

VAERS DATA USE GUIDE

Contents

| | |
|---|----|
| 1. Important Information About VAERS | 1 |
| 2. Brief Description of VAERS | 2 |
| 3. VAERS Data Should be Interpreted with Caution | 3 |
| 4. Description of Data Files | 4 |
| 4.1 VAERSDATA.CSV | 6 |
| 4.2 VAERSVAX.CSV | 8 |
| 4.3 VAERSSYMPTOMS.CSV | 8 |
| 5. Definitions of Terms Used in Data Files | 9 |
| 5.1 VAERSDATA.CSV | 9 |
| 5.2 VAERSVAX.CSV | 12 |
| 5.3 VAERSSYMPTOMS.CSV | 16 |
| 7. Downloadable VAERS Data Sets Disclaimer | 17 |

1. Important Information About VAERS

The Vaccine Adverse Event Reporting System (VAERS) was created by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to receive reports about adverse events that may be associated with vaccines. No prescription drug or biological product, such as a vaccine, is completely free from side effects. Vaccines protect many people from dangerous illnesses, but vaccines, like drugs, can cause side effects, a small percentage of which may be serious. VAERS is used to continually monitor reports to determine whether any vaccine or vaccine lot has a higher than expected rate of events.

Doctors and other vaccine providers are encouraged to report adverse events, even if they are not certain that the vaccination was the cause. Since it is difficult to distinguish a coincidental event from one truly caused by a vaccine, the VAERS database will contain events of both types.

In addition, it is often the case that more than one vaccine was administered, making it difficult to know to which of the vaccines the event might be attributed. In analyzing individual reports, researchers examine the medical information about the event, and obtain more specific information from the reporters whenever necessary. Patterns of reporting associated with vaccines and vaccine lots are also analyzed.

About 85-90% of vaccine adverse event reports concern relatively minor events, such as fevers or redness and swelling at the injection site. The remaining reports (less than 15%) describe serious events, such as hospitalizations, life-threatening illnesses, or deaths. The reports of serious events are of greatest concern and receive the most careful scrutiny by VAERS staff.

VAERS researchers apply procedures and methods of analysis to help us closely monitor the safety of vaccines. When a concern arises, action is taken. We hope that this brief explanation of the factors associated with vaccines and adverse events will assist you in understanding the data you are viewing.

Requests for additional information should be addressed to:

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

2. Brief Description of VAERS

The U.S. Department of Health and Human Services (DHHS) established VAERS, which is co-administered by the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC), to accept all reports of suspected adverse events, in all age groups, after the administration of any U.S. licensed vaccine. On November 1, 1990 VAERS replaced CDC's Monitoring System for Adverse Events Following Immunization (MSAEFI) for public sector reporting and FDA's Spontaneous Reporting System for private sector and manufacturer reporting. The primary purpose for maintaining the database is to serve as an early warning or signaling system for adverse events not detected during pre-market testing. In addition, the National Childhood Vaccine Injury Act of 1986 (NCVIA) requires health care providers and vaccine manufacturers to report to the DHHS specific adverse events following the administration of those vaccines outlined in the Act.

All reports are coded and entered to the VAERS database. The adverse events described in each report were coded utilizing the FDA's Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART) from November 1990 until 1/16/2007. On 1/17/2007 the VAERS coding system was converted to an international coding system that is used worldwide. This system is called the Medical Dictionary for Regulatory Activities (MedDRA). The MedDRA coding system uses key words representing the medical condition(s) described in the case report and converts them to standardized codes. The MedDRA codes provided in the dataset are called the "Preferred Terms"; there are more than 17,000 Preferred

Term codes in the MedDRA system. The MedDRA coding system is more detailed than the COSTART system. Therefore, the MedDRA system is not only standardized for international use, but also able to code medical terms in a more exacting manner than the COSTART system design. All the COSTART codes that were used in the VAERS data prior to January 17, 2007 have been converted to MedDRA coding terms. The MedDRA coding system is updated semi-annually, and terms may be added, deleted, or changed with each new release. VAERS reports are coded using the MedDRA version in effect at the time the codes are entered; therefore, different terms may be used to describe similar events in reports coded at different times.

If you desire more information about MedDRA, please visit the following web site:
<http://www.meddramsso.com/>

A new version of the VAERS form, **VAERS 2**, was released in July 2017. Some fields in the **VAERS 1** form were modified and others discontinued. We currently accept both versions of the form and identify them in the public data files.

3. VAERS Data Should be Interpreted with Caution

- VAERS data are from a passive surveillance system and represent unverified reports of health events that occur after vaccination. Such data are subject to limitations of under-reporting, simultaneous administration of multiple vaccine antigens, reporting bias, and lack of incidence rates in unvaccinated comparison groups.
- When reporting and evaluating data from VAERS, it is important to note that for any reported event, no cause and effect relationship has been established. The event may have been related to an underlying disease or condition, to medications being taken concurrently, or may have occurred by chance.
- A report often involves more than one vaccine and may involve more than one reported adverse event.
- In certain cases, VAERS requests additional information from reporters, healthcare providers and other parties.
- When multiple reports of a single case or event are received, only the first report received is included in the publicly accessible dataset. Subsequent reports may contain additional or conflicting data, and there is no assurance that the data provided in the public dataset is the most accurate or current available.
- A given report may meet more than one criterion for classification as "serious."
- Accumulations of events reported to a passive surveillance system do not allow incidence rate calculations due to the generally unknown extent of under-reporting as well as lack of information on the number of people being vaccinated.

Disclaimer: Please note that VAERS staff follow-up on all serious and other selected adverse event reports to obtain additional medical, laboratory, and/or autopsy records to help understand the concern raised. However, in general, coding terms in VAERS do not change based on the information received during the follow-up process. VAERS data should be used with caution as numbers and conditions do not reflect data collected during follow-up. Note that the inclusion of events in VAERS data does not infer causality.

4. Description of Data Files

VAERS data is accessible by two mechanisms: by downloading raw data in comma-separated value (CSV) files for import into a database, spreadsheet, or text editing program, or by use of the CDC WONDER online search tool.

The downloadable VAERS public data set consists of three separate data files. These files are provided by calendar year beginning with the first VAERS reports reported in the latter part of 1990. The public data set is updated periodically, and the date of the update is referenced on the website. We currently accept the 2 versions of the VAERS form; fields in the **VAERS 2** form are referred to as Items and Boxes in the **VAERS 1** version. Comma-separated-value (CSV) files are industry-standard text files compatible with most of the major database or statistical analysis products on the market. Each data set is available for download in 2 formats: as three separate CSV files or as a compressed Zip file that contains the three CSV files listed for the specific year. Please note that for security reasons we require a CAPTCHA password to be entered by the user during download.

CDC WONDER, developed by the Centers for Disease Control and Prevention (CDC), is an easy-to-use menu-driven system requiring no computer expertise or special software that provides access to a wide array of public health information. With CDC WONDER you can produce tables, maps, charts, and data extracts showing the incidence of vaccine adverse events, and select specific event, vaccine, and demographic criteria to produce cross-tabulated incidence measures. You can also limit and index your data by several variables. VAERS data is available on CDC WONDER at <http://wonder.cdc.gov/vaers.html>. Additional information about CDC WONDER is available at <http://wonder.cdc.gov/wonder/help/vaers.html>.

For each section below, each row in a table refers to a separate field (or column) in the data. The "Header" provides the field name or column "header." "Type" describes the type of data contained in the data field. The information in parenthesis specifies the data format or number of digits or characters contained in the field. There are three data types:

1. NUM = numeric data
2. CHAR = text or "character" data
3. DATE = date fields in mm/dd/yy format

No data is provided that would allow identification of any individuals associated with these reports. Each field, each row, in the table pertains to information recorded in (or derived from) the various numbered sections of the VAERS form except when otherwise specified.

4.1 VAERSDATA.CSV

The following table provides a detailed description of the data provided in each field of the VAERSDATA.CSV file. The first two fields in this table are the only fields of the dataset not derived from the VAERS form. As we currently accept 2 versions of the VAERS form, the corresponding mapping is included to facilitate review. The fields are listed in the order they appear on the file not on the VAERS form

| Header | Type | VAERS 2 Form | VAERS 1 Form | Description of Contents |
|--------------|--------------|--------------|--------------|--|
| VAERS_ID | Num(6) | ✓ | ✓ | VAERS Identification Number |
| RECVDATE | Date | ✓ | ✓ | Date report was received |
| STATE | Char(2) | Derived | Box 1 | State |
| AGE_YRS | Num(xxx.x) | Item 6 | Box 4 | Age in Years |
| CAGE_YR | Num(xxx) | Derived | Derived | Calculated age of patient in years |
| CAGE_MO | Num(.x or 1) | Derived | Derived | Calculated age of patient in months |
| SEX | Char(1) | Item 3 | Box 5 | Sex |
| RPT_DATE | Date | Discontinued | Box 6 | Date Form Completed |
| SYMPTOM_TEXT | Char(32,000) | Item 18 | Box 7 | Reported symptom text |
| DIED | Char(1) | Item 21 | Box 8 | Died |
| DATEDIED | Date | Item 21 | Box 8 | Date of Death |
| L_THREAT | Char(1) | Item 21 | Box 8 | Life-Threatening Illness |
| ER_VISIT | Char(1) | Discontinued | Box 8 | Emergency Room or Doctor Visit |
| HOSPITAL | Char(1) | Item 21 | Box 8 | Hospitalized |
| HOSPDAYS | Num(3) | Item 21 | Box 8 | Number of days Hospitalized |
| X_STAY | Char(1) | Item 21 | Box 8 | Prolongation of Existing Hospitalization |
| DISABLE | Char(1) | Item 21 | Box 8 | Disability |
| RECOVD | Char(1) | Item 20 | Box 9 | Recovered |
| VAX_DATE | Date | Item 4 | Box 10 | Vaccination Date |
| ONSET_DATE | Date | Item 5 | Box 11 | Adverse Event Onset Date |
| NUMDAYS | Num(5) | Derived | Derived | Number of days (Onset date - Vax. Date) |



| Header | Type | VAERS 2 Form | VAERS 1 Form | Description of Contents |
|--------------|--------------|--------------|--------------|---|
| LAB_DATA | Char(32,000) | Item 19 | Box 12 | Diagnostic laboratory data |
| V_ADMINBY | Char(3) | Item 16 | Box 15 | Type of facility where vaccine was administered |
| V_FUNDBY | Char(3) | Discontinued | Box 16 | Type of funds used to purchase vaccines |
| OTHER_MEDS | Char(240) | Item 9 | Box 17 | Other Medications |
| CUR_ILL | Char(32,000) | Item 11 | Box 18 | Illnesses at time of vaccination |
| HISTORY | Char(32,000) | Item 12 | Box 19 | Chronic or long-standing health conditions |
| PRIOR_VAX | Char(128) | Item 23 | Box 21 | Prior Vaccination Event information |
| SPLTTYPE | Char(25) | Item 26 | Box 24 | Manufacturer/Immunization Project Report Number |
| FORM_VERS | Num(1) | | | VAERS form version 1 or 2 |
| TODAYS_DATE | Date | Item 7 | X | Date Form Completed |
| BIRTH_DEFECT | Char(1) | Item 21 | X | Congenital anomaly or birth defect |
| OFC_VISIT | Char(1) | Item 21 | X | Doctor or other healthcare provider office/clinic visit |
| ER_ED_VISIT | Char(1) | Item 21 | X | Emergency room/department or urgent care |
| ALLERGIES | Char(32,000) | Item 10 | X | Allergies to medications, food, or other products |

* The summation of the two variables CAGE_YR and CAGE_MO provide the calculated age of a person. For example, if CAGE_YR=1 and CAGE_MO=.5 then the age of the individual is 1.5 years or 1 year 6 months.

4.2 VAERSVAX.CSV

The fields described in this table provide the remaining vaccine information (e.g., vaccine name, manufacturer, lot number, route, site, and number of previous doses administered), for each of the vaccines listed in Item 17 (VAERS 2 form) or Box 13 (VAERS 1.0 form). The **VAERS 1** field VAX_DOSE was discontinued in the **VAERS 2** form; when a value exists, a 1 is added to equate to the VAX_DOSE_SERIES field. There is a matching record in this file with the VAERSDATA file identified by VAERS_ID.

| Header | Type | Description of Contents |
|-----------------|-----------|------------------------------|
| VAERS_ID | Num(6) | VAERS Identification Number |
| VAX_TYPE | Char(15) | Administered Vaccine Type |
| VAX_MANU | Char(40) | Vaccine Manufacturer |
| VAX_LOT | Char(15) | Manufacturer's Vaccine Lot |
| VAX_DOSE_SERIES | Char (3) | Number of doses administered |
| VAX_ROUTE | Char(6) | Vaccination Route |
| VAX_SITE | Char(6) | Vaccination Site |
| VAX_NAME | Char(100) | Vaccination Name |

4.3 VAERSSYMPTOMS.CSV

The fields described in this table provide the adverse event coded terms utilizing the MedDRA dictionary. Coders will search for specific terms in Items 18 and 19 in **VAERS 2** form or Boxes 7 and 12 on the **VAERS 1** form and code them to a searchable and consistent MedDRA term; note that terms are included in the .csv file in alphabetical order. There can be an unlimited amount of coded terms for a given event. Each row in the .csv will contain up to 5 MedDRA terms per VAERS ID; thus, there could be multiple rows per VAERS ID. For each of the VAERS_ID's listed in the VAERSDATA.CSV table, there is a matching record in this file, identified by VAERS_ID.

| Header | Type | Description of Contents |
|-----------------|--------------|------------------------------------|
| VAERS_ID | Num(6) | VAERS Identification Number |
| SYMPTOM1 | Char(100) | Adverse Event MedDRA Term 1 |
| SYMPTOMVERSION1 | Num(XX.XX) | MedDRA dictionary version number 1 |
| SYMPTOM2 | Char(100) | Adverse Event MedDRA Term 1 |
| SYMPTOMVERSION2 | Num(XX.XX) | MedDRA dictionary version number 2 |
| SYMPTOM3 | Char(100) | Adverse Event MedDRA Term 3 |

| | | |
|-----------------|--------------|------------------------------------|
| SYMPTOMVERSION3 | Num(XX.XX) | MedDRA dictionary version number 3 |
| SYMPTOM4 | Char(100) | Adverse Event MedDRA Term 4 |
| SYMPTOMVERSION4 | Num(XX.XX) | MedDRA dictionary version number 4 |
| SYMPTOM5 | Char(100) | Adverse Event MedDRA Term 5 |
| SYMPTOMVERSION5 | Num(XX.XX) | MedDRA dictionary version number 5 |

5. Definitions of Terms Used in Data Files

The following definitions pertain to the fields found in the three separate data files.

5.1 VAERSDATA.CSV

The following definitions pertain to the fields found in the VAERSDATA.CSV file described in section 4.1 above.

- 1) VAERS Identification Number (VAERS_ID):** A sequentially assigned number used for identification purposes. It serves as a link between the three data files.
- 2) Receive Date (RECVDATE):** The date the VAERS form information was received to our processing center.
- 3) State (STATE):** The two-letter US Postal Service abbreviation for the home state of the vaccinee. Please note that all foreign reports are contained in a separate data file.
- 4) Age in Years (AGE_YRS):** The recorded vaccine recipient's age in years.
- 5) Age in Years (CAGE_YR):** Age of patient in years calculated by (vax_date-birthdate).
- 6) Age in Months (CAGE_MO):** Age of patient in months calculated by (vax_date-birthdate). The values for this variable range from 0 to <1. It is only calculated for patients age 2 years or less. The summation of the two variables CAGE_YR and CAGE_MO provide the calculated age of a person. For example, if CAGE_YR=1 and CAGE_MO=.5 then the age of the individual is 1.5 years or 1 year 6 months.
- 7) Sex (SEX):** Sex of the vaccine recipient (M = Male, F = Female, Unknown = Blank).

8) Date Form Completed (RPT_DATE): Date the VAERS form was completed by the reporter as recorded on the specified field of the form. This is a **VAERS 1** form field only.

9) Reported Symptom Text (SYMPTOM_TEXT): This is the symptom text recorded in the form. MedDRA Terms are derived from this text and placed in the VAERSSYMPTOMS file.

10) Patient Outcomes: The reporter's assessment of the vaccine recipient outcome is recorded on the VAERS form. Selections checked in the form determine whether a report is considered to be a non-serious report, a serious report, or a death report.

- **Died (DIED):** If the vaccine recipient died a "Y" is used; otherwise the field will be blank.
- **Date of Death (DATEDIED):** If the vaccine recipient died there is space in this field to record the date of death; otherwise the field will be blank.
- **Life Threatening (L_THREAT):** If the vaccine recipient had a life-threatening event associated with the vaccination a "Y" is placed is used; otherwise the field will be blank.
- **Emergency Room (ER_VISIT):** If the vaccine recipient required an emergency room or doctor visit a "Y" is placed in this field; otherwise the field will be blank. If this is the only option checked the report is not considered serious. This is a **VAERS 1** form field only.
- **Hospitalized (HOSPITAL):** If the vaccine recipient was hospitalized as a result of the vaccination a "Y" is used; otherwise the field will be blank.
- **Days Hospitalized (HOSPDAYS):** If the reporter checked that the vaccine recipient was hospitalized a space is provided in this field to record the number of days hospitalized; otherwise the field will be blank.
- **Prolonged Hospitalization (X_STAY):** If a patient's hospitalization is prolonged as a result of the adverse event associated with the vaccination a "Y" will be placed in this field; otherwise the field will be blank.
- **Disability (DISABLE):** If the vaccine recipient was disabled as a result of the vaccination a "Y" is placed in this field; otherwise the field will be blank.
- **Congenital Anomaly or Birth Defect (BIRTH_DEFECT):** If the vaccine recipient had a congenital anomaly or birth defect associated with the vaccination, a "Y" is used; otherwise the field will be blank. This is a **VAERS 2** form field only.
- **Doctor or other healthcare professional office/clinic visit:** If the vaccine recipient had a doctor or other healthcare professional

office/clinic visit associated with the vaccination a "Y" is used; otherwise the field will be blank. This is a **VAERS 2** form field only.

- **Emergency room/department or urgent care:** If the vaccine recipient had an emergency room/department or urgent care visit associated with the vaccination a "Y" is used; otherwise the field will be blank. This is a **VAERS 2** form field only.

11) Recovered (RECOVD): A "Y" is placed in the field if the vaccine recipient recovered from the adverse event. "N" indicates that the vaccinee has not recovered from the adverse event. "U" or blank indicates that the vaccine recipient's recovery status is unknown.

12) Vaccination Date (VAX_DATE): The date of vaccination as recorded in the specified field of the form.

13) Onset Date (ONSET_DATE): The date of the onset of adverse event symptoms associated with the vaccination as recorded in the specified field of the form.

14) Onset Interval (NUMDAYS): The calculated interval (in days) from the vaccination date to the onset date.

15) Relevant Diagnostic Tests/Laboratory Data (LAB_DATA): This text field contains narrative about any relevant diagnostic tests or laboratory results as recorded on the specified field of the form.

16) Vaccine Administered at (V_ADMINBY): The reporter may note on the VAERS form the type of facility administering the vaccine. The options are different depending on the form version; additional options were added on the **VAERS 2** form.

- **VAERS 1.0:** PUB=Public, PVT=Private, MIL=Military, OTH=Other, UNK=Unknown
- **VAERS 2.0:** PUB=Public, PVT=Private, MIL=Military, PHM=Pharmacy or store, SCH=School or student health clinic, SEN=Nursing home or senior living facility, WRK=Workplace clinic, OTH=Other, UNK=Unknown

17) Vaccine Purchased with (V_FUNDBY): This is a **VAERS 1** field only. The reporter may note in Box 16 on the VAERS form which type of funds were used to purchase the vaccines administered in Box 13 (PUB=Public, PVT=Private, MIL=Military; OTH=Other/Unknown).

18) Other Medications (OTHER_MEDS): This text field contains narrative about any prescription or non-prescription drugs the vaccine recipient was taking at the time of vaccination as recorded on the specified field of the form.

19) Current Illnesses (CUR_ILL): This text field contains narrative about any illnesses at the time of the vaccination as noted on the specified field of the form.

20) Pre-existing Conditions (HISTORY): This text field contains narrative about any pre-existing physician-diagnosed birth defects or medical condition that existed at the time of vaccination as noted on the specified field of the form. For the **VAERS 1** form, this field also includes pre-existing physician-diagnosed allergies.

21) Allergies to medications, food or other products (ALLERGIES): This text field contains narrative about any pre-existing physician-diagnosed allergies that existed at the time of vaccination as noted in the specified field of the form. This is a **VAERS 2** form field only.

22) Prior Vaccination Event Information (PRIOR_VAX): This field provides prior vaccination event information as recorded on the specified field of the form.

23) Manufacturer Number (SPLTTYPE): Manufacturer number or Immunization Project number as recorded on the specified field of the form.

5.2 VAERSVAX.CSV

The following definitions pertain to the fields found in the VAERSVAX.CSV file described in section 4.2 above. Except for VAERS_ID, the information reflects Item 17 on **VAERS 2** form or Box 13 on **VAERS 1** form.

1) VAERS Identification Number (VAERS_ID): A sequentially assigned number used for identification purposes. It serves as a link between the three data files.

2) Vaccine Type (VAX_TYPE): The data list the vaccines group name by code. Similar vaccines are grouped together (e.g., FLU, DTAP).

| Vaccine Code | Vaccine Type |
|--------------|--|
| 6VAX-F | DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS ADSORBED + INACTIVATED POLIOVIRUS + HEPATITIS B + HAEMOPHILUS B CONJUGATE VACCINE |
| ADEN | ADENOVIRUS VACCINE LIVE ORAL TYPE 7 |
| ADEN_4_7 | ADENOVIRUS TYPE 4 & 7 VACCINE, LIVE ORAL |

| | |
|-------------------|--|
| ANTH | ANTHRAX VACCINE |
| BCG | BACILLUS CALMETTE-GUERIN VACCINE |
| CEE | CENTRAL EUROPEAN ENCEPHALITIS |
| CHOL | CHOLERA VACCINE |
| DF | DENGUE FEVER VACCINE |
| DPIPv | DIPHTHERIA, PERTUSSIS + INACTIVATED POLIO VIRUS |
| DPP | DIPHTHERIA/PERTUSSIS/POLIO (ORAL [LIVE OR INACTIVATED NOT NOTED]) |
| DT | DIPHTHERIA AND TETANUS TOXOIDS, PEDIATRIC |
| DTAP | DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE |
| DTAPH | DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE |
| DTAPHEPBIP | DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE |
| DTAPIPV | DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE |
| DTAPIPVHIB | DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE |
| DTIPV | DIPHTHERIA AND TETANUS TOXOIDS, PEDIATRIC + INACTIVATED POLIOVIRUS VACCINE |
| DTOX | DIPHTHERIA TOXOID |
| DTP | DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE |
| DTPHEP | DIPHTHERIA, TETANUS, PERTUSSIS + HEPATITIS B |
| DTPHIB | DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE |
| DTPIHI | DIPHTHERIA/TETANUS/WHOLE PERTUSSIS + INACTIVATED POLIO VIRUS + HAEMOPHILUS INFLUENZA B |
| DTPIPV | DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE |
| DTPPHIB | DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE) |
| EBZR | EBOLA ZAIRE VACCINE |
| FLU(H1N1) | INFLUENZA (H1N1) MONOVALENT |
| FLU3 | INFLUENZA VIRUS VACCINE, TRIVALENT |
| FLU4 | INFLUENZA VIRUS VACCINE, QUADRIVALENT |

| | |
|-------------------|---|
| FLUA3 | INFLUENZA VIRUS VACCINE, TRIVALENT, ADJUVANT |
| FLUA4 | INFLUENZA VIRUS VACCINE, QUADRIVALENT, ADJUVANT |
| FLUC3 | INFLUENZA VIRUS VACCINE, TRIVALENT, CELL-CULTURE-DERIVED |
| FLUC4 | INFLUENZA VIRUS VACCINE, QUADRIVALENT, CELL-CULTURE-DERIVED |
| FLUN(H1N1) | INFLUENZA (H1N1) MONOVALENT (NASAL SPRAY) |
| FLUN3 | INFLUENZA VIRUS VACCINE (NASAL SPRAY) |
| FLUN4 | INFLUENZA VIRUS VACCINE QUADRIVALENT (NASAL SPRAY) |
| FLUR3 | INFLUENZA VIRUS VACCINE, TRIVALENT, RECOMBINANT |
| FLUR4 | INFLUENZA VIRUS VACCINE, QUADRIVALENT, RECOMBINANT |
| FLUX | INFLUENZA VIRUS VACCINE, UNKNOWN MANUFACTURER |
| FLUX(H1N1) | INFLUENZA (H1N1) MONOVALENT, UNKNOWN MANUFACTURER |
| H5N1 | PANDEMIC FLU VACCINE |
| HBHEPB | HAEMOPHILUS B CONJUGATE VACCINE + HEPATITIS B |
| HBPV | HAEMOPHILUS B POLYSACCHARIDE VACCINE |
| HEP | HEPATITIS B VIRUS VACCINE |
| HEPA | HEPATITIS A |
| HEPAB | HEPATITIS A + HEPATITIS B |
| HEPATYP | INACTIVATED HEPATITIS A + TYPHOID POLYSACCHARIDE VACCINE ADSORBED |
| HIBV | HAEMOPHILUS B CONJUGATE VACCINE |
| HPV2 | HUMAN PAPILLOMAVIRUS BIVALENT |
| HPV4 | HUMAN PAPILLOMAVIRUS QUADRIVALENT |
| HPV9 | HUMAN PAPILLOMAVIRUS 9-VALENT |
| HPVX | HUMAN PAPILLOMAVIRUS (NO BRAND NAME) |
| IPV | POLIOVIRUS VACCINE INACTIVATED |
| JEV | JAPANESE ENCEPHALITIS VIRUS VACCINE, INACTIVATED |
| JEV1 | JAPANESE ENCEPHALITIS VIRUS VACCINE, INACTIVATED |
| JEVX | JAPANESE ENCEPHALITIS VIRUS VACCINE (NO BRAND NAME) |
| LYME | LYME DISEASE VACCINE |
| MEA | MEASLES |
| MEN | MENINGOCOCCAL POLYSACCHARIDE VACCINE |
| MENB | MENINGOCOCCAL GROUP B VACCINE, rDNA ABSORBED |
| MENHIB | MENINGOCOCCAL CONJUGATE + HIB |
| MER | MEASLES AND RUBELLA VIRUS VACCINE, LIVE |
| MM | MEASLES AND MUMPS VIRUS VACCINE, LIVE |
| MMR | MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, LIVE |
| MMRV | MEASLES, MUMPS, RUBELLA AND VARICELLA VACCINE LIVE |
| MNC | MENINGOCOCCAL CONJUGATE VACCINE |

| | |
|-----------------|---|
| MNQ | MENINGOCOCCAL CONJUGATE VACCINE |
| MNQHIB | MENINGOCOCCAL GROUPS C AND Y + HAEMOPHILUS B TETANUS TOXOID CONJUGATE VACCINE |
| MU | MUMPS VIRUS VACCINE, LIVE |
| MUR | MUMPS AND RUBELLA VIRUS VACCINE, LIVE |
| OPV | POLIOVIRUS VACCINE TRIVALENT, LIVE, ORAL |
| PER | PERTUSSIS VACCINE |
| PLAGUE | PLAGUE VACCINE |
| PNC | PNEUMOCOCCAL 7-VALENT CONJUGATE VACCINE |
| PNC10 | PNEUMOCOCCAL 10-VALENT CONJUGATE VACCINE |
| PNC13 | PNEUMOCOCCAL 13-VALENT CONJUGATE VACCINE |
| PPV | PNEUMOCOCCAL VACCINE, POLYVALENT |
| RAB | RABIES VIRUS VACCINE |
| RUB | RUBELLA |
| RV | ROTAVIRUS VACCINE, LIVE, ORAL, TETRAVALENT |
| RV1 | ROTAVIRUS VACCINE, LIVE, ORAL |
| RV5 | ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT |
| RVX | ROTAVIRUS (NO BRAND NAME) |
| SMALL | SMALLPOX VACCINE |
| SMALLMNK | SMALLPOX + MONKEYPOX VACCINE |
| SSEV | SPRING/SUMMER ENCEPHALITIS VACCINE |
| TBE | TICK-BORNE ENCEPHALITIS VACCINE |
| TD | TETANUS AND DIPHTHERIA TOXOIDS, ADULT |
| TDAP | TETANUS TOXOID, REDUCED DIPHTHERIA TOXOID AND ACELLULAR PERTUSSIS VACCINE, ADSORBED |
| TDAPIPV | TETANUS, DIPHTHERIA AND ACELLULAR PERTUSSIS, AND INACTIVATED POLIO VIRUS |
| TTX | TETANUS TOXOID |
| TYP | TYPHOID VACCINE |
| UNK | UNKNOWN VACCINE TYPE |
| VARCEL | VARIVAX-VARICELLA VIRUS LIVE |
| VARZOS | VARICELLA-ZOSTER VACCINE |
| YF | YELLOW FEVER VACCINE |

3) Vaccine Manufacturer (VAX_MANU): This field identifies the manufacturer of the each of the vaccines listed.

4) Manufacturers Vaccine Lot (VAX_LOT): This field identified the lot number of the vaccines listed.

5) Doses administered (VAERS_DOSE_SERIES): This field identifies the vaccine dose of the recorded vaccines listed. The **VAERS 1** field VAX_DOSE was discontinued in the **VAERS 2** form; when a value exists, a 1 is added to equate to the VAX_DOSE_SERIES field.

6) Vaccination Route (VAX_ROUTE): This field identifies the vaccine route of administration.

| Abbreviation | Route |
|--------------|--|
| UN | Unknown |
| ID | Intradermal |
| IM | Intramuscular |
| SC | Subcutaneous |
| IN | Intranasal |
| PO | Per Oral |
| SYR | Needle and syringe (not specified further) |
| JET | Needle free jet injector device |
| OT | Other |

7) Vaccination Site (VAX_SITE): This field identified the anatomic site where the vaccination was administered.

8) Vaccine Name (VAX_NAME): This field provides the brand name of the vaccine administered.

5.3 VAERSSYMPTOMS.CSV

The following definitions pertain to the fields found in the VAERSSYMPTOMS.CSV file described in section 4.3 above.

1) VAERS Identification Number (VAERS_ID): A sequentially assigned number used for identification purposes. It serves as a link between the three data files.

2) MedDRA Term (SYMPTOM1-5): The data in these fields are equivalent to the PT TERM from the MedDRA codebook. MedDRA terms are extracted from the narrative text in **VAERS 2** (Item 18 and 19) and **VAERS 1** (Box 7 and 12). Duplicates may appear in data and terms are listed in alphabetical order. In case a report has more than 5 terms multiple rows with 5 terms each will be listed for that VAERS ID.

3) MedDRA Term Version (SYMPTOMVERSION1-5): Version of MedDRA dictionary from which the MedDRA term was first created.

7. Downloadable VAERS Data Sets Disclaimer

Please note that VAERS staff follow-up on all serious and other selected adverse event reports to obtain additional medical, laboratory, and/or autopsy records to help understand the concern raised. However, in general coding terms in VAERS do not change based on the information received during the follow-up process. VAERS data should be used with caution as numbers and conditions do not reflect data collected during follow-up. Note that the inclusion of events in VAERS data does not infer causality.