



# Vaccine Administration Standard

## National Vaccine Advisory Committee Meeting

Rhonda Facile  
Vice President, Partnerships, Development and Education

11 February 2022



# Agenda

Brief Introduction to CDISC

CDISC COVID-19 Guide v1

CDISC and Learning Health Community  
Collaboration

Vaccine Administration Standard v1

# What is CDISC?



Founded in 1997 by Volunteers



Global Standards Development Organization (SDO)  
501(c)(3) non-profit organization



Community consensus standards development for  
clinical & translational research



Standards are freely available [www.cdisc.org](http://www.cdisc.org)

# CDISC Standards and Global Regulation

<https://www.fda.gov/media/88120/download>

Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)

December 2014  
Electronic Submissions

<https://www.fda.gov/media/82716/download>

Providing Regulatory Submissions In Electronic Format — Standardized Study Data Guidance for Industry

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Oncology Center of Excellence (OCE)

June 2021  
Electronic Submissions  
Revision 2

<https://www.fda.gov/media/147233/download>

STUDY DATA  
TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following Guidance Document(s):

Guidance for Industry: *Providing Regulatory Submissions in Electronic Format — Standardized Study Data*

For questions regarding this technical specifications document, contact CDER at [cderelem@fda.hhs.gov](mailto:cderelem@fda.hhs.gov) or CBER at [cberelem@fda.hhs.gov](mailto:cberelem@fda.hhs.gov)

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)

August 2021

<https://www.nmpa.gov.cn/directory/web/nmpa/images/obbSqG7wvdm0ssrU0enKb7dtd29u9a4tbzUrdTyo6jK1NDQo6mhty5wZGY=.pdf>

药物临床试验数据递交指导原则  
(试行)

Translation: *Guidance for Submission of Drug Clinical Trial Data (Draft)*

2020年7月

**BINDING  
DOCUMENTS**

- CDISC standards are required for submission to FDA and Japan PMDA.
- CDISC standards are the only standards recognized for submissions by China NMPA.
- CDISC standards are recommended by EU EMA for patient-level data submission.

# What CDISC Does

- Convenes a global community of experts to develop and advance data standards of the highest quality, CDISC helps to create clarity in clinical research.
- Together, we enable the accessibility, interoperability, and reusability of data for more meaningful and efficient research that has greater impact on global health. (FAIR data)



# COVID-19 User Guide v1.0

- What
  - Translate a core set of vaccine research concepts into CDISC standards
- Why
  - Improve semantic understanding, support data sharing, and facilitate global regulatory submission
- Outcome
  - The Covid-19 expedited User Guide was used by companies to speed application preparation & submission. Which helped speed & facilitate the FDA review process.

[https://www.cdisc.org/system/files/members/standard/ta/TAUG-COVID-19\\_v1.0\\_0.pdf](https://www.cdisc.org/system/files/members/standard/ta/TAUG-COVID-19_v1.0_0.pdf)



## Therapeutic Area User Guide for COVID-19

Version 1.0 (Provisional)

Prepared by the CDISC COVID-19 Task Force

### Notes to Readers

- This is the provisional Version 1.0 of the Therapeutic Area User Guide for COVID-19.
- This document is based on SDTM v1.7 and SDTMIG v3.3.

### Revision History

Date	Version
2021-07-08	1.0 Final

See [Appendix D](#) for representations and warranties, limitations of liability, and disclaimers.

**Mission:** Galvanize a global grassroots movement in which multiple and diverse stakeholders work together to transform healthcare and health by collaboratively realizing the Learning Health System vision embodied by the consensus *Core Values*.



learninghealth.org/2020-global-collaboration-for-public-health

LEARNING HEALTH COMMUNITY

**Initiatives**  
COMMUNITY INITIATIVES  
2021 LHS TOOLKIT  
2020 ESOURCE SYMPOSIUM

Received: 13 July 2020 | Revised: 2 November 2020 | Accepted: 17 November 2020  
DOI: 10.1002/hl2.10253

Check for updates

**Learning Health Systems**

**TECHNICAL REPORT**

**Addressing the Covid-19 pandemic and future public health challenges through global collaboration and a data-driven systems approach**

Francisco Ros<sup>1</sup> | Rebecca Kush<sup>2</sup> | Charles Friedman<sup>3</sup> | Esther Gil Zorzo<sup>4</sup> | Pablo Rivero Corte<sup>5</sup> | Joshua C. Rubin<sup>3</sup> | Borja Sanchez<sup>6</sup> | Paolo Stocco<sup>7</sup> | Douglas Van Houweling<sup>3</sup>

**Global Information for Public Health Transformation (GIPHT) Initiative**

**Global Collaboration to Address the COVID-19 Pandemic and Future Public Health Challenges**

LAUNCHED MARCH 2020

PROJECT OVERVIEW

GIPHT Project: TOWARDS ONE GLOBAL STANDARD FOR DIGITAL PROOF OF COVID-19 VACCINATION

Why Should We have a Global Common Digital way to Show Proof of COVID-19 vaccination?

Partnered with CDISC on Global Vaccine Administration Standard V1.0  
[www.LearningHealth.org](http://www.LearningHealth.org)

# Vaccine Administration v1.0 – Mapping Curation

## Rationale & Goals

- Use case – International Travel
- Urgent need - global COVID-19 pandemic
- Support emerging applications with an international data standard for interoperability of core data elements and underlying metadata related to vaccine administration
- Harmonize a set of core vaccine administration data elements
- Deliver a short readily implementation standard that leverages and maps to **available** and widely used data standards and terminologies
- No new standards
- Follow endorsed governance process.

## Activities

- Harmonize a set of 20 core elements
  - Based on European eHealth Network – Guidelines for proof of vaccination for medical purposes - basic interoperability elements\*
- Align with:
  - US CDC Endorsed Data Elements
  - Digital Green Certificate
  - WHO Interim Guidance for Developing a Smart Vaccine Certificate (SVC)
- Map/point to:
  - CDISC
  - HL7-FHIR
  - ISO Standards
    - ISO 8601
    - ISO 3166
    - IDMP
  - ICD 10/11
  - SNOMED CT
  - WHODrug
  - ATC Classification
- Develop a CDISC Vaccine Administration v1.0 Guide and mapping spreadsheet

## Core Data Elements\*

- **Vaccination Information**
  - Disease or agent targeted
  - Vaccine/Prophylaxis
  - Vaccine medicinal product
  - Marketing Authorization Holder
  - Manufacturer
  - Number in a series of vaccinations/doses
  - Batch/lot number
  - Date of Vaccination
  - Administering center
  - Health Professional identification
  - Country of vaccination
  - Next vaccination date
- **Patient Identification Information**
  - Person Name: First and last
  - Person Identifier
  - Sex/Gender
  - Date of Birth
- **Certificate Metadata**
  - Certificate issuer
  - Certificate Identifier
  - Certificate Valid from
  - Certificate Valid until

Developed in collaboration with



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: OIGM Collaboration to Address the COVID-19 Pandemic and Future Public Health Challenges



### Notes to Readers

- This mapping document is based on the eHealth Network Guidelines on proof of vaccination for medical purposes - basic interoperability elements v1.0 and focuses on mapping the international standard on use.
- The mappings included are consistent with the US CDC National Data Elements, the US Digital Green Certificate and the WHO Interim Guidance for Developing a Smart Vaccine Certificate (SVC) and partly with existing guidance including CDISC HL7 FHIR, ISO Standards (ISO 3166 and ISO 8601) HL7 IDMP, SNOMED, ICD10 and ICD11 Classifications.

### Revision History

Version	Author	Date
1.0	CDISC	2021-03-12

For the full list of representation and harmonization, definitions of SNOMED, ICD10 and ICD11



Photo by National Cancer Institute on Unsplash





## Vaccine Administration v1.0

### Mapping Curation of Minimum Data Elements and Metadata



*Vaccine Administration V1.0 is a powerful data mapping solution created to connect diverse travelers, security officials, and application solutions providers with global vaccine entry requirements.*

As countries around the world reopen, the increase in international travel is creating confusion and delays due to inconsistent vaccine regulation and status. Differing regulations for each country create confusion for travelers who must sort through different sets of vaccine status entry rules. Once they arrive at the airport, these travelers are increasingly met with delays due to long lines as airline personnel work to process additional vaccine-related paperwork. The difficulties continue as new variants of the COVID-19 virus emerge globally.

Version 1.0 of the Vaccine Administration: Mapping Curation of Minimum Data Elements maps existing international standards to facilitate interoperability of data and metadata related to vaccine administration.

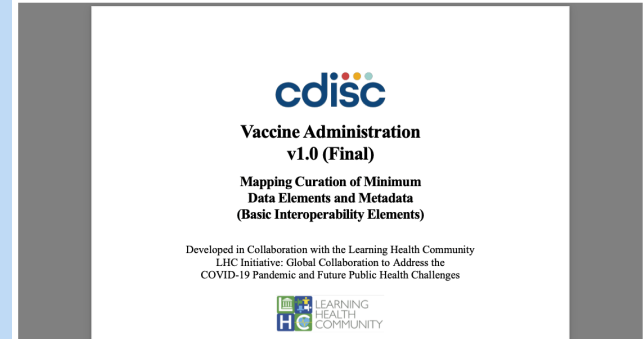
The goal is to achieve a multinational agreement around one global core data standard that will enable the success of various vaccine credentialing and vaccine 'passport' applications to foster rapid and comprehensible sharing of essential information for uses such as safe international travel. Security, validation, and privacy remain the responsibility and expertise of the technology developers and implementers.

Clear data.  
Clear impact.

## Files

Vaccine Administration v1.0 provides direction on how to define and organize data elements by delivering metadata that enables machine readability, data sharing, and semantic interoperability, with the added benefit of facilitating the flow of data for submission to global regulatory authorities.

The standard and metadata are free to download and implement. Security, validation, and privacy remain the responsibility and expertise of the technology developers and implementers.



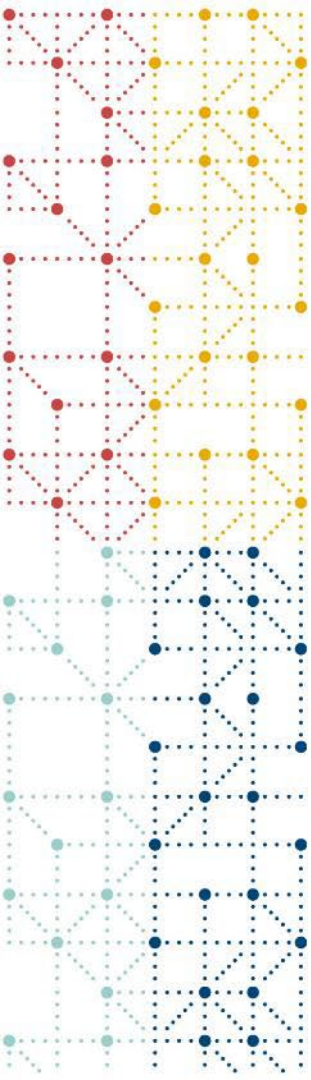
[Vaccine\\_Administration\\_v1.0\\_Final](#) [Download](#)

[Vaccine\\_Administration\\_Metadata](#) [Download](#)

CDISC posts [Public Review](#) comments and resolutions to ensure transparency and show implementers how comments were addressed in the standard development process.

[Vaccine\\_Administration\\_v1.0](#) information available on the CDISC Website.

<https://www.vaccineadministration.org>



**Thank You!**

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