VAERS Vaccine Adverse Event Reporting System

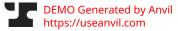
Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed.

www.vaers.nns.gov	Patient identi	dentity is kept confidential. Instructions are provided on the last two pages.									
INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)											
1. Patient name: (first) Robin (last) Smith			nter medications, dietary supplements, or								
Street address: 123 Main St			n at the time of vaccination: sit amet, consectetur								
City: San Francisco State: CA County: 123 M			do eiusmod tempor.								
ZIP code: 94106 Phone: (555) 444-3333 Email: testy (559) 444-3333	₩98.€8m	10. Allergies to medications,	ood, or other products:								
2. Date of birth: (mm/dd/yyyy) 12/25/2025	le		sit amet, consectetur								
4. Date and time of vaccination: (mm/dd/yyyy) 12/25/2025 🏥 Time: \	Vaccin- XAM	11. Other illnesses at the time	do eiusmod tempor. e of vaccination and up to one month prior:								
5. Date and time adverse event started: (mm/dd/yyyy) 12/25/2025 🛗 Time: j	Lorem ipsum dolor sit amet, consectetur										
6. Age at vaccination:2,34 Eeans 2,34 Months 7. Today's date: (mm/dd/yyyy) 12)	Atioerse Am DMP2025 mm	adipiscing elit, sed 12. Chronic or long-standing h	do eiusmod tempor. ealth conditions:								
8. Pregnant at time of vaccination?: 🖾 Yes 🗆 No 🗆 Unknown		Lorem ipsum dolor sit amet, consectetur									
(If yes, describe the event, any pregnancy complications, and estimated due date if known in	다(m c 8)	adipiscing elit, sed do eiusmod tempor.									
INFORMATION ABOUT THE PERSON COMPLETING THIS FORM	INFORM	IATION AROUT THE FACILITY	WHERE VACCINE WAS GIVEN								
13. Form completed by: (name) Robin W. Smith	15. Facility/clinic		16. Type of facility: (Check one)								
	Facility/clinic name		Doctor's office, urgent care, or hospital								
Relation to patient: 🖾 Healthcare professional/staff 🗆 Patient (yourself) □ Parent/guardian/caregiver □ Other: Form	Fax: (555) 44		☐ Pharmacy or store								
			☐ Workplace clinic								
Street address: 123 Main St, San 🖾 Check if same as item 1		t, San Francisco CA,	□ Public health clinic								
City: 123 Matrascissen CA, 94 state: 123 ZIP code descripti-		t, San Francisco CA,	☐ Nursing home or senior living facility								
Phone: F(395)S494-333310 mail: test Main test Main	r:941063 Ma	in St, San Francisco	☐ School or student health clinic								
14. Best doctor/healthcare Name: Robin W. Smith Francis-	•	06 ZIP code: 123 Main	□ Other: Facility type -								
professional to contact about the adverse event: Phone: (555) 444-3333 Ext: Best		ain St, San Francisco									
CA. 94986-	₹3 334	106 Francisco									
9 WHICH VACCINES WERE GIVEN											
17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was give		-	e Continuation Page if needed Dose number								
Vaccine (type and brand name) Vaccine 1 - Type and brand name Vaccine profidar		Lot number Route Vaccine 1 - Vaccin	Body site in series ne 1 - Vaccine 1 Vaccine								
Vaccine 2 - Type and brand name Vaccine 2 Mar	nufacturer	Vassine 1 - Vassi	ne 2 - Vaccine 2 - Vaccine								
Vaccine 3 - Type and brand name Vaccine 3 - Mar Vaccine 4 - Type and brand name Vaccine 4 - Type and brand name	nufacturer	Vaffilmber Kattle Vaffilmber Kattle Vaffilmber Kattle									
18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs	s, time course, etc.)	Lot number Rouse Lot n21mResult or putcome	of adverse event(s); Gheek all the shift s								
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tempor.			epartment or urgent care in series								
		mber of days (if known) 12,									
	Hospital name: Hospital name 345										
	City: 123 Ma										
	Prolongation of ext	ing Hospitalization St, San ng existing hospitalization) Francisco									
llsa C	Continuation Page if		ess (immediate risk of death from the event)								
19. Medical tests and laboratory results related to the adverse event(s): (include dates	☐ Disability or perma	0.44.00									
Lorem ipsum dolor sit amet, consectetur adipiscing elit	, sed do eius	mod Patient died – Date	0.0								
tempor.	Continuation Page if		25,05,00-10								
	□ Unknown	□ None of the above	25 25								
			20								
	IAL INFORMATION		5								
22. Any other vaccines received within one month prior to the date listed in item 4: Vaccine (type and brand name) Manufacturer	Lot number	Use Continuation Route B	Page if needed Dose number Date ody site in series Given								
Prior vaccine 1 - Type and brand Prior vaccine 1 -	Prior		Prior Prior 12/25/								
Prior vaccine 2 - Type and brand Prior vaccine 2 -	₽aiQfine	1 - Väletine 1 - V	Drion 4 Drion 12425/								
49a 所表 Lorem ipsum dolor sit amet, consectetur adiniscir	s, describe adverse ev na elit sed di	ent, patient age at yaccipation, van Der De Elusmod Tempor	cination dates, vaccine dynamia brandnami)								
Againe at the patient ever had an adverse event following any previous vaccine 1 - Vaccine											
(Check all that apply)											
25. Patient's ethnicity: ☑ Hispanic or Latino ☐ Not Hispanic or Latino ☐		nmuniz. proj. report number: (He									
			project report								
COMPLETE ONLY FOR U.S. MILITARY/DEF	PARTMENT OF DE	FENSE (DoD) RELATED REPO	rts number								
27. Status at vaccination: ☒ Active duty ☐ Reserve ☐ National Guard ☐ Bel	neficiary 🗆 Other	: Military 28. Vacci	nated at Military/DoD site: ☒ Yes □ No								

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Enter all vaccines given on the dat	e listed in item 4 (continued):					Dose numbe
cine (type and brand name)		Manufacturer		umber	Route	Body site	in series
accine 1 - Type and Bra	nd Name	Vaccine 1 - Manu Vaccine 2 - Manu	ufacturer Vac	ccine 1 -	Vaccine 1 -	Vaccine 1 -	Vaccine
iccine 2 - Type and Bra accine 3 - Type and Bra accine 4 - Type and Bra	nd Name	Vaccine 3 - Manu	ufacturer vac	Number	Macaine 2 -	Baccine 3 -	Agene
ccine 4 - Type and Bra	nd Name	Vaccine 4 - Manu	ufacturer Va	Number Number Number	Kacrine 2 - Racrine 3 - Racrine 4 -	Bacyingta - Bacyingta - Bacyingta -	Yacsine Yacsine Yacsine
Any other vaccines received withi	n one month prior t	to the date listed in item 4 (con	tinued): Lot	Number	Route	B Dbye Silimber	
cine (type and brand name)		Manufacturer	Lot number	Route	Body site	in series	Muggiba
her Vaccine 1 - Type a	nd Brand	Other Vaccine 1 -	Other	Other	Other	Other	in 867 fe
her Vaccine 2 - Type al her Vaccine 3 - Type al her Vaccine 4 - Type al her Vaccine 5 - Type al her Vaccine 6 - Type al	nd Brand nd Brand	Mineritature 2 - Otherwacune 3 -	Valene 1 -	Otherne Capene	1 - Valleine	1 - Valeine	12525
her Vaccine 4 - Type a	nd Brand	Otherfyacciae 4 -	59 Sumper	· Margare	5 5	te 69120se	12525
heğ Vaccine 5 - Type a	nd Brand	Other Kergiae 2 - Vijner Kergiae 3 - Vijner Kergiae 4 - Vijner Kergiae 5 - Vijner Kergiae 6 -	Odelfie 1 - Karaman Ka	- Kalena	4 - 731216	1 - Otherne 13 - Kristise 14 - Kristise 15 - Kristise 16 - Kristise 16 - Kristise	1655 1655 1655
neg vaccine 6 - Type al	nd Brand	Minertyacchae 6 -	TOURINGIA	1/Our	5 - 5000		
the space below to provide any ac			Vat Niumber	Noute	6 - Backing	te - Music	2025
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						in Series	;

FORM FDA VAERS 2.0 (03/25)





COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile/.
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an
 email to info@vaers.org.
- Fill out the VAERS form as completely as possible and use the Continuation Page if needed. Use a separate VAERS form for
 each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether
 the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.html for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who
 administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS

Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed.

- Items 4 and 5: Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- Item 6: If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (item 2) and date and time of vaccination (item 4).
- Item 8: If the patient who received the vaccine was pregnant at time of vaccination, select "Yes" and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- Item 9: List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/alternative medicines being taken by the patient when the vaccine(s) was given.
- Item 10: List any allergies the patient has to medications, foods, or other products.
- Item 11: List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- Item 12: List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- Item 13: List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
- Item 14: List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- Item 15: Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- Item 16: Select the option that best describes the type of facility where the vaccine(s) was given.

• Item 17: Include only vaccines given on the date provided in item 4. The vaccine route options include:

 Injection/shot (intramuscular, subcutaneous, intradermal, jet injection, and unknown) By mouth/oral

· Other (specify)

• In nose/intranasal

• Unknown

For body site, the options include:

• Right arm

Right thigh

Nose

Other (specify)

Left arm

· Left thigh

Mouth

Unknown

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• Arm (side unknown)

Thigh (side unknown)

For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose number in series."

- Item 18: Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- Item 19: List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- Item 20: Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- Item 21: Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- Item 22: List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- Item 23: Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of
 vaccination, vaccine type, and brand name.
- Item 24: Check all races that apply.
- Item 25: Check the single best answer for ethnicity.
- Item 26: For health department use only.
- Items 27 and 28: Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

GENERAL INFORMATION

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- VAERS (<u>www.vaers.hhs.gov</u>) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.

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- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

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