Primary hyperthyroidism	1	0
Thyrotoxic crisis	5	0
Thyroid hypofunction disorders		
Autoimmune hypothyroidism	1	0
Hypothyroidic goitre	1	0
Hypothyroidism	38	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	329	0

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Reaction Name	Total	Fatal
Eye disorders		
Amblyopic vision impairment		
Amblyopia	7	0
Anterior chamber bleeding and vascular disorders		
Spontaneous hyphaema	1	0
Cataract conditions		
Cataract	14	0
Choroid and vitreous haemorrhages and vascular disorders		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	4	0
Choroid and vitreous structural change, deposit and degeneration		
Chorioretinopathy	8	0
Vitreous detachment	19	0
Vitreous floaters	111	0
Colour blindness (incl acquired)		
Colour blindness acquired	1	0
Dyschromatopsia	10	0
Conjunctival and corneal bleeding and vascular disorders		
Conjunctival haemorrhage	50	0
Scleral haemorrhage	1	0
Conjunctival infections, irritations and inflammations		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctival ulcer	1	0
Conjunctivitis allergic	2	0
Corneal infections, oedemas and inflammations		
Corneal oedema	3	0
Keratitis	7	0
Ulcerative keratitis	5	0
Corneal structural change, deposit and degeneration		
Corneal scar	1	0
Eyelid movement disorders		
Blepharospasm	161	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	47	0
Paralytic lagophthalmos	2	0
Glaucomas (excl congenital)		
Angle closure glaucoma	2	0
Glaucoma	7	0
Ocular hypertension	1	0
Iris and ciliary body structural change, deposit and degeneration		
Eye colour change	3	0
Iris and uveal tract infections, irritations and inflammations		
Autoimmune uveitis	3	0
Iridocyclitis	18	0
Iritis	12	0
Uveitis	54	0
Vogt-Koyanagi-Harada disease	1	0
Lacrimation disorders		
Dry eye	171	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Lacrimation increased	156	0
Lid bleeding and vascular disorders		
Eyelid bleeding	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Blepharitis	18	0
Blepharitis allergic	1	0
Chalazion	7	0
Eczema eyelids	9	0
Erythema of eyelid	10	0
Eyelid cyst	7	0
Eyelid irritation	4	0
Eyelid margin crusting	5	0
Eyelid oedema	14	0
Eyelid rash	20	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	142	0
Swollen tear duct	2	0
Lid, lash and lacrimal structural disorders		
Dacryostenosis acquired	1	0
Dermatochalasis	1	0
Ectropion	1	0
Eyelash changes	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	2	0
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lacrimal gland enlargement	1	0
Lagophthalmos	3	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	36	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Chorioretinal disorder	1	0
Dark circles under eyes	8	0
Eye disorder	40	0
Eye oedema	18	0
Eye pain	1253	0
Eye swelling	624	0
Eye symptom	9	0
Eye ulcer	5	0
Eyelid disorder	16	0
Eyelid pain	14	0
Eyelids pruritus	7	0
Ocular discomfort	31	0
Periorbital oedema	19	0
Periorbital pain	2	0
Periorbital swelling	126	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye allergy	21	0
Eye discharge	32	0
Eye inflammation	37	0
Eye irritation	102	0
Eye pruritus	277	0
Limbal swelling	4	0
Ocular hyperaemia	258	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	2	0
Eye movement disorder	40	0
Gaze palsy	2	0
Ocular myasthenia	1	0
Ophthalmoplegia	5	0
Strabismus	10	0
Ocular sensation disorders		
Abnormal sensation in eye	21	0
Asthenopia	169	0
Eye paraesthesia	2	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	18	0
Hypoaesthesia eye	18	0
Photophobia	518	0
Optic disc abnormalities NEC		
Papilloedema	7	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Miosis	2	0
Mydriasis	24	0
Pupil fixed	3	0
Pupillary disorder	1	0
Pupils unequal	14	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	5	0
Astigmatism	2	0
Hypermetropia	3	0
Myopia	2	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	16	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	11	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	39	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Epiretinal membrane	1	0
Macular degeneration	4	0
Macular hole	3	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	3	0
Retinal degeneration	1	0
Retinal detachment	7	0
Retinal tear	3	0
Retinal toxicity	3	0
Retinal, choroid and vitreous infections and inflammations		
Birdshot chorioretinopathy	2	0
Choroiditis	1	0
Cystoid macular oedema	1	0
Macular oedema	6	0
Retinal oedema	2	0
Retinal vasculitis	3	0
Retinopathies NEC		
Acute macular neuroretinopathy	3	0
Retinal exudates	2	0
Retinopathy	4	0
Scleral infections, irritations and inflammations		
Episcleritis	9	0
Scleritis	6	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	2	0
Structural change, deposit and degeneration of eye NEC		
Endocrine ophthalmopathy	1	0
Exophthalmos	4	0
Visual colour distortions		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	4	0
Erythropsia	2	0
Xanthopsia	1	0
Visual disorders NEC		
Charles Bonnet syndrome	2	0
Diplopia	176	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	8	0
Heteronymous diplopia	1	0
Metamorphopsia	23	0
Oscillopsia	3	0
Photopsia	153	0
Scintillating scotoma	4	0
Vision blurred	1382	0
Visual brightness	3	0
Visual snow syndrome	8	0
Visual field disorders		
Visual field defect	36	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	4	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Blindness	152	0
Blindness cortical	1	0
Blindness transient	18	0
Blindness unilateral	17	0
Central vision loss	6	0
Sudden visual loss	4	0
Visual acuity reduced	27	0
Visual acuity reduced transiently	1	0
Visual impairment	438	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	**7618**	**0**

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Abdominal findings abnormal		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	17	0
Abdominal hernias NEC		
Abdominal hernia	2	0
Abdominal wall conditions NEC		
Abdominal wall haematoma	2	0
Acute and chronic pancreatitis		
Alcoholic pancreatitis	1	0
Autoimmune pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	18	0
Pancreatitis acute	17	1
Pancreatitis chronic	1	0
Pancreatitis necrotising	2	0
Anal and rectal disorders NEC		
Anal fissure	2	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
Anal and rectal pains		
Proctalgia	15	0
Anal and rectal signs and symptoms		
Anal blister	1	0
Anal erythema	1	0
Anal hypoaesthesia	1	0
Anal pruritus	2	0
Anal spasm	1	0
Anorectal discomfort	5	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal tenesmus	1	0
Anal and rectal ulcers and perforation		
Anal ulcer	1	0
Benign oral cavity neoplasms		
Mouth cyst	6	0
Tongue cyst	4	0
Tongue polyp	2	0
Colitis (excl infective)		
Autoimmune colitis	2	0
Colitis	54	1
Colitis ischaemic	2	0
Colitis microscopic	2	0
Colitis ulcerative	77	0
Crohn's disease	47	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	10	0
Dental and periodontal infections and inflammations		
Dental caries	2	0
Periodontal inflammation	1	0
Dental developmental disorders and anomalies		
Tooth impacted	1	0
Dental disorders NEC		
Loose tooth	5	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders (Gastrointestinal disorders cont'd)		
Malpositioned teeth	2	0
Periodontal disease	1	0
Teeth brittle	3	0
Teething	9	0
Tooth disorder	2	0
Tooth erosion	1	0
Tooth socket haemorrhage	1	0
Dental pain and sensation disorders		
Dental discomfort	7	0
Dental paraesthesia	14	0
Hyperaesthesia teeth	38	0
Toothache	193	0
Dental surface disorders		
Tooth discolouration	10	0
Diaphragmatic hernias		
Hiatus hernia	8	0
Diarrhoea (excl infective)		
Diarrhoea	5970	0
Diarrhoea haemorrhagic	26	0
Diverticula		
Diverticulum	6	0
Diverticulum intestinal	1	0
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	2	0
Duodenal ulcers and perforation		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
Dyspeptic signs and symptoms		
Dyspepsia	518	0
Epigastric discomfort	14	0
Eructation	61	0
Faecal abnormalities NEC		
Abnormal faeces	20	0
Faecaloma	7	0
Faeces discoloured	63	0
Faeces hard	2	0
Faeces pale	4	0
Faeces soft	12	0
Mucous stools	10	0
Flatulence, bloating and distension		
Abdominal distension	568	0
Aerophagia	3	0
Flatulence	196	0
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
Gastric ulcers and perforation		
Gastric ulcer	7	0
Gastritis (excl infective)		
Chronic gastritis	4	0
Gastritis	67	0
Reflux gastritis	8	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders (Gastrointestinal disorders cont'd)		
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal migraine	2	0
Abdominal pain	1631	0
Abdominal pain lower	147	0
Abdominal pain upper	2718	0
Abdominal rigidity	25	0
Abdominal tenderness	14	0
Gastrointestinal pain	158	0
Oesophageal pain	13	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	272	0
Duodenogastric reflux	4	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	183	0
Impaired gastric emptying	10	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
Gastrointestinal disorders NEC		
Appendicolith	1	0
Appendix disorder	2	0
Food poisoning	7	0
Functional gastrointestinal disorder	10	0
Gastric disorder	10	0
Gastrointestinal disorder	27	0
Stomach mass	4	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	8	0
Change of bowel habit	12	0
Dyschezia	4	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	1	0
Gastrointestinal fistulae		
Diverticular fistula	2	0
Gastrointestinal inflammatory disorders NEC		
Duodenitis	1	0
Enteritis	6	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
Gastrointestinal mucosal dystrophies and secretion disorders		
Barrett's oesophagus	2	0
Hyperchlorhydria	4	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	678	0
Abdominal symptom	1	0
Acute abdomen	7	0
Anal incontinence	19	0
Breath odour	22	0
Dysphagia	230	2
Gastrointestinal wall thickening	1	0
Odynophagia	44	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Gastrointestinal spastic and hypermotility disorders		
Cardiospasm	1	0
Defaecation urgency	11	0
Frequent bowel movements	30	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	97	0
Oesophageal spasm	5	0
Pylorospasm	1	0
Gastrointestinal stenosis and obstruction NEC		
Ileus	1	0
Intestinal obstruction	7	0
Neonatal intestinal obstruction	1	0
Volvulus	1	0
Gastrointestinal vascular malformations		
Gastric antral vascular ectasia	11	0
Gastrointestinal vascular occlusion and infarction		
Intestinal ischaemia	7	2
Mesenteric vein thrombosis	9	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
Gingival disorders, signs and symptoms NEC		
Gingival blister	13	0
Gingival discomfort	8	0
Gingival disorder	4	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	129	0
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	42	0
Gingival ulceration	2	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	10	0
Gingival haemorrhages		
Gingival bleeding	78	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	34	1
Haemorrhoids thrombosed	1	0
Inguinal hernias		
Inguinal hernia	1	0
Intestinal haemorrhages		
Anal haemorrhage	23	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	80	0
Small intestinal haemorrhage	5	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	5	2
Large intestinal ulcer	1	0
Large intestinal ulcer haemorrhage	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Large intestine perforation	1	0
Large intestinal stenosis and obstruction		
Large intestinal obstruction	1	1
Malabsorption syndromes		
Bile acid malabsorption	4	0
Coeliac disease	14	0
Malabsorption	1	0
Steatorrhoea	4	0
Nausea and vomiting symptoms		
Discoloured vomit	13	0
Infantile vomiting	7	0
Nausea	14964	0
Regurgitation	1	0
Retching	111	0
Vomiting	4986	1
Vomiting projectile	68	0
Non-mechanical ileus		
Ileus paralytic	2	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	18	1
Haematemesis	38	2
Haematochezia	60	0
Melaena	9	0
Upper gastrointestinal haemorrhage	13	0
Oesophageal stenosis and obstruction		
Oesophageal stenosis	3	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	1	0
Oesophagitis	6	0
Oral dryness and saliva altered		
Aptyalism	5	0
Dry mouth	531	0
Lip dry	48	0
Saliva altered	8	0
Salivary hypersecretion	51	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	1	0
Chapped lips	26	0
Cheilitis	26	0
Enlarged uvula	15	0
Leukoplakia oral	2	0
Lip blister	33	0
Lip disorder	5	0
Oral disorder	21	0
Oral lichen planus	14	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	7	0
Oral soft tissue haemorrhages		
Lip haemorrhage	1	0
Mouth haemorrhage	16	0
Oral blood blister	17	0
Oral purpura	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Oral soft tissue infections		
Angular cheilitis	4	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	3	0
Burning mouth syndrome	6	0
Coating in mouth	1	0
Hypoaesthesia oral	510	0
Lip discolouration	9	0
Lip erythema	4	0
Lip exfoliation	6	0
Lip pain	63	0
Lip pruritus	18	0
Lip scab	1	0
Oral discomfort	86	0
Oral dysaesthesia	1	0
Oral mucosal blistering	16	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	19	0
Oral mucosal erythema	7	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	181	0
Oral pruritus	23	0
Paraesthesia oral	936	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	860	0
Mouth swelling	113	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	3	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Pancreatic failure	1	0
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	15	0
Peritoneal and retroperitoneal disorders		
Ascites	2	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	2	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	2	1
Rectal inflammations NEC		
Proctitis	3	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland disorder	1	0
Salivary gland pain	13	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Salivary gland enlargements		
Parotid gland enlargement	11	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	8	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	2	0
Stomatitis and ulceration		
Aphthous ulcer	57	0
Lip ulceration	21	0
Mouth ulceration	471	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	67	0
Tongue disorders		
Glossitis	21	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	4	0
Tongue disorder	43	0
Tongue geographic	7	0
Tongue haemorrhage	3	0
Tongue ulceration	32	0
Trichoglossia	4	0
Tongue signs and symptoms		
Glossodynia	226	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	539	0
Tongue blistering	19	0
Tongue coated	20	0
Tongue discolouration	39	0
Tongue discomfort	44	0
Tongue dry	16	0
Tongue eruption	11	0
Tongue erythema	13	0
Tongue exfoliation	2	0
Tongue movement disturbance	7	0
Tongue oedema	23	0
Tongue pruritus	2	0
Tongue rough	5	0
Tongue spasm	12	0
Tooth missing		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	**40972**	**17**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site bruise	9	0
Administration site erythema	4	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	2	0
Administration site joint pain	1	0
Administration site nerve damage	1	0
Administration site pain	20	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	4	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	42	0
Puncture site pain	8	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
Adverse effect absent		
No adverse event	10	0
Application and instillation site reactions		
Application site acne	2	0
Application site bruise	12	0
Application site burn	1	0
Application site dryness	1	0
Application site erythema	18	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	7	0
Application site warmth	1	0
Instillation site warmth	9	0
Asthenic conditions		
Asthenia	2248	0
Chronic fatigue syndrome	80	0
Decreased activity	10	0
Fatigue	25169	1
Malaise	5683	1

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Sluggishness	19	0
Body temperature altered		
Hyperthermia	7	0
Hyperthermia malignant	1	0
Hypothermia	26	0
Temperature regulation disorder	14	0
Breast complications associated with device		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	2	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	2	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	5	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
Death and sudden death		
Brain death	3	3
Cardiac death	3	3
Clinical death	1	1
Death	191	191
Sudden cardiac death	1	1
Sudden death	26	26
Febrile disorders		
Hyperpyrexia	9	0
Pyrexia	16383	0
Feelings and sensations NEC		
Chills	10275	0
Feeling abnormal	1756	0
Feeling cold	1332	0
Feeling drunk	81	0
Feeling hot	1247	0
Feeling jittery	34	0
Feeling of body temperature change	359	0
Feeling of relaxation	3	0
Hangover	84	0
Hunger	50	0
Sensation of blood flow	5	0
Sensation of foreign body	60	0
Temperature intolerance	50	0
Thirst	376	0
Thirst decreased	1	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait deviation	1	0
Gait disturbance	264	0
Gait inability	100	0
Loss of control of legs	28	0
General signs and symptoms NEC		
Adhesion	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Chronic disease	1	0
Concomitant disease progression	1	1
Condition aggravated	289	0
Crepitations	4	0
Crying	164	0
Deformity	2	0
Developmental delay	1	0
Discharge	13	0
Disease progression	2	0
Disease recurrence	32	0
Effusion	3	0
Energy increased	26	0
Exercise tolerance decreased	28	0
Exercise tolerance increased	1	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	17	2
General symptom	3	0
Glassy eyes	7	0
High-pitched crying	3	0
Illness	2166	0
Induration	17	0
Influenza like illness	2599	0
Irritability postvaccinal	2	0
Local reaction	92	0
Moaning	3	0
Multiple organ dysfunction syndrome	12	4
Nonspecific reaction	2	0
Organ failure	3	1
Perforation	2	0
Peripheral swelling	4284	0
Physical deconditioning	2	0
Pre-existing condition improved	9	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	24	0
Swelling	3453	0
Swelling face	951	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Tissue rupture	1	0
Healing abnormal NEC		
Impaired healing	6	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflammations		
Foreign body reaction	1	0

Case Series Drug Analysis Print

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Data Lock Date: 25-Jan-2022 18:32:39

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Granuloma	1	0
Inflammation	594	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Systemic inflammatory response syndrome	5	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site discolouration	1	0
Infusion site joint effusion	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	5	0
Infusion site pruritus	3	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
Injection site reactions		
Injected limb mobility decreased	37	0
Injection site bruising	71	0
Injection site coldness	1	0
Injection site cyst	3	0
Injection site discolouration	5	0
Injection site discomfort	11	0
Injection site eczema	1	0
Injection site erythema	429	0
Injection site extravasation	1	0
Injection site haematoma	1	0
Injection site haemorrhage	8	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	15	0
Injection site indentation	9	0
Injection site induration	4	0
Injection site inflammation	47	0
Injection site injury	2	0
Injection site irritation	2	0
Injection site joint discomfort	2	0
Injection site joint erythema	4	0
Injection site joint movement impairment	1	0
Injection site joint pain	15	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	627	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site nodule	1	0
Injection site oedema	18	0
Injection site pain	3143	0
Injection site pallor	1	0
Injection site paraesthesia	13	0

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site pruritus	241	0
Injection site rash	200	0
Injection site reaction	57	0
Injection site scab	4	0
Injection site scar	4	0
Injection site swelling	338	0
Injection site urticaria	36	0
Injection site vesicles	10	0
Injection site warmth	207	0
Interactions		
Alcohol interaction	5	0
Drug interaction	30	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	54	0
Mass	81	0
Nodule	41	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	10	0
Mucosal inflammation	3	0
Oedema mucosal	2	0
Polyp	6	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	6	0
Oedema NEC		
Face oedema	34	0
Generalised oedema	5	0
Localised oedema	21	0
Oedema	87	0
Oedema peripheral	98	0
Pain and discomfort NEC		
Axillary pain	3929	0
Breakthrough pain	1	0
Chest discomfort	1954	0
Chest pain	6212	0
Discomfort	538	0
Facial discomfort	21	0
Facial pain	231	0
Inflammatory pain	19	0
Non-cardiac chest pain	33	0
Pain	9683	0
Suprapubic pain	1	0
Tenderness	727	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	66	0
Adverse food reaction	3	0
Adverse reaction	12	0
Drug ineffective	379	0
Drug intolerance	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Drug resistance	1	0
Immediate post-injection reaction	4	0
Inadequate analgesia	9	0
No reaction on previous exposure to drug	22	0
Product intolerance	1	0
Therapeutic product effect decreased	2	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	2	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	81	0
Therapy non-responder	1	0
Treatment failure	10	0
Vaccination failure	60	0
Trophic disorders		
Abnormal organ growth	1	0
Atrophy	2	0
Calcinosis	2	0
Hyperplasia	1	0
Hypertrophy	1	0
Ulcers NEC		
Ulcer	37	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	23	0
Shoulder injury related to vaccine administration	55	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	141	0
Vaccination site coldness	4	0
Vaccination site cyst	7	0
Vaccination site dermatitis	1	0
Vaccination site discharge	1	0
Vaccination site discolouration	17	0
Vaccination site discomfort	52	0
Vaccination site dryness	2	0
Vaccination site eczema	1	0
Vaccination site erythema	677	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	29	0
Vaccination site hypersensitivity	5	0
Vaccination site hypoaesthesia	19	0
Vaccination site induration	78	0
Vaccination site inflammation	65	0
Vaccination site irritation	15	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	12	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	20	0
Vaccination site joint pain	34	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	8	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site macule	1	0
Vaccination site mass	322	0
Vaccination site movement impairment	92	0
Vaccination site nerve damage	1	0
Vaccination site nodule	5	0
Vaccination site oedema	3	0
Vaccination site pain	2315	0
Vaccination site papule	1	0
Vaccination site paraesthesia	9	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	183	0
Vaccination site rash	153	0
Vaccination site reaction	36	0
Vaccination site scab	2	0
Vaccination site scar	2	0
Vaccination site swelling	633	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	2	0
Vaccination site urticaria	10	0
Vaccination site vesicles	12	0
Vaccination site warmth	297	0
Vascular complications associated with device		
Vascular stent thrombosis	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	48	0
General disorders SOC TOTAL	**116650**	**235**

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Hepatic disorders		
Bile duct infections and inflammations		
Biliary colic	18	0
Cholangitis	1	0
Cholecystitis and cholelithiasis		
Cholecystitis	4	0
Cholecystitis acute	2	0
Cholelithiasis	11	0
Cholestasis and jaundice		
Cholestasis	2	0
Jaundice	26	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
Gallbladder disorders NEC		
Gallbladder disorder	3	0
Gallbladder enlargement	1	0
Hepatic and hepatobiliary disorders NEC		
Hepatic cyst	1	0
Hepatic lesion	1	0
Liver disorder	14	0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	7	0
Hepatic failure and associated disorders		
Acute hepatic failure	2	0
Hepatic failure	2	1
Hepatic fibrosis and cirrhosis		
Hepatic cirrhosis	1	0
Hepatic vascular disorders		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	8	0
Hepatobiliary signs and symptoms		
Hepatic pain	33	0
Hepatomegaly	6	0
Liver tenderness	3	0
Hepatocellular damage and hepatitis NEC		
Autoimmune hepatitis	13	0
Drug-induced liver injury	3	0
Hepatic steatosis	5	0
Hepatitis	14	0
Hepatitis acute	3	0
Hepatitis toxic	1	0
Immune-mediated hepatic disorder	1	0
Liver injury	24	0
Hepatic disorders SOC TOTAL	232	1

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Immune system disorders		
Acute and chronic sarcoidosis		
Loefgren syndrome	1	0
Sarcoidosis	20	0
Allergic conditions NEC		
Allergic oedema	18	0
Allergy to animal	2	0
Allergy to arthropod bite	6	0
Allergy to arthropod sting	2	0
Allergy to metals	3	0
Allergy to sting	1	0
Hypersensitivity	1111	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	16	0
Serum sickness	3	0
Serum sickness-like reaction	6	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	6	0
Allergies to foods, food additives, drugs and other chemicals		
Allergic reaction to excipient	6	0
Allergy to chemicals	6	0
Allergy to vaccine	46	0
Contrast media reaction	2	0
Drug hypersensitivity	40	0
Food allergy	40	0
Milk allergy	2	0
Oral allergy syndrome	3	0
Polymers allergy	1	0
Reaction to colouring	1	0
Reaction to excipient	10	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	550	1
Anaphylactic shock	63	0
Anaphylactoid reaction	25	0
Anaphylactoid shock	4	0
Atopic disorders		
Atopy	3	0
Seasonal allergy	109	0
Autoimmune disorders NEC		
Autoimmune disorder	52	0
Immune and associated conditions NEC		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	64	0
Cytokine storm	1	0
Decreased immune responsiveness	3	0
Graft versus host disease	2	0
Haemophagocytic lymphohistiocytosis	3	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	32	0

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Reaction Name	Total	Fatal
Immune system disorders (Immune system disorders cont'd)		
Immune-mediated adverse reaction	7	0
Immunisation reaction	2	0
Multisystem inflammatory syndrome in children	4	0
Sensitisation	9	0
Systemic immune activation	2	0
Immunodeficiency disorders NEC		
Hypogammaglobulinaemia	1	0
Immunodeficiency	4	0
Immunosuppression	4	0
Transplant rejections		
Corneal graft rejection	10	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
Immune system disorders SOC TOTAL	**2329**	**1**

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Reaction Name	Total	Fatal
Infections		
Abdominal and gastrointestinal infections		
Abdominal abscess	2	0
Abdominal infection	1	0
Anal abscess	3	0
Anorectal infection	1	0
Appendicitis	46	0
Appendicitis perforated	7	0
Diarrhoea infectious	1	0
Diverticulitis	17	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	31	0
Mesenteric abscess	1	0
Peritonitis	3	1
Rectal abscess	1	0
Adenoviral infections		
Adenoviral conjunctivitis	1	0
Adenovirus infection	1	0
Aspergillus infections		
Bronchopulmonary aspergillosis	1	0
Bacterial infections NEC		
Abscess bacterial	2	0
Administration site cellulitis	1	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	16	0
Bacterial sepsis	1	0
Bacterial vaginosis	2	0
Cellulitis	199	0
Cellulitis orbital	1	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	19	0
Gangrene	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Myocarditis bacterial	1	0
Paronychia	3	0
Perichondritis	3	0
Periorbital cellulitis	3	0
Pneumonia bacterial	2	0
Sinusitis bacterial	2	0
Skin bacterial infection	4	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	20	0
Zoonotic bacterial infection	1	1
Bartonella infections		
Cat scratch disease	1	0
Bone and joint infections		

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Abscess jaw	1	0
Arthritis infective	2	0
Osteomyelitis	2	0
Bordetella infections		
Pertussis	1	0
Borrelial infections		
Lyme disease	4	0
Relapsing fever	1	0
Breast infections		
Breast abscess	3	0
Mastitis	85	0
Caliciviral infections		
Gastroenteritis norovirus	3	0
Campylobacter infections		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
Candida infections		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	71	0
Oral candidiasis	40	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	53	0
Cardiac infections		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Endocarditis	2	0
Myocarditis infectious	1	0
Pericarditis infective	2	0
Central nervous system and spinal infections		
Brain abscess	2	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	22	0
Encephalomyelitis	1	0
Meningitis	12	0
Meningitis aseptic	3	0
Myelitis	11	0
Subdural abscess	1	0
Clostridia infections		
Clostridium difficile infection	2	0
Coronavirus infections		
Asymptomatic COVID-19	21	0
COVID-19	2121	42
COVID-19 pneumonia	51	14
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	5	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	75	4
Corynebacteria infections		

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Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022
Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Infections Infections cont'd		
Diphtheria	2	0
Coxiella infections		
Q fever	13	0
Cytomegaloviral infections		
Cytomegalovirus colitis	1	0
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
Dental and oral soft tissue infections		
Abscess oral	6	0
Gingival abscess	1	0
Gingivitis	14	0
Oral infection	1	0
Parotitis	12	0
Pericoronitis	3	0
Periodontitis	1	0
Pulpitis dental	2	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	10	0
Ear infections		
Ear infection	100	0
Labyrinthitis	110	0
Mastoiditis	3	0
Otitis externa	4	0
Otitis media	3	0
Otitis media acute	1	0
Otitis media chronic	5	0
Ectoparasitic infestations		
Acarodermatitis	6	0
Bed bug infestation	1	0
Demodicidosis	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	5	0
Epstein-Barr virus infection reactivation	1	0
Infectious mononucleosis	28	0
Escherichia infections		
Escherichia bacteraemia	1	0
Escherichia infection	1	0
Eye and eyelid infections		
Conjunctivitis	82	0
Eye abscess	1	0
Eye infection	28	0
Eye infection intraocular	1	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	30	0
Keratouveitis	1	0
Periorbital infection	2	0
Female reproductive tract infections		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Funisitis	1	0
Pelvic inflammatory disease	2	0
Vaginal infection	2	0
Vulval abscess	1	0
Vulvitis	1	0
Fungal infections NEC		
Fungal infection	20	0
Fungal skin infection	5	0
Myocarditis mycotic	1	0
Onychomycosis	2	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Severe asthma with fungal sensitisation	1	0
Vulvovaginal mycotic infection	8	0
Hepatitis virus infections		
Hepatitis A	2	0
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
Herpes viral infections		
Eczema herpeticum	3	0
Genital herpes	94	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	34	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	3	0
Herpes virus infection	13	0
Herpes zoster	1561	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	16	0
Herpes zoster reactivation	3	0
Meningitis herpes	1	0
Nasal herpes	5	0
Ophthalmic herpes simplex	3	0
Ophthalmic herpes zoster	4	0
Oral herpes	331	0
Varicella	31	0
Varicella zoster virus infection	3	0
Infections NEC		
Abscess	39	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Groin abscess	2	0
Infected bite	3	0
Infected cyst	2	0
Infection	266	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	38	0
Lymph gland infection	18	0
Lymph node abscess	6	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	12	0
Superinfection	1	0
Vaccination site abscess	11	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	2	0
Infectious transmissions		
Nosocomial infection	1	0
Secondary transmission	8	0
Vaccine virus shedding	1	0
Influenza viral infections		
H1N1 influenza	1	0
Influenza	1765	0
Klebsiella infections		
Klebsiella infection	1	0
Lower respiratory tract and lung infections		
Bronchitis	26	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	280	9
Pneumonia	164	15
Pneumonia aspiration	10	6
Sputum purulent	1	0
Male reproductive tract infections		
Epididymitis	10	0
Orchitis	6	0
Prostate infection	2	0
Molluscum contagiosum viral infections		
Molluscum contagiosum	1	0
Mumps viral infections		
Mumps	8	0
Muscle and soft tissue infections		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Psoas abscess	1	0
Soft tissue infection	2	0
Neisseria infections		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
Meningococcal infection	1	0
Orthopox viral infections		
Smallpox	1	0
Vaccinia virus infection	2	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Plasmodia infections		
Malaria	2	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	2	0
Pseudomonal infections		
Pseudomonas infection	1	0
Retroviral infections		
Acquired immunodeficiency syndrome	1	0
HIV infection	2	0
Persistent generalised lymphadenopathy	1	0
Rhinoviral infections		
Rhinovirus infection	1	0
Rotaviral infections		
Gastroenteritis rotavirus	1	0
Rubeola viral infections		
Measles	5	0
Salmonella infections		
Typhoid fever	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Neutropenic sepsis	4	1
Sepsis	62	10
Sepsis syndrome	2	0
Septic rash	2	0
Septic shock	6	1
Urosepsis	5	0
Skin structures and soft tissue infections		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	3	0
Impetigo	11	0
Infected skin ulcer	2	0
Injection site pustule	3	0
Nail infection	2	0
Pustule	19	0
Pyoderma	1	0
Rash pustular	12	0
Skin infection	32	0
Subcutaneous abscess	12	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
Staphylococcal infections		
Furuncle	44	1
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	5	0
Staphylococcal sepsis	1	0
Streptococcal infections		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	8	0
Pneumonia pneumococcal	1	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Streptococcal infection	1	0
Streptococcal sepsis	1	0
Tinea infections		
Body tinea	4	0
Tinea capitis	1	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	4	0
Treponema infections		
Syphilis	2	0
Trypanosomal infections		
African trypanosomiasis	4	0
Tuberculous infections		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
Upper respiratory tract infections		
Acute sinusitis	4	0
Chronic sinusitis	3	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	34	0
Nasopharyngitis	1134	1
Peritonsillar abscess	6	0
Pharyngitis	35	0
Rhinitis	53	0
Sinusitis	196	0
Tonsillitis	137	0
Tracheitis	5	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0
Urinary tract infections		
Cystitis	84	0
Kidney infection	52	0
Pyelonephritis	3	0
Urethritis	1	0
Urinary tract infection	215	0
Vascular infections		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	12	0
Viral infections NEC		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	33	0
Hepatitis viral	3	0
Meningitis viral	9	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	2	0
Pneumonia viral	4	2
Post viral fatigue syndrome	50	0
Sweating fever	124	0
Vestibular neuronitis	35	0
Viral diarrhoea	2	0
Viral infection	63	0
Viral labyrinthitis	4	0
Viral myocarditis	4	0
Viral pericarditis	3	0
Viral pharyngitis	23	0
Viral rash	66	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
Infections SOC TOTAL	**11214**	**110**

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Reaction Name	Total	Fatal
Injuries		
Abdominal and gastrointestinal injuries NEC		
Gallbladder injury	1	0
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	5	0
Oral mucosal scar	1	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	7	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
Accidental exposures to product		
Accidental exposure to product	21	0
Anaesthetic and allied procedural complications		
Airway complication of anaesthesia	2	0
Delayed recovery from anaesthesia	3	0
Sedation complication	1	0
Atmospheric pressure injuries		
Barotitis media	1	0
Barotrauma	2	0
Hypobarism	2	0
Bone and joint injuries NEC		
Bursa injury	3	0
Joint injury	11	0
Meniscus injury	2	0
Cardiac and vascular procedural complications		
Ischaemic contracture of the left ventricle	1	0
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
Cardiovascular injuries		
Vascular injury	9	0
Cerebral injuries NEC		
Brain contusion	4	0
Brain herniation	2	0
Concussion	4	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	0
Subdural haemorrhage	7	0
Traumatic intracranial haemorrhage	1	1
Chemical injuries		
Chemical burn	1	0
Chemical burn of skin	9	0
Chemical cystitis	2	0
Chest and respiratory tract injuries NEC		
Bronchial injury	1	0
Chest crushing	14	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	71	0
Cold shock response	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Frostbite	1	0
Cranial nerve injuries		
Vth nerve injury	1	0
Ear injuries NEC		
Deafness traumatic	1	0
Ear injury	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	10	0
Exposure via breast milk	156	0
Foetal exposure during pregnancy	63	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	22	0
Maternal exposure during breast feeding	1936	0
Maternal exposure during delivery	1	0
Maternal exposure during pregnancy	1051	0
Maternal exposure timing unspecified	13	0
Paternal exposure before pregnancy	3	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Corneal abrasion	1	0
Eye contusion	16	0
Eye injury	27	0
Foreign body in eye	4	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		
Bone fragmentation	1	0
Fracture	3	0
Joint dislocation	3	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	11	0
Procedural vomiting	2	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	2	0
Heat oedema	14	0
Heat stroke	3	0
Intentional product use issues		
Intentional dose omission	1	0
Intentional product use issue	1	0
Limb fractures and dislocations		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Atypical femur fracture	1	0
Clavicle fracture	28	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	2	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	2	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	26	0
Prescription drug used without a prescription	3	0
Product use complaint	2	0
Product use issue	32	0
Vaccination error	5	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	7	0
Muscle, tendon and ligament injuries		
Epicondylitis	21	0
Ligament injury	2	0
Ligament sprain	9	0
Mallet finger	1	0
Muscle hernia	1	0
Muscle injury	37	0
Muscle rupture	9	0
Muscle strain	36	0
Post-traumatic neck syndrome	2	0
Tendon injury	7	0
Tendon rupture	25	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	105	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	12	0
Non-occupational environmental exposures		
Exposure to extreme temperature	2	0
Non-site specific injuries NEC		
Animal scratch	1	0
Arthropod bite	9	0
Arthropod sting	6	0
Bite	1	0
Bone contusion	1	0
Crush injury	1	0
Electric shock	19	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Fall	204	0
Foreign body	4	0
Injury	14	0
Multiple injuries	2	0
Nervous system injury	2	0
Post concussion syndrome	2	0
Traumatic haematoma	1	0
Wound	7	0
Wound complication	12	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	6	0
Non-site specific procedural complications		
Administration related reaction	2	0
Incision site pain	3	0
Infusion related reaction	8	0
Injection related reaction	66	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Post procedural pruritus	1	0
Procedural pain	4	0
Seroma	1	0
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		
Off label use	409	0
Overdoses NEC		
Intentional overdose	1	0
Overdose	53	0
Pathways and sources of exposure		
Exposure via contaminated device	1	0
Exposure via unknown route	1	0
Pelvic fractures and dislocations		
Pelvic fracture	1	0
Peripheral nerve injuries		
Axillary nerve injury	1	0
Brachial plexus injury	1	0
Radial nerve injury	2	0
Sciatic nerve injury	2	0
Ulnar nerve injury	4	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	14	0
Toxicity to various agents	4	0
Product administration errors and issues		
Accidental overdose	8	0
Contraindicated product administered	1	0
Duplicate therapy error	1	0
Expired product administered	13	0
Inappropriate schedule of product administration	669	0
Incomplete course of vaccination	2	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Incorrect dose administered	55	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	7	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0
Product administered at inappropriate site	23	0
Product administered to patient of inappropriate age	1	0
Product administration error	12	0
Product dose omission issue	6	0
Wrong product administered	20	0
Product confusion errors and issues		
Product dosage form confusion	1	0
Product label confusion	5	0
Product packaging confusion	1	0
Product dispensing errors and issues		
Product dispensing error	4	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Labelled drug-drug interaction medication error	1	0
Product preparation errors and issues		
Product preparation error	3	0
Product preparation issue	6	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product prescribing error	2	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	23	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Foreign body in urogenital tract	1	0
Reproductive system and breast injuries		
Breast injury	1	0
Cervix injury	1	0
Penile contusion	1	0
Penis injury	2	0
Reproductive tract and breast procedural complications		
Failed in vitro fertilisation	1	0
Site specific injuries NEC		
Back injury	3	0
Face crushing	3	0
Face injury	1	0
Head injury	36	0
Limb crushing injury	4	0
Limb injury	178	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	1	0
Pharyngeal contusion	1	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Skin injuries NEC		
Contusion	1345	0
Hair injury	1	0
Nail avulsion	1	0
Scar	31	0
Scratch	7	0
Skin abrasion	7	0
Skin injury	4	0
Skin laceration	4	0
Skin wound	3	0
Splinter	1	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
Skull fractures, facial bone fractures and dislocations		
Facial bones fracture	1	0
Fractured skull depressed	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Spinal fractures and dislocations		
Spinal compression fracture	1	0
Spinal fracture	4	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	4	0
Burn of internal organs	4	0
Burn oral cavity	5	0
Burns second degree	3	0
Burns third degree	1	0
Cold burn	1	0
Thermal burn	25	0
Thermal burns of eye	17	0
Underdoses NEC		
Underdose	6	0
Vaccination related complications		
Adverse event following immunisation	1	0
Post vaccination syndrome	1	0
Vaccination complication	53	0
Injuries SOC TOTAL	**7531**	**1**

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Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Cortisol decreased	4	0
Adrenal medulla tests		
Epinephrine	1	0
Epinephrine abnormal	1	0
Epinephrine increased	1	0
Auditory and vestibular diagnostic procedures		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
Weber tuning fork test abnormal	1	0
Autoimmunity analyses		
Antineutrophil cytoplasmic antibody positive	1	0
Antinuclear antibody	3	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Beta-2 glycoprotein antibody positive	1	0
Cardiolipin antibody positive	1	0
Rheumatoid factor	3	0
Rheumatoid factor increased	1	0
Rheumatoid factor positive	1	0
Bacteria identification and serology (excl mycobacteria)		
Bacterial test positive	1	0
Blood counts NEC		
Full blood count	7	0
Full blood count abnormal	2	0
Blood gas and acid base analyses		
Acid base balance abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	5	0
Blood pH	7	0
Blood pH abnormal	1	0
Blood pH increased	12	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	10	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	91	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
Bone marrow and immune tissue histopathology procedures		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
Bone marrow and immune tissue imaging procedures		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	11	0
Blood glucose abnormal	14	0
Blood glucose decreased	38	0
Blood glucose fluctuation	17	0
Blood glucose increased	107	0
Blood glucose normal	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Glycosylated haemoglobin increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	46	0
Heart sounds	9	0
Heart sounds abnormal	6	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	3	0
Myocardial strain imaging	2	0
Right atrial volume abnormal	1	0
Stroke volume decreased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	2	0
Central nervous system imaging procedures		
Computerised tomogram head	10	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	2	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
CSF protein increased	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level	1	0
Histamine level increased	2	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	4	0
Inflammatory marker test	1	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	12	0
Remnant-like lipoprotein particles	4	0
Coagulation and bleeding analyses		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	2	0
Bleeding time prolonged	10	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	25	0
International normalised ratio abnormal	8	0
International normalised ratio decreased	22	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
International normalised ratio fluctuation	3	0
International normalised ratio increased	53	0
Platelet factor 4	1	0
Prothrombin time prolonged	1	0
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	5	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	11	0
Electrocardiogram ST segment depression	2	0
Electrocardiogram ST segment elevation	11	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	6	0
Electrocardiogram abnormal	23	0
Electrocardiogram change	1	0
Electrocardiogram normal	3	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	78	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Semen volume increased	1	0
Sperm concentration	2	0
Sperm concentration decreased	2	0
Spermatozoa abnormal	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	5	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	4	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	2	0
Blood insulin decreased	1	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	1	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	7	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Heart rate and pulse investigations		
Carotid pulse	1	0
Heart rate	555	0
Heart rate abnormal	72	0
Heart rate decreased	101	0
Heart rate increased	1124	0
Heart rate irregular	268	0
Heart rate normal	1	0
Heart rate variability decreased	1	0
Maximum heart rate	2	0
Maximum heart rate increased	2	0
Pulse abnormal	22	0
Pulse absent	1	0
Pulse pressure increased	2	0
Radial pulse abnormal	1	0
Sinus rhythm	7	0
Hepatobiliary imaging procedures		
Liver scan	1	0
Imaging procedures NEC		
Computerised tomogram	4	0
Magnetic resonance imaging	5	0
Magnetic resonance imaging abnormal	2	0
Scan	2	0
X-ray	2	0
Immune response protein analyses NEC		
Cytokine test	1	0
Immunoglobulin analyses		
Blood immunoglobulin E increased	2	0
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	2	0
Immunology analyses NEC		
Antibody test	4	0
Antibody test positive	1	0
Immunology test	12	0
Immunology skin tests NEC		
Allergy alert test	1	0
Skin test positive	2	0
Investigations NEC		
Blood test	28	0
Blood test abnormal	47	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	1	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	27	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	5	0

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme increased	10	0
Liver function test	1	0
Liver function test abnormal	32	0
Liver function test increased	28	0
Transaminases increased	5	0
Metabolism tests NEC		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood ketone body present	1	0
Blood uric acid increased	2	0
Brain natriuretic peptide increased	1	0
N-terminal prohormone brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body present	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Culture throat	1	0
Culture urine	1	0
Vaccine induced antibody absent	1	0
Mineral and electrolyte analyses		
Blood calcium increased	1	0
Blood copper increased	1	0
Blood iron	2	0
Blood iron decreased	10	0
Blood iron increased	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	3	0
Blood sodium decreased	10	0
Serum ferritin	1	0
Serum ferritin decreased	5	0
Serum ferritin increased	1	0
Sweat test	1	0
Urine copper	2	0
Musculoskeletal and soft tissue imaging procedures		
Skull X-ray	6	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count	1	0
Swollen joint count increased	1	0
Mycobacteria identification and serology		
Tuberculin test positive	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	5	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	6	0
Magnetic resonance neurography	1	0
Nerve conduction studies	1	0
Pain threshold decreased	1	0

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Sensory level	1	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
Intraocular pressure test	3	0
Pupil dilation procedure	1	0
Visual acuity tests	1	0
Physical examination procedures and organ system status		
Body temperature	285	0
Body temperature abnormal	52	0
Body temperature decreased	44	0
Body temperature fluctuation	64	0
Body temperature increased	490	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	3	0
Grip strength decreased	23	0
Gynaecological examination	1	0
Head lag	8	0
Lymph node palpable	45	0
Male genital examination abnormal	1	0
Menstruation normal	3	0
Muscle strength abnormal	3	0
Ophthalmological examination	2	0
Orthopaedic examination	1	0
Palpatory finding abnormal	2	0
Product residue present	2	0
Psoriasis area severity index decreased	2	0
Psoriasis area severity index increased	1	0
Respiratory rate	9	0
Respiratory rate decreased	27	0
Respiratory rate increased	45	0
Skin temperature	44	0
Temperature difference of extremities	13	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	127	0
Weight increased	49	0
Pituitary analyses anterior		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	3	0
Blood growth hormone	3	0
Blood prolactin	3	0
Blood prolactin increased	4	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	10	0
Platelet analyses		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Platelet count abnormal	1	0
Platelet count decreased	79	0
Platelet count increased	6	0
Protein analyses NEC		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	28	0
Red blood cell analyses		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin decreased	15	0
Haemoglobin increased	2	0
Red blood cell count decreased	1	0
Red blood cell rouleaux formation present	1	0
Renal function analyses		
Blood creatinine	1	0
Blood creatinine decreased	1	0
Blood creatinine increased	4	0
Glomerular filtration rate decreased	4	0
Glomerular filtration rate increased	1	0
Reproductive hormone analyses		
Blood oestrogen	1	0
Blood oestrogen decreased	2	0
Blood testosterone decreased	1	0
Blood testosterone increased	2	0
False negative pregnancy test	9	0
Female sex hormone level	3	0
Human chorionic gonadotropin increased	1	0
Pregnancy test	18	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
Progesterone decreased	1	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	3	0
Reproductive organ and breast imaging procedures		
Breast scan	1	0
Hysteroscopy	2	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	2	0
Peak expiratory flow rate decreased	6	0
Pulmonary function test	3	0
Total lung capacity decreased	4	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	19	0

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	2	0
Ventilation/perfusion scan	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	10	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	2	0
Troponin T increased	2	0
Troponin increased	22	0
Therapeutic drug monitoring analyses		
Analgesic drug level	8	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
Thyroid analyses		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	5	0
Thyroxine	1	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	5	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase abnormal	1	0
Blood alkaline phosphatase increased	5	0
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
Toxicology laboratory analyses		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
Urinalysis NEC		
Blood urine	17	0
Blood urine present	73	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Protein urine present	1	0
Red blood cells urine	1	0
Urine analysis abnormal	6	0
Urine leukocyte esterase positive	1	0
Urine uric acid increased	1	0
pH urine	6	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	13	0
Urine output decreased	14	0
Urine output increased	7	0

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Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Urinary tract histopathology procedures		
Urine cytology	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Cystoscopy	2	0
Ultrasound kidney normal	1	0
Vascular imaging procedures NEC		
Venogram	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	11	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	88	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure difference of extremities	1	0
Blood pressure increased	284	0
Blood pressure measurement	48	0
Blood pressure normal	2	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	4	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	11	0
Coronavirus test positive	4	0
Cytomegalovirus test positive	1	0
HIV antibody positive	1	0
HIV test	1	0
SARS-CoV-1 test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	10	0
SARS-CoV-2 antibody test negative	15	0
SARS-CoV-2 antibody test positive	6	0
SARS-CoV-2 test	35	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	10	0
SARS-CoV-2 test positive	106	0
Viral load	2	0
Viral test	4	0
Viral test positive	1	0
Vitamin analyses		
Blood folate decreased	6	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	2	0
Vitamin D	4	0
Vitamin D decreased	3	0
Water and electrolyte analyses NEC		
Urine osmolarity	1	0
Volume blood	1	0
White blood cell analyses		
Eosinophil count	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Eosinophil count decreased	1	0
Eosinophil count increased	3	0
Lymphocyte count	1	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	2	0
Neutrophil count	4	0
Neutrophil count decreased	11	0
Neutrophil count increased	4	0
White blood cell count	4	0
White blood cell count decreased	13	0
White blood cell count increased	11	0
Investigations SOC TOTAL	**5996**	**3**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Appetite disorder	20	0
Decreased appetite	1446	0
Diet refusal	1	0
Eating disorder symptom	3	0
Food craving	12	0
Food refusal	16	0
Hyperphagia	15	0
Hypophagia	18	0
Increased appetite	35	0
Salt craving	2	0
Calcium metabolism disorders		
Hypocalcaemia	3	0
Tetany	3	0
Copper metabolism disorders		
Copper deficiency	1	0
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	52	0
Diabetes mellitus inadequate control	16	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	16	0
Type 2 diabetes mellitus	4	0
Diabetic complications NEC		
Diabetic complication	2	0
Diabetic ketoacidosis	12	0
Diabetic ketosis	1	0
Disorders of purine metabolism		
Gout	104	0
Electrolyte imbalance NEC		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
Fat soluble vitamin deficiencies and disorders		
Vitamin D deficiency	8	0
Fluid intake decreased		
Fluid intake reduced	2	0
Fluid intake increased		
Polydipsia	7	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Alcohol intolerance	6	0
Breast milk substitute intolerance	1	0
Dairy intolerance	4	0
Food intolerance	18	0
Gluten sensitivity	7	0
Histamine intolerance	4	0
General nutritional disorders NEC		
Abnormal loss of weight	34	0
Abnormal weight gain	20	0
Cachexia	1	0
Feeding disorder	100	0
Food aversion	10	0
Malnutrition	3	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Neonatal insufficient breast milk syndrome	7	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	16	0
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	68	0
Insulin resistance	5	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	80	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
Iron deficiencies		
Iron deficiency	13	0
Iron excess		
Haemochromatosis	2	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1	0
Magnesium deficiency	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	5	1
Lactic acidosis	2	0
Metabolic acidosis	2	0
Metabolic disorders NEC		
Hypercatabolism	1	0
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	4	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	5	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hypernatraemia	1	1
Hyponatraemia	12	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	5	0
Total fluid volume decreased		
Dehydration	230	0
Total fluid volume increased		
Fluid retention	63	0
Hypervolaemia	5	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Vitamin deficiencies NEC		
Hypovitaminosis	6	0
Water soluble vitamin deficiencies		
Folate deficiency	6	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	6	0
Metabolic disorders SOC TOTAL	**2587**	**3**

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	369	0
Arthropathy	32	0
Autoimmune arthritis	9	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	2	0
Polyarthritis	15	0
Rheumatic fever	2	0
Sacroiliitis	6	0
Seronegative arthritis	2	0
Bone disorders NEC		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	6	0
Osteitis	9	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
Bone related signs and symptoms		
Bone pain	439	0
Bone swelling	10	0
Coccydynia	4	0
Metatarsalgia	1	0
Pain in jaw	417	0
Pubic pain	2	0
Spinal pain	92	0
Bursal disorders		
Bursitis	93	0
Cartilage disorders		
Chondritis	1	0
Costochondritis	127	0
Osteochondritis	1	0
Polychondritis	3	0
Connective tissue disorders NEC		
Connective tissue disorder	2	0
Polymyalgia rheumatica	73	0
Reynold's syndrome	1	0
Sjogren's syndrome	7	0
Systemic scleroderma	1	0
Crystal arthropathic disorders		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	2	0
Gouty arthritis	1	0
Epiphyseal disorders		
Epiphyses premature fusion	1	0
Extremity deformities		
Bone deformity	1	0
Finger deformity	2	0
Foot deformity	2	0
Hand deformity	2	0
Knee deformity	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
Limb deformity	5	0
Musculoskeletal deformity	1	0
Fractures NEC		
Osteoporotic fracture	1	0
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Carpal collapse	1	0
Chondromalacia	1	0
Hypermobility syndrome	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	2	0
Joint laxity	3	0
Joint lock	33	0
Ligament laxity	1	0
Patellofemoral pain syndrome	2	0
Periarthritis	231	0
Rotator cuff syndrome	38	0
Temporomandibular joint syndrome	14	0
Joint related signs and symptoms		
Arthralgia	10151	0
Jaw clicking	6	0
Joint effusion	16	0
Joint noise	40	0
Joint range of motion decreased	32	0
Joint stiffness	285	0
Joint swelling	641	0
Joint vibration	3	0
Joint warmth	16	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	4	0
Ligamentitis	1	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	27	0
Metabolic bone disorders		
Osteopenia	4	0
Osteoporosis	7	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	2	0
Myositis	45	0
Polymyositis	9	0
Muscle pains		
Fibromyalgia	135	0
Myalgia	11536	0
Myalgia intercostal	2	0
Myofascial pain syndrome	12	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
Muscle atrophy	25	0
Muscle discomfort	8	0
Muscle disorder	10	0
Muscle fatigue	384	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	4	0
Muscle spasms	2270	0
Muscle swelling	43	0
Muscle tightness	98	0
Muscle twitching	538	0
Muscle tone abnormalities		
Muscle rigidity	18	0
Nuchal rigidity	13	0
Torticollis	7	0
Trismus	40	0
Muscle weakness conditions		
Muscular weakness	1083	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	4	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	23	0
Mandibular mass	2	0
Mastication disorder	7	0
Mobility decreased	135	0
Muscle contracture	1	0
Musculoskeletal disorder	11	0
Musculoskeletal stiffness	1444	0
Pelvic misalignment	1	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	4	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	1	0
Head deformity	2	0
Nose deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Dactylitis	3	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	14	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2752	0
Flank pain	85	0
Growing pains	1	0
Limb discomfort	1624	0
Musculoskeletal chest pain	299	0
Musculoskeletal discomfort	122	0
Musculoskeletal pain	133	0
Neck pain	2145	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
Pain in extremity	14113	1
Rheumatic disorder	15	0
Sacral pain	4	0
Myopathies		
Mitochondrial myopathy acquired	1	0
Myopathy	7	0
Rhabdomyolysis	14	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	60	0
Spinal osteoarthritis	2	0
Psoriatic arthropathies		
Psoriatic arthropathy	20	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	134	0
Rheumatoid nodule	1	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	302	0
Fluctuance	1	0
Groin pain	123	0
Neck mass	43	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	7	0
Spine and neck deformities		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	2	0
Spondyloarthropathies		
Ankylosing spondylitis	10	0
Arthritis reactive	67	0
Spondylitis	4	0
Spondyloarthropathy	1	0
Synovial disorders		
Synovial cyst	22	0
Synovitis	11	0
Tendon disorders		
Enthesopathy	3	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	6	0
Tendon pain	27	0
Tendonitis	56	0
Tenosynovitis	4	0
Tenosynovitis stenosans	2	0
Trigger finger	32	0
Trunk deformities		
Deformity thorax	1	0
Drooping shoulder syndrome	2	0
Shoulder deformity	3	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022

Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders (Muscle & tissue disorders cont'd)		
Muscle & tissue disorders SOC TOTAL	53562	1

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Neoplasms		
Adrenal neoplasms malignant		
Adrenal gland cancer	1	0
Angioimmunoblastic T-cell lymphomas		
Angioimmunoblastic T-cell lymphoma	1	0
B-cell lymphomas NEC		
B-cell lymphoma	2	1
Follicular lymphoma	4	0
Bone neoplasms malignant (excl sarcomas)		
Bone cancer	1	1
Bone neoplasms unspecified malignancy		
Bone neoplasm	1	0
Breast and nipple neoplasms benign		
Benign breast neoplasm	2	0
Fibroadenoma of breast	2	0
Breast and nipple neoplasms malignant		
Breast cancer	42	0
Breast cancer female	1	0
Breast cancer male	2	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
Cardiovascular neoplasms benign		
Haemangioma	2	0
Pericardial lipoma	1	0
Cartilage sarcomas		
Chondrosarcoma	1	0
Central nervous system neoplasms malignant NEC		
Brain cancer metastatic	1	0
Cervix neoplasms malignant		
Cervix carcinoma	2	0
Colorectal neoplasms malignant		
Colon cancer	2	0
Colorectal cancer	1	0
Rectal cancer	2	0
Endocrine neoplasms malignant and unspecified NEC		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
Endometrial neoplasms malignant		
Endometrial cancer	2	0
Follicular lymphomas		
Primary gastrointestinal follicular lymphoma	1	0
Gastric neoplasms malignant		
Gastric cancer	1	1
Gastrointestinal neoplasms malignant NEC		
Gastrointestinal carcinoma	3	0
Hepatic neoplasms malignant		
Hepatocellular carcinoma	1	0
Hepatobiliary neoplasms malignancy unspecified		
Hepatic neoplasm	1	0
Hodgkin's disease NEC		
Hodgkin's disease	4	0
Islet cell neoplasms and APUDoma NEC		

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Pancreatic neuroendocrine tumour	1	0
Kaposi's sarcomas		
Kaposi's sarcoma	1	0
Leukaemias NEC		
Leukaemia	5	1
Leukaemias acute NEC		
Acute leukaemia	2	0
Leukaemias chronic NEC		
Chronic leukaemia	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	3	0
Leukaemias chronic myeloid		
Chronic myeloid leukaemia	1	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer recurrent	1	0
Lymphomas unspecified NEC		
Lymphoma	44	1
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		
Histiocytic necrotising lymphadenitis	1	0
Metastases to specified sites		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
Metastases to unknown and unspecified sites		
Metastasis	1	0
Myelodysplastic syndromes		
Myelodysplastic syndrome	3	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	2	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	9	0
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	2	0
Neoplasm recurrence	1	0
Nervous system neoplasms benign NEC		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	3	0
Meningioma	1	0
Spinal cord neoplasm	1	0
Neuromas		
Acoustic neuroma	3	0
Neuroma	1	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	3	0
Ocular neoplasms benign		
Eye naevus	1	0
Oesophageal neoplasms malignant		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Oesophageal cancer metastatic	4	0
Oncologic complications and emergencies		
Cancer pain	1	0
Tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	4	0
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	4	0
Plasma cell myelomas		
POEMS syndrome	1	0
Plasma cell myeloma	2	0
Plasma cell neoplasms NEC		
Hypergammaglobulinaemia benign monoclonal	1	0
TEMPI syndrome	2	0
Prostatic neoplasms malignant		
Prostate cancer	4	0
Renal neoplasms malignant		
Clear cell renal cell carcinoma	1	0
Renal cancer	3	0
Reproductive neoplasms female benign NEC		
Benign hydatidiform mole	3	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Bronchial carcinoma	1	0
Lung cancer metastatic	1	1
Lung neoplasm malignant	13	1
Salivary gland neoplasms unspecified malignancy		
Salivary gland neoplasm	2	0
Skin melanomas (excl ocular)		
Malignant melanoma	2	0
Skin neoplasms benign		
Acrochordon	6	0
Anogenital warts	7	0
Fibrous histiocytoma	1	0
Haemangioma of skin	6	0
Melanocytic naevus	9	0
Pyogenic granuloma	1	0
Seborrhoeic keratosis	1	0
Skin papilloma	21	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	3	0
Skin cancer	1	0
Squamous cell carcinoma of skin	1	0
Soft tissue neoplasms benign NEC		
Lipoma	7	0
Lymphangioma	1	0
Soft tissue sarcomas histology unspecified		
Sarcoma	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022

Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Thyroid neoplasms malignant		
Huerthle cell carcinoma	1	0
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
Uterine neoplasms benign		
Uterine leiomyoma	13	0
Neoplasms SOC TOTAL	**340**	**7**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
Abnormal reflexes		
Areflexia	7	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	10	0
Reflexes abnormal	2	0
Abnormal sleep-related events		
Sleep paralysis	30	0
Absence seizures		
Petit mal epilepsy	29	0
Acute polyneuropathies		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	89	2
Miller Fisher syndrome	4	0
Subacute inflammatory demyelinating polyneuropathy	1	0
Autonomic nervous system disorders		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	11	0
Autonomic neuropathy	2	0
Horner's syndrome	2	0
Orthostatic intolerance	2	0
Central nervous system aneurysms and dissections		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
Central nervous system haemorrhages and cerebrovascular accidents		
Basal ganglia haemorrhage	1	0
Basal ganglia infarction	1	0
Brain stem haemorrhage	2	2
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	4	0
Cerebellar artery thrombosis	1	0
Cerebellar haemorrhage	3	0
Cerebellar infarction	3	0
Cerebellar ischaemia	1	0
Cerebellar stroke	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	4	0
Cerebral haemorrhage	57	14
Cerebral infarction	30	2
Cerebral ischaemia	1	0
Cerebral thrombosis	14	0
Cerebrovascular accident	468	20
Embolic stroke	9	1
Haemorrhage intracranial	12	3
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	11	4
Internal capsule infarction	1	0
Intracranial haematoma	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Ischaemic cerebral infarction	1	0
Ischaemic stroke	55	2
Lacunar infarction	4	0
Lacunar stroke	5	0
Lateral medullary syndrome	2	0
Pseudostroke	2	0
Ruptured cerebral aneurysm	1	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	18	7
Thalamic infarction	1	0
Thrombotic stroke	5	1
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	5	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	5	0
Cerebral small vessel ischaemic disease	3	0
Cerebrovascular disorder	3	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	53	5
Cerebral venous thrombosis	6	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	2	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	2	0
Cervicobrachial syndrome	6	0
Choreiform movements		
Chorea	3	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	1	0
Diabetic neuropathy	1	0
Coma states		
Coma	16	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	20	0
Balance disorder	483	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0
Coordination abnormal	68	0
Dysdiadochokinesis	1	0
Dysstasia	68	0
Nystagmus	16	0
Cortical dysfunction NEC		
Alexia	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
Aphasia	99	0
Apraxia	1	0
Dysgraphia	2	0
Dyslexia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	3	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Dementia (excl Alzheimer's type)		
Dementia	18	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	7	0
Clinically isolated syndrome	1	0
Demyelination	9	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	12	0
Consciousness fluctuating	3	0
Depressed level of consciousness	52	0
Infant sedation	1	0
Lethargy	2472	0
Loss of consciousness	771	1
Postictal state	5	0
Sedation	8	0
Somnolence	1175	0
Stupor	5	0
Syncope	2669	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	2	0
Non-24-hour sleep-wake disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	7	0
Ballismus	2	0
Bradykinesia	24	0
Clumsiness	23	0
Dyskinesia	76	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	13	0
Foetal movement disorder	5	0
Hyperkinesia	4	0
Hypokinesia	101	0
Motor dysfunction	4	0
Movement disorder	66	0
Psychomotor hyperactivity	28	0
Synkinesis	2	0
Tardive dyskinesia	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Dystonias		
Dystonia	16	0
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	6	0
Encephalopathies NEC		
Autoimmune encephalopathy	1	1
Encephalopathy	5	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	7	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0
VIth nerve disorder	1	0
VIth nerve paralysis	11	0
Facial cranial nerve disorders		
Bell's palsy	607	0
Facial nerve disorder	9	0
Facial paralysis	456	0
Facial paresis	103	0
Facial spasm	54	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	70	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	282	0
Cold-stimulus headache	33	0
Drug withdrawal headache	3	0
Exertional headache	9	0
External compression headache	2	0
Headache	29438	1
Medication overuse headache	2	0
New daily persistent headache	8	0
Occipital neuralgia	17	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	9	0
Sinus headache	390	0
Tension headache	619	0
Thunderclap headache	22	0
Vascular headache	21	0
Hydrocephalic conditions		
Hydrocephalus	5	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	2	0
Brain oedema	13	2
Idiopathic intracranial hypertension	12	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Intracranial pressure increased	5	0
Intellectual disabilities		
Intellectual disability	4	0
Lumbar spinal cord and nerve root disorders		
Sciatica	127	0
Memory loss (excl dementia)		
Amnesia	216	0
Memory impairment	236	0
Transient global amnesia	9	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	100	0
Cognitive linguistic deficit	1	0
Disturbance in attention	376	0
Mental impairment	56	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	37	0
Migraine	3401	0
Migraine with aura	223	0
Migraine without aura	22	0
Ophthalmic migraine	7	0
Retinal migraine	37	0
Typical aura without headache	8	0
Vestibular migraine	26	0
Mixed cranial nerve disorders		
Bulbar palsy	2	0
Mononeuropathies		
Carpal tunnel syndrome	31	0
Cubital tunnel syndrome	4	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	29	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	20	0
Piriformis syndrome	2	0
Pudendal canal syndrome	3	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0
Motor neurone diseases		
Lower motor neurone lesion	1	0
Motor neurone disease	7	2
Progressive bulbar palsy	1	0
Upper motor neurone lesion	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	36	0
Multiple sclerosis relapse	25	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Hypertonia	2	0
Hypotonia	36	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	32	0
Narcolepsy and hypersomnia		
Cataplexy	3	0
Hypersomnia	122	0
Narcolepsy	6	0
Nervous system disorders NEC		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	22	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	2	0
Tunnel vision	23	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Cerebrospinal fluid leakage	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	10986	0
Dizziness exertional	49	0
Dizziness postural	832	0
Drooling	24	0
Fontanelle bulging	2	0
Head discomfort	386	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0
Myoclonus	34	0
Neurological symptom	65	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	17	0
Presyncope	693	0
Sensory overload	5	0
Slow response to stimuli	4	0
Tongue biting	8	0
Unresponsive to stimuli	59	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	30	0
Muscle spasticity	18	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Nervous system disorders		
Myasthenia gravis	8	0
Myasthenia gravis crisis	2	0
Olfactory nerve disorders		
Anosmia	315	0
Hyposmia	18	0
Parosmia	309	0
Optic nerve disorders NEC		
Optic neuritis	34	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	13	0
Burning sensation	634	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	45	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	4	0
Hemiparaesthesia	5	0
Hyperaesthesia	120	0
Hypoaesthesia	3380	0
Lhermitte's sign	1	0
Paraesthesia	4636	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	19	0
Hemiparesis	66	0
Hemiplegia	47	0
Locked-in syndrome	1	0
Monoparesis	88	0
Monoplegia	99	0
Paralysis	146	0
Paraparesis	3	0
Paraplegia	3	0
Paresis	9	0
Quadriparesis	1	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	16	0
Hypokinetic dysarthria	1	0
Parkinson's disease	4	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	11	0
Partial complex seizures		
Dreamy state	6	0
Focal dyscognitive seizures	5	0
Temporal lobe epilepsy	2	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Peripheral neuropathies NEC		
Axonal neuropathy	2	0
Brachial plexopathy	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Nervous system disorders		
Neuralgic amyotrophy	4	0
Neuritis	8	0
Neuropathy peripheral	148	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	4	0
Small fibre neuropathy	3	0
Thoracic outlet syndrome	2	0
Seizures and seizure disorders NEC		
Atonic seizures	9	0
Change in seizure presentation	2	0
Clonic convulsion	4	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	165	0
Epileptic aura	2	0
Epileptic encephalopathy	2	0
Febrile convulsion	18	0
Idiopathic generalised epilepsy	1	0
Neonatal epileptic seizure	1	0
Partial seizures	29	0
Partial seizures with secondary generalisation	1	0
Post stroke seizure	1	0
Psychogenic seizure	11	0
Seizure	709	1
Seizure anoxic	3	0
Seizure cluster	6	0
Seizure like phenomena	3	0
Status epilepticus	39	0
Tonic clonic movements	5	0
Tonic convulsion	35	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	587	0
Allodynia	30	0
Aura	28	0
Central pain syndrome	1	0
Complex regional pain syndrome	6	0
Dysgeusia	1274	0
Electric shock sensation	49	0
Hypergeusia	1	0
Hypogeusia	8	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	3	0
Neuralgia	675	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	7	0
Post herpetic neuralgia	15	0
Restless arm syndrome	3	0
Restless legs syndrome	157	0
Sensory disturbance	123	0
Sensory loss	98	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Taste disorder	301	0
Visual perseveration	3	0
Sleep disturbances NEC		
Microsleep	1	0
Sleep deficit	13	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	228	0
Incoherent	14	0
Language disorder	2	0
Repetitive speech	5	0
Slow speech	23	0
Speech disorder	80	0
Speech disorder developmental	1	0
Spinal cord and nerve root disorders NEC		
Acquired syringomyelia	1	0
Cauda equina syndrome	1	0
Myelopathy	1	0
Radiculitis brachial	17	0
Radiculopathy	8	0
Structural brain disorders NEC		
Brain injury	9	2
Cerebral ventricle dilatation	2	0
Hyperintensity in brain deep nuclei	1	0
Transient cerebrovascular events		
Transient ischaemic attack	188	3
Tremor (excl congenital)		
Essential tremor	5	0
Head titubation	13	0
Resting tremor	4	0
Tremor	2063	0
Trigeminal disorders		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	82	0
Trigeminal neuritis	3	0
Vagus nerve disorders		
Vocal cord paralysis	2	0
Vertigos NEC		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	**77706**	**82**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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Reaction Name	Total	Fatal
Pregnancy conditions		
Abortion related conditions and complications		
Anembryonic gestation	3	0
Abortions not specified as induced or spontaneous		
Abortion	1	0
Abortion missed	7	0
Abortions spontaneous		
Abortion spontaneous	459	0
Abortion threatened	2	0
Amniotic fluid and cavity disorders of pregnancy NEC		
Amniorrhoea	2	0
Oligohydramnios	1	0
Foetal complications NEC		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	14	0
Foetal conditions due to maternal conditions		
Maternal condition affecting foetus	1	0
Foetal growth complications		
Foetal growth restriction	7	0
Gestational age and weight conditions		
Low birth weight baby	1	0
Premature baby	7	1
Haemorrhagic complications of pregnancy		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Subchorionic haematoma	3	0
Subchorionic haemorrhage	1	0
Hypertension associated disorders of pregnancy		
Pre-eclampsia	2	0
Labour onset and length abnormalities		
Induced labour	1	0
Premature delivery	1	0
Premature labour	8	0
Premature rupture of membranes	3	0
Threatened labour	1	0
Maternal complications of delivery NEC		
Retained placenta or membranes	2	0
Maternal complications of labour NEC		
Uterine contractions abnormal	1	0
Uterine hypertonus	9	0
Maternal complications of pregnancy NEC		
Biochemical pregnancy	2	0
Complication of pregnancy	1	0
Decidual cast	5	0
Ectopic pregnancy	13	0
Hyperemesis gravidarum	1	0
Morning sickness	16	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
Neonatal hepatobiliary disorders		
Jaundice neonatal	1	0
Normal newborn status		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Pregnancy conditions Pregnancy conditions cont'd		
Normal newborn	1	0
Normal pregnancy, labour and delivery		
Labour pain	1	0
Live birth	7	0
Pregnancy	34	0
Term birth	1	0
Uterine contractions during pregnancy	6	0
Placental abnormalities (excl neoplasms)		
Foetal vascular malperfusion	2	0
Placental disorder	1	0
Placental insufficiency	1	0
Small size placenta	1	0
Postpartum complications NEC		
Postpartum haemorrhage	5	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	4	4
Stillbirth	11	11
Umbilical cord complications		
Umbilical cord thrombosis	1	0
Unintended pregnancies		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	3	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	1	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	4	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	**684**	**16**

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Device electrical issues		
Electromagnetic interference	1	0
Device issues NEC		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
Device malfunction events NEC		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	20	0
Thrombosis in device	15	0
Undersensing	1	0
Device physical property and chemical issues		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	3	0
Manufacturing materials issues		
Manufacturing materials contamination	1	0
Product contamination and sterility issues		
Product contamination	14	0
Product contamination physical	10	0
Product packaging issues		
Packaging design issue	1	0
Product closure issue	1	0
Product physical issues		
Liquid product physical issue	12	0
Product after taste	3	0
Product deposit	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	9	0
Product quality issues NEC		
Product complaint	1	0
Product origin unknown	5	0
Product supply and availability issues		
Product availability issue	1	0
null SOC TOTAL	**123**	**0**

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	28	0
Behaviour disorder	2	0
Breath holding	6	0
Staring	7	0
Adjustment disorders		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	4	0
Affect alterations NEC		
Affect lability	15	0
Constricted affect	5	0
Flat affect	13	0
Inappropriate affect	23	0
Amnestic symptoms		
Paramnesia	7	0
Anxiety disorders NEC		
Anxiety disorder	2	0
Generalised anxiety disorder	3	0
Neurosis	1	0
Anxiety symptoms		
Agitation	91	0
Anxiety	1036	0
Immunisation anxiety related reaction	4	0
Nervousness	206	0
Stress	127	0
Tension	42	0
Attention deficit and disruptive behaviour disorders		
Attention deficit hyperactivity disorder	7	0
Behaviour and socialisation disturbances		
Aggression	17	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	3	0
Indifference	7	0
Paranoia	29	0
Personality change	5	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
Bipolar disorders		
Bipolar I disorder	2	0
Bipolar disorder	5	0
Cognitive and attention disorders and disturbances NEC		
Daydreaming	9	0
Distractibility	4	0
Mental fatigue	243	0
Communications disorders		
Communication disorder	5	0
Mutism	4	0
Confusion and disorientation		
Confusional state	1030	0
Disorientation	321	0
Decreased physical activity levels		

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Catatonia	1	0
Deliria		
Delirium	149	0
Delusional symptoms		
Delusion	16	0
Depressive disorders		
Agitated depression	6	0
Depression	401	0
Depression suicidal	19	0
Major depression	14	0
Mixed anxiety and depressive disorder	4	0
Dissociative states		
Depersonalisation/derealisation disorder	12	0
Dissociation	36	0
Dissociative amnesia	4	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	29	0
Insomnia	1871	0
Middle insomnia	34	0
Terminal insomnia	34	0
Dyssomnias		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	265	0
Eating disorders NEC		
Bulimia nervosa	1	0
Eating disorder	12	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	43	0
Dysphoria	2	0
Emotional disorder	69	0
Emotional distress	62	0
Emotional poverty	2	0
Euphoric mood	50	0
Frustration tolerance decreased	2	0
Irritability	231	0
Mood altered	63	0
Morose	1	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	2	0
Claustrophobia	1	0
Fear	32	0
Fear of death	2	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Performance fear	1	0
Phobia	3	0

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Phonophobia	3	0
Social anxiety disorder	2	0
Social fear	1	0
Fluctuating mood symptoms		
Mood swings	163	0
Hallucinations (excl sleep-related)		
Hallucination	246	0
Hallucination, auditory	22	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	31	0
Hallucinations, mixed	4	0
Increased physical activity levels		
Restlessness	175	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Mental disorders NEC		
Mental disorder	19	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	10	0
Depressed mood	445	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	2	0
Negative thoughts	3	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	47	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	11	0
Mood disorders NEC		
Affective disorder	4	0
Apathy	38	0
Boredom	1	0
Laziness	3	0
Listless	25	0
Mood disorder due to a general medical condition	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	5	0

Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	248	0
Panic disorder	9	0
Panic reaction	31	0
Paraphilias and paraphilic disorders		
Transvestism	1	0
Parasomnias		
Abnormal dreams	209	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	230	0
Parasomnia	4	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	29	0
Somnambulism	9	0
Perception disturbances NEC		
Autoscopy	20	0
Deja vu	2	0
Derealisation	13	0
Flashback	4	0
Illusion	6	0
Near death experience	1	0
Time perception altered	2	0
Personality disorders NEC		
Personality disorder	1	0
Self esteem decreased	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	31	0
Psychiatric symptoms NEC		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	13	0
Psychological trauma	4	0
Trance	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	30	0
Schizophrenia NEC		
Schizophrenia	2	0
Sexual and gender identity disorders NEC		
Gender dysphoria	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	4	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Sexual inhibition	1	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	19	0
Libido disorder	1	0
Libido increased	8	0
Loss of libido	21	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	2	0
Sleep disorders NEC		
Sleep disorder	271	0
Sleep disorder due to general medical condition, insomnia type	5	0
Somatic symptom disorders		
Conversion disorder	25	0
Habit cough	22	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	10	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	27	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Automatism	1	0
Bruxism	14	0
Head banging	12	0
Stereotypy	1	0
Stress disorders		
Burnout syndrome	2	0
Post-traumatic stress disorder	5	0
Substance related and addictive disorders		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Nicotine dependence	2	0
Suicidal and self-injurious behaviour		
Completed suicide	2	2
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	48	0
Suicide attempt	8	0
Suicide threat	2	0
Thinking disturbances		
Bradyphrenia	44	0
Flight of ideas	1	0
Intrusive thoughts	8	0
Morbid thoughts	1	0
Tachyphrenia	8	0
Thinking abnormal	21	0
Thought blocking	2	0
Tic disorders		

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Tic	16	0
Psychiatric disorders SOC TOTAL	**9702**	**2**

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder discomfort	3	0
Bladder irritation	11	0
Bladder pain	34	0
Bladder spasm	2	0
Dysuria	55	0
Incontinence	41	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	51	0
Pollakiuria	156	0
Stress urinary incontinence	2	0
Urethral pain	7	0
Urge incontinence	3	0
Urinary hesitation	3	0
Urinary incontinence	70	0
Urinary retention	53	0
Urine flow decreased	19	0
Bladder disorders NEC		
Bladder disorder	11	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	4	0
Bladder infections and inflammations		
Cystitis haemorrhagic	1	0
Cystitis interstitial	6	0
Cystitis noninfective	1	0
Genital and urinary tract disorders NEC		
Genitourinary symptom	2	0
Urinary tract disorder	4	0
Glomerulonephritis and nephrotic syndrome		
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	0
Nephrotic syndrome	18	0
Myoneurogenic bladder disorders		
Bladder dysfunction	6	0
Hypertonic bladder	4	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
Nephritis NEC		
Lupus nephritis	1	0
Nephritis	3	0
Tubulointerstitial nephritis	2	0
Nephropathies and tubular disorders NEC		
Nephropathy	1	0
Renal disorders NEC		
Renal disorder	7	1
Renal haemorrhage	1	0
Renal mass	1	0
Renal failure and impairment		
Acute kidney injury	51	4

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Reaction Name	Total	Fatal
Renal & urinary disorders Renal & urinary disorders cont'd		
Anuria	3	0
Chronic kidney disease	4	0
Oliguria	1	0
Renal failure	24	1
Renal impairment	28	0
Renal injury	2	0
Renal failure complications		
Azotaemia	1	0
Renal lithiasis		
Nephrolithiasis	12	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	2	0
Renal structural abnormalities and trauma		
Kidney enlargement	1	0
Kidney small	2	0
Renal vascular and ischaemic conditions		
Renal aneurysm	1	0
Renal infarct	4	0
Renal tubular necrosis	2	0
Renal vasculitis	1	1
Structural and obstructive urethral disorders (excl congenital)		
Urethral stenosis	1	0
Ureteric disorders NEC		
Ureteric stenosis	1	0
Urinary abnormalities		
Albuminuria	1	0
Chromaturia	66	0
Haematuria	50	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	12	0
Urine abnormality	12	0
Urine odour abnormal	10	0
Urinary tract lithiasis (excl renal)		
Calculus bladder	1	0
Calculus urinary	1	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	28	1
Nocturia	3	0
Polyuria	9	0
Renal colic	4	0
Renal pain	355	0
Urinary tract discomfort	2	0
Urinary tract pain	6	0
Renal & urinary disorders SOC TOTAL	**1313**	**8**

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Benign and malignant breast neoplasms		
Breast cyst	16	0
Breast disorders NEC		
Breast atrophy	1	0
Breast disorder	3	0
Breast enlargement	31	0
Breast mass	142	0
Fibrocystic breast disease	1	0
Gynaecomastia	7	0
Mastoptosis	1	0
Nipple disorder	1	0
Breast infections and inflammations		
Breast inflammation	6	0
Nipple inflammation	2	0
Breast signs and symptoms		
Breast discharge	5	0
Breast discomfort	14	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	8	0
Breast pain	833	0
Breast swelling	189	0
Breast tenderness	99	0
Nipple pain	46	1
Nipple swelling	4	0
Cervix disorders NEC		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	4	0
Cervix infections and inflammations		
Cervix inflammation	1	0
Cervix neoplasms		
Cervical polyp	1	0
Erection and ejaculation conditions and disorders		
Ejaculation disorder	3	0
Ejaculation failure	3	0
Erectile dysfunction	71	0
Erection increased	4	0
Organic erectile dysfunction	14	0
Painful ejaculation	1	0
Spontaneous ejaculation	2	0
Spontaneous penile erection	2	0
Fallopian tube and ovary infections and inflammations		
Noninfective oophoritis	5	0
Lactation disorders		
Breast milk discolouration	3	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	10	0
Lactation puerperal increased	5	0
Suppressed lactation	47	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders Reproductive & breast disorders cont'd		
Menopausal effects NEC		
Artificial menopause	1	0
Menopausal disorder	1	0
Menopausal symptoms	43	0
Menopause delayed	1	0
Premature menopause	23	0
Menopausal effects on the genitourinary tract		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	106	0
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	3	0
Bleeding anovulatory	1	0
Dysmenorrhoea	3197	0
Intermenstrual bleeding	1260	0
Menstrual discomfort	32	0
Menstrual disorder	2162	0
Menstruation irregular	3830	0
Premenstrual dysphoric disorder	12	0
Premenstrual headache	12	0
Premenstrual pain	141	0
Premenstrual syndrome	128	0
Retrograde menstruation	1	0
Withdrawal bleed	16	0
Menstruation with decreased bleeding		
Amenorrhoea	678	0
Hypomenorrhoea	729	0
Menstruation delayed	5459	0
Oligomenorrhoea	208	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	6057	0
Menometrorrhagia	20	0
Polymenorrhoea	978	0
Ovarian and fallopian tube cysts and neoplasms		
Haemorrhagic ovarian cyst	3	0
Ovarian cyst	29	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	50	0
Ovarian and fallopian tube disorders NEC		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian failure	1	0
Ovarian haemorrhage	8	0
Ovarian hyperstimulation syndrome	1	0
Ovarian mass	2	0
Ovulation disorder	4	0
Ovulation pain	79	0
Premature ovulation	4	0
Superovulation	1	0
Pelvic prolapse conditions		
Vaginal prolapse	1	0
Pelvis and broad ligament disorders NEC		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Adnexa uteri mass	1	0
Adnexa uteri pain	69	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	22	0
Penile and scrotal infections and inflammations		
Balanoposthitis	4	0
Penile disorders NEC (excl erection and ejaculation)		
Foreskin oedema	1	0
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile oedema	1	0
Penile pain	1	0
Penile rash	1	0
Penile size reduced	1	0
Penile swelling	6	0
Penis disorder	12	0
Prostate and seminal vesicles infections and inflammations		
Prostatitis	4	0
Prostatic neoplasms and hypertrophy		
Benign prostatic hyperplasia	2	0
Prostatic signs, symptoms and disorders NEC		
Prostatic pain	1	0
Prostatomegaly	3	0
Reproductive tract disorders NEC (excl neoplasms)		
Genital erosion	1	0
Genital haemorrhage	25	0
Genital hypoaesthesia	1	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	8	0
Perineal ulceration	1	0
Reproductive tract infections and inflammations NEC		
Genital tract inflammation	1	0
Reproductive tract signs and symptoms NEC		
Genital burning sensation	2	0
Genital erythema	1	0
Genital pain	6	0
Genital rash	6	0
Genital swelling	5	0
Pelvic discomfort	6	0
Pelvic pain	126	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	6	0
Scrotal disorders NEC		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	2	0

Reproductive & breast disorders cont'd

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Scrotal exfoliation	2	0
Scrotal pain	22	0
Scrotal swelling	5	0
Scrotum erosion	1	0
Varicocele	2	0
Sexual function and fertility disorders NEC		
Dyspareunia	7	0
Infertility	16	0
Infertility female	4	0
Sexual dysfunction	9	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haematospermia	8	0
Semen discolouration	1	0
Testicular and epididymal disorders NEC		
Testicular atrophy	1	0
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	70	0
Testicular swelling	13	0
Testicular torsion	1	0
Testis discomfort	3	0
Testicular and epididymal neoplasms		
Testicular cyst	1	0
Uterine disorders NEC		
Adenomyosis	11	0
Endometrial thickening	4	0
Endometriosis	92	0
Uterine haemorrhage	43	0
Uterine pain	17	0
Uterine infections and inflammations (excl cervix)		
Uterine inflammation	1	0
Uterine neoplasms		
Uterine polyp	5	0
Uterine tone disorders		
Uterine spasm	36	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	2	0
Vaginal cyst	7	0
Vaginal polyp	1	0
Vulva cyst	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1732	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	4	0
Vulval disorder	2	0
Vulval haemorrhage	34	0
Vulval ulceration	7	0
Vulvovaginal ulceration	5	0
Vulvovaginal signs and symptoms		
Clitoral engorgement	1	0
Coital bleeding	7	0
Labia enlarged	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders (Reproductive & breast disorders cont'd)		
Vaginal discharge	85	0
Vaginal lesion	1	0
Vaginal odour	3	0
Vulval oedema	2	0
Vulvovaginal burning sensation	8	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	5	0
Vulvovaginal erythema	2	0
Vulvovaginal pain	30	0
Vulvovaginal pruritus	10	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
Reproductive & breast disorders SOC TOTAL	**29594**	**1**

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Apnoea	6	0
Apnoeic attack	1	0
Dyspnoea	6388	5
Dyspnoea at rest	11	0
Dyspnoea exertional	41	1
Grunting	1	0
Hyperventilation	60	0
Hypopnoea	124	0
Hypoventilation	1	0
Irregular breathing	24	0
Mouth breathing	7	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	70	0
Respiratory arrest	18	0
Respiratory depression	1	0
Respiratory distress	20	0
Sleep apnoea syndrome	15	0
Tachypnoea	31	0
Bronchial conditions NEC		
Bronchial secretion retention	4	0
Bronchiectasis	15	0
Bronchospasm and obstruction		
Asthma	406	0
Asthma late onset	3	0
Bronchospasm	19	0
Chronic obstructive pulmonary disease	26	1
Cough variant asthma	7	0
Obstructive airways disorder	11	0
Reversible airways obstruction	1	0
Wheezing	461	0
Conditions associated with abnormal gas exchange		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	32	2
Respiratory acidosis	2	0
Coughing and associated symptoms		
Allergic cough	9	0
Cough	2878	1
Cough decreased	2	0
Haemoptysis	69	0
Productive cough	191	0
Sputum discoloured	11	0
Sputum increased	4	0
Diaphragmatic disorders		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
Diaphragmatic disorder	1	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		
Laryngeal disorder	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Reflux laryngitis	3	0
Vocal cord disorder	1	0
Vocal cord dysfunction	3	0
Laryngeal spasm, oedema and obstruction		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	3	0
Stridor	27	0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	1	0
Autoimmune lung disease	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	34	2
Pulmonary sarcoidosis	2	0
Lower respiratory tract signs and symptoms		
Hiccups	36	0
Increased bronchial secretion	3	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	3	0
Pleuritic pain	25	0
Pulmonary haemorrhage	1	0
Pulmonary pain	114	0
Rales	5	0
Respiratory fremitus	1	0
Mediastinal disorders		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
Nasal congestion and inflammations		
Nasal congestion	327	0
Nasal inflammation	4	0
Rhinitis allergic	26	0
Nasal disorders NEC		
Epistaxis	1052	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	4	0
Nasal dryness	36	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	8	0
Nasal polyps	1	0
Nasal pruritus	12	0
Nasal ulcer	1	0
Neonatal hypoxic conditions		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	2	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Paranasal sinus inflammation	4	0
Sinonasal obstruction	14	0
Sinus congestion	70	0
Sinus disorder	7	0
Parenchymal lung disorders NEC		
Atelectasis	3	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	11	0
Lung consolidation	5	0
Lung infiltration	2	1
Organising pneumonia	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	9	0
Pulmonary toxicity	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	9	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	40	0
Pharyngeal inflammation	4	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	55	0
Pharyngeal swelling	288	0
Pharyngeal ulceration	16	0
Tonsillar erythema	13	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	96	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
Pleural infections and inflammations		
Pleurisy	37	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	39	0
Pneumothorax	11	0
Pneumothorax spontaneous	5	0
Pulmonary hypertensions		
Pulmonary hypertension	3	0
Pulmonary oedemas		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	19	0
Pulmonary oedema	22	2
Pulmonary thrombotic and embolic conditions		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	518	36
Pulmonary infarction	6	0
Pulmonary thrombosis	11	1
Respiratory failures (excl neonatal)		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Acute respiratory failure	3	1
Respiratory failure	13	2
Respiratory signs and symptoms NEC		
Allergic respiratory symptom	6	0
Diaphragmalgia	9	0
Nasal flaring	1	0
Painful respiration	16	1
Pleural rub	1	0
Respiratory symptom	22	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
Respiratory tract disorders NEC		
Allergic respiratory disease	1	0
Aspiration	4	0
Lung disorder	8	0
Pulmonary mass	5	0
Respiratory disorder	16	1
Respiratory tract congestion	5	0
Respiratory tract haemorrhage	2	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	4	0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	2	0
Tracheal disorders (excl infections and neoplasms)		
Tracheal disorder	1	0
Tracheal pain	2	0
Upper respiratory tract neoplasms		
Tonsillar cyst	1	0
Upper respiratory tract signs and symptoms		
Aphonia	137	0
Catarrh	32	0
Choking	19	0
Choking sensation	6	0
Dry throat	185	0
Dysphonia	181	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	35	0
Laryngeal pain	1	0
Nasal discharge discolouration	3	0
Nasal discomfort	58	0
Nasal obstruction	2	0
Oropharyngeal blistering	11	0
Oropharyngeal discolouration	1	0
Oropharyngeal discomfort	71	0
Oropharyngeal pain	3169	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	51	0
Rhinalgia	14	0
Rhinorrhoea	1035	0
Sinus pain	244	0
Sneezing	441	0
Snoring	8	0

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022

Data Lock Date: 25-Jan-2022 18:32:39

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Throat clearing	8	0
Throat irritation	257	0
Throat lesion	1	0
Throat tightness	280	0
Upper airway obstruction	3	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	14	0
Yawning	28	0
Vascular pulmonary disorders NEC		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	**20547**	**58**

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022
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Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	212	0
Acne cystic	28	0
Dermatitis acneiform	13	0
Oil acne	1	0
Alopecias		
Alopecia	385	0
Alopecia areata	61	0
Alopecia totalis	3	0
Alopecia universalis	2	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Hypotrichosis	3	0
Lichen planopilaris	1	0
Madarosis	9	0
Angioedemas		
Angioedema	268	0
Circumoral oedema	1	0
Circumoral swelling	1	0
Idiopathic angioedema	1	0
Apocrine and eccrine gland disorders		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	861	0
Hidradenitis	5	0
Hyperhidrosis	2629	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	114	0
Night sweats	908	0
Sweat discolouration	1	0
Bullous conditions		
Blister	521	0
Blister rupture	1	0
Blood blister	35	0
Dermatitis bullous	14	0
Erythema multiforme	43	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	28	0
Pemphigus	9	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	2	1
Connective tissue disorders		
Cutaneous lupus erythematosus	3	0
Dermatomyositis	10	1
Subacute cutaneous lupus erythematosus	3	0
Dermal and epidermal conditions NEC		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	278	0
Koebner phenomenon	1	0
Macule	5	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Neutrophilic dermatosis	1	0
Pain of skin	323	0
Papule	117	0
Pathergy reaction	1	0
Scab	25	0
Scar discomfort	1	0
Scar pain	18	0
Sensitive skin	223	0
Shagreen skin	1	0
Skin burning sensation	256	0
Skin degenerative disorder	1	0
Skin discolouration	151	0
Skin discomfort	5	0
Skin disorder	33	0
Skin fissures	8	0
Skin indentation	3	0
Skin induration	5	0
Skin lesion	49	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin odour abnormal	23	0
Skin plaque	4	0
Skin reaction	167	0
Skin sensitisation	45	0
Skin swelling	115	0
Skin texture abnormal	2	0
Skin tightness	29	0
Skin warm	359	0
Skin weeping	13	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	29	0
Dermatitis and eczema		
Dermatitis	156	0
Dermatitis allergic	293	0
Dermatitis atopic	52	0
Dermatitis contact	25	0
Dermatitis diaper	4	0
Dyshidrotic eczema	30	0
Eczema	386	0
Eczema asteatotic	14	0
Eczema infantile	1	0
Eczema nummular	5	0
Eczema weeping	6	0
Hand dermatitis	2	0
Intertrigo	1	0
Neurodermatitis	3	0
Perioral dermatitis	3	0
Seborrhoeic dermatitis	7	0
Skin irritation	147	0
Stasis dermatitis	2	0
Dermatitis ascribed to specific agent		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Drug eruption	35	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Palmar-plantar erythrodysaesthesia syndrome	2	0
Toxic skin eruption	2	0
Erythemas		
Erythema	2440	0
Palmar erythema	4	0
Pernio-like erythema	1	0
Red man syndrome	2	0
Exfoliative conditions		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	25	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	136	0
Granulomatous and deep cutaneous inflammatory conditions		
Cutaneous sarcoidosis	1	0
Granuloma annulare	7	0
Necrobiosis lipoidica diabeticorum	1	0
Hyperkeratoses		
Hyperkeratosis	2	0
Keratosis pilaris	3	0
Lichenoid keratosis	4	0
Hyperpigmentation disorders		
Argyria	1	0
Chloasma	2	0
Ephelides	1	0
Skin hyperpigmentation	6	0
Solar lentigo	4	0
Hypertrichoses		
Hirsutism	2	0
Hypertrichosis	1	0
Hypopigmentation disorders		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	23	0
Lipodystrophies		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
Nail and nail bed conditions (excl infections and infestations)		
Ingrowing nail	1	0
Nail discolouration	12	0
Nail disorder	7	0
Nail growth abnormal	1	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	9	0
Onychoclasis	6	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
Panniculitides		
Erythema nodosum	31	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022
Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Panniculitis	1	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	23	0
Lichen sclerosus	9	0
Parapsoriasis	4	0
Pityriasis alba	1	0
Pityriasis rosea	136	0
Pityriasis rubra pilaris	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	69	0
Polymorphic light eruption	3	0
Solar dermatitis	2	0
Pigmentation changes NEC		
Haemosiderin stain	1	0
Pigmentation disorder	15	0
Pilar disorders NEC		
Hair colour changes	11	0
Hair disorder	1	0
Hair growth abnormal	8	0
Hair texture abnormal	6	0
Piloerection	29	0
Pseudofolliculitis	3	0
Trichorrhexis	3	0
Pruritus NEC		
Itching scar	10	0
Polymorphic eruption of pregnancy	1	0
Pruritus	6201	0
Psoriatic conditions		
Dermatitis psoriasiform	5	0
Guttate psoriasis	22	0
Nail psoriasis	2	0
Palmoplantar pustulosis	2	0
Psoriasis	227	0
Pustular psoriasis	3	0
Rebound psoriasis	1	0
Purpura and related conditions		
Ecchymosis	1	0
Henoch-Schonlein purpura	12	0
Petechiae	151	0
Purpura	60	0
Pustular conditions		
Acute generalised exanthematous pustulosis	2	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	6	0
Rash	6466	1
Rash erythematous	1406	0
Rash macular	564	0
Rash maculo-papular	67	0
Rash morbilliform	48	0
Rash papular	394	0
Rash pruritic	1367	0
Rash scarlatiniform	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash vesicular	84	0
Systemic lupus erythematosus rash	7	0
Rosaceas		
Rosacea	39	0
Scaly conditions		
Dandruff	5	0
Pityriasis	27	0
Sebaceous gland disorders		
Sebaceous glands overactivity	1	0
Seborrhoea	13	0
Skin and subcutaneous conditions NEC		
Cellulite	2	0
Cutaneous symptom	6	0
Reactive perforating collagenosis	1	0
Skin mass	27	0
Skin and subcutaneous tissue ulcerations		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	2	0
Scleroderma associated digital ulcer	1	0
Skin erosion	31	0
Skin ulcer	23	0
Skin cysts and polyps		
Dermal cyst	16	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	3	0
Skin haemorrhages		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	20	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin atrophy	3	0
Skin striae	8	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	3	0
Needle track marks	5	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vascular conditions NEC		
Angiodermatitis	1	0
Skin oedema	4	0
Skin vasculitides		
Capillaritis	3	0
Cutaneous vasculitis	15	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	22	0
Skin vasomotor conditions		
Livedo reticularis	26	0
Telangiectasia and related conditions		
Spider naevus	1	0
Telangiectasia	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticarias		
Chronic spontaneous urticaria	13	0
Cold urticaria	8	0
Idiopathic urticaria	2	0
Mechanical urticaria	12	0
Solar urticaria	3	0
Urticaria	2204	0
Urticaria cholinergic	2	0
Urticaria chronic	37	0
Urticaria contact	1	0
Urticaria papular	6	0
Urticaria thermal	9	0
Urticarial vasculitis	6	0
Skin disorders SOC TOTAL	**32514**	**3**

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Social circumstances		
Age related issues		
Infant	2	0
Menarche	3	0
Menopause	47	0
Postmenopause	4	0
Criminal activity		
Verbal abuse	1	0
Dependents		
Sick relative	6	0
Dietary and nutritional issues		
Feeding tube user	1	0
Disability issues		
Bedridden	33	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	3	0
Housebound	1	0
Immobile	13	0
Impaired driving ability	5	0
Impaired work ability	21	0
Loss of personal independence in daily activities	46	0
Physical disability	5	0
Sight disability	13	0
Sitting disability	4	0
Walking disability	1	0
Wheelchair user	1	0
Economic circumstances		
High income	1	0
Low income	1	0
Educational issues		
Educational problem	1	0
Illiteracy	2	0
Employment issues		
Job dissatisfaction	1	0
Retirement	4	0
Sick leave	1	0
Stress at work	3	0
Family and partner issues		
Bed sharing	1	0
Non-occupational and unspecified environmental problems		
Flooding	2	0
Water pollution	2	0
Pregnancy related circumstances		
Breast feeding	17	0
Multigravida	1	0
Parity	1	0
Social issues NEC		
Exercise adequate	2	0
Hair dye user	2	0
Impaired quality of life	3	0
Tobacco use		
Ex-tobacco user	1	0
Non-tobacco user	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Tobacco user	1	0
Social circumstances SOC TOTAL	**266**	**0**

Case Series Drug Analysis Print

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Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
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Reaction Name	Total	Fatal
Surgical & medical procedures		
Anaesthesia and allied procedures		
Local anaesthesia	2	0
Nerve block	5	0
Analgesia supportive care		
Analgesic therapy	1	0
Antiinfective therapies		
COVID-19 prophylaxis	2	0
COVID-19 treatment	4	0
Arterial therapeutic procedures (excl aortic)		
Splenic artery embolisation	1	0
Blood and blood product treatment		
Transfusion	2	0
Breast therapeutic procedures NEC		
Axillary lymphadenectomy	3	0
Mammoplasty	1	0
Bronchial and pulmonary therapeutic procedures		
Airway secretion clearance therapy	1	0
Cardiac device therapeutic procedures		
Cardiac pacemaker insertion	1	0
Cardiac therapeutic procedures NEC		
Cardiac operation	1	0
Contraceptive methods female		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
Contraceptive methods male		
Condom	1	0
Dietary and nutritional therapies		
Medical diet	8	0
Nothing by mouth order	13	0
Wheat-free diet	1	0
External ear therapeutic procedures		
Ear irrigation	1	0
Facial therapeutic procedures		
Face lift	1	0
Fertility and fertilisation interventions female		
Endometrial scratching	1	0
Ovulation induction	2	0
Gastric therapeutic procedures		
Gastric operation	1	0
Gastrointestinal therapeutic procedures NEC		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	16	0
Gynaecological therapeutic procedures NEC		
Menstrual cycle management	13	0
Haematological therapeutic procedures NEC		
Anticoagulant therapy	1	0
Head, neck and oral cavity therapeutic procedures NEC		
Neck lift	1	0
Hernia repairs		
Hernia repair	1	0
Hormonal therapeutic procedures NEC		
Hormone replacement therapy	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures Surgical & medical procedures cont'd		
Hormone therapy	8	0
Immunisations		
COVID-19 immunisation	104	0
Immunisation	641	1
Induced abortions		
Abortion induced	2	0
Joint therapeutic procedures		
Joint injection	4	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendicectomy	4	0
Limb therapeutic procedures		
Arm amputation	1	0
Limb immobilisation	13	0
Limb operation	9	0
Lip therapeutic procedures		
Lip lesion excision	1	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	3	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	4	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	2	0
Obstetric therapeutic procedures		
Caesarean section	1	0
Labour stimulation	1	0
Orbit and globe therapeutic procedures		
Strabismus correction	1	0
Ovarian therapeutic procedures		
Ovarian operation	1	0
Peripheral nerve therapeutic procedures		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
Phototherapies		
UV light therapy	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	3	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	3	0
Retinal therapeutic procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures	Surgical & medical procedures cont'd	
Dermal filler injection	4	0
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Small intestine therapeutic procedures		
Ileostomy	1	0
Spine and spinal cord therapeutic procedures		
Spinal decompression	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	5	0
Fatigue management	1	0
Hospitalisation	14	0
Injection	61	0
Interchange of vaccine products	221	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	5	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	3	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stoma care	1	0
Therapeutic procedure	1	0
Therapy change	1	0
Vehicle solution use	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	2	0
Vascular therapeutic procedures NEC		
Thrombolysis	1	0
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	**1260**	**1**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders		
Accelerated and malignant hypertension		
Hypertensive crisis	13	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
Aneurysms and dissections non-site specific		
Aneurysm	3	0
Artery dissection	2	0
Aortic aneurysms and dissections		
Acute aortic syndrome	1	0
Aortic aneurysm	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
Aortic embolism and thrombosis		
Aortic embolus	5	0
Aortic thrombosis	4	0
Aortic infections and inflammations		
Aortitis	1	0
Aortic necrosis and vascular insufficiency		
Aortic occlusion	1	0
Arterial infections and inflammations		
Arteritis	1	0
Giant cell arteritis	18	0
Blood pressure disorders NEC		
Blood pressure fluctuation	14	0
Labile blood pressure	3	0
Bruising, ecchymosis and purpura		
Achenbach syndrome	4	0
Circulatory collapse and shock		
CT hypotension complex	2	0
Circulatory collapse	83	0
Hypoperfusion	2	0
Hypovolaemic shock	2	1
Neurogenic shock	24	0
Peripheral circulatory failure	6	0
Shock	23	0
Shock symptom	3	0
Haemorrhages NEC		
Arterial haemorrhage	1	0
Bloody discharge	25	0
Haematoma	54	0
Haemorrhage	1366	2
Internal haemorrhage	12	0
Venous haemorrhage	2	0
Lymphangiopathies		
Lymphangiopathy	1	0
Lymphocele	7	0
Lymphorrhoea	2	0
Lymphostasis	1	0
Lymphoedemas		
Lymphoedema	239	0
Non-site specific embolism and thrombosis		
Arterial thrombosis	4	0
Embolism	64	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Embolism arterial	2	0
Embolism venous	8	1
Microembolism	2	0
Thrombosis	495	11
Venous thrombosis	7	0
Non-site specific necrosis and vascular insufficiency NEC		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	4	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	11	0
Peripheral venous disease	1	0
Vascular occlusion	1	0
Vasospasm	1	0
Non-site specific vascular disorders NEC		
Capillary disorder	1	0
Capillary fragility	4	0
Endothelial dysfunction	1	0
Haemodynamic instability	1	0
Superficial vein prominence	2	0
Vascular pain	40	0
Vascular wall hypertrophy	1	0
Vasodilatation	45	0
Vein discolouration	8	0
Vein disorder	7	0
Vein rupture	7	0
Peripheral aneurysms and dissections		
Peripheral artery aneurysm	1	0
Peripheral embolism and thrombosis		
Axillary vein thrombosis	1	0
Blue toe syndrome	34	0
Deep vein thrombosis	337	1
Femoral artery embolism	1	0
Jugular vein thrombosis	4	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	2	0
Peripheral embolism	2	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	30	0
Thrombophlebitis	26	0
Peripheral vascular disorders NEC		
Cyanosis	49	0
Erythromelalgia	2	0
Flushing	468	0
Hot flush	1241	0
Peripheral vascular disorder	2	0
Vein wall hypertrophy	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	3	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 28-Jan-2022 Data Lock Date: 25-Jan-2022 18:32:39
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Ischaemic limb pain	2	0
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	375	0
Peripheral ischaemia	12	0
Poor peripheral circulation	21	0
Raynaud's phenomenon	66	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	37	0
Phlebitis superficial	9	0
Site specific vascular disorders NEC		
Aortic disorder	1	0
Aortic rupture	1	1
Inferior vena cava dilatation	1	0
Pallor	418	0
Varicose veins NEC		
Spider vein	7	0
Varicophlebitis	4	0
Varicose vein	39	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	6	0
Essential hypertension	4	0
Hypertension	716	0
Labile hypertension	2	0
Orthostatic hypertension	2	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	1	0
Diastolic hypotension	1	0
Hypotension	449	1
Orthostatic hypotension	34	0
Vasculitides NEC		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	51	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	**7163**	**19**
TOTAL REACTIONS FOR DRUG	**464934**	**713**
TOTAL REPORTS	**162207**	
TOTAL FATAL OUTCOME REPORTS		**713**

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Covid-19 vaccines and treatments: we must have raw data, now

Data should be fully and immediately available for public scrutiny

Peter Doshi, Fiona Godlee, Kamran Abbasi

In the pages of *The BMJ* a decade ago, in the middle of a different pandemic, it came to light that governments around the world had spent billions stockpiling antivirals for influenza that had not been shown to reduce the risk of complications, hospital admissions, or death. The majority of trials that underpinned regulatory approval and government stockpiling of oseltamivir (Tamiflu) were sponsored by the manufacturer; most were unpublished, those that were published were ghostwritten by writers paid by the manufacturer, the people listed as principal authors lacked access to the raw data, and academics who requested access to the data for independent analysis were denied.[1-4]

The Tamiflu saga heralded a decade of unprecedented attention to the importance of sharing clinical trial data.[5,6] Public battles for drug company data,[7,8] transparency campaigns with thousands of signatures,[9,10] strengthened journal data sharing requirements,[11,12] explicit commitments from companies to share data,[13] new data access website portals,[8] and landmark transparency policies from medicines regulators[14,15] all promised a new era in data transparency.

Progress was made, but clearly not enough. The errors of the last pandemic are being repeated. Memories are short. Today, despite the global rollout of covid-19 vaccines and treatments, the anonymised participant level data underlying the trials for these new products remain inaccessible to doctors, researchers, and the public—and are likely to remain that way for years to come.[16] This is morally indefensible for all trials, but especially for those involving major public health interventions.

Unacceptable delay

Pfizer's pivotal covid vaccine trial was funded by the company and designed, run, analysed, and authored by Pfizer employees. The company and the contract research organisations that carried out the trial hold all the data.[17] And Pfizer has indicated that it will not begin entertaining requests for trial data until May 2025, 24 months after the primary study completion date, which is listed on ClinicalTrials.gov as 15 May 2023 (NCT04368728).

The lack of access to data is consistent across vaccine manufacturers.[16] Moderna says data "may be available ... with publication of the final study results in 2022."[18] Datasets will be available "upon request and subject to review once the trial is complete," which has an estimated primary completion date of 27 October 2022 (NCT04470427).

As of 31 December 2021, AstraZeneca may be ready to entertain requests for data from several of its large phase III trials.[19] But actually obtaining data could be slow going. As its website explains, "timelines vary per request and can take up to a year upon full submission of the request."[20]

Underlying data for covid-19 therapeutics are similarly hard to find. Published reports of Regeneron's phase III trial of its monoclonal antibody therapy REGEN-COV flatly state that participant level data will not be made available to others.[21] Should the drug be approved (and not just emergency authorised), sharing "will be considered." For remdesivir, the US National Institutes of Health, which funded the trial, created a new portal to share data (https://accessclinicaldata.niaid.nih.gov/), but the dataset on offer is limited. An accompanying document explains: "The longitudinal data set only contains a small subset of the protocol and statistical analysis plan objectives."

We are left with publications but no access to the underlying data on reasonable request. This is worrying for trial participants, researchers, clinicians, journal editors, policy makers, and the public. The journals that have published these primary studies may argue that they faced an awkward dilemma, caught between making the summary findings available quickly and upholding the best ethical values that support timely access to underlying data. In our view, there is no dilemma; the anonymised individual participant data from clinical trials must be made available for independent scrutiny.

Journal editors, systematic reviewers, and the writers of clinical practice guideline generally obtain little beyond a journal publication, but regulatory agencies receive far more granular data as part of the regulatory review process. In the words of the European Medicine Agency's former executive director and senior medical officer, "relying solely on the publications of clinical trials in scientific journals as the basis of healthcare decisions is not a good idea ... Drug regulators have been aware of this limitation for a long time and routinely obtain and assess the full documentation (rather than just publications)."[22]

Among regulators, the US Food and Drug Administration is believed to receive the most raw data but does not proactively release them. After a freedom of information request to the agency for Pfizer's vaccine data, the FDA offered to release 500 pages a month, a process that would take decades to complete, arguing in court that publicly releasing data was slow owing to the need to first redact sensitive information.[23] This month, however, a judge rejected the FDA's offer and ordered the data be released at a rate of 55 000 pages a month. The data are to be made available on the requesting organisation's website (https://phmpt.org/).

In releasing thousands of pages of clinical trial documents, Health Canada and the EMA have also provided a degree of transparency that deserves acknowledgment.[24 25] Until recently, however, the data remained of limited utility, with copious redactions aimed at protecting trial blinding. But study reports with fewer redactions have been available since September 2021,[24 25] and missing appendices may be accessible through freedom of information requests.

Even so, anyone looking for participant level datasets may be disappointed because Health Canada and the EMA do not receive or analyse these data, and it remains to be seen how the FDA responds to the court order. Moreover, the FDA is producing data only for Pfizer's vaccine; other manufacturers' data cannot be requested until the vaccines are approved, which the Moderna and Johnson & Johnson vaccines are not. Industry, which holds the raw data, is not legally required to honour requests for access from independent researchers.

Like the FDA, and unlike its Canadian and European counterparts, the UK's regulator—the Medicines and Healthcare Products Regulatory Agency—does not proactively release clinical trial documents, and it has also become delayed in posting information released in response to freedom of information requests on its website.[26]

Transparency and trust

As well as access to the underlying data, transparent decision making is essential. Regulators and public health bodies could release details[27] such as why vaccine trials were not designed to test efficacy against infection and spread of SARS-CoV-2.[28] Had regulators insisted on this outcome, countries would have learnt sooner about the effect of vaccines on transmission and been able to plan accordingly.[29]

Big pharma is the least trusted industry.[30] At least three of the many companies making covid-19 vaccines have past criminal and civil settlements costing them billions of dollars.[31] One pleaded guilty to fraud.[31] Other companies have no pre-covid track record. Now the covid pandemic has minted many new pharma billionaires, and vaccine manufacturers have reported tens of billions in revenue.[32]

The BMJ supports vaccination policies based on sound evidence. As the global vaccine rollout continues, it cannot be justifiable or in the best interests of patients and the public that we are left to just trust "in the system," with the distant hope that the underlying data may become available for independent scrutiny at some point in the future. The same applies to treatments for covid-19. Transparency is the key to building trust and an important route to answering people's legitimate questions about the efficacy and safety of vaccines and treatments and the clinical and public health policies established for their use.

Twelve years ago we called for the immediate release of raw data from clinical trials.[1] We reiterate that call now. Data must be available when trial results are announced, published, or used to justify regulatory decisions. There is no place for wholesale exemptions from good practice during a pandemic. The public has paid for covid-19 vaccines through vast public funding of research, and it is the public that takes on the balance of benefits and harms that accompany vaccination. The public, therefore, has a right and entitlement to those data, as well as to the interrogation of those data by experts.

Pharmaceutical companies are reaping vast profits without adequate independent scrutiny of their scientific claims.[33] The purpose of regulators is not to dance to the tune of rich global corporations and enrich them further; it is to protect the health of their populations. We need complete data transparency for all studies, we need it in the public interest, and we need it now.

Competing interests: We have read and understood BMJ policy on declaration of interests and declare that *The BMJ* is a co-founder of the AllTrials campaign. PD was one of the Cochrane reviewers studying influenza antivirals beginning in 2009, who campaigned for access to data. He also helped organise the Coalition Advocating for Adequately Licensed Medicines (CAALM), which formally petitioned the FDA to refrain from fully approving any covid-19 vaccine this year (docket FDA-2021-P-0786). PD is also a member of Public Health and Medical Professionals for Transparency, which has sued the FDA to obtain the Pfizer covid-19 vaccine data. The views and opinions do not necessarily reflect the official policy or position of the University of Maryland.

Provenance and peer review: Commissioned; externally peer reviewed.

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Intended for healthcare professionals

Rapid response to:

News

AstraZeneca vaccine: Blood clots are “extremely rare” and benefits outweigh risks, regulators conclude

BMJ 2021; 373 doi: https://doi.org/10.1136/bmj.n931 (Published 08 April 2021) Cite this as: BMJ 2021;373:n931

Rapid Response:

Pharmacovigilance needs improvement

Dear Editor

The European Medicines Agency (EMA) safety committee has reported that the serious adverse events of blood clots with low platelets after administration of the AstraZeneca Covid-19 Vaccine are estimated to occur in 1 out of 150,000 people vaccinated [1]. However, there are wide variations across countries. From the UK data (not counted in the EMA figure as not part of the EU), the rate of events is 1 in 250,000. In Germany the rate is 1 in 100,000. In Norway the rate is the highest, at 1 in 20,000 [2]. Norway detected 6 cases after only 120,000 vaccinations (largely young female healthcare workers), at which point it suspended the AstraZeneca vaccine. This immediately contrasts with the UK having continued with 20 million vaccinations and detecting proportionally twelve times less blood clotting events.

In the UK, the Yellow Card Scheme, a passive voluntary reporting system, is the backbone of the Medicines and Healthcare products Regulatory Agency (MHRA) pharmacovigilance strategy. The scheme is notoriously inefficient. In a 2019 pledge directed at healthcare professionals to encourage their use of the scheme, the MHRA stated that the scheme is able to capture only 10% of serious adverse drug events [3]. Interestingly, factoring in this in the UK rate of blood-clotting event would bring UK rate close to the Norway rate. The inter-countries variations are unlikely due to statistical clustering. They are more likely to be correlated to, among a myriad of other factors, the efficiency of the countries’ respective pharmacovigilance infrastructures, and each country’s health service ability to diagnose rare and unusual syndromes when they occur. Hence, through an international collaborative approach, the individual pharmacovigilance agencies should focus on explaining the wide variations across countries, rather than solely relying on their own limited data.

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Revealed: Why Britain's regulator missed the link between the AstraZeneca jab and rare blood clots

The first cases occurred in January and February but their significance was not picked up by the MHRA's algorithms

By Jennifer Rigby, GLOBAL HEALTH SECURITY CORRESPONDENT *and* Paul Nuki, GLOBAL HEALTH SECURITY EDITOR, LONDON

17 April 2021 • 6:00pm

Early in March, some four weeks after the first AstraZeneca vaccine was administered in Europe, little signals - like flares - started to go off all over the continent.

regulators began to report small numbers of blood clots and deaths among people who had received the vaccination.

Then on 15 March, Germany announced seven cases and three deaths and, like others, suspended use of the vaccine. The AstraZeneca jab was associated with a “striking accumulation of a special form of very rare cerebral vein thrombosis in connection with a deficiency of blood platelets and bleeding,” said the Paul-Ehrlich Institut, Germany’s renowned medicines regulator.

But in Britain, where the AstraZeneca rollout had started a full month earlier and 11 million doses had already been administered, there was nothing. On March 11, the UK's newly sovereign Medicines and Healthcare products Regulatory Agency (MHRA) put out a statement saying it could see no evidence of a problem.

“We continually monitor the safety of vaccines to ensure that the benefits outweigh any potential risks,” said Dr Phil Bryan, the MHRA’s Vaccines Safety Lead.

“Reports of blood clots received so far are not greater than the number that would have occurred naturally in the vaccinated population.

“The safety of the public will always come first.”

But the MHRA was, it appears, wrong. An investigation by The Telegraph has established that signals had been firing unnoticed in the UK’s Yellow Card database for at least a month, perhaps longer.

In January, a patient suffered a brain clot following their first dose of the AstraZeneca jab, The Telegraph has confirmed. Then in early February, two similar cases followed, including a death and a life-changing CVST clot in a young adult. All had low platelets and all were reported into the Yellow Card system.

On Friday, the MHRA told The Telegraph: “We are aware of thromboembolic events that occurred in January, however, our first report was received in the week commencing 8 February.... we cannot disclose information about individual cases to protect patient and reporter confidentiality.”

There remains no doubt the benefit of taking the AstraZeneca jab outweighs the risk now associated with the vaccine. This is the judgment not just of the MHRA but also the European Medicines Agency (EMA) and the World Health Organization (WHO).

The risk of developing cerebral venous sinus thrombosis (CVST) in combination with a low platelet count or thrombocytopenia after getting the vaccine is vanishingly small, and estimated to occur in just 1-in-100,000 cases, perhaps less.

This, says Sir David Spiegelhalter, Britain’s foremost expert in risk, is about the same chance of

phone number. With Covid itself, the risk of CVST alone is estimated to be eight to 10 times higher, according to an analysis of US data published last week.

Nonetheless, the MHRA faces serious questions as to why it did not detect the signals sooner. The issue is not that it has been left looking flatfooted or even that earlier detection would necessarily have altered its advice, but that the delay left it unable to shape international policy and confidence in what remains a vital vaccine in the fight against Covid 19 for the world.

Prof Stephan Lewandowsky, a psychologist at the University of Bristol studying the rollout of Covid-19 vaccines, told the Financial Times on Friday: "The MHRA was slow in responding to the emergence of a specific constellation of symptoms associated with the AstraZeneca vaccine and slow to communicate what they were finding — and I am not the only one who thinks so."

So why was the MHRA slower than others to spot the early signals? The Telegraph's investigation suggests the issue relates to the algorithms it had in place to interrogate the UK data and its limited access to early emerging data from Europe.

Observers say this should be seen in the context of the "operational and logistical challenges" the regulator faced in the run-up to the UK formally leaving the EMA on December 31, and the MHRA formally becoming a sovereign regulator for the first time on January 1.

The key to fast-moving pharmacovigilance is to efficiently sift the wheat from the chaff. When a new drug launches thousands of adverse reactions start pouring into regulatory reporting systems from both patients and clinicians.

From January 4 to March 14, a total of 532 "blood system events", including 20 deaths, came through the UK's Yellow Card system relating to the AstraZeneca jab, according to an analysis of published MHRA data by Dr Hamid Merchant, a pharmaceutical scientist at the University of Huddersfield. There were thousands of non-blood-related reports besides.

Of the thrombotic events recorded, four related to CVST (but no deaths were recorded), 55 were non-site specific and there were clusters of 64 and 66 cases in the lungs and deep veins respectively. There were then 267 general bleeding events and six deaths, three of which resulted from cerebral haemorrhage. Finally, there were 60 cases of thrombocytopenia, including 2 deaths.

To sift such data, regulators build algorithms that must balance "sensitivity" against leg-work. The more sensitive the algorithm, the more warning signals it will throw up to investigate - and many of those labour-intensive investigations will prove fruitless.

It is not known exactly what parameters the MHRA set but it is clear they were not as sensitive as those used by some regulators in Europe.

statement when it said clotting reports were not above normal.

But other countries turned the sensitivity gauge up to 11. “Our policy is if it is associated with a death, or very serious adverse drug reaction, we will look into it right away,” David Benee Olsen, senior advisor at the Norwegian Medicines Agency, told The Telegraph.

“I think you have to be careful with looking at the background rate, because for example in this instance, what we were told by physicians was that this rare combination, this thrombocytopenia and CVST, they had never seen this in these kinds of patients, young patients, so it was very difficult to do a background rate versus incidence rate.”

There are also cultural differences as regards paternalism and transparency between regulators. An extreme example of the latter was demonstrated in the US last week when distribution of the Johnson and Johnson Covid vaccine was “paused” and a public hearing called to discuss the six cases of CVST and thrombocytopenia which had prompted it.

A similar approach was taken in Europe. In Norway, the first suspicious death was reported on the day it occurred, March 12 - the day after similar reports emerged from neighbouring Denmark.

On March 13, Norway identified three more cases, and all of the patients were flown to the same hospital for treatment and real-time analysis by a single team of specialists. Again, the incident was made public immediately in a bid to build trust.

When the Pfizer jab was first launched in the UK, the MHRA appeared to have resolved to adopt the same, very modern approach.

On December 9, just a day after the UK vaccine rollout started, the regulator announced three people had suffered serious allergic reactions after receiving the Pfizer jab and warned that “any person with a history of anaphylaxis to a vaccine, medicine or food” should not have it. The tell-it-like-it-is approach worked perfectly and scarcely a word was written about the issue until the advice was withdrawn a month later when more data showed it was not a risk.

Unfortunately, perhaps, the MHRA did not adopt the same approach with the problems surrounding the AstraZeneca jab - or at least it does not appear to have.

The MHRA says it got its first report of CVST with thrombocytopenia in the week of February 8, but the regulator did not tell the public about the issue until March 18 when it announced five cases. It did so just moments before the EMA opened a high profile press briefing on the issue, which by then was dominating world headlines.

Since then, the MHRA has made three further announcements regarding new cases identified in the

quietly released on Thursday evening, show the number of UK clotting cases with thrombocytopenia to stand at 100 with 22 deaths.

It is not known how many of those 22 deaths are covered in the Yellow Card data Dr Merchant analysed between January 4 and 14 March but it seems likely that a large number of them - perhaps the great bulk - will date back to that period.

Despite requests from several newspapers including The Telegraph, the MHRA has not released the dates on which the deaths occurred or were reported into the Yellow Card system, citing the need to preserve patient confidentiality.

There is no suggestion whatever that the MHRA covered up the reporting of CVST with thrombocytopenia - it just did not spot the still unproven issue as early as others.

Another reason for the MHRA's slower reaction, suggest observers, could be that it lost access to Eudravigilance, the vast European database into which all adverse drug reactions are reported, when the UK left the orbit EMA regulation on 31 December last year.

An EMA spokeswoman told The Telegraph: "The MHRA has access to the EudraVigilance gateway only. This allows them to submit cases (or to receive Northern Irish cases), but they cannot check the data in EudraVigilance.

"Should the MHRA need data they will have to ask for it... In addition, they can of course look at the data published on the adverse drug reaction (ADR) website."

Dr June Raine, chief executive of the MHRA, faced "operational and logistical challenges" caused by the UK leaving the EMA in January, including loss of access to the EU's Eudravigilance database | CREDIT: Pippa Fowles

British haematologists described the rare clotting associated with the AstraZeneca jab, and now the Johnson & Johnson vaccine, as "a unique syndrome that we have never seen before" and said it only became apparent once the alarm had been raised in Europe.

On March 16, a group of leading UK experts had started to discuss a case seen by Dr Sue Pavord, a consultant haematologist at Oxford University Hospitals, which had the same hallmarks as the German cases being openly reported.

"I'd actually seen a mild case, and I remember he had thrombosis and his platelets were very low, and it was very rare to see that combination in our experience," Dr Pavord told The Telegraph. The normal tests came back negative but then it was confirmed through background checks he had been given the AstraZeneca jab.

"So I was talking to colleagues and we realised that this was probably a unique syndrome. And as more data came out from the German group, we could see that there was a proposed mechanism and it all fitted."

The following day - March 17 - Dr Pavord and her colleagues called the MHRA.

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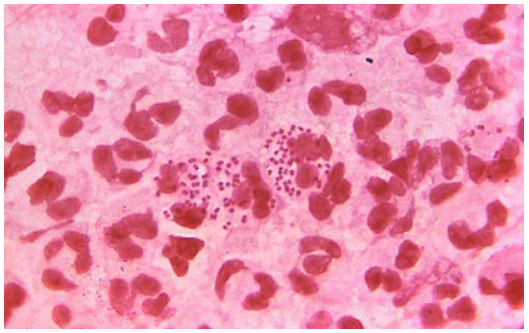

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