

**Data Use and Sharing Agreement to Support the United States Government’s
COVID-19 Emergency Response
Jurisdiction Immunization and Vaccine
Administration Data Agreement**

This Data Use and Sharing Agreement (“DUA”) is made between [State of Connecticut, Department of Public Health Immunization Information System (CT IIS) located at 410 Capitol Avenue, MS 11 MUN, Hartford, CT 06134] (“Data Source” or “Jurisdiction”) and the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (“HHS”), to describe the data use and sharing parameters for certain immunization and vaccine administration data, as further described herein. This DUA: 1) describes platforms for the rapid collection, transmission, use, storage, and maintenance of these data available to data sources, CDC, and other users; 2) establishes the terms and conditions for the sharing, protection, and use of these with CDC, HHS and other federal partners; and 3) sets forth the roles and responsibilities of each party.

The DUA is effective as of 11/01/2020 (“Effective Date”)

Background and Purpose

Access to immunization and vaccine administration data is critical to the whole of government response to the Coronavirus Disease 2019 (COVID-19) public health emergency. In furtherance of federal government response efforts, HHS and CDC seek to obtain and utilize these data from various immunization and vaccine data sources, including a jurisdiction’s immunization information system (IIS), pharmacies, federal Provider Organizations, and other relevant parties for a range of purposes, including but not limited to rapidly assessing patterns of vaccination among the population; identifying pockets of undervaccination ; assisting in determining vaccine resource allocation to address the needs of jurisdictions; monitoring vaccine effectiveness and safety; assessing spectrum of illness, disease burden, risk factors for severe disease and outcomes; and helping to understand. the impact of COVID-19 on the healthcare system and communities.

To support these purposes, HHS and CDC: 1) have made available a platform for use by data sources to manage, share, and store their immunization data; 2) have developed platforms for use by HHS, CDC, and other federal partners to extract, accept, manage, share, and store relevant immunization data in furtherance of the response; 3) will, consistent with applicable law, enable the secure transmission of extracted data from and across these platforms for further use by a jurisdiction, CDC, HHS, and other federal partners in furtherance of the response; 4) as applicable, will assure compliance of these platforms with the Federal Information Security Management Act (FISMA) and other federal data security policies; and 5) will provide operational support to the data sources and other authorized users of the various platforms, as appropriate.

Authority

HHS and CDC are authorized by Sections 301 and 319D of the Public Health Service Act [42 U.S.C. §§ 241 and 247d-4], as amended, to maintain active surveillance of diseases through epidemiologic and laboratory investigations and data collection, analysis, and distribution. The Jurisdiction entering this DUA agrees that it is authorized to send the Covered Data to and through the COVID-19 Clearinghouse, the Immunization (IZ) Data Lake, the Vaccine Administration Management System (VAMS), and HHS Protect/Tiberius, as those platforms and systems are further defined herein, and/or will obtain consent from any external entities or individuals from whom it collects data to allow for such sharing and use.

In addition, HHS and CDC each is a “public health authority” as defined at 45 C.F.R. §164.501 and as used in 45 C.F.R. §164.512(b), Standards for Privacy of Individually Identifiable Health Information, promulgated under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and, as such, are authorized by 45 CFR 164.512(b) to receive Protected Health Information (“PHI”).

As applicable, the Parties acknowledge that Jurisdiction may be a hybrid entity for purposes of HIPAA. Jurisdiction’s healthcare component is neither involved nor implicated in this DUA. For purposes of this DUA, Jurisdiction is a public health authority under 45 CFR §164.512 and is neither a covered entity nor a business associate, as defined under 45 CFR §160.103. The Parties expressly do not intend to create a HIPAA business associate relationship, and nothing in this DUA may be construed to make Jurisdiction a covered entity or business associate for purposes of this agreement.

Data Use and Sharing Terms

1. Platforms

In furtherance of the activities set out in this DUA, HHS and CDC, either directly or by and through a service provider, have stood up, are supporting, and/or are expanding the capacity of the following secure, certified, cloud-based data management platforms:

- a. Immunization (IZ) Gateway: The IZ Gateway is a cloud-hosted message routing service offered by the Association for Public Health Laboratories (APHL) and is intended to enable data exchange across IISs, other provider systems, the COVID-19 Clearinghouse, and the IZ Data Lake. A jurisdiction may enter into appropriate agreements with APHL to enable its IIS to update, query, and report immunization data to and through the IZ Gateway. The IZ Gateway is intended to allow a jurisdiction to connect its IIS and other provider systems to the COVID-19 Clearinghouse and the IZ Data Lake; connect its IIS to VAMS data, where applicable; enable queries and route messages to/from its IIS; and route secured, standardized HL7 messages from its IIS, VAMS, or other provider organizations to the COVID-19 Clearinghouse and the IZ Data Lake.

A jurisdiction choosing to use the IZ Gateway will enter into relevant agreements with APHL with respect to use of the IZ Gateway.

- b. **COVID-19 Clearinghouse:** The COVID-19 Clearinghouse is a cloud-hosted data repository provided and managed by HHS that, as a functional tool, provides a secure space for a jurisdiction to upload and store COVID-19 vaccination data collected from provider organizations via electronic health records (EHRs) and from pharmacy systems. The COVID-19 Clearinghouse is intended to allow a jurisdiction to upload, store, reconcile, and manage data for general COVID-19 vaccine administration, to meet reporting requirements and needs, and to allow providers to search for a patient, see what brand of COVID-19 vaccine they received, and when they received their first dose of COVID-19 vaccine to ensure dose matching to complete the vaccine series (see Appendix A).

The COVID-19 Clearinghouse will be able to receive data from VAMS and other vaccination sources not already onboarded as providers to an immunization registry and will allow the data to be shared across relevant jurisdictions for reconciliation of patient registry records. Neither CDC nor HHS, either directly or by and through the cloud service provider, will have access to personally identifiable vaccination data submitted by a jurisdiction's IIS, VAMS, or other vaccine source record system during transport or record processing or while in storage without the express consent of the jurisdiction. HHS and CDC, either directly or by and through the service provider, will take all reasonable measures to secure the data residing in the COVID-19 Clearinghouse and, except as may be required by applicable federal law, will not, without the prior written authorization from the jurisdiction, further use, disclose, or transmit the data beyond what is described within this DUA. Should disclosure or transmission of a jurisdiction's data be required by federal law, HHS and/or CDC will promptly notify the jurisdiction in writing of the required release.

- c. **Immunization (IZ) Data Lake:** The IZ Data Lake is a CDC_secure, cloud-hosted data repository created to receive and store redacted COVID-19 vaccination data for doses administered, coverage, inventory, and distribution. The IZ Data Lake will receive the data from various data flows, including internal CDC sources (VTrckS), Provider Agreement data via an upload portal, VaccineFinder, and the COVID-19 Clearinghouse. These data will be used by CDC to provide aggregate-level reports for COVID-19 vaccine administration, ordering, inventory, and provider information. The IZ Data Lake will also aggregate and analyze data and provide data summaries and analytics via platforms such as the Data Storefront HHS Protect, and HHS Tiberius.

- d. **VaccineFinder:** The VaccineFinder website (www.vaccinefinder.org) helps people find providers who offer specific vaccines. VaccineFinder will serve two roles during the COVID-19 Vaccination Program:

1. **Inventory reporting:** Approved COVID-19 vaccination providers will report on-hand COVID-19 vaccine inventory daily.
2. **Increase access to COVID-19 vaccines:** COVID-19 vaccination providers may choose to make their location(s) visible on VaccineFinder to increase access to COVID-19 vaccines once supply is available for the general population.

VaccineFinder will exchange data with the IZ Data Lake for the purposes of provider pre-enrollment, data analysis, and summaries via platforms such as the Data Storefront, HHS Protect, and HHS Tiberius.

e. VTrckS: CDC’s Vaccine Tracking System is the platform for ordering all COVID-19 vaccines. VTrckS users will use the system to:

- View vaccine allocations allotted to each program.
- Place and/or manage vaccine orders for their providers.
- Generate reports throughout the vaccine distribution process, from placing vaccine orders through distribution.

VTrckS receives data from jurisdiction immunization registries and transmits data to these registries, VaccineFinder, and the IZ Data Lake.

f. Provider system: A provider system is any platform used by a vaccination provider to track the administration and uptake of vaccine among their patient populations. Vaccination providers generally utilize an Electronic Health Record (EHR) to connect directly to IISs for vaccine uptake tracking. In some instances, vaccination providers will utilize a direct user interface (UI) to enter vaccination information directly into an IIS UI portal.

g. Other vaccine source: These are alternative sources (in addition to IISs and EHRs) that may store vaccination information about an individual. Examples include travel vaccination records, passports, vital records/birth records, Medicaid records, insurance claim information, etc. and their corresponding systems.

h. HHS Tiberius: Tiberius provides a COVID-19 vaccine distribution planning, tracking, modeling, and analysis ecosystem. Tiberius leverages the same technologies as the HHS Protect Platform (“HHS Protect”) and integrates data sources from federal agencies, state and local partners, private sector partners, and open data providers to create a comprehensive common operating picture for the COVID-19 vaccine planning, distribution, and administration effort.

2. Definitions:

For purposes of this Agreement, the following definitions shall apply and may be used in the main body of the DUA and/or in relevant appendices:

“Authorized User,” for purposes of this DUA, means an individual who, as part of directly supporting the whole of government response efforts, has a need for data stored in the COVID-19 Clearinghouse, the IZ Data Lake and/or the Tiberius platforms in furtherance of the purposes and uses set forth herein. Authorized Users will generally be employees, contractors, and/or other agents specified by Jurisdiction or federal agencies engaged in the response for purposes of addressing critical public health and emergency response activities, including assessing infrastructure needs and resource allocation. Authorized Users must adhere to applicable federal law and, as consistent and applicable the provisions set out in this DUA with respect to the data stored in the respective platforms.

“Data Source,” for purposes of this DUA, is a Jurisdiction which, by and through an IIS and/or similar system(s) created to serve a range of administrative functions related to vaccines, provides Covered Data as set forth herein. Generally, the IIS or related system(s) will collect

data from public and private health care provider organization e.g. EHRs, health information systems, (e.g., vital statistics, state Medicaid agencies, etc.), and pharmacies.

“Covered Data” means the information that is being shared by the Data Source with each relevant platform as further described in Appendices A-D, but that is generally categorized into four primary datasets: the VAMS data, the COVID-19 Clearinghouse Data, the IZ Data Lake Data, and the Tiberius Data. HHS and CDC acknowledge that the Covered Data to which each agency will have access is the minimum amount of information necessary to accomplish public health or emergency response needs. A list of Covered Data elements for each dataset is provided in Appendices A-D.

Covered Data may be used by Authorized Users within the parameters set forth in this DUA. The data elements listed in Appendices A-D will be updated periodically as more information on COVID-19 immunization is available. The overall DUA will remain unaffected by subsequent updates. Appendices A-D also provide the mode and method of secure transmission of the data from the Jurisdiction’s IIS or similar system(s) directly to the COVID-19 Clearinghouse; from the COVID-19 Clearinghouse to the IZ Data Lake; and from the IZ Data Lake to Tiberius. This information includes the potential availability and use of a privacy-preserving record linkage (PPRL) tool, which may be made available by HHS or CDC, either directly or by and through a contractor (Appendix E). Of note, data entering the COVID-19 Clearinghouse through the IZ Gateway will be governed by agreements between the IIS jurisdiction and APHL.

“Jurisdiction” means the state, territorial or local health jurisdiction operating under either statutory or regulatory authority to obtain and use health-related data for population health protection. For the purposes of this document, Jurisdictions are funded under CDC-RFA-IP19-1901 317 Notice of Funding Opportunity.

“Immunization Information System” or “IIS are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area.

“Deidentified Data” means data that do not identify an individual and there is no reasonable basis to believe the information can be used to identify an individual because the data have been rendered not identifiable in accordance with the HIPAA standards set forth in 45 CFR §164.514.

“Party” means a state, territorial or local jurisdiction or CDC; **“Parties”** means state, territorial, or local jurisdiction and CDC.

“Privacy-Preserving Record Linkage (PPRL)” means the process whereby personally identifiable information (PII) is redacted from a patient/customer record using a one-way, irreversible encryption algorithm to create one or more unique tokens that replace PII elements and allow data systems to match patient/customer records. PPRL is an industry standard that has been implemented and integrated across several data collection sectors where an individual’s privacy must be maintained (e.g., health care, biomedical research, payment and claims, retail, intelligence, social research, and public health). For COVID-19 immunization reporting, PPRL offers jurisdictions a mechanism to meet applicable jurisdiction regulations where data sharing with partners such as HHS and CDC may be limited.

“Vaccine Administration Management System” or “VAMS” means the CDC-provided and supported web-based application that provides an option for a jurisdiction to plan and execute COVID-19 vaccine administration in a mass vaccination setting. VAMS has four users with multiple roles within each user module: 1) jurisdictions can provide end-to-end mass vaccination capability and manage mass vaccination clinics; 2) healthcare providers can manage patient scheduling, vaccine administration workflow, and patient monitoring, support social distancing requirements with a scheduling feature, track vaccine inventory and usage, and include warnings when inventory is low; 3) employers/organizations can bulk input employees who will receive an email to register in VAMS; and 4) vaccine recipients can schedule vaccination appointments and receive appointment reminders. For purposes of this DUA, VAMS may be used to send data directly to the COVID-19 Clearinghouse or through the IZ Gateway either back to the Jurisdiction IIS and/or to the COVID-19 Clearinghouse. The Jurisdiction IIS may choose to use VAMS or an alternate mechanism (e.g., state-based vaccination clinic solution) to transmit the data to the IZ Gateway and/or the COVID-19 Clearinghouse.

3. Description of Data Requested and Transmission

Data Source agrees to provide data as described in Appendices A-D to and through platforms as indicated therein, subject to the terms and conditions included in this DUA and applicable to that option.

4. Data Use Terms

The Data Source acknowledges and agrees that HHS, CDC, and Authorized Users may use the Covered Data transmitted to the various platforms as described in this DUA and Appendices A-D in furtherance of response activities related to the COVID-19 pandemic. This includes, at a minimum, the following activities:

- a. Analyze and visualize the Covered Data to which they have access to improve the monitoring of vaccine and vaccine-related activities related to the COVID-19 pandemic response including vaccine safety and assessment of vaccine effectiveness;
- b. Analyze and visualize the Covered Data to improve the monitoring of vaccine safety and assessment of vaccine effectiveness;
- c. As applicable to the platform, share the Covered Data and analyses thereof with official federal, state, local, tribal, and territorial government health agencies or other agencies and entities conducting their public health and vaccine response responsibilities consistent with applicable federal law and the terms of this DUA;
- d. Develop analytic methods using the Covered Data to identify immediate public health events or concerns at the federal, state, territorial and local level that warrant further public health investigation or immediate public health intervention actions;
- e. Enable Authorized Users, including public health and emergency response officials, to query the Covered Data within the HHS and CDC-provided data platforms as may be necessary to carry out critical public health functions;
- f. Share specified data elements with HHS Tiberius for the visualization of Vaccine Administration Data; and
- g. Publish findings and conclusions related to their analyses of the data provided. As appropriate, publications will acknowledge Data Source as the source of the data in any such

publication. Given the emergent nature of the response, HHS and CDC may not be able to inform or seek approval from Data Source for such publications but will coordinate as soon as possible and practicable.

5. Data Confidentiality and Security

As applicable to the platform, HHS and CDC will establish appropriate administrative, technical, procedural, and physical safeguards to assure the confidentiality and security of Covered Data in their custody and control, consistent with federal requirements under the FISMA) and other applicable federal laws. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by applicable law for the type of data provided under this DUA. Where Covered Data provided pursuant to this DUA are identifiable or potentially identifiable, CDC agrees to maintain the confidentiality of the Covered Data to the fullest extent required by applicable law, which includes, as applicable, the Privacy Act of 1974; standards promulgated pursuant to), and the Freedom of Information Act (FOIA), including exemptions provided thereunder.

Where required by law and/or where practicable, HHS and CDC agree to notify Data Source before releasing Covered Data to a third party pursuant to a judicial, governmental, or other request under law, to allow Data Source the opportunity to state any objection to the disclosure of the Covered Data.

Transmission of the Covered Data by and through the various platforms in the control of HHS and CDC shall be done in accordance with acceptable practices for ensuring the protection, confidentiality, and integrity of the contents. Covered Data will be maintained and stored in compliance with CDC's security policies and procedures and consistent with applicable law.

Miscellaneous

1. **Data Disposition:** Data that have been provided to HHS and CDC under this DUA will be archived, stored, protected, or disposed of in accordance with relevant federal records retention requirements.
2. **Funding:** This DUA is not an obligation or a commitment of funds, or a basis for a transfer of funds, and does not create an obligation or commitment to transfer data, but rather is a statement of understanding between the parties concerning the sharing and use of covered data. Expenditures by each party are subject to its budgetary processes and to the availability of funds and resources pursuant to applicable laws, regulations, and policies.
3. **Settlement of Disputes:** Disagreements between the parties arising under or relating to this DUA will be resolved by consultation between the parties and referral of the dispute to appropriate management officials of the parties whenever possible.
4. **Applicable Laws:** U.S. federal law shall govern the construction, interpretation, and performance of this Agreement.

Term of Agreement, Amendment, and Termination:

1. The term of this DUA shall be one year commencing from the date of the final signature or the duration of the national emergency. The DUA may be renewed upon mutual written consent of the parties.
2. Except as otherwise expressly provided herein, this DUA may be amended only by the mutual written consent of the authorized representatives for each party.
3. This DUA may otherwise be terminated with ninety days' advance notice upon written notice by either party.
4. Any notice required under this DUA must be in writing and sent by electronic mail with written acknowledgement of receipt to the email address for each party provided below.
5. Each party represents that the individual signing below on behalf of the party has the authorization to bind the party indicated to this DUA. This DUA may be signed in counterparts and signatures provided electronically will be deemed originals.

DPH LEGAL REVIEW:

DocuSigned by:
 By: Kevin Hansted
ADF932EDBBD341A...
 Name: Kevin Hansted
 Date: 10/28/2020 | 3:02 PM EDT
 Title: Staff Attorney 3
 Email: Kevin.Hanstead@ct.gov

**DEPARTMENT OF PUBLIC HEALTH
(DATA SOURCE)**

DocuSigned by:
 By: Heather Aaron
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 Date: 10/28/2020 | 5:15 PM EDT
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 Email: Heather.Aaron@ct.gov

CENTERS FOR DISEASE CONTROL AND PREVENTION

DocuSigned by:
 By: Megan C. Lindley
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 Name: Megan C. Lindley
 Date: 11/6/2020 | 3:46 PM EST
 Title: Acting Associate Director for Science, CDC/NCIRD/ISD
 Email: IISInfo@cdc.gov

Appendix A: Covered Data–CDC IIS Data Elements for COVID-19 Vaccine Monitoring

A strong, nationally coordinated approach is critical to collecting, tracking, and analyzing vaccination data, especially in early phases of vaccine administration, which is expected to occur in nontraditional settings during this COVID-19 response. This document outlines the anticipated data elements that will be reported to various platforms supported by HHS and CDC, ultimately with certain elements being shared with HHS and CDC. The required data elements in this document represent demographic and vaccination information routinely captured by an IIS during a vaccination event.

Discrete Data Elements

In order to ensure appropriate vaccine administration and distribution by HHS and CDC to jurisdictions and, ultimately, to providers, certain data elements must be provided to HHS and CDC.

Table 1 includes each data element a Jurisdiction will report to VAMS (if applicable), to the IZ Clearinghouse, and to the CDC IZ Data Lake. Table 2 includes each data element that will be optional for submission to each platform. Optional data requirements will support additional national coverage analysis and vaccination monitoring efforts.

Any identifiable data elements will be used to facilitate deduplication of data within the COVID-19 Clearinghouse, an analytic environment that will be used to consolidate, deduplicate, and reconcile vaccine administration information from multiple sources (e.g., jurisdictional immunization programs, pharmacies, Department of Defense, Veterans Affairs, Bureau of Prisons, Indian Health Service). Directly identifiable elements will not be sent or stored in the CDC IZ Data Lake environment. The IZ Data Lake will aggregate and analyze data and will provide data summaries and analytics via platforms such as the Data Storefront, HHS Protect, and the HHS Tiberius systems. Data flowing from the IZ Data Lake to Tiberius will be used by Operation Warp Speed members to track progress of vaccine distribution, provider inventory, and administration.

Table 1. Required Data Elements

Required Data Element	<u>VAMS</u>	<u>COVID-19 Clearinghouse</u>	<u>Immunization Data Lake</u>
<i>Data elements required for reporting by IIS</i>			
Administered at location: facility name/ID	✓	✓	✓
Administered at location: type		✓	✓
Administration address (including county)		✓	✓
Administration date		✓	✓

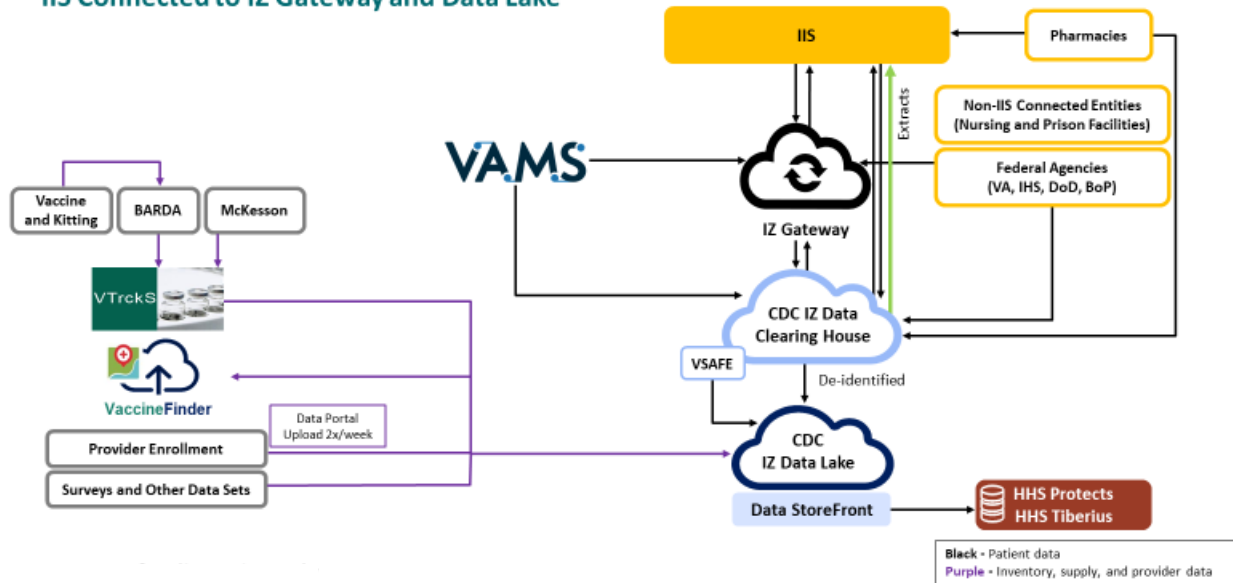
CVX (product)		<u>✓</u>	<u>✓</u>
Dose number		<u>✓</u>	<u>✓</u>
IIS recipient ID*		<u>✓</u>	<u>✓</u>
<u>Recipient race</u>		<u>✓</u>	<u>✓</u>
<u>Recipient ethnicity</u>		<u>✓</u>	<u>✓</u>
IIS vaccination event ID		<u>✓</u>	<u>✓</u>
Lot number: unit of use and/or unit of sale		<u>✓</u>	<u>✓</u>
MXV (manufacturer)		<u>✓</u>	<u>✓</u>
Recipient address*		<u>✓</u>	
Recipient date of birth*		<u>✓</u>	
Recipient name*		<u>✓</u>	
Recipient sex		<u>✓</u>	<u>✓</u>
Sending organization		<u>✓</u>	<u>✓</u>
Vaccine administering provider suffix		<u>✓</u>	<u>✓</u>
Vaccine administering site (on the body)		<u>✓</u>	<u>✓</u>
Vaccine expiration date		<u>✓</u>	<u>✓</u>
Vaccine route of administration		<u>✓</u>	<u>✓</u>
Vaccination series complete		<u>✓</u>	<u>✓</u>
<u>Optional Data Elements</u>			
<u>Optional Data Element</u>	<u>VAMS</u>	<u>COVID-19 Clearinghouse</u>	<u>Immunization Data Lake</u>
<u>Comorbidity status</u>	<u>✓</u>	<u>✓</u>	<u>✓</u>
<u>Recipient missed vaccination</u>	<u>✓</u>	<u>✓</u>	<u>✓</u>
<u>Appointment (Y/N)</u>			
<u>Serology results (Y/N)</u>	<u>✓</u>	<u>✓</u>	<u>✓</u>
<u>Vaccination refusal (Y/N)</u>	<u>✓</u>	<u>✓</u>	<u>✓</u>

*Identifiable Information

Appendix B: Vaccine Administration Data Workflow

Primary Path:

IIS Connected to IZ Gateway and Data Lake



Description of Data Workflow and Transmission

Data Source will provide vaccine administration data (Appendix A) to the COVID-19 Clearinghouse as described in Appendix D, in part, for purposes of deduplication, record matching, and reconciliation. The COVID-19 Clearinghouse will encrypt and store personally identifiable vaccine administration data, allowing secure, role-based access for authorized data users/systems. It will also support multijurisdictional lookup/queries by vaccination providers for validating vaccine type and manufacturer for administration of a second dose. Once processed in the COVID-19 Clearinghouse, certain data elements (see Appendices A and C) from the COVID-19 Clearinghouse Data will be transmitted to the CDC IZ Data Lake platform for additional analyses by CDC and HHS.

Data may be transmitted to the COVID-19 Clearinghouse through the following applications and technology solutions:

- Option 1: Directly, via a Jurisdiction IIS or Mass Vaccination Clinic Application (e.g., VAMS or a state-based vaccination clinic solution)
- Option 2: Via a Jurisdiction IIS or vaccination clinic application through the IZ Gateway provided by APHL
- Option 3: Submission of record-level vaccination and demographic data to the COVID-19 Clearinghouse through a data extract (see Appendix D)

For Data Sources using the IZ Gateway, data from a vaccination clinic application are submitted to the IZ Gateway through a Simple Object Access Protocol (SOAP) Transport in the form

of vaccine record updates (VXU) and acknowledgment (ACK) messages. A similar mechanism is used for the submission from the IZ Gateway into the IZ Data Clearinghouse.

Data from both technical solutions will be submitted directly to the COVID-19 Clearinghouse through functionality existing within the technology and will not require direct action on the part of the Data Source. If the Data Source is unable to submit data through the aforementioned technical solutions, Data Source may transmit Covered Data directly in the form of a data extract to the COVID-19 Clearinghouse.

The COVID-19 Clearinghouse will then deliver certain data to the IZ Data Lake. The Data Source will submit information about COVID-19 vaccinations only. The Data Source agrees to provide all required data elements described in Appendix A unless prohibited by state law. Written documentation of these legal restrictions must be provided.

Data from the IZ Data Lake will transmit into HHS Tiberius. The IZ Data Lake connects to Tiberius by using the IZ Data Lake Azure Synapse component. The Tiberius IP addresses are white-listed, and credentials are exchanged over a secure channel. Tiberius credentials in IZ Data Lake Synapse are only provided access to the data approved by CDC programs. Tiberius pulls the data from IZ Data Lake Synapse when it needs to refresh.

Appendix C: Data Dictionary for CDC Vaccine Administration Requirements for COVID-19 Vaccine Monitoring (attached)

Appendix D: COVID-19 Vaccination Reporting Specifications Document (CRVS) (attached)

APPENDIX E: PRIVACY-PRESERVING RECORD LINKAGE

Currently, there is no consistent way for public health jurisdictions to share vaccine administration data with each other, due to two major constraints. First, these data are considered personally identifiable information (PII) and/or protected health information (PHI) and may be subject to a jurisdiction's laws and regulations that may prohibit or limit the sharing of such information outside the jurisdiction. Second, though most people will complete their dose series in the same jurisdiction, some individuals may cross jurisdictions before completion of the series. There are currently no optimal technical solutions to link vaccine administration data electronically across jurisdictional boundaries.

Privacy preserving record linkage (PPRL) provides a practical way for jurisdictions to exchange information on vaccine administration with federal agencies, while preserving and protecting PII and PHI. By creating tokenized, deduplicated data, PPRL can link an individual's COVID-19 vaccination records to inform booster dose delivery decisions without sharing PII across jurisdiction boundaries. PPRL has the potential to optimize vaccination administration efforts by streamlining processes and resolving orphaned data issues within the IIS by providing record linking without the need to exchange PII.

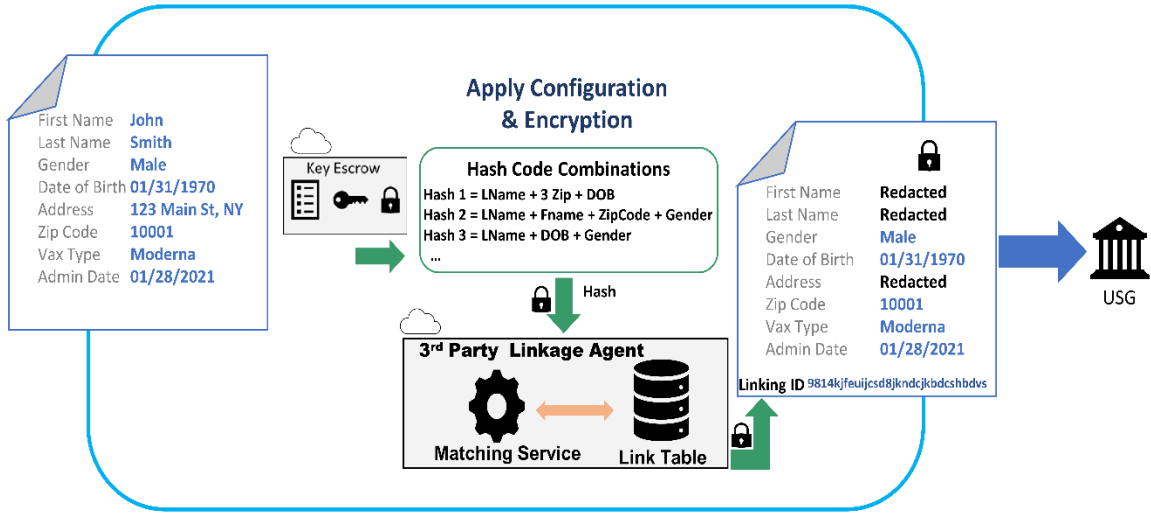
Beyond the dose series look-up use case, PPRL can also enable CDC to associate vaccine administration data from multiple sources (e.g., epidemiologic, laboratory and immunization data) to a specific individual without receiving any PII that might compromise the privacy of that individual.

In the PPRL process, PII is hashed using a one-way, irreversible encryption algorithm to create one or more tokens in a series of prescribed steps prior to transmission beyond an organizational boundary for matching. Hashing works by passing a piece of data through a mathematical function to convert the data into a multi-character code that can be used by computers to match records in the same way that personally identifiable data would be used; the code(s) act as new record identifiers that are used to match with other records similarly converted to codes. The process of hashing results in the creation of unique information based on the PII data of interest that prevents an outside party from recovering the PII, while allowing for the establishment of links across organizations in order to share PII when necessary.

PPRL offers more than one protocol for establishing links. In a "direct" protocol, each party hashes and encrypts their PII and shares the hashed tokens directly with the other party to compare matches. In a "blind" protocol, a third party known as a "linkage agent" is provided access to the hashed data but is unable to view PII. The linkage agent then compares the obfuscated information to establish linkages using the tokens (see Figure below).

Commercial implementations of PPRL services operating in the health domain need to demonstrate that the tokens created are deidentified per the HIPAA standard. This includes demonstrating ability to resist cryptanalytic attacks, dictionary attacks, and statistical attacks (e.g., frequency attacks, collusion attacks).

Figure 1. Tokenization/Unique ID Creation



VTrckS Data Dictionary

Last Updated 08/24/2020

Field Name	Category	Descriptions/Details
Provider number	VTrckS Provider Master Data	System-generated number
Provider PIN	VTrckS Provider Master Data	State-assigned provider ID made up of a three- character state code concatenated with a state assigned alphanumeric provider ID of up to 6 digits (optional field)
Provider Name	VTrckS Provider Master Data	Concatenated First and Last name or practice name
Street (Shipping)	VTrckS Provider Master Data	Street name and street number
Street2 (Shipping)	VTrckS Provider Master Data	Extra information, such as suite number
City (Shipping)	VTrckS Provider Master Data	Shipping City
State (Shipping)	VTrckS Provider Master Data	Shipping State
Zip Code (Shipping)	VTrckS Provider Master Data	Shipping zip code (can include 5 or 9 digit zip codes)
Provider record creation date	VTrckS Provider Master Data	Date on which the provider record was created in VTrckS
Provider status	VTrckS Provider Master Data	Active, Inactive, Pending, Suspended, Terminated
Provider email	VTrckS Provider Master Data	Email for main contact or provider site
COVID-19 Flag	VTrckS Provider Master Data	Provider eligible to receive COVID-19 vaccine
COVID-19 Flag Update Date	VTrckS Provider Master Data	Date when COVID-19 flag was updated
Awardee	VTrckS Provider Master Data	Immunization program under which provider is enrolled
Awardee ID	VTrckS Provider Master Data	Immunization program number
Provider number	Provider Attribute View	System-generated number
Provider PIN	Provider Attribute View	State-assigned provider ID made up of a three- character state code concaten
H1N1 attribute	Provider Attribute View	Non-VFC provider who was received H1N1 vaccine
Ever received VFC vax	Provider Attribute View	Has provider ever received VFC funded doses?
Ever received 317 vax	Provider Attribute View	Has provider ever received 317 funded doses?
Ever received Pandemic vax	Provider Attribute View	Has provider ever received
Awardee	Provider Attribute View	Immunization program under which provider is enrolled
Awardee ID	Provider Attribute View	Immunization program number
Provider number	Vaccine Shipment Data	System-generated number
Provider PIN	Vaccine Shipment Data	State-assigned provider ID; three- character alphabetic state code concatenat
Provider Name	Vaccine Shipment Data	Concatenated First and Last name or practice name
Order number	Vaccine Shipment Data	System-generated number
Order number line item	Vaccine Shipment Data	System-generated number
NDC	Vaccine Shipment Data	Product identification code—pandemic vaccines, adjuvant, and ancillary supp
NDC Description	Vaccine Shipment Data	Product description –pandemic vaccines, adjuvant, and ancillary supply kits

Vaccine Manufacturer Name	Vaccine Shipment Data	Name of Vaccine Manufacturer
Lot number(s)	Vaccine Shipment Data	Manufacturer lot number
Expiration date(s)	Vaccine Shipment Data	Manufacturer expiration date
Shipped Date	Vaccine Shipment Data	Date the order was shipped out from McKesson
Quantity Shipped	Vaccine Shipment Data	Doses shipped to provider office
Shipment Tracking Tracking	Vaccine Shipment Data	Multiple shipment tracking numbers
Awardee	Vaccine Shipment Data	Immunization program under which provider is enrolled
Awardee ID	Vaccine Shipment Data	Immunization program number
Provider number	Provider Inventory	System-generated number
Provider PIN	Provider Inventory	State-assigned provider ID made up of a three- character state code concaten
Awardee	Provider Inventory	Immunization program under which provider is enrolled
Awardee ID	Provider Inventory	Immunization program number
IOH Submitted Date	Provider Inventory	Data on which the inventory on hand was submitted
NDC(s)	Provider Inventory	Product identification code—pandemic vaccines, adjuvant, and ancillary supply kits
NDC Description (s)	Provider Inventory	Product description –pandemic vaccines, adjuvant, and ancillary supply kits
Quantity (s)	Provider Inventory	Doses
Lot number (s)	Provider Inventory	Manufacturer lot number
Expiration date (s)	Provider Inventory	Manufacturer expiration date
Depot ID	Depot Inventory	Centralized distribution depot number
Depot Name	Depot Inventory	Centralized distribution depot name
NDC(s)	Depot Inventory	Product identification code—pandemic vaccines, adjuvant, and ancillary supply kits
NDC Description (s)	Depot Inventory	Product description –pandemic vaccines, adjuvant, and ancillary supply kits
Lot number (s)	Depot Inventory	Manufacturer lot number
Expiration date (s)	Depot Inventory	Manufacturer expiration date
Vaccine Manufacturer Name	Depot Inventory	Name of Vaccine Manufacturer
Operational stock quantity (ies)	Depot Inventory	Doses in operating inventory
Hold for release stock quantity (ies)	Depot Inventory	Doses being held prior to release
Quality inspection stock quantity (ies)	Depot Inventory	Dose being held for quality inspection as they are received into Depot until it is cleared by BARDA
Restricted stock quantity (ies)	Depot Inventory	Doses being restricted for use (expired, damaged, temporarily on hold other than held for release)
Awardee ID	Vaccine Order Data	Immunization program number
Provider number	Vaccine Order Data	System-generated number
Order number	Vaccine Order Data	System-generated number
Order number line item	Vaccine Order Data	System-generated number
Provider PIN	Vaccine Order Data	State-assigned provider ID; three- character alphabetic state code concatenated with a state assigned alphanumeric provider ID of up to 6
Provider Name	Vaccine Order Data	Concatenated First and Last name or practice name

NDC	Vaccine Order Data	Product identification code—pandemic vaccines, adjuvant, and ancillary supply kits
NDC Description	Vaccine Order Data	Product description –pandemic vaccines, adjuvant, and ancillary supply kits
Vaccine Manufacturer Name	Vaccine Order Data	Name of Vaccine Manufacturer
Approved Date	Vaccine Order Data	Date order was approved for transmission
Quantity Approved	Vaccine Order Data	Quantity of doses ordered by Provider
Awardee	Vaccine Order Data	Immunization program under which provider is enrolled
Awardee ID	Allocation Data	Immunization program number
NDC	Allocation Data	Product identification code—pandemic vaccines, adjuvant, and ancillary supply kits
Date Allocated	Allocation Data	Date of Allocation
NDC Description	Allocation Data	Product description –pandemic vaccines, adjuvant, and ancillary supply kits
Quantity Allocated	Allocation Data	Quantity Allocated
Awardee	Allocation Data	Immunization program under which provider is enrolled

FIELD DEFINITIONS				DATA POPULATION			FIELD-LEVEL		
Field Number	COVID-19 Data Element	Variable Name	Data Element Description and Extract Guidance	Vaccination Event Data	Vaccination Refusal Data	Missed Appointment	Value Set	Data Type	Sample Responses
1	Vaccination event ID	vax_event_id	The vaccination event's unique identifier within the system. This should be a unique identifier for each vaccination event.	Required	Required	Required	n/a	String	568971356
2	Extract type	ext_type	Extract type defines whether this file contains completely de-identified data, PPRL ID, or fully identifiable data.	Required. Set to the value 'D'	Required. Set to the value 'D'	Required. Set to the value 'D'	Locally Defined Value Set: D (Deidentified) P (PPRL) I (Identified)	Coded Value	D
3	PPRL generated ID	pprl_id	Privacy Preserving Record Linkage ID.	Do not populate	Do not populate	Do not populate	n/a	String	
4	Recipient ID	recip_id	Unique ID for this recipient. This can be the ID used by your system or a randomly assigned unique identifier. However, the ID must be consistent across reports to allow linking doses to the same recipient ID.	Required	Required	Required	n/a	String	135498413
5	Recipient name: first	recip_first_name	Recipient's first name	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	n/a	String	Redacted
6	Recipient name: middle	recip_middle_name	Recipient's middle name	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	n/a	String	Redacted
7	Recipient name: last	recip_last_name	Recipient's last name	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	n/a	String	Redacted
8	Recipient date of birth	recip_dob	Recipient's date of birth	Required	Required	Required	n/a	Date	1968-05-27
9	Recipient sex	recip_sex	Recipient sex	Required	Required	Required	HL7 User Defined table 0001 M (Male) F (Female) U (Unknown/undifferentiated)	Coded Value	F
10	Recipient address: street	recip_address_street	The street component of the recipient's address	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	n/a	String	Redacted
11	Recipient address: street 2	recip_address_street_2	The street 2 component of the recipient's address	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	n/a	String	Redacted
12	Recipient address: city	recip_address_city	The city component of the recipient's address	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	Required. Set to the value "Redacted"	n/a	String	Redacted
13	Recipient address: county	recip_address_county	The county component of the recipient's address	Required if known for this recipient	Required if known for this recipient	Required if known for this recipient	FIPS Codes https://www.census.gov/geographies/reference-files/2019/demo/popest/2019-fips.html	Coded Value	13121
14	Recipient address: state	recip_address_state	The state component of the recipient's address	Required if known for this recipient	Required if known for this recipient	Required if known for this recipient	US Postal Service two-character State Codes	Coded Value	GA
15	Recipient address: zip code	recip_address_zip	The zip code of the recipient's address (5 digit or 10 digits, with hyphen, are acceptable)	Required if known for this recipient	Required if known for this recipient	Required if known for this recipient	n/a	String	30301
16	Recipient race 1	recip_race_1	Patient's race	Required	Required	Required	HL7 User Defined table 0005 1002-5 (American Indian or Alaska Native) 2028-9 (Asian) 2076-8 (Native Hawaiian or Other Pacific Islander) 2054-5 (Black or African American) 2106-3 (White) 2131-1 (Other Race) UNK (Unknown) POL (Unable to report due to	Coded Value	1002-5

17	Recipient race 2	recip_race_2	Patient's race. Fields recipient race 2-6 support recipients with more than 1 race. (Skip if only one race reported).	Required if known for this recipient	Required if known for this recipient	Required if known for this recipient	See Value Set in "Recipient Race 1" field	Coded Value	2076-8
18	Recipient race 3	recip_race_3	Patient's race. Fields recipient race 2-6 support recipients with more than 1 race. (Skip if only one race reported).	Required if known for this recipient	Required if known for this recipient	Required if known for this recipient	See Value Set in "Recipient Race 1" field	Coded Value	2106-3
19	Recipient race 4	recip_race_4	Patient's race. Fields recipient race 2-6 support recipients with more than 1 race. (Skip if only one race reported).	Required if known for this recipient	Required if known for this recipient	Required if known for this recipient	See Value Set in "Recipient Race 1" field	Coded Value	2131-1
20	Recipient race 5	recip_race_5	Patient's race. Fields recipient race 2-6 support recipients with more than 1 race. (Skip if only one race reported).	Required if known for this recipient	Required if known for this recipient	Required if known for this recipient	See Value Set in "Recipient Race 1" field	Coded Value	2054-5
21	Recipient race 6	recip_race_6	Patient's race. Fields recipient race 2-6 support recipients with more than 1 race. (Skip if only one race reported).	Required if known for this recipient	Required if known for this recipient	Required if known for this recipient	See Value Set in "Recipient Race 1" field	Coded Value	2028-9
22	Recipient ethnicity	recip_ethnicity	The ancestry of the patient	Required	Required	Required	HL7 User Defined table 0189 2135-2 (Hispanic or Latino) 2186-5 (Not Hispanic or Latino) UNK (Unknown ethnicity) POL (Unable to report to do policy/law)	Coded Value	2135-2
23	Administration date	admin_date	The date the vaccination event occurred (or was intended to occur)	Required	Required. This will represent the date the	Required. This will represent the date of	n/a	Date	2020-12-15
24	CVX	cvx	The vaccine type that was administered.	Required	Required	Do not populate	To be updated when COVID vaccine is available. Factitious codes for development purposes are provided here: 900 (COVID-19 Vaccine A) 901 (COVID-19 Vaccine B) 902 (COVID-19 Vaccine -	Coded Value	901
25	NDC	ndc	The vaccine product that was administered. Unit of Use (UoU) is preferred if both UoU and Unit of Sale (UoS) are available.	Required if known for this vaccination event	Do not populate	Do not populate	To be updated when COVID vaccine is available	Coded Value	
26	MVX	mvx	The manufacturer of the vaccine administered	Required if known for this vaccination event	Do not populate	Do not populate	To be updated when COVID vaccine is available. Factitious codes for development purposes are provided here: AAA (COVID-19 Manufacturer A)	Coded Value	BBB
27	Lot number	lot_number	The lot number of the vaccine administered: Unit of Use (UoU) is preferred if both UoU and Unit of Sale (UoS) are available.	Required if known for this vaccination event	Do not populate	Do not populate	n/a	String	A###A
28	Vaccine expiration date	vax_expiration	The expiration date of the vaccine administered. This can either be YYYY-MM-DD or YYYY-MM	Required if known for this vaccination event	Do not populate	Do not populate	n/a	Date	2021-06-18

29	Vaccine administering site	vax_admin_site	The body site of vaccine administration.	Required if known for this vaccination event	Do not populate	Do not populate	HL7 defined table 0163 LT (Left thigh) LA (left arm) LD (left deltoid) LG (left gluteus medius) LVL (left vastus lateralis) LLFA (left lower forearm) RT (right thigh) RA (right arm) RD (right deltoid) RG (right gluteus medius) RVL (right vastus lateralis) RLFA (right lower forearm)	Coded Value	LA
30	Vaccine route of administration	vax_route	The route of vaccine administration (e.g., oral, subcutaneous)	Required if known for this vaccination event	Do not populate	Do not populate	HL7 defined table 0162 or FDA NCI Thesaurus (NCIT) NCIT values preferred and provided for reference C38238 (Intradermal) C28161 (Intramuscular) C38284 (Nasal) C38276 (Intravenous) C38288 (Oral) C38676 (Percutaneous) C38299 (Subcutaneous) C38305 (Transdermal)	Coded Value	C38238
31	Dose number	dose_num	Dose # in vaccination series provided dose is considered valid (e.g., counts towards immunity).	Required	Do not populate	Do not populate	Locally Defined Value Set: 1 (Valid first dose) 2 (Valid second dose) 3 (Valid third dose) 4 (Valid fourth dose) 5 (Valid Fifth dose) 6 (Valid sixth dose) INV (Invalid dose) UNK (Unknown validity)	Coded Value	2
32	Vaccination series complete	vax_series_complete	Report if the vaccination series is complete. Select "YES" when the recipient has completed the required doses for the specific vaccine product. If more doses are required select "NO." If unknown, or cannot be calculated, select "UNK."	Required	Do not populate	Do not populate	Locally Defined Value Set: YES (Yes) NO (No) UNK (Unknown)	Coded Value	YES
33	Responsible organization	responsible_org	The name of the parent organization or health system that originated and is accountable for the content of the record. If an organization has several clinics or facilities, this would be the organization that represents all of the clinics/facilities. (The "Administered at location" field is the name of individual physical location.)	Required	Required	Required	n/a	String	Emory Hospital
34	Administered at location	admin_name	The name of the physical clinic or facility that reported the vaccination, refusal, or missed appointment. In some cases, this could be the same as the responsible organization.	Required	Required	Required	n/a	String	Hope Clinic
35	VTrckS provider PIN	vtrcks_prov_pin	This is the 6-digit Provider PIN in VTrckS. For VFC Providers, this is the VFC PIN. This ID is being used for linking across data sources.	Required	Required	Required	n/a	String	123456

36	Administered at location: type	admin_type	The characteristic of the provider site that reported the vaccination, refusal, or missed appointment	Required	Required	Required if known for this missed appointment	Locally Defined Value Set: Childcare or daycare facility College, technical school, or university Community center Correctional/detention facility Health care provider office, health center, medical practice, or outpatient clinic In-home Hospital (i.e., inpatient facility) Pharmacy Long-term care facility (e.g., nursing home, assisted living, independent living, skilled nursing) Public health clinic (e.g., local health department) School (K – grade 12) Shelter Temporary or off-site vaccination clinic – point of dispensing (POD) Temporary location – mobile clinic Urgent care facility	Coded Value	PH
37	Administration address: street	admin_address_street	The street component of where the vaccine is being administered/planned to be administered.	Required if known for this vaccination event	Required if known for this refusal	Required if known for this missed appointment	n/a	String	123 Long Road
38	Administration address: street 2	admin_address_street_2	The street 2 component of where the vaccine is being administered/planned to be administered.	Required if known for this vaccination event	Required if known for this refusal	Required if known for this missed appointment	n/a	String	Suite #300
39	Administration address: city	admin_address_city	The city component of where the vaccine is being administered/planned to be administered.	Required if known for this vaccination event	Required if known for this refusal	Required if known for this missed appointment	n/a	String	Atlanta
40	Administration address: county	admin_address_county	The county component of where the vaccine is being administered/planned to be administered.	Required if known for this vaccination event	Required if known for this refusal	Required if known for this missed appointment	FIPS codes https://www.census.gov/geographies/reference-files/2019/demo/popest/2019-fips.html	Coded Value	13121
41	Administration address: state	admin_address_state	The state component of where the vaccine is being administered/planned to be administered.	Required if known for this vaccination event	Required if known for this refusal	Required if known for this missed appointment	US Postal Service two-character state codes	Coded Value	GA
42	Administration address: zip code	admin_address_zip	The zip code component of where the vaccine is being administered/planned to be administered.	Required if known for this vaccination event	Required if known for this refusal	Required if known for this missed appointment	n/a	String	30301
43	Vaccine administering provider suffix	vax_prov_suffix	The professional designation of the person administering the vaccination. (e.g., MD, LPN, RN). May also be referenced as vaccination administering provider type.	Required	Do not populate	Do not populate	Locally Defined Value Set: RN (Registered nurse) MD (Medical doctor) NP (Nurse practitioner) PA (Physician assistant) LPN (Licensed practical nurse) OTH (Other) UNK (Unknown)	Coded Value	NP

