Vaccine Administration Standard

National Vaccine Advisory Committee Meeting

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11 February 2022

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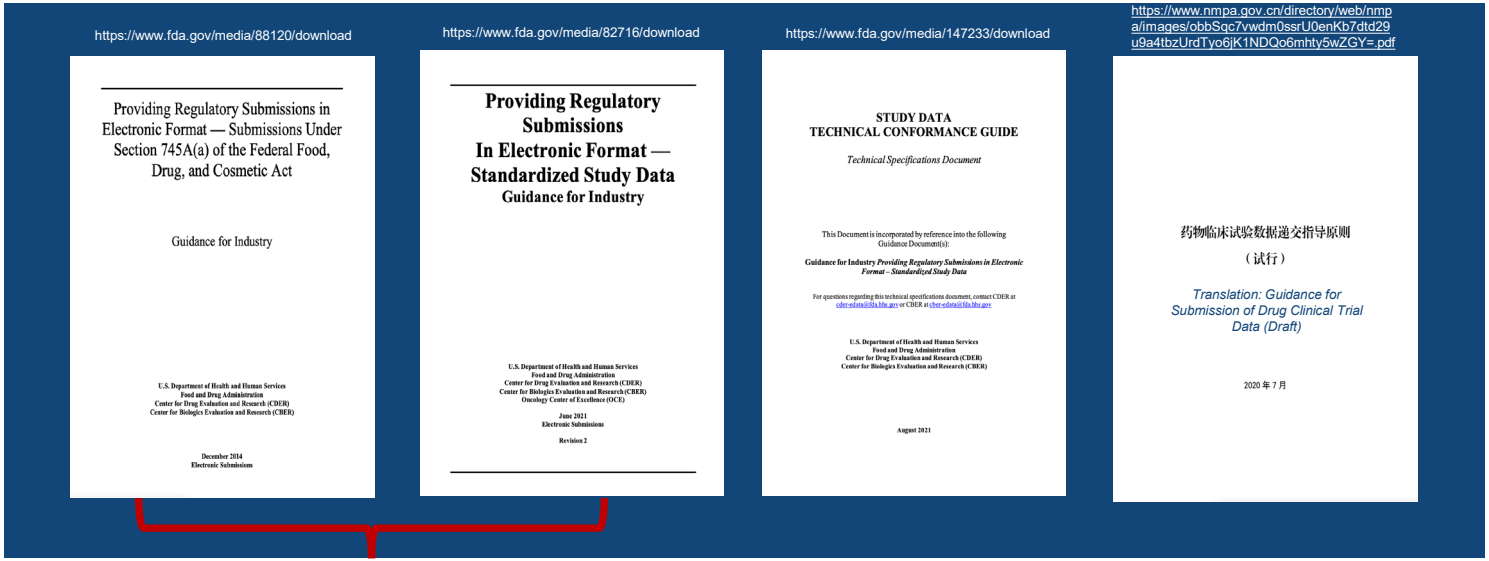
Agenda

- 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

CDISC Standards and Global Regulation



- 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.

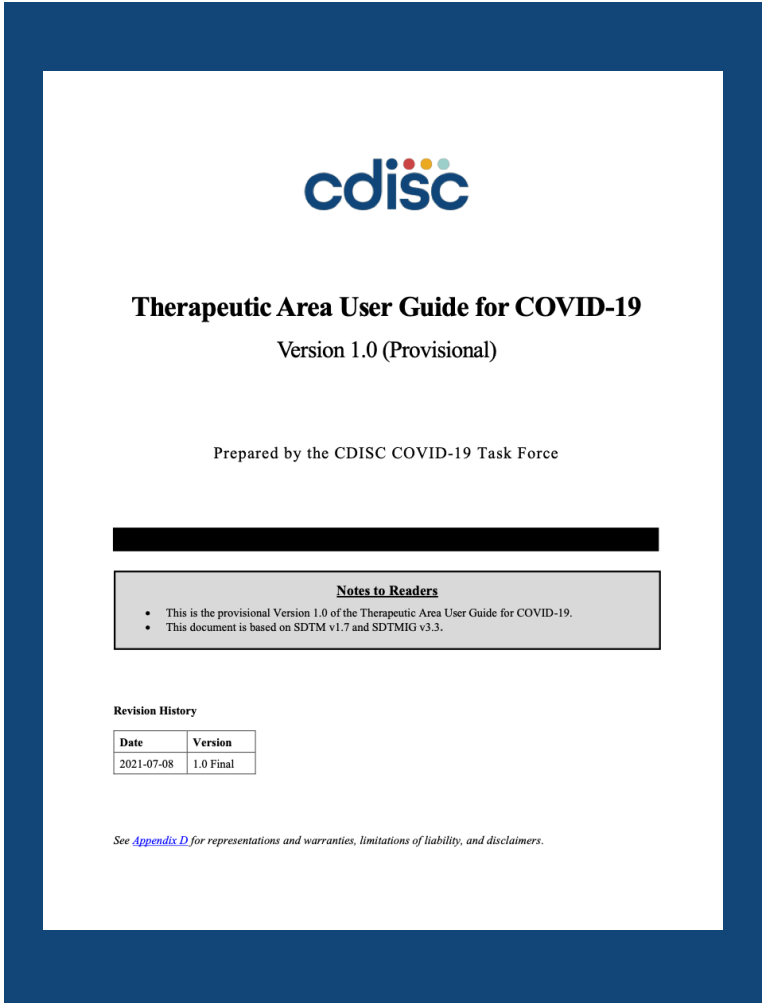
What CDISC Does

- 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



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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.

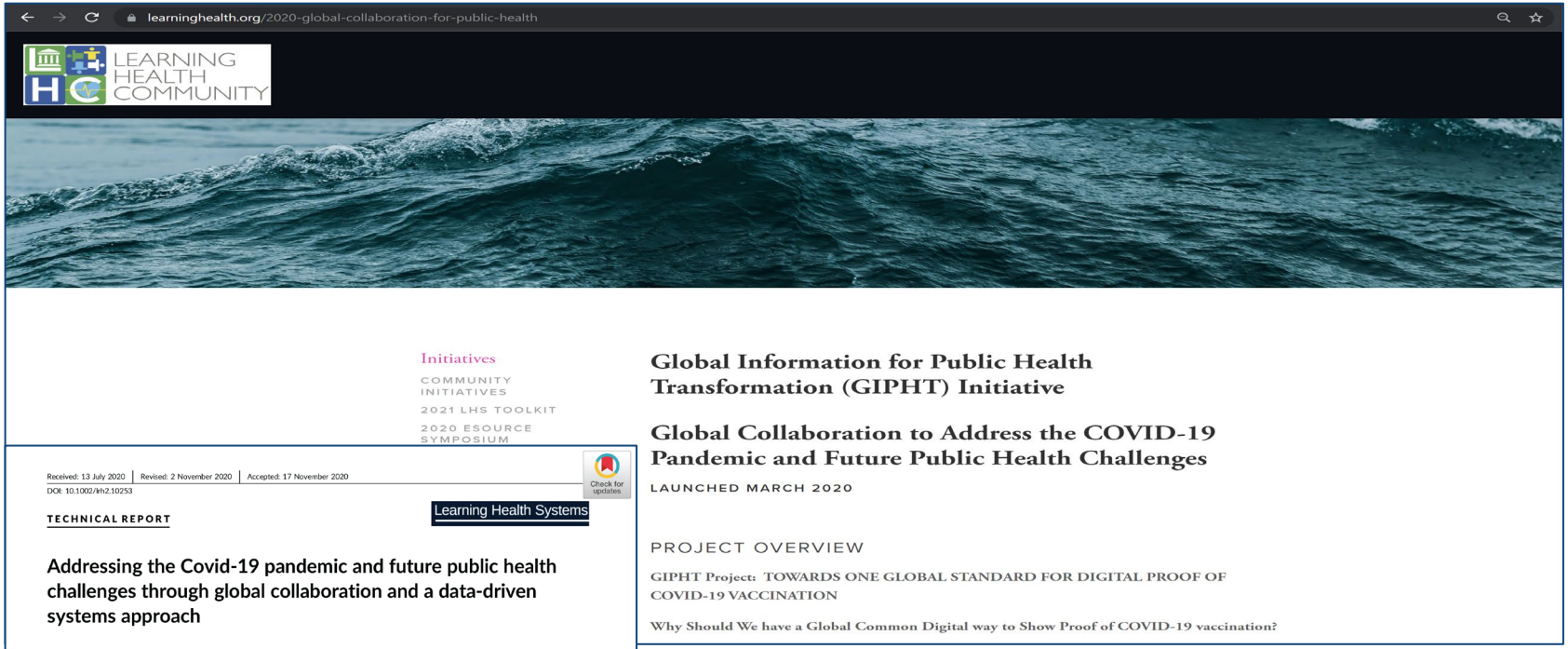
Revision History

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*.

LEARNING HEALTH COMMUNITY



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/lrh2.10253

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[1] | Rebecca Kush[2] | Charles Friedman[3] | Esther Gil Zorzo[4] | Pablo Rivero Corte[5] | Joshua C. Rubin[3] | Borja Sanchez[6] | Paolo Stocco[7] | Douglas Van Houweling[3]

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

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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

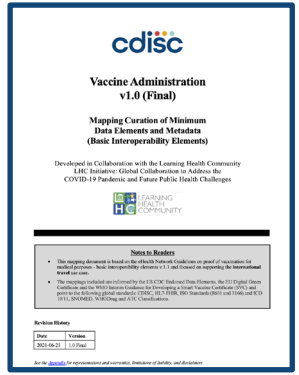
- Harmonize a set of 20 core elements
  - Based on European eHealth Network – Guidelines for proof of vaccination for medical purposes - basic interoperability elements*
- Align with:
  - US CDC Endorsed Data Elements
  - Digital Green Certificate
  - WHO Interim Guidance for Developing a Smart Vaccine 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

LEARNING HEALTH COMMUNITY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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

Notes to Readers

Revision History

Date	Version
2021-06-21	1.0 Final

Photo by National Cancer Institute on Unsplash

*Source: eHealth Network, Guidelines on proof of vaccination for medical purposes - basic interoperability elements, V 2. March 12, 2021. Retrieved from: https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

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Vaccine Administration v1.0

Mapping Curation of Minimum Data Elements and Metadata

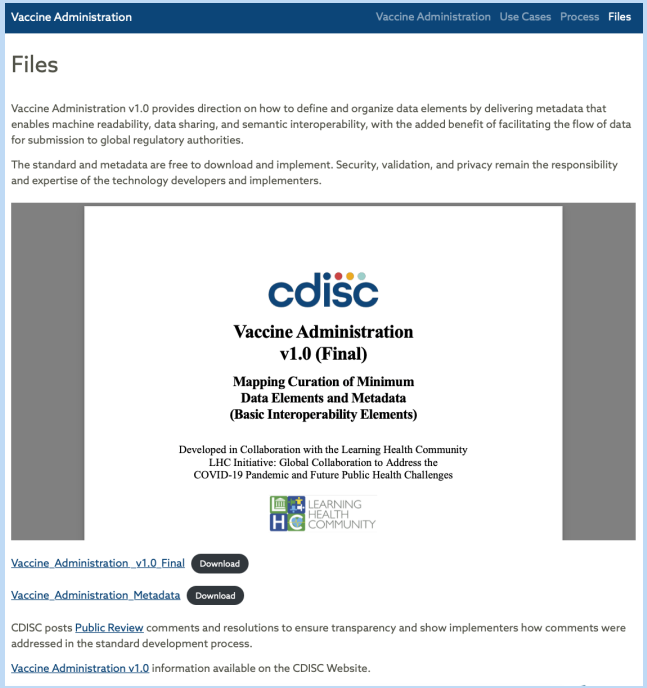
Vaccine Administration V1.0 is a powerful data mapping solution created to connect diverse travelers, security officials, and application solutions providers with global vaccine entry requirements.

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.



https://www.vaccineadministration.org

Thank You!