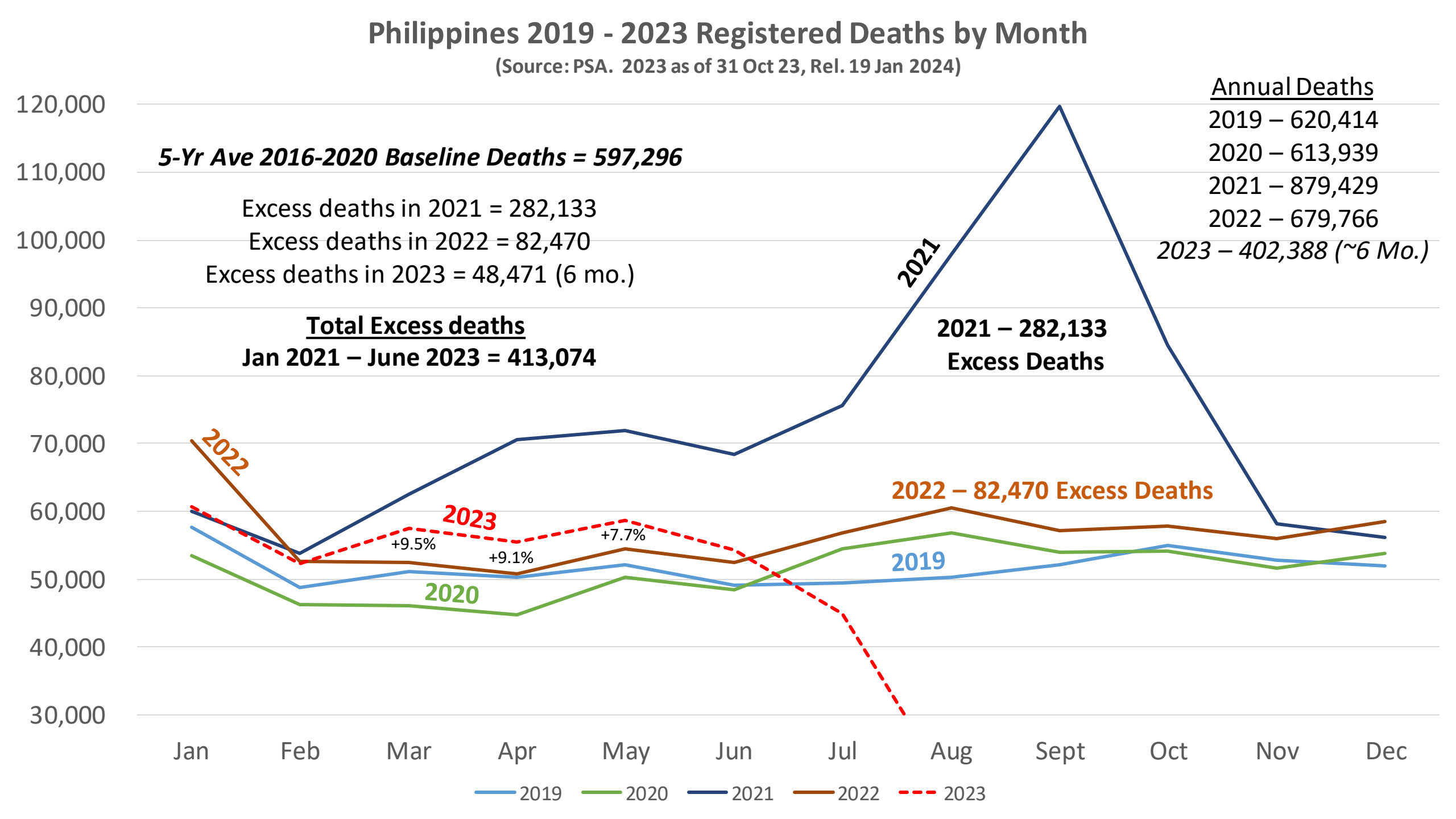
Evaluation of Philippines Population Outcomes for All-Cause Mortality and Covid-19 Deaths Relative to Covid-19 Vaccine Deployment in 2021

27 February 2024

Committee on Public Order and Safety

Philippines 2019 - 2023 Registered Deaths by Month

(Source: PSA. 2023 as of 31 Oct 23, Rel. 19 Jan 2024)



What is Pharmacovigilance?

- The **science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem**.
- Monitors drugs for unexpected, or unanticipated adverse events.
- Systems set up to collect and evaluate reports from health professionals and consumers.
- Examples include VAERS (US), Yellow Card (UK), DAEN (Australia), Vigiaccess (WHO)
- The Philippines FDA is responsible for pharmacovigilance activities

Philippines Pharmacovigilance.

Were There Any Filipino HOT Lots?

Review of Pharmacovigilance Data referencing Philippines FDA and the US VAERS System.

Philippines Covid-19 Pharmacovigilance

- FDA provided a site for reporting of AEFI
- Provided a regular Pharmacovigilance report

COVID-19 Vaccine: Report a Side Effect

The safety of the COVID-19 vaccine is monitored through reports of suspected side effects after receiving the vaccine. Healthcare providers and vaccine recipients are strongly encouraged to report suspected side effects online.

+ Click here to Report side effects

Please include the "**vaccination site**" including the City or Municipality and Province where you were vaccinated, "**Batch or Lot No**." of the vaccine, and "**Time of vaccination**" under Describe what happened.

After being vaccinated, here are the possible side effects and what to do in case you experience a side effect.

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

Reports of Suspected Adverse Reaction to COVID-19 Vaccines (01 March to 12 December 2021)

Contents

12 Dec. 2021, FDA assures that there have been no deaths directly related to Covid-19 Vaccination

HEADLINES

DOH: No deaths directly related to COVID-19 vaccination

Sheila Crisostomo - The Philippine Star ⓘ

December 12, 2021 | 12:00am

MANILA, Philippines – To this day, not a single death in the Philippines can be directly linked to the administration of a COVID-19 vaccine, the Department of Health (DOH) said yesterday.

"Based on causality assessment, there is no death directly linked to the (COVID-19) vaccination," said Health Undersecretary Maria Rosario Vergeire, citing expert evaluations recorded by the Food and Drug Administration (FDA).

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

Reports of Suspected Adverse Reaction to COVID-19 Vaccines (01 March to 12 December 2021)

Table 2. Distribution of reports of adverse reactions for each vaccine

Vaccine	Date started	Total vaccine doses administered [b]	Number of fully vaccinated individuals [b]	Number of individuals partly Vaccinated	Number of individuals with booster shots	Total number of reports [a]	Reports of non-serious events	Reports of serious events
CoronaVac	01 Mar 2021	38,627,363	17,129,635	4,325,495	42,598	31,096	29,171	1,925
AstraZeneca	07 Mar 2021	13,119,859	4,758,376	3,515,891	87,216	33,494	32,436	1,058
Sputnik V	04 May 2021	832,586	338,398	155,645	145	774	745	29
Comirnaty	13 May 2021	28,794,588	10,640,988	6,985,485	527,127	9,765	9,299	466
Moderna	30 June 2021	10,562,013	4,113,867	2,217,127	117,152	3,499	3,278	221
Janssen	20 July 2021	3,607,570	3,607,570	-	1	3,636	3,165	471
Sinopharm	25 Aug 2021	975,232	450,501	74,147	83	157	143	14
TOTAL		**96,519,211**	**41,039,335**	**17,273,790**	**774,321**	**82,421**	**78,237**	**4,184**

Despite their 12 December report showing

- **82,421 Reports of AEFI**
- **4,184 Reports of Serious Events**
- **Hospitalizations @ 2.58/100,000 doses**

- **1,589 Reports of Fatal events received:**
  12-17: 10 **18-39: 149,**
  40-59: 366 **60+: 1,044**

In Response to a Jan 2023 FOI request FDA said there are NO Filipino HOT LOTS!

FOI No.
#DOH-838890184237

Request: 6 Jan 2023

Question Asked:
Have FDA identified any vaccine batch hot lots?

Response:
FDA is aware of lot specific problems in other countries.

"Lots affected are not distributed in the Philippines and therefore, no action is Necessary".

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Tracking No.	Date of Request	FDA RESPONSE
#DOH-838890184238	January 6, 2023	Reports of AEFIs contains information such as lot numbers of the product for ease of traceability in case of any problem that may arise. However, based on our monitoring and analysis, we have not identified any signals (observed vs expected) relative to a specific lot. Though we are receiving information from other countries on lot specific problems, lots affected are not distributed in the Philippines and therefore no action is necessary. Please note that all covid-19 vaccine brands have been reported with AEFIs and you may refer to our latest report on AEFIs to COVID-19 vaccines on the FDA website for the total number of serious, non-serious and death.: https://www.fda.gov.ph/list-of-fda-issued-emergency-use-authorization/.

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Website: www.fda.gov.ph Email: info@fda.gov.ph

The most recent FDA Pharmacovigilance Report (12/31/23) shows 113,166 AEFI & 10,805 SAE

Data shown below are cumulative reports from the start of the vaccination program on 01 March 2021 until 31 December 2023.

Table 2. Distribution of reports of adverse reactions for each vaccine

Vaccine	Date started	Total vaccine doses administered[b]	Total number of reports[a]	Reports of non-serious events	Reports of serious events
CoronaVac	01 Mar 2021	48,734,507 26.8%	37,353 33.0%	33,879 33.1%	3,474 32.2%
AstraZeneca	07 Mar 2021	23,931,246 13.2%	37,764 33.4%	35,684 34.9%	2,080 19.3%
Sputnik V/ Sputnik Light	04 May 2021	1,584,507 0.87%	922 0.81%	866 0.85%	56 0.52%
Comirnaty	13 May 2021	77,024,785 42.4%	23,974 21.2%	20,994 20.5%	2,980 27.6%
Moderna	30 June 2021	21,605,790 11.9%	7,044 6.2%	6,117 6.0%	927 8.6%
Janssen	20 July 2021	7,654,344 4.2%	5,668 5.0%	4,468 4.4%	1,200 11.1%
Sinopharm	25 Aug 2021	1,110,072 0.6%	441 0.4%	353 0.34%	88 0.81%
TOTAL		**181,645,251**	**113,166**	**102,361**	**10,805**

Data source: [a]VigiFlow, [b]DOH (as of 19 March 2023)
Notes: Additional information may become available in individual cases, which may change the figures presented.
Data concerning various vaccines are not directly comparable. COVID-19 vaccines profile varies, they have not been used for equal periods of time and they have been administered to number of people with different profiles including various age and sex.

Equally safe products should have dose-proportionate reports of AEFI and SAE.

CoronaVac 26.8% of doses, but 32.2% of SAE

AstraZeneca 13.2% of doses, but 19.3% of SAE

Janssen 4.2% of doses, but 11.1% of SAE

Includes 2,864 Deaths

Limitations of PH FDA Pharmacovigilance

- Most persons do not know it exists and/or do not have the resources to make a report.
- Many people are hesitant to draw attention to themselves by reporting.
- Many people refuse to make a report, even if offered assistance with reporting.
- Known international UNDERREPORTING FACTORS (URF) range from 40 - >100x. URF in the Philippines will be much higher, possibly 440x.
- FOI #DOH-127428796174 stated that Covid-19 Pharmacovigilance budget was PHP40M for 3 years from 2020 to 2022 was PHP40M.

FDA has a 3-Year Covid-19 Pharmacovigilance Budget of PHP40 Million

14 October 2022

MEMORANDUM

TO : **APRIL RHEA M. MOLINA**
FOI Receiving Officer
Administrative Officer III
Knowledge Management and Information Technology Service

FROM : **IRENE V. FLORENTINO-FARIÑAS, RPh, MD, MNSA**
OIC-Director III, Policy and Planning Service
FDA FOI Decision Maker

SUBJECT : **Response to eFOI Request #DOH-127428796174**

This refers to your eFOI request received through fda@foi.gov.ph on 16 September 2022. Below is the official FDA response to the above subject, for your information and reference.

Tracking No.	Date of Request	Requested Information
#DOH-127428796174	September 16, 2022	Please provide the following information on public expenditure / budget to the FDA. 1. Please list by year the allocated budget for the Covid-19 Specific FDA Pharmacovigilance system, including the data collection and investigation of the suspected adverse events following covid-19 vaccination. 2. What was the actual expenditure in 2021 compared to the budget allocation? 3. Please list the specific activities covered by the allocated budget, by year, with breakdown by area. 4. What is the assigned manpower level for the Covid-19 Specific FDA Pharmacovigilance system.

May we provide the information tabulated below for numbers 1 to 3.

	Year 2020	Year 2021	Year 2022	
Allocated Budget	14,060,693	15,115,775	11,362,982	
Utilization Rate	83%	83%	62%	***note: % in year 2022- as of Sept only
Utilization	11,670,374.87	12,546,093.25	7,045,048.89	

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For item number 4, there are 11 personnel in the Pharmacovigilance Section of the FDA who engage in the processing and evaluation of AEFIs from COVID-19 vaccines. This does not include personnel from FDA Regional Field Offices who are also part of the investigation to COVID-19 vaccines.

Also, the Department of Health (DOH) Epidemiology Bureau has its own budget for Adverse Drug Reaction monitoring or the implementation of Pharmacovigilance.

FILIPINO REPORTS IN US VAERS

- The Philippines FDA passes reports of serious reactions to drug manufacturers for their assessment.
- US Based Drug Manufacturers are mandated to file these reports with the US Pharmacovigilance system, VAERS.
- The VAERS System contains Filipino Reports for Pfizer, Moderna, and Janssen
- VAERS is a publicly accessible data base, which has various excellent access platforms including www.openvaers.com and www.vaersaware.com .

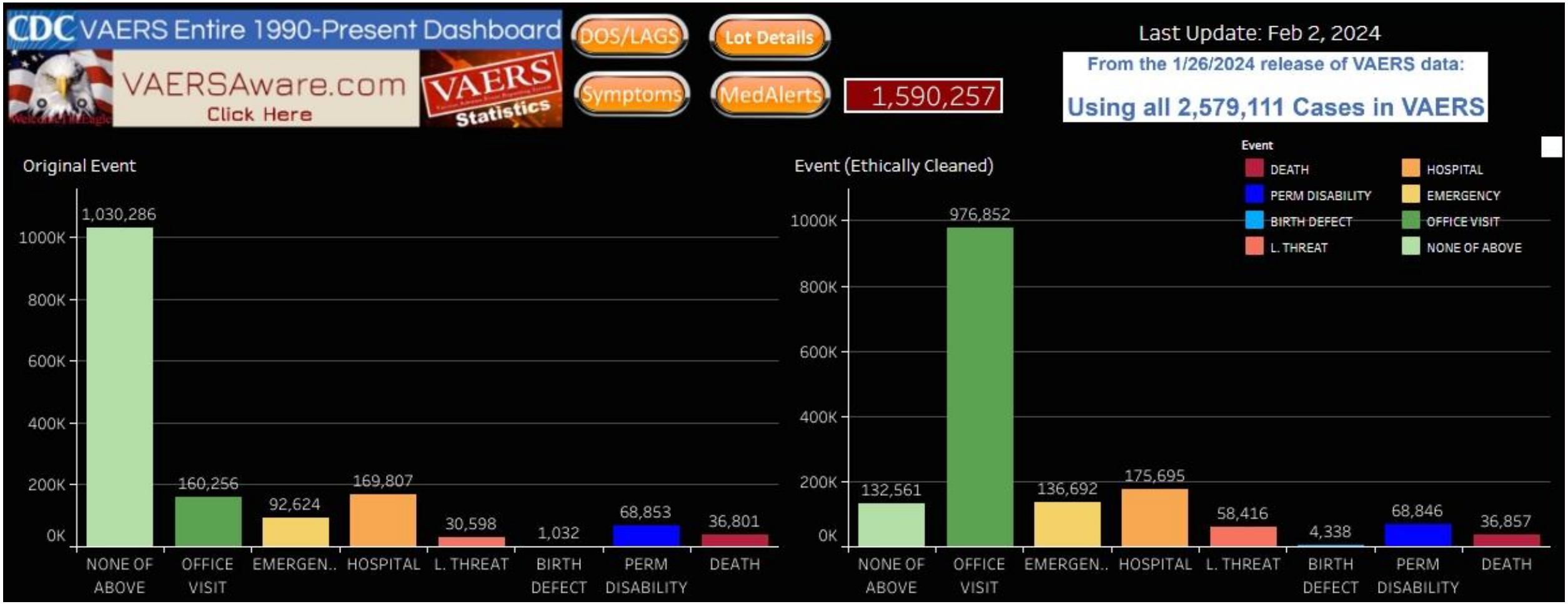
VAERS DATA BASE – COVID-19 VACCINE REPORTS

Reports filed in VAERS are accessible to the public for review and searching, by reference no., batch no., symptoms, etc.

Contains **1,590,257 C19 Vaccine Reports**.
36,857 Total Reports of Deaths

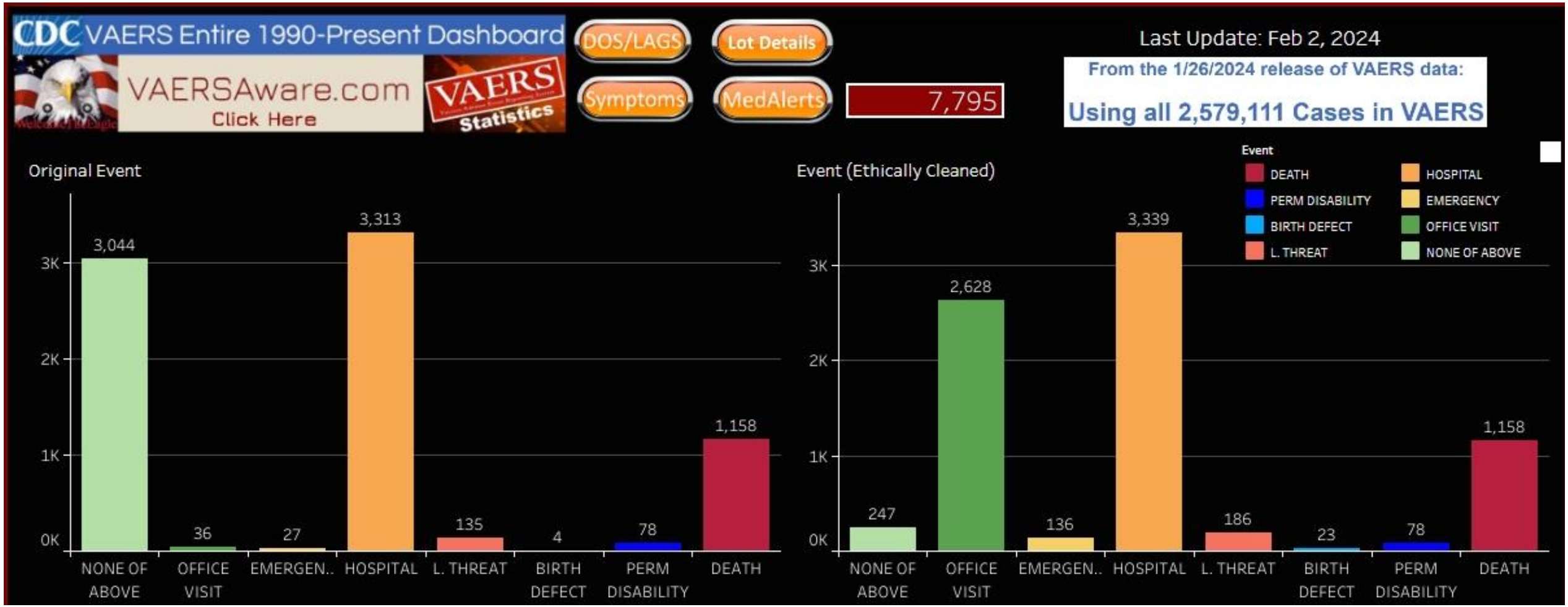
Contains 620,051 Foreign Reports.
18,467 Foreign Deaths

Contains 7,795 Filipino Reports.
1,158 Filipino Deaths



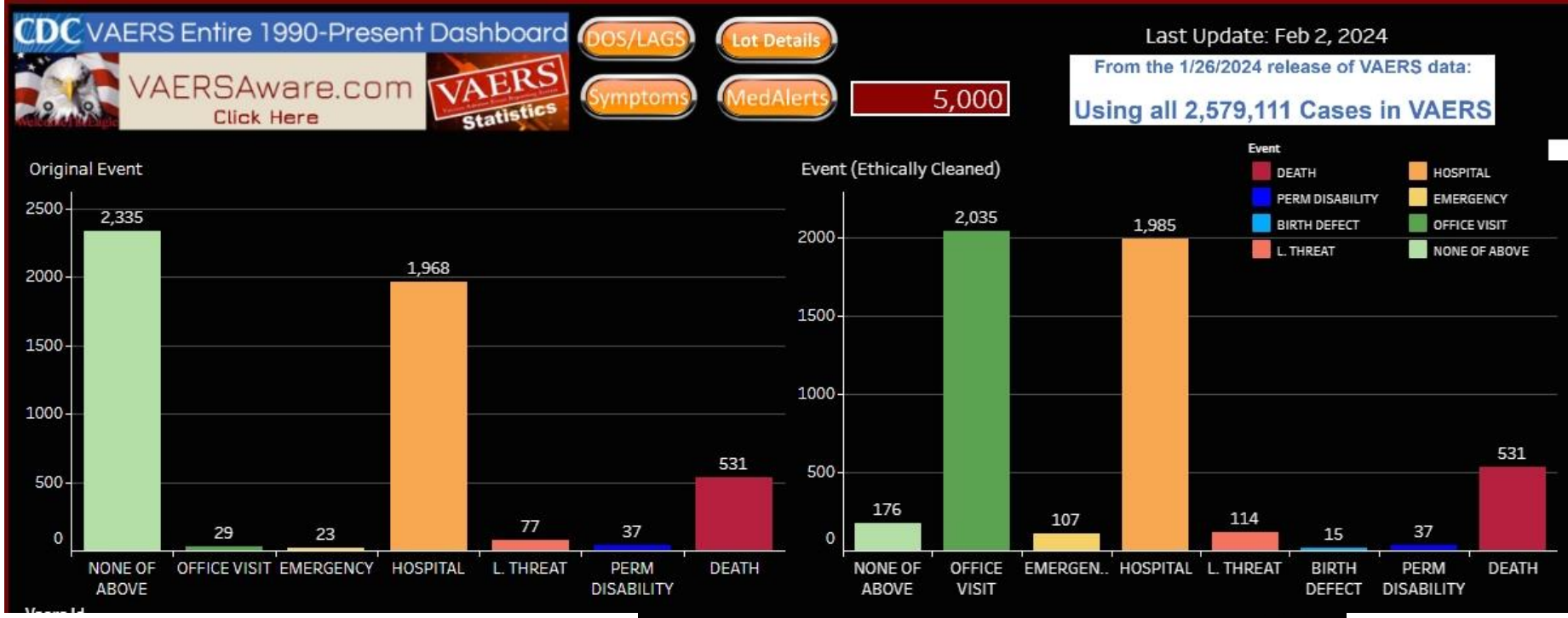
7,795 PHILIPPINES VAERS REPORTS

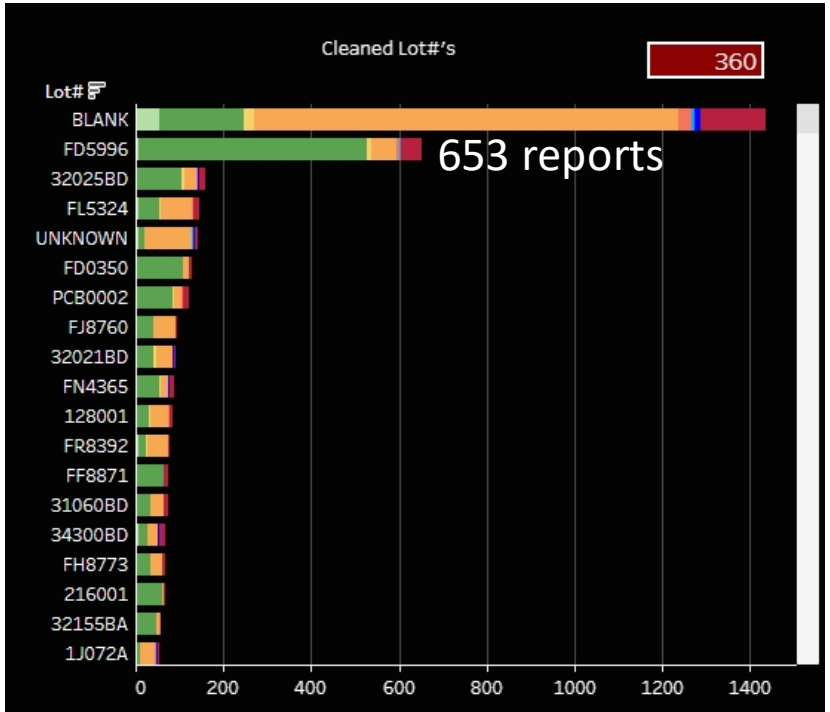
- 2,628 Office Visits
- 23 birth defects
- 1,158 Deaths
- 3,339 Hospitalizations
- 186 life threatening
- 78 permanent disability



Philippines Pfizer Outcomes

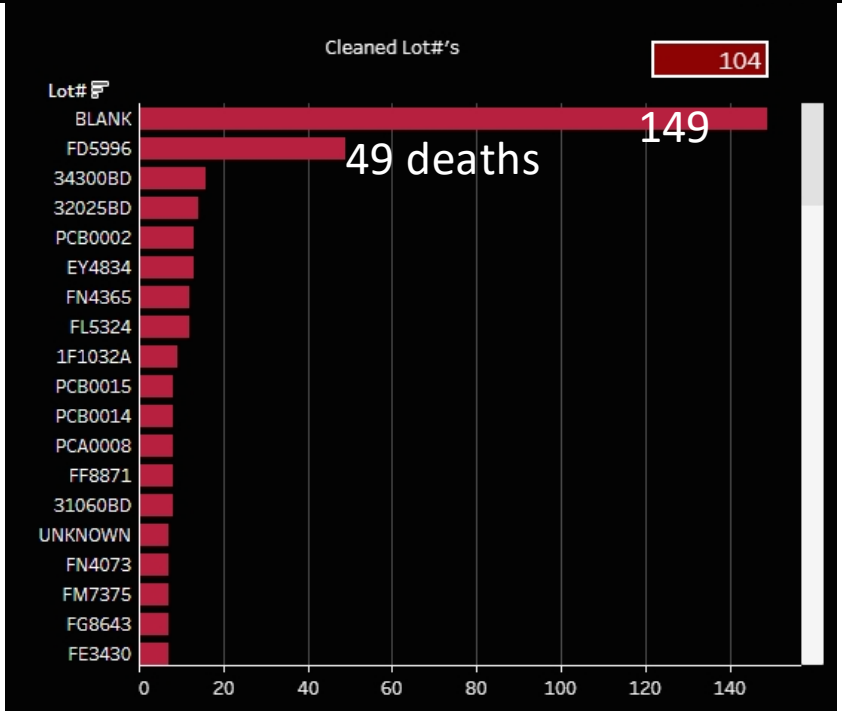
- 5,000 reports
- 531 deaths





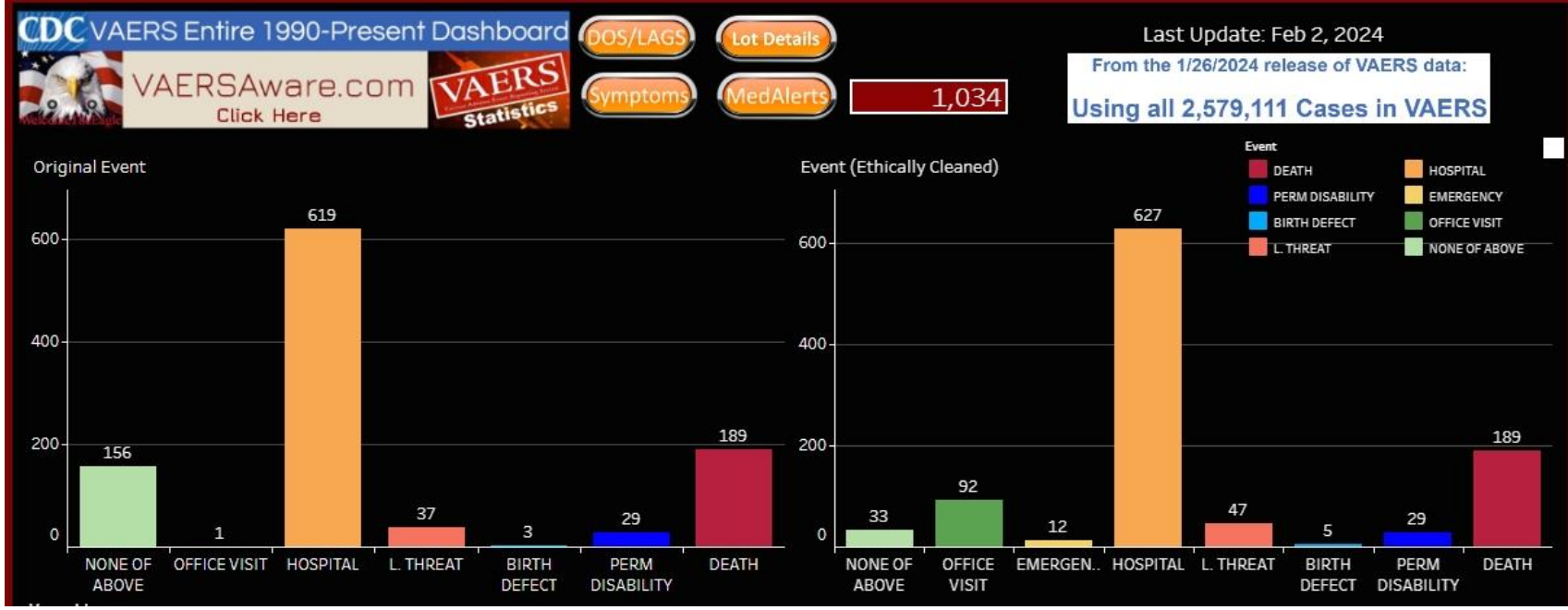
HOT LOTS?

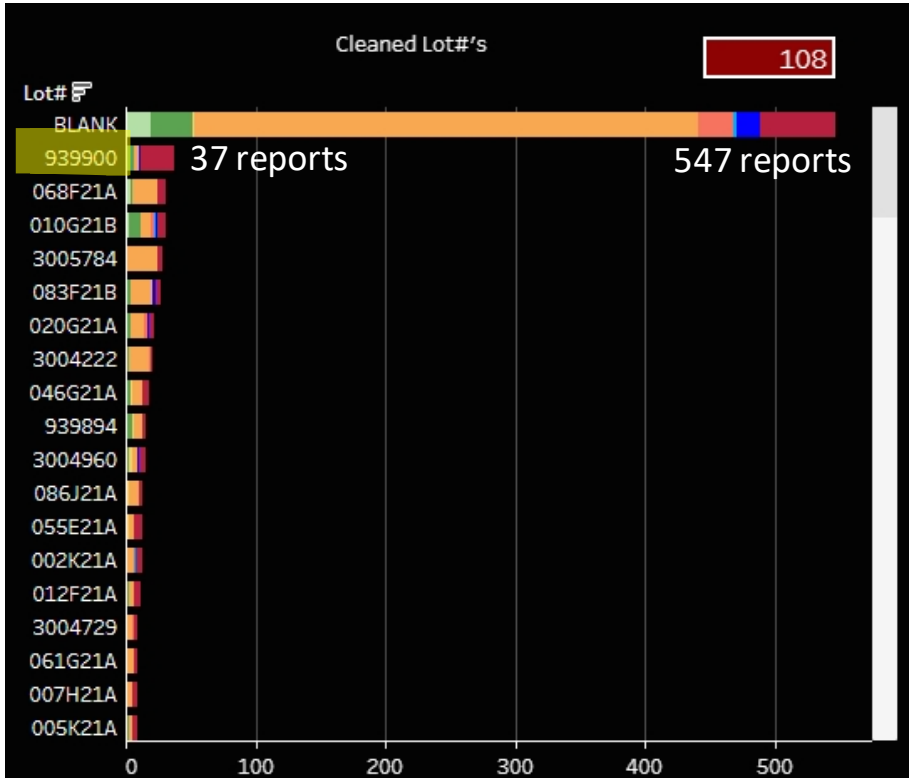
- #FD5996 has highest reports of AE & deaths



Moderna Outcomes in Philippines

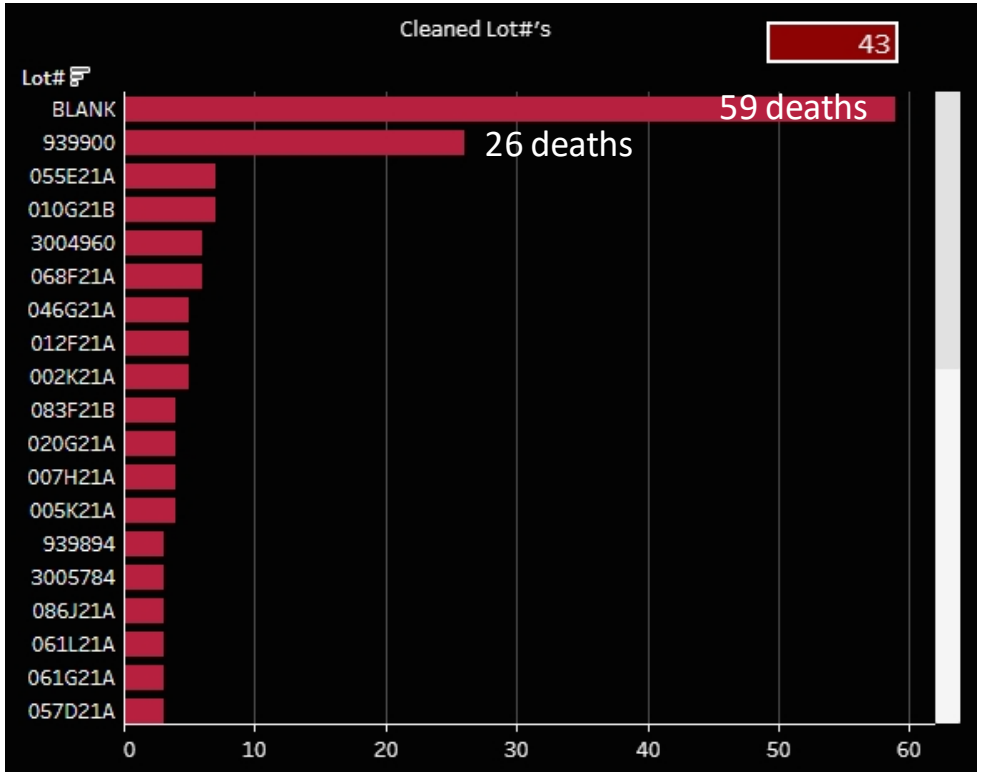
- 1,034 reports
- 189 deaths





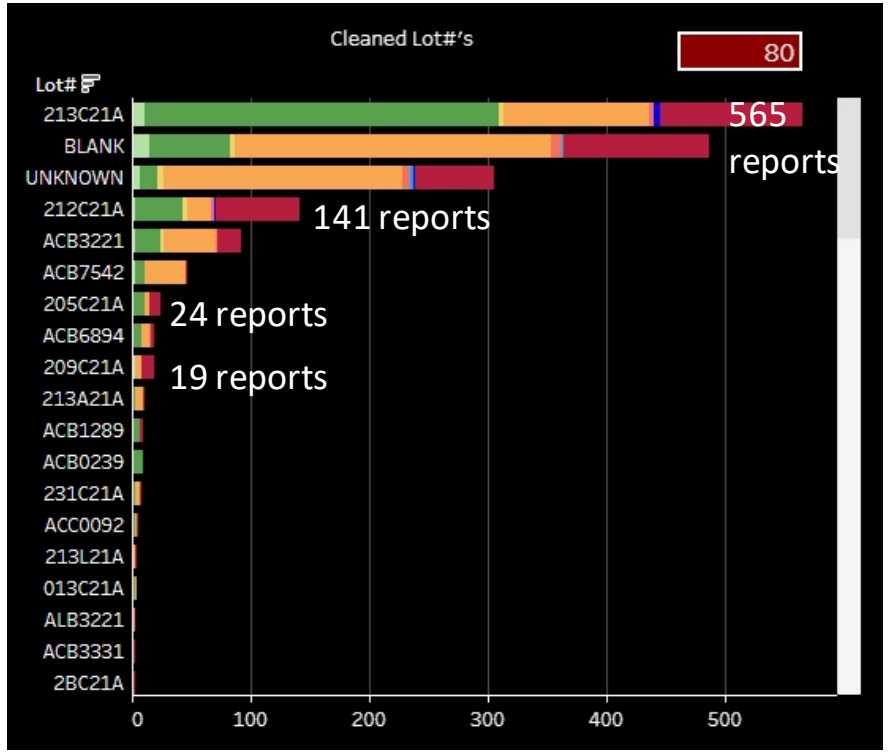
HOT LOTS?

#939900 has highest reported AE & deaths



Janssen Outcomes in Philippines

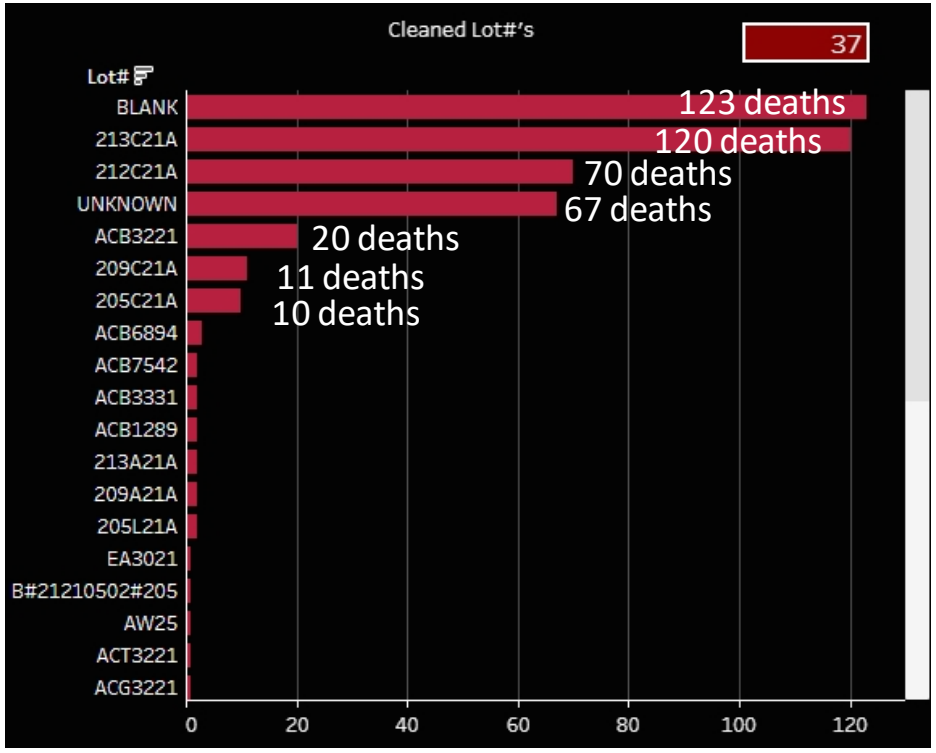
- 1,816 reports
- 459 deaths



MANY HOT LOTS!

#213C21A, #212C21A, #ACB3221, #209C21A #205C21A

All have high reports & deaths

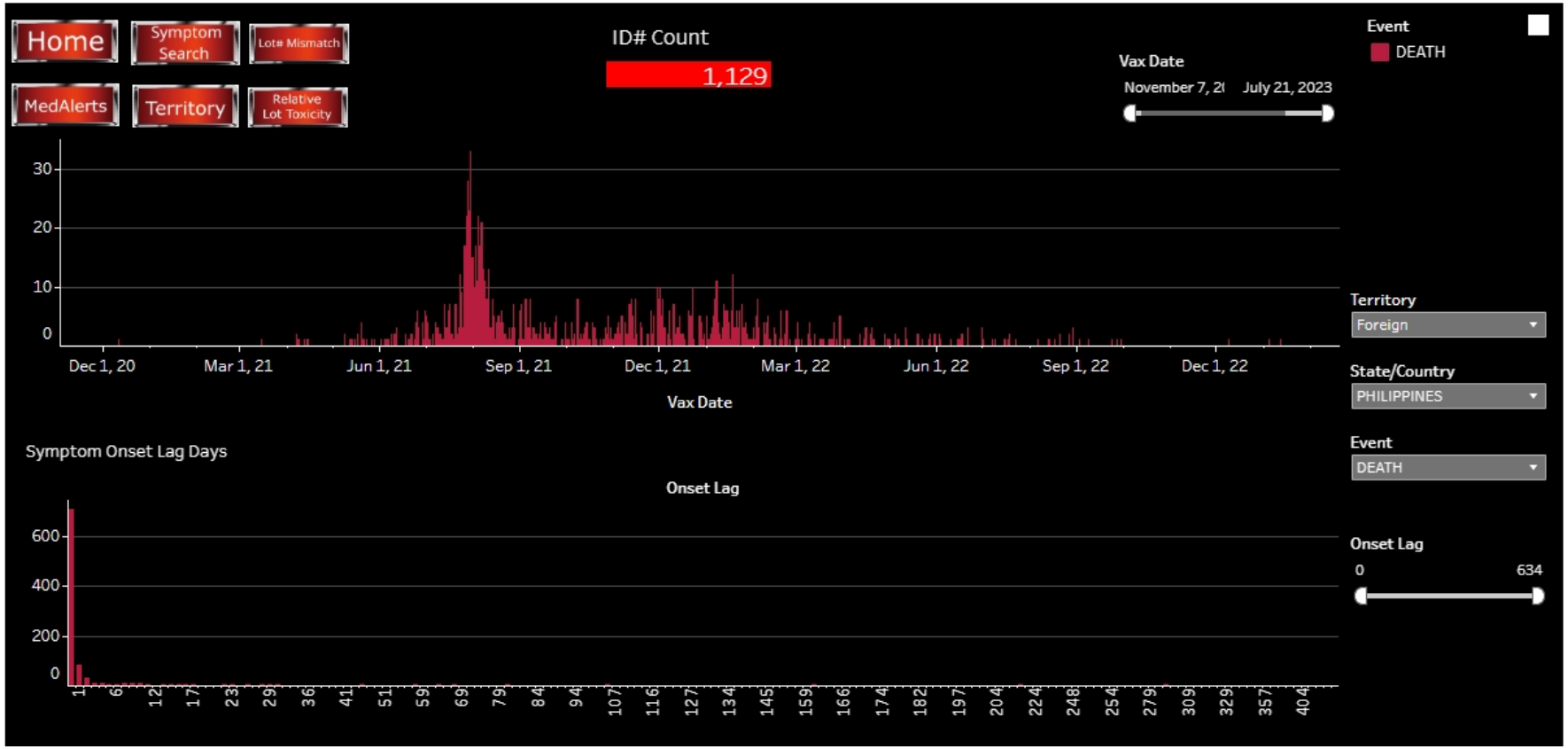


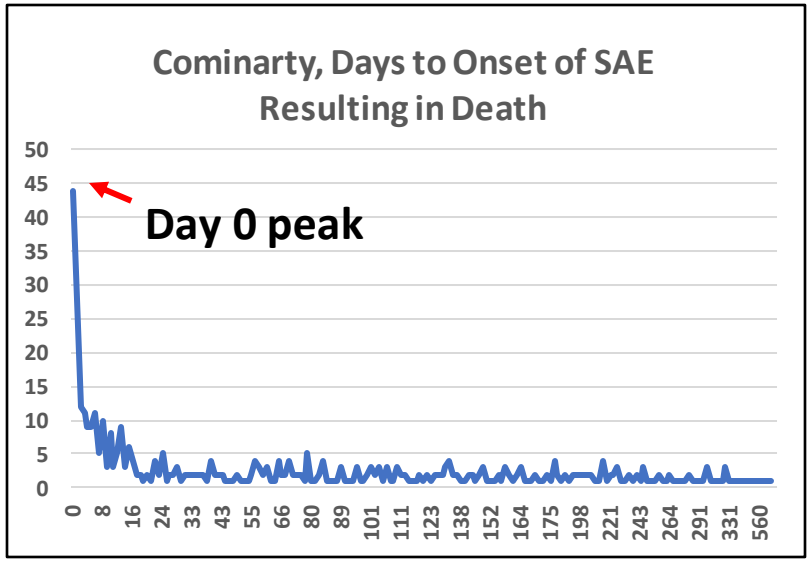
Janssen in all Foreign Territories.

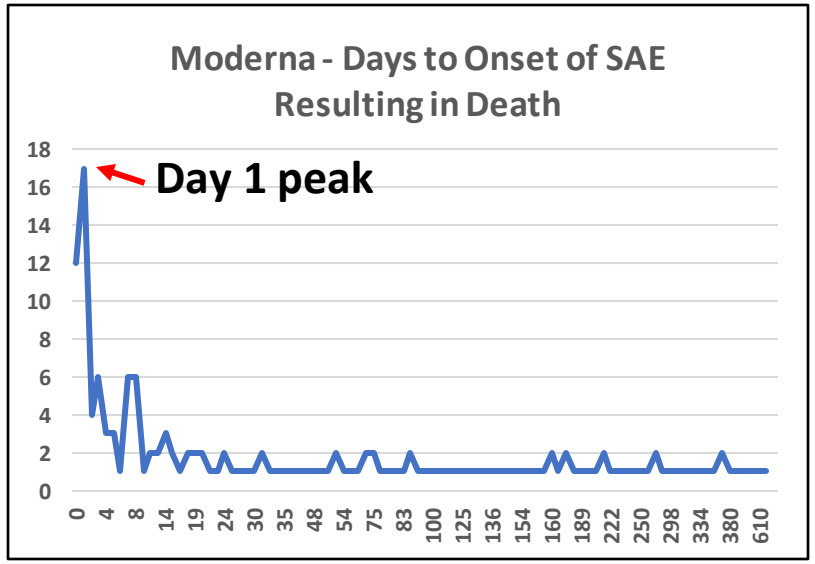
Philippines has by far the **HOTTEST** Janssen Batches

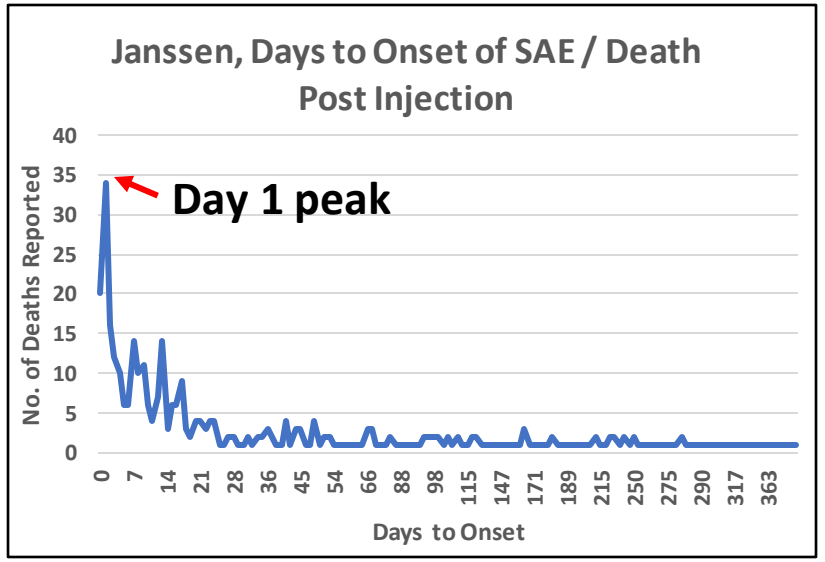
VAERS: Date of death event onset matches dosing.

Deaths are temporally linked to dose date.

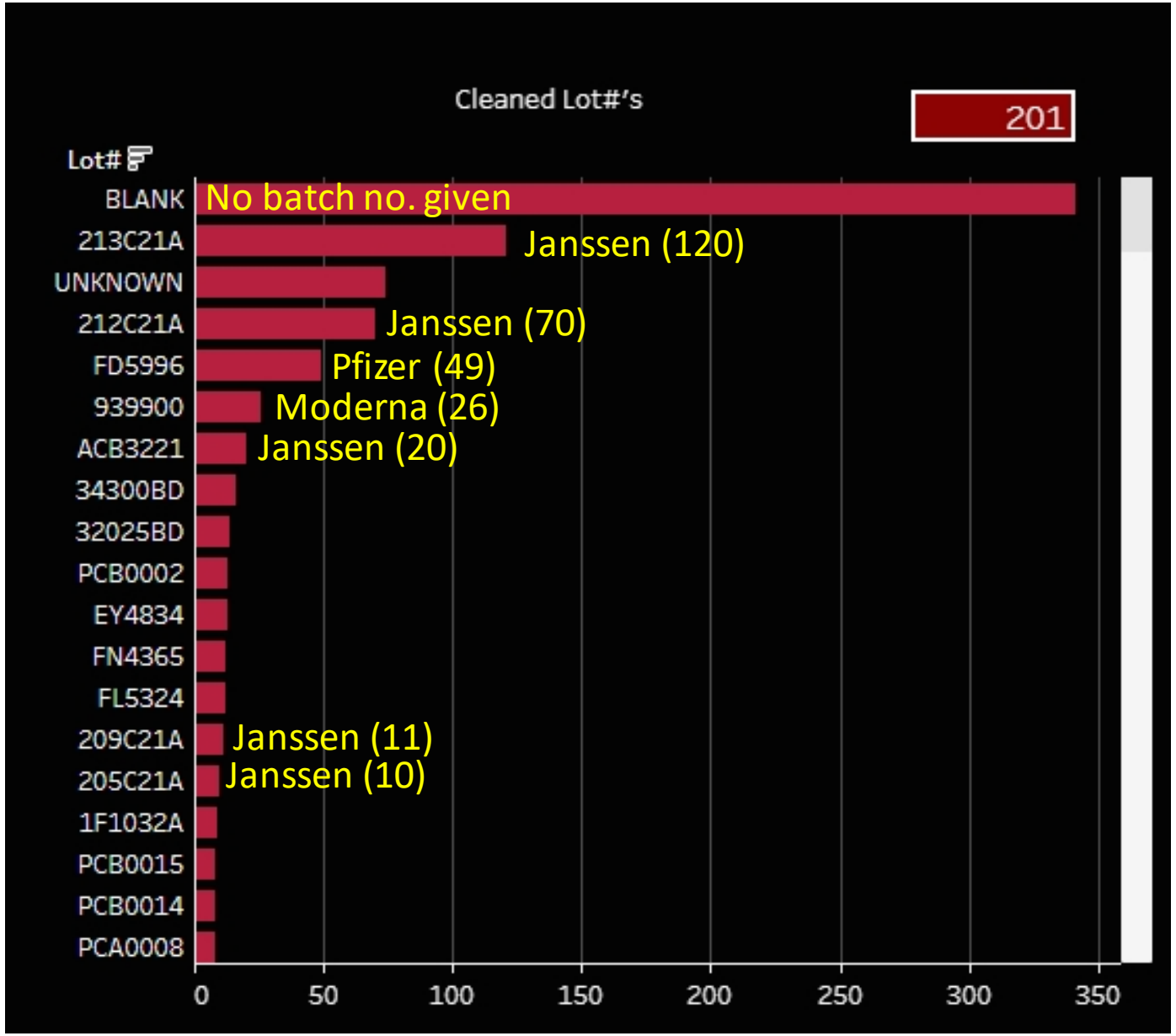


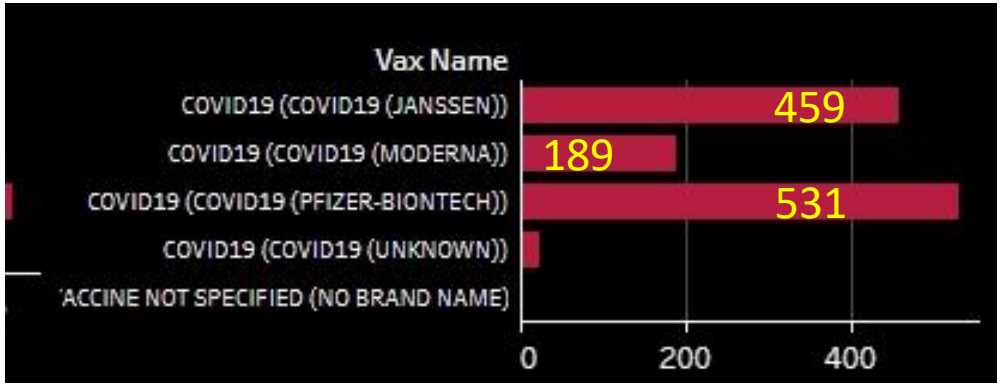






Filipino Outstanding Death Lots – JANSSEN WINS!





- Janssen: 4.2% of PH doses has 37% of VAERS deaths (459) & 3/5 topmost fatal batches.
- Pfizer: 42.4% of PH doses has 45% of deaths (531).
- Moderna: 12% of PH doses has 16.4% of deaths (189).

Summary VAERS vs PH FDA Pharmacovigilance

PHILIPPINES FOOD & DRUG AGENCY					VAERS PHILIPPINES REPORTS	
Vaccine Type	TOTAL DOSES - up to March 2023	TOTAL AEFI REPORTS – up to December 2023	TOTAL SAE REPORTS – up to December 2023	TOTAL DEATHS – Up to December 2023	VAERS REPORTS as of 2/2/2024 **7,795**	VAERS DEATHS as of 2/2/2024 **1,158**
Comirnaty / Pfizer	77,024,785 (42.4%)	23,974 (21.2% of PH AEFI reports)	2,980 (of PH SAE reports)	2,864 (all brands) No breakdown provided by Philippines FDA.	5,003 (65% of PH VAERS reports)	531 (45% of PH VAERS deaths)
Moderna	21,605,790 (11.9%)	7,044 (6.2% of PH AEFI reports)	927 (8.6% of PH SAE reports)		1,036 (13.3% of PH VAERS reports)	190 (16.4% of PH VAERS deaths)
Janssen	7,654,344 (4.2%)	5,668 (5.0% of PH AEFI reports)	1,200 (11.1% of PH SAE reports)		1,818 (23.3% of PH VAERS reports)	459 (36.9% of PH VAERS deaths)

Examination of Patterns of Covid-19 and All-Cause Deaths Relative to Various Vaccine Brands

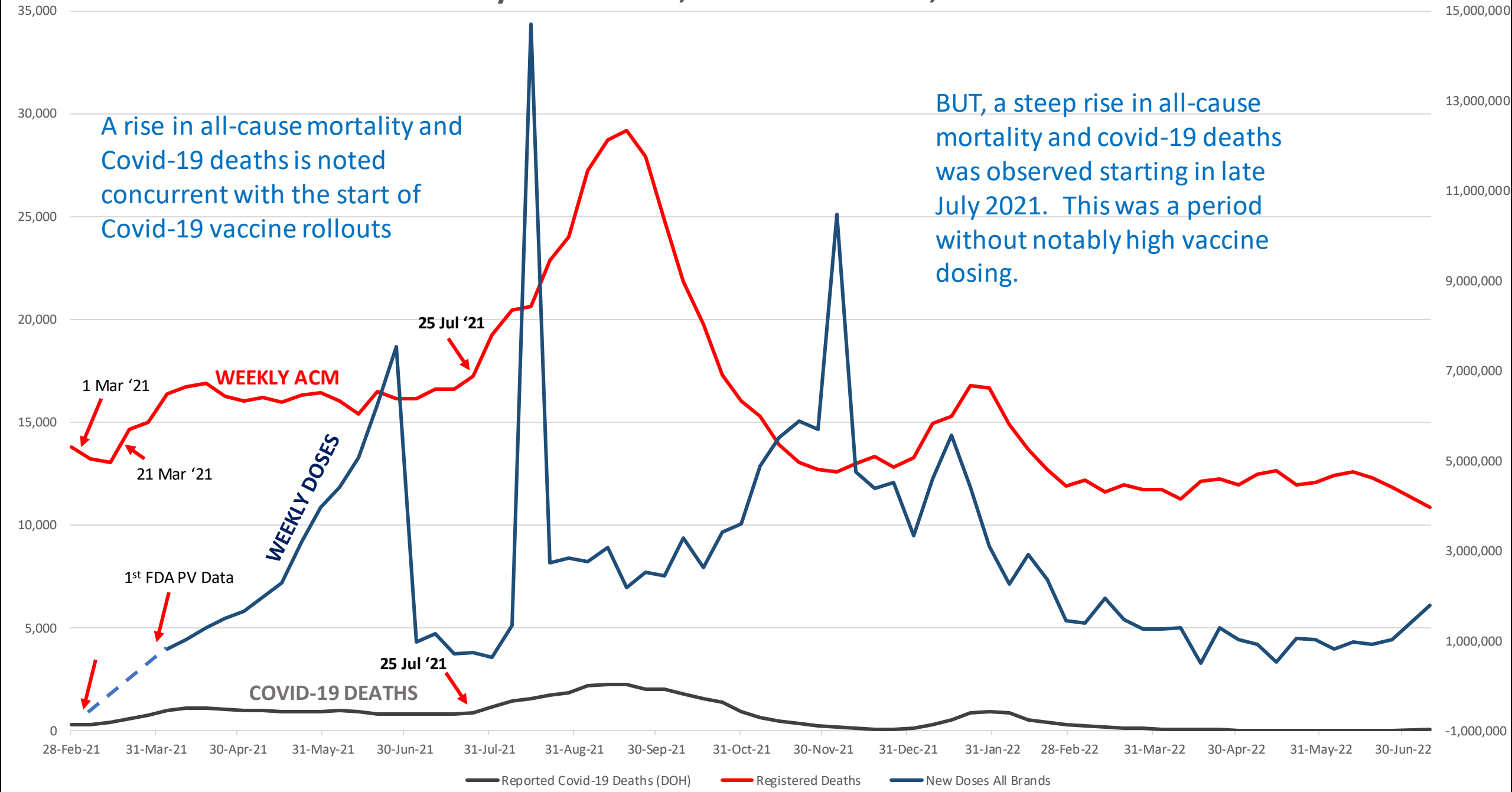
Plotted weekly Covid-19 Vaccine Doses Administered against weekly Covid-19 Deaths and Weekly All-Cause Mortality.

Sources of Information & Methodology

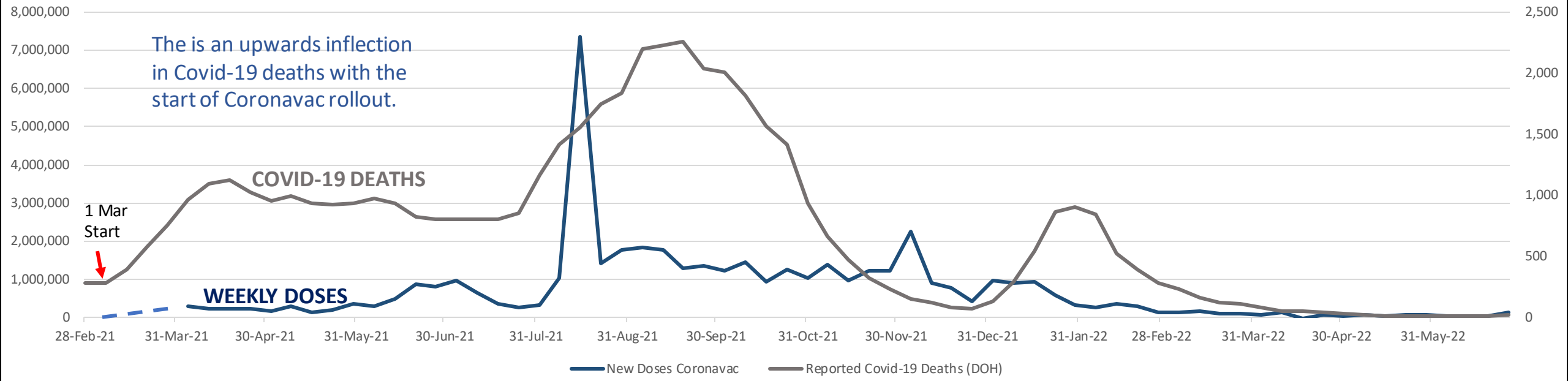
- PH FDA Pharmacovigilance Reports, for weekly vaccine doses, data starts on 4th April 2021 (rollout started on 1st March 2021).
- US VAERS System, Foreign Reports, Philippines DATA (www.vaersaware.com, www.openvaers.com)
- Philippines Statistics Authority – Daily deaths for 2021
- PH Department of Health – Daily Covid-19 deaths for 2021
- Media reports for vaccine doses and delivery schedules

- Weekly all-cause mortality was plotted against weekly vaccine administration and weekly Covid-19 Deaths.
- PH FDA Pharmacovigilance Data was Assessed Against VAERS Reports.

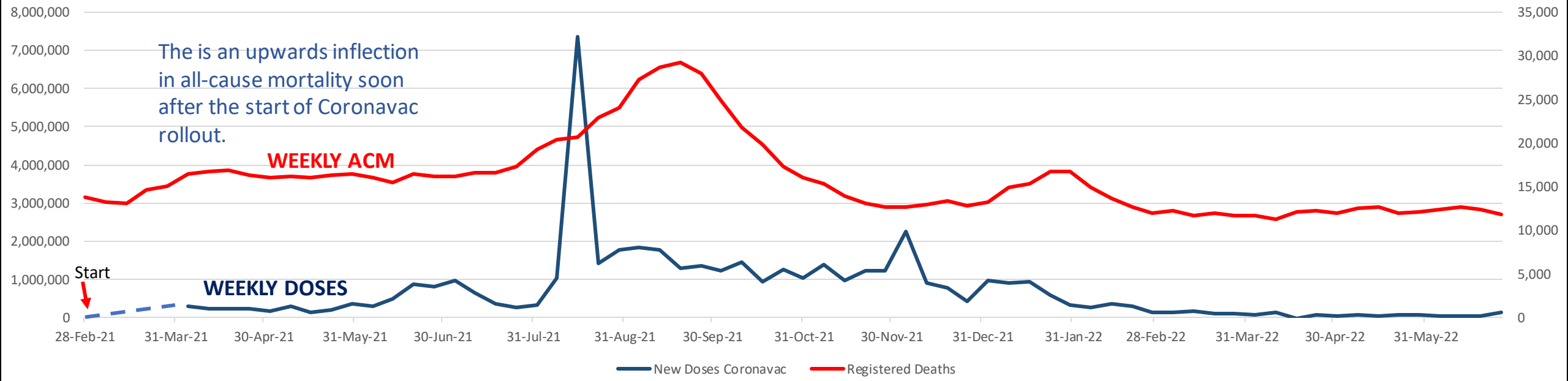
PHILIPPINES – Weekly New Doses, Covid-19 Deaths, and All Cause Deaths

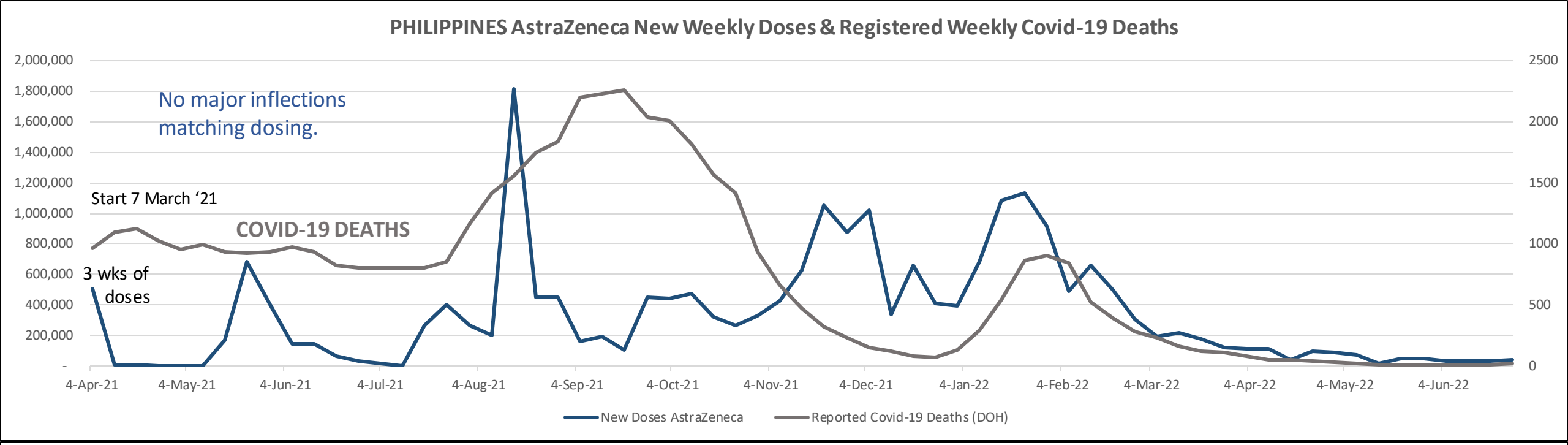


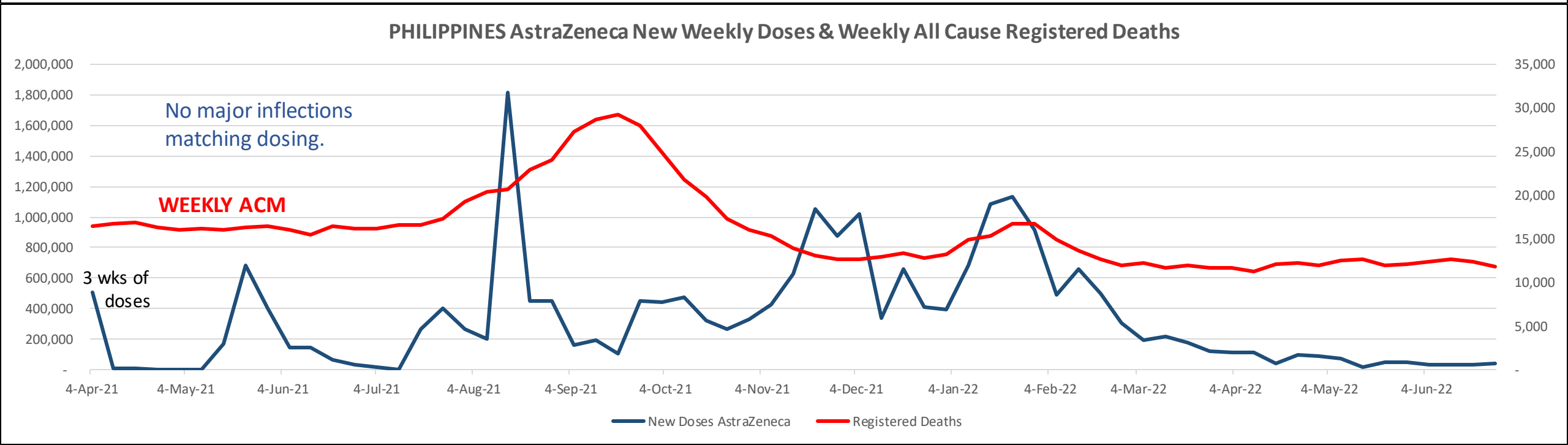
PHILIPPINES Coronavac Weekly New Doses & Registered Covid-19 Deaths



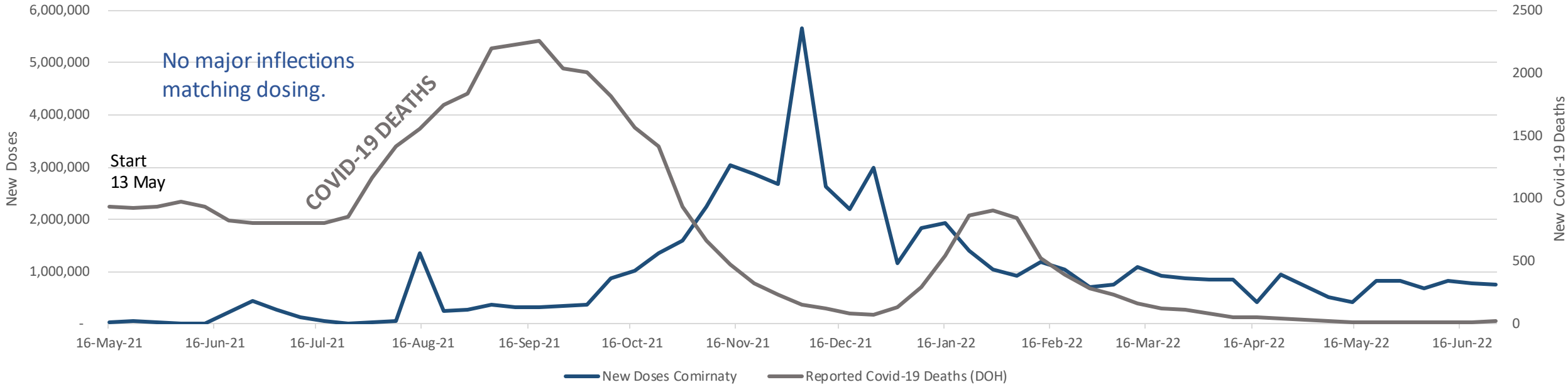
PHILIPPINES Coronavac Weekly New Doses & All Cause Weekly Registered Deaths



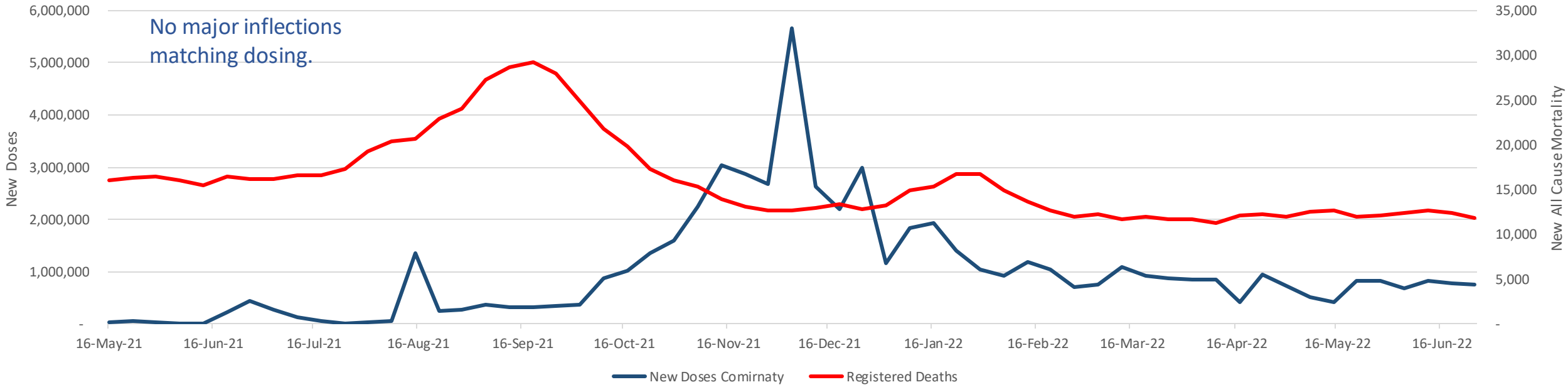

PHILIPPINES AstraZeneca New Weekly Doses & Registered Weekly Covid-19 Deaths
No major inflections matching dosing.
Start 7 March '21
COVID-19 DEATHS
3 wks of doses
2,000,000
1,800,000
1,600,000
1,400,000
1,200,000
1,000,000
800,000
600,000
400,000
200,000
-
2500
2000
1500
1000
500
0
4-Apr-21
4-May-21
4-Jun-21
4-Jul-21
4-Aug-21
4-Sep-21
4-Oct-21
4-Nov-21
4-Dec-21
4-Jan-22
4-Feb-22
4-Mar-22
4-Apr-22
4-May-22
4-Jun-22
New Doses AstraZeneca
Reported Covid-19 Deaths (DOH)

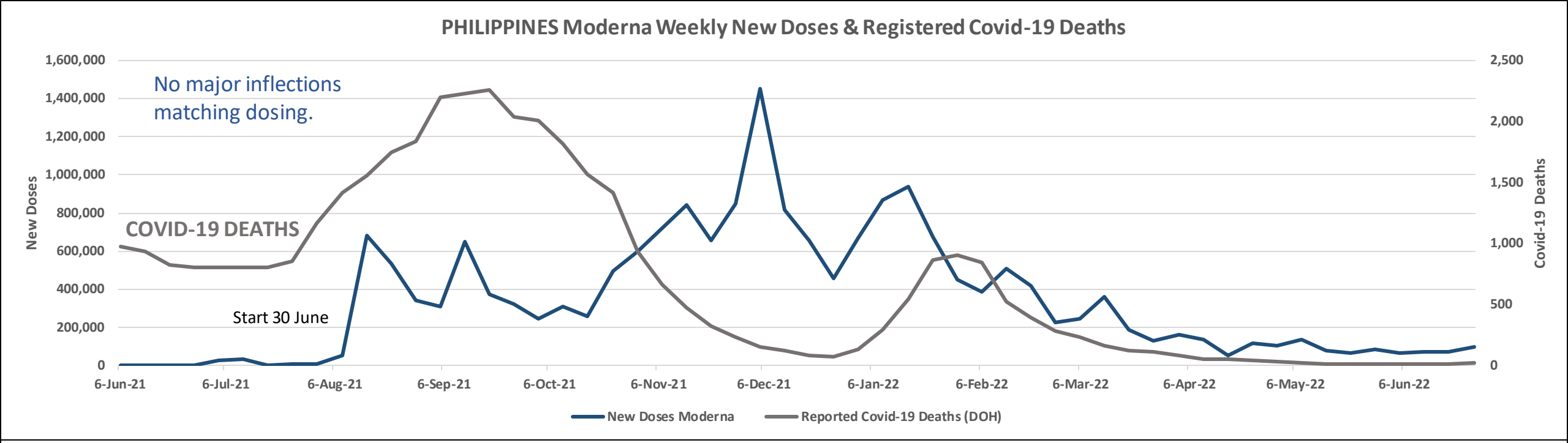

PHILIPPINES AstraZeneca New Weekly Doses & Weekly All Cause Registered Deaths
No major inflections matching dosing.
WEEKLY ACM
3 wks of doses
2,000,000
1,800,000
1,600,000
1,400,000
1,200,000
1,000,000
800,000
600,000
400,000
200,000
-
35,000
30,000
25,000
20,000
15,000
10,000
5,000
-
4-Apr-21
4-May-21
4-Jun-21
4-Jul-21
4-Aug-21
4-Sep-21
4-Oct-21
4-Nov-21
4-Dec-21
4-Jan-22
4-Feb-22
4-Mar-22
4-Apr-22
4-May-22
4-Jun-22
New Doses AstraZeneca
Registered Deaths

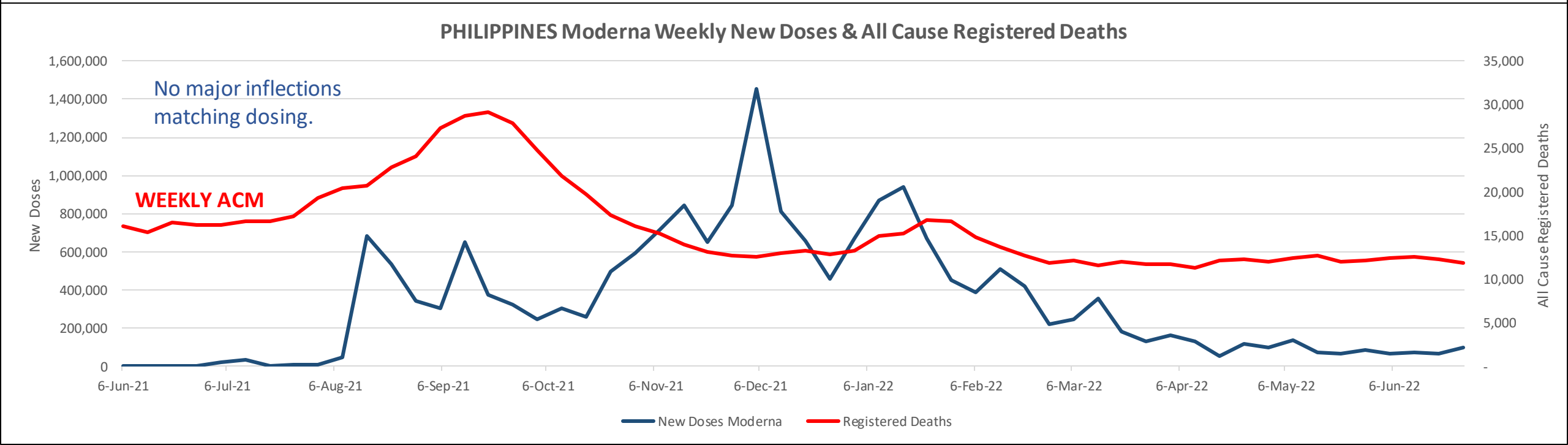
PHILIPPINES Comirnaty Weekly New Doses & Registered Covid-19 Deaths



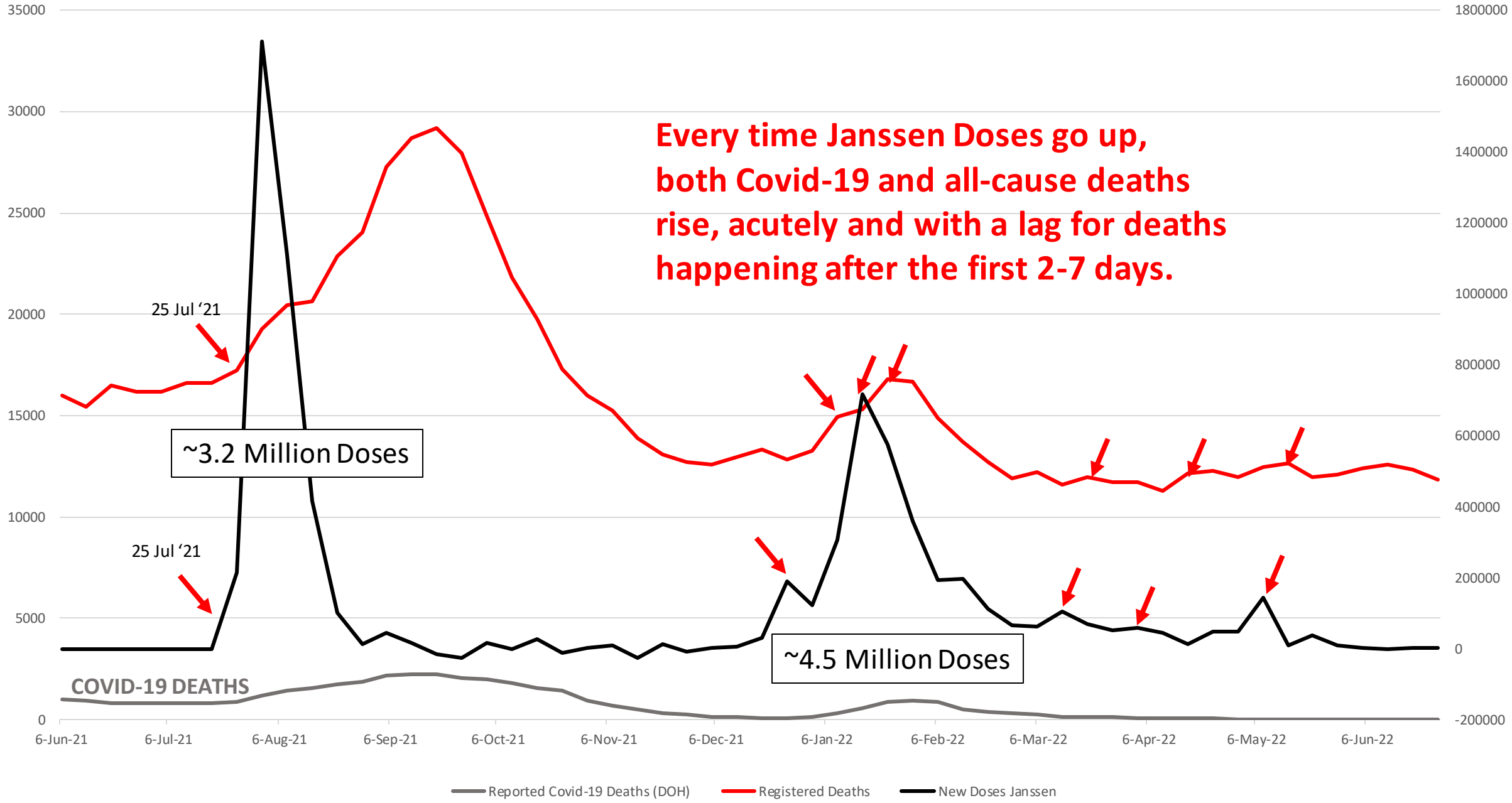
PHILIPPINES Comirnaty Weekly New Doses & All Cause Registered Deaths



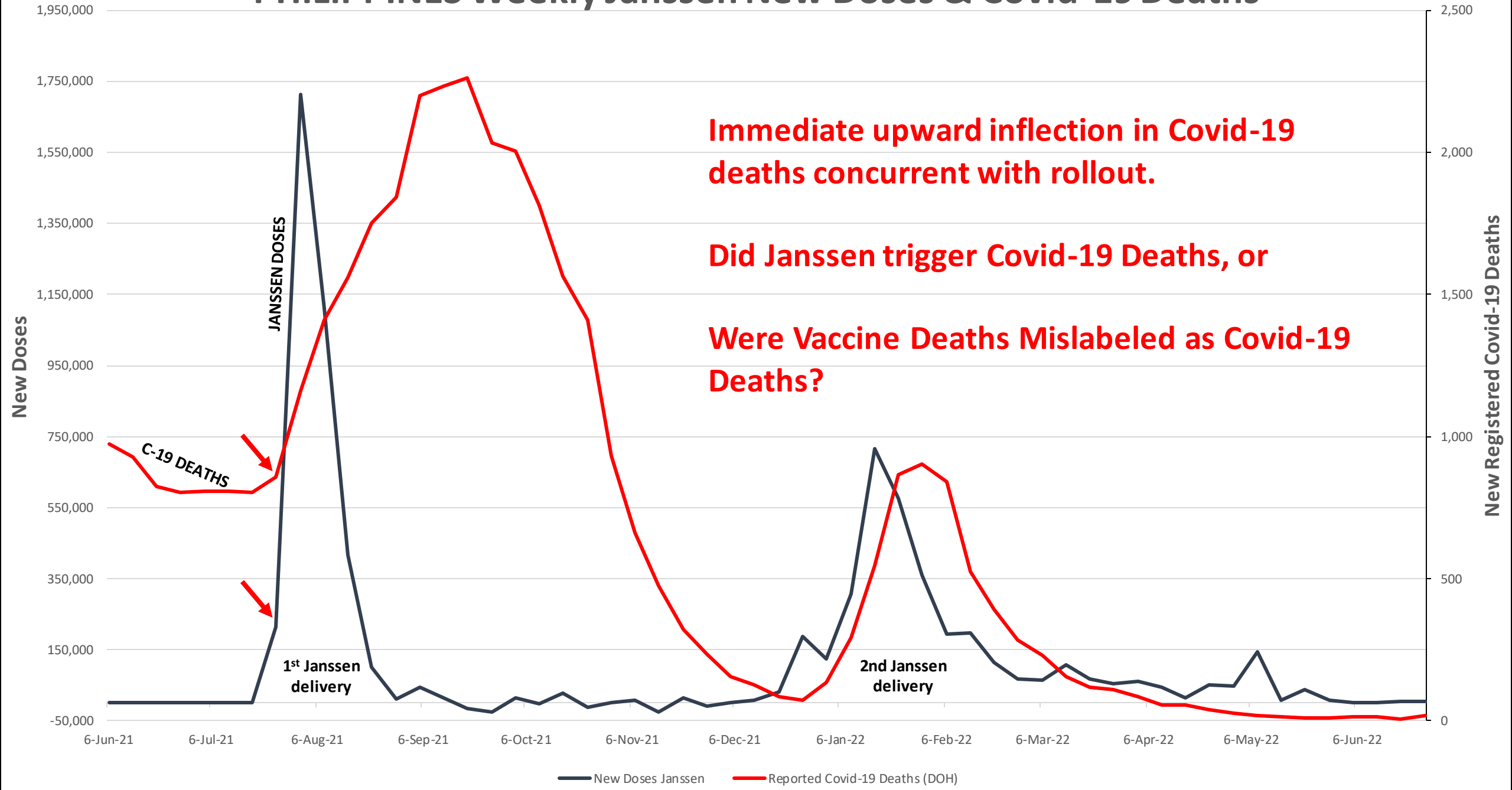

PHILIPPINES Moderna Weekly New Doses & Registered Covid-19 Deaths
No major inflections matching dosing.
COVID-19 DEATHS
Start 30 June
New Doses
Covid-19 Deaths
1,600,000
1,400,000
1,200,000
1,000,000
800,000
600,000
400,000
200,000
0
2,500
2,000
1,500
1,000
500
0
6-Jun-21
6-Jul-21
6-Aug-21
6-Sep-21
6-Oct-21
6-Nov-21
6-Dec-21
6-Jan-22
6-Feb-22
6-Mar-22
6-Apr-22
6-May-22
6-Jun-22
New Doses Moderna
Reported Covid-19 Deaths (DOH)


PHILIPPINES Moderna Weekly New Doses & All Cause Registered Deaths
No major inflections matching dosing.
WEEKLY ACM
New Doses
All Cause Registered Deaths
1,600,000
1,400,000
1,200,000
1,000,000
800,000
600,000
400,000
200,000
0
35,000
30,000
25,000
20,000
15,000
10,000
5,000
-
6-Jun-21
6-Jul-21
6-Aug-21
6-Sep-21
6-Oct-21
6-Nov-21
6-Dec-21
6-Jan-22
6-Feb-22
6-Mar-22
6-Apr-22
6-May-22
6-Jun-22
New Doses Moderna
Registered Deaths

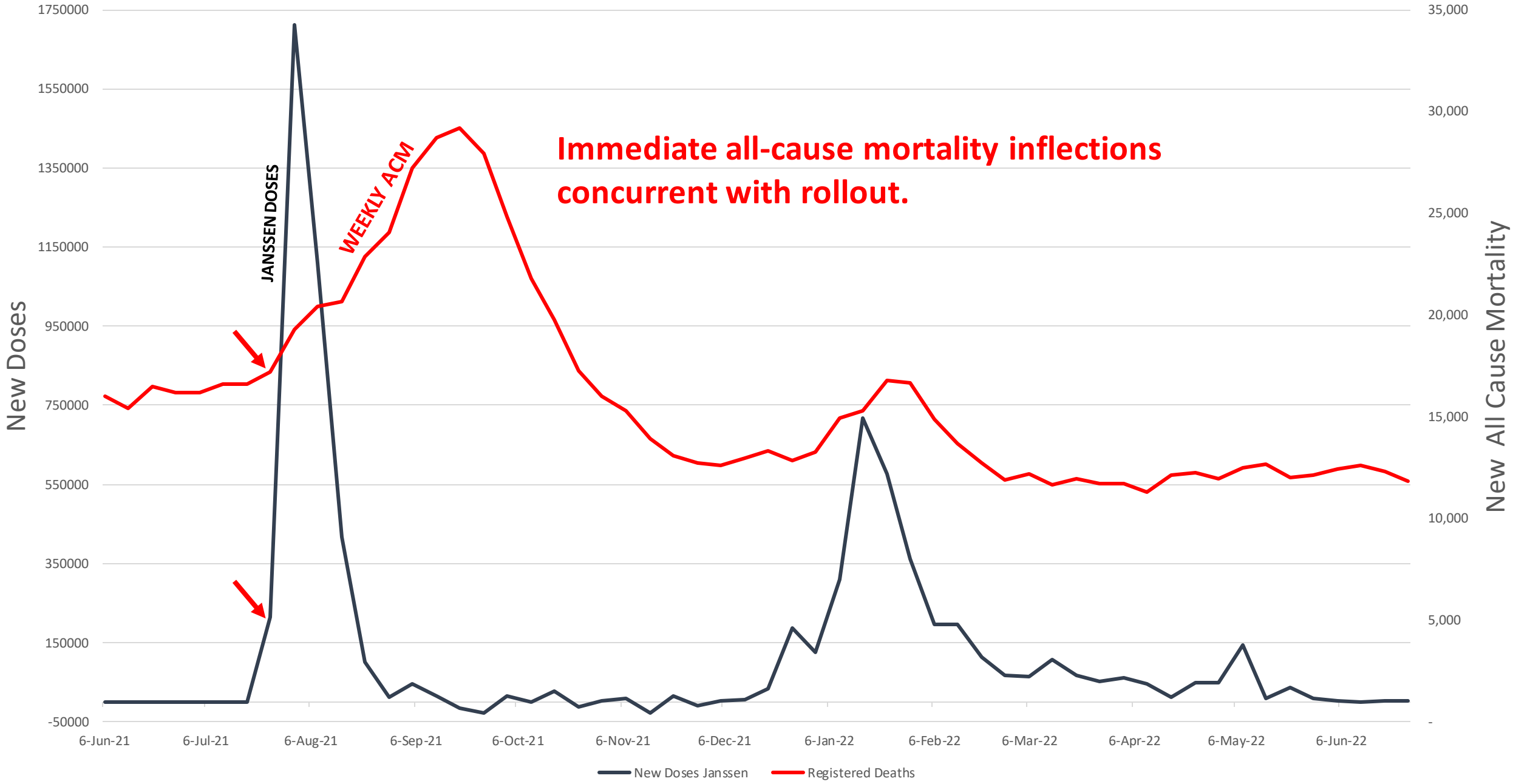
PHILIPPINES Weekly Janssen Doses, Covid-19 Deaths, & All Cause Mortality



PHILIPPINES Weekly Janssen New Doses & Covid-19 Deaths



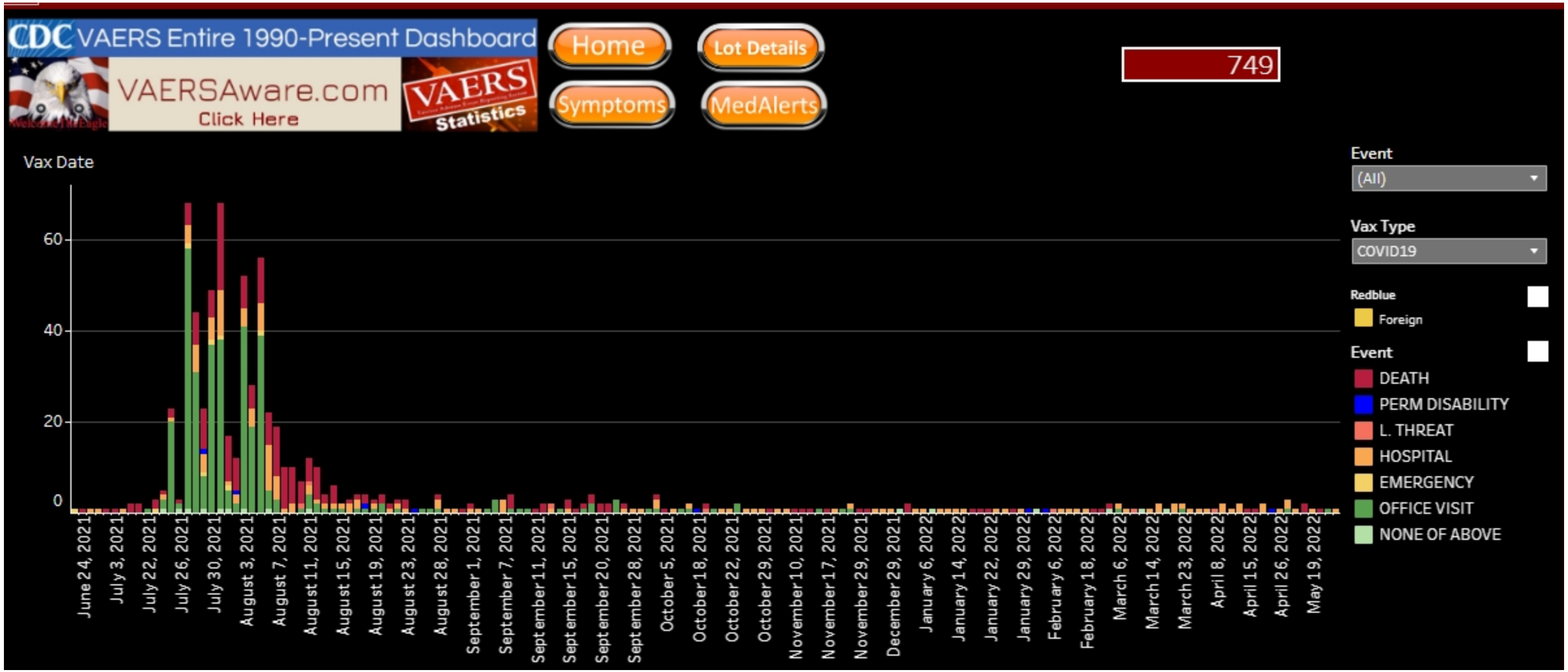
PHILIPPINES Weekly Janssen Doses and All Cause Deaths

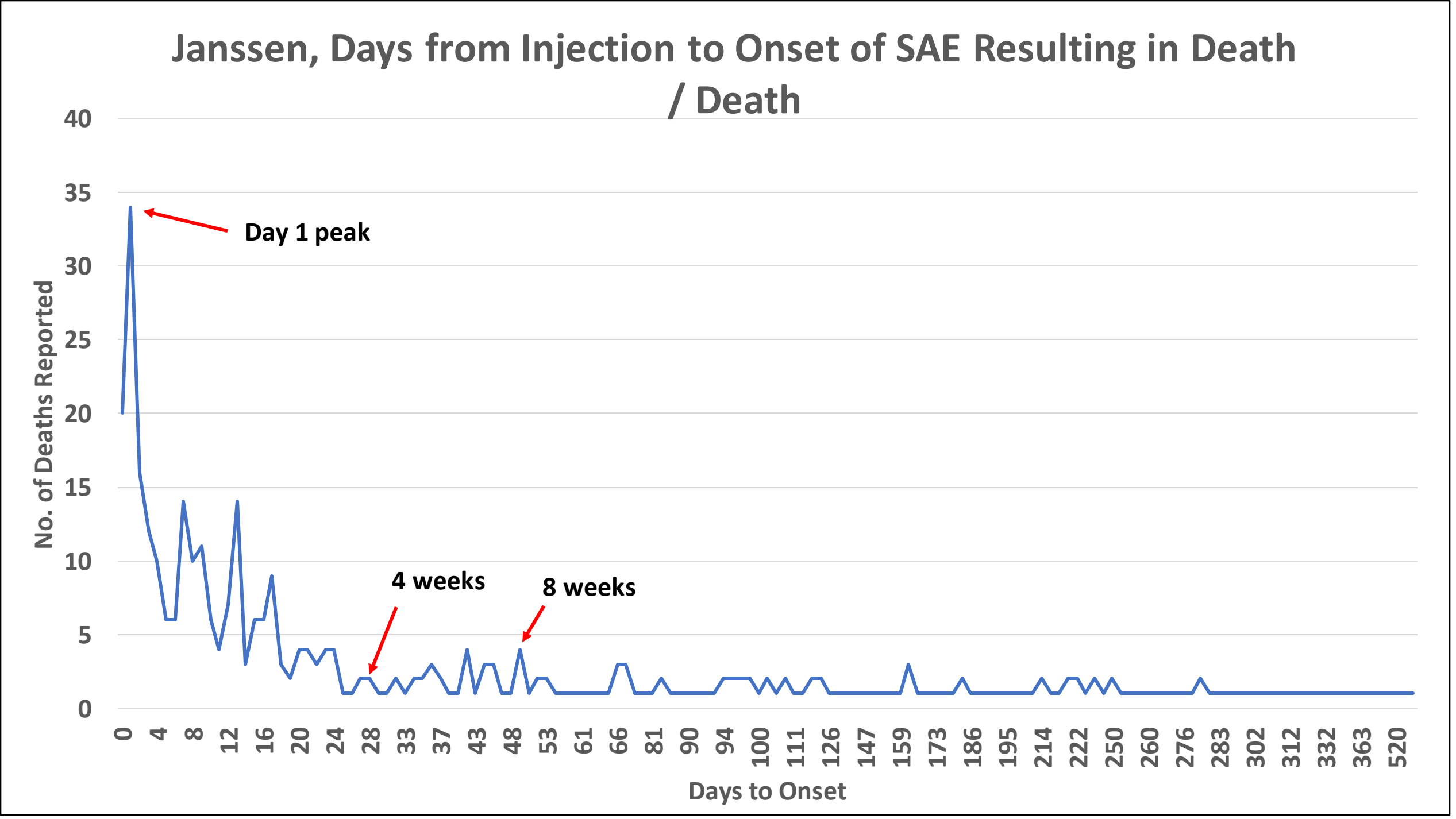


DID JANSSEN CAUSE HYPER-EXCESS DEATHS?

- Janssen shows highest dose-report rate of any product in both PH FDA and VAERS Pharmacovigilance.
- Janssen distribution exactly matches timing of hyper-excess deaths.
- Deaths dropped off 4 – 8 weeks after completed administration of 1st Batches of Janssen was complete (mid-August), matches VAERS temporal patterns of reports.
- The start of hyper-excess deaths in every region of Philippines closely follow Janssen rollout from 20th July 2021.
- VAERS Janssen reports show peak AEFI and deaths on days 0-1, but with a notable tail lasting 4 to 8 weeks.

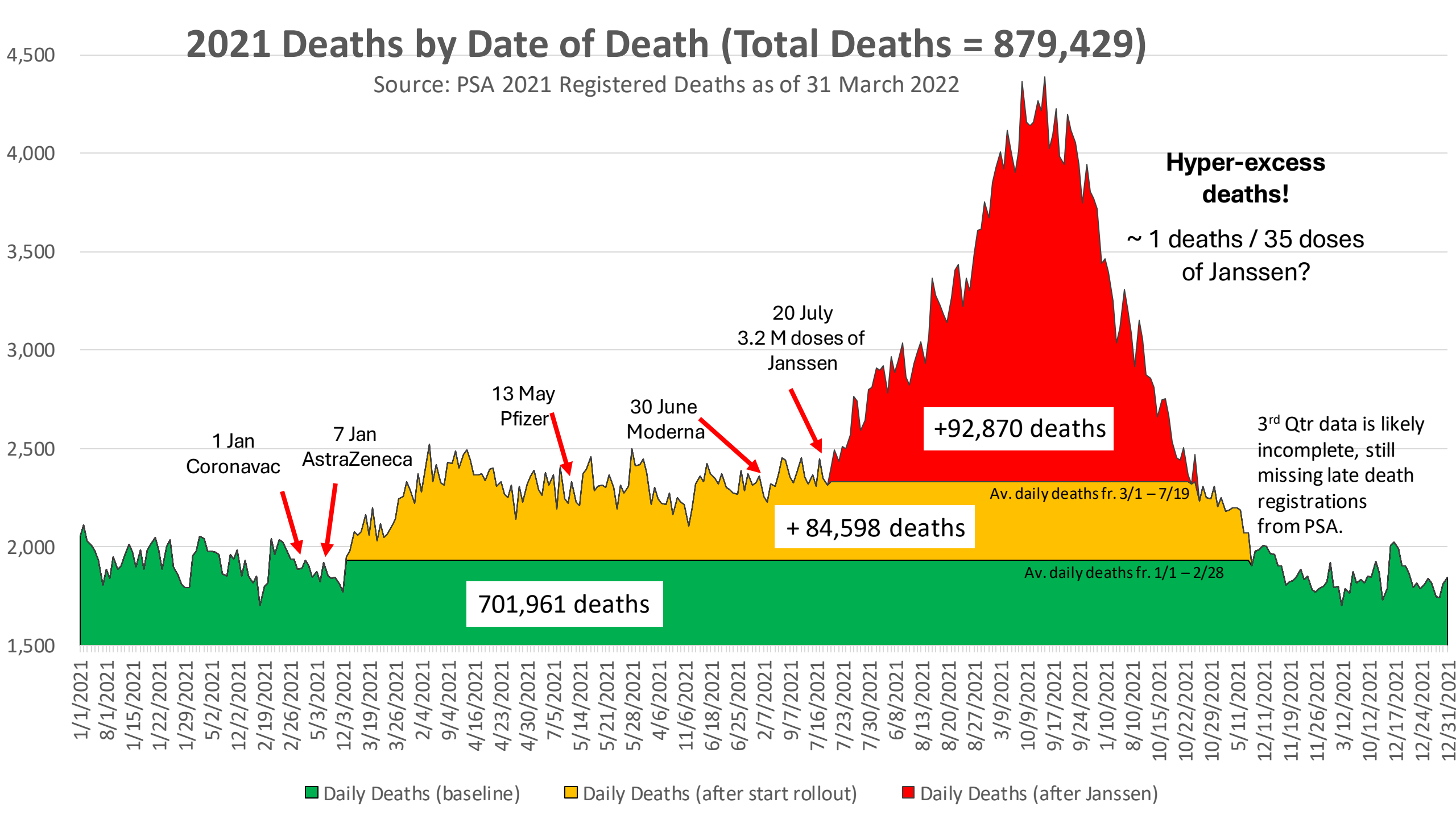
ONSET – Janssen Batches 212C21A, 213C21A, 205C21A, 209C21A (1st PH Delivery)




Janssen, Days from Injection to Onset of SAE Resulting in Death / Death
No. of Deaths Reported
40
35
30
25
20
15
10
5
0
Day 1 peak
4 weeks
8 weeks
0 4 8 12 16 20 24 28 33 37 43 48 53 61 66 81 90 94 100 111 126 147 159 173 186 195 214 222 250 260 276 283 302 312 332 363 520
Days to Onset

2021 Deaths by Date of Death (Total Deaths = 879,429)

Source: PSA 2021 Registered Deaths as of 31 March 2022



Health topics | Our work | News | Emergencies

Philippines receives over 3.2M vaccines donated by the US Government through the COVAX Facility

16 July 2021 | Joint News Release | Manila

The Philippines received today an initial delivery of over 1.6 million doses of Johnson & Johnson's Janssen vaccine donated by the United States (US) Government through the COVAX Facility. A second delivery, expected to arrive on 17 July 2021, will complete the donation of around 3.2 million doses.

The deliveries are part of global vaccine-sharing strategy by the US Government, which aims to provide at least 80 million vaccine doses to countries most affected by the pandemic.

"These vaccines from the COVAX facility would be given to our senior citizens who are at risk for severe COVID-19 and deaths. These single-dose vaccines would help fully vaccinate more of our lolos and lolas and increase coverage among the A2 priority group. By fully vaccinating them, we could hopefully reduce hospitalization and decongest our hospitals. Kaya naman po inaanyayahan ko ang ating mga lolo at lola na magpabakuna na laban sa COVID-19," said Secretary of Health Francisco T. Duque III.

As of July 14, around 10 million Filipinos have received the first dose of the COVID-19 vaccine, and 4 million have completed two doses. However, the vaccination coverage among the A2 priority group – the senior citizens – remains lagging at 31% coverage for the first dose.

3.213 Million Doses from COVAX
100,000 Doses to each region
Dosed from 20 July to mid-Aug

4 Batches, 3 EXCLUSIVE to PH

#212C21A
#213C21A
#209C21A
#205C21A

Exclusive to PH

#213C21A – 565 reports, 120 deaths
#212C21A – 141 reports, 70 deaths
#209C21A – 19 reports, 11 deaths

#205C21A – 25 reports, 10 deaths

Janssen Hot Lot Summary

- 3,213,200 doses delivered by COVAX on 17 & 18 July, start administration on 20 July 2021 and completed by mid-August 2021.
- At least 100K doses distributed to each region for immediate deployment
- 4 batches this delivery, 3 of these ***exclusive*** to the Philippines
- Immediate rise in registered deaths and Covid-19 deaths with rollout
- 92,870 ***hyper-excess deaths*** following rollout.

17-18 July 2021 COVAX DELIVERY	TOTAL DOSES	BATCH NUMBERS	TOTAL VAERS REPORTS	TOTAL VAERS DEATHS	POSSIBLE URF	HYPER-EXCESS DEATHS
Janssen	3,213,200	205C21A 209C21A 212C21A 213C21A	749	211 (28.2% of reports)	440	92,870

Additional Data

Mortality Patterns by Region showing spike in all regions on or after 20 July 2021.

Selected VAERs Reports showing acute reactions to Covid-19 Vaccines.

A spike in all-cause mortality started on 3rd week of July 2021 across all regions of the Philippines.

Were these spike in deaths caused by Janssen?

HEADLINES

J&J vaccine delivery starts this week

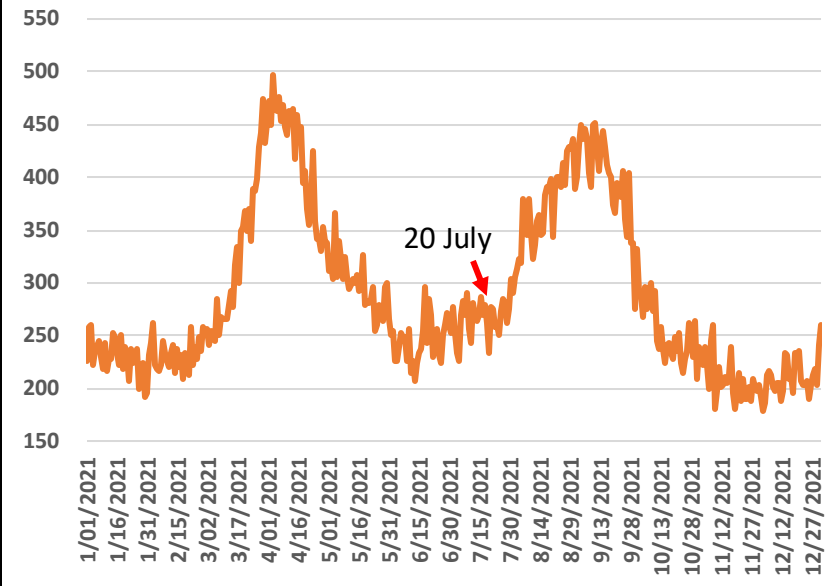
Neil Jayson Servallos - The Philippine Star ⓘ

July 12, 2021 | 12:00am

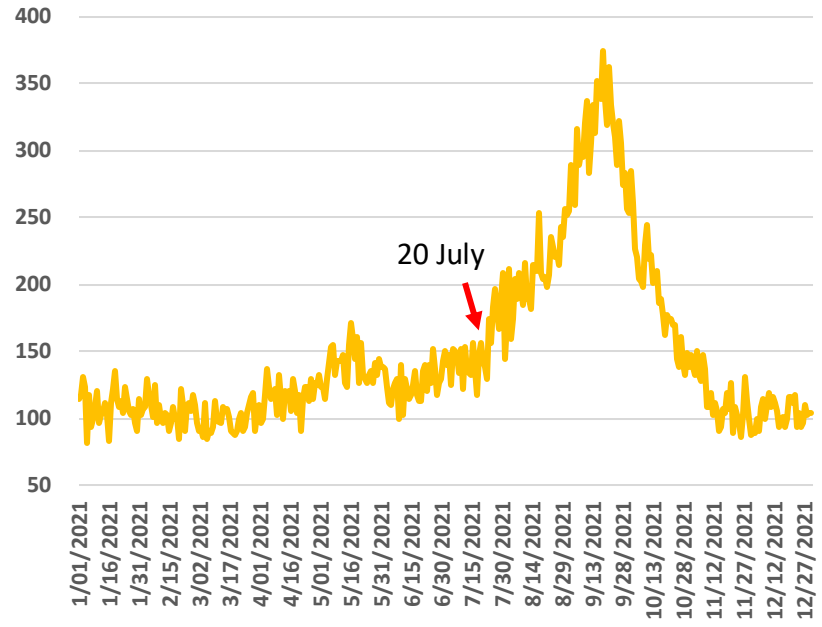
Vaccine czar Carlito Galvez Jr. said the donated J&J vaccine doses would be deployed regionally, with each region expected to receive at least 100,000 doses.

AFP / Justin Tallis

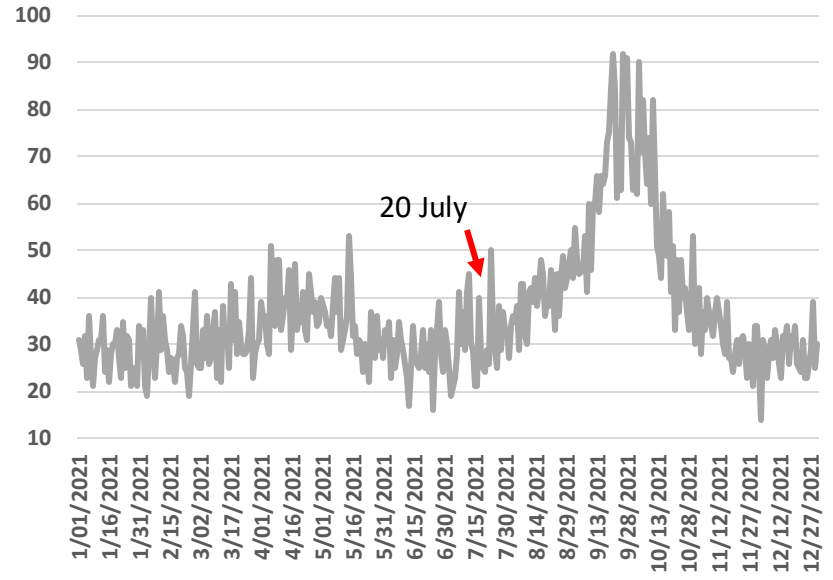
DAILY DEATHS NATIONAL CAPITAL REGION (NCR)



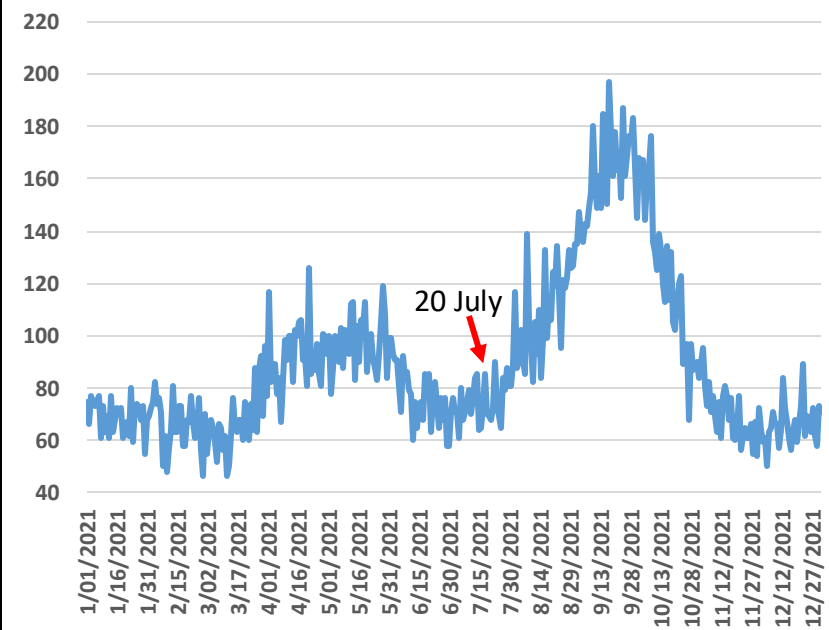
REGION I (ILOCOS REGION)



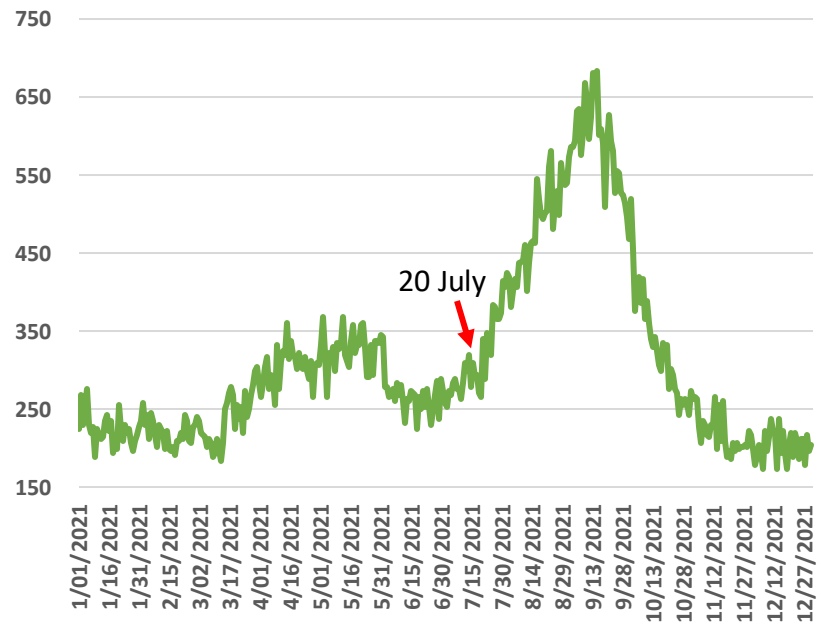
CORDILLERA ADMINISTRATIVE REGION (CAR)



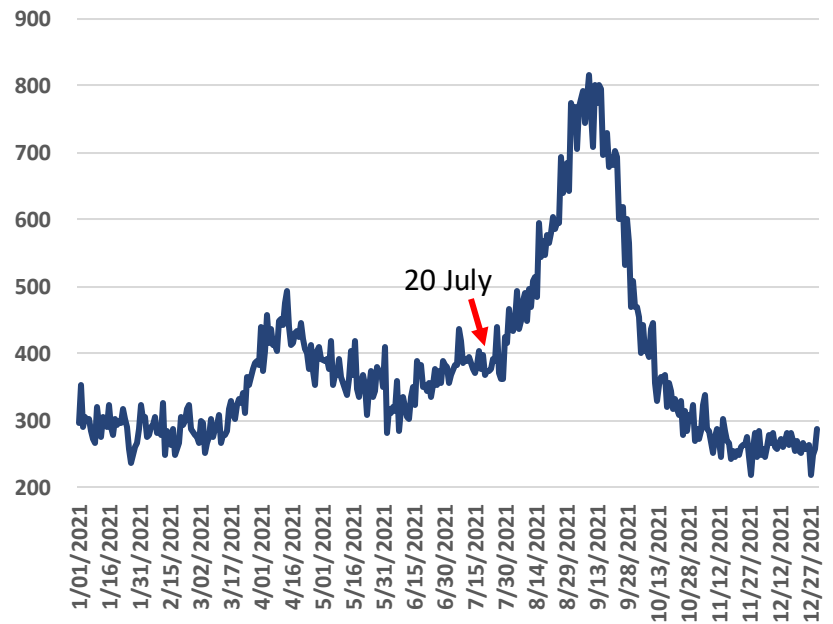
REGION II (CAGAYAN VALLEY)



REGION III (CENTRAL LUZON)



REGION IV-A (CALABARZON)



VAERS ID: 2373124

AGE: 5 | **SEX:** F | **STATE:** FR (Unknown)

Description

Cold; This is a spontaneous report received from a contactable reporter(s) (Other HCP) from Regulatory Authority. Regulatory number: PH-PHFDA-300151017. A 5-year-old female patient (unknown if pregnant) received BNT162b2 (COMIRNATY), on 10Jun2022 as dose number unknown, single (Lot number: FN4073) at the age of 5 years intramuscular for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: NASOPHARYNGITIS (death) with onset 11Jun2022 at 03:00, outcome "fatal", described as "Cold". The patient date of death was 2022. Reported cause of death: "Cold". It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Cold

 # 2373124

Philippines FDA report

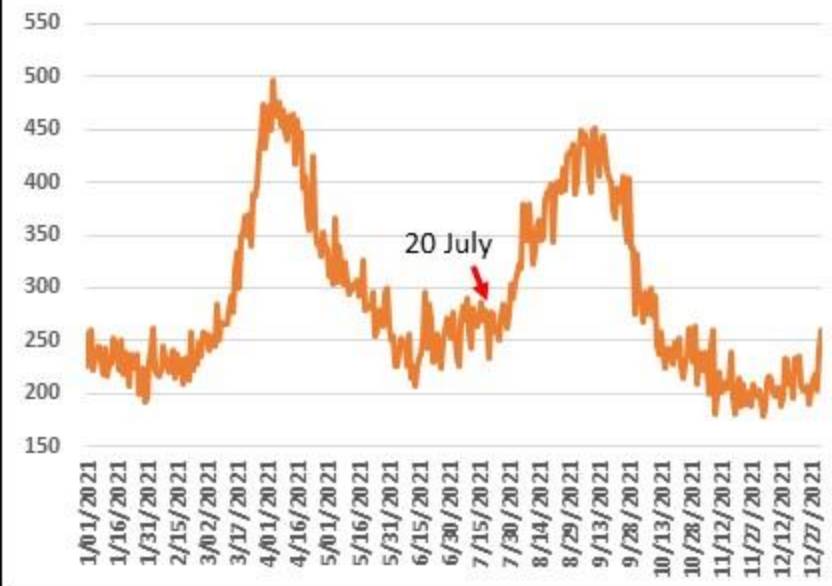
5 YO Female – Next Day Death

Received Pfizer, Lot No. FN4073 on 10 June 2022.

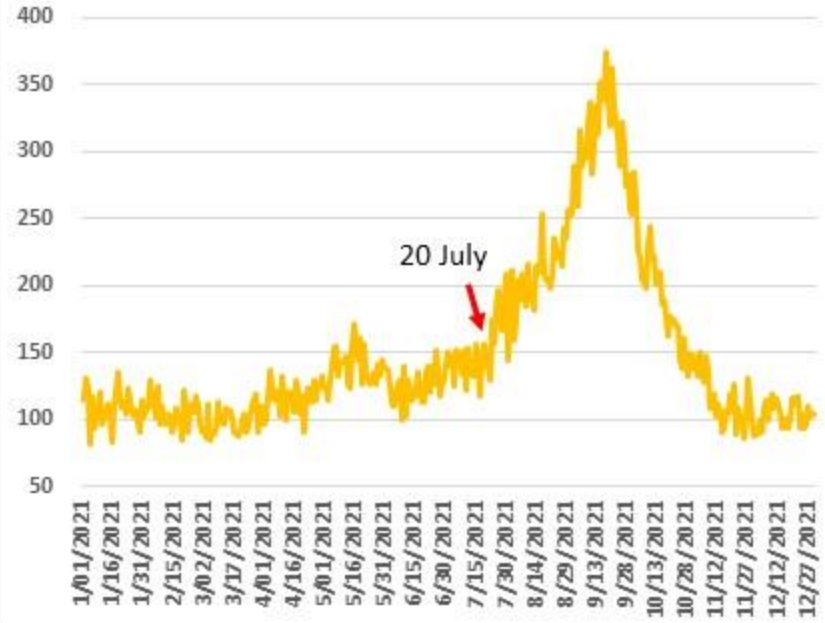
Nasopharyngitis “Cold” onset on 11 June 2022, with fatal outcome.

The report states no follow-up attempts are possible. No further information is expected.

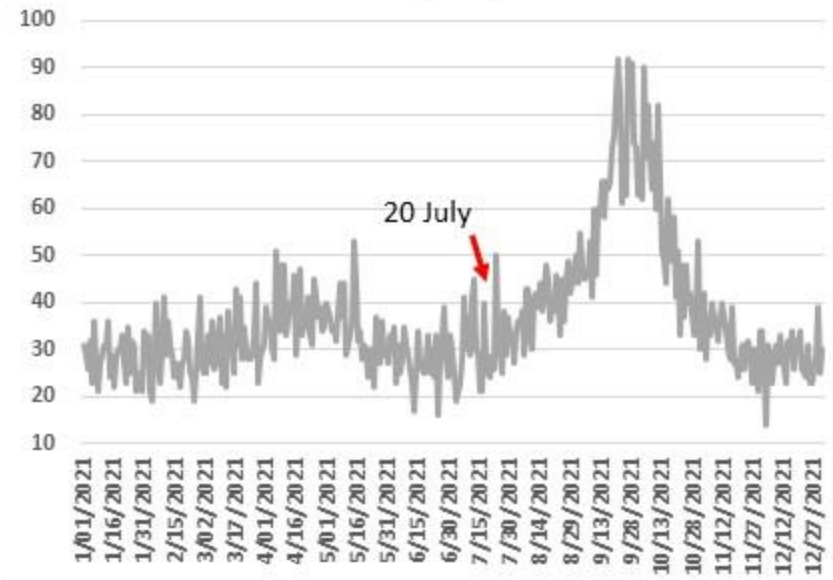
DAILY DEATHS NATIONAL CAPITAL REGION (NCR)



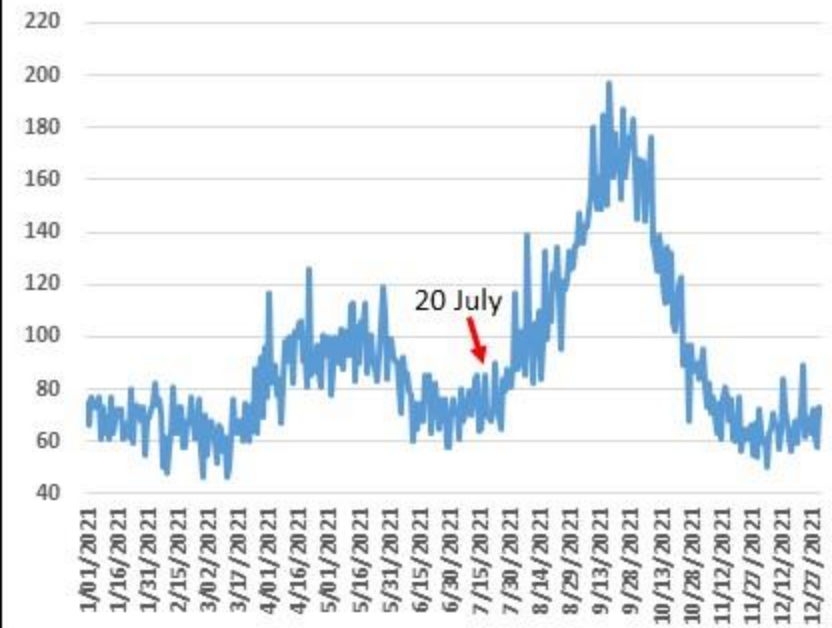
REGION I (ILOCOS REGION)



CORDILLERA ADMINISTRATIVE REGION (CAR)

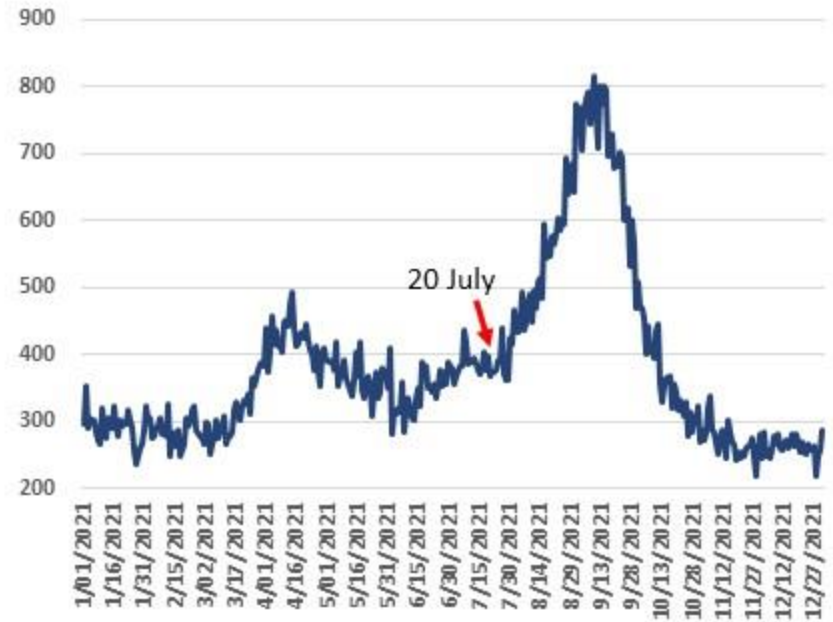


REGION II (CAGAYAN VALLEY)

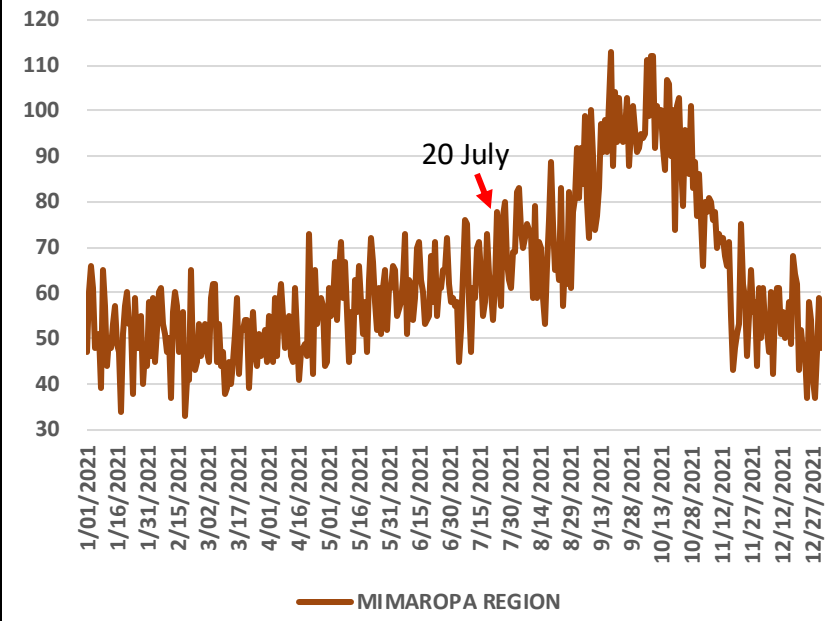


REGION III (CENTRAL LUZON)

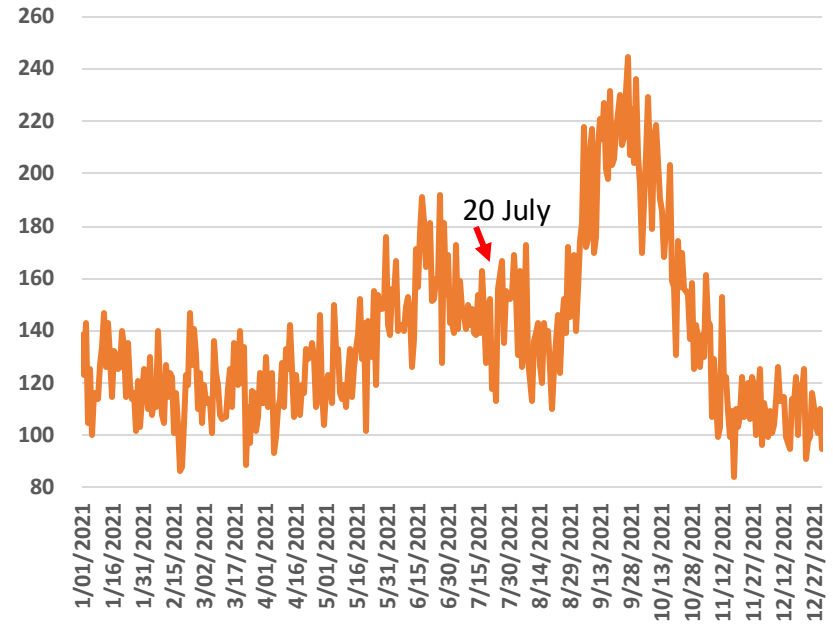
REGION IV-A (CALABARZON)



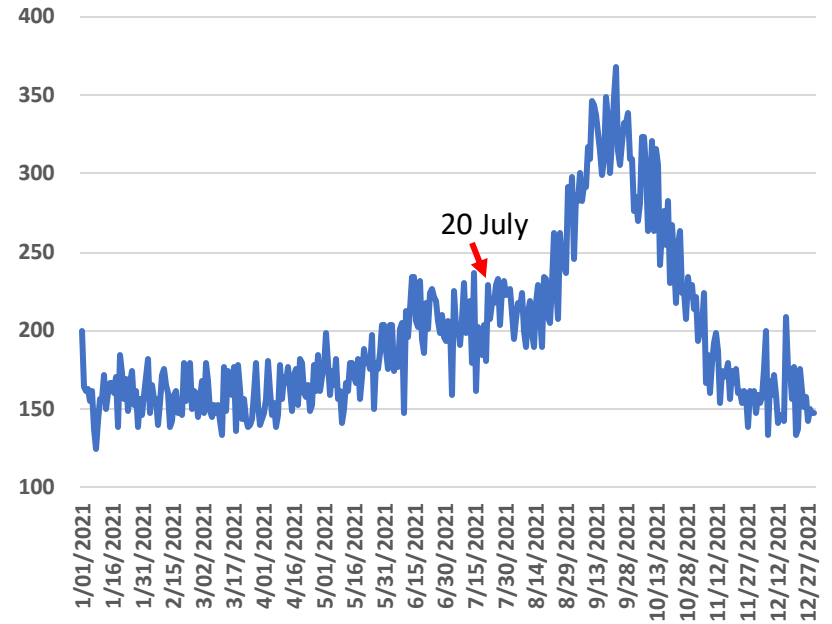
MIMAROPA REGION



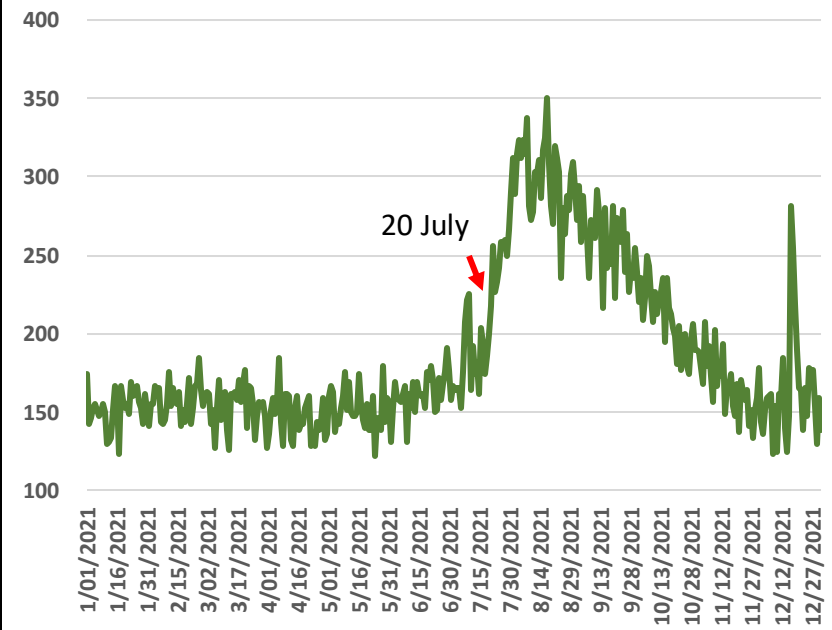
REGION V (BICOL REGION)



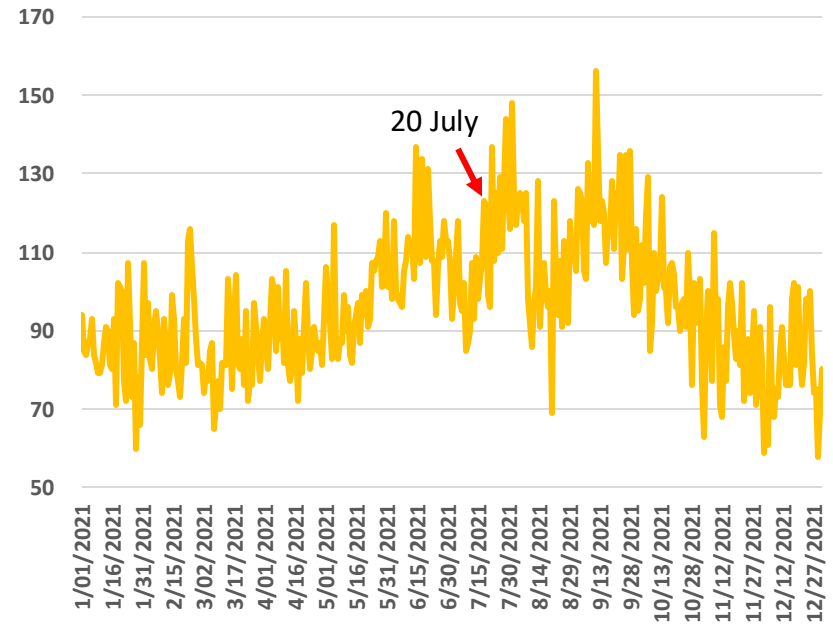
REGION VI (WESTERN VISAYAS)



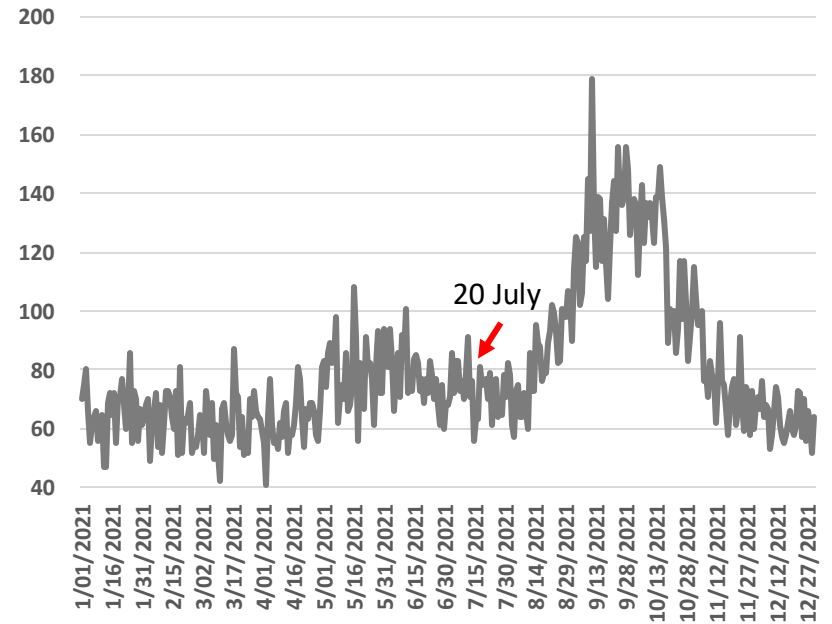
REGION VII (CENTRAL VISAYAS)



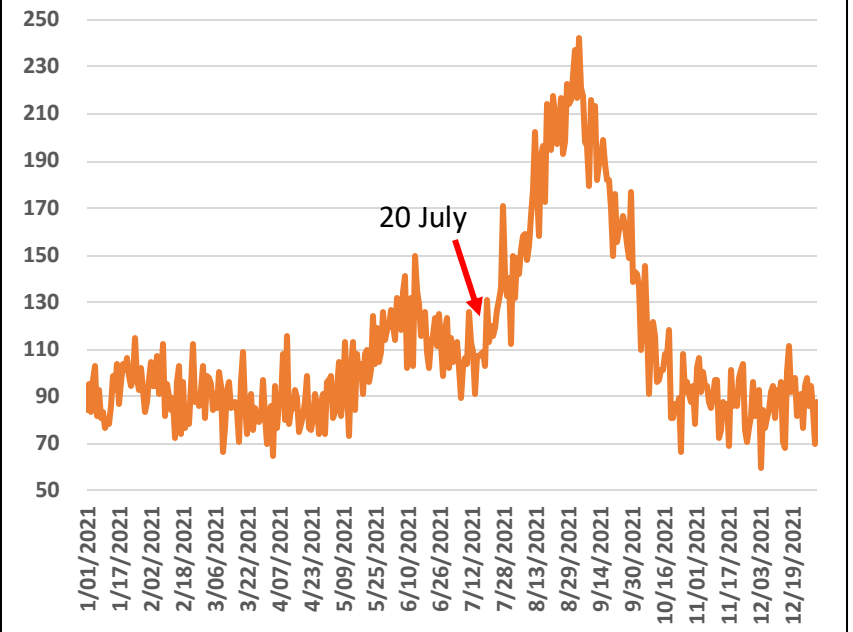
REGION VIII (EASTERN VISAYAS)



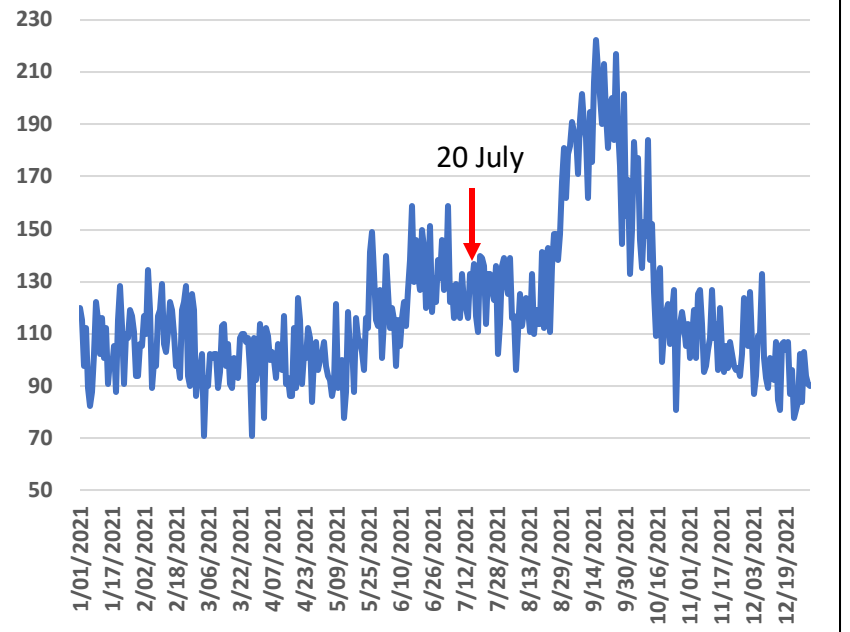
REGION IX (ZAMBOANGA PENINSULA)



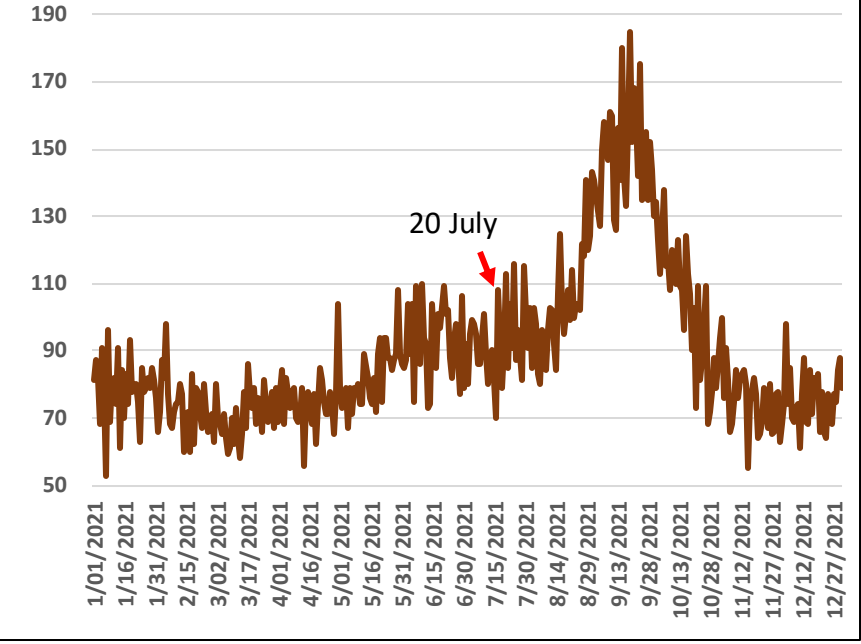
REGION X (NORTHERN MINDANAO)



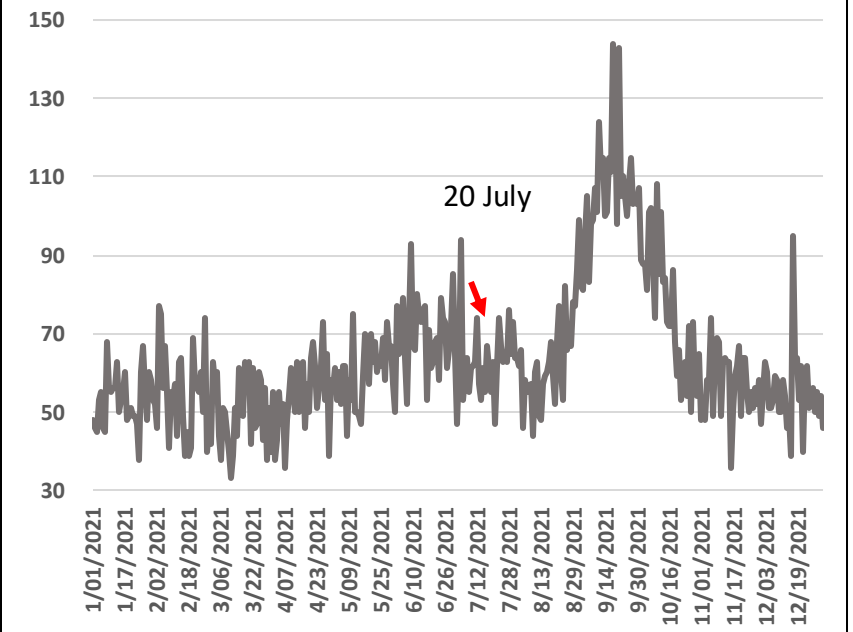
REGION XI (DAVAO REGION)



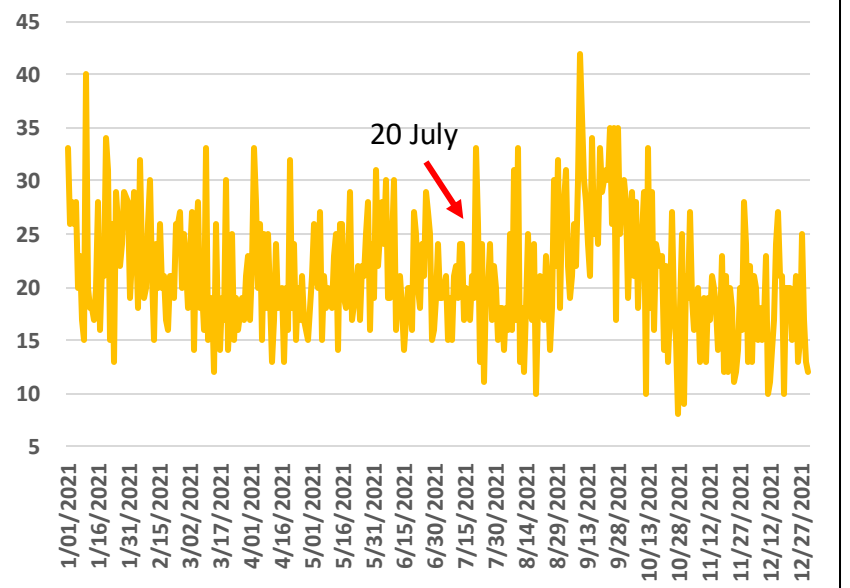
REGION XII (SOCCSKSARGEN)



REGION XIII (Caraga)



BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO (BARMM)



VAERS PHILIPPINE REPORTS – 10 SELECTED ACUTE DEATH CASES

10 Cases of Deaths immediately following Injection. All passed from PH FDA to Manufacturer and then to VAERS.

There are still 7,785 MORE REPORTS if you are interested. INCLUDING 1,148 Reports of People who DIED. You can easily search these at www.openvaers.com or www.vaersaware.com

VAERS ID: 1536924

AGE: 20 | **SEX:** F | **STATE:** FR (Unknown)

Description

NAUSEA; HYPOTENSION; VOMITING; SEIZURE; This spontaneous report received from a health care professional via a Regulatory Authority [PH-PHFDA-300095376] concerned a 20 year old female of an unspecified race and ethnic origin. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 212C21A, and expiry: unknown) dose was not reported, with frequency 1 total administered on 29-JUL-2021 for prophylactic vaccination. No concomitant medications were reported. On 29-JUL-2021, the patient experienced seizure at 05:40, hypotension at 05:45, vomiting at 06:25. Laboratory data included: Blood pressure (NR: not provided) hypotension. On an unspecified date, the patient experienced nausea. On an unspecified date, the patient died from nausea, seizure, hypotension, and vomiting. It was unknown, if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: V0: 20210810013-COVID-19 VACCINE AD26.COV2.S - Seizure, hypotension, and vomiting. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). 20210810013-COVID-19 VACCINE AD26.COV2.S - Nausea. This event is considered unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: NAUSEA; SEIZURE; HYPOTENSION; VOMITING

 # 1536924

Philippines FDA report

20 YO Female – Same day death

Received Janssen 212C21A on 29 July 2021.
Seizure and death on 29 July 2021

The report was serious.
Event is considered unassessable.

Unknown/unclear temporal relationship
(How is it unclear, she died of seizure the same day she was injected!)

Unknown scientific plausibility.

VAERS ID: 1978327

AGE: 14 | **SEX:** F | **STATE:** FR (Unknown)

Description

the patient died of an aneurysm; cerebellar hemorrhage, left cerebellar hemisphere with subdular hematoma and subarachnoid hemorrhage; cerebellar hemorrhage, left cerebellar hemisphere with subdular hematoma and subarachnoid hemorrhage; cerebellar hemorrhage, left cerebellar hemisphere with subdular hematoma and subarachnoid hemorrhage; severe headache; dizzy; vomited; passed out; This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP). The reporter is the parent. A 14 year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), administration date 08Nov2021 (Lot number: PCA0008) at the age of 14 years as dose 1, single for covid-19 immunisation. Relevant medical history included: "g6pd" (unspecified if ongoing). There were no concomitant medications. Past drug history included: None, reaction(s): "Allergy", notes: Name of Drug as Reported: None, Reaction: Allergy. The following information was reported: ANEURYSM (death) with onset 30Nov2021, outcome "fatal", described as "the patient died of an aneurysm"; CEREBELLAR HAEMORRHAGE (death), SUBDURAL HAEMATOMA (death), SUBARACHNOID HAEMORRHAGE (death) all with onset 30Nov2021, outcome "fatal" and all described as "cerebellar hemorrhage, left cerebellar hemisphere with subdular hematoma and subarachnoid hemorrhage"; HEADACHE (death) with onset 29Nov2021 22:00, outcome "fatal", described as "severe headache"; DIZZINESS (death) with onset 29Nov2021 22:00, outcome "fatal", described as "dizzy"; VOMITING (death) with onset 29Nov2021 22:00, outcome "fatal", described as "vomited"; LOSS OF CONSCIOUSNESS (death) with onset 29Nov2021, outcome "fatal", described as "passed out". The events "the patient died of an aneurysm", "cerebellar hemorrhage, left cerebellar hemisphere with subdular hematoma and subarachnoid hemorrhage", "cerebellar hemorrhage, left cerebellar hemisphere with subdular hematoma and subarachnoid hemorrhage", "cerebellar hemorrhage, left cerebellar hemisphere with subdular hematoma and subarachnoid hemorrhage", "severe headache", "dizzy", "vomited" and "passed out" were evaluated at the emergency room visit. The patient underwent the following laboratory tests and procedures: computerised tomogram: unknown results. Therapeutic measures were taken as a result of aneurysm, cerebellar haemorrhage, subdural haematoma, subarachnoid haemorrhage, headache, dizziness, vomiting, loss of consciousness. The patient date of death was 30Nov2021. The reported cause of death was cerebellar haemorrhage, subdural

#1978327

Philippines FDA report

14 YO Female – 3 weeks to death

Received 1st dose of Comirnaty, Lot No. PCA0008 on 8 Nov 2021.

Had no underlying health conditions, no illness, no vaccines or medications in the month prior to death other than the Covid-19 vaccine.

Collapsed with subarachnoid hemorrhage (brain aneurysm) on 29 Nov 2021, died on 30 Nov 2021.

No comment on causality, scientific plausibility, or followup were provided.

VAERS ID: 1987601

AGE: 16 | **SEX:** F | **STATE:** FR (Unknown)

Description

very cold; Vaccination Site Pain; very stiff; Vaccination Site Pain; This is a spontaneous report received from a contactable reporter(s) (Other HCP) from Regulatory Authority. Regulatory number: PH-PHFDA-300125432. A 16 year-old female patient received bnt162b2 (COMIRNATY), intramuscular, administration date 02Dec2021 11:15 (Lot number: PCA0030) at the age of 16 years as dose 2, single and administration date 11Nov2021 (Batch/Lot number: unknown) as dose 1, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: VACCINATION SITE PAIN (death) with onset 02Dec2021 14:30, outcome "fatal", UNRESPONSIVE TO STIMULI (death) with onset 03Dec2021 07:00, outcome "fatal" and all described as "Vaccination Site Pain"; FEELING COLD (non-serious), outcome "unknown", described as "very cold"; MUSCULOSKELETAL STIFFNESS (non-serious) with onset 03Dec2021, outcome "unknown", described as "very stiff". The patient date of death was unknown. The reported cause of death was vaccination site pain, unresponsive to stimuli. It was not reported if an autopsy was performed. As assessed by a pediatrician the patient had not reported adverse reaction or any untoward incident after her fist dose. On 02Dec2021 at around 8PM the patient replied to her aunt as she was okay. On 03Dec2021, at around 7 AM the patient was found with her face down on her bed, unresponsive, very cold and very stiff. " No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reported Cause(s) of Death: Vaccination Site Pain; unresponsive to stimuli

 # 1987601

Philippines FDA report

16 YO Female – Found dead in bed the morning after injection.

Received 2nd dose of Comirnaty, Lot No. PCA0030 on 2 Dec 2021.

Told her aunty she was fine at 8 pm on 2nd Dec as she went to bed.

She was found facedown, cold and stiff in bed on 3rd Dec 2021.

The report states no follow-up attempts are possible. No further information is expected.

VAERS ID: 1625760

AGE: 20 | **SEX:** M | **STATE:** FR (Unknown)

Description

LOSS OF CONSCIOUSNESS; This spontaneous report received from a health care professional via a Regulatory Authority (PHFDA-300098549) concerned a 20 year old male of an unspecified race and ethnic origin. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 205C21A, expiry: unknown) dose was not reported, with frequency time 1 total administered on 04-AUG-2021 for prophylactic vaccination. No concomitant medications were reported. On 04-AUG-2021 at 08:00, the patient died from loss of consciousness was reported. It was unknown, if an autopsy was performed. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0:20210838968 -JANSSEN COVID-19 VACCINE Ad26.COV2.S- loss of consciousness (fatal outcome)-This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: LOSS OF CONSCIOUSNESS

 # 1625760

Philippines FDA report

20 YO Male – Same day death

Received Janssen 205C21A on 4 August 2021.

Lost of consciousness and death on 4 August 2021

The report was serious.

Event is considered unassessable.

Suggestive temporal relationship

Unknown scientific plausibility.

VAERS ID: 1828171

AGE: 19 | **SEX:** F | **STATE:** FR (Unknown)

Description

DIFFICULTY OF BREATHING; This spontaneous report received from a health care professional via a Regulatory Authority [PHIFDA, PH-PHFDA-300112747] concerned a 19-year-old female patient of an unspecified race and ethnic origin. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: unknown and expiry: unknown) dose was not reported, 1 total, administered on 08-OCT-2021 for an unknown indication. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On 08-OCT-2021, the patient experienced difficulty of breathing. On an unspecified date, the patient died from difficulty of breathing. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of difficulty of breathing was reported as fatal. This report was serious (Death).; Sender's Comments: V0: 20211055892-COVID-19 VACCINE AD26.COV2.S- difficulty of breathing. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: DIFFICULTY OF BREATHING

 # 1828171

Philippines FDA report

19 YO Female – Same Day Death

Received Janssen unknown batch no. on 8 October 2021.

Difficulty breathing and death on 8 October 2021.

The batch was not reported, and no follow-up will be requested.

The report was serious.
Event is considered unassessable.
Suggestive temporal relationship
Unknown scientific plausibility.

VAERS ID: 1623001

AGE: 77 | **SEX:** M | **STATE:** FR (Unknown)

Description

Fever; Chills; Fatigue; This spontaneous report received from a health care professional via a Regulatory Authority [PHFDA-300098515] concerned a 77 year old male. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, and batch number: 213C21A expiry: UNKNOWN) dose was not reported, administered on 27-JUL-2021 for prophylactic vaccination. No concomitant medications were reported. On 27-JUL-2021, after vaccination at 8:00pm, the patient experienced mild fever and headache. On 27-JUL-2021, the patient also experienced chills and fatigue. On 29-JUL-2021, the patient experienced events of vomiting, diarrhea and nausea. On 01-AUG-2021, The patient daughter consulted in a private doctor via telephone and got all prescription. On 02-Aug-2021, the patient was stable but still have body weakness. On 03-AUG-2021, the patient was stable until the patient experienced hiccups on and off that last the whole night so the patient's daughter called their private doctor and advised them to bring the patient to the nearest hospital, they went to 4 hospitals but not admitted because of full capacity, so they decided to bring the patient in their home until the patient died. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. On an unspecified date of AUG-2021, the patient died from fever, chills and fatigue. It was unspecified if an autopsy was performed. This report was serious (Death).; Sender's Comments: 20210839072- covid-19 vaccine ad26.cov2.s -Fever, chills & fatigue. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: FEVER; CHILLS; FATIGUE

 # 1623001

Philippines FDA report

77 YO Male – 7 Days to Death

Received Janssen batch 213C21A on 27 July 2021.

- Mild headache and fever on 27 July.
- 29 July experienced vomiting, diarrhea and nausea.
- 1 Aug daughter consulted a doctor.
- 3 Aug hiccups and went to hospital.
- 4 Aug patient died at home, no available hospital bed in 4 hospitals visited.

The report was serious.
Event is considered unassessable.
Compatible temporal relationship
Unknown scientific plausibility.

VAERS ID: 2448891

AGE: 54 | **SEX:** M | **STATE:** FR (Unknown)

Description

cardiovascular accident; This is a spontaneous report received from a contactable reporter(s) (Other HCP) from Regulatory Authority. Regulatory number: PH-PHFDA-300155182. A 54-year-old male patient received BNT162b2 (COMIRNATY), on 26Aug2022 at 13:34 as dose 3 (booster), single (Lot number: PCB0015, Expiration Date: 22Jul2022) at the age of 54 years intramuscular, in left arm for covid-19 immunization. The patient's relevant medical history and concomitant medications were not reported. Vaccination history included: Covid-19 vaccine (primary immunization series, Dose 1, manufacturer unknown), for COVID-19 immunization; Covid-19 vaccine (primary immunization series, Dose 2, manufacturer unknown), for COVID-19 immunization. The following information was reported: CARDIOVASCULAR DISORDER (death) with onset 26Aug2022 at 14:05, outcome "fatal", described as "cardiovascular accident". The patient underwent the following laboratory tests and procedures: Blood pressure measurement: (26Aug2022) 130/70; (26Aug2022) 140/80, notes: before vaccination; Body temperature: (26Aug2022) 36.9; (26Aug2022) 36.6, notes: before vaccination; Heart rate: (26Aug2022) 78; (26Aug2022) 95, notes: before vaccination; Oxygen saturation: (26Aug2022) 95; (26Aug2022) 96, notes: before vaccination; Respiratory rate: (26Aug2022) 19; (26Aug2022) 19, notes: before vaccination; Weight: (26Aug2022) 42. Therapeutic measures were taken as a result of cardiovascular disorder. The patient date of death was 26Aug2022. Reported cause of death: "cardiovascular accident". Reviving the patient was continuously done. Hooked to oxygen, intravenous therapy started, 1 ampule epinephrine was given, at around 2:30 PM with no response noted, the patient was declared dead. Clinical course: The client came to the vaccination site in normal condition on August 26, 2022. He sat with other clients in the waiting area waiting for his name to be called. He was No. 19 on the list. After registering his name, he was counseled and taken vital signs with V/S: (BP-140/80, T-36.6, PR-95, RR-19, 02sat- 96, Wt-42). He was extremely willing to have a booster shot because of planning to travel for his son's graduation. After that, he was examined by a doctor for clearance to be vaccinated. He had his first booster dose at 1:34 pm, vaccinated with Pfizer vaccine with Lot# PCB0015 Exp date of July 2022 with an extended shelf life of October 2022 as per dated June 16, 2022. After he was vaccinated, he was advised to take a rest and wait for about 15mins or until his name will be called. His Post-vaccination vital signs that were taken at around 1:49 pm: were BP-130/70, T-36.9, PR-78, RR- 19, and SPO2-95. He was advised to take it slowly going back to their home as the weather was very sunny at that time of the day. At 2:00 pm the client went home by foot together with his nephew. 5minutes walk from the vaccination site, the client complained to his nephew that he was dizzy but upon turning his nephew's head, he was already on the ground. His nephew mentioned that the client fell backward. The client was rescued at 2:05 pm. BP cannot be heard, pulsation was palpatory. CPR did on-site and then transferred to a health station. Reviving the patient was continuously done. Hooked to oxygen, intravenous therapy

 # 2448891

Philippines FDA report

54 YO Male – Died as he was walking home, just outside the Vax Center 30 minutes after injection.

Received Dose 3 Booster, Comirnaty batch PCB0015 on 26 August 2021, in order to be able to attend his son's graduation.

Died from "cardiovascular accident"

Cause of death "CVA" and "Fall".

VAERS ID: 1640654

AGE: 51 | **SEX:** F | **STATE:** FR (Unknown)

Description

Headache; This spontaneous report received from a health care professional via a Regulatory Authority [PHFDA-300100054] concerned a 51 year old female. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 213C21A, and expiry: UNKNOWN) dose was not reported, 1 total administered on 12-AUG-2021 for prophylactic vaccination. No concomitant medications were reported. On 13-AUG-2021, at 09:00 hours the patient experienced severe headache and sudden loss of consciousness. On an unspecified date in AUG-2021, the patient died from headache. It was unknown whether an autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: 20210852698-COVID-19 VACCINE AD26.COV2.S-Headache. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: HEADACHE

 # 1640654

Philippines FDA report

51 YO Female – Died 1 day after injection.

Received Janssen batch 213C21A on 12 August 2021.

At 9 am on 13th August 2021 experienced headache and sudden loss of consciousness. "Patient died from headache".

Suggestive temporal relationship. Has unknown scientific plausibility. Is considered unassessable.

VAERS ID: 1676861

AGE: | **SEX:** M | **STATE:** FR (Unknown)

Description

MI; ELEVATED BLOOD PRESSURE; This spontaneous report received from a health care professional via a Regulatory Authority [PHIFDA, PH-PHFDA-300102827] concerned a 74-year-old male of an unspecified race and ethnic origin. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 212C21A expiry: unknown) dose was not reported, 1 total administered on 04-AUG-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-AUG-2021 at 12:00 hours, the patient experienced myocardial infarction (MI) and elevated blood pressure. Laboratory data included: Blood pressure (NR: not provided) elevated. On an unspecified date, the patient died from myocardial infarction and elevated blood pressure. It was unspecified if an autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of myocardial infarction and elevated blood pressure was fatal. This report was serious (Death).; Sender's Comments: V0: 20210904733-covid-19 vaccine ad26.cov2.s- Myocardial Infarction, Elevated blood pressure. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: ELEVATED BLOOD PRESSURE; MI.

 # 1640654

Philippines FDA report

74 YO Male – Died 3 days after injection.

Received Janssen batch 212C21A on 4 August 2021.

At 12 noon on 7th August 2021 the Patient died from myocardial infarction / elevated blood pressure.

Suggestive temporal relationship. Has unknown scientific plausibility. Is considered unassessable.