![cdisc]

Vaccine Administration
v1.0 (Final)

Mapping Curation of Minimum
Data Elements and Metadata
(Basic Interoperability Elements)

Developed in Collaboration with the Learning Health Community
LHC Initiative: Global Collaboration to Address the
COVID-19 Pandemic and Future Public Health Challenges

![LEARNING HEALTH COMMUNITY logo]

Notes to Readers

- This mapping document is based on the eHealth Network Guidelines on proof of vaccination for medical purposes - basic interoperability elements v.1.1 and focused on supporting the **international travel** use case.

- The mappings included are informed by the US CDC Endorsed Data Elements, the EU Digital Green Certificate and the WHO Interim Guidance for Developing a Smart Vaccine Certificate (SVC) and point to the following global standards: CDISC, HL7-FHIR, ISO Standards (8601 and 3166) and ICD 10/11, SNOMED, WHODrug and ATC Classifications.

Revision History

Date	Version
2021-06-22	1.0 Final

See the Appendix for representations and warranties, limitations of liability, and disclaimers.

CONTENTS

1 Introduction

One lesson from the COVID-19 pandemic is that the greatest public health challenges of our generation will show no respect for national boundaries, will impact the lives and health of people of all nations, and will affect economies and quality of life in unprecedented and unpredictable ways. The collaboration required to address these challenges must be cross-sector, multi-stakeholder, transdisciplinary, and global in nature. A pandemic is not just a worldwide disease epidemic; it is a global health emergency which, as such, requires advanced tools, qualified data sharing, and multi-stakeholder cross-border collaboration.

One of the most explicit obstacles to implementing this collaboration is a lack of comprehensive and standardized ways of structuring qualified data selected such that it can be rapidly exchanged and accessed. When the health and well-being of entire populations are at stake, the world must speak one language and must be seamlessly interconnected. Silos of data may work to benefit people who reside in specific regions or who receive their health care through specific organizations, but microbes do not respect these boundaries. "*When viruses cross geographic boundaries, the information to manage the disease must see no boundaries.*"[1]

Most national health information systems have faced significant limitations in coping with the current pandemic challenge. Approaches to collecting and managing pandemic-related data have been fragmented and the data are often incomplete and almost always lack the compatibility required for simple and timely transfers between different sources even within given regions of countries. *A pandemic in the digital era should not be fought with analog data and manual procedures of the previous century*.[1] A growing body of literature points to how the lack of relevant data, as well as collection gaps and inconsistencies in data, undermined responses to the pandemic and has needlessly cost hundreds of thousands of lives worldwide, not to mention resulting in incremental economic damage.

To address this situation, a collaboration was formed among experts from 3 countries—Spain, Italy, and the United States, all of which experienced serious challenges during the COVID-19 pandemic. The mission, as an initiative of the Learning Health Community (LHC), is to design and explore a systems-based approach to COVID-19 data management to inform real-time strategic decision making during a pandemic or other public health emergency. After publication of Ros et al.'s article describing such an approach,[1] the collaborating experts decided that an initial project of reasonable scope should be identified and undertaken to make a real impact of potentially global nature. Through this collaboration, the Clinical Data Interchange Standards Consortium (CDISC) and the LHC are advocating for a single global data standard for documenting vaccination status for travel across all borders.

The proposed standard minimum set of common data elements is based upon existing standards in use around the world. This standard will reduce the effort required to develop applications on which data will be based and it will greatly facilitate semantic interoperability among applications that leverage these data elements. This in turn should avert delays and other issues for travelers at international borders and future such use cases.

1.1 Goal

The goal is to achieve multinational agreement around a core minimum set of data elements that document vaccine administration, to enable smart-data application and sharing for uses such as safe travel, statistical inferences, and learning, among all nations of the world. The long-term goal is to be able to make informed decisions based on trustworthy data to improve international management of pandemics.

This document provides public health implementers with direction on how to define and organize these data elements in a database, by providing data element metadata to enable machine readability, data sharing, and semantic interoperability, with the added benefit of facilitating the flow of data for submission to global regulatory authorities.

1.2 Scope and Outcomes

The data standard for a minimum set of data elements has been informed by and mapped to a number of international standards; these are not new data elements. This unified standard is intended to serve as a concrete common structure to facilitate data gathering, storage, processing, and sharing (by institutions and certified registries) in relation to vaccine inoculation/administration documentation.

- The proposed set of common data elements is based upon recommendations from the European eHealth Network (EHN),[2] as referenced by the European Commission in announcing their plans for a "green certificate,"[3] and World Health Organization (WHO) "smart certificate" guidance[4] to facilitate travel by Europeans among European Union (EU) countries. This set of common data elements has also been informed by the US Centers for Disease Control and Prevention (CDC) identified data elements.[5] These elements have been aligned with standards from standards-developing organizations including CDISC, Health Level Seven International (HL7), and the International Standards Organization (ISO), where applicable.

- Decisions regarding whether to require a travel certification and the associated legal and ethical implications should be addressed by the appropriate institutions; we are not attempting to address such policies in this document proposal.

- A common data framework like this one, adopted by national and international institutions and their respective data repositories/registries, will provide relevant vaccination data for analyses and the development and implementation of technology applications; we are not attempting to advise on these downstream activities.

- Vaccine safety data is out of scope for this project; such data are being addressed by vaccine manufacturers and regulators.

- Implementers are strongly advised to refer to local and national data privacy regulations prior to using these standards. The inclusion of these data elements and mappings should not be interpreted as approval for use in all countries.

2 Methodology

We purposefully limited the scope of this project to core elements contained in the eHealth Network guidelines for proof of vaccination[2] and identified corresponding elements in the CDC endorsed data elements posted by the American Immunization Registry Association.[6] We also identified corresponding EU digital green passport and WHO smart certificate guidance data elements.[4]

To streamline collection and organization of these 20 basic interoperability data elements, we identified CDISC Clinical Data Acquisition Standards Harmonization (CDASH)[7] and Study Data Tabulation Model (SDTM)[8] data elements with associated terminology curated by the US National Institute of Health's Enterprise Vocabulary Services,[9] and the HL7 implementation guide[10] for data elements not available in CDISC's published data standards. As a separate layer, we mapped to the CDC endorsed data elements[4] for these elements. Finally, we have referred to terminologies from ICD 10/11,[11] SNOMED CT,[12], WHODrug,[13] ATC classification,[14] and CDISC SDTM terminology,[8] as applicable.

In the tables that follow, the origins of each data element have been identified as EHN for the European eHealth Network, CDC for the US CDC endorsed data elements,[4] HL7, and CDISC, as appropriate. In addition, we have identified appropriate use of ISO 3166 for country codes,[15] ISO 8601 for date formats,[16] and the ISO standard for identification of medicinal products (IDMP).[17]

3 Collaborating Organizations

3.1 About the Learning Health Community

The Learning Health Community (LHC) is a global grassroots movement in which multiple and diverse stakeholders work together to transform healthcare and health by collaboratively realizing person-centered Learning Health Systems (LHSs) anchored in shared consensus Core Values; LHSs aim to efficiently and equitably serve the learning needs of all participants, as well as the overall public good.

Global Information for Public Health Transformation (GIPHT) is an initiative of the LHC. This multinational collaboration was initially guided by experts from 3 countries—Spain, Italy, and the United States—which experienced serious challenges during the COVID-19 pandemic. The GIPHT mission is to design and explore a data-driven, standards-based systems approach to COVID-19 data management to inform real-time and strategic decisions during a pandemic or other public health emergencies.

3.2 About CDISC

CDISC is a global nonprofit charitable organization with over 500 member organizations. CDISC is incorporated as a 501(c)(3) association and has an office in Austin, Texas, and employees based in the US and Europe. CDISC Europe Foundation is based in Brussels, Belgium. CDISC standards are harmonized globally and do not vary by country. The use of globally harmonized CDISC data standards has facilitated regulatory reviews of data supporting new therapies and vaccines for COVID-19 and other therapeutic areas. CDISC published a standard for sharing data from clinical research on COVID-19 therapies and vaccines in April 2020.[18]

4 Consensus Minimum Dataset - Data Elements

4.1 Patient Identification

Section	Data Element (Origin)	Description (Maps to)
Patient Identification	Family Name (EHN, Digital Green Certificate, CDC, WHO)	The legal surname of the vaccinated person (surname(s) and forename(s)) in that order HL7-FHIR
	Given Name (EHN, Digital Green Certificate, CDC, WHO)	The legal forename of the vaccinated person HL7-FHIR
	Person Identifier (EHN)	The identifier of the vaccinated person CDISC NSV
	Person Identifier Type (EHN, WHO)	The type of identifier of the vaccinated person, according to the policies applicable in each country. Examples: citizen ID and/document number (ID- card/passport) or identifier within the health system/ISS/e- registry. CDISC NSV
	Date of Birth (EHN, CDC, WHO)	Vaccinated person's date of birth CDISC BRTHDAT ISO 8601 date and time format
	Gender/Sex (EHN, CDC, WHO)	Administrative gender/sex CDISC (SEX) HL7-FHIR (SEX, Gender)

4.2 Vaccine Information

In the eHealth Network guidance (Annex, p. 9), one of the data elements is "Number in a series of vaccinations/doses."[2] CDISC has split this element into 2 elements, one a property of the vaccine and the other a property of the individual vaccine administration. This allows collection of information about the vaccine once while allowing collection of information about multiple individual doses. The first data element is "Number in a series of vaccinations/doses" (see following table) and the second is "Dose number" (see Section 4.3, Vaccine Administration Information).

Section	Data Element (Origin)	Description (Maps to)
Vaccine Information	Disease or agent targeted (EHN, WHO)	Disease or agents that vaccination provides protection against CDISC variable/data element, Terminology from ICD 10 or ICD 11, terminology from SNOMED CT
	Vaccine/ Prophylaxis (EHN, CDC, WHO)	Generic description of the vaccine/prophylaxis or its components (populated from product name or derived from coding) CDISC, terminology from WHODrug and ATC Classification
	Vaccine Medicinal Product (EHN, CDC, WHO)	Medicinal product name ISO IDMP (example terminology (EDQM) that can be used but any regional terminology is acceptable for use)
	Marketing Authorization holder or manufacturer (EHN, CDC, WHO)	Marketing authorization holder or manufacturer Populated from product name CDISC NSV
	Number in a series of vaccinations/ doses (EHN)	Intended dose regimen Populated from product name CDISC NSV

4.3 Vaccine Administration Information

This section may be repeated for dose 2, as applicable.

Section	Data Element (Origin)	Description (Mapping)
Vaccine Information	Dose number (EHN, WHO)	Dose within the intended dose regimen CDISC NSV
	Date of dose (EHN, CDC, WHO)	Actual date of this vaccination/dose CDISC, ISO 8601 date and time format
	Batch/Lot Number (EHN, CDC, WHO)	A distinctive combination of numbers and/or letters which specifically identifies a batch CDISC CMLOT
	Next Vaccination Date (optional)	Date on which the next administration should be given. CDISC, ISO 8601 date and time format
	Administering Center/Site (EHN, CDC, WHO)	Name/code of administering center or health authority responsible for the vaccination event HL7-FHIR
	Dose Administered by (EHN, CDC, WHO)	Name or health professional code responsible for administering the vaccine or prophylaxis HL7-FHIR
	Country of vaccination (EHN, WHO)	The country in which the individual has been vaccinated HL7-FHIR ISO 3166 3-letter country codes

4.4 Certificate Metadata

Section	Data Element (Origin)	Description (Mapping)
Certificate Metadata (administrative)	Certificate issuer (EHN)	Entity that has issued the certificate (allowing to check the certificate)
	Certificate Identifier (EHN)	Unique identifier of the certificate (UVCI), to be printed (human readable) into the certificate; the unique identifier can be included in Immunization Information Systems (IIS)
	Certificate Valid From (optional) (EHN)	Certificate valid from (required if known) ISO 8601 date and time format
	Certificate Valid Until (optional) (EHN)	Certificate valid until (validity can differ from the expected immunization period) ISO 8601 date and time format
Certificate schema	Certificate schema version (EHN)	Version of this minimum dataset definition. Version of EHN guideline. No mapping necessary.

5 Example of Collected Data in the SDTM

This example shows data for 3 subjects who were vaccinated for COVID-19.

Collected data appears in 2 SDTM domains: subject information in Demographics (DM), and vaccine administration in Concomitant and Prior Medications (CM; see SDTM Implementation Guide (SDTMIG) v3.3[19]).

This document includes 2 examples: one showing data as collected, the other showing how data about vaccinations might appear if it were included in submission datasets for a clinical study. The main difference is that data as collected includes personal details, whereas clinical study data does not. Depending on the protocol for a clinical study, some data originally collected may not be of interest for the purposes of the study submission.

5.1 Vaccination Data at Collection

5.1.1 Demographic Data

At vaccination, demographic data, including personal information, is collected.

- Use of HL7-FHIR elements for Person Name is recommended for this use case.

- As an alternative to HL7- FHIR, CDISC NSVs can be used.

  - In the first table (dm.xpt), standard SDTM variables are on the left, before the break. Note that SDTM standard variables related to study participation (e.g., study identifier, study-specific subject identifiers) are not presented for this use case. Non-standard variables (NSVs) are on the right after the break. These include personal identification information. The values shown for personal identifier type are generic; actual values would include the name of a specific hospital, country, or other jurisdiction. Values shown for personal identifiers are fictional.

  - The second table (DM NSV Metadata) provides information about NSVs. Metadata about standard variables are in the SDTMIG, so this table includes only metadata for NSVs.

DM Metadata

dm.xpt

Row	DOMAIN	BRTHDTC	SEX	PIDTYP	PERSONID	FAMNAME	GIVENAM1	GIVENAM2
1	DM	1950-06-10	F	National Person Identifier	000 00 0000	SMITH	JANE	ELLEN
2	DM	1962-09-17	M	Hospital Patient Identifier	AZ1234	JOHNSON	JOHN	JACOB
3	DM	1956-10-12	F	Country Drivers License	12345689	BROWN	MARY	ANN

DM NSV Metadata

Variable	Label	Type	Role	Origin
PIDTYP	Person Identifier Type	text	Non-Standard Record Qualifier	CRF
PERSONID	Person Identifier	text	Non-Standard Record Qualifier	CRF
FAMNAME	Family Name	text	Non-Standard Record Qualifier	CRF
GIVENAM1	First Given Name	text	Non-Standard Record Qualifier	CRF
GIVENAM2	Second Given Name	text	Non-Standard Record Qualifier	CRF

5.1.2 Data about Vaccination

Data about vaccination is represented in a CM dataset.

- Use of HL7-FHIR elements for Person Name is recommended for this use case. Please refer to table 4.3 for recommendations.

- As an alternative to HL7- FHIR, CDISC NSVs can be used.

- This dataset includes multiple records per subject; CMSEQ identifies different records for the same subject.

- The CMMOOD variable distinguishes between performed vaccinations and planned vaccinations (i.e., appointments scheduled for future vaccinations). Only records for actual performed vaccinations include information about dose and lot.
- NSVs include
  - Personal identifiers
  - The variables CMNUMSER and CMREPNUM, which indicate the number of vaccinations in a series for the vaccine given and whether this is a first or second dose
  - Identifiers for the facility at which the vaccine was administered (CMADMCEN) and the health professional who administered the vaccine (CMADMHCP). The values given are placeholders.
  - For the final dose of vaccine, the variables CMCRTISS, CMRTID, CMCSTDTC, CMENDTC, and CMCVERNO, which document certification that the person has been vaccinated. The start and end dates of certification given are based on the assumption that certification begins on the date of last vaccination and lasts 2 years; these assumptions may not be true for actual certification.

Row 1:   Shows the first subject's first dose of vaccine.

Row 2:   Shows the scheduled date of the second dose of vaccine for this subject.

Row 3:   Shows the administration of this subject's second dose of vaccine. For the authority who certified this vaccination, certification was issued when all doses of the vaccine were given, so the certification was represented in non-standard variables for this record.

Rows 4-6:   Show the administration of the second subject's first dose, the scheduled date of the second dose, and the administration of the third dose.

Row 7:   Shows the administration of the second subject's vaccine, which required only 1 dose. Information on the certification of this vaccination was not collected.

DM Metadata

cm.xpt

cm.xpt

Row	DOMAIN	CMSEQ	CMTRT	CMDECOD	CMMOOD	CMINDC	CMLOT	CMSTDTC	PIDTYP	PERSONID	FAMNAME	GIVENAM1	GIVENAM2	CMMNFAC	CMNUMSER	CMREPNUM	CMADMCEN	CMADMHCP	CMCNTRY	CMCRTISS	CMCRTID	CMCSTDTC	CMCENDTC	CMCVERNO
1	CM	1	Comirnaty	COVID-19 mRNA vaccine	PERFORMED	SARS-CoV-2	XYZ490	2021-02-02	National Person Identifier	000 00 0000	SMITH	JANE	ELLEN	PFIZER	2	1	1097430387	124098OIHJ	USA					
2	CM	2	Comirnaty	COVID-19 mRNA vaccine	SCHEDULED	SARS-CoV-2		2021-02-23	National Person Identifier	000 00 0000	SMITH	JANE	ELLEN	PFIZER	2				USA					
3	CM	3	Comirnaty	COVID-19 mRNA vaccine	PERFORMED	SARS-CoV-2	XYZ5198	2021-02-23	National Person Identifier	000 00 0000	SMITH	JANE	ELLEN	PFIZER	2	2	1097430387	09780AIOG	USA	Country Department of Health	12345678	2021-02-23	2023-02-23	v1.0.0
4	CM	1	Moderna COVID-19 Vaccine	COVID-19 mRNA vaccine	PERFORMED	SARS-CoV-2	014M20A	2021-02-08	Hospital Patient Identifier	AZ1234	JOHNSON	JOHN	JACOB	MODERNA	2	1	234098700	52343CULE	USA					
5	CM	2	Moderna COVID-19 Vaccine	COVID-19 mRNA vaccine	SCHEDULED	SARS-CoV-2		2021-03-08	Hospital Patient Identifier	AZ1234	JOHNSON	JOHN	JACOB	MODERNA	2				USA					
6	CM	3	Moderna COVID-19 Vaccine	COVID-19 mRNA vaccine	PERFORMED	SARS-CoV-2	014M20D	2021-03-08	Hospital Patient Identifier	AZ1234	JOHNSON	JOHN	JACOB	MODERNA	2	2	234098700	35136AOUD	USA	Country Department of Health	12356789	2021-03-08	2023-03-08	v1.0.0
7	CM	1	Janssen COVID-19 Vaccine	COVID-19 antigen vaccine	PERFORMED	SARS-CoV-2	ABC234	2021-03-05	Country Drivers License	12345689	BROWN	MARY	ANN	JOHNSON AND JOHNSON	1			357338186	35654AULE	USA				

CM Non-Standard Variable Metadata

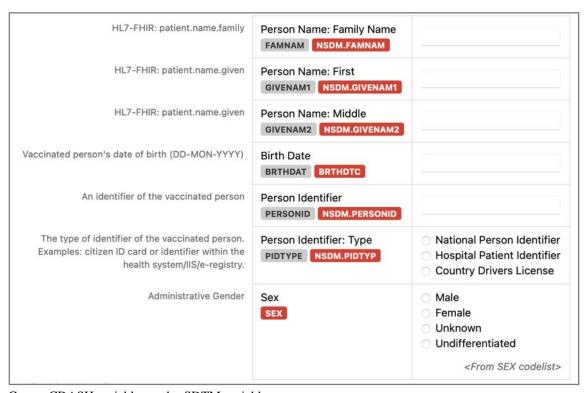| Variable	Label	Type	Role	Origin
PIDTYP	Personal Identifier Type	text	Non-standard Record Qualifier	CRF
PERSONID	Person Identifier	text	Non-standard Record Qualifier	CRF
FAMNAME	Family Name	text	Non-standard Record Qualifier	CRF
GIVENAM1	First Given Name	text	Non-standard Record Qualifier	CRF
GIVENAM2	Second Given Name	text	Non-standard Record Qualifier	CRF
CMMNFAC	Manufacturer	text	Non-standard Record Qualifier	Assigned
CMNUMSER	Number of Doses in Series	integer	Non-standard Record Qualifier	Assigned
CMREPNUM	Repetition Number	integer	Non-standard Record Qualifier	CRF
CMADMCEN	Administering Center Identifier	text	Non-standard Record Qualifier	CRF
CMADMHCP	Administering Health Professional Identifier	text	Non-standard Record Qualifier	CRF
CMCNTRY	Country of Administration	text	Non-standard Record Qualifier	CRF
CMCRTISS	Certification Issuer	text	Non-standard Record Qualifier	CRF
CMCRTID	Certification Identifier	text	Non-standard Record Qualifier	CRF
CMCSTDTC	Certification Valid From Date	date	Non-standard Record Qualifier	CRF
CMCENDTC	Certification Valid to Date	date	Non-standard Record Qualifier	CRF
CMCVERNO	Certification Version Number	text	Non-standard Record Qualifier	CRF

6 Case Report Form Visualizations

Text to the left of a field contains either a CDISC prompt or, for data elements with no standard CDISC prompt, the name of an HL7-Fast Healthcare Interoperability Resources (FHIR) data element.

This CRF collects the vaccination data for each separate visit to the administering site. This form allows for the possibility of a booster shot being administered in the future.

Implementers may elect to create a separate record in the SDTM Concomitant and Prior Medications (CM) dataset for the next scheduled dose date. Alternatively, the next scheduled date could be included on the first dose record using a non-standard variable (NSV).

The name of the person administering the vaccine was represented using an NSV. This was done so because vaccine sites may employ many individuals to administer the vaccine and it may not be the same individual at each visit.

6.1 Person Identification

Grey = CDASH variables; red = SDTM variables
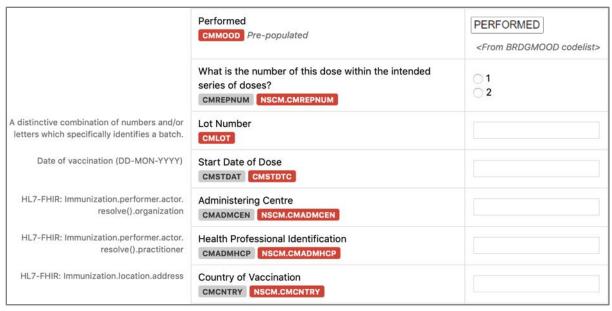
6.2 Vaccine Product

Only the name of the treatment is collected. Manufacturer, WHODrug coding, and the number of vaccinations in the series are determined from the treatment name.

For example:

Treatment Name (CMTRT)	Manufacturer (CMMNFAC)	WhoDrug product name (CMDECOD)	Number of vaccinations in series (CMNUMSER)
Comirnaty	PFIZER	COVID-19 mRNA vaccine	2
Moderna COVID-19 Vaccine	MODERNA	COVID-19 mRNA vaccine	2
Janssen COVID-19 Vaccine	JOHNSON AND JOHNSON	COVID-19 antigen vaccine	1

Medicinal product name	Indication `CMINDC` *Pre-populated*	COVID-19/SARS-CoV-2
	What was the vaccine administered? `CMTRT`	◯ Comirnaty ◯ Moderna COVID-19 Vaccine ◯ Janssen COVID-19 Vaccine

Grey = CDASH variables; red = SDTM variables
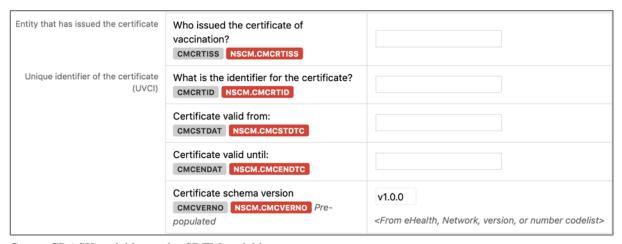
6.3 Vaccine Administration

	Performed `CMMOOD` *Pre-populated*	PERFORMED *<From BRDGMOOD codelist>*
	What is the number of this dose within the intended series of doses? `CMREPNUM` `NSCM.CMREPNUM`	◯ 1 ◯ 2
A distinctive combination of numbers and/or letters which specifically identifies a batch.	Lot Number `CMLOT`	
Date of vaccination (DD-MON-YYYY)	Start Date of Dose `CMSTDAT` `CMSTDTC`	
HL7-FHIR: Immunization.performer.actor. resolve().organization	Administering Centre `CMADMCEN` `NSCM.CMADMCEN`	
HL7-FHIR: Immunization.performer.actor. resolve().practitioner	Health Professional Identification `CMADMHCP` `NSCM.CMADMHCP`	
HL7-FHIR: Immunization.location.address	Country of Vaccination `CMCNTRY` `NSCM.CMCNTRY`	

Grey = CDASH variables; red = SDTM variables

6.4 Next Vaccination (if applicable)

Next Vaccination (if applicable)		
	Scheduled **CMMOOD** *Pre-populated*	SCHEDULED *<From BRDGMOOD codelist>*
Date on which the next vaccination date should be administered (DD-MON-YYYY)	Start Date of Dose **CMSTDAT** **CMSTDTC**	

Grey = CDASH variables; Red = SDTM variables

6.5 Certification Metadata

Entity that has issued the certificate	Who issued the certificate of vaccination? **CMCRTISS** **NSCM.CMCRTISS**	
Unique identifier of the certificate (UVCI)	What is the identifier for the certificate? **CMCRTID** **NSCM.CMCRTID**	
	Certificate valid from: **CMCSTDAT** **NSCM.CMCSTDTC**	
	Certificate valid until: **CMCENDAT** **NSCM.CMCENDTC**	
	Certificate schema version **CMCVERNO** **NSCM.CMCVERNO** *Pre-populated*	v1.0.0 *<From eHealth, Network, version, or number codelist>*

Grey = CDASH variables; red = SDTM variables

7 References

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8 Appendix: Representations and Warranties, Limitations of Liability, and Disclaimers

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